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(71) Applicant *(for all designated States except US)*: **KONINKLIJKE PHILIPS ELECTRONICS N.V.** [NL/NL]; Groenewoudseweg 1, NL-5621 BA Eindhoven (NL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **FEER, David, L.** [US/US]; P.O. Box 3001, 345 Scarborough Road, Briarcliff Manor, New York 10510-8001 (US). **SILBER, Daniel, A.** [US/US]; P.O. Box 3001, 345 Scarborough Road, Briarcliff Manor, New York 10510-8001 (US).

(74) Agent: **DAMEN, Daniel, M.**; Philips Intellectual Property & Standards, High Tech Campus 44, P.O. Box 220, NL-5600 AE Eindhoven (NL).

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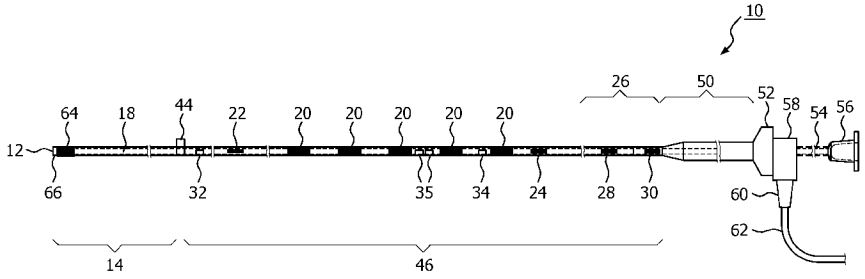

FIG. 1

(57) Abstract: A medical device comprises: a feeding tube (70) including a feeding lumen (80) with an opening (152) at a distal end of the feeding tube and an electrical lumen (84) having access openings (120) spaced apart along the feeding tube; a set of insulated electrical conductors (82) disposed in the electrical lumen, the set of insulated electrical conductors having electrically exposed portions (132, 132a, 132b) proximate to the access openings; and electrodes (72, 73, 74, 75, 78, 79, 140) comprising electrically conductive material portions (140) disposed in the access openings and electrically contacting the proximate electrically exposed portions of the set of insulated electrical conductors disposed in the electrical lumen. The electrodes include at least one upper or proximal electrode (74, 75, 78, 79) disposed above an expected patient heart electrical centerline (CL) and at least one lower or distal electrode (72, 73) disposed below the expected patient heart electrical centerline.

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MULTIFUNCTION FEEDING TUBE

DESCRIPTION

The following relates to the medical care arts, neonatal and pediatric care, feeding tubes for neonatal patients or pediatric or adult patients, physiological monitoring arts, and so forth.

A neonatal patient, such as a newborn baby with an identified medical condition, or a prematurely born baby, or so forth, is sometimes fed via feeding tube. In a nasogastric feeding tube arrangement, for example, a feeding tube is inserted into a nasal orifice and is passed down through the esophagus to terminate in the stomach. Feeding tubes are also used for pediatric or adult patients who cannot ingest adequate sustenance due to a medical condition.

Patients undergoing therapy employing a feeding tube are typically also subject to monitoring of one or more physiological parameters such as cardiac cycling (e.g., heart rate and/or ECG), respiration, core body temperature, or so forth. The neonatal or other patient is thus connected with a feeding tube and physiological probes such as electrocardiograph (ECG) electrodes, a thermister or other temperature sensor, or so forth. The feeding tube and the various physiological probes are connected with corresponding monitoring devices (ECG monitor, patient thermometer, or so forth) by wires or cables. The patient is made uncomfortable by these connections, patient movement is restricted by the wires or cables, and the various wires and cables present physical obstacles for physicians, nurses, or other attending medical personnel. In the case of a neonatal patient, adhesion of skin electrodes can also be problematic due to poor skin development and the humidity and temperature controlled incubator environment.

During insertion of a new feeding tube, care must be taken to ensure that the feeding tube follows the esophageal path to the stomach (rather than the bronchial path into the lungs), and to ensure that the distal end of the feeding tube is properly positioned (typically in the stomach, rather than in the esophagus or lower down in the stomach). Incorrect positioning of the feeding tube can result in aspiration of feeding material into the lungs or other medical complications. Problematically, existing feeding tubes typically do not provide positive positional feedback during insertion.

The feeding tube is a disposable device, that is, it is generally not reused for different patients. In the case of a prematurely born baby, undersized baby, or other neonatal patient, the feeding tube may need to be replaced frequently due to typically rapid neonatal growth rate. As a disposable item, it is advantageous for the feeding tube to be of low manufacturing cost. The feeding tube also should remain reliable under exposure to the esophageal and stomach environment, which is highly acidic and includes corrosive digestive fluids. In practice, feeding tubes are typically simple hollow tubular elements of silicone, polyurethane, or another robust material.

The present application provides new and improved feeding tubes, and methods of manufacturing and using same, which overcome the above-referenced problems and others.

In accordance with one aspect, a device comprises: a feeding tube including a feeding lumen with an opening at a distal end of the feeding tube and an electrical lumen having access openings spaced apart along the feeding tube; a set of insulated electrical conductors disposed in the electrical lumen, the set of insulated electrical conductors having electrically exposed portions proximate to the access openings; and electrodes comprising electrically conductive material portions disposed in the access openings and electrically contacting the proximate electrically exposed portions of the set of insulated electrical conductors disposed in the electrical lumen.

In accordance with another aspect, a method of constructing a device is disclosed, the method comprising: forming a feeding tube including a feeding lumen and an electrical lumen parallel with at least a portion of the feeding lumen and having access openings spaced apart along the feeding tube; inserting a set of insulated electrical conductors into the electrical lumen of the feeding tube, the set of insulated electrical conductors having electrically exposed portions that are proximate to the access openings after the inserting; and after the inserting, forming electrodes by a process including injecting electrically conductive material portions into the access openings of the electrical lumen to electrically contact the proximate electrically exposed portions of the set of insulated electrical conductors disposed in the electrical lumen.

In accordance with another aspect, a device is disclosed which is constructed by the method of the immediately preceding paragraph.

In accordance with another aspect, a device comprises: a feeding tube including a feeding lumen with an opening at a distal end of the feeding tube and an electrical lumen; a set of insulated electrical conductors disposed in the electrical lumen; electrodes disposed along the feeding tube and electrically contacting the set of insulated electrical conductors, the electrodes including a set of upper or proximal electrodes and a set of lower or distal electrodes; and a switch configured to operatively connect one electrode of the set of upper or proximal electrodes and one electrode of the set of lower or distal electrodes to an electrocardiograph (ECG) instrument.

One advantage resides in a reduced number of wires or cables connected with the patient.

Another advantage resides in more accurate physiological monitoring.

Another advantage resides in providing a feeding tube with one or more integral physiological monitoring sensors.

Another advantage resides in reduced manufacturing cost for a feeding tube with one or more integral physiological monitoring sensors.

Another advantage resides providing increased robustness for a feeding tube with one or more integral physiological monitoring sensors.

Still further advantages of the present invention will be appreciated to those of ordinary skill in the art upon reading and understanding the following detailed description.

FIGURE 1 depicts a neonatal feeding tube with instrumentation, in accordance with the present application.

FIGURE 2 is a cross sectional view of the feeding tube of FIGURE 1 through a distal portion.

FIGURE 3 is a cross sectional view of the feeding tube of FIGURE 1 through a thermistor.

FIGURE 4 is a cross sectional view of the feeding tube of FIGURE 1 through an electrode.

FIGURE 5 is a cross sectional view of the feeding tube of FIGURE 1 through a proximal portion.

FIGURE 6 diagrammatically depicts a medical patient monitoring system including a medical device comprising a multifunction feeding tube.

FIGURE 7 shows an enlarged perspective view of the multifunction feeding tube of FIGURE 6.

FIGURE 8 shows an enlarged perspective view of the multifunction feeding tube extrusion including access openings formed after the extrusion used in fabricating the multifunction feeding tube of FIGURES 6 and 7.

FIGURES 9, 9A, and 9B show various suitable embodiments or aspects of the electrical assembly of the multifunction feeding tube of FIGURES 6 and 7 prior to insertion of the electrical assembly into the electrical lumen of the feeding tube extrusion.

FIGURE 10 shows the multifunction feeding tube of FIGURES 6 and 7 with the extrusion removed to reveal the temperature sensor and electrode connections.

FIGURE 11 shows a cross section of the feeding tube extrusion of FIGURE 8 revealing the feeding lumen and electrical lumen.

FIGURES 12-13 show perspective views of one suitable embodiment of the distal tip of the multifunction feeding tube of FIGURES 6 and 7.

FIGURE 14 diagrammatically shows an electrical schematic of a medical device comprising the multifunction feeding tube of FIGURES 6-13 connected to provide electrocardiography capability with selectable ECG electrodes.

With reference to FIGURE 1, a neonatal feeding tube **10** is depicted. In one embodiment, the tube **10** is an instrumented disposable feeding tube for newborn infants (neonates) who have not yet developed their sucking capabilities, or who are unable to feed normally for some other reason. The tube **10** is a 5 French tube, or 1.67 mm in diameter, in one embodiment. Appropriate scaling can be performed for larger or smaller tubes. It is also to be understood that although neonatal feeding tubes are described as illustrative examples herein, more generally the disclosed feeding tube embodiments and disclosed aspects thereof are readily applied to feeding tubes for adult patients, veterinary subjects (e.g., dogs or cats undergoing veterinary care), or so forth. For convenience, the tube **10** is shown segmented, though its actual size is approximately 300 mm in length, for example.

The neonates are fed formula or breast milk through the tube **10**. The tube **10** is typically inserted into the nose (that is, a nasogastric feeding tube arrangement) or mouth and advanced into and through the esophagus, and into the stomach. The tube **10** has a tip **12** at the distal end of the tube that is typically disposed in an upper region of the stomach when the feeding tube **10** is properly inserted. FIGURE 2 depicts a cross sectional view of the distal portion **14**. A hole **16** in the tip **12** permits food, such as infant formula or breast milk, to exit the tube. One or more additional holes **18**, offset from the tip **12,** allow feeding to exit in the event that the end hole **16** becomes clogged or otherwise blocked. The tip **12** and cross holes **18** are preferably located in the subject's stomach in one embodiment. The distal portion **14** is suitably molded of a soft, biocompatible material, such as (in one embodiment) silicone rubber.

The feeding tube **10** also includes electrodes **20**. The electrodes **20** are on an outside of the feeding tube and, when inserted, make contact with the subject's esophagus. Insulated leads extend proximally from each electrode, either inside the feeding tube **10** or the outer wall of the feeding tube. A temperature sensor, which in the illustrated example is a thermister **22**, is disposed inside the tube for taking temperature measurements and, in one embodiment, lies distal to the electrodes **20**. FIGURE 3 shows a cross section of the tube **10** including the thermistor **22** in cross-section. Other temperature sensors can be used in place of the illustrated thermister **22**, such as a thermocouple, a thermodiode, or so forth.

The thermistor **22** is assembled to a pair of wires, at least one insulated. In one embodiment, the thermistor **22** is calibrated to operate with a specific patient monitor or series of monitors. The calibration is optionally checked prior to insertion of the feeding tube **10** into the patient, for example by measuring resistance and compared to a specification. In an optional calibration operation, resistance is increased as appropriate until the thermistor resistance meets the specification, so as to bring the thermistor into compliance with specified standards for accuracy. The illustrative thermistor **22** may be one piece of semiconductor material or it may be two or more segments connected in parallel, with a small gap between each segment. This allows the assembly to flex in two directions and to twist, even if the length is several multiples of the tube diameter. The overall resistance of the thermistor is proportional to its thickness and inversely proportional to the area. Because the width of the thermistor and thickness of the

thermistor are constrained by the size of the tube **10,** the effective length of the thermistor assembly is selected based on the electrical requirements of the monitoring system. This method of construction also minimizes difficulty and discomfort during insertion, removal, and use. It is also more flexible and more resistant to breakage during manufacture, insertion, and use. In one embodiment, the thermistor **22** has a resistance of approximately 2250 Ω at 25°C and approximately 1360 Ω at 37°C.

In a single-thermistor embodiment, when the tube is inserted the thermistor **22** is suitably located in the esophagus so as to accurately measure core temperature, rather than the stomach or pharynx, where readings would be less accurate. Placement in the stomach can be problematic due to the corrosive effects of gastric fluids and the inaccuracy that might be caused by air or food in the stomach.

