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(54) **USE OF A DEDICATED REMOTE CONTROL AS AN INTERMEDIARY DEVICE TO COMMUNICATE WITH AN IMPLANTABLE MEDICAL DEVICE**

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CPC ***A61N 1/37247*** (2013.01); ***A61N 1/37229*** (2013.01)

(58) **Field of Classification Search**
None
See application file for complete search history.

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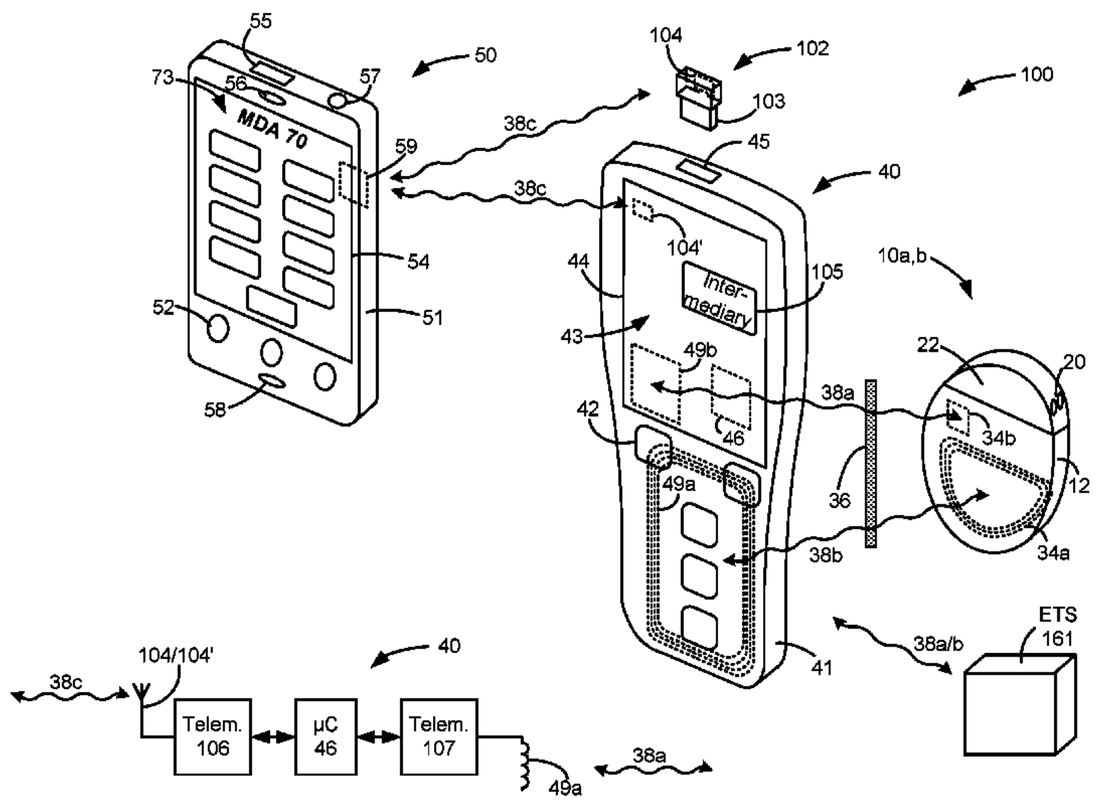
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(57) **ABSTRACT**

Systems and methods are disclosed in which an external device such as a consumer mobile device (e.g., smart phone) is used as an external controller to bi-directionally communicate with an Implantable Medical Device (IMD) using a dedicated patient remote control (RC) as an intermediary device to translate communications between the two. The dedicated RC contains a graphical user interface allowing for control and monitoring of the IMD even if the mobile device is not present in the system, which is useful as a back-up should the mobile device experience problems. Use of the dedicated RC as an intermediary device broadens the utility of other computing devices to operate as an external controller for an IMD even if the computing device and IMD do not have compliant communication means.

20 Claims, 8 Drawing Sheets



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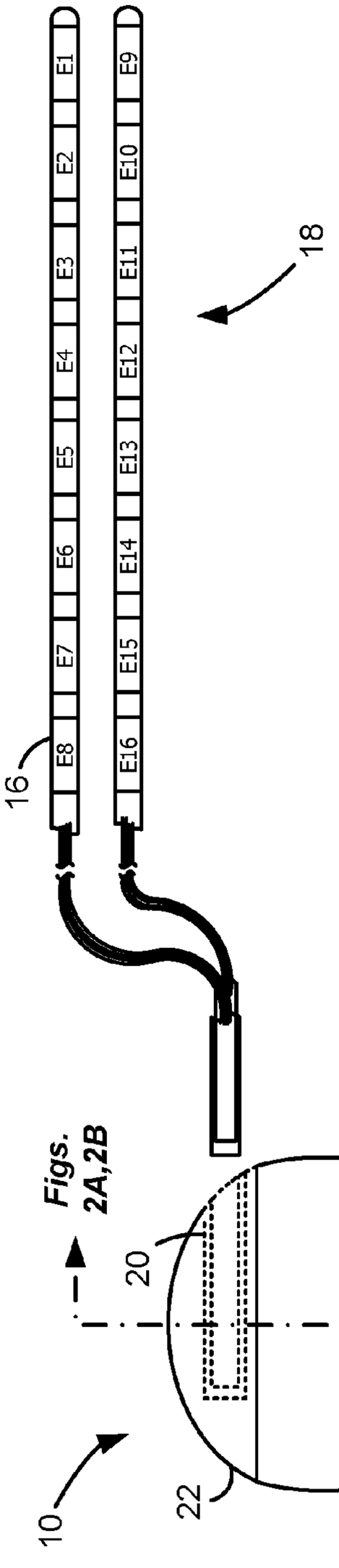


Figure 1 (prior art)

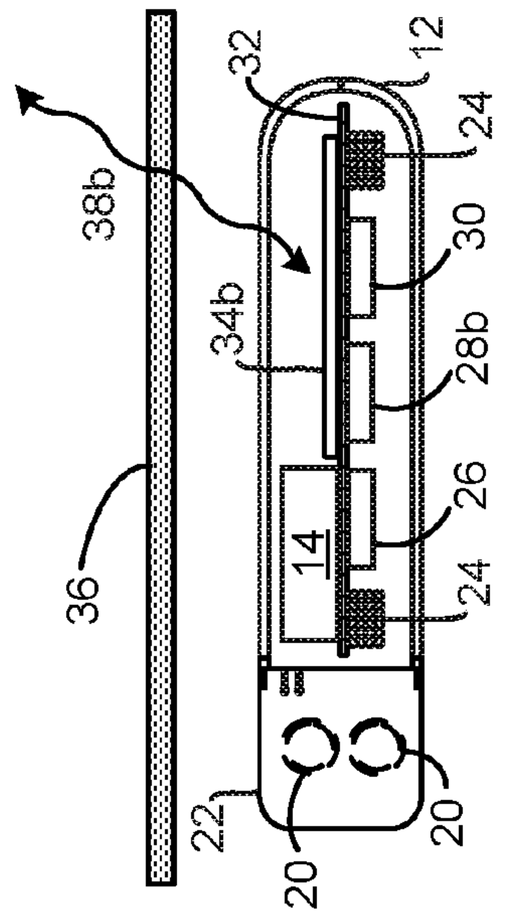


Figure 2B (prior art)

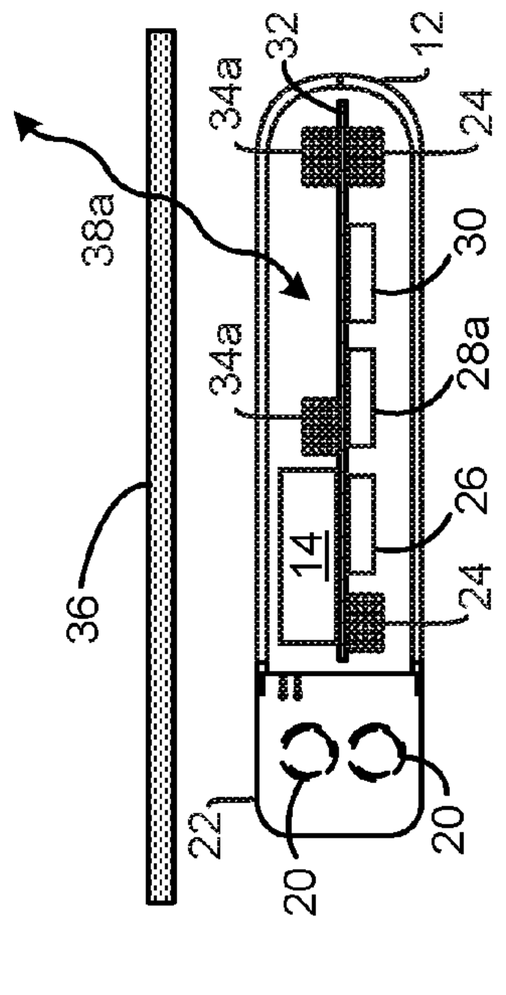


Figure 2A (prior art)

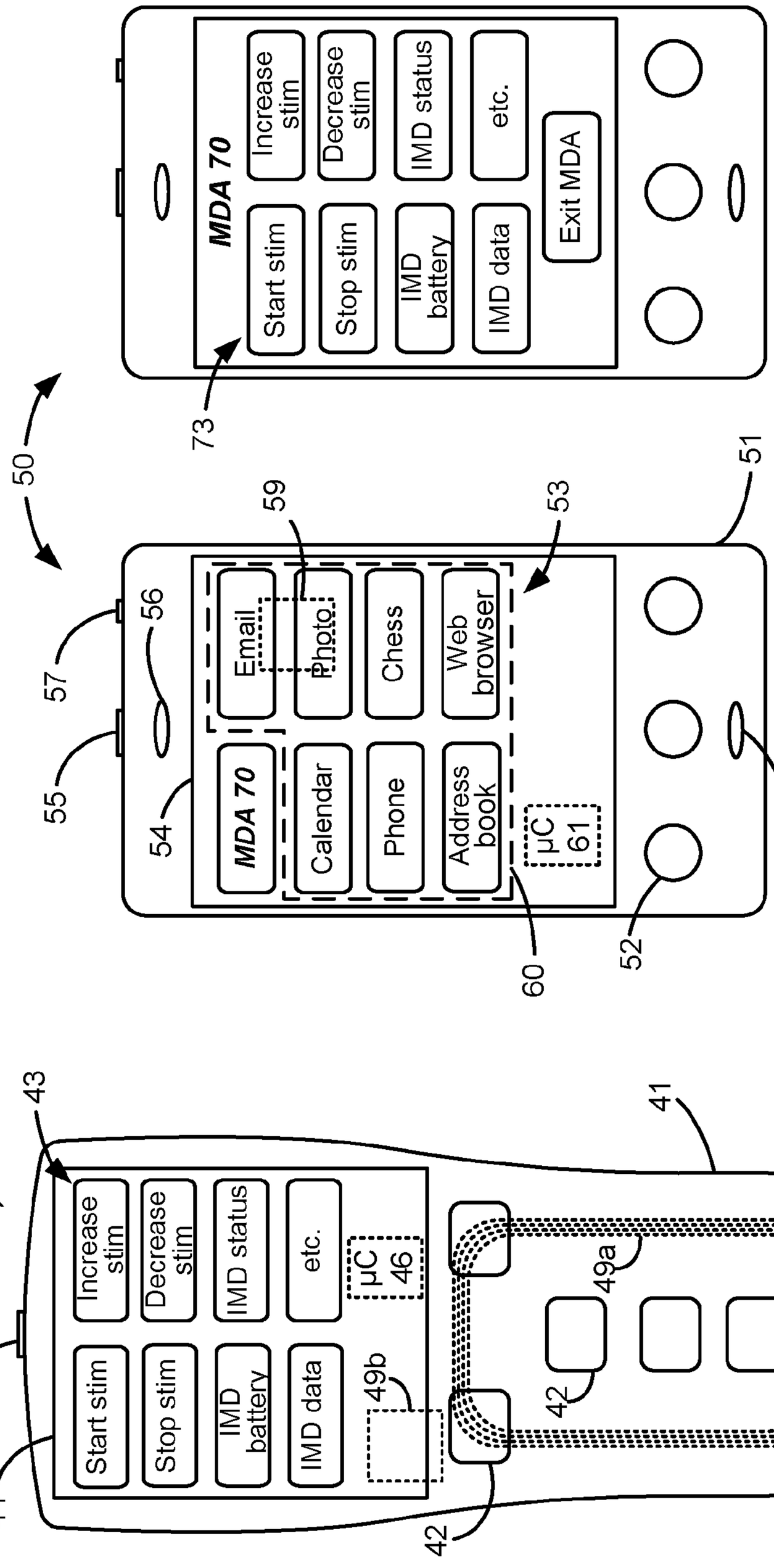


Figure 4B (prior art)

