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Hareland

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(54) **NOISE DETECTION AND MODULATION OF CLOSED-LOOP THERAPY ACTION**

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(52) **U.S. Cl.**
CPC ***A61N 1/36135*** (2013.01); ***A61N 1/025*** (2013.01); ***A61N 1/36062*** (2017.08); ***A61N 1/36125*** (2013.01); ***A61N 1/36132*** (2013.01); ***A61N 1/36139*** (2013.01); *A61N 1/37235* (2013.01)

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

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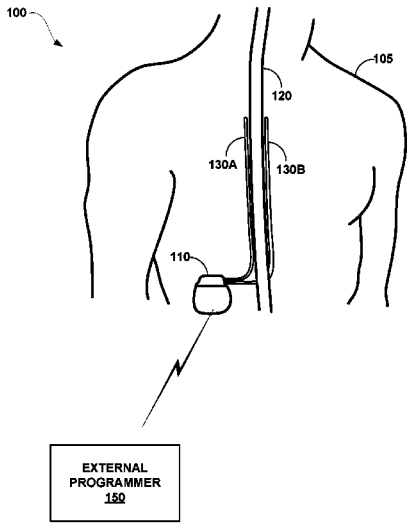
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(57) **ABSTRACT**

A medical device with closed-loop responsive stimulation may include techniques to mitigate the impact on the therapy output of noise coupled into the medical device. A medical device according to this disclosure may determine the presence of noise and alter the closed loop policy to provide the necessary therapy to the patient and avoid prolonged under stimulation caused by the noise. The medical device may continue therapy while testing for noise. When the device determines the noise level no longer affects the output therapy, the device may return the closed loop policy to a no-noise mode of operation. The medical device may also include techniques to mitigate the impact of manual adjustment while the medical device is subject to noise or is responding to changes in the patient's physiological signals.

25 Claims, 16 Drawing Sheets



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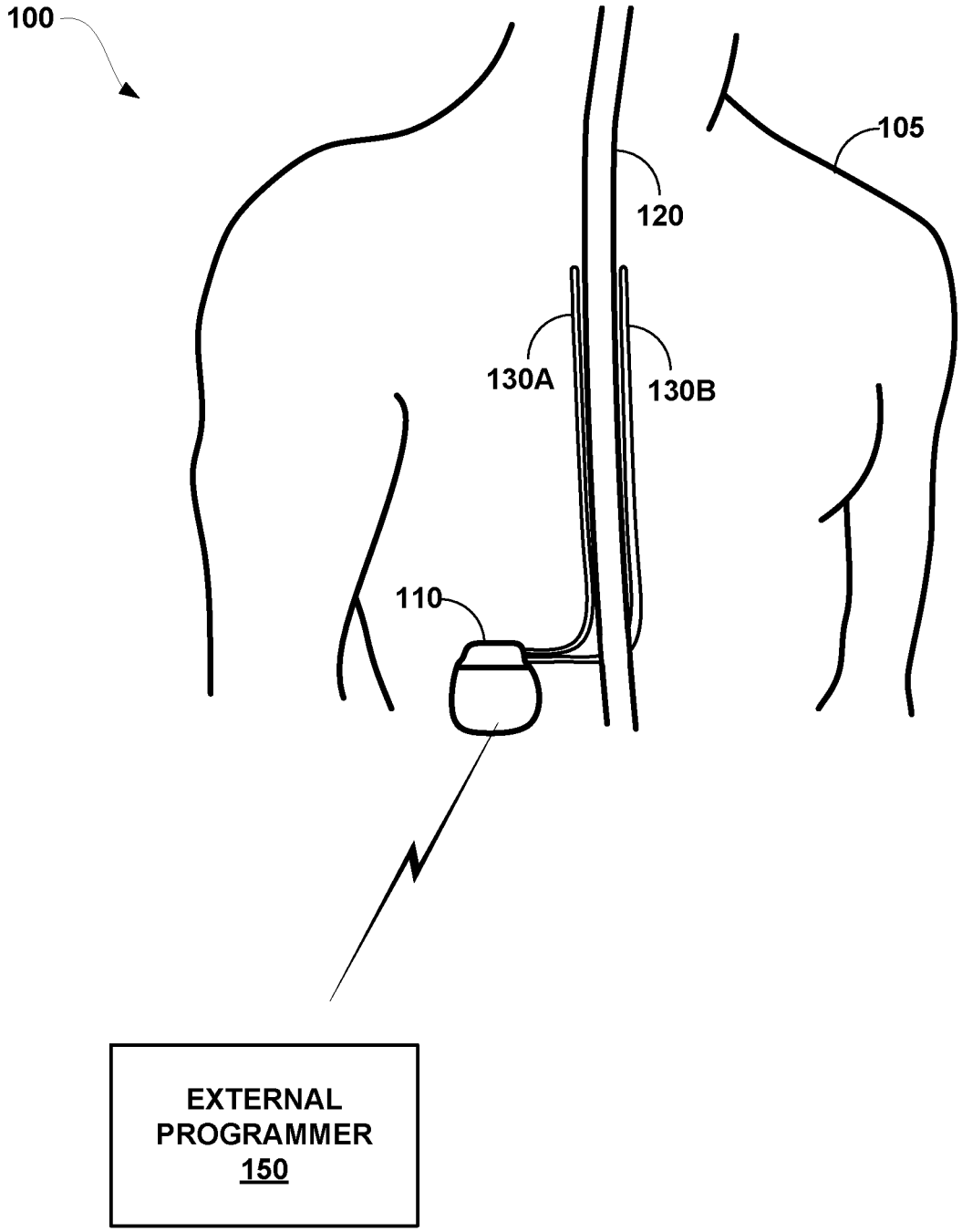


FIG. 1

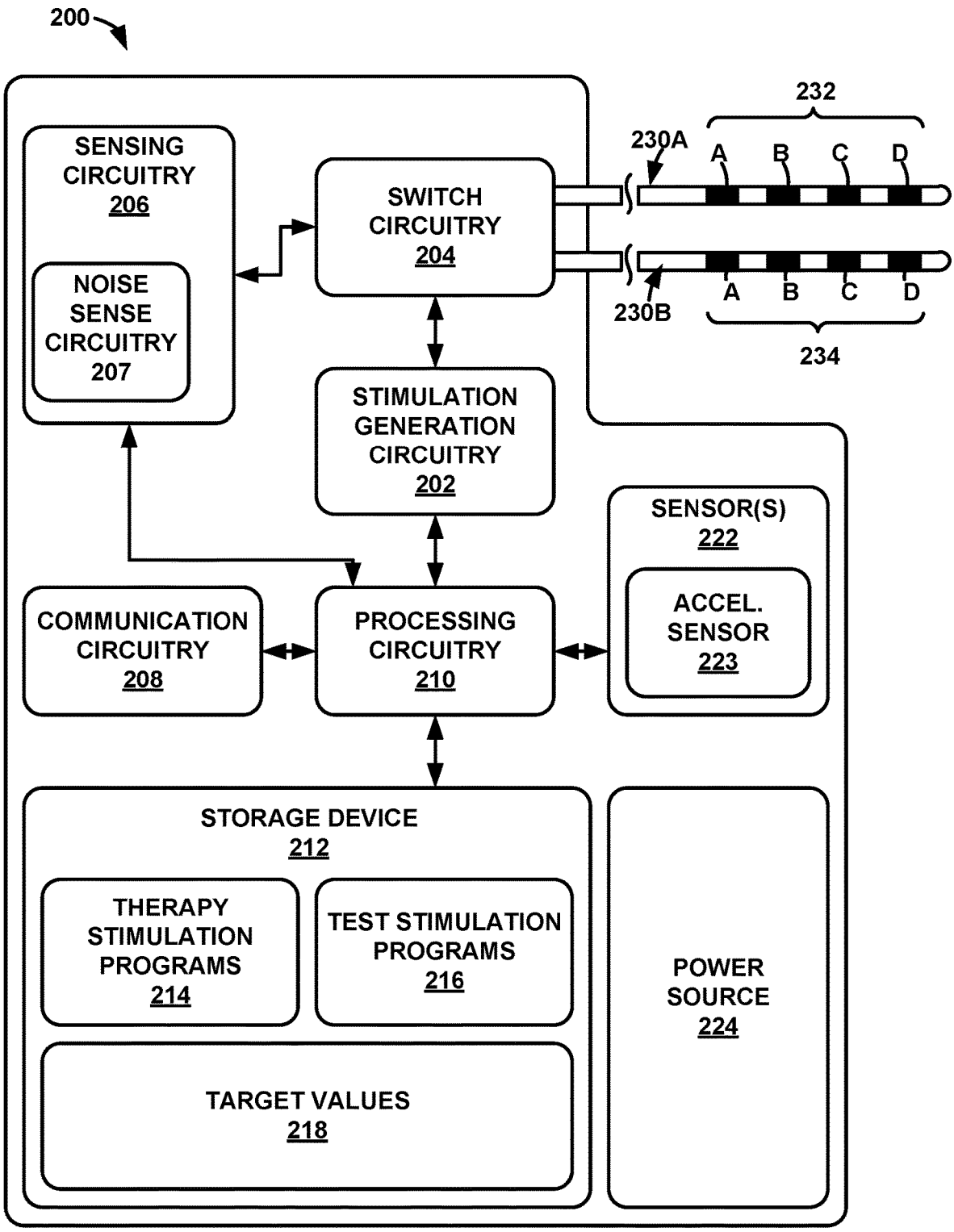

200
232
230A
A
B
C
D
SENSING CIRCUITRY 206
NOISE SENSE CIRCUITRY 207
SWITCH CIRCUITRY 204
230B
A
B
C
D
234
STIMULATION GENERATION CIRCUITRY 202
SENSOR(S) 222
ACCEL. SENSOR 223
COMMUNICATION CIRCUITRY 208
PROCESSING CIRCUITRY 210
STORAGE DEVICE 212
THERAPY STIMULATION PROGRAMS 214
TEST STIMULATION PROGRAMS 216
TARGET VALUES 218
POWER SOURCE 224

