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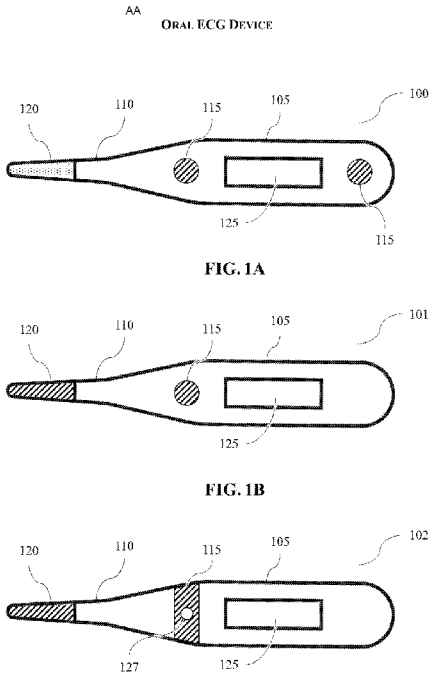


FIG. 1A




FIG. 1B




FIG. 1C

(57) Abstract: The present invention relates to a 1- or 3 -lead oral ECG device, shaped and implemented like a household digital thermometer. The 3 -lead device comprises three contact electrodes: two contact electrodes on a body of the device, configured for contact with the left and right hands; and one contact electrode on a metallic tip of the device — which may comprise a thermometer — configured for contact with the mouth, The 1- lead device comprises any two of these three contact electrodes and a temperature sensor disposed in the metallic tip. A novel transformation of the three leads from the 3 -lead device enables the ECG signals to be processed like a standard ECG that comprises a contact electrode in contact with the leg instead of the mouth. An oral ECG device of the invention may comprise other sensors, such as a pulse-oximetry sensor, respiratory rate sensor, skin temperature sensor, body impedance sensor, galvanic skin response sensor, and/or blood-flow sensor.

WO 2020/255149 A1

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# ORAL ECG DEVICE

## FIELD OF THE INVENTION

The invention is in the field of home diagnostic medical devices, and in particular to an ECG device usable like a household thermometer.

## BACKGROUND TO THE INVENTION

Home medical devices that measure one or more vital parameters, including ECG, are disclosed in the prior art:

US2018/0110418A discloses a self-contained hand-held device. The device can obtain all vital signs +ECG and pulse-ox by being held by the patient for approximately half a minute. The device contains sensors on the hand-held unit as well as on the individual/disposable mouthpiece. The method of the present invention includes simultaneously acquiring the following measurements: temperature, pulse rate, breathing rate, blood pressure, electrocardiogram, heart rate and pulse-ox waveform and blood oxygen level.

US2013/0253286 discloses an intraoral multisensor device that includes a mouthpiece, a plurality of sensors at least one of attached to or integrated with the mouthpiece, and a data communications unit configured to receive signals from the plurality of sensors. The mouthpiece has a form to permit stable arrangement at least partially within a person's mouth such that it can remain for hands-free sensing of a plurality of biological parameters. Also, an intraoral multisensor system includes an intraoral multisensor device and a data processing device adapted to communicate with the intraoral multisensor device.

The present invention advances the state-of-the-art in multi-functional home medical devices, as further described below.

## SUMMARY

A number of different types of ECG exist. The simplest is the 2-contact, 1-lead ECG, which is typically measures between the left hand and the right hand. More complex versions include a 3-contact 3- or 6-lead ECG, 12-lead ECG and 15-lead ECG. In order to increase

the likelihood that arrhythmias, ventricular fibrillation, atrial fibrillation etc. will be detected, it is preferable to have at least a 3-lead ECG trace for a physician to analyze.

Applying a 3-lead ECG to the body is relatively more cumbersome than a 1-lead ECG as the third contact needs to be attached to the left leg. This requires some sort of cable to be extended from the device to the leg or lower abdomen, and some form of electrode to be attached to the foot or elsewhere on the leg or lower abdomen.

Unlike the thermometer— which is the one medical device present in most homes in the developed world—the use of an ECG at home is unfamiliar and requires some kind of learning curve. There is therefore a need to provide a simple form of ECG which is easy to use and exploits the familiar thermometer format; and where both types of readings—temperature and ECG—are performed at the same time.

It is within the scope of the present invention to provide an oral 3-lead ECG device in the shape of a digital-thermometer comprising three contact electrodes:

a left-hand contact electrode configured for contact with the left hand of a subject;

a right-hand contact electrode configured for contact with the right hand of the subject; and

a mouth contact electrode disposed on a metallic tip of the device, configured for contact with the patient's mouth;

wherein the device further comprises a processor configured to perform a transformation of signals from lead II and lead III, terminating at the mouth contact electrode, thereby producing ECG traces mimicking traces of a standard ECG whose lead II and lead III terminate at a left-leg electrode.

It is further within the scope of the present invention to provide the abovementioned oral 3-lead ECG device, wherein the processor is configured to perform the transformation by

transposing the order of Leads II and III;

reversing the polarity and increasing the gain of the waveform of Lead II, and

reversing the polarity of the waveform of Lead III.

It is further within the scope of the present invention to provide any one of the abovementioned oral 3-lead ECG devices, further comprising one or more sensors from a group consisting of an oral temperature sensor disposed in the metallic tip, a pulse-oximetry

sensor, a respiratory rate sensor, a skin temperature sensor, a body impedance sensor, a galvanic skin response sensor, and a blood-flow sensor.

It is further within the scope of the present invention to provide the previous oral 3-lead ECG devices, wherein the pulse-oximetry sensor is positioned proximate to or opposite the left-hand contact electrode or right-hand contact electrode.

It is further within the scope of the present invention to provide any one of the abovementioned oral 3-lead ECG devices, further comprising a communications module enabling the display of the ECG trace on an external device (e.g., smartphone or computer).

It is further within the scope of the present invention to provide the previous oral 3-lead ECG device, wherein the display further comprises sensor data from one or more sensors from the group consisting an oral temperature sensor, a pulse-oximetry sensor, a respiratory rate sensor, a skin temperature sensor, a body impedance sensor, a galvanic skin response sensor, and a blood-flow sensor; and the oral 3-lead ECG device further comprises the one or more sensors.

It is further within the scope of the present invention to provide any one of the previous two oral 3-lead ECG devices, further comprising a data-transfer agent module installed in the external device, the data-transfer agent module configured to transmit the ECG and/or sensor data over the Internet to a remote device (e.g., for storage and/or analysis).

It is further within the scope of the present invention to provide the previous oral 3-lead ECG device, further comprising a remote agent module installed in the remote device; the remote agent module is configured to perform medical analysis of the transmitted ECG data and/or the transmitted sensor data.

