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(71) Applicant: **MEDTRONIC XOMED, INC.** [US/US];
6743 Southpoint Drive, Jacksonville, Florida 32216 (US).

(72) Inventors: **CANTWELL, Matthew L.**; 3791 Cardinal
Oaks Circle, Orange Park, Florida 32065 (US). **LI, Wen-
jeng**; 1296 Matengo Circle, St. Johns, Florida 32259 (US).
MCFARLIN, Kevin L.; 163 Rockcreek Dr., St. Johns,
Florida 32259 (US). **NARASIMHAN, Anirudhan**; 2872
3rd Street South, Jacksonville Beach, Florida 32250 (US).

(74) Agent: **WARNER, Richard W.** et al.; Harness, Dickey &
Pierce, P.L.C., P.O. Box 828, Bloomfield Hills, Michigan
48303 (US).

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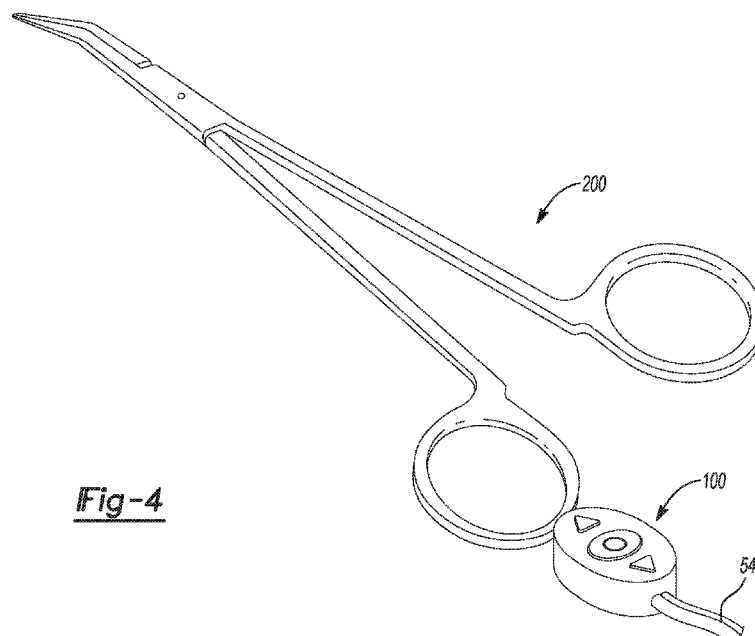


Fig-4

(57) Abstract: A monitoring system may include a processor and display system for displaying results from the monitoring. A user may be in a sterile field away from the processor and display system and selected input devices. A controller may be physically connected to the monitoring system from the sterile field to allow the user to control the monitoring system.



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REMOTE CONTROL MODULE FOR INSTRUMENTS

FIELD

[0001] The subject disclosure relates to nerve monitoring systems, and particularly to remote control of nerve monitoring systems.

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BACKGROUND

[0002] This section provides background information related to the present disclosure which is not necessarily prior art.

[0003] Nerve monitoring systems such as the NIM-Response® 3.0 and/or NIM-Neuro® 3.0 nerve monitoring systems, sold by Medtronic, Inc., may be used to monitor electromyography (EMG) responses. In particular, the monitoring systems may provide stimulation at a selected nerve and a response sensed or detected at muscles remote from the location of the stimulation. Monitoring the EMG responses may be used to determine whether one or more nerves has been damaged during a select procedure. In various systems, the monitoring system may be controlled by a monitor user that is spaced apart from a procedure user and a subject. Therefore, the monitor user may require instructions from the procedure user to operate the monitoring system according to a selected use by the procedure user.

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SUMMARY

[0004] This section provides a general summary of the disclosure, and is not a comprehensive disclosure of its full scope or all of its features.

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[0005] A nerve monitoring system may be used to monitor the integrity of a nerve. During a procedure, a procedure user may operate and/or alter an operation of the nerve monitoring system with a remote control system provided at the procedure user. The remote control system may include hardware that can be manipulated by the procedure user at the procedure user's location. Therefore, instructions or control to the nerve monitoring system may be provided at a location remote from the monitoring system.

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[0006] The monitoring system may include a processor and display system for displaying results from the nerve monitoring. The monitoring system, however, may not be immediately available for placement in a sterile field or for placement proximal to a subject. The subject may be monitored with the monitoring system for a selected

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procedure. The procedure user may include a surgeon. The surgeon may be sterile for the selected procedure. A remote control may be connected to a monitoring and/or stimulating instrument during a procedure. A remote control may also be connected to the surgeon and interconnected with the instrument and the monitoring system. The remote control may be sterile and appropriate for placement in the sterile field.

[0007] The remote control includes a physical connection to the monitoring system with a length of conductive material. The physical connection may include a wire (e.g. copper or aluminum wire), conductive polymer, or other appropriate conductive material. The physical connection may allow for both a signal from the remote to the monitoring system to interact with the monitoring system and/or to transmit a signal to and/or from the instrument.

[0008] Further areas of applicability will become apparent from the description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

DRAWINGS

[0009] The drawings described herein are for illustrative purposes only of selected embodiments and not all possible implementations, and are not intended to limit the scope of the present disclosure.

[0010] Fig. 1 is a schematic environmental view of a stimulation instrument used during a procedure;

[0011] Fig. 2 is a detailed view of a remote disconnected from the instrument;

[0012] Fig. 3 is a detailed view of the connector of the remote control;

[0013] Fig. 4 is a view of the remote connected to an alternative instrument;

[0014] Fig. 5 is an environmental illustration of a remote control, according to various embodiments, connected with an instrument; and

[0015] Fig. 6 is a detailed view of a remote disconnected from an instrument, according to various embodiments.

[0016] Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION

[0017] Example embodiments will now be described more fully with reference to the accompanying drawings.

[0018] With initial reference to FIG. 1 a monitoring system 16, such as a NIM®
5 nerve integrity monitoring system, sold by Medtronic, Inc. having a place of business in Minneapolis, MN, is illustrated in an environmental setting. The monitoring system 16 may include a monitor assembly 20 that has a display screen or device 22 and one or more input devices. The input device may include one or more systems or structures to input commands of information such as a knob 24a, a touch screen 24b, a keyboard
10 24c, or other appropriate input devices. Input devices may also include other tactile input devices, audio input devices, visual input devices, etc.

[0019] The monitor assembly 20 may further include a processor 26 and a memory 28. It is understood that the processor 26 may access the memory 28 to execute instructions stored thereon or access other data on the memory 28. The
15 memory 28 may include a physical memory, such as a spinning hard disk drive, solid state memory, or other appropriate types of memory. Further, the memory 28 may not be incorporated into the monitor assembly 20, but may be accessed by processor 26, such as via communications network. The processor 26 may be a general purpose processor that is operable to execute instructions for generating a selected output, as
20 discussed further herein. The processor 26 may further include onboard memory. Moreover, the processor 26 may include a specific purpose processor such as an application specific integrated circuit (ASIC). Accordingly, the processor 26 may execute instructions stored on memory 28, which may be a non-transitory memory, to provide an output for display on the display device 22.

