

When the signal changes, what happens next

Two Medtronic patents. Two different ways to decide what electrical stimulation should do next: question a noisy neural response, or use a different feedback signal.

01 / A pulse is not a nerve response.

One signal reflects the electrical pulse and its associated charge changes. The other is a physiological response travelling along nerve fibres. Confusing the two would obscure the central difference between these inventions.

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02 / A noisy loop needs a way out.

The first patent describes suspending ECAP-based adjustment after persistent high readings and a minimum-output test. Its illustrated recovery restores stimulation settings, monitors the signal and waits before restarting the loop.

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03 / Too few responses can change the feedback source.

The second patent compares detectable neural responses with the number of pulses. When that ratio is insufficient, it can use the directly sensed stimulation signal instead. That decision does not itself establish that noise caused the low ratio.

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The complete explanation follows, with annotated source drawings and all 94 original pages. Blue source references work inside this PDF.

Investigation overview

Two different feedback priorities

The two disclosures address different failure modes in closed-loop electrical stimulation. US 11,559,689 B2 begins with an evoked compound action potential (ECAP), meaning a sensed neural response, and focuses on preventing a corrupted or persistently abnormal ECAP measurement from driving therapy progressively downward. US 12,128,235 B2 instead makes the directly sensed stimulation signal usable as feedback when ECAPs are absent or occur too infrequently for ECAP-based control. These are patent disclosures and inventor-reported technical observations, rather than evidence of a combined product or clinical benefit.

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Artifact is not neural response

The distinction requested by the reader is fundamental. A stimulation signal, called an artifact in the first disclosure, is electrical potential sensed directly from delivery of the pulse and associated tissue charge changes. It occurs during, or substantially overlaps, pulse delivery. An ECAP is different: it is the physiological response after a pulse excites nerve fibers, with a propagating action potential reaching sensing electrodes later. A large pulse-correlated signal therefore does not by itself establish neural recruitment. Both disclosures also recognize that the direct stimulation signal can be larger than, and obscure, the ECAP.

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US 11,559,689 B2: Noise-Resilient ECAP Control

The device, the leads and the programmer

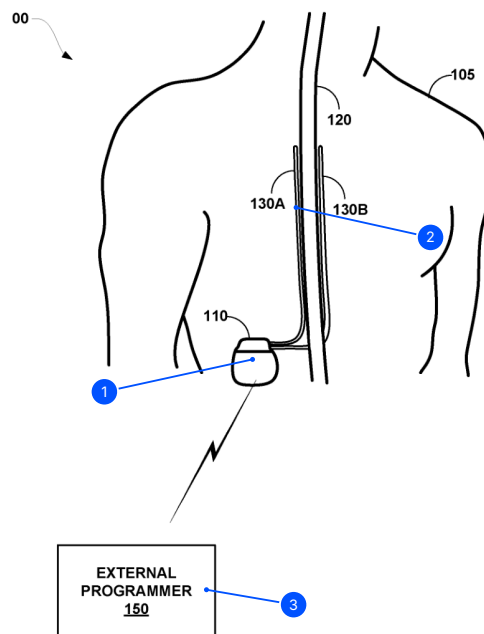


FIG. 1

US11559689B2 · Original FIG. 1. Blue leaders identify parts; they add no new signal paths.

01 / 110 / Implantable device — Generate the stimulation

The implant delivers programmed electrical stimulation through electrodes on the leads. This drawing supplies physical context, not the feedback policy.

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02 / 130A / 130B / Leads — Reach the target tissue

The illustrated leads place electrodes near the spinal cord. The description allows other electrode configurations and target tissues.

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03 / 150 / External programmer — Set and adjust programs

A clinician or patient can use the programmer to send programs, settings or commands, within the described controls.

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ECAP closes the normal loop

C1's ordinary control loop receives a characteristic of an ECAP elicited by stimulation, compares that characteristic with an expected range, and changes a therapy-defining parameter. Disclosed ECAP features include amplitude, area, slope, peak ratios, timing, and latency; an example uses N1-P2 amplitude. The cited feedback examples identify changes to current or voltage amplitude, pulse width, frequency, and pulse shape. Electrode combinations are also programmable parameters, but these examples do not establish that the ECAP loop changes the electrode arrangement. In the illustrated high-ECAP response, processing circuitry reduces the current amplitudes of both control pulses (I_c) and informed pulses (I_i) when the reading exceeds the ECAP high threshold, ETH. When the reading returns within range, it moves them toward defaults. A reading below the low threshold can instead cause increments. These are disclosed examples, not fixed numerical settings mandated for every implementation. Figure 1 in C1 provides the physical context: implantable medical device 110, leads 130A and 130B near spinal cord 120, and external programmer 150. It is an orientation drawing, not a diagram of the feedback decisions.

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When a high reading stops being useful feedback

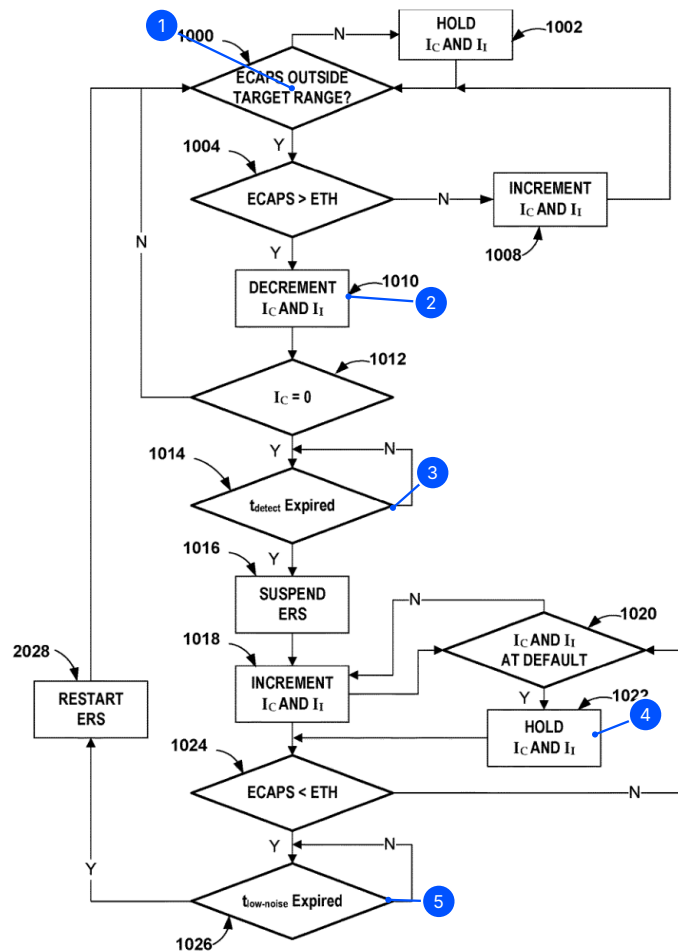


FIG. 10

US11559689B2 · Original FIG. 10. Follow the patent's YES/NO branches. ERS means ECAP-responsive stimulation. Its restart box is labelled 2028 in the drawing and 1028 in the description.

01 / 1000 / Target-range test — Hold when the reading is in range

The NO branch keeps the current settings. An outside-range reading proceeds to the high-threshold test; a low reading has a separate increment branch.

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03 / 1012–1014 / Minimum and timer — Test persistent high readings

With control-pulse amplitude at the illustrated minimum, zero, a continuing high reading through the detection timer can trigger suspension.

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05 / 1024–1026 / Recovery conditions — Wait before restarting

The ECAP value must fall below the high threshold and the low-noise timer must expire before the pictured restart. Other recovery embodiments are described separately.

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02 / 1010 / Decrement — Reduce after a high reading

The high-threshold branch reduces the control and informed pulse amplitudes. This is one illustrated response, not a universal setting.

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04 / 1016–1022 / Suspension and restoration — Pause adjustment, restore output

The diagram suspends ERS, then raises the pulse amplitudes toward defaults and holds them there while monitoring continues. Suspending the loop does not mean stopping all stimulation.

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Persistent high readings change state

The important limit is that a high ECAP-like measurement may be coupled noise rather than a neural response. C1 gives external noise as an example that can be interpreted as an ECAP. If the controller keeps reducing output until a parameter reaches its minimum—illustrated by control-pulse amplitude I_c reaching approximately zero—and the sensed value remains above ETH through a noise-detection timer, the processor suspends or disables ECAP-responsive stimulation rather than continuing to reduce therapy. It may restore control and informed parameters to defaults, or optionally to a sub-default level, while sensed ECAPs are monitored but no longer used to adjust therapy. The sub-default alternative is described as a way to provide some stimulation while reducing possible overstimulation risk in an awkward posture.

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Alternative test preserves therapy

A second C1 recovery route keeps the control-pulse amplitude at minimum while returning informed-pulse amplitude to its default. That matters because a control pulse is the pulse intended to elicit the measured ECAP: with I_c at zero, a detectable ECAP should not be produced by a control pulse. If the sensed value falls below ETL and remains low through a low-noise timer, I_c can be raised toward its default. A separate confirmation timer can then expire before the closed loop restarts. If the reading again exceeds ETH during that attempted recovery, I_c is reduced again. C1 also describes blocking a requested patient increase while the controller is actively changing parameters or values sit outside tolerance around defaults; decreases may remain permissible in examples.

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Claims define the ECAP safeguard

Claim 1 recites receiving information indicative of an ECAP elicited by a stimulation pulse, executing the closed-loop policy, and determining whether the characteristic lies inside or outside an expected range. It does not expressly condition that execution step on an inside-range determination. When outside, the claim requires disabling the policy, setting the parameter to a threshold value, starting a noise-detection timer, and enabling the policy after that timer expires. Dependent claim 4 adds control and informed pulses, sensing the ECAP after a control pulse, ETH and ETL, and incremental changes to control- and informed-pulse parameters for a value above ETH. Claims 5 through 9 add particular suspension, low-noise-timer, restoration, and confirmation-timer conditions. Thus, the source supplies a state-machine-like set of alternatives, but does not specify universal timer durations, fixed thresholds, or one required fallback amplitude.

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US 12,128,235 B2: Direct Stimulation-Signal Control

Similar hardware does not imply the same control rule

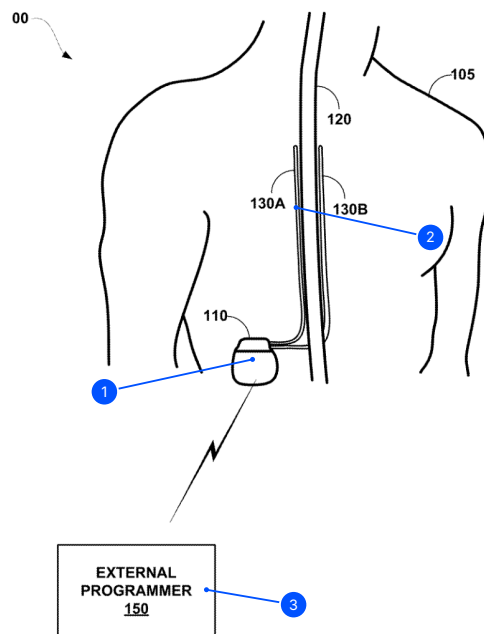


FIG. 1

US12128235B2 · Original FIG. 1. The physical arrangement resembles the first patent's drawing. The different feedback policy is established by the text and claims.

01 / 110 / Implantable device — Deliver pulses and use feedback

The disclosed device can deliver control pulses and therapy pulses. The text also describes temporary or external-device examples.

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02 / 130A / 130B / Leads — Connect to the electrodes

The two pictured leads carry electrodes. The description allows one lead, additional leads or other configurations.

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03 / 150 / External programmer — Transfer the chosen program

The programmer can send settings and commands. Its presence alone does not tell the reader which feedback signal controls a later pulse.

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The direct pulse signal is feedback

C2 permits feedback control from the stimulation signal itself: the directly sensed electrical signature of the delivered pulse and related charge changes. The processor compares a measured characteristic, such as full or partial amplitude, slope, or area, with a target value or range and changes a parameter for a later pulse. Below a target minimum, it may increase a parameter; above a target maximum, it may decrease one; inside the range, it may hold the setting. The disclosed change can be a fixed step, proportional to the deviation, or function-based. C2 presents this signal as information that may reflect electrode-to-target distance and help choose stimulation parameters; it does not equate artifact amplitude with a direct measurement of a propagated neural response. Figure 1 in C2 provides the physical context: implantable medical device 110, leads 130A and 130B near spinal cord 120, and external programmer 150. It is an orientation drawing, not a diagram of the feedback decisions.

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Measure, compare, then keep or change

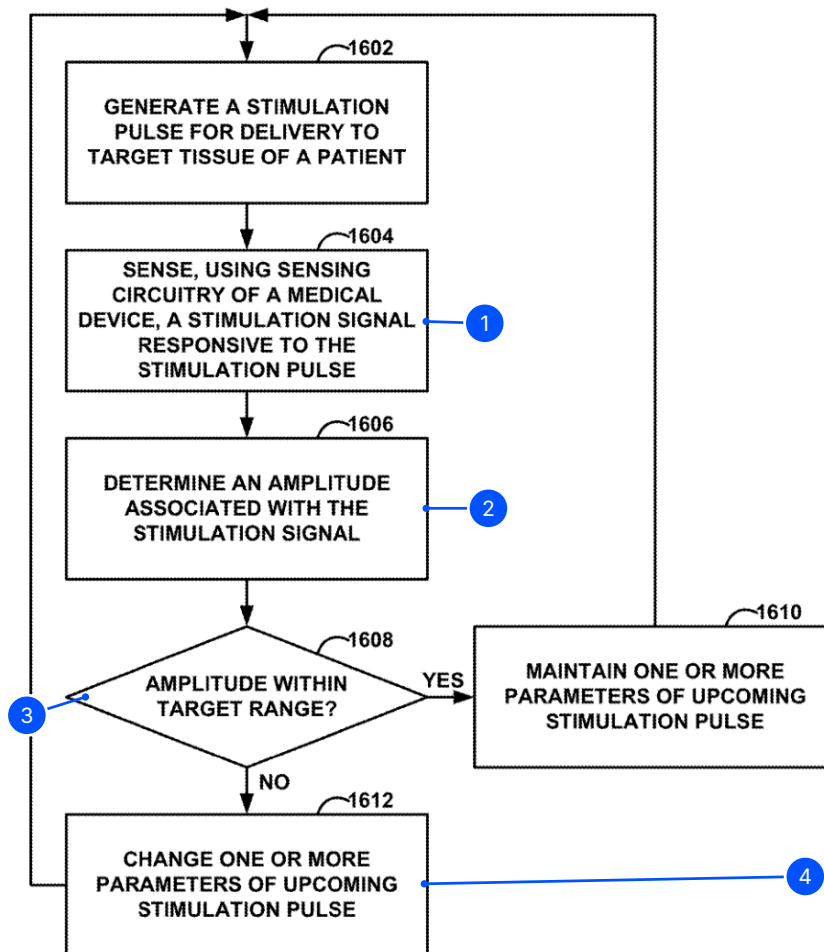


FIG. 16

US12128235B2 · Original FIG. 16. This sheet shows stimulation-signal amplitude feedback. It does not depict the separate ECAP-count ratio test described in the text.

01 / 1602–1604 / Generate and sense — Sense the delivered pulse

The feedback here is the stimulation signal associated with the pulse. It is distinct from a propagated neural response.

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03 / 1608 / Compare with range — Decide whether adjustment is needed

The measured amplitude is compared with a target range. The drawing preserves both outcomes rather than assuming that every pulse requires a change.

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02 / 1606 / Measure amplitude — Turn the signal into a value

This flow uses amplitude. The description also discusses other measurable characteristics, including slope and area.

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04 / 1610 / 1612 / Keep or change — Act on a later pulse

YES maintains one or more upcoming-pulse parameters; NO changes them. The description gives increase-below and decrease-above examples.

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Scarce ECAPs select another input

C2 addresses pulses that yield too few detectable ECAPs under its threshold-ratio test, including examples where the neural response is too small or absent. The processor may examine a sequence of pulses, count detectable ECAPs, calculate the ratio of detectable ECAPs to pulses, and compare that result with a threshold ratio. If the ratio is greater than the threshold, later control may use ECAP characteristics, optionally together with stimulation-signal characteristics. If it is not greater, later control may instead use stimulation-signal characteristics and not the corresponding ECAP characteristic. This can cover sub-threshold pulses that do not produce detectable ECAPs but still yield a directly detectable stimulation signal. Control and informed pulses may be interleaved; control pulses may or may not contribute to therapy, and longer informed pulses need not provide a fully measurable signal.

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Targets depend on context

C2 changes the expected stimulation-signal target as well as the stimulation setting. An accelerometer can identify posture, and the processor may select a target range using both posture and the delivered pulse amplitude. Posture-associated transfer functions relate pulse amplitude to expected stimulation-signal amplitude; described examples distinguish supine, seated, and standing relationships. C2 also identifies a third, residual phase after the first and second pulse-related phases. In an example, that phase represents ionic rebalancing from residual charge and can supply feedback, although it may not be detectable when an ECAP is detectable. These are context-sensitive target-selection embodiments, not a declared method for identifying noise.

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Claims preserve branch distinctions

Independent claim 1 requires sensing a first delivered stimulation pulse, determining that a characteristic exceeds a target stimulation-pulse value, changing a parameter for a later pulse, detecting ECAPs from the pulse sequence, and determining whether the ECAP-to-pulse ratio exceeds a threshold. Claim 2 adds the upper-target case and a decrease. Claim 4 adds the lower-target case and an increase. Claims 6 and 7 distinguish the ECAP-plus-stimulation-signal branch from the stimulation-signal-without-corresponding-ECAP branch; claim 8 adds posture and amplitude selection of the target. The fallback parameter and restoration sequence is not an independent-claim requirement: dependent claim 3 adds setting a fallback parameter and restoring the prior value if a later sensed pulse no longer exceeds target. Claims 19 through 24 separately address residual-phase sensing and corresponding ratio branches.

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Cross-publication comparison

Same architecture, different fallback

The publications describe comparable feedback architectures: stimulation generation, electrodes and sensing circuitry, processor-selected pulse parameters, optional control/informed pulse schedules, and possible ECAP sensing. Their central difference is the decision made when feedback becomes unsuitable. C1 treats a persistently out-of-range ECAP measurement after reduction to a limit as a possible noise condition. It suspends ECAP-driven adjustment and returns therapy to default or an alternative level while checking whether the measurement stabilizes. C2 treats an insufficient proportion of detectable ECAPs as a basis to select direct stimulation-signal feedback instead. C2 does not prescribe C1's timer-based noise-suspension sequence, and C1's cited claims do not require C2's ECAP-ratio selection logic.

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Three boundary cases compared

When an ECAP is detectable, both disclosures can use neural-response feedback to change later stimulation. When the ECAP is too small or appears too infrequently, C2 formalizes a threshold-ratio decision and can use the directly sensed stimulation signal instead; C1 notes that stimulation signals can be useful when too few ECAPs are detectable, although its central claimed regime is ECAP range handling and possible-noise control. When a high reading persists despite output reduction, C1 treats the pattern as possible distortion and suspends the adaptive loop with timed re-entry checks. In C2, independent claim 1 instead requires a target-exceedance determination and parameter change; dependent claim 3, not claim 1, adds a fallback parameter followed by restoration when a later sensed pulse no longer exceeds target. Neither disclosure makes every abnormal signal noise or makes direct artifact sensing proof of efficacy.

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Figures show shared physical context

The selected Figure 1 sheets are orientation drawings rather than control-flow diagrams. In C1, Figure 1 labels system 100, patient 105, spinal cord 120, implantable medical device 110, leads 130A and 130B, and external programmer 150. C2's Figure 1 uses the same type of depicted system arrangement and labels. The figures help separate the implanted device-and-lead pathway from the external programmer. They do not depict C1's ETH, ETL, timers, or suspension state, nor C2's ECAP-ratio calculation, residual phase, or posture transfer functions. Those control details come from the descriptions and claims, not from the selected sheets.

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Recommended reading route

Read C1 as a state machine

Start with C1P21S01 for the source's direct distinction between pulse artifact and ECAP. Then read C1P31S03 for ordinary ETH/ETL adjustment; C1P32S01 through C1P33S03 for minimum-output testing, timer-driven suspension, and restart; and C1P34S01 through C1P34S02 for the alternative that restores informed therapy while holding control pulses at minimum. Finish with claims 1 and 4 through 9 at C1P39S03 through C1P40S02, followed by device claims 13 through 23 at C1P40S02 through C1P41S02. This route separates the broad operational examples from the narrower claim dependencies.

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Read C2 from signal choice

For C2, begin with C2P28S01 through C2P28S03 for why direct pulse sensing is proposed when ECAPs cannot be detected and for the artifact-versus-ECAP definition. Next read C2P35S03 and C2P36S01 through C2P36S03 for the threshold-ratio branch and high, low, and in-range decisions. Read C2P37S02 through C2P37S04 and C2P43S01 through C2P43S03 for posture-specific targets, transfer functions, and residual-phase embodiments. Finally, read claims 1 through 8 at C2P50S03 through C2P51S02, then claims 19 through 27 at C2P52S01 through C2P53S01. In particular, compare independent claim 1 with dependent claim 3 before treating fallback-and-restoration behavior as required.

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Use the figure sheets last

After reading the logic, return to the admitted original Figure 1 sheets. C1F1 identifies the C1 disclosed physical system: IMD 110 connects to leads 130A and 130B placed along spinal cord 120, with external programmer 150 outside the body. C2F1 identifies the analogous C2 layout. Use the images to anchor which components deliver, sense, and communicate, but use the cited text for the decision conditions and claims because neither sheet visualizes the feedback branches.

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Sources and review

Two selected publications, with 39 of 51 identified description and claim pages supplied to the AI comparison. Four original drawings are explained here. All 94 original pages are included in the downloadable PDF and offline edition; this is a focused reading, not an exhaustive review of every page.

The comparison passed a complete source and image review after recorded editorial corrections. Those corrections and their provider usage remain in the original job history. Codex separately inspected the original control-flow sheets, source passages, callout targets and final presentation. The overlays are assisted editorial work, not independent human review.

Independent research about this patent; its organization is a subject of research, not a claimed customer or endorser.

(12) **United States Patent**
Hareland

(10) **Patent No.:** **US 11,559,689 B2**
(45) **Date of Patent:** **Jan. 24, 2023**

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

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(73) Assignee: **MEDTRONIC, INC.**, Minneapolis, MN (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 66 days.

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(Continued)

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(65) **Prior Publication Data**

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Primary Examiner — Paula J Stice

(51) **Int. Cl.**

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A61N 1/372 (2006.01)

A61N 1/02 (2006.01)

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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)

ABSTRACT

(57) 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.

(58) **Field of Classification Search**

None

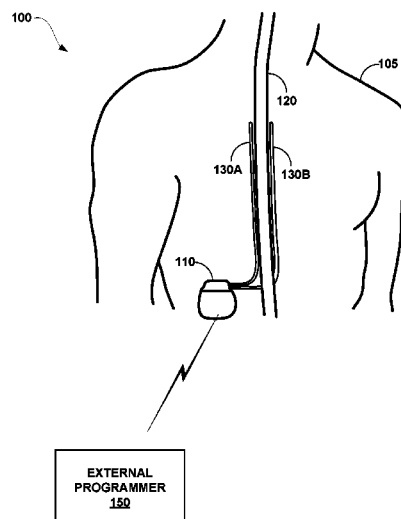
See application file for complete search history.

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25 Claims, 16 Drawing Sheets



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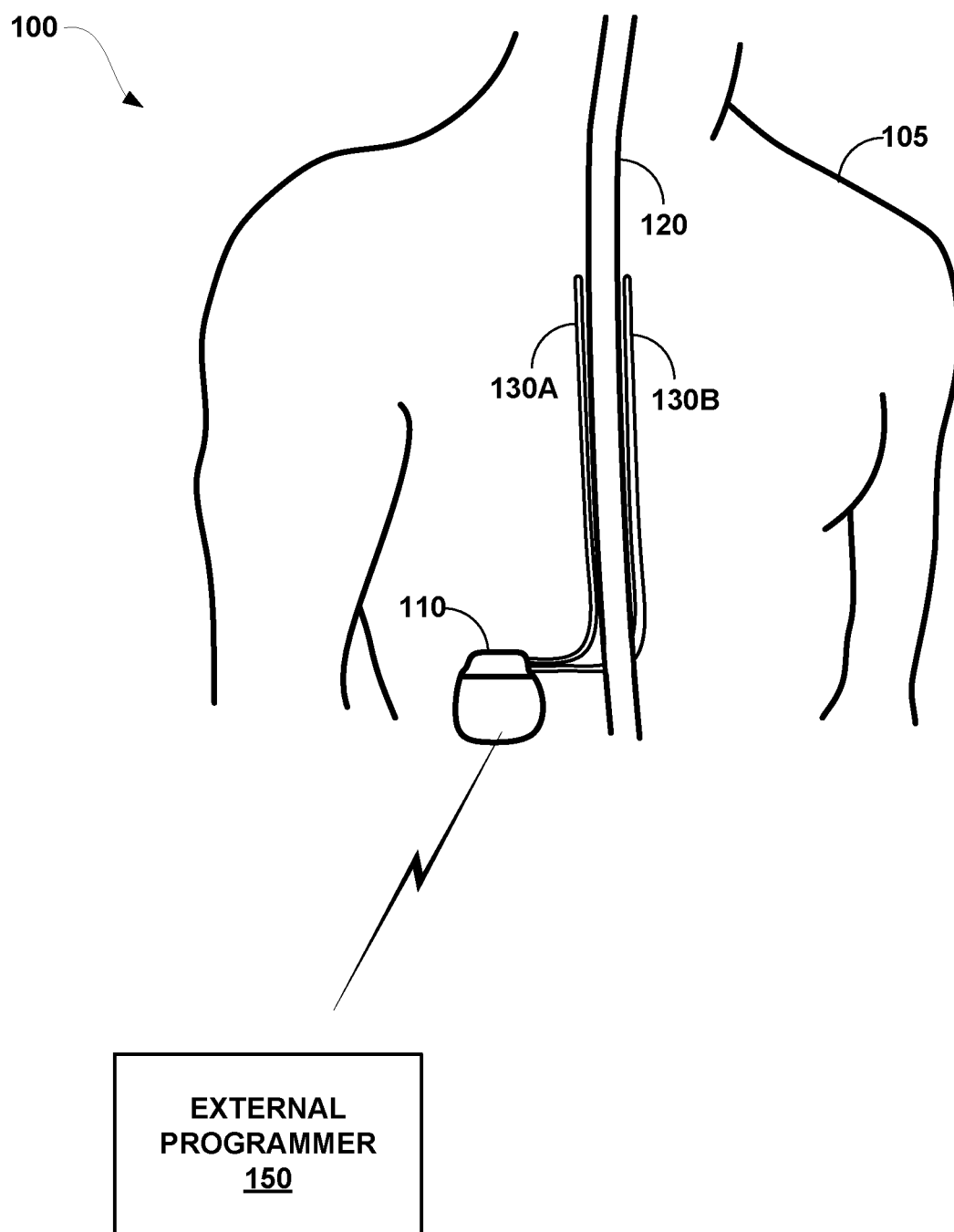