Proximal to the electrodes **20** is a nasopharyngeal section **26** of the feeding tube **10**. The nasopharyngeal section **26,** as the name indicates, lies inside the pharynx and nose when inserted. This section is suitably smooth and small in diameter to reduce irritation to the subject and interference with air flow during breathing. In an alternate embodiment, it has a non-circular shape and/or concave flutes to reduce the possibility of complete blockage of a nare. In some embodiments, a hypopharynx thermistor **28** and an oropharynx thermistor **30** are included in the nasopharyngeal section **26**. The thermistors **28, 30** are used to measure respiration flow, in addition the distal or caudal thermistorprovides a core temperature measurement. The respiration flow is measured as a relative temperature change between the oropharynx thermistor **30** and the hypopharynx thermistor **28**. An array of these thermistor pairs may be provided to accommodate various patient sizes.

A pressure differential ΔP is measured by a pressure gradient between a sub-diaphragmatic (or caudal) port **32** and a supra-diaphragmatic (or cephalic) port **34**. ΔP represents the respiration effort of the subject. Flow can be measured separately (with thermistors **28** and **30**), as an airway obstruction may produce increased effort but no ΔP. Respiration flow and respiration effort are measured separately and can differ. For example, in the case of an airway obstruction, effort will increase but flow will decrease. The measured flow can be cross-checked against ΔP for accuracy, and can signal an alarm if the two do not coincide.

In the illustrative embodiment of FIGURE 1, proximal to the supra-diaphragmatic pressure port **34** are two fiber optic windows **35**. The fiber optic windows **35** are polished ends of many fiber optic strands. At the proximal end of the feeding tube the fiber optic strands separate into a source fiber (run from a light source, not shown) and a return fiber. Both fiber bundles run down the tube **10** to the fiber optic windows **35**. One fiber optic bundle terminates in the esophagus and another at the distal tip of the feeding tube. The distal fiber bundle does not need to be separated into a sending and receiving bundle as it is used only to send light down which would emanate from the small patient due to the thin membranes and relatively translucent nature of the skin. This tip light is used for placement verification by energizing the fibers from an external light source and in a darkened room and visualizing the location of the light emanating from the patient's abdomen (if properly placed) or thorax (if not properly placed). The pulse of the subject is measured by reflectance photo-plethysmogram through the fiber optic window using traditional reflectance pulse oximetry techniques. Core SpO_2 is also measured at the fiber optic window **35**. The supra-diaphragmatic port **34** serves as a flush location to clean the fiber optic window **35** as needed.

With reference now to FIGURE 4, and continuing reference to FIGURES 1-3, an illustrative method of manufacture is disclosed. In one embodiment, there are four feeding lumens **36**. In a three-electrode embodiment, three of the four lumens **36** carry a contact for an electrode **20**, and one lumen **36** does not. In a four-electrode embodiment, each of the four lumens **36** can carry a contact for an electrode **20**. In a five-electrode embodiment, three of the four lumens **36** carry one contact while the fourth lumen **36** carries two contacts. Fewer or additional electrodes **20** can be positioned appropriately following the same pattern. The lumens **36** are cut to length. At the appropriate location for each electrode **20**, an un-insulated end of a wire is secured. In one embodiment, the wire is electrically and mechanically connected to a metal fitting **38** by soldering, welding, bonding with a conductive adhesive, crimping, or the like. The fitting **38** is then attached to the lumen **36** in the appropriate position, either by swaging, crimping, adhesive, or the like.

The lumen **36** and the thermistors **22, 24, 28, 30** are placed together with the thermistors **22, 24, 28, 30** and wires **40** in the center of the lumens **36,** as depicted in FIGURE 3. The distal portion **14** is brought together with the lumens **36** and thermistors

22, 24, 28, 30, held in place, and a jacket **42** is applied by extrusion, heat-shrinking, tape wrapping, or the like. The lumens **36** may reshape somewhat during this process, but this is inconsequential to the operation of the feeding tube **10**. The wires **40** are preferably located in the center of the tube **10** for maximum flexibility. If additional bond strength is needed, a mechanical strength member (wire or fiber) can be added to the distal portion **14** and secured to the wires **40**. A gap **44** between the distal portion **14** and a proximal portion **46** inside the jacket **42** serves as a blending area for flow from the multiple lumen **36** to blend and enter the distal part **14** and flow out the holes **16, 18** into the subject's stomach. Next, the electrodes **20** are added.

With reference to FIGURE 4, the jacket **42** is removed in the area of the electrode **20**. A conductive transition **48** such as a conductive adhesive, spring-like device, or the like is placed in the resulting removed area. An electrode **20**, in the form of a short thin-wall cylinder, is placed over each conductive transition **48** and is then swaged to lock it in place. The proximal and distal edges are then bent into the jacket **42** to provide a smooth surface to reduce risk of injury to the patient.

An outside portion **50** of the tube **10** lies outside of the subject when the feeding tube **10** is inserted. The outside portion **50** may have a larger cross section. The wires **40** that run from the components within the tube **10** terminate in a tube-side connector **52**. A feeding lumen extension **54** may pass through the approximate center of the tube-side connector **52** and terminates in an oral style fitting **56** that permits baby formula or breast milk to be injected by syringe, drip, pump, or other means. In one embodiment, the fitting **56** is marked or physically differentiated to distinguish it from ports meant for vascular injection.

Mating with the tube-side connector **52** is a cable-side connector **58**. In one embodiment, the cable-side connector **58** has a slot (not shown) that allows the cable-side connector **58** to be connected or disconnected without disturbing the feeding tube lumen extension **54**. After passing through a flex relief section **60**, external electrical wires **62** continue to a monitor. The external wires **62** may be fitted with an adapter that allows interface to various makes or models of patient monitors.

The outside portion **50**, tube-side connector **52**, feeding connector **56** and lumen extension **54** are secured using conventional insert molding, over-molding, and bonding techniques. An over-molded or assembled tube-side connector **52** mates with the

cable-side connector **58** on the external wiring **62**. The multiple feeding lumens **36** transition into a single lumen in the outside portion **50**. The lumen extension **54** continues through openings in the connector parts **52, 58**. In the lumen extension **54** there are no wires involved, and it is relatively transparent, which facilitates visual confirmation of flow. The lumen extension **54** is also flexible. If a caregiver needs to interrupt flow by pinching off the lumen, it should be done at the lumen extension **54**. Once assembled, the feeding tube **10** is ready to be sterilized and packaged.

Typically, three electrodes are employed for ECG readings. For small neonates, the distal three electrodes **20** are suitably used. For medium neonates, the middle three electrodes **20** are suitably used. For larger neonates, the proximal three electrodes **20** are suitably used. In one embodiment, the electrodes are selected manually based on the size of the neonate, and the judgment of the caregiver. The setting can be selected by the caregiver by temporarily disconnecting the connector, rotating the cable-side part **58** relative to the connector **52**, and then re-connecting, thereby changing which internal contacts are used. In another embodiment, the electrodes are selected by the monitor. Once the tube is inserted, all electrodes **20** send signals to the monitor. The monitor displays multiple wave-forms, and the operator selects the clearest display. In other embodiments, all signals are recorded or the monitor automatically chooses the best electrodes.

In some embodiments, respiration rate is determined by injecting a low-voltage electrical signal into the patient via a pair of spaced ECG electrodes. The electrical impedance of the connection varies during the act of respiration, so the rate and depth of respiration can be estimated based on the electrical impedance variation. In some embodiments, the respiration rate is derived using electrodes selected from the array of available electrodes.

In an alternate embodiment a U-shaped connector on the monitor side is used so that the feeding tube **10** can be in the center, with mating in the axial direction. The U-shape allows the electrical connection and the feeding connection to be made or disconnected in any sequence, without mutual interference. In another alternate embodiment, a connector is on the side of the feeding tube, with mating in the radial or oblique direction. In another alternate embodiment, the tube **10** has a rectangular (linear) connector rather than a circular or U-shaped connector. In this embodiment, the feeding

tube side would have a number of sockets (pins) equal to the number of electrodes, while the cable side would have a number of pins equal to the number of electrodes used by the monitor. The cable could then be plugged in to the feeding tube **10** in a number of locations, thereby selecting which electrodes are operative. In another alternate embodiment, the tube **10** has a connector where the selection of the electrodes is performed by a switching device inside the cable-side connector **58**, or the cable **62** itself. In another alternate embodiment, the tube **10** has a connector with a rotating collar or other device which could be locked into place to assure that the connector, after disconnection, can only be re-connected in the selected position. In another alternate embodiment, the tube **10** has a slide or rotary switch on the connector to allow the caregiver to manually select the electrodes with the strongest signal as shown on a monitor display. The foregoing are merely illustrative examples.

Proper insertion of the feeding tube **10** can be problematic in some instances. The tube is to be inserted to a depth that places the tip **12** of the tube **10** in the stomach of the neonate. It is undesirable to insert the tube too far, e.g. into the duodenum, and it is also undesirable to insert the tube not far enough, such that the openings **16**, **18** are in the esophagus. With reference again to FIGURE 1, a distal electrode **64** on the tip **12** of the tube **10** is optionally included to facilitate placement confirmation. While the distal electrode **64** remains in the esophagus, contact with the wall of the esophagus produces electrical continuity. However, when the distal electrode **64** passes through the esophageal sphincter into the larger opening of the stomach, the electrical continuity decreases or disappears. Because the relative location of the electrode **64** and the openings **18** is established by the detailed design of the device, the location of the openings **18** is thus known to the clinician relative to the beginning of the patient's stomach.

In conjunction with the electrode **64**, an optional light source **66** can be used to judge the position of the tip **12** as it is passed down the subject's esophagus. The neonate's chest is relatively thin and translucent. The light source **66**, if bright enough, can be seen through the neonate's chest, and the caregiver can visually verify the position of the tip **12**. The light source **66** may be illuminated by a lamp outside the proximal end and an optic fiber running the length of the tube **10**. It is also contemplated that a fiber optic camera could be located at or fiber optically connected to the tip **12** and used as a traditional endoscope to aid in positioning the tube **10**. In some embodiments, the fiber

optic device is a permanent part of the tube **10**; whereas, in alternative embodiments, the fiber optic device is inserted into a feeding lumen **36** prior to placement in the body and removed after the tube **10** is properly placed, so that the lumen **36** may be used for feeding.

When inserting the tube **10**, the tube should follow the esophagus and not veer into the lungs. One way to tell which path is being followed is by a temperature measurement with thermistors at the tip **12**. If different temperatures are measured with inhale and exhale respiration, the tip is in an air passage. If the temperature is constant, the tip is in the esophagus. Monitoring pressure at the tip can be used analogously. Pressure can be measured by sealing one of the lumens and adding a pressure port.

Another optional aid in positioning the tube **10** is to include a sensor that measures pH. If the tip **12** is properly in the stomach, the measured pH should be acidic. If the tip **12** is in the lungs, the measured pH will be neutral. If the tip **12** is in the esophagus, the measured pH will be somewhat acidic, depending on reflux, etc.

With reference to FIGURES 6-14, some other feeding tube embodiments are described. Again, these embodiments are described with reference to neonatal application, but the disclosed feeding tube systems are also readily adapted for pediatric or adult patients by suitable size scaling and the like. The illustrative feeding tube system shown in FIGURES 6-14 is a multifunction system that provide both feeding and monitoring, and has aspects disclosed herein that enhance manufacturability, reduce manufacturing cost, enhance feeding tube robustness and reliability, accommodate patient growth, and provide other benefits.

With reference to FIGURES 6 and 7, a medical device includes a feeding tube **70** designed to provide both feeding functionality and additional electrocardiographic (ECG), respiration monitoring, temperature, and optional other monitoring functionality. Toward the latter end, the feeding tube **70** (or, more precisely, a distal end of the feeding tube designed for nasogastric or other insertion into the subject) includes electrode rings **72**, **73**, **74**, **75**, **78**, **79**, a and a temperature sensor **130**. Food flows through a feeding lumen **80** of the feeding tube **70**. The electrode rings **72**, **73**, **74**, **75**, **78**, **79**, and the temperature sensor **130** are connected with a set of wires **82** disposed in an electrical lumen **84** of the feeding tube **70**. At a proximal end of the feeding tube **70** a bifurcation **90** or other coupling element connects a feeding inlet **92** with a formula source **94** or other

source of food that is delivered to the feeding inlet and through the feeding lumen **80** into the subject's stomach. The feeding inlet **92** is preferably a standardized connector for this purpose; accordingly, the connection of the formula source **94** with the feeding inlet **92** is shown diagrammatically. At the bifurcation **90**, a connector **91** connects the set of wires **82** to an electrical adaptor **96**, which adapts the wires of the set of wires **82** from the ECG electrode rings **72**, **73**, **74**, **75**, **78**, **79** into a standard electrocardiograph (ECG) trunk cable **100.** The connector **91** also connects the wires of the set of wires **82** from the temperature sensor **130** to a standard temperature probe cable **102**. The ECG trunk cable **100** has a connector **104** for connecting to the electrocardiograph (ECG) instrument **110**, while the temperature probe cable **102** has a standardized connector **112** for connecting to a temperature monitor **114**. In the illustrated embodiment, the ECG instrument **110** and the temperature monitor **114**, along with a respiration monitor **115**, are embodied in unitary fashion by a standard multi-parameter patient monitor **116**. The respiration monitor **115** is also (like the ECG instrument **110**) operatively connected with the ECG trunk cable **100**. In an alternative configuration, individual instruments may be used for monitoring ECG, temperature, or so forth, rather than employing the unitary multi-parameter device **116**.

