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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/260,664	03/08/2022	11266345	046905/554252	1082

826 7590 02/16/2022

ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

Guennadi SAIKO, Mississauga, CANADA;
Kenneth MACKO, Toronto, CANADA;
Andrei BETLEN, Pickering, CANADA;

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Swift Medical Inc., Toronto, CANADA;

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

826 7590 11/03/2021

ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/260,664	01/15/2021	Guennadi SAIKO	046905/554252	1082

TITLE OF INVENTION: APPARATUS FOR VISUALIZATION OF TISSUE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	02/03/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-306000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Alston & Bird LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE	(B) RESIDENCE: (CITY and STATE OR COUNTRY)
Swift Medical Inc.	Toronto, CANADA

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ☒ Corporation or other private group entity ❑ Government

4a. Fees submitted: ☒ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 160605

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Christopher P. Lightner/ Date 2022-01-19

Typed or printed name Christopher P. Lightner Registration No. 62156

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	17260664
Filing Date:	15-Jan-2021
Title of Invention:	APPARATUS FOR VISUALIZATION OF TISSUE
First Named Inventor/Applicant Name:	Guennadi SAIKO
Filer:	Christopher Patrick Lightner/Grace Caffey
Attorney Docket Number:	046905/554252

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1200**

Electronic Acknowledgement Receipt	
EFS ID:	44778976
Application Number:	17260664
International Application Number:	
Confirmation Number:	1082
Title of Invention:	APPARATUS FOR VISUALIZATION OF TISSUE
First Named Inventor/Applicant Name:	Guennadi SAIKO
Customer Number:	826
Filer:	Christopher Patrick Lightner/Grace Caffey
Filer Authorized By:	Christopher Patrick Lightner
Attorney Docket Number:	046905/554252
Receipt Date:	19-JAN-2022
Filing Date:	15-JAN-2021
Time Stamp:	15:47:40
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1200
RAM confirmation Number	E20221IF47574475
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	2022-01-19_554252IssueFeePayment.pdf	117163 02756699c70e27268ecaed9c729a53a98a5a07fe	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37751 9ddf68a5aec57a20518922b273aec4a194ea893e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	154914		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Attorney Docket: 046905/554252

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 17/260,664 filed on January 15, 2021.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

WARNING: Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Guennadi SAIKO Citizenship: Canada

Signature: / DocuSigned by: Gennadi Saiko / Date (Optional): _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

Attorney Docket: 046905/554252

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE

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☐ The attached application, or

☒ United States application or PCT international application number 17/260,664 filed on January 15, 2021.

The above-identified application was made or authorized to be made by me.

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LEGAL NAME OF INVENTOR

Inventor: Kenneth MACKO Citizenship: Canada

Signature: / DocuSigned by: Kenneth Macko / Date (Optional): _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

Attorney Docket: 046905/554252

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 17/260,664 filed on January 15, 2021.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

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LEGAL NAME OF INVENTOR

Inventor: Andrei BETLEN Citizenship: Canada

Signature: / DocuSigned by: Date (Optional): _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

Electronic Acknowledgement Receipt	
EFS ID:	44763889
Application Number:	17260664
International Application Number:	
Confirmation Number:	1082
Title of Invention:	APPARATUS FOR VISUALIZATION OF TISSUE
First Named Inventor/Applicant Name:	Guennadi SAIKO
Customer Number:	826
Filer:	Christopher Patrick Lightner/Grace Caffey
Filer Authorized By:	Christopher Patrick Lightner
Attorney Docket Number:	046905/554252
Receipt Date:	18-JAN-2022
Filing Date:	15-JAN-2021
Time Stamp:	13:36:58
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2022-01-18_554252Declarations.pdf	174562 0dce20eb2dc46bf982aa8b2bad9e873ea13fb6c1	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Oath or Declaration filed	1	1
	Oath or Declaration filed	2	2
	Oath or Declaration filed	3	3
Warnings:			
Information:			
	Total Files Size (in bytes):	174562	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	17/260,664	Confirmation No.: 1082
Applicant(s):	Saiko, et al.	
Filed:	January 15, 2021	
Art Unit:	3791	
Examiner:	Abouelela, May A.	
Title:	APPARATUS FOR VISUALIZATION OF TISSUE	

Docket No.: 046905/554252
Customer No.: 00826

Submitted via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION TO FILE CORRECTED APPLICATION PAPERS

In response to the Notification to File Corrected Application Papers mailed November 10, 2021, please amend the above-identified application as follows:

Amendments to the Drawings are reflected on page 2 of this paper and in the Replacement Sheet attached herewith.

Remarks begin on page 3 of this paper.

An **Appendix** containing a single **Replacement Sheet** is attached following page 3 of this paper.

A copy of the Notice to File Corrected Application Papers is also attached for reference.

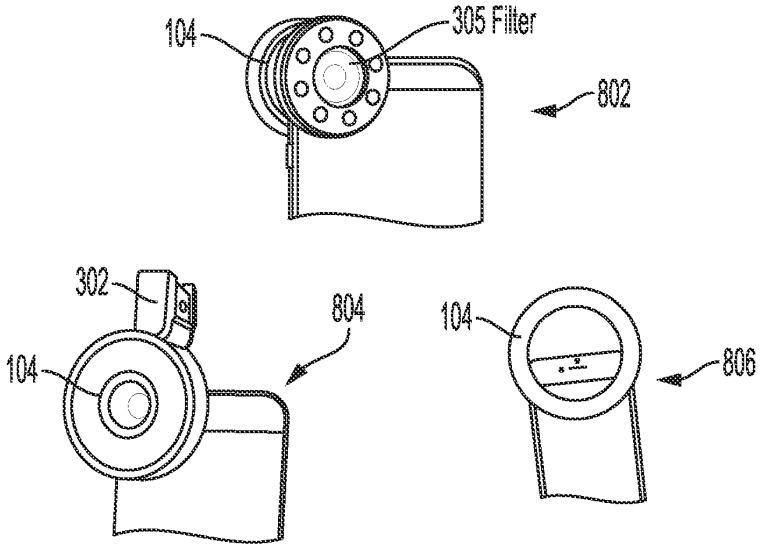

FIG. 8

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/260.664	01/15 2021	Guennadi SAIKO	046905/554252	1082

826 7590 11/10/2021

ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/10/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@alston.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 17260664
Applicant : Saiko
Filing Date : 01/15/2021
Date Mailed : 11/10/2021

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Anita Grimmage/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 17260664 **Drawings filed: 01/15/2021**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [ ] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s)
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [X] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s) 8
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

Electronic Acknowledgement Receipt	
EFS ID:	44708154
Application Number:	17260664
International Application Number:	
Confirmation Number:	1082
Title of Invention:	APPARATUS FOR VISUALIZATION OF TISSUE
First Named Inventor/Applicant Name:	Guennadi SAIKO
Customer Number:	826
Filer:	Christopher Patrick Lightner/Grace Caffey
Filer Authorized By:	Christopher Patrick Lightner
Attorney Docket Number:	046905/554252
Receipt Date:	10-JAN-2022
Filing Date:	15-JAN-2021
Time Stamp:	16:36:24
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2022-01-10_554252ResponseNTFCAP.pdf	273528 5a1d9ca804b9dd71180e1b0c114c32384af957bd	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Response to Pre-Exam Formalities Notice	1	1
	Drawings-only black and white line drawings	2	2
	Applicant Arguments/Remarks Made in an Amendment	3	3
	Drawings-only black and white line drawings	4	4
	Miscellaneous Incoming Letter	5	7
Warnings:			
Information:			
	Total Files Size (in bytes):	273528	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Amendments to the Drawings:

Please amend the originally filed drawings with the attached Replacement Sheet. Applicant respectfully submits that no new matter has been introduced herewith. Instead, the Replacement Sheet merely formalizes the previously photographic nature of Figure 8, as highlighted in the received Notice. Entry of this Replacement Sheet is thus respectfully requested.

REMARKS

In response to the Notification to File Corrected Application Papers, please amend the originally filed drawings with the attached Replacement Sheet. Applicant respectfully submits that no new matter has been introduced herewith. Instead, the Replacement Sheet merely formalizes the previously photographic nature of Figure 8, as highlighted in the received Notice. Entry of this Replacement Sheet is thus respectfully requested, and Applicant respectfully submits that the same fully addresses and overcomes all the issues raised in the received Notification to File Corrected Application Papers.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefor (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

/Christopher P. Lightner/

Christopher P. Lightner
Registration No. 62,156

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/260.664	01/15 2021	Guennadi SAIKO	046905/554252	1082

826 7590 11/10/2021

ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/10/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@alston.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 17260664
Applicant : Saiko
Filing Date : 01/15/2021
Date Mailed : 11/10/2021

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Anita Grimmage/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 17260664 **Drawings filed: 01/15/2021**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [ ] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s)
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [X] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s) 8
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

826 7590 11/03/2021

ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	**PAPER NUMBER**
3791	

DATE MAILED: 11/03/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/260,664	01/15/2021	Guennadi SAIKO	046905/554252	1082

TITLE OF INVENTION: APPARATUS FOR VISUALIZATION OF TISSUE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	02/03/2022

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

826 7590 11/03/2021

ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/260,664	01/15/2021	Guennadi SAIKO	046905/554252	1082

TITLE OF INVENTION: APPARATUS FOR VISUALIZATION OF TISSUE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	02/03/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-306000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1_____
2_____
3_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/260,664	01/15/2021	Guennadi SAIKO	046905/554252	1082

826 7590 11/03/2021

ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	**PAPER NUMBER**
3791	

DATE MAILED: 11/03/2021

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 02/11)

Notice Requiring Inventor's Oath or Declaration	Application No. 17/260,664	Applicant(s) Guennadi SAIKO	
	Examiner ABOUELELA, MAY A	Art Unit 3791	

This notice is an attachment to the Notice of Allowability (PTOL-37), or the Notice of Allowability For A Design Application (PTOL-37D).

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor has not yet been submitted.

An oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each inventor (for any inventor for which a compliant oath, declaration, or substitute statement has not yet been submitted) MUST be filed no later than the date on which the issue fee is paid. See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application.

A properly executed inventor's oath to declaration has not been received for the following inventor(s):

If applicant previously filed one or more oaths, declarations, or substitute statements, applicant may have received an informational notice regarding deficiencies therein.

The following deficiencies are noted:

INFORMAL ACTION PROBLEMS

- Properly executed inventor's oath or declaration for the following inventor(s) has not been submitted: **Guennadi SAIKO**, **Kenneth MACKO**, and **Andrei BETLEN**

Questions relating to this Notice should be directed to the Application Assistance Unit at 571-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/260,664	Applicant(s) SAIKO et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 10/12/2021.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 22-41 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☑ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 10/19/2021.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☑ Other A.NE.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

EXAMINER'S AMENDMENT

2. Authorization for this examiner's amendment was given in an interview with CHRISTOPHER P. LIGHTNER on 10/19/2021.

The claims should be amended as follows:

Claim 22 should be amended as follow:

22. (Currently Amended) A portable illumination apparatus for facilitating visualizations of tissue, the apparatus comprising:

a portable housing for detachable attachment proximal to an image capturing unit; and

an illumination unit comprising one or more narrow band light sources configured to shine m flashes **of light on a target area of the tissue** at n predetermined wavelengths, wherein: n/4 ≤ m ≤ n; and m is ~~the~~ **a** number of **light** flashes in one cycle and n is ~~the~~ **a** number of wavelengths.

Claim 23 should be amended as follow:

23. (Currently Amended) The portable illumination apparatus of claim 22, wherein the illumination unit further comprises a lens covering the one or more light sources, the lens having a focal length that is 80%-120% of a working distance between the illumination unit and ~~a~~ **the** target area of the tissue.

Claim 28 should be amended as follow:

28. (Previously Presented) The illumination apparatus according to claim 22, wherein the portable housing comprises a compression clip or a spring clip for mounting the apparatus on ~~a mobile device along~~ at least one edge of ~~the~~ **a** mobile device and proximal to a camera of the mobile device.

Claim 29 should be amended as follow:

29. (Currently Amended) A tissue imaging system for visualizing of tissue health indicators, the system comprising: a portable computing device, an image capture unit, and an illumination unit, wherein: the illumination unit comprises one or more narrow band light sources configured to shine m flashes **of light on a target area of the tissue** at n predetermined wavelengths, wherein $n/4 \leq m \leq n$; and wherein m is ~~the~~ **a** number of **light** flashes in one cycle and n is ~~the~~ **a** number of wavelengths;

the image capture unit and the illumination unit are configured to capture measurement data for ~~a~~ **the** target area of the tissue; and

the computing device comprises a processor configured to access and execute instructions in accordance with a tissue visualization application stored in a non-transitory computer-readable memory of the computing device, for capturing measurement data, and pre-processing and processing the measurement data to generate the tissue health indicators.

Claim 34 should be amended as follow:

34. (Currently Amended) A method for generating visualizations of tissue, the method comprising:

positioning a computing device at a proper distance from a target area of the tissue for capturing an image of the target area, the computing device comprising a processor and a non- transitory computer-readable memory storing computer-executable instructions comprising a tissue visualization application;

capturing measurement data using an image capturing unit and an illumination unit, the image capturing unit and the illumination unit communicatively coupled to the computing device and the illumination unit configured to shine m flashes **of light on the target area of the tissue** at n predetermined wavelengths during capturing of the measurement data, wherein $n/4 \leq m \leq n$; and wherein m is ~~the~~ **a** number of **light** flashes in one cycle and n is ~~the~~ **a** number of wavelengths;

pre-processing the measurement data using the tissue visualization application to obtain reflectance images;

extracting indications of tissue health indicators from the pre-processed measurement data;

generating interface elements corresponding to the visualization tissue health indicators; and

at least one of storing or transmitting the extracted indications of the tissue health indicators.

Claim 38 should be amended as follow:

38. (Currently Amended) The method according to claim 34, wherein pre-processing comprises at least one of:

(i) registering images to avoid camera motion artifacts,

(ii) subtracting images with no illumination from the illumination unit from images with illumination from the illumination unit to account for ~~the~~ **a** presence of ambient light,

(iii) recalibrating each measurement accordingly to control parameters related to intensity of illumination using a self-reference object positioned within the target area,

(iv) dividing the captured images on reference images to obtain reflectance images, or

(v) flattening the reflectance images to account for reflections from curved surfaces.

Claim 39 should be amended as follow:

39. (Currently Amended) The method according to claim 34, wherein exposure time of the image capturing unit is T and a flash time is said T or any ~~whole number~~ multiple of said T.

Allowable Subject Matter

3. Claims 22-41 are allowed.

4. The following is an examiner's statement of reasons for allowance: the most pertinent art does not teach, disclose and/or fairly suggest a tissue imaging system for visualizing of tissue health indicators, the system comprising: a portable computing device, an image capture unit, and an illumination unit, wherein: the illumination unit comprises one or more narrow band light sources configured to shine m flashes of light

on a target area of the tissue at n predetermined wavelengths, wherein n/4 ≤ m ≤ n; and wherein m is a number of light flashes in one cycle and n is a number of wavelengths.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-

2

7 Information regarding the status of published or unpublished applications may be

8 obtained from Patent Center. Unpublished application information in Patent Center is

available to registered users. To file and manage patent submissions in Patent Center,

9 visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-

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center for more information about Patent Center and

https://www.uspto.gov/patents/docx for information about filing in DOCX format. For

additional questions, contact the Electronic Business Center (EBC) at 866-217-9197

(toll-free). If you would like assistance from a USPTO Customer Service

Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Examiner-Initiated Interview Summary	**Application No.** 17/260,664	**Applicant(s)** SAIKO et al.		
	Examiner MAY A ABOUELELA	**Art Unit** 3791	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
MAY A ABOUELELA	Primary Examiner	Telephonic
CHRISTOPHER P. LIGHTNER	Attorney of Record	

Date of Interview: 19 October 2021

Issues Discussed:

35 U.S.C. 112

Applicant and Examiner discussed the claims set mailed on 10/12/2021. Applicant and Examiner discussed the claim language with respect to the applied prior art and the disclosure. Applicant and Examiner discussed proposed claim amendments represented by the Examiner to overcome 112 rejection. The Applicant has authorized the Examiner to amend the claims.

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Notice of References Cited	Application/Control No. 17/260,664	Applicant(s)/Patent Under Reexamination SAIKO et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-10127661-B2	11-2018	Wang; Yen-Chang	A61B5/0066	1/1
*	B	US-6685635-B2	02-2004	Shani; Haim	A61B5/0059	356/425
*	C	US-6792137-B2	09-2004	Kenet; Robert	G16H10/20	382/128
*	D	US-7179227-B2	02-2007	Shirai; Yasuo	A61B5/0059	600/306
*	E	US-20090177051-A1	07-2009	Arons; Edward M.	A61B5/445	600/306
*	F	US-20130096392-A1	04-2013	Adams; Bruce	A61B5/0064	600/301
*	G	US-20150099947-A1	04-2015	Qu; Di	A61B5/442	600/306
*	H	US-20200281512-A1	09-2020	Grubb; Scott	A61B5/489	1/1
*	I	US-20200383630-A1	12-2020	XU; Min	A61B5/0075	1/1
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/260,664	SAIKO et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/07/2021	10/19/2021							
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	4	-	-							
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18	39	✓	=							
19	40	✓	=							
20	41	✓	=							

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/260,664	SAIKO et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

CPC						
Symbol					**Type**	**Version**
A61B	/	5	/	445	F	2013-01-01
A61B	/	5	/	0013	I	2013-01-01
A61B	/	5	/	0077	I	2013-01-01
A61B	/	5	/	6898	I	2013-01-01
A61B	/	5	/	742	I	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	19 October 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	29	4

U.S. Patent and Trademark Office — Part of Paper No.: 20211019

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/260,664	SAIKO et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B	/	5	/	00	
NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
600	306

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791 (Primary Examiner)	19 October 2021 (Date)	O.G. Print Claim(s) 29	O.G. Print Figure 4

U.S. Patent and Trademark Office — Part of Paper No.: 20211019

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/260,664	SAIKO et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10		19	7	28	19	37						
	2		11		20	8	29	17	38						
	3		12		21	9	30	18	39						
	4		13	1	22	10	31	19	40						
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	6		15	3	24	12	33								
	7		16	4	25	13	34								
	8		17	5	26	14	35								
	9		18	6	27	15	36								

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	19 October 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	29	4

U.S. Patent and Trademark Office Part of Paper No.: 20211019

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/260,664	SAIKO et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B5/445 or A61B5/742 or A61B5/6898 or A61B5/0013 or A61B5/0077	07/07/2021	MA
A61B5/445 or A61B5/0013 or A61B5/0077 or A61B5/6898 or A61B5/742 or G03B33/08 or G03B2215/0514 or G03B15/05 or A61B5/7264 or A61B5/14551 or A61B5/1455 or A61B5/14546 or A61B5/4878 or A61B5/4875 or A61B5/0075	10/19/2021	MA

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
600	306	07/07/2021	MA
updated as above		10/19/2021	MA

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
east text search, inventor name search, class/subclass search	07/07/2021	MA
updated as above	10/19/2021	MA

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/260,664	SAIKO et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
as above		10/19/2021	MA

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 17/260,664 Confirmation No.: 1082
Applicant(s): Saiko, et al.
Filed: January 15, 2021
Art Unit: 3791
Examiner: Abouelela, May A.
Title: APPARATUS FOR VISUALIZATION OF TISSUE

Docket No.: 046905/554252
Customer No.: 00826

OK TO ENTER: /M.A.A/

Submitted via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

10/19/2021

AMENDMENT UNDER 37 CFR § 1.111

In response to the Office Action dated July 12, 2021 please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims beginning on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Bibliographic Data

Application No: 17/260,664

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☑ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ (Examiner's Signature) | M.A.A (Initials)

Title: APPARATUS FOR VISUALIZATION OF TISSUE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
01/15/2021	600	3791	046905/554252
RULE			

APPLICANTS

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Kenneth MACKO, Toronto, CANADA

Andrei BETLEN, Pickering, CANADA

CONTINUING DATA

This application is a 371 of PCT/CA2019/050981 07/16/2019

PCT/CA2019/050981 has PRO of 62698799 07/16/2018

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

05/18/2021

STATE OR COUNTRY

CANADA

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CHARLOTTE, NC 28280-4000
UNITED STATES

FILING FEE RECEIVED

$1,820

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	0	(17/260664).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/07 14:23
S2	1	("20190090751").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/07 14:27
S3	0	("2019/0090751").URPN.	USPAT	OR	ON	2021/07/07 14:42
S4	22	"2017012675"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:15
S5	11	"2017155265"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:18
S6	57,363	(A61B5/445 or A61B5/742 or A61B5/6898 or A61B5/0013 or A61B5/0077).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:20
S7	5,377	S6 and ((illuminat$4 or light$4 or shin$4) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:27
S8	2,499	S7 and ((imag$4 or captur$4 or camera) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:28

S9	2,036	S8 and @ad<"20180716"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:29
S10	1,327	S9 and ((illuminat$4 or light$4 or shin$4) near4 wavelength)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:30
S11	0	("2020/0121243").URPN.	USPAT	OR	ON	2021/07/07 16:48
S12	0	("2020/0003683").URPN.	USPAT	OR	ON	2021/07/07 16:48
S13	1	("2019/0082998").URPN.	USPAT	OR	ON	2021/07/07 16:50
S14	374	(600/306).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/07 16:50
S15	152	S14 and ((illuminat$4 or light$4 or shin$4) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 16:50
S16	193,114	10and ((imag$4 or captur$4 or camera) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 16:51
S17	84	S15 and ((imag$4 or captur$4 or camera) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 16:52
S18	58	S17 and wavelength	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2021/07/07 16:52

			DERWENT; IBM_TDB			
S19	10	("2009/0220415").URPN.	USPAT	OR	ON	2021/07/07 16:53
S20	38	("20040125996" | "20040202685" | "20040218810" | "20070002479" | "20070064978" | "20070064979" | "20070064985" | "20070064989" | "4894547" | "5074306" | "5343536" | "5836872" | "6069689" | "6571003" | "6587711" | "6763262" | "7369692").PN. OR ("7454046").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/07 16:55
S21	2	(16/203879).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/07 17:46
S22	1	((("SAIKO") near3 ("Guennadi")) OR (("MACKO") near3 ("Kenneth")) OR (("BETLEN") near3 ("Andrei"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2021/10/19 15:45
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S26	4,452	S25 and ((imag$4 or captur$4 or camera) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/19 16:19

S27	3,513	S26 and wavelength	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/19 16:20
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S31	152	S30 and ((illuminat$4 or light$4 or shin$4) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/19 18:09
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S34	12	("2015/0099947").URPN.	USPAT	OR	ON	2021/10/19 18:30
S35	3	("2011/0288385").URPN.	USPAT	OR	ON	2021/10/19 19:35
S36	2,564	S23 and ((visual$6 or screen$4) near4 (skin or tissue))	US-PGPUB; USPAT; USOCR	OR	ON	2021/10/19 20:18
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S38	1,182	S37 and (wavelength near4 (light$4 or illuminat$4 or shin$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/19 20:19
S39	1,098	S38 and imag$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/10/19 20:20

EAST Search History (Interference)

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S41	7	(illuminat$4 and tissue and captur$4 and wavelength$4 and light$4 and imag$4 and flash$4).clm.	US-PGPUB; USPAT	OR	ON	2021/10/19 19:51
S42	204	(illuminat$4 and tissue and captur$4 and wavelength$4 and light$4 and imag$4 and camera).clm.	US-PGPUB; USPAT	OR	ON	2021/10/19 19:54
S43	4	(illuminat$4 and tissue and captur$4 and wavelength$4 and light$4 and imag$4 and shin$4).clm.	US-PGPUB; USPAT	OR	ON	2021/10/19 19:55

10/19/2021 9:48:39 PM
C:\Users\mabouelela\Documents\EAST\Workspaces\17260664 apparatus for visualization of tissue.wsp

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	17/260,664	Confirmation No.: 1082
Applicant(s):	Saiko, et al.	
Filed:	January 15, 2021	
Art Unit:	3791	
Examiner:	Abouelela, May A.	
Title:	APPARATUS FOR VISUALIZATION OF TISSUE	

Docket No.: 046905/554252
Customer No.: 00826

Submitted via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 CFR § 1.111

In response to the Office Action dated July 12, 2021 please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims beginning on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

1-21. (Cancelled)

22. (Currently Amended) A portable illumination apparatus for facilitating visualizations of tissue, the apparatus comprising:

a portable housing for detachable attachment proximal to an image capturing unit; and

an illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths,

wherein**:**

$n/4 \leq m \leq n$**; and**

m is the number of flashes in one cycle and n is the number of wavelengths.

23. (Currently Amended) The portable illumination apparatus of claim 22, wherein the illumination unit further comprises a lens covering the one or more light sources, the lens having a focal length that is 80%-120% of a working distance between the illumination unit and a target area of **the** tissue.

24. (Currently Amended) The portable illumination apparatus according to claim 22, wherein the one or more light sources is configured to provide flashes that are at least one of:

(i) 405±10nm wavelength, and having at least one of: (a) a long pass filter with a cut-on wavelength of 450±25nm or (b) a bandpass filter with transmission in a 425nm-1000nm range,

(ii) two wavelengths in a 450nm-750nm range, at least one of which in **a** ~~**the**~~ green range,

(iii) three wavelengths in a 450nm-750nm range, at least one of which in the green range, or

(iv) 970±10nm wavelength.

25. (Previously Presented) The portable illumination apparatus according to claim 22, wherein the illumination unit further comprises at least one of:

(i) a controller to control illumination of the one or more light sources, or

(ii) a rechargeable battery for powering the apparatus.

26. (Currently Amended) The illumination apparatus according to claim 22, wherein the one or more light sources are arranged about a central aperture **of the illumination unit, the central aperture** having a radius of 0.5-3cm.

27. (Previously Presented) The illumination apparatus of claim 26, wherein the one or more light sources are arranged in a ring having a radius of 1.5-6cm.

28. (Previously Presented) The illumination apparatus according to claim 22, wherein the portable housing comprises a compression clip or a spring clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

29. (Currently Amended) A tissue imaging system for **visualizing** ~~visualization of~~ tissue health indicators, the system comprising:

a portable computing device,

an image capture unit, and

an illumination unit,

wherein:

the illumination unit comprises one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$**, and wherein m is the number of flashes in one cycle and n is the number of wavelengths**;

the image capture unit and the illumination unit are configured to capture measurement data for a target area of **the** tissue; and

the computing device comprises a processor configured to access and execute instru**c**tions in accordance with a tissue visualization application stored in a non-transitory computer-readable memory of the computing device, for capturing measurement data, and pre-processing and processing the measurement data to generate **the** tissue health indicators.

30. (Previously Presented) The tissue imaging system of claim 29, wherein the computing device comprises a mobile device and the image capture unit is a camera integrated with the mobile device.

31. (Currently Amended) The tissue imaging system according to claim 29, wherein the illumination unit comprises:

a portable housing for detachable attachment proximal to **the** ~~**an**~~ image capturing unit~~**; and**~~

~~**an illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths,**~~

~~**wherein n/4 ≤ m ≤ n**~~.

32. (Previously Presented) The tissue imaging system according to claim 29, wherein the portable illumination unit further comprises a wireless communication module for receiving commands from the computing device.

33. (Currently Amended) A tissue visualization system operatively connected to one or more tissue imaging systems according to claim 29, comprising a communications module for communicating with the one or more tissue imaging systems, a system processor, and system non-transitory computer-readable memory thereon, configured to receive **the** measurement data and **the** tissue health indicators from the one or more tissue imaging systems and to generate a visualization of tissue health indicators of tissue images received from the one or more tissue imaging systems, for display to a user display unit.

34. (Currently Amended) A method for generating visualizations of tissue, the method comprising:

positioning a computing device at a proper distance from a target area of the tissue for capturing an image of the target area, the computing device comprising a processor and a non-transitory computer-readable memory storing computer-executable instructions comprising a tissue visualization application;

capturing measurement data using an image capturing unit and an illumination unit, the image capturing unit and the illumination unit communicatively coupled to the computing device and the illumination unit configured to shine m flashes at n predetermined wavelengths during capturing of the measurement data, wherein $n/4 \leq m \leq n$**, and wherein m is the number of flashes in one cycle and n is the number of wavelengths**;

pre-processing the measurement data using the tissue visualization application to obtain **reflectance** ~~**normalized**~~ images;

extracting indications of tissue health indicators from the pre-processed measurement data;

generating interface elements corresponding to the visualization tissue health indicators; and

at least one of storing or transmitting the **extracted** indications of the tissue health indicators.

35. (Previously Presented) The method of claim 34 further comprising, prior to capturing the measurement data, capturing a reference image, wherein the positioning the computing device for the reference image capturing comprises positioning the computing device using a reference object.

36. (Previously Presented) The method of claim 34, wherein the illumination unit and the computing device are configured to provide a working distance of 15±5cm from the target area of tissue.

37. (Previously Presented) The method of claim 36, wherein the positioning of the computing device for capturing the measurement data comprises positioning the computing device using a self-reference object.

38. (Currently Amended) The method according to claim 34, wherein pre-processing comprises at least one of:

(i) registering images to avoid camera motion artifacts,

(ii) subtracting images with no illumination from the illumination unit from images with illumination from the illumination unit to account for the presence of ambient light,

(iii) recalibrating each measurement accordingly to control parameters related to intensity of illumination using a self-reference object positioned within the target area,

(iv) dividing the **captured** ~~**intensity**~~ images on reference images to obtain **reflectance** ~~**normalized**~~ images, or

(v) flattening the **reflectance** ~~**obtained**~~ images to account for reflections from curved surfaces.

39. (Currently Amended) The method according to claim 34, wherein ~~**camera**~~ exposure time **of the image capturing unit** is T and a flash time is said T or any whole number multiple of said T.

40. (Currently Amended) The method according to claim 39, wherein the ~~**camera**~~ exposure time **of the image capturing unit** is 50ms.

41. (Previously Presented) The method according to claim 34, wherein the measurement data comprises wound-related data.

REMARKS

This Amendment is filed in response to the Office Action dated July 12, 2021. Of note, no substantive prior art-based rejections were raised in the Office Action; only a series of claim objections and indefiniteness-related rejections are present for Applicant's review and response. In view of the amendments and remarks provided herein—all without introduction of any new matter and submitted as a complete response to the Office Action—reconsideration and allowance of the present application is respectfully requested.

A. Claim Objections

Applicant respectfully submits that the amendments and remarks provided herein fully address and overcome all the claim objections raised in the Office Action.

Specifically, Applicant has herein amended Claim 23 to recite "the tissue" for appropriate antecedent basis support. In Claim 29, "of tissue health indicators" has been changed to "tissue health indicators" in the preamble, followed by "the tissue" and "the tissue health indicators" in the body of the claim. Recitation of "the measurement data" and "the tissue health indicators" also now appears in Claim 33. Each of these amendments follows direction and/or recommendations set forth in the Office Action itself.

Withdrawal of all claim objections raised in the Office Action and mailing of a Notice of Allowance is thus respectfully requested.

B. Rejections under § 112

In the Office Action, certain of Claims 22-41 were rejected for alleged indefiniteness. Applicant respectfully submits that the amendments and remarks provided herein fully address and overcome all the rejections on this basis raised in the Office Action.

Specifically, regarding Claims 22, 29, and 34, Applicant references the terms "m flashes" and "n predetermined wavelengths." As amended herein, these claims now explicitly and clearly define that "m is the number of flashes in one cycle and n is the number of wavelengths." Support for this definition can be traced, as a non-limiting example, to at least [0159] and [0178] of Applicant's original disclosure. Withdrawal of the indefiniteness rejection with respect to Claims 22, 29, and 34 is thus respectfully requested.

Regarding Claim 26, the Office Action alleged that the features recited in the expression "the one or more light sources are arranged about a central aperture" are not defined such that those of ordinary skill in the industry would know which structural element includes the recited "central aperture" and/or the light sources. Although Applicant does not necessarily agree, to facilitate an immediate allowance of this claim (and others presently pending) Applicant has herein clarified this claim to explicitly recite that the "central aperture" is that of the "illumination unit." Support for this structural configuration may be traced, as a non-limiting example, to at least [0103] and Figure 8 of Applicant's original disclosure. Withdrawal of the indefiniteness rejection with respect to Claim 26 is thus respectfully requested.

In amending Claim 31 herein, Applicant has removed the features duplicated therein, as compared to independent Claim 29. Antecedent basis has also been appropriately updated in this claim. Withdrawal of the indefiniteness rejection with respect to Claim 31 is thus respectfully requested.

Regarding Claims 34-35 and 38, according to the Office Action the following features are unclear and/or insufficiently defined: "obtain normalized image" (Claim 34); "reference image" (Claim 35); "subtracting images" (Claim 38); "intensity images on reference images to obtain normalized images" (Claim 38); and "obtained images" (Claim 38). Although Applicant does not necessarily agree with the bases of these rejections, to facilitate allowance of these claims (and other remaining pending claims) without delay, claim amendments have been made herein to each. Specifically, instances of "normalized" and "obtained" images have been replaced with consistent and supported usage of the terminology "reflectance image." The term "intensity" has also been replaced with "captured." Withdrawal of the indefiniteness rejections on this basis with respect to Claims 34-35 and 38 is thus respectfully requested.

Addressing the expression "reference image"—as located in Claim 35—further, Applicant also notes that those of ordinary skill in the industry would have readily understood and appreciated that this relates to an image taken for calibration (e.g., reference) purposes. Support for this may also be seen in [0216] of Applicant's original disclosure, cited as a mere non-limiting example. Therein it is stated that the reference image is captured using a reference object, which "refers to an object with known homogeneous optical properties." Similarly, with reference to at least [0221] and [0223] of Applicant's original disclosure, Applicant respectfully submits that

those of ordinary skill in the industry would have readily understood and appreciated what "subtracting images" in Claim 38 entails. Withdrawal of the indefiniteness rejections on this basis with respect to Claims 35 and 38 is thus respectfully requested.

Claim 34 was also rejected in the Office Action with respect to the feature of "generating interface elements." For clarification, Applicant cites to—as a non-limiting example—at least [0077] and Figure 5 of Applicant's original disclosure. Based thereon and based further upon the common general knowledge and understanding, Applicant respectfully submits that those of ordinary skill in the industry would have readily appreciated the scope of this limitation. Withdrawal of the indefiniteness rejection on this basis is thus respectfully requested.

In the Office Action, both of Claims 39-40 were rejected as allegedly being incomplete for omitting essential structural cooperative relationships of elements. To address, Applicant has amended Claim 39 to positively recite that the "exposure time of the image capturing unit is T and a flash time is said T or any whole number multiple of T." Similar amendments have been made in Claim 40. Of note, Applicant respectfully emphasizes and submits that, with reference to at least [0160]-[0161] of Applicant's original disclosure, those of ordinary skill in the industry would have readily understood and appreciated the value of T may be any "exposure time," with a non-limiting example of T=50ms being provided. Relatedly, those of ordinary skill in the industry would have readily understood and appreciated from Applicant's original disclosure that any "whole number multiple of T" could be the non-limiting example of "2T" given or any other whole number contemplated (e.g., 5T, 7T, 3T, or the like). These features, as amended herein, are thus clear and in conformance with US practice (i.e., not narrative in form). Still further, it is well-established that breadth of claim is not necessarily indefiniteness in this context (*see* MPEP 2173 generally). Withdrawal of the indefiniteness rejection on this basis with respect to Claims 39-40 is thus respectfully requested.

Lastly, regarding the antecedent basis issues identified in Claims 24, 34, and 38, although not necessarily in agreement therewith, Applicant has herein amended these claims to positively recite "a green range," "the extracted indications," and "the captured images." Applicant thus respectfully submits that appropriate antecedent basis appears in these claims, along with all others presently pending. Withdrawal of the indefiniteness rejection on this basis with respect to Claims 24, 34, and 38 is thus respectfully requested.

C. Conclusion

The foregoing is submitted as a full and complete response to the Non-Final Office Action dated July 12, 2021. The foregoing amendments and remarks are believed to have placed the present application in condition for allowance, and such action is respectfully requested. The Examiner is encouraged to contact Applicant's undersigned attorney at chris.lightner@alston.com, 404/881/7882 or 678/517/6662 to resolve any remaining issues in order to expedite examination of the present application.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

/Christopher P. Lightner/

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Electronic Acknowledgement Receipt	
EFS ID:	44009115
Application Number:	17260664
International Application Number:	
Confirmation Number:	1082
Title of Invention:	APPARATUS FOR VISUALIZATION OF TISSUE
First Named Inventor/Applicant Name:	Guennadi SAIKO
Customer Number:	826
Filer:	Christopher Patrick Lightner/Grace Caffey
Filer Authorized By:	Christopher Patrick Lightner
Attorney Docket Number:	046905/554252
Receipt Date:	12-OCT-2021
Filing Date:	15-JAN-2021
Time Stamp:	16:08:39
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2021-10-12_554252Amendment.pdf	261505 73b926d8e9322f2e8a713bfad8b4f5aced9d101e	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	10
Warnings:			
Information:			
	Total Files Size (in bytes):	261505	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/260,664	Filing Date 01/15/2021	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	01/15/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	10/12/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/JEFFERY L OLSEN/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/260,664	01/15/2021	Guennadi SAIKO	046905/554252

CONFIRMATION NO. 1082

826
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CHARLOTTE, NC 28280-4000

POA ACCEPTANCE LETTER

OC000000128078483

Date Mailed: 09/01/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 08/27/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/byemane/

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	17/260,664
Filing Date	01-15-2021
First Named Inventor	Guennadi SAIKO
Title	APPARATUS FOR VISUALIZATION OF TISSUE
Art Unit	3791
Examiner Name	ABOUELELA, MAY A.
Attorney Docket Number	046905/554252

SIGNATURE of Applicant or Patent Practitioner

Signature	/Christopher P. Lightner/	Date (Optional)	2021-08-27
Name	Christopher P. Lightner	Registration Number	62156
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 00826

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

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OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Swift Medical Inc.

☐ Inventor or Joint Inventor (title not required below)

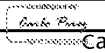
☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	8/20/2021
Name	Carlo Perez		
Title	CEO		, of Swift Medical Inc.

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

Electronic Acknowledgement Receipt	
EFS ID:	43623184
Application Number:	17260664
International Application Number:	
Confirmation Number:	1082
Title of Invention:	APPARATUS FOR VISUALIZATION OF TISSUE
First Named Inventor/Applicant Name:	Guennadi SAIKO
Customer Number:	826
Filer:	Christopher Patrick Lightner/Grace Caffey
Filer Authorized By:	Christopher Patrick Lightner
Attorney Docket Number:	046905/554252
Receipt Date:	27-AUG-2021
Filing Date:	15-JAN-2021
Time Stamp:	13:40:15
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	2021-08-27_554252POA.pdf	217981 336f5c506d833d90995adce1822ca1d3b1914c8c	no	2
Warnings:					

Information:	
Total Files Size (in bytes):	217981

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/260,664	01/15/2021	Guennadi SAIKO	046905/554252

CONFIRMATION NO. 1082

PUBLICATION NOTICE

826
ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

OC00000127987636

Title:APPARATUS FOR VISUALIZATION OF TISSUE

Publication No.US-2021-0259625-A1
Publication Date:08/26/2021

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/260,664	01/15/2021	Guennadi SAIKO	046905/554252	1082

826 7590 07/12/2021

ALSTON & BIRD LLP
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EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
07/12/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@alston.com

Office Action Summary	Application No. 17/260,664	Applicant(s) SAIKO et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 01/15/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 22-41 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 22-41 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 01/15/2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Priority

2. Receipt is acknowledged of certified copies of papers required by 37 CFR 1.55.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 01/15/2021. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

4. Claim 23 is objected to because of the following informalities: the phrase "tissue" in line 3 should be amended to read –the tissue--. Appropriate correction is required.

5. Claim 29 is objected to because of the following informalities: the phrase "of tissue health indicators" in line 1 should be amended to read –tissue health indicators--, the phrase "tissue" in line 10 should be amended to read –the tissue--, and the phrase "tissue health indicators" in line 14 should be amended to read –the tissue health indicators-- . Appropriate correction is required.

6. Claim 33 is objected to because of the following informalities: the phrase "measurement data" in line 4 should be amended to read –the measurement data--, and the phrase "tissue health indicators" in line 4 should be amended to read –the tissue health indicators--. Appropriate correction is required.

Claim Interpretation

7. The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word “means,” but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

Limitation “image capturing unit” in claims 22, 29, 31 and 34, the claims does not recite sufficient structure to correspond to the claimed “image capturing unit”.

Limitation “controller” in claim 25, the claim does not recite sufficient structure to correspond to the claimed “controller”.

Limitation “communication(s) module” in claims 32 and 33, does not recite sufficient structure to correspond to the claimed “communication(s) module”.

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to

cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

8. This application includes one or more claim limitations that use the word "means" or "step" but are nonetheless not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph because the claim limitation(s) recite(s) sufficient structure, materials, or acts to entirely perform the recited function. Such claim limitation(s) is/are:

Limitation "illumination unit" in claims 22, 29, 31, 34, 36 and 38, the claims recite "one or more narrow band light sources" that corresponds to the structure of the claimed "illumination unit".

Limitation "image capture unit" in claim 30, the claim recite "a camera" that corresponds to the structure of the claimed "image capture unit".

Because this/these claim limitation(s) is/are **not** being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are **not** being interpreted to cover only the corresponding structure, material, or acts described in the specification as performing the claimed function, and equivalents thereof.

If applicant intends to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to remove the structure, materials, or acts that performs the claimed function; or (2) present a sufficient showing that the claim limitation(s) does/do not recite sufficient structure, materials, or acts to perform the claimed function.

Claim Rejections - 35 USC § 112

9. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specifications shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-41 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

10. Claims 22, 29 and 34, recite the limitation “m flashes” and “n predetermined wavelengths” these limitations are not defined by the claims, which renders the claims

indefinite. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It also doesn't change the fact that under the broadest reasonably interpretation one with ordinary skill in the art isn't sure what parameters the claimed "m" and "n" refers to and/or represents. The scope of the claim remains indeterminate because of the claimed "m flashes" and "n predetermined wavelengths".

11. Claim 26 recite the limitation "the one or more light sources are arranged about a central aperture" in lines 1-2. This limitation is not defined by the claims, and one with ordinary skill in the art wouldn't be able to know which structural element has/comprises the claimed "central aperture", and/or the light sources are arranged on which structural element. As broadly as claimed the scope of the claim is indeterminate with respect to the claimed "central aperture".

12. Claim 31 recite the limitation "the illumination unit comprises: a portable housing for detachable attachment proximal to an image capturing unit; and an illumination unit comprising one or more narrow band light sources" this limitation is not defined by the claims, which renders the claims indefinite. One with ordinary skill in the art isn't sure if the claimed "image capturing unit", "illumination unit" and "light sources" in claim 31 are the same and/or different than the clamed in claim 29. The scope of the claim remains indeterminate because of the claimed "the illumination unit comprises: a portable housing for detachable attachment proximal to an image capturing unit; and an illumination unit comprising one or more narrow band light sources".

13. Claim 34 recite the limitation "obtain normalized images" in line 11, claim 35 recite the limitation "reference image" in line 2, claim 38 recite the limitations "subtracting mages" in line 4, "intensity images on reference images to obtain normalized images" in line 10, and "the obtained images" in line 11, these limitations are not defined by the claims which renders the claims indefinite. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It also doesn't change the fact that under the broadest reasonably interpretation one with ordinary skill in the art isn't sure the claimed "images" are images of which parameter/structure. The scope of the claim remains indeterminate because of the claimed limitations above.

14. Claim 34 recite the limitation "generating interference elements" in line 13, The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It also doesn't change the fact that under the broadest reasonably interpretation one with ordinary skill in the art isn't sure what the claimed "interference elements" must or must not include. The scope of the claim remains indeterminate because of the claimed "generating interference elements".

15. Claim 35 recite the limitation "reference object" in line 3, claims 37 and 38 recite the limitation "self-reference object" in line 2 and line 8, respectively. These limitations are not defined by the claims, which renders the claims indefinite. One with ordinary skill in the art isn't sure what structural elements the claimed "reference object" must or must

not include. As broadly as claimed the scope of the claim is indeterminate with respect to the claimed “reference object” and “self-reference object”.

16. Claims 39-40 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: claim 39 recite the limitation “camera exposure time” in line 1, one with ordinary skill in the art isn’t sure what is the structural relationship between the claimed “camera” in claim 39 and the claimed “computing device, image capturing unit, and illumination unit” in claim 34.

17. Claims 39-40 are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

For example: claim 39 recite the limitation “camera exposure time is T and a flash time is said T or any whole number multiple of said T” one with ordinary skill in the art wouldn’t be able to know what is “any whole number multiple of said T”.

18. Claim 24 recites the limitation "the green range" in line 6. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 34 recites the limitation "the indications" in line 15. There is insufficient antecedent basis for this limitation in the claim.

20. Claim 38 recites the limitation "the presence of ambient light" in line 5, the limitation “the intensity images” in line 10. There is insufficient antecedent basis for these limitations in the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached on 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access

to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/260,664	Applicant(s)/Patent Under Reexamination SAIKO et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 5

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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*	B	US-20200320683-A1	10-2020	HORIUCHI; Koji	A61B5/444	1/1
*	C	US-20200281513-A1	09-2020	Grubb; Scott	A61B5/489	1/1
*	D	US-20200179713-A1	06-2020	SUBHASH; Hrebesh Molly	A61N5/0616	1/1
*	E	US-20200176099-A1	06-2020	WELSS; THOMAS	A61B5/443	1/1
*	F	US-20200129069-A1	04-2020	INGLESE; Jean-Marc	A61B5/1077	1/1
*	G	US-20200121262-A1	04-2020	DE HAAN; Gerard	A61B5/0245	1/1
*	H	US-20200121243-A1	04-2020	Anderson; Richard R.	A61B5/00	1/1
*	I	US-20200113441-A1	04-2020	VARGHESE; Babu	A61B5/7278	1/1
*	J	US-20200113438-A1	04-2020	BOURQUIN; Yannyk Parulian Julian	A61B18/203	1/1
*	K	US-20200092534-A1	03-2020	ECKHOUSE; Vardit	A61B5/443	1/1
*	L	US-20200046999-A1	02-2020	LIM; Gueisam	A61B5/0077	1/1
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Notice of References Cited	Application/Control No. 17/260,664	Applicant(s)/Patent Under Reexamination SAIKO et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 5

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*	A	US-20190388022-A1	12-2019	TALGORN; Elise Claude Valentine	A61B5/02055	1/1
*	B	US-20190231249-A1	08-2019	DASCALU; Avi	A61B5/0095	1/1
*	C	US-20190216340-A1	07-2019	HOLZ; Christian	A61B5/7221	1/1
*	D	US-20190125197-A1	05-2019	FUKUDA; Nobuhiro	G06T7/0016	1/1
*	E	US-20190082998-A1	03-2019	Nowroozi; Bryan	A61B5/445	1/1
*	F	US-20190069836-A1	03-2019	HETTRICK; Heather	A61B5/447	1/1
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*	I	US-20110117025-A1	05-2011	Dacosta; Ralph Sebastian	G01N21/6456	424/9.6
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*	K	US-20150374277-A1	12-2015	PATWARDHAN; Sachin V.	A61B5/0013	600/306
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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 3 of 5

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*	B	US-20140378779-A1	12-2014	Freeman; Gary A.	A61B5/1032	600/301
*	C	US-20130094730-A1	04-2013	Segman; Yosef	A61B5/445	382/128
*	D	US-20140088380-A1	03-2014	Sprigle; Stephen H.	A61B5/0077	600/306
*	E	US-20130204101-A1	08-2013	Rumberg; Axel	A61B5/0062	600/306
*	F	US-20120041284-A1	02-2012	Krishnan; Srinivasan	A61B5/448	600/306
*	G	US-20120041283-A1	02-2012	Krishnan; Srinivasan	A61B5/448	600/306
*	H	US-20110301441-A1	12-2011	Bandic; Jadran	A61B5/0059	600/306
*	I	US-20110288385-A1	11-2011	Stamatas; Georgios N.	A61B5/0059	600/306
*	J	US-20100271470-A1	10-2010	Stephan; Sandrine	A61B5/445	348/77
*	K	US-20100185064-A1	07-2010	Bandic; Jadran	A61B5/415	600/306
*	L	US-20090220415-A1	09-2009	Shachaf; Catherine M.	A61K49/0004	424/1.11
*	M	US-20090080727-A1	03-2009	Cotton; Symon D.	G06T7/42	382/128

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 17/260,664	Applicant(s)/Patent Under Reexamination SAIKO et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 4 of 5

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20080319283-A1	12-2008	Cotton; Symon	A61B5/0059	600/306
*	B	US-20080214907-A1	09-2008	Gutkowicz-Krusin; Dina	A61B5/0059	600/306
*	C	US-20080194928-A1	08-2008	Bandic; Jadran	A61B5/442	600/306
*	D	US-20080161661-A1	07-2008	Gizewski; Theodore M.	A61B5/0059	600/306
*	E	US-8591413-B2	11-2013	Kruglick; Ezekiel	A61B5/441	600/306
*	F	US-7454046-B2	11-2008	Chhibber; Rajeshwar	A61B5/442	382/118
*	G	US-8116852-B2	02-2012	Baker, Jr.; Clark R.	A61B5/0059	600/476
*	H	US-7657101-B2	02-2010	Christiansen, II; William T	G06T7/90	382/218
*	I	US-8026942-B2	09-2011	Payonk; Gregory	H04N5/2354	348/77
*	J	US-6251070-B1	06-2001	Khazaka; Gabriel	A61B5/0059	600/306
*	K	US-10182757-B2	01-2019	Gareau; Daniel	A61B5/0075	1/1
*	L	US-9662076-B2	05-2017	Jia; Lei	A61B6/08	1/1
*	M	US-20070064979-A1	03-2007	Chhibber; Rajeshwar	G06K9/2018	382/118

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
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	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 17/260,664	Applicant(s)/Patent Under Reexamination SAIKO et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 5 of 5

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20070002479-A1	01-2007	Menke; James	A61B5/0079	359/892
*	B	US-20040218810-A1	11-2004	Momma, Tomoyuki	A61B5/0064	382/162
*	C	US-20040202685-A1	10-2004	Manzo, Robert P.	A45D44/00	424/401
*	D	US-20040125996-A1	07-2004	Eddowes, Miles Hugh	A61B5/442	382/128
*	E	US-5074306-A	12-1991	Green; Howard A.	A61B5/445	600/317
*	F	US-6571003-B1	05-2003	Hillebrand; Greg George	A61B5/0064	382/100
	G					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
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	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/260,664	SAIKO et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/445 or A61B5/742 or A61B5/6898 or A61B5/0013 or A61B5/0077	07/07/2021	MA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
600	306	07/07/2021	MA

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
east text search, inventor name search, class/subclass search	07/07/2021	MA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/260,664	SAIKO et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/07/2021								
	1	-								
	2	-								
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	39	✓								
	40	✓								
	41	✓								

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L6	0	("2020/0121243").URPN.	USPAT	OR	ON	2021/07/07 16:48
L7	0	("2020/0003683").URPN.	USPAT	OR	ON	2021/07/07 16:48
L8	1	("2019/0082998").URPN.	USPAT	OR	ON	2021/07/07 16:50
L9	374	(600/306).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/07 16:50
L10	152	9 and ((illuminat$4 or light$4 or shin$4) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 16:50
L11	193,114	10and ((imag$4 or captur$4 or camera) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 16:51
L12	84	10 and ((imag$4 or captur$4 or camera) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 16:52
L13	58	12 and wavelength	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 16:52
L14	10	("2009/0220415").URPN.	USPAT	OR	ON	2021/07/07 16:53
L15	38	("20040125996" | "20040202685" | "20040218810" | "20070002479" | "20070064978" | "20070064979" |	US-PGPUB; USPAT; USOCR	OR	ON	2021/07/07 16:55

		"20070064985" | "20070064989" | "4894547" | "5074306" | "5343536" | "5836872" | "6069689" | "6571003" | "6587711" | "6763262" | "7369692").PN. OR ("7454046").URPN.				
S1	0	(17/260664).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/07 14:23
S2	1	("20190090751").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/07 14:27
S3	0	("2019/0090751").URPN.	USPAT	OR	ON	2021/07/07 14:42
S4	22	"2017012675"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:15
S5	11	"2017155265"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:18
S6	57,363	(A61B5/445 or A61B5/742 or A61B5/6898 or A61B5/0013 or A61B5/0077).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:20
S7	5,377	S6 and ((illuminat$4 or light$4 or shin$4) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:27
S8	2,499	S7 and ((imag$4 or captur$4 or camera) near4 (tissue or skin))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:28

S9	2,036	S8 and @ad<"20180716"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:29
S10	1,327	S9 and ((illuminat$4 or light$4 or shin$4) near4 wavelength)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/07/07 15:30

EAST Search History (Interference)

<This search history is empty>

7/7/2021 5:03:43 PM
C:\Users\mabouelela\Documents\EAST\Workspaces\17260664 apparatus for visualization of tissue.wsp

Substitute for form 1449/PTO (Revised 07/2007)				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Int'l Application Number	PCT/CA2019/050981
				Int'l Filing Date	July 16, 2019
				First Named Inventor	Guennadi Saiko
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	046905/554252

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
	1.	US-2019/0090751 A1	03-28-2019	Hwang et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
	2.	WO-2017/012675 A1	01-26-2017	Latvijas Universitate		
	3.	WO-2017/155265 A1	09-14-2017	Daegu Gyeongbuk Ins Science & Tech		Abstract; English Equivalent US 2019/0090751 A1

OTHER DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) , volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	4.	INTERNATIONAL SEARCHING AUTHORITY, International Search Report and Written Opinion for International Application No. PCT/CA2019/050981; October 9, 2019, (6 pages), Canadian Intellectual Property Office, Quebec, Canada.	

Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/07/2021

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Bibliographic Data

Application No: 17/260,664

Foreign Priority claimed: (•) Yes ( ) No

35 USC 119 (a-d) conditions met: [✓] Yes [ ] No [ ] Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ [ ]

Examiner's Signature | Initials

Title: APPARATUS FOR VISUALIZATION OF TISSUE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
01/15/2021	600	3791	046905/554252
RULE			

APPLICANTS

Swift Medical Inc., Toronto, ON, CANADA

INVENTORS

Guennadi SAIKO, Mississauga, CANADA

Kenneth MACKO, Toronto, CANADA

Andrei BETLEN, Pickering, CANADA

CONTINUING DATA

This application is a 371 of PCT/CA2019/050981 07/16/2019

PCT/CA2019/050981 has PRO of 62698799 07/16/2018

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

05/18/2021

STATE OR COUNTRY

CANADA

ADDRESS

ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000
UNITED STATES

FILING FEE RECEIVED

$1,820

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/260,664	01/15/2021	Guennadi SAIKO	046905/554252	1082

826 7590 06/25/2021

ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
06/25/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@alston.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Application of	:	
SAIKO et al.	:	
Application No. 17/260,664	:	
Filed: 15 January 2021	:	DECISION ON PETITION
For: APPARATUS FOR VISUALIZATION	:	
OF TISSUE	:	

This is a decision on the request to participate in the Patent Prosecution Highway (PPH) program and the petition under 37 C.F.R. § 1.102(a), filed 04 May 2021, to make the above-identified application special.

The request and petition under 37 C.F.R. § 1.102(a) are **GRANTED.**

DISCUSSION

A grantable request to participate in the PPH pilot program and petition to make special require:

1. The U.S. application for which participation in the Global/IP5 PPH pilot program is requested must have the same earliest date, whether this is the priority date or filing date, as that of a corresponding national or regional application filed with another Global/IP5 PPH participating office or a corresponding PCT international application for which one of the Global/IP5 PPH participating offices was the International Searching Authority (ISA) or the International Preliminary Examining Authority (IPEA);

2. Applicant must:
    a. Ensure all the claims in the U.S. application must sufficiently correspond or be amended to sufficiently correspond to the allowable/patentable claim(s) in the corresponding Office of Earlier Examination (OEE) application and
    b. Submit a claims correspondence table in English;

3. Examination on the merits of the U.S. application has not begun;

4. Applicant must submit:
    a. Documentation of prior office action:
        i. a copy of the office action(s) just prior to the "Decision to Grant a Patent" from each of the Global/IP5 PPH participating office application(s) containing the allowable/patentable claim(s) or

ii. if the allowable/patentable claims(s) are from a "Notification of Reasons for Refusal" then the Notification of Reasons for Refusal or
iii. if the Global/IP5 PPH participating office application is a first action allowance then no office action from the Global/IP5 PPH participating office is necessary should be indicated on the request/petition form or
iv. the latest work product in the international phase of the OEE PCT application;

b. An English language translation of the Global/IP5 PPH participating office action or work product from (4)(a)(i)-(ii) or (iv) above; and

5. Applicant must submit:
   a. An IDS listing the documents cited by the Global/IP5 PPH participating office examiner in the Global/IP5 PPH participating office action or work product (unless already submitted in this application) and
   b. Copies of the documents except U.S. patents or U.S. patent application publications (unless already submitted in this application).

The request to participate in the PPH pilot program and petition comply with the above requirements. Accordingly, the above-identified application has been accorded "special" status.

Telephone inquiries concerning this decision should be directed to Tamie Jarrett at (571) 270-1309.

All other inquiries concerning the examination or status of the application are accessible in the PAIR system at http://portal.uspto.gov/.

/Angela Walker/
Angela Walker
Paralegal Specialist, OPET

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/260,664

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	540
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*			OR	x 100 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 480 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1660

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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www.uspto.gov

U.S. APPLICATION NO.	FIRST NAMED INVENTOR	ATTY. DOCKET NO.
17/260,664	Guennadi SAIKO	046905/554252

826
ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

INTERNATIONAL APPLICATION NO.	
PCT/CA2019/050981	
I.A. FILING DATE	PRIORITY DATE
07/16/2019	07/16/2018

CONFIRMATION NO. 1082
371 ACCEPTANCE LETTER

OC000000125695436

Date Mailed: 05/20/2021

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office, in its capacity as a Designated / Elected Office (37 CFR 1.495), has ACCEPTED the above identified international application for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above. A Filing Receipt will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE "FILING DATE or 371(c) DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1) and (c)(2) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN BELOW.** The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363)

01/15/2021
DATE OF RECEIPT OF 35 U.S.C.
371(c)(1) and (c)(2) REQUIREMENTS

The following items have been received:

- Copy of the International Application filed on 01/15/2021
- Copy of the International Search Report filed on 01/15/2021
- Preliminary Amendments filed on 01/15/2021
- Information Disclosure Statements filed on 01/15/2021
- Request for Immediate Examination filed on 01/15/2021
- U.S. Basic National Fees filed on 01/15/2021
- Authorize Access to Search Results filed on 01/15/2021
- Priority Documents filed on 01/15/2021
- Authorization to Permit Access filed on 01/15/2021
- Application Data Sheet (37 CFR 1.76) filed on 01/15/2021

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.495(c).

- Properly executed inventor's oath or declaration for the following inventor(s) has not been submitted: **Guennadi SAIKO**, **Kenneth MACKO**, and **Andrei BETLEN**

FORM PCT/DO/EO/903 (371 Acceptance Notice)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

NINA D MOTLEY

Telephone: (703) 756-1751

FORM PCT/DO/EO/903 (371 Acceptance Notice)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/260,664	01/15/2021		1820	046905/554252	20	3

CONFIRMATION NO. 1082

FILING RECEIPT

826
ALSTON & BIRD LLP
ONE SOUTH AT THE PLAZA
101 SOUTH TRYON STREET
SUITE 4000
CHARLOTTE, NC 28280-4000

OC000000125895435

Date Mailed: 05/20/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Guennadi SAIKO, Mississauga, CANADA;
Kenneth MACKO, Toronto, CANADA;
Andrei BETLEN, Pickering, CANADA;

Applicant(s)

Swift Medical Inc., Toronto, ON, CANADA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/CA2019/050981 07/16/2019
which claims benefit of 62/698,799 07/16/2018

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 05/18/2021
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/260,664**
Projected Publication Date: 08/26/2021
Non-Publication Request: No
Early Publication Request: No
Title

APPARATUS FOR VISUALIZATION OF TISSUE

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

Substitute for Form PTO-1360
(For use with Form PTO/SB/06)

Application Number	Filing Date
17260664	

Applicant(s) Guennadi SAIKO

* May be used for additional claims or amendments

CLAIMS	AS FILED		AFTER FIRST AMENDMENT		AFTER SECOND AMENDMENT	
	Indep	Depend	Indep	Depend	Indep	Depend
1	1		---	---		
2		1	---	---		
3		2	---	---		
4		(1)	---	---		
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6		(1)	---	---		
7		(1)	---	---		
8		(1)	---	---		
9	1		---	---		
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11		2	---	---		
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14	1		---	---		
15		1	---	---		
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Total Indep	3		3		0	
Total Depend	22	↵	17	↵	0	↵
Total Claims	25		20		0	

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PTO/SB/20GLBL (12-16)
Approved for use through 04/30/2018. OMB 0651-0058
U.S. Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE

REQUEST FOR PARTICIPATION IN THE GLOBAL/IP5 PATENT PROSECUTION HIGHWAY (PPH) PILOT PROGRAM IN THE USPTO

Application No.:	17/260,664	First Named Inventor:	Guennadi SAIKO
Filing Date:	01/15/2021	Attorney Docket No.:	046905/554252
Title of the Invention:	APPARATUS FOR VISUALIZATION OF TISSUE		

THIS REQUEST FOR PARTICIPATION IN THE PPH PILOT PROGRAM ALONG WITH THE REQUIRED DOCUMENTS MUST BE SUBMITTED VIA EFS-WEB. INFORMATION REGARDING EFS-WEB IS AVAILABLE AT HTTP://WWW.USPTO.GOV/PATENTS-APPLICATION-PROCESS/APPLYING-ONLINE/ABOUT-EFS-WEB

APPLICANT HEREBY REQUESTS PARTICIPATION IN THE PATENT PROSECUTION HIGHWAY (PPH) PILOT PROGRAM AND PETITIONS TO MAKE THE ABOVE-IDENTIFIED APPLICATION SPECIAL UNDER THE PPH PILOT PROGRAM.

Office of earlier examination (OEE): United States (United States Patent and Trademark Office)

OEE application number: PCT/CA2019/050981

Both the OEE application and the above-identified U.S. application have the following earliest date (filing or priority date): July 16, 2018

Type of OEE work product relied upon: Written Opinion of the International Searching Authority (WO/ISA)

Mailing date of OEE work product: October 9, 2019

Supporting Documents

1. OEE Work Product and Translation

A copy of the OEE work product and translation if not already in English:

☐ Attached ☒ Previously submitted ☐ Not required because the decision to grant a patent was the first office action

☐ Applicant requests the USPTO to attempt to obtain the OEE work product from the Dossier Access System or PATENTSCOPE

NOTE: If the applicant requests the USPTO to obtain the OEE work product electronically and such attempt is unsuccessful, the applicant will be required to supply the document. Accordingly, to avoid dismissal of the initial PPH request and potential denial of participation in the PPH program, the applicant should verify that the OEE work product is actually available via the Dossier Access System or PATENTSCOPE before requesting retrieval. If the applicant is unable to verify availability, then the applicant should submit the document with the PPH request.

2. References Cited in OEE Work Product

An information disclosure statement (IDS) listing the references cited in the OEE work product and document copies (except U.S. patents and U.S. published patent applications):

☐ Attached ☒ Previously Submitted ☐ Not required because no references were cited in the OEE work product

PTO/SB/20GLBL (05-16)
Approved for use through 04/30/2018. OMB 0651-0058
U.S. Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE

REQUEST FOR PARTICIPATION IN THE GLOBAL/IP5 PPH PILOT PROGRAM IN THE USPTO
(continued)

Application No.:	17/260,664	First Named Inventor:	Guennadi SAIKO

3. Claims Correspondence Certification Statement

All of the claims in this application sufficiently correspond to the patentable/allowable claims in the OEE application.

4. Claims Correspondence Table

Claims in U.S. Application	Patentable Claims in OEE Application	Explanation Regarding the Correspondence
1-21 (Canceled)	N/A	These claims were canceled in the US Preliminary Amendment.
22-27	1 -6	Identical but for non-substantive changes for US practice.
28	7-8	Identical but for combining compression and spring clips in single claim.
29-41	9-21	Identical but for non-substantive changes for US practice.

Signature /Christopher P. Lightner/	Date May 4, 2021
Name (print or type) Christopher P. Lightner	Registration Number 62,156

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt	
EFS ID:	42634049
Application Number:	17260664
International Application Number:	
Confirmation Number:	1082
Title of Invention:	APPARATUS FOR VISUALIZATION OF TISSUE
First Named Inventor/Applicant Name:	Guennadi SAIKO
Customer Number:	826
Filer:	Christopher Patrick Lightner/Grace Caffey
Filer Authorized By:	Christopher Patrick Lightner
Attorney Docket Number:	046905/554252
Receipt Date:	04-MAY-2021
Filing Date:	
Time Stamp:	16:11:04
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Petition to make special under Patent Prosecution Hwy	2021-05-04_554252PPHRequest.pdf	95976 08b4fa4f59c46a09b60b7539442afa017b2e5c47	no	3
Warnings:					

Information:	
Total Files Size (in bytes):	95976

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO-1390 (10-20)
Approved for use through 10/31/2022. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

Attorney Docket No.	U.S. Application No. (if known, see 37 CFR 1.5)
046905/554252	Filed Concurrently Herewith

International Application No.	International Filing Date	Priority Date Claimed
PCT/CA2019/050981	July 16, 2019	July 16, 2018

Title of Invention
APPARATUS FOR VISUALIZATION OF TISSUE

First Named Inventor
Guennadi SAIKO

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.

1. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). NOTE: The express request under 35 U.S.C. 371(f) will not be effective unless the requirements under 35 U.S.C. 371(c)(1), (2), and (4) for payment of the basic national fee, copy of the International Application and English translation thereof (if required), and the oath or declaration of the inventor(s) have been received.
2. ☒ A copy of the International Application (35 U.S.C. 371(c)(2)) is attached hereto (not required if the International Application was previously communicated by the International Bureau or was filed in the United States Receiving Office (RO/US)).
3. An English language translation of the International Application (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
4. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4))
   a. ☐ is attached.
   b. ☐ was previously filed in the international phase under PCT Rule 4.17(iv).

Items 5 to 8 below concern amendments made in the international phase.

PCT Article 19 and 34 amendments

5. ☐ Amendments to the claims under PCT Article 19 are attached (not required if communicated by the International Bureau) (35 U.S.C. 371(c)(3)).
6. ☐ English translation of the PCT Article 19 amendment is attached (35 U.S.C. 371(c)(3)).
7. ☐ English translation of annexes (Article 19 and/or 34 amendments only) of the International Preliminary Examination Report is attached (35 U.S.C. 371(c)(5)).

Cancellation of amendments made in the international phase

8a. ☐ Do not enter the amendment made in the international phase under PCT Article 19.

8b. ☐ Do not enter the amendment made in the international phase under PCT Article 34.

NOTE: A proper amendment made in English under Article 19 or 34 will be entered in the U.S. national phase application absent a clear instruction from applicant not to enter the amendment(s).

The following items 9 to 17 concern a document(s) or information included.

9. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
10. ☒ A preliminary amendment.
11. ☒ An Application Data Sheet under 37 CFR 1.76.
12. ☐ A substitute specification. NOTE: A substitute specification cannot include claims. See 37 CFR 1.125(b).
13. ☐ A power of attorney and/or change of address letter.
14. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.3 and 37 CFR 1.821-1.825 (not required if sequence listing in text format was indicated on the PCT Request as part of the International Application and the sequence listing was published as part of the international application).
15. ☐ Assignment papers *(cover sheet and document(s))*. Name of Assignee: _____
16. ☐ 37 CFR 3.73(c) Statement *(when there is an Assignee)*.

