(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 April 2010 (01.04.2010)

PCT

(10) International Publication Number
WO 2010/036746 A1

(51) International Patent Classification:
A61B 19/00 (2006.01) *A61B 18/18* (2006.01)

(21) International Application Number:
PCT/US2009/058121

(22) International Filing Date:
23 September 2009 (23.09.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/099,904	24 September 2008 (24.09.2008)	US
12/347,811	31 December 2008 (31.12.2008)	US
12/347,826	31 December 2008 (31.12.2008)	US
12/347,842	31 December 2008 (31.12.2008)	US
12/347,835	31 December 2008 (31.12.2008)	US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

[Continued on next page]

(54) **Title**: SYSTEM AND METHOD OF AUTOMATIC DETECTION OF OBSTRUCTIONS FOR A ROBOTIC CATHETER SYSTEM

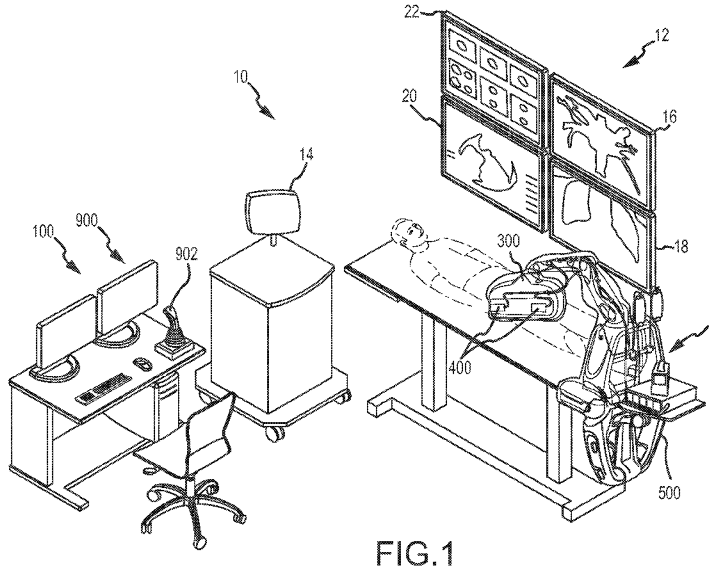

FIG.1

(57) **Abstract**: An obstruction detection system for a robotic catheter system including a robotic catheter manipulator assembly including one or more catheter manipulation bases and one or more sheath manipulation bases. Each manipulation base may be generally linearly movable on one or more tracks relative to the robotic catheter manipulator assembly. The obstruction detection system may include one or more obstruction detection sensors disposed on the track or on the manipulation bases to detect an obstruction along a path of motion of one or more manipulation bases. A software system may be provided for monitoring movement of the catheter and sheath manipulation bases, and/or a status of the obstruction detection sensors.

WO 2010/036746 A1

Published:

— *with international search report (Art. 21(3))*

SYSTEM AND METHOD OF AUTOMATIC DETECTION OF OBSTRUCTIONS FOR A ROBOTIC CATHETER SYSTEM

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of United States non-provisional application nos. 12/347,811, filed 31 December 2008 (the '811 application), 12/347,826, filed 31 December 2008 (the '826 application), 12/347,835, filed 31 December 2008 (the '835 application), and 12/347,842, filed 31 December 2008 (the '842 application), each of which claim the benefit of United States provisional application no. 61/099,904, filed 24 September 2008 (the '904 application). The '811, '826, '835, '842 and '904 applications are hereby incorporated by reference as though fully set forth herein.

BACKGROUND OF THE INVENTION

a. Field of the Invention

[0002] This invention relates to a robotic catheter system and method for automated control of a catheter and related components. In particular, the instant invention relates to a robotic catheter system including a system and method for detection of obstructions that may hinder or otherwise stop movement of catheter and/or sheath manipulation bases, and related components during operation of the robotic catheter system.

b. Background Art

[0003] Electrophysiology catheters are used in a variety of diagnostic and/or therapeutic medical procedures to correct conditions such as atrial arrhythmia, including for example, ectopic atrial tachycardia, atrial fibrillation, and atrial flutter. Arrhythmia can create a variety of dangerous conditions including irregular heart rates, loss of synchronous atrioventricular contractions and stasis of blood flow which can lead to a variety of ailments and even death.

[0004] Typically in a procedure, a catheter is manipulated through a patient's vasculature to, for example, a patient's heart, and carries one or more electrodes which may be used for mapping, ablation, diagnosis, or other treatments. Once at the intended site, treatment may include radio frequency (RF) ablation, cryoablation, lasers, chemicals, high-intensity focused ultrasound, etc. An ablation catheter imparts such ablative energy to cardiac tissue to create a lesion in the cardiac tissue. This lesion disrupts undesirable electrical pathways and thereby limits or prevents stray electrical signals that lead to arrhythmias. As readily apparent, such treatment requires precise control of the catheter during manipulation to and at the treatment site, which can invariably be a function of a user's skill level.

[0005] One method of minimizing invariability due to a user's skill level involves the use of robotic catheter systems, such as the robotic catheter system described in detail in commonly owned and copending Application Serial No. 12/347,811 titled "Robotic Catheter System". As readily evident, such robotic catheter systems include a variety of safety concerns that must be addressed to prevent harm to a patient and the system operator. One such safety concern includes the possibility of an obstruction in the path of manipulation bases supporting the catheter and sheath cartridges, the layout and operation of which is also described in detail in the aforementioned "Robotic Catheter System" application.

[0006] The inventors herein have thus recognized the need for a system and method for detection of obstructions that may hinder or otherwise stop movement of manipulation bases and related components, and have further recognized the need for a system and method for controlling movement of the manipulation bases in a predetermined manner based on the type and location of an obstruction, and other factors involving movement of the manipulation bases.

BRIEF SUMMARY OF THE INVENTION

[0007] An obstruction detection system for a robotic catheter system may include a robotic catheter manipulator assembly including one or more catheter and sheath manipulation bases, with each manipulation base being generally linearly movable on one or more tracks relative to the robotic catheter manipulator assembly. The obstruction detection system may include one or more obstruction detection sensors disposed on the track and/or on the manipulation bases to detect an obstruction along a path of motion of the manipulation bases.

[0008] For the obstruction detection system described above, in one embodiment, the obstruction detection sensors may be ultrasonic sensors or light-emitting sensors. In one embodiment, the obstruction detection system may include obstruction detection sensors located at both ends of the track. In another embodiment, the obstruction detection system may include obstruction detection sensors located at both longitudinal ends of the catheter and sheath manipulation bases. In one embodiment of the obstruction detection system, the obstruction detection sensors enable maintenance of a predetermined distance between the catheter and sheath manipulation bases.

[0009] For the obstruction detection system described above, in one embodiment, the system may include a software system for monitoring movement of the catheter and sheath manipulation bases, and/or a sensor status of one or more obstruction detection sensors. In one embodiment of the obstruction detection system, the software system may include code for determining if a relative distance between the catheter and sheath manipulation bases is less than a predetermined distance; if the relative distance is less than the predetermined distance, then indicating an obstruction status of the catheter and sheath manipulation bases as obstructed, and stopping motion of the catheter and sheath manipulation bases, and if the relative distance is greater than or equal to the predetermined distance, then indicating the obstruction status of the catheter and sheath manipulation bases as unobstructed, and allowing motion of the catheter and sheath manipulation bases. In another embodiment, the obstruction detection system may include LEDs, visual signals, audible signals, and/or haptic feedback to a user input device, for indicating the obstruction status of the catheter and sheath manipulation bases.

[0010] For the obstruction detection system described above, in one embodiment, the system may include code for determining a relative distance between the catheter and sheath manipulation bases by determining an amount of rotation of motors that drive the catheter and sheath manipulation bases. In one embodiment of the obstruction detection system, the software system may include code for stopping motion of the catheter and sheath manipulation bases if the sensor status of the obstruction detection sensors is obstructed, and allowing motion of the catheter and sheath manipulation bases if the sensor status of all obstruction detection sensors is unobstructed.

[0011] For the obstruction detection system described above, in one embodiment, the system may include code for determining a direction of travel of the catheter and sheath manipulation bases, and allowing motion of the catheter and sheath manipulation bases if the sensor status of one of the obstruction detection sensors is obstructed, only if the direction of travel is away from the obstruction. In one embodiment of the obstruction detection system, the software system may include code for determining a direction of travel of the catheter and sheath manipulation bases by determining a direction of rotation of motors that drive the catheter and sheath manipulation bases.

[0012] For the obstruction detection system described above, in one embodiment, the system may include LEDs, visual signals, audible signals, and/or haptic feedback to a user input device, for indicating the sensor status of the obstruction detection sensor. In one embodiment of the obstruction detection system, the software system may monitor the manipulation bases and the obstruction detection sensors by means of a CANOpen protocol standard.

[0013] The invention also provides an obstruction detection system for a robotic catheter system including a robotic catheter manipulator assembly including one or more catheter manipulation bases and one or more sheath manipulation bases, with each manipulation base being generally linearly movable on one or more tracks relative to the robotic catheter manipulator assembly. The obstruction detection system may include detection means disposed on the track or on the manipulation bases to detect an obstruction along a path of motion of the manipulation bases, and monitoring means for monitoring movement of the catheter and sheath manipulation bases, and/or a detection status of the detection means.

[0014] For the obstruction detection system described above, in one embodiment, the detection means may be an ultrasonic sensor or a light-emitting sensor. In one embodiment of the obstruction detection system, the detection means may include obstruction detection sensors located at both ends of the track. In another embodiment of the obstruction detection system, the detection means may include obstruction detection sensors located at both longitudinal ends of the catheter and sheath manipulation bases. In one embodiment of the obstruction detection system, the obstruction detection sensors may enable maintenance of a predetermined distance between the catheter and sheath manipulation bases.

[0015] For the obstruction detection system described above, in one embodiment, the system may include monitoring means in the form of a software system including code for determining if a relative distance between the catheter and sheath manipulation bases is less than a predetermined distance; if the relative distance is less than the predetermined distance, then indicating an obstruction status of the catheter and sheath manipulation bases as obstructed, and stopping motion of the catheter and sheath manipulation bases, and if the relative distance is greater than or equal to the predetermined distance, then indicating the obstruction status of the catheter and sheath manipulation bases as unobstructed, and allowing motion of the catheter and sheath manipulation bases.

[0016] For the obstruction detection system described above, in one embodiment, the system may include means for indicating the obstruction status of the catheter and sheath manipulation bases. In one embodiment of the obstruction detection system, the means for indicating may include LEDs, visual signals, audible signals, and/or haptic feedback to a user input device.

[0017] For the obstruction detection system described above, in one embodiment, the system may include monitoring means in the form of a software system including code for determining a relative distance between the catheter and sheath manipulation bases by determining an amount of rotation of motors that drive the catheter and sheath manipulation bases.

