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(54) **INJECTABLE DEVICE FOR PHYSIOLOGICAL MONITORING**

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See application file for complete search history.

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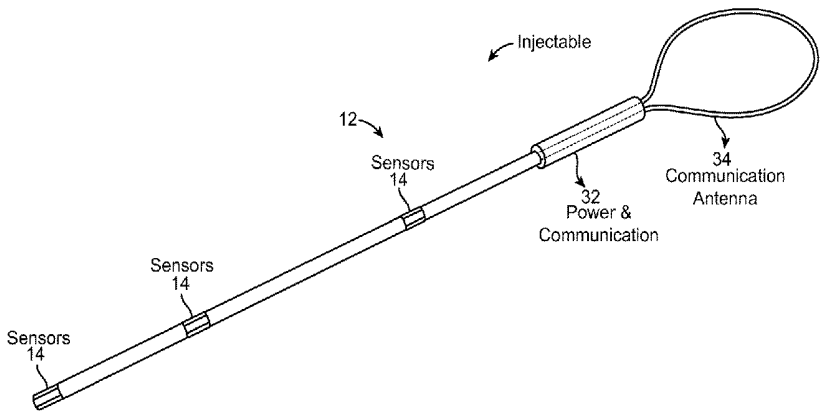
(57) **ABSTRACT**

An injectable detecting device is provided for use in physiological monitoring. The device includes a plurality of sensors axially spaced along a body that provide an indication of at least one physiological event of a patient, a monitoring unit within the body coupled to the plurality of sensors configured to receive data from the plurality of sensors and create processed patient data, a power source within the body coupled to the monitoring unit, and a communication antenna external to the body coupled to the monitoring unit configured to transfer data to/from other devices.

17 Claims, 15 Drawing Sheets



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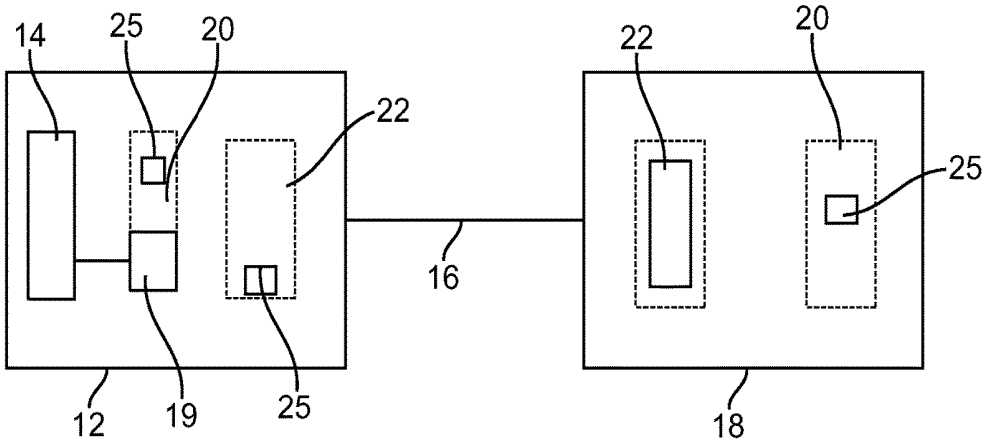


FIG. 1

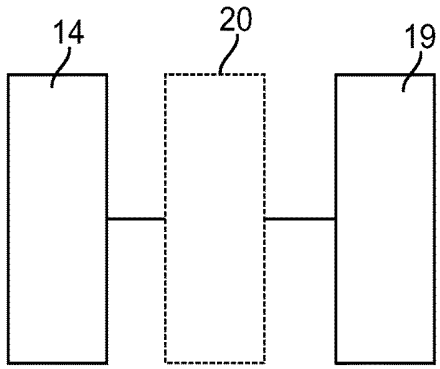
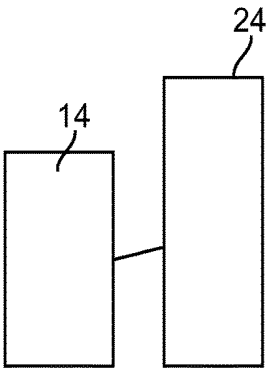


FIG. 3



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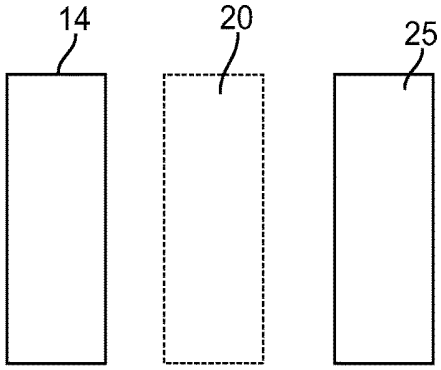

FIG. 5

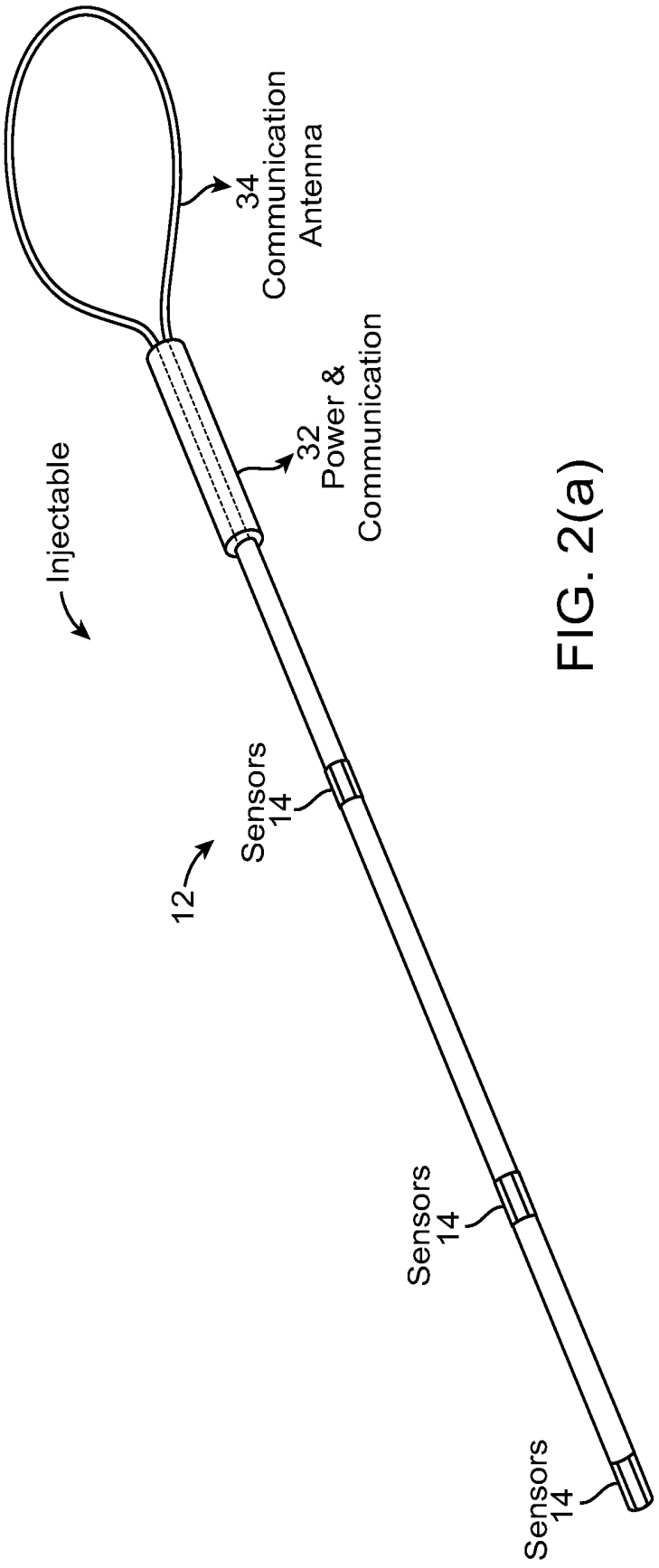
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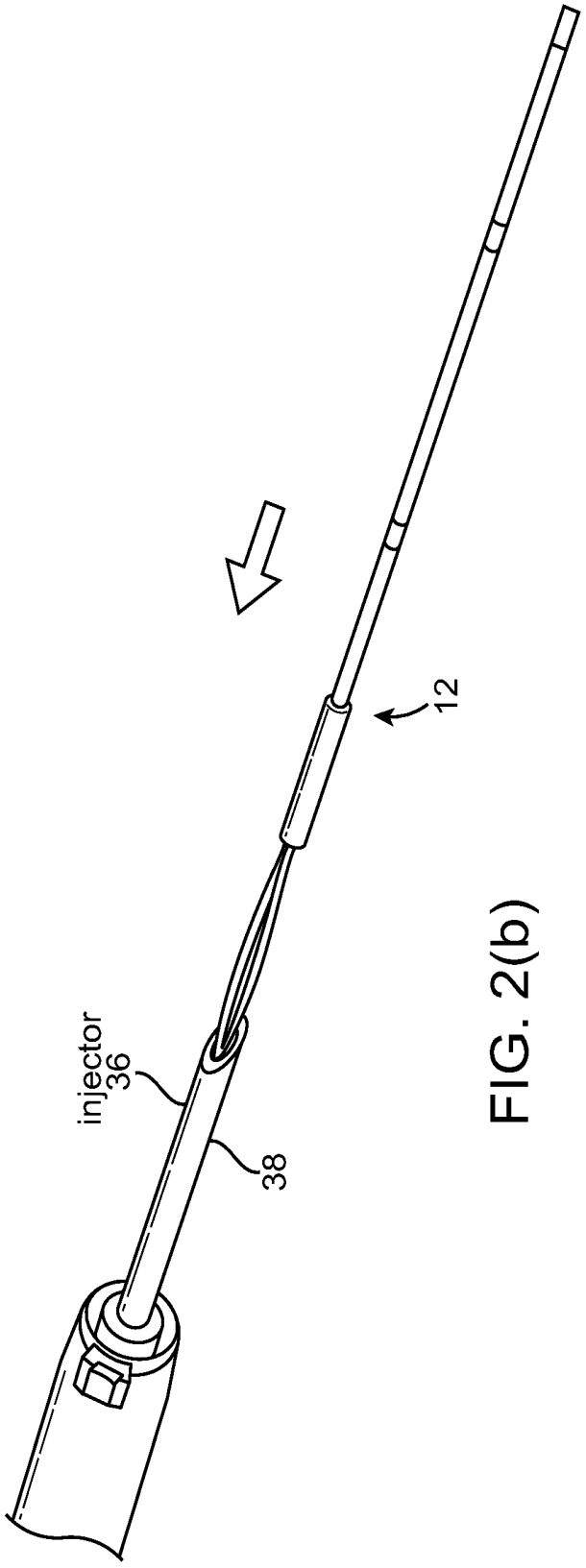
FIG. 2(a)



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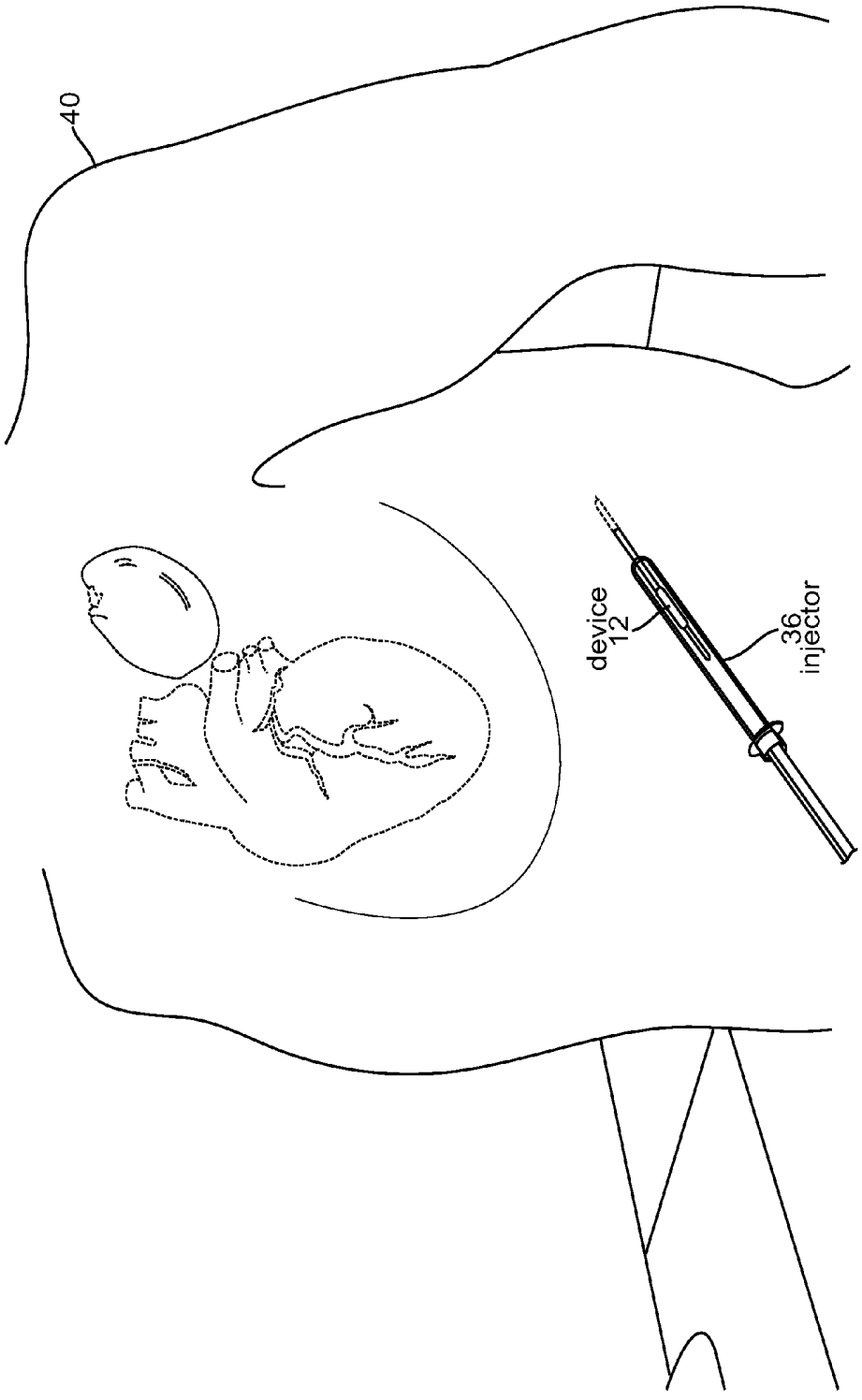

