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(71) Applicant: **AMBER THERAPEUTICS LTD** [GB/GB]; 42 Sutherland Place, London W2 5BY (GB).

(72) Inventors: **DENISON, Timothy**; 42 Sutherland Place, London W2 5BY (GB). **DE WACHTER, Stefan**; 42 Sutherland Place, London W2 5BY (GB). **KNOWLES, Charles**; 42 Sutherland Place, London W2 5BY (GB). **CRAWLEY, Aidan**; 42 Sutherland Place, London W2 5BY (GB).

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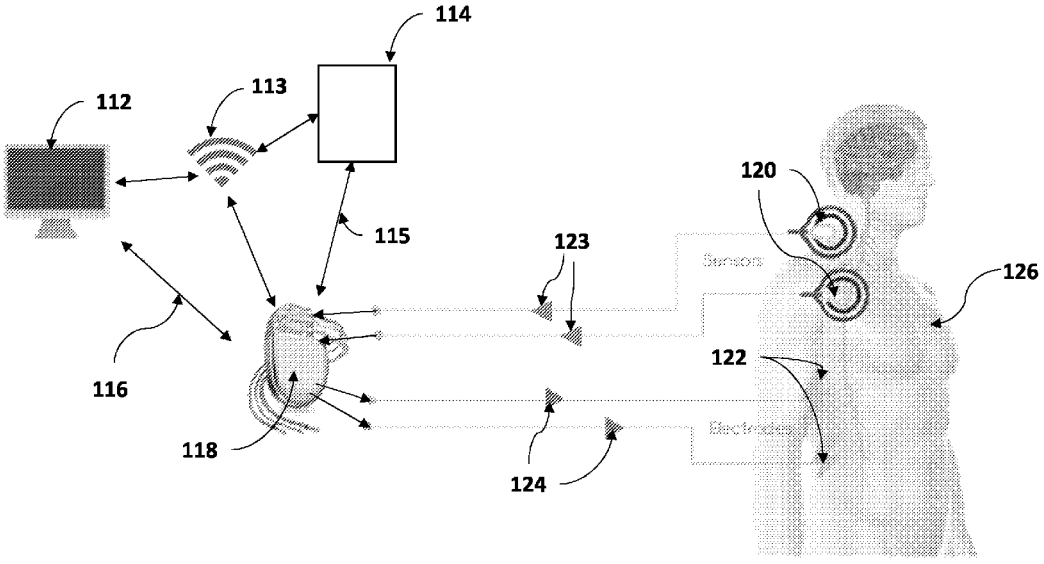



FIG. 2

(57) Abstract: Provided are devices and methods for preventing an episode of incontinence in an individual in need thereof. The devices comprise a sensor and a stimulator electrode that can be implanted into the body of the individual. Once the device is implanted in the individual, the sensor of the device senses a parameter that is associated with a response from the individual that is intended to prevent an episode of incontinence. Then, the device provides an electrical stimulation using the electrode that, together with the response, helps to prevent the episode of incontinence.

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# SYSTEMS FOR INCONTINENCE CONTROL

## CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 63/160,322, filed March 12, 2021 which is incorporated herein by reference in its entirety.

## BACKGROUND

[0002] Incontinence, or a lack of control over micturition or bowel movements, has many causes but commonly involves injury or weakness of the pelvic floor muscles and the nerves that innervate these muscles and involved organs. Electrical stimulation has been used to treat incontinence by stimulating the muscle directly or the sacral nerve to improve control over micturition and defecation.

## SUMMARY

[0003] A lack of voluntary control over micturition, defecation, incontinence, or any combination thereof is a problem that can impact quality of life and cause social embarrassment. Urinary incontinence, or loss of bladder control, fecal incontinence, loss of control of bowel movements, or any combination thereof often relate to neurological issues.

[0004] Electrical stimulation has been used to treat incontinence by stimulating the muscle directly, sacral nerve, or other pelvic nerves to improve control over micturition and bowel movements. However, electrical nerve stimulation approaches usually only deliver a set stimulation protocol and are not capable of adapting to the condition of the subject. This can result in overstimulating or under stimulating the target area, resulting in inadequate control over micturition or bowel defecation. Therefore, it would be beneficial to deliver an electrical stimulation that accounts for the condition of the subject and adapts the stimulation level accordingly.

[0005] Additionally, traditional approaches to treating incontinence overlook that an innate human response (i.e. reflex) to prevent an incontinent event may be insufficient rather than absent. For some individuals who exhibit incontinence events, it may be that an innate mechanism for preventing incontinence is not entirely absent but rather is insufficient. For example, some individuals who suffer from incontinence may experience insufficient preventative response, such as a muscle contraction of at least one pelvic floor muscle to prevent a leakage event in response to an increased intra-abdominal pressure. In some instances, the leakage event may be urine, or alternatively gas or stool. Additionally, some individuals who

suffer from stress incontinence may exhibit a delayed response to preventing an incontinence event in response to a stress event. Alternatively, some individuals may suffer from stress incontinence related to urethral hypermobility (i.e., insufficient support) that may lead to an increased pressure transmitted to the bladder and subsequently an incontinence event.

**[0006]** Aspects of the disclosure herein provide a method for preventing an episode of incontinence in an individual in need thereof, the method comprising: (a) implanting a sensor and an stimulator electrode within a body of the individual; (b) sensing, with the sensor electrode, a parameter that is associated with a response from the individual that is intended to prevent an episode of incontinence; and (c) providing an electrical stimulation with the stimulation electrode, that together with the response, prevents the episode of incontinence. In some embodiments, the episode of incontinence comprises urinary incontinence. In some embodiments, the episode of incontinence comprises fecal incontinence. In some embodiments, the sensor is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter or a pelvic floor muscle that controls bladder or bowel voiding. In some embodiments, the sensor electrode is positioned within the pelvis of the individual. In some embodiments, the stimulator electrode provides an electrical stimulation to the pudendal nerve. In some embodiments, the sensor and the stimulator electrode are located on a single lead. In some embodiments, the method comprises a step of providing a constant electrical stimulation at a lower intensity level than the electrical stimulation provided in step (c). In some embodiments, the episode of incontinence is urinary incontinence and is urge incontinence type. In some embodiments, the intensity or duration of the electrical stimulation provided in step (c) varies according to the response that is sense in step (b). In some embodiments, the response that is sensed in step (b) is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided in step (b) adds just enough, together with the response, to prevent the episode of incontinence. In some embodiments, the response that is sense in step (b) is insufficient on its own to prevent the episode of incontinence and the electric stimulation provided in step (b), together with the response, prevent the episode on incontinence. In some embodiments, the method comprises a step of implanting a second stimulator electrode, wherein a first stimulator electrode stimulates one pudendal nerve, and the second stimulator electrode stimulates the a different pudendal nerve. In some embodiments, the stimulator electrode stimulates one pudendal nerve, and the different stimulator electrode stimulates another spatially independent region of the same pudendal nerve. In some embodiments, the method comprises a step of implanting a different stimulator electrode, wherein the stimulator electrode stimulates the main trunk of the pudendal nerve and the different stimulator electrode stimulates the distal nerve of the pudendal nerve. In some embodiments, the distal nerve of the pudendal nerve

comprises branches thereof the distal pudendal nerve. In some embodiments, the method comprises a step of implanting a different stimulator electrode, wherein the electrode stimulates the trunk of the pudendal nerve the different stimulator electrode stimulates a main branch of the pudendal nerve e.g., dorsal genital nerve. In some embodiments, the method comprises a step of implanting a different stimulator electrode, wherein the first stimulator electrode stimulates a pudendal nerve, and the different stimulator electrode stimulates a sacral spinal nerve. In some embodiments, the individual suffers from urinary incontinence of varying classification. In some cases, the various classification may comprise stress incontinence, urge incontinence, overflow incontinence, or any combination thereof (i.e., mixed incontinence). In some embodiments, the sensor and stimulator electrodes are operatively coupled to a processor and a non-transitory computer readable medium that includes software. In some embodiments, the sensor electrode is calibrated by the individual using an external input device that interfaces with the software. In some embodiments, the software is configured to record a signal from the sensor electrode. In some embodiments, the software is configured to adjust the sensor electrode in response to signal.

**[0007]** In some embodiments, the sensor electrode is configured to sense an EMG signal. In some embodiments, the EMG signal determines that a contraction of at least one pelvic muscle has occurred. In some embodiments, the strength of the EMG signal determines that a contraction of at least one pelvic muscle has occurred. In some embodiments, the strength of the EMG signal is proportional to the strength of the contraction of at least one pelvic muscle.

**[0008]** Aspects of the disclosure herein provide a system for preventing an episode of incontinence in an individual in need thereof, the apparatus comprising: (a) a sensor electrode configured to sense a parameter that is associated with a response from the individual that is intended to prevent the episode of incontinence; (b) an stimulator electrode configured to provide electrical stimulation; (c) a processor operably coupled to the sensor and stimulator electrodes; (d) a non-transitory computer readable storage medium including software configured to cause the processor to: (i) receive the parameter that is associated with the response from the individual that is intended to prevent the episode of incontinence; (ii) analyze the parameter that is associated with the response from the individual that is intended to prevent the episode of incontinence; and (iii) cause the stimulator electrode to provide the electrical stimulation to the individual so that the electrical stimulation together with the response from the individual that is intended to prevent the episode of incontinence prevents the episode of incontinence. In some embodiments, the software comprises analyzing a global positioning system (GPS) location of the individual that in combination with the parameter associated with the response from the individual is intended to prevent the episode of incontinence. In some

embodiments, the episode of incontinence comprises urinary incontinence. In some embodiments, the episode of incontinence comprises fecal incontinence. In some embodiments, the episode of incontinence comprises a combination of urinary incontinence and fecal incontinence. In some embodiments, the episode of incontinence comprises urinary stress incontinence. In some embodiments, the sensor electrode is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding. In some embodiments, the sensor electrode is positioned within the pelvis of the individual. In some embodiments, the stimulator electrode provides the electrical stimulation to the pudendal nerve. In some embodiments, the sensor and stimulator electrodes are located on a single lead. In some embodiments, the stimulator electrode is configured to provide a constant electrical stimulation at a lower intensity level than the electrical stimulation provided to prevent an episode of incontinence. In some embodiments, the episode of incontinence is urinary incontinence and is urge incontinence type. In some embodiments, an intensity or duration of the electrical stimulation varies according to the response that is sensed. In some embodiments, the response that is sensed by the sensor electrode is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided adds together with the response, to prevent the episode of incontinence. In some embodiments, the system provides a lower intensity stimulation to the subject, whereby the lower intensity stimulation increased or improves the subject's tolerance to the stimulation signal. In some embodiments, the increase or improvement in the subject's tolerance provides tolerance of higher intensity stimulation signal. In some embodiments, the sensor electrode is configured to sense an EMG signal. In some embodiments, the EMG signal determines that a contraction of at least one pelvic muscle has occurred. In some embodiments, the strength of the EMG signal is proportional to the strength of the contraction of at least one pelvic muscle. In some embodiments, the stimulator electrode comprises a first stimulator electrode and a second stimulator electrode, wherein the first stimulator electrode stimulates a first pudendal nerve, and the second stimulator electrode stimulates a second pudendal nerve. In some embodiments, the individual suffers from urinary incontinence of a mixed type. In some embodiments, the sensor electrode is calibrated by the individual using an external input device that interfaces with the software. In some embodiments, the software is configured to further cause the processor to record a signal from the sensor electrode. In some embodiments, the software is configured to adjust the sensor electrode in response to the signal.

**[0009]** Aspects of the disclosure herein provide a non-transitory computer readable storage medium including software for preventing an episode of incontinence in an individual in need thereof, configured to cause a processor to: (i) receive a parameter by a sensor electrode that is associated with a response from the individual intended to prevent the episode of incontinence;

(ii) analyze the parameter that is associated with the response from the individual that is intended to prevent the episode of incontinence; and (iii) cause an stimulator electrode to provide an electrical stimulation to the individual so that the electrical stimulation together with the response from the individual that is intended to prevent the episode of incontinence prevents the episode of incontinence. In some embodiments, the software comprises analyzing a global positioning system (GPS) location of the individual that in combination with the parameter associated with the response from the individual is intended to prevent the episode of incontinence. In some embodiments, the episode of incontinence comprises urinary incontinence. In some embodiments, the episode of incontinence comprises fecal incontinence. In some embodiments, the episode of incontinence comprises urinary stress incontinence. In some embodiments, the sensor electrode is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding. In some embodiments, the sensor electrodes, stimulation electrodes, or any combination thereof is positioned within, adjacent, or around the pelvis of the individual. In some embodiments, the stimulator electrode provides the electrical stimulation to the pudendal nerve. In some embodiments, the sensor and stimulator electrodes are located on a single lead. In some embodiments, the stimulator electrode is configured to provide a constant electrical stimulation at a lower intensity level than the electrical stimulation provided to prevent an episode of incontinence. In some embodiments, the episode of incontinence is urinary incontinence and is urge incontinence type. In some embodiments, an intensity or duration of the electrical stimulation varies according to the response that is sensed. In some embodiments, the response that is sensed by the sensor electrode may be insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided adds just enough, together with the response, to prevent the episode of incontinence In some embodiments, the response that is sensed by the sensor electrode may be insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided, together with the response, prevents the episode of incontinence. In some embodiments, the sensor electrode may be configured to sense an EMG signal. In some embodiments, the EMG signal may determine that a contraction of at least one pelvic muscle has occurred. In some embodiments, the strength of the EMG signal may be proportional to the strength of the contraction of at least one pelvic muscle. In some embodiments, the stimulator electrode may comprise a first stimulator electrode and a second stimulator electrode, wherein the first stimulator electrode may stimulate a first pudendal nerve and the second stimulator electrode may stimulate another portion of the pudendal nerve. In some embodiments, the first stimulator electrode may stimulate one pudendal nerve, and the second stimulator electrode may stimulate another spatially independent region of the same

pudendal nerve. In some embodiments, the first stimulator electrode may stimulate the main trunk of the pudendal nerve and the second stimulator electrode may stimulate the distal nerve of the pudendal nerve. In some embodiments, the distal nerve of the pudendal nerve may comprise branches thereof the distal pudendal nerve. In some embodiments, the first stimulator electrode may stimulate the trunk of the pudendal nerve and the second stimulator electrode may stimulate a main branch of the pudendal nerve e.g., dorsal genital nerve. In some embodiments, the individual suffers from urinary incontinence of a mixed type. In some embodiments, the sensor electrode is calibrated by the individual using an external input device that interfaces with the software. In some embodiments, the software is configured to further cause the processor to record a signal from the sensor electrode. In some embodiments, the software is configured to adjust the sensor electrode in response to the signal.

**[0010]** Aspects of the disclosure herein provide a device for preventing an episode of incontinence in an individual in need thereof, the device comprising: (a) a sensor electrode configured to sense a parameter that is associated with a response from the individual that is intended to prevent the episode of incontinence; a stimulator electrode configured to provide electrical stimulation; and a processor operatively coupled to the sensor and stimulator electrode. In some embodiments, the episode of incontinence comprises urinary incontinence. In some embodiments, the episode of incontinence comprises fecal incontinence. In some embodiments, the episode of incontinence comprises urinary stress incontinence. In some embodiments, the sensor electrode is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding. In some embodiments, the sensor electrode is positioned within the pelvis of the individual. In some embodiments, the stimulator electrode provides the electrical stimulation to the pudendal nerve. In some embodiments, the stimulator electrode is configured to provide a constant electrical stimulation at a lower intensity level than the electrical stimulation provided to prevent an episode of incontinence. In some embodiments, the episode of incontinence is urinary incontinence and is urge incontinence type. In some embodiments, the intensity or duration of the electrical stimulation varies according to the response that is sensed. In some embodiments, the response that is sensed is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided adds just enough, together with the response, to prevent the episode of incontinence. In some embodiments, the response that is sensed is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided, together with the response, prevents the episode of incontinence. In some embodiments, the sensor electrode is configured to sense an EMG signal, ENG signal, or any combination thereof. In some embodiments, the EMG signal determines that a contraction of at least one pelvic muscle has

occurred. In some embodiments, the strength of the EMG signal is proportional to the strength of the contraction of at least one pelvic muscle. In some embodiments, the stimulator electrode comprises a first stimulator electrode and a second stimulator electrode, wherein the first stimulator electrode stimulates a first pudendal nerve and the second stimulator electrode stimulates a second pudendal nerve. In some embodiments, the individual suffers from urinary incontinence of a mixed type. In some embodiments, the device further comprises a non-transitory computer readable medium that includes software. In some embodiments, the sensor electrode is calibrated by the individual using an external input device that interfaces with the software. In some embodiments, the software is configured to record a signal from the sensor electrode. In some embodiments, the software is configured to adjust the sensor electrode in response to the signal.

**[0011]** Aspects of the disclosure herein provide a method of data processing, said method comprising: (i) receiving a measurement of a parameter previously measured by a sensor electrode, which parameter is predictive of an episode of incontinence in an individual; (ii) analyzing the parameter; and (iii) synthesizing an electrical stimulation signal for the individual, so that when the electrical stimulation signal is provided by a stimulator electrode to the individual, the electrical stimulation signal, together with an effort from the individual that is intended to prevent an episode of incontinence, prevents the episode of incontinence. In some embodiments, the parameter is associated with a response from the individual intended to prevent an episode of incontinence. In some embodiments, the parameter is associated with the individual's effort in trying to prevent an episode of incontinence, and wherein the electrical stimulation signal is synthesized so as to supplement the individual's effort with an electrical stimulation pattern that will, together with the effort from the individual, be sufficient to prevent an episode of incontinence. In some embodiments, the response from the individual is insufficient on its own to prevent the episode of incontinence and the electrical stimulation signal is such that, when applied, it adds enough, together with the response, to prevent the episode of incontinence. In some embodiments, the episode of incontinence comprises urinary incontinence. In some embodiments, the episode of incontinence comprises fecal incontinence. In some embodiments, the episode of incontinence comprises urinary stress incontinence. In some embodiments, the parameter is a signal from a sensor electrode that is configured to sense a contraction of a muscle of the individual related to a partial contraction of a sphincter that controls bladder or bowel voiding. In some embodiments, the electrical stimulation signal is for the electrical stimulation of the pudendal nerve. In some embodiments, the electrical stimulation signal is synthesized to include a constant electrical stimulation component and a measurement parameter specific component. In some embodiments, the episode of incontinence is urinary

incontinence and is urge incontinence type. In some embodiments, an intensity or duration of the electrical stimulation that will be provided by the electrical stimulation signal varies according to the value of the parameter that is received. In some embodiments, the parameter is an EMG signal. In some embodiments, the EMG signal determines that a contraction of at least one pelvic muscle has occurred. In some embodiments, a strength of the EMG signal is proportional to the strength of the contraction of at least one pelvic muscle. In some embodiments, the electrical stimulation signal comprises first and second signals for the stimulation of a first pudendal nerve and a second pudendal nerve respectively. In some embodiments, the method further comprises recording the signal previously measured by the sensor electrode. In some embodiments, the method further comprises synthesizing an adjustment signal to adjust the sensor electrode in response to the recorded signal.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0012]** The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

**[0013]** **FIG. 1** shows an exemplary embodiment of an open-loop bioelectronic system comprising an implantable pulse generator. The system delivers a predefined stimulation protocol and does not receive input from the subject.

**[0014]** **FIG. 2** shows an exemplary embodiment of a closed-loop bioelectronic system comprising a two-way neural interface comprising a sensor electrode that captures the neural response of the subject and a processing module that can interpret the neural response. The system is capable of delivering an adapted stimulation based on the neural response.

**[0015]** **FIG. 3** shows an exemplary embodiment of the devices and methods described herein targeting the pudendal nerve by placing the sensor and stimulator electrodes near the pudendal nerve. The sensor electrode captures the bio-signal to classify any stress events, and the stimulator electrodes deliver the stress electrical stimulation ("bio-simulator"), which is adapted from the base stimulation to account for the stress event, to act on the target sphincter muscle.

**[0016]** **FIG. 4** shows exemplary embodiments of depicting a bio-signal and a bio-stimulator electrical stimulation. The bio-signal captured by the sensor electrode is analyzed and classified to identify any stress events, such as a cough or a sudden movement, from an electromyography

(EMG) signal. The stimulator electrodes deliver the bio-simulator, an electrical stimulation that is adapted from the base stimulation to account for the stress event.

[0017] **FIG. 5** shows an exemplary embodiment of a system block diagram for the devices and methods described herein configured to implement slow- and fast-adapting algorithms. API is an application programming interface; MICS is the Medical Information and Communication band.

[0018] **FIGS. 6A-6B** show a flowchart of a method of closed-loop operation of the device of the disclosure.

[0019] **FIGS. 7A-7B** show an example embodiment of the patient controller module, as described in some embodiments herein.

[0020] **FIG. 8** shows a flow diagram for purposeful patient contraction and manual operation of the devices and systems, as described in some embodiments herein.

[0021] **FIG. 9** shows a flow diagram for the closed loop system operation, as described in some embodiments herein.

[0022] **FIG. 10** shows a flow diagram for signal processing and threshold detection of incontinent events, as described in some embodiments herein.

[0023] **FIGS. 11A-11E** show patient purposeful muscle contraction, Valsalva maneuver, and coughing EMG data acquired and processed with the methods of the disclosure, as described in some embodiments herein.

[0024] **FIGS. 12A-12B** show flow diagrams for detecting a purposeful or intent based contraction by the patient and providing electrical stimulation to prevent an incontinent event, as described in some embodiments herein.

[0025] **FIG. 13** shows a flow diagram for training on-board machine learning classifier of the devices and systems of the disclosure, as described in some embodiments herein.

## DETAILED DESCRIPTION

[0026] A lack of voluntary control over micturition or defecation, known as urinary and fecal incontinence, respectively, is a problem that can impact quality of life and cause social embarrassment. Urinary and fecal incontinence may affect individuals of all ages. In some cases, older individuals may exhibit a greater probability of incontinence with varied pathophysiology. Both urinary incontinence and fecal incontinence may involve injury, weakness, or overactivity of the pelvic floor muscles, including but not limited to the urethral and anal sphincter, and the nerves that innervate these muscles and involved organs, such as the bladder, rectum, or anus.

[0027] Urinary incontinence may be categorized into one of four main types: urge incontinence, stress incontinence, overflow incontinence, and mixed incontinence. Urge

incontinence is often due to an overactive bladder. Individuals with urge incontinence have a strong and sudden need to urinate immediately, often leaving them with insufficient time to reach a bathroom. Stress incontinence is usually due to a poorly functioning urethral sphincter muscle or hypermobility of the urethra or bladder neck. An individual may experience stress incontinence during activities such as coughing, sneezing, laughing, or exercise. Overflow incontinence may typically be due to poor bladder contraction or blockage of the urethra. Mixed incontinence may involve features of stress and urge incontinence. Incontinence often involves neurological issues, including but not limited to impaired nerve conduction between the brain and/or the affected muscles, and nervous system conditions or injuries (e.g., multiple sclerosis or stroke), or mental confusion. Other causes of incontinence include but are not limited to weakness of pelvic or urethral muscles and pelvic prolapse.

**[0028]** Fecal incontinence, also referred to as bowel incontinence, is the loss of bowel control, causing an individual to pass stool unexpectedly from the rectum. Fecal incontinence may be categorized into two main types: urge incontinence, and passive incontinence, or a combination thereof. Urge incontinence is due to an overactive bowel. Individuals with urge incontinence have a strong and sudden need to defecate immediately, often leaving them with insufficient time to reach a bathroom. Passive incontinence is when an individual feels no urge to open their bowel although the rectum is full and ready to be voided. Individuals suffering from passive incontinence cannot consciously control their bowel movements and stool can pass without their knowledge. Incontinence often involves neurological issues, including but not limited to impaired nerve conduction between the brain and/or the affected muscles, and nervous system conditions or injuries (e.g., multiple sclerosis or stroke), or mental confusion. Causes of fecal incontinence include but are not limited to nerve damage, anal sphincter muscle damage, constipation, diarrhea, hemorrhoids, surgery, loss of rectum storage capacity, rectal prolapse, and rectocele.

**[0029]** Electro galvanic stimulation of muscles has been used to treat incontinence by training the pelvic floor muscles thereby improving strength and function and/or by stimulating the sacral nerve to improve control over urination and defecation. However, these electrical nerve stimulation approaches are not able to adapt to the condition and circumstances of the subject and are only capable of delivering a predefined stimulation protocol. This can result in overstimulating or under stimulating the target area, resulting in inadequate control over muscles involved in urination or bowel movements. As such, it would be beneficial to be able to deliver an electrical stimulation that accounts for the condition of the subject and adapts the stimulation level accordingly.

[0030] Provided herein are devices, systems, and methods for preventing, and/or reducing the severity of an episode of incontinence in an individual in need thereof. In some instances, the episode of incontinence may comprise urinary incontinence, fecal incontinence, or any combination thereof. The devices, systems and methods disclosed herein may treat a sub-type of incontinence. In some cases, the sub-type of incontinence may comprise urge incontinence, stress incontinence, overflow incontinence, or mixed incontinence.

[0031] In some instances, the devices, systems, and methods described herein may increase bladder capacity. Bladder capacity may be measured as the maximum liquid volume a bladder may contain without inducing pain or micturition. In some cases, bladder capacity of a healthy individual as a baseline value may comprise a liquid volume of about 400 milliliters (mL) to about 600 mL. In some cases, bladder capacity may be measured by ultrasound calculations of a still ultrasound image of a subject's bladder. The bladder's volume may be measured by multiplying the length, width, and height of the measured bladder on the still ultrasound image. Alternatively, or in addition to, bladder capacity may be measured by cytometry where a catheter is inserted into the subject's urethra to fill and may measure the volume of urine. In some cases, a subject's bladder capacity may be reduced by disease. In some cases, the devices and systems described herein may increase bladder capacity by a percent increase from baseline bladder capacity. In some instances, bladder capacity may be increased by providing to the patient, an electrical stimulation by the stimulator electrode leads, described herein. In some cases, the stimulator may provide a frequency or pulse width of electrical stimulation, described elsewhere herein.

[0032] In some cases, bladder capacity may be increased utilizing either open or closed-loop system, described elsewhere herein. In some instances, bladder capacity may be increased by about 5% to about 75%. In some instances, bladder capacity may be increased by about 5% to about 10%, about 5% to about 15%, about 5% to about 20%, about 5% to about 25%, about 5% to about 30%, about 5% to about 35%, about 5% to about 40%, about 5% to about 45%, about 5% to about 50%, about 5% to about 70%, about 5% to about 75%, about 10% to about 15%, about 10% to about 20%, about 10% to about 25%, about 10% to about 30%, about 10% to about 35%, about 10% to about 40%, about 10% to about 45%, about 10% to about 50%, about 10% to about 70%, about 10% to about 75%, about 15% to about 20%, about 15% to about 25%, about 15% to about 30%, about 15% to about 35%, about 15% to about 40%, about 15% to about 45%, about 15% to about 50%, about 15% to about 70%, about 15% to about 75%, about 20% to about 25%, about 20% to about 30%, about 20% to about 35%, about 20% to about 40%, about 20% to about 45%, about 20% to about 50%, about 20% to about 70%, about 20% to about 75%, about 25% to about 30%, about 25% to about 35%, about 25% to about

40%, about 25% to about 45%, about 25% to about 50%, about 25% to about 70%, about 25% to about 75%, about 30% to about 35%, about 30% to about 40%, about 30% to about 45%, about 30% to about 50%, about 30% to about 70%, about 30% to about 75%, about 35% to about 40%, about 35% to about 45%, about 35% to about 50%, about 35% to about 70%, about 35% to about 75%, about 40% to about 45%, about 40% to about 50%, about 40% to about 70%, about 40% to about 75%, about 45% to about 50%, about 45% to about 70%, about 45% to about 75%, about 50% to about 70%, about 50% to about 75%, or about 70% to about 75%. In some instances, bladder capacity may be increased by about 5%, about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, about 50%, about 70%, or about 75%. In some instances, bladder capacity may be increased by at least about 5%, about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, about 50%, or about 70%. In some instances, bladder capacity may be increased by at most about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, about 50%, about 70%, or about 75%.

**[0033]** In some cases, the devices, systems, and methods described herein may increase urethral closure pressures. In some cases the urethral closure pressure may be expressed by a profile of pressures. Urethral closure pressure, in some instances, may be described as measurement of integrated pressure curves from the entire length of a subject's urethra. In some instances, urethral closure pressures may be measured by the slow withdrawal of a pressure-measuring catheter through the subject's urethra at a constant rate. In some instances, urethral closure pressures may be measured by a trans-urethral pressure profile catheter. In some cases, transurethral pressure may be measured in units of centimeters of water (cm $H_2O$). In some instances, the devices and systems described herein may increase urethral closure pressure by stimulating one or more nerves of the subject. In some instances, the one or more nerves may comprise the pudendal nerve, sacral nerve, or any combinations or branches thereof. In some cases, the stimulator described elsewhere herein, may provide an electrical stimulation at the subject's nerve, via a stimulator electrode lead at a frequency and/or frequency ranges, described elsewhere herein, to increase urethral closure pressure. In some instances, the urethral closure pressure may comprise about 10 centimeters of water (cm $H_2O$) to about 75 cm $H_2O$. In some instances, the urethral closure pressure may comprise about 10 cm $H_2O$ to about 15 cm $H_2O$, about 10 cm $H_2O$ to about 20 cm $H_2O$, about 10 cm $H_2O$ to about 25 cm $H_2O$, about 10 cm $H_2O$ to about 30 cm $H_2O$, about 10 cm $H_2O$ to about 35 cm $H_2O$, about 10 cm $H_2O$ to about 40 cm $H_2O$, about 10 cm $H_2O$ to about 45 cm $H_2O$, about 10 cm $H_2O$ to about 50 cm $H_2O$, about 10 cm $H_2O$ to about 60 cm $H_2O$, about 10 cm $H_2O$ to about 70 cm $H_2O$, about 10 cm $H_2O$ to about 75 cm $H_2O$, about 15 cm $H_2O$ to about 20 cm $H_2O$, about 15 cm $H_2O$ to about 25 cm $H_2O$, about

15 cm $H_2O$ to about 30 cm $H_2O$, about 15 cm $H_2O$ to about 35 cm $H_2O$, about 15 cm $H_2O$ to about 40 cm $H_2O$, about 15 cm $H_2O$ to about 45 cm $H_2O$, about 15 cm $H_2O$ to about 50 cm $H_2O$, about 15 cm $H_2O$ to about 60 cm $H_2O$, about 15 cm $H_2O$ to about 70 cm $H_2O$, about 15 cm $H_2O$ to about 75 cm $H_2O$, about 20 cm $H_2O$ to about 25 cm $H_2O$, about 20 cm $H_2O$ to about 30 cm $H_2O$, about 20 cm $H_2O$ to about 35 cm $H_2O$, about 20 cm $H_2O$ to about 40 cm $H_2O$, about 20 cm $H_2O$ to about 45 cm $H_2O$, about 20 cm $H_2O$ to about 50 cm $H_2O$, about 20 cm $H_2O$ to about 60 cm $H_2O$, about 20 cm $H_2O$ to about 70 cm $H_2O$, about 20 cm $H_2O$ to about 75 cm $H_2O$, about 25 cm $H_2O$ to about 30 cm $H_2O$, about 25 cm $H_2O$ to about 35 cm $H_2O$, about 25 cm $H_2O$ to about 40 cm $H_2O$, about 25 cm $H_2O$ to about 45 cm $H_2O$, about 25 cm $H_2O$ to about 50 cm $H_2O$, about 25 cm $H_2O$ to about 60 cm $H_2O$, about 25 cm $H_2O$ to about 70 cm $H_2O$, about 25 cm $H_2O$ to about 75 cm $H_2O$, about 30 cm $H_2O$ to about 35 cm $H_2O$, about 30 cm $H_2O$ to about 40 cm $H_2O$, about 30 cm $H_2O$ to about 45 cm $H_2O$, about 30 cm $H_2O$ to about 50 cm $H_2O$, about 30 cm $H_2O$ to about 60 cm $H_2O$, about 30 cm $H_2O$ to about 70 cm $H_2O$, about 30 cm $H_2O$ to about 75 cm $H_2O$, about 35 cm $H_2O$ to about 40 cm $H_2O$, about 35 cm $H_2O$ to about 45 cm $H_2O$, about 35 cm $H_2O$ to about 50 cm $H_2O$, about 35 cm $H_2O$ to about 60 cm $H_2O$, about 35 cm $H_2O$ to about 70 cm $H_2O$, about 35 cm $H_2O$ to about 75 cm $H_2O$, about 40 cm $H_2O$ to about 45 cm $H_2O$, about 40 cm $H_2O$ to about 50 cm $H_2O$, about 40 cm $H_2O$ to about 60 cm $H_2O$, about 40 cm $H_2O$ to about 70 cm $H_2O$, about 40 cm $H_2O$ to about 75 cm $H_2O$, about 45 cm $H_2O$ to about 50 cm $H_2O$, about 45 cm $H_2O$ to about 60 cm $H_2O$, about 45 cm $H_2O$ to about 70 cm $H_2O$, about 45 cm $H_2O$ to about 75 cm $H_2O$, about 50 cm $H_2O$ to about 60 cm $H_2O$, about 50 cm $H_2O$ to about 70 cm $H_2O$, about 50 cm $H_2O$ to about 75 cm $H_2O$, about 60 cm $H_2O$ to about 70 cm $H_2O$, about 60 cm $H_2O$ to about 75 cm $H_2O$, or about 70 cm $H_2O$ to about 75 cm $H_2O$. In some instances, the urethral closure pressure may comprise about 1O cm $H_2O$, about 15 cm $H_2O$, about 20 cm $H_2O$, about 25 cm $H_2O$, about 30 cm $H_2O$, about 35 cm $H_2O$, about 40 cm $H_2O$, about 45 cm $H_2O$, about 50 cm $H_2O$, about 60 cm $H_2O$, about 70 cm $H_2O$, or about 75 cm $H_2O$. In some instances, the urethral closure pressure may comprise at least about 1O cm $H_2O$, about 15 cm $H_2O$, about 20 cm $H_2O$, about 25 cm $H_2O$, about 30 cm $H_2O$, about 35 cm $H_2O$, about 40 cm $H_2O$, about 45 cm $H_2O$, about 50 cm $H_2O$, about 60 cm $H_2O$, or about 70 cm $H_2O$. In some instances, the urethral closure pressure may comprise at most about 15 cm $H_2O$, about 20 cm $H_2O$, about 25 cm $H_2O$, about 30 cm $H_2O$, about 35 cm $H_2O$, about 40 cm $H_2O$, about 45 cm $H_2O$, about 50 cm $H_2O$, about 60 cm $H_2O$, about 70 cm $H_2O$, or about 75 cm $H_2O$.

