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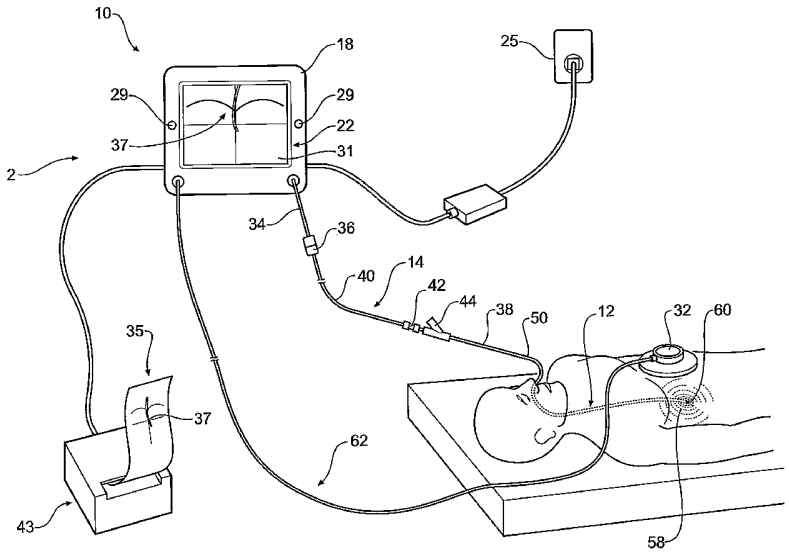

(57) Abstract: A tubing assembly (14) is disclosed, for use in conjunction with a catheter position guidance system (2) including a guiding insert (12) and any catheter (50), which assists in placing a catheter (50) at a chosen site in a body (78). A tubing assembly (14), when used in conjunction with a catheter position guidance system (2) assists in identifying the location of a catheter (50) (typically the distal end of the catheter) inside a patient's body (78) at the time the catheter (50) is inserted and as necessary during treatment of the patient. A tubing assembly (14) that can be used in conjunction with guiding inserts (2) of different characteristics is disclosed and in one embodiment comprises a tubular protector (40), a union device (42) and a fastener (44) for fastening the moveable guiding insert in relation to the catheter (50).

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TUBING ASSEMBLY FOR USE WITH A CATHETER POSITION GUIDANCE SYSTEM

CROSS REFERENCE TO RELATED APPLICATION

This application incorporates by reference the following co-pending patent application: "Catheter Locator Apparatus and Method of Use," filed on 21 August, 2003 having Australian Patent Application 2001283703 (83703/01) assigned to Micronix Pty Ltd.

BACKGROUND OF THE INVENTION

Physicians and other health care providers frequently use catheters to treat patients. An example of a known catheter includes a tube that is inserted into the human body.

Certain catheters are commonly inserted through the patient's nose, mouth or surgical incision to gain access to the gastrointestinal tract. These catheters sometimes referred to as enteral catheters are used to provide nutrients to the patient and are typically referred to as feeding tubes. The distal end of the catheter is placed into the stomach or intestines, and a feeding bag delivers liquid nutrient or water, or a combination of the two through the tube to the patient. Other functions that enteral catheters are used for include gastric decompression and functional motility studies.

Other types of catheters are inserted into the patient's veins or arteries to gain access to the cardiovascular system. These catheters include, among others, central venous catheters, peripheral venous catheter and peripherally inserted central catheter (PICC). These catheters are often multi-lumen tubes that are passed through the patient's veins or arteries. The health care provider uses these catheters for diagnostic purposes and to provide patients with medications, drugs, fluids, nutrients, or blood products over a pre-determined period of time, typically several days up to several months.

When using any of the abovementioned types of catheters, it is important to place the distal end of the catheter at the preferred site within the human body. Incorrect placement of the catheter tip may endanger the patient or decrease functionality of the catheter. For example, if the health care provider places an enteral catheter into the patient's lungs by mistake, liquid intended for the stomach or bowel may be introduced into the lungs with harmful consequences. If the health care provider places a catheter into the wrong site within the cardiovascular system, the patient may experience complications such as irritation of the vein leading to cardiac tamponade or increased incidence of thrombus formation, which can impair the function of the catheter. Further any medication passing into the tube will be delivered to the incorrect site.

In some cases, health care providers use X-ray machines to gather information that is used to confirm the correct placement of the catheter tip within the body. There are several disadvantages with using X-ray machines. For example, these machines are relatively large and cumbersome to use, require highly trained operators and expose the patient to radiation in instances where other methods might suffice. Also, due to their size, these machines are typically not readily accessible for use because, they are usually installed in a special X-ray room that is not necessarily convenient for any particular patient.

Best practice for radiation hygiene mandates the use of X-rays only in instances where there is a high benefit relative to the inherent risks.

There are also constraints in the effectiveness of X-rays to demonstrate correct placement that are inherent in the technology. Optimal two-dimensional representation of a three dimensional set of objects on X-rays is subject to operator technique and requires expert interpretation.

Therefore, health care providers can find it inconvenient and expensive to use X-ray machines for assistance or confirmation of their catheter

placement procedures. Furthermore, X-ray machines are inconvenient to transport to enable delivery of catheter placement procedures at their hospital bedside or at the patient's home for immediate confirmation of the location of the distal end of the catheter.

Accordingly, there is a need to overcome one or more of these disadvantages to enable timely treatment of the patient.

Electronic guidance systems are used to assist the health care provider to place the distal end of catheters to a chosen target area. Such electronic guidance systems may utilize the principle of inductive sensing of an electromagnetic signal. The guiding insert described herein may function as a radiator or a sensor for these systems and includes the use of a radiator or sensor located at or near the tip of the catheter being inserted that can be detected and its relative position indicated to the heath care provider during or after insertion of the catheter into the patient. Furthermore, the guiding insert can be used by the health care provider to manipulate the distal end of the catheter through the various passageways and cavities inside the patient, as it is usable to stiffen the catheter along its length by itself or in combination with the catheter to allow the useful manipulation of the catheter.

The electronic guidance systems can be used in conjunction with the guiding insert for catheters and used for the placement of catheters suitable for enteral or parenteral feeding and the other above-mentioned catheter types for their particular uses.

Electronic guidance systems can be used in conjunction with a guiding insert for catheters, and further applications include placement of Endotracheal Tubes, peritoneal dialysis catheters, Epidural, peripheral neurological catheters, investigational catheters and interventional catheters. An electronic guidance system used in conjunction with a guiding insert in the placement of cardiology catheters can also be useful for endoscopic investigation and percutaneous endoscopic gastrectomy catheter location,

these being only some of the possible uses of such a system. Without the guiding insert of the type described above, the catheter can be used with stiffening wire sometimes referred to as a stylet or used over a previously inserted guide-wire but typically only in conjunction with traditional location assistance, such as protocols and X-ray guidance and/or X-ray confirmation to locate the distal end of the catheter in the patient.

Accordingly, there is a need to overcome or minimize the disadvantages described and provide a means to better utilize electronic guidance systems when used in conjunction with a guiding insert to locate the distal end of a catheter. Part of that better utilization is the use of assemblies of tubing and other devices to assist the user of the electronic guidance system.

SUMMARY OF THE INVENTION

The present invention generally relates to a tubing assembly used in conjunction with a guiding insert that is used within a catheter as part of the disposable components of electronic catheter guidance systems. The electronic catheter guidance system can be used, and is not limited to the location of catheters for enteral, parenteral or other suitable catheter feeding applications or for the delivery of drugs to the heart or other parts and organs of the body by other types of catheters.

A guiding insert can be inserted into the catheter either during manufacture or at the time of the procedure for use in conjunction with the electronic catheter guidance system and is supplied with a tubing assembly for use at the time of placement of the catheter.

The guiding insert may consist of an elongated stiffener for stiffening the catheter when inserted therein and having a first end and a distal end located, when inserted in the catheter, adjacent the distal end of the catheter and a signal conductor wire connectable by its two ends to the electronic

catheter guidance system. The signal conductor wire forming a winding along a portion of the length of the elongated stiffener and further forming an electromagnetic field element located adjacent the distal end of the elongated stiffener that may radiate or receive an electromagnetic signal.

In the instance when the electromagnetic field element radiates a signal from inside the patient, the radiated signal is received external to the body of the patient.

Alternatively, the electromagnetic field element may be used as a signal receiver in instances when a signal is radiated from the outside of the patient.

In both instances, a received signal is communicated to an electronic catheter guidance system for processing, to provide the clinician with electronic data that aids the operator in the placement of the distal end of the catheter within the body of the patient.

For convenience, this specification will refer to the example of specialized tubing assembly that operates in conjunction with a guiding insert and elongated stiffener having an electromagnetic field element without limitation to whether it functions as a receiver or transmitter, when referring to the electromagnetic field element located at the distal end of a catheter.

The disposable guiding insert is housed within the catheter, thereby adding virtually no encumbrance to the user in the instance that the electronic guidance system is portable. This enables the benefit of utility that is not available by the use of X-rays for placement confirmation.

The following component parts of a tubing assembly can be supplied for use by the health care provider in conjunction with a catheter position guidance system:

Tubing which functions as a protector over part of the guiding insert assembly;

a union device, which is connectable to the tubular protector; and

a fastener for fastening the tubing protector to a user selectable location on the union device.

The tubing assembly can be supplied with or without a guiding insert and a catheter.

The tubing assembly can be supplied with or without a multi-way connector located at the proximal end of the catheter that is used for making connections to the catheter once its distal end has been appropriately located in the patient.

Catheters are constructed in a variety of dimensions of length. Tubing outer diameter and number of lumens are amongst the range of variations to which the guiding insert must be made to fit in order to function as intended.

Therefore, the calibre or outside diameter of the guiding insert must be of such a dimension that the guiding insert can be easily assembled into the catheter at the time of production or subsequently and easily removed during the procedure when required.

The guiding insert can be supplied separately and the health care provider places it into the catheter at the time of the procedure. The guiding insert can also be made to a pre-determined flexibility, robustness and be available in a variety of materials offering for example biocompatibility and other features.

The coupling mechanism between the tubing assembly and the catheter will also vary according to the shape of the opening at the proximal end of the catheter. Typically, this opening is configured to mate with a syringe or a connector to a tubing set, which is itself connected to a container, such as a bag, which holds fluids, or medications that are being administered to the patient, or a pump, which is, attached to a such a container.

The shape of the opening at the proximal end of the catheter is typically governed by the profile of the connector, which may have flanges that latch to the connector that is attached to the tubing that is connected to

the container referred to. An example of such a connector is a Luer lock connector.

Other connectors may use the principle of friction between tapered profiles of the mating parts, which fit together intimately and remain so when pushed together with moderate hand pressure. This type of design also utilizes the effect of slight compression of the male part and stretching of the female part that occurs due to deformation of the materials of which the connector components are fabricated. Manufacturers of catheters and connectors use a variety of materials in a range of combinations in order to achieve effective coupling between the connector on the catheter and the connector that attaches the container referred to, either directly or by means of tubing.

The opening to the catheter at the proximal end may be attached to a connector with multiple ports.

The present invention does not purport to assert any claim of novelty or proprietary interest in the multitude of solutions that enable coupling of syringes, tubing sets, pumps or other devices that enable a connection between a catheter and the container used to store fluids, medications or drugs, either with single or multiple connections. Of necessity, the present invention only has utility when coupled to a catheter. The present invention cites one example of such a coupling mechanism. Tube couplings that employ longer or shorter profiles or latching mechanisms or otherwise, may be equally applied to the present invention.

The tubing assembly can be mated to a multitude of catheter connectors by employing the mechanism that is already the default for an existing connector. The opening in the connector into which the guiding insert is assembled may or may not have an end plug, which is used to prevent the ingress of foreign matter into a catheter when the port is not in use. Such

plugs are removed and discarded before placing the guiding insert into the catheter and connecting any associated tubing assembly.

The friction fit mechanisms can be designed to include an electrical connector during manufacture in order to adapt them to the guiding insert.

The present invention is applicable, but not restricted to catheters that have a "Y" port. A "Y" port enables the guiding insert to remain 'in situ' within the catheter while the operator introduces or withdraws fluid through the side port in the example shown.

Catheters are manufactured in various lengths to suit different applications.

The user may choose a specific length of catheter according to the size of the patient and the procedure being performed, or the user may alter the length of the catheter by cutting to length at the time of the procedure. The cutting of the catheter can be done at the distal or proximal ends and specific catheters are provided for each type of shortening procedure. For both instances, the relationship between the position of the electromagnetic radiation element and the distal tip end of the catheter must be consistent. Even catheters that are manufactured for supply with a particular guiding insert will likely require some mechanism for setting the length of the guiding insert into the catheter to correctly position the electromagnetic radiation element, since catheter manufacturing processes still involve some variability of length.

