(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 2 889 013 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
30.05.2018 Bulletin 2018/22

(21) Application number: **14200527.1**

(22) Date of filing: **30.12.2014**

(51) Int Cl.:
A61B 18/14 *(2006.01)*
A61B 5/145 *(2006.01)*
A61B 18/00 *(2006.01)*
A61B 5/00 *(2006.01)*
A61B 5/1459 *(2006.01)*

(54) Catheter utilizing optical spectroscopy for measuring tissue contact area

Katheter mit optischer Spektroskopie zur Messung der Gewebekontaktfläche

Cathéter utilisant une spectroscopie optique pour la mesure de zone de contact de tissu

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **31.12.2013 US 201314145858**

(43) Date of publication of application:
01.07.2015 Bulletin 2015/27

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EP 2 889 013 B1

Printed by Jouve, 75001 PARIS (FR)

Description

FIELD OF INVENTION

[0001] This invention relates to catheters, in particular, cardiac catheters for ablation and tissue diagnostics.

BACKGROUND

[0002] Radiofrequency (RF) ablation of cardiac and other tissue is a well-known method for creating thermal injury lesions at the tip of an electrode. Radiofrequency current is delivered between a skin (ground) patch and the electrode. Electrical resistance at the electrode-tissue interface results in direct resistive heating of a small area, the size of which depends upon the size of the electrode, electrode tissue contact, and current (density). Further tissue heating results from conduction of heat within the tissue to a larger zone. Tissue heated beyond a threshold of approximately 50-55 degrees C is irreversibly injured (ablated).

[0003] Resistive heating is caused by energy absorption due to electrical resistance. Energy absorption is related to the square of current density and inversely with tissue conductivity. Current density varies with contact area conductivity, voltage and inversely with the square of radius from the ablating electrode. Therefore, energy absorption varies with conductivity, the square of applied voltage, and inversely with the fourth power of radius from the electrode. Resistive heating, therefore, is most heavily influenced by radius, and penetrates a very small distance from the ablating electrode. The rest of the lesion is created by thermal conduction from the area of resistive heating. This imposes a limit on the size of ablation lesions that can be delivered from a surface electrode.

[0004] Theoretical methods to increase lesion size would include increasing electrode diameter, increasing the area of electrode contact with tissue, increasing tissue conductivity and penetrating the tissue to achieve greater depth and increase the area of contact, and delivering RF until maximal lesion size has been achieved (60-90 seconds for full maturation).

[0005] The electrode can be introduced to the tissue of interest directly (for superficial/skin structures), surgically, endoscopically, laparoscopically or using percutaneous transvascular (catheter-based) access. Catheter ablation is a well-described and commonly performed method by which many cardiac arrhythmias are treated.

[0006] Catheter ablation is sometimes limited by insufficient lesion size. Ablation of tissue from an endovascular approach results not only in heating of tissue, but heating of the electrode. When the electrode reaches critical temperatures, denaturation of blood proteins causes coagulum formation. Impedance can then rise and limit current delivery. Within tissue, overheating can cause steam bubble formation (steam "pops") with risk of uncontrolled tissue destruction or undesirable perforation of bodily structures. In cardiac ablation, clinical success is sometimes hampered by inadequate lesion depth and transverse diameter even when using catheters with active cooling of the tip. Theoretical solutions have included increasing the electrode size (increasing contact surface and increasing convective cooling by blood flow), improving electrode-tissue contact, actively cooling the electrode with fluid infusion, changing the material composition of the electrode to improve current delivery to tissue, and pulsing current delivery to allow intermittent cooling.

[0007] To improve electrode-tissue contact, current catheters may have pressure sensors at the distal tip to detect whether the tip electrode is in contact with tissue. However, merely detecting contact does not indicate how much of the tip electrode is actually surrounded by tissue or by fluid and blood. Introduction of an energized electrode into cardiac space results in the formation of a simplified resistive circuit; current flows from the electrode through two parallel resistors via the surrounding blood and the contacting tissue. Understanding the relative surface area of each of these paths will allow for an estimation of each path's respective resistance and therefore the current flow. Such information would be helpful to improve estimation of size and shape of lesions created by ablation, as lesion size and shape are likely a function of power, time and size of contact area of electrode and tissue.

[0008] Method and apparatus employing optical spectroscopy for determining tissue attributes are known. For example, U.S. Patent No. 7,623,906 discloses a method and an apparatus for a diffuse reflectance spectroscopy which includes a specular control device that permits a spectroscopic analyzer to receive diffusely reflected light reflected from tissue. U.S. Patent No. 7952719 discloses an optical catheter configuration combining Raman spectroscopy with optical fiber-based low coherence reflectometry. U.S. Patent No. 6,377,841 discloses the use of optical spectrometry for brain tumor demarcation. EP2008603A1 describes a catheter having a catheter tip design which isolates illumination and collection paths. US2012/0265184A1 describes an ablation catheter having a distal portion with an illumination and collection optical elements which are optically isolated from one another. US2009/0005768 describes a catheter with a tip section with a generally omni-directional light diffusion chamber.

[0009] Accordingly, it is desirable that a catheter be able to assess and measure the amount of contact between an ablation electrode and tissue versus fluid, such as blood, for improving lesion size and depth. It is also desirable that the catheter effectuate such assessment and measurement by optical means that can measure accurately and fit inside the tip electrode without disruption to the function of the tip electrode.

SUMMARY OF THE INVENTION

[0010] In the following any example and embodiment

which does not fall under the scope of the independent claims is not part of the invention. The present invention is directed to a catheter with an irrigated distal tip ablation electrode adapted to assess and measure the extent of contact between the ablation electrode and surrounding tissue. The catheter comprises an elongated catheter shaft, a control handle, and a distal tip electrode having a thin shell with a radially-symmetrical portion defining a cavity. The tip electrode has one or more light emitters configured to emit light from a first predetermined location in the cavity and one or more light detectors configured to collect light from a second predetermined location in the cavity, where the second predetermined location may or may not be generally identical to the first predetermined location. In accordance with a feature of the invention, the light is radiated from the first predetermined location toward the shell where it reflects off the inner surface of the shell or it passes through apertures formed in the shell and interacts with matter(s) outside of the tip electrode. Depending on the interactions of the light with the matter(s) encountered outside of the apertures, the light inside the cavity as collected by the one or more collector waveguides is analyzed to provide an indication of the matter(s) encountered, including, for example, the nature of the matter(s), the amount of the matter(s) and/or the position or orientation of the matter(s) relative to the tip electrode, where the matter(s) may include, for example, tissue and fluid, such as blood. The indication may be used in selective energization of the tip electrode for ablating tissue. In one embodiment, the light received by the light detector is analyzed to determine a ratio of light reflected by tissue versus light absorbed by fluid for indicating the amount of contact between the tip electrode and tissue.

[0011] Alternatively, fluorescence may similarly be employed instead of basic light reflectance. During fluorescence, light may be emitted by the catheter at one wavelength and absorbed by the tissue or blood. As a result of the energy absorbed, the tissue or blood then emits lights back at a different wavelength, and the catheter detects the amount or intensity of light at this other wavelength. Tissue and blood have different fluorescence properties at various wavelengths, and this difference can be also utilized to determine what ratio of the tip is contacting tissue versus blood. For example, it has been shown that at an excitation wavelength of 330nm, myocardium (in cardiac tissue) fluoresces more than hemoglobin (in blood) in the range of 350-550nm, with a peak difference at about 390nm (see FIG. 8). Venius, J., et al., J. Biomed. Opt. 16(10) 2011.

[0012] The present invention includes an integrated catheter-based ablation and spectroscopy system having the aforementioned catheter, an RF generator for providing RF energy to the tip electrode assembly, a light source to provide light energy, and an optical analyzer, for example, a spectrometer, to detect and analyze optical data collected by the one or more collector wave guides. In that regard, it is understood that the spectrometer is any instrument used to probe a property of light as a function of its portion of the electromagnetic spectrum, typically its wavelength, frequency, or energy. The property being measured is often, but not limited to, intensity of light, but other variables like polarization can also be measured. Technically, a spectrometer can function over any range of light, but most operate in a particular region of the electromagnetic spectrum.

[0013] The system may also include a patient interface unit and a communication (COM) unit, a processor and a display, where the COM unit provides electronics for ECG, electrogram collection, amplification, filtering and real-time tracing of catheter distal tip and the PIU allows communication with various components of the system, including signal generator, recording devices, etc. The system may include a location pad with magnetic field generators (e.g., coils) to generate magnetic fields within the patient's body. Signals detected by a sensor housed in the catheter in response to the magnetic fields are processed by the processor order to determine the position (location and/or orientation) coordinates of the catheter distal end. Other signals from the catheter, for example, tissue electrical activity and temperature, are also collected by the catheter and transmitted to the COM unit and the processor via the PIU for processing and analysis.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a perspective view of a catheter of the present invention, in accordance with one embodiment.

FIG. 2A is a side cross-sectional view of the catheter of FIG. 1, including a junction between a catheter body and a deflectable intermediate section, along a first diameter.

FIG. 2B is a side cross-sectional view of the catheter of FIG. 1, including a junction between a catheter body and a deflectable intermediate section, along a second diameter generally perpendicular to the first diameter of FIG. 2A.

FIG. 2C is an end cross-sectional view of the deflectable intermediate section of FIGS. 2A and 2B, taken along line C-C.

FIG. 3 is a side cross-sectional view of a distal section, including a connector member and a distal tip electrode of the present invention, in accordance with one embodiment.

FIG. 3A is an end cross-sectional view of a connector member of FIG. 3, taken along line A-A.

FIG. 3B is an end cross-sectional view of the distal tip electrode of FIG. 3, taken along line B-B.

FIG. 4A is a side cross-sectional view of a junction between a deflectable intermediate section and a connector member, in accordance with one embodiment, taken along a first diameter

FIG. 4B is a side cross-sectional view of a junction between a deflectable intermediate section and a connector member, in accordance with one embodiment, taken along a second diameter generally perpendicular to the first diameter.

FIGS. 5A-5D are side cross-sectional views of a distal tip electrode in accordance with alternate embodiments of the present invention.