The assembly comprising the feeding tube **70** and the bifurcation **90** is suitably treated as a disposable item that is used one a single patient and then discarded. The electrical adaptor **96** is reusable. The ECG trunk cable **100** and temperature probe cable **102** are also reusable, and in some embodiments are standardized components that may also be used with conventional ECG lead sets or temperature probes, respectively. In an alternative embodiment, the two cables may be replaced by a single cable with two connectors, or by a single cable with a single connector serving both functions.

With continuing reference to FIGURE 7 and with further reference to FIGURES 8-10, a suitable construction of the medical device is as follows. The feeding tube **70** is formed, for example by an extrusion process. The formed feeding tube **70** includes the feeding lumen **80** and the electrical lumen **84** parallel with at least a portion of the feeding lumen. The feeding tube **70** is suitably formed of polyurethane, silicone, or another material suitably soft, flexible, corrosion resistant and biocompatible for insertion into the esophagus and stomach. After the extrusion process, access openings **120** are formed into the feeding tube **70** by mechanical drilling, punching, laser cutting, or another suitable process. The access openings **120** are spaced apart along the feeding tube **70**, and

are located along the feeding tube **70** proximate to the eventual locations of the electrodes. The access openings **120** provide access to the electrical lumen **84**. Although not illustrated, it is also contemplated to provide access openings to the electrical lumen **84** for other purposes. For example, optionally a thermal access opening (not illustrated) is similarly formed at the eventual location of the temperature sensor **130**. FIGURE 8 shows the feeding tube **70** after extrusion and formation of the access openings **120**. As extruded, the feeding and electrical lumens **80**, **84** extend completely through the distal end **124** of the extruded feeding tube **70**, and the distal end **124** typically has relatively sharp or abrupt edges. Preferably, the distal end **124** is processed to plug up or otherwise close off the electrical lumen **84** at the distal end **124**, and to smooth edges of the distal end **124** to reduce the likelihood of damage to the esophagus or other contacted tissues during insertion of the feeding tube **70**. Some suitable approaches for smoothing the distal end **124** include: mechanical smoothing by grinding, lapping, or so forth; smoothing by thermal reflow using heating by a flame, laser, or other heat source; smoothing by chemical etching; or so forth. Any such processing of the distal end **124** should ensure that the feeding lumen **80** continues to have an opening at the distal end **124** to allow food to pass from the feeding lumen **80** into the stomach – however, this opening at the distal end **124** may optionally be reshaped or otherwise adjusted by the distal end processing.

With reference to FIGURE 9, in a separate process the electrical assembly including the set of wires **82** (or, more generally, insulated electrical conductors) and a thermister **130** (or, more generally, a thermister, thermocouple, thermodiode, or other temperature sensor) is assembled. Construction of this assembly includes arranging the wires of the set of wires **82** into a bundle, connecting the temperature sensor **130** with appropriate wires of the set of wires **82**, optionally cutting wires to selected lengths, and stripping insulation from wire portions of the wires that are to connect with electrode rings preparatory to making electrical contact with the electrodes. There are eight wires in the illustrative set of wires **82**, namely six wires for connecting with the electrode rings **72**, **73**, **74**, **75**, **78**, **79** and two additional wires for connecting the temperature sensor **130**. More or fewer wires can be provided, depending on the number of electrodes, number of temperature sensors (if any), exact electrical requirements of the monitoring instrument, and the number of any additional electrical elements to be connected. For example, in one contemplated variation of the embodiment shown in FIGURE 9, the temperature sensor

130 is connected with two wires that also connect with respective electrodes, such that the temperature sensor and the two electrodes share two wires; in this way, the number of wires in the set of wires **82** could be reduced from eight wires to six wires. Moreover, although the wires of the set of wires **82** are illustrated as being straight, the wires of the set of wires may instead be twisted or braided together to enhance the bundling of the wires.

In constructing the electrical assembly, the temperature sensor wires are trimmed to a desired length corresponding to the position of the temperature sensor in the feeding tube, and the temperature sensor **130** is soldered or otherwise connected with the these trimmed wires. The wires that are to connect with electrodes are processed as follows. For each such wire, the insulation is stripped proximate to where the electrode will be connected, so as to form electrically exposed conductor portions in the form of bare wire portions **132** as shown in FIGURE 9. (Note that one bare wire portion is not visible in the perspective view of FIGURE 9). The bare wire portions **132** are located along the length of the electrical assembly so as to coincide with and be proximate to corresponding access openings **120** when installed in the electrical lumen **84** of the feeding tube **70**. Optionally, as shown in FIGURE 9 the excess wire length of each wire distal from the bare wire portion **132** is trimmed, and may also be looped, coined, folded back or otherwise modified to facilitate a mechanical interconnection of the electrically exposed conductor with the electrically conductive adhesive portions disposed in the access openings or external electrode portion as will be described. FIGURE 9A shows a modified bare wire portion **132a** that is modified (as compared with the bare wire portions **132** of FIGURE 9) by being looped. In other contemplated embodiments, the bare wire portion is not trimmed; rather, the excess wire length is retained, so that most bare wire portions are located at other than the extreme end of the processed wire.

To form the final multifunction feeding tube shown in FIGURE 7, the electrical assembly of FIGURE 9 is inserted into the electrical lumen **84** of the feeding tube extrusion of FIGURE 8 with the bare wire portions **132** aligned along the feeding tube with corresponding access openings **120**.

With continuing reference to FIGURES 7-9 and further reference to FIGURE 10 (which illustrates the assembled multifunction feeding tube with the extrusion removed), the electrodes are formed by a process that includes injecting

electrically conductive material portions **140** into the access openings **120** of the electrical lumen **84** to electrically contact the proximate bare wire portions **132** of the set of insulated wires **82** disposed in the electrical lumen **84**. The electrically conductive material portions **140** are visible only in FIGURE 10. In a suitable embodiment, the electrically conductive material portions **140** comprise electrically conductive adhesive portions **140** disposed in the access openings and adhering to the proximate bare wire portions **132**. The robustness of this adhesive connection is optionally enhanced by the aforementioned optional looping (e.g., the looped bare wire portion **132a** of FIGURE 9A), coining, or other modification of the bare wire portions. Optionally, the electrically conductive adhesive portions **140** also adhere to an inner surface of the electrical lumen **84** to assist in retaining the position of the electrical assembly in the electrical lumen **84**. In some embodiments the electrically conductive adhesive portions **140** comprises cured electrically conductive polymer material portions, such as, by way of example, cured electrically conductive epoxy portions. In such embodiments, the formation of the electrically conductive adhesive portions **140** includes injecting the material into the access openings **120** to electrically contact the proximate bare wire portions **132**, followed by a curing operation that may, by way of illustrative example, include delaying a curing time and optionally applying curing heat by way of an oven or the like. In other contemplated embodiments, the electrically conductive adhesive portions may be made of another material that can be controllably flowed into the access openings **120** and solidified, such as a solder material. Although not illustrated, it is also contemplated to provide additional adhesive portions through additional access openings (features not illustrated), in which the additional adhesive portions may be either electrically conductive or electrically non-conductive, and provide mechanical anchoring of the electrical assembly in the electrical lumen **84**.

The electrically conductive material portions **140** extend to be fill the access openings **120**, and are flush with or extend slightly beyond the outer surface of the feeding tube extrusion. In some embodiments, these flush or slightly protruding exposed surfaces of the electrically conductive adhesive portions **140** are the accessible electrodes. In other embodiments, an additional electrode element is disposed on the flush or slightly protruding exposed surface of each electrically conductive adhesive portions **140**. In the illustrative embodiment, these additional elements are the electrode rings **72**, **73**, **74**, **75**,

78, **79**, which are annular electrically conductive elements disposed around the outside of the feeding tube and electrically contacting the electrically conductive material portions **140** disposed in the access openings **120**. The electrode rings **72**, **73**, **74**, **75**, **78**, **79** contact the flush or slightly protruding surfaces of the electrically conductive adhesive portions to make electrical contact therewith, and advantageously provide exposed electrode surfaces with radial symmetry. In one suitable embodiment, the electrode rings **72**, **73**, **74**, **75**, **78**, **79** are made of short cut lengths of stainless steel or platinum tubing.

In other embodiments the additional electrode elements comprise electrically conductive coatings disposed at least over the electrically conductive material portions disposed in the access openings. Optionally, such coatings can extend over the outer surface of the feeding tube extrusion, for example to define annular rings analogous to the illustrated electrode rings **72**, **73**, **74**, **75**, **78**, **79**.

An advantage of including the additional electrode elements (such as the illustrative electrode rings **72**, **73**, **74**, **75**, **78**, **79**, or electrically conductive coatings, or so forth) is that the additional electrode elements can be designed to optimize electrical coupling with the esophagus or other proximate anatomy with which electrical communication is desired. This design may include selection of the material of the additional electrode elements, providing the illustrative electrode rings **72**, **73**, **74**, **75**, **78**, **79** with sufficient thickness to ensure that they protrude radially outward to make contact with the esophagus wall or other proximate tissue, or so forth. This then allows the electrically conductive adhesive portions **140** to be optimized respective to aspects such as minimizing contact resistance with the bare wire portions **132**, optimizing mechanical properties for facilitating the injection and curing, optimizing adhesive qualities, and so forth. Optimization of the electrically conductive adhesive portions **140** may include, for example, selection of material type and amount injected into each access opening **120**, control of the injection process mechanics, optimization of the curing process, and so forth.

The electrodes optionally seal the access openings **120** so that the electrical lumen **84** is not exposed to stomach acid or other corrosive biological tissue. The seals can be made in various ways. In some embodiments, the electrically conductive material portions **140** completely fill the access openings **120** so as to seal the access openings **120**. Additionally or alternatively, the electrode rings **72**, **73**, **74**, **75**, **78**, **79** can provide

the seal, for example by the mechanism of a tight friction fit to the feeding tube extrusion. Additionally or alternatively, an additional sealant fluid (not shown) may be applied, for example at the periphery of the electrode rings to seal the gap between the electrode ring and the feeding tube extrusion. The seal may be less than perfect, for example permitting some ingress of corrosive fluid into the electrical lumen **84** over a time frame that is statistically longer than the expected useful life of the inserted multifunction feeding tube.

Optionally, and optional thermal access opening (not shown) is also provided, and is suitably filled with a thermally conductive material portion that thermally contacts the temperature sensor **130** and is flush with or protrudes slightly from the external surface of the feeding tube extrusion to define an external thermal contact. The thermally conductive material portion is optionally electrically nonconductive so as to avoid the potential for introducing electrical shunting. As a further option, a thermally conductive ring analogous to the electrode rings **72**, **73, 74**, **75, 78**, **79** may be disposed over the thermal access opening after injection of the optional thermally conductive material portion.

In the electrical assembly of FIGURE 9, the electrical conductors comprise the set of wires **82** which are a bundle of discrete insulated wires extending along the electrical lumen **84**, and the electrically exposed portions comprise bare wire portions **132** which are formed by stripping the insulation to expose the bare wire portions, and optionally performing further modification such as looping as shown in FIGURE 9A.

With reference to FIGURE 9B, in an alternative embodiment, the electrical conductors comprise a set of insulated electrically conductive traces disposed on or in a flexible circuit board (i.e., "flex circuit board") **82b** extending along the electrical lumen **84**. In this embodiment, the electrically exposed portions are suitably embodied as exposed portions **132b** of the electrically conductive traces at which an insulative coating (for example, an oxide, nitride, or oxynitride coating) is removed (or not deposited in the first place) by a suitable photolithographic or other patterning technique. The exposed portions **132b** are thus similar to bonding pads of circuit boards at which components are conventionally soldered. Optionally, the exposed portions **132b** are formed on both sides of the flexible circuit board **82b**, or pass through the flex circuit board **82b** completely, so that the conductive epoxy is assured of making electrical contact with at least one of the pads. Additionally or alternatively, the flexible circuit board may be twisted to facilitate

the electrical contact. In this alternative embodiment, a modified temperature sensor **130b** may be embodied as a surface mount component that is directly soldered to the elongated insulated flexible circuit board **82b** at the desired location along the elongated insulated flexible circuit board **82b**. In a variant embodiment, a socket for the temperature sensor is soldered on the board, and the temperature sensor is mounted via the socket. In yet another alternative embodiment, exposed portions **132bb** (only one example of which is diagrammatically shown in FIGURE 9B) are embodied as tabs that extend away from an edge of the flex circuit board **82b**. The tabs **132bb** are suitably pulled through the aligned access openings **120** and wrapped around the outside of the extrusion to provide externally accessible electrodes. The wrapped tabs may be secured by suitable adhesive, which may be electrically conducting or electrically non-conducting.