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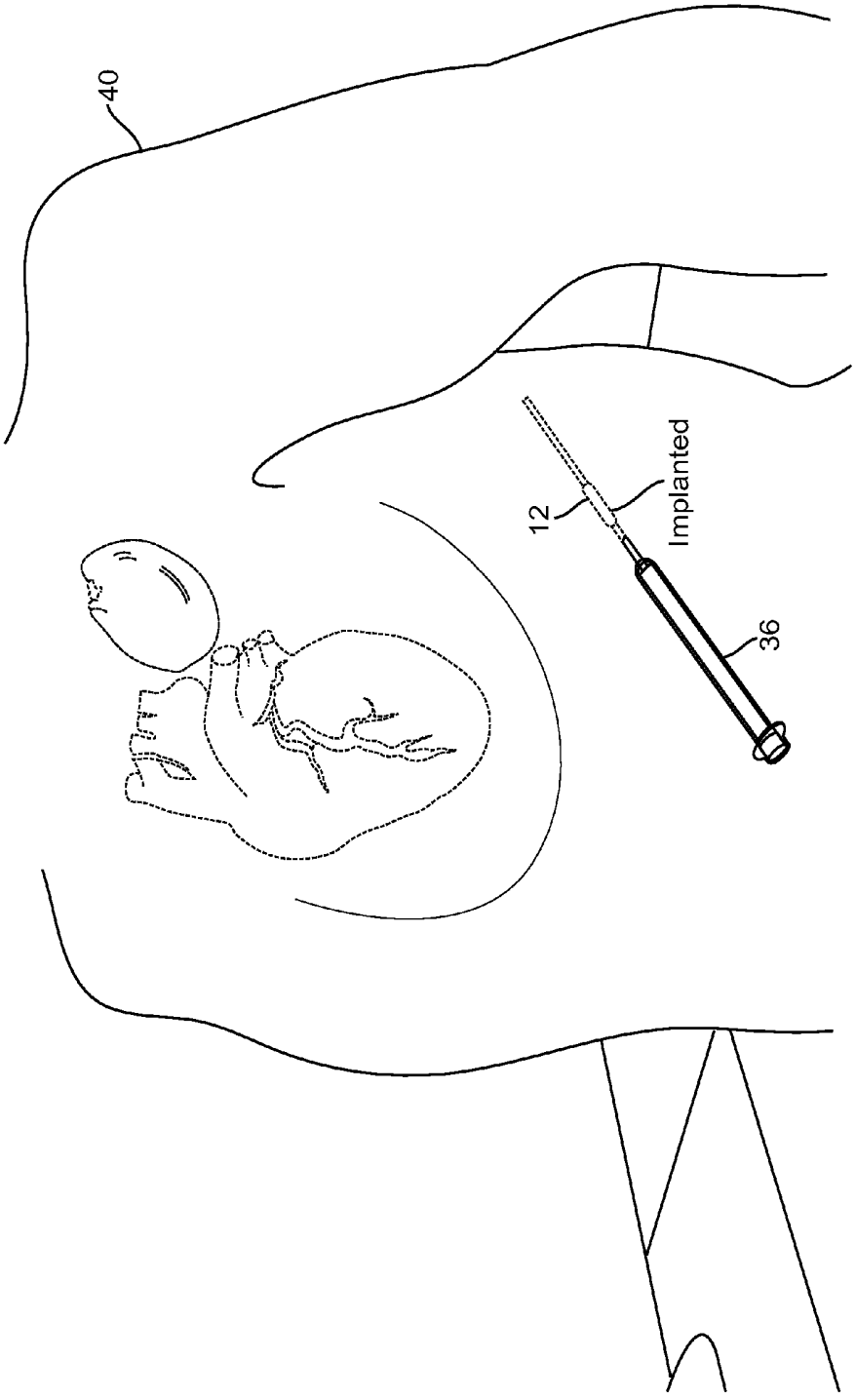

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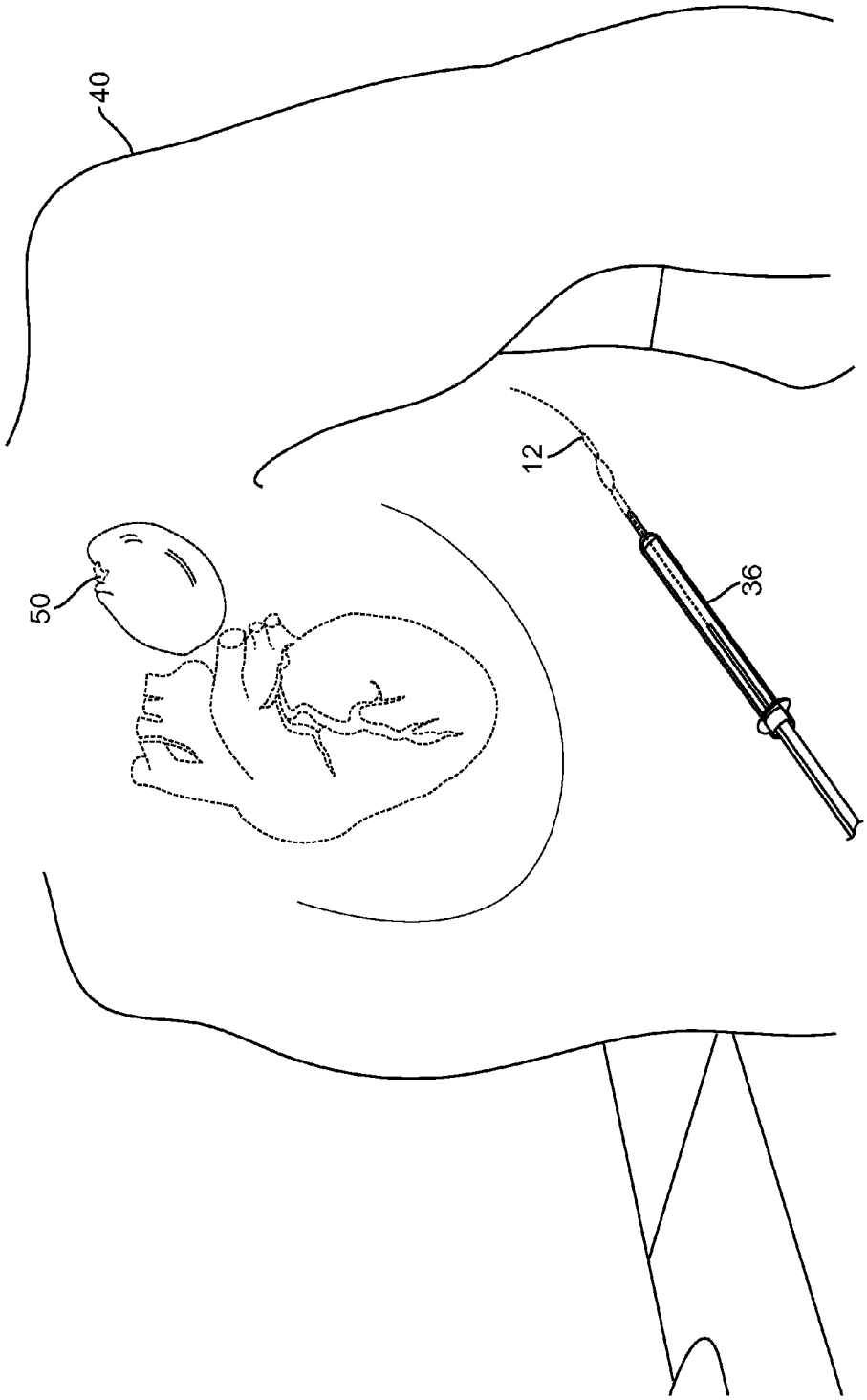

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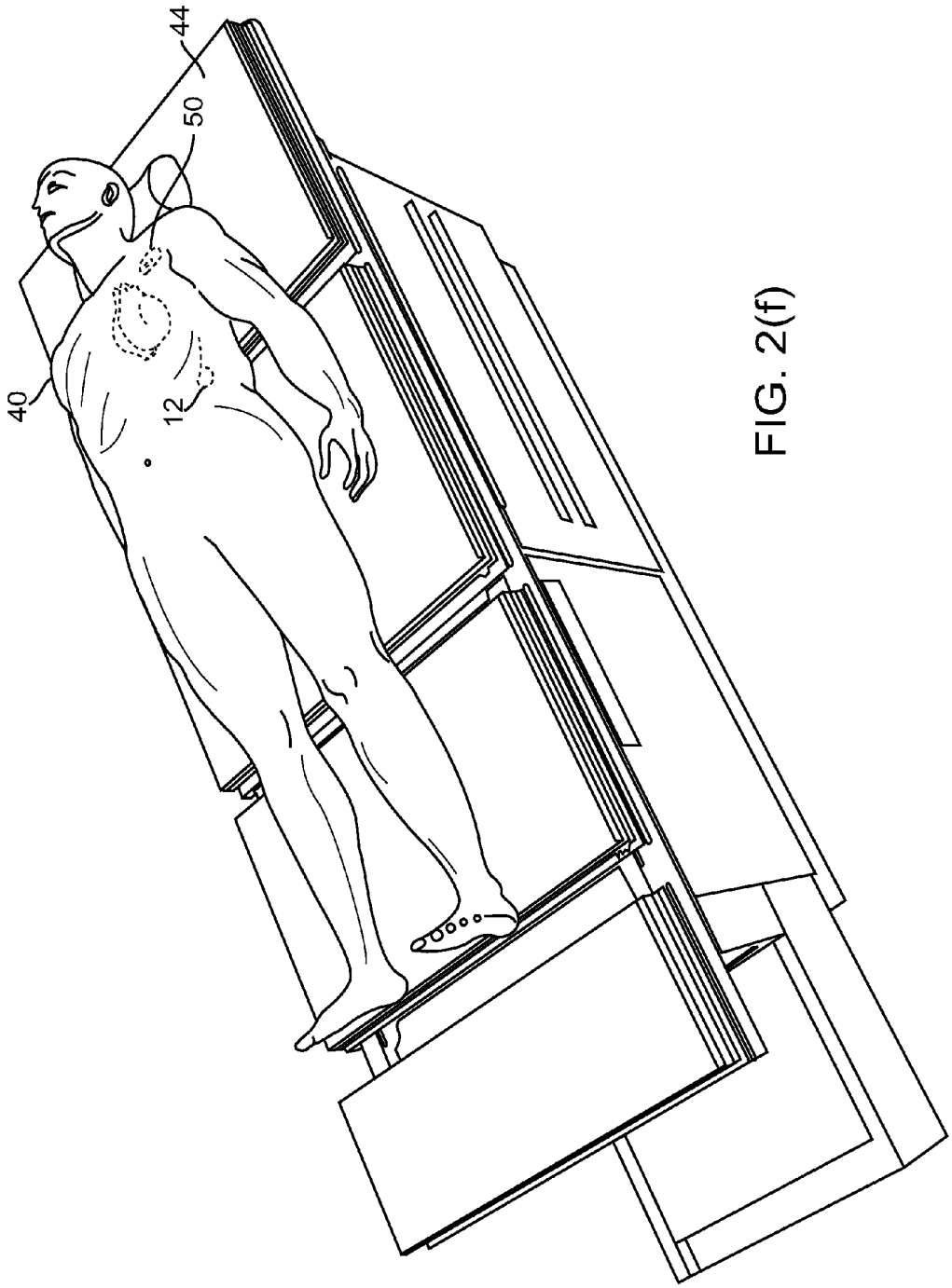

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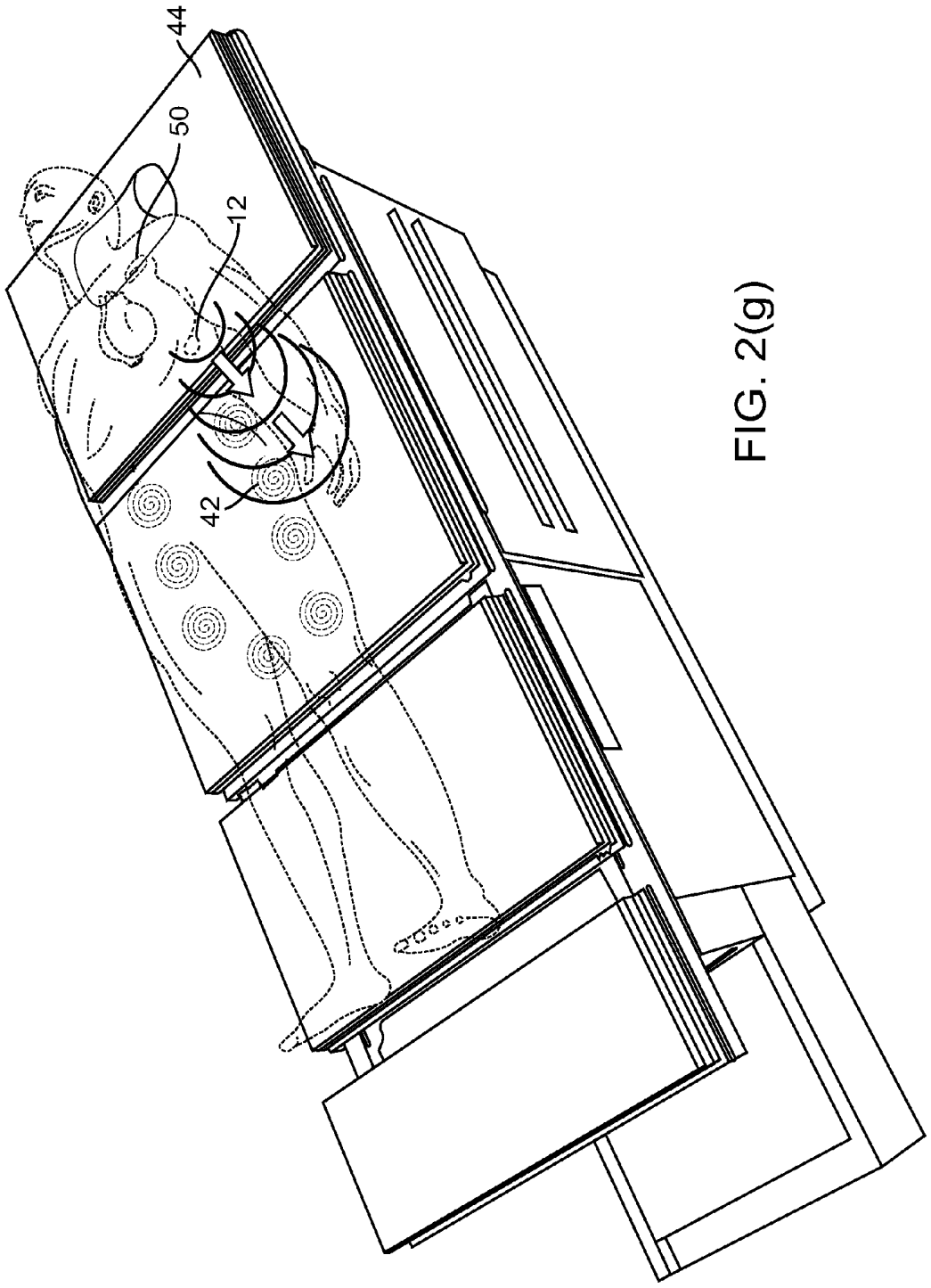

