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(54) **TATTOO BIOSENSOR AND HEALTH MONITORING SYSTEM**

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(52) **U.S. Cl.**

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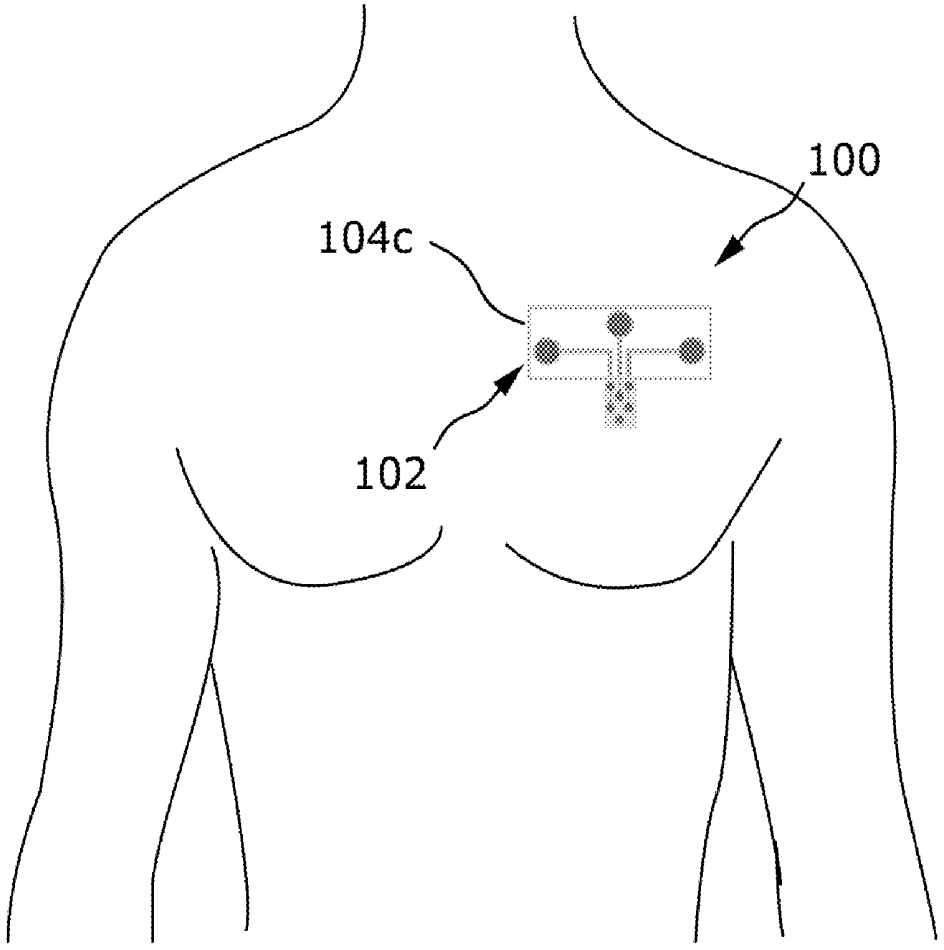
(57) **ABSTRACT**

A conformal tattoo biosensor device includes a pattern of sensor regions formed of a conductive polymer. In embodiments, the conductive polymer may have up to six sensor regions. The pattern is electrically connected to a contact region which is electrically connectable to a wearable signal monitor. The monitor is suitable for transmitting ECG, EEG, or EMG signals. In a monitoring system, the monitor wirelessly transmits signals to a mobile communication device for processing. The mobile communication device transmits signals to a monitor network which may include medical personnel and caregivers. A network module may allow automatic medical alerts, monitoring, and further signal processing.