With reference to FIGURE 11, a cross-section of the feeding tube extrusion is shown, revealing the cross-sections of the feeding lumen **80** and the electrical lumen **84**. In the illustrated embodiment there is a single feeding lumen and a single electrical lumen. (However, it is also contemplated to include more than one feeding lumen, analogous to the embodiment of FIGURES 1-5, and/or more than one electrical lumen). The electrical assembly (shown in FIGURE 9) has a small cross-section sufficient to accommodate the bundle of the set of wires **82** and the temperature sensor **130**. Thus, the cross-sectional area of the electrical lumen **84** can be made small and consequently the feeding lumen **80** can be made large. In some embodiments, a ratio of the cross-section of the feeding lumen **80** to the cross-section of the electrical lumen **84** is greater than two. In some embodiments, a ratio of the cross-section of the feeding lumen **80** to the cross-section of the electrical lumen **84** is greater than three. In one embodiment, a ratio of the cross-section of the feeding lumen **80** to the cross-section of the electrical lumen **84** is about four, although even larger ratios are contemplated.

The feeding lumen **80** is preferably a single lumen (as shown), although multiple feeding lumens are also contemplated. A single feeding lumen is less likely to become clogged as compared with a plurality of separate feeding lumens of equivalent cross-sectional area. For rapidity of manufacturing, it is also advantageous for the electrical lumen **84** to be a single lumen (as shown in FIGURE 11) and for a single electrical assembly (as shown in FIGURE 9) to be constructed and inserted into the single electrical lumen **84**. However, the use of multiple electrical lumens with a corresponding

multiplicity of electrical assemblies (some or all of which could include a single wire with stripped wire portion) are also contemplated. In the illustrative example of FIGURE 11, the electrical lumen **84** has a circular cross-section and is offset from the center of the feeding tube extrusion, and the feeding lumen **80** has a convex outer surface **144** that is approximately parallel with an outer surface of the feeding tube extrusion, and a concave inner surface **146** that is approximately parallel with a portion of the surface of the electrical lumen **84**. This configuration is referred to herein as a "smiling Cyclops" configuration (where the electrical lumen **84** is the single "eye" of the Cyclops, and the electrical lumen **80** is the "smiling mouth" of the Cyclops). The smiling Cyclops arrangement provides for a large uninterrupted cross-sectional area for the feeding lumen **80** while retaining a circular cross-section for the electrical lumen **84**, and additionally places the feeding lumen **80** proximate to an outer surface of the feeding tube extrusion so as to facilitate formation of the access openings **120**. Other cross-sectional configurations are also contemplated.

Another advantage of the embodiments disclosed with reference to FIGURES 7-10 is that the temperature sensor **130** can have various placements along the feeding tube. For example, additional electrodes, such as illustrative electrodes **72**, can be located distal from the temperature sensor **130**. More generally, the temperature sensor can be located along the feeding tube between electrodes. The temperature sensor wires are thereby shorter, which is advantageous, and the centrally located temperature sensor is less likely to be exposed to corrosive stomach acid which could decrease its longevity. Moreover, by placing the temperature sensor in the esophagus rather than in the stomach more accurate core body temperature measurements are expected to be obtained.

As initially extruded, the feeding tube extrusion has the uniform cross-section shown in FIGURE 11 for its entire length, including at its distal end. To protect the electrical assembly from the corrosive esophageal or stomach environment, it is advantageous to seal the distal end of the electrical lumen **84** using a plug, heat sealing, or so forth. Additionally, it is useful to smooth the shape of the distal end by mechanical polishing, grinding, reflow processing, or so forth in order to remove sharp edges.

With reference to FIGURES 12 and 13, an illustrative smoothed distal end **150** is shown, which includes a single reshaped opening **152** that is in fluid communication with the feeding lumen **80**, but is not in fluid communication with the

electrical lumen **84**. The illustrative distal end also includes an auxiliary side opening **154**. There are one or more openings near the tip of the tube to permit the food to leave the lumen and enter the stomach of the patient. By way of illustrative example, in one configuration the opening **152** is at the tip (as shown in FIGURE 12) and the side opening **154** is perpendicular to the feeding lumen **80** and approximately 5 mm proximal. The side opening **154** allows suctioning of a sample from the stomach even if the primary opening **152** is blocked.

In one suitable approach for forming the tip of FIGURES 12 and 13, a sealing process employs a heated mold that forms the end to the illustrated smoothed shape that is configured for ease of insertion and patient safety and comfort. The feeding tube extrusion advantageously has thin walls for most of its length. Beyond the most distal electrode, however, the electrical lumen **84** is no longer needed and the cross-section is changed from the dual lumen "smiling Cyclops" configuration of FIGURE 11 to the single, central, circular lumen **152** shown in FIGURE 12. The walls curve inward, allowing the end radius to be maximized for each outside diameter.

Optionally, a radio-opaque marker (not shown) is disposed at the tip of the multifunction feeding tube, for example in the electrical lumen **84** close to the distal end, to enable the tip of the multifunction feeding tube to be viewed with a radiological imaging technique such as x-ray or fluoroscopy. The radio-opaque marker may, for example, be a metallic slug disposed in the electrical lumen **84** close to the distal end.

With reference to FIGURES 6 and 7, the electrodes are spaced apart along the feeding tube with at least one upper or proximal electrode (namely four upper or proximal electrode rings **74**, **75**, **78**, **79**, in the illustrative embodiment) disposed above an expected patient heart electrical centerline **CL** (diagrammatically shown in FIGURE 6) and at least one lower or distal electrode (namely two lower electrode rings **72**, **73**, in the illustrative embodiment) disposed below the expected patient heart electrical centerline **CL**. This arrangement enables acquisition of electrocardiograph (ECG) signals across the heart.

To accommodate patients of different sizes, the at least one upper or proximal electrode comprises a set of upper or proximal electrodes (namely four upper or proximal electrode rings **74**, **75**, **78**, **79**, in the illustrative embodiment) spaced apart along the feeding tube above the expected patient heart electrical centerline **CL**, the at least one

lower or distal electrode comprises a set of lower or distal electrodes (namely two lower or distal electrode rings **72**, **73**, in the illustrative embodiment) spaced apart along the feeding tube below the expected patient heart electrical centerline. In order to ensure the correct placement of the upper (proximal) and lower (distal) electrodes in the esophagus, a suitable feeding tube placement technique is employed that ensures that the end of the feeding tube is located in the stomach. One suitable approach is the standard ear/nose/xyphoid process method for placement of the distal end in the stomach. Alternatively, a suitable sensor feedback technique can be employed. The feeding tube should be sized so that when properly placed the lower or distal electrodes are in the esophagus, and so that the patient heart electrical centerline **CL** is between the set of upper (proximal) electrodes and the set of lower (distal) electrodes.

To accommodate variations in patient size or anatomical dimensions, and to accommodate patient growth in neonatal applications, the ECG instrument **110** is configured to selectably operatively connect with a selected one of the set of upper (proximal) electrodes **74**, **75**, **78**, **79**and with a selected one of the set of lower (distal) electrodes **72**, **73** via the set of insulated wires **82** disposed in the electrical lumen **84**. With reference to FIGURE 6, the illustrative electrical adaptor **96** that adapts the wires of the set of wires **82** from the electrode rings into the electrocardiograph (ECG) trunk cable **100** includes a manual switch **160** that enables a nurse, physician, or other qualified person to select the operative upper and lower electrodes from the upper and lower sets of electrodes, respectively, based on a suitable criterion such as patient size. In some embodiments, an electronic or paper chart (not shown) is provided, which lists recommended depth of insertion (naris to stomach) based on spine length, distance from sternum or clavicle to navel, or another suitable externally determinable anatomical dimension. An additional or alternative approach for selecting the selectable upper and lower ECG electrodes is trial-and-error. In the example with four upper electrodes and two lower electrodes, there are eight possible selection combinations, which can be sampled in turn and the combination providing the best ECG trace is then selected.

With reference to FIGURE 14, an illustrative switching circuit is shown, which can be implemented using a manual switch such as the switch **160** (see FIGURE 6) or automatically using a computer, digital patient monitor (such as the illustrative unitary patient monitor **116** that embodies the ECG, temperature, and respiration monitors **110**,

114, **115**), or other system having software-based switching capability. In this example, there are six ECG electrodes, i.e. the electrodes **72**, **73, 74, 75, 78, 79**, that can be switchably connected to simulate the conventional "RA" (right arm), "LA" (left arm), and "LL" (left leg) ECG leads, conventionally used for measuring ECG and respiration. Alternatively, a patient monitor can be designed around the array of esophageal electrodes, with the potential to measure parameters not measureable using only external chest electrodes.

Optionally, as indicated in FIGURE 6, the electrodes **72**, **73, 74, 75, 78, 79** can also be used to measure respiration. For example, the approach already described with reference to the embodiment of FIGURES 1-5 can be used, in which respiration rate is determined by injecting a low-voltage electrical signal into the patient via a pair of spaced electrodes. The electrical impedance of the connection varies during the act of respiration, so the rate and depth of respiration can be estimated based on the electrical impedance variation. In the case of the array of upper electrodes and the array of lower electrodes, good respiration measurement can be obtained by using the same selected upper and lower electrodes as are used for the ECG measurement. This facilitates, for example, the arrangement of FIGURE 6 in which the same ECG trunk **100** suitably feeds both the ECG instrument **100** and the respiration monitor **115**.

The embodiments disclosed with reference to FIGURES 6-14 can be manufactured to be "MR conditional" or even "MR safe". The latter designation indicates that a patient having the multifunction feeding tube can safely undergo examination in any magnetic resonance (MR) system; the former designation indicates that a safe diagnosis is possible in some MR systems and/or with under certain specified limitations such as a maximum magnetic field strength. If the multifunction feeding tube is "MR unsafe", it is optionally marked externally to indicate this designation using a metallic coating on plastic parts to supplement the required label icon and enhance the probability that the feeding tube will be removed before an MRI examination.

By way of further illustrative example of embodiments conforming with the examples of FIGURES 6-14, in one suitable embodiment a polyurethane tube is extruded to define the feeding tube extrusion. The size is approximately 1.7 mm outside diameter which corresponds to 5 on the "French" (Fr) scale conventionally used for catheter diameter specification. The two lumens **80**, **84** run the length of the extrusion,

which is approximately 30 cm in one contemplated embodiment. The electrical lumen **84** has a substantially circular cross-section of about 0.5 mm (.02 in) diameter. The feeding lumen **80** has a larger cross-section and resembles a crescent in shape, as shown in FIGURE 11, and in one embodiment has cross-section area of approximately 0.78 mm^2. Advantageously, this 5 Fr multifunction feeding tube has about same feeding lumen area as a conventional (single-function) feeding tube, and, therefore, the flow rate is similar.

At the proximal end, the multifunction feeding tube has the inlet fitting **92** (that is, a "hub") to permit entry of liquid food into the feeding lumen **80**. In some embodiments, the inlet fitting **92** is an "enteral-only fitting" rather than a standard Luer-taper fitting. Such an enteral fitting accommodates only those syringes, pumps and adaptors with a mating fitting, so that the feeding tube cannot be inadvertently connected to the patient's vascular system. Optionally, a second hub (not shown) permits administration of oral medications or food supplements without disturbing the primary connection to a pump or reservoir. Both hubs are preferably provided with plugs or caps to prevent backflow and keep the hub clean. The fitting is optionally color-coded orange or amber to help identify its use as a feeding connection.

In one suitable embodiment, the temperature sensing device **130** (or surface-mount or socketed device **130b**) disposed inside the electrical lumen **84** is a ceramic thermistor whose electrical resistance decreases as the ambient temperature increases. A suitable location of the thermistor **130** in the subject is in the esophagus, where the lead-length can be relatively short. Placement of the temperature sensor in the stomach is expected to provide less accurate core body temperature measurement due to possible temperature transients during ingestion of food, and may reduce the operational life of the ceramic thermister due to the potential for corrosion from the acid environment inside the stomach. On the other hand, placement of the temperature sensor too high up in the esophagus (that is too proximally in the feeding tube) results in a large number of wires of the set of wires **82** passing alongside the temperature sensor, which can be problematic. Accordingly, in some embodiments a central placement is chosen in which the temperature sensor **130** is between the upper set of electrodes **74, 75, 78, 79** and the lower set of electrodes **72, 73** (as illustrated).

