



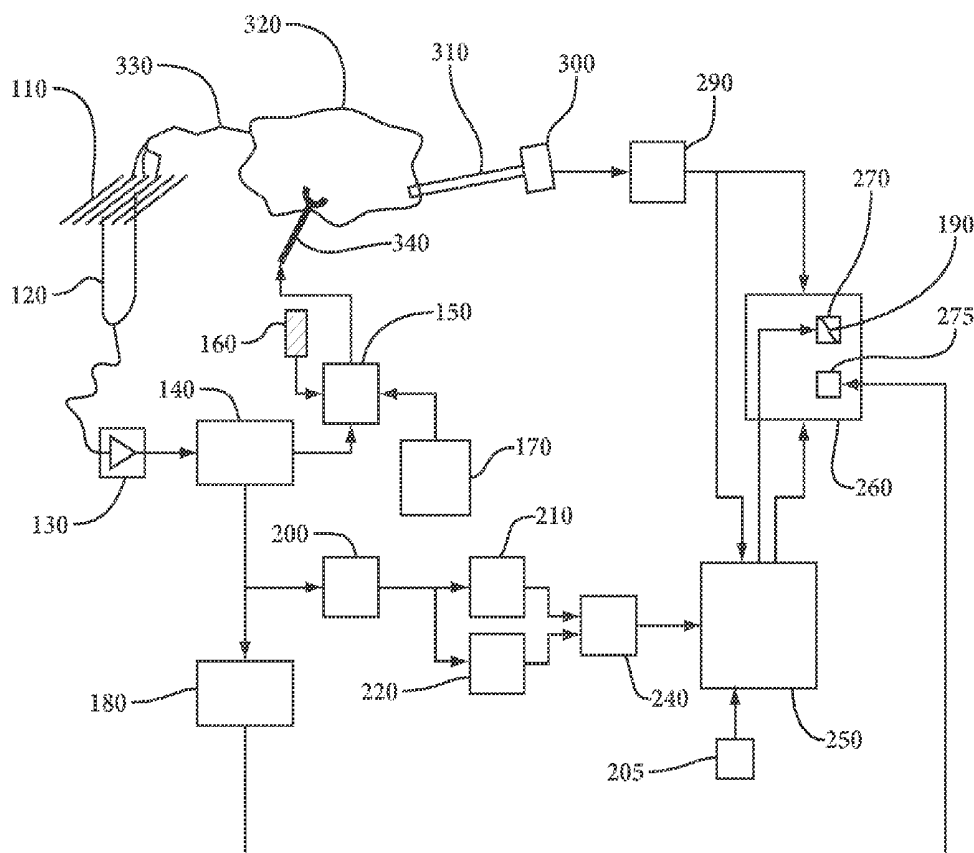
US 20170150923A1

(19) **United States**(12) **Patent Application Publication**
Bonfils-Rasmussen(10) **Pub. No.: US 2017/0150923 A1**(43) **Pub. Date: Jun. 1, 2017**(54) **SYSTEM AND METHOD FOR
LAPAROSCOPIC NERVE IDENTIFICATION,
NERVE LOCATION MARKING, AND NERVE
LOCATION RECOGNITION****Publication Classification**(51) **Int. Cl.***A61B 5/00* (2006.01)*A61B 18/12* (2006.01)*A61B 1/313* (2006.01)*A61B 34/30* (2006.01)*A61B 1/00* (2006.01)*A61B 1/04* (2006.01)(52) **U.S. Cl.**CPC *A61B 5/4893* (2013.01); *A61B 1/00009*(2013.01); *A61B 1/00045* (2013.01); *A61B**1/04* (2013.01); *A61B 1/3132* (2013.01); *A61B**34/30* (2016.02); *A61B 18/1206* (2013.01);*A61B 2018/00595* (2013.01)(71) Applicant: **ProPep Surgical, LLC**, Austin, TX
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(US)(21) Appl. No.: **15/323,356**(22) PCT Filed: **Jul. 20, 2015**(86) PCT No.: **PCT/US2015/041213**

§ 371 (c)(1),

(2) Date: **Dec. 30, 2016****Related U.S. Application Data**(60) Provisional application No. 62/027,130, filed on Jul.
21, 2014.