Figure 4A (prior art)

Figure 3 (prior art)

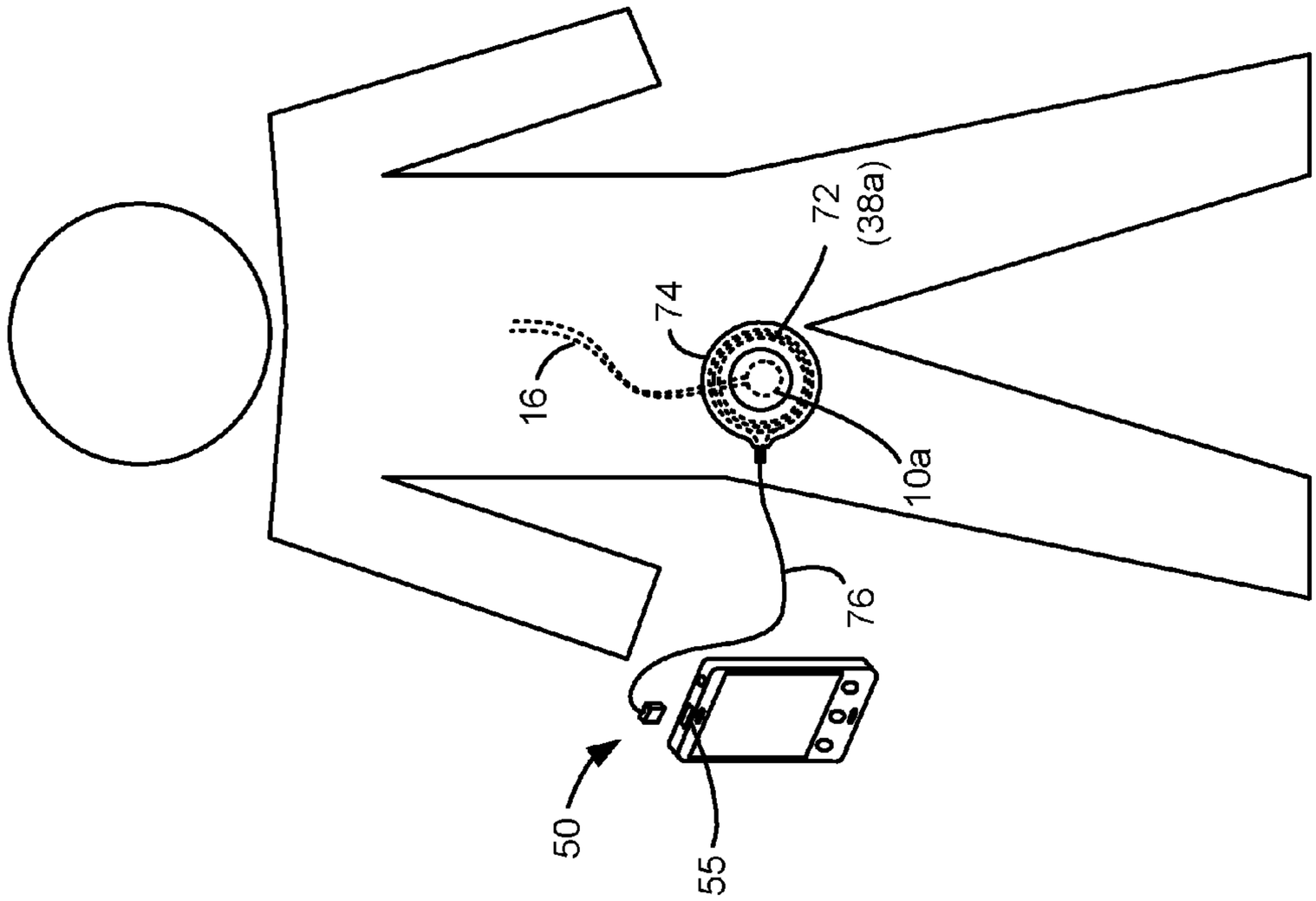


Figure 5B
(prior art)

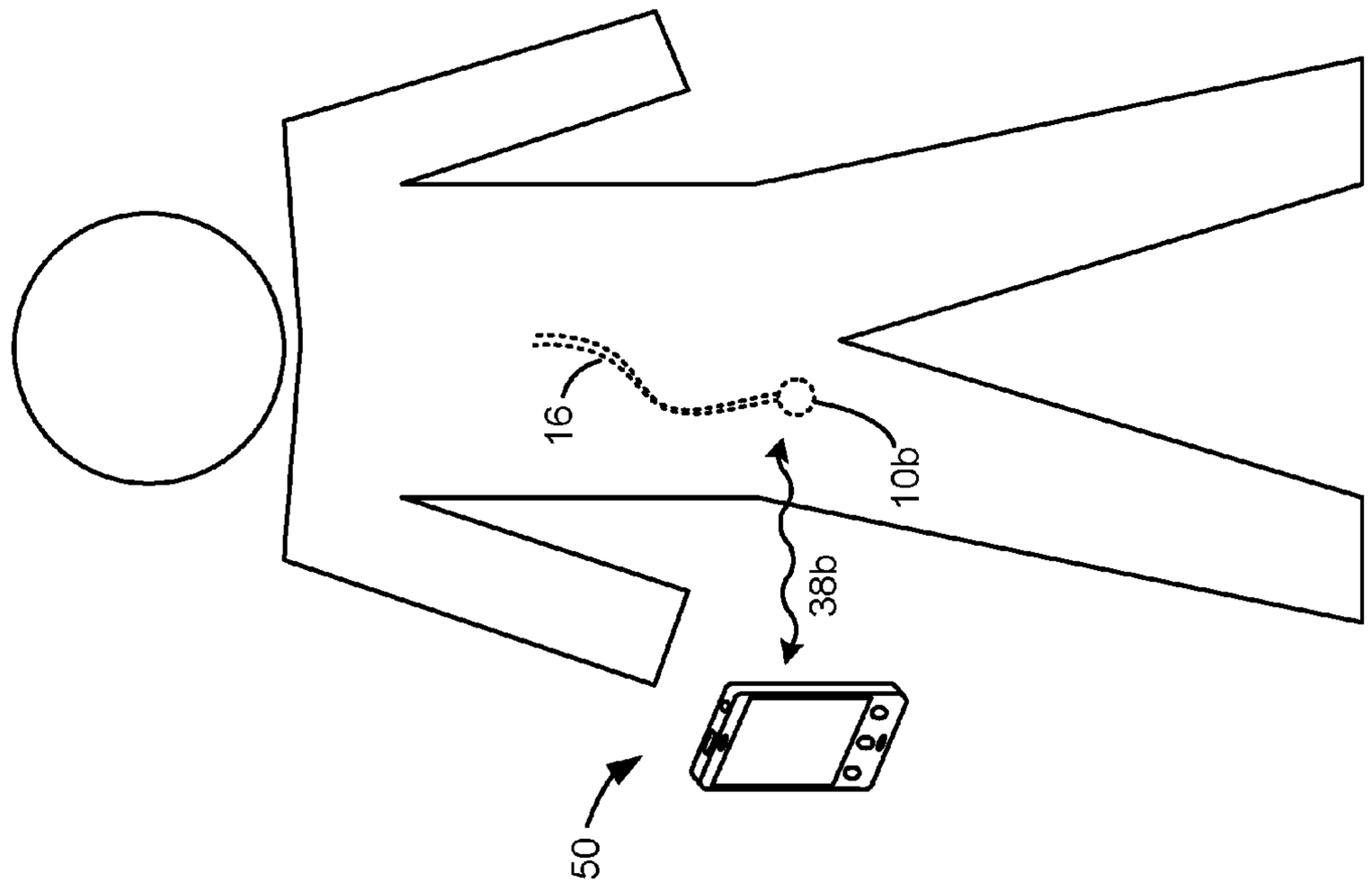


Figure 5A
(prior art)

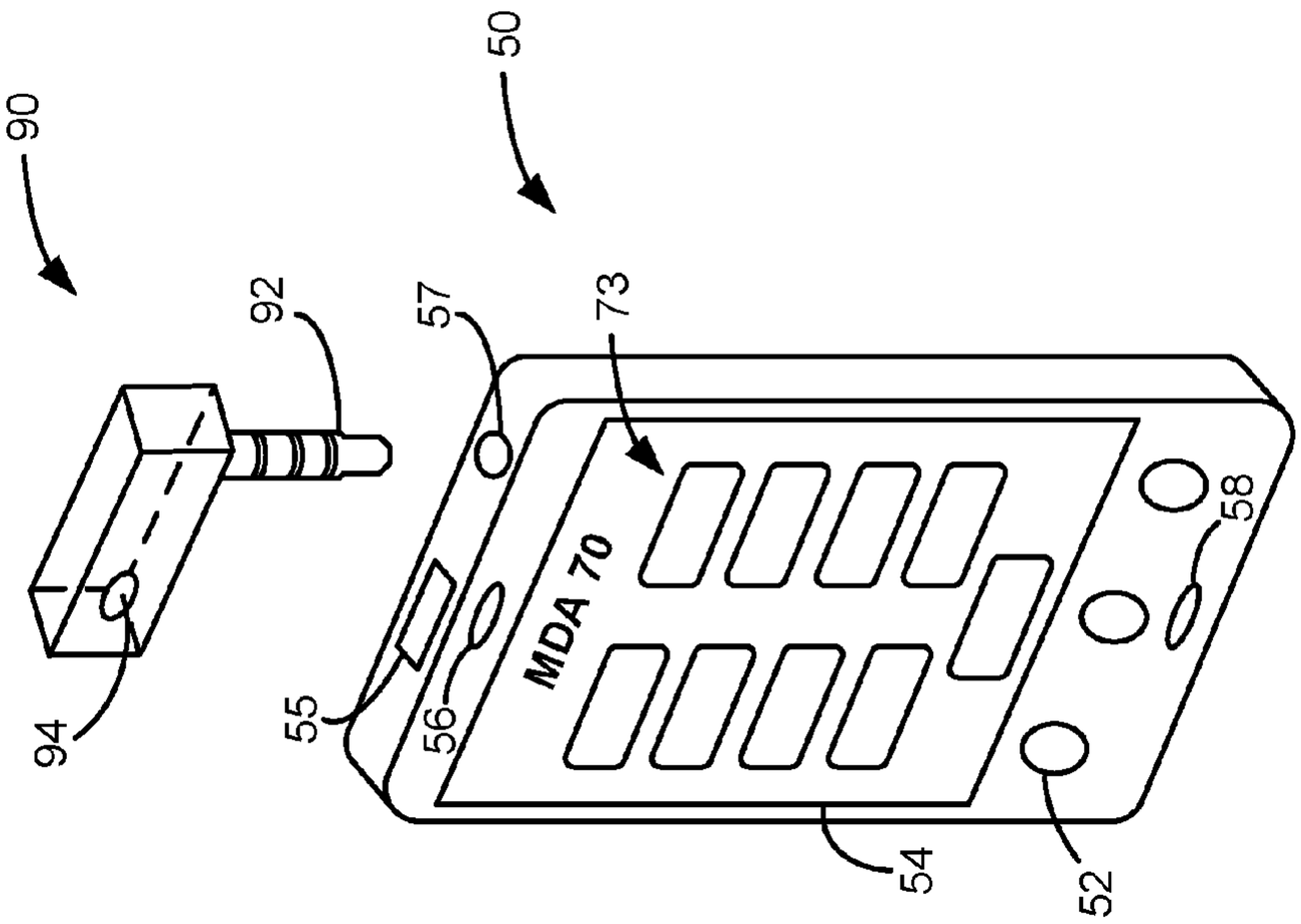


Figure 6A
(prior art)