The user of a catheter guidance system will have the expectation that the electromagnetic radiation element is always at a known distance from the distal tip of the catheter, as the two ends cannot be at identical locations.

In order to maintain a predetermined distance between the electromagnetic radiation element and the distal end of the catheter during the assembly procedure, the tubing assembly, which couples the guiding insert to the catheter and the catheter position guidance system, may be

adjustable so that the electromagnetic radiation element can be inserted to a consistent distance adjacent to and spaced from the distal end of the catheter.

In other instances, the guiding insert may be supplied separately to a customer and not pre-assembled and packaged inside the catheter.

The coupling between the guiding insert and the catheter in this instance must be adjustable with a mechanism that can be locked, so that when the user has inserted the guiding insert themselves and are satisfied that the electromagnetic radiation element is the appropriate distance from the tip of the catheter, the coupling mechanism can be securely locked so as to fix the end of the electromagnetic radiation element with respect to the end of the catheter that is to be located in the patient.

Catheter guidance systems require radiation of an electromagnetic signal, which is either radiated from or received by an electromagnetic radiation element within the catheter.

The construction of the said electromagnetic radiation element is described but not limited to a coil made from highly conductive wire such as copper. The dimensions of the coil are optimized in order to meet the mechanical requirements of the catheter to which the guiding insert is adapted. This adaptation must take into account the user requirements regarding the minimum bend radius that the catheter may be subject to during the placement procedure, to ensure that the mechanical dimensions of the coil do not interfere with the proper functioning of the catheter.

The electromagnetic radiation element may be associated with an inductance-enhancing element operatively, that in a preferred arrangement is a high permeability core material such as ferrite, soft iron, or other material that enhances the field strength of the radiator or receiver, according to the configuration of the electromagnetic radiation element.

In order to assess the location of the distal tip of the catheter within useable accuracy, it is useful to confine the signal pick up/ radiation point to

the electromagnetic radiation element only. It is preferable for the receiver of the system not to pick up any noise radiating from other objects in the vicinity or for the signal conductors that connect the electromagnetic radiation element to the catheter position guidance system to radiate electromagnetic fields from that conductive wire. In the example described, the conducting wires are twisted upon themselves. In alternative designs, the conducting wires may be helically wound around an elongated stiffening wire in the instances when the wire is a pair of twisted stainless steel wires. In a further variation of the design, the conducting wires may be twisted upon themselves before being helically wound around the said stylet wires.

Another aspect of the invention is to isolate the conducting wire from its carrier the guiding insert to eliminate potentially damaging contact.

Another aspect of the present invention is to reduce the amount of time necessary to properly guide a catheter to a chosen site within the body.

Yet, another aspect of the present invention is to reduce the amount of radiation exposure associated with machines that assist in catheter placement.

Another aspect of the present invention is to reduce the likelihood of harm caused due to incorrect placement of a catheter within the body.

Yet, another aspect is to simplify the process of catheter placement procedures.

Still another aspect of the present invention is to increase the safety of catheter placement procedures.

Another aspect of the present invention is to adapt catheters of variable lengths to receive a guiding insert of a pre-set length.

Yet, another aspect of the present invention is to assist health care providers in guiding and locating catheters within the body at the patient's bedside.

Another aspect of the present invention is to increase the convenience of obtaining catheter placement information during and after placement of a catheter.

Additional features and advantages of the present invention are described in, and will be apparent from, the following Detailed Description of the Invention and the accompanying figures. In these descriptions, a radiating version of the electromagnetic radiation element in the guiding insert has been referred to. However, the same principle applies when the electromagnetic radiation element is a signal-receiving element.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 is a perspective view of the catheter position guidance system illustrating the display device, guiding insert and a receiver being used to position a catheter within a patient in one embodiment of the present invention.

Fig. 2 is schematic block diagram of the electronic configuration of the catheter position guidance system illustrating the processor, memory device, signal generator, input devices and output devices in one embodiment of the present invention.

Fig. 3 is a top or plan view of the guiding insert and the display device illustrating an enteral application involving a catheter inserted into a human body and indication of catheter information on the display device.

Fig. 4 is a top or plan view of the guiding insert and the display device illustrating a parenteral application involving a catheter inserted into a human body and indication of catheter information on the display device.

Fig. 5 is a perspective view of the guiding insert illustrating the tubing assembly and the signal generator being received by and housed in the tubing assembly in one embodiment of the present invention.

Fig. 6 is a perspective view of the guiding insert removed from the tubing assembly illustrating the tubular protector, union device, y-port connection, catheter and tip of the tubing assembly in one embodiment of the present invention.

Fig. 7 is a cross-section view of the tubular protector housing the wire assembly taken substantially along line VII - VII of Fig. 5.

Fig. 8A is a perspective view of the union device in one embodiment of the present invention.

Fig. 8B is a cross-section view of the union device taken substantially along line 8B – 8B of Fig. 8A.

Fig. 9 is a top or plan view of the proximal end of the union device in one embodiment of the present invention.

Fig. 10 is a perspective view of the y-port connector illustrating the feeding branch, additional branch, connection branch and flexible arms in one embodiment of the present invention.

Fig. 11 is a cross-section of the y-port connector taken substantially along line XI – XI of Fig. 10.

Fig. 12 is a perspective view of the y-port connector and catheter attached to the connection branch of the y-port connector in one embodiment of the present invention.

Fig. 13 is a perspective view of the end member or tip of the catheter in one embodiment of the present invention.

Fig. 14 is a top or plan view of a catheter not having the stop member or position controller arrangement of the present invention illustrating an example of an electromagnetic field radiator improperly extending beyond the distal opening of the catheter.

Fig. 15 is another view of a catheter not having the stop member or position controller arrangement of the present invention illustrating an

example of an electromagnetic field radiator improperly positioned with respect to the distal opening of the catheter.

Fig. 16 is a top or plan view of different sized catheters illustrating varying positions of the electromagnetic field radiator near the tip of the catheter due to manufacturing variations among the catheters.

Fig. 17 is a perspective view of the union device and the tubular protector illustrating a user inserting the distal end of the tubular protector into the union device.

Fig. 18 is a perspective view of the union device and the tubular protector illustrating a user adjusting the position of the electromagnetic field radiator within the catheter by placing the distal end of the tubular protector at various positions within the union device.

DETAILED DESCRIPTION OF THE INVENTION

I. Catheter Position Guidance System

Referring now to the drawings, in an embodiment illustrated in Figs. 1 and 2, the catheter position guidance system 2 includes: (a) an apparatus 10 having a housing 18 which supports a controller or processor 20 (Figure 2) and a display device 22; (b) a non-invasive movable receiver 32 electronically coupled to the processor 20 by a wire, cable, signal data connection or signal carrier 62; (c) a power source 25; (d) a hard copy device 43 electronically coupled to the apparatus 10 for in one example printing out paper or slips 35 having data and/or graphics 37 which indicate relative catheter location information also indicated on the display device 22; and (e) a guiding insert assembly 12 in communication with the receiver 32 and operatively coupled to the apparatus 10 by a signal conductor wire, cable, chord or electrical extension 34, which, in turn, is operatively coupled to the processor 20.

It should be appreciated that the device 32 is a receiver in one embodiment described in detail herein, where an electromagnetic field

radiator of the guiding insert assembly 12, is located inside the body of the patient. However, the device 32 may include a signal receiver and a signal transmitter that operate independently of each other to respectively receive and transmit a signal from and to a respective electromagnetic field radiator or receiver element located inside the body of the patient. Alternatively, the device 32 may include a transmitter to transmit a signal into the body of the patient to be received by a receiver element located therein being part of the guiding insert assembly.

As best illustrated in Fig. 2, the system 2, in one embodiment, includes: (a) a plurality of input devices 17 for providing input signals to the system 2 such as one or more control buttons 29, a touch screen 31 (that may be incorporated into the display device 22 as can the control buttons 29) and the receiver 32; (b) an electromagnetic field radiator 58 (Fig. 1) which radiates signals that are received by the receiver 32; (c) a memory device 21 including machine readable instructions and one or more computer programs (which, for example, may include a software program 30 and a plurality of algorithms 23) which are used by the processor 20 to process the signal data transmitted by the electromagnetic field radiator 58 and received by the receiver 32, as well as processing the type of guiding insert being used and the various control buttons operated or touch screen instructions required to operate the system; and (d) a plurality of output devices 19 such as the display device 22, the hard copy device 43 both of which indicate catheter tracking information to the health care provider and a signal transmitter device 51 for coupling to the electromagnetic field radiator 58. The display device 22 may be any suitable display including, but not limited to, a liquid crystal display (LCD), light-emitting diode (LED) display, cathode-ray tube display (CRT), or plasma screen.

Health care providers can use the system 2 in a variety of catheter positioning applications.

II. Guiding Inserts

In one example illustrated in Figure 3, the system 2 is used in an enteral application.

As best illustrated in Figs. 1, 3, 5 and 13 in one embodiment most suited to larger internal diameter catheters, the guiding insert assembly 12 includes: (a) an electrical connector 36 operatively connected to the processor 20 (shown in Figure 2); (b) a signal conductor wire assembly 38 operatively coupled to the connector 36; (c) an elongated stiffener 39 (this element when used alone is best known as a "stylet" that is used to stiffen the catheter 50 and assist the manipulation of the catheter into position) coupled to the connector 36 and serving in this embodiment as a support for the signal conductor wire assembly 38; and (d) an electromagnetic field radiator 58 (Figs. 1, 2, 3 and 13) operatively part of the signal conductor wire and located at the distal end of the signal conductor wire assembly 38. Further details of embodiments of various guiding inserts are provided in the co-pending commonly owned patent application referred to herein and incorporated by reference.

Fig. 3 shows a portion 70 of the guiding insert assembly 12 placed through the patient's nose 72 (or mouth). The distal end or tip 60 of the catheter 50 is positioned in the most appropriate location for enteral feeding which in Fig. 14 is shown in the jejunum 74, which is accessed by placing the catheter through the pyloric orifice of the stomach to gain internal access to the intestines of the patient. The guiding insert is shown in phantom in Fig. 3 because the jejunum 74 is located rearward of the large intestine shown forward most in the illustration.

The health care provider places the receiver 32 over the chest area 76 of a body 78 in accordance with procedures associated with the particular catheter position guidance system and the display provides an indication of the path of the distal end of the catheter while it is being placed. In particular,

the display device 22 and the hard copy device 43 indicate information related to the location of the tip portion 60 of the catheter which is adjacent the electromagnetic field radiator 58 of the guiding insert assembly 12 within the body 78, as well as information related to the shape of the pathway taken by the catheter unit 12 over time.

It should be appreciated that the system 2 need not indicate the exact location or path of the catheter unit 12 to assist the clinician in the placement of the distal end of the catheter at a desired location in the patient. In one embodiment, the indicia 33 on the display device 22 indicates where the distal end of the guiding insert assembly 12 is positioned with respect to an anatomical template of human anatomy. The health care provider uses the graphical indications 37 as a guide that is helpful in properly placing the distal end of the guiding insert assembly 12 in the jejunum 74 in preparation for enteral feeding.

In another example illustrated in Figure 4, a portion 71 of the guiding insert assembly 12 (which is not the same configuration as detailed in the earlier figures) is introduced into the patient's body 78 through a vein or artery 73 leading to the heart 75. The guiding insert assembly 12 of Figure 4 is in one embodiment a tubular protector and a signal conductor wire both connected to a connector at the proximal end of the tubular protector, the signal conductor wire connected to an electromagnetic radiation element located at the distal end of the tubular protector.

The tube like guiding insert is positioned within the catheter so that the electromagnetic radiation element is located adjacent the distal end of the catheter. Since the guiding insert is a tubular protector covering the signal conductor wire along its full length to the connector, the tubing assembly of the prior example is not required. In particular, the protective tubing from the connection of the catheter over the guiding insert is not required, but an arrangement to fix the guiding insert in relation to the end of the catheter that

in turn fixes the location of the distal end of the guiding insert adjacent the distal end of the catheter is still required. In this example, a quarter turn Leur lock connector 41 is typically available on the proximal end of the catheter and this is coupled to, in this embodiment, a Touhy Borst adaptor 45 through which the guiding insert is passed. In use, the Touhy Borst adaptor can be turned (approximately a half turn) to lock the outer surface of the guiding insert against any lateral movement so that the distal end of the guiding insert is fixed in location with respect to the catheter. The system 2 assists the health care provider in guiding the portion 71 of the guiding insert assembly 12 in the patient's vein or artery 73 to a desired cavity in the heart 75 in preparation for drug or other liquid delivery.

Referring to Figure 5, in one embodiment, guiding insert assembly 12 of the elongated stiffening wire type is connectable by the signal conductor wires to a catheter position guidance system having a processor. The tubing assembly 14 receives, protects and locks the electromagnetic radiator element 58 of the guiding insert assembly 12 adjacent the distal end (tip 60) of the catheter 50.