(57)

ABSTRACTA method and system for nerve identification, monitoring,
location marking, and location recognition system used
during laparoscopic surgery

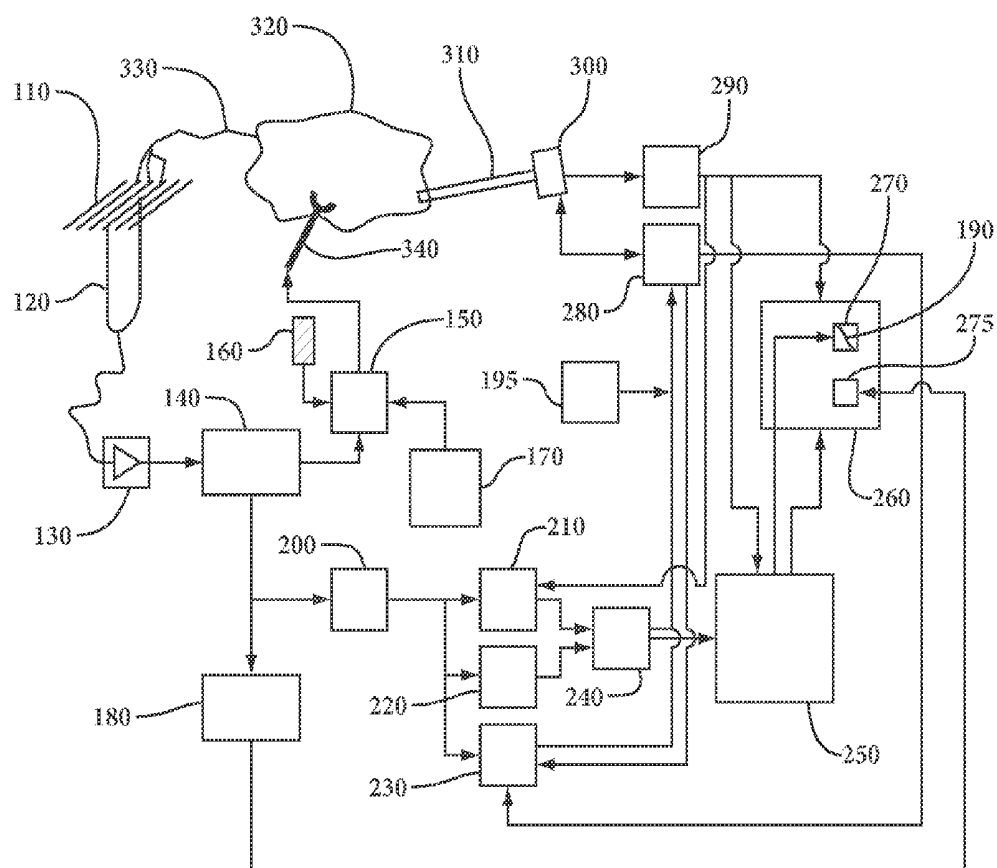


FIG 1

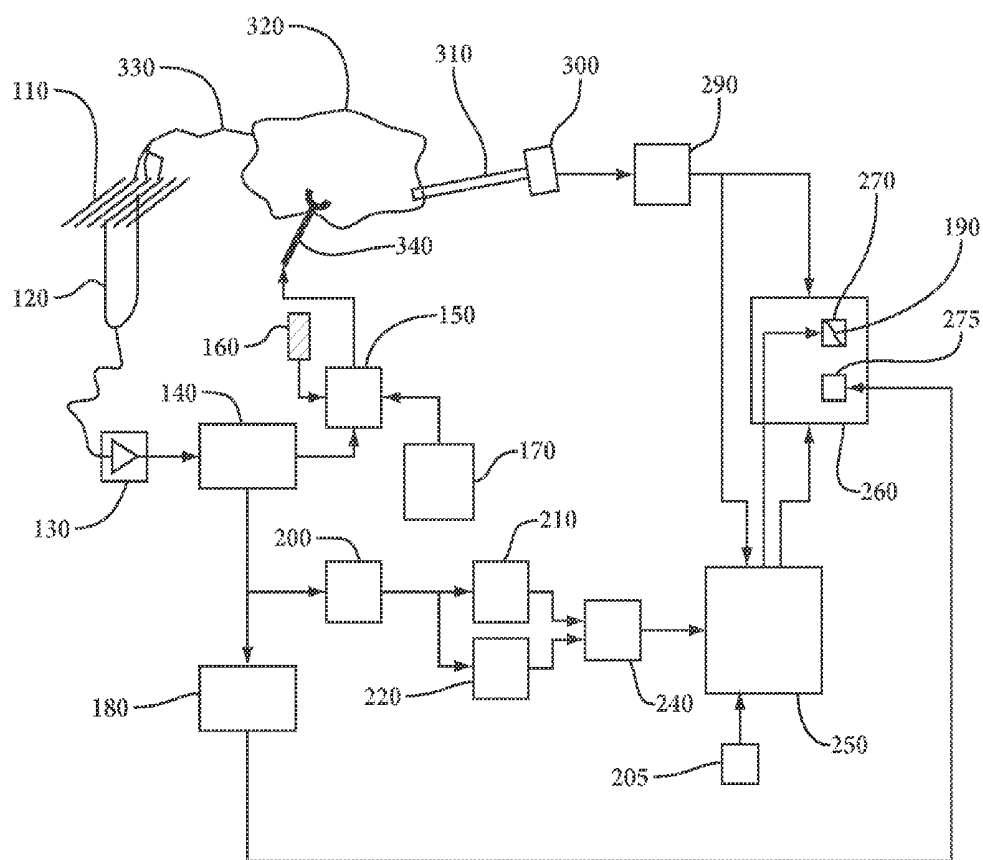


FIG 2

SYSTEM AND METHOD FOR LAPAROSCOPIC NERVE IDENTIFICATION, NERVE LOCATION MARKING, AND NERVE LOCATION RECOGNITION

BACKGROUND

[0001] Traditionally, surgery on internal body parts is performed by cutting an incision in the skin to access the internal body parts. Such open surgery entails a number of known risks including infection, inadvertent damage to other organs, nerves and other structures, scarring, and loss of blood. In an effort to reduce some of these risks and improve patient outcomes surgeons have developed laparoscopic, and more recently robotic techniques to perform surgery. Robotic surgery is essentially an advanced type of laparoscopic surgery in which the arms that enter the body cavity are robotically controlled instead of manually controlled. During a laparoscopic or robotic surgery, such as the da Vinci® surgery system, small incisions are made in the skin through which 5-12 millimeter access ports are placed. These ports serve as doorways through which small working instruments and an optical element can be placed. The optical element/camera creates a magnified view of the internal organs that the surgeon sees on a monitor or console. Such less invasive laparoscopic and robotic surgeries typically have reduced side effects for the patient to allow a more rapid and complete recovery. They have not, however, substantially decreased the incidence of intraoperative nerve damage that has been attributed to post-surgery side effects such as paralysis, erectile dysfunction, and urinary and fecal incontinence.

[0002] This inadvertent nerve damage often occurs because the surgeon cannot identify the nerves during surgery because they are either buried in tissue and/or are too small to be seen with the naked eye or with the magnification typically used during laparoscopic and robotic surgery. This problem is complicate in laparoscopic and robotic surgery because not only can the surgeons not see the nerves but, because their hands are not in the surgical field, they cannot palpate them either.

