

May 24, 2022

VIA EMAILRichard F. Martinelli
Orrick, Herrington & Sutcliffe LLP
rmartinelli@orrick.com***Re: Bardy Diagnostics, Inc. v. Vital Connect, Inc., No. 22-cv-00351-CFC (D. Del.)***

Richard:

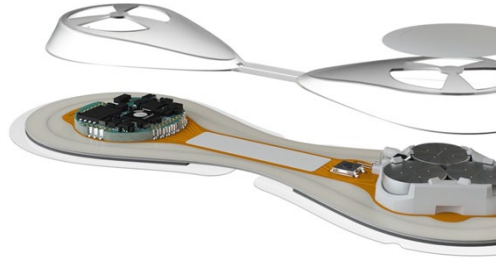
We write in response to your letter of May 2, 2022, and to follow up on our conferences of May 13 and May 23. Your letter raised an “everything but the kitchen sink” list of supposed shortcomings with Bardy’s Complaint for patent infringement against VitalConnect. None of it is well taken. In short:

- VitalConnect’s device plainly infringes Bardy’s U.S. Patent No. 11,051,743;
- The ’743 patent is valid, as the claim limitations are not indefinite, and your asserted Mazar reference is effectively identical to other Mazar art that was before by the U.S. Patent Office during the patent’s prosecution; the USPTO correctly issued the patent over that art; and
- No appellate authority holds that Bardy’s claims for post-filing willful and indirect infringement are improper, and multiple district court opinions disagree with your position.

First, it is irrelevant that VitalConnect has a patent—No. 9,277,864—predating Bardy’s ’743 patent. To the extent you contend that VitalConnect somehow is an earlier innovator than Bardy, that is false, as Bardy has many patents predating VitalConnect’s ’864 patent. Furthermore, VitalConnect chose not to practice the device disclosed in its ’864 patent, but instead practices the device claimed in Bardy’s ’743 patent. VitalConnect is free to modify its product to practice the prior art or otherwise design around the claims of the ’743 patent, including by removing the narrower midsection of the device as suggested by your letter. But as long as VitalConnect fails to do so, it is willfully infringing the ’743 patent.

Second, Bardy set out a detailed claim chart in the Complaint, which showed that the VitalPatch includes a backing comprising an elongated strip. For the avoidance of doubt,

VitalPatch has a backing—the batteries (silver circles on right of image below) are on it—and that backing comprises an elongated strip:



Your non-infringement argument is erroneous and ignores a cornerstone principle of patent law. For example, you conclude that “elongated strip” should be construed to mean a material with a 1:7.75 width-to-length ratio because a figure of the ’743 patent supposedly measures to that ratio. That construction has no legitimate basis in the intrinsic evidence. You assume that the figures are to scale, which is improper. *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005) (“arguments based on drawings not explicitly made to scale in issued patents are unavailing”).

Third, “elongated strip” is not indefinite. These are plain English words that would be understood by a person of ordinary skill in the art reviewing the patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). Further, contrary to your contention, the specification provides numerous disclosures concerning the shape. *See, e.g.*, ’743 patent at Figs. 1, 2, 4, 6, 8; 4:26–55.

Fourth, we disagree that WO 2010/104952 (“Mazar ’952 publication”) anticipates the claims of the ’743 patent. As an initial matter, a reference with identical or nearly identical disclosures as those shown in your Mazar ’952 publication claim chart—U.S. Patent No. 8,116,841, also to Mazar—was before the USPTO during the prosecution of the ’743 patent, and the USPTO nonetheless issued the patent. Having allowed the patent-in-suit over the Mazar ’841 patent, we have no reason to believe the Office would have reached a different conclusion based on the effectively identical disclosures in the Mazar ’952 publication.

Additionally, your purported invalidity chart does not and cannot show any disclosure of the “battery on one of the ends of the backing.” The Mazar ’952 publication repeatedly shows and describes the batteries (150) as “separated from” the backing (111) and “positioned over the flex printed circuit board and electronic components”—not on the backing:



Your claim chart quotes from Mazar a passing reference that “the adherent device may comprise a reusable electronics module with replaceable patches, and each of the replaceable patches may include a battery,” but this is unavailing. Indeed, the Mazar ’952 publication’s description of embodiments with “electronic modules” demonstrates that Mazar only contemplates that the battery will be separate from and off any backing. Specifically, Mazar describes the structural components of the replaceable patch utilized with the electronics module, and the battery is not on the patch. *See* Mazar ’952 publication at ¶153 (“The patch component may comprise adherent patch 110 comprising the breathable tape with adhesive coating 116A, at least one electrode, for example electrode 114A and gel 114.”) Mazar then describes the electronic module as being “*removable for recharging* and data transfer,” which a person of ordinary skill in the art would understand to mean that the battery was attached to the electronic module and not “on the backing,” as it would be physically impossible for the electronic module to be removed and recharged if the battery was on the replaceable patch. *Id.* (emphasis added). Additionally, nothing in the disclosure indicates that the battery would be on *one end* of the backing. Instead, Mazar teaches that attachments to the patch should be limited to “a central portion” of the patch. *See, e.g., id.* at ¶ 142.

Fifth, Bardy—consistent with the holdings of many courts—disagrees with your assertion that the claims for indirect and willful infringement cannot be based on knowledge provided via the Complaint. While some district courts have held that, since *Halo*, pre-suit knowledge is required for indirect and willful infringement claims, neither the Supreme Court nor the Federal Circuit have so held. *See Sonos, Inc. v. Google LLC*, No. C 21-07559 WHA, 2022 WL 799367, at *2, 6–7 (N.D. Cal. Mar. 16, 2022). Indeed, numerous decisions have held that a complaint can provide the required notice for indirect and willful infringement claims, including decisions from courts in the District of Delaware. *See, e.g., IOENGINE, LLC v. PayPal Holdings, Inc.*, No. CV 18-452-WCB, 2019 WL 330515, at *4, *8 (D. Del. Jan. 25, 2019) (Bryson, J.). Bardy is entitled to raise these issues with the Court, at minimum to preserve the issue for appeal.

Richard F. Martinelli
May 24, 2022
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Sincerely,

RILEY SAFER HOLMES & CANCELIA LLP

/s/ Louis A. Klapp

Louis A. Klapp



May 2, 2022

Via E-Mail

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Re: 1:22-cv-00351-CFC; *Bardy Diagnostics, Inc. v. Vital Connect, Inc.* (D. Del.)

Counsel:

We write to put you on notice that Bardy Diagnostics, Inc.'s ("Bardy") infringement suit against Vital Connect, Inc. ("VitalConnect") alleging infringement of U.S. Patent No. 11,051,743 (the "'743 Patent," attached as Exhibit 1) is fatally flawed and should be dismissed immediately.

First, VitalConnect's foundational wireless patch technology predates Bardy's '743 patent. Indeed, Bardy cited VitalConnect's US Patent 9,277,864 (attached as Exhibit 2) on the face of the '743 patent.¹ As such, Bardy should be fully aware that VitalConnect possessed its wireless patch technology before Bardy. Moreover, as discussed in detail below, the few distinguishing characteristics between the '743

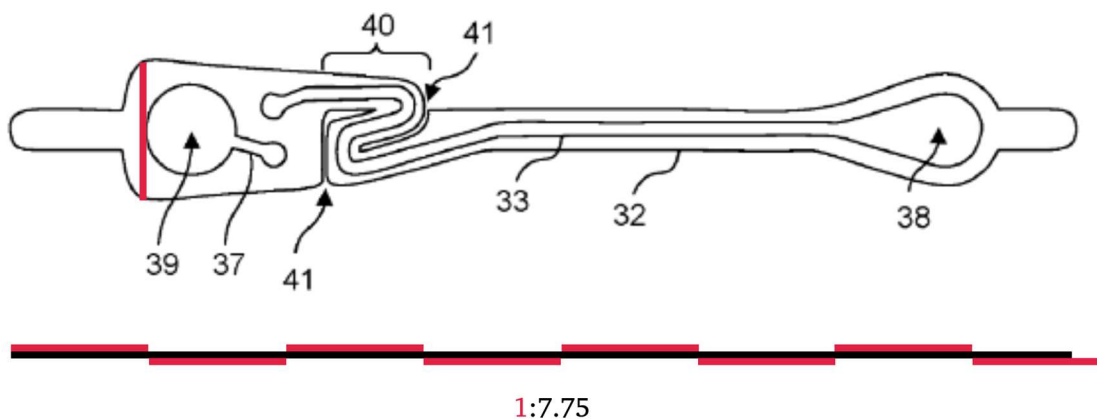
¹ Bardy's needlessly voluminous citation to hundreds of references strongly suggests Bardy was improperly trying to bury relevant prior art for whatever features of its claim it believes to be patentable, which may be inequitable conduct. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) (The court, citing MPEP § 2004, noted that "'burying' a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith."); *see also Nomadix, Inc. v. Hosp. Core Servs. LLC*, 2015 WL 3948804, at *9 (C.D. Cal. June 29, 2015); *SynQor, Inc. v. Cisco Sys., Inc.*, 2012 WL 12892779, at *4-6 (E.D. Tex. Aug. 7, 2012), *report and recommendation adopted*, 2012 WL 3984865 (E.D. Tex. Sept. 11, 2012).

patent and VitalConnect's prior art technology are trivial unpatentable details. For example, the '743 patent claims require that the patch's "mid-section is narrower." But during prosecution the Examiner expressly held:

the present claims are directed to obvious features incorporated in the electrocardiography patch device....The skilled artisan would recognize narrowing a mid-section between the two ends of the backing obviously reduces weight by eliminating un-necessary material. Likewise, it is obvious to provide an accelerometer to measure movement and a hydrocolloid adhesive to attach the device to a patient.

Jan. 25, 2021, Non-Final Rejection at p. 3 (attached as Exhibit 3). Of course, the Examiner's view on this point is completely correct and Bardy found no fault with it in its subsequent responses.

Second, the claim chart accompanying Bardy's Complaint fails to plausibly allege or demonstrate infringement. Bardy's chart does not apply the '743 patent's asserted claims to the accused product. Rather, the chart consists only of screenshots without explanation of how the VitalPatch 2.0 allegedly corresponds to any of the claim limitations. For example, it is unclear what Bardy contends is the claimed "backing comprising an elongated strip." Bardy's chart fails to identify the claimed backing in the VitalPatch because the Vital Patch *lacks* a backing that comprises an elongated strip and, therefore, does not infringe. A "strip" is a "**long narrow** piece of material."² The narrowness of the claimed strip is further emphasized by the inclusion of the adjective "elongated" modifying strip. "Elongated," means "stretched out"³ and, thus, the claimed "elongated strip" must have proportions that are even narrower than shapes that might otherwise be called a "strip." As shown below, the "elongated strip" disclosed in the '743 patent is very thin and narrow, having a general proportion of **1 unit** of width to 7.75 units of length.



² <https://www.merriam-webster.com/dictionary/strip>.

³ <https://www.merriam-webster.com/dictionary/elongated>.

In contrast, while it is unclear what Bardy contends the backing is, the overall proportions of the VitalPatch are blockier, with merely 1 unit of width to 3 units of length. This blocky shape is inconsistent with the disclosed and claimed, “elongated strip,” to the extent that term can be understood at all.



But these deficiencies in Bardy’s infringement allegations demonstrate another serious flaw with the ’743 patent. The “elongated strip” limitation is indefinite and the claims of the ’743 patent are invalid as a result. As shown above, the VitalPatch does not correspond to the “elongated strip” disclosed in the ’743 patent. And, beyond the one example in the specification, the ’743 patent provides no basis for a person of skill in the art to determine the bounds of what constitutes an “elongated strip” or a “strip” for that matter. If Bardy contends the VitalPatch comprises a backing that is an elongated strip, it must identify the backing and what makes it an *elongated* strip. And how can a person of skill in the art know whether the structure they are building is or is not an elongated strip? The answer to this question would only be valid if it finds support in the specification. But the specification of the ’743 patent provides no objective basis to determine whether a backing is an elongated strip, a strip, or neither. As such, the ’743 patent fails to provide notice to the public of the scope of the claimed “elongated strip” and the claims of the patent are invalid as indefinite. See, *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014).

Third, the ’743 patent is invalid as anticipated or obvious over numerous pieces of prior art. As just one example, Int’l Publ. No. WO 2010/104952 to Mazar et al. (hereinafter “Mazar”), published September 16, 2010, discloses a “body-worn health monitoring device.” The Mazar patch “comprises two electrodes...to measure the electrocardiogram (ECG) of the patient.” *Id.* at ¶ 98. As shown in Fig. 1F1, below, Mazar discloses a patch in the same hourglass shape, with rounded outer edges, as the allegedly infringing VitalPatch. *Id.* at ¶ 93. As shown in Fig. 1B, the electrodes 112A and 112D are on each end of the patch and exposed on the contact surface of patch with a hydrocolloid adhesive to capture electrocardiograph signals. *Id.* at ¶¶ 98, 127.

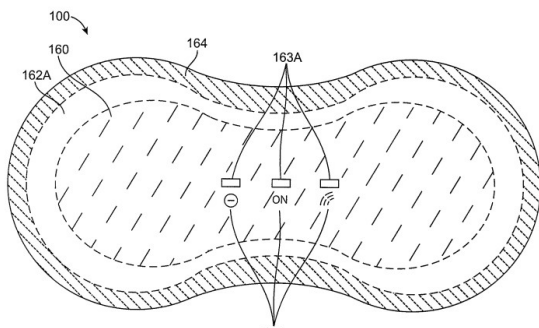


FIG. 1F1

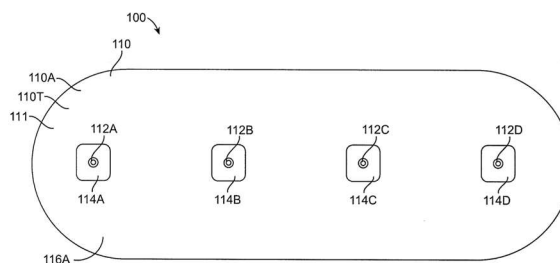


FIG. 1B

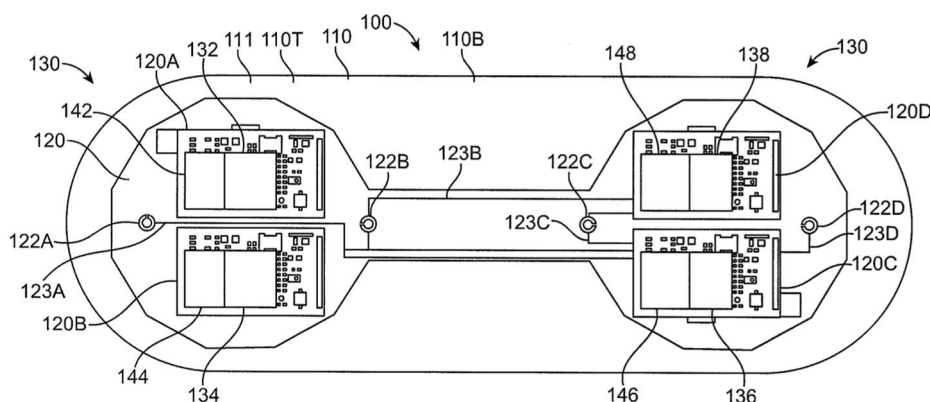


FIG. 1D

The Mazar patch further comprises a “flex printed circuit board” with traces connecting electrodes 112A and 112D. *Id.* at ¶100 and Fig. 1D. And the electrical components 130 of the Mazar patch, include a processor “configured to control a collection and transmission of data from the ... electrocardiogram circuitry” and “comprise wireless communication circuitry 132.” *Id.* at ¶¶ 104-05. The Mazar patch further comprises a “memory for storing the physiological signals” (¶¶ 48, 104), a processor 146 (¶ 104), a battery 150 on one end of the backing (¶ 113), an accelerometer (¶ 107), a temperature sensor (¶ 102). Furthermore, the signals recorded by the patch are processed, reformatted and sent to another computer. See, ¶214 *et seq.* The anticipation of every claim of the '743 patent by Mazar is further demonstrated in the attached claim chart, Exhibit 4. Note, this is simply one of a number of similar references that cover the features claimed by the '743 patent.

Fourth, Bardy’s allegations of indirect infringement and claim of willfulness-based enhanced damages also warrant immediate dismissal. VitalConnect’s lack of pre-suit knowledge precludes any finding of indirect infringement or willfulness-based enhancement of damages.

Liability under § 271(b) “requires knowledge that the induced acts constitute patent infringement.” *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011). Therefore, to support Bardy’s pre-suit claims of induced infringement, Bardy is required to allege and show that “the defendant’s conduct occurred after the defendant (1) knew of the existence of the asserted patent and (2) knew that a third



party's acts constituted infringement of the patent." *ZapFraud, Inc. v. Barracuda Networks, Inc.*, 528 F. Supp. 3d 247, 249 (D. Del. 2021). Bardy's allegations fail as Bardy openly acknowledges that VitalConnect's knowledge of the '743 Patent was only as of "the filing and service of this Complaint." Complaint, ¶¶ 17, 26.

Bardy's post-filing allegations of indirect infringement and claim of willfulness-based enhanced damages are also improper. The District of Delaware and Judge Connolly, specifically, have repeatedly held that "the complaint itself cannot be the source of the knowledge required to sustain claims of induced infringement and willfulness-based enhanced damages." *ZapFraud, Inc.*, 528 F. Supp. 3d at 250; *citing VLSI Tech. LLC v. Intel Corp.*, 2019 WL 1349468, at *2 (D. Del. Mar. 26, 2019) (dismissing willfulness-based enhanced damages claim where the plaintiff had alleged that the defendant gained "knowledge of the [patent] at least since the filing of this complaint"); *Dynamic Data Techs., LLC v. Brightcove Inc.*, 2020 WL 4192613, at *3 (D. Del. July 21, 2020) (dismissing induced infringement claims where the plaintiff had alleged that the defendant became "aware that its accused products allegedly infringe as of the filing of the Complaint").

Judge Connolly has emphasized that "[t]he limited authority vested in our courts by the Constitution and the limited resources made available to our courts by Congress counsel against encouraging plaintiffs to create claims by filing claims. It seems to me neither wise nor consistent with principles of judicial economy to allow court dockets to serve as notice boards for future legal claims for indirect infringement and enhanced damages.... [I]n the absence of binding authority to the contrary from the Federal Circuit and Supreme Court, I will adopt the rule that the operative complaint in a lawsuit fails to state a claim for indirect patent infringement where the defendant's alleged knowledge of the asserted patents is based solely on the content of that complaint or a prior version of the complaint filed in the same lawsuit. And I conclude that the operative complaint in a lawsuit fails to state a claim for willfulness-based enhanced damages under § 284 where the defendant's alleged knowledge of the asserted patents is based solely on the content of that complaint or a prior version of the complaint filed in the same lawsuit." *ZapFraud, Inc.*, 528 F. Supp. 3d at 251-252 (emphasis added).

Thus, in light of the numerous failings and improprieties⁴ of Bardy's allegations, there is no way for Bardy to maintain a good faith and nonfrivolous claim of infringement against VitalConnect. Given this, we demand that Bardy immediately dismiss its claims against Vital Connect, Inc. in Case No. 1:22-cv-00351-CFC (D. Del.).