FIG. 6 is a detailed side cross-sectional view of a distal tip electrode in contact with tissue.

FIG. 7A is a schematic diagram of a system of the present invention, in accordance to one embodiment.

FIG. 7B is a block diagram of the system of FIG. 7A.

FIG. 8 is a fluorescence spectra of HCS (heart conduction system), CT (connective tissue) and MC (myocardium) normalized to the first band (at 390 nm). The normalized absorption spectra of oxyhemoglobin HbO2 and hemoglobin Hb are also added. Venius, J., et al., J. Biomed. Opt. 16(10) 2011.

DETAILED DESCRIPTION OF THE INVENTION

[0015] As shown in FIG. 1, the catheter 10 comprises an elongated catheter body 12, deflectable intermediate section 14, a distal tip electrode 15 and a deflection control handle 16 attached to the proximal end of the catheter body 12. As described further below, the distal tip electrode 15 is adapted to provide optically-based indications of matter surrounding the tip electrode, including for example, the degree to which the tip electrode is surrounded by or in contact with soft tissue, versus fluid, such as blood.

[0016] With reference to FIGS. 2A and 2B, the catheter body 12 comprises a single, central or axial lumen 18. The catheter body 12 is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body 12 may be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall 22 made of polyurethane or nylon. The outer wall 22 comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body 12 so that, when the deflection control handle 16 is rotated, the intermediate section 14 of the catheter 10 will rotate in a corresponding manner.

[0017] The outer diameter of the catheter body 12 is not critical, but is preferably no more than about 8 French. Likewise the thickness of the outer wall 22 is not critical. In the depicted embodiment, the inner surface of the outer wall 22 is lined with a stiffening tube 20, which can be made of any suitable material, preferably polyimide. The stiffening tube 20, along with the braided outer wall 22, provides improved torsional stability while at the same time minimizing the wall thickness of the catheter, thus maximizing the diameter of the single lumen. The outer diameter of the stiffening tube 20 is about the same as or slightly smaller than the inner diameter of the outer wall 22.

[0018] As shown in FIGS. 2A, 2B and 2C, the intermediate section 14 comprises a short section of multilumened tubing 19 having, for example, at least four lumens, namely a first lumen 30, a second lumen 31, a third lumen 32, a fourth off-axis puller wire lumen 33 for uni-directional deflection, and a fifth off-axis lumen 34 diametrically opposite of lumen 33 for bidirectional deflection. The tubing 19 is made of a suitable non-toxic material that is preferably more flexible than the catheter body 12. A suitable material for the tubing 19 is braided polyurethane, i.e., polyurethane with an embedded mesh of braided stainless steel or the like. The outer diameter of the intermediate section 14, like that of the catheter body 12, is preferably no greater than about 8 French.

[0019] A suitable means for attaching the catheter body 12 to the intermediate section 14 is illustrated in FIGS. 2A and 2B. The proximal end of the intermediate section 14 comprises an inner counter bore 24 that receives the outer surface of the stiffener 20. The intermediate section 14 and catheter body 12 are attached by glue or the like. Other methods for attaching can be used in accordance with the invention.

[0020] The stiffening tube 20 is held in place relative to the outer wall 22 at the catheter body 12. In a suitable construction of the catheter body 12, a force is applied to the proximal end of the stiffening tube 20, which causes the distal end of the stiffening tube 20 to firmly push against the counter bore 24. While under compression, a first glue joint is made between the stiffening tube 20 and the outer wall 22 by a fast drying glue, e.g. Super Glue.RTM.. Thereafter, a second glue joint is formed between the proximal ends of the stiffening tube 20 and outer wall 22 using a slower drying but stronger glue, e.g., polyurethane.

[0021] Extending from the control handle 16 and through the center lumen 18 of the catheter body 12 and the first lumen 30 of the tubing 19 are a lead wire 29 for the tip electrode 15, a thermocouple wire pair 50 and 51 for sensing temperature of the tip electrode, and a cable 52 for an electromagnetic location sensor 54 housed near the tip electrode 15. Extending from the control handle 16 and through the center lumen 18 and the second lumen 31 is an irrigation tubing 56 for passing fluid, e.g., saline, from the control handle 16 and along the length of the catheter to the tip electrode 15. Extending from the control handle 16 and through the center lumen 18 and the third lumen 32 is at least two optical waveguides, for example, an emitter waveguide 60E and a collector waveguide 60C. In the disclosed embodiment, there are one emitter waveguide and three collector waveguides.

[0022] The depicted catheter includes a mechanism for deflecting the catheter body 12. In the depicted embodiment, the catheter is adapted for bi-directional de-

flection with a first puller wire 43 extending into the puller wire lumen 33 and a second puller wire 44 extending into the puller wire lumen 34. The puller wires 43 and 44 are anchored at their proximal ends in the deflection control handle 16 and anchored at their distal end at or near a distal end of the intermediate section 14. The puller wires are made of any suitable metal, such as stainless steel or Nitinol, and are preferably coated with Teflon.RTM. or the like. The coating imparts lubricity to the puller wires. Each puller wire preferably has a diameter ranging from about 0.015 to about 0.025 cm (0.006 to about 0.010 inches).

[0023] To effectuate deflection of the intermediate section 14, each puller wire is surrounded by a respective compression coil 45 that extends from the proximal end of the catheter body 12 and terminates at or near the proximal end of the intermediate section 14. Each compression coil 45 is made of any suitable metal, preferably stainless steel. The compression coil 45 is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil 45 is preferably slightly larger than the diameter of the puller wire. For example, when the puller wire has a diameter of about 0.018 cm (0.007 inches), the compression coil preferably has an inner diameter of about 0.02 cm (0.008 inches). The Teflon.RTM. coating on the puller wire allows it to slide freely within the compression coil 45. Along its length, the outer surface of each compression coil 45 is covered by a respective flexible, non-conductive sheath 26 to prevent contact between the compression coils and any other components inside the catheter body 12. The non-conductive sheath 26 may be made of polyimide tubing. Each compression coil 45 is anchored at its proximal end to the proximal end of the stiffening tube 20 in the catheter body 12 by glue (not shown). At its distal end, each compression coil is anchored in the respective puller wire lumen 33 and 34 by glue joint 46 (FIG. 2B). Within the intermediate section 14, the puller wires 43 and 44 extend through a respective protective sheath 81, for example of Teflon.RTM., which prevents the puller wire from cutting into the wall of the tubing 19 when the section 14 is deflected.

[0024] The puller wires are anchored at their distal ends to the sides of the tubing 19 of the intermediate section shaft 14, as shown in FIG. 4B. In this embodiment, a T-shaped anchor 23 is used for each puller wire. The anchor 23 comprises a short piece of tubular stainless steel 25, e.g., hypodermic stock, which is fitted over the distal end of each puller wire and crimped to fixedly secure it to the puller wire. The distal end of the tubular stainless steel 25 is fixedly attached, e.g., by welding, to a stainless steel cross-piece 27, such as stainless steel ribbon or the like. The cross-piece 27 sits in a notch 28 in a wall of the tubing 19. The stainless steel cross-piece 27 is larger than the notch 28 and, therefore, cannot be pulled through the notch. The portion of the notch 28 not filled by the cross-piece 27 is filled with glue 21 or the like, preferably a polyurethane glue, which is harder than the material of the tubing 19 of the intermediate section 14. Rough edges, if any, of the cross-piece 27 are polished to provide a smooth, continuous surface with the outer surface of the distal shaft 14.

[0025] Any other suitable technique for anchoring the puller wires in the intermediate section 14 can also be used. Alternatively, other means for deflecting the distal region can be provided, such as the deflection mechanism described in U.S. Pat. No. 5,537,686.

[0026] Longitudinal movement of the puller wires relative to the catheter body 12, which results in deflection of the intermediate section 14, is accomplished by suitable manipulation of a deflection control knob 17 on the control handle 16 (FIG. 1). Examples of suitable control handles manipulating a single puller wire for unidirectional deflection are disclosed, for example, in U.S. Pat. Nos. Re 34,502, 5,897,529 and 6,575,931. Suitable control handles manipulating at least two puller wires for bidirectional deflection are described in U.S. Pat. Nos. 6,123,699, 6,171,277, and 6,183,463.

[0027] As shown in FIGS. 3, 4A and 4B, distal of the intermediate section 14 is a distal section including a tip electrode 70 that is connected to the distal end of the tubing 19 by a connector tubing 71. The tubing 71 has a single center lumen 72 that allows components extending between the section 14 and the tip electrode 70 to reposition/realign as needed. The tubing 71 also houses an electromagnetic location sensor 54. The location sensor is used to determine the coordinates of the tip electrode in the patient's body. The corresponding sensor cable 52 extends from the control handle 16, through the lumen 18 of the catheter body 12, the lumen 30 of the intermediate section, and into the lumen 72 of the connector tubing 71. In the control handle 16, the sensor cable 52 is connected to a circuit board (not shown). Signals from the circuit board are transmitted to a computer and a monitor. The electromagnetic sensor 54 allows a physician to create a visual representation of the heart chamber and to view the location of the sensor, and therefore the catheter tip, within the chamber. The sensor cable 52 comprises multiple wires encased within a plastic covered sheath. The circuit board amplifies the signal received from the location sensor 54 and transmits it to the computer in a form understandable by the computer. Also, because the catheter is designed for single use only, the circuit board may contain an EPROM chip that shuts down the circuit board approximately twenty-four hours after the catheter has been used. This prevents the catheter, or at least the location sensor 54, from being used twice. A suitable control handle 16 is described in U.S. Pat. No. 6,024,739.

[0028] The location sensor 54 may comprise a magnetic-field-responsive coil, as described in U.S. Pat. No. 5,391,199. The plurality of coils enables the six-dimensional coordinates (i.e. the three positional and the three orientational coordinates) of the location sensor 77 to be determined. Alternatively, any suitable location sensor known in the art may be used, such as electrical, mag-

netic or acoustic sensors. Suitable location sensors for use with the present invention are also described, for example, in U.S. Pat. Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951, and 5,568,809, International Publication Nos. WO 95/02995, WO 97/24983, and WO 98/29033, and U.S. patent application Ser. No. 09/882,125 filed Jun. 15, 2001, entitled "Position Sensor Having Core with High Permeability Material,".

