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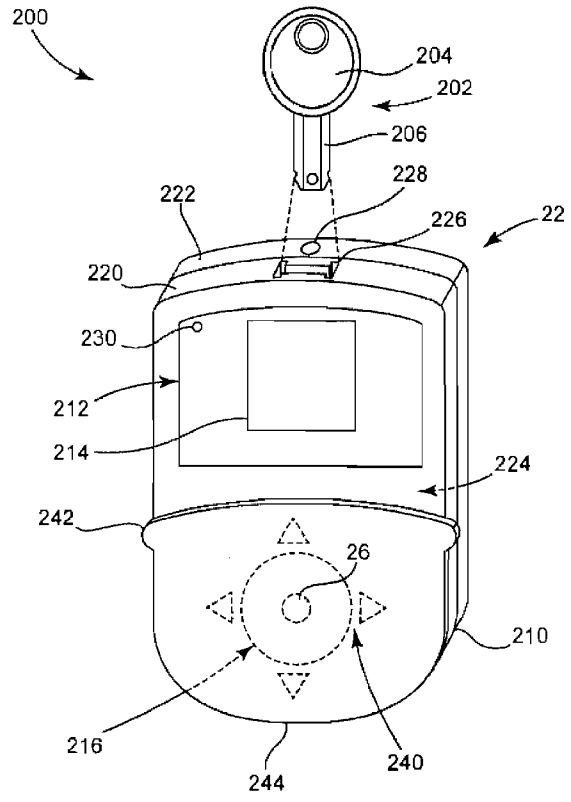
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(54) Title: IMPLANTABLE MONITORING DEVICE ACTIVATOR AND SYSTEM INCLUDING A MAGNETIC-MECHANICAL KEY



(57) Abstract: An activator system includes an activator device configured to electrically communicate with an implantable monitoring device, and a key insertable into the activator device. The activator device includes a housing enclosing a printed circuit board and at least one switch, where the housing defines an access slot communicating with the switch(es). The key is insertable into the access slot and configured to close the switch(es) and change a communication state of the activator device.

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IMPLANTABLE MONITORING DEVICE ACTIVATOR AND SYSTEM INCLUDING A MAGNETIC-MECHANICAL KEY

Background

Implantable devices are capable of sensing and recording various biological signals from the body, such as, for example, electrocardiogram (ECG) signals. Internal implantable devices offer advantages over external sensing devices that have at least one electrode attached externally to the patient. For example, internal implantable devices can provide a high degree of measurement sensitivity as they decrease the distance between the source of the signals and the sensing device. These highly sensitive measurements are recordable in the electronic components of the implantable device.

In some cases, telemetry is employed to transmit the measurements recorded by the implanted device to an external communication link that processes the data for subsequent analysis and diagnosis. In order to expand the diagnostic capabilities of the implantable device in some cases, there is a need to sense, record, and transmit significant volumes of information. Furthermore, in order to extend the life cycle of the implantable device, the implantable device should be as compact and should consume as little power as possible.

Summary

One embodiment provides an activator system for a body implantable device. The activator system includes an activator device configured to electrically communicate with an implantable monitoring device, and a key insertable into the activator device. The activator device includes a housing enclosing a printed circuit board and at least one switch, where the housing defines an access slot communicating with the switch(es). The key is insertable into the access slot and configured to close the switch(es) and change a communication state of the activator device.

Brief Description of the Drawings

The accompanying drawings are included to provide a further understanding of the present invention and are incorporated in and constitute a part of this specification. The drawings illustrate example embodiments and together with the description serve to explain principles of the invention. Other embodiments and many of the intended advantages of the embodiments will be readily appreciated as they become better understood by reference to the following detailed description. The elements of the drawings are not necessarily to scale relative to each other. Like reference numerals designate corresponding similar parts.

Figure 1 illustrates a block diagram of a telemetry system including an implantable device in accordance with one embodiment.

Figure 2 illustrates a block diagram of an implantable device in accordance with one embodiment.

Figure 3 illustrates a perspective view of an activator system including an activator device and a key according to one embodiment.

Figure 4 illustrates an exploded view of a spacer and the activator device of Figure 3 with a housing section removed according to one embodiment.

Figure 5 illustrates a top view of the spacer shown in Figure 4.

Figure 6 illustrates a plan view of the key shown in Figure 3 according to one embodiment.

Figure 7 illustrates a side view of the key shown in Figure 6.

Figure 8 illustrates a top end view of the key shown in Figure 6.

Figure 9 illustrates a bottom end view of the key shown in Figure 6.

Figure 10 illustrates an end view of the activator system showing the key inserted into an access slot of the activator device according to one embodiment.

Figure 11 illustrates a method employed by the activator device shown in Figure 3 according to one embodiment.

Detailed Description

In the following Detailed Description, reference is made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. In this regard, directional terminology, such as "top," "bottom," "front," "back," "leading," "trailing," etc., is used with reference to the orientation of the Figure(s) being described. Because components of embodiments can be positioned in a number of different orientations, the directional terminology is used for purposes of illustration and is in no way limiting. It is to be understood that other embodiments may be utilized and structural or logical changes may be made without departing from the scope of the present invention. The following detailed description, therefore, is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

Embodiments relate to an implantable device configured with a signal monitoring system that is configured to continuously measure and selectively record biological signals, such as heart signals, and transmit the recorded biological signal information for subsequent analysis.

Figure 1 illustrates telemetry system 10 in accordance with one embodiment. Telemetry system 10 includes patient hub 12 and service hub 14. Patient hub 12 includes a patient 16 provided with an implantable monitoring device (IMD) 20 that is configured to collect biological data from patient 16, a programmable external activator 22 configured to electronically communicate with (i.e., receive and transmit data from) IMD 20, and a base station 24 in telemetric communication with activator 22 that is configured to remotely transmit data collected by IMD 20 and activator 22. In one embodiment, IMD 20 and activator 22 are "paired" when manufactured by programming a unique IMD 20 identification number into a memory bank of activator 22. In this manner, activator 22 is configured to recognize and communicate with a single, specific, and identifiable IMD 20.

Service hub 14 includes service system 30 configured to remotely receive the data collected by IMD 20 that is uploaded to activator 22, and a service

technician 32 and a physician or other medical personnel 34 that are enabled to access the data collected by IMD 20 after the data is transmitted to service system 30. Base station 24 of patient hub 12 is linked via a phone system or other communication system to service system 30 of service hub 14, for example by a land-based telephone line system, a wireless communication system, or the Internet, and service technician 32/medical personnel 34 have access to service system 30.