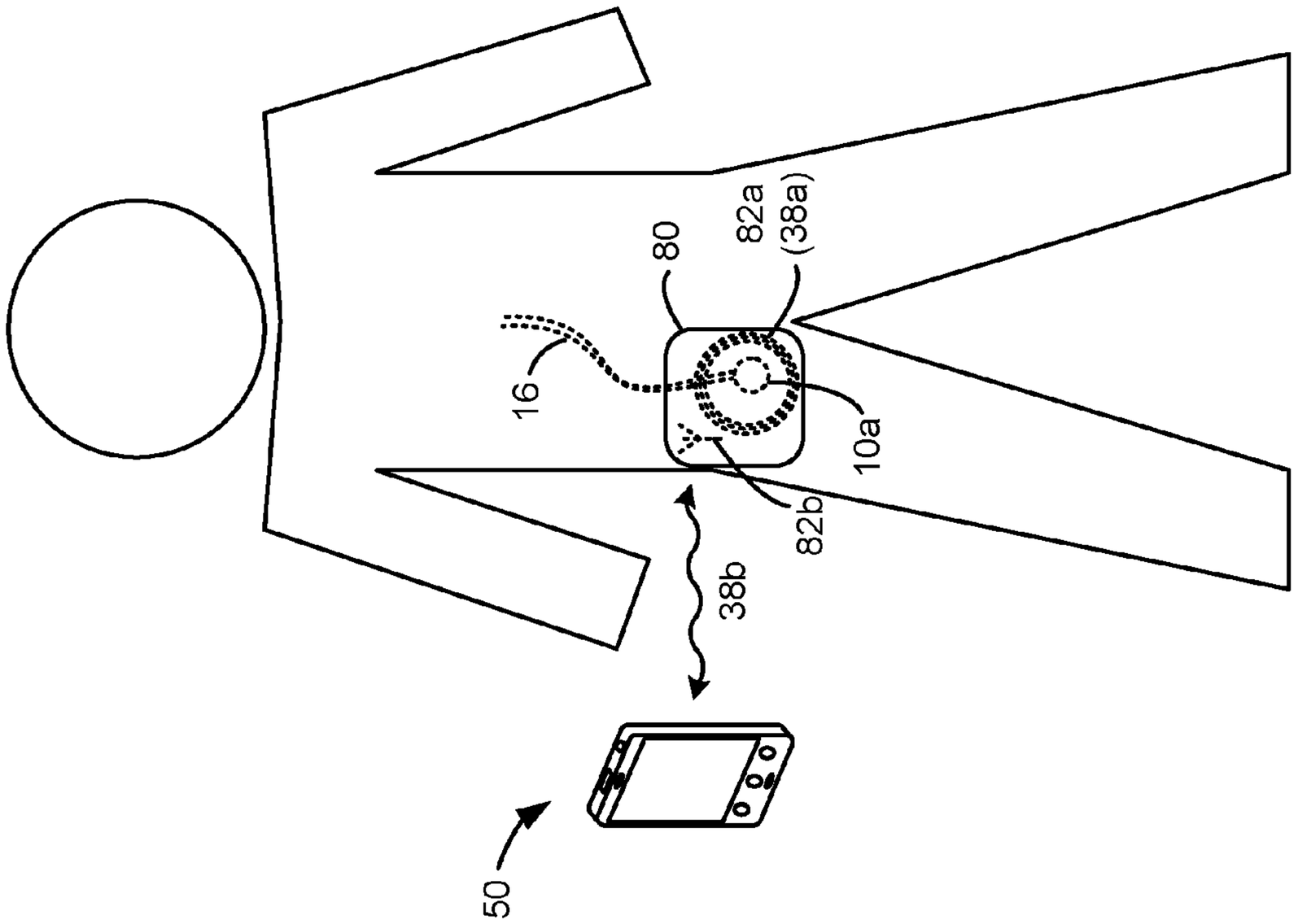


Figure 5C
(prior art)

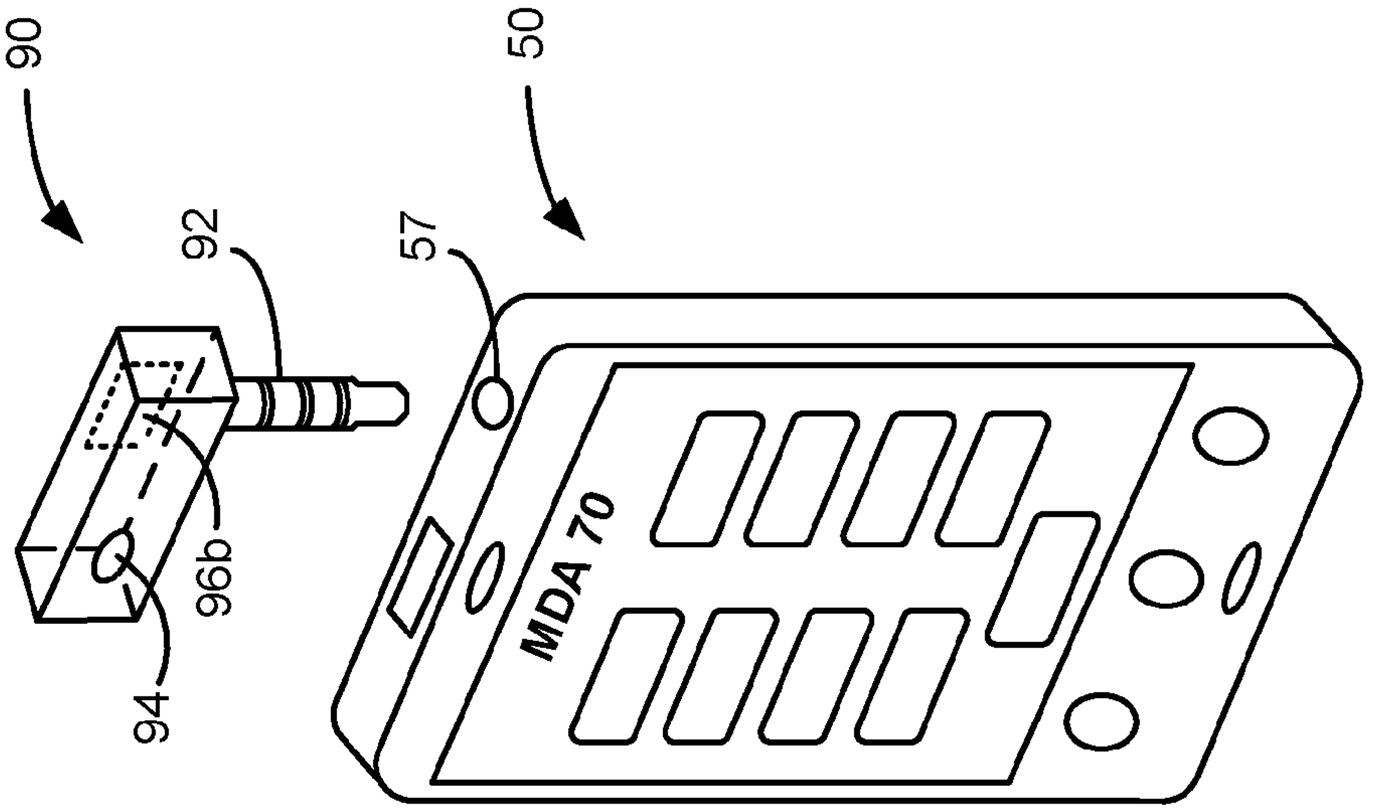


Figure 6C (prior art)

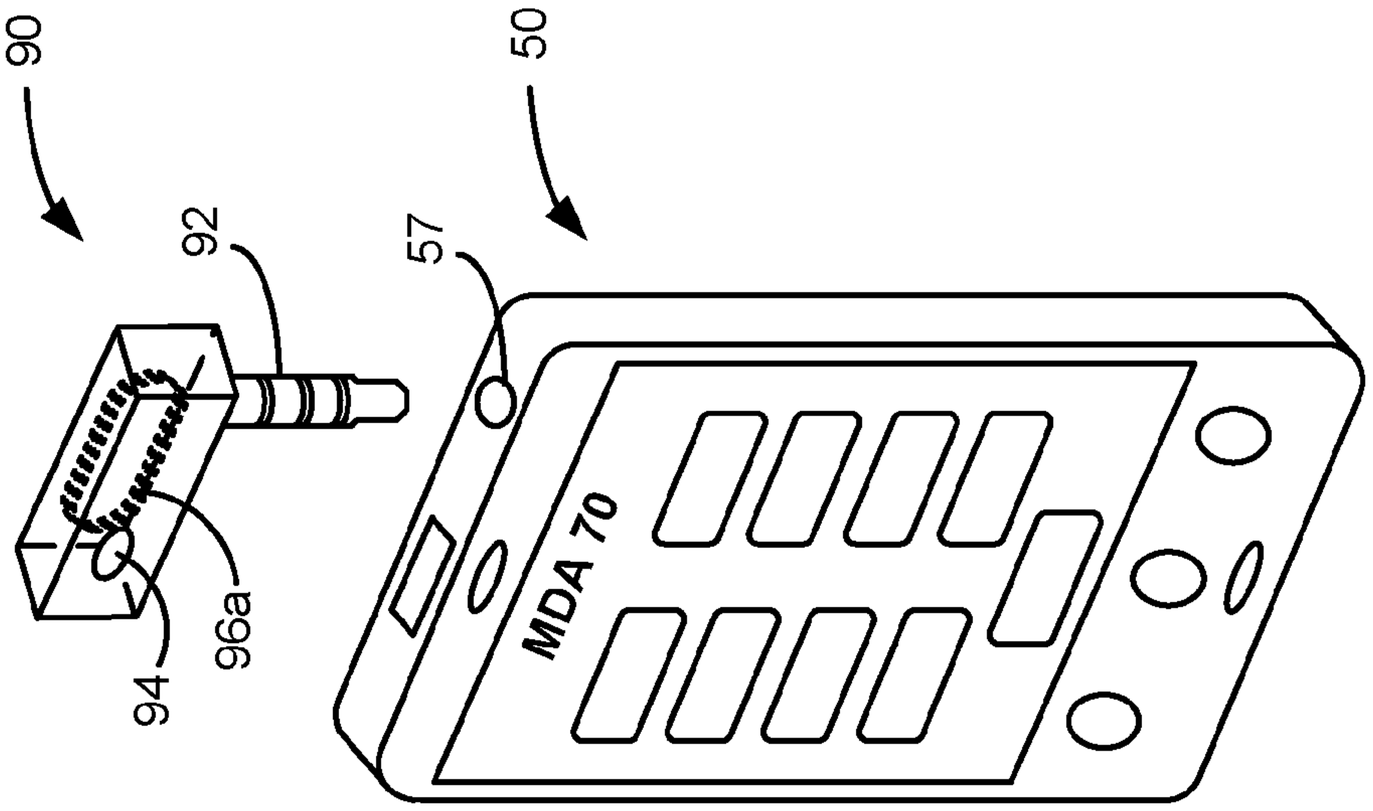


Figure 6B (prior art)