**[0034]** The devices and systems described herein may comprise one or more sensor electrodes, one or more stimulator electrodes, a processor, a power source, or any combination thereof. In some instances, the one or more stimulator electrodes, one or more sensor electrodes, processor, power source, or any combination thereof may be implanted into the body of the

individual. In some instances, the one or more stimulator electrodes, one or more sensor electrodes, processor, power source, or any combination thereof may be placed superficially on the body of the individual. In some instances, the processor, power source, or any combination thereof may be implanted into the body of the individual. In some instances, the device may comprise a wireless transmission module capable of transmitting and receiving wireless data wireless by and between a remote device (e.g., a mobile phone, a tablet, a computer, etc.) and the incontinence prevention device described herein. In some cases, the device may be implantable into an individual. Alternatively, the device may comprise a hermetically sealed connector placed on the individual's skin superficially that may electrically couple to a remote device by a cable. In some instances, the individual may manually modify or change the one or more sensor electrode or one or more stimulator electrode parameters through a graphical user interface. In some instances, the device may automatically modify or change the one or more sensor electrode or one or more stimulator electrode parameters.

**[0035]** In some cases, an implanted sensor electrode of the device may be configured to sense one or more parameters that may be associated with a response of an episode of incontinence or an attempt of the individual in trying to prevent an episode of incontinence. In some cases, the parameter may comprise an electromyography (EMG) signal that may be predictive of an episode of incontinence. In some instances, EMG signals may comprise electrical activity of muscles, specifically from action potentials in muscle fibers. In some cases, the parameter may comprise an electroneurogram (ENG). In some cases, an electroneurogram may comprise electrical activity from one or more neurons and typically refers to recordings made from bundles of axons in peripheral nerves. In some cases, the parameter may comprise a change of electric impedance caused by physical deformation of the sensor electrode material. In some instances, the physical deformation may comprise stretching, compression, or any combination thereof. Alternatively, the parameter may comprise a change in pressure, velocity, acceleration, or 3-D spatial direction. In some instances, 3-D spatial direction may be determined by GPS signal. The GPS signal, in some cases, may indicate and recognize when the individual is in proximity to locations such as the individual's home. In some instances, the GPS signal may be configured to modulate the stimulator, described elsewhere herein, based on the GPS coordinates and/or GPS location of the subject. In some instances, modulating the stimulator may comprise adjusting a detection parameter (e.g., signal intensity threshold) of the classifier, described elsewhere herein. In some cases, the GPS signal of a location and/or GPS coordinates may indicate locations and/or regions traveled to the subject that may impose a higher risk of an incontinent event. In some cases, 3-D spatial direction may measure the posture of an individual. In some instances, changes in pressure may be measured by a pressure sensor.

In some cases, the pressure sensor may comprise a differential pressure sensor, absolute pressure sensor, or any combination thereof. In some cases, changes in velocity, acceleration, or changes in 3-D spatial direction may be measured by an accelerometer, gyroscope, magnetometer, or any combination thereof. In some instances, the device may provide an electrical stimulation using the one or more implanted stimulator electrodes that, together with the individual's preventative response, may prevent the episode of incontinence.

[0036] The devices, systems, and methods described herein may be capable of preventing and/or reducing the severity of an incontinent event by detecting an individual's incontinence preventative parameter and adjusting an electrical stimulation by one or more stimulator electrodes based on the incontinence preventative parameter's characteristics. In some cases, the incontinence preventative parameter characteristics may comprise the changes in the amplitude, frequency, phase, or any combination thereof one or more EMG, ENG, accelerometer, gyroscope, magnetometer, pressure sensor signals, or any combination thereof . In some instances, an incontinence preventative parameter may comprise physical movement of the individual, one or more EMG signals, or any combination thereof. By providing adaptive electrical stimulation in combination to the individual's response, the devices, systems, and methods described herein may prevent incontinence episodes.

[0037] Described herein are devices, systems, and methods for preventing and/or reducing the severity of an episode of incontinence in an individual by providing adaptive electrical stimulation based on the individual's incontinence preventative parameter. The device may be implanted in the individual in proximity to the pudendal nerve, sacral nerve, or branches thereof. In some cases, the one or more stimulator electrodes of the device may be placed at or near the pudendal nerve or the sacral nerve. In some cases, the one or more stimulator electrodes or one or more sensor electrodes may be implanted in proximity to the pudendal nerve unilaterally or bilaterally. In some cases, the one or more stimulator electrodes may be implanted to stimulate motor nerve fibers (e.g., to the pelvic floor and sphincters). Alternatively, the one or more stimulator electrodes may be implanted within, proximate, or adjacent to the muscle (e.g., pelvic floor and sphincter muscles). The sensor electrode of the implanted device may sense a signal that indicates that an individual may exhibit an episode of incontinence or is trying to prevent an episode of incontinence. The device may analyze the signal and classify the signal as a real-time or prospective episode of incontinence. The device may generate an electrical stimulation that is modulated based on the classified episode of incontinence and may deliver the modulated electrical stimulation using one or more stimulator electrodes to the targeted nerve. In some instances, the modulation of the one or more stimulator electrodes electrical stimulation may comprise changing the frequency of electric stimulation, amplitude of electrical stimulation,

pulse width of electric stimulation, stimulator electrode configuration, or any combination thereof. In some cases, the one or more electrodes may comprise one or more stimulation electrodes and one or more sensing electrodes. The one or more stimulation electrodes and one or more sensing electrodes may be configured to switch between stimulating and sensing operations on demand, programmatically, user controlled, medical personal control, or any combination thereof. The electrical stimulation may be modulated to improve the muscle and/or nerve response to prevent the episode of incontinence. The modulated electrical stimulation may result in improved muscle response, as measured by response time, muscle function, or other markers of incontinence prevention, to prevent the potential episode of incontinence. The electrical stimulation may be modulated to reduce a severity and/or duration of an episode of incontinence. For example, a subject who exhibits an urge incontinence event (e.g., a cough) may receive an electrical stimulation provided by the devices, systems, and methods provided herein, in response to the incontinence episode. In some cases, the electrical stimulation may reduce the volume of uncontrolled micturition and/or defecation. In some cases, the electrical stimulation may reduce the volume of uncontrolled micturition and/or defecation without preventing the episode of incontinence entirely. In some cases, the electrical stimulation may reduce the duration of the incontinent event that would occur without the electrical stimulation. In some cases, the electrical stimulation may be configured to inhibit reflex incontinence. In some cases, the electrical stimulation may inhibit a bladder detrusor muscle contraction experienced during reflex incontinence.

**[0038]** The electrical stimulation may comprise an electrical stimulation provided over a period of time. In some cases, the period of time may comprise the period of time a subject may provide an intent based or purposeful muscle contraction to trigger an EMG threshold detection.

**[0039]** In some cases, the period of time for the electrical stimulation may comprise about 1 second to about 30 seconds. In some cases, the period of time for the electrical stimulation may comprise about 1 second to about 5 seconds, about 1 second to about 10 seconds, about 1 second to about 15 seconds, about 1 second to about 20 seconds, about 1 second to about 25 seconds, about 1 second to about 30 seconds, about 5 seconds to about 10 seconds, about 5 seconds to about 15 seconds, about 5 seconds to about 20 seconds, about 5 seconds to about 25 seconds, about 5 seconds to about 30 seconds, about 10 seconds to about 15 seconds, about 10 seconds to about 20 seconds, about 10 seconds to about 25 seconds, about 10 seconds to about 30 seconds, about 15 seconds to about 20 seconds, about 15 seconds to about 25 seconds, about 15 seconds to about 30 seconds, about 20 seconds to about 25 seconds, about 20 seconds to about 30 seconds, or about 25 seconds to about 30 seconds. In some cases, the period of time may comprise about 1 second, about 5 seconds, about 10 seconds, about 15 seconds, about 20

seconds, about 25 seconds, or about 30 seconds. In some cases, the period of time for the electrical stimulation may comprise at least about 1 second, about 5 seconds, about 10 seconds, about 15 seconds, about 20 seconds, or about 25 seconds. In some cases, the period of time for the electrical stimulation may comprise at most about 5 seconds, about 10 seconds, about 15 seconds, about 20 seconds, about 25 seconds, or about 30 seconds.

**Embodiments of a Device for Treating and Preventing Incontinence**

**[0040]** The disclosure describes devices for preventing an episode of incontinence comprising one or more sensor electrodes, one or more stimulator electrodes, an electric stimulator, or any combination thereof. In some cases, the electric stimulator may comprise a processor, memory, a user interface, a power source, or any combination thereof for preventing an episode of incontinence. The devices may be implantable. The surgical procedure to implant the device may be completed under awake sedation, general anesthesia, local anesthesia, twilight anesthesia, or any combination thereof. The devices may be implanted wholly or partly in an individual's pelvic region. In some cases, the devices may be implanted by one or more surgical instruments. In some instances, surgical instruments may comprise introducers, sheaths, directable probes, wires, needles, or any combination thereof.

**[0041]** In some cases, the device may further comprise a transmitter electrically coupled to a processor capable of wirelessly transmitting and receiving data from a remote device, such as a mobile phone, a tablet, or a computer. In some cases, the device may be configured for open-loop configuration. In some cases, the device may be configured for a close-loop or feedback-controlled configuration. The devices described herein may be used to prevent an episode of urinary incontinence. In some instances, urinary incontinence may comprise urge incontinence, stress incontinence, overflow incontinence, mixed incontinence, or any combination thereof. In some embodiments, the episode of incontinence is urinary incontinence and is urge incontinence type. In some cases, the devices described herein may be used to prevent an episode of fecal incontinence.

***Open Loop Configuration***

**[0042]** **FIG. 1** shows an open loop configuration of the device described herein configured to prevent an episode of incontinence for an individual **110**. The device in an open loop configuration may comprise an implantable pulse generator **102** comprising one or more stimulator electrodes **106**, and a power source. In some cases, the implantable pulse generator **102** may comprise a processor, and a wireless transmission module configured to execute

software to administer an electrical stimulation pattern **104**. In some cases, the power source may comprise a battery. In some instances, the battery may be a lithium polymer ion battery, lithium iodine, lithium manganese dioxide, lithium carbon monofluoride, or any combination thereof. In some cases, the battery may be wirelessly charged by an inductive charger. Alternatively, the battery power source may be a single use.

**[0043]** The implantable pulse generator **102** may deliver a predefined electrical stimulation pattern **104** that has been set by a healthcare provider on a remote device **100** (e.g., a mobile phone, a tablet, a computer, etc.) and transmitted wirelessly **105** to the implantable pulse generator **102**. Alternatively, the implantable pulse generator **102** may deliver a predefined electrical stimulation pattern **104** that has been set by a healthcare provider on a remote computing device **100** (e.g., a mobile phone, a tablet, a computer, etc.) and transmitted via a wired communication **101** to the implantable pulse generator **102**. In some instances, the healthcare provider may set the predefined electrical stimulation parameters through a graphical user interface on the remote device. In some cases, an individual **110** with an implantable pulse generator **102** may modify or set electrical stimulation parameters via an external input device **103**(e.g., a mobile phone, a tablet, a computer, etc.) via a wireless communication **105** of the implantable pulse generator **102**. Alternatively, an individual **110** with an implantable pulse generator **102** may modify or set electrical stimulation parameters via an external input device **103** via a wired communication **107** of the implantable pulse generator **102.** In some instances, an individual **110** with an implantable pulse generator **102** may adjust the electrical stimulation pattern **104** using a graphical user interface on the external input device **103**. In some cases, the electrical stimulation pattern **104** parameters that may be adjusted comprise frequency, amplitude, pulse width, or any combination thereof.

***Closed Loop Configuration***

**[0044]** **FIG. 2** shows a closed loop configuration of the device described herein configured to prevent an episode of incontinence for an individual **126.** The device in a closed loop configuration may comprise an implantable pulse generator **118,** one or more stimulator electrodes **122,** one or more sensor electrodes **120**, and a power source. In some cases, the implantable pulse generator **118** may comprise a processor, and a wireless transmission module configured to execute software to detect, analyze myoelectric electromyograph (EMG) signals via one or more sensor electrodes **120** and administer an electrical stimulation pattern **124**. In some instances, the power source may comprise a battery. The battery may be rechargeable or single use. In some cases, the battery may be charged through inductive charging. In some instances, the device configured in a closed loop configuration may measure EMG signals via

one or more sensor electrodes **120** to detect the onset of a stress incontinence event or a level of innate myoelectric electrical activity. In some instances the device configured in a closed loop configuration may measure inertial signals such as rapid acceleration, shock, posture-orientation, or any combination thereof via the one or more sensor electrodes **120** to detect the onset of a stress incontinence event or a level of innate myoelectric electrical activity. In some cases, the stress incontinence event may comprise actions such as coughing, sneezing, laughing, or exercise. Once detected the implantable pulse generator **118** may provide an electrical stimulation pattern **124** to prevent micturition or uncontrolled defecation. In some cases, the threshold level for detecting a stress incontinence event may be modified and adjusted by the individual **126** via graphical user interface on an external input device **114** either via wireless communication **113** or a wired connection **115.**

**[0045]** In some embodiments, a closed-loop configuration of the systems and methods described herein, may comprise a fully synchronized system, as shown in **FIG. 9**. In some cases, an electrode **902**, comprising a sensor and/or stimulator electrode may detect an EMG, ENG, and/or pressure signal through circuitry **904** (e.g., analog to digital circuitry) and then may pass the detected signal to a classifier algorithm **906**. Once the classifier algorithm **906** has classified the detected EMG, ENG, and/or pressure signal as an incontinent event, the classifier may enable an electric stimulation **908** to be delivered to the patient. As shown in **FIG. 9**, the electrical stimulation may be provided by the same electrode **902** that sensed the EMG and/or ENG signal initially.

**[0046]** In some embodiments, a closed loop configuration of the device described herein may be configured to detect an individual's effort in trying to prevent an episode of incontinence. In some instances, the methods and systems described here may supplement the patient's effort with an electrical stimulation pattern via one or more stimulator electrodes **122** sufficient to prevent urinary or fecal defecation. In some cases, an individual's effort may comprise an EMG, ENG, pressure, acceleration, gyroscope, magnetometer, 3-D spatial, or any combination thereof signal at a threshold. In some instances, the threshold myoelectric signal may be detected by one or more sensor electrodes **120**. In some cases, the supplemental excitation, may comprise an excitation signal provided by the stimulator electrodes, described elsewhere herein, with parameters e.g., frequency, pulse width, and/or amplitude such that in combination with the detected individual's effort may prevent an episode of incontinence (e.g., urinary, and/or fecal defecation). In some instances, the supplemental excitation may comprise an excitation signal provided by the stimulator electrodes with parameters e.g., frequency, pulse width, and/or amplitude to prevent an episode of incontinence in response to detecting a stress incontinence event. In some instances, the stress incontinence event may comprise actions such

as coughing, sneezing, laughing, or exercise, detectable by e.g., a gyroscope, accelerometer, and/or magnetometer, described elsewhere herein. In some instances the one or more parameters of the supplemental excitation, may be determined on an individual subject basis and/or on a large-scale population of subjects with similar presentation of incontinence. For example, a given subject's supplemental excitation one or more parameters may be tuned and/or determined by whether such supplemental excitation signal prevented an episode of incontinence in real-time or after the incontinent event through a user interface of the device and systems, described elsewhere herein. In some instances, a given subject's supplemental excitation one or more parameters may be tuned to values and/or parameters found to prevent incontinence events in subjects with similar clinical presentation (e.g., age, type of incontinence, frequency of incontinence events, other subject clinical meta data, etc.).

**[0047]** In some instances, the system and methods described herein may comprise system and methods configured to provide an electrical stimulation to prevent an incontinent event based on a subject and/or patient's purposeful muscle contraction and/or movement, as seen in **FIG. 8.** In some cases, the subject and/or patient **814** may, upon realizing that they may exhibit an incontinent event, induce movement and/or contraction of one or more muscles or muscle groups to trigger an EMG, ENG, pressure, acceleration, gyroscope, magnetometer, 3-D spatial, or any combination thereof signal **818**. In some instances, the induced movement and/or contraction of one or more muscle groups may be amplified **808**, classified (by a classifier) **806**, passed through a control logic algorithm **804**, and used as a trigger **820** to enable the flow of therapy and respective basal **802** and/or active **801,** described elsewhere herein, stimulation pattern parameters through the stimulator **810** and neural interface **812** to prevent an incontinent event. In some cases, the classifier may comprise a machine learning classifier. In some instances, the classifier may comprise an intensity threshold classifier, described elsewhere herein. In some cases, the patient and/or subject **814** may manually **816** enable the delivery of electrical stimulation via a button on the patient controller module **156**, described elsewhere herein.

**[0048]** In some cases, the detection threshold of the implantable pulse generator **118** (i.e., stimulator) may be modified and tuned via a graphical user interface on an external input device **114**. The external input device **114** may be able to modify and tune the threshold of the implantable pulse generator **118** via a wireless communication **113** or a wired connection **115**. In some cases, the implantable pulse generator threshold may be tuned via a healthcare provider on a remote computing device **112** (e.g., a mobile phone, a tablet, a computer, etc.) and transmitted via a wired communication **116** to the implantable pulse generator **118**. Alternatively, the implantable pulse generator threshold may be tuned via a healthcare provider on a remote

computing device **112** (e.g., a mobile phone, a tablet, a computer, etc.) and transmitted via wireless communication **113** to the implantable pulse generator **118**. In some cases, the implantable pulse generator threshold may be tuned via the individual **110** on a remote computing device **112** (e.g., a mobile phone, a tablet, a computer, etc.) and transmitted via a wired communication **116** to the implantable pulse generator **118**. Alternatively, the implantable pulse generator threshold may be tuned via the individual **110** on a remote computing device **112** (e.g., a mobile phone, a tablet, a computer, etc.) and transmitted via wireless communication **113** to the implantable pulse generator **118**.

**[0049]** In some cases, the electrical stimulation pattern **124** provided via one or more stimulator electrodes **122** may be tuned and adjusted by the detected threshold level to supplement an individual's effort to prevent an episode of incontinence. In some instances, the adjusted electrical stimulation pattern **124** may be determined by mapping a detectable physiological signal representing effort and a provided electrical stimulation pattern **124** by, piecewise linear mapping, linear mapping, sigmoidal mapping, or any variations thereof. The electric stimulation pattern **124** may be tuned by modifying or changing the electrical stimulation pattern parameters comprising frequency, pulse-width, and amplitude. In some cases, the electrical stimulation pattern parameters of the implantable pulse generator **118** may be modified and tuned via a graphical user interface on an external input device **114**. The external input device **114** may be able to modify and tune the electrical stimulation pattern parameters of implantable pulse generator **118** via a wireless communication **113** or a wired connection **115**. In some cases, the electrical stimulation pattern parameters of implantable pulse generator **118** may be tuned via a healthcare provider on a remote computing device **112** (e.g., a mobile phone, a tablet, a computer, etc.) and transmitted via a wired communication **116** to the implantable pulse generator **118**. In some cases, the electrical stimulation pattern parameters of implantable pulse generator **118** may be tuned via a healthcare provider on a remote computing device **112** (e.g., a mobile phone, a tablet, a computer, etc.) and transmitted via wireless communication **113** to the implantable pulse generator **118**. In some cases, the electrical stimulation pattern parameters of implantable pulse generator **118** may be tuned by a machine learning model executed by the processor of the implantable pulse generator **118** based on input from the individual **126**. In some cases, the machine learning model may be configured to determine a whether or not a subject is at risk of unwanted micturition and/or fecal defecation based on muscle EMG signals detected by the one or more sensor electrodes. In some cases, the machine learning model may be trained to determine the presence or lack thereof an individual's effort, described elsewhere herein. For example, the machine learning model may be trained

with one or more EMG signals characteristic of a subject's muscle contractions in particular EMG signals that lead to unwanted micturition and/or fecal defecation.

**[0050]** In some embodiments, the electrical stimulation pattern parameters, as described elsewhere herein (e.g., frequency, amplitude, etc.), may be set or determined by a stimulation machine learning model. In some cases, the stimulation machine learning model may comprise a Bayesian optimization model. In some instances, the stimulation machine learning model may be trained with stimulation patterns that users of the devices and systems, described elsewhere herein, indicate as inhibiting incontinent events for particular types and/or subtypes of incontinence. In some cases, the stimulation machine learning model may be trained with the patient's type of incontinence. The stimulation machine learning algorithms may be trained in a cloud computing network and/or server in communication with the implantable and user-devices, described elsewhere herein, and re-distributed or downloaded to one or more users and/or patients. In effect users and/or patients may update and/or download new updates to the software of the devices and systems described herein. This aspect of the invention described herein provides an unexpected result of a patient specific and optimized electrical stimulation signal that would otherwise not be achievable with a traditional stimulator.

**[0051]** One or more machine learning algorithms may be used to construct the machine learning model, such as support vector machines that deploy stepwise backwards parameter selection and/or graphical models, both of which may have advantages of inferring interactions between parameters. For example, machine learning algorithms or other statistical algorithms may be used such as alternating decision trees (ADTree), decision stumps, functional trees (FT), logistic model trees (LMT), logistic regression, random forests (rf), receiver operational characteristic curves (ROC), linear regression, extreme gradient boosting (xgb), classification and regression trees, support vector machines (SVM), generalized additive model using splines (e.g., gamSpline), glmnet, multivariate adaptive regression splint (earth), neural network, k-means clustering, or any machine learning algorithm or statistical algorithm known in the art. One or more algorithms may be used together to generate an ensemble method, wherein the ensemble method may be optimized using a machine learning ensemble meta-algorithm such as boosting (e.g., AdaBoost, LPBoost, TotalBoost, BrownBoost, MadaBoost, LogitBoost, etc.) to reduce bias and/or variance.

**[0052]** In some embodiments, the machine learning algorithm may comprise a constrained machine learning algorithm configured to run on micro-processors. In some cases, the machine learning algorithm may comprise a machine learning algorithm operating on within a TinyML framework. In some instances, the machine learning algorithm, described elsewhere herein may be trained offline. The offline training may be completed on a server, cloud, or other dedicated

computing clusters. In some cases, the offline trained machine learning algorithm could then be downloaded, deployed, and/or imported into the device to iteratively improve upon the device and system performance in preventing incontinent events.

**[0053]** One of ordinary skill would realize that such an off-line training structure is feasible and realized in related but different implementation. For example, such a machine learning architecture may be utilized in performing "wake up-word" text classification that are commonly seen in smartphone devices (e.g., "hey siri", "okay google", etc.). In some cases, the machine learning algorithms described herein may operate within a framework similar to the "wake up-words" speech machine learning classifier. In some cases, the machine learning algorithms described herein may operate on processing power and memory allocation determined to be sufficient for "wake up" speech machine learning classifiers.

**[0054]** In some cases, the software, described elsewhere herein, may be executed by a processor located on the implanted stimulator. In some cases, the software located on the implanted stimulator may utilize a TinyML constrained machine learning model to accommodate the processing and memory parameters of the implanted stimulator. In some instances, the software may be executed offline on a cloud based computing and/or dedicated computing cluster(s). In some cases, the offline processing workflow may include a high-speed (Bluetooth, Wi-Fi, medical implant communication systems, etc.) data transfer between the implanted stimulator and a local personal computing device (smartphone, tablet, laptop, etc.). The personal processing device may then communicate the implanted stimulator data to a one or more cloud and/or computer clusters that will then send back a resulting output, command, and/or notification to the device. In some cases, the command and/or notification may comprise a warning, alert, initiation of electrical stimulation, or any combination thereof. In some cases, the command may comprise the output of a machine learning classifier configured to determine a threshold intensity of EMG and/or ENG signals indicative of an incontinence event.

**[0055]** The machine learning models may be trained on one or more datasets. In some instances, the one or more datasets may comprise data generated by a user and/or subject, or data generated by a population or segment thereof. In some cases, the data generated by subject and/or the data generated by a population may comprise effort signals, excitation signals, that indicated an incontinent event, and prevented an incontinent event, respectively. In some cases, the devices, systems, and corresponding methods described herein, may record user data and/or input of the user when interacting with the systems and devices described elsewhere herein. In some cases, the data may comprise user labeled EMG, ENG, accelerometer, gyroscope, or any combination thereof sensors, as described elsewhere herein, that lead to an incontinent event. In some cases, these signals may be obtained from the device **1302**, and used in characterizing

**1304** and training a machine learning classifier **1306**, as seen in **FIG. 13.** In some instances, the trained machine learning classifiers trained on or more datasets may then be downloaded to each patient's device **1308** to further improve the machine learning classifier's accuracy. In some cases, the machine learning models may be configured to sense subject effort and/or providing sufficient excitation based on e.g., parameters of frequency, amplitude, and/or pulse-width as described elsewhere herein. In some instances, the datasets of one or more individuals may be pooled together as a training dataset where the subjects show characteristics of similarity between clinical presentation and parameters of excitatory/sensory input. In some cases, clinical presentation may comprise clinical incontinence type, subject clinical meta data, e.g., gender, age, past medical history, current medications taken, past surgical intervention, etc. In some cases, a pooled training datasets may be utilized for an individual during the initial period of training a device implanted into a subject.

**[0056]** In some cases, the one or more machine learning models, described elsewhere herein, may be trained on raw and/or processed signals measured by the devices, sensors, and systems, described elsewhere herein. In some cases, the processed signals may comprise original raw signals that have been filtered to optimize the signal-to-noise ratio of the raw signal. In some cases, the filter may comprise a high-pass, low-pass, band-pass, notch, or any combination thereof filters. In some instances, the one or more machine learning models may alternatively or in addition to, be trained on user feedback regarding prior excitation signal parameters and whether or not such excitation signal parameters prevented an incontinent event.

**[0057]** In some aspects, the disclosure provides a method of processing detected signals **1001**, described elsewhere herein to determine incontinent event precursor signal intensity thresholds, as seen in **FIG. 10**. In some cases, the EMG, ENG, accelerometer, gyroscope, magnetometer, pressure sensor signals, or any combination thereof signals **1000** may be detected through an amplifier circuit **1002**. In some cases, the amplifier circuit may comprise an operational amplifier circuit.

**[0058]** In some instances, the amplifier circuit may be configured to amplify signals from about 10 microvolt (μV) to about 1,000 μV. In some instances, the amplifier circuit may be configured to amplify signals from about 10 μV to about 50 μV, about 10 μV to about 100 μV, about 10 μV to about 150 μV, about 10 μV to about 300 μV, about 10 μV to about 500 μV, about 10 μV to about 700 μV, about 10 μV to about 900 μV, about 10 μV to about 1,000 μV, about 50 μV to about 100 μV, about 50 μV to about 150 μV, about 50 μV to about 300 μV, about 50 μV to about 500 μV, about 50 μV to about 700 μV, about 50 μV to about 900 μV, about 50 μV to about 1,000 μV, about 100 μV to about 150 μV, about 100 μV to about 300 μV, about 100 μV to about 500 μV, about 100 μV to about 700 μV, about 100 μV to about 900 μV,

about 100 μV to about 1,000 μV, about 150 μV to about 300 μV, about 150 μV to about 500 μV, about 150 μV to about 700 μV, about 150 μV to about 900 μV, about 150 μV to about 1,000 μV, about 300 μV to about 500 μV, about 300 μV to about 700 μV, about 300 μV to about 900 μV, about 300 μV to about 1,000 μV, about 500 μV to about 700 μV, about 500 μV to about 900 μV, about 500 μV to about 1,000 μV, about 700 μV to about 900 μV, about 700 μV to about 1,000 μV, or about 900 μV to about 1,000 μV. In some instances, the amplifier circuit may be configured to amplify signals from about 10 μV, about 50 μV, about 100 μV, about 150 μV, about 300 μV, about 500 μV, about 700 μV, about 900 μV, or about 1,000 μV. In some instances, the amplifier circuit may be configured to amplify signals from at least about 10 μV, about 50 μV, about 100 μV, about 150 μV, about 300 μV, about 500 μV, about 700 μV, or about 900 μV. In some instances, the amplifier circuit may be configured to amplify signals from at most about 50 μV, about 100 μV, about 150 μV, about 300 μV, about 500 μV, about 700 μV, about 900 μV, or about 1,000 μV.

