US 20180042553A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2018/0042553 A1

Min et al. (43) Pub. Date: Feb. 15, 2018

(54) **IMPLANTABLE DEVICE WITH A TAIL EXTENSION INCLUDING EMBEDDED SENSOR AND ANTENNA**

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(21) Appl. No.: **15/233,772**

(22) Filed: **Aug. 10, 2016**

**Publication Classification**

(51) **Int. Cl.**

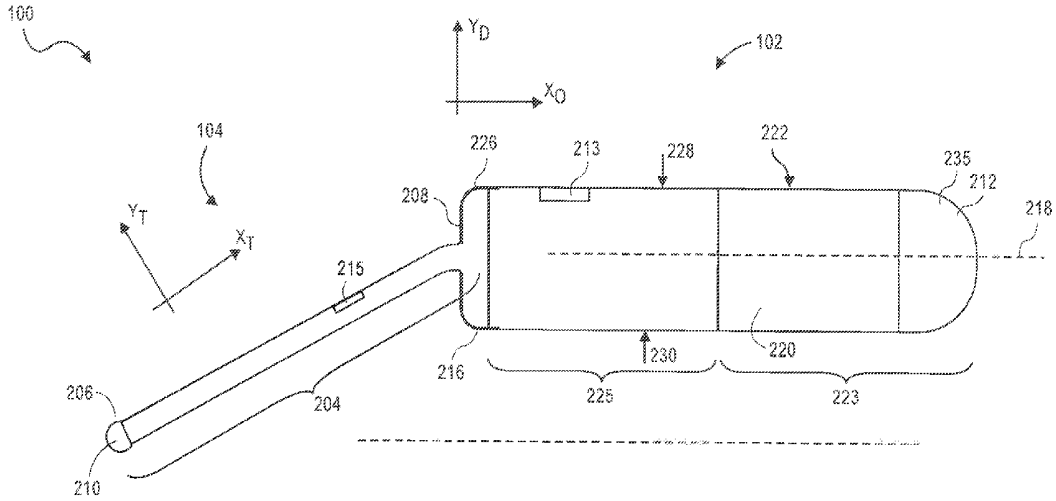
| | |
|---|---|
| ***A61B 5/00*** | (2006.01) |
| ***A61B 5/07*** | (2006.01) |
| ***A61B 5/042*** | (2006.01) |

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

CPC ..... ***A61B 5/686*** (2013.01); ***A61B 5/0031*** (2013.01); ***A61B 5/042*** (2013.01); ***A61B 5/076*** (2013.01); ***A61B 5/0006*** (2013.01); *A61B 2562/16* (2013.01)

(57) **ABSTRACT**

A device and method for an implantable cardiac monitor device are provided comprising a device housing having sensing circuits and radio frequency (RF) communications circuits housed within the housing. The device further comprising a tail extension having a proximal end, a distal end, and an extension body extended there between wherein the proximal end is coupled to the housing. The extension body being formed of a flexible material and including at least one conductor that includes a proximal end conductively coupled to the sensing and RF communications circuits. At least a portion of the conductor of the tail extension forms an antenna to be utilized by the RF communications circuit to communicate to an external device. Further, an electrode is provided on the tail extension and is conductively coupled to the conductor and the sensing circuit.