U.S. APPLN. No. (if known – see 37 CFR 1.5)	INTERNATIONAL APPLICATION No.	ATTORNEY DOCKET No.
Filed Concurrently Herewith	PCT/CA2019/050981	046905/554252

17. ☐ Other items or information:

The following fees have been submitted.	CALCULATIONS
18. ■ Basic national fee (37 CFR 1.492(a)) **$320**	$ 320
19. ■ Examination fee (37 CFR 1.492(c)) • If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... **$0** • All other situations **$800**	$ 800
20. ■ Search fee (37 CFR 1.492(b)) • If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... **$0** • Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... **$140** • International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... **$540** • All other situations **$700**	$ 540
TOTAL OF 18, 19, and 20 =	$ 1660
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). Fee for each additional 50 sheets of paper or fraction thereof **$420**	$

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round **up** to a whole number)	RATE
- 100 =	/ 50 =		x **$420**

Surcharge for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)) **$160**	$ 160

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	20 - 20 =	0	x **$100**	$ 0
Independent claims	3 - 3 =	0	x **$480**	$ 0
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$860**	$

Fee for submission of Sequence Listing text file of 300 MB to 800 MB (37 CFR 1.21(o)(1)) **$1,060**	$
Fee for submission of Sequence Listing text file of more than 800 MB (37 CFR 1.21(o)(2)) **$10,500**	$
Processing fee for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)) ..... **$140** +	$
TOTAL OF ABOVE CALCULATIONS =	$ 1820
☐ **Applicant asserts small entity status.** See 37 CFR 1.27. Fees above are reduced by ½.	
☐ **Applicant certifies micro entity status.** See 37 CFR 1.29. Fees above are reduced by ¾. Applicant must attach form PTO/SB/15A or B or equivalent.	
TOTAL NATIONAL FEE =	$ 1820
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) ..... **$50.00** per property +	$
TOTAL FEES ENCLOSED =	$ 1820

a. ☐ A check in the amount of $_____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. 160605 in the amount of $ 3620 to cover the above fees.

c. ☒ The Director is hereby authorized to charge additional fees which may be required, or credit any overpayment, to Deposit Account No. 160605 as follows:

i. ☐ any required fee.

ii. ☒ any required fee except for excess claims fees required under 37 CFR 1.492(d) and (e) and multiple dependent claim fee required under 37 CFR 1.492(f).

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

ADVISORY: If filing by EFS-Web, do **NOT** attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is **not** recommended and by doing so your **credit card information may be displayed via PAIR**. To protect your information, it is recommended to pay fees online by using the electronic payment method.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013, and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE 1: By providing this statement under 37 CFR 1.55 or 1.78, **this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA**.

NOTE 2: A U.S. national stage application may not claim priority to the international application of which it is the national phase. The filing date of a U.S. national stage application is the international filing date. See 35 U.S.C. 363.

Correspondence Address

☒ The address associated with Customer Number: 00826 **OR** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone			
Email					

Signature	/Christopher P. Lightner/	Date	2021-01-15
Name (Print/Type)	Christopher P. Lightner	Registration No. (Attorney/Agent)	62,156

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2019/050981

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***G03B 15/03*** (2006.01) , ***A61B 5/00*** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(2006.01): G03B, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Questel Orbit: (Keywords: multispectral imaging; skin/tissue; capture image/data; smartphone; illumination; portable housing; detachable; narrow band light; flash; wavelength)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2017/155265 A1 (HWANG et al.) 14 September 2017 (14-09-2017) * Whole document *	1-21
A	WO 2017/012675 A1 (SPIGULIS et al.) 26 January 2017 (26-01-2017) * Whole document *	1-21

☐ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"D"	document cited by the applicant in the international application	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"E"	earlier application or patent but published on or after the international filing date	"&"	document member of the same patent family
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)		
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 26 September 2019 (26-09-2017)	Date of mailing of the international search report 09 October 2019 (09-10-2019)
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 819-953-2476	Authorized officer Patrick Abou-Antoun (819) 639-1681

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2019/050981

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO2017155265A1	14 September 2017 (14-09-2017)	WO2017155265A1	14 September 2017 (14-09-2017)
		KR20170104708A	18 September 2017 (18-09-2017)
		KR101799184B1	20 November 2017 (20-11-2017)
		US2019090751A1	28 March 2019 (28-03-2019)
WO2017012675A1	26 January 2017 (26-01-2017)	None	

Attorney Docket No. 046905/554252

IN THE UNITED STATES DESIGNATED OFFICE (DO/US)

In re: Guennadi Saiko Attn: DO/US
International Appln No.: PCT/CA2019/050981
International Filing Date: July 16, 2019
For: APPARATUS FOR VISUALIZATION OF TISSUE

Submitted via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Attached is a list of documents on form PTO-SB08.

The listed documents were cited in the International Search Report, the United States priority Application No. 62/698,799, and/or the specification of International Application No. PCT/CA2019/050981. A copy of the International Search Report is enclosed for the Examiner's convenience.

In accordance with the Office waiver published July 11, 2003, copies of the cited U.S. patents and patent application publications are not enclosed. Applicant does enclose copies of any cited foreign patent documents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

The Examiner may wish to consider the notations on the International Search Report itself regarding the relevance of each item. It is requested that the Examiner consider these references and officially make them of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP. By identifying the listed documents, Applicant in no way makes any admission as to the prior art status of the listed documents, but is instead submitting the listed documents for the sake of full disclosure.

Respectfully submitted,

/Christopher P. Lightner/

Christopher P. Lightner
Registration No. 62,156

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Substitute for form 1449/PTO (Revised 07/2007)				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Int'l Application Number	PCT/CA2019/050981
				Int'l Filing Date	July 16, 2019
				First Named Inventor	Guennadi Saiko
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	046905/554252

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
	1.	US-2019/0090751 A1	03-28-2019	Hwang et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
	2.	WO-2017/012675 A1	01-26-2017	Latvijas Universitate		
	3.	WO-2017/155265 A1	09-14-2017	Daegu Gyeongbuk Ins Science & Tech		Abstract; English Equivalent US 2019/0090751 A1

OTHER DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) , volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	4.	INTERNATIONAL SEARCHING AUTHORITY, International Search Report and Written Opinion for International Application No. PCT/CA2019/050981; October 9, 2019, (6 pages), Canadian Intellectual Property Office, Quebec, Canada.	

Examiner Signature		Date Considered	

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
38753-2010		see Form PCT/ISA/220 as well as, where applicable, item 5 below
International application No.	International filing date *(day/month/year)*	(Earliest)Priority date *(day/month/year)*
PCT/CA2019/050981	16 July 2019 (16-07-2019)	16 July 2018 (16-07-2018)
Applicant		
SWIFT MEDICAL INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☑ the international application in the language in which it was filed.

☐ a translation of the international application into which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☑ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☑ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 4

☑ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2019/050981

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***G03B 15/03*** (2006.01) , ***A61B 5/00*** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(2006.01): G03B, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Questel Orbit: (Keywords: multispectral imaging; skin/tissue; capture image/data; smartphone; illumination; portable housing; detachable; narrow band light; flash; wavelength)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2017/155265 A1 (HWANG et al.) 14 September 2017 (14-09-2017) * Whole document *	1-21
A	WO 2017/012675 A1 (SPIGULIS et al.) 26 January 2017 (26-01-2017) * Whole document *	1-21

☐ Further documents are listed in the continuation of Box C.

☑ See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	
"D" document cited by the applicant in the international application	
"E" earlier application or patent but published on or after the international filing date	
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	
	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
	"&" document member of the same patent family

Date of the actual completion of the international search 26 September 2019 (26-09-2017)	Date of mailing of the international search report 09 October 2019 (09-10-2019)
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 819-953-2476	Authorized officer Patrick Abou-Antoun (819) 639-1681

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2019/050981

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO2017155265A1	14 September 2017 (14-09-2017)	WO2017155265A1	14 September 2017 (14-09-2017)
		KR20170104708A	18 September 2017 (18-09-2017)
		KR101799184B1	20 November 2017 (20-11-2017)
		US2019090751A1	28 March 2019 (28-03-2019)
WO2017012675A1	26 January 2017 (26-01-2017)	None	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
TORYS LLP
79 WELLINGTON ST. WEST
30TH FLOOR
BOX 270, TD SOUTH TOWER
TORONTO, Ontario
Canada, M5K 1N2

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	9 October 2019 (09-10-2019)
Applicant's or agent's file reference 38753-2010	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA2019/050981	16 July 2019 (16-07-2019)	16 July 2018 (16-07-2018)

International Patent Classification (IPC) or both national classification and IPC
IPC: ***G03B 15/03*** (2006.01) , ***A61B 5/00*** (2006.01)

Applicant
SWIFT MEDICAL INC.

1. This opinion contains indications relating to the following items:

- ☑ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☑ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/CA	Date of completion of this opinion	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	04 October 2019 (04-10-2019)	Patrick Abou-Antoun (819) 639-1681

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/CA2019/050981

Box No I **Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

☑ the international application in the language in which it was filed.

☐ a translation of the international application into which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed:

☐ in the form of an Annex C/ST.25 text file.

☐ on paper or in the form of an image file.

b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-21	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-21	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims	NONE	NO

2. Citations and explanations:

Reference is made to the following documents:

D1: WO 2017/155265 A1 (HWANG et al.) 14 September 2017 (14-09-2017)
D2: WO 2017/012675 A1 (SPIGULIS et al.) 26 January 2017 (26-01-2017)

The inventive concept of the present application is considered to be a portable illumination apparatus for facilitating visualizations of tissue, the apparatus comprising a portable housing for detachable attachment proximal to an image capturing unit, and an illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$.

Novelty and Inventive Step

Claims 1-21 are considered to be novel and inventive as the characteristic features of these claims are not specifically disclosed in the prior art documents D1 and D2.

Regarding independent claims 1, 9, 13 and 14, D1 discloses a portable illumination apparatus (120 in figure 1; figure 2) for facilitating visualizations of tissue (abstract), the apparatus comprising a portable housing for detachable attachment proximal to an image capturing unit (see figure 1), and an illumination unit comprising one or more narrow band light sources (see figure 2; paragraphs [63]-[64]).

Regarding independent claims 1, 9, 13 and 14, D2 discloses a portable illumination apparatus (see figure 1a) for facilitating visualizations of tissue (abstract), the apparatus comprising a portable housing (see figure 1a) for detachable attachment proximal to an image capturing unit (3 in figure 1b), and an illumination unit comprising one or more narrow band light sources (7 in figure 2; page 5, lines 24-25).

However, regarding independent claims 1, 9, 13 and 14, neither D1 nor D2, alone or in combination, teach or fairly suggest a portable illumination apparatus, tissue imaging system, or method for generating visualizations of tissue, comprising an illumination unit having one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$.

As such, claims 1-21 are considered novel and inventive as required by PCT Articles 33(2) and 33(3).

Industrial Applicability

Claims 1-21 are directed to a portable illumination apparatus, tissue imaging system, and method for generating visualizations of tissue. As such, the subject matter of claims 1-21 is considered to be industrially applicable, and thus the claims comply with the requirements of Article 33(4) of the PCT.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 January 2017 (26.01.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/012675 A1

(51) International Patent Classification:
A61B 5/00 (2006.01)

(21) International Application Number:
PCT/EP2015/066913

(22) International Filing Date:
23 July 2015 (23.07.2015)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant: **LATVIJAS UNIVERSITATE** [LV/LV]; Raina bulvaris 19, LV-1586 Riga (LV).

(72) Inventors: **SPIGULIS, Janis**; Zalves 9, LV-1046 Riga (LV). **LACIS, Matiss**; Garozes 19-64, LV-1004 Riga (LV). **KUZMINA, Ilona**; Rusonu 3-43, LV-1057 Riga (LV). **LIHACOVS, Aleksejs**; Laivu 1-18, LV-1004 Riga (LV). **RUPENHEITS, Zigmars**; M.Keldisa 24-1, LV-1021 Riga (LV). **UPMALIS, Vladimirs**; Zaku 1-40, LV-5001 Ogre (LV).

(74) Agent: **FORAL PATENT LAW OFFICES**; P.O.Box 98, 1050 Riga (LV).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *with amended claims (Art. 19(1))*

(54) **Title**: METHOD AND DEVICE FOR SMARTPHONE MAPPING OF TISSUE COMPOUNDS

(57) **Abstract**: The invention relates to imaging technologies, in particular to remote imaging of tissue chromophore and/or fluorophore distribution by means of a smartphone or a similar mobile device. Goal of the invention is to ensure easy use of smartphones (or similar mobile devices, originally comprising at least one camera, display, processing unit and battery) with appropriate software for remote mapping of tissue compounds. Invention proposes tissue chromophore and/or fluorophore mapping and/or indication of clinically critical values of their content on the display of smartphone by converting images of the same tissue area taken by smartphone camera under spectrally specific illumination and using the internal computing resources of smartphone for image processing. Five supporting device designs are proposed along with two methods used for image processing.

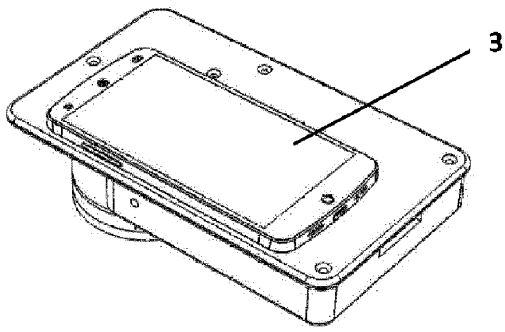


Fig.1b

WO 2017/012675 A1

Method and device for smartphone mapping of tissue compounds

Technical field

The invention relates to imaging technologies, in particular to remote imaging of tissue chromophore and/or fluorophore distribution by means of a smartphone or a similar mobile device.

Background art

Distribution maps of tissue compounds, e.g. skin chromophores, provide diagnostic information about the tissue condition and its changes during physiological processes like inflammations, post-therapy recovery, burn healing, development of tumours and bruises, etc. Three main chromophores that determine skin colour in normal conditions are melanin, oxy-haemoglobin and deoxy-haemoglobin (*A. R. Young, "Chromophores in human skin", Phys. Med. Biol. 42, 789, 1997*). Content of another skin chromophore – bilirubin increases in result of liver insufficiency and/or mechanical interventions (bruises, post-surgery healing; as a reference, see *L.L.Randeberg et al., "Skin changes following minor trauma." Lasers Surg. Med. 39(5), 403–413, 2007*). Fast and reliable 2D-mapping of the named chromophores in pathologic cases is of interest for dermatologists, oncologists, forensic experts, intensive care physicians, family doctors and other professionals, as well as for wider audience interested in self-monitoring, e-medicine, personalized healthcare and similar aspects.

Tissue chromophore maps can be derived from large data sets of multi-spectral and/or hyperspectral reflection images, by means of spectral fitting algorithms with respect to absorption properties of the chromophores under interest (e.g. *D. Jakovels and J. Spigulis, "2-D mapping of skin chromophores in the spectral range 500-700 nm", J. Biophoton. v.3, No. 3, pp. 125–129, 2010*). To avoid errors due to detection of tissue specular reflection, such systems usually comprise two mutually crossed polarizers – one in front of the illuminator and the other in front of the imaging camera (*US2005030372 A1 Method and apparatus for characterization of chromophore content and distribution in skin using cross-polarized diffuse reflectance imaging*). Digital RGB cameras are also well-suited for chromophore mapping, since the red (R), green (G) and blue (B) spectral images of the

target can be separated and/or specifically related (e.g. *Kapsokalyvas D. et al.,. "Spectral morphological analysis of skin lesions with a polarization multispectral dermoscope." Opt. Express. 21(4), 4826–40, 2013*). To acquire spectral images, also spectrally narrowband tissue illumination can be used, e.g. by means of different colour LEDs (*D.Jakovels et al., "Noncontact monitoring of vascular lesion phototherapy efficiency by RGB multispectral imaging", J. Biomed. Opt. 18(12), 126019, 2013*). In this and similar studies three illumination spectral bands are exploited, each in frame of one photo-detection sensitivity band (R, G or B) of the image sensor; the three main chromophore content at each image pixel (or selected pixel group) are found by solving a system of 3 equations:

$$\begin{cases} \log\frac{I_{0K}}{I_K} = \int_{\lambda_1}^{\lambda_2} M_K(\lambda)L_B(\lambda)\cdot(\sum_i C_i l(\lambda)\varepsilon_i(\lambda))d\lambda + \\ + \int_{\lambda_3}^{\lambda_4} M_K(\lambda)L_G(\lambda)\cdot(\sum_i C_i l(\lambda)\varepsilon_i(\lambda))d\lambda + \int_{\lambda_5}^{\lambda_6} M_K(\lambda)L_R(\lambda)\cdot(\sum_i C_i l(\lambda)\varepsilon_i(\lambda))d\lambda \\ K = R, G, B \end{cases} \quad (1),$$

where C_i- concentrations of particular chromophores to be calculated, ε_i- extinction coefficients of the chromophores, I_{0R}, I_{0G}, I_{0B}- detected R, G, B signals from the white reference, I_R, I_G, I_B – detected R, G, B signals from the target tissue, $M_R(\lambda)$, $M_G(\lambda)$, $M_B(\lambda)$ – R, G and B spectral sensitivity bands of the image sensor, $L_R(\lambda)$, $L_G(\lambda)$, $L_B(\lambda)$ – illumination spectra at the three spectral intervals, $l(\lambda)$- absorption path length in tissue at the particular wavelength.

Skin fluorescence is useful technique for imaging of hidden tissue structures (*US2014364745 A1), Multi-spectral tissue imaging*). Skin fluorophore distributions can be mapped using specific lifetime imaging (as example - *A.Ehlers et al., "Fluorescence lifetime imaging of human skin and hair", Proc. SPIE, v. 6089, 6089ON, 2006*) or imaging of fluorescence photo-bleaching rates (*J.Spigulis et al., "Imaging of laser-excited tissue autofluorescence bleaching rates," Appl. Opt., v. 48, No. 10, pp. D163-D168, 2009*). Fluorescence lifetime imaging devices usually are large-sized and robust, therefore not well-suited for clinical environment, while the known photo-bleaching rate distribution imagers typically need external computer for image processing. Wider applications of fluorescence techniques would require more compact designs.

Portable handheld devices with built-in illumination, imaging and processing units able to map skin chromophores and fluorophores are known, as well (e.g. *LV14749 A), Multimodal displaying device for non-contact skin diagnosis; J.Spigulis et al., "SkImager: a concept device for in-vivo skin assessment by multimodal imaging", Proc. Est. Acad. Sci. 63(3), 213-220, 2014*). The proposed concept and prototype are at an early development stage and need further clinical validation.

There are now close to 2 billion smartphone users (http://www.emarketer.com/Article/Smartphone-Users-Worldwide-Will-Total-175-Billion-2014/1010536). Many of them, especially those involved in healthcare sector, would like to use smartphone also as a tool for assessment of health condition and tissue composition. Smartphones, tablet PCs, laptop PCs and similar mobile devices of the latest generations comprise elements that are commonly exploited for mapping of tissue compounds - high-resolution digital RGB cameras, liquid-crystal displays, powerful processing units and white LED light source(s) on the rear panel. It was proposed earlier to use these features of smartphones for optical skin assessment (https://www.skinvision.com/; *US2014313303 A1, Longitudinal dermoscopic study employing smartphone-based image registration; JP2014131121 A, Skin imaging system*). External optical filters can be applied to the white LED and/or to the RGB camera of smartphone in order to modify spectral sensitivity of the imaging system. A smartphone with rear camera covered by special three-band transmission filter was used to estimate skin bilirubin content under the white LED illumination (*C.A.Patil et al., Feasibility of mobile phone based transcutaneous bilirubinometry, Proc.SPIE, 9303, 2015*). However, such filters with acceptable performance are expensive and need specific designs for simultaneous detection of several different chromophores. The front-camera of smartphone also can be exploited for tissue analysis, e.g. under liquid crystal display illumination (*US2015005644 A1, Dermoscopic data acquisition employing display illumination).* This technique eventually may be adapted also for tissue chromophore mapping. Spectrally specific illumination makes possible to map the distributions of skin chromophores by RGB cameras very rapidly, even by a single snapshot. Simultaneous illumination of tissue by discrete spectral lines allows extracting several monochromatic spectral images from single RGB image data set (*WO2013135311 A1, Method and device for imaging of spectral reflectance at several wavelength bands*). Snapshot mapping of three main skin chromophores under triple-laser illumination has been demonstrated recently (*J.Spigulis and I.Oshina, "Snapshot RGB*

mapping of skin melanin and haemoglobin", J.Biomed.Opt, 20(5), 050503, 2015). This approach might be efficient if smartphone is used for image acquisition.

Generally, the regarded background information confirms that smartphones and/or similar mobile devices might be applied efficiently for distant mapping of tissue compounds if appropriate methods and supporting devices become available.

Disclosure of the invention

Goal of the invention is to ensure easy use of smartphones (or similar mobile devices, originally comprising at least one camera, display, processing unit and battery) for remote mapping of tissue compounds.

Invention proposes tissue chromophore and/or fluorophore mapping and/or indication of clinically critical values of their content on the display of smartphone by converting images of the same tissue area taken by smartphone camera under spectrally specific illumination and using the internal computing resources of smartphone for image processing. Five supporting device designs are proposed along with two methods used for image processing.

Brief description of the drawings

Fig.1 presents design scheme of the embodiment 1 without smartphone (a) and with smartphone (b).

Fig.2 specifies design of the ring light source covered by diffusive film and polarizer of the embodiment 1.

Fig.3 illustrates design of the embodiment 1 with conical shielding wall.

Fig.4 shows design scheme of the embodiment 3 with cylindrical (a) and conical (b) shielding wall.

Fig.5 presents the measured emission spectra from mono-coloured displays of the *Sony Xperia Go* smartphone: B – blue, G – green, R – red.

Fig.6 provides scheme for image capturing by front camera of smartphone with side-turned display illumination of the tissue.

Fig.7 illustrates design scheme of the embodiment 4 without (a) and with (b) smartphone.

Fig.8 explains optical system of the embodiment 5 providing tissue illumination at several laser wavelengths.

Fig.9a and 9b specifies design of laser illumination system of the embodiment 5.

Fig.10 presents the scheme of image-processing algorithm for mapping of tissue chromophores.

Fig.11 presents the scheme of image-processing algorithm for mapping of tissue fluorophores.

Embodiment 1. Universal platform for tissue chromophore mapping by smartphone.

The proposed device (Fig.1) comprises a flat platform 1 with first polarizer-covered opening 2 for the rear camera of a smartphone 3 or similar mobile device with installed appropriate software. The platform 1 is covered with a sticky non-smearing substance able to fix the smartphone, tablet computer or other mobile device with its camera against the opening 2 during the image acquisition. This design is universal because any model of smartphone, tablet computer or other mobile device can be used, independently on its size and specifications.

On the other side of platform 1 a compartment 4 for rechargeable batteries and electronic circuits is mounted, as well as non-transparent cylindrical light shielding wall 5 that also ensures fixed distance between the camera objective and the examined tissue, placed under the cylinder in contact with it. In order to image smaller tissue areas under examination, on the bottom of shielding cylinder 5 manually tuneable iris diaphragm 6 or, alternatively, a set of shielding rings with internal openings of different diameters, is mounted.

Spectrally-specific illumination of tissue is performed by a ring of suitable narrowband LEDs 7 with internal diameter larger than that of the opening 2 (Fig.2). The LED ring 7 is mounted on the down-side side of platform 1 within the shielding cylinder 5 and is covered by a ring of diffusive film 8 that provides uniform illumination of the target area, and, behind it, by a ring of polarizing film 9 with orthogonal orientation relatively to the first polarizer 10, so preventing detection of the tissue surface-reflected radiation. The ring 7 comprises a set of narrowband LEDs emitting at least in the blue, green and red spectral

ranges. Each emission colour is sequentially 0.1...1.0 second switched on by a driver mounted in the compartment 4 for taking one or several spectral images; the driver is managed by smartphone's software using either cable or wireless connection. The LEDs can be also switched on simultaneously to provide white illumination for taking a colour photo of the tissue under examination. All acquired images are further processed using the method described below; the calculated tissue chromophore maps appear on the screen of smartphone within few seconds and can be examined visually and/or saved for further analysis in the smartphone memory card.

Another design option of embodiment 1 is presented on Fig.3. To ensure better access to curved, caved or hard-to-reach tissue areas, the cylindrical shielding unit is replaced by a conical shielding nozzle 11 with correspondingly reduced image field.

Embodiment 2. Universal platform for tissue fluorophore mapping by smartphone.

Device comprises most of the elements of the embodiment 1, with some modifications to adapt the device for fluorescence measurements. The ring-shaped LED illuminator 7 is uncovered and comprises one or several LEDs suitable for tissue fluorescence excitation, e.g. emitting in the spectral range 400-450nm, and one or several white LEDs for obtaining colour photos of the tissue area under examination by the smartphone camera. Instead of the first polarizer 10, the opening 2 is covered by an optical filter, cutting-off the wavelengths used for fluorescence excitation.

LEDs are operated by the smartphone software; they are continuously emitting for a pre-defined time interval. Fluorescence images of the same tissue area are recorded by smartphone camera in video-mode for at least 20 seconds with framerate at least 1 fr/s. The B-output signals of each image pixel or selected pixel group are used for reference, while the G- and R-outputs are imaging the tissue fluorescence and detecting its photo-bleaching over time. If several fluorophores are excited, their photo-bleaching rates may differ, causing temporal changes in output signals of the G- and R-detection bands. The tissue flourophores and/or their groups are identified and mapped using the method described below; the resulting maps and/or videos of tissue fluorophore distribution appear on the smartphone display and can be saved for further analysis in the memory card of smartphone.

Embodiment 3. Compact design for tissue chromophore and/or fluorophore mapping by smartphone.

In order to reduce size of the embodiment 1 and/or embodiment 2, the platform 1 represents a disc with external diameter equal to that of the shielding cylinder 5 or basement of the shielding cone 10 (Fig.4). Both power supply and management of the LED ring 7 operation is provided by the smartphone battery and the installed appropriate software, respectively, via a flexible cable 12 connected to the USB port of the smartphone. Image processing, display and saving of the tissue chromophore and/or fluorophore maps is performed as described above. This design is handier than the two previously described, but it is not that universal due to limitations of LED current provided by the battery of the specified model of smartphone or similar mobile device.

Embodiment 4. Smartphone holder with light-turning element for tissue chromophore mapping.

Our laboratory measurements confirmed that mono-coloured display of smartphone can emit relatively narrow spectral bands, comparable to those of LEDs (Fig.5). It opens the possibility to perform spectrally selective tissue illumination directly by smartphone's display, avoiding the need of external multi-coloured LEDs for obtaining the set of tissue spectral images. Front camera of smartphone (usually located in the upper corner of front panel) can be used for image acquisition; however, the drawback is uneven illumination of the camera's field of view, if smartphone is used without any additional components.

To assure uniform illumination of the tissue area facing the front camera, micro-structured prism film (http://www.film-optics.co.uk/index.php/lighting) or similar light turning element is proposed to be attached to the smartphone display, with respect to the geometrical condition for distance x between the front panel of smartphone and the examined tissue: $x = A * \mathrm{ctg}\ \alpha$, where A is the distance between the middle-points of the display and the front camera, respectively, and α is the light turning angle (Fig.6).

The device according to the present embodiment represents a hollow holder with light-shielding walls 13, placed on the tissue surface. Holder has and upper surface adapted to size of the smartphone with properly oriented micro-structured prism film (or similar light

turning element) 14 supposed to be in contact with the illuminating display of smartphone (Fig.7). The upper surface also comprises an opening for the front camera of smartphone, possibly covered by a properly oriented polarizing film to minimize detection of surface-reflected light. The upper surface of holder is fixed at the distance x from the tissue surface. Extension of the shielding wall 15 provides optimal field of view of the front camera.

Alternatively, display of the smartphone remains open while a sloped mirror, transparent wedge or other optical element turning the front camera's field of view for the angle α observing the same geometrical condition for the distance x) is attached to the front camera of smartphone so that the display-illuminated area of tissue is optimally imaged.

Embodiment 5. Universal platform for single-snapshot mapping of tissue chromophores.

Our previous studies demonstrated that uniform illumination of tissue simultaneously by a fixed number of discrete spectral lines assures extraction of the same number of monochromatic spectral images from a single RGB image data set, with their further conversion into chromophore maps (*J.Spigulis and I.Oshina, "Snapshot RGB mapping of skin melanin and haemoglobin", J.Biomed.Opt, 20(5), 050503, 2015*). This concept is implemented in device-5 for smartphone snapshot mapping of tissue chromophores.

Device comprises elements 1-5 of the device-1 (Fig.1), as well as the ring-shaped polarizing film 9. For tissue illumination the LED ring 7 is replaced by a flat diffusive disc 16 with round central opening, made of a milk-glass or similar material. Disc 16 is tightly covered by another ring-shaped disc 17 of the same thickness but made of a transparent material, e.g. glass, with polished 45deg-sloped external edge; the upper surfaces and sloped edges of both discs are mirror-coated (Fig.8). Inside the shielding cylinder 5 a number of laser modules 18 emitting spectral lines with selected wavelengths are fixed so that their output beams are directed to the sloped mirrored edge of the external disc 17 and after reflection are directed radially to the diffusive disc 16. The scattered in disc 16 laser light provides uniform illumination of the examined tissue surface at all exploited laser wavelengths (Fig.9).

Alternatively, the external disc 17 is replaced by a set of radially oriented flexible optical fibres or other appropriate light guide(s) that deliver the laser radiation to the diffusive ring 16 from the laser modules that are placed elsewhere.

If compared with known laser illumination methods that exploit beam-expanding or scattering elements located between the laser source and target area, the proposed design provides more uniform illumination of the selected tissue surface because disc 16 acts as an isotropic surface emitter, not as a point-source.

The single snapshot of selected tissue area is taken by smartphone rear camera when all lasers are switched on. Image processing for obtaining tissue chromophore maps on the smartphone display is performed by software installed on the smartphone using the algorithm from the above-cited publication.

Method for tissue chromophore mapping

To determine spectral reflectance or optical density in reflection mode as proposed by eq. (1), a reference signal from specific reflector is needed. Most commonly a white reflector (e.g. white ceramic plate, white paper) is used for reference. However, it may cause significant errors in tissue chromophore maps, especially if specular reflection from the tissue surface if prevented by combination of linearly polarized illumination and detection via orthogonally oriented polarizer and only diffusely scattered light is detected. The scattering anisotropy factor g, defined as $g = \langle \cos \phi \rangle$, where ϕ photon deflection angle at single scattering event, may be essentially different within the reference material and within the tissue. From this point, more reliable reference could be specifically selected area(s) of the tissue under examination, thanks to similar internal structure and scattering properties.

Invention proposes to exploit as reference for chromophore mapping the area(s) of healthy tissue adjacent to the pathology region or sufficiently close to it - e.g. in cases when the adjacent part is inflamed or when the pathology covers nearly all field of view. Smartphone software establishes equally sized regions of interest (RoI) for further analysis – e.g. at least one in central (pathology) region of the image and four at all corners of image (or a different number of differently located RoIs), with subsequent averaging of the reference values of reflected intensity. In the cases when the adjacent to pathology part of

tissue is inflamed or when the pathology covers nearly all field of view, additional reference image has to be taken from completely healthy tissue near to the pathology region.

The scheme of image-processing algorithm is presented on Fig.10. The process of obtaining chromophore distribution maps starts with reference image obtaining 801. For reference data image of patient skin without damage is used. The reference images are obtained for every illumination wavelength. Then operator chooses priority chromophore mapping 802 which are most interesting - PH. The next step 803 is obtaining 3 images I_i - one per one illumination wavelength, where every image is dedicated to chromophore i. After that 2 algorithm variables are initialized for every chromophore i mapping – split factor for images N_i 804 and speed factor SF_i 805. Speed factor SF specifies how fast algorithm converges and is adjusted for computing platform according to requirements for mapping obtaining speed and available computing resources. Split every image pixels into groups 807. On every group pixels intensity is replaced with average intensity of group's pixels. After that 808 using average intensities are solved equation system (1) or using mathematical optimization found values for C_i from equation (1) minimizing error over all pixels between intensities on captured images I_i and calculated using (1). Obtained values are stored for later post processing. Every loop 806-809 produces new values C_i for every pixel on image I_i. New values for N_i are calculated 809 using current values N_i and speed factor SF_i. If for any of i (Image I_i width / N_i < 1 or Image I_i height / N_i < 1), collected chromophore distribution mapping value sets are analyzed 810. During analyzing are removed values < 0 and values that differ from the rest too much. The final stage is creating chromophore map using the filtered values.

After chromophore mapping, the smartphone software calculates and shows on its display value(s) of physiologically and clinically significant criteria - spectral reflectance

$$k(\lambda) = I(\lambda)/I_o(\lambda) \qquad (2),$$

where $I(\lambda)$ and $I_o(\lambda)$ are intensities detected at wavelength □from the target and reference, respectively, and/or optical density

$$OD(\lambda) = \log k(\lambda) \qquad (3),$$

and/or the pathology criterion

$$Z = C(pat)/ C(hea) \qquad (4),$$

related to the derived concentrations of particular chromophore in the pathology region C(pat) and in the reference (healthy tissue) region C(hea).

Relative concentrations of chromophores are calculated from the measurement data by solving eq. (1) or by any other suitable algorithm. Then the smartphone software compares the obtained values with pre-defined clinical threshold values related to severity of the examined tissue pathology and indicates the severity level of the displayed values by different colour coding, flashing the displayed numbers at different frequencies, sound signalling, or similar.

Method for tissue fluorophore mapping

Invention proposes to map tissue fluorophores or their groups accordingly to the recorded photo-bleaching rate distributions as detected separately in the G- and R-channels of the smartphone image sensor, and additionally to characterize the dynamics of photo-bleaching by providing sequential parametric images formed by the ratios of the G- and R-signals recorded from each pixel or group of pixels over time (e.g. by creating a parametric video file). Both static fluorophore distribution maps and the dynamic video-recordings are displayed on the smartphone touch-screen.

The processing procedure involves the following steps:

1. RGB image snapshot under white LED illumination $R_{x,y}=f[R,G,B]$
2. Periodic capture of the set of spectrally filtered tissue AF images during the 20 seconds with 1fr/sec framerate under continuous 405 nm LED excitation
3. Creating from AF images a coordinate-color-time data array $A_{x,y,t}=[R,G,B,t_{scc}]$
4. Calculating the difference of color components between AF image at excitation start moment (t=0) and AF image of time moment t (t=1:20 sec.): $D_{x,y,t}=G_{t=0} - R_t$
5. Define the mask according to the threshold: if $D_{x,y,t}\geq 0$ then $M_{x,y,t}=255$, else $M_{x,y,t}=0$.
6. Mark areas of $R_{x,y}$ image within mask $M_{x,y,t}$.
7. Creating an image sequence $R_{x,y}$ within the masks $M_{x,y,t}$

The scheme of image-processing algorithm is presented on Fig.11, where abbreviation AF means "autofluorescence".

Claims

1. A device for mapping of tissue chromophores on a display of smartphone or similar mobile device using transformations of spectral images taken from the same tissue area by RGB digital camera of smartphone at sequential tissue illumination by narrowband radiation with different central wavelengths within the RGB sensitivity interval, the device comprising a flat sticky platform with a first polarizer-covered opening for the rear camera of smartphone or similar mobile device with installed appropriate software, a compartment for rechargeable batteries and/or electronic circuits, a ring of suitable light emitting diodes (LED) covered with diffuser and polarizing film oriented orthogonally to the first polarizer, situated around said opening at the other side of platform and placed within a cylindrical or conical light shielding wall which is also adapted to ensure fixed distance between the camera and the examined tissue.

2. The device according to Claim 1, wherein the platform represents a disc with external diameter equal to that of the shielding cylinder or cone basement and both power supply and management of the LED ring emission is provided by the battery and software of the smartphone or similar mobile device, respectively, via flexible cable connected to the USB port of the smartphone, while the captured images are processed by appropriate smartphone software.

3. The device according to Claim 1 or 2, wherein to assure mapping of tissue fluorophores the first polarizer is replaced by cut-off optical filter and the LED ring comprises one or several light emitting diodes suitable for tissue fluorescence excitation, e.g. emitting in the spectral range 400-450 nm, and at least one white light emitting diode for tissue illumination to ensure capturing of colour photo of the tissue.

4. The device according to Claim 1 or 2, wherein spectrally specific sequential tissue illumination is provided by mono-coloured display of smartphone or similar mobile device with appropriate software and tissue images are taken by front camera of the smartphone, providing that a micro-structured prism film or other light turning element is attached to the smartphone display so that the display-emitted light is side-directed and provides optimal illumination of the tissue area facing the front-camera of smartphone and the distance between them is $x = A * \mathrm{ctg}\ \alpha$, where A is the distance between the middle-points of the display and the front camera, respectively, and α is the light turning angle, where the light shielding is ensured by means of a hollow smartphone holder placed on the tissue

surface and having upper surface comprising an opening for the front camera objective, possibly covered by a properly oriented polarizing film; alternatively, the upper surface of the holder comprises a sloped mirror, transparent wedge or another element that turns aside field-of-view of the front camera for angle α so ensuring optimal imaging of the display-illuminated tissue surface placed at the distance x from the front panel of smartphone.

5. The device according to Claim 1 or 2, wherein the LED ring covered with diffuser is replaced by a disc-shaped scattering diffuser with round central opening which is radially side-illuminated by several laser beams with different wavelengths, emitted from a number of laser modules placed inside the cylindrical wall, using appropriate optical element for laser beam management, e.g. external transparent disc with sloped edge; alternatively, laser modules are placed elsewhere and laser beams are radially illuminating the disc-shaped diffuser via flexible optical fibres or other light guide(s).

6. A method for tissue chromophore mapping providing that selected area(s) of healthy tissue adjacent to the pathology region or sufficiently close to it is/are exploited as the reference(s) for determination of spectral reflectance and/or optical density of reflectance by defining specific areas of interest at the images captured by smartphone camera and using the recorded reflected signals for quantifying severity of the particular pathology by their comparing with pre-defined threshold values of spectral reflectance, optical density and/or the criterion [C(pat)/C(hea)], where C(pat) and C(hea) are the derived chromophore concentrations in the pathology region and in the healthy tissue region, respectively, with indicating the severity level(s) of pathology(-ies) on the smartphone display by different colours, flashing signs, sound signal(s), or similar.

7. A method for mapping of tissue fluorophores using video-images taken by RGB digital camera of a smartphone or similar mobile device under temporally stable irradiation by light emitting diode(s) or other light source(s) emitting wavelength(s) fitting within the absorption band(s) of particular fluorophore(s), typically in the violet-blue spectral range 400-450 nm, providing that fluorescence images of the specified tissue area are sequentially recorded for at least 20 seconds with a period 1 second or less, wherein the B-output signal of each image pixel or selected pixel group is used for reference while the G- and R-output signals are used to monitor tissue fluorescence and its photo-bleaching over time, resulting in identification of fluorophores or their groups by analysis of parametric maps of photo-bleaching rate distribution and/or video file(s) or similar format that

properly reflects temporal changes of the parameter k = G/R, where G an R are the G- and R-signal output value for each image pixel or specified group(s) of pixels, respectively.

AMENDED CLAIMS
received by the International Bureau on 22 June 2016 (22.06.2016)

1. A device for mapping of tissue chromophores on a display of smartphone or similar mobile device using transformations of spectral images taken from the same tissue area by RGB digital camera of smartphone at sequential tissue illumination by narrowband radiation with different central wavelengths within the RGB sensitivity interval, the device comprising a flat sticky platform with a first polarizer-covered opening for the rear camera of smartphone or similar mobile device with installed appropriate software, a compartment for rechargeable batteries and/or electronic circuits, a ring of suitable light emitting diodes (LED) covered with diffuser and polarizing film oriented orthogonally to the first polarizer, situated around said opening at the other side of platform and placed within a cylindrical or conical light shielding wall which is also adapted to ensure fixed distance between the camera and the examined tissue, wherein the platform represents a disc with external diameter equal to that of the shielding cylinder or cone basement and both power supply and management of the LED ring emission is provided by the battery and software of the smartphone or similar mobile device, respectively, via flexible cable connected to the USB port of the smartphone, while the captured images are processed by appropriate smartphone software, wherein to assure mapping of tissue fluorophores the first polarizer is replaced by cut-off optical filter and the LED ring comprises one or several light emitting diodes suitable for tissue fluorescence excitation, e.g. emitting in the spectral range 400-450 nm, and at least one white light emitting diode for tissue illumination to ensure capturing of colour photo of the tissue.

2. The device according to Claim 1, wherein spectrally specific sequential tissue illumination is provided by mono-coloured display of smartphone or similar mobile device with appropriate software and tissue images are taken by front camera of the smartphone, providing that a micro-structured prism film or other light turning element is attached to the smartphone display so that the display-emitted light is side-directed and provides optimal illumination of the tissue area facing the front-camera of smartphone and the distance between them is $x = A * \mathrm{ctg}\,\alpha$, where A is the distance between the middle-points of the display and the front camera, respectively, and α is the light turning angle, where the light shielding is ensured by means of a hollow smartphone holder placed on the tissue surface and having upper surface comprising an opening for the front camera objective, possibly covered by a properly oriented polarizing film; alternatively, the upper surface of

the holder comprises a sloped mirror, transparent wedge or another element that turns aside field-of-view of the front camera for angle α so ensuring optimal imaging of the display-illuminated tissue surface placed at the distance x from the front panel of smartphone.

3. The device according to Claim 1, wherein the LED ring covered with diffuser is replaced by a disc-shaped scattering diffuser with round central opening which is radially side-illuminated by several laser beams with different wavelengths, emitted from a number of laser modules placed inside the cylindrical wall, using appropriate optical element for laser beam management, e.g. external transparent disc with sloped edge; alternatively, laser modules are placed elsewhere and laser beams are radially illuminating the disc-shaped diffuser via flexible optical fibres or other light guide(s).

4. A method for mapping of tissue fluorophores using video-images taken by RGB digital camera of a smartphone or similar mobile device under temporally stable irradiation by light emitting diode(s) or other light source(s) emitting wavelength(s) fitting within the absorption band(s) of particular fluorophore(s), typically in the violet-blue spectral range 400-450 nm, providing that fluorescence images of the specified tissue area are sequentially recorded for at least 20 seconds with a period 1 second or less, wherein the B-output signal of each image pixel or selected pixel group is used for reference while the G- and R-output signals are used to monitor tissue fluorescence and its photo-bleaching over time, resulting in identification of fluorophores or their groups by analysis of parametric maps of photo-bleaching rate distribution and/or video file(s) or similar format that properly reflects temporal changes of the parameter $k = G/R$, where G and R are the G- and R-signal output value for each image pixel or specified group(s) of pixels, respectively.

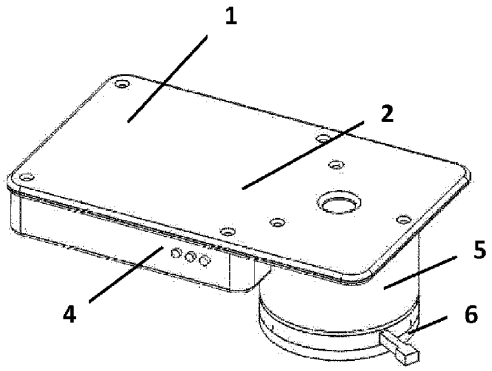


Fig.1a

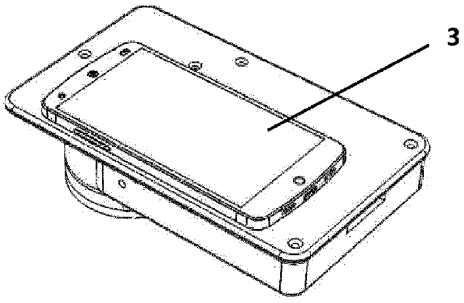


Fig.1b

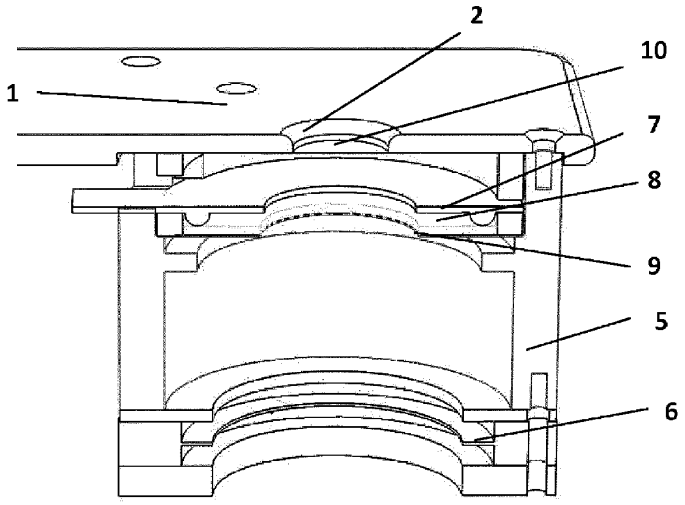


Fig.2.

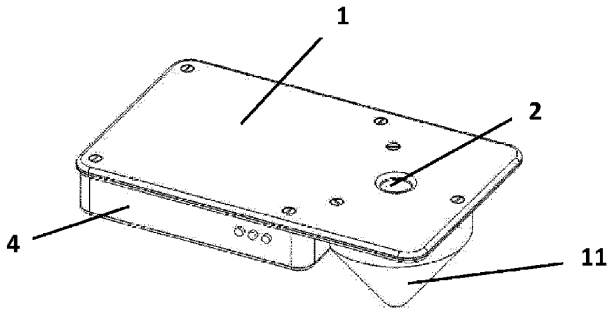


Fig.3

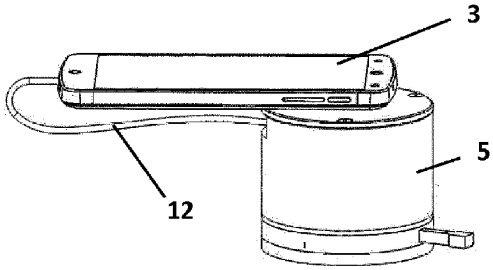


Fig.4a

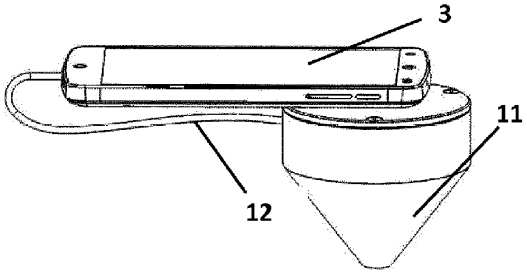


Fig.4b

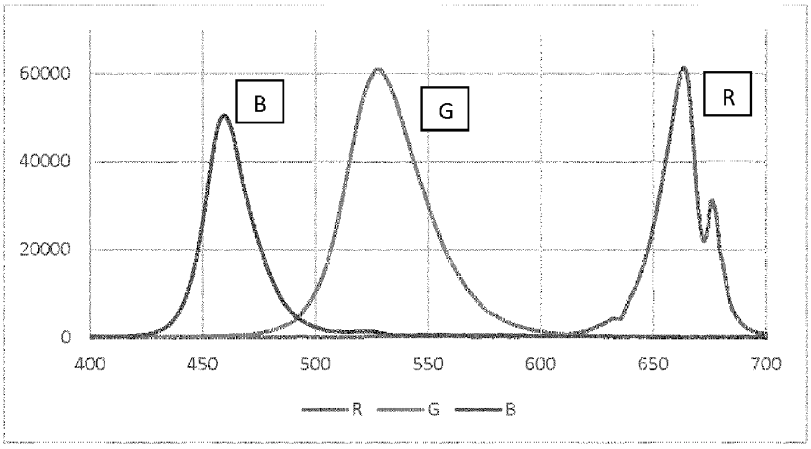


Fig.5.

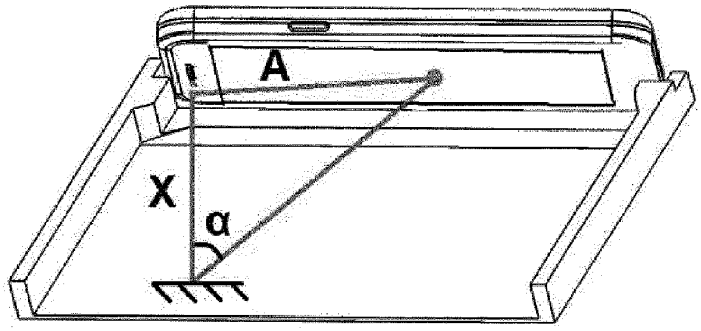


Fig.6.

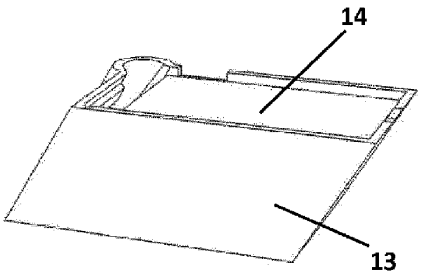


Fig.7a

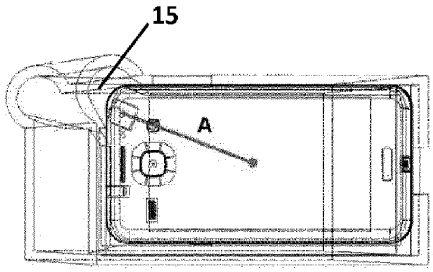


Fig.7b

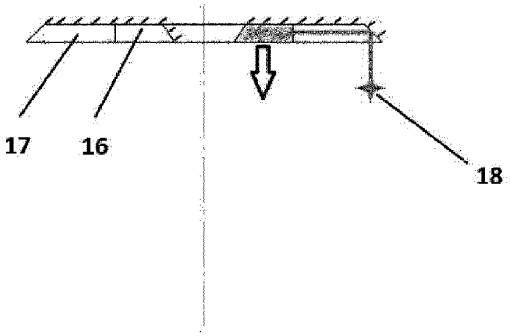


Fig.8.

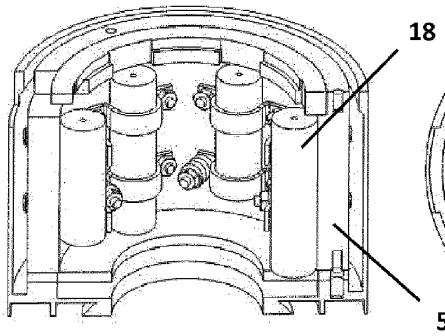


Fig.9a

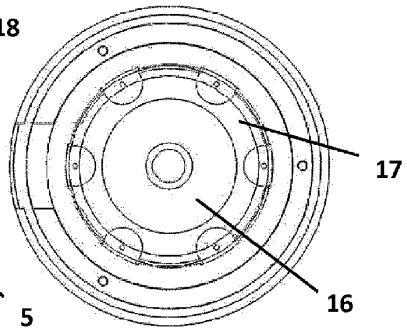


Fig.9b

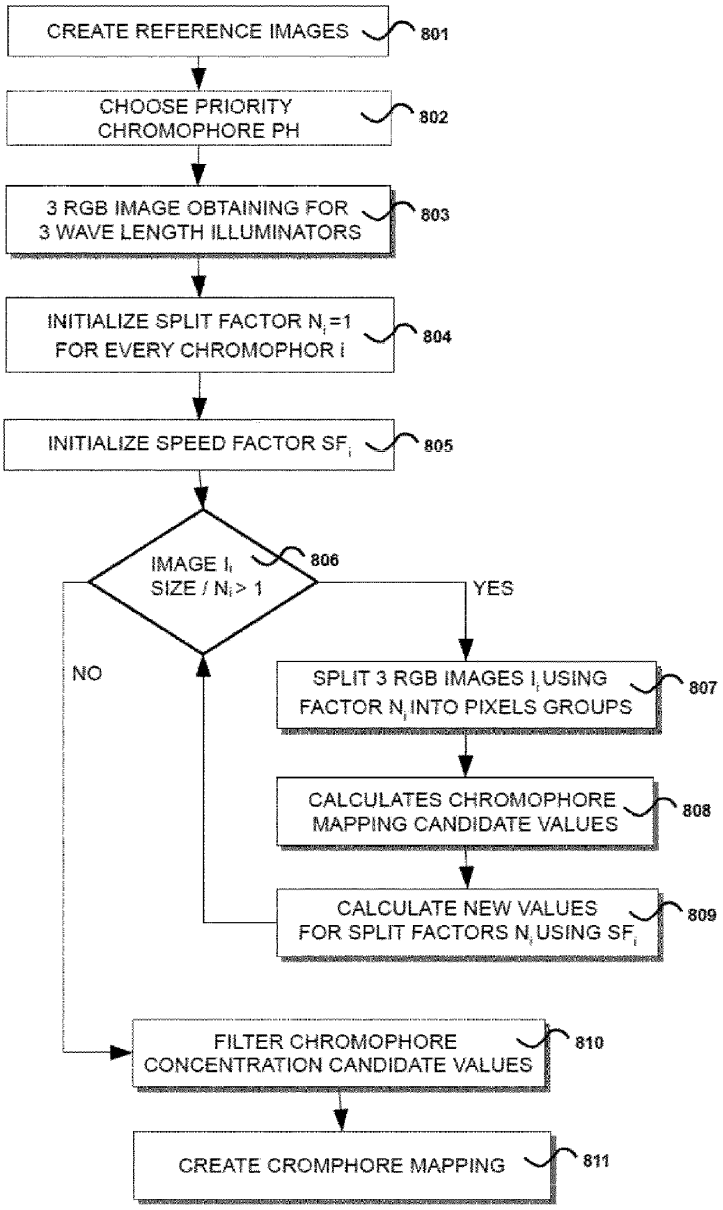

CREATE REFERENCE IMAGES
801
CHOOSE PRIORITY CHROMOPHORE PH
802
3 RGB IMAGE OBTAINING FOR 3 WAVE LENGTH ILLUMINATORS
803
INITIALIZE SPLIT FACTOR N_i=1 FOR EVERY CHROMOPHOR i
804
INITIALIZE SPEED FACTOR SF_i
805
IMAGE I_i SIZE / N_i > 1
806
YES
NO
SPLIT 3 RGB IMAGES I_i USING FACTOR N_i INTO PIXELS GROUPS
807
CALCULATES CHROMOPHORE MAPPING CANDIDATE VALUES
808
CALCULATE NEW VALUES FOR SPLIT FACTORS N_i USING SF_i
809
FILTER CHROMOPHORE CONCENTRATION CANDIDATE VALUES
810
CREATE CROMPHORE MAPPING
811

Fig.10

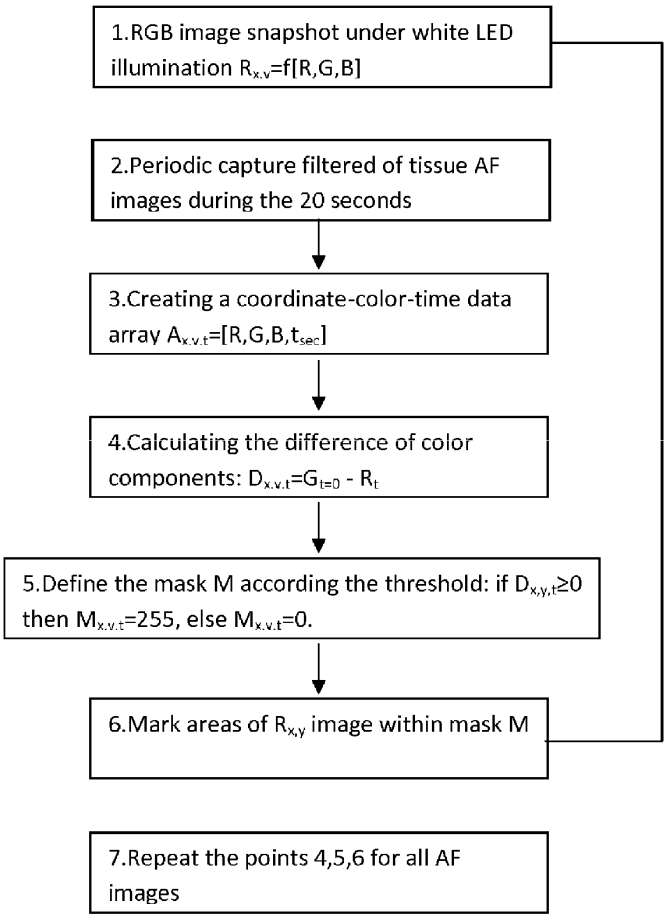

1.RGB image snapshot under white LED illumination $R_{x,y}=f[R,G,B]$
2.Periodic capture filtered of tissue AF images during the 20 seconds
3.Creating a coordinate-color-time data array $A_{x,y,t}=[R,G,B,t_{sec}]$
4.Calculating the difference of color components: $D_{x,y,t}=G_{t=0} - R_t$
5.Define the mask M according the threshold: if $D_{x,y,t}\geq 0$ then $M_{x,y,t}=255$, else $M_{x,y,t}=0$.
6.Mark areas of $R_{x,y}$ image within mask M
7.Repeat the points 4,5,6 for all AF images

Fig.11

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/066913

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	BEKINA A ET AL: "Skin chromphore mapping by means of a modified video-microscope for skin malformation diagnosis", PROCEEDINGS OF THE SPIE - THE INTERNATIONAL SOCIETY FOR OPTICAL ENGINEERING SPIE - THE INTERNATIONAL SOCIETY FOR OPTICAL ENGINEERING USA, vol. 8856, 2013, page 88562G (7 pp.), XP002755427, ISSN: 0277-786X the whole document -----	1-7
Y	JP 2014 131121 A (HITACHI MAXELL) 10 July 2014 (2014-07-10) cited in the application abstract figures 1-26 -----	1-7
	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 March 2016	29/03/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Abraham, Volkhard

1

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SPIGULIS J ET AL: "A device for multimodal imaging of skin", PROCEEDINGS OF THE SPIE - THE INTERNATIONAL SOCIETY FOR OPTICAL ENGINEERING SPIE - THE INTERNATIONAL SOCIETY FOR OPTICAL ENGINEERING USA, vol. 8574, 2013, XP002755428, ISSN: 0277-786X the whole document	1-7
A	SPIGULIS J ET AL: "Single snapshot RGB multispectral imaging at fixed wavelengths: proof of concept", PROCEEDINGS OF THE SPIE - PROGRESS IN BIOMEDICAL OPTICS AND IMAGING SPIE - THE INTERNATIONAL SOCIETY FOR OPTICAL ENGINEERING USA, vol. 8937, 2014, XP002755429, ISSN: 1605-7422 the whole document	1-7
A	JAKOVELS D ET AL: "Noncontact monitoring of vascular lesion phototherapy efficiency by RGB multispectral imaging", JOURNAL OF BIOMEDICAL OPTICS SPIE - THE INTERNATIONAL SOCIETY FOR OPTICAL ENGINEERING USA, vol. 18, no. 12, December 2013 (2013-12), XP002755430, ISSN: 1083-3668 the whole document	1-7
A	SPIGULIS J ET AL: "Snapshot RGB mapping of skin melanin and hemoglobin", JOURNAL OF BIOMEDICAL OPTICS SPIE USA, vol. 20, no. 5, May 2015 (2015-05), XP002755431, ISSN: 1083-3668 cited in the application the whole document	1-7
A	WO 2013/135311 A1 (UNIV LATVIJAS [LV]; SPIGULIS JANIS [LV]; ELSTE LIENE [LV]) 19 September 2013 (2013-09-19) cited in the application the whole document	1-7
A	US 2005/030372 A1 (JUNG BYUNGJO [US] ET AL) 10 February 2005 (2005-02-10) cited in the application paragraph [0019] - paragraph [0024] figures 1-17	1-7

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2015/066913

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 2014131121 A	10-07-2014	NONE	
WO 2013135311 A1	19-09-2013	NONE	
US 2005030372 A1	10-02-2005	NONE	

Espacenet

Bibliographic data: WO2017155265 (A1) — 2017-09-14

MULTISPECTRAL IMAGING DEVICE

Inventor(s): HWANG JAE YOUN [KR]; JANG JAE EUN [KR]; KIM MAN JAE [KR] ± (황재윤, ; 장재은, ; 김만재)

Applicant(s): DAEGU GYEONGBUK INST SCIENCE & TECH [KR] ± (재단법인대구경북과학기술원)

Classification: - international: ***A61B5/00; F21S2/00; F21V5/04; F21V9/00; F21Y101/00***

- cooperative: **A61B5/0033 (US); A61B5/0077 (EP, US); A61B5/441 (EP, US); F21S2/005 (US); F21V5/04 (EP, US); F21V9/00 (EP, US);** A61B2562/0233 (EP); A61B5/6898 (EP)

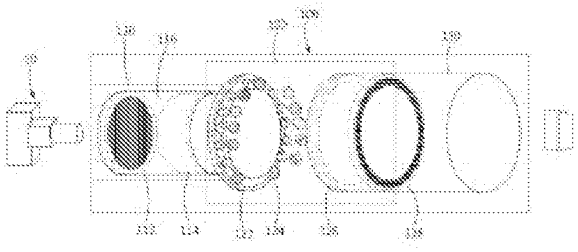
Application number: WO2017KR02423 20170307 Global Dossier

Priority number(s): KR20160027156 20160307

Also published as: KR101799184 (B1) KR20170104708 (A) US2019090751 (A1)

Abstract of WO2017155265 (A1)

A multispectral imaging device in accordance with one embodiment comprises: an illumination unit for emitting LED lighting to the skin for skin illumination; and a detection unit for causing light reflected from the skin to be incident on a camera, wherein the illumination unit is arranged on the outer side of the detection unit, so that a path of the LED lighting emitted from the illumination unit is formed on the outer side of the detection unit, and a path of the light reflected from the skin is formed on the inner side of the detection unit.



(12) 특허협력조약에 의하여 공개된 국제출원

(19) 세계지식재산권기구
국제사무국

(43) 국제공개일
2017 년 9 월 14 일 (14.09.2017)

WIPO | PCT

(10) 국제공개번호
WO 2017/155265 A1

(51) 국제특허분류:
A61B 5/00 (2006.01) *F21S 2/00* (2006.01)
F21V 5/04 (2006.01) *F21Y 101/00* (2006.01)
F21V 9/00 (2006.01)

(21) 국제출원번호: PCT/KR2017/002423

(22) 국제출원일: 2017 년 3 월 7 일 (07.03.2017)

(25) 출원언어: 한국어

(26) 공개언어: 한국어

(30) 우선권정보:
10-2016-0027156 2016 년 3 월 7 일 (07.03.2016) KR

(71) 출원인: **재단법인대구경북과학기술원 (DAEGU GYEONGBUK INSTITUTE OF SCIENCE AND TECHNOLOGY)** [KR/KR]; 42988 대구시 달성군 현풍면 테크노중앙대로 333, Daegu (KR).

(72) 발명자: **황재윤 (HWANG, Jae Youn)**; 42988 대구시 달성군 현풍면 테크노중앙대로 333, 401 동 901 호 (대구경북과학기술원), Daegu (KR). **장재은 (JANG, Jae Eun)**; 42178 대구시 수성구 청수로 214, 1513 동 1301 호 (황금동), Daegu (KR). **김만재 (KIM, Man Jae)**; 15287 경기도 안산시 상록구 충장로 565 110 동 105 호 (월피동), Gyeonggi-do (KR).

(74) 대리인: **특허법인 무한 (MUHANN PATENT & LAW FIRM)**; 06044 서울시 강남구 학동로 3 길 9, 5 층 (논현동, 명림빌딩), Seoul (KR).

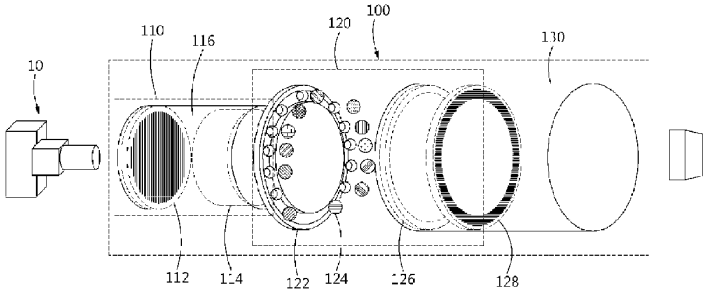
(81) 지정국 (별도의 표시가 없는 한, 가능한 모든 종류의 국내 권리의 보호를 위하여): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) 지정국 (별도의 표시가 없는 한, 가능한 모든 종류의 역내 권리의 보호를 위하여): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), 유라시아 (AM, AZ, BY, KG, KZ, RU, TJ, TM), 유럽 (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

공개:
— 국제조사보고서와 함께 (조약 제 21 조(3))

(54) Title: MULTISPECTRAL IMAGING DEVICE

(54) 발명의 명칭 : 다중 분광 이미징 디바이스



(57) Abstract: A multispectral imaging device in accordance with one embodiment comprises: an illumination unit for emitting LED lighting to the skin for skin illumination; and a detection unit for causing light reflected from the skin to be incident on a camera, wherein the illumination unit is arranged on the outer side of the detection unit, so that a path of the LED lighting emitted from the illumination unit is formed on the outer side of the detection unit, and a path of the light reflected from the skin is formed on the inner side of the detection unit.

(57) 요약서: 일 실시예에 따른 다중 분광 이미징 디바이스는, 피부 조사를 위한 LED 조명을 피부로 송출하는 조명부; 및 상기 피부에서 반사되는 빛을 카메라로 입사시키는 검출부;를 포함하고, 상기 조명부는 상기 검출부의 외측에 배치되어, 상기 조명부에서 송출된 LED 조명의 경로는 상기 검출부의 외측에 형성되고, 상기 피부에서 반사되는 빛의 경로는 상기 검출부 내측에 형성될 수 있다.

WO 2017/155265 A1

명세서

발명의 명칭: 다중 분광 이미징 디바이스

기술분야

[1] 본 발명은 다중 분광 이미징 디바이스에 관한 것으로서, 보다 구체적으로 연속적인 파장대역에서 좁은 대역폭을 가지는 빛의 조사가 가능하며, 모바일 기기의 종류에 관계없이 착탈이 가능한 다중 분광 이미징 디바이스에 관한 것이다.

배경기술

[2] 일반적으로, 피부 질환 여부나 피부의 상태를 확인하기 위해서는 환자가 직접 병원이나 피부 관리실에 방문하여 피부 진단기기를 사용하여 정밀 검사를 수행하여야 한다. 병원이나 피부 관리실에서 사용되는 피부 진단기기는 정밀한 검사를 위해 의사 또는 숙련된 전문가에 의해 조작되고, 피부 진단기기로부터 획득한 결과를 이용하여 의사가 최종 확진을 하는 것이 일반적이기 때문에, 환자가 스스로 피부 진단기기를 이용한 진단을 수행하기 어렵다는 문제점이 존재한다.

[3] 특히, 피부 진단기기들 중 분광 이미징 기능을 보유하고 있는 기기들은, 일반 피부 진단기기에 비해 높은 진단 정확도를 보유하고 있으며 정량 분석이 가능한 장점을 가지고 있지만, 대부분 부피가 크고 가격이 비싸기 때문에 일반 가정에서 사용하기 적합하지 않다는 문제점이 존재한다.