It is further within the scope of the present invention to provide any one of the previous two oral 3-lead ECG devices, comprising either:

an ECG circuit with three ECG channels configured for simultaneously sampling the three leads; or

an ECG circuit with one ECG channel, said ECG circuit configured for simultaneously sampling the three leads.

It is further within the scope of the present invention to provide a method for transformation of the signals from ECG leads of an oral 3-lead ECG, comprising steps of

obtaining ECG traces from any one of the abovementioned oral 3-lead ECG devices;

transposing the order of Leads II and III;

reversing the polarity and increasing the gain of the waveform of Lead II; and

reversing the polarity of the waveform of Lead III.

It is further within the scope of the present invention to provide an oral 1-lead ECG/thermometer device comprising

two ECG contact electrodes and an ECG circuit and processor;

a thermistor, disposed in a metallic tip of the device;

wherein the two contact electrodes are in one of two configurations:

both contact electrodes disposed on a body of the device: a left-hand contact electrode configured for contact with the left hand of the subject and a right-hand contact electrode configured for contact with the right hand of the subject; or

a hand contact electrode, disposed on a body of the device, configured for contact with a hand of the subject and a mouth contact electrode, disposed on the metallic tip, configured for contact with the mouth of the subject.

It is further within the scope of the present invention to provide the abovementioned oral 1-lead ECG/thermometer device, further comprising one or more sensors from a group consisting of a pulse-oximetry sensor, a respiratory rate sensor, a skin temperature sensor, a body impedance sensor, a galvanic skin response sensor, and a blood-flow sensor.

It is further within the scope of the present invention to provide the previous oral 1-lead ECG/thermometer device, wherein the pulse-oximetry sensor is positioned proximate to or opposite the left-hand contact electrode or right-hand contact electrode.

It is further within the scope of the present invention to provide any one of the abovementioned oral 1-lead ECG/thermometer devices, further comprising a communications module enabling the display of the ECG trace on an external device (e.g., smartphone or computer).

It is further within the scope of the present invention to provide the previous oral 1-lead ECG/thermometer device, wherein the display further comprises sensor data from one or more sensors from the group consisting an oral temperature sensor, a pulse-oximetry sensor,

a respiratory rate sensor, a skin temperature sensor, a body impedance sensor, a galvanic skin response sensor, and a blood-flow sensor; and the oral 1-lead ECG/thermometer device further comprises the one or more sensors.

It is further within the scope of the present invention to provide any one of the previous two oral 1-lead ECG/thermometer devices, further comprising a data-transfer agent module installed in the external device, the data-transfer agent module configured to transmit the ECG and/or sensor data over the Internet to a remote device (e.g., for storage and/or analysis).

It is further within the scope of the present invention to provide the previous oral 1-lead ECG/thermometer device, further comprising a remote agent module installed in the remote device; the remote agent module is configured to perform medical analysis of the transmitted ECG data and/or the transmitted sensor data.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figs. **1A–1C** each show a 1-lead oral ECG/thermometer device, according to some embodiments of the invention.

Fig. **2** shows a usage configuration of a standard 3-lead ECG of the prior art.

Fig. **3** shows an oral 3-lead ECG device according to some embodiments of the invention.

Fig. **4** shows a usage arrangement of an oral 3-lead ECG device, according to some embodiments of the invention. The dashed lines represent ECG leads. The dashed lines are for illustrative purposes, and are not intended to trace or suggest actual electrical paths of the leads.

Figure **5A** shows a regular ECG trace from a standard 3-lead ECG when used with electrodes in the standard position.

Figure **5B** shows a typical pre-transformation ECG trace from a device of some embodiments of the present invention.

Figure **5C** shows a transformed version of the pre-transformation ECG trace.

Fig. **6** shows a functional block diagram of oral ECG/thermometer devices, according some embodiments of the invention.

DETAILED DESCRIPTION

Reference is now made to Figs. **1A–1C**, each showing an oral 1-lead ECG/thermometer **100**, according to some embodiments of the invention.

A device of the present invention comprises a thermometer-shaped device **100** comprising a body **105** and a neck **110**. The body **105** contains at least one contact electrode **115**, which can be circular as shown or any other shape. A contact electrode **115** may be disposed on the floor of a surrounding indent; the indent can serve as a guide for placement of a finger on the contact electrode **115**. Contact electrodes **115** may be disposed on the front of the device, as shown. Alternatively, one or more of the contact electrodes **115** may be disposed on the reverse side of the device, such that a thumb is placed on a contact electrode **115**. The neck **110** comprises a thermally and electrically conductive (typically metallic) tip **120** having a temperature sensor within, for measuring body temperature. In preferred embodiments, the body **105** further comprises a display **125** such as an LCD display, which can show at least body temperature. Fig. **1A** shows an embodiment device **100** in which there are two contact electrodes **115** on the body **105**. A 1-lead ECG circuit (internal to the device **100**) connects to the two contact electrodes **115**—configured for contact with two hands—and derives a 1-lead ECG trace. Fig. **1B** shows an embodiment device **101** in which there is only one contact electrode **115** on the body **105.** A 1-lead ECG circuit connects between the contact electrode **115** and the metallic tip **120**.

A potential advantage of monitoring ECG and temperature is that a fever is known to cause electrocardiographic changes that can mimic life-threatening conditions [Mody, P., Pandey, A. & Joglar, J. Fever-Induced Electrocardiographic Changes. *J GEN INTERN MED* **30,** 136–137 (2015)]. An elevated body temperature measured by the device **100** can therefore serve as an indication that the ECG trace generated by the device **100** is less reliable.

Fig. **1C** shows an embodiment device **102** in which a pulse oximetry sensor **127** is disposed proximate to a contact electrode **115**, such that the patient's hand is in contact with both the contact electrode **115** and the pulse oximetry sensor **127**. For example, the pulse oximetry sensor **127** may be disposed within a contact electrode **115**, as shown, or adjacent to a contact electrode **115**. In embodiments with a contact electrode **115** on the reverse side for contact with a thumb, the pulse oximetry sensor **127** can be disposed opposite to the reverse-side contact electrode **115**, for placement by a finger opposing the thumb.

The pulse oximetry sensor **127** provides additional function to the device **100** while also enabling ECG-pulse oximeter sensor fusion, for example to provide cross-verification between the ECG and pulse oximetry sensor **127**.