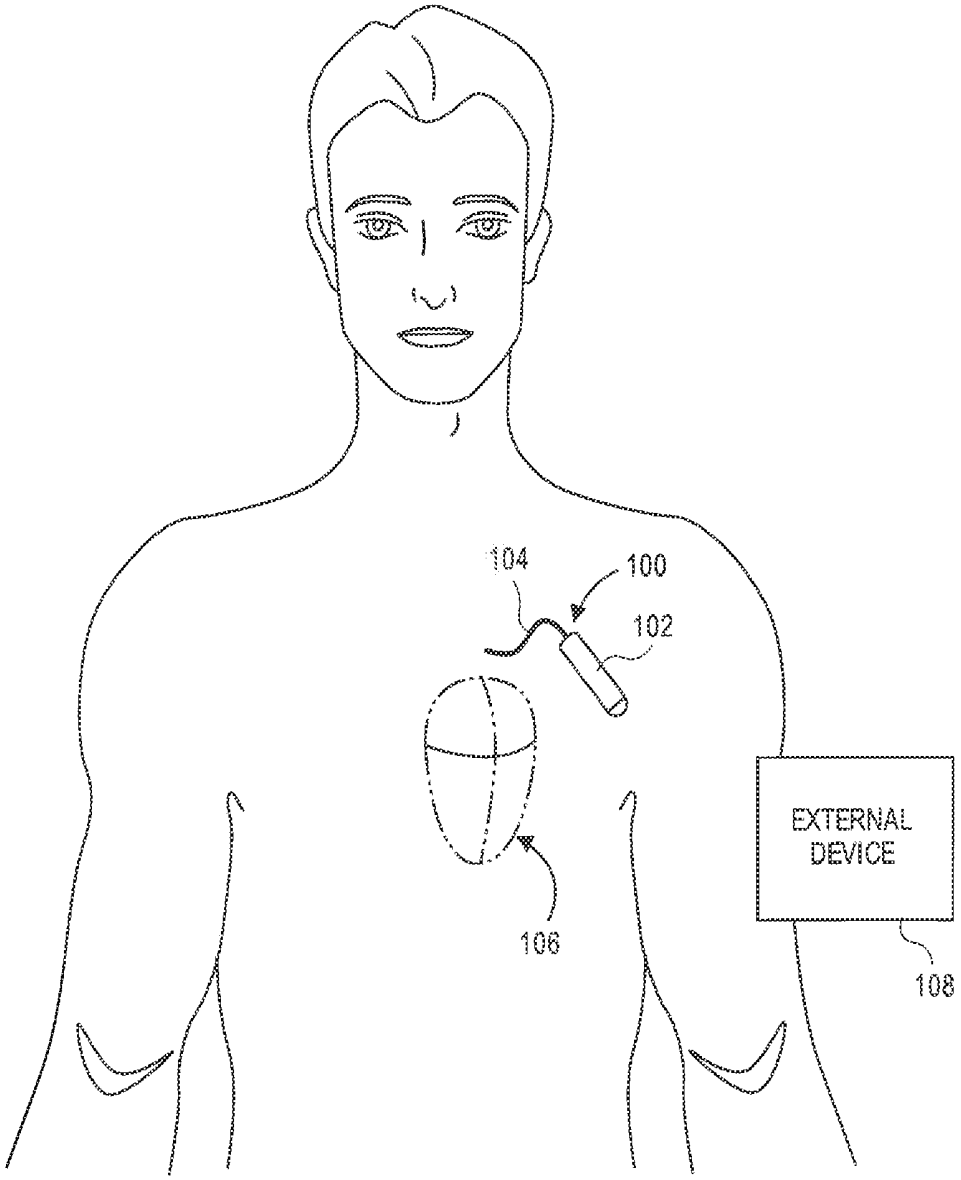



FIG. 1

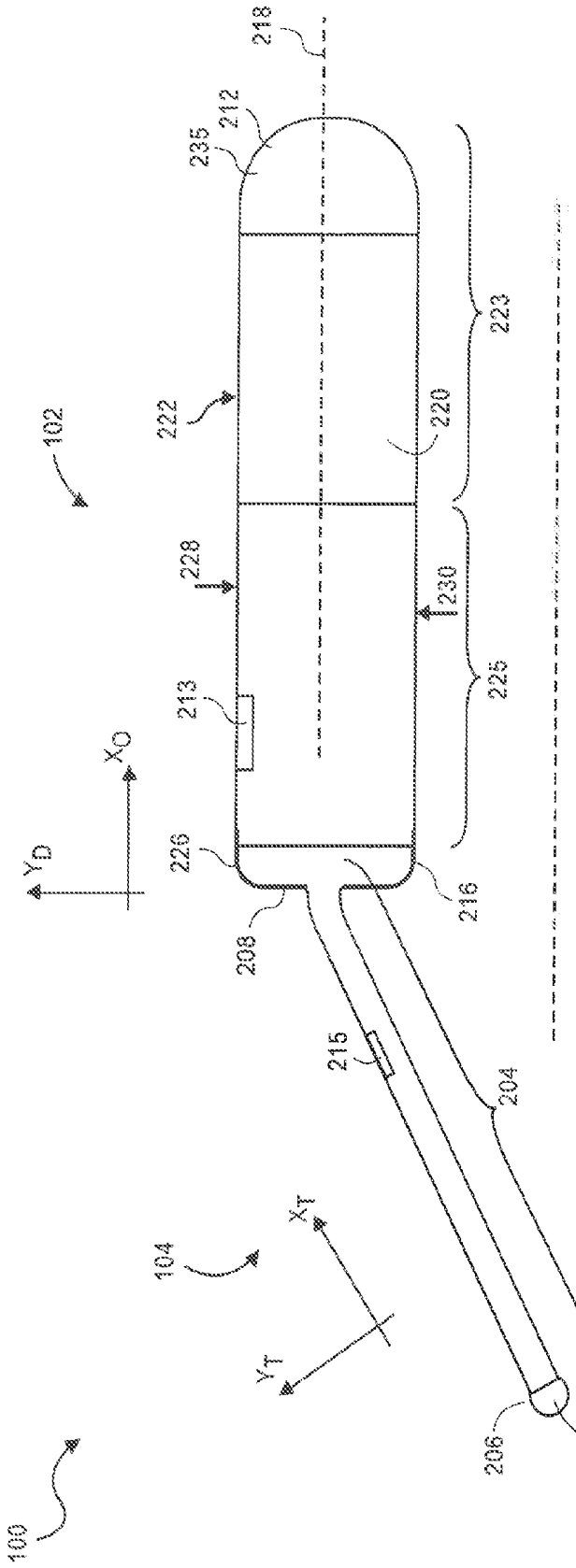

100
102
104
204
206
208
210
212
213
215
216
218
220
222
223
225
226
228
230
235
$X_O$
$Y_D$
$X_T$
$Y_T$

FIG. 2

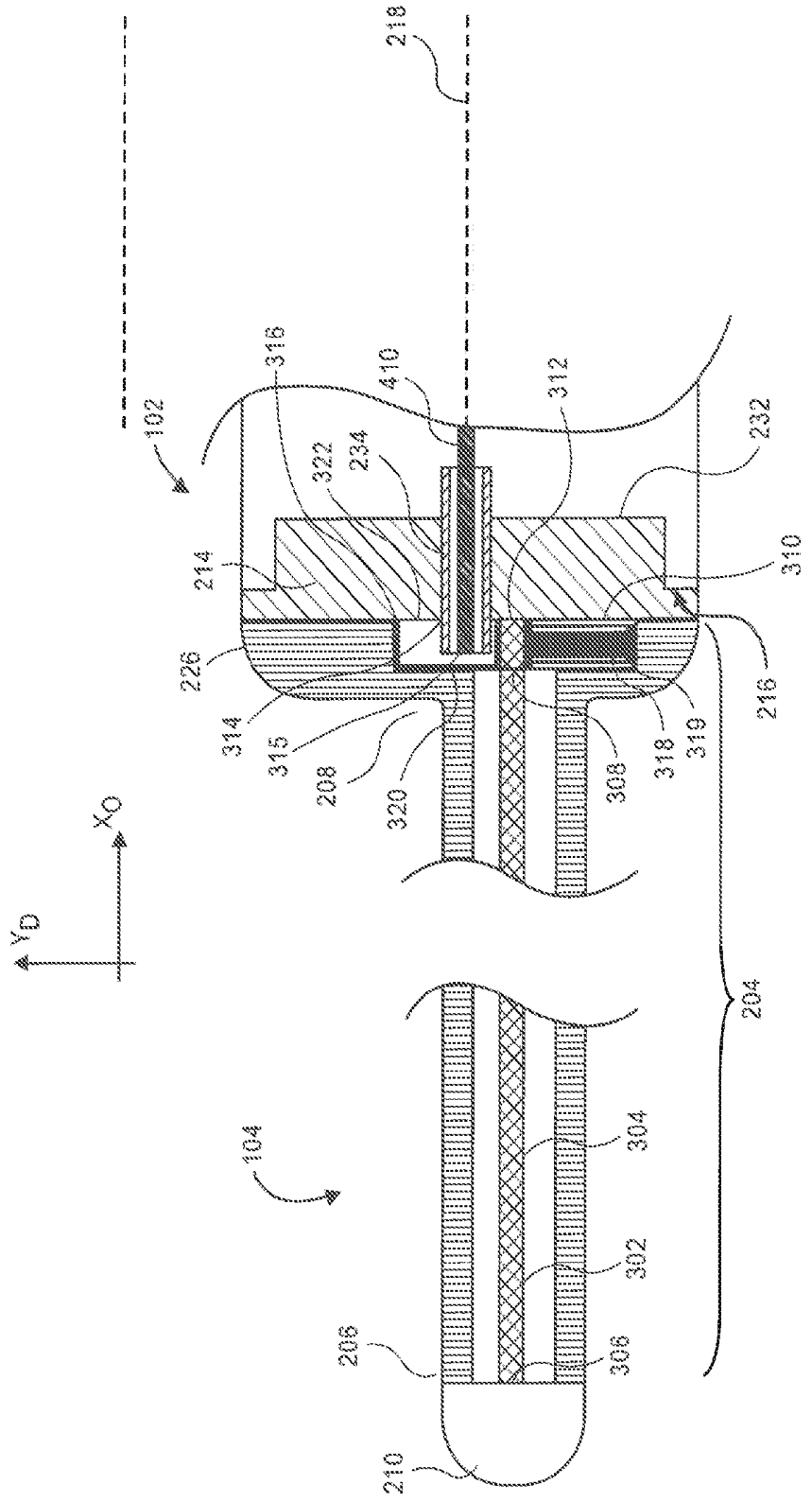

218
316
410
312
102
232
322
234
214
310
226
216
314
315
208
320
308
318
319
$X_O$
$Y_D$
204
104
304
302
206
306
210

FIG. 3

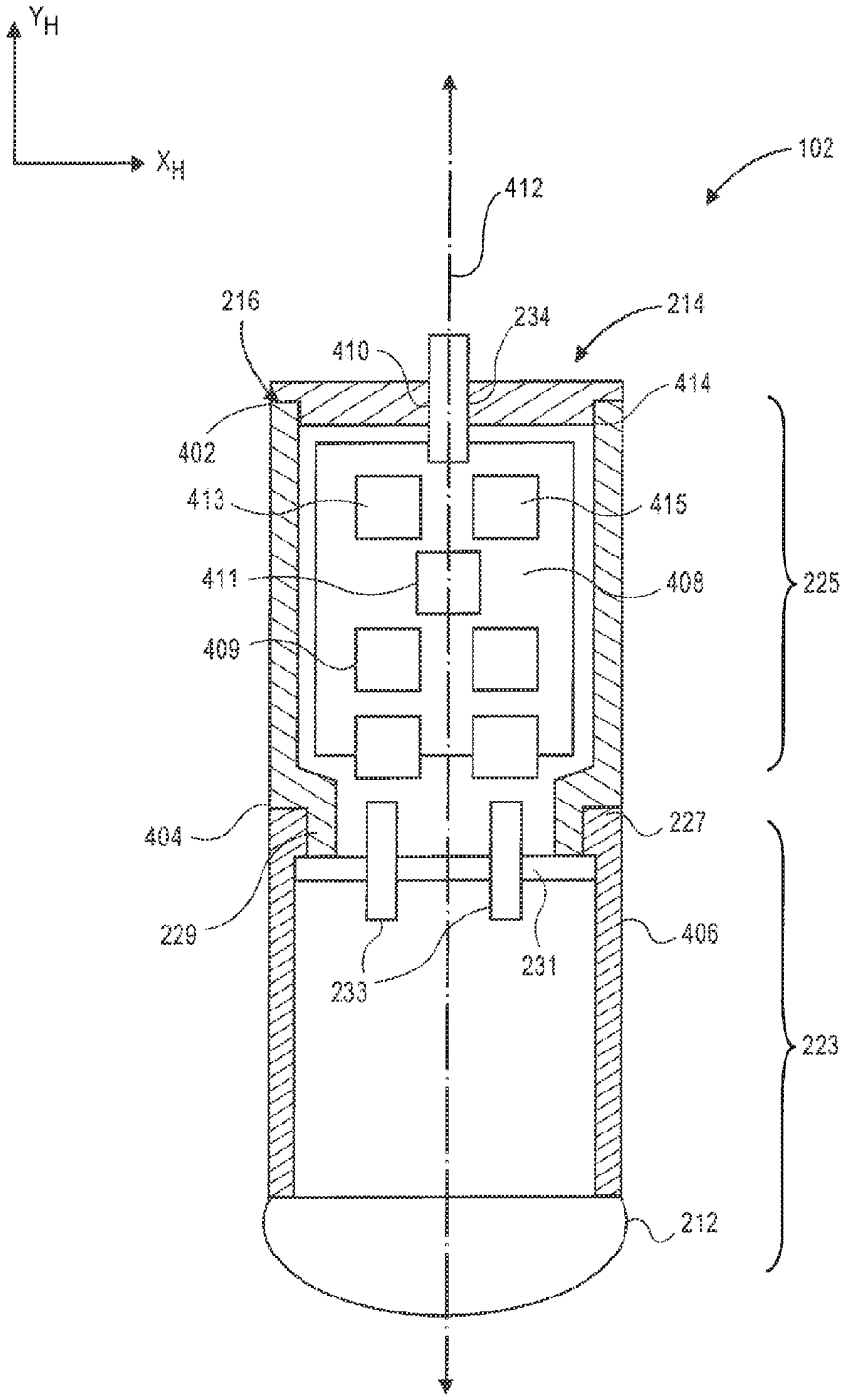

$Y_H$
$X_H$
102
412
216
234
214
410
414
402
413
415
411
408
225
409
404
227
229
406
233
231
223
212

FIG. 4

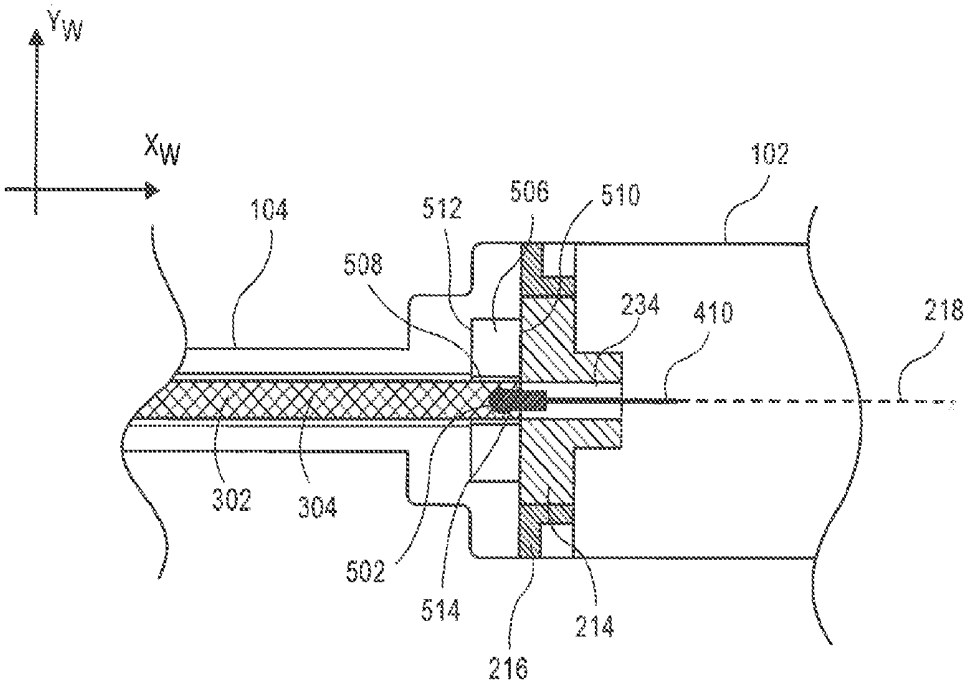

$Y_W$
$X_W$
102
104
512
506
510
508
234
410
218
302
304
502
514
214
216

FIG. 5A

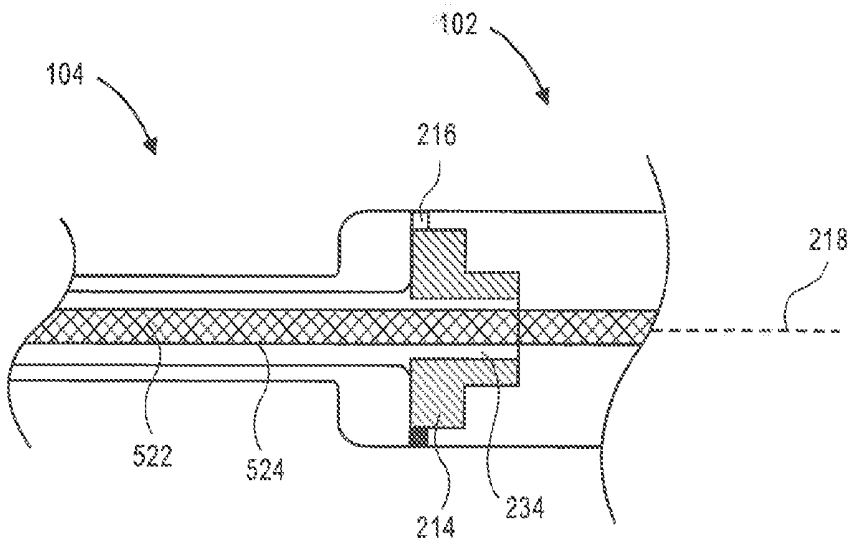

102
104
216
218
522
524
214
234

FIG. 5B

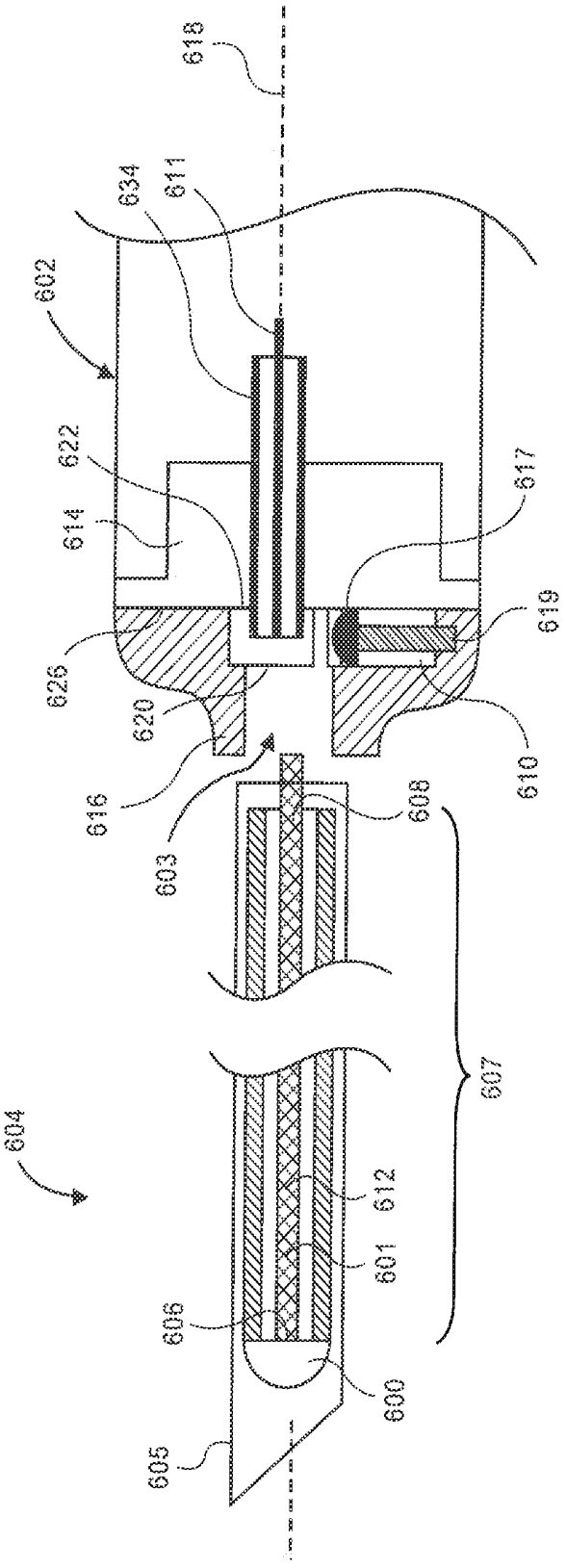
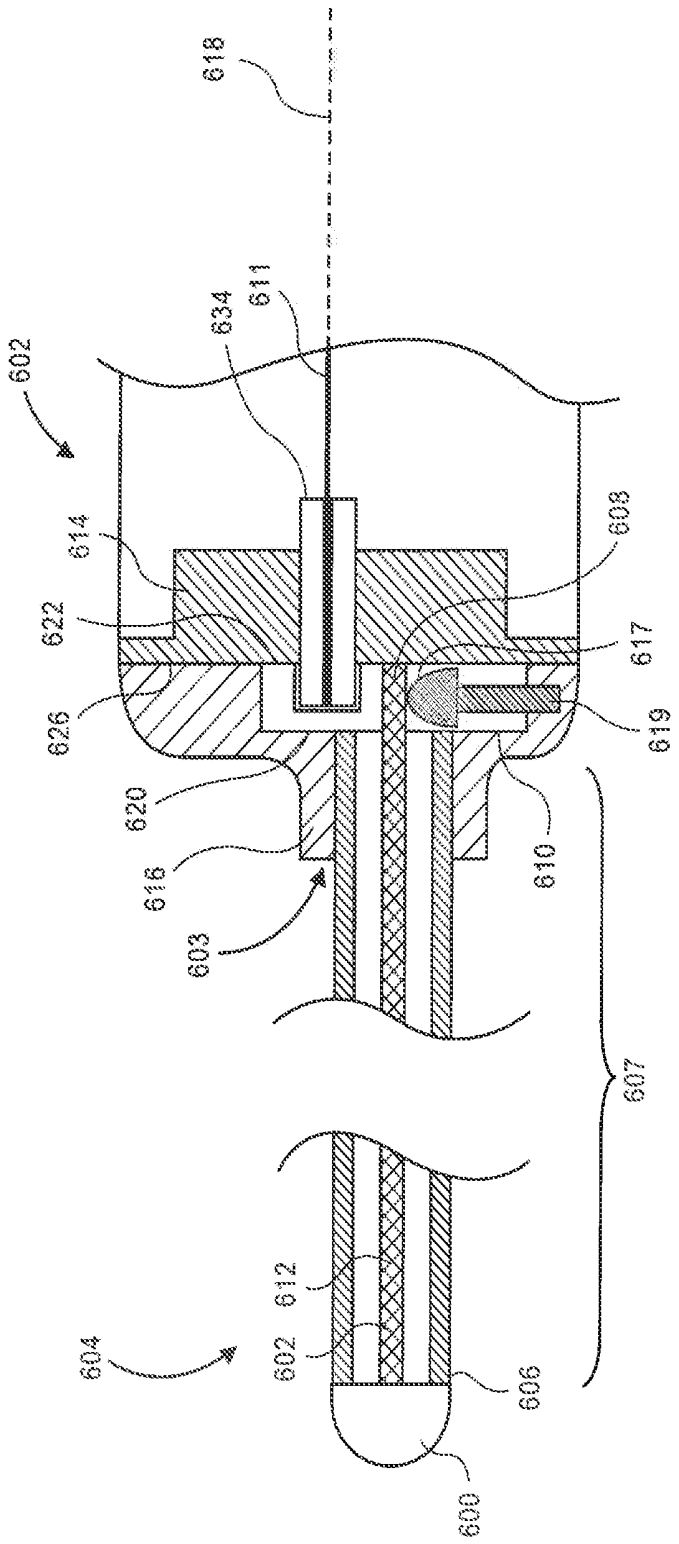

618
634
611
602
622
614
617
619
626
620
610
616
603
608
607
604
612
601
606
600
605

FIG. 6A


618
611
634