In one embodiment, IMD 20 is a surgically implanted electrocardiogram (ECG) monitoring device configured to continuously capture and selectively record both symptomatic (i.e., patient detected) and asymptomatic (i.e., non-patient detected, or IMD 20 detected) ECG events. In one embodiment, IMD 20 is configured to capture and record trending ECG waveform data based on periodic timed triggering of IMD 20. In this regard, ECG events and other biological signals are monitored and recorded within IMD 20, which is configured with transceiver capabilities for uploading data to activator 22. In one embodiment, activator 22 uploads the biological data from the patient 16 and is configured to wirelessly transmit the data to the base station 24 when the patient 16 is, for example, within wireless fidelity (WiFi) range of base station 24.

In one embodiment, activator 22 is rechargeable and sized to be worn externally or carried by patient 16. In one embodiment, activator 22 is a computational device including memory and programmable software that combine to enable activator 22 to program IMD 20, display waveforms of data collected by IMD 20 on a real-time basis, respond to patient commands storing symptomatic data collected by IMD 20, store asymptomatic data collected by IMD 20, upload data from IMD 20, download data to IMD 20, and transmit data to service system 30 via base station 24.

One embodiment of activator 22 includes a patient interface 26 that is configured to enable patient 16 to send an activation signal to selectively activate IMD 20 to record a symptomatic ECG event (e.g., an anomalous cardiac event detected by patient 16) and, in one form of this embodiment, upload information from IMD 20 to activator 22, and then to service system 30 via base station 24

during the event. In one embodiment, activator 22 passively uploads ECG events recorded by IMD 20 at regular time intervals (e.g., daily) and transmits this data to service system 30 via base station 24. In one embodiment, activator 22 is configured to receive information, such as, for example, clock synchronization information transmitted from service system 30 through base station 24, for activator 22 and/or for downloading to IMD 20.

Base station 24 may be coupled to service system 30 in a variety of suitable ways. For example, base station 24 and service system 30 may be coupled by telephone lines, wireless communication, or the Internet. Other suitable communication links between base station 24 and service system 30 are also acceptable. Regardless of the communication link between base station 24 and service system 30, technician 32 has access to the patient 16 data measured by IMD 20.

Figure 2 illustrates a block diagram of IMD 20 in accordance with one embodiment. In one embodiment, IMD 20 includes a case 50, leads 52, a battery 54, a receiver 56, a transmitter 58, and an application specific integrated circuit (ASIC) 60 contained within case 50. In one embodiment, case 50 is a sealed titanium case sized to house various components of IMD 20, such as battery 54, receiver 56, transmitter 58, and ASIC 60. When implanted, IMD 20 can measure biological signals, such as ECG potentials, across leads 52 and store segments of the biological signal waveforms within ASIC 60. In one embodiment, one of leads 52 is coupled to an extending lead having a remote tip electrode, and the other of leads 52 is coupled to case 50, such that an ECG potential is measurable between the remote tip electrode and case 50. In one embodiment, ASIC 60 is coupled to an IMD memory device, such as a static random access memory (SRAM), which can be configured to store segments of the signal waveforms for subsequent transmission to activator 22.

Receiver 56 is configured to receive commands signals, for example, from activator 22. In one embodiment, activator 22 sends an activation signal that indicates that a segment of an ECG waveform should be recorded and then

transmitted. When such an activation signal is received, receiver 56 can be configured to pass the activation signal to ASIC 60 so that segments of the ECG waveform are recorded. In some embodiments, the waveform signals can be stored in ASIC 60 and/or an IMD memory device external from ASIC 60. The recorded segments of the ECG waveform can then be sent to transmitter 58 for transmission to activator 22. In some embodiments, the signals can be transmitted directly to activator 22 rather than first storing them in ASIC 60 and/or an IMD memory device.

Once measured and transmitted, the data is available to service system 30 via the link between base station 24 and system 30. Thereafter, technician 32/medical personnel 34 have access to the measured signals. As such, the information in the measured signals may be used by a physician to remotely diagnose a condition of patient 16, to observe and record the measured signals, and/or to further instruct IMD 20 based on the measured signals.

Figure 3 illustrates a perspective view of an activator system 200 according to one embodiment. Activator system 200 includes activator device 22 and a key 202 that is insertable into the activator device 22 to change a state of the activator device 22 from a data receiving mode (i.e., a "patient mode" in which key 202 is not inserted) to a programming mode (i.e., a "physician mode" in which key 202 is inserted into activator 22).

In one embodiment, key 202 includes a head 204 and a shaft 206 extending from head 204 that provides redundant safety features that preclude changing the state of activator 22 from the patient mode unless at least two switches are closed. For example, in one embodiment shaft 206 includes a mechanical portion configured to mechanically close a micro-switch, and a magnetic portion configured to magnetically close a magnetic switch. In this regard, in one embodiment key 202 is a magnetic-mechanical key, or a key including mechanical and magnetic components.

In one embodiment, activator 22 includes a housing 210 enclosing electronic components (See Figure 4), a graphical user interface (GUI) 212 including a display

panel 214, and a user control panel 216 electrically coupled to GUI 212 and display panel 214.

In one embodiment, housing 210 defines a first housing section 220 and a second housing section 222 that are sized to be reciprocally mated to one another to define an enclosure 224 that retains the electronic components of activator 22. In one embodiment, first housing section 220 forms a cover (or top) defining an access slot 226 and second housing section 222 forms a base (or bottom) defining a connector port 228, where access slot 226 and connector port 228 communicate with enclosure 224. In other embodiments, access slot 226 and connector port 228 are formed in other suitable locations of housing 210.

GUI 212 provides a data interface and display panel 214 to enable a user to view information and waveforms monitored by IMD 20 (Figure 1) and uploaded to activator 22. In one embodiment, display panel 214 is a back lighted LED display screen and includes a separate LED light 230 or light guide 230. In one embodiment, LED light 230 is configured to illuminate to indicate an on/off status of activator 22, or a status of data uploading into activator 22 from IMD 20, or a status of data downloading from activator 22 to service center 30.

User control panel 216 includes a plurality of buttons 240 including patient button 26. In one embodiment, buttons 240 are push-activated, for example by a user's thumb, and are configured to enable the user to signal IMD 20 to record a symptomatic event, or to toggle between display screens and other data screens displayed on display panel 214. In one embodiment, housing 210 includes a movable protective cover 242 that is hinged to one end 244 of housing 210. In this manner, cover 242 can be displaced away from user control panel 216 to provide access to buttons 240, or closed to protectively shield patient button 26 from inadvertent pressing and/or undesired data recording.

Figure 4 illustrates an exploded view of activator 22 with first housing section 220 (Figure 3) removed and enclosure 224 exposed. In particular, second housing section 222 forms a base configured to retain a printed circuit board 250

and a spacer 260 coupled with a portion of circuit board 250, where both printed circuit board 250 and spacer 260 are disposed within enclosure 224.