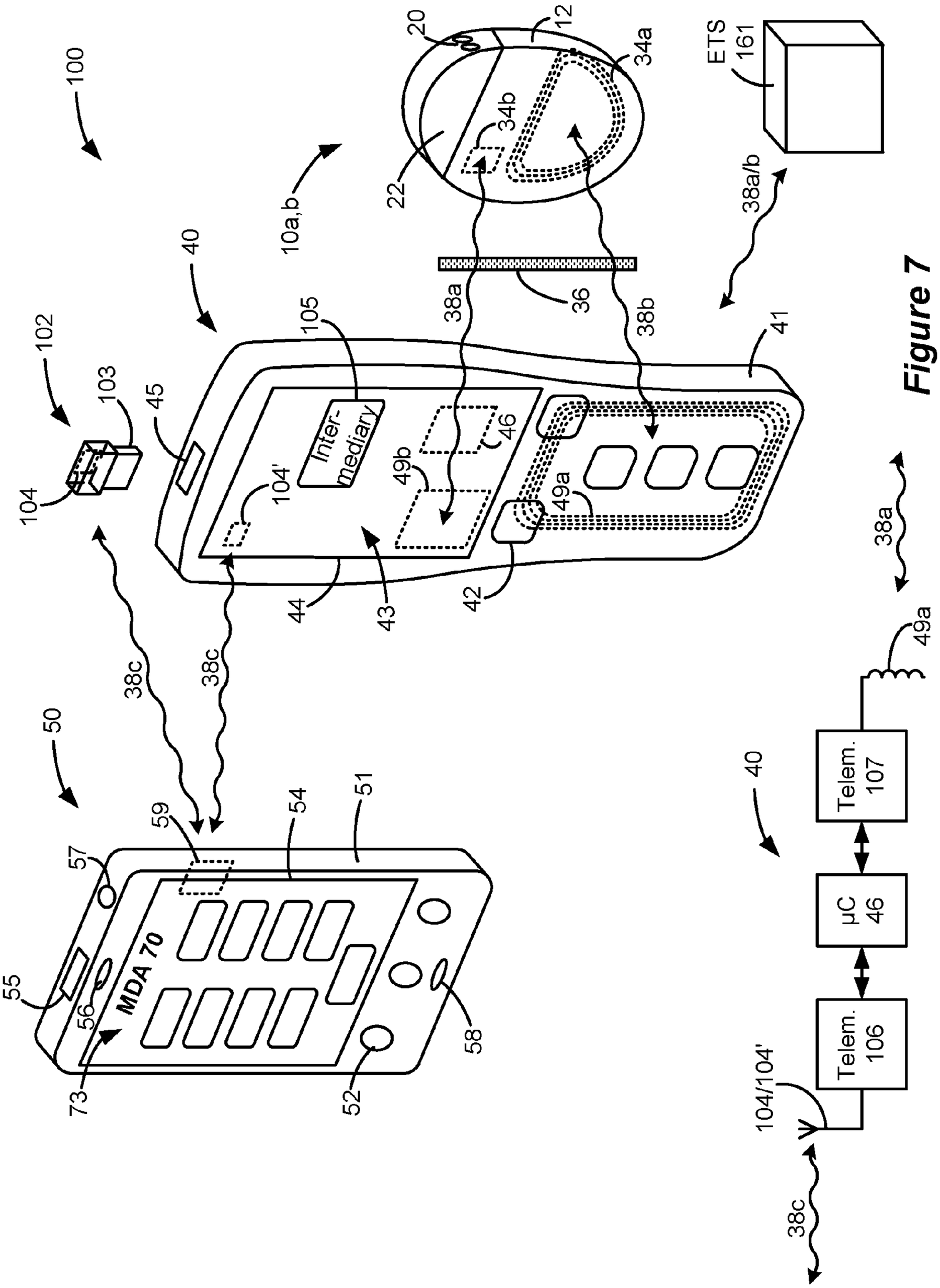

100
10a,b
20
12
34a
34b
22
ETS
161
38a/b
36
38a
38b
41
105
102
103
45
104
Inter-
mediary
46
49b
104'
49a
44
43
42
38c
38c
50
59
54
51
40
57
MDA 70
55
56
73
52
58
38a
49a
Telem.
107
µC
46
Telem.
106
104/104'
38c

Figure 7

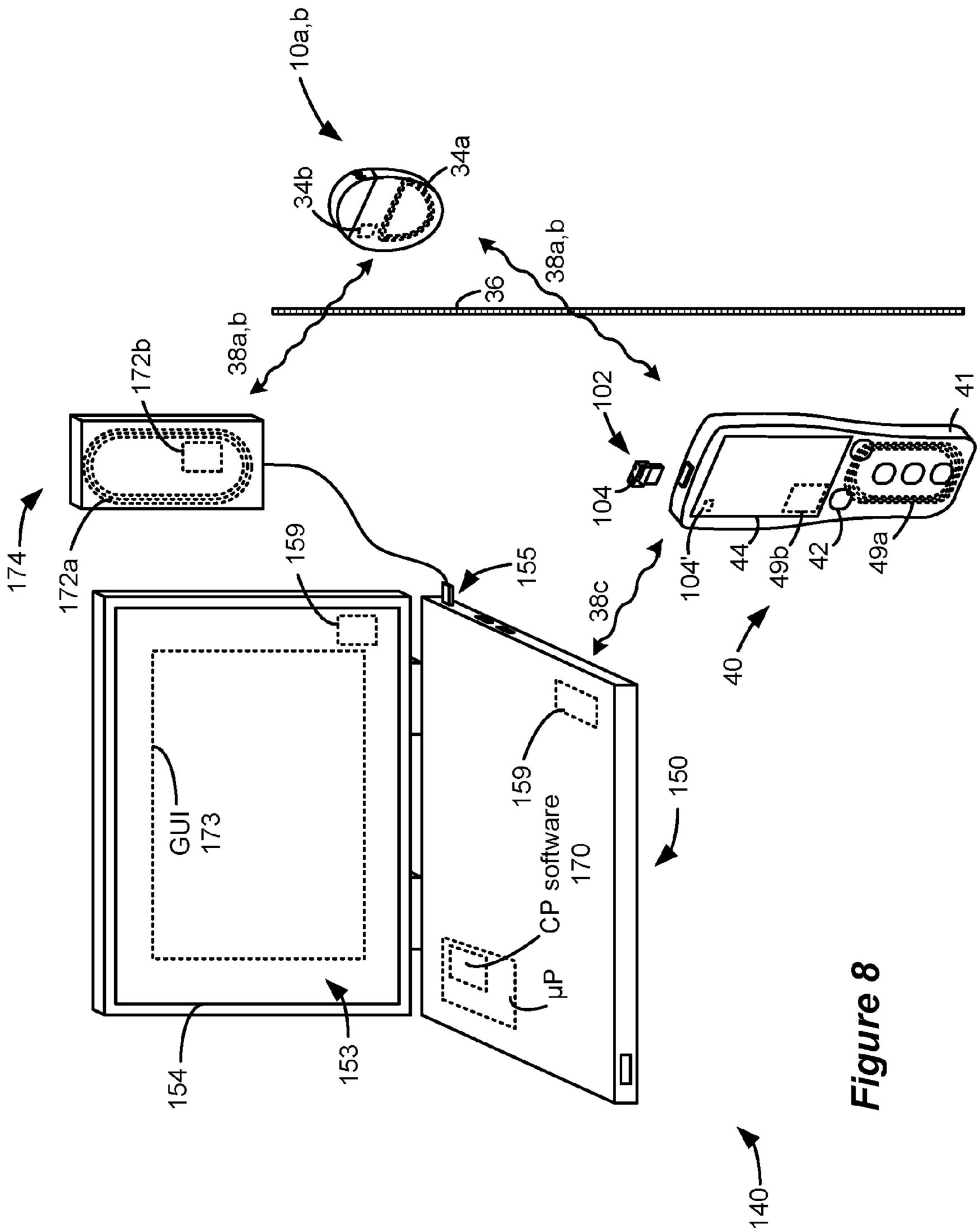

10a,b
34a
34b
38a,b
36
38a,b
172b
102
41
104
174
172a
159
155
38c
104'
44
49b
42
49a
40
159
150
GUI
173
CP software
170
μP
154
153
140

Figure 8

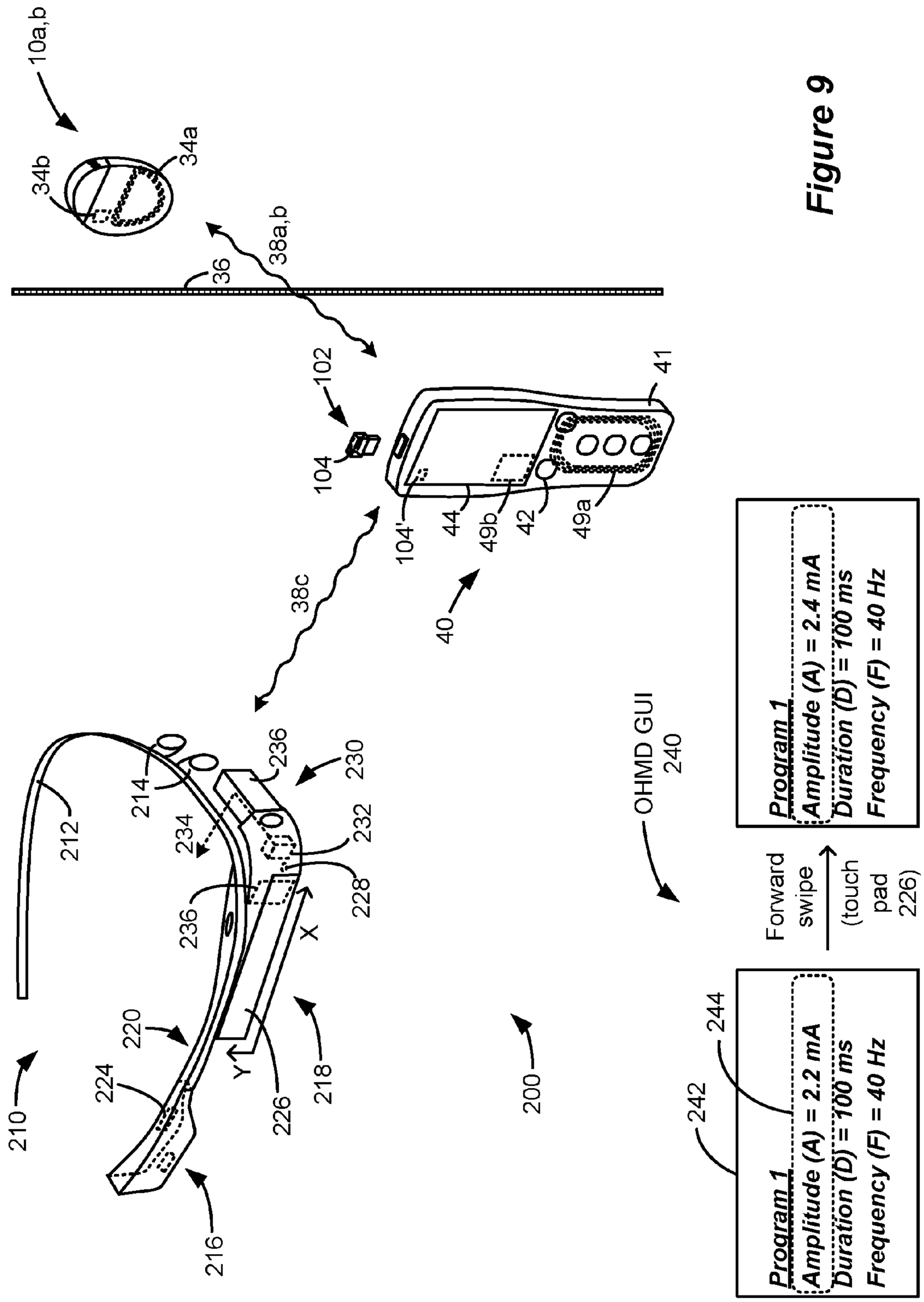

10a,b
34b
34a
36
38a,b
102
104
104'
44
49b
42
49a
40
38c
212
214
234
236
230
232
228
236
X
Y
220
224
226
218
216
210
200
OHMD GUI
240
Program 1
Amplitude (A) = 2.4 mA
Duration (D) = 100 ms
Frequency (F) = 40 Hz
Forward swipe
(touch pad 226)
242
244
Program 1
Amplitude (A) = 2.2 mA
Duration (D) = 100 ms
Frequency (F) = 40 Hz

Figure 9

USE OF A DEDICATED REMOTE CONTROL AS AN INTERMEDIARY DEVICE TO COMMUNICATE WITH AN IMPLANTABLE MEDICAL DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Non-Provisional application Ser. No. 14/789,564, filed Jul. 1, 2015 (now U.S. Pat. No. 9,533,162), which is a non-provisional of U.S. Provisional Patent Application Ser. Nos. 62/108,908, filed Jan. 28, 2015, and 62/040,369, filed Aug. 21, 2014. Priority is claimed to these applications, and they are incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

The present invention relates generally to implantable medical device systems, and more particularly to external systems and methods for communicating with an implantable medical device.

