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Kaib et al.

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(54) **SYSTEMS AND METHODS FOR UTILIZING IDENTIFICATION DEVICES IN A WEARABLE MEDICAL THERAPY DEVICE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 15 days.

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(51) **Int. Cl.**

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H01M 2/10	(2006.01)
A61B 90/90	(2016.01)
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H01M 10/48	(2006.01)

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

CPC ***A61N 1/3925*** (2013.01); ***A61B 90/98*** (2016.02); ***A61N 1/3987*** (2013.01); ***H01M 2/1022*** (2013.01); ***H01M 10/48*** (2013.01); *A61B 90/90* (2016.02); *A61N 1/3968* (2013.01); *A61N 1/3975* (2013.01); *H01M 2220/30* (2013.01)

(58) **Field of Classification Search**

USPC 340/10.51

See application file for complete search history.

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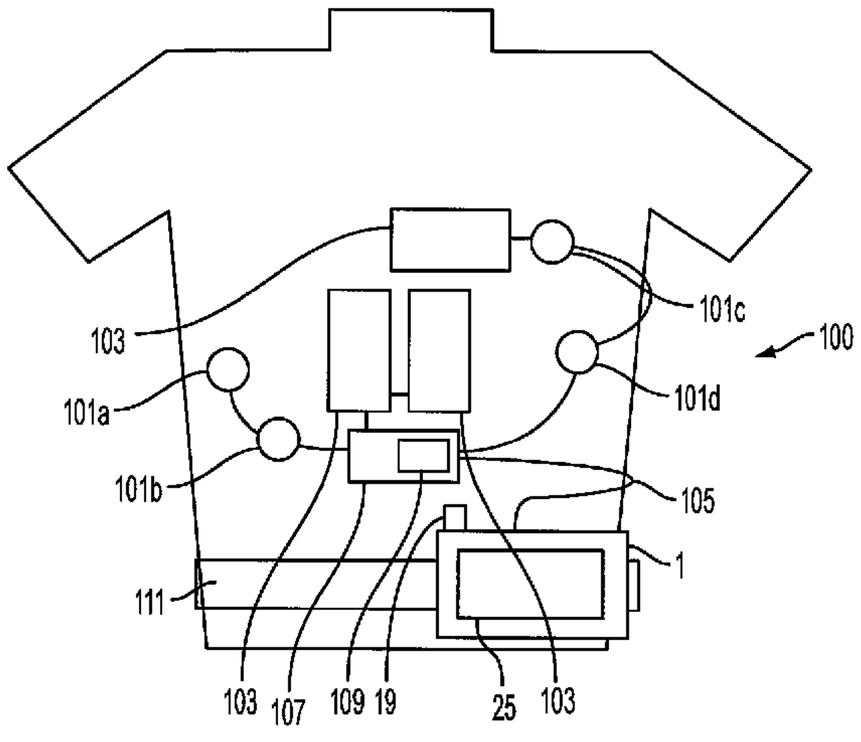
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(57) **ABSTRACT**

A system includes: at least one identification device associated with a wearable medical therapy device and configured to have information read therefrom and written thereto; at least one controller operatively connected to the at least one identification device and configured to at least one of retrieve the information from the at least one identification device and write the information to the at least one identification device; and at least one device positioned externally from the wearable medical therapy device and configured to interrogate the at least one identification device to at least one of obtain the information from the at least one identification device and write additional information to the at least one identification device.

17 Claims, 22 Drawing Sheets



Related U.S. Application Data

on Jul. 7, 2014, provisional application No. 62/025,660, filed on Jul. 17, 2014.

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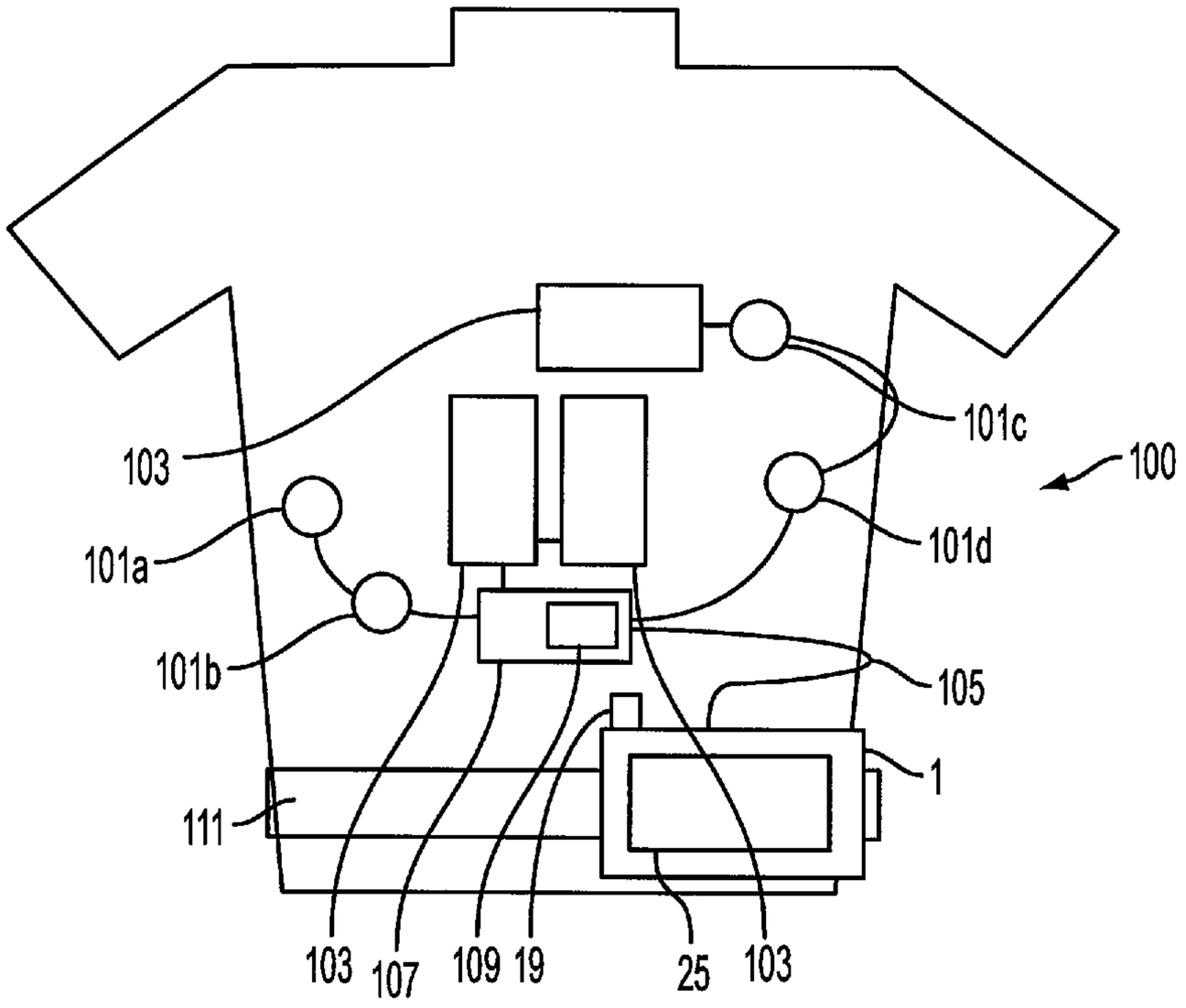


FIG. 1

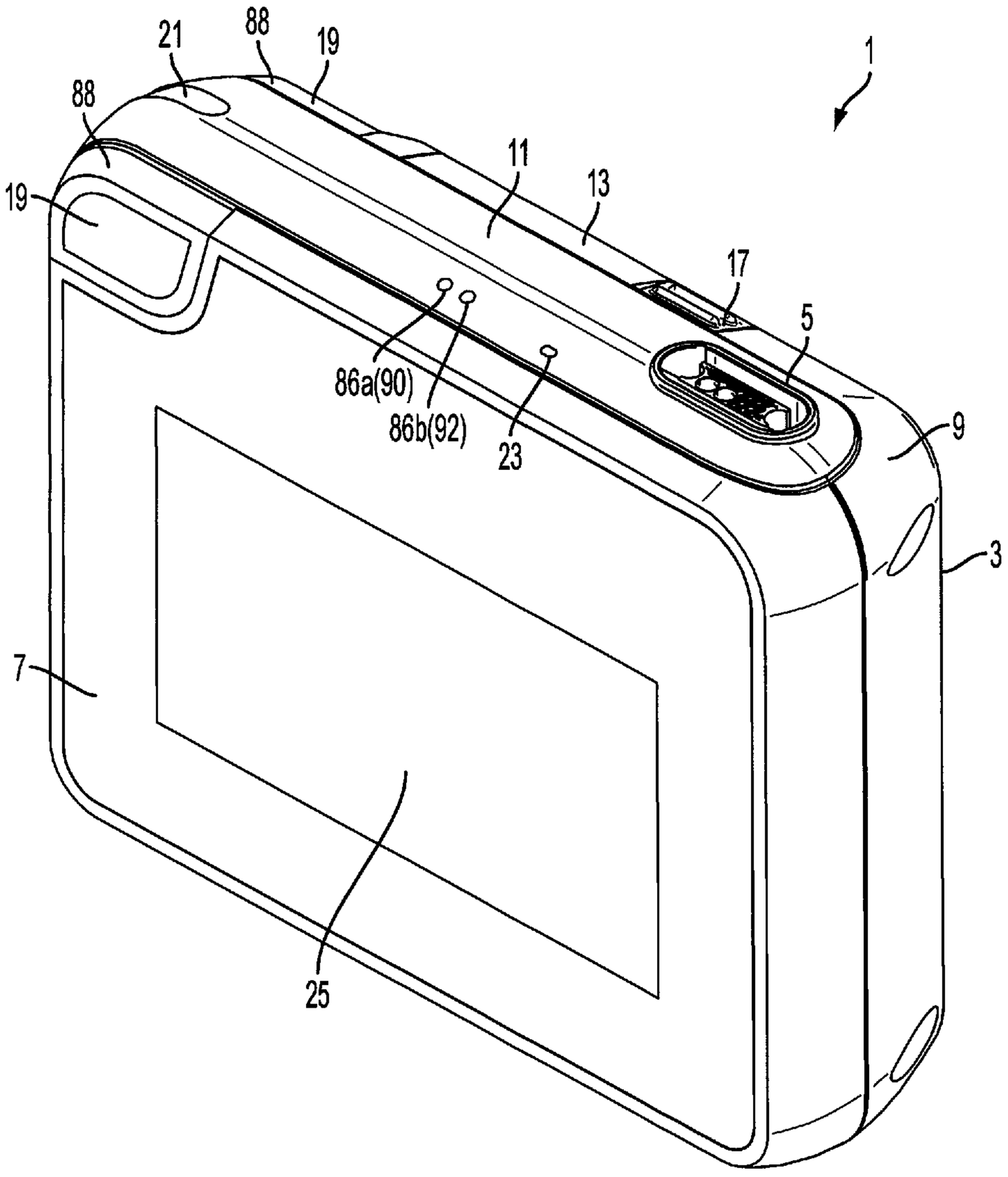


FIG. 2

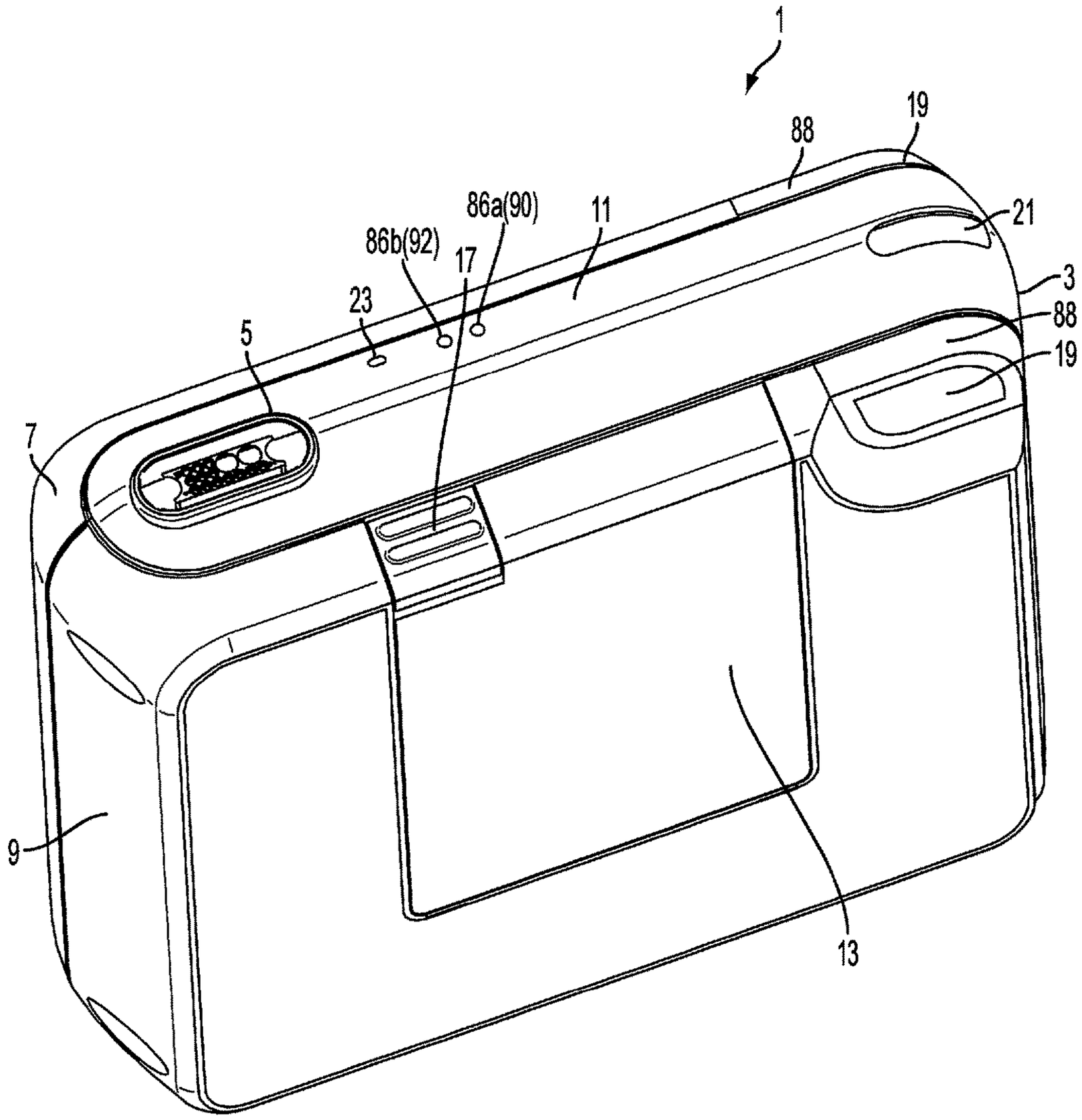


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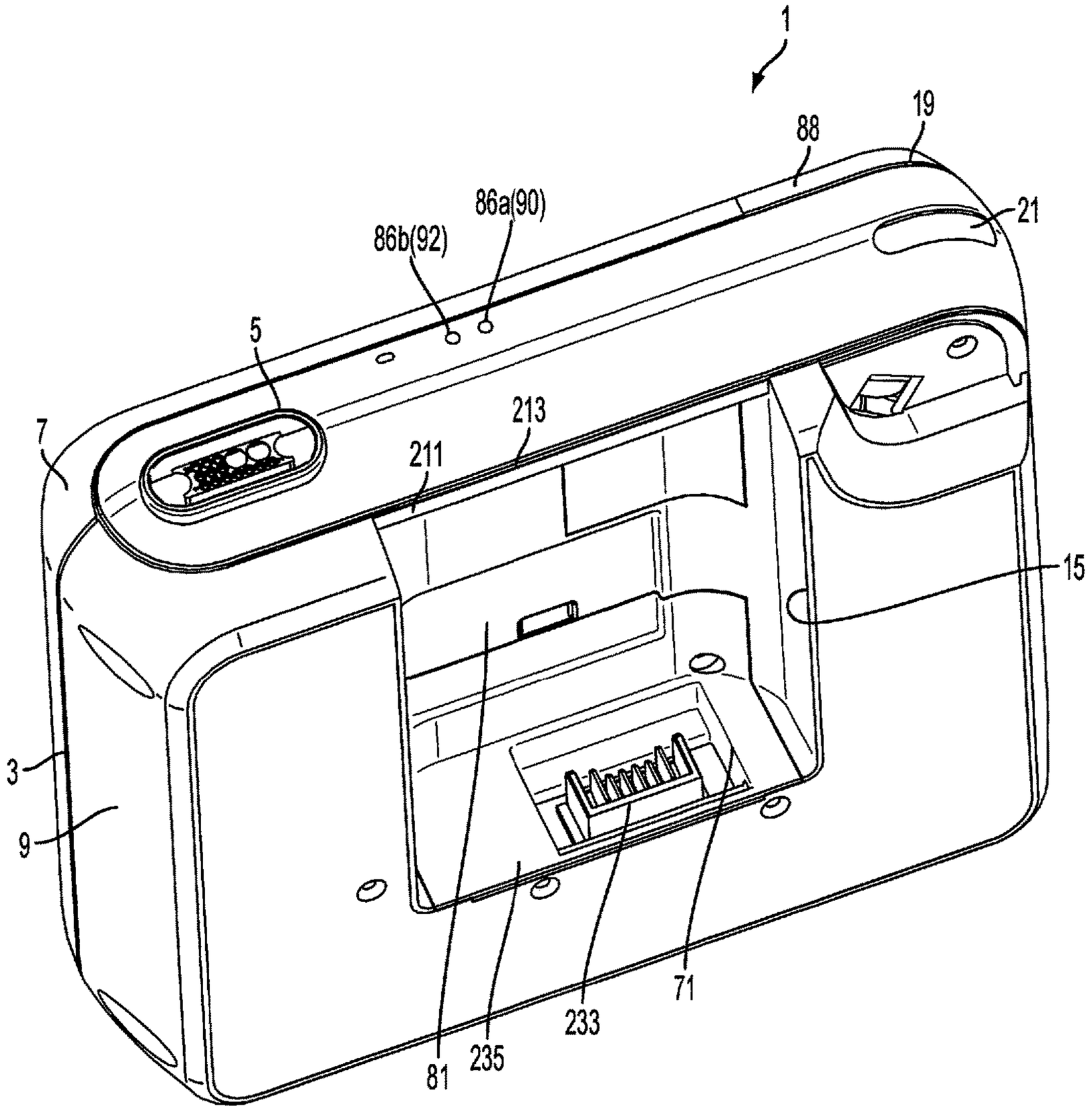