FIG. 1

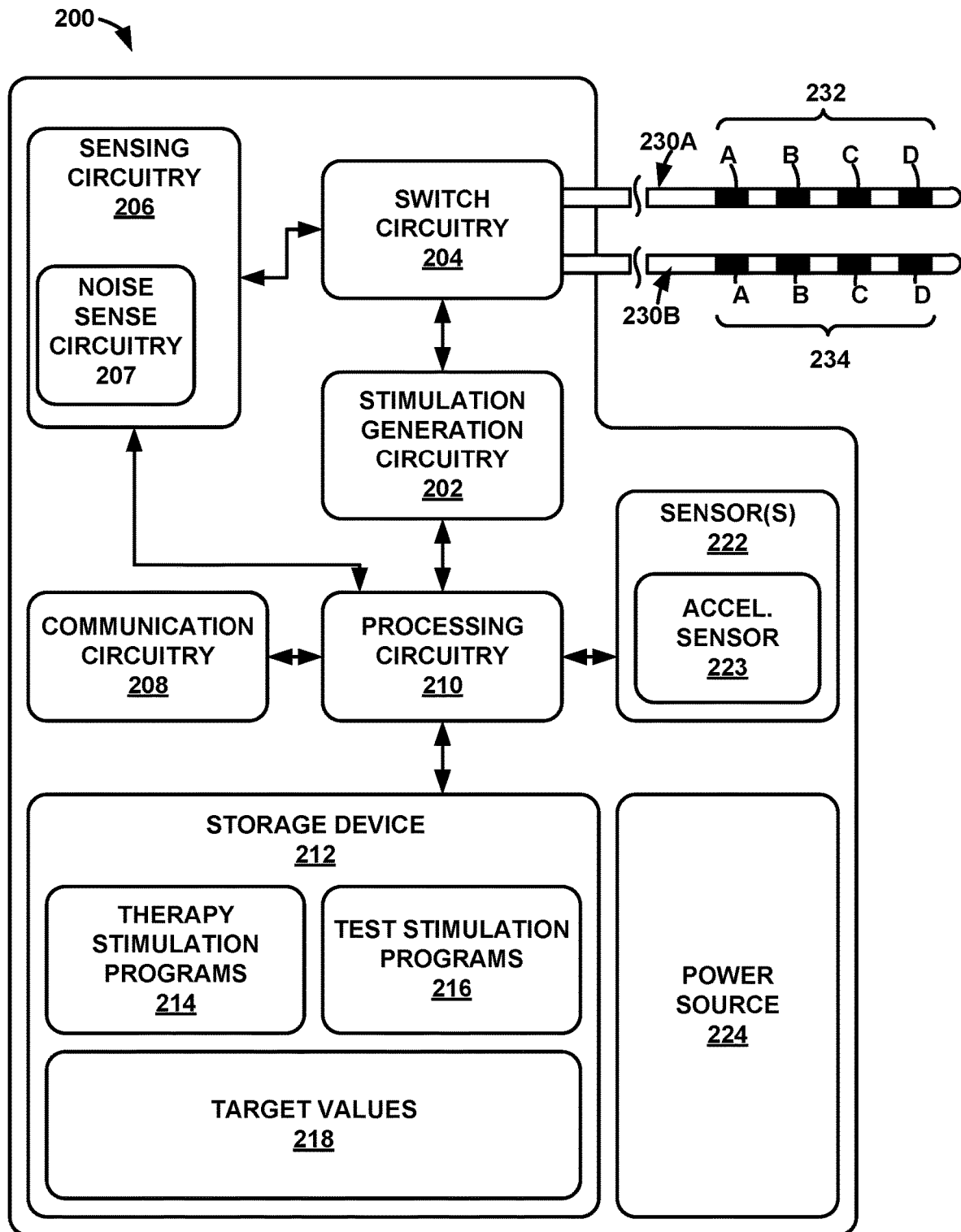


FIG. 2

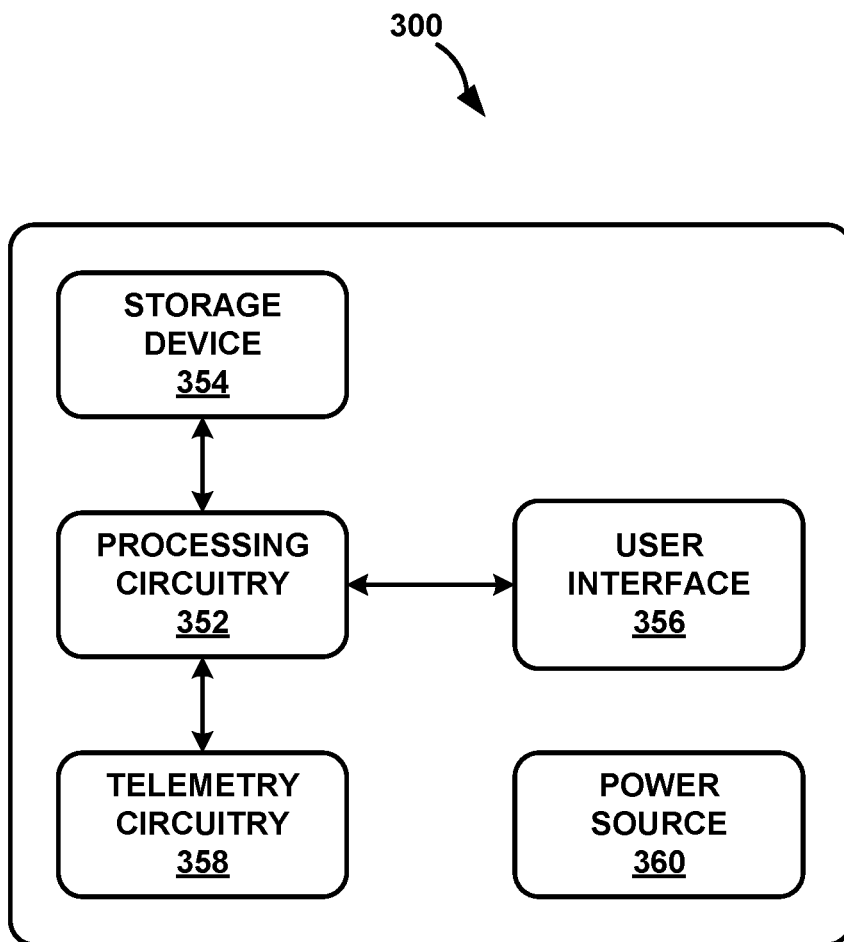


FIG. 3

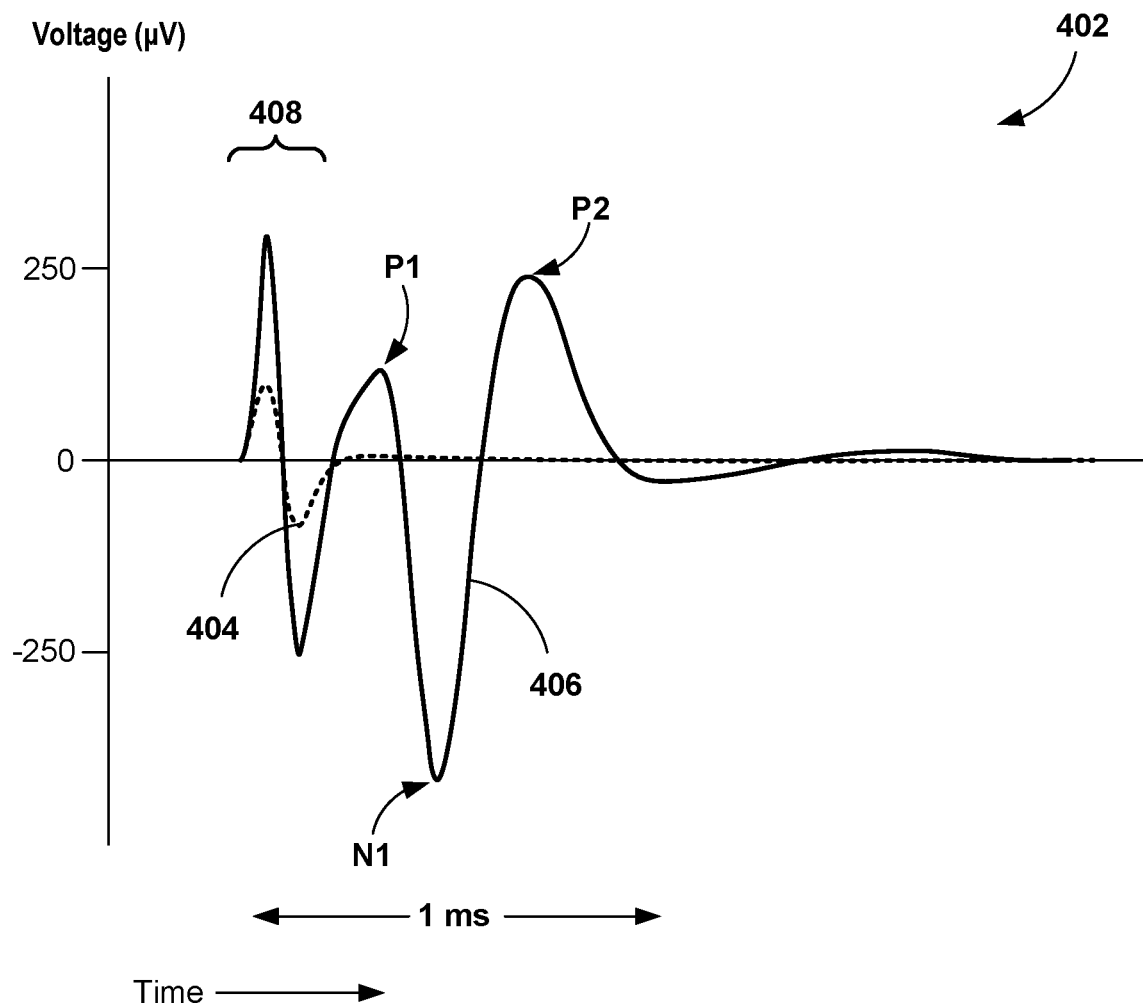


FIG. 4

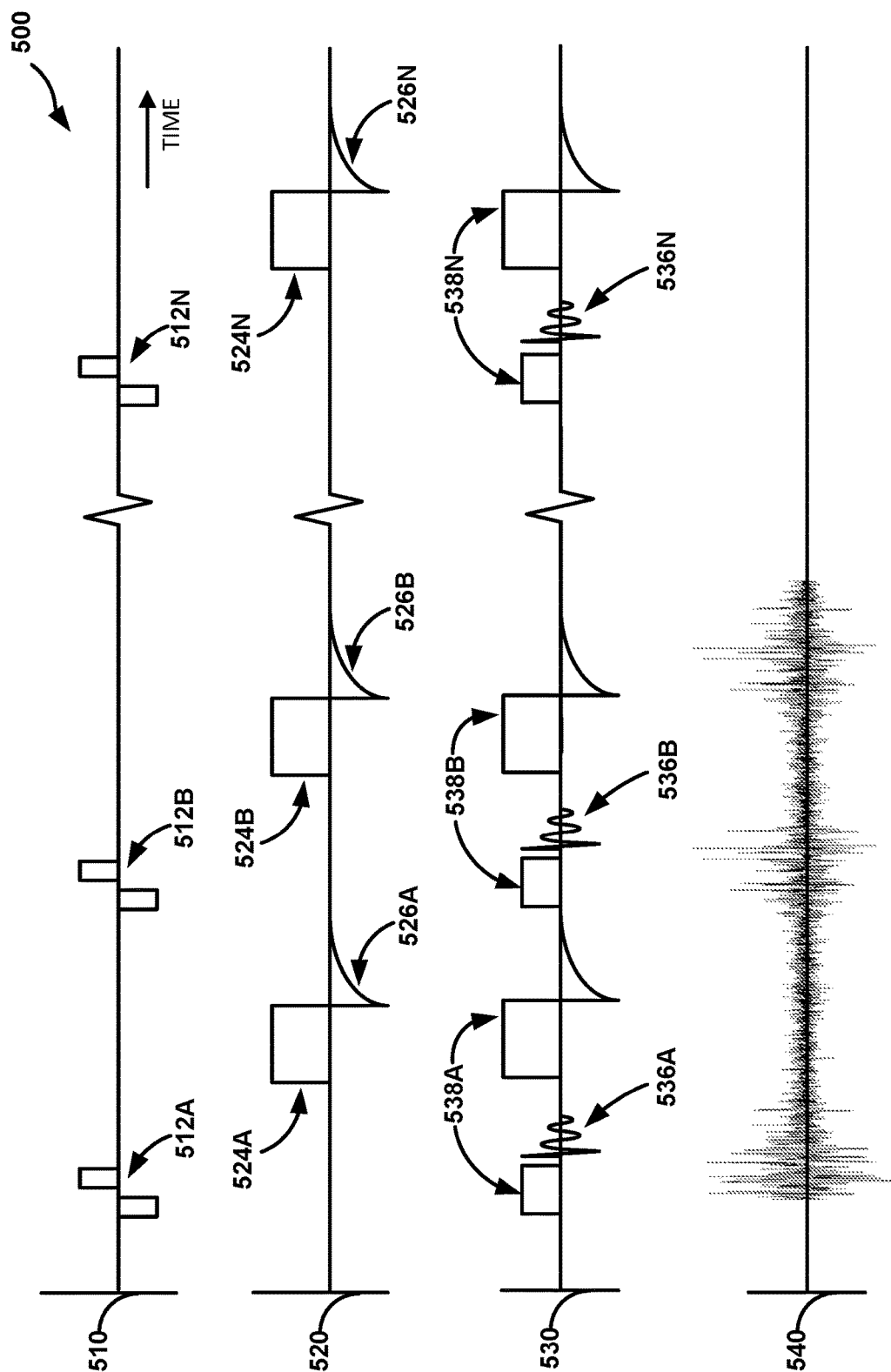


FIG. 5

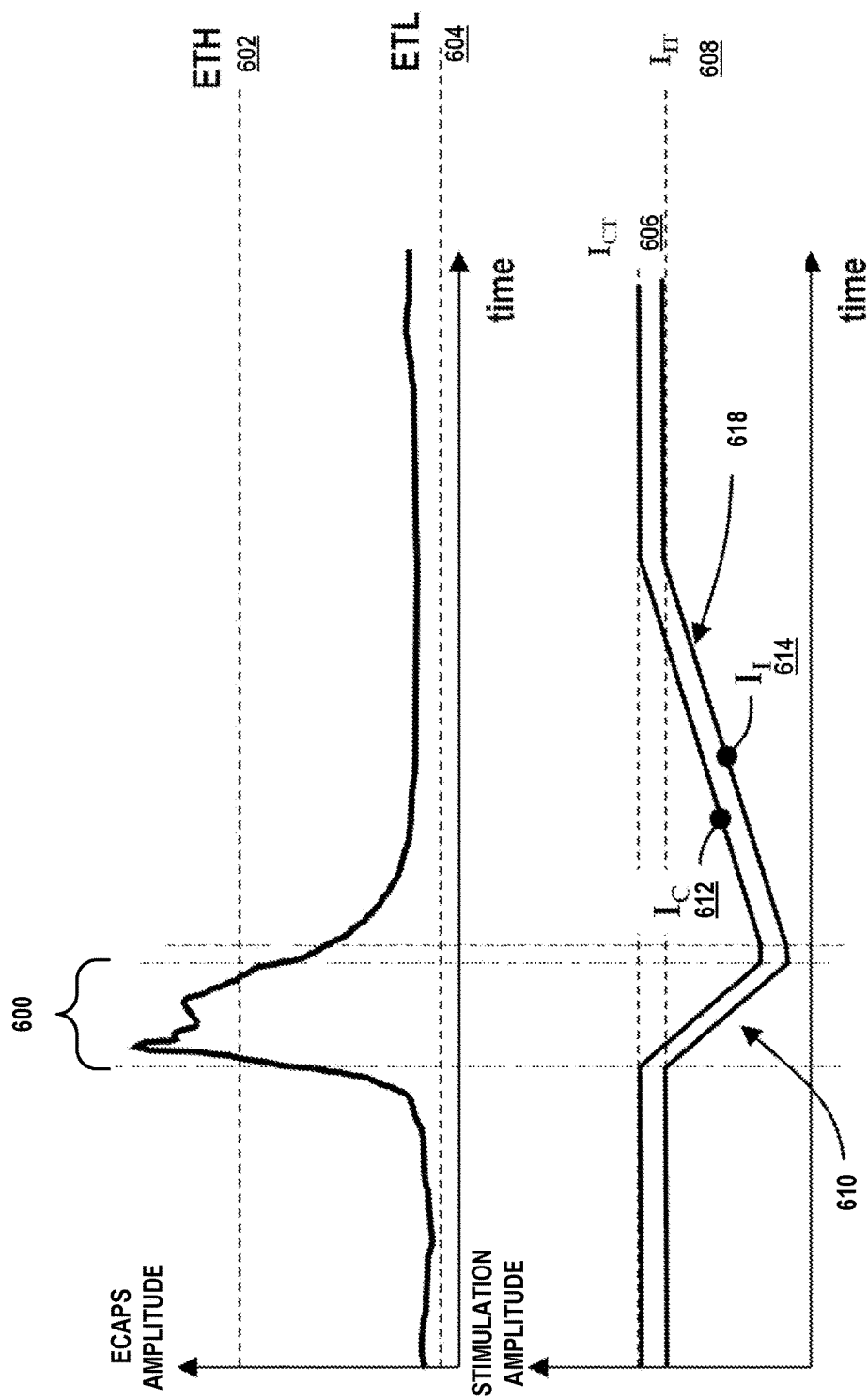


FIG. 6

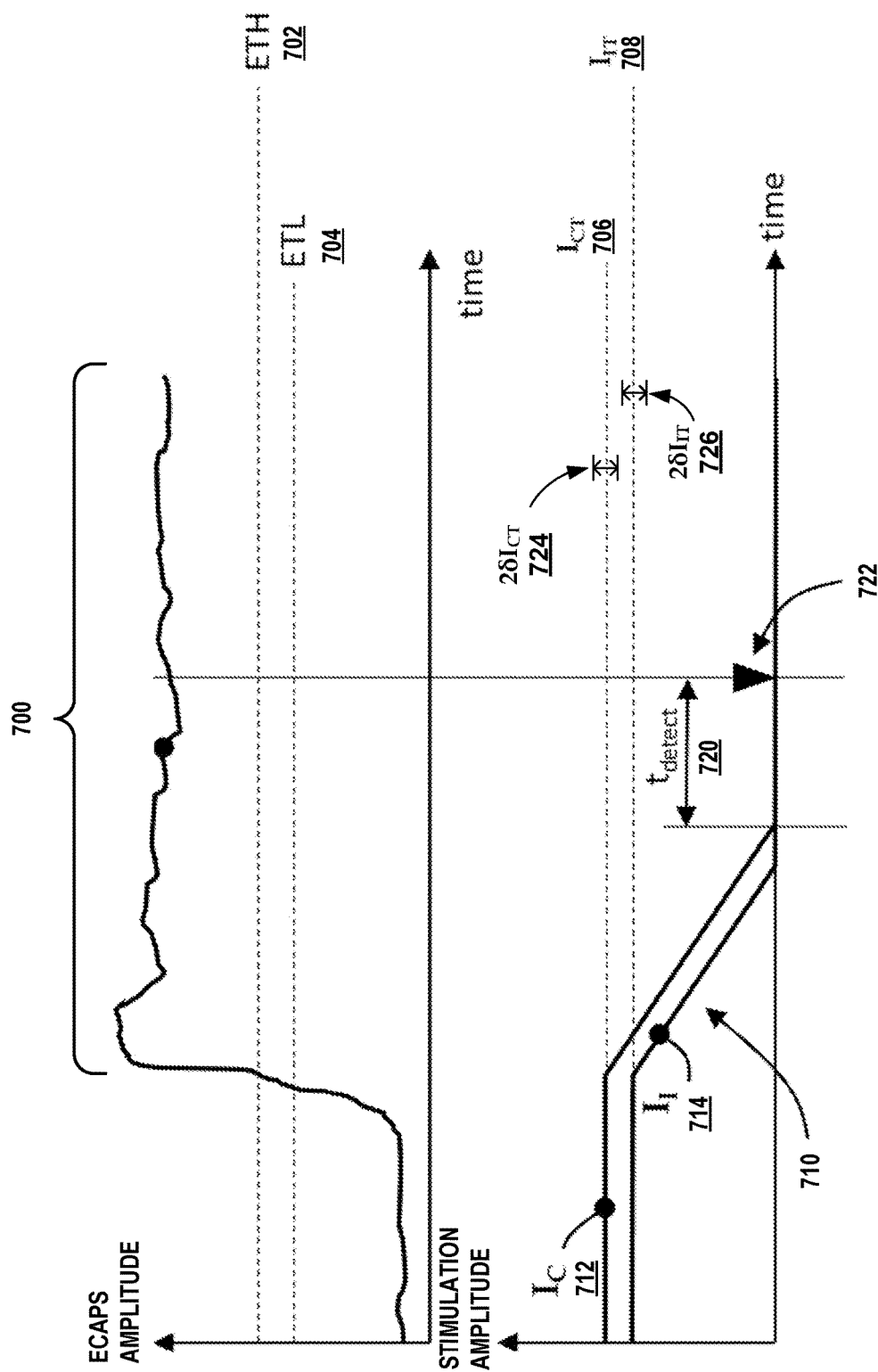


FIG. 7

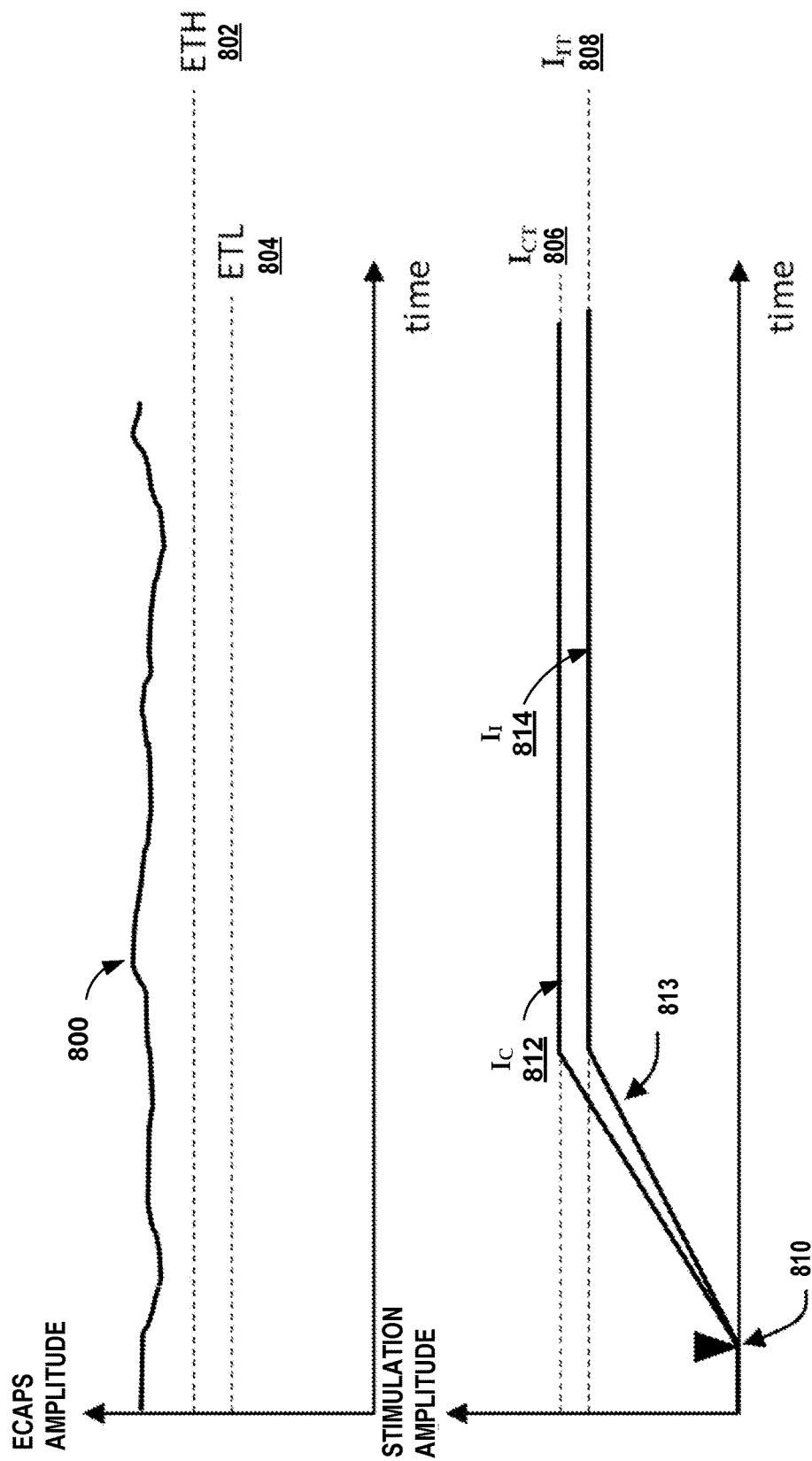


FIG. 8

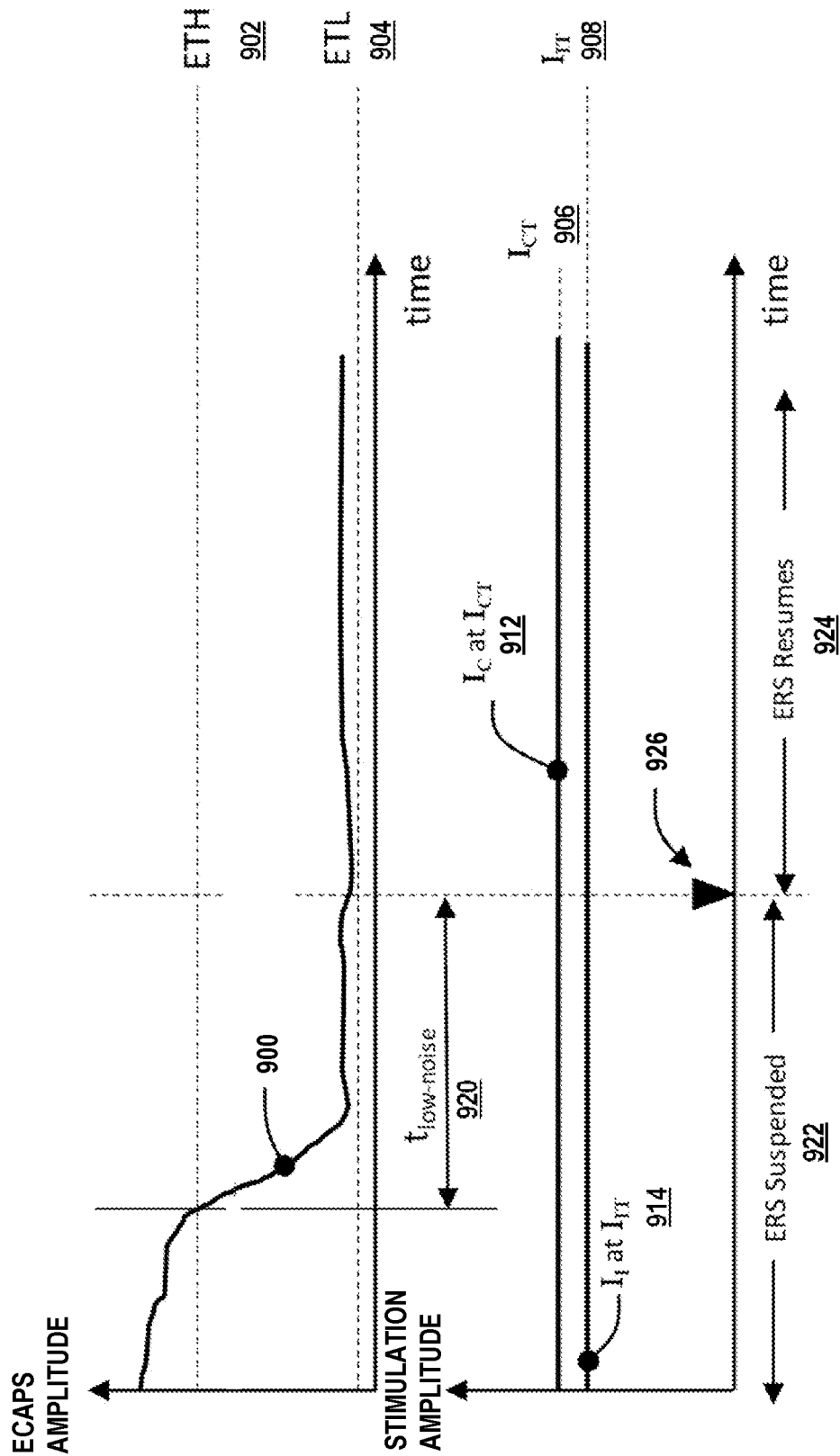


FIG. 9

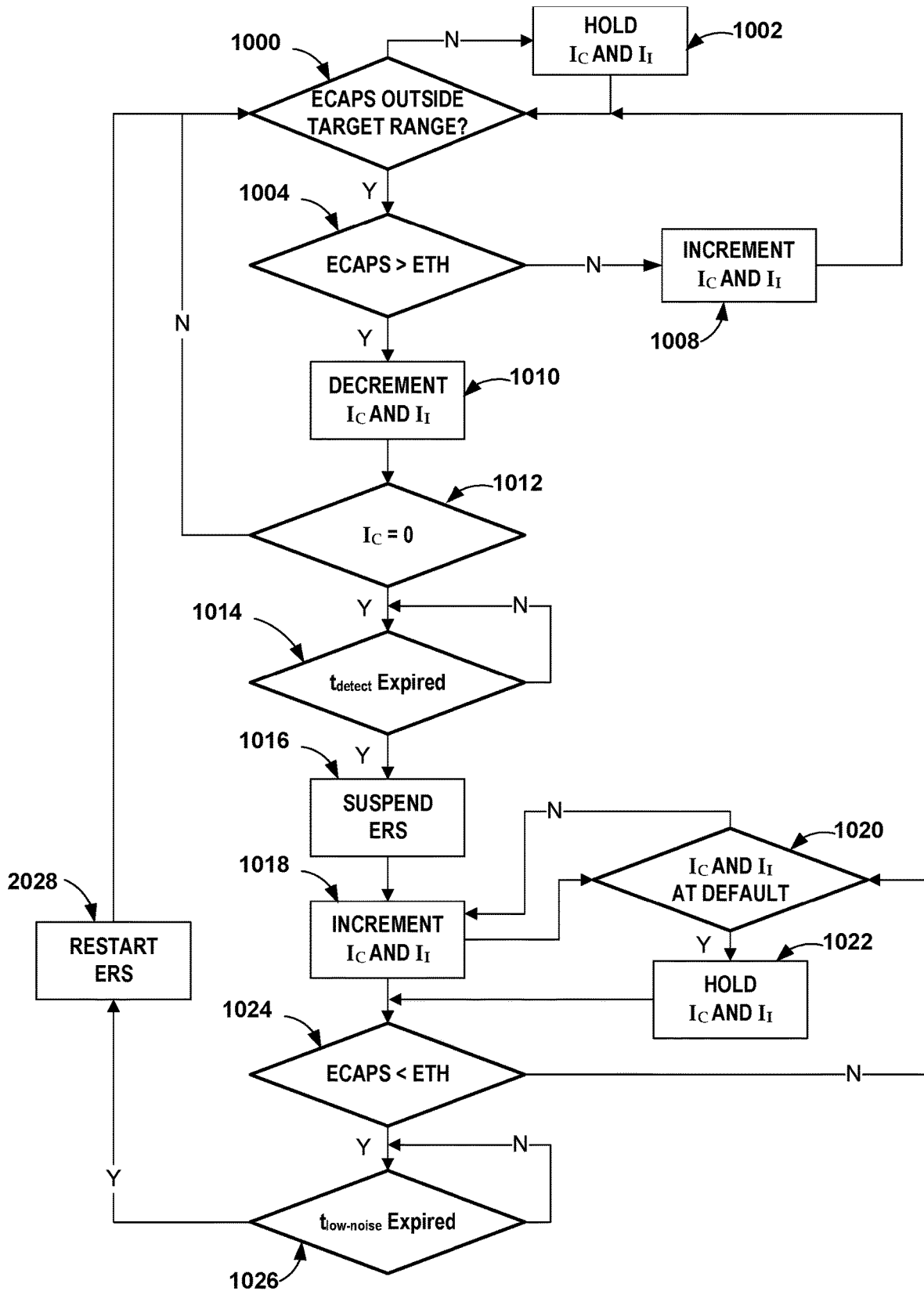


FIG. 10

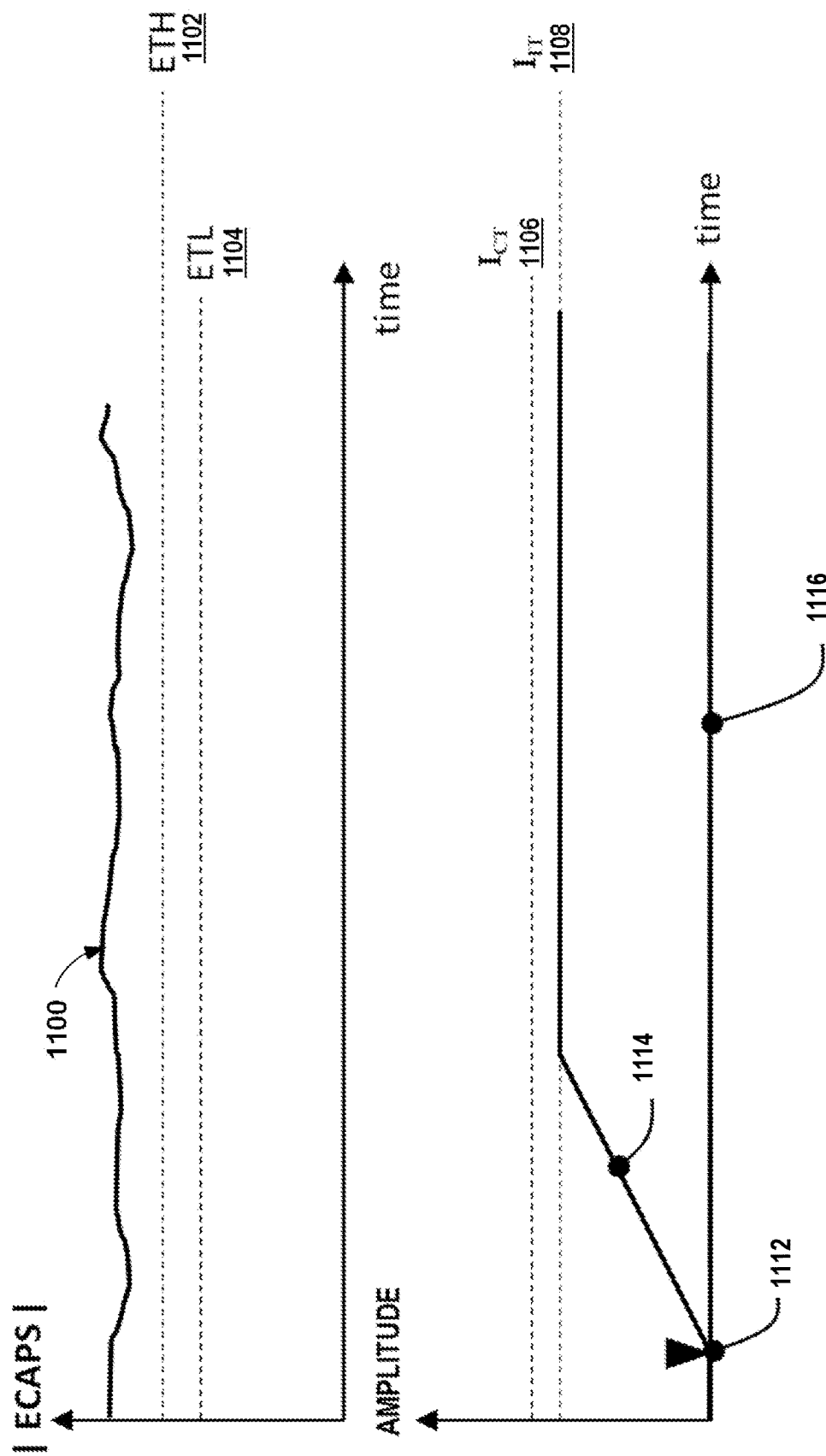


FIG. 11

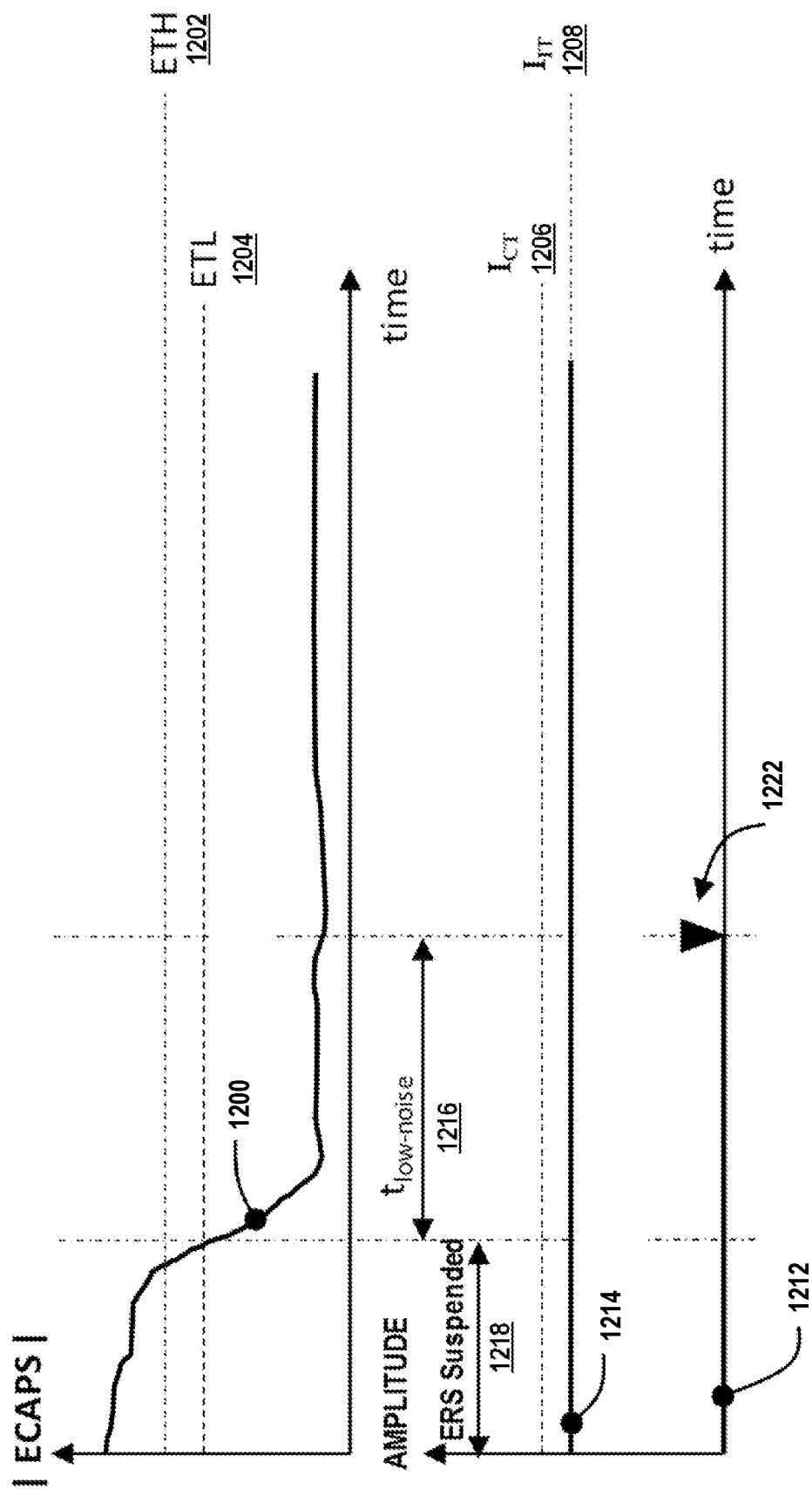


FIG. 12

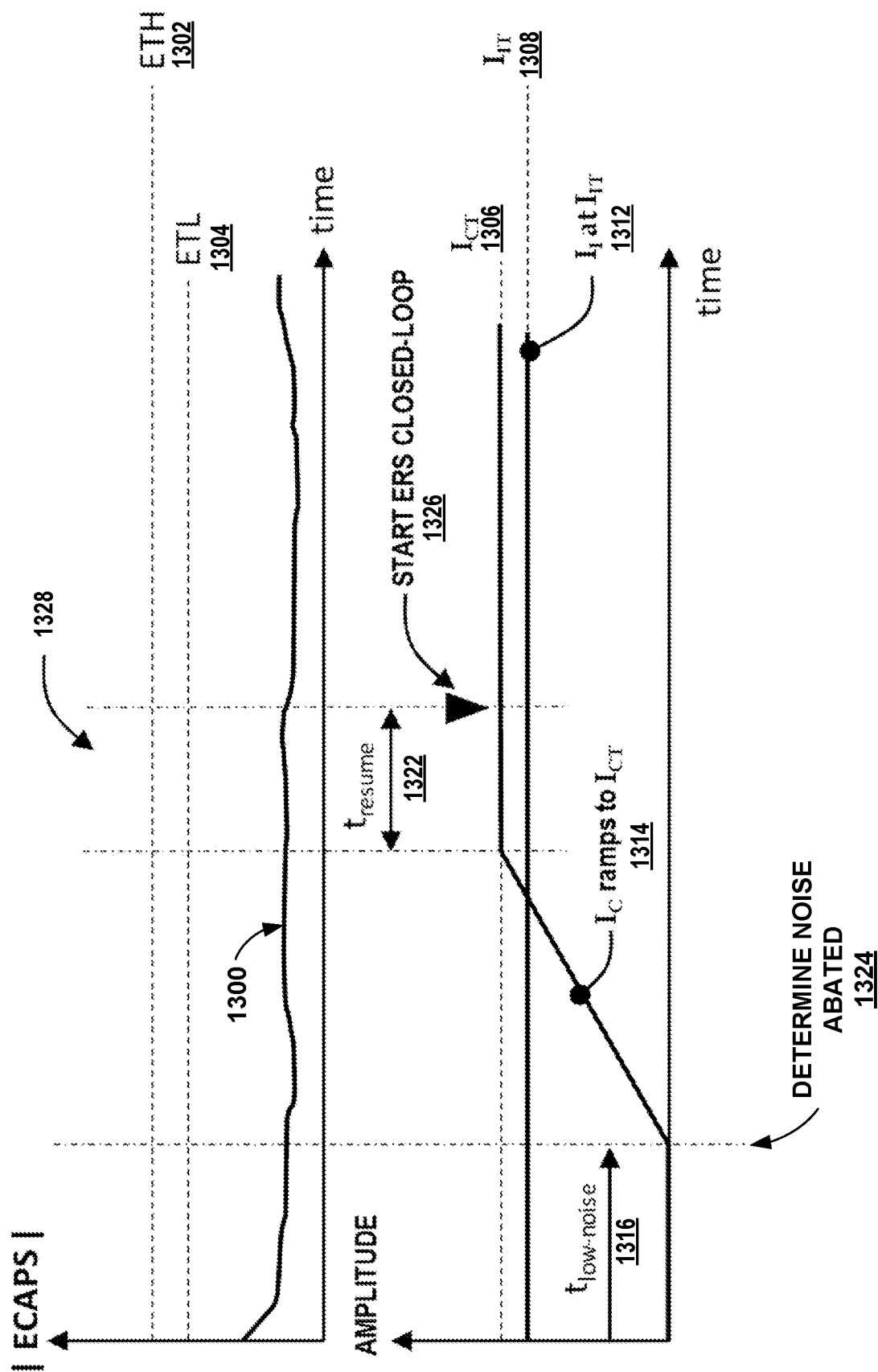


FIG. 13

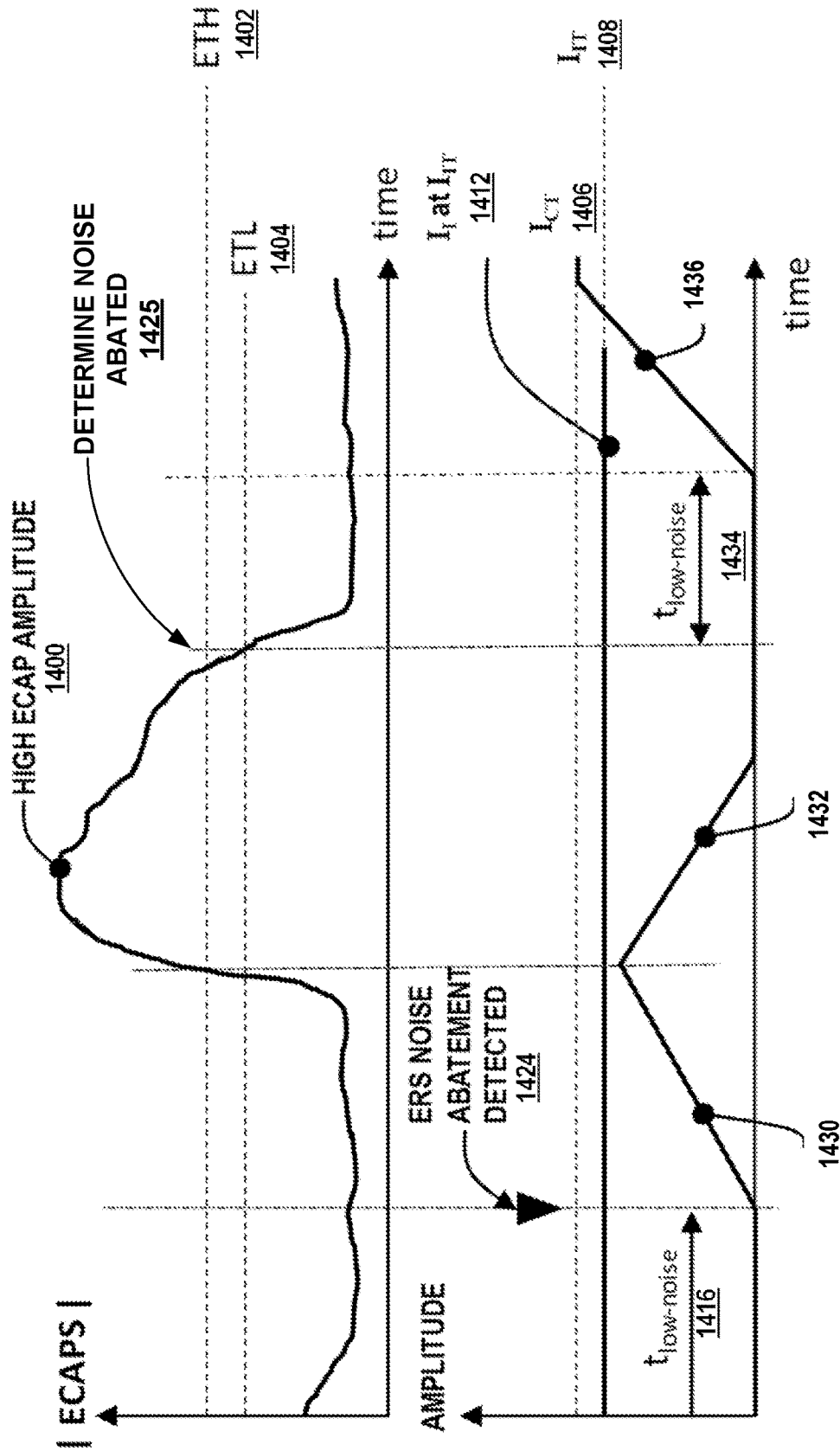
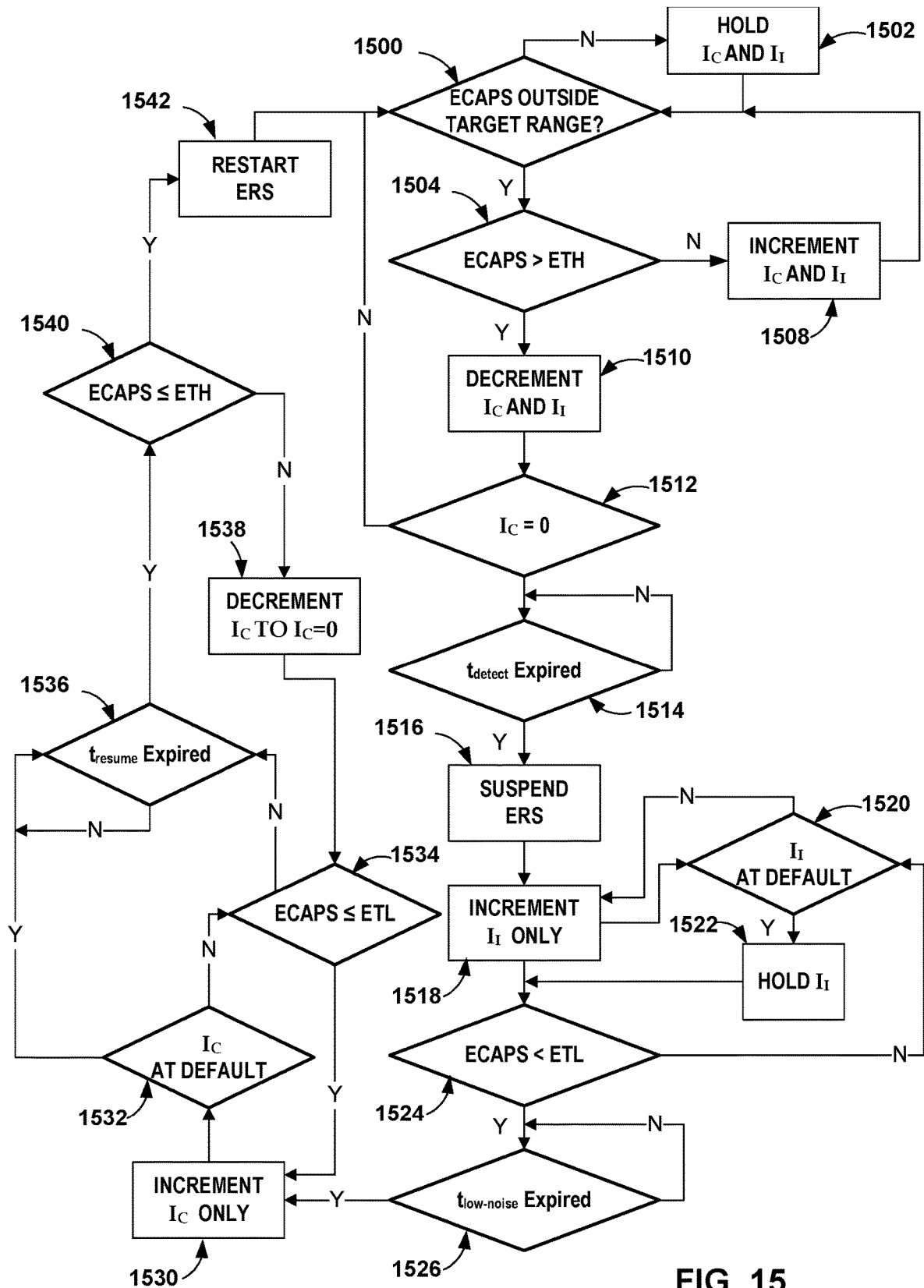


FIG. 14



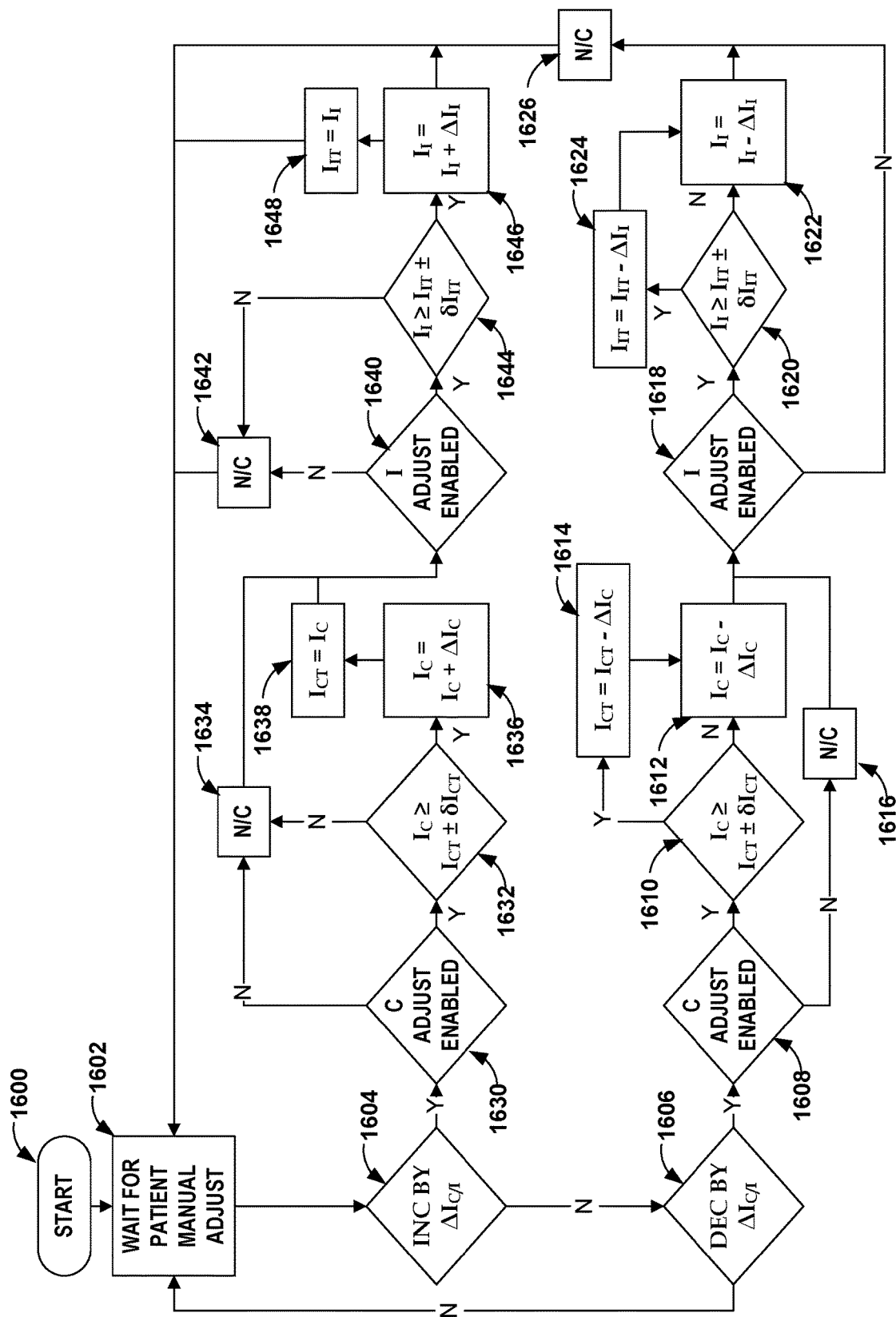


FIG. 16

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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

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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 pulses) 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 pulses) 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 130A and 130B, 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 130A and/or 130B (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 detectable 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

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 IMD **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 **232A**, **232B**, **232C**, and **232D**, and the set of electrodes **234** includes electrodes **234A**, **234B**, **234C**, and **234D**. 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 detectable ECAPs for processing circuitry **210** to determine therapy based on one or more characteristics of the respective detectable ECAPs. It may be beneficial for processing circuitry **210** to determine therapy based on characteristics of detectable ECAPs rather than characteristics of detectable stimulation signals, if possible. However, if not enough responsive ECAPs are detectable 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 detectable even when some or all of elicited ECAPs are not detectable 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 detectable 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 detectable 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 detectable by sensing circuitry 206, but another one or more stimulation pulses of the sequence of consecutive pulses do elicit ECAPs that are detectable by sensing circuitry 206. In such cases, processing circuitry 210 may be configured to determine therapy based on one or more characteristics of the detectable ECAPs rather than determine therapy based on one or more characteristics of detectable stimulation signals. In some examples, processing circuitry 210 may determine whether the ratio of detectable 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 detectable 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 detectable stimulation signals.

In some examples, responsive to determining that a plurality of pulses elicit greater than a threshold ratio of detectable 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 detectable 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 detectable 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 P1, N1, and P2, which are three typical peaks representative of propagating action potentials from an ECAP. The example duration of the stimulation signal and peaks P1, N1, and P2 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 N1 and P2. This N1-P2 amplitude may be easily detectable even if the stimulation signal impinges on P1, a relatively large signal, and the N1-P2 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 P1, N1, or P2 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 P1, N1, or P2. In other examples, the characteristic of ECAP signal 406 may be the area under one or more of peaks P1, N1, and/or P2. In other examples, the characteristic of the ECAP may be a ratio of one of peaks P1, N1, or P2 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 N1 and P2. In other examples, the characteristic of the ECAP may be the time between two points of the ECAP, such as the time between N1 and P2.

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 512A-512N (collectively “control pulses 512”), second channel 520, a plurality of informed pulses 524A-524N (collectively “informed pulses 524”) including passive recharge phases 526A-526N (collectively “passive recharge phases 526”), third channel 530, a plurality of respective ECAPs 536A-536N (collectively “ECAPs 536”), and a plurality of stimulation signals 538A-538N (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 μ s 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 μ s and less than approximately 1000 μ s. 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 538A, 538B, and 538N 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

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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

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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 Li 714 is outside of a predetermined range from the default values Ict 706 and Lit 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 ($\pm \delta Ict$) about the controlled pulse default value i.e., $2\delta Ict$ 724. Similarly, the predetermined range may be a range ($\pm \delta Lit$) about the informed pulse default value, i.e., $2\delta Lit$ 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 Li 714 is approximately equal to the default set of parameter values Ict 706 and Lit 708. Because the sensed ECAP 700 is high and ERS has caused Ic 712 and Li 714 to decrease to minimum levels, processing circuitry would determine that Ic 712 and Li 714 are outside the predetermined range, $2\delta Ict$ 724 and $2\delta Lit$ 726 respectively, from the default values Ict 706 and Lit 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 Li 814 back to the default values Ict 806 and Lit 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 Li 814 to a value different from the default values Ict 806 and Lit 808. For example, IMD 200 may ramp the parameter values to a percentage of the default values Ict 806 and Lit 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 Li 914 to increase back to the default values Ict 906 and Lit 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, $T_{low-noise}$ 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 $T_{low-noise}$ 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 Li 914 approximately equal to the default values Ict 906 and Lit 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 Li, 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).

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Processing circuitry **210** may decrement I_c and I_i (**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 (I_c) 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 I_c and I_i (**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 $I_c=0$, i.e. the minimum value of control pulse amplitude (YES branch of **1012**), processing circuitry may start a noise detection timer, T_{detect} . If the ECAP values stay above ETH during T_{detect} and T_{detect} expires (YES branch of **1014**), processing circuitry **210** may suspend ERS (**1016**) and begin to increment both I_c and I_i (**1018**) until I_c and I_i reach the default values, e.g. I_{ct} **606** and I_{it} **608** from FIG. **6** (NO branch of **1020**). When I_c and I_i reach the default values (YES branch of **1020**), processing circuitry may hold I_c and I_i at the default values (**1022**) and monitor ECAP values. In other examples, (not shown in FIG. **10**), processing circuitry **210** may set I_c and I_i 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 I_c and I_i (**1018**) until I_c and I_i 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. $T_{low-noise}$ **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 I_i **1114** to the default value I_{it} **1108**. The control pulse amplitude I_c , may remain at the minimum value, rather than returning to the default value of I_{ct} **1106** (**1116**). Since the control pulse amplitude I_c is what elicits the sensed ECAP signal, a control pulse amplitude I_c at zero should not result in any detectable ECAP signal. In contrast, informed pulse

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current amplitude I_i can return to default value I_{it} **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 I_i **1214** to the default value I_{it} **1208** while control pulse amplitude I_c **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 ($I_c=0$), 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 $T_{low-noise}$ **1216**. In the example of FIG. **12**, processing circuitry may determine noise has abated when $I_c=0$, the ECAP value is below both ETH **1202** and ETL **1204** and $T_{low-noise}$ **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 $T_{low-noise}$ **1316** has expired (**1324**).