FIG. 2

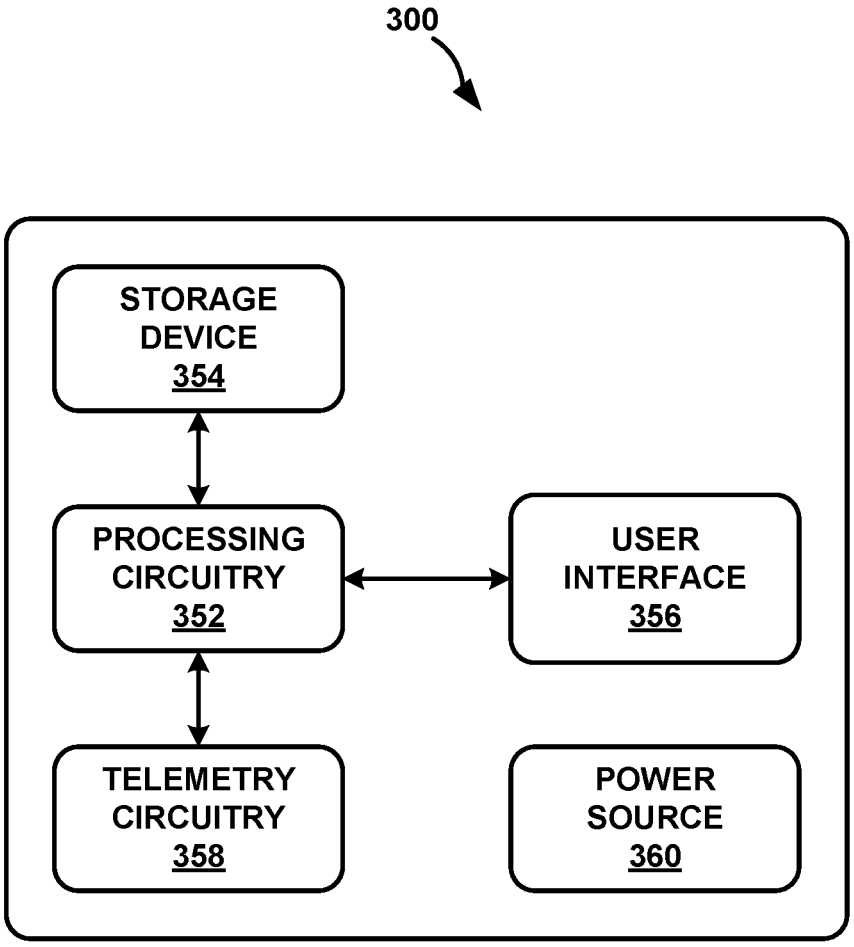

300
STORAGE DEVICE 354
PROCESSING CIRCUITRY 352
USER INTERFACE 356
TELEMETRY CIRCUITRY 358
POWER SOURCE 360

FIG. 3

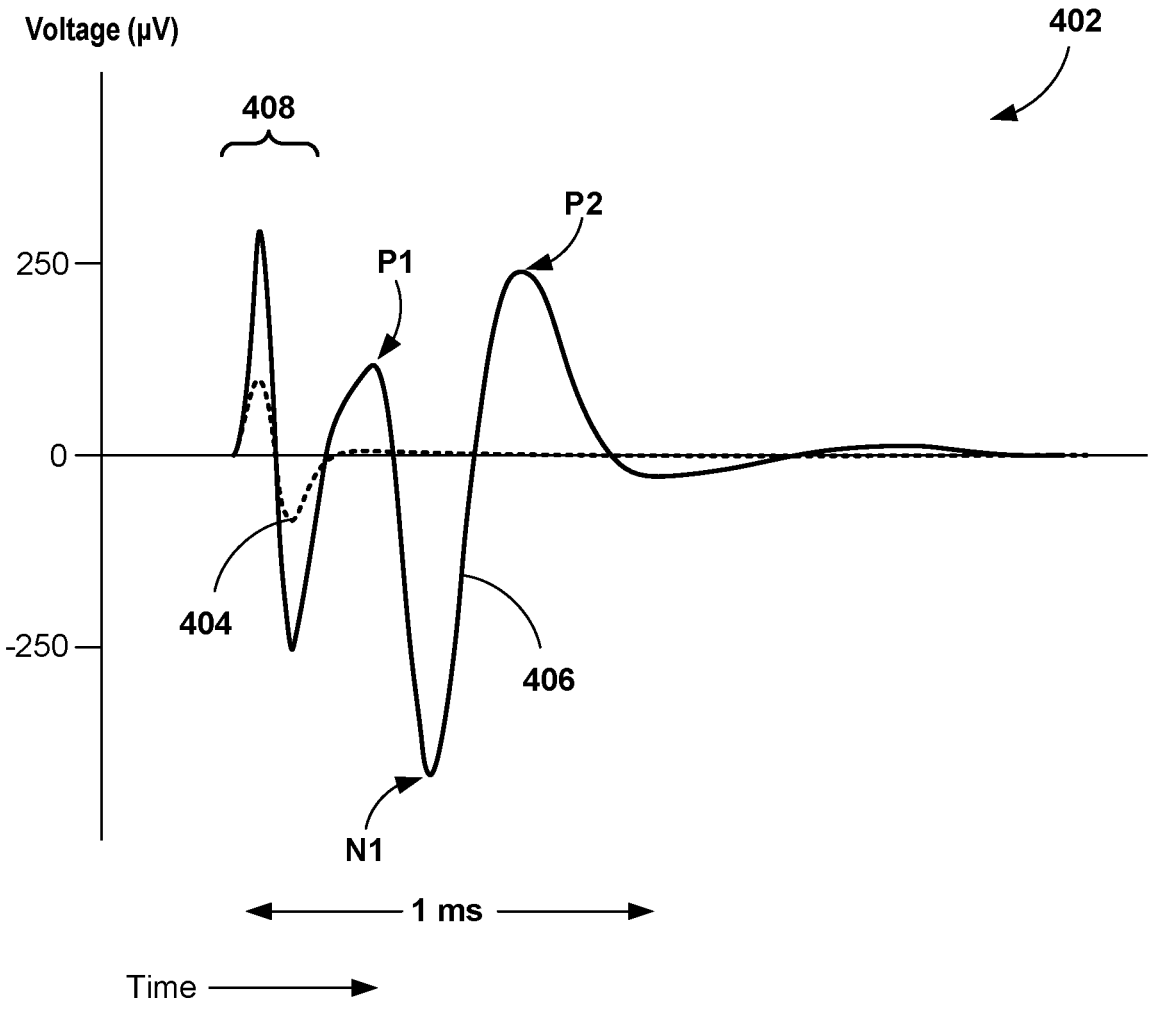


FIG. 4

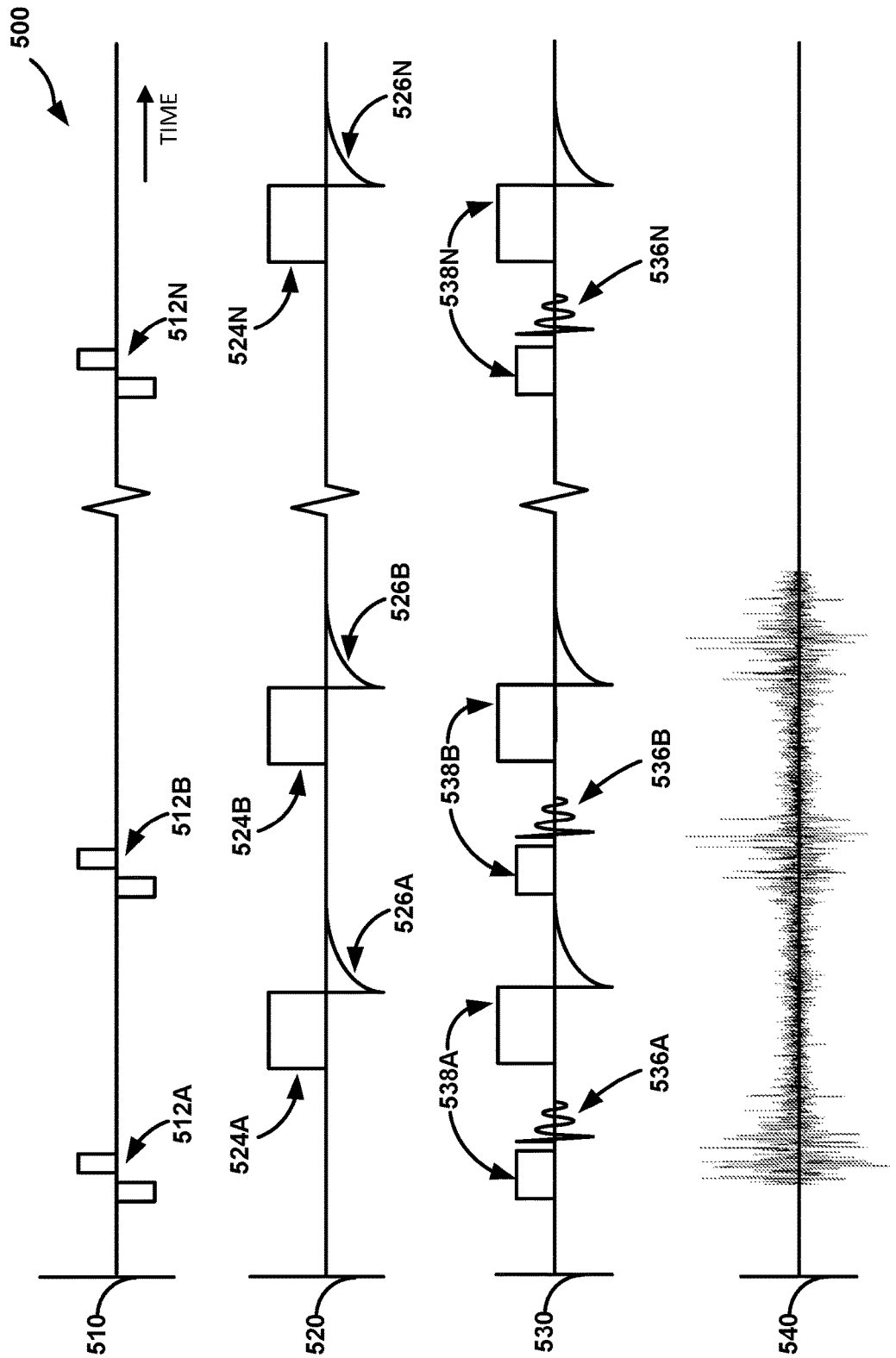

500
TIME
512N
512B
512A
524N
524B
524A
526N
526B
526A
538N
538B
538A
536N
536B
536A
510
520
530
540

FIG. 5

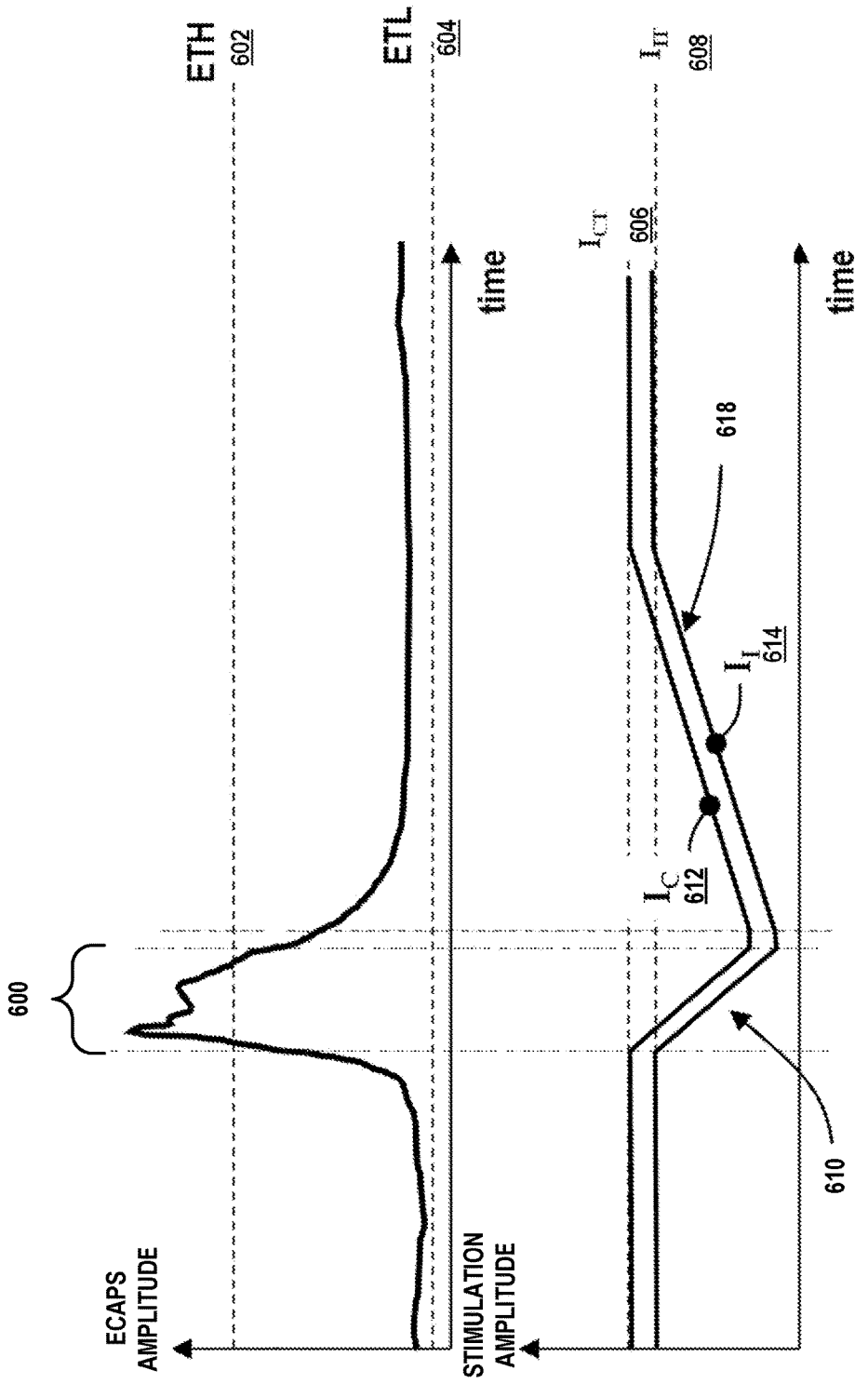

ETH
602
ETL
604
time
600
ECAPS AMPLITUDE
I_{CT}
606
I_{IT}
608
618
I_I
614
I_C
612
610
STIMULATION AMPLITUDE
time

FIG. 6

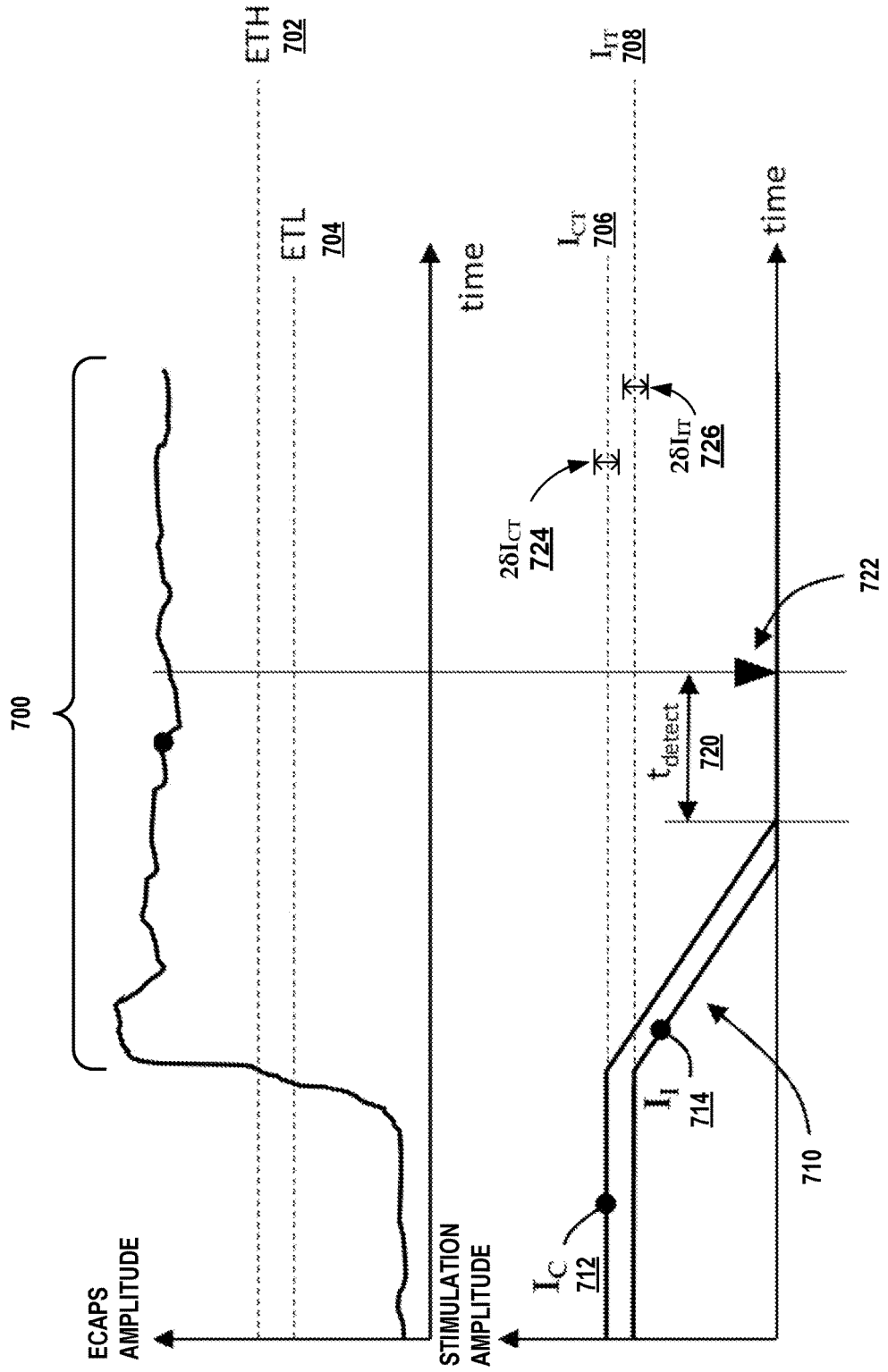

ETH
702
ETL
704
I_{CT}
706
I_{TT}
708
time
time
700
ECAPS AMPLITUDE
STIMULATION AMPLITUDE
$2\delta I_{CT}$
724
$2\delta I_{TT}$
726
t_{detect}
720
722
I_C
712
I_I
714
710

FIG. 7

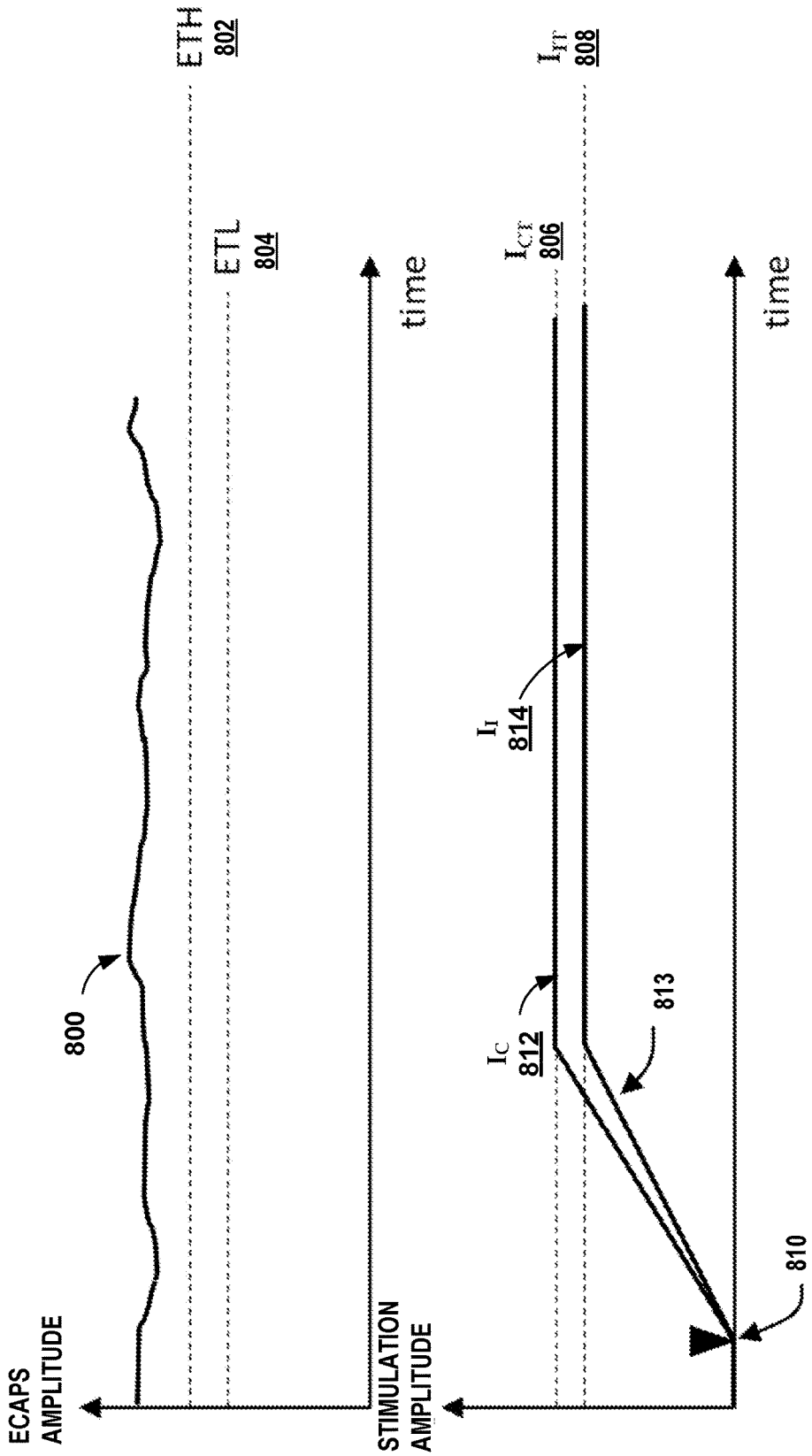

ETH
802
ETL
804
time
800
ECAPS
AMPLITUDE
STIMULATION
AMPLITUDE
I_{CT}
806
I_{IT}
808
I_I
814
I_C
812
813
810
time

FIG. 8

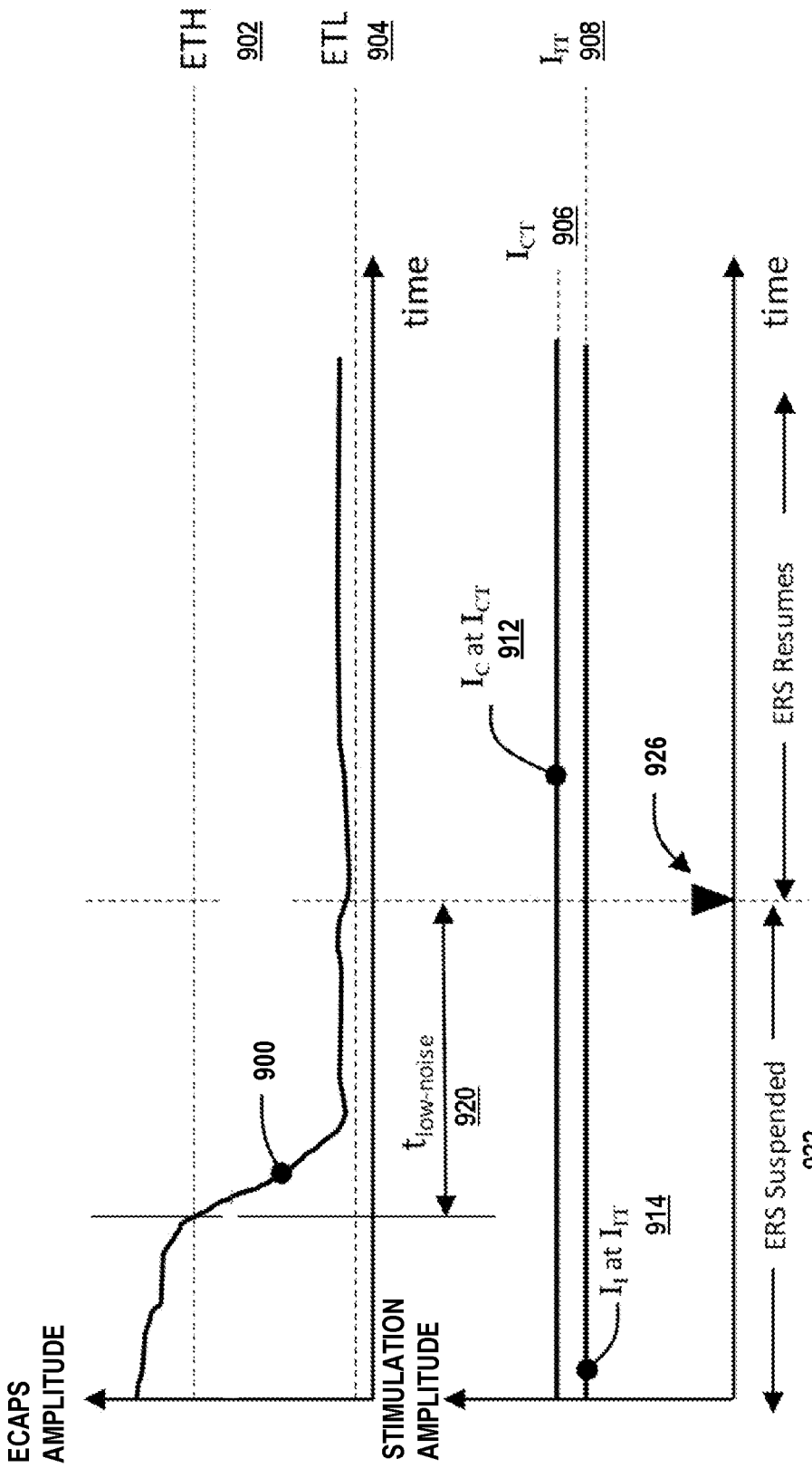

ETH
902
ETL
904
I_{IT}
908
I_{CT}
906
time
time
I_C at I_{CT}
912
926
ERS Resumes
924
900
$t_{low\text{-}noise}$
920
I_I at I_{IT}
914
ERS Suspended
922
ECAPS AMPLITUDE
STIMULATION AMPLITUDE

FIG. 9

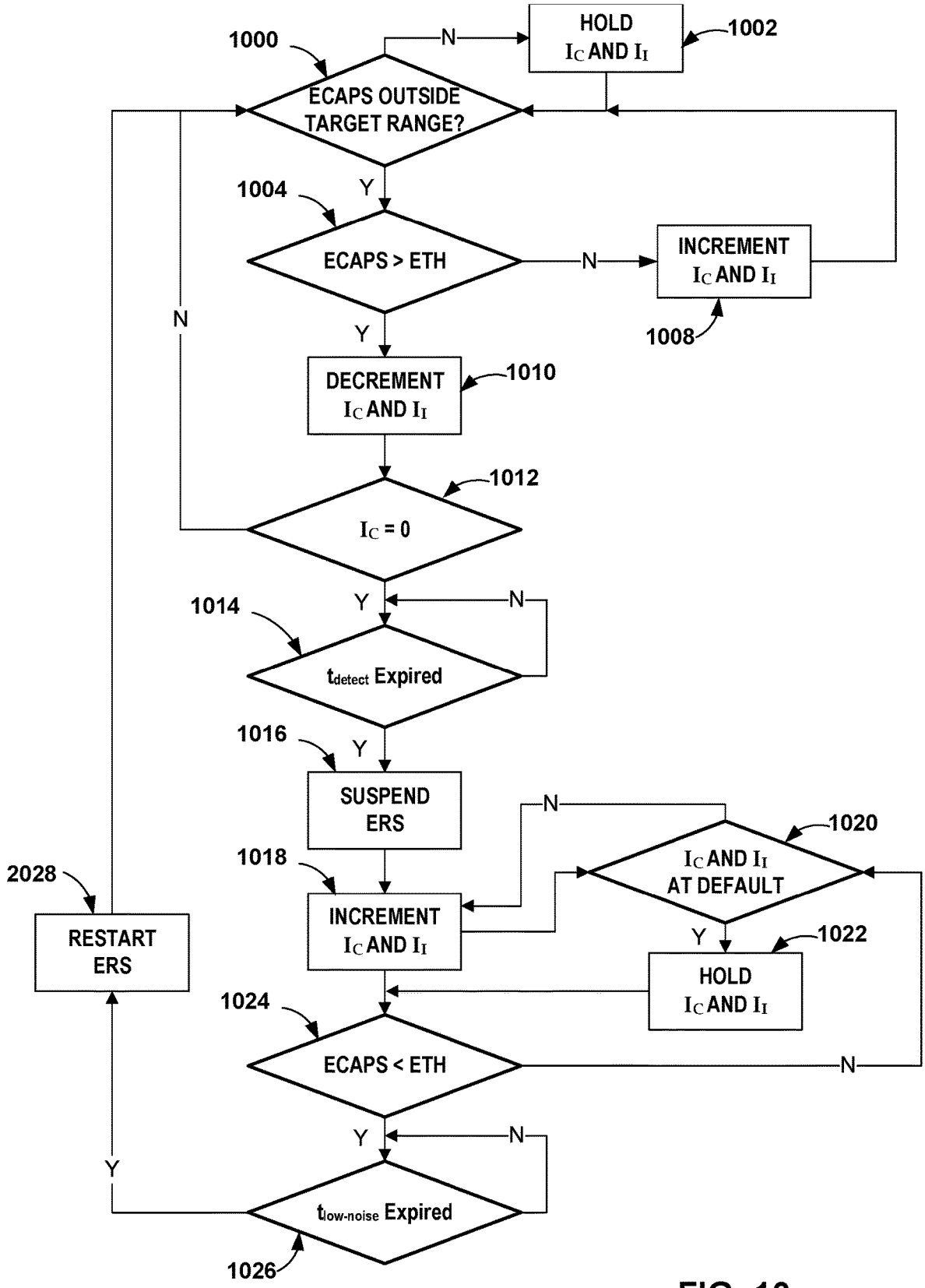

1000
ECAPS OUTSIDE TARGET RANGE?
N
HOLD I_C AND I_I
1002
Y
1004
ECAPS > ETH
N
INCREMENT I_C AND I_I
1008
Y
DECREMENT I_C AND I_I
1010
1012
I_C = 0
N
Y
1014
t_{detect} Expired
N
Y
1016
SUSPEND ERS
N
1020
I_C AND I_I AT DEFAULT
1018
INCREMENT I_C AND I_I
Y
1022
HOLD I_C AND I_I
2028
RESTART ERS
1024
ECAPS < ETH
N
Y
N
Y
$t_{low-noise}$ Expired
1026

FIG. 10

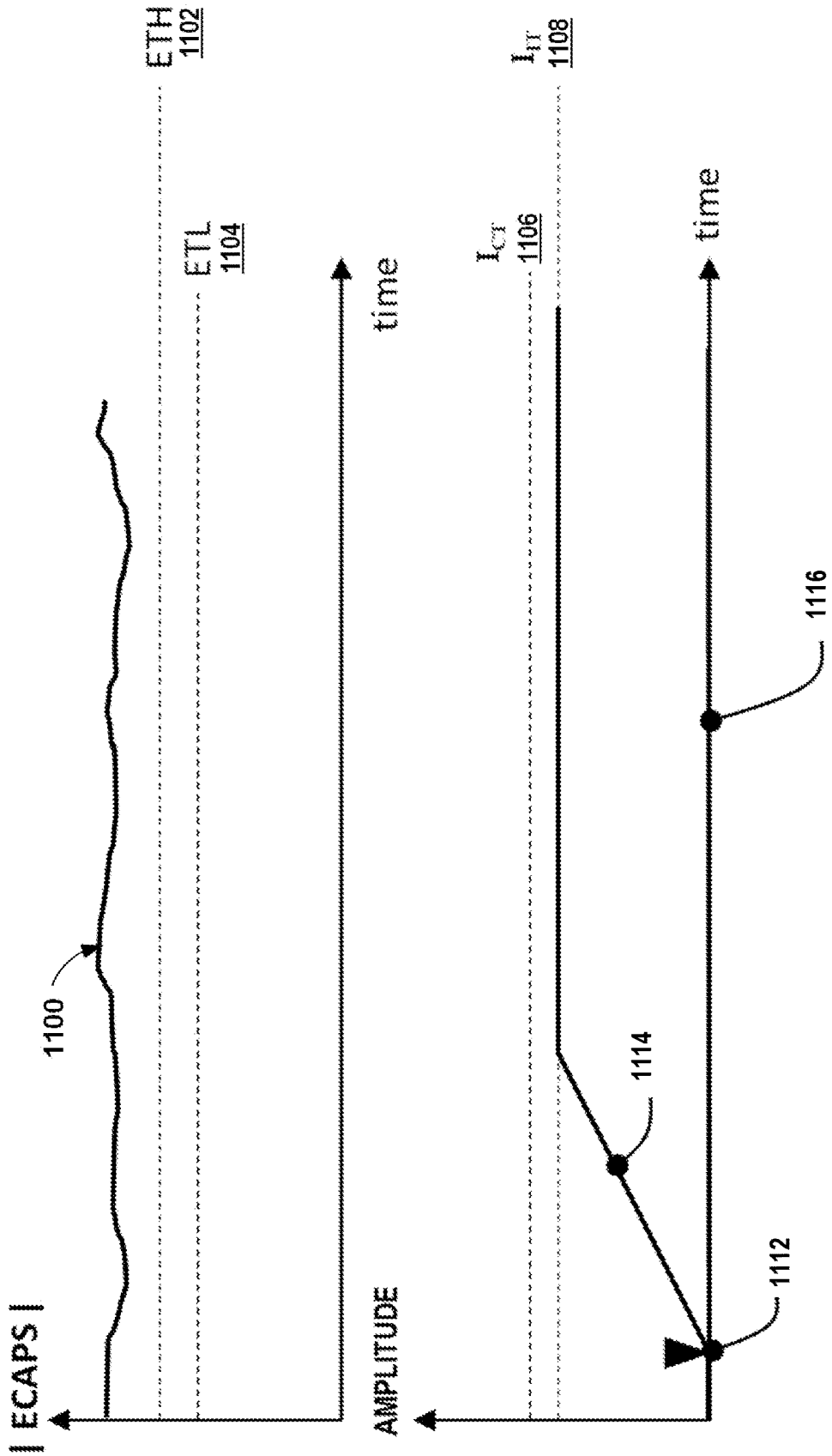

| ECAPS |
AMPLITUDE
time
ETH
1102
ETL
1104
1100
I_{CT}
1106
I_{IT}
1108
time
1114
1116
1112

FIG. 11

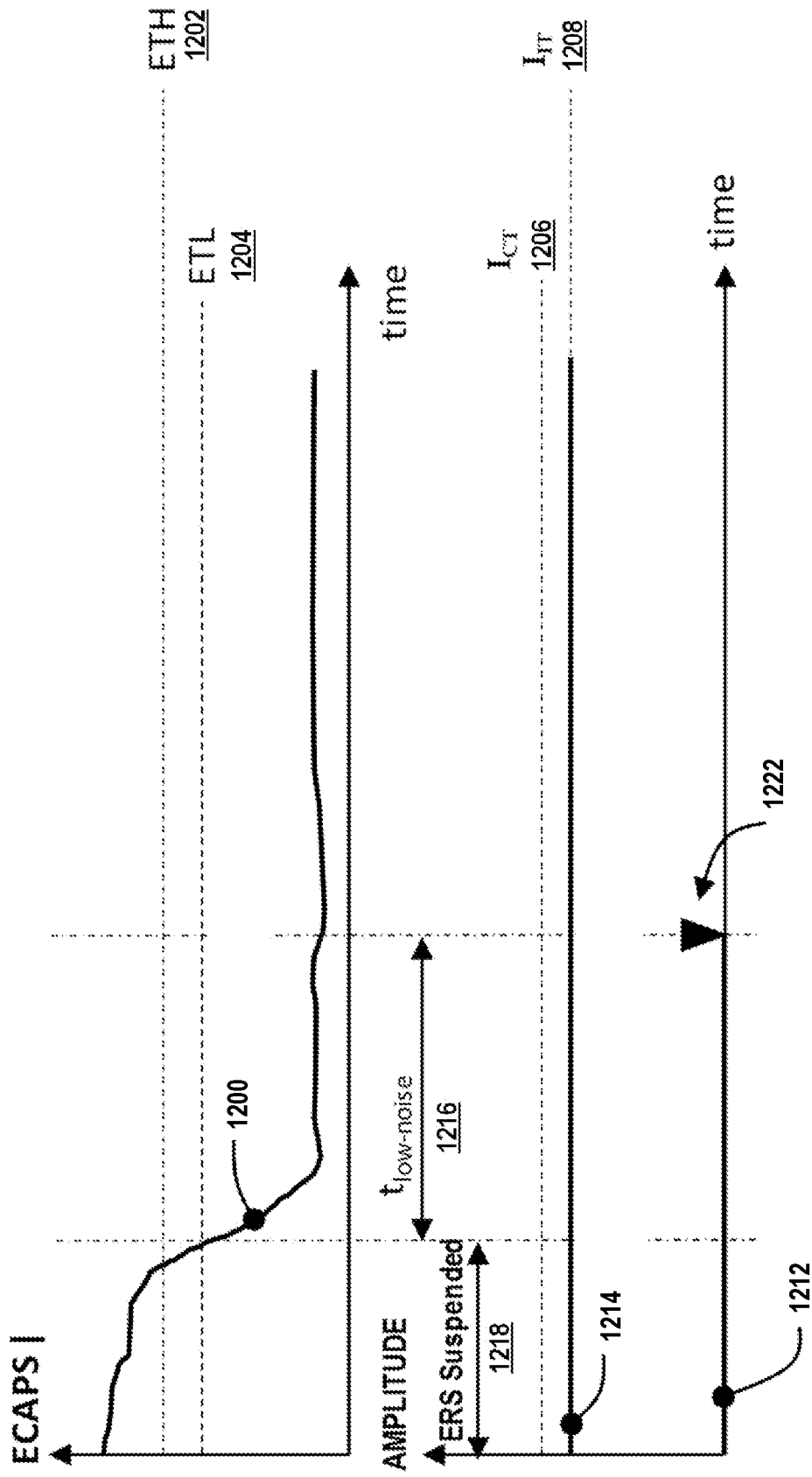

ETH
1202
ETL
1204
I_{CT}
1206
I_{IT}
1208
time
time
| ECAPS |
AMPLITUDE
1200
$t_{low-noise}$
1216
ERS Suspended
1218
1214
1212
1222