Printed circuit board 250 includes circuitry 252 having a variety of electronic components such as integrated circuits, memory cells, capacitors, diodes, antenna, etc. that enable activator 22 to electronically communicate with IMD 20 (Figure 1), and includes at least two mode switches 270, 272. For example, in one embodiment printed circuit board 250 includes a mechanical switch 270 and a magnetic switch 272 that are retained within enclosure 224 adjacent to access slot 226. In one embodiment, mechanical switch 270 is a micro-electronic switch configured to be shunted to a closed position when depressed, and magnetic switch 272 is a Hall effect sensor that is sensitive to the presence of a magnet (and more particularly, sensitive to the presence of magnetic flux density).

Figure 5 illustrates a top plan view of spacer 260 according to one embodiment. Spacer 260 includes a body 280 and a scaffold 282 extending from body 280. Body 280 is configured to mate with printed circuit board 250 (Figure 4) such that scaffold 282 aligns with access slot 226 (Figure 4).

In one embodiment, scaffold 282 defines a first flexible arm 290 spaced apart from a second flexible arm 292 to define a key slot 294 between arms 290, 292 that is sized to removably receive key 202. In one embodiment, first flexible arm 290 defines a prong 300, and second flexible arm 292 defines an opposing prong 302 that combine to retain key 202 (Figure 4) when key 202 is inserted into key slot 294. In particular, flexible arms 290, 292 are configured to flex and spread apart one from the other as key 202 is inserted into key slot 294, and when key 202 is fully seated within scaffold 282, prongs 300, 302 engage with detents formed in key 202 to securely retain and align key 202 in scaffold 282, as described below.

In one embodiment, spacer 260 is configured to be lightweight and rigid. In this regard, embodiments provide body 280 formed of a polymer to include one or more fenestrations that are compatible with electrical circuitry 252 of printed circuit board 250. In one embodiment, spacer 260 is formed of a molded polymer such as a polycarbonate, although other suitable polymer compositions are also acceptable.

Figure 6 illustrates a plan view of key 202 including head 204 and shaft 206 according to one embodiment. In one embodiment, head 204 defines a first major surface 310 opposite a second major surface 312, a peripheral ring 314 disposed at an outer circumference of the first and second major surfaces 310, 312, and an antenna 316. In one embodiment, peripheral ring 314 is a raised peripheral ring 314 and antenna 316 is disposed within the raised portion of peripheral ring 314.

In some embodiments, head 204 defines an optional key ring hole 320 extending between the first and second major surfaces 310, 312, and includes indicia 322 printed on at least one of the first and second major surfaces 310, 312. For example, in one embodiment "Physician Programming Key" is printed, or molded, into first major surface 310 and "Not for Patient Use" is printed, or molded, into second major surface 312 to remind the user that key 202 is to be used by a trained professional to change a state of activator 22. In this regard, it is desired that key 202 be provided only to a trained clinician and not provided to patient 16 (Figure 1).

In general, shaft 206 extends from head 204 and defines a distal end 330 opposite a proximal end 332 that is adjacent and coupled to head 204. In one embodiment, shaft 206 includes a central longitudinal section 340, a first flange 342 coupled to a first side of central longitudinal section 340, a second flange 344 opposite first flange 342, and a magnet 346 integrally formed in central longitudinal section 340. In one embodiment, first flange 342 defines a first detent 352 and second flange 344 defines a second detent 354, where the detents 352, 354 are configured to be engaged by prongs 300, 302 (Figure 5) and securely retain key 202 when it is inserted into scaffold 282 (Figure 5). To this end, one embodiment provides magnet 346 integrally formed in central longitudinal section 340 adjacent to distal end 330 such that magnet 346 aligns with magnetic switch 272 when detents 352, 354 are engaged by prongs 300, 302, respectively.

In one embodiment, key 202 is molded or formed as an integral piece including head 204 connected to shaft 206, where antenna 316 is molded into head 204 and magnet 346 is molded into shaft 206. In other embodiments, magnet 346 is

press fit into a suitable recess formed within shaft 206. In general, key 202 is molded from a suitably durable polymer such as a polycarbonate, or a blend of polycarbonate and another polymer. One suitable polymer for key 202 includes a Lexan™ polycarbonate thermoplastic resin. Another suitable polymer for key 202 includes a blend of Lexan™ and acrylonitrile butadiene styrene (ABS), although other suitable polymers and/or blends of polymers are also acceptable.

In one embodiment, antenna 316 is configured to receive electrical signals from a transmitter of activator 22 circuitry 252 and convert the signals to radio-frequency signals for transmission to IMD 20 (Figure 1). In this regard, antenna 316 is sized to have a length that matches or is proportional to the wavelength of the transmitted radio-frequency signal. One suitable antenna 316 is a wire coiled antenna, although other suitable antenna configurations are also acceptable.

In one embodiment, magnet 346 is a rare earth magnet having a coercive force of greater than 14 kOe, although other suitable magnets are also acceptable. In one embodiment, magnet 346 is a sintered NdFeB magnetized rare earth magnet identified as N40M and available from Applied Magnet Technology, Portage, IN.

Figure 7 illustrates a left side view of key 202. Proximal end 332 of shaft 206 is connected to head 204. Antenna 316 is not shown in this view for ease of illustration. Regarding shaft 206, detent 354 extends the full width of shaft 206, and magnet 346 extends between opposing surfaces of central longitudinal section 340.

Figure 8 illustrates a top end view of key 202. First and second major surfaces 310, 312 are substantially planar. In one embodiment, raised peripheral ring 314 defines a first concave curvature 351 relative to first major surface 310 and a second concave curvature 353 relative to second major surface 312. Concave curvatures 351, 353 of peripheral ring 314 combine to define opposing central concave troughs 355, 357, respectively, when key 202 is viewed along a longitudinal axis.

Figure 9 illustrates a front view of key 202. Central longitudinal section 340 defines a first major surface 360 opposite a second major surface 362. Magnet 346 extends between first major surface 360 and second major surface 362. In one

embodiment, first and second flanges 342, 344 extend beyond first major surface 360 and beyond second major surface 362. In this regard, a lateral cross-sectional view of one embodiment of shaft 206 defines a substantially H-shaped cross-section. In one embodiment, central longitudinal section 340 is recessed relative to first and second flanges 342, 344.

Figure 10 illustrates an end view of activator system 200 showing key 202 inserted into access slot 226 of activator 22. In one embodiment, key 202 may be inserted such that first concave curvature 351 is oriented "up." Alternatively, key 202 may be inserted such that first concave curvature 351 is oriented "down." In this regard, shaft 206 may be inserted into access slot 226 in either orientation, and key 202 is thus not orientation specific. When key 202 is inserted into activator 22, one of the concave curvatures 355, 357 of head 204 is oriented to provide clearance for the connection of a power cord, for example, into connector slot 228.