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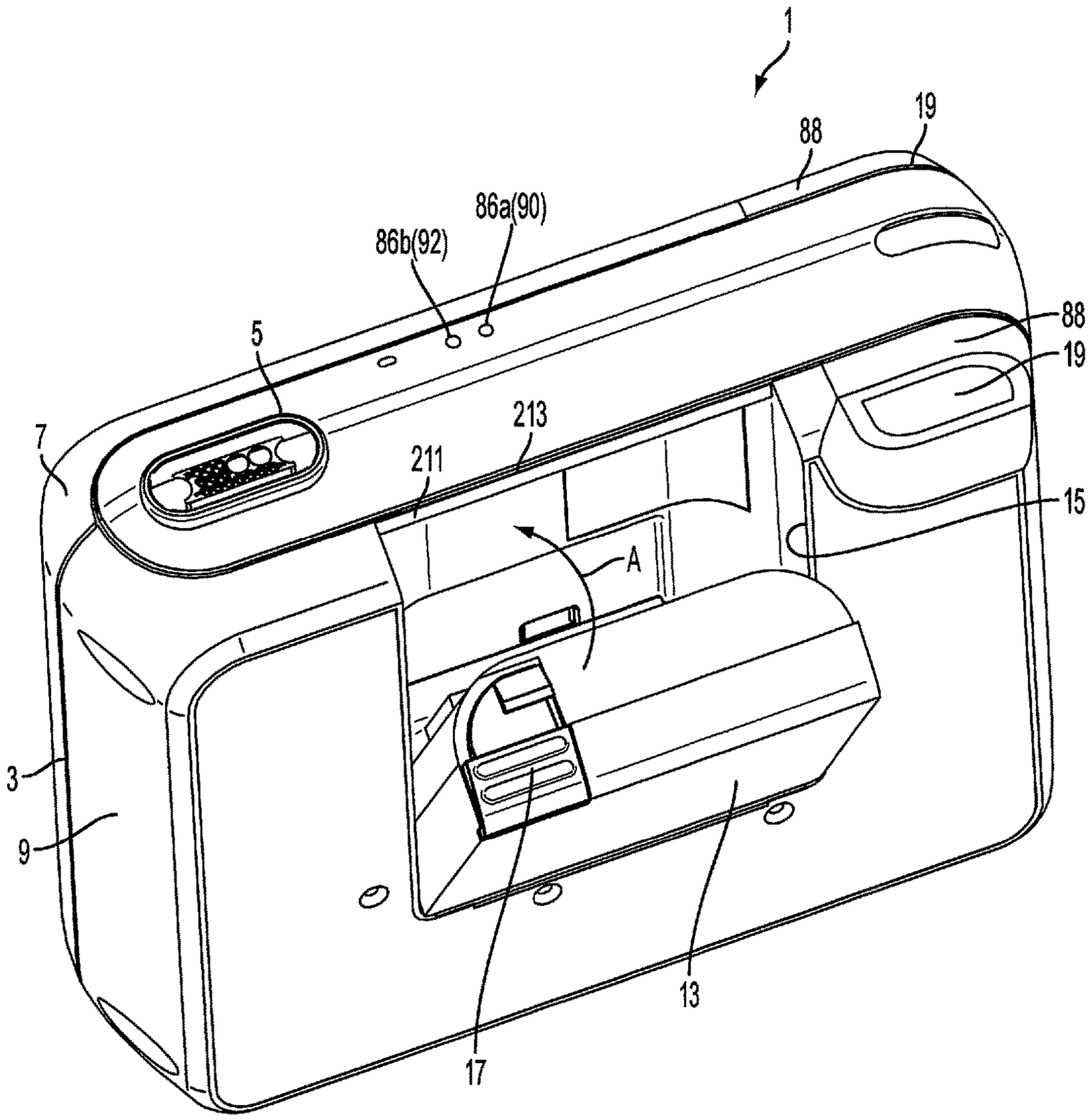


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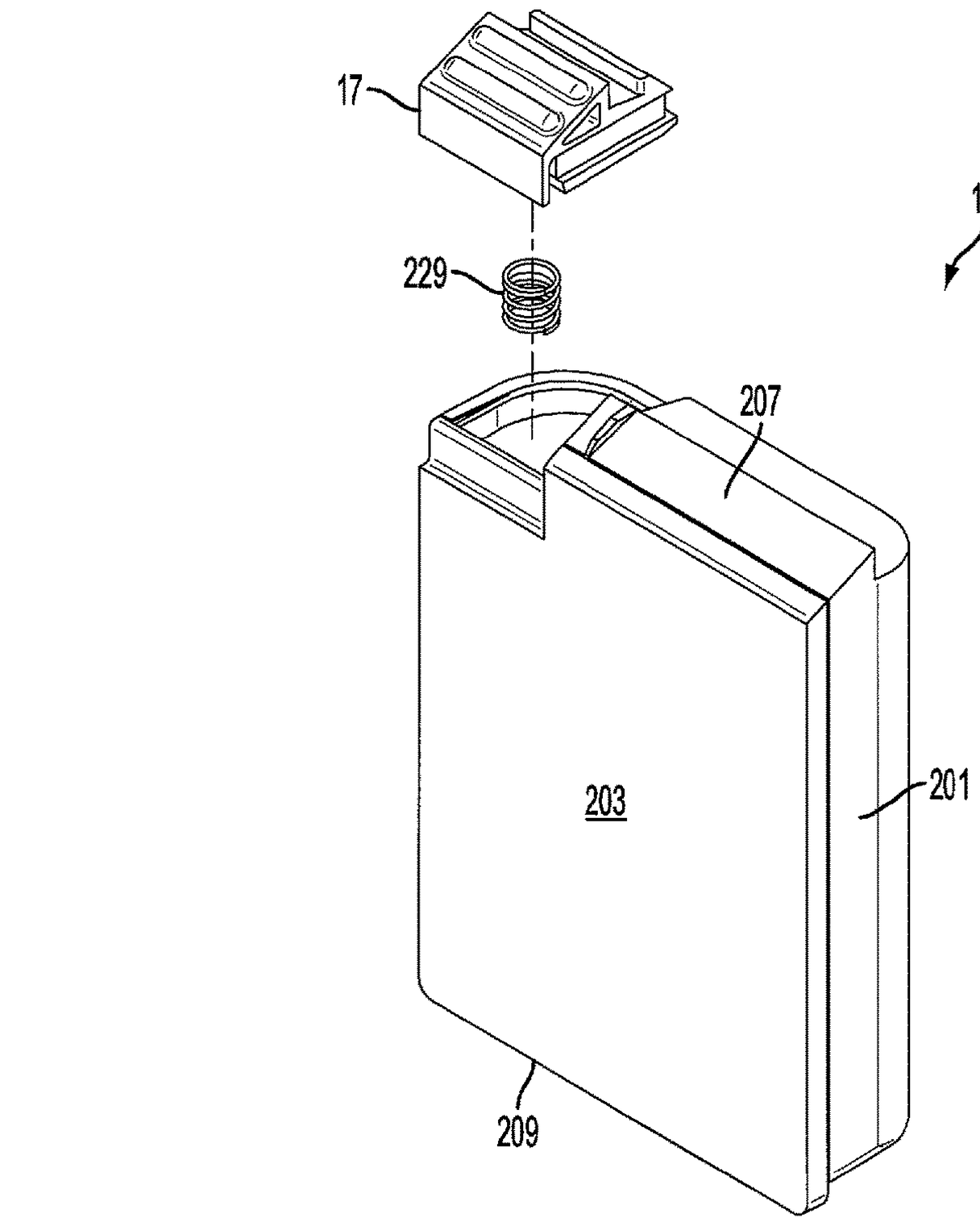


FIG. 6

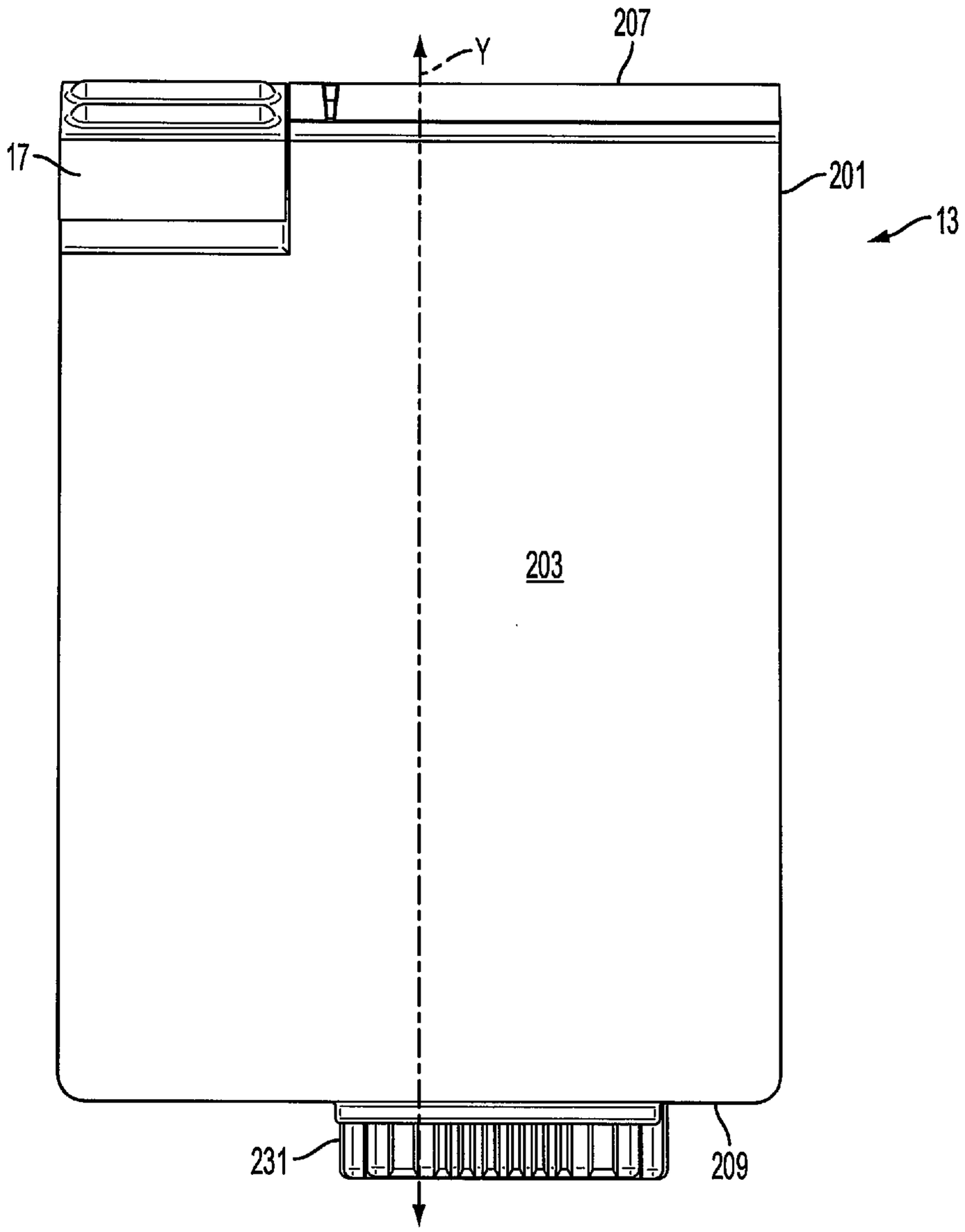


FIG. 7

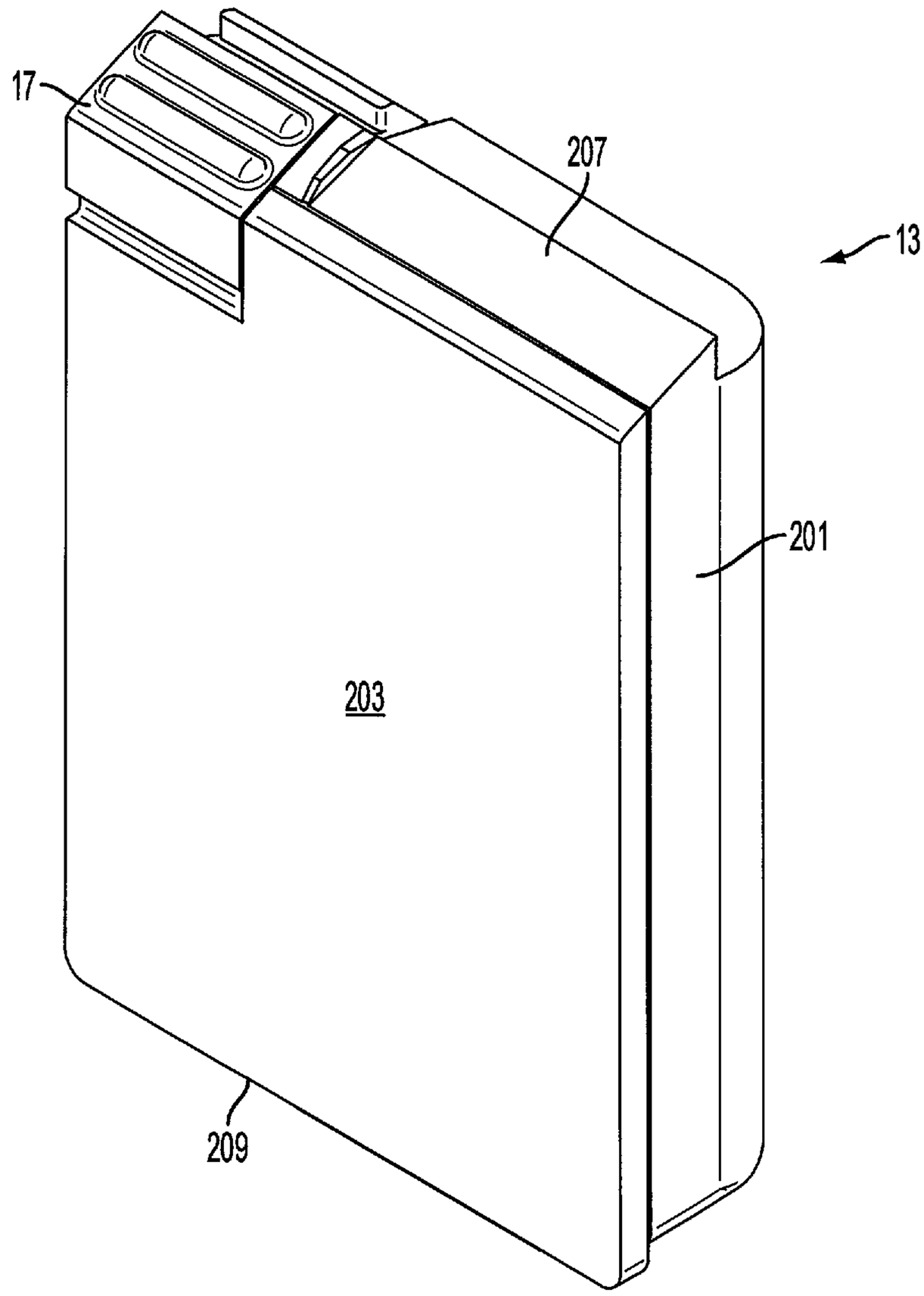


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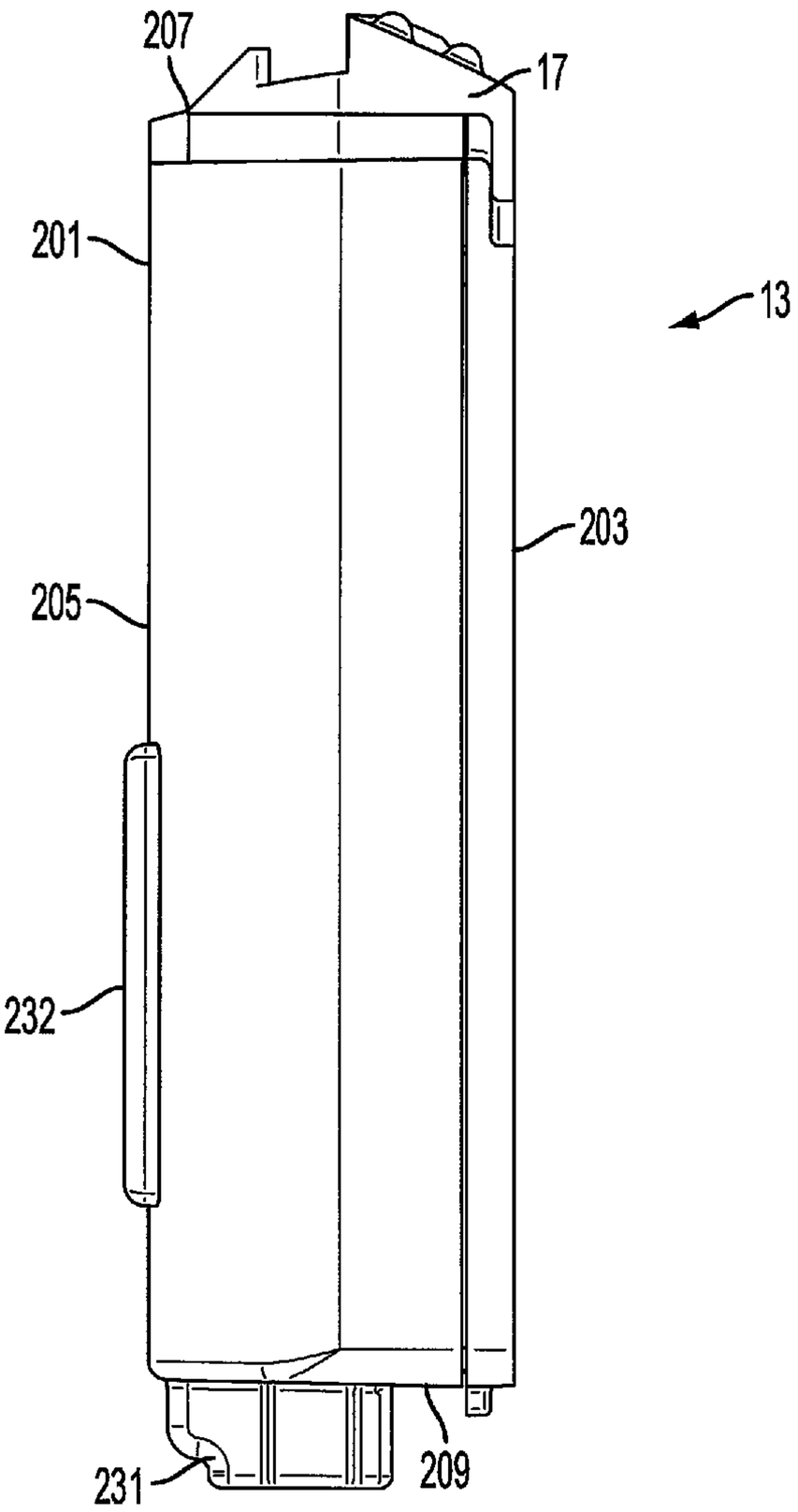