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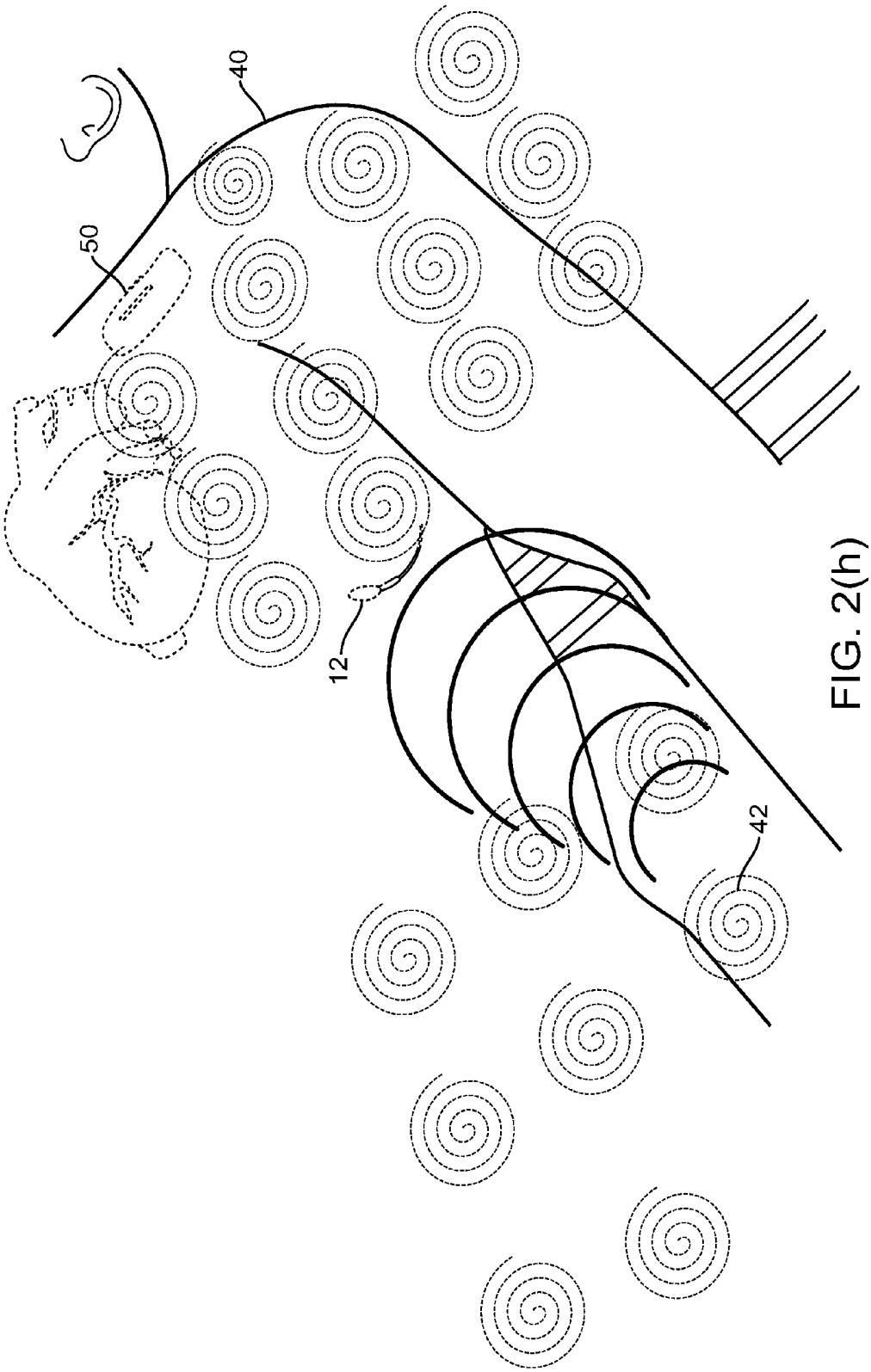

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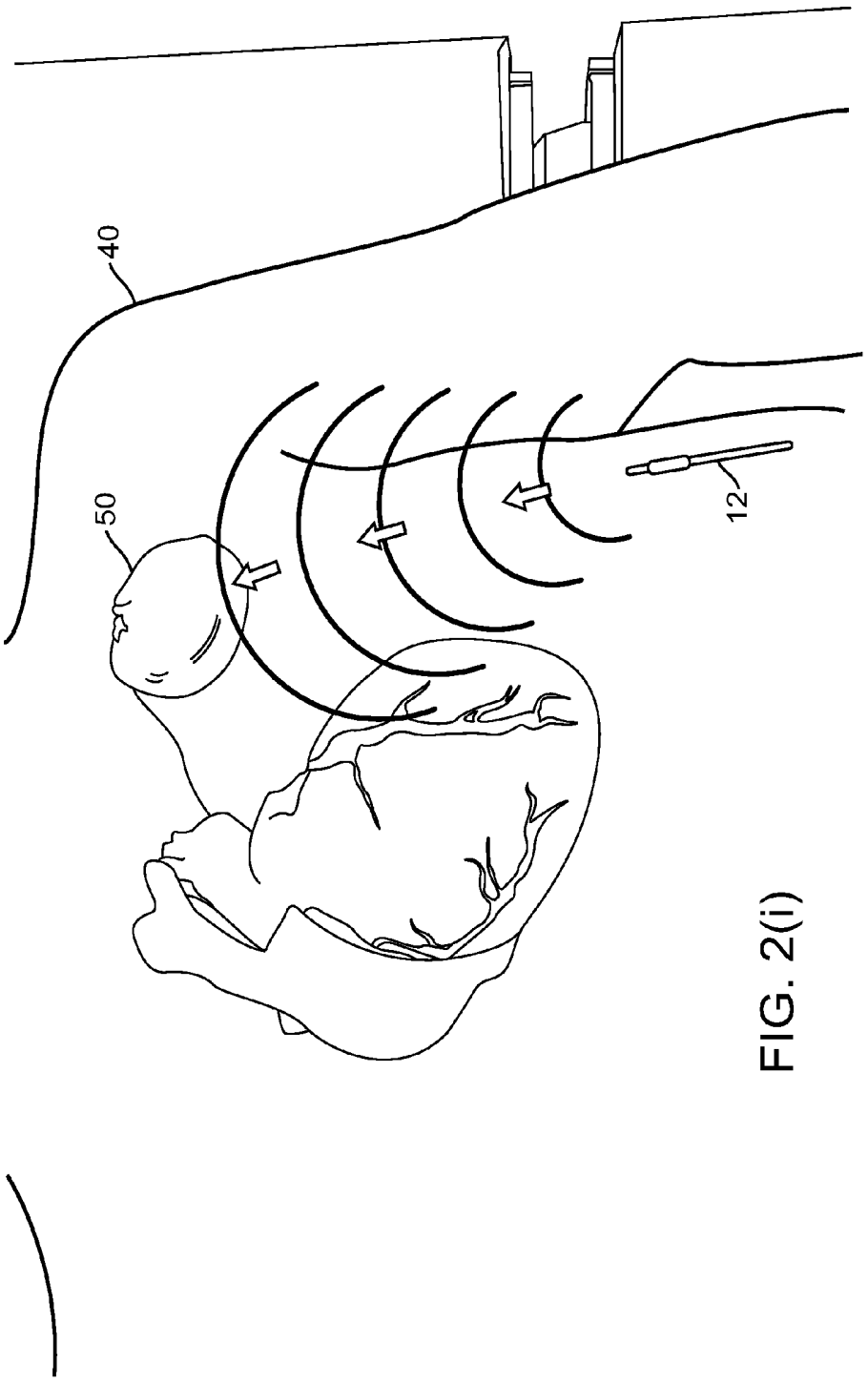

FIG. 2(i)