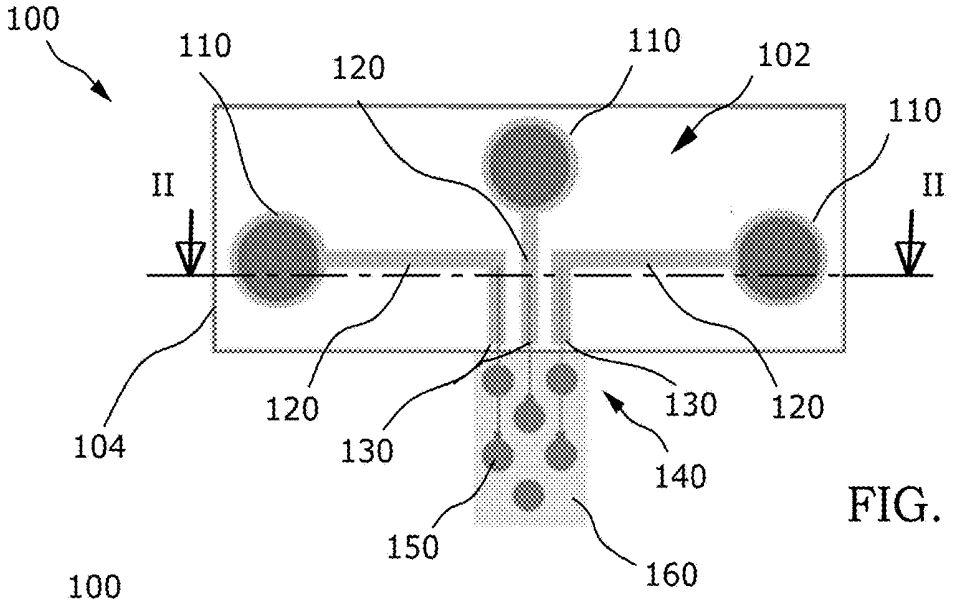


FIG. 1

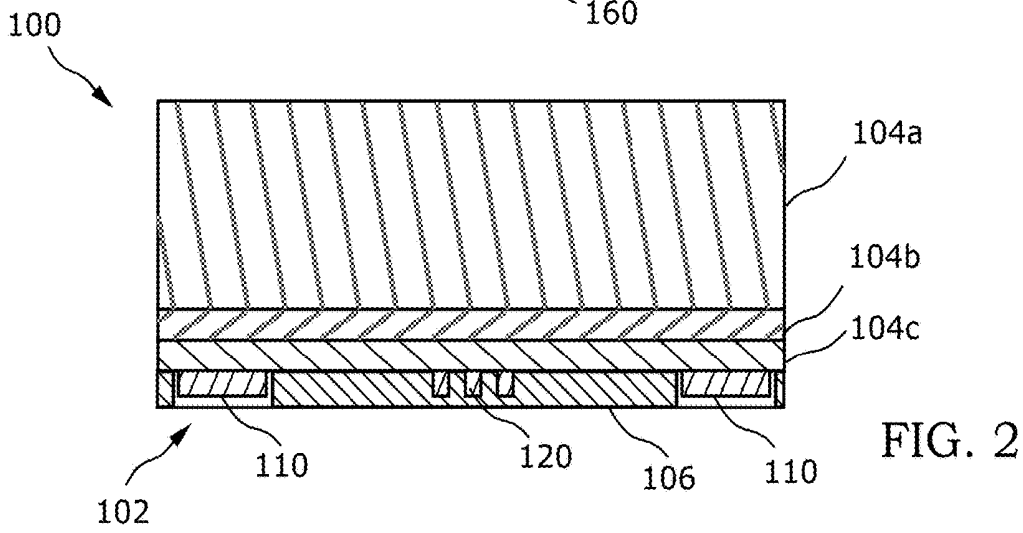


FIG. 2

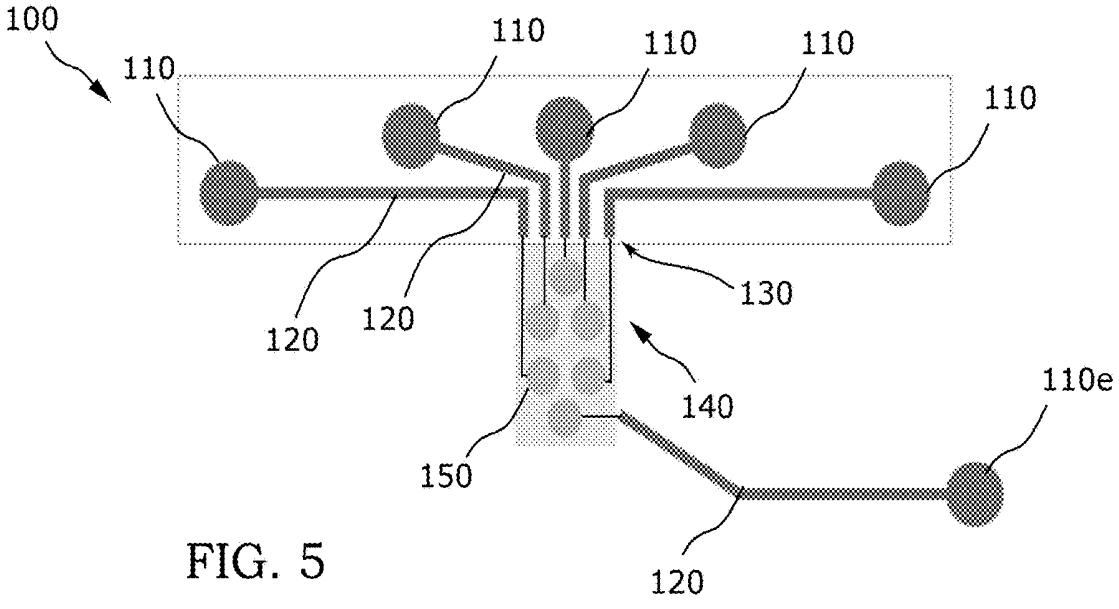


FIG. 5

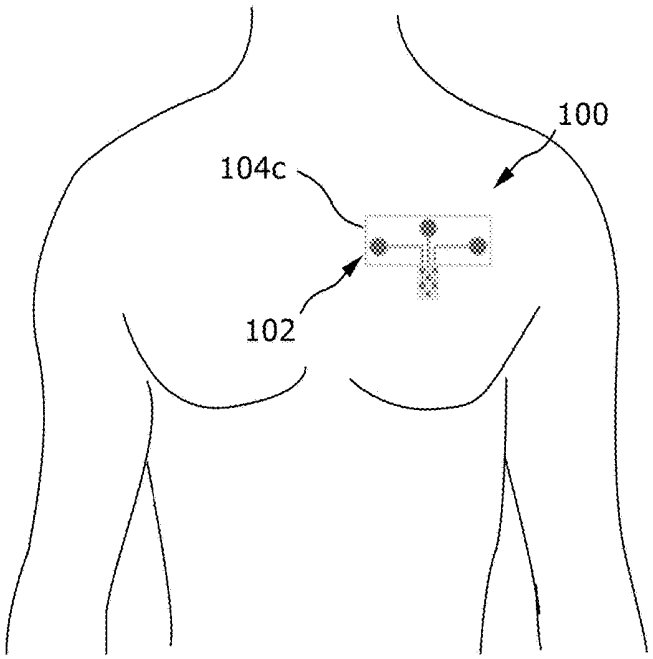


FIG. 3a

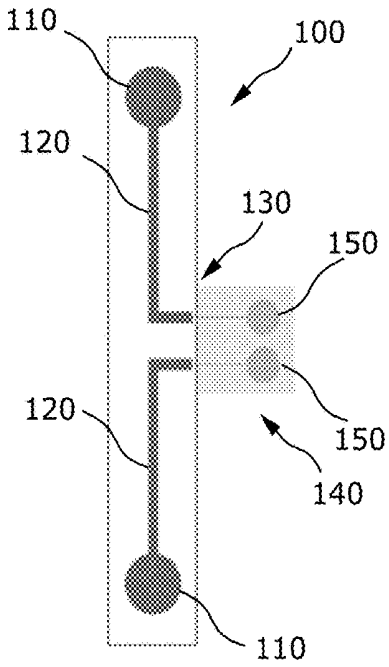


FIG. 4

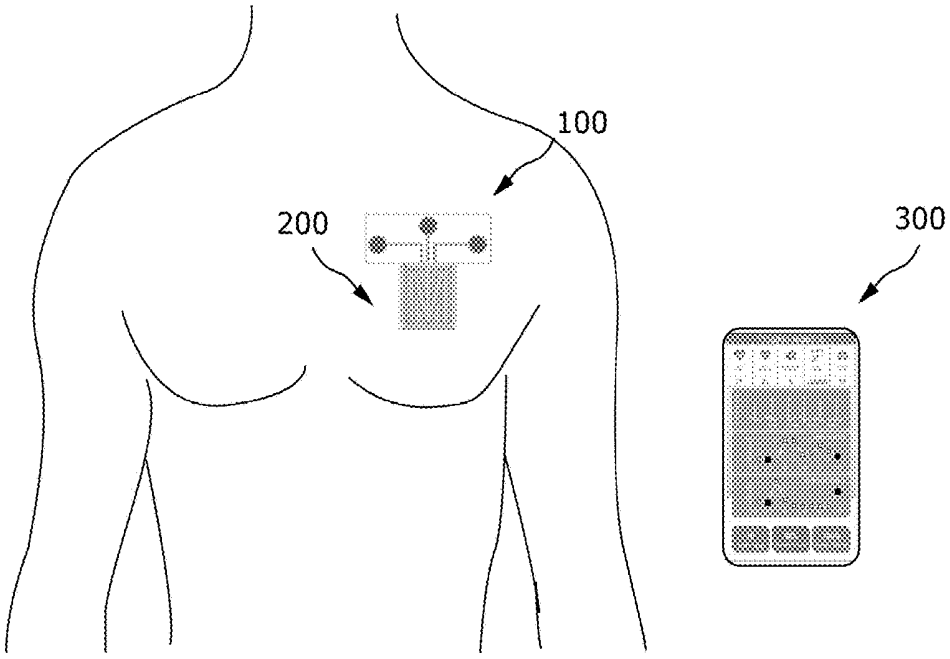


FIG. 3b

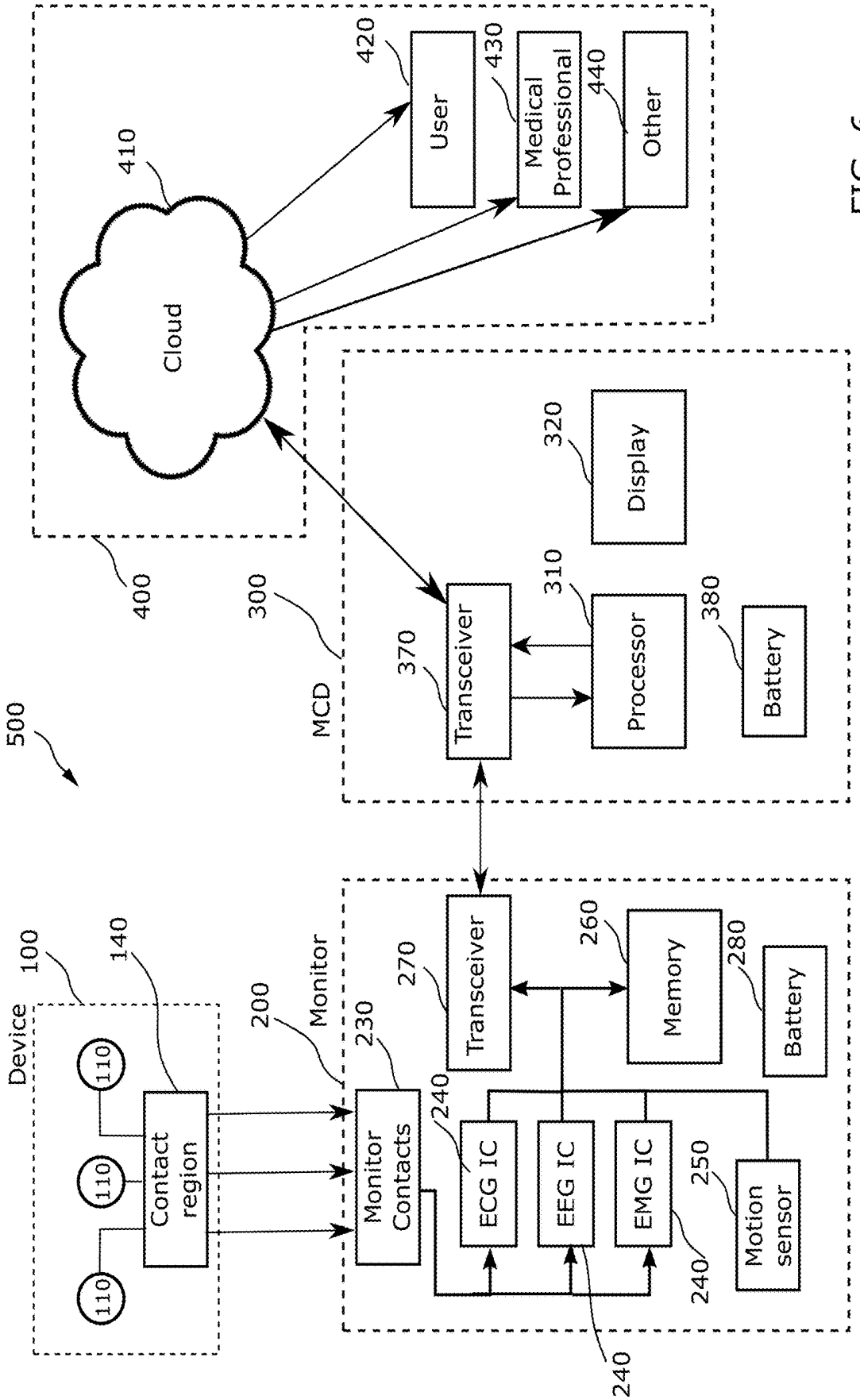

500
Device
100
110
110
110
140
Contact region
200
Monitor
230
Monitor Contacts
240
ECG IC
EEG IC
EMG IC
240
240
250
Motion sensor
270
Transceiver
260
Memory
280
Battery
MCD
300
370
Transceiver
310
Processor
320
Display
380
Battery
400
410
Cloud
420
User
430
Medical Professional
440
Other

FIG. 6

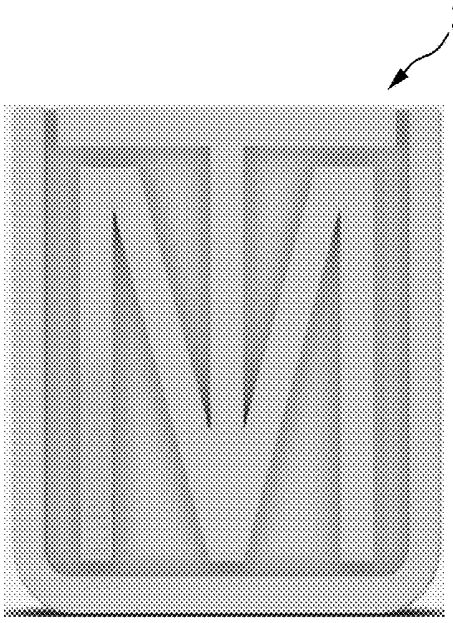


FIG. 7a

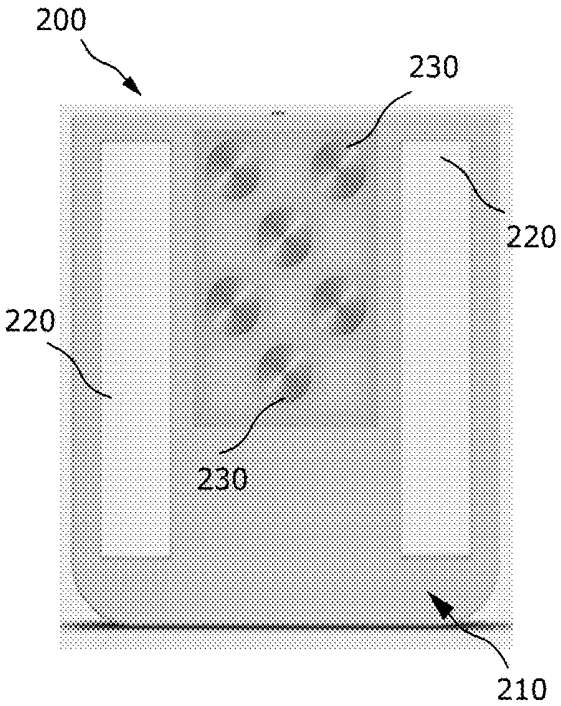


FIG. 7b

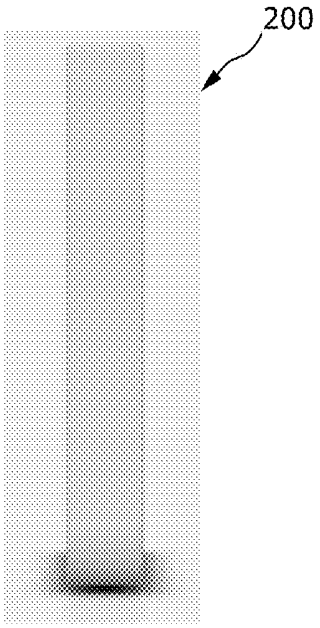


FIG. 7c

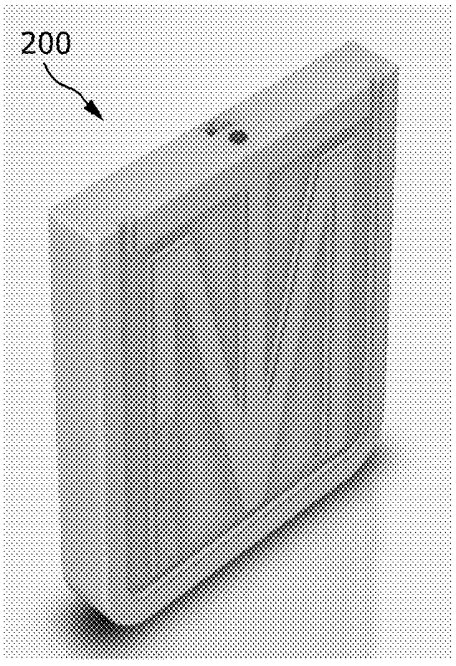


FIG. 7d

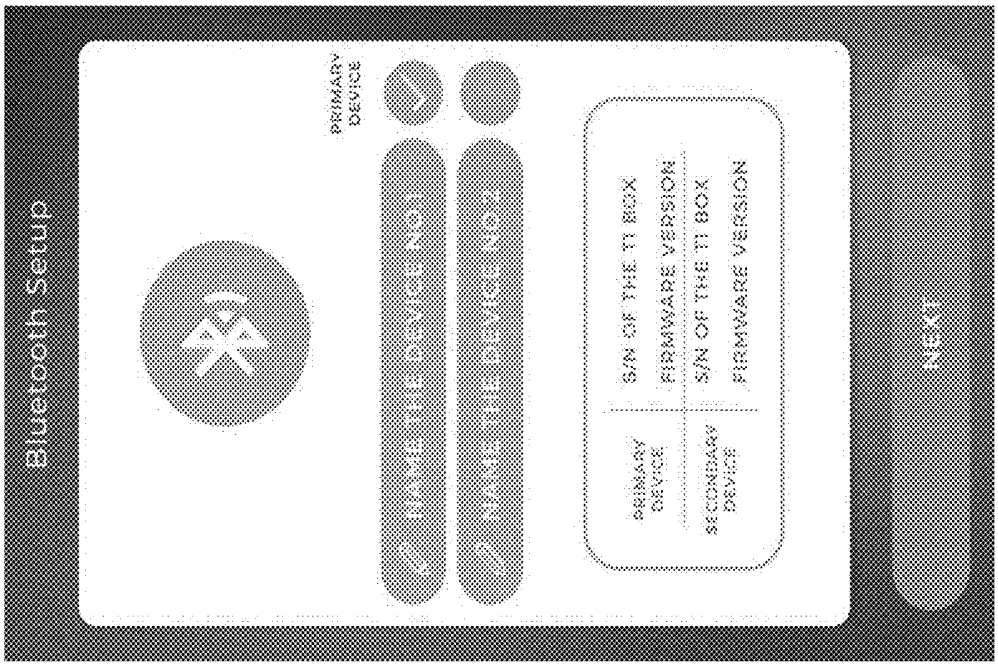

Bluetooth Setup
PRIMARY DEVICE
PAIR THE DEVICE NO.1
PAIR THE DEVICE NO.2
PRIMARY DEVICE
S/N OF THE TI BOX
FIRMWARE VERSION
SECONDARY DEVICE
S/N OF THE TI BOX
FIRMWARE VERSION
NEXT

FIG. 8B

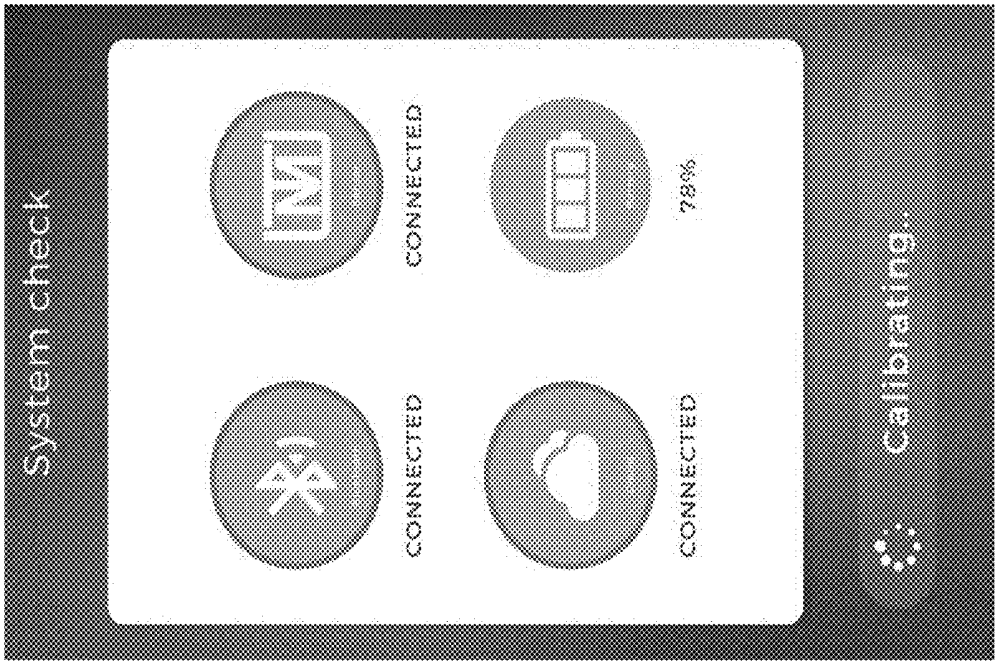

System check
CONNECTED
CONNECTED
78%
CONNECTED
Calibrating.