Processing circuitry **210** may increase I_c **1314** until I_c **1314** reaches the default value of I_{ct} **1306**. The informed pulse current magnitude I_i **1312** may remain at I_{it} **1308**. To ensure the noise is gone, processing circuitry **210** may start a confirmation timer, e.g. T_{resume} **1322**, and only restart the closed loop algorithm when T_{resume} **1322** expires (**1326**). In other words, in response to determining that I_c **1314** is at I_{ct} **1306**, the ECAP value is less than ETL **1304** and the confirmation timer T_{resume} **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 I_c **1314** and I_i **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 $T_{low-noise}$ **1416**, processing circuitry **210** may increase I_c to the default value and start a confirmation timer, e.g. T_{resume} **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**, I_c ramps toward I_{ct} (**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 I_c to decrease toward the minimum value of $I_c=0$ (**1432**). In

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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, $T_{low-noise}$ 1434. When $T_{low-noise}$ 1434, processing circuitry 210 may re-attempt to ramp I_c toward I_{ct} (1436). To avoid under stimulation, the informed pulse amplitude I_i 1412 may remain at the default value I_{it} 1408. Once processing circuitry 210 ramps I_c back to I_{ct} , 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. I_c and I_i , 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 I_c and I_i (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 $I_c=0$, i.e. the minimum value of control pulse amplitude (YES branch of 1512), processing circuitry may start a noise detection timer, T_{detect} . If the ECAP values stay above ETH during T_{detect} and T_{detect} expires (YES branch of 1514), processing circuitry 210 may suspend ERS (1516) and begin to increment only I_i (1518) until I_i reach the default value, e.g. I_{it} 608 from FIG. 6 (NO branch of 1520). When I_i reaches the default value (YES branch of 1520), processing circuitry may hold I_i 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 $T_{low-noise}$. When expires, processing circuitry may begin to increase I_c only (1530) because I_i is already at the default value, I_{it} . As I_c 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 I_c (1530).

When I_c reaches the default value, I_{ct} (YES branch of 1532), processing circuitry 210 may start a confirmation timer T_{resume} , 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 I_c (1538) back to the minimum value of I_c , and continue to monitor the ECAP values. If the ECAP values remain less

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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, I_c and I_i , are approximately equal to the default levels, I_{ct} and I_{it} , respectively. As described above in relation to FIGS. 5-15, one or both of I_c and I_i , may approximately equal the default levels, I_{ct} and I_{it} , when ERS is disabled for a particular. One or both of I_c and I_i may approximately equal the default levels ERS was enabled, but not actively suppressing stimulation therapy levels due to high ECAP measurements. If I_c and/or I_i 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 (I_c or I_i) are at the default levels of I_{ct} and I_{it} , respectively, then the request to decrement the therapy may also adjust the default amplitude level, I_{ct} and I_{it} .

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. I_c , or the informed pulse parameter, e.g. I_i by a specified amount. In the example of FIG. 16, the specified increment (YES branch of 1604) is $\Delta I_{C/P}$, which indicates an increase in either or both of ΔI_c or ΔI_i .

Note that in the example of FIG. 16, an increase in ΔI_c or ΔI_i 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 I_c are disabled, then a command to increase I_c 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 I_i are disabled, then a command to increase I_i 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 I_c (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 I_c is outside the predetermined range of the respective default parameter value, e.g. differs from I_{CT} by more than $\pm \delta I_{CT}$ (NO branch of 1632), then processing circuitry 210 may not increment I_c (1634). When I_c is with the predetermined range (YES branch of 1632), processing circuitry 210 may increment I_c by ΔI_c (1636) and change the default value I_{CT} to the new value of I_c (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 I_i (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 I_i is outside the predetermined range of the respective default parameter value, e.g. differs from I_{IT} by more than $\pm \delta I_{IT}$ (NO branch of 1644), then processing circuitry 210 may not increment I_i (1642). When I_i is with the predetermined range (YES branch of 1644), processing circuitry 210 may increment I_i by ΔI_i (1646) and change the default value I_{IT} to the new value of I_i (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 I_c are disabled, then a command to decrease I_c 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 I_i are disabled, then a command to decrease I_i 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 I_c (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 I_c is outside the predetermined range of the respective default parameter value, e.g. differs from I_{CT} by more than $\pm \delta I_{CT}$ (NO branch of 1610), then, in contrast to the increment command, processing circuitry 210 may decrement I_c by ΔI_c , i.e. $I_c = I_c - \Delta I_c$ (1612), but make no change to the default value I_{CT} . In other examples, when I_c is with the predetermined range (YES branch of 1610), processing circuitry 210 may decrement both I_c by ΔI_c (1612) and change the default value I_{CT} to the new value of I_c , i.e. $I_{CT} = I_{CT} - \Delta I_c$ (1614).

In examples in which processing circuitry 210 may enable adjustments to I_i (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 I_i is outside the predetermined range of the respective default parameter value, e.g. differs from I_{IT} by more than $\pm \delta I_{IT}$ (NO branch of 1620), in contrast to the increment command, processing circuitry 210 may decrement I_i by ΔI_i , i.e. $I_i = I_i - \Delta I_i$ (1622), but make no change to the default value I_{IT} . In other examples, when I_i is with the predetermined range (YES branch of 1620), processing circuitry 210 may decrement both I_i by ΔI_i (1622) and change the default value I_{IT} to the new value of I_i , i.e. $I_{IT} = I_{IT} - \Delta I_i$ (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

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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

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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 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 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 within 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 first command, and wherein the processing circuitry is further configured to: receive a sec-

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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 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

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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 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 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.

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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.

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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.

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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

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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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(54) **CONTROLLING ELECTRICAL STIMULATION BASED ON A SENSED STIMULATION SIGNAL**

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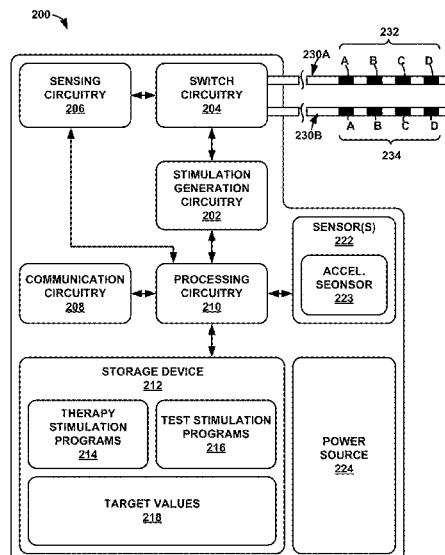
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None
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(57) **ABSTRACT**

This disclosure is directed to devices, systems, and techniques for controlling electrical stimulation therapy. In some examples, a medical device includes stimulation generation circuitry configured to deliver a first stimulation pulse to a patient, sensing circuitry configured to sense the first stimulation pulse, and processing circuitry. The processing circuitry is configured to determine that a value of a characteristic of the sensed first stimulation pulse exceeds a target stimulation pulse value and responsive to determining that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value, change a first value of a parameter to a second value of the parameter that at least partially defines a second stimulation pulse deliverable by the stimulation generation circuitry after the first stimulation pulse was sensed.

27 Claims, 21 Drawing Sheets



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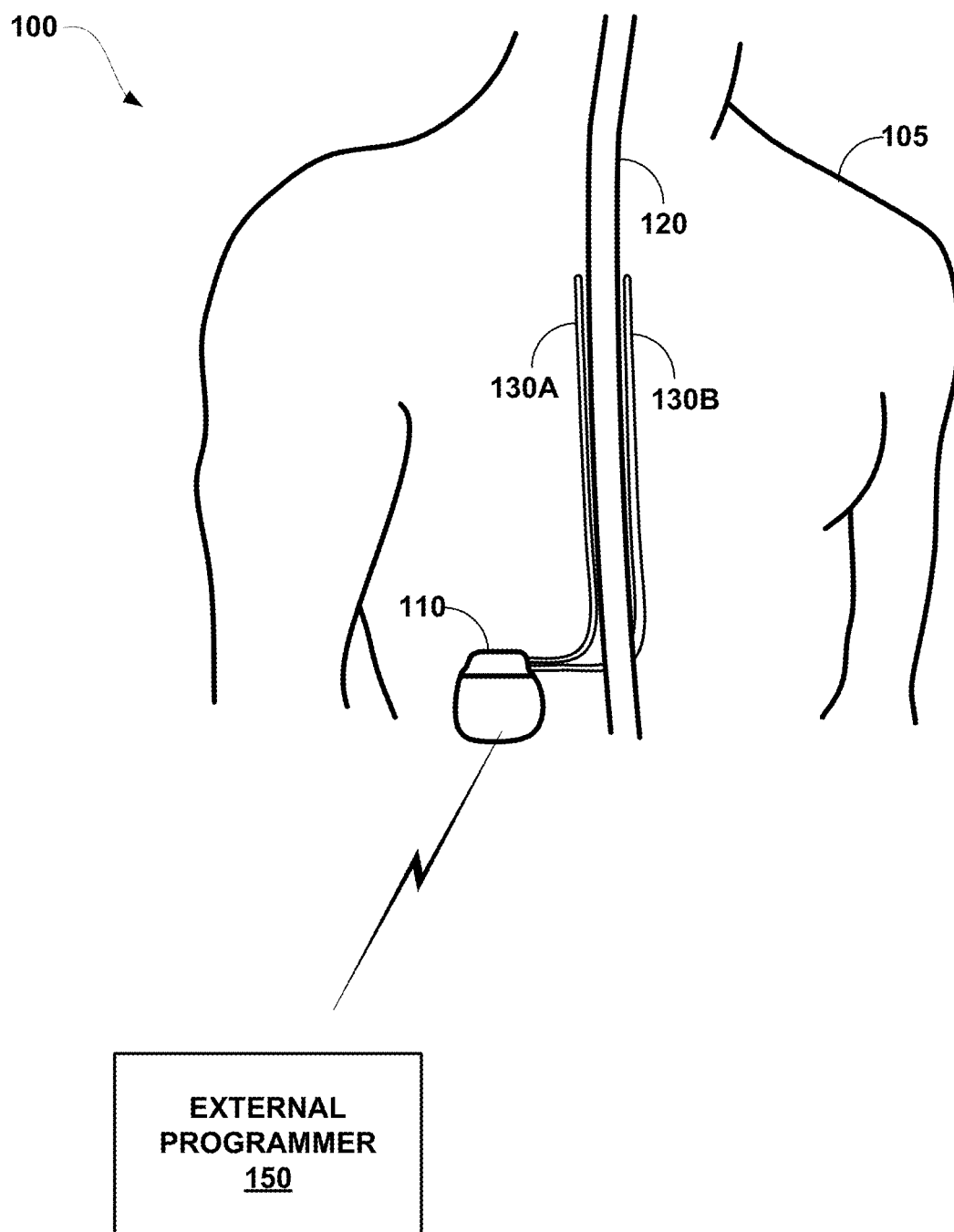