[0020] The monitoring system 20 may further include a stimulation portion and/or generator. The stimulation portion may be configured to generate a voltage based upon control by the processor 26. The processor 26 may execute instructions of a program stored on the memory 28 and/or control by a user 30. As discussed herein, the monitoring system 20, therefore, may be operated to generate a stimulation at or
25 with a stimulation instrument based upon control of the user 30.

[0021] The information displayed on the display device 22 may include information selected by the user 30. The selection made by the user 30 may be desired or selected information regarding a subject 34. The subject 34 is illustrated as a human subject, but it is understood that the subject may be any appropriate living

subject, including non-human subjects. Further, the monitoring system 16 may be used with non-living subjects. Non-living subjects may have systems that are selected to be monitored for selected activity, such as electrical activity, and the monitoring system 16 may be used. In selected embodiments, however, the user 30 may be performing a surgical procedure on the subject 34. The user 30, therefore, may select to monitor nerve response and/or integrity such as by monitoring electromyography (EMG) responses.

[0022] One or more stimulation or monitoring assemblies may be incorporated in the monitoring system 16 and connected with the monitor assembly 20. For example, in various procedures such as a thyroidectomy or other thyroid surgeries, monitoring of a recurrent laryngeal nerve (RLN), a vagus nerve, or other appropriate nerve 36, in the subject 30. Other or alternative nerves may also be monitored, including other selected cranial nerves and/or spinal nerves. Monitoring of the RLN may include a nerve monitoring esophageal tube 38, which may have one or more conductive electrodes 40 that are in contact with selected portions of the subject 34. The electrode 40 may be affixed to an exterior of the tube 38 and/or incorporated into the structure of the tube 38. The electrode 40 can be connected to the monitor assembly 20 via a connection 42.

[0023] In addition, other instruments may be connected to the monitor assembly 20, such as electrode assemblies, including an electrode that may send or receive periodic stimulation pulses. In various embodiments, one or more stimulation instruments 50 may be used. The stimulation instrument 50 may be connected to the monitor assembly 20 with a connector 54. The connector 54 may allow for a physical connection between the stimulation instrument 50 and the monitoring assembly 20. The connector 54 may include a conductive member (e.g. a metal wire, conductive polymer, etc.). The stimulation instrument 50 may include various instruments such as surgical instruments and the like. Examples of stimulation instruments include those disclosed in U.S. Pat. App. No. 14/678,485 filed on April 3, 2015 and U.S. Pat. App. No. 14/678,452 filed on April 3, 2015; both incorporated herein by reference.

[0024] The stimulation instrument 50 is connected with the monitor assembly 20 with the connector 54 to send and/or receive stimulation signals to the subject 34 to assist in determining whether nerve damage or other tissue damage has occurred or could occur. A surgical instrument, such as a scalpel, may be manipulated by the user 30, such as a human surgeon. The surgical instrument may not or need not be directly connected to the monitor assembly 20. The stimulation instrument 50, however, may

access various portions of the subject 34, such as through an incision 58. The stimulation instrument 50 may be used to contact the nerve 36 or tissue near the nerve 36 to stimulate a response in the nerve or an EMG response at a location located a distance from the location of the stimulus application.

5 **[0025]** The monitor assembly 20 may be provided to monitor signals through or from the stimulation instrument 50 without requiring interactive stimulation or monitoring through the scalpel while performing the procedure on the subject 34. It is understood, however, that other electrode assemblies may be connected to the subject 34 as is understood by one skilled in the art. Stimulation to the subject 34 may account for a
10 refractory period of one or more nerves.

[0026] The operation of the monitoring system and the use of the monitoring system 16 may be similar to the NIM® monitoring system sold by Medtronic, Inc., including the NIM-Response® 3.0 nerve monitoring system. In operation, the stimulation instrument 50 may be placed on contact, or at least in stimulation
15 connection, with the nerve 36, as discussed further herein, and a signal may be transmitted along the connection 54 from the monitor system 20. The electrode 40 on the tube 38 may be a receiving electrode. It is understood, however, that other receiving electrodes may be associated and/or in contact with the subject 34.

[0027] During a procedure, user 30 may attempt or select to determine whether
20 the integrity or continuity of the nerve 36 has been damaged during the surgical procedure. For example, various cutting or tissue moving procedures may strain or cause damage to the nerve 36 and ensuring that the nerve 36 is undamaged may be selected. The user 30, therefore, may position the instrument 50 near and/or in contact with the nerve 36. The monitoring system 16, including the stimulation system or
25 generator of the monitoring assembly 20, may provide a stimulating voltage and/or current through the instrument 50 to attempt to evoke a response in a tissue 70. The tissue 70 may include a muscle that upon an evoked response will cause movement of the muscle 70 and/or associated tissues, such as vocal folds. The evoked response may be sensed by the EMG sensing electrodes 40 and the signal may be transmitted to
30 the monitoring assembly 20 to allow a presentation of a message to the user 30, such as a graph, warning, auditory message (e.g. tone representing a signal received regarding the evoked EMG), or the like. The user 30 may control the monitoring assembly 20 with a remote control 100.

[0028] The remote control 100 may be positioned with the user 30, according to various embodiments, such as being connected to the instrument 50. The remote control 100 may be removably connected to the instrument 50, as discussed further herein. The remote control 100 may include switches that allow operation or control of all or certain functions of the monitoring assembly 20 while using the monitoring system 16.

[0029] The monitoring system 16 may include certain portions such as the tube assembly 38 and the instrument 50 that are configured to be used in a sterile field area 104 which is separated from a non-sterile area 110. According to various embodiments, a physical structure may be positioned to separate the sterile field 104 from the non-sterile field 110 in an operating theatre or other selected location. Nevertheless, the monitoring assembly 20, including the various inputs, such as the keyboard 24c, may not generally be accessible to the user 30 if the user 30 is in the sterile field 104. The user 30 may attempt to provide instructions to a second user in the non-sterile field 110 to operate the monitoring assembly 20, which may be inefficient. Accordingly, the remote control 100 may allow the user 30 to directly control at least portions or certain operations of the monitoring assembly 20 without moving out of the sterile field 104.

[0030] Control of the monitoring assembly 20 by the user 30 from within the sterile field 104 may allow the user 30 to make immediate decisions and configuration selections regarding operation of the monitoring system 16. Moreover, the user 30 may be a distance from the other input devices, such as the keyboard 24c, and the remote 100 may be local (e.g. within arm's length or closer) to the user 30. As discussed above, the monitoring system 16 may be used to determine or confirm integrity of the nerve 36 by providing stimulation through the nerve 36 to evoke a response in the muscle 70. Therefore, the user 30 may wish to alter a configuration or operation of the monitoring system 16 during a use of the monitoring system 16 without attempting to convey the selected change of configuration as verbal or other types of instructions to a second user or individual to attempt to reconfigure or change operation of the monitoring assembly 20 positioned in the non-sterile field 110.

