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(54) **CONNECTOR INTERFACE FOR ECG-BASED CATHETER POSITIONING SYSTEM**

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(52) **U.S. Cl.**

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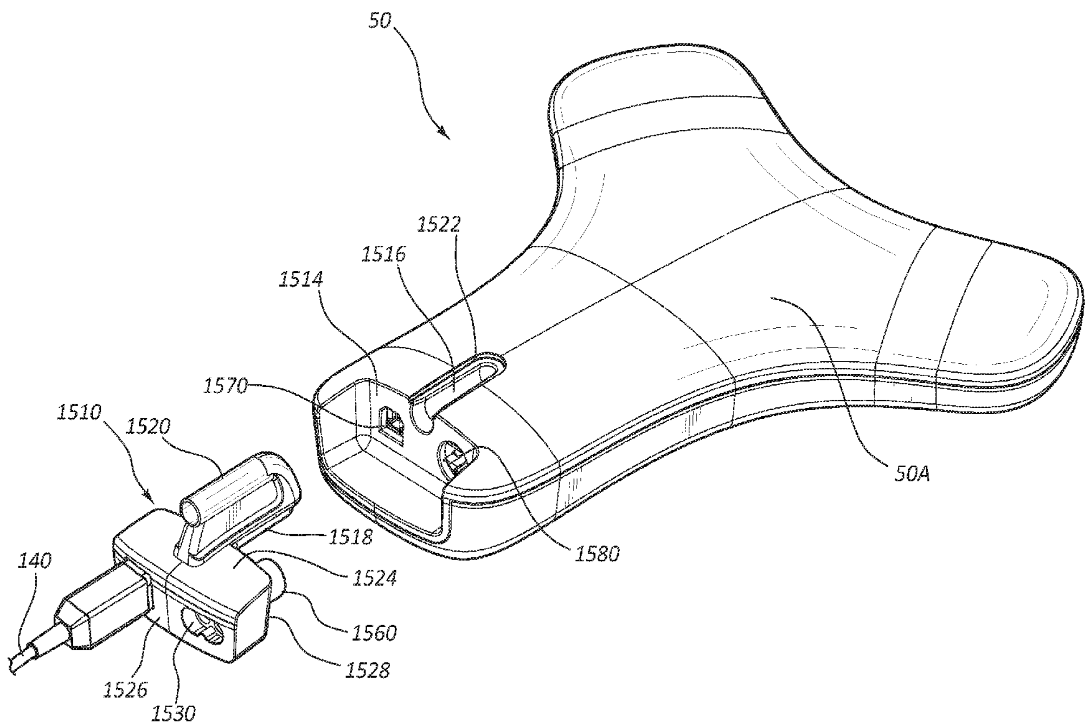
(57) **ABSTRACT**

A connector interface configured to enable component interconnection with a location sensor of a catheter placement system is disclosed. The catheter placement system is configured to assist a clinician in positioning a catheter in a desired location within a body of a patient. In one embodiment, the location sensor assembly comprises a location sensor body for temporary placement on a portion of the patient body, and a connector interface. The connector interface is configured to removably attach to the location sensor and provide a plurality of electrically conductive pathways between the location sensor and additional components of the catheter placement system to enable the additional components to operably connect with the location sensor. The connector interface further includes a first connector configured to operably connect with a second connector of one of the additional components of the catheter placement system through a drape interposed between the first and second connectors.



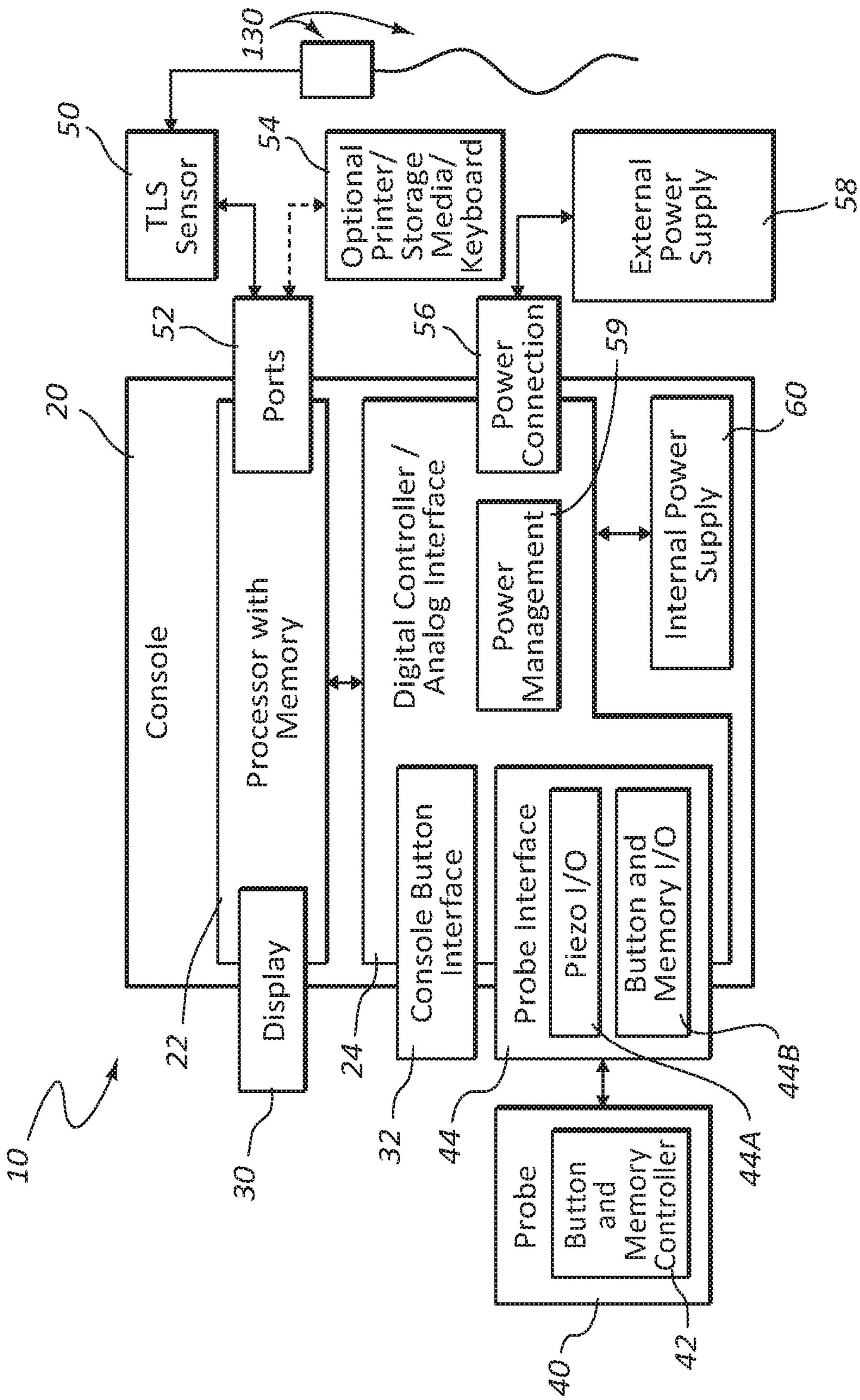

10
20
Console
22
Processor with Memory
Ports
52
Display
30
24
Digital Controller / Analog Interface
Console Button Interface
32
Probe Interface
44
Piezo I/O
44A
Button and Memory I/O
44B
Power Connection
56
Power Management
59
Internal Power Supply
60
TLS Sensor
50
Optional Printer/ Storage Media/ Keyboard
54
External Power Supply
58
130
Probe
40
Button and Memory Controller
42

FIG. 1

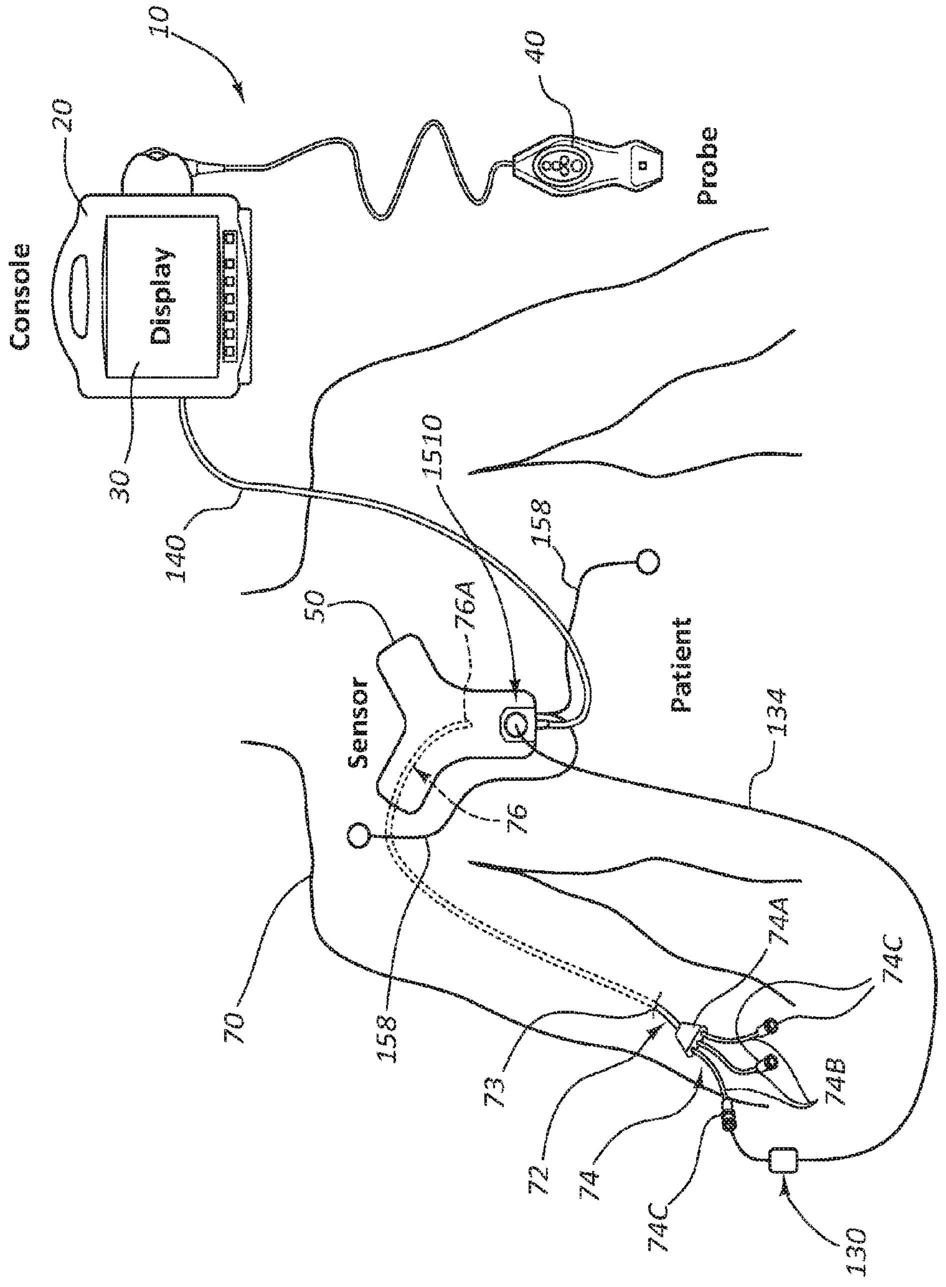

10
20
Console
Display
30
40
Probe
140
1510
158
50
76A
Sensor
Patient
134
76
158
70
74A
74C
73
72
74
74B
74C
130