[4] 따라서, 이러한 단점을 해결하기 위해 일반적으로 사용자가 직접 휴대할 수 있으며, 모바일 기기와 탈부착이 가능한 소형화된 다중 분광 이미징 기기가 개발되고 있다. 이때, 기존의 다중 분광 이미징 기기는 광학필터 휠을 소형 모터를 통해 회전시켜 광학 필터를 교환함으로써 다중 분광 이미징을 수행하였지만, 모터를 사용하는 경우 다중 분광 이미징의 영상 획득 속도가 느리고, 부피를 감소시키는데 한계가 있기 때문에 휴대가 용이하지 않다는 문제점이 존재한다.

[5] 또한, 다중 분광 이미징 기능이 보유되지 않은 피부 진단기기인 우드등(Wood lamp)을 이용하여 피부 질환 또는 피부 진단을 수행하고 있다. 이러한 우드등은 자외선을 피부에 조사하여 피부의 피지나 민감도 및 각질 상태에 따라 다른 색으로 나타나는 원리를 이용한 것으로, 육안으로 세밀하게 볼 수 없는 피부의 상태를 확인할 수 있어 피부 유형에 따른 적절한 관리를 하는데 도움을 주고 있다.

[6] 하지만, 이러한 우드등의 경우, 휴대성이 떨어지며, 화면에 나타나는 색을 통해서만 피부의 상태를 표현하기 때문에 비전문가인 사용자가 현재 피부의 상태를 정확히 진단하기 어려운 문제점이 존재한다.

발명의 상세한 설명

기술적 과제

[7] 일 실시예에 따른 목적은 휴대성이 높고 사용이 간편하며, 사용자가 쉽게 현재 피부의 상태를 정확히 진단할 수 있는 다중 분광 이미징 디바이스를 제공하는 것이다.

[8] 일 실시예에 따른 목적은 모바일 기기의 형태와 무관하게 탈/부착이 가능한 다중 분광 이미징 디바이스를 제공하는 것이다.

[9] 일 실시예에 따른 목적은 LED 기판을 회전시킬 필요 없이 LED 광원의 선택적 점멸 또는 점등에 의해 특정 파장 대역의 이미지를 획득하게 할 수 있는 다중 분광 이미징 디바이스를 제공하는 것이다.

[10] 일 실시예에 따른 목적은 외부 빛의 차단 및 피부와의 상호 작용 없이 피부 표면에서 반사된 빛의 차단을 통하여 보다 선명한 이미지를 획득할 수 있는 다중 분광 이미징 디바이스를 제공하는 것이다.

[11] 일 실시예에 따른 목적은 조명부에서 송출된 LED 조명의 경로 및 피부에서 반사 또는 산란된 빛의 경로는 서로 다르게 형성될 수 있는 다중 분광 이미징 디바이스를 제공하는 것이다.

[12] 일 실시예에 따른 목적은 피부 수화도 및 지루성 피부염 같은 피부 질환 등을 진단하는 데 활용될 수 있는 다중 분광 이미징 디바이스를 제공하는 것이다.

과제 해결 수단

[13] 상기 목적을 달성하기 위한 일 실시예에 따른 다중 분광 이미징 디바이스는, 피부 조사를 위한 LED 조명을 피부로 송출하는 조명부; 및 상기 피부에서 반사되는 빛을 카메라로 입사시키는 검출부;를 포함하고, 상기 조명부는 상기 검출부의 외측에 배치되어, 상기 조명부에서 송출된 LED 조명의 경로는 상기 검출부의 외측에 형성되고, 상기 피부에서 반사되는 빛의 경로는 상기 검출부 내측에 형성될 수 있다.

[14] 일 측에 의하면, 상기 검출부는, 상기 피부에서 반사되는 빛을 굴절시키는 광학 렌즈; 및 상기 광학 렌즈에서 굴절된 빛을 제1 방향으로 편광시키는 제1 편광판;을 포함하고, 상기 카메라는 상기 광학 렌즈 및 상기 제1 편광판의 중심축 상에 배치될 수 있다.

[15] 일 측에 의하면, 상기 검출부는, 상기 광학 렌즈 및 상기 제1 편광판을 내부에 수용하는 가림막;을 더 포함하고, 상기 가림막의 외측에 상기 조명부가 배치될 수 있다.

[16] 일 측에 의하면, 상기 조명부는, 복수 개의 LED 광원이 실장된 LED 기판; 및 상기 복수 개의 LED 광원 중 적어도 일부와 접하도록 구비되는 복수 개의 대역통과 필터;를 포함하고, 상기 LED 기판은 링 형상으로 마련될 수 있다.

[17] 일 측에 의하면, 상기 복수 개의 LED 광원은 하나의 UV LED, 하나의 NIR LED, 복수 개의 백색 LED, 또는 상기 대역통과 필터의 중심 파장에 대응되도록 서로 다른 파장을 갖는 복수 개의 LED를 포함하고, 상기 복수 개의 대역통과 필터는

상기 복수 개의 백색 LED 또는 상기 복수 개의 LED에 접하도록 배치될 수 있다.

[18] 일 측에 의하면, 상기 복수 개의 대역통과 필터의 개수는 상기 복수 개의 백색 LED의 개수보다 한 개 적게 구비될 수 있다.

[19] 일 측에 의하면, 상기 복수 개의 LED 광원 및 상기 복수 개의 대역통과 필터는 상기 복수 개의 LED 광원의 점등 또는 점멸의 제어를 통해 선택적으로 결합되고, 상기 복수 개의 LED 광원의 점등 또는 점멸은 상기 모바일 기기를 통해 제어되는 임베디드 시스템에 의해 제어될 수 있다.

[20] 일 측에 의하면, 상기 조명부는, 상기 LED 조명이 진행하는 방향으로 상기 복수 개의 대역통과 필터와 접하도록 배치되어 상기 LED 조명을 확산시키는 확산판;을 더 포함하고, 상기 확산판은 상기 복수 개의 LED 광원이 실장된 형상과 동일한 형상으로 빛을 확산시키는 확산부를 구비할 수 있다.

[21] 일 측에 의하면, 상기 조명부는, 상기 LED 조명이 진행하는 방향으로 상기 확산판에 접하도록 배치되어 상기 확산판에 의해 확산된 LED 조명을 제2 방향으로 편광시키는 제2 편광판;을 더 포함하고, 상기 제2 편광판은 상기 확산부와 동일한 형상으로 편광부를 구비할 수 있다.

[22] 일 측에 의하면, 상기 조명부 및 상기 검출부가 내부에 수용되는 덮개부;를 더 포함하고, 상기 덮개부에 의해 상기 조명부 및 상기 검출부가 암실 내에 배치되어, 상기 조명부에서 송출된 LED 조명 또는 상기 피부에서 반사된 빛에 대한 외부 빛의 영향이 차단될 수 있다.

[23] 일 측에 의하면, 상기 덮개부는, 상기 모바일 기기에 장착을 위한 결합 부재;를 포함하고, 상기 결합 부재는 길이 조절 가능하도록 마련될 수 있다.

[24] 상기 목적을 달성하기 위한 다른 실시예에 따른 다중 분광 이미징 디바이스는, 피부 조사를 위한 LED 조명을 피부로 송출하는 조명부; 및 상기 피부에서 산란되는 빛을 카메라로 입사시키는 검출부;를 포함하고, 상기 조명부 및 상기 검출부는 동축 상에 배치되고, 상기 조명부에서 송출된 LED 조명의 경로는 상기 피부를 향하여 경사지게 형성되고, 상기 피부에서 반사 또는 산란되는 빛의 경로는 상기 동축 상에 형성될 수 있다.

[25] 일 측에 의하면, 상기 조명부는, 복수 개의 LED 광원이 실장된 LED 기판; 및 상기 복수 개의 LED 광원 중 적어도 일부와 접하도록 구비되는 복수 개의 대역통과 필터;를 포함하고, 상기 LED 기판은 상기 피부를 향하여 경사지게 형성된 경사면을 포함하고, 상기 경사면 상에 상기 복수 개의 LED 광원이 장착될 수 있다.

[26] 일 측에 의하면, 상기 조명부는, 상기 LED 조명이 진행하는 방향으로 상기 복수 개의 대역통과 필터와 접하도록 배치되어 상기 LED 조명을 확산시키는 확산판; 및 상기 LED 조명이 진행하는 방향으로 상기 확산판과 접하도록 배치되어 상기 확산판에서 확산된 LED 조명을 제1 방향으로 편광시키는 제1 편광판;을 더 포함할 수 있다.

[27] 일 측에 의하면, 내부에 상기 검출부가 수용되도록 원통 형상으로 마련된

가림막;을 더 포함하고, 상기 가림막에 의해 상기 확산판에서 확산된 LED 조명이 상기 피부에서 반사 또는 산란되는 빛의 경로에 안내되는 것이 방지될 수 있다.

[28] 일 측에 의하면, 상기 검출부는, 상기 피부에서 반사 또는 산란된 빛을 상기 제1 방향과 직교하는 제2 방향으로 편광시키는 제2 편광판;을 포함하고, 상기 제2 편광판에 의해 상기 카메라에 대한 상기 피부에서 반사되는 빛의 입사가 차단될 수 있다.

[29] 일 측에 의하면, 상기 검출부는, 상기 제2 편광판에서 편광된 빛을 굴절시키는 광학 렌즈;를 더 포함하고, 상기 피부, 상기 제2 편광판, 상기 광학 렌즈 및 상기 카메라가 동일 선상에 위치될 수 있다.

[30] 일 측에 의하면, 상기 LED 기판은 링 형상으로 마련되며, 상기 LED 기판을 관통하여 상기 검출부가 배치되고, 상기 복수 개의 LED 광원은 상기 LED 기판 상에 방사상 방향으로 이격 배치될 수 있다.

[31] 일 측에 의하면, 상기 조명부 및 상기 검출부가 내부에 수용되는 덮개부;를 더 포함하고, 상기 덮개부의 중심축 상에 상기 검출부가 배치되고, 상기 덮개부의 중심축으로부터 방사상 방향으로 이격되어 상기 조명부가 배치될 수 있다.

[32] 일 측에 의하면, 상기 덮개부의 일단은 상기 카메라에 인접하게 배치되고, 상기 덮개부의 타단은 상기 피부에 인접하게 배치되며, 상기 덮개부는 일단으로부터 타단을 향하여 단면적이 좁아지게 형성될 수 있다.

발명의 효과

[33] 일 실시예에 따른 다중 분광 이미징 디바이스에 의하면, 휴대성이 높고 사용이 간편하며, 사용자가 쉽게 현재 피부의 상태를 정확히 진단할 수 있다.

[34] 일 실시예에 따른 다중 분광 이미징 디바이스에 의하면, 모바일 기기의 형태와 무관하게 탈/부착이 가능할 수 있다.

[35] 일 실시예에 따른 다중 분광 이미징 디바이스에 의하면, LED 기판을 회전시킬 필요 없이 LED 광원의 선택적 점멸 또는 점등에 의해 특정 파장 대역의 이미지를 획득하게 할 수 있다.

[36] 일 실시예에 따른 다중 분광 이미징 디바이스에 의하면, 외부 빛의 차단 및 피부와의 상호 작용 없이 피부 표면에서 반사된 빛의 차단을 통하여 보다 선명한 이미지를 획득할 수 있다.

[37] 일 실시예에 따른 다중 분광 이미징 디바이스에 의하면, 조명부에서 송출된 LED 조명의 경로 및 피부에서 반사 또는 산란된 빛의 경로는 서로 다르게 형성될 수 있다.

[38] 일 실시예에 따른 다중 분광 이미징 디바이스에 의하면, 피부 수화도 및 지루성 피부염 같은 피부 질환 등을 진단하는 데 활용될 수 있다.

도면의 간단한 설명

[39] 도 1은 일 실시예에 따른 다중 분광 이미징 디바이스의 분해도이다.

[40] 도 2는 조명부의 상세도이다.

[41] 도 3은 모바일 기기에 다중 분광 이미지 디바이스가 장착된 모습을 도시한다.

[42] 도 4는 다중 분광 이미징 디바이스를 모바일 기기에 연결하고, 모바일 기기를 통해 장치를 제어하여 빛을 검출하는 방법을 나타내는 순서도이다.

[43] 도 5는 다른 실시예에 따른 다중 분광 이미징 디바이스를 도시한다.

[44] 도 6은 조명부의 상세도이다.

[45] 도 7은 다른 실시예에 따른 다중 분광 이미징 디바이스에 의한 이미지 획득 방법을 나타내는 순서도이다.

[46] 도 8은 다른 실시예에 따른 다중 분광 이미징 디바이스에서 이미지 획득을 위한 인터페이스 회로를 나타낸다.

발명의 실시를 위한 형태

[47] 이하, 실시예들을 예시적인 도면을 통해 상세하게 설명한다. 각 도면의 구성요소들에 참조부호를 부가함에 있어서, 동일한 구성요소들에 대해서는 비록 다른 도면상에 표시되더라도 가능한 한 동일한 부호를 가지도록 하고 있음에 유의해야 한다. 또한, 실시예를 설명함에 있어, 관련된 공지 구성 또는 기능에 대한 구체적인 설명이 실시예에 대한 이해를 방해한다고 판단되는 경우에는 그 상세한 설명은 생략한다.

[48] 또한, 실시예의 구성 요소를 설명하는 데 있어서, 제1, 제2, A, B, (a), (b) 등의 용어를 사용할 수 있다. 이러한 용어는 그 구성 요소를 다른 구성 요소와 구별하기 위한 것일 뿐, 그 용어에 의해 해당 구성 요소의 본질이나 차례 또는 순서 등이 한정되지 않는다. 어떤 구성 요소가 다른 구성요소에 "연결", "결합" 또는 "접속"된다고 기재된 경우, 그 구성 요소는 그 다른 구성요소에 직접적으로 연결되거나 접속될 수 있지만, 각 구성 요소 사이에 또 다른 구성 요소가 "연결", "결합" 또는 "접속"될 수도 있다고 이해되어야 할 것이다.

[49] 어느 하나의 실시예에 포함된 구성요소와, 공통적인 기능을 포함하는 구성요소는, 다른 실시예에서 동일한 명칭을 사용하여 설명하기로 한다. 반대되는 기재가 없는 이상, 어느 하나의 실시예에 기재한 설명은 다른 실시예에도 적용될 수 있으며, 중복되는 범위에서 구체적인 설명은 생략하기로 한다.

[50] 도 1은 일 실시예에 따른 다중 분광 이미징 디바이스의 분해도이고, 도 2는 조명부의 상세도이고, 도 3은 모바일 기기에 다중 분광 이미지 디바이스가 장착된 모습을 도시한다.

[51] 도 1을 참조하여, 일 실시예에 따른 다중 분광 이미징 디바이스(100)는 일 측으로 빛을 획득하여 타 측에 결합된 카메라(10)에 획득한 빛을 전달할 수 있다. 이때, 카메라(10)는 모바일 기기의 카메라일 수도 있고, 독립적으로 사용되는 카메라일 수도 있다.

[52] 구체적으로, 일 실시예에 따른 다중 분광 이미징 디바이스(100)는 검출부(110),

조명부(120) 및 덮개부(130)를 포함할 수 있다.

[53] 검출부(110)는 다중 분광 이미징 디바이스(100)의 일단에 카메라(10)와 접하도록 구비된다. 이때, 검출부(110)는 제1 편광판(112), 광학 렌즈(114) 및 가림막(116)을 포함할 수 있다. 그리고 카메라(10)는 제1 편광판(112) 및 광학 렌즈(114)의 중심축 상에 배치될 수 있다.

[54] 제1 편광판(112)은 광학 렌즈(114)를 통과한 빛을 편광시켜 카메라(10)에 입사시킨다. 이때, 제1 편광판(112)은 일 예로 수직 편광판으로 구성되어 입사되는 빛 중 수직 방향의 빛만 통과시킬 수 있다. 이를 이용하여 카메라(10)는 직접 반사되어 편광되지 않은 빛 등이 일 예로 형성되는 노이즈가 감소한 빛을 획득할 수 있다.

[55] 광학 렌즈(114)는 제1 편광판(112)과 접하도록 구비된다. 광학 렌즈(114)는 단수 또는 복수의 렌즈로 구성될 수 있으며, 바람직하게는 카메라(10)의 렌즈로부터 일정 거리에 초점을 형성할 수 있다.

[56] 이를 통해, 광학 렌즈(114)는 다중 분광 이미징 디바이스(100)가 항상 일정한 위치에 초점을 형성하도록 구성하여 다양한 종류의 카메라(10)에 용이하게 사용될 수도 있도록 할 수 있다.

[57] 가림막(116)은 제1 편광판(112) 및 광학 렌즈(114)의 외부에 구비되어 제1 편광판(112)과 광학 렌즈(114) 사이에 암실을 형성한다. 가림막(116)은 암실을 형성함으로써 광학 렌즈(114)를 거쳐 제1 편광판(112)으로 수집되는 빛이 외부의 빛에 영향을 받지 않도록 한다. 또, 가림막(116)은 광학 렌즈(114)를 통과한 빛이 제1 편광판(112)을 거치지 않고 후술되는 덮개부(130)에 반사되어 카메라(10)로 직접 입사하는 노이즈를 방지할 수 있다.

[58] 조명부(120)는 가림막(116)의 외측에 배치될 수 있으며, 제1 편광판(112)과 접하도록 구비된다. 조명부(120)는 피부 관찰을 위한 조명을 송출하고, 피부에서 반사되는 반사광을 통과시켜 제1 편광판(112)으로 전달할 수 있다.

[59] 이때, 조명부(120)는 LED 기판(122), 복수 개의 대역통과 필터(124), 확산판(126) 및 제2 편광판(128)을 포함할 수 있다.

[60] LED 기판(122)은 광학 렌즈(114)와 접하도록 구비되며, 광학 렌즈(114)에 장착될 수 있다. 즉, 일 예로, LED 기판(122)은 링 형상으로 광학 렌즈(114)의 주변부에 구비될 수 있으며, LED 기판(122)은 광학 렌즈(114)와의 사이에 빛이 직접 카메라(10)로 향하지 않도록 하는 가림막을 더 구비할 수 있다. 이하에서는 설명의 편의상 LED 기판(122)을 링 형상으로 정의하도록 하지만, 본 발명은 이에 한정되지 않으며, LED 기판(122)은 다양한 형상으로 구비될 수 있다

[61] 또한, LED 기판(122)은 링 형상의 LED PCB로 제작되고 광학 렌즈(114)와 대향하는 방향으로 복수개의 LED 광원이 실장되며, LED 기판(122)이 광학 렌즈(114)에 장착되는 경우, LED 기판(122)에서 발광되는 빛의 그림자 및 왜곡 현상을 최소화할 수 있다.

[62] 게다가, 복수개의 LED 광원은 다양한 파장대의 빛을 방출함으로써 다중 분광

이미징을 수행할 수 있고, 방출되는 백색광을 통해 사용자가 직접 병변 부위를 관찰할 수도 있으며, 자외선 및 적외선을 이용하여 피부 상태를 확인할 수도 있다.

[63] 특히, 도 2를 참조하여, LED 기판(122)의 일면에는 복수 개의 LED 광원(1222)이 실장되어 LED 광을 방출할 수 있다. 이때, 복수 개의 LED 광원(1222)은 하나의 UV LED(1222a), 하나의 NIR LED(1222b) 및 백색 LED(1222c)들로 구성되고, UV LED(1222a)는 자외선 LED광을 방출하고, NIR LED(1222b)는 적외선 LED광을 방출하며 백색 LED들(1222c)은 백색 LED 광을 방출한다.

[64] 상기 백색 LED(1222c)는 복수 개의 대역통과 필터(124)의 중심 파장에 대응되도록 서로 다른 파장을 갖는 LED 광을 방출하는 복수 개의 LED로 대체될 수 있으며, 예를 들어 복수 개의 LED는 424nm 또는 450nm의 파장을 갖는 LED 광을 방출하는 bluc LED, 550nm의 파장을 갖는 LED 광을 방출하는 green LED 등을 포함할 수 있다.

[65] 한편, 복수의 대역통과 필터(124)는 백색 LED(1222c)에 접하도록 구비된다. 이때, 복수의 대역통과 필터(124)는 바람직하게는 백색 LED(1222c)의 개수보다 하나 적은 수만큼 구비될 수 있다. 즉, 백색 LED(1222c)의 개수가 N개인 경우, 복수의 대역통과 필터(124)는 N-1개만큼 구비되어 하나의 백색 LED(1222c)를 제외한 나머지 백색 LED(1233c)에서 방출되는 백색 LED광의 대역을 변경할 수 있다. 또, 복수의 대역통과 필터(124)는 400 내지 700nm 대역에서 각각 서로 다른 빛의 파장을 필터링할 수 있다.

[66] 전술된 바와 같이 복수의 대역통과 필터(124)는 복수 개의 대역통과 필터(124)의 중심 파장에 대응되도록 서로 다른 파장을 갖는 LED 광을 방출하는 복수 개의 LED에 접하도록 구비될 수 있다. 예를 들어, 424nm 또는 450nm의 중심 파장을 갖는 대역통과 필터는 424nm 또는 450nm의 파장을 갖는 LED 광을 방출하는 blue LED에 접하도록 배치되고, 550nm의 중심 파장을 갖는 대역통과 필터는 550nm의 파장을 갖는 LED 광을 방출하는 green LED에 접하도록 배치될 수 있다.

[67] 또한, LED 기판(122)은 임베디드 시스템으로 제어되어 대역통과 필터(124)의 선택 또는 조합을 수행할 수 있다. 구체적으로, LED 기판(122)은 LED광을 방출하는 복수 개의 LED 광원(1222)의 점등 동작을 외부 제어를 통해 수행함으로써 모터를 이용하여 필터를 제어하는 대신 LED 광원(1222)의 점등 또는 점멸을 이용하여 필터를 선택 또는 조합할 수 있다.

[68] 이때, 바람직하게는 임베디드를 위한 제어부는 LED 기판(122)에 구비될 수도 있지만, 본 발명은 이에 한정되지 않고, 송출되는 LED광 및 피부에서 반사된 반사광의 경로를 방해하지 않는 위치에 구비될 수도 있다.

[69] 확산판(126)은 LED 기판(122)과 접하도록 구비된다. 확산판(126)은 복수 개의 LED 광원(1222)에서 송출되는 LED 광을 확산시키기 위해 LED 광이 출력되는 영역에 확산부를 구비하고, 확산부가 구비되지 않은 구역인 광 통과영역으로

반사광을 통과시킨다.

[70] 이는, 복수 개의 LED 광원(1222)에서 방출되는 LED 광은 광방출각도가 상대적으로 좁아 광이 집중되기 때문에, 이러한 집중 광을 방지하기 위하여 확산판(126)을 이용해 확산시켜 LED 광의 면 발광이 가능하도록 함과 동시에 반사광이 송출되는 LED 광에 받는 영향을 최소화 하기 위함이다. 이때, 확산판(126)은 LED 기판(122)이 링 형상을 이루고 있기 때문에 확산판(126) 또는 확산판(126)의 확산부 또한 링 형태를 이룰 수 있다

[71] 제2 편광판(128)은 확산판(126)과 접하도록 구비된다. 제2 편광판(128)은 확산판(126)에서 확산된 LED 광을 일 방향으로 편광시키기 위해 LED 광이 확산되는 영역에 편광부를 구비하여 확산된 빛을 편광시킨다.

[72] 또한, 제2 편광판(128)은 확산판(126)에서 LED 광을 확산시키는 확산부가 링 형상을 이루고 있기 때문에 제2 편광판(128)의 편광부 역시 링 형상을 이룰 수 있다. 즉, 바람직하게는 제2 편광판(128)의 편광부는 확산판(126)의 확산부와 동일한 형상으로 구비될 수 있다.

[73] 이때, 일 실시예에 따른 다중 분광 이미징 디바이스(100)는 피부에서 반사되어 산란되는 빛을 이용하기 때문에 제2 편광판(128)은 바람직하게는 제1 편광판(112)과 직교하는 방향으로 편광시키도록 구비될 수 있다.

[74] 일 예로 제1 편광판(112)이 수직 편광판으로 구성되는 경우 제2 편광판(128)은 수평 편광판으로 구성됨으로써 제1 편광판(112)과 직교할 수 있다.

[75] 하지만, 본 발명은 이에 한정되지 않으며, 이용하는 빛의 종류에 따라 제1 편광판과 제2 편광판이 이루는 각도를 수정할 수 있다.

[76] 또한 LED 기판(122), 확산판(124) 및 제2 편광판(128)은 전술된 형상 외에도 피부 방향으로 송출되는 LED 광의 경로와 피부에서 산란 또는 반사되어 카메라 방향으로 진행하는 빛의 경로가 교차하지 않는 형상으로 형성될 수도 있다.

[77] 덮개부(130)는, 제1 편광판(112), 광학 렌즈(114), LED 기판(122), 확산판(126) 및 제2 편광판(128)의 외부에 구비되어 암실을 형성한다. 덮개부(130)는 암실을 형성함으로써, 복수 개의 LED 광원(1222)에서 송출되는 LED 광 및 피부에서 반사되는 반사광이 외부의 빛에 영향을 받지 않도록 하고, 이로 인해 카메라(10)는 피부에서 반사되는 반사광을 보다 선명하게 획득할 수 있다.

[78] 또한, 도 3을 참조하여, 덮개부(130)는 카메라(10)와 접하는 측에 결합 부재(132)를 포함할 수 있다.

[79] 일 실시예에 따른 다중 분광 이미징 디바이스(100)는 휴대 단말기 등 카메라(10)가 구비된 장치 또는 모바일 기기와의 착탈이 용이하기 위해 덮개부(130)의 일 단에 해당 장치와의 착탈이 가능한 결합 부재(132)를 포함할 수 있다. 이 경우, 일 예로 덮개(130)에 구비되는 결합 부재(132)는 삽입형태, 갈고리 형태, 압착형태 등 다양한 형태로 형성될 수도 있다.

[80] 또한, 결합 부재(132)는, 모바일 기기(11)와 다중 분광 이미징 디바이스(100)의 호환성을 위해 각각의 길이가 조절될 수도 있다. 다시 말해, 결합 부재(132)는

다중 분광 이미징 디바이스(100)와의 거리를 조절함으로써 결합 부재(132)와 연결된 다중 분광 이미징 디바이스(100)의 위치를 조절할 수 있고, 이를 이용하여 모바일 기기(11)에 장착되는 카메라(10)의 위치에 관계 없이 카메라(10)와 결합할 수도 있다.

[81] 이하에서는, 일 실시예에 따른 다중 분광 이미징 디바이스의 동작을 도 1 내지 도 3의 장치 구조를 이용하여 설명하도록 한다.

[82] 먼저, LED 기판(122)의 복수 개의 LED 광원(1222)에서 각각 LED 광을 방출한다. 이때, 사용자는 다중 분광 이미징 디바이스(100)가 연결된 모바일 기기를 이용하여 임베디드 제어를 통해 원하는 대역통과 필터(124)와 접하는 백색 LED(1222c)의 LED 광만을 방출시킬 수도 있고, 모든 LED 광원(1222)의 LED광을 방출시킬 수도 있다.

[83] LED 기판(122)은 광학 렌즈(114)의 주변부에 링 형상으로 형성된다. 따라서, LED 기판(122)에서 방출되는 LED 광은 LED 기판(122)의 형상과 동일한 링 모양으로 방출되어 확산판(126)에 도달한다. 이때, LED 기판(122)은 링 형상 뿐만 아니라 다양한 형상으로 형성될 수 있지만, 이하에서는 편의상 링 형상으로 설명하기로 하고, 이러한 LED 기판의 형상이 본 발명을 제한하는 것이라고 볼 수만은 없다.

[84] 다음으로, 방출된 LED 광은 확산판(126) 및 제2 편광판(128)을 통과하여 피부를 조명한다. 링 모양으로 방출된 LED 광은 광방출 각도가 상대적으로 좁기 때문에 광이 집중되는 현상이 발생하며, 이러한 집중광을 확산시키기 위해서 확산판(126)은 방출된 LED 광이 확산판(126)에 도달하는 영역에 확산부를 구비할 수 있다. 이를 통해 방출된 LED 광은 확산판(126)과 덮개부(130)의 일단 사이의 거리에서도 면 광원으로 형성되어 피부를 조명할 수 있다.

[85] 한편, 확산판(126)을 통과하여 확산된 LED 광은 제2 편광판(128)에 입사하고, 제2 편광판(128)은 확산된 LED 광을 편광시키기 위해 확산된 LED 광이 제2 편광판(128)에 도달하는 영역에 편광부를 구비할 수 있다. 따라서, 확산된 LED 광은 제2 편광판(128)의 편광부를 통과하며 일 방향으로 편광되어 피부를 면광원으로 조명할 수 있다.

[86] 다음으로, 피부에 조사된 LED 광은 피부에 의해 산란되거나 반사되고, 피부로부터 산란되거나 반사된 빛은 광학 렌즈(114)로 수집된다. 이때, 산란되거나 반사된 LED 광은 광학 렌즈(114)에 입사하여 굴절되며, 광학 렌즈(114)에 입사하여 굴절된 LED 광을 카메라(10)로 모을 수 있다.

[87] 마지막으로, 광학 렌즈(114)를 통과한 피부에서 반사 또는 산란된 LED 광은 제1 편광판(112)을 통과하며 일 방향으로 편광되어 카메라(10)로 송출된다.

[88] 이때, 수집된 LED 광에는 복수 개의 LED 광원(1222)에서 송출된 서로 다른 파장의 광, 백색광, 자외선, 및 적외선 중 적어도 하나가 포함되어 있기 때문에 카메라(10)와 연결되는 중앙 처리 장치(미도시)는 카메라(10)로부터 획득한 광을 처리하여 다중 분광 이미징, 백색광을 이용한 직접 관찰 및 자외선 또는

적외선을 이용한 피부 진단을 수행할 수 있다.

[89] 여기서, 중앙 처리 장치는 카메라가 구비된 모바일 기기에 포함될 수도 있으며, 카메라(10)와 유선 또는 무선 통신으로 연결되어 수집된 LED 광의 분석을 수행하는 전자 장치일 수도 있다.

[90] 또한, 광학 렌즈(114)를 통과한 피부에서 반사 또는 산란된 LED 광은, 광학 렌즈(114) 및 제1 편광판(112)의 외부에 구비되는 가림막(116)에 의해 카메라(10)로 직접 입사되지 않고 제1 편광판(112)으로 입사될 수 있다.

[91] 한편, 도 4에는 일 실시예에 따른 다중 분광 이미징 디바이스를 모바일 기기에 연결하고, 모바일 기기를 통해 장치를 제어하여 빛을 검출하는 방법이 도시되어 있다.

[92] 도 4를 참조하면, 일 실시예에 따른 피부 다중 분광 이미징 디바이스를 모바일 기기에 연결하고, 모바일 기기를 통해 제어하여 빛을 검출하는 방법은, 모바일 기기를 이용하여 임베디드 시스템에 촬영 명령을 입력하는 단계(S10), 임베디드 시스템을 통해 입력된 촬영 명령을 이용하여 조명부, 특히 복수 개의 LED 광원을 제어하는 단계(S11) 및 조명부에서 송출되어 분광된 빛 중 산란된 빛을 검출부에서 검출하는 단계(S12)를 포함한다.

[93] 먼저, 사용자는 모바일 기기를 이용하여 임베디드 시스템에 촬영 명령을 입력한다(S11). 일 실시예에 따른 다중 분광 이미징 디바이스는 임베디드 시스템을 포함하고 있기 때문에 외부로부터 유선 또는 무선 통신을 이용하여 촬영 명령을 입력 받을 수 있다.

[94] 이때, 임베디드 시스템에 입력되는 촬영 명령은 바람직하게는 모바일 기기에 설치된 어플리케이션 등에서 출력될 수 있지만, 본 발명은 이에 한정되지 않고 다양한 방법을 통해 임베디드 시스템에 촬영 명령을 입력할 수 있다.

[95] 다음으로, 임베디드 시스템은, 입력된 촬영 명령을 이용하여 조명부를 제어한다(S11). 임베디드 시스템은 단계 S10에서 획득한 촬영 명령을 이용하여 조명부의 제어를 수행한다. 조명부는, 상술한 바와 같이 복수 개의 LED 광원이 실장된 LED 기판 및 복수 개의 대역통과 필터를 포함하며, 특히 복수 개의 LED 광원은 UV LED 및 NIR LED를 포함하기 때문에 조명부는 임베디드 시스템의 제어를 통해 빛을 방출하는 LED를 설정할 수 있다.

[96] 한편, 복수 개의 대역통과 필터는, 복수 개의 LED 광원에서 방출되는 빛의 경로에 구비되어 LED 광을 특정 파장 대역의 빛으로 분광한다. 따라서, 임베디드 시스템은 복수 개의 LED 광원 중 원하는 파장 대역의 빛으로 분광될 수 있는 LED를 선택적으로 점등시킴으로써 촬영 명령을 이용하는 조명부의 제어를 수행할 수 있다.

[97] 마지막으로, 모바일 기기는 조명부에서 송출되어 분광된 빛 중 산란된 빛을 검출부에서 검출한다(S12). 조명부에서 송출되어 분광된 빛은 피부 조사를 수행하기 위해 확산판 및 제2 편광판을 통과하여 피부로 송출되고, 피부에서 산란된 빛은 광학 렌즈 및 제1 편광판을 통과하여 모바일 기기의 카메라로

입사한다. 이때, 바람직하게는 제1 편광판 및 제2 편광판은 빛을 서로 직교하는 방향으로 편광시키도록 구비될 수 있다.

[98] 모바일 기기의 카메라로 입사된 빛은 모바일 기기에 설치된 어플리케이션 등을 통하여 분석되고, 그 분석 결과는 사용자에게 텍스트, 사진 또는 영상 등으로 제공될 수 있다.

[99] 이와 같이 일 실시예에 따른 다중 분광 이미징 디바이스는 휴대성이 높고 사용이 간편하며, 사용자가 쉽게 현재 피부의 상태를 정확히 진단할 수 있다. 그리고 모바일 기기의 형태와 무관하게 탈/부착이 가능하다.

[100] 이상 일 실시예에 따른 다중 분광 이미징 디바이스에 대하여 설명되었으며, 이하에서는 다중 분광 이미징 디바이스에 대하여 설명된다.

[101] 도 5는 다른 실시예에 따른 다중 분광 이미징 디바이스를 도시하고, 도 6은 조명부의 상세도이다.

[102] 도 5를 참조하여, 다른 실시예에 따른 다중 분광 이미징 디바이스(200)는 조명부(210), 검출부(220), 가림막(230) 및 덮개부(240)를 포함할 수 있다.

[103] 이때, 다른 실시예에 따른 다중 분광 이미징 디바이스(200)는 전체적으로 조명부(210) 및 검출부(220)가 동축 상에 배치될 수 있고, 조명부(210) 내에 검출부(220)가 배치되며, 검출부(220)의 외측에는 가림막(230)이 배치되고 조명부(210)의 외측에는 덮개부(240)가 배치되는 구조를 구비할 수 있다.

[104] 구체적으로, 조명부(210)는 피부 조사를 위한 LED 조명을 피부로 송출할 수 있으며, LED 기판(212)과 LED 기판(212) 상에 장착된 복수 개의 LED 모듈(214)을 포함할 수 있다.

[105] 상기 LED 기판(212)은 피부를 향하는 일면에 경사면(212a)을 포함할 수 있다. 상기 경사면(212a)은 LED 기판(212)의 일면에서 피부를 향하여 경사지게 형성될 수 있다.

[106] 이때, 경사면(212a) 상에 복수 개의 LED 모듈(214)이 장착될 수 있다. 이에 의해 복수 개의 LED 모듈(214)에서 송출된 LED 조명이 경사면(212a)의 경사 방향에 따라 경사지게 전달될 수 있다. 예를 들어, 복수 개의 LED 모듈(214)에서 송출된 LED 조명은 조명부(210) 및 검출부(220)의 동축 상에 또는 조명부(210), 검출부(220), 가림막(230) 또는 덮개부(240)의 중심축 상의 한 점에 전달될 수 있다.

[107] 한편, 상기 복수 개의 LED 모듈(214)은 복수 개의 LED 광원(2142), 복수 개의 대역통과 필터(2144), 확산판(2146) 및 제1 편광판(2148)을 포함할 수 있다.

[108] 상기 복수 개의 LED 광원(2142)은 복수 개의 백색광 LED, 적외선 LED 및 자외선 LED 등을 포함할 수 있다. 이때, 복수 개의 백색광 LED는 서로 다른 파장을 갖는 LED 광을 방출하는 복수 개의 LED로 대체될 수 있으며, 복수 개의 LED에서 방출되는 LED 광의 파장은 복수 개의 LED에 장착된 대역통과 필터(2144)의 중심 파장에 부합될 수 있다.

[109] 또한, 복수 개의 LED 광원(2142)은 LED 기판(212)의 경사면(212a)에 의해 상기

동축에 대하여 경사지게 배치될 수 있다.

[110] 구체적으로, 도 6을 참조하여, 복수 개의 LED 광원(2142)은 링 형상으로 마련된 LED 기판(212) 상에 방사상 방향으로 이격 배치될 수 있다. 예를 들어, 복수 개의 LED 광원(2142)은 LED 기판(212) 상에 등각으로 이격 배치될 수 있다.

[111] 상기 복수 개의 대역통과 필터(2144)는 복수 개의 LED 광원(2142) 또는 복수 개의 LED 중 적어도 일부와 접하도록 구비될 수 있다.

[112] 이때, 복수 개의 LED 광원(2142)은 비교적 넓은 대역폭을 갖고 있기 때문에 복수 개의 대역통과 필터(2144)가 대역폭이 좁은 필터로 마련됨으로써, 분광 이미징 성능을 더욱 향상시킬 수 있다.

[113] 또한, 복수 개의 대역통과 필터(2144)는 복수 개의 백색광 LED 중 일부에 접하도록 구비되지 않아, 예를 들어 도 6에서 해칭으로 표현되지 않은 백색광 LED(2142a)로부터 백색광이 송출되게 할 수 있고, 적외선 LED(2142b) 및 자외선 LED(미도시)에도 접하도록 구비되지 않을 수 있다.

[114] 특히, 백색광 LED(2142a)로부터 송출된 백색광을 통해 카메라(10)에서 획득된 이미지의 분광 지표 또는 강도는 분광 이미지의 보정 시 보정 계수를 결정하는 데 활용될 수 있다.

[115] 이때, 복수 개의 대역통과 필터(2144) 또한 LED 기판(212)의 경사면(212a)에 의해 상기 동축에 대하여 경사지게 배치될 수 있다.

[116] 또한, 복수 개의 대역통과 필터(2144)와 접하도록 배치된 복수 개의 LED 광원(2142)은 각각 서로 다른 중심 파장을 갖는 LED 조명을 송출할 수 있다.

[117] 예를 들어, 복수 개의 대역통과 필터(2144)는 9개로 마련되어 435nm, 453nm, 493nm, 520nm, 545nm, 580nm, 605nm, 638nm 및 663nm와 같이 9개의 특정 대역의 파장을 송출 가능하게 할 수 있다. 그러나 복수 개의 대역통과 필터(2144)의 개수는 이에 국한되지 아니하며, 경우에 따라서 9보다 많거나 9보다 적은 개수로 마련될 수 있음은 당연하다.

[118] 상기 확산판(2146)은 LED 조명이 진행하는 방향으로 복수 개의 대역통과 필터(2144)와 접하도록 배치될 수 있다. 이때, 확산판(2146) 또한 LED 기판(212)의 경사면(212a)에 의해 상기 동축에 대하여 경사지게 배치될 수 있다.

[119] 구체적으로, 확산판(2146)은 복수 개로 마련되어 각각의 대역통과 필터(2144)와 접하도록 배치되거나, 확산판(2146) 자체가 링 형상으로 마련될 수 있음은 당연하다.

[120] 이러한 확산판(2146)에 의해 복수 개의 대역통과 필터(2144)를 통과한 LED 조명이 고르게 확산될 수 있으며, LED 조명이 피부 표면 상에서 보다 넓은 범위에 조사될 수 있다.

[121] 상기 제1 편광판(2148)은 LED 조명이 진행하는 방향으로 상기 확산판(2146)과 접하도록 배치될 수 있다. 이때, 제1 편광판(2148) 또한 LED 기판(212)의 경사면(212a)에 의해 상기 동축에 대하여 경사지게 배치될 수 있다.

[122] 예를 들어, 제1 편광판(2148)은 제1 방향, 예를 들어 수직 방향으로 LED 조명을

편광시키는 수직 편광판으로 마련될 수 있으며, 수직 편광판의 경우 직진성 또는 투과성이 향상되어 피부 속 깊은 곳에 전달되게 할 수 있다.

[123] 그러나, 제1 편광판(2148)이 수평 편광판으로 마련될 수 있음은 당연하며, 검출부(220)의 제2 편광판(222)과 서로 직교하는 방향으로 이루어진다면 어느 것이든지 가능하다.

[124] 또한, 제1 편광판(2148)은 복수 개로 마련되어 각각의 확산판(2146)과 접하도록 배치되거나, 제1 편광판(2148) 자체가 링 형상으로 마련될 수 있다.

[125] 특히, 도 6을 참조하여, LED 기판(212) 상에 복수 개의 LED 모듈(214)이 장착되어, 복수 개의 LED 모듈(214)을 LED 기판(212)에 대하여 용이하게 탈부착시킬 수 있다.

[126] 또한, LED 기판(212) 상에는 광 탐지기(216)가 더 장착될 수 있다. 이때, 광 탐지기(216)는 예를 들어 피부에 대한 임피던스 측정을 위해 이용될 수 있다. 광 탐지기(216)는 광 신호를 검출하여 전기적인 신호로 바꾸어 주는 역할을 하며, 적외선 LED(2142b)에서 송출된 적외선을 검출하여 전기적인 신호로 바꾸거나, 피부 표면에서 반사된 적외선을 검출하여 전기적인 신호로 바꿀 수 있다. 이러한 경우, 다른 실시예에 따른 분광 이미징 디바이스(200)를 통해 피부에 대한 분광 이미징 획득과 동시에 피부의 수화도 측정 또한 가능할 수 있다.

[127] 이때, 적외선 LED(2142b) 및 광 탐지기(216)은 LED 기판(212) 상에 서로 인접하게 이격 배치되거나, 서로 마주보도록 배치될 수 있다.

[128] 다시 도 5를 참조하여, 전술된 조명부(210) 내에는 검출부(220)가 배치될 수 있다.

[129] 상기 검출부(220)는 피부에서 산란되는 빛을 카메라(10)로 입사시키는 것으로서, 제2 편광판(222) 및 광학 렌즈(224)를 포함할 수 있다.

[130] 이때, 조명부(210)에서 송출된 LED 조명의 경로(A)는 피부를 향하여 경사지게 형성되는 반면, 피부에서 반사 또는 산란되는 빛의 경로(B)는 조명부(210) 및 검출부(220)가 배치된 동축 상에 형성될 수 있다. 그리고 조명부(210)에서 송출된 LED 조명의 경로(A)는 검출부(220)의 외측에 형성되고, 피부에서 반사 또는 산란되는 빛의 경로(B)는 검출부(220) 내측에 형성되므로 조명부(210)에서 송출된 LED 조명의 경로(A) 및 피부에서 반사 또는 산란된 빛의 경로(B)는 서로 다르게 형성될 수 있다.

[131] 상기 제2 편광판(222)은 피부에서 반사 또는 산란된 빛을 제2 방향으로 편광시킬 수 있다. 이때, 제2 방향은 제1 편광판(2148)의 제1 방향과 직교하는 방향으로서 예를 들어 수평 방향이 될 수 있다.

[132] 이와 같이 제2 편광판(222)에서 제1 편광판(2148)의 제1 방향과 직교하는 방향으로 피부에서 반사 또는 산란된 빛을 편광시킴으로써, 카메라(10)에 대한 피부에서 반사되는 빛의 입사가 차단될 수 있다.

[133] 구체적으로, LED 조명이 피부 표면에 입사되면, LED 조명 중 일부는 피부 속에 침투되어 피부와 상호작용 후에 산란되거나, LED 조명 중 일부는 피부와

상호작용 없이 바로 반사될 수 있다.

[134] 이때, LED 조명이 피부 속에 침투되어 피부와 상호작용을 하게 되면 LED 조명이 편광성을 잃게 되는 반면, 피부와 상호작용 없이 바로 반사되면 LED 조명이 편광성을 유지하게 되므로, 제2 편광판(222)에서 제1 편광판(2148)의 제1 방향과 직교하는 방향으로 빛을 편광시키게 되면, 피부와 상호작용 없이 바로 반사된 빛은 제2 편광판(222)을 통과할 수 없다. 다시 말해서, 피부와 상호작용 없이 바로 반사된 빛은 카메라(10)에 입사될 수 없고, 피부 속에 침투되어 피부와 상호작용한 빛을 효과적으로 카메라(10)에 입사시킬 수 있다.

[135] 또한, 제2 편광판(222)으로부터 피부에서 반사 또는 산란되는 빛의 진행 방향으로 광학 렌즈(224)가 배치될 수 있다.

[136] 구체적으로, 피부, 제2 편광판(222), 광학 렌즈(224) 및 카메라(10)는 피부에서 반사 또는 산란되는 빛의 경로(B)를 따라 연상되는 동일 선상에 위치될 수 있다.

[137] 상기 광학 렌즈(224)는 제2 편광판(222)에서 편광된 빛, 구체적으로 피부 속에 침투되어 피부와 상호작용한 빛 또는 피부에서 산란된 빛을 굴절시킬 수 있다. 이에 의해 피부에서 산란되는 빛이 카메라(10)에 효과적으로 입사될 수 있다.

[138] 이에 의해 카메라(10)에서 피부에 대한 다중 분광 이미지를 획득할 수 있다.

[139] 이때, 도 5에는 카메라(10)가 다중 분광 이미징 디바이스(200)와 분리된 형태로 도시되어 있으나, 카메라(10)의 구성은 이에 국한되지 아니할 수 있다.

[140] 예를 들어, 카메라(10)는 다중 분광 이미징 디바이스(200)에서 피부와 반대되는 측에 장착되도록 마련될 수 있으며, 카메라(10)가 다중 분광 이미징 디바이스(200)의 일부분이 될 수 있다.

[141] 또는 카메라(10)는 스마트폰 등과 같은 모바일 기기에 장착될 수 있으며, 모바일 기기에 다중 분광 이미징 디바이스(200)를 장착하여, 카메라(10)에서 획득한 이미지를 모바일 기기에서 확인할 수 있다.

[142] 또는 카메라(10)는 예를 들어 CMOS 카메라로 마련될 수 있으며, CMOS 카메라에 다중 분광 이미징 디바이스(200)가 장착되고, 카메라(10)와 모바일 기기가 유무선으로 연결될 수 있다. 이와 같이 카메라(10)는 다양한 구성으로 마련될 수 있다.

[143] 한편, 전술된 조명부(210) 및 검출부(220) 사이에는 가림막(230)이 배치될 수 있다.

[144] 상기 가림막(230)은 내부에 검출부(220)가 수용되도록 원통 형상으로 마련될 수 있다. 구체적으로, 가림막(230) 내부에는 제2 편광판(222) 및 광학 렌즈(224)가 배치될 수 있다. 이때, 가림막(230)의 형상은 원통 형상에 국한되지 아니하며, 내부에 검출부(220)가 수용될 수 있다면 어느 것이든지 가능하다.

[145] 또한, 가림막(230)의 외측에는 조명부(210)가 배치될 수 있다.

[146] 도 5에는 LED 기판(212) 및 LED 모듈(214)이 확대되어 도시되어 있어, LED 모듈(214)이 가림막(230) 보다 피부를 향하여 배치된 것으로 도시되어 있으나, 가림막(230)의 외측에 LED 기판(212) 및 LED 모듈(214)이 배치될 수 있다.

[147] 이때, 가림막(230)에 의해 확산판(2146)에서 확산된 LED 조명이 피부에서 반사 또는 산란되는 빛의 경로(B)에 안내되는 것을 방지할 수 있다. 따라서 확산판(2146)에서 확산된 LED 조명은 조명부(210)에서 송출된 LED 조명의 경로(A)를 따라서 피부를 향해서만 조사될 수 있다. 이는 검출부(220)를 통해 피부에서 산란된 빛 외의 다른 빛은 카메라(10)에 입사될 수 없으므로 노이즈를 감소시킬 수 있다.

[148] 또한, 덮개부(240) 내에는 전술된 조명부(210) 및 검출부(220)가 수용될 수 있다.

[149] 상기 덮개부(240)의 중심축 상에는 검출부(220)가 배치되고, 덮개부(240)의 중심축으로부터 방사상 방향으로 이격되어 조명부(210)가 배치될 수 있다. 따라서 덮개부(240)의 중심축을 기준으로 검출부(220)가 내측에 그리고 조명부(210)가 외측에 배치될 수 있다.

[150] 이때, 덮개부(240)의 일단은 카메라(10)에 인접하게 배치되고, 덮개부(240)의 타단은 피부에 인접하게 배치될 수 있다.

[151] 구체적으로, 덮개부(240)는 일단으로부터 타단을 향하여 단면적이 좁아지게 형성될 수 있다. 덮개부(240)의 이러한 형상은 조명부(210)에서 송출된 LED 조명의 경로(A)에 영향을 미칠 수 있으며, 조명부(210)에서 송출된 LED 조명이 피부에 집중되게 할 수 있다.

[152] 또한, 덮개부(240)의 일단에 인접한 내부 공간에 조명부(210), 검출부(220) 및 가림막(230)이 배치될 수 있으며, 이 부분에서는 덮개부(240)의 단면적이 일정하게 유지될 수 있다. 따라서 조명부(210)에서 송출된 LED 조명의 경로(A) 및 피부에서 반사 또는 산란되는 빛의 경로(B)가 위치되는 부분에서 덮개부(240)의 단면적이 감소될 수 있다.

[153] 게다가, 덮개부(240)는 광-기밀 인클로저로서 조명부(210) 및 검출부(220)가 암실 내에 배치되게 하여, 외부 조명을 차단하여 카메라(10)에서 보다 선명한 이미지를 획득할 수 있다.

[154] 이하에서는 다른 실시예에 따른 다중 분광 이미징 디바이스에 의한 이미지 획득 방법에 대하여 설명된다.

[155] 도 7은 다른 실시예에 따른 다중 분광 이미징 디바이스에 의한 이미지 획득 방법을 나타내는 순서도이고, 도 8은 다른 실시예에 따른 다중 분광 이미징 디바이스에서 이미지 획득을 위한 인터페이스 회로를 나타낸다.

[156] 이하에서는 다른 실시예에 따른 다중 분광 이미징 디바이스가 예를 들어 COMS 카메라에 장착되고, COMS 카메라와 스마트폰이 서로 연결된 경우를 예로 들어 설명하기로 한다.

[157] 도 7을 참조하여, 우선 스마트폰 앱에서 촬영 시작 명령이 예를 들어 블루투스를 통해 마이크로컨트롤러에 전달되고, 마이크로컨트롤러에서는 복수 개의 LED 광원 중 LED 선택을 위하여 정전류 칩에 명령어를 전송한다.

[158] 그런 다음, 복수 개의 LED 광원 중 특정 파장 대역의 LED 선택된다.

[159] 구체적으로, 복수 개의 LED 광원에는 복수 개의 대역통과 필터가 접하도록

배치되므로, 특정 파장 대역의 LED를 선택하는 것은 복수 개의 대역통과 필터 중 특정 파장 대역의 필터와 LED 광원을 결합시킨다는 것을 의미한다.

[160] 따라서 특정 LED 광원이 점등되면, 특정 LED 광원이 특정 파장 대역의 필터를 통과하여 특정 파장 대역의 LED 조명을 송출할 수 있다.

[161] 그런 다음, LED 광원으로부터 송출된 LED 조명은 피부에서 산란 또는 반사되어 다중 분광 이미지 디바이스를 거쳐 CMOS 카메라에 입사될 수 있다. 그리고 CMOS 카메라에 입사된 빛은 이미지를 형성하고, 예를 들어 블루투스를 통하여 스마트폰에 이미지 획득 신호를 전송한다. 이와 같이 스마트폰에서 특정 파장 대역의 이미지 획득가 획득된다.

[162] 이후에, 스마트폰에서는 전 파장 대역에 대한 이미지가 획득되었는지 여부를 확인하여, 전 파장 대역에 대한 이미지가 획득되지 않았을 경우, 다음 파장 대역의 LED 조명을 위한 명령어를 마이크로컨트롤러에 전송하고, 마이크로킨트롤러에서는 복수 개의 LED 광원 중 LED 선택을 위하여 정전류 칩에 명령어를 전송한다.

[163] 그런 다음, 복수 개의 LED 광원 중 이전에 이미지가 획득되지 않은 특정 파장 대역의 LED 선택된다.

[164] 구체적으로, 복수 개의 LED 광원에는 복수 개의 대역통과 필터가 접하도록 배치되므로, 이미지가 획득되지 않은 특정 파장 대역의 LED를 선택하는 것은 복수 개의 대역통과 필터 중 이미지가 획득되지 않은 특정 파장 대역의 필터와 LED 광원을 결합시킨다는 것을 의미한다.

[165] 따라서 특정 LED 광원이 점등되면, 특정 LED 광원이 특정 파장 대역의 필터를 통과하여 특정 파장 대역의 LED 조명을 송출할 수 있다.

[166] 이러한 과정을 거쳐, 스마트폰에서 전 파장 대역에 대한 이미지가 획득되었는지 여부를 확인하여, 전 파장 대역에 대한 이미지가 획득된 경우에는 이미지가 저장되고 서버, 예를 들어 분광 이미지 처리 서버에 전송될 수 있다. 그리고 서버에 전송된 이미지는 분석되고 서버에서 이미지 분석된 결과가 스마트폰에 다시 전송된다.

[167] 이와 같이 특정 파장에서 LED가 점등되는 동안, COMS 카메라에서는 동시적으로 이미지가 획득 또는 기록되고, 이러한 절차가 반복되어 다중 분광 이미징 및 분석을 위한 연속적인 파장들에서의 이미지가 획득될 수 있다.

[168] 이때, 스마트폰 및 다중 분광 이미징 디바이스는 동기화를 위해 인터페이스 회로에 의해 연결될 수 있다. 상기 인터페이스 회로는 다중 분광 이미징 디바이스 내에 내장될 수 있다.

[169] 특히, 도 8을 참조하여, 인터페이스 회로는 MCU(microcontroller unit), 블루투스 모듈, LED를 위한 정전류 칩, 스텝-업 조정기, 저 드롭아웃 조정기 및 클록 발생기(clock generator)를 포함할 수 있다.

[170] 이때, MCU는 블루투스 모듈을 통해 스마트폰으로부터 명령어들을 수신하고, 복수 개의 LED 광원 중 선택된 파장의 LED를 점등 또는 점멸하기 위해 UART

통신(Universal asynchronous recevier/transmitter)을 통해 정전류 칩에 명령어를 전달한다.

[171] 그리고 인터페이스 회로에 대한 전원 공급을 위해, 예를 들어 3.7V의 리튬 배터리가 활용될 수 있다. 3.7V의 입력 전압은 MCU 및 정전류 칩을 모두 구동하기 위해 5V로 승압되어, LED 조명을 보다 안정적으로 송출할 수 있다. 반면, 3.7V의 입력 전압은 블루투스 모듈에 전원을 공급하기 위해 3.3V로 저하될 수 있다.

[172] 이와 같이 다중 분광 이미징 디바이스는 LED 기판을 회전시킬 필요 없이 LED 광원의 선택적 점멸 또는 점등에 의해 특정 파장 대역의 이미지를 획득하게 할 수 있으며, 외부 빛의 차단 및 피부와의 상호 작용 없이 피부 표면에서 반사된 빛의 차단을 통하여 보다 선명한 이미지를 획득할 수 있다.

[173] 이상과 같이 본 발명의 실시예에서는 구체적인 구성 요소 등과 같은 특정 사항들과 한정된 실시예 및 도면에 의해 설명되었으나 이는 본 발명의 보다 전반적인 이해를 돕기 위해서 제공된 것일 뿐, 본 발명은 상기의 실시예에 한정되는 것은 아니며, 본 발명이 속하는 분야에서 통상적인 지식을 가진 자라면 이러한 기재로부터 다양한 수정 및 변형이 가능하다. 따라서, 본 발명의 사상은 설명된 실시예에 국한되어 정해져서는 아니 되며, 후술하는 특허청구범위뿐 아니라 이 특허청구범위와 균등하거나 등가적 변형이 있는 모든 것들은 본 발명 사상의 범주에 속한다고 할 것이다.

청구범위

[청구항 1] 피부 조사를 위한 LED 조명을 피부로 송출하는 조명부; 및
상기 피부에서 반사되는 빛을 카메라로 입사시키는 검출부;
를 포함하고,
상기 조명부는 상기 검출부의 외측에 배치되어,
상기 조명부에서 송출된 LED 조명의 경로는 상기 검출부의 외측에 형성되고, 상기 피부에서 반사되는 빛의 경로는 상기 검출부 내측에 형성되는 다중 분광 이미징 디바이스.

[청구항 2] 제1항에 있어서,
상기 검출부는,
상기 피부에서 반사되는 빛을 굴절시키는 광학 렌즈; 및
상기 광학 렌즈에서 굴절된 빛을 제1 방향으로 편광시키는 제1 편광판;
을 포함하고,
상기 카메라는 상기 광학 렌즈 및 상기 제1 편광판의 중심축 상에 배치되는 다중 분광 이미징 디바이스.

[청구항 3] 제2항에 있어서,
상기 검출부는,
상기 광학 렌즈 및 상기 제1 편광판을 내부에 수용하는 가림막;
을 더 포함하고,
상기 가림막의 외측에 상기 조명부가 배치되는 다중 분광 이미징 디바이스.

[청구항 4] 제1항에 있어서,
상기 조명부는,
복수 개의 LED 광원이 실장된 LED 기판; 및
상기 복수 개의 LED 광원 중 적어도 일부와 접하도록 구비되는 복수 개의 대역통과 필터;
를 포함하고,
상기 LED 기판은 링 형상으로 마련되는 다중 분광 이미징 디바이스.

[청구항 5] 제4항에 있어서,
상기 복수 개의 LED 광원은 하나의 UV LED, 하나의 NIR LED, 복수 개의 백색 LED, 또는 상기 복수 개의 대역통과 필터의 중심 파장에 대응되도록 서로 다른 파장을 갖는 복수 개의 LED를 포함하고,
상기 복수 개의 대역통과 필터는 상기 복수 개의 백색 LED 또는 상기 복수 개의 LED에 접하도록 배치되는 다중 분광 이미징

디바이스.

[청구항 6] 제5항에 있어서,
상기 복수 개의 대역통과 필터의 개수는 상기 복수 개의 백색 LED의 개수보다 한 개 적게 구비되는 다중 분광 이미징 디바이스.

[청구항 7] 제4항에 있어서,
상기 복수 개의 LED 광원 및 상기 복수 개의 대역통과 필터는 상기 복수 개의 LED 광원의 점등 또는 점멸의 제어를 통해 선택적으로 결합되고,
상기 복수 개의 LED 광원의 점등 또는 점멸은 상기 모바일 기기를 통해 제어되는 임베디드 시스템에 의해 제어되는 다중 분광 이미징 디바이스.

[청구항 8] 제4항에 있어서,
상기 조명부는,
상기 LED 조명이 진행하는 방향으로 상기 복수 개의 대역통과 필터와 접하도록 배치되어 상기 LED 조명을 확산시키는 확산판;
을 더 포함하고,
상기 확산판은 상기 복수 개의 LED 광원이 실장된 형상과 동일한 형상으로 빛을 확산시키는 확산부를 구비하는 다중 분광 이미징 디바이스.

[청구항 9] 제8항에 있어서,
상기 조명부는,
상기 LED 조명이 진행하는 방향으로 상기 확산판에 접하도록 배치되어 상기 확산판에 의해 확산된 LED 조명을 제2 방향으로 편광시키는 제2 편광판;
을 더 포함하고,
상기 제2 편광판은 상기 확산부와 동일한 형상으로 편광부를 구비하는 다중 분광 이미징 디바이스.

[청구항 10] 제1항에 있어서,
상기 조명부 및 상기 검출부가 내부에 수용되는 덮개부;
를 더 포함하고,
상기 덮개부에 의해 상기 조명부 및 상기 검출부가 암실 내에 배치되어,
상기 조명부에서 송출된 LED 조명 또는 상기 피부에서 반사된 빛에 대한 외부 빛의 영향이 차단되는 다중 분광 이미징 디바이스.

[청구항 11] 제10항에 있어서,
상기 덮개부는,
상기 모바일 기기에 장착을 위한 결합 부재;
를 포함하고,

상기 결합 부재는 길이 조절 가능하도록 마련되는 다중 분광 이미징 디바이스.

[청구항 12] 피부 조사를 위한 LED 조명을 피부로 송출하는 조명부; 및
상기 피부에서 산란되는 빛을 카메라로 입사시키는 검출부;
를 포함하고,
상기 조명부 및 상기 검출부는 동축 상에 배치되고,
상기 조명부에서 송출된 LED 조명의 경로는 상기 피부를 향하여 경사지게 형성되고, 상기 피부에서 반사 또는 산란되는 빛의 경로는 상기 동축 상에 형성되는 다중 분광 이미징 디바이스.

[청구항 13] 제12항에 있어서,
상기 조명부는,
복수 개의 LED 광원이 실장된 LED 기판; 및
상기 복수 개의 LED 광원 중 적어도 일부와 접하도록 구비되는 복수 개의 대역통과 필터;
를 포함하고,
상기 LED 기판은 상기 피부를 향하여 경사지게 형성된 경사면을 포함하고,
상기 경사면 상에 상기 복수 개의 LED 광원이 장착되는 다중 분광 이미징 디바이스.

[청구항 14] 제13항에 있어서,
상기 조명부는,
상기 LED 조명이 진행하는 방향으로 상기 복수 개의 대역통과 필터와 접하도록 배치되어 상기 LED 조명을 확산시키는 확산판; 및
상기 LED 조명이 진행하는 방향으로 상기 확산판과 접하도록 배치되어 상기 확산판에서 확산된 LED 조명을 제1 방향으로 편광시키는 제1 편광판;
을 더 포함하는 다중 분광 이미징 디바이스.

[청구항 15] 제14항에 있어서,
내부에 상기 검출부가 수용되도록 원통 형상으로 마련된 가림막;
을 더 포함하고,
상기 가림막에 의해 상기 확산판에서 확산된 LED 조명이 상기 피부에서 반사 또는 산란되는 빛의 경로에 안내되는 것이 방지되는 다중 분광 이미징 디바이스.

[청구항 16] 제14항에 있어서,
상기 검출부는,
상기 피부에서 반사 또는 산란된 빛을 상기 제1 방향과 직교하는 제2 방향으로 편광시키는 제2 편광판;

을 포함하고,
상기 제2 편광판에 의해 상기 카메라에 대한 상기 피부에서
반사되는 빛의 입사가 차단되는 다중 분광 이미징 디바이스.

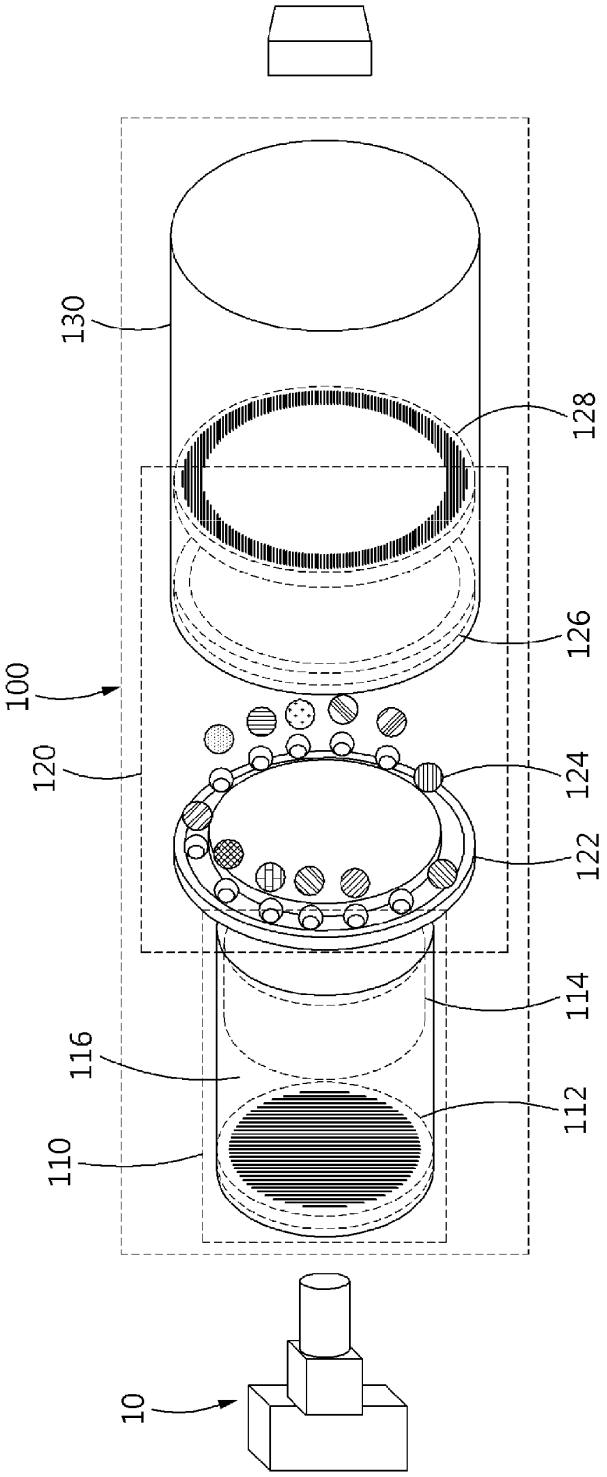
[청구항 17] 제16항에 있어서,
상기 검출부는,
상기 제2 편광판에서 편광된 빛을 굴절시키는 광학 렌즈;
를 더 포함하고,
상기 피부, 상기 제2 편광판, 상기 광학 렌즈 및 상기 카메라가 동일
선상에 위치되는 다중 분광 이미징 디바이스.

[청구항 18] 제12항에 있어서,
상기 LED 기판은 링 형상으로 마련되며,
상기 LED 기판을 관통하여 상기 검출부가 배치되고,
상기 복수 개의 LED 광원은 상기 LED 기판 상에 방사상 방향으로
이격 배치되는 다중 분광 이미징 디바이스.