In a suitable embodiment, the dual-lumen **80, 84** feeding tube extrusion (see FIGURE 8) is extruded from polyurethane, silicone, or another suitable material.

The access openings **120**, **122** are suitably made from the outside of the extrusion into the electrical lumen **84** (but not through to the feeding lumen **80**) by drilling, punching or so forth in the locations where electrodes are to be provided. The electrical assembly (see FIGURE 9) includes the thermistor **130** with its two lead wires. (In some embodiments, it is contemplated to provide two or more temperature sensors, for example with one or more temperature sensors used in respiration measurement as per the thermistors **28, 30** of the embodiment of FIGURE 1). The electrical assembly also includes a lead-wire for each electrode to be connected. The insulation of each electrode wire is removed to form the bare wire portions **132**, either at the distal end of the wire or at some intermediate point along the wire. The components are then arranged or bundled together to form the electrical assembly with the thermistor and the bare wire portions located in the correct relative positions. During insertion into the electrical lumen **84**, the electrical assembly may be held together manually. Additionally or alternatively, the electrical assembly may be held together by an adhesive, a fixture (e.g. ties or so forth), or the like.

The electrical assembly is pulled into the electrical lumen **84** and aligned with the access openings **120**. The electrically conductive adhesive portions **140** are injected into the access openings **120** so that these portions are flush with, or slightly protruding from, the tops of the access openings **120**. The electrically conductive adhesive defines an electrical path from the appropriate bare wire portion to the outside of the feeding tube extrusion. The electrically conductive adhesive portions **140** optionally also adhere to the inside wall of the electrical lumen **84** to secure the electrical assembly. Optionally, a thermally conductive adhesive portion is injected into the thermal access opening **122** to mechanically secure the thermistor **130** and to provide improved thermal coupling with the exterior of the feeding tube.

The thermistor **130** is suitably a separate component with a cylindrical case and two axial, insulated wire leads on the same side. In an alternative embodiment, the thermistor **130** is fabricated directly on a flexible circuit (which may or may not be an elongated flexible circuit board defining the wires of the set of wires **82**), trimmed to meet performance specifications, and encapsulated for electrical insulation.

Additional electrode elements, such as the illustrative electrode rings **72**, **73, 74**, **75, 78**, **79**, are optionally added. In one suitable approach, thin coating portions of moderately-conductive paint are applied to the outside of the tube, over the electrically

conductive adhesive portions **140**. This material can be chosen for properties appropriate to the electrode and for effective bonding to the conductive adhesive portions **140**. Alternatively, the electrically conductive adhesive portions **140** can directly define the external electrodes. In this latter case, after injection into the access openings **120**, an external roller or other smoothing device is optionally used to spread the material around the outside surface to define an annular external contact surface for each electrode. Alternatively, the additional electrode element (e.g., exterior conductive coating portions) can be applied to the exterior of the feeding tube extrusion before the access openings **120** are punched or otherwise formed.

The multifunction feeding tube embodiments described herein with reference to FIGURES 6-14 are placed and used for feeding in the same way as with a conventional feeding tube. Additionally, ECG waveform, heart rate, and, optionally, impedance respiration rate are obtained by connecting the electrical adaptor **96** to the conventional ECG trunk cable **100** the same way as an array of surface electrodes are conventionally connected. Advantageously, the same upper and lower electrodes across the patient heart electrical centerline **CL** can be used for both ECG and respiration measurements. An advantage of the disclosed multifunction feeding tube is that the nurse, physician or other medical personnel do not need to connect electrodes for ECG to their respective "correct" locations (e.g., right-arm electrode to the RA channel, left leg to the LL channel, et cetera). When using the ECG capability of the multifunction feeding tube, the standard labels on the monitor (e.g. "Lead II") do not apply, the waveforms may not precisely replicate those of a conventional ECG. However, the heart rate and respiration rate are accurately measured. In similar fashion, by connecting the electrical adaptor **96** to the temperature probe cable **102**, core body temperature is monitored continuously from the esophagus.

The invention has been described with reference to the preferred embodiments. Modifications and alterations may occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

CLAIMS

Having thus described the preferred embodiments, the invention is now claimed to be:

1. A device comprising:

a feeding tube **(70)** including a feeding lumen **(80)** with an opening **(152)** at a distal end of the feeding tube and an electrical lumen **(84)** having access openings **(120)** spaced apart along the feeding tube;

a set of insulated electrical conductors **(82)** disposed in the electrical lumen, the set of insulated electrical conductors having electrically exposed portions **(132, 132a, 132b)** proximate to the access openings; and

electrodes **(72, 73, 74, 75, 78, 79, 140)** comprising electrically conductive material portions **(140)** disposed in the access openings and electrically contacting the proximate electrically exposed portions of the set of insulated electrical conductors disposed in the electrical lumen.

2. The device as set forth in claim **1**, wherein the electrically conductive material portions **(140)** comprise electrically conductive adhesive portions disposed in the access openings **(120)** and adhering to the proximate electrically exposed portions **(132, 132a, 132b)**.

3. The device as set forth in claim **2**, wherein the electrically conductive adhesive portions **(140)** also adhere to the electrical lumen **(84)**.

4. The device as set forth in any one of claims **2-3**, wherein the electrically conductive adhesive portions **(140)** comprise electrically conductive polymer material portions.

5. The device as set forth in claim **4**, wherein the cured electrically conductive polymer material portions **(140)** comprise electrically conductive epoxy portions.

6. The device as set forth in any one of claims **1-5**, wherein the electrodes **(72, 73, 74, 75, 78, 79, 140)** further comprise annular electrically conductive elements **(72, 73, 74, 75, 78, 79)** disposed around the outside of the feeding tube **(70)** and electrically contacting the electrically conductive material portions **(140)** disposed in the access openings **(120)**.

7. The device as set forth in any one of claims **1-5**, wherein the electrodes **(72, 73, 74, 75, 78, 79, 140)** further comprise annular electrically conductive elements **(72, 73, 74, 75, 78, 79)** disposed around the outside of the feeding tube **(70)** and electrically contacting the set of insulated electrical conductors having electrically exposed portions **(132, 132a, 132b)** proximate to the access openings.

8. The device as set forth in any one of claims **1-5**, wherein the electrodes **(72, 73, 74, 75, 78, 79, 140)** further comprise electrically conductive coatings disposed at least over the electrically conductive material portions **(140)** disposed in the access openings **(120)**.

9. The device as set forth in claim **8**, wherein the electrically conductive coatings are further disposed over proximate portions of the outside of the feeding tube **(70)**.

10. The device as set forth in any one of claims **1-5**, wherein the electrically conductive material portions **(140)** extend outside the access openings **(120)** to cover portions of the outside of the feeding tube **(70)**.

11. The device as set forth in any one of claims **1-10**, wherein the electrodes **(72, 73, 74, 75, 78, 79, 140)** seal the access openings **(120)**.

12. The device as set forth in any one of claims **1-11**, wherein the feeding tube **(70)** is sized and the electrodes **(72, 73, 74, 75, 78, 79, 140)** are placed such that at least one lower or distal electrode **(72, 73)** is disposed in the esophagus, at least one upper or proximal electrode **(74, 75, 78, 79)** is disposed in the esophagus, and an

expected patient heart electrical centerline **(CL)** is disposed between the at least one lower or distal electrode and the at least one upper or proximal electrode.

13. The device as set forth in claim **12**, wherein:

the at least one upper or proximal electrode comprises a set of upper or proximal electrodes **(74, 75, 78, 79)**,

the at least one lower or distal electrode comprises a set of lower or distal electrodes **(72, 73)**, and

the device is configured to selectably operatively connect a selected one of the set of upper ECG electrodes **(74, 75, 78, 79)** and a selected one of the set of lower ECG electrodes **(72, 73)** with an ECG instrument **(110)** via the set of insulated electrical conductors **(82)** disposed in the electrical lumen **(84)**.

14. The device as set forth in claim **13**, further comprising one of:

a manual switch **(160)** providing said configuration for selective operative connection, and

an electrocardiograph instrument **(110)** or patient monitor **(116)** electronically providing said configuration for selective operative connection.

15. The device as set forth in any one of claims **12-14**, further comprising:

a temperature sensor **(130)** disposed in the electrical lumen **(84)** along the feeding tube **(70)** between the at least one lower or distal electrode **(72, 73)** and the at least one upper or proximal electrode **(74, 75, 78, 79)**, the temperature sensor being operatively connected with the set of insulated electrical conductors **(82)** disposed in the electrical lumen.

16. The device as set forth in any one of claims **1-15**, wherein the set of insulated electrical conductors disposed in the electrical lumen **(84)** comprises a set of wires **(82)**, and the electrically exposed portions comprise bare wire portions **(132, 132a)**.

17. The device as set forth in claim **16**, wherein the bare wire portions **(132, 132a)** included looped bare wire portions **(132a)**.

18. The device as set forth in any one of claims **1-15**, wherein the set of insulated electrical conductors disposed in the electrical lumen **(84)** comprises electrically conductive traces of a flexible circuit board **(82b)**, and the electrically exposed portions comprise exposed portions **(132b)** of the electrically conductive traces.

19. The device as set forth in claim **18**, wherein the exposed portions **(132b)** of the electrically conductive traces are on both sides of the flexible circuit board **(82b)**.

20. The device as set forth in any one of claims **18-19**, further comprising a temperature sensor electrically connected to the flexible circuit board **(82b)** by surface mounting or socket mounting or other standard means of direct electrical interconnection such as soldering.

21. The device as set forth in any one of claims **1-20**, wherein the feeding tube **(70)** comprises a polyurethane feeding tube or a silicone feeding tube.

22. The device as set forth in any one of claims **1-21**, wherein the feeding lumen **(80)** comprises a single feeding lumen and the electrical lumen **(84)** comprises a single electrical lumen.

23. The device as set forth in any one of claims **1-22**, wherein the device is MR unsafe and is marked externally to indicate this designation using a metallic coating on the feeding tube **(70)**.

24. A method of constructing a device, the method comprising:

forming a feeding tube **(70)** including a feeding lumen **(80)** and an electrical lumen **(84)**, the electrical lumen having access openings **(120)** spaced apart along the feeding tube;

inserting a set of insulated electrical conductors **(82)** into the electrical lumen of the feeding tube, the set of insulated electrical conductors having electrically exposed portions **(132, 132a, 132b)** that are proximate to the access openings after the inserting; and

after the inserting, forming electrodes **(72, 73, 74, 78, 79, 140)** by a process including injecting electrically conductive material portions **(140)** into the access openings of the electrical lumen to electrically contact the proximate electrically exposed portions of the set of insulated electrical conductors disposed in the electrical lumen.

25. The method as set forth in claim **24**, further comprising, after the injecting, disposing outer electrode elements **(72, 73, 74, 75, 78, 79)** or coating portions over at least the electrically conductive material portions **(140)** so as to define exterior surfaces of the electrodes.

26. A medical device constructed by a method set forth in any one of claims **24-25**.

27. A device comprising:

a feeding tube **(70)** including a feeding lumen **(80)** with an opening **(152)** at a distal end of the feeding tube and an electrical lumen **(84)**;

a set of insulated electrical conductors **(82)** disposed in the electrical lumen;

electrodes **(72, 73, 74, 78, 79, 140)** disposed along the feeding tube and electrically contacting the set of insulated electrical conductors, the electrodes including a set of upper or proximal electrodes **(74, 78, 79)** and a set of lower or distal electrodes **(72, 73)**; and

a switch **(116, 160)** configured to operatively connect one electrode of the set of upper or proximal electrodes **(74, 78, 79)** and one electrode of the set of lower or distal electrodes **(72, 73)** to an electrocardiograph (ECG) instrument **(110)**.

28. The device as set forth in claim **27**, wherein the feeding tube **(70)** is sized and the electrodes **(72, 73, 74, 78, 79, 140)** are placed respective to a patient such that the set of upper or proximal electrodes **(74, 78, 79)** are disposed in an esophagus, the

set of lower or distal electrodes **(72, 73)** are disposed in an esophagus, and an expected patient heart electrical centerline **(CL)** is disposed between the operatively connected one electrode of the set of upper or proximal electrodes **(74, 78, 79)** and operatively connected one electrode of the set of lower or distal electrodes **(72, 73)**.