Reference is now made to Fig. **2**, a usage configuration of a 3-lead ECG according to the prior art, where a standard-type ECG device **10** is connected by means of three electrodes to the standard locations on the body surface; namely Lead I **13** is between the right-hand electrode **14** and the left-hand electrode **12**, Lead II **15** is between the right-hand electrode **14** and the left-leg electrode **16**, and Lead III **17** is between the left-hand electrode **12** and the left-leg electrode **16**.

Reference is now made to Figure **3**, an oral 3-lead ECG device **20** according to some embodiments of the invention. The device **20** comprises a thermometer-shaped device **20** comprising a body **105** and a neck **110**. The body **105** contains two contact electrodes: a right-hand contact electrode **24** and a left-hand contact electrode **22**. The neck **110** contains a mouth contact electrode **26**. Either or both hand contact electrodes **22, 24** may be disposed on the floor of a surrounding indent; the indent can serve as a guide for placement of a finger on the contact electrode **22, 24**. The hand contact electrodes **22, 24** may be disposed on the front of the device, as shown. Alternatively, either or both of the hand contact electrodes **22, 24** may be disposed on the reverse side of the device, such that a thumb is placed on a hand contact electrode **22, 24**. The device may further comprise a pulse oximetry sensor, disposed proximate to or opposite a hand contact electrode **22, 24** (see Fig. **1C**, **115** and **127**, and description pertaining thereto), thereby providing additional function to the device **100** while also enabling ECG-pulse oximeter sensor fusion. For example, to provide cross-verification between the ECG and pulse oximetry sensor, such as comparing the pulse rate obtained from the pulse oximetry waveform and the heart rate calculated from the ECG waveform. The neck **110** may further contain a temperature sensor within, for measuring body temperature. In preferred embodiments, the body **105** further comprises a display **125** such as an LCD display, which can show at least body temperature.

Reference is now made to Fig. **4**, showing a usage arrangement of the oral 3-lead ECG device **20**. The right hand is positioned on the right-hand contact electrode **24** and the left hand is positioned on the left-hand contact electrode **22**. The mouth contact electrode **26**—corresponding to the left-leg electrode **16** of the leg-attached three-lead ECG **10**—is positioned in contact with the mouth. In this arrangement, Lead I **23** is between the right-

hand contact electrode **24** and the left-hand contact electrode **22**, Lead II **25** is between the right hand contact electrode **24** and the mouth contact electrode **26**, and Lead III is between the left-hand contact electrode **22** and the mouth contact electrode **26**. As is clear from the figure, the mouth contact electrode **26** is implemented as a contact located at or near the patient's mouth, for example on the lips, the philtrum or under the tongue. In a preferred embodiment of the invention, the mouth contact electrode **26** is a metallic component such as a metal tip of the temperature sensor.

Surprisingly, even though the two configurations shown in Fig. **3** and Fig. **5** are significantly different, our team determined that a transformation of the signals received could be implemented such that the ECG trace produced post-transformation is substantively equivalent to a trace that would have been produced had an ECG device been connected in the standard fashion. The present invention comprises the thermometer-shaped ECG device described above in conjunction with the transformation approach.

Reference is made now to Figs. **5A–5C**. Fig. **5A** shows traces of Lead I **13**, Lead II **16**, and Lead III **17** from a leg-attached three-lead ECG **10** of Fig. **3**. Fig. **5B** shows traces of Lead I **23**, Lead II **26**, and Lead III **27** from the oral 3-lead ECG device **20** of Fig. **4**. The waveforms from Lead I of both ECGs (trace **13** and trace **23**) are identical, inasmuch as both derive from signal between left-hand and right-hand electrodes. However, Leads II and III of the oral 3-lead ECG **20** have become transposed and the polarity of the signal on each has become reversed from those of the leg-attached 3-lead ECG **10**—such that the waveform of trace **27** is the inverse polarity of trace **16** and the waveform of trace **26** is the inverse polarity of trace **17**. These transformations are a consequence of the reverse in direction that has taken place of the signal from each of the two hands via the heart to mouth contact **26**, when compared to the standard configuration.

The transformation that therefore needs to be performed in order to transform the electrical signals received from the ECG device **20** of the present invention, shown in Fig. **5B**, into the standard traces shown in Fig. **5A** comprises the following steps:

1. Leave Lead I of the trace without change.
2. Transpose the order of Lead II **25** and Lead III **26**.
3. Reverse the polarity and increase the gain of the waveform of Lead II **25**, resulting in transposed, reversed, amplified Lead II **37** in Fig. **5C**.

4. Reverse the polarity of the waveform of Lead III, resulting in transposed, reversed Lead III **35** in Fig. **5C**.

The traces of the transformed waveforms from the oral 3-lead ECG **20**, shown in Figure **5C**—traces **33**, **35**, and **37** are substantially equivalent to the traces of the leg-attached 3-lead ECG **10** traces **13**, **15**, and **17** shown in Fig. **5A**. This enables an ECG display to be produced using the device **20** of the present invention which mimics traces from a standard, leg-attached ECG **10**, despite the fact that the oral device **20** is connected and used in a different manner than the leg-attached device **10**.

Advantageously, by providing ECG trace displays which mimic a standard one, the display can readily be understood by a physician and/or remote physician viewing it, and also be interpreted by software programs which interpret ECG traces. Such programs are available over the Internet, enabling ECG interpretation to be performed in the cloud.

Advantageously, implementing a 3-lead ECG device in accordance with the current invention makes the device very simple to use as (a) the thermometer shape is familiar and convenient, and (b) the need to run a cable down to the left leg is obviated.

Unlike ECG devices like the Apple Watch or the KardiaMobile ECG product (AliveCor, Mountain View, CA, USA), where the patient places a finger on an electric plate—and therefore the quality of the skin-electrode contact is subject to shaking of the finger—the device **20** of the present invention is grasped between the forefinger and the thumb, such that the finger against the electrode is held there stably due to the counterposing force from the thumb underneath the device. Advantageously, this stable connection between the electrode(s) and the finger(s) represents an additional synergy between the thermometer shape and the ECG implementation therein.

Additional advantages deriving from the thermometer-based shape of devices **20, 100** of the present invention include the ability to measure vital signs and other physiological data as measured using sensors mounted on or within the body of the device together with the ECG signals gathered by the device **20, 100**. The sensors can include any combination of the following: an oral temperature sensor implemented within the oral tip of the device, a pulse-oximetry sensor, a respiratory rate sensor, a skin temperature sensor, a body impedance sensor, a galvanic skin response sensor and a blood-flow sensor.

In a preferred embodiment of the device, the output is displayed on a smartphone or PC connected to the device **20, 100** either wirelessly over Bluetooth or WiFi, etc., or via a wired connection. This display may contain a 1-lead ECG output (not shown) or a transformed 3-lead ECG trace as per Fig. **5C**, together with any combination of the vital-signs readings taken using the additional sensors as listed above.