With reference to Figure 1, activator 22 includes a patient mode and is configured as a receiver to upload data and/or information from IMD 20. Activator 22 is typically worn by the patient 16, or held by the patient 16, and is thus associated with the location of the patient 16 relative to base station 24. Throughout the day or the wearing cycle, activator 22 periodically uploads data from IMD 20 and downloads data and/or information to base station 24. In addition, during symptomatic events that the patient 16 senses, patient 16 can press patient button 26 on control panel 216 to signal IMD 20 to record biological data for subsequent uploading to activator 22 and eventual downloading to service system 30. In these embodiments, activator device 22 is maintained in a low-power patient mode when key 202 is not inserted into activator device 22.

With additional reference to Figure 4 and Figure 6, when key 202 is inserted into access slot 226, the state of activator device 22 changes from the patient mode state to a physician mode. In particular, when key 202 is fully inserted into access slot 226, central longitudinal section 340 contacts mechanical switch 270 and magnet 346 aligns with magnetic switch 272, and activator device 22 is enabled into the physician mode. The physician mode of activator 22 is characterized by

activator 22 being configured as a transmitter that can wirelessly program IMD 20. In one embodiment, antenna 316 within head 204 of key 202 is configured to extend a telemetry range of activator 22. For example, in one embodiment inserting key 202 into activator 22 (i.e., when activator 22 is in physician mode) increases power to activator 22 and enables activator 22 to overcome potential nearby electrical interference, such as is present from other electronic devices in a surgical suite during implantation of IMD 20.

In one embodiment, and with reference to Figure 5, when key 202 is fully inserted into key slot 294, prong 300 seats into first detent 352 and prong 302 seats into detent 354 to retain and align magnet 346 over magnetic switch 272. In this manner, shaft 206 of key 202 and scaffold 282 of spacer 260 combine to position key 202 such that both mechanical switch 270 and magnetic switch 272 are closed and activator device 22 changes state to the physician mode. In one embodiment, the state of activator device 22 changes only when both the mechanical switch 270 and the magnetic switch 272 are simultaneously closed.

Figure 11 illustrates a method 400 employed by activator device 22 in switching between modes according to one embodiment. Activator device 22 is in the patient mode as indicated at 402. As a point of reference, activator device 22 is in the patient mode during event monitoring in general, and whenever key 202 is not inserted into activator 22.

At 404, a program of printed circuit board 250 queries whether activator device 22 senses the presence of magnet 346, and more specifically, whether switch 272 (Figure 4) is Hall effect coupled due to increased magnetic flux density from magnet 346. If activator device 22 does not sense the presence of the magnet 346, then activator device 22 remains in the patient mode indicated at 402.

If activator device 22 does sense the presence of magnet 346, process 406 provides a query as to whether activator device 22 senses mechanical switch 270 having been depressed, as processed through circuitry 252 (Figure 4), for example. In this case, if magnetic switch 272 is closed but mechanical switch 270 is open, then activator device 22 remains in the patient mode. Otherwise, if both the

magnetic switch 272 and the mechanical switch 270 are sensed and both are closed, then the activator device 22 is enabled to change state to the physician mode, as illustrated at process 408. In this manner, activator device 22 is provided with redundant safety features that assures that both mechanical switch 270 and magnetic switch 272 (Figure 4) are closed simultaneously before enabling the physician/programming mode of activator device.

Although specific embodiments have been illustrated and described herein, it will be appreciated by those of ordinary skill in the art that a variety of alternate and/or equivalent implementations may be substituted for the specific embodiments shown and described without departing from the scope of the present invention. This application is intended to cover any adaptations or variations of the specific embodiments discussed herein. Therefore, it is intended that this invention be limited only by the claims and the equivalents thereof.

WHAT IS CLAIMED IS:

1. An activator system for a body implantable device, the activator system comprising:

an activator device configured to electrically communicate with an implantable monitoring device, the activator device including:

a housing enclosing a printed circuit board and at least one switch, the housing defining an access slot communicating with the at least one switch; and

a key insertable into the access slot, the key configured to close the at least one switch and change a communication state of the activator device.

2. The activator system of claim 1, wherein the key comprises a mechanical key.

3. The activator system of claim 1, wherein the key comprises a magnetic-mechanical key.

4. The activator system of claim 1, wherein the housing encloses a mechanical switch and a magnetic switch, each of the switches communicating with the access slot.

5. The activator system of claim 4, wherein the key is configured to activate the magnetic switch and simultaneously activate the mechanical switch to change the communication state of the activator device from a data receiving state to a programming state.

6. The activator system of claim 1, wherein the key comprises a head, a shaft extending from the head, the shaft defining a distal end opposite a proximal end, and a magnet coupled to the shaft adjacent to the distal end.

7. The activator system of claim 6, wherein the shaft comprises a central longitudinal section including a first major surface opposite a second major surface, the central longitudinal section extending between the distal and proximal ends, the magnet integrally formed in the central longitudinal section of the shaft.

8. The activator system of claim 7, wherein the magnet is fitted into the central longitudinal section of the shaft and extends between the first and second major surfaces.

9. The activator system of claim 7, wherein when the key is inserted into the access slot, the central longitudinal section couples with the mechanical switch and the magnet couples with the magnetic switch.

10. The activator system of claim 7, wherein the shaft comprises a first flange coupled to a first side of the central longitudinal section and a second flange coupled to a second side of the central longitudinal section opposite the first flange.

11. The activator system of claim 7, wherein the central longitudinal section is recessed relative to the shaft.

12. The activator system of claim 6, wherein the head comprises a raised peripheral ring disposed at an outermost circumference.

13. The activator system of claim 12, wherein the raised peripheral ring of the head defines a first concave trough opposite a second concave trough.

14. The activator system of claim 12, wherein the head comprises an antenna configured to increase power output from the activator device when the key is inserted into the access slot.

15. The activator system of claim 14, wherein the antenna is disposed within the raised peripheral ring.

16. The activator system of claim 6, wherein the activator device further comprises:

a spacer inside the housing mounted to the printed circuit board, the spacer defining a scaffold sized to be received by the access slot, the scaffold configured to receive the key and align the magnet with the magnetic switch.

17. The activator system of claim 16, wherein when the magnet is aligned with the magnetic switch a central portion of the shaft contacts the mechanical switch.

18. The activator system of claim 16, wherein the scaffold defines a first flexible arm spaced apart from a second flexible arm to define a key slot between the arms, the key slot aligned with the access slot.