FIG. 1

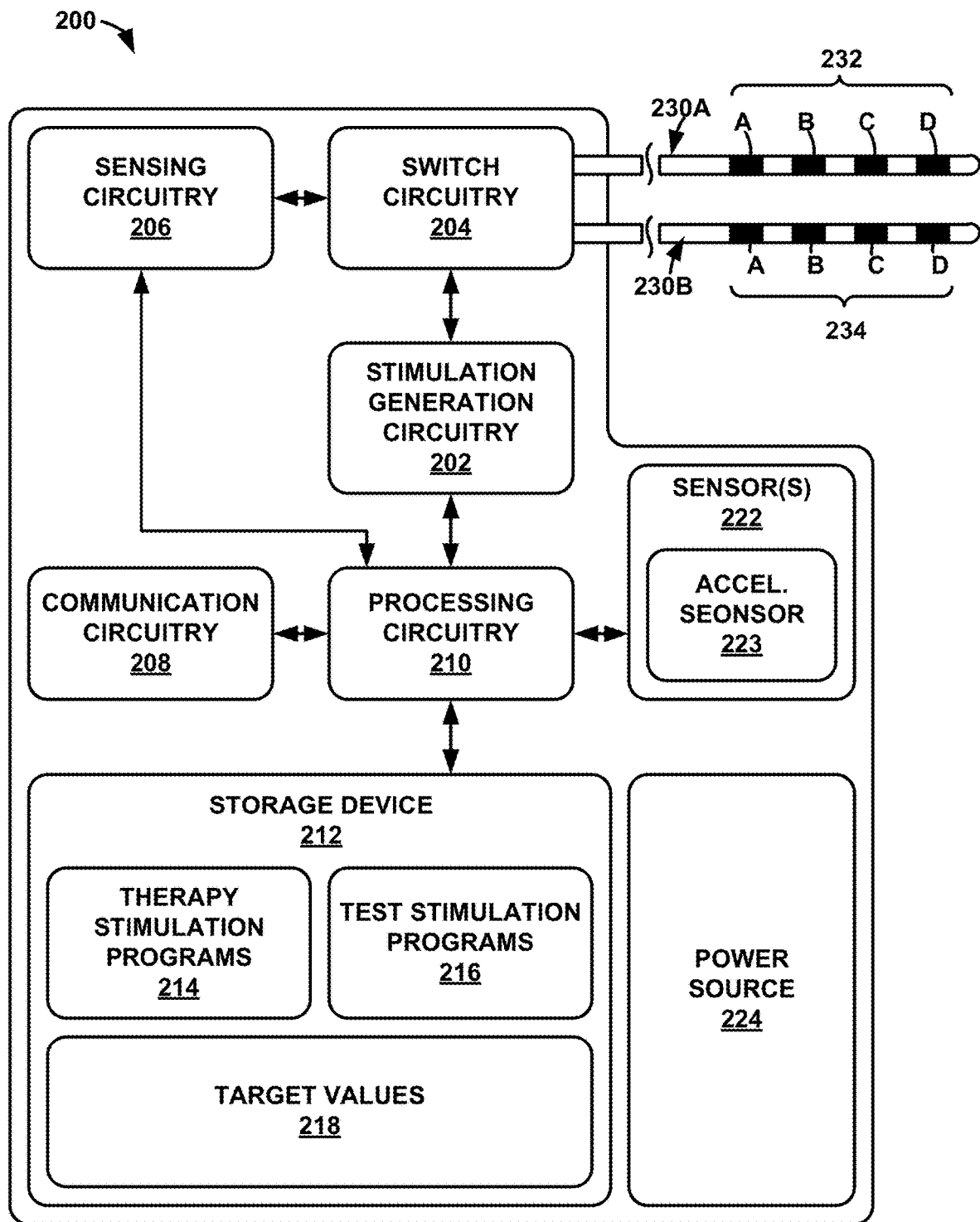


FIG. 2

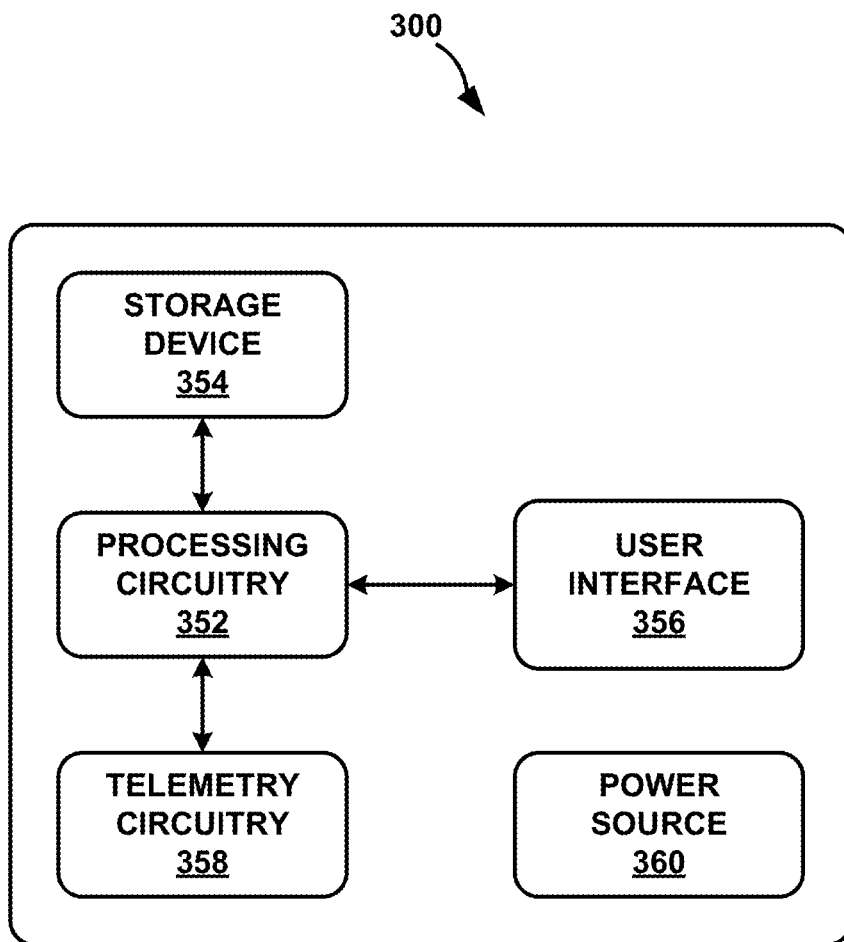


FIG. 3

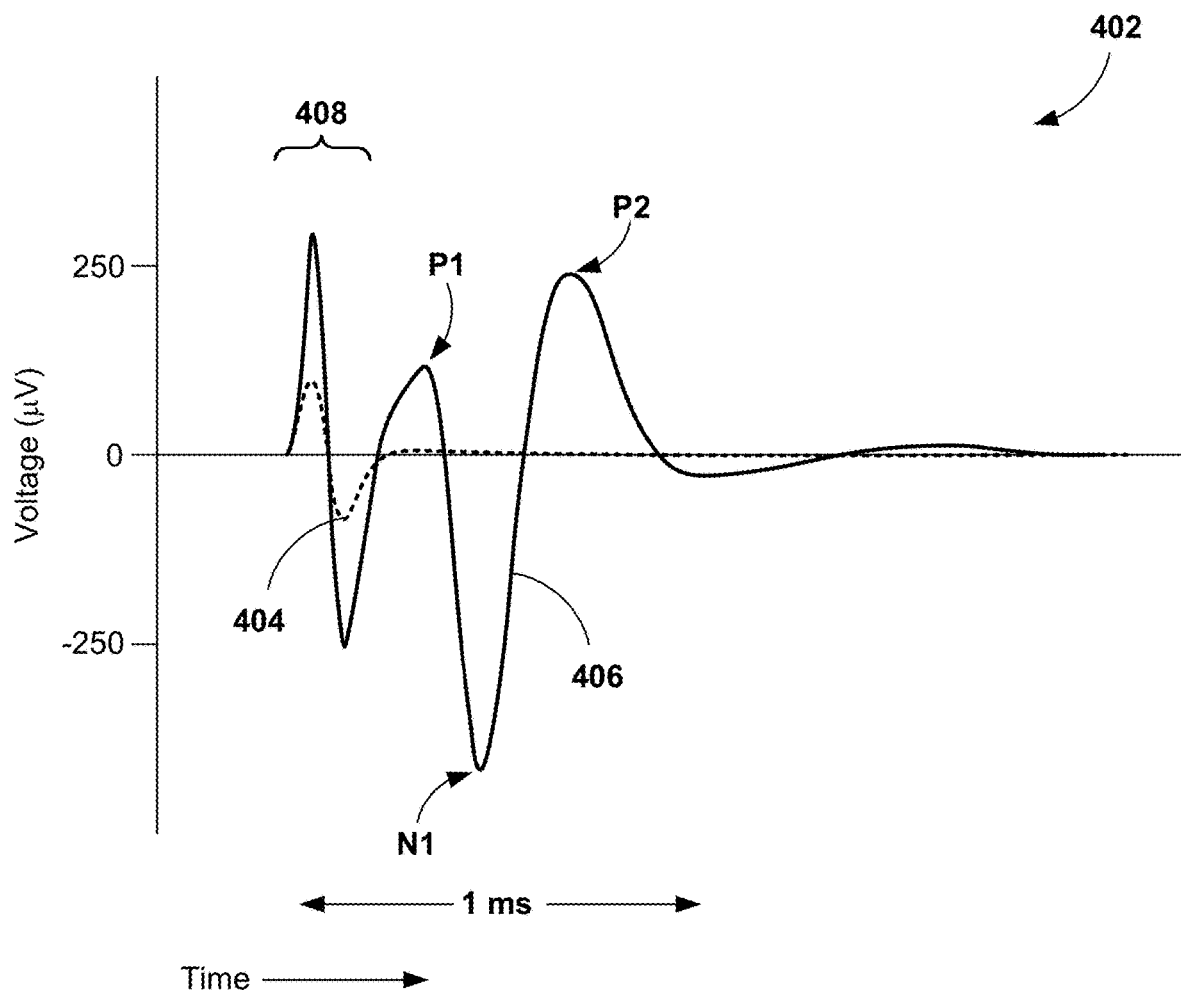


FIG. 4

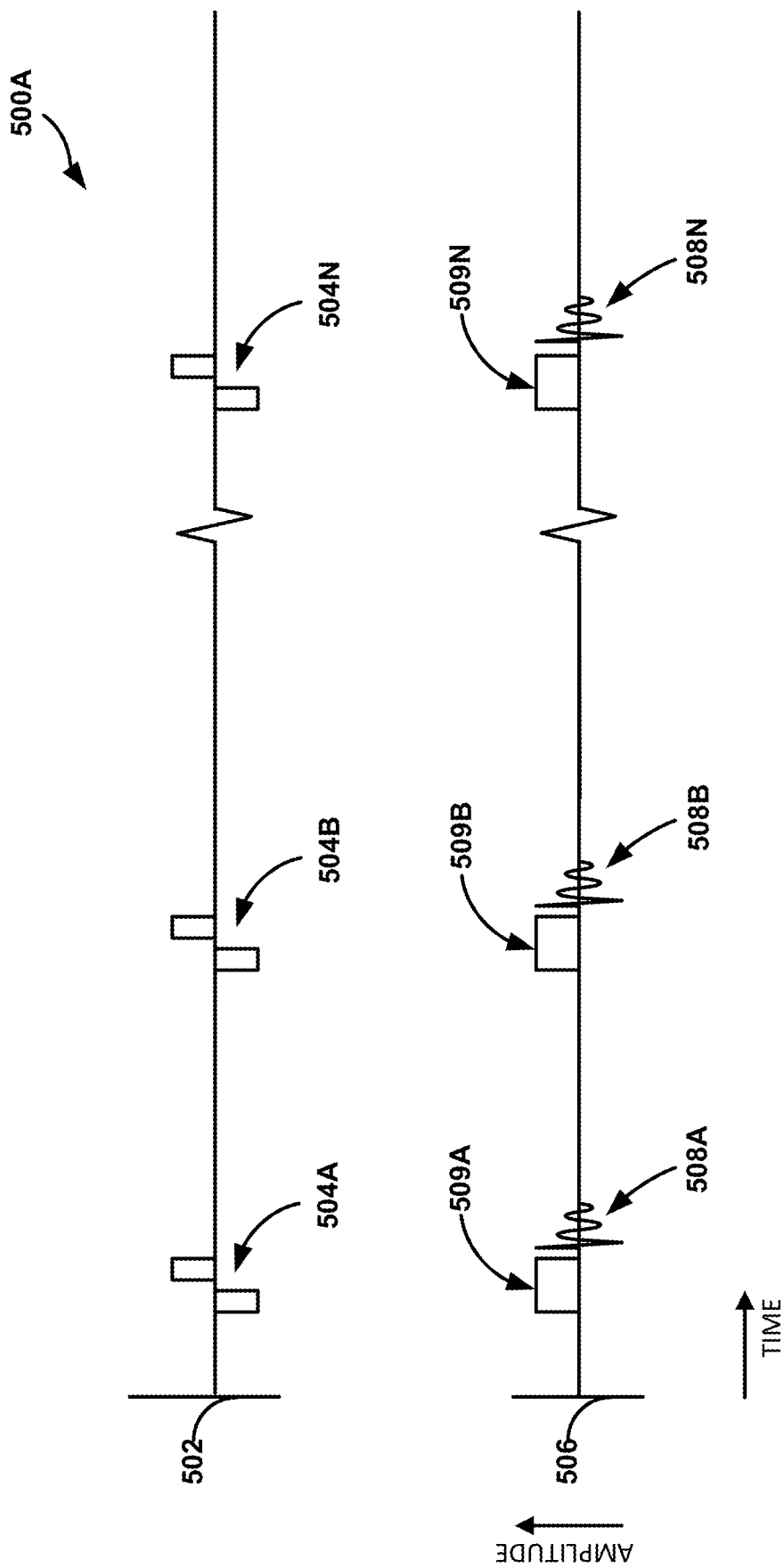


FIG. 5A

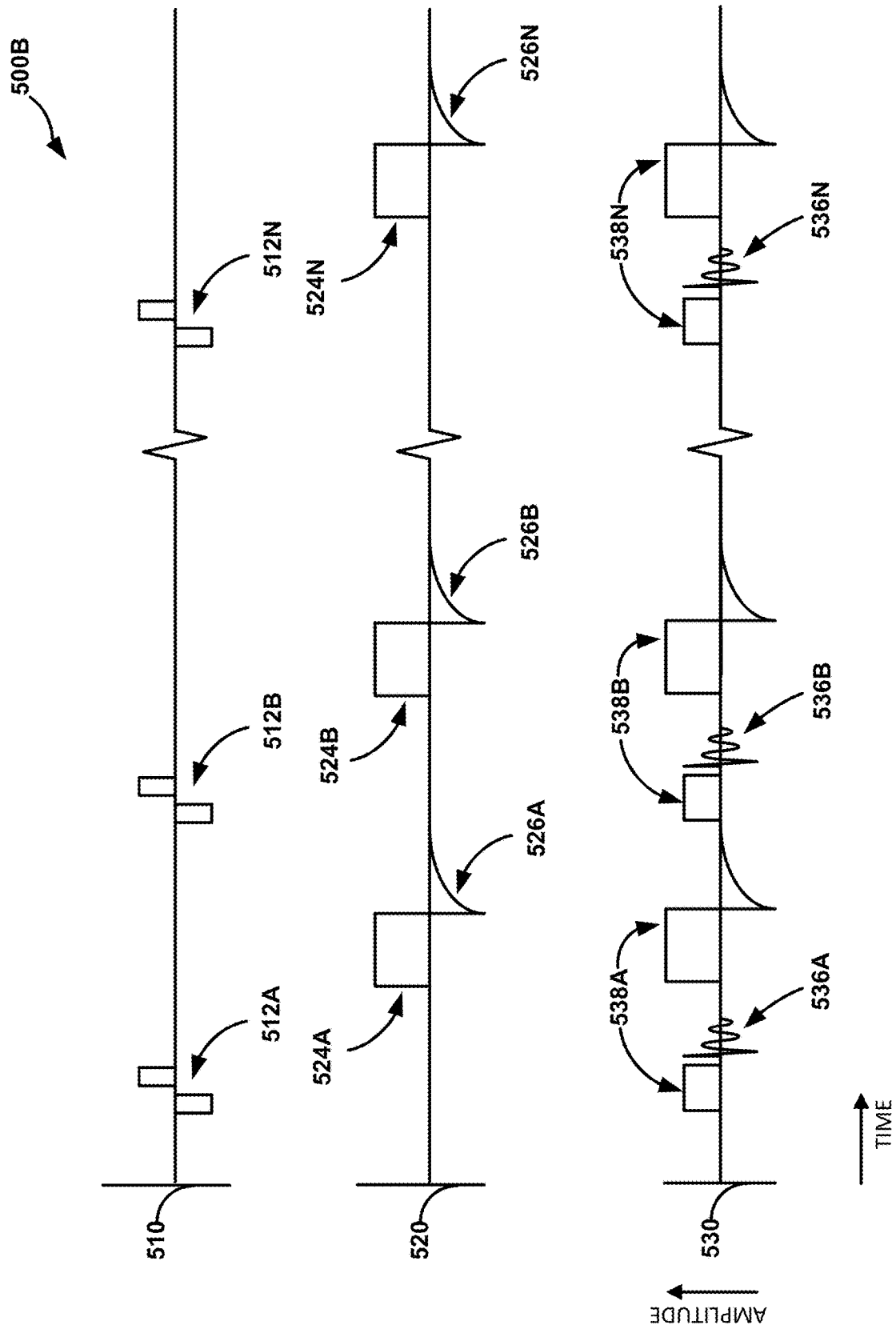


FIG. 5B

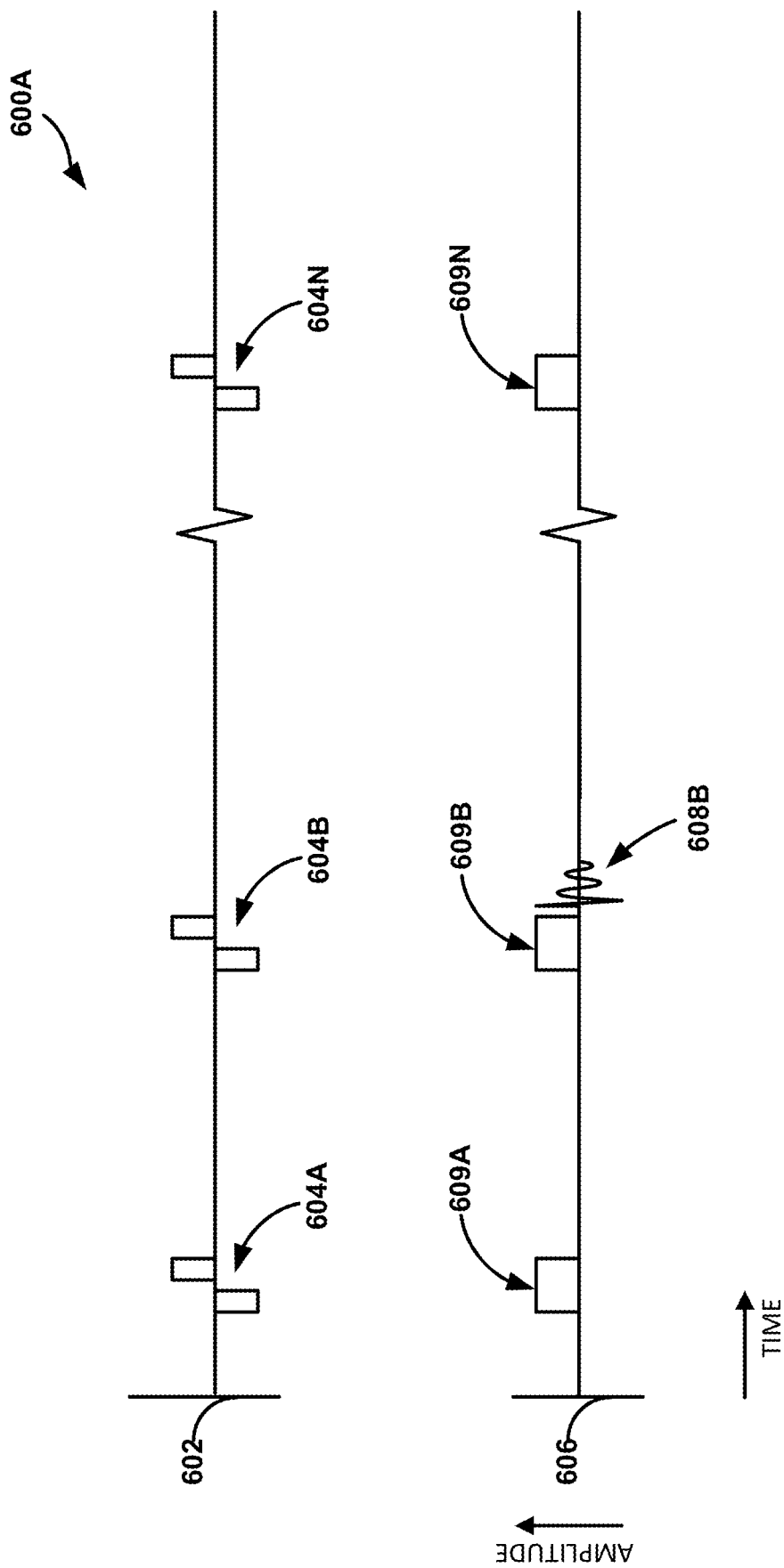


FIG. 6A

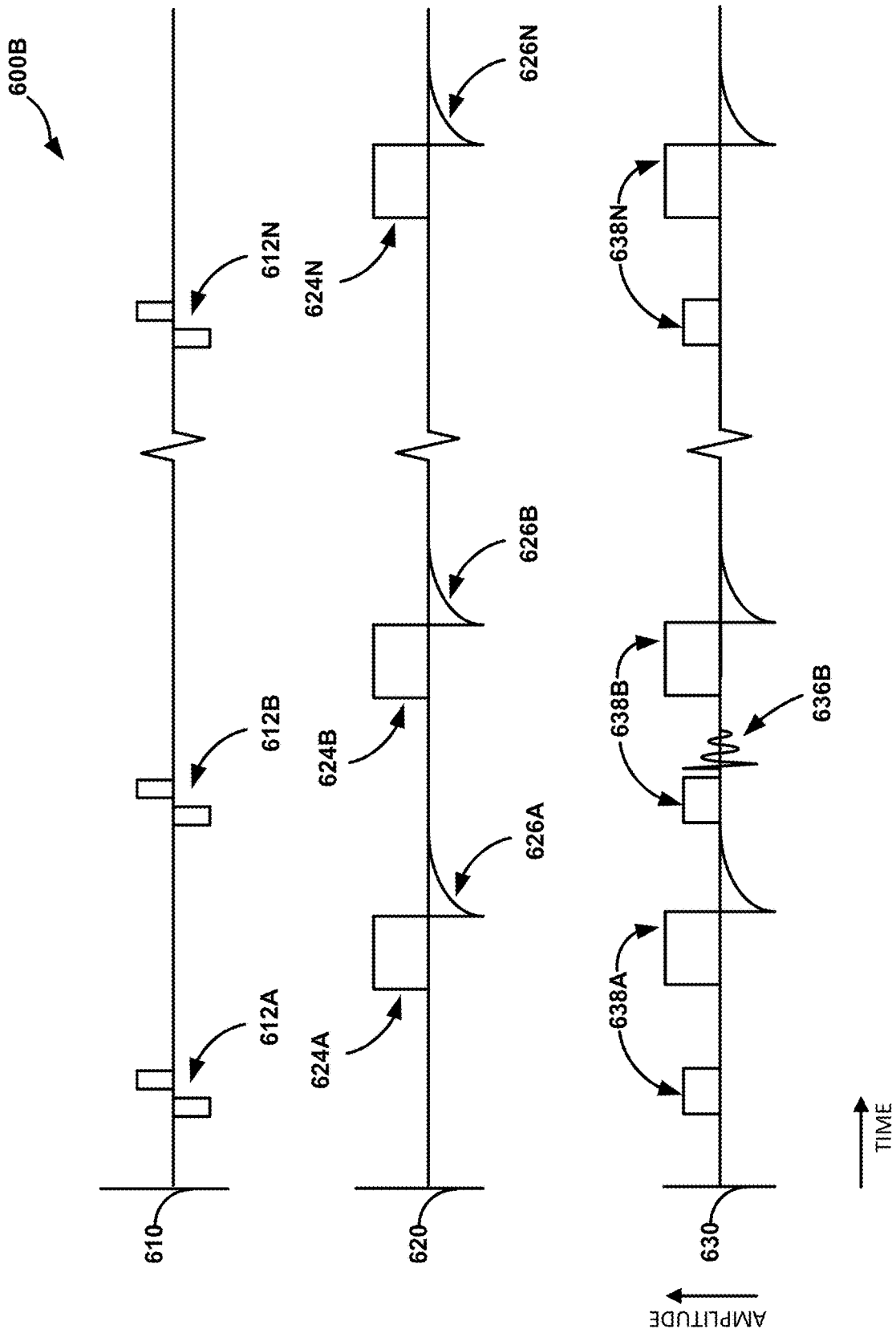


FIG. 6B

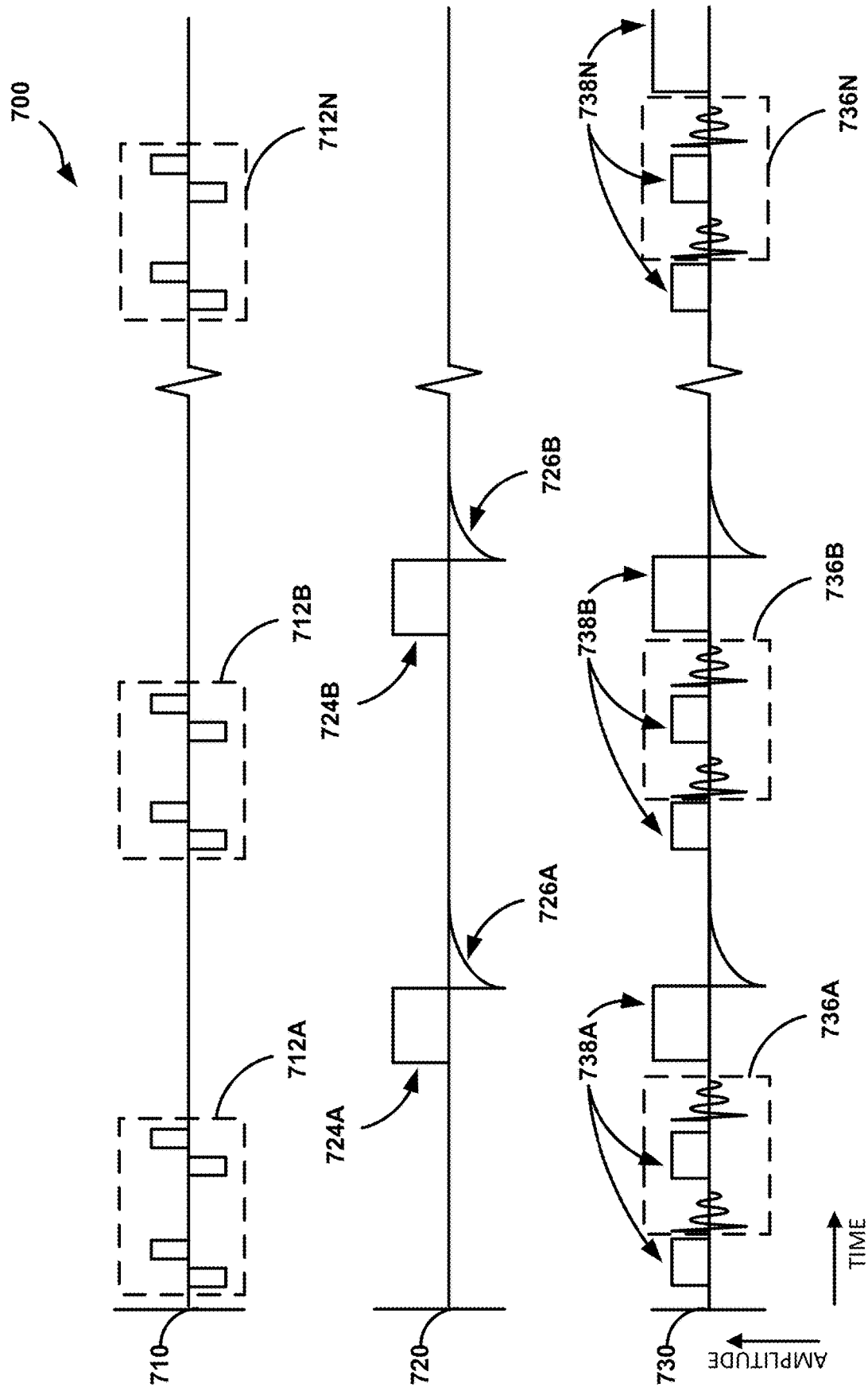


FIG. 7

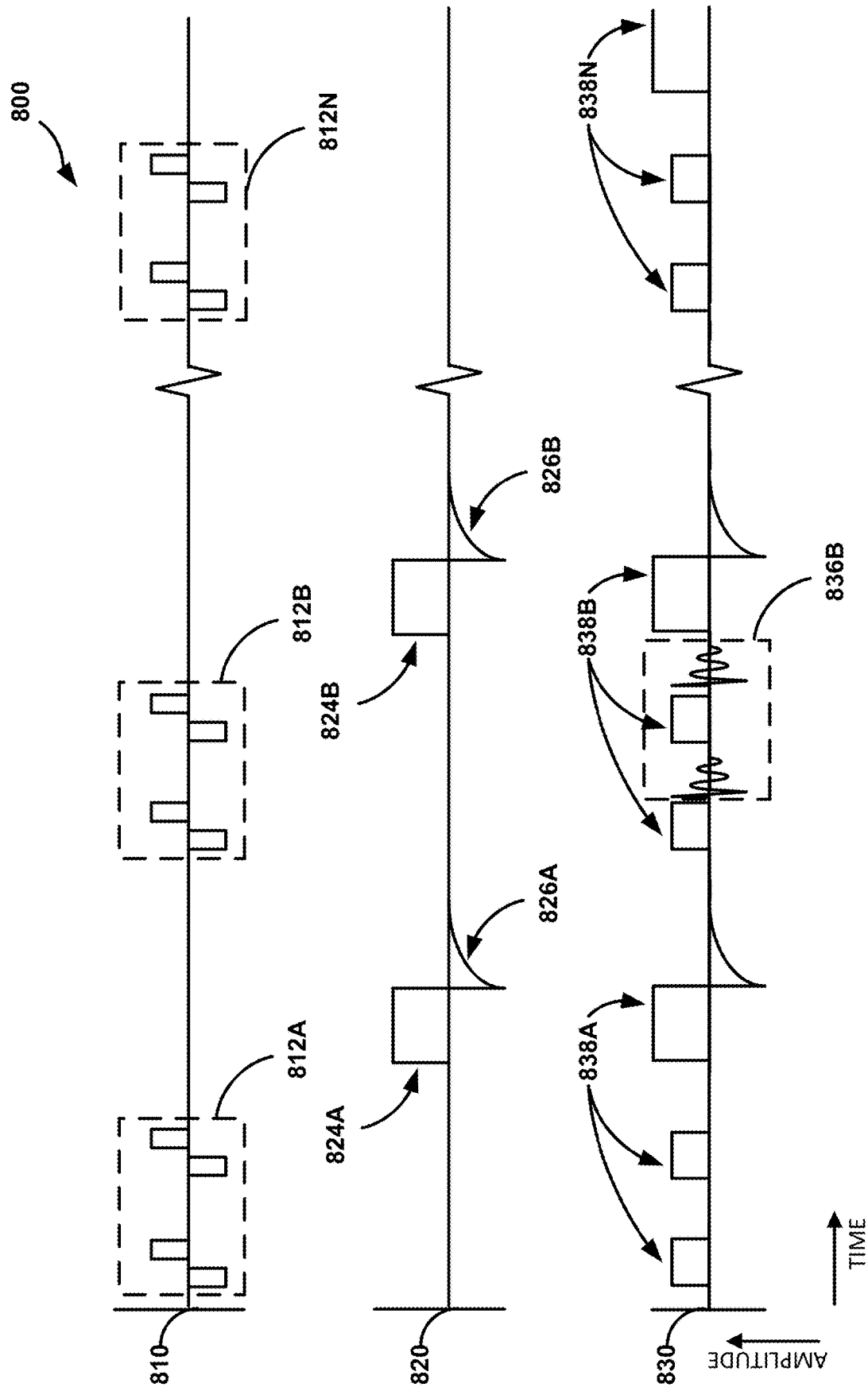


FIG. 8

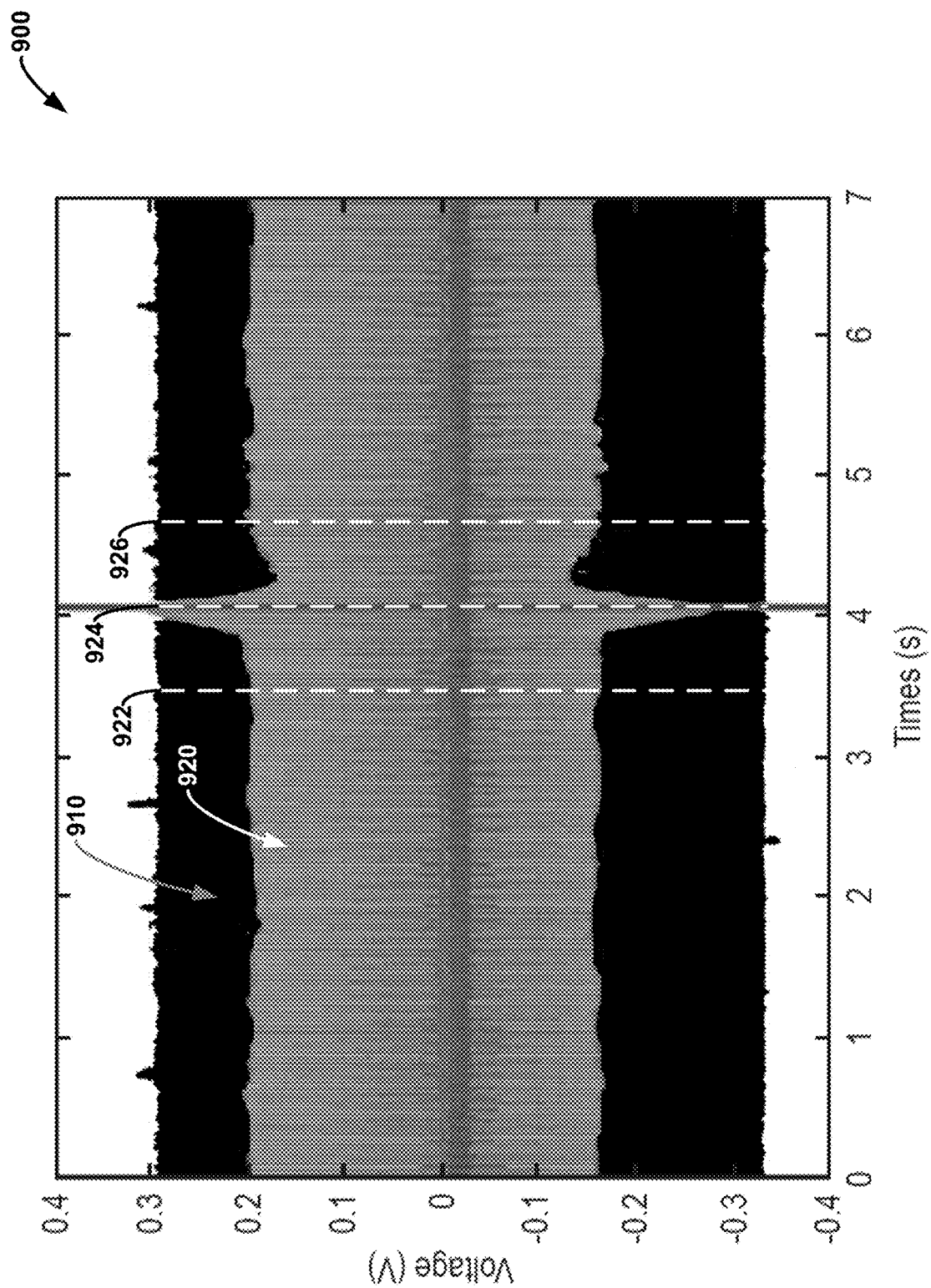


FIG. 9

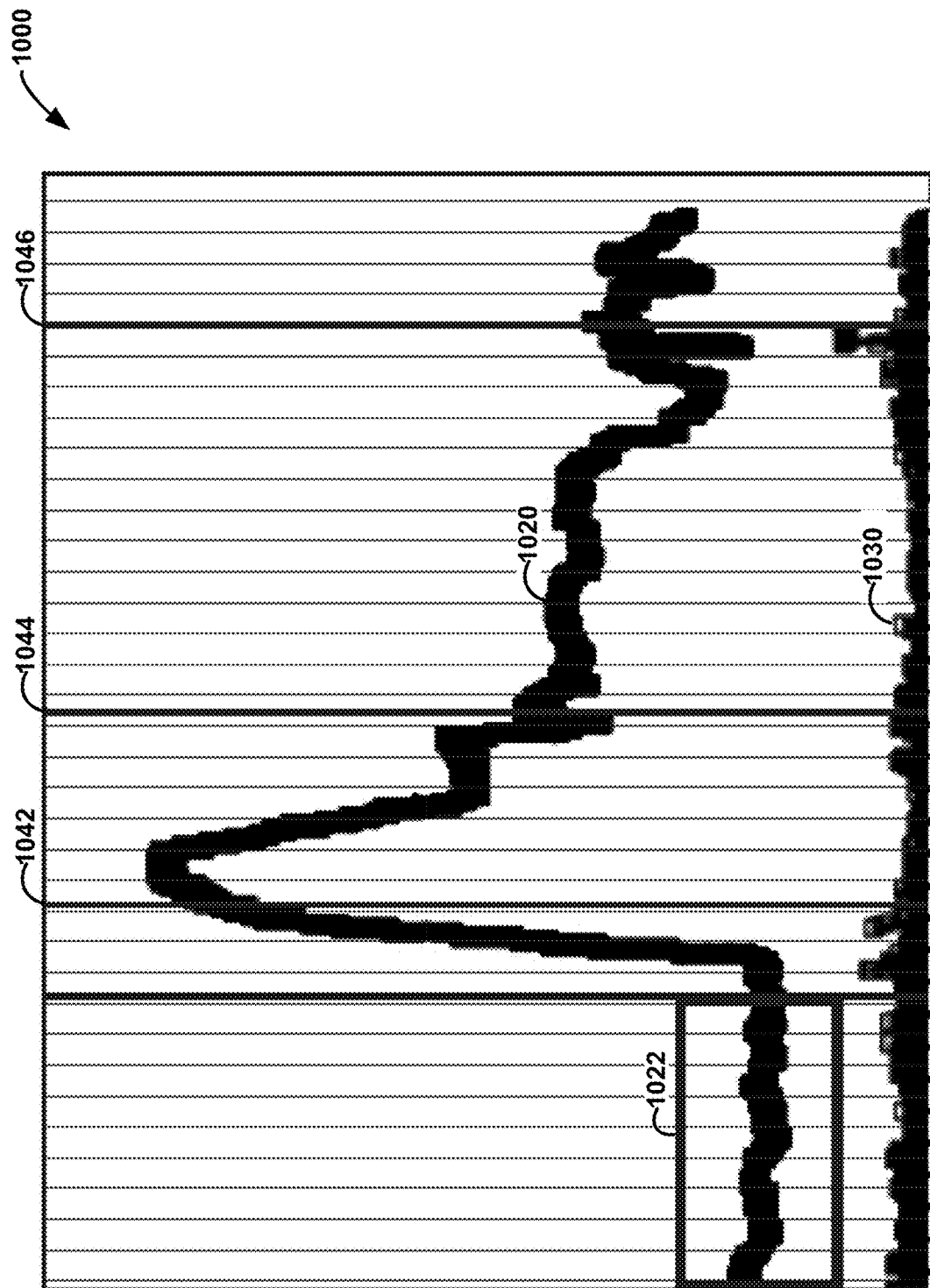


FIG. 10

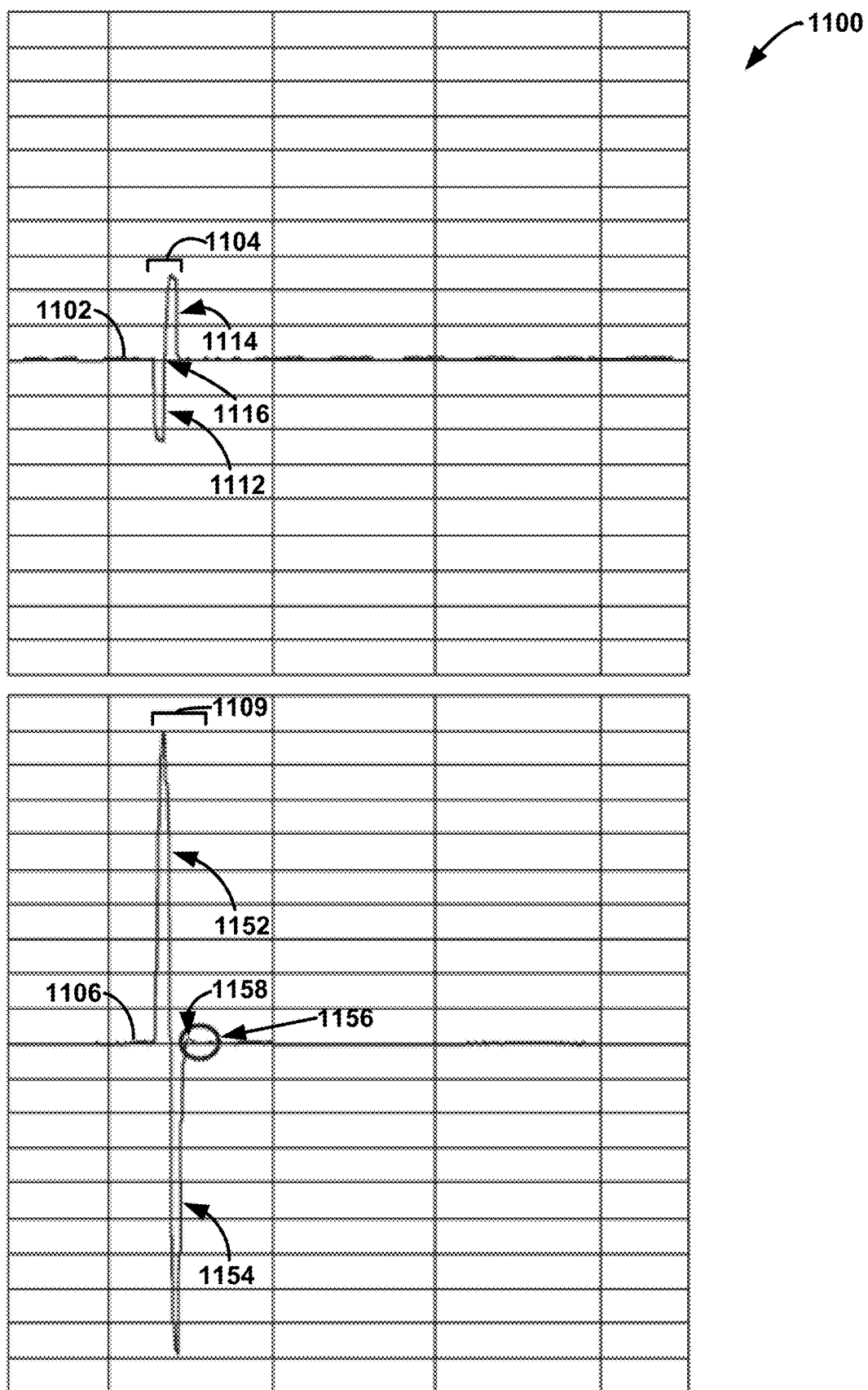


FIG. 11

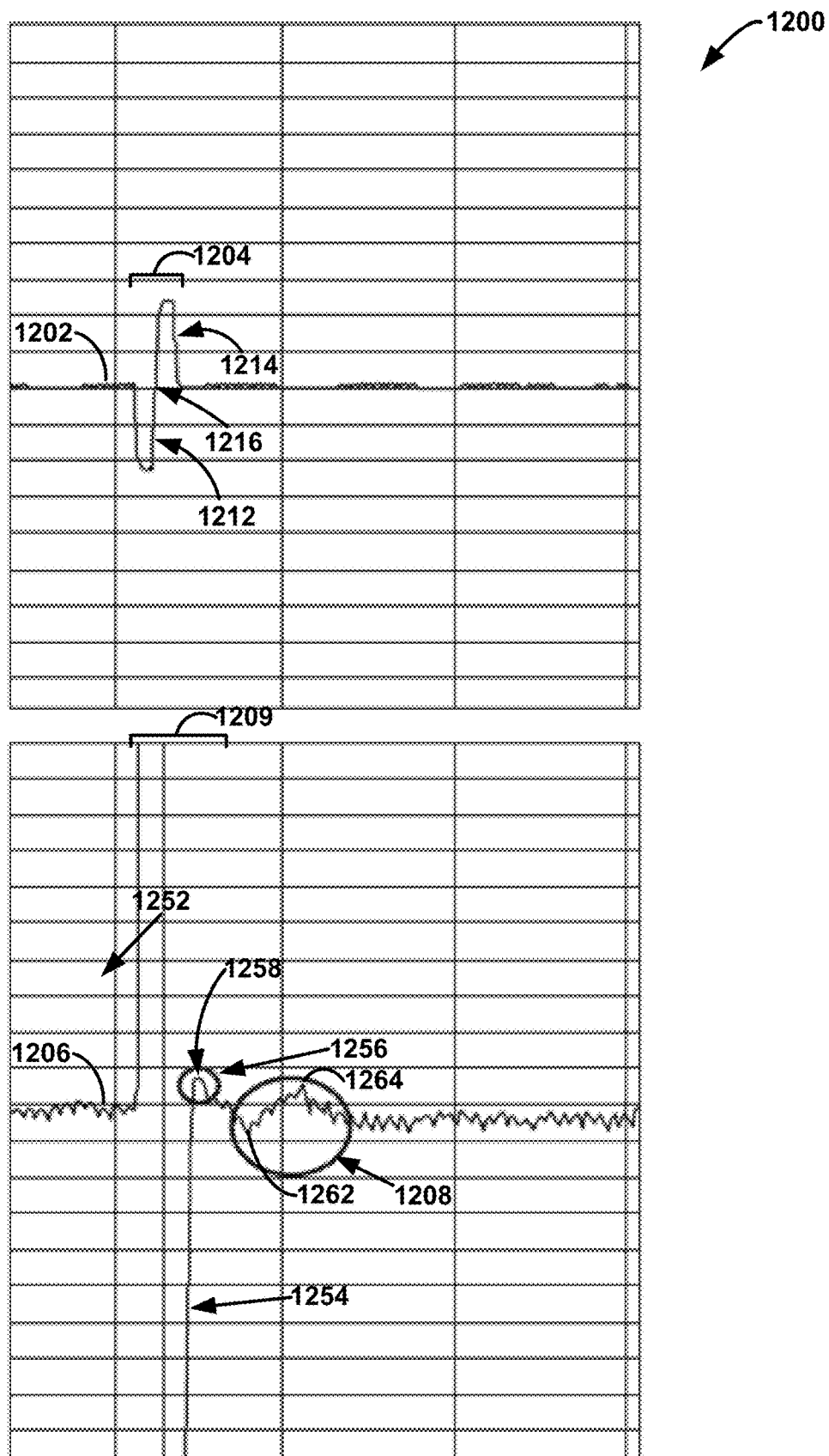


FIG. 12