[0018] For the obstruction detection system described above, in one embodiment, the system may include monitoring means in the form of a software system including code for stopping motion of the catheter and sheath manipulation bases if the detection status of the obstruction detection sensors is obstructed, and allowing motion of the catheter and sheath manipulation bases if the detection status of all obstruction detection sensors is unobstructed. In one embodiment of the obstruction detection system, the monitoring means may be a software system including code for determining a direction of travel of the catheter and sheath manipulation bases, and allowing motion of the catheter and sheath manipulation bases if the detection status of one of the obstruction detection sensors is obstructed, only if the direction of travel is away from the obstruction. In one embodiment of the obstruction detection system, the monitoring means may be a software system including code for determining a direction of travel of the catheter and sheath manipulation bases by determining a direction of rotation of motors that drive the catheter and sheath manipulation bases.

[0019] For the obstruction detection system described above, in one embodiment, the system may include means for indicating the detection status of the obstruction detection sensor. In one embodiment of the obstruction detection system, the means for indicating may include LEDs, visual signals, audible signals, and/or haptic feedback to a user input device. In one embodiment of the obstruction detection system, the monitoring means may monitor the manipulation bases and the detection means by means of a CANOpen protocol standard.

[0020] The foregoing and other aspects, features, details, utilities and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] Fig. 1 is an isometric diagrammatic view of a robotic catheter system, illustrating an exemplary layout of various system components;

[0022] Fig. 2 is an enlarged isometric view of an exemplary robotic catheter manipulator assembly, also shown in Fig. 1;

[0023] Figs. 3a-3c are enlarged isometric views of an embodiment of a robotic catheter manipulator assembly, and Figs. 3d-3g are respectively enlarged left side, right side, top and front views of the robotic catheter manipulator assembly of Fig. 3a, illustrating use of the manipulator assembly with a robotic catheter rotatable device cartridge;

[0024] Figs. 4a-4c are enlarged isometric views of an embodiment of a manipulation base;

[0025] Figs. 5a-5e are enlarged isometric views of an embodiment of a robotic catheter device cartridge, with Fig. 3a illustrating an exemplary usage of the robotic catheter device cartridge;

[0026] Fig. 6 is a sketch illustrative of exemplary placement of obstruction detection sensors for the obstruction detection system according to the invention; and

[0027] Fig. 7 is a flow-chart of the control logic for the obstruction detection system according the invention.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0028] Referring now to the drawings wherein like reference numerals are used to identify identical components in the various views, an embodiment of robotic catheter system 10 (described in detail in commonly owned and copending Application Serial No. 12/347,811 titled “Robotic Catheter System”), also referred to as “the system,” may be likened to “fly by wire” operation for a catheter system. The system may be used, for example, to manipulate the location and orientation of catheters and sheaths in a heart chamber or in another body cavity. As shown in Fig. 1, robotic catheter system 10 may generally incorporate a human input device and control system (referred to as “input control system”) 100, e.g., a joystick and related controls (described briefly below and in detail in commonly owned and copending Application Serial No. PCT/US2009/038618 titled “Robotic Catheter System Input Device”), that a user such as an electrophysiologist (EP) may interact with, an electronic control system 200 (described briefly below and in detail in commonly owned and copending Application Serial No. PCT/US2009/038597 titled “Robotic Catheter System with Dynamic Response”) that translates motions of the user at the input device into a resulting movement of a catheter tip, and a visualization system 12 that provides a user with real-time or near-real-time positioning information concerning the catheter tip. The system may further include closed-loop feedback using an EnSite NavX^{TM} Navigation and Visualization system 14 and/or optical force transducers, a robotic catheter manipulator assembly 300 (described briefly below and in detail in commonly owned and copending Application Serial No. 12/347,826 titled “Robotic Catheter Manipulator Assembly”) for operating a robotic catheter device cartridge 400 (described briefly below and in detail in commonly owned and copending Application Serial No. 12/347,835 titled “Robotic Catheter Device Cartridge” and Application Serial No. 12/347,842 "Robotic Catheter Rotatable Device Cartridge"), and manipulator support structure 500 (described briefly below and in detail in commonly owned and copending Application Serial No. 12/347,811 titled “Robotic Catheter System”). As discussed in detail below, robotic catheter system 10 may include an obstruction detection system 600 for detection of obstructions that may hinder or otherwise stop movement of catheter and sheath manipulation bases, and related components during operation of the robotic catheter system. The respective disclosures of the above-identified and other commonly owned and copending applications discussed in this application are incorporated herein by reference.

[0029] Before proceeding with a detailed description of obstruction detection system 600, the general layout and operation of the components of robotic catheter system 10 will be described with reference to Figs. 1-5e to provide a basis for the operation of obstruction detection system 600.

[0030] An embodiment of robotic catheter system 10 may involve automated catheter movement. A user, such as an EP, could identify locations (potentially forming a path) on a rendered computer model of the cardiac anatomy. The system can be configured to relate those digitally selected points to positions within a patient’s actual/physical anatomy, and may command and control the movement of a catheter to defined positions. Once in position, either the user or system could then perform the desired treatment or therapy – which may further be in accordance with a defined algorithm. This system could enable full robotic control by using optimized path planning routines together with closed-loop position control. Furthermore, the system could automate certain “best-practices,” such as pulling the catheter across the surface, or making contact at an oblique angle.

[0031] Referring to Fig. 1, input control system 100, described below and in commonly owned and copending application titled “Robotic Catheter System Input Device,” may generally allow a user to control the movement and advancement of both the catheter and sheath. Generally, several types of joysticks may be employed, including, without limitation, instrumented traditional catheter handle controls, oversized catheter models, instrumented, user-wearable gloves, and traditional joysticks. In embodiments, for example and without limitation, the joystick may be spring or motor centering so that any movement from the center position causes an incremental movement of the actual catheter tip, or the joystick may work in absolute terms.

[0032] Referring to Fig. 1, electronic control system 200 will be described briefly.

[0033] As discussed in detail in commonly owned and copending applications titled “Robotic Catheter System Input Device,” and “Robotic Catheter System with Dynamic Response,” many additional features may be included with embodiments of the system to, for example, improve the accuracy or effectiveness of the system. Such features may include, closed-loop feedback using EnSite NavX™ Navigation and Visualization system 14 for creating realistic cardiac chamber geometries or models, displaying activation timing and voltage data to identify arrhythmias, and guiding precise catheter movement, and/or optical force transducers; active tensioning of “passive” steering wires to reduce the system response time; cumulative ablation while the tip is following a front-to-back ironing motion; and/or reactive/resistive impedance monitoring.

[0034] Referring to Fig. 1, visualization system 12 will be described briefly.

[0035] Visualization system 12 may provide a user with real-time or near-real-time positioning information concerning the catheter tip. In an exemplary embodiment, system 12 may include an EnSite NavX™ Navigation and Visualization monitor 16 for displaying cardiac chamber geometries or models, displaying activation timing and voltage data to identify arrhythmias, and for facilitating guidance of catheter movement. A fluoroscopy monitor 18 may be provided for displaying a real-time x-ray image or for assisting a physician with catheter movement. Additional exemplary displays may include an ICE and EP Pruka displays, 20, 22, respectively.

[0036] Referring to Fig. 1, EnSite NavX™ Navigation and Visualization system 14 will be described briefly.

[0037] EnSite NavX™ Navigation and Visualization system 14 (described in detail in U.S. Patent No. 7,263,397, titled “Method and Apparatus for Catheter Navigation and

Location and Mapping in the Heart," incorporated by reference in its entirety) may be provided for creating realistic cardiac chamber geometries or models, displaying activation timing and voltage data to identify arrhythmias, and guiding precise catheter movement. System 14 may collect electrical data from catheters and use this information to track or navigate their movement and construct three-dimensional (3-D) models of the chamber.

[0038] Referring to Figs. 1-5e, robotic catheter manipulator assembly 300 for operating robotic catheter device cartridges 400, various embodiments of which are described in detail in the aforementioned commonly owned and copending applications, will be described briefly for facilitating an understanding of input control system 100, and the operational integration of an haptic feedback system 900 with manipulator assembly 300 for controlling cartridges 400.

[0039] As generally shown in Figs. 1 and 3a-5e, robotic catheter system 10 which includes one or more robotic catheter manipulator assemblies 300, includes an embodiment of robotic catheter manipulator assembly 302 including both catheter and sheath manipulation mechanisms 304, 306 for manipulating, for example, catheter and sheath cartridges 402, 404. Manipulator assembly 302 may include interconnected/interlocking manipulation bases 308, 310 for catheter and sheath cartridges 402, 404, and likewise may include electrical "handshake" functionality as discussed below. Each interlocking base 308, 310 may be capable of travel in the longitudinal direction of the catheter/sheath (D_1, D_2 respectively). In an embodiment, D_1 and D_2 may each represent a translation of approximately 8 linear inches. As shown in Fig. 3a, each interlocking base may be translated by high precision drive mechanisms 312, 314. Such drive mechanisms may include, for example and without limitation, a motor driven lead screw or ball screw.

[0040] As shown in Figs. 3a-5e, for each cartridge 402, 404, an associated manipulation base 308, 310 may include a plurality of fingers 316, 318, 320 and 322, (e.g., one per steering wire) that extend or protrude upwardly to contact and interact with the steering wire slider blocks (such as slider blocks 412, 414, 416, 418) to independently tension select steering wires 420, 422, 424, 426. Each finger can be configured to be independently actuated by a precision drive mechanism, such as a motor driven ball screw 324, and may be outfitted with force sensors to measure corresponding steering wire tension. A distal steering wire encoder (not shown) may also be provided for force measurements at the distal end of the steering wires adjacent the catheter distal end. Each motor driven ball screw (for both finger control and cartridge translation control) may further include encoders to measure a relative and/or an absolute position of each element of the system. As shown in Fig. 4a, bearing 332 and coupler 330 of ball screw 324 may engage frame 340 of respective bases 308, 310 and a corresponding finger 316, 318, 320 or 322 may be mounted adjacent a strain gauge for measuring the corresponding steering wire tension.

[0041] Referring to Figs. 4a-4c, bases 308, 310 may include exemplary components such as motors 342, 344, 346 and 348, respectively coupled to fingers 316, 318, 320 and 322. A bearing 354 may be provided for sliding of bases 308, 310 on track 356. A plurality of inductive sensors (e.g. home sensors) 358 may be provided for guiding each manipulation base to a safe position.