Should Bardy not immediately dismiss these claims, this letter provides a detailed explanation of why continued assertion of this case is exceptional and warrants sanctions under 35 U.S.C. § 285. And VitalConnect will move to dismiss the Complaint with prejudice and reserves its right to seek all available remedies.

⁴ The '743 patent is invalid, infringement is not plausibly pled, and the Court has repeatedly rejected indirect infringement and willfulness-based enhanced damages claims as asserted here.

Michael H. Fleck
May 2, 2022
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Therefore, if Bardy intends to maintain is case, VitalConnect demands a meet and confer early this week to discuss Bardy's alleged bases for maintaining the claims and VitalConnect's motion to dismiss.

The matters described above are merely exemplary and made without waiver of the additional defenses and claims VitalConnect may make in this action.

Sincerely,

/s/ Richard F. Martinelli

Richard F. Martinelli

cc: Michael Wolf, Esq.
Peter Van Haur

EXHIBIT 1

Re: 1:22-cv-00351-CFC; *Bardy
Diagnostics, Inc. v. Vital Connect, Inc.*
(D. Del.)



US011051743B2

(12) **United States Patent**
Felix et al.

(10) **Patent No.:** **US 11,051,743 B2**

(45) **Date of Patent:** ***Jul. 6, 2021**

(54) **ELECTROCARDIOGRAPHY PATCH**

(71) Applicant: **Bardy Diagnostics, Inc.**, Seattle, WA (US)

(72) Inventors: **Jason Felix**, Vashon Island, WA (US);
Jon Mikalson Bishay, Seattle, WA (US); **Gust H. Bardy**, Carnation, WA (US)

(73) Assignee: **Bardy Diagnostics, Inc.**, Bellevue, WA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **17/119,945**

(22) Filed: **Dec. 11, 2020**

(65) **Prior Publication Data**

US 2021/0093219 A1 Apr. 1, 2021

Related U.S. Application Data

(63) Continuation of application No. 16/241,929, filed on Jan. 7, 2019, now Pat. No. 10,888,239, which is a (Continued)

(51) **Int. Cl.**
A61B 5/335 (2021.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61B 5/335** (2021.01); **A61B 5/0006** (2013.01); **A61B 5/0022** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC A61B 5/335; A61B 5/259; A61B 5/0006;
A61B 5/82; A61B 5/0022; A61B 5/02055;

(Continued)

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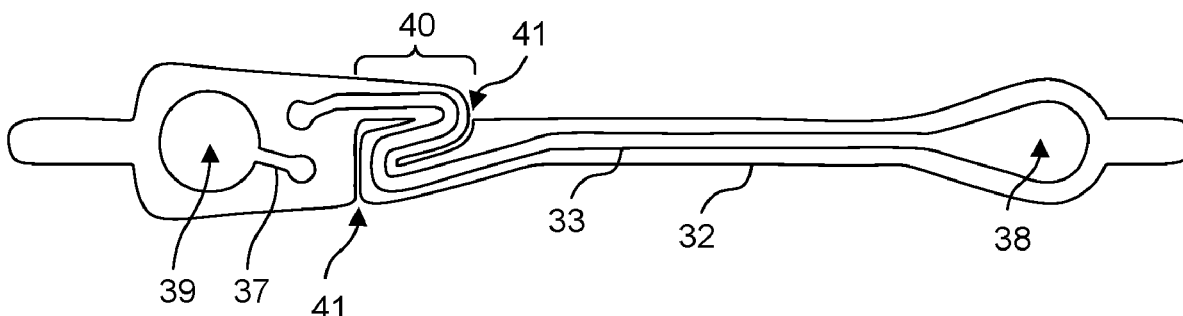
Primary Examiner — George Manuel

(74) *Attorney, Agent, or Firm* — Krista A. Wittman

(57) **ABSTRACT**

An electrocardiography patch is provided. A backing forms an elongated strip with a mid-section connecting two ends of the backing. The mid-section is narrower than the two ends of the backing. An electrocardiographic electrode is provided on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals.

20 Claims, 8 Drawing Sheets



Related U.S. Application Data

continuation of application No. 15/818,437, filed on Nov. 20, 2017, now Pat. No. 10,172,534, which is a continuation of application No. 15/256,266, filed on Sep. 2, 2016, now Pat. No. 9,820,665, which is a continuation of application No. 14/082,071, filed on Nov. 15, 2013, now Pat. No. 9,433,367, which is a continuation-in-part of application No. 14/080,717, filed on Nov. 14, 2013, now Pat. No. 9,545,204, and a continuation-in-part of application No. 14/080,725, filed on Nov. 14, 2013, now Pat. No. 9,730,593.

- (60) Provisional application No. 61/882,403, filed on Sep. 25, 2013.

(51) Int. Cl.

A61B 5/145 (2006.01)
G16H 40/67 (2018.01)
A61B 5/0205 (2006.01)
A61B 5/259 (2021.01)
A61B 5/282 (2021.01)
A61B 5/1455 (2006.01)
A61B 5/021 (2006.01)
A61B 5/03 (2006.01)
A61B 5/08 (2006.01)
A61B 5/11 (2006.01)
A61B 5/087 (2006.01)
A61B 5/349 (2021.01)

(52) U.S. Cl.

CPC *A61B 5/02055* (2013.01); *A61B 5/14532* (2013.01); *A61B 5/14542* (2013.01); *A61B 5/259* (2021.01); *A61B 5/282* (2021.01); *A61B 5/6823* (2013.01); *A61B 5/6833* (2013.01); *A61B 5/7405* (2013.01); *A61B 5/7455* (2013.01); *A61B 5/7475* (2013.01); *G16H 40/67* (2018.01); *A61B 5/021* (2013.01); *A61B 5/03* (2013.01); *A61B 5/087* (2013.01); *A61B 5/0816* (2013.01); *A61B 5/1118* (2013.01); *A61B 5/14551* (2013.01); *A61B 5/349* (2021.01); *A61B 2560/0214* (2013.01); *A61B 2560/0443* (2013.01)

(58) Field of Classification Search

CPC *A61B 5/14532*; *A61B 5/14542*; *A61B 5/6823*; *A61B 5/6833*; *A61B 5/7405*; *A61B 5/7455*; *A61B 5/349*; *A61B 5/021*; *A61B 5/03*; *A61B 5/0816*; *A61B 5/1118*; *A61B 5/14551*; *A61B 2560/0214*; *A61B 2560/0443*; *A61N 5/7475*; *G16H 40/67*; *G16H 40/63*

See application file for complete search history.

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Fig. 1.

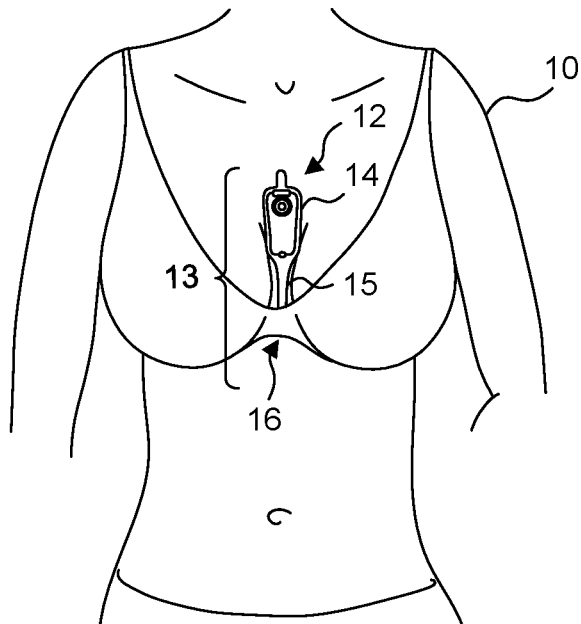


Fig. 2.

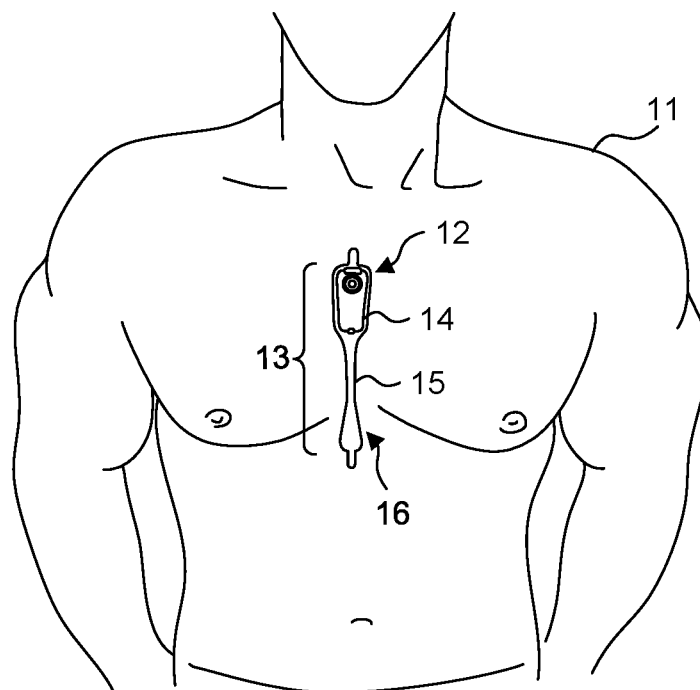


Fig. 3.

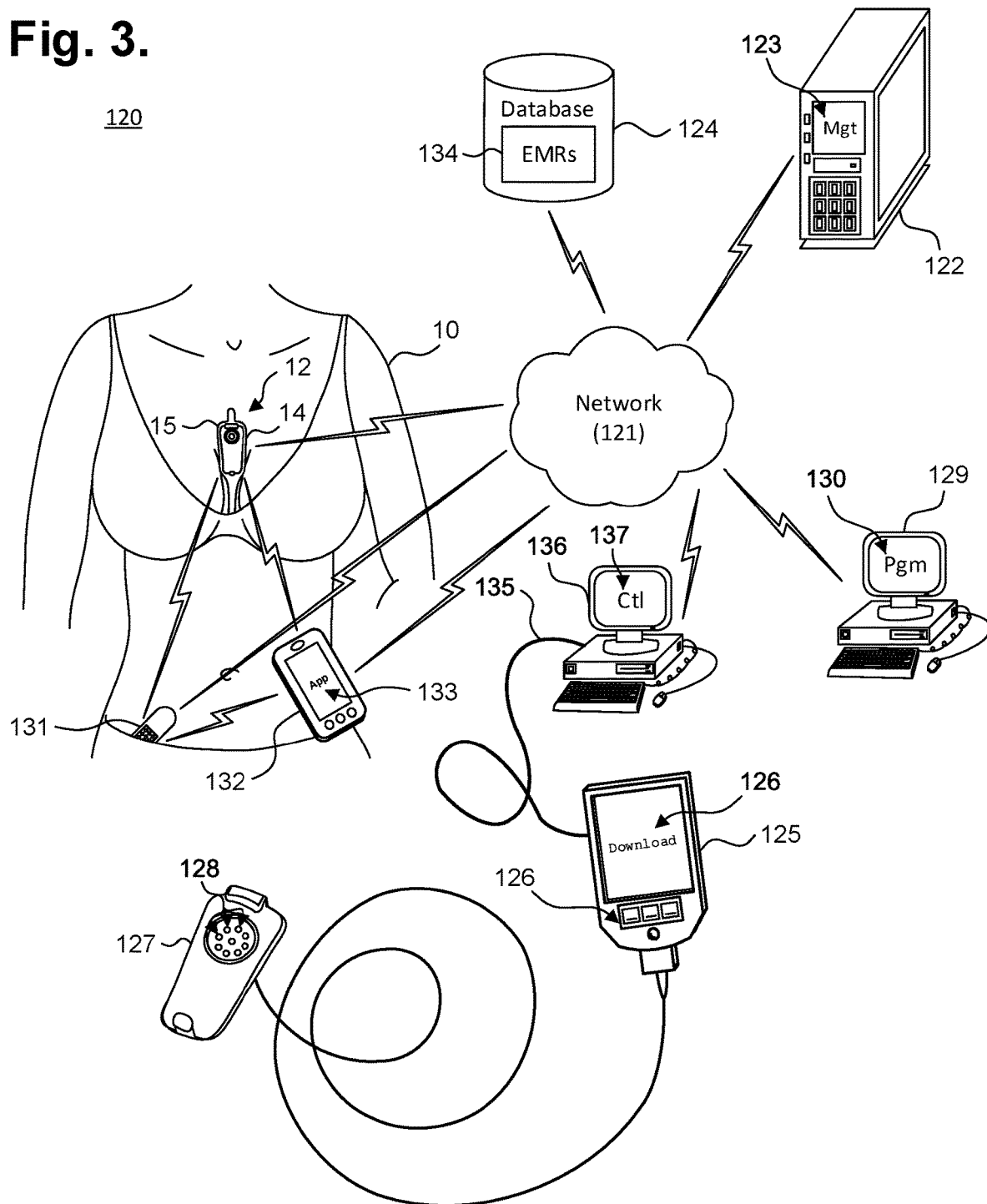


Fig. 4.

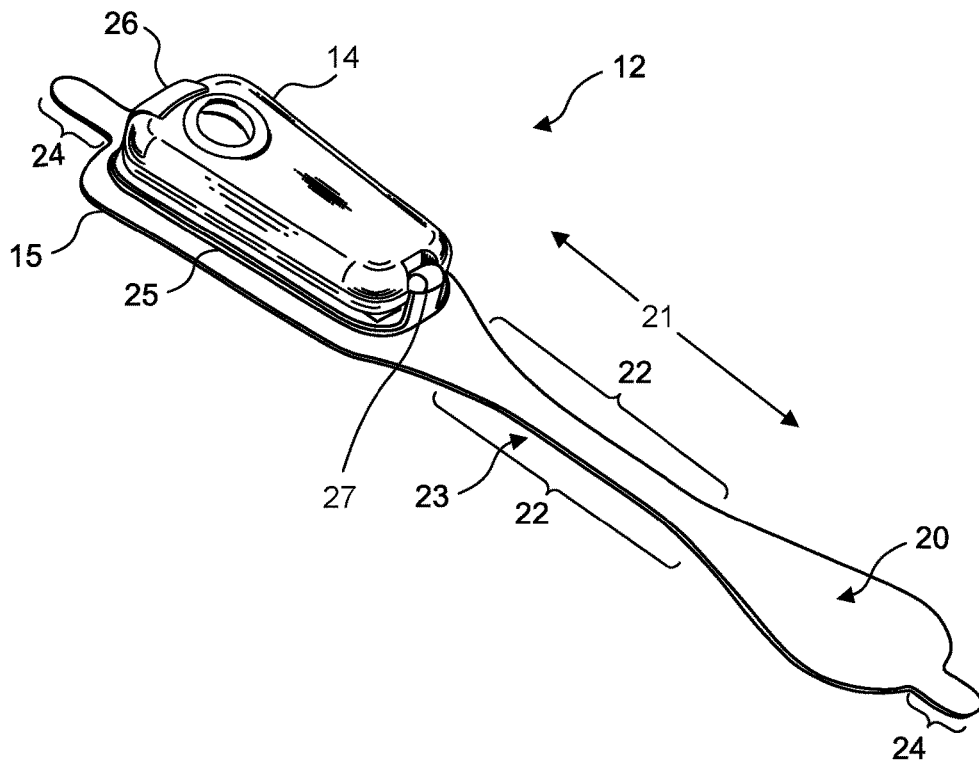


Fig. 5.

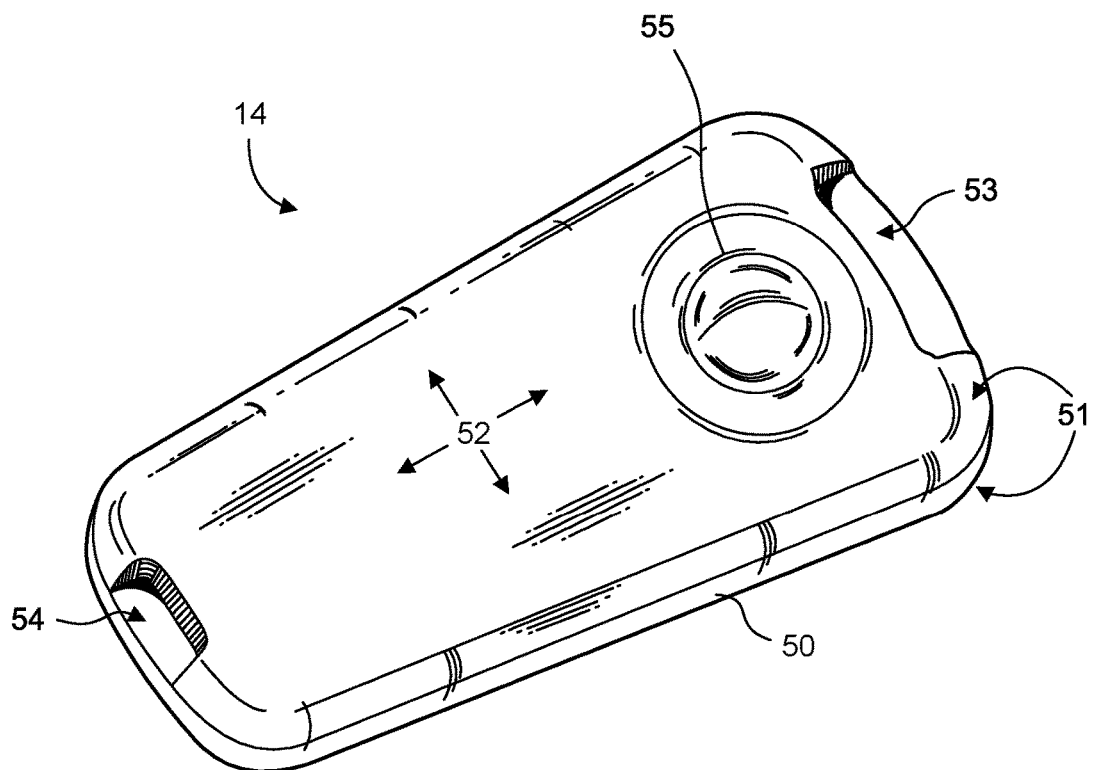


Fig. 6.

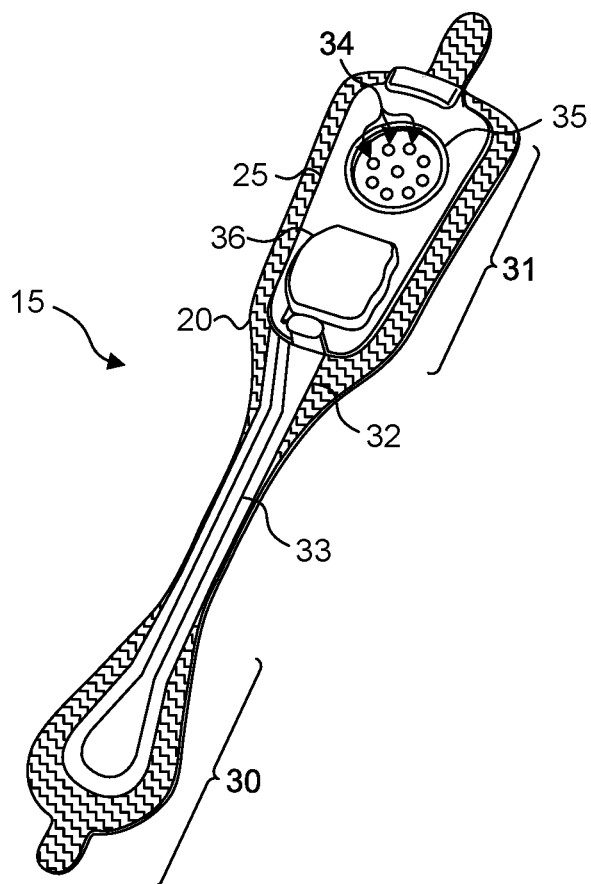


Fig. 7.