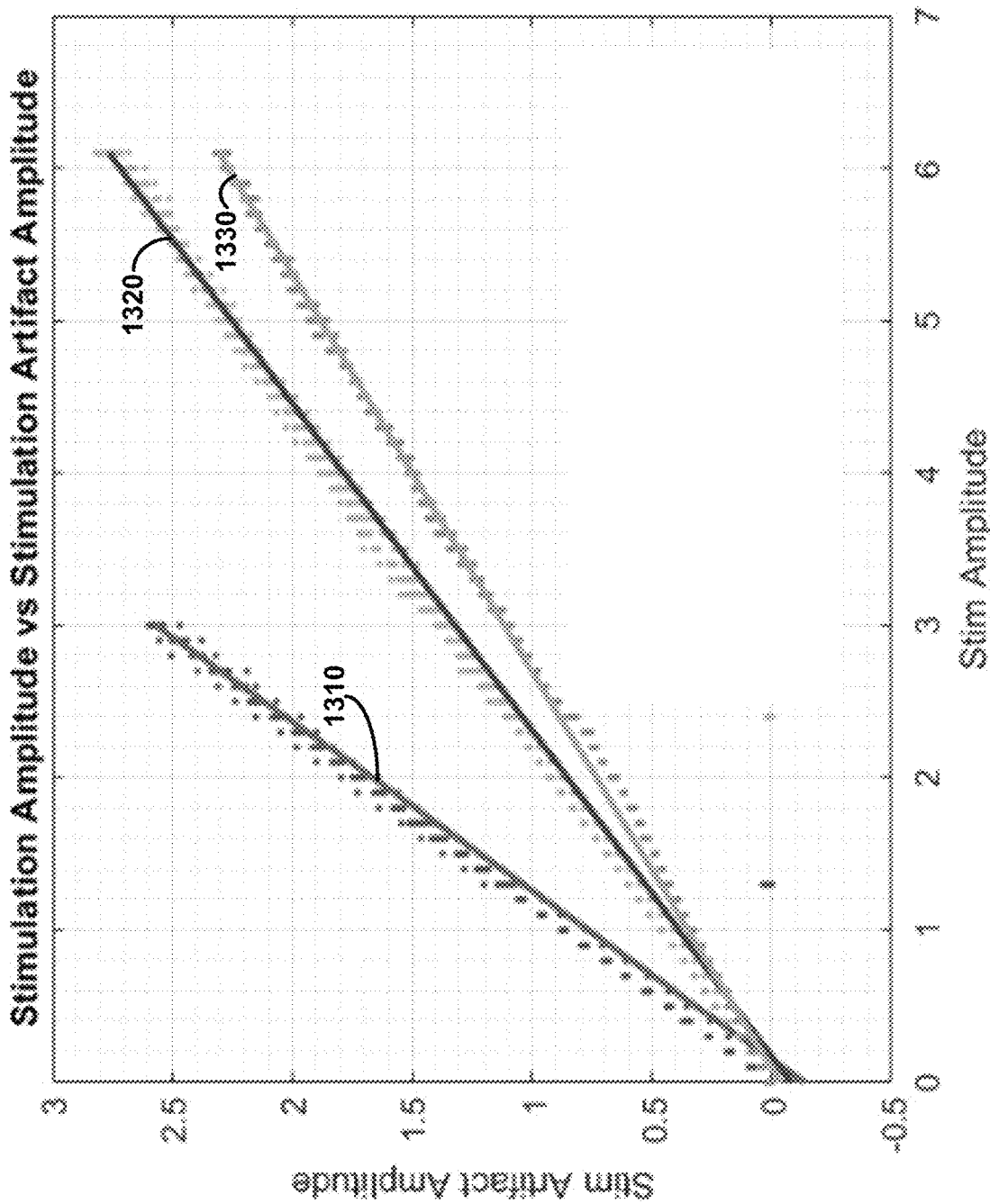


FIG. 13

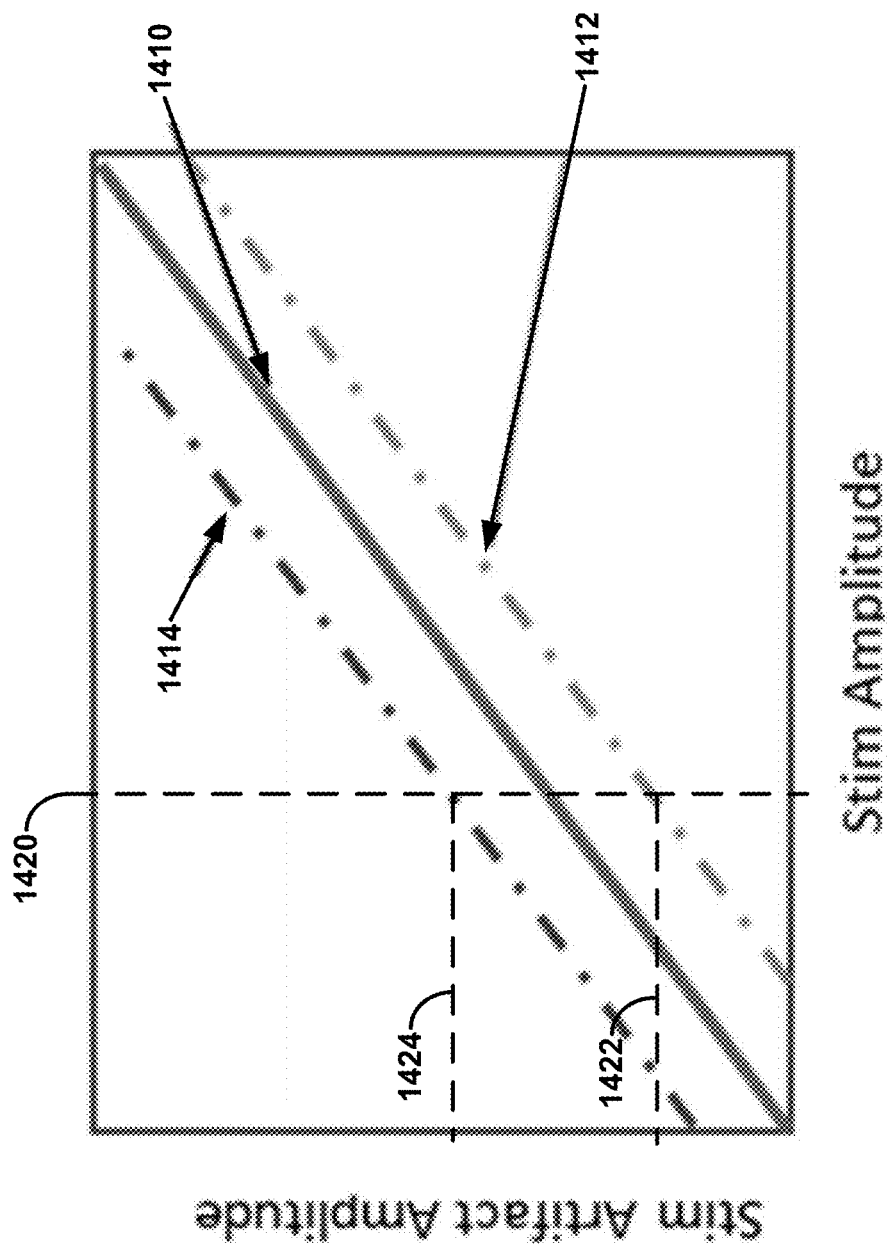


FIG. 14

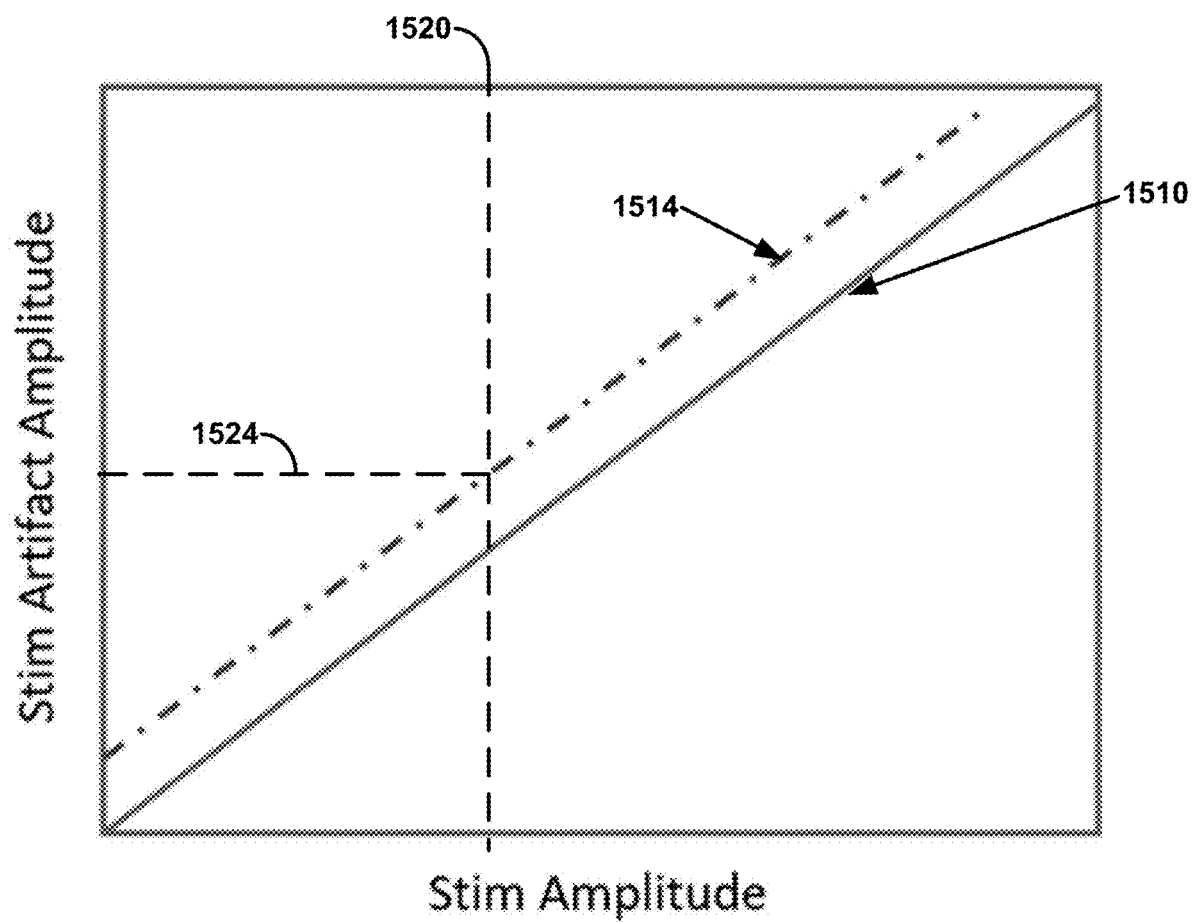


FIG. 15

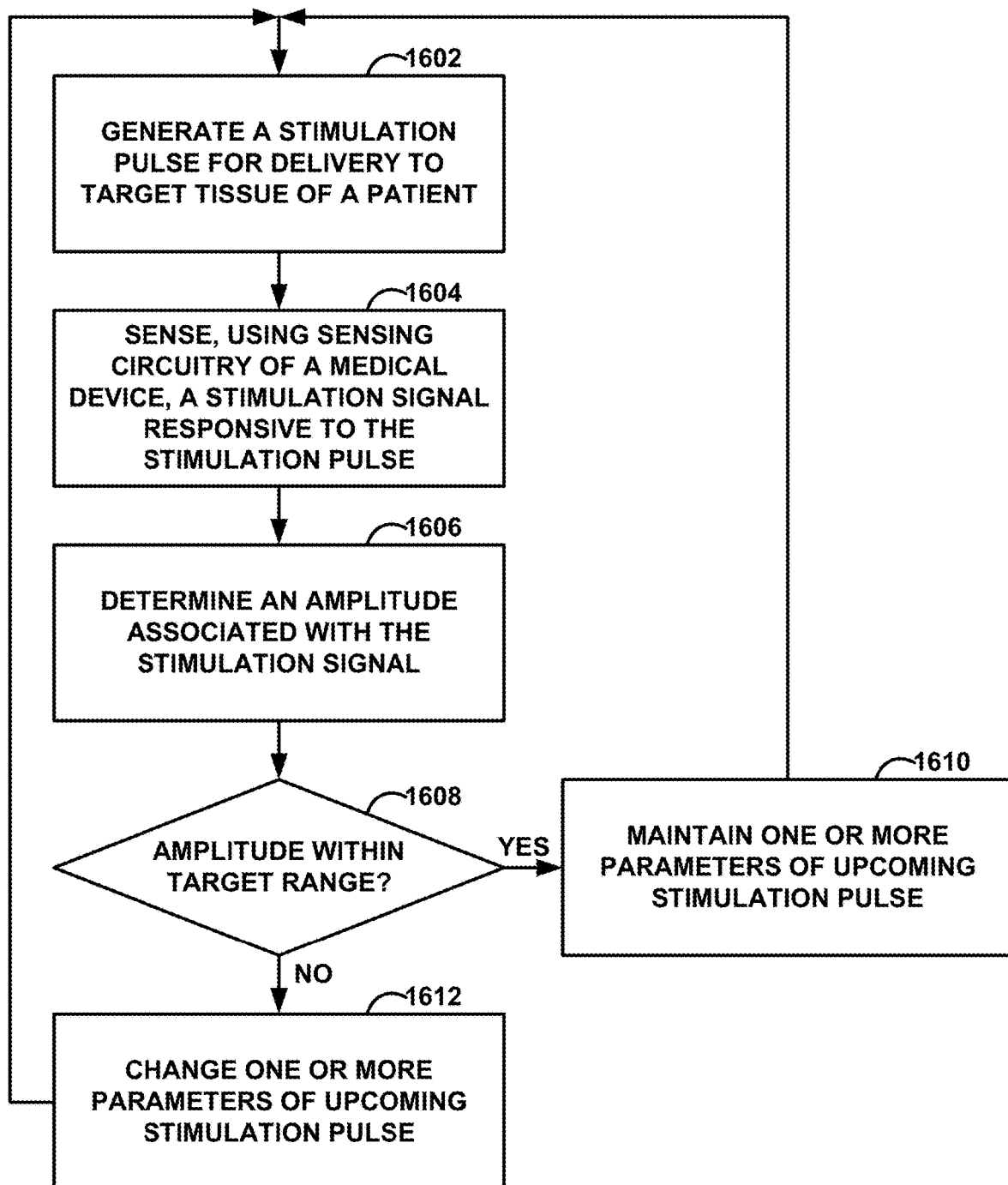


FIG. 16

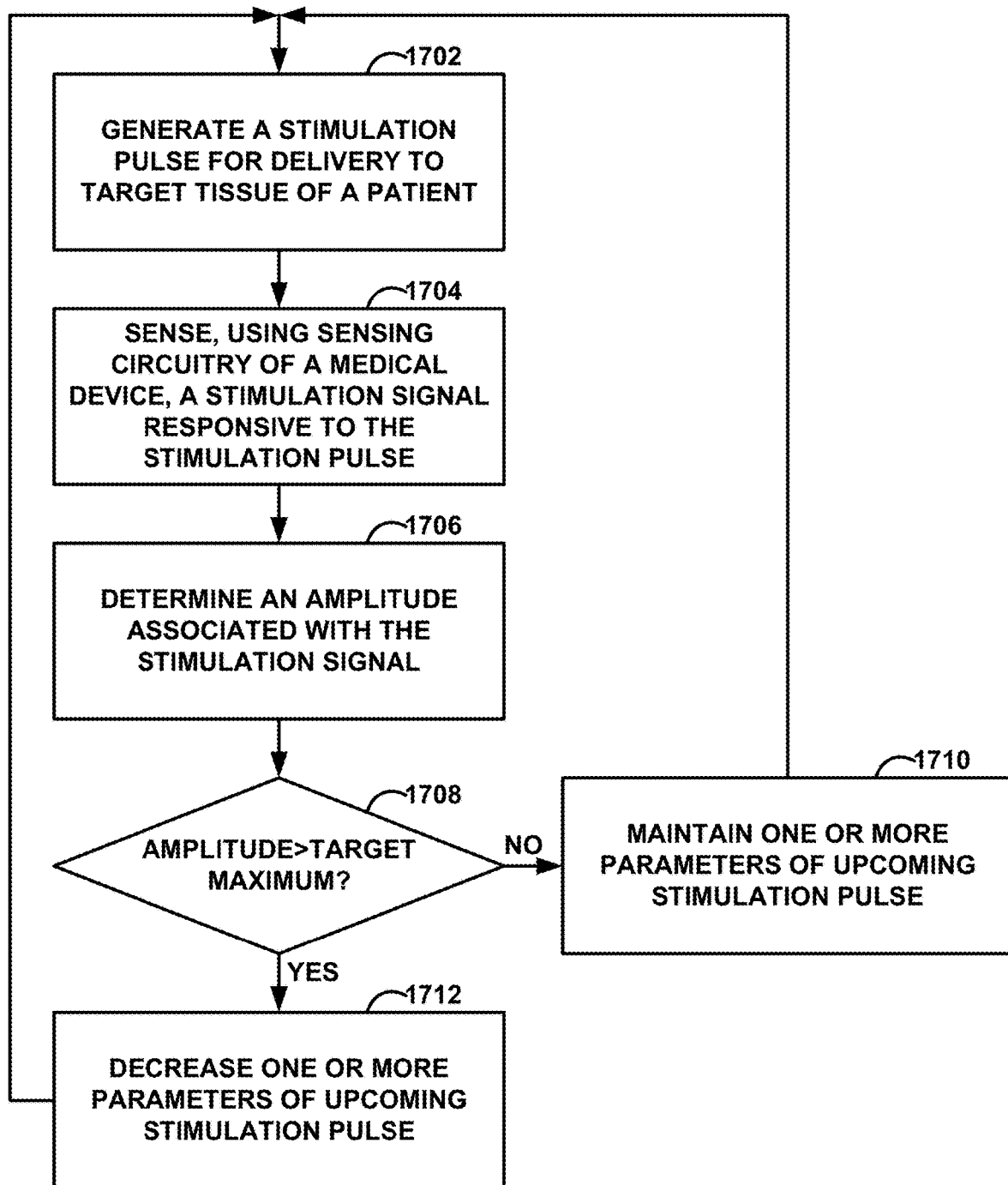


FIG. 17

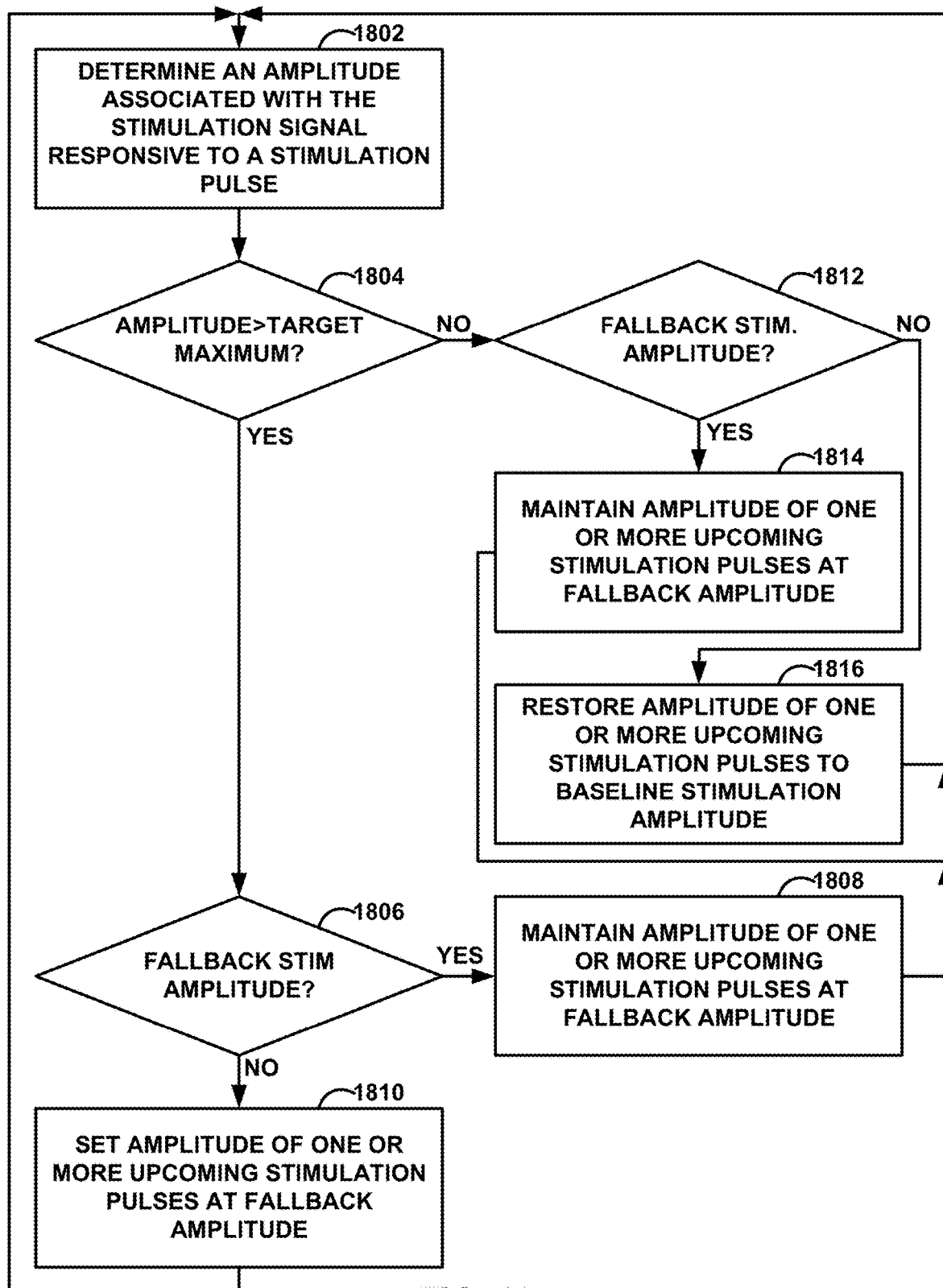


FIG. 18

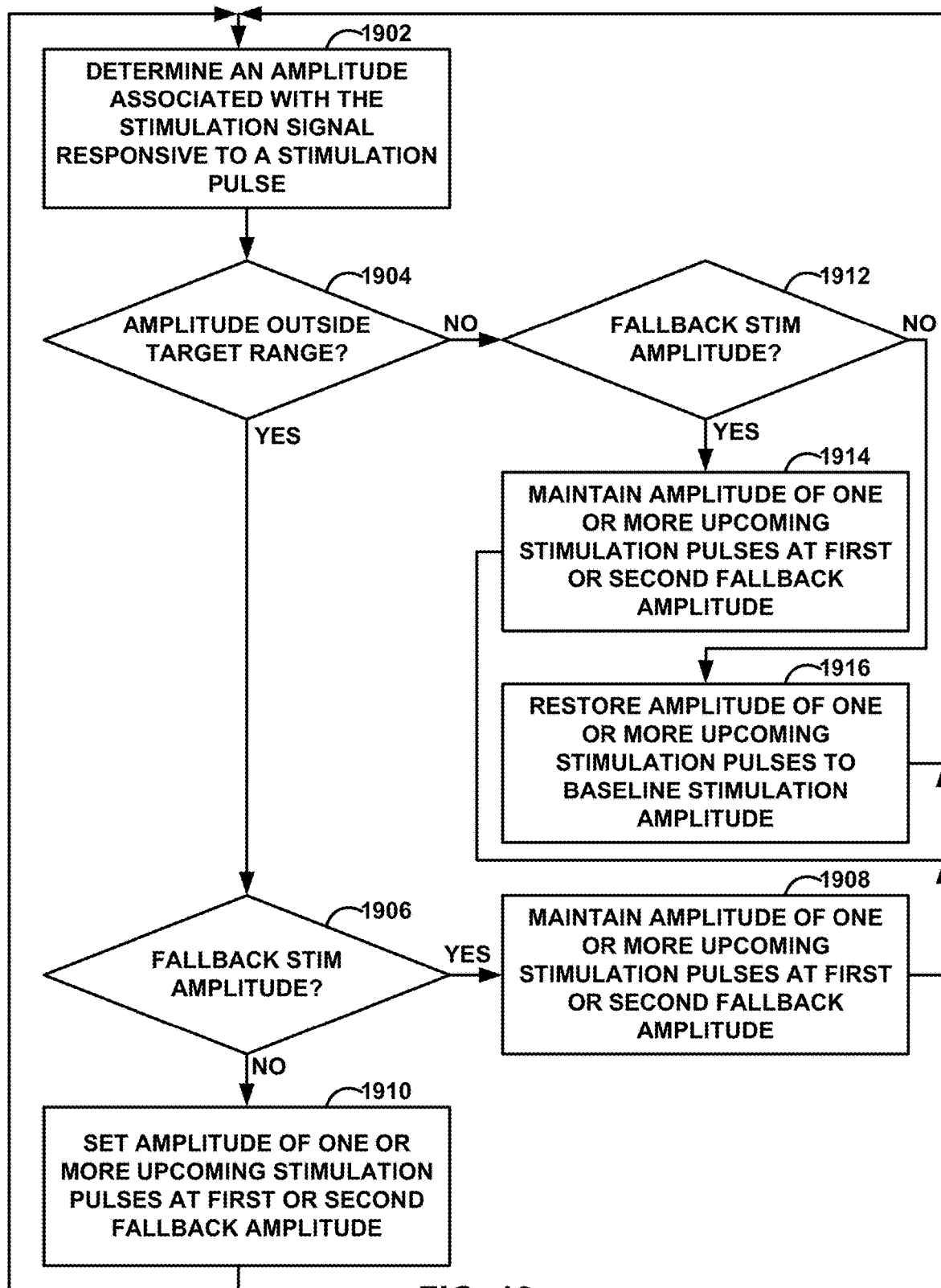


FIG. 19

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CONTROLLING ELECTRICAL STIMULATION BASED ON A SENSED STIMULATION SIGNAL

This application claims the benefit of U.S. Provisional Patent Application No. 62/986,458, filed on Mar. 6, 2020, the entire content of which is incorporated herein by reference.

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 is directed to devices, systems, and techniques for controlling electrical stimulation therapy by sensing at least one of stimulation signals or evoked compound action potentials (ECAPs). A medical device (e.g., an implantable medical device) can deliver one or more stimulation signals (e.g., one or more pulses) to the patient via one or more leads, and the medical device may sense respective stimulation signals and/or ECAPs elicited by the pulses. For example, the medical device may be configured to sense electrical signals. While sensing electrical signals, the medical device may sense one or more stimulation signals that are indicative of the delivered pulse. The medical device may also sense an ECAP from the delivered pulse if the delivered pulse causes a sufficient number of nerve fibers to depolarize. In response to determining that a characteristic of one or more stimulation signals (e.g., a voltage amplitude) have deviated from a target stimulation signal characteristic value, the medical device may adjust a value of one or more stimulation parameters that define a subsequent (e.g., a next) stimulation pulse to be delivered to the patient. For example, the medical device may increase or decrease a current amplitude of the next pulse(s) by a predetermined step size or based on a gain value representative of an amount of deviation from the target stimulation signal characteristic value. In this manner, the medical device may be configured to maintain a consistent volume of neural activation by adjusting the value of one or more stimulation parameters that at least partially define stimulation pulses.

In some examples, a medical device includes stimulation generation circuitry configured to deliver a first stimulation pulse to a patient; sensing circuitry configured to sense the

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first stimulation pulse; and processing circuitry configured to: determine that a value of a characteristic of the sensed first stimulation pulse exceeds a target stimulation pulse value; and responsive to determining that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value, change a first value of a parameter to a second value of the parameter that at least partially defines a second stimulation pulse deliverable by the stimulation generation circuitry after the first stimulation pulse was sensed.

In some examples, a method includes delivering, by stimulation generation circuitry, a first stimulation pulse to a patient; sensing, by sensing circuitry, the first stimulation pulse; determining, by processing circuitry, that a value of a characteristic of the sensed first stimulation pulse exceeds a target stimulation pulse value; and responsive to determining that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value, changing, by the processing circuitry, a first value of a parameter to a second value of the parameter that at least partially defines a second stimulation pulse deliverable by the stimulation generation circuitry after the first stimulation pulse was sensed.

In some examples, a medical device includes stimulation generation circuitry configured to deliver a first stimulation pulse to a patient; sensing circuitry configured to sense a residual phase of the first stimulation pulse; and processing circuitry configured to: determine that a value of a characteristic of the sensed residual phase of the first stimulation pulse exceeds a target residual phase value; and responsive to determining that the value of the characteristic of the sensed residual phase exceeds the target residual phase value, change a first value of a parameter to a second value of the parameter that at least partially defines a second stimulation pulse deliverable by the stimulation generation circuitry after the residual phase of the first stimulation pulse was sensed.

The summary is intended to provide an overview of the subject matter described in this disclosure. It is not intended to provide an exclusive or exhaustive explanation of the systems, device, and methods described in detail within the accompanying drawings and description below. Further details of one or more examples of this disclosure are set forth in the accompanying drawings and in the description below. Other features, objects, and advantages 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 402 of example evoked compound action potentials (ECAPs) sensed for respective stimulation pulses, in accordance with one or more techniques of this disclosure.

FIG. 5A is an example timing diagram illustrating an example of electrical stimulation pulses, respective stimu-

lation signals, and respective sensed ECAPs, in accordance with one or more techniques of this disclosure.

FIG. 5B is another 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. 6A is another 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. 6B is another example timing diagram illustrating one example of electrical stimulation pulses, respective stimulation signals, and respective sensed ECAPs, in accordance with one or more techniques of this disclosure.

FIG. 7 is another example timing diagram illustrating an example of electrical stimulation pulses, respective stimulation signals, and respective ECAPs, in accordance with one or more techniques of this disclosure.

FIG. 8 is another example timing diagram illustrating an example of electrical stimulation pulses, respective stimulation signals, and respective ECAPs, in accordance with one or more techniques of this disclosure.

FIG. 9 is a graph illustrating a stimulation pulse amplitude plot and a stimulation signal amplitude plot, in accordance with one or more techniques of this disclosure.

FIG. 10 is a graph illustrating a stimulation signal amplitude plot and an ECAP amplitude plot, in accordance with one or more techniques of this disclosure.

FIG. 11 is a timing diagram illustrating an example of an electrical stimulation pulse and a respective stimulation signal, in accordance with one or more techniques of this disclosure.

FIG. 12 is a timing diagram illustrating an example of an electrical stimulation pulse, a respective ECAP, and a respective stimulation signal, in accordance with one or more techniques of this disclosure.

FIG. 13 is a graph illustrating a first transfer function corresponding to a first posture, a second transfer function corresponding to a second posture, and a third transfer function corresponding to a third posture, in accordance with one or more techniques of this disclosure.

FIG. 14 is a graph illustrating a target range of amplitude values for a stimulation signal in relation to a transfer function corresponding to a respective patient posture, in accordance with one or more techniques of this disclosure.

FIG. 15 is a graph illustrating target maximum values for a stimulation signal in relation to a transfer function corresponding to a respective patient posture, in accordance with one or more techniques of this disclosure.

FIG. 16 is a flow diagram illustrating an example operation for controlling simulation based on one or more stimulation signals, in accordance with one or more techniques of this disclosure.

FIG. 17 is a flow diagram illustrating another example operation for controlling simulation based on one or more stimulation signals, in accordance with one or more techniques of this disclosure.

FIG. 18 is a flow diagram illustrating another example operation for controlling simulation based on one or more stimulation signals, in accordance with one or more techniques of this disclosure.

FIG. 19 is a flow diagram illustrating another example operation for controlling simulation based on one or more stimulation signals, in accordance with one or more techniques of this disclosure.

Like reference characters denote like elements throughout the description and figures.

DETAILED DESCRIPTION

The disclosure describes examples of medical devices, systems, and techniques for automatically adjusting electrical stimulation therapy delivered to a patient based on a characteristic of one or more stimulation signals sensed by a medical device in response to stimulation pulses (e.g., control pulses and/or informed pulses) delivered by the medical device and, in some examples, characteristics of evoked compound action potentials (ECAPs) detected by a medical device. Electrical stimulation therapy is typically delivered to a target tissue (e.g., one or more nerves or muscle) of a patient via two or more electrodes. Parameters of the electrical stimulation therapy (e.g., electrode combination, voltage or current amplitude, pulse width, pulse frequency, etc.) are selected by a clinician and/or the patient to provide relief from various symptoms, such as pain, muscle disorders, etc. However, as the patient moves, the distance between the electrodes and the target tissues changes. Since neural recruitment is a function of stimulation intensity and distance between the target tissue and the electrodes, movement of the electrode closer to the target tissue may result in increased perception by the patient (e.g., possible painful sensations), and movement of the electrode further from the target tissue may result in decreased efficacy of the therapy for the patient.

ECAPs are a measure of neural recruitment because each ECAP signal represents the superposition of electrical potentials generated from axons firing in response to an electrical stimulus (e.g., a stimulation pulse). Changes in a characteristic (e.g., an amplitude of a portion of the signal, an area under one or more peaks, frequency content, and/or maximum and/or minimum peak timing) of an ECAP signal occur as a function of how many axons have been activated by the delivered stimulation pulse. A system can monitor changes in the characteristic of the ECAP signal and use that change in the characteristic to adjust one or more stimulation parameters that at least partially defines the stimulation pulses delivered to the patient. For example, the system can reduce the intensity of stimulation pulses (e.g., reduce a current amplitude and/or pulse width) in response to detecting an increase in an amplitude of an ECAP signal.

Nerve impulses may be detectable as the ECAP signal travels quickly along the nerve fiber after the delivered stimulation pulse first depolarizes the nerve. Therefore, if the stimulation pulse delivered by first electrodes has a pulse width that is too long, different electrodes configured to sense the ECAP will sense the stimulation pulse itself as a stimulation signal that obscures the lower amplitude ECAP signal. However, the ECAP signal loses fidelity as the electrical potentials propagate from the electrical stimulus because different nerve fibers propagate electrical potentials at different speeds. Therefore, sensing the ECAP at a far distance from the stimulating electrodes may avoid the stimulation signal caused by a stimulation pulse with a long pulse width, but the ECAP signal may lose fidelity needed to detect changes to the ECAP signal that occur when the electrode to target tissue distance changes or when a targeted activated fiber distribution changes or terminates before a sensing electrode location. In other words, the system may not be able to identify, at any distance from the stimulation electrodes, ECAPs from stimulation pulses configured to provide a therapy to the patient.

Although a system can use ECAP signals to detect changes to stimulation therapy, ECAP signals may not always be present or detectable. For example, the delivered stimulation pulse may have an intensity that is too low to

elicit a detectable ECAP signal. For example, the stimulation pulse may be referred to as a “sub-threshold” stimulation pulse because the stimulation pulse is below at least one of a perception threshold, a motor threshold, or an ECAP detection threshold. Sub-threshold stimulation pulses may cause a therapeutic effect for the patient, but the lack of a detectable ECAP signal may prevent the system from using an ECAP signal to modulate stimulation parameter values in response to changes in the distance between electrodes and target tissue (e.g., target nerves).

A medical device may be configured to sense stimulation signals and adjust stimulation parameters based on a characteristic of one or more stimulation signals. As discussed above, ECAPs elicited by stimulation pulses delivered by the medical device might not be detectable by the medical device. Even if an ECAP signal is not detectable, the medical device may detect one or more stimulation signals caused by the stimulation pulse. The medical device may determine or adjust values of one or more parameters that at least partially define subsequent stimulation pulses based characteristic of the respective stimulation signals. More specifically, the stimulation signals detected by the medical device may include information indicative of an efficacy of therapy delivered to the patient by the medical device. For example, the stimulation signals may include information indicative of a distance between one or more electrodes of the medical device and the target tissue. In this way, the medical device may adjust stimulation therapy according to the characteristics of one or more stimulation signals in order to maintain efficacy of the therapy and/or reduce undesirable side effects during or as a result of patient movement.

The term “stimulation signal” may be used herein to describe a signal that the medical device senses in response to a stimulation pulse delivered by the medical device. 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 stimulation signals and/or 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 informed pulses) 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 informed pulses) 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.

The medical device may, in some cases, determine whether a characteristic of a stimulation signal detected in response to a stimulation pulse (e.g., a control pulse) is within a range from a first threshold characteristic value to a second threshold characteristic value. The first threshold characteristic value and the second threshold characteristic value which define the range may, in some cases, depend on a posture of the patient and a magnitude of the stimulation pulse which provokes the stimulation signal sensed by the medical device. The medical device may determine the posture of the patient using an accelerometer signal. In this way, the medical device may determine one or more parameters of stimulation delivered to the patient based on whether the characteristic of the stimulation signal is within the respective range of stimulation signal characteristic values, where the range is determined based on the posture of the patient and the magnitude of the stimulation pulses (e.g., voltage magnitude, current magnitude).

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.

The techniques of this disclosure may provide one or more advantages. For example, a medical device may control stimulation based on one or more stimulation signals when an ECAP is not elicited by the delivered pulse or the ECAP is otherwise not detectable. In this way, the medical device may determine a value for one or more parameters that define stimulation pulses based on a characteristic value of the one or more stimulation signals detected from previous stimulation pulse. In one example, the value for one or more parameters of the stimulation pulses may be determined from a characteristic of a third phase or residual phase of the stimulation signal (e.g., one of the stimulation signals) detected from a stimulation pulse. The third phase may occur within the final third of the stimulation signal, and the third phase may be referred to as a residual phase because it represents ionic rebalancing of any residual charge resulting from the stimulation pulse that was delivered. In this way, the medical device may be configured to determine therapy based on one or more stimulation signals when an ECAP is not present or is otherwise not detectable by the medical device. Additionally, the medical device may adjust stimulation parameters for subsequent pulses based on a characteristic value of a stimulation signal and a characteristic of an ECAP elicited by the same pulse that caused the stimulation signal. In this manner, the stimulation signal may improve the quality of feedback signals available for controlling stimulation even if the ECAP signal is detectable.

FIG. 1 is a conceptual diagram illustrating an example system 100 that includes an implantable medical device (IMD) 110 configured to deliver spinal cord stimulation

(SCS) therapy and an external programmer 150, 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. More particularly, the disclosure will refer to an implantable SCS system for purposes of illustration, but without limitation as 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 130A and 130B, 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 130A and/or 130B (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 and/or cause IMD 110 to sense stimulation 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 or cause IMD 110 to detect every phase of responsive stimulation signals. 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 constant current or constant voltage-based pulses, for example, is 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 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 and detect responsive stimulation 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, 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 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

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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, 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 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, 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 some examples, control pulses might not elicit ECAPs that are detectable by IMD 110, however IMD 110 may detect stimulation signals responsive to the control pulses. The control pulses may include information that is useful for determining parameters of one or more stimulation delivered to patient 105. 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 that 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.

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A user, such as a clinician or patient 105, may interact with a user interface of an 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 characterized as 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). Additionally, or alternatively, efficacy of electrical stimulation therapy may be indicated by one or more characteristics (e.g., a voltage magnitude) of a stimulation signal that is sensed in response to the stimulation pulse delivered by IMD 110. The stimulation signal may be indicative of the detection of the delivered stimulation pulse and related signals instead of action potentials evoked by the delivered stimulation pulse.

In one or more cases where stimulation pulses elicit detectable 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. 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 one or more cases where a stimulation pulse causes IMD 110 to sense one or more respective stimulation signals, one or more characteristics of the respective stimulation signal may indicate an efficacy of the electrical stimulation delivered to patient 105 by IMD 110. For example, it may be beneficial for a voltage magnitude of the stimulation signal to be at a target stimulation signal value. In one example, the target stimulation signal value may be a target range from a first threshold magnitude value to a second threshold magnitude value. If the voltage magnitude of the stimulation signal is less than the first threshold magnitude value, the electrical stimulation might not be as effective at treating pain perceived by patient 105 as compared with scenarios in which the voltage magnitude of the stimulation signal is within the target range. On the other hand, if the voltage magnitude of the stimulation signal is greater than the second threshold magnitude value, the electrical stimulation might be inducing an uncomfortable (e.g., unwanted or painful) sensation perceived by patient 105 as compared with examples in which the voltage magnitude of the stimulation signal is within the target range. In some examples, IMD 110 may control the voltage magnitude of the stimulation signal to be within a target range by changing and/or setting one or more parameters of subsequent stimulation pulses (e.g., control pulses and/or informed pulses) delivered to patient 105 in response to measuring the voltage magnitude of one or more detected stimulation signals.

A target stimulation signal value (e.g., a target range or a target value) for characteristic values of the stimulation signals may, in some cases, be different depending on one or more conditions. In some examples, the target range may include an upper-bound value, a lower-bound value, a target characteristic value between the lower-bound value and the upper-bound value, or a target characteristic value plus and/or minus a tolerance value. In some examples, the upper-bound and the lower-bound of a target range of a characteristic of a stimulation signal may depend on an amplitude of the stimulation pulse which causes IMD 110 to sense the stimulation signal. For example, a first stimulation pulse including a first parameter value may cause IMD 110 to sense a first stimulation signal and a second stimulation pulse including a second parameter value may cause IMD 110 to sense a second stimulation signal, where the second parameter value is greater than the first parameter value. In at least some such cases, IMD 110 may compare a characteristic of the first stimulation signal to a first target range of characteristic values and IMD 110 may compare a characteristic of the second stimulation signal to a second target range of characteristic values, where the upper-bound value of the second target range is greater than the upper-bound value of the first target range and where the lower-bound value of the second target range is greater than the lower-bound value of the first target range. In this way, the target range of characteristic values corresponding to a characteristic of a stimulation signal may generally increase as the parameter of the stimulation pulse (e.g., an amplitude of the pulse or an area under the pulse) which causes IMD 110 to sense the stimulation signal increases.

Additionally, or alternatively, the target stimulation signal value (e.g., the target range) of characteristic values of the stimulation signals may depend on a posture of patient 105. For example, IMD 110 may include an accelerometer (not illustrated in FIG. 1) which is configured to generate an accelerometer signal. IMD 110 may be configured to determine, based on the accelerometer signal, a posture of patient 105. The determined posture may be a posture of a set of postures including a standing posture, a seated posture, a supine posture, a prone posture, and a side-lying posture, as examples. IMD 110 may be configured to select the target range of characteristic values of a stimulation signal based on the determined posture of patient 105. As discussed above, in some examples, the IMD 110 may be configured to select the target stimulation signal value of the stimulation signal based on a magnitude of the stimulation pulse which causes IMD 110 to sense the stimulation signal in addition to selecting the target range of characteristic values based on the posture of patient 105. In fact, the target range of characteristic values for a particular stimulation signal may be defined by one or more "transfer functions," where each posture of the set of postures being associated with a respective transfer function.

As described herein, a transfer function may define a relationship between a magnitude of a stimulation pulse which causes IMD 110 to sense a stimulation signal and a target stimulation signal value of the stimulation signal. Each posture of patient 105 may be associated with a transfer function which defines the respective relationship between stimulation magnitude and the target stimulation signal value of the stimulation signal. In some examples, one or more transfer functions that are each associated with a respective posture may represent a linear function, meaning that such transfer functions define a linear relationship between the magnitude of a stimulation pulse and the target range of characteristic values of the stimulation signal.

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resulting from the stimulation pulse. However, this does not need to be the case. Transfer functions may represent any one or combination of functions including linear functions, quadratic functions, exponential functions, piecewise functions, power functions, polynomial functions, rational functions, logarithmic functions, and sinusoidal functions.

In some examples, a standing posture is associated with a first transfer function including a first slope, a sitting posture is associated with a second transfer function including a second slope, and a supine posture is associated with a third transfer function including a third slope. In some examples, the first transfer function, the second transfer function may each represent functions where a target range of characteristic values of one or more stimulation signals are plotted against a magnitude of a stimulation pulse which causes IMD 110 to sense the respective stimulation signal, where the target range of characteristic values are plotted on a y-axis of a graph, and the stimulation magnitude is plotted on an x-axis of the graph. In at least some such examples, the first slope of the first transfer function is greater than the second slope of the second transfer function, and the second slope of the second transfer function is greater than the third slope of the third transfer function. Consequently, at times when patient 105 is occupying a supine posture, the target stimulation signal value (e.g., a target range of characteristic values) is more sensitive to changes in stimulation amplitude as compared with times when patient 105 is standing or sitting.

Since the first transfer function, the second transfer function, and the third transfer function each have different slopes, IMD 110 may change the target stimulation signal value (e.g., the target range of characteristic values) based on detecting a change in the posture of patient 105. For example, in response to IMD 110 determining that patient 105 is standing, IMD 110 may select a first target range including a first lower-bound value and a first upper-bound value. If stimulation magnitude is held constant and in response to IMD 110 determining that patient 105 is sitting, IMD 110 may select a second target range including a second lower-bound value and a second upper-bound value. Additionally, if stimulation magnitude is held constant and in response to IMD 110 determining that patient 105 is occupying a supine posture, IMD 110 may select a third target range including a third lower-bound value and a third upper-bound value. In some examples, the third upper-bound value may be greater than the second upper-bound value and the second upper-bound value may be greater than the first upper-bound value. Additionally, the third lower-bound value may be greater than the second lower-bound value and the second lower-bound value may be greater than the first lower-bound value.

In the example of FIG. 1, IMD 110 is described as performing 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 functions to relay sensed signals to external programmer 150 for analysis, and external programmer 150 transmits 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 a stimulation signal to external programmer 150. External programmer 150 may compare a characteristic value of the stimulation signal to the respective target range of characteristic values, and in response to the comparison, external

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programmer 150 may instruct IMD 110 to adjust one or more parameters that define the electrical stimulation pulses delivered to patient 105.

In some examples, stimulation generation circuitry of IMD 110 may be configured to deliver at least one stimulation pulse between a time in which the stimulation generation circuitry delivers a first stimulation pulse and a time in which the stimulation generation circuitry delivers a second stimulation pulse which is based on a stimulation signal responsive to the first stimulation pulse. In some examples, stimulation generation circuitry of IMD 110 may be configured to deliver the second stimulation pulse consecutive to the first stimulation pulse.

In the example techniques described in this disclosure, the control stimulation parameters and the target stimulation signal value (e.g., a target range of characteristic values) of the stimulation signals may be initially set at the clinic but may be set and/or adjusted at home by patient 105. Once a target stimulation signal value (e.g., a target range of characteristic values) are set, the example techniques allow for automatic adjustment of parameters of the stimulation pulses in order to maintain consistent volume of neural activation and consistent perception of therapy for patient 105 when the electrode-to-neuron distance changes. The ability to change the stimulation parameter values may also allow the therapy to have long term efficacy, with the ability to keep the intensity of the stimulation (e.g., as indicated by the detected stimulation signals) consistent by comparing the measured characteristic values of the stimulation signals to the target range of characteristic values. IMD 110 may perform these changes without intervention by a physician or patient 105.

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 supports 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 IMD 110 or the external programmer.

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 232A, 232B, 232C, and 232D, and the set of electrodes 234 includes electrodes 234A, 234B, 234C, and 234D. 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 stimulation 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.

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, 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 detectable ECAPs for processing circuitry **210** to determine therapy based on one or more characteristics of the respective detectable ECAPs. It may be beneficial for processing circuitry **210** to determine therapy based on characteristics of detectable ECAPs rather than characteristics of detectable stimulation signals, if possible. However, if not enough responsive ECAPs are detectable 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 detectable even when some or all of elicited ECAPs are not detectable 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 detectable 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 detectable 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 cases in which a particular one or more stimulation pulses of the sequence of consecutive pulses might not elicit ECAPs that are detectable by sensing circuitry **206**, but another one or more stimulation pulses of the sequence of consecutive pulses do elicit ECAPs that are detectable by sensing circuitry **206**. In such cases, processing circuitry **210** may be configured to determine therapy based on one or more characteristics of the detectable ECAPs rather than determine therapy based on one or more characteristics of detectable stimulation signals. In some examples, processing circuitry **210** may determine whether the ratio of detectable 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 detectable 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 detectable stimulation signals.

In some examples, responsive to determining that a plurality of pulses elicit greater than a threshold ratio of detectable 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

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ECAP. In some examples, responsive to determining that a plurality of pulses do not elicit greater than a threshold ratio of detectable 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 detectable 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.

Processing circuitry 210 may be configured to compare a characteristic value of a stimulation signal to a target stimulation signal value and adjust a stimulation parameter value based on the comparison. For example, processing circuitry may be configured to determine whether a characteristic value of a stimulation signal is within a range from a first threshold characteristic value to a second threshold characteristic value. In some examples, the characteristic value may include an amplitude of the stimulation signal, an amplitude of a portion of the stimulation signal, a slope of a portion of the stimulation signal, an area under a curve of at least a portion of the stimulation signal, or any combination thereof. In this way, sensing circuitry 206 may be configured to determine whether an amplitude of a portion of the stimulation signal is within a range from a first threshold amplitude value for the portion of the stimulation signal to a second threshold amplitude value for the portion of the stimulation signal, for example, but this is not required. The characteristic value may represent any measurable characteristic of a stimulation signal.

Responsive to determining that the characteristic value of the stimulation signal is not within a range from a first threshold characteristic value to a second threshold characteristic value, processing circuitry 210 may change one or more parameters which at least partially define one or more pulses deliverable by the stimulation generation circuitry after the stimulation signal as compared with the one or more parameters which at least partially define one or more pulses deliverable by the stimulation generation circuitry before the stimulation signal. In some examples, processing

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circuitry 210 may determine that the characteristic value is lower than the first threshold characteristic value.

In response to the characteristic value being lower than the first threshold characteristic value, processing circuitry 210 may be configured to increase (e.g., increment) one or more parameters which at least partially define one or more pulses deliverable by stimulation generation circuitry 202 after the stimulation signal (e.g., increase one or more parameters which define pulses of therapy stimulation programs 214 and/or test stimulation programs 216). In some examples, processing circuitry 210 may increase the one or more parameters proportional to an amount that the characteristic value is lower than the first threshold characteristic value. In some examples, processing circuitry 210 may increase the one or more parameters by a predetermined amount no matter the amount that the characteristic value is lower than the first threshold characteristic value. In some examples, processing circuitry 210 may increase the one or more parameters according to a function, where an input to the function is the characteristic value of the stimulation signal.

In response to the characteristic value being greater than the second threshold characteristic value, processing circuitry 210 may be configured to decrease (e.g., decrement) one or more parameters which at least partially define one or more pulses deliverable by stimulation generation circuitry 202 after the stimulation signal (e.g., decrease one or more parameters which define pulses of therapy stimulation programs 214 and/or test stimulation programs 216). In some examples, processing circuitry 210 may decrease the one or more parameters proportional to an amount that the characteristic value is greater than the second threshold characteristic value. In some examples, processing circuitry 210 may decrease the one or more parameters by a predetermined amount no matter the amount that the characteristic value is greater than the second threshold characteristic value. In some examples, processing circuitry 210 may decrease the one or more parameters according to a function, where an input to the function is the characteristic value of the stimulation signal.

Processing circuitry 210 may maintain one or more parameters of which at least partially define one or more pulses deliverable by stimulation generation circuitry 202 after a respective stimulation signal responsive to determining that a value of a characteristic of the stimulation signal is within a range from a first threshold characteristic value to a second threshold characteristic value. For example, if the characteristic of the stimulation signal is within the range, this may indicate that the one or more parameters which at least partially define one or more pulses deliverable by stimulation generation circuitry 202 are within a desired range.

A characteristic value of a stimulation signal may, in some cases, depend on one or more parameters of the delivered pulse (e.g., pulse amplitude, pulse duration, area under a curve of the pulse, pulse shape, pulse slope, or any combination thereof) from which sensing circuitry 206 detects one or more stimulation signal. For example, determining therapy based on a stimulation signal may, in some cases, depend on an amplitude of the pulse which causes sensing circuitry 206 to detect the stimulation signal. This is because sensing circuitry 206 senses stimulation signals by detecting electrical signals indicative of stimulation pulses delivered by electrodes 232, 234. In this way, it may be expected that a first stimulation pulse having a first amplitude will cause sensing circuitry 206 to detect a stimulation signal having an amplitude within a first range of amplitude values. Addi-

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tionally, it may be expected that a second stimulation pulse having a second amplitude will cause sensing circuitry 206 to detect a stimulation signal having an amplitude within a second range of amplitude values. If the first amplitude of the first stimulation pulse is lower than the second amplitude of the second stimulation pulse, a lower-bound of the first range may be lower than a lower-bound of the second range and an upper-bound of the first range may be lower than an upper-bound of the second range. In some examples, a range of target amplitude values for a stimulation signal may be linearly related to an amplitude of a stimulation pulse which causes sensing circuitry 206 to detect the stimulation signal. Storage device 212 may store target values 218 which include a set of target ranges and other target values, where each target range and target value of target values 218 corresponds to a respective stimulation pulse amplitude value of a set of stimulation pulse amplitude values.

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 axis, 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

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values 218 may include a respective transfer function corresponding 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.

In some examples, processing circuitry 210 is configured to determine, based on the accelerometer signal generated by acceleration sensor 223, a transition from a first posture to a second posture of the set of postures. Responsive to determining the transition from the first posture to the second posture, processing circuitry 210 is configured to update the target stimulation signal value (e.g., the target range of characteristic values) for a respective sensed stimulation signal from a first target stimulation signal value to a second target stimulation signal value. In some examples, the detected change in posture may trigger the transition from a first target range to a second target range, but this is not required. In some cases, processing circuitry 102 may monitor the posture of patient 105 and the amplitude of stimulation pulses generated by stimulation generation circuitry 202 in real time or near real-time. Accordingly, processing circuitry 210 may set the range of target characteristic values for responsive stimulation signals in real time or near real-time.

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 suitable arrangement of hardware, alone or in combination with software and/or firmware, 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 stimulation signal and/or 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.

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 contrast to ECAP signal **404**, ECAP signal **406** represents the voltage amplitude detected from a supra-detection 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 **P1**, **N1**, and **P2**, which are three typical peaks representative of propagating action potentials from an ECAP. The example duration of the stimulation signal and peaks **P1**, **N1**, and **P2** 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 **N1** and **P2**. This **N1-P2** amplitude may be easily detectable even if the stimulation signal impinges on **P1**, a relatively large signal, and the **N1-P2** 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 **P1**, **N1**, or **P2** 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 **P1**, **N1**, or **P2**. In other examples, the characteristic of ECAP signal **406** may be the area under one or more of peaks **P1**, **N1**, and/or **P2**. In other examples, the characteristic of the ECAP may be a ratio of one of peaks **P1**, **N1**, or **P2** 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 **N1** and **P2**. In other examples, the characteristic of the ECAP may be the time between two points of the ECAP, such as the time between **N1** and **P2**.

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 char-

acteristic (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. **5A** is a timing diagram **500A** illustrating an 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. **5A** is described with reference to IMD **200** of FIG. **2**. As illustrated, timing diagram **500A** includes first channel **502**, a plurality of stimulation pulses **504A-504N** (collectively “stimulation pulses **504**”), second channel **506**, a plurality of respective ECAPs **508A-508N** (collectively “ECAPs **508**”), and a plurality of stimulation signals **509A-509N** (collectively “stimulation signals **509**”). In some examples, stimulation pulses **504** may represent control pulses which are configured to elicit ECAPs **508** that are detectable by IMD **200**, but this is not required. Stimulation pulses **504** may represent any type of pulse that is deliverable by IMD **200**. In the example of FIG. **5A**, IMD **200** can deliver therapy with control pulses instead of, or without, informed pulses.

First channel **502** 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 **502** may be located on the opposite side of the lead as the sensing electrodes of second channel **506**. Stimulation pulses **504** may be electrical pulses delivered to the spinal cord of the patient by at least one of electrodes **232**, **234**, and stimulation pulses **504** may be balanced biphasic square pulses with an interphase interval. In other words, each of stimulation pulses **504** are shown with a negative phase and a positive phase separated by an interphase interval. For example, a stimulation pulse **504** may have a negative voltage for the same amount of time and amplitude that it has a positive voltage. It is noted that the negative voltage phase may be before or after the positive voltage phase. Stimulation pulses **504** 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, stimulation pulses **504** 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, stimulation pulses **504** may have a pulse width of approximately 100 μ s for each phase of the bi-phasic pulse. As illustrated in FIG. **5A**, stimulation pulses **504** may be delivered via channel **502**. Delivery of stimulation pulses **504** 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 **506** 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 second channel **506** may be located on the opposite

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side of the lead as the electrodes of first channel **502**. ECAPs **508** may be sensed at electrodes **232**, **234** from the spinal cord of the patient in response to stimulation pulses **504**. ECAPs **508** are electrical signals which may propagate along a nerve away from the origination of stimulation pulses **504**. In one example, ECAPs **508** are sensed by different electrodes than the electrodes used to deliver stimulation pulses **504**. As illustrated in FIG. 5A, ECAPs **508** may be recorded on second channel **506**.

Stimulation signals **509A**, **509B**, and **509N** may be sensed by leads **230** and sensing circuitry **206** and may be sensed during the same period of time as the delivery of stimulation pulses **504**. Since the stimulation signals may have a greater amplitude and intensity than ECAPs **508**, any ECAPs arriving at IMD **200** during the occurrence of stimulation signals **509** might not be adequately sensed by sensing circuitry **206** of IMD **200**. However, ECAPs **508** may be sufficiently sensed by sensing circuitry **206** because each ECAP **508**, or at least a portion of ECAP **508** used as feedback for stimulation pulses **504**, falls after the completion of each a stimulation pulse **504**. As illustrated in FIG. 5A, stimulation signals **509** and ECAPs **508** may be recorded on channel **506**. In some examples, ECAPs **508** may not follow respective stimulation signals **509** when ECAPs are not elicited by stimulation pulses **504** or the amplitude of ECAPs is too low to be detected (e.g., below the detection threshold).