[0042] Referring to Figs. 1-3g, particularly Figs. 3d-3g, robotic catheter manipulator assembly 302 may be usable with a robotic catheter rotatable device cartridge 490, described in detail in commonly owned and copending application titled "Robotic Catheter Rotatable Device Cartridge." As shown in Fig. 3g, manipulator base 308 may be replaced with a robotic catheter rotatable drive head 492 and a robotic catheter rotatable drive mechanism 494, described in detail in commonly owned and copending application titled "Robotic Catheter Rotatable Drive Mechanism."

[0043] Referring to Figs. 1 and 5a-5e, an embodiment of catheter and sheath cartridges 402, 404 will be described in detail.

[0044] As briefly discussed above, robotic catheter system 10 may include one or more cartridges 400, with manipulator 302 including at least two cartridges 402, 404, each of which may be respectively designed to control the distal movement of either the catheter or the sheath. With respect to catheter cartridge 402, catheter 406 may be substantially connected or affixed to cartridge 402, so that advancement of cartridge 402 correspondingly advances catheter 406, and retraction of the cartridge retracts the catheter. As further shown in Figs. 5a-5e and discussed above, in an embodiment, each cartridge 402, 404 may include slider blocks (e.g., 412, 414, 416, 418), each rigidly (and independently) connected or affixed to one of a plurality of catheter steering wires (e.g., 420, 422, 424, 426) in a manner that permits independent tensioning of each steering wire. The cartridge may be provided as a disposable item that is capable of being easily positioned (e.g., snapped) into place in an overall assembly. In an embodiment, as discussed in detail below, the cartridge may include an electrical "handshake" device or component to allow the system to properly identify the cartridge (e.g., by type and/or proper placement/positioning). Sheath cartridge 404 may be designed in a similar manner as the catheter cartridge 402, but will typically be configured to provide for the passage of catheter 406. Assembly 302 may include a plurality (e.g., as many as ten or more) of independent driving mechanisms (e.g. motor driven ball screws 324).

[0045] For some embodiments, the catheter and sheath cartridge can be designed to be substantially similar, and in that context a reference to either may relate to both. For example, as shown in Figs. 5a-5e, the design of the catheter/sheath cartridge may include upper and lower cartridge sections 428, 430, and independent slider blocks 412, 414, 416, 418. The system is not generally limited to specific material selection or formation techniques. However, in an embodiment, the upper and lower cartridge sections 428, 430 may be injection molded using a polycarbonate material. Each slider block 412, 414, 416, 418 may be connected to a separate catheter steering wire 420, 422, 424, 426, and may be formed of a Teflon-like material such as, for example, Delrin AF. When in contact with the cartridge housing portions 428, 430, such Teflon-like slider blocks may maintain a low static and dynamic coefficient of friction and may avoid the need for additional lubrication.

[0046] Referring to Figs. 3a-5e and as discussed above, catheter and sheath cartridges 402, 404 may be configured to secure or lock down onto respective interconnecting catheter and sheath manipulation bases 308, 310. To couple cartridge 402 (and 404) with base 308 (and 310), one or more locking pins (e.g., 432 in Figs. 5a, 5d and 5e) on the cartridge may engage one or more mating recesses 360 in the base (see Fig. 4a). In an embodiment, such recesses 360 may include an interference lock such as a spring detent or other locking means. In an embodiment, such other locking means may include a physical interference that may require affirmative/positive action by the user to release the cartridge. Such action may include or require actuation of a release lever 362. Additionally, as shown in Figs. 5c, 5d and 5e, cartridge 402 (and 404) may include one or more locator pins 434 that are configured to passively fit into mating holes on the base (e.g., 364 in Fig. 4a).

[0047] In an embodiment, a user (e.g. an EP) may first manually position catheter 406 and sheath 410 (with catheter 406 inserted in sheath 410) within the vasculature of a patient. Once the devices are roughly positioned in relation to the heart, the user may then engage or connect (e.g., "snap-in") the catheter cartridge into place on interconnecting/interlocking bases 308, 310 of manipulator assembly 302, for example, by inserting the locking/locating pins 432, 434 of the cartridges into mating holes 360, 364 of respective base 308, 310. When the cartridge is interconnected with the base, each of the plurality of fingers 316, 318, 320 or 322 may fit into recesses formed between the distal edge of slider blocks 412, 414, 416, 418 and a lower portion of the cartridge housing. Such recesses are shown in, for example, Figs.

5d and 5e. With sufficiently rigid coupling between each slider block and a corresponding steering wire, pushing a slider block in a proximal direction may cause an attached steering wire to tension and thus laterally deflect the distal end of the catheter and sheath 406, 410.

[0048] The aforementioned electrical handshake between manipulation bases 308, 310 and catheter and sheath cartridges 402, 404 will be described briefly.

[0049] Robotic catheter system 10 may be useful for a variety of procedures and in connection with a variety of tools and/or catheters. Such tools and/or catheters may include, without limitation, spiral catheters, ablation catheters, mapping catheters, balloon catheters, needle/dilator tools, cutting tools, cauterizing tools, and/or gripping tools. The system may additionally include a means of identifying the nature and/or type of catheter/tool cartridge that is installed for use, and/or position or connection related information. The system may automatically access/obtain additional information about the cartridge, such as, without limitation, its creation date, serial number, sterilization date, prior uses, etc.

[0050] Further, some embodiments of the system may include an ability to "read" or detect the type or nature of the connected cartridge through the use of memory included with the disposable cartridge together with some data/signal transmission means. By way of example, each cartridge may contain a chip (e.g., an EEPROM chip) that can be electrically interfaced by the manipulator head. Such a chip could, for instance, be programmed during the manufacturing process and may electronically store various data, such as the make; model; serial number; creation date; and/or other special features associated with the cartridge or tool. Additionally the chip may contain other worthwhile information, such as an indication of previous use, catheter specific calibration data, and/or any other information that may relate to the safety or performance of the particular device.

[0051] In an embodiment, upon interconnecting the cartridge (e.g. 402, 404) with the manipulator head (e.g. 302), a detection means, such as an optical or magnetic sensor, may initially detect the presence of the cartridge. Once presence is detected, the manipulator may energize a chip and initiate data/signal retrieval. Such retrieved data/signal may then be used by the system to control or alter various features and/or displays based on the type of device and/or information provided. While one embodiment may use a chip (e.g., EEPROM), due to its design flexibility, another embodiment may include a wireless transmission device, such as an RFID, which may be employed to facilitate the data storage/transfer instead of, or in addition to a chip.

[0052] Referring now to Figs. 1-7, and particularly Figs. 6 and 7, obstruction detection system 600 of the invention will be described in detail, and may generally include a hardware system 700 and a software system 800.

[0053] Referring to Fig. 6, hardware system 700 may include a plurality of obstruction detection sensors 702, 704, 706, 708, 710 and 712 (described in detail below) generally operatively interconnected with software system 800 for enabling, disabling or otherwise controlling movement of manipulation bases 308, 310. Obstruction detection system 600 may initiate control, or otherwise disable movement of manipulation bases 308, 310 as the bases generally move towards or away from each other on track 356 based on the particular nature of the operation being performed by a physician during surgery or by a technician, for example, during maintenance, or by a physician or technician during attachment or detachment of cartridges 402, 404. Since manipulator assembly 302 generally includes an enclosure 370 as shown in Fig. 2 partially or fully covering manipulation bases 308, 310, during typical operation, the general working area of manipulation bases 308, 310 remains covered. However, in the event of an obstruction being present in the path of manipulation bases 308, 310 or during routine maintenance of manipulator assembly 302 where a technician or operator may insert an object or finger in the area of manipulation bases 308, 310, enclosure 370 may be removed for access to manipulation bases 308, 310. The combination of hardware system 700 and a software system 800, as discussed herein, may detect the presence of an obstruction in the path of manipulation bases 308, 310 and stop movement of bases 308, 310 when certain criteria have been met.

[0054] In further detail, as shown in Figs. 3a and 6, hardware system 700 may generally include obstruction detection sensors 702, 704, 706, 708, 710 and 712 respectively disposed on or along track 356 and manipulation bases 308, 310. In a particular embodiment of the invention, sensors 702-712 may be ultrasonic sensors, or alternatively, light-emitting sensors for detecting the presence of an obstruction. Sensors 702 and 712 may be disposed at the opposing ends of track 356, and sensors 704, 706, and 708, 710 may be respectively disposed at the corners or other suitable locations on manipulation bases 310, 308. Sensors 702, 704 may monitor the presence of any obstructions along Path 1 between manipulation base 310 and end 714 of track 356. Sensors 706, 708 may monitor the presence of any obstructions along Path 2 between manipulation bases 310 and 308, and sensors 710, 712 may monitor the presence of any obstructions along Path 3 between manipulation base 308 and end 716 of track 356. As discussed below, any positive (e.g. toward end 714) and negative (e.g. toward end 716) translation of manipulation base 308, 310 would be stopped in case of an obstruction along track 356.

[0055] Referring to Fig. 7, software system 800 operates in combination with hardware system 700 to track motion of manipulation bases 308, 310 on track 356, and more specifically, whether the manipulation bases are moving in a positive or negative direction, and their distance from each other. Typically, manipulation bases 308, 310 are designed to move within 2-3 millimeters of each other to prevent collision. Software system 800 may selectively activate one or more of sensors 702-712 upon actuation or movement of manipulation bases 308, 310 in a predetermined direction to detect any obstructions in the path of translation of a specific manipulation base. Alternatively, all sensors 702-712 may be activated so that software system 800 determines a proper course of action based on the location of an obstruction (e.g. along Path 1, Path 2 or Path 3), and other factors such as the direction of movement of the manipulation bases, and the actual function being performed (e.g. surgery or routine maintenance). Based on the specific function being performed, software system 800 may stop movement of the manipulation bases (e.g. by cutting power to high precision drive mechanisms 312, 314), allow movement of the manipulation bases, or reverse movement of the manipulation bases.

[0056] For example, if an obstruction is present along Path 2 and routine maintenance is being performed on manipulator assembly 302, software system 800 may stop movement of manipulation bases 308, 310 if they are moving toward each other, but can allow movement of the manipulation bases if they are moving away from each other. In this manner, if an obstruction (e.g. a hand or finger of a service technician) is present along Path 2, movement of the manipulation bases may only be halted if the bases are moving towards each other (e.g. to prevent contact with an obstruction), but may be otherwise allowed to continue. If the obstructions is present along Path 2, in a routine maintenance mode, manipulation bases 308, 310 may be directed to move away from each other such that a predetermined distance (e.g. 20 mm) remains between the bases for insertion of a technician's fingers or another object along Path 2 for maintenance operations.