[0003] This problem of inadvertent nerve damage during surgery gave birth to the intraoperative neuromonitoring industry over 20+ years ago. Since that time, intraoperative nerve identification and monitoring has become standard of care in open surgical procedures in spine, ENT, vascular and many other surgical specialties. Until recently, however, intraoperative nerve monitoring was not performed during laparoscopic or robotic surgery. This changed with the introduction of the ProPep Nerve Monitoring System. This System allows nerve identification and nerve monitoring to be performed in real-time during both robotic-assisted and traditional laparoscopic surgery. Unfortunately, the system does not “remember” or mark where the nerves are when the surgeon moves the laparoscopic/robotic optical element, changing his view of the anatomy. This is cumbersome for the surgeon and can increase the procedure time as the surgeon has to reaffirm the location of the nerve throughout a surgical procedure.

SUMMARY

[0004] This application addresses this shortcoming by coupling optical digital image marking and position and

image recognition software with an intraoperative neuro-monitoring system such as the ProPep Surgical nerve monitoring system.

[0005] In a robotic-assisted surgery, the surgeon is “viewing” the tissue of interest using an optical element connected to a camera. The system works by allowing the surgeon to digitally “mark” the location of a nerve in a visual field associated with a specific location, magnification and orientation of the robotic-assisted optical element when the surgeon identifies a nerve using an intraoperative neuro-monitoring system. If the surgeon moves the optical element after “marking” the nerve location in order to facility some aspect of the surgery, he/she can return the optical element to the position it was in when the location of the nerve was “marked” by activating a Recall Switch. This not only returns the optical element to the original position (via the position recognition software) but also returns it to the original magnification and re-displays the nerve location in the surgeon’s visual field.