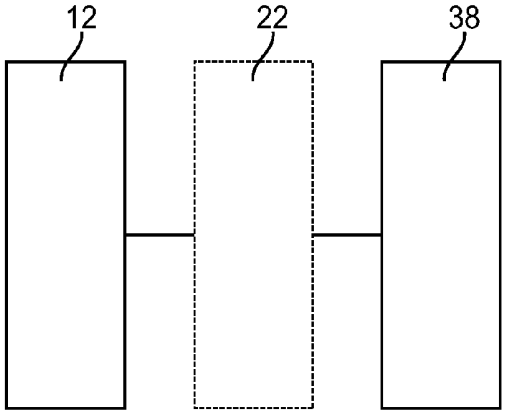

FIG. 6

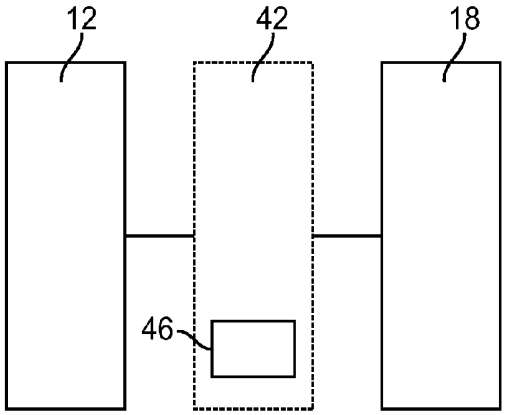

FIG. 7

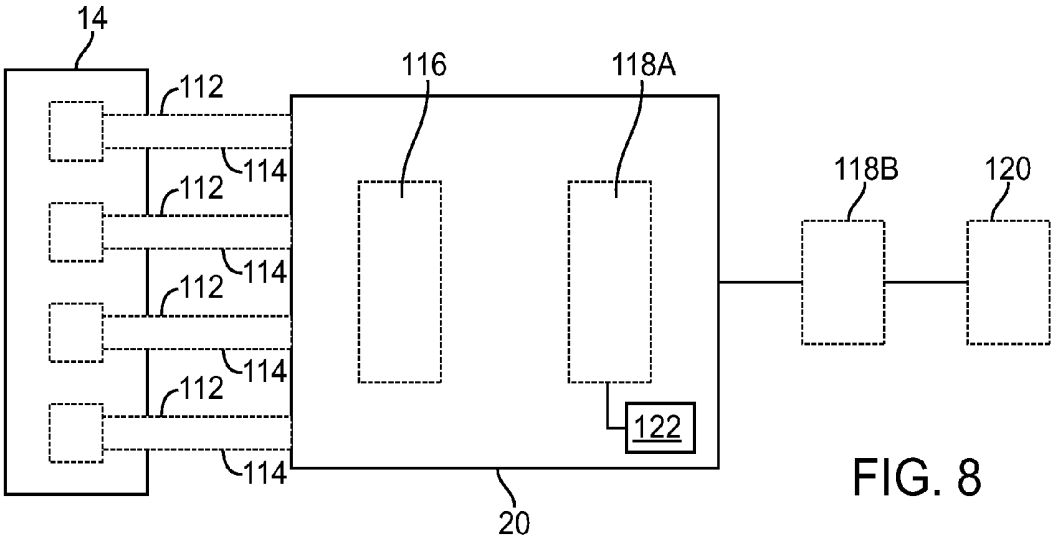

FIG. 8

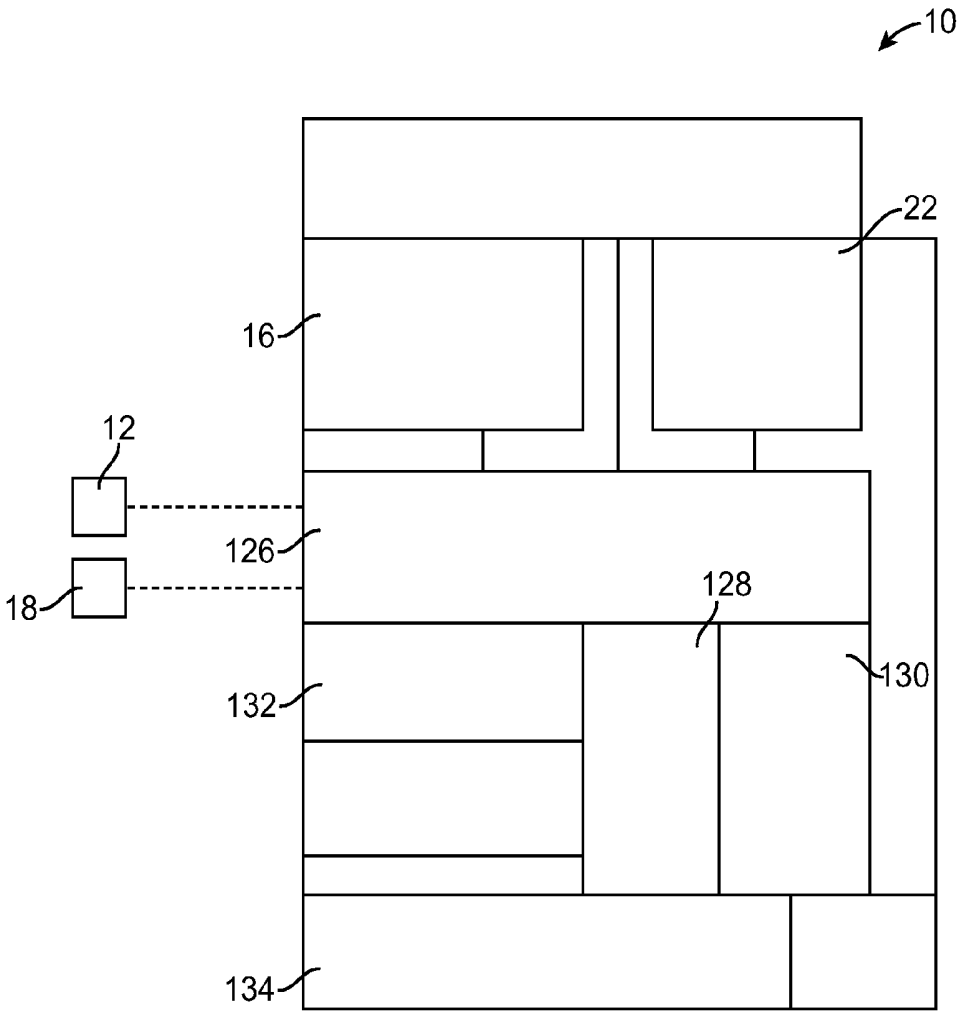

FIG. 9

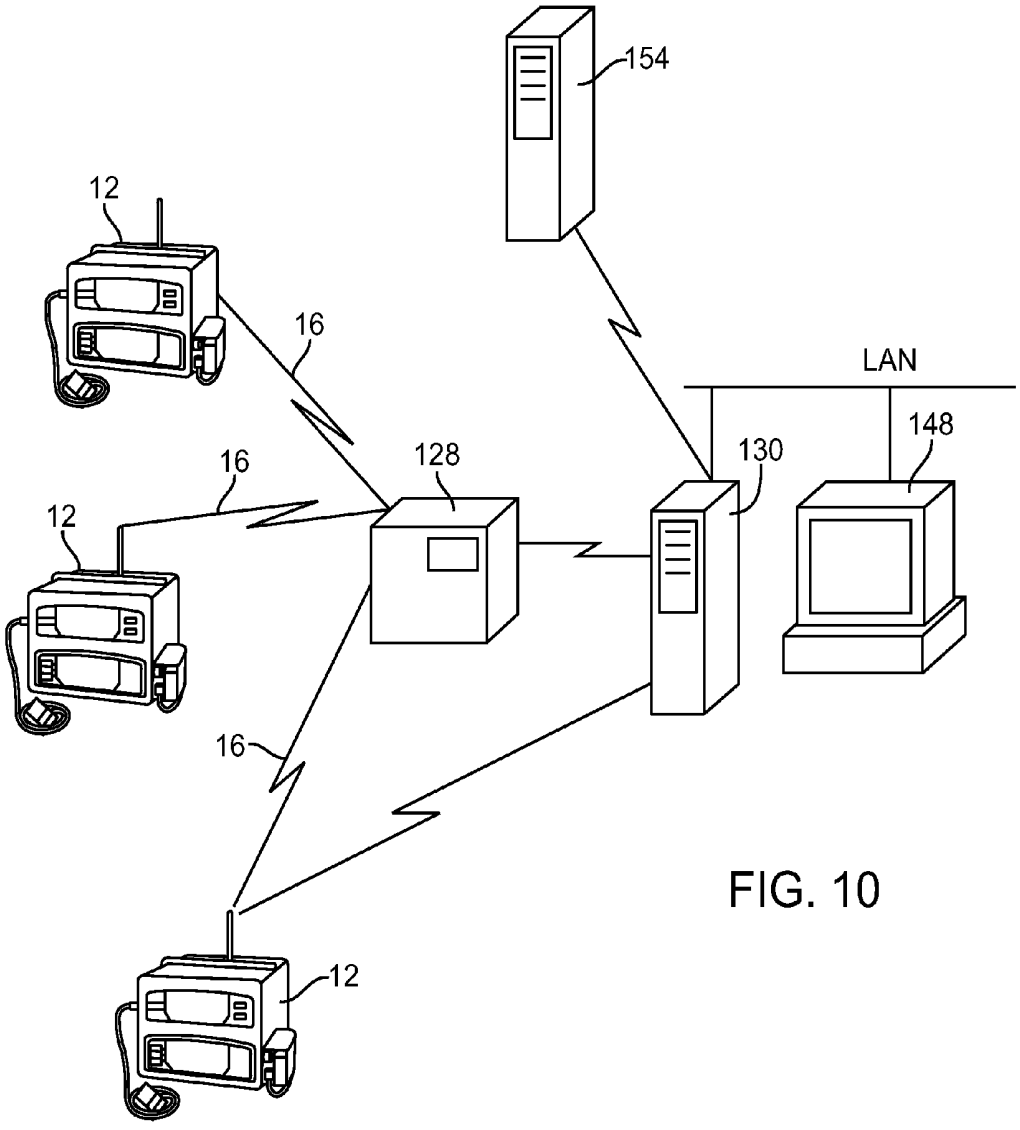

FIG. 10

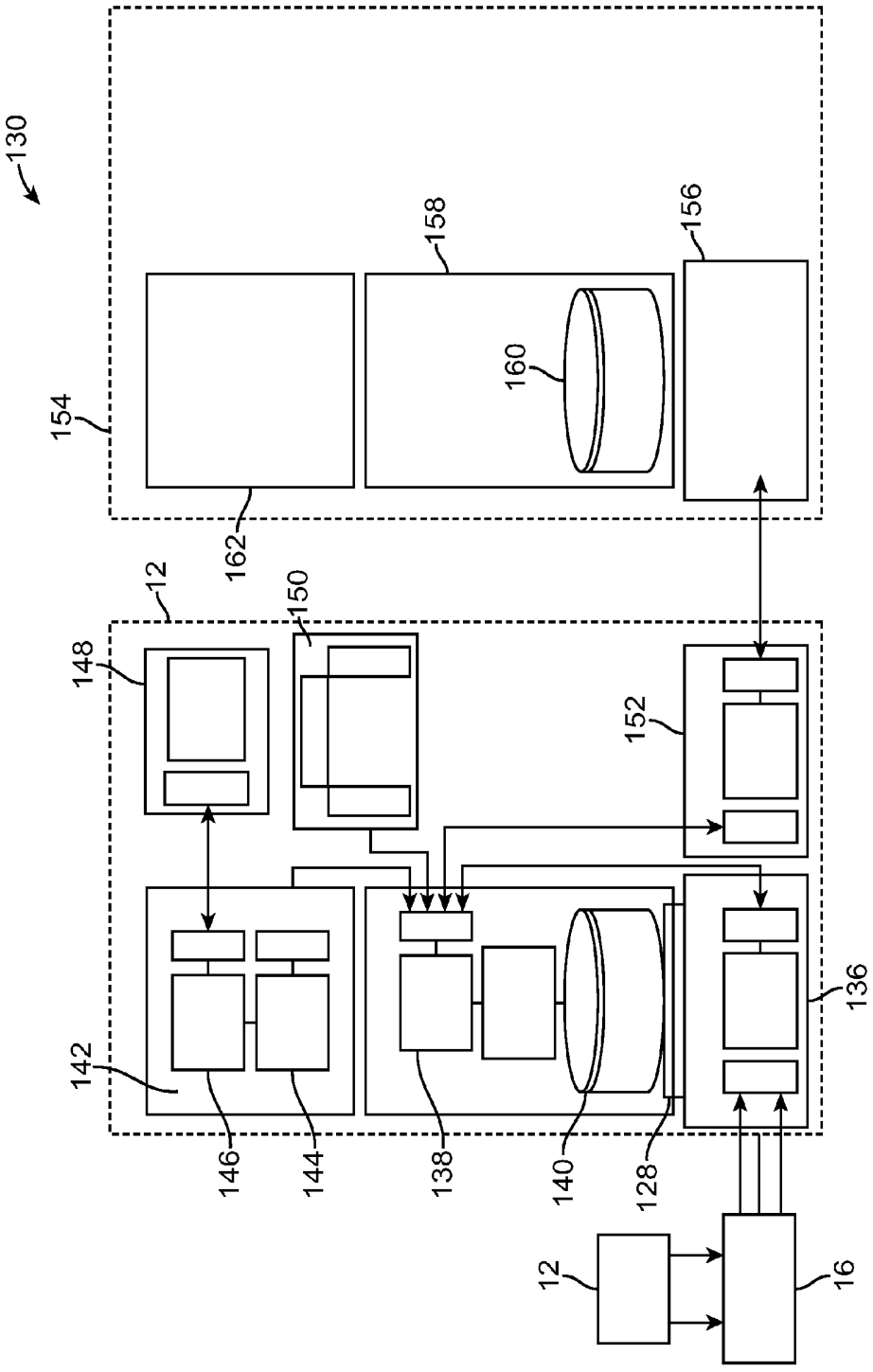
130
154
158
156
160
162
12
150
148
152
142
146
144
138
140
128
136
12
16

FIG. 11

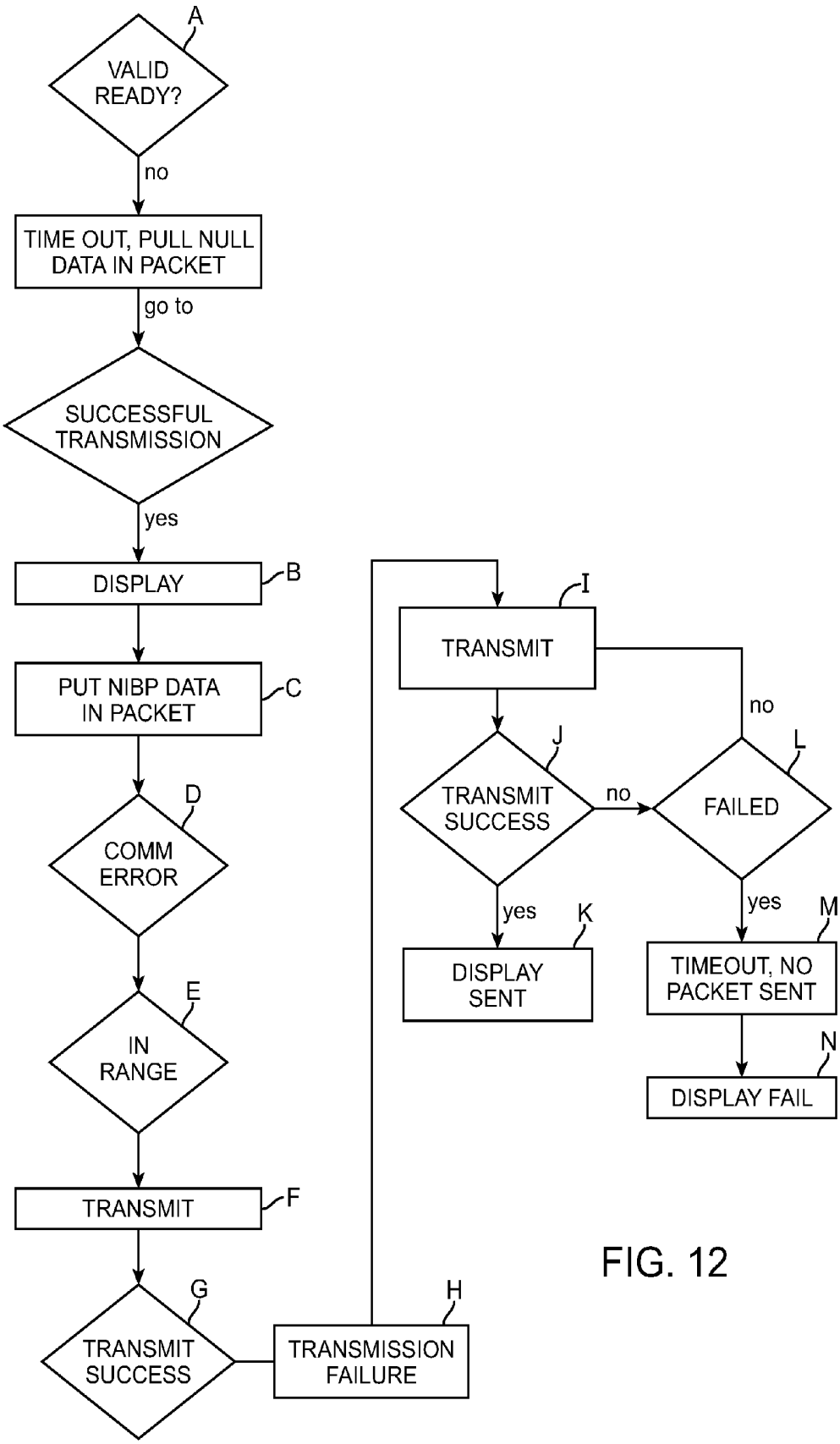
A
VALID READY?
no
TIME OUT, PULL NULL DATA IN PACKET
go to
SUCCESSFUL TRANSMISSION
yes
DISPLAY
B
PUT NIBP DATA IN PACKET
C
D
COMM ERROR
E
IN RANGE
TRANSMIT
F
G
TRANSMIT SUCCESS
H
TRANSMISSION FAILURE
I
TRANSMIT
J
TRANSMIT SUCCESS
no
L
FAILED
yes
K
DISPLAY SENT
yes
M
TIMEOUT, NO PACKET SENT
N
DISPLAY FAIL
no

FIG. 12

INJECTABLE DEVICE FOR PHYSIOLOGICAL MONITORING

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a continuation of pending U.S. patent application Ser. No. 12/209,430 filed Sep. 12, 2008 and titled "Injectable Device for Physiological Monitoring", which claims the benefit under 35 USC 119(e) of U.S. Provisional Application Nos. 60/972,329, 60/972,336, 60/972,354 and 60/972,537, all filed Sep. 14, 2007, and 61/055,666 filed May 23, 2008; the full disclosures of which are incorporated herein by reference in their entirety.