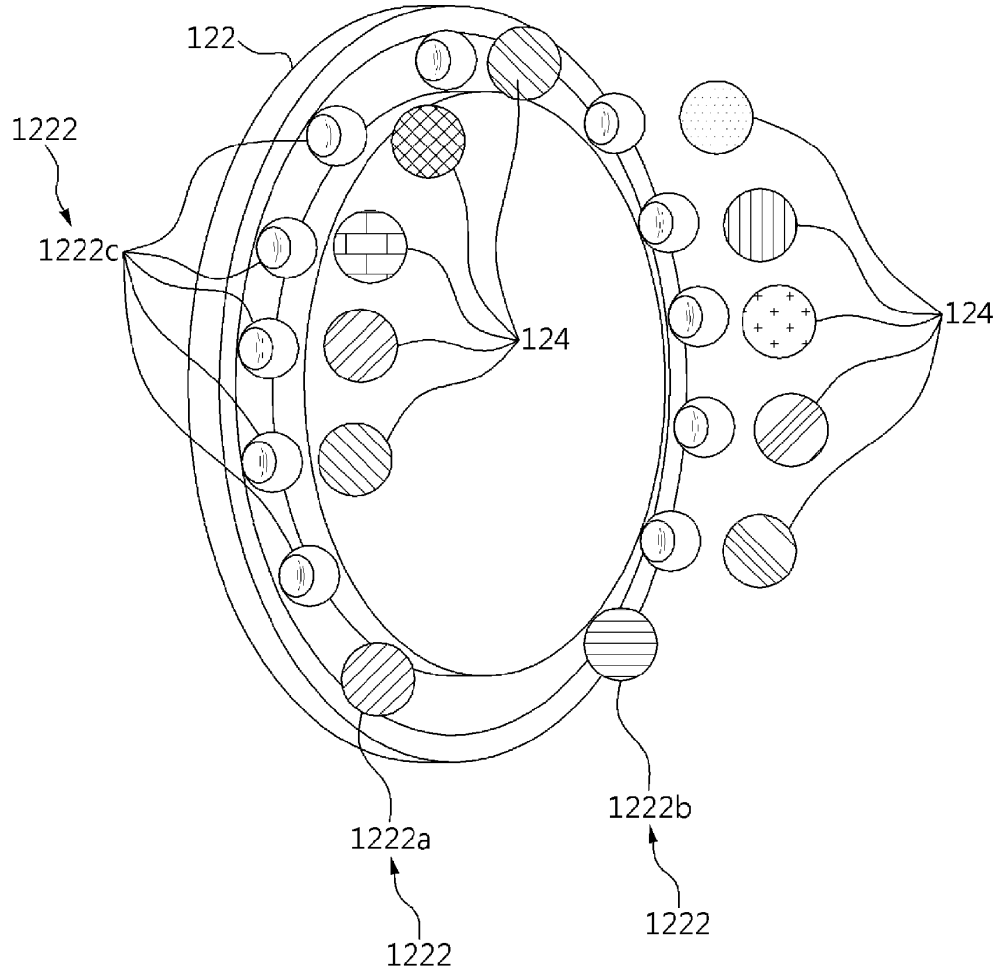
[청구항 19] 제12항에 있어서,
상기 조명부 및 상기 검출부가 내부에 수용되는 덮개부;
를 더 포함하고,
상기 덮개부의 중심축 상에 상기 검출부가 배치되고, 상기
덮개부의 중심축으로부터 방사상 방향으로 이격되어 상기
조명부가 배치되는 다중 분광 이미징 디바이스.

[청구항 20] 제19항에 있어서,
상기 덮개부의 일단은 상기 카메라에 인접하게 배치되고,
상기 덮개부의 타단은 상기 피부에 인접하게 배치되며,
상기 덮개부는 일단으로부터 타단을 향하여 단면적이 좁아지게
형성되는 다중 분광 이미징 디바이스.

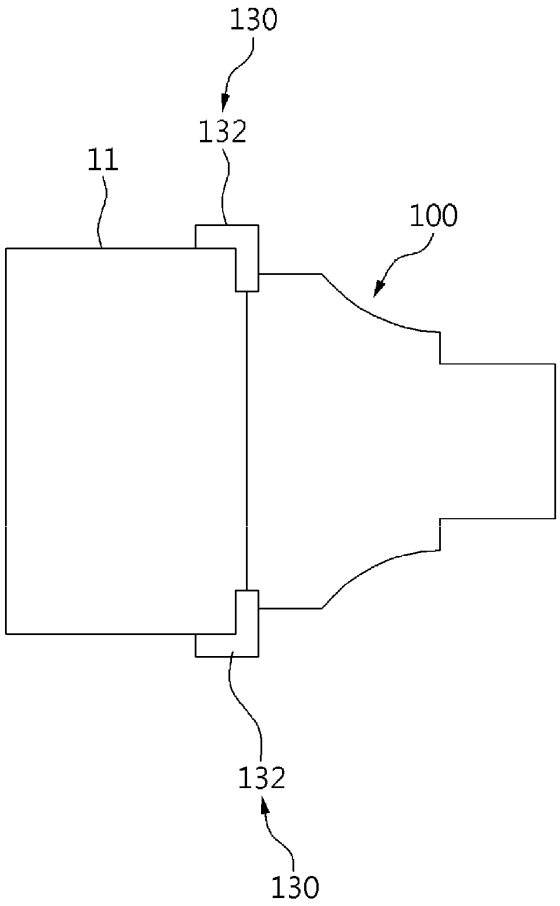
[Fig. 1]



[Fig. 2]



[Fig. 3]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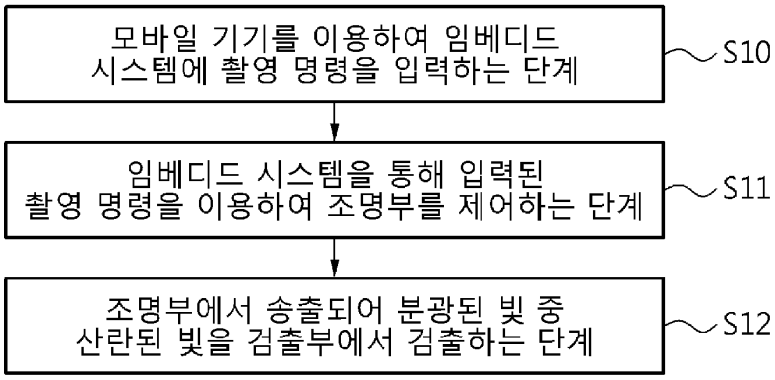
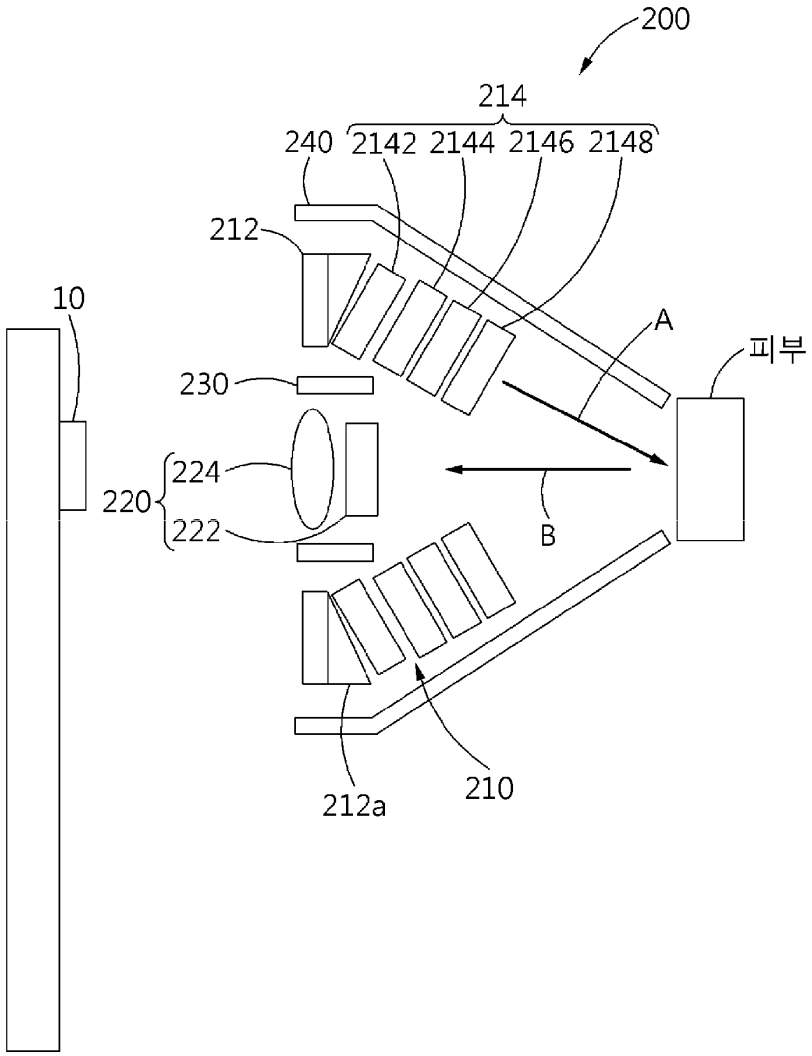
[Fig. 4]


모바일 기기를 이용하여 임베디드 시스템에 촬영 명령을 입력하는 단계
S10
임베디드 시스템을 통해 입력된 촬영 명령을 이용하여 조명부를 제어하는 단계
S11
조명부에서 송출되어 분광된 빛 중 산란된 빛을 검출부에서 검출하는 단계
S12

[Fig. 5]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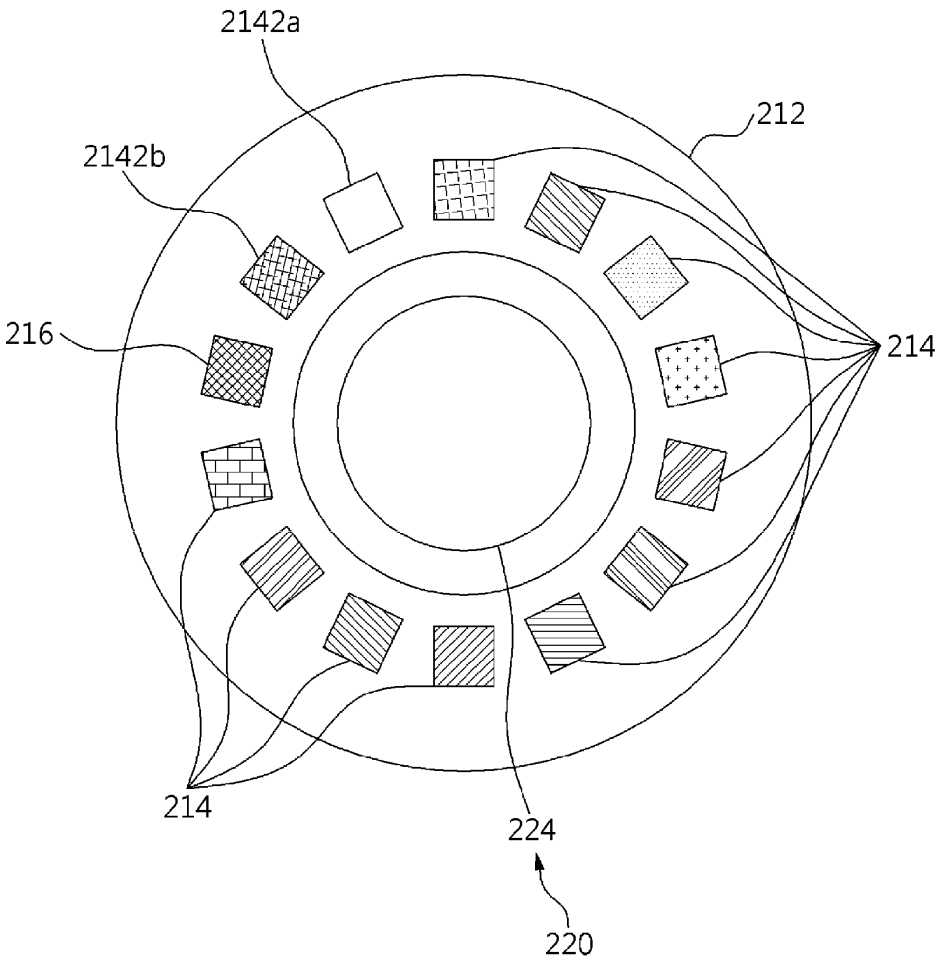
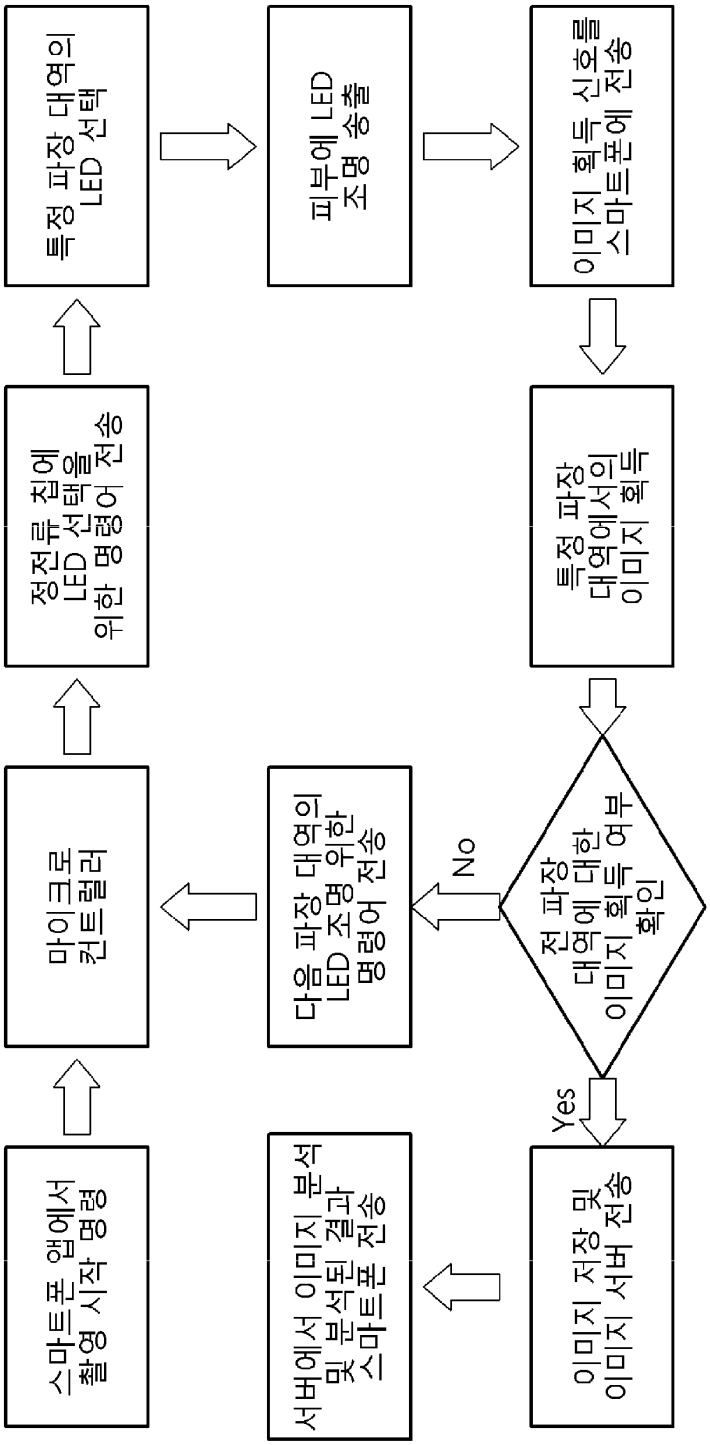
210

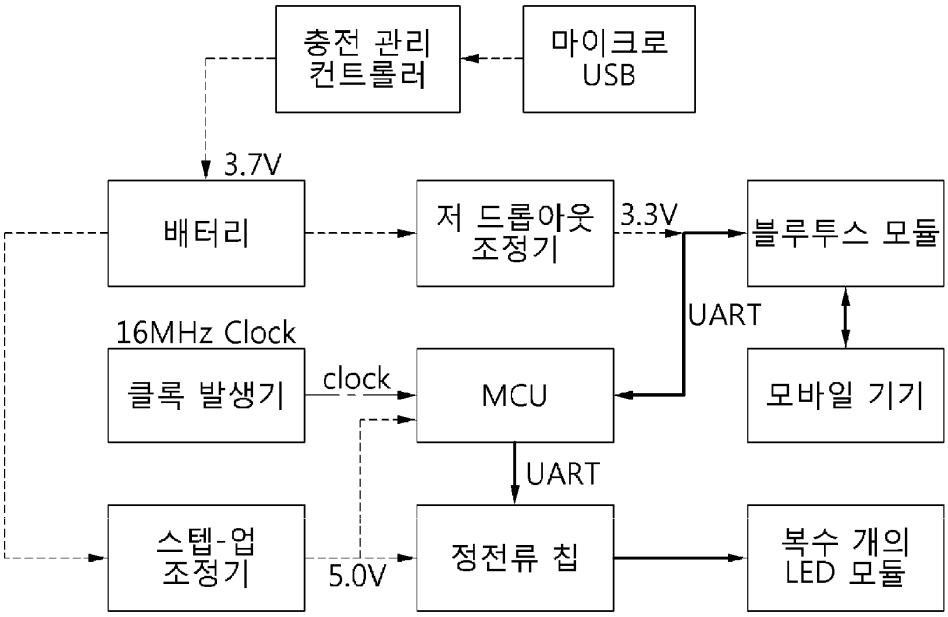
[Fig. 6]



[Fig. 7]


스마트폰 앱에서 촬영 시작 명령
마이크로 컨트롤러
정전류 칩에 LED 선택을 위한 명령어 전송
특정 파장 대역의 LED 선택
피부에 LED 조명 송출
이미지 획득 신호를 스마트폰에 전송
특정 파장 대역에서의 이미지 획득
전 파장 대역에 대한 이미지 획득 여부 확인
No
다음 파장 대역의 LED 조명 위한 명령어 전송
Yes
이미지 저장 및 이미지 서버 전송
서버에서 이미지 분석 및 분석된 결과 스마트폰 전송

[Fig. 8]


충전 관리
컨트롤러
마이크로
USB
3.7V
배터리
저 드롭아웃
조정기
3.3V
블루투스 모듈
UART
16MHz Clock
클록 발생기
clock
MCU
모바일 기기
UART
스텝-업
조정기
5.0V
정전류 칩
복수 개의
LED 모듈

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2017/002423

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/00(2006.01)i, F21V 5/04(2006.01)i, F21V 9/00(2006.01)i, F21S 2/00(2006.01)i, F21Y 101/00(2006.01)n

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 5/00; G03B 17/56; A61B 5/02; A61B 6/00; H04B 1/40; G06T 1/00; F21V 5/04; F21V 9/00; F21S 2/00; F21Y 101/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Utility models and applications for Utility models: IPC as above
Japanese Utility models and applications for Utility models: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS (KIPO internal) & Keywords: spectrum, LED, mobile, attachment/detachment, skin, irradiation, route, polarization

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	KR 10-0781235 B1 (KIM, Chang Hwan) 30 November 2007 See paragraphs [26]-[39] and figure 2.	1-20
Y	KR 10-2015-0018973 A (JUNG, Ha Cheol) 25 February 2015 See paragraph [21] and figures 1-3.	1-20
Y	KR 10-2006-0111906 A (LYMPUS CORPORATION) 30 October 2006 See paragraphs [105]-[440] and figures 53-57.	2-11,13-20
A	KR 20-2015-0003564 U (PARK, Sung Sik) 02 October 2015 See paragraph [8], claims 1, 2 and figure 1.	1-20
A	JP 2008-129446 A (NIDEC COPAL CORP.) 05 June 2008 See claims 1-5 and figures 1-5.	1-20

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 JUNE 2017 (12.06.2017)	**12 JUNE 2017 (12.06.2017)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
Government Complex-Daejeon, 189 Seonsa-ro, Daejeon 302-701, Republic of Korea
Facsimile No. +82-42-481-8578

Authorized officer

Telephone No.

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/KR2017/002423

Patent document cited in search report	Publication date	Patent family member	Publication date
KR 10-0781235 B1	30/11/2007	WO 2008-062967 A1	29/05/2008
KR 10-2015-0018973 A	25/02/2015	NONE	
KR 10-2006-0111906 A	30/10/2006	AU 2003-252254 A1	04/05/2004
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		CN 101259010 B	25/08/2010
		CN 101332080 A	31/12/2008
		CN 1672021 A	21/09/2005
		EP 1528380 A1	04/05/2005
		EP 2433555 A2	28/03/2012
		EP 2433555 A3	16/01/2013
		JP 2008-165806 A	17/07/2008
		JP 2008-170437 A	24/07/2008
		JP 2008-292495 A	04/12/2008
		JP 2008-304466 A	18/12/2008
		JP 4870067 B2	08/02/2012
		JP 4937971 B2	23/05/2012
		KR 10-0714349 B1	04/05/2007
		KR 10-0722897 B1	31/05/2007
		KR 10-2005-0026009 A	14/03/2005
		US 2006-0152586 A1	13/07/2006
		US 2008-0192235 A1	14/08/2008
		US 2009-0067695 A1	12/03/2009
		US 7756327 B2	13/07/2010
		US 7876955 B2	25/01/2011
		WO 2004-036162 A1	29/04/2004
KR 20-2015-0003564 U	02/10/2015	NONE	
JP 2008-129446 A	05/06/2008	NONE	

국 제 조 사 보 고 서

국제출원번호
PCT/KR2017/002423

A. 발명이 속하는 기술분류(국제특허분류(IPC))

A61B 5/00(2006.01)i, F21V 5/04(2006.01)i, F21V 9/00(2006.01)i, F21S 2/00(2006.01)i, F21Y 101/00(2006.01)n

B. 조사된 분야

조사된 최소문헌(국제특허분류를 기재)
A61B 5/00; G03B 17/56; A61B 5/02; A61B 6/00; H04B 1/40; G06T 1/00; F21V 5/04; F21V 9/00; F21S 2/00; F21Y 101/00

조사된 기술분야에 속하는 최소문헌 이외의 문헌
한국등록실용신안공보 및 한국공개실용신안공보: 조사된 최소문헌란에 기재된 IPC
일본등록실용신안공보 및 일본공개실용신안공보: 조사된 최소문헌란에 기재된 IPC

국제조사에 이용된 전산 데이터베이스(데이터베이스의 명칭 및 검색어(해당하는 경우))
eKOMPASS(특허청 내부 검색시스템) & 키워드: 분광, LED, 모비힘, 착탈, 피부, 조사, 경로, 편광

C. 관련 문헌

카테고리*	인용문헌명 및 관련 구절(해당하는 경우)의 기재	관련 청구항
Y	KR 10-0781235 B1 (김창환) 2007.11.30 문단번호 [26]-[39] 및 도면 2 참조.	1-20
Y	KR 10-2015-0018973 A (정하철) 2015.02.25 문단번호 [21] 및 도면 1-3 참조.	1-20
Y	KR 10-2006-0111906 A (올림푸스 가부시키가이샤) 2006.10.30 문단번호 [105]-[440] 및 도면 53-57 참조.	2-11,13-20
A	KR 20-2015-0003564 U (박성식) 2015.10.02 문단번호 [8], 청구항 1,2 및 도면 1 참조.	1-20
A	JP 2008-129446 A (NIDEC COPAL CORP.) 2008.06.05 청구항 1-5 및 도면 1-5 참조.	1-20

☐ 추가 문헌이 C(계속)이 기재되어 있습니다.

☒ 대응특허에 관한 별지를 참조하십시오.

* 인용된 문헌의 특별 카테고리:

"A" 특별히 관련이 없는 것으로 보이는 일반적인 기술수준을 정의한 문헌

"E" 국제출원일보다 빠른 출원일 또는 우선일을 가지나 국제출원일 이후에 공개된 선출원 또는 특허 문헌

"L" 우선권 주장에 의문을 제기하는 문헌 또는 다른 인용문헌의 공개일 또는 다른 특별한 이유(이유를 명시)를 밝히기 위하여 인용된 문헌

"O" 구두 개시, 사용, 전시 또는 기타 수단을 언급하고 있는 문헌

"P" 우선일 이후에 공개되었으나 국제출원일 이전에 공개된 문헌

"T" 국제출원일 또는 우선일 후에 공개된 문헌으로, 출원과 상충하지 않으며 발명의 기초가 되는 원리나 이론을 이해하기 위해 인용된 문헌

"X" 특별한 관련이 있는 문헌. 해당 문헌 하나만으로 청구된 발명의 신규성 또는 진보성이 없는 것으로 본다.

"Y" 특별한 관련이 있는 문헌. 해당 문헌이 하나 이상의 다른 문헌과 조합하는 경우로 그 조합이 당업자에게 자명한 경우 청구된 발명은 진보성이 없는 것으로 본다.

"&" 동일한 대응특허문헌에 속하는 문헌

국제조사의 실제 완료일	국제조사보고서 발송일
2017년 06월 12일 (12.06.2017)	2017년 06월 12일 (12.06.2017)

ISA/KR의 명칭 및 우편주소
대한민국 특허청
(35208) 대전광역시 서구 청사로 189,
4동 (둔산동, 정부대전청사)
팩스 번호 +82-42-481-8578

심사관
김연경
전화번호 +82-42-481-3325

서식 PCT/ISA/210 (두 번째 용지) (2015년 1월)

국제조사보고서
대응특허에 관한 정보

국제출원번호
PCT/KR2017/002423

국제조사보고서에서 인용된 특허문헌	공개일	대응특허문헌	공개일
KR 10-0781235 B1	2007/11/30	WO 2008-062967 A1	2008/05/29
KR 10-2015-0018973 A	2015/02/25	없음	
KR 10-2006-0111906 A	2006/10/30	AU 2003-252254 A1	2004/05/04
		CN 101259010 A	2008/09/10
		CN 101259010 B	2010/08/25
		CN 101332080 A	2008/12/31
		CN 1672021 A	2005/09/21
		EP 1528380 A1	2005/05/04
		EP 2433555 A2	2012/03/28
		EP 2433555 A3	2013/01/16
		JP 2008-165806 A	2008/07/17
		JP 2008-170437 A	2008/07/24
		JP 2008-292495 A	2008/12/04
		JP 2008-304466 A	2008/12/18
		JP 4870067 B2	2012/02/08
		JP 4937971 B2	2012/05/23
		KR 10-0714349 B1	2007/05/04
		KR 10-0722897 B1	2007/05/31
		KR 10-2005-0026009 A	2005/03/14
		US 2006-0152586 A1	2006/07/13
		US 2008-0192235 A1	2008/08/14
		US 2009-0067695 A1	2009/03/12
		US 7756327 B2	2010/07/13
		US 7876955 B2	2011/01/25
		WO 2004-036162 A1	2004/04/29
KR 20-2015-0003564 U	2015/10/02	없음	
JP 2008-129446 A	2008/06/05	없음	

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	APPARATUS FOR VISUALIZATION OF TISSUE
First Named Inventor/Applicant Name:	Guennadi SAIKO
Filer:	Christopher Patrick Lightner/Grace Caffey
Attorney Docket Number:	046905/554252

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
NATIONAL STAGE FEE	1631	1	320	320
NATL STAGE SEARCH FEE - REPORT PROVIDED	1642	1	540	540
NATIONAL STAGE EXAM - ALL OTHER CASES	1633	1	800	800
Pages:				
Claims:				
Miscellaneous-Filing:				
OATH/DECL > 30 MOS FROM 371 COMMENCEMENT	1617	1	160	160
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	1820

Electronic Acknowledgement Receipt	
EFS ID:	41657686
Application Number:	17260664
International Application Number:	PCT/CA2019/050981
Confirmation Number:	1082
Title of Invention:	APPARATUS FOR VISUALIZATION OF TISSUE
First Named Inventor/Applicant Name:	Guennadi SAIKO
Customer Number:	826
Filer:	Christopher Patrick Lightner/Grace Caffey
Filer Authorized By:	Christopher Patrick Lightner
Attorney Docket Number:	046905/554252
Receipt Date:	15-JAN-2021
Filing Date:	
Time Stamp:	12:32:37
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1820
RAM confirmation Number	E20211EC32532647
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	2021-01-15_554252ADS.pdf	1256294 277777d58bb32968aaef1ab1fc2574dd8a4b7179	no	9
Warnings:					
Information:					
2		2021-01-15_554252Preliminary Amendment.pdf	196318 bd0012232646682346 2b7067a1299b74c60e23ca	yes	9
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Preliminary Amendment		1	1	
	Specification		2	3	
	Claims		4	8	
	Applicant Arguments/Remarks Made in an Amendment		9	9	
Warnings:					
Information:					
3	Transmittal of New Application	2021-01-15_554252Transmittal NewApp.pdf	393301 5d10332f9cd9bae0dca3a8871ad799b39d810a72	no	4
Warnings:					
Information:					
4		2021-01-15_554252WO2020014779.pdf	2912816 2c647140c9617196e27dacd43e81f36ad7d88689	yes	56
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	

	Abstract		1		2
	Specification		3		39
	Claims		40		44
	Drawings-only black and white line drawings		45		54
	Documents submitted with 371 Applications		55		56
Warnings:					
Information:					
5	Transmittal Letter	2021-01-15_554252IDS.pdf	96740 a4b0a5897be2b0ca5d46b5d4eb2a414af7b2c670	no	1
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Information:					
6	Information Disclosure Statement (IDS) Form (SB08)	2021-01-15_554252SB08.pdf	136099 c3a7556d8ba25115e064c674d3f88ed6cba0427a	no	1
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This is not an USPTO supplied IDS fillable form					
7	Non Patent Literature	2021-01-15_554252NPL.pdf	993143 01bd0ae1dd61e425220cc93f38f65396b7e8f62b	no	6
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Information:					
8		2021-01-15_554252ForeignRefs.pdf	10595770 20a9377b8bd8a5f108f87e7d2db55fe277e8a780	yes	60
	Multipart Description/PDF files in .zip description				
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	Foreign Reference		1		26
	Foreign Reference		27		60
Warnings:					
Information:					

9	Fee Worksheet (SB06)	fee-info.pdf	37112 78dee6f16e835e585a0cd97fdbc89a796c9200cf	no	2
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Information:					
			Total Files Size (in bytes):	16617593	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	046905/554252
	Application Number	
Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Guennadi		SAIKO	

Residence Information (Select One) US Residency ● Non US Residency Active US Military Service

City	Country of Residence [i]
Mississauga	CA

Mailing Address of Inventor:

Address 1	2474 Trondheim Cr
Address 2	
City	Mississauga
State/Province	ON
Postal Code	L5N 1P4
Country [i]	CA

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Kenneth		MACKO	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	Country of Residence [i]
Toronto	CA

Mailing Address of Inventor:

Address 1	715-80 St Patrick St
Address 2	
City	Toronto
State/Province	ON
Postal Code	M5T 2X6
Country [i]	CA

Inventor 3 Remove

Legal Name

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	046905/554252
	Application Number	
Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE	

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrei		BETLEN	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	Pickering	Country of Residence i	CA

Mailing Address of Inventor:

Address 1	776 Eyer Dr		
Address 2			
City	Pickering	State/Province	ON
Postal Code	L1W 3C2	Country i	CA

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	00826		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	APPARATUS FOR VISUALIZATION OF TISSUE		
Attorney Docket Number	046905/554252	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	10	Suggested Figure for Publication (if any)	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	046905/554252
	Application Number	
Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE	

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	00826		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	a 371 of international	PCT/CA2019/050981	2019-07-16
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/CA2019/050981	Claims benefit of provisional	62698799	2018-07-16

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	046905/554252
	Application Number	
Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	046905/554252
	Application Number	
Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	046905/554252
	Application Number	
Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Swift Medical Inc.

Mailing Address Information For Applicant:

Address 1	1 Richmond Street West		
Address 2	Suite 500		
City	Toronto	**State/Province**	ON
Country	CA	Postal Code	M5H 3W4
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	046905/554252
	Application Number	
Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Christopher P. Lightner/			Date (YYYY-MM-DD)	2021-01-15
First Name	Christopher	Last Name	Lightner	Registration Number	62156

Additional Signature may be generated within this form by selecting the Add button. Add

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	046905/554252
	Application Number	
Title of Invention	APPARATUS FOR VISUALIZATION OF TISSUE	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Attn: DO/US

IN THE UNITED STATES DESIGNATED OFFICE (DO/US)

Applicant(s):	Saiko, et al.
International Appl. No.:	PCT/CA2019/050981
International Filing Date:	July 16, 2019
Title:	APPARATUS FOR VISUALIZATION OF TISSUE

Docket No.: 046905/554252
Customer No.: 00826

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT
37 CFR § 1.115

Please enter this Preliminary Amendment before calculating the claim fee and amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims beginning on page 4 of this paper.

Remarks begin on page 9 of this paper.

Amendments to the Specification:

1) On page 1 of the published International Application, please amend the existing title as follows:

~~**TITLE: APPARATUS FOR VISUALIZATION OF TISSUE**~~

APPARATUS FOR VISUALIZATION OF TISSUE

2) On page 1, before the existing header before paragraph [0001] of the published International Application, please insert the following headings and paragraph:

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a National Stage Application, filed under 35 U.S.C. § 371, of International Application No. PCT/CA2019/050981, filed July 16, 2019, which claims priority to United States Provisional Application No. 62/698,799, filed July 16, 2018; the contents of both of which as are hereby incorporated by reference in their entireties.

BACKGROUND

Related Field

3) On page 1 of the published International Application, please delete the existing "FIELD" header.

4) On page 1, line 4 of the published International Application, please amend the existing "BACKGROUND" header, as follows:

~~**BACKGROUND**~~

Description of Related Art

5) On page 1, line 27 of the published International Application, please amend the existing "SUMMARY" heading as follows:

~~**SUMMARY**~~

BRIEF SUMMARY

6) On page 5, line 24 of the published International Application, please amend the existing "DESCRIPTION OF THE FIGURES" heading as follows:

~~**DESCRIPTION OF THE FIGURES**~~

BRIEF DESCRIPTION OF THE FIGURES

7) On page 6, line 15 of the published International Application, please amend the existing "DETAILED DESCRIPTION" heading as follows:

~~**DETAILED DESCRIPTION**~~

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

Amendments to the Claims:

1-21. (Cancelled)

22. (New) A portable illumination apparatus for facilitating visualizations of tissue, the apparatus comprising:

a portable housing for detachable attachment proximal to an image capturing unit; and

an illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths,

wherein $n/4 \leq m \leq n$.

23. (New) The portable illumination apparatus of claim 22, wherein the illumination unit further comprises a lens covering the one or more light sources, the lens having a focal length that is 80%-120% of a working distance between the illumination unit and a target area of tissue.

24. (New) The portable illumination apparatus according to claim 22, wherein the one or more light sources is configured to provide flashes that are at least one of:

(i) 405±10nm wavelength, and having at least one of: (a) a long pass filter with a cut-on wavelength of 450±25nm or (b) a bandpass filter with transmission in a 425nm-1000nm range,

(ii) two wavelengths in a 450nm-750nm range, at least one of which in the green range,

(iii) three wavelengths in a 450nm-750nm range, at least one of which in the green range, or

(iv) 970±10nm wavelength.

25. (New) The portable illumination apparatus according to claim 22, wherein the illumination unit further comprises at least one of:

(i) a controller to control illumination of the one or more light sources, or

(ii) a rechargeable battery for powering the apparatus.

26. (New) The illumination apparatus according to claim 22, wherein the one or more light sources are arranged about a central aperture having a radius of 0.5-3cm.

27. (New) The illumination apparatus of claim 26, wherein the one or more light sources are arranged in a ring having a radius of 1.5-6cm.

28. (New) The illumination apparatus according to claim 22, wherein the portable housing comprises a compression clip or a spring clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

29. (New) A tissue imaging system for visualization of tissue health indicators, the system comprising:

a portable computing device,

an image capture unit, and

an illumination unit,

wherein:

the illumination unit comprises one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$;

the image capture unit and the illumination unit are configured to capture measurement data for a target area of tissue; and

the computing device comprises a processor configured to access and execute instrutions in accordance with a tissue visualization application stored in a non-transitory computer-readable memory of the computing device, for capturing measurement data, and pre-processing and processing the measurement data to generate tissue health indicators.

30. (New) The tissue imaging system of claim 29, wherein the computing device comprises a mobile device and the image capture unit is a camera integrated with the mobile device.

31. (New) The tissue imaging system according to claim 29, wherein the illumination unit comprises:

a portable housing for detachable attachment proximal to an image capturing unit; and

an illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths,

wherein $n/4 \leq m \leq n$.

32. (New) The tissue imaging system according to claim 29, wherein the portable illumination unit further comprises a wireless communication module for receiving commands from the computing device.

33. (New) A tissue visualization system operatively connected to one or more tissue imaging systems according to claim 29, comprising a communications module for communicating with the one or more tissue imaging systems, a system processor, and system non-transitory computer-readable memory thereon, configured to receive measurement data and tissue health indicators from the one or more tissue imaging systems and to generate a visualization of tissue health indicators of tissue images received from the one or more tissue imaging systems, for display to a user display unit.

34. (New) A method for generating visualizations of tissue, the method comprising:

positioning a computing device at a proper distance from a target area of the tissue for capturing an image of the target area, the computing device comprising a processor and a non-transitory computer-readable memory storing computer-executable instructions comprising a tissue visualization application;

capturing measurement data using an image capturing unit and an illumination unit, the image capturing unit and the illumination unit communicatively coupled to the computing device and the illumination unit configured to shine m flashes at n predetermined wavelengths during capturing of the measurement data, wherein $n/4 \leq m \leq n$;

pre-processing the measurement data using the tissue visualization application to obtain normalized images;

extracting indications of tissue health indicators from the pre-processed measurement data;

generating interface elements corresponding to the visualization tissue health indicators; and

at least one of storing or transmitting the indications of the tissue health indicators.

35. (New) The method of claim 34 further comprising, prior to capturing the measurement data, capturing a reference image, wherein the positioning the computing device for the reference image capturing comprises positioning the computing device using a reference object.

36. (New) The method of claim 34, wherein the illumination unit and the computing device are configured to provide a working distance of 15±5cm from the target area of tissue.

37. (New) The method of claim 36, wherein the positioning of the computing device for capturing the measurement data comprises positioning the computing device using a self-reference object.

38. (New) The method according to claim 34, wherein pre-processing comprises at least one of:

(i) registering images to avoid camera motion artifacts,

(ii) subtracting images with no illumination from the illumination unit from images with illumination from the illumination unit to account for the presence of ambient light,

(iii) recalibrating each measurement accordingly to control parameters related to intensity of illumination using a self-reference object positioned within the target area,

(iv) dividing the intensity images on reference images to obtain normalized images, or

(v) flattening the obtained images to account for reflections from curved surfaces.

39. (New) The method according to claim 34, wherein camera exposure time is T and a flash time is said T or any whole number multiple of said T.

40. (New) The method according to claim 39, wherein the camera exposure time is 50ms.

41. (New) The method according to claim 34, wherein the measurement data comprises wound-related data.

REMARKS

The above amendments are made to remove multiple dependencies of the claims to save claim fees and to place the claims in better form for U.S. examination. Please enter these amendments prior to calculation of any filing-related fees (including excess claim fees) and examination.

Respectfully submitted,

/Christopher P. Lightner/

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PCT REQUEST

(Original in Electronic Form)

0	**For receiving Office use only**	
0-1	International Application No.	**PCT/CA2019/050981**
0-2	International Filing Date	**16 July 2019 (16.07.2019)**
0-3	Name of receiving Office and "PCT International Application"	**RO/CA**

0-4	**Form PCT/RO/101 PCT Request**	
0-4-1	Prepared Using	**ePCT-Filing Version 4.5.010 MT/FOP 20190710/1.1**
0-5	**Petition**	
	The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	**Canadian Intellectual Property Office (RO/CA)**
0-7	**Applicant's or agent's file reference**	**38753-2010**
I	**Title of Invention**	**APPARATUS FOR VISUALIZATION OF TISSUE**
II	**Applicant**	
II-1	This person is	**Applicant only**
II-2	Applicant for	**All designated States**
II-4	Name	**SWIFT MEDICAL INC.**
II-5	Address	**1 Richmond Street West, Suite 500 Toronto, Ontario M5H 3W4 Canada**
II-6	State of nationality	**CA**
II-7	State of residence	**CA**
III-1	**Applicant and/or inventor**	
III-1-1	This person is	**Inventor only**
III-1-3	Inventor for	**All designated States**
III-1-4	Name (LAST, First)	**SAIKO, GUENNADI**
III-1-5	Address	**2474 Trondheim Cr Mississauga, Ontario L5N1P4 Canada**
III-2	**Applicant and/or inventor**	
III-2-1	This person is	**Inventor only**
III-2-3	Inventor for	**All designated States**
III-2-4	Name (LAST, First)	**MACKO, KENNETH**
III-2-5	Address	**715-80 St Patrick St Toronto, Ontario M5T2X6 Canada**

PCT REQUEST

(Original in Electronic Form)

III-3	**Applicant and/or inventor**	
III-3-1	This person is	**Inventor only**
III-3-3	Inventor for	**All designated States**
III-3-4	Name (LAST, First)	**BETLEN, ANDREI**
III-3-5	Address	**776 Eyer Dr** **Pickering, Ontario L1W3C2** **Canada**
IV-1	**Agent or common representative; or address for correspondence**	
	The person identified below is hereby/ has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	**Agent**
IV-1-1	Name	**TORYS LLP**
IV-1-2	Address	**79 Wellington Street West, 30th Floor** **Box 270, TD South Tower** **Toronto, Ontario M5K 1N2** **Canada**
IV-1-3	Telephone No.	**416-865-0040**
IV-1-5	e-mail	**ipadmin@torys.com**
IV-1-5(a)	E-mail authorization The receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority are authorized to use this e-mail address, if the Office or Authority so wishes, to send notifications issued in respect of this international application:	**exclusively in electronic form (no paper notifications will be sent)**
V	**DESIGNATIONS**	
V-1	**The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.**	
VI-1	**Priority claim of earlier national application**	
VI-1-1	Filing date	**16 July 2018 (16.07.2018)**
VI-1-2	Number	**62/698,799**
VI-1-3	Country or Member of WTO	**US**
VI-2	**Priority document request**	
	The International Bureau is requested to obtain from a digital library a certified copy of the earlier application(s) identified above as item(s), using, where applicable, the access code(s) indicated:	**VI-1 Access code: 3511**
VI-3	**Incorporation by reference :**	
	where an element of the international application referred to in Article 11(1)(iii)(d) or (e) or a part of the description, claims or drawings referred to in Rule 20.5(a) is not otherwise contained in this international application but is completely contained in an earlier application whose priority is claimed on the date on which one or more elements referred to in Article 11(1)(iii) were first received by the receiving Office, that element or part is, subject to confirmation under Rule 20.6, incorporated by reference in this international application for the purposes of Rule 20.6.	

PCT REQUEST

(Original in Electronic Form)

VII-1	**International Searching Authority Chosen**	**Canadian Intellectual Property Office (ISA/CA)**	
VIII	**Declarations**	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	-	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	-	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	-	
IX	**Check list**	Number of sheets	Electronic file(s) attached
IX-1	Request (including declaration sheets)	**4**	✓
IX-2	Description	**37**	✓
IX-3	Claims	**5**	✓
IX-4	Abstract	**1**	✓
IX-5	Drawings	**10**	✓
IX-7	TOTAL	**57**	
	Accompanying Items	Paper document(s) attached	Electronic file(s) attached
IX-8	Fee calculation sheet	-	✓
IX-20	**Figure of the drawings which should accompany the abstract**	**4**	
IX-21	**Language of filing of the international application**	**English**	
X-1	**Signature of applicant, agent or common representative**	**/Edward Tat Kau FAN/**	
X-1-1	Name	**TORYS LLP**	
X-1-2	Name of signatory	**Edward Tat Kau FAN**	
X-1-3	Capacity (if such capacity is not obvious from reading the request)	**Patent Agent**	

PCT REQUEST

(Original in Electronic Form)

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10-1	**Date of actual receipt of the purported international application**	**16 July 2019 (16.07.2019)**
10-2	**Drawings:**	
10-2-1	Received	
10-2-2	Not received	
10-3	**Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application**	
10-4	**Date of timely receipt of the required corrections under PCT Article 11(2)**	
10-5	**International Searching Authority**	**ISA/CA**
10-6	**Transmittal of search copy delayed until search fee is paid**	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	**Date of receipt of the record copy by the International Bureau**	

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 January 2020 (23.01.2020)

WIPO | PCT

(10) International Publication Number
WO 2020/014779 A1

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G03B 15/03 (2006.01) *A61B 5/00* (2006.01)

(21) International Application Number:
PCT/CA2019/050981

(22) International Filing Date:
16 July 2019 (16.07.2019)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/698,799 16 July 2018 (16.07.2018) US

(71) Applicant: **SWIFT MEDICAL INC.** [CA/CA]; 1 Richmond Street West, Suite 500, Toronto, Ontario M5H 3W4 (CA).

(72) Inventors: **SAIKO, Guennadi**; 2474 Trondheim Cr, Mississauga, Ontario L5N 1P4 (CA). **MACKO, Kenneth**; 715-80 St Patrick St, Toronto, Ontario M5T 2X6 (CA). **BETLEN, Andrei**; 776 Eyer Dr, Pickering, Ontario L1W 3C2 (CA).

(74) Agent: **TORYS LLP**; 79 Wellington Street West, 30th Floor, Box 270, TD South Tower, Toronto, Ontario M5K 1N2 (CA).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(54) Title: APPARATUS FOR VISUALIZATION OF TISSUE

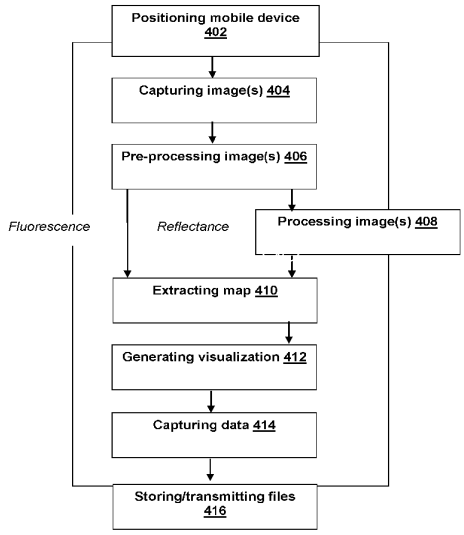

FIG. 4

(57) Abstract: A tissue imaging system comprising a computing device, tissue visualization application, image capturing unit, and an illumination unit, is configured to capture measurement data. The visualization application extracts visualizations of tissue health indicators from the measurement data. The application generates an interface with one or more interface elements corresponding to the visualization of tissue health indicators.

[Continued on next page]

WO 2020/014779 A1

Published:
— *with international search report (Art. 21(3))*
— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

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UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

July 25, 2019

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: *62/698,799*
FILING DATE: *July 16, 2018*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US62/698,799*

Certified by

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	
	Application Number	
Title of Invention	Apparatus for visualization of tissue	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Guennadi		Saiko	

Residence Information (Select One) US Residency ● Non US Residency Active US Military Service

City	Mississauga	Country of Residence [i]	CA

Mailing Address of Inventor:

Address 1	2474 Trondheim Cr
Address 2	
City	Mississauga
State/Province	ON
Postal Code	L5N1P4
Country [i]	CA

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Kenneth		Macko	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	Toronto	Country of Residence [i]	CA

Mailing Address of Inventor:

Address 1	715-80 St Patrick St,
Address 2	
City	Toronto
State/Province	ON
Postal Code	M5T2X6
Country [i]	CA

Inventor 3 Remove

Legal Name

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	
	Application Number	
Title of Invention	Apparatus for visualization of tissue	

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrei		Betlen	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	Pickering	Country of Residence [i]	CA

Mailing Address of Inventor:

Address 1	776 Eyer Dr		
Address 2			
City	Pickering	**State/Province**	ON
Postal Code	L1W3C2	**Country** [i]	CA

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☒ **An Address is being provided for the correspondence Information of this application.**

Name 1	Oxilight Inc	**Name 2**	
Address 1	1 Yonge St		
Address 2	Suite 1801		
City	Toronto	**State/Province**	ON
Country [i]	CA	**Postal Code**	M5E1W7
Phone Number		**Fax Number**	
Email Address	gsayko@yahoo.com	Add Email	Remove Email

Application Information:

Title of the Invention	Apparatus for visualization of tissue		
Attorney Docket Number		**Small Entity Status Claimed**	☒
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	10	**Suggested Figure for Publication (if any)**	

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	
	Application Number	
Title of Invention	Apparatus for visualization of tissue	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number			

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	
	Application Number	
Title of Invention	Apparatus for visualization of tissue	

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	
	Application Number	
Title of Invention	Apparatus for visualization of tissue	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	
	Application Number	
Title of Invention	Apparatus for visualization of tissue	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

Assignee	Legal Representative under 35 U.S.C. 117	● Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix
	Guennadi		Saiko	

Mailing Address Information For Applicant:

Address 1	2474 Trondheim Cr		
Address 2			
City	Mississauga	**State/Province**	ON
Country	CA	Postal Code	L5N1P4
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	
	Application Number	
Title of Invention	Apparatus for visualization of tissue	

Applicant 2 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

Assignee	Legal Representative under 35 U.S.C. 117	◉ Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix
	Kenneth		Macko	

Mailing Address Information For Applicant:

Address 1	715-80 St Patrick St		
Address 2			
City	Toronto	**State/Province**	ON
Country	CA	Postal Code	M5T2X6
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Applicant 3 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

Assignee	Legal Representative under 35 U.S.C. 117	◉ Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	
	Application Number	
Title of Invention	Apparatus for visualization of tissue	

Name of the Deceased or Legally Incapacitated Inventor:	
If the Applicant is an Organization check here.	☐

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TITLE: APPARATUS FOR VISUALIZATION OF TISSUE

FIELD

[0001] The improvements generally relate to the field of medical devices.

INTRODUCTION

[0002] People suffer from chronic and compromised wounds with debilitating pain and reduced quality of life for those whose health is already compromised. Patients with this condition often present to a doctor at late stages of the disease, which leads to many amputations, which may be avoidable. Moreover, proper diagnostics requires specialized vascular labs, which precludes these types of tests from being performed outside major hospitals and in an expedited fashion.

[0003] The wound is considered chronic if it is not healed within four weeks. The tissue health and wound healing process can be compromised by various factors, including insufficient blood supply, edema, and the presence of bacteria. These factors (oxygenation/perfusion, subepidermal moisture, and bacteria presence) among others will be referred to as tissue health indicators.

[0004] Multispectral (hyperspectral) imaging is a promising non-invasive optical modality for early detection of problematic wounds.

[0005] Visualization of skin distribution of oxyhemoglobin and deoxyhemoglobin can give insight into perfusion and oxygenation of the tissue. It can be used for assessment of tissue health (for example, ischemia).

[0006] Such as elevated levels of subepidermal moisture are typical for pressure injuries, visualization of water distribution in tissue can be used for early (pre-ulcer) diagnostics of pressure injuries.

[0007] Fluorescence imaging is a promising non-invasive optical modality for detection of bacterial burden. Visualization of bacterial burden can be used to assess bacterial burden and guide swabbing and cleansing.

SUMMARY

[0008] In accordance with an aspect, there is provided a process for generating visualizations of tissue. The process captures measurement data by a user device (e.g., smartphone), and processes the measurement data using the visualization application. The process extracts indications of tissue health from the processed measurement data, and stores or transmits the underlying data. The process generates interface elements corresponding to the visualization tissue health indicators.

[0009] In some embodiments, the process involves calibrating the visualization application using a reference object;

[0010] In some embodiments, a small self-reference can be used to position the device properly

[0011] In some embodiments, a small self-reference can be used to calibrate the measurement data based on an intensity of illumination.

[0012] In some embodiments, an illumination unit independent of the mobile device can be used for calibration and capture measurements together with a camera, laptop, or tablet.

[0013] In accordance with an aspect, there is provided a tissue imaging system comprised of a user device with a visualization application, an image capturing unit, and an illumination unit. The illumination unit is configured to illuminate the target area; the image capturing unit captures measurement data, the visualization application extracts visualizations of tissue health indicators from the measurement data and generates an interface with one or more interface elements corresponding to the visualization of tissue health indicators.

[0014] In accordance with an aspect, there is provided a tissue visualization system connected to a tissue imaging system (user device with a visualization application, an image capturing unit, and an illumination unit). The illumination unit illuminates the target area; the image capturing unit captures measurement data. The visualization application extracts visualization of tissue health indicators from the measurement data and transmits the visualization of tissue health indicators or underlying data to the tissue visualization system. The tissue visualization system processes and stores the visualization of tissue health indicators or underlying data, and displays them on user devices.

[0015] Many further features and combinations thereof concerning embodiments described herein will appear to those skilled in the art following a reading of the instant disclosure.

DESCRIPTION OF THE FIGURES

[0016] Embodiments will now be described, by way of example only, with reference to the attached figures, wherein in the figures:

[0017] Fig. 1 is a view of an example of the overall system architecture with various configurations of tissue imaging systems according to some embodiments;

[0018] Fig. 2 is a view of an example of a tissue visualization system according to some embodiments;

[0019] Fig. 3 is a view of an example of the illumination unit and a mobile device according to some embodiments;

[0020] Fig. 4 is a flowchart of an example method for capturing measurements and visualizing tissue according to some embodiments;

[0021] Fig. 5 is a view of an example interface for visualizing tissue according to some embodiments;

[0022] Fig. 6 is a diagram of an example architecture of a mobile device according to some embodiments;

[0023] Fig. 7 is an example of illumination and image capturing scheme according to some embodiments;

[0024] Fig. 8 is a view of example illumination units according to some embodiments.

[0025] Fig. 9 is an example of the workflow used to take reference images; and

[0026] Fig. 10 is a view of a schematic of imaging tissue and self-reference objects.

DETAILED DESCRIPTION

[0027] Some clinical-grade tools can only be used in specialized medical establishments. They can be large, require special training, and are mostly suitable for the use in inpatient settings only. For example, they cannot be easily carried to a patient's home or remote communities. Thus, these solutions cannot be used as early diagnostic tools as a patient would have to be referred to a hospital having one of these tools.

[0028] Many people suffer from diabetes. Diabetic foot ulcers (DFU) and the resulting lower extremity amputations are a frequent, disabling and costly complication of diabetes. Many diabetics can develop a foot ulcer. DFU is a cause of non-traumatic below knee amputation. In addition to the reduced quality of life, amputees might not survive for that long after amputation. Consequently, early detection of DFU can lead to better outcomes, thus saving limbs and lives.

[0029] Peripheral vascular disease (PVD) affects arteries (peripheral arterial disease, PAD) and veins (chronic venous insufficiency, CVI). PAD is of particular importance, such as it affects about eight million Americans and is responsible for 10% of all leg ulcers.

[0030] Pressure ulcers (PU) or pressure injuries represent a serious health problem to patients impacting up to 25-50% of patients across acute and long-term care settings.

[0031] The cost of treatment of diabetic foot ulcer, pressure ulcer, and leg ulcer is high. Diagnosing these conditions at an earlier stage (e.g., before actual ulceration) might be able to save significant money for healthcare systems and patients.

[0032] Other clinical indications associated with abnormal blood perfusion and/or oxygenation, such as skin cancer (angiogenesis), port-wine stains, and skin disorders, can benefit from a system for tissue imaging.

[0033] Subepidermal moisture, a measure of localized edema, is associated with erythema, Stage I and II PUs [Bates-Jensen 2007, Bates-Jensen 2008, Guihan 2012, Ching 2011], and can (ii) differentiate between healthy skin and skin with pressure-induced tissue damage [Harrow 2014] and (iii) serve as a predictor of imminent ulceration (PUs, sDTIs) in various populations [Bates-Jensen 2007, Bates-Jensen 2008, Bates-Jensen 2009]. Thus, changes in measures of subepidermal moisture could be utilized for both prevention and detection of PUs. Radiofrequency impedance measurement with spatially separated electrodes is a current standard way to measure skin moisture including subepidermal moisture. However, it is a contact single-point measurement technique, which may suffer from operator inconsistency.

[0034] NIR reflectance can be used to determine water content in the skin. Water spectrum dominating NIR spectra with overtone bands of the O-H bonds with peak absorption at 760 nm, 970 nm (due to the second overtone of the O-H stretching band), 1190nm (the combination of the first overtone of the O-H stretching and the O-H bending

band), 1450 nm first overtone of the OH-stretching band and a combination band), and 1940 nm (combination of the O-H stretching band and the O-H bending band) [Luck 1974]

[0035] Water absorption at 1440nm is 30 times stronger than at 1190nm, which in turn more than two times stronger than absorption at 970nm. Thus, 1440nm and 1920nm wavelengths are suitable for imaging of water content in uppermost skin layers (stratum corneum), while 970nm and 1190nm can be used for water content determination and imaging in deeper skin layers, including epidermis, dermis (1190nm) and even subcutaneous tissues (970nm).

[0036] Bacteria presence can significantly impact tissue health and wound healing progress. Bacteria are always present in the wound. There are several distinct levels of bacterial burden in the wound: contamination, colonization, and infection.

[0037] Wound contamination is the presence of non-replicating organisms in the wound. All chronic wounds are contaminated. These contaminants come from the indigenous microflora and/or the environment.

[0038] Wound colonization: the presence of replicating microorganisms adherent to the wound in the absence of injury to the host. Most of these organisms are normal skin flora: *Staphylococcus epidermidis, an*other coagulase negative Staph., *Corynebacterium* sp., *Brevibacterium* sp., *Proprionibacterium acnes*, *Pityrosporum* sp..

[0039] Wound Infection: the presence of replicating microorganisms within a wound that cause host injury. Primarily pathogens are of concern here: *Staphylococcus aureus,* Beta-hemolytic *Streptococcus (S. pyogenes, S. agalactiae), E. coli, Proteus, Klebsiella,* anaerobes, *Pseudomonas, Acinetobacter, Stenotrophomonas (Xanthomonas).*

[0040] Contamination and colonization by low concentrations of microbes are considered normal and are not believed to inhibit healing. However, critical colonization and infection are associated with a significant delay in wound healing.

[0041] Clinical test for bacterial presence include swabs from the tissue. In addition to long processing time (several days) these tests suffer from possible contamination during swabbing and randomness in the selection of swabbing sites. Thus, current clinical diagnostics techniques are sub-optimal.

[0042] Portable fluorescence imaging can be used for visualization of bacterial presence. It was found that while excited at 405nm, *S. aureus*, *S. epidermidis*, *Candida*, *S. marcescens, Viridans streptococci, Corynebacterium diphtheriae, S. pyogenes,*

Enterobacter, and *Enterococcus* produced red (610-640nm) fluorescence from porphyrin [Kjeldstad 1985] while *P. aeruginosa* produced a bluish-green (490-550nm) fluorescence from pyoverdin [Cody 1987]. Thus, fluorescence imaging can be used to assess bacterial burden and guide swabbing and wound cleansing.

[0043] Thus, multispectral/hyperspectral-based reflectance imaging, fluorescence imaging or their combination can provide valuable insights on tissue health and wound healing potential.

[0044] Embodiments described herein can provide a tool for tissue imaging.

[0045] Fig. 1 is a view of an example tissue visualization system 100 that connects to a tissue imaging system 105.

[0046] Tissue imaging system 105 is a device for visualization of abnormalities of blood circulation, moisture distribution, and bacterial burden in surface tissues (skin or mucosa). For example, the device can be used for identification of ischemic or angiogenic conditions. It can be used by primary care physicians, nurses, or even patients themselves in any type of settings: inpatient, outpatient, long-term facilities, patient's home, and so on, thus allowing earlier identification of problematic wounds. Tissue imaging system 105 contains a mobile device 108, tissue visualization app 112, image capturing unit 103, and the illumination unit 104.

[0047] A mobile device 108 can be an off-the-shell computing device (a mobile device, smartphone, tablet, laptop, a personal computer) or a custom-built computing device. In a preferred embodiment, the mobile device 108 is a smartphone.

[0048] Tissue visualization app 112 is installed and run on mobile device 108. Tissue visualization app 112 coordinates image capturing unit 103 and illumination unit 104 during data capturing, process images, display results on a mobile device 108 and transmit data to tissue visualization system 100.

[0049] Image capturing unit 103 is an internal (built-in mobile device 108) or external device capable of capturing images. In a preferred embodiment, it is a 3 channel (RGB) or 4 channel (RGB-NIR) camera.

[0050] The illumination unit 104 is an internal (built-in the mobile device 108) or external device (multispectral flash) capable of illuminating a target area with required intensity, wavelengths, and duration.

[0051] Typical tissue imaging system 105 architectures are presented on Fig.1: In some embodiments, the tissue imaging system 105 can be a single device. In some embodiments, the tissue imaging system 105 can have two separate parts (e.g., image capturing unit 103 built-in mobile device 108 and separate illumination unit 104 or illumination unit 104 built-in mobile device 108 and separate image capturing unit 103). In some embodiments, the tissue imaging system 105 can have three separate parts (a mobile device 108, an image capturing unit 103, and a separate illumination unit 104)

[0052] In a preferred embodiment, the illumination unit 104 can be a device attached (e.g., clip-on or by compression clip) to a mobile device 108, such as a smartphone.

[0053] In some embodiments, the illumination unit 104 can be connected or synchronized with the tissue visualization application 112 (installed or accessible by mobile device 108) for example by Bluetooth, optic or optoelectric couping, or wired connection. In some embodiments, the illumination unit 104 can be triggered manually, and the visualization application 112 recognizes the light sequence and synchronizes image capturing.

[0054] In some embodiments, the image capturing unit 103 can connect to the tissue visualization application 112 (installed or accessible by mobile device 108) for example by Bluetooth, optoelectric couping, or wired connection.

[0055] The tissue visualization application 112 can, in turn, be connected to tissue visualization system 100 (e.g., backend server). The tissue visualization system 100 can collect data from tissue visualization applications 112. The tissue visualization system 100 can transmit the data (or transformations and aggregations of the data) to user device 102 (e.g., computer, laptop, tablet, or smartphone) which can be operated by a physician or other user. Thus, a qualified specialist may review the data collected in a different location by a frontline health practitioner (e.g., nurse) or patient. This may facilitate early diagnostic by the physician.

[0056] The tissue imaging system 105 can capture measurement data as images of a patient's tissue. The visualization application 112 can extract visualizations of tissue health indicators from the measurement data. The visualization application 112 can generate one or more interface elements corresponding to the visualization of tissue health indicators. The interface elements populate an interface for display on the mobile device 108.

[0057] In some embodiments, the mobile device 108 can connect to a tissue visualization system 100 to transmit the measurement data and the visualization of tissue health

indicators, for example. The tissue visualization system 100 can aggregate the measurement data and the visualization of tissue health indicators from multiple tissue imaging systems 105. The tissue visualization system 100 can process and store the measurement data and the visualization of tissue health indicators.

[0058] In some embodiments, the tissue imaging system 105 can connect to a user device 102. The mobile device 108 with tissue visualization app 112 can aggregate the measurement data and generate the visualization of tissue health indicators from multiple tissue imaging system 105 for transmission to tissue visualization system 100. The tissue visualization system 100 can aggregate the measurement data and the visualization of tissue health indicators from multiple tissue imaging systems 105.

[0059] The tissue visualization system 100 receives imaging data from the tissue imaging system 105 to generate a visualization of tissue and detect wounds and abnormalities. The tissue visualization system 100 and tissue imaging system 105 connects to other components in various ways including directly coupled and indirectly coupled via the network. Network 110 (or multiple networks) is capable of carrying data and can involve wired connections, wireless connections, or a combination thereof. Network 110 may involve different network communication technologies, standards, and protocols.

[0060] Fig. 2 is a view of an example tissue visualization system according to some embodiments.

[0061] Tissue visualization system 100 receives imaging data from the tissue imaging system 105 via data I/O unit 218. Data I/O unit 218 facilitates transmission of data to data processing unit 220. Data processing unit 220 processes data received from the data I/O unit 218 or one or more databases 224. For example, data processing unit 220 can apply one or more algorithms or extract data that may be used for, or that may facilitate the visualization or processing related to detection of problematic wounds or abnormalities of blood circulation, for example, in surface tissues. Data processing unit 220 can extract, create, and/or aggregate from that data a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacteria presence, and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues.

[0062] Data processing unit 220 can receive via data I/O unit 218 instructions for computation from one or more external systems 106, user device 102, tissue imaging

system 105, and/or tissue visualization app 112. The instructions for computation can be used by data processing unit 220 to facilitate the extraction, creation, and/or aggregation of data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues. In some embodiments, data processing unit 220 can process imaging data to prepare the data for presentation via the interface unit 222 in an appropriate form or to prepare the data for transmission to an external system 106, user device 102, and/or tissue imaging system 105 to be presented in an appropriate form.

[0063] Data processing unit 220 can receive data or processed data from aggregation unit 226 and may extract, create, and/or aggregate from that data, data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues. The map, visualization, or other indication that can be extracted, created, and/or aggregated by data processing unit 220 can reflect imaging data or measurements corresponding to a plurality of patients. The data processed by data processing unit 220 may be imaging data collected at one or more tissue imaging systems 105 and/or one or more user devices 102. The data processed by data processing unit 220 may be measurement data reflecting one or more images of a patient's tissue.

[0064] Aggregation unit 226 can receive via data I/O unit 218 and/or one or more databases 224 imaging data corresponding to a plurality of patients, tissue imaging systems 105, or user devices 102. Aggregation unit 226 can aggregate or modify the data by applying instructions for computation. Aggregation unit 226 can cause the aggregated or modified data to be transmitted to data processing unit 220 where the data can be processed to prepare the data for presentation via interface unit 222 in an appropriate form or to prepare the data for transmission to an external system 106, user device 102, and/or tissue imaging system 105 to be presented in an appropriate form.

[0065] Aggregation unit 226 can receive processed data from data processing unit 220 corresponding to a plurality of patients, tissue imaging system 105, or user devices 102. Aggregation unit 226 can aggregate or modify the processed data by applying the instructions for computation. Aggregation unit 226 can cause the aggregated or modified data to be transmitted to data processing unit 220 where the data can be further processed

to prepare the data for presentation via interface unit 222 in an appropriate form or to prepare the data for transmission to an external system 106, user device 102, and/or tissue imaging system 105 to be presented in an appropriate form.

[0066] Aggregation unit 226 can receive via data I/O unit 218 and instructions for computation from one or more external systems 106, user device 102, tissue imaging system 105, and/or tissue visualization app 112. The instructions for computation can be used by aggregation unit 226 to facilitate aggregation of imaging data corresponding to a plurality of patients.

[0067] Tissue visualization system 100 can receive imaging data, for example, aggregate imaging data, from mobile device 108 via data I/O unit 218. Tissue visualization system 100 can receive imaging data, for example, aggregate imaging data, from external systems 102 via data I/O unit 218. Tissue visualization system 100 can receive computer instructions for processing or computation from external systems 106. External systems 106 can store, cause to be stored, and/or receive data from one or more external databases 216.

[0068] Aggregation unit 226 can receive via data I/O unit 218 the instructions for computation from one or more external systems 106, user device 102, tissue imaging system 105, and/or tissue visualization application 112.

[0069] Tissue visualization system 100 can be associated with one or more databases or data storages 224, for example, one or more local databases. The one or more databases 224 can store or processed data received or transmitted by data I/O unit 218, data processing unit 220, and/or aggregation unit 226. The data stored in the one or more databases 224 can be accessed by various units including these. For example, data I/O unit 218 may cause database 224 to store data received via network 110 and/or from user device 102, external systems 106, tissue imaging system 105, and/or tissue visualization app 112. Data processing unit 220 and aggregation unit 226 can cause data to be retrieved from database 224, for example, before processing or aggregating the data.

[0070] Data processing unit 220 can cause data to be stored in database or data storage 224 after it processes the data by applying instructions or extracting data that may be used for or facilitate the visualization or processing related to detection of problematic wounds or abnormalities of blood circulation in surface tissues. Data processing unit 220 can retrieve the processed data from database or data storage 224 and cause the processed data to be

transmitted to the interface unit 222 or network 110, for example, for presentation to a patient or physician.

[0071] Data processing unit 220 can cause data to be stored in database or data storage 224 after it extracts, creates, and/or aggregates data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues.

[0072] Data processing unit 220 can use Machine Learning (including supervised ML and unsupervised ML) to extract information from collected images and other data. In particular, data processing unit 220 can build and train models, which can discriminate between various conditions and provide users with additional information. In some embodiments data processing unit 220 uses convolutional neural networks for automatic or semi-automatic detection and/or classification of the skin or wound conditions. In some embodiments, ML models built and trained using other tools and deployed to data processing unit 220 for image/data detection/classification.

[0073] Aggregation unit 226 can cause data to be stored in database 224 after it aggregates imaging data or processed data that corresponds to a plurality of patients and/or user devices 102. Aggregation unit 226 can retrieve the aggregated data from one or more databases 224 and cause the aggregated data to be transmitted to the interface unit 222 or network 110, for example, for presentation to a patient or physician.

