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Paper 35
Date: November 29, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SOTERA WIRELESS, INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-01078
Patent RE47,218 E

Before GEORGE R. HOSKINS, JENNIFER MEYER CHAGNON, and AMANDA F. WIEKER, *Administrative Patent Judges*.

HOSKINS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Sotera Wireless, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of all claims 1–10 and 12–18 of U.S. Patent No. RE47,218 E (Ex. 1001, “the ’218 patent”). Masimo Corporation (“Patent Owner”) opposes the Petition. We instituted the petitioned review (Paper 12, “Institution Decision” or “Inst. Dec.”).

Patent Owner filed a Patent Owner Response (Paper 23, “PO Resp.”) to the Petition. Petitioner filed a Reply (Paper 25, “Pet. Reply”) to the Patent Owner Response. Patent Owner filed a Sur-reply (Paper 27, “Sur-reply”) to the Reply. An oral hearing was held, for which the transcript was entered into the record (Paper 34, “Tr.”).

We have jurisdiction under 35 U.S.C. § 6(b)(4) and § 318(a). This Decision is a final written decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of claims 1–10 and 12–18 of the ’218 patent. We determine Petitioner has shown by a preponderance of the evidence that claims 1–10 and 12–18 are unpatentable.

II. BACKGROUND

A. Real Parties-in-Interest and Related Proceedings

Sotera Wireless, Inc. and Hon Hai Precision Industry Co., Ltd. are the real parties-in-interest for Petitioner, and Masimo Corporation is the real party-in-interest for Patent Owner. Pet. 1; Paper 5, 1. *Masimo Corp. v. Sotera Wireless, Inc. and Hon Hai Precision Industry Co. Ltd.*, Civil Action No. 3:19-cv-01100-BAS-NLS (S.D. Cal.) is a related judicial proceeding. Pet. 2; Paper 5, 1.

B. The '218 Patent

The '218 patent concerns a system for monitoring a patient's blood oxygen saturation (SpO_2), and generating an alarm if the saturation falls too low. *See* Ex. 1001, code (57), 1:34–39, 2:54–58. The system includes an optical sensor attached to the patient's finger, to emit light into the fingertip tissue and detect light that is attenuated by blood flow within the fingertip, to provide a numerical readout of oxygen saturation. *See id.* at 1:39–55.

Figure 1 of the '218 patent is reproduced here:

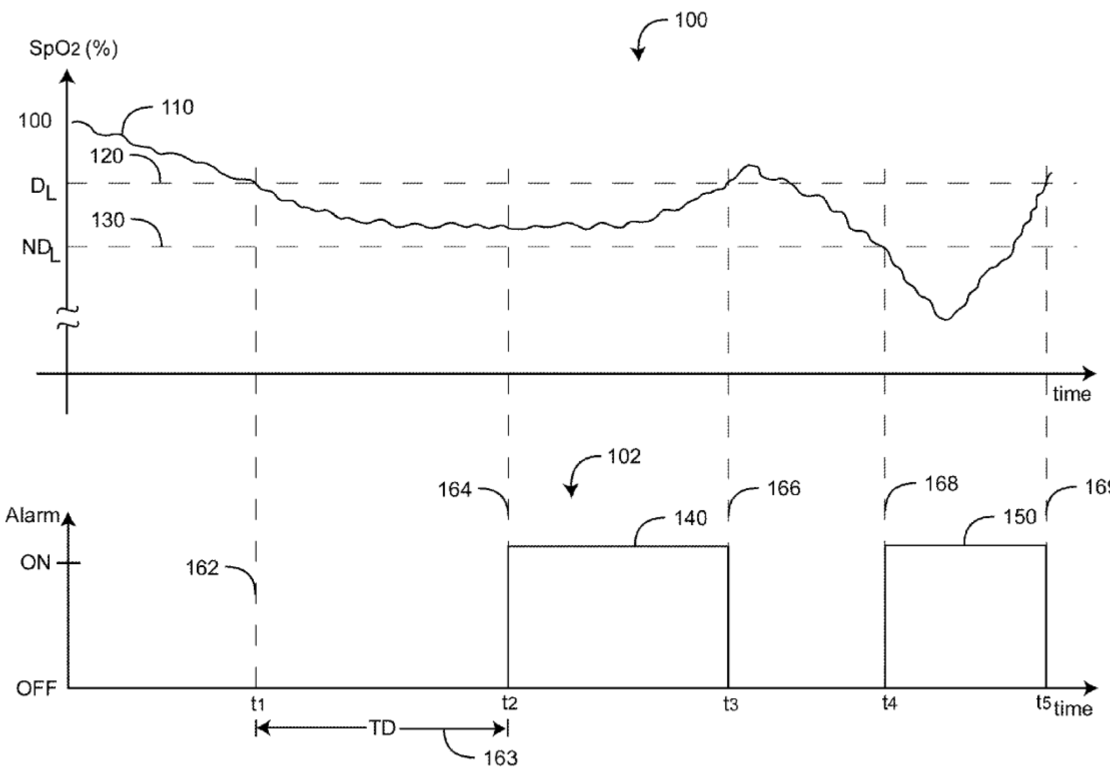

Figure 1 illustrates a prior art oxygen saturation measurement system having two "lower-limit, *fixed-threshold* alarm" schemes, at "delay" alarm threshold D_L and at "no delay" alarm threshold ND_L. *Id.* at 2:54–59 (emphasis added). If the patient's measured oxygen saturation 110 falls and stays below delay threshold D_L for a time period greater than time delay TD, as shown in Figure 1 from time t_1 to time t_2, then delayed alarm 140 is triggered. *Id.* at 2:59–3:2. If the patient's measured oxygen saturation 110 falls below no delay threshold ND_L, as shown in Figure 1 at time t_4, then alarm 150 is triggered immediately, without delay. *Id.* at 2:61–62, 3:2–4.