III. Tubing Assembly

As best illustrated in Figures 5, 6, 7, 8A, 8B and 9, in one embodiment, the tubing assembly 14 includes: (a) a tubular protector 40; (b) a union device 42 which receives the tubular protector 40 at one end and other elements at its other end; (c) an optional multi-port connector or y-port connector 44 attachable to the union device 42; (d) a catheter 50 connected to the optional y-port connector 44; and (e) a catheter end, bolus or tip 60 attached to the distal end of the catheter 50.

In one embodiment, the tubular protector 40 includes: (a) a proximal end 100 attachable to an attachment member or neck 108 of the connector 36; (b) a distal end 102 receivable by the union device 42 as shown in Fig. 5; (c) an internal diameter 104 (D1) which is substantially equal to or greater than an

external diameter 110 (D3), as shown in Fig. 7, of a guiding insert assembly 12 (consisting of an elongated stiffening wire and signal wire assembly 38, described below) so as to slide over the guiding insert assembly 12; and (d) having an external diameter 106 (D2). In another embodiment, the tubular protector 40 may fit tightly over the guiding insert assembly 12 so as to be secured to the wire assembly.

As best illustrated in Figs. 8A, 8B and 9, in one embodiment, the union device 42 includes: (a) a proximal end 116; (b) a distal end 118; (c) a position adjuster, extender or elongated neck 120 positioned between the proximal end 116 and the distal end 118; (d) a grasp or gripping member 122 positioned adjacent to the distal end 118 so as to assist users in grasping and manipulating the union device 42; (e) an insert 124 positioned adjacent to the gripping member 122 which is received by the y-port connector 44; and (f) an internal surface 126 of the passage 134 having a blocking member or stop 132 which prevents the tubular protector 40 from passing through the end 118. The gripping member 122 includes a plurality of protruding walls or ribbed members 136 protruding from a surface 123 of the gripping member 122 assisting the user in grasping the union device 42. In alternative embodiments, the surface 123 of the gripping member 122 may be rough or include other suitably shaped protrusions.

As shown in Fig. 9 the proximal end 116 of the union device 42 has an internal diameter 128 (D4) and an external diameter 130 (D5). When assembled, the proximal end 116 of the union device 42 is coupled to the distal end 102 of the tubular protector 40. In one embodiment, the internal diameter 128 (D4) of the proximal end 116 of the union device 42 is substantially equal to or larger than the external diameter 106 (D2) of the distal end 102 of the tubular protector 40. Referring back to Figure 6, this enables a portion 103 of the distal end 102 of the tubular protector 40 to be movably received by the elongated neck 120 of the union device 42. As

described above, the stop 132 having an internal diameter 133 (D3) of the union device 42 prevents the distal end 102 of the tubular protector 40 from passing through the distal end 118 of the union device 42 because 133 (D3) is smaller than 106 (D2) but equal to or larger than 110 (D3) the outer diameter of the guiding insert assembly 12.

Referring to Figs. 10-11, in one embodiment, the multi-port or y-port connector 44 includes: (a) a body 140; (b) an additional delivery branch 142 attached to the body 140 can be used for administration of saline or sterile water to assist removal of the guiding insert or to flush nutrients from the catheter, although not common the additional delivery branch 142 can be used for administration of drugs, medicine or other medicinal liquids to the patient; (c) a nutrient delivery branch or feeding branch 144 attached to the body 140 and sized to receive the insert 124 of the union device 42; (d) a catheter connection branch 146 attached to the catheter 50 (although this is shown as a frictional fit connection, since catheters very often have a Leur lock connector terminating the proximal end, some multi-port connectors may be fitted with a terminating end suitable for connection to a Luer lock connector); (e) a flexible or movable arm 148 attached to the body 140; and (f) a flexible or movable arm 150 attached to the body 140. In an alternative embodiment, y-port connector 44 includes additional branches for administering water, saline and various nutrients to the body 78. In another alternative embodiment, the y-port connector 44 includes only a feeding branch 144 and a connection branch 146. The arm 148 has a stopper 152 for fitment when not in use to the port 142, and the arm 150 has a stopper 154 for fitment when not in use to the port 144.

The stoppers 152 and 154 of the y-port connector are sized to prevent fluid from passing through the branches 142 and 144 after such branches 142 and 144 are plugged with stoppers 152 and 154, respectively. In addition, the arm 150 includes a fastener 155 that secures a tube-size adapter 156 to the arm

150. The tube-size adapter 156 enables fluid delivery tubes (not shown) having various diameters to connect to the feeding branch 144 of the y-port connector 44.

As illustrated in Figs. 12-13, in one embodiment, the catheter 50 includes a catheter with a body 160 having: (a) a proximal end 162 attached to the catheter connection branch 146 of the y-port connector 44; (b) a distal end 164; and (c) an external surface 166. The proximal end 162 is insertable into the catheter connection branch 146 of the y-port connector 44 to bring the catheter 50 into fluid communication with the y-port connector 44. In one embodiment, the external surface 166 has a plurality of volumetric, measurement or unit markings 168 uniformly spaced along the body 160 of the catheter 50. These markings 168 assist the user in measuring the flow or distribution of liquid to or from the patient. In an alternative embodiment, markings 168 on the catheter function as placement markers, which assist the user in assessing the depth that the catheter tube 50 is placed within the human body.

As best illustrated in Figure 13, in one embodiment, the end member, bolus or tip 60 is attached to the distal end 164 of the catheter 50. The tip 60 includes a body 172 and an end member 176. The body 172 defines a passage 178 and an opening 180. The opening 180 is positioned between the proximal end and the end member 176 of the tip. A portion 177 of the end member 176 can have a rounded shape. The shape of the passage 178 and opening 180 of the tip 60 is configured to facilitate the flow of fluid from the catheter 50 into the patient's body while decreasing the likelihood that the opening 180 will become clogged.

The tubular connector 40, union device 42, y-port connector 44, catheter 50 and tip 60 can be made from any suitable polymer or plastic material including, but not limited to, polyamide, polyethylene, polypropylene, polyurethane, silicone and polyacrylonitrile.

IV. Use of the Union Device

Referring now to Figs. 14-18, if there was no union device 42 or the union device 42 did not have the stop member 132 and a position adjuster or controller 120 of the present invention, several difficulties could arise. For example, a catheter procedure may involve positioning the tip 60 of a catheter 50 to a desired location. During the manufacturing process for catheters 50, the catheters 50 may have length variations V_1, V_2 and V_3 ranging up to about 7mm. In one embodiment, catheters 50 are constructed of silicon material, which provides the catheters 50 with a tendency to expand or contract during or after the manufacturing process thereby causing such variations. If one of the catheters 50 is too long, the electromagnetic field radiator 58 could protrude through the tip 60 as illustrated in Figure 14. If one of the catheters 50 is too short, the electromagnetic field radiator 302 could substantially stop short of the tip 60 as illustrated in Figure 15. This may result in a decrease in reliability of the information and graphical assistance provided by the catheter position guidance system 2 of the present invention.

The system 2 is more helpful when the electromagnetic field radiator 58 is positioned adjacent the tip 60 of the catheter 50. This positioning helps maintain an adequate level of reliability of guidance information provided by the system 2. In the embodiments illustrated, the union device 42 assists in maintaining the position of the electromagnetic field radiator 58 at or near the tip 60. The use of the union device 42, in one such embodiment, reduces the likelihood that the electromagnetic field radiator 58 might protrude through the tip 60 or stop substantially short of the tip 60. Therefore, the union device 42 functions as an electromagnetic field radiator placement control device. In one embodiment, this placement and control function of the union device 42 is adjustable to conform to catheters 50 that have different lengths.

As best illustrated in Figs. 16, 17 and 18, the union device 42 has a proximal end 116, a distal end 118 and a position controller, position adjuster or elongated neck 120. The position adjuster or elongated neck 120 defines a passage 134 that provides the position adjustment function or adjustment device of the union device 42. The user can adjustably position the second end 102 of the tubular protector 40 to a plurality of different locations 138 (for example, L_1 - L_3) along the passage 134. Once the user determines the proper location, as shown pictorially in Fig. 18 the user fixes the tubular protector 40 to the position adjuster 120 at that selected location.

The position may be fixed using any suitable fastening device or agent, a non-exhaustive example list includes, adhesive, clip, clasp, tape or any other suitable fastener. Because the tubular protector 40 is connected to the electrical connector 36 that, in turn, is connected to the electromagnetic field radiator 58, the fastening of the tubular protector 40 to the appropriate location on the position adjuster 120 assists in the useful positioning of the electromagnetic field radiator 58 relative to the tip 60 of the catheter 50 which itself is connected either directly to or via another connector to the distal end of the union device 42. This allows the user to position the electromagnetic field radiator 58 at a desired or designated location relative to the end members or tips 60 of catheters 50 of various lengths. Thus, users can use the system 2 with manufactured catheters 50 having various lengths or those that may need to be cut to length before use.

In one example, the system 2 is used by first determining the length of the catheter 50. Prior to placing the catheter 50 into the human body for enteral or parenteral feeding, the user or assembler places the electromagnetic field radiator 58 at a desired location within the catheter 50. Next, the assembler locks this placement by fastening the tubular protector 40 to the union device 42 using a suitable fastener, which may include an adhesive.

The health care provider then places the receiver 32 on the patient's chest and inserts the catheter 50 into the body. While doing so, the display device 22 displays graphics 37 that help the user in guiding the catheter tip 60 to a desired location within the human body. Once the catheter 50 is placed in the desired location, the user removes the guiding insert assembly 12 while the position of the catheter 50 is maintained. The user then attaches saline and nutritional delivery tubes to the y-port connector 44 for introducing fluids into the body for medical treatment.

It will also be understood by those skilled in the art that, in alternate embodiments, the guiding insert assembly of the present invention need not include the radiator position control device described above. Here, the assemblers may measure each catheter and disregard each catheter that is too long or too short. It should be appreciated that other assembly processes and mechanisms may be used to control the proper location of the field generator 58 relative to the catheter tip 60.

It should also be appreciated that the tubing assembly, guiding insert assembly and catheter position guidance system of the present invention can be used in a variety of catheter procedures and applications. These procedures may involve the treatment of the gastrointestinal tract, cardiovascular system or other portions of the human body. These procedures may involve treatment of humans by physicians, physician assistants, nurses or other health care providers. In addition, these procedures may involve treatment of other mammals and animals by veterinarians, researchers and others.

The present invention, in one embodiment, includes a tubing assembly and a guiding insert having an electromagnetic field radiator of a catheter position guidance system. The tubing assembly and guiding insert assembly are used in conjunction with other components of the system to assist the user in performing a catheter placement procedure. The tubing assembly has a

position controller that enables the system to be used with catheters of variable lengths. Therefore, the tubing assembly and guiding insert assembly, used in conjunction with the catheter position guidance system of the present invention, provide an enhancement in medical treatment.

It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

THE CLAIMS:

1. A tubing assembly used in conjunction with a catheter position guidance system, the tubing assembly comprising:

a guiding insert for use with a catheter during placement of the catheter, the guiding insert having an electrical connector for connection of the guiding insert to the catheter position guidance system and an electromagnetic field radiator at the distal end of the guiding insert;

a tubular protector having a first end connected to the electrical connector, a second end, an internal diameter and an external diameter, the internal diameter being substantially equal to or greater than the diameter of the guiding insert;

a union device having a first end and a second end, the first and second ends each having an internal diameter and an external diameter, the first end of the union device being inserted into the second end of the tubular protector, the internal diameter of said first end being substantially equal to or larger than the external diameter of the second end of the tubular protector;

a fastener securing the tubular protector to a user-selectable location on the union device; and

a catheter having a first end and a second end, the first end being attached to the second end of the union device wherein, the electromagnetic field radiator at the distal end of the guiding insert is located adjacent the second end of the catheter.

2. The tubing assembly of Claim 1, further comprising:

a tube connector having a plurality of ends located between the union device and the catheter, wherein a first one of the ends of the tube connector is attached to the second end of the union device and a second one of the ends of the tube connector is attached to the first end of the catheter.

3. The tubing assembly of Claim 1, wherein the union device includes an elongated neck positioned between the first and second ends of the union device.

4. The tubing assembly of Claim 1, wherein the union device includes a gripping member positioned between the first and second ends of the union device.

5. The tubing assembly of Claim 1, wherein the union device includes a position controller.

6. The tubing assembly of Claim 1, wherein the union device includes a stop.

7. The tubing assembly of Claim 1, wherein the tube connector has an additional branch, a feeding branch, a connection branch and plurality of movable arms.