The subject matter of the present application is related to the following applications: 60/972,512; 60/972,616; 60/972,363; 60/972,343; 60/972,581; 60/972,629; 60/972,316; 60/972,333; 60/972,359; 60/972,336; 60/972,340 all of which were filed on Sep. 14, 2007; 61/046,196 filed Apr. 18, 2008; 61/047,875 filed Apr. 25, 2008; 61/055,645, 61/055,656, 61/055,662, all filed May 23, 2008; and 61/079,746 filed Jul. 10, 2008.

The following applications are being filed concurrently with the present application, on Sep. 12, 2008: U.S. patent application Ser. No. 12/209,279 entitled "Multi-Sensor Patient Monitor to Detect Impending Cardiac Decompensation Prediction"; U.S. patent application Ser. No. 12/209,288 entitled "Adherent Device with Multiple Physiological Sensors"; U.S. patent application Ser. No. 12/209,479 entitled "Injectable Physiological Monitoring System"; U.S. patent application Ser. No. 12/209,262 entitled "Adherent Device for Cardiac Rhythm Management"; U.S. patent application Ser. No. 12/209,268 entitled "Adherent Device for Respiratory Monitoring"; U.S. patent application Ser. No. 12/209,269 entitled "Adherent Athletic Monitor"; U.S. patent application Ser. No. 12/209,259 entitled "Adherent Emergency Monitor"; U.S. patent application Ser. No. 12/209,273 entitled "Adherent Device with Physiological Sensors"; U.S. patent application Ser. No. 12/209,276 entitled "Medical Device Automatic Start-up upon Contact to Patient Tissue"; U.S. patent application Ser. No. 12/210,078 entitled "System and Methods for Wireless Body Fluid Monitoring"; U.S. patent application Ser. No. 12/209,265 entitled "Adherent Cardiac Monitor with Advanced Sensing Capabilities"; U.S. patent application Ser. No. 12/209,292 entitled "Adherent Device for Sleep Disordered Breathing"; U.S. patent application Ser. No. 12/209,278 entitled "Dynamic Pairing of Patients to Data Collection Gateways"; U.S. patent application Ser. No. 12/209,508 entitled "Adherent Multi-Sensor Device with Implantable Device Communications Capabilities"; U.S. patent application Ser. No. 12/209,528 entitled "Data Collection in a Multi-Sensor Patient Monitor"; U.S. patent application Ser. No. 12/209,271 entitled "Adherent Multi-Sensor Device with Empathic Monitoring"; U.S. patent application Ser. No. 12/209,274 entitled "Energy Management for Adherent Patient Monitor"; and U.S. patent application Ser. No. 12/209,294 entitled "Tracking and Security for Adherent Patient Monitor."

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to systems and methods for remote patient monitoring, and more particularly, to systems and methods for remote patient monitoring with percutaneously implanted sensors.

Frequent monitoring of patients permits the patients' physician to detect worsening symptoms as they begin to occur, rather than waiting until a critical condition has been reached. As such, home monitoring of patients with chronic conditions is becoming increasingly popular in the health care industry for the array of benefits it has the potential to provide. Potential benefits of home monitoring are numerous and include: better tracking and management of chronic disease conditions, earlier detection of changes in the patient condition, and reduction of overall health care expenses associated with long term disease management. The home monitoring of a number of diverse "chronic diseases" is of interest, where such diseases include diabetes, dietary disorders such as anorexia and obesity, depression, anxiety, epilepsy, respiratory diseases, AIDS and other chronic viral conditions, conditions associated with the long term use of immunosuppressant's, e.g., in transplant patients, asthma, chronic hypertension, chronic use of anticoagulants, and the like.

Of particular interest in the home monitoring sector of the health care industry is the remote monitoring of patients with heart failure (HF), also known as congestive heart failure. HF is a syndrome in which the heart is unable to efficiently pump blood to the vital organs. Most instances of HF occur because of a decreased myocardial capacity to contract (systolic dysfunction). However, HF can also result when an increased pressure-stroke-volume load is imposed on the heart, such as when the heart is unable to expand sufficiently during diastole to accommodate the ventricular volume, causing an increased pressure load (diastolic dysfunction).

In either case, HF is characterized by diminished cardiac output and/or damming back of blood in the venous system. In HF, there is a shift in the cardiac function curve and an increase in blood volume caused in part by fluid retention by the kidneys. Indeed, many of the significant morphologic changes encountered in HF are distant from the heart and are produced by the hypoxic and congestive effects of the failing circulation upon other organs and tissues. One of the major symptoms of HF is edema, which has been defined as the excessive accumulation of interstitial fluid, either localized or generalized.

HF is the most common indication for hospitalization among adults over 65 years of age, and the rate of admission for this condition has increased progressively over the past two decades. It has been estimated that HF affects more than 3 million patients in the U.S. (O'Connell, J. B. et al., *J. Heart Lung Transpl.,* 13(4):S107-112 (1993)).

In the conventional management of HF patents, where help is sought only in crisis, a cycle occurs where patients fail to recognize early symptoms and do not seek timely help from their care-givers, leading to emergency department admissions (Miller, P. Z., *Home monitoring for congestive heart failure patients*, Caring Magazine, 53-54 (August 1995)). Recently, a prospective, randomized trial of 282 patients was conducted to assess the effect of the intervention on the rate of admission, quality of life, and cost of medical care. In this study, a nurse-directed, multi-disciplinary intervention (which consisted of comprehensive education of the patient and family, diet, social-service consultation and planning, review of medications, and intensive assessment of patient condition and follow-up) resulted in fewer readmissions than the conventional treatment group and a concomitant overall decrease in the cost of care (Rich, M. W. et al., *New Engl. J. Med.,* 333:1190-95 (1995)).

Similarly, comprehensive discharge planning and a home follow-up program was shown to decrease the number of

readmissions and total hospital charges in an elderly population (Naylor, M. et al., *Amer. College Physicians,* 120: 999-1006 (1994)). Therefore, home monitoring is of particular interest in the HF management segment of the health care industry.

Another area in which home-monitoring is of particular interest is in the remote monitoring of a patient parameter that provides information on the titration of a drug, particularly with drugs that have a consequential effect following administration, such as insulin, anticoagulants, ACE inhibitors, beta-blockers, diuretics and the like.

Although a number of different home monitoring systems have been developed, there is continued interest in the development of new monitoring systems. Of particular interest would be the development of a system that provides for improved patient compliance, ease of use, etc. Of more particular interest would be the development of such a system that is particularly suited for use in the remote monitoring of patients suffering from HF.

Subcutaneous implantation of sensors has been achieved with an insertion and tunneling tool. The tunneling tool includes a stylet and a peel-away sheath. The tunneling tool is inserted into an incision and the stylet is withdrawn once the tunneling tool reaches a desired position. An electrode segment is inserted into the subcutaneous tunnel and the peel-away sheath is removed. In another delivery device, a pointed tip is inserted through the skin and a plunger is actuated to drive the sensor to its desired location.

In other delivery systems, an implant trocar includes a cannula for puncturing the skin and an obturator for delivering the implant. A spring element received within the cannula prevents the sensor from falling out during the implant process. Another sensor delivery device includes an injector that has a tubular body divided into two adjacent segments with a hollow interior bore. A pair of laterally adjacent tines extend longitudinally from the first segment to the distal end of the tubular body. A plunger rod has an exterior diameter just slightly larger than the interior diameter of the tubular body. With the second segment inserted beneath the skin, the push rod is advanced longitudinally through the tubular body, thereby pushing the sensor through the bore. As the implant and rod pass through the second segment, the tines are forced radially away from each other, thereby dilating or expanding the incision, and facilitating implant. The instrument is removed from the incision following implantation.

For the above and other reasons, it would be desirable to provide an improved percutaneous sensor device for physiological monitoring.

BRIEF SUMMARY OF THE INVENTION

In a first aspect, embodiments of the present invention provide an injectable detecting device for use in physiological monitoring is provided. The device comprises a plurality of sensors axially spaced along a body that provide an indication of at least one physiological event of a patient, a monitoring unit within the body coupled to the plurality of sensors configured to receive data from the plurality of sensors and create processed patient data, a power source within the body coupled to the monitoring unit, and a communication antenna external to the body coupled to the monitoring unit configured to transfer data to/from other devices.

In many embodiments, the monitoring unit includes a processor. In many embodiments, the processor includes program instructions for evaluating values received from the sensors with respect to acceptable physiological ranges for each value received by the processor and determine variances.

In many embodiments, the monitoring unit includes logic resources that determine heart failure status and predict impending decompensation.

In many embodiments, the monitoring unit is configured to perform one or more of, data compression, prioritizing of sensing by a sensor, cycling sensors, monitoring all or some of sensor data by all or a portion of the sensors, sensing by the sensors in real time, noise blanking to provide that sensor data is not stored if a selected noise level is determined, low-power of battery caching and decimation of old sensor data.

In many embodiments, the monitoring unit includes a notification device configured to provide notification when values received from the plurality of sensors are not within acceptable physiological ranges.

In many embodiments, the monitoring unit is configured to serve as a communication hub for multiple medical devices, coordinating sensor data and therapy delivery while transmitting and receiving data from a remote monitoring system.

In many embodiments, the monitoring unit is configured to deactivate selected sensors to reduce redundancy.

In many embodiments, each of a sensor is selected from at least one of, bioimpedance, heart rate, heart rhythm, HRV, HRT, heart sounds, respiratory sounds, respiratory rate and respiratory rate variability, blood pressure, activity, posture, wake/sleep, orthopnea, temperature, heat flux and an accelerometer.

In many embodiments, each of a sensor is an activity sensor selected from at least one of, ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise and posture.

In many embodiments, the sensors are made of at least a material selected from, silicone, polyurethane, Nitinol, titanium, a biocompatible material, ceramics and a bioabsorbable material.

In many embodiments, at least a portion of sensors of the plurality of sensors have an insulative material selected from, PEEK, ETFE, PTFE, and polyimide, silicon, polyurethane.

In many embodiments, at least a portion of sensors of the plurality of sensors have openings or an absorbent material configured to sample a hydration level or electrolyte level in a surrounding tissue site of the plurality of sensors.

In many embodiments, the plurality of sensors includes current delivery electrodes and sensing electrodes.

In many embodiments, the outputs of the plurality of sensors is used to calculate and monitor blended indices. The blended indices include at least one of, heart rate (HR) or respiratory rate (RR) response to activity, HR/RR response to posture change, HR+RR, HR/RR+bioimpedance, and/or minute ventilation/accelerometer.

In many embodiments, the body and antenna are injectable in the patient by at least one of, catheter delivery, blunt tunneling, insertion with a needle, by injection, with a gun or syringe device with a stiffening wire stylet, guidewire, or combination of stylet or guidewire with a catheter.

In many embodiments, the body is flexible.

In many embodiments, at least a portion of the body has a drug eluting coating.

In many embodiments, the power source comprises a rechargeable battery transcutaneously chargeable with an external unit.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram illustrating one embodiment of a patient monitoring system of the present invention.

FIG. **2**(*a*) illustrates one embodiment of an implanted sensor device of the present invention that is injectable and includes multiple sensors, power and communication and a communication antenna.

FIG. **2**(*b*) illustrates the insertion of the device of FIG. **2**(*a*) into an injector.

FIG. **2**(*c*) illustrates the device of FIG. **2**(*a*) in the injector and ready to be introduced into the patient.

FIG. **2**(*d*) illustrates the implanted sensor device of FIG. **2**(*a*).

FIG. **2**(*e*) illustrates the implanted sensor device of FIG. **2**(*a*) as it flexes from a rigid state in the body.

FIG. **2**(*f*) illustrates a patient laying on top of a matt that has coils, where downloading of patient data and recharging can occur via the matt.

FIG. **2**(*g*) illustrates the patient laying on top of the matt from FIG. **2**(*f*) and the downloading of data from the sensors to the matt.

FIG. **2**(*h*) is a close up view of FIG. **2**(*g*), showing the downloading of data from the sensors to the matt, and then transfer of the data from the matt to a modem.

FIG. **2**(*i*) illustrates a patient with an implanted device, such as a pacing device, and the implanted device of FIG. **2**(*a*) in communication with the implanted device.

FIG. **3** illustrates one embodiment of an energy management device that is coupled to the plurality of sensors of FIG. **1**.

FIG. **4** illustrates one embodiment of present invention illustrating logic resources configured to receive data from the sensors and/or the processed patient for monitoring purposes, analysis and/or prediction purposes.

FIG. **5** illustrates an embodiment of the patient monitoring system of the present invention with a memory management device.

FIG. **6** illustrates an embodiment of the patient monitoring system of the present invention with an external device coupled to the sensors.

FIG. **7** illustrates an embodiment of the patient monitoring system of the present invention with a notification device.

FIG. **8** is a block diagram illustrating an embodiment of the present invention with sensor leads that convey signals from the sensors to a monitoring unit at the detecting system, or through a wireless communication device to a remote monitoring system.

FIG. **9** is a block diagram illustrating an embodiment of the present invention with a control unit at the detecting system and/or the remote monitoring system.

FIG. **10** is a block diagram illustrating an embodiment of the present invention where a control unit encodes patient data and transmits it to a wireless network storage unit at the remote monitoring system.

FIG. **11** is a block diagram illustrating one embodiment of an internal structure of a main data collection station at the remote monitoring system of the present invention.

FIG. **12** is a flow chart illustrating an embodiment of the present invention with operation steps performed by the system of the present invention in transmitting information to the main data collection station.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to a heart failure patient management system consisting of one or more subcutaneously injectable devices inserted below the patient's skin. The system continuously monitors physiological parameters, communicates wirelessly with a remote center, and provides alerts when necessary.