According to the '218 patent, the fixed nature of delay alarm threshold D_L undesirably leads to "a baseline drift problem," which can generate a "nuisance" or "false" alarm. *Id.* at 2:54–56, 3:24–46 (Fig. 3). The '218 patent therefore proposes "an adaptive alarm system," which adjusts the delay alarm threshold downwards when an oxygen saturation baseline is established at lower values. *Id.* at 3:59–62. In this way, the inventive "alarm threshold . . . adapts to baseline drift in [oxygen saturation] and reduce[s] false alarms without a corresponding increase in missed true alarms." *Id.* at 4:4–8.

This is illustrated in Figure 6 of the '218 patent, reproduced here:

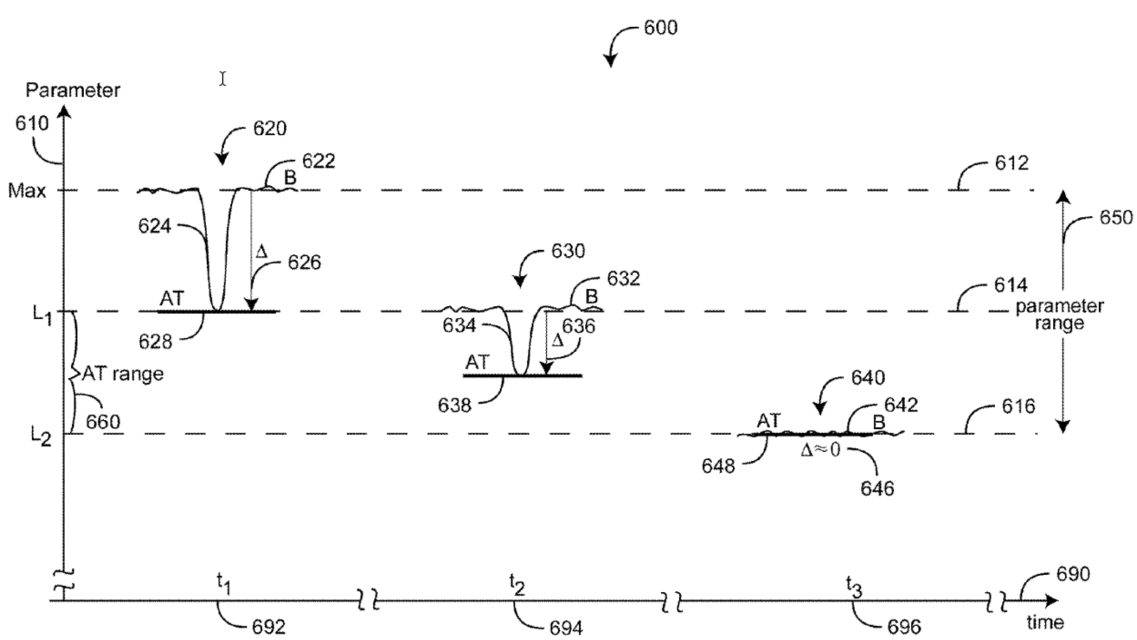

Figure 6 graphs a measured physiological parameter such as oxygen saturation (the vertical axis) over time (the horizontal axis), as generated by an alarm system having a lower limit adaptive alarm threshold AT. *Id.* at 5:34–36, 7:40–47. An adaptive alarm threshold AT is applied whenever the measured oxygen saturation falls within range 650, extending from lower limit L_2 up to maximum value Max, such as illustrated at segments 620, 630, and 640. *Id.* at 6:15–30, 7:9–67, Fig. 5B (horizontal axis values extend from L_2 to Max). The adaptive thresholds AT are constrained to lie within range 660, extending from lower limit L_2 up to limit L_1. *Id.* at 6:15–30, 7:9–67, Fig. 5A (adaptive threshold AT line 442 is constrained between limits L_2 and L_1 along vertical axis).

In a preferred embodiment, lower limit L_2 corresponds to the value of the no delay alarm threshold ND_L of the prior art system shown in Figure 1, and limit L_1 corresponds to the value of the delay alarm threshold D_L of the prior art system. *Id.* at 5:66–6:4, 6:20–34. The fixed alarm threshold that the prior art implements at limit L_1 is replaced by adaptive alarm thresholds AT. *Id.* at 6:22–34. Each threshold AT, during a given time period such as t_1, t_2, or t_3, may advantageously be implemented as a time delay alarm, as the prior art system does with its fixed delay alarm threshold D_L. *Id.* at 6:38–43.

The system determines a baseline B of the patient's oxygen saturation during different time periods t_1, t_2, and t_3. *Id.* at 6:11–15, 6:44–7:8. For each different baseline B, the system applies a different adaptive alarm threshold AT. *Id.* at 6:15–19. Specifically, the system calculates delta Δ as a function of: the varying baseline B; pre-set limits L_1 and L_2; and maximum

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