[0031] One skilled in the art will understand that even if the monitoring assembly 20 is positioned in the non-sterile field 110 near the user 30, the user 30 is not able to generally interact with items in the non-sterile field 110 and immediately return to the sterile field 104 to continue the operation on the subject 34. Therefore, positioning the

remote 100 in the sterile field 104 allows the user 30 to use the remote 100 in the sterile field 104 to operate the monitoring assembly 20. The conductor 54 allows a signal from the remote control 100 to be carried to the monitoring assembly 20 and/or a stimulation signal from the monitoring system 20 to be delivered through the instrument 50 to the patient 34, such as to the nerve 36.

[0032] With continuing reference to Fig. 1 and additional reference to Fig. 2 and Fig. 3, the remote 100 will be discussed in greater detail. As illustrated in greater detail in Fig. 2 and Fig. 3, the remote 100 may be removably connected to the instrument 50. The controller 100, however, may be rigidly connected to the instrument 50. In various embodiments, the controller 100, when rigidly connected to the instrument 50, will not move relative to the instrument 50 until disconnected from the instrument by the user 30.

[0033] To assist in the rigid connection, the instrument 50 may include a connecting portion, such as a male connector 120 having an external wall 122 and an internal wall 124. The external wall 122 may have a non-circular geometry, such as a square shape. The square shape may assist in resisting or eliminating rotation of the controller 100 relative to the instrument 50. The remote 100, as specifically illustrated in Fig. 3, may include a mating connector having a female connector 130 having an internal wall 132. The female connector 130 may be formed as a depression within a housing 136 of the remote 100. The housing 136 may include an external wall or surface 138 into which the female connection portion 130 may be formed. The male connection portion 120 and the female connection portion 130 may form a physical and rigid connection between the instrument 50 and the remote 100. The female connector 130, therefore, may have a complementary shape to the male connector 120 to assist in maintaining rotational and axial rigid connection. The connection, however, may allow for rotation if selected, such as both connector portions being round in shape.

[0034] An electrical or conductive connection may be made via the connecting portions 120, 130 or other portions. For example, the instrument 50 may form a female conducting connection portion 140, such as with or on the internal wall 124. The internal wall 124 may include one or more conductors to connect with various portions of the instrument 50, such as providing multiple connections for a bi-polar or multi-polar stimulation. The remote 100 may include a male conductive connector 144 within the female connection 130. The male conductive connector 144 may be formed as a selected male connection, such as a banana plug or clip. The male connector 144 may

make a conductive connection with the female connector 140 on the instrument 50. The male connector 144 may further be electrically connected to the conductor 54 that connects the remote 100 to the monitoring assembly 20. The conductor 54 allows for a physical connection of the remote 100 to the remote assembly 20. Therefore, the instrument 50 may be electrically and physically connected to the remote assembly 20 to allow for operation of the instrument 50 by the user 30 in the monitoring system 16.

[0035] The remote control 100 can include various control options including audio inputs, physical inputs, and the like. For example, the remote control 100 may include one or more push buttons such as a first push button 160, a second push button 164, and a third push button 168. Each of the push buttons 160, 164, and 168 may be physical buttons or members that move relative to the housing 136 to actuate a respective switch that is positioned below the button, but associated with the button on a printed circuit board (PCB) 172 positioned within the housing 136. The PCB 172 may include electrical switches 160a, 168a, 164a corresponding to the respective buttons 160, 168, and 164. The PCB 172 may include electrical connections or conductive connections from each of the switches 160a, 164a, and 168a to the conductor 54. Therefore, a signal from the respective switches 160a, 164a, and 168a may be transmitted to the monitoring assembly 20 to control and/or operate the monitoring assembly 20. It is understood that other appropriate switches may be provided such as mechanical toggle switches, touch sensitive portions (e.g., capacitive surfaces), a joystick, trackball, roller button (e.g. center rolling button on a computer mouse), or the like.

[0036] It is further understood that any appropriate number of input buttons or portions may be provided with the remote 100. Accordingly, including three buttons 160, 164, 168 are merely exemplary. Moreover, pressing or actuating more than one of the buttons at a time may operate the monitoring assembly 20 in a manner different and distinct from depressing any single one of the buttons 160, 164, 168 individually. Further, operating or depressing any one of the buttons in sequence in a selected amount of time (e.g., depressing a first button and a second button within two seconds of the first button) may operate the monitoring assembly 20 in a further different manner.

[0037] In various embodiments, the monitoring system 20 may be used to provide stimulation to the nerve 36 and receive a signal regarding an evoked response, such as in the muscle 70, such as through the contacts 40. Therefore, the user 30 may

operate the remote control 100 to manually provide a stimulation pulse to the nerve 36, alter an amplitude of the stimulation pulse, alter a frequency of the stimulation pulse, or the like. According to various embodiments the remote control 100 may be operated to increase and/or decrease a stimulation current. For example, the first button 160 may
5 be operated to increase stimulation current while the second button 164 may be operated to decrease the stimulation current. The buttons may include visual indicia to indicate a selected operation. For example, the first button 160 may be formed as an arrow or a triangle generally pointing “up” such as towards the instrument 50. The second button 164 may include a visual indication, such as an arrow or triangle pointing
10 “down”, such as away, from the instrument 50, to assist in indicating a decrease in operation. The third button 168 may be a selection button, such as a menu selection, confirmation, or other general input that may be used to switch a current operation of the monitoring assembly 20.

[0038] The remote 100 may further be used to control the monitoring assembly
15 20 such as to increase or decrease an audio output or message from the monitoring assembly 20. Again, the first button 160 may be used to increase the volume while the second button 164 may be used to decrease the volume. The third button 168 may be used to cycle through various controllable options, such as between increasing and decreasing stimulation current and increasing and decreasing a message volume from
20 the monitoring assembly 20.

[0039] The remote 100 may be further used to operate to collect information or store information being received or displayed by the monitoring assembly 20. Again, as discussed above, the electrodes 40 may receive an evoked response due to a stimulation of the nerve 36. The evoked response may be displayed on the display
25 device 22 or otherwise presented as a message to the user 30. The remote 100 may be operated to acquire or save a snapshot (e.g., a screenshot) of information currently being displayed or represented by the monitoring assembly 20. For example, the display device 22 may display a graph regarding the perceived or sensed evoked response. Acquiring a screenshot of the display device 22 allows the user 30 to save a
30 selected signal received by the monitoring assembly 20 from the electrodes 40. The user 30 may use the saved screenshot, such as at a later time, for comparison to a later acquired or later received signal. Further, the saved screenshot may be used to assist in training at a later period.