FIG. 5B is a timing diagram **500B** 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. 5B is described with reference to IMD **200** of FIG. 2. As illustrated, timing diagram **500B** includes first channel **510**, a plurality of control pulses **512A-512N** (collectively "control pulses **512**"), second channel **520**, a plurality of informed pulses **524A-524N** (collectively "informed pulses **524**") including passive recharge phases **526A-526N** (collectively "passive recharge phases **526**"), third channel **530**, a plurality of respective ECAPs **536A-536N** (collectively "ECAPs **536**"), and a plurality of stimulation signals **538A-538N** (collectively "stimulation signals **538**").

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 μ s for each phase of the bi-phasic pulse. As illustrated in FIG. 5B, control

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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 μ s and less than approximately 1000 μ s. In fact, informed pulses **524** may be configured to have longer pulse widths than control pulses **512**. As illustrated in FIG. 5B, 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. 5B), 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. 5B, ECAPs **536** may be recorded on third channel **530**.

Stimulation signals **538A**, **538B**, and **538N** 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 arriv-

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ing 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. 5B, stimulation signals 538 and ECAPs 536 may be recorded on channel 530.

FIG. 6A is a timing diagram 600A illustrating an 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. 6A is described with reference to IMD 200 of FIG. 2. As illustrated, timing diagram 600A includes first channel 602, a plurality of stimulation pulses 604A-604N (collectively “stimulation pulses 604”), second channel 606, a plurality of respective ECAPs 608A-608N (collectively “ECAPs 608”), and a plurality of stimulation signals 609A-609N (collectively “stimulation signals 609”). In some examples, stimulation pulses 604 may represent control pulses which are configured to elicit ECAPs 608 that are detectible by IMD 200, but this is not required. Stimulation pulses 604 may represent any type of pulse that is deliverable by IMD 200. In the example of FIG. 6A, IMD 200 can deliver therapy with control pulses instead of, or without, informed pulses.

Timing diagram 600A of FIG. 6A may be substantially the same as timing diagram 500A FIG. 5A except that stimulation pulse 604A and stimulation pulse 604N do not evoke an ECAP that is detectible by IMD 200. Although stimulation pulse 604B emits ECAP 608B, which is detectible by IMD 200, it may be the case that IMD 200 does not sense enough detectible ECAPs for therapy determination in the example of FIG. 6A. As such, IMD 200 may determine one or more characteristics of stimulation signals 609 in order to determine one or more parameters of upcoming stimulation pulses following stimulation pulse 604N. For example, IMD 200 may determine an amplitude of at least a portion of each stimulation signal of stimulation signals 609 and determine the one or more parameters of the upcoming stimulation pulses based on the determined amplitudes. Although stimulation signals 609 are illustrated as square pulses, stimulation signals 609 may include other shapes and/or waveforms, in some examples. In some examples, each stimulation signal of stimulation signals 509 may include two or more phases. Processing circuitry 210 of IMD 200 may analyze the two or more phases of stimulation signals 509 in order to determine therapy.

FIG. 6B is a timing diagram 600B 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. 6B is described with reference to IMD 200 of FIG. 2. As illustrated, timing diagram 600B includes first channel 610, a plurality of control pulses 612A-612N (collectively “control pulses 612”), second channel 620, a plurality of informed pulses 624A-624N (collectively “informed pulses 624”) including passive recharge phases 626A-626N (collectively “passive recharge phases 626”), third channel 630, a plurality of respective ECAPs 636A-636N (collectively “ECAPs 636”), and a plurality of stimulation signals 638A-638N (collectively “stimulation signals 638”).

Timing diagram 600B of FIG. 6B may be substantially the same as timing diagram 500B FIG. 5B except that control pulse 612A and control pulse 612N do not evoke an ECAP that is detectible by IMD 200. Although control pulse 612B emits ECAP 636B, which is detectible by IMD 200, it may

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be the case that IMD 200 does not sense enough detectible ECAPs for therapy determination in the example of FIG. 6B. As such, IMD 200 may determine one or more characteristics of stimulation signals 638 in order to determine one or more parameters of upcoming stimulation pulses following control pulse 612N. For example, IMD 200 may determine an amplitude of at least a portion of each stimulation signal of stimulation signals 638 and determine the one or more parameters of the upcoming stimulation pulses based on the determined amplitudes. Although stimulation signals 638 are illustrated as square pulses, stimulation signals 639 may include other shapes and/or waveforms, in some examples. In some examples, each stimulation signal of stimulation signals 638 may include two or more phases. Processing circuitry 210 of IMD 200 may analyze the two or more phases of stimulation signals 638 in order to determine therapy.

FIG. 7 is a timing diagram 700 illustrating another example of electrical stimulation pulses, respective stimulation signals, and respective ECAPs, in accordance with one or more techniques of this disclosure. For convenience, FIG. 7 is described with reference to IMD 200 of FIG. 2. As illustrated, timing diagram 700 includes first channel 710, a plurality of control pulses 712A-712N (collectively “control pulses 712”), second channel 720, a plurality of informed pulses 724A-724B (collectively “informed pulses 724”) including passive recharge phases 726A-726B (collectively “passive recharge phases 726”), third channel 730, a plurality of respective ECAPs 736A-736N (collectively “ECAPs 736”), and a plurality of stimulation interference signals 738A-738N (collectively “stimulation interference signals 738”). FIG. 7 may be substantially similar to FIG. 5B, except for the differences detailed below.

Two or more (e.g. two) control pulses 712 may be delivered during each time event (e.g., window) of a plurality of time events, and each time event represents a time between two consecutive informed pulses 724. For example, during each time event, a first control pulse may be directly followed by a first respective ECAP, and subsequent to the completion of the first respective ECAP, a second control pulse may be directly followed by a second respective ECAP. Informed pulses may commence following the second respective ECAP. In other examples not illustrated here, three or more control pulses 712 may be delivered, and respective ECAP signals sensed, during each time event of the plurality of time events.

FIG. 8 is a timing diagram 800 illustrating another example of electrical stimulation pulses, respective stimulation signals, and respective ECAPs, in accordance with one or more techniques of this disclosure. For convenience, FIG. 8 is described with reference to IMD 200 of FIG. 2. As illustrated, timing diagram 800 includes first channel 810, a plurality of control pulses 812A-812N (collectively “control pulses 812”), second channel 820, a plurality of informed pulses 824A-824B (collectively “informed pulses 824”) including passive recharge phases 826A-826B (collectively “passive recharge phases 826”), third channel 830, respective ECAPs 836B (collectively “ECAPs 836”), and a plurality of stimulation interference signals 838A-838N (collectively “stimulation interference signals 838”). Timing diagram 800 of FIG. 8 may be substantially the same as timing diagram 700 FIG. 7 except that control pulses 812A and control pulses 812N do not evoke ECAPs that are detectible by IMD 200. Although control pulses 812B emit ECAPs 836B, which are detectible by IMD 200, it may be the case that IMD 200 does not sense enough detectible ECAPs for therapy determination in the example of FIG. 8.

As such, IMD 200 may determine one or more characteristics of stimulation signals 838 in order to determine one or more parameters of upcoming stimulation pulses following control pulses 812N.

FIG. 9 is a graph 900 illustrating a stimulation pulse amplitude plot 910 and a stimulation signal amplitude plot 920, in accordance with one or more techniques of this disclosure. Additionally, graph 900 indicates a first time 922, a second time 924, and a third time 926. FIG. 9 is described with reference to IMD 200 of FIG. 2.

Stimulation pulse amplitude plot 910 may represent a plot of respective amplitudes of a set of consecutive stimulation pulses delivered by IMD 200. As seen, in FIG. 9, each stimulation pulse of the set of stimulation pulses may include a substantially similar amplitude. Stimulation signal amplitude plot 920, however, indicates a patient event occurring between first time 922 and third time 926 where the amplitudes of responsive stimulation signals increases sharply before settling at a baseline value at third time 926. In some examples, the patient event may represent a cough, a sneeze, a posture movement, or another action. In any case, the patient event may represent an occurrence between first time 922 and third time 926 in which a distance between one or more of electrodes 232, 234 of IMD 200 and target tissue (e.g., spinal cord 120) of patient 105 decreases as compared with a baseline distance. The distance between the one or more of electrodes 232, 234 of IMD 200 and the target tissue may return to the baseline distance at third time 926. Second time 924 may indicate a time in which a peak in stimulation signal amplitude occurs.

In some examples, it may be beneficial for processing circuitry 210 to set one or more parameters of stimulation pulses delivered by IMD 200 based on detecting the patient event between first time 922 and third event 926. In some examples, although not illustrated in FIG. 9, processing circuitry 210 may decrease an amplitude of one or more therapy pulses delivered by IMD 200 between first time 922 and third time 926 in order to decrease a probability that patient 105 will experience pain or discomfort induced by the stimulation pulses during the patient event. Put another way, the increased amplitudes of stimulation signals in plot 920 indicate that the risk of increased nerve activation and possible discomfort increases due to a likely change in distance between electrodes and nerve fibers.

FIG. 10 is a graph 1000 illustrating a stimulation signal amplitude plot 1020 and an ECAP amplitude plot 1030, in accordance with one or more techniques of this disclosure. Additionally, graph 1000 includes a region 1022, a first time 1042, a second time 1044, and a third time 1046. FIG. 10 is described with reference to IMD 200 of FIG. 2. In some examples, a first patient event may occur between first time 1042 and second time 1044, a second patient event may occur between second time 1044 and third time 1046, and a third patient event may occur after third time 1046. In some examples, processing circuitry 210 may detect one or more signals which represent stimulation signal amplitude plot 1020 and one or more signals which represent ECAP amplitude plot 1030. In some examples, processing circuitry 210 may identify the first patient event, the second patient event, and the third patient event based on one or both of the stimulation signal amplitude plot 1020 and the ECAP amplitude plot 1030. As seen in FIG. 10, the amplitude of stimulation signals is generally greater than the amplitude of ECAPs. For this reason, it may be beneficial to determine patient events using the amplitude of stimulation signals

which are sensed by IMD 200 in response to delivered stimulation pulses in addition, or as an alternative to, ECAP signals.

Region 1022 may represent a period of time in which patient 105 is sitting still and both of the stimulation signal amplitude plot 1020 and the ECAP amplitude plot 1030 are stable. An amplitude of stimulation pulses delivered by IMD 200 is kept stable throughout the duration of graph 1000. Each of the first patient event, the second patient event, and the third patient event may represent an aggressor event (e.g., a cough, a sneeze, or a body stretch) which causes a distance between one or more of electrodes 232, 234 moves closer to spinal cord 120, causing stimulation pulses to induce a stronger, and sometimes uncomfortable, sensation in patient 105. As such, it may be beneficial to adjust stimulation in response to detecting an aggressor event such as the first patient event.

FIG. 11 is a timing diagram 1100 illustrating an example of an electrical stimulation pulse 1104 and a respective stimulation signal 1109, in accordance with one or more techniques of this disclosure. For convenience, FIG. 11 is described with reference to IMD 200 of FIG. 2. As illustrated, timing diagram 1100 includes stimulation signal 1102 and a sense signal 1106. In some examples, stimulation signal 1102 includes electrical stimulation pulse 1104 and sense signal includes stimulation signal 1109. Stimulation signal 1109 includes a first phase 1152, a second phase 1154, and a third phase 1156. Third phase 1156 includes a third phase peak 1158. The first phase 1152 and second phase 1154 may also include a respective phase peak.

As seen in FIG. 11, electrical stimulation pulse 1104 may represent a balanced, bi-phasic square pulse that employs an active recharge phase. In other examples not illustrated in FIG. 11, electrical stimulation pulse 1104 may represent a monophasic pulse that employs a passive recharge phase or an imbalanced bi-phasic pulse that employs a passive recharge phase. Electrical stimulation pulse 1104 includes a negative phase 1112 and a positive phase 1114. In examples where electrical stimulation pulse 1104 represents a balanced, bi-phasic square pulse, negative phase 1112 and positive phase 1114 may include approximately the same magnitude and approximately the same duration. In some examples, electrical stimulation pulse 1104 may include an interphase interval 1116 between negative phase 1112 and positive phase 1114 to promote propagation of a nerve impulse in response to negative phase 1112 of the bi-phasic pulse. As discussed herein, pulses have different numbers of phases, such as a monophasic or tri-phasic pulse may be employed in other examples.

Stimulation generation circuitry 202 may generate electrical stimulation pulse 1104 based on one of therapy stimulation programs 214 or test stimulation programs 216 and deliver electrical stimulation pulse 1104 to target tissue of patient 105 via any one or combination of electrodes 232, 234. Since the one or combination of electrodes 232, 234 (e.g., "stimulation electrodes") which deliver electrical stimulation pulse 1104 to the target tissue may be located to proximate to a one or combination of electrodes 232, 234 (e.g., "sensing electrodes") which are configured to sense electrical signals, the sensing electrodes may detect one or more electrical signals emitted by the stimulation electrodes as electrical stimulation pulse 1104. Sensing circuitry 206 may detect these one or more electrical signals as stimulation signal 1109. In this way, sensing circuitry 106 may detect stimulation signal 1109 as a direct result of stimulation generation circuitry 202 delivering electrical stimulation pulse 1104 to the target tissue.

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Sensing circuitry 206 may sense the first phase 1152 of stimulation signal 1109 in response to stimulation generation circuitry 202 delivering the negative phase 1112 of electrical stimulation pulse 1104. Additionally, sensing circuitry 206 may sense the second phase 1154 of stimulation signal 1109 in response to stimulation generation circuitry 202 delivering the positive phase 1114 of electrical stimulation pulse 1104. As seen in FIG. 11, the first phase 1152 is a positive phase and the second phase 1154 is a negative phase. In this way, sensing circuitry 206 may sense a positive stimulation signal phase in response to stimulation generation circuitry 202 delivering a negative stimulation pulse phase and sensing circuitry 206 may sense a negative stimulation signal phase in response to stimulation generation circuitry 202 delivering a positive stimulation pulse phase, but this is not required. In some examples not illustrated in FIG. 11, sensing circuitry 206 may sense a positive stimulation signal phase in response to stimulation generation circuitry 202 delivering a positive stimulation pulse phase and sensing circuitry 206 may sense a negative stimulation signal phase in response to stimulation generation circuitry 202 delivering a negative stimulation pulse phase.

In some examples, processing circuitry 210 may determine one or more parameters (e.g., voltage amplitude, current amplitude, pulse duration, pulse shape, or any combination thereof) of upcoming stimulation pulses for generation by stimulation generation circuitry 202 based on one or both of the first phase 1152 and the second phase 1154 of stimulation signal 1109. Additionally, or alternatively, processing circuitry 210 may determine the one or more parameters of upcoming stimulation pulses for generation by stimulation generation circuitry 202 based on one or more characteristics of third phase 1156 (e.g., an amplitude of peak 1158). Third phase 1156 may be referred to as a residual phase in some examples and occurs after second phase 1154. More specifically, third phase 1156 begins after stimulation signal 1109 returns to zero at the conclusion of second phase 1154. As illustrated, peak 1158 occurs shortly after the conclusion of second phase 1154. In some examples, a magnitude of peak 1158 of third phase 1156 may be more affected by a posture of patient 105 as compared with a magnitude of first phase 1152 and a magnitude of second phase 1154. As such, when using the magnitude of peak 1158 to determine therapy, it may be beneficial for processing circuitry 210 to determine a posture of patient 105 based on the acceleration signal generated by acceleration sensor 223. It is noted that the third phase 1156 may or may not be detectable when an ECAP signal is detectable after stimulation signal 1109.

FIG. 12 is a timing diagram 1200 illustrating an example of an electrical stimulation pulse 1104, a respective ECAP 1208, and a respective stimulation signal 1209, in accordance with one or more techniques of this disclosure. For convenience, FIG. 12 is described with reference to IMD 200 of FIG. 2. As illustrated, timing diagram 1200 includes stimulation signal 1202 and a sense signal 1206. In some examples, stimulation signal 1202 includes electrical stimulation pulse 1204 and sense signal 1206 includes ECAP 1208 and stimulation signal 1209. Stimulation signal 1209 includes a first phase 1252, a second phase 1254, and a third phase 1256. Third phase 1256 includes a third phase peak 1258. Third phase 1256 may be referred to as a residual phase in some cases and may represent an ionic rebalancing occurring on one or more of electrodes 232, 234 of IMD 200. Although the third phase 1256 may not represent actively delivered charge from IMD 200, third phase 1256

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may still be associated with the first and second phase because the residual charge present in the tissue is due to the pulse that was just delivered. Timing diagram 1200 of FIG. 12 may be substantially the same as timing diagram 1100 of FIG. 11 except that sense signal 1206 includes ECAP 1208 in addition to third phase 1256 of stimulation signal 1209. ECAP 1208 includes N1 peak 1262 and P2 peak 1264. As described herein, IMD 200 may adjust one or more parameter values for subsequent stimulation pulses based on characteristics of stimulation signal 1209 and/or ECAP 1208.

FIG. 13 is a graph illustrating a first transfer function 1310 corresponding to a first posture, a second transfer function 1320 corresponding to a second posture, and a third transfer function 1330 corresponding to a third posture, in accordance with one or more techniques of this disclosure. As described herein, a “transfer function” may represent a curve which establishes a relationship between a first parameter and a second parameter. In the case of FIG. 13, a transfer function represents a relationship between an amplitude of a stimulation pulse and an expected amplitude of a portion of a stimulation signal that is detected by sensing circuitry 206 in response to delivering the stimulation pulse. In some examples, each transfer function may be used to determine a gain or multiplier that IMD 200 applies to detected stimulation signal amplitudes in order increase or decrease parameter values an appropriate amount (e.g., smaller changes for larger slopes of a transfer function and larger changes for smaller slopes of a transfer function).

First transfer function 1310 may represent a relationship between stimulation pulse amplitude and an expected stimulation signal amplitude while patient 105 is occupying a supine posture. Second transfer function 1320 may represent a relationship between stimulation pulse amplitude and an expected stimulation signal amplitude while patient 105 is occupying a seated posture. Third transfer function 1330 may represent a relationship between stimulation pulse amplitude and an expected stimulation signal amplitude while patient 105 is occupying a standing posture. A prone posture may provide another transfer function that may be different or similar to transfer function 1330 of the standing posture. As seen in FIG. 13, the relationship between stimulation amplitude and expected stimulation signal amplitude is “steeper” for first transfer function 1310 as compared with second transfer function 1320. In this way, an increase in stimulation amplitude may cause a first increase in expected stimulation signal amplitude according to first transfer function 1310 and a second increase in expected stimulation signal amplitude according to second transfer function 1320, where the first increase is greater than the second increase. Additionally, the relationship between stimulation amplitude and expected stimulation signal amplitude is steeper for second transfer function 1320 as compared with third transfer function 1330.

As discussed in more detail below, processing circuitry 210 of IMD 200 may select, based on a determined posture of patient 105, a transfer function for identifying an expected amplitude for a stimulation signal sensed by IMD 200 in response to a delivery of a stimulation pulse. The selected transfer function may include first transfer function 1310, second transfer function 1320, third transfer function 1330, or another transfer function not illustrated in FIG. 13. A set of transfer functions each corresponding to a respective patient posture may be stored by storage device 212 of IMD 200. Subsequent to selecting a transfer function, processing circuitry may determine the expected amplitude of the stimulation signal based on an amplitude of the respective

stimulation pulse. In some examples, processing circuitry 210 may determine whether to change one or more parameters of upcoming stimulation pulses based on whether a measured amplitude of a stimulation signal falls outside a range of amplitude values, where the range includes the expected amplitude of the stimulation signal.

In some examples, IMD 200 may determine first transfer function 1310, second transfer function 1320, and third transfer function 1330 based on characteristics of one or more stimulation signals sensed by IMD 200. For example, IMD 200 may calculate first transfer function 1310 based on respective amplitude values of a set of stimulation signals detected by IMD 200 while patient 105 is occupying the supine posture. Additionally, IMD 200 may calculate second transfer function 1320 based on respective amplitude values of a set of stimulation signals detected by IMD 200 while patient 105 is occupying the seated posture, and IMD 200 may calculate third transfer function 1330 based on respective amplitude values of a set of stimulation signals detected by IMD 200 while patient 105 is occupying the standing posture. Additionally, or alternatively, IMD 200 may determine first transfer function 1310, second transfer function 1320, and third transfer function 1330 based on characteristics of stimulation signals detected in other patients.

FIG. 14 is a graph illustrating a target range of amplitude values for a stimulation signal in relation to a transfer function 1410 corresponding to a respective patient posture, in accordance with one or more techniques of this disclosure. In some examples, transfer function 1410 may represent first transfer function 1310, second transfer function 1320, third transfer function 1330, or another transfer function not illustrated in FIG. 13. In some examples, a lower boundary function 1412 and an upper boundary function 1414 may define an expected range of stimulation signal amplitudes based on an amplitude of the respective stimulation pulse delivered by stimulation generation circuitry 202. For example, stimulation pulse amplitude 1420 may correspond to a range of expected stimulation signal amplitude values ranging from lower-bound target stimulation signal amplitude 1422 to upper-bound target stimulation signal amplitude 1424.

Using an acceleration signal generated by acceleration sensor 223 of IMD 200, processing circuitry 210 may determine a posture of patient 105. Additionally, in some cases, processing circuitry 210 may acquire an amplitude of a stimulation pulse and select a transfer function associated with the determined patient posture in order to compute a target estimated stimulation signal amplitude. In some examples, the upper boundary function 1414 and the lower boundary function 1412 may be established based on information representing user input received from external programmer 150. In some examples, the upper and lower boundary functions 1414 and 1412 may be determined as a tolerance from the target value of transfer function 1410. However, upper and lower boundary functions 1414 and 1412 may deviate from transfer function 1410 by unequal amounts in other examples.

A stimulation pulse delivered by IMD 200 while patient 105 is occupying a given posture may have a stimulation pulse amplitude. If the responsive stimulation signal amplitude is above the upper-bound target stimulation signal amplitude, processing circuitry 210 may decrease a stimulation pulse amplitude of future stimulation pulses until a responsive stimulation signal includes an amplitude within the target range of stimulation signal amplitudes. If the responsive stimulation signal amplitude is lower than the lower-bound target stimulation signal amplitude, processing

circuitry 210 may increase a stimulation pulse amplitude of future stimulation pulses until a responsive stimulation signal includes an amplitude within the target range of stimulation signal amplitudes. If the amplitude of a stimulation signal is within the target range of amplitudes, processing circuitry 210 may hold the amplitude of stimulation pulses constant. In some examples in which processing circuitry 210 detects a shift in posture of patient 105, processing circuitry 210 may accordingly adjust an amplitude of subsequent stimulation pulses.

As described above, processing circuitry 210 may be configured to set, based on one or more characteristics of a stimulation signal, one or more parameters (e.g., pulse amplitude, pulse duration, and pulse shape) of stimulation pulses following the respective stimulation signal. One way in which processing circuitry 210 may set the one or more parameters of the stimulation pulses includes adjusting an amplitude of a set of stimulation pulses following the respective stimulation signal by a predetermined amplitude value. For example, processing circuitry 210 may determine, based on the acceleration signal generated by the acceleration sensor 223, a posture of the patient and determine an amplitude of a stimulation pulse delivered by IMD 200. Processing circuitry 210 may select a transfer function from storage device 212 based on the determined posture, and determine a target range of amplitudes for a stimulation signal corresponding to the stimulation pulse based on the amplitude of the stimulation pulse and the selected transfer function.

In some examples, IMD 200 may change an amplitude of stimulation pulses delivered by IMD 200 based on determining that an amplitude of a stimulation signal is outside of a target range of stimulation signal amplitudes. For example, if an amplitude of a stimulation signal is above an upper bound of the target range of stimulation signal amplitudes, processing circuitry 210 may decrement an amplitude of stimulation pulses until processing circuitry 210 identifies a stimulation signal having an amplitude within the target range of stimulation signal amplitudes. Additionally, or alternatively, if an amplitude of a stimulation signal is below a lower bound of the target range of stimulation signal amplitudes, processing circuitry 210 may increment an amplitude of stimulation pulses until processing circuitry 210 identifies a stimulation signal having an amplitude within the target range of stimulation signal amplitudes. Responsive to identifying a stimulation signal having an amplitude within the target range of stimulation signal amplitudes following a period in which stimulation signal amplitudes are outside of the target range, processing circuitry 210 may restore an amplitude of stimulation pulses delivered by processing circuitry 210 to a baseline value.

In some examples, processing circuitry 210 may determine whether an amplitude of the stimulation signal sensed by IMD 200 in response to the stimulation pulse is within the target range of amplitudes. If the amplitude of the stimulation signal is greater than an upper-bound of target range, processing circuitry 210 may set an amplitude of one or more stimulation pulses following the stimulation signal to a first fall back amplitude. For example, an amplitude transition of consecutive stimulation signals from within the target range to being greater than an upper-bound of the target range may trigger processing circuitry 210 to transition an amplitude of stimulation pulses from a target stimulation pulse amplitude to the first fall back amplitude. In some examples, the first fall back amplitude is lower than the target stimulation pulse amplitude. For example, pro-

processing circuitry 210 may calculate the first fall back amplitude using the following equation 1.

$$\text{first fall back amplitude} = \text{target stimulation pulse amplitude} - [x] \quad (1)$$

The value “[x]” may be saved by storage device 212 of IMD 200. In some examples, processing circuitry 210 may save the value “[x]” to storage device 212 based on information received by IMD 200 via communication circuitry 208. In some examples, processing circuitry 210 may adjust the target stimulation pulse amplitude like based on information indicative of a user input to an external device (e.g., external programmer 150), and processing circuitry 210 may automatically calculate the first fall back amplitude based on equation 1. In some examples, processing circuitry 210 may maintain an amplitude of stimulation pulses delivered by processing circuitry 210 at the first fall back amplitude until processing circuitry 210 identifies a stimulation signal having an amplitude within the target range. In response to detecting the stimulation signal having an amplitude within the target range, processing circuitry 210 may restore the amplitude of stimulation pulses delivered by IMD 200 to the target stimulation pulse amplitude.

Additionally, in some examples, processing circuitry 210 may determine whether an amplitude of a stimulation signal is less than a lower-bound of a target range of stimulation signal amplitude values, processing circuitry 210 may set an amplitude of one or more stimulation pulses following the stimulation signal to a second fall back amplitude. For example, an amplitude transition of consecutive stimulation signals from being within the target range to being greater than an upper-bound of the target range may trigger processing circuitry 210 to transition an amplitude of stimulation pulses from a target stimulation pulse amplitude to the second fall back amplitude. In some examples, the second fall back amplitude is greater than the target stimulation pulse amplitude. For example, processing circuitry 210 may calculate the second fall back amplitude using the following equation 2.

$$\text{second fall back amplitude} = \text{target stimulation pulse amplitude} - [y] \quad (2)$$

The value “[y]” may be saved by storage device 212 of IMD 200. In some examples, processing circuitry 210 may save the value “[y]” to storage device 212 based on information received by IMD 200 via communication circuitry 208. The value “[y]” may be a negative value. In some examples, processing circuitry 210 may adjust the target stimulation pulse amplitude like based on information indicative of a user input to an external device (e.g., external programmer 150), and processing circuitry 210 may automatically calculate the second fall back amplitude based on equation 2. In some examples, processing circuitry 210 may maintain an amplitude of stimulation pulses delivered by processing circuitry 210 at the second fall back amplitude until processing circuitry 210 identifies a stimulation signal having an amplitude within the target range. In response to detecting the stimulation signal having an amplitude within the target range, processing circuitry 210 may restore the amplitude of stimulation pulses delivered by IMD 200 to the target stimulation pulse amplitude.

FIG. 15 is a graph illustrating target maximum values for a stimulation signal in relation to a transfer function 1510 corresponding to a respective patient posture, in accordance with one or more techniques of this disclosure. In some examples, transfer function 1510 may represent first transfer function 1310, second transfer function 1320, third transfer

function 1330, or another transfer function not illustrated in FIG. 13. In some examples, an upper boundary function 1514 may define a target maximum stimulation signal amplitude value based on an amplitude of the respective stimulation pulse delivered by stimulation generation circuitry 202. For example, stimulation pulse amplitude 1520 may correspond to a target maximum stimulation signal amplitude value 1524. In the example of FIG. 15, the target range may correspond to the values less than upper boundary function 1514.

In one example, IMD 200 delivers a stimulation pulse at stimulation pulse amplitude 1520. If a resulting stimulation signal amplitude is greater than target maximum stimulation signal amplitude value 1524, IMD 200 may decrease the stimulation amplitude of one or more subsequent stimulation pulses until a stimulation pulse causes IMD 200 to sense a stimulation signal defining a stimulation signal amplitude value that is less than a respective target maximum stimulation signal amplitude value. If the stimulation signal amplitude value is less than the respective target maximum stimulation signal amplitude value, IMD 200 may hold the stimulation amplitude until a posture of patient 105 is shifted and IMD 200 may adjust a stimulation amplitude based on identifying a new transfer function associated with the shifted posture.

In some examples, processing circuitry 210 may determine whether an amplitude of a stimulation signal sensed by IMD 200 in response to a stimulation pulse is greater than a target maximum stimulation signal amplitude value of upper boundary function 1514. If the amplitude of the stimulation signal is greater than the target maximum stimulation signal amplitude value, processing circuitry 210 may set an amplitude of one or more stimulation pulses following the stimulation signal to a fall back amplitude. For example, an amplitude transition of consecutive stimulation signals from being less than the target maximum stimulation signal amplitude value to being greater than the target maximum stimulation signal amplitude value may trigger processing circuitry 210 to decrease an amplitude of stimulation pulses from a target stimulation pulse amplitude to the fall back amplitude. In some examples, the fall back amplitude is lower than the target stimulation pulse amplitude. For example, processing circuitry 210 may calculate the fall back amplitude using the following equation 3.

$$\text{fall back amplitude} = \text{target stimulation pulse amplitude} - [z] \quad (3)$$

The value “[z]” may be saved by storage device 212 of IMD 200. In some examples, processing circuitry 210 may save the value “[z]” to storage device 212 based on information received by IMD 200 via communication circuitry 208. In some examples, processing circuitry 210 may adjust the target stimulation pulse amplitude based on information indicative of a user input to an external device (e.g., external programmer 150), and processing circuitry 210 may automatically calculate the fall back amplitude based on equation 3. In some examples, processing circuitry 210 may maintain an amplitude of stimulation pulses delivered by processing circuitry 210 at the fall back amplitude until processing circuitry 210 identifies a stimulation signal having an amplitude between the respective stimulation signal value of transfer function 1520 and the target maximum stimulation signal amplitude value of upper boundary 1514. In response to detecting the stimulation signal having an amplitude between the respective stimulation signal value of transfer function 1520 and the target maximum stimulation signal amplitude value of upper boundary 1514, processing

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circuitry **210** may restore the amplitude of stimulation pulses delivered by IMD **200** to the target stimulation pulse amplitude.

FIG. **16** is a flow diagram illustrating an example operation for controlling simulation based on one or more stimulation signals, in accordance with one or more techniques of this disclosure. FIG. **16** is described with respect to IMD **200** of FIG. **2**. However, the techniques of FIG. **16** may be performed by different components of IMD **200** or by additional or alternative medical devices. The technique of FIG. **15** may be similar to the example of FIG. **14** in some examples.

Stimulation generation circuitry **202** is configured to generate a stimulation pulse for delivery to target tissue of patient **105** (**1602**). In some examples, stimulation generation circuitry **202** is configured to generate the stimulation pulse according to therapy stimulation programs **214** and/or test stimulation programs **216** as a one of a set of stimulation pulses. In some examples, therapy stimulation programs **214** and/or test stimulation programs **216** may include one or more parameter values which define stimulation pulses delivered by IMD **200**. Sensing circuitry **206** may sense a stimulation signal responsive to the stimulation pulse delivered to the target tissue of patient **105** (**1604**). In some examples, the stimulation signal may include one or more phases (e.g., a first phase, a second phase, and a third phase). In some examples, a first phase of the stimulation signal may be responsive to a first phase of the stimulation pulse and a second phase of the stimulation signal may be responsive to a second phase of the stimulation pulse. In some examples, a third phase of the stimulation signal may directly follow the second phase of the stimulation signal and the third phase of the stimulation signal may include information indicative of an efficacy of electrical stimulation therapy which includes the stimulation pulse.

Processing circuitry **210** may determine an amplitude associated with the stimulation signal (**1606**). The amplitude may be a characteristic of the stimulation signal. In some examples, the amplitude may represent an amplitude of the third phase of the stimulation signal. In some examples, the amplitude may represent an amplitude of one or both of the first phase of the stimulation signal and the second phase of the stimulation signal. Processing circuitry **210** may determine whether the amplitude associated with the stimulation signal is within a target range of stimulation signal amplitude values (**1608**). In some examples, processing circuitry **210** may select the target range of stimulation signal amplitude values from target values **218** stored in storage device **212**. For example, processing circuitry **210** may select the target range of stimulation signal amplitude values based on a determined posture of patient **105** and an amplitude of the stimulation pulse which causes IMD **200** to sense the stimulation signal. In response to determining that the amplitude associated with the stimulation signal is within the target range of stimulation signal amplitude values (“YES” branch of block **1608**), processing circuitry **210** may maintain one or more parameters of an upcoming one or more stimulation pulses (**1610**) and the example operation may return to block **1602**. In response to determining that the amplitude associated with the stimulation signal is not within the target range of stimulation signal amplitude values (“NO” branch of block **1608**), processing circuitry **210** may change one or more parameters of an upcoming one or more stimulation pulses (**1612**) and the example operation may return to block **1602**.

FIG. **17** is a flow diagram illustrating another example operation for controlling simulation based on one or more

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stimulation signals, in accordance with one or more techniques of this disclosure. FIG. **17** is described with respect to IMD **200** of FIG. **2**. However, the techniques of FIG. **17** may be performed by different components of IMD **200** or by additional or alternative medical devices. The technique of FIG. **17** may be similar to the example of FIG. **15**.