Advantageously, the combination of providing an ECG trace while also providing additional medical data such as temperature and pulse oximetry enables the patient to perform an extensive and comprehensive medical check during one simple deployment of the device **20**.

Reference is now made to Fig. **6**, showing an electronic block diagram according to some embodiments of an oral 1-lead ECG/thermometer **100** and an oral 3-lead ECG device **20**. An ECG circuit **130** for a 1-lead device **100** may comprise a MAX86150 PPG/ECG bio-sensor module from Maxim Integrated (San Jose, USA). Suitable chips for implementing a 3-lead ECG device **20** include the ADS1293 chip from Texas Instruments (Texas, USA). Alternatively, the electrode pairs of each of the leads of the 3-lead device **20** may be read out serially by a 1-lead ECG chip.

For embodiments comprising a thermometer, a thermistor **135** for temperature sensing may comprise an MF51E2252F3950C thermistor from Cantherm (Montreal, Canada). A microprocessor **140** may comprise one of the PSoC 63 family MCU from Cypress Semiconductors (San Jose, California, USA). Some embodiments comprise a communication chip **150**, for wireless or wired communication with an external device. However, in preferred embodiments the microprocessor **140** comprises built-in communication function, such as Bluetooth Low Energy (BLE), such that a separate communication chip **150** is not required. In embodiments with a pulse oximetry sensor **127**, electronic components further comprise a pulse oximeter circuit **155**.

CLAIMS

1. An oral 3-lead ECG device in the shape of a digital-thermometer comprising three contact electrodes:

   a left-hand contact electrode configured for contact with the left hand of a subject;

   a right-hand contact electrode configured for contact with the right hand of the subject; and

   a mouth contact electrode disposed on a metallic tip of said device, configured for contact with the patient's mouth;

   wherein the device further comprises a processor configured to perform a transformation of signals from lead II and lead III, terminating at the mouth contact electrode, thereby producing ECG traces mimicking traces of a standard ECG whose lead II and lead III terminate at a left-leg electrode.

2. The oral 3-lead ECG device of claim 1, wherein the processor is configured to perform the transformation by

   transposing the order of Leads II and III;

   reversing the polarity and increasing the gain of the waveform of Lead II, and

   reversing the polarity of the waveform of Lead III.

3. The oral 3-lead ECG device of claim 1, further comprising one or more sensors from a group consisting of an oral temperature sensor disposed in said metallic tip, a pulse-oximetry sensor, a respiratory rate sensor, a skin temperature sensor, a body impedance sensor, a galvanic skin response sensor, and a blood-flow sensor.

4. The oral 3-lead ECG device of claim 1, wherein the pulse-oximetry sensor is positioned proximate or opposite to the left-hand contact electrode or right-hand contact electrode.

5. The oral 3-lead ECG device of claim 1, further comprising a communications module enabling the display of said ECG trace on an external device (e.g., smartphone or computer).

6. The oral 3-lead ECG device of claim 5, wherein said display further comprises sensor data from one or more sensors from the group consisting an oral temperature sensor, a pulse-oximetry sensor, a respiratory rate sensor, a skin temperature sensor, a body impedance

sensor, a galvanic skin response sensor, and a blood-flow sensor; and said oral 3-lead ECG device further comprises said one or more sensors.

7. The oral 3-lead ECG device of any one of claims 5 and 6, further comprising a data-transfer agent module installed in the external device, said data-transfer agent module configured to transmit said ECG and/or sensor data over the Internet to a remote device (e.g., for storage and/or analysis).

8. The oral 3-lead ECG device of claim 7, further comprising a remote agent module installed in the remote device; the remote agent module is configured to perform medical analysis of the transmitted ECG data and/or the transmitted sensor data.

9. The oral 3-lead ECG device of claim 1, further comprising an ECG circuit with three ECG channels configured for simultaneously sampling the three leads.

10. The oral 3-lead ECG device of claim 1, further comprising an ECG circuit with one ECG channel, said ECG circuit configured for simultaneously sampling the three leads.

11. A method for transformation of the signals from ECG leads of an oral 3-lead ECG, comprising steps of

    obtaining ECG traces from oral 3-lead ECG device of claim 1;

    transposing the order of Leads II and III;

    reversing the polarity and increasing the gain of the waveform of Lead II, and

    reversing the polarity of the waveform of Lead III.

12. An oral 1-lead ECG/thermometer device comprising

    two ECG contact electrodes and an ECG circuit and processor;

    a thermistor, disposed in a metallic tip of said device;

    wherein said two contact electrodes are in one of two configurations:

    both contact electrodes disposed on a body of said device: a left-hand contact electrode configured for contact with the left hand of the subject and a right-hand contact electrode configured for contact with the right hand of the subject; or

    a hand contact electrode, disposed on a body of said device, configured for contact with a hand of the subject and a mouth contact electrode, disposed on said metallic tip, configured for contact with the mouth of the subject.

13. The oral 1-lead ECG/thermometer device of claim 12, further comprising one or more sensors from a group consisting of a pulse-oximetry sensor, a respiratory rate sensor, a skin temperature sensor, a body impedance sensor, a galvanic skin response sensor, and a blood-flow sensor.

14. The oral 1-lead ECG/thermometer device of claim 13, wherein the pulse-oximetry sensor is positioned proximate to or opposite the left-hand contact electrode or right-hand contact electrode.

15. The oral 1-lead ECG/thermometer device of claim 12, further comprising a communications module enabling the display of said ECG trace on an external device (e.g., smartphone or computer).

16. The oral 1-lead ECG/thermometer device of claim 15, wherein said display further comprises sensor data from one or more sensors from the group consisting an oral temperature sensor, a pulse-oximetry sensor, a respiratory rate sensor, a skin temperature sensor, a body impedance sensor, a galvanic skin response sensor, and a blood-flow sensor; and said oral 1-lead ECG/thermometer device further comprises said one or more sensors.

17. The oral 1-lead ECG/thermometer device of any one of claims 15 and 16, further comprising a data-transfer agent module installed in the external device, said data-transfer agent module configured to transmit said ECG and/or sensor data over the Internet to a remote device (e.g., for storage and/or analysis).

18. The oral 1-lead ECG/thermometer device of claim 17, further comprising a remote agent module installed in the remote device; the remote agent module is configured to perform medical analysis of the transmitted ECG data and/or the transmitted sensor data.