[0074] Tissue visualization system 100 can cause data to be displayed on interface unit 222, for example, aggregated and/or processed data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health in surface tissues. Patients and physicians can engage with an interface unit to view or analyze the indicia.

[0075] Tissue visualization system 100 can cause data, for example, aggregated data, processed data, imaging data, and/or data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health in surface tissues, to be transmitted to one or more external systems 106.

[0076] For example, tissue visualization system 100 can receive imaging data from a plurality of tissue imaging systems 105, process and/or aggregate the data using data processing unit 220 and/or aggregation unit 226, and cause the data to be routed, via one or more networks 110, to a proper physician (e.g., family doctor) for evaluation. The physician may be engaged with a user device 102, an external system 106, or a tissue imaging system 105.

[0077] A user device 102 may receive, process, and/or aggregate data from a multiplicity of tissue imaging system 105 and/or corresponding to a multiplicity of patients or tissue measurements. User device 102 may receive instructions for computation from one or more external systems 106 or tissue imaging system 105.

[0078] Tissue visualization system 100 can connect to various components, including user device 102, tissue imaging system 105, external systems 106, external database 216, in various ways including directly coupled and indirectly coupled via network 110 (or multiple networks). Each of these components can connect to each other in various ways including directly coupled and indirectly coupled via network 110 (or multiple networks).

[0079] Fig. 3 is a view of an example of tissue imaging system 105 comprised of the illumination unit 104 and mobile device 108 with the internal image capturing unit 103 and installed app 112 according to some embodiments.

[0080] A tissue imaging system 105 is associated with an image capture unit 103. The image capture unit 103 can be a smartphone camera (front or back), for example.

[0081] A mobile device 108 is associated with a display interface 318. The display interface 318 can be a screen or viewfinder, for example. In some embodiments, a mobile device 108 is associated with an app I/O unit 322 that may facilitate data transmission between an illumination unit 104 and the mobile device 108.

[0082] An illumination unit 104 is associated with a mobile device 108, for example, through a physical connector 302 that attaches the illumination unit 104 to the mobile device 108. An illumination unit 104, which acts as an external flash is associated with a lighting unit 300, which may include multiple light sources 300. The light units 300 may be arranged in a circle on illumination unit 104, for example. In the preferred embodiment, light units 300 are arranged in the circle around the central aperture.

[0083] In some embodiments, an I/O unit 304 associated with the illumination unit 104 may facilitate data transmission between the illumination unit 104 and the mobile device 108.

For example, I/O unit 304 may send and receive data from an app I/O unit 322. I/O unit 304 and app I/O unit 322 may implement connectivity via Bluetooth, a cable (e.g., USB, lightning, audio jack), WiFi, near-field communication, optic or optoelectronic coupling, or other means. This communication can facilitate synchronization of the lighting unit 300 and the data capture by image capture unit 103, for example, in accordance with an illumination schema that can account for various types of external illumination.

[0084] A controller 301 causes light sources to flash in a predetermined fashion. The controller 301 can receive commands from I/O unit 304 or be triggered manually (e.g., using a button). The controller 301 can be based on any type of general-purpose microprocessor or microcontroller, a digital signal processing (DSP) processor, an integrated circuit, a central processing unit (CPU), a graphics processing unit (GPU), a field programmable gate array (FPGA), a reconfigurable processor, a programmable read-only memory (PROM), or any combination thereof). In the preferred embodiment, the controller 301 is based on a microcontroller.

[0085] In some embodiments, the lens 307 covering the light sources 300 can be used to homogenize the light distribution on the target area. In the preferred embodiment, the Fresnel lens is used. The focal length of the lens can be chosen in the range 80-120% of the working distance between the illumination unit 104 and the target area. In the preferred embodiment, the focal length of the lens is equal to the working distance.

[0086] For bacterial burden measurements, the emission filter 305 covering the image capturing unit 103 (e.g., the camera of a smartphone) is used to block the excitation illumination at 405±10nm. In the preferred embodiment, the emission filter is attached to the illumination unit 104. In some embodiments, the emission filter 305 is a long pass filter with cut-on wavelength 450±25nm. In some embodiments, the emission filter is a band pass filter with the transmission in the 425-750nm range, which has the lower cut-on wavelength in the 450±25nm range.

[0087] A mobile device 108 supports a tissue visualization application 112. A mobile device 108 may run on any operating system such as iOS, Android, or Windows. The tissue visualization app 112 can help position the smartphone at a proper distance to a target area; can synchronize flashes from an illumination unit 104 with the image capturing unit 103; can cause or coordinate the capture of a set of images; can cause or facilitate local processing of the images or of data captured; can cause capturing target area info (e.g., location, laterality,

description, wound size, tissue type, patient ID, etc); can cause or facilitate the extract, creation, and/or aggregation of data providing a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health in surface tissues; can cause or facilitate storing data on mobile device 108; and can cause or facilitate data to be transmitted over one or more networks 110.

[0088] The tissue visualization app 112 includes a positioning unit 324, pre-processing unit 326, calibration unit 328, and app processing unit 330.

[0089] Positioning unit 324 can cause or facilitate the positioning of the image capture unit 103 in relation to an area of patient tissue targeted for measurement.

[0090] For example, in some embodiments, positioning unit 324 can use a reference object (e.g., a white circle, square, rectangle, or another shape, colour, or object) on the target area, where the reference object and target area can be imaged through a viewfinder or screen associated with the mobile device 108. In some embodiments, the positioning unit 324 can recognize the reference object and cause an overlay to be presented on the display interface 318.

[0091] In some embodiments, the overlay can be marks, lines, arrows, shapes, and/or other attributes that can be used by a person engaged with the display interface 318 to move the mobile device 108, for example, forwards and/or backward to create appropriate positioning of the image capture unit 103. The tissue visualization app 112 can adjust the presentation of the overlay on the display interface 318 in relation to the presentation of the reference object or tissue on the display interface 318. This may help guide the person's movement of the image capture unit 103 or mobile device 108 to achieve proper positioning of the image capture unit 103 or mobile device 108 in relation to the area of patient tissue targeted for measurement.

[0092] In some embodiments, the overlay presented on the display interface 318 can be of a predetermined size and presented at predetermined locations on the display interface 318.

[0093] In some embodiments, positioning unit 324 can use the size of the reference object to trigger automatic data capturing when the mobile device 108 or image capturing unit 103 is on a certain distance from the target area.

[0094] In some embodiments, positioning unit 324 can guide a user to move the mobile device 108, for example, forwards and/or backward to create appropriate positioning of the image capture unit 103, by graphical, text or voice commands

[0095] In some embodiments, reference objects may be used to facilitate calculation of a distance from a wound and/or to rescale images or measurement data.

[0096] In some embodiments, image capture unit 103 may be positioned at a proper distance from a target area, for example, a wound, by other means such as using a rangefinder or ruler.

[0097] The tissue visualization app 112 may help control the illumination of the patient tissue targeted for measurement and/or the illumination of one or more images captured by image capture unit 103 to help ensure the illumination is stable and/or predictable. The intensity of illumination may depend on the distance of the image capture unit 103 to the target area and the stability of LED intensity, which may degrade with time or within a battery cycle. This control may be facilitated by pre-processing unit 326. For example, the tissue visualization app 112 may use a self-reference object (e.g., white or gray circle) that is placed within a target area to find the proper position or find the distance of the mobile device 108 or image capture unit 103 from the target area. The pre-processing unit 326 can use the self-reference object to measure the intensity of each channel in each flash and recalibrate each measurement accordingly. A single measurement can include multiple flashes and channels.

[0098] In some embodiments, the pre-processing unit 326 can compare the intensity of a self- reference object in the target image with the intensity of the same region in the reference image and uses the ratio between the two to scale the intensity of the target image pixel-by-pixel.

[0099] For reflectance images, app processing unit 330 can process image data captured by image capture unit 103 and pre-processed by unit 326. For example, the user or app processing unit 330 can compare one or more images or patient measurements of a suspicious area to one or more images or patient measurements of a non-affected area.

[00100] An observation may consist of one or more measurements on a patient. The one or more images or patient measurements of a non-affected area (control sites) can be used to establish a baseline for a particular patient. Ideally, one can select a control site as a spot with intact skin symmetrical to the suspicious area. However, if it is not possible (e.g., limb

amputation or widespread ulcers), then other locations (e.g., antecubital fossa) can be used as a control site. In the case of a single measurement (e.g., suspicious area only), the suspicious area readings can be compared with an area on the same image distant from the suspicious area.

[00101] In some embodiments, tissue visualization app 112 can compare an image of a suspicious area to one or more images of control sites. The tissue visualization app 112 can process an image and can also operate in video mode to the process of series of images or video frames.

[00102] App processing unit 330 can use the data captured by image capture unit 103 to facilitate the extraction, creation, and/or aggregation of data providing a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacteria presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues.

[00103] The outcome of the system can be a false color or grayscale 2D maps of tissue health indicators. These maps can be presented via the display interface 318 and/or transmitted over one or more networks 110, for example, to a tissue visualization system 100 or a user device 102. For example, levels of oxygenation and perfusion can highlight areas with abnormal blood supply, namely ischemic (significantly reduced perfusion and oxygenation) and angiogenic (increased perfusion) areas. A trained physician will be able to interpret these 2D maps to assess the significance of findings and decide on next steps, for example, requesting further studies, monitoring the progress, or dismissing.

[00104] App processing unit 330 can cause the processed data to be presented via display interface 318 and/or transmitted over a network 110.

[00105] In some embodiments, app processing unit 330 can cause transmission over a network 110 preprocessed images (after step 406)

[00106] In some embodiments app processing unit 330 can use Machine Learning (including supervised ML and unsupervised ML) to extract information from collected images and other data. In particular, app processing unit 330 can build and train models, which can discriminate between various conditions and provide users with additional information. In some embodiments, the app processing unit 330 uses convolutional neural networks for automatic or semi-automatic detection and/or classification of the skin or wound conditions. In some embodiments, ML models can be built and trained using other tools (e.g., the data

processing unit 220) and deployed to app processing unit 330 for image/data detection/classification.

[00107] Fig. 4 is a flowchart of an example method for capturing measurements and visualizing tissue according to some embodiments.

[00108] At 402, a mobile device 108 is positioned at a proper distance (working distance) in relation to an area of tissue (e.g., using a positioning unit 324). In some embodiments, the mobile device 108 or image capturing unit 103 is positioned 10-30cm from the tissue. In the preferred embodiment, the image capturing unit 103 is positioned 15cm from the tissue.

[00109] At 404, image capture unit 103 in conjunction with illumination unit 104 captures a measurement of tissue according to an illumination schema.

[00110] At 406, in some embodiments, pre-processing unit 326 preprocesses the measurement data by a) registering (aligning) images to avoid camera motion artifacts, b) subtracting image with no illumination from images with illumination, c) recalibrating each measurement accordingly in order to control parameters related to the intensity of illumination, d) dividing the intensity images on reference images to obtain normalized images. In other embodiment, the frequency domain processing (e.g. fast Fourier transformation) has been used.

[00111] In some embodiments, registration (alignment) of images can be done using phase correlation or block matching algorithms (e.g., using a self-reference object)

[00112] In some embodiments, recalibration can be done by pre-processing unit 326 using a self-reference object to measure the intensity of each channel in each flash

[00113] In some embodiments, any or all steps after the step 406 can be skipped.

[00114] In some embodiments, app processing unit 330 can send to the network 110 data after the step 406. In this case data processing unit 220 will extract and visualize tissue health indicators.

[00115] At 408, app processing unit 330 extracts concentrations of tissue chromophores. In some embodiments, it extracts indications of oxyhemoglobin and deoxyhemoglobin. In some embodiments, in addition to oxy- and deoxyhemoglobin it extracts the indication of melanin. In some embodiments app processing unit additionally extracts water content.

[00116] In some embodiments, the least square fitting (with or without regularization) can be used to extract the concentration of each chromophore

[00117] At 410, app processing unit 330 extracts indicia that allows the tissue health indicators of the imaged tissue to be presented. For example, the indicia may allow the oxygenation and/or perfusion to be presented as a map.

[00118] In some embodiments, app processing unit 330 can send to the network 110 data from the step 408. In this case data processing unit 220 will visualize tissue health indicators.

[00119] At 412 tissue visualization app 112 generates a visualization of the tissue health indicators of the imaged tissue and causes same to be presented via the display interface 318.

[00120] At 414 the tissue visualization app 112 collects data related to the image (e.g., patient ID, laterality, location, diagnosis, comments, measurements) using user interface. In some embodiments, the graphical user interface is used. In some embodiments, the speech-recognition system is used to collect data.

[00121] At 416, tissue visualization app 112 causes a results file of the data or indicia to be stored and/or transmitted, for example, over a network 110 to a user device 102, tissue visualization system 100, and/or external systems 106.

[00122] Fig. 5 is a view of an example interface for visualizing tissue according to some embodiments.

[00123] In some embodiments, the color bar 502 can be implemented to guide the user

[00124] In some embodiments, the averaging tool (which averages tissue health index within the small area) 504 can be implemented to assist the user. In some embodiments, the averaging tool 504 can be a small circle on a touchscreen.

[00125] Fig. 6 is a schematic diagram of mobile device 108, an exemplary embodiment. As depicted, mobile device 108 includes at least one processor 602, memory 604, at least one I/O interface 606, and at least one network interface 608.

[00126] Each processor 602 may be, for example, any type of general-purpose microprocessor or microcontroller, a digital signal processing (DSP) processor, an integrated circuit, a central processing unit (CPU), a graphics processing unit (GPU), a field programmable gate array (FPGA), a reconfigurable processor, a programmable read-only memory (PROM), or any combination thereof.

[00127] Memory 604 may include a suitable combination of any type of computer memory that is located either internally or externally such as, for example, random-access memory

(RAM), read-only memory (ROM), compact disc read-only memory (CDROM), electro-optical memory, magneto-optical memory, erasable programmable read-only memory (EPROM), and electrically-erasable programmable read-only memory (EEPROM), Ferroelectric RAM (FRAM) or the like.

[00128] Each I/O interface 606 enables mobile device 108 to interconnect with one or more input devices, such as a keyboard, mouse, camera, touch screen and a microphone, or with one or more output devices such as a display screen and a speaker.

[00129] Each network interface 608 enables mobile device 108 to communicate with other components, to exchange data with other components, to access and connect to network resources, to serve applications, and perform other computing applications by connecting to a network (or multiple networks) capable of carrying data.

[00130] Mobile device 108 is operable to register and authenticate users (using a login, unique identifier, and password for example) prior to providing access to applications, a local network, network resources, other networks and network security devices. Computing devices 102 may serve one user or multiple users.

[00131] Fig. 7 is an example of illumination and image capturing scheme according to some embodiments. Other illumination and image capturing schemas can be used. In order to account for external illumination, the image capturing/illumination schema in Fig.7 has been developed.

[00132] Fig. 7 plots the flash 702 coordinated by illumination unit 104, as a function of time. The device uses the synchronization of flash if the illumination unit 104 is used to provide the external flash. As shown at 702, the illumination schema (cycle) consists of m flashes and one period without flash, with $n/4 \leq m \leq n$, where n is the number of channels. Cycles can be repeated continuously for a video mode capturing.

[00133] The exposure time for each frame (in milliseconds) can be selected as $T=k/2*f$, where k is an integer, f is the utility frequency for a particular country in Hz (e.g., 60Hz for North America, 50Hz for Europe). In a video mode, the framerate can be selected as $fps=2*f/k$ (e.g., 30, 24, 20, 15, 12, and 10 fps for North America and 25, 20, and 10 fps for Europe. The frame rate of 20fps (T=50ms) can be an example of selection. It can work without any configurations with external light sources connected to any grid (50Hz or 60Hz). Other frame rates can also be used.

[00134] The duration of each flash can be T or 2T. Thus, the cycle consists of m back to back flashes with duration T or 2T milliseconds each, followed by no lit period T or 2T milliseconds long (702).

[00135] In some embodiments, mobile device 108 associated with an illumination unit 104 may use the same frame to capture an image illuminated at 2, 3, or 4 wavelengths (channels), which can be captured by different color channels of an RGB camera (e.g. 480 and 660nm, which will be captured by blue and red channels, respectively) or RGB-NIR camera.

[00136] Fig. 8 is a view of example illumination units according to some embodiments.

[00137] An illumination unit 104 can be an external flash that can be attached to a smartphone. In some embodiments, it can be synchronized with a tissue visualization app 112 or mobile device 108 using Bluetooth or other connectivity. In some embodiments, the illumination unit 104 can be built into a case for a mobile device 108. In some embodiments, the illumination unit 104 receives power from the mobile device 108 or an external source (e.g., wall charger).

[00138] In some embodiments, illumination unit 104 has its battery. The illumination unit 104 can be chargeable using a standard micro USB port, wirelessly or by way of inductive charging.

[00139] The illumination unit 104 can be used with front- or back camera of a mobile device 108. Illumination unit view 806 illustrates an illumination unit 104 used in conjunction with a front-facing camera of a user device 108.

[00140] In some embodiments, the illumination unit 104 can be optimally designed to associate with a mobile device 108 by way of a clip or other means 302 that can be attached to the mobile device 108, with the thickness up to 15mm, as shown in views 802 and 804.

[00141] In the preferred embodiment, the illumination unit 104 uses a compression clip that can be attached to the mobile device 108, with the thickness up to 15mm, as shown in view 802. In some embodiments, the illumination unit 104 can be mounted using a spring clip, as shown in views 804 and 806.

[00142] The illumination unit 104 can produce a sequence of flashes of predetermined length. A channel can refer to light sources shining at the same wavelength, with the possibility of multiple channels shining in a single flash. Each of flashes may shine at 1-4 particular wavelengths (channels).

[00143] The illumination unit 104 can use narrow band high-efficiency light sources 300 such as LEDs. The light source in the illumination unit 104 may contain single wavelength or multi-wavelengths LEDs.

[00144] As shown in view 802, the light sources 300 can be preferably arranged in a circle, with a center close to the center of a camera 103 of mobile device 108.

[00145] In some embodiments, each channel can consist of two or four light sources 300, arranged in a symmetrical pattern on an illumination unit 104 (e.g., every 180 or 90 degrees on a circle).

[00146] For oxygenation measurements, the illumination unit 104 can use two or more channels in the range of 450-750nm. For measurements of oxygenation and perfusion and the compensation of skin color (melanin), the illumination unit 104 can use three or more channels in the range of 450-750nm. In the preferred embodiment 450-650nm range is used.

[00147] Wavelengths can be selected from one or more of the following regions: a) biggest discrimination in light absorption between oxy- and deoxyhemoglobin: 450-500nm and 600-750nm, b) isobestic points (e.g., 510±10nm, 525±10nm, and 590±10nm), c) largest absorption by oxy- and deoxyhemoglobin: 540-580nm.

[00148] For water content measurement in addition to two or more channels in 450-750nm (or preferably 450-650nm) range a channel with a central wavelength 970±10nm is used

[00149] For bacterial burden measurements, a channel with a center wavelength 405±10nm is used. In some embodiments, it can be combined with two or more channels in 450-750nm (or preferably 450-650nm) range, which capture reflectance images

[00150] For bacterial burden measurements, the illumination unit 104 or image capture unit 103 contains the emission filter 305. In the preferred embodiment, the emission filter is attached to the illumination unit 104. In some embodiments, the emission filter 305 is a long pass filter with cut-on wavelength 450±25nm. In some embodiments, the emission filter is a band pass filter with the transmission in the 425-750nm range, which has the lower cut-on wavelength in the 450±25nm range.

[00151] The illumination unit 104 can be synchronized with an image capture unit 103 of mobile device 108 to produce an illumination schema. The illumination unit 104 associated with an image capture unit 103 can follow an illumination schema where each channel

shines sequentially (n=m, where n is the number of channels, m is the number of flashes in one measurement).

[00152] In various embodiments, lighting unit 300 configured to engage with a mobile device 108 or image capture unit 103 can have the following implementations:

- the lighting unit 300 may provide light from sources arranged in a circle or otherwise
- the lighting unit 300 may use two, four or another number of light sources per channel
- the lighting unit 300 may use light sources with central wavelength 405±10nm for bacteria imaging
- the lighting unit 300 may use an additional 750-1000nm range for user devices 102 without an IR filter on camera (e.g., front-facing camera on a smartphone)
- the lighting unit 300 may use light sources with central wavelength 970±10nm for water imaging for user devices 102 without an IR filter on camera (e.g., front-facing camera on a smartphone)
- the illumination unit 104 and/or lighting unit 300 and a mobile device 108 can be mounted on an extension device (e.g., on a selfie stick)
- the imaging unit 104 can be associated with an external lens (e.g., macro lens), emission filter, polarizer or not

[00153] In some embodiments, the illumination unit 104, for example, including a multispectral external flash, can be operable with an image capture unit 103 or another recording device, for example, integrated with a personal computer, tablet, or otherwise.

[00154] The system offers distinct advantages. These include the flash design, which can be used with any smartphone (iOS, Android, etc.) of any shape; the flash/image capturing schema, which allows measurements in any type of ambient lights and with any type of a smartphone; self-calibration using a self-reference object to increase accuracy; proper positioning of the camera (distance from the wound) using a self-reference object (e.g. a circle); and the illumination schema, which produces reproducible and homogeneous illumination.

[00155] The system can overcome challenges, for example, of building the flash in the case for a smartphone, such as a challenge that each smartphone can have its own form-factor and thus would require multiple cases to be built at least for the most popular models. Other challenges that the system can overcome include:

- use of IR filter on some smartphone cameras. These filters, which are used to improve the quality of pictures, filter out light with wavelengths over 750nm and are being used mostly on more expensive smartphones. Typical pulse oximetry schemas employ 660 and 900nm bands. Thus, these schemas cannot be employed universally on smartphones.
- A plurality of with existing EHR systems.
- Motion artifacts (e.g., due to tremor) while taking measurements
- Taking images in various light conditions (e.g., indirect sunlight, office light, observation room, etc.). Thus, flickering, high dynamic range, etc. is combatted.
- Various utility frequencies (causing flickering) in different countries
- Producing predictable light distribution, not very sensitive to slight misplacements of the flash or the smartphone.
- Difficulty in synchronizing the phone and external flash.
- Use of the lens (e.g., Fresnel lens) covering the light sources homogenizes the light distribution on the target area, thus extending dynamic range and increasing the accuracy of measurements
- use of multiwavelength LEDs (e.g., RGB LEDs) creates the similar intensity distribution for each channel and save space on the illumination unit
- The intensity of illumination can vary, for example, based on the distance to a target area and the stability of LED intensity (e.g., LED intensity may change with time, temperature, or within battery cycle).
- porphirin and pyoverdine have an absorption peak in Soret band, where oxyhemoglobin and deoxyhemoglobin have absorption peaks as well. The presence of blood component may significantly impact porphyrin/pyoverdine emission. True fluorescence intensity can be deconvoluted using known oxyhemoglobin and deoxyhemoglobin concentrations

[00156] A tissue imaging system 105 can be used in a variety of applications, including in the following scenarios.

[00157] **Use case 1**: The doctor at a hospital during a physical exam of a patient in acute care found a suspicious wound on the leg. The patient has diabetes, so the MD has a suspicion that it can be a non-healing DFU. The current standard of care for this is angiography, which is not available in his community hospital. It will cost around $20,000 for

the procedure and arrange medical transportation to/from another hospital. However, using the device he can screen the wound on the spot and see whether it is ischemic (and require angiography for proper assessment) or nonischemic (and will heal well without any extra efforts).

[00158] **Use case 2:** The family doctor during an annual checkup found a suspicious wound on the leg. The patient has diabetes, so the MD has a suspicion that it can be non-healing DFU. The current standard of care for this is angiography. However, it can be performed in major hospitals only. It is associated with $1,500 per procedure (in the US) or waiting time (41 days in Ontario). Using the device he can screen the wound on the spot and see whether it is ischemic (and require angiography for proper assessment) or nonischemic (and will heal well without any extra efforts).

[00159] **Use case 3**: The family doctor during an annual checkup found a suspicious wound on the leg. The patient has diabetes, so the MD has a suspicion that it can be a non-healing DFU. The current standard of care for this is angiography. It can be performed in major hospitals only. It is associated with $1,500 per procedure (in the US) or waiting time (41days in Ontario). Using the device, he captures images of the wound on the spot. However, such as he does not have significant experience in wound care, he decided to send images to a podiatrist, who provides him with an assessment whether it is ischemic (and require angiography for proper assessment) or nonischemic (and will heal well without any extra efforts). The doctor sends a referral to the patient.

[00160] **Use case 4**: A nurse is attending a small rural community. During an exam of a patient, she found suspicious ulceration near the small toe. She has a suspicion that it can be a peripheral arterial disease. She uses the device to take a snapshot of the wound using the device and sends images to a family physician (if the patient has it) or a podiatrist. The doctor reviews the images and provides guidance within a few hours. The nurse returns to the patient and instructs him on further actions.

[00161] **Use case 5**: A medical nurse is attending a small long-term residence. During an exam of a patient, she found suspicious ulceration near the big toe. She has a suspicion that it can be a peripheral arterial disease. She uses the device to take a snapshot of the wound using the device and send images to a family physician (if the patient has it) or a podiatrist. The doctor reviews images and provides guidance within a few hours. The nurse returns to the patient and instructs him on further actions.

[00162] **Use case 6**: The senior with diabetes found a suspicious cut on his heel. He is aware of the dreadful consequences of DFU, so he decides to buy the device in a drugstore. With the help of his wife he takes images of the wound and sends them to his family doctor. The doctor makes an assessment and advises the patient within a few hours.

[00163] **Use case 7**: The senior with diabetes found a suspicious cut on her forefoot. She is aware of the dreadful consequences of DFU, so she told her concerns to a daughter. The daughter bought a flash attachment 104 in the drugstore, attached it to her smartphone 108, downloads the app, and takes images of the wound. As her mother does not have a family doctor, she sends images to a podiatrist. The doctor makes an assessment and sends a referral within a few hours.

[00164] **Use case 8:** The family doctor during an annual checkup found a suspicious mole. Using the device, he can screen the mole on the spot and see whether it is suspicious (has increased blood supply and require additional studies) or not suspicious.

[00165] **Use case 9:** The nurse in long-term facility checks a bed-bound patient for potential pressure ulcers. Using the device, she can screen bony prominence areas and see whether it is suspicious.

[00166] **Use case 10:** The advanced wound care nurse cleanses the existing wound. She uses the device to visualize bacteria presence and guide debridement

[00167] **Use case 11:** The nurse takes a swab from the existing wound. She uses the device to visualize bacteria presence and guide swabbing

[00168] The accuracy of measurements can be improved if the light intensity distribution produced by illumination unit 104 is known. In a preferred embodiment, to capture light intensity distribution produced by illumination unit 104, the reference image is used

[00169] Fig. 9 shows the workflow used to take reference images. In some embodiments, the reference image can be captured by calibration unit 328 of tissue visualization app 112 and then used by the tissue imaging system 105 or tissue visualization system 100 to obtain a processed measurement 501.

[00170] The reference image is captured using a reference object 901. Reference object refers to an object with known homogeneous optical properties (e.g., spectral dependence of reflectance). Reference object 901 can be various shapes such as a circle or rectangle. The preferred embodiment is a rectangle with an aspect ratio of 4:3. Various colors can be used for reference object 901 such as white or gray. The preferred embodiment is an 18% gray.

[00171] In one embodiment, screen markers 902 displayed on a screen of the mobile device 108 can be used to position the device the optimal distance away from the reference object 901. The screen markers 902 should line up with the reference object 901 to ensure an optimal distance. If in some embodiments, measurements taken by conventional distance measuring devices such as a rangefinder or ruler can be used to position device at the optimal distance. In one preferred embodiment, the device object recognition can be used to position the device.

[00172] In the preferred embodiment, the device can take the required reference image automatically upon proper placement of the device. In other embodiments, the device can take the image upon manual user initiation. The device takes several images. In the preferred embodiment, one or more images are taken with flash, and one is taken without. Alternatively, images can be taken only with flash.

[00173] The device can pre-process the reference image to improve the image quality. The pre-processing may contain the following steps: a) image registration, b) image subtraction.

[00174] In some embodiments, the device uses image registration to reduce shake during capturing. This can be accomplished using phase correlation or block matching algorithms.

[00175] In some embodiments, the device uses image subtraction to remove ambient light in the image. In this case, the image without external illumination (no flash) is subtracted from images with external illumination (with flash). Image subtraction is not required if only images with flash are used.

[00176] The reference image can be stored locally on the mobile device 108 or remotely for future use.

[00177] The reference image can be captured before the first measurement and at any time later. There is no need to capture reference images before every measurement

[00178] Fig. 10 is an example of a primary workflow outlining steps taken by the disclosed invention to produce measurement map 501.

[00179] The mobile device 108 is held at a specific distance away from the human body in order to optimally image the area of interest.

[00180] In some embodiments, a self-reference object 1002 is used to ensure the proper distance from the human body. A self-reference object 1002 is placed within the device target area 1001 imaged by the mobile device 108. The preferred embodiment of the self-reference object 1002 is an 18% gray circle 1-2 cm in diameter.

[00181] In some embodiments, the mobile device 108 or image capturing unit 103 is moved so that the screen marker 1003 is shown as the same size as self-reference object 1002 on the device target area 1001.

[00182] In a preferred embodiment, the device uses object recognition to trigger automatic image capturing upon certain screen size of the self-reference object in pixels.

[00183] Alternatively, other means of measuring a distance such as a rangefinder or a ruler can be used to position the device at the proper distance from the area of interest.

[00184] Once the optimal distance from the human body is determined, the device can take the required images. In a preferred embodiment, the device takes the required image automatically upon the proper placement of the mobile device 108 or image capturing unit 103. The device takes several images. In a preferred embodiment, one or more images will be taken with flash, and one will be taken without.

[00185] The device pre-processes the image in order to improve the quality of the image and the future measurement map 501. The pre-processing may contain the following steps: a) image registration, b) image subtraction,

[00186] In some embodiments, the device uses image registration to reduce shake. This can be accomplished through phase correlation or block matching.

[00187] In some embodiments, the device uses image subtraction to remove ambient light in the image. In this case, the image without external illumination (flash) is subtracted from images with external illumination (flash).

[00188] To further increase the quality of results, the self-calibration of each measurement using a self-reference object 1002 can be implemented. In this case the pre-processing may contain the following steps: a) image registration, b) image subtraction, c) self-calibration, and d) division on the reference image

[00189] If the embodiment utilizes self-reference object 1002, the intensity of the image is adjusted using the self-reference object to account for any imperfections or changes in intensity In the preferred embodiment, pre-processing unit 328 can compare the intensity of a self- reference object in the target image with the intensity of the same region in the reference image and uses the ratio between the two to scale the intensity of the target image pixel-by-pixel.

[00190] . If the embodiment utilizes previously taken reference images, the device finds the normalized image by dividing pixel-by-pixel image onto reference image and multiplying by a known reflectance of the reference object.

[00191] In some embodiments, the tissue imaging system 105 can perform the processing of the image to obtain measurements. This can be achieved through all or some of the following steps: a) The absorption coefficient is determined from reflectance (e.g., using Beer-Lambert, or modified Beer-Lambert law). b) The chromophore concentration is determined from the absorption coefficient (e.g., using least square fitting). c) The perfusion and oxygenation is determined from the chromophore concentration (oxygenation = oxyhemoglobin/(oxyhemoglobin+deoxyhemoglobin), perfusion= oxyhemoglobin + deoxyhemoglobin).

[00192] In some embodiments, the pre-processed measurement (normalized image) is taken on the device then sent through the network to the tissue visualization system 100.

[00193] Bacterial burden indicator can be used stand-alone or in combination with reflectance images. Porphyrin and pyoverdine have an absorption peak in Soret band, where oxyhemoglobin and deoxyhemoglobin have absorption peaks as well. Thus, the presence of blood component may significantly impact porphyrin/pyoverdine emission. True fluorescence intensity can be deconvoluted using known oxyhemoglobin and deoxyhemoglobin concentrations found in step 410. In the preferred embodiment, a light source with the center wavelength 405±10nm is used in combination with 2 or 3 wavelengths from the 450-650nm range.

[00194] Once tissue health indicators levels are found, the invention presents the color or grayscale maps through processing via tissue visualization system 100 or tissue imaging system 105. These results can be stored locally on the device or remotely. The pre-processed normalized image and the processed tissue health indicators maps can all be stored.

[00195] The embodiments of the devices, systems, and methods described herein may be implemented in a combination of both hardware and software. These embodiments may be implemented on programmable computers, each computer including at least one processor, a data storage system (including volatile memory or non-volatile memory or other data storage elements or a combination thereof), and at least one communication interface.

[00196] Program code is applied to input data to perform the functions described herein and to generate output information. The output information is applied to one or more output devices. In some embodiments, the communication interface may be a network communication interface. In embodiments in which elements may be combined, the communication interface may be a software communication interface, such as those for inter-process communication. In still other embodiments, there may be a combination of communication interfaces implemented as hardware, software, and combination thereof.

[00197] Throughout the foregoing discussion, numerous references will be made regarding servers, services, interfaces, portals, platforms, or other systems formed from computing devices. It should be appreciated that the use of such terms is deemed to represent one or more computing devices having at least one processor configured to execute software instructions stored on a computer-readable tangible, non-transitory medium. For example, a server can include one or more computers operating as a web server, database server, or another type of computer server in a manner to fulfill described roles, responsibilities, or functions.

[00198] Various example embodiments are described herein. Although each embodiment represents a single combination of inventive elements, all possible combinations of the disclosed elements include the inventive subject matter. Thus if one embodiment comprises elements A, B, and C, and a second embodiment comprises elements B and D, then the inventive subject matter is also considered to include other remaining combinations of A, B, C, or D, even if not explicitly disclosed.

[00199] The term “connected” or "coupled to" may include both direct coupling (in which two elements that are coupled to each other contact each other) and indirect coupling (in which at least one additional element is located between the two elements).

[00200] The technical solution of embodiments may be in the form of a software product. The software product may be stored in a non-volatile or non-transitory storage medium, which can be a compact disk read-only memory (CD-ROM), a USB flash disk, or a removable hard disk. The software product includes a number of instructions that enable a computer device (personal computer, server, or network device) to execute the methods provided by the embodiments.

[00201] The embodiments described herein are implemented by physical computer hardware, including computing devices, servers, receivers, transmitters, processors,

memory, displays, and networks. The embodiments described herein provide useful physical machines and particularly configured computer hardware arrangements. The embodiments described herein are directed to electronic machines and methods implemented by electronic machines adapted for processing and transforming electromagnetic signals which represent various types of information.

[00202] Although the embodiments have been described in detail, it should be understood that various changes, substitutions, and alterations can be made herein without departing from the scope as defined by the appended claims.

[00203] Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed, that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

[00204] As can be understood, the examples described above and illustrated are intended to be exemplary only.

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[00206] Bates-Jensen BM, McCreath HE, Pongquan V, Apeles NCR. Subepidermal moisture differentiates erythema and stage I pressure ulcers in nursing home residents. Wound Repair Regen 2008;16(2):189-97.

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WHAT IS CLAIMED IS:

1. A process for generating visualizations of tissue comprising

   Positioning the device at a proper distance from a target area

   capture measurement data using the image capturing unit and the illumination unit;

   pre-process the measurement data using the tissue visualization application to obtain normalized images;

   extract indications of tissue health indicators (tissue oxygenation, perfusion, subepidermal water content, bacterial burden) from the processed measurement data;

   generate interface elements corresponding to the visualization tissue health indicators,

   collect wound-related data (e.g., laterality, location); and

   store or transmit the indications of tissue health indicators

2. The process of claim 1 wherein the positioning of the device for reference image capturing comprises positioning the user device using a reference object;

3. The process of claim 1 wherein the positioning of the device for measurement capturing comprises positioning the user device using a self-reference object;

4. The process of claim 1 wherein self-calibration of light intensity during measurement comprises using a self-reference object positioned within a target area.

5. The process of claim 1, which uses T=50ms exposure time and T or 2T flash time

6. A tissue imaging system consisting of the mobile device with visualization application, image capturing unit, and an illumination unit, is configured to capture measurement data, the visualization application extracts visualizations of tissue health indicators from the measurement data and generates an interface with one or more interface elements corresponding to the visualization of tissue health indicators according to claims 1-5.

7. A tissue visualization system connected to a tissue imaging system consisting of mobile device with tissue visualization application, image capturing unit, and an illumination unit, Image capturing unit and an illumination unit capture measurement data, the tissue visualization application pre-process and process the measurement data and transmits the processed or pre-processed images to the tissue visualization system, the tissue visualization system processing, storing, and displaying the visualization of tissue health indicators.

8. The illumination unit of claim 6, which contains a lens (including Fresnel lens) covering some or all light sources with the focal length 80-120% of the working distance between the portable illumination unit and the target area

9. The illumination unit of claim 6, which uses light sources at the 970±10nm range and/or 2 or 3 wavelengths in the 450-750nm range

10. The illumination unit of claim 6, which has a light source with the center wavelength 405±10nm and a long pass filter with a cut-on wavelength in the 450±25nm range

11. The illumination unit of claim 6, which has a light source with the center wavelength 405±10nm and a bandpass filter with transmission somewhere in the 425-750nm range, which has the lower cut-on wavelength in the 450±25nm range

12. The illumination unit of claims 10 or 11, which uses 2 or 3 wavelengths in the 450-750nm range

13. The illumination unit according to claims 8-12 with working distance15±5cm from the target area

14. A portable illumination unit according to claims 1-13, wherein the illumination unit comprises

    A clip-based housing; which can be mounted on one edge of a mobile device close to the device's camera.

    One or multiple narrow band light sources, which shine m flashes at n predetermined wavelengths (channels). $n/4 \leq m \leq n$

    A controller connected to light sources, which can generate a required illumination sequence.

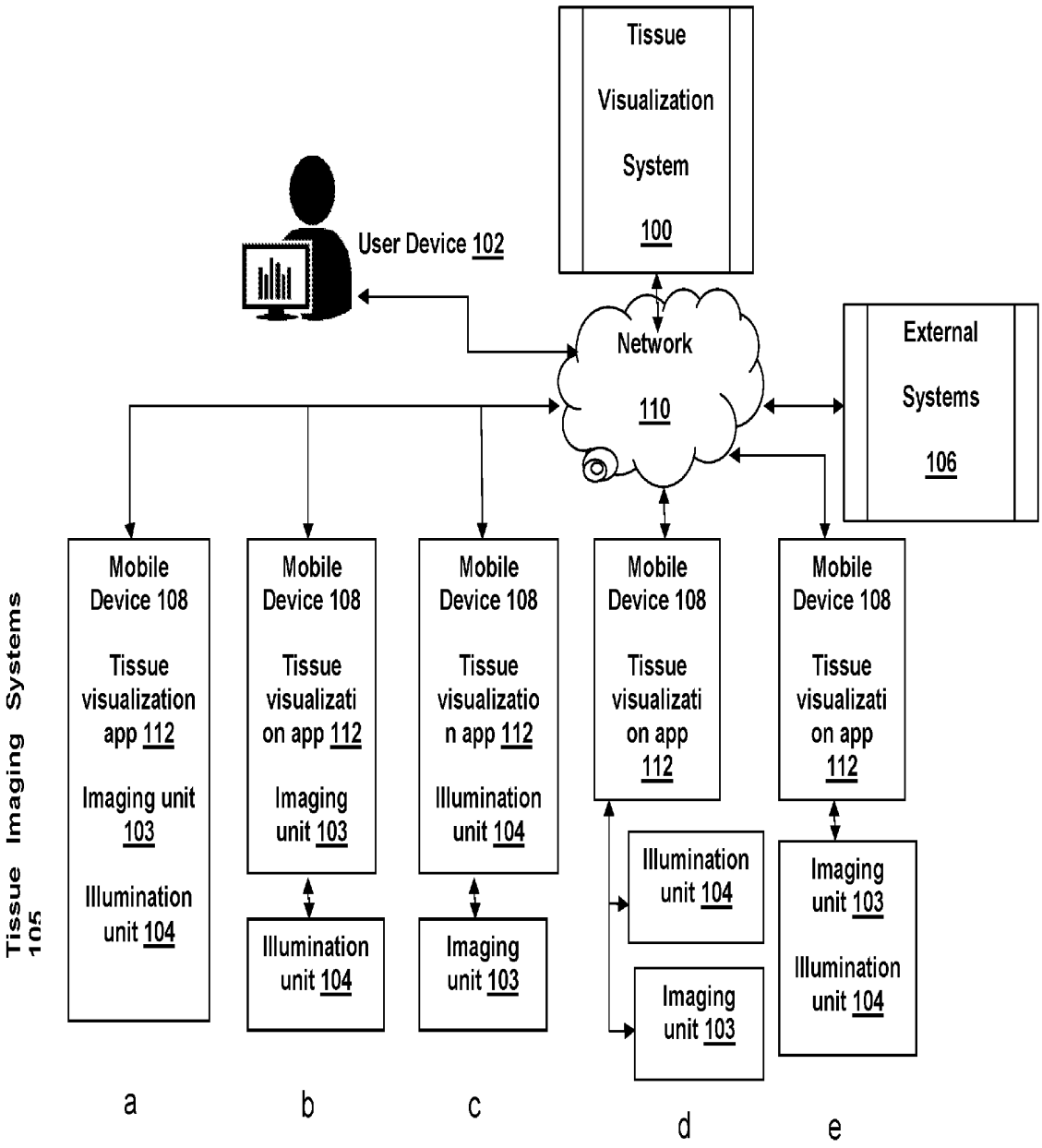
15. The portable illumination unit of claim 14, which has a round shape with the radius 2-6cm and the central aperture with the radius 0.5-3cm.

16. The portable illumination unit of claim 14, which uses compression clip for mounting on the mobile device

17. The portable illumination unit of claim 14, which uses spring clip for mounting on the mobile device

ABSTRACT

A tissue imaging system consisting of mobile device, tissue visualization application, image capturing unit, and an illumination unit, is configured to capture measurement data, the visualization application extracts visualizations of tissue health indicators from the measurement data. The application generates an interface with one or more interface elements corresponding to the visualization of tissue health indicators. Devices, systems, and processes are also described.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Network 110
External Systems 106
Tissue Imaging Systems 105
Mobile Device 108
Tissue visualization app 112
Imaging unit 103
Illumination unit 104
Mobile Device 108
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Imaging unit 103
Illumination unit 104
Mobile Device 108
Tissue visualization app 112
Illumination unit 104
Imaging unit 103
Mobile Device 108
Tissue visualization app 112
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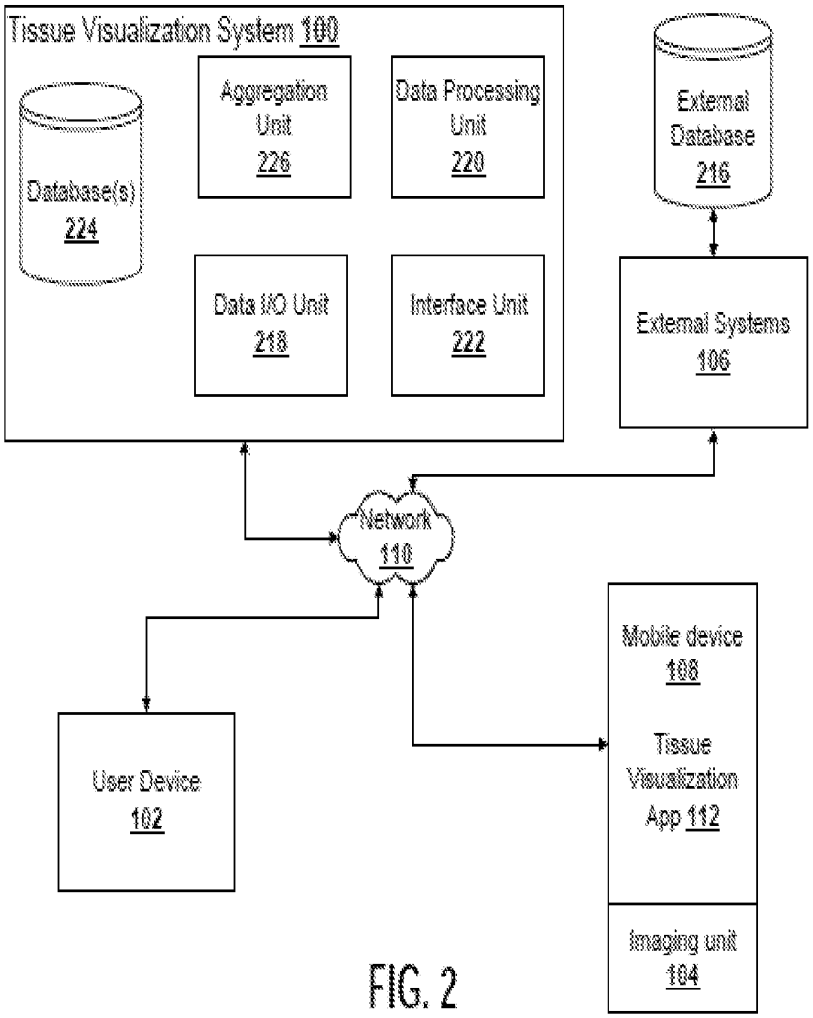
a
b
c
d
e

FIG. 1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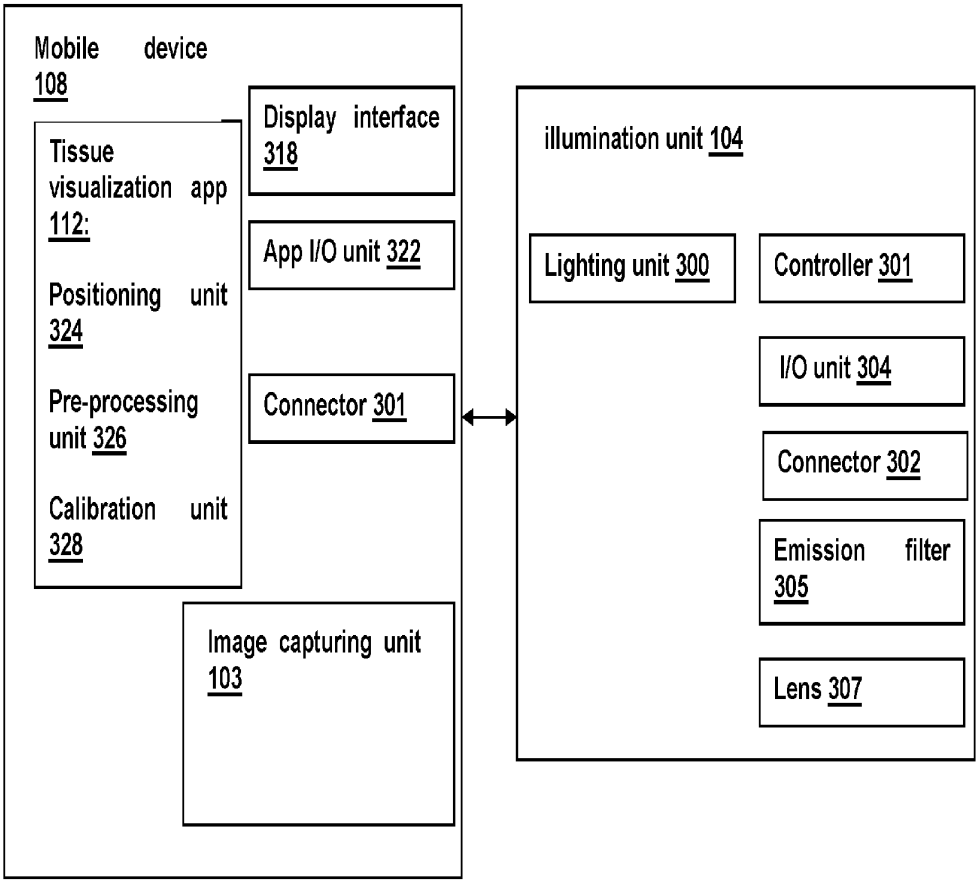
Aggregation Unit 226
Data Processing Unit 220
Data I/O Unit 218
Interface Unit 222
External Database 216
External Systems 106
Network 110
User Device 102
Mobile device 108
Tissue Visualization App 112
Imaging unit 104

FIG. 2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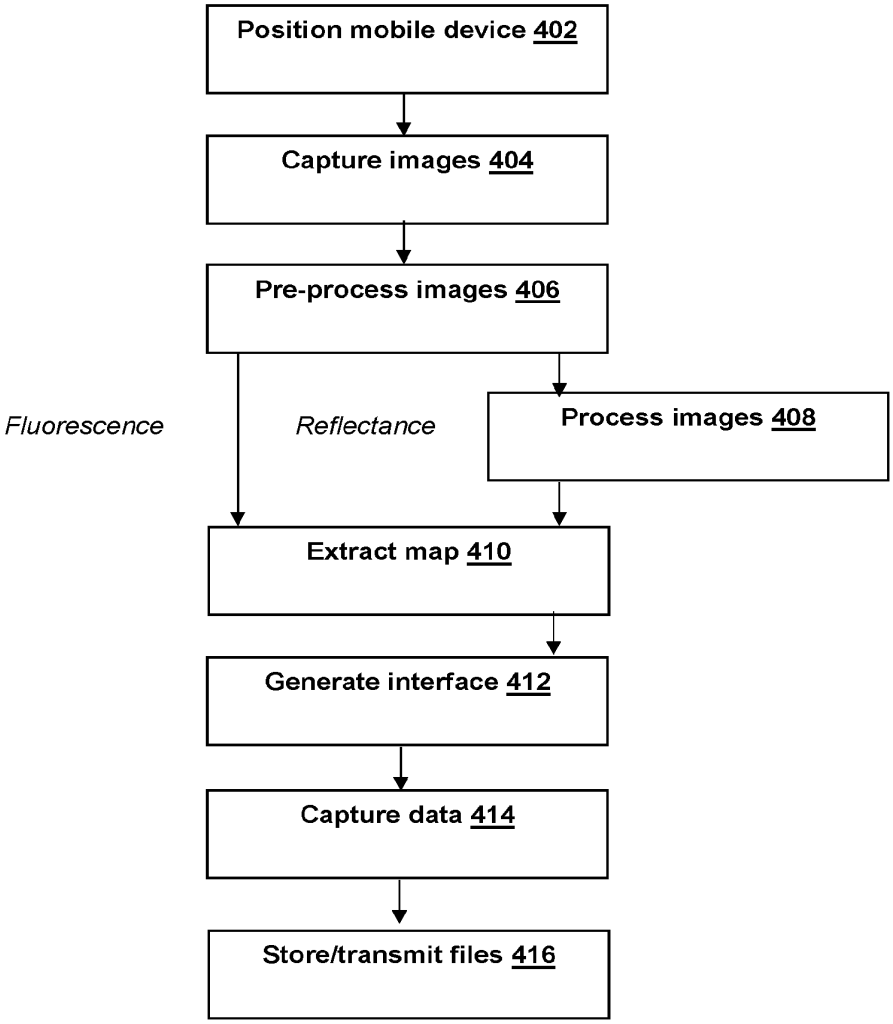
Tissue visualization app 112:
Positioning unit 324
Pre-processing unit 326
Calibration unit 328
Display interface 318
App I/O unit 322
Connector 301
Image capturing unit 103
illumination unit 104
Lighting unit 300
Controller 301
I/O unit 304
Connector 302
Emission filter 305
Lens 307

FIG. 3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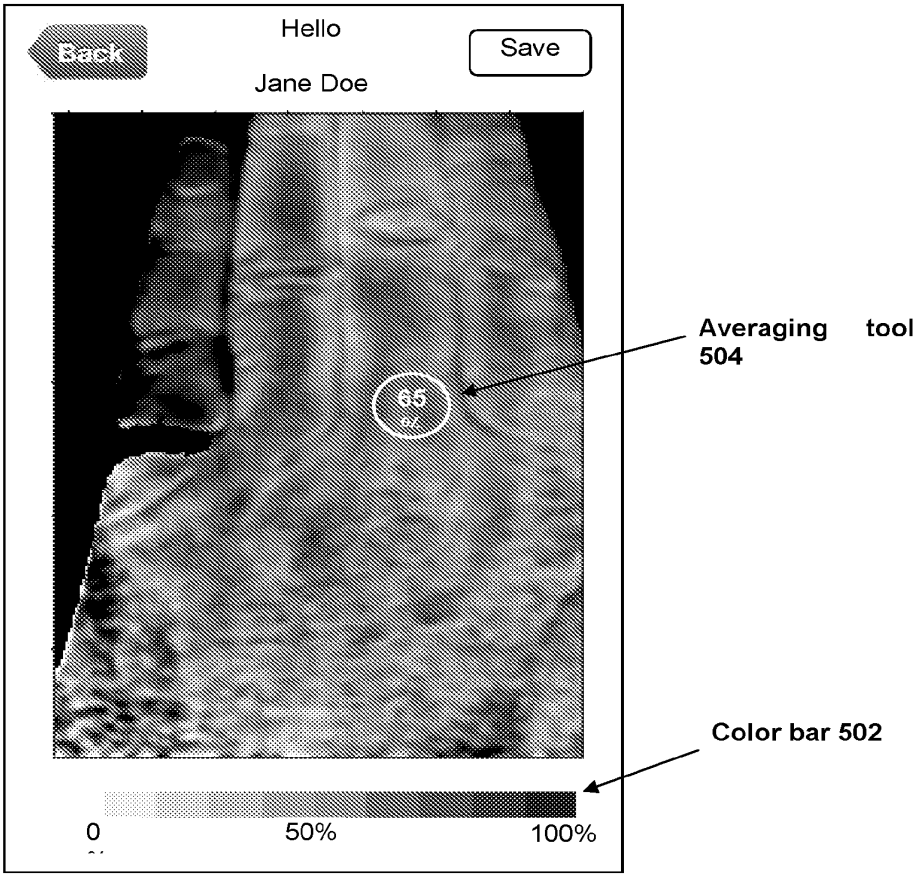
Capture images 404
Pre-process images 406
Fluorescence
Reflectance
Process images 408
Extract map 410
Generate interface 412
Capture data 414
Store/transmit files 416

FIG. 4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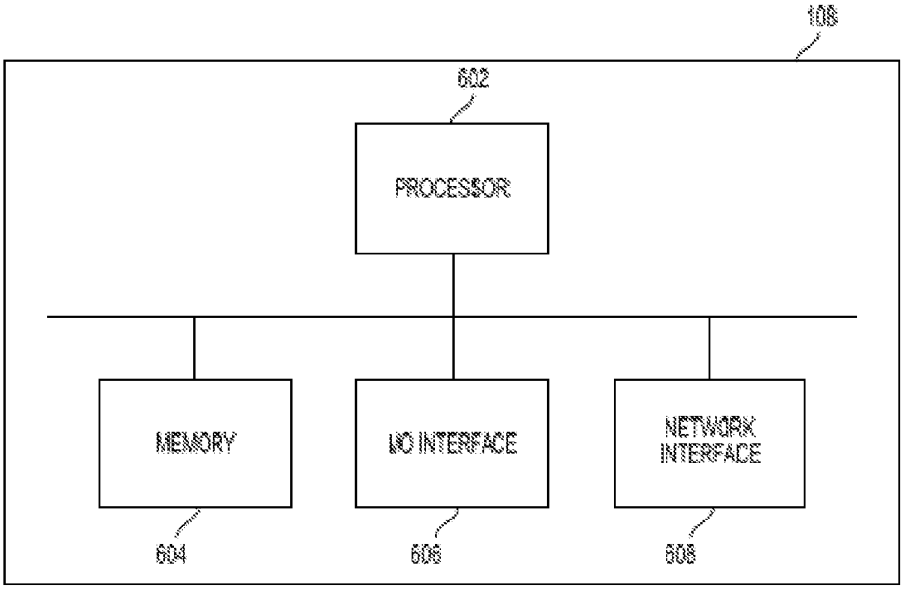
65
Averaging tool 504
Color bar 502
0
50%
100%

FIG. 5


108
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PROCESSOR
MEMORY
I/O INTERFACE
NETWORK INTERFACE
604
606
608

FIG. 6

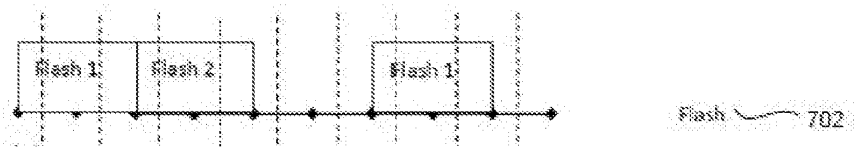

FIG. 7

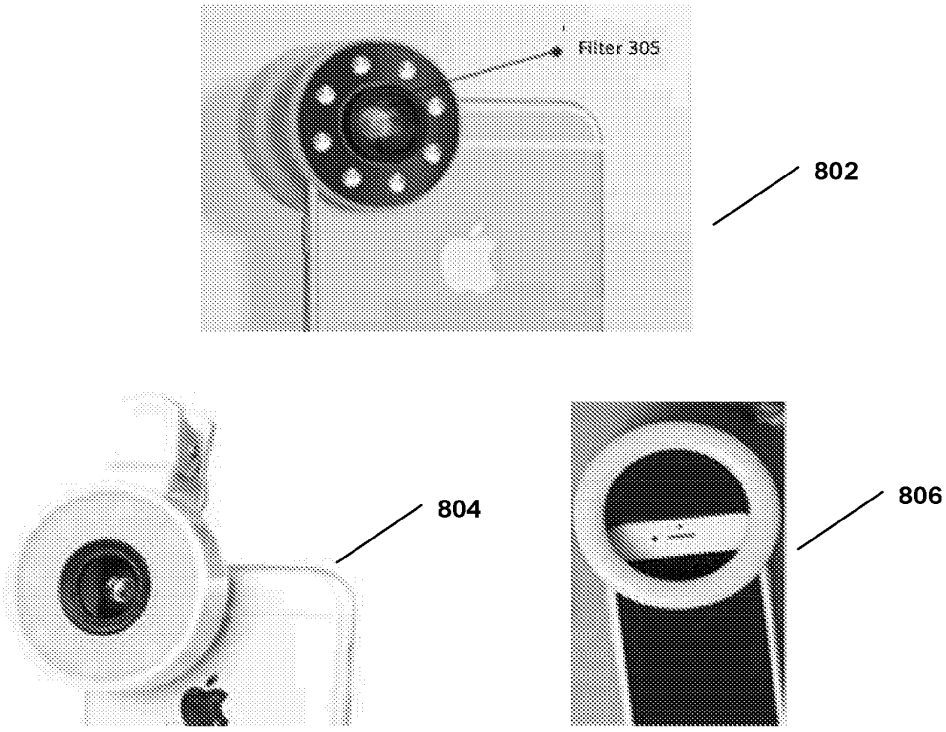

FIG. 8

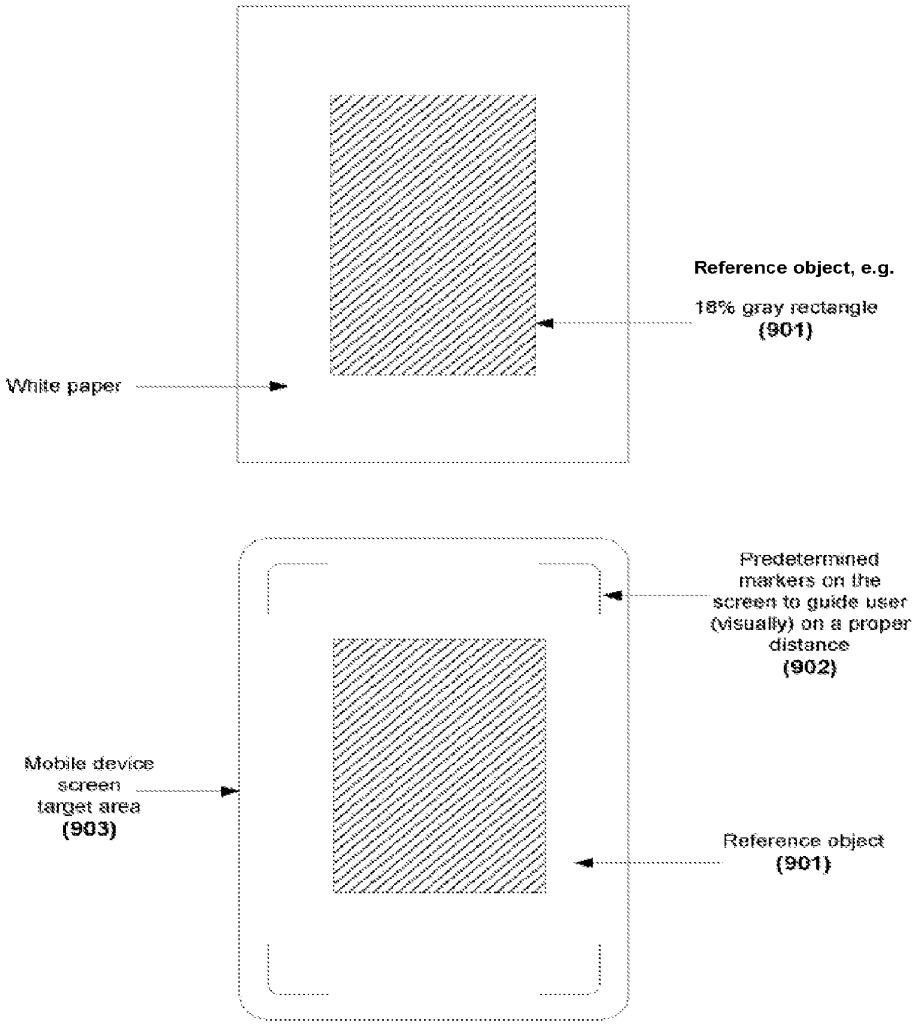
Reference object, e.g.
18% gray rectangle
(901)
White paper
Predetermined markers on the screen to guide user (visually) on a proper distance
(902)
Mobile device screen target area
(903)
Reference object
(901)

FIG. 9

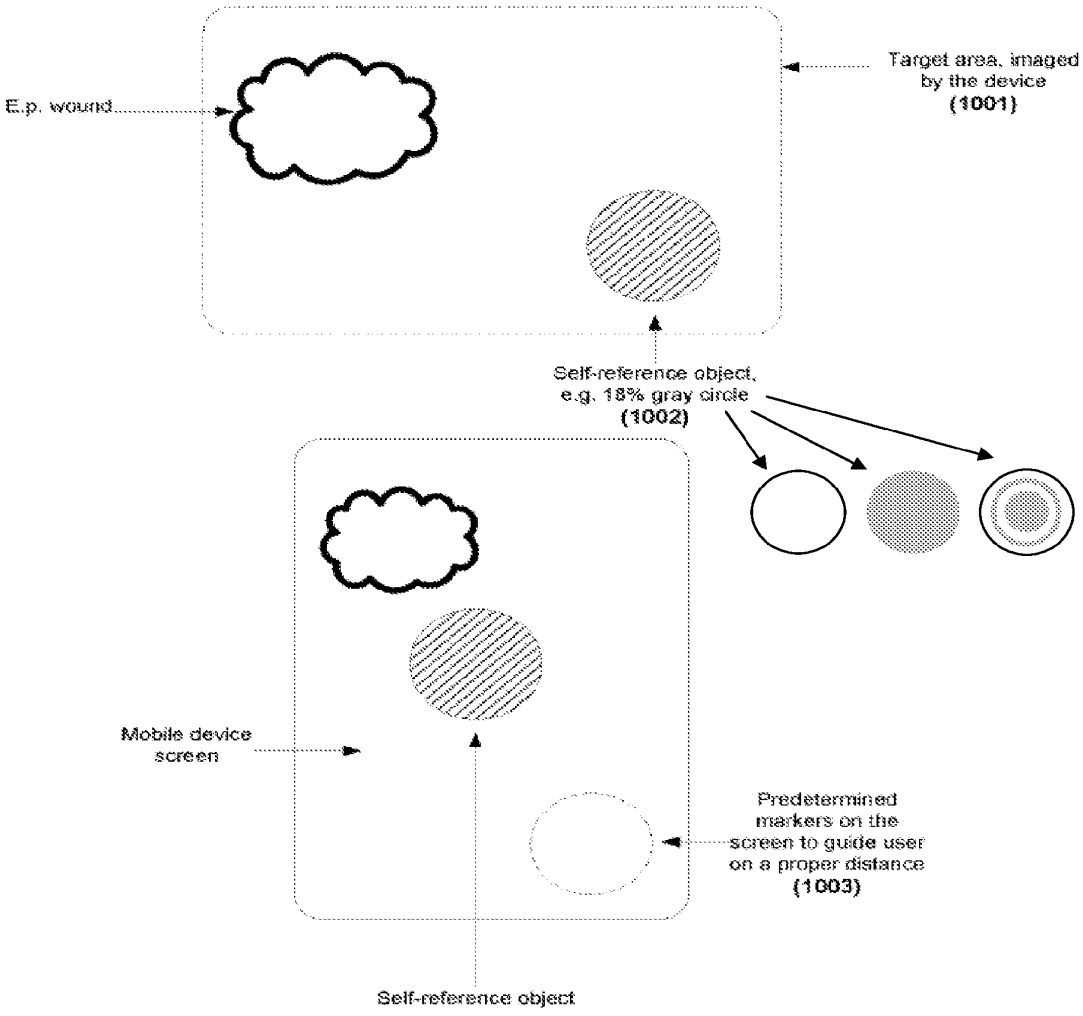
E.p. wound
Target area, imaged by the device (1001)
Self-reference object, e.g. 18% gray circle (1002)
Mobile device screen
Predetermined markers on the screen to guide user on a proper distance (1003)
Self-reference object

FIG. 10

PTO/SB/16 (01-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. _____

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Guennadi	Saiko	Mississauga, Canada
Kenneth	Macko	Toronto, Canada
Andrei	Betlen	Pickering, Canada

Additional inventors are being named on the _____ separately numbered sheets attached hereto.

TITLE OF THE INVENTION (500 characters max):

APPARATUS FOR VISUALIZATION OF TISSUE

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ The address corresponding to Customer Number: _____

OR

☒ Firm or Individual Name Guennadi Saiko

Address 2474 Trondheim Cr

City Mississauga	State ON	Zip L5N1P4
Country Canada	Telephone	Email

ENCLOSED APPLICATION PARTS (*check all that apply*)

☒ Application Data Sheet. See 37 CFR 1.76.
☐ CD(s), Number of CDs _____
☒ Drawing(s) *Number of Sheets* 10
☐ Other (specify) _____
☒ Specification (e.g., description of the invention) *Number of Pages* 32

Fees Due: Filing Fee of $280 ($140 for small entity) ($70 for micro entity). If the specification and drawings exceed 100 sheets of paper, an application size fee is also due, which is $400 ($200 for small entity) ($100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

METHOD OF PAYMENT OF THE FILING FEE AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant asserts small entity status. See 37 CFR 1.27.
☒ Applicant certifies micro entity status. See 37 CFR 1.29.
Applicant must attach form PTO/SB/15A or B or equivalent.
☐ A check or money order made payable to the *Director of the United States Patent and Trademark Office* is enclosed to cover the filing fee and application size fee (if applicable).
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: _____.