[0057] One method of detecting motion of manipulation bases 308, 310 may be to detect the direction of motion of high precision drive mechanisms 312, 314, which operate via the CANOpen protocol standard. Referring to Fig. 7, the algorithm for software system 800 is illustrated and may include a motion command request at location 802 for initiating or continuing motion of manipulation bases 308, 310. At location 804, software system 800 may determine if high precision drive mechanisms 312, 314 are moving, and if not, motion may be initiated at location 806. At location 808, if high precision drive mechanisms 312, 314 are moving at step 804 or motion is initiated at step 806, then system 800 may determine if the position of the sheath manipulation base 310 minus the position of the catheter manipulation base 308 is less than a predetermined obstruction position delta (e.g. a predetermined safe distance between the sheath and catheter drive mechanisms; 20 mm in the example discussed above). Alternatively, at location 808, the system may also determine if any of the obstruction detection sensors 702-712 have been activated. If the determination at location 808 is no, then motion may continue at location 810. If the determination at location 808 is yes, then at location 812, system 800 may set an Obstruction Status flag to Obstructed, and turn LED 718 to red, as discussed in detail below with reference to Fig. 2. Thereafter at location 814, high precision drive mechanisms 312, 314 may be stopped by turning the power off or by other means. The off status of high precision drive mechanisms 312, 314 may then be fed to CANOpen protocol 816 for further evaluation. Once the Obstruction Status flag is cleared (e.g. no obstruction), LED 718 may be turned to green, as also discussed below.

[0058] The LED will be turned off as soon as the obstruction status flag is cleared.

[0059] In a particular embodiment, software system 800 may monitor high precision drive mechanisms 312, 314, for example, every 50 ms to determine the direction of movement and location of manipulation bases 308, 310 (e.g. location along track 356, and relative location). Software system 800 may thus monitor manipulation bases 308, 310, which operate via the CANOpen protocol standard, and further monitor the presence of any obstruction along Paths 1-3 as detected by sensors 702-712. Upon the detection of an obstruction, software system 800 may issue instructions through the CANOpen protocol to stop high precision drive mechanisms 312, 314, and thus manipulation bases 308, 310.

[0060] Thus, referring again to Fig. 7, at location 816, CANOpen protocol may receive input from locations 810, 820 and 822, which are respectively, monitors for sheath high precision drive mechanism 314, catheter high precision drive mechanism 312, and obstruction sensors 702-712. The data from the respective locations 810, 820 and 822 may be sampled at a predetermined rate (e.g. 50 ms) and fed into location 804 to determine movement of the catheter/sheath high precision drive mechanisms, and further evaluation as discussed above.

[0061] The combination of hardware system 700 including obstruction detection sensors 702-712, and software system 800 which monitors sensors 702-712 and high precision drive mechanisms 312, 314 operable via the CANOpen protocol standard, provides for an obstruction detection system 600 that monitors for obstructions along Paths 1-3 and stops motion of manipulation bases 308, 310 depending on factors such as the position of an obstruction, the direction of travel of the manipulation bases, and the type of operation being performed (e.g. surgery, routine maintenance, or cartridge replacement). Yet further, depending on the extent and location of an obstruction, system 600 may cut off power to all high precision drive mechanisms (e.g. 312, 314, 342, 344, 346 and 348; see Figs. 3a and 4b), or just selective drive mechanisms depending on whether the obstruction is detected during surgery or maintenance. During surgery, this selective disablement of certain high precision drive mechanisms would allow critical functions to be performed, without entire system shut-down.

[0062] Referring to Fig. 2, a LED 718 may be provided for conveying the operational status of robotic catheter system 10 to a user. In a particular embodiment, LED 718 may include, for example, three light color indicators such as red, yellow, green for respectively indicating the requirement for system shutdown, a problem and the requirement for system maintenance, or proper system operation. Alternatively, LED 718 may include codes via, for example, blinks to indicate the type of problem. An emergency on/off switch 720 may also be provided to manually shut robotic catheter system 10 off in the event of an emergency, and as a redundant measure for shutting down system 10 and motion of manipulation bases 308, 310.

[0063] With the addition of obstruction detection system 600 to robotic catheter system 10, set-point calibration can be fully automated with the presence of obstruction detection sensors 702-712. Set-point calibration assures that when catheter and sheath cartridges 402, 404 are in place, there is a minimum amount of tension on steering wires 420, 422, 424 and 426 to enable control of the catheter/sheath. For example, in order to automate movement of catheter and sheath 406, 410, and set-point calibration during system initialization, system 600 may prevent movement of manipulation bases 308, 310 if an obstruction is detected along Paths 1-3. Specifically, once catheter and sheath cartridges 402, 404 are snapped onto manipulation bases 308, 310, if an obstruction is detected along Paths 1-3 by obstruction detection sensors 702-712, set-point calibration would not initiate until the user clears the obstruction. Such functionality would enhance the EP experience by providing additional safety for the robotic catheter system, and would also provide safety to a patient so that the desired movement of the sheath and catheter can be achieved without any obstruction.

Additionally, obstruction detection system 600 may be include other visible or audible signals, and/or be integrated with haptic feedback system 900 so that when an obstruction is detected, haptic feedback is provided to a user via input control system 100 to stop further motion of the manipulation bases 308, 310, as well as catheter and sheath cartridges 402, 404, as needed.

[0064] The invention thus provides an obstruction detection system 600 for detection of obstructions that may hinder or otherwise stop movement of manipulation bases 308, 310, and related components. As discussed above, hardware system 700 and software system 800 of obstruction detection system 600 may operate in a cohesive manner to control movement of the manipulation bases in a predetermined manner based on the type and location of an obstruction, and other factors involving direction of movement of the manipulation bases.

[0065] Although several embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention. All directional references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not as limiting. Changes in detail or structure may be made without departing from the invention as defined in the appended claims.

CLAIMS

What is claimed is:

1. An obstruction detection system for a robotic catheter system including a robotic catheter manipulator assembly including at least one catheter manipulation base and at least one sheath manipulation base, each manipulation base being generally linearly movable on at least one track relative to the robotic catheter manipulator assembly, the obstruction detection system comprising:

at least one obstruction detection sensor disposed on the track or on at least one of the manipulation bases to detect an obstruction along a path of motion of at least one of the manipulation bases.

2. An obstruction detection system according to claim 1, wherein the obstruction detection sensor is an ultrasonic sensor or a light-emitting sensor.

3. An obstruction detection system according to claim 1, further comprising obstruction detection sensors located at both ends of the track.

4. An obstruction detection system according to claim 1, further comprising obstruction detection sensors located at both longitudinal ends of the catheter and sheath manipulation bases.

5. An obstruction detection system according to claim 4, wherein the obstruction detection sensors enable maintenance of a predetermined distance between the catheter and sheath manipulation bases.

6. An obstruction detection system according to claim 1, further comprising a software system for monitoring at least one of movement of the catheter and sheath manipulation bases, and a sensor status of at least one of the obstruction detection sensors.

7. An obstruction detection system according to claim 6, wherein the software system includes code for:

determining if a relative distance between the catheter and sheath manipulation bases is less than a predetermined distance,

if the relative distance is less than the predetermined distance, then indicating an obstruction status of the catheter and sheath manipulation bases as obstructed, and stopping motion of the catheter and sheath manipulation bases,

if the relative distance is greater than or equal to the predetermined distance, then indicating the obstruction status of the catheter and sheath manipulation bases as unobstructed, and allowing motion of the catheter and sheath manipulation bases.

8. An obstruction detection system according to claim 7, further comprising at least one of a LED, a visual signal, an audible signal, and haptic feedback to a user input device, for indicating the obstruction status of the catheter and sheath manipulation bases.

9. An obstruction detection system according to claim 6, wherein the software system includes code for:

determining a relative distance between the catheter and sheath manipulation bases by determining an amount of rotation of motors that drive the catheter and sheath manipulation bases.

10. An obstruction detection system according to claim 6, wherein the software system includes code for:

stopping motion of the catheter and sheath manipulation bases if the sensor status of at least one of the obstruction detection sensors is obstructed; and

allowing motion of the catheter and sheath manipulation bases if the sensor status of all obstruction detection sensors is unobstructed.

11. An obstruction detection system according to claim 6, wherein the software system includes code for:

determining a direction of travel of the catheter and sheath manipulation bases; and

allowing motion of the catheter and sheath manipulation bases if the sensor status of one of the obstruction detection sensors is obstructed, only if the direction of travel is away from the obstruction.

12. An obstruction detection system according to claim 6, wherein the software system includes code for:

determining a direction of travel of the catheter and sheath manipulation bases by determining a direction of rotation of motors that drive at least one of the catheter and sheath manipulation bases.

13. An obstruction detection system according to claim 10, further comprising at least one of a LED, a visual signal, an audible signal, and haptic feedback to a user input device, for indicating the sensor status of the obstruction detection sensor.

14. An obstruction detection system according to claim 6, wherein the software system monitors the manipulation bases and the obstruction detection sensors by means of a CANOpen protocol standard.

15. An obstruction detection system for a robotic catheter system including a robotic catheter manipulator assembly including at least one catheter manipulation base and at least one sheath manipulation base, each manipulation base being generally linearly movable on at least one track relative to the robotic catheter manipulator assembly, the obstruction detection system comprising:

detection means disposed on the track or on at least one of the manipulation bases to detect an obstruction along a path of motion of at least one of the manipulation bases; and

monitoring means for monitoring at least one of movement of the catheter and sheath manipulation bases, and a detection status of the detection means.

16. An obstruction detection system according to claim 15, wherein the detection means is an ultrasonic sensor or a light-emitting sensor.

17. An obstruction detection system according to claim 15, wherein the detection means includes obstruction detection sensors located at both ends of the track.

18. An obstruction detection system according to claim 15, wherein the detection means includes obstruction detection sensors located at both longitudinal ends of the catheter and sheath manipulation bases.

19. An obstruction detection system according to claim 18, wherein the obstruction detection sensors enable maintenance of a predetermined distance between the catheter and sheath manipulation bases.

20. An obstruction detection system according to claim 15, wherein the monitoring means is a software system including code for:

determining if a relative distance between the catheter and sheath manipulation bases is less than a predetermined distance,

if the relative distance is less than the predetermined distance, then indicating an obstruction status of the catheter and sheath manipulation bases as obstructed, and stopping motion of the catheter and sheath manipulation bases,

if the relative distance is greater than or equal to the predetermined distance, then indicating the obstruction status of the catheter and sheath manipulation bases as unobstructed, and allowing motion of the catheter and sheath manipulation bases.

21. An obstruction detection system according to claim 20, further comprising means for indicating the obstruction status of the catheter and sheath manipulation bases.

22. An obstruction detection system according to claim 20, wherein the means for indicating is at least one of a LED, a visual signal, an audible signal, and haptic feedback to a user input device.

23. An obstruction detection system according to claim 15, wherein the monitoring means is a software system including code for:

determining a relative distance between the catheter and sheath manipulation bases by determining an amount of rotation of motors that drive the catheter and sheath manipulation bases.