The heart failure patient management system monitors physiological parameters and uses a proprietary algorithm to determine heart failure status and predict impending decompensation. The one or more injectable devices communicate with a remote center, preferably via an intermediate device in the patient's home. In some embodiments, the injectable device monitoring unit receives the data and applies the prediction algorithm. When a flag is raised, the center may communicate with the patient, hospital, nurse, and/or physician to allow for therapeutic intervention to prevent decompensation.

The injectable devices would perform the following functions: initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying.

The system contains one or more injectable devices, each consisting of a hermetically sealed package containing and contains a power source, memory, logic, wireless communication capabilities, and a subset of the following physiological sensors: bioimpedance, heart rate (ave, min, max), heart rhythm, HRV, HRT, heart sounds (e.g. S3), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, and temperature/heat flux. The activity sensor may be one of the following: ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, and posture.

The injectable devices may communicate directly with each other, allow for coordinated sensing between the units. The injectable devices may also communicate with an external unit (either adherent, wearable, or non-wearable) or with an implantable device, such as a cardiac rhythm management device.

The injectable devices wirelessly communicates with a remote center. Such communication may occur directly (via a cellular or Wi-Fi network), or indirectly through an intermediate device. The intermediate device may consist of multiple devices which communicate wired or wirelessly to relay data to the remote center.

The injectable devices may have a rechargeable battery, which is transcutaneously charged with an external unit.

The injectable device package may contain one or more features to allow for tissue anchoring. Such features may include passive or actively-deployed barbs or anchors, tissue adhesion pads, and/or suture loops. Tissue adhesion pads (or grooves or holes) may be designed to be small enough to stabilize the device while allowing for easy extraction.

The injectable devices may use one or more of the following component technologies: flex circuits, thin film resistors, and organic transistors.

The injectable devices may have one of the following form factors: cylinder, dog-bone, half dog-bone, trapezoidal cross-section, semicircular cross-section, star-shaped cross-section, v-shaped cross-section, helical/spiral, fin electrodes, and linear device with a radius of curvature to match radius of implant site.

The injectable devices may be constructed of one or more of the following materials: silicone, polyurethane, Nitinol, a biocompatible material, and a bioabsorbable material. The electrodes may use one or more of the following metal conductors: platinum, MP35N, MP35N/Ag core, platinum/tantalum core, stainless steel, and titanium. Insulative materials may include one or more of the following: PEEK,

ETFE, PTFE, and polyimide. Ceramics may be used to enclose electronics (especially the RF unit, to enable RF transmission).

The injectable devices may contain a drug eluting coating, which would slowly release a drug such as an antibiotic or anti-inflammatory agent.

The injectable devices may contain openings and/or absorbent material, through which the device may sample the hydration level and/or electrolytes in the surrounding tissue.

The injectable devices may include multiple features to enhance physiological sensing performance. Such features may include multiple sensing vectors, including redundant vectors. This configuration would allow the injectable devices to determine the optimal sensing configuration, and electronically reposition each sensing vector.

The injectable device electrodes may be partially masked to minimize contamination of the sensed signal. The size and shape of current delivery electrodes (for bioimpedance) and sensing electrodes would be optimized to maximize sensing performance.

While the present invention is intended for heart failure patient monitoring, the system may be applicable to any human application in which wireless physiological monitoring and prediction is required.

The percutaneous sensing device may be used in conjunction with remote patient monitoring to track a patient's physiological status, detect and predict negative physiological events. In one embodiment, the implanted sensing device includes a plurality of sensors that are used in combination to enhance detection and prediction capabilities as more fully explained below.

In one embodiment, illustrated in FIG. **1**, the system **10** includes an injectable detecting system **12** that includes a plurality of sensors **14** and/or electrodes, that provide an indication of at least one physiological event of a patient. The injectable detecting system **12** is inserted subcutaneously. In one embodiment the injectable detecting system **12** is inserted in the patient's thorax. The system **10** also includes a wireless communication device **16**, coupled to the plurality of sensors **14**. The wireless communication device transfers patient data directly or indirectly from the plurality of sensors **14** to a remote monitoring system **18**. The remote monitoring system **18** uses data from the sensors to determine the patient's status. The system **10** can continuously, or non-continuously, monitor the patient, alerts are provided as necessary and medical intervention is provided when required. In one embodiment, the wireless communication device **16** is a wireless local area network for receiving data from the plurality of sensors.

The sensors **14** are subcutaneously inserted with the injectable detecting system **12** that is catheter based, blunt tunneling (with either a separate tunneling tool or a wire-stiffened lead), needle insertion gun or syringe-like injection. The injectable detecting system **12** can be flexible, and be used with a stiffening wire, stylet, catheter or guidewire. The injectable detecting system **12** can include any of the following to assist in subsequent extraction: (i) an isodiametric profile, (ii) a breakaway anchor, (iii) a bioabsorbable material, (iv) coatings to limit tissue in-growth, (v) an electrically activated or fusable anchor, and the like. The injectable detecting system **12** can be modular, containing multiple connected components, a subset of which is easily extractable.

The injectable detecting system **12** can be inserted in the patient in a non-sterile or sterile setting, non-surgical setting or surgical setting, implanted with our without anesthesia and implanted with or without imaging assistance from an imaging system. The injectable detecting system **12** can be anchored in the patient by a variety of means including but not limited to, barbs, anchors, tissue adhesion pads, suture loops, with sensor shapes that conform to adjacent tissue anatomy or provide pressure against the adjacent tissue, with the use of self-expanding materials such as a nitinol anchor and the like.

FIG. **2**(*a*) shows one embodiment of the injectable detecting system **12** with sensors **14** that is introduced below the skin surface. The sensor device includes power and communication elements **32**, and a communication antenna **34**. The antenna may be a self expanding antenna expandable from a first compressed shape to a second expanded shape, such as disclosed in U.S. Provisional Application No. 61/084,567, filed Jul. 29, 2008 entitled "Communication-Anchor Loop For Injectable Device", the full disclosure of which is incorporated herein by reference. FIG. **2**(*b*) illustrates the injectable detecting system **12** being loaded into an injector **36** having a needle end **38**. FIG. **2**(*c*) shows the injectable detecting system **12** being introduced subcutaneously into a patient **40**. FIG. **2**(*d*) shows the injectable detecting system **12** being implanted subcutaneously from the injector **36**. In FIG. **2**(*e*), the injector **36** is removed and the injectable detecting system **12** flexes from a rigid configuration.

In one embodiment, illustrated in FIGS. **2**(*f*) and **2**(*g*), recharging coils **42** are placed in a mat **44** on the patient's bed, such as under a mattress pad. Recharging of the sensors/battery and data transfer can occur during sleep of the patient. The rechargeable batteries can be transcutaneously charged with an external unit other than the mat. FIG. **2**(*g*) shows downloading from the sensors and data transfer during sleep of the patient. In FIG. **2**(*h*), the sensors download data to the mat and a modem is used from data transfer. In FIG. **2**(I), an implantable device **50**, such as a pacing device communicates with the injectable detecting system **12** of FIG. **2**(*a*).

In one embodiment, the wireless communication device **16** is configured to receive instructional data from the remote monitoring system and communicate instructions to the injectable detecting system.

As illustrated in FIG. **3**, an energy management device **19** is coupled to the plurality of sensors. In one embodiment, the energy management device **19** is part of the detecting system. In various embodiments, the energy management device **19** performs one or more of, modulate drive levels per sensed signal of a sensor **14**, modulate a clock speed to optimize energy, watch cell voltage drop—unload cell, coulomb-meter or other battery monitor, sensor dropoff at an end of life of a battery coupled to a sensor, battery end of life dropoff to transfer data, elective replacement indicator, call center notification, sensing windows by the sensors **14** based on a monitored physiological parameter and sensing rate control.

In one embodiment, the energy management device **19** is configured to manage energy by at least one of, a thermo-electric unit, kinetics, fuel cell, nuclear power, a micro-battery and with a rechargeable device.

The system **10** is configured to automatically detect events. The system **10** automatically detects events by at least one of, high noise states, physiological quietness, sensor continuity and compliance. In response to a detected physiological event, patient states are identified when data collection is inappropriate. In response to a detected physiological event, patient states are identified when data collection is desirable. Patient states include, physiological

quietness, rest, relaxation, agitation, movement, lack of movement and a patient's higher level of patient activity.

The system uses an intelligent combination of sensors to enhance detection and prediction capabilities, as more fully discloses in U.S. patent application Ser. Nos. 60/972,537 filed Sep. 14, 2008 and 61/055,666 filed May 23, 2008, both titled "Adherent Device with Multiple Physiological Sensors", incorporated herein by reference, and as more fully explained below.

In one embodiment, the injectable detecting system **12** communicates with the remote monitoring system **18** periodically or in response to a trigger event. The trigger event can include but is not limited to at least one of, time of day, if a memory is full, if an action is patient initiated, if an action is initiated from the remote monitoring system, a diagnostic event of the monitoring system, an alarm trigger, a mechanical trigger, and the like.

The injectable detecting system **12** can continuously, or non-continuously, monitor the patient, alerts are provided as necessary and medical intervention is provided when required. In one embodiment, the wireless communication device **16** is a wireless local area network for receiving data from the plurality of sensors in the injectable detecting system.

A processor **20** is coupled to the plurality of sensors **14** in the injectable detecting system **12**. The processor **20** receives data from the plurality of sensors **14** and creates processed patient data. In one embodiment, the processor **20** is at the remote monitoring system **18**. In another embodiment, the processor **20** is at the detecting system **12**. The processor **20** can be integral with a monitoring unit **22** that is part of the injectable detecting system **12** or part of the remote monitoring system **18**.

The processor **20** has program instructions for evaluating values received from the sensors **14** with respect to acceptable physiological ranges for each value received by the processor **20** and determine variances. The processor **20** can receive and store a sensed measured parameter from the sensors **14**, compare the sensed measured value with a predetermined target value, determine a variance, accept and store a new predetermined target value and also store a series of questions from the remote monitoring system **18**.

As illustrated in FIG. **4**, logic resources **24** are provided that take the data from the sensors **14**, and/or the processed patient data from the processor **20**, to predict an impending decompensation. The logic resources **24** can be at the remote monitoring system **18** or at the detecting system **12**, such as in the monitoring unit **22**.

In one embodiment, a memory management device **25** is provided as illustrated in FIG. **5**. In various embodiments, the memory management device **25** performs one or more of data compression, prioritizing of sensing by a sensor **14**, monitoring all or some of sensor data by all or a portion of the sensors **14**, sensing by the sensors **14** in real time, noise blanking to provide that sensor data is not stored if a selected noise level is determined, low-power of battery caching and decimation of old sensor data.

The injectable detecting system **12** can provide a variety of different functions, including but not limited to, initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying of a physiological event of the patient. The injectable detecting system **12** can be sealed, such as housed in a hermetically sealed package. In one embodiment, at least a portion of the sealed packages include a power source, a memory, logic resources and a wireless communication device. In one embodiment, an antenna is included that is exterior to the sealed package of the injectable detecting system **12**. In one embodiment, the sensors **14** include, flex circuits, thin film resistors, organic transistors and the like. The sensors **14** can include ceramics, titanium PEEK, along with a silicon, PU or other insulative adherent sealant, to enclose the electronics. Additionally, all or part of the injectable detecting system **12** can include drug eluting coatings, including but not limited to, an antibiotic, anti-inflammatory agent and the like.

A wide variety of different sensors **14** can be utilized, including but not limited to, bioimpedance, heart rate, heart rhythm, HRV, HRT, heart sounds, respiration rate, respiration rate variability, respiratory sounds, SpO_2, blood pressure, activity, posture, wake/sleep, orthopnea, temperature, heat flux, an accelerometer, glucose sensor, other chemical sensors associated with cardiac conditions, and the like. A variety activity sensors can be utilized, including but not limited to a, ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture and the like.

The output of the sensors **14** can have multiple features to enhance physiological sensing performance. These multiple features have multiple sensing vectors that can include redundant vectors. The sensors **14** can include current delivery electrodes and sensing electrodes. Size and shape of current delivery electrodes, and the sensing electrodes, can be optimized to maximize sensing performance. The system **10** can be configured to determine an optimal sensing configuration and electronically reposition at least a portion of a sensing vector of a sensing electrode. The multiple features enhance the system's **10** ability to determine an optimal sensing configuration and electronically reposition sensing vectors. In one embodiment, the sensors **14** can be partially masked to minimize contamination of parameters sensed by the sensors **14**.

The size and shape of current delivery electrodes, for bioimpedance, and sensing electrodes can be optimized to maximize sensing performance Additionally, the outputs of the sensors **14** can be used to calculate and monitor blended indices. Examples of the blended indices include but are not limited to, heart rate (HR) or respiratory rate (RR) response to activity, HR/RR response to posture change, HR+RR, HR/RR+bioimpedance, and/or minute ventilation/accelerometer and the like.

The sensors **14** can be cycled in order to manage energy, and different sensors **14** can sample at different times. By way of illustration, and without limitation, instead of each sensor **14** being sampled at a physiologically relevant interval, e.g. every 30 seconds, one sensor **14** can be sampled at each interval, and sampling cycles between available sensors.

By way of illustration, and without limitation, the sensors **14** can sample 5 seconds for every minute for ECG, once a second for an accelerometer sensor, and 10 seconds for every 5 minutes for impedance.

In one embodiment, a first sensor **14** is a core sensor **14** that continuously monitors and detects, and a second sensor **14** verifies a physiological status in response to the core sensor **14** raising a flag. Additionally, some sensors **14** can be used for short term tracking, and other sensors **14** used for long term tracking.

The injectable detecting system **12** is inserted into the patient by a variety of means, including but not limited to, catheter delivery, blunt tunneling, insertion with a needle, by injection, with a gun or syringe device with a stiffening wire and stylet and the like. The sensors **14** can be inserted in the patient in a non-sterile or sterile setting, non-surgical setting or surgical setting, injected with our without anesthesia and

injected with or without imaging assistance. The injectable detecting system **12** can be anchored in the patient by a variety of means including but not limited to, barbs, anchors, tissue adhesion pads, suture loops.