BACKGROUND

Implantable stimulation devices deliver electrical stimuli to nerves and tissues for the therapy of various biological disorders, such as pacemakers to treat cardiac arrhythmia, defibrillators to treat cardiac fibrillation, cochlear stimulators to treat deafness, retinal stimulators to treat blindness, muscle stimulators to produce coordinated limb movement, spinal cord stimulators to treat chronic pain, cortical and deep brain stimulators (DBS) to treat motor and psychological disorders, and other neural stimulators to treat urinary incontinence, sleep apnea, shoulder subluxation, etc. The description that follows will generally focus on the use of the invention within a Spinal Cord Stimulation (SCS) system, such as that disclosed in U.S. Pat. No. 6,516,227. However, the present invention may find applicability with any Implantable Medical Device (IMD) or in any IMD system.

As shown in FIG. **1**, a SCS system includes an Implantable Pulse Generator (IPG) **10** (hereinafter, and more generically, IMD **10**), which includes a biocompatible device case **12** formed of titanium for example. The case **12** typically holds the circuitry and battery **14** necessary for the IMD **10** to function. The IMD **10** is coupled to electrodes **16** via one or more electrode leads **18** (two of which are shown). The proximal ends of the leads **18** are coupled to the IMD **10** at one or more lead connectors **20** fixed in a header **22**, which can comprise an epoxy for example. In the illustrated embodiment, there are sixteen electrodes, although the number of leads and electrodes is application specific and therefore can vary. In an SCS application, two electrode leads **18** are typically implanted on the right and left side of the dura within the patient's spinal column. The proximal ends of the leads **18** are then tunneled through the patient's flesh to a distant location, such as the buttocks, where the IMD case **12** is implanted, at which point they are coupled to the lead connectors **20**.

Cross sections of two examples of IMD **10**, **10***a* and **10***b*, are shown in FIGS. **2**A and **2**B. Both contain a charging coil **24** for wirelessly charging the IMD's battery **14** using an external charging device (not shown). (If battery **14** is not rechargeable, charging coil **26** can be dispensed with). Both IMDs **10***a* and **10***b* also contain control circuitry such as a microcontroller **26**, telemetry circuitry **28** (discussed further below), and various components **30** necessary for IMD

operation, such as stimulation circuitry for forming therapeutic pulses at the electrodes **16**. The charging coil **24**, battery **14**, microcontroller **26**, telemetry circuitry **28**, and other components **30** are electrically coupled to a printed circuit board (PCB) **32**.

Different in the two IMDs **10***a* and **10***b* are the telemetry antennas **34***a* and **34***b* used to transcutaneously communicate data through the patient's tissue **36** with devices external to the patient (not shown in FIGS. **2**A and **2**B). In IMD **10***a* (FIG. **2**A), the antenna comprises a coil **34***a*, which can bi-directionally communicate with an external device along a magnetic induction communication link **38***a*, which comprises a magnetic field of typically less than 10 MHz operable in its near-field to communicate at a distance of 12 inches or less for example. Telemetry circuitry **28***a* is electrically coupled to the coil antenna **34***a* to enable it to communicate via magnetic induction link **38***a*, and generally includes driver circuitry for energizing the coil antenna **34***a* to transmit data and amplifier/filter circuitry for resolving data received at the coil **34**. Telemetry circuitry **28***a* generally also operates in accordance with a modulation scheme (defining how data to be transmitted is modulated on the link **38***a* and will be demodulated when received) and a communication protocol (defining the manner in which the data is formatted). Telemetry circuitry **28***a* receives the data to be transmitted in digital form from the microcontroller **26**, and provides received digital data to the microcontroller **26** for interpretation. A typical modulation scheme used by telemetry circuitry **28***a* is Frequency Shift Keying (FSK), although other modulation schemes could also be used. In FIG. **2**A, the external device would also contain communication means (e.g., a coil antenna; telemetry circuitry) compatible with the magnetic induction link **38***a* and the protocol used by the IMD **10***a*, as explained subsequently.

In IMD **10***b* (FIG. **2**B), short-range Radio Frequency (RF) communication means—including short-range RF antenna **34***b* and compliant short-range RF telemetry circuitry **28***b*—are provided that operate in accordance with a short-range RF communication standard and its underlying protocols to bi-directionally communicate with an external device along a short-range RF communication link **38***b*. Short-range RF communication link **38***b* typically operates using far-field electromagnetic waves ranging from 10 MHz to 10 GHz or so, and allows communications between devices at distances of about 50 feet or less. Short-range RF standards supported by short-range RF telemetry circuitry **28***b* and antenna **34***b* include, for example, Bluetooth, BLE, NFC, Zigbee, WiFi (802.11x), and the Medical Implant Communication Service (MICS). Short-range RF antenna **34***b* can take any number of well-known forms for an electromagnetic antenna, such as patches, slots, wires, etc., and can operate as a dipole or a monopole. The external device in FIG. **2**B would also contain short-range RF communication means compatible with short-range RF link **38***b* and the standard/protocols used in IMD **10***b*, as explained subsequently.

Although both of antennas **34***a* and **34***b* in IMDs **10***a* and **10***b* are shown in FIGS. **2**A and **2**B inside of case **12**, they may also be placed within the IMD's header **22**, or on the outside of the case **12**. Although shown as exclusive in FIGS. **2**A and **2**B, an IMD **10** may have both of the different types of antennas **10***a* and **10***b*.

Different configurations for external devices used to communicate with IMDs such as **10***a* and **10***b* exist in the prior art. Such external devices are typically used to send or adjust the therapy settings the IMD **10***a* or **10***b* will provide to the patient (such as which electrodes **16** are active to issue pulses; whether such electrodes sink or source current (i.e.,

polarity); the duration, frequency, and amplitude of pulses, etc.), which settings together comprise a stimulation program for the patient. External devices can also act as receivers of data from the IMD **10***a* or **10***b*, such as various data reporting on the IMD's status and the level of the IMD's battery **14**.

An external device having such functionality is shown in FIG. **3** in the form of a patient remote control **40**. Remote control (RC) **40** is typically hand-held, portable, and powered by a battery (not shown) within the RC's housing **41**, which battery may be a primary battery or rechargeable. The RC **40** includes a Graphical User Interface (GUI) **43** similar to that used for a cell phone, including buttons **42** and a screen **44**, and may have other interface aspects as well, such as a speaker. The RC **40** also includes within its housing **41** communication means, including a coil antenna **49***a* and/or a short-range RF antenna **49***b*, compatible with the link(s) **38***a* and/or **38***b* and the communication means in the IMDs **10***a* and/or **10***b*. Processing in the RC **40** is controlled via a microcontroller **46**. As described above with respect to the IMDs **10***a* and **10***b*, antennas **49***a* and **49***b* would be associated with telemetry circuitry, although this is not shown in FIG. **3**. One or more orthogonal coil antennas **49***a* driven out of phase could be used in RC **40** as well to improve communication coupling with the IMD **10***a* along magnetic induction link **38***a*, as discussed in U.S. Patent Application Publication 2009/0069869, with which the reader is assumed familiar.

Shown on the screen **44** in FIG. **3** are various options provided by the GUI **43** and selectable by a patient to control his IMD **10** (e.g. the stimulation program it is executing) or to monitor his IMD **10**. Just a few typical options are depicted for simplicity that enable the patient to: start or stop stimulation; increase or decrease the amplitude of the stimulation pulses; check IMD monitoring information, such as the battery **14** level, operating status of the IMD, or other data telemetered from the IMD; etc.

Also shown in FIG. **3**, and as disclosed in U.S. Pat. Nos. 8,498,716 and 8,588,925 which are incorporated herein by reference, an RC **40** can includes a port **45** on its housing **41**, which may comprise a USB port for example. The '716 patent teaches that USB port **45** can be used to: recharge the RC **40**'s battery from a wall plug (assuming such battery is rechargeable); exchange data with another external device (such as an external computer; not shown); or couple to an external charging coil (not shown) to charge the IMD's battery **14** (assuming such battery **14** is rechargeable), in effect allowing RC **40** to operate as a combination RC/charger.

The '925 patent teaches that USB port **45** can be used to convey contraindication information—e.g., activities that might be counter-indicated for an IMD patient such as Magnetic Resonance Imaging (MRI) or some physical activity—to a person of interest, such as the patient or her clinician. In this regard, the '925 patent teaches that a cable can couple between port **45** on the RC **40** and a port on an external computer to allow contraindication information to be reviewed outside of the RC **40** itself Alternatively, the '925 patent teaches that a memory stick (not shown) may be coupled to port **45** to allow contraindication information resident in the RC **40** to be written to the memory stick, which memory stick can then be removed from the RC **40** and coupled to the external computer where the contraindication information can be reviewed.

External devices such as the RC **40** of FIG. **3** were historically built by the manufacturer of the IMDs, and thus were generally dedicated to communicate only with such IMDs. As such, dedicated RC **40** is not freely programmable by a patient, but is instead limited to the IMD functionality provided by the manufacturer. (However, the microcode operating in the RC's microcontroller **46** may be upgraded from time to time in manners specified by the manufacturer). However, there are many user-programmable commercial mobile devices, such as cell phones, that can provide GUIs and have inherent communication means suitable for functioning as a wireless external controller for an IMD.

FIGS. **4**A and **4**B show an example of a mobile device **50** configured for use as an external controller for an IMD, as described in commonly-owned U.S. Patent Application Publications 2015/0073498 and 2015/0231402, which are incorporated herein by reference. The mobile device **50** may be a commercial, multipurpose, consumer device, such as a cell phone, tablet, personal data assistant, laptop or notebook computer, or like device—essentially any mobile, hand-holdable device capable of functioning as a wireless external controller for an IMD. Examples include the Apple iPhone or iPad, Microsoft Surface, Nokia Lumia devices, Samsung Galaxy devices, and Google Android devices for example.