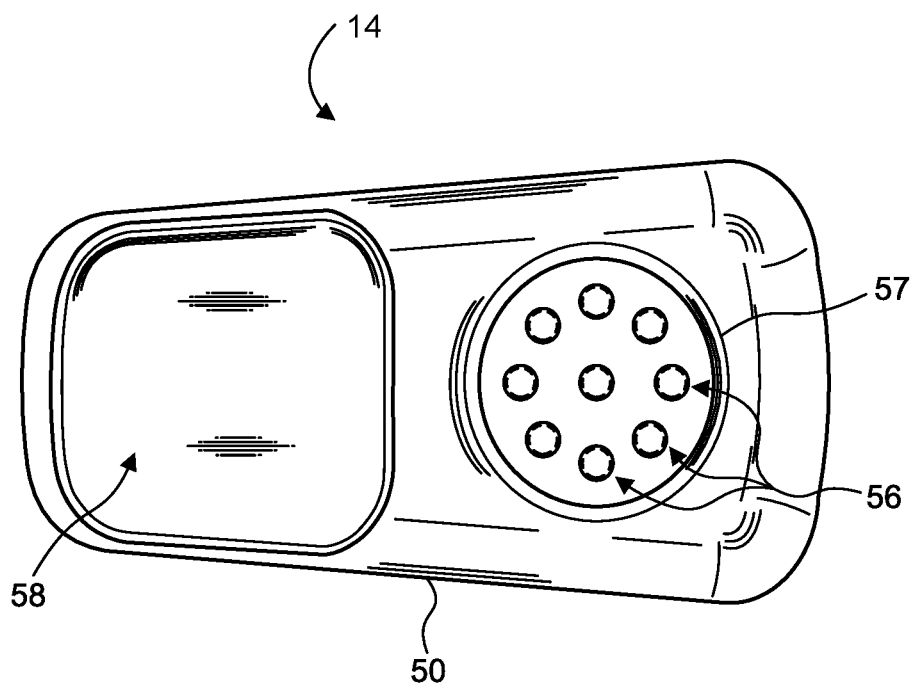


Fig. 8.

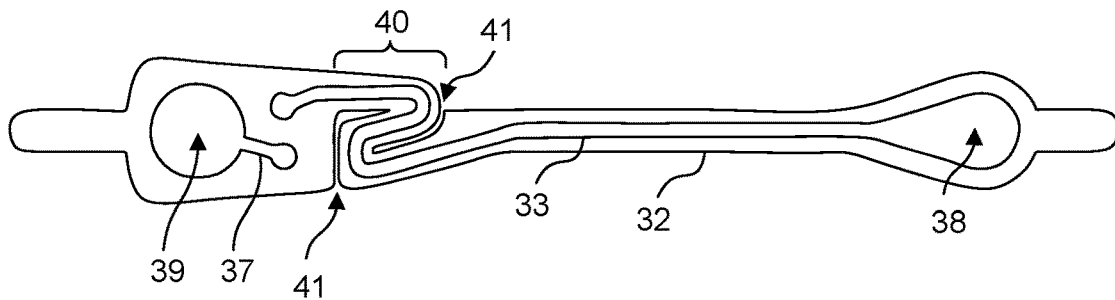


Fig. 9.

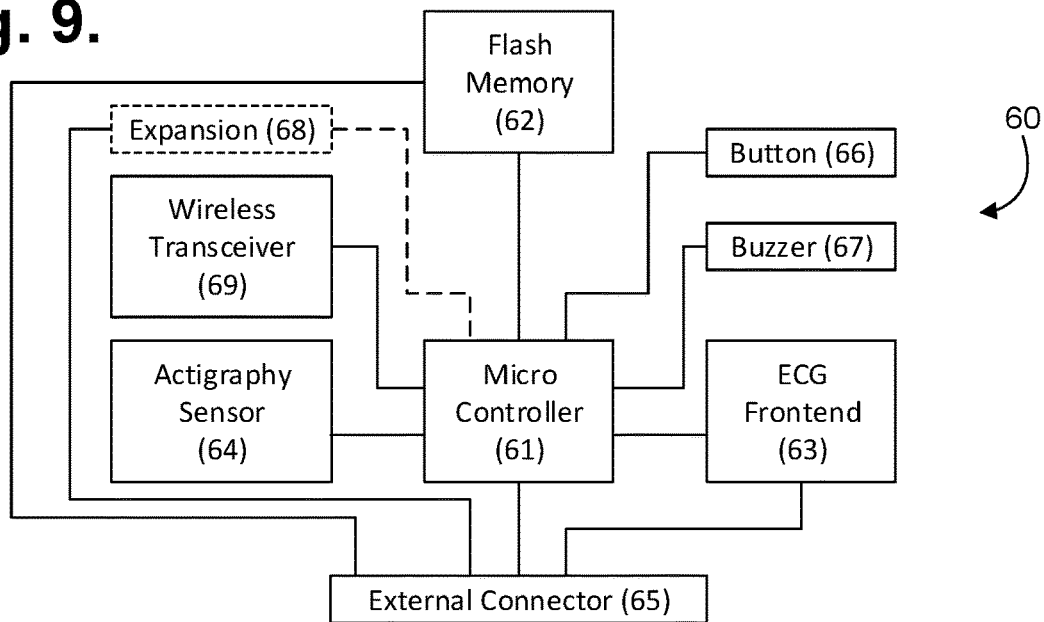


Fig. 10.

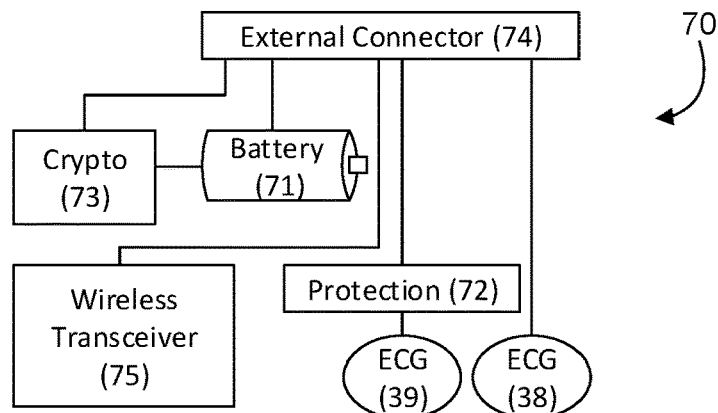


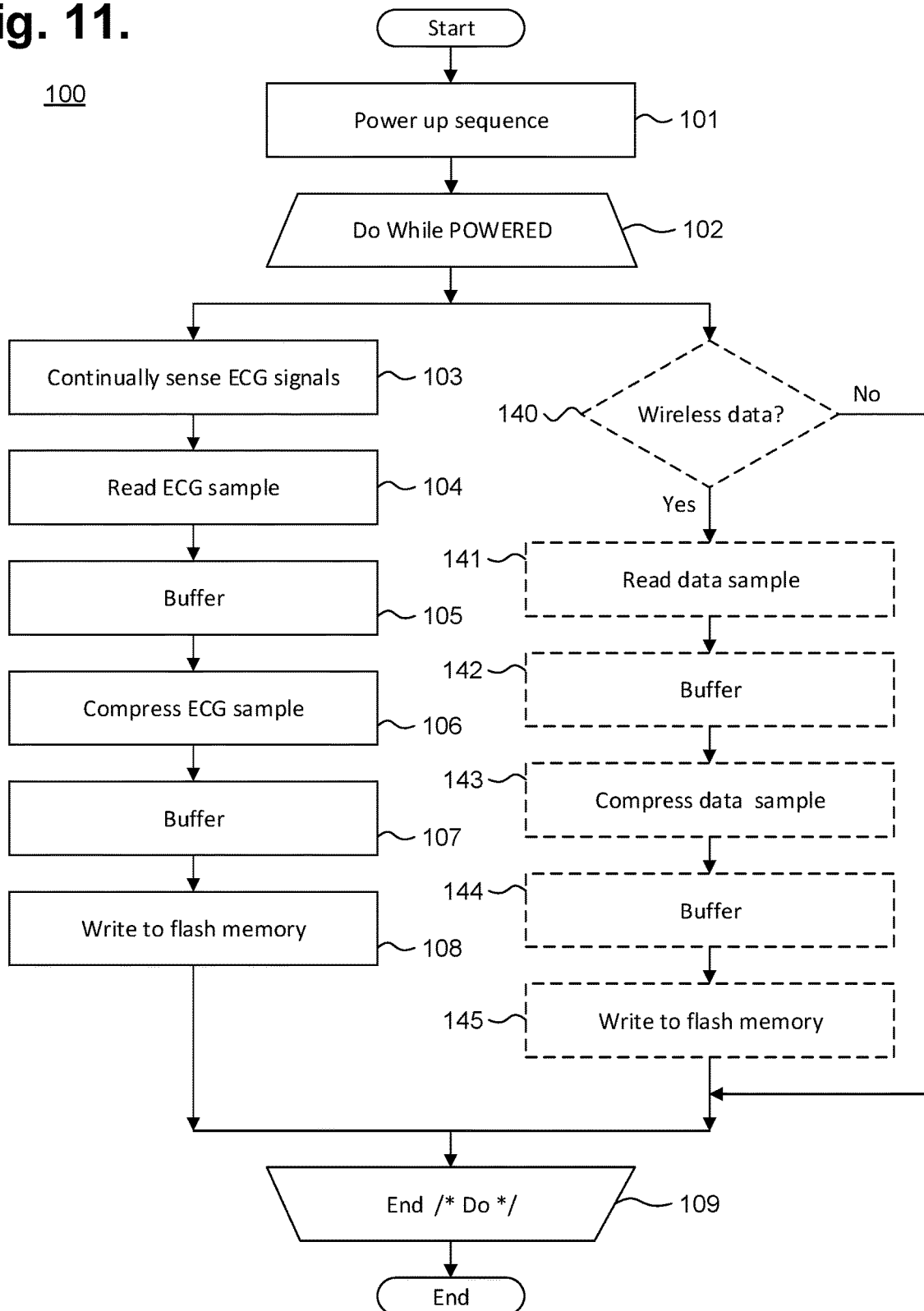
Fig. 11.

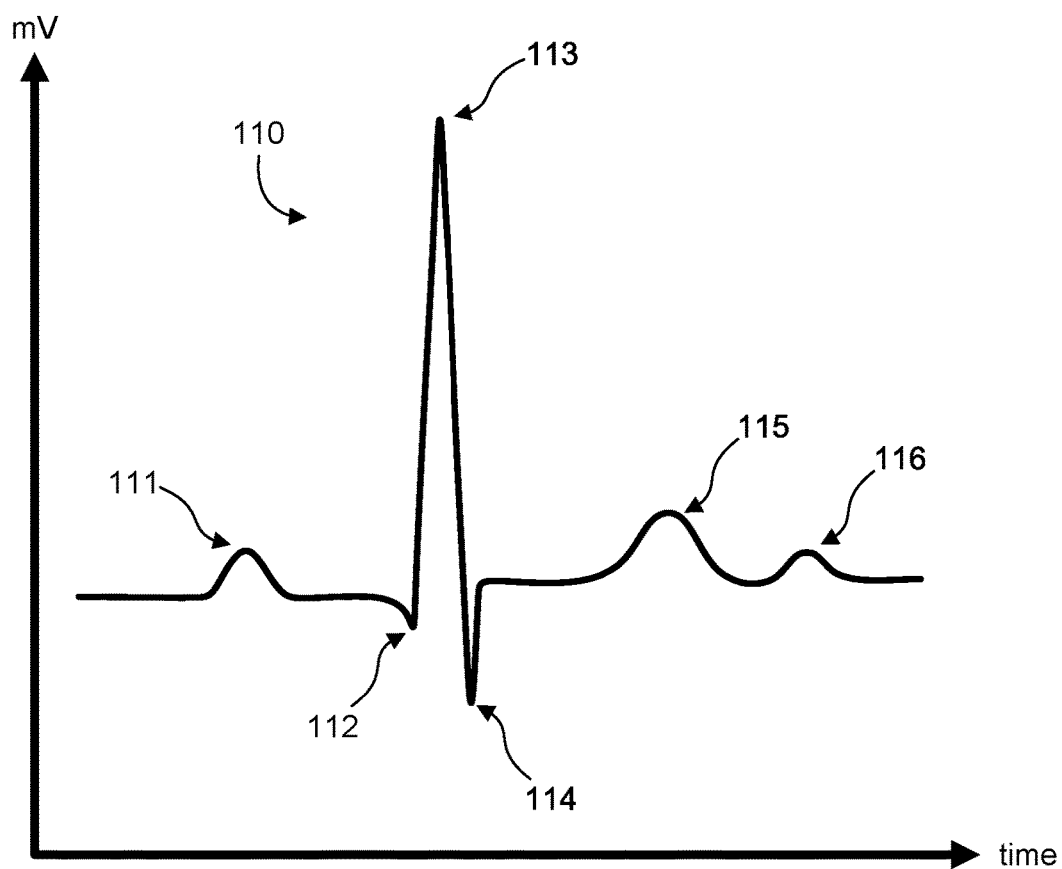
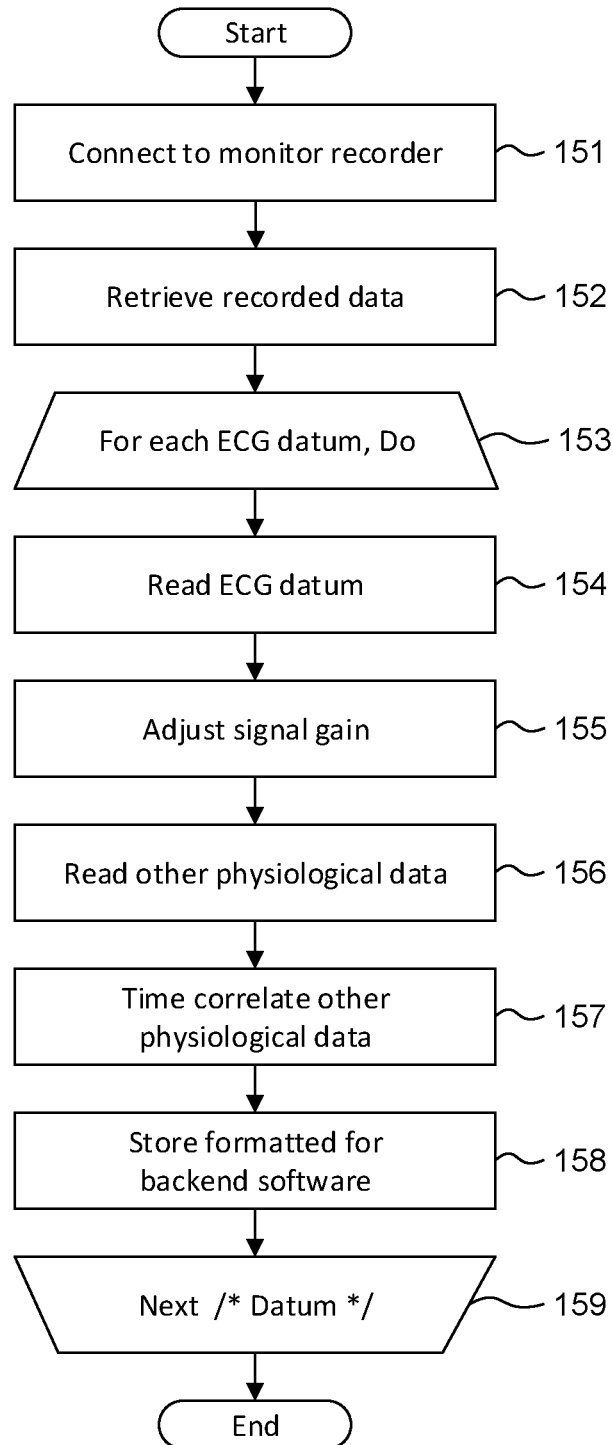
Fig. 12.

Fig. 13.150

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ELECTROCARDIOGRAPHY PATCH**CROSS-REFERENCE TO RELATED APPLICATIONS**

This non-provisional patent application is a continuation of U.S. Pat. No. 10,888,239, issued Jan. 12, 2021, which is a continuation of U.S. Pat. No. 10,172,534, issued Jan. 8, 2019, which is a continuation of U.S. Pat. No. 9,820,665, issued Nov. 21, 2017, which is a continuation of U.S. Pat. No. 9,433,367, issued Sep. 6, 2016, which is a continuation-in-part of U.S. Pat. No. 9,545,204, issued Jan. 17, 2017 and a continuation-in-part of U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, and further claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent application, Ser. No. 61/882,403, filed Sep. 25, 2013, the disclosures of which are incorporated by reference.

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to an electrocardiography patch.

BACKGROUND

The heart emits electrical signals as a by-product of the propagation of the action potentials that trigger depolarization of heart fibers. An electrocardiogram (ECG) measures and records such electrical potentials to visually depict the electrical activity of the heart over time. Conventionally, a standardized set format 12-lead configuration is used by an ECG machine to record cardiac electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs. Sensed cardiac electrical activity is represented by PQRSTU waveforms that can be interpreted post-ECG recording to derive heart rate and physiology. The P-wave represents atrial electrical activity. The QRS components represent ventricular electrical activity.

An ECG is a tool used by physicians to diagnose heart problems and other potential health concerns. An ECG is a snapshot of heart function, typically recorded over 12 seconds, that can help diagnose rate and regularity of heartbeats, effect of drugs or cardiac devices, including pacemakers and implantable cardioverter-defibrillators (ICDs), and whether a patient has heart disease. ECGs are used in-clinic during appointments, and, as a result, are limited to recording only those heart-related aspects present at the time of recording. Sporadic conditions that may not show up during a spot ECG recording require other means to diagnose them. These disorders include fainting or syncope; rhythm disorders, such as tachyarrhythmias and bradyarrhythmias; apneic episodes; and other cardiac and related disorders. Thus, an ECG only provides a partial picture and can be insufficient for complete patient diagnosis of many cardiac disorders.

Diagnostic efficacy can be improved, when appropriate, through the use of long-term extended ECG monitoring. Recording sufficient ECG and related physiology over an extended period is challenging, and often essential to enabling a physician to identify events of potential concern. A 30-day observation period is considered the "gold standard" of ECG monitoring, yet achieving a 30-day observation day period has proven unworkable because such ECG

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monitoring systems are arduous to employ, cumbersome to the patient, and excessively costly. Ambulatory monitoring in-clinic is implausible and impracticable. Nevertheless, if a patient's ECG could be recorded in an ambulatory setting, thereby allowing the patient to engage in activities of daily living, the chances of acquiring meaningful information and capturing an abnormal event while the patient is engaged in normal activities becomes more likely to be achieved.