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603
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602
604
606
600

FIG. 6B

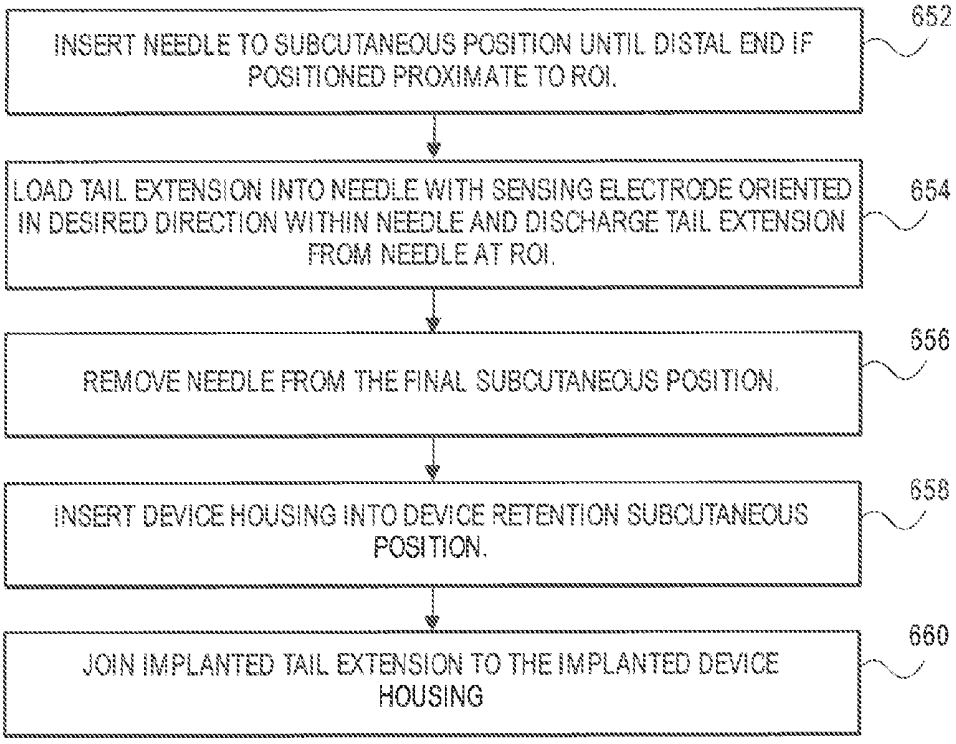
INSERT NEEDLE TO SUBCUTANEOUS POSITION UNTIL DISTAL END IF POSITIONED PROXIMATE TO ROI.
652
LOAD TAIL EXTENSION INTO NEEDLE WITH SENSING ELECTRODE ORIENTED IN DESIRED DIRECTION WITHIN NEEDLE AND DISCHARGE TAIL EXTENSION FROM NEEDLE AT ROI.
654
REMOVE NEEDLE FROM THE FINAL SUBCUTANEOUS POSITION.
656
INSERT DEVICE HOUSING INTO DEVICE RETENTION SUBCUTANEOUS POSITION.
658
JOIN IMPLANTED TAIL EXTENSION TO THE IMPLANTED DEVICE HOUSING
660

FIG. 6C

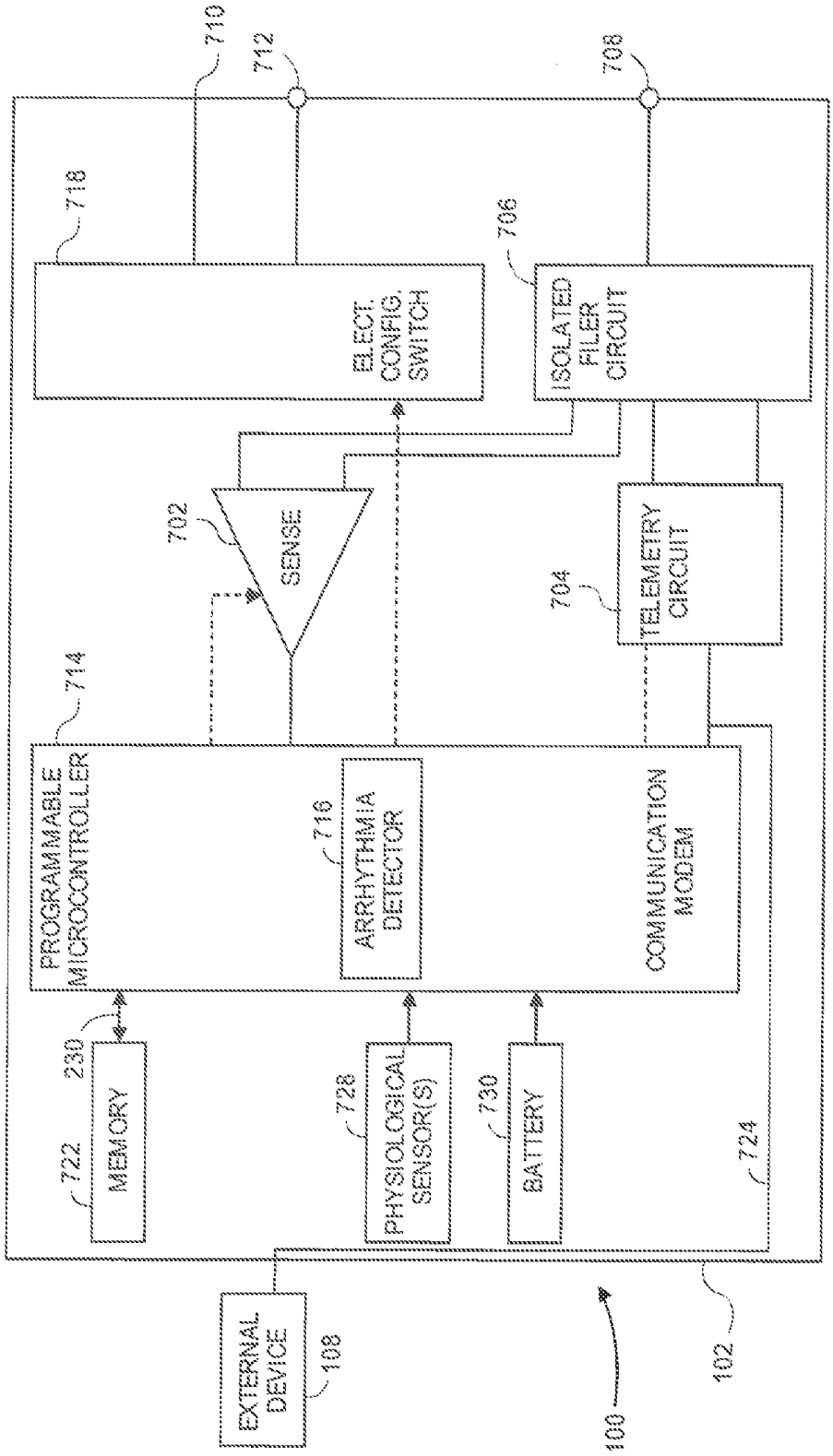
710
712
708
718
706
ELECT. CONFIG. SWITCH
ISOLATED FILER CIRCUIT
702
SENSE
704
TELEMETRY CIRCUIT
714
PROGRAMMABLE MICROCONTROLLER
716
ARRHYTHMIA DETECTOR
COMMUNICATION MODEM
230
722
MEMORY
728
PHYSIOLOGICAL SENSOR(S)
730
BATTERY
724
EXTERNAL DEVICE
108
100
102