FIG. 2

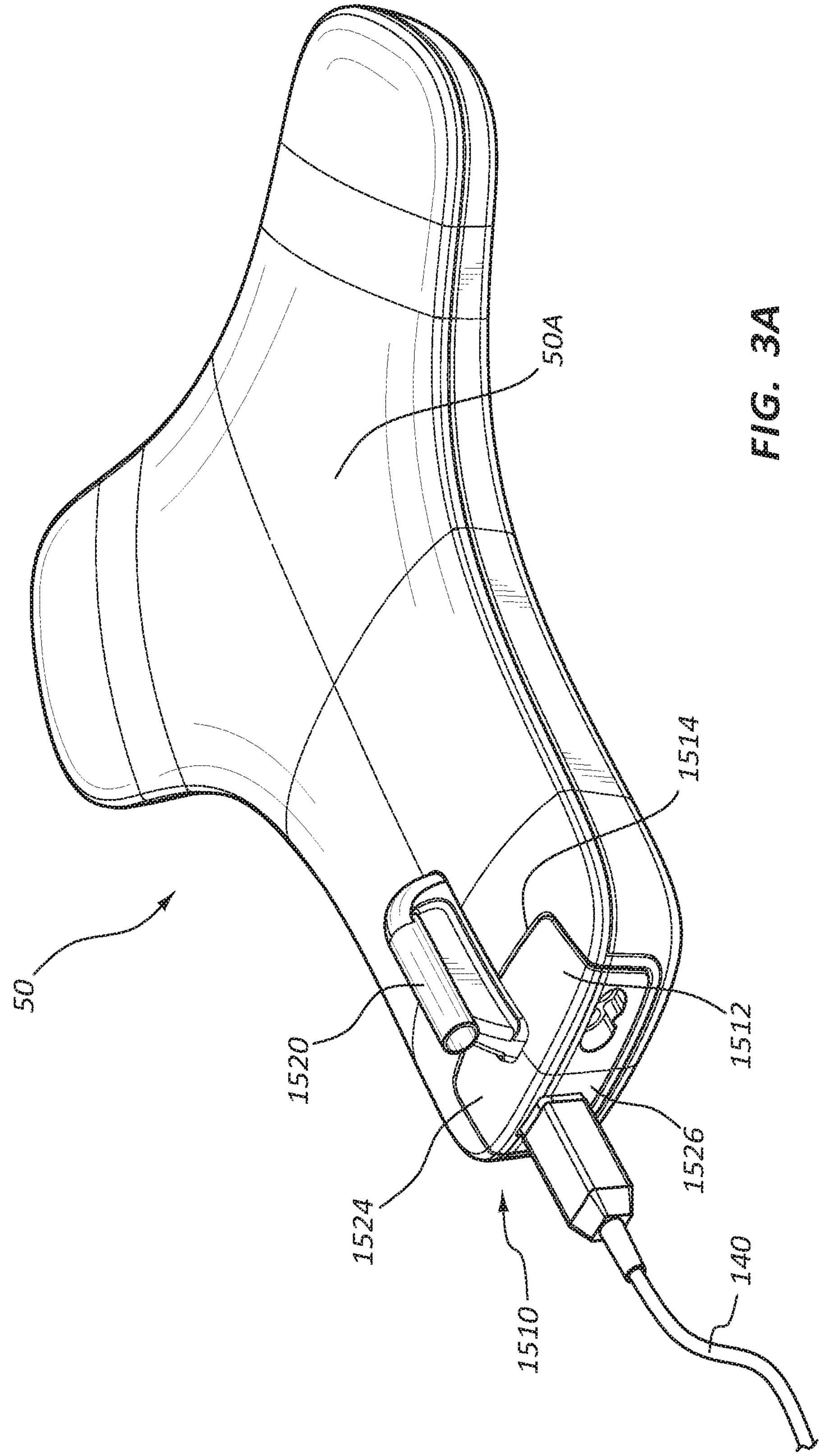


FIG. 3A

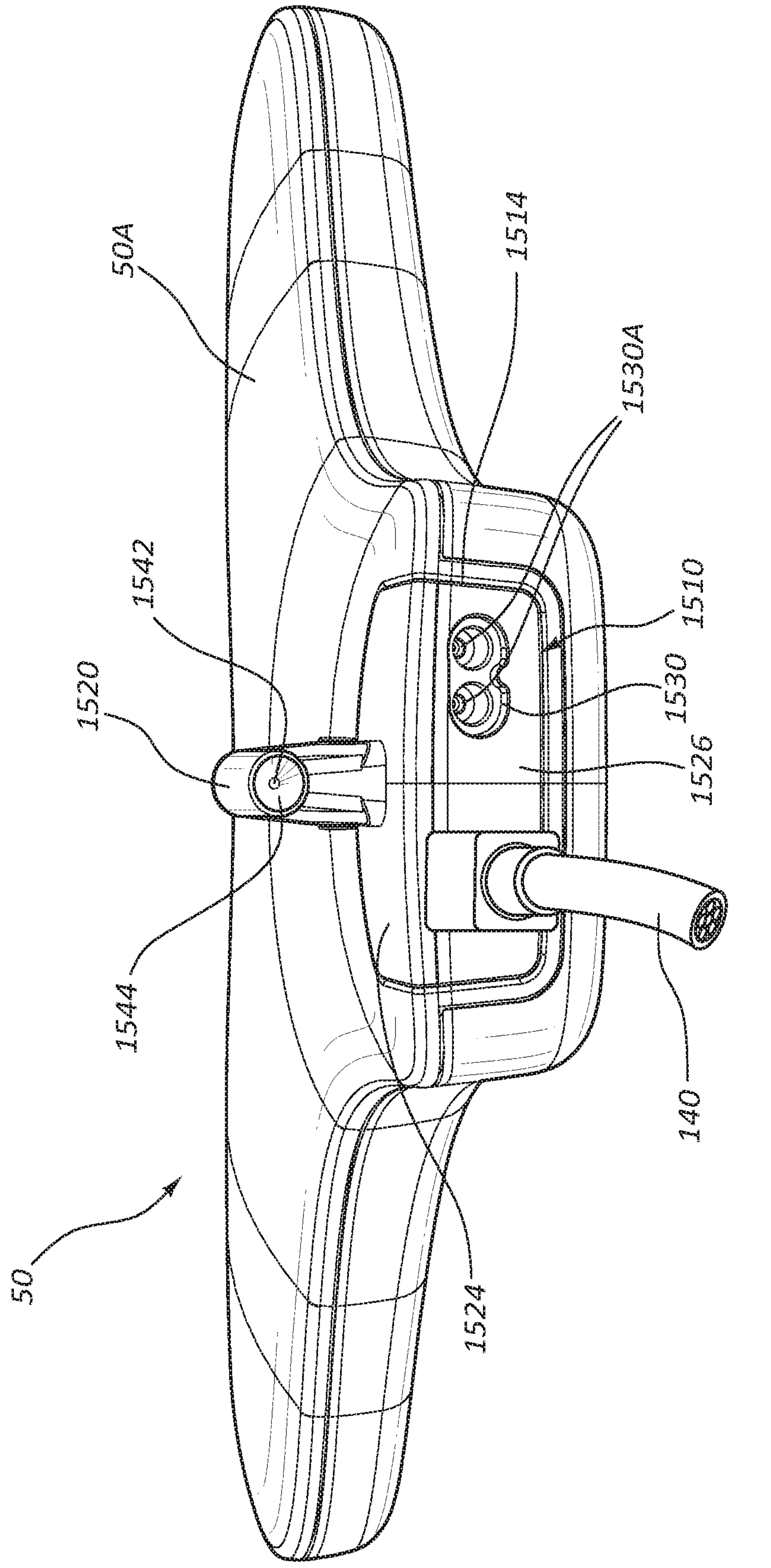


FIG. 3B

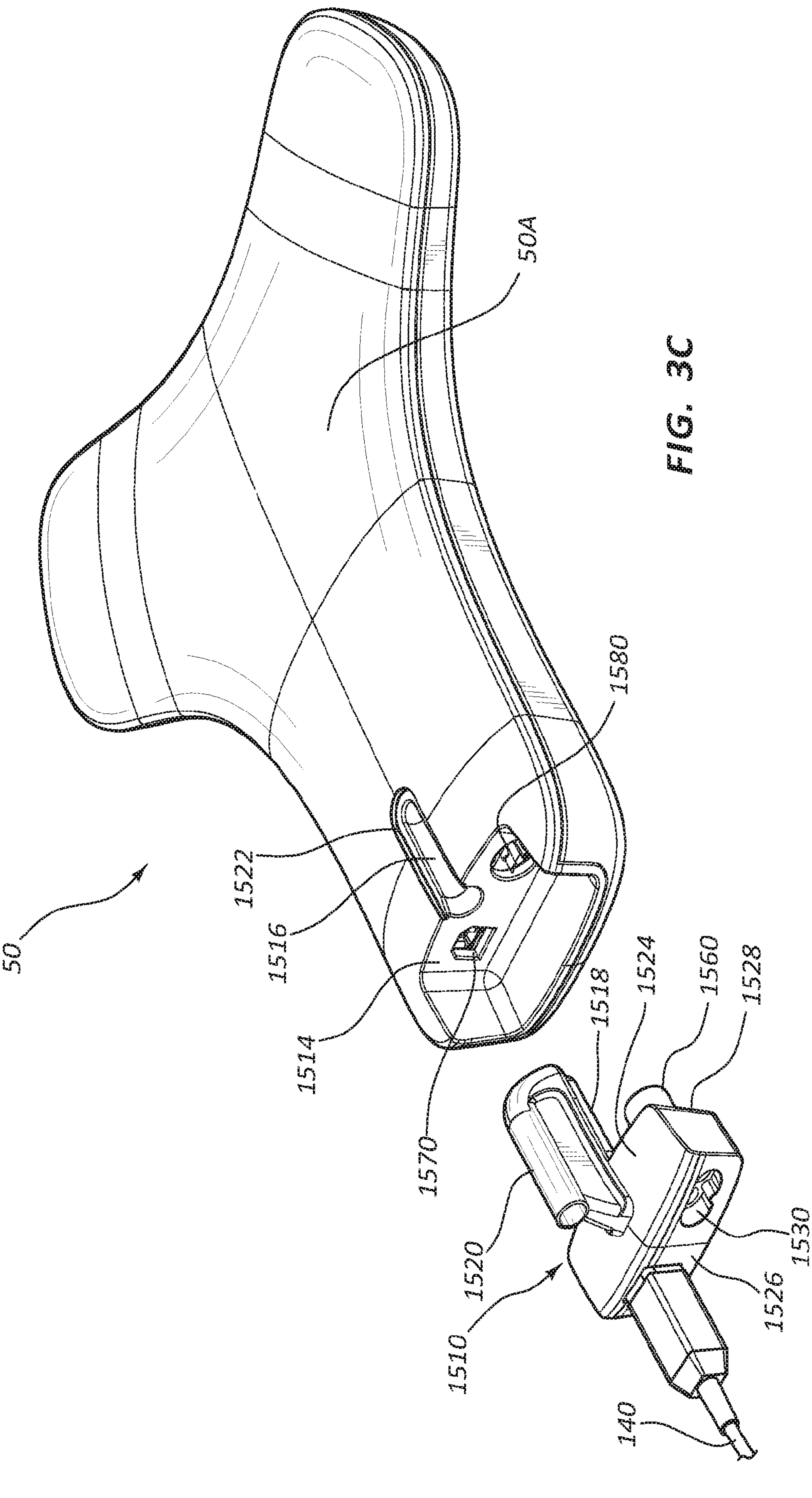

50
50A
1580
1522
1516
1514
1570
1518
1524
1560
1528
1520
1530
1526
1510
140

FIG. 3C

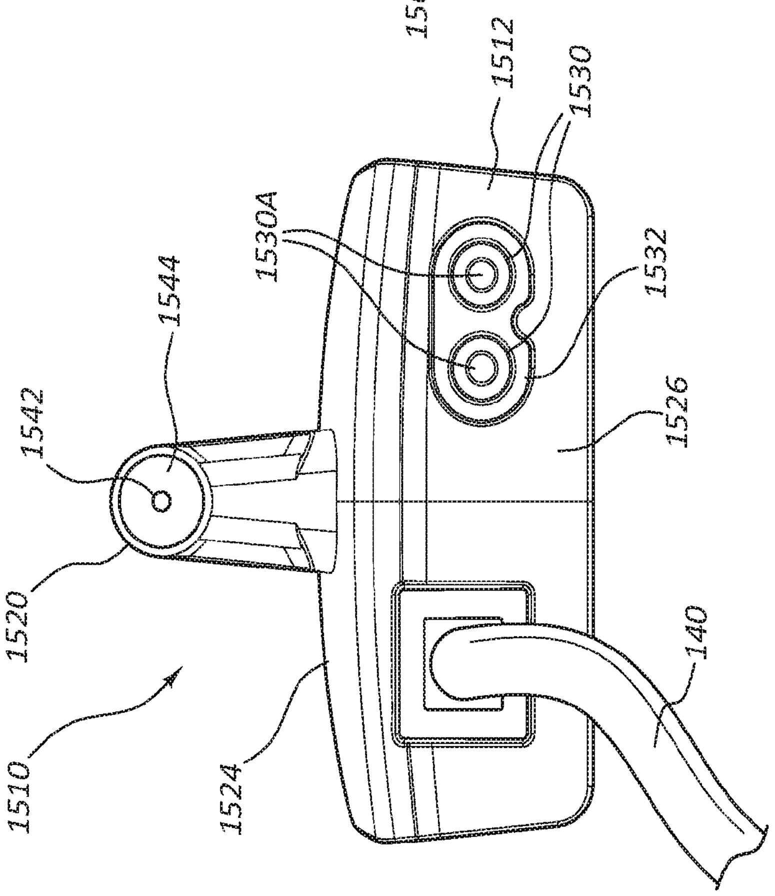

1510
1520
1542
1544
1524
1530A
1512
1530
1532
1526
140

FIG. 4A

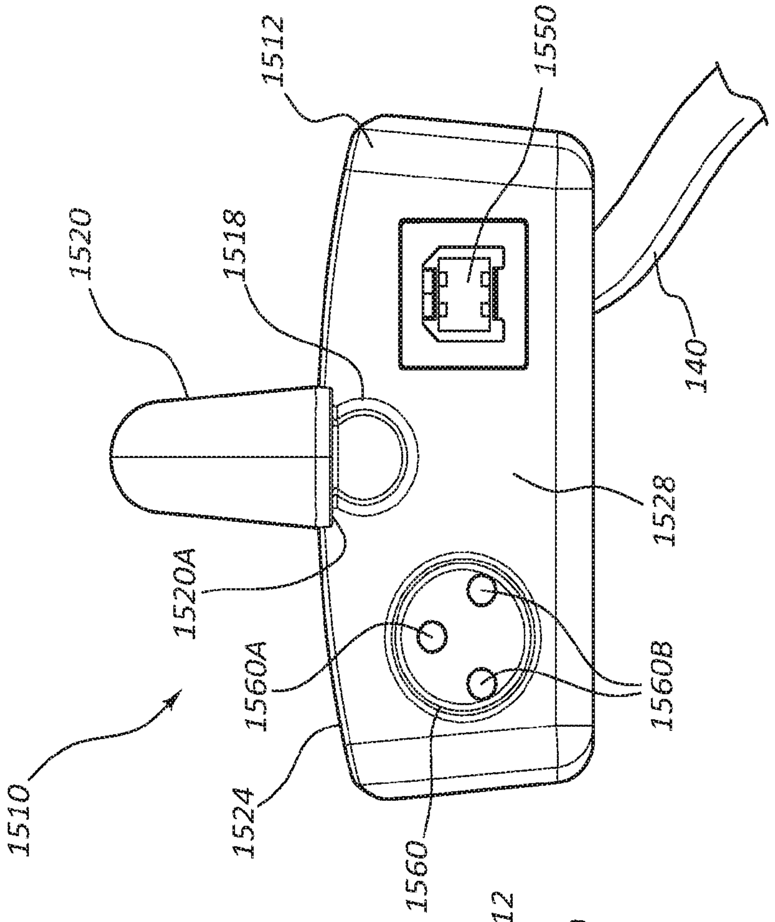

1510
1524
1560
1560A
1520A
1520
1518
1512
1550
1528
1560B
140

FIG. 4B

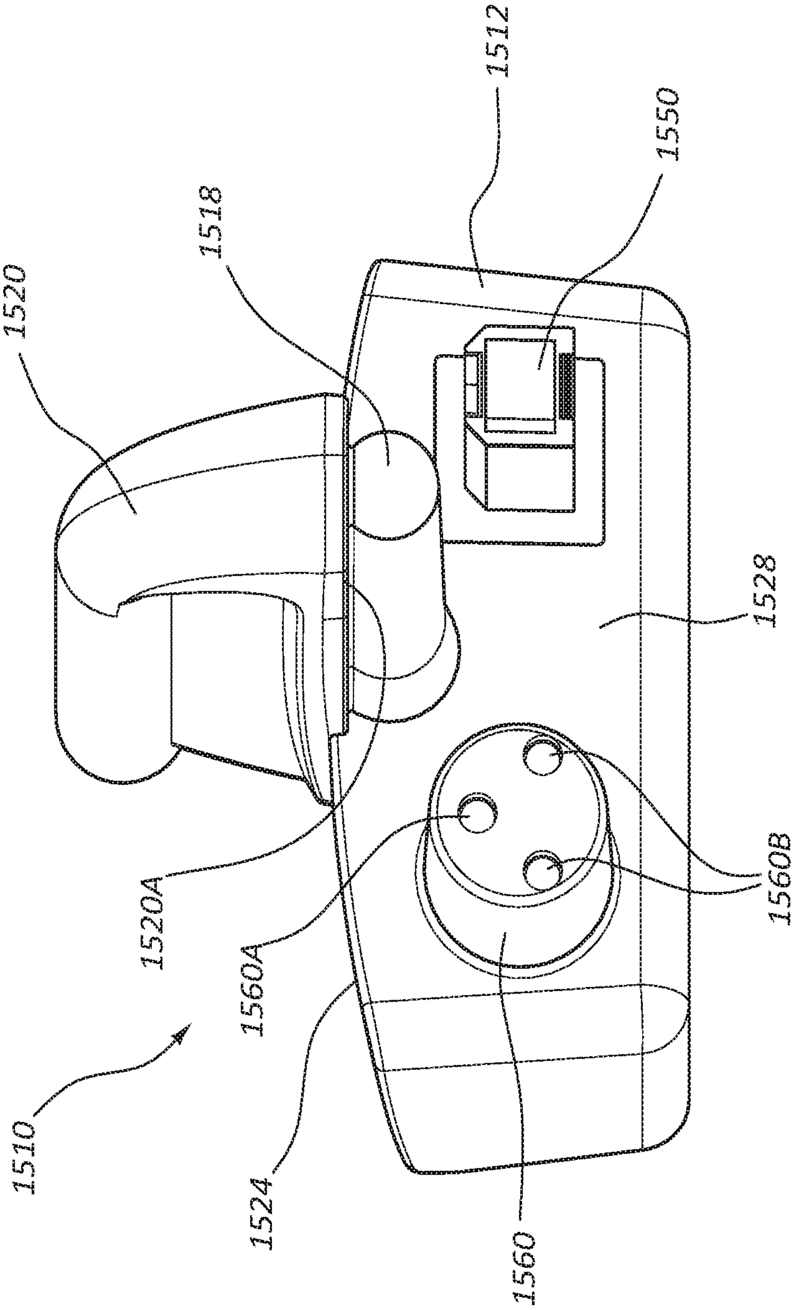


FIG. 4C

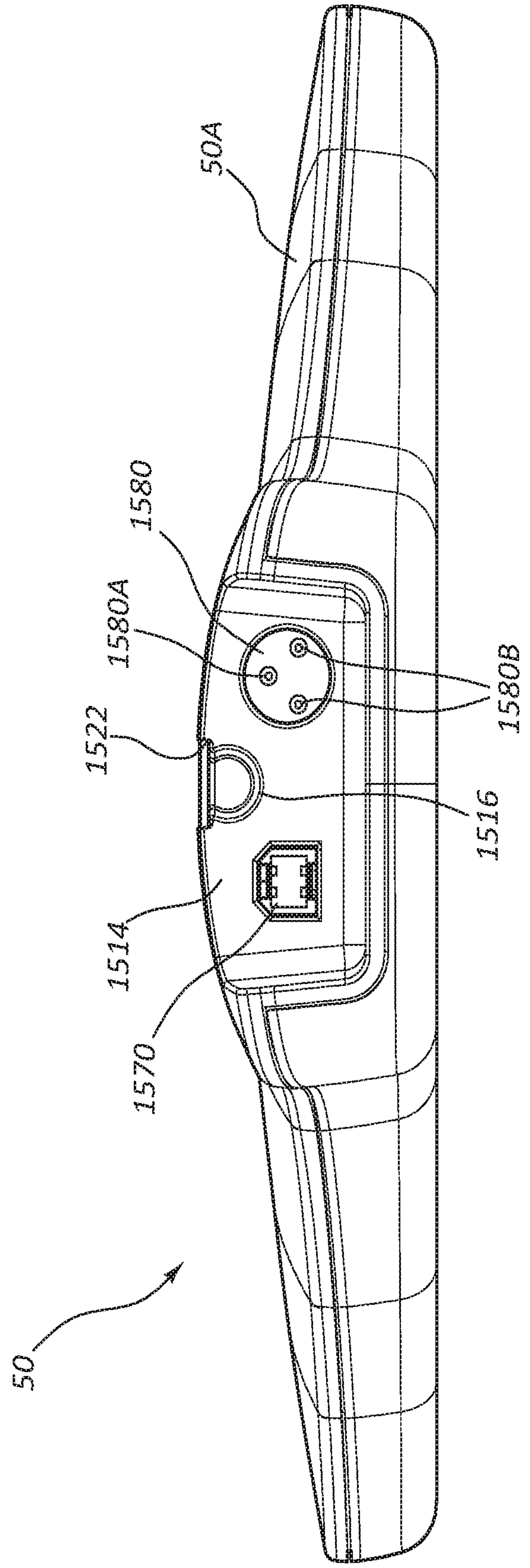


FIG. 5

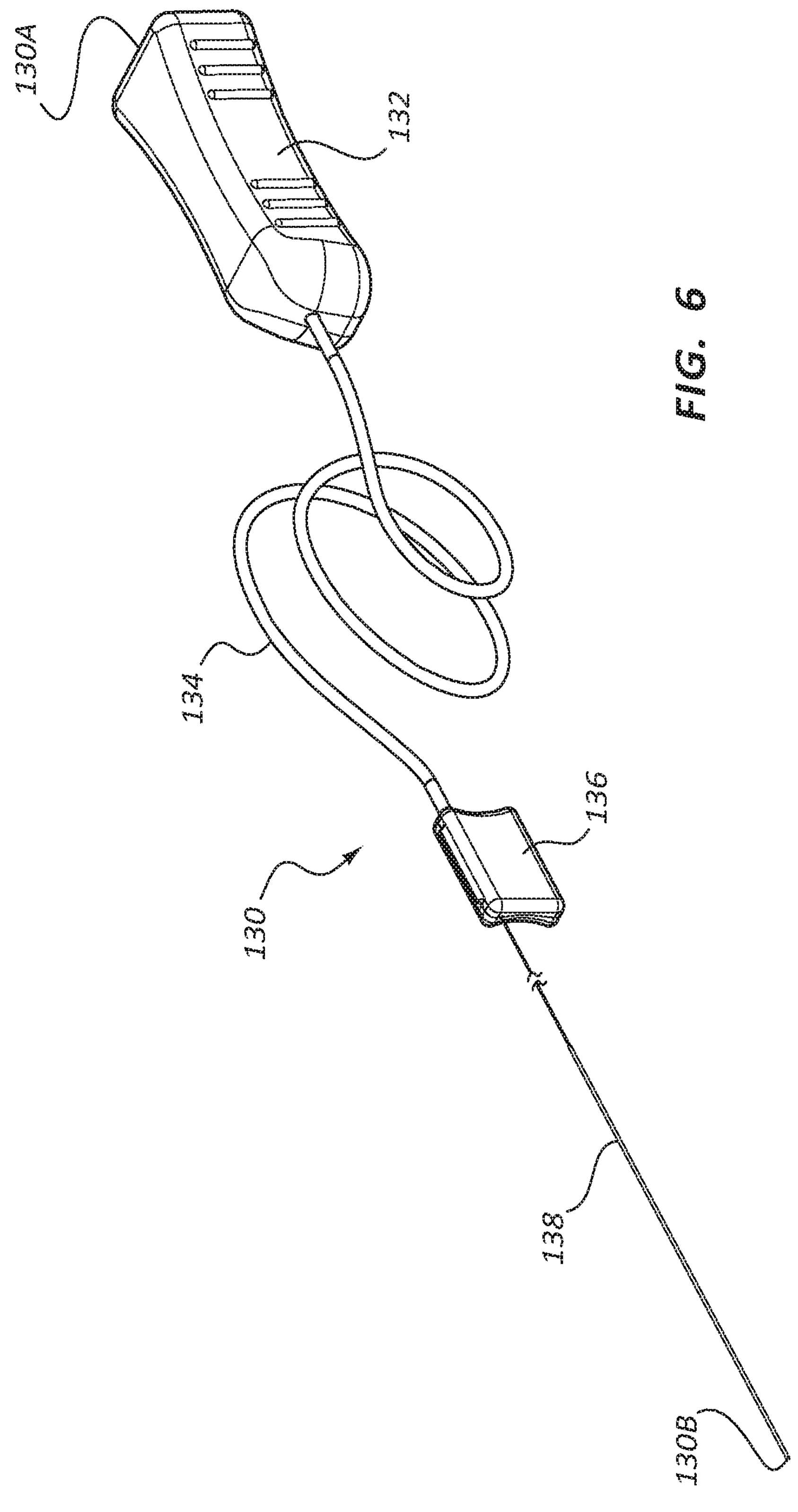


FIG. 6

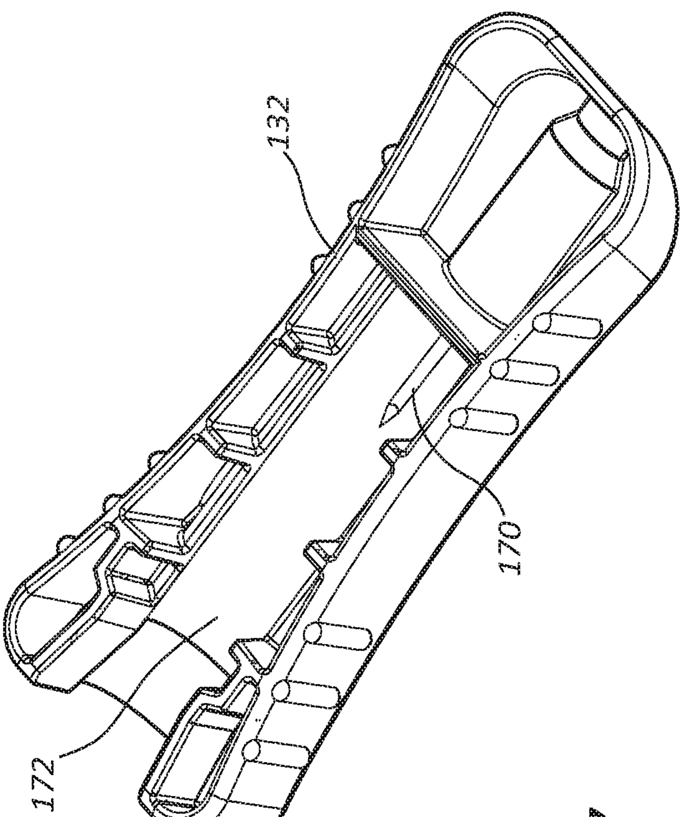


FIG. 7

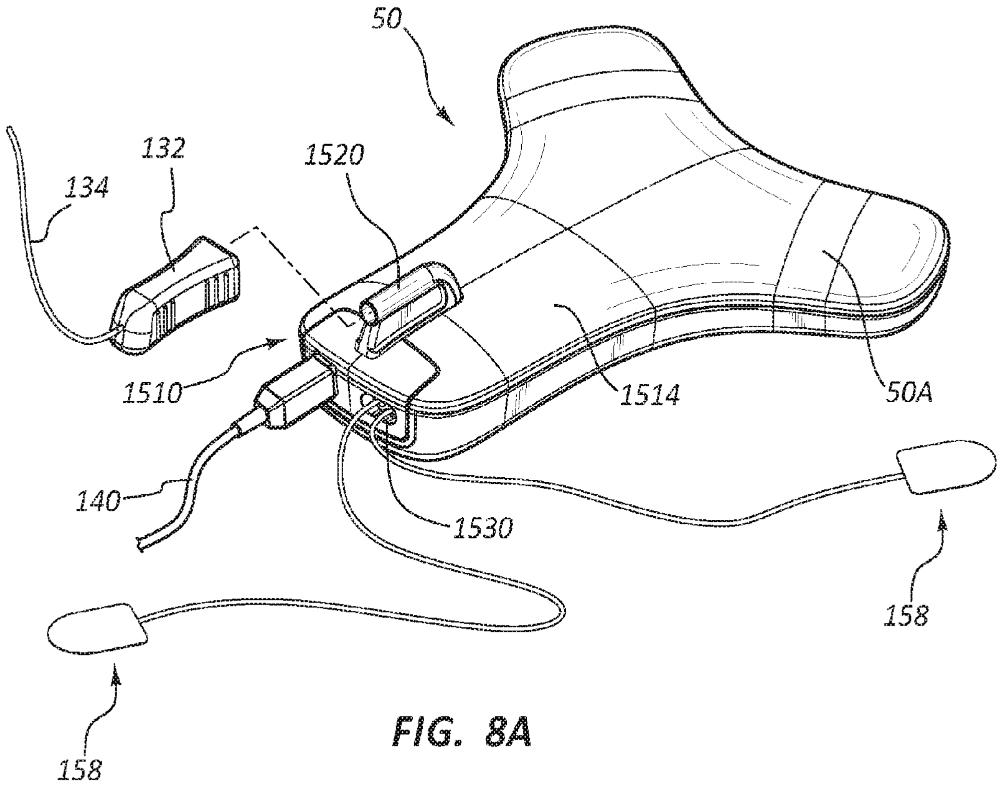

50
134
132
1520
1510
1514
50A
140
1530
158
158

FIG. 8A

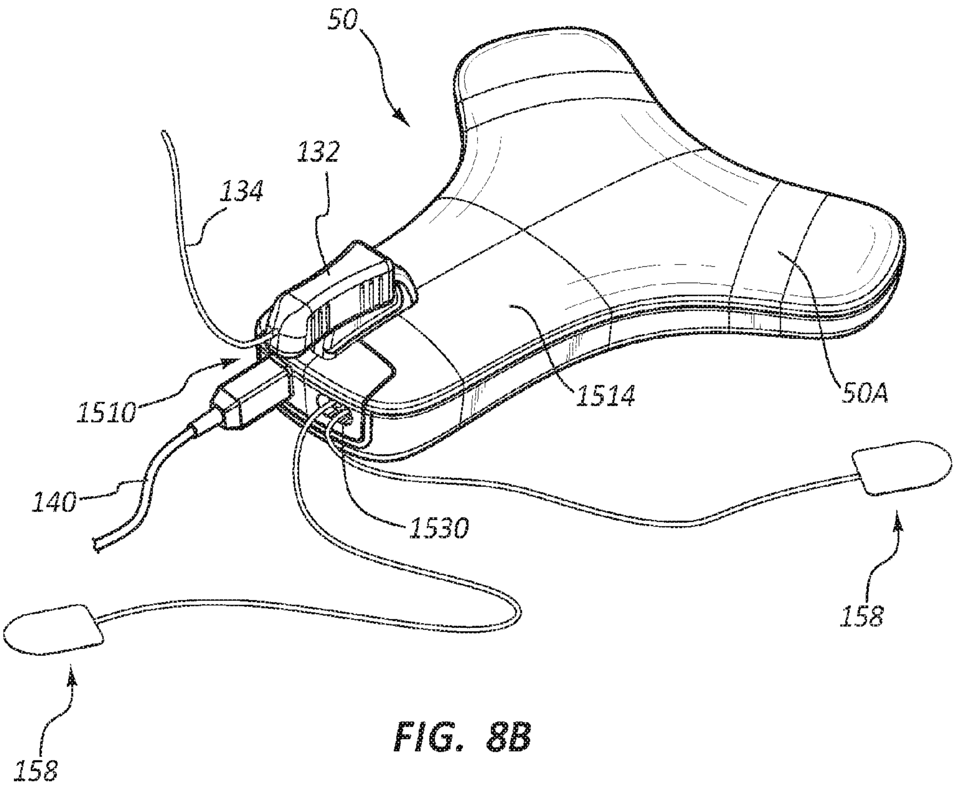

50
132
134
1510
1514
50A
140
1530
158
158

FIG. 8B

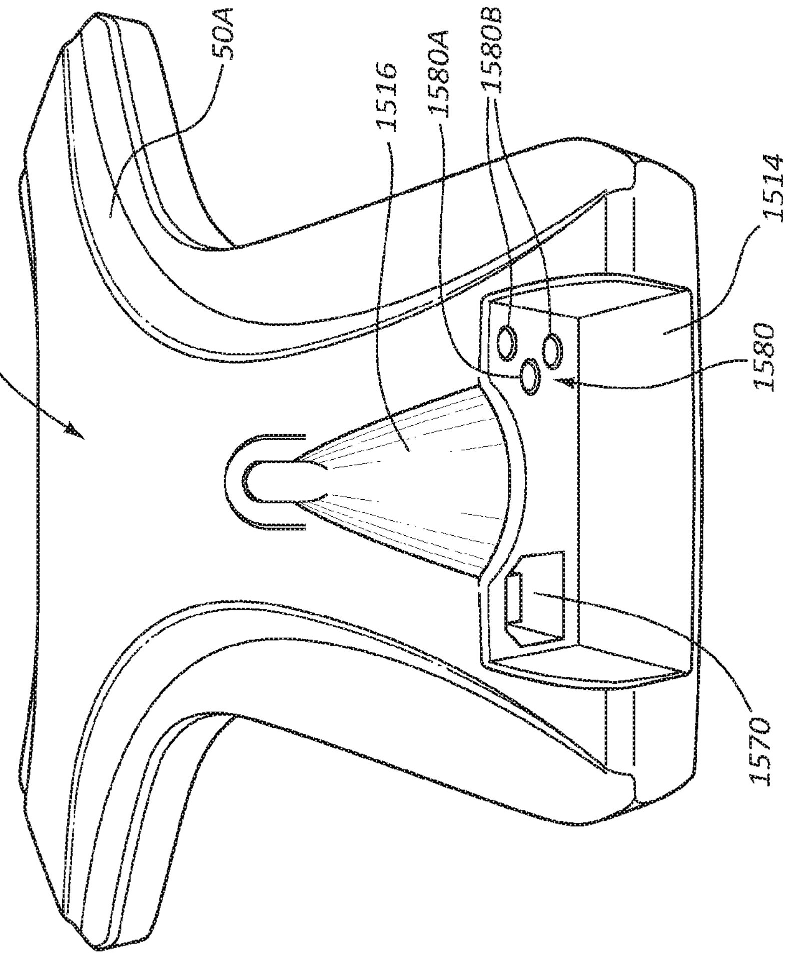

50
50A
1516
1580A
1580B
1514
1580
1570

FIG. 9

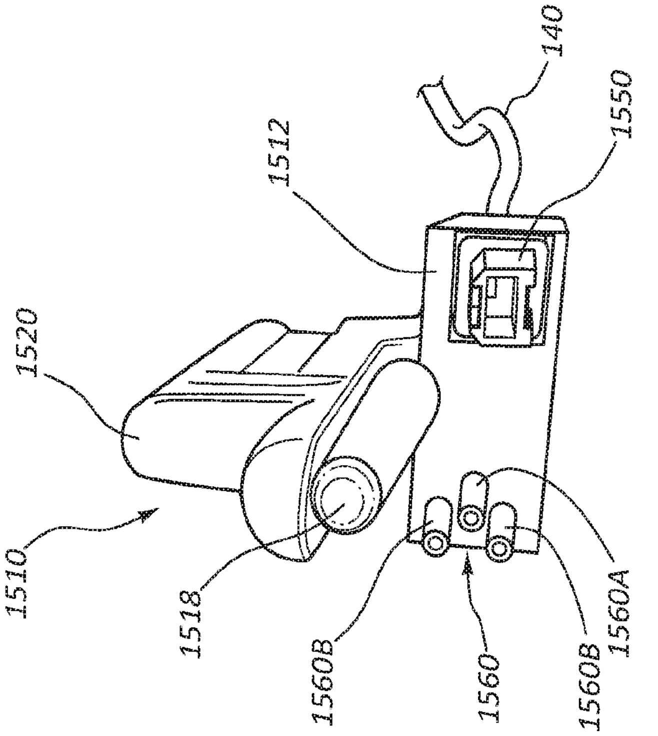

140
1550
1512
1520
1510
1518
1560B
1560
1560B
1560A

FIG. 10

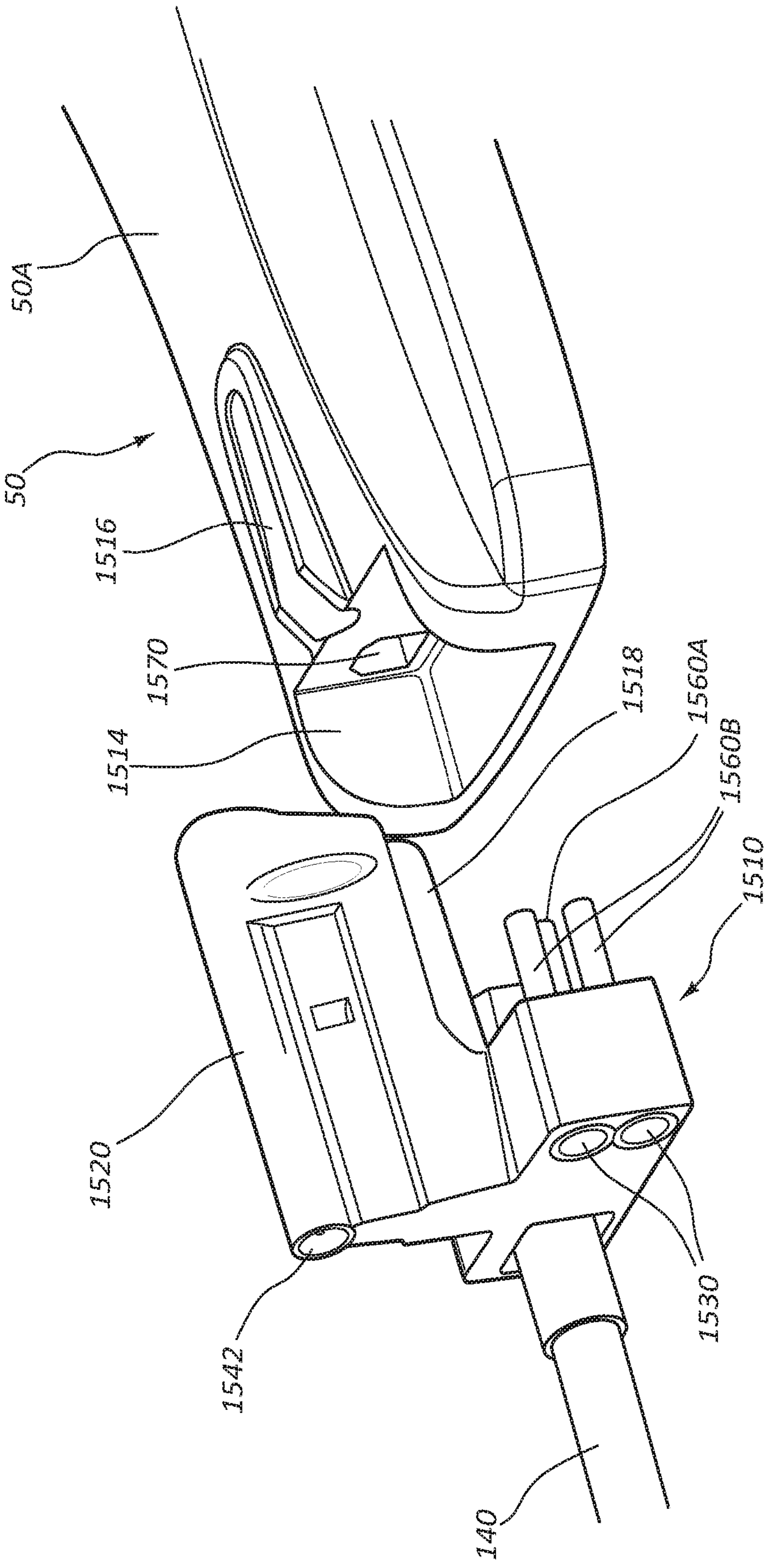

50A
50
1516
1570
1514
1518
1560A
1560B
1510
1520
1542
1530
140

FIG. 11

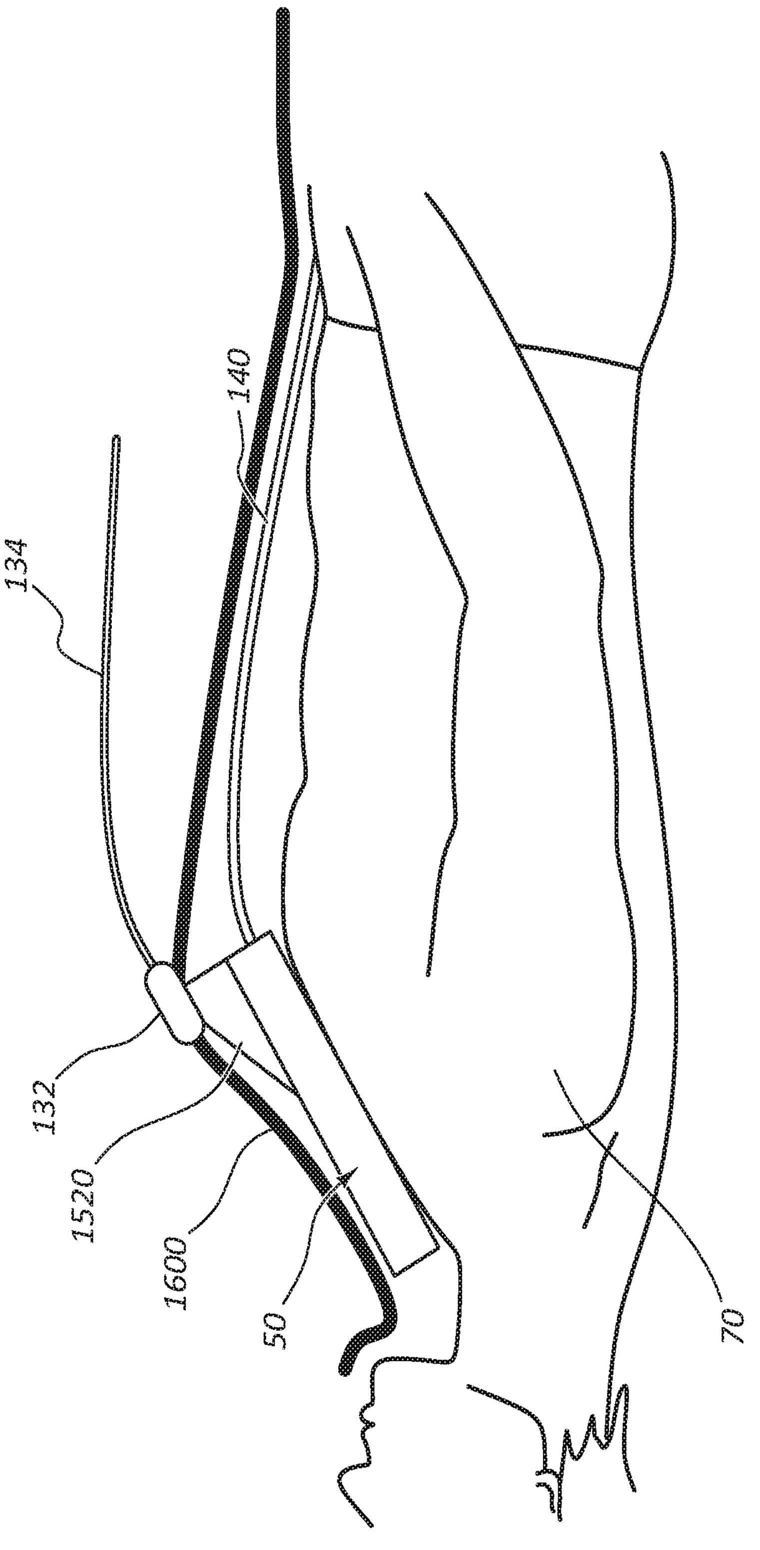


FIG. 12

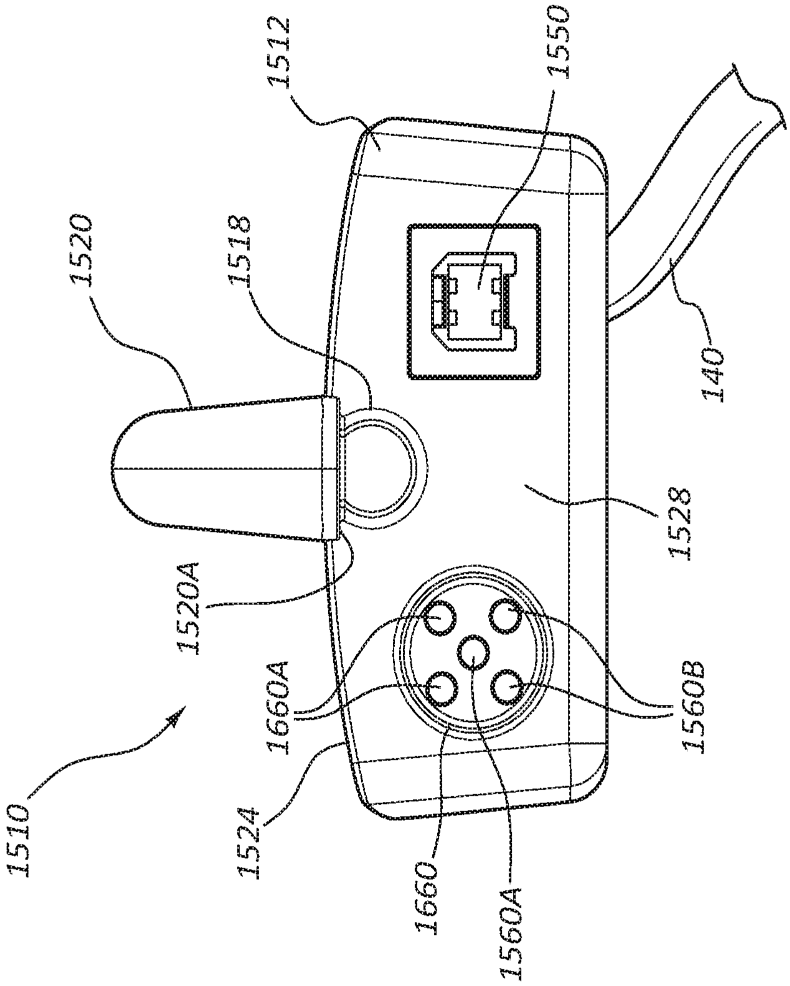

1512
1550
1520
1518
140
1528
1520A
1660A
1560B
1510
1524
1660
1560A

FIG. 13

CONNECTOR INTERFACE FOR ECG-BASED CATHETER POSITIONING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/185,477, filed Jun. 26, 2015, and titled "Interface Connector for ECG-based Catheter Positioning System," which is incorporated herein by reference in its entirety.

BRIEF SUMMARY

[0002] Briefly summarized, embodiments of the present invention are directed to a connector interface that is configured to enable component interconnection with a location sensor of a catheter placement system. The catheter placement system is configured to assist a clinician in positioning a catheter in a desired location within a body of a patient, such as a lower $\frac{1}{3}^{rd}$ portion of the superior vena cava within the patient's vasculature.

[0003] In one embodiment, the location sensor assembly comprises a location sensor body for temporary placement on a portion of the patient body, and a connector interface. The connector interface is configured to removably attach to the location sensor and provide a plurality of electrically conductive pathways between the location sensor and additional components of the catheter placement system to enable the additional components to operably connect with the location sensor. The connector interface further includes a first connector configured to operably connect with a second connector of one of the additional components of the catheter placement system through a sterile barrier, such as a surgical drape, interposed between the first and second connectors.