As shown in FIG. **4**A, the mobile device **50** includes a GUI **53** with a screen **54**, which may also receive input if it is a touch screen. The mobile device **50** may also have buttons **52** (e.g., a keyboard) for receiving input from the patient, a speaker **56**, and a microphone **58**. Mobile device **50** further includes a battery within its housing **51**, although not shown, which battery may be a primary battery or rechargeable. Mobile device **50** can also include ports **55** and **57**, which are subsequently explained. Mobile device **50** further includes at least one short-range RF antenna **59**, again as subsequently explained, and would include telemetry circuitry compliant with that antenna(s), although not shown. Processing in the mobile device **50** is controlled by a microcontroller **61**.

Shown on the screen **54** is a typical home screen GUI **53** provided by the mobile device **50** when first booted or reset. A number of applications ("apps") **60** may be present and displayed as icons on the mobile device home screen GUI **53**, which the patient can select and execute.

One of the applications (icons) displayed in FIG. **4**A is a Medical Device Application (MDA) **70**, which may reside as microcode in the mobile device **50**'s microcontroller **61**. When MDA **70** is executed by the patient, the microcontroller **61** will configure the mobile device **50** for use as an external controller to communicate with an IMD. FIG. **4**B shows the GUI **73** provided by the MDA **70** after it is executed, which includes options selectable by a patient to control his stimulation program or monitor his IMD, similar to what was described earlier with respect to the GUI **43** of the dedicated RC **40** of FIG. **3**.

The MDA **70**, like other applications **60** selectable in the mobile device **50**, may have been downloaded using traditional techniques, such as from an Internet server or an "app store." Although not strictly necessary, MDA **70** is logically developed and provided by the manufacturer of the IMD, and may be made available in different versions to work with different mobile device operating systems (e.g., iOS, Android, Windows, etc.). One skilled in the art will understand that MDA **70** comprises instructions that can be stored in the mobile device **50** or on an Internet server for example on non-transistory machine-readable media, such as magnetic, optical, or solid-state discs, integrated circuits, memory sticks, tapes, etc.

When the MDA **70** on the mobile device **50** is first selected and executed, or when an appropriate selection is made in the MDA, wireless communications with the IMD

can be established using a communication means in the mobile device **50** and enabled by the MDA **70**. The above-incorporated '498 Publication discloses different examples in which such communication can occur, illustrated here in FIGS. **5**A-**5**C.

In FIG. **5**A, the MDA **70** establishes wireless communication directly with the IMD**10***b* along short-range RF link **38***b* using short-range RF communication means supported by the mobile device **50** (e.g., WiFi or Bluetooth), including one of its short-range RF antennas **59** (FIG. **4**A). In this instance, the IMD **10***b* would include short-range communication means compatible with short-range RF link **38***b* such as a short-range RF antenna **34***b* shown earlier with respect to FIG. **2**B.

In FIG. **5**B, a coil antenna **72** in a communication head **74** is coupled by a cable **76** to the port **55** on the mobile device **50**, such as a USB port. In this example, the coil antenna **72** can be placed proximate to the IMD **10***a* to establish a magnetic induction link **38***a*, perhaps as modulated via FSK as mentioned earlier. The IMD **10***a* would include communication means compatible with magnetic induction link **38***a* such as a coil antenna **34***a* shown earlier with respect to FIG. **2**A. The MDA **70** in this example would cause the mobile device **50** to issue and receive data at its USB port **55**, which data may be modulated or digital depending whether the modulation/demodulation circuitry resides in the mobile device **50** or the communication head **74**.

In FIG. **5**C, the mobile device **50** communicates with the IMD **10***a* via an intermediary bridge **80**. The bridge **80** contains first communication means including a short-range RF antenna **82***b* for wirelessly communicating with the mobile device **50** via short-range RF link **38***b*, and second communication means including a coil antenna **82***a* for wirelessly communicating with the IMD **10***a* via a magnetic induction link **38***a*. The bridge **80**, which is preferably battery powered (battery not shown), essentially "translates" data on short-range RF link **38***b* into (FSK) data on magnetic induction link **38***a*, and vice versa. The MDA **70** can thus program the mobile device **50** to use its inherent short-range RF communication means (e.g., short-range antenna **59**) to communicate with the IMD **10***a*, even if the IMD **10***a* is not compatible with such means, because the bridge **80** can translate and communicate with both. The communication system of FIG. **5**C is further explained in U.S. Patent Application Publication 2013/0215285, which is incorporated herein by reference.

The '498 Publication further teaches that the MDA **70** can secure the mobile device **50** by controlling hardware and software that could affect, or worse corrupt, its use as an IMD external controller. Addressing such security issues is prudent because general-purpose commercial mobile devices by virtue of their broad connectivity are potentially subject to software viruses or tampering ("hacking"). For example, the '498 Publication discloses that the MDA **70** upon execution can temporarily configure the mobile device **50** to prevent operation inconsistent with external controller functionality, such as by disabling or reconfiguring hardware modules in the mobile device **50** that are either unnecessary or could potentially interfere with operation of the MDA **70**. The MDA **70** can also terminate or temporarily suspend software tasks that might interfere with secure operation of the mobile device **50** as an external controller, such as other apps **60** displayable and executable from the mobile device home screen GUI **53** (FIG. **4**A), or other software tasks that may run in the background of the mobile device in manners not immediately noticeable to the patient.

The above-incorporated '402 Publication describes other techniques for using a mobile device **50** to communicate with an IMD **10***a* or **10***b*, which are illustrated here in FIGS. **6**A-**6**C. In these techniques, an accessory **90** with a connector **92** is coupled to an audio port **57** on the mobile device. The connector **92** and audio port **57** are co-axial, and typically comprise a left and right audio output signal, an audio input signal (MIC), and a ground. Typically a pair of headphones and/or a microphone (not shown) can be coupled to the audio port **57** on the mobile device **50** as is well known. Such signaling allows the accessory **90** to communicate bi-directionally with the mobile device **50**. Additionally, the accessory **90** can receive power from the mobile device **50** for its circuitry via connector **92**/audio port **57**, or can include its own battery, as explained in the '402 Publication. Although not depicted here, the '402 Publication teaches that the accessory **90** can be coupled to a different type of port on the mobile device **50**, such as the USB port **55**.

In the '402 Publication, the accessory **90** is used to facilitate quick execution of the MDA **70** on the mobile device **50**, essentially allowing a user instant access to GUI **73** to communicate with his IMD **10**. In one example, the accessory **90** is used to immediately execute the MDA **70** on the mobile device, either upon pressing a switch **94** and/or when the accessory **90** is inserted into the audio port **57** and automatically validated by the mobile device **50**. The accessory **90** can facilitate immediate execution of the MDA **70** by by-passing security measures inherent in the mobile device **50**, such as screen locks or passwords, thus removing these encumbrances. The accessory **90** can further enable securing of the mobile device **50** for use as an IMD external controller, as explained above with respect to the '498 Publication. The use of the accessory **90** also provides a physical measure of IMD security, as the MDA **70** can be programmed to not execute if the patient's accessory **90** is not present and validated. Electronics in the accessory **90** are described in the '402 Publication but are largely omitted here.

In the example of FIG. **6**A, once the MDA **70** is executed, communication with the IMD occurs using short-range communication means provided in the mobile device **50** itself, including at least one of its short-range RF antennas **59**. This assumes use with an IMD (e.g., **10***b*) having a short-range RF antenna (e.g., **34***b*) compliant with the communication standard used by antenna **59**.

If the IMD is not so compliant, other examples in the '402 Publication provide antennas in the accessories **90**, as shown in FIGS. **6**B and **6**C. In FIG. **6**B, the accessory **90** includes a coil antenna **96***a* capable of communicating with an IMD compliant with such communication means, such as IMD **10***a* of FIG. **2**A. In FIG. **6**C, the accessory **90** includes a short-range RF antenna **96***b* compliant with the IMD, such as IMD **10***b* of FIG. **2**B. In this example, the accessory **90**'s short-range RF antenna **96***b* can communicate using a standard supported by the IMD **10***b* (e.g., MICS) which may not be supported by the short-range RF antenna **59** in the mobile device **50** (e.g., WiFi or Bluetooth). In either of the examples of FIGS. **6**B and **6**C, communications with the IMD **10***a* or **10***b* as controlled by the MDA **70** on the mobile device **50** occurs bi-directionally using the accessory **90**'s antennas **96***a* or **96***b* and the data path provided by audio port **57**/connector **92**. As such, the mobile device **50** in this example is only used for its easy provision of a GUI, rather than for its inherent communication capabilities (such as its non-compliant short-range RF antenna **59**). Otherwise, the

accessories **90** of FIGS. **6**B and **6**C provide the same benefits to security and ease of use provided by the accessory **90** of FIG. **6**A.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows an Implantable Medical Device (IMD) in accordance with the prior art.

FIGS. **2**A and **2**B respectively show cross sections of an IMD having a coil telemetry antenna and an RF telemetry antenna, in accordance with the prior art.

FIG. **3** show a dedicated remote control (RC) for communicating with an IMD, in accordance with the prior art.

FIG. **4**A shows a graphical user interface (GUI) of a mobile device, and FIG. **4**B shows a GUI of a Medical Device Application (MDA) on the mobile device for communicating with an IMD, in accordance with the prior art.

FIGS. **5**A-**5**C show different manners in which a mobile device can wirelessly communicate with an IMD using the MDA of FIG. **4**B, in accordance with the prior art.

FIGS. **6**A-**6**C show various plug-in accessories to configure a mobile device to operate as an external controller for an IMD, in accordance with the prior art.

FIG. **7** shows an improved system in which a dedicated RC (FIG. **3**) is used as an intermediary device to translate communication between a mobile device and an IMD, in accordance with an example of the invention.

FIG. **8** shows use of the dedicated RC as described in FIG. **7** as an intermediary in a clinician programmer system, thus obviating the need for a wand in such system, in accordance with an example of the invention.

FIG. **9** shows use of the dedicated RC as described in FIG. **7** as an intermediary in a system in which an Optical Head-Mounted Display (OHMD) is used as the mobile device to control and monitor the IMD, accordance with an example of the invention.

DETAILED DESCRIPTION

While the prior art techniques described in the Background provide workable manners for communicating with an IMD that are advantageous in leveraging the programmable and communicative aspects inherent in commercial mobile devices, the inventors see room for improvement.

In particular, the inventors recognize that while mobile devices **50** can substitute for dedicated external IMD controllers **40** provided by the manufacturer, perhaps as assisted by supporting software and hardware discussed previously (such as MDA **70**, FIGS. **4**A and **4**B; communication head **74**, FIG. **5**B; bridge **80**, FIG. **5**C; or plug-in accessories **90**, FIGS. **6**A-**6**B), it may still be prudent for manufacturer to provide a dedicated RC **40** to the IMD patient, such as shown in FIG. **3**.

Providing a dedicated RC **40** to IMD patients is prudent at least to act as a "back up" to allow IMD communications should the mobile device **50** experience problems. While a manufacturer can provide and guarantee a MDA **70** and supporting hardware to enable a mobile device **50** to function as an external controller, the manufacturer cannot guarantee the reliability and operation of the mobile device itself, let alone all of the various mobile devices its patients may wish to use to communicate with their IMDs. General-purpose mobile devices **50** also present security issues that should generally not be inherent in dedicated RCs **40**, as discussed in the Background with reference to the '498 Publication.

Additionally, a manufacturer cannot assume that a patient will have a mobile device **50** operable to communicate with an IMD. A given patient may simply not own a mobile device **50**, or her device **50** may not be suitable for IMD communications—for example, if it is too old, or if its operating system is otherwise not compliant with the IMD manufacturer's requirements (such as the manufacturer's MDA **70**). Or, a given patient's mobile device **50** may not have the inherent capability of communicating with the patient's IMD, at least directly. As discussed in the Background, a patient's mobile device **50** may inherently have short-range RF communication means such as antenna **59** (operating per Bluetooth or WiFi communication standards) that may not be compatible with the communication means provided in an IMD—such as a magnetic induction coil antenna **34***a* in the IMD **10***a* of FIG. **2**A, or a short-RF MICS antenna **34***b* in the IMD **10***b* of FIG. **2**B. As discussed in the Background, supporting hardware may be necessary to allow communications between incompatible mobile devices **50** and IMDs **10** (e.g., communication head **74**, bridge **80**, plug-in accessories **90**, etc.), which again the manufacturer cannot assume the patient will have at their disposal.