FIG. 8A

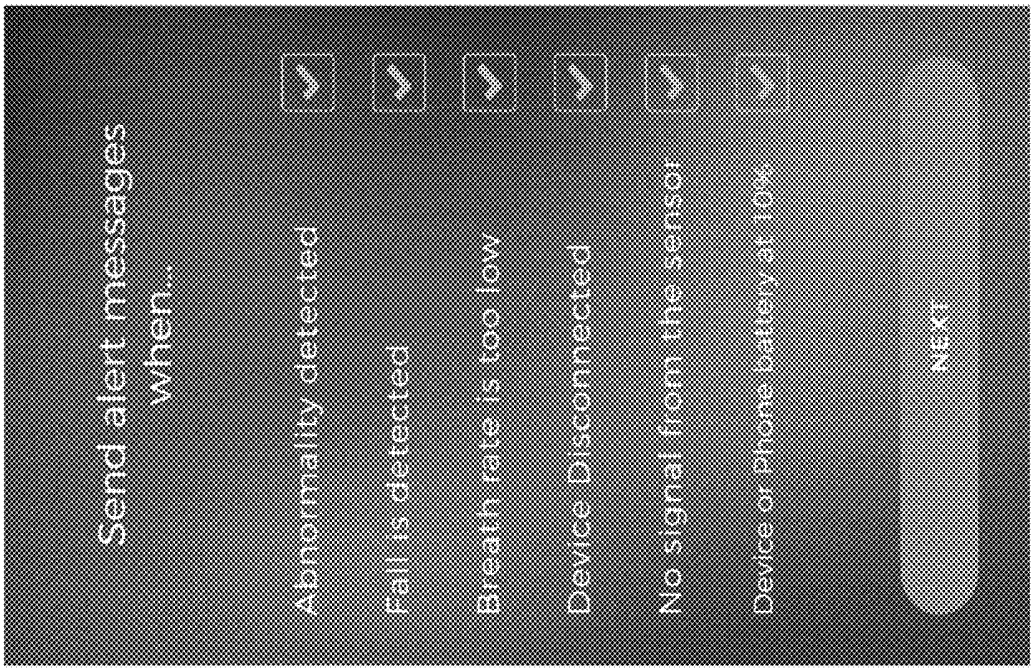

Send alert messages
When...
Abnormality detected
Fall is detected
Breath rate is too low
Device Disconnected
No signal from the sensor
Device or Phone battery at 10%
NEXT

FIG. 8D

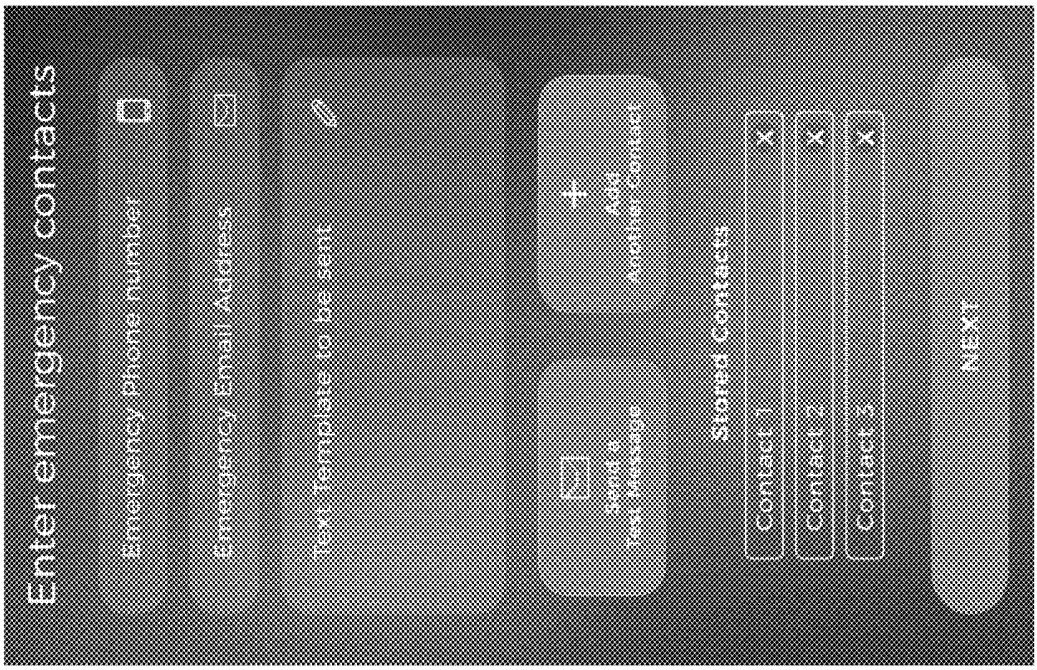

Enter emergency contacts
Emergency Phone Number
Emergency Email Address
Send Template to be sent
Add Contacts
Stored Contacts
Contact 1
Contact 2
Contact 3
NEXT