29. The device as set forth in claim **27**, wherein the feeding tube **(70)** is sized and the electrodes **(72, 73, 74, 78, 79, 140)** are placed respective to a patient such that the set of upper or proximal electrodes **(74, 78, 79)** are disposed in an esophagus, the set of lower or distal electrodes **(72, 73)** are disposed in an esophagus, and an expected patient heart electrical centerline **(CL)** is disposed between the operatively connected one electrode of the set of upper or proximal electrodes **(74, 78, 79)** and operatively connected one electrode of the set of lower or distal electrodes **(72, 73)** while the distal end of the feeding tube is in the stomach.

30. The device as set forth in any one of claims **27-29**, further comprising:

said ECG instrument **(110)**; and

a respiration monitor **(115)**, the switch **(116, 160)** further configured to operatively connect the same one electrode of the set of upper or proximal electrodes **(74, 78, 79)** and the same one electrode of the set of lower or distal electrodes **(72, 73)** to the respiration monitor **(115)**.

31. The device as set forth in any one of claims **27-30**, wherein the switch **(116, 160)** is selected from a group consisting of:

a manual switch **(160)** providing said configuration for selective operative connection, and

an electrocardiograph instrument **(110)** or patient monitor **(116)** electronically providing said configuration for selective operative connection.

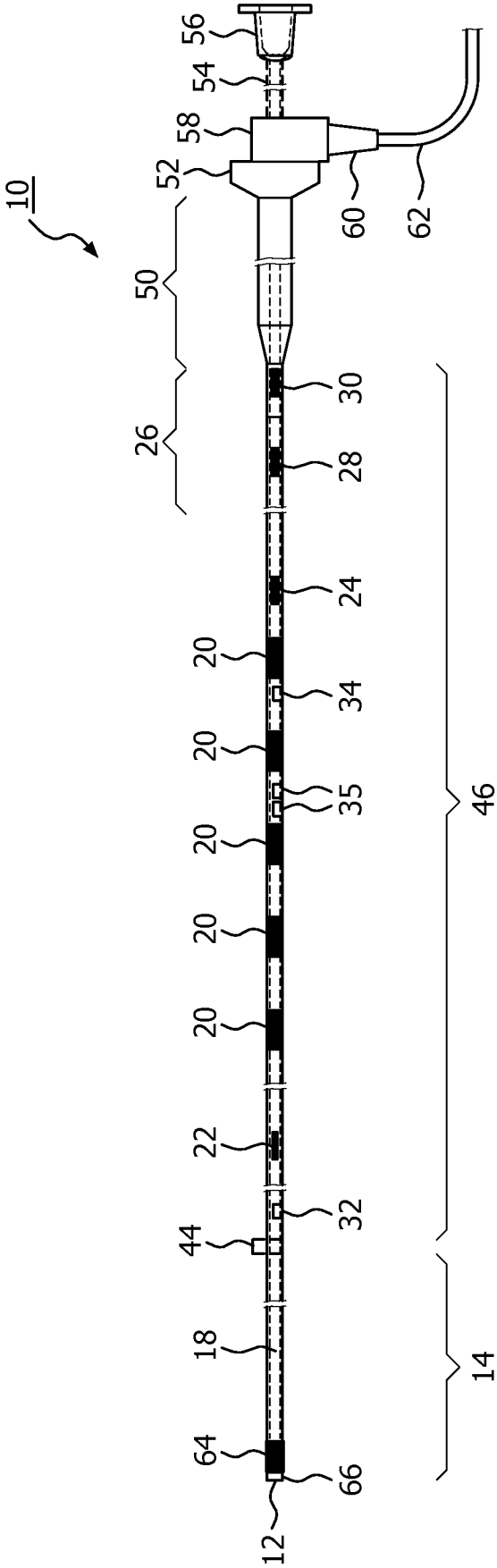

FIG. 1

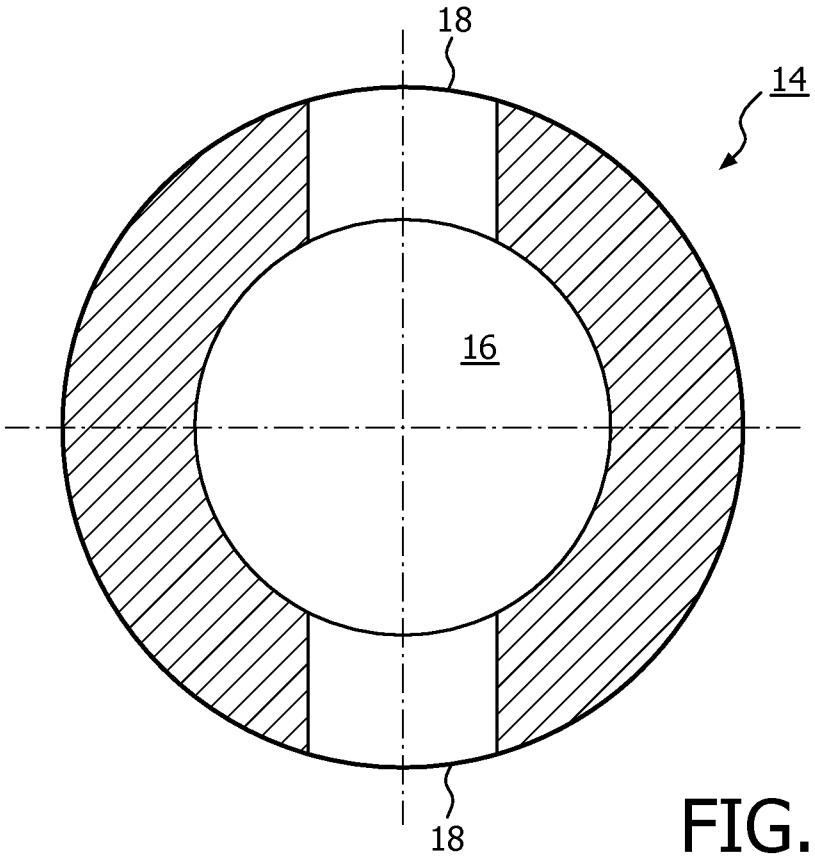

FIG. 2

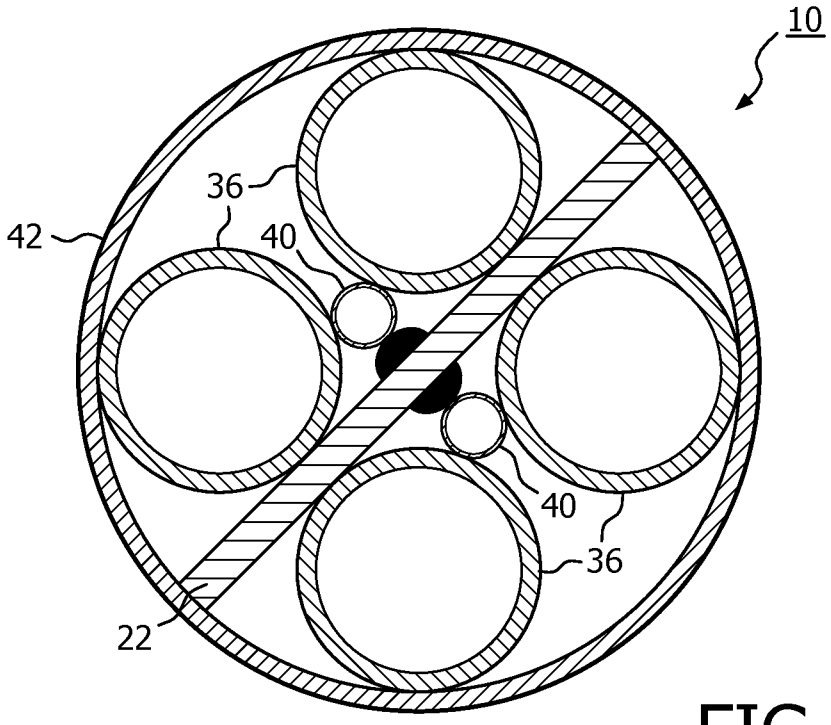

FIG. 3

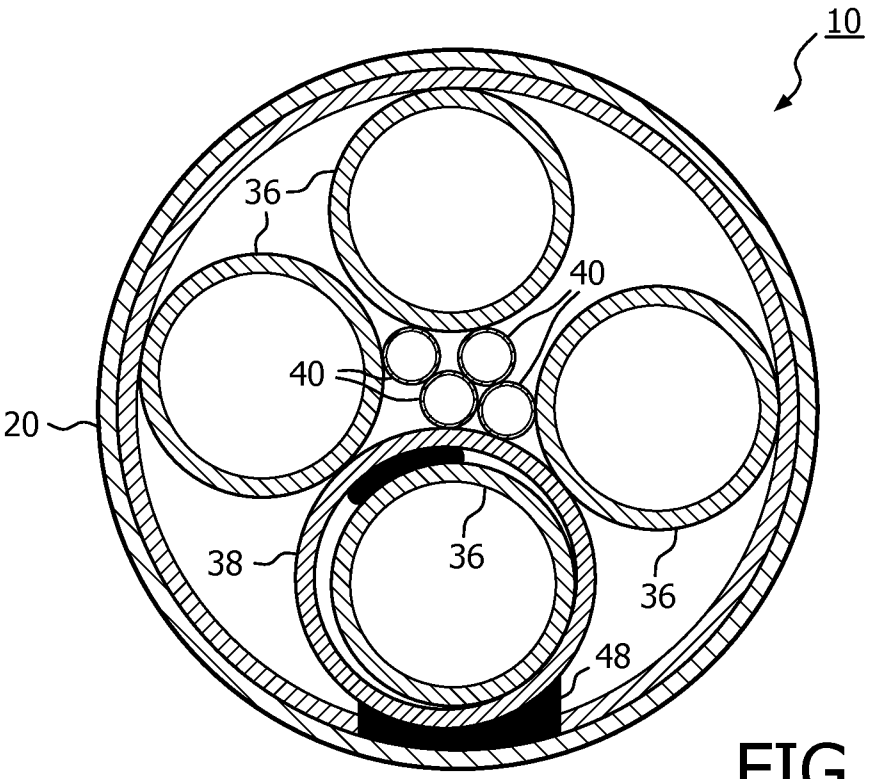

FIG. 4

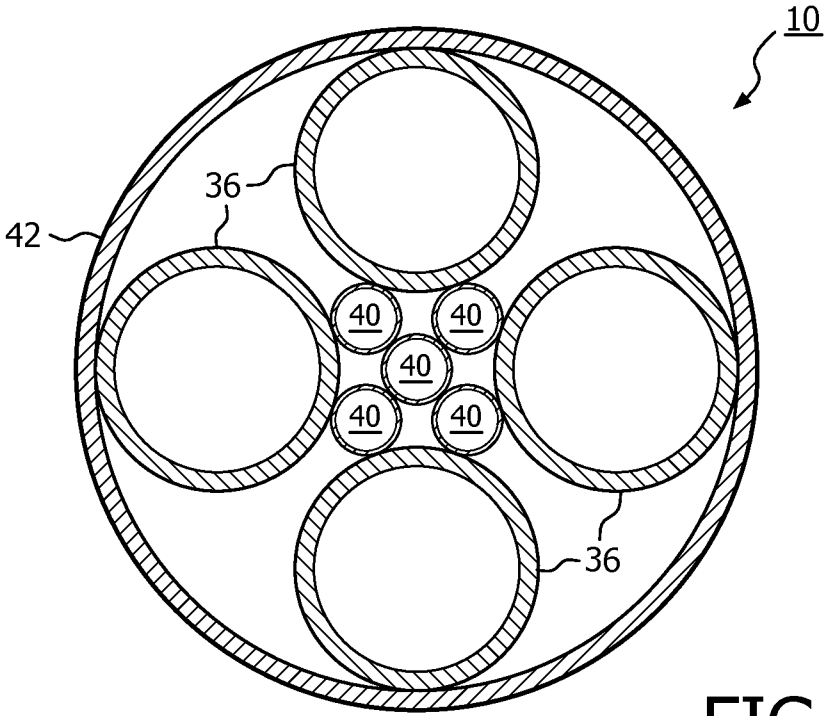

FIG. 5

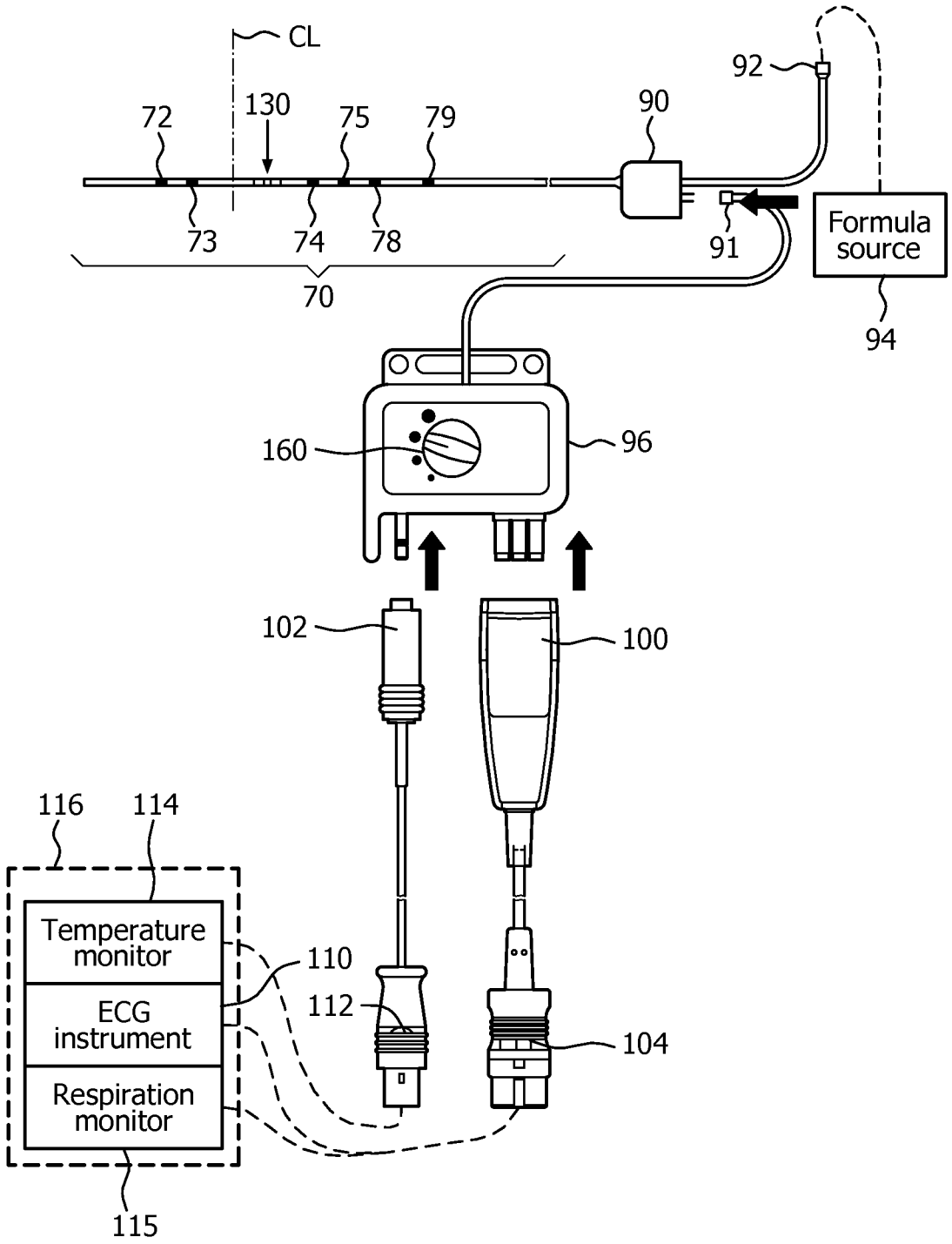
CL
72
130
75
79
90
92
73
74
78
91
Formula source
70
94
160
96
102
100
116
114
Temperature monitor
ECG instrument
Respiration monitor
110
112
104
115

FIG. 6

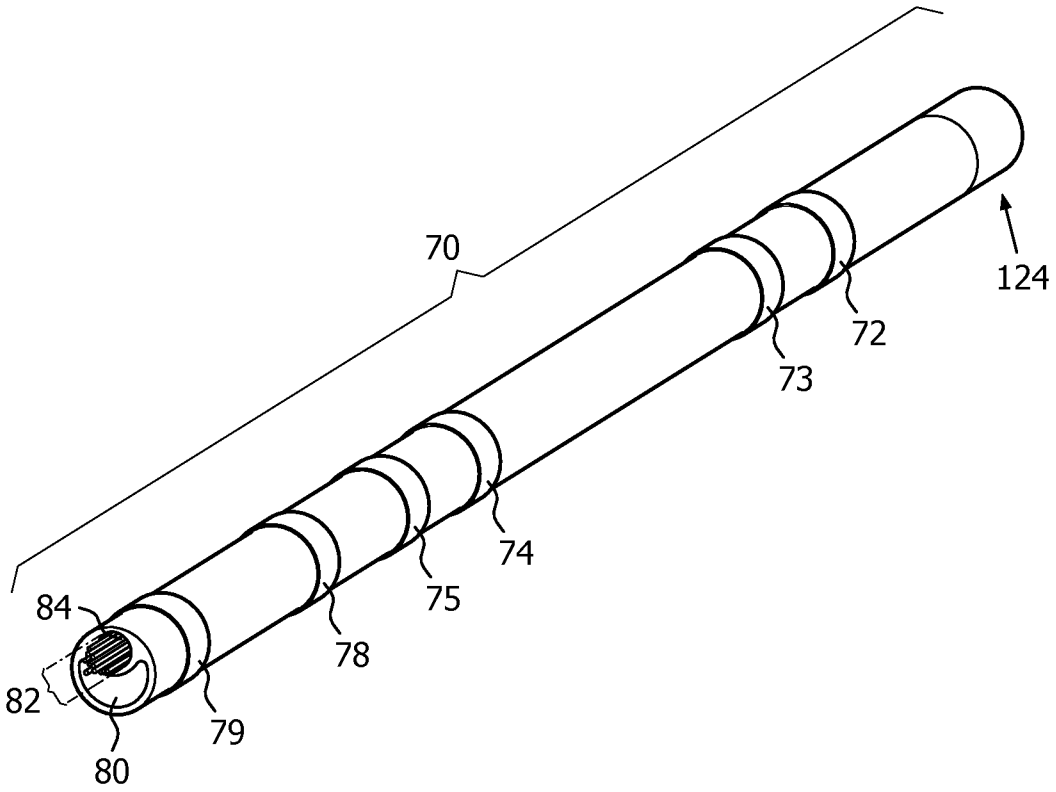

FIG. 7

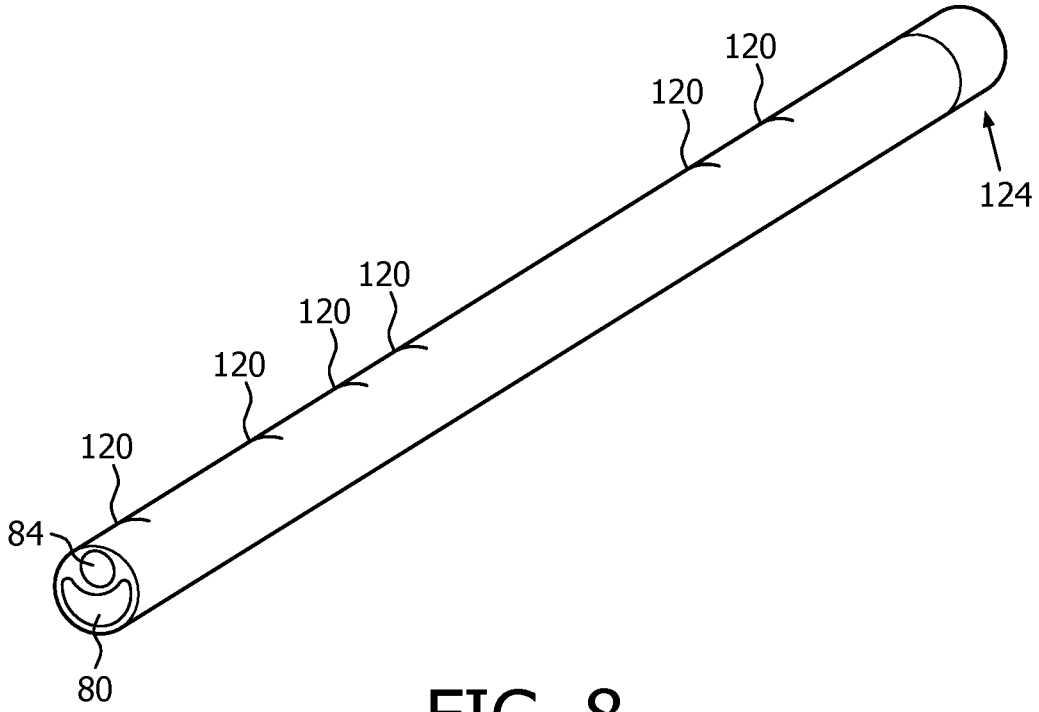

FIG. 8

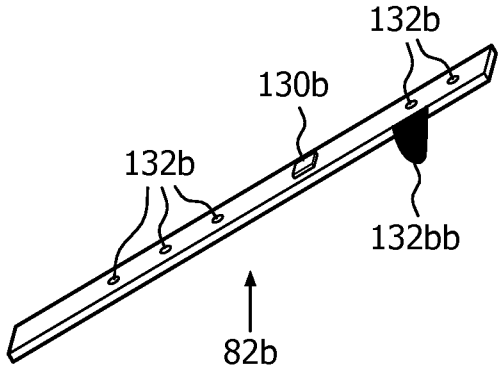

FIG. 9B

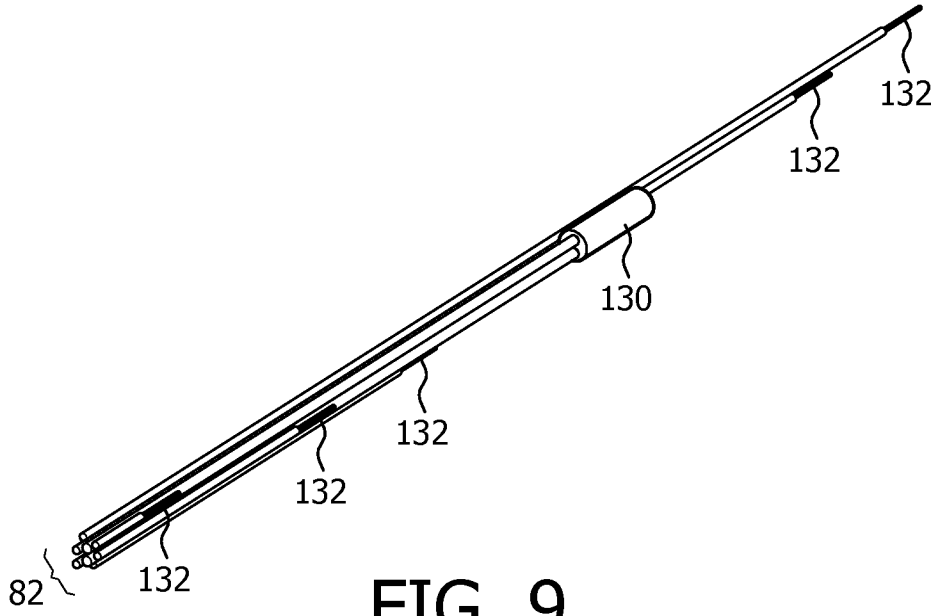

FIG. 9

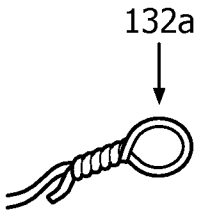

FIG. 9A

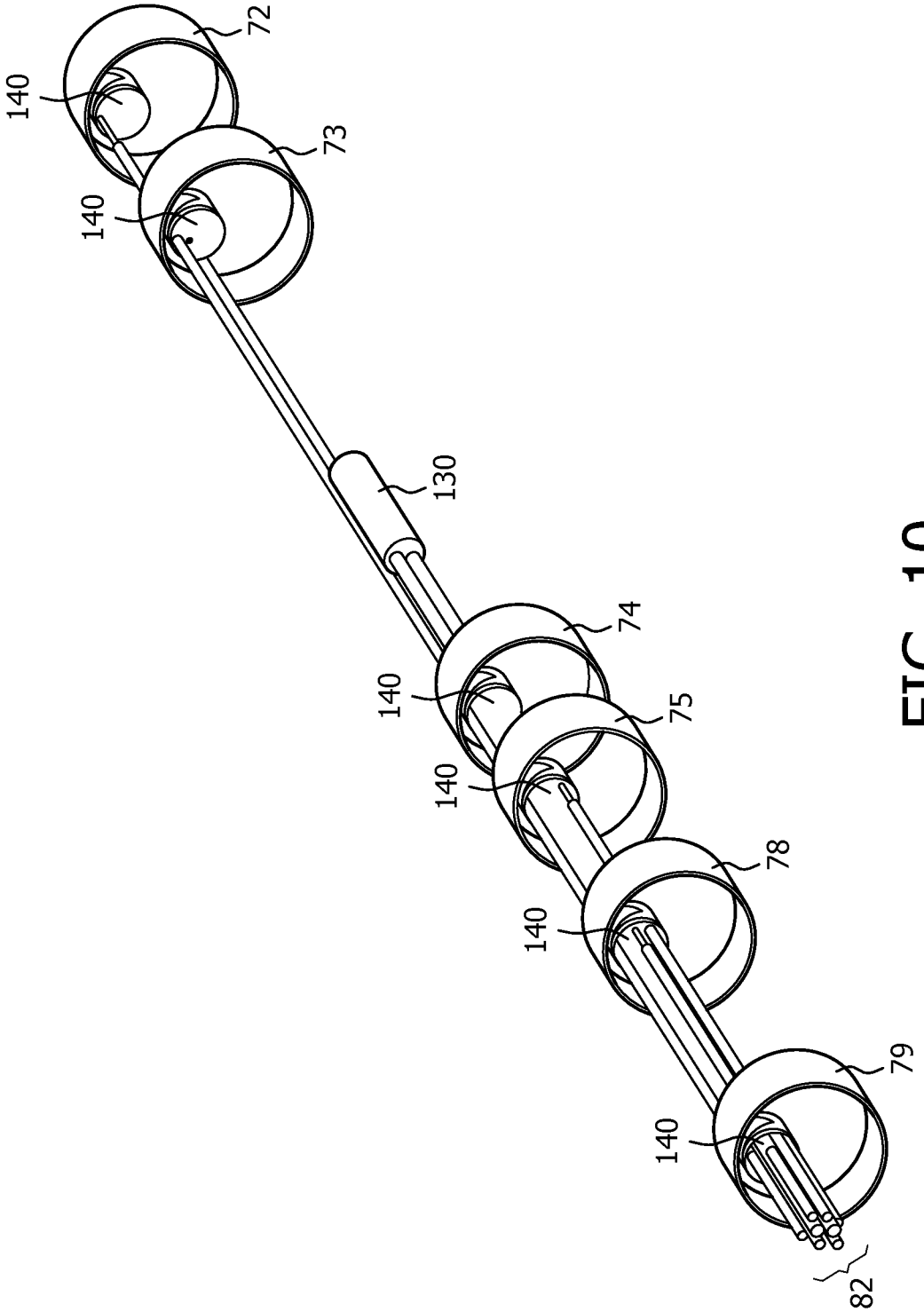

FIG. 10

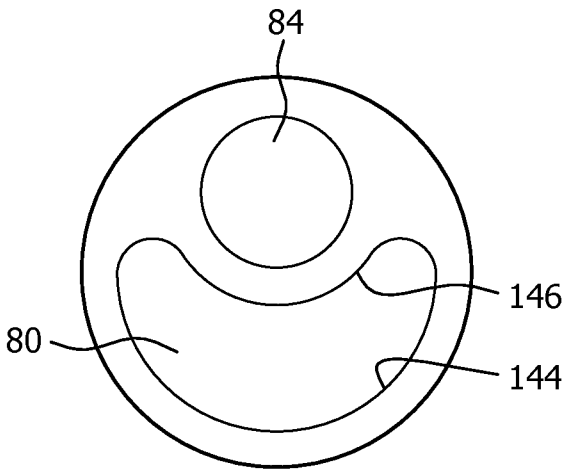

FIG. 11

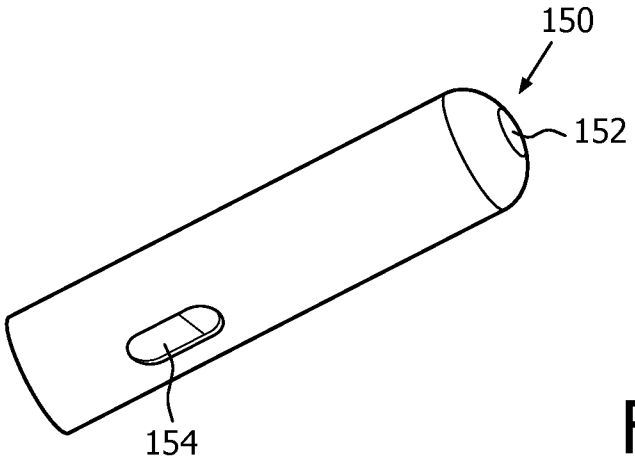

FIG. 12

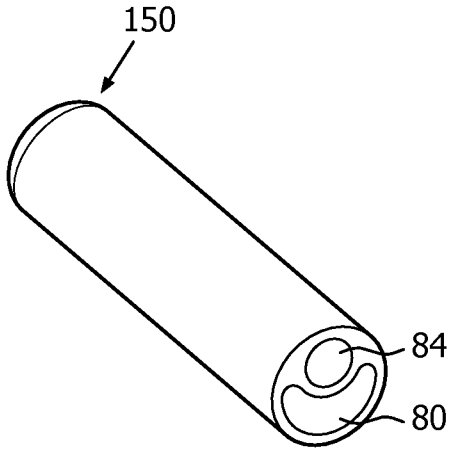

FIG. 13

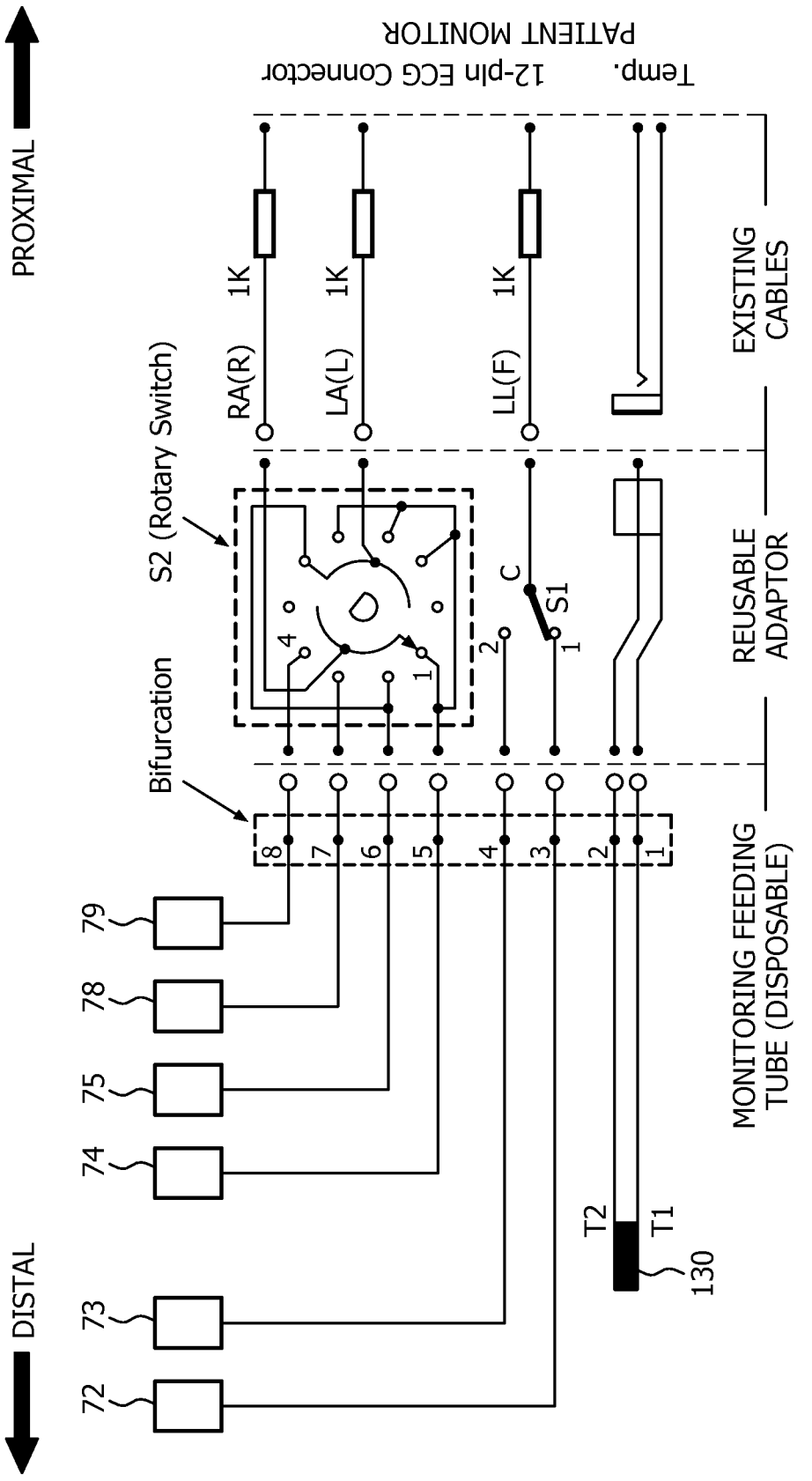
PROXIMAL
DISTAL
PATIENT MONITOR
12-pin ECG Connector
Temp.
EXISTING CABLES
REUSABLE ADAPTOR
MONITORING FEEDING TUBE (DISPOSABLE)
RA(R)
LA(L)
LL(F)
1K
1K
1K
S2 (Rotary Switch)
Bifurcation
C
S1
T2
T1
130
72
73
74
75
78
79

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/050454

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/0205 A61B5/04 A61B5/042 A61J15/00
A61B5/1459
ADD.
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)
A61J A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 397 231 A (EP ADVANCE LTD [GB]) 21 July 2004 (2004-07-21)	1-5,12, 16, 21-24, 26,28-31
Y	page 6 - page 11	13-15, 18-20,27

Y	US 5 199 433 A (METZGER WILLIAM T [US] ET AL) 6 April 1993 (1993-04-06) column 3, line 11 - column 3, line 58 column 5, line 25 - column 5, line 36	13-15, 18-20,27

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[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 document 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
31 May 2011	16/06/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Edlauer, Martin

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/050454

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/072150 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; WEEKAMP JOHANNES W [NL]; SAVENIJE) 19 June 2008 (2008-06-19) page 5, line 11 - page 5, line 14 page 7, line 20 - page 7, line 29 page 7, line 30 - page 9, line 2 page 9, line 29 - page 9, line 30	1,2,4,8, 10,12, 16,17, 21,23