In short, sole reliance on mobile devices **50** as external IMD controllers may be problematic. As a result, IMD manufacturers may still wish to additionally provide dedicated external IMD controllers **40** to their IMD patients to ensure a reliable and safe means to allow IMD therapy to be adjusted, monitored, or even turned off if necessary.

Thus, a patient may have two means available to communicate with his IMD **10**—a dedicated RC **40** and a mobile device **50**. The inventors have discerned that these devices **40** and **50** can function together in a manner easing use of the mobile device **50** to operate as an external controller by allowing the patient's dedicated RC **40** to act as an intermediary bridge to couple communication from the mobile device **50** to the patient's IMD **10**. This is similar in functionality to the bridge device **80** discussed in the Background with reference to FIG. **5**C, and as disclosed in the above-referenced '285 Publication. However, unlike the bridge **80**, the dedicated RC **40** includes a full user graphical user interface (GUI) **43** (including screen **44** and buttons **42**) which allows the patient to control therapy settings the IMD and to monitor data transmitted from the IMD. Bridge **80**, by contrast, merely contains communication means to in effect translate communications to and from the IMD **10**. Bridge **80** contains no user interface, let alone a graphical user interface, to allow IMD control or monitoring.

FIG. **7** shows an example of a system **100** in which a mobile device **50** uses a dedicated RC **40** to communicate with an IMD **10**. The mobile device **50** as before can be programmed with an MDA **70** to allow IMD control and monitoring of IMD information via GUI **73**, and which may perform additional security related tasks befitting mobile device **50** use as an external controller, as discussed earlier. Also shown is one of the mobile device **50**'s inherent antennas **59** and (associated telemetry circuitry not shown), which is internal to the mobile device's housing **51**. Antenna **59** as explained earlier is preferably a short-range RF antenna operable with communication means typically inherent in mobile device **50**, such as those operable according to Bluetooth and WiFi standards.

The dedicated RC **40** in system **100** has been modified to include a short-range RF antenna **104** which is compliant with the short-range RF communication means (e.g., antenna **59**) in the mobile device **50**, thus enabling bi-directional communications between the mobile device **50**

and the dedicated RC **40** via a short-range RF link **38***c*. The GUI **43** provided by the dedicated RC **40** may be identical to the GUI **73** rendered by the MDA **70** at the mobile device **50**, or at least may include identical functionality in terms of selectable options useable to control and monitor the IMD **10**. Alternatively, the GUIs **73** and **43** of the devices **50** and **40** may comprise a subset of the functionality provided by the other device **40** or **50**.

Different versions of short-range RF antennas can be used in the dedicated RC **40**. An external short-range antenna **104** is shown in FIG. **7** as contained within a dongle **102** coupleable to a port on the dedicated RC **40**'s housing **41**. In the example shown, a connector **103** on the dongle **102** is coupleable to the dedicated RC **40**'s USB port **45**. Such RF-compliant dongles **102** are well known and need not be specially manufactured for use with the dedicated RC. For example, suitable dongles **102** coupleable to USB ports can include those used by a wireless computer mouse (input device) to communicate with a computer. As one skilled in the art will understand, dongle **102** may contain other control circuitry (not shown) as necessary to supplement operation of the short-range RF antenna **104**.

Use of an external short-range antenna **104** is beneficial as it allows the type of short-range RF antenna to be readily changed to match the standard being used by the short-range RF antenna **59** in the mobile device **50**. For example, one dongle **102** may include a Bluetooth antenna **104**, while another may include a WiFi antenna **104**, etc. Short-range antenna **104'** by contrast is contained within dedicated RC **40**'s housing **41**. As the antenna **104'** is internal and not accessible, care should be taken to ensure that the antenna **104'** will be compliant with communication standard used in a majority of mobile devices **50** (e.g., Bluetooth).

Communications between the dedicated RC **40** and the IMD **10** occurs using the antenna **49***a/b* used for communications with the IMD **10** even when the mobile device **50** is not present. As explained in the Background, the type of antenna **49** used can be dictated by the type of antenna **34** used in the IMD **10**. If the IMD **10***a* includes a coil antenna **34***a* (FIG. **2**A), the dedicated RC **40** would likewise include a coil antenna **49***a* for bi-directional communication along a magnetic induction link **38***a*. If the IMD **10***b* includes a short-range RF antenna **34***b* (FIG. **2**B), the dedicated RC **40** would likewise include a short-range RF antenna **49***b* for bi-directional communication along a short-range RF link **38***b*. In this case, care should be taken to ensure that the antennas **49***b* and **34***b* are compliant with the same short-range RF communication standard (e.g., MICS). Preferably, and as is typical, the antenna **49***a/b* is internal to the housing **41** of the dedicated RC **40**.

Regardless of the particular antennas and links used, the dedicated RC **40** acts as an intermediary device to permit bi-directional communication between the mobile device **50** and the IMD **10**, regardless of the communication means supported by those two devices. In this regard, the microcontroller **46** in the dedicated RC **40** can operate to translate between different communication formats (i.e., different standards, different modulation schemes, different protocols, etc.) used by the mobile device **50** and the IMD **10**.

Assume for example that the MDA **70** operating on the mobile device **50** enables the mobile device's Bluetooth short-range RF antenna **59** to transmit and receive communications to and from the IMD **10**, and that the IMD has a coil antenna **34***a* (FIG. **2**A). In this circumstance, the dedicated RC **40** will have a Bluetooth short-range RF antenna **104/104'** compliant with the communication means in the mobile device **50**, and a coil antenna **49***a* compliant with the communication means in the IMD **10***a*, as shown in the schematic at the bottom of FIG. **7**. Also shown in the schematic are telemetry circuitries **106** and **107** coupled to and between each of the antennas **104/104'** and **49***a* and the RC's microcontroller **46**. The telemetry circuitries **106** and **107** generally include modulation/antenna driver circuitry for transmitting data and amplifier/filter/demodulation circuitry for receiving data in accordance with the format of the data on the links they support. Each of the telemetry circuitries **106** and **107** communicated digital data bi-directionally with the microcontroller.

The microcontroller **46** in the dedicated RC **40** can be programmed to translate data received in one format and to transmit that data in a second format. For example, when antenna **104/104'** receives Bluetooth formatted data from short-range antenna **59** in the mobile device **59** via short-range RF link **38***c* (such as a control instruction for the IMD to increase or decrease stimulation, etc.), the microcontroller **46** can cause FSK telemetry circuitry **107** to transmit that data in an FSK format from its coil antenna **49***a* via magnetic induction link **38***a* to the coil antenna **34***a* in the IMD **10***a*, allowing the IMD **10***a* to then execute the control instruction. Likewise, the dedicated RC **40** can receive monitoring information transmitted from the coil antenna **34***a* in the IMD **10***a* via magnetic induction link **38***a* at its coil antenna **49***a*, and its microcontroller **46** can cause Bluetooth telemetry circuitry **106** to transmit that data in a Bluetooth format from its short-range RF antenna **104/104'** via short-range RF link **38***c* to the short-range antenna **59** in the mobile device **50**, where such received data can be viewed using the MDA GUI **73**.

When so operating as an intermediary, the dedicated RC **40** may enter an intermediary mode of operation in which the dedicated RC **40** only operates to translate between the mobile device **50** and IMD **10**. Such an intermediary mode can be separate and distinct from a normal operating mode in which the dedicated RC **40**'s GUI **43** is active to receive user inputs to control and monitor the IMD. In other words, the GUI **43** of the dedicated RC **40** may be disabled during the intermediary mode to prevent use of the dedicated RC **40** to control and monitor the IMD **10**. Alternatively, the dedicated RC **40** can enable intermediary translating functionality between the mobile device **50** and the IMD **10** even during a normal operating mode in which IMD control and monitoring functions are still accessible from the dedicated RC **40**'s GUI **43**.

Entering the intermediary operation mode, or otherwise enabling intermediary translating functionality, can be enabled in the dedicated RC **40** in any number of ways. For example, if the dedicated RC **40**'s short-range RF antenna **104** is external (e.g., in dongle **102**), the dedicated RC **40** can enable translating of data when it senses that the dongle **102** has been inserted into an appropriate port (e.g., **45**) on the dedicated RC **40**. Alternatively, translating of data can comprise an option **105** selectable by a user on the GUI **43** of the dedicated RC **40**, as shown in FIG. **7**. In another alternative, the dedicated RC **40** will always translate data received at one antenna **49***a/b* or **104/104'** and translate and retransmit that data at the other antenna **104/104'** or **49***a/b*, even if there is no device (mobile device **50** or IMD **10**) in proximity to receive the translated data, in which case needless transmission of the translated data will be harmless.

Note in the system of FIG. **7** that the dedicated RC **40**, as well as providing its own GUI **43** permitting control and monitoring of the IMD **10**, supplants supporting hardware otherwise used in the prior art to alleviate incompatibilities between the communication means used in the mobile

device **50** and the IMD **10**. For example, communication head **74** (FIG. **5**B) and plug-in accessories **90** (FIGS. **6**A-**6**B) are not required to be used with the mobile device **50**.

When the system of FIG. **7** is used, and in particular when the IMD **10***a* has a coil antenna **34***a* (FIG. **2**A), it is preferable to place the dedicated RC **40** in proximity to the IMD **10***a* because the magnetic induction link **38***a* supported by coil antenna **34***a* in the IMD **10***a* between them is relatively short (e.g., 12 inches or less as noted earlier). Assuring dedicated RC-to-IMD **10***a* proximity can occur in any number of ways, depending on where the IMD **10** is implanted in the body. For example, if the IMD is a Spinal Cord Stimulation (SCS) IPG **10**, it would be implanted in the upper buttocks. If it is a Deep Brain Stimulator (DBS) IPG **10**, it would be implanted under the collar bone in the patient's chest. Various belts or holsters into which the dedicated RC **40** can be inserted can be used hold the dedicated RC **40** in place and proximate to the IMD. Alternatively, a cord can be attached to the dedicated RC **40** to suspend it from the neck or waist in good proximity to the IMD **10***a*. The dedicated RC **40** could also include fastening means attached to its housing **41** to allow it to be attached to the patient's clothing, such as a clip for example. Dedicated RC-to-IMD proximity is less important if the IMD **10***b* has a short-range RF antenna **34***b* (FIG. **2**B) operable at longer distances.

It should be noted that devices and systems other than a mobile device **50** can benefit from use of the dedicated RC **40** as an intermediary to communicate with an IMD. For example, FIG. **8** shows use of the dedicated RC **40** as an intermediary device in the context of a clinician programmer (CP) system **140** such as is described in U.S. Patent Application Publication 2015/0360038, which is incorporated herein by reference. CP system **140** is typically used by a clinician to set up operation of a patient's IMD after implantation and to determine optimal stimulation programs for a patient. In contrast to a mobile device **50**, a CP system **140** is generally stationary and located at an office of the clinician.

As shown, CP system **140** comprises a computing device **150**, such as a desktop, laptop, or notebook computer, a tablet, a mobile smart phone, a Personal Data Assistant (PDA)—type mobile computing device, etc. (hereinafter "CP computer"). In FIG. **8**, CP computer **150** is shown as a laptop computer that includes a typical computer GUI **153** such as a screen **154**, a mouse, a keyboard, speakers, a stylus, a printer, etc., not all of which are shown for convenience.