8. The tubing assembly of Claim 1, wherein the catheter includes an external surface having a plurality of designated unit markings uniformly spaced along the catheter.

9. The tubing assembly of Claim 1, wherein the catheter includes on the second end an end member.

10. The tubing assembly of Claim 9, wherein the end member includes a first portion and a second portion, the second portion having a rounded shape and the first portion defining a passage and an opening

between the second end of the catheter and the second portion of the end member.

11. A tubing assembly for use in conjunction with a catheter position guidance system, a guiding insert for use with a catheter during placement of the catheter, the guiding insert having an electrical connector for connection of the guiding insert to the catheter position guidance system and a electromagnetic field radiator at the distal end of the guiding insert, in use the electromagnetic field radiator of the guiding insert located at the distal end of the catheter; the tubing assembly comprising:

a tubular protector having a first end attachable to the electrical connector, a second end, an internal diameter and an external diameter, the internal diameter being substantially equal to or greater than the diameter of the guiding insert;

a union device having a first end and a second end, the first and second ends each having an internal diameter and an external diameter, the first end of the union device being coupled to the second end of the tubular protector, the internal diameter of said first end being substantially equal to or larger than the external diameter of the second end of the tubular protector;

a fastener securing the tubular protector to a user-selectable location on the union device.

12. The tubing assembly of Claim 1, further comprising:

a tube connector having a plurality of ends located between the union device and the catheter, wherein a first one of the ends of the tube connector is attached to the second end of the union device and a second one of the ends of the tube connector is attached to the first end of the catheter.

13. The tubing assembly of Claim 1, wherein the union device includes an elongated neck positioned between the first and second ends of the union device.

14. The tubing assembly of Claim 1, wherein the union device includes a gripping member positioned between the first and second ends of the union device.

15. The tubing assembly of Claim 1, wherein the union device includes a position controller.

16. The tubing assembly of Claim 1, wherein the union device includes a stop.

17. The tubing assembly of Claim 12, wherein the tube connector has an additional branch, a feeding branch, a connection branch and plurality of movable arms.

18. A tubing assembly for use in conjunction with a catheter position guidance system, a guiding insert for use with a catheter during placement of the catheter, the guiding insert having an electrical connector for connection of the guiding insert to the catheter position guidance system and an electromagnetic field radiator at the distal end of the guiding insert, the elongated electrical conductor having a diameter, the tubing assembly comprising:

a tubular protector having a first end, a second end, an internal diameter and an external diameter, said first end attachable to the connector, the internal diameter being substantially equal to or greater than the diameter of the elongated electrical conductor;

a union device having a first end, a second end, an elongated neck, a gripping member, an insert and an internal surface, the first end of the union device being coupled to the second end of the tubular protector, the internal surface having a stop, the elongated neck, gripping member and insert being positioned between the first and second ends, the first and second ends each having an internal diameter and an external diameter, the internal diameter of said first end being substantially equal to or larger than the external diameter of the second end of the tubular protector;

a fastener securing the tubular protector to a user-selectable location on the union device;

a y-port connector defining an additional branch, a feeding branch, a connection branch and a plurality of movable arms, the feeding branch sized to receive the insert of the union device, each of the movable arms having a stopper;

a catheter including a body having a first end, a second end and an external surface, said first end being attached to the connection branch of the y-port connector, the external surface having a plurality of designated unit markings uniformly spaced along the body of the catheter; and

a tip attached to the second end of the catheter, the tip including a body having a collar and an end member, the body defining a passage and an opening, the opening positioned between the collar and the end member, a portion of the end member having a rounded shape.

19. The tubing assembly of Claim 18, which has a fastener securing the tubular protector to a user-selectable location on the elongated neck.

20. The tubing assembly of Claim 18, wherein the gripping member of the union device includes a plurality of ribbed members.

21. The tubing assembly of Claim 20, wherein the elongated neck and the fastener include a position controller.

22. The tubing assembly of Claim 19, wherein the fastener includes an adhesive.

23. A tubing assembly for use in conjunction with: (a) a catheter position guidance system having a connector; (b) an electromagnetic field radiator; (c) one of a plurality of catheters, each of the catheters having an end member and being of a different length; and (d) at least one elongated electrical conductor connecting the connector to the electromagnetic field radiator, the tubing assembly comprising:

a tubular protector having a first end and a second end, said first end attachable to the connector;

a union device having a first end, a second end and a neck positioned between the first end and the second end, said first end being movably coupled to the second end of the tubular protector, the neck defining a passage, the second end of the tubular protector adjustably positionable to a plurality of different locations along the passage so that the electromagnetic field radiator is positionable at a desired location relative to the end member of any one of the catheters;

a fastener securing the tubular protector to the neck at one of the different locations; and

a multi-way connector defining a plurality of branches, a first one of the branches of the multi-way connector attachable to the second end of the union device.

24. The tubing assembly of Claim 23, wherein the fastener includes a device selected from the group consisting of an adhesive, a clip, a pin and tape.

25. The tubing assembly of Claim 23, wherein the union device includes a gripping member having a plurality of ribbed members.

26. The tubing assembly of Claim 23, which includes a tube-size adapter.

27. The tubing assembly of Claim 26, wherein the multi-way connector has at least one movable arm, wherein at least one section of the movable arms engages with the tube-size adapter.

28. The tubing assembly of Claim 23, which includes a catheter in fluid communication with the multi-way connector.

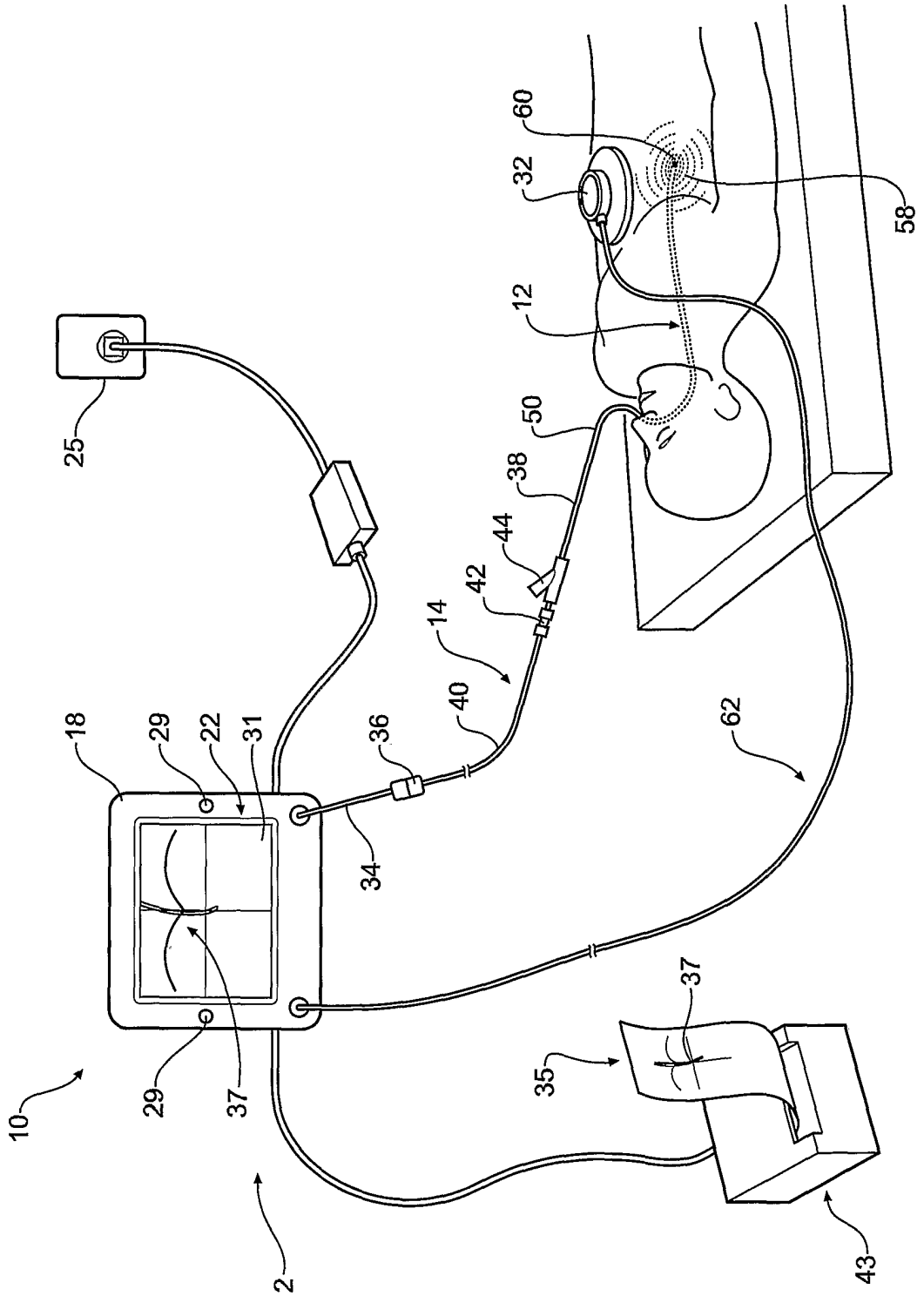
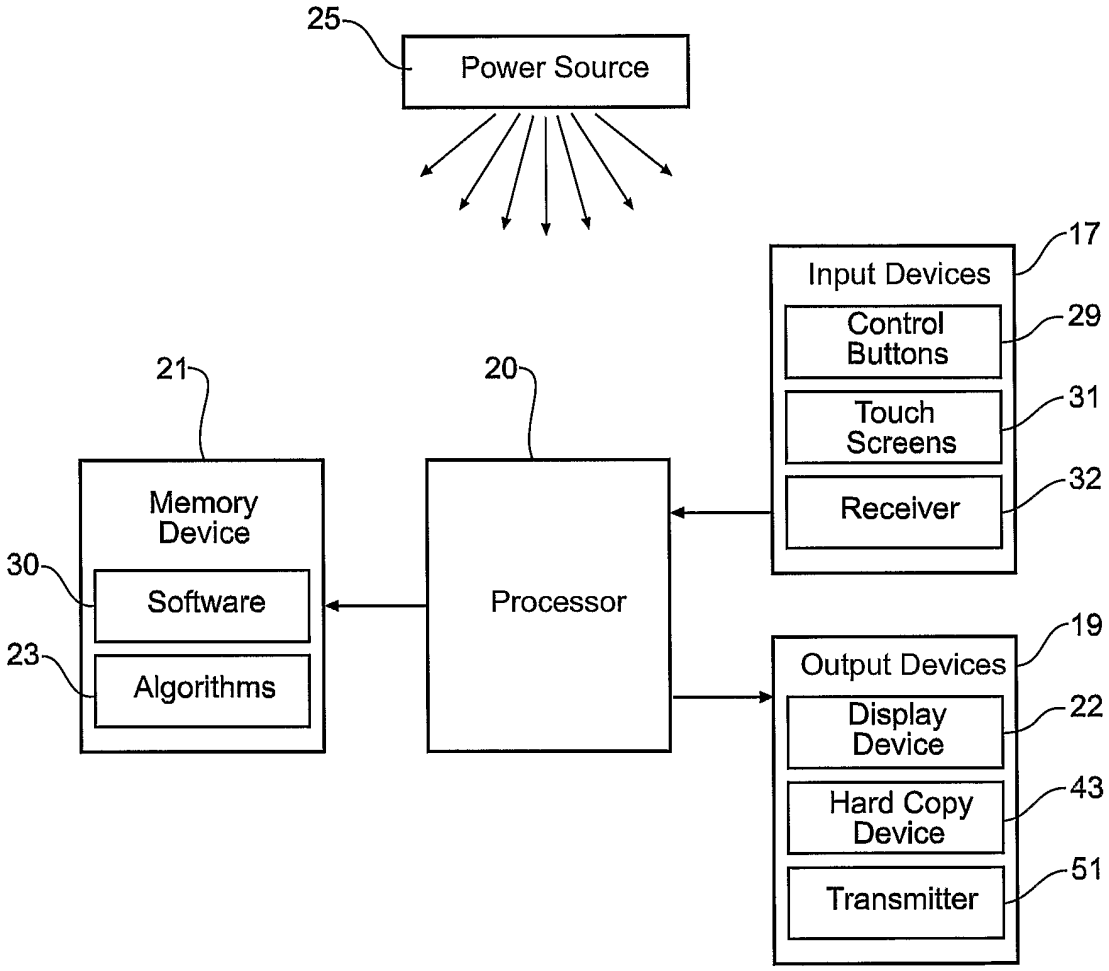


FIG. 1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Power Source
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Input Devices
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Control Buttons
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Touch Screens
32
Receiver
21
Memory Device
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Software
23
Algorithms
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Processor
19
Output Devices
22
Display Device
43
Hard Copy Device
51
Transmitter