**[0059]** In some cases, the amplifier circuit may be configured to amplify signals with a frequency of about 1 Hz to about 1,500 Hz. In some cases, the amplifier circuit may be configured to amplify signals with a frequency of about 1 Hz to about 20 Hz, about 1 Hz to about 40 Hz, about 1 Hz to about 80 Hz, about 1 Hz to about 100 Hz, about 1 Hz to about 150 Hz, about 1 Hz to about 200 Hz, about 1 Hz to about 250 Hz, about 1 Hz to about 500 Hz, about 1 Hz to about 750 Hz, about 1 Hz to about 1,000 Hz, about 1 Hz to about 1,500 Hz, about 20 Hz to about 40 Hz, about 20 Hz to about 80 Hz, about 20 Hz to about 100 Hz, about 20 Hz to about 150 Hz, about 20 Hz to about 200 Hz, about 20 Hz to about 250 Hz, about 20 Hz to about 500 Hz, about 20 Hz to about 750 Hz, about 20 Hz to about 1,000 Hz, about 20 Hz to about 1,500 Hz, about 40 Hz to about 80 Hz, about 40 Hz to about 100 Hz, about 40 Hz to about 150 Hz, about 40 Hz to about 200 Hz, about 40 Hz to about 250 Hz, about 40 Hz to about 500 Hz, about 40 Hz to about 750 Hz, about 40 Hz to about 1,000 Hz, about 40 Hz to about 1,500 Hz, about 80 Hz to about 100 Hz, about 80 Hz to about 150 Hz, about 80 Hz to about 200 Hz, about 80 Hz to about 250 Hz, about 80 Hz to about 500 Hz, about 80 Hz to about 750 Hz, about 80 Hz to about 1,000 Hz, about 80 Hz to about 1,500 Hz, about 100 Hz to about 150 Hz, about 100 Hz to about 200 Hz, about 100 Hz to about 250 Hz, about 100 Hz to about 500 Hz, about 100 Hz to about 750 Hz, about 100 Hz to about 1,000 Hz, about 100 Hz to about 1,500 Hz, about 150 Hz to about 200 Hz, about 150 Hz to about 250 Hz, about 150 Hz to about 500 Hz, about 150 Hz to about 750 Hz, about 150 Hz to about 1,000 Hz, about 150 Hz to about 1,500 Hz, about 200 Hz to about 250 Hz, about 200 Hz to about 500 Hz, about 200 Hz to about 750 Hz, about 200 Hz to about 1,000 Hz, about 200 Hz to about 1,500 Hz, about 250 Hz to about 500 Hz, about 250 Hz to about 750 Hz, about 250 Hz to about 1,000 Hz, about 250 Hz to about 1,500 Hz, about 500

Hz to about 750 Hz, about 500 Hz to about 1,000 Hz, about 500 Hz to about 1,500 Hz, about 750 Hz to about 1,000 Hz, about 750 Hz to about 1,500 Hz, or about 1,000 Hz to about 1,500 Hz. In some cases, the amplifier circuit may be configured to amplify signals with a frequency of about 1 Hz, about 20 Hz, about 40 Hz, about 80 Hz, about 100 Hz, about 150 Hz, about 200 Hz, about 250 Hz, about 500 Hz, about 750 Hz, about 1,000 Hz, or about 1,500 Hz. In some cases, the amplifier circuit may be configured to amplify signals with a frequency of at least about 1 Hz, about 20 Hz, about 40 Hz, about 80 Hz, about 100 Hz, about 150 Hz, about 200 Hz, about 250 Hz, about 500 Hz, about 750 Hz, or about 1,000 Hz. In some cases, the amplifier circuit may be configured to amplify signals with a frequency of at most about 20 Hz, about 40 Hz, about 80 Hz, about 100 Hz, about 150 Hz, about 200 Hz, about 250 Hz, about 500 Hz, about 750 Hz, about 1,000 Hz, or about 1,500 Hz.

**[0060]** In some cases, the amplified signal may then be passed to a filter **1004**. In some cases, the filter may comprise a low-pass, high-pass, band-pass, notch, or any combination thereof filter.

**[0061]** In some cases, the filter may be configured to filter the frequency band of about 1 Hz to about 70 Hz. In some cases, the filter may be configured to filter the frequency band of about 1 Hz to about 5 Hz, about 1 Hz to about 10 Hz, about 1 Hz to about 15 Hz, about 1 Hz to about 20 Hz, about 1 Hz to about 25 Hz, about 1 Hz to about 40 Hz, about 1 Hz to about 50 Hz, about 1 Hz to about 60 Hz, about 1 Hz to about 70 Hz, about 5 Hz to about 10 Hz, about 5 Hz to about 15 Hz, about 5 Hz to about 20 Hz, about 5 Hz to about 25 Hz, about 5 Hz to about 40 Hz, about 5 Hz to about 50 Hz, about 5 Hz to about 60 Hz, about 5 Hz to about 70 Hz, about 10 Hz to about 15 Hz, about 10 Hz to about 20 Hz, about 10 Hz to about 25 Hz, about 10 Hz to about 40 Hz, about 10 Hz to about 50 Hz, about 10 Hz to about 60 Hz, about 10 Hz to about 70 Hz, about 15 Hz to about 20 Hz, about 15 Hz to about 25 Hz, about 15 Hz to about 40 Hz, about 15 Hz to about 50 Hz, about 15 Hz to about 60 Hz, about 15 Hz to about 70 Hz, about 20 Hz to about 25 Hz, about 20 Hz to about 40 Hz, about 20 Hz to about 50 Hz, about 20 Hz to about 60 Hz, about 20 Hz to about 70 Hz, about 25 Hz to about 40 Hz, about 25 Hz to about 50 Hz, about 25 Hz to about 60 Hz, about 25 Hz to about 70 Hz, about 40 Hz to about 50 Hz, about 40 Hz to about 60 Hz, about 40 Hz to about 70 Hz, about 50 Hz to about 60 Hz, about 50 Hz to about 70 Hz, or about 60 Hz to about 70 Hz. In some cases, the filter may be configured to filter the frequency band of about 1 Hz, about 5 Hz, about 10 Hz, about 15 Hz, about 20 Hz, about 25 Hz, about 40 Hz, about 50 Hz, about 60 Hz, or about 70 Hz. In some cases, the filter may be configured to filter the frequency band of at least about 1 Hz, about 5 Hz, about 10 Hz, about 15 Hz, about 20 Hz, about 25 Hz, about 40 Hz, about 50 Hz, or about 60 Hz. In some cases, the filter may be

configured to filter the frequency band of at most about 5 Hz, about 10 Hz, about 15 Hz, about 20 Hz, about 25 Hz, about 40 Hz, about 50 Hz, about 60 Hz, or about 70 Hz.

**[0062]** After passing the signal through the filter, the systems and methods described herein, may rectify **1006** the filtered signal. In the process of rectifying the signal, as understood by one of ordinary skill in the art, the signal will convert the alternating current detected signal to a direct current signal. The rectified signal may be additionally filtered with a low pass filter **1007** that may smooth the rectified signal. The signal may be subjected to a threshold detector **1008**, where the threshold detector determines the onset of an incontinent event from a threshold intensity value of the rectified and smooth processed signals **1000** of EMG, ENG, accelerometer, gyroscope, magnetometer, pressure sensor signals, or any combination thereof. If an incontinent event is determined by the threshold detector **1008**, the system may enable the delivery of electrical stimulation **1010**, as described elsewhere herein.

**[0063]** In some cases, training may be supervised training. Alternatively, training may be unsupervised training. In some instances, the data set may be a retrospective data set. Alternatively, the data set may be prospectively developed dataset, and the machine learning model may be iteratively improved over time.

**[0064]** In some aspects, the disclosure provided herein may comprise a method to train a machine learning model with a data set that comprises sensed signal profiles and excitation signals that have and have not prevented incontinent events. The method may comprise the steps of: preprocessing, training, and predicting.

**[0065]** The method may extract training data from a database, or intake new data, described elsewhere herein. The preprocessing step may apply one or more transformations to standardize the training data or new data for the training step or the prediction step. The preprocessed training data may be passed to the training step, which may construct a machine learning model based on training data. The training step may further comprise a validation step, configured to validate the trained machine learning model using any appropriate validation algorithm (e.g., Stratified K-fold cross-validation). In some cases, the k-fold cross-validation may comprise at least 1-fold, 2, folds, 3 folds, 4 folds, 5 folds, 6 folds, 7 folds, 8 folds, 9 folds, or 10 folds. In some cases, the k-fold cross-validation may comprise up to 1-fold, 2 folds, 3 folds, 4 folds, 5 folds, 6 folds, 7 folds, 8 folds, 9 folds, or 10 folds.

**[0066]** The preprocessing step may apply one or more transformations to the training data to clean and normalize the data. The preprocessing step may be configured to discard parameters which contain spurious data or contain very few observations. The preprocessing module can be further configured to standardize the encoding of parameter values. The preprocessing step may recognize the encoding variation for the same value and standardize the dataset to have a

uniform encoding for a given parameter value. The processing step may thus reduce irregularities in the input data for the training and prediction steps, thereby improving the robustness of the training and prediction steps.

**[0067]** The training step may utilize a machine learning algorithm or other algorithm to construct and train a machine learning model to be used in the association of an excitation stimulation, sensed signal profile, and the presence or lack thereof an incontinent event. A machine learning model may be constructed to capture, based on the training data, the statistical relationship, if any, between excitation stimulation parameters, sensed signal profiles, and the presence or lack thereof an incontinent event.

**[0068]** The machine learning algorithm may have an accuracy greater than about 60%, 70%, 80%, 85%, 90%, 95%, or 99%. The machine learning algorithm may have a positive predictive value greater than about 60%, 70%, 75%, 80%, 85%, 90%, 95%, or 99%. The machine learning algorithm may have a negative predictive value greater than about 60%, 70%, 80%, 90%, 95%, or 99%.

**[0069]** Machine learning data analysis, machine learning model training, or any combination thereof may be performed using one or more of many programming languages and platforms known in the art, such as R, Weka, Python, and/or MATLAB, for example.

**[0070]** The use of such closed-loop bioelectronic systems may potentially provide improved electrical stimulation devices to prevent or reduce stress incontinence. In some cases, the use of such closed-loop bioelectronic systems may provide a more precise approach to prevent or reduce or treat urge incontinence and mixed incontinence (combination of urge and stress incontinence). In some instances, individuals having the implanted device may provide feedback to the parameters provided positive outcomes, negative outcomes, or neutral outcomes. In some cases, positive outcomes may comprise preventing an incontinence event. In some instances, negative outcomes may comprise not preventing an incontinence event, producing pain, or any combination thereof. In some cases, neutral outcomes may comprise not preventing an incontinence event, not producing pain, or any combination thereof . In some cases, the positive outcomes, negative outcomes, neutral outcomes, sensor data, or any combination thereof from a plurality of individuals having the implanted device may be used in tuning algorithms to suggest changes to sensor electrode thresholds and electrical stimulation patterns **124**.

***Electrical Simulation Pattern***

**[0071]** In some cases, the electric stimulation pattern provided by an implantable pulse generator and one or more stimulator electrodes may be modified or changed to suit the needs of the individual in need thereof preventing an episode of incontinence. In some cases, the one or

more stimulator electrodes **122** may output an electric stimulation pattern **124** in response to what is detected by the one or more sensor electrodes **120**. In some cases, the electric stimulation pattern **124** may comprise one or more electrical signals. For example, the electric stimulation pattern **124** may comprise a continuous wave signal (e.g., an electric stimulation signal with a constant frequency in time) and a burst or beating signal superimposed onto the continuous wave signal. In some cases, the burst or beating signal may only be enabled for a short duration of time compared to the continual temporal aspect of the continuous wave signal. In some instances, the combination of the continuous wave signal and/or a burst or beating signal may increase a pain threshold of a subject allowing the stimulator to provide higher amplitude electric stimulation burst pattern to prevent incontinent events. In some instances, the frequency of the electric stimulation pattern may be modified or changed. The frequency pattern may comprise a constant profile, swept profile, beating profile, burst profile, chirped profile, monophasic profile, biphasic profile, or any combination thereof. In some instances, the constant profile is comprised of excitation values at a constant amplitude with a frequency value of 0 Hz. In some cases, a swept profile may comprise a signal with time varying frequency of excitation. In some instances, a beating profile may comprise a combination of one or more excitation signals of varying frequency. In some cases, the burst profile may comprise a signal with a constant frequency that is enveloped by a square, delta, sine, or any combination thereof envelope functions. In some instances, a monophasic profile may comprise an excitation signal with only positive or negative amplitude (e.g., signal with values from 0 to -5V or 0 to 5V only) with a constant frequency. In some cases, the beating or burst profile may comprise an electric simulation pattern that is provided to a patient and/or subject for during an on-state for a first period of time and is not provided to a patient and/or subject during an off-state for a second period of time. In some cases, beating or bust profiles may provide an excitation signal that may provide for a lengthier period of muscle excitation without suffering muscle fatigue. In some cases, the on-state and/or off-state may comprise about 0.1 second (s) to about 6.5 s. In some cases, the on-state and/or off-state may comprise about 0.1 s to about 0.5 s, about 0.1 s to about 1 s, about 0.1 s to about 1.2 s, about 0.1 s to about 1.5 s, about 0.1 s to about 2 s, about 0.1 s to about 2.5 s, about 0.1 s to about 3 s, about 0.1 s to about 3.5 s, about 0.1 s to about 4 s, about 0.1 s to about 5 s, about 0.1 s to about 6.5 s, about 0.5 s to about 1 s, about 0.5 s to about 1.2 s, about 0.5 s to about 1.5 s, about 0.5 s to about 2 s, about 0.5 s to about 2.5 s, about 0.5 s to about 3 s, about 0.5 s to about 3.5 s, about 0.5 s to about 4 s, about 0.5 s to about 5 s, about 0.5 s to about 6.5 s, about 1 s to about 1.2 s, about 1 s to about 1.5 s, about 1 s to about 2 s, about 1 s to about 2.5 s, about 1 s to about 3 s, about 1 s to about 3.5 s, about 1 s to about 4 s, about 1 s to about 5 s, about 1 s to about 6.5 s, about 1.2 s to about 1.5 s, about 1.2 s to about 2 s, about 1.2 s to about

2.5 s, about 1.2 s to about 3 s, about 1.2 s to about 3.5 s, about 1.2 s to about 4 s, about 1.2 s to about 5 s, about 1.2 s to about 6.5 s, about 1.5 s to about 2 s, about 1.5 s to about 2.5 s, about 1.5 s to about 3 s, about 1.5 s to about 3.5 s, about 1.5 s to about 4 s, about 1.5 s to about 5 s, about 1.5 s to about 6.5 s, about 2 s to about 2.5 s, about 2 s to about 3 s, about 2 s to about 3.5 s, about 2 s to about 4 s, about 2 s to about 5 s, about 2 s to about 6.5 s, about 2.5 s to about 3 s, about 2.5 s to about 3.5 s, about 2.5 s to about 4 s, about 2.5 s to about 5 s, about 2.5 s to about 6.5 s, about 3 s to about 3.5 s, about 3 s to about 4 s, about 3 s to about 5 s, about 3 s to about 6.5 s, about 3.5 s to about 4 s, about 3.5 s to about 5 s, about 3.5 s to about 6.5 s, about 4 s to about 5 s, about 4 s to about 6.5 s, or about 5 s to about 6.5 s. In some cases, the on-state and/or off-state may comprise about 0.1 s, about 0.5 s, about 1 s, about 1.2 s, about 1.5 s, about 2 s, about 2.5 s, about 3 s, about 3.5 s, about 4 s, about 5 s, or about 6.5 s. In some cases, the on-state and/or off-state may comprise at least about 0.1 s, about 0.5 s, about 1 s, about 1.2 s, about 1.5 s, about 2 s, about 2.5 s, about 3 s, about 3.5 s, about 4 s, or about 5 s. In some cases, the on-state and/or off-state may comprise at most about 0.5 s, about 1 s, about 1.2 s, about 1.5 s, about 2 s, about 2.5 s, about 3 s, about 3.5 s, about 4 s, about 5 s, or about 6.5 s.

**[0072]** In some instances, an electrical stimulation pattern provided during an on-state may comprise an oscillating electric stimulation pattern. In some cases, the oscillating electric stimulation pattern may comprise one or more frequencies. In some cases, the frequency of the oscillating electrical stimulation may be chosen based upon prior knowledge of how similar subjects respond with a particular frequency or range of frequencies of the oscillating electrical stimulation pattern. In some cases, a low frequency (e.g., 2-15 Hz) may induces reductions in bladder contractility and thus prevent voiding or a potential incontinent event. In some instances, a higher frequency (e.g., 20-50Hz) may lead to potentiation of bladder contractions and voiding. In some instances, the frequency of the electrical stimulation pattern may be about 1 Hz to about 60 Hz. In some instances, the frequency of the electrical stimulation pattern may be about 1 Hz to about 5 Hz, about 1 Hz to about 10 Hz, about 1 Hz to about 15 Hz, about 1 Hz to about 25 Hz, about 1 Hz to about 30 Hz, about 1 Hz to about 35 Hz, about 1 Hz to about 40 Hz, about 1 Hz to about 45 Hz, about 1 Hz to about 50 Hz, about 1 Hz to about 55 Hz, about 1 Hz to about 60 Hz, about 5 Hz to about 10 Hz, about 5 Hz to about 15 Hz, about 5 Hz to about 25 Hz, about 5 Hz to about 30 Hz, about 5 Hz to about 35 Hz, about 5 Hz to about 40 Hz, about 5 Hz to about 45 Hz, about 5 Hz to about 50 Hz, about 5 Hz to about 55 Hz, about 5 Hz to about 60 Hz, about 10 Hz to about 15 Hz, about 10 Hz to about 25 Hz, about 10 Hz to about 30 Hz, about 10 Hz to about 35 Hz, about 10 Hz to about 40 Hz, about 10 Hz to about 45 Hz, about 10 Hz to about 50 Hz, about 10 Hz to about 55 Hz, about 10 Hz to about 60 Hz, about 15 Hz to about 25 Hz, about 15 Hz to about 30 Hz, about 15 Hz to about 35 Hz, about 15 Hz to about 40 Hz, about 15 Hz to

about 45 Hz, about 15 Hz to about 50 Hz, about 15 Hz to about 55 Hz, about 15 Hz to about 60 Hz, about 25 Hz to about 30 Hz, about 25 Hz to about 35 Hz, about 25 Hz to about 40 Hz, about 25 Hz to about 45 Hz, about 25 Hz to about 50 Hz, about 25 Hz to about 55 Hz, about 25 Hz to about 60 Hz, about 30 Hz to about 35 Hz, about 30 Hz to about 40 Hz, about 30 Hz to about 45 Hz, about 30 Hz to about 50 Hz, about 30 Hz to about 55 Hz, about 30 Hz to about 60 Hz, about 35 Hz to about 40 Hz, about 35 Hz to about 45 Hz, about 35 Hz to about 50 Hz, about 35 Hz to about 55 Hz, about 35 Hz to about 60 Hz, about 40 Hz to about 45 Hz, about 40 Hz to about 50 Hz, about 40 Hz to about 55 Hz, about 40 Hz to about 60 Hz, about 45 Hz to about 50 Hz, about 45 Hz to about 55 Hz, about 45 Hz to about 60 Hz, about 50 Hz to about 55 Hz, about 50 Hz to about 60 Hz, or about 55 Hz to about 60 Hz. In some instances, the frequency of the electrical stimulation pattern may be about 1 Hz, about 5 Hz, about 10 Hz, about 15 Hz, about 25 Hz, about 30 Hz, about 35 Hz, about 40 Hz, about 45 Hz, about 50 Hz, about 55 Hz, or about 60 Hz. In some instances, the frequency of the electrical stimulation pattern may be at least about 1 Hz, about 5 Hz, about 10 Hz, about 15 Hz, about 25 Hz, about 30 Hz, about 35 Hz, about 40 Hz, about 45 Hz, about 50 Hz, or about 55 Hz. In some instances, the frequency of the electrical stimulation pattern may be at most about 5 Hz, about 10 Hz, about 15 Hz, about 25 Hz, about 30 Hz, about 35 Hz, about 40 Hz, about 45 Hz, about 50 Hz, about 55 Hz, or about 60 Hz. In some embodiments, the frequency refers to mean frequency of the electrical stimulation pattern. In some embodiments, the frequency refers to the median frequency. In some embodiments, the frequency refers to the maximum frequency.

**[0073]** In some cases, a burst signal with an on-state and/or an off-state, described elsewhere herein may be provided to the subject to prevent fatigue on the one or more muscles innervated by the subject's pudendal nerve. In some cases, the burst electrical stimulation pattern may comprise one or more frequencies described elsewhere herein.

**[0074]** In some instances, the amplitude of the electric stimulation pattern may be modified or changed. In some instances, the amplitude of the electrical stimulation pattern may be about 1 volt (V) to about 15 V. In some instances, the amplitude of the electrical stimulation pattern may be about 1 V to about 2 V, about 1 V to about 3 V, about 1 V to about 4 V, about 1 V to about 5 V, about 1 V to about 6 V, about 1 V to about 7 V, about 1 V to about 8 V, about 1 V to about 9 V, about 1 V to about 10 V, about 1 V to about 12 V, about 1 V to about 15 V, about 2 V to about 3 V, about 2 V to about 4 V, about 2 V to about 5 V, about 2 V to about 6 V, about 2 V to about 7 V, about 2 V to about 8 V, about 2 V to about 9 V, about 2 V to about 10 V, about 2 V to about 12 V, about 2 V to about 15 V, about 3 V to about 4 V, about 3 V to about 5 V, about 3 V to about 6 V, about 3 V to about 7 V, about 3 V to about 8 V, about 3 V to about 9 V, about 3 V to about 10 V, about 3 V to about 12 V, about 3 V to about 15 V, about 4 V to about 5 V,

about 4 V to about 6 V, about 4 V to about 7 V, about 4 V to about 8 V, about 4 V to about 9 V, about 4 V to about 10 V, about 4 V to about 12 V, about 4 V to about 15 V, about 5 V to about 6 V, about 5 V to about 7 V, about 5 V to about 8 V, about 5 V to about 9 V, about 5 V to about 10 V, about 5 V to about 12 V, about 5 V to about 15 V, about 6 V to about 7 V, about 6 V to about 8 V, about 6 V to about 9 V, about 6 V to about 10 V, about 6 V to about 12 V, about 6 V to about 15 V, about 7 V to about 8 V, about 7 V to about 9 V, about 7 V to about 10 V, about 7 V to about 12 V, about 7 V to about 15 V, about 8 V to about 9 V, about 8 V to about 10 V, about 8 V to about 12 V, about 8 V to about 15 V, about 9 V to about 10 V, about 9 V to about 12 V, about 9 V to about 15 V, about 10 V to about 12 V, about 10 V to about 15 V, or about 12 V to about 15 V. In some instances, the amplitude of the electrical stimulation pattern may be about 1 V, about 2 V, about 3 V, about 4 V, about 5 V, about 6 V, about 7 V, about 8 V, about 9 V, about 10 V, about 12 V, or about 15 V. In some instances, the amplitude of the electrical stimulation pattern may be at least about 1 V, about 2 V, about 3 V, about 4 V, about 5 V, about 6 V, about 7 V, about 8 V, about 9 V, about 10 V, or about 12 V. In some instances, the amplitude of the electrical stimulation pattern may be at most about 2 V, about 3 V, about 4 V, about 5 V, about 6 V, about 7 V, about 8 V, about 9 V, about 10 V, about 12 V, or about 15 V. In some embodiments, the amplitude refers to the mean amplitude. In some embodiments, the amplitude refers to the median amplitude. In some embodiments, the amplitude refers to the maximum amplitude. In some embodiments, the amplitude refers to peak to peak amplitude.

**[0075]** In some instances, the amplitude of the electrical stimulation pattern may be about 0.05 milliampere (mA) to about 10 mA. In some instances, the amplitude of the electrical stimulation pattern may be about 0.05 mA to about 1 mA, about 0.05 mA to about 2 mA, about 0.05 mA to about 3 mA, about 0.05 mA to about 4 mA, about 0.05 mA to about 5 mA, about 0.05 mA to about 6 mA, about 0.05 mA to about 7 mA, about 0.05 mA to about 8 mA, about 0.05 mA to about 9 mA, about 0.05 mA to about 10 mA, about 1 mA to about 2 mA, about 1 mA to about 3 mA, about 1 mA to about 4 mA, about 1 mA to about 5 mA, about 1 mA to about 6 mA, about 1 mA to about 7 mA, about 1 mA to about 8 mA, about 1 mA to about 9 mA, about 1 mA to about 10 mA, about 2 mA to about 3 mA, about 2 mA to about 4 mA, about 2 mA to about 5 mA, about 2 mA to about 6 mA, about 2 mA to about 7 mA, about 2 mA to about 8 mA, about 2 mA to about 9 mA, about 2 mA to about 10 mA, about 3 mA to about 4 mA, about 3 mA to about 5 mA, about 3 mA to about 6 mA, about 3 mA to about 7 mA, about 3 mA to about 8 mA, about 3 mA to about 9 mA, about 3 mA to about 10 mA, about 4 mA to about 5 mA, about 4 mA to about 6 mA, about 4 mA to about 7 mA, about 4 mA to about 8 mA, about 4 mA to about 9 mA, about 4 mA to about 10 mA, about 5 mA to about 6 mA, about 5 mA to about 7 mA, about 5 mA to about 8 mA, about 5 mA to about 9 mA, about 5 mA to about 10 mA, about

6 mA to about 7 mA, about 6 mA to about 8 mA, about 6 mA to about 9 mA, about 6 mA to about 10 mA, about 7 mA to about 8 mA, about 7 mA to about 9 mA, about 7 mA to about 10 mA, about 8 mA to about 9 mA, about 8 mA to about 10 mA, or about 9 mA to about 10 mA. In some instances, the amplitude of the electrical stimulation pattern may be about 0.05 mA, about 1 mA, about 2 mA, about 3 mA, about 4 mA, about 5 mA, about 6 mA, about 7 mA, about 8 mA, about 9 mA, or about 10 mA. In some instances, the amplitude of the electrical stimulation pattern may be at least about 0.05 mA, about 1 mA, about 2 mA, about 3 mA, about 4 mA, about 5 mA, about 6 mA, about 7 mA, about 8 mA, or about 9 mA. In some instances, the amplitude of the electrical stimulation pattern may be at most about 1 mA, about 2 mA, about 3 mA, about 4 mA, about 5 mA, about 6 mA, about 7 mA, about 8 mA, about 9 mA, or about 10 mA. In some embodiments, the amplitude refers to the mean amplitude. In some embodiments, the amplitude refers to the median amplitude. In some embodiments, the amplitude refers to the maximum amplitude.

**[0076]** In some instances, the pulse width of the electric stimulation pattern may be modified or changed. In some instances, the pulse width of the electrical stimulation pattern may be about 60 μs to about 390 μs. In some instances, the pulse width of the electrical stimulation pattern may be about 60 μs to about 90 μs, about 60 μs to about 120 μs, about 60 μs to about 150 μs, about 60 μs to about 180 μs, about 60 μs to about 210 μs, about 60 μs to about 240 μs, about 60 μs to about 270 μs, about 60 μs to about 300 μs, about 60 μs to about 330 μs, about 60 μs to about 360 μs, about 60 μs to about 390 μs, about 90 μs to about 120 μs, about 90 μs to about 150 μs, about 90 μs to about 180 μs, about 90 μs to about 210 μs, about 90 μs to about 240 μs, about 90 μs to about 270 μs, about 90 μs to about 300 μs, about 90 μs to about 330 μs, about 90 μs to about 360 μs, about 90 μs to about 390 μs, about 120 μs to about 150 μs, about 120 μs to about 180 μs, about 120 μs to about 210 μs, about 120 μs to about 240 μs, about 120 μs to about 270 μs, about 120 μs to about 300 μs, about 120 μs to about 330 μs, about 120 μs to about 360 μs, about 120 μs to about 390 μs, about 150 μs to about 180 μs, about 150 μs to about 210 μs, about 150 μs to about 240 μs, about 150 μs to about 270 μs, about 150 μs to about 300 μs, about 150 μs to about 330 μs, about 150 μs to about 360 μs, about 150 μs to about 390 μs, about 180 μs to about 210 μs, about 180 μs to about 240 μs, about 180 μs to about 270 μs, about 180 μs to about 300 μs, about 180 μs to about 330 μs, about 180 μs to about 360 μs, about 180 μs to about 390 μs, about 210 μs to about 240 μs, about 210 μs to about 270 μs, about 210 μs to about 300 μs, about 210 μs to about 330 μs, about 210 μs to about 360 μs, about 210 μs to about 390 μs, about 240 μs to about 270 μs, about 240 μs to about 300 μs, about 240 μs to about 330 μs, about 240 μs to about 360 μs, about 240 μs to about 390 μs, about 270 μs to about 300 μs, about 270 μs to about 330 μs, about 270 μs to about 360 μs, about 270 μs to about 390 μs, about 300 μs to about

330 μs, about 300 μs to about 360 μs, about 300 μs to about 390 μs, about 330 μs to about 360 μs, about 330 μs to about 390 μs, or about 360 μs to about 390 μs. In some instances, the pulse width of the electrical stimulation pattern may be about 60 μs, about 90 μs, about 120 μs, about 150 μs, about 180 μs, about 210 μs, about 240 μs, about 270 μs, about 300 μs, about 330 μs, about 360 μs, or about 390 μs. In some instances, the pulse width of the electrical stimulation pattern may be at least about 60 μs, about 90 μs, about 120 μs, about 150 μs, about 180 μs, about 210 μs, about 240 μs, about 270 μs, about 300 μs, about 330 μs, or about 360 μs. In some instances, the pulse width of the electrical stimulation pattern may be at most about 90 μs, about 120 μs, about 150 μs, about 180 μs, about 210 μs, about 240 μs, about 270 μs, about 300 μs, about 330 μs, about 360 μs, or about 390 μs. In some embodiments, the pulse width refers to the mean pulse width. In some embodiments, the pulse width refers to the median pulse width. In some embodiments, the pulse width refers to the maximum pulse width.

**Sensors for Use with Embodiments of the Device Described Herein**

**[0077]** In some instances, a sensor electrode for use with embodiments of the device described herein may be configured to senses a parameter associated with a response of an individual intending to prevent an episode of incontinence or that indicates the individual may have an episode of incontinence. In some cases, the sensor electrode may be configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding. In some cases, a sensor electrode may be configured to sense bulk motion or anatomical stress of an individual. In some instances, the sensor electrode may comprise a sensor configured to detect electromyography (EMG) signals. In some cases, the sensor electrode may be configured to sense myoelectric activity. In some instances, an EMG signal threshold may determine that a contraction of at least one pelvic muscle has occurred. In some cases, the strength of the EMG signal may be proportional to the strength of the contraction of at least one pelvic muscle. In some instances, the sensor electrode detects an action potential signal. In some cases, the device comprises an amplifier to amplify the signal obtained by the sensor electrode, to facilitate analysis and classification of the signal by the processor.