[0006] In a manually operated laparoscopic surgery the system will work in a similar manner. The surgeon is now manually controlling the movement of the optical element and will digitally “mark” the location of a nerve in a visual field after identifying the nerve with an intraoperative neuromonitoring system. If the surgeon moves the optical element after “marking” the nerve location in order to facility some aspect of the surgery, he/she can physically reposition the optical element to the position it was in when the location of the nerve was “marked” via the image recognition software. The surgeon can then use a Re-Display Switch to re-display the nerve location in the surgeon’s visual field.

[0007] The shortcoming can also be met by a method for nerve identification, location marking, and location recognition during laparoscopic surgery including at least: providing an optical element connected to a camera; providing a surgical instrument for use as an exploratory probe; providing at least one electrode probe inserted into a body cavity through a surface of the body, the at least one electrode probe being positionable by a surgical instrument and being operable to couple to muscle tissue within the body cavity; introducing an electrical signal via the surgical instrument operating as an exploratory probe to the muscle tissue within the body cavity along a presumed pathway of a nerve, thereby selectively creating an electrical potential received by the at least one electrode probe coupled to the muscle tissue within the body cavity; displaying the electrical potential; analyzing and evaluating the electrical potential with the analyzer to determine the location of the nerve; capturing an image of the pathway of the nerve; generating and displaying a visual marker of that pathway and storing that image for future reference; saving the exact positioning of the optical element when the visual marker was generated, allowing a return to that exact position through position or image recognition; and re-displaying the visual marker of the nerve pathway upon return of the optical element to the stored position.

[0008] The shortcoming can also be addressed by a nerve identification, monitoring, location marking, and location recognition system used during laparoscopic surgery including at least: an optical element connected to a camera and surgeon monitor; at least one recording electrode probe; a surgical instrument for use as an exploratory probe; an analyzer in operable communication with the at least one

recording electrode; the analyzer operable to indicate the proximity of the exploratory probe to the nerve based on the strength of an electrical signal sensed by the at least one recording electrode probe; an analyzer monitor to display the electrical signal sensed; an image capture and digital marker system activated by a criteria gate that sets and stores a digitally generated marker at the location of an identified nerve; an image control processor that sends the stored image to be displayed on a surgeon monitor; and an position or image recognition processor operating position or image recognition software that can store the position of the optical element or the image of the surgeon's visual field in the surgeon monitor when the visual marker of the nerves is first generated and redisplay the digitally generated marker of an identified nerve at its location on a the surgeon monitor when desired; and a recall or re-display switch that can return the optical element to the position it was in when the visual marker was generated or recognize the image in the surgeon visual field when the optical element is returned to the position it was in when the visual marker was generated, and signal the position or image recognition processor to redisplay the digitally generated marker on the surgeon monitor.

[0009] The surgical benefits of using this include the ability for the surgeon to instantly relocate non-visible nerve tissue marked earlier during the surgical procedure so as to know what tissue to spare/not compromise during subsequent surgical intervention and manipulation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is an overall schematic illustration of the proposed system and the resultant integration into a robotic-assisted laparoscopic surgery system.

[0011] FIG. 2 is an overall schematic illustration of the proposed system and the result integration into a manually operated laparoscopic surgery system.

DETAILED DESCRIPTION

[0012] This need, to identify and recall the position of non-visible nerve tissue during laparoscopic surgery, can be met with the system to be described below in reference to FIG. 1. In general many of the elements shown on the left hand side of the drawing are part of the (modified) ProPep Surgical nerve monitoring system. The description of the ProPep system is presented in U.S. Pat. No. 8,083,685, issued on Dec. 7, 2011 and incorporated herein by reference in its entirety.

[0013] In accordance with the present disclosure, a system and method are provided which substantially reduces the disadvantages and problems associated with previous methods and systems for identifying non-visible nerve tissue during robotic-assisted laparoscopic surgery.