# ORAL ECG DEVICE

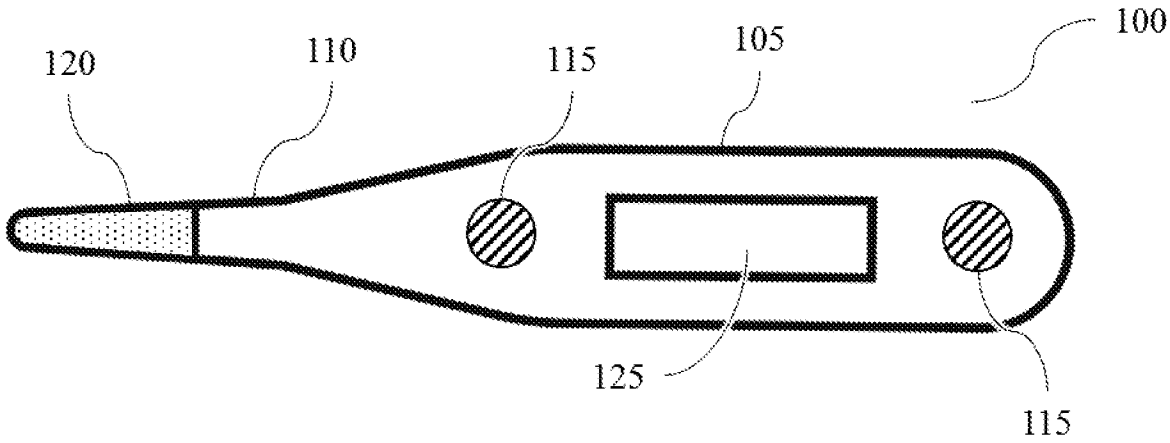



FIG. 1A

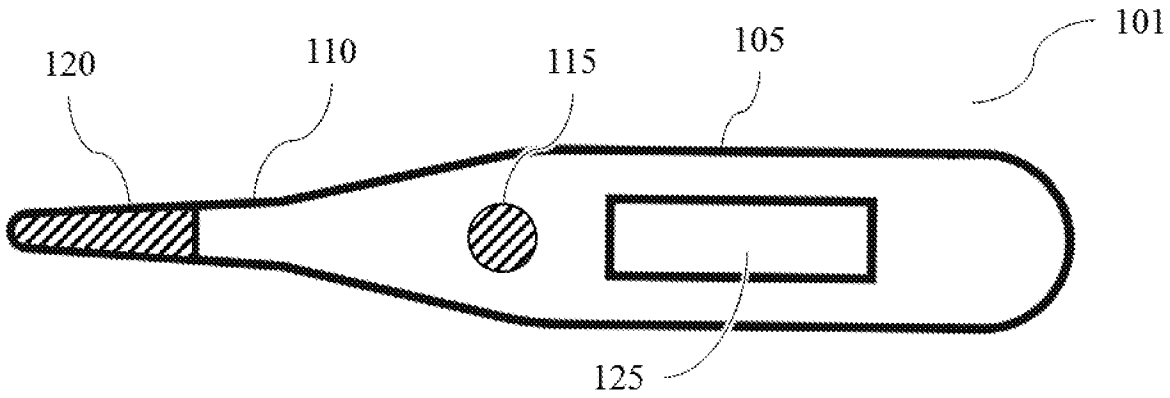



FIG. 1B

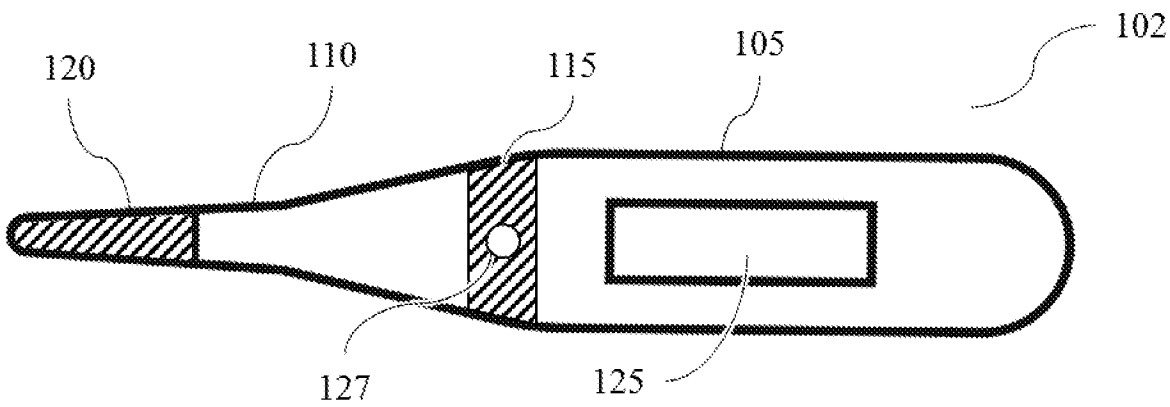



FIG. 1C