Stimulation generation circuitry **202** is configured to generate a stimulation pulse for delivery to target tissue of patient **105** (**1702**). In some examples, stimulation generation circuitry **202** is configured to generate the stimulation pulse according to therapy stimulation programs **214** and/or test stimulation programs **216** as a one of a set of stimulation pulses. In some examples, therapy stimulation programs **214** and/or test stimulation programs **216** may include one or more parameter values which define stimulation pulses delivered by IMD **200**. Sensing circuitry **206** may sense a stimulation signal responsive to the stimulation pulse delivered to the target tissue of patient **105** (**1704**). In some examples, the stimulation signal may include one or more phases (e.g., a first phase, a second phase, and a third phase). In some examples, a first phase of the stimulation signal may be responsive to a first phase of the stimulation pulse and a second phase of the stimulation signal may be responsive to a second phase of the stimulation pulse. In some examples, a third phase of the stimulation signal may directly follow the second phase of the stimulation signal and the third phase of the stimulation signal may include information indicative of an efficacy of electrical stimulation therapy which includes the stimulation pulse.

Processing circuitry **210** may determine an amplitude associated with the stimulation signal (**1706**). The amplitude may be a characteristic of the stimulation signal. In some examples, the amplitude may represent an amplitude of the third phase of the stimulation signal. In some examples, the amplitude may represent an amplitude of one or both of the first phase of the stimulation signal and the second phase of the stimulation signal. Processing circuitry **210** may determine whether the amplitude associated with the stimulation signal is greater than a target maximum stimulation signal amplitude value (**1708**). In some examples, processing circuitry **210** may select the target maximum stimulation signal amplitude value from target values **218** stored in storage device **212**. For example, processing circuitry **210** may select the target maximum stimulation signal amplitude value based on a determined posture of patient **105** and an amplitude of the stimulation pulse which causes IMD **200** to sense the stimulation signal. In response to determining that the amplitude associated with the stimulation signal is not greater than the target maximum stimulation signal amplitude value (“NO” branch of block **1708**), processing circuitry **210** may maintain one or more parameters of an upcoming one or more stimulation pulses (**1710**) and the example operation may return to block **1702**. In response to determining that the amplitude associated with the stimulation signal is greater than the target maximum stimulation signal amplitude value (“YES” branch of block **1708**), processing circuitry **210** may decrease one or more parameters of an upcoming one or more stimulation pulses (**1712**) and the example operation may return to block **1702**.

FIG. **18** is a flow diagram illustrating another example operation for controlling simulation based on one or more stimulation signals, in accordance with one or more techniques of this disclosure. FIG. **18** is described with respect to IMD **200** of FIG. **2**. However, the techniques of FIG. **18** may be performed by different components of IMD **200** or by additional or alternative medical devices.

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Processing circuitry 210 may determine an amplitude associated with a stimulation signal responsive to a stimulation pulse (1802) delivered by IMD 200. The amplitude may be a characteristic of the stimulation signal. In some examples, the amplitude may represent an amplitude of the third phase of the stimulation signal. In some examples, the amplitude may represent an amplitude of one or both of the first phase of the stimulation signal and the second phase of the stimulation signal. Processing circuitry 210 may determine whether the amplitude associated with the stimulation signal is greater than a target maximum stimulation signal amplitude value (1804). In some examples, processing circuitry 210 may select the target maximum stimulation signal amplitude value from target values 218 stored in storage device 212. For example, processing circuitry 210 may select the target maximum stimulation signal amplitude value based on a determined posture of patient 105 and an amplitude of the stimulation pulse which causes IMD 200 to sense the stimulation signal.

In response to determining that the amplitude associated with the stimulation signal is greater than the target maximum stimulation signal amplitude value ("YES" branch of block 1804), processing circuitry 210 may determine whether a current stimulation pulse amplitude represents a fallback stimulation pulse amplitude (1806). In some examples, the fallback stimulation amplitude may be calculated according to equation 3. If the current stimulation pulse amplitude represents the fallback stimulation pulse amplitude ("YES" branch of block 1806), processing circuitry 210 maintains an amplitude of one or more upcoming stimulation pulses at the fallback stimulation amplitude (1808) and the example operation returns to block 1802. If the current stimulation pulse amplitude does not represent the fallback stimulation pulse amplitude ("NO" branch of block 1806), processing circuitry 210 may set the amplitude of one or more upcoming stimulation pulses at the fallback stimulation amplitude (1810) and the example operation returns to block 1802.

In response to determining that the amplitude associated with the stimulation signal is not greater than the target maximum stimulation signal amplitude value ("NO" branch of block 1804), processing circuitry 210 may determine whether a current stimulation pulse amplitude represents a fallback stimulation pulse amplitude (1812). In some examples, the fallback stimulation amplitude may be calculated according to equation 3. If the current stimulation pulse amplitude represents the fallback stimulation pulse amplitude ("YES" branch of block 1812), processing circuitry 210 maintains an amplitude of one or more upcoming stimulation pulses at the fallback stimulation amplitude (1814) and the example operation returns to block 1802. If the current stimulation pulse amplitude does not represent the fallback stimulation pulse amplitude ("NO" branch of block 1812), processing circuitry 210 may restore the amplitude of one or more upcoming stimulation pulses to a baseline stimulation amplitude (1816) and the example operation returns to block 1802. In some examples, the baseline stimulation amplitude represents the target stimulation pulse amplitude of equation 3.

FIG. 19 is a flow diagram illustrating another example operation for controlling stimulation based on one or more stimulation signals, in accordance with one or more techniques of this disclosure. FIG. 19 is described with respect to IMD 200 of FIG. 2. However, the techniques of FIG. 19 may be performed by different components of IMD 200 or by additional or alternative medical devices.

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Processing circuitry 210 may determine an amplitude associated with a stimulation signal responsive to a stimulation pulse (1902) delivered by IMD 200. The amplitude may be a characteristic of the stimulation signal. In some examples, the amplitude may represent an amplitude of the third phase of the stimulation signal. In some examples, the amplitude may represent an amplitude of one or both of the first phase of the stimulation signal and the second phase of the stimulation signal. Processing circuitry 210 may determine whether the amplitude associated with the stimulation signal is outside of a target range of stimulation signal amplitude values which extends from a lower bound amplitude value to an upper bound amplitude value (1904). In some examples, processing circuitry 210 may select the target range from target values 218 stored in storage device 212. For example, processing circuitry 210 may select the target range based on a determined posture of patient 105 and an amplitude of the stimulation pulse which causes IMD 200 to sense the stimulation signal.

In response to determining that the amplitude associated with the stimulation signal is outside of the target range ("YES" branch of block 1904), processing circuitry 210 may determine whether a current stimulation pulse amplitude represents a first fallback stimulation pulse amplitude or a second fallback stimulation pulse amplitude (1906). For example, if processing circuitry 210 determines that the amplitude associated with the stimulation signal is greater than the upper bound of the target range, processing circuitry 210 may determine whether a current stimulation pulse amplitude represents the first fallback amplitude (e.g., calculated using equation 1) and if processing circuitry 210 determines that the amplitude associated with the stimulation signal is less than the lower bound of the target range, processing circuitry 210 may determine whether a current stimulation pulse amplitude represents the second fallback amplitude (e.g., calculated using equation 2).

If the current stimulation pulse amplitude represents the first fallback stimulation pulse amplitude or the second fallback stimulation pulse amplitude ("YES" branch of block 1906), processing circuitry 210 maintains an amplitude of one or more upcoming stimulation pulses at the respective first or second fallback stimulation amplitude (1908) and the example operation returns to block 1902. If the current stimulation pulse amplitude does not represent the respective first or second fallback stimulation pulse amplitude ("NO" branch of block 1906), processing circuitry 210 may set the amplitude of one or more upcoming stimulation pulses at the respective one of the first fallback stimulation amplitude or the second fallback stimulation amplitude (1910) and the example operation returns to block 1902. For example, if processing circuitry 210 determines that the amplitude associated with the stimulation signal is greater than the upper bound of the target range, processing circuitry 210 may set the amplitude of one or more upcoming stimulation pulses at the first fallback stimulation pulse amplitude and if processing circuitry 210 determines that the amplitude associated with the stimulation signal is less than the lower bound of the target range, processing circuitry 210 may set the amplitude of one or more upcoming stimulation pulses at the second fallback stimulation pulse amplitude.

In response to determining that the amplitude associated with the stimulation signal is not outside of the target range ("NO" branch of block 1904), processing circuitry 210 may determine whether a current stimulation pulse amplitude represents the first fallback stimulation pulse amplitude or the second fallback stimulation pulse amplitude (1912). If the current stimulation pulse amplitude represents the first

fallback stimulation pulse amplitude or the second fallback stimulation pulse amplitude (“YES” branch of block 1912), processing circuitry 210 maintains an amplitude of one or more upcoming stimulation pulses at the respective first or second fallback stimulation amplitude (1914) and the example operation returns to block 1902. If the current stimulation pulse amplitude does not represent the first fallback stimulation pulse amplitude or the second fallback stimulation pulse amplitude (“NO” branch of block 1912), processing circuitry 210 may restore the amplitude of one or more upcoming stimulation pulses to a baseline stimulation amplitude (1916) and the example operation returns to block 1902. In some examples, the baseline stimulation amplitude represents the target stimulation pulse amplitude of equation 1 and equation 2.

The following examples are example systems, devices, and methods described herein.

Example 1: A medical device comprising: stimulation generation circuitry configured to deliver a first stimulation pulse to a patient; sensing circuitry configured to sense the first stimulation pulse; and processing circuitry configured to: determine that a value of a characteristic of the sensed first stimulation pulse exceeds a target stimulation pulse value; and responsive to determining that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value, change a first value of a parameter to a second value of the parameter that at least partially defines a second stimulation pulse deliverable by the stimulation generation circuitry after the first stimulation pulse was sensed.

Example 2: The medical device of example 1, wherein to determine that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value, the processing circuitry is configured to: determine that the value of the characteristic of the sensed first stimulation pulse is greater than a target maximum stimulation pulse characteristic value, and wherein to change the first value of the parameter to the second value of the parameter, the processing circuitry is configured to: decrease the first value of the parameter to the second value of the parameter, the second value of the parameter at least partially defining the second stimulation pulse.

Example 3: The medical device of example 2, wherein to decrease the first value of the parameter to the second value of the parameter that at least partially defines the second stimulation pulse, the processing circuitry is configured to: set the parameter which at least partially defines the second stimulation pulse to a fallback parameter value that at least partially defines the second stimulation pulse, wherein the processing circuitry is further configured to: sense a third stimulation pulse following the second stimulation pulse; and responsive to determining that a value of a characteristic of the sensed third stimulation pulse does not exceed the target stimulation pulse value, restore the parameter that at least partially defines a fourth stimulation pulse deliverable by the stimulation generation circuitry to the first value of the parameter.

Example 4: The medical device of any of examples 2-3, wherein the processing circuitry is further configured to: determine that the value of the characteristic of the sensed first stimulation pulse is less than a target minimum stimulation pulse characteristic value, wherein a target range of stimulation pulse characteristic values extend from the target minimum stimulation pulse characteristic value to the target maximum stimulation pulse characteristic value; and responsive to determining that the value of the characteristic of the sensed first stimulation pulse is less than the target

minimum stimulation pulse characteristic value, increase the first value of the parameter to the second value of the parameter that at least partially defines the second stimulation pulse.

Example 5: The medical device of any of examples 1-4, wherein the stimulation generation circuitry is configured to deliver a plurality of stimulation pulses including the first stimulation pulse and the second stimulation pulse, and wherein the sensing circuitry is further configured to: detect a plurality of evoked compound action potentials (ECAPs), wherein each ECAP of the plurality of ECAPs is elicited by a respective pulse of the plurality of pulses, and wherein the number of ECAPs of the plurality of ECAPs is lower than a number of stimulation pulses of the plurality of stimulation pulses.

Example 6: The medical device of example 5, wherein the processing circuitry is further configured to determine whether the plurality of stimulation pulses elicit greater than a threshold ratio of detectable ECAPs per stimulation pulse.

Example 7: The medical device of example 6, wherein to determine whether the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs per stimulation pulse, the processing circuitry is configured to: identify a set of ECAPs elicited by a sequence of consecutive stimulation pulses of the plurality of stimulation pulses; calculate a ratio of a number of the set of ECAPs to a number of the sequence of consecutive stimulation pulses; and determine whether the ratio is greater than the threshold ratio.

Example 8: The medical device of any of examples 6-7, wherein the processing circuitry is further configured to: responsive to determining that the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs: change, based on the value of the characteristic of the sensed first stimulation pulse and a value of a characteristic of an ECAP corresponding to the first stimulation pulse, the value of the parameter that at least partially defines the second stimulation pulse.

Example 9: The medical device of any of examples 6-8, wherein the processing circuitry is further configured to: responsive to determining that the plurality of stimulation pulses does not elicit greater than the threshold ratio of detectable ECAPs: change, based on the value of the characteristic of the first stimulation pulse and not based on a value of a characteristic of an ECAP corresponding to the first stimulation pulse, the value of the parameter that at least partially defines the second stimulation pulse.

Example 10: The medical device of examples 1-9, further comprising: an accelerometer configured to generate an accelerometer signal, wherein the processing circuitry is further configured to: identify, based on the accelerometer signal, a posture of a set of postures which the patient is occupying; identify an amplitude of the first stimulation pulse; and select, based on the identified posture and the amplitude of the first stimulation pulse, the target stimulation pulse value from a set of target stimulation pulse values, wherein each target stimulation pulse value of the set of target stimulation pulse values corresponds to a respective posture of the set of postures and a respective amplitude of the first stimulation pulse.

Example 11: The medical device of examples 1-10, wherein the medical device comprises an implantable medical device, and wherein the implantable medical device comprises the stimulation generation circuitry, the sensing circuitry, and the processing circuitry.

Example 12: The medical device of any of examples 1-11, wherein the first value of the parameter at least partially defines the first stimulation pulse.

Example 13: The medical device of any of examples 1-12, wherein the first stimulation pulse represents a control pulse of a set of control pulses, wherein the second stimulation pulse represents an informed pulse of a set of informed pulses, wherein the first value of the parameter at least partially defines a previous informed pulse of the set of informed pulses.

Example 14: The medical device of any of examples 1-13, wherein the stimulation generation circuitry is configured to deliver at least one stimulation pulse between a time in which the stimulation generation circuitry delivers the first stimulation pulse and a time in which the stimulation generation circuitry delivers the second stimulation pulse.

Example 15: The medical device of any of examples 1-14, wherein the first stimulation pulse is one of a first set of one or more stimulation pulses, wherein the second stimulation pulse is one of a second set of one or more stimulation pulses, wherein the characteristic of the sensed first stimulation pulse represents a characteristic of the sensed first set of one or more stimulation pulses, and wherein the processing circuitry is configured to calculate the characteristic of the sensed first set of one or more stimulation pulses based on respective characteristic values of each stimulation pulse of the first set of one or more stimulation pulses.

Example 16: A method comprising: delivering, by stimulation generation circuitry, a first stimulation pulse to a patient; sensing, by sensing circuitry, the first stimulation pulse; determining, by processing circuitry, that a value of a characteristic of the sensed first stimulation pulse exceeds a target stimulation pulse value; and responsive to determining that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value, changing, by the processing circuitry, a first value of a parameter to a second value of the parameter that at least partially defines a second stimulation pulse deliverable by the stimulation generation circuitry after the first stimulation pulse was sensed.

Example 17: The method of example 16, wherein determining that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value comprises: determining that the value of the characteristic of the sensed first stimulation pulse is greater than a target maximum stimulation pulse characteristic value, and wherein changing the first value of the parameter to the second value of the parameter comprises: decreasing the first value of the parameter to the second value of the parameter, the second value of the parameter at least partially defining the second stimulation pulse.

Example 18: The method of example 17, wherein decreasing the first value of the parameter to the second value of the parameter that at least partially defines the second stimulation pulse comprises: setting the parameter which at least partially defines the second stimulation pulse to a fallback parameter value that at least partially defines the second stimulation pulse, wherein the method further comprises: sensing a third stimulation pulse following the second stimulation pulse; and responsive to determining that a value of a characteristic of the sensed third stimulation pulse does not exceed the target stimulation pulse value, restoring the parameter that at least partially defines a fourth stimulation pulse deliverable by the stimulation generation circuitry to the first value of the parameter.

Example 19: The method of examples 17-18, further comprising: determining, by the processing circuitry, that

the value of the characteristic of the sensed first stimulation pulse is less than a target minimum stimulation pulse characteristic value, wherein a target range of stimulation pulse characteristic values extend from the target minimum stimulation pulse characteristic value to the target maximum stimulation pulse characteristic value; and responsive to determining that the value of the characteristic of the sensed first stimulation pulse is less than the target minimum stimulation pulse characteristic value, increasing the first value of the parameter to the second value of the parameter that at least partially defines the second stimulation pulse.

Example 20: The method of examples 16-19, further comprising: delivering, by the stimulation generation circuitry, a plurality of stimulation pulses including the first stimulation pulse and the second stimulation pulse; and detecting, by the sensing circuitry, a plurality of evoked compound action potentials (ECAPs), wherein each ECAP of the plurality of ECAPs is elicited by a respective pulse of the plurality of pulses, and wherein the number of ECAPs of the plurality of ECAPs is lower than a number of stimulation pulses of the plurality of stimulation pulses.

Example 21: The method of examples 16-20, further comprising: generating, by an accelerometer, an accelerometer signal; identifying, by the processing circuitry based on the accelerometer signal, a posture of a set of postures which the patient is occupying; identifying, by the processing circuitry, an amplitude of the first stimulation pulse; and selecting, by the processing circuitry based on the identified posture and the amplitude of the first stimulation pulse, the target stimulation pulse value from a set of target stimulation pulse values, wherein each target stimulation pulse value of the set of target stimulation pulse values corresponds to a respective posture of the set of postures and a respective amplitude of the first stimulation pulse.

Example 22: A medical device comprising: stimulation generation circuitry configured to deliver a first stimulation pulse to a patient; sensing circuitry configured to sense a residual phase of the first stimulation pulse; and processing circuitry configured to: determine that a value of a characteristic of the sensed residual phase of the first stimulation pulse exceeds a target residual phase value; and responsive to determining that the value of the characteristic of the sensed residual phase exceeds the target residual phase value, change a first value of a parameter to a second value of the parameter that at least partially defines a second stimulation pulse deliverable by the stimulation generation circuitry after the residual phase of the first stimulation pulse was sensed.

Example 23: The medical device of example 22, wherein the stimulation generation circuitry is configured to deliver a plurality of stimulation pulses including the first stimulation pulse and the second stimulation pulse, and wherein the sensing circuitry is further configured to: detect a plurality of evoked compound action potentials (ECAPs), wherein each ECAP of the plurality of ECAPs is elicited by a respective pulse of the plurality of pulses, and wherein the number of ECAPs of the plurality of ECAPs is lower than a number of stimulation pulses of the plurality of stimulation pulses.

Example 24: The medical device of example 23, wherein the processing circuitry is further configured to determine whether the plurality of stimulation pulses elicit greater than a threshold ratio of detectable ECAPs per stimulation pulse.

Example 25: The medical device of example 24, wherein to determine whether the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs per stimulation pulse, the processing circuitry is configured to: identify a set of ECAPs elicited by a sequence of

consecutive stimulation pulses of the plurality of stimulation pulses; calculate a ratio of a number of the set of ECAPs to a number of the sequence of consecutive stimulation pulses; and determine whether the ratio is greater than the threshold ratio.

Example 26: The medical device of claims **24-25**, wherein the processing circuitry is further configured to: responsive to determining that the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs: change, based on the value of the characteristic of the sensed residual phase of the first stimulation pulse and a value of a characteristic of an ECAP corresponding to the first stimulation pulse, the value of the parameter that at least partially defines the second stimulation pulse.

Example 27: The medical device of claims **24-26**, wherein the processing circuitry is further configured to: responsive to determining that the plurality of stimulation pulses does not elicit greater than the threshold ratio of detectable ECAPs: change, based on the value of the characteristic of the sensed residual phase of the first stimulation pulse and not based on a value of a characteristic of an ECAP corresponding to the first stimulation pulse, the value of the parameter that at least partially defines the second stimulation pulse.

The techniques described in this disclosure may be implemented, at least in part, in hardware, software, firmware, or any combination thereof. For example, various aspects of the techniques may be implemented within one or more microprocessors, DSPs, ASICs, FPGAs, or any other equivalent integrated or discrete logic QRS circuitry, as well as any combinations of such components, embodied in external devices, such as physician or patient programmers, stimulators, or other devices. The terms “processor” and “processing circuitry” may generally refer to any of the foregoing logic circuitry, alone or in combination with other logic circuitry, or any other equivalent circuitry, and alone or in combination with other digital or analog circuitry.

For aspects implemented in software, at least some of the functionality ascribed to the systems and devices described in this disclosure may be embodied as instructions on a computer-readable storage medium such as RAM, DRAM, SRAM, magnetic discs, optical discs, flash memories, or forms of EPROM or EEPROM. The instructions may be executed to support one or more aspects of the functionality described in this disclosure.

In addition, in some aspects, the functionality described herein may be provided within dedicated hardware and/or software modules. Depiction of different features as modules or units is intended to highlight different functional aspects and does not necessarily imply that such modules or units must be realized by separate hardware or software components. Rather, functionality associated with one or more modules or units may be performed by separate hardware or software components or integrated within common or separate hardware or software components. 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 IMD, an external programmer, a combination of an IMD and external programmer, an integrated circuit (IC) or a set of ICs, and/or discrete electrical circuitry, residing in an IMD and/or external programmer.

What is claimed is:

1. A medical device comprising: stimulation generation circuitry configured to deliver a plurality of stimulation pulses including a first stimu-

lation pulse and a second stimulation pulse to a patient, the first stimulation pulse at least partially defined by a first value of a parameter;

sensing circuitry configured to sense, via an electrode combination, the first stimulation pulse delivered to the patient; and

processing circuitry configured to:

identify a value of a characteristic of the first stimulation pulse sensed via the sensing circuitry and the electrode combination;

determine that the value of a characteristic of the sensed first stimulation pulse exceeds a target stimulation pulse value; and

responsive to determining that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value, change the first value of the parameter to a second value of the parameter that at least partially defines the second stimulation pulse deliverable by the stimulation generation circuitry after the first stimulation pulse was sensed, wherein:

the sensing circuitry is configured to detect a plurality of evoked compound action potentials (ECAPs), each ECAP of the plurality of ECAPs being elicited by a respective pulse of the plurality of stimulation pulses, the number of ECAPs of the plurality of ECAPs is lower than a number of stimulation pulses of the plurality of stimulation pulses, and

the processing circuitry is configured to determine whether the plurality of stimulation pulses elicit greater than a threshold ratio of detectable ECAPs to stimulation pulses.

2. The medical device of claim 1, wherein to determine that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value, the processing circuitry is configured to:

determine that the value of the characteristic of the sensed first stimulation pulse is greater than a target maximum stimulation pulse characteristic value, and wherein to change the first value of the parameter to the second value of the parameter, the processing circuitry is configured to:

decrease the first value of the parameter to the second value of the parameter, the second value of the parameter at least partially defining the second stimulation pulse.

3. The medical device of claim 2, wherein to decrease the first value of the parameter to the second value of the parameter that at least partially defines the second stimulation pulse, the processing circuitry is configured to:

set the parameter which at least partially defines the second stimulation pulse to a fallback parameter value that at least partially defines the second stimulation pulse,

wherein the sensing circuitry is further configured to sense a third stimulation pulse following the second stimulation pulse, and

wherein the processing circuitry is configured to:

identify a value of a characteristic of the third stimulation pulse sensed via the sensing circuitry;

responsive to determining that the value of a characteristic of the sensed third stimulation pulse does not exceed the target stimulation pulse value, restore the parameter that at least partially defines a fourth stimulation pulse deliverable by the stimulation generation circuitry to the first value of the parameter.

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4. The medical device of claim 2, wherein the processing circuitry is further configured to:

determine that the value of the characteristic of the sensed first stimulation pulse is less than a target minimum stimulation pulse characteristic value, wherein a target range of stimulation pulse characteristic values extend from the target minimum stimulation pulse characteristic value to the target maximum stimulation pulse characteristic value; and

responsive to determining that the value of the characteristic of the sensed first stimulation pulse is less than the target minimum stimulation pulse characteristic value, increase the first value of the parameter to the second value of the parameter that at least partially defines the second stimulation pulse.

5. The medical device of claim 1, wherein to determine whether the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs to stimulation pulses, the processing circuitry is configured to:

identify a set of ECAPs elicited by a sequence of consecutive stimulation pulses of the plurality of stimulation pulses;

calculate a ratio of a number of the set of ECAPs to a number of the sequence of consecutive stimulation pulses; and

determine whether the ratio is greater than the threshold ratio.

6. The medical device of claim 1, wherein the processing circuitry is further configured to:

responsive to determining that the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs:

change, based on the value of the characteristic of the sensed first stimulation pulse and a value of a characteristic of an ECAP corresponding to the first stimulation pulse, the value of the parameter that at least partially defines the second stimulation pulse.

7. The medical device of claim 1, wherein the processing circuitry is further configured to:

responsive to determining that the plurality of stimulation pulses does not elicit greater than the threshold ratio of detectable ECAPs:

change, based on the value of the characteristic of the first stimulation pulse and not based on a value of a characteristic of an ECAP corresponding to the first stimulation pulse, the value of the parameter that at least partially defines the second stimulation pulse.

8. The medical device of claim 1, further comprising:

an accelerometer configured to generate an accelerometer signal, wherein the processing circuitry is further configured to:

identify, based on the accelerometer signal, a posture of a set of postures which the patient is occupying;

identify an amplitude of the first stimulation pulse; and

select, based on the identified posture and the amplitude of the first stimulation pulse, the target stimulation pulse value from a set of target stimulation pulse values, wherein each target stimulation pulse value of the set of target stimulation pulse values corresponds to a respective posture of the set of postures and a respective amplitude of the first stimulation pulse.

9. The medical device of claim 1, wherein the medical device comprises an implantable medical device, and wherein the implantable medical device comprises the stimulation generation circuitry, the sensing circuitry, and the processing circuitry.

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10. The medical device of claim 1, wherein the first value of the parameter at least partially defines the first stimulation pulse.

11. The medical device of claim 1, wherein the first stimulation pulse represents a control pulse of a set of control pulses, wherein the second stimulation pulse represents an informed pulse of a set of informed pulses, wherein the first value of the parameter at least partially defines a previous informed pulse of the set of informed pulses.

12. The medical device of claim 1, wherein the stimulation generation circuitry is configured to deliver at least one stimulation pulse between a time in which the stimulation generation circuitry delivers the first stimulation pulse and a time in which the stimulation generation circuitry delivers the second stimulation pulse.

13. The medical device of claim 1, wherein the first stimulation pulse is one of a first set of one or more stimulation pulses, wherein the second stimulation pulse is one of a second set of one or more stimulation pulses, wherein the characteristic of the sensed first stimulation pulse represents a characteristic of the sensed first set of one or more stimulation pulses, and wherein the processing circuitry is configured to calculate the characteristic of the sensed first set of one or more stimulation pulses based on respective characteristic values of each stimulation pulse of the first set of one or more stimulation pulses.

14. A method comprising:

delivering, by stimulation generation circuitry, a first stimulation pulse to a patient, the first stimulation pulse at least partially defined by a first value of a parameter; sensing, by sensing circuitry and via an electrode combination, the first stimulation pulse delivered to the patient;

identifying, by processing circuitry, a value of a characteristic of the first stimulation pulse sensed via the sensing circuitry and the electrode combination;

determining, by the processing circuitry, that a value of a characteristic of the sensed first stimulation pulse exceeds a target stimulation pulse value;

responsive to determining that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value, changing, by the processing circuitry, the first value of the parameter to a second value of the parameter that at least partially defines a second stimulation pulse deliverable by the stimulation generation circuitry after the first stimulation pulse was sensed;

delivering, by the stimulation generation circuitry, a plurality of stimulation pulses, the plurality of stimulation pulses including the first stimulation pulse and the second stimulation pulse; and

detecting, by the sensing circuitry, a plurality of evoked compound action potentials (ECAPs), each ECAP of the plurality of ECAPs being elicited by a respective pulse of the plurality of stimulation pulses, wherein the number of ECAPs of the plurality of ECAPs is lower than a number of stimulation pulses of the plurality of stimulation pulses; and

determining, by the processing circuitry, whether the plurality of stimulation pulses elicit greater than a threshold ratio of detectable ECAPs to stimulation pulses.

15. The method of claim 14, wherein determining that the value of the characteristic of the sensed first stimulation pulse exceeds the target stimulation pulse value comprises: determining that the value of the characteristic of the sensed first stimulation pulse is greater than a target

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maximum stimulation pulse characteristic value, and wherein changing the first value of the parameter to the second value of the parameter comprises:

decreasing the first value of the parameter to the second value of the parameter, the second value of the parameter at least partially defining the second stimulation pulse.

16. The method of claim 15, wherein decreasing the first value of the parameter to the second value of the parameter that at least partially defines the second stimulation pulse comprises:

setting the parameter which at least partially defines the second stimulation pulse to a fallback parameter value that at least partially defines the second stimulation pulse, wherein the method further comprises:

sensing, by the sensing circuitry, a third stimulation pulse following the second stimulation pulse;

identifying, by the processing circuitry, a value of a characteristic of the third stimulation pulse sensed via the sensing circuitry; and

responsive to determining that the value of a characteristic of the sensed third stimulation pulse does not exceed the target stimulation pulse value, restoring the parameter that at least partially defines a fourth stimulation pulse deliverable by the stimulation generation circuitry to the first value of the parameter.

17. The method of claim 15, further comprising:

determining, by the processing circuitry, that the value of the characteristic of the sensed first stimulation pulse is less than a target minimum stimulation pulse characteristic value, wherein a target range of stimulation pulse characteristic values extend from the target minimum stimulation pulse characteristic value to the target maximum stimulation pulse characteristic value; and responsive to determining that the value of the characteristic of the sensed first stimulation pulse is less than the target minimum stimulation pulse characteristic value, increasing the first value of the parameter to the second value of the parameter that at least partially defines the second stimulation pulse.

18. The method of claim 14, further comprising:

generating, by an accelerometer, an accelerometer signal; identifying, by the processing circuitry based on the accelerometer signal, a posture of a set of postures which the patient is occupying;

identifying, by the processing circuitry, an amplitude of the first stimulation pulse; and

selecting, by the processing circuitry based on the identified posture and the amplitude of the first stimulation pulse, the target stimulation pulse value from a set of target stimulation pulse values, wherein each target stimulation pulse value of the set of target stimulation pulse values corresponds to a respective posture of the set of postures and a respective amplitude of the first stimulation pulse.

19. A medical device comprising:

stimulation generation circuitry configured to deliver a first stimulation pulse to a patient, the first stimulation pulse at least partially defined by a first value of a parameter, wherein the first stimulation pulse comprises a first phase and a second phase;

sensing circuitry configured to sense, via an electrode combination, a residual phase of the first stimulation pulse delivered to the patient, the residual phase occurring after the first phase and the second phase; and processing circuitry configured to:

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identify a value of a characteristic of the residual phase of the first stimulation pulse sensed via the sensing circuitry and the electrode combination;

determine that the value of a characteristic of the residual phase of the first stimulation pulse exceeds a target residual phase value; and

responsive to determining that the value of the characteristic of the sensed residual phase exceeds the target residual phase value, change the first value of the parameter to a second value of the parameter that at least partially defines a second stimulation pulse deliverable by the stimulation generation circuitry after the residual phase of the first stimulation pulse was sensed.

20. The medical device of claim 19, wherein the stimulation generation circuitry is configured to deliver a plurality of stimulation pulses including the first stimulation pulse and the second stimulation pulse, and wherein the sensing circuitry is further configured to:

detect a plurality of evoked compound action potentials (ECAPs), wherein each ECAP of the plurality of ECAPs is elicited by a respective pulse of the plurality of pulses, and wherein the number of ECAPs of the plurality of ECAPs is lower than a number of stimulation pulses of the plurality of stimulation pulses.

21. The medical device of claim 20, wherein the processing circuitry is further configured to determine whether the plurality of stimulation pulses elicit greater than a threshold ratio of detectable ECAPs to stimulation pulses.

22. The medical device of claim 21, wherein to determine whether the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs to stimulation pulses, the processing circuitry is configured to:

identify a set of ECAPs elicited by a sequence of consecutive stimulation pulses of the plurality of stimulation pulses;

calculate a ratio of a number of the set of ECAPs to a number of the sequence of consecutive stimulation pulses; and

determine whether the ratio is greater than the threshold ratio.

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

responsive to determining that the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs:

change, based on the value of the characteristic of the sensed residual phase of the first stimulation pulse and a value of a characteristic of an ECAP corresponding to the first stimulation pulse, the value of the parameter that at least partially defines the second stimulation pulse.

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

responsive to determining that the plurality of stimulation pulses does not elicit greater than the threshold ratio of detectable ECAPs:

change, based on the value of the characteristic of the sensed residual phase of the first stimulation pulse and not based on a value of a characteristic of an ECAP corresponding to the first stimulation pulse, the value of the parameter that at least partially defines the second stimulation pulse.

25. The medical device of claim 1, wherein the processing circuitry is configured to:

determine that the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs to stimulation pulses; and

responsive to the determination, control electrical stimulation therapy based on one or more characteristics of detectable ECAP signals. 5

26. The medical device of claim **1**, wherein the processing circuitry is configured to:

determine that the plurality of stimulation pulses elicit less than the threshold ratio of detectable ECAPs to stimulation pulses; and 10

responsive to the determination, control electrical stimulation therapy based on one or more characteristics of detected stimulation pulses.

27. The method of claim **14**, wherein determining whether the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs to stimulation pulses comprises: 15

determining that the plurality of stimulation pulses elicit greater than the threshold ratio of detectable ECAPs to stimulation pulses; 20

responsive to determining that the plurality of stimulation pulses elicit greater than the threshold ratio, control electrical stimulation therapy based on one or more characteristics of detectable ECAP signals; 25

determining that the plurality of stimulation pulses elicit less than the threshold ratio of detectable ECAPs to stimulation pulses; and

responsive to determining that the plurality of stimulation pulses elicit less than the threshold ratio, control electrical stimulation therapy based on one or more characteristics of detected stimulation pulses. 30

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