FIG. 12

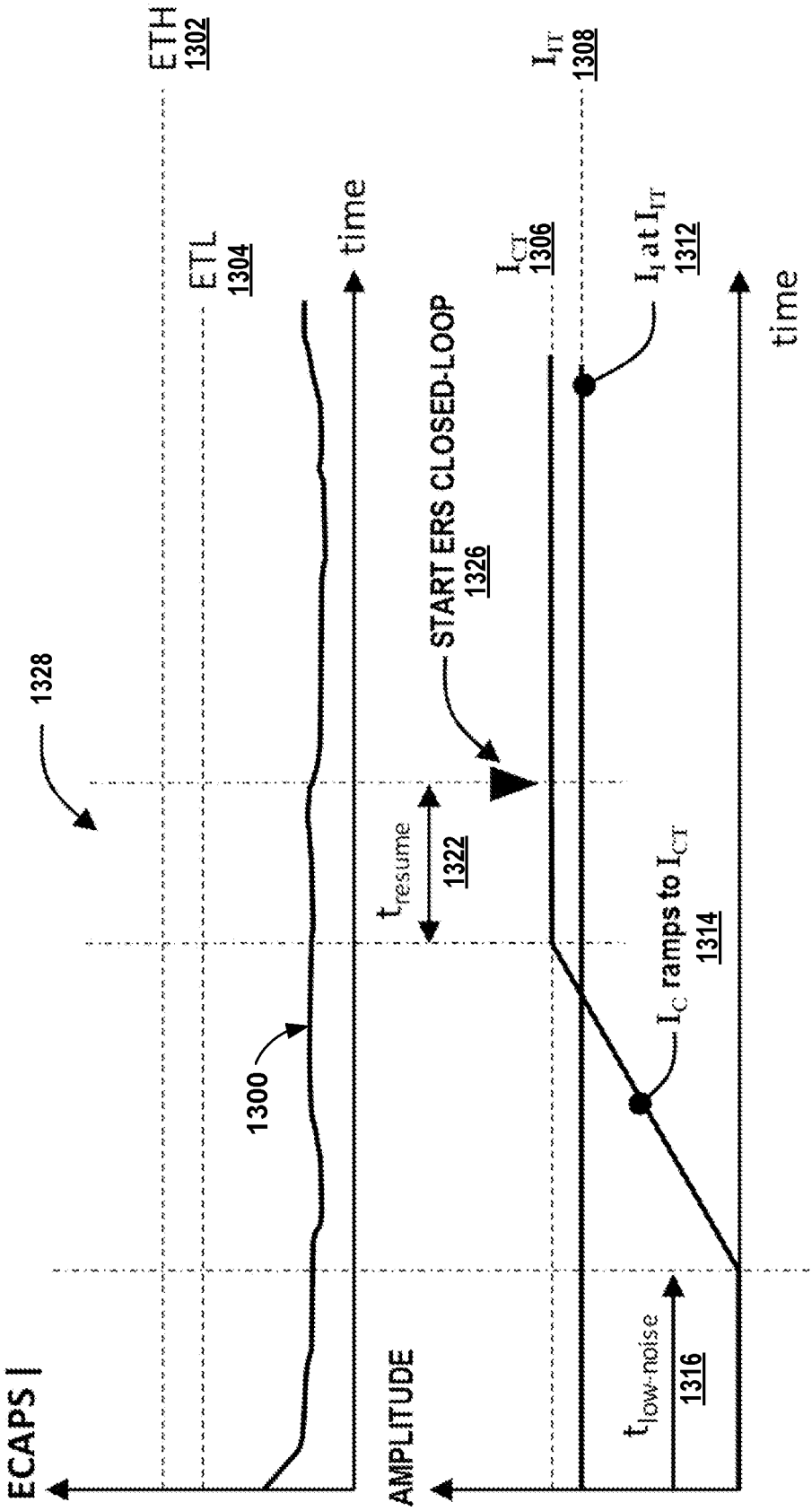

| ECAPS |
AMPLITUDE
time
ETH
1302
ETL
1304
1300
1328
START ERS CLOSED-LOOP
1326
t_{resume}
1322
$t_{low\text{-}noise}$
1316
I_{IT}
1308
I_{CT}
1306
I_I at I_{IT}
1312
I_C ramps to I_{CT}
1314
DETERMINE NOISE ABATED
1324
time

FIG. 13

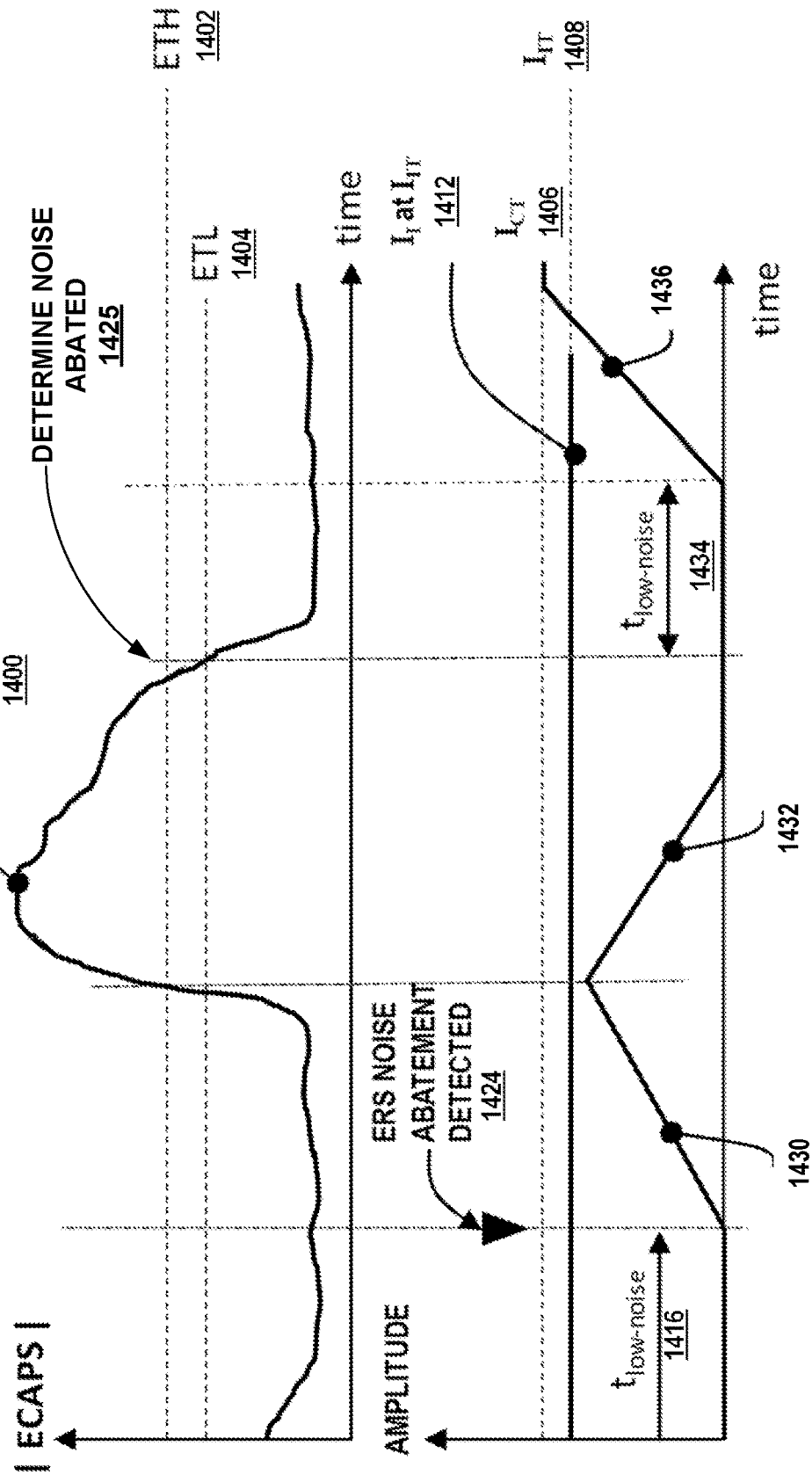

| ECAPS |
HIGH ECAP AMPLITUDE
1400
DETERMINE NOISE ABATED
1425
ETH
1402
ETL
1404
time
AMPLITUDE
ERS NOISE ABATEMENT DETECTED
1424
I_t at I_{IT}
1412
I_{CT}
1406
I_{IT}
1408
1436
$t_{low\text{-}noise}$
1434
time
1432
1430
$t_{low\text{-}noise}$
1416

FIG. 14

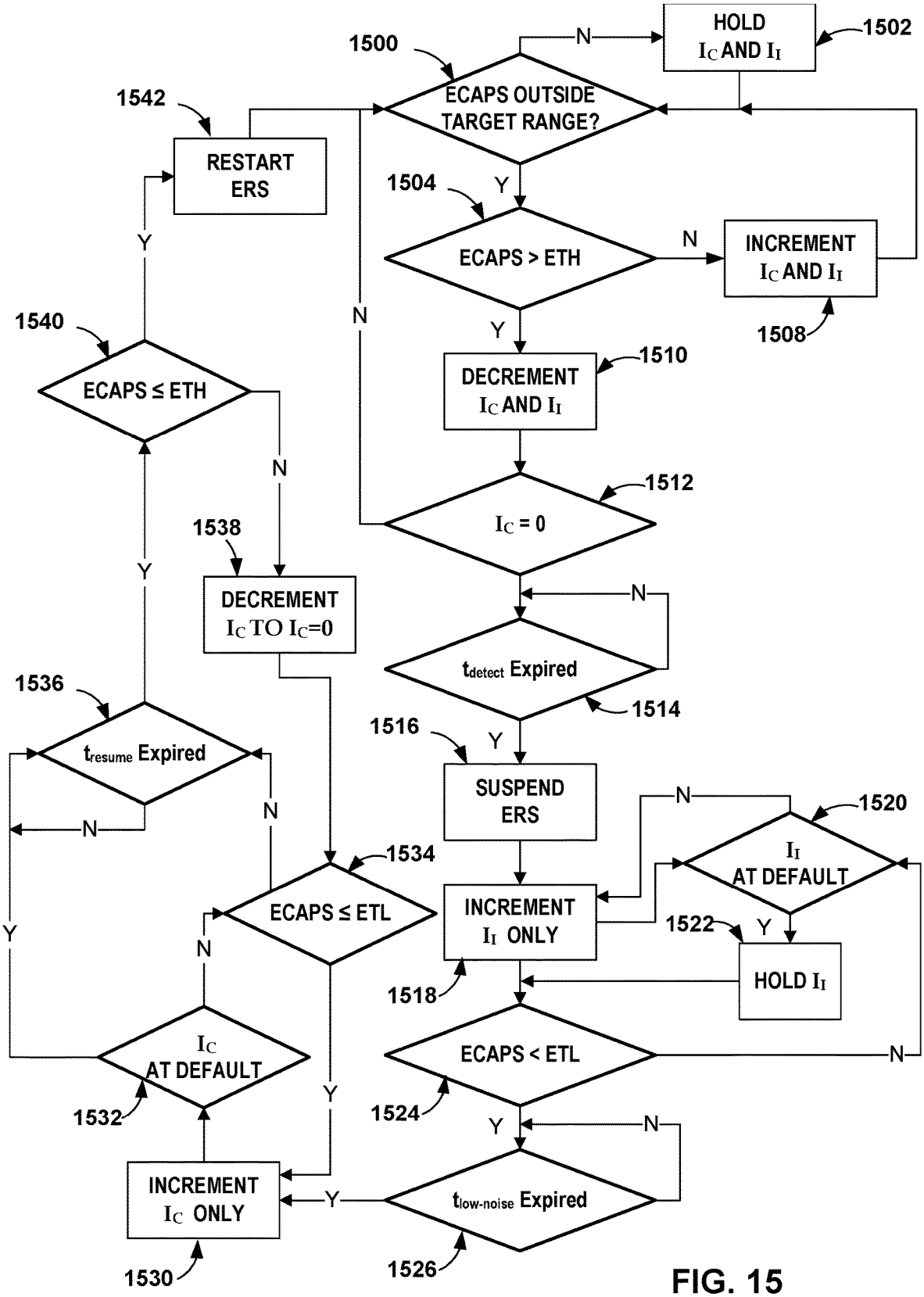

1500
ECAPS OUTSIDE TARGET RANGE?
N
HOLD I_C AND I_I
1502
1542
RESTART ERS
Y
1504
ECAPS > ETH
N
INCREMENT I_C AND I_I
1508
Y
1510
DECREMENT I_C AND I_I
1512
I_C = 0
N
1514
t_{detect} Expired
N
Y
1516
SUSPEND ERS
Y
1520
I_I AT DEFAULT
N
1522
Y
HOLD I_I
1518
INCREMENT I_I ONLY
N
1524
ECAPS < ETL
N
Y
1526
$t_{low-noise}$ Expired
N
Y
1530
INCREMENT I_C ONLY
Y
1532
I_C AT DEFAULT
N
Y
1534
ECAPS ≤ ETL
N
Y
1536
t_{resume} Expired
N
Y
1538
DECREMENT I_C TO I_C=0
1540
ECAPS ≤ ETH
N
Y

FIG. 15

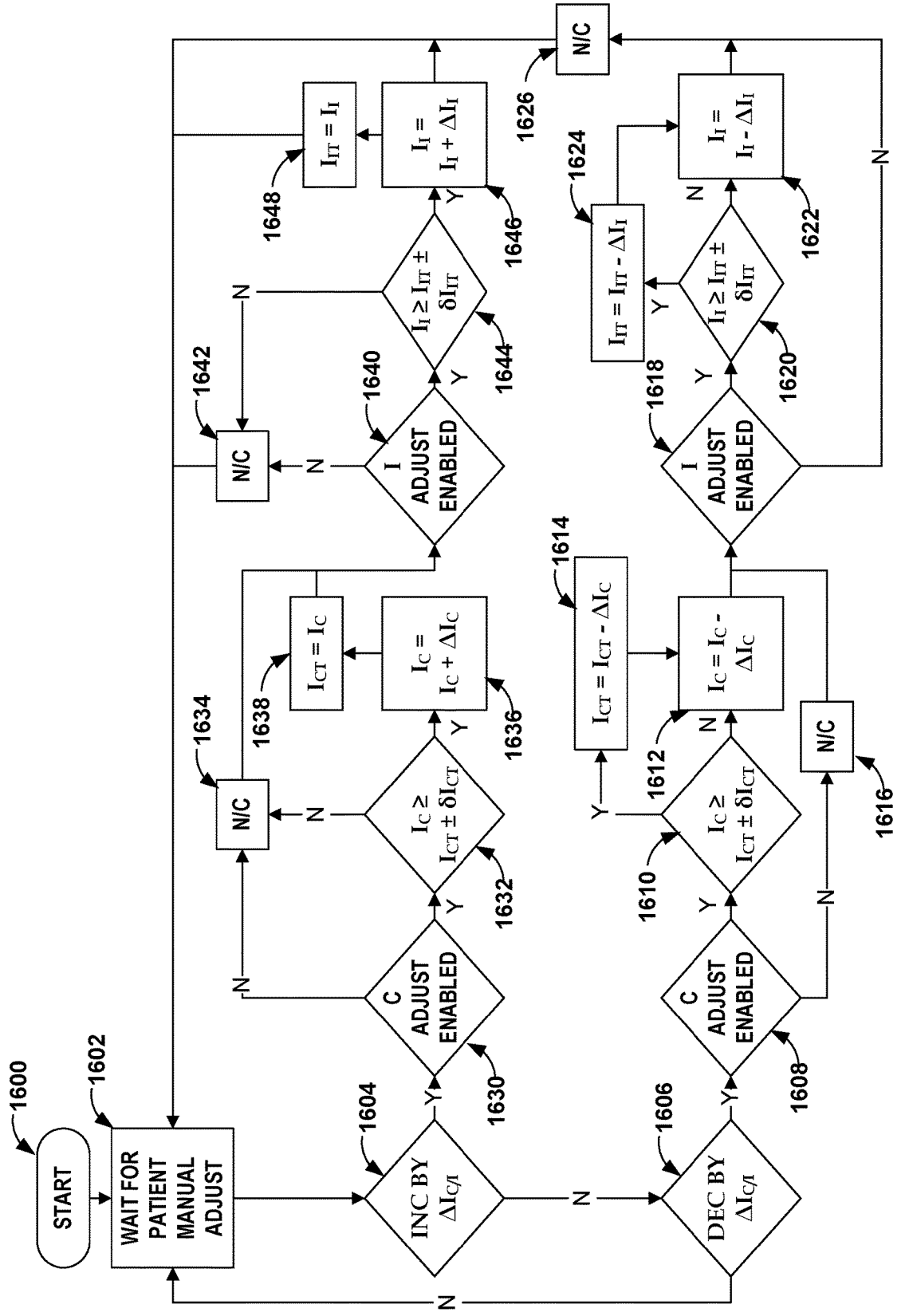

1600
START
1602
WAIT FOR PATIENT MANUAL ADJUST
1604
INC BY ΔIC/I
1606
DEC BY ΔIC/I
1608
C ADJUST ENABLED
1610
IC ≥ ICT ± δICT
1612
IC = IC - ΔIC
1614
ICT = ICT - ΔIC
1616
N/C
1618
I ADJUST ENABLED
1620
II ≥ IIT ± δIIT
1622
II = II - ΔII
1624
IIT = IIT - ΔII
1626
N/C
1630
C ADJUST ENABLED
1632
IC ≥ ICT ± δICT
1634
N/C
1636
IC = IC + ΔIC
1638
ICT = IC
1640
I ADJUST ENABLED
1642
N/C
1644
II ≥ IIT ± δIIT
1646
II = II + ΔII
1648
IIT = II
Y
N

FIG. 16

NOISE DETECTION AND MODULATION OF CLOSED-LOOP THERAPY ACTION

TECHNICAL FIELD

This disclosure generally relates to electrical stimulation therapy, and more specifically, control of electrical stimulation therapy.

BACKGROUND

Medical devices may be external or implanted and may be used to deliver electrical stimulation therapy to patients via various tissue sites to treat a variety of symptoms or conditions such as chronic pain, tremor, Parkinson's disease, epilepsy, urinary or fecal incontinence, sexual dysfunction, obesity, or gastroparesis. A medical device may deliver electrical stimulation therapy via one or more leads that include electrodes located proximate to target locations associated with the brain, the spinal cord, pelvic nerves, peripheral nerves, or the gastrointestinal tract of a patient. Stimulation proximate the spinal cord, proximate the sacral nerve, within the brain, and proximate peripheral nerves are often referred to as spinal cord stimulation (SCS), sacral neuromodulation (SNM), deep brain stimulation (DBS), and peripheral nerve stimulation (PNS), respectively.

SUMMARY

In general, the disclosure describes techniques for implementing closed-loop responsive stimulation in which a medical device may adjust therapy output based on sensed signals. A medical device according to this disclosure may implement techniques to mitigate the impact on the therapy output of noise coupled into the medical device. A medical device according to this disclosure also may implement techniques to mitigate the impact of manual adjustment while the medical device is subject to noise or is responding to changes in the patient's physiological signals.

In one example, this disclosure describes a method includes receiving information indicative of a sensed evoked compound action potential (ECAP) signal; determining a value of a characteristic of the ECAP signal based on the information, wherein the ECAP signal is elicited by a respective stimulation pulse of a plurality of stimulation pulses; executing a closed loop policy that adjusts, based on the value of the characteristic of the ECAP signal, a value of a parameter that at least partially defines stimulation therapy; determining that the value of the characteristic of the ECAP signal is outside of an expected range; and responsive to determining that the value of the characteristic of the ECAP signal is outside of the expected range, disabling the closed loop policy.

In another example, this disclosure describes a medical device comprising processing circuitry configured to: receive information indicative of a sensed evoked compound action potential (ECAP) signal determine a value of a characteristic of the ECAP signal based on the information, wherein the ECAP signal is elicited by respective stimulation pulses of a plurality of pulses; determine whether a value of a characteristic of the ECAP signal is outside of an expected range; execute a closed loop policy, wherein the closed loop policy adjusts a value of a parameter that at least partially defines stimulation therapy, based on the value of the characteristic of the ECAP signal; and responsive to determining that the value of the characteristic of the ECAP signal is outside of the expected range, disable the closed-loop policy.

In another example, this disclosure describes a computer-readable medium comprising instructions for causing programmable processor processing circuitry to: receive information indicative of a sensed evoked compound action potential (ECAP) signal determine a value of a characteristic of the ECAP signal based on the information, wherein the ECAP signal is elicited by respective stimulation pulses of a plurality of pulses; determine whether a value of a characteristic of the ECAP signal is outside of an expected range; execute a closed loop policy, wherein the closed loop policy adjusts a value of a parameter that at least partially defines stimulation therapy, based on the value of the characteristic of the ECAP signal; and responsive to determining that the value of the characteristic of the ECAP signal is outside of the expected range, disable the closed-loop policy.

In one example, this disclosure describes a method includes delivering, by stimulation generation circuitry of a medical device, electrical stimulation therapy to a patient, the electrical stimulation therapy comprising a plurality of pulses defined by a set of parameters; receiving, by processing circuitry of the medical device, a command from an external programmer to change a value of a parameter defining the plurality of pulses, wherein the external programmer is external to the medical device; determining, by the processing circuitry, that the requested change to the parameter is a request to increase the value of the parameter defining the plurality of pulses; determining, by the processing circuitry, that a control policy executed by the processing circuitry is determining values of the parameter that defines the electrical stimulation therapy; responsive to determining that the control policy is determining values of at the parameter that defines the electrical stimulation therapy, rejecting, by the processing circuitry, the request to change the value of the parameter.

In another example, this disclosure describes a medical device includes stimulation generation circuitry configured to deliver electrical stimulation therapy to a patient, the electrical stimulation therapy comprising a plurality of pulses defined by a set of parameters; and processing circuitry configured to: receive a command from an external programmer (**1602**) to change a value of a parameter defining the plurality of pulses, wherein the external programmer is external to the medical device; determine that the requested change to the parameter is a request to increase the value of the parameter defining the plurality of pulses; determining that a control policy executed by the processing circuitry is determining values of the parameter that defines the electrical stimulation therapy responsive to determining that the control policy is determining values of at the parameter that defines the electrical stimulation therapy, reject the request to change the value of the parameter.

In another example, this disclosure describes a computer-readable medium comprising instructions for causing a programmable processor of a medical device to: cause stimulation generation circuitry of the medical device to deliver electrical stimulation therapy to a patient, the electrical stimulation therapy comprising a plurality of pulses defined by a set of parameters; receive of the medical device, a command from an external programmer to change a value of a parameter defining the plurality of pulses, wherein the external programmer is external to the medical device; determine that the requested change to the parameter is a request to increase the value of the parameter defining the plurality of pulses; determine that a control policy executed

by the processing circuitry is determining values of the parameter that defines the electrical stimulation therapy; responsive to determining that the control policy is determining values of at the parameter that defines the electrical stimulation therapy, reject the request to change the value of the parameter.

The details of one or more examples of the disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the disclosure will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

FIG. **1** is a conceptual diagram illustrating an example system that includes an implantable medical device (IMD) configured to deliver spinal cord stimulation (SCS) therapy and an external programmer, in accordance with one or more techniques of this disclosure.

FIG. **2** is a block diagram illustrating an example configuration of components of the IMD of FIG. **1**, in accordance with one or more techniques of this disclosure.

FIG. **3** is a block diagram illustrating an example configuration of components of the external programmer of FIG. **1**, in accordance with one or more techniques of this disclosure.

FIG. **4** is a graph of example evoked compound action potentials (ECAPs) sensed for respective stimulation pulses, in accordance with one or more techniques of this disclosure.

FIG. **5** is an example timing diagram illustrating an example of electrical stimulation pulses, respective stimulation signals, and respective sensed ECAPs, in accordance with one or more techniques of this disclosure.

FIG. **6** is a timing diagram illustrating an example closed loop response to a sensed ECAP that is outside of a predetermined range, in accordance with one or more techniques of this disclosure.

FIG. **7** is a timing diagram illustrating an example technique for suspending a closed loop algorithm, in accordance with one or more techniques of this disclosure.

FIG. **8** is a timing diagram illustrating an example medical device providing electrical stimulation while suspending a closed loop algorithm, in accordance with one or more techniques of this disclosure.

FIG. **9** is a timing diagram illustrating an example of recovering a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure.

FIG. **10** is a flow diagram illustrating an example operation for suspending and recovering a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure.

FIG. **11** is a timing diagram illustrating an example of a medical device providing electrical stimulation while suspending a closed loop algorithm, in accordance with one or more techniques of this disclosure.

FIG. **12** is a timing diagram illustrating an example of a medical device sensing noise abatement while suspending a closed loop algorithm, in accordance with one or more techniques of this disclosure.

FIG. **13** is a timing diagram illustrating an example of re-starting a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure.

FIG. **14** is a timing diagram illustrating an example of an attempted recovery for a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure.

FIG. **15** is a flow diagram illustrating an example operation for suspending and recovering a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure.

FIG. **16** is a flow chart illustrating an example operation for managing patient input while delivering electrical stimulation therapy, in accordance with one or more techniques of this disclosure.

DETAILED DESCRIPTION

The disclosure describes techniques for implementing closed-loop responsive stimulation in which a medical device may adjust therapy output based on sensed signals. A medical device according to this disclosure may include techniques to mitigate the impact on the therapy output of noise coupled into the medical device.