[0040] The remote 100 may further be used to set or control threshold limits. Threshold limits may relate to stimulation current and/or voltage. Further, the threshold limits may relate to the received responses or received signals at the electrodes 40. The control threshold limit may set an upper or lower limit regarding a waveform that is identified as the received signal by the electrodes 40.

[0041] The remote control 100 may be further operated to operate a selected system. For example, the monitoring assembly 20 may be operated with a continuous or automatic pulse system. For example, the automatic periodic stimulation (APS® Stimulation System, sold by Medtronic, Inc.) may be connected with the nerve 36. The remote control 100 may be used to operate the periodic stimulation through an automatic periodic stimulation system. For example, adjusting a stimulation current may be made, similar to that discussed above, through the electrode. Further, the APS® Monitoring System may include various features such as determining a baseline evoked response from the periodic stimulation and alarm conditions relating to deviations from the baseline. The remote control 100 may be used to control the monitoring system 20 during and/or to initiate a baseline determination (e.g., inputting a beginning and ending time for identifying a baseline, changing the volume and/or muting a presented signal (e.g. a periodic tone relating to the evoked and sensed response), changing or controlling alarm conditions regarding a deviation from the baseline, and other appropriate features of the APS® Monitoring System). Accordingly, the remote control may be used to operate various features of the monitoring assembly 20 within the monitoring system 16.

[0042] Turning reference to Fig. 4 it is understood that the remote 100 may be interconnected with any appropriate instrument. For example, the instrument may be a stimulating electrode forceps 200 and may include a connection similar to the male connector 120 of the instrument 50 to be interconnected with the female connection portion 130 of the remote 100. The forceps 200 may include one or more contact electrodes to contact various portions of the subject 34, such as near or at the nerve 36 and/or other tissue portions.

[0043] Nevertheless, it is understood that the remote 100 may be connected with selected instruments, such as either a single tip probe or a dual tip forceps, or other appropriate instrument. Moreover, it is understood that the remote 100 may be connected to a first instrument, disconnected from the first instrument 50, and then connected to the second instrument 200. The remote may then be disconnected from

the second instrument 200 and reconnected to the first instrument 50. Further, it is understood that a kit of instruments may include any appropriate number of instruments and the remote 100 may be connected, disconnected, and reconnected to different instruments a selected number of times.

5 **[0044]** The remote 100 may be connected substantially directly to the instrument 50, 200 to allow for ease of operation of the remote by the user 30 while grasping the respective instrument 50, 200. The user 30 may use one or both hands 30a, 30b to manipulate both the instrument 50, 200 and/or the remote 100. The user 30 may use a digit of one or both hands to depress or operate the inputs, such as the buttons 160, 10 164, 168, to control the monitoring assembly 20. For example, only a single digit (e.g. finger of a hand) may be used to press the first button 160. As noted above, pressing the first button may increase a stimulation current.

[0045] According to various embodiments, however, as illustrated in Fig. 5, a remote control 250 may be connected via a connector, similar to the connector 54, 15 including an instrument connection connector 260. The instrument connection connector 260 may include a first connection portion 262 that connects to a second connection portion 264. The second connection portion 264 may extend and be connected to an instrument 270. The instrument 270 may be similar to the instrument 200, as discussed above, or may also be similar to the instrument 50 as discussed 20 above.

[0046] The connector 260 allows the remote 250 to be positioned a distance from the instrument 270. For example, the remote 250 may be connected to a holder, such as including a clip 280. The clip 280 may be clipped to a select portion, such as a sterile draping (e.g. placed over the subject 34 or portion near the subject 34) or to a 25 garment of the user 30, to position the remote 250 near or at the user 30 and away from the patient 34. The user 30 may then move one or more of the hands 30a, 30b to operate the remote 250.

[0047] The remote 250 may be similar or identical to the remote 100 and includes the first button 160, the second button 164, and the third button 168. Further, 30 the remote 250 may include any appropriate input portions including those discussed above. Nevertheless, the remote 250 may be positioned at a convenient and advantageous location for operation by the user 30. The instrument connector 260 may be connected via the conductor 54 to the monitoring assembly 20 in the non-sterile field 110. The instrument connector 260 may be interconnected with the conductor 54

and/or directly connected to the monitoring assembly 20. The instrument connection portion 260 may be provided to allow for positioning of the remote 250 at a selected location remote and away from the instrument 270. Therefore, it is understood that the remotes 250 may be positioned away from the instrument 270 for operation by the user 30. The remote 100, however, may be directly connected to the selected instrument to be operated by the user 30.

[0048] It is further understood, that the remote 250 may be positioned in line with the conductor 260. The remote 250 need not be connected to the instrument 200 or instrument 270, but need not be on a separated conductor connected to the conductor 260. Thus, the remote 250 may be positioned a distance from the instrument 270, but be electrically connected thereto, such as with the conductor 260.

[0049] Further, the clip 280 need not be rigidly connected to the remote 250. For example, the clip 280 may be connected to the conductor 260. The clip 280 may then be connected to an object, such as the surgeon 30, as discussed above, and the conductor 260 would then assist in maintaining the remote 250 near the surgeon 30. Thus, the clip 280 need not be formed as a part of the remote 250.

[0050] According to various embodiments, a display 300 may be included on the remote 100 or remote 250. For example, as illustrated in Fig. 6, the display 300 on a remote 100' may be viewable by the surgeon 30. The remote 100' may be substantially similar or identical to the remote 100, save for the addition of the screen 300. The screen 300 may be any appropriate display such as a liquid crystal display, light emitting diode display, etc. The display 300 may also allow for direct input from the surgeon 30 and/or display of selections that may be altered with the other switches 160, 164, and 168. Direct input may be with a touch sensitive screen while other inputs may be selected with the buttons 160, 164, 168.

[0051] The display 300 may display selected information to the surgeon 30, such as present operation of monitoring assembly 20. The present operation may include whether or not stimulation is occurring, the type of stimulation, stimulation current or voltage, etc. The display 300 may also display control options, such as START, STOP, CONTINUOUS, increase stimulation, decrease stimulation,

[0052] The screen 300 may also be used on the remote to operate the monitoring assembly 20, in a manner similar to that discussed above. For example, a selected type of operation may be displayed or selected by the surgeon 30. As illustrated in Fig. 6, the display may display "STOP" or an icon related to stopping

stimulation and the STOP icon may be highlighted, as selected by the user 30, with an underline. The surgeon 30 may select STOP via a touch screen or selection, such as with the buttons 160, 164, 168. The system may then operate as selected by the surgeon 30. Thus, the display 300 may be used on the remote 100' alone or in combination with the other buttons to control the monitoring assembly 20.