FIG. 8C

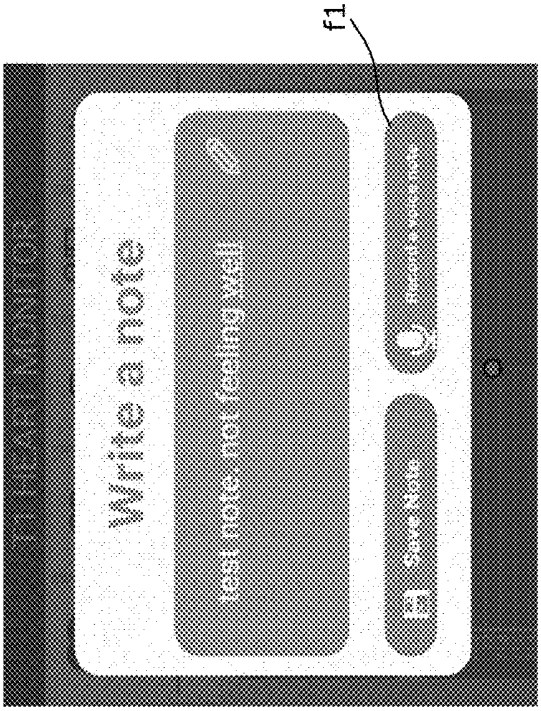

f1
Write a note
Save Note

FIG. 8F

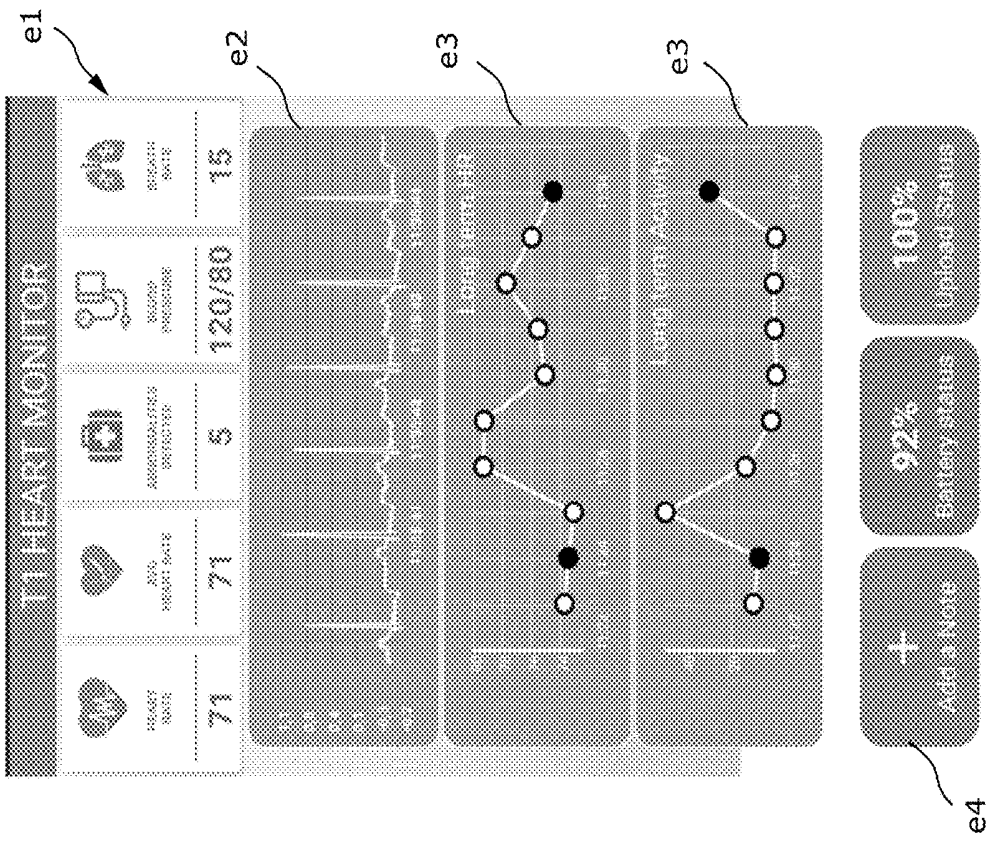

e1
e2
e3
e3
e4
MY HEART MONITOR
71
71
5
120/80
15
100%
92%
+

FIG. 8E

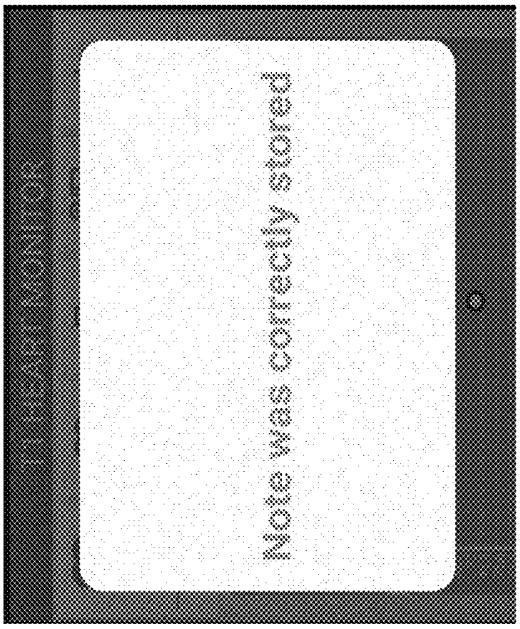


FIG. 8H

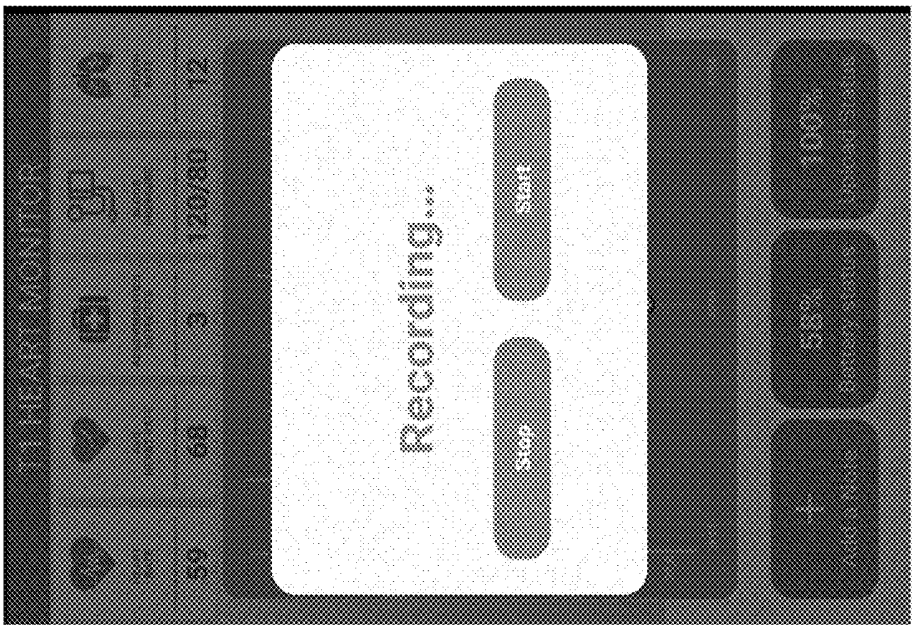


FIG. 8G

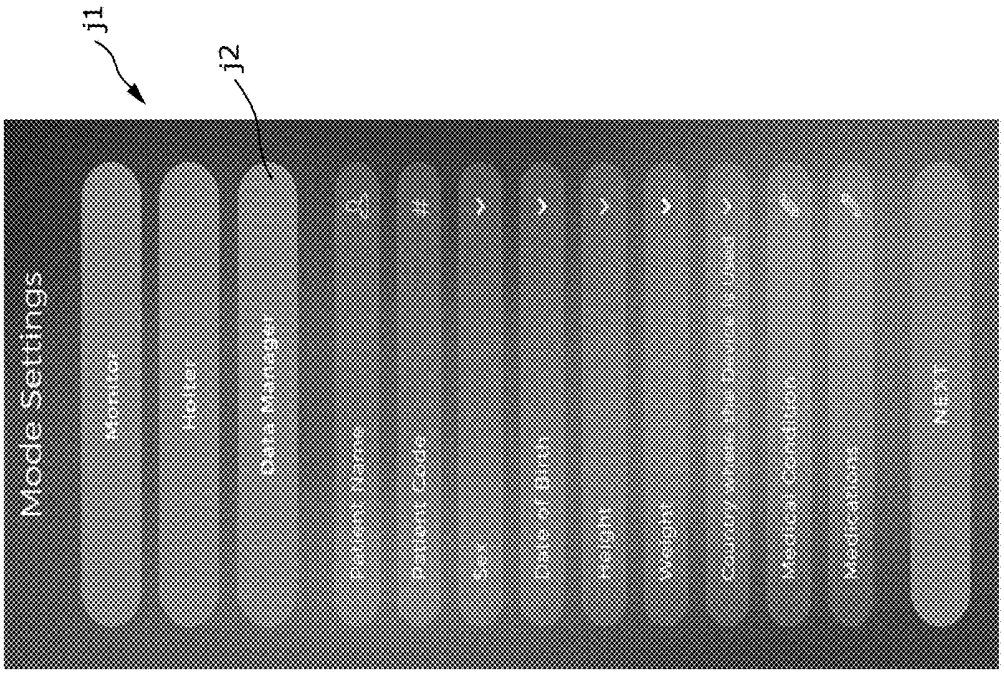

j1
j2
Mode Settings
Profile
Info
Data Manage

FIG. 8J

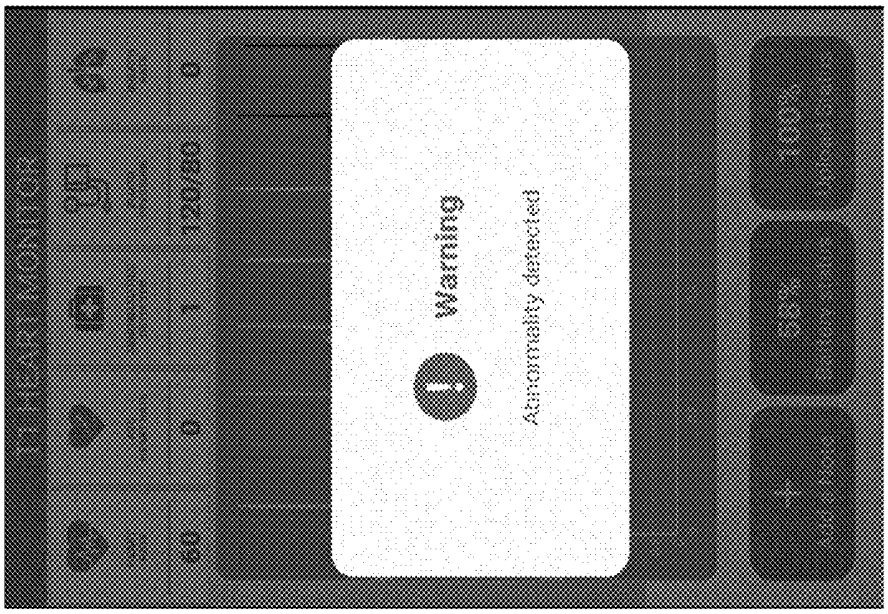

Warning
Abnormality detected

FIG. 8I

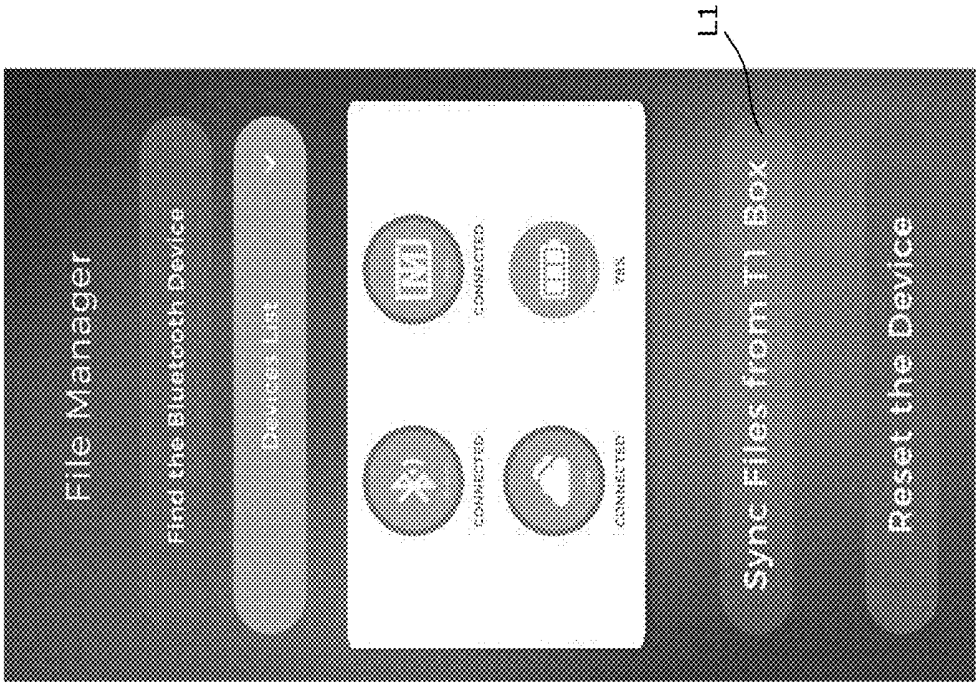

File Manager
Find the Bluetooth Device
Sync Files from TT Box
Reset the Device
L1