In some examples, a closed-loop responsive medical device may control electrical stimulation therapy by sensing an evoked compound action potential (ECAP). An ECAPS Responsive Stimulation (ERS) therapy based medical device may be configured to modulate therapy output (e.g., control and adjust one or more parameter values that define therapy) in response to measured ECAPS. Therapy output may be in the form of an electrical stimulation pulse, such as a voltage pulse or a current pulse, defined by a set of therapy parameters, e.g. stimulation amplitude, frequency, pulse width, pulse shape and other parameters. For example, in response to determining that a characteristic of the measured ECAP signal (e.g., a voltage amplitude) has deviated from a target ECAP characteristic, the system may change the values of one or more stimulation parameters of the next one or more output pulses delivered to the patient. For example, the system may increase or decrease a current amplitude or a pulse width of the output electrical stimulation pulse.

In some examples, changes in patient physiology, such as changes in hydration level, patient response to a virus, changes in drug therapy, activity level and many other factors may cause a given output pulse to result in a different measured ECAP. Also, changes in patient posture may change a distance between an implanted electrode and a target nerve. For example, as a patient moves between a supine posture state to a standing posture state or when a patient coughs or sneezes may change relative location of one or more electrodes and a target nerve. An ERS therapy based medical device may include a closed-loop algorithm to reduce the device stimulation output when high ECAP signals are measured to prevent over-stimulation and may lead to patient discomfort. When the sensed ECAP signals reduce, the closed-loop ERS algorithm may return the medical device output settings to default values.

However, a closed-loop responsive medical device may be susceptible to noise, such as external noise that may be coupled into the sensing system that the medical device employs for feedback into closed-loop control. The noise may adversely impact the ability of the medical device to appropriately detect the ECAP signal from patient tissues, such as the system sensing the amplitude of the noise when it is greater than the ECAP signals themselves. In response to the detected noise, the system may respond by reducing stimulation to the patient. Reduced stimulation can lead to under stimulation and resulting patient discomfort from untreated symptoms. In some examples, the patient may have an adjustment tool (e.g., an external programmer) configured to communicate with the medical device to increase or decrease therapy intensity based on the patient's

perceived response to the therapy provided by the medical device. A patient may manually increase the default stimulation level using the adjustment tool. In examples in which the patient manually adjusts the default stimulation level while the medical device is reducing stimulation intensity because of the presence of noise, or the medical device is adapting to changes in the patient's physiological signals, when the noise is removed, or when the physiological signals change again, the new default stimulation parameter values may cause the system to deliver inappropriate stimulation (over or under stimulation) resulting in patient discomfort. A medical device according to this disclosure may include techniques to mitigate the impact of noise on the therapy output and mitigate the impact of manual adjustment while the medical device is subject to noise or is responding to changes in the patient's physiological signals. Also, a medical device according to this disclosure may determine the presence of noise and alter the closed-loop algorithm to provide the necessary therapy to the patient and avoid prolonged under stimulation caused by the noise.

The term "stimulation signal" may be used herein to describe a signal that the medical device senses that represents a stimulation pulse delivered by the medical device. This stimulation signal may also be referred to as an "artifact" in the sensed signals. One or more sense electrodes of the medical device may detect a stimulation signal due to one or more stimulation electrodes proximate to the sense electrodes delivering a stimulation pulse. In this way, delivering a stimulation pulse may cause the medical device to sense a respective stimulation signal during a window of time substantially overlapping with the delivery of the stimulation pulse. An electrical potential of the stimulation electrodes during the window of time in which the medical device delivers the stimulation pulse may cause the sensing circuitry of the medical device to generate a sense signal which is representative of the stimulation pulse delivered during the window of time. The stimulation signal is thus representative of electrical potential changes in tissue directly caused by the delivered stimulation pulse. Conversely, an ECAP is a signal representative of physiological action (e.g., depolarizing nerve fibers) caused by the stimulation pulse. In this way, stimulation signals may be at least partially distinguished from ECAPs, since ECAPs represent electrical signals sensed by the medical device due to an excitation of target tissue of the patient in response to the delivery of a stimulation pulse. In other words, an ECAP represents a detected physiological response to a stimulation pulse, and a stimulation signal represents the direct detection of the stimulation pulse itself and associated changes in the charge in tissue.

In some examples, the medical device may deliver stimulation pulses in the form of control pulses and informed pulses. More specifically, electrical stimulation pulses are delivered in the form of informed pulses and control pulses that are at least partially interleaved with each other. Control pulses (e.g., stimulation signal test pulses) are those stimulation pulses that are configured to elicit one or both of a stimulation signal and a detectable ECAP signal. In some examples, control pulses may contribute to the therapy for a patient. In other examples, control pulses do not contribute to the therapy for the patient, e.g., non-therapeutic pulses. In this manner, control pulses may or may not be configured to elicit a therapeutic effect for the patient. Informed pulses are those stimulation pulses that are at least partially defined by one or more parameters based on the detectable stimulation signal elicited from one or more control pulses. In some examples, one or more informed pulses are at least partially defined by one or more parameters based on a respective ECAP elicited from one or more control pulses. In this manner, the informed pulses are "informed" by the ECAP signal detected from a control pulse. Informed pulses are also configured to provide a therapy to a patient, such as paresthesia that relieves pain symptoms.

As described herein, a medical device may be configured to deliver a plurality of informed pulses and/or control pulses configured to provide a therapy to the patient based on one or more parameters of ECAP signals elicited by previously delivered control pulses. The medical device, in some cases, may deliver a plurality of informed pulses, which are configured to provide or at least contribute to a therapy to the patient based on one or more parameters of ECAP signals elicited by control pulses. In some examples, the control pulses may be configured to elicit ECAP signals without contributing to the therapy of the patient. However, in other examples, the control pulses may provide therapy to the patient either alone or in combination with the informed pulses. The control pulses may be interleaved with the delivery of the informed pulses. For example, the medical device may alternate the delivery of informed pulses with control pulses such that a control pulse is delivered, and an ECAP signal is sensed from the control pulses, between consecutive informed pulses. In some examples, multiple control pulses are delivered, and respective ECAP signals sensed, between the delivery of consecutive informed pulses.

In some examples, multiple informed pulses will be delivered between consecutive control pulses. In any case, the informed pulses may be delivered according to a predetermined pulse frequency selected so that the informed pulses can produce or contribute to a therapeutic result for the patient. One or more control pulses are then delivered, and the respective ECAP signals sensed, within one or more time windows between consecutive informed pulses delivered according to the predetermined pulse frequency. The predetermined pulse frequency may be a single consistent frequency or a varied frequency that varies over time. The pulse width of the control pulses may be shorter than the pulse width of the informed pulses to enable the medical device to detect the ECAP signals elicited from the control pulses. Put another way, the longer pulse width of the informed pulses may prevent all phases of the resulting stimulation signals and prevent the resulting ECAP signals from being detected due to, for example, overlapping of the informed pulse with the ECAP signal and the stimulation signal. In this manner, a medical device can administer informed pulses from the medical device uninterrupted while one or both of ECAPs and stimulation signals can be sensed from control pulses delivered during times at which the informed pulses are not being delivered.

In some examples, a pulse frequency of stimulation pulses (e.g., control pulses and/or informed pules) delivered by the medical device may be within a range from 50 Hertz (Hz) to 70 Hz, but this is not required. In some examples, a pulse frequency of stimulation pulses (e.g., control pulses and/or informed pules) delivered by the medical device may be within a range from 0.1 Hz to 100 kilohertz (KHz), The pulse frequency of the stimulation pulses may be within a range from 0.5 KHz to 5 KHz (e.g., 1 KHz) and/or within a range from 5 KHz to 15 KHz (e.g., 10 KHz), as examples. In some examples, when a frequency of control pulses and informed pulses increases, a maximum pulse width of control pulses which do not obscure respective control pulses decreases. These ranges are just examples. In some examples, both control and informed pulses can be delivered

over a wide range of frequencies and informed pulses may be interspersed between multiple control pulses.

Although electrical stimulation is generally described herein in the form of electrical stimulation pulses, electrical stimulation may be delivered in non-pulse form in other examples. For example, electrical stimulation may be delivered as a signal having various waveform shapes, frequencies, and amplitudes. Therefore, electrical stimulation in the form of a non-pulse signal may be a continuous signal than may have a sinusoidal waveform or other continuous waveform.

FIG. **1** is a conceptual diagram illustrating an example system that includes an implantable medical device (IMD) configured to deliver spinal cord stimulation (SCS) therapy and an external programmer, in accordance with one or more techniques of this disclosure. Although the techniques described in this disclosure are generally applicable to a variety of medical devices including external devices and IMDs, application of such techniques to IMDs and, more particularly, implantable electrical stimulators (e.g., neurostimulators) will be described for purposes of illustration. The disclosure will refer to an implantable SCS system for purposes of illustration, but the techniques described may also apply, without limitation, to other types of medical devices or other therapeutic applications of medical devices.

As shown in FIG. **1**, system **100** includes an IMD **110**, leads **130**A and **130**B, and external programmer **150** shown in conjunction with a patient **105**, who is ordinarily a human patient. In the example of FIG. **1**, IMD **110** is an implantable electrical stimulator that is configured to generate and deliver electrical stimulation therapy to patient **105** via one or more electrodes of electrodes of leads **130**A and/or **130**B (collectively, "leads **130**"), e.g., for relief of chronic pain or other symptoms. In other examples, IMD **110** may be coupled to a single lead carrying multiple electrodes or more than two leads each carrying multiple electrodes. This electrical stimulation may be delivered in the form of stimulation pulses. In some examples, IMD **110** may be configured to generate and deliver stimulation pulses to include control pulses configured to elicit ECAP signals. The control pulses may or may not contribute to therapy in some examples. In some examples, IMD **110** may, in addition to control pulses, deliver informed pulses that contribute to the therapy for the patient, but which do not elicit detectable ECAPs. IMD **110** may be a chronic electrical stimulator that remains implanted within patient **105** for weeks, months, or even years. In other examples, IMD **110** may be a temporary, or trial, stimulator used to screen or evaluate the efficacy of electrical stimulation for chronic therapy. In one example, IMD **110** is implanted within patient **105**, while in another example, IMD **110** is an external device coupled to percutaneously implanted leads. In some examples, IMD **110** uses one or more leads, while in other examples, IMD **110** is leadless.

IMD **110** may be constructed of any polymer, metal, or composite material sufficient to house the components of IMD **110** (e.g., components illustrated in FIG. **2**) within patient **105**. In this example, IMD **110** may be constructed with a biocompatible housing, such as titanium or stainless steel, or a polymeric material such as silicone, polyurethane, or a liquid crystal polymer, and surgically implanted at a site in patient **105** near the pelvis, abdomen, or buttocks. In other examples, IMD **110** may be implanted within other suitable sites within patient **105**, which may depend, for example, on the target site within patient **105** for the delivery of electrical stimulation therapy. The outer housing of IMD **110** may be configured to provide a hermetic seal for components, such as a rechargeable or non-rechargeable power source. In addition, in some examples, the outer housing of IMD **110** is selected from a material that facilitates receiving energy to charge the rechargeable power source.

Electrical stimulation energy, which may be, for example, constant current or constant voltage-based pulses may be delivered from IMD **110** to one or more target tissue sites of patient **105** via one or more electrodes (not shown) of implantable leads **130**. In the example of FIG. **1**, leads **130** carry electrodes that are placed adjacent to the target tissue of spinal cord **120**. One or more of the electrodes may be disposed at a distal tip of a leads **130** and/or at other positions at intermediate points along the lead. Leads **130** may be implanted and coupled to IMD **110**. The electrodes may transfer electrical stimulation generated by an electrical stimulation generator in IMD **110** to tissue of patient **105**. Although leads **130** may each be a single lead, leads **130** may include a lead extension or other segments that may aid in implantation or positioning of leads **130**. In some other examples, IMD **110** may be a leadless stimulator with one or more arrays of electrodes arranged on a housing of the stimulator rather than leads that extend from the housing. In addition, in some other examples, system **100** may include one lead or more than two leads, each coupled to IMD **110** and directed to similar or different target tissue sites.

The electrodes of leads **130** may be electrode pads on a paddle lead, circular (e.g., ring) electrodes surrounding the body of the lead, conformable electrodes, cuff electrodes, segmented electrodes (e.g., electrodes disposed at different circumferential positions around the lead instead of a continuous ring electrode), any combination thereof (e.g., ring electrodes and segmented electrodes) or any other type of electrodes capable of forming unipolar, bipolar or multipolar electrode combinations for therapy. Ring electrodes arranged at different axial positions at the distal ends of lead **130** will be described for purposes of illustration.

The deployment of electrodes via leads **130** is described for purposes of illustration, but arrays of electrodes may be deployed in different ways. For example, a housing associated with a leadless stimulator may carry arrays of electrodes, e.g., rows and/or columns (or other patterns), to which shifting operations may be applied. Such electrodes may be arranged as surface electrodes, ring electrodes, or protrusions. As a further alternative, electrode arrays may be formed by rows and/or columns of electrodes on one or more paddle leads. In some examples, electrode arrays include electrode segments, which are arranged at respective positions around a periphery of a lead, e.g., arranged in the form of one or more segmented rings around a circumference of a cylindrical lead. In other examples, one or more of leads **130** are linear leads having 8 ring electrodes along the axial length of the lead. In another example, the electrodes are segmented rings arranged in a linear fashion along the axial length of the lead and at the periphery of the lead.

The stimulation parameter of a therapy stimulation program that defines the stimulation pulses of electrical stimulation therapy by IMD **110** through the electrodes of leads **130** may include information identifying which electrodes have been selected for delivery of stimulation according to a stimulation program, the polarities of the selected electrodes, i.e., the electrode combination for the program, and voltage or current amplitude, pulse frequency, pulse width, pulse shape of stimulation delivered by the electrodes. These stimulation parameters of stimulation pulses (e.g., control pulses and/or informed pulses) are typically predetermined parameter values determined prior to delivery of the stimulation pulses (e.g., set according to a stimulation program).

However, in some examples, system **100** changes one or more parameter values automatically based on one or more factors or based on user input.

A test stimulation program may define stimulation parameter values that define control pulses delivered by IMD **110** through at least some of the electrodes of leads **130**. These stimulation parameter values may include information identifying which electrodes have been selected for delivery of control pulses, the polarities of the selected electrodes, i.e., the electrode combination for the test stimulation program, and voltage or current amplitude, pulse frequency, pulse width, and pulse shape of stimulation delivered by the electrodes. The stimulation signals (e.g., one or more stimulation pulses or a continuous stimulation waveform) defined by the parameters of each test stimulation program are configured to evoke a compound action potential from nerves. In some examples, the test stimulation program defines when the control pulses are to be delivered to the patient based on the frequency and/or pulse width of the informed pulses when informed pulse are also delivered. In some examples, the stimulation defined by each test stimulation program are not intended to provide or contribute to therapy for the patient. In other examples, the stimulation defined by each test stimulation program may contribute to therapy when the control pulses elicit one or both of detectable ECAP signals. In this manner, the test stimulation program may define stimulation parameters the same or similar to the stimulation parameters of therapy stimulation programs.

Although FIG. **1** is directed to SCS therapy, e.g., used to treat pain, in other examples system **100** may be configured to treat any other condition that may benefit from electrical stimulation therapy. For example, system **100** may be used to treat tremor, Parkinson's disease, epilepsy, a pelvic floor disorder (e.g., urinary incontinence or other bladder dysfunction, fecal incontinence, pelvic pain, bowel dysfunction, or sexual dysfunction), obesity, gastroparesis, or psychiatric disorders (e.g., depression, mania, obsessive compulsive disorder, anxiety disorders, and the like). In this manner, system **100** may be configured to provide therapy taking the form of deep brain stimulation (DBS), peripheral nerve stimulation (PNS), peripheral nerve field stimulation (PNFS), cortical stimulation (CS), pelvic floor stimulation, gastrointestinal stimulation, or any other stimulation therapy capable of treating a condition of patient **105**.

In some examples, leads **130** includes one or more sensors configured to allow IMD **110** to monitor one or more parameters of patient **105**, such as patient activity, pressure, temperature, posture, or other characteristics. The one or more sensors may be provided in addition to, or in place of, therapy delivery by leads **130**.

IMD **110** is configured to deliver electrical stimulation therapy to patient **105** via selected combinations of electrodes carried by one or both of leads **130**, alone or in combination with an electrode carried by or defined by an outer housing of IMD **110**. The target tissue for the electrical stimulation therapy may be any tissue affected by electrical stimulation, which may be in the form of electrical stimulation pulses or continuous waveforms. In some examples, the target tissue includes nerves, smooth muscle, or skeletal muscle. In the example illustrated by FIG. **1**, the target tissue is tissue proximate spinal cord **120**, such as within an intrathecal space or epidural space of spinal cord **120**, or, in some examples, adjacent nerves that branch off spinal cord **120**. Leads **130** may be introduced into spinal cord **120** in via any suitable region, such as the thoracic, cervical, or lumbar regions. Stimulation of spinal cord **120** may, for example, prevent pain signals from traveling through spinal cord **120** and to the brain of patient **105**. Patient **105** may perceive the interruption of pain signals as a reduction in pain and, therefore, efficacious therapy results. In other examples, stimulation of spinal cord **120** may produce paresthesia which may be reduce the perception of pain by patient **105**, and thus, provide efficacious therapy results.

IMD **110** generates and delivers electrical stimulation therapy to a target stimulation site within patient **105** via the electrodes of leads **130** to patient **105** according to one or more therapy stimulation programs. A therapy stimulation program defines values for one or more parameters that define an aspect of the therapy delivered by IMD **110** according to that program. For example, a therapy stimulation program that controls delivery of stimulation by IMD **110** in the form of pulses may define values for voltage or current pulse amplitude, pulse width, pulse shape, and pulse rate (e.g., pulse frequency) for stimulation pulses delivered by IMD **110** according to that program.

In some examples where relevant phases of stimulation signals cannot be detected from the types of pulses intended to be delivered to provide therapy to the patient, control pulses and informed pulses may be delivered. For example, IMD **110** is configured to deliver control stimulation in the form of control pulses to patient **105** via a combination of electrodes of leads **130**, alone or in combination with an electrode carried by or defined by an outer housing of IMD **110**. The tissue targeted by the control stimulation may be the same tissue targeted by the electrical stimulation therapy, delivered in the form of informed pulses. But IMD **110** may deliver control stimulation pulses via the same, at least some of the same, or different electrodes. Since control stimulation pulses are delivered in an interleaved manner with informed pulses, a clinician and/or user may select any desired electrode combination for informed pulses. Like the electrical stimulation therapy, the control stimulation may be in the form of electrical stimulation pulses or continuous waveforms.

In one example, each control stimulation pulse may include a balanced, bi-phasic square pulse that employs an active recharge phase. However, in other examples, the control stimulation pulses may include a monophasic pulse followed by a passive recharge phase. In other examples, a control pulse may include an imbalanced bi-phasic portion and a passive recharge portion. In other examples, a control stimulation pulse may include a tri-phasic pulse or pulse having more than three phases. Although not necessary, a bi-phasic control pulse may include an interphase interval between the positive and negative phase to promote propagation of the nerve impulse in response to the first phase of the bi-phasic pulse. The control stimulation may be delivered without interrupting the delivery of the electrical stimulation informed pulses, such as during the window between consecutive informed pulses. In some cases, the control pulses may elicit an ECAP signal from the tissue, and IMD **110** may sense the ECAP signal via two or more electrodes on leads **130**. In cases where the control stimulation pulses are applied to spinal cord **120**, the signal may be sensed by IMD **110** from spinal cord **120**.

IMD **110** may deliver control stimulation to a target stimulation site within patient **105** via the electrodes of leads **130** according to one or more test stimulation programs. The one or more test stimulation programs may be stored in a storage device of IMD **110**. Each test program of the one or more test stimulation programs includes values for one or more parameters that define an aspect of the control stimulation delivered by IMD **110** according to each respective

test program, such as current or voltage amplitude, pulse width, pulse frequency, electrode combination, and, in some examples, timing based on informed pulses to be delivered to patient **105**. In some examples, IMD **110** delivers control stimulation to patient **105** according to multiple test stimulation programs.

A user, such as a clinician (not shown in FIG. **1**) or patient **105**, may interact with a user interface (not shown in FIG. **1**) of external programmer **150** to program IMD **110**. Programming of IMD **110** may refer generally to the generation and transfer of commands, programs, or other information to control the operation of IMD **110**. In this manner, IMD **110** may receive the transferred commands and programs from external programmer **150** to control electrical stimulation therapy (e.g., informed pulses) and control stimulation (e.g., control pulses). For example, external programmer **150** may transmit therapy stimulation programs, test stimulation programs, stimulation parameter adjustments, therapy stimulation program selections, test program selections, user input, or other information to control the operation of IMD **110**, e.g., by wireless telemetry or wired connection. As described herein, stimulation delivered to the patient may include control pulses, and, in some examples, stimulation may include control pulses and informed pulses.

In some cases, external programmer **150** may be called a physician or clinician programmer if it is primarily intended for use by a physician or clinician. In other cases, external programmer **150** may be characterized as a patient programmer if it is primarily intended for use by a patient. A patient programmer may be generally accessible to patient **105** and, in many cases, may be a portable device that may accompany patient **105** throughout the patient's daily routine. For example, a patient programmer may receive input from patient **105** when the patient wishes to terminate or change electrical stimulation therapy. In general, a physician or clinician programmer may support selection and generation of programs by a clinician for use by IMD **110**, whereas a patient programmer may support adjustment and selection of such programs by a patient during ordinary use. In other examples, external programmer **150** may include, or be part of, an external charging device that recharges a power source of IMD **110**. In this manner, a user may program and charge IMD **110** using one device, or multiple devices.

As described herein, information may be transmitted between external programmer **150** and IMD **110**. Therefore, IMD **110** and external programmer **150** may communicate via wireless communication using any techniques known in the art. Examples of communication techniques may include, for example, radiofrequency (RF) telemetry and inductive coupling, but other techniques are also contemplated. In some examples, external programmer **150** includes a communication head that may be placed proximate to the patient's body near the IMD **110** implant site to improve the quality or security of communication between IMD **110** and external programmer **150**. Communication between external programmer **150** and IMD **110** may occur during power transmission or separate from power transmission.

In some examples, IMD **110**, in response to commands from external programmer **150**, delivers electrical stimulation therapy according to a plurality of therapy stimulation programs to a target tissue site of the spinal cord **120** of patient **105** via electrodes (not depicted) on leads **130**. In some examples, IMD **110** modifies therapy stimulation programs as therapy needs of patient **105** evolve over time. For example, the modification of the therapy stimulation programs may cause the adjustment of at least one parameter of the plurality of informed pulses. When patient **105** receives the same therapy for an extended period, the efficacy of the therapy may be reduced. In some cases, parameters of the plurality of informed pulses may be automatically updated.

Efficacy of electrical stimulation therapy may, in some cases, be indicated by one or more characteristics (e.g. an amplitude of or between one or more peaks or an area under the curve of one or more peaks) of an action potential that is evoked by a stimulation pulse delivered by IMD **110** (i.e., a characteristic of the ECAP signal). In one or more cases where stimulation pulses elicit detectible ECAPs, electrical stimulation therapy delivery by leads **130** of IMD **110** may cause neurons within the target tissue to evoke a compound action potential that travels up and down the target tissue (e.g., nerve fibers), eventually arriving at sensing electrodes of IMD **110**. Furthermore, control stimulation may also elicit at least one ECAP, and ECAPs responsive to control stimulation may also be a surrogate for the effectiveness of the therapy. The amount of action potentials (e.g., number of neurons propagating action potential signals) that are evoked may be based on the various parameters of electrical stimulation pulses such as amplitude, pulse width, frequency, pulse shape (e.g., slew rate at the beginning and/or end of the pulse), etc. The slew rate may define the rate of change of the voltage and/or current amplitude of the pulse at the beginning and/or end of each pulse or each phase within the pulse. For example, a very high slew rate indicates a steep or even near vertical edge of the pulse, and a low slew rate indicates a longer ramp up (or ramp down) in the amplitude of the pulse over time. In some examples, these parameters contribute to an intensity of the electrical stimulation. In addition, a characteristic of the ECAP signal (e.g., an amplitude) may change based on the distance between the stimulation electrodes and the nerves subject to the electrical field produced by the delivered control stimulation pulses.

In the example of FIG. **1**, IMD **110** may perform a plurality of processing and computing functions. However, external programmer **150** instead may perform one, several, or all of these functions. In this alternative example, IMD **110** may relay sensed signals to external programmer **150** for analysis, and external programmer **150** may transmit instructions to IMD **110** to adjust the one or more parameters defining the electrical stimulation therapy based on analysis of the sensed signals. For example, IMD **110** may relay the sensed signal indicative of the sensed ECAP signal to external programmer **150**.