X	WO 2006/015230 A2 (BIOMEDICAL RES ASSOCIATES LLC [US]; VALENTA HARRY L JR [US]; LIPP ELIZ) 9 February 2006 (2006-02-09) page 10, line 11 - page 11, line 29	1,10-12, 15,16, 21-23
X	WO 2005/115234 A1 (MCLEOD CHRISTOPHER NEIL [GB]; BAKER A BARRINGTON [AU]; MCLEOD KATIE A) 8 December 2005 (2005-12-08) the whole document	1,6-10, 12,16, 22,23
X	WO 99/59463 A1 (RESPIRONICS INC [US]) 25 November 1999 (1999-11-25) page 8, line 3 - line 9 page 10, line 11 - page 11, line 1 page 11, line 14 - page 11, line 19 page 14, line 14 - page 14, line 17 page 24, line 5 - page 24, line 17	1,6,7, 10,12, 15,16, 21,23

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/050454

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 6259938 B1	10-07-2001

专利名称(译)	多功能喂食管		
公开(公告)号	EP2542143A1	公开(公告)日	2013-01-09
申请号	EP2011709188	申请日	2011-02-02
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦电子N.V.		
当前申请(专利权)人(译)	皇家飞利浦电子N.V.		
[标]发明人	FEER DAVID L SILBER DANIEL A		
发明人	FEER, DAVID, L. SILBER, DANIEL, A.		
IPC分类号	A61B5/00 A61B5/0205 A61B5/04 A61B5/042 A61J15/00 A61B5/1459 A61B5/01 A61B5/03 A61B5/053 A61B5/08 A61B5/087		
CPC分类号	A61B5/01 A61B5/037 A61B5/0421 A61B5/0422 A61B5/053 A61B5/0538 A61B5/0816 A61B5/0878 A61B5/6846 A61B2562/0271 A61B2562/043 A61J15/0003 A61J15/0073 A61J15/0084 Y10T29/49117		
优先权	61/310308 2010-03-04 US		
其他公开文献	EP2542143B1		
外部链接	Espacenet		

摘要(译)

一种医疗装置，包括：进料管（70），其包括进料管腔（80），所述进料管腔（80）在所述进料管的远端具有开口（152），并且电腔（84）具有沿所述进料管间隔开的进入开口（120）。管;一组绝缘电导体（82）设置在电气腔中，该组绝缘电导体具有靠近进入开口的电暴露部分（132,132a，132b）;电极和电极（72,73,74,75,78,79,140）包括设置在进入开口中的导电材料部分（140），并与设置在电气腔中的一组绝缘电导体的邻近电暴露部分电接触。电极包括设置在预期患者心脏电中心线（CL）上方的至少一个上部或近侧电极（74,75,78,79）和设置在预期患者心脏电气下方的至少一个下部或远侧电极（72,73）。中心线。