FIG. 7

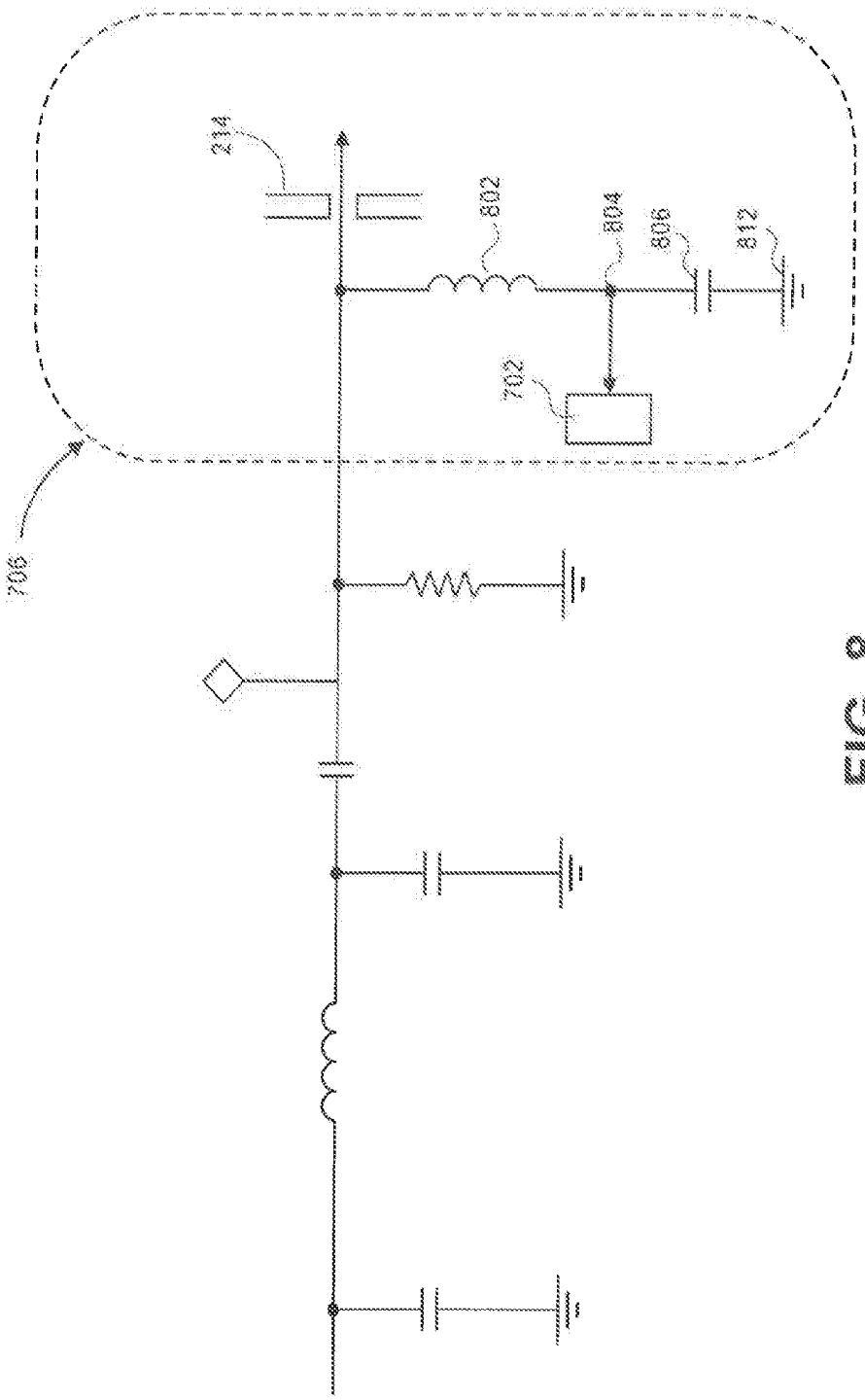


FIG. 8

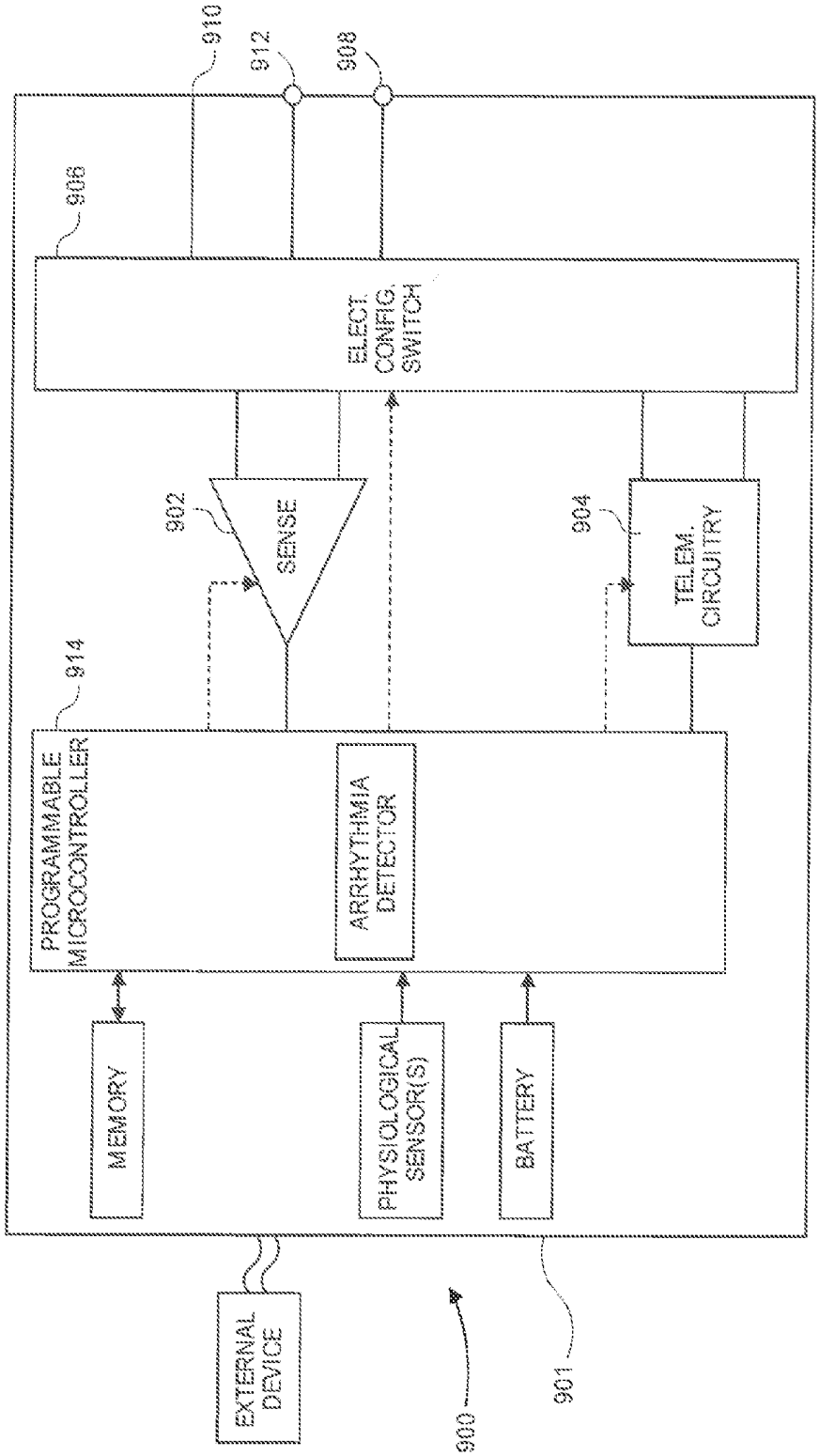
910
912
908
906
ELECT. CONFIG. SWITCH
902
SENSE
904
TELEM. CIRCUITRY
914
PROGRAMMABLE MICROCONTROLLER
ARRHYTHMIA DETECTOR
MEMORY
PHYSIOLOGICAL SENSOR(S)
BATTERY
EXTERNAL DEVICE
900
901

FIG. 9

# IMPLANTABLE DEVICE WITH A TAIL EXTENSION INCLUDING EMBEDDED SENSOR AND ANTENNA

## BACKGROUND OF THE INVENTION

**[0001]** Embodiments herein generally relate to implantable cardiac monitoring devices.

**[0002]** An implantable cardiac monitoring (ICM) device is a medical device that is implanted in a patient to, among other things, monitor electrical activity of a heart. An ICM device may record cardiac activity of a patient over time and report such cardiac activity to an external device. The ICM device may optionally perform various levels of sophisticated analysis of the cardiac activity and based thereon perform additional recording operations. The ICM device may also be configured to deliver appropriate electrical and/or drug therapy, and as such is also referred to as an implantable medical device (IMD). Examples of IMDs include pacemakers, cardioverters, cardiac rhythm management devices, defibrillators, and the like. The electrical therapy produced by an IMD may include, for example, pacing pulses, cardioverting pulses, and/or defibrillator pulses. The device is used to both provide treatment for the patient and to inform the patient and medical personnel of the physiologic condition of the patient and the status of the treatment.

**[0003]** In general, an ICM includes a battery, memory and electronic circuitry that are hermetically sealed within a metal housing (generally referred to as the "can"). The metal housing typically is formed of titanium and includes a shell with an interconnect cavity, in which the memory, pulse generator and/or processor module reside. The device housing is configured to receive a header assembly. The header assembly comprises a mechanical structure which houses an antenna and a sensing electrode. A feed-through assembly is located at the header receptacle area and is sealed to the device housing to form an interface for conductors to enter/exit the interconnect cavity.

**[0004]** However, ICM devices have experienced some limitations. Certain types of ICM devices include one or more sensing electrodes and an antenna that are located within the ICM device. For example, the sensing electrode/electrodes and antenna may be located in the header of the ICM device. Heretofore, the header assembly structure joined to the device limits the length of the antenna and limits the placement of the sensing electrode/electrodes relative to the region of interest.

**[0005]** A need remains for improved ICM devices and methods of manufacture thereof.

## SUMMARY

**[0006]** In accordance with embodiments herein, a device is provided for an implantable cardiac monitor device comprising a device housing having a sensing circuit and a radio frequency (RF) communications circuit housed within the housing. The device further comprising a tail extension having a proximal end, a distal end, and an extension body extended there between wherein the proximal end is coupled to the housing. The extension body is formed of a flexible material and includes at least one conductor that includes a proximal end conductively coupled to the sensing and RF communications circuit. At least a portion of the conductor of the tail extension forms an antenna to be utilized by the RF communications circuit to communicate with an external device. Further, an electrode is provided on the tail extension and is conductively coupled to the conductor and the sensing circuit.

**[0007]** Optionally, the portion of the conductor that forms the antenna is electrically coupled to the electrode. In at least one embodiment, the conductor consists of a single conductor that both forms the antenna and carries cardiac sensed signals from the electrode. In at least one other embodiment, the conductor may include first and second conductors, wherein the first conductor is coupled to the electrode and is configured to carry cardiac sensed signals, and the second conductor forms the antenna and is configured to carry communications data to and/or from the RF communications circuit.

**[0008]** Optionally, the proximal end of the tail extension is joined directly at a non-header interface on a surface of the device housing. The device further comprises a feed-through assembly joined to the device housing. The feed-through assembly including a single conductor extending there through. The single conductor has a proximal end connected to the sensing and RF communications circuits and a distal end projecting from the feed-through assembly.

**[0009]** Optionally, the device housing further comprises a filter circuit conductively coupled between the at least one conductor and the sensing and RF communications circuits. The filter circuit is configured to block RF transmissions from reaching the sensing circuit. The filter circuit includes an inductive element and a capacitive element connected in series with one another at an intermediate node. The sensing circuit joins to the intermediate node. The capacitor element is configured to form an open circuit when experiencing cardiac sensing signals and to form a closed circuit when experiencing RF transmissions. The filter further comprises a low pass filter branch configured to pass cardiac sensed signals and a band pass filter branch configured to pass RF communications in a frequency range that includes approximately 2.4 GHz.

**[0010]** Optionally, the tail extension of the device comprises a predetermined length between the distal end and the proximal end. The predetermined length is tuned based on the center of frequency of the RF communications bandwidth.

**[0011]** In accordance with embodiments herein, a method is provided for implanting a cardiac monitor device comprising positioning a device subcutaneously, the device comprising a device housing having a sensing circuit and a radio frequency (RF) communications circuit housed within the housing. The device further comprises a tail extension having an extension body with a proximal end joined to the device housing. The extension body is formed of a flexible material and includes at least one conductor. The tail extension is positioned in a subcutaneous area with an electrode provided on the tail extension located proximate to a region of interest (ROI) in a heart. The electrode collects cardiac signals from the ROI provided on the tail extension and conveys the RF communications data to an external device using an antenna that is formed from at least a portion of the conductor.

**[0012]** Optionally, the method comprises a positioning operation of locating a distal end of the tail extension remote from the device housing and an electrode provided at the distal end of the tail extension located proximate to a region of interest in the heart. The conductor includes a first and

second conductor, wherein the first conductor is coupled to the electrode and configured to carry the cardiac signals and the second conductor forms the antenna and is configured to carry the RF communications data to and/or from the RF communications circuit.