FIG. 8L

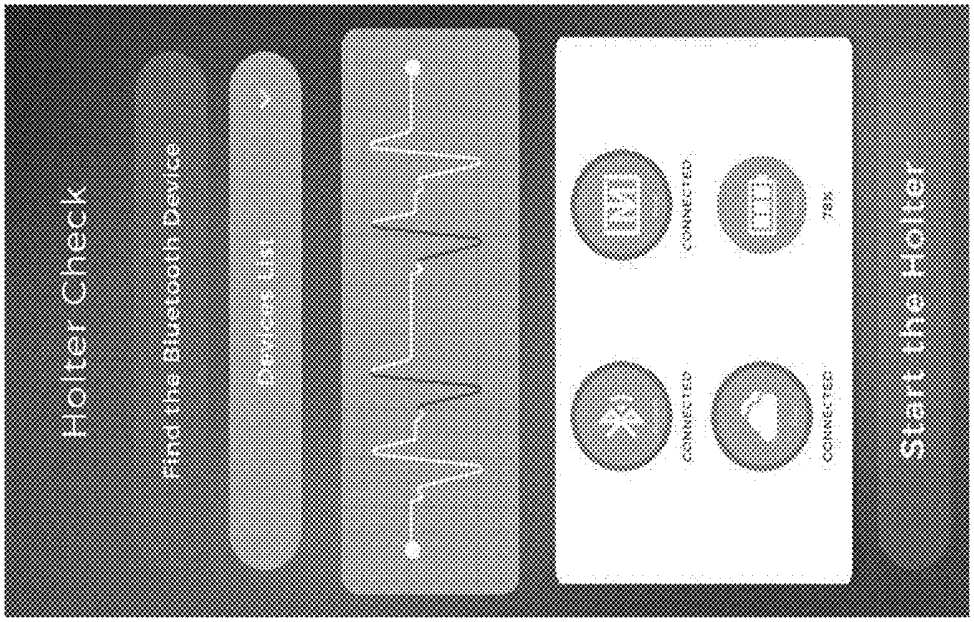

Holter Check
Find the Bluetooth Device
Start the Holter

FIG. 8K

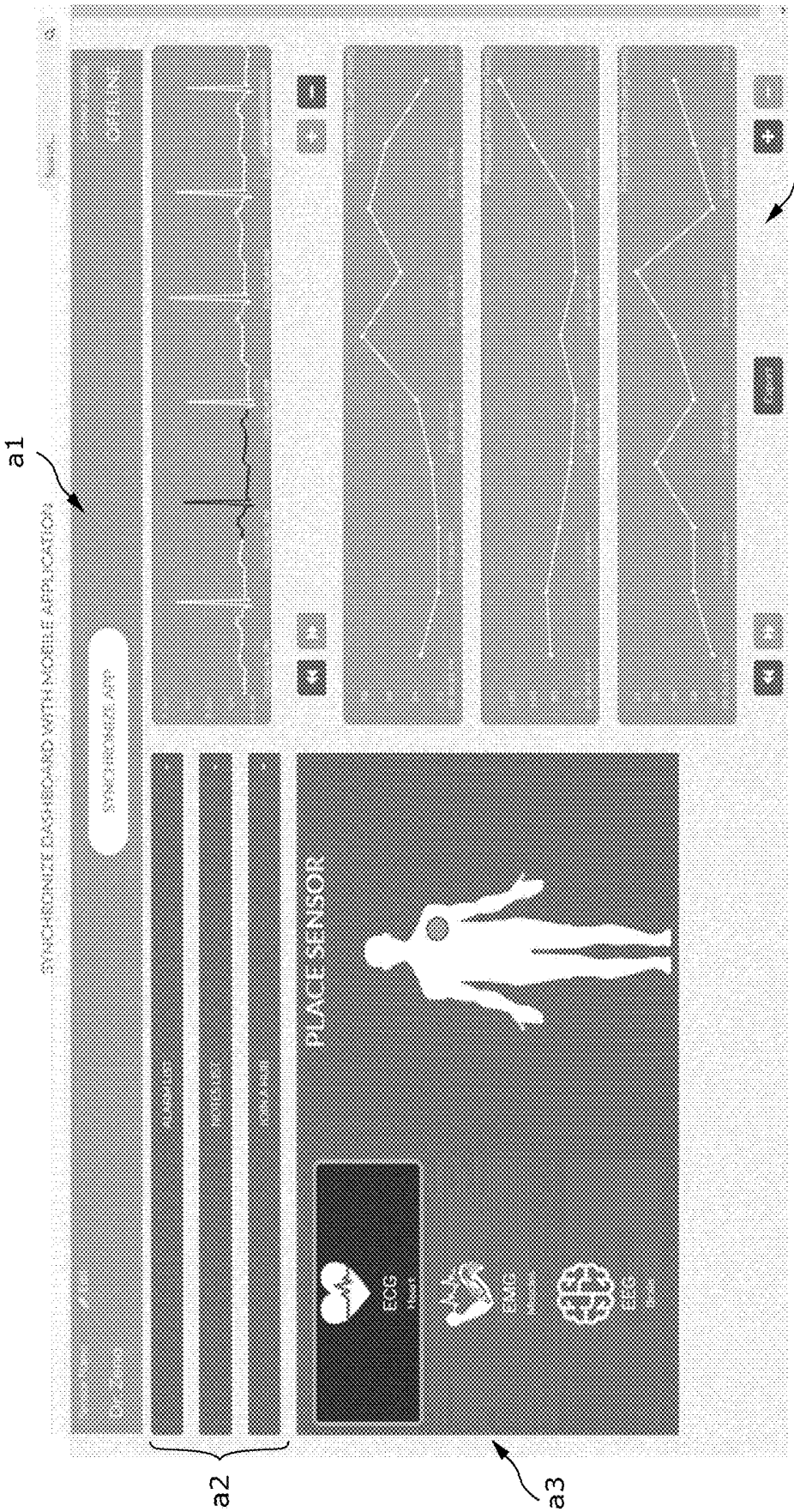

a1
a2
a3
a4
SYNCHRONIZE DASHBOARD WITH MOBILE APPLICATION
SYNCHRONIZE APP
PLACE SENSOR

FIG. 9A

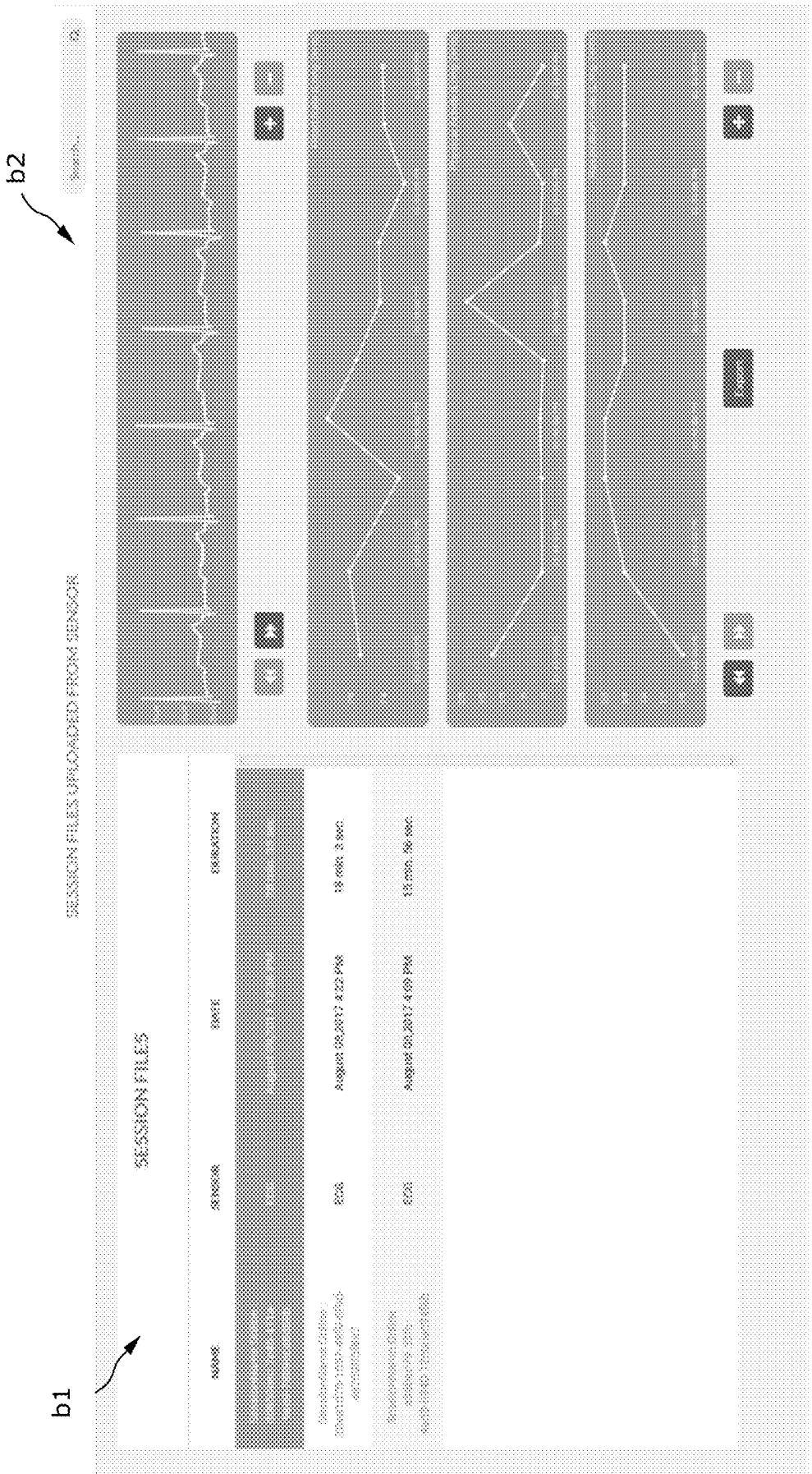


FIG. 9B

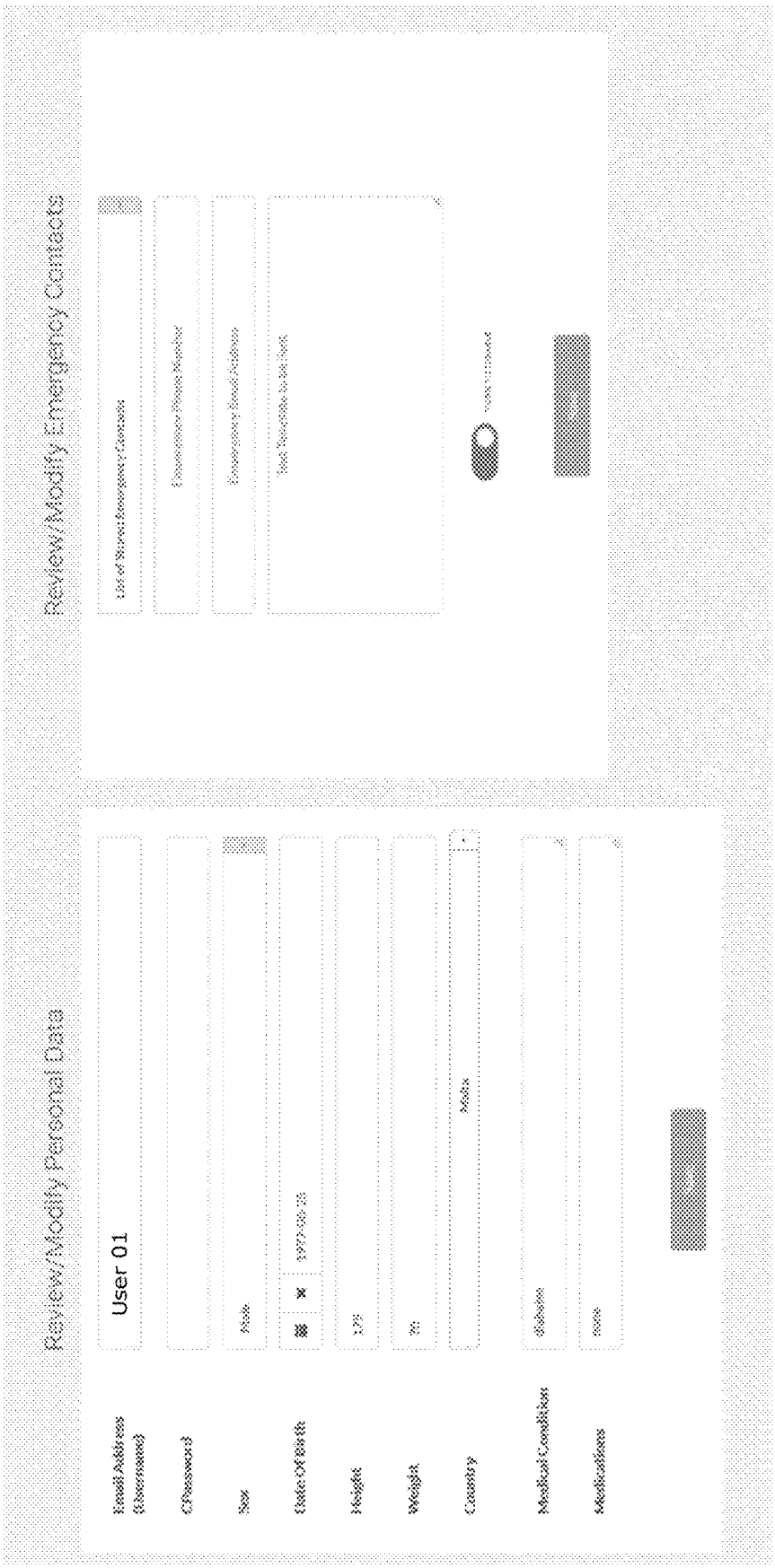

Review/Modify Emergency Contacts
Review/Modify Personal Data
User 01
Male
Medical Condition
Medications

FIG. 9C


d1
d2
d3
User 01
offline
ALARMS
TIME
Fail
August 08,2017 2:49 PM
Fail
August 08,2017 11:59 AM
Fail
August 08,2017 11:56 AM
Fail
August 08,2017 11:53 AM
Fail
August 08,2017 11:53 AM
User 02
offline
ALARMS
TIME
Fail
August 02,2017 3:47 PM
Fail
August 02,2017 3:47 PM
Fail
August 02,2017 3:34 PM
Fail
August 02,2017 3:28 PM
Fail
August 02,2017 3:26 PM
User 03
offline
ALARMS
TIME
Abnormality
July 28,2017 7:22 PM
Abnormality
July 28,2017 7:22 PM
Abnormality
July 28,2017 7:22 PM
Abnormality
July 28,2017 7:20 PM
Abnormality
July 28,2017 7:20 PM
User 04
offline
ALARMS
TIME
Fail
August 01,2017 3:31 PM
Fail
August 01,2017 3:31 PM
User 05
offline
ALARMS
TIME
Abnormality
July 28,2017 11:37 AM
Abnormality
July 28,2017 11:36 AM
User 06
offline
ALARMS
TIME
Fail
August 03,2017 1:06 PM
Fail
August 03,2017 1:06 PM