FIG. **2** is a block diagram illustrating an example configuration of components of IMD **200**, in accordance with one or more techniques of this disclosure. IMD **200** may be an example of IMD **110** of FIG. **1**. In the example shown in FIG. **2**, IMD **200** includes stimulation generation circuitry **202**, switch circuitry **204**, sensing circuitry **206**, communication circuitry **208**, processing circuitry **210**, storage device **212**, sensor(s) **222**, and power source **224**. As seen in FIG. **2**, sensor(s) **222** include acceleration sensor **223**.

In the example shown in FIG. **2**, storage device **212** stores therapy stimulation programs **214** and test stimulation programs **216** in separate memories within storage device **212** or separate areas within storage device **212**. Each stored therapy stimulation program of therapy stimulation programs **214** defines values for a set of electrical stimulation parameters (e.g., a stimulation parameter set), such as a stimulation electrode combination, electrode polarity, current or voltage amplitude, pulse width, pulse rate, and pulse shape. Each stored test stimulation programs **216** defines values for a set of electrical stimulation parameters (e.g., a

control stimulation parameter set), such as a stimulation electrode combination, electrode polarity, current or voltage amplitude, pulse width, pulse rate, and pulse shape. Test stimulation programs **216** may also have additional information such as instructions regarding when to deliver control pulses based on the pulse width and/or frequency of the informed pulses defined in therapy stimulation programs **214**. In examples in which control pulses are provided to the patient without the need for informed pulses, a separate test stimulation program may not be needed. Instead, the test stimulation program for therapy that only includes control pulses may define the same control pulses as the corresponding therapy stimulation program for those control pulses.

Accordingly, in some examples, stimulation generation circuitry **202** generates electrical stimulation signals in accordance with the electrical stimulation parameters noted above. Other ranges of stimulation parameter values may also be useful and may depend on the target stimulation site within patient **105**. While stimulation pulses are described, stimulation signals may be of any form, such as continuous-time signals (e.g., sine waves) or the like. Switch circuitry **204** may include one or more switch arrays, one or more multiplexers, one or more switches (e.g., a switch matrix or other collection of switches), or other electrical circuitry configured to direct stimulation signals from stimulation generation circuitry **202** to one or more of electrodes **232**, **234**, or directed sensed signals from one or more of electrodes **232**, **234** to sensing circuitry **206**. In other examples, stimulation generation circuitry **202** and/or sensing circuitry **206** may include sensing circuitry to direct signals to and/or from one or more of electrodes **232**, **234**, which may or may not also include switch circuitry **204**.

Sensing circuitry **206** monitors signals from any combination of electrodes **232**, **234**. In some examples, sensing circuitry **206** includes one or more amplifiers, filters, and analog-to-digital converters. Sensing circuitry **206** may be used to sense physiological signals, such as ECAPs. Additionally, or alternatively, sensing circuitry **206** may sense one or more stimulation pulses delivered to patient **105** via electrodes **232**, **234**. In some examples, sensing circuitry **206** detects electrical signals, such as stimulation signals and/or ECAPs from a particular combination of electrodes **232**, **234**. In some cases, the particular combination of electrodes for sensing ECAPs includes different electrodes than a set of electrodes **232**, **234** used to deliver stimulation pulses. Alternatively, in other cases, the particular combination of electrodes used for sensing ECAPs includes at least one of the same electrodes as a set of electrodes used to deliver stimulation pulses to patient **105**. Sensing circuitry **206** may provide signals to an analog-to-digital converter, for conversion into a digital signal for processing, analysis, storage, or output by processing circuitry **210**.

Communication circuitry **208**, in the example of FIG. **2**, supports communication, including wireless communication, between IMD **200** and an external programmer (not shown in FIG. **2**) or another computing device under the control of processing circuitry **210**. Processing circuitry **210** of IMD **200** may receive, as updates to programs, values for various stimulation parameters such as amplitude and electrode combination, from the external programmer via communication circuitry **208**. Updates to the therapy stimulation programs **214** and test stimulation programs **216** may be stored within storage device **212**. Communication circuitry **208** in IMD **200**, as well as communication circuits in other devices and systems described herein, such as the external programmer, may accomplish communication by radiofrequency (RF) communication techniques. In addition, communication circuitry **208** may communicate with an external medical device programmer (not shown in FIG. **2**) via proximal inductive interaction of IMD **200** with the external programmer. The external programmer may be one example of external programmer **150** of FIG. **1**. Accordingly, communication circuitry **208** may send information to the external programmer on a continuous basis, at periodic intervals, or upon request from 1 MB **200** or the external programmer. In some examples, communication circuitry **208** may also support communication between other medical devices, either implanted in, worn by or in proximity to patient **105** depicted in FIG. **1**.

Processing circuitry **210** may include any one or more of a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), discrete logic circuitry, or any other processing circuitry configured to provide the functions attributed to processing circuitry **210** herein may be embodied as firmware, hardware, software or any combination thereof. Processing circuitry **210** controls stimulation generation circuitry **202** to generate stimulation signals according to therapy stimulation programs **214** and test stimulation programs **216** stored in storage device **212** to apply stimulation parameter values specified by one or more of programs, such as amplitude, pulse width, pulse rate, and pulse shape of each of the stimulation signals.

In the example shown in FIG. **2**, the set of electrodes **232** includes electrodes **232**A, **232**B, **232**C, and **232**D, and the set of electrodes **234** includes electrodes **234**A, **234**B, **234**C, and **234**D. In other examples, a single lead may include all eight electrodes **232** and **234** along a single axial length of the lead. Processing circuitry **210** also controls stimulation generation circuitry **202** to generate and apply the stimulation signals to selected combinations of electrodes **232**, **234**. In some examples, stimulation generation circuitry **202** includes a switch circuit (instead of, or in addition to, switch circuitry **204**) that may couple stimulation signals to selected conductors within leads **230**, which, in turn, deliver the stimulation signals across selected electrodes **232**, **234**. Such a switch circuit may be a switch array, switch matrix, multiplexer, or any other type of switching circuit configured to selectively couple stimulation energy to selected electrodes **232**, **234** and to selectively sense bioelectrical neural signals of a spinal cord of the patient (not shown in FIG. **2**) with selected electrodes **232**, **234**.

In other examples, however, stimulation generation circuitry **202** does not include a switch circuit and switch circuitry **204** does not interface between stimulation generation circuitry **202** and electrodes **232**, **234**. In these examples, stimulation generation circuitry **202** includes a plurality of pairs of voltage sources, current sources, voltage sinks, or current sinks connected to each of electrodes **232**, **234** such that each pair of electrodes has a unique signal circuit. In other words, in these examples, each of electrodes **232**, **234** is independently controlled via its own signal circuit (e.g., via a combination of a regulated voltage source and sink or regulated current source and sink), as opposed to switching signals between electrodes **232**, **234**.

Electrodes **232**, **234** on respective leads **230** may be constructed of a variety of different designs. For example, one or both of leads **230** may include one or more electrodes at each longitudinal location along the length of the lead, such as one electrode at different perimeter locations around the perimeter of the lead at each of the locations A, B, C, and D. In one example, the electrodes may be electrically coupled to stimulation generation circuitry **202**, e.g., via switch circuitry **204** and/or switching circuitry of the stimu-

lation generation circuitry **202**, via respective wires that are straight or coiled within the housing of the lead and run to a connector at the proximal end of the lead. In another example, each of the electrodes of the lead may be electrodes deposited on a thin film. The thin film may include an electrically conductive trace for each electrode that runs the length of the thin film to a proximal end connector. The thin film may then be wrapped (e.g., a helical wrap) around an internal member to form the lead **230**. These and other constructions may be used to create a lead with a complex electrode geometry.

Although sensing circuitry **206** is incorporated into a common housing with stimulation generation circuitry **202** and processing circuitry **210** in FIG. **2**, in other examples, sensing circuitry **206** may be in a separate housing from IMD **200** and may communicate with processing circuitry **210** via wired or wireless communication techniques. Processing circuitry **210** may be configured to receive information indicative of a sensed ECAP signal via sensing circuitry **206**. In some examples, processing circuitry may receive an analog signal from sensing circuitry **206**. In other examples, processing circuitry **210** may receive a digital signal.

In some examples, sensing circuitry **206** may include specific noise sensing circuitry **207**. Noise sensing circuitry **207** may include one or more bandpass filters, band stop filters, amplifiers, analog and digital analysis circuitry, and related circuitry configured to detect noise that could couple onto leads **230** and be received by sensing circuitry **206**. In some examples, noise sensing circuitry **207** may be configured to detect specific noise signals, such as 60 Hz signals, 50 Hz signals, or other expected noise signals. Noise sensing circuitry **207** may provide an indication to processing circuitry **210** that noise is present and that the ECAP sensing may not be reliable. In some examples, in response to an indication of noise from noise sensing circuitry **207**, processing circuitry **210** may reject a request from a patient programmer to adjust stimulation parameters. For example, processing circuitry **210** may reject patient programmer requests to increase stimulation amplitude to avoid possible patient discomfort when the noise source is removed.

In some examples, one or more of electrodes **232** and **234** are suitable for sensing one or more ECAPs. For instance, electrodes **232** and **234** may sense the voltage amplitude of a portion of the ECAP signals, where the sensed voltage amplitude is a characteristic of the ECAP signal.

In some examples, one or more of electrodes **232** and **234** are suitable for sensing stimulation signals. For instance, electrodes **232** and **234** may sense the voltage amplitude of a portion of the stimulation signals, where the sensed voltage amplitude is a characteristic of the stimulation signals. In some examples, one or more of electrodes **232** and **234** may sense a stimulation signal in response to one or more of electrodes **232** and **234** delivering a stimulation pulse to target tissue of patient **105**. In some examples, the one or more of electrodes **232** and **234** which sense the stimulation signal are not the same as the one or more of electrodes **232** and **234** which deliver the stimulation pulse.

Storage device **212** may be configured to store information within IMD **200** during operation. Storage device **212** may include a computer-readable storage medium or computer-readable storage device. In some examples, storage device **212** includes one or more of a short-term memory or a long-term memory. Storage device **212** may include, for example, random access memories (RAM), dynamic random access memories (DRAM), static random access memories (SRAM), magnetic discs, optical discs, flash memories, or forms of electrically programmable memories (EPROM) or electrically erasable and programmable memories (EEPROM). In some examples, storage device **212** is used to store data indicative of instructions for execution by processing circuitry **210**. As discussed above, storage device **212** is configured to store therapy stimulation programs **214**, test stimulation programs **216**, and target values **218**. In some examples, processing circuitry **210** may implement the closed loop policy based on an algorithm stored at storage device **212**.

In some examples, stimulation generation circuitry **202** may be configured to deliver electrical stimulation therapy to patient **105**. In some examples, the electrical stimulation therapy may include a plurality of informed pulses. Additionally, stimulation generation circuitry **202** may be configured to deliver a plurality of control pulses, where the plurality of control pulses is interleaved with at least some informed pulses of the plurality of informed pulses. Stimulation generation circuitry may deliver the plurality of informed pulses and the plurality of control pulses to target tissue (e.g., spinal cord **120**) of patient **105** via electrodes **232**, **234** of leads **230**. By delivering such informed pulses and control pulses, stimulation generation circuitry **202** may cause IMD **200** to sense stimulation signals that are indicative of the delivered pulses Additionally, or alternatively, stimulation generation circuitry **202** may deliver control pulses that evoke detectable responsive ECAPs in the target tissue, the responsive ECAPs propagating through the target tissue before arriving back at electrodes **232**, **234**. Stimulation signals or ECAPs caused by or elicited by informed pulses may not be detectable by IMD **200**. In some examples, a different combination of electrodes **232**, **234** may sense responsive ECAPs and/or responsive stimulation signals than a combination of electrodes **232**, **234** that delivers informed pulses and a combination of electrodes **232**, **234** that delivers control pulses. Sensing circuitry **206** may be configured to detect the responsive ECAPs and/or the responsive stimulation signals via electrodes **232**, **234** and leads **230**. In other examples, stimulation generation circuitry **202** may be configured to deliver a plurality of control pulses, without any informed pulses, when control pulses also provide or contribute to a therapeutic effect for the patient.

Processing circuitry **210** may, in some cases, direct sensing circuitry **206** to continuously monitor for ECAPs and stimulation signals. In other cases, processing circuitry **210** may direct sensing circuitry **206** to monitor for ECAPs and stimulation signals based on signals from sensor(s) **222**. For example, processing circuitry **210** may activate sensing circuitry **206** based on an activity level of patient **105** exceeding an activity level threshold (e.g., acceleration sensor **223** rises above a threshold). Activating and deactivating sensing circuitry **206** may, in some examples, extend a battery life of power source **224**.

Processing circuitry **210** may determine whether electrical stimulation therapy delivered to target tissue of patient **105** via electrodes **232**, **234** elicits enough detectible ECAPs for processing circuitry **210** to determine therapy based on one or more characteristics of the respective detectible ECAPs. It may be beneficial for processing circuitry **210** to determine therapy based on characteristics of detectible ECAPs rather than characteristics of detectible stimulation signals, if possible. However, if not enough responsive ECAPs are detectible by sensing circuitry **206**, it may be beneficial for processing circuitry **210** to determine therapy based on one or more characteristics of respective stimulation signals, which are often still detectible even when some or all of elicited ECAPs are not detectible in response to a

stimulation pulse. In addition, sensing circuitry **206** may still detect stimulation signals when the delivered stimulation pulses were insufficient to elicit a detectable ECAP signal (e.g., when the stimulation pulses are configured to be sub-threshold pulses).

In one example, to determine if the electrical stimulation therapy elicits enough detectible ECAPs, processing circuitry **210** is configured to perform a test to determine whether the plurality of pulses of the electrical stimulation therapy elicit greater than a threshold ratio of detectible ECAPs. For example, to perform the test, processing circuitry **210** may identify a set of ECAPs elicited by a sequence of consecutive pulses of the plurality of pulses. Subsequently, processing circuitry **210** may calculate a ratio of the set of ECAPs to the sequence of consecutive pulses. For example, processing circuitry **210** may first determine a number of ECAPs of the set of ECAPs and a number of pulses of the sequence of consecutive pulses, and then calculate a ratio of the number of ECAPs to the number of pulses.

There may be examples in which a particular one or more stimulation pulses of the sequence of consecutive pulses might not elicit ECAPs that are detectible by sensing circuitry **206**, but another one or more stimulation pulses of the sequence of consecutive pulses do elicit ECAPs that are detectible by sensing circuitry **206**. In such cases, processing circuitry **210** may be configured to determine therapy based on one or more characteristics of the detectible ECAPs rather than determine therapy based on one or more characteristics of detectible stimulation signals. In some examples, processing circuitry **210** may determine whether the ratio of detectible ECAPs to stimulation pulses is greater than the threshold ratio. In one or more cases where the ratio is greater than the threshold ratio, processing circuitry **210** may determine therapy based on characteristics of the detectible ECAPs. In one or more cases where the ratio is not greater than the threshold ratio, processing circuitry **210** may determine therapy based on characteristics of the detectible stimulation signals.

In some examples, responsive to determining that a plurality of pulses elicit greater than a threshold ratio of detectible ECAPs, processing circuitry **210** is configured to set, based on one or more characteristics of an ECAP, one or more parameters which at least partially define the one or more pulses deliverable by stimulation generation circuitry **202** after a stimulation pulse which elicits the respective ECAP. In some examples, responsive to determining that a plurality of pulses do not elicit greater than a threshold ratio of detectible ECAPs, processing circuitry **210** is configured to set, based on one or more characteristics of a stimulation signal, one or more parameters which at least partially define the one or more pulses deliverable by stimulation generation circuitry **202** after a stimulation pulse which elicits the respective stimulation signal. In some examples, processing circuitry **210** may set one or more parameters which at least partially define the one or more pulses deliverable by stimulation generation circuitry **202** based on a combination of characteristics of one or more detectable ECAPs and characteristics of one or more detectible stimulation signals.

Stimulation generation circuitry **202** may be configured to deliver one or more stimulation pulses, at least one of which may cause sensing circuitry **206** to sense a stimulation signal in response to the delivery of the respective pulse. In some examples, to sense a stimulation signal, sensing circuitry **206** may detect, via any one or combination of electrodes **232**, **234**, one or more electrical signals which are generated by stimulation generation circuitry **202** and delivered to patient **105** via any one or combination of electrodes **232**, **234**. In some examples, stimulation signals may include information which is useful for determining one or more parameters of upcoming therapy pulses generated by stimulation generation circuitry **202**. For example, information included by a stimulation signal may include one or more characteristics which indicate an efficacy of therapy delivered to patient **105** via electrodes **232**, **234**. In some cases, the one or more characteristics may reflect a separation between one or more of electrodes **232**, **234** and target tissue of patient **105** (e.g., spinal cord **120**). Such a distance between electrodes **232**, **234** and spinal cord **120** may be relevant to determining therapy since a smaller intensity (e.g., amplitude and/or pulse length) of therapy pulses is required to stimulate a nerve if electrodes **232**, **234** move closer to spinal cord **120** and vice versa.

Determining therapy based on one or more stimulation signals may, in some cases, depend on a posture of patient **105**. For example, processing circuitry **210** may be configured to determine a posture of patient **105** based on an acceleration signal generated by acceleration sensor **223**. In some examples, the accelerometer signal includes a vertical component, a lateral component, and a frontal component corresponding to a vertical axis, a lateral axis, and a frontal axis, respectively. In this way, the accelerometer signal represents a three-dimensional measurement of acceleration. It may be beneficial for processing circuitry **210** to analyze one or more of the vertical axes, the lateral axis, and the frontal axis in order to determine a posture of patient **105**.

In some examples, acceleration sensor **223** is configured to generate an accelerometer signal. Processing circuitry **210** is configured to identify, based on the accelerometer signal, a posture of a set of postures which patient **105** is occupying. The set of postures may include, for example, a standing posture, a sitting posture, a supine posture, a prone posture, a side-lying posture, or any combination thereof. In some examples, expected parameter values of the accelerometer signal corresponding to each posture of the set of postures are stored in storage device **212**. Subsequently, processing circuitry **210** may select, based on the identified posture, a target stimulation signal value (e.g., a target range of characteristic values) for a stimulation signal sensed by IMD **200** in response to a delivery of a corresponding stimulation pulses. For example, if stimulation generation circuitry **202** generates a stimulation pulse having a stimulation amplitude and delivers the stimulation pulse to target tissue of patient **105** via one or a combination of electrodes **232**, **234**, processing circuitry **210** may select, based on a posture of patient **105** during the delivery of the stimulation pulse, a target range for a characteristic of the resulting stimulation signal sensed by sensing circuitry **106**. Subsequently, processing circuitry **210** may determine whether to change one or more parameters of therapy stimulation programs **314** and/or test stimulation programs **216** based on whether the characteristic value is within the target range of characteristic values selected based on the posture of patient **105**.

In some examples, processing circuitry **210** is configured to identify, based on the accelerometer signal, a posture of a set of postures which patient **105** is occupying while a stimulation pulse is delivered and identify an amplitude of the stimulation pulse. Subsequently, processing circuitry **210** may select a target range of characteristic values for a characteristic of a stimulation signal sensed by sensing circuitry **206** in response to the delivery of the stimulation pulse based on both of the posture of patient **105** and the amplitude of the stimulation pulse. For example, target values **218** may include a respective transfer function cor-

responding to each posture of the set of postures. Each transfer function represents a relationship (e.g., a linear relationship) between the amplitude of a stimulation pulse and the target stimulation signal value (e.g., a target range of characteristic values) for a stimulation signal sensed by IMD **200** in response to the delivery of the stimulation pulse. As such, processing circuitry **210** may, when evaluating whether to change one or more parameters of upcoming stimulation pulses, first select a transfer function corresponding to a present stimulation pulse and subsequently select a target range of characteristics based on the amplitude of the present stimulation pulse, but this is not required. Processing circuitry **210** may first analyze the amplitude of the stimulation pulse and subsequently determine the posture of patient **105**, in some cases.

Power source **224** is configured to deliver operating power to the components of IMD **200**. Power source **224** may include a battery and a power generation circuit to produce the operating power. In some examples, the battery is rechargeable to allow extended operation. In some examples, recharging is accomplished through proximal inductive interaction between an external charger and an inductive charging coil within IMD **200**. Power source **224** may include any one or more of a plurality of different battery types, such as nickel cadmium batteries and lithium ion batteries.

FIG. **3** is a block diagram illustrating an example configuration of components of external programmer **300**, in accordance with one or more techniques of this disclosure. External programmer **300** may be an example of external programmer **150** of FIG. **1**. Although external programmer **300** may generally be described as a hand-held device, external programmer **300** may be a larger portable device or a more stationary device. In addition, in other examples, external programmer **300** may be included as part of an external charging device or include the functionality of an external charging device. As illustrated in FIG. **3**, external programmer **300** may include processing circuitry **352**, storage device **354**, user interface **356**, telemetry circuitry **358**, and power source **360**. Storage device **354** may store instructions that, when executed by processing circuitry **352**, cause processing circuitry **352** and external programmer **300** to provide the functionality ascribed to external programmer **300** throughout this disclosure. Each of these components, circuitry, or modules, may include electrical circuitry that is configured to perform some, or all of the functionality described herein. For example, processing circuitry **352** may include processing circuitry configured to perform the processes discussed with respect to processing circuitry **352**.

In general, external programmer **300** includes any arrangement of hardware, alone or in combination with software and/or firmware, configured to perform the techniques attributed to external programmer **300**, and processing circuitry **352**, user interface **356**, and telemetry circuitry **358** of external programmer **300**. In various examples, external programmer **300** may include one or more processors, such as one or more microprocessors, DSPs, ASICs, FPGAs, or any other equivalent integrated or discrete logic circuitry, as well as any combinations of such components. External programmer **300** also, in various examples, may include a storage device **354**, such as RAM, ROM, PROM, EPROM, EEPROM, flash memory, a hard disk, a CD-ROM, including executable instructions for causing the one or more processors to perform the actions attributed to them. Moreover, although processing circuitry **352** and telemetry circuitry **358** are described as separate modules, in some examples, processing circuitry **352** and telemetry circuitry **358** are functionally integrated. In some examples, processing circuitry **352** and telemetry circuitry **358** correspond to individual hardware units, such as ASICs, DSPs, FPGAs, or other hardware units.

Storage device **354** (e.g., a storage device) may store instructions that, when executed by processing circuitry **352**, cause processing circuitry **352** and external programmer **300** to provide the functionality ascribed to external programmer **300** throughout this disclosure. For example, storage device **354** may include instructions that cause processing circuitry **352** to obtain a parameter set from memory, select a spatial electrode movement pattern, or receive a user input and send a corresponding command to IMD **200**, or instructions for any other functionality. In addition, storage device **354** may include a plurality of programs, where each program includes a parameter set that defines stimulation pulses, such as control pulses and/or informed pulses. Storage device **354** may also store data received from a medical device (e.g., IMD **110**). For example, storage device **354** may store ECAP related data recorded at a sensing module of the medical device, and storage device **354** may also store data from one or more sensors of the medical device.

User interface **356** may include a button or keypad, lights, a speaker for voice commands, a display, such as a liquid crystal (LCD), light-emitting diode (LED), or organic light-emitting diode (OLED). In some examples the display includes a touch screen. User interface **356** may be configured to display any information related to the delivery of electrical stimulation, identified patient behaviors, sensed patient parameter values, patient behavior criteria, or any other such information. User interface **356** may also receive user input via user interface **356**. The input may be, for example, in the form of pressing a button on a keypad or selecting an icon from a touch screen. The input may request starting or stopping electrical stimulation, the input may request a new spatial electrode movement pattern or a change to an existing spatial electrode movement pattern, of the input may request some other change to the delivery of electrical stimulation. For example, the input may request an increase or decrease to stimulation intensity (e.g., amplitude, pulse width, or frequency). Programmer **300** can then transmit these requests to IMD **200**. Programmer **300** may receive, and transmit, the input requesting changes to one or more parameter values during closed-loop stimulation in some examples.

Telemetry circuitry **358** may support wireless communication between the medical device and external programmer **300** under the control of processing circuitry **352**. Telemetry circuitry **358** may also be configured to communicate with another computing device via wireless communication techniques, or direct communication through a wired connection. In some examples, telemetry circuitry **358** provides wireless communication via an RF or proximal inductive medium. In some examples, telemetry circuitry **358** includes an antenna, which may take on a variety of forms, such as an internal or external antenna.