FIG. 2

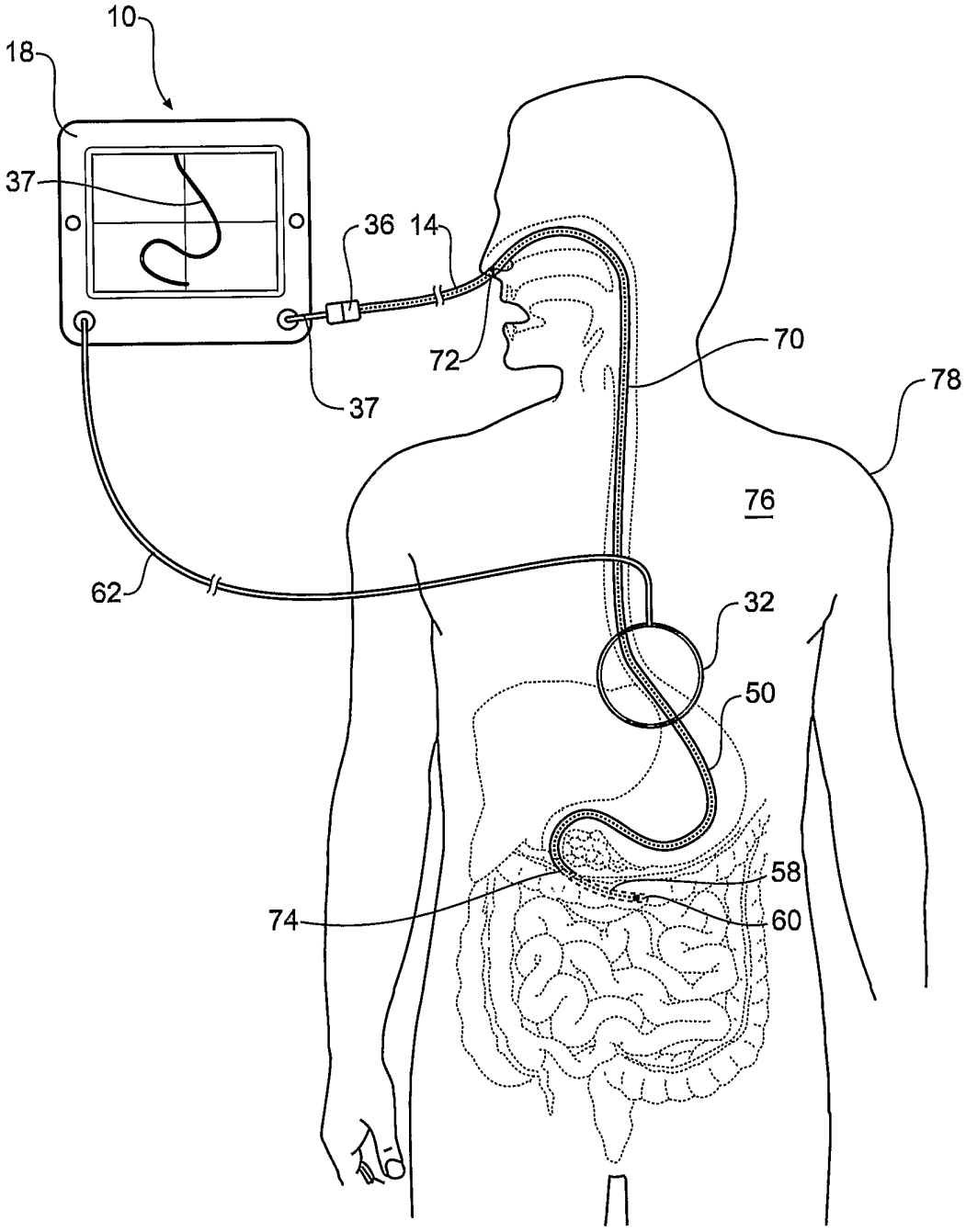

FIG. 3

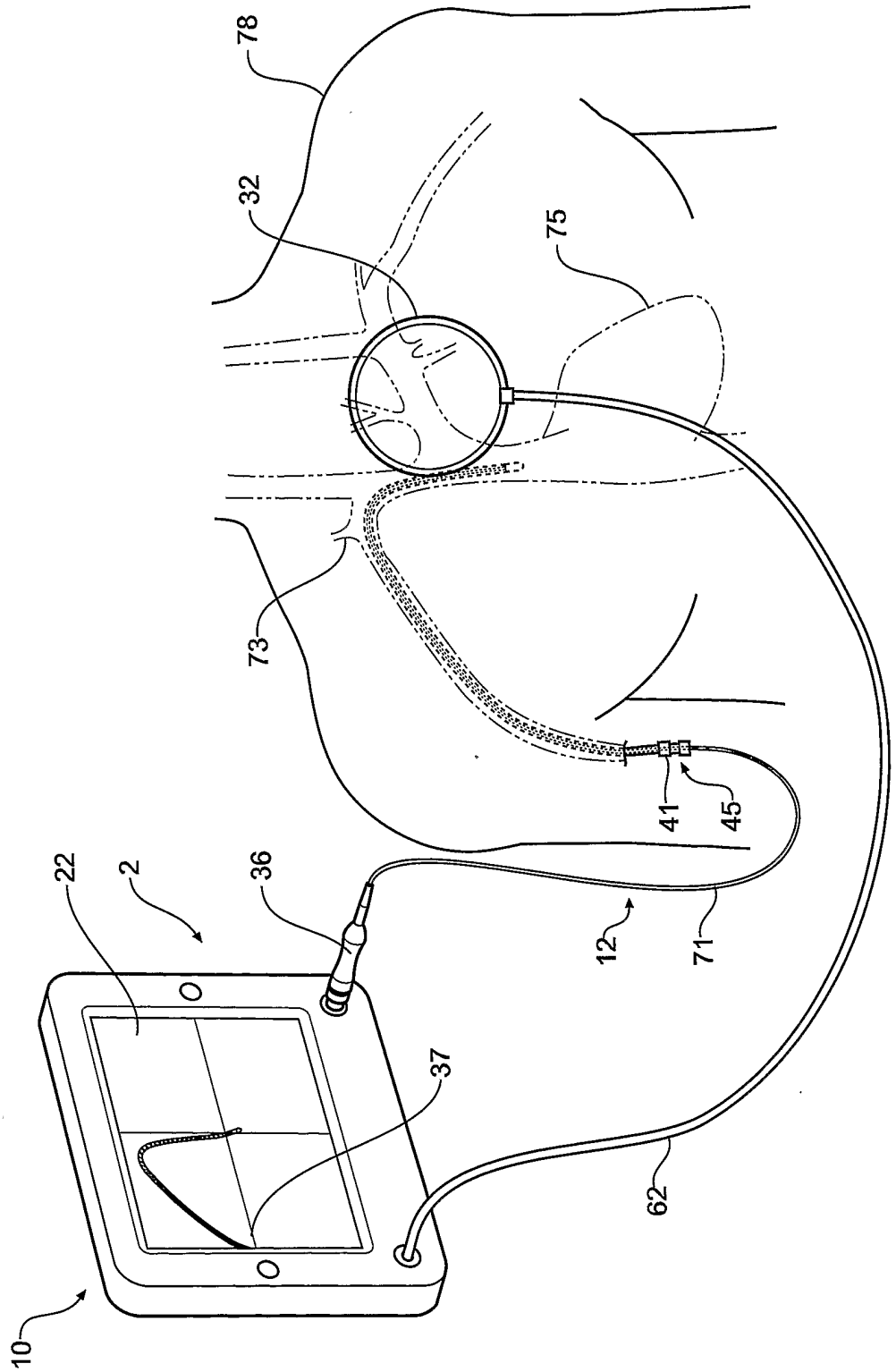

FIG. 4

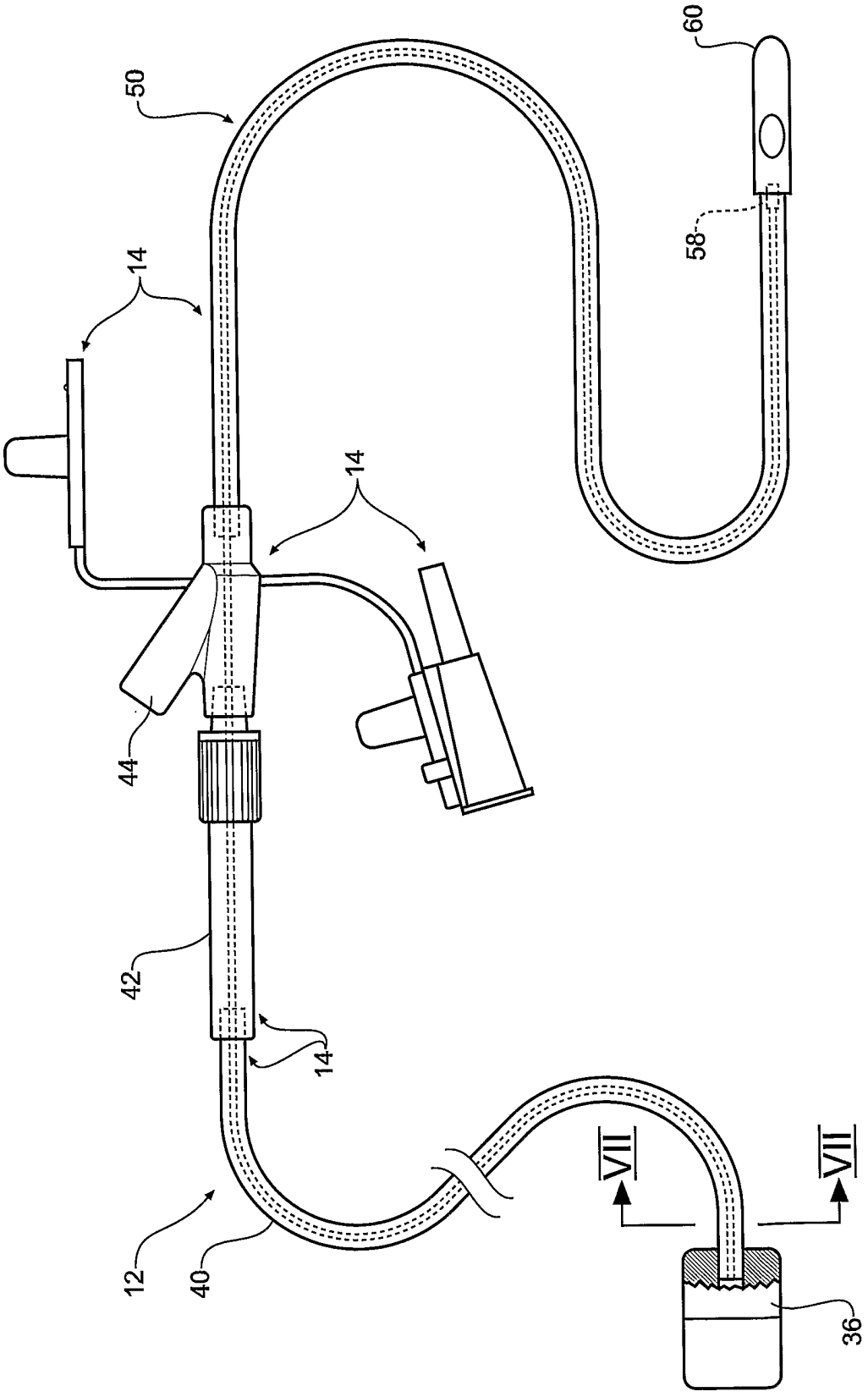

FIG. 5

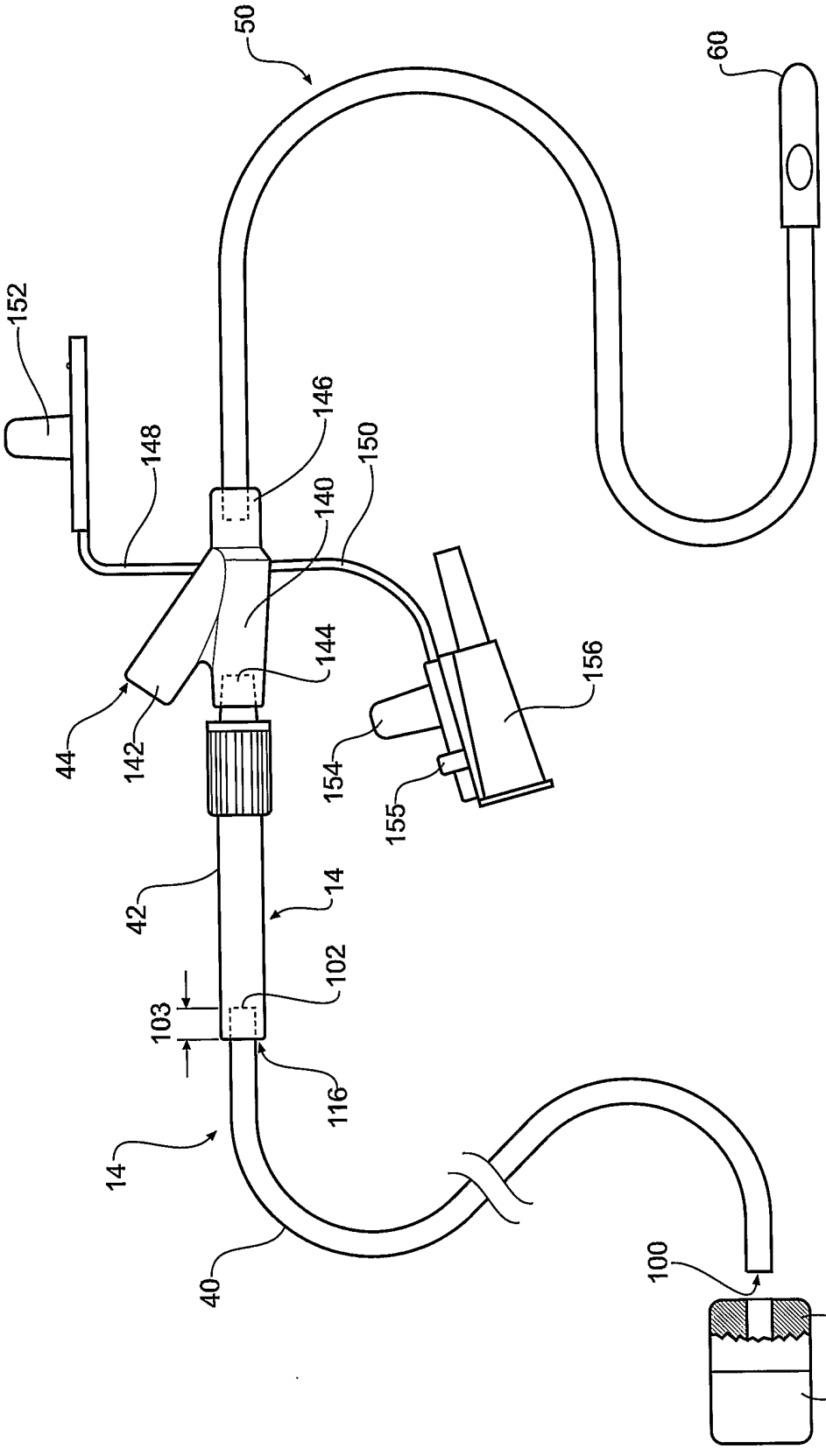
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FIG. 6

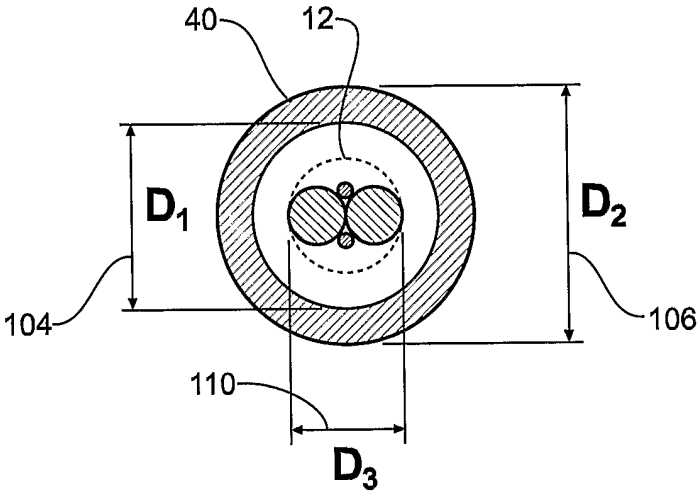