[0053] The display 300 may display various icons and communications based on instructions that are stored and accessed by the processor 26. For example, the processor 26 may execute instructions to display on the display 300 a selection of a command to start and stop stimulation. The user may then operate the remote 100', such as with the button 160, to select or highlight (e.g. with an underline displayed on the display 300) one of the displayed icons. The user 30 may then input a command by selecting, such as by depressing the button 168, the highlighted or selected icon. It is understood that such instructions may be incorporated into selected algorithms and instructions, as is understood by one skilled in the art.

[0054] According to various embodiments, the remote, such as the remote 100 need not be physically connected to the conductor 54 for communicating with the monitoring assembly 20. As discussed above, the conductor 54 allows a signal from the remote control 100 to be carried to the monitoring assembly 20 and/or a stimulation signal from the monitoring assembly 20 to be delivered through the instrument 50 to the patient 34, such as to the nerve 36. The remote 100, however, may include a wireless communication system or portion, such as those generally known in the art, to communicate with the monitoring assembly 20. The remote 100 may be operated, as discussed above, however, an instruction from the surgeon 30 may be communicated to the monitoring assembly 20 with a wireless or over the air (OTA) transmission. Also, transmissions from the monitoring assembly 20 regarding operation of the monitoring assembly 20 may be wireless or OTA to the remote 100. The conductor 54, or other selected conductor, may be connected to the selected instrument, such as the instrument 200, for providing the stimulation to the electrodes. Control, or at least selected control, of the monitoring assembly 20 may be with the remote 100 that is wirelessly communicating with the monitoring assembly 20.

[0055] Example embodiments are provided so that this disclosure will be thorough, and will fully convey the scope to those who are skilled in the art. Numerous specific details are set forth such as examples of specific components, devices, and methods, to provide a thorough understanding of embodiments of the present

disclosure. It will be apparent to those skilled in the art that specific details need not be employed, that example embodiments may be embodied in many different forms and that neither should be construed to limit the scope of the disclosure. In some example embodiments, well-known processes, well-known device structures, and well-known technologies are not described in detail.

[0056] The foregoing description of the embodiments has been provided for purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure. Individual elements or features of a particular embodiment are generally not limited to that particular embodiment, but, where applicable, are interchangeable and can be used in a selected embodiment, even if not specifically shown or described. The same may also be varied in many ways. Such variations are not to be regarded as a departure from the disclosure, and all such modifications are intended to be included within the scope of the disclosure.

CLAIMS

What is claimed is:

1. A stimulation monitoring system positioned in a non-sterile field out of a sterile field to stimulate at least a portion of a patient within the sterile field, comprising:
- 5 a stimulation system configured to generate a stimulation voltage;
- a stimulation instrument configured to be positioned within the sterile field near the patient;
- a controller conductively connected to the stimulation instrument and configured to be positioned within the sterile field near the patient;
- 10 a conductor physically connected to the stimulation system and the controller;
- wherein the controller includes an input to control at least one operation of the stimulation system.
- 15 2. The stimulation monitoring system of Claim 1, wherein the input includes at least one switch;
- wherein the at least one switch is configured to be operated by a user within the sterile field.
- 20 3. The stimulation monitoring system of Claim 2, wherein the at least one switch includes a push button switch configured to be depressed with a digit by the user.
4. The stimulation monitoring system of Claim 3, wherein the controller
- 25 includes an external housing;
- wherein the push button switch includes a first portion configured to extend from the housing to be directly engaged by the digit and a second portion having a toggle switch fixed to a printed circuit board placed within the housing;
- wherein the toggle switch is configured to generate a signal that is
- 30 transmitted to the stimulation system;
- wherein the stimulation system includes a processor configured to receive the signal to control at least one operation of the stimulation system.

5. The stimulation monitoring system of any one of Claims 1 to 4, wherein the stimulation system includes a processor configured to receive a signal from the input to control at least one operation of the stimulation system;

wherein the at least one operation of the stimulation system includes at least one of changing a stimulation period, changing a stimulation voltage, starting stimulation, stopping stimulation; capturing a screen shot, control a threshold limit, or changing a message volume.

6. The stimulation monitoring system of any one of Claims 1 to 5, wherein the controller has a housing that is rigidly connected to the stimulation instrument;

wherein the conductor extends from the controller in the sterile field to the stimulation system in the non-sterile field.

7. The stimulation monitoring system of any one of Claims 1 to 6, wherein the conductor includes a first portion connecting the controller to the stimulation instrument and a second portion extending from the sterile field to the stimulation system in the non-sterile field.

8. The stimulation monitoring system of any one of Claims 1 to 7, wherein the controller includes a display,

wherein the display is configurable to illustrate information regarding present operation of the stimulation system and/or commands to be input by the user.

9. A stimulation monitoring system having a stimulation system positioned in a non-sterile field out of a sterile field to stimulate at least a portion of a patient with a stimulation instrument within the sterile field, comprising:

a controller conductively connected to the stimulation instrument and configured to be positioned within the sterile field near the patient;

an input portion formed with the controller to send a signal to the stimulation system when actuated by a user; and

a connecting communication portion between the controller within the sterile field and the stimulation system in the non-sterile field;

wherein the signal from the input portion is to control at least one operation of the stimulation system.

10. The stimulation monitoring system of Claim 9, wherein the stimulation system includes a stimulation generator having a processor and configured to generate a stimulation current;

5 wherein the stimulation instrument has a stimulation conducting portion configured to be positioned within the sterile field near the patient;
 wherein the controller is rigidly connected to the stimulation instrument.

11. The stimulation monitoring system of Claim 9, wherein the stimulation
10 system includes a stimulation generator having a processor and configured to generate a stimulation current;

 wherein the stimulation instrument has a stimulation conducting portion configured to be positioned within the sterile field near the patient;

 wherein the controller connected to the conductor a distance from the
15 stimulation instrument within the sterile field;

 wherein the conductor extends from the controller to the stimulation instrument and from the controller to the stimulation system.

12. The stimulation monitoring system of any one of Claims 9 to 11, wherein
20 the input portion includes at least one switch;

 wherein the at least one switch is configured to be operated by the user within the sterile field.

13. The stimulation monitoring system of Claim 12, wherein the controller
25 includes an external housing;

 wherein the at least one switch includes a push button switch having a first portion configured to extend from the housing to be directly engaged by a digit of the user and a second portion having a toggle switch fixed to a printed circuit board placed within the housing;

30 wherein the toggle switch is configured to generate a signal that is transmitted to the stimulation system;

 wherein the stimulation system includes a processor configured to receive the signal to control at least one operation of the stimulation system.

14. The stimulation monitoring system of any one of Claims 9 to 13, wherein the stimulation system includes a processor configured to receive the signal from the input portion;

5 wherein the at least one operation of the stimulation system includes at least one of changing a stimulation period, changing a stimulation voltage, starting stimulation, stopping stimulation; capturing a screen shot, control a threshold limit, or changing a message volume.

10 15. The stimulation monitoring system of any one of Claims 9 to 14, wherein the connecting communication portion includes a conductor that physically connects the controller within the sterile field and the stimulation system in the non-sterile field.