**[0078]** In some cases, the sensor electrode may be implanted within the pelvis of the individual. In some instances, the sensor electrode may be implanted at or adjacent to the pudendal nerve. In some cases, the sensor electrode may be implanted at or adjacent to the sacral nerve. In some cases, the sensor electrode may be implanted within or adjacent to one or more of the pelvic muscles. In some instances, the sensor electrode may be implanted at or adjacent to the pelvic floor. In some cases, the sensor electrode may be implanted at or adjacent to the

urethral sphincter. In some instances, the sensor electrode may be implanted at or adjacent to one or more of the urethra, ureter, and bladder. In some cases, the sensor electrode may be implanted at or adjacent to the anal sphincter. In some instances, the sensor electrode may be implanted at or adjacent to one or more of the anus, rectum, and bowel. In some instances, the devices described herein may comprise a plurality of sensor electrodes. In some cases, the devices described herein may comprise one or more sensor electrodes. In some instances, the devices described herein may comprise a different sensor electrode, or a second sensor electrode. In some cases, the sensor electrode may detect the signal from a muscle area innervated by a first pudendal nerve and the different or second sensor electrode may detect signal from a muscle area innervated by a second pudendal nerve. In some instances, the sensor electrode may detect a signal from a muscle area innervated by a first sacral nerve and the different or second sensor electrode detects a signal from a muscle area innervated by a second sacral nerve.

[0079] In some instances, the sensor electrode may comprise a casing and a lead. In some instances, the casing may be made of titanium, titanium alloy, tantalum, or any combination thereof. In some cases, the lead may be made of a metal alloy. In some embodiments, a sensor electrode and a stimulator electrode may be positioned on a single lead. In some instances, the lead may be electrically coupled to one or more sensor electrodes or one or more stimulator electrodes. In some embodiments, a sensor electrode and a stimulator electrode are positioned on separate leads. In some cases, the one or more sensor electrodes may comprise bioelectrical sensor electrodes.

**Electrodes for Use with Embodiments of the Device Described Herein**

[0080] In some cases, the sensor electrode and the stimulator electrode may be located on a single lead. In some instances, one or more sensor electrodes and one or more stimulator electrodes may be located on a single lead. In some cases, one sensor electrode and one stimulator electrode may be located on a single lead. In some instances, the sensor electrode and the stimulator electrode may be located on separate leads. In some cases, the sensor electrode and the stimulator electrode may each be located on its own lead. In some cases, the one or more sensor electrodes and one or more stimulator electrodes may be in a linear geometry, triangular geometry, square geometry, hexagonal geometry, or a general polygonal geometry. In some cases, the electrodes located on a single lead may be spaced by a distance. In some cases, the spacing provides the capability to stimulate multiple locations along the length of the nerve. In some cases, the electrodes may be separated by a distance of at least about 1 mm, about 1.5 mm, about 2 mm, about 2.5 mm, about 5 mm, about 10 mm, about 20 mm, about 30 mm, about

40 mm, about 50 mm, or about 60 mm. In some cases, the electrodes may be separated by a distance of at most about 1.5 mm, about 2 mm, about 2.5 mm, about 5 mm, about 10 mm, about 20 mm, about 30 mm, about 40 mm, about 50 mm, about 60 mm, or about 80 mm.

[0081] In some instances, the device may comprise one or more leads. In some cases, the device may comprise at least two leads. In some instances, the device may comprise at least 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 leads. In some cases, the device may comprise at most 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 leads. In some instances, the device may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 leads. In some cases, each lead may comprise one or more electrodes. In some cases, the one or more electrodes may comprise one or more sensor and/or stimulation electrodes. In some cases, the one or more electrodes on a lead may comprise about 1 electrode to about 10 electrodes. In some cases, the one or more electrodes on a lead may comprise about 1 electrode to about 2 electrodes, about 1 electrode to about 3 electrodes, about 1 electrode to about 4 electrodes, about 1 electrode to about 5 electrodes, about 1 electrode to about 6 electrodes, about 1 electrode to about 7 electrodes, about 1 electrode to about 8 electrodes, about 1 electrode to about 9 electrodes, about 1 electrode to about 10 electrodes, about 2 electrodes to about 3 electrodes, about 2 electrodes to about 4 electrodes, about 2 electrodes to about 5 electrodes, about 2 electrodes to about 6 electrodes, about 2 electrodes to about 7 electrodes, about 2 electrodes to about 8 electrodes, about 2 electrodes to about 9 electrodes, about 2 electrodes to about 10 electrodes, about 3 electrodes to about 4 electrodes, about 3 electrodes to about 5 electrodes, about 3 electrodes to about 6 electrodes, about 3 electrodes to about 7 electrodes, about 3 electrodes to about 8 electrodes, about 3 electrodes to about 9 electrodes, about 3 electrodes to about 10 electrodes, about 4 electrodes to about 5 electrodes, about 4 electrodes to about 6 electrodes, about 4 electrodes to about 7 electrodes, about 4 electrodes to about 8 electrodes, about 4 electrodes to about 9 electrodes, about 4 electrodes to about 10 electrodes, about 5 electrodes to about 6 electrodes, about 5 electrodes to about 7 electrodes, about 5 electrodes to about 8 electrodes, about 5 electrodes to about 9 electrodes, about 5 electrodes to about 10 electrodes, about 6 electrodes to about 7 electrodes, about 6 electrodes to about 8 electrodes, about 6 electrodes to about 9 electrodes, about 6 electrodes to about 10 electrodes, about 7 electrodes to about 8 electrodes, about 7 electrodes to about 9 electrodes, about 7 electrodes to about 10 electrodes, about 8 electrodes to about 9 electrodes, about 8 electrodes to about 10 electrodes, or about 9 electrodes to about 10 electrodes. In some cases, the one or more electrodes on a lead may comprise about 1 electrode, about 2 electrodes, about 3 electrodes, about 4 electrodes, about 5 electrodes, about 6 electrodes, about 7 electrodes, about 8 electrodes, about 9 electrodes, or about 10 electrodes. In some cases, the one or more electrodes on a lead may comprise at least about 1 electrode, about 2 electrodes, about 3 electrodes, about 4

electrodes, about 5 electrodes, about 6 electrodes, about 7 electrodes, about 8 electrodes, or about 9 electrodes. In some cases, the one or more electrodes on a lead may comprise at most about 2 electrodes, about 3 electrodes, about 4 electrodes, about 5 electrodes, about 6 electrodes, about 7 electrodes, about 8 electrodes, about 9 electrodes, or about 10 electrodes.

**[0082]** In some cases, each electrode may comprise a length, whereby the length may provide localized excitation of one or more nerves of the sacral or pudendal nerve. In some cases, each electrode may comprise a length of about 0.1 millimeter (mm) to about 2 mm. In some cases, each electrode may comprise a length of about 0.1 mm to about 0.3 mm, about 0.1 mm to about 0.5 mm, about 0.1 mm to about 0.7 mm, about 0.1 mm to about 0.8 mm, about 0.1 mm to about 1 mm, about 0.1 mm to about 1.2 mm, about 0.1 mm to about 1.4 mm, about 0.1 mm to about 1.5 mm, about 0.1 mm to about 2 mm, about 0.3 mm to about 0.5 mm, about 0.3 mm to about 0.7 mm, about 0.3 mm to about 0.8 mm, about 0.3 mm to about 1 mm, about 0.3 mm to about 1.2 mm, about 0.3 mm to about 1.4 mm, about 0.3 mm to about 1.5 mm, about 0.3 mm to about 2 mm, about 0.5 mm to about 0.7 mm, about 0.5 mm to about 0.8 mm, about 0.5 mm to about 1 mm, about 0.5 mm to about 1.2 mm, about 0.5 mm to about 1.4 mm, about 0.5 mm to about 1.5 mm, about 0.5 mm to about 2 mm, about 0.7 mm to about 0.8 mm, about 0.7 mm to about 1 mm, about 0.7 mm to about 1.2 mm, about 0.7 mm to about 1.4 mm, about 0.7 mm to about 1.5 mm, about 0.7 mm to about 2 mm, about 0.8 mm to about 1 mm, about 0.8 mm to about 1.2 mm, about 0.8 mm to about 1.4 mm, about 0.8 mm to about 1.5 mm, about 0.8 mm to about 2 mm, about 1 mm to about 1.2 mm, about 1 mm to about 1.4 mm, about 1 mm to about 1.5 mm, about 1 mm to about 2 mm, about 1.2 mm to about 1.4 mm, about 1.2 mm to about 1.5 mm, about 1.2 mm to about 2 mm, about 1.4 mm to about 1.5 mm, about 1.4 mm to about 2 mm, or about 1.5 mm to about 2 mm. In some cases, each electrode may comprise a length of about 0.1 mm, about 0.3 mm, about 0.5 mm, about 0.7 mm, about 0.8 mm, about 1 mm, about 1.2 mm, about 1.4 mm, about 1.5 mm, or about 2 mm. In some cases, each electrode may comprise a length of at least about 0.1 mm, about 0.3 mm, about 0.5 mm, about 0.7 mm, about 0.8 mm, about 1 mm, about 1.2 mm, about 1.4 mm, or about 1.5 mm. In some cases, each electrode may comprise a length of at most about 0.3 mm, about 0.5 mm, about 0.7 mm, about 0.8 mm, about 1 mm, about 1.2 mm, about 1.4 mm, about 1.5 mm, or about 2 mm.

**[0083]** In some cases, the one or more leads may comprise a length between the proximal tip of the lead to the distal end electrically coupled to the stimulator. In some cases, the length of the lead may vary based upon the anatomy of the individual or subject receiving the implanted device and leads. In some cases, the lead length may comprise a length, whereby the lead electrodes may be placed near and/or adjacent to the sacral and/or pudendal nerve yet reach the placement of the stimulator in buttock fat pockets of the subject. In some instances, the one or

more leads may comprise a length of about 20 centimeters (cm) to about 50 cm. In some instances, the one or more leads may comprise a length of about 20 cm to about 25 cm, about 20 cm to about 30 cm, about 20 cm to about 35 cm, about 20 cm to about 40 cm, about 20 cm to about 45 cm, about 20 cm to about 50 cm, about 25 cm to about 30 cm, about 25 cm to about 35 cm, about 25 cm to about 40 cm, about 25 cm to about 45 cm, about 25 cm to about 50 cm, about 30 cm to about 35 cm, about 30 cm to about 40 cm, about 30 cm to about 45 cm, about 30 cm to about 50 cm, about 35 cm to about 40 cm, about 35 cm to about 45 cm, about 35 cm to about 50 cm, about 40 cm to about 45 cm, about 40 cm to about 50 cm, or about 45 cm to about 50 cm. In some instances, the one or more leads may comprise a length of about 20 cm, about 25 cm, about 30 cm, about 35 cm, about 40 cm, about 45 cm, or about 50 cm. In some instances, the one or more leads may comprise a length of at least about 20 cm, about 25 cm, about 30 cm, about 35 cm, about 40 cm, or about 45 cm. In some instances, the one or more leads may comprise a length of at most about 25 cm, about 30 cm, about 35 cm, about 40 cm, about 45 cm, or about 50 cm.

**[0084]** In some cases, the one or more leads may comprise a diameter. In some cases, the diameter of the lead may vary based upon the anatomy of the individual or subject receiving the implanted device and leads. In some cases, the lead diameter may comprise a diameter, whereby the diameter provides a form factor for minimally invasive placement of the lead in the subject. In some cases, the diameter of the lead may comprise a diameter at which the lead will resist breakage. In some cases, the one or more leads may have an outer diameter of about 0.1 mm to about 2 mm. In some cases, the one or more leads may have an outer diameter of about 0.1 mm to about 0.2 mm, about 0.1 mm to about 0.3 mm, about 0.1 mm to about 0.5 mm, about 0.1 mm to about 0.8 mm, about 0.1 mm to about 1 mm, about 0.1 mm to about 1.2 mm, about 0.1 mm to about 1.4 mm, about 0.1 mm to about 1.5 mm, about 0.1 mm to about 2 mm, about 0.2 mm to about 0.3 mm, about 0.2 mm to about 0.5 mm, about 0.2 mm to about 0.8 mm, about 0.2 mm to about 1 mm, about 0.2 mm to about 1.2 mm, about 0.2 mm to about 1.4 mm, about 0.2 mm to about 1.5 mm, about 0.2 mm to about 2 mm, about 0.3 mm to about 0.5 mm, about 0.3 mm to about 0.8 mm, about 0.3 mm to about 1 mm, about 0.3 mm to about 1.2 mm, about 0.3 mm to about 1.4 mm, about 0.3 mm to about 1.5 mm, about 0.3 mm to about 2 mm, about 0.5 mm to about 0.8 mm, about 0.5 mm to about 1 mm, about 0.5 mm to about 1.2 mm, about 0.5 mm to about 1.4 mm, about 0.5 mm to about 1.5 mm, about 0.5 mm to about 2 mm, about 0.8 mm to about 1 mm, about 0.8 mm to about 1.2 mm, about 0.8 mm to about 1.4 mm, about 0.8 mm to about 1.5 mm, about 0.8 mm to about 2 mm, about 1 mm to about 1.2 mm, about 1 mm to about 1.4 mm, about 1 mm to about 1.5 mm, about 1 mm to about 2 mm, about 1.2 mm to about 1.4 mm, about 1.2 mm to about 1.5 mm, about 1.2 mm to about 2 mm, about 1.4 mm to about 1.5

mm, about 1.4 mm to about 2 mm, or about 1.5 mm to about 2 mm. In some cases, the one or more leads may have an outer diameter of about 0.1 mm, about 0.2 mm, about 0.3 mm, about 0.5 mm, about 0.8 mm, about 1 mm, about 1.2 mm, about 1.4 mm, about 1.5 mm, or about 2 mm. In some cases, the one or more leads may have an outer diameter of at least about 0.1 mm, about 0.2 mm, about 0.3 mm, about 0.5 mm, about 0.8 mm, about 1 mm, about 1.2 mm, about 1.4 mm, or about 1.5 mm. In some cases, the one or more leads may have an outer diameter of at most about 0.2 mm, about 0.3 mm, about 0.5 mm, about 0.8 mm, about 1 mm, about 1.2 mm, about 1.4 mm, about 1.5 mm, or about 2 mm.

**[0085]** In some cases, the one or more leads described elsewhere herein may comprise an internal stylet and/or mandrel configured to provide rigidity to the lead for implantation and/or insertion to a subject. In some cases, the internal stylet may be removed from the lead once the lead has been inserted and implanted. In some instances, the one or more leads described elsewhere herein may be sterilizable with conventional methods of sterilization used in the medical field, e.g., gas sterilization, steam sterilization, UV sterilization, etc.

**[0086]** In some instances, the one or more leads, described elsewhere herein, may be electrically coupled to the electric stimulator, described elsewhere herein. In some instances, the one or more leads may be coupled to the stimulator and may at a later point in time be uncoupled from the stimulator. In some instances, the one or more leads may couple to the electric stimulator with a quick release electrical coupling. In some cases, the one or more leads may be coupled to the electric stimulator by a set screw fastener, whereby a lead is inserted into a hollow cylindrical geometry in electrical communication with the electric stimulator internal circuitry. The lead may then be fastened i.e., held in tension against the inner wall of the hollow cylindrical geometry, to the conductive hollow cylindrical geometry with a non-conductive machine set screw. The one or more leads may be placed into the electric stimulator prior to or during the surgical implantation procedure.

**[0087]** In some instances, the sensor electrode and the stimulator electrode may be operatively coupled to a processor and a non-transitory computer readable medium that includes software. In some cases, the sensor electrode may be calibrated by the individual using an external input device that interfaces with the software. In some instances, the software may be configured to record a signal from the sensor electrode. In some cases, the software may be configured to adjust the sensor electrode in response to the signal.

**[0088]** In some instances, the stimulator electrode may provide an electrical stimulation to the pudendal nerve. In some cases, the stimulator electrode may provide an electrical stimulation to the sacral nerve. In some instances, the stimulator electrode may provide an electrical stimulation to one or more of the nerves innervating the pelvic muscles. In some cases, the

electrode may comprise one or more electrodes or leads e.g., a first and second electrode. In some instances, the electrode may comprise one or more stimulator electrodes. In some cases, an electrode may comprise a first stimulator electrode configured to stimulate one pudendal nerve, and a second stimulator electrode configured to stimulate another spatially independent region of the same pudendal nerve. In some cases, the first stimulator electrode may stimulate the main trunk of the pudendal nerve and the second stimulator electrode may stimulate the distal nerve of the pudendal nerve. In some instances, the distal nerve of the pudendal nerve comprises branches thereof the distal pudendal nerve. In some cases, the first stimulator electrode may stimulate the trunk of the pudendal nerve and the second stimulator electrode may stimulate a main branch of the pudendal nerve e.g., dorsal genital nerve. In some cases, the stimulator electrode may provide an electrical stimulation to one or more of the nerves innervating the urethral sphincter. In some instances, the stimulator electrode may provide an electrical stimulation to one or more of the nerves innervating the urethra. In some cases, the stimulator electrode may provide an electrical stimulation to one or more of the nerves innervating the bladder. In some instances, the stimulator electrode may provide an electrical stimulation to one or more of the nerves innervating the ureter. In some cases, the stimulator electrode may provide an electrical stimulation to one or more of the nerves innervating the anal sphincter. In some cases, the stimulator electrode may provide an electrical stimulation to one or more of the nerves innervating the anus. In some instances, the stimulator electrode may provide an electrical stimulation to one or more of the nerves innervating the rectum. In some cases, the stimulator electrode may provide an electrical stimulation to one or more of the nerves innervating the bowel. In some instances, the devices described herein may comprise a plurality of stimulator electrodes. In some instances, the devices described herein may comprise one or more stimulator electrodes. In some instances, the devices described herein may comprise a different stimulator electrode, or a second stimulator electrode. In some cases, the stimulator electrode may stimulate a first pudendal nerve and the different or second stimulator electrode stimulates a second pudendal nerve. In some cases, the stimulator electrode may stimulate a first sacral nerve and the different or second stimulator electrode stimulates a second sacral nerve.

**[0089]** In some instances, the stimulator electrode of the device may provide a constant electrical stimulation. In some cases, the stimulator electrode of the device may provide a constant electrical stimulation at a lower intensity level than the electrical stimulation provided to prevent an episode of incontinence. In some cases, constant electrical stimulation may comprise constant frequency, amplitude, current, or any combination thereof. In some instances, the intensity or duration of the electrical stimulation provided may prevent an episode of incontinence varies according to the individual's response to a possible episode of incontinence

that is sensed by the sensor electrode. In some cases, the individual's response to prevent a possible episode of incontinence that is sensed by the sensor electrode may be insufficient on its own to prevent the episode of incontinence and the electrical stimulation delivered by the stimulator electrode of the device provides sufficient stimulation, together with the response, to prevent the episode of incontinence. In some cases, the individual's response to prevent a possible episode of incontinence that may be sensed by the sensor electrode combined with the electrical stimulation delivered by the stimulator electrode of the device provides sufficient stimulation to trigger the action potential of the muscles responsible for the incontinence, resulting in contraction of the muscle. In some cases, the combined stimulation from the individual and the device may result in contraction of a muscle. In some instances, the muscle may comprise a urethral sphincter. In some cases, the muscle may comprise an anal sphincter. In some cases, the muscle may comprise one or more of the pelvic floor muscles.

[0090] In some instances, the sensor electrode may comprise casing and a lead. In some instances, the casing may be made of titanium or a titanium alloy. In some cases, the lead may be made of a metal alloy.

**Device Anchors**

[0091] In some cases, the devices may be anchored when implanted by one the one or more surgical device. In some instances, anchoring of the devices may be achieved by sliding the device over the lead, described elsewhere herein, and then compressing it onto the lead using ligatures such that it is immobile. These ligatures may be used to fix the anchoring device to native adjacent tissue such as ligament or periosteum. In some instances, the device may comprise groves for the purpose of aligning compression ligatures. In some instances, the anchoring device may comprise a torque system to compress the device onto the lead such that it is immobile. In some instances, the device may be compressed at a single point onto the lead. In some instances, the device is compressed at two or more points onto the lead. The electric stimulator may comprise radio-opaque markers that may permit visualization of the electric stimulator under x-ray e.g., fluoroscopy during and/or after implantation. In some instances, fluoroscopy may be used alone or in combination with EMG sensor electrode readings of pelvic floor muscles to verify placement or to adjustment placement of sensor electrode leads, stimulator electrode leads, and/or the stimulator.

***Electrical Signal***

[0092] **FIG. 4** depicts the sensed myoelectric EMG signal and a corresponding electrical stimulation ("Bio-stimulator") provided by the devices disclosed herein. In some cases, the

myoelectric EMG signal ("Bio-signal") **140** may comprise electrical fluctuations **142** corresponding to contractile activity of the muscle near the sensor electrode. In some cases, the electrical fluctuations **142** may represent a cough, sudden movement, change in inertia, or any combination thereof from an electromyography (EMG) reading. In some instances, the bio-signal captured by the sensor electrode may be analyzed and classified **144** to identify any stress events, such as a cough or a sudden movement, from an EMG reading. In some cases, the identified stress event may initiate a process **146** by which the implantable electric stimulator may deliver an electric stimulation pattern **148** to via one or more stimulator electrodes to a one or more pudendal nerve to prevent an episode of incontinence. In some cases, the stimulator electrode may deliver an electrical stimulation by the one or more stimulator electrodes **122** that is configured to supplement the innate reflex detected by the one or more sensor electrodes **120** to account for the stress event otherwise leading to an incontinence event.

**[0093]** In some cases, the electric stimulator may comprise a width and length to be readily implantable in a patient. In some cases, the electric stimulator may comprise a width and length to accommodate circuitry and/or other system level components, described elsewhere herein.

**[0094]** In some instances, the electric stimulator may comprise a width and length to provide sufficient space for a battery, where the battery may comprise a lifetime after which the battery may be replaced. In some cases, the battery lifetime may comprise about 5 years to about 15 years. In some cases, the battery lifetime may comprise about 5 years to about 6 years, about 5 years to about 7 years, about 5 years to about 8 years, about 5 years to about 9 years, about 5 years to about 10 years, about 5 years to about 11 years, about 5 years to about 12 years, about 5 years to about 13 years, about 5 years to about 14 years, about 5 years to about 15 years, about 6 years to about 7 years, about 6 years to about 8 years, about 6 years to about 9 years, about 6 years to about 10 years, about 6 years to about 11 years, about 6 years to about 12 years, about 6 years to about 13 years, about 6 years to about 14 years, about 6 years to about 15 years, about 7 years to about 8 years, about 7 years to about 9 years, about 7 years to about 10 years, about 7 years to about 11 years, about 7 years to about 12 years, about 7 years to about 13 years, about 7 years to about 14 years, about 7 years to about 15 years, about 8 years to about 9 years, about 8 years to about 10 years, about 8 years to about 11 years, about 8 years to about 12 years, about 8 years to about 13 years, about 8 years to about 14 years, about 8 years to about 15 years, about 9 years to about 10 years, about 9 years to about 11 years, about 9 years to about 12 years, about 9 years to about 13 years, about 9 years to about 14 years, about 9 years to about 15 years, about 10 years to about 11 years, about 10 years to about 12 years, about 10 years to about 13 years, about 10 years to about 14 years, about 10 years to about 15 years, about 11 years to about 12 years, about 11 years to about 13 years, about 11 years to about 14 years, about 11 years to

about 15 years, about 12 years to about 13 years, about 12 years to about 14 years, about 12 years to about 15 years, about 13 years to about 14 years, about 13 years to about 15 years, or about 14 years to about 15 years. In some cases, the battery lifetime may comprise about 5 years, about 6 years, about 7 years, about 8 years, about 9 years, about 10 years, about 11 years, about 12 years, about 13 years, about 14 years, or about 15 years. In some cases, the battery lifetime may comprise at least about 5 years, about 6 years, about 7 years, about 8 years, about 9 years, about 10 years, about 11 years, about 12 years, about 13 years, or about 14 years. In some cases, the battery lifetime may comprise at most about 6 years, about 7 years, about 8 years, about 9 years, about 10 years, about 11 years, about 12 years, about 13 years, about 14 years, or about 15 years.

[0095] In some cases, the electric stimulator battery may require charging once in about 1 day to about 12 days. In some cases, the electric stimulator battery may require charging once in about 1 day to about 2 days, about 1 day to about 3 days, about 1 day to about 4 days, about 1 day to about 5 days, about 1 day to about 6 days, about 1 day to about 7 days, about 1 day to about 8 days, about 1 day to about 9 days, about 1 day to about 10 days, about 1 day to about 11 days, about 1 day to about 12 days, about 2 days to about 3 days, about 2 days to about 4 days, about 2 days to about 5 days, about 2 days to about 6 days, about 2 days to about 7 days, about 2 days to about 8 days, about 2 days to about 9 days, about 2 days to about 10 days, about 2 days to about 11 days, about 2 days to about 12 days, about 3 days to about 4 days, about 3 days to about 5 days, about 3 days to about 6 days, about 3 days to about 7 days, about 3 days to about 8 days, about 3 days to about 9 days, about 3 days to about 10 days, about 3 days to about 11 days, about 3 days to about 12 days, about 4 days to about 5 days, about 4 days to about 6 days, about 4 days to about 7 days, about 4 days to about 8 days, about 4 days to about 9 days, about 4 days to about 10 days, about 4 days to about 11 days, about 4 days to about 12 days, about 5 days to about 6 days, about 5 days to about 7 days, about 5 days to about 8 days, about 5 days to about 9 days, about 5 days to about 10 days, about 5 days to about 11 days, about 5 days to about 12 days, about 6 days to about 7 days, about 6 days to about 8 days, about 6 days to about 9 days, about 6 days to about 10 days, about 6 days to about 11 days, about 6 days to about 12 days, about 7 days to about 8 days, about 7 days to about 9 days, about 7 days to about 10 days, about 7 days to about 11 days, about 7 days to about 12 days, about 8 days to about 9 days, about 8 days to about 10 days, about 8 days to about 11 days, about 8 days to about 12 days, about 9 days to about 10 days, about 9 days to about 11 days, about 9 days to about 12 days, about 10 days to about 11 days, about 10 days to about 12 days, or about 11 days to about 12 days. In some cases, the electric stimulator battery may require charging once in about 1 day, about 2 days, about 3 days, about 4 days, about 5 days, about 6 days, about 7 days, about 8 days, about 9

days, about 10 days, about 11 days, or about 12 days. In some cases, the electric stimulator battery may require charging once in at least about 1 day, about 2 days, about 3 days, about 4 days, about 5 days, about 6 days, about 7 days, about 8 days, about 9 days, about 10 days, or about 11 days. In some cases, the electric stimulator battery may require charging once in at most about 2 days, about 3 days, about 4 days, about 5 days, about 6 days, about 7 days, about 8 days, about 9 days, about 10 days, about 11 days, or about 12 days.

**[0096]** In some instances, the electric stimulator may comprise a width of about 1 mm to about 50 mm. In some instances, the electric stimulator may comprise a width of about 1 mm to about 5 mm, about 1 mm to about 10 mm, about 1 mm to about 15 mm, about 1 mm to about 20 mm, about 1 mm to about 25 mm, about 1 mm to about 30 mm, about 1 mm to about 35 mm, about 1 mm to about 40 mm, about 1 mm to about 45 mm, about 1 mm to about 50 mm, about 5 mm to about 10 mm, about 5 mm to about 15 mm, about 5 mm to about 20 mm, about 5 mm to about 25 mm, about 5 mm to about 30 mm, about 5 mm to about 35 mm, about 5 mm to about 40 mm, about 5 mm to about 45 mm, about 5 mm to about 50 mm, about 10 mm to about 15 mm, about 10 mm to about 20 mm, about 10 mm to about 25 mm, about 10 mm to about 30 mm, about 10 mm to about 35 mm, about 10 mm to about 40 mm, about 10 mm to about 45 mm, about 10 mm to about 50 mm, about 15 mm to about 20 mm, about 15 mm to about 25 mm, about 15 mm to about 30 mm, about 15 mm to about 35 mm, about 15 mm to about 40 mm, about 15 mm to about 45 mm, about 15 mm to about 50 mm, about 20 mm to about 25 mm, about 20 mm to about 30 mm, about 20 mm to about 35 mm, about 20 mm to about 40 mm, about 20 mm to about 45 mm, about 20 mm to about 50 mm, about 25 mm to about 30 mm, about 25 mm to about 35 mm, about 25 mm to about 40 mm, about 25 mm to about 45 mm, about 25 mm to about 50 mm, about 30 mm to about 35 mm, about 30 mm to about 40 mm, about 30 mm to about 45 mm, about 30 mm to about 50 mm, about 35 mm to about 40 mm, about 35 mm to about 45 mm, about 35 mm to about 50 mm, about 40 mm to about 45 mm, about 40 mm to about 50 mm, or about 45 mm to about 50 mm. In some instances, the electric stimulator may comprise a width of about 1 mm, about 5 mm, about 10 mm, about 15 mm, about 20 mm, about 25 mm, about 30 mm, about 35 mm, about 40 mm, about 45 mm, or about 50 mm. In some instances, the electric stimulator may comprise a width of at least about 1 mm, about 5 mm, about 10 mm, about 15 mm, about 20 mm, about 25 mm, about 30 mm, about 35 mm, about 40 mm, or about 45 mm. In some instances, the electric stimulator may comprise a width of at most about 5 mm, about 10 mm, about 15 mm, about 20 mm, about 25 mm, about 30 mm, about 35 mm, about 40 mm, about 45 mm, or about 50 mm.

**[0097]** In some instances, the electric stimulator may comprise a length of about 1 mm to about 50 mm. In some instances, the electric stimulator may comprise a length of about 1 mm to

about 5 mm, about 1 mm to about 10 mm, about 1 mm to about 15 mm, about 1 mm to about 20 mm, about 1 mm to about 25 mm, about 1 mm to about 30 mm, about 1 mm to about 35 mm, about 1 mm to about 40 mm, about 1 mm to about 45 mm, about 1 mm to about 50 mm, about 5 mm to about 10 mm, about 5 mm to about 15 mm, about 5 mm to about 20 mm, about 5 mm to about 25 mm, about 5 mm to about 30 mm, about 5 mm to about 35 mm, about 5 mm to about 40 mm, about 5 mm to about 45 mm, about 5 mm to about 50 mm, about 10 mm to about 15 mm, about 10 mm to about 20 mm, about 10 mm to about 25 mm, about 10 mm to about 30 mm, about 10 mm to about 35 mm, about 10 mm to about 40 mm, about 10 mm to about 45 mm, about 10 mm to about 50 mm, about 15 mm to about 20 mm, about 15 mm to about 25 mm, about 15 mm to about 30 mm, about 15 mm to about 35 mm, about 15 mm to about 40 mm, about 15 mm to about 45 mm, about 15 mm to about 50 mm, about 20 mm to about 25 mm, about 20 mm to about 30 mm, about 20 mm to about 35 mm, about 20 mm to about 40 mm, about 20 mm to about 45 mm, about 20 mm to about 50 mm, about 25 mm to about 30 mm, about 25 mm to about 35 mm, about 25 mm to about 40 mm, about 25 mm to about 45 mm, about 25 mm to about 50 mm, about 30 mm to about 35 mm, about 30 mm to about 40 mm, about 30 mm to about 45 mm, about 30 mm to about 50 mm, about 35 mm to about 40 mm, about 35 mm to about 45 mm, about 35 mm to about 50 mm, about 40 mm to about 45 mm, about 40 mm to about 50 mm, or about 45 mm to about 50 mm. In some instances, the electric stimulator may comprise a length of about 1 mm, about 5 mm, about 10 mm, about 15 mm, about 20 mm, about 25 mm, about 30 mm, about 35 mm, about 40 mm, about 45 mm, or about 50 mm. In some instances, the electric stimulator may comprise a length of at least about 1 mm, about 5 mm, about 10 mm, about 15 mm, about 20 mm, about 25 mm, about 30 mm, about 35 mm, about 40 mm, or about 45 mm. In some instances, the electric stimulator may comprise a length of at most about 5 mm, about 10 mm, about 15 mm, about 20 mm, about 25 mm, about 30 mm, about 35 mm, about 40 mm, about 45 mm, or about 50 mm.