70-00
TOTAL FEE AMOUNT ($)

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 2 of 2

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

- [x] No.
- [ ] Yes, the invention was made by an agency of the U.S. Government. The U.S. Government agency name is: _____
- [ ] Yes, the invention was made under a contract with an agency of the U.S. Government. The name of the U.S. Government agency and Government contract number are: _____

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SIGNATURE /guennadisaiko/ DATE 7/15/2018

TYPED OR PRINTED NAME GUENNADI SAIKO REGISTRATION NO. _____ (*if appropriate*)

TELEPHONE 416-616-7820 DOCKET NUMBER _____

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt	
EFS ID:	33193448
Application Number:	62698799
International Application Number:	
Confirmation Number:	3511
Title of Invention:	Apparatus for visualization of tissue
First Named Inventor/Applicant Name:	Guennadi Saiko
Correspondence Address:	Guennadi Saiko - 2474 Trondheim Cr - Mississauga - - CA - -
Filer:	Guennadi Saiko
Filer Authorized By:	
Attorney Docket Number:	
Receipt Date:	16-JUL-2018
Filing Date:	
Time Stamp:	20:37:28
Application Type:	Provisional

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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Warnings:					
Information:					
2	Certification of Micro Entity (Gross Income Basis)	Certification_GS.pdf	159061 9c57a1aaa0c765acc7f3cc9c06a5c8c55e6f5b01	no	2
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3	Certification of Micro Entity (Gross Income Basis)	Certification_KM.pdf	159042 0248bf9a25106bf2dd73f1f53bbc970495ac6e7f	no	2
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4	Application Data Sheet	aia0014_completed.pdf	1256517 ea84b2238f9799363d6959e00fe2d2b9e38a7e6c	no	11
Warnings:					
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5		patent_application.pdf	458100 1a5dc42a6e4a34afc4c34e84a8064c344b1967fe	yes	45

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	31
Claims	32	34
Abstract	35	35
Drawings-only black and white line drawings	36	45

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6	Provisional Cover Sheet (SB16)	sb0016.pdf	1948560 8bc7bfc78bd8c865fe0316ef99e99f21a8fa32e5	no	3
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7	Fee Worksheet (SB06)	fee-info.pdf	29007 05e2437e29ab0862dcb43b7606ad7fdec7e2edf7	no	2
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WHAT IS CLAIMED IS:

1. A portable illumination apparatus for facilitating visualizations of tissue, the apparatus comprising:

   a portable housing for detachable attachment proximal to an image capturing unit; and

   an illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$.

2. The portable illumination apparatus of claim 1, wherein the illumination unit further comprises a lens covering the one or more light sources, the lens having a focal length that is 80%-120% of a working distance between the illumination unit and a target area of tissue.

3. The portable illumination apparatus according to any one of claims of 1-2, wherein the one or more light sources is configured to provide flashes that are at least one of

   (i) 405±10nm wavelength, and having at least one of (a) a long pass filter with a cut-on wavelength of 450±25nm or (b) a bandpass filter with transmission in a 425nm-1000nm range,

   (ii) two wavelengths in a 450nm-750nm range, at least one of which in the green range,

   (iii) three wavelengths in a 450nm-750nm range, at least one of which in the green range, or

   (iv) 970±10nm wavelength.

4. The portable illumination apparatus according to any one of claims 1-3, wherein the illumination unit further comprises at least one of (i) a controller to control

illumination of the one or more light sources and (ii) a rechargeable battery for powering the apparatus.

5. The illumination apparatus according to any one of claims 1-4, wherein the one or more light sources are arranged about a central aperture having a radius of 0.5-3cm.

6. The illumination apparatus of claim 5, wherein the one or more light sources are arranged in a ring having a radius of 1.5-6cm.

7. The illumination apparatus according to any one of claims of 1-6, wherein the portable housing comprises a compression clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

8. The illumination apparatus according to any one of claims of 1-6, wherein the portable housing comprises a spring clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

9. A tissue imaging system for visualization of tissue health indicators comprising a portable computing device, an image capture unit, and an illumination unit;

the illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$;

the image capture unit and the illumination unit being configured to capture measurement data for a target area of tissue;

the computing device comprising a processor configured to access and execute instrutions in accordance with a tissue visualization application stored in a non-transitory computer-readable memory of the computing device, for capturing measurement data, and pre-processing and processing the measurement data to generate tissue health indicators.

10. The tissue imaging system of claim 9, wherein the computing device comprises a mobile device and the image capture unit is a camera integrated with the mobile device.

11. The tissue imaging system according to any one of claims of 9-10, wherein the illumination unit comprises the illumination apparatus according to any one of claims of 1-8.

12. The tissue imaging system according to any one of claims 10-11, wherein the portable illumination unit further comprises a wireless communication module for receiving commands from the computing device.

13. A tissue visualization system operatively connected to one or more tissue imaging systems according to any one of claims of 9-12, comprising a communications module for communicating with the one or more tissue imaging systems, a system processor, and system non-transitory computer-readable memory thereon, configured to receive measurement data and tissue health indicators from the one or more tissue imaging systems and to generate a visualization of tissue health indicators of tissue images received from the one or more tissue imaging systems, for display to a user display unit.

14. A method for generating visualizations of tissue, the method comprising:

positioning a computing device at a proper distance from a target area of the tissue for capturing an image of the target area, the computing device comprising a processor and a non-transitory computer-readable memory storing computer-executable instructions comprising a tissue visualization application;

capturing measurement data using an image capturing unit and an illumination unit, the image capturing unit and the illumination unit communicatively coupled to the computing device and the illumination unit configured to shine m flashes at n predetermined wavelengths during capturing of the measurement data, wherein $n/4 \leq m \leq n$;

pre-processing the measurement data using the tissue visualization application to obtain normalized images;

extracting indications of tissue health indicators from the pre-processed measurement data;

generating interface elements corresponding to the visualization tissue health indicators; and

storing and/or transmitting the indications of the tissue health indicators.

15. The method of claim 14 further comprising, prior to capturing the measurement data:

capturing a reference image, wherein the positioning the computing device for the reference image capturing comprises positioning the computing device using a reference object.

16. The method of any one of claims 14-15, wherein the illumination unit and the computing device are configured to provide a working distance of 15±5cm from the target area of tissue.

17. The method of claim 16 wherein the positioning of the computing device for capturing the measurement data comprises positioning the computing device using a self-reference object.

18. The method according to any one of claims of 14-17 wherein pre-processing comprises at least one of (i) registering images to avoid camera motion artifacts, (ii) subtracting images with no illumination from the illumination unit from images with illumination from the illumination unit to account for the presence of ambient light, (iii) recalibrating each measurement accordingly to control parameters related to intensity of illumination using a self-reference object positioned within the target area, (iv) dividing the intensity images on reference images to obtain normalized images, and/or (v) flattening the obtained images to account for reflections from curved surfaces.

19. The method according to any one of claims of 14-18, wherein camera exposure time is T and a flash time is said T or any whole number multiple of said T.

20. The method according to claim 19, wherein the camera exposure time is 50ms.

21. The method according to any one of claims of 14-19, wherein the measurement data comprises wound-related data.

TITLE: APPARATUS FOR VISUALIZATION OF TISSUE

FIELD

[0001] The improvements generally relate to the field of medical devices.

BACKGROUND

[0002] People suffer from chronic and compromised wounds with debilitating pain and reduced quality of life for those whose health is already compromised. Patients with this condition often present to a doctor at late stages of the disease, which leads to many amputations, which may be avoidable. Moreover, proper diagnostics requires specialized vascular labs, which precludes these types of tests from being performed outside major hospitals and in an expedited fashion.

[0003] The wound is considered chronic if it is not healed within four weeks. The tissue health and wound healing process can be compromised by various factors, including insufficient blood supply, edema, and the presence of bacteria. These factors (oxygenation/perfusion, subepidermal moisture, and bacteria presence) among others will be referred to as tissue health indicators.

[0004] Multispectral (hyperspectral) imaging is a promising non-invasive optical modality for early detection of problematic wounds.

[0005] Visualization of skin distribution of oxyhemoglobin and deoxyhemoglobin can give insight into perfusion and oxygenation of the tissue. It can be used for assessment of tissue health (for example, ischemia).

[0006] Such as elevated levels of subepidermal moisture are typical for pressure injuries, visualization of water distribution in tissue can be used for early (pre-ulcer) diagnostics of pressure injuries.

[0007] Fluorescence imaging is a promising non-invasive optical modality for detection of bacterial burden. Visualization of bacterial burden can be used to assess bacterial burden and guide swabbing and cleansing.

SUMMARY

[0008] In accordance with an aspect, there is provided a process for generating visualizations of tissue. The process captures measurement data by a user device (e.g., smartphone), and processes the measurement data using the visualization application. The

process extracts indications of tissue health from the processed measurement data, and stores or transmits the underlying data. The process generates interface elements corresponding to the visualization tissue health indicators.

[0009] In some embodiments, the process involves calibrating the visualization application using a reference object.

[0010] In some embodiments, a small self-reference can be used to position the device properly.

[0011] In some embodiments, a small self-reference can be used to calibrate the measurement data based on an intensity of illumination.

[0012] In some embodiments, an illumination unit independent of the mobile device can be used for calibration and capture measurements together with a camera, laptop, or tablet.

[0013] In accordance with an aspect, there is provided a tissue imaging system comprised of a user device with a visualization application, an image capturing unit, and an illumination unit. The illumination unit is configured to illuminate the target area; the image capturing unit captures measurement data, the visualization application extracts visualizations of tissue health indicators from the measurement data and generates an interface with one or more interface elements corresponding to the visualization of tissue health indicators.

[0014] In accordance with an aspect, there is provided a tissue visualization system connected to a tissue imaging system (user device with a visualization application, an image capturing unit, and an illumination unit). The illumination unit illuminates the target area; the image capturing unit captures measurement data. The visualization application extracts visualization of tissue health indicators from the measurement data and transmits the visualization of tissue health indicators or underlying data to the tissue visualization system. The tissue visualization system processes and stores the visualization of tissue health indicators or underlying data, and displays them on user devices.

[0015] In accordance with an aspect, there is provided a portable illumination apparatus for facilitating visualizations of tissue. The apparatus comprises: a portable housing for detachable attachment proximal to an image capturing unit; and an illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$.

[0016] In accordance with a further aspect, the illumination unit further comprises a lens covering the one or more light sources, and having a focal length that is 80%-120% of a working distance between the illumination unit and a target area of tissue.

[0017] In yet a further aspect, the one or more light sources is configured to provide flashes that are at least one of: (i) 405±10nm wavelength, and having at least one of (a) a long pass filter with a cut-on wavelength of 450±25nm or (b) a bandpass filter with transmission in a 425nm-1000nm range; (ii) two wavelengths in a 450nm-750nm range, at least one of which in the green range; (iii) three wavelengths in a 450nm-750nm range, at least one of which in the green range; or (iv) 970±10nm wavelength.

[0018] In accordance with a further aspect, the illumination unit further comprises at least one of (i) a controller to control illumination of the one or more light sources, and (ii) a rechargeable battery for powering the apparatus.

[0019] In accordance with another aspect, the one or more light sources are arranged along a central aperture having a radius of 0.5-3cm.

[0020] In accordance with a further aspect, the one or more light sources are arranged in a ring having a radius of 1.5-6cm.

[0021] In accordance with an aspect, the portable housing comprises a compression clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

[0022] In accordance with another aspect, the portable housing comprises a spring clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

[0023] In accordance with a further aspect, there is provided a tissue imaging system for visualization of tissue health indicators comprising a portable computing device, an image capture unit, and an illumination unit. The illumination unit comprises one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$. The image capture unit and the illumination unit are configured to capture measurement data for a target area of tissue. The computing device comprises a processor configured to access and execute instrutions in accordance with a tissue visualization application stored in a non-transitory computer-readable memory of the computing device, for capturing measurement data, and pre-processing and processing the measurement data to generate tissue health indicators.

[0024] In accordance with an aspect, the computing device comprises a mobile device and the image capture unit is a camera integrated with the mobile device.

[0025] In accordance with a further aspect, the illumination unit of the tissue imaging system comprises any of the embodiments of the illumination apparatus described above.

[0026] In accordance with yet a further aspect, the portable illumination unit further comprises a wireless communication module for receiving commands from the computing device.

[0027] In accordance with a further aspect, there is provided a tissue visualization system operatively connected to one or more tissue imaging systems (such as any of the tissue imaging systems described above), comprising a communications module for communicating with the one or more tissue imaging systems, a system processor, and system non-transitory computer-readable memory thereon, configured to receive measurement data and tissue health indicators from the one or more tissue imaging systems and to generate a visualization of tissue health indicators of tissue images received from the one or more tissue imaging systems, for display to a user display unit.

[0028] In accordance with a further aspect, there is provided a method for generating visualizations of tissue. The method comprises: positioning a computing device at a proper distance from a target area of the tissue for capturing an image of the target area, the computing device comprising a processor and a non-transitory computer-readable memory storing computer-executable instructions comprising a tissue visualization application; capturing measurement data using an image capturing unit and an illumination unit, the image capturing unit and the illumination unit communicatively coupled to the computing device and the illumination unit configured to shine m flashes at n predetermined wavelengths during capturing of the measurement data, wherein $n/4 \leq m \leq n$; pre-processing the measurement data using the tissue visualization application to obtain normalized images; extracting indications of tissue health indicators from the pre-processed measurement data; generating interface elements corresponding to the visualization tissue health indicators; and storing and/or transmitting the indications of the tissue health indicators.

[0029] In accordance with an aspect, the method further comprises, prior to capturing the measurement data: capturing a reference image, wherein the positioning the computing

device for the reference image capturing comprises positioning the computing device using a reference object.

[0030] In accordance with a further aspect, the illumination unit and the computing device are configured to provide a working distance of 15±5cm from the target area of tissue.

[0031] In accordance with yet a further aspect, the positioning of the computing device for capturing the measurement data comprises positioning the computing device using a self-reference object.

[0032] In accordance with another aspect, pre-processing comprises at least one of (i) registering images to avoid camera motion artifacts, (ii) subtracting images with no illumination from the illumination unit from images with illumination from the illumination unit to account for the presence of ambient light, (iii) recalibrating each measurement accordingly to control parameters related to intensity of illumination using a self-reference object positioned within the target area, (iv) dividing the intensity images on reference images to obtain normalized images, and/or (v) flattening the obtained images to account for reflections from curved surfaces.

[0033] In accordance with an aspect, camera exposure time is T and a flash time is T or any whole number multiple of T.

[0034] In accordance with another aspect, the camera exposure time is 50ms.

[0035] In accordance with a further aspect, the measurement data comprises wound-related data.

[0036] Many further features and combinations thereof concerning embodiments described herein will appear to those skilled in the art following a reading of the instant disclosure.

DESCRIPTION OF THE FIGURES

[0037] Embodiments will now be described, by way of example only, with reference to the attached figures, wherein in the figures:

[0038] Fig. 1 depicts a view of an example of the overall system architecture with various configurations of tissue imaging systems according to some embodiments;

[0039] Fig. 2 depicts a view of an example of a tissue visualization system according to some embodiments;

[0040] Fig. 3 depicts a view of an example of the illumination unit and a computing device according to some embodiments;

[0041] Fig. 4 depicts a flowchart of an example method for capturing measurements and visualizing tissue according to some embodiments;

[0042] Fig. 5 depicts a view of an example interface for visualizing tissue according to some embodiments;

[0043] Fig. 6 depicts a diagram of an example architecture of a computing device according to some embodiments;

[0044] Fig. 7 depicts an example of illumination and image capturing scheme according to some embodiments;

[0045] Fig. 8 depicts a view of example illumination units according to some embodiments;

[0046] Fig. 9 depicts an example of the workflow used to take reference images; and

[0047] Fig. 10 depicts a view of a schematic of imaging tissue and self-reference objects.

DETAILED DESCRIPTION

[0048] Some clinical-grade tools can only be used in specialized medical establishments. They can be large, require special training, and are mostly suitable for the use in inpatient settings only. For example, they cannot be easily carried to a patient's home or remote communities. Thus, these solutions cannot be used as early diagnostic tools as a patient would have to be referred to a hospital having one of these tools.

[0049] Many people suffer from diabetes. Diabetic foot ulcers (DFU) and the resulting lower extremity amputations are a frequent, disabling and costly complication of diabetes. Many diabetics can develop a foot ulcer. DFU is a cause of non-traumatic below knee amputation. In addition to the reduced quality of life, amputees might not survive for that long after amputation. Consequently, early detection of DFU can lead to better outcomes, thus saving limbs and lives.

[0050] Peripheral vascular disease (PVD) affects arteries (peripheral arterial disease, PAD) and veins (chronic venous insufficiency, CVI). PAD is of particular importance, as it affects about eight million Americans and is responsible for 10% of all leg ulcers.

[0051] Pressure ulcers (PU) or pressure injuries represent a serious health problem to patients impacting up to 25-50% of patients across acute and long-term care settings.

[0052] The cost of treatment of diabetic foot ulcer, pressure ulcer, and leg ulcer is high. Diagnosing these conditions at an earlier stage (e.g., before actual ulceration) might result in significant financial savings for healthcare systems and patients.

[0053] Other clinical indications associated with abnormal blood perfusion and/or oxygenation, such as skin cancer (angiogenesis), port-wine stains, and skin disorders, can benefit from a system for tissue imaging.

[0054] Subepidermal moisture, a measure of localized edema, is associated with erythema, Stage I and II PUs [Bates-Jensen 2007, Bates-Jensen 2008, Guihan 2012, Ching 2011], and can (ii) differentiate between healthy skin and skin with pressure-induced tissue damage [Harrow 2014] and (iii) serve as a predictor of imminent ulceration (PUs, sDTIs) in various populations [Bates-Jensen 2007, Bates-Jensen 2008, Bates-Jensen 2009]. Thus, changes in measures of subepidermal moisture could be utilized for both prevention and detection of PUs. Radiofrequency impedance measurement with spatially separated electrodes is a current standard way to measure skin moisture including subepidermal moisture. However, it is a contact single-point measurement technique, which may suffer from operator inconsistency.

[0055] Near-Infrared spectroscopy (NIR) reflectance can be used to determine water content in the skin. Water spectrum dominating NIR spectra with overtone bands of the O-H bonds with peak absorption at 760 nm, 970 nm (due to the second overtone of the O-H stretching band), 1190nm (the combination of the first overtone of the O-H stretching and the O-H bending band), 1450 nm (first overtone of the OH-stretching band and a combination band), and 1940 nm (combination of the O-H stretching band and the O-H bending band). [Luck 1974]

[0056] Water absorption at 1440nm is 30 times stronger than at 1190nm, which in turn is more than two times stronger than absorption at 970nm. Thus, 1440nm and 1920nm wavelengths are suitable for imaging of water content in uppermost skin layers (stratum corneum), while 970nm and 1190nm can be used for water content determination and imaging in deeper skin layers, including epidermis, dermis (1190nm) and even subcutaneous tissues (970nm).

[0057] Bacteria presence can significantly impact tissue health and wound healing progress. Bacteria are always present in the wound. There are several distinct levels of bacterial burden in the wound: contamination, colonization, and infection.

[0058] Wound contamination is the presence of non-replicating organisms in the wound. All chronic wounds are contaminated. These contaminants come from the indigenous microflora and/or the environment.

[0059] Wound colonization is the presence of replicating microorganisms adherent to the wound in the absence of injury to the host. Most of these organisms are normal skin flora; such as *Staphylococcus epidermidis,* another coagulase negative Staph., *Corynebacterium* sp., *Brevibacterium* sp., *Proprionibacterium acnes*, and *Pityrosporum* sp..

[0060] Wound Infection is the presence of replicating microorganisms within a wound that cause host injury. Primarily, pathogens are of concern here, such as *Staphylococcus aureus,* Beta-hemolytic *Streptococcus (S. pyogenes, S. agalactiae), E. coli, Proteus, Klebsiella,* anaerobes, *Pseudomonas, Acinetobacter,* and *Stenotrophomonas (Xanthomonas).*

[0061] Contamination and colonization by low concentrations of microbes are considered normal and are not believed to inhibit healing. However, critical colonization and infection are associated with a significant delay in wound healing.

[0062] Clinical testing for bacterial presence includes analysis of swabs from the tissue. In addition to long processing time (several days), these tests suffer from possible contamination during swabbing and randomness in the selection of swabbing sites. Thus, current clinical diagnostics techniques are sub-optimal.

[0063] Portable fluorescence imaging can be used for visualization of bacterial presence. It was found that while excited at 405nm, *S. aureus*, *S. epidermidis*, *Candida*, *S. marcescens, Viridans streptococci, Corynebacterium diphtheriae, S. pyogenes, Enterobacter*, and *Enterococcus* produced red (610-640nm) fluorescence from porphyrin [Kjeldstad 1985] while *P. aeruginosa* produced a bluish-green (450-520nm) fluorescence from pyoverdin [Cody 1987]. Thus, fluorescence imaging can be used to assess bacterial burden and guide swabbing and wound cleansing.

[0064] Thus, multispectral/hyperspectral-based reflectance imaging, fluorescence imaging or their combination can provide valuable insights on tissue health and wound healing potential.

[0065] Embodiments described herein can provide a tool for tissue imaging.

[0066] Fig. 1 depicts a view of an example tissue visualization system 100 that connects to tissue imaging systems 105 via network 110.

[0067] Tissue imaging system 105 is a device for visualization of abnormalities of blood circulation, moisture distribution, and bacterial burden in surface tissues (skin or mucosa). For example, the device can be used for identification of ischemic or angiogenic conditions. It can be used by primary care physicians, nurses, or even patients themselves in any type of settings: inpatient, outpatient, long-term facilities, patient's home, and so on, thus allowing earlier identification of problematic wounds. Tissue imaging system 105 may comprise a computing device 108 which may comprise a mobile device 108, processor(s) 108a, non-transitory computer readable storage medium or memory 108b, image capturing unit 103, and illumination unit 104. Memory 108b may comprise computer executable instructions comprising tissue visualization app 112.

[0068] Computing device 108 may be an off-the-shell computing device (for example, a mobile device, smartphone, tablet, laptop, a personal computer) or a custom-built computing device. In an example embodiment, computing device 108 comprises a smartphone.

[0069] Tissue visualization app 112 coordinates image capturing unit 103 and illumination unit 104 during data capturing, process images, display results on computing device 108, and store and/or transmit data to tissue visualization system 100.

[0070] Image capturing unit 103 may comprise an internal (built-in to computing device 108) or external device capable of capturing images. In an example embodiment, image capturing unit 103 comprises a 3 channel (RGB) or 4 channel (RGB-NIR) camera.

[0071] Illumination unit 104 may comprise an internal (built-in to computing device 108) or external device (e.g., multispectral flash) capable of illuminating a target area with required intensity, wavelengths, and duration.

[0072] Example tissue imaging system 105 architectures are presented on Fig.1. In some embodiments, the tissue imaging system 105 can be a single device. In some embodiments, the tissue imaging system 105 can have two separate parts (e.g., image capturing unit 103 built-in to computing device 108 and a separate illumination unit 104, or illumination unit 104 built-in to computing device 108 (e.g., a mobile device 108) and a separate image capturing unit 103). In some embodiments, tissue imaging system 105 can have three separate parts (for example, a computing device 108, a separate image capturing unit 103, and a separate illumination unit 104). The separate components of tissue imaging system 105 may communicate by known wired or wireless communications protocols.

[0073] In an example embodiment, illumination unit 104 can be a device attached (e.g., clip-on or by compression clip) to a computing device 108, such as a mobile device or smartphone.

[0074] In some embodiments,illumination unit 104 can be connected or synchronized with the tissue visualization application 112 (installed on or otherwise accessible by computing device 108) for example by known wireless connections (for example, Bluetooth™), optic or optoelectric coupling, or wired connection. In some embodiments, the illumination unit 104 can be triggered manually, and the visualization application 112 recognizes the light sequence and synchronizes image capturing.

[0075] In some embodiments, the image capturing unit 103 can connect to the tissue visualization application 112 (installed on or otherwise accessible by computing device 108 (e.g., a mobile device 108)) for example by known wireless connections (for example, Bluetooth™), optic or optoelectric coupling, or wired connection.

[0076] The tissue visualization application 112 can, in turn, be connected to tissue visualization system 100 (which may comprise, e.g., a backend server). The tissue visualization system 100 can collect data from tissue visualization applications 112 of tissue imaging systems 105, via network 110. The tissue visualization system 100 can transmit the data (or transformations and aggregations of the data) to user device 102, which may comprise any device with computer processing capability (e.g., computer, laptop, tablet, or smartphone) for use by a user (e.g. a physician or other user). Thus, a qualified specialist may review the data collected by tissue visualization system 100 from one or more tissue imaging systems 105 used to capture image(s) in a different location by, e.g., a frontline health practitioner (e.g., nurse) or patient. This may facilitate early diagnostic by the physician.

[0077] Tissue imaging system 105 can capture measurement data as images of a patient's tissue. The visualization application 112 can extract visualizations of tissue health indicators from the measurement data. The visualization application 112 can generate one or more interface elements corresponding to the visualization of tissue health indicators. The interface elements populate an interface for display on the computing device 108 (e.g., a mobile device 108).

[0078] In some embodiments, the computing device 108 can connect to a tissue visualization system 100 to transmit the measurement data and the visualization of tissue

health indicators, for example. The tissue visualization system 100 can aggregate the measurement data and the visualization of tissue health indicators from multiple tissue imaging systems 105. The tissue visualization system 100 can process and store the measurement data and the visualization of tissue health indicators.

[0079] In some embodiments, tissue imaging system 105 can connect to a user device 102. In some embodiments, the computing device 108 (e.g., a mobile device 108) with tissue visualization app 112 can receive and aggregate measurement data from multiple tissue imaging system(s) 105, and generate the visualization of tissue health indicators for transmission to tissue visualization system 100. The tissue visualization system 100 can aggregate the measurement data and the visualization of tissue health indicators from multiple tissue imaging systems 105.

[0080] The tissue visualization system 100 receives imaging data from the tissue imaging system(s) 105 to generate a visualization of tissue and detect wounds and abnormalities. The tissue visualization system 100 and tissue imaging system(s) 105 connect to other components in various ways including directly coupled, and indirectly coupled via network 110. Network 110 (which may comprise multiple communications networks) is capable of carrying data and can involve wired connections, wireless connections, or a combination thereof. Network 110 may involve different network communication technologies, standards, and protocols.

[0081] Fig. 2 depicts a view of an example tissue visualization system 100 according to some embodiments, interfaced with system components.

[0082] Tissue visualization system 100 receives imaging data from the tissue imaging system 105 via data I/O unit 218. Data I/O unit 218 facilitates transmission of data to data processing unit 220. Data processing unit 220 processes data received from the data I/O unit 218 or one or more databases 224. For example, data processing unit 220 can apply one or more algorithms or extract data that may be used for, or that may facilitate the visualization or processing related to detection of problematic wounds or abnormalities of blood circulation, for example, in surface tissues. Data processing unit 220 can extract, create, and/or aggregate from that data a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacteria presence, and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues.

[0083] Data processing unit 220 can receive, via data I/O unit 218 and network 110, instructions for computation from one or more external systems 106, user device 102, tissue imaging system 105, and/or tissue visualization app 112. The instructions for computation can be used by data processing unit 220 to facilitate the extraction, creation, and/or aggregation of data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues. In some embodiments, data processing unit 220 can process imaging data to prepare the data for presentation via the interface unit 222 in an appropriate form or to prepare the data for transmission to an external system 106, user device 102, and/or tissue imaging system 105 to be presented in an appropriate form.

[0084] Data processing unit 220 can receive data or processed data from aggregation unit 226 and may extract, create, and/or aggregate from that data, data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues. The map, visualization, or other indication that can be extracted, created, and/or aggregated by data processing unit 220 can reflect imaging data or measurements corresponding to a plurality of patients. The data processed by data processing unit 220 may be imaging data collected at one or more tissue imaging systems 105 and/or one or more user devices 102. The data processed by data processing unit 220 may be measurement data reflecting one or more images of a patient's tissue.

[0085] Aggregation unit 226 can receive via data I/O unit 218 and/or one or more databases 224 imaging data corresponding to a plurality of patients, tissue imaging systems 105, or user devices 102. Aggregation unit 226 can aggregate or modify the data by applying instructions for computation, and so may comprise one or more processors. Aggregation unit 226 can cause the aggregated or modified data to be transmitted to data processing unit 220 where the data can be processed to prepare the data for presentation via interface unit 222 in an appropriate form or to prepare the data for transmission to an external system 106, user device 102, and/or tissue imaging system 105 to be presented in an appropriate form.

[0086] Aggregation unit 226 can receive processed data from data processing unit 220 corresponding to a plurality of patients, tissue imaging systems 105, or user devices 102.

Aggregation unit 226 can aggregate or modify the processed data by applying the instructions for computation. Aggregation unit 226 can cause the aggregated or modified data to be transmitted to data processing unit 220 where the data can be further processed to prepare the data for presentation via interface unit 222 in an appropriate form or to prepare the data for transmission to an external system 106, user device 102, and/or tissue imaging system 105 to be presented in an appropriate form.

[0087] Aggregation unit 226 can receive via data I/O unit 218 and instructions for computation from one or more external systems 106, user device 102, tissue imaging system 105, and/or tissue visualization app 112. The instructions for computation can be used by aggregation unit 226 to facilitate aggregation of imaging data corresponding to a plurality of patients.

[0088] Tissue visualization system 100 can receive imaging data, for example, aggregate imaging data, from computing device 108 (e.g., a mobile device 108) via data I/O unit 218. Tissue visualization system 100 can receive imaging data, for example, aggregate imaging data, from external systems 106 via data I/O unit 218. Tissue visualization system 100 can receive computer instructions for processing or computation from external systems 106. External systems 106 can store, cause to be stored, and/or receive data from one or more external databases 216.

[0089] Aggregation unit 226 can receive via data I/O unit 218 and network 110 the instructions for computation from one or more external systems 106, user device 102, tissue imaging system 105, and/or tissue visualization application 112.

[0090] Tissue visualization system 100 can be associated with one or more databases or data storages 224, for example, one or more local databases. The one or more databases 224 can store or process data received or transmitted by data I/O unit 218, data processing unit 220, and/or aggregation unit 226. The data stored in the one or more databases 224 can be accessed by various units, including data I/O unit 218, data processing unit 220, and/or aggregation unit 226. For example, data I/O unit 218 may cause database 224 to store data received via network 110 and/or from user device 102, external systems 106, tissue imaging system 105, and/or tissue visualization app 112. Data processing unit 220 and aggregation unit 226 can cause data to be retrieved from database 224, for example, before processing or aggregating the data.

[0091] Data processing unit 220 can cause data to be stored in database or data storage 224 after it processes the data by applying instructions or extracting data that may be used for or facilitate the visualization or processing related to detection of problematic wounds or abnormalities of blood circulation in surface tissues. Data processing unit 220 can retrieve the processed data from database or data storage 224 and cause the processed data to be transmitted to the interface unit 222 or network 110, for example, for presentation to a patient or physician using user device 102, 105 or 106, for example.

[0092] Data processing unit 220 may cause data to be stored in database or data storage 224 after it extracts, creates, and/or aggregates data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues.

[0093] Data processing unit 220 may use Machine Learning (including supervised ML and unsupervised ML) to extract information from collected images and other data. In particular, data processing unit 220 can build and train models, which can discriminate between various conditions and provide users with additional information. In some embodiments, data processing unit 220 uses convolutional neural networks for automatic or semi-automatic detection and/or classification of the skin or wound conditions. In some embodiments, ML models built and trained using other tools may be deployed to data processing unit 220 for image/data detection/classification, such as from an external system 106.

[0094] Aggregation unit 226 can cause data to be stored in database 224 after it aggregates imaging data or processed data that corresponds to a plurality of patients and/or user devices 102. Aggregation unit 226 can retrieve the aggregated data from one or more databases 224 and cause the aggregated data to be transmitted to the interface unit 222 or network 110, for example, for presentation to a patient or physician using user device 102, 105 or 106, for example.

[0095] Tissue visualization system 100 can cause data to be displayed on interface unit 222, for example, aggregated and/or processed data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health in surface tissues. Patients and physicians can engage with an interface unit to view or analyze the indicia.

[0096] Tissue visualization system 100 can cause data, for example, aggregated data, processed data, imaging data, and/or data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health in surface tissues, to be transmitted to one or more external systems 106, such as via network 110.

[0097] For example, tissue visualization system 100 can receive imaging data from a plurality of tissue imaging systems 105, process and/or aggregate the data using data processing unit 220 and/or aggregation unit 226, and cause the data to be routed, via one or more networks 110, to, e.g. the appropriate physician (e.g., family doctor) for evaluation. The physician may be engaged with a user device 102, an external system 106, or a tissue imaging system 105.

[0098] A user device 102 may receive, process, and/or aggregate data from a plurality of tissue imaging systems 105 and/or corresponding to a plurality of patients or tissue measurements. User device 102 may receive instructions for computation from one or more external systems 106 or tissue imaging systems 105.

[0099] Tissue visualization system 100 can connect to various components, including user device 102, tissue imaging system 105, external systems 106, external database 216, in various ways including directly coupled and indirectly coupled via network 110 (which may comprise multiple networks). Each of these components can connect to each other in various ways including directly coupled and indirectly coupled via network 110 (or multiple networks).

[00100] Fig. 3 depicts a view of an example of tissue imaging system 105 comprised of the illumination unit 104 and computing device 108 (e.g., a mobile device 108) comprising an internal image capturing unit 103 and installed tissue visualization app 112, according to some embodiments.

[00101] A tissue imaging system 105 is associated with an image capture unit 103. The image capture unit 103 may comprise a smartphone camera (front or back), for example.

[00102] A computing device 108 (e.g., a mobile device 108) is associated with a display interface 318. The display interface 318 can be a screen or viewfinder, for example. In some embodiments, a computing device 108 (e.g., a mobile device 108) is associated with

an app I/O unit 322 that may facilitate data transmission between an illumination unit 104 and the computing device 108.

[00103] An illumination unit 104 may be associated with a computing device 108, for example, through a physical connector 302 that attaches the illumination unit 104 to the computing device 108, such as mobile device 108. An illumination unit 104, which acts as an external flash-generating device, is associated with a lighting unit 300, which may include multiple light sources 300. The light units 300 may be arranged in a circle on illumination unit 104, for example. In an example embodiment, light units 300 are arranged in a circular configuration around a central aperture.

[00104] In some embodiments, an I/O unit 304 associated with the illumination unit 104 may facilitate data transmission between the illumination unit 104 and the computing device 108. For example, I/O unit 304 may send and receive data from an app I/O unit 322. I/O unit 304 and app I/O unit 322 may implement connectivity via Bluetooth, a cable (e.g., USB, lightning, audio jack), WiFi, near-field communication, optic or optoelectronic coupling, or other means. This communication can facilitate synchronization of the lighting unit 300 and the data capture by image capture unit 103, for example, in accordance with an illumination schema that can account for various types of external illumination.

[00105] A controller 301 causes light sources to flash in a predetermined fashion. The controller 301 can receive commands from I/O unit 304 or be triggered manually (e.g., using a button). The controller 301 can be based on any type of general-purpose microprocessor or microcontroller, a digital signal processing (DSP) processor, an integrated circuit, a central processing unit (CPU), a graphics processing unit (GPU), a field programmable gate array (FPGA), a reconfigurable processor, a programmable read-only memory (PROM), or any combination thereof. In an example embodiment, the controller 301 is based on a microcontroller.

[00106] In some embodiments, the lens 307 covering the light sources 300 can be used to homogenize the light distribution on the target area. In an example embodiment, the Fresnel lens is used. The focal length of the lens can be chosen in the range 80-120% of the working distance between the illumination unit 104 and the target area. In the preferred embodiment, the focal length of the lens is equal to the working distance. Such a focal length tends to create a homogeneous illumination light distribution on the target area, which tends to result

in more optimal use of dynamic range and higher accuracy of measurements on periphery of the target area.

[00107] For bacterial burden measurements, the emission filter 305 covers the image capturing unit 103 (e.g., the camera of a smartphone) to block the excitation illumination at 405±10nm. In an example embodiment, the emission filter is attached to the illumination unit 104. In some embodiments, the emission filter 305 is a long pass filter with cut-on wavelength 450±25nm. In some embodiments, the emission filter is a band pass filter with the transmission in the 425-750nm range, which has the lower cut-on wavelength in the 450±25nm range.

[00108] Computing device 108 (e.g., a mobile device 108) supports a tissue visualization application 112. Computing device 108 may run on any suitable operating system such as iOS, Android, or Windows. The tissue visualization app 112 can help position the computing device, e.g. a smartphone, at a proper distance to a target area; can synchronize flashes from an illumination unit 104 with the image capturing unit 103; can cause or coordinate the capture of a set of images; can cause or facilitate local processing of the images or of data captured; can cause capturing target area info (e.g., location, laterality, description, wound size, tissue type, patient ID, etc.); can cause or facilitate the extraction, creation, and/or aggregation of data providing a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health in surface tissues; can cause or facilitate storing data on computing device 108; and can cause or facilitate data to be transmitted over one or more networks 110.

[00109] The tissue visualization app 112 includes a positioning unit 324, pre-processing unit 326, calibration unit 328, and app processing unit 330.

[00110] Positioning unit 324 can cause or facilitate the positioning of the image capture unit 103 in relation to an area of patient tissue targeted for measurement.

[00111] For example, in some embodiments, positioning unit 324 can use a reference (or self-reference) object (e.g., a white circle, square, rectangle, or another shape, colour, or object) on the target area, where the reference (or self-reference) object and target area can be imaged through a viewfinder or screen associated with the, for example, mobile device 108. In some embodiments, the positioning unit 324 can recognize the reference object and cause an overlay to be presented on the display interface 318.

[00112] In some embodiments, the overlay can be marks, lines, arrows, shapes, and/or other attributes that can be used by a person engaged with the display interface 318 to move the computing device 108 (e.g. mobile device 108), for example, forwards and/or backward to create appropriate positioning of the image capture unit 103. The tissue visualization app 112 can adjust the presentation of the overlay on the display interface 318 in relation to the presentation of the reference object or tissue on the display interface 318. This may help guide the user's movement of the image capture unit 103 or computing device 108 (e.g., a mobile device 108) to achieve proper positioning of the image capture unit 103 or computing device 108 (e.g., mobile device 108) in relation to the area of patient tissue targeted for measurement.

[00113] In some embodiments, the overlay presented on the display interface 318 can be of a predetermined size and presented at predetermined locations on the display interface 318.

[00114] In some embodiments, positioning unit 324 can use the size of the reference object to trigger automatic data capturing when the computing device 108 (e.g. mobile device) or image capturing unit 103 is at a certain distance from the target area.

[00115] In some embodiments, positioning unit 324 can guide a user to move the computing device 108 (e.g. mobile device), for example, forwards and/or backward to create appropriate positioning of the image capture unit 103, by graphical, text or voice commands.

[00116] In some embodiments, reference objects may be used to facilitate calculation of a distance from a wound and/or to rescale images or measurement data.

[00117] In some embodiments, image capture unit 103 may be positioned at a proper distance from a target area, for example, a wound, by other means such as using a rangefinder or ruler.

[00118] The tissue visualization app 112 may help control the illumination of the patient tissue targeted for measurement and/or the illumination of one or more images captured by image capture unit 103 to help ensure the illumination is stable and/or predictable. The intensity of illumination may depend on the distance of the image capture unit 103 to the target area and the stability of, for example, intensity of the light source, e.g. LED, which may degrade with time or within a battery cycle. Control of such factors may be facilitated by pre-processing unit 326. For example, the tissue visualization app 112 may use a self-reference object (e.g., white or gray circle) that is placed within a target area to measure the

intensity of each wavelength in each flash and recalibrate each measurement accordingly. A single measurement can include multiple flashes and wavelengths.

[00119] In some embodiments, the pre-processing unit 326 can compare the intensity of a self-reference object in the target image with the intensity of the same region in the reference image and uses the ratio between the two to scale the intensity of the target image pixel-by-pixel.

[00120] For reflectance images, app processing unit 330 can process image data captured by image capture unit 103 and pre-processed by pre-processing unit 326. For example, the user or app processing unit 330 can compare one or more images or patient measurements of a suspicious area to one or more images or patient measurements of a non-affected area.

[00121] An observation may consist of one or more measurements on a patient. The one or more images or patient measurements of a non-affected area (control sites) can be used to establish a baseline for a particular patient. Ideally, one can select a control site as a spot with intact skin symmetrical with respect to the spinal cord (e.g. on another extremity) to the suspicious area (this may be another extremity; for example, if the left ankle of a person is affected, then the right ankle may be selected as the control site). However, if it is not possible (e.g., limb amputation or widespread ulcers), then other locations (e.g., antecubital fossa) can be used as a control site. In the case of a single measurement (e.g., suspicious area only), the suspicious area readings can be compared with an area on the same image distant from the suspicious area.

[00122] In some embodiments, tissue visualization app 112 can compare an image of a suspicious area to one or more images of control sites. The tissue visualization app 112 can process an image and can also operate in video mode to process a series of images or video frames.

[00123] App processing unit 330 can use the data captured by image capture unit 103 to facilitate the extraction, creation, and/or aggregation of data providing a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacteria presence, and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues.

[00124] The outcome of the system can be a false color or grayscale 2D map of tissue health indicators. These maps can be presented via the display interface 318 and/or transmitted over one or more networks 110, for example, to a tissue visualization system

100 or a user device 102. For example, levels of oxygenation and perfusion can highlight areas with abnormal blood supply, namely ischemic (significantly reduced perfusion and oxygenation) and angiogenic (increased perfusion) areas. A trained physician will be able to interpret these 2D maps to assess the significance of findings and decide on next steps, for example, requesting further study, monitoring progress, or dismissing the matter.

[00125] App processing unit 330 can cause the processed data to be presented via display interface 318 and/or transmitted over a network 110.

[00126] In some embodiments app processing unit 330 can use Machine Learning (ML)(including supervised ML and unsupervised ML) to extract information from collected images and other data. In particular, app processing unit 330 can build and train models, which can discriminate between various conditions and provide users with additional information. In some embodiments, the app processing unit 330 uses convolutional neural networks for automatic or semi-automatic detection and/or classification of the skin or wound conditions. In some embodiments, ML models can be built and trained using other tools (e.g., the data processing unit 220) and deployed to app processing unit 330 for image/data detection/classification.

[00127] Fig. 4 is a flowchart of an example method for capturing measurements and visualizing tissue according to some embodiments.

[00128] At 402, a computing device 108 (e.g. a mobile device 108) is positioned at a proper distance (working distance) in relation to an area of tissue (e.g., using a positioning unit 324). In some embodiments, the computing device 108 or image capturing unit 103 is positioned 10-30cm from the tissue. In an embodiment, the image capturing unit 103 is positioned 10-15cm from the tissue.

[00129] At 404, image capture unit 103 in conjunction with illumination unit 104 captures a measurement of tissue according to an illumination schema.

[00130] At 406, in some embodiments, pre-processing unit 326 preprocesses the measurement data by a) registering (aligning) images to avoid camera motion artifacts, b) subtracting image with no illumination from images with illumination to account for the presence of an ambient light.

[00131] In some embodiments, the step 406 may include any or all additional steps: c) recalibrating each measurement accordingly in order to control parameters related to the intensity of illumination, d) dividing the intensity images on reference images to obtain

normalized images, e) flattening the images. In other embodiments, the filtering and frequency domain processing (e.g. fast Fourier transformation) may be used additionally for denoising.

[00132] Recalibration of each measurement using a self-reference object may take into account any possible drift or degradation of illumination light intensity, which will tend to improve the quality of results.

[00133] Dividing the intensity images on reference images may take into account the heterogeneity of illumination light distribution on a target area, resulting in normalized images that tend to improve quality of results

[00134] Imaging of body parts with high curvature (for example, heels or toes) can pose a significant clinical challenge. Different parts of the target area are on different distance from the illumination unit and the camera, and since the camera registers light intensity that depends on that distance, the curvature(s) can negatively affects accuracy of measurements or may produce erroneous results. In an embodiment, the step of flattening images is to take into account the reflection of light from curved surfaces. This can be achieved by plurality of methods. In some embodiments, approximation of the shape of the body part and rescaling normalized image to compensate for these deviations from the working distance is used. In other embodiments, shape fitting (for example, spherical, ellipsoidal, or cylindrical) may be used.

[00135] In some embodiments, registration (alignment) of images can be done using phase correlation or block matching algorithms (e.g., using a self-reference object).

[00136] In some embodiments, recalibration can be done by pre-processing unit 326 using a self-reference object to measure the intensity of each wavelength in each flash.

[00137] In some embodiments, any or all steps after the step 406 can be skipped.

[00138] In some embodiments, app processing unit 330 can cause transmission over network 110 of data, such as pre-processed images after step 406. In this case, upon receipt of the data, data processing unit 220 of tissue visualization system 100 may extract and visualize tissue health indicators.

[00139] At 408, app processing unit 330 processes the images to extract information, such as concentrations of tissue chromophores. In some embodiments, app processing unit 330 extracts indications of oxyhemoglobin and deoxyhemoglobin. In some embodiments, in addition to oxy- and deoxyhemoglobin, app processing unit 330 extracts the indication of

melanin. In some embodiments, app processing unit 330 additionally extracts water content indications.

[00140] In some embodiments, indications of oxyhemoglobin, deoxyhemoglobin, and water can be extracted directly from the obtained images using a Beer-Lambert or modified Beer-Lambert model.

[00141] In an exemplary embodiment, an additional step is taken to extract tissue absorption coefficients from the obtained images using a tissue optical model (or a tissue light propagation model). A tissue optical model would link the reflected signal with optical properties of the tissues, namely coefficients of absorption and scattering. Various light propagation models (for example, diffuse approximation model) can be used to extract such relationship. The appropriate model can be selected based on acceptable accuracy vs. computational intensity considerations.

[00142] In some embodiments, the least squares fitting, or LSF (with or without regularization) can be used to extract the concentration of each chromophore. In some embodiments, LSF extracts indications of chromophores directly from the obtained images. In an exemplary embodiment, LSF is applied after extraction of indication of absorption coefficient using the tissue light propagation model.

[00143] In other embodiments, other curve fitting methods (for example, least absolute deviations) may be used to extract indications of chromophores.

[00144] At 410, app processing unit 330 extracts indicia that allows the tissue health indicators of the imaged tissue to be presented. For example, the indicia may allow the oxygenation and/or perfusion to be presented as a map.

[00145] In some embodiments, app processing unit 330 can send to the network 110 data from the step 408. In this case, data processing unit 220 will visualize tissue health indicators.

[00146] At 412, tissue visualization app 112 generates a visualization of the tissue health indicators of the imaged tissue and causes the visualization to be presented via the display interface 318.

[00147] In some embodiments, computing device 108 comprises a graphical user interface displayed on display interface 318 by app processing unit 330. At 414, the tissue visualization app 112 collects data related to the image (e.g., patient ID, laterality, location,

diagnosis, comments, measurements). In some embodiments, a speech-recognition system is used to collect data.

[00148] At 416, tissue visualization app 112 causes a results file of the data or indicia to be stored and/or transmitted, for example, over a network 110 to a user device 102, tissue visualization system 100, and/or external system(s) 106.

[00149] Fig. 5 is a view of an example interface for visualizing tissue according to some embodiments.

[00150] In some embodiments, a color bar 502 can be implemented to guide the user when viewing the image.

[00151] In some embodiments, the averaging tool 504 (which averages tissue health index within a defined area) can be implemented to assist the user. In some embodiments, the averaging tool 504 can be a small circle on a touchscreen, such as the relatively small area shown in Fig. 5.

[00152] Fig. 6 is a schematic diagram of an exemplary embodiment of computing device 108. As depicted, computing device 108 (e.g. mobile device 108) includes at least one processor 602, memory 604, at least one I/O interface 606, and at least one network interface 608.

[00153] Each processor 602 may be, for example, any type of general-purpose microprocessor or microcontroller, a digital signal processing (DSP) processor, an integrated circuit, a central processing unit (CPU), a graphics processing unit (GPU), a field programmable gate array (FPGA), a reconfigurable processor, a programmable read-only memory (PROM), or any combination thereof.

[00154] Memory 604 may include a suitable combination of any type of computer memory that is located either internally or externally such as, for example, random-access memory (RAM), read-only memory (ROM), compact disc read-only memory (CDROM), electro-optical memory, magneto-optical memory, erasable programmable read-only memory (EPROM), and electrically-erasable programmable read-only memory (EEPROM), Ferroelectric RAM (FRAM), or the like.

[00155] Each I/O interface 606 enables computing device 108 (e.g., a mobile device 108) to interconnect with one or more input devices, such as a keyboard, mouse, camera, touch screen, and a microphone, or with one or more output devices such as a display screen and a speaker.

[00156] Each network interface 608 enables computing device 108 (e.g., a mobile device 108) to communicate with other components, to exchange data with other components, to access and connect to network resources, to serve applications, and perform other computing applications by connecting to a network (or multiple networks) capable of carrying data.

[00157] Computing device 108 is operable to register and authenticate users (using a login, unique identifier, and password, for example) prior to providing access to applications, a local network, network resources, other networks, and network security devices. Computing devices 108 may serve one user or multiple users.

[00158] Fig. 7 is an example of an illumination and image capturing schema according to some embodiments. Other illumination and image capturing schemas can be used. In order to account for external illumination, the example image capturing/illumination schema in Fig.7 has been developed.

[00159] Fig. 7 plots the flash 702 coordinated by illumination unit 104, as a function of time. Computing device 108 (e.g., a mobile device 108) uses the synchronization of flash if the illumination unit 104 is used to provide the external flash. As shown at 702, the illumination schema (cycle) consists of m flashes (with m=2 in the example of Fig. 7) and one period without flash, with $n/4 \leq m \leq n$, where n is the number of wavelengths. Cycles can be repeated continuously during video mode capturing.

[00160] The exposure time (T) for each frame (in milliseconds) can be selected as $T=k/2*f$, where k is an integer, and f is the utility frequency for a particular country in Hz (e.g., 60Hz for North America, 50Hz for Europe). In a video mode, the framerate can be selected as $fps=2*f/k$ (e.g., 30, 24, 20, 15, 12, and 10 fps for North America and 25, 20, and 10 fps for Europe). The frame rate of 20fps (T=50ms) is an example selection. It can work without any configurations with external light sources connected to any electrical grid (50Hz or 60Hz). Other frame rates can also be used.

[00161] The duration of each flash can be T or any whole number multiple of T. This arrangement facilitates easy optical synchronization between illumination unit and image capturing unit. For example, the cycle consists of m back to back flashes with duration 2T milliseconds each, followed by no lit period 2T milliseconds long, as shown in the plot 702.

[00162] In some embodiments, computing device 108 (e.g. mobile device 108) associated with an illumination unit 104 may use the same frame to capture an image illuminated at 2,

3, or 4 wavelengths, which can be captured by different color wavelengths of an RGB camera (e.g. 480 and 660nm, which will be captured by blue and red wavelengths, respectively) or an RGB-NIR camera.

[00163] Fig. 8 is a view of example illumination units according to some embodiments.

[00164] An illumination unit 104 can be an external flash device that can be attached to a computing device 108, for example, a smartphone. In some embodiments, it can be synchronized with a tissue visualization app 112 or computing device 108 (e.g., a mobile device 108) using Bluetooth or other connectivity. In some embodiments, the illumination unit 104 can be built into a case for a computing device 108 (e.g., a mobile device 108). In some embodiments, the illumination unit 104 receives power from the computing device 108 (e.g., a mobile device 108) or an external source (e.g., wall charger).

[00165] In some embodiments, illumination unit 104 comprises a battery. The illumination unit 104 can also be chargeable using a standard micro USB port, wirelessly or by way of inductive charging.

[00166] The illumination unit 104 can be used with a front- or back camera of a mobile device 108, for example. Illumination unit view 806 illustrates an illumination unit 104 used in conjunction with a front-facing camera of a user computing device 108.

[00167] In some embodiments, the illumination unit 104 can be optimally designed to associate with a computing device 108 (e.g. mobile device 108) by way of a clip or other means 302 that can be attached to the computing device 108 (e.g. mobile device 108) with the thickness of up to 15mm, as shown in views 802 and 804.

[00168] In an example embodiment, illumination unit 104 uses a compression clip that can be attached to the computing device 108 (e.g. mobile device 108), with the thickness up to 15mm, as shown in view 802. In some embodiments, the illumination unit 104 can be mounted using a spring clip, as shown in views 804 and 806.

[00169] The illumination unit 104 can produce a sequence of flashes of predetermined length. A wavelength can refer to light sources shining at the same wavelength, or the possibility of multiple wavelengths shining in a single flash. Each of the flashes may shine at 1-4 particular wavelengths.

[00170] The illumination unit 104 can use narrow band high-efficiency light sources 300, such as LEDs. The light source in the illumination unit 104 may contain single wavelength or multi-wavelength LEDs.

[00171] As shown in view 802, the light sources 300 can be arranged in a circle, with a center close to the center of a camera 103 of computing device 108 (e.g. mobile device 108).

[00172] In some embodiments, each wavelength can consist of two or four light sources 300, arranged in a symmetrical pattern on an illumination unit 104 (e.g., every 180 or 90 degrees on a circle).

[00173] For oxygenation measurements, the illumination unit 104 can use two or more wavelengths in the range of 450-750nm. For measurements of oxygenation and perfusion and the compensation of skin color (melanin), the illumination unit 104 can use three or more wavelengths in the range of 450-750nm. In an example embodiment, 450-650nm range is used.

[00174] Wavelengths can be selected from one or more of the following regions: a) biggest discrimination in light absorption between oxy- and deoxyhemoglobin: 450-500nm and 600-750nm, b) isobestic points (e.g., 510±10nm, 525±10nm, and 590±10nm), c) largest absorption by oxy- and deoxyhemoglobin: 540-580nm.

[00175] For water content measurement in addition to two or more wavelengths in 450-750nm (or preferably 450-650nm) range a wavelength of 970±10nm is used.

[00176] For bacterial burden measurements, a wavelength of 405±10nm is used. In some embodiments, it can be combined with two or more wavelengths in 450-750nm (or preferably 450-650nm) range, which captures reflectance images.

[00177] For bacterial burden measurements, the illumination unit 104 or image capture unit 103 may contain emission filter 305. In an example embodiment, the emission filter is attached to the illumination unit 104. In some embodiments, the emission filter 305 is a long pass filter with cut-on wavelength 450±25nm. In some embodiments, the emission filter is a band pass filter with the transmission in the 425-750nm range, which has the lower cut-on wavelength in the 450±25nm range.

[00178] The illumination unit 104 can be synchronized with an image capture unit 103 of computing device 108 (e.g. mobile device 108) to produce an illumination schema. The illumination unit 104 associated with an image capture unit 103 can follow an illumination schema where each wavelength shines sequentially (n=m, where n is the number of wavelengths, m is the number of flashes in one cycle).

[00179] In some embodiments, lighting unit 300 configured to engage with a computing device 108 (e.g. mobile device 108) or image capture unit 103 may have the following example implementations:

- the lighting unit 300 may provide light from sources arranged in a circle or otherwise;
- the lighting unit 300 may use two, four or another number of light sources per wavelength;
- the lighting unit 300 may use light sources with central wavelength 405±10nm for bacteria imaging;
- the lighting unit 300 may use an additional 750-1000nm range for user devices 102 without an IR filter on camera (e.g., front-facing camera on a smartphone);
- the lighting unit 300 may use light sources with a central wavelength of 970±10nm for water imaging for user devices 102 without an IR filter on camera (e.g., front-facing camera on a smartphone);
- the illumination unit 104 and/or lighting unit 300 and a computing device 108 (e.g. mobile device 108) can be mounted on an extension device (e.g., on a selfie stick);
- the imaging unit 104 can be associated with an external lens (e.g., macro lens), emission filter, polarizer, or not.

[00180] In some embodiments, illumination unit 104, for example, including a multispectral external flash, can be operable with an image capture unit 103 or another recording device. For example, illumination unit 104 may be integrated with a personal computer, tablet, or otherwise.

[00181] The systems described tends to offer distinct advantages. For example: the flash design may be used with any computing device 108, such as a smartphone (iOS, Android, etc.) of any shape; the flash/image capturing schema, may allow measurements in any type of ambient light and with any type of smartphone; self-calibration using a self-reference object increases accuracy; proper positioning of the camera (distance from the wound) is facilitated by use of a self-reference object (e.g. a circle); and the illumination schema produces reproducible and homogeneous illumination. The above-noted expected advantages are examples of advantages and may not comprise all advantages of the present systems/devices.

[00182] The system can also tend to overcome challenges, for example, of building the flash, in the case for a smartphone, such as a challenge that each smartphone can have its

own form-factor and thus would require multiple cases to be built at least for the most popular models. Other challenges that the system may overcome, or benefits of the system, include:

- use of IR filter on some smartphone cameras. These filters, which are used to improve the quality of pictures, filter out light with wavelengths over 750nm and are being used mostly on more expensive smartphones. Typical pulse oximetry schemas employ 660 and 900nm bands. Thus, these schemas cannot be employed universally on smartphones.
- Connection to a plurality of existing EHR systems.
- Motion artifacts (e.g., due to tremor) while taking measurements.
- The flickering, high dynamic range, etc. that may result from taking images in various light conditions (e.g., indirect sunlight, office light, observation room, etc.) is combatted.
- Flickering caused by the various utility frequencies in different countries.
- Producing predictable light distribution, not very sensitive to slight misplacements of the flash or the smartphone.
- Difficulty in synchronizing the phone and external flash.
- Use of the lens (e.g., Fresnel lens) covering the light sources homogenizes the light distribution on the target area, thus extending dynamic range and increasing the accuracy of measurements.
- use of multiwavelength LEDs (e.g., RGB LEDs) creates the similar intensity distribution for each wavelength and saves space on the illumination unit.
- The intensity of illumination can vary, for example, based on the distance to a target area and the stability of LED intensity (e.g., LED intensity may change with time, temperature, or within battery cycle). In particular, the intensity of illumination light on the surface of the tissue drops as an inverse square with the distance from the illumination unit to the target area. Thus, increasing working distance by 50%, will cause drop of illumination intensity by 55%, and so the system can compensate by capturing the intensity of illumination at the revised working distance and normalizing images on these values.
- porphirin and pyoverdine have an absorption peak in Soret band, where oxyhemoglobin and deoxyhemoglobin have absorption peaks as well. The presence

of a blood component may significantly impact porphyrin/pyoverdine emission. True fluorescence intensity can be deconvoluted using known oxyhemoglobin and deoxyhemoglobin concentrations.

- Ability to change or upgrade components of the system independently. For example, a user can use his or her own smartphone as a computing device, and upgrade such device with updated versions without a necessity to buy a whole new system.

[00183] A tissue imaging system 105 can be used in a variety of applications, including in the following scenarios.

[00184] **Use case 1**: A doctor at a hospital during a physical exam of a patient in acute care has found a suspicious wound on the leg. The patient has diabetes, so the MD has a suspicion that it can be a non-healing DFU. The current standard of care for this is angiography, which is not available in his community hospital. It will cost around $20,000 for the procedure and arrangement of medical transportation to/from another hospital. However, using the device the doctor can screen the wound on the spot and see whether it is ischemic (and require angiography for proper assessment) or nonischemic (and will heal well without any extra efforts).

[00185] **Use case 2:** A family doctor during an annual checkup has found a suspicious wound on a patient's leg. The patient has diabetes, so the MD has a suspicion that it can be a non-healing DFU. The current standard of care for this is angiography. However, it can be performed in major hospitals only. It is associated with $1,500 per procedure (in the US) or waiting time (for example, 41 days in Ontario, Canada). Using the device, the doctor can screen the wound on the spot and see whether it is ischemic (and require angiography for proper assessment) or nonischemic (and will heal well without any extra efforts).

[00186] **Use case 3**: A family doctor during an annual checkup has found a suspicious wound on a patient's leg. The patient has diabetes, so the MD has a suspicion that it can be a non-healing DFU. The current standard of care for this is angiography. It can be performed in major hospitals only. It is associated with $1,500 per procedure (in the US) or waiting time (for example, 41 days in Ontario, Canada). Using the device, the doctor captures images of the wound on the spot. However, such as he does not have significant experience in wound care, he decides to send images to a podiatrist, who provides him with an assessment of whether it is ischemic (and requires angiography for proper assessment) or nonischemic

(and will heal well without any extra efforts). The doctor accordingly refers the patient to the podiatrist.

[00187] **Use case 4**: A nurse is attending a small rural community. During an exam of a patient, she has found a suspicious ulceration near the small toe. She has a suspicion that it can be a peripheral arterial disease. She uses the device to take a snapshot of the wound and sends images to a family physician (if the patient has one) or a podiatrist. The doctor reviews the images and provides guidance within a few hours. The nurse instructs the patient on further actions.

[00188] **Use case 5**: A medical nurse is attending a small long-term residence. During an exam of a patient, she has found a suspicious ulceration near the big toe. She has a suspicion that it can be a peripheral arterial disease. She uses the device to take a snapshot of the wound and sends images to a family physician (if the patient has one) or a podiatrist. The doctor reviews the images and provides guidance within a few hours. The nurse instructs the patient on further actions.

[00189] **Use case 6**: A senior with diabetes finds a suspicious cut on his heel. He is aware of the dreadful consequences of DFU, so he decides to buy the device in a drugstore. With the help of his wife he takes images of the wound and sends them to his family doctor. The doctor makes an assessment and advises the patient within a few hours.

[00190] **Use case 7**: A senior with diabetes finds a suspicious cut on her forefoot. She is aware of the dreadful consequences of DFU, and tells her concerns to her daughter. Her daughter bought a flash attachment 104 in a drugstore, attaches it to her smartphone 108, downloads the tissue visualization app 112, and takes images of the wound. As her mother does not have a family doctor, she sends the images to a podiatrist. The doctor makes an assessment and sends a referral within a few hours.

[00191] **Use case 8:** A family doctor during an annual checkup of a patient finds a suspicious mole. Using the device, he can screen the mole on the spot and see whether it is suspicious (has increased blood supply and requires additional study) or not suspicious.

[00192] **Use case 9:** The nurse in a long-term care facility checks a bed-bound patient for potential pressure ulcers. Using the device, she can screen bony prominence areas to determine if any are suspicious.

[00193] **Use case 10:** An advanced wound care nurse cleanses an existing wound. She uses the device to visualize bacterial presence and to guide debridement.

[00194] **Use case 11:** A nurse takes a swab from an existing wound. She uses the device to visualize bacterial presence and to guide swabbing.

[00195] The accuracy of measurements can be improved if the light intensity distribution produced by illumination unit 104 is known. In an example embodiment, to capture light intensity distribution produced by illumination unit 104, a reference image is used.

[00196] With reference to Fig. 9, example features used for capturing reference images are depicted. In some embodiments, the reference image can be captured by calibration unit 328 of tissue visualization app 112 and then used by the tissue imaging system 105 or tissue visualization system 100 to obtain a processed measurement 501 (an example of which is shown in FIG. 5).

[00197] The reference image is captured using a reference object 901. Reference object refers to an object with known homogeneous optical properties (e.g., spectral dependence of reflectance). Reference object 901 can be various shapes, such as a circle or rectangle. In an example embodiment, reference object 901 is a rectangle with an aspect ratio of 4:3. Various colors can be used for reference object 901, such as white or gray (for example, an 18% gray rectangle on a white background 904, such as a white sheet of paper).

[00198] In one embodiment, screen markers 902 displayed on a screen 318 of the computing device 108 (e.g. mobile device 108) can define a target area 903 which can be used to position the device an optimal distance away from the reference object 901. The computing device 108 should be positioned such that screen markers 902 line up with the reference object 901 to ensure an optimal image-capturing distance is achieved. Other distance measuring devices, such as a rangefinder or ruler, can be used to position device at the optimal distance. In an example embodiment, object recognition by tissue visualization app 112 can be used to position the device at the optimal image capturing distance.

[00199] In an example embodiment, the computing device 108 (e.g., a mobile device 108) can take the required reference image automatically upon proper placement of the device. In other embodiments, the computing device 108 takes the image upon manual user initiation. In an embodiment, upon activation of the image capture unit 103, the computing device 108 takes several images. In an example embodiment, one or more images are taken with flash, and one is taken without. Alternatively, images can be taken only with flash.

[00200] The computing device 108 (e.g., a mobile device 108) can pre-process the reference image to improve the image quality. The pre-processing may comprise the following steps: a) image registration, b) image subtraction.

[00201] In some embodiments, computing device 108 (e.g., a mobile device 108) uses image registration to reduce shake during image capturing. This can be accomplished using phase correlation or block matching algorithms.

[00202] In some embodiments, computing device 108 (e.g., a mobile device 108) uses image subtraction to remove ambient light in the image. In this case, the image without external illumination (no flash) is subtracted from images with external illumination (with flash). Image subtraction is not required if only images with flash are used.

[00203] The reference image can be stored locally on the computing device 108 (e.g. mobile device 108) or remotely, for future use.

[00204] The reference image can be captured before the first measurement and at any time thereafter. There is no need to capture reference images before every measurement.

[00205] Steps for producing measurement map 501 are now discussed, with respect to Fig. 10.

[00206] Computing device 108 (e.g. mobile device 108) is held at a specific distance away from the subject, for example a human body, in order to optimally image the area of interest.

[00207] In some embodiments, a self-reference object 1002 is used to ensure the proper distance from the human body. A self-reference object 1002 is placed within the device target area 1001 imaged by the computing device 108 (e.g., a mobile device 108). In an example embodiment, the self-reference object 1002 comprises an 18% gray circle 1-2 cm in diameter.

[00208] In some embodiments, the computing device 108 (e.g. mobile device 108) or image capturing unit 103 is moved so that a predefined screen marker 1003 is shown as the same size as self-reference object 1002 on the device target area 1001, so as to guide the user to the optimal image capturing distance.

[00209] In an example embodiment, computing device 108 (e.g., a mobile device 108) uses object recognition to trigger automatic image capturing upon a certain screen size of the self-reference object, in pixels, being achieved.

[00210] Alternatively, other means of measuring a distance, such as a rangefinder or a ruler, can be used to position the device at the proper distance from the area of interest.

[00211] Once the optimal distance from the human body is determined, computing device 108 (e.g., a mobile device 108) can take the required images. In an example embodiment, the device takes the required image automatically upon the proper placement of the computing device 108 (e.g., a mobile device 108) or image capturing unit 103. The device may take several images. In an example embodiment, one or more images will be taken with flash, and one will be taken without flash.

[00212] The device pre-processes the image in order to improve the quality of the image and measurement map 501. The pre-processing may contain the following steps: a) image registration, b) image subtraction.

[00213] In some embodiments, the device uses image registration to reduce shake. This can be accomplished through phase correlation or block matching.

[00214] In some embodiments, the device uses image subtraction to remove ambient light in the image. In this case, the image without external illumination (flash) is subtracted from images with external illumination (flash).

[00215] To further increase the quality of results, the self-calibration of each measurement using a self-reference object 1002 can be implemented. In this case the pre-processing may contain the following steps: a) image registration, b) image subtraction, c) self-calibration, and d) division on the reference image, e) flattening the images.

[00216] If the embodiment utilizes self-reference object 1002, the intensity of the image is adjusted using the self-reference object to account for any imperfections or changes in intensity. In an example embodiment, pre-processing unit 328 can compare the intensity of a self- reference object in the target image with the intensity of the same region in the reference image and use the ratio between the two to scale the intensity of the target image pixel-by-pixel.

[00217] If the embodiment utilizes previously taken reference images, the device finds the normalized image by dividing pixel-by-pixel image onto the reference image and multiplying by a known reflectance of the reference object.

[00218] In some embodiments, the tissue imaging system 105 can perform the processing of the image to obtain measurements. This can be achieved through all or some of the following steps: a) the absorption coefficient is determined from reflectance (e.g., using Beer-Lambert, or modified Beer-Lambert law); b) the chromophore concentration is determined from the absorption coefficient (e.g., using least square fitting); c) the perfusion

and oxygenation is determined from the chromophore concentration (oxygenation = oxyhemoglobin/(oxyhemoglobin+deoxyhemoglobin), perfusion= oxyhemoglobin + deoxyhemoglobin).