FIG. 9D

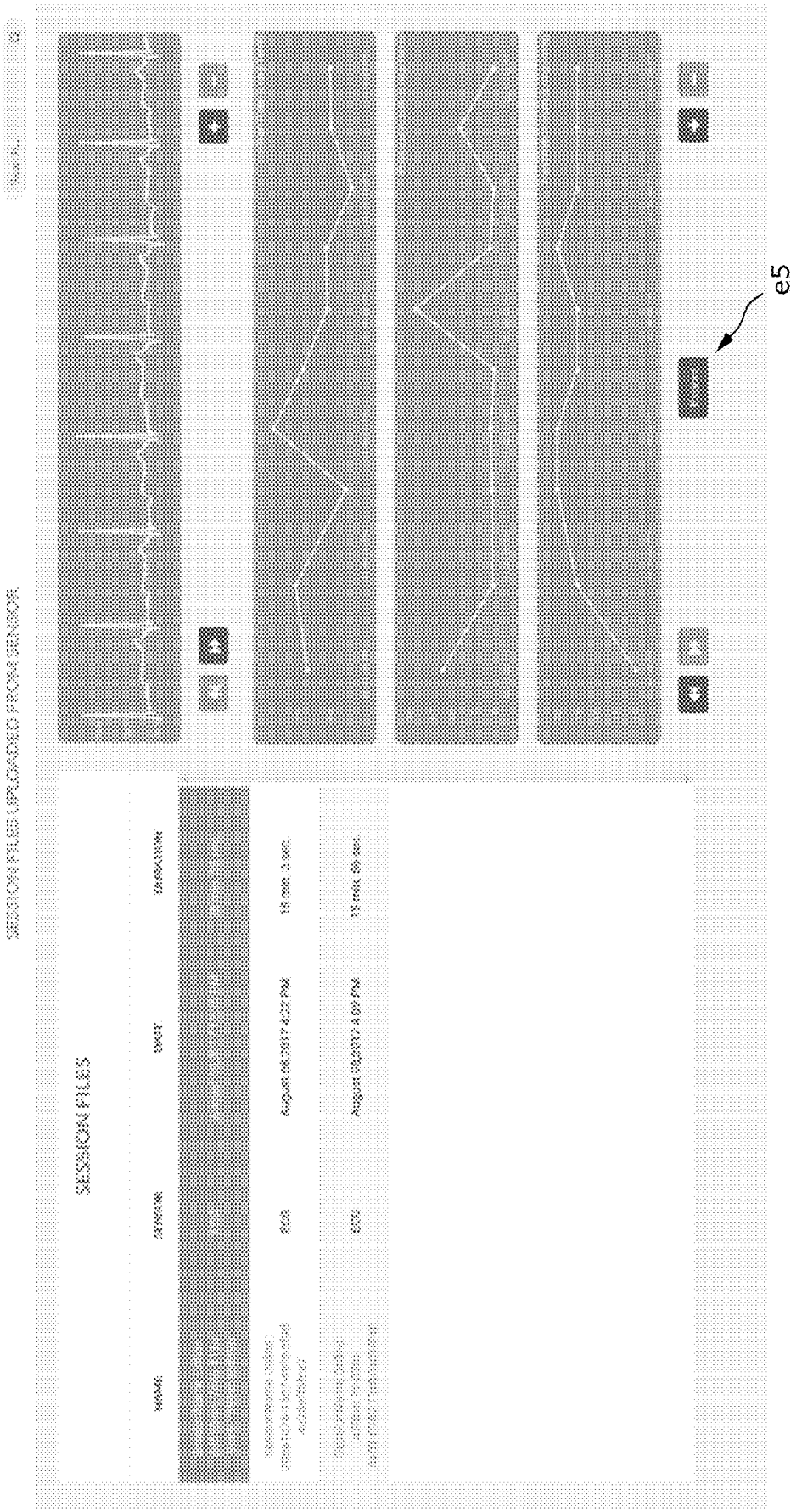


FIG. 9E

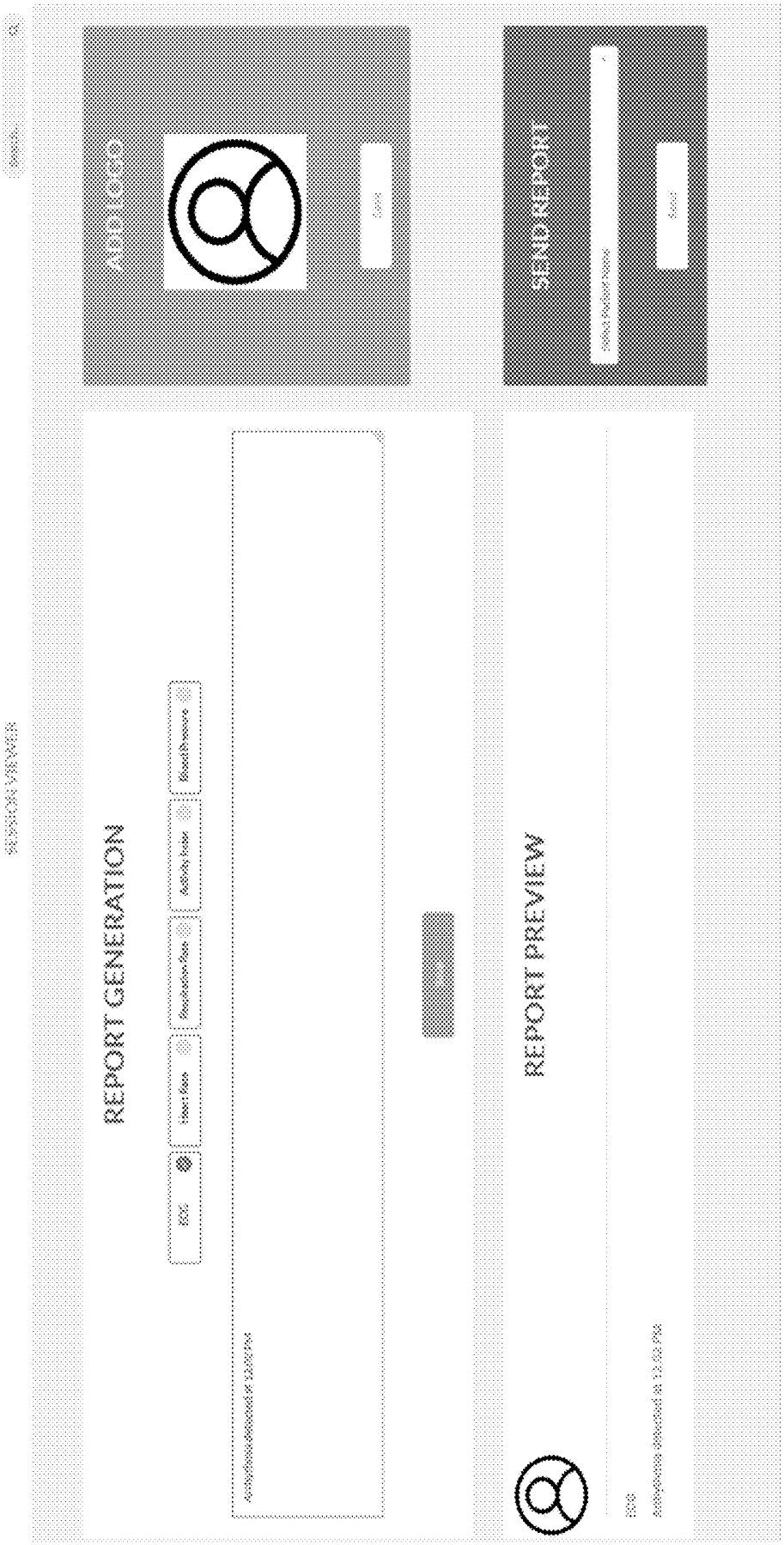


FIG. 9F

TATTOO BIOSENSOR AND HEALTH MONITORING SYSTEM

CROSS REFERENCE TO RELATED APPLICATION

[0001] NONE

TECHNICAL FIELD

[0002] The present invention pertains generally to electrophysiological monitoring, and more particularly to temporary tattoo biosensors and health monitoring systems therewith.

BACKGROUND OF THE INVENTION

[0003] Conventional electrophysiological monitoring methods, such as electrocardiography (ECG or EKG), electromyography (EMG), and electroencephalography (EEG), use conductive electrodes adhered to the skin of a patient with an adhesive or electrolytic gel. The electrodes are wired to a data acquisition unit. The size and wired connections of such systems make them impractical and inconvenient for long-term or mobile use. In addition, gels have a short useful lifetime before drying out. Furthermore, adhesives, gels, and the preparation method used to attach gelled sensors often irritate the patient's skin.

[0004] Recently, conductive polymer films have been demonstrated to have properties suitable for use as biosensors (Greco et al., 2011). Conformable tattoo biosensors having submicrometric thickness were demonstrated in polymer films (Zucca et al., 2015). Other tattoo biosensors have been demonstrated using silver nanoparticles (Casson et al., 2016), polymer-enhanced carbon (Bareket et al., 2016), and graphene (Ameri, et al., 2017). Demonstrated applications include ECG, EMG, and EEG monitoring.

BRIEF SUMMARY OF THE INVENTION

[0005] Generally speaking, the present disclosure teaches a conformable temporary tattoo biosensor having a submicrometric thickness. The sensor device is readily transferred from a substrate sheet to the skin of a patient, and is highly conformable, enabling better impedance response than conventional adhesive or pre-gelled sensors. The sensor regions (or electrode surfaces) of the tattoo biosensor maintain contact with the skin by means of physical adhesion (van der Waals forces), without the use of glue, gel, or other solutions. In embodiments, the tattoo sensors may be surrounded by, and their patterned leads may be covered in, a biocompatible adhesive layer.

[0006] Further disclosed is a electrophysiological monitoring system including the tattoo sensor device which is capable of monitoring and processing ECG, EMG, or EEG signals, and wireless communication with a monitor network. The system includes a reusable monitor configured for direct electrical connection with a contact region of the tattoo sensor device (i.e. electrical connection between the monitor and the contact region of the tattoo sensor does not utilize wires or leads). The system is suitable for long-time monitoring of a patient's vital parameters in ambulatory, in-home, or outpatient settings.

[0007] The embodiments disclosed herein may be summarized as follows.

Embodiment 1

[0008] A device (**100**) for sensing electrophysiological signals, the device cooperating with a signal monitor (**200**), the device comprising:

[0009] a substrate sheet (**104**) having a backing sheet (**104***a*) and a releasable coating layer (**104***c*) formed on the backing sheet;

[0010] a conductive polymer pattern (**102**) formed on the releasable coating layer, the pattern including a plurality of sensor regions (**110**) each connected to a patterned lead (**120**) having a terminus (**130**) adjacent to a common contact region (**140**);

[0011] a plurality of sensor contacts (**150**) arranged within the contact region, each terminus of the patterned leads in electrical communication with one of the sensor contacts; and,

[0012] wherein the sensor contacts are configured for direct electrical connection to the signal monitor.

Embodiment 2

[0013] The device of Embodiment 1, wherein the conductive polymer pattern and the releasable coating layer have a combined thickness of less than 1 micrometer.

Embodiment 3

[0014] The device of Embodiment 1 or 2, wherein the plurality of sensor regions consists of two, three, four, five, or six sensor regions.

Embodiment 4

[0015] The device of any one of Embodiments 1 to 3, wherein the conductive polymer is poly(3,4-ethylenedioxythiophene):poly(styrenesulfonate).

Embodiment 5

[0016] The device of any one of Embodiments 1 to 4, wherein the contact region comprises a nonconductive support layer (**160**) to which the sensor contacts are connected.

Embodiment 6

[0017] The device of any one of Embodiments 1 to 5, wherein the sensor contacts are configured for snap-fitting to the signal monitor.

Embodiment 7

[0018] A wireless electrophysiological monitoring system (**500**), comprising:

[0019] a conductive polymer pattern (**102**) configured for transfer to the skin of a patient, the pattern including a plurality of sensor regions (**110**) each connected to a patterned lead (**120**) having a terminus (**130**) adjacent to a common contact region (**140**);

[0020] a plurality of sensor contacts (**150**) arranged within the contact region, each terminus of the patterned leads in electrical communication with one of the sensor contacts;

[0021] an electrophysiological monitor (**200**) having a plurality of monitor contacts (**230**) and configured to adhere to the skin of the patient such that one of the monitor contacts is in electrical connection with each of the sensor contacts, the monitor further including an integrated circuit (**240**) configured to digitize at least one of ECG, EEG, or

EMG signals, a memory (**260**), and a transceiver (**270**) configured for wireless transmission of the digitized signals; and,

[0022] a mobile communication device (**300**) having a transceiver (**370**) configured for wireless communication with the monitor and a processor (**310**) configured to process the digitized signals, the mobile communication device configured to transmit the processed signals to a monitor network (**400**).

Embodiment 8

[0023] The wireless electrophysiological monitoring system of Embodiment 7, wherein the plurality of sensor regions consists of two, three, four, five, or six sensor regions.

Embodiment 9

[0024] The wireless electrophysiological monitoring system of Embodiment 7 or 8, wherein the monitor includes one or more integrated circuits (**240**) and is configured to digitize ECG, EEG, and EMG signals.

Embodiment 10

[0025] The wireless electrophysiological monitoring system of any one of Embodiments 7 to 9, wherein the monitor includes a motion sensor (**250**).

Embodiment 11

[0026] The wireless electrophysiological monitoring system of any one of Embodiments 7 to 10, wherein the mobile communication device is configured to continuously transmit the processed signals to the monitor network.

Embodiment 12

[0027] The wireless electrophysiological monitoring system of any one of Embodiments 7 to 11, wherein the transmission of signals to the monitor network is accompanied by an indicator of at least one of: cardiac arrhythmia, ECG shape abnormality, respiration rate, heart rate, blood pressure, physical activity index, detected fall, or pre-seizure condition.

[0028] Further disclosed are methods of monitoring electrophysiological signals using the system of any one of Embodiments 7 to 12.

[0029] The following publications are hereby incorporated herein by reference in their entirety. In the case of any conflict between this document and the disclosure of the below references, this document controls.

[0030] Ameri et al. (2017), "Graphene Electronic Tattoo Sensors" (ACS Nano July 2017).

[0031] Bareket et al. (2016), "Temporary-tattoo for long-term high fidelity biopotential recordings" (Nature Scientific Reports, 2016, 6:25727, DOI: 10.1038/srep25727).

[0032] Casson et al. (2016), "Five day attachment ECG electrodes for longitudinal bio-sensing using conformal tattoo substrates" (IEEE Sensors Journal, DOI 10.1109/JSEN.2017.2650564).

[0033] Greco et al. (2011), "Ultra-thin conductive free-standing PEDOT/PSS nanofilms" (Soft Matter, 2011, 7, 10642).

[0034] Zucca et al. (2015), "Conformable Electronics: Tattoo Conductive Polymer Nanosheets for Skin-Contact Applications" (Adv. Healthcare Mater. July 2015, 4: 983).

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] FIG. **1** is a top plan view of a device for sensing electrophysiological signals.

[0036] FIG. **2** is an enlarged cross-sectional view along the line II-II of FIG. **1**.

[0037] FIG. **3**A shows the device being worn by a patient; and FIG. **3**B shows a portion of an electrophysiological monitoring system in use.

[0038] FIG. **4** is a top plan view of another embodiment of the device.

[0039] FIG. **5** is a top plan view of another embodiment of the device.

[0040] FIG. **6** is a schematic representation of the electrophysiological monitoring system.

[0041] FIGS. **7**A-**7**D are front, rear, side, and perspective views, respectively, of a monitor of the system.

[0042] FIGS. **8**A-**8**L are screen displays of a mobile software application of the system.

[0043] FIGS. **9**A-**9**F are screen displays presented to clients of a monitor network of the system.

LIST OF DRAWING REFERENCE NUMERALS

[0044] **100** device
[0045] **102** conductive polymer pattern
[0046] **104** substrate sheet
[0047] **104***a* backing sheet
[0048] **104***b* water-soluble layer
[0049] **104***c* releasable coating layer
[0050] **106** adhesive layer
[0051] **110** sensor region
[0052] **120** patterned lead
[0053] **130** terminus
[0054] **140** contact region
[0055] **150** sensor contact
[0056] **160** nonconductive support layer
[0057] **200** electrophysiological monitor
[0058] **210** rear face
[0059] **220** adhesive
[0060] **230** monitor contact
[0061] **240** integrated circuit
[0062] **250** motion sensor
[0063] **260** memory
[0064] **270** transceiver
[0065] **300** mobile communication device
[0066] **310** processor
[0067] **320** display
[0068] **370** transceiver
[0069] **380** battery
[0070] **400** monitor network
[0071] **410** cloud
[0072] **420** user client
[0073] **430** medical professional client
[0074] **440** other client
[0075] **500** electrophysiological monitoring system

DETAILED DESCRIPTION OF THE INVENTION

[0076] Referring initially to FIGS. **1**-**2**, there are illustrated top plan and enlarged cross-sectional views, respectively, of

a device for sensing electrophysiological signals (biosignals), the device generally designated as **100**. Device **100** comprises a conductive polymer pattern **102** on a substrate sheet **104**, such as decal transfer paper which is commonly used for temporary tattoos. Conductive polymer pattern **102** includes a plurality of sensor regions **110** (hereinafter referred to as sensors), three sensors **110** being present in the shown embodiment. In other embodiments, 2, 4, 5, 6, or another number of sensors **110** may be included.

[0077] In embodiments, conductive polymer pattern **102** comprises a high-conductivity polymer complex poly(3,4-ethylenedioxythiophene):poly(styrenesulfonate) (PEDOT:PSS). The polymer pattern may be ink-jet patterned onto the decal transfer paper substrate sheet **104**, in one of the manners described by Zucca, et al. (2015). Substrate sheet **104** may comprise three layers: i) a backing sheet **104***a*, such as a water-permeable paper; ii) a water-soluble layer **104***b*, such as a starch-dextrin coating, and iii) a releasable coating layer **104***c*, such as ethylcellulose (EC). Polymer pattern **102** is patterned on releasable coating layer **104***c* of substrate sheet **104**.

[0078] In further embodiments, an adhesive layer **106** is applied to device **100** after the polymer pattern has been patterned on substrate **104**. Adhesive layer **106** may be a double-sided biocompatible adhesive one side of which is adhered to layer **104***c* and pattern **102** and the other side of which is configured to adhere to the skin of the patient. Preferably, before application of adhesive layer **106** to device **100**, holes are cut in adhesive layer **106** corresponding to the locations of sensors **110** of pattern **102**, thereby permitting direct contact between sensors **110** and the skin when in use. Adhesive layer **106** provides longer term durable adhesion of device **110** and protects small features of the pattern, such as patterned leads **120**, from wear.