**[0098]** In some instances, the electric stimulator may comprise a height of about 0.5 mm to about 5.5 mm. In some instances, the electric stimulator may comprise a height of about 0.5 mm to about 1 mm, about 0.5 mm to about 1.5 mm, about 0.5 mm to about 2 mm, about 0.5 mm to about 2.5 mm, about 0.5 mm to about 3 mm, about 0.5 mm to about 3.5 mm, about 0.5 mm to about 4 mm, about 0.5 mm to about 4.5 mm, about 0.5 mm to about 5 mm, about 0.5 mm to about 5.5 mm, about 1 mm to about 1.5 mm, about 1 mm to about 2 mm, about 1 mm to about 2.5 mm, about 1 mm to about 3 mm, about 1 mm to about 3.5 mm, about 1 mm to about 4 mm, about 1 mm to about 4.5 mm, about 1 mm to about 5 mm, about 1 mm to about 5.5 mm, about 1.5 mm to about 2 mm, about 1.5 mm to about 2.5 mm, about 1.5 mm to about 3 mm, about 1.5 mm to about 3.5 mm, about 1.5 mm to about 4 mm, about 1.5 mm to about 4.5 mm, about 1.5

mm to about 5 mm, about 1.5 mm to about 5.5 mm, about 2 mm to about 2.5 mm, about 2 mm to about 3 mm, about 2 mm to about 3.5 mm, about 2 mm to about 4 mm, about 2 mm to about 4.5 mm, about 2 mm to about 5 mm, about 2 mm to about 5.5 mm, about 2.5 mm to about 3 mm, about 2.5 mm to about 3.5 mm, about 2.5 mm to about 4 mm, about 2.5 mm to about 4.5 mm, about 2.5 mm to about 5 mm, about 2.5 mm to about 5.5 mm, about 3 mm to about 3.5 mm, about 3 mm to about 4 mm, about 3 mm to about 4.5 mm, about 3 mm to about 5 mm, about 3 mm to about 5.5 mm, about 3.5 mm to about 4 mm, about 3.5 mm to about 4.5 mm, about 3.5 mm to about 5 mm, about 3.5 mm to about 5.5 mm, about 4 mm to about 4.5 mm, about 4 mm to about 5 mm, about 4 mm to about 5.5 mm, about 4.5 mm to about 5 mm, about 4.5 mm to about 5.5 mm, or about 5 mm to about 5.5 mm. In some instances, the electric stimulator may comprise a height of about 0.5 mm, about 1 mm, about 1.5 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, about 4.5 mm, about 5 mm, or about 5.5 mm. In some instances, the electric stimulator may comprise a height of at least about 0.5 mm, about 1 mm, about 1.5 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, about 4.5 mm, or about 5 mm. In some instances, the electric stimulator may comprise a height of at most about 1 mm, about 1.5 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, about 4.5 mm, about 5 mm, or about 5.5 mm.

[0099] In some instances, the electric stimulator may comprise a mass of about 1 g to about 18 g. In some instances, the electric stimulator may comprise a mass of about 1 g to about 3 g, about 1 g to about 6 g, about 1 g to about 8 g, about 1 g to about 10 g, about 1 g to about 12 g, about 1 g to about 14 g, about 1 g to about 16 g, about 1 g to about 17 g, about 1 g to about 18 g, about 3 g to about 6 g, about 3 g to about 8 g, about 3 g to about 10 g, about 3 g to about 12 g, about 3 g to about 14 g, about 3 g to about 16 g, about 3 g to about 17 g, about 3 g to about 18 g, about 6 g to about 8 g, about 6 g to about 10 g, about 6 g to about 12 g, about 6 g to about 14 g, about 6 g to about 16 g, about 6 g to about 17 g, about 6 g to about 18 g, about 8 g to about 10 g, about 8 g to about 12 g, about 8 g to about 14 g, about 8 g to about 16 g, about 8 g to about 17 g, about 8 g to about 18 g, about 10 g to about 12 g, about 10 g to about 14 g, about 10 g to about 16 g, about 10 g to about 17 g, about 10 g to about 18 g, about 12 g to about 14 g, about 12 g to about 16 g, about 12 g to about 17 g, about 12 g to about 18 g, about 14 g to about 16 g, about 14 g to about 17 g, about 14 g to about 18 g, about 16 g to about 17 g, about 16 g to about 18 g, or about 17 g to about 18 g. In some instances, the electric stimulator may comprise a mass of about 1 g, about 3 g, about 6 g, about 8 g, about 10 g, about 12 g, about 14 g, about 16 g, about 17 g, or about 18 g. In some instances, the electric stimulator may comprise a mass of at least about 1 g, about 3 g, about 6 g, about 8 g, about 10 g, about 12 g, about 14 g, about 16 g, or

about 17 g. In some instances, the electric stimulator may comprise a mass of at most about 3 g, about 6 g, about 8 g, about 10 g, about 12 g, about 14 g, about 16 g, about 17 g, or about 18 g.

**[0100]** In some instances, the electric stimulator may be sterilizable with conventional methods of sterilization used in the medical field, e.g., gas sterilization, steam sterilization, UV sterilization, etc.

**[0101]** In some cases, the one or more stimulator electrodes may provide a constant electrical stimulation, or base stimulation **146** and **150** for an individual experiencing urge incontinence. In some cases, constant electrical stimulation may comprise constant frequency, amplitude, current, or any combination thereof. In some instances, the stimulator electrode may provide a temporary electrical stimulation lasting the duration of a stress incontinence **148** episode for an individual experiencing stress incontinence. In some cases, the stimulator electrode may provide a constant electrical stimulation (i.e., basal stimulation pattern) with a temporary activated stimulation (i.e., activation stimulation pattern) lasting the duration of a stress incontinence episode for an individual experiencing mixed incontinence.

**[0102]** In some instances, the device disclosed herein may comprise a non-transitory computer readable medium that includes software. In some cases, the software may be configured to record a signal from the one or more sensor electrodes. In some cases, the software may be configured to process the recorded signal from the one or more sensor electrodes to determine whether an electrical stimulation pattern may need to be delivered to the one or more stimulator electrodes innervating the one or more pudendal nerves. In some instances, the software may be configured to adjust parameters of the sensor electrode in response to the observed signal. In some cases, the recorded signal of the sensor electrode by the software may observe a signal that saturates the sensor electrode's dynamic range. In some cases, the gain of the sensor electrode may be adjusted by the software to allow for sufficient monitoring and thresholding of the myoelectric EMG signals of the individual.

**Nerve Stimulation Using the Device**

**[0103]** **FIG. 3** shows an exemplary embodiment of the devices and methods described herein implanted in an individual. In some cases, the implanted device may target the pudendal nerve **133** by placing the sensor electrodes **134** and **136** and stimulation electrodes near pudendal nerve **130** and **132**. The sensor electrode **134** and **136** may capture the bio-signal to classify any stress events, and the stimulator electrodes **130** and **132** may deliver the stress electrical stimulation ("bio-simulator"), which is adapted from the base stimulation to account for the stress event, to act on the target sphincter muscle.

[0104] In some cases, providing electrical stimulation to the pudendal nerve instead of the sacral nerve may provide a greater precision as the pudendal nerve or branches thereof is lower than the sacral nerve and closer to the organs and tissues involved in incontinence than the sacral nerves. The sensor electrodes of the device capture the bio-signal to classify any stress events, and the stimulator electrodes of the device deliver the stress electrical stimulation ("bio-simulator"), which is adapted from the base stimulation to account for the stress event, to act on the target sphincter muscle.

**System for Nerve Stimulation for Managing Incontinence**

[0105] **FIG. 5** shows an exemplary embodiment of a system block diagram for the devices and methods described herein with the slow- and fast-adapting algorithms. In some cases, the systems disclosed herein may comprise a plurality of sub-modules. In some instances, the sub-modules may comprise: an offline analysis module **152**, a clinician control module **154**, a patient controller module **156**, an implantable module **160**, or any combination thereof.

[0106] In some cases, the offline analysis module **152** may comprise a data repository , an analysis software a visualization software , or any combination thereof. In some instances, the offline analysis module may be used to retrospectively analyze and graphically visualize an individual's implant performance to prevent episodes of incontinence. The off-line analysis module **152** may be programmatically coupled to the clinician control module through an application programming interface (API) . In some instances, the clinician control module may comprise software that may tune or change the electrical stimulation patterns of the individual's electrical stimulation implant.

[0107] In some cases, the clinical control module **154** may comprise stimulation management and device monitor software, stimulation programming map, classification configuration dashboard, streaming data collection dashboard, or any combination thereof. In some cases, a health care personnel may assist an individual with an electrical implant by updating or modifying their electrical implant parameters through the clinical control module **154.** In some cases, the clinical control module may be utilized to initialize an individual's electrical implant after implantation through an USB interface to the patient controller module **156.**

[0108] In some cases, the patient controller module **156** may comprise a direct interface to control aspects of their electrical stimulator as described herein. In some instances, the patient controller module **156** may comprise: medical information and communication band (MICS) communication platform, manual electrical stimulator control, enable or disable algorithm

functionality, algorithm patient alerts, an inductive or wired charger for the implantable pulse generator rechargeable battery, or any combination thereof.

**[0109]** In some cases, the patient controller module **156** may be configured to wirelessly and/or inductively charge the implantable pulse generator rechargeable battery with a recharger of the patient controller module **156**. In some cases, the patient controller module **156** may magnetically couple to the implantable pulse generator **160** from outside the subject's skin. In some cases, the magnetic coupling of the controller module **156** to the implantable pulse generator **160** may be made such that the coupling is ergonomic for the subject such that the subject may conduct him/herself as if the controller module **156** is not magnetically coupled to the implantable pulse generator **160**. In some cases, the patient controller module **156** may comprise a battery that may be recharged through wireless inductive charging via the recharger and/or wired charging. In some cases, the patient controller module **156** may comprise a rechargeable lithium-ion battery. In some instances, the recharger may comprise one or more inductive coils used when charging the patient controller module **156** and/or when using the patient controller module **156** to charge the implantable pulse generator **160**. In some cases, the patient controller module, shown as shown in **FIG. 7B** may be configured **722** to accept additional memory storage **723**. In some cases, the additional memory storage may be used to transport patient data and/or information between patient/subject and provider.

**[0110]** In some cases, the patient controller module **156** may directly or automatically control the implantable pulse generator **160**. In some cases, the implantable pulse generator **160** may comprise a corresponding MICS-telemetry communication platform to that of the MICS communication platform of the patient controller module, enabling the communication between the two devices over an ad hoc Wi-Fi network **158**. In some instances, the implantable pulse generator **160** may further comprise a three-axis accelerometer biopotential amplifier that may be electrically coupled to one or more electrodes leads **214**. In some cases the one or more electrode leads may comprise one or more stimulator and/or sensor electrodes. In some cases, a biopotential amplifier may be electrically coupled to a computation sub module comprising a classifier, control policy, real-time clock scheduler, microprocessor, or any combination thereof. In some instances, the biopotential amplifier, classifier, control policy, real-time clock scheduler, and microprocessor , or any combination thereof, may process and interpret detected myoelectric EMG signals in the patient to determine the necessary electrical stimulation pattern provided by the actuator to the one or more stimulator electrodes to prevent an episode of incontinence in an individual.

In some instances, the patient controller module **156** may comprise a user interface, ports, indicators, or any combination thereof as seen in **FIGS. 7A-7B**. The user interface and/or ports

of the patient controller module may comprise an input charging socket **704**, keypad navigation button **706**, stimulation indicator, communication indicator, output charging adapter port, battery level indicator in both percentage and number of days **712**, manual excitation over-ride button **716**, or any combination thereof. In some cases, the input charging socket may be configured to accept a USB A, B, and/or C, Firewire, any micro versions thereof, or any combinations thereof. connections. In some instances, the patient controller module **156** may be connected to a power converter to through a corresponding cable adapted to the input charging socket to charge the patient controller module **156**.

**User Interface**

**[0111]** The patient controller module **156** may comprise a user interface **700** where the user interface may comprise one or more user interface objects (**701, 702, 705, 711, 712, 715, 716, 717, 721, 730, 723**), and/or views as seen in **FIG. 7A-7B**. In some cases, the user interface **700** may comprise a touch screen display configured to receive touch or pressing input from a user, patient, and/or medical care personnel. In some cases, a user, patient, and/or medical care personnel may press and/or interact with button **716** based mixed graphic and text indicators, and/or switch mixed graphic and text indicators ( **705, 711**). In some cases, the user, patient, and/or medical care personnel may double tap a user interface object to enable an emergency state. In some instances, the emergency state may enable the implanted stimulator to provide electrical stimulation immediately in response to the double tap command. In some cases, a parameter or setting value of the user interface objects may be modified and/or changed by tilting the patient controller module. In some cases, tilting the patient controller module in a first direction may increase the parameter and/or setting value of the user interface object whereas tilting the patient controller module in a second direction opposite the first direction may decrease the parameter and/or setting value.

**[0112]** In some cases, the user interface between devices such as smart phones and tablets or other personal computing device may comprise a scaled version of the user interface. In some cases, the different user interface views e.g., the view shown in **FIG. 7A** and **FIG. 7B** may display varying user interface objects. In some cases, the user interface objects may comprise one or more buttons **716**, switches (**711,716**), and/or graphical or image based representation of data (**721,730, 723**).

**[0113]** In some cases, users may customize the user interface object with a selection of one or more user interface objects (e.g., buttons, switch button to enable various device operation modes, graphical displays of device data, etc.). In some cases, the user views may be a predetermine set of views with set user interface object. In some instances, the user may

customize and/or create one or more views accessible by the a menu icon **702**. In some cases, the menu icon **702** may be configured to display one or more submenu options. In some instances, the one or more submenu options may comprise personal identification, account information, device registration, customer support, or any combination thereof submenus. In some cases, one submenu may comprise information of how to connect the device platform to pre-existing health care providers. In some cases, the user interface may comprise a notification object **701.** The notification object may display a unique or highlighted state if a particular notification of device performance, detection of an incontinence event, or any combination thereof is to be provided to the user of the device. A user may interact with a press the notification object to view, in the form of a pop-up dialogue, the particular notification.

**[0114]** In some cases, the one or more user interface objects may comprise text and/or mixed text and vector objects representations of the various API function calls and/or sub-user interface views, as seen in **FIGS. 7A-7B**. In some cases, the user interface may comprise mixed text and vector objects that permit the subject or user to activate **705** or de-activate **711** electrical stimulation of the device **716**, adjust device parameters **715**, indicate therapy state **717**, view device measured EMG signals **721**, view stimulator electrode electrical signal characteristics (e.g., frequency, amplitude, pulse width, etc.) delivered, view a medical portal to submit user data to a health care provider, log resulting incontinent events **719** overlaid on top of measured ENG/EMG signals, or any combination thereof. In some cases, the user interface may further comprise a battery **712** and wireless communication connectivity indicator for the users and/or subjects to visualize patient controller module **156** operating properties.

**[0115]** In some cases, the keypad navigation button **706** may be configured to navigate between various user interface views e.g., the user interface views provided in **FIG. 7A** and **FIG. 7B**

**[0116]** In some instances, the patient controller module **156** may comprise visual indicators (**715, 717, 712**), configured to indicate whether the implanted electrical stimulator is outputting electrical stimulation and/or the presence or lack thereof connectivity with a second or third device. In some cases, the patient controller module may comprise a device adjustment parameter, where the device adjustment parameter may comprise a stimulation indicator, or an activation of a stimulation mode **715**. In some cases, the stimulation indicator may be in electrical communication with a processor, described elsewhere herein, configured to display a visual indicator when the stimulator is providing an electrical stimulation to a subject. In some instances, the patient controller module may comprise a connectivity indicator. In some cases, the connectivity indicator may be in electrical communication with a processor, described elsewhere herein, and configured to provide a visual indicator when the patient controller

module is connected to one or more discrete devices, data servers, local WIFI or ad-hoc WIFI networks, Bluetooth, medical implant communication system (MICS), or any combination thereof. In some cases, the connectivity indicator may indicate the wireless connection with the implanted electrical stimulator. In some cases, the connectivity indicator may comprise one or more states. In some instances, a first state my comprise a solid image indicator, where such a solid image indicator may notify a user, subject, individual, and/or health care personnel, a successfully established communication pairing between the patient controller module and a third device, server, etc. A second state may comprise a flashing image indicator, where such a flashing image indicator indicates a paired communication state between the patient controller module and a third device, server, etc. In some cases, the image indicator may comprise the universal symbol for Bluetooth that may be observed on smart devices and/or devices with Bluetooth connectivity. In some cases, the image indicator may comprise a graphic of the universal symbol indicator for Wi-Fi (e.g., a quarter circle of concentric rings) seen commonly on smart devices and/or devices with Wi-Fi connectivity.

**[0117]** In some cases, device data (e.g., EMG/ENG, accelerometer, gyroscopic, magnetometer, 3-D spatial movement, global positioning system (GPS) data, or any combination thereof) may be transmitted **718** over Wi-Fi, Bluetooth, MICS, or other ad-hoc networks between one or more devices, as described elsewhere herein.

**[0118]** **FIG. 7B** shows a different user interface view than that of the **FIG. 7A.** In some cases, the user interface of **FIG. 7B** may comprise one or more user interface objects (**721, 730, 723**), where each user interface object displays device data received **718** through wireless transmission **707** as described above. In some cases, one of the user interface objects may comprise a graphical therapy object **721**. The graphical therapy object may display detected EMG/ENG signals **726** and corresponding stimulation profiles **728**. In some cases, the graphical therapy object may display leak events **719** of where the user indicated an incontinent event but where the device did not provide stimulation. Another user interface object may comprise a GPS and motion activity object **730**. In some instances, the motion activity object **730** may display GPS and motion data of the subject over time. The GPS and motion data may be useful considerations when improving the classifier described elsewhere herein. Another user interface object may comprise a charging indicator object **723**. In some cases, the charging indicator object may display charge capacitance of the implanted stimulator over a period of time. In some cases, the charging indicator object may be used to monitor the health of the battery of the implanted stimulator. A user interacting with the display view shown in FIG. 7B may pinch, swipe, or otherwise interact with the data of each user interface object (**721, 730, 723**) to view other temporal regions of data or to zoom in on a particular scale of a measurement. In some

cases, through the menu object **702** a user and/or subject may export their medical data to one or more provides.

**Method of Preventing an Incontinence Episode**

**[0119]** **FIG. 6A** illustrates a workflow of a method **216** for preventing an episode of incontinence in an individual sufferer. The method may comprise the steps of (a) implanting a sensor electrode and stimulator electrode within a body of an individual **218;** (b) sensing with the sensor electrode, a parameter that is associated with a response from the individual to prevent an episode of incontinence **220**; and (c) providing an electrical stimulation, with the stimulator electrode, that, together with the response, prevents the episode of incontinence **222**. Often, the methods described herein prevent the episode of urinary incontinence. In some cases, the urinary incontinence may comprise at least one of urge incontinence, stress incontinence, overflow incontinence, or mixed incontinence. In some instances, the methods described herein may prevent the episode of fecal incontinence. In some cases, the method may comprise a step of providing a constant electrical stimulation at a lower intensity level than the electrical stimulation provided in step (c). The constant electrical stimulation provided at a lower intensity may assist individual's suffering from urge incontinence. In some instances, the intensity or duration of the electrical stimulation provided in step (c) may vary according to the response that is sensed in step (b). The response may vary in step (c) due to stress events such as coughing, laughing, or exercising that may require an increase in electrical stimulation to prevent an episode of incontinence. In some cases, the time period between sensing a parameter **224** and providing an electrical stimulation **226** may be described as a response time **228**,as shown in **FIG. 6B**. In some cases, the stimulation may be provided for a duration of stimulation **227**.

**[0120]** In some cases, the duration of stimulation **227** may comprise about 1 second to about 30 seconds. In some cases, the duration of stimulation **227** may comprise about 1 second to about 2 seconds, about 1 second to about 3 seconds, about 1 second to about 4 seconds, about 1 second to about 5 seconds, about 1 second to about 10 seconds, about 1 second to about 12 seconds, about 1 second to about 14 seconds, about 1 second to about 16 seconds, about 1 second to about 20 seconds, about 1 second to about 25 seconds, about 1 second to about 30 seconds, about 2 seconds to about 3 seconds, about 2 seconds to about 4 seconds, about 2 seconds to about 5 seconds, about 2 seconds to about 10 seconds, about 2 seconds to about 12 seconds, about 2 seconds to about 14 seconds, about 2 seconds to about 16 seconds, about 2 seconds to about 20 seconds, about 2 seconds to about 25 seconds, about 2 seconds to about 30 seconds, about 3 seconds to about 4 seconds, about 3 seconds to about 5 seconds, about 3 seconds to about 10 seconds, about 3 seconds to about 12 seconds, about 3 seconds to about 14 seconds, about 3 seconds to about 16 seconds, about 3 seconds to about 20 seconds, about 3

seconds to about 25 seconds, about 3 seconds to about 30 seconds, about 4 seconds to about 5 seconds, about 4 seconds to about 10 seconds, about 4 seconds to about 12 seconds, about 4 seconds to about 14 seconds, about 4 seconds to about 16 seconds, about 4 seconds to about 20 seconds, about 4 seconds to about 25 seconds, about 4 seconds to about 30 seconds, about 5 seconds to about 10 seconds, about 5 seconds to about 12 seconds, about 5 seconds to about 14 seconds, about 5 seconds to about 16 seconds, about 5 seconds to about 20 seconds, about 5 seconds to about 25 seconds, about 5 seconds to about 30 seconds, about 10 seconds to about 12 seconds, about 10 seconds to about 14 seconds, about 10 seconds to about 16 seconds, about 10 seconds to about 20 seconds, about 10 seconds to about 25 seconds, about 10 seconds to about 30 seconds, about 12 seconds to about 14 seconds, about 12 seconds to about 16 seconds, about 12 seconds to about 20 seconds, about 12 seconds to about 25 seconds, about 12 seconds to about 30 seconds, about 14 seconds to about 16 seconds, about 14 seconds to about 20 seconds, about 14 seconds to about 25 seconds, about 14 seconds to about 30 seconds, about 16 seconds to about 20 seconds, about 16 seconds to about 25 seconds, about 16 seconds to about 30 seconds, about 20 seconds to about 25 seconds, about 20 seconds to about 30 seconds, or about 25 seconds to about 30 seconds. In some cases, the duration of stimulation **227** may comprise about 1 second, about 2 seconds, about 3 seconds, about 4 seconds, about 5 seconds, about 10 seconds, about 12 seconds, about 14 seconds, about 16 seconds, about 20 seconds, about 25 seconds, or about 30 seconds. In some cases, the duration of stimulation **227** may comprise at least about 1 second, about 2 seconds, about 3 seconds, about 4 seconds, about 5 seconds, about 10 seconds, about 12 seconds, about 14 seconds, about 16 seconds, about 20 seconds, or about 25 seconds. In some cases, the duration of stimulation **227** may comprise at most about 2 seconds, about 3 seconds, about 4 seconds, about 5 seconds, about 10 seconds, about 12 seconds, about 14 seconds, about 16 seconds, about 20 seconds, about 25 seconds, or about 30 seconds.

**[0121]** In some cases the response time **228** may comprise about 60 μs to about 100 μs. In some cases the response time **228** may comprise about 60 μs to about 65 μs, about 60 μs to about 70 μs, about 60 μs to about 75 μs, about 60 μs to about 80 μs, about 60 μs to about 85 μs, about 60 μs to about 90 μs, about 60 μs to about 95 μs, about 60 μs to about 100 μs, about 65 μs to about 70 μs, about 65 μs to about 75 μs, about 65 μs to about 80 μs, about 65 μs to about 85 μs, about 65 μs to about 90 μs, about 65 μs to about 95 μs, about 65 μs to about 100 μs, about 70 μs to about 75 μs, about 70 μs to about 80 μs, about 70 μs to about 85 μs, about 70 μs to about 90 μs, about 70 μs to about 95 μs, about 70 μs to about 100 μs, about 75 μs to about 80 μs, about 75 μs to about 85 μs, about 75 μs to about 90 μs, about 75 μs to about 95 μs, about 75 μs to about 100 μs, about 80 μs to about 85 μs, about 80 μs to about 90 μs, about 80 μs to about 95 μs,

about 80 μs to about 100 μs, about 85 μs to about 90 μs, about 85 μs to about 95 μs, about 85 μs to about 100 μs, about 90 μs to about 95 μs, about 90 μs to about 100 μs, or about 95 μs to about 100 μs. In some cases the response time **228** may comprise about 60 μs, about 65 μs, about 70 μs, about 75 μs, about 80 μs, about 85 μs, about 90 μs, about 95 μs, or about 100 μs. In some cases the response time 228 may comprise at least about 60 μs, about 65 μs, about 70 μs, about 75 μs, about 80 μs, about 85 μs, about 90 μs, or about 95 μs. In some cases the response time **228** may comprise at most about 65 μs, about 70 μs, about 75 μs, about 80 μs, about 85 μs, about 90 μs, about 95 μs, or about 100 μs. Through the development of iteratively trained machine learning classifiers the response time may be minimized, and improved incontinence prevention may be realized.

**[0122]** **FIGS. 12A-12B** illustrate a workflow of a method **1200** for preventing an episode of incontinence in an individual sufferer. The method may comprise the steps of (a) implanting a sensor electrode and stimulator electrode within a body of an individual **1202**; (b) sensing a parameter associated with a response from the individual, where the response is user induced stimulus **1204**; and (c) providing an electric stimulation with the stimulator electrode to prevent the incontinence event **1206**. In some cases, the user induced stimulus may be intended to prevent an episode of incontinence. As shown graphically in **FIG. 12B**, a detected EMG signal **1208** may be analyzed by a classifier **1210**, described elsewhere herein, to determine when the EMG, ENG, accelerometer, gyroscope, magnetometer, pressure sensor signals or any combination thereof signals have crossed a pre-determined threshold, described elsewhere herein. Once the classifier **1210** has determined that the signal **1208** does represent an incontinent event, the processor, described elsewhere herein, may enable stimulation **1212** to prevent the incontinent event from occurring. In some cases, stimulation **1212** may comprise an extension of stimulation **1211** that may extend beyond the time the classifier **1210** determines there to be an incontinent event. In some cases the extension of stimulation **1211** may comprise a duration of time equal to the duration the subject continues to purposefully or with intent produce a muscle contraction.

**[0123]** In some cases the extension of stimulation **1211** may comprise about 1 s to about 30 s. In some cases the extension of stimulation **1211** may comprise about 1 s to about 3 s, about 1 s to about 5 s, about 1 s to about 8 s, about 1 s to about 10 s, about 1 s to about 12 s, about 1 s to about 15 s, about 1 s to about 18 s, about 1 s to about 20 s, about 1 s to about 22 s, about 1 s to about 24 s, about 1 s to about 30 s, about 3 s to about 5 s, about 3 s to about 8 s, about 3 s to about 10 s, about 3 s to about 12 s, about 3 s to about 15 s, about 3 s to about 18 s, about 3 s to about 20 s, about 3 s to about 22 s, about 3 s to about 24 s, about 3 s to about 30 s, about 5 s to about 8 s, about 5 s to about 10 s, about 5 s to about 12 s, about 5 s to about 15 s, about 5 s to

about 18 s, about 5 s to about 20 s, about 5 s to about 22 s, about 5 s to about 24 s, about 5 s to about 30 s, about 8 s to about 10 s, about 8 s to about 12 s, about 8 s to about 15 s, about 8 s to about 18 s, about 8 s to about 20 s, about 8 s to about 22 s, about 8 s to about 24 s, about 8 s to about 30 s, about 10 s to about 12 s, about 10 s to about 15 s, about 10 s to about 18 s, about 10 s to about 20 s, about 10 s to about 22 s, about 10 s to about 24 s, about 10 s to about 30 s, about 12 s to about 15 s, about 12 s to about 18 s, about 12 s to about 20 s, about 12 s to about 22 s, about 12 s to about 24 s, about 12 s to about 30 s, about 15 s to about 18 s, about 15 s to about 20 s, about 15 s to about 22 s, about 15 s to about 24 s, about 15 s to about 30 s, about 18 s to about 20 s, about 18 s to about 22 s, about 18 s to about 24 s, about 18 s to about 30 s, about 20 s to about 22 s, about 20 s to about 24 s, about 20 s to about 30 s, about 22 s to about 24 s, about 22 s to about 30 s, or about 24 s to about 30 s. In some cases the extension of stimulation **1211** may comprise about 1 s, about 3 s, about 5 s, about 8 s, about 10 s, about 12 s, about 15 s, about 18 s, about 20 s, about 22 s, about 24 s, or about 30 s. In some cases the extension of stimulation **1211** may comprise at least about 1 s, about 3 s, about 5 s, about 8 s, about 10 s, about 12 s, about 15 s, about 18 s, about 20 s, about 22 s, or about 24 s. In some cases the extension of stimulation **1211** may comprise at most about 3 s, about 5 s, about 8 s, about 10 s, about 12 s, about 15 s, about 18 s, about 20 s, about 22 s, about 24 s, or about 30 s.

**[0124]** In some instances, there may be a delay **1209** between the onset of the incontinent event in the raw EMG, ENG, accelerometer, gyroscope, magnetometer, pressure sensor, or any combination thereof signal data, and the onset of the electrical stimulation. Upon training the classifier **1210** on sufficiently large and varied datasets, such delay may be minimized further improving the device performance in prevent incontinent events. In some cases, sensing may comprise determining a global positioning system (GPS) location of the individual that in combination with the parameter associated with the response from the individual is used to prevent the episode of incontinence.

**[0125]** Aspects of the disclosure provided herein may comprise a method of data processing. In some cases, the method of data processing may comprise: (i) receiving a measurement of a parameter previously measured by a sensor electrode, which parameter is predictive of an episode of incontinence in an individual; (ii) analyzing the parameter; and (iii) synthesizing an electrical stimulation signal for the individual, such that when the electrical stimulation signal is provided by a stimulator electrode to the individual, the electrical stimulation signal, together with an effort from the individual that is intended to prevent an episode of incontinence, prevents the episode of incontinence. In some cases, the parameter may be associated with a response from the individual intended to prevent an episode of incontinence. In some instances, the parameter may be associated with the individual's effort in trying to prevent an episode of

incontinence, and where the electrical stimulation signal is synthesized so as to supplement the individual's effort with an electrical stimulation pattern that will, together with the effort from the individual, be sufficient to prevent an episode of incontinence. In some cases, the response from the individual may be insufficient on its own to prevent the episode of incontinence and the electrical stimulation signal is such that, when applied, it adds enough, together with the response, to prevent the episode of incontinence.

[0126] In some instances, the episode of incontinence may comprise urinary incontinence. In some cases, the episode of incontinence may comprise fecal incontinence. In some cases, the episode of incontinence may comprise urinary stress incontinence. In some instances, the episode of incontinence is urinary incontinence and is urge incontinence type.

[0127] In some instances, the parameter may comprise a signal from a sensor electrode that is configured to sense a contraction of a muscle of the individual related to a partial contraction of a sphincter that controls bladder or bowel voiding. In some cases, the electrical stimulation signal may comprise an electrical stimulation of the pudendal nerve. In some instances, the electrical stimulation signal may be synthesized to include a constant electrical stimulation component and a measurement parameter specific component. In some cases, an intensity or duration of the electrical stimulation that will be provided by the electrical stimulation signal may vary according to the value of the parameter that is received. In some instances, the parameter may comprise an EMG signal. In some cases, the EMG signal may determine that a contraction of at least one pelvic muscle has occurred. In some cases, a strength of the EMG signal may be proportional to the strength of the contraction of at least one pelvic muscle. In some instances, the electrical stimulation signal may comprise a first and second signals for the stimulation of a first pudendal nerve and a second pudendal nerve respectively. In some cases, the method may further comprise recording the signal previously measured by the sensor electrode. In some cases, the method may further comprise synthesizing an adjustment signal to adjust the sensor electrode in response to the recorded signal.