Examples of local wireless communication techniques that may be employed to facilitate communication between external programmer **300** and IMD **110** include RF communication according to the 802.11 or Bluetooth® specification sets or other standard or proprietary telemetry protocols. In this manner, other external devices may be capable of communicating with external programmer **300** without needing to establish a secure wireless connection. As described herein, telemetry circuitry **358** may be configured to transmit a spatial electrode movement pattern or other

stimulation parameter values to IMD **110** for delivery of electrical stimulation therapy.

In some examples, selection of stimulation parameters or therapy stimulation programs are transmitted to the medical device for delivery to a patient (e.g., patient **105** of FIG. **1**). In other examples, the therapy may include medication, activities, or other instructions that patient **105** must perform themselves or a caregiver perform for patient **105**. In some examples, external programmer **300** provides visual, audible, and/or tactile notifications that indicate there are new instructions. External programmer **300** requires receiving user input acknowledging that the instructions have been completed in some examples.

According to the techniques of the disclosure, user interface **356** of external programmer **300** receives an indication from a clinician instructing a processor of the medical device to update one or more therapy stimulation programs or to update one or more test stimulation programs. Updating therapy stimulation programs and test stimulation programs may include changing one or more parameters of the stimulation pulses delivered by the medical device according to the programs, such as amplitude, pulse width, frequency, and pulse shape of the informed pulses and/or control pulses. User interface **356** may also receive instructions from the clinician commanding any electrical stimulation, including control pulses and/or informed pulses to commence or to cease.

Power source **360** is configured to deliver operating power to the components of external programmer **300**. Power source **360** may include a battery and a power generation circuit to produce the operating power. In some examples, the battery is rechargeable to allow extended operation. Recharging may be accomplished by electrically coupling power source **360** to a cradle or plug that is connected to an alternating current (AC) outlet. In addition, recharging may be accomplished through proximal inductive interaction between an external charger and an inductive charging coil within external programmer **300**. In other examples, traditional batteries (e.g., nickel cadmium or lithium ion batteries) may be used. In addition, external programmer **300** may be directly coupled to an alternating current outlet to operate.

FIG. **4** is a graph **402** of example evoked compound action potentials (ECAPs) sensed for respective stimulation pulses, in accordance with one or more techniques of this disclosure. As shown in FIG. **4**, graph **402** shows example ECAP signal **404** (dotted line) and ECAP signal **406** (solid line). In some examples, each of ECAP signals **404** and **406** are sensed from stimulation pulses (e.g., a control pulse) that were delivered from a guarded cathode, where the stimulation pulses are bi-phasic pulses including an interphase interval between each positive and negative phase of the pulse. In some such examples, the guarded cathode includes stimulation electrodes located at the end of an 8-electrode lead (e.g., leads **130** of FIG. **1**) while two sensing electrodes are provided at the other end of the 8-electrode lead. ECAP signal **404** illustrates the voltage amplitude sensed as a result from a sub-detection threshold stimulation pulse, or a stimulation pulse which results in no detectable ECAP. It is noted that monophasic, tri-phasic, or pulses with another quantity of phases may be in other examples.

Peaks **408** of ECAP signal **404** are detected and represent stimulation signals of the delivered stimulation pulse. However, no propagating signal is detected after the stimulation signal in ECAP signal **404** because the stimulation pulse had an intensity (e.g., an amplitude and/or pulse width) that was "sub-threshold" or below a detection threshold (e.g., a sub-detection threshold) and/or below a propagation threshold (e.g., a sub-propagation threshold). In other examples, sensing circuitry, such as sensing circuitry **206** described above in relation to FIG. **2**, may measure other signal features, such as features based on a derivative of the sensed signal, slope, linearity, and so on. The processing circuitry may react to the peaks **408** of ECAP signal **404**, or any other measurable or calculated signal feature.

In contrast to ECAP signal **404**, ECAP signal **406** represents the voltage amplitude detected from a supra-detection stimulation threshold stimulation pulse. Peaks **408** of ECAP signal **406** are detected and represent stimulation signals of the delivered stimulation pulse. After peaks **408**, ECAP signal **406** also includes peaks P**1**, N**1**, and P**2**, which are three typical peaks representative of propagating action potentials from an ECAP. The example duration of the stimulation signal and peaks P**1**, N**1**, and P**2** is approximately 1 millisecond (ms).

When detecting the ECAP of ECAP signal **406**, different characteristics may be identified. For example, the characteristic of the ECAP may be the amplitude between N**1** and P**2**. This N**1**-P**2** amplitude may be easily detectable even if the stimulation signal impinges on P**1**, a relatively large signal, and the N**1**-P**2** amplitude may be minimally affected by electronic drift in the signal. In other examples, the characteristic of the ECAP used to control subsequent stimulation pulses (e.g., control pulses and/or informed pulses) may be an amplitude of P**1**, N**1**, or P**2** with respect to neutral or zero voltage. In some examples, the characteristic of the ECAP used to control subsequent stimulation pulses is a sum of two or more of peaks P**1**, N**1**, or P**2**. In other examples, the characteristic of ECAP signal **406** may be the area under one or more of peaks P**1**, N**1**, and/or P**2**. In other examples, the characteristic of the ECAP may be a ratio of one of peaks P**1**, N**1**, or P**2** to another one of the peaks. In some examples, the characteristic of the ECAP is a slope between two points in the ECAP signal, such as the slope between N**1** and P**2**. In other examples, the characteristic of the ECAP may be the time between two points of the ECAP, such as the time between N**1** and P**2**.

The time between when the stimulation pulse is delivered and a point in the ECAP signal may be referred to as a latency of the ECAP and may indicate the types of fibers being captured by the stimulation pulse (e.g., a control pulse). ECAP signals with lower latency (i.e., smaller latency values) indicate a higher percentage of nerve fibers that have faster propagation of signals, whereas ECAP signals with higher latency (i.e., larger latency values) indicate a higher percentage of nerve fibers that have slower propagation of signals. Latency may also refer to the time between an electrical feature is detected at one electrode and then detected again at a different electrode. This time, or latency, is inversely proportional to the conduction velocity of the nerve fibers. Other characteristics of the ECAP signal may be used in other examples.

The amplitude of the ECAP signal increases with increased amplitude of the stimulation pulse, as long as the pulse amplitude is greater than threshold such that nerves depolarize and propagate the signal. The target ECAP characteristic (e.g., the target ECAP amplitude) may be determined from the ECAP signal detected from a stimulation pulse (or a control pulse) when informed pulses are determined to deliver effective therapy to patient **105**. The ECAP signal thus is representative of the distance between the stimulation electrodes and the nerves appropriate for the stimulation parameter values of the informed pulses delivered at that time. Therefore, IMD **110** may attempt to use

detected changes to the measured ECAP characteristic value to change therapy pulse parameter values and maintain the target ECAP characteristic value during therapy pulse delivery.

FIG. **5** is a timing diagram **500** illustrating one example of electrical stimulation pulses, respective stimulation signals, and respective sensed ECAPs, in accordance with one or more techniques of this disclosure. For convenience, FIG. **5** is described with reference to IMD **200** of FIG. **2**. As illustrated, timing diagram **500** includes first channel **510**, a plurality of control pulses **512**A-**512**N (collectively "control pulses **512**"), second channel **520**, a plurality of informed pulses **524**A-**524**N (collectively "informed pulses **524**") including passive recharge phases **526**A-**526**N (collectively "passive recharge phases **526**"), third channel **530**, a plurality of respective ECAPs **536**A-**536**N (collectively "ECAPs **536**"), and a plurality of stimulation signals **538**A-**538**N (collectively "stimulation signals **538**").

In some examples, external noise from a fourth channel **540** may interfere with the operation of an IMD, such as IMD **200** of FIG. **2** and IMD **110** of FIG. **1**. Noise on channel **540** may couple to any of leads **230**, electrodes **232** and **234**, and in some examples couple to the IMD. Sensing circuitry **206** may sense noise from channel **540**. Some of the noise may not be canceled or excluded by the filter circuitry of sensing circuitry **206**, and processing circuitry **210** may interpret noise from channel **540** as a received ECAP signal. Sources of noise may include nearby electric motors, microwave ovens, machinery, computing devices, recharging circuits, generators, and so on. As one example, patient **105** may be seated in a powered massage chair that may include motors and other circuitry. Noise generated by the massage chair circuitry may couple into sensing circuitry **206**. Also, pressure rollers in the massage chair may press against leads **230** and change the position of the lead with respect to the target tissue of patient **105**. As shown in FIG. **5**, the noise signal on channel **540** may vary in amplitude, frequency, and other characteristics, and may start and stop at different times during operation of IMD **200**.

First channel **510** is a time/voltage (and/or current) graph indicating the voltage (or current) of at least one electrode of electrodes **232**, **234**. In one example, the stimulation electrodes of first channel **510** may be located on the opposite side of the lead as the sensing electrodes of third channel **530**. Control pulses **512** may be electrical pulses delivered to the spinal cord of the patient by at least one of electrodes **232**, **234**, and control pulses **512** may be balanced biphasic square pulses with an interphase interval. In other words, each of control pulses **512** are shown with a negative phase and a positive phase separated by an interphase interval. For example, a control pulse **512** may have a negative voltage for the same amount of time that it has a positive voltage. It is noted that the negative voltage phase may be before or after the positive voltage phase. Control pulses **512** may be delivered according to test stimulation programs **216** stored in storage device **212** of IMD **200**, and test stimulation programs **216** may be updated according to user input via an external programmer and/or may be updated according to a signal from sensor(s) **222**. In one example, control pulses **512** may have a pulse width of less than approximately 300 microseconds (e.g., the total time of the positive phase, the negative phase, and the interphase interval is less than 300 microseconds). In another example, control pulses **512** may have a pulse width of approximately 100 μs for each phase of the bi-phasic pulse. As illustrated in FIG. **5**, control pulses **512** may be delivered via first channel **510**. Delivery of control pulses **512** may be delivered by leads **230** in a guarded cathode electrode combination. For example, if leads **230** are linear 8-electrode leads, a guarded cathode combination is a central cathodic electrode with anodic electrodes immediately adjacent to the cathodic electrode.

Second channel **520** is a time/voltage (and/or current) graph indicating the voltage (or current) of at least one electrode of electrodes **232**, **234** for the informed pulses. In one example, the electrodes of second channel **520** may partially or fully share common electrodes with the electrodes of first channel **510** and third channel **530**. Informed pulses **524** may also be delivered by the same leads **230** that are configured to deliver control pulses **512**. Informed pulses **524** may be interleaved with control pulses **512**, such that the two types of pulses are not delivered during overlapping periods of time. However, informed pulses **524** may or may not be delivered by exactly the same electrodes that deliver control pulses **512**. Informed pulses **524** may be monophasic pulses with pulse widths of greater than approximately 300 μs and less than approximately 1000 μs. In fact, informed pulses **524** may be configured to have longer pulse widths than control pulses **512**. As illustrated in FIG. **5**, informed pulses **524** may be delivered on second channel **520**.

Informed pulses **524** may be configured for passive recharge. For example, each informed pulse **524** may be followed by a passive recharge phase **526** to equalize charge on the stimulation electrodes. Unlike a pulse configured for active recharge, where remaining charge on the tissue following a stimulation pulse is instantly removed from the tissue by an opposite applied charge, passive recharge allows tissue to naturally discharge to some reference voltage (e.g., ground or a rail voltage) following the termination of the therapy pulse. In some examples, the electrodes of the medical device may be grounded at the medical device body. In this case, following the termination of informed pulse **524**, the charge on the tissue surrounding the electrodes may dissipate to the medical device, creating a rapid decay of the remaining charge at the tissue following the termination of the pulse. This rapid decay is illustrated in passive recharge phases **526**. Passive recharge phase **526** may have a duration in addition to the pulse width of the preceding informed pulse **524**. In other examples (not pictured in FIG. **5**), informed pulses **524** may be bi-phasic pulses having a positive and negative phase (and, in some examples, an interphase interval between each phase) which may be referred to as pulses including active recharge. An informed pulse that is a bi-phasic pulse may or may not have a following passive recharge phase.

Third channel **530** is a time/voltage (and/or current) graph indicating the voltage (or current) of at least one electrode of electrodes **232**, **234**. In one example, the electrodes of third channel **530** may be located on the opposite side of the lead as the electrodes of first channel **510**. ECAPs **536** may be sensed at electrodes **232**, **234** from the spinal cord of the patient in response to control pulses **512**. ECAPs **536** are electrical signals which may propagate along a nerve away from the origination of control pulses **512**. In one example, ECAPs **536** are sensed by different electrodes than the electrodes used to deliver control pulses **512**. As illustrated in FIG. **5**, ECAPs **536** may be recorded on third channel **530**.

Stimulation signals **538**A, **538**B, and **538**N may be sensed by leads **230** and may be sensed during the same period of time as the delivery of control pulses **512** and informed pulses **524**. Since the stimulation signals may have a greater amplitude and intensity than ECAPs **536**, any ECAPs arriving at IMD **200** during the occurrence of stimulation signals **538** may not be adequately sensed by sensing circuitry **206** of IMD **200**. However, ECAPs **536** may be sufficiently

sensed by sensing circuitry **206** because each ECAP **536** falls after the completion of each a control pulse **512** and before the delivery of the next informed pulse **524**. As illustrated in FIG. **5**, stimulation signals **538** and ECAPs **536** may be recorded on channel **530**. In some examples, noise from channel **540** may be interpreted as ECAPs **536**. In other words, noise from channel **540** may cause the IMD to interpret that a value of a characteristic of one or more sensed ECAPs **536** is outside of a predetermined range. As described above in relation to FIGS. **1** and **2**, a closed loop algorithm executed by processing circuitry on either IMD **110**, IMD **200** or external programmer **150** may adjust the one or more parameters defining the electrical stimulation therapy based on analysis of the sensed signals. For example, the processing circuitry may compare a characteristic value of the stimulation signal to the respective target range of characteristic values, and in response to the comparison, the closed loop algorithm executed by the processing circuitry may adjust one or more parameters that define the electrical stimulation pulses delivered to patient **105**. In some examples, based on the closed loop algorithm, processing circuitry **210** may cause stimulation generation circuitry **202** to adjust a first set of parameter values for the plurality of pulses to a second set of parameter values. As one example, stimulation generation circuitry **202** may reduce an amplitude of current for a control pulse or for an informed pulse, or both, from a first current amplitude to a second current amplitude. In other examples, stimulation generation circuitry **202** may also adjust one or more of pulse width, voltage amplitude or other parameters in the set of parameters from a first value to a second value.

As described above in relation to FIG. **2**, processing circuitry **210** may receive commands from a patient programmer, e.g. external programmer **150**, when the patient wishes to terminate or change electrical stimulation therapy. In some examples, the medical device may be adapting to changes in the patient's physiological signals, such as when the patient changes posture, activity level. The patient may request an increase in stimulation (e.g., increase the value of the amplitude parameter) while IMD **200** is decreasing stimulation due to elevated characteristic values of the sensed ECAP signals (which may be due to noise). In other examples, noise from channel **540** may be sensed as ECAPs **536** exceeding an upper limit of a predetermined range and the closed loop algorithm of IMD **200** may respond by decreasing a parameter value to reduce the sensed ECAP. To avoid the risk of patient discomfort when the noise is removed (or no longer present), or when the physiological signals change again, in some examples, processing circuitry **210** may prevent stimulation generation circuitry **202** from responding to the commands from the patient programmer when processing circuitry **210** determines that stimulation therapy parameters, e.g. informed pulse amplitude, is outside of a predetermined pulse amplitude range of a default pulse amplitude. For example, processing circuitry **210** may reject a user command to increase amplitude of stimulation when the closed loop algorithm is reducing amplitude in response to elevated characteristics of the ECAP signal.

In some examples, when noise from channel **540** is sensed as ECAPs **536** exceeding an upper limit of a predetermined range and the closed loop algorithm of IMD **200** responds by decreasing a parameter value to reduce the sensed ECAP, processing circuitry may determine that the sensed ECAP is distorted by noise. For example, a control pulse or an informed pulse may have a minimum parameter value, such as a pulse amplitude of zero or pulse width of zero. When the closed loop algorithm adjusts the parameter to the minimum value, and the ECAP sensed by sensing circuitry **206** is still above the upper limit, processing circuitry **210** may determine that noise coupled from channel **540** may be causing the high value of the sensed ECAP. In some examples, processing circuitry **210** may disable the closed loop algorithm when processing circuitry determines that the sensed ECAPs **536** may be influenced by noise coupled from channel **540**. Processing circuitry **210** may execute a control policy to ramp the stimulation pulse parameter to a specified value, such as a default value, until processing circuitry **210** determines that the noise has diminished or been removed. In this manner, IMD **200** may avoid pulse stimulation parameter levels that may cause the patient to receive inappropriate stimulation (over or under stimulation) resulting in patient discomfort.

FIG. **6** is a timing diagram illustrating a closed loop response to a sensed ECAP that is outside of a predetermined range, in accordance with one or more techniques of this disclosure. As described above, in this disclosure the closed loop algorithm may be referred to as ECAP responsive stimulation or ERS. The example of FIGS. **6-16** will be described in terms of FIG. **2**, unless otherwise noted. Programming commands for ERS may be stored at storage device **212**, e.g. at test stimulation programs **216**.

Storage device **212** may store a predetermined range for one or more values of a characteristic of the sensed ECAP. In the example of FIG. **6**, the predetermined range includes an ECAP high threshold (ETH **602**) and an ECAP low threshold (ETL **604**) for a sensed magnitude (voltage or current). Processing circuitry **210** may determine a value of a characteristic of the sensed ECAP (**600**) that is outside of a predetermined range, when the sensed ECAP signal exceeds the ECAP high threshold **602**. In response, ERS may be configured to adjust a first set of parameter values for stimulation pulses delivered during the time the sensed ECAP exceeds ETH **602** to a second set of parameter values (**610**). In the example of FIG. **6**, processing circuitry **210** may cause stimulation generation circuitry **202** to reduce the control pulse current amplitude Ic **612** from Ict **606** to a lower amplitude. Similarly, stimulation generation circuitry **202** may reduce informed pulse current amplitude Ii **614** from Iit **608** to a lower amplitude. In this disclosure, Ict **606** is the default control pulse current amplitude, and Iit **608** is the default informed pulse current amplitude. As described above in relation to FIGS. **1** and **2**, current pulse amplitude is just one example of a parameter value that defines the stimulation pulse delivered by IMD **200**. In other examples, stimulation generation circuitry **202** may adjust pulse width, voltage amplitude, pulse shape, frequency, and so on, based on commands from processing circuitry **210**.

As the high sensed ECAP signal **600** falls below ETH **602** and back within the predetermined range, ERS, executed by processing circuitry **210**, may increase control pulse current amplitude Ic **612** and informed pulse current amplitude Ii **614** back to the default values of Ict **606** and Iit **608** (**618**).

FIG. **7** is a timing diagram illustrating suspending a closed loop algorithm, in accordance with one or more techniques of this disclosure. Similar to the example of FIG. **6**, processing circuitry **210** may determine that the high sensed ECAP signal **700** exceeds ETH **702** and begin to decrease control pulse current amplitude Ic **712** from Ict **706** to a lower amplitude. Similarly, stimulation generation circuitry **202** may reduce informed pulse current amplitude Ii **714** from Iit **708** to a lower amplitude. However, in the example of FIG. **7**, high sensed ECAP **700** persists, which may result in processing circuitry **210** adjusting control pulse current amplitude Ic **712** and/or informed pulse current amplitude Ii

714 to a minimum value, such as an amplitude of approximately zero amps (710). In response to adjusting the stimulation amplitude to the minimum value, processing circuitry 210 may start a noise detection timer, Tdetect 720. In the example of FIG. 7, in response to determining that Tdetect 720 has expired and the sensed ECAP 700 still exceed ETH 702, processing circuitry 210 may disable the closed-loop algorithm (722).

As described above in relation to FIG. 5, processing circuitry 210 may also disable some requests from patient programmer 150 while a control policy is adjusting stimulation parameters. One of several possible techniques to determine whether a control policy is adjusting stimulation parameters is to determine whether control pulse current amplitude Ic 712 and/or informed pulse current amplitude Ii 714 is outside of a predetermined range from the default values Ict 706 and Iit 708. Other example techniques may include checking a flag stored in memory that processing circuitry 210 may set when adjusting stimulation parameters. For example, if the flag is cleared, processing circuitry 210 may allow requests from patient programmer 150 to adjust stimulation parameters. If the flag is set, processing circuitry 210 may allow requests to decrease stimulation, but reject requests to increase stimulation.

In the example of FIG. 7, the predetermined range from the default values may be a range (±δIct) about the controlled pulse default value i.e., 2δIct 724. Similarly, the predetermined range may be a range (±δIit) about the informed pulse default value, i.e., 2δIit 726. In other words, processing circuitry 210 may determine whether the set of parameter values for the electrical stimulation therapy control pulse current amplitude Ic 712 and/or informed pulse current amplitude Ii 714 is approximately equal to the default set of parameter values Ict 706 and Iit 708. Because the sensed ECAP 700 is high and ERS has caused Ic 712 and Ii 714 to decrease to minimum levels, processing circuitry would determine that Ic 712 and Ii 714 are outside the predetermined range, 2δIct 724 and 2δIit 726 respectively, from the default values Ict 706 and Iit 708, and therefore may disable patient programmer input from changing the stimulation pulse parameters.

FIG. 8 is a timing diagram illustrating a medical device providing electrical stimulation while suspending a closed loop algorithm, in accordance with one or more techniques of this disclosure. In the example of noise, e.g. from channel 540 of FIG. 5, causing sensed ECAP 800 to exceed ETH 802 for an extended period, the closed loop algorithm may decrease the stimulation pulses, e.g. as shown in FIG. 7, which may result in under stimulation for the patient. The patient, e.g. patient 105 of FIG. 1, may experience discomfort such as a return of pain symptoms, Parkinson's symptoms etc. as a result of the under stimulation caused by the presence of noise.

In the example of FIG. 8, in response to suspending ERS (810), processing circuitry 210 may cause stimulation generation circuitry 202 to increase the pulse parameter values of Ic 812 and Ii 814 back to the default values Ict 806 and Iit 808. In other words, in response to disabling the closed loop algorithm (810), the processing circuitry may adjust the informed pulse parameter values and the control pulse parameter values from the minimum of parameter values to the default set of parameter values (813). In this manner IMD 200 may continue to deliver therapy in the presence of noise. ERS may remain suspended and any sensed ECAP may be only monitored, but not affect the therapy delivery. Although the control pulse amplitude and informed pulse amplitude are shown as a continuous ramped back to their respective default levels, IMD 200 may use a step-wise ramp or immediate single jump back to their default levels in other examples.

In other examples, (not shown in FIG. 8), IMD 200 may ramp the parameter values, e.g. the stimulation levels of Ic 812 and Ii 814 to a value different from the default values Ict 806 and Iit 808. For example, IMD 200 may ramp the parameter values to a percentage of the default values Ict 806 and Iit 808, e.g. 70%, 75% or some other percentage. Returning to a sub-default level may provide an advantage by providing some stimulation for therapeutic purposes while avoiding possible overstimulating the patient if the patient is in an awkward posture where returning to the default level would overstimulate the target tissue, e.g. the spinal cord. In other words, returning to a sub-default may balance sufficient stimulation while lowering the risk of 'overstimulation' caused by patient posture or other reasons.

FIG. 9 is a timing diagram illustrating an example of recovering a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure. As described above in relation to FIG. 8, processing circuitry 210 may cause Ic 912 and Ii 914 to increase back to the default values Ict 906 and Iit 908 to avoid under stimulation while noise may impact ECAP measurement. In the example of FIG. 9, while ERS is suspended 922, processing circuitry 210 may monitor ECAP signals from sensing circuitry 206 but make no adjustments to stimulation pulse parameters.

When the sensed ECAP falls back into the predetermined range, between ETH 902 and ETL 904, processing circuitry 210 may start a low-noise timer, $T_{low\text{-}noise}$ 920. In response to determining that low-noise timer 920 has expired, processing circuitry 210 may resume the closed-loop algorithm (924). In other words, when processing circuitry 210 detects that the noise has abated, e.g. ECAP 900 is less than ETH 902 for at least the duration of $T_{low\text{-}noise}$ 920, processing circuitry 210 may enable ERS. With ERS enabled, processing circuitry may cause stimulation generation circuitry 202 to adjust stimulation pulse parameters in response to changes in the sensed ECAP. Also, with Ic 912 and Ii 914 approximately equal to the default values Ict 906 and Iit 908, processing circuitry may respond to commands from patient programmer 150.

FIG. 10 is a flow diagram illustrating an example operation for suspending and recovering a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure. The flow diagram of FIG. 10 is an example of the techniques described by FIGS. 7-9. Although processing circuitry 210 is described as performing the technique of FIG. 10, other circuitry of IMD and/or other devices may perform some or all of the technique in other examples.