**[0013]** Optionally, the method comprises filtering the cardiac signals to isolate the RF communications circuit from the cardiac signals sensed over the conductor, and filtering the RF communications to isolate the sensing circuit from the RF communications data carried by the conductor. The collecting and conveying operations utilize a common conductor in the tail extension. The filtering operation comprises low pass filtering to pass the cardiac signals along a sensing branch and band pass filtering to pass RF communications data that is in a frequency range that includes approximately 2.4 GHs, along a communications branch.

**[0014]** Optionally, the method comprises inserting the tail extension into a lumen in a tail implant tool and inserting the tail implant tool subcutaneously to a location proximate to the ROI. The tail implant tool is removed while leaving the tail extension implanted. Optionally, the ROI is located proximate to an atrium of the heart such that the cardiac signals include sensed P-waves.

**[0015]** In accordance with embodiments herein, a method is provided for providing an implantable cardiac monitor device comprising providing a device comprising a device housing have a sensing circuit and a radio frequency (RF) communications circuit housed within the housing. The method further comprising joining a tail extension to the device housing, the tail extension having an extension body with a proximal end joined to the device housing. The extension body formed of a flexible material and including at least one conductor. An electrode may be positioned on the tail extension to sense cardiac signals when the tail extension is located proximate to a region of interest (ROI) in the heart. A portion of the conductor forms an antenna and tuning the antenna and RF communications circuit to convey RF communications data to an external device utilizing a predetermined communications frequency.

**[0016]** Optionally, the tuning operation includes tuning the antenna to utilize the predetermined communications frequency centered at one of 2.4 GHz and 400 MHz.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0017]** FIG. **1** illustrates an implantable cardiac monitoring (ICM) device intended for subcutaneous implantation at a site near the heart in accordance with embodiments herein.

**[0018]** FIG. **2** illustrates a side perspective view of the ICM device in accordance with embodiments herein.

**[0019]** FIG. **3** illustrates a side sectional view of a tail extension joined to the ICM device in accordance with embodiments herein.

**[0020]** FIG. **4** illustrates a side sectional view of a device housing in accordance with embodiments herein.

**[0021]** FIG. **5**A illustrates a side sectional view of the tail extension joined to the device housing in accordance with embodiments herein.

**[0022]** FIG. **5**B. illustrates a side sectional view of the tail extension joined to the device housing in accordance with embodiments herein.

**[0023]** FIG. **6**A illustrates a side sectional view of a tail extension separated from a device housing in accordance with embodiments herein.

**[0024]** FIG. **6**B illustrates a side sectional view of a tail extension joined to the device housing in accordance with embodiments herein.

**[0025]** FIG. **6**C illustrates a flowchart method for implanting and connecting a tail extension and a device housing in accordance with embodiments herein.

**[0026]** FIG. **7** illustrates a block diagram of an exemplary ICM device that is configured to be implanted into the patient in accordance with embodiments herein.

**[0027]** FIG. **8** illustrates a circuit diagram of the exemplary ICM device of FIG. **7** in accordance with embodiments herein.

**[0028]** FIG. **9** illustrates a block diagram of an alternative exemplary ICM device that is configured to be implanted into the patient in accordance with embodiments herein.

## DETAILED DESCRIPTION

**[0029]** In accordance with the embodiments herein, devices and methods are described that afford improved placement of a sensing electrode and antenna performance in implantable cardiac monitoring (ICM) devices (including implantable medical devices configured to deliver therapies). In accordance with at least some embodiments, the devices and methods described herein provide improved sensing of cardiac signals as compared to conventional implantable cardiac monitoring devices and eliminate conventional structural limitations. In accordance with at least some embodiments, the devices and methods described herein provide improved wireless communications performance in a compact footprint.

**[0030]** FIG. **1** illustrates an implantable cardiac monitoring (ICM) device **100** intended for subcutaneous implantation in a patient at a site near a heart **106**. The ICM device **100** includes a device housing **102** that is joined to a proximal end of a tail extension **104**. The device housing **102** is a solid component that communicates with an external device **108**. The tail extension **104** is a flexible component that receives cardiac signals from the heart **106**. The ICM device **100** is placed in a subcutaneous area of the patient with a distal end of the tail extension **104** located proximate to a region of interest (ROI) in the heart. For example, the ROI is located proximate to an atrium of the heart such that cardiac signals that are collected by the ICM device **100** include P-waves. Optionally, the ROI could be a number of anatomical aspects of a patient, such as the heart wall, the right ventricle, left ventricle, etc. The ICM device **100** may be positioned in various orientations relative to a patient anatomy, such as relative to various aspects of the heart, parallel to the sternum, non-parallel to the sternum, and the like.

**[0031]** The device housing **102** includes various other components such as one or more sense circuits for receiving and collecting cardiac signals from one or more combinations of electrodes, a microprocessor for processing the cardiac signals in accordance with various algorithms (e.g., an AF detection algorithm), a memory for temporary storage of electrogram data, a device memory for long-term storage of electrogram data (e.g., based on certain triggering events, such as AF detection), sensors for detecting patient activity and a battery for powering circuits and other components.

**[0032]** The ICM device **100** senses near field and/or far field cardiac signals and stores the cardiac signals as electrogram data. The ICM device **100** processes the electrogram (EGM) data in various manners such as to detect

physiologic characteristics of interest (e.g., arrhythmias). The ICM device **100** automatically records segments of the electrogram data in temporary or long-term memory based on identification of the characteristics of interest. By way of example, the EGM data may be stored in memory of the ICM device **100** until subsequent transmission to the external device **108**. Electrogram processing and arrhythmia detection is provided for, at least in part, by algorithms embodied in program instructions that are executed by one or more microprocessors. In one configuration, the monitoring device is operative to detect atrial fibrillation.

**[0033]** FIG. **2** illustrates a side perspective view of the ICM device **100** in accordance with an embodiment herein. FIG. **2** illustrates the tail extension **104** and device housing **102** of the ICM device **100** in more detail.

**[0034]** The tail extension **104** is elongated to extend along a longitudinal axis (designated by arrow $X_T$). The tail extension **104** is formed in a tubular shape about the longitudinal axis (designated by the arrow $X_T$) and is generally circular in shape about a cross sectional axis (designated by arrow $Y_T$). For example, the tail extension **104** is shaped similarly to a hollow wire. Optionally, the tail extension could be formed with a number of shapes. Additionally, the tail extension **104** is a flexible structure made of a flexible, insulating, biocompatible material (e.g., silicone rubber, polyurethane, etc.).

**[0035]** The tail extension **104** comprises a distal end **206** and a proximal end **208**, with an extension body **204** spanning between the distal end **206** and the proximal end **208**. The distal end **206** of the tail extension **104** is located remote from the device housing **102**. The proximal end **208** of the tail extension **104** is positioned near, and coupled to, the device housing **102**.

**[0036]** One or more primary sensing electrodes **210** are positioned at the distal end **206** of the tail extension **104**. One or more secondary sensing electrodes **212**, **213**, **215** may be provided on the device housing **102** and/or on the tail extension **104** at an intermediate point(s) along the length of the extension body **204**. The sensing electrodes **210**, **212**, **213**, **215** are configured to receive cardiac signals from the heart **106**. The sensing electrodes **210**, **212**, **213**, **215** may vary in shape and size.

**[0037]** The device housing **102** extends along a longitudinal axis **218**. In the embodiment of FIG. **2**, the device housing **102** is formed in a rectangular shape about the longitudinal axis **218** and in a rectangular shape about a cross sectional axis (designated by the arrow $Y_D$). However, the device housing **102** may be constructed with alternative shapes (e.g., a tubular shape, a circular shape, a shape similar to pacemakers, ICDs, CRM devices and other implantable devices). The device housing **102** comprises opposed elongated sides **220**, **222**, a top edge **228**, a bottom edge **230**, a header end **226** and a base end **235**. The base end **235** includes the secondary electrode **212** provided thereon. The opposed elongated sides **220**, **222** are generally parallel, but may be constructed with alternative contours. The opposed sides **220**, **222** merge with the top and bottom edges **228** and **230** along smooth beveled regions about the cross sectional axis (designated by the arrow $Y_D$).

**[0038]** In FIG. **2**, the device housing **102** is constructed in two pieces, namely with a battery portion **223** and an electronics shell portion **225**. The battery portion **223** is formed as a self-contained, hermetically sealed battery. The electronics shell portion **225** encloses the various electronic components and circuits as discussed herein.

**[0039]** FIG. **3** illustrates a detailed cross-sectional view of the tail extension **104** joined to the device housing **102** in accordance with an embodiment. The tail extension **104** and the device housing **102** are oriented to extend along the longitudinal axis **218**. FIG. **3** illustrates the tail extension **104** and header end **226** of the device housing **102** in more detail.

**[0040]** The tail extension **104** comprises at least one conductor **302**. The conductor **302** is positioned generally centered within the tail extension **104** and extends longitudinally the length of the extension body **204**. The conductor **302** may be a single strand wire, a multi-strand wire, a filar, or the like. Optionally, the conductor **302** may be formed as a tubular mesh. The tubular mesh may be constructed to include an interior lumen that is configured to receive an insertion tool (e.g., a guide wire, stylet, etc.).

**[0041]** The conductor **302** includes a distal end **306** and a proximal end **308**. The distal end **306** of the conductor is conductively joined to the sensing electrode **210**. The proximal end **308** of the conductor is positioned proximate to the device housing **102**.

**[0042]** In accordance with embodiments herein, all or a portion of the conductor **302** within the tail extension **104** is also utilized as an antenna **304**. The antenna **304**, for example, may be utilized to support communications in accordance with various wireless protocols such as, but not limited to, a Medical Implant Communications Service (MICS) protocol, a Bluetooth protocol, a Bluetooth Low Energy protocol, a Wi-Fi protocol, and the like.

**[0043]** The tail extension **104** (and antenna **304**) may be constructed with various lengths based upon select criteria. For example, the length of the tail extension **104** may be varied based upon the application for which the ICM device **100** is constructed. For example, different length tail extensions may be used when monitoring P-waves, or monitoring R-waves. Additionally or alternatively, one or more length(s) of tail extensions may be useful when sensing electrical activity of the heart as R-waves or P-waves, whereas one or more other length(s) of tail extensions may be useful when monitoring impedance, such as across various blood pools in the heart and/or in vessels proximate to the heart (e.g., the five great vessels of the heart). In addition, the length of the tail extension may be varied based on a desired combination of anatomical locations to be monitored by the ICM device **100**. For example, it may be desirable to locate the device housing **102** on one side of the heart (e.g., proximate the apex of the heart), while positioning the distal end of the tail extension **104** proximate to a different side/portion of the heart (e.g., proximate to the base of the heart). The length of the tail extension may be varied for other reasons as well.

**[0044]** In addition, the length of the tail extension may also be based on characteristics of the antenna **304**. In particular, the length of the antenna is set to a predetermined or select length based on various criteria. For example, the length of the conductor, that defines the antenna **304**, may be set to a predetermined or select length in order to electrically tune the antenna **304** and the RF communications circuit to a predetermined frequency. For example, the length of the antenna may be set to a predetermined length in order to provide a desired antenna performance when communicating RF communications data centered at a select center frequency (e.g., 2.4 GHz, 400 MHz, etc.). Optionally, the

length of the antenna may be sized to a different length to communicate over a different frequency.

**[0045]** Optionally, more than one conductor may be provided within the tail extension with the conductors conductively isolated from one another (e.g., individually insulated). When more than one conductively insulated conductor is provided within the tail extension, a first conductor (sensor conductor) may be dedicated to carrying sensed signals from the sensing electrode **210** on the distal end, while a second conductor (antenna conductor) may be dedicated to transmitting and receiving communications data. When separate sensor and antenna conductors are provided in the tail extension, the sensor and antenna conductors may be shaped and formed to provide a desired level of performance relative to the corresponding usage. For example, a sensor conductor may be sized differently from an antenna conductor. Additionally or alternatively, the sensor conductor may be formed from a different material than the antenna conductor. Additionally or alternatively, the sensor conductor may utilize a multi-strand filar with a select first diameter, while the antenna conductor is a single strand with a different (e.g., thicker) diameter.

**[0046]** Optionally, when separate sensor and antenna conductors are utilized, the antenna conductor may be formed with a different length than the sensor conductor. For example, in some applications, it may be desirable for the antenna conductor to have a length that is a fraction of a wavelength of the center communications frequency (e.g., one quarter wavelength in length). In addition, it may be desirable for the overall length of the tail extension to be longer that the predetermined length for the antenna conductor. In the foregoing example, the sensor conductor may extend the full length of the tail extension X (corresponding to a sensor spacing or sensor placement parameter), while the antenna conductor may extend a shorter length Y (corresponding to a timing related parameter). Utilizing separate conductors for sensing and for the antenna provides more flexibility to tailor the design parameters of the sensing characteristics and the antenna characteristics.

**[0047]** In FIG. **3**, the header end **226** of the device housing **102** comprises a housing mounting surface **216**. The housing mounting surface **216** is a non-header interface that comprises a recessed chamber **232**. The recessed chamber **232** is positioned to open on to the housing mounting surface **216**. The recessed chamber **232** is shaped and dimensioned to receive a feed-through assembly **214** on the device housing **102**. In the present example, the recessed chamber **232** is rectangular in shape, although alternative shapes may be used based on the shape of the feed-through assembly **214**. A passage **234** extends from the recessed chamber **232** through the feed-through assembly **214** along the longitudinal axis **218**.

**[0048]** The size and/or shape of the proximal end **208** of the tail extension **104** corresponds to the size and/or shape of the header end **226** of the device housing **102**. For example, the proximal end **208** of the tail extension **104** may be formed in a hollow-rectangular shape to form a cap over the device housing **102** at the header end **226** when joined. Optionally, alternative shapes may be used based on the shape and/or size of the housing mounting surface **216** of the device housing **102**. The hollow-rectangular shape of the proximal end **208** of the tail extension may be joined to the device housing by a press fit onto the device housing **102**. Additionally or alternatively, the proximal end **208** of the tail extension may be joined to the device housing by alternative methods.

**[0049]** In FIG. **3**, a collar **310** is joined to the feed-through assembly **214** of the device housing **102** along the longitudinal axis **218**. The collar **310** comprises a distal end **320** and a proximal end **322**. The distal end **320** is positioned facing the sensing electrode **210** of the tail extension **104**. The proximal end **322** of the collar joins to the feed-through assembly **214**. The collar **310** may be joined to the feed-through assembly by various methods. For example, the collar **310** may be joined to the feed-through assembly by welding, over-molding, mechanical fasteners, or the like. For example, the collar **310** may be welded to the feed-through assembly **214** at a weld joint **316**.

**[0050]** Furthermore, the collar **310** comprises one or more openings. The distal end **320** of the collar **310** comprises a distal-opening **312**. The distal-opening **312** is sized and shaped to receive the proximal end **308** of the conductor **302** of the tail extension **104**. The proximal end **322** of the collar **310** comprises a proximal-opening **314**. The proximal-opening **314** is sized and shaped to receive the passage **234** of the feed-through assembly **214**.

**[0051]** According to an embodiment, the collar **310** is configured with a third opening **318**. The third opening **318** may be positioned perpendicular to the longitudinal axis **218** and may be constructed to intersect with the distal-opening **312**. The third opening **318** comprises a set-screw **319**. The set-screw **319** of the third opening **318** joins the proximal end **308** of the conductor **302** to the collar **310** to electrically couple the conductor **302** with the collar **310**.

**[0052]** FIG. **4** illustrates a detailed cross-sectional view of the device housing **102** formed in accordance with an embodiment. The device housing **102** is oriented to extend along the longitudinal axis **218**. FIG. **4** illustrates the battery portion **223** and electronics shell portion **225** in more detail. The distal end of the battery portion **223** includes the secondary electrode **212**, while a proximal end **227** includes a shell reception opening sized and shaped to receive an end **229** of the electronics shell portion **225**. A battery feed-through **231** is provided at the interface between the electronics shell portion **225** and battery portion **223**. Conductors **233** extend through the battery feed-through **231** to provide electrical connections to a battery **406**. A weld joint **404** hermetically seals the electronics shell portion **225** to the battery portion **223**.

**[0053]** FIG. **4** further illustrates the interface between the feed-through assembly **214** and the electronics shell portion **225** at the housing mounting surface **216**. A weld joint **402** hermetically seals the feed-through assembly **214** to the proximal end of the electronics shell portion **225**. In the foregoing example, welds are provided at component interfaces, however it is understood that alternative attachment techniques may be utilized.

**[0054]** The electronics shell portion **225** includes various circuits, components and memory based on the individual operations and application for which the ICM device **100** is configured. In FIG. **4**, an example electronics board **408** includes one or more processors **409**, memory **411**, sensing circuit **413**, and RF communications circuit **415**, as well as other electrical components. Examples of the various electronic components may include sensing circuitry to sense cardiac signals of interest, one or more processors to per-

form monitoring operations, transceiver circuitry to communicate with external devices and other components as described herein.

**[0055]** The sensing circuit **413** and RF communications circuit **415** are electrically coupled with a single conductor **410** at a proximal end **414**. A distal end **412** of the single conductor **410** extends from the electronics board **408** through the passage **234** of the feed-through assembly **214**. For example, in the present example, the single conductor **410** is a single-strand wire that is electrically coupled to the electronic components on the electronics board **408** (e.g. the sensing circuit **413** and RF communications circuit **415**). The single conductor **410** projects outward from the feed-through assembly **214** to provide a connection point to be conductively joined to the proximal end of one or more conductors within the tail extension **104**.

**[0056]** Returning to FIG. **3**, the single conductor **410**, extending from the electronics shell portion **225** of the device housing **102**, may be received into the proximal-opening **314** of the collar **310**. The single conductor **410** may be conductively coupled to the collar **310**. For example, the single conductor **410** may be conductively coupled to the collar **310** by a weld joint **315**. Additionally or alternatively, the single conductor may be joined to the collar using alternative attachment techniques. The collar **310** interconnects the proximal end **308** of the conductor **302** of the tail extension **104** with the single conductor **410** extending from the device housing **102**. For example, the collar **310** conductively couples the proximal end **308** of the conductor **302** with the sensing circuit **413** and RF communications circuit **415**. The collar **310** enables electrical communication between the sensing electrode **210** of the tail extension **104** and the electronic components of the device housing **102**.

**[0057]** FIG. **5**A illustrates an alternative example of a connection mechanism for interconnecting the conductor **302** of the tail extension **104** to the electronic components of the device housing **102**. A collar **506** is joined to the feed-through assembly **214**. A distal end **512** of the collar **506** is positioned facing away from the feed-through assembly **214**. A proximal end **510** of the collar is positioned facing towards the feed-through assembly **214**. In the embodiment of FIG. **5**A, the collar **506** comprises a collar-passage **508**. The collar-passage **508** is open along the longitudinal axis **218**. The collar-passage **508** is sized and shaped to receive the conductor **302** of the tail extension **104** on the distal end **512** and to receive the passage **234** of the feed-through assembly **214** on the proximal end **510**.

**[0058]** The single conductor **410** is electrically coupled to the electronic components of the device housing **102** at the proximal end **414** (not shown). The distal end **412** of the single conductor **410** extends from the device housing through the feed-through assembly **214** along the longitudinal axis **218**. The distal end **412** of the single conductor **410** is conductively joined to a pin **514**. The pin **514** extends from the distal end **412** of the single conductor **410** towards the collar **506** along the longitudinal axis **218**. The conductor **302** of the tail extension **104** may be conductively coupled with the pin **514** at a weld joint **502**. For example, the pin **514** conductively couples the proximal end **308** of the conductor **302** with the sensing circuit **413** and RF communications circuit **415**.

**[0059]** FIG. **5**B illustrates an alternative example of a connection mechanism for interconnecting the conductor of the tail extension **104** to the electronic components of the device housing **102**. In accordance with an embodiment in FIG. **5**B, a single conductor **522** (corresponding to the conductor **302** of FIG. **3**) extends within the tail extension **104** along the longitudinal axis **218**. All or a portion of the conductor **522** within the tail extension **104** is also utilized as an antenna **524** (corresponding to the antenna **304** of FIG. **3**). The single conductor **522** is conductively joined to the sensing electrode **210** on the distal end of the tail extension **104** (not shown). The single conductor **522** extends between the sensing electrode **210** and the device housing **102**. In the present embodiment, the single conductor **522** extends through the passage **234** of the feed-through assembly **214** and into the device housing **102**. The single conductor **522** is electrically coupled to the electronic components of the device housing **102** (not shown). For example, the single conductor **522** is conductively joined to the sensing electrode **210** at a distal end, and conductively joined to the electronic components of the device housing **102** at a proximal end.

**[0060]** The previous embodiments illustrate three examples demonstrating how the conductor of the tail extension **104** may be conductively coupled to the electronic components of the device housing **102**. However, it is understood that alternative attachment techniques may be utilized. The conductor of the tail extension **104**, electrically coupled with the electronic components of the device housing **102**, enables electrical communication between the sensing electrode **210** of the tail extension and the electronic components of the device housing **102**. The conductor **302**, electrically coupled to the sensing electrode **210**, performs the operations of conveying collected cardiac sensing signals from the ROI in the heart to the sensing circuitry **413** of the device housing. The portion of the conductor **302** that forms the antenna **304** performs the operations of communicating the RF communications data to and/or from the RF communications circuitry **415** of the device housing **102** and the external device **108**.

**[0061]** FIGS. **6**A and **6**B illustrate an embodiment of a tail extension **604** and a device housing **602** formed in accordance with an alternative embodiment. The tail extension **604** and device housing **602** are configured to be subcutaneously positioned at a ROI of the heart prior to the tail extension **604** being joined to the device housing **602**. FIG. **6**A illustrates the tail extension **604** separated from the device housing **602**. FIG. **6**B illustrates the tail extension **604** joined to the device housing **602**. FIGS. **6**A and **6**B will be discussed in detail together in connection with FIG. **6**C.

**[0062]** FIG. **6**C illustrates a flowchart for a process for separately subcutaneously implanting the tail extension **604** and the device housing **602**, and then joining the tail extension **604** to the device housing **602** after implant.

**[0063]** The tail extension **604** (corresponding to the tail extension **104** of FIG. **2**) comprises a distal end **606** and a proximal end **608**, with an extension body **607** spanning between the distal end **606** and the proximal end **608**. The distal end **606** of the tail extension **604** is located remote from the device housing **602**. A primary sensing electrode **600** (corresponding to the primary sensing electrode **210** of FIG. **2**) is positioned at the distal end **606** of the tail extension **604**. The proximal end **608** of the tail extension **604** is positioned near, and configured to be coupled to, the device housing **602**.

**[0064]** A single conductor **601** (corresponding to the conductor **302** of FIG. **3**) extends within the tail extension **604**

along a longitudinal axis **618**. For example, the single conductor **601** extends between the sensing electrode **600** and the proximal end **608** of the tail extension **604**. All or a portion of the conductor **601** within the tail extension **604** is also utilized as an antenna **612** (corresponding to the antenna **304** of FIG. **3**).

**[0065]** A header gasket **616** forms a cap over the device housing **602** at the header end **626**. The header gasket **616** is a hollow piece that is sized and/or shaped to fit over the device housing **602**. The header gasket **616** is a flexible structure made of a flexible, insulating, biocompatible material (e.g., silicone rubber, polyurethane, etc.). The header gasket **616** comprises a receiving slot **603** that is sized and/or shaped to receive the proximal end **608** of the tail extension **604**. For example, the receiving slot **603** of the header gasket **616** receives the proximal end **608** of the tail extension **604** in order to join the tail extension **604** to the device housing **602**. Optionally, the header gasket **616** may be omitted entirely.

**[0066]** In FIG. **6**C, beginning at **652**, a needle **605** is inserted into a subcutaneous position at a ROI of the heart. The needle **605** is maneuvered until a distal end of the needle **605** is located at a final subcutaneous location of interest (not shown). The final subcutaneous location could be a ROI proximate to the heart. For example, the final location may be positioned on one side of the heart (e.g., proximate the base of the heart). Additionally or alternatively, the final location may be any other ROI that is proximate to the heart. Optionally, the final location may be proximate to another anatomy of interest, such as an ROI in or near the lungs, an organ, a portion of the nervous system, the spine, the brainstem, the brain, etc.