**Assessment of Treatment of Incontinence**

***Ambulatory assessments after procedure***

[0128] In some embodiments, various ambulatory assessments may be taken to determine the effectiveness of the implantation procedure. In some embodiments, the implanted IPG permits telemetric downloading of data (inputs, outputs, and event classification). In some embodiments, the participant may be in an awake ambulatory setting and a series of resting and provoked electrophysiological data may be recorded. In some embodiments, at treatment initiation (24-48 hours post-implant) sensory and motor responses may be determined from the

different sensor electrodes on the implanted leads. In some embodiments, based upon the responses, the electrodes with the most adequate response may be selected to initiate treatment.

[0129] In some embodiments, the patients may be subjected to different physiological events to program the IPG. In some embodiments, these events may comprise coughing, Valsalva maneuvers, picking up a 5kg weight, or any combination thereof. In some embodiments, pelvic floor EMG may be measured with a transvaginal and/or anal probe. In some embodiments urethral pressures may be measured. In some embodiments, 1 hour continuous 'resting' recording of inputs and outputs (downloaded by telemetry) may be taken. In some embodiments, recording during controlled participant provoked events, such as coughing, Valsalva, lifting 5 Kg weight, may be obtained. In some embodiments, recording during pelvic floor surface EMG (from transvaginal probe: women only) to correlate inputs from lead vs. surface EMG may be obtained. In some embodiments, patient tolerances of basal stimulation ramping, and actuation parameters may be obtained. In some embodiments, standard urodynamic tests are performed at 48 hours. In some embodiments, UDCs (with or without reporting of urge) may be recorded during bladder filling to assess the acute effect of patient-actuation of device. In some embodiments, a standard 1 hour pad test may be performed.

***Clinical outcomes***

[0130] In some embodiments, clinical outcomes may be assessed using a 5-day voiding diary recording number of voids, number of urgency episodes, number of leaks with severity of leaks to derive: stress and urge UI (summative) episodes per unit time; stress UI episodes per unit time; urge UI episodes per unit time; urgency to void episodes per unit time; total voiding frequency per unit time; responder rate: based on >50% decrease in UI episodes per unit time; functional cure rate defined as either >90% decrease in mean total UI episodes from baseline OR mean <1 UIE per week; ICIQ-SF-UI questionnaire; or any combination thereof.

## Definitions

[0131] Unless defined otherwise, all terms of art, notations and other technical and scientific terms or terminology used herein are intended to have the same meaning as is commonly understood by one of ordinary skill in the art to which the claimed subject matter pertains. In some cases, terms with commonly understood meanings are defined herein for clarity and/or for ready reference, and the inclusion of such definitions herein should not necessarily be construed to represent a substantial difference over what is generally understood in the art.

[0132] Throughout this application, various embodiments may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the

disclosure. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

**[0133]** As used in the specification and claims, the singular forms "a", "an" and "the" include plural references unless the context clearly dictates otherwise. For example, the term "a sample" includes a plurality of samples, including mixtures thereof.

**[0134]** The terms "determining", "measuring", "evaluating", "assessing," "assaying," and "analyzing" are often used interchangeably herein to refer to forms of measurement and include determining if an element is present or not (for example, detection). These terms can include quantitative, qualitative, or quantitative and qualitative determinations. Assessing is alternatively relative or absolute. "Detecting the presence of" includes determining the amount of something present, as well as determining whether it is present or absent.

**[0135]** The terms "subject," "individual," or "patient" are often used interchangeably herein. A "subject" can be a biological entity containing expressed genetic materials. The biological entity can be an animal. The subject can be a mammal. The mammal can be a human. The subject may be diagnosed or suspected of being at high risk for a disease or a condition. The disease can be incontinence. In some cases, the disease can be urinary incontinence. In some cases, the disease is bowel incontinence. In some cases, the subject is not necessarily diagnosed or suspected of being at high risk for the disease.

**[0136]** The term "*in vivo*" is used to describe an event that takes place in a subject's body.

**[0137]** The term "*ex vivo*" is used to describe an event that takes place outside of a subject's body. An "*ex vivo*" assay is not performed on a subject. Rather, it is performed upon a sample separate from a subject. An example of an "*ex vivo*" assay performed on a sample is an "in vitro" assay.

**[0138]** As used herein, the term 'about' a number refers to that number plus or minus 10% of that number. The term 'about' a range refers to that range minus 10% of its lowest value and plus 10% of its greatest value.

**[0139]** As used herein, the terms "treatment" or "treating" are used in reference to an intervention regimen for obtaining beneficial or desired results in the recipient. Beneficial or desired results include but are not limited to a therapeutic benefit and/or a prophylactic benefit. A therapeutic benefit may refer to prevention or amelioration of symptoms or of an underlying disorder being treated. Also, a therapeutic benefit can be achieved with prevention or

amelioration of one or more of the physiological symptoms associated with the underlying disorder such that an improvement is observed in the subject, notwithstanding that the subject may still be afflicted with the underlying disorder. A prophylactic effect includes delaying, preventing, or eliminating the appearance of a disease or a condition, delaying or eliminating the onset of symptoms of a disease or a condition, slowing, halting, or reversing the progression of a disease or a condition, or any combination thereof. For prophylactic benefit, a subject at risk of developing a particular disease or a condition, or to a subject reporting one or more of the physiological symptoms of a disease or a condition may undergo treatment.

[0140] The section headings used herein are for organizational purposes only and are not to be construed as limiting the subject matter described.

[0141] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

## NUMERATED EMBODIMENTS

[0142] Numbered embodiment 1 comprises a method for preventing an episode of incontinence in an individual in need thereof, the method comprising: (a) implanting a sensor and stimulator electrode within a body of the individual; (b) sensing, with the sensor electrode, a parameter that is associated with a response from the individual that is intended to prevent an episode of incontinence; and (c) providing an electrical stimulation, with the stimulator electrode, that, together with the response, prevents the episode of incontinence. Numbered embodiment 2 comprises the method of embodiment 1, wherein the episode of incontinence comprises urinary incontinence. Numbered embodiment 3 comprises the method of embodiment 1, wherein the episode of incontinence comprises fecal incontinence. Numbered embodiment 4 comprises the method of embodiment 1, wherein the episode of incontinence comprises urinary stress incontinence. Numbered embodiment 5 comprises the method of embodiment 1, wherein the sensor electrode is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding. Numbered embodiment 6 comprises the method of embodiment 5, wherein the sensor electrode is positioned within the pelvis of the individual. Numbered embodiment 7 comprises the method of

embodiment 1, wherein the stimulator electrode provides an electrical stimulation to the pudendal nerve. Numbered embodiment 8 comprises the method of embodiment 7, wherein the sensor and the stimulator electrode are located on a single lead. Numbered embodiment 9 comprises the method of embodiment 1, comprising a step of providing a constant electrical stimulation at a lower intensity level than the electrical stimulation provided in step (c). Numbered embodiment 10 comprises the method of embodiment 9, wherein the episode of incontinence is urinary incontinence and is urge incontinence type. Numbered embodiment 11 comprises the method of embodiment 1, wherein the intensity or duration of the electrical stimulation provided in step (c) varies according to the response that is sensed in step (b). Numbered embodiment 12 comprises the method of embodiment 11, wherein the response that is sensed in step (b) is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided in step (b) adds just enough, together with the response, to prevent the episode of incontinence. Numbered embodiment 13 comprises the method of embodiment 11, wherein the response that is sensed in step (b) is insufficient on its own to prevent the episode of incontinence, and wherein the electrical stimulation provided in step (b) together with the response, prevents the episode of incontinence. Numbered embodiment 14 comprises the method of embodiment 1, wherein the sensor electrode is configured to sense an EMG signal. Numbered embodiment 15 comprises the method of embodiment 14, wherein the EMG signal determines that a contraction of at least one pelvic muscle has occurred. Numbered embodiment 16 comprises the method of embodiment 15, wherein a strength of the EMG signal is proportional to a strength of the contraction of at least one pelvic muscle. Numbered embodiment 17 comprises the method of embodiment 1, comprising a step of implanting a first stimulator electrode and second stimulator electrode, wherein the first stimulator electrode stimulates one region on a pudendal nerve and the second stimulator electrode stimulates a different region on the pudendal nerve. Numbered embodiment 18 comprises the method of embodiment 1, wherein the individual suffers from urinary incontinence of a mixed type. Numbered embodiment 19 comprises the method of embodiment 1, wherein the sensor and the stimulator electrode are operatively coupled to a processor and a non-transitory computer readable medium that includes software. Numbered embodiment 20 comprises the method of embodiment 19, wherein the sensor electrode is calibrated by the individual using an external input device that interfaces with the software. Numbered embodiment 21 comprises the method of embodiment 19, wherein the software is configured to record a signal from the sensor electrode. Numbered embodiment 22 comprises the method of embodiment 21, wherein the software is configured to adjust the sensor electrode's response to the signal. Numbered embodiment 23 comprises the method of embodiment 19, wherein the software comprises a

machine learning model, and wherein the machine learning model is configured to classify signals detected by the sensor electrode and generate signals with the stimulator electrode. Numbered embodiment 24 comprises the method of embodiment 23, wherein the machine learning model is trained on prior data acquired from the individual or a set of individuals and the corresponding incontinence prevention or lack thereof information. Numbered embodiment 25 comprises the method of embodiment 24, wherein the prior data comprises the signals detected by the sensor electrode, the generated signals generated by the stimulator electrode, or any combination thereof. Numbered embodiment 26 comprises the method of embodiment 1, wherein sensing further comprises determining a global positioning system (GPS) location of the individual that in combination with the parameter associated with the response from the individual prevents the episode of incontinence.

**[0143]** Numbered embodiment 27 comprises a system for preventing an episode of incontinence in an individual in need thereof, the apparatus comprising: (a) a sensor electrode configured to sense a parameter that is associated with a response from the individual that is intended to prevent the episode of incontinence; (b) a stimulator electrode configured to provide electrical stimulation; (c) a processor operably coupled to the sensor and stimulator electrode; and (d) a non-transitory computer readable storage medium including software configured to cause the processor to: (i) receive the parameter that is associated with the response from the individual that is intended to prevent the episode of incontinence; (ii) analyze the parameter that is associated with the response from the individual that is intended to prevent the episode of incontinence; and (iii) cause the stimulator electrode to provide the electrical stimulation to the individual such that the electrical stimulation together with the response from the individual that is intended to prevent the episode of incontinence prevents the episode of incontinence. Numbered embodiment 28 comprises the system of embodiment 27, wherein the episode of incontinence comprises urinary incontinence. Numbered embodiment 29 comprises the system of embodiment 27, wherein the episode of incontinence comprises fecal incontinence. Numbered embodiment 30 comprises the system of embodiment 27, wherein the episode of incontinence comprises urinary stress incontinence. Numbered embodiment 31 comprises the system of embodiment 27, wherein the sensor electrode is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding. Numbered embodiment 32 comprises the system of embodiment 27, wherein the sensor electrode is positioned within the pelvis of the individual. Numbered embodiment 33 comprises the system of embodiment 27, wherein the stimulator electrode provides the electrical stimulation to the pudendal nerve of the individual. Numbered embodiment 34 comprises the system of embodiment 27, wherein the sensor and stimulator electrodes are located on a single

lead. Numbered embodiment 35 comprises the system of embodiment 27, wherein the stimulator electrode is configured to provide a constant electrical stimulation at a lower intensity level than the electrical stimulation. Numbered embodiment 36 comprises the system of embodiment 27, wherein the episode of incontinence is urinary incontinence and is urge incontinence type. Numbered embodiment 37 comprises the system of embodiment 27, wherein an intensity or duration of the electrical stimulation varies according to the response that is sensed. Numbered embodiment 38 comprises the system of embodiment 27, wherein the response that is sensed by the sensor electrode is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided adds just enough, together with the response, to prevent the episode of incontinence. Numbered embodiment 39 comprises the system of embodiment 27, wherein the response that is sensed by the sensor electrode is insufficient on its own to prevent the episode of incontinence, and wherein the electrical stimulation provided in step (b), together with the response, prevents the episode of incontinence. Numbered embodiment 40, the system of embodiment 27, wherein the sensor electrode is configured to sense an EMG signal. Numbered embodiment 41 comprises the system of embodiment 40 wherein the EMG signal determines that a contraction of at least one pelvic muscle has occurred. Numbered embodiment 42 comprises the system of embodiment 41, wherein a strength of the EMG signal is proportional to a strength of the contraction of at least one pelvic muscle. Numbered embodiment 43 comprises the system of embodiment 27, wherein the stimulator electrode comprises a first stimulator electrode and a second stimulator electrode, wherein the first stimulator electrode stimulates a first pudendal nerve and the second stimulator electrode stimulates a second pudendal nerve. Numbered embodiment 44 comprises the system of embodiment 27, wherein the individual suffers from urinary incontinence of a mixed type. Numbered embodiment 45 comprises the system of embodiment 27, wherein the sensor electrode is calibrated by the individual using an external input device that interfaces with the software. Numbered embodiment 46 comprises the system of embodiment 27, wherein the software is configured to further cause the processor to record a signal from the sensor electrode. Numbered embodiment 47 comprises the system of embodiment 46, wherein the software is configured to adjust the sensor electrode's response to the signal. Numbered embodiment 48 comprises the system of embodiment 27, wherein the software comprises a machine learning model, and wherein the machine learning model is configured to classify signals detected by the sensor electrode and generate signals with the stimulator electrode. Numbered embodiment 49 comprises the system of embodiment 48, wherein the machine learning model is trained on prior data acquired from the individual or a set of individuals and the corresponding incontinence prevention or lack thereof information. Numbered embodiment 50 comprises the system of

embodiment 49, wherein the prior data comprises the signals detected by the sensor electrode, the generated signals generated by the stimulator electrode, or any combination thereof. Numbered embodiment 51 comprises the system of embodiment 27, wherein the software comprises analyzing a global positioning system (GPS) location of the individual that in combination with the parameter associated with the response from the individual prevents the episode of incontinence.

**[0144]** Numbered embodiment 52 comprises a non-transitory computer readable storage medium including software for preventing an episode of incontinence in an individual in need thereof, configured to cause a processor to: (i) receive a parameter by a sensor electrode that is associated with a response from the individual intended to prevent the episode of incontinence; (ii) analyze the parameter that is associated with the response from the individual that is intended to prevent the episode of incontinence; and (iii) cause a stimulator electrode to provide an electrical stimulation to the individual so that the electrical stimulation together with the response from the individual that is intended to prevent the episode of incontinence prevents the episode of incontinence. Numbered embodiment 53 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the episode of incontinence comprises urinary incontinence. Numbered embodiment 54 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the episode of incontinence comprises fecal incontinence. Numbered embodiment 55 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the episode of incontinence comprises urinary stress incontinence. Numbered embodiment 56 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the sensor electrode is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding. Numbered embodiment 57 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the sensor electrode is positioned within the pelvis of the individual. Numbered embodiment 58 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the stimulator electrode provides the electrical stimulation to the individual's pudendal nerve. Numbered embodiment 59 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the sensor and stimulator electrodes are located on a single lead. Numbered embodiment 60 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the stimulator electrode is configured to provide a constant electrical stimulation at a lower intensity level than the electrical stimulation. Numbered embodiment 61 comprises the non-transitory computer

readable storage medium including software of embodiment 52, wherein the episode of incontinence is urinary incontinence and is urge incontinence type. Numbered embodiment 62 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein an intensity or duration of the electrical stimulation varies according to the response that is sensed. Numbered embodiment 63 comprises the non-transitory computer readable storage medium including software of embodiment 62, wherein the response that is sensed by the sensor electrode is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided adds just enough, together with the response, to prevent the episode of incontinence. Numbered embodiment 64 comprises the non-transitory computer readable storage medium including software of embodiment 62, wherein the response that is sensed by the sensor is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided together with the response, prevents the episode of incontinence. Numbered embodiment 65 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the sensor electrode is configured to sense an EMG signal. Numbered embodiment 66 comprises the non-transitory computer readable storage medium including software of embodiment 65, wherein the EMG signal determines that a contraction of at least one pelvic muscle has occurred. Numbered embodiment 67 comprises the non-transitory computer readable storage medium including software of embodiment 66, wherein a strength of the EMG signal is proportional to a strength of the contraction of at least one pelvic muscle. Numbered embodiment 68 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the stimulator electrode comprises a first stimulator electrode and a second stimulator electrode, wherein the first stimulator electrode stimulates a first pudendal nerve and the second stimulator electrode stimulates a second pudendal nerve. Numbered embodiment 69 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the individual suffers from urinary incontinence of a mixed type. Numbered embodiment 70 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the sensor electrode is calibrated by the individual using an external input device that interfaces with the software. Numbered embodiment 71 comprises the non-transitory computer readable storage medium including software of embodiment 52, wherein the software is configured to further cause the processor to record a signal from the sensor electrode. Numbered embodiment 72 comprises the non-transitory computer readable storage medium including software of embodiment 71, wherein the software is configured to adjust the sensor electrode's response to the signal. Numbered embodiment 73 comprises the non-transitory computer readable storage medium of embodiment 52, wherein the software comprises a

machine learning model, and wherein the machine learning model is configured to classify signals detected by the sensor electrode and generate signals with the stimulator electrode. Numbered embodiment 74 comprises the non-transitory computer readable storage medium of embodiment 73, wherein the machine learning model is trained on prior data acquired from the individual or a set of individuals and the corresponding incontinence prevention or lack thereof information. Numbered embodiment 75 comprises the non-transitory computer readable storage medium of embodiment 74, wherein the prior data comprise the signals detected by the sensor electrode, the generated signals, or any combination thereof. Numbered embodiment 76 comprises the non-transitory computer readable medium of embodiment 52, wherein the software comprises analyzing a global positioning system (GPS) location of the individual that in combination with the parameter associated with the response from the individual prevents the episode of incontinence.

**[0145]** Numbered embodiment 77 comprises a method of data processing, said method comprising: (i) receiving a measurement of a parameter previously measured by a sensor electrode, which parameter is predictive of an episode of incontinence in an individual; (ii) analyzing the parameter; and (iii) synthesizing an electrical stimulation signal for the individual, so that when the electrical stimulation signal is provided by a stimulator electrode to the individual, the electrical stimulation signal, together with an effort from the individual that is intended to prevent an episode of incontinence, prevents the episode of incontinence. Numbered embodiment 78 comprises the method of embodiment 77, wherein the parameter is associated with a response from the individual intended to prevent an episode of incontinence. Numbered embodiment 79 comprises the method of embodiment 78, wherein the parameter is associated with the individual's effort in trying to prevent an episode of incontinence, and wherein the electrical stimulation signal is synthesized so as to supplement the individual's effort with an electrical stimulation pattern that will, together with the effort from the individual, be sufficient to prevent an episode of incontinence. Numbered embodiment 80 comprises the method of embodiment 79, wherein the response from the individual is insufficient on its own to prevent the episode of incontinence and the electrical stimulation signal is such that, when applied, it adds enough, together with the response, to prevent the episode of incontinence. Numbered embodiment 81 comprises the method of any one of embodiments 77 to 80, wherein the episode of incontinence comprises urinary incontinence. Numbered embodiment 82 comprises the method of embodiments 77 or 80, wherein the episode of incontinence comprises fecal incontinence. Numbered embodiment 83 comprises the method of any one of embodiments 77 to 80, wherein the episode of incontinence comprises urinary stress incontinence. Numbered embodiment 84 comprises the method of any one of embodiments 77 to 83, wherein the

parameter is a signal from a sensor electrode that is configured to sense a contraction of a muscle of the individual related to a partial contraction of a sphincter that controls bladder or bowel voiding. Numbered embodiment 85 comprises the method of any one of embodiments 77 to 84, wherein the electrical stimulation signal is for the electrical stimulation of the pudendal nerve. Numbered embodiment 86 comprises the method of any one of embodiments 77 to 85, wherein the electrical stimulation signal is synthesized to include a constant electrical stimulation component and a measurement parameter specific component. Numbered embodiment 87 comprises the method of any one of embodiments 77 to 86, wherein the episode of incontinence is urinary incontinence and is urge incontinence type. Numbered embodiment 88 comprises the method of any one of embodiments 77 to 87, wherein an intensity or duration of the electrical stimulation that will be provided by the electrical stimulation signal varies according to the value of the parameter that is received. Numbered embodiment 89 comprises the method of any one of embodiments 77 to 88, wherein the parameter is an EMG signal. Numbered embodiment 90 comprises the method of embodiment 89, wherein the EMG signal determines that a contraction of at least one pelvic muscle has occurred. Numbered embodiment 91 comprises the method of embodiment 9066, wherein a strength of the EMG signal is proportional to the strength of the contraction of at least one pelvic muscle. Numbered embodiment 92 comprises the method of any one of embodiments 77 to 91, wherein the electrical stimulation signal comprises first and second signals for the stimulation of a first pudendal nerve and a second pudendal nerve respectively. Numbered embodiment 93 comprises the method of any one of embodiments 77 to 92, further comprising recording the signal previously measured by the sensor electrode. Numbered embodiment 94 comprises the method of embodiment 93, further comprising synthesizing an adjustment signal to adjust the sensor electrode in response to the recorded signal.

## EXAMPLES

### Example 1: EMG Measurement Reproducibility

**[0146]** Using the systems, methods, and devices, described herein, patient EMG signals were measured and processed as patients performed muscle contractions, coughing, and Valsalva maneuvers, as can be seen in **FIGS. 11A-11E**. For each patient, raw EMG data **1102** was recorded and amplified, as described elsewhere herein. Subsequently, the raw EMG data was filtered **1106**, rectified, and smoothed **1104.**

**[0147]** From the data shown in FIGS. **11A-11C,** where a single patient iteratively performed the same sequence of muscle contractions three times, a distinct group of three signals may be observed in the temporal EMG data. Such a finding supports the reproducibility of the sensor

electrodes of the devices and systems described herein and the potential ability of a trained classifier to distinguish EMG signals temporally. Similarly data for a different patient shown in **FIGS. 11D-11E** shows similar results as the patient in **FIGS. 11A-11C**.

## CLAIMS

What is claimed:

1. A method for preventing an episode of incontinence in an individual in need thereof, the method comprising:
   (a) implanting a sensor and stimulator electrode within a body of the individual;
   (b) sensing, with the sensor electrode, a parameter that is associated with a response from the individual that is intended to prevent an episode of incontinence; and
   (c) providing an electrical stimulation, with the stimulator electrode, that, together with the response, prevents the episode of incontinence.
2. The method of claim 1, wherein the episode of incontinence comprises urinary incontinence.
3. The method of claim 1, wherein the episode of incontinence comprises fecal incontinence.
4. The method of claim 1, wherein the episode of incontinence comprises urinary stress incontinence.
5. The method of claim 1, wherein the sensor electrode is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding.
6. The method of claim 5, wherein the sensor electrode is positioned within the pelvis of the individual.
7. The method of claim 1, wherein the stimulator electrode provides an electrical stimulation to the pudendal nerve of the individual.
8. The method of claim 7, wherein the sensor and the stimulator electrode are located on a single lead.
9. The method of claim 1, comprising a step of providing a constant electrical stimulation at a lower intensity level than the electrical stimulation provided in step (c).
10. The method of claim 9, wherein the episode of incontinence is urinary incontinence and is urge incontinence type.
11. The method of claim 1, wherein the intensity or duration of the electrical stimulation provided in step (c) varies according to the response that is sensed in step (b).
12. The method of claim 11, wherein the response that is sensed in step (b) is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided in step (b) adds just enough, together with the response, to prevent the episode of incontinence.

13. The method of claim 11, wherein the response that is sensed in step (b) is insufficient on its own to prevent the episode of incontinence, and wherein the electrical stimulation provided in step (b), together with the response, prevents the episode of incontinence.
14. The method of claim 1, wherein the sensor electrode is configured to sense an EMG signal.
15. The method of claim 14, wherein the EMG signal determines that a contraction of at least one pelvic muscle has occurred.
16. The method of claim 15, wherein a strength of the EMG signal is proportional to the strength of the contraction of at least one pelvic muscle.
17. The method of claim 1, comprising a step of implanting a first stimulator electrode and a second stimulator electrode, wherein the first stimulator electrode stimulates one region on a pudendal nerve and the second stimulator electrode stimulates a different region on the pudendal nerve.
18. The method of claim 1, wherein the individual suffers from urinary incontinence of a mixed type.
19. The method of claim 1, wherein the sensor and the stimulator electrode are operatively coupled to a processor and a non-transitory computer readable medium that includes software.
20. The method of claim 19, wherein the sensor electrode is calibrated by the individual using an external input device that interfaces with the software.
21. The method of claim 19, wherein the software is configured to record a signal from the sensor electrode.
22. The method of claim 21, wherein the software is configured to adjust the sensor electrode's response to the signal.
23. The method of claim 19, wherein the software comprises a machine learning model, and wherein the machine learning model is configured to classify signals detected by the sensor electrode and generate signals with the stimulator electrode.
24. The method of claim 23, wherein the machine learning model is trained on prior data acquired from the individual or a set of individuals and the corresponding incontinence prevention or lack thereof information.
25. The method of claim 24, wherein the prior data comprises the signals detected by the sensor electrode, the generated signals generated by the stimulator electrode, or any combination thereof.
26. The method of claim 1, wherein sensing further comprises determining a global positioning system (GPS) location of the individual that in combination with the

parameter associated with the response from the individual prevents the episode of incontinence.

27. A system for preventing an episode of incontinence in an individual in need thereof, the apparatus comprising:
    (a) a sensor electrode configured to sense a parameter that is associated with a response from the individual that is intended to prevent the episode of incontinence;
    (b) a stimulator electrode configured to provide electrical stimulation;
    (c) a processor operably coupled to the sensor and stimulator electrodes; and
    (d) a non-transitory computer readable storage medium including software configured to cause the processor to:
        (i) receive the parameter that is associated with the response from the individual that is intended to prevent the episode of incontinence;
        (ii) analyze the parameter that is associated with the response from the individual that is intended to prevent the episode of incontinence; and
        (iii) cause the stimulator electrode to provide the electrical stimulation to the individual such that the electrical stimulation together with the response from the individual that is intended to prevent the episode of incontinence prevents the episode of incontinence.
28. The system of claim 27, wherein the episode of incontinence comprises urinary incontinence.
29. The system of claim 27, wherein the episode of incontinence comprises fecal incontinence.
30. The system of claim 27, wherein the episode of incontinence comprises urinary stress incontinence.
31. The system of claim 27, wherein the sensor electrode is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding.
32. The system of claim 27, wherein the sensor electrode is positioned within the pelvis of the individual.
33. The system of claim 27, wherein the stimulator electrode provides the electrical stimulation to the pudendal nerve of the individual.
34. The system of claim 27, wherein the sensor and stimulator electrodes are located on a single lead.
35. The system of claim 27, wherein the stimulator electrode is configured to provide a constant electrical stimulation at a lower intensity level than the electrical stimulation.

36. The system of claim 27, wherein the episode of incontinence is urinary incontinence and is urge incontinence type.
37. The system of claim 27, wherein an intensity or duration of the electrical stimulation varies according to the response that is sensed.
38. The system of claim 27, wherein the response that is sensed by the sensor electrode is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided adds just enough, together with the response, to prevent the episode of incontinence.
39. The system of claim 27, wherein the response that is sensed by the sensor electrode is insufficient on its own to prevent the episode of incontinence, and wherein the electrical stimulation provided in step (b), together with the response, prevents the episode of incontinence.
40. The system of claim 27, wherein the sensor electrode is configured to sense an EMG signal.
41. The system of claim 40, wherein the EMG signal determines that a contraction of at least one pelvic muscle has occurred.
42. The system of claim 41, wherein a strength of the EMG signal is proportional to a strength of the contraction of at least one pelvic muscle.
43. The system of claim 27, wherein the stimulator electrode comprises a first stimulator electrode and a second stimulator electrode, wherein the first stimulator electrode stimulates a first pudendal nerve and the second stimulator electrode stimulates a second pudendal nerve.
44. The system of claim 27, wherein the individual suffers from urinary incontinence of a mixed type.
45. The system of claim 27, wherein the sensor electrode is calibrated by the individual using an external input device that interfaces with the software.
46. The system of claim 27, wherein the software is configured to further cause the processor to record a signal from the sensor electrode.
47. The system of claim 46, wherein the software is configured to adjust the sensor electrode's response to the signal.
48. The system of claim 27, wherein the software comprises a machine learning model, and wherein the machine learning model is configured to classify signals detected by the sensor electrode and generate signals with the stimulator electrode.

49. The system of claim 48, wherein the machine learning model is trained on prior data acquired from the individual or a set of individuals and the corresponding incontinence prevention or lack thereof information.
50. The system of claim 49, wherein the prior data comprises the signals detected by the sensor electrode, the generated signals generated by the stimulator electrode, or any combination thereof.
51. The system of claim 27, wherein the software comprises analyzing a global positioning system (GPS) location of the individual that in combination with the parameter associated with the response from the individual prevents the episode of incontinence.
52. A non-transitory computer readable storage medium including software for preventing an episode of incontinence in an individual in need thereof, configured to cause a processor to:

    (i) receive a parameter by a sensor electrode that is associated with a response from the individual intended to prevent the episode of incontinence;
    (ii) analyze the parameter that is associated with the response from the individual that is intended to prevent the episode of incontinence; and
    (iii) cause a stimulator electrode to provide an electrical stimulation to the individual so that the electrical stimulation together with the response from the individual that is intended to prevent the episode of incontinence prevents the episode of incontinence.
53. The non-transitory computer readable storage medium including software of claim 52, wherein the episode of incontinence comprises urinary incontinence.
54. The non-transitory computer readable storage medium including software of claim 52, wherein the episode of incontinence comprises fecal incontinence.
55. The non-transitory computer readable storage medium including software of claim 52, wherein the episode of incontinence comprises urinary stress incontinence.
56. The non-transitory computer readable storage medium including software of claim 52, wherein the sensor electrode is configured to sense a contraction of a muscle of the individual that results in a partial contraction of a sphincter that controls bladder or bowel voiding.
57. The non-transitory computer readable storage medium including software of claim 52, wherein the sensor electrode is positioned within the pelvis of the individual.
58. The non-transitory computer readable storage medium including software of claim 52, wherein the stimulator electrode provides the electrical stimulation to the individual's pudendal nerve.