19. The activator system of claim 18, wherein the shaft of the key defines a first detent and a second detent opposite of the first detent, the first detent configured to be retained by the first flexible arm and the second detent configured to be retained by the second flexible arm when the key is inserted into the key slot.

20. A key insertable into an activator device that is configured to communicate with a body implantable monitoring device, the key comprising:

a head; and

a shaft extending from the head, the shaft defining:

opposing major surfaces extending between a distal end and a proximal end opposite the distal end,

a magnet extending between the opposing major surfaces adjacent to the distal end;

wherein at least one of the opposing major surfaces is configured to activate a mechanical switch of the activator device and the magnet is configured to activate a magnetic switch of the activator device to change a state of the activator device from a data receiving state to a programming state.

21. The key of claim 20, wherein the head comprises a raised peripheral ring.

22. The key of claim 21, wherein the raised peripheral ring defines a first longitudinal concave trough opposite a second longitudinal concave trough.

23. The key of claim 20, wherein the head comprises an antenna configured to increase power output from the activator device when the key is inserted into the activator device.

24. The key of claim 23, wherein the antenna is disposed adjacent a perimeter of the head.

25. The key of claim 20, wherein the magnet is disposed between the opposing major surfaces adjacent to the distal end.

26. The key of claim 20, wherein the magnet is configured to activate the magnetic switch and at least one of the opposing major surfaces is configured to simultaneously activate the mechanical switch to change a state of the activator device from the data receiving state to the programming state.

27. An activator device configured to electrically communicate with an implantable monitoring device, the activator device comprising:

a housing enclosing a printed circuit board;

a mechanical switch and a magnetic switch disposed within the housing; and

an access slot formed in the housing and configured to communicate with the switches;

wherein the access slot is configured to receive insertable device configured to close the mechanical switch and the magnetic switch and change a communication state of the activator device.

28. The activator device of claim 27, wherein the access slot comprises a pair of opposing flexible arms that are configured to retain the insertable device.

29. The activator device of claim 27, further comprising:

a graphical user interface configured to display waveforms collected by the implantable monitoring device on real-time basis.

30. A method of changing modes in an activator device that is configured to electrically communicate with an implantable monitoring device, the method comprising:

providing an activator device including a first mode configured to receive data of asymptomatic events passively recorded by the implantable monitoring device; and

switching the activator device to a programming mode that is different from the first mode, the programming mode configured to program electronic settings of the implantable monitoring device.

31. The method of claim 30, wherein the first mode is configured to enable manual signaling of the implantable monitoring device to record data of symptomatic events.

32. The method of claim 30, wherein switching the activator device to a programming mode comprises magnetically and mechanically switching the activator device to change a state and enter the programming mode.

33. The method of claim 32, wherein magnetically and mechanically switching the activator device to change a state and enter the programming mode comprises inserting a key into a housing of the activator device.

34. An activator device configured to electrically communicate with an implantable monitoring device, the activator device comprising:

a transmitter operable to wirelessly communicate with the implantable monitoring device;

a push-activated button configured to initiate a communication with the implantable monitoring device via the transmitter, the communication directing the implantable monitoring device to record a physiologic event;

a housing enclosing the transmitter and including a moveable cover that in a first position restricts access to the button and in a second position provides access to the button.

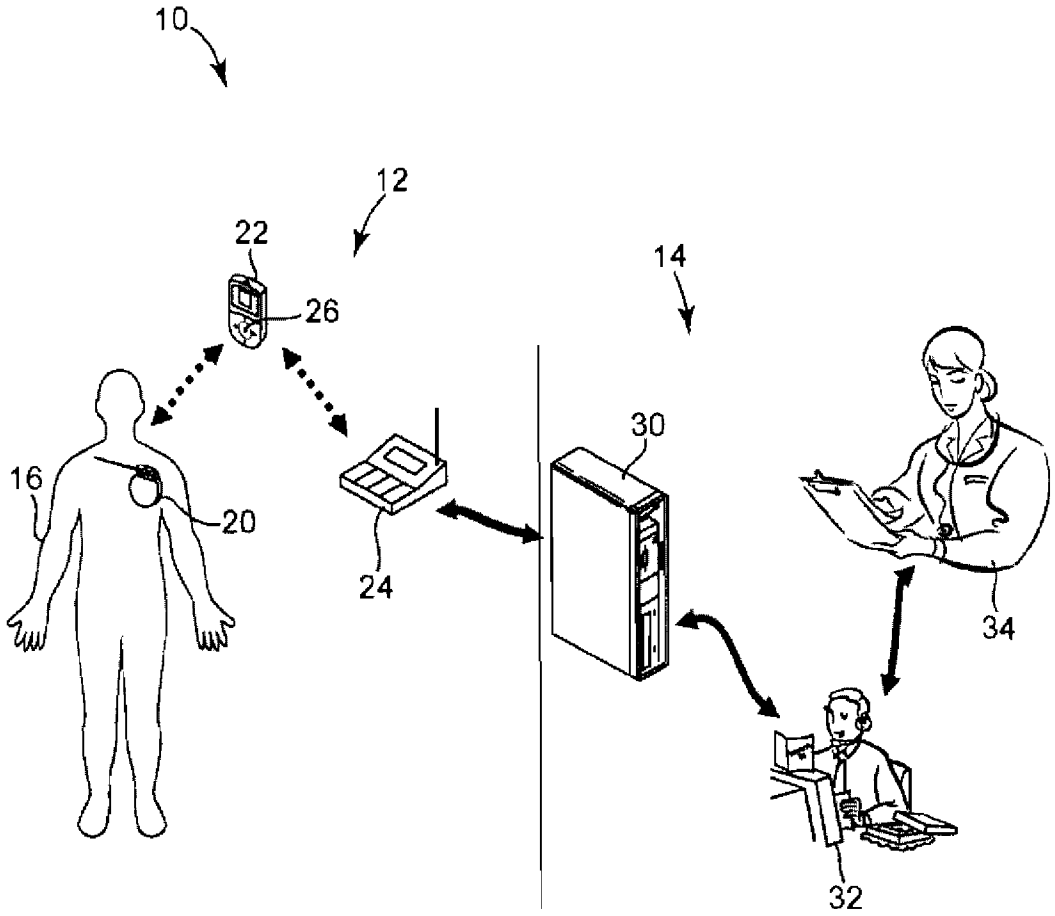


Fig. 1

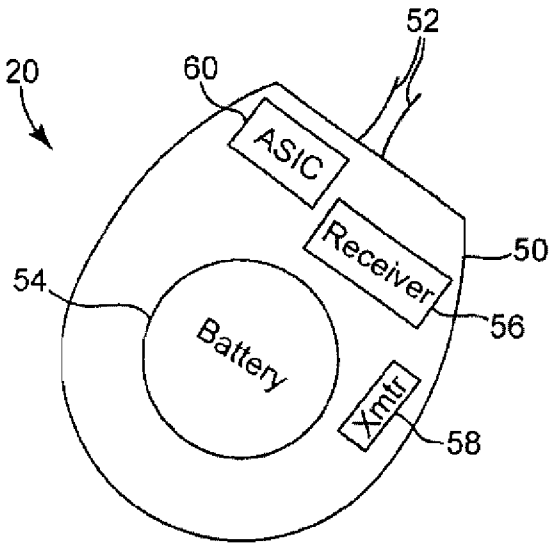


Fig. 2

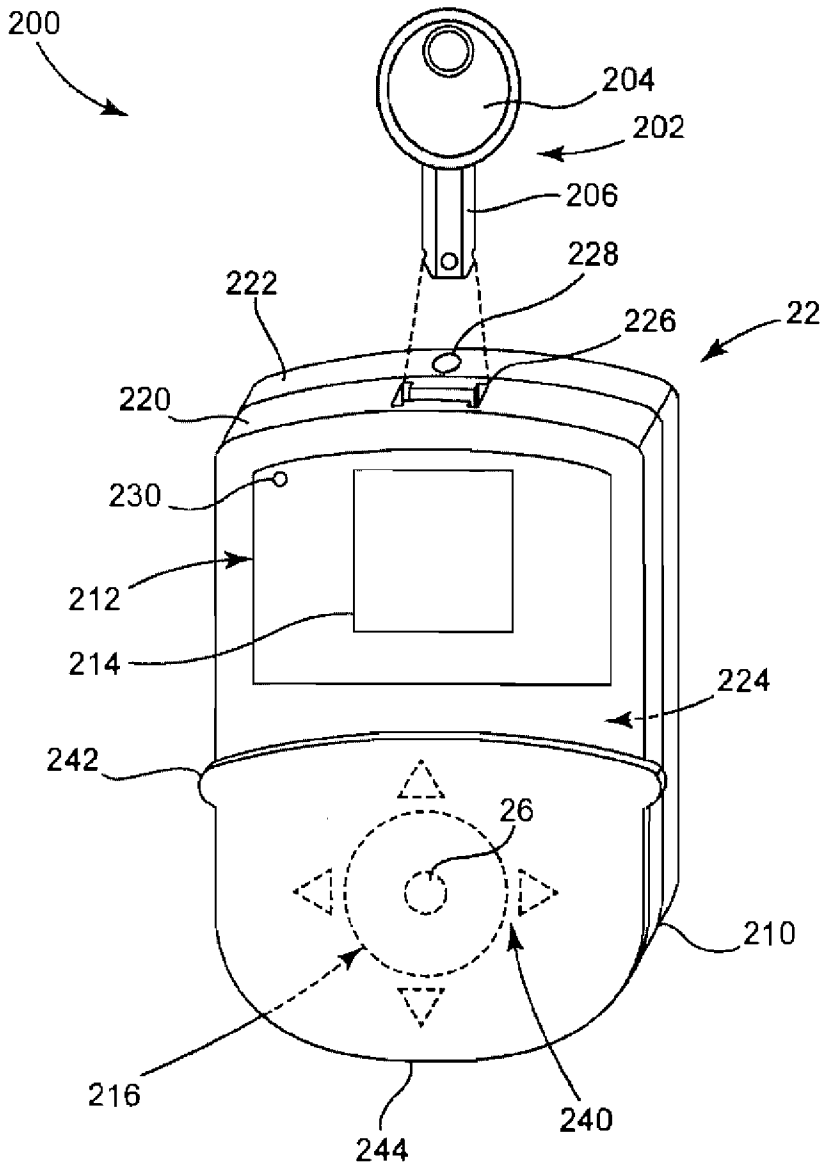

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Fig. 3

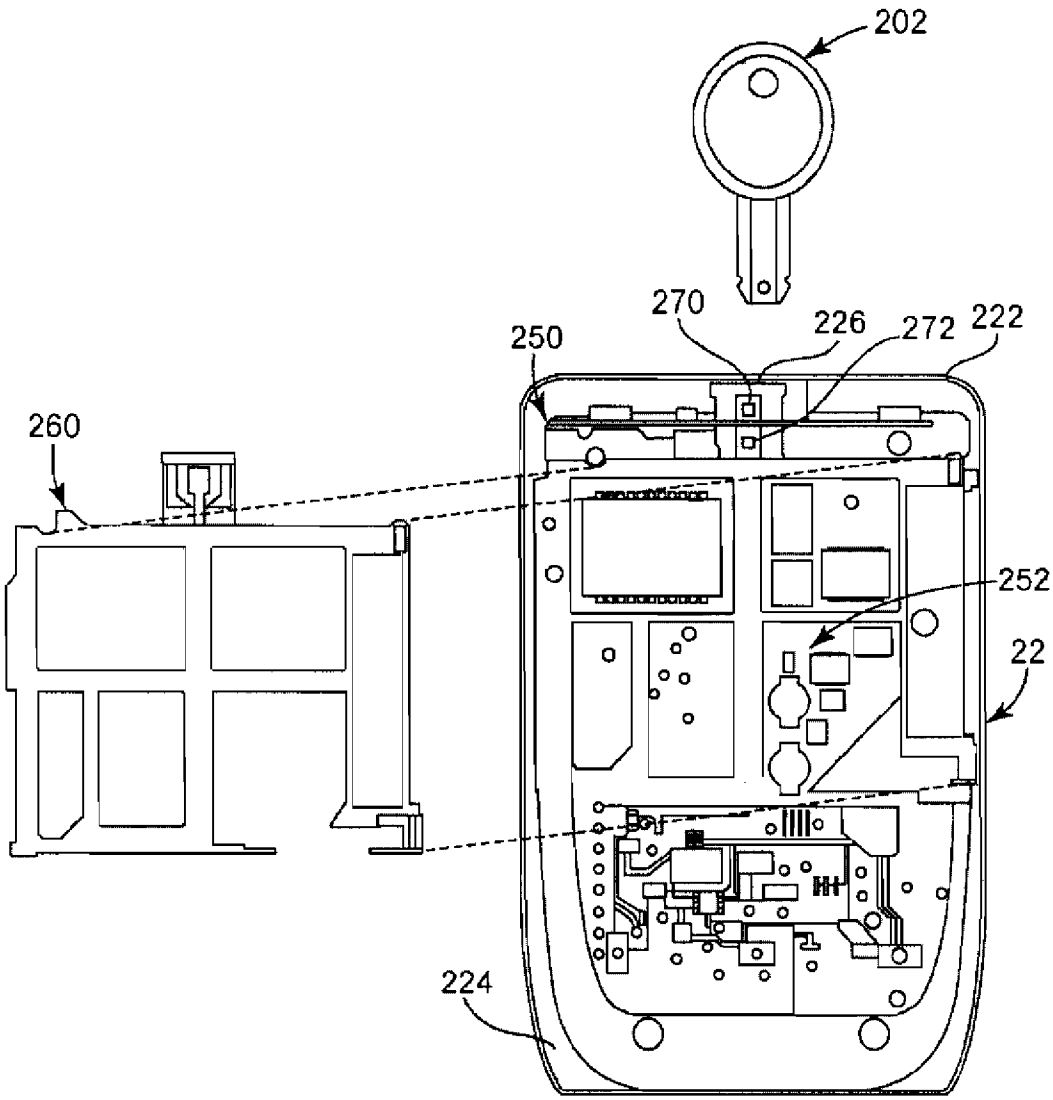