**[0067]** At **654**, the distal end **606** of the tail extension **604** is loaded into the needle **605**. For example, the distal end **606** with the sensing electrode **600** is inserted through the needle **605** and discharged from the distal end of the needle in order to position the sensing electrode **600** at the final subcutaneous location. Optionally, the tail extension **604** may be loaded into the needle before or after the needle is inserted to the ROI. At **656**, the needle **605** is removed from the final subcutaneous position leaving the tail extension **604** implanted and the sensing electrode **600** at the final subcutaneous position.

**[0068]** At **658**, the device housing **602** is implanted to a device retention subcutaneous position. Various methods and tools may be used to implant the device housing **602**. For example, a sheath, catheter and the like may be introduced through a vein or artery to a device retention position. Optionally, the device housing **602** may be located in a pocket through an open incision (e.g., at a sub-clavicle pocket). For example, it may be desirable to position the device housing **602** on a different side/portion of the heart (e.g., proximate the apex of the heart) from the distal end **606** of the tail extension **604**. At **660**, once the device housing **602** is implanted at the desired location, the implanted tail extension **604** is joined to the implanted device housing **602**. The device housing **602** and the tail extension **604** may be secured to one another in various manners. For example, device housing **602** and the tail extension **604** may be secured to one another in a manner similar to attaching a proximal end of a lead to a pacemaker, cardioverter defibrillator, neuro-stimulation device and the like.

**[0069]** FIG. **6**B illustrates the tail extension **604** joined to the header gasket **616**. In the embodiment of FIG. **6**B, a collar **610** (corresponding to the collar **310** of FIG. **3**) is joined to a feed-through assembly **614** of the device housing **602** along the longitudinal axis **618**. The collar receives the conductor **601** of the tail extension at a distal end **620**. The collar receives a single conductor **611** (corresponding to the single conductor **410** of FIG. **3**) extending from the device housing **602** through a passage **634** of the feed-through assembly **614** of the device housing **602** at a proximal end **622**.

**[0070]** The collar **610** is configured with an opening **617** perpendicular to the longitudinal axis **618**. The opening **617** comprises a set-screw **619**. The header gasket **616** flexes to allow access to the collar **610** in order to join the conductor **601** of the tail extension **604** to the collar **610** with the set-screw **619**. The set-screw **619** of the opening **617** joins the conductor **601** to the collar **610** to electrically couple the conductor **601** with the collar **610**. The collar **610** interconnects the conductor **601** of the tail extension **604** with the single conductor **611** extending from the device housing **602**. The collar **610** enables electrical communication between the sensing electrode **600** of the tail extension **604** and the electronic components of the device housing **602**. Once the conductor **601** is joined to the collar **610**, the header gasket **616** rebounds to the original position. In the original position, the proximal end **608** of the tail extension **604** is held to the header gasket **616** by a press fit into the receiving slot **603**.

**[0071]** The previous embodiment illustrates one example demonstrating how the conductor of the tail extension **604** may be conductively coupled to the electronic components of the device housing **602** after the tail extension **604** and the device housing **602** have been individually subcutaneously implanted. However, it is understood that alternative attachment techniques may be utilized.

**[0072]** FIG. **7** illustrates a block diagram of the ICM device **100** that is configured to be subcutaneously implanted into the patient. Optionally, the ICM device **100** may be provided as an external device that is worn, held or otherwise located proximate to the patient during operation. The ICM device **100** may be implemented to monitor ventricular activity alone, or both ventricular and atrial activity through sensing circuitry. The ICM device **100** has the device housing **102** to hold the electronic/computing components. The device housing **102** (which is often referred to as the "can", "case", "encasing", or "case electrode") may be programmably selected to act as an electrode for certain sensing modes.

**[0073]** In the present embodiment, the sensing electrode **210** positioned on the tail extension **104** is coupled to a terminal **708**. The device housing **102** further includes a connector (not shown) with at least one terminal **710** and preferably a second terminal **712**. The terminals **710**, **712** may be coupled to additional sensing electrodes on the device housing, on the tail extension, or located otherwise. For example, the terminals **710**, **712** may be coupled to the sensing electrodes **212**, **213** and/or **215** of FIG. **2**. Additionally or alternatively, the terminals **710**, **712** may be connected to one or more leads having one or more electrodes provided thereon, where the electrodes are located in various locations about the heart. The type and location of each electrode may vary.

**[0074]** The ICM device **100** is configured to be placed subcutaneously utilizing a minimally invasive approach. Subcutaneous electrodes are provided on the device housing **102** to simplify the implant procedure and eliminate a need for a transvenous lead system. The sensing electrodes may be located on opposite sides/ends of the device and designed to provide robust episode detection through consistent contact at a sensor-tissue interface. The ICM device **100** may be configured to be activated by the patient or automatically activated, in connection with recording subcutaneous ECG signals.

**[0075]** The ICM device **100** includes a programmable microcontroller **714** that controls various operations of the ICM device **100**, including cardiac monitoring. Microcontroller **714** includes a microprocessor (or equivalent control circuitry), RAM and/or ROM memory, logic and timing circuitry, state machine circuitry, and I/O circuitry. The microcontroller **714** also performs the operations in connection with collecting cardiac activity data and analyzing the cardiac activity data to identify episodes of interest. Microcontroller **714** includes an arrhythmia detector **716** that is configured to analyze cardiac activity data to identify potential AF episodes as well as other arrhythmias (e.g. Tachcardias, Bradycardias, Asystole, etc.).

**[0076]** A switch **718** is optionally provided to allow selection of different electrode configurations connected to the terminals **710**, **712** under the control of the microcontroller **714**. The switch **718** is controlled by a control signal from the microcontroller **714**. Optionally, the switch **718** may be omitted and the I/O circuits directly connected to the housing electrode and a second electrode.

**[0077]** The ICM device **100** is further equipped with telemetry circuitry **704**. The telemetry circuitry **704** uses high frequency modulation, for example uses RF or Bluetooth telemetry protocols. The telemetry circuitry **704** may include one or more transceivers. For example, the telemetry circuitry **704** may be coupled to the antenna **304** in the tail extension **104** that transmits communications signals in a high frequency range that will travel through the body tissue in fluids without stimulating the heart or being felt by the patient.

**[0078]** The ICM device **100** includes sensing circuitry **702** selectively coupled to one or more electrodes that perform sensing operations to detect cardiac activity data indicative of cardiac activity. For example, the sensing circuitry **702** may be coupled to the conductor **302** in the tail extension that conveys sensing signals from the ROI in the heart in a low frequency range. The sensing circuitry **702** may include dedicated sense amplifiers, multiplexed amplifiers, or shared amplifiers. It may further employ one or more low power, precision amplifiers with programmable gain and/or automatic gain control, bandpass filtering, and threshold detection circuit to selectively sense the cardiac signal of interest.

**[0079]** An isolating filter circuit **706** is electrically coupled between the terminal **708** and the telemetry circuitry **704** and the sensing circuitry **702**. The isolating filter circuit **706** receives low frequency cardiac signal data communicated by the conductor **302** and high frequency RF communications data communicated by the antenna **304** through the terminal **708**. The isolating filter circuit **706** is provided to pass or block the data communicated over the single-strand conductor **302** and antenna **304**. The isolating filter circuit **706** passes the low frequency data to the sensing circuitry **702** and blocks the low frequency data from the telemetry circuitry **704**. For example, the isolating filter receives low frequency sensed cardiac signals from the conductor **302** of the tail extension **104**. The isolating filter circuit **706** passes the sensed cardiac signals to the sensing circuitry **702**. The isolating filter circuit **706** blocks the sensed cardiac signals from the telemetry circuitry **704**.

**[0080]** The isolating filter circuit **706** passes high frequency data to the telemetry circuitry **704** and blocks the high frequency data from the sensing circuitry **702**. For example, the isolating filter circuit **706** receives high frequency RF communications data from the antenna **304** of the tail extension **104**. The isolating filter circuit **706** passes the high frequency RF communications data to the telemetry circuit **704**. The isolating filter circuit **706** blocks the RF communications data from the sensing circuitry **702**.

**[0081]** FIG. **8** provides a detailed illustration of the isolating filter circuit **706** of FIG. **7**. The isolating filter circuit **706** includes an inductive element **802** and a capacitive element **806** that are connected in series with one another. An intermediate node **804** is positioned between the inductive element **802** and the capacitive element. The sensing circuitry **702** is conductively joined to the intermediate node. The capacitive element **806** is configured to form an open circuit when experiencing low frequency cardiac sensing signals from the sensing electrode **210** of the tail extension **104**. For example, the open circuit enables the sensing signals to electrically flow towards the sensing circuitry **702**. Alternatively, the capacitor **806** is configured to form a closed circuit when experiencing high frequency RF transmissions to and/or from the antenna. The closed circuit capacitive element **806** passes the high frequency RF transmissions to a ground **812** and blocks the high frequency RF transmissions from the sensing circuitry **702**. Optionally, alternative circuitry may be used to filter the low frequency data from the high frequency data provided on a single-strand conductor and antenna.

**[0082]** Returning to FIG. **7**, by way of example, the external device **108** may represent a bedside monitor installed in a patient's home and utilized to communicate with the ICM device **100** while the patient is at home, in bed or asleep. The external device **108** may be a programmer used in the clinic to interrogate the device, retrieve data and program detection criteria and other features. The external device **108** may be a device that can be coupled over a network (e.g. the Internet) to a remote monitoring service, medical network and the like. The external device **108** facilitates access by physicians to patient data as well as permitting the physician to review real-time ECG signals while being collected by the ICM device **100**.

**[0083]** The microcontroller **714** is coupled to a memory **722** by a suitable data/address bus **726**. The programmable operating parameters used by the microcontroller **714** are stored in memory **722** and used to customize the operation of the ICM device **100** to suit the needs of a particular patient. Such operating parameters define, for example, detection rate thresholds, sensitivity, automatic features, arrhythmia detection criteria, activity sensing or other physiological sensors, and electrode polarity, etc. The operating parameters of the ICM device **100** may be non-invasively programmed into the ICM device **100** through the telemetry circuitry **704**. The telemetry circuitry **704** allows intracardiac electrograms and status information relating to the operation of the ICM device **100** to be sent to the external device **108** through an established communication link **724**.

**[0084]** The ICM device **100** may further include magnet detection circuitry (not shown), coupled to the microcontroller **714**, to detect when a magnet is placed over the unit. A magnet may be used by a clinician to perform various test functions of the ICM device **100** and/or to signal the microcontroller **714** that the external device **108** is in place to receive or transmit data to the microcontroller **714** through the telemetry circuitry **704**.

**[0085]** The ICM device **100** can further include one or more physiologic sensor **728**. Such sensors are commonly referred to (in the pacemaker arts) as "rate-responsive" or "exercise" sensors. The physiological sensor **728** may further be used to detect changes in the physiological condition of the heart, or diurnal changes in activity (e.g., detecting sleep and wake states). Signals generated by the physiological sensors **728** are passed to the microcontroller **714** for analysis and optional storage in the memory **722** in connection with the cardiac activity data, markers, episode information and the like. While shown as included within the ICM device **100**, the physiologic sensor(s) **728** may be external to the ICM device **100**, yet still be implanted within or carried by the patient. Examples of physiologic sensors might include sensors that, for example, activity, temperature, sense respiration rate, pH of blood, ventricular gradient, activity, position/posture, minute ventilation (MV), and so forth.

**[0086]** A battery **730** provides operating power to all of the components in the ICM device **100**. The battery **730** is capable of operating at low current drains for long periods of time. The battery **730** also desirably has a predictable discharge characteristic so that elective replacement time can be detected. As one example, the ICM device **100** employs lithium/silver vanadium oxide batteries. The battery **730** may afford various periods of longevity (e.g. three years or more of device monitoring). In alternate embodiments, the batter **730** could be rechargeable. See for example, U.S. Pat. No. 7,294,108, Cardiac event microrecorder and method for implanting same, which is hereby incorporated by reference.