59. The non-transitory computer readable storage medium including software of claim 52, wherein the sensor and stimulator electrodes are located on a single lead.
60. The non-transitory computer readable storage medium including software of claim 52, wherein the stimulator electrode is configured to provide a constant electrical stimulation at a lower intensity level than the electrical stimulation.
61. The non-transitory computer readable storage medium including software of claim 52, wherein the episode of incontinence is urinary incontinence and is urge incontinence type.
62. The non-transitory computer readable storage medium including software of claim 52, wherein an intensity or duration of the electrical stimulation varies according to the response that is sensed.
63. The non-transitory computer readable storage medium including software of claim 62, wherein the response that is sensed by the sensor electrode is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided adds just enough, together with the response, to prevent the episode of incontinence.
64. The non-transitory computer readable storage medium including software of claim 62, wherein the response that is sensed by the sensor electrode is insufficient on its own to prevent the episode of incontinence and the electrical stimulation provided, together with the response, prevent the episode of incontinence.
65. The non-transitory computer readable storage medium including software of claim 52, wherein the sensor electrode is configured to sense an EMG signal.
66. The non-transitory computer readable storage medium including software of claim 65, wherein the EMG signal determines that a contraction of at least one pelvic muscle has occurred.
67. The non-transitory computer readable storage medium including software of claim 66, wherein a strength of the EMG signal is proportional to a strength of the contraction of at least one pelvic muscle.
68. The non-transitory computer readable storage medium including software of claim 52, wherein the stimulator electrode comprises a first stimulator electrode and a second stimulator electrode, wherein the first stimulator electrode stimulates a first pudendal nerve and the second stimulator electrode stimulates a second pudendal nerve.
69. The non-transitory computer readable storage medium including software of claim 52, wherein the individual suffers from urinary incontinence of a mixed type.

70. The non-transitory computer readable storage medium including software of claim 52, wherein the sensor electrode is calibrated by the individual using an external input device that interfaces with the software.
71. The non-transitory computer readable storage medium including software of claim 52, wherein the software is configured to further cause the processor to record a signal from the sensor electrode.
72. The non-transitory computer readable storage medium including software of claim 71, wherein the software is configured to adjust the sensor electrode's response to the signal.
73. The non-transitory computer readable storage medium of claim 52, wherein the software comprises a machine learning model, and wherein the machine learning model is configured to classify signals detected by the sensor electrode and generate signals with the stimulator electrode.
74. The non-transitory computer readable storage medium of claim 73, wherein the machine learning model is trained on prior data acquired from the individual or a set of individuals and the corresponding incontinence prevention or lack thereof information.
75. The non-transitory computer readable storage medium of claim 74, wherein the prior data comprise the signals detected by the sensor electrode, the generated signals, or any combination thereof.
76. The non-transitory computer readable storage medium of claim 52, wherein the software comprises analyzing a global positioning system (GPS) location of the individual that in combination with the parameter associated with the response from the individual prevents the episode of incontinence.
77. A method of data processing, said method comprising:
(i) receiving a measurement of a parameter previously measured by a sensor electrode, which parameter is predictive of an episode of incontinence in an individual;
(ii) analyzing the parameter; and
(iii) synthesizing an electrical stimulation signal for the individual, such that when the electrical stimulation signal is provided by a stimulator electrode to the individual, the electrical stimulation signal, together with an effort from the individual that is intended to prevent an episode of incontinence, prevents the episode of incontinence.
78. The method of claim 77, wherein the parameter is associated with a response from the individual intended to prevent an episode of incontinence.
79. The method of claim 78, wherein the parameter is associated with an individual's effort in trying to prevent an episode of incontinence, and wherein the electrical stimulation

signal is synthesized so as to supplement the individual's effort with an electrical stimulation pattern that will, together with the effort from the individual, be sufficient to prevent an episode of incontinence.

80. The method of claim 79, wherein the response from the individual is insufficient on its own to prevent the episode of incontinence and the electrical stimulation signal is such that, when applied, it adds enough, together with the response, to prevent the episode of incontinence.
81. The method of any one of claims 77 to 80, wherein the episode of incontinence comprises urinary incontinence.
82. The method of claim 77 or 80, wherein the episode of incontinence comprises fecal incontinence.
83. The method of any one of claims 77 to 80, wherein the episode of incontinence comprises urinary stress incontinence.
84. The method of any one of claims 77 to 83, wherein the parameter is a signal from a sensor that is configured to sense a contraction of a muscle of the individual related to a partial contraction of a sphincter that controls bladder or bowel voiding.
85. The method of any one of claims 77 to 84, wherein the electrical stimulation signal is for the electrical stimulation of the pudendal nerve.
86. The method of any one of claims 77 to 85, wherein the electrical stimulation signal is synthesized to include a constant electrical stimulation component and a measurement parameter specific component.
87. The method of any one of claims 77 to 86, wherein the episode of incontinence is urinary incontinence and is urge incontinence type.
88. The method of any one of claims 77 to 87, wherein an intensity or duration of the electrical stimulation that will be provided by the electrical stimulation signal varies according to the value of the parameter that is received.
89. The method of any one of claims 77 to 88, wherein the parameter is an EMG signal.
90. The method of claim 89, wherein the EMG signal determines that a contraction of at least one pelvic muscle has occurred.
91. The method of claim 90, wherein a strength of the EMG signal is proportional to the strength of the contraction of at least one pelvic muscle.
92. The method of any one of claims 77 to 91, wherein the electrical stimulation signal comprises first and second signals for the stimulation of a first pudendal nerve and a second pudendal nerve respectively.

93. The method of any one of claims 77 to 92, further comprising recording the signal previously measured by the sensor.
94. The method of claim 93, further comprising synthesizing an adjustment signal to adjust the sensor in response to the recorded signal.

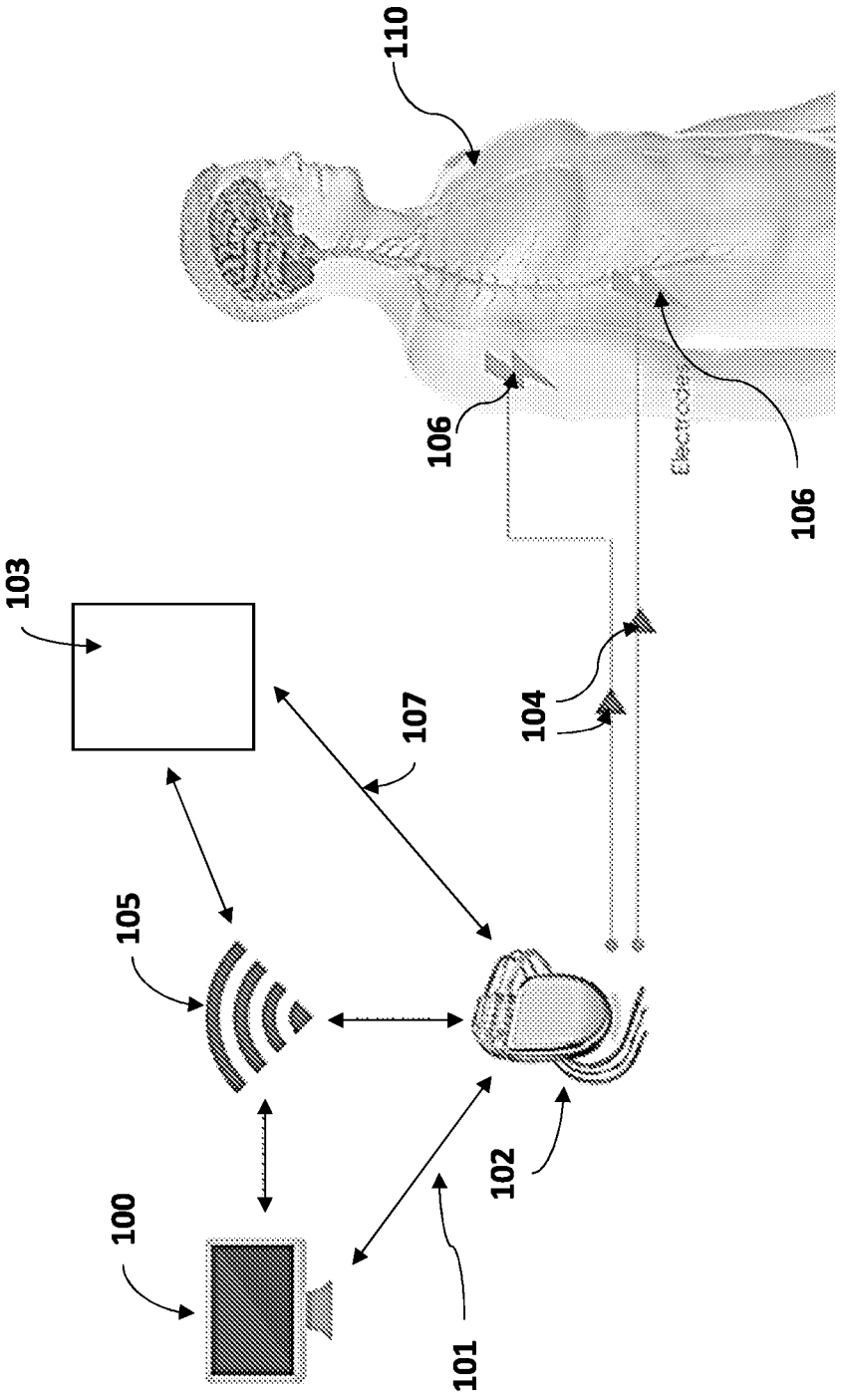



FIG. 1

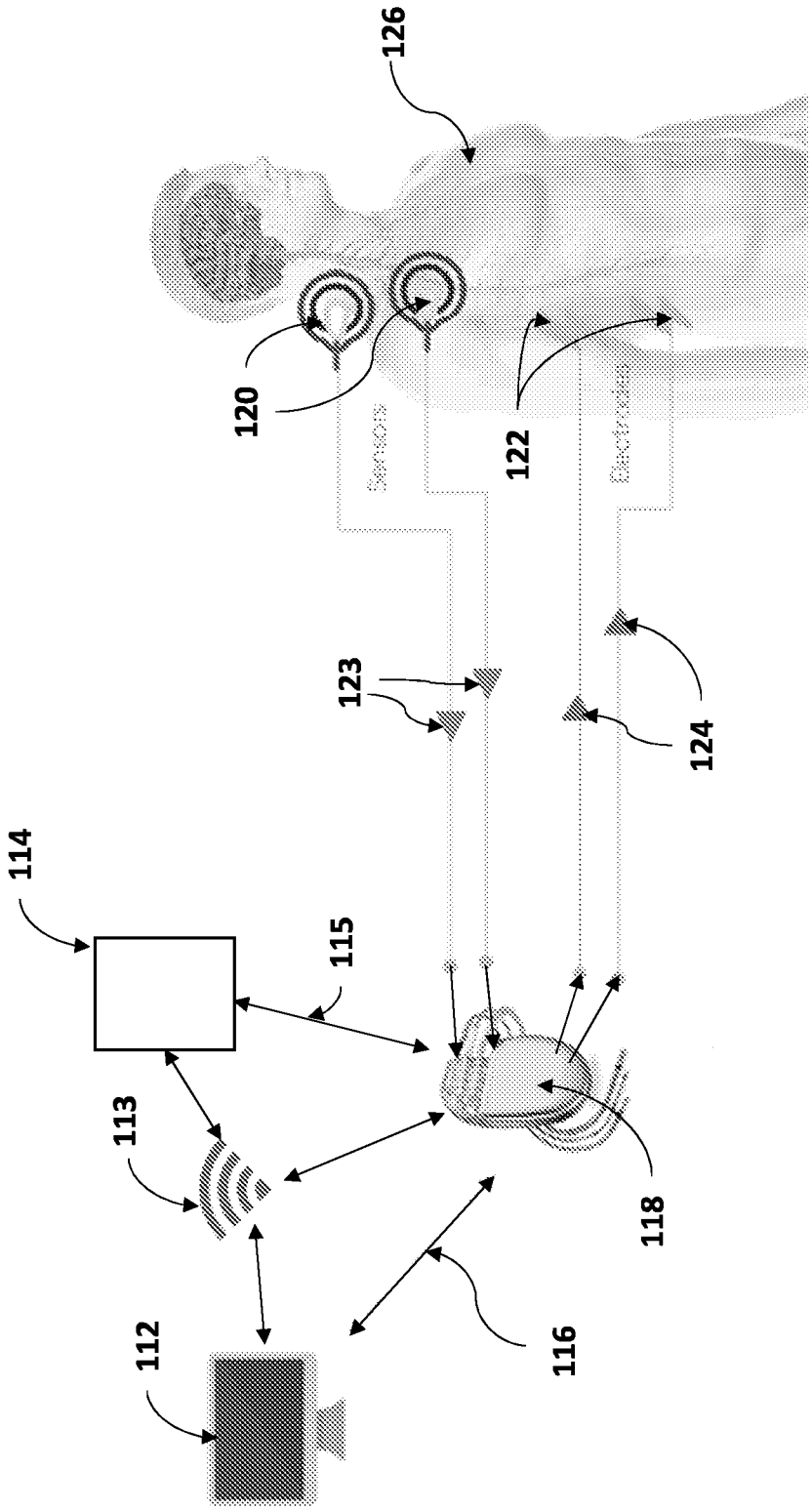



FIG. 2

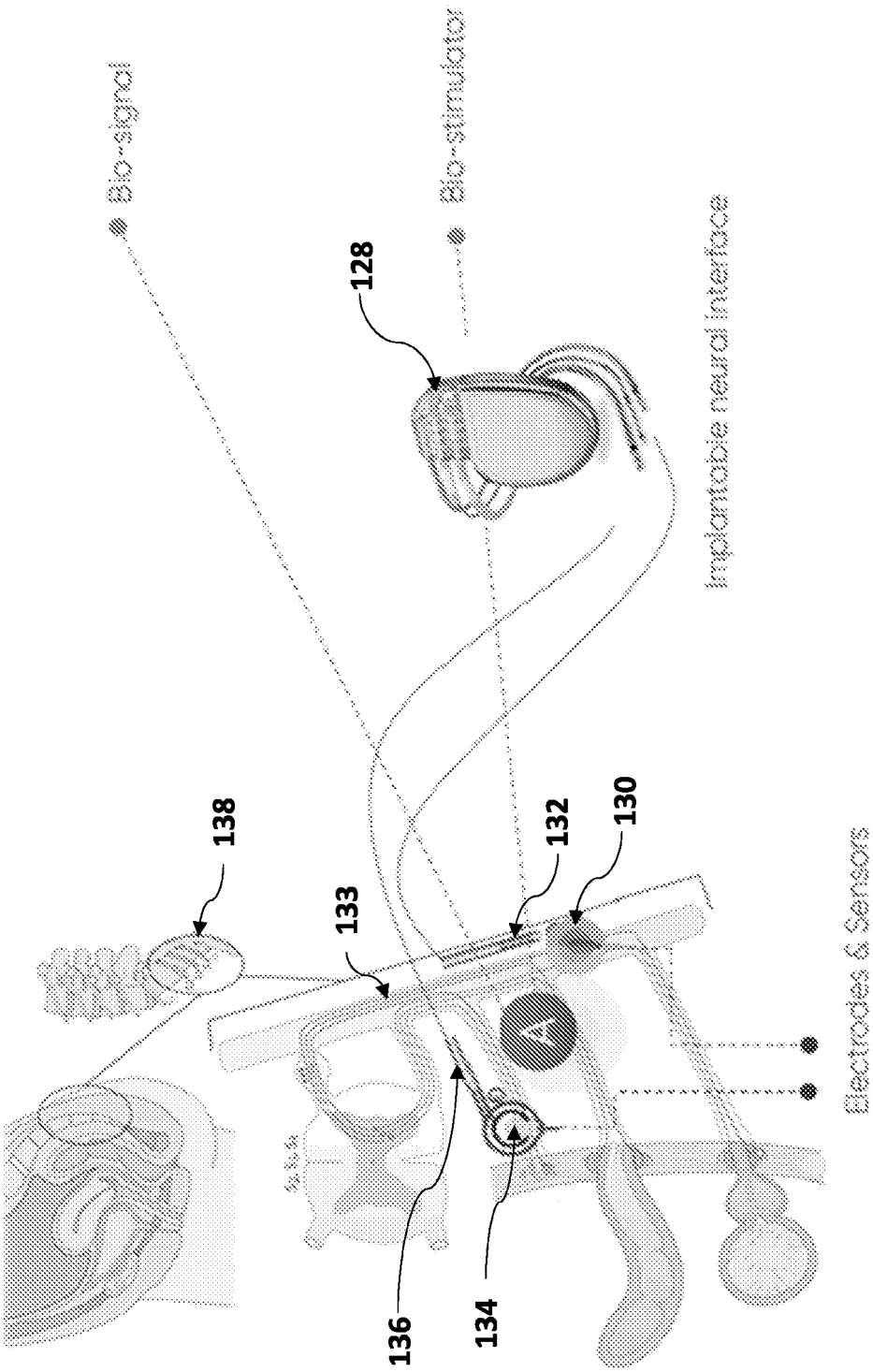

Bio-signal
Bio-stimulator
Implantable neural interface
Electrodes & Sensors
128
138
133
132
130
136
134

FIG. 3

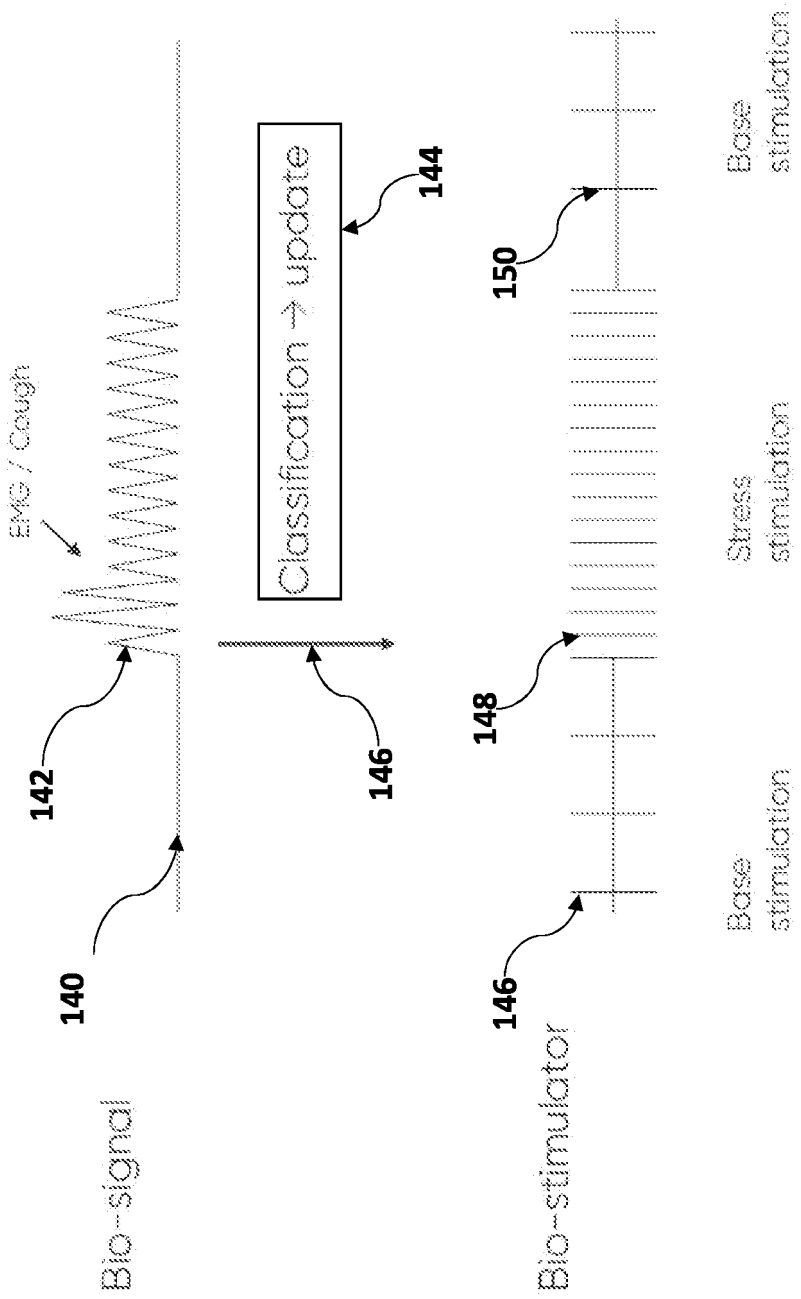

Bio-signal
EMG / Cough
140
142
146
Classification → update
144
Bio-stimulator
146
148
150
Base stimulation
Stress stimulation
Base stimulation

FIG. 4

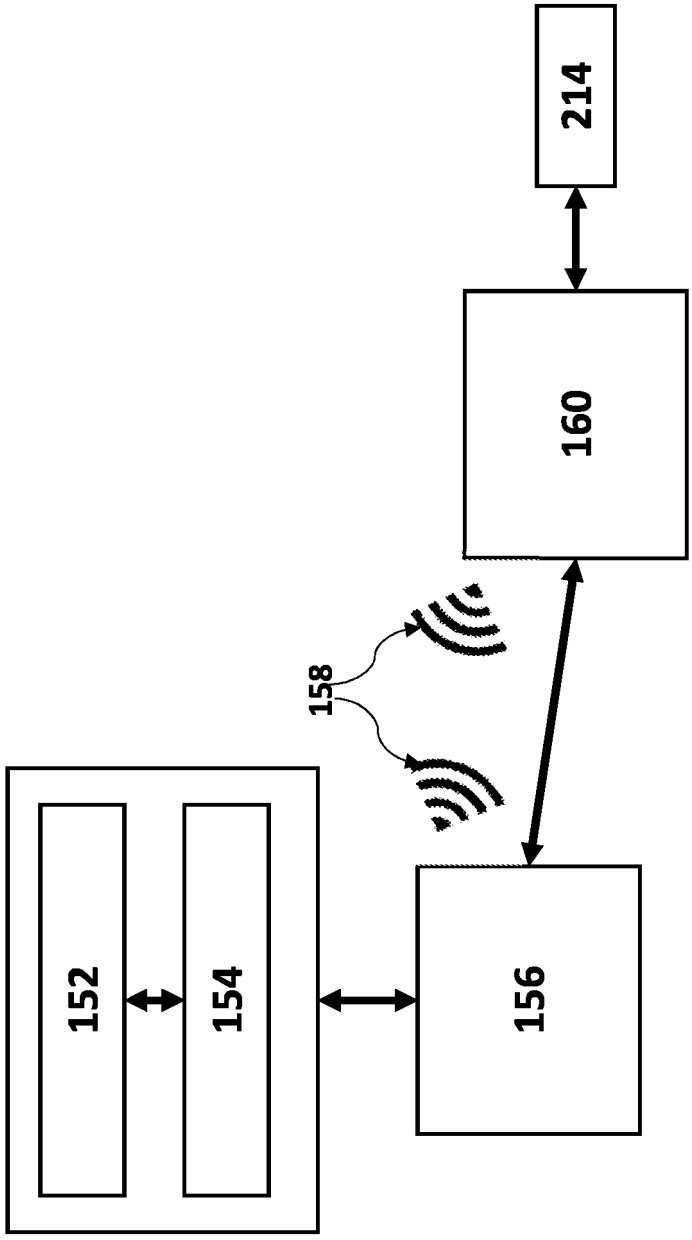



FIG. 5

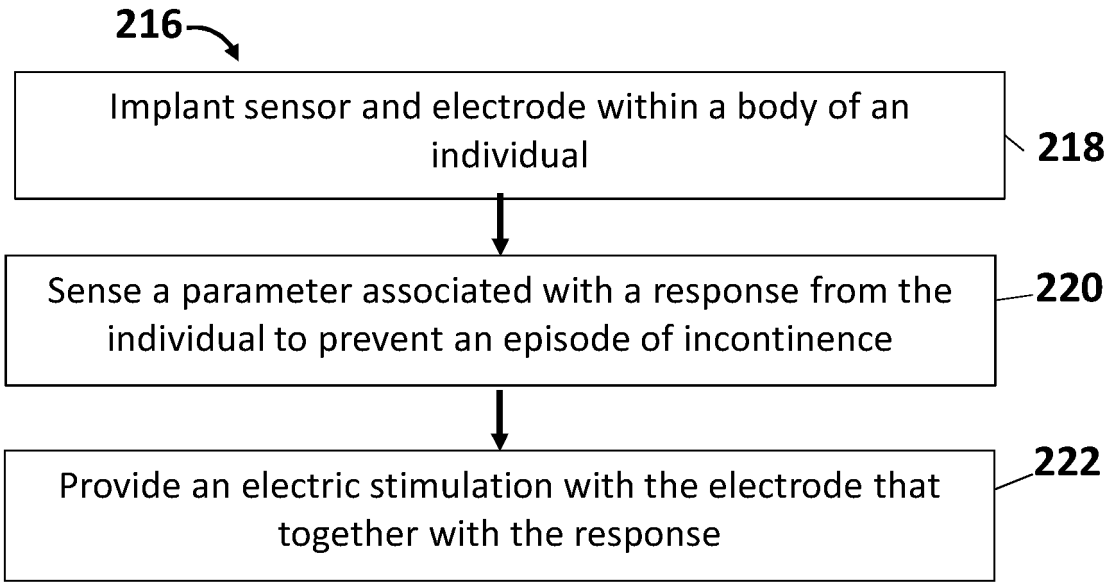

216
Implant sensor and electrode within a body of an individual
218
Sense a parameter associated with a response from the individual to prevent an episode of incontinence
220
Provide an electric stimulation with the electrode that together with the response
222

FIG.6A

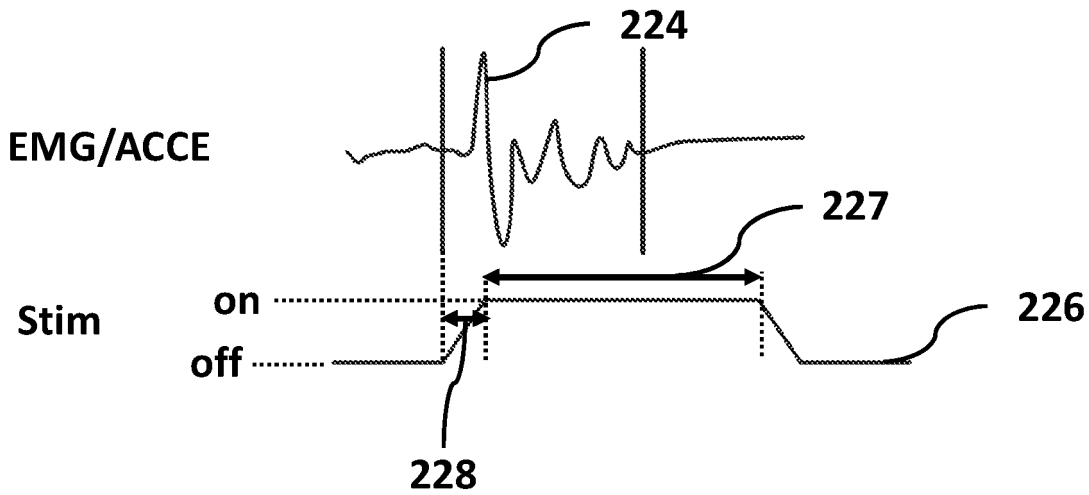

224
EMG/ACCE
227
Stim
on
off
226
228

FIG. 6B

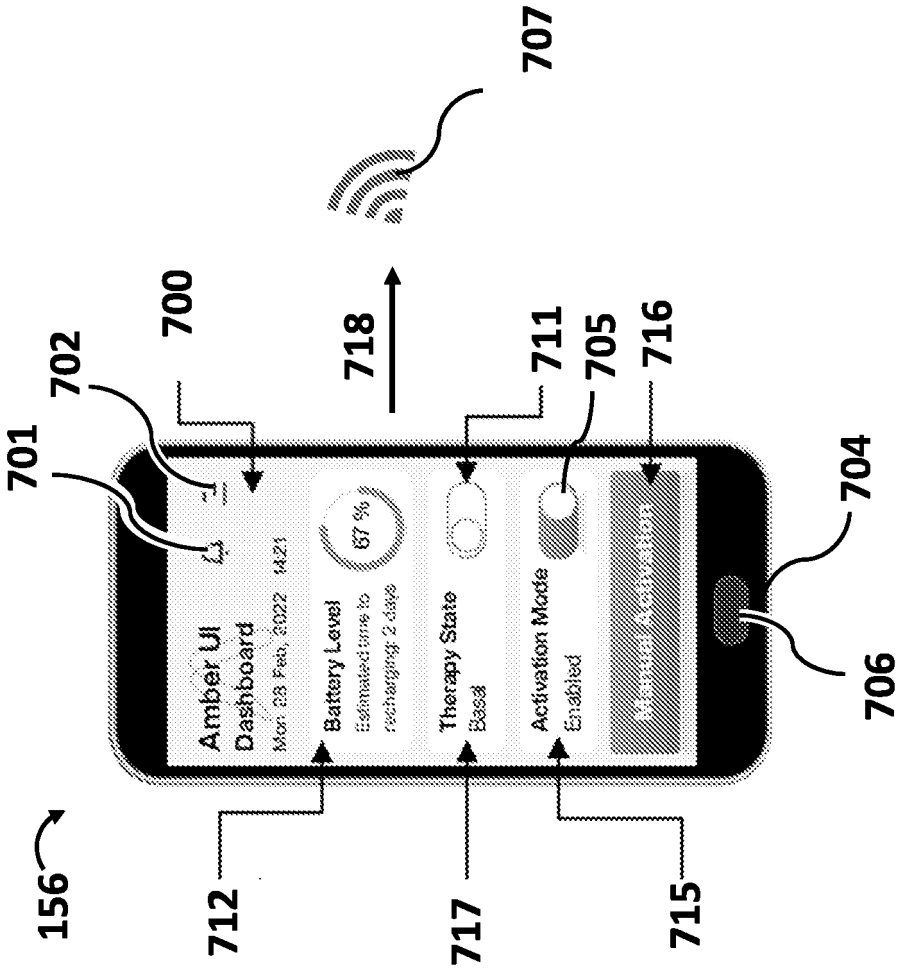

707
700
718
711
705
716
702
701
704
706
156
712
717
715
Amber UI
Dashboard
Mon 28 Feb, 2022 14:21
Battery Level
67 %
Estimated time to recharging 2 days
Therapy State
Basal
Activation Mode
Enabled
Manual Activation