[0079] FIG. **2** shows a cross-sectional view along line II-II of FIG. **1**, the view enlarged in height to better illustrate the thickness of the layers of the device (contact region **140** not shown for clarity). In the orientation shown, the bottommost layer is in contact with the skin of the patient during application and use. In embodiments, conductive polymer pattern **102** and the releasable coating layer **104***c* have a combined thickness of less than 1 micrometer, less than 750 nanometers (nm), less than 700 nm, less than 650 nm, or less than 600 nm. In an example embodiment, conductive polymer pattern **102** has a thickness of about 250 nm and releasable coating layer **104***c* has a thickness of about 360 nm, giving the transferred tattoo a total thickness of about 610 nm. In other embodiments, adhesive layer **106** also has a thickness of less than 1 micrometer.

[0080] FIG. **3**A shows conductive polymer pattern **102** being worn by a patient, in a manner suitable for electrocardiography (ECG or EKG). Conductive polymer pattern **102** is transferred to the skin of a patient in the manner of applying a temporary tattoo. Device **100** is put in contact with the skin of a patient such that the backing sheet **104***a* (not shown, see FIG. **2**) is away from the body. When backing sheet **104***a* is moistened with water, the water-soluble layer **104***b* dissolves and releasable coating layer **104***c* and conductive polymer pattern **102** are released from substrate sheet **104** and transferred to the patient's skin. Backing sheet **104***a* may be moistened, such as with a wet cloth, and pressure applied for approximately 30 seconds, by which time the polymer pattern **102** and releasable coating layer **104***c* will be transferred to the patient. Backing sheet layer **104***a* may then be removed and discarded.

[0081] FIG. **3**B shows the patient wearing device **100** with a cooperating monitor **200** and mobile communication device (MCD) **300**, which are further discussed below.

[0082] Referring again to FIG. **1**, each sensor **110** of the pattern is connected to a patterned lead **120** formed of the same conductive polymer as sensor **110**. Each patterned lead **120** has a terminus **130** adjacent to or within a common contact region **140**. In an embodiment each sensor **110** has a diameter of about 15 mm. In the embodiment of FIG. **1** the spacing between sensors **110** on the far left and far right is about 80 mm. In the shown embodiment, patterned leads **120** have a width on the order of 2.5 mm. In other embodiments, patterned leads may be wider to support a longer length of lead.

[0083] Each terminus **130** is in electrical connection with a sensor contact **150** located within contact region **140** (six of sensor contact **150** are present in the shown embodiment). In an embodiment, ultrathin wires connect each terminus **130** to a sensor contact **150**. In another embodiment, the wires are sandwiched between two layers of tape which provide support and protection for the wires. In embodiments, one end of each wire is located between a terminus **130** of conductive polymer pattern **102** and releasable coating layer **104***c*. The other end of each wire is connected to a sensor contact **150**, such as by clipping between a male and female component of sensor contact **150**.

[0084] In another embodiment of the electrical connection between terminus **130** and sensor contact **150**, the connection may include a substantially planar layer of conductive polymer, such as PEDOT:PSS, rather than ultrathin wires. In embodiments, the conductive polymer may be printed on a support layer to which sensor contacts **150** are connected.

[0085] Contact region **140** is configured such that a monitor having electrical contacts for direct electrical connection with some or all of sensor contacts **150** may be easily and conveniently positioned over contact region **140** (see FIG. **3**B). This direct electrical connection is made without the use of wires or leads. In embodiments, sensor contacts **150** are configured for snap-fitting to the signal monitor, for example sensor contacts **150** may be a male or female electroconductive stud configured for snap-fitting to the complementary female or male monitor contact **230**. Each sensor contact **150** may be sized on the order of 3 mm diameter, and arranged with an interstitial spacing of around 5-10 mm.

[0086] In an embodiment, contact region **140** comprises a nonconductive support layer **160** to which the sensor contacts are connected. For example support layer **160** may be made from polyethylene terephthalate (PET), and sensor contacts **150** may be electroconductive studs having front and back components which are connected with the PET support layer between the front and back components. In an embodiment, contact region **140** may not be attached to the skin of the patient and may be supported by connection to the tattoo substrate **104***c*.

[0087] FIGS. **4** & **5** are top plan views of additional embodiments of device **100**, the conductive polymer pattern **102** of FIG. **4** having two sensors **110** and that of FIG. **5** having six sensors **110**. The device of FIG. **4** may be transferred to a patient's skin near a skeletal muscle (such as locations on an arm or leg) for use in electromyography (EMG). In the shown embodiment, sensors **110** have a

spacing of about 12 cm and are configured for placement on a biceps muscle. In another example embodiment, sensors **110** have a spacing of about 20 cm for placement on a quadriceps muscle. The device of FIG. **5** may be transferred to a patient's scalp for use in electroencephalography (EEG). Sensor **110***e* may be transferred to the patient's earlobe, and used as a reference electrode. Sensors **110** may be otherwise arranged for detection of biosignals, for example any number from three to six of sensors **110** may be arranged in accordance with the 10-20 electrode placement system for EEG. In other embodiments, the size, shape, number, and arrangement of sensors **110**, as well as that of contacts **150** may be custom designed for specific applications.

[0088] FIG. **6** is a schematic representation of an electrophysiological monitoring system **500** including a device **100** generally as described above.

[0089] An electrophysiological monitor **200** is configured to adhere to the skin of the patient and connect electrically with conductive polymer pattern **102**, via contact region **140**. FIGS. 7A-7D are front, rear, side, and perspective views, respectively, of monitor **200**. A plurality of electrical monitor contacts **230** are located on the rear face **210** of the monitor (six contacts **230** shown in FIG. 7B). Contacts **230** are located so that when monitor **200** is positioned over contact region **140** and adhered to the patient's skin with rear face **210** facing the skin, one of monitor contacts **230** is in electrical connection with each sensor contact **150** which is in electrical connection with one of the patterned leads **120** of the conductive polymer pattern **102**. For example, monitor **200** may have six monitor contacts **230**. When used with a tattoo sensor having six of sensor **110**, each monitor contact is in electrical connection with one sensor contact **150**. When the same example monitor is used with a tattoo sensor having two or three of sensor **110**, one monitor contact **230** is in electrical connection with each electrically connected sensor contact **150**, while the remaining four or three monitor contacts **230** are unused (not connected).

[0090] Monitor contacts **230** may be electroconductive studs having an overall diameter of about 3.5 mm. Strips of biocompatible adhesive **220** on rear face **210** of monitor **200** enable ready attachment to the skin of the patient. In embodiments, adhesive **220** is readily replaceable each time monitor **200** is removed from the patient's skin, or as otherwise desired to maintain proper adhesion. Monitor **200** and/or contact region **140** may have indicia marking proper placement of monitor **200** over contact region **140**. In an embodiment, monitor **200** has a height of 45 mm, a width of 40 mm, and a thickness of 7 mm.

[0091] Referring again to FIG. **6**, electrophysiological monitor **200** includes at least one integrated circuit (IC) **240** configured to digitize biosignals received from sensors **110** which may be any one of ECG, EEG, or EMG signals. In the shown embodiment, monitor **200** includes three of IC **240**, each of which digitizes one of ECG, EEG, or EMG signals. In another embodiment, a single IC **240** may be configured to digitize all of ECG, EEG, and EMG signals. Other IC configurations maybe readily envisioned to achieve the same result. IC **240** may further perform additional functions, such as signal amplification, filtering, lead-off detection, signal resampling, impedance measurement, etc. Signals processed by IC **240** in any of the above-mentioned manners are referred to herein as digitized signals.

[0092] In an embodiment, monitor **200** includes a motion sensor **250** such as an accelerometer or piezoelectric sensor, for detecting sudden movements of the patient, such as a fall.

[0093] Monitor **200** is powered by a replaceable or rechargeable battery **280**, such as a standard button cell battery. Multiple batteries **280** may be provided with monitor **200** so that while a first battery is installed in monitor **200** a second battery may be recharged and ready to replace the first (in use) battery as needed. In this manner, monitor **200** may be used substantially uninterrupted for prolonged periods of time (up to several years).

[0094] A transceiver **270** in monitor **200** wirelessly transmits digitized signals or motion sensor data to a mobile communications device (MCD) **300**, such as a cellular telephone, tablet, or the like. In one embodiment, transceiver **270** uses the Bluetooth Low Energy (BLE) specification to prolong battery life of the monitor. In embodiments, a BLE transceiver may be left on continuously or may alternate between a full power "wake" mode and a lower power "sleep" mode. In other embodiments, transceiver **270** may use wireless internet communication, standard Bluetooth, or other communication protocols known in the art.

[0095] Monitor **200** includes a memory **260**, such as a flash memory, ROM, EEPROM, or the like. In one embodiment, memory **260** is an SD card, and digitized signals may be stored internally to monitor **200** for up to a 24 hour period.

[0096] In an embodiment, monitor **200** has two operating modes, Holter mode and monitor mode. When operated in Holter mode, digitized signals are stored on memory **260** of monitor **200** for a period of time such as 12, 24, 36, or 48 hours. When in Holter mode monitor **200** stores sensor data without transferring data to MCD **300** or other devices or networks. When monitor **200** is operated in monitor mode, digitized signals may be temporarily stored on memory **260** of monitor **200** and are transferred to MCD **300** either in pseudo-real time or as soon as a network connection is available.

[0097] MCD **300** includes a transceiver **370** for wirelessly receiving and transmitting signals to or from monitor **200** and a monitor network **400**, which may be a cloud network or other internet network. While transceiver **370** is referred to herein in the singular, transceiver **370** may comprise multiple distinct hardware elements for communication via various protocols. For example, transceiver **370** may include a BLE transceiver for sending/receiving signals to/from monitor **200**; a wireless network interface which supports a typical wireless local area network (WLAN), for example, Wi-Fi, or some other wireless local network capability, like, for example, femtocell or picocell wireless, Wireless USB, etc. for transmitting signals to monitor network **400**; and/or an interface to a cellular network for transmitting signals to the monitor network.

[0098] In addition to transceiver **370** receiving digitized signals from monitor **200**, transceiver **370** may transmit signals or instructions to monitor **200**, such as to change the operational configuration of IC **240** (e.g., changing gain, sampling rate, or filter settings), to alternate between Holter and monitor modes, to query status of connections or battery levels, to request data transfer from memory **260**, or other operational instructions.

[0099] MCD **300** further includes a processor **310** configured to process the digitized signals received from monitor **200** by transceiver **370**. Processing performed by processor

310 may include signal filtering; artifact removal; comparison of digitized signals with databases of normal and pathologic ECG/EMM/EEG signals; template matching; detecting ECG abnormalities, such as arrhythmias and abnormalities in the morphology ("shape") of the ECG wave which may be predictive of critical cardiac events; determining vital signs such as heart rate, respiration rate, physical activity index or blood pressure; detecting falls; and applying fast Fourier transform (FFT) to extract amplitudes or relevant frequencies for EMG and EEG signals. Outputs of any of the aforementioned processing performed on the MCD are referred to hereinafter as processed data.

[0100] MCD **300** further includes a display **320**, which may display to the user certain digitized signals or processed data, and a battery **380**. It is particularly advantageous to perform signal processing on processor **310** of MCD **300** rather than on monitor **200** itself, due to the high speed and processing power of commercially available MCDs at relatively low cost as compared to processors customized to specific applications. By minimizing the signal processing performed on-board monitor **200**, the time before discharge of battery **280** may be extended and the overall size of the monitor reduced. Signal processing may be controlled via a mobile software application (app), suitable for installation on commercially available MCDs. In an embodiment, the MCD is dedicated for use with system **500**.

[0101] Signals processed by processor **310** are transmitted by transceiver **370** to monitor network **400**. In addition, unprocessed digitized signals received by MCD **300** may be transmitted to monitor network **400** for analysis or processing outside of MCD **300**, such as by a medical professional connected to monitor network **400**. When monitor **200** is in monitor mode and wireless communication channels are active, data transfer from MCD **300** to monitor network **400** is continuous.

[0102] In embodiments, monitor network **400** includes a cloud **410** which may be accessed by a number of clients such as a user **420** (the patient wearing device **100**); a medical professional **430**, which may be an individual or team of doctors, a hospital network, out-patient care provider, or similar; and other clients **440** such as an emergency points of contact, lay caregivers, patient supervisors, etc.

[0103] FIGS. **8**A-**8**I are example screen displays of a mobile software application (app) shown on display **320** (see FIGS. **3**B & **6**) of MCD **300** when monitoring system **500** is in use. FIG. **8**A shows a screen displaying various system status indicators, such as connection to Bluetooth or other short-distance wireless communication link, connection to the monitor, connection to the monitor network, and battery charge level. FIG. **8**B shows a screen for configuring wireless connection to one or more monitors. FIG. **8**C shows a screen for configuring emergency contacts to whom emails or SMS (text) alert messages may be sent notifying them that intervention may be required. FIG. **8**D shows a configuration screen for selecting when to send alert messages to the emergency contact. Alerts may be sent for detected conditions such as a ECG/EMG/EEG signal abnormality, detected fall, low breathing rate, disconnected monitor, sensor signal not detected, low battery on monitor or MCD, or other conditions of interest not shown.