[0014] Referring first to FIG. 1 for a robotic surgery system, numeral 320 represents human tissue located within a body cavity containing non-visible nerve tissue. A dual function laparoscopic surgical instrument 340 from a robotic surgical system is being used to perform laparoscopic surgery within the body cavity and to stimulate tissue. In this context the term dual function refers to the use of the surgical instrument as either an exploratory probe used to stimulate tissue or an electro cautery instrument for surgery. The dual function laparoscopic surgical instrument is connected to a control switch 150, which in turn is connected to

both an electro cautery generator 170 (power supply) and an electromyographic analyzer 140. The control switch 150 allows the surgeon to switch the power going to the surgical instrument 340 between the cauterizing energy from the electro cautery generator 170 needed to perform surgery and the stimulation energy from the electromyographic analyzer 140 needed to stimulate tissue for the purpose of identifying and monitoring nerves. The control switch can be triggered by a foot pedal 160 or any appropriate switch. The surgeon is aided in these surgical procedures by an optical element 310 protruding into the body cavity and attached to a camera 300. The optical element facilitates visualization of the laparoscopic surgical field. This element can take many forms but is in general a remotely operated endoscopic imaging system with variable magnification and infinite positioning in 3 dimensional space. It is controlled by the Optical Element Positioning Device 280 in such a way as to be able to return to any previous viewing position through the control of the surgeon. The image information from the optical element/camera is fed via a Video Data Analyzer 290 to the surgeon's view finder 260.

[0015] There are numerous other elements of the robotic surgery device that are not shown to simplify the description of the instant application. A representative description of such a device is shown in U.S. application 20080065107 A1 (Larkin et. al) published Mar. 13, 2008.

[0016] To identify non-visible nerve tissue, two recording electrode probes 120, one active and one reference and both connected to the analyzer 140, are inserted through the body surface via a introducer trocar device and into a body cavity so as to be accessible by a laparoscopic surgical instrument (not necessarily the dual function laparoscopic surgical instrument 340) for placement into muscle tissue 110 wherein the non-visible nerve of interest 330 terminates. The dual function laparoscopic surgical instrument 340 switched to stimulation mode is then used to stimulate the tissue 320 along the presumed nerve pathway. If a nerve 330 is present in the tissue, the electric current causes a depolarization of the nerve, which results in a nerve action potential. The nerve action potential then propagates along the nerve to the neuromuscular junction (the synapse between the nerve and the muscle cell) where a neurotransmitter (acetylcholine) is released in response to the action potential. This neurotransmitter depolarizes the postsynaptic muscle cells creating an electrical potential received by the electrode probes 120, analyzed by the analyzer 140 and displayed as a wave form on the analyzer's display 180, an image of which is sent to electromyography (EMG) Window 275 in the Surgeon's View Finder 260. The relative strength of the electrical potential received at an electrode probe 120 will increase as surgical instrument 340 is placed closer to the nerve 330. Thus by moving the surgical instrument 340 along the presumed nerve pathway, the surgeon maps the actual nerve pathway based upon the strength of the signal received at electrode probes 120 for each position of the surgical instrument 340.

[0017] As the nerve pathway becomes evident a criteria gate 200 sends information to an image frame capture system 210, and a digital image marker generator 220 that provides a visual marker of the discovered nerve in the surgeon's visual field. In addition the exact positioning of the optical element 310 at the time of the digitally generated marker setting is stored by an Optical Element Position Data Storage 230. An image control processor 240 sends the

image of the surgeon's visual field with the visual markers of the nerves **190** to be displayed to a Surgical Field Window **270** in the surgeon's viewfinder **260**. Image and Position Recognition Processor **250** manages all of this and stores the image of the surgeon's visual field and the position of the visual markers of the nerves.

[0018] As surgery proceeds, the surgeon operating the robotic surgical element may move the optical element of the camera numerous times but can, at any time, return to the position the optical element was in when the nerve of interest was mapped by activating a Recall Switch **195** that signals the Optical Element Positioning Device **280** to pull the position information from the Optical Element Position Data Storage **230** and position the optical element accordingly. In one embodiment, clicking on the Surgical Field Window **270** in the Surgeon's View Finder **260** activates the Recall Switch **195**. Once the Optical Element **310** returns to the position it was in when the nerve of interest was marked, the Image and Position Recognition Processor **250** will redisplay the visual marker of the discovered nerve in the Surgeon View Finder **260** at its location.