FIG. 9

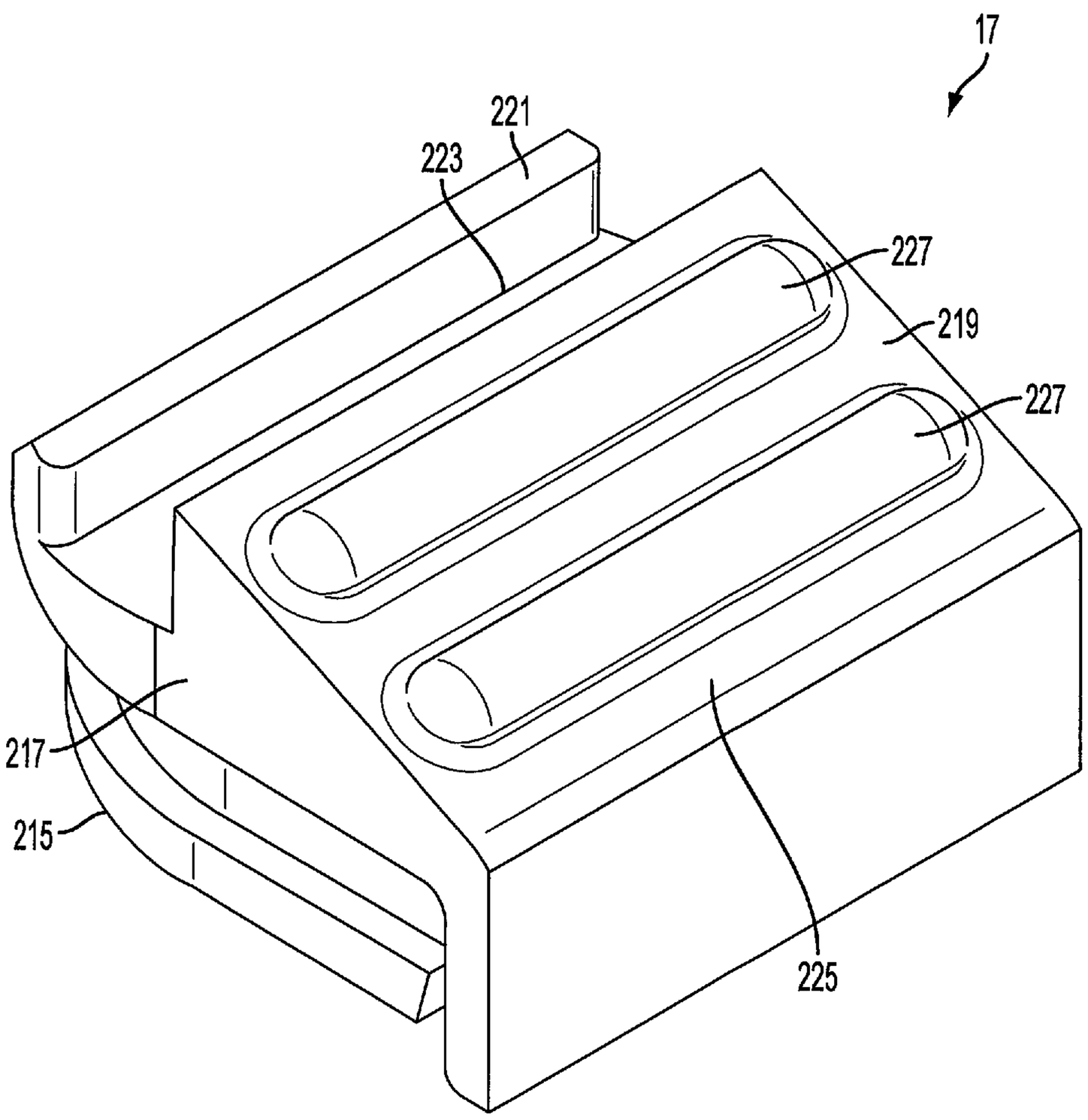


FIG. 10

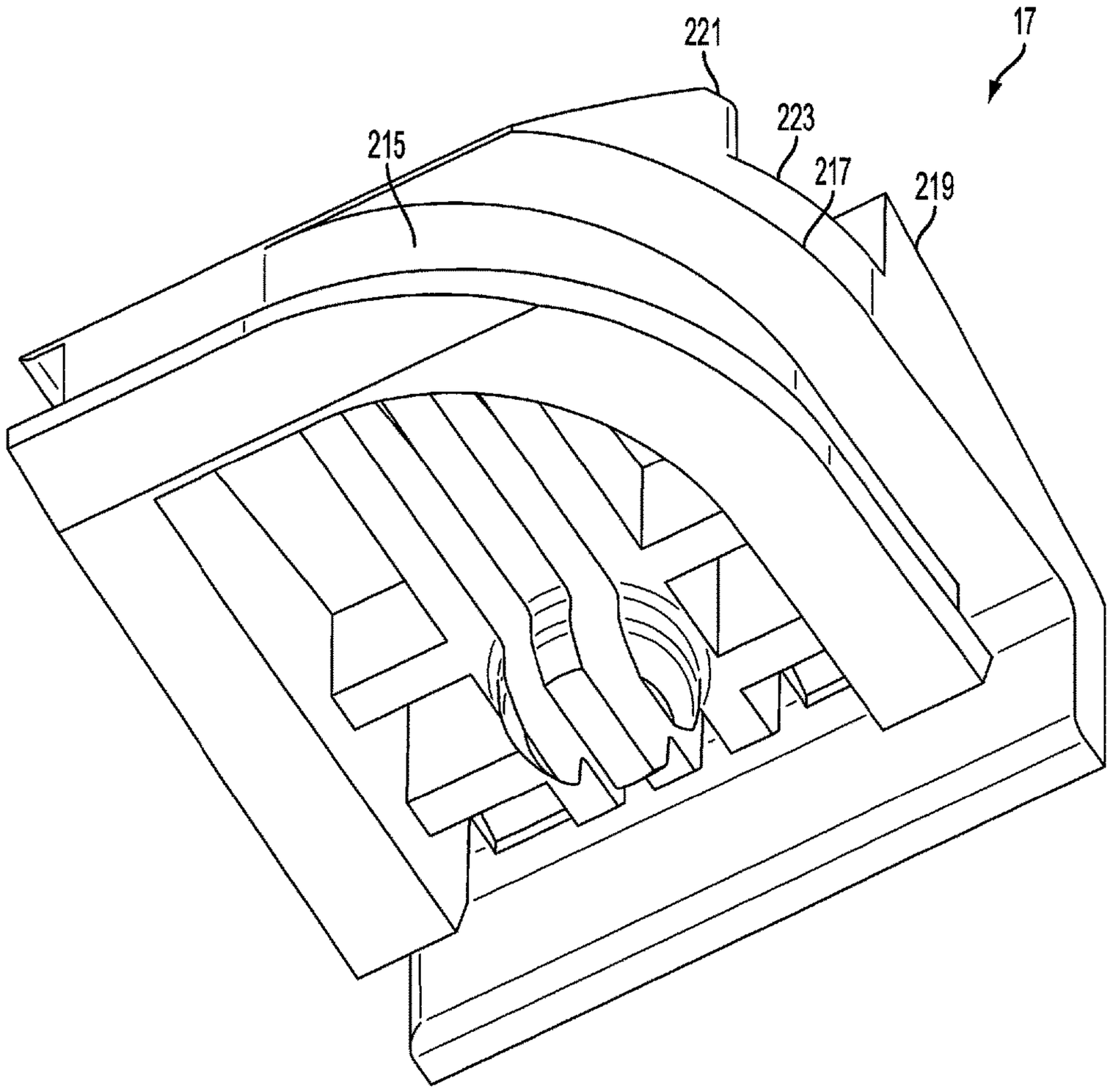


FIG. 11

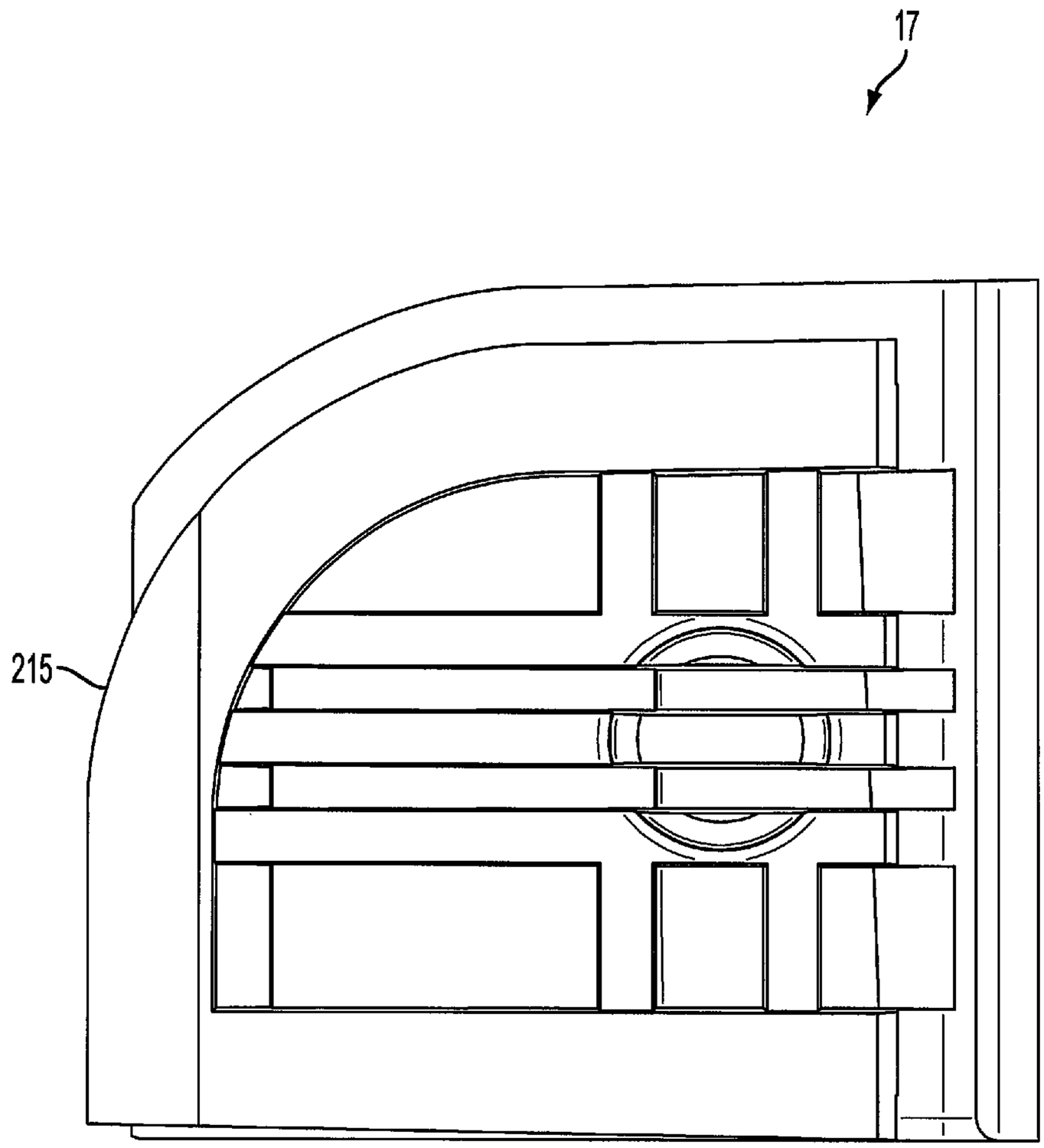


FIG. 12

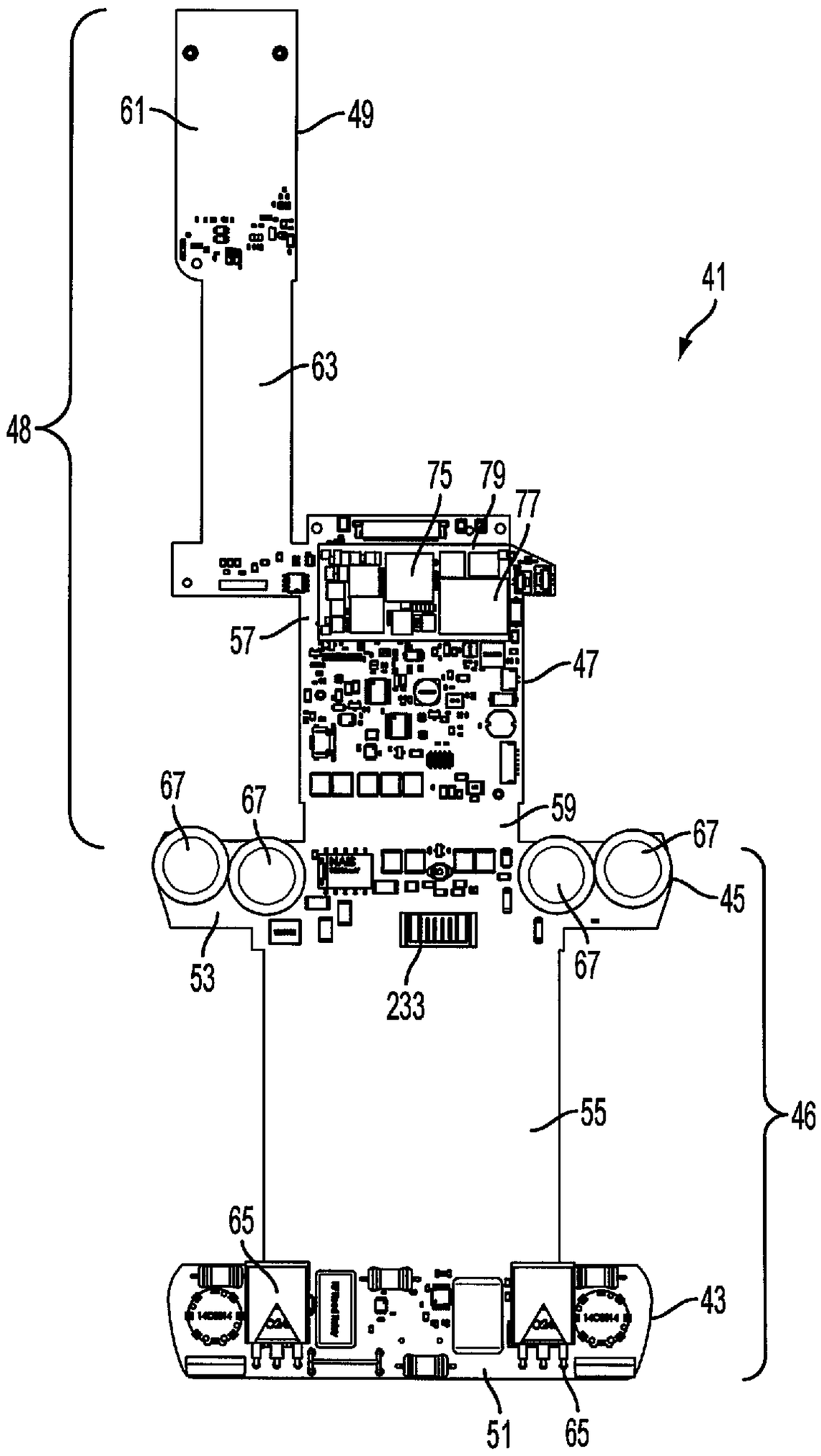


FIG. 13

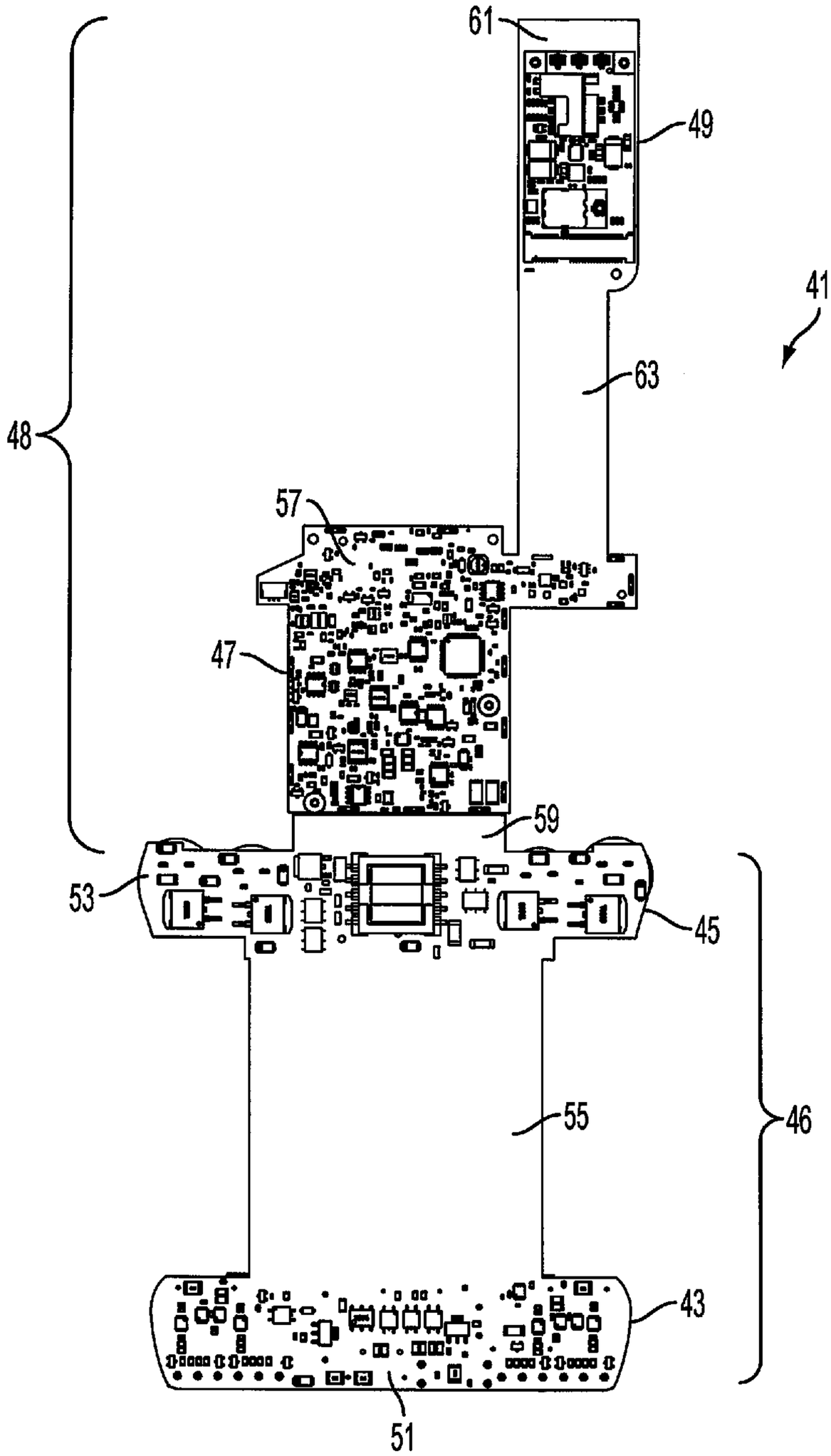


FIG. 14

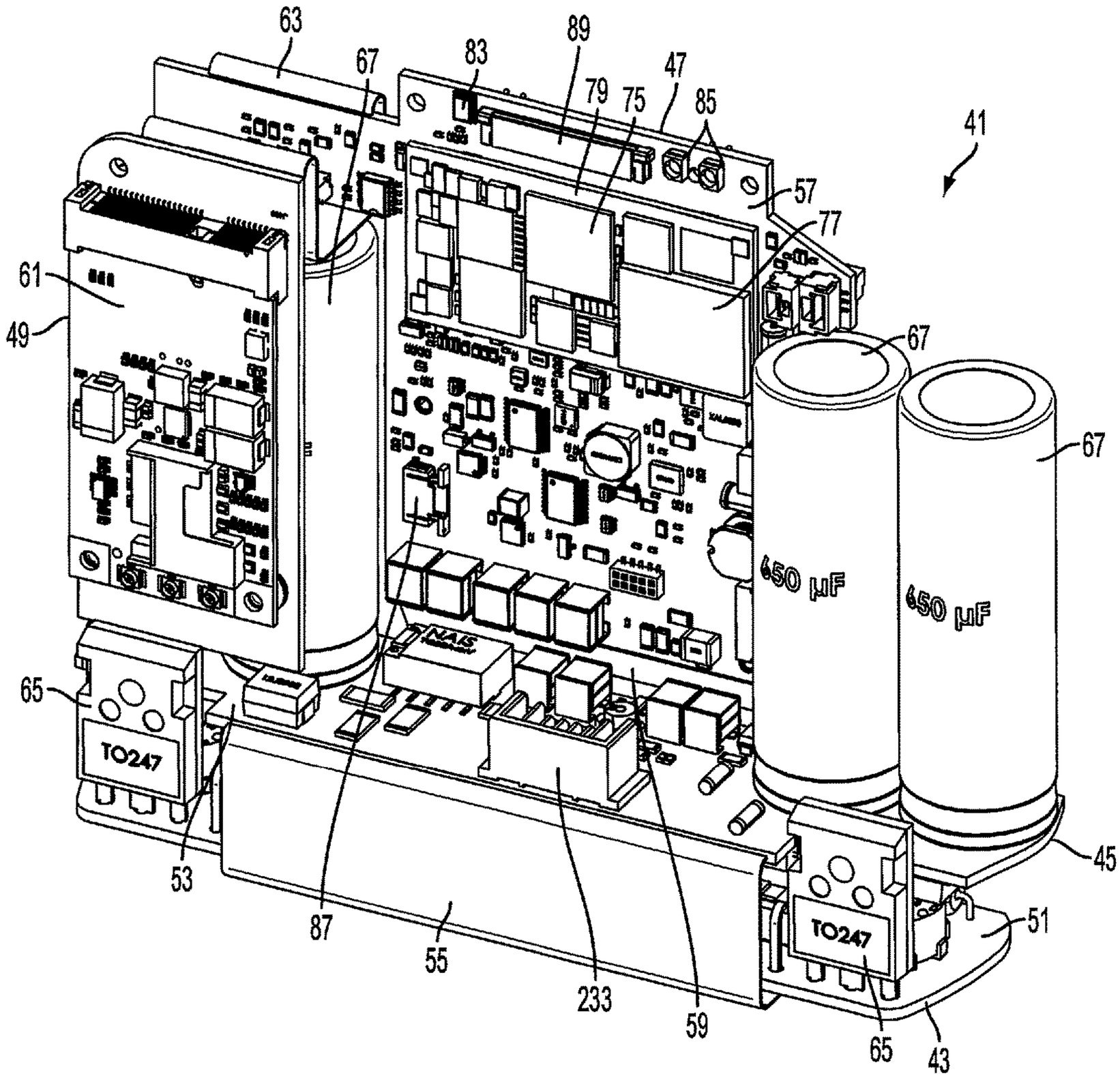

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FIG. 15

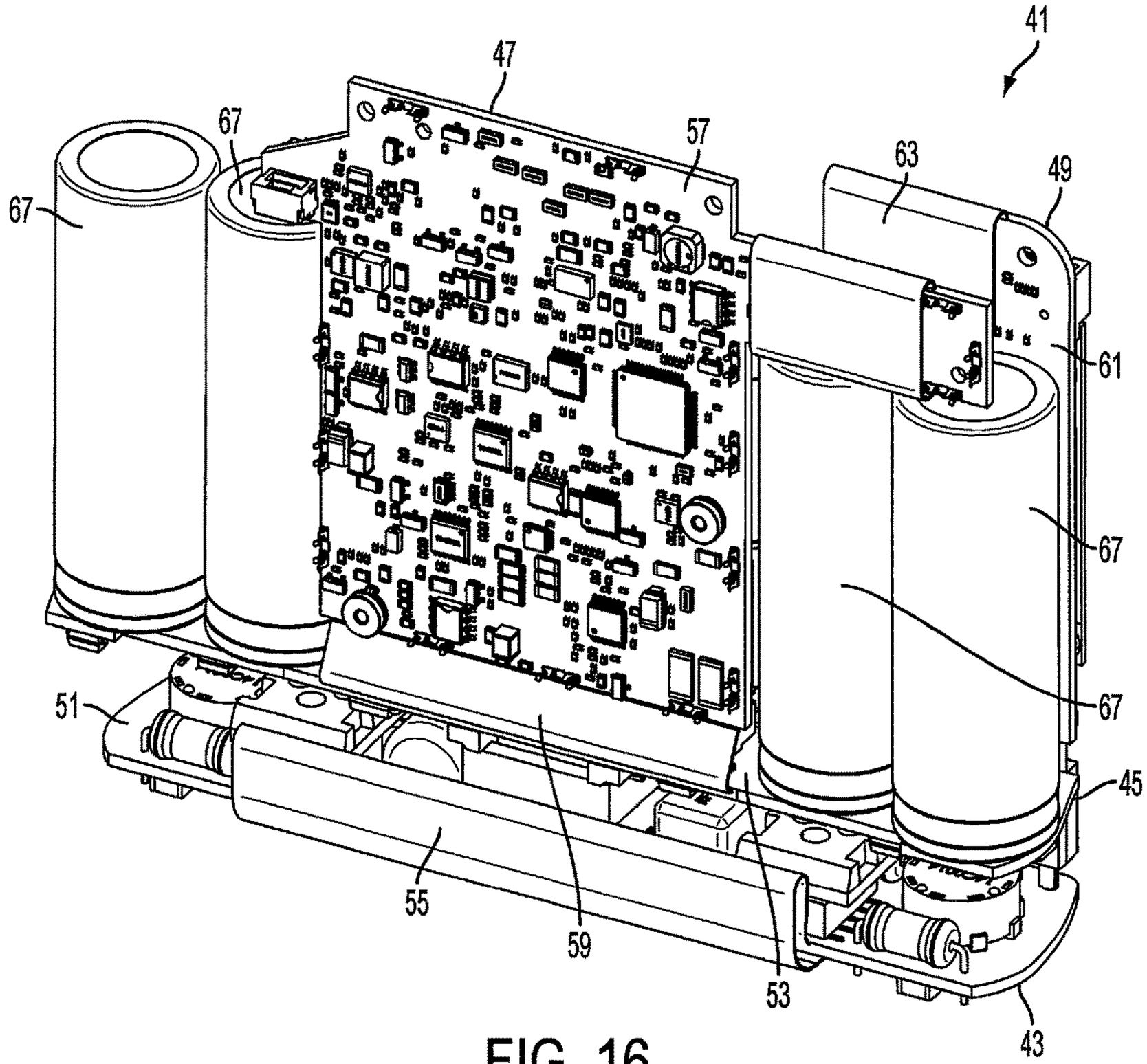


FIG. 16

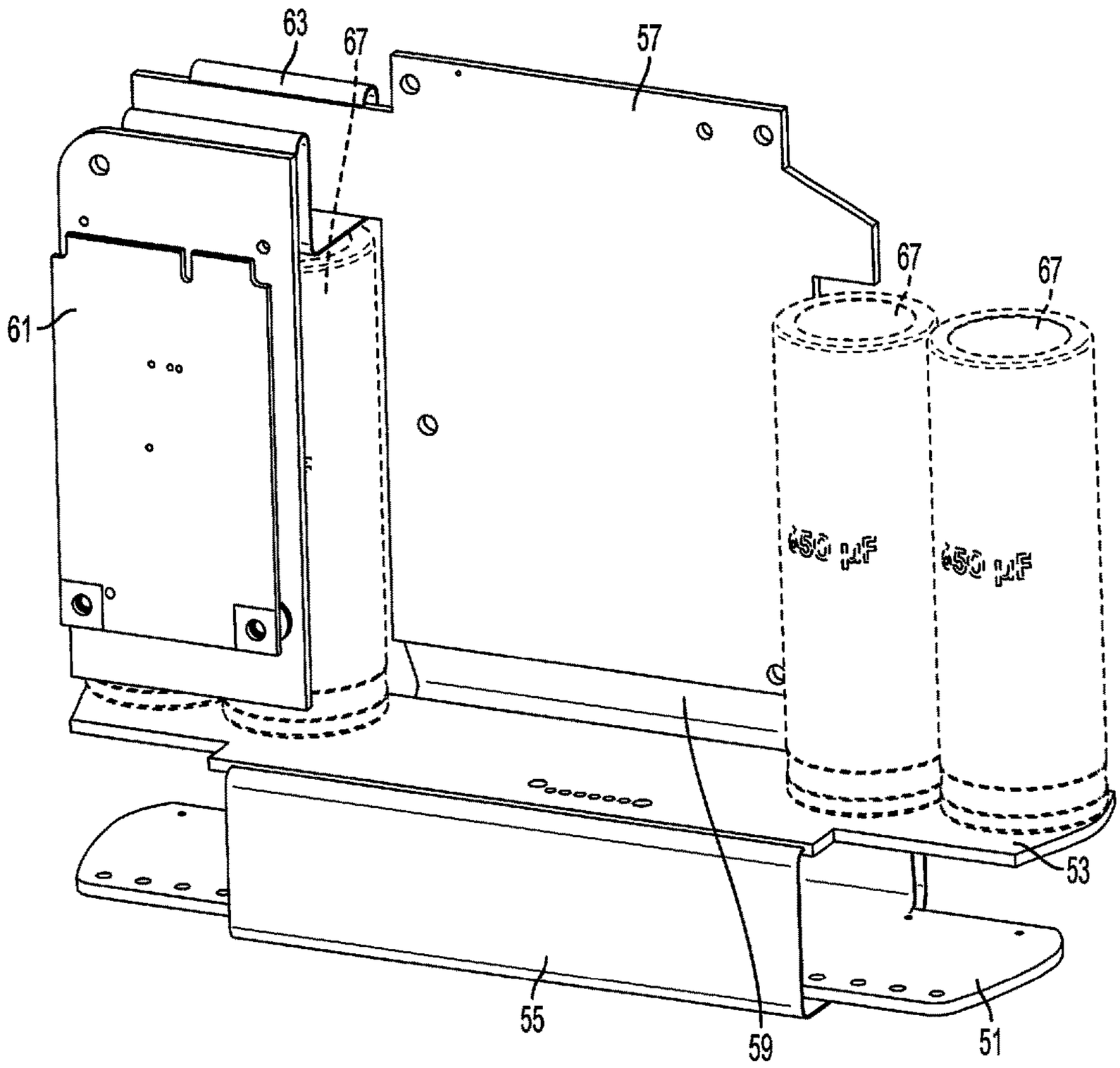


FIG. 17

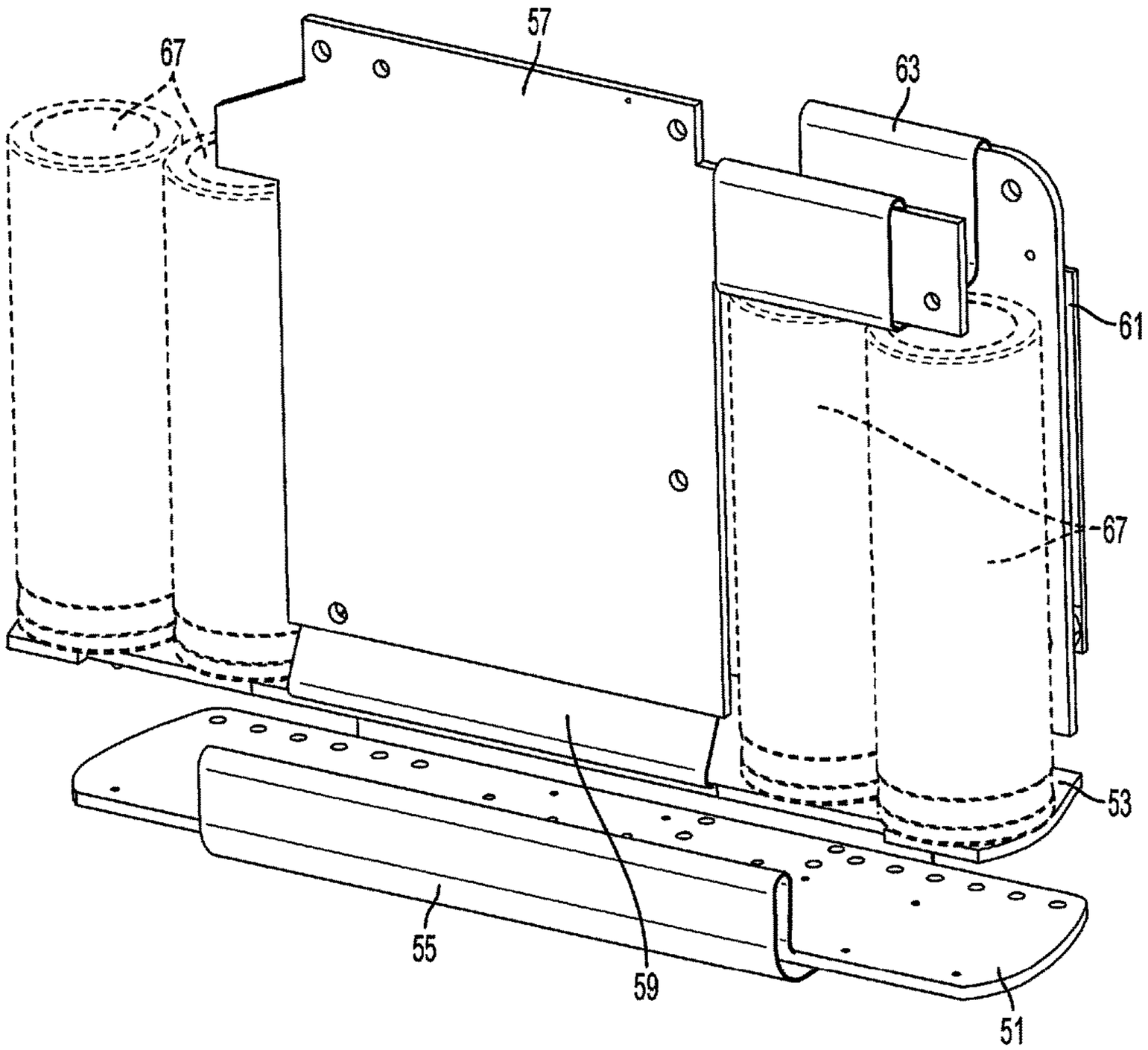


FIG. 18

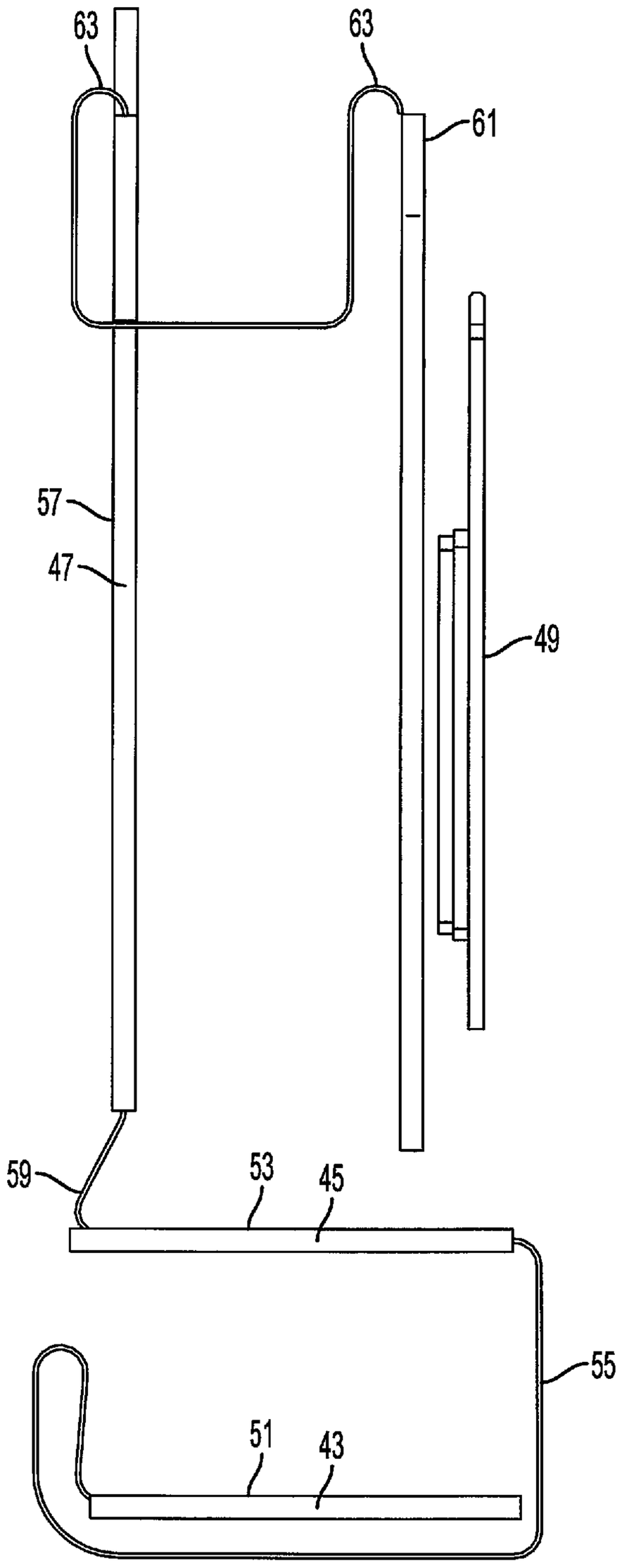


FIG. 19

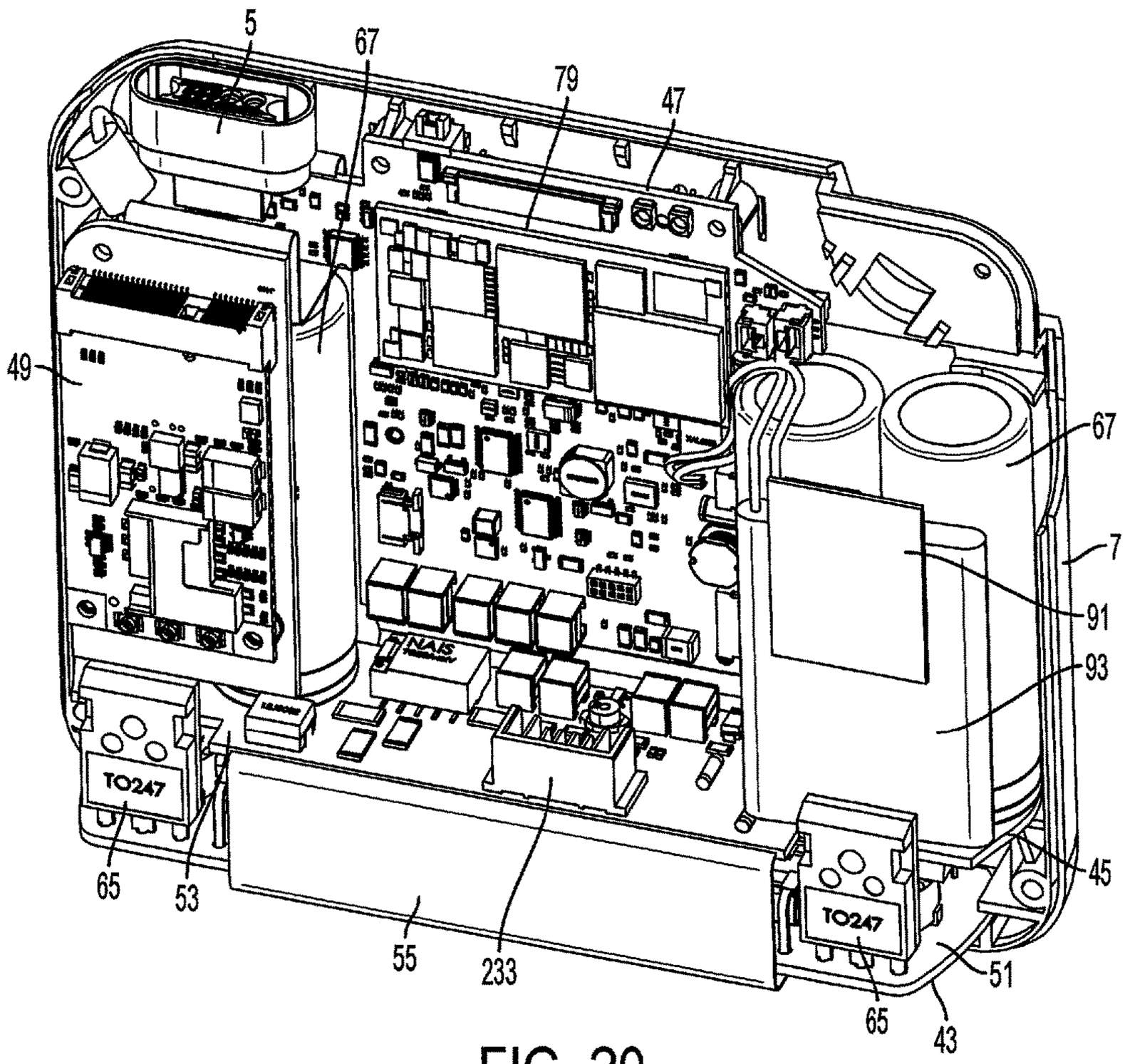


FIG. 20

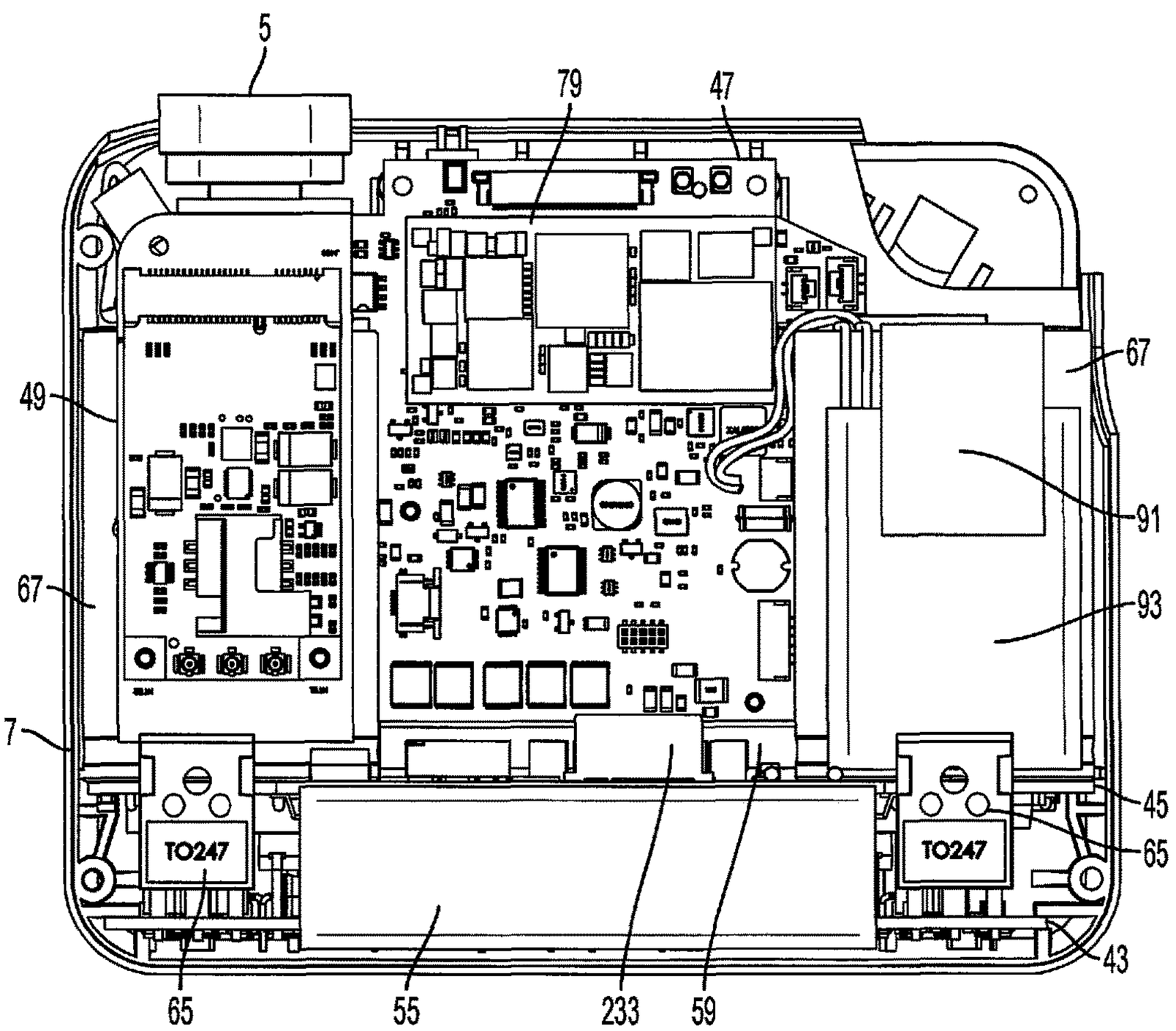


FIG. 21

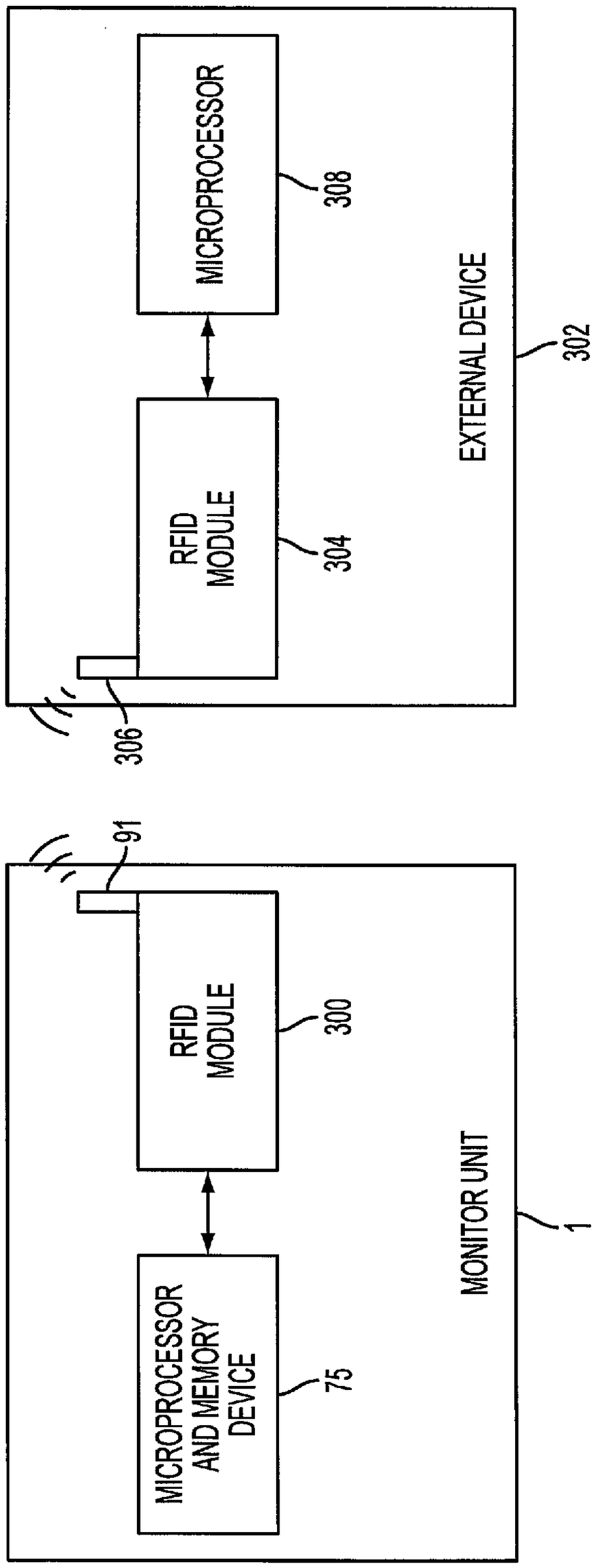

MICROPROCESSOR
308
EXTERNAL DEVICE
302
RFID MODULE
304
306
91
RFID MODULE
300
MICROPROCESSOR AND MEMORY DEVICE
75
MONITOR UNIT
1

FIG. 22

SYSTEMS AND METHODS FOR UTILIZING IDENTIFICATION DEVICES IN A WEARABLE MEDICAL THERAPY DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application Ser. No. 61/861,110 entitled "Compact Controller Device for Defibrillator" filed Aug. 1, 2013, U.S. Provisional Patent Application Ser. No. 62/021,609 entitled "Wearable