For instance, the long-term wear of ECG electrodes is complicated by skin irritation and the inability ECG electrodes to maintain continual skin contact after a day or two. Moreover, time, dirt, moisture, and other environmental contaminants, as well as perspiration, skin oil, and dead skin cells from the patient's body, can get between an ECG electrode, the non-conductive adhesive used to adhere the ECG electrode, and the skin's surface. All of these factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

Conventionally, Holter monitors are widely used for long-term extended ECG monitoring. Typically, they are used for only 24-48 hours. A typical Holter monitor is a wearable and portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The cable and electrode combination (or leads) are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine. The duration of a Holter monitoring recording depends on the sensing and storage capabilities of the monitor, as well as battery life. A "looping" Holter monitor (or event) can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usability. Further, the skill required to properly place the electrodes on the patient's chest hinders or precludes a patient from replacing or removing the precordial leads and usually involves moving the patient from the physician office to a specialized center within the hospital or clinic.

The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, Calif., are wearable stick-on monitoring devices that are typically worn on the upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day monitoring period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch

device combines both electronic recordation components, including battery, and physical electrodes into a unitary assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period of time and to resist disadherence from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. Moreover, throughout monitoring, the battery is continually depleted and battery capacity can potentially limit overall monitoring duration. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring, especially with respect to ease of long term use, female-friendly fit, and quality of atrial (P-wave) signals.

In addition, with the advent of wireless communications and wearable computing, other types of personal ambulatory monitors, of varying degrees of sophistication, have become increasingly available. For example, adherents to the so-called "Quantified Self" movement combine wearable sensors and wearable computing to self-track activities of their daily lives, including inputs, states, and performance. The Nike+ FuelBand, manufactured by Nike Inc., Beaverton, Oreg., for instance, provides an activity tracker that is worn on the wrist and allows the wearer to temporally track the number of foot steps taken each day and an estimation of the calories burned. The activity tracker can interface with a smart phone device to allow a wearer to monitor their progress towards a fitness goal. Such quantified physiology, however, is typically tracked for only the personal use of the wearer and is not time-correlated to physician-supervised monitoring.

Therefore, a need remains for an extended wear continuously recording ECG monitor practicably capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.

A further need remains for facilities to integrate wider-ranging physiological and "life tracking"-type data into long-term ECG and physiological data monitoring.

SUMMARY

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch anywhere within the general region of the sternum, the area most likely to record high quality atrial signals or P-waves. The wearable monitor can also interoperate wirelessly with other wearable physiology and activity sensors and with wearable or mobile communications devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The monitor recorder can also be equipped with a wireless transceiver to either provide data or other information to, or receive data or other information from, an interfacing wearable physiology and activity sen-

sor, or wearable or mobile communications devices for relay to a further device, such as a server, analysis, or other purpose.

One embodiment provides a remotely-interfaceable electrocardiography patch. The remotely-interfaceable electrocardiography patch includes a backing formed of a strip of material and an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least one of the electrocardiographic signals and other physiological measures with one or more of a physiology and activity sensor, communication device, server, and personal computer.

A further embodiment provides an electrocardiography patch. A backing forms an elongated strip with a mid-section connecting two ends of the backing. The mid-section is narrower than the two ends of the backing. An electrocardiographic electrode is provided on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals.

A still further embodiment provides an electrocardiography monitor. A backing forms an elongated strip with a mid-section connecting two ends of the backing. The mid-section is narrower than the two ends of the backing. An electrocardiographic electrode is provided on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals. A battery is positioned on one of the ends of the backing and a processor is powered by the battery. A memory is electrically interfaced with the processor and operable to store samples of the electrocardiographic signals.

The monitoring patch is especially suited to the female anatomy. The narrow longitudinal midsection can fit nicely within the intermammary cleft of the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhered between the breasts, would cause chafing, irritation, frustration, and annoyance, leading to low patient compliance.

The foregoing aspects enhance ECG monitoring performance and quality, facilitating long-term ECG recording, critical to accurate arrhythmia diagnosis.

In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best location possible for optimizing the recording of cardiac signals from the atrium, another feature critical to proper arrhythmia diagnosis.

Finally, the foregoing aspects as relevant to monitoring are equally applicable to recording other physiological measures, such as temperature, respiratory rate, blood sugar, oxygen saturation, and blood pressure, as well as other measures of body chemistry and physiology.

Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their

spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor respectively fitted to the sternal region of a female patient and a male patient.

FIG. 3 is a functional block diagram showing a system for remote interfacing of an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

FIG. 4 is a perspective view showing an extended wear electrode patch with a monitor recorder inserted.

FIG. 5 is a perspective view showing the monitor recorder of FIG. 4.

FIG. 6 is a perspective view showing the extended wear electrode patch of FIG. 4 without a monitor recorder inserted.

FIG. 7 is a bottom plan view of the monitor recorder of FIG. 4.

FIG. 8 is a top view showing the flexible circuit of the extended wear electrode patch of FIG. 4 when mounted above the flexible backing.

FIG. 9 is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. 4.

FIG. 10 is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. 4.

FIG. 11 is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. 4.

FIG. 12 is a graph showing, by way of example, a typical ECG waveform.

FIG. 13 is a flow diagram showing a method for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

DETAILED DESCRIPTION

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGS. 1 and 2 are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor 12, including a monitor recorder 14 in accordance with one embodiment, respectively fitted to the sternal region of a female patient 10 and a male patient 11. The wearable monitor 12 sits centrally (in the midline) on the patient's chest along the sternum 13 oriented top-to-bottom with the monitor recorder 14 preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor 12 can be corrected post-monitoring, as further described infra. The electrode patch 15 is shaped to fit comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline 16 (or immediately to either side of the sternum 13). The distal end of the electrode patch 15 extends towards the Xiphoid process and, depending upon the patient's build, may straddle the region over the Xiphoid process. The proximal end of the electrode patch 15, located under the monitor recorder 14, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

The placement of the wearable monitor 12 in a location at the sternal midline 16 (or immediately to either side of the sternum 13) significantly improves the ability of the wearable monitor 12 to cutaneously sense cardiac electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals in the ECG waveforms that indicate ventricular activity, while simultaneously facilitating comfortable long-term wear for many weeks. The sternum 13 overlies the right atrium of the heart and the placement of the wearable monitor 12 in the region of the sternal midline 13 puts the ECG electrodes of the electrode patch 15 in a location better adapted to sensing and recording P-wave signals than other placement locations, say, the upper left pectoral region or lateral thoracic region or the limb leads. In addition, placing the lower or inferior pole (ECG electrode) of the electrode patch 15 over (or near) the Xiphoid process facilitates sensing of ventricular activity and provides superior recordation of the QRS interval.

When operated standalone, the monitor recorder 14 of the extended wear electrocardiography and physiological sensor monitor 12 senses and records the patient's ECG data into an onboard memory. In addition, the wearable monitor 12 can interoperate with other devices. FIG. 3 is a functional block diagram showing a system 120 for remote interfacing of an extended wear electrocardiography and physiological sensor monitor 12 in accordance with one embodiment. The monitor recorder 14 is a reusable component that can be fitted during patient monitoring into a non-conductive receptacle provided on the electrode patch 15, as further described infra with reference to FIG. 4, and later removed for offloading of stored ECG data or to receive revised programming. The monitor recorder 14 can then be connected to a download station 125, which could be a programmer or other device that permits the retrieval of stored ECG monitoring data, execution of diagnostics on or programming of the monitor recorder 14, or performance of other functions. The monitor recorder 14 has a set of electrical contacts (not shown) that enable the monitor recorder 14 to physically interface to a set of terminals 128 on a paired receptacle 127 of the download station 125. In turn, the download station 125 executes a communications or offload program 126 ("Off-load") or similar program that interacts with the monitor recorder 14 via the physical interface to retrieve the stored ECG monitoring data. The download station 125 could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of interfacing with a monitor recorder 14. Still other forms of download station 125 are possible.

Upon retrieving stored ECG monitoring data from a monitor recorder 14, middleware first operates on the retrieved data to adjust the ECG capture quality, as necessary, and to convert the retrieved data into a format suitable for use by third party post-monitoring analysis software, as further described infra with reference to FIG. 13. The formatted data can then be retrieved from the download station 125 over a hard link 135 using a control program 137 ("Ctl") or analogous application executing on a personal computer 136 or other connectable computing device, via a communications link (not shown), whether wired or wireless, or by physical transfer of storage media (not shown). The personal computer 136 or other connectable device may also execute middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program, as further described infra with reference to FIG. 13. Note that formatted data stored on the personal computer 136 would have to be maintained and safeguarded in the same manner as electronic medical

records (EMRs) **134** in the secure database **124**, as further discussed infra. In a further embodiment, the download station **125** is able to directly interface with other devices over a computer communications network **121**, which could be some combination of a local area network and a wide area network, including the Internet, over a wired or wireless connection.

A client-server model could be used to employ a server **122** to remotely interface with the download station **125** over the network **121** and retrieve the formatted data or other information. The server **122** executes a patient management program **123** ("Mgt") or similar application that stores the retrieved formatted data and other information in a secure database **124** cataloged in that patient's EMRs **134**. In addition, the patient management program **123** could manage a subscription service that authorizes a monitor recorder **14** to operate for a set period of time or under pre-defined operational parameters.

The patient management program **123**, or other trusted application, also maintains and safeguards the secure database **124** to limit access to patient EMRs **134** to only authorized parties for appropriate medical or other uses, such as mandated by state or federal law, such as under the Health Insurance Portability and Accountability Act (HIPAA) or per the European Union's Data Protection Directive. For example, a physician may seek to review and evaluate his patient's ECG monitoring data, as securely stored in the secure database **124**. The physician would execute an application program **130** ("Pgm"), such as a post-monitoring ECG analysis program, on a personal computer **129** or other connectable computing device, and, through the application **130**, coordinate access to his patient's EMRs **134** with the patient management program **123**. Other schemes and safeguards to protect and maintain the integrity of patient EMRs **134** are possible.

The wearable monitor **12** can interoperate wirelessly with other wearable physiology and activity sensors **131** and with wearable or mobile communications devices **133**. Wearable physiology and activity sensors **131** encompass a wide range of wirelessly interconnectable devices that measure or monitor data physical to the patient's body, such as heart rate, temperature, blood pressure, and so forth; physical states, such as movement, sleep, footsteps, and the like; and performance, including calories burned or estimated blood glucose level. These devices originate both within the medical community to sense and record traditional medical physiology that could be useful to a physician in arriving at a patient diagnosis or clinical trajectory, as well as from outside the medical community, from, for instance, sports or lifestyle product companies who seek to educate and assist individuals with self-quantifying interests.

Frequently, wearable physiology and activity sensors **131** are capable of wireless interfacing with wearable or mobile communications devices **133**, particularly smart mobile devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The wearable or mobile communications device **133** executes an application ("App") that can retrieve the data collected by the wearable physiology and activity sensor **131** and evaluate the data to generate information of interest to the wearer, such as an estimation of the effectiveness of the wearer's exercise efforts. Still other wearable or mobile communications device **133** functions on the collected data are possible.

The wearable or mobile communications devices **133** could also serve as a conduit for providing the data collected by the wearable physiology and activity sensor **131** to a server **122**, or, similarly, the wearable physiology and activ-

ity sensor **131** could itself directly provide the collected data to the server **122**. The server **122** could then merge the collected data into the wearer's EMRs **134** in the secure database **124**, if appropriate (and permissible), or the server **122** could perform an analysis of the collected data, perhaps based by comparison to a population of like wearers of the wearable physiology and activity sensor **131**. Still other server **122** functions on the collected data are possible.

Finally, the monitor recorder **14** can also be equipped with a wireless transceiver, as further described infra with reference to FIGS. **9** and **10**. Thus, when wireless-enabled, both wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** could wirelessly interface with the monitor recorder **14**, which could either provide data or other information to, or receive data or other information from an interfacing device for relay to a further device, such as the server **122**, analysis, or other purpose. In addition, the monitor recorder **14** could wirelessly interface directly with the server **122**, personal computer **129**, or other computing device connectable over the network **121**, when the monitor recorder **14** is appropriately equipped for interfacing with such devices. Still other types of remote interfacing of the monitor recorder **14** are possible.

During use, the electrode patch **15** is first adhered to the skin along the sternal midline **16** (or immediately to either side of the sternum **13**). A monitor recorder **14** is then snapped into place on the electrode patch **15** to initiate ECG monitoring. FIG. **4** is a perspective view showing an extended wear electrode patch **15** with a monitor recorder **14** in accordance with one embodiment inserted. The body of the electrode patch **15** is preferably constructed using a flexible backing **20** formed as an elongated strip **21** of wrap knit or similar stretchable material with a narrow longitudinal mid-section **23** evenly tapering inward from both sides. A pair of cut-outs **22** between the distal and proximal ends of the electrode patch **15** create a narrow longitudinal midsection **23** or "isthmus" and defines an elongated "hourglass"-like shape, when viewed from above.

The electrode patch **15** incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. During wear, the electrode patch **15** is susceptible to pushing, pulling, and torquing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch **15** incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Electrocardiography Patch," U.S. Pat. No. 9,545,204, issued Jan. 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs **22** and longitudinal midsection **23** help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs **22** and longitudinal midsection **23** further allow better conformity of the electrode patch **15** to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the intermammary cleft between the breasts, especially in buxom women. The cut-outs **22** and longitudinal midsection **23** help the electrode patch **15** fit nicely between a pair of female breasts in the intermammary cleft. Still other shapes, cut-outs and conformities to the electrode patch **15** are possible.

The monitor recorder **14** removably and reusably snaps into an electrically non-conductive receptacle **25** during use. The monitor recorder **14** contains electronic circuitry for recording and storing the patient's electrocardiography as sensed via a pair of ECG electrodes provided on the elec-

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trode patch **15**, such as described in commonly-assigned U.S. Patent, entitled “Extended Wear Ambulatory Electrocardiography and Physiological Sensor Monitor,” U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, the disclosure of which is incorporated by reference. The non-conductive receptacle **25** is provided on the top surface of the flexible backing **20** with a retention catch **26** and tension clip **27** molded into the non-conductive receptacle **25** to conformably receive and securely hold the monitor recorder **14** in place.

The monitor recorder **14** includes a sealed housing that snaps into place in the non-conductive receptacle **25**. FIG. **5** is a perspective view showing the monitor recorder **14** of FIG. **4**. The sealed housing **50** of the monitor recorder **14** intentionally has a rounded isosceles trapezoidal-like shape **52**, when viewed from above, such as described in commonly-assigned U.S. Design Patent, entitled “Electrocardiography Monitor,” No. D717,955, issued Nov. 18, 2014, the disclosure of which is incorporated by reference. The edges **51** along the top and bottom surfaces are rounded for patient comfort. The sealed housing **50** is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high, excluding a patient-operable tactile-feedback button **55**. The sealed housing **50** can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button **55** is waterproof and the button’s top outer surface is molded silicon rubber or similar soft pliable material. A retention detent **53** and tension detent **54** are molded along the edges of the top surface of the housing **50** to respectively engage the retention catch **26** and the tension clip **27** molded into non-conductive receptacle **25**. Other shapes, features, and conformities of the sealed housing **50** are possible.

The electrode patch **15** is intended to be disposable. The monitor recorder **14**, however, is reusable and can be transferred to successive electrode patches **15** to ensure continuity of monitoring. The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch **15** anywhere within the general region of the sternum **13**.

As a result, at any point during ECG monitoring, the patient’s skin is able to recover from the wearing of an electrode patch **15**, which increases patient comfort and satisfaction, while the monitor recorder **14** ensures ECG monitoring continuity with minimal effort. A monitor recorder **14** is merely unsnapped from a worn out electrode patch **15**, the worn out electrode patch **15** is removed from the skin, a new electrode patch **15** is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder **14** is snapped into the new electrode patch **15** to reinitiate and continue the ECG monitoring.

During use, the electrode patch **15** is first adhered to the skin in the sternal region. FIG. **6** is a perspective view showing the extended wear electrode patch **15** of FIG. **4** without a monitor recorder **14** inserted. A flexible circuit **32** is adhered to each end of the flexible backing **20**. A distal circuit trace **33** and a proximal circuit trace (not shown) electrically couple ECG electrodes (not shown) to a pair of electrical pads **34**. The electrical pads **34** are provided within a moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. When the monitor recorder **14** is securely received into the non-conductive

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from the bottom surface of the monitor recorder **14**, and the moisture-resistant seal **35** enables the monitor recorder **14** to be worn at all times, even during bathing or other activities that could expose the monitor recorder **14** to moisture.

In addition, a battery compartment **36** is formed on the bottom surface of the non-conductive receptacle **25**, and a pair of battery leads (not shown) electrically interface the battery to another pair of the electrical pads **34**. The battery contained within the battery compartment **35** can be replaceable, rechargeable or disposable.

The monitor recorder **14** draws power externally from the battery provided in the non-conductive receptacle **25**, thereby uniquely obviating the need for the monitor recorder **14** to carry a dedicated power source. FIG. **7** is a bottom plan view of the monitor recorder **14** of FIG. **4**. A cavity **58** is formed on the bottom surface of the sealed housing **50** to accommodate the upward projection of the battery compartment **36** from the bottom surface of the non-conductive receptacle **25**, when the monitor recorder **14** is secured in place on the non-conductive receptacle **25**. A set of electrical contacts **56** protrude from the bottom surface of the sealed housing **50** and are arranged in alignment with the electrical pads **34** provided on the bottom surface of the non-conductive receptacle **25** to establish electrical connections between the electrode patch **15** and the monitor recorder **14**. In addition, a seal coupling **57** circumferentially surrounds the set of electrical contacts **56** and securely mates with the moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**.

The placement of the flexible backing **20** on the sternal midline **16** (or immediately to either side of the sternum **13**) also helps to minimize the side-to-side movement of the wearable monitor **12** in the left- and right-handed directions during wear. To counter the dislodgment of the flexible backing **20** due to compressional and torsional forces, a layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact surface of the flexible backing **20**, but only on the distal end **30** and the proximal end **31**. As a result, the underside, or contact surface of the longitudinal midsection **23** does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection **23** forms a crimp relief that respectively facilitates compression and twisting of the flexible backing **20** in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing **20**, the flexible circuit **32** is only able to bend and cannot stretch in a planar direction. The flexible circuit **32** can be provided either above or below the flexible backing **20**. FIG. **8** is a top view showing the flexible circuit **32** of the extended wear electrode patch **15** of FIG. **4** when mounted above the flexible backing **20**. A distal ECG electrode **38** and proximal ECG electrode **39** are respectively coupled to the distal and proximal ends of the flexible circuit **32**. A strain relief **40** is defined in the flexible circuit **32** at a location that is partially underneath the battery compartment **36** when the flexible circuit **32** is affixed to the flexible backing **20**. The strain relief **40** is laterally extendable to counter dislodgment of the ECG electrodes **38**, **39** due to tensile and torsional forces. A pair of strain relief cutouts **41** partially extend transversely from each opposite side of the flexible circuit **32** and continue longitudinally towards each other to define an ‘S’-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit **32** in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

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ECG monitoring and other functions performed by the monitor recorder **14** are provided through a micro controlled architecture. FIG. **9** is a functional block diagram showing the component architecture of the circuitry **60** of the monitor recorder **14** of FIG. **4**. The circuitry **60** is externally powered through a battery provided in the non-conductive receptacle **25** (shown in FIG. **6**). Both power and raw ECG signals, which originate in the pair of ECG electrodes **38, 39** (shown in FIG. **8**) on the distal and proximal ends of the electrode patch **15**, are received through an external connector **65** that mates with a corresponding physical connector on the electrode patch **15**. The external connector **65** includes the set of electrical contacts **56** that protrude from the bottom surface of the sealed housing **50** and which physically and electrically interface with the set of pads **34** provided on the bottom surface of the non-conductive receptacle **25**. The external connector includes electrical contacts **56** for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector **65** of the monitor recorder **14** and the device into which the monitor recorder **14** is attached, whether an electrode patch **15** or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector **65** also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder **14**, and performance of other functions.