Processing circuitry 210 may receive an indication from sensing circuitry 206 whether the value of a characteristic of sensed one or more sensed ECAPs 536 from FIG. 5 may be outside of a target range (1000). When sensed ECAP values are within the target range (NO branch of 1000) processing circuitry 210 may hold the value of the set of parameter values, e.g. Ic and Ii, for the plurality of pulses (1002). Processing circuitry 210 may continue to monitor ECAP values. In this disclosure, "sensing an ECAP" and "measuring an ECAP" is equivalent to sensing one or more ECAP values, and "a value of a characteristic of the ECAP," such as, sensing a voltage amplitude as described above in relation to FIG. 4, by sensing circuitry 206.

If processing circuitry 210 determines that ECAP values are outside the target range (YES branch of 1000), processing circuitry 210 may check whether the ECAP values are higher than the ECAP high threshold (YES branch of 1004).

Processing circuitry **210** may decrement Ic and Ii (**1010**) until the one or more values of the set of values reaches a minimum value. In the example of FIG. **10**, processing circuitry **210** may determine that the amplitude of current for the control pulses (Ic) has not reached the minimum value (NO branch of **1012**) and continue to monitor ECAP values.

If the ECAP values are outside of the range, but not higher than the ECAP high threshold (NO branch of **1004**), processing circuitry **210** may increment Ic and Ii (**1008**) and continue to monitor ECAP values. In other words, if the ECAP values are outside of the range, but less than the ECAP high threshold, the ECAP values must be less than the low ECAP threshold.

When processing circuitry **210** determines that Ic=0, i.e. the minimum value of control pulse amplitude (YES branch of **1012**), processing circuitry may start a noise detection timer, Tdetect. If the ECAP values stay above ETH during Tdetect and Tdetect expires (YES branch of **1014**), processing circuitry **210** may suspend ERS (**1016**) and begin to increment both Ic and Ii (**1018**) until Ic and Ii reach the default values, e.g. Ict **606** and Iit **608** from FIG. **6** (NO branch of **1020**). When Ic and Ii reach the default values (YES branch of **1020**), processing circuitry may hold Ic and Ii at the default values (**1022**) and monitor ECAP values. In other examples, (not shown in FIG. **10**), processing circuitry **210** may set Ic and Ii directly to the default values during this period without the incremental increases.

As described above in relation to FIG. **8**, in other examples, processing circuitry may increment both Ic and Ii (**1018**) until Ic and Ii reach a sub-default value (not shown in FIG. **10**). In other words, processing circuitry may temporarily disable closed-loop operation in the presence of noise and return to some level of therapeutic energy. In some examples, the sub-default value may be a percentage of the default value (not shown in FIG. **10**). In other examples, processing circuitry may return the parameter values to an average, median or some other calculated stimulation level collected during some interval prior to the detection of noise. For example, processing circuitry may use a moving window of delivered stimulation levels and calculate a parameter value over the duration of the moving window. If noise is detected, then the processing circuitry may return the parameter value to the calculated level determined prior to the initial noise detect.

As described above in relation to FIG. **9**, when the ECAP values are less than ETH (YES branch of **1024**) processing circuitry may start a low noise timer, e.g. Tlow-noise **920**. When the low noise timer has expired (YES branch of **1026**), processing circuitry **210** may restart the closed loop algorithm, e.g. ERS, (**1028**) and continue to monitor ECAP values.

FIG. **11** is a timing diagram illustrating an example of a medical device providing electrical stimulation while suspending a closed loop algorithm, in accordance with one or more techniques of this disclosure. The example of FIG. **11** provides an alternative option to the techniques described by FIGS. **7-10**. In contrast to FIGS. **7** and **10**, once processing circuitry **210** determines that ERS should be suspended (**1112**), e.g. because ECAPs value **1100** is above ETL **1104** and ETH **1102** for an extend time, processing circuitry **210** may increment only the informed pulse current amplitude Ii **1114** to the default value Iit **1108**. The control pulse amplitude Ic, may remain at the minimum value, rather than returning to the default value of Ict **1106** (**1116**). Since the control pulse amplitude Ic is what elicits the sensed ECAP signal, a control pulse amplitude Ic at zero should not result in any detectable ECAP signal. In contrast, informed pulse current amplitude Ii can return to default value Iit **1108** in order to reestablish stimulation therapy.

FIG. **12** is a timing diagram illustrating an example of a medical device sensing noise abatement while suspending a closed loop algorithm, in accordance with one or more techniques of this disclosure. As described above in relation to FIG. **11**, processing circuitry **210** may increase informed pulse current amplitude Ii **1214** to the default value Iit **1208** while control pulse amplitude Ic **1212**, may remain at the minimum value during noise detection and ERS is suspended **1218**.

When the noise no longer affects the ECAP value, the ECAP value may drop below ETL **1204** because while the control pulse amplitude is zero (Ic=0), IMD **200** should not generate a detectable ECAP value (e.g., there should be no ECAP signal without a stimulation pulse to elicit such an ECAP signal). Processing circuitry **210** may receive an indication from sensing circuitry **206** that the ECAP value has settled below ETL **1204** (**1200**) and may start a low-noise timer $T_{low\text{-}noise}$ **1216**. In the example of FIG. **12**, processing circuitry may determine noise has abated when Ic=0, the ECAP value is below both ETH **1202** and ETL **1204** and $T_{low\text{-}noise}$ **1216** has expired (**1222**). Put another way, processing circuitry **210** may determine that the noise has abated because the ECAP value has dropped to expected levels with a lack of any control pulse being delivered that is capable of eliciting a detectable ECAP signal.

FIG. **13** is a timing diagram illustrating another example of recovering a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure. As described above in relation to FIG. **12**, processing circuitry **210** may determine that noise impacting a sensed ECAPs value has abated when $T_{low\text{-}noise}$ **1316** has expired (**1324**).

Processing circuitry **210** may increase Ic **1314** until Ic **1314** reaches the default value of Ict **1306**. The informed pulse current magnitude Ii **1312** may remain at Iit **1308**. To ensure the noise is gone, processing circuitry **210** may start a confirmation timer, e.g. Tresume **1322**, and only restart the closed loop algorithm when Tresume **1322** expires (**1326**). In other words, in response to determining that Ic **1314** is at Ict **1306**, the ECAP value is less than ETL **1304** and the confirmation timer Tresume **1322** has expired, processing circuitry **210** may restart ERS (**1328**). In other examples, (not shown in FIG. **13**) processing circuitry **210** may re-enable the closed loop algorithm rather than increasing the parameter values for Ic **1314** and Ii **1312** until the values reach the default value. In other words, processing circuitry **210** may re-enable the closed-loop algorithm such that IMD **200** may provide appropriate stimulation once the system determines that the noise source is gone.

FIG. **14** is a timing diagram illustrating an example of an attempted recovery for a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure. As described above in relation to FIG. **13**, when processing circuitry **210** determines that the noise has abated (**1424**), at the expiration of $T_{low\text{-}noise}$ **1416**, processing circuitry **210** may increase Ic to the default value and start a confirmation timer, e.g. Tresume **1322**. At some time in the interval between determining the noise has abated and the confirmation timer has expired, processing circuitry **210** may receive an indication from sensing circuitry **206** that the ECAP value has exceeded ETH **1402** (**1400**).

In the example of FIG. **14**, Ic ramps toward Ict (**1430**) after processing circuitry determines noise has abated (**1424**). However, noise again couples to the sensing circuitry **206** of IMD **200** and processing circuitry **210** controls Ic to decrease toward the minimum value of Ic=0 (**1432**). In

this manner, processing circuitry **210** can react to any restart of noise when attempting to reestablish ERS. When processing circuitry **210** again determines that the noise has abated (**1425**) because the ECAP value **1400** is less than ETH **1402** and ETL **1404**, processing circuitry may again start a low noise timer, $T_{low\text{-}noise}$ **1434**. When $T_{low\text{-}noise}$ **1434**, processing circuitry **210** may re-attempt to ramp Ic toward Ict (**1436**). To avoid under stimulation, the informed pulse amplitude Ii **1412** may remain at the default value Iit **1408**. Once processing circuitry **210** ramps Ic back to Ict, processing circuitry **210** can continue ERS as normal.

FIG. **15** is a flow diagram illustrating another example operation for suspending and recovering a suspended closed-loop algorithm, in accordance with one or more techniques of this disclosure. The example of FIG. **15** describes techniques illustrated by FIGS. **11-14**. Although processing circuitry **210** is described as performing the technique of FIG. **15**, other circuitry of IMD and/or other devices may perform some or all of the technique in other examples.

Similar to FIG. **10** described above, processing circuitry **210** may receive an indication from sensing circuitry **206** whether the value of a characteristic of sensed one or more sensed ECAPs **536** from FIG. **5** may be outside of a target range (**1500**). When sensed ECAP values are within the target range (NO branch of **1500**) processing circuitry **210** may hold the value of the set of parameter values, e.g. Ic and Ii, for the plurality of pulses (**1502**). Processing circuitry **210** may continue to monitor ECAP values.

If the ECAP values are outside of the range, but not higher than the ECAP high threshold (NO branch of **1504**), processing circuitry **210** may increment Ic and Ii (**1508**) and continue to monitor ECAP values. In other words, if the ECAP values are outside of the range, but less than the ECAP high threshold, the ECAP values must be less than the low ECAP threshold.

When processing circuitry **210** determines that Ic=0, i.e. the minimum value of control pulse amplitude (YES branch of **1512**), processing circuitry may start a noise detection timer, Tdetect. If the ECAP values stay above ETH during Tdetect and Tdetect expires (YES branch of **1514**), processing circuitry **210** may suspend ERS (**1516**) and begin to increment only Ii (**1518**) until Ii reach the default value, e.g. Iit **608** from FIG. **6** (NO branch of **1520**). When Ii reaches the default value (YES branch of **1520**), processing circuitry may hold Ii at the default values (**1522**) and monitor ECAP values (NO branch of **1524**). In this manner, IMD **200** may deliver therapy to patient **105** of FIG. **1** and avoid under stimulation caused by noise.

As described above in relation to FIGS. **12-14**, when processing circuitry **210** receives an indication that the ECAP values are less than ETL, processing circuitry **210** may start $T_{low\text{-}noise}$. When expires, processing circuitry may begin to increase Ic only (1530) because Ii is already at the default value, Iit. As Ic is increasing, processing circuitry **210** may continue to monitor the ECAP values (NO branch of **1532**). While the ECAP values remain less than or equal to ETL (YES branch of **1534**), processing circuitry **210** may continue to increase Ic (**1530**).

When Ic reaches the default value, Ict (YES branch of **1532**), processing circuitry **210** may start a confirmation timer Tresume, described above in relation to FIGS. **13** and **14**. If the ECAP values exceed the ECAP high threshold (NO branch of **1540**) after the confirmation timer expires (YES branch of **1536**), processing circuitry **210** may decrement Ic (**1538**) back to the minimum value of IC, and continue to monitor the ECAP values. If the ECAP values remain less than ETH (YES branch of **1540**), then processing circuitry **210** may restart the closed loop algorithm, e.g. ERS (**1542**).

FIG. **16** is a flow chart illustrating an example operation for managing patient input while delivering electrical stimulation therapy, in accordance with one or more techniques of this disclosure. As described above in relation to FIGS. **5** and **7**, it may be desirable to disable certain programming commands from external programmer **150** while an IMD of this disclosure is responding to patient physiological signals or to noise.

In example of FIG. **16**, the system may only increment therapy (e.g. increase amplitude) in response to a patient adjustment if the current control pulse and informed amplitude levels, Ic and Ii, are approximately equal to the default levels, Ict and Iit, respectively. As described above in relation to FIGS. **5-15**, one or both of Ic and Ii, may approximately equal the default levels, Ict and Iit, when ERS is disabled for a particular. One or both of Ic and Ii may approximately equal the default levels ERS was enabled, but not actively suppressing stimulation therapy levels due to high ECAP measurements. If Ic and/or Ii are not at their default levels (e.g. being suppressed by the ERS algorithm), then the system, may not increase the therapy and, more importantly, may not increase the default levels, according to the techniques of this disclosure. As described above in relation to FIG. **2**, the "system" and "processing circuitry **210**" may refer to IMD **110** and IMD **200** alone, or in communication with external programmer **150**.

In some examples, the patient may choose to decrement the therapy amplitude. Should the patient decrease therapy amplitude then the system may decrement the amplitude of the stimulation therapy being delivered. In addition, if the stimulation pulse amplitude (Ic or Ii) are at the default levels of Ict and Iit, respectively, then the request to decrement the therapy may also adjust the default amplitude level, Ict and Iit.

The techniques of this disclosure will therefore permit the system to be responsive to patient requests, especially to decrement a therapy, but may avoid unwanted conditions where a patient may increase a default stimulation level without a real-time increase in the therapy being delivered and perceived by the patient. In this manner, the techniques of this disclosure may prevent issues of incorrect default level adjustments above a comfortable level when a closed-loop therapy algorithm has altered the stimulation levels away from the normal default stimulation levels for either a control pulse waveform or an informed pulse waveform in the presence of noise or other sensing issue. Thus, a closed-loop responsive stimulation system of this disclosure that includes the ability of patient adjustment needs may account for situations when the system is responding to changes in physiological signals or noise.

At the start (**1600**) of FIG. **16**, processing circuitry **210** may continue to monitor ECAP values and deliver electrical stimulation therapy as needed while waiting for manual adjustment commands from a patient programmer (**1602**). In some examples, processing circuitry **210** may receive a command to increment one or both of the control pulse parameter, e.g. Ic, or the informed pulse parameter, e.g. Ii by a specified amount. In the example of FIG. **16**, the specified increment (YES branch of **1604**) is $\Delta I_{C/I}$, which indicates an increase in either or both of ΔIc or ΔIi.

Note that in the example of FIG. **16**, an increase in ΔIc or ΔIi corresponds to an increase in stimulation level. Similarly, an increase in other parameters for the control pulse or the informed pulse may also increase the stimulation level. Some examples may include an increase in voltage magni-

tude, an increase in duty cycle, an increase in pulse width and similar parameters may increase the stimulation level. In other examples, requested changes to parameters may decrease the stimulation level. For example, selecting different electrodes, changing the output impedance and other parameter changes may decrease stimulation levels. The increase of block **1604** and decrease of block **1606** use changes in electrical current amplitude as in an example of an increase or decrease in stimulation level and the description of FIG. **16** should not be interpreted limited to just an increase or decrease in current amplitude, but interpreted more broadly as an increase or decrease in stimulation level.

In some examples, processing circuitry **210** may include a setting, e.g. stored at storage device **212**, that disables any manual adjustments in the control pulse parameters (NO branch of **1630**). If changes to Ic are disabled, then a command to increase Ic would result in no change (**1634**). In the example of FIG. **16**, at any time that processing circuitry **210** rejects a request from the patient programmer, processing circuitry **210** may communicate with the patient programmer, e.g., external device **30**, and provide an indication that the request has been rejected. For example, at the NO branch of **1630**, **1632**, **1644**, **1608** and so on.

Processing circuitry **210** may be further configured to disable any manual adjustments in the informed pulse parameters (NO branch of **1640**). If changes to Ii are disabled, then a command to increase Ii would result in no change (**1642**) and processing circuitry may continue to monitor for manual adjustments (**1602**).

In other examples, processing circuitry **210** may enable adjustments to Ic (YES branch of **1630**) and processing circuitry **210** may determine whether the set of parameter values for the electrical stimulation therapy is approximately equal to a default set of parameter values, e.g., whether $I_C \geq I_{CT} \pm \delta I_{CT}$. When Ic is outside the predetermined range of the respective default parameter value, e.g. differs from Ict by more than $\pm\delta I_{CT}$, (NO branch of **1632**), then processing circuitry **210** may not increment Ic (**1634**). When Ic is with the predetermined range (YES branch of **1632**), processing circuitry **210** may increment Ic by ΔIc (**1636**) and change the default value Ict to the new value of Ic (**1638**). Said another way, processing circuitry **210**, may first determine that the value of the parameter defining the electrical stimulation therapy is not within a tolerance, $\pm\delta I_{CT}$, of a default parameter before rejecting the request to change the parameter. The tolerance, $\pm\delta I_{CT}$, is a small value, compared to the default value, that may be zero.

In examples in which processing circuitry **210** may enable adjustments to Ii (YES branch of **1640**) and processing circuitry **210** may determine whether the set of parameter values for the electrical stimulation therapy is approximately equal to a default set of parameter values, e.g., whether $I_I \geq I_{IT} \pm \delta I_{IT}$. When Ii is outside the predetermined range of the respective default parameter value, e.g. differs from Iit by more than $\pm\delta I_{IT}$, (NO branch of **1644**), then processing circuitry **210** may not increment Ii (**1642**). When Ii is with the predetermined range (YES branch of **1644**), processing circuitry **210** may increment Ii by ΔIi (**1646**) and change the default value Iit to the new value of Ii (**1688**).

In other examples, processing circuitry may receive a decrement command from external programmer **150** (NO branch of **1604** and YES branch of **1606**).

Processing circuitry **210** may be configured to disable any manual adjustments in the control pulse parameters (NO branch of **1608**). If changes to Ic are disabled, then a command to decrease Ic would result in no change (**1616**).

Processing circuitry **210** may be further configured to disable any manual adjustments in the informed pulse parameters (NO branch of **1618**). If changes to Ii are disabled, then a command to decrease Ii would result in no change (**1626**) and processing circuitry may continue to monitor for manual adjustments (**1602**).

In other examples, processing circuitry **210** may be configured to enable adjustments to Ic (YES branch of **1608**) and processing circuitry **210** may determine whether the set of parameter values for the electrical stimulation therapy is approximately equal to a default set of parameter values, e.g., whether $I_C \geq I_{CT} \pm \delta I_{CT}$. When Ic is outside the predetermined range of the respective default parameter value, e.g. differs from Ict by more than $\pm\delta I_{CT}$, (NO branch of **1610**), then, in contrast to the increment command, processing circuitry **210** may decrement Ic by ΔIc, i.e. Ic=Ic−ΔIc (**1612**), but make no change to the default value Ict. In other examples, when Ic is with the predetermined range (YES branch of **1610**), processing circuitry **210** may decrement both Ic by ΔIc (**1612**) and change the default value Ict to the new value of Ic, i.e. Ict=Ict−ΔIc (**1614**).

In examples in which processing circuitry **210** may enable adjustments to Ii (YES branch of **1618**) and processing circuitry **210** may determine whether the set of parameter values for the electrical stimulation therapy is approximately equal to a default set of parameter values, e.g., whether $I_I \geq I_{IT} \pm \delta I_{IT}$. When Ii is outside the predetermined range of the respective default parameter value, e.g. differs from Et by more than ±(NO branch of **1620**), in contrast to the increment command, processing circuitry **210** may decrement Ii by ΔIi, i.e. Ii=Ii−ΔIi (**1622**), but make no change to the default value Iit. In other examples, when Ii is with the predetermined range (YES branch of **1620**), processing circuitry **210** may decrement both Ii by ΔIi (**1622**) and change the default value Iit to the new value of Ii, i.e. Iit=Iit−ΔIi (**1624**).

In one or more examples, the functions described above may be implemented in hardware, software, firmware, or any combination thereof. For example, the various components of FIGS. **1** and **2**, such as processing circuitry **210**, sensing circuitry **206**, and communication circuitry **208** may be implemented in hardware, software, firmware, or any combination thereof. If implemented in software, the functions may be stored on or transmitted over, as one or more instructions or code, a computer-readable medium and executed by a hardware-based processing unit. Computer-readable media, such as storage device **212**, may include computer-readable storage media, which corresponds to a tangible medium such as data storage media, or communication media including any medium that facilitates transfer of a computer program from one place to another, e.g., according to a communication protocol. In this manner, computer-readable media generally may correspond to (1) tangible computer-readable storage media which is non-transitory or (2) a communication medium such as a signal or carrier wave. Data storage media may be any available media that can be accessed by one or more computers or one or more processors to retrieve instructions, code and/or data structures for implementation of the techniques described in this disclosure. A computer program product may include a computer-readable medium. The term "non-transitory" may indicate that the storage medium is not embodied in a carrier wave or a propagated signal. In certain examples, a non-transitory storage medium may store data that can, over time, change (e.g., in RAM or cache).

By way of example, and not limitation, such computer-readable storage media, such as storage device **212**, may

include random access memory (RAM), read only memory (ROM), programmable read only memory (PROM), erasable programmable read only memory (EPROM), electronically erasable programmable read only memory (EEPROM), flash memory, a hard disk, a compact disc ROM (CD-ROM), a floppy disk, a cassette, magnetic media, optical media, or other computer readable media. In some examples, an article of manufacture may include one or more computer-readable storage media.

Also, any connection is properly termed a computer-readable medium. For example, if instructions are transmitted from a website, server, or other remote source using a coaxial cable, fiber optic cable, twisted pair, digital subscriber line (DSL), or wireless technologies such as infrared, radio, and microwave, then the coaxial cable, fiber optic cable, twisted pair, DSL, or wireless technologies such as infrared, radio, and microwave are included in the definition of medium. It should be understood, however, that computer-readable storage media and data storage media do not include connections, carrier waves, signals, or other transient media, but are instead directed to non-transient, tangible storage media. Combinations of the above should also be included within the scope of computer-readable media.

Instructions may be executed by one or more processors, such as one or more DSPs, general purpose microprocessors, ASICs, FPGAs, or other equivalent integrated or discrete logic circuitry. Accordingly, the term "processor," as used herein, such as processing circuitry **210**, may refer to any of the foregoing structure or any other structure suitable for implementation of the techniques described herein. Also, the techniques could be fully implemented in one or more circuits or logic elements.

The techniques of this disclosure may be implemented in a wide variety of devices or apparatuses, including, an integrated circuit (IC) or a set of ICs (e.g., a chip set). Various components, modules, or units are described in this disclosure to emphasize functional aspects of devices configured to perform the disclosed techniques, but do not necessarily require realization by different hardware units. Rather, as described above, various units may be combined in a hardware unit or provided by a collection of interoperative hardware units, including one or more processors as described above, in conjunction with suitable software and/or firmware.

Example 1: A method that includes receiving information indicative of a sensed evoked compound action potential (ECAP) signal; determining a value of a characteristic of the ECAP signal based on the information, wherein the ECAP signal is elicited by a respective stimulation pulse of a plurality of stimulation pulses; executing a closed loop policy that adjusts, based on the value of the characteristic of the ECAP signal, a value of a parameter that at least partially defines stimulation therapy; determining that the value of the characteristic of the ECAP signal is outside of an expected range; and responsive to determining that the value of the characteristic of the ECAP signal is outside of the expected range, disabling the closed loop policy.

Example 2: The method of example 1, wherein the value of the parameter is a first value, wherein a set of values for the parameter comprises a threshold value, and wherein the method further comprises: responsive to adjusting the first value to the threshold value based on the closed loop policy, starting a noise detection timer; determining that the noise detection timer has expired; and responsive to determining that the noise detection timer has expired, determining that the value of the characteristic of the ECAP signal remains outside of the expected range; and responsive to determining that the value of the characteristic of the ECAP signal remains outside of the expected range, disabling the closed-loop policy.

Example 3: The method of example 2, wherein the threshold value of the parameter of the respective stimulation pulses comprises a minimum value for the parameter.

Example 4: The method of example 2, wherein the plurality of pulses comprises a plurality of control pulses and a plurality of informed pulses, wherein the respective stimulation pulses comprise respective control pulses of the plurality of control pulses, wherein receiving information indicative of a ECAP signal comprises sensing a respective ECAP signal after a respective control pulse of the plurality of control pulses, wherein an informed pulse of the plurality of informed pulses is defined by one or more parameters based on a respective ECAP signal elicited from a respective control pulse while executing the closed loop policy; wherein the expected range of the value of the characteristic comprises an ECAP high threshold (ETH) and an ECAP low threshold (ETL), and wherein the method further comprises: responsive to the value of the characteristic of the ECAP signal greater than the ECAP high threshold, incrementally adjusting: a respective value of the parameter defining the plurality of respective control pulses from a first control pulse value toward a second control pulse value; and a respective value of the parameter defining the plurality of respective informed pulses from a first informed pulse value toward a second informed pulse value.

Example 5: The method of example 4, further that includes responsive to disabling the closed loop policy, adjusting, by the processing circuitry, informed pulse parameter values back to the first informed pulse value, and measuring, by the sensing circuitry, the respective ECAP signal after the respective control pulse, wherein the processing circuitry makes no adjustments to informed pulse parameter values nor control pulse parameter values based on the measured respective ECAP signal while the closed loop policy is disabled.

Example 6: The method of example 4, further comprising, responsive to sensing, by the sensing circuitry, that the value of the characteristic of the measured respective ECAP signal is less than the ECAP high threshold, starting, by the processing circuitry a low-noise timer.