Defibrillator" filed Jul. 7, 2014, and U.S. Provisional Patent Application Ser. No. 62/025,660 entitled "Wearable Defibrillator" filed Jul. 17, 2014, all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

The present disclosure generally relates to the treatment of heart defects by the administration of electrical therapy and, more particularly, to a defibrillator for imparting the electrical therapy to the heart.

Description of Related Art

Technology is available for correcting excessively slow heart rates (bradycardia) using implantable devices, commonly referred to as pacemakers, which deliver microjoule electrical pulses to a slowly beating heart in order to speed the heart rate up to an acceptable level. Also, it is well known to deliver high energy shocks (e.g., 180 to 360 joules) via external paddles applied to the chest wall in order to correct excessively fast heart rates, and prevent the possible fatal outcome of ventricular fibrillation or certain ventricular tachycardias. Bradycardia, ventricular fibrillation, and ventricular tachycardia are all electrical malfunctions (arrhythmias) of the heart. Each may lead to death within minutes unless corrected by the appropriate electrical stimulation.

One of the most deadly forms of heart arrythmias is ventricular fibrillation, which occurs when the normal, regular electrical impulses are replaced by irregular and rapid impulses, causing the heart muscle to stop normal contractions and to begin to quiver. Normal blood flow ceases, and organ damage or death may result in minutes if normal heart contractions are not restored. Although frequently not noticeable to the victim, ventricular fibrillation is often preceded by ventricular tachycardia, which is a regular but fast rhythm of the heart. Because the victim has no noticeable warning of the impending fibrillation, death often occurs before the necessary medical assistance can arrive.

Because time delays in applying the corrective electrical treatment may result in death, implantable pacemakers and defibrillators have significantly improved the ability to treat these otherwise life-threatening conditions. Being implanted within the patient, the device continuously monitors the patient's heart for treatable arrhythmias and, when such is detected, the device applies corrective electrical pulses directly to the heart.

Normal heart function often can be restored to a person suffering ventricular fibrillation or ventricular tachycardia by a procedure known as cardioversion, the synchronized application of electrical therapy to the heart muscle. Pacemakers and defibrillators that apply corrective electrical pulses externally to the patient's chest wall also are used to correct such life-threatening arrhythmias, but suffer from a drawback insofar as it may not be possible to apply the

device in time during an acute arrhythmic emergency to save the patient's life. Such treatment is needed within a few minutes to be effective.

Consequently, when a patient is deemed at high risk of death from such arrhythmias, electrical devices often are implanted so as to be readily available when treatment is needed. However, patients that have recently had a heart attack or are awaiting such an implantable device, may be kept in a hospital where corrective electrical therapy is generally close at hand. Long-term hospitalization is frequently impractical due to its high cost, or due to the need for patients to engage in normal daily activities.

Defibrillators have been developed for patients that have recently experienced a heart attack, that are susceptible to heart arrhythmias and are at temporary risk of sudden death, and that are awaiting an implantable device. However, current wearable defibrillators may lack the required size and durability to provide maximum comfort and usability to the patient.

Accordingly, a need exists for a portable, wearable defibrillator that is small, lightweight, and extremely durable.

SUMMARY OF THE INVENTION

According to one aspect of the invention, a system is provided that comprises: at least one identification device associated with a wearable medical therapy device and configured to have information read therefrom and written thereto; at least one controller operatively connected to the at least one identification device and configured to at least one of retrieve the information from the at least one identification device and write the information to the at least one identification device; and at least one device positioned externally from the wearable medical therapy device and configured to interrogate the at least one identification device to at least one of obtain the information from the at least one identification device and write additional information to the at least one identification device.

The at least one identification device may be a radio frequency identification (RFID) module comprising at least an RFID transceiver and antenna. The antenna may be spaced from a backup battery within a housing of the wearable medical device. The wearable medical therapy device may be a wearable defibrillator. The at least one identification device may have information identifying the wearable medical therapy device stored thereon that can be accessed by the at least one device positioned externally from the wearable medical therapy device such that the wearable medical therapy device can be identified thereby.

The at least one controller may be configured to write problems that occur with the wearable medical therapy device during patient field use to the at least one identification device, and the at least one identification device may be interrogated by the at least one device positioned externally from the wearable medical therapy device to obtain the problems that have been written to the at least one identification device such that the problems can be diagnosed by service personnel.

The additional information that is written to the at least one identification device may comprise shipping information, such as, but not limited to, shipping boxes, software versions, board revisions, and assembly revisions.

The information written to the at least one identification device by the at least one controller may comprise patient parameters of a patient utilizing the wearable medical therapy device. The at least one device positioned externally from the wearable medical therapy device may be config-

ured to interrogate the at least one identification device to obtain the patient parameters therefrom. The at least one device positioned externally from the wearable medical therapy device may be configured to communicate with at least one second identification device associated with a second wearable medical therapy device to write the patient parameters to the at least one second identification device. At least one controller of the second wearable medical therapy device may be configured to read the patient parameters from the at least one second identification device and store the patient parameters.

The additional information written to the at least one identification device by the at least one device positioned externally from the wearable medical therapy device may be a command to at least one of enter into a test mode and initiate a self-test. The at least one controller may be configured to read the command from the at least one identification device and at least one of enter into the test mode and begin the self-test.

The at least one identification device may be a storage device having reading and writing capabilities and wireless communication capabilities or wired communication capabilities. Examples of storage devices having wireless communication capabilities include, but are not limited to, a cellular-ready storage device, a Wi-Fi-ready storage device, and a short-range wireless communication protocol-ready storage device. Examples of storage devices having wired communication capabilities include, but are not limited to, a flash drive, a USB device, a mini-USB device, a SD card, a miniSD card, and a microSD card.

According to another aspect of the invention, provided is a method for utilizing at least one identification configured to have information read therefrom and written thereto associated with a wearable medical therapy device. The method comprises: at least one of retrieving the information from the at least one identification device and writing the information to the identification device by at least one controller operatively connected to the at least one identification device; and interrogating the at least one identification device by at least one device positioned externally from the wearable medical therapy device to at least one of obtain the information from the at least one identification device and write additional information to the at least one identification device.

According to yet another aspect of the invention, provided is a method for servicing a wearable medical therapy device. The method comprises: configuring at least one identification device associated with the wearable medical therapy device to have problems that occur with the wearable medical therapy device during patient field use written thereto by at least one controller operatively connected to the at least one identification device; and interrogating the at least one identification device by at least one device positioned externally from the wearable medical therapy device to obtain the written problems for diagnosis of the problems by service personnel.

According to still another aspect of the invention, provided is a method for cloning patient parameters from a first wearable medical therapy device to a second wearable medical therapy device. The method comprises: configuring at least one first identification device associated with the first wearable medical therapy device to have patient parameters of a patient utilizing the first wearable medical therapy device written thereto by at least one first controller operatively connected to the at least one first identification device; interrogating the at least one first identification device by at least one device positioned externally from the first wearable medical therapy device to obtain the written patient parameters; establishing communication between the at least one device positioned externally from the first wearable medical therapy device and at least one second identification device associated with the second wearable medical therapy device; rewriting the written patient parameters to the at least one second identification device; reading the rewritten patient parameters by at least one second controller operatively connected to the at least one second identification device; and storing the read patient parameters in a memory operatively connected to the at least one second controller.

These and other features and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structures and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention. As used in the specification and the claims, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic view of a wearable defibrillator in accordance with the invention;

FIG. **2** is a front perspective view of the external housing of a monitor unit of a defibrillator in accordance with the invention;

FIG. **3** is a rear perspective view of the external housing of FIG. **2**;

FIG. **4** is a rear perspective view of the external housing of FIG. **2** with a top cover plate and battery pack removed;

FIG. **5** is a rear perspective view of the external housing of FIG. **2** with the battery pack partially inserted;

FIG. **6** is an exploded perspective view of a battery pack for use with a defibrillator;

FIG. **7** is an assembled front view of the battery pack of FIG. **6**;

FIG. **8** is an assembled perspective view of the battery pack of FIG. **6**;

FIG. **9** is an assembled side view of the battery pack of FIG. **6**;

FIG. **10** is a front perspective view of a latching mechanism for use with the battery pack of FIG. **6**;

FIG. **11** is a bottom perspective view of the latching mechanism of FIG. **10**;

FIG. **12** is a bottom view of the latching mechanism of FIG. **10**;

FIG. **13** is a top plan view of a distributed circuit board configured to be positioned within the housing of the monitor unit in accordance with the invention;

FIG. **14** is a bottom plan view of the distributed circuit board of FIG. **13**;

FIG. **15** is a front perspective view of the distributed circuit board of FIG. **13** in a folded configuration;

FIG. **16** is a rear perspective view of the distributed circuit board of FIG. **15**;

FIG. **17** is a front perspective view of the distributed circuit board of FIG. **15** with all of the electronic components removed from the portions of the circuit boards thereof;

FIG. **18** is a rear perspective view of the distributed circuit board of FIG. **17**;

FIG. **19** is an end view of the distributed circuit board of FIG. **18**;

FIG. **20** is a front perspective view of the distributed circuit board of FIG. **15** positioned within a front cover plate of the external housing of FIG. **2**;

FIG. **21** is a front plan view of the distributed circuit board and housing of FIG. **20**; and

FIG. **22** is a schematic block diagram of an RFID module for use with the monitor unit of the defibrillator in accordance with the invention.

DESCRIPTION OF THE INVENTION

As used herein, spatial or directional terms, such as "inner", "left", "right", "up", "down", "horizontal", "vertical" and the like, relate to the invention as it is described herein. However, it is to be understood that the invention can assume various alternative orientations and, accordingly, such terms are not to be considered as limiting. For the purposes of this specification, unless otherwise indicated, all numbers expressing quantities of ingredients, reaction conditions, dimensions, physical characteristics, and so forth used in the specification and claims, are to be understood as being modified in all instances by the term "about." Accordingly, unless indicated to the contrary, the numerical parameters set forth in the following specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained by the present invention. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques.

Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

Also, it should be understood that any numerical range recited herein is intended to include all sub-ranges subsumed therein. For example, a range of "1 to 10" is intended to include any and all sub-ranges between and including the recited minimum value of 1 and the recited maximum value of 10, that is, all subranges beginning with a minimum value equal to or greater than 1 and ending with a maximum value equal to or less than 10, and all subranges in between, e.g., 1 to 6.3, or 5.5 to 10, or 2.7 to 6.1.

With reference to FIG. **1**, a medical therapy device may be configured as a wearable defibrillator, denoted generally as reference numeral **100**, such as the LifeVest® wearable defibrillator available from ZOLL® Lifecor Corporation of Pittsburgh, Pa. The wearable defibrillator **100** may be worn by a patient and may include a belt or harness or other apparel configured to permit the patient to wear the defibrillator **100**. Such wearable defibrillators may be typically worn nearly continuously for two to three months at a time. During the period of time in which they are worn by the patient, the wearable defibrillator **100** may be configured to continuously monitor the vital signs of the patient, to be user-friendly and accessible, to be as light-weight, comfortable, and portable as possible, and to be capable of delivering one or more life-saving therapeutic shocks when needed.

The wearable defibrillator **100** may comprise a monitor unit **1** positioned within an external housing **3** that is configured to be worn by a patient and connected to a therapeutic or treatment device, such as an upper body harness or vest that includes ECG electrodes **101***a*, **101***b*, **101***c*, and **101***d* and therapy pads **103**. The ECG electrodes **101***a*, **101***b*, **101***c*, and **101***d* and therapy pads **103** of the harness or vest are operatively connected to the monitor unit **1** via a trunk cable **105** or other suitable connection mechanism. Non-limiting examples of suitable wearable defibrillators are disclosed in U.S. Pat. Nos. 4,928,690; 5,078,134; 5,741,306; 5,944,669; 6,065,154; 6,253,099; 6,280,461; 6,681,003; 8,271,082; and 8,369,944; the entirety of all of which are incorporated by reference herein. The upper body harness or vest may also include other sensing electrodes (not shown) such as heart beat sensors, accelerometers, and sensors capable of measuring blood pressure, heart rate, thoracic impedance, respiration rate, heart sounds, acoustic sensors, audio transducers, and the activity level of the subject.

Electrodes **101***a*, **101***b*, **101***c*, and **101***d* are removably attached to the patient when the wearable defibrillator **100** is worn by the patient. The electrodes **101***a*, **101***b*, **101***c*, and **101***d* form part of an electrode assembly **107**. According to one example, the electrode assembly **107** receives ECG signals from a front-to-back channel and from a side-to-side channel. The front-to-back (FB) channel includes an electrode **101***a*, **101***b*, **101***c*, and **101***d* positioned on the chest of the patient and another electrode **101***a*, **101***b*, **101***c*, and **101***d* positioned on the back of the patient. The side-to-side (SS) channel includes an electrode **101***a*, **101***b*, **101***c*, and **101***d* positioned on the left side of the chest and another electrode **101***a*, **101***b*, **101***c*, and **101***d* positioned on the right side of the patient.

The monitor unit **1** is operatively connected to the therapy pads **103**, at least one tactile stimulator **109**, and electrode assembly **107**. The therapy pads **103** are removably connected to the patient when the defibrillator **100** is worn. Optionally, the monitor unit **1** may be operatively connected to other electrodes/devices which provide data to the controller regarding other physiological conditions or parameters of the patient.

While a trunk cable **105** may be used to connect the electrode assembly **107** to the monitor unit **1**, other types of cables or other connection devices to operatively connect the electrode assembly **107** to the monitor unit **1** may also be used. Wiring or other connection devices may be used to connect at least one portion of the electrode assembly **107** to the electrodes **101***a*, **101***b*, **101***c*, and **101***d*. In addition, the monitor unit **1** may alternatively be operatively connected to one or more of the electrodes **101***a*, **101***b*, **101***c*, and **101***d*, therapy pads **103**, electrode assembly **107**, and tactile stimulator **109** by a wireless connection or a combination of wireless and wired connections.

In some embodiments, the monitor unit **1** may include, without limitation, one or more processors, one or more controllers, and/or one or more programs or other software stored in memory operatively connected to one or more processors, as will be discussed in greater detail hereinafter.

With reference to FIGS. **2-4**, the monitor unit **1** is configured to implement the functions of monitoring an ambulatory patient's ECG information and, when needed, administering a therapeutic shock to the patient. The monitor unit **1** comprises a distributed printed circuit board **41** positioned within an external housing **3** configured to be worn by a patient and connected to a therapeutic or treatment device, such as an upper body harness or vest that includes ECG

electrodes **101***a*, **101***b*, **101***c*, and **101***d* and therapy pads **107** as discussed hereinabove. The ECG electrodes **101***a*, **101***b*, **101***c*, and **101***d* and therapy pads **107** of the harness or vest are operatively coupled to the distributed printed circuit board **41** within the external housing **3** via a port **5**. Such wearable therapeutic devices are described in U.S. Pat. No. 5,741,306 and United States Patent Publication No. 2012/0011382, which are assigned to the assignee of the present application and are hereby incorporated by reference in their entirety.

In some embodiments, the external housing **3** of the monitor unit **1** comprises a front cover **7**, a rear cover **9**, and a top cover **11**. A rechargeable and removable battery pack **13** is positioned within a battery well **15** provided in the rear cover **9**. The battery pack **13** is secured to the rear cover **9** by a battery latching mechanism **17**. The battery latching mechanism **17** is positioned at the top left corner of the battery pack **13** to allow for the battery pack **13** to be removed from the external housing **3** with one rocking motion. This rocking motion increases usability for patients with decreased dexterity, such as a patient with arthritis. The battery pack **13** has sufficient capacity to administer one or more therapeutic shocks to the therapeutic electrodes as well as provide power to all of the internal components of the defibrillator **1**.

With reference to FIGS. **6-9**, the battery pack **13** is designed to: a) allow for placing and replacing the battery to avoid fine motor control or simultaneous actions; b) allow for placing and replacing the battery to accommodate patients with limited reach and strength; c) provide the battery with a surface/texture that makes it easy to grip and control; d) provide insertion and removal of the battery to avoid simultaneous actions such as depressing and pulling; and e) provide battery insertion to allow for positive feedback, such as an audible indication that the battery is properly inserted.

The battery pack **13** may include a body **201** having a front side **203**, rear side **205**, top side **207**, and bottom side **209**. Desirably, the body **201** of the battery pack **13** has a substantially parallelepiped shape and is manufactured from plastic or any other suitable material. The latching mechanism **17** may be positioned at one of the upper corners of the top side **207** of the body **201** and is configured to be placed in an extended position to grasp a portion **211** (see FIG. **3**) of an upper edge **213** of the battery well **15** when the battery pack **13** is positioned within the battery well **15** and a depressed position to allow removal of the battery pack **13** from the battery well **15**.

The latching mechanism **17** of the battery pack **13** desirably comprises a single latch that is automatically engaged when the battery is slid into position, and deactivated with a downward pushing action of a single finger. With specific reference to FIGS. **10-12**, the latching mechanism **17** may comprise a body **215** having a top surface **217** with a finger engaging portion **219** and a flange member **221** extending therefrom and a channel **223** positioned between the flange member **221** and the finger engaging portion **219**. The portion **211** of the upper edge **213** of the battery well **15** is grasped in the channel **223** when the latching mechanism **17** is in the extended position. The finger engaging portion **219** may have a downwardly angled front face **225** with at least one ridge **227** provided thereon. Desirably, two ridges **227** are provided that are manufactured from a rubber or other suitable material.

The battery pack **13** also includes a biasing element **229** (see FIG. **5**) positioned within the body **215** of the latching mechanism **17**. The biasing element **229** is configured to bias the latching mechanism **17** to the extended position. The battery pack **13** further includes a contact mechanism **231** extending from the bottom side **209** of the body **201** of the battery pack **13**. The contact mechanism **231** may be configured to engage a corresponding contact mechanism **233** of the battery well **15** of the monitor unit **1**. The contact mechanism **231** may be positioned asymmetrically relative to a longitudinal axis Y of the body **201** of the battery pack **13** to prevent the battery pack **13** from being inserted incorrectly into the battery well **15** and so that the correct orientation to insert the battery pack **13** into the battery well **15** is apparent to the user. The battery pack **13** may also include an extension member **232** (see FIG. **9**) that is configured to cover an access opening **81** for an SD card or other memory device, as will be discussed hereinafter when the battery pack **13** is positioned within the battery well **15**.

The battery pack **13** houses rechargeable cells. Two battery packs **13** may be supplied to a patient to provide continuous device use while one is charging. When fully charged, the battery pack **13** may provide power to monitor the patient for a minimum of 24 hours at an ambient temperature of 20° C. (with the patient wearing the device), with sufficient reserve capacity to deliver at least one 5-pulse defibrillating sequence at the maximum joule setting (150 joules) (−5%/+5% into a 50 ohm resistive load). The battery pack **13** also provides sufficient capacity to support full energy pacing for 60 minutes at the end of a 24 hour monitoring period.

With specific reference to FIG. **5**, in operation, the battery pack **13** is inserted into the battery well **15** by orienting the bottom side **209** of the body **201** with a bottom edge **235** of the battery well **15** and rotating the battery pack **13** in the direction of arrow A into the battery well **15** such that the latching mechanism **17** engages the portion **211** of the upper edge **213** of the battery well **15** to move the latching mechanism **17** to the depressed position and continued rotation of the battery pack **13** allows the latching mechanism **17** to return to the extended position to grasp the portion **211** of the upper edge **213** of the battery well **15** within the channel **223** of the latching mechanism **17**. The latching mechanism **17** is configured to provide an audible indication, such as a "snap" or "click", when it returns to the extended position and grasps the portion **211** of the upper edge **213** of the battery well **15** to provide feedback to the user that the battery pack **13** is properly installed.