**[0087]** FIG. **9** illustrates a block-diagram of an alternative embodiment of the circuitry of an ICM device **900**. The ICM device **900** has a device housing **901** to hold the electronic/computing components. The ICM device **900** is equipped with telemetry circuitry **904** and sensing circuitry **902**. The telemetry circuitry **904** may include one or more transceivers. The sensing circuitry **902** is selectively coupled to one or more electrodes that perform sensing operations to detect cardiac activity data indicative of cardiac activity. The sensing circuitry **902** may include dedicated sense amplifiers, multiplexed amplifiers, or shared amplifiers. It may further employ one or more low power, precision amplifiers with programmable gain and/or automatic gain control, bandpass filtering, and threshold detection circuit to selectively sense the cardiac signal of interest.

**[0088]** In the present embodiment, the sensing electrode **210** positioned on the tail extension **104** is coupled to a terminal **908**. The device housing **102** further includes a connector (not shown) with at least one terminal **910** and preferably a second terminal **912**. The terminals **910**, **912** may be coupled to additional sensing electrodes positioned on the device housing, on the tail extension, or located otherwise. For example, the terminals **910**, **912** may be coupled to the sensing electrodes **212**, **213**, and/or **215** of FIG. **2**. Additionally or alternatively, the terminals **910**, **912** may be connected to one or more leads having one or more electrodes provided thereon, where the electrodes are located in various locations about the heart. The type and location of each electrode may vary.

**[0089]** A switch **906** is electrically coupled between the terminals **908**, **910**, **912** and the telemetry circuitry **904** and the sensing circuitry **902**. In the present example, the switch **906** is provided to allow selection of different electrode configurations connected to the terminals **908**, **910**, and **912** under the control of a microcontroller **914**. The switch **906** is controlled by a control signal from the microcontroller **914**. The switch **906** is used to determine the sensing polarity of the cardiac signal by selectively closing the appropriate electrical circuitry paths. For example, the switch **906** comprises a low pass filter branch and a band pass filter branch (not shown). The low pass filter branch is configured to pass the low frequency cardiac sensed signals from the sensing electrode **210** coupled to the conductor **302** of the tail extension **104** to the sensing circuitry **902**. The band pass filter branch is configured to pass the high frequency RF communications, in a frequency range that includes approximately 2.4 GHz, from the antenna **304** of the tail extension **104** to the telemetry circuitry **904**.

**[0090]** A physician implants the ICM device **100** into a subcutaneously location in the patient via a tail implant tool. The tail implant tool comprises a lumen with a distal end and a proximal end. The lumen is sized and shaped to receive the tail extension **104** of the ICM device **100** within the lumen. The distal end **206** of tail extension **104** is inserted into the distal end of the lumen of the tail implant tool. The physician inserts the distal end of the lumen into a subcutaneous area of the patient located proximate to the ROI in the heart. For example, the physician may insert the distal end of the lumen of the tail implant tool into the patient in order to position the sensing electrode **210** of the tail extension **104** proximate one side of the heart. The physician may position the device housing **102** proximate an opposite side of the heart. Optionally, the physician may position the tail extension **104** and the device housing **102** on the same side of the heart. The tail implant tool releases the tail extension **104**, and is removed from the patient while leaving the tail extension **104** of the ICM device **100** implanted in the patient. Optionally, alternative tools may be utilized to implant the ICM device **100** into the patient.

**[0091]** The various methods as illustrated in the FIGS. and described herein represent exemplary embodiments of methods. The methods may be implemented in software, hardware, or a combination thereof. In various of the methods, the order of the steps may be changed, and various elements may be added, reordered, combined, omitted, modified, etc. Various of the steps may be performed automatically (e.g., without being directly prompted by user input) and/or programmatically (e.g., according to program instructions).

**[0092]** Various modifications and changes may be made as would be obvious to a person skilled in the art having the benefit of this disclosure. It is intended to embrace all such modifications and changes and, accordingly, the above description is to be regarded in an illustrative rather than a restrictive sense.

**[0093]** The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense. It will, however, be evident that various modifications and

changes may be made thereunto without departing from the broader spirit and scope of the invention as set forth in the claims.

**[0094]** Other variations are within the spirit of the present disclosure. Thus, while the disclosed techniques are susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

**[0095]** The use of the terms "a" and "an" and "the" and similar referents in the context of describing the disclosed embodiments (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including" and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted. The term "connected," when unmodified and referring to physical connections, is to be construed as partly or wholly contained within, attached to or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein and each separate value is incorporated into the specification as if it were individually recited herein. The use of the term "set" (e.g., "a set of items") or "subset" unless otherwise noted or contradicted by context, is to be construed as a nonempty collection comprising one or more members. Further, unless otherwise noted or contradicted by context, the term "subset" of a corresponding set does not necessarily denote a proper subset of the corresponding set, but the subset and the corresponding set may be equal.

**[0096]** All references, including publications, patent applications and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

**[0097]** It is to be understood that the subject matter described herein is not limited in its application to the details of construction and the arrangement of components set forth in the description herein or illustrated in the drawings hereof. The subject matter described herein is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including," "comprising," or "having" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

**[0098]** It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described embodiments (and/or aspects thereof) may be used in combination with each other. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from its scope. While the dimensions, types of materials and coatings described herein are intended to define the parameters of the invention, they are by no means limiting and are exemplary embodiments. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Moreover, in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects. Further, the limitations of the following claims are not written in means-plus-function format and are not intended to be interpreted based on 35 U.S.C. §112(f), unless and until such claim limitations expressly use the phrase "means for" followed by a statement of function void of further structure.

**1**. An implantable cardiac device, comprising:

a device housing having sensing circuit and radio frequency (RF) communications circuit housed within the housing; and

a tail extension having a proximal end, a distal end and an extension body extending there between, the proximal end coupled to the housing, the extension body formed of a flexible material and including a single conductor that includes a proximal end conductively coupled to the sensing and RF communications circuit;

at least a portion of the single conductor forming an antenna to be utilized by the RF communications circuit to communicate with an external device;

an electrode provided on the extension body and conductively coupled to the single conductor, the single conductor being adapted to transmit sensed cardiac signals from the electrode to the sensing circuit, the tail extension being adapted for implantation in a subcutaneous area with the electrode located proximate to a region of interest (ROI) of a heart; and

a filter circuit conductively coupled between the single conductor and the sensing and RF communications circuits, the filter circuit configured to block RF transmissions from reaching the sensing circuit.

**2**. The device of claim **1**, wherein the portion of the at least one conductor that forms the antenna is coupled to the electrode.

**3-4**. (canceled)

**5**. The device of claim **1**, wherein the proximal end of the tail extension is joined directly at a non-header interface on a surface of the housing.

**6**. The device of claim **1**, further comprising a feed-through assembly joined to the device housing, the feed-through assembly including a single conductor extending there through, the conductor having a proximal end connected to the sensing and RF communications circuits and having a distal end projecting from the feed-through assembly.

**7**. (canceled)

**8**. The device of claim **1**, wherein the filter circuit includes an inductive element and capacitive element connected in series with one another at an intermediate node, the sensing circuit joined to the intermediate node, the capacitor configured to form an open circuit when experiencing cardiac sensing signals and to form a closed circuit when experiencing RF transmissions.

**9**. The device of claim **1**, wherein the filter circuit comprises a low pass filter branch configured to pass cardiac sensed signals and a band pass filter branch configured to pass RF communications in a frequency range that includes approximately 2.4 GHz.

**10**. The device of claim **1**, wherein the extension body has a predetermined length between the distal and proximal ends, the predetermined length being tuned based on a center frequency of the RF communications bandwidth.

**11**. A method for implanting a cardiac device, the method comprising:

positioning a device subcutaneously, the device comprising a device housing having a sensing circuit and a radio frequency (RF) communications circuit housed within the housing, the device further comprising a tail extension having an extension body with a proximal end joined to the device housing, the extension body formed of a flexible material and including at least one conductor;

positioning the tail extension in a subcutaneous area with an electrode provided on the tail extension located proximate to a region of interest (ROI) in a heart;

collecting cardiac signals from the ROI utilizing the electrode provided on the tail extension; and

conveying RF communications data to an external device utilizing an antenna that is formed from at least a portion of the at least one conductor.

**12**. The method of claim **11**, wherein the positioning operation includes locating a distal end of the tail extension remote from the device housing and an electrode provided at the distal end of the tail extension located proximate to a region of interest in a heart

**13**. The method of claim **11**, wherein the at least one conductor includes first and second conductors, the first conductor coupled to the electrode and configured to carry the cardiac signals, the second conductor forming the antenna and configured to carry the RF communications data to or from the RF communications circuit.

**14**. The method of claim **11**, further comprising filtering the cardiac signals to isolated the RF communications circuit from the cardiac signals sensed over the at least one conductor; and filter the RF communications to isolate the sensing circuit from the RF communications data carried by the at least one conductor.

**15**. The method of claim **11**, wherein the collecting and conveying operations utilize a common conductor in the tail extension.

**16**. The method of claim **11**, the filtering operation comprises low pass filtering to pass the cardiac signals along a sensing branch and band pass filtering to pass RF communications data that is in a frequency range that includes approximately 2.4 GHz, along a communications branch.

**17**. The method of claim **11**, further comprising inserting the tail extension into a lumen in a tail implant tool, inserting the tail implant tool subcutaneously to a location proximate to the ROI, and removing the tail implant tool while leaving the tail extension implanted.

**18**. The method of claim **11**, wherein the ROI is located proximate to an atrium of the heart such that the cardiac signals include sensed P-waves.

**19**. A method for providing an implantable cardiac device, the method comprising:

providing a device comprising a device housing having a sensing circuit and a radio frequency (RF) communications circuit housed within the housing;

joining a tail extension to the device housing, the tail extension having an extension body with a proximal end joined to the device housing, the extension body formed of a flexible material and including at least one conductor;

positioning an electrode on the tail extension to sense cardiac signals when the tail extension is located proximate to a region of interest (ROI) in a heart;

forming an antenna from at least a portion of the at least one conductor; and

tuning the antenna and RF communications circuit to convey RF communications data to an external device utilizing a predetermined communications frequency.

**20**. The method of claim **19**, wherein the tuning operation includes tuning the antenna to utilize the predetermined communications frequency centered at one of 2.4 GHz and 400 MHz.

**21**. An implantable cardiac device, comprising:

a device housing having sensing circuit and radio frequency (RF) communications circuit housed within the housing; and

a tail extension having a proximal end, a distal end and an extension body extending there between, the extension body formed of a flexible material and including first and second conductors; and

an electrode provided on the extension body and conductively coupled to the first conductor and the sensing circuit, the tail extension being adapted for implantation in a subcutaneous area with the electrode located proximate to a region of interest (ROI) of a heart; and

a feed-through assembly coupled to the device housing and adapted to electrically couple the first conductor to the sensing circuit and the second conductor to the RF communications circuit, wherein the first conductor is coupled to the electrode and configured to carry cardiac sensed signals to the sensing circuit and wherein at least a portion of the second conductor forms the antenna and is configured to carry communications data to or from the RF communications circuit to communicate with an external device.

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| 专利名称(译) | 具有尾部延伸的可植入设备，包括嵌入式传感器和天线 | | |
| 公开(公告)号 | US20180042553A1 | 公开(公告)日 | 2018-02-15 |
| 申请号 | US15/233772 | 申请日 | 2016-08-10 |
| [标]申请(专利权)人(译) | 标兵 | | |
| 申请(专利权)人(译) | PACESETTER，INC. | | |
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| IPC分类号 | A61B5/00 A61B5/07 A61B5/042 | | |
| CPC分类号 | A61B5/686 A61B5/0031 A61B2562/16 A61B5/076 A61B5/0006 A61B5/042 | | |
| 外部链接 | Espacenet USPTO | | |


摘要(译)

提供了一种用于可植入心脏监视器设备的设备和方法，包括具有感测电路的设备外壳和容纳在外壳内的射频（RF）通信电路。该装置还包括尾部延伸部，该尾部延伸部具有近端，远端和在其间延伸的延伸体，其中近端连接到壳体。延伸体由柔性材料形成并且包括至少一个导体，该导体包括导电地耦合到感测和RF通信电路的近端。尾部延伸部的导体的至少一部分形成将由RF通信电路用于与外部设备通信的天线。此外，电极设置在尾部延伸部上并且导电地耦合到导体和感测电路。