24. An obstruction detection system according to claim 15, wherein the monitoring means is a software system including code for:

stopping motion of the catheter and sheath manipulation bases if the detection status of at least one of the obstruction detection sensors is obstructed; and allowing motion of the catheter and sheath manipulation bases if the detection status of all obstruction detection sensors is unobstructed.

25. An obstruction detection system according to claim 15, wherein the monitoring means is a software system including code for:

determining a direction of travel of the catheter and sheath manipulation bases; and

allowing motion of the catheter and sheath manipulation bases if the detection status of one of the obstruction detection sensors is obstructed, only if the direction of travel is away from the obstruction.

26. An obstruction detection system according to claim 15, wherein the monitoring means is a software system including code for:

determining a direction of travel of the catheter and sheath manipulation bases by determining a direction of rotation of motors that drive at least one of the catheter and sheath manipulation bases.

27. An obstruction detection system according to claim 24, further comprising means for indicating the detection status of the obstruction detection sensor.

28. An obstruction detection system according to claim 27, wherein the means for indicating is at least one of a LED, a visual signal, an audible signal, and haptic feedback to a user input device.

29. An obstruction detection system according to claim 15, wherein the monitoring means monitors the manipulation bases and the detection means by means of a CANOpen protocol standard.

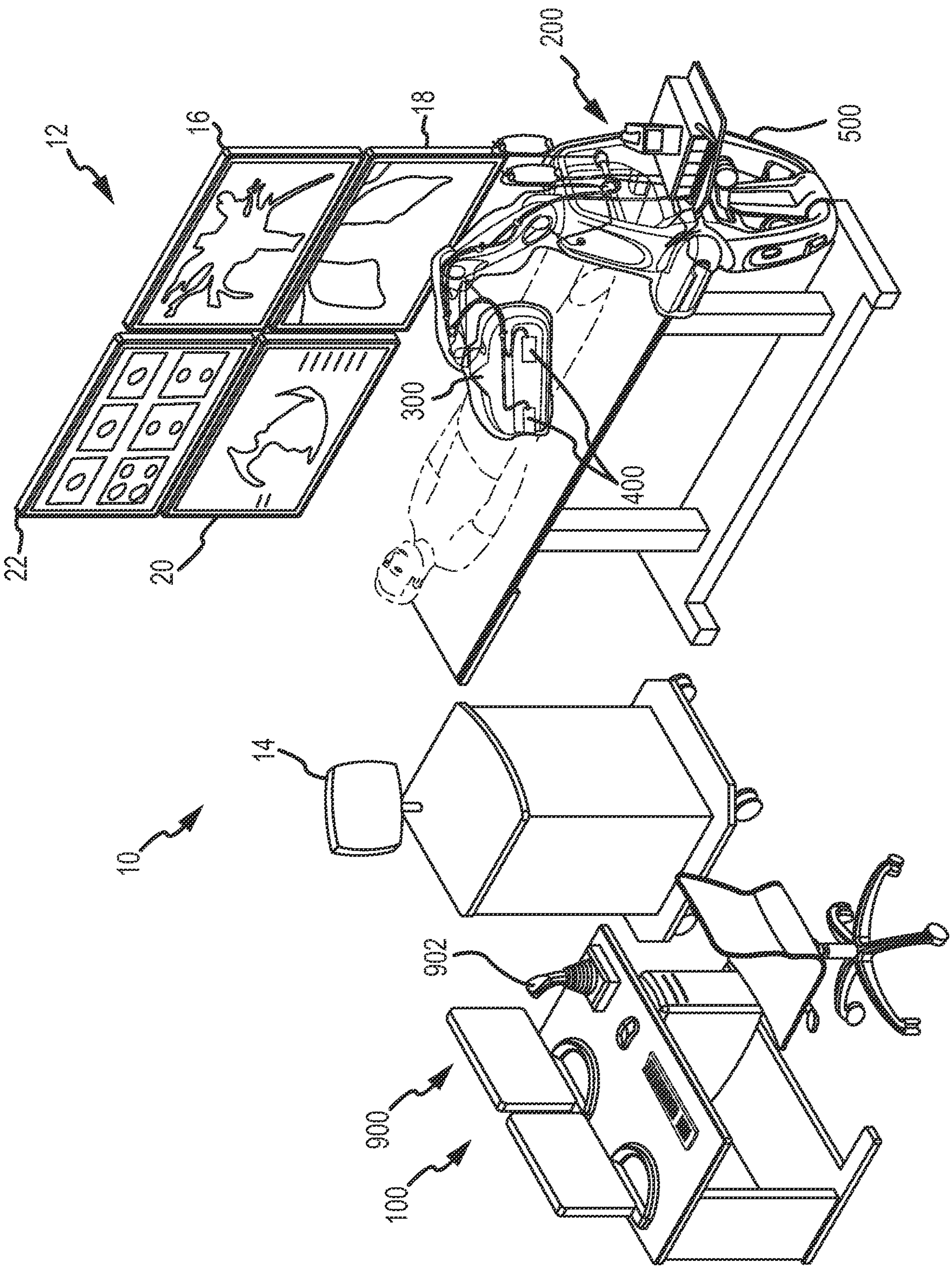

FIG.1

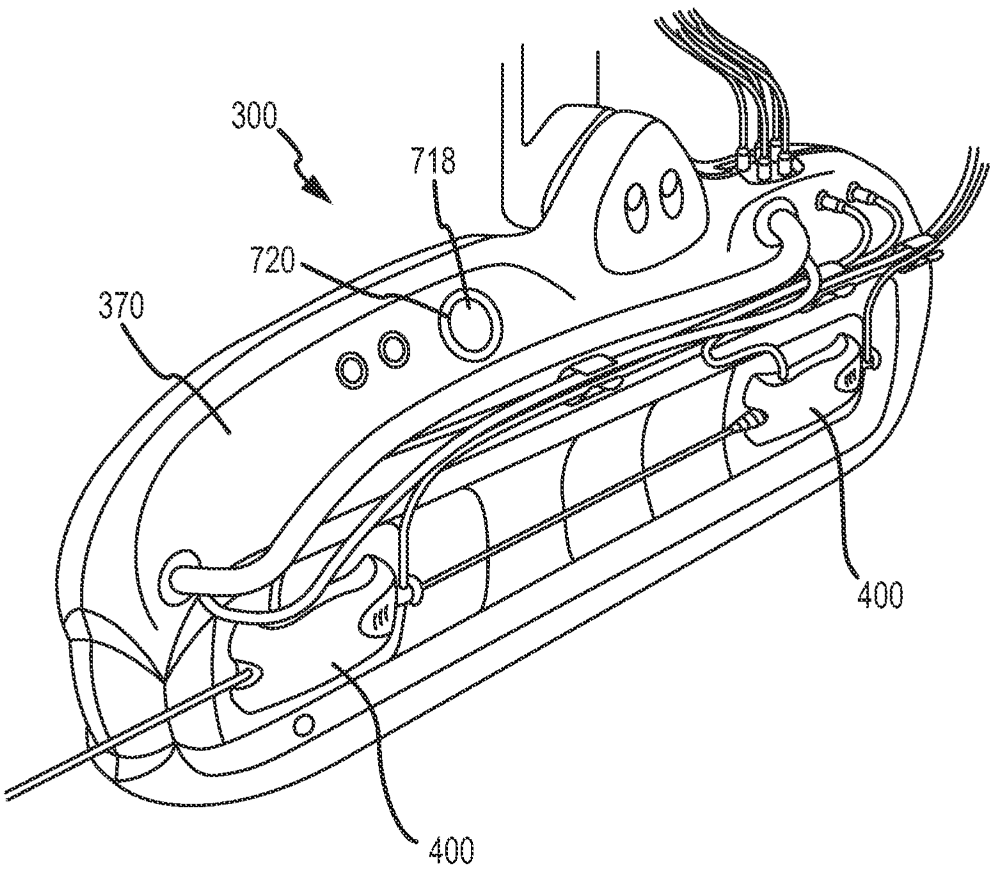

FIG. 2

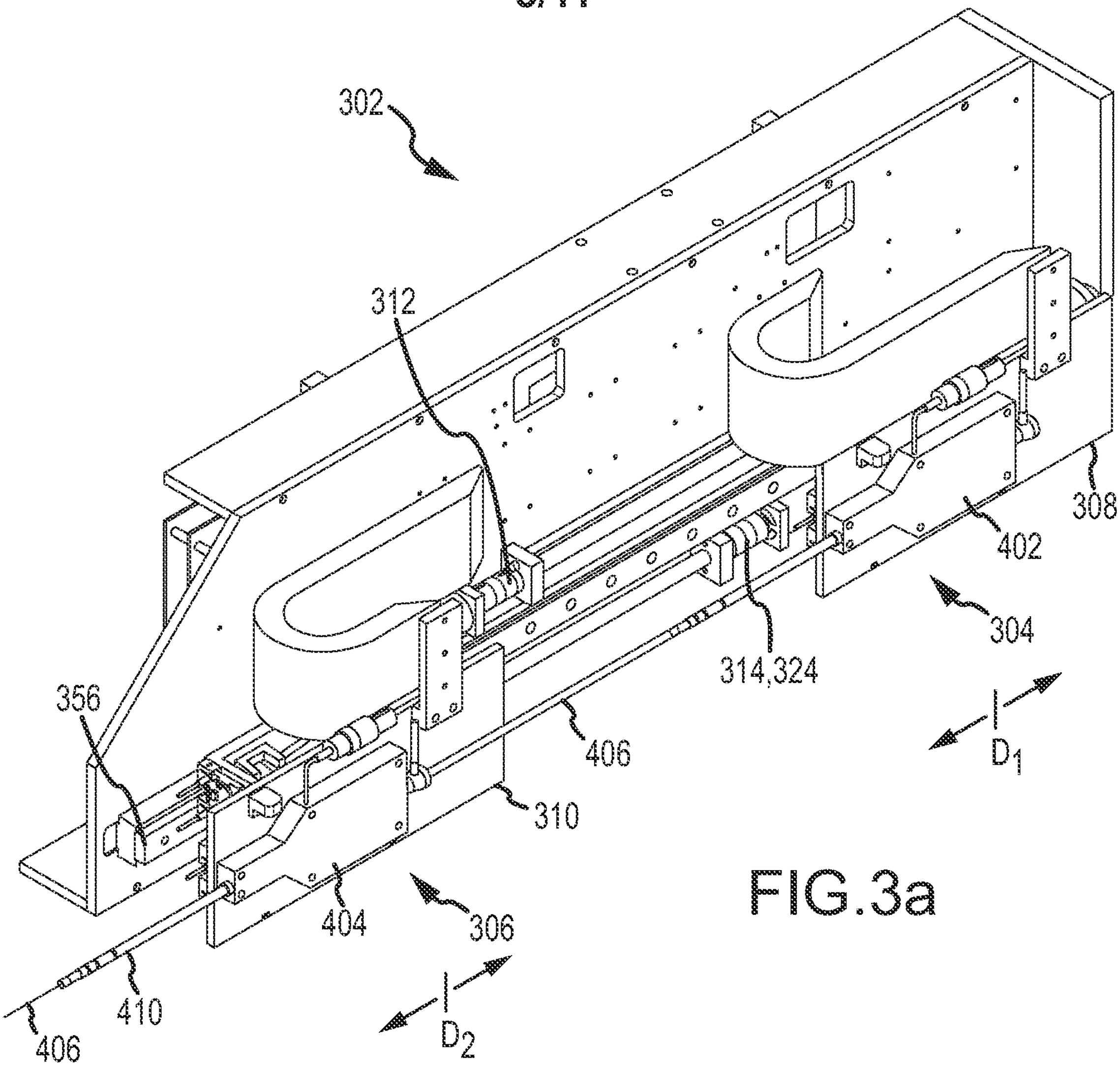
302
312
356
314,324
308
402
304
406
310
404
306
410
406
D_1
D_2