The battery pack **13** may be removed from the battery well **15** by pressing on the latching mechanism **17** to move the latching mechanism **17** into the depressed position, thereby disengaging the portion **211** of the upper edge **213** of the battery well **15** from the channel **223** of the latching mechanism **17**, and rotating the battery pack **13** away from the battery well **15**. Accordingly, removal of the battery pack **13** can be accomplished with one hand.

As mentioned hereinabove, the external housing **3** of the monitor unit **1** is configured to be worn by the patient and is, accordingly, sized such that it does not interfere with the patient's movement and activity. More particularly, the external housing **3** may have a length of about 5 to 6 inches, a height of about 4 to 5 inches, and a width of about 1 to 2 inches. Desirably, the weight of the monitor unit **1** is 1.8 pounds.

Returning to FIGS. **2-4**, in some embodiments, the external housing **3** further comprises a pair of patient response buttons **19** positioned, for example, in the top left corner of the housing **3**. The response buttons **19** are positioned a small distance apart, desirably less than 1.5 inches. The location of the response buttons **19**, and the distance

between the response buttons **19**, was chosen to enable patients with limited dexterity to easily and quickly operate the response buttons **19**. The response buttons **19** may further incorporate a light emitting diode (LED) therein so that they can be illuminated to provide a visual indication to a patient as discussed in greater detail hereinafter.

In some embodiments, the monitor unit **1** further comprises an audio system having a speaker port **21** and a microphone port **23** positioned on the external housing **3**. The speaker port **21** is desirably positioned at least 2.5 inches away from the microphone port **23** to minimize feedback. In addition, the speaker port **21** and the microphone port **23** can be located on the top cover **11** of the external housing **3** in order to face the patient for better orientation and functionality. The speaker port **21** is also positioned on an upper corner of the external housing **3** and wraps from the top of the external housing **3** to a side thereof. This allows the speaker port **21** to be more difficult to block if the top of the monitor unit **1** is obstructed. In addition, the speaker is mounted in a reverberator which uses a specific volume of air to artificially amplify audio at specific frequencies. The outlet of the reverberator is the speaker port **21**. In one non-limiting embodiment, the reverberator is tuned to amplify the alarm frequencies at 2.272 kHz and 2.5 kHz in order to get to 95 dB at 1 m for the alarm. The microphone port **23** and the speaker port **21** are covered by a mesh or other suitable covering to prevent the ingress of fluid and/or particles into the external housing **3**.

The external housing **3** of the monitor unit **1** also includes a display screen **25** for providing information to a patient and for providing a user input device to the patient. The display screen **25** provides information such as, but not limited to, time, battery life, volume, signal strength, device status, and any other useful information to the patient. In addition, the display screen **25** also allows the user to access various data regarding the monitor unit **1** such as, but not limited to, the settings of the device, data stored by the device, and various other data accumulated by the monitor unit **1**. The display screen **25** further acts as a communication interface to allow the patient to send and receive data.

The display screen **25** may be any suitable capacitive touch screen device. For instance, the display screen **25** may include a 1.1 mm thick Dragontrail™ lens, manufactured by Asahi Glass Co. of Tokyo, JP, which supports a projected capacitive touch screen having a 4.3 inch LCD on the reverse side. A glass display may be provided to cover the entire front of the monitor unit **1**, except for the response buttons **19**, to provide the monitor unit **1** with a smooth, finished look and feel.

In operation and, as will be discussed in greater detail hereinafter, if the monitor unit **1** detects an abnormal condition, the monitor unit **1** is configured to stimulate the patient for a predetermined time period. The stimulus may be any stimulus perceptible by the patient. Examples of stimuli that the monitor unit **1** may produce include visual (via the display screen **25** and/or indicator LEDs discussed in greater detail hereinafter), audio (via the speaker port **21**), tactile stimulation (via tactile stimulator **109**) or a mild stimulating alarm shock (via the therapy pads **103**). The response buttons **19** are provided to allow a user to turn off the stimulus by pressing both of the response buttons **19** within the predetermined time period. By pressing both of the response buttons **19**, the stimulus is ceased and no further action is taken by the monitor unit **1**. If the patient does not press both of the response buttons **19** within the predetermined time period, the monitor unit **1** administers one or more therapeutic shocks to the therapy pads **103**.

With reference to FIGS. **13-16**, and with continuing reference to FIGS. **2-4**, the functional components of the monitor unit **1** are illustrated. The functional components of the monitor unit **1** are provided on a distributed printed circuit board, denoted generally as reference numeral **41**, such as a rigid flex printed circuit board. Rigid flex printed circuit boards are boards using a combination of flexible and rigid board technologies. The rigid flex board can comprise multiple layers of flexible circuit substrates embedded within one or more rigid boards. Rigid flex printed circuit boards are designed in a three-dimensional space, which offers greater spatial efficiency. In addition, through the use of rigid flex printed circuit boards, all board-to-board connections have been eliminated, thereby increasing the durability of the monitor unit **1**.

The distributed printed circuit board **41** comprises a discharge module **43**, an energy storage module **45**, a controller module **47**, and, optionally, a communication module **49**. The discharge module **43** is disposed on a first portion **51** of the distributed printed circuit board **41** and is for selectively delivering an energy pulse to the patient. The energy storage module **45** is disposed on a second portion **53** of the distributed printed circuit board **41**. The energy storage module **45** is operatively connected to the discharge module **43** by a first flexible member **55**. The controller module **47** is provided to control the delivery of the energy pulse to the patient and is disposed on a third portion **57** of the distributed printed circuit board **41**. The controller module **47** is operatively connected to the energy storage module **45** by a second flexible member **59**. The communication module **49** can be disposed on a fourth portion **61** of the distributed printed circuit board **41** and can be operatively connected to the controller module **47** by a third flexible member **63**.

The discharge module **43** and the energy storage module **45** can be considered high-voltage modules as each of these modules requires a high voltage for operation. These modules **43**, **45** are provided on a high-voltage portion **46** of the distributed printed circuit board **41**. The controller module **47** and the communication module **49** can be considered low-voltage modules as each of these modules requires a low voltage for operation. These modules **47**, **49** are provided on a low-voltage portion **48** of the distributed printed circuit board **41**. The flexible members **55**, **59**, and **63** (or connectors) are positioned such that, when the distributed printed circuit board **41** is folded to be positioned within the external housing **3**, as discussed in greater detail hereinafter, the spacing between the high-voltage modules and the low-voltage modules provides at least one of isolation of high-voltage from low-voltage or minimizes interference, such as electromagnetic interference, between the modules. The spacing provided between the high-voltage modules and the low-voltage modules is desirably at least 0.350 inches. In some embodiments, one or more of the members **55**, **59**, and **63** can include a flexible portion of the distributed printed circuit board **41**. In some embodiments, one or more of the members **55**, **59**, and **63** can be a separate connector, for example, a wire, cable, flex connector such as a ZIF (zero insertion force) connector, or any suitable electrical connector known to those skilled in the art.

The first portion **51** of the distributed printed circuit board **41** that encompasses the discharge module **43** may be a long, narrow printed circuit board. It has a length in the range of about 4 to 6 inches and a width in the range of about 0.5 to 1.5 inches. This configuration of the first portion **51** allows it to be fit securely within a bottom portion of the external housing **3** substantially perpendicular to the front cover **7**

and the rear cover **9**. The first portion **51** of the distributed printed circuit board **41** comprises a plurality of high voltage switches **65**, such as Insulated Gate Bipolar Transistors (IGBTs), Field Effect Transistors (FETs), transistors, or Metal-Oxide Semiconductor Field-Effect Transistors (MOSFETs). Desirably, IGBTs are used as the high voltage switch. The discharge module **43** is configured to selectively deliver an energy pulse stored in the energy storage module **45** to the patient based on a signal from the controller module **47**. The energy pulse is sent from the discharge module **43** through the port **5** to the therapy pads **103**.

The second portion **53** of the distributed printed circuit board **41** that encompasses the energy storage module **45** is also a long, narrow printed circuit board. It has a length in the range of about 5 to 6 inches and a width in the range of about 0.5 to 1.5 inches. This configuration of the second portion **53** allows it to be fit securely within a bottom portion of the external housing **3** substantially perpendicular to the front cover **7** and the rear cover **9** and substantially parallel to the first portion **51**. The second portion **53** of the distributed printed circuit board **41** includes a capacitive device mounted thereon, such as a bank of capacitors **67**. Each of the capacitors in the bank of capacitors **67** may have a capacitance value of greater than 300 microfarads, such as 650 microfarads.

The second portion **53** further comprises the contact mechanism **233** for the battery pack **13** mounted thereon. The contact mechanism **233** is configured to extend through an opening **71** (see FIG. **4**) provided within the battery well **15** of the external housing **3**. The contact mechanism **233** is protected from the ingress of fluids by using an epoxy coating to seal off the underside of its blades. This allows the monitor unit **1** to be resistant to water or ingress of other materials into the interior of the external housing **3**.

The first flexible member **55** is folded such that the first portion **51** of the distributed printed circuit board **41** is positioned substantially parallel to the second portion **53** of the distributed printed circuit board **41**. The first flexible member **55** has a sufficient length to prevent the first portion **51** from colliding with the second portion **53** when the distributed circuit board **41** is folded into the folded configuration (see FIGS. **15** and **16**). Accordingly, the first flexible member **55** is folded such that it has a substantially C-shaped cross-section. With reference to FIGS. **17** and **18**, all of the components have been removed from the distributed circuit boards **41** such that the manner in which the first flexible member **55** is folded can be more easily observed.

The third portion **57** of the distributed printed circuit board **41** that encompasses the controller module **47** generally has a length in the range of about 3.5 to 4.5 inches and a width in the range of about 2.5 to 3.5 inches. This configuration of the third portion **57** allows it to be fit securely within a central portion of the external housing **3** substantially parallel to the front cover **7** and the rear cover **9** and substantially perpendicular to the first portion **51** and the second portion **53**. The second flexible member **59** extending between the second portion **53** and the third portion **57** of the distributed printed circuit board **41** is folded such that the third portion **57** is positioned substantially perpendicular to the first portion **51** and the second portion **53** of the distributed printed circuit board **41**. The second flexible member **59** is folded such that it has a substantially L-shaped cross-section. With reference to FIGS. **17** and **18**, all of the components have been removed from the distributed circuit boards such that the manner in which the second flexible member **59** is folded can be more easily observed.

The controller module **47** may comprise a microprocessor and memory device **75** and an SD card holder **77** mounted on a separate printed circuit board **79** that is operatively connected to the third portion **57** of the distributed printed circuit board **41**. The memory device is desirably flash memory. These elements can be operatively connected to the separate printed circuit board **79** by ball grid arrays (BGAs) that are located so as to be minimally affected by mechanical stress that can be transmitted through the monitor unit **1**, for example, such as upon impact of a portion of the housing of the monitor unit **1** with a hard surface. The BGAs can be located upon a separate printed circuit board **79** and/or upon a portion of the distributed printed circuit board **41** that is not susceptible to excess flexing, for example, on the third portion **57** of the distributed printed circuit board **41**. If the BGAs that control the memory were placed indiscriminately on the distributed printed circuit board **41**, they would be more susceptible to flexing, ultimately breaking the brittle solder balls that make up the base of the component. By moving the BGAs to the separate printed circuit board **79**, or by selecting a portion of the distributed printed circuit board **41** that is not susceptible to excess flexing, for example, on the third portion **57** of the distributed printed circuit board **41**, an extra layer of protection for the BGAs is provided since they are isolated from the bending of the distributed printed circuit board **41** during impacts or other mechanical loads, making the design more rugged, and increasing longevity.

The BGAs can be secured to the separate printed circuit board **79** or the third portion **57** of the distributed printed circuit board **41** by a suitable adhesive, for example, by being under-filled with an epoxy material, such as Loctite **3536** epoxy, available from Henkel AG & Co. KGaA of Dusseldorf, Germany. This process allows for the epoxy material to flow under the BGAs and around the solder balls that make the electro-mechanical connections to the separate printed circuit board **79** to form a rigid and secure support for the BGAs. Once under-filled, the BGAs are subjected to stress shielding, which further protects them from flexing.

Finally, finite element analysis (FEA) was utilized to estimate the flexure of the boards during drop simulations. To set up the analysis, a fixed boundary was established on the side of the external housing **3** impacting the ground, and then a 400G gravity load was applied to the system in the direction of a fall. This is a quasi-static estimation of a dynamic load, but is generally accurate for a 40 foot drop. Once the external housing **3** and distributed printed circuit board **41** are assembled, and the simulation run, the results of the analysis illustrated the area on third portion **57** of the distributed printed circuit board **41** where the BGAs of the separate printed circuit board **79** should be mounted (i.e., away from major flexure points in the distributed printed circuit board **41**, which were centered around the screw holes). By mounting the separate printed circuit board **79** in this area, the BGAs thereof are prevented from failing due to flexure, thereby making the monitor unit **1** resistant to drop failures. The above-described measures allow the monitor unit **1** to be highly durable and resistant to breaking.

Furthermore, the separate printed circuit board **79** may be accessed and replaced, if needed, through an access opening **81** provided in a rear portion of the battery well **15** (see FIG. **4**). This also allows a user to access an SD card from the SD card holder **77**.

The microprocessor **75** is configured to receive digital or analog ECG information either directly or indirectly from the ECG electrodes (not shown) of the therapeutic device (not shown), detect abnormal heart rhythms based on the

information received from the ECG electrodes, charge the capacitors **67** of the energy storage module **45**, and control the energy discharge module **43** to administer a therapeutic shock to the patient, unless a user intervenes within a predetermined period of time via the response buttons **19**. In at least one example, the predetermined period of time in which a user may intervene does not end until actual delivery of the therapeutic shock. An example of the methods used to detect abnormal heart rhythms can be found in U.S. Pat. No. 5,944,669, which is assigned to the assignee of the present application and which is hereby incorporated by reference in its entirety. Additionally, an example of the general features of a defibrillator can be found in U.S. Pat. No. 6,280,461, which is assigned to the assignee of the present application and which is also hereby incorporated by reference in its entirety.

The microprocessor **75** is also configured to perform several other functions. These other functions may leverage the robust computing platform provided by the microprocessor **75** without disrupting the therapy delivering functions of the monitor unit **1**. Some examples of these other functions include notifying emergency personnel of the location of a patient who just received a therapeutic shock via the communication module **49**, providing users of the device with the historical physiological data of the wearer of the device via the display screen **25**, and/or notifying the manufacturer of the monitor unit **1** of potential performance issues within the monitor unit **1** that may require repair to or replacement of the monitor unit **1** via the communication module **49**. Moreover, these other functions can include maintaining a history of data and events by storing this information in the memory device, communicating with the user via the display screen **25**, and/or reporting data and events via the communication module **49**. In addition, other functions may perform additional operations on the history of critical data. For instance, in one example, a function analyzes the history of critical data to predict worsening heart failure or an increased risk of sudden cardiac death.

The memory device of the monitor unit **1** is sized to store months or years of sensor information, such as ECG data, that is gathered over several monitoring and treatment periods. These monitoring and treatment periods may include continuous monitoring periods of approximately 23 hours (and substantially continuous monitoring periods of approximately 1-2 months) during which several treatments may be delivered to the patient. In some of these examples, the microprocessor **75** is configured to analyze the stored sensor information and to determine adjustments to the treatment method, or alternative treatment methods, of benefit to the patient. For instance, in one example, the microprocessor **75** is configured to analyze ECG data collected substantially contemporaneously with each instance of patient initiated delay, or cancellation of treatment. In this example, the microprocessor **75** is configured to analyze the stored months of ECG data to recognize individualized, idiosyncratic rhythms that, while not normal, do not indicate a need for treatment. In some examples, the microprocessor **75** may automatically adjust the treatment method of the monitor unit **1** to better suit the patient by not initiating treatment in response to the recognized, idiosyncratic rhythm. Such an adjustment may be performed in conjunction with review by appropriate medical personnel.

Referring now to FIG. **15**, the third portion **57** of the distributed printed circuit board **41** may further comprise a microphone **83** mounted thereon. A silicon gasket (not shown) may be provided to direct the audio through the microphone port **23** provided on the exterior of the monitor unit **1** to the microphone **83**.

In addition, a pair of LEDs **85** are mounted on the third portion **57** of the distributed printed circuit board **41**. Light pipes can redirect the light from the LEDs **85** to a pair of lenses **86***a*, **86***b* provided on the top cover **11** of the monitor unit **1**. In one embodiment, the LEDs **85** may be surface mounted to the distributed printed circuit board **41** such that they project perpendicular to the distributed printed circuit board **41**, and the light pipes are used to bend the light to the pair of lenses **86***a*, **86***b*. In another embodiment, the LEDs **85** project parallel to the distributed printed circuit board **81** and the light pipes essentially shine straight through to the pair of lenses **86***a*, **86***b*. The LEDs **85** are configured as indication mechanisms to provide an indication to the patient of at least one condition of at least one of the defibrillator, the electrodes **101***a*, **101***b*, **101***c*, and **101***d*, the therapy pads **103**, and the patient. The LEDs are viewable on the top cover **11** of the monitor unit **1** such that they are visible without manipulation of the device.

More specifically, the LED **85** visible through lens **86***a* may be a solid green indicator that provides an indication to the patient that the monitor unit **1** is active and operating properly. The LED **85** visible through lens **86***b* may be a flashing yellow indicator that is activated when a notification is displayed on the display screen **25**. In some embodiments, the LED **85** visible through lens **86***b* providing the second flashing yellow indicator is activated only when a notification is displayed on the display screen **25**.