Operation of the circuitry **60** of the monitor recorder **14** is managed by a microcontroller **61**. The micro-controller **61** includes a program memory unit containing internal flash memory that is readable and writeable. The internal flash memory can also be programmed externally. The micro-controller **61** draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The microcontroller **61** connects to the ECG front end circuit **63** that measures raw cutaneous electrical signals and generates an analog ECG signal representative of the electrical activity of the patient's heart over time.

The circuitry **60** of the monitor recorder **14** also includes a flash memory **62**, which the micro-controller **61** uses for storing ECG monitoring data and other physiology and information. The flash memory **62** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory **62** enables the microcontroller **61** to store digitized ECG data. The communications bus further enables the flash memory **62** to be directly accessed externally over the external connector **65** when the monitor recorder **14** is interfaced to a download station.

The circuitry **60** of the monitor recorder **14** further includes an actigraphy sensor **64** implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller **61** by independent initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the monitor recorder **14** if, for instance, the monitor recorder **14** has been inadvertently installed upside down, that is, with the monitor recorder **14** oriented on the electrode patch **15** towards the patient's feet, as well as for other event occurrence analyses, such as described in commonly-assigned U.S. Pat. No. 9,737,224, issued Aug. 22, 2017, the disclosure of which is incorporated by reference.

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The circuitry **60** of the monitor recorder **14** includes a wireless transceiver **69** that can provides wireless interfacing capabilities. The wireless transceiver **69** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The wireless transceiver **69** can be implemented using one or more forms of wireless communications, including the IEEE 802.11 computer communications standard, that is Wi-Fi; the 4G mobile phone mobile communications standard; the Bluetooth data exchange standard; or other wireless communications or data exchange standards and protocols. The type of wireless interfacing capability could limit the range of interoperability of the monitor recorder **14**; for instance, Bluetooth-based implementations are designed for low power consumption with a short communications range.

The microcontroller **61** includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch **15** or other source, can interface to the microcontroller **61** over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry **60** of the monitor recorder **14**, or can be provided on the electrode patch **15** with communication with the micro-controller **61** provided over one of the electrical contacts **56**. The physiology sensor can include an SpO₂ sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources. For instance, the integration of an airflow sensor is described in commonly-assigned U.S. Pat. No. 9,364,155, issued Jun. 14, 2016, the disclosure which is incorporated by reference.

Finally, the circuitry **60** of the monitor recorder **14** includes patient-interfaceable components, including a tactile feedback button **66**, which a patient can press to mark events or to perform other functions, and a buzzer **67**, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer **67** can be used by the microcontroller **61** to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry **60** of the monitor recorder **14** are possible.

While the monitor recorder **14** operates under micro control, most of the electrical components of the electrode patch **15** operate passively. FIG. **10** is a functional block diagram showing the circuitry **70** of the extended wear electrode patch **15** of FIG. **4**. The circuitry **70** of the electrode patch **15** is electrically coupled with the circuitry **60** of the monitor recorder **14** through an external connector **74**. The external connector **74** is terminated through the set of pads **34** provided on the bottom of the non-conductive receptacle **25**, which electrically mate to corresponding electrical contacts **56** protruding from the bottom surface of the sealed housing **50** to electrically interface the monitor recorder **14** to the electrode patch **15**.

The circuitry **70** of the electrode patch **15** performs three primary functions. First, a battery **71** is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle **25**. The battery **71** is electrically interfaced to the circuitry **60** of the monitor recorder **14** as a source of external power. The unique provisioning of the battery **71** on the electrode patch **15** provides several advantages. First, the locating of the battery **71** physically on the electrode patch **15** lowers the center of gravity of the overall wearable monitor **12** and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing **50** of the monitor recorder **14** is sealed against moisture and providing power externally

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avoids having to either periodically open the housing **50** for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder **14** off line for hours at a time. In addition, the electrode patch **15** is intended to be disposable, while the monitor recorder **14** is a reusable component. Each time that the electrode patch **15** is replaced, a fresh battery is provided for the use of the monitor recorder **14**, which enhances ECG monitoring performance quality and duration of use. Finally, the architecture of the monitor recorder **14** is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller **61**. Requiring those additional sensors or components to draw power from a source external to the monitor recorder **14** keeps power considerations independent of the monitor recorder **14**. Thus, a battery of higher capacity could be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry **60**.

Second, the pair of ECG electrodes **38**, **39** respectively provided on the distal and proximal ends of the flexible circuit **32** are electrically coupled to the set of pads **34** provided on the bottom of the non-conductive receptacle **25** by way of their respective circuit traces **33**, **37**. The signal ECG electrode **39** includes a protection circuit **72**, which is an inline resistor that protects the patient from excessive leakage current.

Last, in a further embodiment, the circuitry **70** of the electrode patch **15** includes a cryptographic circuit **73** to authenticate an electrode patch **15** for use with a monitor recorder **14**. The cryptographic circuit **73** includes a device capable of secure authentication and validation. The cryptographic device **73** ensures that only genuine, non-expired, safe, and authenticated electrode patches **15** are permitted to provide monitoring data to a monitor recorder **14**, such as described in commonly-assigned U.S. Pat. No. 9,655,538, issued May 23, 2017, the disclosure which is incorporated by reference.

In a further embodiment, the circuitry **70** of the electrode patch **15** includes a wireless transceiver **75**, in lieu the including of the wireless transceiver **69** in the circuitry **60** of the monitor recorder **14**, which interfaces with the microcontroller **61** over the microcontroller's expansion port via the external connector **74**.

The monitor recorder **14** continuously monitors the patient's heart rate and physiology. FIG. **11** is a flow diagram showing a monitor recorder-implemented method **100** for monitoring ECG data for use in the monitor recorder **14** of FIG. **4**. Initially, upon being connected to the set of pads **34** provided with the non-conductive receptacle **25** when the monitor recorder **14** is snapped into place, the microcontroller **61** executes a power up sequence (step **101**). During the power up sequence, the voltage of the battery **71** is checked, the state of the flash memory **62** is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed. In a further embodiment, an authentication procedure between the microcontroller **61** and the electrode patch **15** are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps **102-109**) is continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, the ECG frontend **63** (shown in FIG. **9**) continually senses the cutaneous ECG electrical signals (step **103**) via the ECG electrodes **38**, **29** and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step **104**) by the micro-

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controller **61** by sampling the analog ECG signal output front end **63**. FIG. **12** is a graph showing, by way of example, a typical ECG waveform **110**. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave **111** has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex usually begins with the downward deflection of a Q wave **112**, followed by a larger upward deflection of an R-wave **113**, and terminated with a downward waveform of the S wave **114**, collectively representative of ventricular depolarization. The T wave **115** is normally a modest upward waveform, representative of ventricular depolarization, while the U wave **116**, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the extended wear ambulatory electrocardiography and physiological sensor monitor described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor **12**, provides valuable insights to the patient's cardiac function and overall well-being.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step **105**), pending compression preparatory to storage in the flash memory **62** (step **106**). Following compression, the compressed ECG digitized sample is again buffered (step **107**), then written to the flash memory **62** (step **108**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

In a further embodiment, the monitor recorder **14** also continuously receives data from wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** (shown in FIG. **3**). The data is received in a conceptually-separate execution thread as part of the iterative processing loop (steps **102-109**) continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, if wireless data is available (step **140**), a sample of the wireless is read (step **141**) by the microcontroller **61** and, if necessary, converted into a digital signal by the onboard ADC of the microcontroller **61**. Each wireless data sample, in quantized and digitized form, is temporarily staged in buffer (step **142**), pending compression preparatory to storage in the flash memory **62** (step **143**). Following compression, the compressed wireless data sample is again buffered (step **144**), then written to the flash memory **62** (step **145**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

The monitor recorder **14** stores ECG data and other information in the flash memory **62** (shown in FIG. **9**) using a proprietary format that includes data compression. As a result, data retrieved from a monitor recorder **14** must first

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be converted into a format suitable for use by third party post-monitoring analysis software. FIG. 13 is a flow diagram showing a method 150 for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor 12 in accordance with one embodiment. The method 150 can be implemented in software and execution of the software can be performed on a download station 125, which could be a programmer or other device, or a computer system, including a server 122 or personal computer 129, such as further described supra with reference to FIG. 3, as a series of process or method modules or steps. For convenience, the method 150 will be described in the context of being performed by a personal computer 136 or other connectable computing device (shown in FIG. 3) as middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program. Execution of the method 150 by a computer system would be analogous mutatis mutandis.

Initially, the download station 125 is connected to the monitor recorder 14 (step 151), such as by physically interfacing to a set of terminals 128 on a paired receptacle 127 or by wireless connection, if available. The data stored on the monitor recorder 14, including ECG and physiological monitoring data, other recorded data, and other information are retrieved (step 152) over a hard link 135 using a control program 137 ("Ctl") or analogous application executing on a personal computer 136 or other connectable computing device.

The data retrieved from the monitor recorder 14 is in a proprietary storage format and each datum of recorded ECG monitoring data, as well as any other physiological data or other information, must be converted, so that the data can be used by a third-party post-monitoring analysis program. Each datum of ECG monitoring data is converted by the middleware (steps 153-159) in an iterative processing loop. During each iteration (step 153), the ECG datum is read (step 154) and, if necessary, the gain of the ECG signal is adjusted (step 155) to compensate, for instance, for relocation or replacement of the electrode patch 15 during the monitoring period.

In addition, depending upon the configuration of the wearable monitor 12, other physiological data (or other information), including patient events, such as a fall, peak activity level, sleep detection, Detection of patient activity levels and states, and so on, may be recorded along with the ECG monitoring data. For instance, actigraphy data may have been sampled by the actigraphy sensor 64 based on a sensed event occurrence, such as a sudden change in orientation due to the patient taking a fall. In response, the monitor recorder 14 will embed the actigraphy data samples into the stream of data, including ECG monitoring data, that is recorded to the flash memory 62 by the micro-controller 61. Post-monitoring, the actigraphy data is temporally matched to the ECG data to provide the proper physiological context to the sensed event occurrence. As a result, the three-axis actigraphy signal is turned into an actionable event occurrence that is provided, through conversion by the middleware, to third party post-monitoring analysis programs, along with the ECG recordings contemporaneous to the event occurrence. Other types of processing of the other physiological data (or other information) are possible.

Thus, during execution of the middleware, any other physiological data (or other information) that has been embedded into the recorded ECG monitoring data is read (step 156) and time-correlated to the time frame of the ECG signals that occurred at the time that the other physiological

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data (or other information) was noted (step 157). Finally, the ECG datum, signal gain adjusted, if appropriate, and other physiological data, if applicable and as time-correlated, are stored in a format suitable to the backend software (step 158) used in post-monitoring analysis.

In a further embodiment, the other physiological data, if apropos, is embedded within an unused ECG track. For example, the SCP-ENG standard allows multiple ECG channels to be recorded into a single ECG record. The monitor recorder 14, though, only senses one ECG channel. The other physiological data can be stored into an additional ECG channel, which would otherwise be zero-padded or altogether omitted. The backend software would then be able to read the other physiological data in context with the single channel of ECG monitoring data recorded by the monitor recorder 14, provided the backend software implemented changes necessary to interpret the other physiological data. Still other forms of embedding of the other physiological data with formatted ECG monitoring data, or of providing the other physiological data in a separate manner, are possible.

Processing continues (step 159) for each remaining ECG datum, after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope.

What is claimed is:

1. An electrocardiography patch, comprising:
 - a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing;
 - an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;
 - a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes; and
 - a wireless transceiver to communicate at least a portion of the electrocardiographic signals.
2. An electrocardiography patch according to claim 1, further comprising:
 - an accelerometer provided on the backing.
3. An electrocardiography patch according to claim 1, further comprising:
 - a physiology sensor provided on the backing to measure body temperature.
4. An electrocardiography patch according to claim 1, wherein each of the ends of the backing is rounded on an outer edge.
5. An electrocardiography patch according to claim 1, further comprising:
 - a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level.
6. An electrocardiography patch according to claim 1, wherein the electrocardiographic signals are converted to a different format and processed.
7. An electrocardiography patch according to claim 6, wherein the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver.

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8. An electrocardiography patch according to claim 1, wherein the electrodes are exposed on a contact surface of the backing.

9. An electrocardiography patch according to claim 1, further comprising:

a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing.

10. An electrocardiography patch according to claim 9, wherein the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface.

11. An electrocardiography monitor, comprising:

a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing;

an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;

a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes;

a wireless transceiver to communicate at least a portion of the electrocardiographic signals;

a battery on one of the ends of the backing;

a processor powered by the battery; and

memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals.

12. An electrocardiography monitor according to claim 11, further comprising:

an accelerometer provided on the backing.

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13. An electrocardiography monitor according to claim 11, further comprising:

a physiology sensor provided on the backing to measure body temperature.

14. An electrocardiography monitor according to claim 11, wherein each of the ends of the backing is rounded on an outer edge.

15. An electrocardiography monitor according to claim 11, further comprising:

a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level.

16. An electrocardiography monitor according to claim 11, wherein the electrocardiographic signals are converted to a different format and processed.

17. An electrocardiography monitor according to claim 16, wherein the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver.

18. An electrocardiography monitor according to claim 11, wherein the electrodes are exposed on a contact surface of the backing.

19. An electrocardiography monitor according to claim 11, further comprising:

a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing.

20. An electrocardiography monitor according to claim 19, wherein the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface.

* * * * *

EXHIBIT 2

Re: 1:22-cv-00351-CFC; *Bardy
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(D. Del.)



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(54) **MODULAR WEARABLE SENSOR DEVICE**

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(Continued)

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CPC **A61B 5/00** (2013.01); **A61B 5/02055** (2013.01); **A61B 5/05** (2013.01); **A61B 5/6833** (2013.01); **A61B 5/0002** (2013.01); **A61B 5/0006** (2013.01); **A61B 5/0008** (2013.01); **A61B 5/0404** (2013.01); **A61B 5/04087** (2013.01); **A61B 5/0809** (2013.01); **A61B 2560/0285** (2013.01); **A61B 2560/0412** (2013.01); **A61B 2560/0443** (2013.01); **A61B 2562/0209** (2013.01); **A61B 2562/125** (2013.01)

(58) **Field of Classification Search**

CPC **A61B 5/00**; **A61B 5/04**; **A61B 5/0402**; **A61B 5/0408**; **A61B 5/04087**; **A61B 5/0432**; **A61B 5/04325**; **A61B 5/0492**; **A61B 5/6801**; **A61B 5/6832**; **A61B 5/6833**; **A61B 5/02855**; **A61B 5/0002**; **A61B 5/0006**; **A61B 5/0008**; **A61B 2560/0412**; **A61B 2560/0443**; **A61B**

2560/045; **A61B 2560/0468**; **A61B 2560/0475**;

A61B 2562/12; **A61B 2562/125**; **A61B**

2562/164; **A61B 2562/166**; **A61B 2562/22**;

A61B 2562/225; **A61B 2562/227**

USPC **600/391**, **392**, **382**, **301**, **549**, **509**;

439/909; **29/825**

See application file for complete search history.

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Primary Examiner — Lee S Cohen

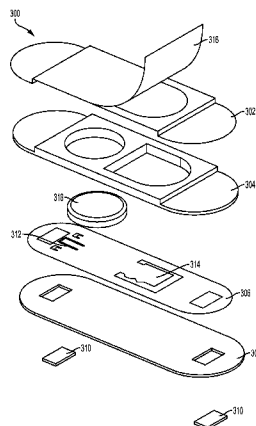
Assistant Examiner — Erin M Cardinal

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(57) **ABSTRACT**

A wearable sensor and method for providing a wearable sensor are disclosed. In a first aspect, the wearable sensor comprises at least one power source and a first module coupled to the at least one power source. The first module includes a first outer shell and a first printed circuit board (PCB) within the first outer shell. The wearable sensor further comprises a second module coupled to the first module. The second module includes a second outer shell and a second PCB within the second outer shell. One of the first and second modules is disposable and the other of the first and second modules is reusable.