FIG.3a

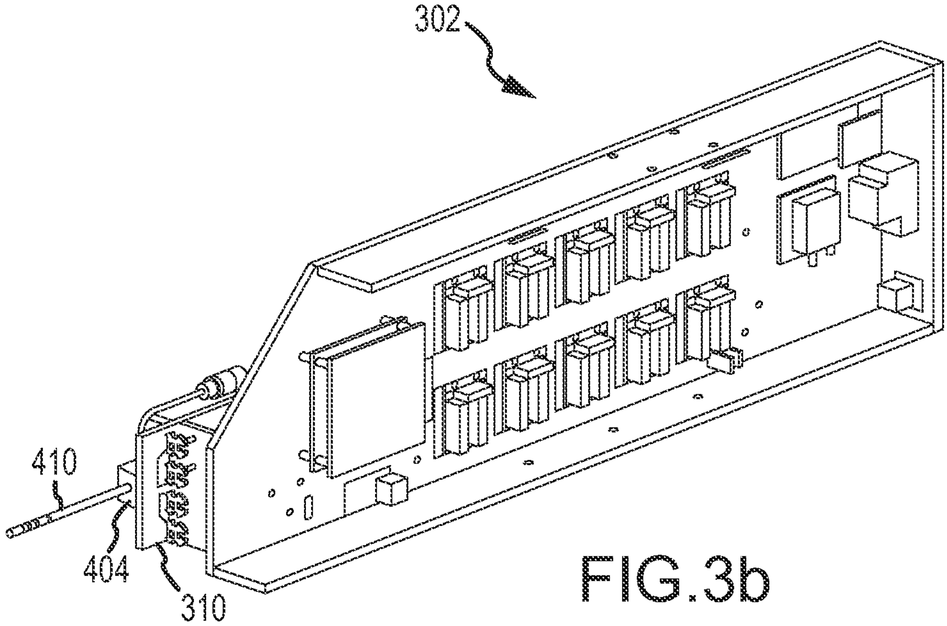
302
410
404
310

FIG.3b

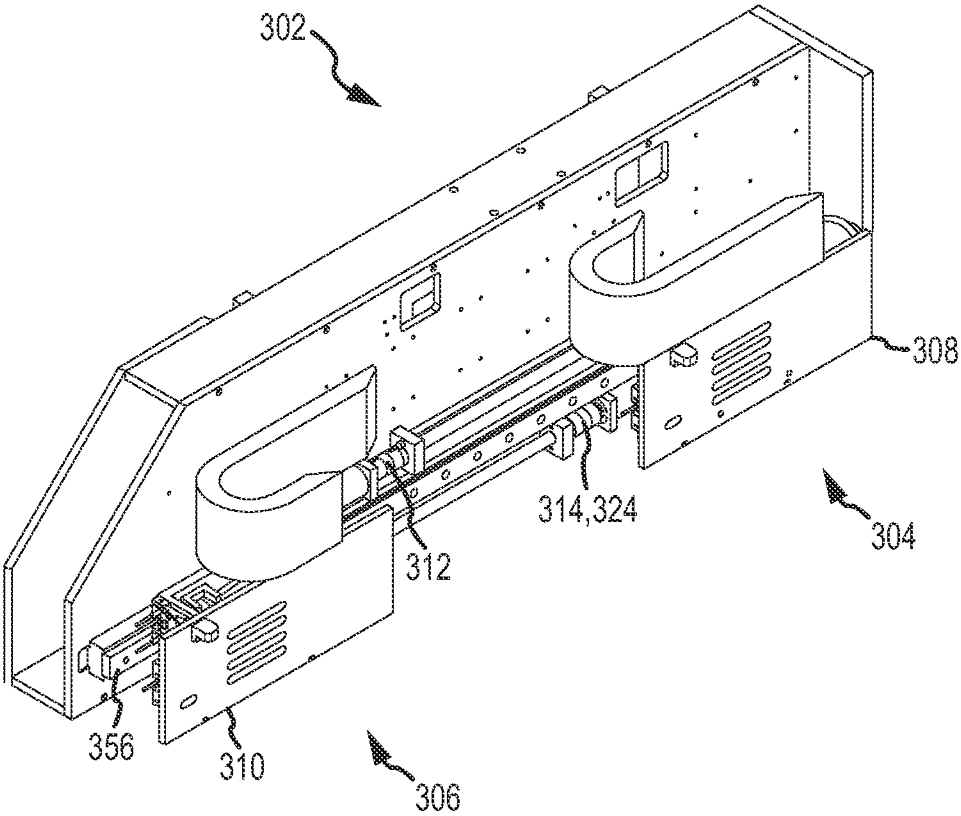

FIG.3c

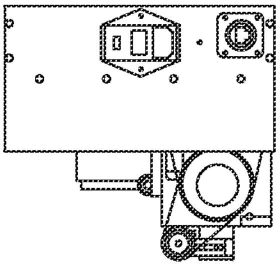

FIG.3e

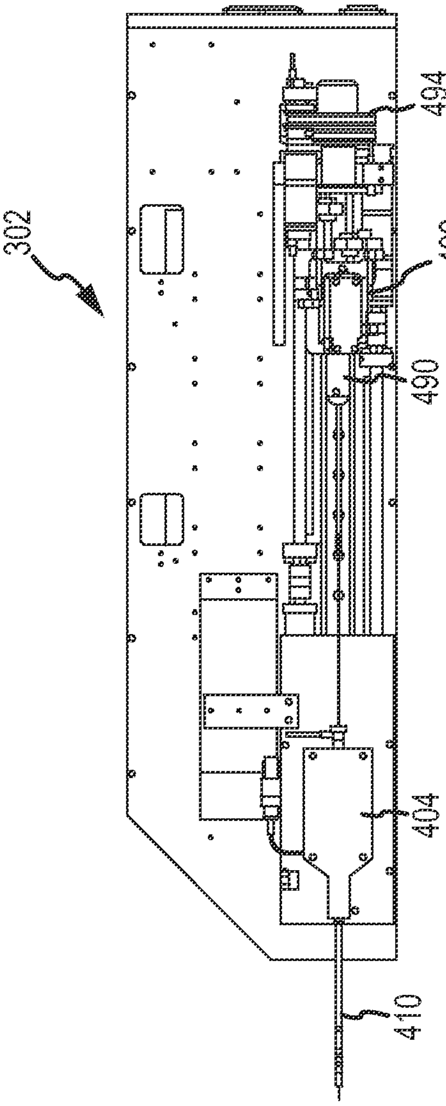

FIG.3f

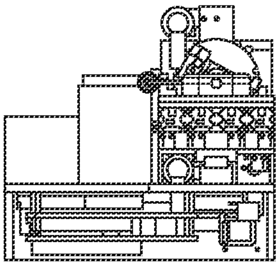

FIG.3d

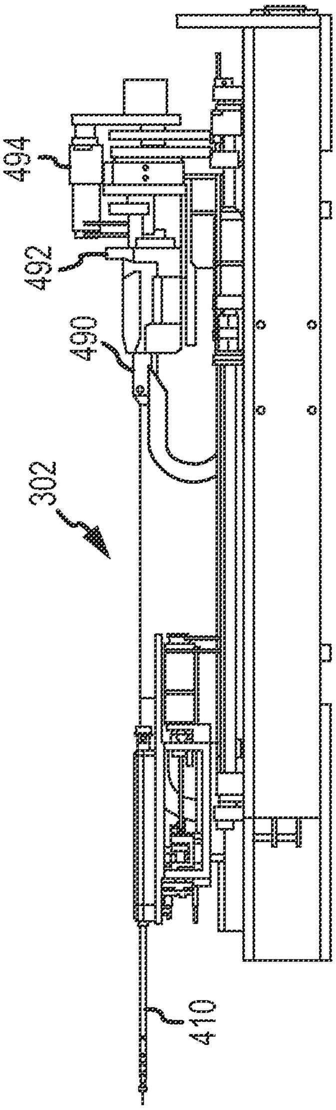

FIG.3g

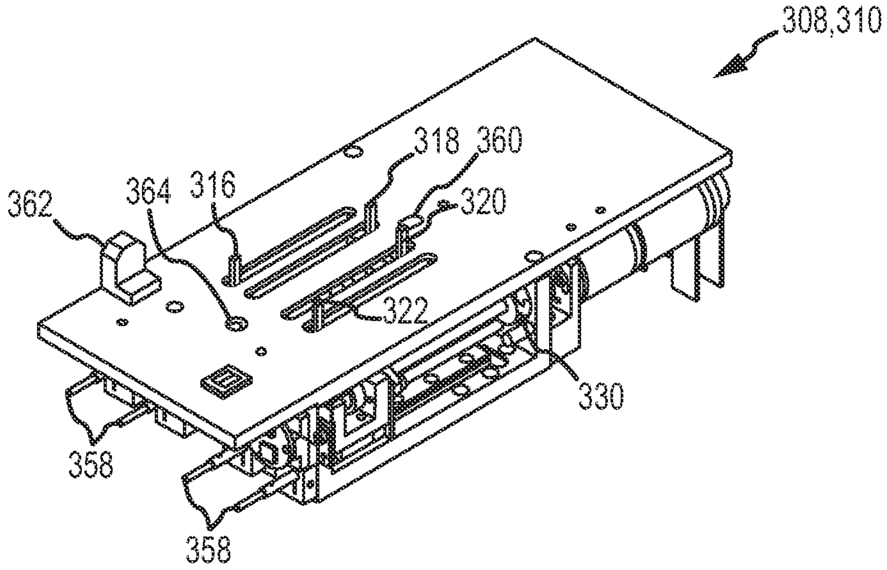
308,310
318
360
316
364
320
362
322
330
358
358