15 16. The stimulation monitoring system of any one of Claims 9 to 14, wherein the connecting communication portion includes a wireless system that connects the controller within the sterile field and the stimulation system in the non-sterile field.

17. A method of controlling a stimulation monitoring system having a stimulation system through a stimulation instrument, comprising:

20 positioning the stimulation instrument within a sterile field;
positioning the stimulation monitoring system having the stimulation system in a non-sterile field out of the sterile field;
physically connecting a controller to the stimulation instrument within the sterile field;
physically connecting the controller to the stimulation monitoring system in
25 the non-sterile field; and
controlling at least one operation of the stimulation system with the controller within the sterile field.

30 18. The method of Claim 17, wherein physically connecting the controller to the stimulation instrument within the sterile field includes rigidly connecting a housing of the controller to the stimulation instrument.

19. The method of any one of Claims 17 or 18, wherein physically connecting the controller to the stimulation instrument within the sterile field includes interconnecting a housing of the controller with the stimulation instrument with a conductor.

5

20. The method of any one of Claims 17 to 19, wherein controlling operation of the stimulation system with the controller within the sterile field includes operating the controller to transmit a signal with a physical conductor from the controller in the sterile field to the stimulation system in the non-sterile field.

10

21. The method of Claim 20, wherein the stimulation system includes a processor configured to receive the signal from the controller;

wherein the controlling at least one operation of the stimulation system includes at least one of changing a stimulation period, changing a stimulation voltage, capturing a screen shot, control a threshold limit, or changing a message volume.

15

22. The method of any one of Claims 20 to 21, further comprising:
manipulating a switch on the controller to generate the signal.

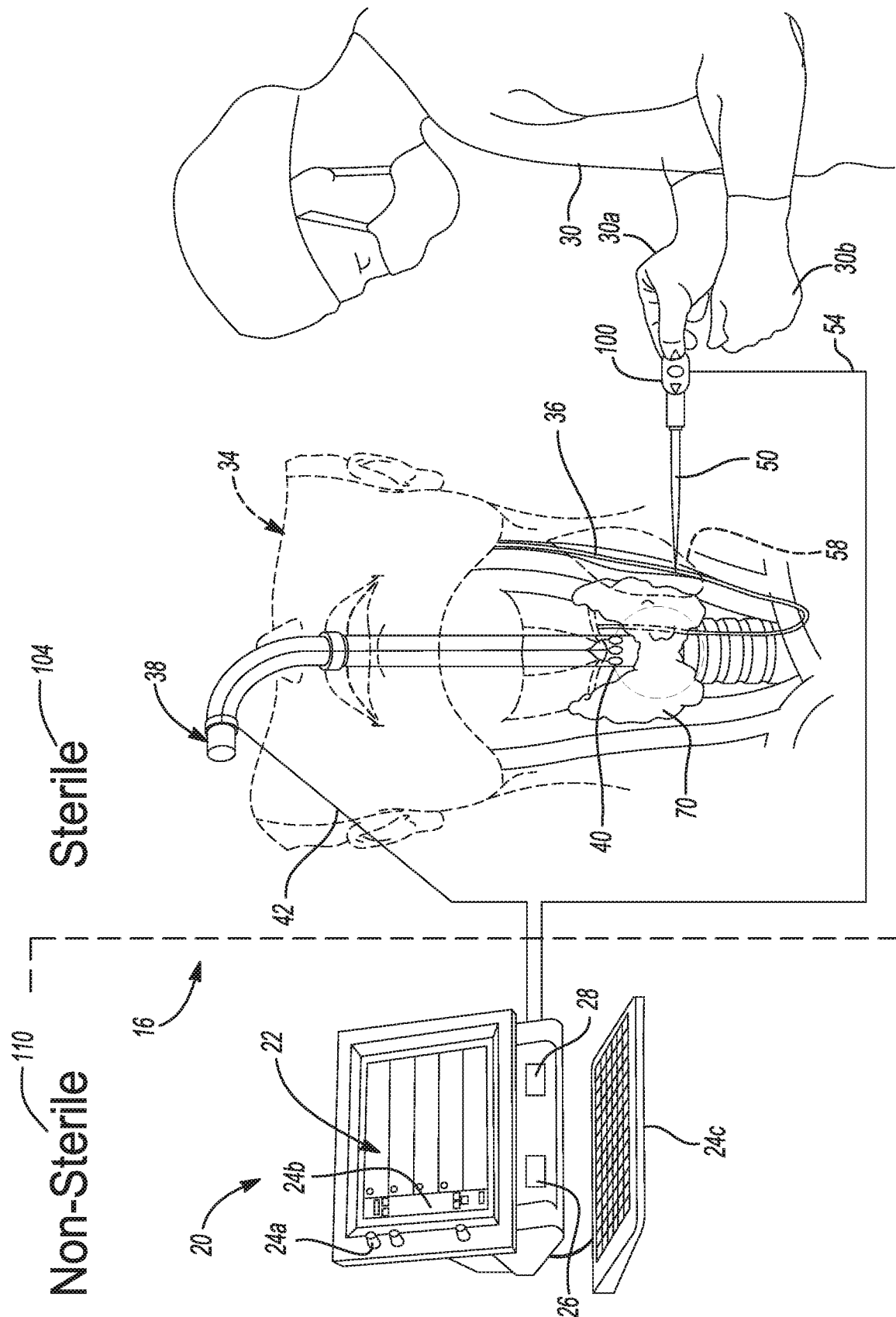
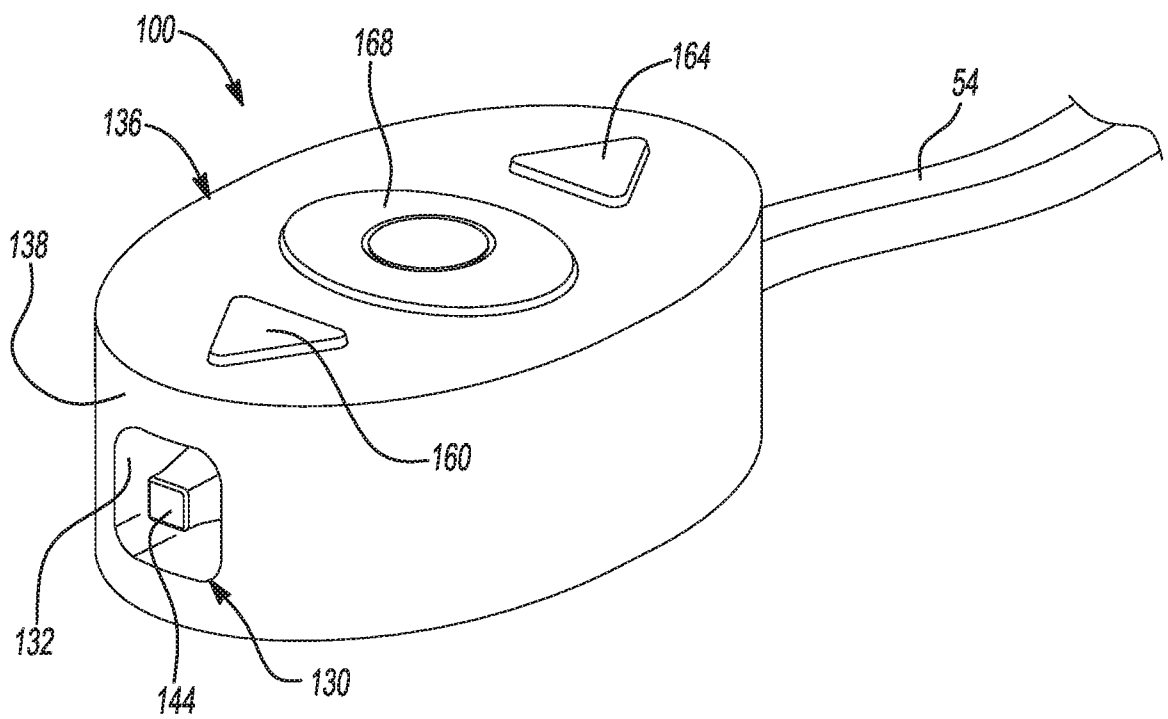
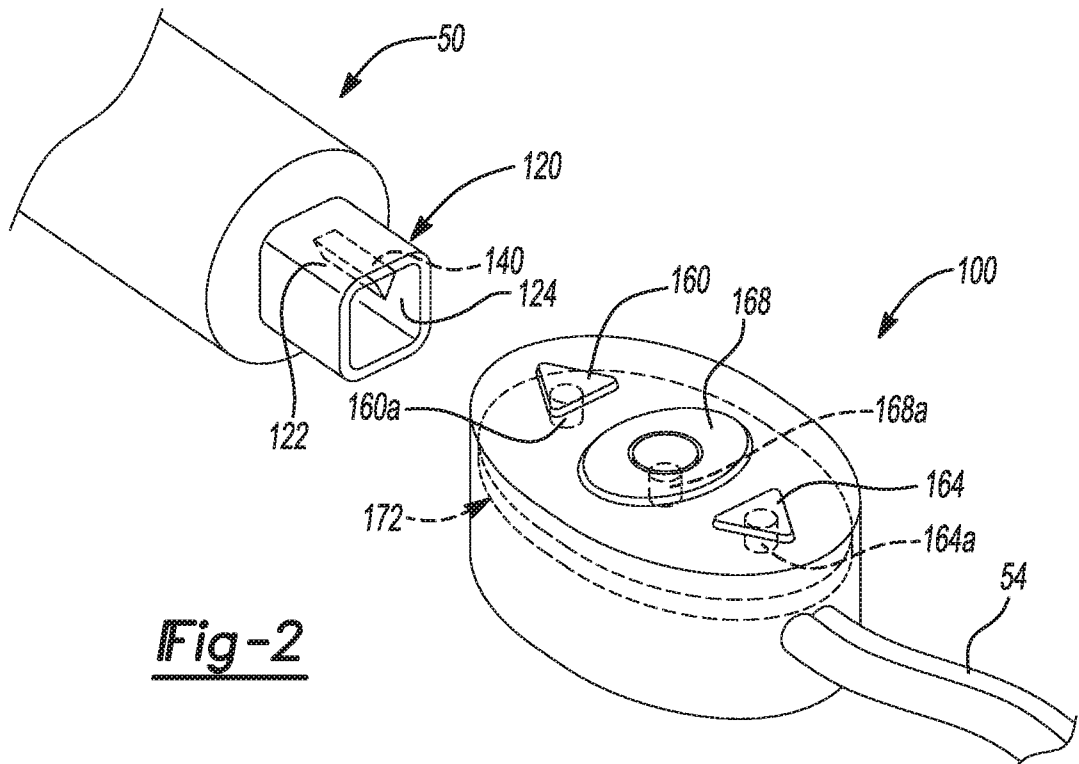