[0004] These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0006] FIG. **1** is a block diagram of a catheter placement system according to one embodiment;

[0007] FIG. **2** is a simplified view of a patient and the catheter placement system of FIG. **1**;

[0008] FIGS. **3**A-**3**C depict various views of a location sensor of the catheter placement system of FIGS. **1** and **2**;

[0009] FIGS. **4**A-**4**C depict various views of a connector interface of the location sensor or FIGS. **3**A-**3**C;

[0010] FIG. **5** is an end view of the location sensor of FIGS. **3**A-**3**C;

[0011] FIG. **6** is a perspective view of a stylet of the catheter placement system of FIGS. **1** and **2**;

[0012] FIG. **7** is a perspective view of a tether connector of the stylet of FIG. **6**;

[0013] FIGS. **8**A and **8**B depict various views of the connection of the tether connector of FIG. **6** with the location sensor of FIGS. **3**A-**3**C;

[0014] FIG. **9** is a perspective view of a location sensor according to one embodiment;

[0015] FIG. **10** is a perspective view of a connector interface for attachment to the location sensor of FIG. **9**;

[0016] FIG. **11** depicts attachment of the connector interface of FIG. **10** with the location sensor of FIG. **9**;

[0017] FIG. **12** shows a side view of a patient with the location sensor of FIG. **8**B placed on the patient; and

[0018] FIG. **13** is an end view of a connector interface according to one embodiment.

DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

[0019] Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present invention, and are neither limiting nor necessarily drawn to scale.

[0020] For clarity it is to be understood that the word "proximal" refers to a direction relatively closer to a clinician using the device to be described herein, while the word "distal" refers to a direction relatively further from the clinician. For example, the end of a catheter placed within the body of a patient is considered a distal end of the catheter, while the catheter end remaining outside the body is a proximal end of the catheter. Also, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

[0021] Embodiments of the present disclosure are generally directed to a connector interface connector for use in interconnecting various elements of a catheter placement system. Use of the present interface connector enables various components of the catheter placement system to be replaced or interchanged while enabling other components to remain. This in turn reduces system cost and allows for a modular system design.

[0022] FIGS. **1** and **2** depict various details of a catheter placement system ("system" or "placement system"), generally designated at **10**, which serves as one example environment wherein embodiments of the present disclosure can be practiced. The system **10** is employed to assist a clinician in the placement of a catheter or other medical device within the body of a patient, such as within the vasculature. In one embodiment, the system **10** enables a distal tip of a catheter to be placed within the patient vasculature in desired proximity to the heart using ECG signals produced by the patient's heart. In one embodiment, the medical device includes a catheter and the intended destination of the catheter within the patient body is such that the distal tip of the catheter is disposed in the lower $\frac{1}{3}^{rd}$ portion of the superior vena cava ("SVC"). The guidance and placement system analyzes the ECG signals of the patient to determine when the catheter has reached its intended destination within the vasculature, then notifies the clinician via a display, for instance. Thus, the system includes an ECG modality for assisting in medical device placement within the patient.

[0023] In one embodiment, the above-referenced ECG guidance modality of the system **10** is accompanied by an ultrasound ("US") modality to assist with initial insertion of the medical device into the body, and a magnetic element-based tracking, or tip location system ("TLS") modality to track the position and orientation of the medical device as it advances toward its intended destination.

[0024] As mentioned, FIGS. **1** and **2** depict various components of the system **10** in accordance with one example embodiment. As shown, the system **10** generally includes a console **20**, display **30**, probe **40**, and sensor **50**, each of which is described in further detail below.

[0025] FIG. **2** shows the general relation of these components to a patient **70** during a procedure to place a catheter **72** into the patient vasculature through a skin insertion site **73**. FIG. **2** shows that the catheter **72** generally includes a proximal portion **74** that remains exterior to the patient and a distal potion **76** that resides within the patient vasculature after placement is complete. In the present embodiment, the system **10** is employed to ultimately position a distal tip **76**A of the catheter **72** in a desired position within the patient vasculature. In one embodiment, the desired position for the catheter distal tip **76**A is proximate the patient's heart, such as in the lower one-third ($1/3^{rd}$) portion of the Superior Vena Cava ("SVC"). Of course, the system **10** can be employed to place the catheter distal tip in other locations. The catheter proximal portion **74** further includes a bifurcation hub **74**A that provides fluid communication between the one or more lumens of the catheter **72**, one or more extension tubes **74**B extending proximally from the hub, and corresponding connectors **74**C for enabling connection to the catheter **72**.

[0026] A processor **22**, including non-volatile memory such as EEPROM for instance, is included in the console **20** for controlling system function during operation of the system **10**, thus acting as a control processor. A digital controller/analog interface **24** is also included with the console **20** and is in communication with both the processor **22** and other system components to govern interfacing between the probe **40**, sensor **50**, and other system components.

[0027] The system **10** further includes ports **52** for connection with the sensor **50** and optional components **54** including a printer, storage media, keyboard, etc. The ports in one embodiment are USB ports, though other port types or a combination of port types can be used for this and the other interfaces connections described herein. A power connection **56** is included with the console **20** to enable operable connection to an external power supply **58**. An internal battery **60** can also be employed, either with or exclusive of an external power supply. Power management circuitry **59** is included with the digital controller/analog interface **24** of the console to regulate power use and distribution.

[0028] The display **30** in the present embodiment is integrated into the console **20** and is used to display information to the clinician during the catheter placement procedure. In another embodiment, the display may be separate from the console. As will be seen, the content depicted by the display **30** changes according to which mode the catheter placement system is in: US, TLS, or in other embodiments, ECG tip confirmation. In one embodiment, a console button interface **32** and buttons included on the probe **40** can be used to immediately call up a desired mode to the display **30** by the clinician to assist in the placement procedure. In one embodiment, information from multiple modes, such as TLS and ECG, may be displayed simultaneously. Thus, the single display **30** of the system console **20** can be employed for ultrasound guidance in accessing a patient's vasculature, TLS guidance during catheter advancement through the vasculature, and (as in later embodiments) ECG-based confirmation of catheter distal tip placement with respect to a node of the patient's heart. In one embodiment, the display **30** is an LCD device.

[0029] The probe **40** is employed in connection with the first modality mentioned above, i.e., ultrasound ("US")-based visualization of a vessel, such as a vein, in preparation for insertion of the catheter **72** into the vasculature. Such visualization gives real time ultrasound guidance for introducing the catheter into the vasculature of the patient and assists in reducing complications typically associated with such introduction, including inadvertent arterial puncture, hematoma, pneumothorax, etc.

[0030] As such, in one embodiment a clinician employs the first, US, modality to determine a suitable insertion site and establish vascular access, such as with a needle and introducer, then with the catheter. The clinician can then seamlessly switch, via button pushes on the probe button pad, to the second, TLS, modality without having to reach out of the sterile field. The TLS mode can then be used to assist in advancement of the catheter **72** through the vasculature toward an intended destination.

[0031] FIG. **1** shows that the probe **40** further includes button and memory controller **42** for governing button and probe operation. The button and memory controller **42** can include non-volatile memory, such as EEPROM, in one embodiment. The button and memory controller **42** is in operable communication with a probe interface **44** of the console **20**, which includes a piezo input/output component **44**A for interfacing with the probe piezoelectric array and a button and memory input/output component **44**B for interfacing with the button and memory controller **42**.

[0032] Note that while a vein is typically depicted on the display **30** during use of the system **10** in the US modality, other body lumens or portions can be imaged in other embodiments. Note that the US mode can be simultaneously depicted on the display **30** with other modes, such as the TLS mode or ECG mode, if desired. In addition to the visual display **30**, aural information, such as beeps, tones, etc., or vibratory/motion-based cues can also be employed by the system **10** to assist the clinician during catheter placement. Moreover, the buttons included on the probe **40** and the console button interface **32** can be configured in a variety of ways, including the use of user input controls in addition to buttons, such as slide switches, toggle switches, electronic or touch-sensitive pads, etc. Additionally, US, TLS, and ECG activities can occur simultaneously or exclusively during use of the system **10**.

[0033] As just described, the handheld ultrasound probe **40** is employed as part of the integrated catheter placement system **10** to enable US visualization of the peripheral vasculature of a patient in preparation for transcutaneous introduction of the catheter. In the present example embodiment, however, the probe is also employed to control functionality of the TLS portion, or second modality, of the system **10** when navigating the catheter toward its desired destination within the vasculature as described below. Again, as the probe **40** is used within the sterile field of the patient, this feature enables TLS functionality to be controlled entirely from within the sterile field. Thus the probe

40 is a dual-purpose device, enabling convenient control of both US and TLS functionality of the system **10** from the sterile field. In one embodiment, the probe can also be employed to control some or all ECG-related functionality, or third modality, of the catheter placement system **10**, as described further below.

[0034] The catheter placement system **10** further includes the second modality mentioned above, i.e., the magnetically-based catheter TLS, or tip location system. The TLS enables the clinician to quickly locate and confirm the position and/or orientation of the catheter **72**, such as a peripherally-inserted central catheter ("PICC"), central venous catheter ("CVC"), or other suitable catheter or medical device, during initial placement into and advancement through the vasculature of the patient **70**. Specifically, the TLS modality detects a magnetic field generated by a magnetic element-equipped tip location stylet, which is pre-loaded in one embodiment into a longitudinally defined lumen of the catheter **72**, thus enabling the clinician to ascertain the general location and orientation of the catheter tip within the patient body. In one embodiment, the magnetic assembly can be tracked using the teachings of one or more of the following U.S. Pat. Nos. 5,775,322; 5,879,297; 6,129,668; 6,216,028; and 6,263,230. The contents of the afore-mentioned U.S. patents are incorporated herein by reference in their entireties. The TLS also displays the direction in which the catheter tip is pointing, thus further assisting accurate catheter placement. The TLS further assists the clinician in determining when a malposition of the catheter tip has occurred, such as in the case where the tip has deviated from a desired venous path into another vein.

[0035] As mentioned, the TLS utilizes a stylet **130** to enable the distal end of the catheter **72** to be tracked during its advancement through the vasculature. In one embodiment and as shown in FIG. **6**, the stylet **130** includes a proximal end **130**A and a distal end **130**B, with am included handle **136**. A core wire **138** distally extends from the handle **136**, and a tether **134** (for operably connecting the stylet **130** to the placement system **10**) extends proximally from the handle. A magnetic assembly is disposed distally of the core wire **138**. The magnetic assembly includes one or more magnetic elements disposed adjacent one another proximate the stylet distal end **130**B and encapsulated by tubing. In the present embodiment, a plurality of magnetic elements is included, each element including a solid, cylindrically shaped ferromagnetic stacked end-to-end with the other magnetic elements. An adhesive tip can fill the distal tip of the tubing, distally to the magnetic elements.

[0036] Note that in other embodiments, the magnetic elements may vary from the design in not only shape, but also composition, number, size, magnetic type, and position in the stylet distal segment. For example, in one embodiment, the plurality of ferromagnetic magnetic elements is replaced with an electromagnetic assembly, such as an electromagnetic coil, which produces a magnetic field for detection by the sensor. Another example of an assembly usable here can be found in U.S. Pat. No. 5,099,845, entitled "Medical Instrument Location Means," which is incorporated herein by reference in its entirety. Yet other examples of stylets including magnetic elements that can be employed with the TLS modality can be found in U.S. Pat. No. 8,784,336, entitled "Stylet Apparatuses and Methods of Manufacture," which is incorporated herein by reference in its entirety. These and other variations are therefore contemplated by embodiments of the present invention. It should appreciated herein that "stylet" as used herein can include any one of a variety of devices configured for removable placement within a lumen of the catheter to assist in placing a distal end of the catheter in a desired location within the patient's vasculature. In one embodiment, the stylet includes a guidewire. As such, it is appreciated that stylets of other forms and configurations can also be acceptably used, in accordance with the present disclosure.

[0037] FIG. **2** shows disposal of the stylet **130** substantially within a lumen in the catheter **72** such that the proximal portion thereof extends proximally from the catheter lumen, through the bifurcation hub **74**A and out through a selected one of the extension tubes **74**B. So disposed within a lumen of the catheter, the distal end **130**B of the stylet **130** in the present embodiment is substantially co-terminal with the distal catheter end **76**A such that detection by the TLS of the stylet distal end correspondingly indicates the location of the catheter distal end. In other embodiments, other positional relationships between the distal ends of the stylet and catheter or medical device are possible.

[0038] The TLS sensor **50** (also referred to herein as a "location sensor") is employed by the system **10** during TLS operation to detect the magnetic field produced by the magnetic elements of the stylet **130**. As seen in FIG. **2**, the TLS sensor **50** is placed on the chest of the patient during catheter insertion. The TLS sensor **50** is positioned on the chest of the patient in a predetermined location, such as through the use of external body landmarks, to enable the magnetic field of the stylet magnetic elements, disposed in the catheter **72** as described above, to be detected during catheter transit through the patient vasculature. Again, as the magnetic elements of the stylet magnetic assembly are co-terminal with the distal end **76**A of the catheter **72** in one embodiment (FIG. **2**), detection by the TLS sensor **50** of the magnetic field of the magnetic elements provides information to the clinician as to the position and orientation of the catheter distal end during its transit.

[0039] In greater detail, the TLS sensor **50** is operably connected to the console **20** of the system **10** via a connection of a console cable **140** with one or more of the ports **52** of the console, as shown in FIG. **1**. The console cable **140** attaches to the TLS sensor **50** in a manner to be described further below. Note that other connection schemes between the TLS sensor and the system console can also be used, without limitation. As just described, the magnetic elements are employed in the stylet **130** to enable the position of the catheter distal end **76**A (FIG. **2**) to be observable relative to the TLS sensor **50** placed on the patient's chest. Detection by the TLS sensor **50** of the stylet magnetic elements is graphically displayed on the display **30** of the console **20** during TLS mode. In this way, a clinician placing the catheter is able to generally determine the location of the catheter distal end **76**A within the patient vasculature relative to the TLS sensor **50** and detect when catheter malposition, such as advancement of the catheter along an undesired vein, is occurring.

[0040] As discussed above, the system **10** includes additional functionality in the present embodiment wherein determination of the proximity of the catheter distal tip **76**A relative to a sino-atrial ("SA") or other electrical impulse-emitting node of the heart of the patient **70** can be determined, thus providing enhanced ability to accurately place the catheter distal tip in a desired location proximate the node. Also referred to herein as "ECG" or "ECG-based tip confirmation," this third modality of the system **10** enables detection of ECG signals from the SA node in order to place the catheter distal tip in a desired location within the patient vasculature. Note that the US, TLS, and ECG modalities are seamlessly combined in the present system **10**, but can be employed in concert or individually to assist in catheter placement. In one embodiment, it is understood that the ECG modality as described herein can be included in a stand-alone system without the inclusion of the US and TLS modalities. Thus, the environments in which the embodiments herein are described are understood as merely example environments and are not considered limiting of the present disclosure.

[0041] As described, the catheter stylet **130** is removably predisposed within the lumen of the catheter **72** being inserted into the patient **70** via the insertion site **73**. The stylet **130**, in addition to including a magnetic assembly for the magnetically-based TLS modality, includes a sensing component, i.e., an internal, intravascular ECG sensor assembly, proximate its distal end and including a portion that is co-terminal with the distal end of the catheter tip for intravascularly sensing ECG signals produced by the SA node, in the present embodiment when the catheter **72** and accompanying stylet **130** are disposed within the patient vasculature. The intravascular ECG sensor assembly is also referred to herein as an internal or "intravascular ECG sensor component," and the stylet **130** as an "ECG stylet."

[0042] As mentioned, the stylet **130** includes the tether **134** extending from its proximal end **130**A that operably connects to the TLS sensor **50** in a manner to be described below, though other connection schemes to the system **10** are contemplated. As will be described in further detail, the stylet tether **134** permits ECG signals detected by the ECG sensor assembly included on a distal portion of the stylet **130** to be conveyed to the TLS sensor **50** during confirmation of the catheter tip location as part of the ECG signal-based tip confirmation modality.

[0043] External reference and ground ECG electrodes **158** attach to the body of the patient **70** in the present embodiment and are operably attached to the TLS sensor **50** to provide an external baseline ECG signal to the system **10** and to enable the system to filter out high level electrical activity unrelated to the electrical activity of the SA node of the heart, thus enabling the ECG-based tip confirmation functionality. As shown, in the present embodiment, one external electrode **158** is placed on the patient skin proximate the upper right shoulder ("right arm" placement) while another external electrode is placed proximate the lower left abdomen ("left leg" placement). This electrode arrangement provides a lead II configuration according to Einthoven's triangle of electrocardiography. Operable attachment of the external electrodes **158** with the sensor **50** in a manner to be described below enables the ECG signals detected by the external electrodes to be conveyed to the console **20** of the system **10** or to another suitable destination. As such, the external electrodes **158** serve as one example of an external ECG sensor component. Other external sensors for detecting a baseline ECG signal external to the patient body can also be employed in other embodiments. In addition, other electrode locations are also possible.

[0044] Together with the external ECG signal received from the external ECG sensor component (i.e., the external ECG electrodes **158** placed on the patient's skin), an internal, intravascular ECG signal sensed by the internal ECG sensor component (i.e., the stylet ECG sensor assembly of the stylet **130**), is received by the TLS sensor **50** positioned on the patient's chest (FIG. **10**) or other designated component of the system **10**. The TLS sensor **50** and/or console processor **22** can process the external and internal ECG signal data to produce one or more electrocardiogram traces, including a series of discrete ECG complexes, on the display **30**, as will be described. In the case where the TLS sensor **50** processes the external and internal ECG signal data, a processor is included therein to perform the intended functionality. If the console **20** processes the ECG signal data, the processor **22**, controller **24**, or other processor can be utilized in the console to process the data.

[0045] Thus, as it is advanced through the patient vasculature, the catheter **72** equipped with the stylet **130** as described above can advance under the TLS sensor **50**, which is positioned on the chest of the patient as shown in FIG. **10**. This enables the TLS sensor **50** to detect the position of the magnetic assembly of the stylet **130** (described further above), which is substantially co-terminal with the distal tip **76**A of the catheter as located within the patient's vasculature. The detection by the TLS sensor **50** of the stylet magnetic assembly is depicted on the display **30** during ECG mode.

[0046] The display **30** can further depict during ECG mode one or more ECG electrocardiogram traces produced as a result of patient heart's electrical activity as detected by the external and internal ECG sensor components described above. In greater detail, the ECG electrical activity of the SA node, including the P-wave of the trace, is detected by the external and internal sensor components and forwarded to the TLS sensor **50** and console **20**. The ECG electrical activity is then processed for depiction on the display **30**, as will be described further below.

[0047] A clinician placing the catheter can then observe the ECG data, which assists in determining optimum placement of the distal tip **76**A of the catheter **72**, such as proximate the SA node, for instance. In one embodiment, the console **20** includes the electronic components, such as the processor **22** (FIG. **1**), necessary to receive and process the signals detected by the external and internal sensor components. In another embodiment, the TLS sensor **50** can include the necessary electronic components processing the ECG signals.

[0048] As already discussed, the display **30** is used to display information to the clinician during the catheter placement procedure. The content of the display **30** changes according to which mode the catheter placement system is in: US, TLS, or ECG. Any of the three modes can be immediately called up to the display **30** by the clinician, and in some cases information from multiple modes, such as TLS and ECG, may be displayed simultaneously. In one embodiment, as before, the mode the system is in may be controlled by the control buttons included on the handheld probe **40**, thus eliminating the need for the clinician to reach out of the sterile field (such as touching the button interface **32** of the console **20**) to change modes. Thus, in the present embodiment the probe **40** is employed to also control some or all ECG-related functionality of the system **10**. Note that the button interface **32** or other input configurations can also be used to control system functionality. Also, in addition to the visual display **30**, aural information, such as beeps, tones, etc., can also be employed by the system to assist the clinician during catheter placement.

[0049] Note that further details regarding the system **10** can be found in U.S. Pat. No. 8,848,382, issued Sep. 30, 2014, and entitled "Apparatus and Display Methods Relating to Intravascular Placement of a Catheter," which is incorporated herein by reference in its entirety. It is further noted that the above-described catheter placement system is but example of a variety of placement systems that can benefit from the principles of the embodiments described herein.

[0050] In view of the above discussion, reference is now made to FIGS. **3**A-3C, which depict various details of the above-described TLS sensor **50**, also referred to herein as a "location sensor." In particular, the location sensor **50** includes a connector interface ("interface") **1510** that is configured according to one embodiment. The interface **1510** is configured to enable interconnection of the location sensor **50** with various other catheter placement system components, including the ECG signal-sensing stylet **130** via the tether **134** (FIG. **6**), the external ECG electrodes **158** (FIG. **2**) via their respective lead wires ("leads"), and the console cable **140** that operably connects the location sensor with the console **20** of the system **10**.

[0051] As shown, the interface **1510** includes a body **1512** that is configured to removably connect to the location sensor **50** within a pocket **1514** defined on a lower portion of the location sensor **50**, from the perspective shown in FIG. 3A. The interface body **1512** includes a rail **1518** defined on a fin **1520** that is configured to be slidably received within a corresponding track **1516** defined on an outer surface **50**A of the location sensor **50** proximate the pocket **1514**, as shown in FIG. 3C. Other connective schemes can be employed in other embodiments. Also, the particular size, shape, and configuration of the interface **1510** can vary. A bottom portion **1520**A of the fin **1520** is configured to be slidably received within a track perimeter **1522** defined about the track **1516** in order to secure the connection between the location sensor **50** and the interface **1510**.

[0052] The interface body **1512** defines an outer surface **1524** that is shaped and configured so as to match the outer surface **50**A of the location sensor **50** when the interface **1510** is attached to the location sensor. Of course, the particular shape and configuration of both the location sensor and the interface can vary from what is shown and described. Also, the particular connection point of the interface with the location sensor can vary. The interface body **1512** further defines an end surface **1528** that remains externally accessible when the interface **1510** is operably attached to the location sensor (FIGS. 3A, 3B), as well as an inner surface **1528** (FIGS. 3C, 4B, 4C) that is inaccessible when the interface is attached to the location sensor. As will be described, various connection points are included on both the end surface **1526** and the inner surface **1528** to enable various components of the catheter placement system **10** to operably connect with the location sensor **50**. The size, shape, type, and number of connection points can vary from the below discussion.

[0053] FIGS. **4**A-4C depict further details regarding the interface **1510**. As shown, the end surface **1526** includes various connection points for enabling interconnection with components of the catheter placement system **10**. Specifically, the end surface **1526** includes a pair of ECG lead connector receptacles **1530** disposed in a recess **1532**. The ECG lead connector receptacles **1530** each include a female contact **1530**A sized and configured to receive therein a male connector end of the leads of the ECG electrodes **158**. In the present embodiment, the recess **1532** is shaped so as to receive a dual connector that includes both male connector ends of the ECG electrodes **158** in a single plug, though other configurations are also possible for the ECG lead connection scheme.

[0054] FIG. **4**A shows that the fin **1520** includes an ECG stylet wire receptacle **1542**, surrounded by a centering cone **1544**, for removably receiving therein a pin contact **170** (FIG. **7**) of a tether connector **132** of the ECG stylet **130** (FIG. **6**). Further details regarding connection of the ECG stylet **130** to the interface **1510** and the location sensor **50** are given further below.

[0055] FIG. **4**A further shows that the console cable **140** is permanently attached so as to extend from the interface **1510**, as shown. The length of the console cable **140** can vary according to need, but is sufficient in the present embodiment to extend between the location sensor **50** and the console **20**, as shown in FIG. **2**.

[0056] The inner surface **1528** of the interface **1510** includes various connection points for enabling interconnection of the aforementioned components with the location sensor. As shown, in FIGS. **4**B and **4**C, a USB type B plug **1550** of the console cable **140** extends from the interface inner surface **1528** to operably connect with a corresponding USB type B receptacle **1570** (FIG. **5**) disposed in the pocket **1514** when the interface **1510** mates with the location sensor **50**. Similarly, a rounded, cylindrical ECG plug **1560** extends from the interface inner surface **1528** to operably connect with a corresponding, cylindrically shaped ECG receptacle **1580** defined in the pocket **1514** when the interface **1510** mates with the location sensor **50**.