FIG. 7

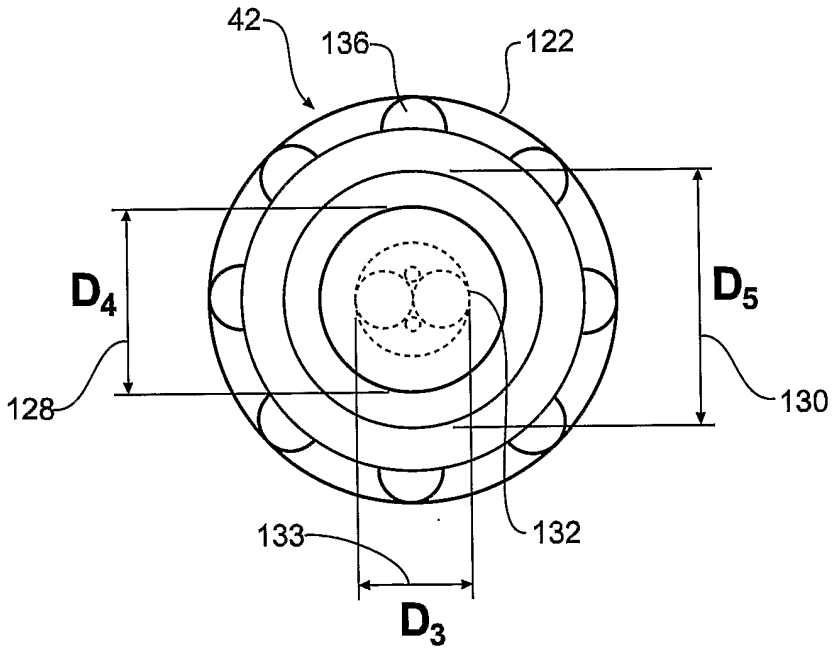

FIG. 9

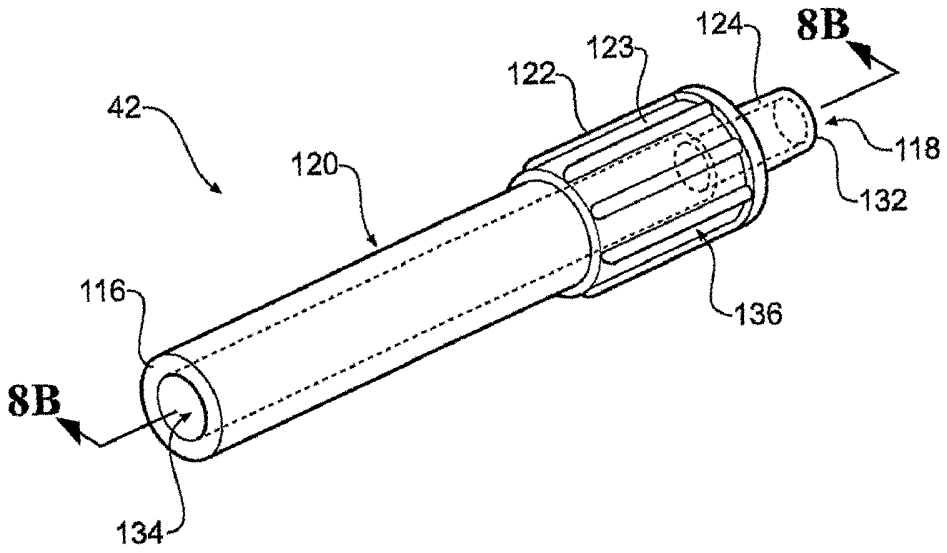
8B
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FIG. 8A

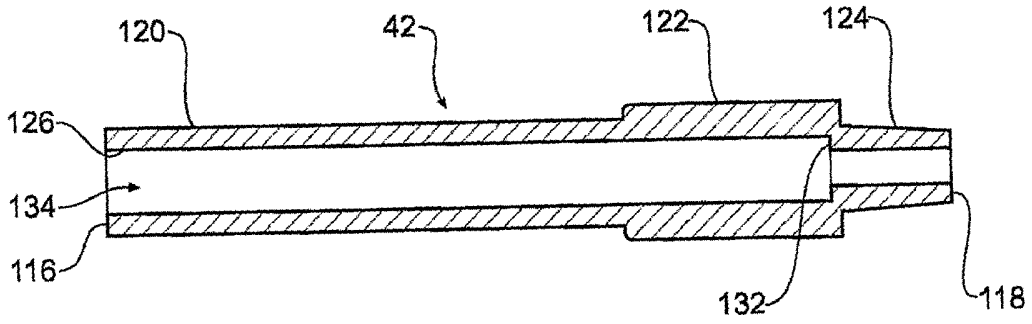
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FIG. 8B