As explained further in the '038 Publication, CP software **170** operable in the CP computer **150** is used to render a GUI **173** on the screen **154** of the CP computer **150** to allow for control and monitoring of the IMD **10**, in addition to many other more-complicated functions of significance to the clinician but not normally accessible by the patient via a mobile device **50** (MDA **70**) or a dedicated RC **40**. In this respect, CP computer **150** and CP software **170** are analogous to the mobile device **50** and MDA **70** described earlier.

In the example shown in FIG. **8**, the antenna used in the CP system **140** to communicate with the IPG **10** includes a wand **174** which is somewhat analogous to the communication head **74** described earlier for use with mobile device **50** (FIG. **5**B) in that it includes a coil antenna **72** for bi-directionally communicating with an IMD **10***a* having a coil antenna **34***a* (FIG. **2**A), and is coupleable to a (USB) port **155** on the CP computer **150**. Wand **174** may also include a short-range RF antenna **172***b* compliant with an IMD **10***b* having a short-range RF antenna **34***b* (FIG. **2**B). (Wand **174** in an actual CP system would likely contain only one of antennas **172***a* or **172***b* depending on the nature of the IMD **10** supported).

Use of the dedicated RC **40** as an intermediary device disposes of the need for a wand **174** in the CP system **140**, even if the CP computer **150** and the IMD **10** cannot otherwise directly communicate. Instead, a patient can bring his dedicated RC **40** to his clinician's office when the CP system **140** will be used. During IPG communications, the CP system **140** can instead use communication means inherent in the CP computer **150**, such as one or more of its internal short-range RF antennas **159**, which may be located in various places in the CP computer **150**. The dedicated RC **40** can receive data via short-range RF link **38***c* from the antenna **159** at antenna **104**/**104'**, translate such data into a proper format, and transmit it to the IMD **10** via one of its antennas **49***a/b* (depending on the nature of the IMD **10***a/b*). Transmission of data in the other direction from the IMD **10** to the CP computer **150** would likewise flow through the dedicated RC **40** as an intermediary. In short, use of the dedicated RC **40** obviates the need for a separate wand **174** coupleable to the CP computer **150** in the CP system **140**.

FIG. **9** shows another example of a system **200** in which a dedicated RC **40** is used as an intermediary to pass communications between a mobile device and an IMD **10**. However, in this example, the mobile device comprises a wearable mobile device **210**, more specifically an Optical Head-Mounted Display **210**, which is also disclosed in the above-referenced '038 Publication. OHMD **210** can in one example comprise the Google Glass™ OHMD, developed by Google, Inc. of Mountain View, Calif.

As described in the '038 Publication, OHMD **210** is configured to be wearable much like a pair of standard eyeglasses, and includes a frame **212** which also serves as the temples supported by the wearer's ears, and nose pads **214**. Lenses (e.g., corrective or sunglasses lenses) may be affixed to the frame **212**, but are not shown in FIG. **9**. OHMD **210** may also be worn in conjunction with a wearer's normal eyeglasses.

Plastic affixed to the frame **212** generally defines a rearward housing **216** and a forward housing **218** on the OHMD **210**'s right temple. Plastic also defines a pass-through portion **220**, which as well as defining a space for the wearer's right ear, also provides for the passing of wires between the two housings **216** and **218**. The rearward housing **216** holds a rechargeable battery (not shown). A bone-conduction audio transducer **224** in the rearward housing **216** protrudes through the plastic and presses over the right ear to permit the wearer to hear sounds provided by the OHMD's GUI, which is explained below. OHMD **210** could also include a more-traditional audio speaker as well.

The forward housing **218** includes a printed circuit board (not shown), which supports the OHMD **210**'s main electronics, such as its microprocessor, and movement sensors providing input to a motion detector module in the electronics, including a three-axis accelerometer and a three-axis gyroscope. Also included in the forward housing **218** is a touch sensor (not shown), which allows the outer surface of the forward housing to operate as a touch pad **226**. The touch pad **226** is sensitive to the wearer's touch across the two-dimensional expanse (X and Y) of the outer surface of the foreword housing **218**, and can additionally be pressed ("tapped") similar to a button. The underside of the forward housing **218** additionally includes a microphone **228** for the receipt of voice input in addition to inputs receivable by the touch pad **226**. The electronics of the OHMD **210** will

include a voice detection module for interpretation of spoken voice inputs, as is well known.

The forward housing **218** also includes a display portion **230** of the OHMD **210**, including an LED array **232** powered by the OHMD's microprocessor. Images **234** created at the LED array **232** are directed to a prism **236** containing a polarizing beam-splitter that direct the images **234** to the wearer's right eye. In this manner, the user is able to perceive the images **234** generated by the OHMD **210** and output by the display portion **230**, which images **234** are provided slightly to the right of the wearer's center of vision, thus allowing the wearer to see the real world and the images on the display portion **230** simultaneously.

OHMD **210** in this example further includes bi-directional short-range RF communication means, which like the mobile device **50** described earlier preferably includes one or more antennas **236** and telemetry circuitry (not shown) compliant with Bluetooth and Wi-Fi communication standards. The antenna **236** is shown located in the forward housing **218**, but could be present elsewhere, such as in the rearward housing **218**.

As explained in the '038 Publication, the OHMD **210** can generate a Graphical User Interface (GUI) **240** using the display portion **230** that can be used to control and monitor the IMD **10**. The input interface of the GUI **240** comprises one or more of the touch pad **226**, the voice detection module (coupled to microphone **228**), and the motion detector module coupled to the accelerometers and gyroscopes. This input interface allows a patient to navigate the GUI **240** to control and monitor his IMD **10** either by touch, voice, or head movements. Audio aspects (e.g., transducer **224** or another speaker) can also comprise part of the OHMD GUI **240**.

The '038 Publication explains the OHMD GUI **240** in detail, and only a simple example is shown in FIG. **9**. As seen by the patient via the display portion **230**, a card **242** of information regarding a patient's current stimulation program (Program 1) is shown, including stimulation (pulse) amplitude, duration and, frequency. A cursor **244** highlights selection of a current parameter (amplitude in this example), which cursor can be moved using the input interface (i.e., by touch, voice, or movement). In the example shown, the patient increases the currently-selected stimulation amplitude by swiping forward on the touch pad **226**, which then updates the information on the displayed card **242** (in this case reflecting an amplitude increase from 2.2 mA to 2.4 mA).

When adjustments in IMD control are made in this fashion, a control instruction is transmitted from the short-range RF antenna **236** in the OHMD **210** to the compliant short-range RF antenna **104/104'** in the dedicated RC **40**, where it is translated as explained earlier, and broadcast to the IMD **10** via its internal antenna **49***a/b* (depending on the nature of the IMD **10***a/b*). Although not depicted, the patient can also interact with the OHMD GUI **240** to retrieve monitoring information from the IMD **10**. When this request is received at the IMD **10**, the IMD **10** will in turn transmit the requested information from antenna **34***a/b* to antenna **49***a/b* in the dedicated RC **40**, where it is translated and transmitted from short-range RF antenna **104/104'** to short-range antenna **236** the OHMD **210**, and rendered for user review via the OHMD GUI **240**. As discussed earlier, use of the dedicated RC **40** as an intermediary between the OHMD **210** and the IMD **10** is particularly useful if the OHMD **210** and IMD cannot directly communicate given incompatibilities in their communication means.

It should be noted that antennas (e.g., **59**, **159**, or **236**) in the various external IMD controllers (mobile device **50**, CP computer **150**, or OHMD **210**) and antenna **104/104'** associated with the dedicated RC **40** need not be short-range RF antennas, but could comprise other antennas for communicating by other means. For example, such antennas can operate in accordance with optical or acoustic principles as well, with the dedicated RC **40** still operating to translate communications with the IMD **10**. Such RF antennas also need not comprise "short range" antennas, but could comprising longer-range RF antennas.

Microcontroller control circuitry operable in the IMD **10**, RC **40**, or in the various disclosed external controller devices (**50**, **150**, **210**) can comprise for example Part Number MSP430, manufactured by Texas Instruments, which is described in data sheets at http://www.ti.com/lsds/ti/microcontroller/16-bit_msp430/overview.page?DCMP=MCU_other&HQS=msp430, which is incorporated herein by reference. However, other types of control circuitry may be used in lieu of a microcontroller as well, such as microprocessors, FPGAs, DSPs, or combinations of these, etc.

Although particular embodiments have been shown and described, it should be understood that the above discussion is not intended to limit the present invention to these embodiments. It will be obvious to those skilled in the art that various changes and modifications may be made without departing from the spirit and scope of the present invention. Thus, the present invention is intended to cover alternatives, modifications, and equivalents that may fall within the spirit and scope of the present invention as defined by the claims.

What is claimed is:

1. A remote control for communicating with an Implantable Medical Device (IMD), comprising:

a user interface and a first coil antenna, wherein the user interface is configured to enable a user to communicate data with the IMD via the first coil antenna in a first format via a first wireless link;

a second short-range RF antenna configured to communicate data with an external device in a second format via a second wireless link;

a housing, wherein the first coil antenna is within the housing; and

control circuitry coupled to the first and second antennas, wherein the control circuitry is configured to translate data received at one of the first or second antenna in the first or second format into the other of the first or second format, and to transmit the translated data from the other of the first or second antenna.

2. The remote control of claim **1**, wherein the first wireless link comprises a magnetic induction link, and the second wireless link comprises a short-range RF link.

3. The remote control of claim **1**, further comprising a port on the housing, wherein the second short-range RF antenna is coupleable to the port outside of the housing.

4. The remote control of claim **3**, wherein the second short-range RF antenna is contained within a dongle coupleable to the port.

5. The remote control of claim **1**, wherein the port comprises a USB port.

6. A system for communicating with an Implantable Medical Device (IMD), comprising:

a Medical Device Application (MDA) executable on an external device, wherein the MDA is configured to

provide a second user interface to enable a user to transmit a second control instruction for the IMD via a second wireless link; and

a remote control, comprising:

a first user interface and a first antenna, wherein the first user interface is configured to enable a user to transmit a first control instruction for the IMD from the first antenna to the IMD via a first wireless link; and

a second antenna configured to receive the second control instruction via the second wireless link,

wherein the remote control is configured to translate the second control instruction and to transmit the translated second control instruction from the first antenna to the IMD via the first wireless link.

7. The system of claim **6**, further comprising the external device, wherein the MDA is stored on the external device.

8. The system of claim **7**, wherein the external device comprises a mobile device.

9. The system of claim **8**, wherein the mobile device comprises a cell phone.

10. The system of claim **8**, wherein the mobile device is wearable.

11. The system of claim **10**, wherein the wearable mobile device comprises an Optical Head Mounted Display (OHMD).

12. The system of claim **6**, wherein the first wireless link carries data in a first format, and wherein the second wireless link carries data in a second format.

13. The system of claim **6**, wherein the first wireless link comprises a magnetic induction link, and the second wireless link comprises a short-range RF link.

14. The system of claim **6**, wherein the first and second wireless links comprise short-range RF links.

15. The system of claim **6**, wherein the remote control further comprises a housing, wherein the first and second antennas are within the housing.

16. The system of claim **6**, wherein the remote control further comprises a housing, wherein the first antenna is within the housing, and wherein the second antenna is coupleable to a port on the housing.

17. The system of claim **16**, wherein the second antenna is contained within a dongle coupleable to the port.

18. The system of claim **16**, wherein the port comprises a USB port.

19. The system of claim **6**, wherein the second antenna is removable from the remote control.

20. The system of claim **6**, wherein the remote control is further configured to:

receive first monitoring information from the IMD at the first antenna via the first wireless link, wherein the first user interface is configured to display the first monitoring information to the user; and

receive second monitoring information from the IMD at the first antenna via the first wireless link; translate the second monitoring information; and transmit the translated second monitoring information from the second antenna to the external device via the second wireless link.

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