The injectable detecting system **12** can come in a variety of different form factors including but not limited to, cylinder, dog-bone, half dog-bone, trapezoidal cross-section, semicircular cross-section, star-shaped cross-section, v-shaped cross-section, L-shaped, canted, W shaped, or in other shapes that assist in their percutaneous delivery, S-shaped, sine-wave shaped, J-shaped, any polygonal shape, helical/spiral, fin electrodes, and linear device with a radius of curvature to match a radius of the injection site and the like. Further, the injectable detecting system **12** can have flexible body configurations. Additionally, the injectable detecting system **12** can be configured to deactivate selected sensors **14** to reduce redundancy.

The sensors **14** can be made of a variety of materials, including but not limited to, silicone, polyurethane, Nitinol, a biocompatible material, a bioabsorbable material and the like. Electrode sensors **14** can have a variety of different conductors, including but not limited to, platinum, MP35N which is a nickel-cobalt-chromium-molybdenum alloy, MP35N/Ag core, platinum/tantalum core, stainless steel, titanium and the like. The sensors **14** can have insulative materials, including but not limited to, polyetheretherketone (PEEK), ethylene-tetrafluoroethylene (ETFE), polytetrafluoroethlene (PTFE), polyimide, silicon, polyurethane, and the like. Further, the sensors **14** can have openings, or an absorbent material, configured to sample a hydration level or electrolyte level in a surrounding tissue site at the location of the sensor **14**. The sensor **14** electrodes can be made of a variety of materials, including but not limited to platinum, iridium, titanium, and the like. Electrode coatings can be included, such as iridium oxide, platinum black, TiN, and the like.

The injectable detecting system **12** can include one or more a rechargeable batteries **36** that can be transcutaneously chargeable with an external unit.

Referring to FIG. **6**, in one embodiment, an external device **38**, including a medical treatment device, is coupled to the injectable detecting system **12**. The external device **38** can be coupled to a monitoring unit **22** that is part of the injectable detecting system **12**, or in direct communication with the sensors **14**. A variety of different external devices **38** can be used, including but not limited to, a weight scale, blood pressure cuff, cardiac rhythm management device, a medical treatment device, medicament dispenser, glucose monitor, insulin pump, drug delivery pumps, drug delivery patches, and the like. Suitable cardiac rhythm management devices include but are not limited to, Boston Scientific's Latitude system, Medtronic's CareLink system, St. Jude Medical's HouseCall system and the like. Such communication may occur directly or via an external translator unit.

The external device **38** can be coupled to an auxiliary input of the monitoring unit **22** at the injectable detecting system **12** or to the monitoring system **22** at the remote monitoring system **18**. Additionally, an automated reader can be coupled to an auxiliary input in order to allow a single monitoring unit **22** to be used by multiple patients. As previously mentioned above, the monitoring unit **22** can be at the remote monitoring system **18** and each patient can have a patient identifier (ID) including a distinct patient identifier. In addition, the ID identifier can also contain patient specific configuration parameters. The automated reader can scan the patient identifier ID and transmit the patient ID number with a patient data packet such that the main data collection station can identify the patient.

It will be appreciated that other medical treatment devices can also be used. The injectable detecting system **12** can communicate wirelessly with the external devices **38** in a variety of ways including but not limited to, a public or proprietary communication standard and the like. The injectable detecting system **12** can be configured to serve as a communication hub for multiple medical devices, coordinating sensor data and therapy delivery while transmitting and receiving data from the remote monitoring system **18**.

In one embodiment, the injectable detecting system **12** coordinate data sharing between the external systems **38** allowing for sensor integration across devices. The coordination of the injectable detecting system **12** provides for new pacing, sensing, defibrillation vectors, and the like.

In one embodiment, the processor **20** is included in the monitoring unit **22** and the external device **38** is in direct communication with the monitoring unit **22**.

In another embodiment, illustrated in FIG. **7**, a notification device **42** is coupled to the injectable detecting system **12** and the remote monitoring system **18**. The notification device **42** is configured to provide notification when values received from the sensors **14** are not within acceptable physiological ranges. The notification device **42** can be at the remote monitoring system **18** or at the monitoring unit **22** that is part of the injectable detecting system **12**. A variety of notification devices **42** can be utilized, including but not limited to, a visible patient indicator, an audible alarm, an emergency medical service notification, a call center alert, direct medical provider notification and the like. The notification device **42** provides notification to a variety of different entities, including but not limited to, the patient, a caregiver, the remote monitoring system, a spouse, a family member, a medical provider, from one device to another device such as the external device **38**, and the like.

Notification can be according to a preset hierarchy. By way of illustration, and without limitation, the preset hierarchy can be, patient notification first and medical provider second, patient notification second and medical provider first, and the like. Upon receipt of a notification, a medical provider, the remote monitoring system **18**, or a medical treatment device can trigger a high-rate sampling of physiological parameters for alert verification.

The system **10** can also include an alarm **46**, that can be coupled to the notification device **42**, for generating a human perceptible signal when values received from the sensors **14** are not within acceptable physiological ranges. The alarm **46** can trigger an event to render medical assistance to the patient, provide notification as set forth above, continue to monitor, wait and see, and the like.

When the values received from the sensors **14** are not within acceptable physiological ranges the notification is with the at least one of, the patient, a spouse, a family member, a caregiver, a medical provider and from one device to another device, to allow for therapeutic intervention to prevent decompensation.

In another embodiment, the injectable detecting system **12** can switch between different modes, wherein the modes are selected from at least one of, a stand alone mode with communication directly with the remote monitoring system **18**, communication with an implanted device, communication with a single implanted device, coordination between different devices (external systems) coupled to the plurality of sensors and different device communication protocols.

By way of illustration, and without limitation, the patient can be a congestive heart failure patient. Heart failure status

is determined by a weighted combination change in sensor outputs and be determined by a number of different means, including but not limited to, (i) when a rate of change of at least two sensor outputs is an abrupt change in the sensor outputs as compared to a change in the sensor outputs over a longer period of time, (ii) by a tiered combination of at least a first and a second sensor output, with the first sensor output indicating a problem that is then verified by at least a second sensor output, (iii) by a variance from a baseline value of sensor outputs, and the like. The baseline values can be defined in a look up table.

In another embodiment, heart failure status is determined using three or more sensors by at least one of, (i) when the first sensor output is at a value that is sufficiently different from a baseline value, and at least one of the second and third sensor outputs is at a value also sufficiently different from a baseline value to indicate heart failure status, (ii) by time weighting the outputs of the first, second and third sensors, and the time weighting indicates a recent event that is indicative of the heart failure status and the like.

In one embodiment, the wireless communication device **16** can include a, modem, a controller to control data supplied by the injectable detecting system **12**, serial interface, LAN or equivalent network connection and a wireless transmitter. Additionally, the wireless communication device **16** can include a receiver and a transmitter for receiving data indicating the values of the physiological event detected by the plurality of sensors, and for communicating the data to the remote monitoring system **18**. Further, the wireless communication device **16** can have data storage for recording the data received from the injectable detecting system **12** and an access device for enabling access to information recording in the data storage from the remote monitoring system **18**.

In various embodiments, the remote monitoring system **18** can include a, receiver, a transmitter and a display for displaying data representative of values of the one physiological event detected by the injectable detecting system **12**. The remote monitoring system can also include a, data storage mechanism that has acceptable ranges for physiological values stored therein, a comparator for comparing the data received from the injectable detecting system **12** with the acceptable ranges stored in the data storage device and a portable computer. The remote monitoring system **18** can be a portable unit with a display screen and a data entry device for communicating with the wireless communication device **16**.

Referring now to FIG. **8**, for each sensor **14**, a sensor lead **112** and **114** conveys signals from the sensor **14** to the monitoring unit **22** at the injectable detecting system **12**, or through the wireless communication device **16** to the remote monitoring system **18**.

In one embodiment, each signal from a sensor **14** is first passed through a low-pass filter **116**, at the injectable detecting system **12** or at the remote monitoring system **18**, to smooth the signal and reduce noise. The signal is then transmitted to an analog-to-digital converter **118**A, which transforms the signals into a stream of digital data values that can be stored in a digital memory **118**B. From the digital memory **118**B, data values are transmitted to a data bus **120**, along which they are transmitted to other components of the circuitry to be processed and archived. From the data bus **120**, the digital data can be stored in a non-volatile data archive memory. The digital data can be transferred via the data bus **120** to the processor **20**, which processes the data based in part on algorithms and other data stored in a non-volatile program memory.

The injectable detecting system **12** can also include a power management module **122** configured to power down certain components of the system, including but not limited to, the analog-to-digital converters **118**A and **124**, digital memories **118**B and the non-volatile data archive memory and the like, between times when these components are in use. This helps to conserve battery power and thereby extend the useful life. Other circuitry and signaling modes may be devised by one skilled in the art.

As can be seen in FIG. **9**, a control unit **126** is included at the detecting system **12**, the remote monitoring system **18**, or at both locations.

In one embodiment, the control unit **126** can be a microprocessor, for example, a Pentium or 486 processor. The control unit **126** can be coupled to the sensors **14** directly at the injectable detecting system **12**, indirectly at the injectable detecting system **12** or indirectly at the remote monitoring system **18**. Additionally the control unit **126** can be coupled to one or more devices, for example, a blood pressure monitor, cardiac rhythm management device, scale, a device that dispenses medication, a device that can indicate the medication has been dispensed, and the like.

The control unit **126** can be powered by AC inputs which are coupled to internal AC/DC converters **134** that generate multiple DC voltage levels. After the control unit **126** has collected the patient data from the sensors **14**, the control unit **126** encodes the recorded patient data and transmits the patient data through the wireless communication device **16** to transmit the encoded patient data to a wireless network storage unit **128** at the remote monitoring system **18**, as shown in FIG. **10**. In another embodiment, wireless communication device **16** transmits the patient data from the injectable detecting system **12** to the control unit **126** when it is at the remote monitoring system **18**.

Every time the control unit **126** plans to transmit patient data to a main data collection station **130**, located at the remote monitoring system **18**, the control unit **126** attempts to establish a communication link. The communication link can be wireless, wired, or a combination of wireless and wired for redundancy, e.g., the wired link checks to see if a wireless communication can be established. If the wireless communication link **16** is available, the control unit **126** transmits the encoded patient data through the wireless communication device **16**. However, if the wireless communication device **16** is not available for any reason, the control unit **126** waits and tries again until a link is established.

Referring now to FIG. **11**, one embodiment of an internal structure of a main data collection station **130**, at the remote monitoring system **18**, is illustrated. The patient data can be transmitted by the remote monitoring system **18** by either the wireless communication device **16** or conventional modem to the wireless network storage unit **128**. After receiving the patient data, the wireless network storage unit **128** can be accessed by the main data collection station **130**. The main data collection station **130** allows the remote monitoring system **18** to monitor the patient data of numerous patients from a centralized location without requiring the patient or a medical provider to physically interact with each other.

The main data collection station **130** can include a communications server **136** that communicates with the wireless network storage unit **128**. The wireless network storage unit **128** can be a centralized computer server that includes a unique, password protected mailbox assigned to and accessible by the main data collection station **130**. The main data collection station **130** contacts the wireless network storage

unit **128** and downloads the patient data stored in a mailbox assigned to the main data collection station **130**.

Once the communications server **136** has formed a link with the wireless network storage unit **128**, and has downloaded the patient data, the patient data can be transferred to a database server **138**. The database server **138** includes a patient database **140** that records and stores the patient data of the patients based upon identification included in the data packets sent by each of the monitoring units **22**. For example, each data packet can include an identifier.

Each data packet transferred from the remote monitoring system **18** to the main data collection station **130** does not have to include any patient identifiable information. Instead, the data packet can include the serial number assigned to the specific injectable detecting system **12**. The serial number associated with the detecting system **12** can then be correlated to a specific patient by using information stored on the patient database **138**. In this manner, the data packets transferred through the wireless network storage unit **128** do not include any patient-specific identification. Therefore, if the data packets are intercepted or improperly routed, patient confidentiality can not be breached.

The database server **138** can be accessible by an application server **142**. The application server **142** can include a data adapter **144** that formats the patient data information into a form that can be viewed over a conventional web-based connection. The transformed data from the data adapter **144** can be accessible by propriety application software through a web server **146** such that the data can be viewed by a workstation **148**. The workstation **148** can be a conventional personal computer that can access the patient data using proprietary software applications through, for example, HTTP protocol, and the like.

The main data collection station further can include an escalation server **150** that communicates with the database server **138**. The escalation server **150** monitors the patient data packets that are received by the database server **138** from the monitoring unit **22**. Specifically, the escalation server **150** can periodically poll the database server **138** for unacknowledged patient data packets. The patient data packets are sent to the remote monitoring system **18** where the processing of patient data occurs. The remote monitoring system **18** communicates with a medical provider in the event that an alert is required. If data packets are not acknowledged by the remote monitoring system **18**. The escalation server **150** can be programmed to automatically deliver alerts to a specific medical provider if an alarm message has not been acknowledged within a selected time period after receipt of the data packet.

The escalation server **150** can be configured to generate the notification message to different people by different modes of communication after different delay periods and during different time periods.

The main data collection station **130** can include a batch server **152** connected to the database server **138**. The batch server **152** allows an administration server **154** to have access to the patient data stored in the patient database **140**. The administration server **154** allows for centralized management of patient information and patient classifications.

The administration server **154** can include a batch server **156** that communicates with the batch server **152** and provides the downloaded data to a data warehouse server **158**. The data warehouse server **158** can include a large database **160** that records and stores the patient data.

The administration server **154** can further include an application server **162** and a maintenance workstation **164** that allow personnel from an administrator to access and monitor the data stored in the database **160**.

The data packet utilized in the transmission of the patient data can be a variable length ASCII character packet, or any generic data formats, in which the various patient data measurements are placed in a specific sequence with the specific readings separated by commas. The control unit **126** can convert the readings from each sensor **14** into a standardized sequence that forms part of the patient data packet. In this manner, the control unit **126** can be programmed to convert the patient data readings from the sensors **14** into a standardized data packet that can be interpreted and displayed by the main data collection station **130** at the remote monitoring system **18**.