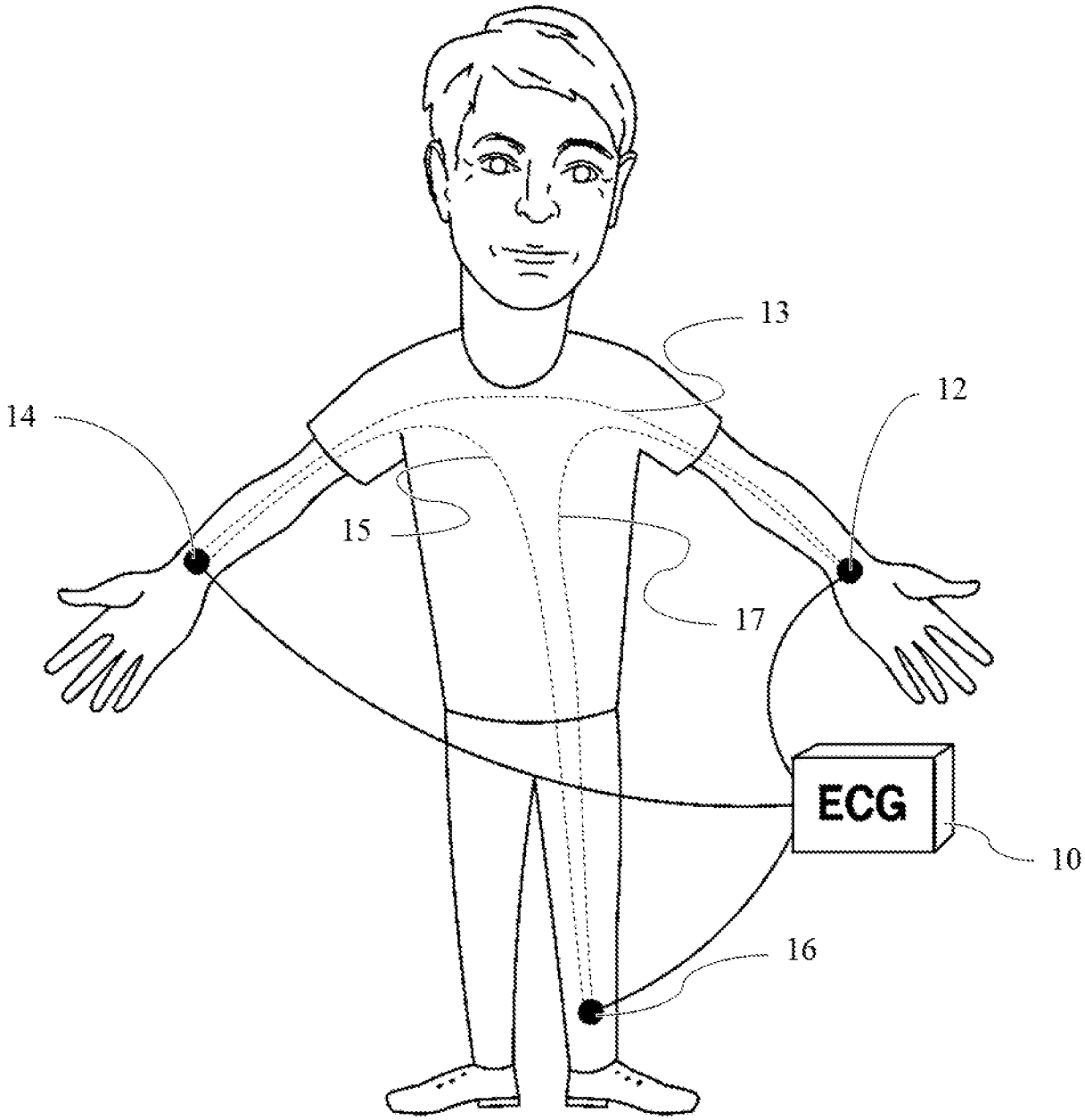



**FIG. 2 – PRIOR ART**

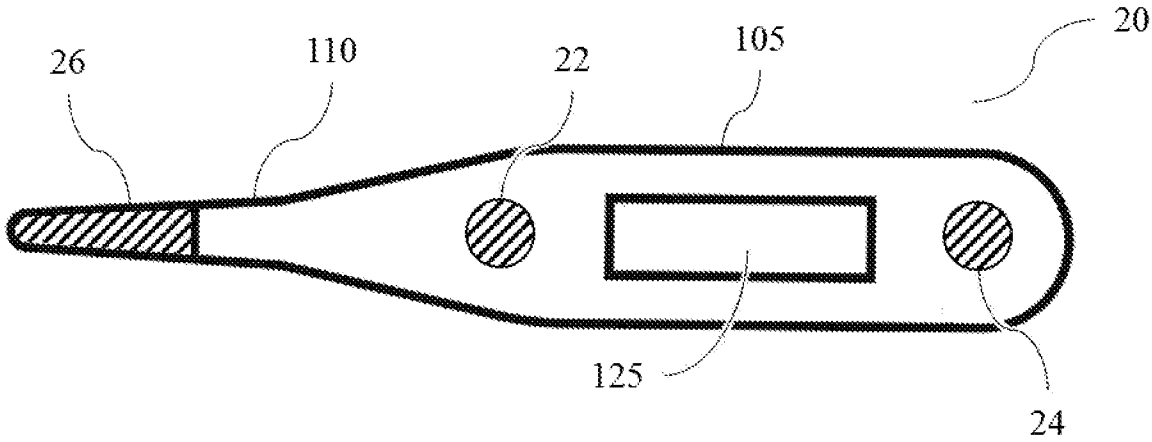



FIG. 3

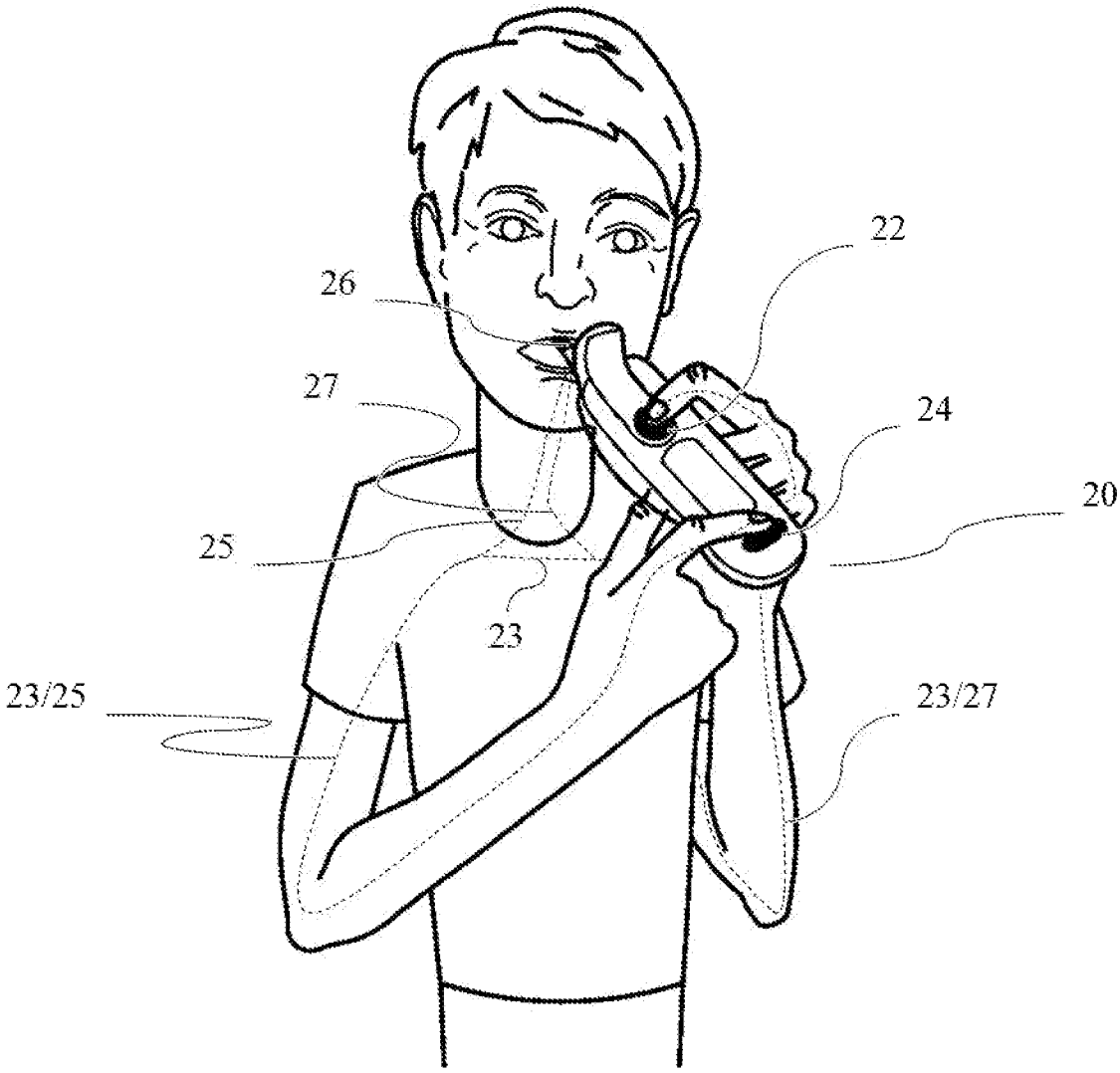



FIG. 4