FIG.7A

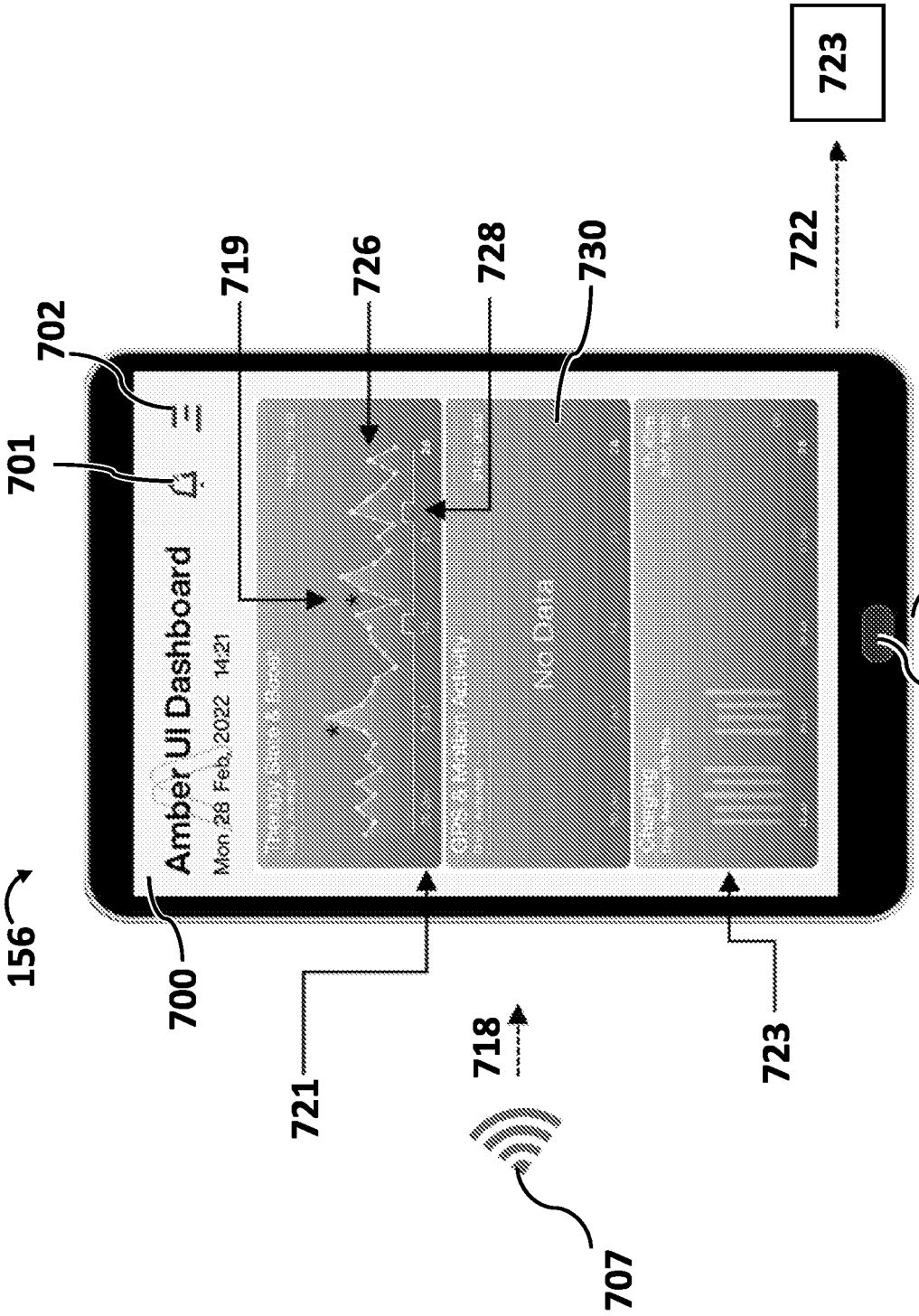

723
722
719
726
728
730
702
701
704
706
Amber UI Dashboard
Mon 28 Feb, 2022 14:21
156
700
721
718
723
707

FIG.7B

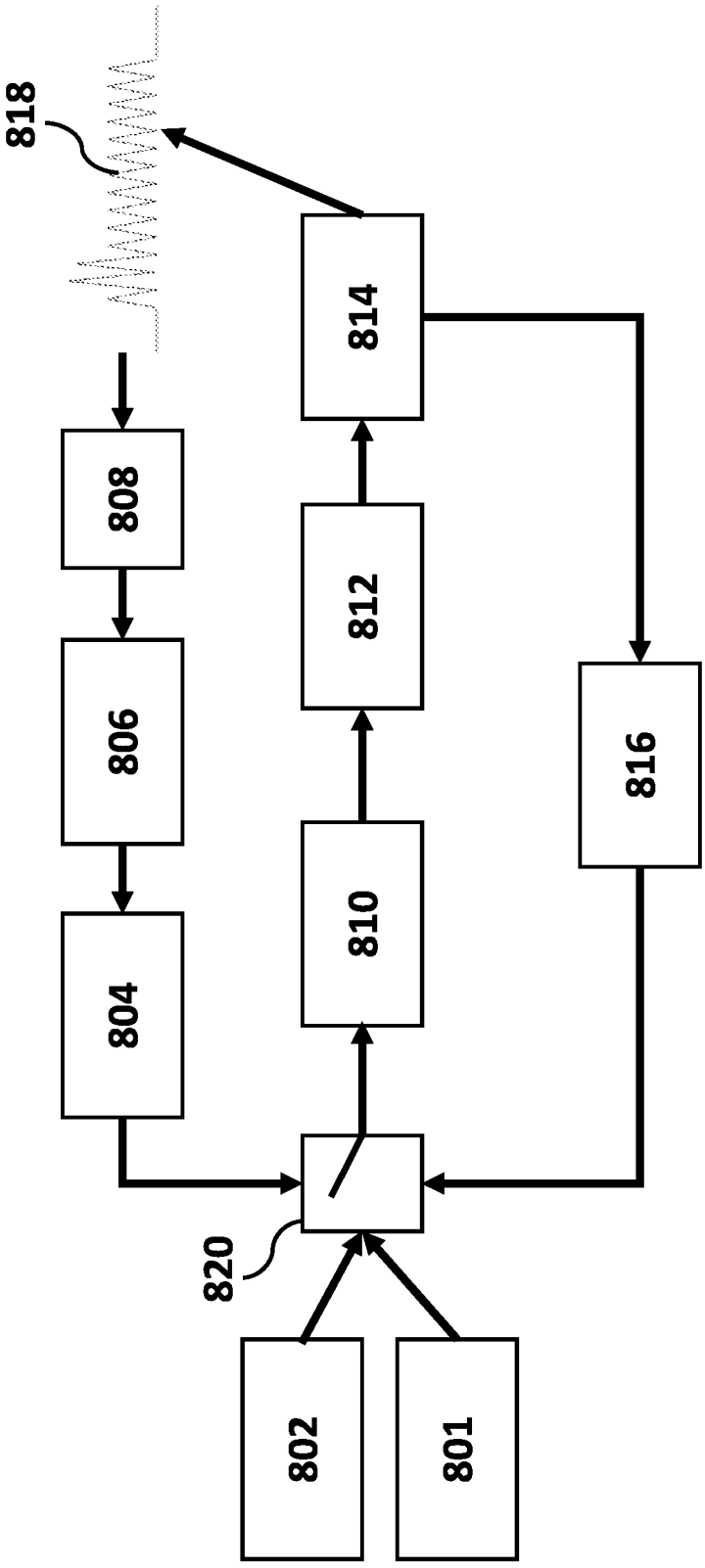



FIG.8

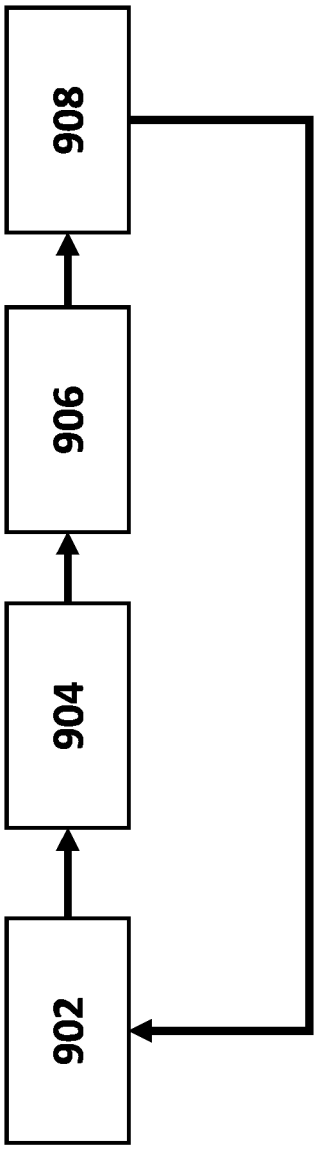



FIG.9

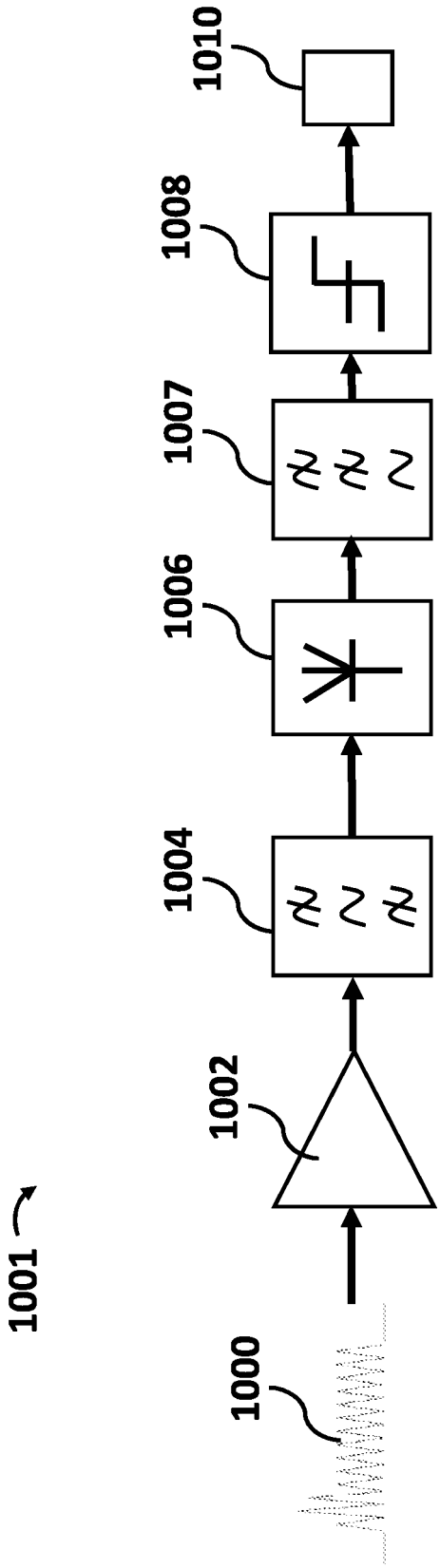



FIG. 10

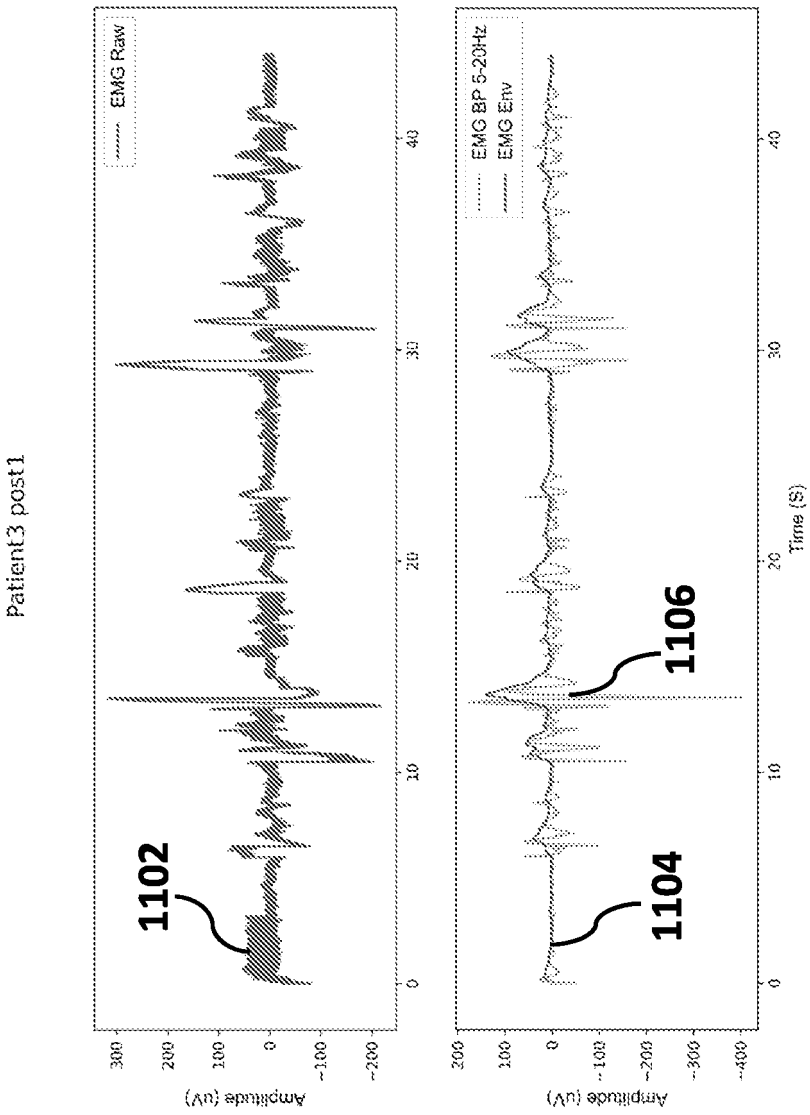

Patient3 post1
EMG Raw
1102
Amplitude (uV)
EMG BP 5-20Hz
EMG Env
1104
1106
Amplitude (uV)
Time (S)

FIG. 11A

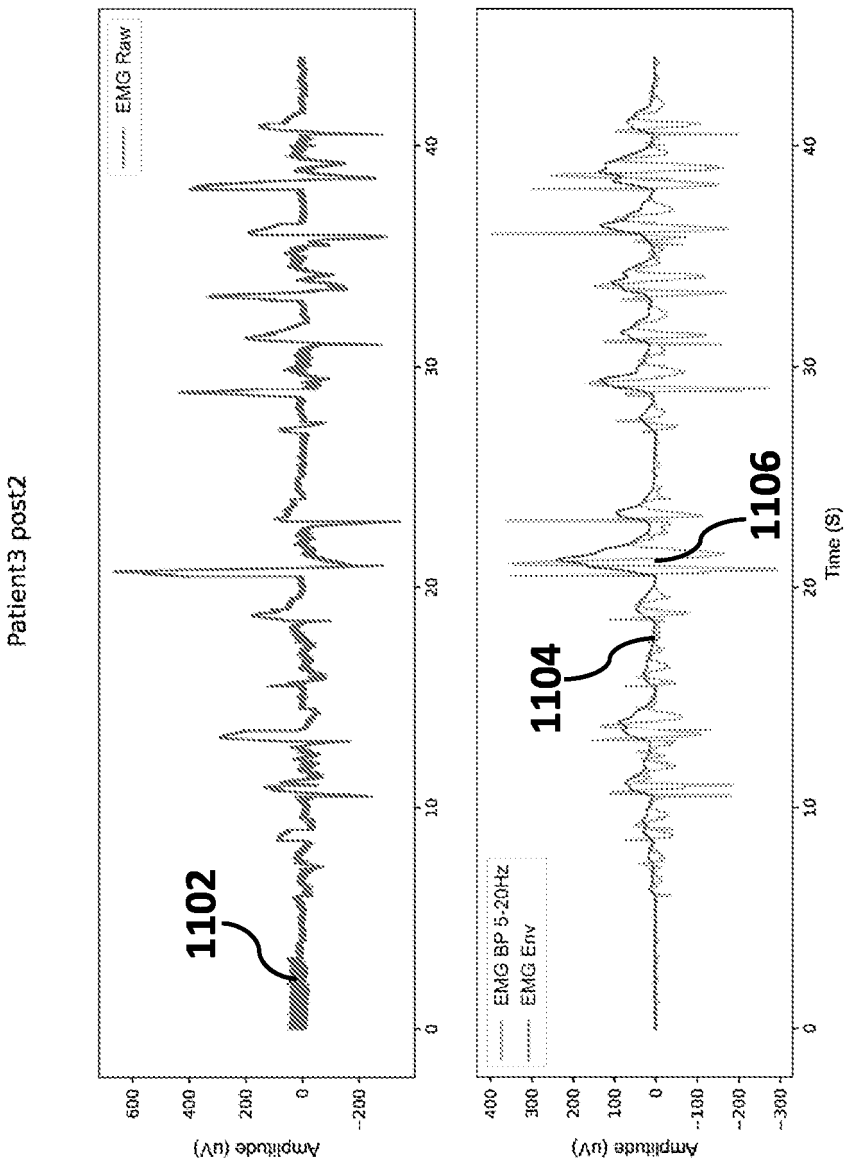

Patient3 post2
EMG Raw
1102
Amplitude (uV)
EMG BP 5-20Hz
EMG Env
1104
1106
Amplitude (uV)
Time (S)

FIG. 11B

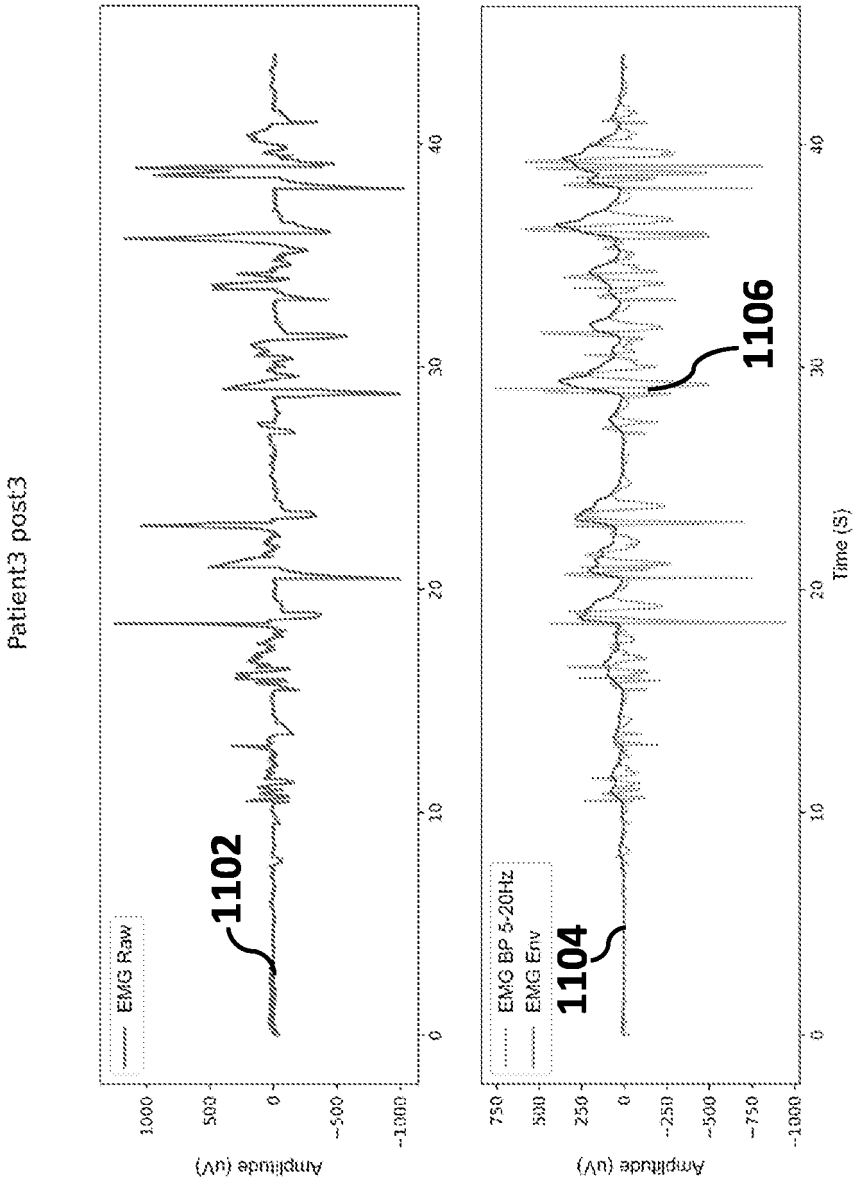

Patient3 post3
EMG Raw
1102
Amplitude (uV)
1000
500
0
-500
-1000
0
10
20
30
40
EMG BP 5-20Hz
EMG Env
1104
1106
Amplitude (uV)
750
500
250
0
-250
-500
-750
-1000
Time (S)

FIG. 11C

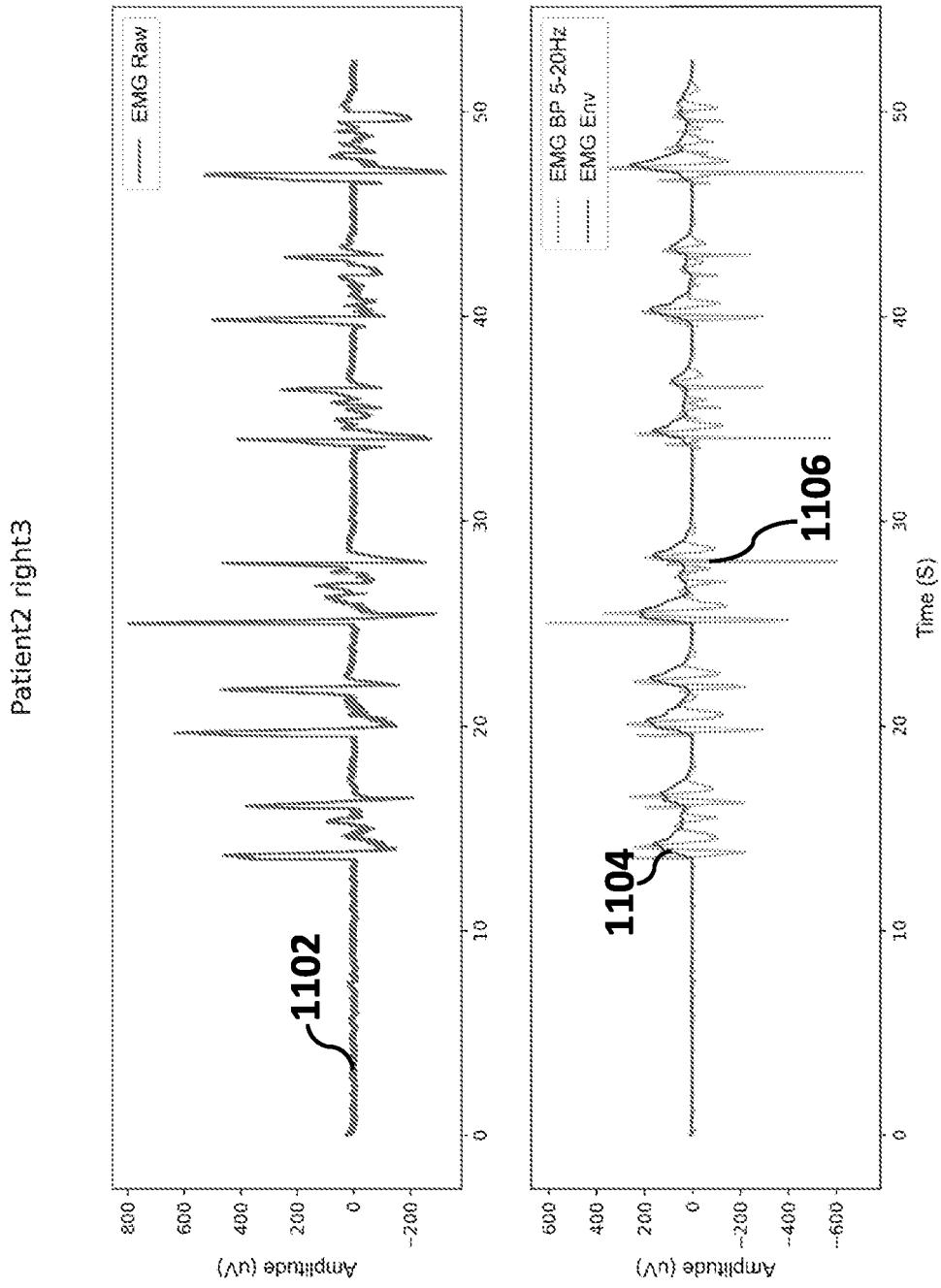

Patient2 right3
EMG Raw
1102
EMG BP 5-20Hz
EMG Env
1104
1106
Amplitude (uV)
Time (S)

FIG. 11D

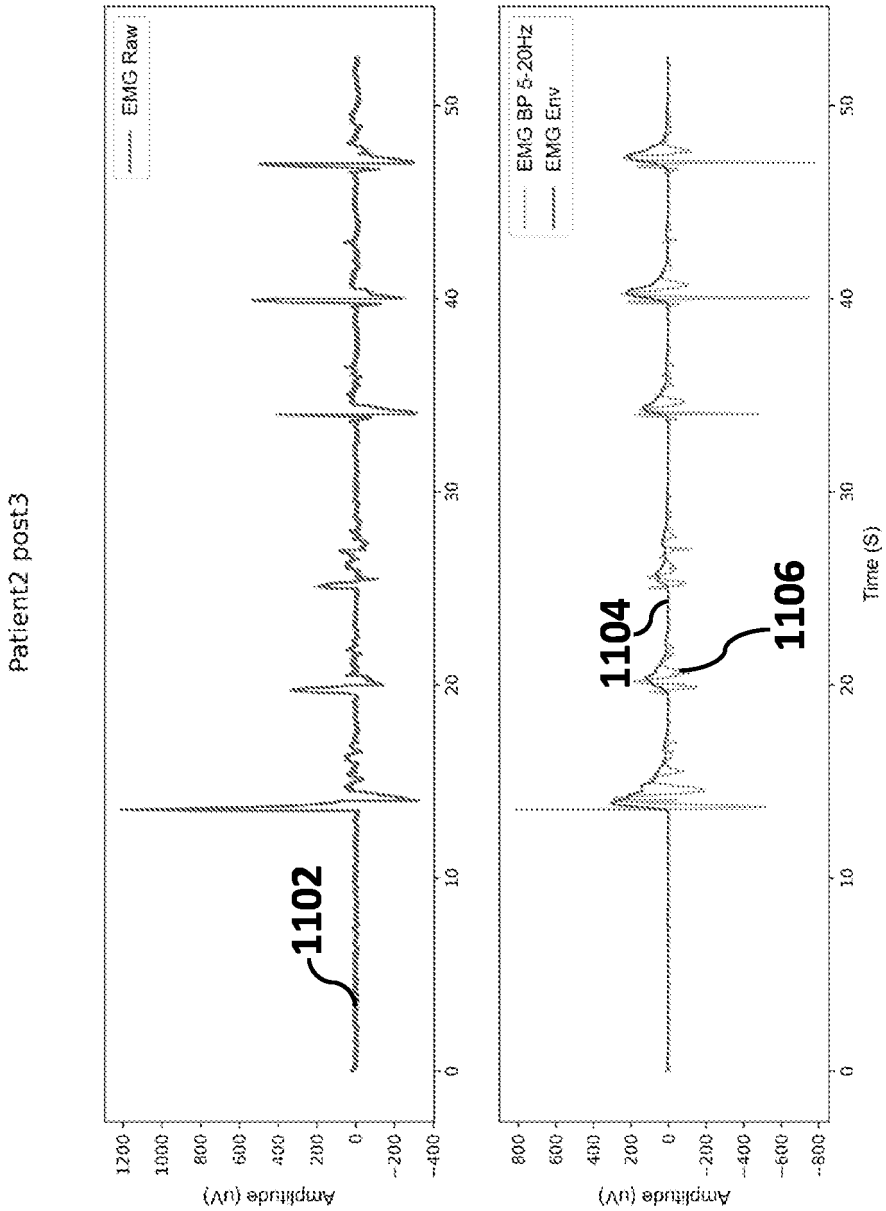

Patient2 post3
EMG Raw
1102
Amplitude (uV)
1200
1000
800
600
400
200
0
-200
-400
0
10
20
30
40
50
EMG BP 5-20Hz
EMG Env
1104
1106
Amplitude (uV)
800
600
400
200
0
-200
-400
-600
-800
Time (S)

FIG. 11E

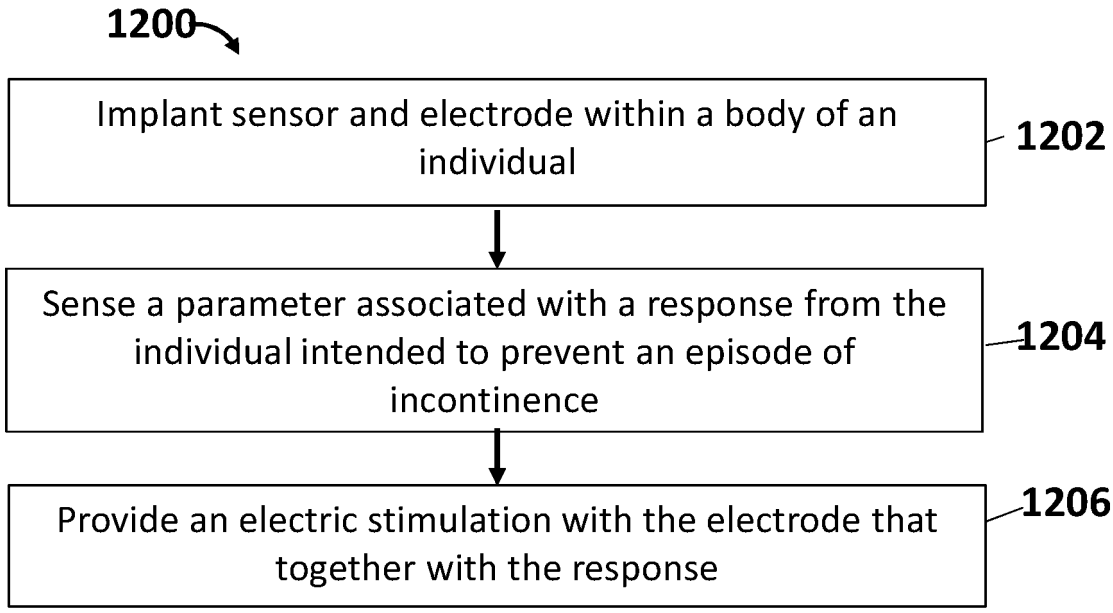



FIG. 12A

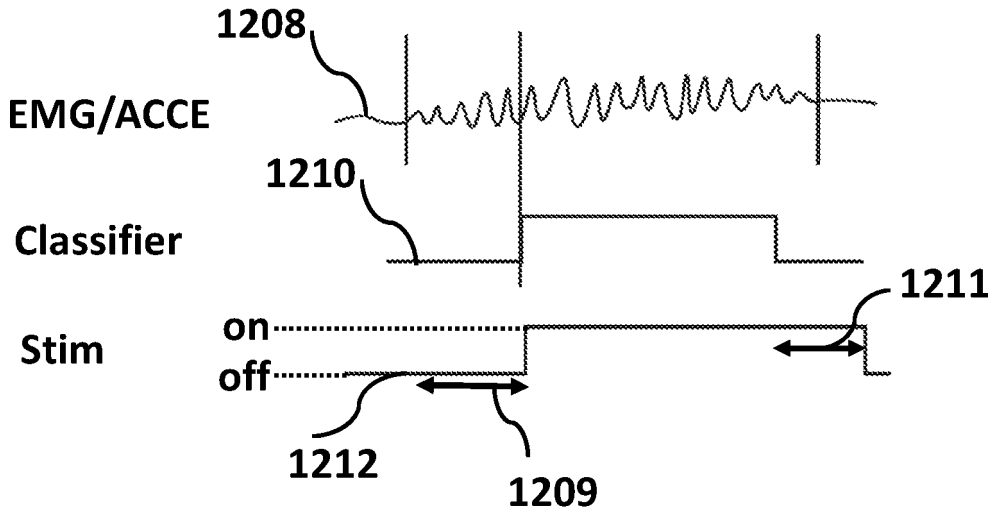



FIG. 12B

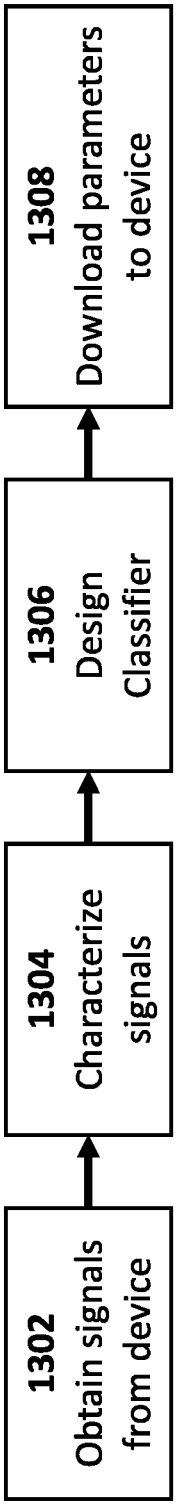

1302
Obtain signals from device
1304
Characterize signals
1306
Design Classifier
1308
Download parameters to device

FIG. 13