[0104] FIG. **8**E is a default monitor display showing a plurality of processed data indicators (e**1**), such as heart rate, blood pressure, breathing rate, and number of abnormalities detected. The display also shows several graphs over time, such as detected signal from sensors (e**2**) and results of data processing (e**3**, long term heart rate and physical activity in the shown display). Occurrences of abnormalities may indicated on the graphs such as in a contrasting color or with distinct markers, as shown in e**3**. The status indicators and graphs to be displayed on the default screen may be selected by the user. Button e**4** at the bottom of the screen allows the user to add a note, and calls the display of FIG. **8**F. The user may type a text note, or record a voice note (button f**1**, which calls the display of FIG. **8**G). Text or voice notes may be stored locally or transmitted to the monitor network. A confirmation of a note being stored is shown on the screen of FIG. **8**H.

[0105] If an abnormality is detected, a warning message is displayed on the MCD, such as that shown in FIG. **8**I. The MCD may simultaneously provide other indications to the user, such as a vibration or an audible alarm. In addition to the warning, emergency contacts are notified when abnormalities occur, as configured by the user on the screens of FIGS. **8**C-**8**D. When a text message is sent to an emergency contact, the screen may display a notification that the message was sent. When monitor **200** is in Holter mode, alarms are not displayed to the user and emergency contact notifications are not sent.

[0106] FIG. **8**J shows a display which enables the MCD user to configure the monitor to operate in Holter or monitor modes (buttons j**1**). When operating in Holter mode, the user may check monitor status and start or stop Holter mode using the screen shown in FIG. **8**K. The user may initiate transfer of data stored on memory **260** during a Holter mode session using button j**2** (FIG. **8**J) or the file manager screen shown in FIG. **8**L (button L**1**).

[0107] An interface module enables client devices (computers, servers, mobile phones and the like) to manage connection to and view data received from the monitor network. The module may be installed locally on a client device or may be remotely hosted and accessed by the client device via an internet browser. The module manages communication between devices within the monitor network, synchronizes data between the MCD and client devices, and provides clients with a graphical user interface ('dashboard') which may be customized for the type of client (user of device, medical professional, emergency contact, etc.). The module enables multiple clients to access session data either in real-time or asynchronously.

[0108] FIGS. **9**A-**9**F are example dashboards presented to clients **420**, **430**, **440** when connected to monitor network **400** (see FIG. **6**). FIG. **9**A is a default dashboard shown to a user **420**. A button a**1** allows the user to synchronize their dashboard display with the app of MCD **300**, ensuring display of the most up to date data and user settings. Pull down menus or buttons a**2** provide additional functionality such as allowing the user to display lists of alarms or notes, or request to join a specific hub or group of network users (e.g. group of patients in the same hospital). The type or location of sensor being used is selected in region a**3**. Region a**4** displays time logs of sensor data and processed data, which may be scrolled and zoomed to display different time windows using the arrow and +/− buttons. Session data may also be exported for saving locally.

[0109] FIG. **9**B shows a dashboard from which user **420** may select from a list of sessions (b**1**) to be displayed.

Sensor data and processed data from the selected session is displayed in region b**2** in a similar manner as described for region a**4** of FIG. **9**A.

[0110] FIG. **9**C shows a dashboard from which user **420** may review or edit personal data and emergency contact information. In a preferred embodiment, edits made by the user in their dashboard are automatically synchronized with the MCD app.

[0111] FIG. **9**D shows a partial default dashboard shown to a medical professional **430**, displaying all users **420** in the monitor network associated with professional **430**, and a user summary box d**1** for each associated user. Each user summary box gives lists of alarms (d**2**) and times of alarm events (d**3**) for the associated user. Alarms may be falls, abnormal events, or other conditions as discussed above. Professional **430** may navigate to an alarm viewer or a session viewer for an individual user **420**, shown in FIG. **9**E, which displays time logs associated with the selected alarm or session, similar to those displayable by the user (FIG. **9**B).

[0112] In an embodiment, the time logs associated with an alarm include 10 minutes of processed data, such as 5 minutes before and 5 minutes after the alarm event. In embodiments, time logs associated with sessions include all processed data from a recording session, such as periods of time while the user is awake, in between battery changes, the duration of a Holter mode session, a session recorded during a particular physical activity, a periodic monitoring session or similar. Recording sessions are typically of longer duration than alarm sessions, and may for example be 1, 8, 10, 12 or 24 hours in length.

[0113] Medical professionals may export alarm or session data (button e**5**) for saving locally, such as for further processing.

[0114] FIG. **9**F shows a dashboard from which user **420** may generate a report related to a particular session or alarm. Reports may contain analysis of data, related medical notes, or the like. The report may be saved and sent to other clients **420**, **430**, **440**.

[0115] A dashboard for another type of client **440**, may provide limited access to session or alarm information viewable by the user or medical professional, or may be configurable by the user to set access permissions for different types of client.

[0116] In terms of use, a method of monitoring electrophysiological signals includes: (refer to FIGS. **1**-**9**)

[0117] a. providing an electrophysiological monitoring system of any one of Embodiments 8-13;

[0118] b. transferring at least a portion of the conductive polymer pattern (**102**) to the skin of a patient;

[0119] c. adhering the electrophysiological monitor (**200**) to the skin of the patient such that one of the monitor contacts (**230**) is in electrical connection with each of the sensor contacts (**150**);

[0120] d. digitizing, by the integrated circuit (**240**) of the monitor, at least one of ECG, EEG, or EMG signals sensed by at least one of the sensor regions (**110**) of the conductive polymer pattern;

[0121] e. wirelessly transmitting, by the transceiver (**270**) of the monitor, the digitized signals to the mobile communication device (**300**);

[0122] f. processing the digitized signals with the processor (**310**) of the mobile communication device; and,

[0123] g. transmitting, by the mobile communication device, the processed signals to the monitor network (**400**).

[0124] The method further including,

[0125] in (g), continuously transmitting the processed signals to the monitor network.

[0126] The method further including,

[0127] transmitting to the monitor network, by the mobile communication device, an indicator of at least one of: cardiac arrhythmia, ECG shape abnormality, respiration rate, heart rate, blood pressure, physical activity index, or detected fall.

[0128] The method further including,

[0129] after (g), further processing transmitted processed signals by a module in communication with the monitor network.

[0130] As used in this application, the term "about" or "approximately" refers to a range of values within plus or minus 10% of the specified number. As used in this application, the term "substantially" means that the actual value is within about 10% of the actual desired value of any variable, element or limit set forth herein.

[0131] The embodiments of the device, system, and method of use described herein are exemplary and numerous modifications, combinations, variations, and rearrangements can be readily envisioned to achieve an equivalent result, all of which are intended to be embraced within the scope of the appended claims. Further, nothing in the above-provided discussions of the device, system, and method should be construed as limiting the invention to a particular embodiment or combination of embodiments. The scope of the invention is defined by the appended claims.

1. A device for sensing electrophysiological signals, the device cooperating with a signal monitor, the device comprising:

a substrate sheet having a backing sheet and a releasable coating layer formed on the backing sheet;

a conductive polymer pattern formed on the releasable coating layer, the conductive polymer pattern including a plurality of sensor regions each connected to a patterned lead having a terminus adjacent to a common contact region;

the common contact region located on a nonconductive support layer distinct from the releasable coating layer, a plurality of sensor contacts connected to the nonconductive support layer within the common contact region, each terminus of the patterned leads in electrical communication with one of the plurality of sensor contacts via a conductive lead distinct from the patterned leads, the conductive lead supported by the nonconductive support layer; and,

wherein the plurality of sensor contacts are configured for snap-fitting to the signal monitor.

2. The device of claim **1**, wherein the conductive polymer pattern and the releasable coating layer have a combined thickness of less than 1 micrometer.

3. The device of claim **1**, wherein the plurality of sensor regions consists of two, three, four, five, or six sensor regions.

4. The device of claim **1**, wherein the conductive polymer pattern is formed of poly(3,4-ethylenedioxythiophene):poly (styrenesulfonate).

5. (canceled)

6. (canceled)

7. A wireless electrophysiological monitoring system, comprising:

a conductive polymer pattern configured for transfer to the skin of a patient, the conductive polymer pattern including a plurality of sensor regions each connected to a patterned lead having a terminus adjacent to a common contact region;

the common contact region located on a nonconductive support layer, a plurality of sensor contacts connected to the nonconductive support layer within the common contact region, each of the plurality of sensor contacts being a male or female electroconductive stud, each terminus of the patterned leads in electrical communication with one of the plurality of sensor contacts via a conductive lead distinct from the patterned leads, the conductive lead supported by the nonconductive support layer;

an electrophysiological monitor having a plurality of monitor contacts located on a rear face, each of the plurality of monitor contacts being a female or male electroconductive stud complementary to one of the plurality of sensor contacts, the electrophysiological monitor configured to be positioned over the common contact region such that the rear face faces the skin of the patient and one of the plurality of monitor contacts is in direct electrical connection with each of the plurality of sensor contacts, the electrophysiological monitor further including an integrated circuit configured to digitize at least one of ECG, EEG, or EMG signals, a memory, and a transceiver configured for wireless transmission of the digitized signals; and,

a mobile communication device having a transceiver configured for wireless communication with the electrophysiological monitor and a processor configured to process the digitized signals, the mobile communication device configured to transmit the processed signals to a monitor network.

8. The wireless electrophysiological monitoring system of claim 7, wherein the plurality of sensor regions consists of two, three, four, five, or six sensor regions.

9. The wireless electrophysiological monitoring system of claim 7, wherein the electrophysiological monitor includes one or more integrated circuits and is configured to digitize ECG, EEG, and EMG signals.

10. The wireless electrophysiological monitoring system of claim 7, wherein the electrophysiological monitor includes a motion sensor.

11. The wireless electrophysiological monitoring system of claim 7, wherein the mobile communication device is configured to continuously transmit the processed signals to the monitor network.

12. The wireless electrophysiological monitoring system of claim 7, wherein the transmission of signals to the monitor network is accompanied by an indicator of at least one of: cardiac arrhythmia, ECG shape abnormality, respiration rate, heart rate, blood pressure, physical activity index, detected fall, or pre-seizure condition.

13. A method of monitoring electrophysiological signals, the method comprising:

a. providing an electrophysiological monitoring system of claim 7;

b. transferring at least a portion of the conductive polymer pattern to the skin of a patient;

c. adhering the electrophysiological monitor to the skin of the patient such that one of the monitor contacts is in electrical connection with each of the plurality of sensor contacts;

d. digitizing, by the integrated circuit of the electrophysiological monitor, at least one of ECG, EEG, or EMG signals sensed by at least one of the sensor regions of the conductive polymer pattern;

e. wirelessly transmitting, by the transceiver of the electrophysiological monitor, the digitized signals to the mobile communication device;

f. processing the digitized signals with the processor of the mobile communication device; and,

g. transmitting, by the mobile communication device, the processed signals to the monitor network.

14. The method of claim 13 further including,

in (g), continuously transmitting the processed signals to the monitor network.

15. The method of claim 13 further including,

transmitting to the monitor network, by the mobile communication device, an indicator of at least one of: cardiac arrhythmia, ECG shape abnormality, respiration rate, heart rate, blood pressure, physical activity index, detected fall, or pre-seizure condition.

16. The method of claim 13 further including,

after (g), further processing transmitted processed signals by a module in communication with the monitor network.

17. The device of claim 1, wherein each terminus of the patterned leads is in electrical communication with one of the plurality of sensor contacts via a layer of conductive polymer formed on the nonconductive support layer.

18. The device of claim 1, wherein each terminus of the patterned leads is in electrical communication with one of the plurality of sensor contacts via a wire supported on the nonconductive support layer.

19. The wireless electrophysiological monitoring system of claim 7, wherein each terminus of the patterned leads is in electrical communication with one of the plurality of sensor contacts via a layer of conductive polymer formed on the nonconductive support layer.

20. The wireless electrophysiological monitoring system of claim 7, wherein each terminus of the patterned leads is in electrical communication with one of the plurality of sensor contacts via a wire supported on the nonconductive support layer.

* * * * *

专利名称(译)	纹身生物传感器和健康监测系统		
公开(公告)号	US20190159731A1	公开(公告)日	2019-05-30
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[标]发明人	CAVALLARI PAOLO GRECO FRANCESCO FERRARI LAURA VARRIALE VINCENZO		
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IPC分类号	A61B5/00 A61B5/0408 A61B5/0492 A61B5/0478		
CPC分类号	A61B5/68335 A61B5/0006 A61B5/04085 A61B5/0492 A61B5/0478 A61B5/747 A61B5/746 A61B5/0452 A61B5/0816 A61B5/021 A61B5/1118 A61B5/1117 A61B5/4094 A61B5/0416 A61B5/6867 A61B5/688 A61B2562/04 A61B2562/125		
外部链接	Espacenet USPTO		

摘要(译)

保形纹身生物传感器装置包括由导电聚合物形成的传感器区域的图案。在实施方案中，导电聚合物可具有多达六个传感器区域。该图案电连接到接触区域，该接触区域可电连接到可穿戴信号监视器。该监视器适用于传输ECG，EEG或EMG信号。在监视系统中，监视器将信号无线地发送到移动通信设备以进行处理。移动通信设备将信号发送到监视器网络，监视器网络可以包括医务人员和护理人员。网络模块可以允许自动医疗警报，监控和进一步的信号处理。