Referring now to the flow chart of FIG. **12**, if an external device **38** fails to generate a valid reading, as illustrated in step A, the control unit **126** fills the portion of the patient data packet associated with the external device **38** with a null indicator. The null indicator can be the lack of any characters between commas in the patient data packet. The lack of characters in the patient data packet can indicate that the patient was not available for the patient data recording. The null indicator in the patient data packet can be interpreted by the main data collection station **130** at the remote monitoring system **18** as a failed attempt to record the patient data due to the unavailability of the patient, a malfunction in one or more of the sensors **14**, or a malfunction in one of the external devices **38**. The null indicator received by the main data collection station **130** can indicate that the transmission from the injectable detecting system **12** to the remote monitoring system **18** was successful. In one embodiment, the integrity of the data packet received by the main data collection station **130** can be determined using a cyclic redundancy code, CRC-16, check sum algorithm. The check sum algorithm can be applied to the data when the message can be sent and then again to the received message.

After the patient data measurements are complete, the control unit **126** displays the sensor data, including but not limited to blood pressure cuff data and the like, as illustrated by step B. In addition to displaying this data, the patient data can be placed in the patient data packet, as illustrated in step C.

As previously described, the system **10** can take additional measurements utilizing one or more auxiliary or external devices **38** such as those mentioned previously. Since the patient data packet has a variable length, the auxiliary device patient information can be added to the patient data packet being compiled by the remote monitoring unit **22** during patient data acquisition period being described. Data from the external devices **38** is transmitted by the wireless communication device **16** to the remote monitoring system **18** and can be included in the patient data packet.

If the remote monitoring system **18** can be set in either the auto mode or the wireless only mode, the remote monitoring unit **22** can first determine if there can be an internal communication error, as illustrated in step D.

A no communication error can be noted as illustrated in step E. If a communication error is noted the control unit **126** can proceed to wireless communication device **16** or to a conventional modem transmission sequence, as will be described below. However, if the communication device is working, the control unit **126** can transmit the patient data information over the wireless network **16**, as illustrated in step F. After the communication device has transmitted the data packet, the control unit **126** determines whether the transmission was successful, as illustrated in step G. If the

transmission has been unsuccessful only once, the control unit **126** retries the transmission. However, if the communication device has failed twice, as illustrated in step H, the control unit **126** proceeds to the conventional modem process if the remote monitoring unit **22** was configured in an auto mode.

When the control unit **126** is at the injectable detecting system **12**, and the control unit **126** transmits the patient data over the wireless communication device **16**, as illustrated in step I, if the transmission has been successful, the display of the remote monitoring unit **22** can display a successful message, as illustrated in step J. However, if the control unit **126** determines in step K that the communication of patient data has failed, the control unit **126** repeats the transmission until the control unit **126** either successfully completes the transmission or determines that the transmission has failed a selected number of times, as illustrated in step L. The control unit **126** can time out the and a failure message can be displayed, as illustrated in steps M and N. Once the transmission sequence has either failed or successfully transmitted the data to the main data collection station, the control unit **126** returns to a start program step O.

As discussed previously, the patient data packets are first sent and stored in the wireless network storage unit **128**. From there, the patient data packets are downloaded into the main data collection station **130**. The main data collection station **130** decodes the encoded patient data packets and records the patient data in the patient database **140**. The patient database **140** can be divided into individual storage locations for each patient such that the main data collection station **130** can store and compile patient data information from a plurality of individual patients.

A report on the patient's status can be accessed by a medical provider through a medical provider workstation that is coupled to the remote monitoring system **18**. Unauthorized access to the patient database can be prevented by individual medical provider usernames and passwords to provide additional security for the patient's recorded patient data.

The main data collection station **130** and the series of work stations **148** allow the remote monitoring system **18** to monitor the daily patient data measurements taken by a plurality of patients reporting patient data to the single main data collection station **130**. The main data collection station **130** can be configured to display multiple patients on the display of the workstations **148**. The internal programming for the main data collection station **130** can operate such that the patients are placed in a sequential top-to-bottom order based upon whether or not the patient can be generating an alarm signal for one of the patient data being monitored. For example, if one of the patients monitored by monitoring system **130** has a blood pressure exceeding a predetermined maximum amount, this patient can be moved toward the top of the list of patients and the patient's name and/or patient data can be highlighted such that the medical personnel can quickly identify those patients who may be in need of medical assistance. By way of illustration, and without limitation, the following paragraphs is a representative order ranking method for determining the order which the monitored patients are displayed:

Alarm Display Order Patient Status Patients are then sorted 1 Medical Alarm Most alarms violated to least alarms violated, then oldest to newest 2 Missing Data Alarm Oldest to newest 3 Late Oldest to newest 4 Reviewed Medical Alarms Oldest to newest 5 Reviewed Missing Data Oldest to newest Alarms 6 Reviewed Null Oldest to newest 7 NDR Oldest to newest 8 Reviewed NDR Oldest to newest

As listed in the above, the order of patients listed on the display can be ranked based upon the seriousness and number of alarms that are registered based upon the latest patient data information. For example, if the blood pressure of a single patient exceeds the tolerance level and the patient's heart rate also exceeds the maximum level, this patient will be placed above a patient who only has one alarm condition. In this manner, the medical provider can quickly determine which patient most urgently needs medical attention by simply identifying the patient's name at the top of the patient list. The order which the patients are displayed can be configurable by the remote monitoring system **18** depending on various preferences.

As discussed previously, the escalation server **150** automatically generates a notification message to a specified medical provider for unacknowledged data packets based on user specified parameters.

In addition to displaying the current patient data for the numerous patients being monitored, the software of the main data collection station **130** allows the medical provider to trend the patient data over a number of prior measurements in order to monitor the progress of a particular patient. In addition, the software allows the medical provider to determine whether or not a patient has been successful in recording their patient data as well as monitor the questions being asked by the remote monitoring unit **22**.

As previously mentioned, the system **10** uses an intelligent combination of sensors to enhance detection and prediction capabilities. Electrocardiogram circuitry can be coupled to the sensors **14**, or electrodes, to measure an electrocardiogram signal of the patient. An accelerometer can be mechanically coupled, for example adhered or affixed, to the sensors **14**, adherent patch and the like, to generate an accelerometer signal in response to at least one of an activity or a position of the patient. The accelerometer signals improve patient diagnosis, and can be especially useful when used with other signals, such as electrocardiogram signals and impedance signals, including but not limited to, hydration respiration, and the like. Mechanically coupling the accelerometer to the sensors **14**, electrodes, for measuring impedance, hydration and the like can improve the quality and/or usefulness of the impedance and/or electrocardiogram signals. By way of illustration, and without limitation, mechanical coupling of the accelerometer to the sensors **14**, electrodes, and to the skin of the patient can improve the reliability, quality and/or accuracy of the accelerometer measurements, as the sensor **14**, electrode, signals can indicate the quality of mechanical coupling of the patch to the patient so as to indicate that the device is connected to the patient and that the accelerometer signals are valid. Other examples of sensor interaction include but are not limited to, (i) orthopnea measurement where the breathing rate is correlated with posture during sleep, and detection of orthopnea, (ii) a blended activity sensor using the respiratory rate to exclude high activity levels caused by vibration (e.g. driving on a bumpy road) rather than exercise or extreme physical activity, (iii) sharing common power, logic and memory for sensors, electrodes, and the like.

While the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention.

What is claimed is:

1. An injectable device for use in physiological monitoring, comprising:

a body having a shape configured for subcutaneous insertion in a patient;

a plurality of sensors axially spaced along the body that provide an indication of at least one physiological event of the patient;

a power source within the body;

a communication antenna external to the body configured to transfer data to/from other devices, wherein the communication antenna is a self-expanding antenna having a compressed state prior to subcutaneous injection and expanded shape immediately after subcutaneous injection;

a power and communication module within the body and coupled to the communication antenna and the plurality of sensors, wherein the power and communication module selectively supplies power to each of the plurality of sensors and receive sensor data from each of the plurality of sensors.

2. The injectable device of claim 1, wherein the body is flexible to allow conformance to adjacent tissue anatomy.

3. The injectable device of claim 1, wherein at least a portion of the body has a drug eluting coating.

4. The injectable device of claim 1, wherein the self-expanding communication antenna in the compressed state has a cross-sectional profile less than or equal to a cross-sectional profile of the body of the injectable device.

5. The injectable device of claim 1, wherein the power and communication module manages power consumption by the plurality of sensors.

6. The injectable device of claim 5, wherein the power and communication module manages power consumption of the plurality of sensors via at least one of modulating drive levels per sensor and modulating a clock speed.

7. The injectable device of claim 5, wherein the power and communication module manages power consumption by selectively sampling different types of sensors including in the plurality of sensors at different times.

8. The injectable device of claim 7, wherein the power and communication module continuously samples a first sensor, and monitors a second sensor in order to verify a physiological status flag raised by the first sensor.

9. The injectable device of claim 1, wherein the plurality of sensors includes two current delivery electrodes and two sensing electrodes for measuring bioimpedance.

10. The injectable device of claim 1, wherein at least one of the plurality of sensors has openings or an absorbent material configured to sample a hydration level or electrolyte level in a surrounding tissue site of the plurality of sensors.

11. The injectable device of claim 1, wherein the plurality of sensors further includes at least one activity sensor selected from at least one of, ball switch, accelerometer, minute ventilation, heart rate (HR), bioimpedance noise, skin temperature/heat flux, blood pressure (BP), muscle noise and posture.

12. The injectable device of claim 1, wherein the power source and the power and communication module are hermetically sealed, and wherein the communication antenna is external to the hermetically sealed portion.

13. The injectable device of claim 1, wherein the body and antenna are injectable in the patient by at least one of, catheter delivery, blunt tunneling, insertion with a needle, by injection, with a gun or syringe device with a stiffening wire stylet, guidewire, or combination of stylet or guidewire with a catheter.

14. An injectable system for physiological monitoring, the injectable system comprising:

an injector having a first end configured to non-surgically puncture a patient's skin for subcutaneous insertion; and

an injectable device having a rigid state that allows it to be housed within the injector and a flexible state assumed after subcutaneous insertion within the patient, wherein the injectable device includes a self-expanding communication antenna having a compressed state maintained by the injector while the injectable device is housed within the injector prior to subcutaneous injection and expanded shape after subcutaneous injection.

15. The injectable system of claim 14, wherein the injectable device includes:

a flexible body having a shape configured for subcutaneous insertion in the patient;

a plurality of sensors axially spaced along the flexible body that provide an indication of at least one physiological event of the patient;

a power source within the flexible body;

a power and communication module within the flexible body and coupled to the communication antenna and the plurality of sensors, wherein the power and communication module selectively supplies power to each of the plurality of sensors and receive sensor data from each of the plurality of sensors, wherein the self-expanding communication antenna is external to the flexible body.

16. The injectable system of claim 15, wherein at least a portion of the body has a drug eluting coating.

17. The injectable device of claim 14, wherein the body and antenna are injectable in the patient by at least one of, catheter delivery, blunt tunneling, insertion with a needle, by injection, with a gun or syringe device with a stiffening wire stylet, guidewire, or combination of stylet or guidewire with a catheter.

* * * * *

专利名称(译)	用于生理监测的可注射装置		
公开(公告)号	US10405809	公开(公告)日	2019-09-10
申请号	US14/218594	申请日	2014-03-18
[标]申请(专利权)人(译)	科文迪斯有限公司		
申请(专利权)人(译)	CORVENTIS，INC		
当前申请(专利权)人(译)	美敦力公司监测，INC		
[标]发明人	MANICKA YATHEENDHAR D AMURTHUR BADRI BLY MARK JAMES KRISTOFER LIBBUS IMAD MAZAR SCOTT T WANG JERRY S		
发明人	MANICKA, YATHEENDHAR D. AMURTHUR, BADRI BLY, MARK JAMES, KRISTOFER LIBBUS, IMAD MAZAR, SCOTT T. WANG, JERRY S.		
IPC分类号	A61B5/07 A61B5/053 A61B5/042 A61B5/00 A61B5/0205 A61B5/145 A61N1/372 A61B5/11		
CPC分类号	A61B5/7282 A61B5/0205 A61B5/02055 A61B5/0422 A61B5/053 A61B5/07 A61B5/076 A61B5/14503 A61B5/4875 A61B5/686 A61B5/0031 A61N1/37205 A61B5/1118 A61B5/7232 A61B2560/0214 A61B2560/0468 A61B2562/0219 A61B2562/04 A61B2562/06 A61B2562/16		
代理人(译)	COLLINS，MICHAEL A.		
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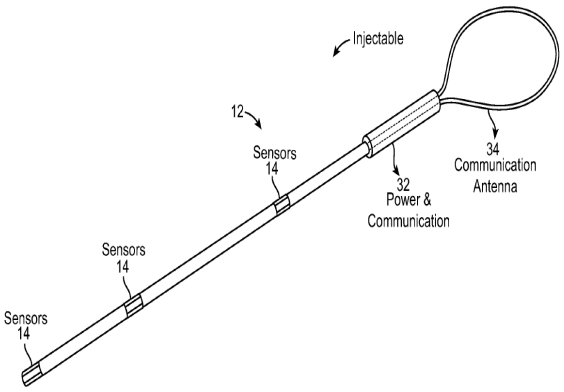
其他公开文献	US20140323821A1		
外部链接	Espacenet		

摘要(译)

提供一种可注射检测装置，用于生理监测。该装置包括沿身体轴向间隔开的多个传感器，其提供患者的至少一个生理事件的指示，身体内的监测单元耦合到多个传感器，所述多个传感器被配置为从多个传感器接收数据并且创建处理的患者数据，连接到监控单元的主体内的电源，以及连接到监控单元的主体外部的通信天线，被配置为向/从其他设备传输数据。


Injectable
12
Sensors
14
34
Communication
Antenna
32
Power &
Communication
Sensors
14
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14