Example 7: The method of example 6, further comprising, responsive to determining, by the processing circuitry, that the low-noise timer has expired, enabling, by the processing circuitry, the closed-loop policy.

Example 8: The method of example 5, wherein the first informed pulse value of the parameter is a control pulse parameter default value, wherein the second control pulse value is less than or equal to the default value, and wherein the control pulse parameter is set to the second control pulse value, the method further comprising, in response to in response to receiving an indication from the sensing circuitry that the value of the characteristic of the measured respective ECAP signal is less than the ECAP low threshold, start a low-noise timer; responsive to determining that the low-noise timer has expired, adjusting, by the processing circuitry, the control pulse parameter values from the second control pulse value to the default value.

Example 9: The method of example 8, further that includes responsive to setting the control pulse parameter values to the default value, starting, by the processing circuitry, a confirmation timer, and responsive to determining that the confirmation timer has expired, enabling, by the processing circuitry, the closed-loop policy.

Example 10: The method of example 8, further that includes responsive to sensing, by the sensing circuitry, that the value of the characteristic of the measured respective ECAP signal is greater than the ECAP high threshold, reducing, by the processing circuitry, the respective value of the parameter for the plurality of respective control pulses; and the respective value of the parameter for the plurality of respective informed pulses.

Example 11: The method of example 10, further that includes responsive to determining that the low-noise timer has expired, adjusting, by the processing circuitry, control pulse value from the second control value to the default control pulse value, responsive to setting the control pulse parameter values to the default control pulse value, starting, by the processing circuitry, a confirmation timer, and responsive to determining that the confirmation timer has expired, enabling, by the processing circuitry, the closed-loop policy.

Example 12: The method of example 1, further comprising controlling the stimulation generation circuitry to deliver electrical stimulation therapy according to: the closed loop policy, or user input.

Example 13: A medical device comprising processing circuitry configured to: receive information indicative of a sensed evoked compound action potential (ECAP) signal determine a value of a characteristic of the ECAP signal based on the information, wherein the ECAP signal is elicited by respective stimulation pulses of a plurality of pulses; determine whether a value of a characteristic of the ECAP signal is outside of an expected range; execute a closed loop policy, wherein the closed loop policy adjusts a value of a parameter that at least partially defines stimulation therapy, based on the value of the characteristic of the ECAP signal; and responsive to determining that the value of the characteristic of the ECAP signal is outside of the expected range, disable the closed-loop policy.

Example 14: The medical device of example 13, wherein the value of the parameter is a first value, wherein a set of values for the parameter comprises a threshold value; the processing circuitry further configured to: responsive to adjusting the value of the parameter from the first value to the threshold value, starting, a noise detection timer; responsive to determining that the noise detection timer has expired, and that the value of the characteristic of the ECAP signal is still outside of the expected range, disable the closed-loop policy.

Example 15: The medical device of example 14, wherein the threshold value of the parameter of the respective stimulation pulses comprises a minimum value for the parameter.

Example 16: The medical device of example 15: wherein the plurality of pulses comprises a plurality of control pulses and a plurality of informed pulses, wherein the respective stimulation pulses comprise respective control pulses of the plurality of control pulses, wherein receiving information indicative of a ECAP signal comprises sensing a respective ECAP signal after a respective control pulse of the plurality of control pulses, wherein an informed pulse of the plurality of informed pulses is defined by one or more parameters based on a respective ECAP signal elicited from a respective control pulse, wherein the expected range of the value of the characteristic comprises an ECAP high threshold (ETH) and an ECAP low threshold (ETL), the processing circuitry further configured to, responsive to the value of the characteristic of the ECAP signal greater than the ECAP high threshold, incrementally adjusting: a respective value of the parameter for the plurality of respective control pulses from a first control pulse value toward a second control pulse value; and a respective value of the parameter for the plurality of respective informed pulses from a first informed pulse value toward a second informed pulse value.

Example 17: The medical device of example 16, wherein the processing circuitry is further configured to: responsive to disabling the closed loop policy, adjust the informed pulse parameter values back to the first informed pulse values, and cause the sensing circuitry to measure the respective ECAP signal after the respective control pulse, wherein the processing circuitry makes no adjustments to the informed pulse parameter values nor the control pulse parameter values based on the measured respective ECAP signal while the closed loop policy is disabled.

Example 18: The medical device of example 17, wherein the processing circuitry further configured to, responsive to receiving an indication from the sensing circuitry that the value of the characteristic of the measured respective ECAP signal is less than the ECAP high threshold, start a low-noise timer.

Example 19: The medical device of example 18, wherein the processing circuitry is further configured to, responsive to determining that the low-noise timer has expired, enable the closed-loop policy.

Example 20: The medical device of example 16, wherein the first informed pulse value of the parameter is a control pulse parameter default value, wherein the second control pulse value is less than or equal to the default value, and wherein the control pulse parameter is set to the second control pulse value, wherein the processing circuitry further configured to: responsive to receiving an indication from the sensing circuitry that the value of the characteristic of the measured respective ECAP signal is less than the ECAP low threshold, start a low-noise timer; and responsive to determining that the low-noise timer has expired, adjust the control pulse parameter values from the second control pulse value to the default control pulse value.

Example 21: The medical device of example 20, wherein the processing circuitry is further configured to, responsive to setting the control pulse parameter values to the default control pulse value, start a confirmation timer, and responsive to determining that the confirmation timer has expired, enable the closed-loop policy.

Example 22: The medical device of example 20, wherein the processing circuitry is further configured to, responsive to receiving an indication from the sensing circuitry, that the value of the characteristic of the measured respective ECAP signal is greater than the ECAP high threshold, reducing the respective value of the parameter for the plurality of respective control pulses.

Example 23: The medical device of example 22, wherein the processing circuitry is further configured to, responsive to determining that the low-noise timer has expired, adjust the control pulse parameter values from the second control pulse value to the default control pulse value, responsive to setting the control pulse parameter values to the default control pulse value, start a confirmation timer, and responsive to determining that the confirmation timer has expired, enable the closed-loop policy.

Example 24: The medical device of example 13, wherein the processing circuitry is further configured to control the stimulation generation circuitry to deliver electrical stimulation therapy according to: the closed loop policy, or user input.

Example 25: A computer-readable medium comprising instructions for causing programmable processor processing circuitry to: receive information indicative of a sensed evoked compound action potential (ECAP) signal determine

a value of a characteristic of the ECAP signal based on the information, wherein the ECAP signal is elicited by respective stimulation pulses of a plurality of pulses; determine whether a value of a characteristic of the ECAP signal is outside of an expected range; execute a closed loop policy, wherein the closed loop policy adjusts a value of a parameter that at least partially defines stimulation therapy, based on the value of the characteristic of the ECAP signal; and responsive to determining that the value of the characteristic of the ECAP signal is outside of the expected range, disable the closed-loop policy.

Example 26: A method that includes delivering, by stimulation generation circuitry of a medical device, electrical stimulation therapy to a patient, the electrical stimulation therapy comprising a plurality of pulses defined by a set of parameters; receiving, by processing circuitry of the medical device, a request from an external programmer to change a value of a parameter defining the plurality of pulses, wherein the external programmer is external to the medical device; determining, by the processing circuitry, that the requested change to the parameter is a request to increase the value of the parameter defining the plurality of pulses; determining, by the processing circuitry, that a control policy executed by the processing circuitry is determining values of the parameter that defines the electrical stimulation therapy; responsive to determining that the control policy is determining values of at the parameter that defines the electrical stimulation therapy, rejecting, by the processing circuitry, the request to change the value of the parameter.

Example 27: The method of example 26, wherein determining that the control policy is determining values of the parameter that defines the electrical stimulation therapy comprises: determining, by the processing circuitry, that the value of the parameter defining the electrical stimulation therapy is not within a tolerance of a default parameter; responsive to determining that the value of the parameter defining the electrical stimulation therapy is not within the tolerance of the default parameter, rejecting, by the processing circuitry the request to increase the value of the parameter.

Example 28: The method of any combination of examples 26-27, wherein the command from the external programmer is a is a first command, the method further that includes receiving, from the external programmer, a second command to change the value of the parameter defining the plurality of pulses; determining, by the processing circuitry, that the requested change to the parameter in the second command is also a request to increase the value of the parameter defining the plurality of pulses; responsive to determining that the value of the parameter defining the electrical stimulation therapy is within the tolerance of the default parameter, increasing, by the processing circuitry both the parameter and the default parameter based on the command from the external programmer.

Example 29: The method of any combination of examples 26-28, wherein the command from the external programmer is a is a first command, the method further that includes receiving, from the external programmer, a second command to change the value of the parameter defining the plurality of pulses; determining, by the processing circuitry, that the requested change to the parameter in the second command is a request to decrease the value of the parameter defining the plurality of pulses; responsive to determining that the requested change is a request to decrease the value of the parameter, changing, by the processing circuitry both the parameter and a default value of the parameter.

Example 30: The method of any combination of examples 26-29, further comprising, responsive to determining that the requested change is a request to decrease the value of the parameter, and before changing both the parameter and the default value of the parameter; determining that the value of the parameter defining the electrical stimulation therapy is within the tolerance of the default parameter; responsive to determining that the value of the parameter defining the electrical stimulation therapy is within a tolerance of the default parameter, changing, by the processing circuitry both the parameter and the default value of the parameter.

Example 31: The method of any combination of examples 26-30, wherein the parameter is an electrical current amplitude.

Example 32: The method of any combination of examples 26-31, wherein the set of parameters comprises the current amplitude that at least partially defines an informed pulse, and wherein the method further comprises: controlling the stimulation generation circuitry to deliver a control pulse configured to elicit a detectable evoked compound action potentials (ECAP) signal; receiving the ECAP signal; and executing the control policy to determine, based on the ECAP signal elicited by the delivered control pulse, an updated value of the current amplitude that at least partially defines a subsequent informed pulse and an updated value of a current amplitude that at least partially defines a subsequent control pulse.

Example 33: The method of any combination of examples 26-32, further comprising, outputting, by the processing circuitry of the medical device, an indication to the external programmer that the processing circuitry has rejected the request to change the value of the parameter.

Example 34: A medical device that includes stimulation generation circuitry configured to deliver electrical stimulation therapy to a patient, the electrical stimulation therapy comprising a plurality of pulses defined by a set of parameters; and processing circuitry configured to: receive a command from an external programmer (**1602**) to change a value of a parameter defining the plurality of pulses, wherein the external programmer is external to the medical device; determine that the requested change to the parameter is a request to increase the value of the parameter defining the plurality of pulses; determining that a control policy executed by the processing circuitry is determining values of the parameter that defines the electrical stimulation therapy responsive to determining that the control policy is determining values of at the parameter that defines the electrical stimulation therapy, reject the request to change the value of the parameter.

Example 35: The medical device of example 34, wherein to determine that the control policy is determining values of at the parameter that defines the electrical stimulation therapy comprises the processing circuitry configured to: determine that the value of the parameter defining the electrical stimulation therapy is with the tolerance of a default parameter; responsive to determining that the value of the parameter defining the electrical stimulation therapy is not within the tolerance of the default parameter, reject the request to change to the parameter to increase the value of the parameter.

Example 36: The medical device of any combination of examples 34-35, wherein the parameter value is an electrical current amplitude.

Example 37: The medical device of any combination of examples 34-36, wherein the command from the external programmer is a is a first command, and wherein the processing circuitry is further configured to: receive a sec-

ond command to change the value of the parameter defining the plurality of pulses; determine that the requested change to the parameter in the second command is also a request to increase the value of the parameter defining the plurality of pulses; responsive to determining that the value of the parameter defining the electrical stimulation therapy is within the tolerance of the default parameter, increase both the parameter and the default parameter based on the command from the external programmer.

Example 38: The medical device of any combination of examples 34-37, wherein the command from the external programmer is a is a first command, and wherein the processing circuitry is further configured to: receive a second command from the external programmer to change the value of the parameter defining the plurality of pulses; determine that the requested change to the parameter in the second command is a request to decrease the value of the parameter defining the plurality of pulses; responsive to determining that the requested change is a request to decrease the value of the parameter, change both the parameter and a default value of the parameter.

Example 39: The medical device of any combination of examples 34-38, wherein the set of parameters comprises the current amplitude that at least partially defines an informed pulse, and wherein the method further comprises: controlling the stimulation generation circuitry to deliver a control pulse configured to elicit a detectable evoked compound action potentials (ECAP) signal; receiving the ECAP signal; and executing the control policy to determine, based on the ECAP signal elicited by the delivered control pulse, an updated value of the current amplitude that at least partially defines a subsequent informed pulse and an updated value of a current amplitude that at least partially defines a subsequent control pulse.

Example 40: The medical device of any combination of examples 34-39, wherein the processing circuitry of the medical device is configured to output an indication to the external programmer that the processing circuitry has rejected the request to change the value of the parameter.

Example 41: A computer-readable medium comprising instructions for causing a programmable processor of a medical device to: cause stimulation generation circuitry of the medical device to deliver electrical stimulation therapy to a patient, the electrical stimulation therapy comprising a plurality of pulses defined by a set of parameters; receive of the medical device, a command from an external programmer to change a value of a parameter defining the plurality of pulses, wherein the external programmer is external to the medical device; determine that the requested change to the parameter is a request to increase the value of the parameter defining the plurality of pulses; determine that a control policy executed by the processing circuitry is determining values of the parameter that defines the electrical stimulation therapy; responsive to determining that the control policy is determining values of at the parameter that defines the electrical stimulation therapy, reject the request to change the value of the parameter.

Example 42: The computer-readable medium of example 41, wherein determining that the control policy is determining values of the parameter that defines the electrical stimulation therapy comprises: determining, by the processing circuitry, that the value of the parameter defining the electrical stimulation therapy is not within a tolerance of a default parameter; responsive to determining that the value of the parameter defining the electrical stimulation therapy is not within the tolerance of the default parameter, rejecting, by the processing circuitry the request to increase the value of the parameter.

Example 43: The computer-readable medium of any combination of examples 41-42, wherein the command from the external programmer is a is a first command, the method further that includes receiving, from the external programmer, a second command to change the value of the parameter defining the plurality of pulses; determining, by the processing circuitry, that the requested change to the parameter in the second command is also a request to increase the value of the parameter defining the plurality of pulses; responsive to determining that the value of the parameter defining the electrical stimulation therapy is within the tolerance of the default parameter, increasing, by the processing circuitry both the parameter and the default parameter based on the command from the external programmer.

Example 44: The computer-readable medium of any combination of examples 41-43, wherein the command from the external programmer is a is a first command, the method further that includes receiving, from the external programmer, a second command to change the value of the parameter defining the plurality of pulses; determining, by the processing circuitry, that the requested change to the parameter in the second command is a request to decrease the value of the parameter defining the plurality of pulses; responsive to determining that the requested change is a request to decrease the value of the parameter, changing, by the processing circuitry both the parameter and the default value of the parameter.

Example 45: The computer-readable medium of any combination of examples 41-44, wherein the parameter is an electrical current amplitude.

Various examples of the disclosure have been described. These and other examples are within the scope of the following claims.

What is claimed is:

1. A method comprising:

receiving information indicative of a sensed evoked compound action potential (ECAP) signal;

determining a value of a characteristic of the ECAP signal based on the information, wherein the ECAP signal is elicited by a respective stimulation pulse of a plurality of stimulation pulses;

executing a closed loop policy that adjusts, based on the value of the characteristic of the ECAP signal, a value of a parameter that at least partially defines stimulation therapy;

determining whether the value of the characteristic of the ECAP signal is inside or outside of an expected range;

responsive to determining that the value of the characteristic of the ECAP signal is outside of the expected range, disabling the closed loop policy and setting the parameter to a threshold value;

responsive to setting the parameter to the threshold value, starting a noise detection timer; and

responsive to determining that the noise detection timer has expired, enabling the closed loop policy.

2. The method of claim **1**, further comprising

responsive to determining that the noise detection timer has expired, determining that the value of the characteristic of the ECAP signal remains outside of the expected range; and

responsive to determining that the value of the characteristic of the ECAP signal remains outside of the expected range, disabling the closed-loop policy.

3. The method of claim 2, wherein the threshold value of the parameter of the respective stimulation pulses comprises a minimum value for the parameter.

4. The method of claim 1,

wherein the plurality of stimulation pulses comprises a plurality of control pulses and a plurality of informed pulses,

wherein the respective stimulation pulses comprise respective control pulses of the plurality of control pulses,

wherein receiving information indicative of a ECAP signal comprises sensing a respective ECAP signal after a respective control pulse of the plurality of control pulses,

wherein an informed pulse of the plurality of informed pulses is defined by one or more parameters based on a respective ECAP signal elicited from a respective control pulse while executing the closed loop policy;

wherein the expected range of the value of the characteristic comprises an ECAP high threshold (ETH) and an ECAP low threshold (ETL), and wherein the method further comprises:

responsive to the value of the characteristic of the ECAP signal greater than the ECAP high threshold, incrementally adjusting:

a respective value of the parameter defining the plurality of respective control pulses from a first control pulse value toward a second control pulse value; and

a respective value of the parameter defining the plurality of respective informed pulses from a first informed pulse value toward a second informed pulse value.

5. The method of claim 4, further comprising:

responsive to disabling the closed loop policy, adjusting, by the processing circuitry, informed pulse parameter values back to the first informed pulse value, and

measuring, by the sensing circuitry, the respective ECAP signal after the respective control pulse, wherein the processing circuitry makes no adjustments to informed pulse parameter values nor control pulse parameter values based on the measured respective ECAP signal while the closed loop policy is disabled.

6. The method of claim 5,

wherein the first informed pulse value of the parameter is a control pulse parameter default value,

wherein the second control pulse value is less than or equal to the default value, and

wherein the control pulse parameter is set to the second control pulse value,

the method further comprising, in response to in response to receiving an indication from the sensing circuitry that the value of the characteristic of the measured respective ECAP signal is less than the ECAP low threshold, start a low-noise timer;

responsive to determining that the low-noise timer has expired, adjusting, by the processing circuitry, the control pulse parameter values from the second control pulse value to the default value.

7. The method of claim 6, further comprising:

responsive to setting the control pulse parameter values to the default value, starting, by the processing circuitry, a confirmation timer, and

responsive to determining that the confirmation timer has expired, enabling, by the processing circuitry, the closed-loop policy.

8. The method of claim 6, further comprising:

responsive to sensing, by the sensing circuitry, that the value of the characteristic of the measured respective ECAP signal is greater than the ECAP high threshold, reducing, by the processing circuitry,

the respective value of the parameter for the plurality of respective control pulses; and

the respective value of the parameter for the plurality of respective informed pulses.

9. The method of claim 8, further comprising:

responsive to determining that the low-noise timer has expired, adjusting, by the processing circuitry, control pulse value from the second control value to the default control pulse value,

responsive to setting the control pulse parameter values to the default control pulse value, starting, by the processing circuitry, a confirmation timer, and

responsive to determining that the confirmation timer has expired, enabling, by the processing circuitry, the closed-loop policy.

10. The method of claim 4, further comprising, responsive to sensing, by the sensing circuitry, that the value of the characteristic of the measured respective ECAP signal is less than the ECAP high threshold, starting, by the processing circuitry a low-noise timer.

11. The method of claim 10, further comprising, responsive to determining, by the processing circuitry, that the low-noise timer has expired, enabling, by the processing circuitry, the closed-loop policy.

12. The method of claim 1, further comprising controlling the stimulation generation circuitry to deliver electrical stimulation therapy according to:

the closed loop policy, or

user input.

13. A medical device comprising processing circuitry configured to:

receive information indicative of a sensed evoked compound action potential (ECAP) signal

determine a value of a characteristic of the ECAP signal based on the information, wherein the ECAP signal is elicited by respective stimulation pulses of a plurality of stimulation pulses;

determine whether the value of the characteristic of the ECAP signal is inside or outside of an expected range of the characteristic;

responsive to determining that the value is inside the expected range, execute a closed loop policy wherein the closed loop policy adjusts a parameter value that at least partially defines stimulation therapy, based on the value of the characteristic of the ECAP signal; and

responsive to determining that the value of the characteristic of the ECAP signal is outside of the expected range, disable the closed-loop policy and set the parameter value to a threshold value;

responsive to setting the parameter value to the threshold value, start a noise detection timer;

responsive to determining that the noise detection timer has expired, enable the closed-loop policy.

14. The medical device of claim 13,

wherein

the processing circuitry further configured to:

responsive to determining that the noise detection timer has expired, and that the value of the characteristic of the ECAP signal is still outside of the expected range, disable the closed-loop policy.

15. The medical device of claim 14, wherein the threshold value of the parameter of the respective stimulation pulses comprises a minimum value for the parameter.

16. The medical device of claim 15:

wherein the plurality of stimulation pulses comprises a plurality of control pulses and a plurality of informed pulses,

wherein the respective stimulation pulses comprise respective control pulses of the plurality of control pulses,

wherein receiving information indicative of a ECAP signal comprises sensing a respective ECAP signal after a respective control pulse of the plurality of control pulses,

wherein an informed pulse of the plurality of informed pulses is defined by one or more parameters based on a respective ECAP signal elicited from a respective control pulse,

wherein the expected range of the value of the characteristic comprises an ECAP high threshold (ETH) and an ECAP low threshold (ETL),

the processing circuitry further configured to, responsive to the value of the characteristic of the ECAP signal greater than the ECAP high threshold, incrementally adjusting:

a respective parameter value for the plurality of respective control pulses from a first control pulse value toward a second control pulse value; and

a respective parameter value for the plurality of respective informed pulses from a first informed pulse value toward a second informed pulse value.

17. The medical device of claim 16, wherein the processing circuitry is further configured to:

responsive to disabling the closed loop policy, adjust the informed pulse parameter values back to the first informed pulse values, and

cause the sensing circuitry to measure the respective ECAP signal after the respective control pulse, wherein the processing circuitry makes no adjustments to the informed pulse parameter values nor the control pulse parameter values based on the measured respective ECAP signal while the closed loop policy is disabled.

18. The medical device of claim 17, wherein the processing circuitry further configured to, responsive to receiving an indication from the sensing circuitry that the value of the characteristic of the measured respective ECAP signal is less than the ECAP high threshold, start a low-noise timer.

19. The medical device of claim 18, wherein the processing circuitry is further configured to, responsive to determining that the low-noise timer has expired, enable the closed-loop policy.

20. The medical device of claim 16,

wherein the first informed pulse value of the parameter is a control pulse parameter default value,

wherein the second control pulse value is less than or equal to the default value, and

wherein the control pulse parameter is set to the second control pulse value,

wherein the processing circuitry further configured to:

responsive to receiving an indication from the sensing circuitry that the value of the characteristic of the measured respective ECAP signal is less than the ECAP low threshold, start a low-noise timer; and

responsive to determining that the low-noise timer has expired, adjust the control pulse parameter values from the second control pulse value to the default control pulse value.

21. The medical device of claim 20, wherein the processing circuitry is further configured to,

responsive to setting the control pulse parameter values to the default control pulse value, start a confirmation timer, and

responsive to determining that the confirmation timer has expired, enable the closed-loop policy.

22. The medical device of claim 20, wherein the processing circuitry is further configured to, responsive to receiving an indication from the sensing circuitry, that the value of the characteristic of the measured respective ECAP signal is greater than the ECAP high threshold, reducing the respective parameter value for the plurality of respective control pulses.

23. The medical device of claim 22, wherein the processing circuitry is further configured to,

responsive to determining that the low-noise timer has expired, adjust the control pulse parameter values from the second control pulse value to the default control pulse value,

responsive to setting the control pulse parameter values to the default control pulse value, start a confirmation timer, and

responsive to determining that the confirmation timer has expired, enable the closed-loop policy.

24. The medical device of claim 13, wherein the processing circuitry is further configured to control the stimulation generation circuitry to deliver electrical stimulation therapy according to:

the closed loop policy, or

user input.

25. A non-transitory computer-readable storage medium comprising instructions, that when executed, cause programmable processing circuitry to:

receive information indicative of a sensed evoked compound action potential (ECAP) signal;

determine a value of a characteristic of the ECAP signal based on the information, wherein the ECAP signal is elicited by respective stimulation pulses of a plurality of stimulation pulses;

determine whether the value of the characteristic of the ECAP signal is inside or outside of an expected range of the characteristic;

responsive to determining that the value is inside the expected range, execute a closed loop policy, based on the value of the characteristic of the ECAP signal, wherein the closed loop policy adjusts a parameter value that at least partially defines stimulation therapy;

responsive to determining that the value of the characteristic of the ECAP signal is outside of the expected range, disable the closed-loop policy and set the parameter value to a threshold value;

responsive to setting the parameter value to the threshold value, start a noise detection timer; and

responsive to determining that the noise detection timer has expired, enable the closed-loop policy.

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