19 Claims, 7 Drawing Sheets



Page 2

* cited by examiner

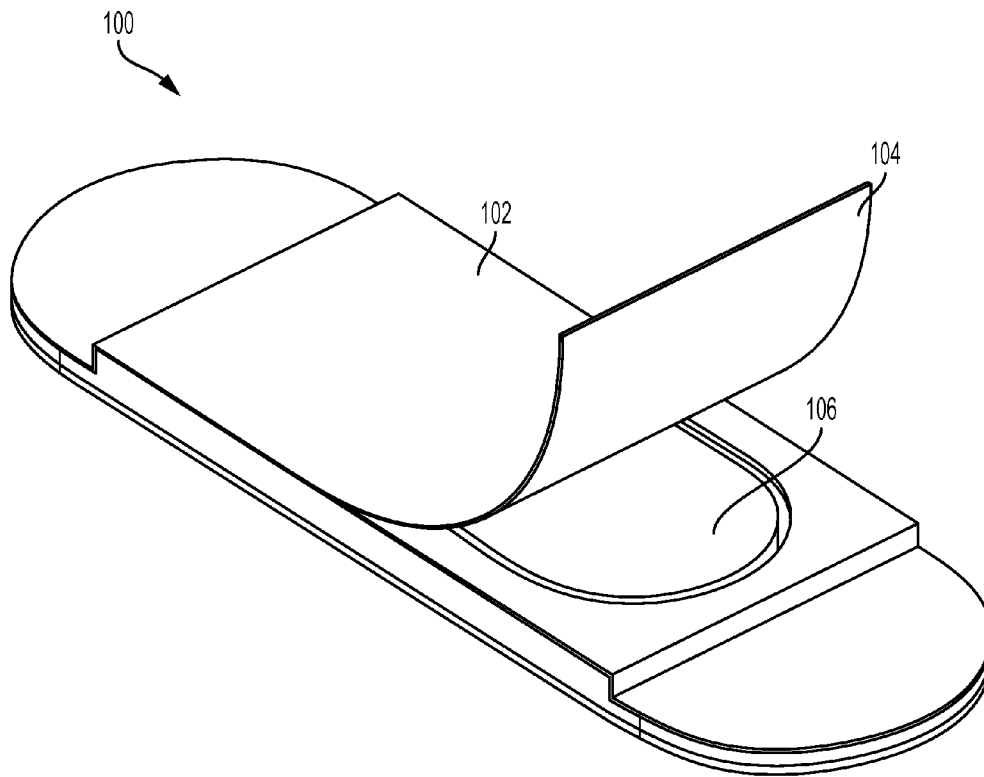


FIG. 1

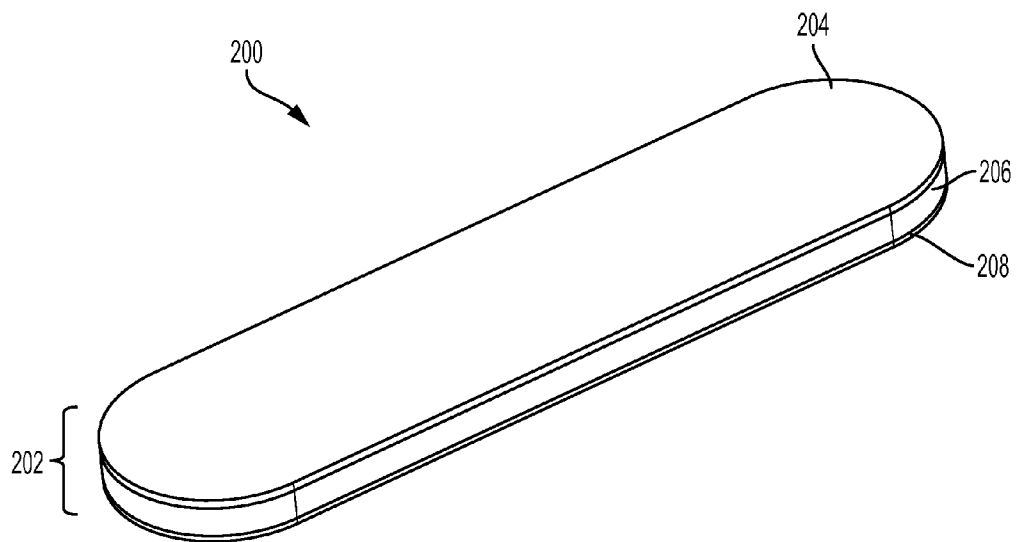


FIG. 2

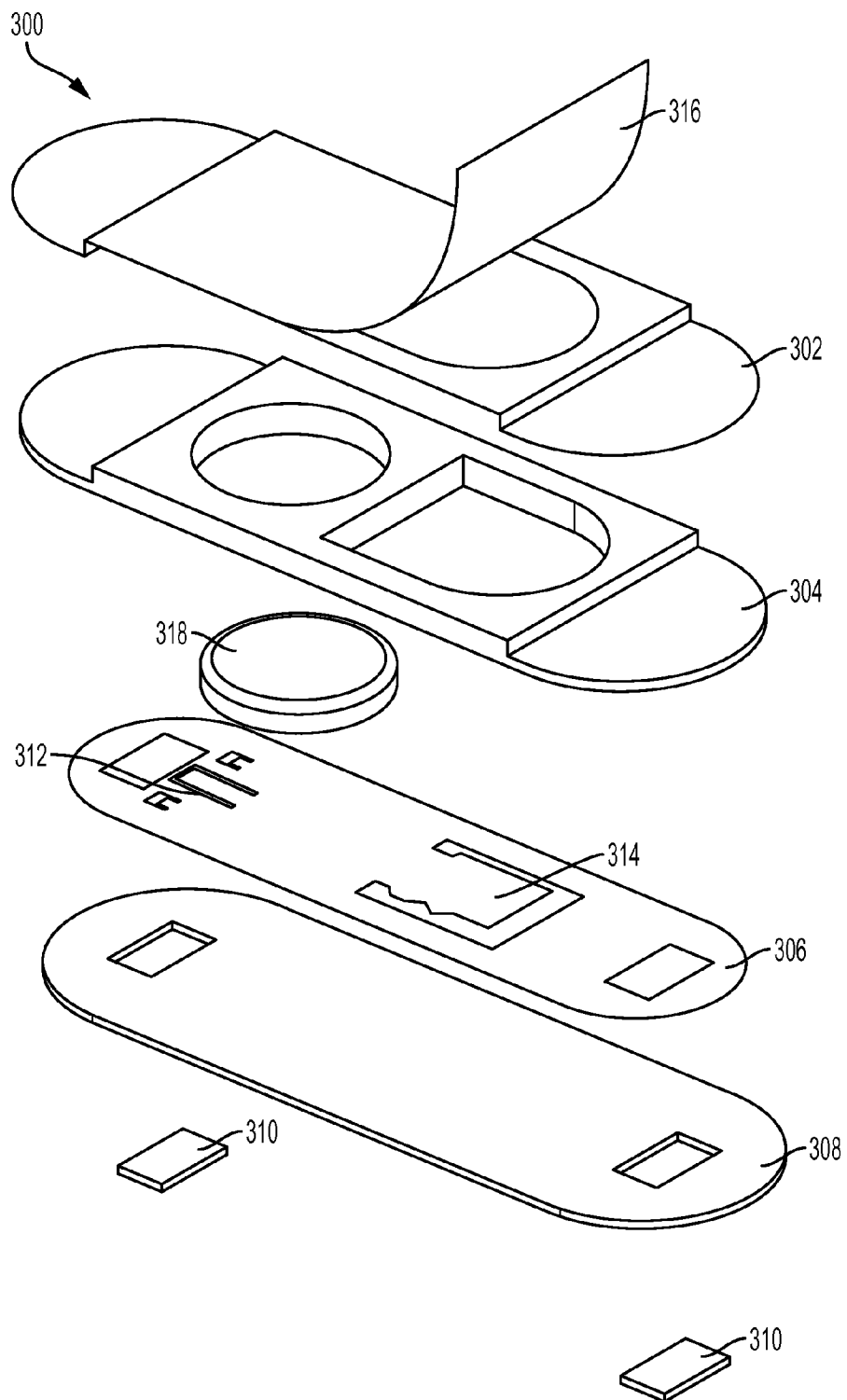


FIG. 3

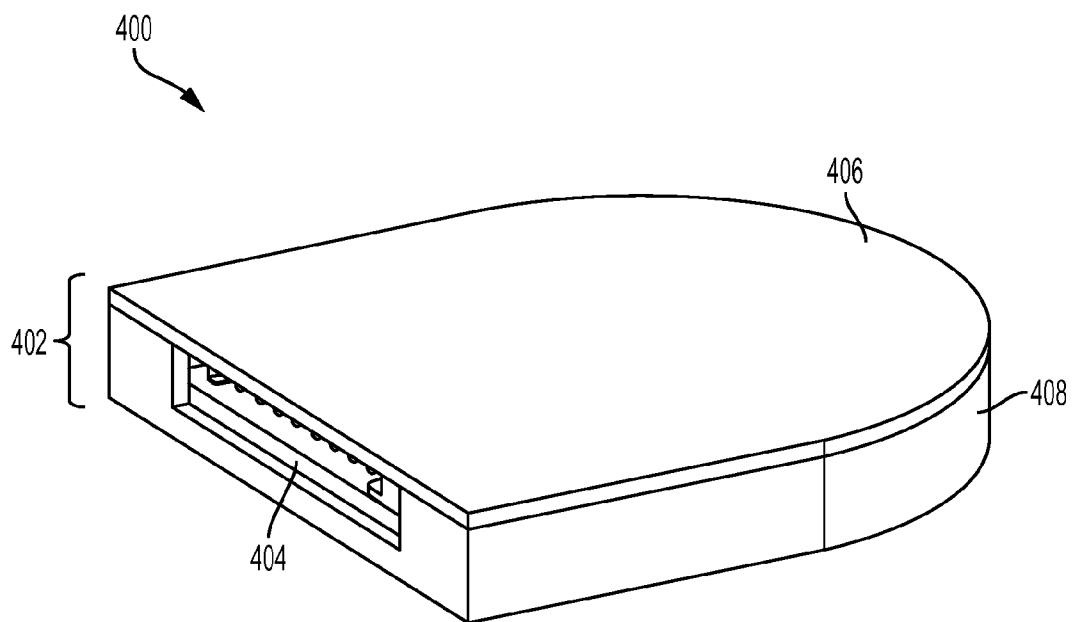


FIG. 4

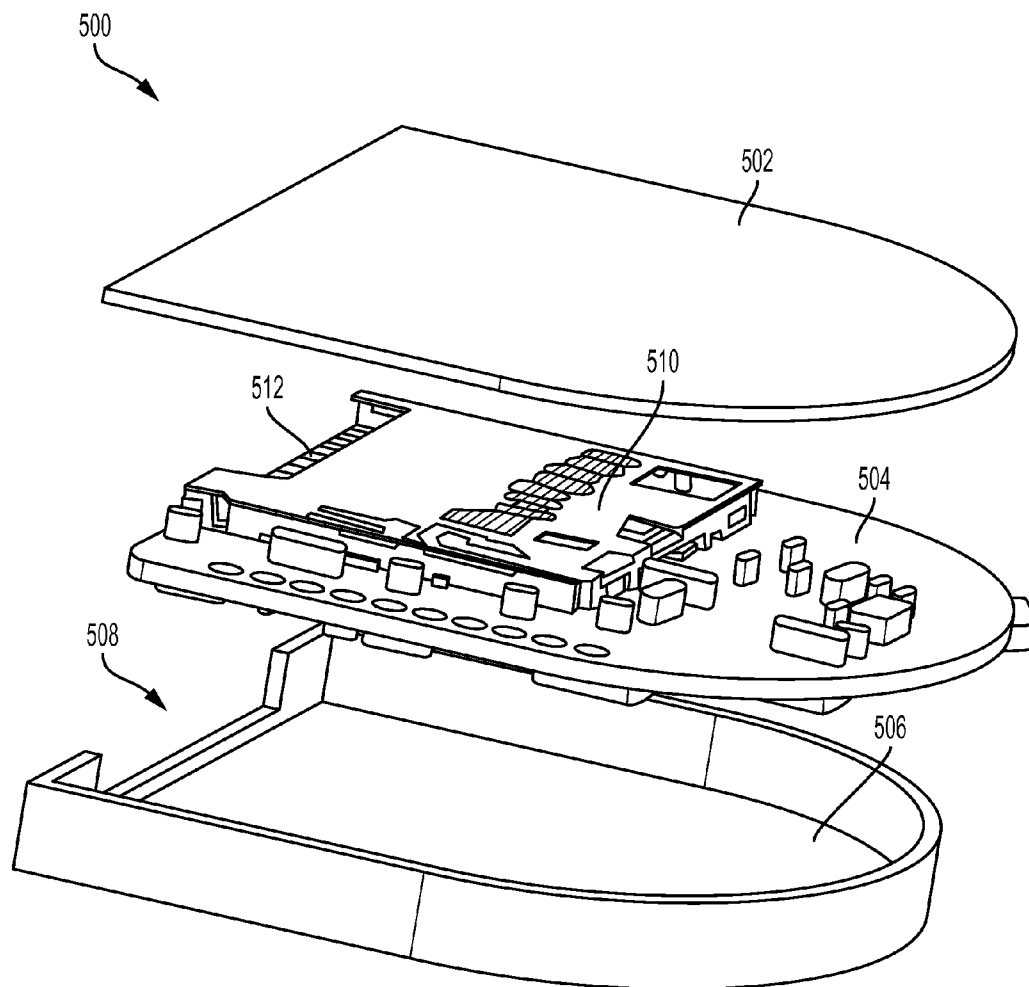


FIG. 5

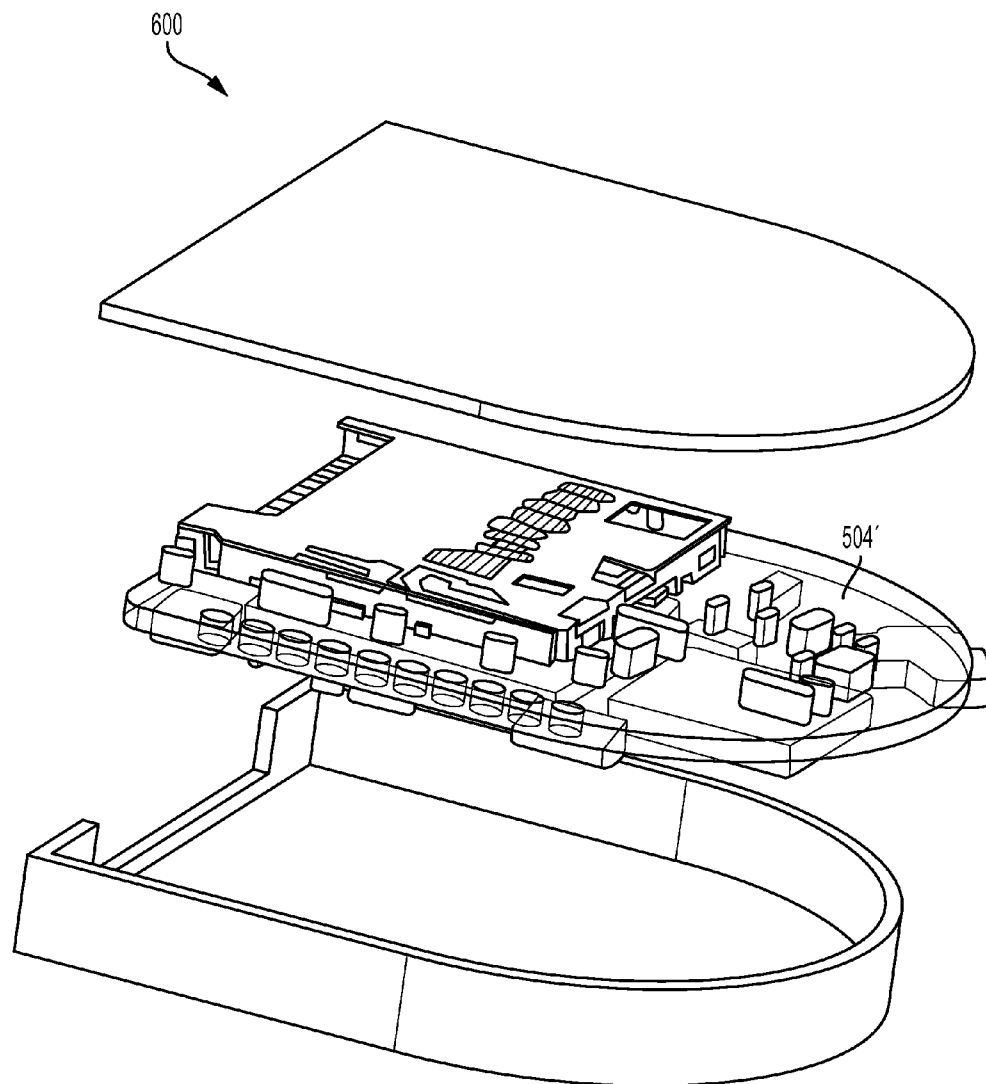


FIG. 6

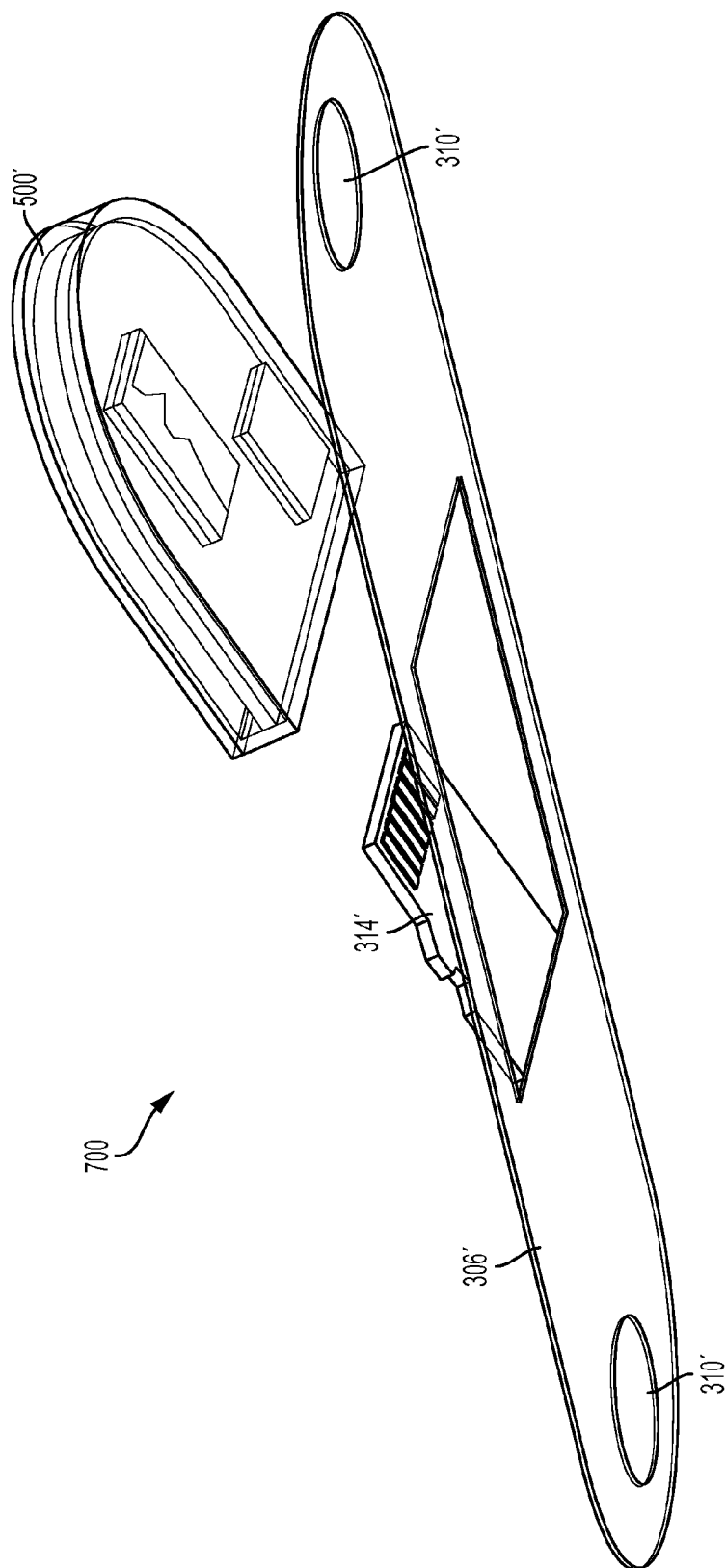


FIG. 7

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MODULAR WEARABLE SENSOR DEVICE**FIELD OF THE INVENTION**

The present invention relates to wireless sensor devices, and more particularly, to a modular wearable sensor.

BACKGROUND

Sensor devices are used in a variety of applications including the health monitoring of users. In many of these health monitoring applications, a wireless sensor device is attached directly to the user's skin to measure certain data. This measured data can then be utilized for a variety of health related applications including but not limited to detecting whether the user has fallen, has suffered a heart attack, has difficulty breathing.

Utilizing these sensor devices, a user's health can be monitored continuously. However, due to the continuous nature of the monitoring, these sensor devices experience repeated use and high wear and tear. As a result, conventional sensor devices must often be replaced regularly to meet the high demands of monitoring a user's health around the clock. Due to the high replacement costs of these sensor devices, monitoring a user's health can become very costly.

These issues limit the usage of sensor devices to continuously measure a user's health. Therefore, there is a strong need for a cost-effective solution that overcomes the above issues by creating a decoupling sensor device that includes both a reusable and a disposable portion. The present invention addresses such a need.

SUMMARY OF THE INVENTION

A wearable sensor and method for providing a wearable sensor are disclosed. In a first aspect, the wearable sensor comprises at least one power source and a first module coupled to the at least one power source. The first module includes a first outer shell and a first printed circuit board (PCB) within the first outer shell. The wearable sensor further comprises a second module coupled to the first module. The second module includes a second outer shell and a second PCB within the second outer shell. One of the first and second modules is disposable and the other of the first and second modules is reusable.

In a second aspect, the method comprises providing at least one power source and coupling a first module to the at least one power source. The first module includes a first outer shell and a first printed circuit board (PCB) within the first outer shell. The method further comprises coupling a second module to the first module. The second module includes a second outer shell and a second PCB within the second outer shell. One of the first and second modules is disposable and the other of the first and second modules is reusable.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying figures illustrate several embodiments of the invention and, together with the description, serve to explain the principles of the invention. One of ordinary skill in the art will recognize that the particular embodiments illustrated in the figures are merely exemplary, and are not intended to limit the scope of the present invention.

FIG. 1 illustrates a modular wearable sensor in accordance with an embodiment.

FIG. 2 illustrates an external view of a disposable module in accordance with an embodiment.

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FIG. 3 illustrates an exploded view of a disposable module in accordance with an embodiment.

FIG. 4 illustrates an external view of a reusable module in accordance with an embodiment.

FIG. 5 illustrates an exploded view of a reusable module in accordance with an embodiment.

FIG. 6 illustrates an exploded view of a reusable module with a transparent PCB in accordance with an embodiment.

FIG. 7 illustrates a view of the connection between the disposable module and the reusable module in accordance with an embodiment.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention relates to wireless sensor devices, and more particularly, to a modular wearable sensor. The following description is presented to enable one of ordinary skill in the art to make and use the invention and is provided in the context of a patent application and its requirements. Various modifications to the preferred embodiment and the generic principles and features described herein will be readily apparent to those skilled in the art. Thus, the present invention is not intended to be limited to the embodiments shown but is to be accorded the widest scope consistent with the principles and features described herein.

A modular wearable sensor device provides a cost-effective health monitoring sensor device. By implementing a reusable module and a disposable module that each decouple from each other and each comprise varying components, the modular wearable sensor device can be utilized to more efficiently and continuously monitor a user's health. One of ordinary skill in the art readily recognizes that the shape and placement of the components of both the reusable module and the disposable module can vary and that would be within the spirit and scope of the present invention.

To describe the features of the present invention in more detail, refer now to the following description in conjunction with the accompanying Figures.

In one embodiment, the modular wearable sensor device is a wireless sensor device in a "patch" form factor that is attached to the user for health monitoring. One of ordinary skill in the art readily recognizes that a variety of wireless sensor devices and form factors can be utilized including but not limited to a wireless sensor device that looks like a band-aid and adheres to the user's body and that would be within the spirit and scope of the present invention.

FIG. 1 illustrates a modular wearable sensor **100** in accordance with an embodiment. The modular wearable sensor **100** includes a disposable module **102**, a cover **104** coupled to the disposable module **102**, and a reusable module **106** coupled to the disposable module **102**. In one embodiment, after the reusable module **106** is coupled to the disposable module **102**, the cover **104** is coupled to the disposable module **102** to enclose the reusable module **106** within the disposable module **102**.

One of ordinary skill in the art readily recognizes that the cover **104** can be a variety of types of covers including but not limited to a flexible cover, a bendable cover, a stiff cover, and an elastic cover and that would be within the spirit and scope of the present invention. Additionally, one of ordinary skill in the art readily recognizes that the cover **104** can be coupled to the disposable module **102** utilizing a variety of coupling mechanism including but not limited to an adhesive and a clip and that would be within the spirit and scope of the present invention.

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In one embodiment, the cover **104** is coupled to a top surface of the disposable module **102**. One of ordinary skill in the art readily recognizes that the cover **104** can be coupled to a variety of surfaces of the disposable module **102** to allow varying coupling orientations of the reusable module **106** to the disposable module **102** including but not limited to a bottom surface and a side surface and that would be within the spirit and scope of the present invention.

In one embodiment, the disposable module **102** includes an outer shell unit that houses various components. The outer shell is soft, flexible, and stretchable to provide optimum wear comfort when attached to the body of a user. Additionally, the outer shell is waterproof and sealed so that a user can come in contact with water without having to detach the modular wearable sensor **100**. The various components housed within the disposable module **102** can include but are not limited to a cover, foam layers, at least one power source, a flexible printed circuit board (PCB) including electrical components such as a connector, a small sensor, and a thermistor, electrode contacts to couple to electrodes, and an adhesive layer.

In one embodiment, the reusable module **106** includes an outer shell unit that houses various components including critical electronics. The outer shell is hard and rigid to protect the critical electronics. The various components including critical electronics housed within the reusable module **106** can include but are not limited to a connector, an antenna, a microcontroller, a sensor, a microelectromechanical system (MEMS), and a wireless transceiver. The reusable module **106** can be de-attached from the disposable module **102** via the connectors for re-use with another disposable module and/or wireless sensor device that includes a related connector.

One of ordinary skill in the art readily recognizes that the at least one power source can be a variety of device types including but not limited to a coin battery, a button battery, a flexible battery, and an energy harvesting unit and that would be within the spirit and scope of the present invention. Additionally, one of ordinary skill in the art readily recognizes that the various other components housed within both the disposable module **102** and the reusable module **106** can vary in device type and material and that would be within the spirit and scope of the present invention.

FIG. 2 illustrates an external view of a disposable module **200** in accordance with an embodiment. The disposable module **200** includes an outer shell **202**. The outer shell **202** includes a top surface **204**, a middle layer **206**, and a bottom surface **208**. In one embodiment, the outer shell **202** has a thickness variation across the top surface **204**. One of ordinary skill in the art readily recognizes that the thickness variation across the top surface **204** can be a variety of thickness patterns including but not limited to a center portion of the top surface **204** being thicker than both end portions of the top surface **204** and that would be within the spirit and scope of the present invention.

FIG. 3 illustrates an exploded view of a disposable module **300** in accordance with an embodiment. The disposable module **300** includes a top cover layer **302**, a top foam layer **304** coupled to the top cover layer **302**, a flexible PCB **306** coupled to the top foam layer **304**, a bottom foam layer **308** coupled to the flexible PCB **306**, and at least two electrodes **310** coupled to the flexible PCB **306**. The flexible PCB **306** enables the disposable module **300** to conform and to adhere to a user's movements. In the disposable module **300**, the flexible PCB **306** includes an electrical component unit **312** including but not limited to a thermistor and a first connector

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unit **314** that enables the coupling of the disposable module **300** to the reusable module **106**.

In one embodiment, the bottom foam layer **310** is a double adhesive layer so that it adheres to the flexible PCB **306** and to a user at the same time. One of ordinary skill in the art readily recognizes that the at least two electrodes **310** can measure a variety of health related values including but not limited to ECG and respiratory rates and that would be within the spirit and scope of the present invention.

In one embodiment, the top cover layer **302** and the top foam layer **304** each have an opening to allow for the insertion and coupling of the reusable module **106**. The opening of the top cover layer **302** is covered by an adjustable cover **316** to protect the reusable module **106** once inserted and coupled to the first connector unit **314**. One of ordinary skill in the art readily recognizes that each of the openings of the top cover layer **302** and the top foam layer **304** can be similarly shaped or different as long as they are shaped in accordance with the shape of the reusable module **106** and that would be within the spirit and scope of the present invention.

In one embodiment, the top foam layer **304** has another opening for the insertion and coupling of a battery **318**. The battery **318** is coupled to the flexible PCB **306** to power both the electrical component unit **312** of the flexible PCB **306** and the reusable module **106** through the connector unit **314**. In another embodiment, a waterproof and breathable battery cover is utilized to protect the battery **318**. One of ordinary skill in the art readily recognizes that the disposable module **300** can include a variety of power sources including but not limited to a single battery and multiple batteries and that would be within the spirit and scope of the present invention.

In one embodiment, the flexible PCB **306** and the bottom foam layer **308** each have two openings to allow for the coupling of the at least two electrodes **310** to the electrode contacts of the flexible PCB **306**. In one embodiment, the at least two electrodes **310** are made of an electrolyte, including but not limited to an electrolytic medium or gel (hydrogel), and an electrochemical electrode, including but not limited to a metallic electrode. One of ordinary skill in the art readily recognizes that each of the two openings of the flexible PCB **306** and the bottom foam layer **308** can be similarly shaped or different as long as they are shaped in accordance with the shape of the at least two electrodes **310** and that would be within the spirit and scope of the present invention.

FIG. 4 illustrates an external view of a reusable module **400** in accordance with an embodiment. The reusable module **400** includes an outer shell **402** and a connector opening **404** coupled to the outer shell **402**. The outer shell **402** includes a top surface **406**, a middle layer **408** that houses electrical components, and a bottom surface. In one embodiment, the outer shell **402** is comprised of a hard material to protect the electrical components housed within.

FIG. 5 illustrates an exploded view of a reusable module **500** in accordance with an embodiment. The reusable module **500** includes a top cover layer **502**, a bottom cover layer **506** coupled to the top cover layer **502**, a PCB **504** coupled between the top cover layer **502** and the bottom cover layer **506**, and a connector opening **508** coupled to both the top cover layer **502** and the bottom cover layer **506**. The PCB **504** includes an electrical component unit **510** and a second connector unit **512** coupled to the electrical component unit **510** for further monitoring and processing of information collected by the at least two electrodes **310**. FIG. 6 illustrates a transparent view **600** of the PCB of the reusable module **500**. In the transparent view **600**, the PCB **504** is transparent so that components coupled on both sides of the PCB **504** are visible.

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The first connector unit **314** of the flexible PCB **306** couples to the second connector unit **512** of the reusable module **500** to provide connectivity between the at least two electrodes **310** and the reusable module **500**. The coupling between the first connector unit **314** and the second connector unit **512** enables the modular wearable sensor **100** to monitor health related values of the user for either a continuous period or predetermined time period. FIG. 7 illustrates a view of the connection **700** between the disposable module and the reusable module in accordance with an embodiment. The second connector unit of the reusable module **500'** can be coupled to the first connector unit **314'** of the flexible PCB **306'** to connect the at least two electrodes **310'** to the reusable module **500'**.

One of ordinary skill in the art readily recognizes that the first connector unit **314** of the flexible PCB **306** within the disposable module **300** and the second connector unit **512** of the PCB **504** within the reusable module **500** can be a variety of connector types including but not limited to Secure Digital (SD) card connectors, miniSD card connectors, microSD card connectors, flash memory card connectors, and custom designed connectors and that would be within the spirit and scope of the present invention.

One of ordinary skill in the art readily recognizes that the flexible PCB **306** of the disposable module **300** can include similar electrical components as the PCB **504** of the reusable module **500** and that would be within the spirit and scope of the present invention. In this embodiment, the modular wearable sensor **100** would include only the disposable module **300** that is capable of monitoring health related values of the user, rendering the modular wearable sensor **100** entirely disposable.

As above described, the modular wearable sensor and method provide for a cost-efficient health monitoring device that includes at least one reusable module and at least one disposable module that are capable of decoupling from each other to enable the continuous monitoring of a user. By implementing similar connector units within both the disposable module and the reusable module of the modular wearable sensor, the reusable module can be decoupled from the disposable module. Complex and costly electrical components for the health monitoring and processing of a user's data can be housed within the reusable module portion so that when the disposable module is discarded, higher monitoring costs do not result.

Although the present invention has been described in accordance with the embodiments shown, one of ordinary skill in the art will readily recognize that there could be variations to the embodiments and those variations would be within the spirit and scope of the present invention. Accordingly, many modifications may be made by one of ordinary skill in the art without departing from the spirit and scope of the appended claims.

What is claimed is:

1. A wearable sensor, wherein the wearable sensor is attachable to a user, the wearable sensor comprising:

at least one power source;

a first module coupled to the at least one power source, wherein the first module includes a first outer shell and a first printed circuit board (PCB) within the first outer shell, wherein the first outer shell comprises a first top cover, a top foam layer coupled to the first top cover, and a bottom foam layer coupled to the first PCB, further wherein the top foam layer includes a first opening for housing the at least one power source and a second opening for housing a second module, wherein the bottom foam layer is a double adhesive layer that adheres to

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both the first PCB and the user, wherein the bottom foam layer includes at least two openings to house at least two electrodes for monitoring of the user; and

the second module coupled to the first module via the second opening, wherein the second module includes a second outer shell and a second PCB within the second outer shell, further wherein the first module is disposable and the second module is reusable.

2. The wearable sensor of claim 1, wherein the first PCB is coupled between the top foam layer and the bottom foam layer.

3. The wearable sensor of claim 2, wherein the second outer shell comprises a second top cover, a bottom cover coupled to the second top cover, and a connector opening coupled to the bottom cover, further wherein the second PCB is coupled between the second top cover and the bottom cover.

4. The wearable sensor of claim 3, wherein the first PCB comprises a first connector coupled to a stiffener.

5. The wearable sensor of claim 4, wherein the first PCB comprises a first electrical component that is selected from the group consisting of a small sensor and a thermistor.

6. The wearable sensor of claim 5, wherein the second PCB comprises a second electrical component that is selected from the group consisting of a second connector, an antenna, a microcontroller, a microelectromechanical system (MEMS), and a wireless transceiver.

7. The wearable sensor of claim 6, further comprising the second connector, wherein the second connector is coupled to the first connector via the second opening of the top foam layer.

8. The wearable sensor of claim 7, wherein the first connector is selected from the group consisting of a standard MicroSD card form factor and a custom designed card form factor.

9. The wearable sensor of claim 2, wherein the second outer shell is selected from the group consisting of two horizontally coupled pieces and a conformal coating form.

10. The wearable sensor of claim 2, wherein the at least one power source is selected from the group consisting of a rechargeable battery, a coin battery, a button battery, a flexible battery, an energy harvesting unit, and a solar cell, further wherein the at least one power source is coupled to the first module via the first PCB.

11. The wearable sensor of claim 2, wherein a center portion of the first top cover is thicker than peripheral portions of the first top cover.

12. The wearable sensor of claim 2, wherein the bottom foam layer comprises a hydrogel layer that includes an adhesive.

13. The wearable sensor of claim 1, wherein the first PCB is selected from the group consisting of a soft PCB, a flexible PCB, and a stretchable PCB to provide wear comfort.

14. A method for providing a wearable sensor, wherein the wearable sensor is attachable to a user, the method comprising:

providing at least one power source;

coupling a first module to the at least one power source, wherein the first module includes a first outer shell and a first printed circuit board (PCB) within the first outer shell, wherein the first outer shell comprises a first top cover, a top foam layer coupled to the first top cover, and a bottom foam layer coupled to the first PCB, further wherein the top foam layer includes a first opening for housing the at least one power source and a second opening for housing a second module, wherein the bot-

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tom foam layer is a double adhesive layer that adheres to both the first PCB and the user;
 providing least two openings within the bottom foam layer;
 housing at least two electrodes within the at least two openings, wherein the at least two electrodes are utilized 5
 to monitor the user; and
 coupling the second module to the first module via the second opening, wherein the second module includes a second outer shell and a second PCB within the second outer shell, further wherein the first module is disposable 10
 and the second module is reusable.

15. The method of claim **14**, further comprising:
 coupling the first PCB between the top foam layer and the bottom foam layer.

16. The method of claim **15**, further comprising: 15
 providing a second top cover and a bottom cover within the second outer shell, wherein the bottom cover includes a connector opening;
 coupling the bottom cover to the second top cover; and

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coupling the second PCB between the second top cover and the bottom cover.

17. The method of claim **16**, further comprising:
 providing a stiffener and a first connector within the first PCB; and
 coupling the stiffener to the first connector.

18. The method of claim **17**, further comprising:
 providing an electrical component within the second PCB, wherein the electrical component is selected from the group consisting of a second connector, an antenna, a microcontroller, a microelectromechanical system (MEMS), and a wireless transceiver.

19. The method of claim **18**, further comprising:
 providing the second connector, and
 coupling
 the second connector to the first connector via the second opening of the top foam layer.

* * * * *

EXHIBIT 3

Re: 1:22-cv-00351-CFC; *Bardy
Diagnostics, Inc. v. Vital Connect, Inc.*
(D. Del.)



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/119,945	12/11/2020	Jason Felix	127.2029.US.CON	7323
22895	7590	01/25/2021		
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SEATTLE, WA 98125				
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			3792	
			MAIL DATE	DELIVERY MODE
			01/25/2021	PAPER

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

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

Office Action Summary	Application No. 17/119,945	Applicant(s) Felix et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	AIA (FITF) Status Yes

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

Period for Reply

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

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

Status

- 1) ☒ Responsive to communication(s) filed on 12/11/2020.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-20 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-20 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

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

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 12/11/2020 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

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

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

Notice of Pre-AIA or AIA Status

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

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to

examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159.

See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 10.888.239. Although the claims at issue are not identical, they are not patentably distinct from each other because the present claims are directed to obvious features incorporated in the electrocardiography patch device as claimed in claims 1-20 of U.S. Patent No. 10.888.239. The skilled artisan would recognize narrowing a mid-section between the two ends of the backing obviously reduces weight by eliminating unnecessary material. Likewise, it is obvious to provide an accelerometer to measure movement, and a hydrocolloid adhesive to attach the device to a patient.

Allowable Subject Matter

Claims 1-20 are rejected, but would be allowable subject to filing an acceptable Terminal Disclaimer.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Paquet (US 2012/0029300) discloses a related wireless monitoring patch.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

The examiner can normally be reached on regular business days.

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

<http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner
Art Unit: 3792

1/20/2021

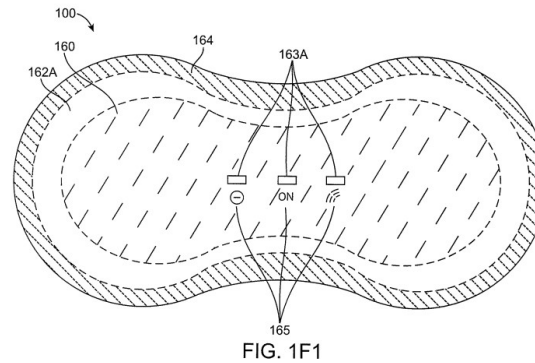
EXHIBIT 4

Re: 1:22-cv-00351-CFC; *Bardy
Diagnostics, Inc. v. Vital Connect, Inc.*
(D. Del.)

Claim Chart – Int’l Publ. No. WO 2010/104952 (“Mazar”) for U.S. Patent No. 11,051,743

International Publication No. WO 2010/104952 (“Mazar”), entitled “Display Systems for Body-Worn Health Monitoring Devices, was filed on March 10, 2010, and claims priority to Provisional Application No. 61/159,028 (March 10, 2009). Mazar is prior art to the ’743 patent under 35 U.S.C. § 102(a)(1) by about 4.5 years. Mazar, like the ’743 patent, is directed to a health monitoring device that includes two electrodes, narrowed mid-section, and describes the collection and transmission of data from the device. *See* Mazar, Figure 1F1. Mazar anticipates every claims of the ’743 patent.