Fig. 4

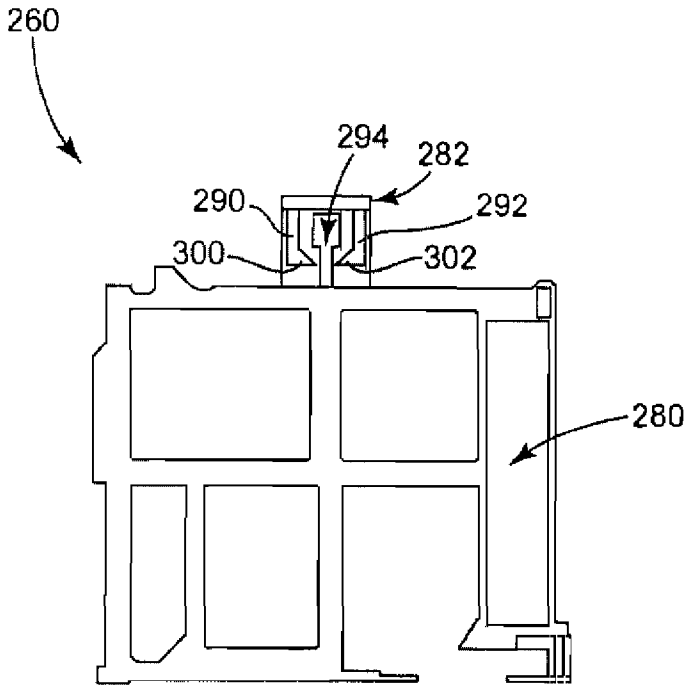


Fig. 5

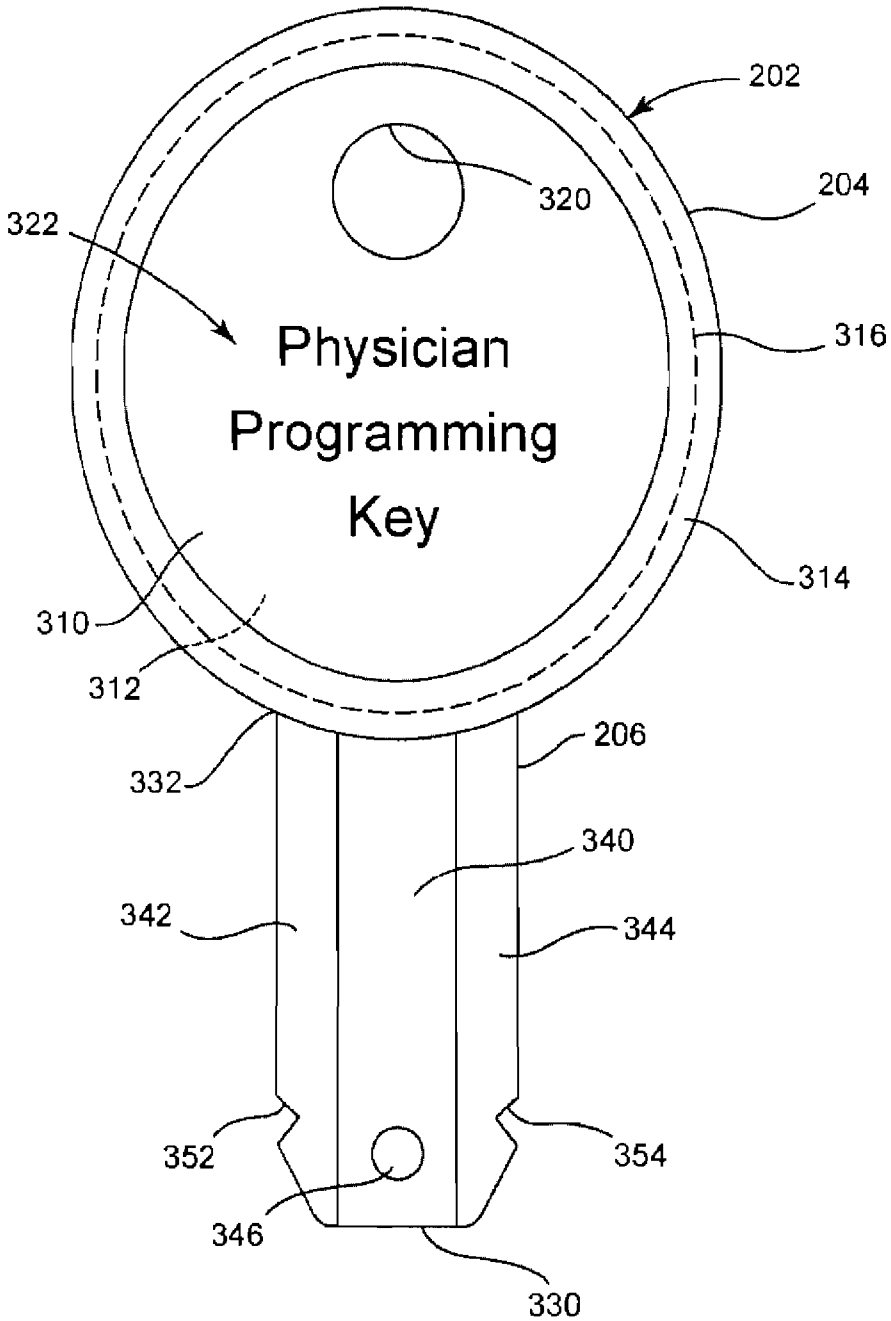

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Physician
Programming
Key
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Fig. 6

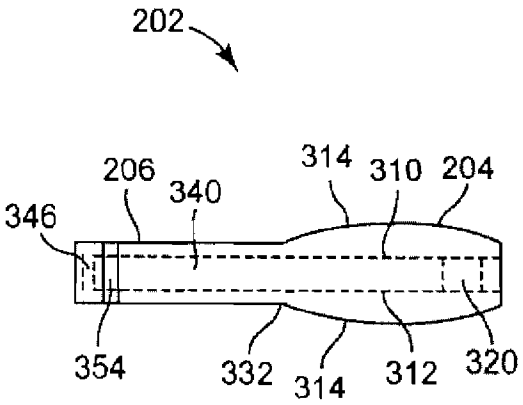


Fig. 7

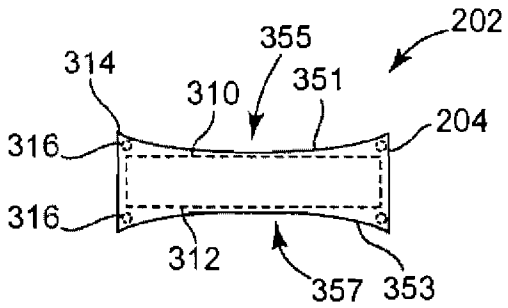


Fig. 8

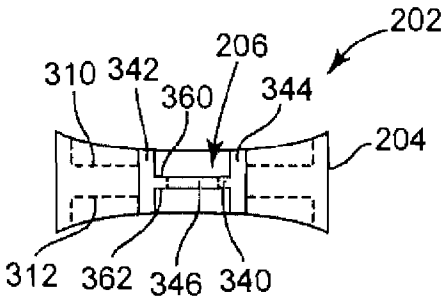


Fig. 9

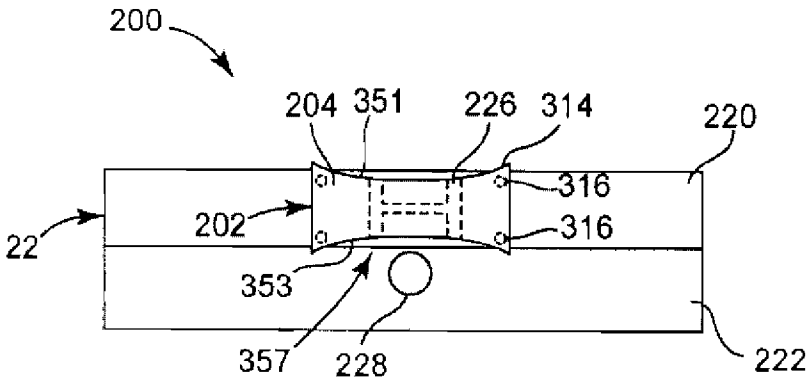


Fig. 10

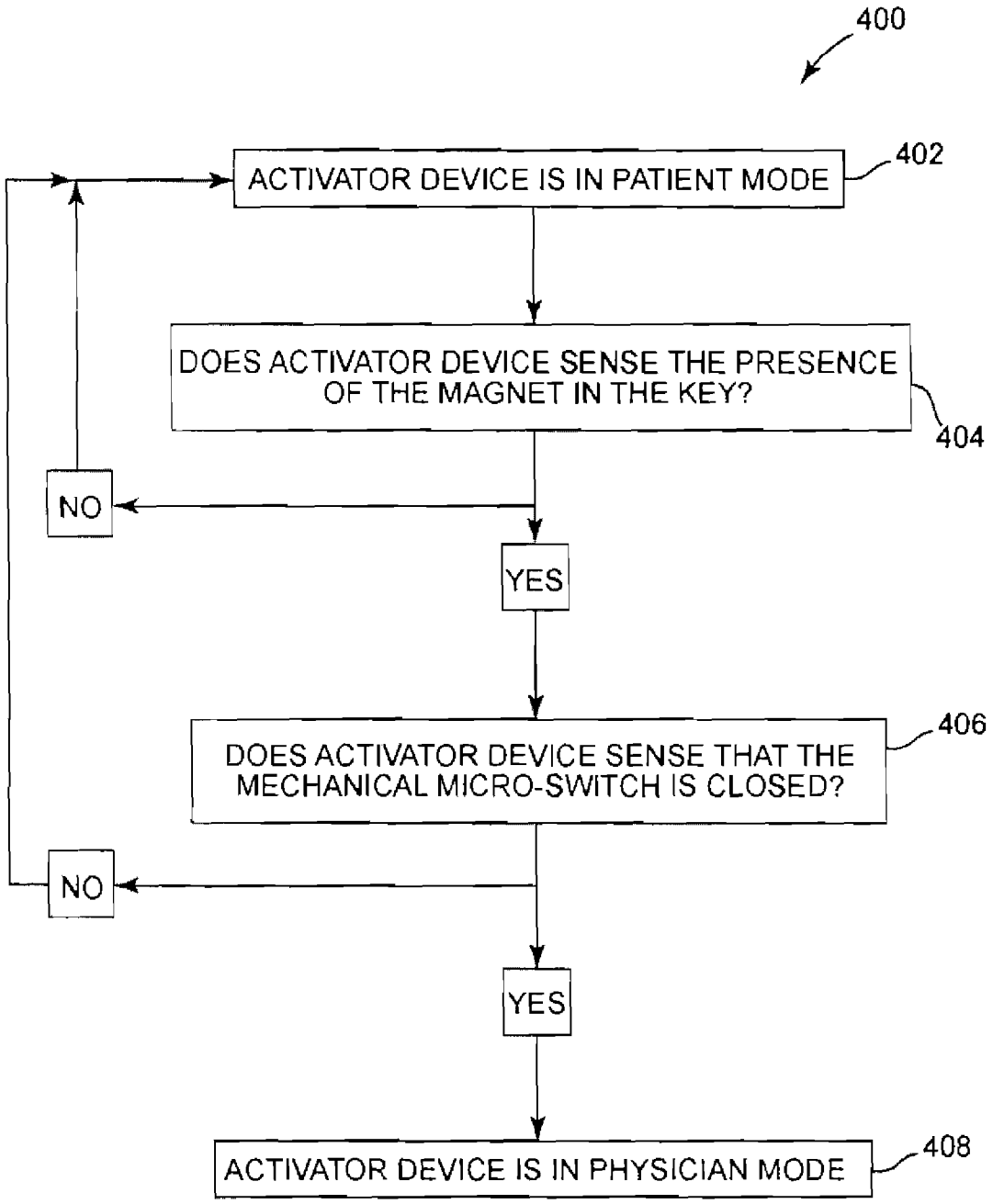

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ACTIVATOR DEVICE IS IN PATIENT MODE
402
DOES ACTIVATOR DEVICE SENSE THE PRESENCE OF THE MAGNET IN THE KEY?
404
NO
YES
DOES ACTIVATOR DEVICE SENSE THAT THE MECHANICAL MICRO-SWITCH IS CLOSED?
406
NO
YES
ACTIVATOR DEVICE IS IN PHYSICIAN MODE
408

Fig. 11