[00219] In some embodiments, the pre-processed measurement (normalized image) is taken on computing device 108 (e.g., a mobile device 108) and then sent through network 110 to the tissue visualization system 100.

[00220] Bacterial burden indicator can be used stand-alone or in combination with reflectance images. Porphyrin and pyoverdine have an absorption peak in the Soret band, where oxyhemoglobin and deoxyhemoglobin have absorption peaks as well. Thus, the presence of a blood component may significantly impact porphyrin/pyoverdine emission. With reference to Fig. 4, true fluorescence intensity can be deconvoluted using known oxyhemoglobin and deoxyhemoglobin concentrations found in step 410. In an example embodiment, a light source with the center wavelength of 405±10nm is used in combination with 2 or 3 wavelengths from the 450-650nm range.

[00221] Once tissue health indicators levels are found, the invention presents the color or grayscale maps through processing via tissue visualization system 100 or tissue imaging system 105. These results can be stored locally on the device or remotely. The pre-processed normalized image and the processed tissue health indicators maps can all be stored in local or remote storage.

[00222] The embodiments of the devices, systems, and methods described herein may be implemented in a combination of both hardware and software. These embodiments may be implemented on programmable computers, each computer including at least one processor, a data storage system (including volatile memory or non-volatile memory or other data storage elements or a combination thereof), and at least one communication interface.

[00223] Program code is applied to input data to perform the functions described herein and to generate output information. The output information is applied to one or more output devices. In some embodiments, the communication interface may be a network communication interface. In embodiments in which elements may be combined, the communication interface may be a software communication interface, such as those for inter-process communication. In still other embodiments, there may be a combination of communication interfaces implemented as hardware, software, and combination thereof.

[00224] Throughout the foregoing discussion, references have been made to servers, devices, systems, units, or computing devices. It should be appreciated that the use of such terms is deemed to represent one or more computing devices having at least one processor configured to execute software instructions stored on a computer-readable tangible, non-transitory medium. For example, a server can include one or more computers operating as a web server, database server, or another type of computer server in a manner to fulfill described roles, responsibilities, or functions.

[00225] Various example embodiments are described herein. Although each embodiment represents a single combination of inventive elements, all possible combinations of the disclosed elements include the inventive subject-matter. Thus, if one embodiment comprises elements A, B, and C, and a second embodiment comprises elements B and D, then the inventive subject-matter is also considered to include other remaining combinations of A, B, C, or D, even if not explicitly disclosed.

[00226] The term “connected” or "coupled to" may include both direct coupling (in which two elements that are coupled to each other contact each other) and indirect coupling (in which at least one additional element is located between the two elements).

[00227] Part of the technical solution of embodiments may be in the form of a software product (while other required aspects, for example the image capture unit 103 and illumination unit 104, necessitate hardware). The software product may be stored in a non-volatile or non-transitory storage medium, which can be a compact disk read-only memory (CD-ROM), a USB flash disk, or a removable hard disk. The software product includes a number of instructions that enable a computer device (personal computer, server, or network device) to execute the methods provided by the embodiments.

[00228] The embodiments described herein are implemented by physical computer hardware, including computing devices, servers, receivers, transmitters, processors, memory, displays, and networks. The embodiments described herein provide useful physical machines and particularly configured computer hardware arrangements. The embodiments described herein are directed to electronic machines and methods implemented by electronic machines adapted for processing and transforming electromagnetic signals which represent various types of information.

[00229] Although the embodiments have been described in detail, it should be understood that various changes, substitutions, and alterations can be made herein without departing from the scope as defined by the appended claims.

[00230] Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed, that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein, may be utilized. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

[00231] As can be understood, the examples described above and illustrated are intended to comprise examples only.

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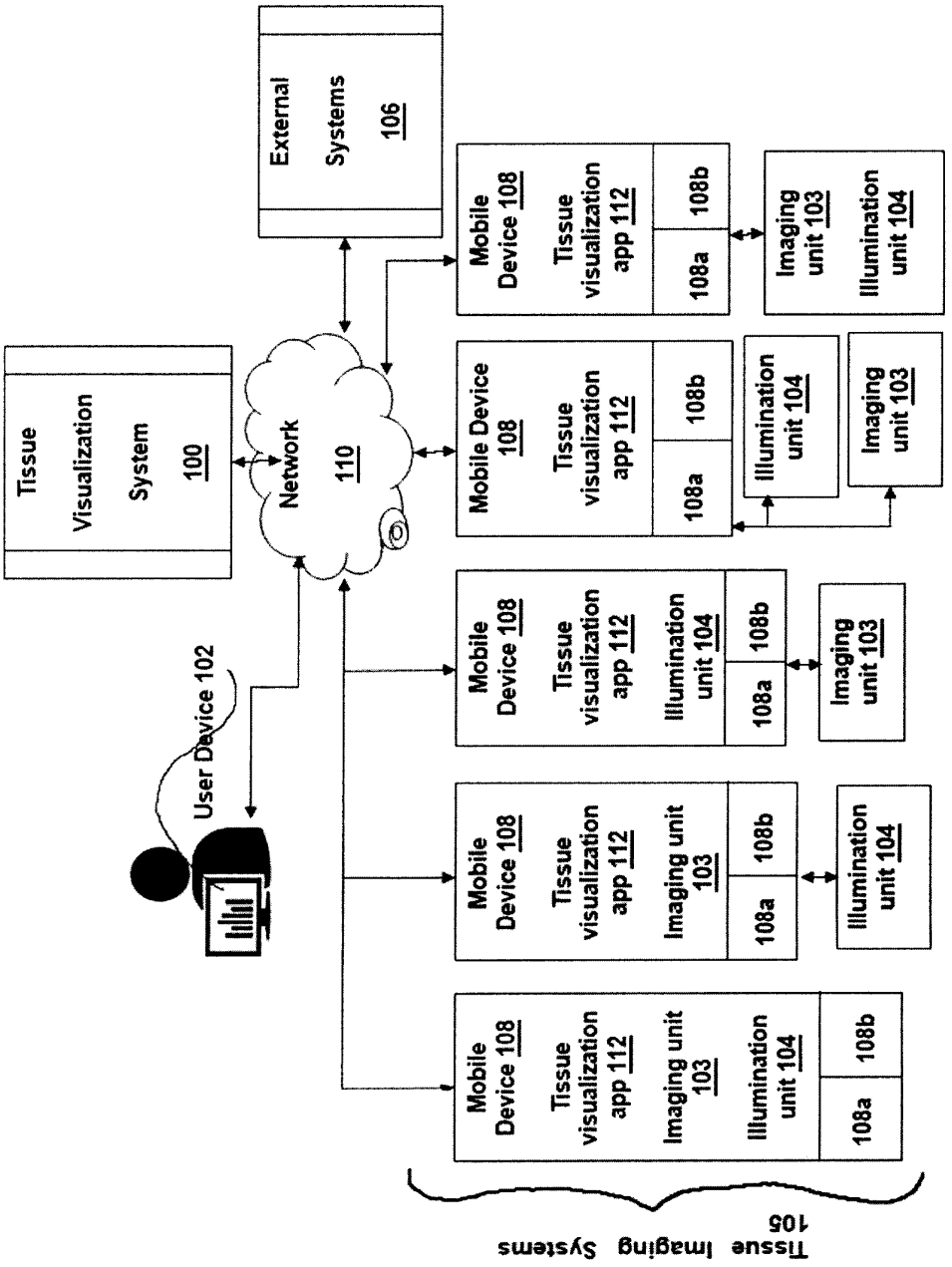
External Systems 106
Tissue Visualization System 100
Network 110
User Device 102
Mobile Device 108
Tissue visualization app 112
Imaging unit 103
Illumination unit 104
108a
108b
Tissue Imaging Systems 105

FIG. 1

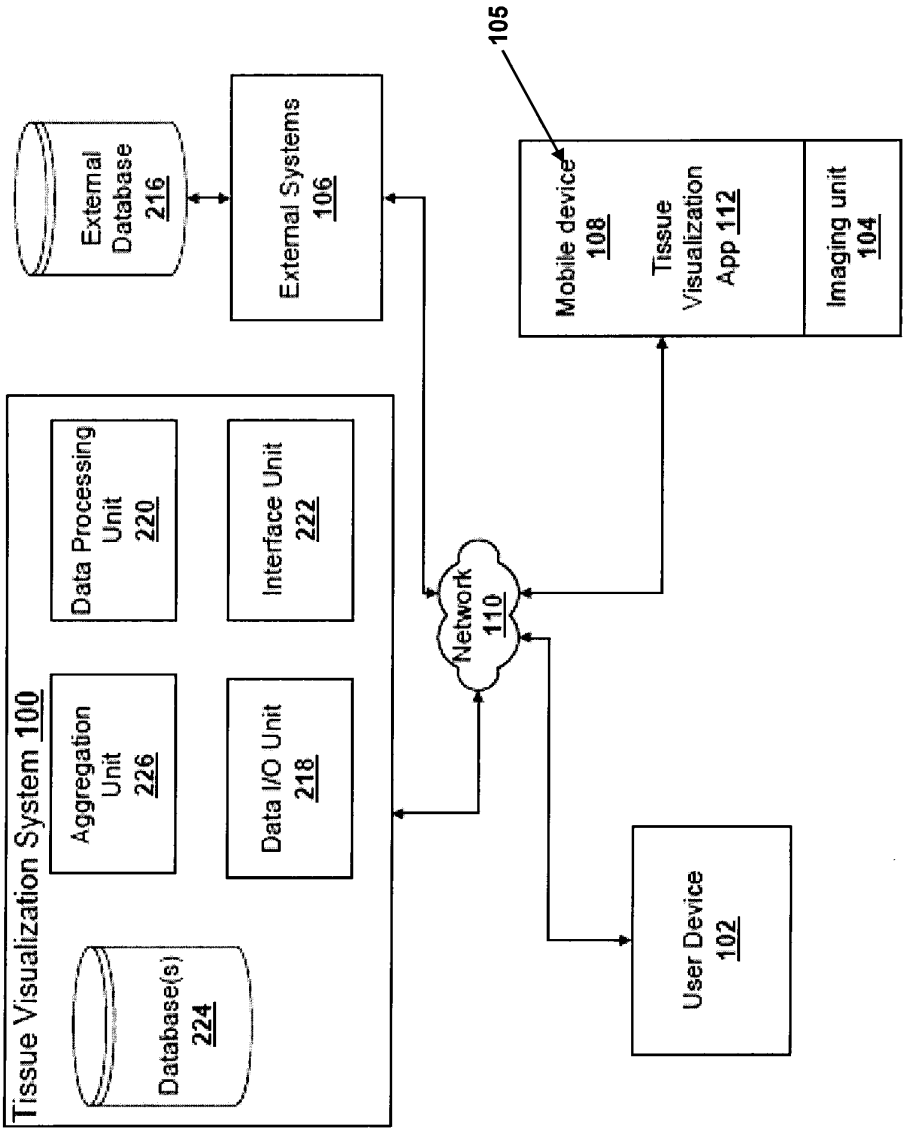
105
External Database 216
External Systems 106
Mobile device 108
Tissue Visualization App 112
Imaging unit 104
Tissue Visualization System 100
Data Processing Unit 220
Interface Unit 222
Aggregation Unit 226
Data I/O Unit 218
Database(s) 224
Network 110
User Device 102

FIG 2

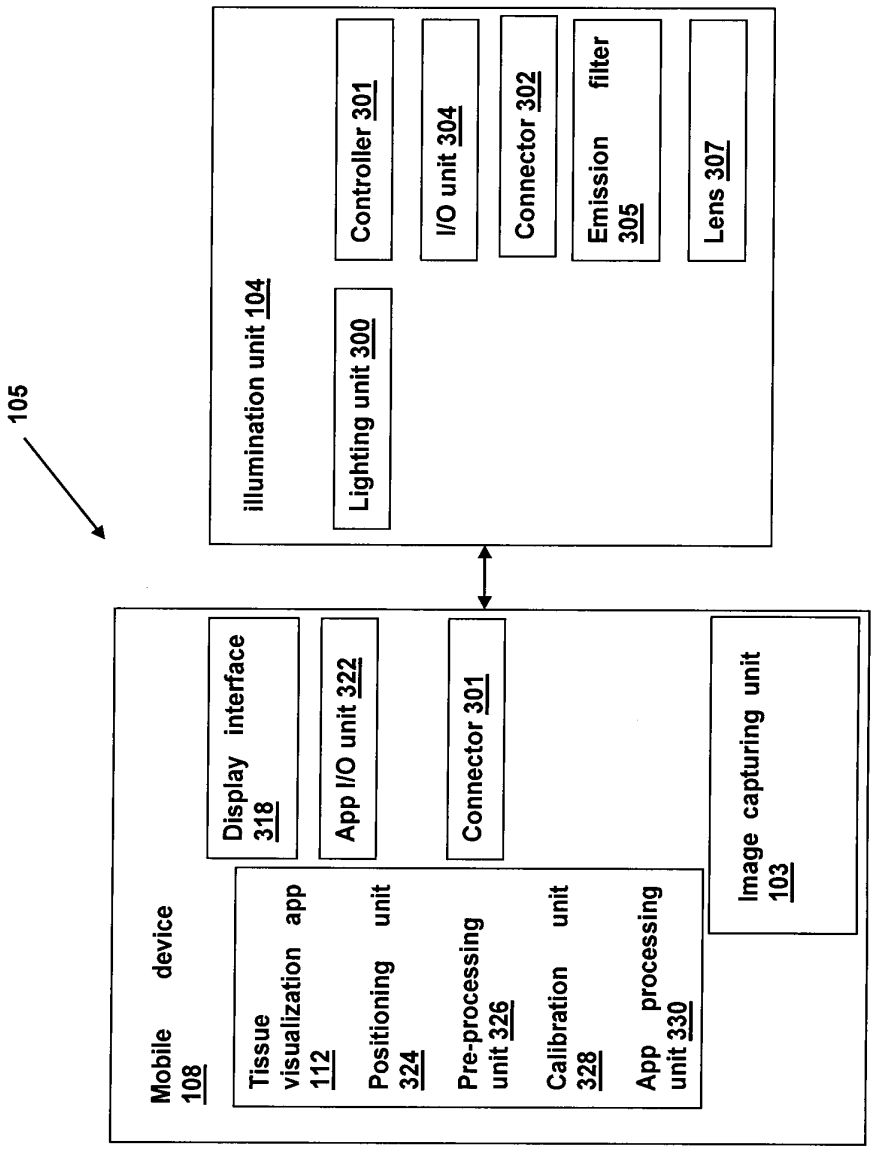
105
illumination unit 104
Lighting unit 300
Controller 301
I/O unit 304
Connector 302
Emission filter 305
Lens 307
Mobile device 108
Display interface 318
App I/O unit 322
Connector 301
Image capturing unit 103
Tissue visualization app 112
Positioning unit 324
Pre-processing unit 326
Calibration unit 328
App processing unit 330

FIG. 3

3/10

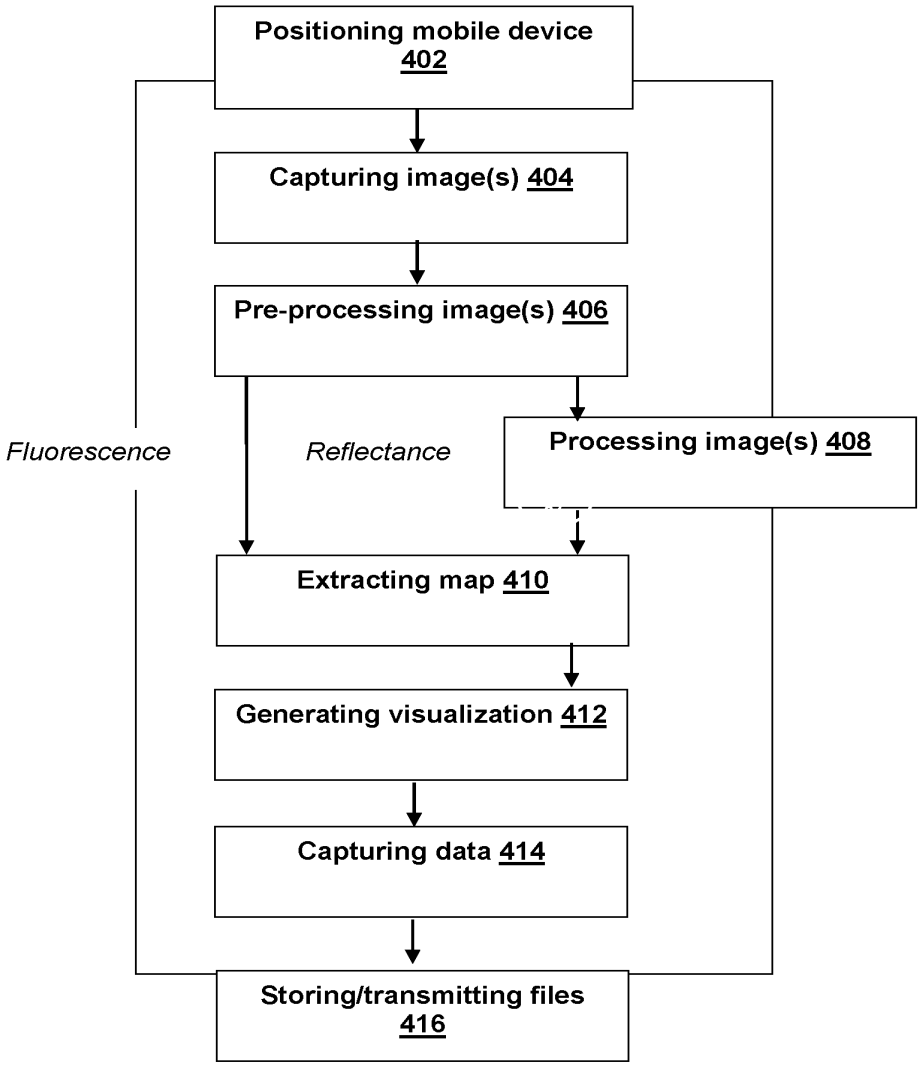
Positioning mobile device 402
Capturing image(s) 404
Pre-processing image(s) 406
Fluorescence
Reflectance
Processing image(s) 408
Extracting map 410
Generating visualization 412
Capturing data 414
Storing/transmitting files 416

FIG. 4

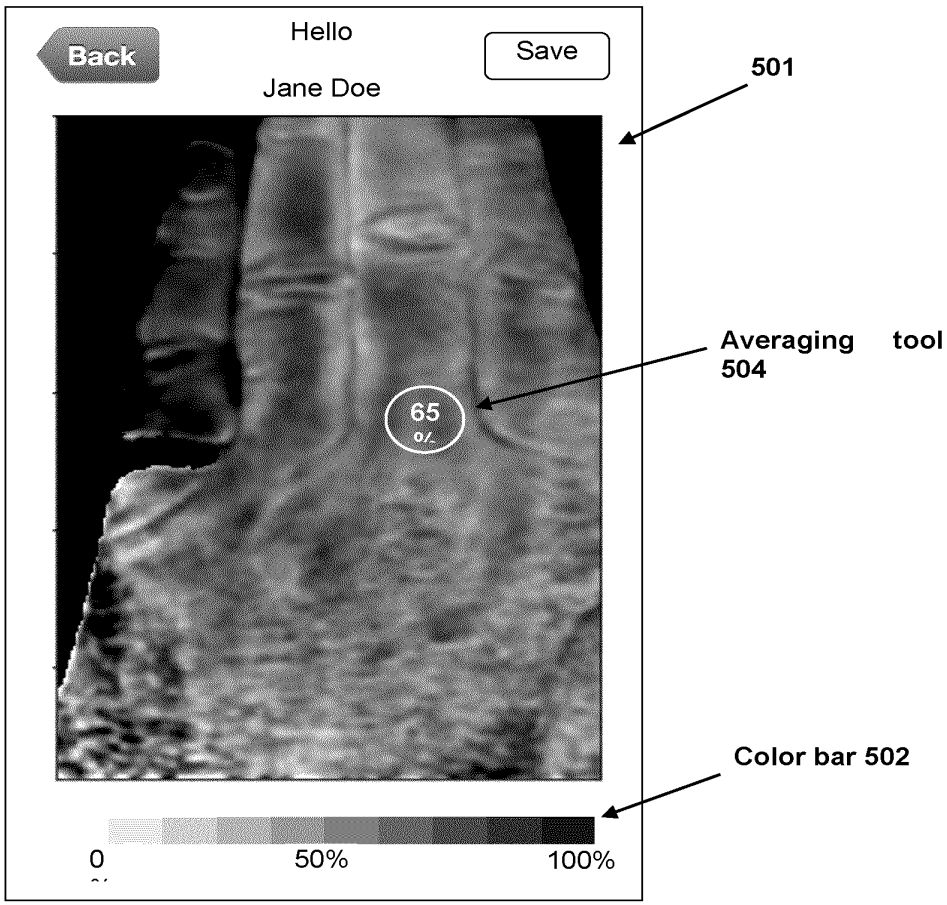
Back
Hello
Jane Doe
Save
501
Averaging tool 504
65
Color bar 502
0
50%
100%

FIG. 5

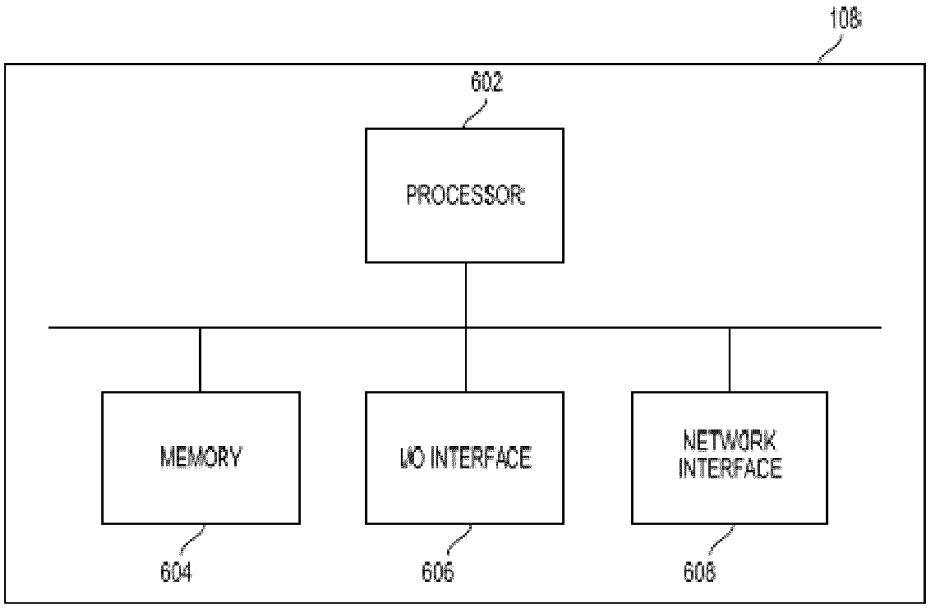
108
602
PROCESSOR
MEMORY
I/O INTERFACE
NETWORK INTERFACE
604
606
608

FIG. 6

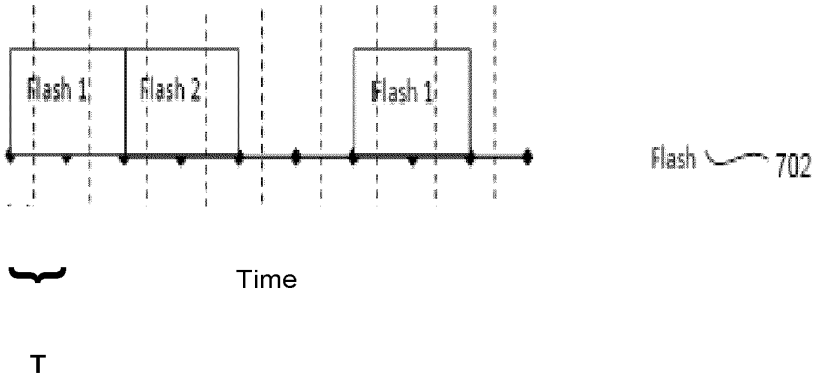

FIG. 7

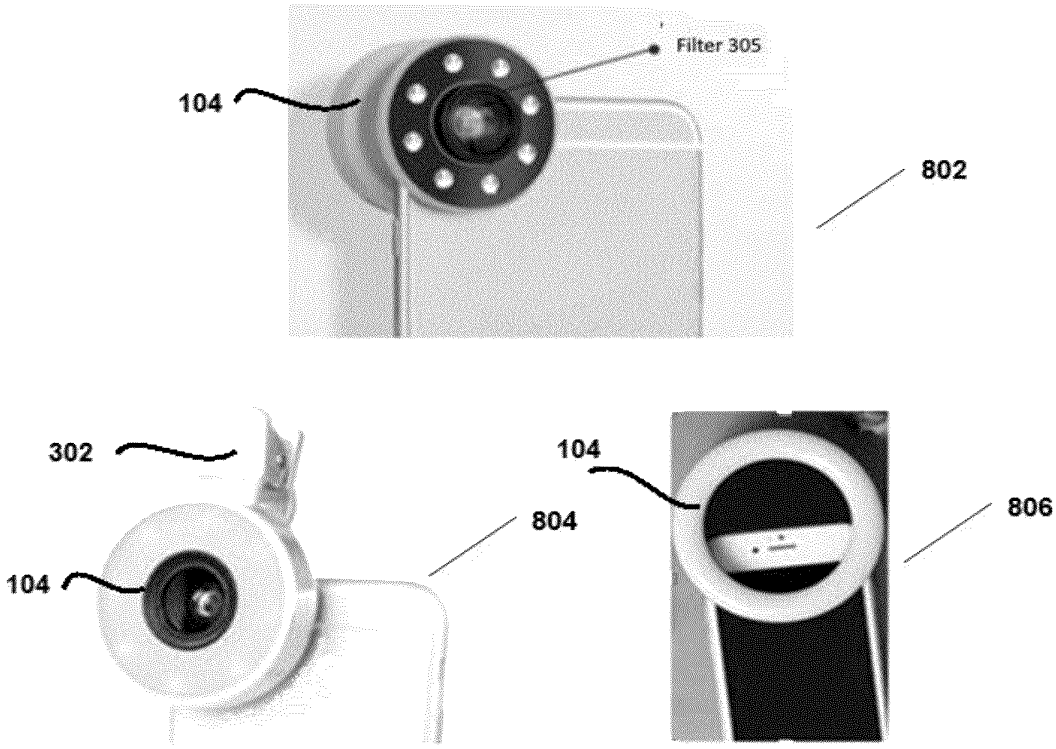

FIG. 8

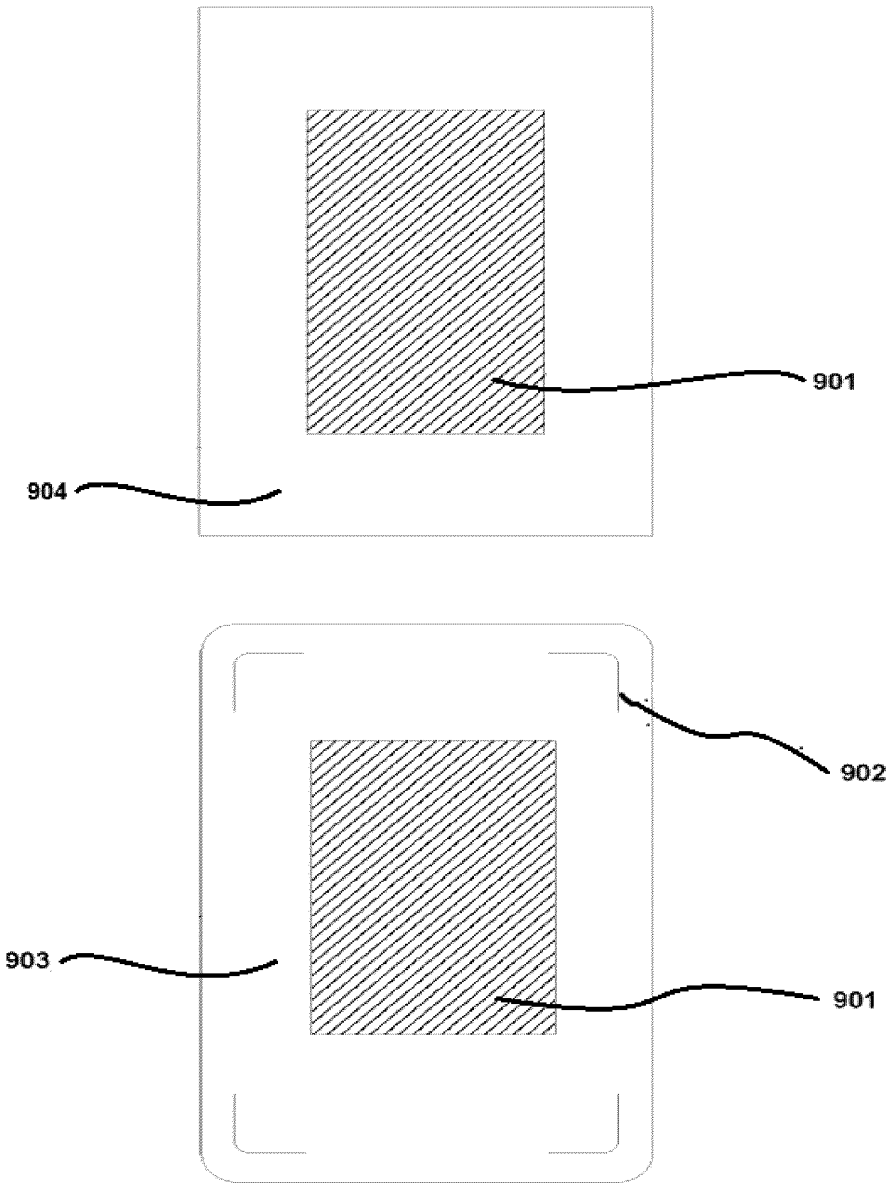

FIG. 9

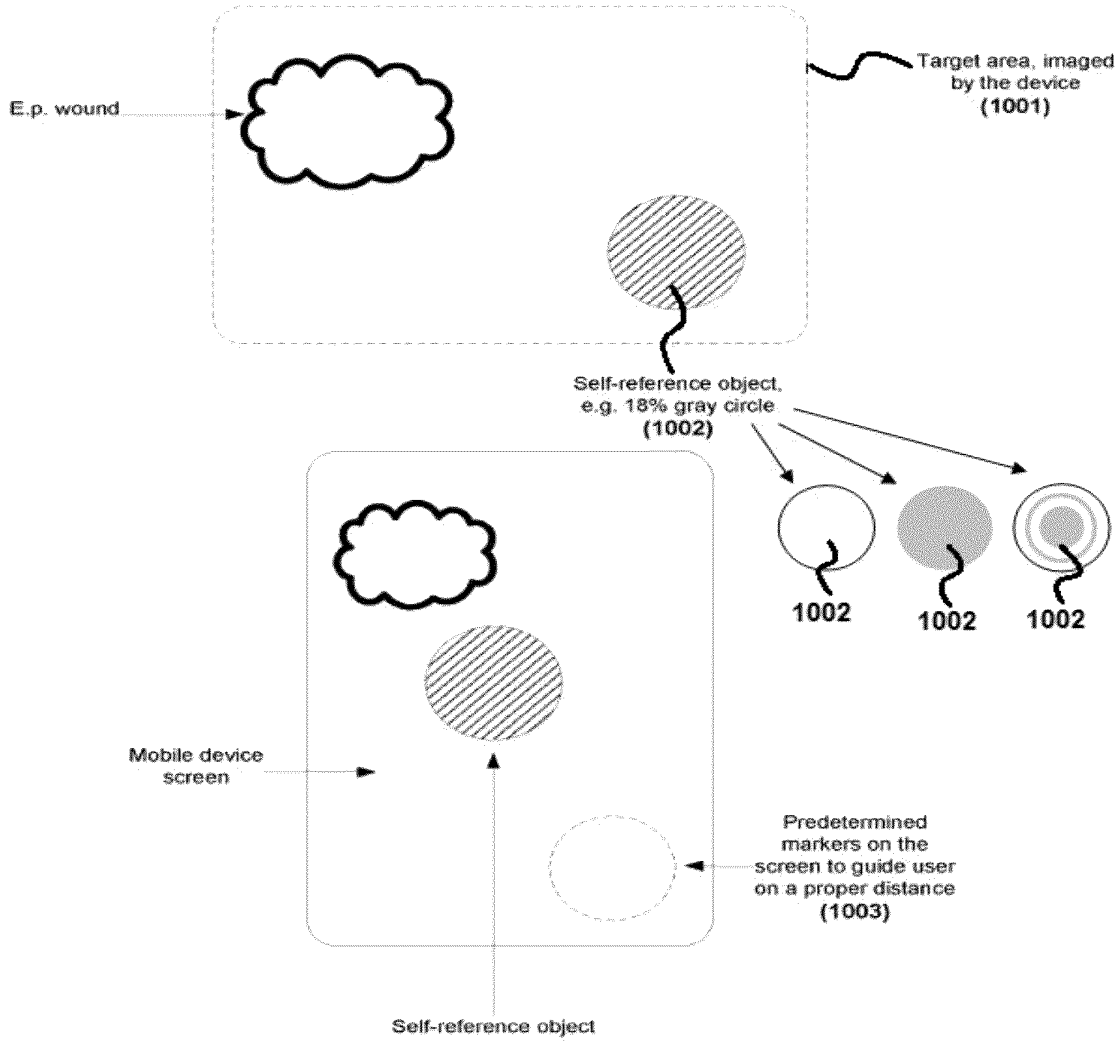
E.p. wound
Target area, imaged by the device (1001)
Self-reference object, e.g. 18% gray circle (1002)
1002
1002
1002
Mobile device screen
Predetermined markers on the screen to guide user on a proper distance (1003)
Self-reference object

FIG. 10

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(54) Title: APPARATUS FOR VISUALIZATION OF TISSUE

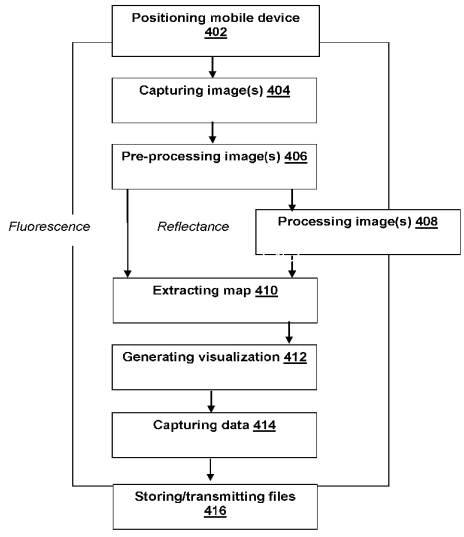

FIG. 4

(57) Abstract: A tissue imaging system comprising a computing device, tissue visualization application, image capturing unit, and an illumination unit, is configured to capture measurement data. The visualization application extracts visualizations of tissue health indicators from the measurement data. The application generates an interface with one or more interface elements corresponding to the visualization of tissue health indicators.

[Continued on next page]

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TITLE: APPARATUS FOR VISUALIZATION OF TISSUE

FIELD

[0001] The improvements generally relate to the field of medical devices.

BACKGROUND

[0002] People suffer from chronic and compromised wounds with debilitating pain and reduced quality of life for those whose health is already compromised. Patients with this condition often present to a doctor at late stages of the disease, which leads to many amputations, which may be avoidable. Moreover, proper diagnostics requires specialized vascular labs, which precludes these types of tests from being performed outside major hospitals and in an expedited fashion.

[0003] The wound is considered chronic if it is not healed within four weeks. The tissue health and wound healing process can be compromised by various factors, including insufficient blood supply, edema, and the presence of bacteria. These factors (oxygenation/perfusion, subepidermal moisture, and bacteria presence) among others will be referred to as tissue health indicators.

[0004] Multispectral (hyperspectral) imaging is a promising non-invasive optical modality for early detection of problematic wounds.

[0005] Visualization of skin distribution of oxyhemoglobin and deoxyhemoglobin can give insight into perfusion and oxygenation of the tissue. It can be used for assessment of tissue health (for example, ischemia).

[0006] Such as elevated levels of subepidermal moisture are typical for pressure injuries, visualization of water distribution in tissue can be used for early (pre-ulcer) diagnostics of pressure injuries.

[0007] Fluorescence imaging is a promising non-invasive optical modality for detection of bacterial burden. Visualization of bacterial burden can be used to assess bacterial burden and guide swabbing and cleansing.

SUMMARY

[0008] In accordance with an aspect, there is provided a process for generating visualizations of tissue. The process captures measurement data by a user device (e.g., smartphone), and processes the measurement data using the visualization application. The

process extracts indications of tissue health from the processed measurement data, and stores or transmits the underlying data. The process generates interface elements corresponding to the visualization tissue health indicators.

[0009] In some embodiments, the process involves calibrating the visualization application using a reference object.

[0010] In some embodiments, a small self-reference can be used to position the device properly.

[0011] In some embodiments, a small self-reference can be used to calibrate the measurement data based on an intensity of illumination.

[0012] In some embodiments, an illumination unit independent of the mobile device can be used for calibration and capture measurements together with a camera, laptop, or tablet.

[0013] In accordance with an aspect, there is provided a tissue imaging system comprised of a user device with a visualization application, an image capturing unit, and an illumination unit. The illumination unit is configured to illuminate the target area; the image capturing unit captures measurement data, the visualization application extracts visualizations of tissue health indicators from the measurement data and generates an interface with one or more interface elements corresponding to the visualization of tissue health indicators.

[0014] In accordance with an aspect, there is provided a tissue visualization system connected to a tissue imaging system (user device with a visualization application, an image capturing unit, and an illumination unit). The illumination unit illuminates the target area; the image capturing unit captures measurement data. The visualization application extracts visualization of tissue health indicators from the measurement data and transmits the visualization of tissue health indicators or underlying data to the tissue visualization system. The tissue visualization system processes and stores the visualization of tissue health indicators or underlying data, and displays them on user devices.

[0015] In accordance with an aspect, there is provided a portable illumination apparatus for facilitating visualizations of tissue. The apparatus comprises: a portable housing for detachable attachment proximal to an image capturing unit; and an illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$.

[0016] In accordance with a further aspect, the illumination unit further comprises a lens covering the one or more light sources, and having a focal length that is 80%-120% of a working distance between the illumination unit and a target area of tissue.

[0017] In yet a further aspect, the one or more light sources is configured to provide flashes that are at least one of: (i) 405±10nm wavelength, and having at least one of (a) a long pass filter with a cut-on wavelength of 450±25nm or (b) a bandpass filter with transmission in a 425nm-1000nm range; (ii) two wavelengths in a 450nm-750nm range, at least one of which in the green range; (iii) three wavelengths in a 450nm-750nm range, at least one of which in the green range; or (iv) 970±10nm wavelength.

[0018] In accordance with a further aspect, the illumination unit further comprises at least one of (i) a controller to control illumination of the one or more light sources, and (ii) a rechargeable battery for powering the apparatus.

[0019] In accordance with another aspect, the one or more light sources are arranged along a central aperture having a radius of 0.5-3cm.

[0020] In accordance with a further aspect, the one or more light sources are arranged in a ring having a radius of 1.5-6cm.

[0021] In accordance with an aspect, the portable housing comprises a compression clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

[0022] In accordance with another aspect, the portable housing comprises a spring clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

[0023] In accordance with a further aspect, there is provided a tissue imaging system for visualization of tissue health indicators comprising a portable computing device, an image capture unit, and an illumination unit. The illumination unit comprises one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$. The image capture unit and the illumination unit are configured to capture measurement data for a target area of tissue. The computing device comprises a processor configured to access and execute instrutions in accordance with a tissue visualization application stored in a non-transitory computer-readable memory of the computing device, for capturing measurement data, and pre-processing and processing the measurement data to generate tissue health indicators.

[0024] In accordance with an aspect, the computing device comprises a mobile device and the image capture unit is a camera integrated with the mobile device.

[0025] In accordance with a further aspect, the illumination unit of the tissue imaging system comprises any of the embodiments of the illumination apparatus described above.

[0026] In accordance with yet a further aspect, the portable illumination unit further comprises a wireless communication module for receiving commands from the computing device.

[0027] In accordance with a further aspect, there is provided a tissue visualization system operatively connected to one or more tissue imaging systems (such as any of the tissue imaging systems described above), comprising a communications module for communicating with the one or more tissue imaging systems, a system processor, and system non-transitory computer-readable memory thereon, configured to receive measurement data and tissue health indicators from the one or more tissue imaging systems and to generate a visualization of tissue health indicators of tissue images received from the one or more tissue imaging systems, for display to a user display unit.

[0028] In accordance with a further aspect, there is provided a method for generating visualizations of tissue. The method comprises: positioning a computing device at a proper distance from a target area of the tissue for capturing an image of the target area, the computing device comprising a processor and a non-transitory computer-readable memory storing computer-executable instructions comprising a tissue visualization application; capturing measurement data using an image capturing unit and an illumination unit, the image capturing unit and the illumination unit communicatively coupled to the computing device and the illumination unit configured to shine m flashes at n predetermined wavelengths during capturing of the measurement data, wherein $n/4 \leq m \leq n$; pre-processing the measurement data using the tissue visualization application to obtain normalized images; extracting indications of tissue health indicators from the pre-processed measurement data; generating interface elements corresponding to the visualization tissue health indicators; and storing and/or transmitting the indications of the tissue health indicators.

[0029] In accordance with an aspect, the method further comprises, prior to capturing the measurement data: capturing a reference image, wherein the positioning the computing

device for the reference image capturing comprises positioning the computing device using a reference object.

[0030] In accordance with a further aspect, the illumination unit and the computing device are configured to provide a working distance of 15±5cm from the target area of tissue.

[0031] In accordance with yet a further aspect, the positioning of the computing device for capturing the measurement data comprises positioning the computing device using a self-reference object.

[0032] In accordance with another aspect, pre-processing comprises at least one of (i) registering images to avoid camera motion artifacts, (ii) subtracting images with no illumination from the illumination unit from images with illumination from the illumination unit to account for the presence of ambient light, (iii) recalibrating each measurement accordingly to control parameters related to intensity of illumination using a self-reference object positioned within the target area, (iv) dividing the intensity images on reference images to obtain normalized images, and/or (v) flattening the obtained images to account for reflections from curved surfaces.

[0033] In accordance with an aspect, camera exposure time is T and a flash time is T or any whole number multiple of T.

[0034] In accordance with another aspect, the camera exposure time is 50ms.

[0035] In accordance with a further aspect, the measurement data comprises wound-related data.

[0036] Many further features and combinations thereof concerning embodiments described herein will appear to those skilled in the art following a reading of the instant disclosure.

DESCRIPTION OF THE FIGURES

[0037] Embodiments will now be described, by way of example only, with reference to the attached figures, wherein in the figures:

[0038] Fig. 1 depicts a view of an example of the overall system architecture with various configurations of tissue imaging systems according to some embodiments;

[0039] Fig. 2 depicts a view of an example of a tissue visualization system according to some embodiments;

[0040] Fig. 3 depicts a view of an example of the illumination unit and a computing device according to some embodiments;

[0041] Fig. 4 depicts a flowchart of an example method for capturing measurements and visualizing tissue according to some embodiments;

[0042] Fig. 5 depicts a view of an example interface for visualizing tissue according to some embodiments;

[0043] Fig. 6 depicts a diagram of an example architecture of a computing device according to some embodiments;

[0044] Fig. 7 depicts an example of illumination and image capturing scheme according to some embodiments;

[0045] Fig. 8 depicts a view of example illumination units according to some embodiments;

[0046] Fig. 9 depicts an example of the workflow used to take reference images; and

[0047] Fig. 10 depicts a view of a schematic of imaging tissue and self-reference objects.

DETAILED DESCRIPTION

[0048] Some clinical-grade tools can only be used in specialized medical establishments. They can be large, require special training, and are mostly suitable for the use in inpatient settings only. For example, they cannot be easily carried to a patient's home or remote communities. Thus, these solutions cannot be used as early diagnostic tools as a patient would have to be referred to a hospital having one of these tools.

[0049] Many people suffer from diabetes. Diabetic foot ulcers (DFU) and the resulting lower extremity amputations are a frequent, disabling and costly complication of diabetes. Many diabetics can develop a foot ulcer. DFU is a cause of non-traumatic below knee amputation. In addition to the reduced quality of life, amputees might not survive for that long after amputation. Consequently, early detection of DFU can lead to better outcomes, thus saving limbs and lives.

[0050] Peripheral vascular disease (PVD) affects arteries (peripheral arterial disease, PAD) and veins (chronic venous insufficiency, CVI). PAD is of particular importance, as it affects about eight million Americans and is responsible for 10% of all leg ulcers.

[0051] Pressure ulcers (PU) or pressure injuries represent a serious health problem to patients impacting up to 25-50% of patients across acute and long-term care settings.

[0052] The cost of treatment of diabetic foot ulcer, pressure ulcer, and leg ulcer is high. Diagnosing these conditions at an earlier stage (e.g., before actual ulceration) might result in significant financial savings for healthcare systems and patients.

[0053] Other clinical indications associated with abnormal blood perfusion and/or oxygenation, such as skin cancer (angiogenesis), port-wine stains, and skin disorders, can benefit from a system for tissue imaging.

[0054] Subepidermal moisture, a measure of localized edema, is associated with erythema, Stage I and II PUs [Bates-Jensen 2007, Bates-Jensen 2008, Guihan 2012, Ching 2011], and can (ii) differentiate between healthy skin and skin with pressure-induced tissue damage [Harrow 2014] and (iii) serve as a predictor of imminent ulceration (PUs, sDTIs) in various populations [Bates-Jensen 2007, Bates-Jensen 2008, Bates-Jensen 2009]. Thus, changes in measures of subepidermal moisture could be utilized for both prevention and detection of PUs. Radiofrequency impedance measurement with spatially separated electrodes is a current standard way to measure skin moisture including subepidermal moisture. However, it is a contact single-point measurement technique, which may suffer from operator inconsistency.

[0055] Near-Infrared spectroscopy (NIR) reflectance can be used to determine water content in the skin. Water spectrum dominating NIR spectra with overtone bands of the O-H bonds with peak absorption at 760 nm, 970 nm (due to the second overtone of the O-H stretching band), 1190nm (the combination of the first overtone of the O-H stretching and the O-H bending band), 1450 nm (first overtone of the OH-stretching band and a combination band), and 1940 nm (combination of the O-H stretching band and the O-H bending band). [Luck 1974]

[0056] Water absorption at 1440nm is 30 times stronger than at 1190nm, which in turn is more than two times stronger than absorption at 970nm. Thus, 1440nm and 1920nm wavelengths are suitable for imaging of water content in uppermost skin layers (stratum corneum), while 970nm and 1190nm can be used for water content determination and imaging in deeper skin layers, including epidermis, dermis (1190nm) and even subcutaneous tissues (970nm).

[0057] Bacteria presence can significantly impact tissue health and wound healing progress. Bacteria are always present in the wound. There are several distinct levels of bacterial burden in the wound: contamination, colonization, and infection.

[0058] Wound contamination is the presence of non-replicating organisms in the wound. All chronic wounds are contaminated. These contaminants come from the indigenous microflora and/or the environment.

[0059] Wound colonization is the presence of replicating microorganisms adherent to the wound in the absence of injury to the host. Most of these organisms are normal skin flora; such as *Staphylococcus epidermidis,* another coagulase negative Staph., *Corynebacterium* sp., *Brevibacterium* sp., *Proprionibacterium acnes*, and *Pityrosporum* sp..

[0060] Wound Infection is the presence of replicating microorganisms within a wound that cause host injury. Primarily, pathogens are of concern here, such as *Staphylococcus aureus,* Beta-hemolytic *Streptococcus (S. pyogenes, S. agalactiae), E. coli, Proteus, Klebsiella,* anaerobes, *Pseudomonas, Acinetobacter,* and *Stenotrophomonas (Xanthomonas).*

[0061] Contamination and colonization by low concentrations of microbes are considered normal and are not believed to inhibit healing. However, critical colonization and infection are associated with a significant delay in wound healing.

[0062] Clinical testing for bacterial presence includes analysis of swabs from the tissue. In addition to long processing time (several days), these tests suffer from possible contamination during swabbing and randomness in the selection of swabbing sites. Thus, current clinical diagnostics techniques are sub-optimal.

[0063] Portable fluorescence imaging can be used for visualization of bacterial presence. It was found that while excited at 405nm, *S. aureus*, *S. epidermidis*, *Candida*, *S. marcescens, Viridans streptococci, Corynebacterium diphtheriae, S. pyogenes, Enterobacter*, and *Enterococcus* produced red (610-640nm) fluorescence from porphyrin [Kjeldstad 1985] while *P. aeruginosa* produced a bluish-green (450-520nm) fluorescence from pyoverdin [Cody 1987]. Thus, fluorescence imaging can be used to assess bacterial burden and guide swabbing and wound cleansing.

[0064] Thus, multispectral/hyperspectral-based reflectance imaging, fluorescence imaging or their combination can provide valuable insights on tissue health and wound healing potential.

[0065] Embodiments described herein can provide a tool for tissue imaging.

[0066] Fig. 1 depicts a view of an example tissue visualization system 100 that connects to tissue imaging systems 105 via network 110.

[0067] Tissue imaging system 105 is a device for visualization of abnormalities of blood circulation, moisture distribution, and bacterial burden in surface tissues (skin or mucosa). For example, the device can be used for identification of ischemic or angiogenic conditions. It can be used by primary care physicians, nurses, or even patients themselves in any type of settings: inpatient, outpatient, long-term facilities, patient's home, and so on, thus allowing earlier identification of problematic wounds. Tissue imaging system 105 may comprise a computing device 108 which may comprise a mobile device 108, processor(s) 108a, non-transitory computer readable storage medium or memory 108b, image capturing unit 103, and illumination unit 104. Memory 108b may comprise computer executable instructions comprising tissue visualization app 112.

[0068] Computing device 108 may be an off-the-shell computing device (for example, a mobile device, smartphone, tablet, laptop, a personal computer) or a custom-built computing device. In an example embodiment, computing device 108 comprises a smartphone.

[0069] Tissue visualization app 112 coordinates image capturing unit 103 and illumination unit 104 during data capturing, process images, display results on computing device 108, and store and/or transmit data to tissue visualization system 100.

[0070] Image capturing unit 103 may comprise an internal (built-in to computing device 108) or external device capable of capturing images. In an example embodiment, image capturing unit 103 comprises a 3 channel (RGB) or 4 channel (RGB-NIR) camera.

[0071] Illumination unit 104 may comprise an internal (built-in to computing device 108) or external device (e.g., multispectral flash) capable of illuminating a target area with required intensity, wavelengths, and duration.

[0072] Example tissue imaging system 105 architectures are presented on Fig.1. In some embodiments, the tissue imaging system 105 can be a single device. In some embodiments, the tissue imaging system 105 can have two separate parts (e.g., image capturing unit 103 built-in to computing device 108 and a separate illumination unit 104, or illumination unit 104 built-in to computing device 108 (e.g., a mobile device 108) and a separate image capturing unit 103). In some embodiments, tissue imaging system 105 can have three separate parts (for example, a computing device 108, a separate image capturing unit 103, and a separate illumination unit 104). The separate components of tissue imaging system 105 may communicate by known wired or wireless communications protocols.

[0073] In an example embodiment, illumination unit 104 can be a device attached (e.g., clip-on or by compression clip) to a computing device 108, such as a mobile device or smartphone.

[0074] In some embodiments,illumination unit 104 can be connected or synchronized with the tissue visualization application 112 (installed on or otherwise accessible by computing device 108) for example by known wireless connections (for example, Bluetooth™), optic or optoelectric coupling, or wired connection. In some embodiments, the illumination unit 104 can be triggered manually, and the visualization application 112 recognizes the light sequence and synchronizes image capturing.

[0075] In some embodiments, the image capturing unit 103 can connect to the tissue visualization application 112 (installed on or otherwise accessible by computing device 108 (e.g., a mobile device 108)) for example by known wireless connections (for example, Bluetooth™), optic or optoelectric coupling, or wired connection.

[0076] The tissue visualization application 112 can, in turn, be connected to tissue visualization system 100 (which may comprise, e.g., a backend server). The tissue visualization system 100 can collect data from tissue visualization applications 112 of tissue imaging systems 105, via network 110. The tissue visualization system 100 can transmit the data (or transformations and aggregations of the data) to user device 102, which may comprise any device with computer processing capability (e.g., computer, laptop, tablet, or smartphone) for use by a user (e.g. a physician or other user). Thus, a qualified specialist may review the data collected by tissue visualization system 100 from one or more tissue imaging systems 105 used to capture image(s) in a different location by, e.g., a frontline health practitioner (e.g., nurse) or patient. This may facilitate early diagnostic by the physician.

[0077] Tissue imaging system 105 can capture measurement data as images of a patient's tissue. The visualization application 112 can extract visualizations of tissue health indicators from the measurement data. The visualization application 112 can generate one or more interface elements corresponding to the visualization of tissue health indicators. The interface elements populate an interface for display on the computing device 108 (e.g., a mobile device 108).

[0078] In some embodiments, the computing device 108 can connect to a tissue visualization system 100 to transmit the measurement data and the visualization of tissue

health indicators, for example. The tissue visualization system 100 can aggregate the measurement data and the visualization of tissue health indicators from multiple tissue imaging systems 105. The tissue visualization system 100 can process and store the measurement data and the visualization of tissue health indicators.

[0079] In some embodiments, tissue imaging system 105 can connect to a user device 102. In some embodiments, the computing device 108 (e.g., a mobile device 108) with tissue visualization app 112 can receive and aggregate measurement data from multiple tissue imaging system(s) 105, and generate the visualization of tissue health indicators for transmission to tissue visualization system 100. The tissue visualization system 100 can aggregate the measurement data and the visualization of tissue health indicators from multiple tissue imaging systems 105.

[0080] The tissue visualization system 100 receives imaging data from the tissue imaging system(s) 105 to generate a visualization of tissue and detect wounds and abnormalities. The tissue visualization system 100 and tissue imaging system(s) 105 connect to other components in various ways including directly coupled, and indirectly coupled via network 110. Network 110 (which may comprise multiple communications networks) is capable of carrying data and can involve wired connections, wireless connections, or a combination thereof. Network 110 may involve different network communication technologies, standards, and protocols.

[0081] Fig. 2 depicts a view of an example tissue visualization system 100 according to some embodiments, interfaced with system components.

[0082] Tissue visualization system 100 receives imaging data from the tissue imaging system 105 via data I/O unit 218. Data I/O unit 218 facilitates transmission of data to data processing unit 220. Data processing unit 220 processes data received from the data I/O unit 218 or one or more databases 224. For example, data processing unit 220 can apply one or more algorithms or extract data that may be used for, or that may facilitate the visualization or processing related to detection of problematic wounds or abnormalities of blood circulation, for example, in surface tissues. Data processing unit 220 can extract, create, and/or aggregate from that data a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacteria presence, and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues.

[0083] Data processing unit 220 can receive, via data I/O unit 218 and network 110, instructions for computation from one or more external systems 106, user device 102, tissue imaging system 105, and/or tissue visualization app 112. The instructions for computation can be used by data processing unit 220 to facilitate the extraction, creation, and/or aggregation of data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues. In some embodiments, data processing unit 220 can process imaging data to prepare the data for presentation via the interface unit 222 in an appropriate form or to prepare the data for transmission to an external system 106, user device 102, and/or tissue imaging system 105 to be presented in an appropriate form.

[0084] Data processing unit 220 can receive data or processed data from aggregation unit 226 and may extract, create, and/or aggregate from that data, data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues. The map, visualization, or other indication that can be extracted, created, and/or aggregated by data processing unit 220 can reflect imaging data or measurements corresponding to a plurality of patients. The data processed by data processing unit 220 may be imaging data collected at one or more tissue imaging systems 105 and/or one or more user devices 102. The data processed by data processing unit 220 may be measurement data reflecting one or more images of a patient's tissue.

[0085] Aggregation unit 226 can receive via data I/O unit 218 and/or one or more databases 224 imaging data corresponding to a plurality of patients, tissue imaging systems 105, or user devices 102. Aggregation unit 226 can aggregate or modify the data by applying instructions for computation, and so may comprise one or more processors. Aggregation unit 226 can cause the aggregated or modified data to be transmitted to data processing unit 220 where the data can be processed to prepare the data for presentation via interface unit 222 in an appropriate form or to prepare the data for transmission to an external system 106, user device 102, and/or tissue imaging system 105 to be presented in an appropriate form.

[0086] Aggregation unit 226 can receive processed data from data processing unit 220 corresponding to a plurality of patients, tissue imaging systems 105, or user devices 102.

Aggregation unit 226 can aggregate or modify the processed data by applying the instructions for computation. Aggregation unit 226 can cause the aggregated or modified data to be transmitted to data processing unit 220 where the data can be further processed to prepare the data for presentation via interface unit 222 in an appropriate form or to prepare the data for transmission to an external system 106, user device 102, and/or tissue imaging system 105 to be presented in an appropriate form.

[0087] Aggregation unit 226 can receive via data I/O unit 218 and instructions for computation from one or more external systems 106, user device 102, tissue imaging system 105, and/or tissue visualization app 112. The instructions for computation can be used by aggregation unit 226 to facilitate aggregation of imaging data corresponding to a plurality of patients.

[0088] Tissue visualization system 100 can receive imaging data, for example, aggregate imaging data, from computing device 108 (e.g., a mobile device 108) via data I/O unit 218. Tissue visualization system 100 can receive imaging data, for example, aggregate imaging data, from external systems 106 via data I/O unit 218. Tissue visualization system 100 can receive computer instructions for processing or computation from external systems 106. External systems 106 can store, cause to be stored, and/or receive data from one or more external databases 216.

[0089] Aggregation unit 226 can receive via data I/O unit 218 and network 110 the instructions for computation from one or more external systems 106, user device 102, tissue imaging system 105, and/or tissue visualization application 112.

[0090] Tissue visualization system 100 can be associated with one or more databases or data storages 224, for example, one or more local databases. The one or more databases 224 can store or process data received or transmitted by data I/O unit 218, data processing unit 220, and/or aggregation unit 226. The data stored in the one or more databases 224 can be accessed by various units, including data I/O unit 218, data processing unit 220, and/or aggregation unit 226. For example, data I/O unit 218 may cause database 224 to store data received via network 110 and/or from user device 102, external systems 106, tissue imaging system 105, and/or tissue visualization app 112. Data processing unit 220 and aggregation unit 226 can cause data to be retrieved from database 224, for example, before processing or aggregating the data.

[0091] Data processing unit 220 can cause data to be stored in database or data storage 224 after it processes the data by applying instructions or extracting data that may be used for or facilitate the visualization or processing related to detection of problematic wounds or abnormalities of blood circulation in surface tissues. Data processing unit 220 can retrieve the processed data from database or data storage 224 and cause the processed data to be transmitted to the interface unit 222 or network 110, for example, for presentation to a patient or physician using user device 102, 105 or 106, for example.

[0092] Data processing unit 220 may cause data to be stored in database or data storage 224 after it extracts, creates, and/or aggregates data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues.

[0093] Data processing unit 220 may use Machine Learning (including supervised ML and unsupervised ML) to extract information from collected images and other data. In particular, data processing unit 220 can build and train models, which can discriminate between various conditions and provide users with additional information. In some embodiments, data processing unit 220 uses convolutional neural networks for automatic or semi-automatic detection and/or classification of the skin or wound conditions. In some embodiments, ML models built and trained using other tools may be deployed to data processing unit 220 for image/data detection/classification, such as from an external system 106.

[0094] Aggregation unit 226 can cause data to be stored in database 224 after it aggregates imaging data or processed data that corresponds to a plurality of patients and/or user devices 102. Aggregation unit 226 can retrieve the aggregated data from one or more databases 224 and cause the aggregated data to be transmitted to the interface unit 222 or network 110, for example, for presentation to a patient or physician using user device 102, 105 or 106, for example.

[0095] Tissue visualization system 100 can cause data to be displayed on interface unit 222, for example, aggregated and/or processed data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health in surface tissues. Patients and physicians can engage with an interface unit to view or analyze the indicia.

[0096] Tissue visualization system 100 can cause data, for example, aggregated data, processed data, imaging data, and/or data providing a wound size and/or a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health in surface tissues, to be transmitted to one or more external systems 106, such as via network 110.

[0097] For example, tissue visualization system 100 can receive imaging data from a plurality of tissue imaging systems 105, process and/or aggregate the data using data processing unit 220 and/or aggregation unit 226, and cause the data to be routed, via one or more networks 110, to, e.g. the appropriate physician (e.g., family doctor) for evaluation. The physician may be engaged with a user device 102, an external system 106, or a tissue imaging system 105.

[0098] A user device 102 may receive, process, and/or aggregate data from a plurality of tissue imaging systems 105 and/or corresponding to a plurality of patients or tissue measurements. User device 102 may receive instructions for computation from one or more external systems 106 or tissue imaging systems 105.

[0099] Tissue visualization system 100 can connect to various components, including user device 102, tissue imaging system 105, external systems 106, external database 216, in various ways including directly coupled and indirectly coupled via network 110 (which may comprise multiple networks). Each of these components can connect to each other in various ways including directly coupled and indirectly coupled via network 110 (or multiple networks).

[00100] Fig. 3 depicts a view of an example of tissue imaging system 105 comprised of the illumination unit 104 and computing device 108 (e.g., a mobile device 108) comprising an internal image capturing unit 103 and installed tissue visualization app 112, according to some embodiments.

[00101] A tissue imaging system 105 is associated with an image capture unit 103. The image capture unit 103 may comprise a smartphone camera (front or back), for example.

[00102] A computing device 108 (e.g., a mobile device 108) is associated with a display interface 318. The display interface 318 can be a screen or viewfinder, for example. In some embodiments, a computing device 108 (e.g., a mobile device 108) is associated with

an app I/O unit 322 that may facilitate data transmission between an illumination unit 104 and the computing device 108.

[00103] An illumination unit 104 may be associated with a computing device 108, for example, through a physical connector 302 that attaches the illumination unit 104 to the computing device 108, such as mobile device 108. An illumination unit 104, which acts as an external flash-generating device, is associated with a lighting unit 300, which may include multiple light sources 300. The light units 300 may be arranged in a circle on illumination unit 104, for example. In an example embodiment, light units 300 are arranged in a circular configuration around a central aperture.

[00104] In some embodiments, an I/O unit 304 associated with the illumination unit 104 may facilitate data transmission between the illumination unit 104 and the computing device 108. For example, I/O unit 304 may send and receive data from an app I/O unit 322. I/O unit 304 and app I/O unit 322 may implement connectivity via Bluetooth, a cable (e.g., USB, lightning, audio jack), WiFi, near-field communication, optic or optoelectronic coupling, or other means. This communication can facilitate synchronization of the lighting unit 300 and the data capture by image capture unit 103, for example, in accordance with an illumination schema that can account for various types of external illumination.

[00105] A controller 301 causes light sources to flash in a predetermined fashion. The controller 301 can receive commands from I/O unit 304 or be triggered manually (e.g., using a button). The controller 301 can be based on any type of general-purpose microprocessor or microcontroller, a digital signal processing (DSP) processor, an integrated circuit, a central processing unit (CPU), a graphics processing unit (GPU), a field programmable gate array (FPGA), a reconfigurable processor, a programmable read-only memory (PROM), or any combination thereof. In an example embodiment, the controller 301 is based on a microcontroller.

[00106] In some embodiments, the lens 307 covering the light sources 300 can be used to homogenize the light distribution on the target area. In an example embodiment, the Fresnel lens is used. The focal length of the lens can be chosen in the range 80-120% of the working distance between the illumination unit 104 and the target area. In the preferred embodiment, the focal length of the lens is equal to the working distance. Such a focal length tends to create a homogeneous illumination light distribution on the target area, which tends to result

in more optimal use of dynamic range and higher accuracy of measurements on periphery of the target area.

[00107] For bacterial burden measurements, the emission filter 305 covers the image capturing unit 103 (e.g., the camera of a smartphone) to block the excitation illumination at 405±10nm. In an example embodiment, the emission filter is attached to the illumination unit 104. In some embodiments, the emission filter 305 is a long pass filter with cut-on wavelength 450±25nm. In some embodiments, the emission filter is a band pass filter with the transmission in the 425-750nm range, which has the lower cut-on wavelength in the 450±25nm range.

[00108] Computing device 108 (e.g., a mobile device 108) supports a tissue visualization application 112. Computing device 108 may run on any suitable operating system such as iOS, Android, or Windows. The tissue visualization app 112 can help position the computing device, e.g. a smartphone, at a proper distance to a target area; can synchronize flashes from an illumination unit 104 with the image capturing unit 103; can cause or coordinate the capture of a set of images; can cause or facilitate local processing of the images or of data captured; can cause capturing target area info (e.g., location, laterality, description, wound size, tissue type, patient ID, etc.); can cause or facilitate the extraction, creation, and/or aggregation of data providing a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacterial presence and/or other indicia that may suggest abnormalities of tissue health in surface tissues; can cause or facilitate storing data on computing device 108; and can cause or facilitate data to be transmitted over one or more networks 110.

[00109] The tissue visualization app 112 includes a positioning unit 324, pre-processing unit 326, calibration unit 328, and app processing unit 330.

[00110] Positioning unit 324 can cause or facilitate the positioning of the image capture unit 103 in relation to an area of patient tissue targeted for measurement.

[00111] For example, in some embodiments, positioning unit 324 can use a reference (or self-reference) object (e.g., a white circle, square, rectangle, or another shape, colour, or object) on the target area, where the reference (or self-reference) object and target area can be imaged through a viewfinder or screen associated with the, for example, mobile device 108. In some embodiments, the positioning unit 324 can recognize the reference object and cause an overlay to be presented on the display interface 318.

[00112] In some embodiments, the overlay can be marks, lines, arrows, shapes, and/or other attributes that can be used by a person engaged with the display interface 318 to move the computing device 108 (e.g. mobile device 108), for example, forwards and/or backward to create appropriate positioning of the image capture unit 103. The tissue visualization app 112 can adjust the presentation of the overlay on the display interface 318 in relation to the presentation of the reference object or tissue on the display interface 318. This may help guide the user's movement of the image capture unit 103 or computing device 108 (e.g., a mobile device 108) to achieve proper positioning of the image capture unit 103 or computing device 108 (e.g., mobile device 108) in relation to the area of patient tissue targeted for measurement.

[00113] In some embodiments, the overlay presented on the display interface 318 can be of a predetermined size and presented at predetermined locations on the display interface 318.

[00114] In some embodiments, positioning unit 324 can use the size of the reference object to trigger automatic data capturing when the computing device 108 (e.g. mobile device) or image capturing unit 103 is at a certain distance from the target area.

[00115] In some embodiments, positioning unit 324 can guide a user to move the computing device 108 (e.g. mobile device), for example, forwards and/or backward to create appropriate positioning of the image capture unit 103, by graphical, text or voice commands.

[00116] In some embodiments, reference objects may be used to facilitate calculation of a distance from a wound and/or to rescale images or measurement data.

[00117] In some embodiments, image capture unit 103 may be positioned at a proper distance from a target area, for example, a wound, by other means such as using a rangefinder or ruler.