[0029] As shown in FIG. 3, the tip electrode 70 has a thin-walled shell member 74 and a plug member 76. The hollow shell member 74 has a distal portion defining a cavity or plenum chamber 80, and an open proximal tubular neck portion 74P which receives and is sealed by a disc-shaped the plug member 82.

[0030] The plug member 76 is formed with a center axial passage 84 to receive the optical waveguides 60E and 60C which extend through the passage 84 from the lumen 31 of the intermediate section 14, through the lumen 72 of the connector tubing 71, through the passage 84 and into the cavity 80. Distal ends of the optical waveguides are positioned at the center location C such that light delivered by the waveguides radiates outwardly throughout the cavity 80 from the center location C, as explained further below.

[0031] The plug member 76 also has an off-axis axial passage 86 for receiving the irrigation tubing 56 which extends from the lumen 35 of the intermediate section 14, through the lumen 72 of the connector tubing 71, and into the passage 86.

[0032] The plug member 76 on its proximal surface has a blind hole 88 which receives a distal end of the lead wire 29 for energizing the tip electrode 15. The plug member 76 also has a blind hole 90 on its proximal surface which receives distal ends of the thermocouple wires 50 and 51. The wires are provided for measuring the temperature of the tissue surrounding the tip electrode 15. Any conventional temperature sensor, e.g., a thermocouple or thermistor, may be used. In the depicted embodiment, the thermocouple is formed by an enameled wire pair. One wire of the wire pair is a copper wire 50, e.g., a 46 AWG copper wire. The other wire of the wire pair is a constantan wire 51, e.g., a 46 AWG constantan wire. The wires 50 and 51 of the wire pair are electrically isolated from each other except at their distal ends, where they are soldered together, covered with a short piece of plastic tubing 91, e.g., polyimide, and covered with polyurethane. The plastic tubing 91 is then glued or otherwise anchored in the blind hole 88.

[0033] Proximal of the control handle 16, the thermocouple wire pair 50 and 51 and the lead wire 29 are attached to an appropriate connector 79 (FIG. 1) connectable to a suitable temperature monitor. Within the catheter body 12 and the deflection control handle 16, the thermocouple wire 50 and 51 and the lead wire 29 may extend through a protective tube (not shown), which may be eliminated if desired. In an alternative embodiment, the copper wire 50 of the thermocouple can also be used as the lead wire for the tip electrode 15.

[0034] In accordance with a feature of the present invention, the shell member 74 of the tip electrode 15 has distal portion with a radially symmetrical configuration relative to the predetermined location in the cavity 80. That is, the portion of the shell member surrounding the cavity is uniformly spaced from the location by a distance R. In the illustrated embodiment of FIG. 3, the location is a center location C and the radially symmetrical configuration of the cavity is hemispherical as defined by a radius R1 for a radial angle Φ sweeping about 180 degrees. The present invention includes other configurations. In the illustrated embodiment of FIG. 5A, the radially symmetrical configuration is defined by a radius R2 for a radial angle $\Phi 1$ sweeping up to about 360 degrees, or alternatively, a radial angle of $\Phi 2$ sweeping up to about 270 degrees. Notably, for larger radial angles of Φ, the distal surface of the plug member 76 may be concave to follow the contour of a spherical cavity. In the illustrated embodiment of FIG. 5B, the radially symmetrical configuration is defined by a radius R3 for a radial angle Φ sweeping up to about 90 degrees. In accordance with a feature of the invention, where the connector tubing 71 has a diameter D, the radially symmetrical configuration of the shell member 74 may have a radius ranging between about D and 2D for radial angle Φ that sweeps up to about 90 to 360 degrees, and preferably up to about 180 to 270 degrees.

[0035] The emitter waveguide 60E delivering light into the tip electrode 15 and the collector waveguide(s) 60C collecting light in the cavity 80 extend generally alongside each other throughout the catheter. They may be bound to each other through the lumen 18 of the catheter body 12, the lumen 31 of the intermediate section 14, the lumen 72 of the connector tubing 71, and the passage 84 of the plug member 76. Light delivered to the tip electrode 15 by the waveguide 60E is emitted into the cavity 80 from the center location C and radiates outwardly toward the shell member 74. The distal portion of the shell member 74 surrounding the cavity 80 is formed with a plurality of apertures 82 and inner surfaces of the distal portion of the shell member 74 surrounding the cavity 80 and of a distal surface of the plug member are coated with a reflective coating 92. As illustrated in FIG. 6, for any portion 74A of the shell member 74 in contact with tissue, apertures 82A in that portion are covered by tissue T. For any portion 74B of the shell member 74 out of contact with tissue, apertures 82B in that portion are covered by fluid F, such as blood. Accordingly, the light entering the cavity 80 from the distal end of the emitter waveguide 60E can either strike the coating 92 inside the cavity and be reflected, or it can pass through the apertures 82 where it interacts either with surrounding tissue T which interacts with the light in one manner, or with fluid F, such as blood, which interacts with the light in another manner. Thus, a difference or change in one or more detectable characteristics or parameters of the light present in the cavity 80 having interacted with either tissue T or fluid F (or any other matter) as collected by the collector waveguides

compared to the light in the cavity as originally emitted by the emitter waveguide should provide an indication as to how much of the light interacted with tissue and how much of the light interacted with fluid. Such an indication can provide further indications, including the number of apertures and the amount or percentage of surface of the shell member surrounding the cavity 80 that is surrounded by or in contact with tissue versus fluid. It is understood that the one or more detectable parameters include amount, intensity or fluorescence. For example, where the detectable parameter is amount or intensity of light, and it is understood that tissue generally reflects light whereas fluid generally absorbs light, the more equal the intensity of light present in the cavity (as collected by the collecting waveguides) is to the intensity of light in the cavity as originally emitted by the emitting waveguide, then presumably the lesser the number of apertures 82 that are covered by light-absorbing fluid, and thus the more the outer surface of the shell member is presumably in contact with tissue for better lesions during ablation. Thus, by analyzing the amount or intensity of light collected in the cavity, for example, by determining a ratio of light reflected versus light absorbed, a determination of how much of the portion of the shell member surrounding the cavity is in contact with tissue.

[0036] For example, where the detectable parameter is fluorescence, and it is understood that tissue and blood have different fluorescence properties at different wavelengths, the differences between the wavelength of light emitted versus the wavelengths of the light collected help determine what ratio of the tip electrode is contacting tissue versus blood.

[0037] In the illustrated embodiment of FIGS. 3, 5A and 5B, the distal ends of both the emitter waveguide 60E and the collector waveguides 60C are positioned generally at the center location C so that the location from where the light radiates outwardly is generally identical to the location where reflected light is collected in the cavity 80.

[0038] It is understood that the total plurality of emitter and collector waveguides may vary depending on desire and need. Moreover, the plurality of emitter waveguide(s) and the plurality of collector wave guide(s) can be equal or unequal to each other. For example, the plurality of each may range between about one and three, including one center emitter wave guide and two adjacent collector wave guides, or any other combinations.

[0039] Proximal of the deflection control handle 16, a proximal end of the irrigation tubing 56 is connected to a luer connector 77, which is connected to an irrigation pump or other suitable fluid infusion source 119, as shown in FIG. (7A). In the control handle 16, the electrode lead wire 29 and the thermocouple wires 50 and 51 are connected to a suitable connector 79, such as a 10-pin electrical connector, for connecting the electrode lead wire to a source of ablation energy and the thermocouple wires to a suitable monitoring system. The emitter wave guide 60E extends out of the proximal end of the control handle 16 and into a protective sheath 35, as shown in FIG. 7A, for communication with a suitable light source, for example, a lamp or multiple lasers. The collector wave guide(s) 60C extend out of the proximal end of the control handle 16 and into a protective sheath 37, as shown in FIG. 7A, for communication with a suitable light analyzer, e.g., a spectrometer, to process the collected light.

[0040] As shown in FIGS. 7A and 7B, the catheter 10 may be used with an integrated ablation and spectroscopy system 200. In the illustrated embodiment, the system includes an RF generator 202, a patient interface unit 203, a communication (COM) unit 204, a location pad 206, a processor 207, input device (e.g., keyboard) 211, and a display 208. The COM unit 204 provides electronics for ECG, electrogram collection, amplification, filtering and real-time tracing of catheter distal tip. The PIU 203 allows communication with various components of the system 200, including signal generator, recording devices, etc. The location pad 206 includes magnetic field generators (e.g., coils) and is typically positioned under a patient's body to generate magnetic fields within the patient's body. Responsive to these magnetic fields, the location sensor 54 housed in the distal end of the catheter generates electrical signals which are received by the PIU 203 and transmitted to the COM unit 204 and processed by the processor 207 in order to determine the position (location and/or orientation) coordinates of the catheter distal end. The processor 207 uses the coordinates in driving the display 208 to show location and status of the catheter. Other signals from the catheter 10, for example, tissue electrical activity and temperature, are also transmitted to the COM unit 204 and the processor 207 via the PIU 203 for processing and analysis, including 3-D mapping of the patient's heart that is shown on the display 208. This method of position sensing and processing is described in detail, for example, in PCT International Publication WO 96/05768, whose entire disclosure is incorporated herein by reference, and is implemented in the CARTO system produced by Biosense Webster Inc. (Diamond Bar, California).

[0041] For ablation, the RF generator 202 supplies RF ablation energy to the tip electrode 15 of the catheter 10 via the PIU 203. For spectroscopy, the system 200 further includes a light source 209 which provides incidental light energy to the catheter 10 via the emitter wave guide 60E. Light collected by collector wave guides 60C are transmitted to a spectrometer 210 which provides representative signals to the processor 207 which processes the signals to determine various parameters and/or characteristics of the target issue illuminated. The system may include a first foot pedal 205A connected to the PIU 203 to be used for acquiring catheter location points and a second food pedal 205B connected to the RF generator 202 for activating/deactivating the RF generator 202.

[0042] To use a catheter of the invention, an electrophysiologist may introduce a guiding sheath and dilator into the patient, as is generally known in the art. A guidewire may also be introduced for a catheter adapted

for such use. For example, the catheter may be introduced to the right atrium (RA) via the inferior vena cava (IVC). To reach the left atrium (LA), the catheter passes through the septum. Through the guiding sheath, the length of the catheter can be passed through the patient's vasculature to the desired location. Once the distal end of the catheter reaches the desired location, e.g., the right atrium RA, the guiding sheath is withdrawn to expose the tip electrode 15 and the intermediate section 14. The control handle 16 may be manipulated as needed to deflect the intermediate section 14 into position. After the distal end of the catheter body 12 is positioned on and in contact with a target tissue, light is transmitted by the emitter wave guide 60E into the cavity 80 of the tip electrode 15. As shown in FIG. 6, the light radiates outwardly from a first predetermined position in the cavity toward the shell member 74 where either it strikes the reflective coating 92 and is redirected within the cavity or it passes through the apertures 82 to outside the cavity where it interacts with tissue T in one manner or with fluid F in another manner, where such interactions affect and/or alter one or more characteristics or parameters of the light. Light so affected or altered is collected by the collector wave guides 60C and transmitted proximally through the catheter to the spectrometer for analysis. Depending on the analysis, selected action(s) may be taken, including energizing the tip electrode for ablation where the indication is that the tip electrode has sufficient contact with tissue.

[0043] RF energy may be applied to the tip electrode 15 for ablation. Irrigation fluid may also be provided to tip electrode during ablation via the fluid source and pump 119 that provides the transported through the irrigating tubing 56. Fluid enters the cavity via the irrigation tubing 56 and exits the cavity via the apertures 82.

[0044] The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced. As understood by one of ordinary skill in the art, the drawings are not necessarily to scale. Also, different features of different embodiments may be combined as needed or appropriate. Moreover, the catheters described herein may be adapted to apply various energy forms, including microwave, laser, RF and/or cryogens. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

Claims

1. A catheter (10) for utilizing optical spectroscopy for measuring tissue contact area comprising:

an elongated catheter body (12);
a distal tip electrode (15) having a shell (74) defining a cavity (80), the shell formed with one or more apertures (82);
at least one emitter optical waveguide (60E) extending through the catheter body and having a distal emitter end positioned in the cavity, the at least one emitter optical waveguide configured to deliver light into the cavity, where at least a first portion of the light exits the one or more apertures; and
at least one collector optical waveguide (60C) extending through the catheter body and having a distal collector end positioned in the cavity, the at least one collector optical waveguide configured to collect light,
wherein the distal tip electrode has a plug member (76) which with the shell defines the cavity and the shell has a distal portion with a radially symmetrical configuration relative to a center location (C) in the cavity, **characterised in that** the shell has an inner surface having a reflective coating (92) and **in that**
the at least one emitter optical waveguide and at least one collector waveguide extending through the plug member, and the distal emitter end and distal collector end are positioned in the center location in the cavity.

2. The catheter of claim 1, wherein the radially symmetrical configuration of the cavity is a hemispherical configuration.

3. The catheter of claim 2 wherein the hemispherical configuration is defined by a radius (R) for a radial angle Φ sweeping about 180 degrees.

4. The catheter of claim 1 or claim 2, wherein the radially symmetrical configuration is defined by a radius (R) for a radial angle sweeping up to about 360 degrees.

5. The catheter of claim 1 or claim 2, wherein the radially symmetrical configuration is defined by a radial angle sweeping up to about 270 degrees.

6. The catheter of claim 1, wherein the plug member (76) has a distal surface with a concavity (76S).

7. The catheter of claim 1, wherein the emitter optical waveguide is adapted to emit light of a first intensity and the collector optical waveguide is adapted to collect light of a second intensity.

8. The catheter of claim 1, wherein the emitter optical waveguide is adapted to emit light of a first wavelength and the collector optical waveguide is adapted to collect light of a second wavelength.

9. A system for ablation and spectroscopy, comprising:

a catheter of claim 1, or claim 2;
an RF generator (202) adapted to provide RF energy to the distal tip electrode;
a light source (209) adapted to provide the light; and
a spectrometer (210) adapted to analyze the light collected by the at least one collector optical waveguide.

10. The system of claim 9 when dependent upon claim 1, further comprising:

a patient interface unit (203);
a communication unit (204);
a processor (207); and
a display (208),
wherein the patient interface unit is adapted to send and receive signals from the RF generator, the communication unit,
wherein the communication unit is adapted to send and receive signals from the patient interface unit,
wherein the processor is adapted to send and receive signals from the communication unit,
wherein the display is adapted to receive signals from the processor.

Patentansprüche

1. Katheter (10) zur Verwendung optischer Spektroskopie zur Messung der Gewebekontaktfläche, umfassend:

einen langgestreckten Katheterkörper (12);
eine distale Spitzenelektrode (15) mit einer Hülle (74), die einen Hohlraum (80) definiert, wobei die Hülle mit einer oder mehreren Öffnungen (82) ausgebildet ist;
mindestens einen optischen Emitter-Wellenleiter (60E), der sich durch den Katheterkörper erstreckt und ein im Hohlraum angeordnetes distales Emitterende aufweist, wobei der mindestens eine optische Emitter-Wellenleiter zur Abgabe von Licht in den Hohlraum ausgelegt ist, wobei mindestens ein erster Teil des Lichts aus der einen oder den mehreren Öffnungen austritt; und
mindestens einen optischen Kollektor-Wellenleiter (60C), der sich durch den Katheterkörper erstreckt und ein im Hohlraum angeordnetes distales Kollektorende aufweist, wobei der mindestens eine optische Kollektor-Wellenleiter zum Sammeln von Licht ausgelegt ist,
wobei die distale Spitzenelektrode ein Pfropfenelement (76) aufweist, das mit der Hülle den Hohlraum definiert und wobei die Hülle einen distalen Abschnitt mit einer radial symmetrischen Konfiguration bezüglich einer zentralen Lage (C) im Hohlraum aufweist,
dadurch gekennzeichnet, dass die Hülle eine Innenfläche mit einer reflektierenden Schicht (92) aufweist und dass sich der mindestens eine optische Emitter-Wellenleiter und der mindestens eine optische Kollektor-Wellenleiter durch das Pfropfenelement erstrecken, und das distale Emitterende und das distale Kollektorende in der zentralen Lage im Hohlraum angeordnet sind.

2. Katheter nach Anspruch 1, wobei die radial symmetrische Konfiguration des Hohlraums eine halbkugelförmige Konfiguration ist.

3. Katheter nach Anspruch 2, wobei die halbkugelförmige Konfiguration von einem Radius (R) für einen Radialwinkel ϕ, der ungefähr 180 Grad umfasst, definiert wird.

4. Katheter nach Anspruch 1 oder Anspruch 2, wobei die radial symmetrische Konfiguration von einem Radius (R) für einen Radialwinkel, der bis zu ungefähr 360 Grad umfasst, definiert wird.

5. Katheter nach Anspruch 1 oder Anspruch 2, wobei die radial symmetrische Konfiguration von einem Radialwinkel, der bis zu ungefähr 270 Grad umfasst, definiert wird.

6. Katheter nach Anspruch 1, wobei das Pfropfenelement (76) eine distale Oberfläche mit einer Konkavität (76S) aufweist.

7. Katheter nach Anspruch 1, wobei der optische Emitter-Wellenleiter zum Aussenden von Licht mit einer ersten Intensität ausgelegt ist und der optische Kollektor-Wellenleiter zum Sammeln von Licht mit einer zweiten Intensität ausgelegt ist.

8. Katheter nach Anspruch 1, wobei der optische Emitter-Wellenleiter zum Aussenden von Licht mit einer ersten Wellenlänge ausgelegt ist und der optische Kollektor-Wellenleiter zum Sammeln von Licht mit einer zweiten Wellenlänge ausgelegt ist.

9. System zur Ablation und Spektroskopie, umfassend:

einen Katheter nach Anspruch 1 oder Anspruch 2;
einen HF-Generator (202), der zur Bereitstellung von HF-Energie für die distale Spitzenelektrode ausgelegt ist;
eine Lichtquelle (209), die zur Bereitstellung des Lichts ausgelegt ist; und

einen Spektrometer (210), der zur Auswertung des von dem mindestens einen optischen Kollektor-Wellenleiter gesammelten Lichts ausgelegt ist.

10. System nach Anspruch 9, in Abhängigkeit von Anspruch 1, ferner umfassend:

eine Patientenschnittstelleneinheit (203);
eine Kommunikationseinheit (204);
einen Prozessor (207); und
einen Anzeigebildschirm (208),
wobei die Patientenschnittstelle zum Senden und Empfangen von Signalen vom HF-Generator, der Kommunikationseinheit ausgelegt ist,
wobei die Kommunikationseinheit zum Senden und Empfangen von Signalen von der Patientenschnittstelleneinheit ausgelegt ist,
wobei der Prozessor zum Senden und Empfangen von Signalen von der Kommunikationseinheit ausgelegt ist,
wobei der Anzeigebildschirm zum Empfangen von Signalen vom Prozessor ausgelegt ist.

Revendications

1. Cathéter (10) permettant d'utiliser la spectroscopie optique pour mesurer une zone de contact de tissu comprenant :

un corps de cathéter allongé (12) ;
une électrode (15) de pointe distale possédant une enveloppe (74) délimitant une cavité (80), l'enveloppe étant pourvue d'une ou de plusieurs ouvertures (82) ;
au moins un guide d'onde optique d'émission (60E) s'étendant à travers le corps de cathéter et possédant une extrémité d'émission distale positionnée dans la cavité, l'au moins un guide d'onde optique d'émission étant conçu pour distribuer la lumière dans la cavité, où au moins une première partie de la lumière sort par la ou les ouvertures ; et
au moins un guide d'onde optique de collecte (60C) s'étendant à travers le corps de cathéter et possédant une extrémité de collecte distale positionnée dans la cavité, l'au moins un guide d'onde optique de collecte étant conçu pour collecter la lumière,
dans lequel l'électrode de pointe distale possède un élément de fiche (76) avec lequel l'enveloppe définit la cavité et l'enveloppe possède une partie distale ayant une configuration radialement symétrique par rapport à un emplacement central (C) dans la cavité,
caractérisé en ce que
l'enveloppe possède une surface interne ayant un revêtement réfléchissant (92) et **en ce que** l'au moins un guide d'onde optique d'émission et l'au moins un guide d'onde de collecte s'étendent à travers l'élément de fiche, et l'extrémité d'émission distale et l'extrémité de collecte distale sont positionnées dans l'emplacement central dans la cavité.

2. Cathéter selon la revendication 1, dans lequel la configuration radialement symétrique de la cavité est une configuration hémisphérique.

3. Cathéter selon la revendication 2 dans lequel la configuration hémisphérique est définie par un rayon (R) pour un angle radial Φ balayant environ 180 degrés.

4. Cathéter selon la revendication 1 ou la revendication 2, dans lequel la configuration radialement symétrique est définie par un rayon (R) pour un angle radial balayant jusqu'à environ 360 degrés.

5. Cathéter selon la revendication 1 ou la revendication 2, dans lequel la configuration radialement symétrique est définie par un angle radial balayant jusqu'à environ 270 degrés.

6. Cathéter selon la revendication 1, dans lequel l'élément de fiche (76) a une surface distale dotée d'une concavité (76S).

7. Cathéter selon la revendication 1, dans lequel le guide d'onde optique d'émission est conçu pour émettre une lumière d'une première intensité et le guide d'onde optique de collecte est conçu pour collecter une lumière d'une seconde intensité.

8. Cathéter selon la revendication 1, dans lequel le guide d'onde optique d'émission est conçu pour émettre une lumière d'une première longueur d'onde et le guide d'onde optique de collecte est conçu pour collecter une lumière d'une seconde longueur d'onde.

9. Système pour l'ablation et la spectroscopie, comprenant :

un cathéter selon la revendication 1, ou la revendication 2 ;
un générateur RF (202) conçu pour fournir de l'énergie RF à l'électrode de pointe distale ;
une source de lumière (209) conçue pour fournir la lumière ; et
un spectromètre (210) conçu pour analyser la lumière collectée par l'au moins un guide d'onde optique de collecte.

10. Système selon la revendication 9 lorsqu'il dépend de la revendication 1, comprenant en outre :

une unité d'interface patient (203) ;
une unité de communication (204) ;
un processeur (207) ; et
un affichage (208),
dans lequel l'unité d'interface patient est conçue pour envoyer et recevoir des signaux provenant du générateur RF, de l'unité de communication,
dans lequel l'unité de communication est conçue pour envoyer et recevoir des signaux provenant de l'unité d'interface patient,
dans lequel le processeur est conçu pour envoyer et recevoir des signaux provenant de l'unité de communication,
dans lequel l'affichage est conçu pour recevoir des signaux provenant du processeur.

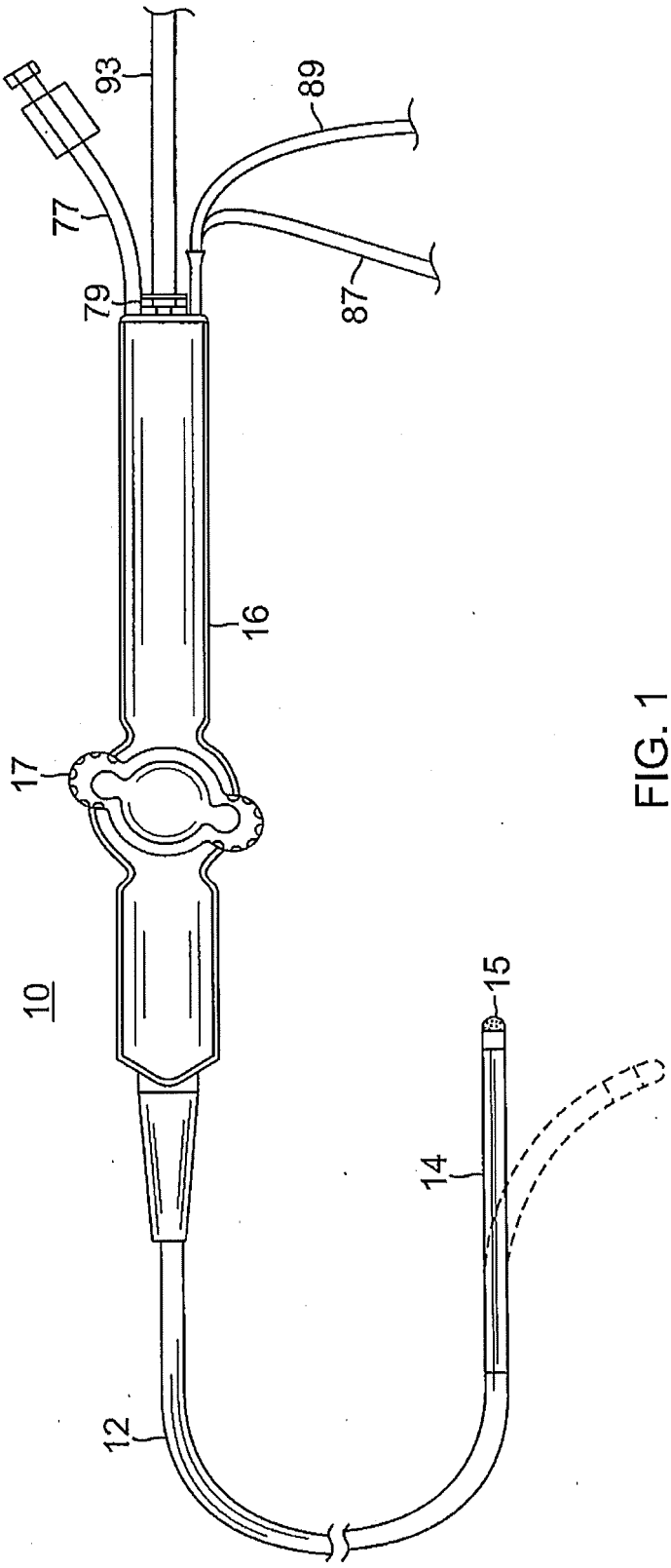


FIG. 1

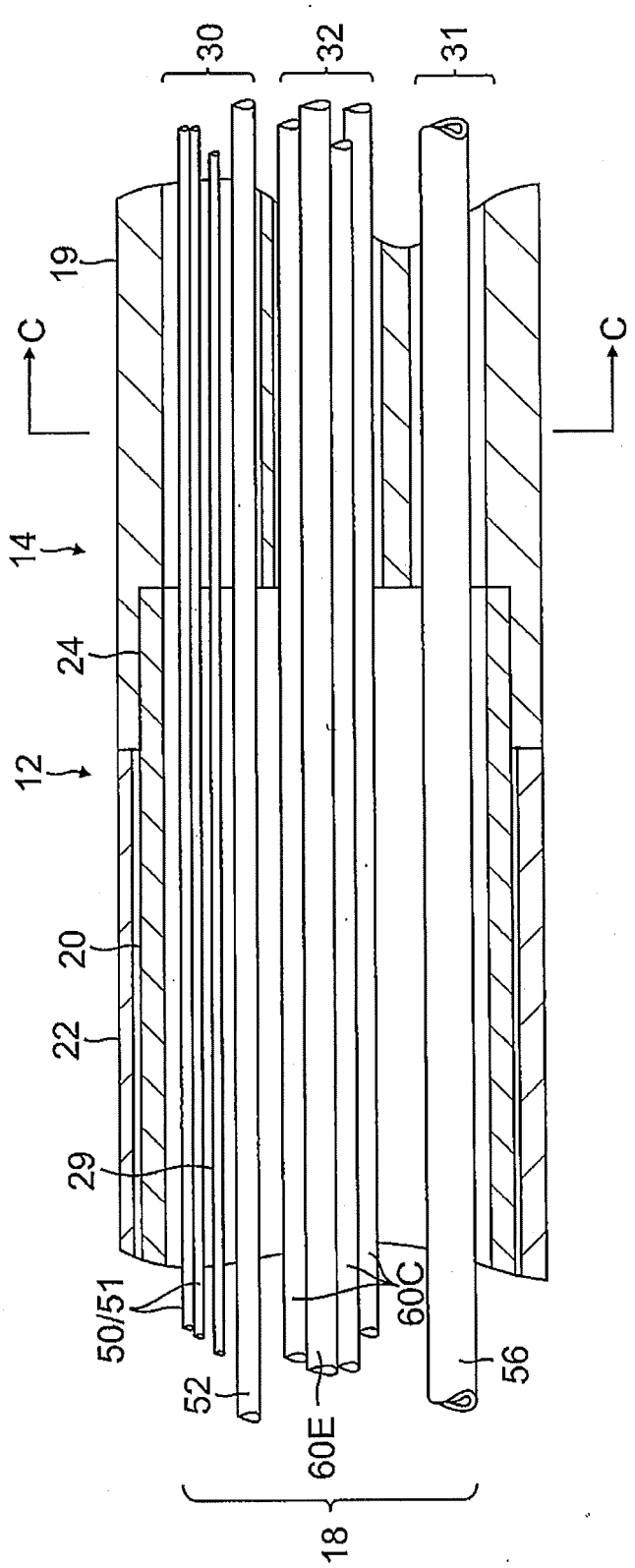


FIG. 2A

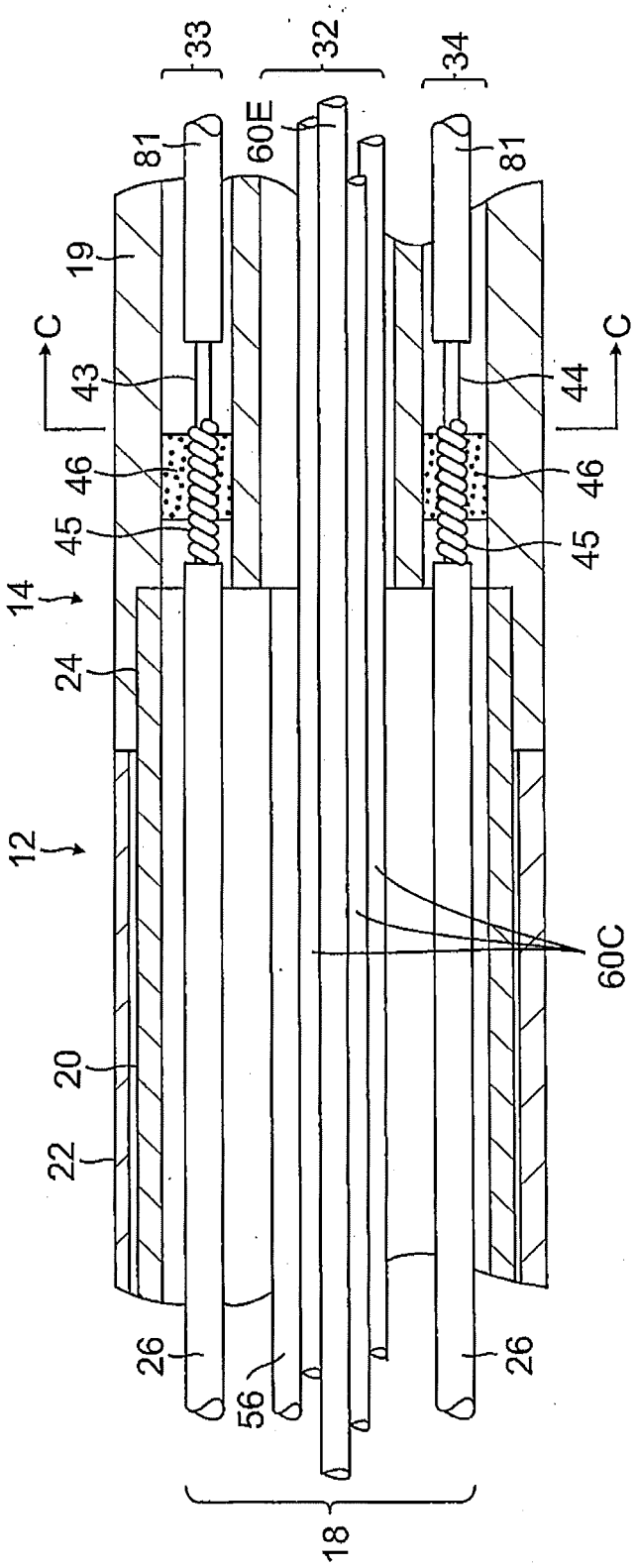

33
32
34
81
60E
81
19
C
C
43
44
46
46
45
45
14
24
12
60C
20
22
26
56
26
18

FIG. 2B

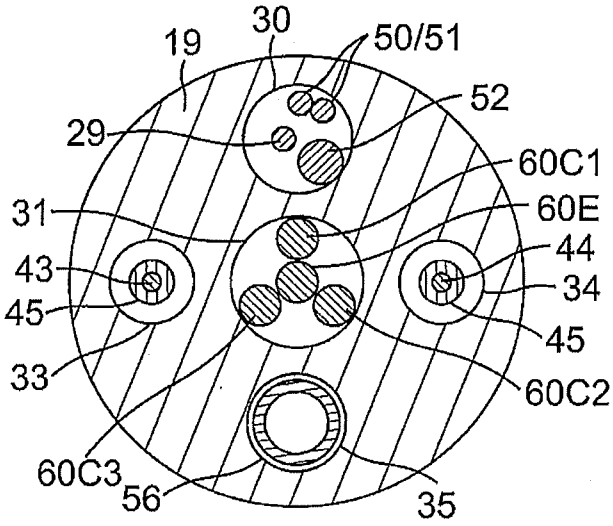


FIG. 2C

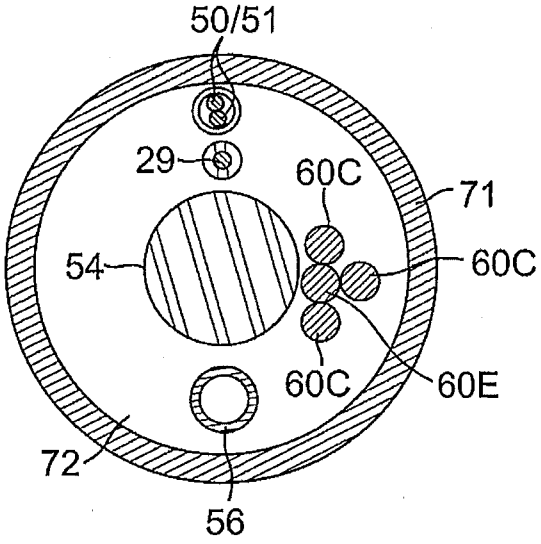


FIG. 3A

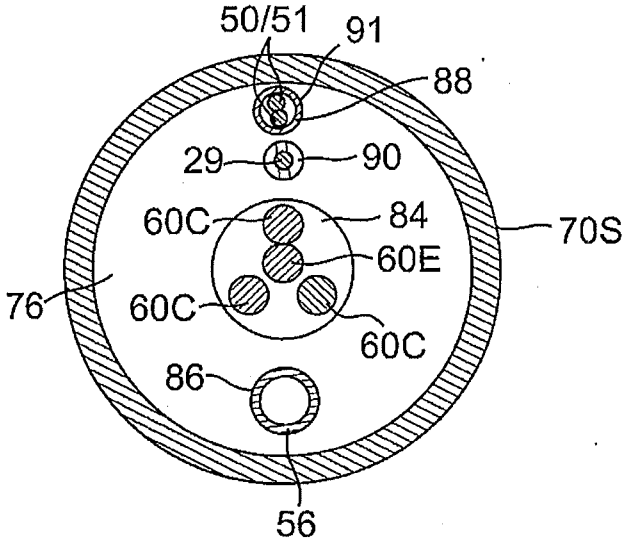
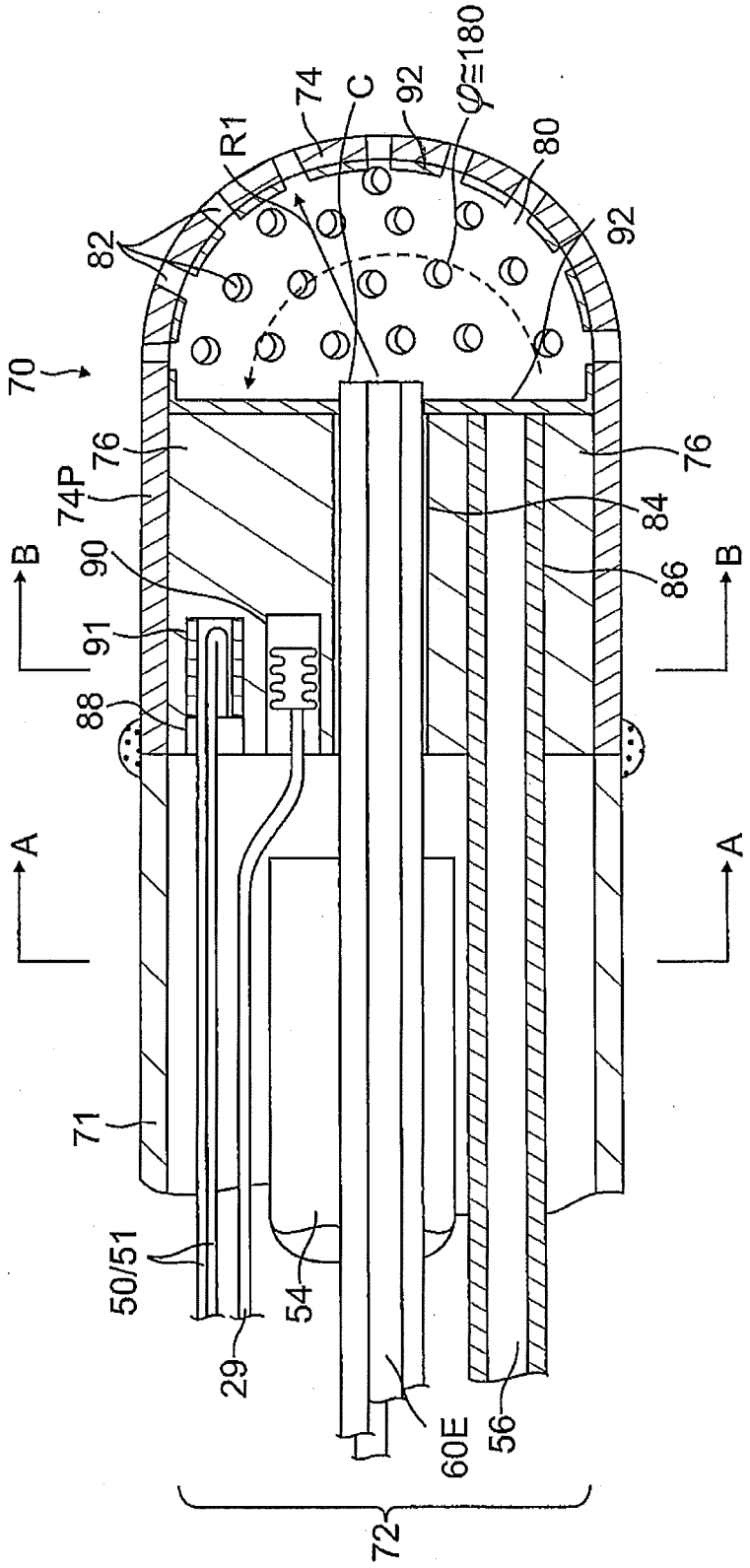


FIG. 3B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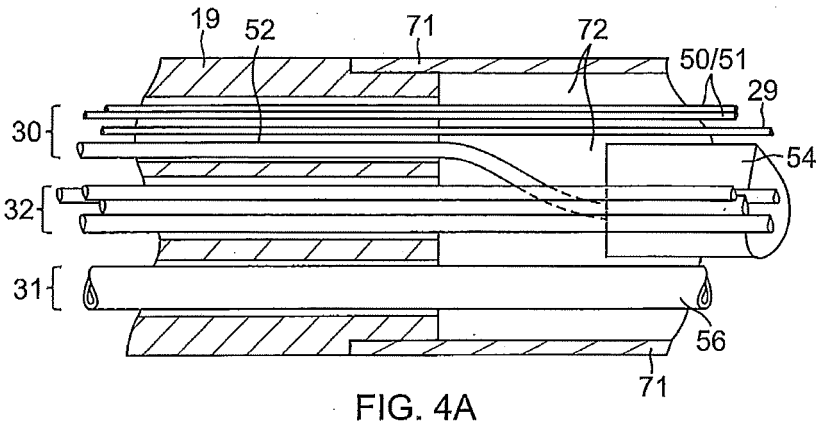
82
R1
74
C
92
φ≅180
80
92
76
74P
76
84
B
90
86
B
91
88
A
A
71
50/51
54
29
60E
56
72

FIG. 3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72
50/51
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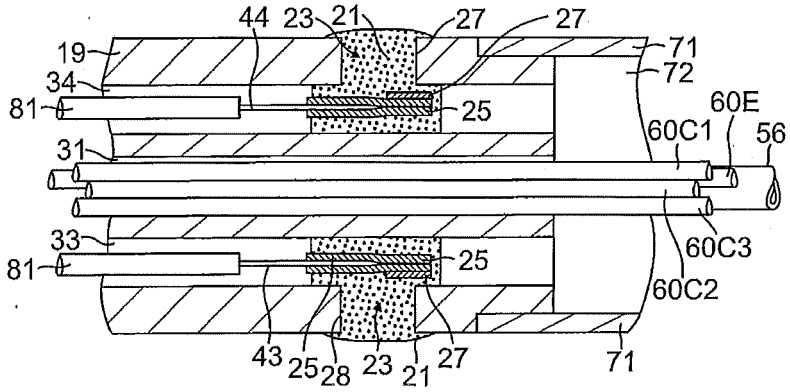
32
31
56
71

FIG. 4A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27
27
71
19
72
34
60E
81
25
60C1
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33
60C3
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25
60C2
43
25
28
23
21
27
71

FIG. 4B

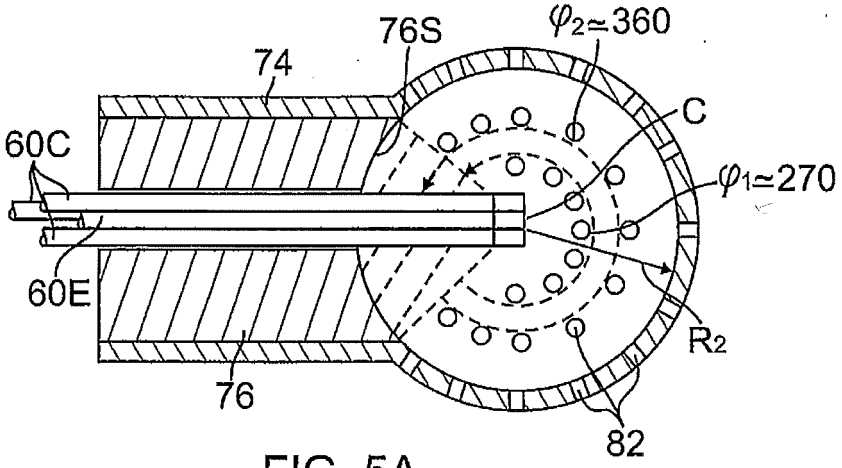


FIG. 5A

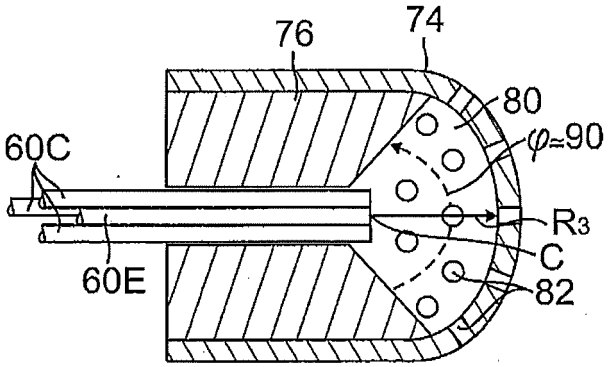


FIG. 5B

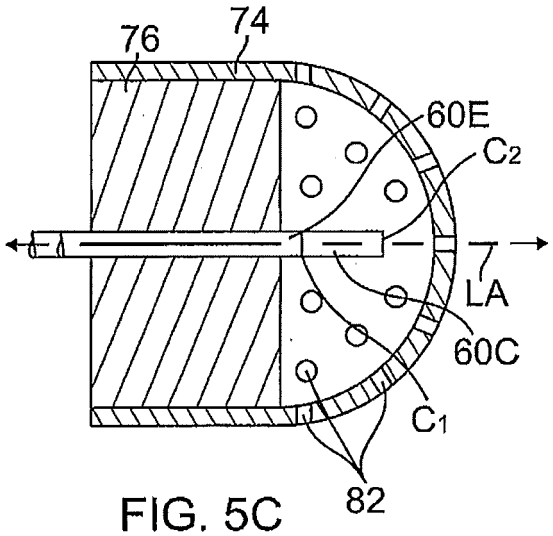


FIG. 5C

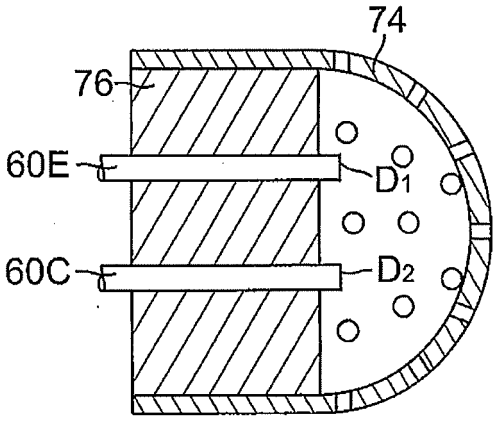


FIG. 5D

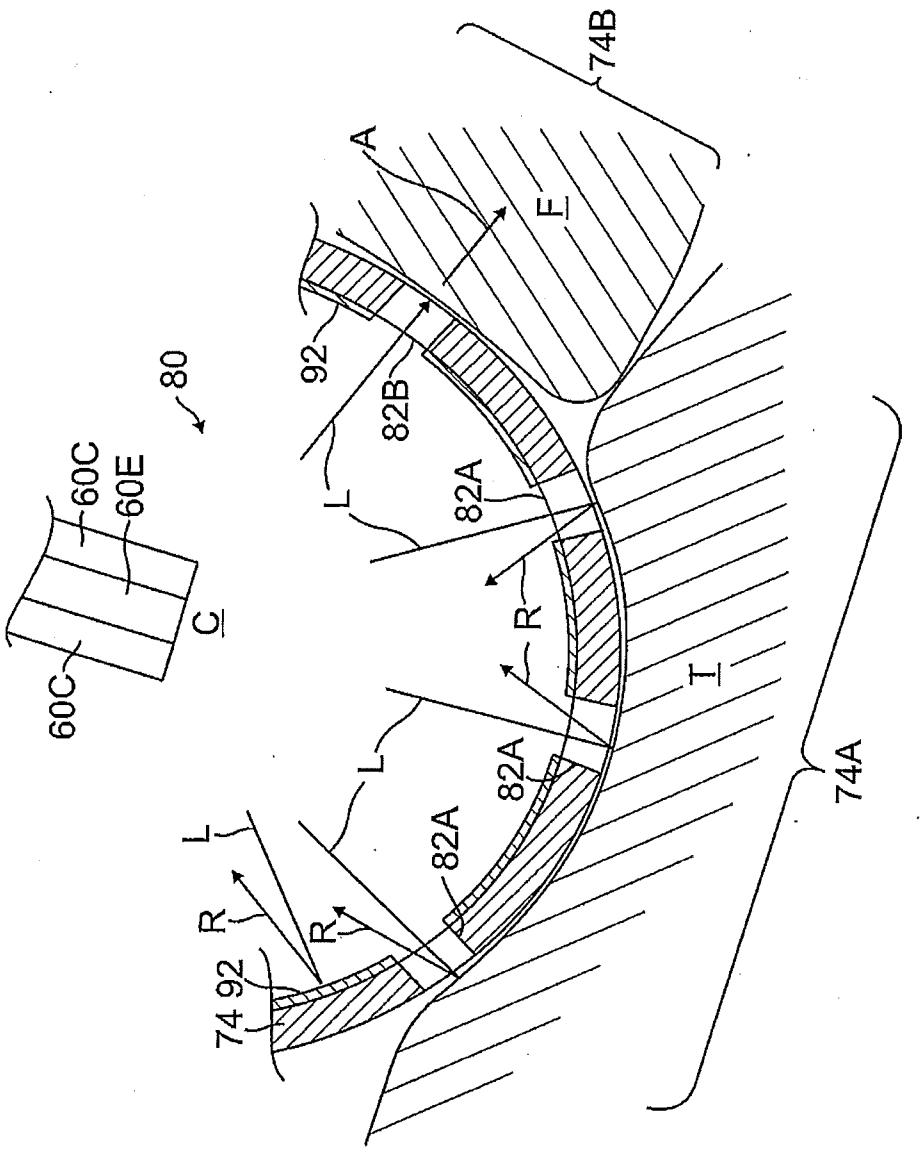
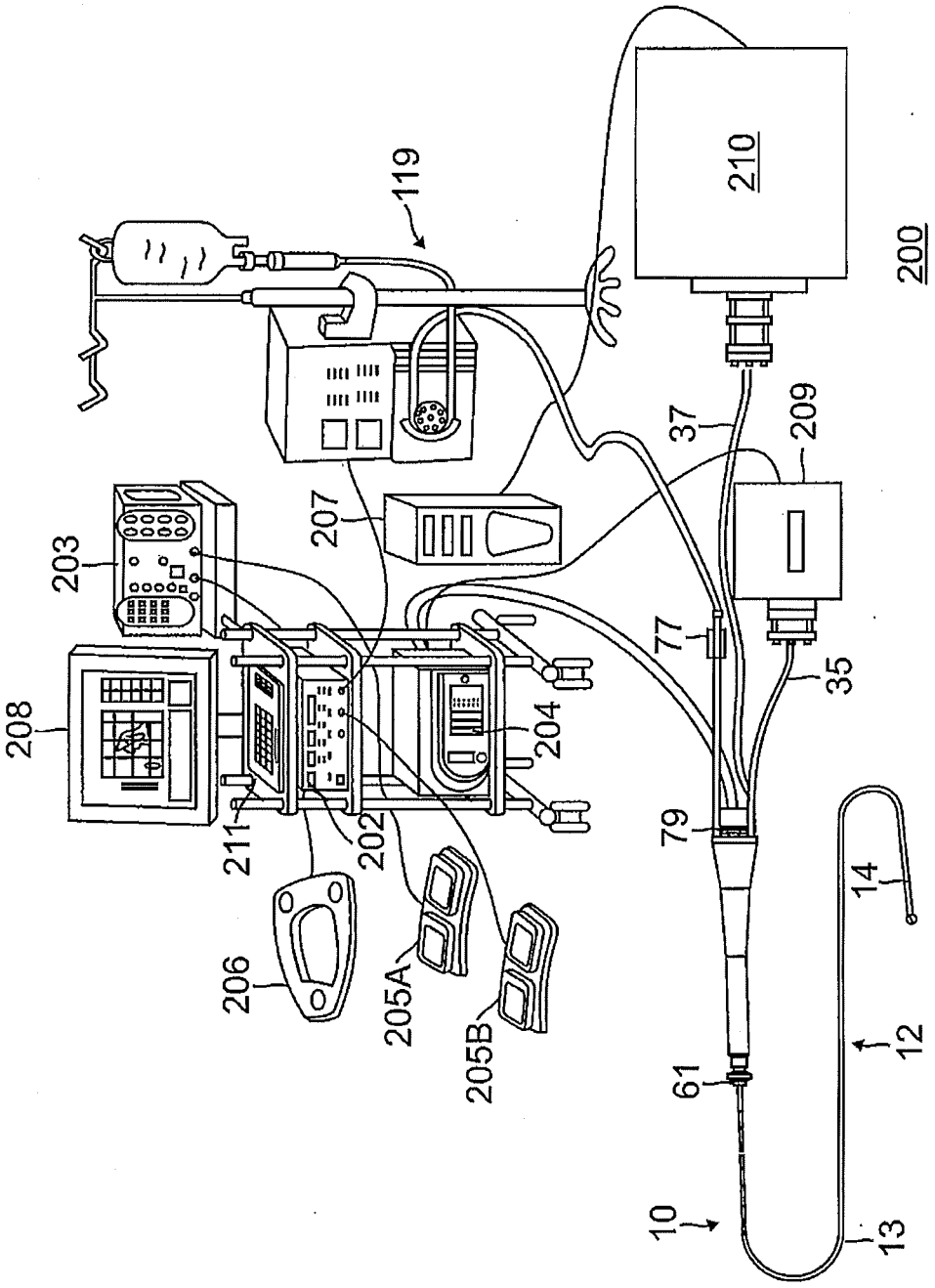


FIG. 6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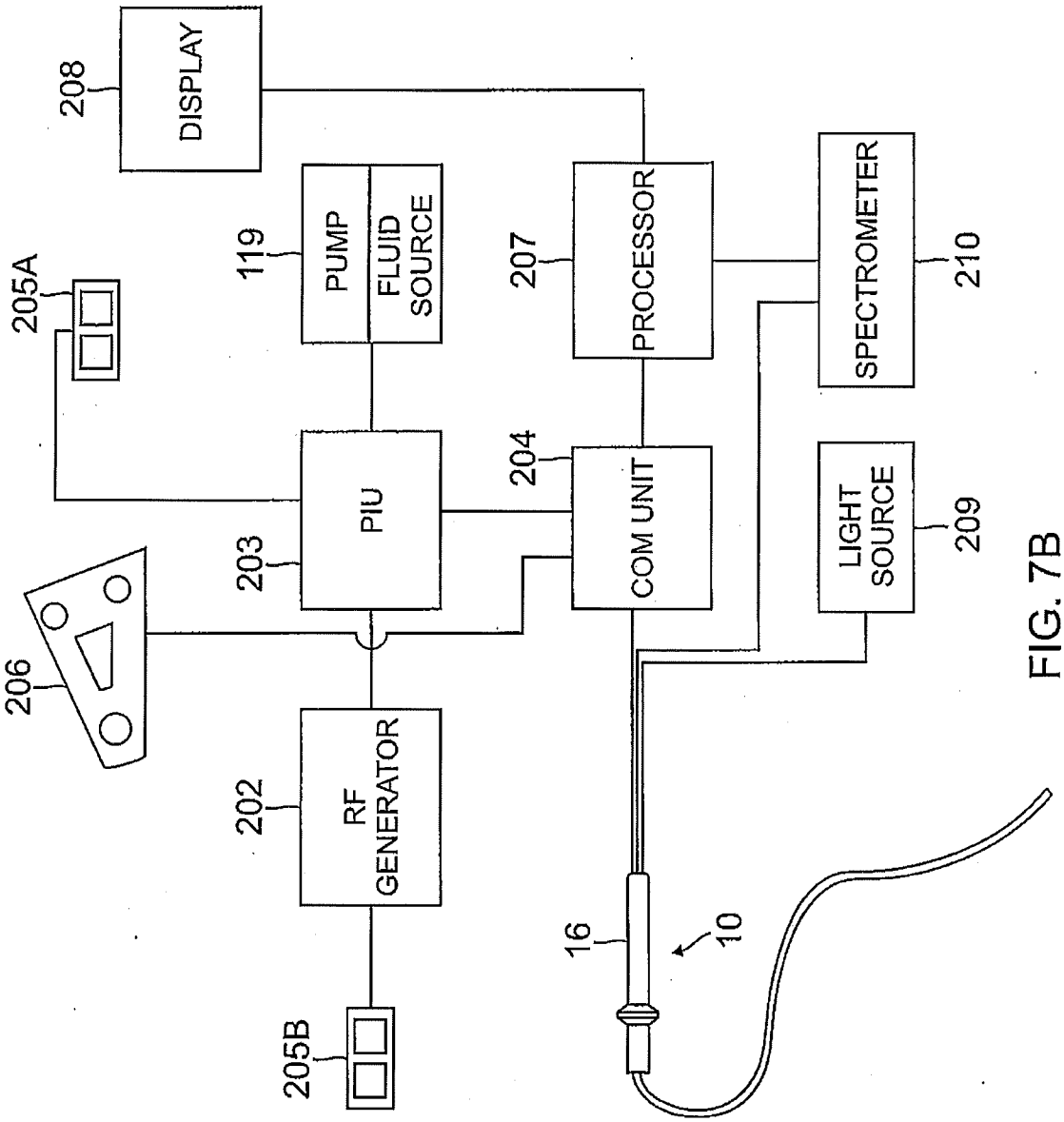
210
200
37
209
207
203
77
35
208
204
79
211
202
14
206
205A
205B
12
61
10
13

FIG. 7A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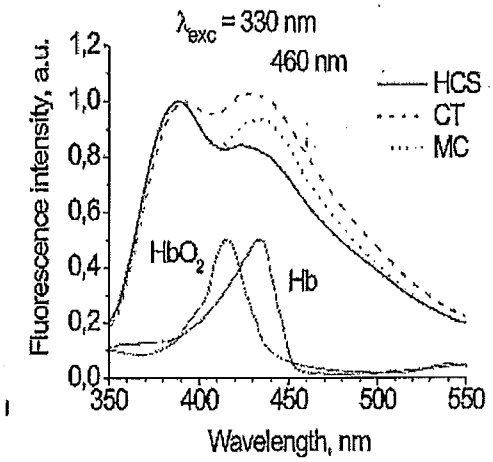
DISPLAY
119
PUMP
FLUID SOURCE
207
PROCESSOR
210
SPECTROMETER
205A
204
COM UNIT
209
LIGHT SOURCE
203
PIU
206
202
RF GENERATOR
16
10
205B

FIG. 7B

FIG. 8



PRIOR ART

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	导管利用光学光谱测量组织接触面积		
公开(公告)号	EP2889013B1	公开(公告)日	2018-05-30
申请号	EP2014200527	申请日	2014-12-30
[标]申请(专利权)人(译)	韦伯斯特生物官能(以色列)有限公司		
申请(专利权)人(译)	生物传感韦伯斯特（以色列）有限公司.		
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IPC分类号	A61B18/14 A61B5/00 A61B5/145 A61B5/1459 A61B18/00		
优先权	14/145858 2013-12-31 US		
其他公开文献	EP2889013A1 EP2889013B8		
外部链接	Espacenet		

摘要(译)

导管包括细长的导管主体，控制手柄和具有径向对称壳体的中空尖端电极，所述壳体限定围绕中心内部位置的腔，光从所述中心内部位置发射以穿过形成在壳体中的多个开口以与之相互作用。组织和/或流体，例如血液，在壳外面和与壳接触。与组织相互作用的光被反射回腔中以便收集，而与流体（例如血液）相互作用的光被吸收。通过分析在腔中收集的光，确定组织反射的光与流体吸收的光的比率，以指示尖端电极和组织之间的接触量。或者，可以类似地使用荧光（光在一个波长发射并在一个或多个不同波长下检测），因为组织和血液在各种波长下具有不同的荧光特性。集成的消融和光谱系统还包括RF发生器，光源和光分析器，其适于分析在腔中收集的光。

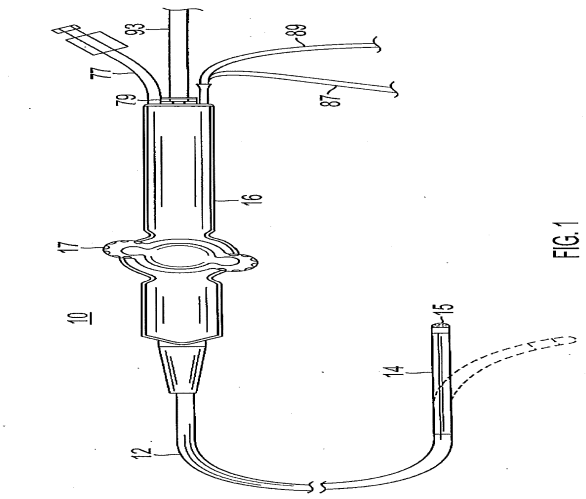

FIG. 1