[0019] In the case of a manually operated laparoscopic surgery, FIG. 2 illustrates a somewhat simpler system in which the surgeon can, at any time, return to the position the Optical Element **310** was in when the nerve of interest was mapped by manually moving the optical element until the image and position recognition software in the Image and Position Recognition Processor **250** confirms the real-time image in the Camera **300** matches the image stored in the Image and Position Recognition Processor **250** of the surgical view displayed when the nerve of interest was marked. The surgeon then can re-display the nerve location **190** in surgeon viewfinder **270** by activating a Re-Display Switch **205**.

[0020] In practice, the method of this application may be described as follows. The method works in close conjunction with a robotic surgery device that has a camera with a positionable optical element presenting an image of the laparoscopic surgical field. It provides at least one electrode probe that is inserted into the body cavity through a surface of the body, the at least one electrode probe being positionable by a laparoscopic device and being operable to couple to the body within the body cavity proximate to a preselected nerve; providing at least one exploratory probe (dual function laparoscopic surgical instrument switched to stimulation mode) separate and distinct from the first at least one electrode probe and adapted to be disposed in the body cavity; introducing an electrical signal via the exploratory probe to the body within the body cavity along a presumed pathway of the nerve of interest thereby depolarizing the tissue surrounding the nerve which results in an action potential that propagates along the nerve to the neuromuscular junction (the synapse between the nerve and the muscle cell) where a neurotransmitter (acetylcholine) is released in response to the action potential. The neurotransmitter depolarizes the postsynaptic muscle cells creating an electrical potential received by the at least one electrode probe, and providing an analyzer interfaced with the at least one electrode probe, the analyzer being operable to indicate the proximity of the at least one exploratory probe to the nerve of interest based on a measurement of the strength of the electrical potential signal sensed by the at least one electrode probe; observing and evaluating the data produced by the analyzer; thus determining the location of the nerve;

generating a visual marker of that pathway of the nerve and displaying and storing that visual marker for future reference. The procedure also saves the exact positioning of the optical element during the procedure, allowing a return to the same exact position and a re-displaying of the visual marker image of the nerve pathway.

[0021] This combination of improvements enables the surgeon to instantly locate non-visible nerve tissue marked earlier during the surgical procedure so as to know what tissue to spare/not compromise during subsequent surgical intervention and manipulation and to instantly recall previous marked nerve tissue locations.

[0022] Although certain embodiments and their advantages have been described herein in detail, it should be understood that various changes, substitutions and alterations could be made without departing from the coverage as defined by the appended claims. Moreover, the potential applications of the disclosed techniques is not intended to be limited to the particular embodiments of the processes, machines, manufactures, means, methods and steps described herein. As a person of ordinary skill in the art will readily appreciate from this disclosure, other processes, machines, manufactures, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufactures, means, methods or steps.

1. A nerve identification, monitoring, location marking, and location recognition system used during laparoscopic surgery comprising:

- a) an optical element connected to a camera;
- b) at least one recording electrode probe;
- c) a surgical instrument for use as an exploratory probe;
- d) an analyzer in operable communication with the at least one recording electrode; the analyzer operable to indicate the proximity of the exploratory probe to the nerve based on the strength of an electrical signal sensed by the at least one recording electrode; the strength of the electrical signal being displayed on a monitor and being sensed by a criteria gate;
- e) an image capture and digital marker system that is activated by the criteria gate and sets and stores a digitally generated marker at the location of an identified nerve in the surgeon's visual field; and
- f) an image control processor that sends the stored image to be displayed on a monitor.

2. The nerve identification, monitoring, location marking, and location recognition system used during laparoscopic surgery of claim 1 wherein the laparoscopic surgery is manual.

3. The nerve identification, monitoring, location marking, and location recognition system used during laparoscopic surgery of claim 2 that includes an image recognition processor operating image recognition software that recognizes the image on a monitor of the surgeon's visual field when the visual marker of the nerve was generated and redisplay the stored image of the marker of an identified nerve at its location on a monitor when the image appears in the monitor.

4. The nerve identification, monitoring, location marking, and location recognition system used during laparoscopic surgery of claim 1 wherein the laparoscopic surgery is robotic.

5. The nerve identification, monitoring, location marking, and location recognition system used during laparoscopic surgery of claim 4 that includes a position recognition processor operating position recognition software that stores the position of the optical element when the visual marker of a nerve is first generated and, upon activation of a recall switch, returns the optical element to that position and redisplay the stored image of the marker of the identified nerve at its location on a monitor.