Fig-1



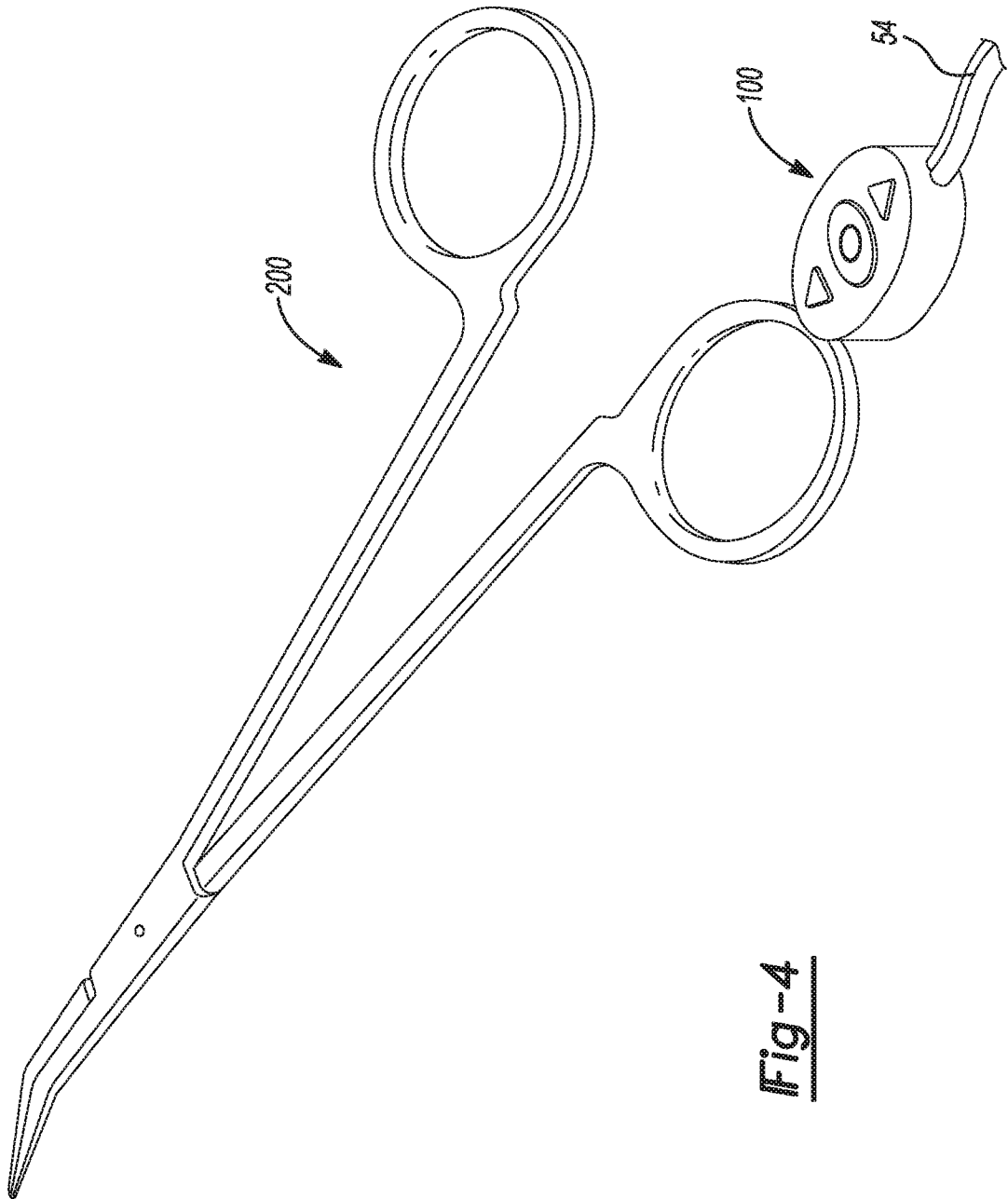


Fig-4

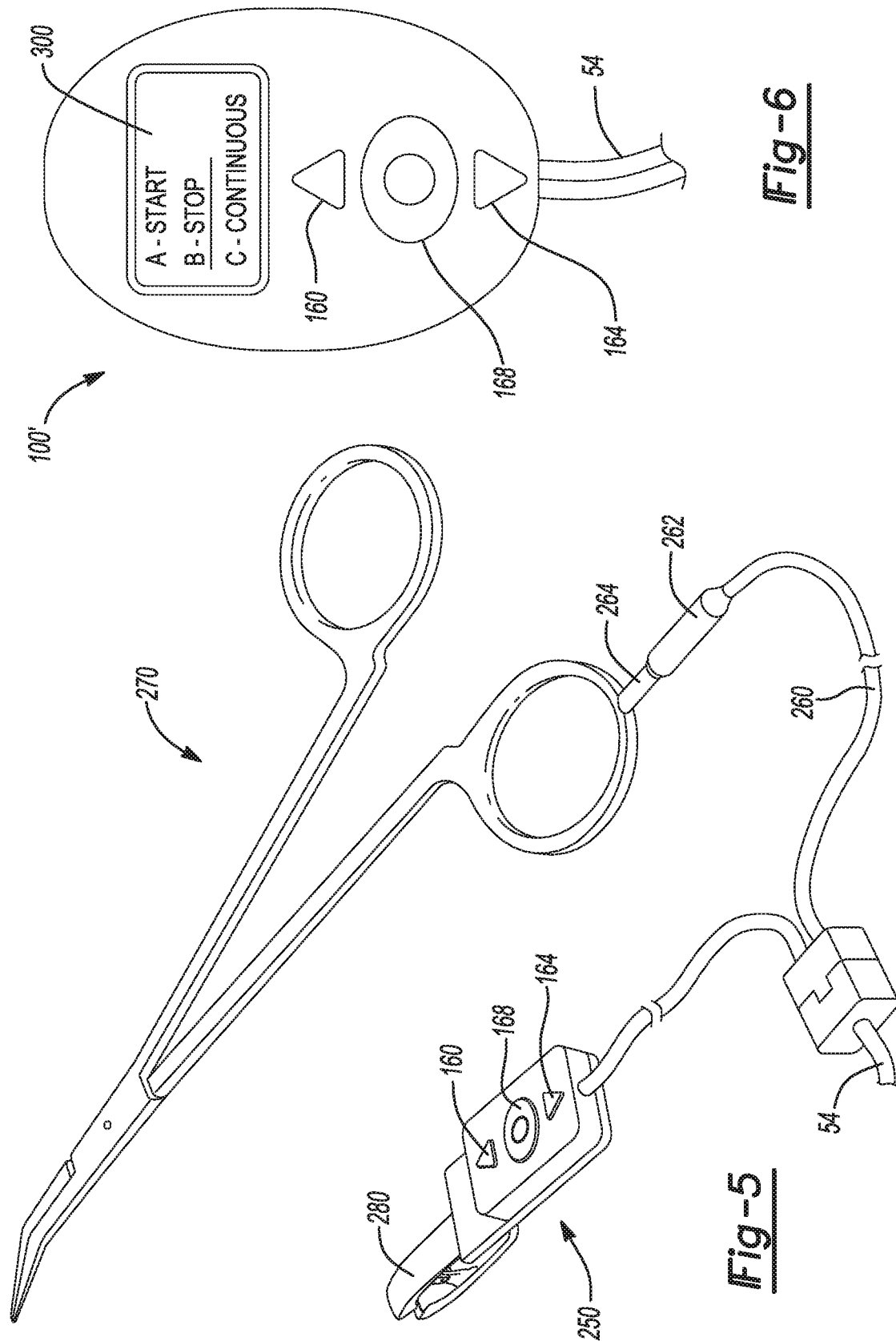


Fig-6

Fig-5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/051825

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17-22
because they relate to subject matter not required to be searched by this Authority, namely:
The method claims 17-22 do not fulfill the requirement of Rule 39.1(iv) PCT because they encompass at least one surgical step (see fig. 1, p. 4 l. 4-5 and p. 5 l. 1) and therefore relate to a method for treatment of the human or animal body by surgery.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/051825

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0488 A61B5/00 A61B5/04
ADD. A61B18/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/073985 A1 (SAKAI JONATHAN [US] ET AL) 13 March 2014 (2014-03-13) paragraph [0065] paragraphs [0068] - [0070]; figures 1-2 paragraphs [0072] - [0074]; figures 3A-3C paragraphs [0080] - [0081] paragraphs [0086] - [0087] paragraphs [0092], [0096], [0181] -----	1-16
X	WO 2015/069962 A1 (NUVASIVE INC [US]) 14 May 2015 (2015-05-14) page 10, line 1 - page 11, line 9; figures 1-2 page 22, line 9 - page 25, line 27; figures 15-21 the whole document ----- -/--	1-16



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

21 November 2017

Date of mailing of the international search report

29/11/2017

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Sarcia, Regis

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/051825

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/270121 A1 (JOHNSON KRISTIN D [US] ET AL) 3 November 2011 (2011-11-03) paragraphs [0028] - [0029], [0032] - [0038]; figures 1A, 1B, 2 paragraphs [0049] - [0050]; figures 3-5 the whole document -----	1-16

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/051825

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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WO 2015069962	A1	14-05-2015	AU 2014346688 A1 19-05-2016
			CN 105744887 A 06-07-2016
			EP 3065634 A1 14-09-2016
			JP 2017503620 A 02-02-2017
			US 2015088030 A1 26-03-2015
			WO 2015069962 A1 14-05-2015
US 2011270121	A1	03-11-2011	US 2011270121 A1 03-11-2011
			US 2014296738 A1 02-10-2014