[00118] The tissue visualization app 112 may help control the illumination of the patient tissue targeted for measurement and/or the illumination of one or more images captured by image capture unit 103 to help ensure the illumination is stable and/or predictable. The intensity of illumination may depend on the distance of the image capture unit 103 to the target area and the stability of, for example, intensity of the light source, e.g. LED, which may degrade with time or within a battery cycle. Control of such factors may be facilitated by pre-processing unit 326. For example, the tissue visualization app 112 may use a self-reference object (e.g., white or gray circle) that is placed within a target area to measure the

intensity of each wavelength in each flash and recalibrate each measurement accordingly. A single measurement can include multiple flashes and wavelengths.

[00119] In some embodiments, the pre-processing unit 326 can compare the intensity of a self-reference object in the target image with the intensity of the same region in the reference image and uses the ratio between the two to scale the intensity of the target image pixel-by-pixel.

[00120] For reflectance images, app processing unit 330 can process image data captured by image capture unit 103 and pre-processed by pre-processing unit 326. For example, the user or app processing unit 330 can compare one or more images or patient measurements of a suspicious area to one or more images or patient measurements of a non-affected area.

[00121] An observation may consist of one or more measurements on a patient. The one or more images or patient measurements of a non-affected area (control sites) can be used to establish a baseline for a particular patient. Ideally, one can select a control site as a spot with intact skin symmetrical with respect to the spinal cord (e.g. on another extremity) to the suspicious area (this may be another extremity; for example, if the left ankle of a person is affected, then the right ankle may be selected as the control site). However, if it is not possible (e.g., limb amputation or widespread ulcers), then other locations (e.g., antecubital fossa) can be used as a control site. In the case of a single measurement (e.g., suspicious area only), the suspicious area readings can be compared with an area on the same image distant from the suspicious area.

[00122] In some embodiments, tissue visualization app 112 can compare an image of a suspicious area to one or more images of control sites. The tissue visualization app 112 can process an image and can also operate in video mode to process a series of images or video frames.

[00123] App processing unit 330 can use the data captured by image capture unit 103 to facilitate the extraction, creation, and/or aggregation of data providing a map, visualization, or indication of oxygenation, oxyhemoglobin, deoxyhemoglobin, perfusion, water, bacteria presence, and/or other indicia that may suggest abnormalities of tissue health, for example, in surface tissues.

[00124] The outcome of the system can be a false color or grayscale 2D map of tissue health indicators. These maps can be presented via the display interface 318 and/or transmitted over one or more networks 110, for example, to a tissue visualization system

100 or a user device 102. For example, levels of oxygenation and perfusion can highlight areas with abnormal blood supply, namely ischemic (significantly reduced perfusion and oxygenation) and angiogenic (increased perfusion) areas. A trained physician will be able to interpret these 2D maps to assess the significance of findings and decide on next steps, for example, requesting further study, monitoring progress, or dismissing the matter.

[00125] App processing unit 330 can cause the processed data to be presented via display interface 318 and/or transmitted over a network 110.

[00126] In some embodiments app processing unit 330 can use Machine Learning (ML)(including supervised ML and unsupervised ML) to extract information from collected images and other data. In particular, app processing unit 330 can build and train models, which can discriminate between various conditions and provide users with additional information. In some embodiments, the app processing unit 330 uses convolutional neural networks for automatic or semi-automatic detection and/or classification of the skin or wound conditions. In some embodiments, ML models can be built and trained using other tools (e.g., the data processing unit 220) and deployed to app processing unit 330 for image/data detection/classification.

[00127] Fig. 4 is a flowchart of an example method for capturing measurements and visualizing tissue according to some embodiments.

[00128] At 402, a computing device 108 (e.g. a mobile device 108) is positioned at a proper distance (working distance) in relation to an area of tissue (e.g., using a positioning unit 324). In some embodiments, the computing device 108 or image capturing unit 103 is positioned 10-30cm from the tissue. In an embodiment, the image capturing unit 103 is positioned 10-15cm from the tissue.

[00129] At 404, image capture unit 103 in conjunction with illumination unit 104 captures a measurement of tissue according to an illumination schema.

[00130] At 406, in some embodiments, pre-processing unit 326 preprocesses the measurement data by a) registering (aligning) images to avoid camera motion artifacts, b) subtracting image with no illumination from images with illumination to account for the presence of an ambient light.

[00131] In some embodiments, the step 406 may include any or all additional steps: c) recalibrating each measurement accordingly in order to control parameters related to the intensity of illumination, d) dividing the intensity images on reference images to obtain

normalized images, e) flattening the images. In other embodiments, the filtering and frequency domain processing (e.g. fast Fourier transformation) may be used additionally for denoising.

[00132] Recalibration of each measurement using a self-reference object may take into account any possible drift or degradation of illumination light intensity, which will tend to improve the quality of results.

[00133] Dividing the intensity images on reference images may take into account the heterogeneity of illumination light distribution on a target area, resulting in normalized images that tend to improve quality of results

[00134] Imaging of body parts with high curvature (for example, heels or toes) can pose a significant clinical challenge. Different parts of the target area are on different distance from the illumination unit and the camera, and since the camera registers light intensity that depends on that distance, the curvature(s) can negatively affects accuracy of measurements or may produce erroneous results. In an embodiment, the step of flattening images is to take into account the reflection of light from curved surfaces. This can be achieved by plurality of methods. In some embodiments, approximation of the shape of the body part and rescaling normalized image to compensate for these deviations from the working distance is used. In other embodiments, shape fitting (for example, spherical, ellipsoidal, or cylindrical) may be used.

[00135] In some embodiments, registration (alignment) of images can be done using phase correlation or block matching algorithms (e.g., using a self-reference object).

[00136] In some embodiments, recalibration can be done by pre-processing unit 326 using a self-reference object to measure the intensity of each wavelength in each flash.

[00137] In some embodiments, any or all steps after the step 406 can be skipped.

[00138] In some embodiments, app processing unit 330 can cause transmission over network 110 of data, such as pre-processed images after step 406. In this case, upon receipt of the data, data processing unit 220 of tissue visualization system 100 may extract and visualize tissue health indicators.

[00139] At 408, app processing unit 330 processes the images to extract information, such as concentrations of tissue chromophores. In some embodiments, app processing unit 330 extracts indications of oxyhemoglobin and deoxyhemoglobin. In some embodiments, in addition to oxy- and deoxyhemoglobin, app processing unit 330 extracts the indication of

melanin. In some embodiments, app processing unit 330 additionally extracts water content indications.

[00140] In some embodiments, indications of oxyhemoglobin, deoxyhemoglobin, and water can be extracted directly from the obtained images using a Beer-Lambert or modified Beer-Lambert model.

[00141] In an exemplary embodiment, an additional step is taken to extract tissue absorption coefficients from the obtained images using a tissue optical model (or a tissue light propagation model). A tissue optical model would link the reflected signal with optical properties of the tissues, namely coefficients of absorption and scattering. Various light propagation models (for example, diffuse approximation model) can be used to extract such relationship. The appropriate model can be selected based on acceptable accuracy vs. computational intensity considerations.

[00142] In some embodiments, the least squares fitting, or LSF (with or without regularization) can be used to extract the concentration of each chromophore. In some embodiments, LSF extracts indications of chromophores directly from the obtained images. In an exemplary embodiment, LSF is applied after extraction of indication of absorption coefficient using the tissue light propagation model.

[00143] In other embodiments, other curve fitting methods (for example, least absolute deviations) may be used to extract indications of chromophores.

[00144] At 410, app processing unit 330 extracts indicia that allows the tissue health indicators of the imaged tissue to be presented. For example, the indicia may allow the oxygenation and/or perfusion to be presented as a map.

[00145] In some embodiments, app processing unit 330 can send to the network 110 data from the step 408. In this case, data processing unit 220 will visualize tissue health indicators.

[00146] At 412, tissue visualization app 112 generates a visualization of the tissue health indicators of the imaged tissue and causes the visualization to be presented via the display interface 318.

[00147] In some embodiments, computing device 108 comprises a graphical user interface displayed on display interface 318 by app processing unit 330. At 414, the tissue visualization app 112 collects data related to the image (e.g., patient ID, laterality, location,

diagnosis, comments, measurements). In some embodiments, a speech-recognition system is used to collect data.

[00148] At 416, tissue visualization app 112 causes a results file of the data or indicia to be stored and/or transmitted, for example, over a network 110 to a user device 102, tissue visualization system 100, and/or external system(s) 106.

[00149] Fig. 5 is a view of an example interface for visualizing tissue according to some embodiments.

[00150] In some embodiments, a color bar 502 can be implemented to guide the user when viewing the image.

[00151] In some embodiments, the averaging tool 504 (which averages tissue health index within a defined area) can be implemented to assist the user. In some embodiments, the averaging tool 504 can be a small circle on a touchscreen, such as the relatively small area shown in Fig. 5.

[00152] Fig. 6 is a schematic diagram of an exemplary embodiment of computing device 108. As depicted, computing device 108 (e.g. mobile device 108) includes at least one processor 602, memory 604, at least one I/O interface 606, and at least one network interface 608.

[00153] Each processor 602 may be, for example, any type of general-purpose microprocessor or microcontroller, a digital signal processing (DSP) processor, an integrated circuit, a central processing unit (CPU), a graphics processing unit (GPU), a field programmable gate array (FPGA), a reconfigurable processor, a programmable read-only memory (PROM), or any combination thereof.

[00154] Memory 604 may include a suitable combination of any type of computer memory that is located either internally or externally such as, for example, random-access memory (RAM), read-only memory (ROM), compact disc read-only memory (CDROM), electro-optical memory, magneto-optical memory, erasable programmable read-only memory (EPROM), and electrically-erasable programmable read-only memory (EEPROM), Ferroelectric RAM (FRAM), or the like.

[00155] Each I/O interface 606 enables computing device 108 (e.g., a mobile device 108) to interconnect with one or more input devices, such as a keyboard, mouse, camera, touch screen, and a microphone, or with one or more output devices such as a display screen and a speaker.

[00156] Each network interface 608 enables computing device 108 (e.g., a mobile device 108) to communicate with other components, to exchange data with other components, to access and connect to network resources, to serve applications, and perform other computing applications by connecting to a network (or multiple networks) capable of carrying data.

[00157] Computing device 108 is operable to register and authenticate users (using a login, unique identifier, and password, for example) prior to providing access to applications, a local network, network resources, other networks, and network security devices. Computing devices 108 may serve one user or multiple users.

[00158] Fig. 7 is an example of an illumination and image capturing schema according to some embodiments. Other illumination and image capturing schemas can be used. In order to account for external illumination, the example image capturing/illumination schema in Fig.7 has been developed.

[00159] Fig. 7 plots the flash 702 coordinated by illumination unit 104, as a function of time. Computing device 108 (e.g., a mobile device 108) uses the synchronization of flash if the illumination unit 104 is used to provide the external flash. As shown at 702, the illumination schema (cycle) consists of m flashes (with m=2 in the example of Fig. 7) and one period without flash, with $n/4 \leq m \leq n$, where n is the number of wavelengths. Cycles can be repeated continuously during video mode capturing.

[00160] The exposure time (T) for each frame (in milliseconds) can be selected as $T=k/2*f$, where k is an integer, and f is the utility frequency for a particular country in Hz (e.g., 60Hz for North America, 50Hz for Europe). In a video mode, the framerate can be selected as $fps=2*f/k$ (e.g., 30, 24, 20, 15, 12, and 10 fps for North America and 25, 20, and 10 fps for Europe). The frame rate of 20fps (T=50ms) is an example selection. It can work without any configurations with external light sources connected to any electrical grid (50Hz or 60Hz). Other frame rates can also be used.

[00161] The duration of each flash can be T or any whole number multiple of T. This arrangement facilitates easy optical synchronization between illumination unit and image capturing unit. For example, the cycle consists of m back to back flashes with duration 2T milliseconds each, followed by no lit period 2T milliseconds long, as shown in the plot 702.

[00162] In some embodiments, computing device 108 (e.g. mobile device 108) associated with an illumination unit 104 may use the same frame to capture an image illuminated at 2,

3, or 4 wavelengths, which can be captured by different color wavelengths of an RGB camera (e.g. 480 and 660nm, which will be captured by blue and red wavelengths, respectively) or an RGB-NIR camera.

[00163] Fig. 8 is a view of example illumination units according to some embodiments.

[00164] An illumination unit 104 can be an external flash device that can be attached to a computing device 108, for example, a smartphone. In some embodiments, it can be synchronized with a tissue visualization app 112 or computing device 108 (e.g., a mobile device 108) using Bluetooth or other connectivity. In some embodiments, the illumination unit 104 can be built into a case for a computing device 108 (e.g., a mobile device 108). In some embodiments, the illumination unit 104 receives power from the computing device 108 (e.g., a mobile device 108) or an external source (e.g., wall charger).

[00165] In some embodiments, illumination unit 104 comprises a battery. The illumination unit 104 can also be chargeable using a standard micro USB port, wirelessly or by way of inductive charging.

[00166] The illumination unit 104 can be used with a front- or back camera of a mobile device 108, for example. Illumination unit view 806 illustrates an illumination unit 104 used in conjunction with a front-facing camera of a user computing device 108.

[00167] In some embodiments, the illumination unit 104 can be optimally designed to associate with a computing device 108 (e.g. mobile device 108) by way of a clip or other means 302 that can be attached to the computing device 108 (e.g. mobile device 108) with the thickness of up to 15mm, as shown in views 802 and 804.

[00168] In an example embodiment, illumination unit 104 uses a compression clip that can be attached to the computing device 108 (e.g. mobile device 108), with the thickness up to 15mm, as shown in view 802. In some embodiments, the illumination unit 104 can be mounted using a spring clip, as shown in views 804 and 806.

[00169] The illumination unit 104 can produce a sequence of flashes of predetermined length. A wavelength can refer to light sources shining at the same wavelength, or the possibility of multiple wavelengths shining in a single flash. Each of the flashes may shine at 1-4 particular wavelengths.

[00170] The illumination unit 104 can use narrow band high-efficiency light sources 300, such as LEDs. The light source in the illumination unit 104 may contain single wavelength or multi-wavelength LEDs.

[00171] As shown in view 802, the light sources 300 can be arranged in a circle, with a center close to the center of a camera 103 of computing device 108 (e.g. mobile device 108).

[00172] In some embodiments, each wavelength can consist of two or four light sources 300, arranged in a symmetrical pattern on an illumination unit 104 (e.g., every 180 or 90 degrees on a circle).

[00173] For oxygenation measurements, the illumination unit 104 can use two or more wavelengths in the range of 450-750nm. For measurements of oxygenation and perfusion and the compensation of skin color (melanin), the illumination unit 104 can use three or more wavelengths in the range of 450-750nm. In an example embodiment, 450-650nm range is used.

[00174] Wavelengths can be selected from one or more of the following regions: a) biggest discrimination in light absorption between oxy- and deoxyhemoglobin: 450-500nm and 600-750nm, b) isobestic points (e.g., 510±10nm, 525±10nm, and 590±10nm), c) largest absorption by oxy- and deoxyhemoglobin: 540-580nm.

[00175] For water content measurement in addition to two or more wavelengths in 450-750nm (or preferably 450-650nm) range a wavelength of 970±10nm is used.

[00176] For bacterial burden measurements, a wavelength of 405±10nm is used. In some embodiments, it can be combined with two or more wavelengths in 450-750nm (or preferably 450-650nm) range, which captures reflectance images.

[00177] For bacterial burden measurements, the illumination unit 104 or image capture unit 103 may contain emission filter 305. In an example embodiment, the emission filter is attached to the illumination unit 104. In some embodiments, the emission filter 305 is a long pass filter with cut-on wavelength 450±25nm. In some embodiments, the emission filter is a band pass filter with the transmission in the 425-750nm range, which has the lower cut-on wavelength in the 450±25nm range.

[00178] The illumination unit 104 can be synchronized with an image capture unit 103 of computing device 108 (e.g. mobile device 108) to produce an illumination schema. The illumination unit 104 associated with an image capture unit 103 can follow an illumination schema where each wavelength shines sequentially (n=m, where n is the number of wavelengths, m is the number of flashes in one cycle).

[00179] In some embodiments, lighting unit 300 configured to engage with a computing device 108 (e.g. mobile device 108) or image capture unit 103 may have the following example implementations:

- the lighting unit 300 may provide light from sources arranged in a circle or otherwise;
- the lighting unit 300 may use two, four or another number of light sources per wavelength;
- the lighting unit 300 may use light sources with central wavelength 405±10nm for bacteria imaging;
- the lighting unit 300 may use an additional 750-1000nm range for user devices 102 without an IR filter on camera (e.g., front-facing camera on a smartphone);
- the lighting unit 300 may use light sources with a central wavelength of 970±10nm for water imaging for user devices 102 without an IR filter on camera (e.g., front-facing camera on a smartphone);
- the illumination unit 104 and/or lighting unit 300 and a computing device 108 (e.g. mobile device 108) can be mounted on an extension device (e.g., on a selfie stick);
- the imaging unit 104 can be associated with an external lens (e.g., macro lens), emission filter, polarizer, or not.

[00180] In some embodiments, illumination unit 104, for example, including a multispectral external flash, can be operable with an image capture unit 103 or another recording device. For example, illumination unit 104 may be integrated with a personal computer, tablet, or otherwise.

[00181] The systems described tends to offer distinct advantages. For example: the flash design may be used with any computing device 108, such as a smartphone (iOS, Android, etc.) of any shape; the flash/image capturing schema, may allow measurements in any type of ambient light and with any type of smartphone; self-calibration using a self-reference object increases accuracy; proper positioning of the camera (distance from the wound) is facilitated by use of a self-reference object (e.g. a circle); and the illumination schema produces reproducible and homogeneous illumination. The above-noted expected advantages are examples of advantages and may not comprise all advantages of the present systems/devices.

[00182] The system can also tend to overcome challenges, for example, of building the flash, in the case for a smartphone, such as a challenge that each smartphone can have its

own form-factor and thus would require multiple cases to be built at least for the most popular models. Other challenges that the system may overcome, or benefits of the system, include:

- use of IR filter on some smartphone cameras. These filters, which are used to improve the quality of pictures, filter out light with wavelengths over 750nm and are being used mostly on more expensive smartphones. Typical pulse oximetry schemas employ 660 and 900nm bands. Thus, these schemas cannot be employed universally on smartphones.
- Connection to a plurality of existing EHR systems.
- Motion artifacts (e.g., due to tremor) while taking measurements.
- The flickering, high dynamic range, etc. that may result from taking images in various light conditions (e.g., indirect sunlight, office light, observation room, etc.) is combatted.
- Flickering caused by the various utility frequencies in different countries.
- Producing predictable light distribution, not very sensitive to slight misplacements of the flash or the smartphone.
- Difficulty in synchronizing the phone and external flash.
- Use of the lens (e.g., Fresnel lens) covering the light sources homogenizes the light distribution on the target area, thus extending dynamic range and increasing the accuracy of measurements.
- use of multiwavelength LEDs (e.g., RGB LEDs) creates the similar intensity distribution for each wavelength and saves space on the illumination unit.
- The intensity of illumination can vary, for example, based on the distance to a target area and the stability of LED intensity (e.g., LED intensity may change with time, temperature, or within battery cycle). In particular, the intensity of illumination light on the surface of the tissue drops as an inverse square with the distance from the illumination unit to the target area. Thus, increasing working distance by 50%, will cause drop of illumination intensity by 55%, and so the system can compensate by capturing the intensity of illumination at the revised working distance and normalizing images on these values.
- porphirin and pyoverdine have an absorption peak in Soret band, where oxyhemoglobin and deoxyhemoglobin have absorption peaks as well. The presence

of a blood component may significantly impact porphyrin/pyoverdine emission. True fluorescence intensity can be deconvoluted using known oxyhemoglobin and deoxyhemoglobin concentrations.

- Ability to change or upgrade components of the system independently. For example, a user can use his or her own smartphone as a computing device, and upgrade such device with updated versions without a necessity to buy a whole new system.

[00183] A tissue imaging system 105 can be used in a variety of applications, including in the following scenarios.

[00184] **Use case 1**: A doctor at a hospital during a physical exam of a patient in acute care has found a suspicious wound on the leg. The patient has diabetes, so the MD has a suspicion that it can be a non-healing DFU. The current standard of care for this is angiography, which is not available in his community hospital. It will cost around $20,000 for the procedure and arrangement of medical transportation to/from another hospital. However, using the device the doctor can screen the wound on the spot and see whether it is ischemic (and require angiography for proper assessment) or nonischemic (and will heal well without any extra efforts).

[00185] **Use case 2:** A family doctor during an annual checkup has found a suspicious wound on a patient's leg. The patient has diabetes, so the MD has a suspicion that it can be a non-healing DFU. The current standard of care for this is angiography. However, it can be performed in major hospitals only. It is associated with $1,500 per procedure (in the US) or waiting time (for example, 41 days in Ontario, Canada). Using the device, the doctor can screen the wound on the spot and see whether it is ischemic (and require angiography for proper assessment) or nonischemic (and will heal well without any extra efforts).

[00186] **Use case 3**: A family doctor during an annual checkup has found a suspicious wound on a patient's leg. The patient has diabetes, so the MD has a suspicion that it can be a non-healing DFU. The current standard of care for this is angiography. It can be performed in major hospitals only. It is associated with $1,500 per procedure (in the US) or waiting time (for example, 41 days in Ontario, Canada). Using the device, the doctor captures images of the wound on the spot. However, such as he does not have significant experience in wound care, he decides to send images to a podiatrist, who provides him with an assessment of whether it is ischemic (and requires angiography for proper assessment) or nonischemic

(and will heal well without any extra efforts). The doctor accordingly refers the patient to the podiatrist.

[00187] **Use case 4**: A nurse is attending a small rural community. During an exam of a patient, she has found a suspicious ulceration near the small toe. She has a suspicion that it can be a peripheral arterial disease. She uses the device to take a snapshot of the wound and sends images to a family physician (if the patient has one) or a podiatrist. The doctor reviews the images and provides guidance within a few hours. The nurse instructs the patient on further actions.

[00188] **Use case 5**: A medical nurse is attending a small long-term residence. During an exam of a patient, she has found a suspicious ulceration near the big toe. She has a suspicion that it can be a peripheral arterial disease. She uses the device to take a snapshot of the wound and sends images to a family physician (if the patient has one) or a podiatrist. The doctor reviews the images and provides guidance within a few hours. The nurse instructs the patient on further actions.

[00189] **Use case 6**: A senior with diabetes finds a suspicious cut on his heel. He is aware of the dreadful consequences of DFU, so he decides to buy the device in a drugstore. With the help of his wife he takes images of the wound and sends them to his family doctor. The doctor makes an assessment and advises the patient within a few hours.

[00190] **Use case 7**: A senior with diabetes finds a suspicious cut on her forefoot. She is aware of the dreadful consequences of DFU, and tells her concerns to her daughter. Her daughter bought a flash attachment 104 in a drugstore, attaches it to her smartphone 108, downloads the tissue visualization app 112, and takes images of the wound. As her mother does not have a family doctor, she sends the images to a podiatrist. The doctor makes an assessment and sends a referral within a few hours.

[00191] **Use case 8:** A family doctor during an annual checkup of a patient finds a suspicious mole. Using the device, he can screen the mole on the spot and see whether it is suspicious (has increased blood supply and requires additional study) or not suspicious.

[00192] **Use case 9:** The nurse in a long-term care facility checks a bed-bound patient for potential pressure ulcers. Using the device, she can screen bony prominence areas to determine if any are suspicious.

[00193] **Use case 10:** An advanced wound care nurse cleanses an existing wound. She uses the device to visualize bacterial presence and to guide debridement.

[00194] **Use case 11:** A nurse takes a swab from an existing wound. She uses the device to visualize bacterial presence and to guide swabbing.

[00195] The accuracy of measurements can be improved if the light intensity distribution produced by illumination unit 104 is known. In an example embodiment, to capture light intensity distribution produced by illumination unit 104, a reference image is used.

[00196] With reference to Fig. 9, example features used for capturing reference images are depicted. In some embodiments, the reference image can be captured by calibration unit 328 of tissue visualization app 112 and then used by the tissue imaging system 105 or tissue visualization system 100 to obtain a processed measurement 501 (an example of which is shown in FIG. 5).

[00197] The reference image is captured using a reference object 901. Reference object refers to an object with known homogeneous optical properties (e.g., spectral dependence of reflectance). Reference object 901 can be various shapes, such as a circle or rectangle. In an example embodiment, reference object 901 is a rectangle with an aspect ratio of 4:3. Various colors can be used for reference object 901, such as white or gray (for example, an 18% gray rectangle on a white background 904, such as a white sheet of paper).

[00198] In one embodiment, screen markers 902 displayed on a screen 318 of the computing device 108 (e.g. mobile device 108) can define a target area 903 which can be used to position the device an optimal distance away from the reference object 901. The computing device 108 should be positioned such that screen markers 902 line up with the reference object 901 to ensure an optimal image-capturing distance is achieved. Other distance measuring devices, such as a rangefinder or ruler, can be used to position device at the optimal distance. In an example embodiment, object recognition by tissue visualization app 112 can be used to position the device at the optimal image capturing distance.

[00199] In an example embodiment, the computing device 108 (e.g., a mobile device 108) can take the required reference image automatically upon proper placement of the device. In other embodiments, the computing device 108 takes the image upon manual user initiation. In an embodiment, upon activation of the image capture unit 103, the computing device 108 takes several images. In an example embodiment, one or more images are taken with flash, and one is taken without. Alternatively, images can be taken only with flash.

[00200] The computing device 108 (e.g., a mobile device 108) can pre-process the reference image to improve the image quality. The pre-processing may comprise the following steps: a) image registration, b) image subtraction.

[00201] In some embodiments, computing device 108 (e.g., a mobile device 108) uses image registration to reduce shake during image capturing. This can be accomplished using phase correlation or block matching algorithms.

[00202] In some embodiments, computing device 108 (e.g., a mobile device 108) uses image subtraction to remove ambient light in the image. In this case, the image without external illumination (no flash) is subtracted from images with external illumination (with flash). Image subtraction is not required if only images with flash are used.

[00203] The reference image can be stored locally on the computing device 108 (e.g. mobile device 108) or remotely, for future use.

[00204] The reference image can be captured before the first measurement and at any time thereafter. There is no need to capture reference images before every measurement.

[00205] Steps for producing measurement map 501 are now discussed, with respect to Fig. 10.

[00206] Computing device 108 (e.g. mobile device 108) is held at a specific distance away from the subject, for example a human body, in order to optimally image the area of interest.

[00207] In some embodiments, a self-reference object 1002 is used to ensure the proper distance from the human body. A self-reference object 1002 is placed within the device target area 1001 imaged by the computing device 108 (e.g., a mobile device 108). In an example embodiment, the self-reference object 1002 comprises an 18% gray circle 1-2 cm in diameter.

[00208] In some embodiments, the computing device 108 (e.g. mobile device 108) or image capturing unit 103 is moved so that a predefined screen marker 1003 is shown as the same size as self-reference object 1002 on the device target area 1001, so as to guide the user to the optimal image capturing distance.

[00209] In an example embodiment, computing device 108 (e.g., a mobile device 108) uses object recognition to trigger automatic image capturing upon a certain screen size of the self-reference object, in pixels, being achieved.

[00210] Alternatively, other means of measuring a distance, such as a rangefinder or a ruler, can be used to position the device at the proper distance from the area of interest.

[00211] Once the optimal distance from the human body is determined, computing device 108 (e.g., a mobile device 108) can take the required images. In an example embodiment, the device takes the required image automatically upon the proper placement of the computing device 108 (e.g., a mobile device 108) or image capturing unit 103. The device may take several images. In an example embodiment, one or more images will be taken with flash, and one will be taken without flash.

[00212] The device pre-processes the image in order to improve the quality of the image and measurement map 501. The pre-processing may contain the following steps: a) image registration, b) image subtraction.

[00213] In some embodiments, the device uses image registration to reduce shake. This can be accomplished through phase correlation or block matching.

[00214] In some embodiments, the device uses image subtraction to remove ambient light in the image. In this case, the image without external illumination (flash) is subtracted from images with external illumination (flash).

[00215] To further increase the quality of results, the self-calibration of each measurement using a self-reference object 1002 can be implemented. In this case the pre-processing may contain the following steps: a) image registration, b) image subtraction, c) self-calibration, and d) division on the reference image, e) flattening the images.

[00216] If the embodiment utilizes self-reference object 1002, the intensity of the image is adjusted using the self-reference object to account for any imperfections or changes in intensity. In an example embodiment, pre-processing unit 328 can compare the intensity of a self- reference object in the target image with the intensity of the same region in the reference image and use the ratio between the two to scale the intensity of the target image pixel-by-pixel.

[00217] If the embodiment utilizes previously taken reference images, the device finds the normalized image by dividing pixel-by-pixel image onto the reference image and multiplying by a known reflectance of the reference object.

[00218] In some embodiments, the tissue imaging system 105 can perform the processing of the image to obtain measurements. This can be achieved through all or some of the following steps: a) the absorption coefficient is determined from reflectance (e.g., using Beer-Lambert, or modified Beer-Lambert law); b) the chromophore concentration is determined from the absorption coefficient (e.g., using least square fitting); c) the perfusion

and oxygenation is determined from the chromophore concentration (oxygenation = oxyhemoglobin/(oxyhemoglobin+deoxyhemoglobin), perfusion= oxyhemoglobin + deoxyhemoglobin).

[00219] In some embodiments, the pre-processed measurement (normalized image) is taken on computing device 108 (e.g., a mobile device 108) and then sent through network 110 to the tissue visualization system 100.

[00220] Bacterial burden indicator can be used stand-alone or in combination with reflectance images. Porphyrin and pyoverdine have an absorption peak in the Soret band, where oxyhemoglobin and deoxyhemoglobin have absorption peaks as well. Thus, the presence of a blood component may significantly impact porphyrin/pyoverdine emission. With reference to Fig. 4, true fluorescence intensity can be deconvoluted using known oxyhemoglobin and deoxyhemoglobin concentrations found in step 410. In an example embodiment, a light source with the center wavelength of 405±10nm is used in combination with 2 or 3 wavelengths from the 450-650nm range.

[00221] Once tissue health indicators levels are found, the invention presents the color or grayscale maps through processing via tissue visualization system 100 or tissue imaging system 105. These results can be stored locally on the device or remotely. The pre-processed normalized image and the processed tissue health indicators maps can all be stored in local or remote storage.

[00222] The embodiments of the devices, systems, and methods described herein may be implemented in a combination of both hardware and software. These embodiments may be implemented on programmable computers, each computer including at least one processor, a data storage system (including volatile memory or non-volatile memory or other data storage elements or a combination thereof), and at least one communication interface.

[00223] Program code is applied to input data to perform the functions described herein and to generate output information. The output information is applied to one or more output devices. In some embodiments, the communication interface may be a network communication interface. In embodiments in which elements may be combined, the communication interface may be a software communication interface, such as those for inter-process communication. In still other embodiments, there may be a combination of communication interfaces implemented as hardware, software, and combination thereof.

[00224] Throughout the foregoing discussion, references have been made to servers, devices, systems, units, or computing devices. It should be appreciated that the use of such terms is deemed to represent one or more computing devices having at least one processor configured to execute software instructions stored on a computer-readable tangible, non-transitory medium. For example, a server can include one or more computers operating as a web server, database server, or another type of computer server in a manner to fulfill described roles, responsibilities, or functions.

[00225] Various example embodiments are described herein. Although each embodiment represents a single combination of inventive elements, all possible combinations of the disclosed elements include the inventive subject-matter. Thus, if one embodiment comprises elements A, B, and C, and a second embodiment comprises elements B and D, then the inventive subject-matter is also considered to include other remaining combinations of A, B, C, or D, even if not explicitly disclosed.

[00226] The term “connected” or "coupled to" may include both direct coupling (in which two elements that are coupled to each other contact each other) and indirect coupling (in which at least one additional element is located between the two elements).

[00227] Part of the technical solution of embodiments may be in the form of a software product (while other required aspects, for example the image capture unit 103 and illumination unit 104, necessitate hardware). The software product may be stored in a non-volatile or non-transitory storage medium, which can be a compact disk read-only memory (CD-ROM), a USB flash disk, or a removable hard disk. The software product includes a number of instructions that enable a computer device (personal computer, server, or network device) to execute the methods provided by the embodiments.

[00228] The embodiments described herein are implemented by physical computer hardware, including computing devices, servers, receivers, transmitters, processors, memory, displays, and networks. The embodiments described herein provide useful physical machines and particularly configured computer hardware arrangements. The embodiments described herein are directed to electronic machines and methods implemented by electronic machines adapted for processing and transforming electromagnetic signals which represent various types of information.

[00229] Although the embodiments have been described in detail, it should be understood that various changes, substitutions, and alterations can be made herein without departing from the scope as defined by the appended claims.

[00230] Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed, that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein, may be utilized. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

[00231] As can be understood, the examples described above and illustrated are intended to comprise examples only.

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WHAT IS CLAIMED IS:

1. A portable illumination apparatus for facilitating visualizations of tissue, the apparatus comprising:

   a portable housing for detachable attachment proximal to an image capturing unit; and

   an illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$.

2. The portable illumination apparatus of claim 1, wherein the illumination unit further comprises a lens covering the one or more light sources, the lens having a focal length that is 80%-120% of a working distance between the illumination unit and a target area of tissue.

3. The portable illumination apparatus according to any one of claims of 1-2, wherein the one or more light sources is configured to provide flashes that are at least one of

   (i) 405±10nm wavelength, and having at least one of (a) a long pass filter with a cut-on wavelength of 450±25nm or (b) a bandpass filter with transmission in a 425nm-1000nm range,

   (ii) two wavelengths in a 450nm-750nm range, at least one of which in the green range,

   (iii) three wavelengths in a 450nm-750nm range, at least one of which in the green range, or

   (iv) 970±10nm wavelength.

4. The portable illumination apparatus according to any one of claims 1-3, wherein the illumination unit further comprises at least one of (i) a controller to control

illumination of the one or more light sources and (ii) a rechargeable battery for powering the apparatus.

5. The illumination apparatus according to any one of claims 1-4, wherein the one or more light sources are arranged about a central aperture having a radius of 0.5-3cm.

6. The illumination apparatus of claim 5, wherein the one or more light sources are arranged in a ring having a radius of 1.5-6cm.

7. The illumination apparatus according to any one of claims of 1-6, wherein the portable housing comprises a compression clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

8. The illumination apparatus according to any one of claims of 1-6, wherein the portable housing comprises a spring clip for mounting the apparatus on a mobile device along at least one edge of the mobile device and proximal to a camera of the mobile device.

9. A tissue imaging system for visualization of tissue health indicators comprising a portable computing device, an image capture unit, and an illumination unit;

the illumination unit comprising one or more narrow band light sources configured to shine m flashes at n predetermined wavelengths, wherein $n/4 \leq m \leq n$;

the image capture unit and the illumination unit being configured to capture measurement data for a target area of tissue;

the computing device comprising a processor configured to access and execute instrutions in accordance with a tissue visualization application stored in a non-transitory computer-readable memory of the computing device, for capturing measurement data, and pre-processing and processing the measurement data to generate tissue health indicators.

10. The tissue imaging system of claim 9, wherein the computing device comprises a mobile device and the image capture unit is a camera integrated with the mobile device.

11. The tissue imaging system according to any one of claims of 9-10, wherein the illumination unit comprises the illumination apparatus according to any one of claims of 1-8.

12. The tissue imaging system according to any one of claims 10-11, wherein the portable illumination unit further comprises a wireless communication module for receiving commands from the computing device.

13. A tissue visualization system operatively connected to one or more tissue imaging systems according to any one of claims of 9-12, comprising a communications module for communicating with the one or more tissue imaging systems, a system processor, and system non-transitory computer-readable memory thereon, configured to receive measurement data and tissue health indicators from the one or more tissue imaging systems and to generate a visualization of tissue health indicators of tissue images received from the one or more tissue imaging systems, for display to a user display unit.

14. A method for generating visualizations of tissue, the method comprising:

positioning a computing device at a proper distance from a target area of the tissue for capturing an image of the target area, the computing device comprising a processor and a non-transitory computer-readable memory storing computer-executable instructions comprising a tissue visualization application;

capturing measurement data using an image capturing unit and an illumination unit, the image capturing unit and the illumination unit communicatively coupled to the computing device and the illumination unit configured to shine m flashes at n predetermined wavelengths during capturing of the measurement data, wherein $n/4 \leq m \leq n$;

pre-processing the measurement data using the tissue visualization application to obtain normalized images;

extracting indications of tissue health indicators from the pre-processed measurement data;

generating interface elements corresponding to the visualization tissue health indicators; and

storing and/or transmitting the indications of the tissue health indicators.

15. The method of claim 14 further comprising, prior to capturing the measurement data:

capturing a reference image, wherein the positioning the computing device for the reference image capturing comprises positioning the computing device using a reference object.

16. The method of any one of claims 14-15, wherein the illumination unit and the computing device are configured to provide a working distance of 15±5cm from the target area of tissue.

17. The method of claim 16 wherein the positioning of the computing device for capturing the measurement data comprises positioning the computing device using a self-reference object.

18. The method according to any one of claims of 14-17 wherein pre-processing comprises at least one of (i) registering images to avoid camera motion artifacts, (ii) subtracting images with no illumination from the illumination unit from images with illumination from the illumination unit to account for the presence of ambient light, (iii) recalibrating each measurement accordingly to control parameters related to intensity of illumination using a self-reference object positioned within the target area, (iv) dividing the intensity images on reference images to obtain normalized images, and/or (v) flattening the obtained images to account for reflections from curved surfaces.

19. The method according to any one of claims of 14-18, wherein camera exposure time is T and a flash time is said T or any whole number multiple of said T.

20. The method according to claim 19, wherein the camera exposure time is 50ms.

21. The method according to any one of claims of 14-19, wherein the measurement data comprises wound-related data.

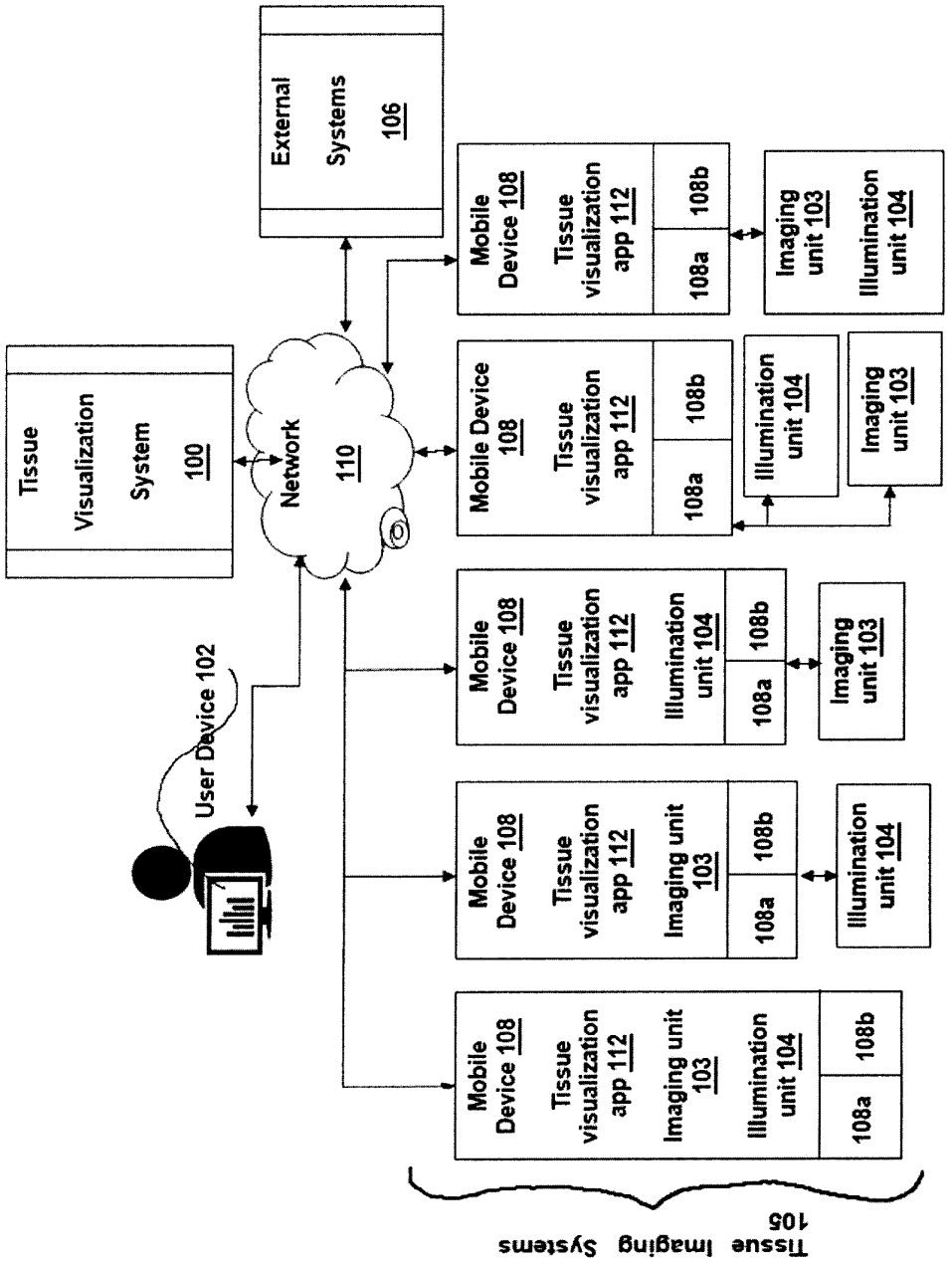
External Systems 106
Tissue Visualization System 100
Network 110
User Device 102
Mobile Device 108
Tissue visualization app 112
Imaging unit 103
Illumination unit 104
108a
108b
Tissue Imaging Systems 105

FIG. 1

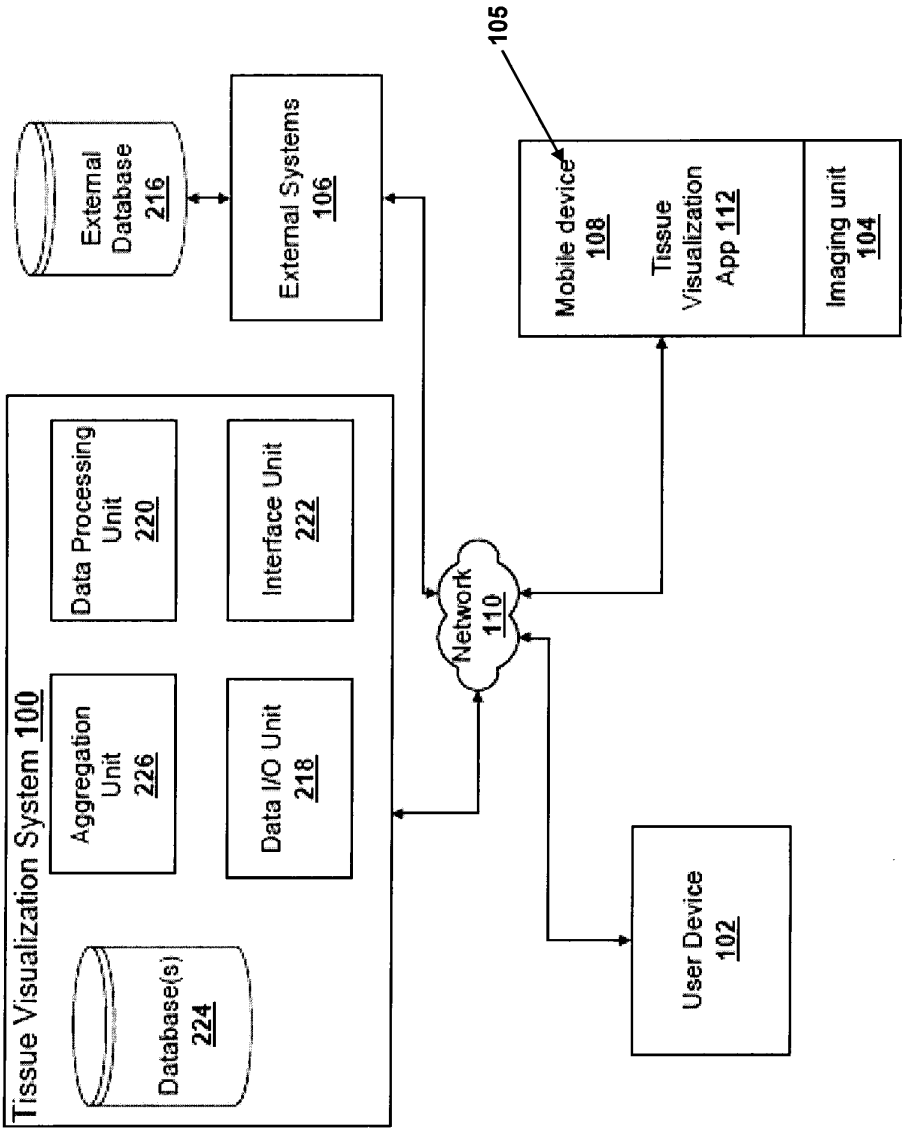
105
External Database 216
External Systems 106
Mobile device 108
Tissue Visualization App 112
Imaging unit 104
Tissue Visualization System 100
Data Processing Unit 220
Interface Unit 222
Aggregation Unit 226
Data I/O Unit 218
Database(s) 224
Network 110
User Device 102

FIG 2

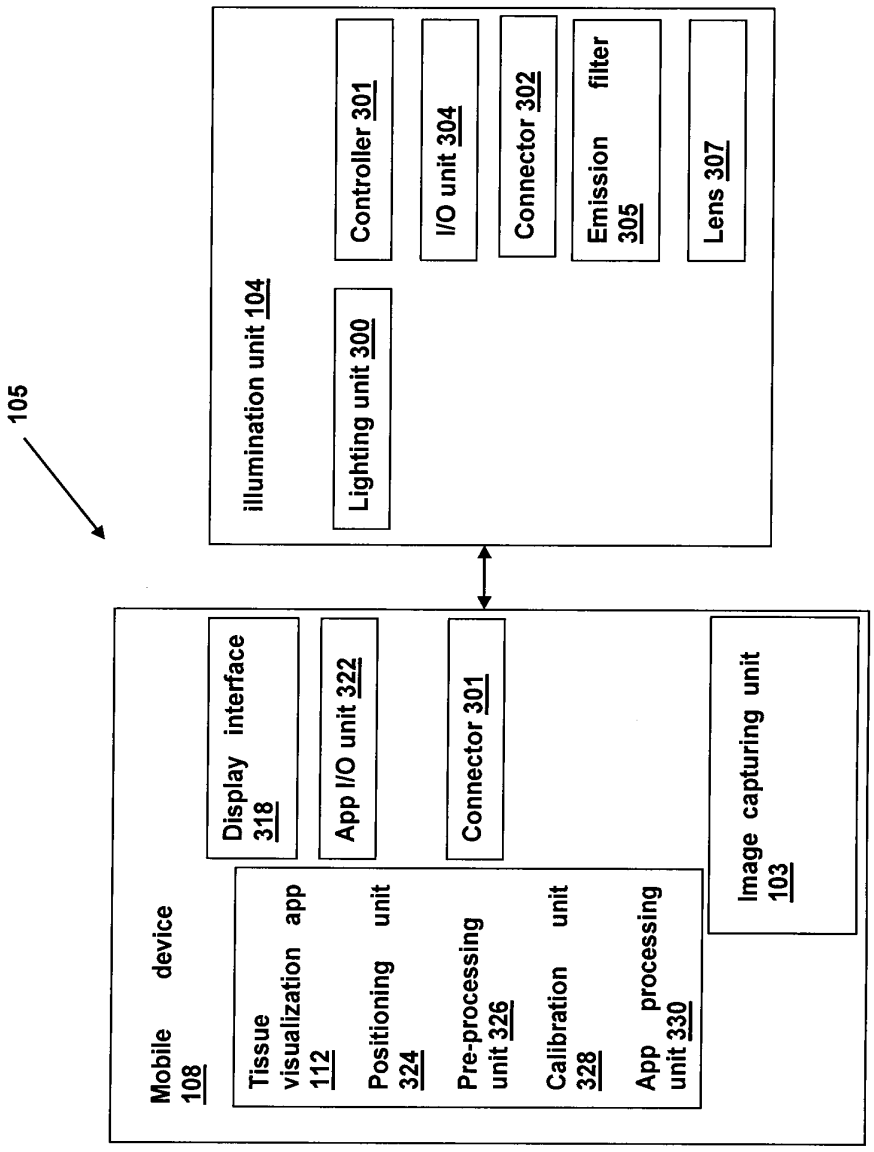
105
illumination unit 104
Lighting unit 300
Controller 301
I/O unit 304
Connector 302
Emission filter 305
Lens 307
Mobile device 108
Display interface 318
App I/O unit 322
Connector 301
Image capturing unit 103
Tissue visualization app 112
Positioning unit 324
Pre-processing unit 326
Calibration unit 328
App processing unit 330

FIG. 3

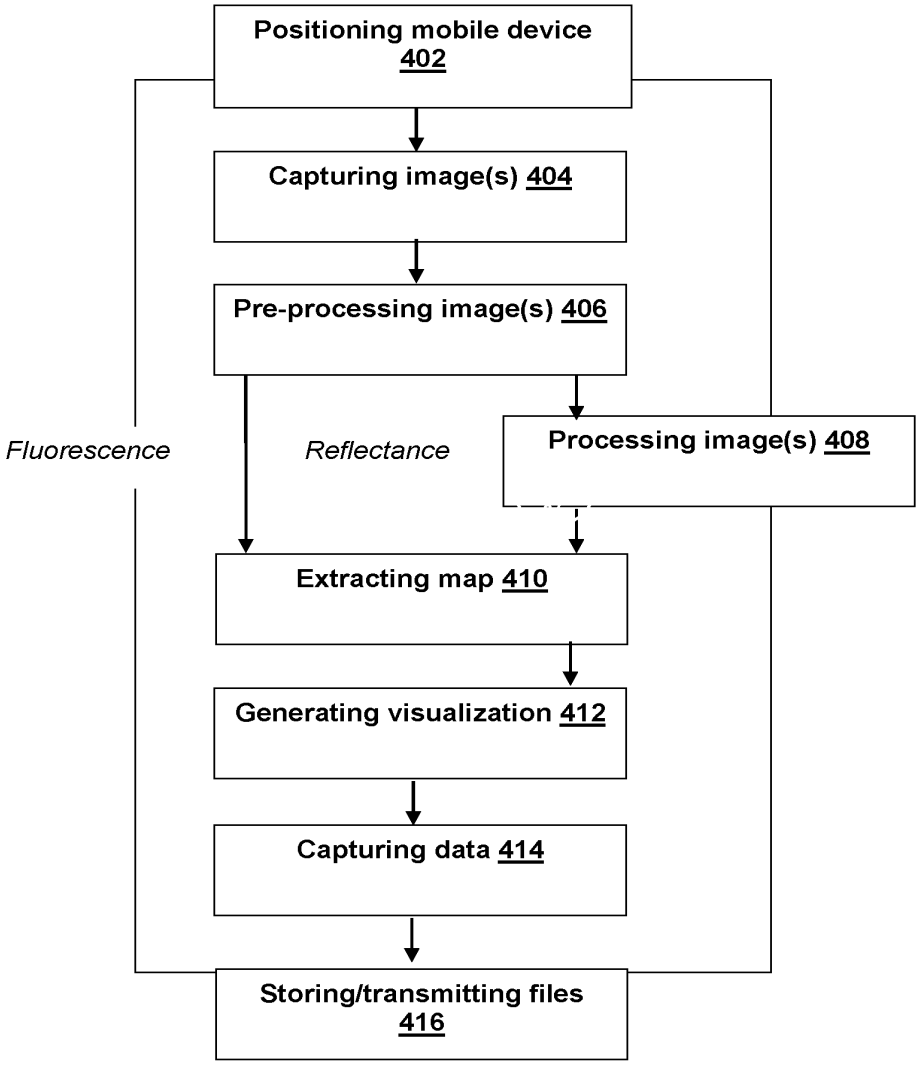
Positioning mobile device 402
Capturing image(s) 404
Pre-processing image(s) 406
Fluorescence
Reflectance
Processing image(s) 408
Extracting map 410
Generating visualization 412
Capturing data 414
Storing/transmitting files 416

FIG. 4

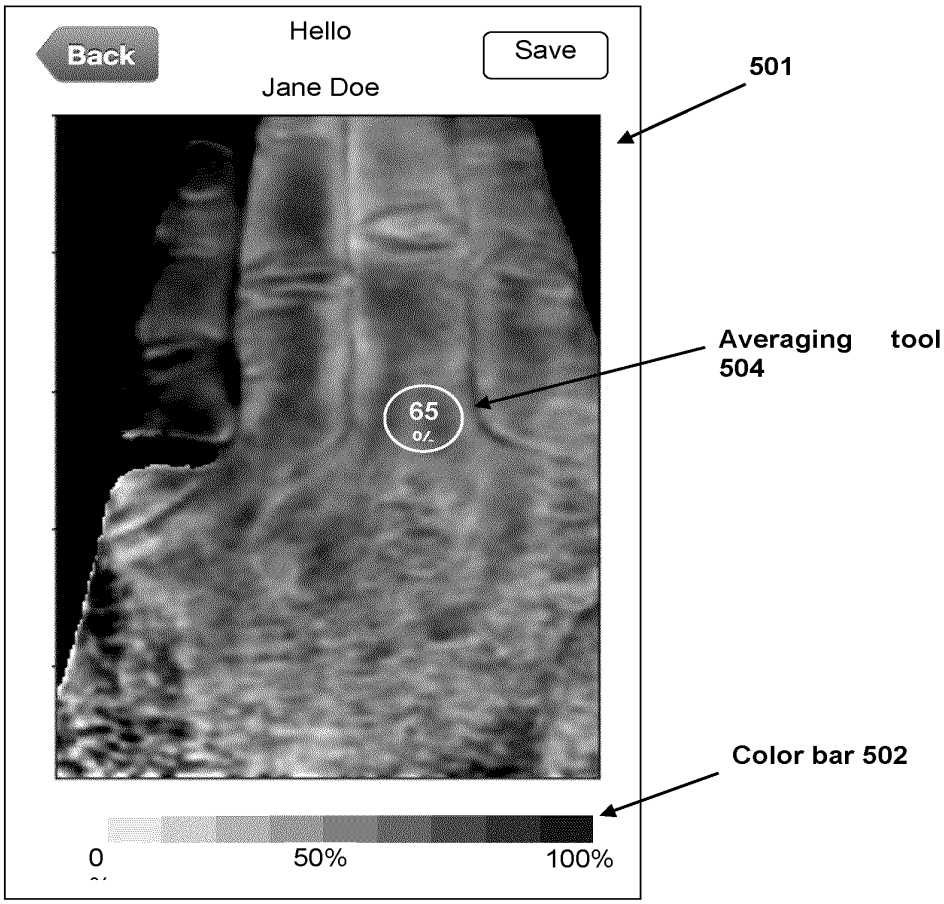
Back
Hello
Jane Doe
Save
501
Averaging tool 504
65
Color bar 502
0
50%
100%

FIG. 5

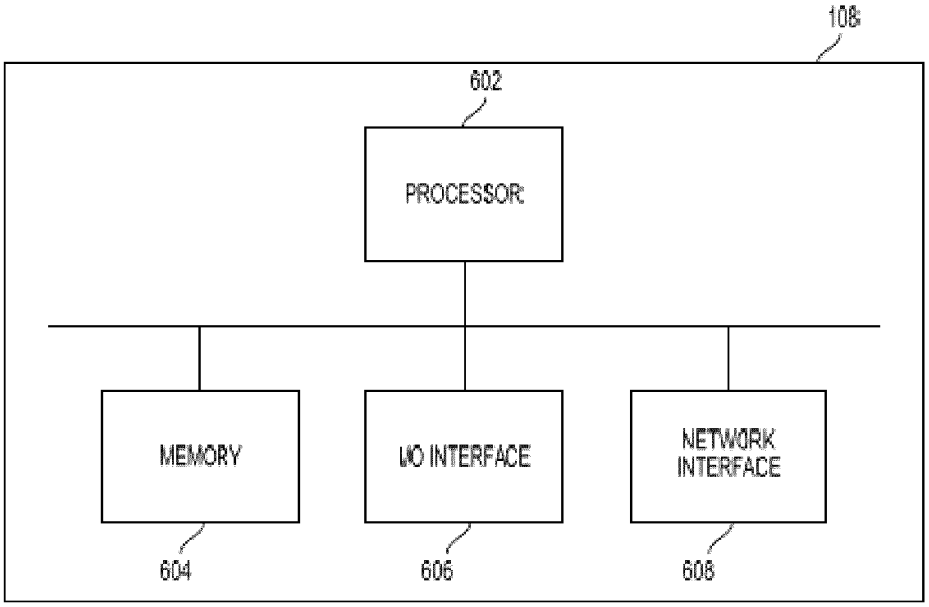
108
602
PROCESSOR
MEMORY
I/O INTERFACE
NETWORK INTERFACE
604
606
608

FIG. 6

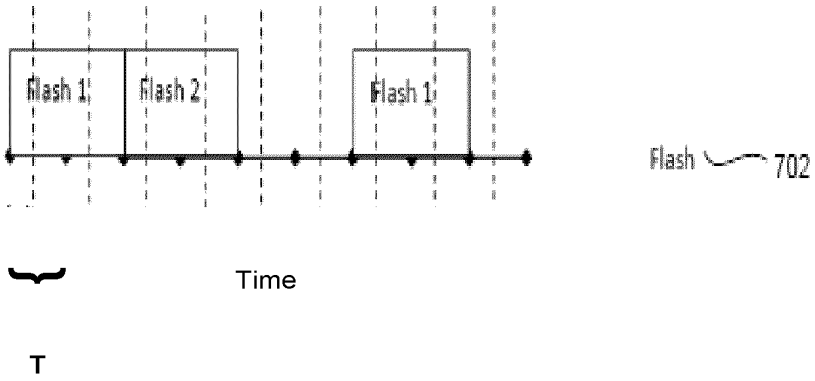

FIG. 7

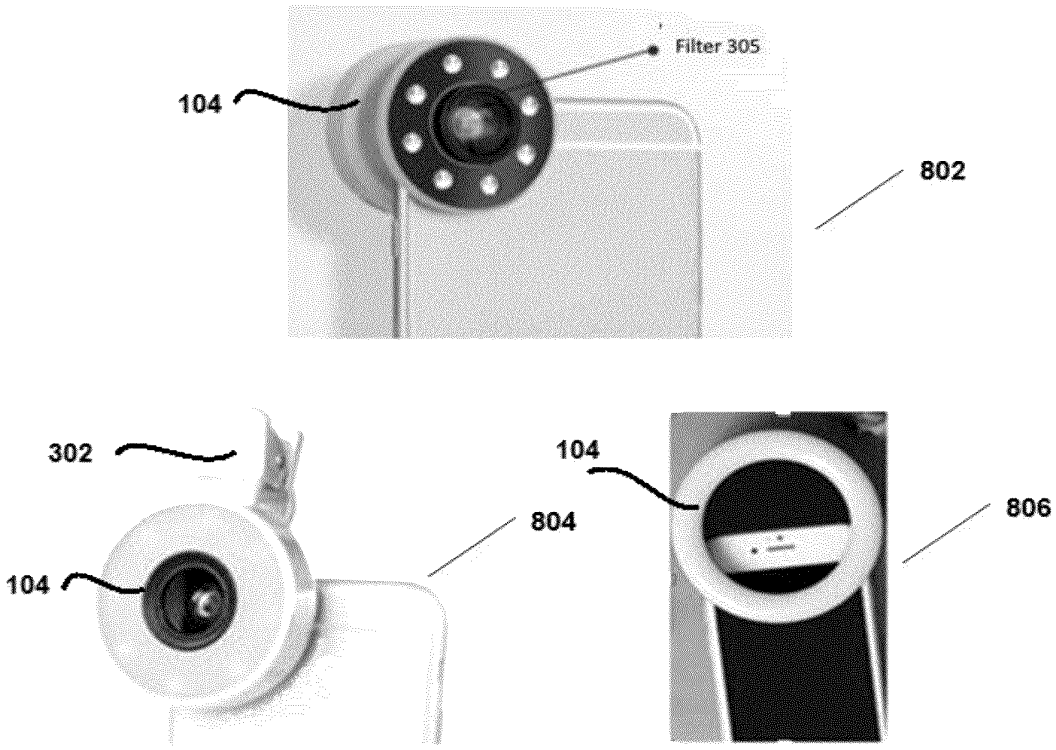

FIG. 8

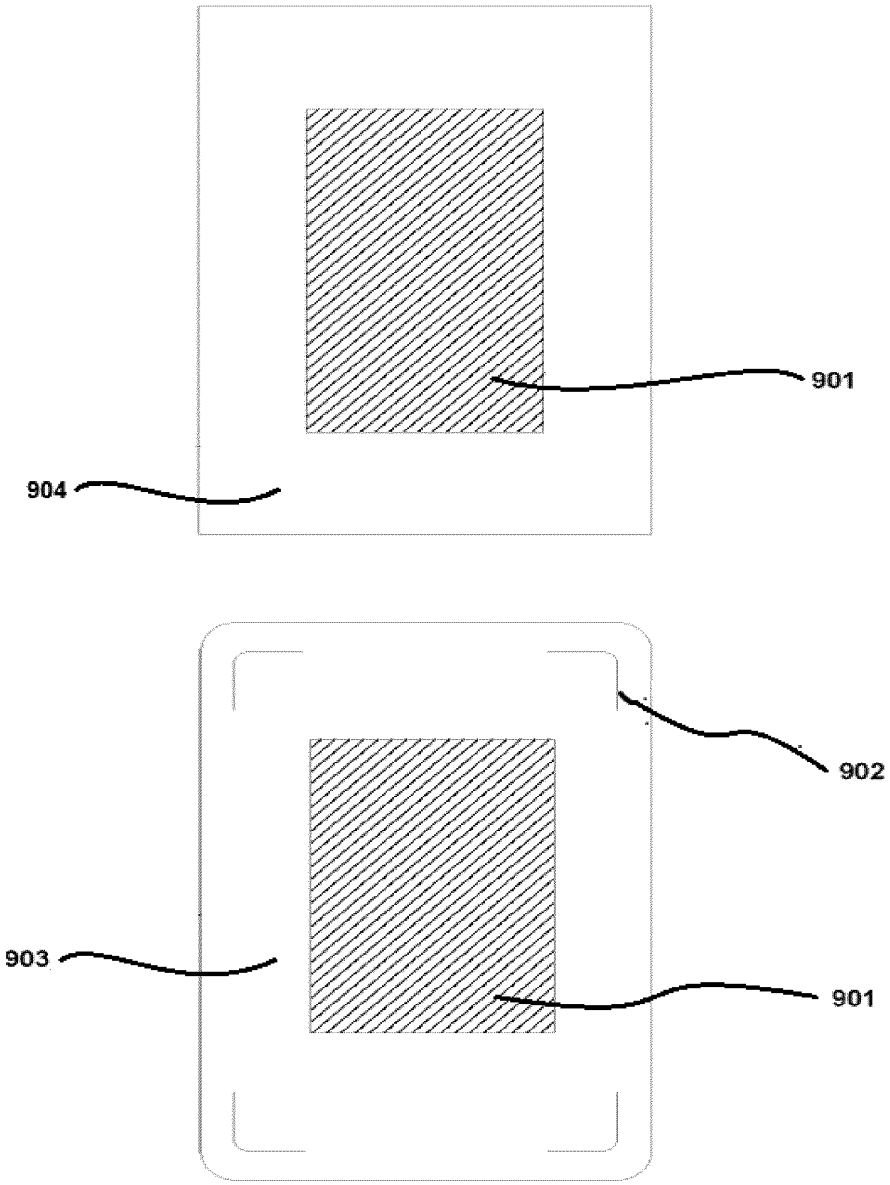

FIG. 9

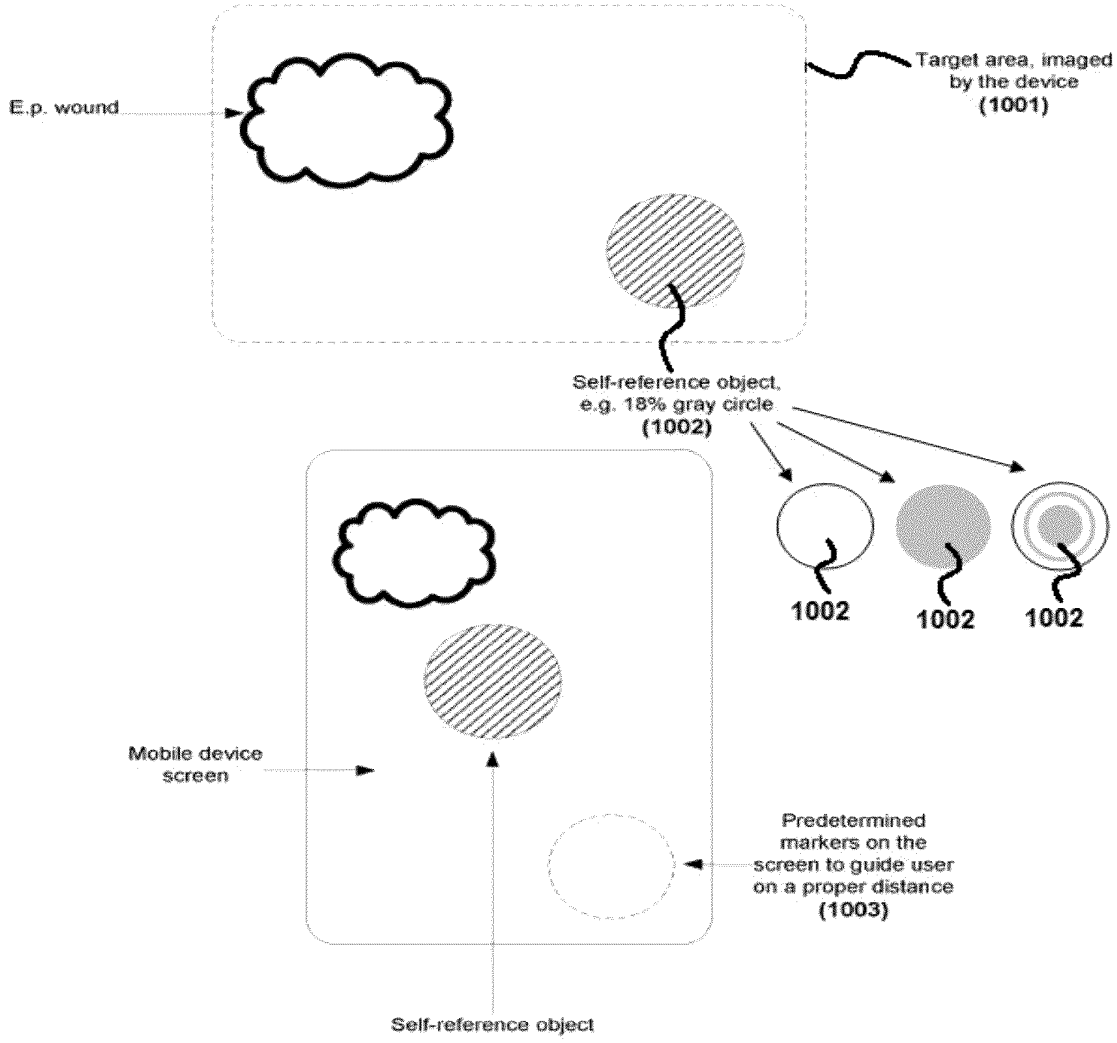
E.p. wound
Target area, imaged by the device (1001)
Self-reference object, e.g. 18% gray circle (1002)
1002
1002
1002
Mobile device screen
Predetermined markers on the screen to guide user on a proper distance (1003)
Self-reference object

FIG. 10