FIG.4a

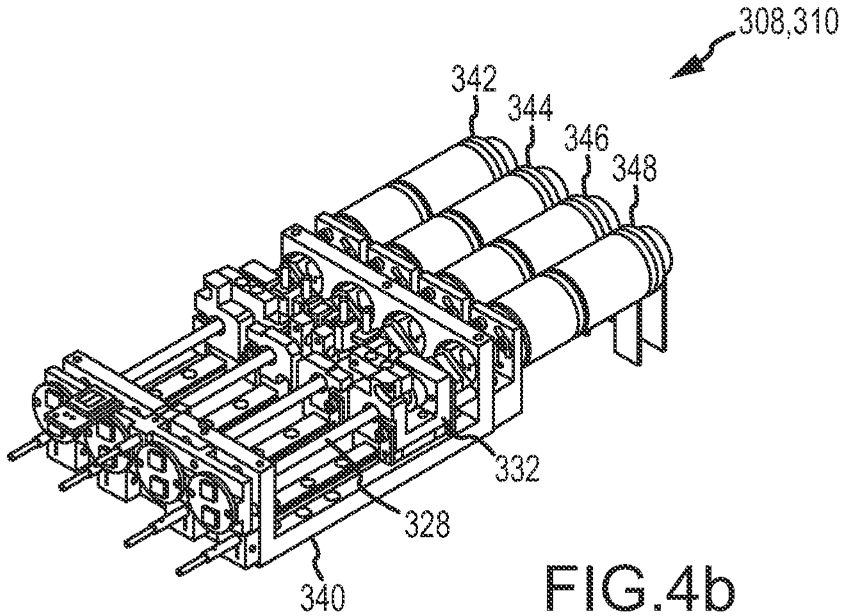
308,310
342
344
346
348
332
328
340

FIG.4b

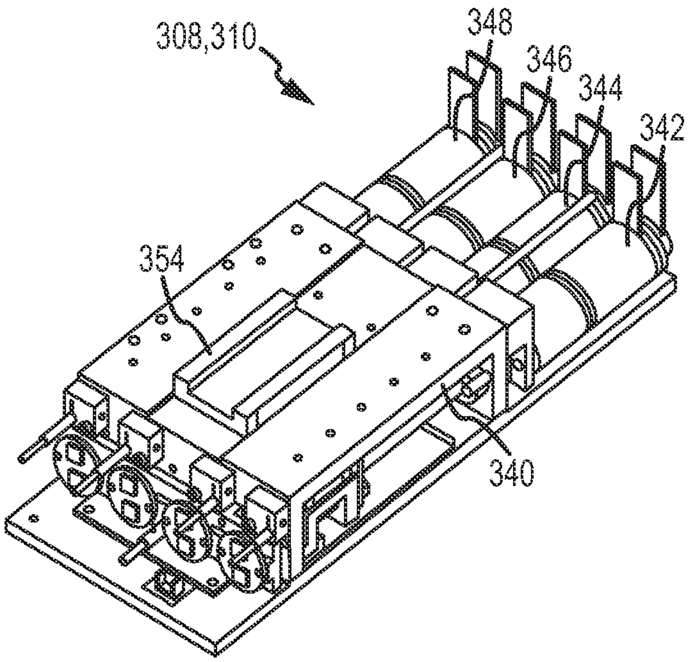

FIG.4c

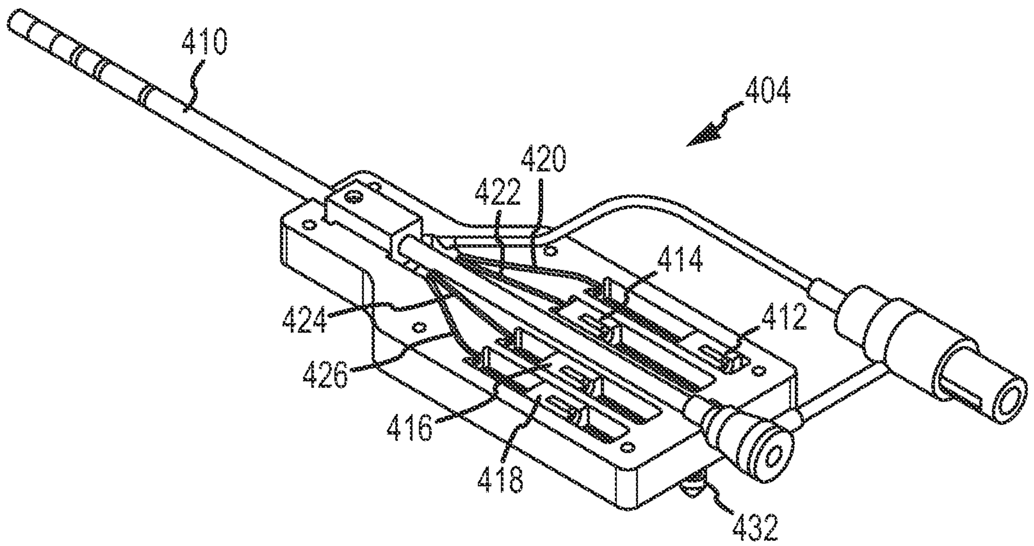

FIG.5a

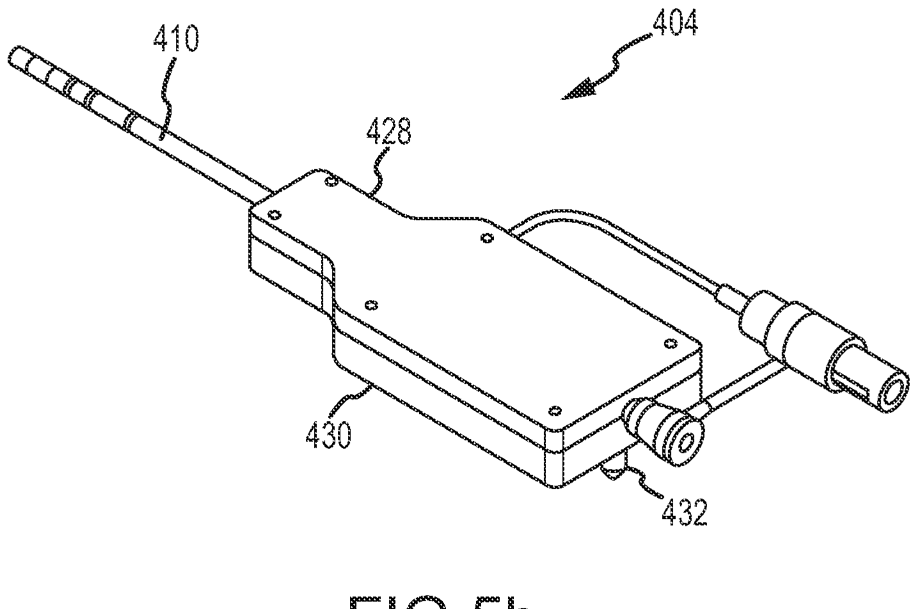

FIG.5b

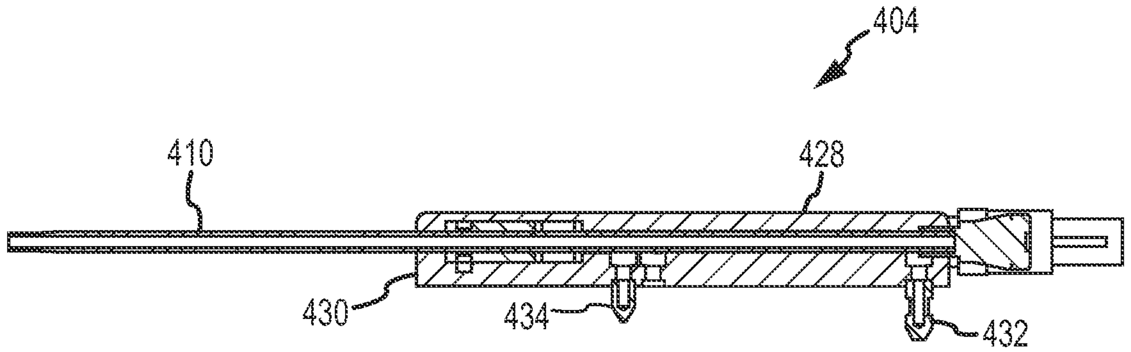

FIG.5c

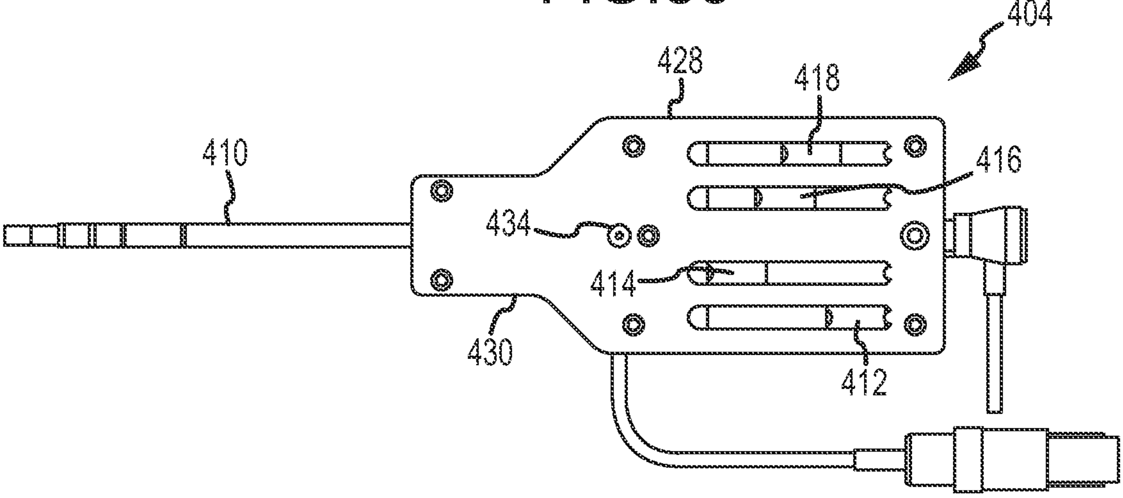

FIG.5d

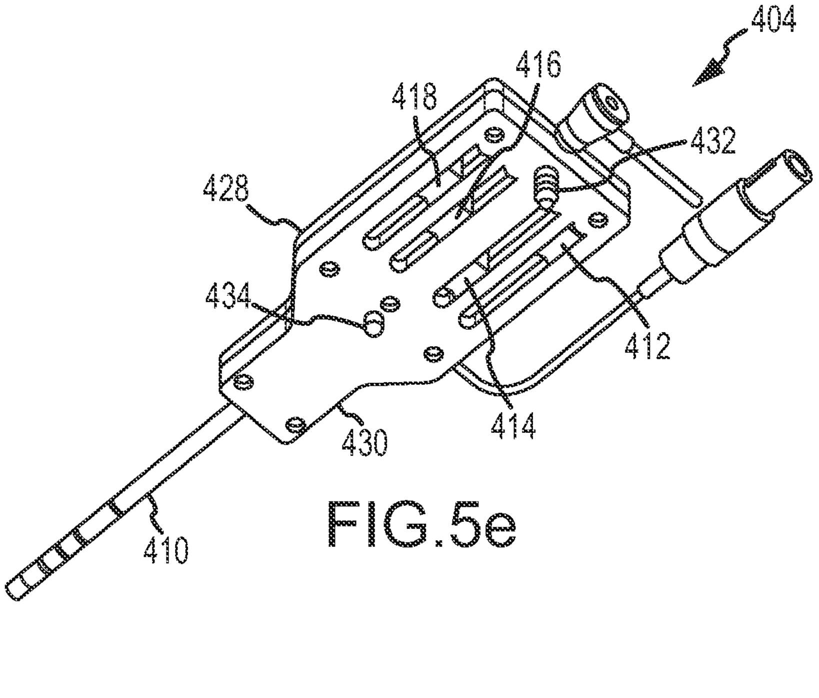

FIG.5e

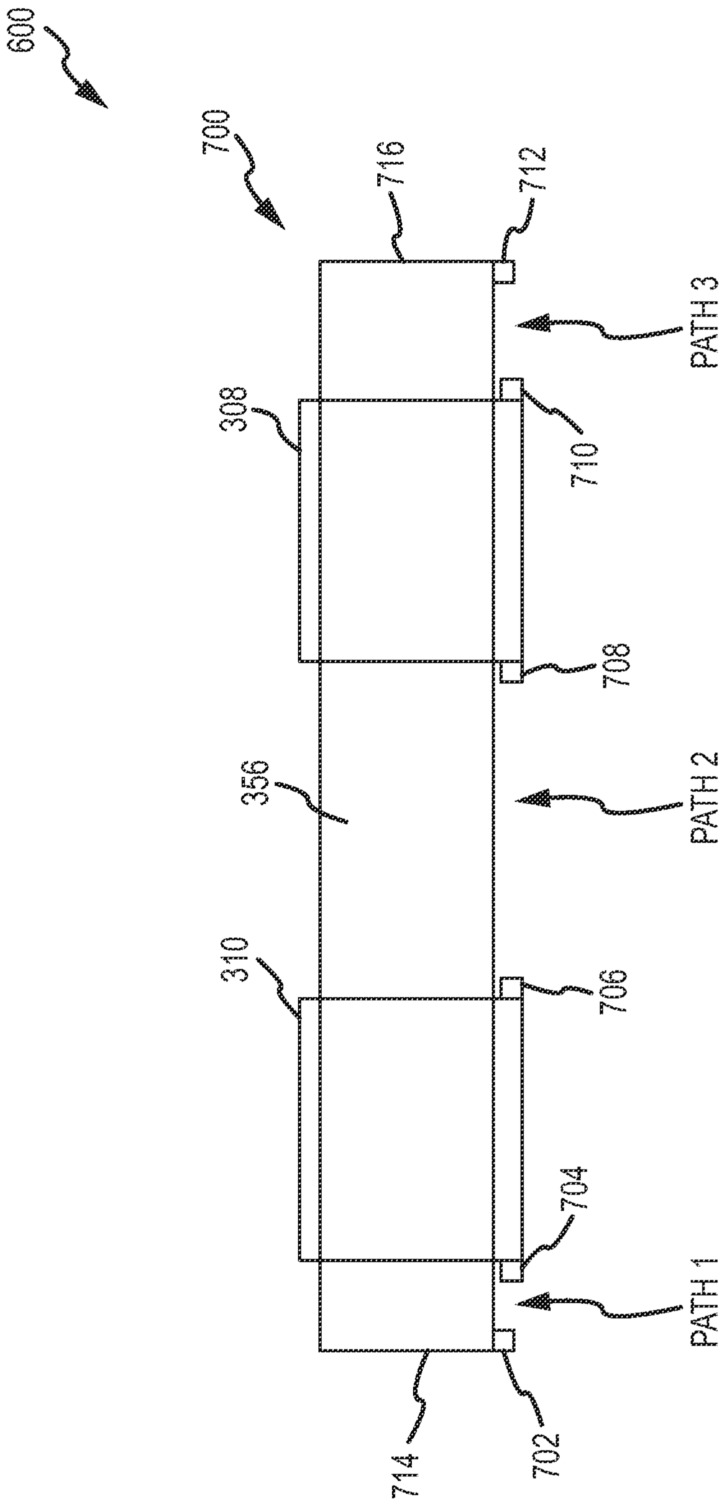
600
700
716
712
PATH 3
308
710
708
356
PATH 2
310
706
704
PATH 1
714
702

FIG.6

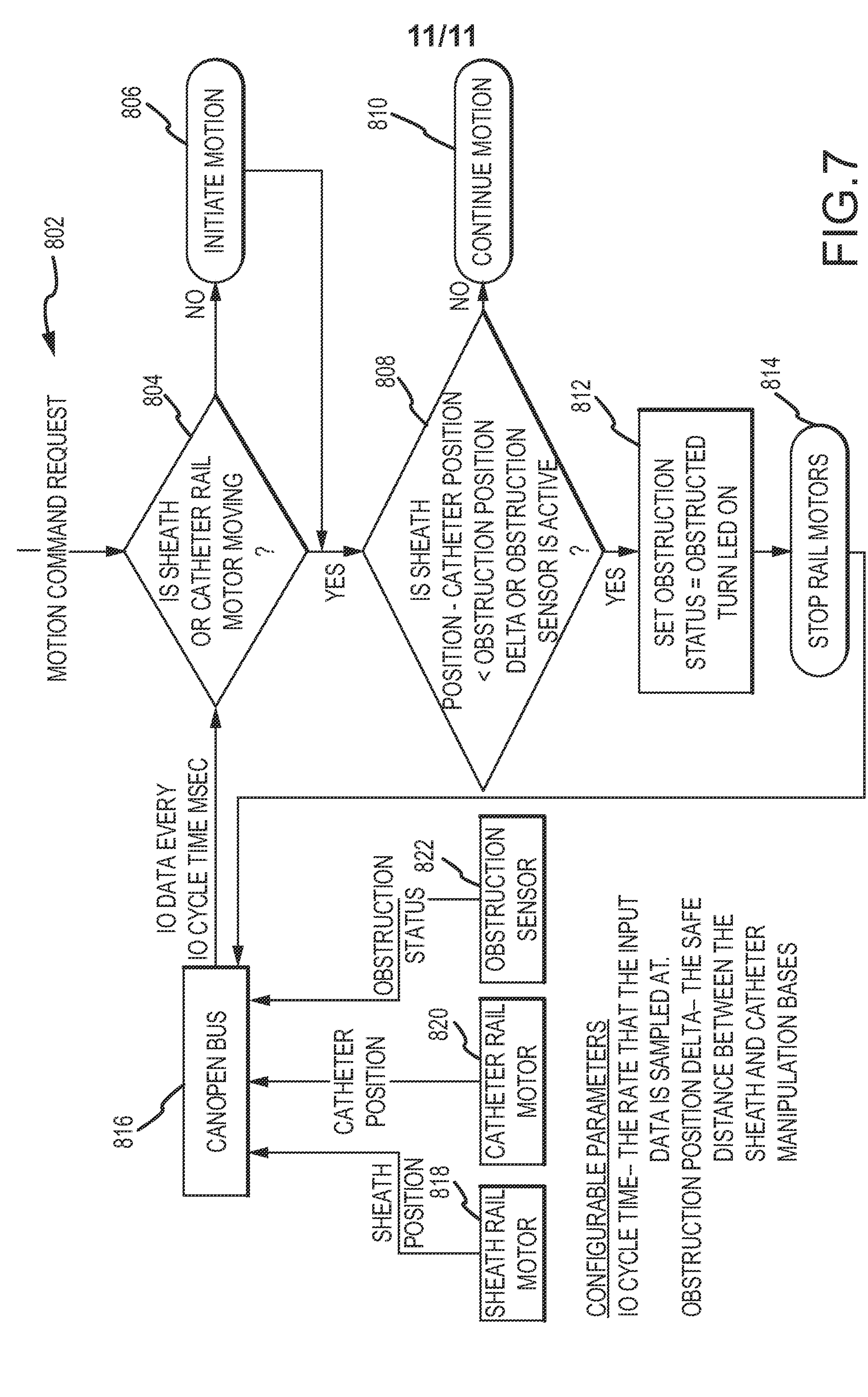
802
MOTION COMMAND REQUEST
804
IS SHEATH OR CATHETER RAIL MOTOR MOVING ?
NO
806
INITIATE MOTION
YES
808
IS SHEATH POSITION - CATHETER POSITION < OBSTRUCTION POSITION DELTA OR OBSTRUCTION SENSOR IS ACTIVE ?
NO
810
CONTINUE MOTION
YES
812
SET OBSTRUCTION STATUS = OBSTRUCTED TURN LED ON
814
STOP RAIL MOTORS
IO DATA EVERY IO CYCLE TIME MSEC
816
CANOPEN BUS
SHEATH POSITION
CATHETER POSITION
OBSTRUCTION STATUS
818
SHEATH RAIL MOTOR
820
CATHETER RAIL MOTOR
822
OBSTRUCTION SENSOR
CONFIGURABLE PARAMETERS
IO CYCLE TIME-- THE RATE THAT THE INPUT DATA IS SAMPLED AT.
OBSTRUCTION POSITION DELTA-- THE SAFE DISTANCE BETWEEN THE SHEATH AND CATHETER MANIPULATION BASES

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/058121

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A 61B 19/00; A61B 18/18 (2009.01)
USPC - 606/130, 41
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)
IPC(8) - A 61B 19/00; A61B 18/18 (2009.01)
USPC - 600/481, 549, 587

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)
PubWEST(USPT,PGPB,EPAB,JPAB); Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2008/101228 A2 (STAHLER et al) 21 August 2008 (21.08.2008) entire document	1-29
Y	US 2007/0185486 A1 (HAUCK et al) 09 August 2007 (09.08.2007) entire document	1-29
Y	US 2007/0233044 A1 (WALLACE et al) 04 October 2007 (04.10.2007) entire document	1-29
Y	US 2007/0142726 A1 (CARNEY et al) 21 June 2007 (21.06.2007) entire document	2, 7-13, 16, 20-28

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"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
10 November 2009

Date of mailing of the international search report
19 NOV 2009

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