6. The identification, monitoring, location marking, and location recognition system used during laparoscopic surgery of claim 5 where the monitor is the surgeon's viewfinder of a robotic surgical device.

7. The nerve identification, monitoring, location marking, and location recognition system used during laparoscopic surgery of claim 1 wherein said surgical instrument also functions as an electro cautery instrument.

8. The nerve identification, monitoring, location marking, and location recognition system used during laparoscopic surgery of claim 4 further comprising an electro cautery generator in operable communication with the surgical instrument.

9. The nerve identification, monitoring, location marking, and location recognition system used during laparoscopic surgery of claim 5 further comprising a control switch in operable communication with said analyzer, said electro cautery generator and said surgical instrument, to thereby permit an operator of said system to selectively alternate use of said surgical instrument between use as an electro cautery instrument and use as an exploratory probe.

10. A method for nerve identification, location marking, and location recognition during laparoscopic surgery comprising:

- a) providing an optical element connected to a camera;
- b) providing a surgical instrument for use as an exploratory probe;
- c) providing at least one electrode probe inserted into a body cavity through a surface of the body, the at least one electrode probe being positionable by the surgical instrument and being operable to couple to muscle tissue within the body cavity;
- d) introducing an electrical signal via the surgical instrument operating as an exploratory probe to the body within the body cavity along a presumed pathway of a

nerve, thereby selectively creating an electrical potential received by the at least one electrode probe coupled to the muscle tissue within the body cavity;

- e) analyzing and displaying the electrical potential;
- f) observing and evaluating the data with the analyzer; to determine the location of the nerve;
- g) capturing an image of the pathway of the nerve;
- h) generating a visual marker of that pathway and displaying and storing that image for future reference;
- i) saving the exact positioning of the optical element during the procedure, allowing a return to the same exact position, and through position or image recognition; and
- j) presenting the visual marker image of the nerve pathway.

11. The method for nerve identification, location marking, and location recognition during laparoscopic surgery of claim 8 wherein the laparoscopic surgery is manual.

12. The method for nerve identification, location marking, and location recognition system used during manual laparoscopic surgery of claim 9 wherein manually returning the optical element to the position it was in when the nerve was marked and the image was stored, and activating a re-display switch, restores the digitally generated marker of the identified nerve on a monitor.

13. The method for nerve identification, location marking, and location recognition during laparoscopic surgery of claim 10 wherein the laparoscopic surgery is robotic and the optical element is returned to the position it was in when the nerve was marked and the image was stored by use of a recall switch.

14. The method for nerve identification, location marking, and location recognition during laparoscopic surgery of claim 13 wherein the activation of the recall switch restores the digitally generated marker of the identified nerve on a monitor.

15. The method for nerve identification, location marking, and location recognition during laparoscopic surgery of claim 14 wherein the monitor is the surgeon's viewfinder of a robotic surgical device.

16. The method for nerve identification, location marking, and location recognition during laparoscopic surgery of claim 10 wherein said surgical instrument also functions as an electro cautery instrument.

* * * * *

专利名称(译)	用于腹腔镜神经识别，神经位置标记和神经位置识别的系统和方法		
公开(公告)号	US20170150923A1	公开(公告)日	2017-06-01
申请号	US15/323356	申请日	2015-07-20
[标]申请(专利权)人(译)	PROPEP手术		
申请(专利权)人(译)	PROPEP手术，LLC		
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发明人	BONFILS-RASMUSSEN, JANN		
IPC分类号	A61B5/00 A61B18/12 A61B1/313 A61B34/30 A61B1/00 A61B1/04		
CPC分类号	A61B5/4893 A61B1/00009 A61B1/00045 A61B1/04 A61B2018/00839 A61B34/30 A61B18/1206 A61B2018/00595 A61B2018/00642 A61B1/3132 A61B5/0488 A61B5/6877 A61B18/1482 A61B90/361 A61B90/37 A61B90/39 A61B2034/2065 A61B2034/302 A61B2090/3612 A61B2090/363 A61B2090/364 A61B2090/368 A61B2090/3937		
优先权	62/027130 2014-07-21 US		
外部链接	Espacenet USPTO		

摘要(译)

一种用于在腹腔镜手术期间使用的神经识别，监测，位置标记和位置识别系统的方法和系统

