

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
16 December 2004 (16.12.2004)

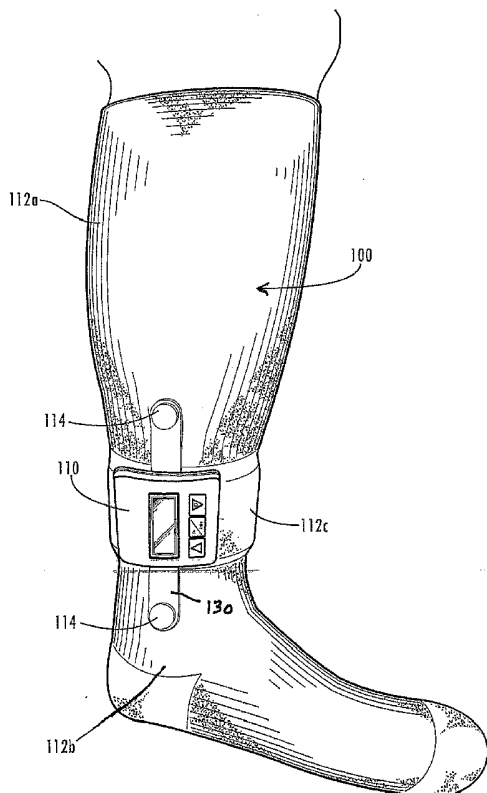
PCT

(10) International Publication Number  
**WO 2004/108209 A1**

- (51) International Patent Classification<sup>7</sup>: **A61N 1/04**, 1/32
- (21) International Application Number:  
PCT/US2004/018198
- (22) International Filing Date: 4 June 2004 (04.06.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
60/476,351 6 June 2003 (06.06.2003) US
- (71) Applicant (for all designated States except US): **PRIZM MEDICAL, INC.** [US/US]; 3400 Corporate Way, Suite 1, Duluth, GA 30096 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **JOHNSON, James, P.** [US/US]; 5853 Ridgetop Drive, Gainesville, GA 30504 (US).
- (74) Agent: **GROFF, Bradley, K.**; Gardner & Groff, PC, Paper Mill Village, Bldg. 23, 600 Village Trace, Suite 300, Marietta, GA 30067 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

[Continued on next page]

(54) Title: ELECTRICAL STIMULATOR AND GARMENT ELECTRODE CONNECTION SYSTEM



(57) Abstract: An electronic stimulator for delivery of energy to a treated body portion through a garment or other form of electrode, and a method of treatment using said stimulator. A connector strap comprising diode bridge circuitry maintains proper polarity on the electrodes regardless of the orientation of connection between the stimulator and the electrode.

WO 2004/108209 A1



FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

**Published:**

— *with international search report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## ELECTRICAL STIMULATOR AND GARMENT ELECTRODE CONNECTION SYSTEM

### Cross-Reference to Related Applications:

This application claims priority to U.S. Provisional Patent Application Serial  
5 No. 60/476,351, filed June 6, 2003, which is hereby incorporated by reference  
herein for all purposes. U.S. Patent Numbers 4,554,923; 4,664,118 and 5,374,283;  
and U.S. Patent Application Serial No. 10/460,084 filed June 12, 2003 (Publication  
No. US-2004-0030270-A1), are also hereby incorporated by reference herein for all  
purposes.

### 10 Field of the Invention:

The present invention relates generally to an electrical stimulator, and to  
connectors and therapeutic garment systems used in connection therewith. More  
particularly, the invention relates to a pulsed electrical stimulator for direct  
attachment onto a garment electrode, for providing electrical stimulation to nerve,  
15 muscle, skin, circulatory and/or other tissue of a human or animal subject.

### Background of the Invention:

Electrical stimulation has been found to provide therapeutic benefit to various  
biological tissue. For example, transcutaneous electrical nerve stimulation (TENS)  
has been used to treat neuromuscular injuries and other conditions by stimulation of  
20 muscle and nerve tissue. Electrical stimulation has also been found to increase  
circulation, promoting faster healing of injuries and preventing adverse conditions  
resulting from poor circulation. For example, many diabetics suffer from poor  
circulation in their extremities. Foot ulceration caused by poor circulation often  
progresses to more severe tissue damage and even loss of limb in many subjects.  
25 These conditions are commonly aggravated as a result of venous stasis or impaired  
function of venous valves in the extremities.

Electrical stimulation may be delivered to treated tissue by one or more  
electrodes, such as adhesive patch electrodes or garment electrodes. U.S. Patent

Numbers 4,554,923; 4,664,118 and 5,374,283 disclose various forms of garment electrodes for applying electrical stimulation from an electronic stimulator to a treated body part. U.S. Patent Application Serial No. 10/460,084 filed June 12, 2003 (Publication No. US-2004-0030270-A1) discloses a garment electrode  
5 capable of applying compression, preferably gradient compression, to a treated body part. Compression applied in combination with electrical stimulation has been found to provide many benefits for human and/or animal patients with venous disease or related and similar conditions.

Many previously known electrical stimulators have been found lacking in one  
10 or more aspects. For example, many known stimulators are large, heavy and unwieldy to connect to the stimulator electrodes used in connection therewith, and tend to be uncomfortable in use. And some known stimulators have been found to be unduly complex in their construction and use, resulting in undue expense and the potential for incorrect application, as for example by misconnection of electrical  
15 contacts. Also, known electrical stimulators are typically worn attached to the user's belt, and long wire leads are connected to transmit the electrical energy signal to electrodes attached to remote locations on the user's body. These wire leads can be inconvenient to connect, and can limit the user's motion or become disconnected as the user moves. Also, known means of connection between the stimulator and  
20 ~~the electrodes must be carefully connected to provide proper polarity of the~~ delivered stimulation energy, and therapeutic benefit may be impaired if the polarity is reversed due to inadvertent misconnection of the leads.

Thus it can be seen that needs exist for improvements in electrical stimulation devices and therapies, and to improved garment electrode connection  
25 systems used in connection therewith. It is to the provision of devices, systems and methods meeting these and other needs that the present invention is primarily directed.

**Summary of the Invention:**

In its various embodiments, the present invention provides an improved stimulator and garment electrode system for delivering therapeutic energy to treated tissue of a human or animal subject. For example, in one aspect, the invention is an electrical stimulator for use in connection with garment electrodes and other electrodes for affixation to the body of a human or animal subject. The stimulator of the present invention preferably comprises an energy source and means for applying energy from the energy source to the treated body portion. The electrical stimulator is preferably relatively small and lightweight, and is simple in construction and use thereby reducing cost and preventing inadvertent misuse as by improper connection of electrical contacts.

In example embodiments, the electrical stimulator of the present invention is particularly adapted for direct attachment onto a garment electrode worn by the wearer, thereby eliminating the need for long wire leads extending from a belt-worn stimulator to a remote electrode position.

In further example embodiments, the stimulator of the present invention is programmable, enabling use of various treatment regimens. In still further embodiments, the stimulator includes sensors or other input means and onboard memory, for collecting and storing biometric data and patient compliance information; and/or a transmitter, display or other output means for monitoring by the subject and/or a medical caregiver.

In another aspect, the present invention is an improved therapeutic system for delivering energy to a treated body portion of a human or animal subject, the system including an electrode for application to the treated body portion, and an electronic stimulator attached directly to the electrode, the electronic stimulator delivering energy to the electrode. The electrode may for example be a garment electrode such as a stocking, sleeve, wrap, glove, or other type of garment to be worn over one or more body parts of a human or animal subject, at least a portion of the garment comprising a conductive material for delivering therapeutic energy to a

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.