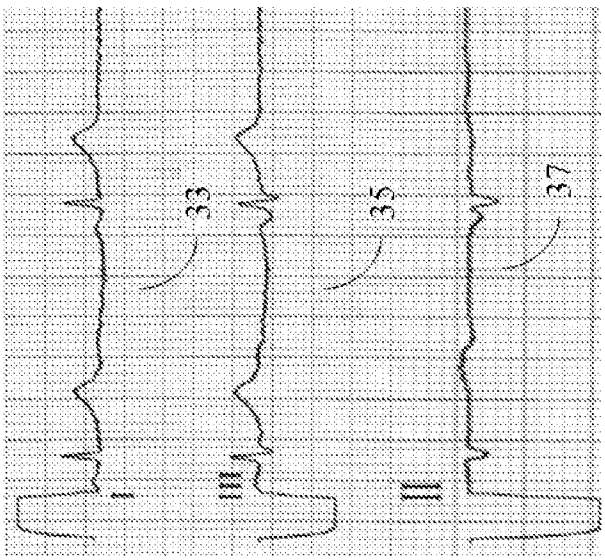



FIG. 5C

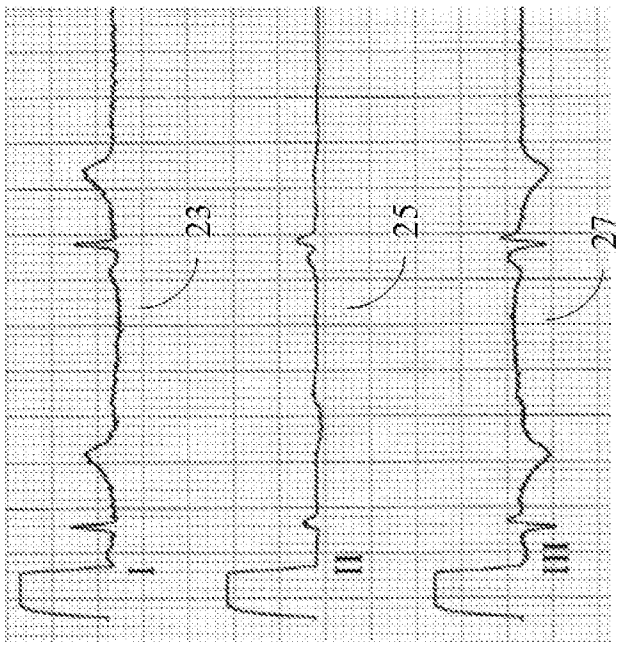



FIG. 5B

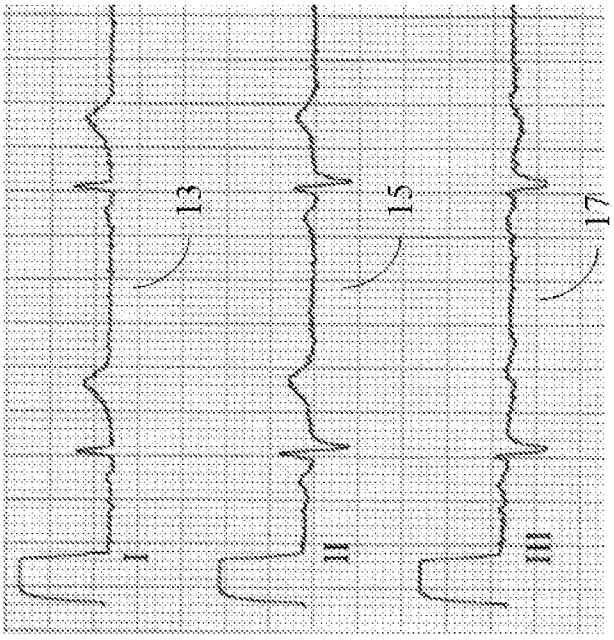
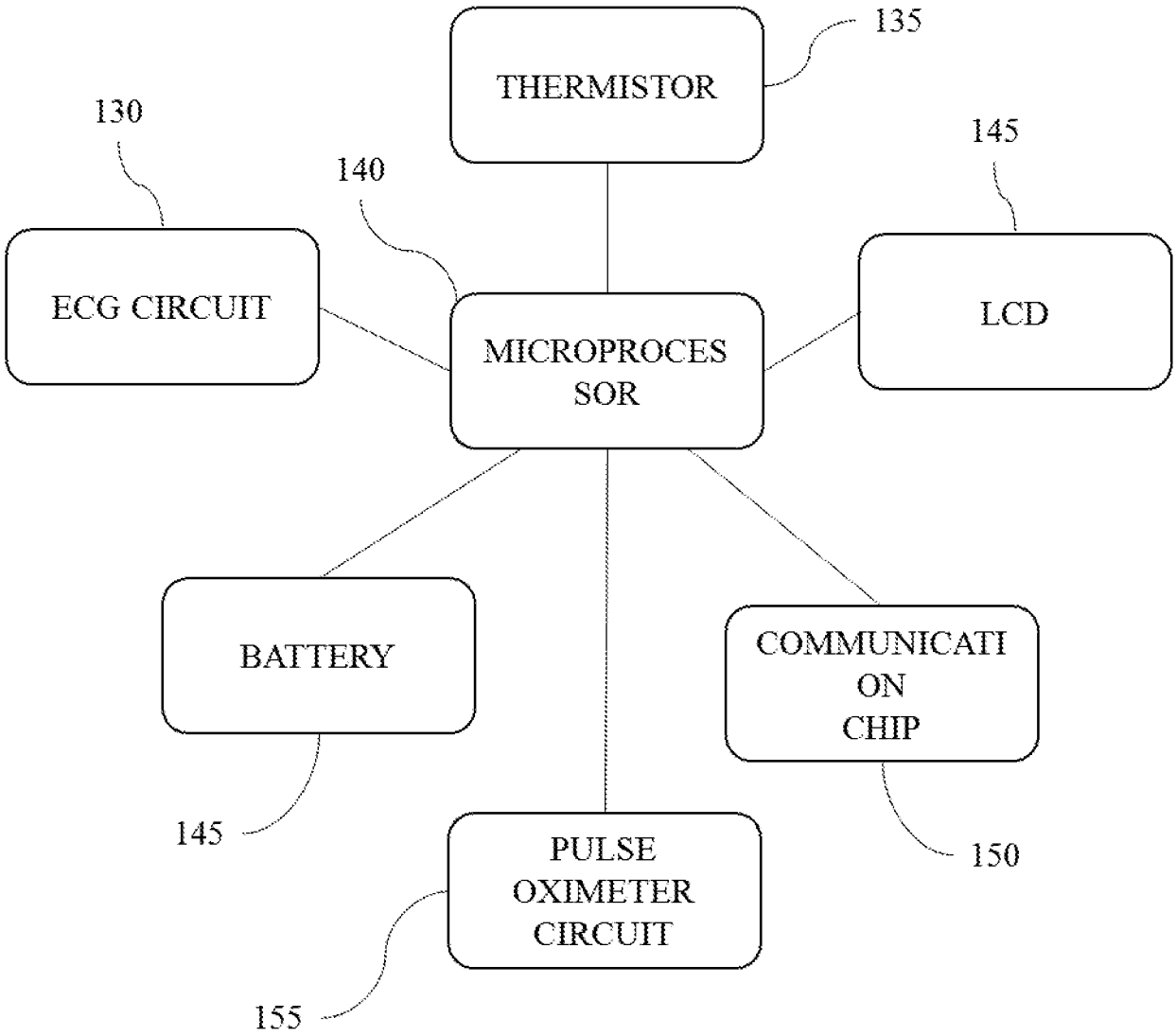



FIG. 5A – PRIOR ART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PULSE
OXIMETER
CIRCUIT
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**FIG. 6**

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2020/050874

A. CLASSIFICATION OF SUBJECT MATTER
IPC (20200101) A61B 5/0408, A61B 5/0402, A61B 5/00
CPC (20130101) A61B 5/04085, A61B 5/0402, A61B 5/0006, A61B 5/0408, A61B 5/682
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 (20200101) A61B 5/0408, A61B 5/0402, A61B 5/00
CPC (20130101) A61B 5/04085, A61B 5/0402, A61B 5/0006, A61B 5/0408, A61B 5/682

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)
Databases consulted: Google Patents, Google Scholar, Orbit, SIMILARI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| D,X | US 2018110418 A1 UNIV JOHNS HOPKINS<br>26 Apr 2018 (2018/04/26)<br>Abstract; Figs. 1, 5; 0006] – lines 9-19, [0031], [0034] – lines 1-10; | 12-17 |
| D,A | Entire document | 12-18 |
| D,Y | Entire document | 18 |
| D,Y | US 2013253286 A1 FRIDMAN GENE YEVGENY, UNIV JOHNS HOPKINS<br>26 Sep 2013 (2013/09/26)<br>[0021] – lines 15-18; | 18 |
| A | US 9161697 B2 AZIMI SAEED<br>20 Oct 2015 (2015/10/20)<br>Entire document | 1-18 |
| A | Nelwan, S. P., et al. "Correction of ECG variations due to non-standard electrode positions." Computers in Cardiology 2001. Vol. 28 (Cat. No. 01CH37287). IEEE, 2001.<br>26 Sep 2001 (2001/09/26)<br>Entire document | 1 |

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 18 Nov 2020 | 19 Nov 2020 |

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| Israel Patent Office<br>Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel<br>Email address: pctoffice@justice.gov.il | RINGEL Avigail<br><br>Telephone No. 972-73-3927190 |

**INTERNATIONAL SEARCH REPORT**

International application No.
PCT/IL2020/050874

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | Kligfield, Paul, et al. "Recommendations for the standardization and interpretation of the electrocardiogram: part I: the electrocardiogram and its technology a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society endorsed by the International Society for Computerized Electrocardiology." Journal of the American College of Cardiology 49.10 (2007): 1109-1127.<br>13 Mar 2007 (2007/03/13)<br>Entire document | 1-18 |

**INTERNATIONAL SEARCH REPORT**
Information on patent family members

International application No.
PCT/IL2020/050874

| Patent document cited search report | Publication date | Patent family member(s) | Publication Date |
|---|---|---|---|
| US 2018110418 A1 | 26 Apr 2018 | US 2018110418 A1 | 26 Apr 2018 |
| | | US 10674922 B2 | 09 Jun 2020 |
| | | US 2020253487 A1 | 13 Aug 2020 |
| | | WO 2016172132 A1 | 27 Oct 2016 |
| US 2013253286 A1 | 26 Sep 2013 | US 2013253286 A1 | 26 Sep 2013 |
| | | US 10674960 B2 | 09 Jun 2020 |
| | | US 2020253551 A1 | 13 Aug 2020 |
| | | WO 2012027648 A2 | 01 Mar 2012 |
| | | WO 2012027648 A3 | 16 Aug 2012 |
| US 9161697 B2 | 20 Oct 2015 | US 2015045629 A1 | 12 Feb 2015 |
| | | US 9161697 B2 | 20 Oct 2015 |
| | | CA 2856879 A1 | 08 Jan 2015 |
| | | CN 103584871 A | 19 Feb 2014 |
| | | CN 103584871 B | 09 Dec 2015 |
| | | DK 2835100 T3 | 22 Feb 2016 |
| | | EP 2835100 A1 | 11 Feb 2015 |
| | | EP 2835100 B1 | 18 Nov 2015 |
| | | ES 2562763 T3 | 08 Mar 2016 |
| | | HK 1206229 A1 | 08 Jan 2016 |
| | | JP 2015033568 A | 19 Feb 2015 |
| | | JP 6006254 B2 | 12 Oct 2016 |
| | | KR 20150017655 A | 17 Feb 2015 |
| | | KR 101607116 B1 | 29 Mar 2016 |
| | | PL 2835100 T3 | 29 Apr 2016 |
| | | PT 2835100 E | 15 Feb 2016 |