[0057] Specifically, the ECG plug **1560** includes an ECG stylet wire contact **1560**A that is operably connected with the ECG stylet wire receptacle **1542** on the fin **1520**, as well as two ECG lead contacts **1560**B that are operably connected with the ECG lead electrical contacts **1530**A in the ECG lead receptacle **1530** included on the interface end surface **1526**. In the present embodiment, the ECG lead contacts **1560**B are integrally formed with the ECG lead contacts **1530**A and are formed as sleeves so as to receive corresponding ECG lead pins **1580**B disposed in the ECG receptacle **1580**. The ECG receptacle **1580** further includes an ECG stylet pin **1580**A for operably connecting with the sleeve-type ECG stylet wire contact **1560**A of the ECG plug **1560**. FIGS. 3A, **8**A, and **8**B show the manner of attachment of the interface **1510** within the pocket **1514** of the location sensor **50**.

[0058] FIGS. **6** and **7** show details of the ECG stylet **130**, including the pin contact **170** included in a channel **172** of the tether connector **132**, as described further above. As shown in FIGS. **8**A and **8**B, the tether connector **132** is slid over the fin **1520** in a snug friction fit such that the pin contact **170** is received within the ECG stylet wire receptacle **1542**. The ECG stylet wire receptacle **1542** is operably connected within the interface body **1512** with the ECG stylet wire contact **1560**A. Thus, this connection establishes an electrically conductive pathway from the ECG stylet **130** to the location sensor **50** via the operable connections of the pin contact **170** with the ECG stylet wire receptacle **1542**, and the ECG stylet wire contact **1560**A (FIG. 4C) of the interface **1510** with the ECG stylet wire pin **1580**A (FIG. **5**) of the location sensor. This, in turn, enables ECG signals detected by the ECG stylet **130** to be conveyed to the location sensor **50** and, in one embodiment, the console **20** for processing by the system **10**.

[0059] Correspondingly, FIG. **8**B shows the connector ends of the leads of the ECG external electrodes **158** received within the ECG lead connector receptacles **1530** of the interface **1510** such that they each operably connect with a corresponding one of the electrical contacts **1530**A therewithin. Thus, conductive pathways are established from the ECG external electrodes **158** to the location sensor via the operable connections of the connector ends of the ECG external electrode leads with ECG lead connector receptacles **1530**, and the ECG lead contacts **1560**B (FIG. **4**C) of the interface **1510** with the ECG lead pins **1580**B (FIG. **5**) of the location sensor.

[0060] Also, conductive pathways are established from the location sensor **50** to the console **20** (FIGS. **1**, **2**) via the operable connection of the console cable **140**, namely, the operable connection of its male connector **1550** of the interface **1510** (FIG. **4**C) with the receptacle **1570** of the location sensor (FIG. **5**). Note that while shown as a USB-type cable, the console cable can include other styles, types, form factors, etc.

[0061] In the above-described configurations, therefore, the location sensor and attached components are ready for use by the catheter placement system **10**, in one embodiment. Indeed, FIG. **12** shows the manner of use of the location sensor **50** when connected with the various components described above during a catheter insertion procedure using the catheter placement system **10**. Note that the tether connecter **132** is configured to pierce a sterile drape **1600** (which is placed over the patient during catheter insertion procedures) such that regions above the drape are considered a sterile environment, while the location sensor **50**, the fin **1520**, and the console cable **140** are not considered sterile. The manner in which the tether connector **132** is able to pierce the drape **1600** and operably connect with the location sensor **50** enables such a connection without compromising the sterility of the sterile field.

[0062] Note that the various connecting components described with the above electrically conductive connections can vary in size, type, number, etc., from what is discussed herein. Note further that in the present embodiment attachment of the interface **1510** with the location sensor **50** is maintained via the friction fit of the various electrical connections between the interface and the location sensor, as just discussed above. In another embodiment, additional features can be included on one or both of the interface body **1512** and the location sensor **50** to provide a friction fit or other type of securement to maintain attachment between the interface and the location sensor.

[0063] FIGS. **9-11** depict the interface **1510** according to another embodiment, wherein the ECG stylet wire contact **1560**A and the two ECG lead contacts **1560**B discretely extend from interface body **1512** instead of being included in a male plug (FIG. **10**). Correspondingly, the ECG stylet wire pin **1580**A and the two ECG lead pins **1580**B of the location sensor **50** are discretely positioned instead of grouped within a receptacle in the location sensor pocket **1514** (FIG. **9**). Also, note that the shape and configuration of the track **1516** of the location sensor **50** (FIG. **9**) differs from that of the previous embodiment. These and other modifications are therefore contemplated.

[0064] FIG. **13** shows an interface connector configuration according to another embodiment, wherein a connector block **1660** includes not only the ECG stylet wire contact **1560**A and the ECG lead contacts **1560**B, but also two electromagnetic contacts **1660**A for providing power to an electromagnet element disposed in the ECG stylet **130** to be used when the system **10** is in TLS mode, described above. The particular arrangement and configuration of the various connectors can vary from what is shown here.

[0065] It is noted that the interface **1510** in one embodiment is reusable for multiple catheter insertion procedures, but is easily removable and replaceable should the need arise, such as in cases where damage to the wires or cables of the catheter insertion system **10** have been damaged due to use, accident, or repeated cleaning cycles. This, in turn enables replacement without the need to replace the entire location sensor, which can involve considerably more cost. Further, it is appreciated that the ECG stylet **130** and the external ECG electrodes and their leads are disposable and are disposed of after a single catheter insertion is complete. The console cable in one embodiment is permanently attached with the interface **1510** and thus is reusable. Also, though described here as employed with a location sensor, the interface in other embodiments can be employed to operably connect with other types of medical devices where interconnections as are enabled by the interface as described herein are needed. Further, note that various types of electrical connectors can be used to operably connect the various components described herein, including circuit board-edge connectors, peg and cuff-type connectors, type-C and other types of USB connectors, spring-loaded pins for pressing against conductive pads, etc. These and other connectors are therefore contemplated.

[0066] Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

1. A location sensor for use with a catheter placement system, the catheter placement system for positioning a catheter in a desired location within a body of a patient, the location sensor assembly comprising:

a location sensor body for temporary placement on a portion of the patient body; and

a connector interface configured to removably attach to the location sensor, the connector interface configured to provide a plurality of electrically conductive pathways between the location sensor and additional components of the catheter placement system to enable the additional components to operably connect with the location sensor, the connector interface further including a first connector configured to operably connect with a second connector of at least one of the additional components of the catheter placement system through a drape interposed between the first connector and the second connector.

2. The location sensor as defined in claim **1**, wherein the additional components include at least one of an ECG stylet configured to be removably disposed within a lumen of the catheter, an ECG external electrode, and a console of the catheter placement system.

3. The location sensor as defined in claim **1**, wherein the first connector includes a receptacle disposed on the connector interface that is configured to receive the second connector included with the ECG stylet.

4. The location sensor as defined in claim **3**, wherein the second connector of the ECG stylet is a male pin connector.

5. The location sensor as defined in claim **4**, wherein the receptacle of the first connector is disposed on a fin portion of the connector interface.

6. The location sensor as defined in claim **5**, wherein the location sensor includes at least one sensor configured to detect a magnetic element included with the ECG stylet to assist in placing the catheter within the body of the patient.

7. The location sensor as defined in claim **1**, wherein the connector interface is removably received within a pocket defined on the location sensor body.

8. The location sensor as defined in claim **7**, wherein the connector interface is disposed in the pocket via a friction fit.

9. The location sensor as defined in claim **8**, wherein a plurality of electrical connections are defined between the connector interface and the location sensor, the electrical connections providing the friction fit of the connector interface within the pocket of the location sensor.

10. The location sensor as defined in claim **1**, wherein the drape is configured to provide a sterile barrier and wherein the first and second connectors are configured to removably connect with one another through the drape without compromising the sterile barrier of the drape.

11. The location sensor as defined in claim **1**, wherein the location sensor is temporarily disposed on a chest portion of the patient.

12. The location as defined in claim **1**, wherein during use of the catheter placement system, the location sensor is disposed on a chest portion of the patient, the connector interface is removably attached to a pocket defined in the location sensor, and an ECG stylet is operably connected to the location sensor via the connector interface.

13. The location sensor as defined in claim **12**, wherein the console is operably connected to the location sensor via the connector interface and wherein a plurality of external ECG electrodes are operably connected to the location sensor via the connector interface.

14. The location sensor as defined in claim **1**, wherein the connector interface includes a cable permanently attached thereto.

15. The location sensor as defined in claim **14**, wherein the cable includes a USB cable that operably connects the location sensor to a console of the catheter placement system.

16. The location sensor as defined in claim **1**, wherein the connector interface is a replaceable component and is configured for use in multiple procedures to position catheters.

17. The location sensor as defined in claim **1**, wherein an ECG stylet and at least one external ECG electrode are disposable and are configured to operably connect to the connector interface.

18. The location sensor as defined in claim **17**, wherein electrical contacts for the ECG stylet and the at least one external ECG electrode are disposed on a male connector plug of the connector interface, the male connector plug configured to operably connect with a receptacle disposed in the pocket of the location sensor when the connector interface operably connects with the location sensor.

19. A catheter placement system for placing a catheter in a body of a patient, comprising:

a system console;

a location sensor operably connected to the system console via a console cable and configured for temporary placement on a portion of a body of the patient;

an ECG stylet configured to be removably disposed within a lumen of the catheter, and detect ECG signals when a distal portion of the catheter is disposed in the body of the patient, the ECG stylet including an electrically conductive second connector;

at least one external ECG electrode configured to be placed on the body of the patient; and

a connector interface configured to removably attach to the location sensor, the connector interface configured to operably interconnect the console, the ECG stylet, and the at least one external ECG electrode with the location sensor, the connector interface including a first connector configured to receive the second connector of the ECG stylet, the second connector configured to pierce a sterile barrier disposed over the location sensor and the connector interface.

20. The system as defined in claim **19**, wherein the first connector of the connector interface includes a receptacle, wherein the second connector of the ECG stylet includes a pin connector, and wherein the receptacle is configured to receive the pin connector of the ECG stylet therein, the pin contact configured to pierce the sterile barrier.

21. The system as defined in claim **20**, wherein the pin connector is disposed in a channel of a tether connector body included with the ECG stylet.

22. The system as defined in claim **21**, wherein the receptacle is included on a fin that extends from a body of the connector interface, the fin including a rounded leading edge.

23. The system as defined in claim **19**, wherein the sterile barrier includes a surgical drape.

24. The system as defined in claim **19**, wherein the connector interface is removably attachable to a pocket defined in the location sensor and wherein the connector interface enables the location sensor to receive ECG signals from the ECG stylet and from the at least one external ECG electrode.

25. The system as defined in claim **24**, wherein a rail of the connector interface is received within a track of the location sensor when the connector interface is attached within the pocket of the location sensor, the track including a recessed perimeter.

26. The system as defined in claim **19**, wherein the connector interface includes an outer surface that matches an outer surface of the location sensor when the connector interface is attached to the location sensor.

27-33. (canceled)

* * * * *

patsnap

专利名称(译)	基于ECG的导管定位系统的连接器接口		
公开(公告)号	US20160374589A1	公开(公告)日	2016-12-29
申请号	US15/192561	申请日	2016-06-24
申请(专利权)人(译)	C. R. BARD，INC.		
当前申请(专利权)人(译)	C. R. BARD，INC.		
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摘要(译)

公开了一种连接器接口，其被配置为实现与导管放置系统的位置传感器的部件互连。导管放置系统被配置为帮助临床医生将导管定位在患者体内的期望位置。在一个实施例中，位置传感器组件包括用于临时放置在患者身体的一部分上的位置传感器主体，以及连接器接口。连接器接口被配置成可移除地附接到位置传感器并在位置传感器和导管放置系统的附加部件之间提供多个导电通路，以使附加部件能够与位置传感器可操作地连接。连接器接口还包括第一连接器，该第一连接器构造成通过插入在第一和第二连接器之间的盖布可操作地与导管放置系统的一个附加部件的第二连接器连接。