These LEDs **85** provide a simple visual status indication to the patient while he/she is wearing the device. Multiple LEDs **85** and multiple color outputs by the LEDs **85** allow multiple status messages to be conveyed to patients during operation of the monitor unit **1**. In one embodiment, two LEDs **85** are viable through lenses **86***a*, **86***b* provided on the top cover **11** of the monitor unit **1**, thereby providing a first or green indicator **90** and a second or yellow indicator **92**. When activated, one LED **85** is green **90** and the other is yellow **92**. A third LED is provided under the response buttons **19** as described hereinabove such that it is viewable to the patient through at least the top surface **88** of at least one of the response buttons **19**. Desirably, the third response button LED is red in color. In certain embodiments, the third LED is a set of LEDs, one associated with each of the buttons **19**.

The following provides a brief description of the manner in which the three LEDs described hereinabove function as status indicators. Please note that this description is for exemplary purposes only and is not to be construed as limiting the invention as other systems may be utilized for providing status indicators using LEDs.

Initially, when the device is turned on both the green and yellow indicators **90**, **92** are provided OFF, as is the response button LED. If the monitor unit **1** requires a test of the response buttons **19**, the response button LED is provided in a solid ON fashion and the green and yellow indicators **90**, **92** are both provided in a solid ON fashion as well. If a belt **111** (see FIG. **1**) attaching the monitor unit **1** and/or the electrodes **101***a*, **101***b*, **101***c*, and **101***d* and therapy pads **103** to the patient are not connected properly, the green indicator **90** is provided OFF and the yellow indicator **92** is provided in a continuously flashing manner. A notification screen is provided on the display screen **25** to aid the user in determining the reason that the yellow indicator **92** is flashing.

The yellow indicator **92** remains flashing until the patient properly connects the belt **111** even if the display screen **25** times out and goes blank.

Once the belt **111** is properly connected and the monitor unit **1** is turned on and monitoring the patient, the green indicator **90** is provided in a solid ON fashion and the yellow indicator **92** is OFF. If during the monitoring, a notification appears on the display screen **25** of the monitor unit **1** (such as indicating that the belt **111** needs adjusted, batteries low, etc.), the green indicator **90** turns OFF and the yellow indicator **92** begins flashing. The yellow indicator **92** may flash at 0.4 Hz to 0.8 Hz with a 20% to 60% ON duty cycle. Once the patient acknowledges the notification screen (i.e., by pressing a button, providing a remedy to the problem, etc.), the yellow indicator **92** stops flashing and the green indicator turns 90 ON. Finally, when the patient is notified that an arrhythmia has been detected and a treatment is expected, the green indicator **90** turns OFF, the yellow indicator **92** turns OFF, and the response button LED begins flashing. The response button LED may flash at 1.4 Hz to 2.8 Hz with a 20% to 60% ON duty cycle.

Alternatively, the at least one indication mechanism may be a visual indication or audible indication. Such visual indications may be provided on a display screen, and may comprise a visual prompt, such as an instruction, a flashing screen, and the like. The audible indications may be provided by the speaker and may include audible prompts, such as instructions or sounds. If instructions are provided, such instructions may be automated instructions recorded on the monitor unit **1** or manual instructions provided by a person at a central monitoring station. Such indications may be coordinated with the LEDs **85**.

A flex connector **87** for the touch screen of the display screen **25** and a flex connector **89** for the LCD of the display screen **25** can be mounted on the third portion **57** of the distributed printed circuit board **41**. These connectors **87**, **89** allow the display screen **25** to be operatively coupled to the third portion **57** of the distributed printed circuit board **41**. Alternatively, one or more of the flex connectors **87**, **89** can include a flexible portion of the distributed printed circuit board **41**.

The fourth portion **61** of the distributed printed circuit board **41** that encompasses the communication module **49** may have a width that is greater than its length. Generally, it has a length in the range of about 0.5 to 1.5 inches and a width in the range of about 2.5 to 3.5 inches. This configuration of the fourth portion **61** allows it to be fit securely within the external housing **3** substantially parallel to the front cover **7** and the rear cover **9** and substantially perpendicular to the first portion **51** and the second portion **53**. The third flexible member **63**, extending between the third portion **57** and the fourth portion **61** of the distributed printed circuit board **41**, is folded such that the fourth portion **61** is positioned substantially perpendicular to the first portion **51** and the second portion **53** of the distributed printed circuit board **41** and substantially parallel to the third portion **57** of the distributed printed circuit board **41**. The third flexible member **63** is folded such that it has a substantially S-shaped cross-section, as shown in FIG. **9***a*.

The communication module **49** provided on the fourth portion **61** of the distributed printed circuit board **41** provides various devices for communicating information to and from the monitor unit **1**. For instance, the communication module **49** may include a GPS transceiver, a Bluetooth™ transceiver, a Wi-Fi transceiver, and/or a cellular transceiver. The communication module **49** is controlled by the controller module **47** to communicate information regarding the monitor unit **1** as discussed hereinabove.

A cellular antenna (not shown) for the cellular transceiver can be positioned within the external housing **3** of the monitor unit **1**. The cellular antenna is optimized to have peak efficiency at the cell frequencies of several regions including, but not limited to, the United States, Japan, and Europe. The cellular antenna is located under the dragon trail lens of the display screen **25** and far enough away from the distributed printed circuit board **41** so that it can communicate efficiently. As shown in FIG. **15**, in some embodiments, a metallic portion of the third portion **57** of the distributed printed circuit board **41** functions as part of the cellular antenna. Alternatively, a metallic portion of the display screen **25** may function as part of the cellular antenna.

Similarly, an RFID antenna **91** (see FIGS. **10** and **11**) may be positioned within the external housing **3** of the monitor unit **1** away from the four portions of the distributed printed circuit board **41** in order to communicate efficiently. In order to accommodate the RFID antenna **91**, a backup battery **93** was positioned in the location shown in FIGS. **20** and **21**. By positioning the RFID antenna **91** and the backup battery in this manner the effective range of the RFID antenna was maximized such the effective read range is about 9 inches. The RFID antenna **91** is used to quickly communicate the identification of the monitor unit **1** to service personnel. With reference to FIG. **22**, a schematic diagram illustrating an RFID system utilized by the monitor unit **1** is described. The RFID system comprises an RFID module **300** comprising an RFID transceiver operatively coupled to the RFID antenna **91**. The RFID module **300** is operatively coupled to the microprocessor and memory device **75** of the monitor unit **1**.

The RFID module **300** is configured to have information written thereto and information read therefrom. Accordingly, the monitor unit **1** is capable of reading and writing information to the RFID module **300** from the microprocessor and memory device **75**. In addition, an external device **302** that includes an RFID module **304** operatively coupled to an RFID antenna **306** and a microprocessor **308**. The RFID module **300** of monitor unit **1** is configured to perform a variety of functions. As mentioned hereinabove, the RFID module **300** may be configured to communicate the identification of the monitor unit **1** to a personal computing device (acting as external device **302**) of service personnel. In addition, the RFID module **300** may further be used as an aid when servicing the monitor unit by configuring the RFID module **300** to automatically record problems during patient field use. The RFID module **300** may then be scanned during service by the RFID module **304** of the personal computing device (acting as external device **302**) of service personnel. During such a scan, the RFID module **300** of the monitor unit provides an indication/flag to the RFID module **304** of the personal computing device (acting as external device **302**) of service personnel of the problems that occurred during patient field use.

In addition, an external data writing mechanism at a shipping location may communicate with the RFID module **300** of the monitor unit **1** to write information thereto, such as shipping boxes, software versions, board revisions, assembly revisions, etc. This information may be later verified by reading this information from the RFID module **300** using an external device **302** such as a personal computer.

A further example of the manner in which RFID module **300** of monitor unit **1** may be utilized to transmit and store

information is the cloning of patient parameters from one monitor unit **1** to another. More specifically, in certain instances, it may be desirable to have patient parameters and information moved from one monitor unit **1** to another. The movement of such parameters and information may be accomplished utilizing the RFID module **300** as follows. First, the microprocessor and memory device **75** of a first monitor unit **1** writes its patient parameters into the RFID module **300**. Thereafter, an external RFID reader (acting as external device **302**) reads these patient parameters out of the RFID module **300** in the monitor unit **1**. The external RFID reader then writes these patient parameters into an RFID module of a second monitor unit and the microprocessor and memory device **75** of the second monitor unit reads and stores these patient parameters and information from its RFID module, thereby cloning the patient parameters from one monitor to another.

Yet another use for RFID module **300** is in manufacturing to automatically configure the monitor unit **1** into a test mode so that it can be tested and/or initiate a self-test. More specifically, a monitor unit **1** may be returned to the manufacturer for servicing. At this time, testing of the monitoring unit is required. An external RFID reader (acting as external device **302**) may be configured to write into the RFID module **300** of the monitor unit **1** a command to enter into a test mode or initiate a self-test. The microprocessor and memory device **75** of the monitor unit **1** then reads this information from the RFID module **300** and enters into the test mode or begins the self test.

While some uses for RFID module **300** of monitor unit **1** are discussed hereinabove, this list of uses is not to be considered as limiting the invention as other uses for RFID module **300** may also be incorporated into monitor unit **1**.

Rather than using RFID, the present disclosure contemplates the use of other identification devices to achieve the above described objectives. For instance, the identification device may be any suitable storage device having reading and writing capabilities and wireless communication capabilities or wired communication capabilities. Examples of storage devices having wireless communication capabilities include, but are not limited to, a cellular-ready storage device, a Wi-Fi-ready storage device, and a short-range wireless communication protocol-ready storage device, such as a Bluetooth™-ready storage device. Examples of storage devices having wired communication capabilities include, but are not limited to, a flash drive, a USB device, a mini-USB device, a SD card, a miniSD card, a microSD card, and any other storage or memory device having a communication port for receiving a cable or bus.

With reference to FIGS. **20** and **21** and with continuing reference to FIGS. **2-4** and **13-19**, the monitor unit **1** may be manufactured as follows. First, the distributed printed circuit board **41** is provided in the unfolded configuration as shown in FIG. **13**. Thereafter, the first flexible member **55** is folded such that the first portion **51** of the distributed printed circuit board **41** is positioned substantially parallel to the second portion **53** of the distributed printed circuit board **41**. Next, the second flexible member **59** is folded such that the third portion **57** of the distributed printed circuit board **41** is positioned substantially perpendicular to the first and second portions **51**, **53** of the distributed printed circuit board **41**. Then, the third flexible connector **63** is folded such that the fourth portion **61** of the distributed printed circuit board **41** is positioned substantially parallel to the third portion **57** of the distributed printed circuit board **41** and substantially perpendicular to the first and second portions **51**, **53** of the distributed printed circuit board **41**, thereby providing a folded distributed circuit board as shown in FIGS. **15** and **16**. When folded in this manner, the high voltage energy storage module **45** and discharge module **43** are isolated from the low voltage controller module **47** and communication module **49**. In addition, by positioning the communication module **49** in this manner, interference between the components of the communication module **49** and other components of the device can be substantially avoided and eliminated.

Next, the front cover **7**, rear cover **9**, and top cover **11** are provided. The folded distributed printed circuit board **41** is positioned within the front cover **7** and secured thereto via an appropriate fastening device, such as screws. Finally, the top cover **11** is positioned in the appropriate location and the rear cover **9** is secured to the front cover **7** and top cover **11** using any appropriate fastening device. This produces a monitor unit **1** as shown in FIGS. **2** and **3**.

Accordingly, a monitor unit **1** is provided that has a small footprint, is very durable, and can be used in a variety of patient care scenarios where a conventional implantable cardioverter-defibrillator cannot. Examples of these scenarios include treatment when the patient is awaiting a pending transplant or where the patient has a systemic infection (e.g., influenza or osteomyelitis), myocarditis, intra-ventricular thrombus, cancer, or a life-limiting serious illness such that an implantable device is not medically prudent.

Although a defibrillator **100** having a monitor unit **1** has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements. For example, it is to be understood that this disclosure contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

The invention claimed is:

1. A wearable medical device configured to be worn by an ambulatory patient, comprising:

a defibrillator configured to deliver therapeutic shocks to the ambulatory patient; at least one sensor operatively connected to the defibrillator and configured to be worn by the ambulatory patient and monitor at least one physiological signal of the ambulatory patient;

one or more therapy pads operatively connected to the defibrillator and configured to administer the therapeutic shocks to the ambulatory patient;

a garment worn by the ambulatory patient and configured to support the at least one sensor and the one or more therapy pads;

at least one first identification device associated with the wearable medical device and configured to have device information read therefrom and written thereto; and

at least one controller operatively connected to the at least one sensor and the at least one identification device and configured to at least one of retrieve the device information from the at least one identification device and write the device information to the at least one identification device,

wherein the at least one first identification device is configured to be;

interrogated by at least one device positioned externally from the wearable medical device to obtain the device information from the at least one first identification device and write the device information to at least one second identification device; and

provided with a command by the at least one device positioned externally from the wearable medical device to cause the at least one controller to enter into a test mode when the command is read from the at least one first identification device; and

wherein the device information comprises at least one of patient parameters of the ambulatory patient wearing the wearable medical device, and self-test mode configuration.

2. The wearable medical device of claim **1**, wherein the at least one first identification device is a radio frequency identification (RFID) module comprising at least an RFID transceiver and antenna.

3. The wearable medical device of claim **2**, wherein the antenna is spaced from a backup battery within a housing of the wearable medical device.

4. The wearable medical device of claim **1**,

wherein the at least one first identification device has information identifying the wearable medical device stored thereon, and

wherein the information identifying the wearable medical device is accessible by the at least one device positioned externally from the wearable medical device for identification of the wearable medical device thereby.

5. The wearable medical device of claim **1**,

wherein the at least one controller is configured to record problems that occur with the wearable medical device during patient field use to the at least one first identification device; and

wherein the at least one first identification device is configured to be interrogated by the at least one device positioned externally from the wearable medical device to obtain the recorded problems for diagnosis by service personnel.

6. The wearable medical device of claim **1**, wherein the device information comprises at least one of software versions, board revisions, and assembly revisions.

7. The wearable medical device of claim **1**, wherein the at least one device positioned externally from the wearable medical device is an external RFID reader.

8. The wearable medical device of claim **1**, wherein the at least one second identification device is associated with a second wearable medical device.

9. The wearable medical device of claim **8**, wherein at least one controller of the second wearable medical device is configured to read the device information from the at least one second identification device and to store the patient parameters.

10. The wearable medical device of claim **1**, wherein the at least one first identification device is a storage device having reading and writing capabilities and wireless communication capabilities.

11. The wearable medical device of claim **10**, wherein the storage device comprises at least one of a cellular-ready storage device, a Wi-Fi-ready storage device, and a short-range wireless communication protocol-ready storage device.

12. The wearable medical device of claim **1**, wherein the at least one first identification device is a storage device having reading and writing capabilities and wired communication capabilities.

13. The wearable medical device of claim **12**, wherein the storage device comprises at least one of a flash drive, a USB device, a mini-USB device, a SD card, a miniSD card, and a microSD card.

14. The wearable medical device of claim **1**, wherein the at least one sensor is configured to be worn by the ambulatory patient to continuously monitor the patient.

15. The wearable medical device of claim **14**, wherein the at least one sensor continuously monitors the ambulatory patient for at least 24 hours.

16. A system comprising:

a first wearable medical device comprising:

a first defibrillator configured to deliver therapeutic shocks to an ambulatory patient;

at least one first sensor operatively connected to the first defibrillator and configured to be worn by the ambulatory patient and monitor at least one physiological signal of the ambulatory patient;

one or more first therapy pads operatively connected to the first defibrillator and configured to administer the therapeutic shocks to the ambulatory patient;

a first garment configured to be worn by the ambulatory patient and configured to support the at least one first sensor and the one or more first therapy pads;

a first identification device configured to have first device information and self-test configuration information read therefrom and written thereto, and

a first controller operatively connected to the first identification device and configured to write the first device information and self-test configuration information to the first identification device,

wherein the first identification device is configured to be interrogated to obtain the first device information and self-test configuration information;

a second wearable medical device, wherein the second wearable medical device is configured to be a clone of the first wearable medical device, the second wearable medical device comprising:

a second defibrillator configured to deliver therapeutic shocks to the ambulatory patient;

at least one second sensor operatively connected to the second defibrillator and configured to be worn by the ambulatory patient and monitor at least one physiological signal of the ambulatory patient;

one or more second therapy pads operatively connected to the second defibrillator and configured to administer the therapeutic shocks to the ambulatory patient;

a second garment configured to be worn by the ambulatory patient and configured to support the at least one second sensor and the one or more second therapy pads;

a second identification device configured to receive the first device information and self-test configuration information from the first identification device such that the first device information and self-test configuration information is written to the second identification device, and

a second controller operatively connected to the second identification device and configured to:

retrieve the first device information and self-test configuration information from the second identification device;

store the first device information and self-test configuration information in a memory operably connected to the second controller such that the retrieved first device information and self-test configuration information is cloned from the written first device information of the first wearable medical device; and

operate the second wearable medical device in accordance with the retrieved first device information and self-test configuration information that is cloned from the written first device information and self-test configuration information of the first wearable medical device; and

at least one device positioned externally from the first wearable medical device and the second wearable medical device to write into the first or second identification device a command to cause the corresponding first controller of the first wearable medical device or second controller of the second wearable medical device to enter into a test mode based on the command.

17. The system of claim **16**, wherein the first identification device and the second identification device are RFID modules that each comprise at least an RFID transceiver and antenna.

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