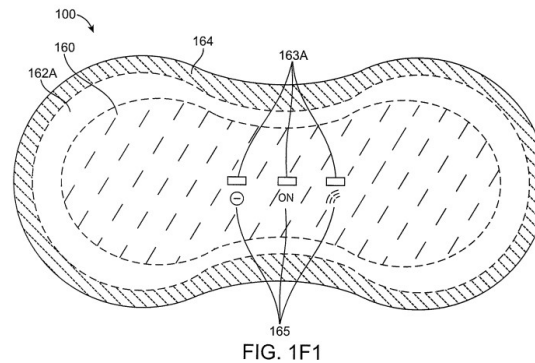
U.S. Pat. No. 11,051,743	
Claim 1	Mazar
1. An electrocardiography patch, comprising:	Mazar (¶ 2) discloses “an electrocardiography patch”: The present invention relates to patient monitoring. Although embodiments make specific reference to monitoring patients with an adherent patch device, the system methods and device described herein may be applicable to many applications in which physiological monitoring is used, for example wireless physiological monitoring with devices for extended periods. And Mazar (¶ 98) discloses: In some embodiments the patch comprises two electrodes, for example two electrodes to measure the electrocardiogram (ECG) of the patient.
[1a] a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing;	Mazar (¶¶ 127; Fig. 1F1) discloses “a backing comprising an elongated strip with a mid-section connecting two ends of the backing”: In many embodiments, tape 110T of adherent patch 110 may comprise backing material, or backing 111, such as a fabric configured to provide properties of patch 110 as described above.

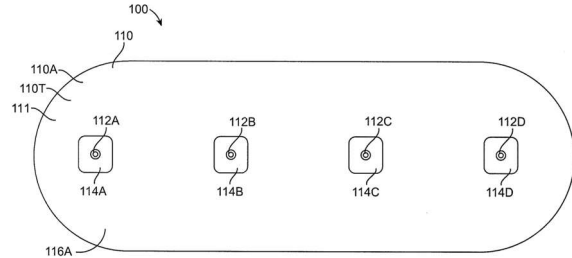


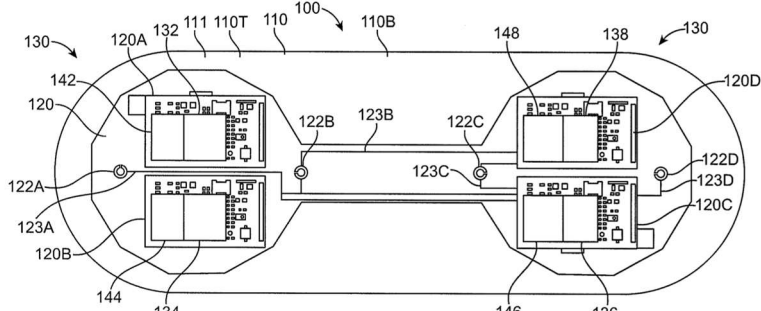
Mazar (¶ 93; Fig. 1F1) discloses “the mid-section is narrower than the two ends of the backing”:

The adherent patch and/or device can comprise many shapes, for example at least one of a dog bone, an hourglass, an oblong, a circular or an oval shape.

Fig. 1F1:



[1b] an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;	Mazar (¶ 98 and Fig. 1B) discloses “an electrocardiographic electrode on each end of the backing” that: In some embodiments the patch comprises two electrodes, for example two electrodes to measure the electrocardiogram (ECG) of the patient. Gel 114A, gel 114B, gel 114C and gel 114D can each be positioned over electrodes 112 A, 112B, 112C and 112D, respectively, to provide electrical conductivity between the electrodes and the skin of the patient. In many embodiments, the electrodes can be affixed to the patch 110, for example with known methods and structures such as rivets, adhesive, stitches, etc. In many embodiments, patch 110 comprises a breathable material to permit air and/or vapor to flow to and from the surface of the skin. Fig. 1B:  FIG. 1B
[1c] a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes; and	Mazar (¶ 100 and Fig. 1D) discloses “a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes”: In some embodiments, a printed circuit board (PCB), for example flex printed circuit board 120, may be connected to electrodes 112 A, 112B, 112C and 112D with connectors 122A, 122B, 122C and 122D. Flex printed circuit board 120 can include traces

	123A, 123B, 123C and 123D that extend to connectors 122A, 122B, 122C and 122D, respectively, on the flex printed circuit board. Connectors 122 A, 122B, 122C and 122D can be positioned on flex printed circuit board 120 in alignment with electrodes 112 A, 112B, 112C and 112D so as to electrically couple the flex PCB with the electrodes. In some embodiments, connectors 122A, 122B, 122C and 122D may comprise insulated wires and/or a film with conductive ink that provide strain relief between the PCB and the electrodes. For example, connectors 122A, 122B, 122C and 122D may comprise a flexible film, such as at least one of known polyester film or known polyurethane film, coated with a conductive ink, for example a conductive silver ink. Fig. 1D:  FIG. 1D
[1d] a wireless transceiver to communicate at least a portion of the electrocardiographic signals.	Mazar (¶¶ 104-105) discloses “a wireless transceiver to communicate at least a portion of the electrocardiographic signals”: Electronic components 130 may comprise a processor 146. Processor 146 comprises a tangible medium, for example read only memory (ROM), electrically erasable programmable read only memory (EEPROM) and/or random access memory (RAM).

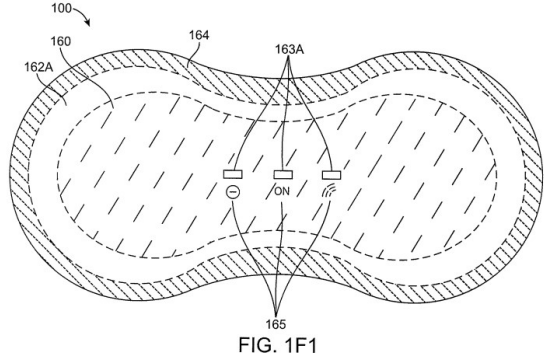
	In some embodiments the tangible medium is configured to continuously store physiologic signals of a patient. In some embodiments the processor 146 is configured to stop storing and/or measuring physiologic signals when the storage capacity of the tangible medium has been exceeded. Electronic circuitry 130 may comprise real time clock and frequency generator circuitry 148. In some embodiments, processor 136 may comprise the frequency generator and real time clock. The processor can be configured to control a collection and transmission of data from the impedance circuitry electrocardiogram circuitry and the accelerometer. In many embodiments, device 100 comprise a distributed processor system, for example with multiple processors on device 100. In some embodiments the processor 146 may be configured to control a visual indicator, such as an LED or a display. In some embodiments the electronic components 130 include a dedicated graphics processor for controlling a visual indicator. In some embodiments the processor 146 includes a clock. In some embodiments the electronic components 130 include dedicated clock hardware. [0105] In many embodiments, electronics components 130 comprise wireless communications circuitry 132 to communicate with remote center 106. Printed circuit board 120 may comprise an antenna to facilitate wireless communication. The antennae may be integral with printed circuit board 120 or may be separately coupled thereto. The wireless communication circuitry can be coupled to the impedance circuitry, the electrocardiogram circuitry and the accelerometer to transmit to a remote center with a communication protocol at least one of the hydration signal, the electrocardiogram signal or the inclination signal. In specific embodiments, wireless communication circuitry is configured to transmit the hydration signal, the electrocardiogram signal and the inclination signal to the remote center with a single wireless hop, for example from wireless communication circuitry
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Claim Chart – Int’l Publ. No. WO 2010/104952 (“Mazar”) for U.S. Patent No. 11,051,743

	132 to intermediate device 102. The communication protocol comprises at least one of Bluetooth, Zigbee, WiFi, WiMax, IR, amplitude modulation or frequency modulation. In many embodiments, the communications protocol comprises a two way protocol such that the remote center is capable of issuing commands to control data collection.
Claim 2	Mazar
2. An electrocardiography patch according to claim 1, further comprising:	<i>See Claim 1.</i>
[2a] an accelerometer provided on the backing.	Mazar (¶¶ 15, 107) discloses “accelerometer provided on the backing”: In many embodiments the activity sensor is chosen from a group consisting of: ball switch, accelerometer, minute ventilation, bioimpedance noise, muscle noise, and posture. Electronic components 130 comprise components to take physiologic measurements, transmit data to remote center 106 and receive commands from remote center 106. In many embodiments, electronics components 130 may comprise known low power circuitry, for example complementary metal oxide semiconductor (CMOS) circuitry components. Electronics components 130 comprise an activity sensor and activity circuitry 134, impedance circuitry 136 and electrocardiogram circuitry, for example ECG circuitry 136. In some embodiments, electronics circuitry 130 may comprise a microphone and microphone circuitry 142 to detect an audio signal from within the patient, and the audio signal may comprise a heart sound and/or a respiratory sound, for example an S3 heart sound and a respiratory sound with rales and/or crackles. Activity sensor and activity circuitry 134 can comprise many known activity sensors and circuitry. In many embodiments, the

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	accelerometer comprises at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer. The accelerometer may comprises a 3-axis accelerometer to measure at least one of an inclination, a position, an orientation or acceleration of the patient in three dimensions. Work in relation to embodiments of the present invention suggests that three dimensional orientation of the patient and associated positions, for example sitting, standing, lying down, can be very useful when combined with data from other sensors, for example ECG data and/or hydration data.
Claim 3	Mazar
3. An electrocardiography patch according to claim 1, further comprising:	<i>See Claim 1.</i>
[3a] a physiology sensor provided on the backing to measure body temperature.	Mazar (¶¶ 48, 95) discloses “a physiology sensor provided on the backing to measure body temperature”: In many embodiments the electrical components comprise a memory for storing the physiologic signals. In many embodiments the predetermined event comprises determination of exceeding capacity of the memory for storing the physiologic signals. The adherent device may contain a subset of the following physiological sensors: bioimpedance, respiration, respiration rate variability, heart rate (avg, min, max), heart rhythm, heart rate variability (hereinafter "HRV"), heart rate turbulence (hereinafter "HRT"), heart sounds (e.g. S3), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature/heat flux, and weight.

Claim 4	Mazar
4. An electrocardiography patch according to claim 1, wherein each of the ends of the backing is rounded on an outer edge.	Mazar (¶ 93; Fig. 1F1) discloses “each of the ends of the backing is rounded on an outer edge”: The adherent patch and/or device can comprise many shapes, for example at least one of a dog bone, an hourglass, an oblong, a circular or an oval shape. Fig. 1F1:  FIG. 1F1
Claim 5	Mazar
5. An electrocardiography patch according to claim 1, further comprising: [5a] a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level.	See Claim 1. Mazar (¶¶ 13-14) discloses “a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level.” In many embodiments the electronic components comprise a processor and a plurality of sensors coupled to the printed circuit board. The processor is configured to process data

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	received from the sensors and to display information regarding the data on the printed circuit board. ... In many embodiments each of the plurality of sensors are chosen from a group consisting of: ECG, tissue resistance, bioimpedance, respiration, respiration rate variability, heart rate, heart rhythm, heart rate variability, heart rate turbulence, heart sounds, respiratory sounds, blood pressure, activity, posture, wake, sleep, orthopnea, temperature, heat flux, and weight.
Claim 6	Mazar
6. An electrocardiography patch according to claim 1, wherein the electrocardiographic signals are converted to a different format and processed.	Mazar (¶¶ 173, 214) discloses “the electrocardiographic signals are converted to a different format and processed”: Processor system 260 may comprise processors in addition to processor 262, for example a remote processor as described above. Processor 262 comprises tangible medium 266 that can be configured with instructions, and tangible medium 266 may comprise memory such as random access memory (RAM), read only memory (ROM), erasable read only memory (EPROM), and many additional types of known computer memory. Processor system 260 comprising processor 262 can be connected to impedance circuitry 250, switches 252, a processor 262, ECG circuitry 270, accelerometer circuitry 280, and wireless circuitry 290 to transmit and/or process data. The processor system, as described above, can be configured to perform the method 200, including many of the steps described above. It should be appreciated that the specific steps illustrated in Figure 4A provide a particular method of predicting an impending cardiac decompensation, according to an embodiment of the present invention. Other sequences of

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	steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in Figure 4A may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.
Claim 7	Mazar
7. An electrocardiography patch according to claim 6, wherein the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver.	Mazar (¶ 91) discloses “the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver”: Adherent device 100 can communicate wirelessly to an intermediate device 102, for example with a single wireless hop from the adherent device on the patient to the intermediate device. Intermediate device 102 can communicate with remote center 106 in many ways, for example with an internet connection and/or with a cellular connection. In many embodiments, monitoring system 10 comprises a distributed processing system with at least one processor comprising a tangible medium on device 100, at least one processor on intermediate device 102, and at least one processor 106P at remote center 106, each of which processors can be in electronic communication with the other processors. At least one processor 102P comprises a tangible medium 102T, and at least one processor 106P comprises a tangible medium 106T. Remote processor 106P may comprise a backend server located at the remote center.

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Claim 8	Mazar
8. An electrocardiography patch according to claim 1, wherein the electrodes are exposed on a contact surface of the backing.	Mazar (¶¶ 122-123) discloses “the electrodes are exposed on a contact surface of the backing”: In some embodiments, the adherent device can comprise electrodes configured to couple to tissue through apertures (not shown) in the breathable tape. The electrodes can be fabricated in many ways. For example, the electrodes can be printed on a flexible connector, such as silver ink on polyurethane. Breathable tape 110T may comprise apertures. The electrodes are exposed to the gel through apertures of breathable tape 110T. Gel 114A, gel 114B, gel 114C and gel 114D can be positioned over electrodes and the respective portions of breathable tape 110T proximate apertures so as to couple the electrodes to the skin of the patient. The flexible connector comprising the electrodes can extend from under the gel cover to the printed circuit board to connect to the printed circuit boards and/or components supported thereon. For example, flexible connector may comprise flexible connector 122A to provide strain relief, as described above. In many embodiments, the gel layer of each electrode comprises an exposed surface area to contact the skin within a range from about 100 mm² to about 1500 mm², for example a range from about 250 mm² to about 750 mm², and in specific embodiments within a range from about 350 mm² to about 650 mm². Work in relation with embodiments of the present invention suggests that such dimensions and/or exposed surface areas can provide enough gel area for robust skin interface without excessive skin coverage.
Claim 9	Mazar
9. An electrocardiography patch according to claim 1, further comprising:	See Claim 1.

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[9a] a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing.	Mazar (¶ 128) also discloses the “hydrocolloid adhesive provided on at least a portion of a contact surface of the backing”: In many embodiments, an adhesive 116A, for example breathable tape adhesive comprising a layer of acrylate pressure sensitive adhesive, can be disposed on underside 110A of patch 110. In many embodiments, adhesive 116A adheres adherent patch 110 comprising backing 111 to the skin of the patient, so as not to interfere with the functionality of breathable tape, for example water vapor transmission as described above. In many embodiments, adhesive 116A comprises at least one of acrylate, silicone, synthetic rubber, synthetic resin, hydrocolloid adhesive, pressure sensitive adhesive (PSA), or acrylate pressure sensitive adhesive.
Claim 10	Mazar
10. An electrocardiography patch according to claim 9, wherein the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface.	Mazar (¶ 128) also discloses the “the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface”: In many embodiments, an adhesive 116A, for example breathable tape adhesive comprising a layer of acrylate pressure sensitive adhesive, can be disposed on underside 110A of patch 110. In many embodiments, adhesive 116A adheres adherent patch 110 comprising backing 111 to the skin of the patient, so as not to interfere with the functionality of breathable tape, for example water vapor transmission as described above. In many embodiments, adhesive 116A comprises at least one of acrylate, silicone, synthetic rubber, synthetic resin, hydrocolloid adhesive, pressure sensitive adhesive (PSA), or acrylate pressure sensitive adhesive.
Claim 11	Mazar
11. An electrocardiography monitor, comprising:	<i>See Claim 1.</i>
[11a] a backing comprising an elongated strip with a mid-section connecting two ends of the backing,	<i>See Claim 1a.</i>

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wherein the mid-section is narrower than the two ends of the backing;	
[11b] an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;	<i>See Claim 1b.</i>
[11c] a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes;	<i>See Claim 1c.</i>
[11d] a wireless transceiver to communicate at least a portion of the electrocardiographic signals;	<i>See Claim 1d.</i>
[11e] a battery on one of the ends of the backing;	Mazar (¶¶ 33, 94) also discloses “a battery on one of the ends of the backing”: The method comprises detecting tissue coupled to at least two electrodes of a flexible support, which is coupled to a skin of the patient, connecting a battery of the support to electronic components of the support in response to detecting tissue, and triggering at least one visual indicator of the support in response to detecting tissue coupled to at least two electrodes of the support. In many embodiments, the adherent device may comprise a reusable electronics module with replaceable patches, and each of the replaceable patches may include a battery.
[11f] a processor powered by the battery; and	Mazar (¶ 167) also discloses “a processor powered by the battery”: Thereafter, processor 262 can continue to assert control line 264 with a digital on signal voltage such that sustain circuitry 230 remains closed, even after tissue is removed from the electrodes. When processor 262 asserts an off signal voltage on control line 264, sustain circuitry 230 opens at least one switch 214 between battery output 204 and voltage regulator 206 and may turn off the components connected to voltage regulator 206, including the processor.

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[11g] memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals.	Mazar ¶¶ 48, 95, 104) discloses “memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals”: In many embodiments the electrical components comprise a memory for storing the physiologic signals. In many embodiments the predetermined event comprises determination of exceeding capacity of the memory for storing the physiologic signals. The adherent device may contain a subset of the following physiological sensors: bioimpedance, respiration, respiration rate variability, heart rate (avg, min, max), heart rhythm, heart rate variability (hereinafter "HRV"), heart rate turbulence (hereinafter "HRT"), heart sounds (e.g. S3), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature/heat flux, and weight. In some embodiments the tangible medium is configured to continuously store physiologic signals of a patient.
Claim 12	Mazar
12. An electrocardiography monitor according to claim 11, further comprising:	<i>See Claim 11.</i>
[12a] an accelerometer provided on the backing.	<i>See Claim 2a.</i>
Claim 13	Mazar
13. An electrocardiography monitor according to claim 11, further comprising:	<i>See Claim 11.</i>
[13a] a physiology sensor provided on the backing to measure body temperature.	<i>See Claim 3a.</i>
Claim 14	Mazar
14. An electrocardiography monitor according to claim 11, wherein each of the ends of the backing is rounded on an outer edge.	<i>See Claim 4.</i>

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Claim 15	Mazar
15. An electrocardiography monitor according to claim 11, further comprising:	<i>See Claim 11.</i>
[15a] a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level.	<i>See Claim 5a.</i>
Claim 16	Mazar
16. An electrocardiography monitor according to claim 11, wherein the electrocardiographic signals are converted to a different format and processed.	<i>See Claim 6.</i>
Claim 17	Mazar
17. An electrocardiography monitor according to claim 16, wherein the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver.	<i>See Claim 7.</i>
Claim 18	Mazar
18. An electrocardiography monitor according to claim 11, wherein the electrodes are exposed on a contact surface of the backing.	<i>See Claim 8.</i>
Claim 19	Mazar
19. An electrocardiography monitor according to claim 11, further comprising:	<i>See Claim 11.</i>
[19a] a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing.	<i>See Claim 9a.</i>
Claim 20	Mazar
20. An electrocardiography monitor according to claim 19, wherein the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface.	<i>See Claim 10.</i>