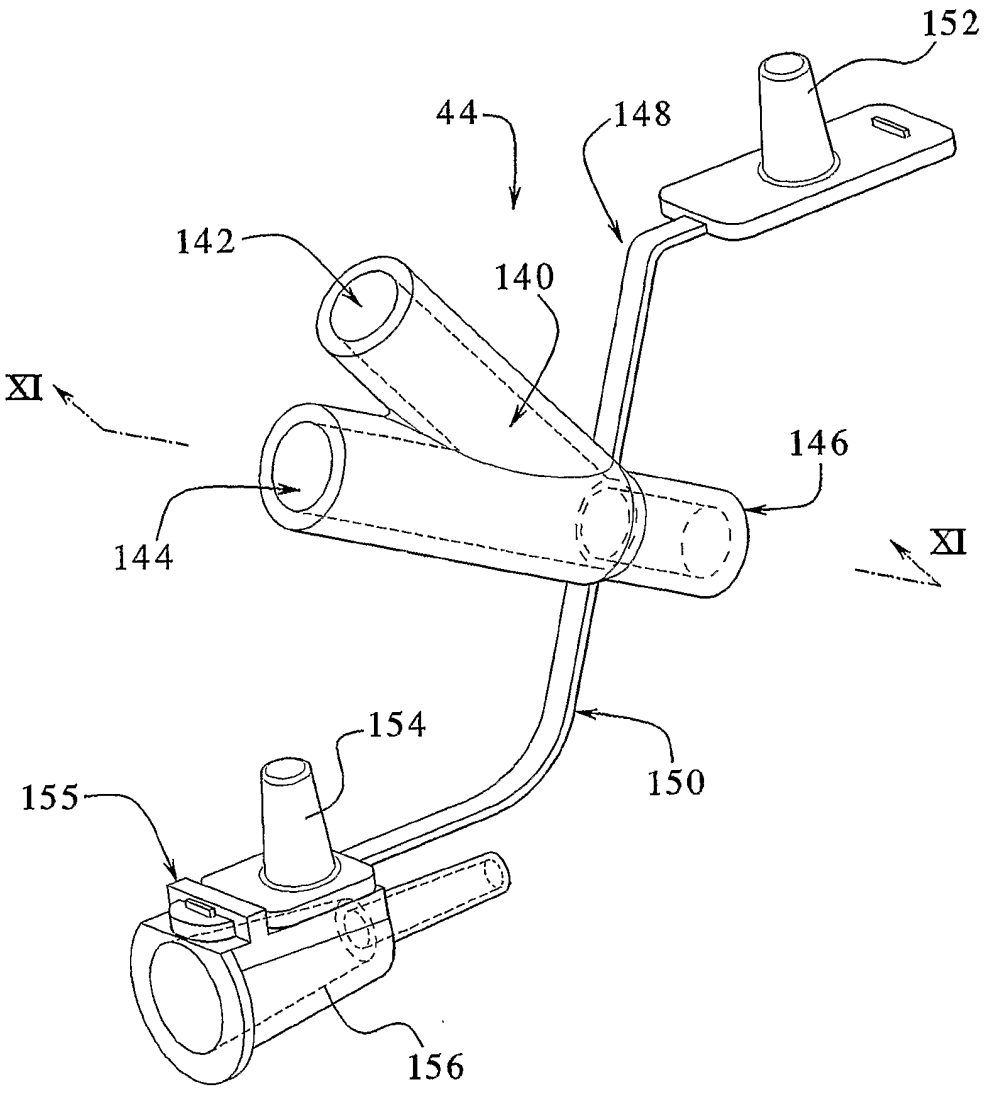

FIG. 10

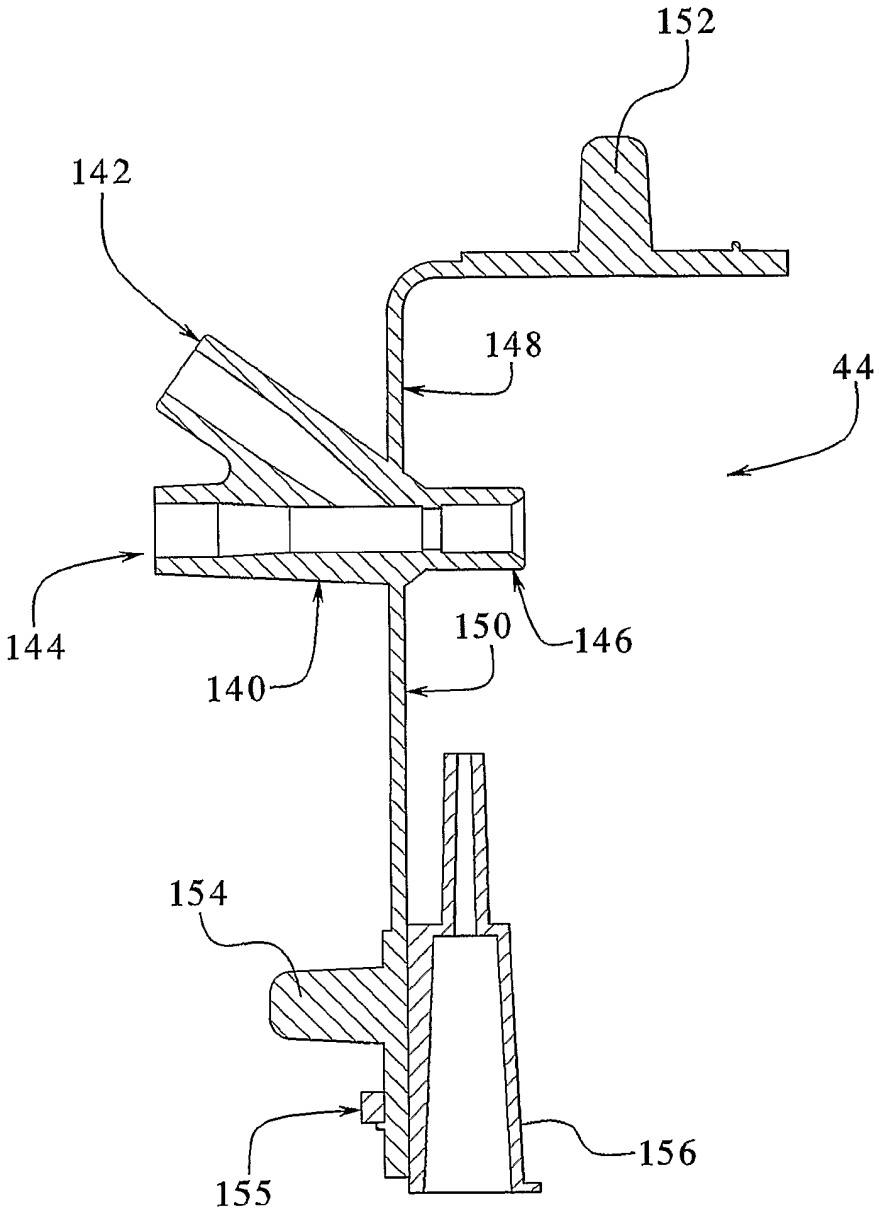

FIG. 11

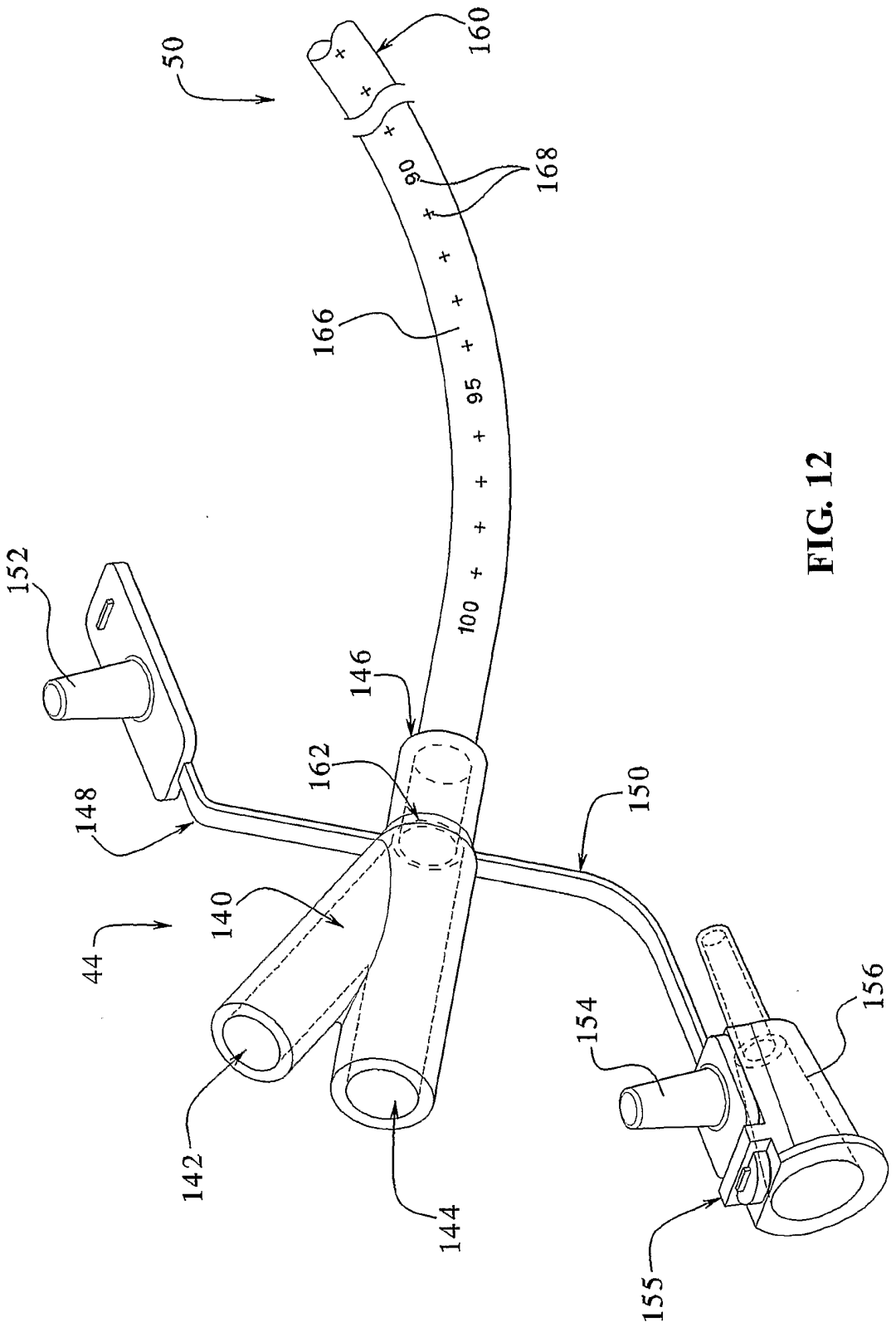

FIG. 12

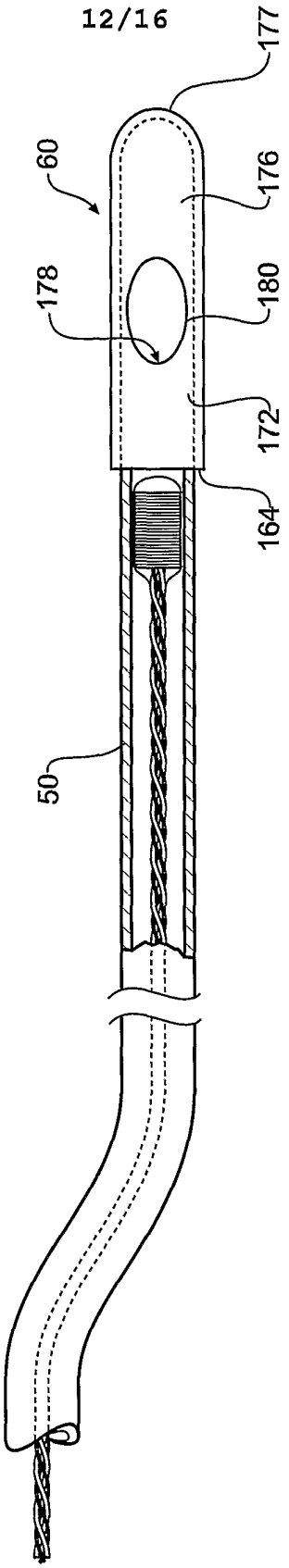

FIG. 13

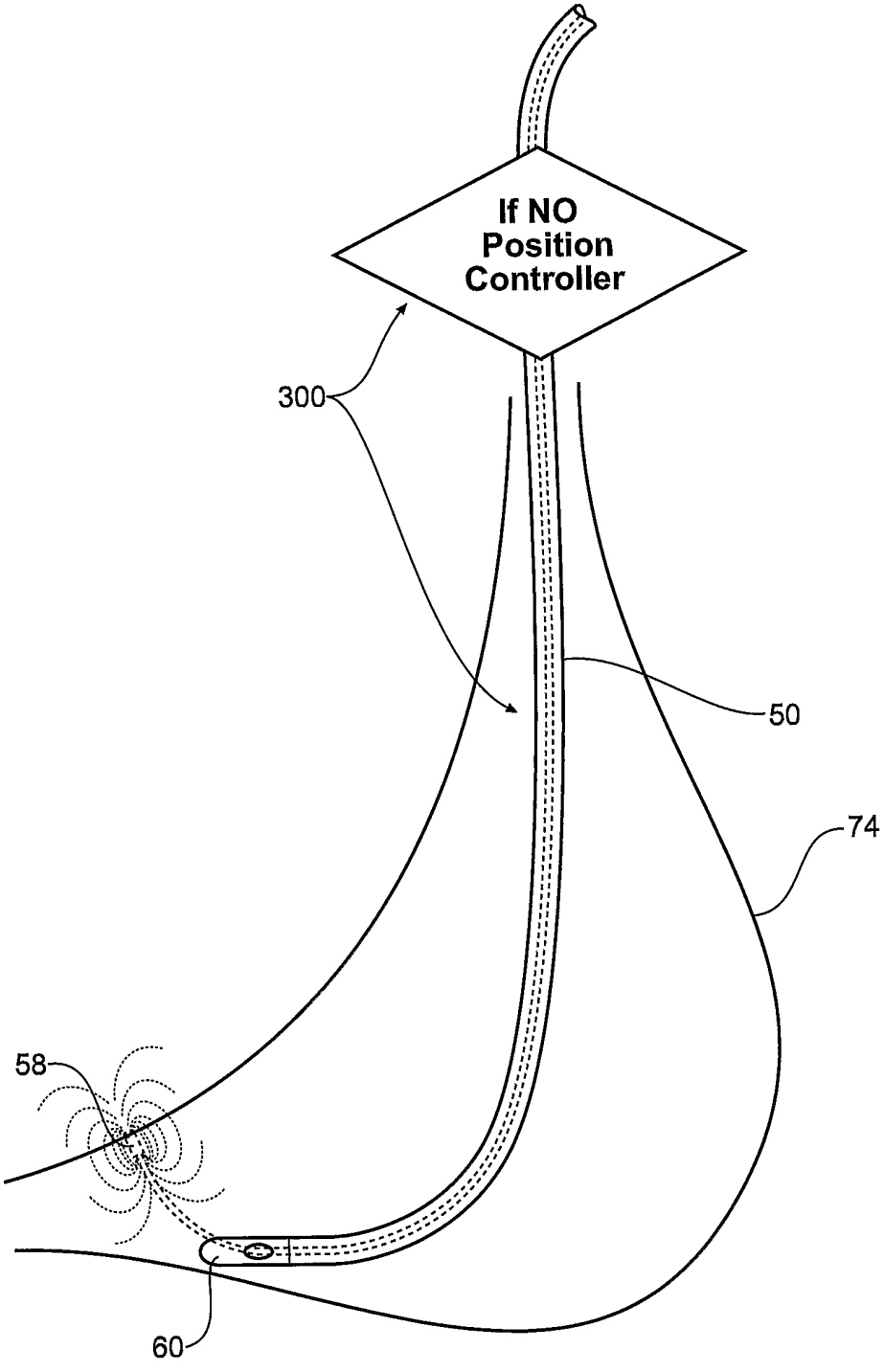

FIG. 14

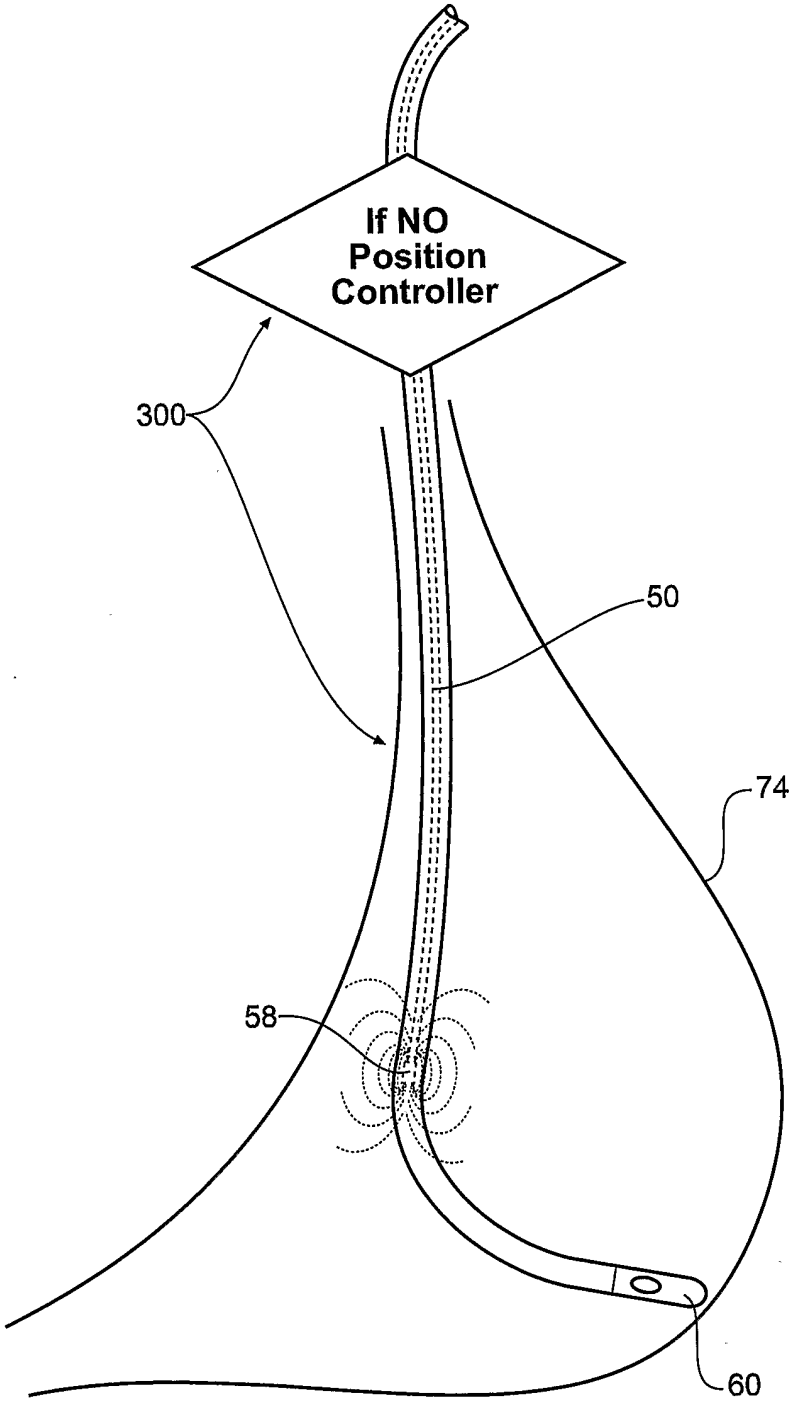

FIG. 15

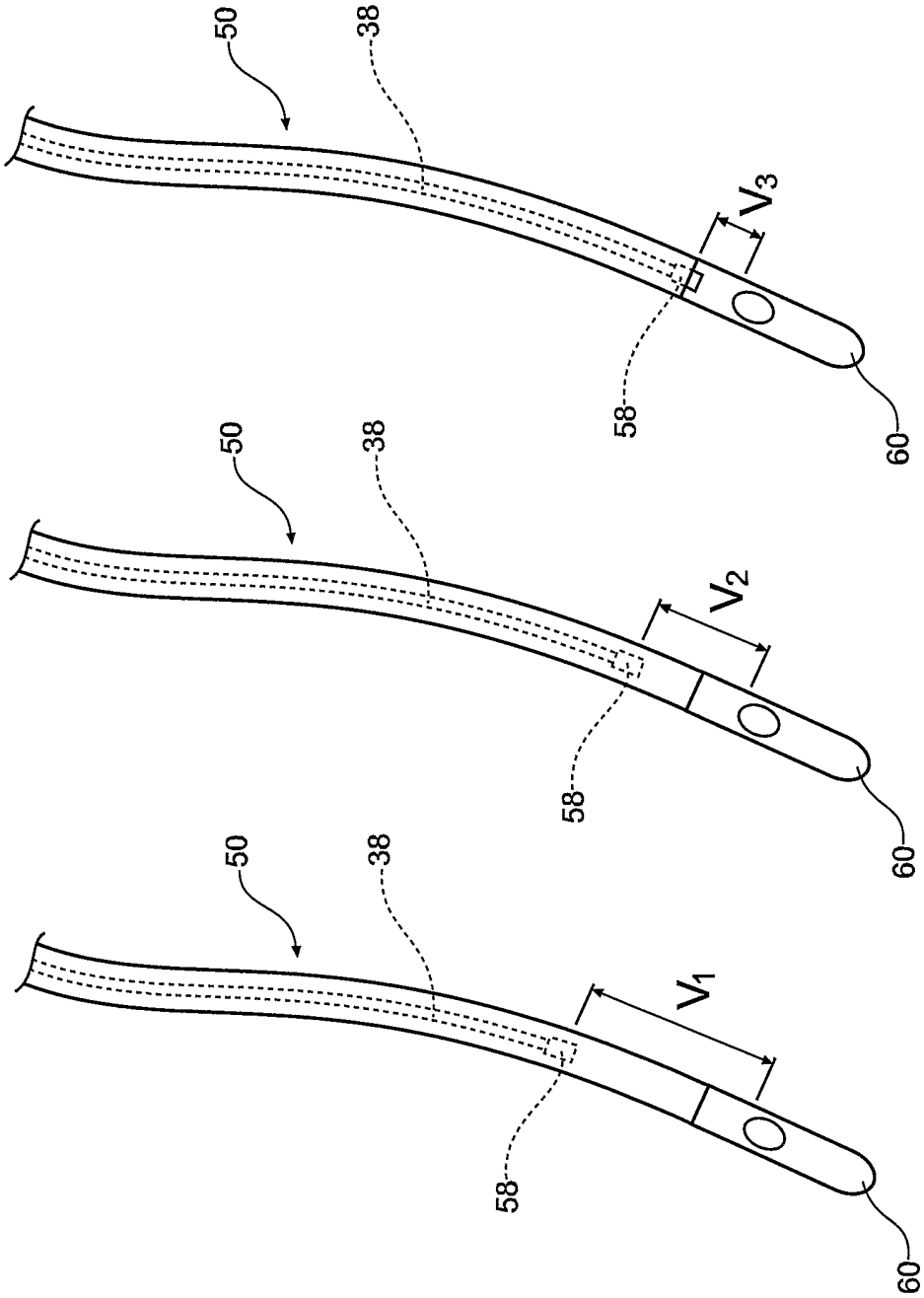

FIG. 16

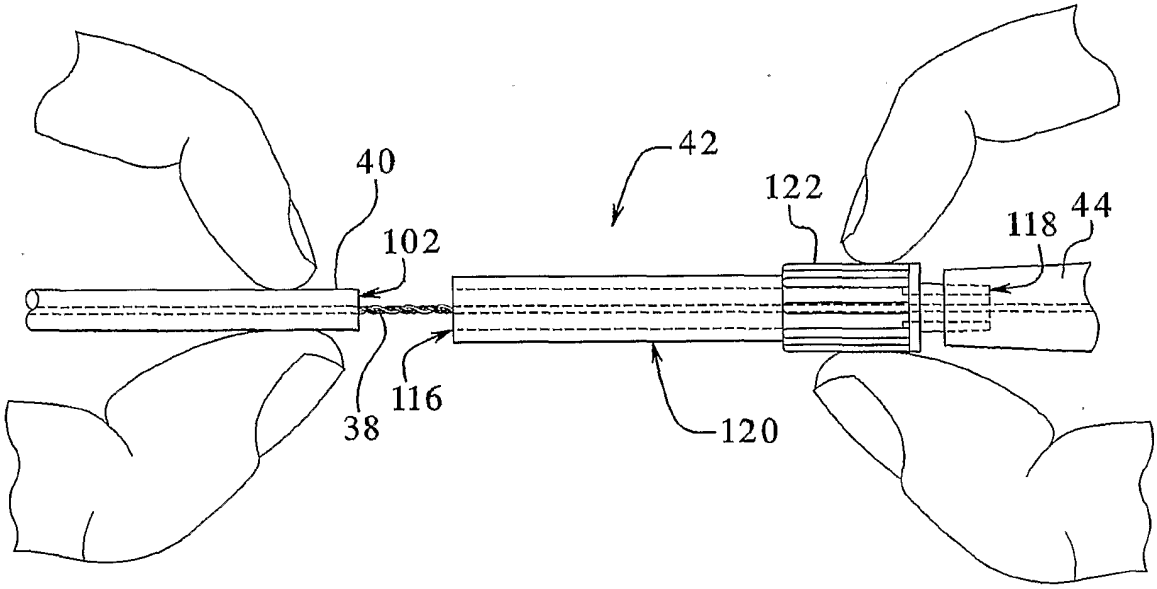
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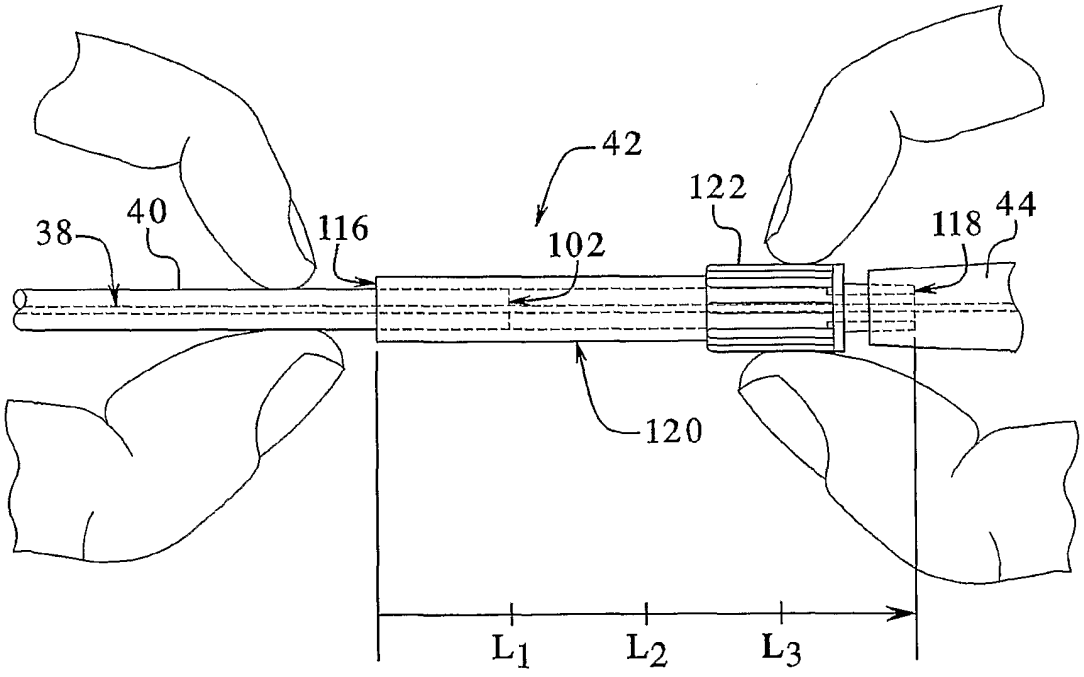
FIG. 17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L2
L3

FIG. 18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000026

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 25/095 (2006.01)

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)

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)
DWPI:IPC A61M 25/; A61B & keywords: (catheter, connector, adaptor, union, adjust, vary, length, distance, tip, tube, stiff, style, wire, EM, electromagnetic, RF, position, guide, radiate, transmit, receive, detect, sensor) and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5211165 A (DUMOULIN ET AL) 18 May 1993 Whole document	1-17, 23-28
Y	WO 2003/089037 A1 (JOMED GMBH) 30 October 2003 Whole document	1-17, 23-28
X	US 2004/0138570 A1 (NITA ET AL) 15 July 2004 Whole document	1-17, 23-28

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 February 2006	10 FEB 2006
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **KAREN VIOLANTE** Telephone No : (02) 6283 7933

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000026

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 10043310 A (TERUMO CORP) 17 February 1998 Abstract and figures 1-14	1-28
A	WO 2003/061752 A1 (QUINN) 31 July 2003 Whole document	1-28
A	US 6200305 B1 (BERTHIAUME ET AL) 13 March 2001 Whole document	1-28
A	US 5727553 A (SAAD) 17 March 1998 Whole document	1-28

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2006/000026**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5211165		NONE				
WO	03089037	DE	10217868	EP	1496971	US	2006004328
US	2004138570	EP	1594424	WO	2004064677		
JP	10043310		NONE				
WO	03061752	EP	1409061	EP	1557192	US	2004158229
US	6200305		NONE				
US	5727553		NONE				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX