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(54) **CARDIAC ABLATION CATHETERS AND METHODS OF USE THEREOF**

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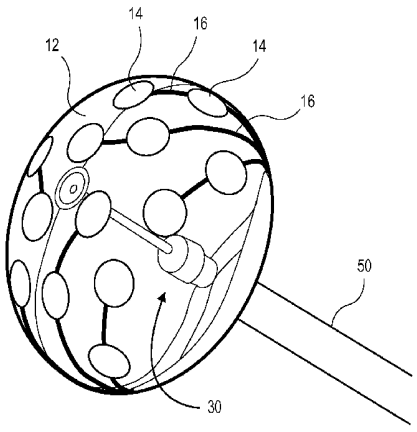
(57) **ABSTRACT**

Cardiac ablation catheters and methods of use. Catheters that include an expandable membrane, an imaging member disposed within the expandable membrane, the imaging member having a field of view, a light source disposed within the expandable member adapted to deliver light towards the field of view of the imaging member, and an electrode comprising an outer conductive layer and inner light absorbing layer disposed between the electrode and the expandable membrane, the inner light absorbing layer adapted to absorb light from the light source and thereby reduce reflection of the light from the outer conductive electrode.

7 Claims, 26 Drawing Sheets



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(58) **Field of Classification Search**

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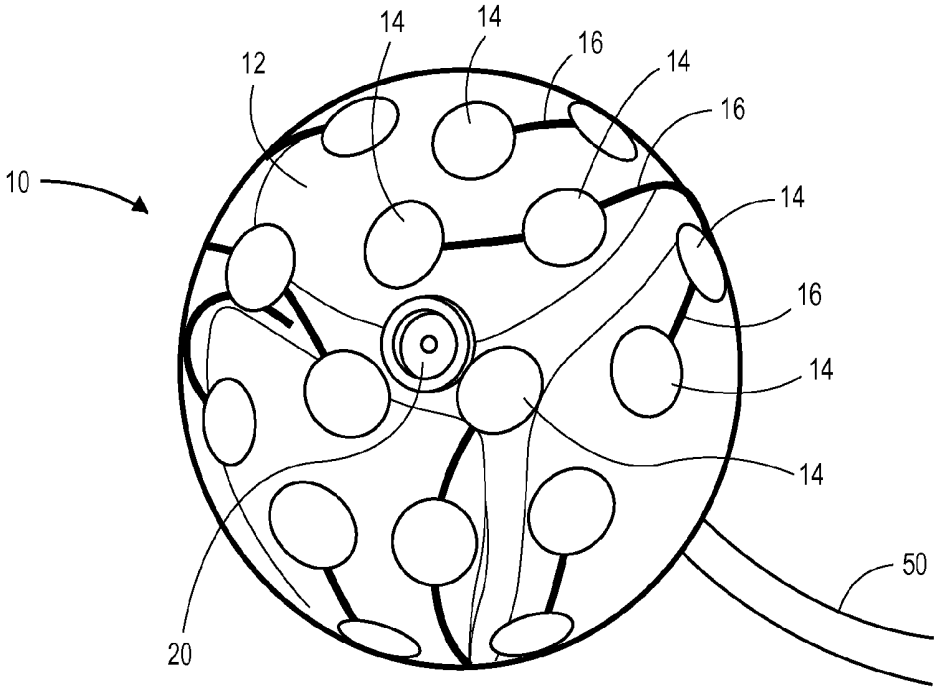
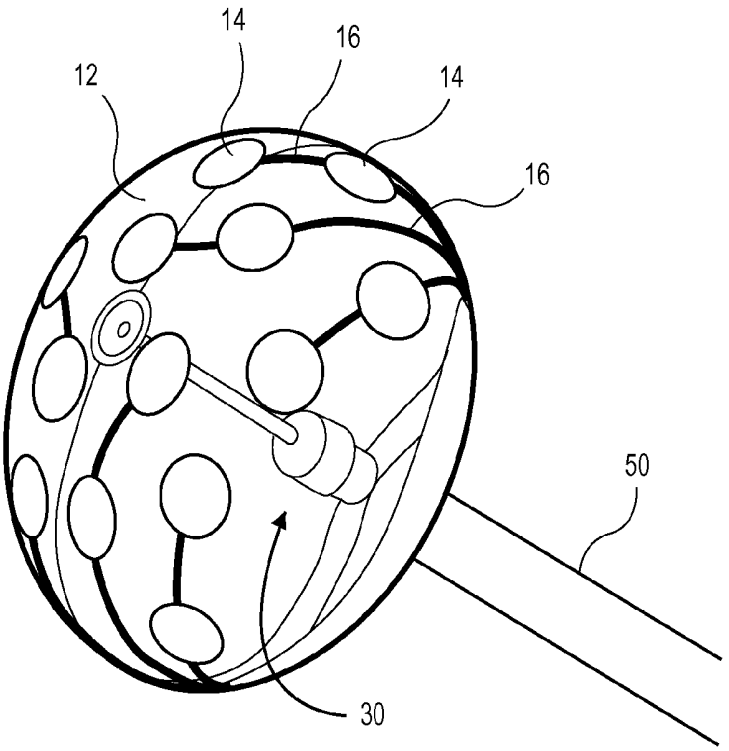


FIG. 1A



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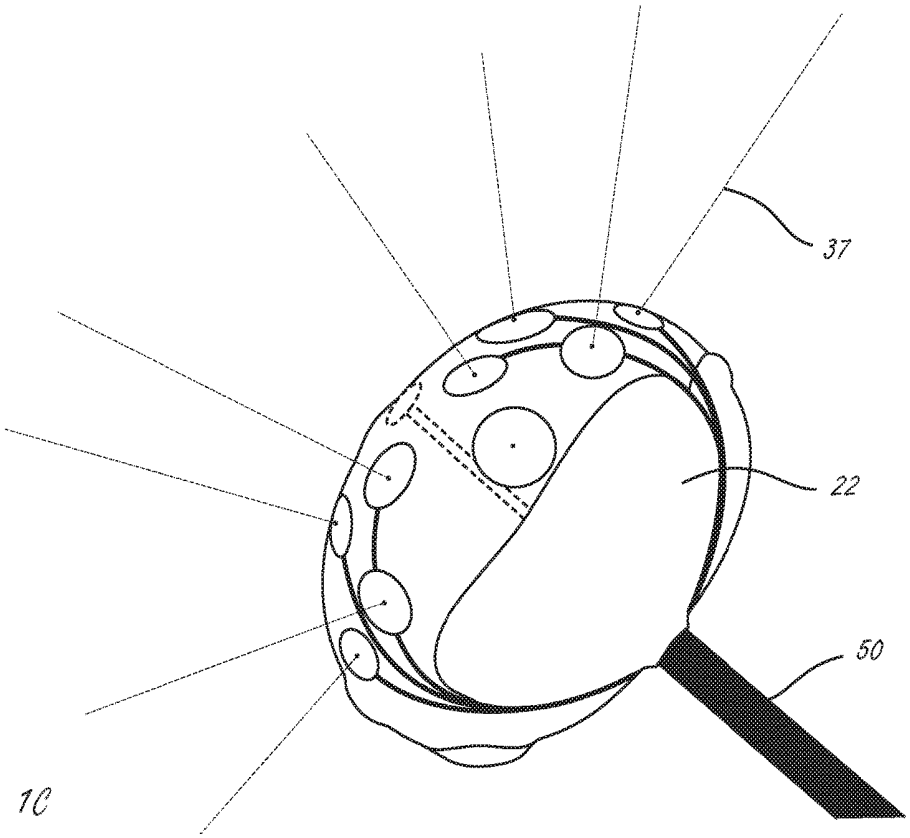


Fig. 1C

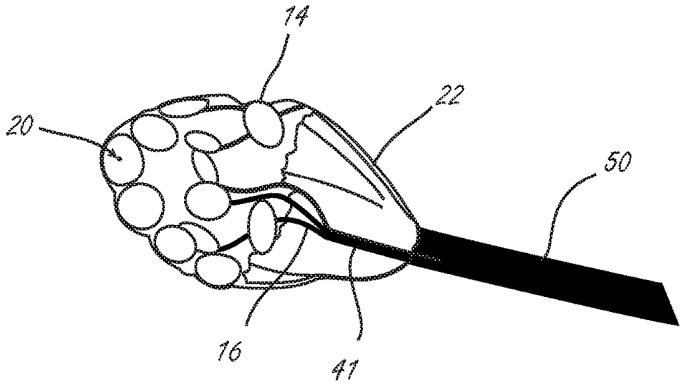
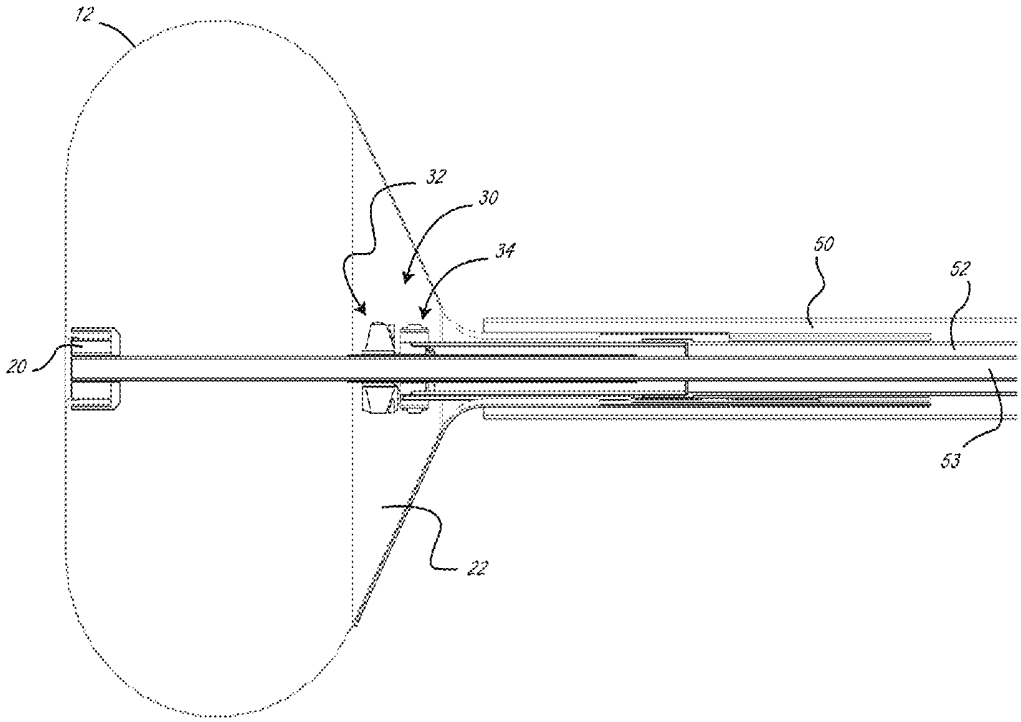


Fig. 1D



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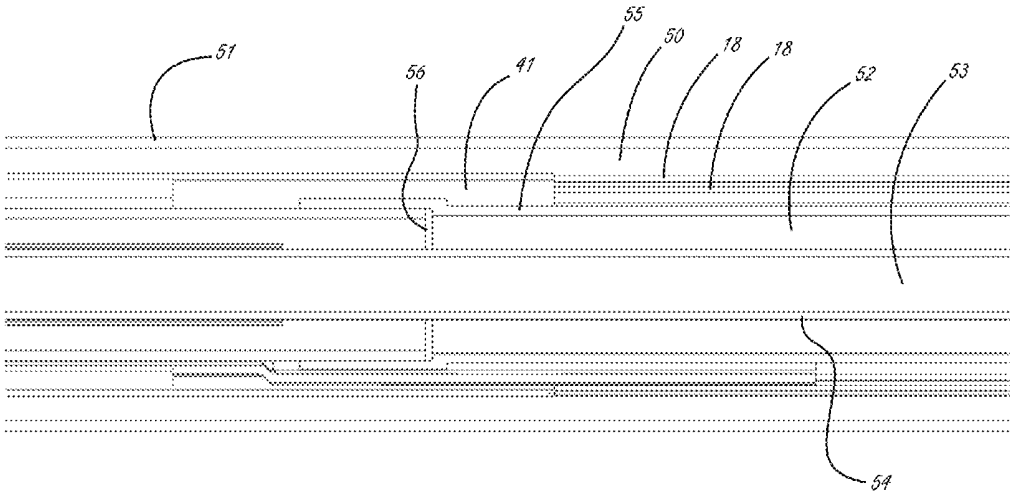

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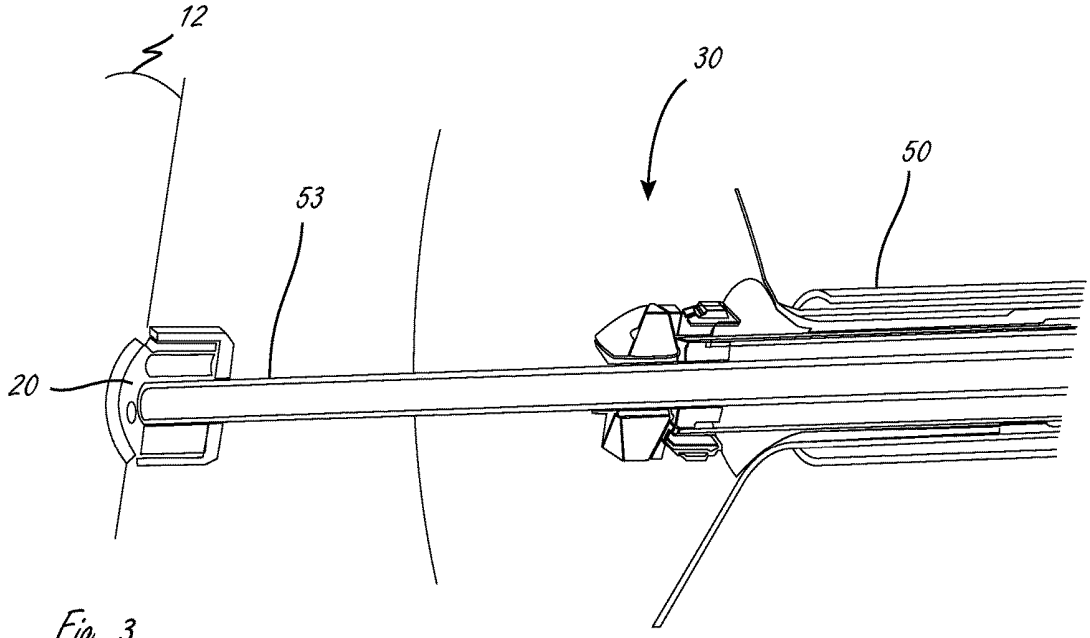

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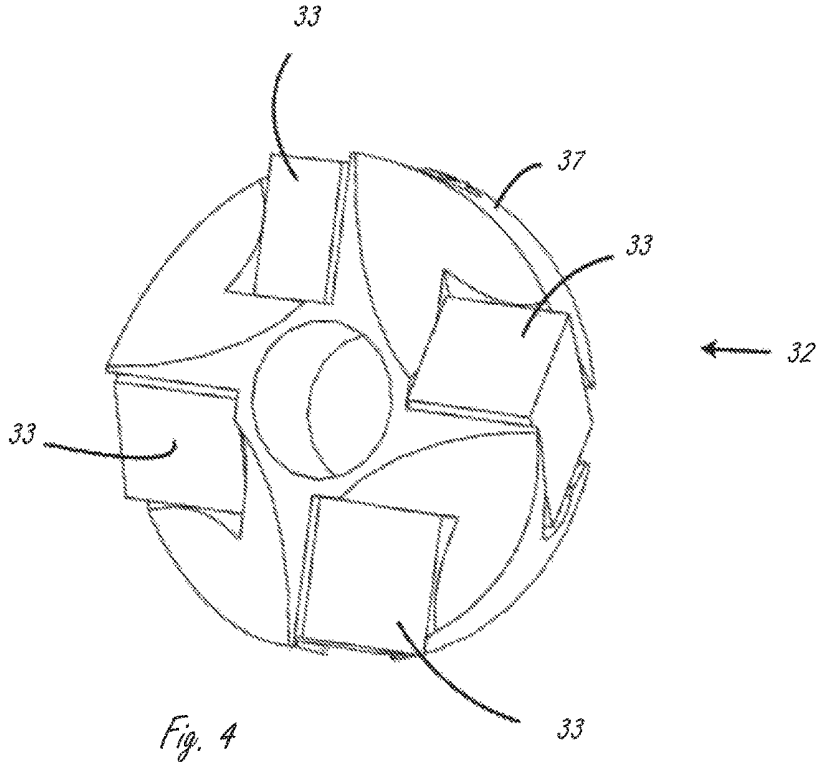

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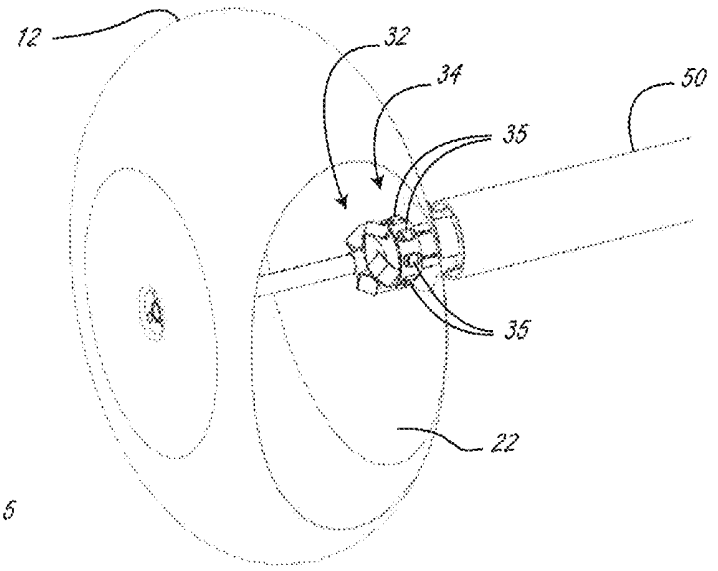

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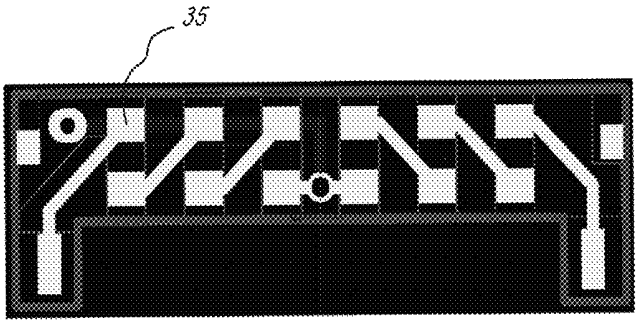

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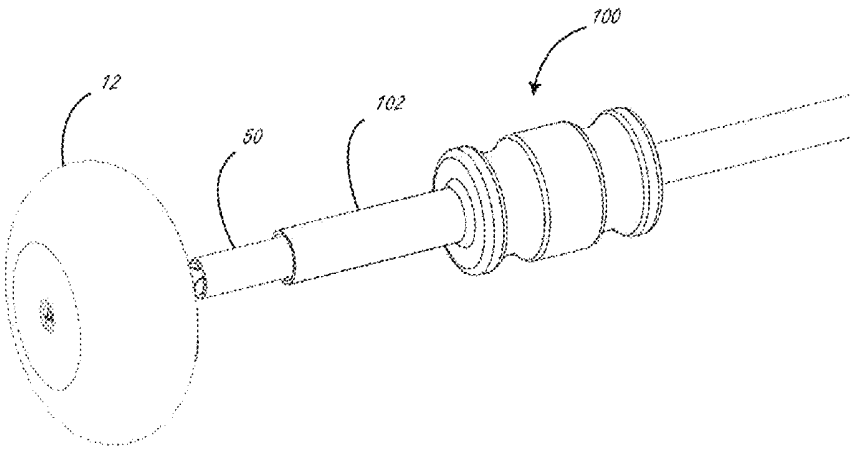

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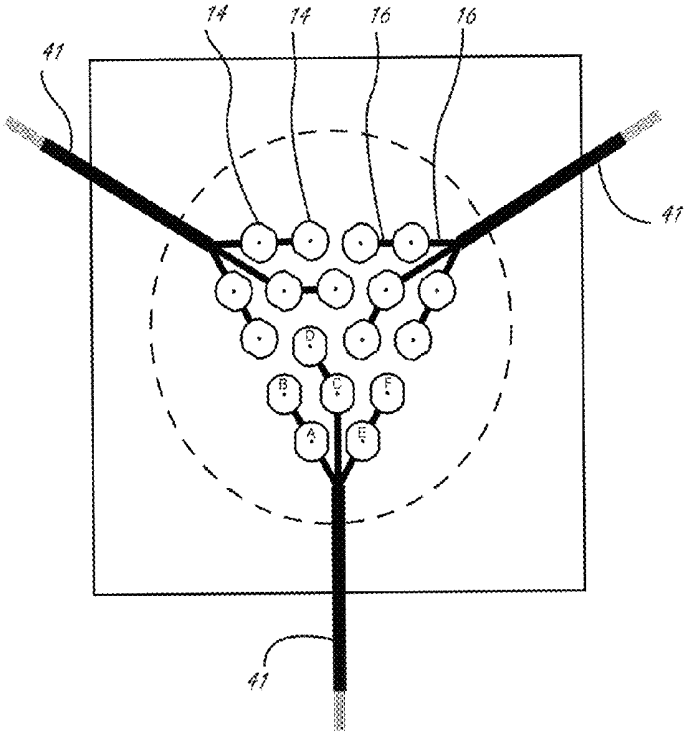

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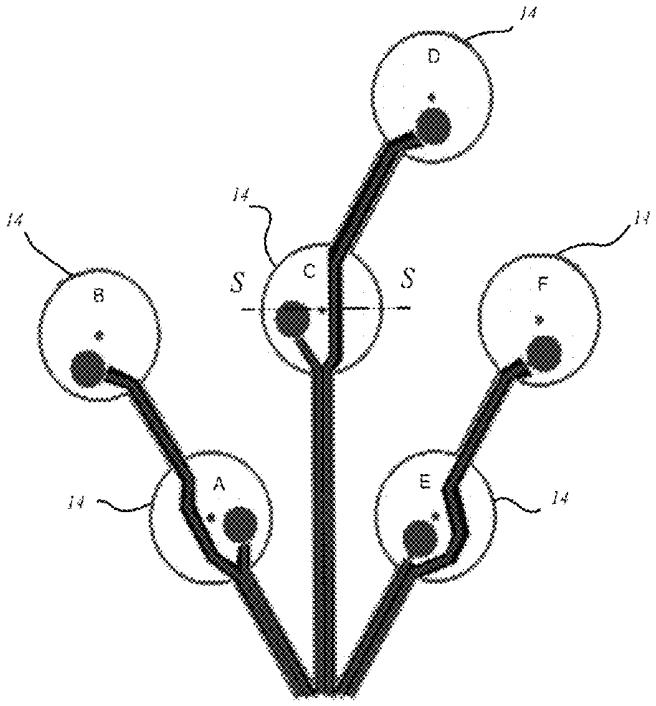

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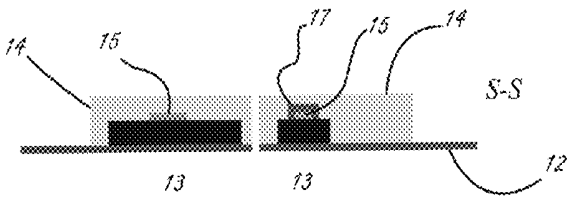

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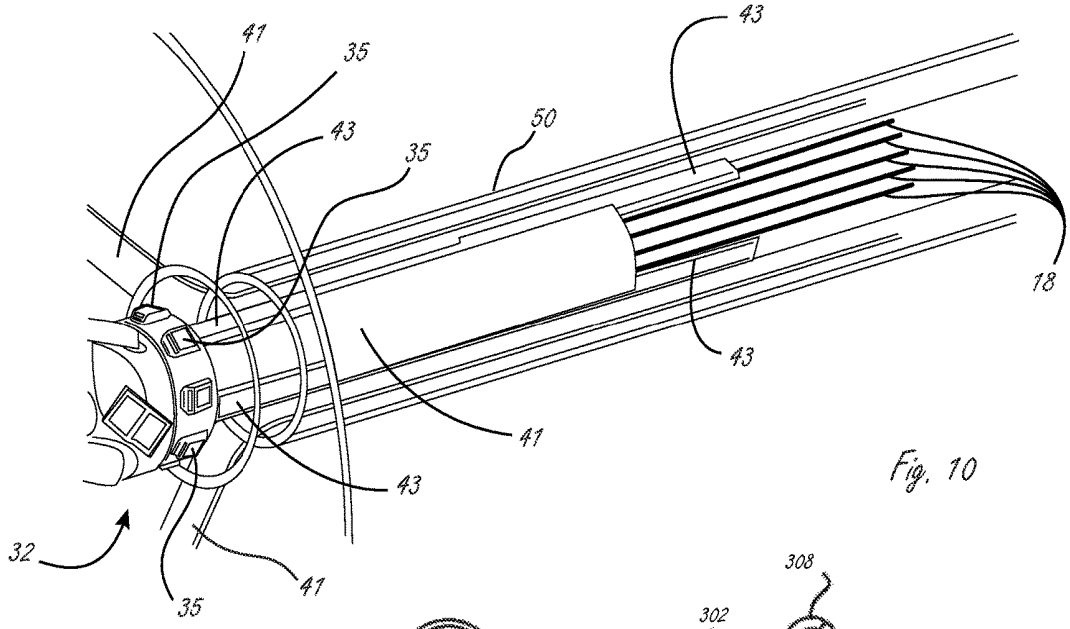
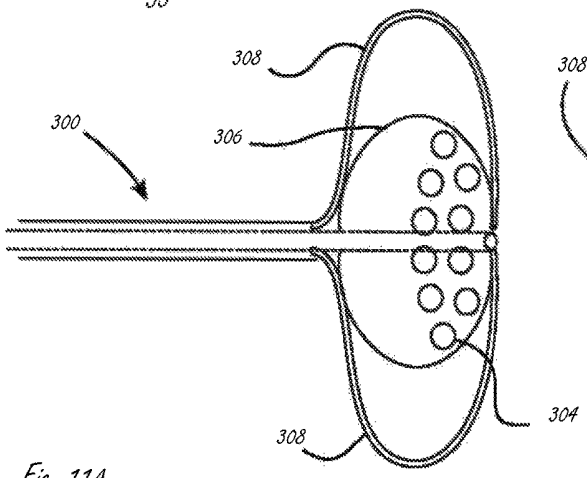


Fig. 10



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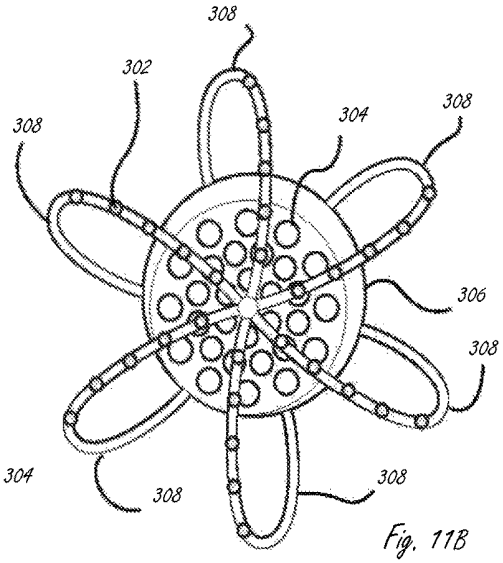

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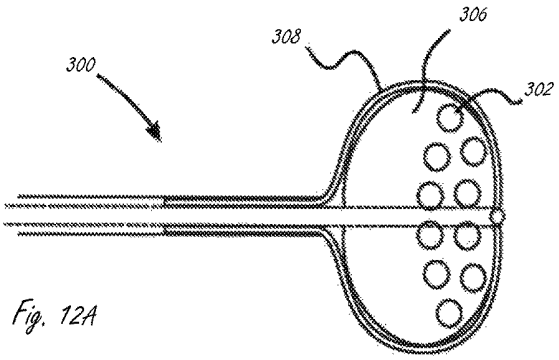

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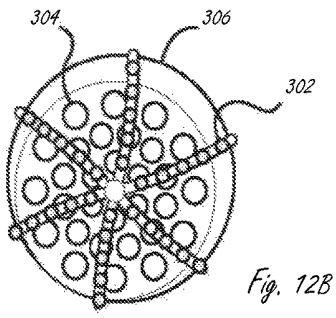

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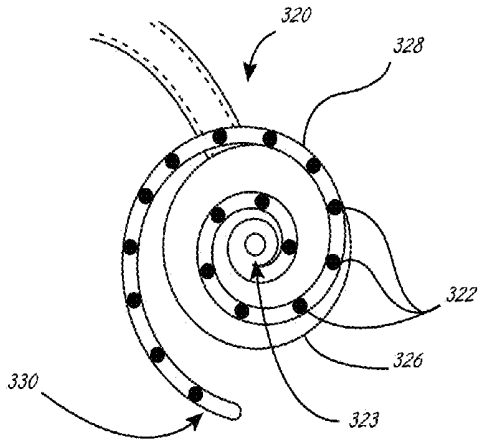

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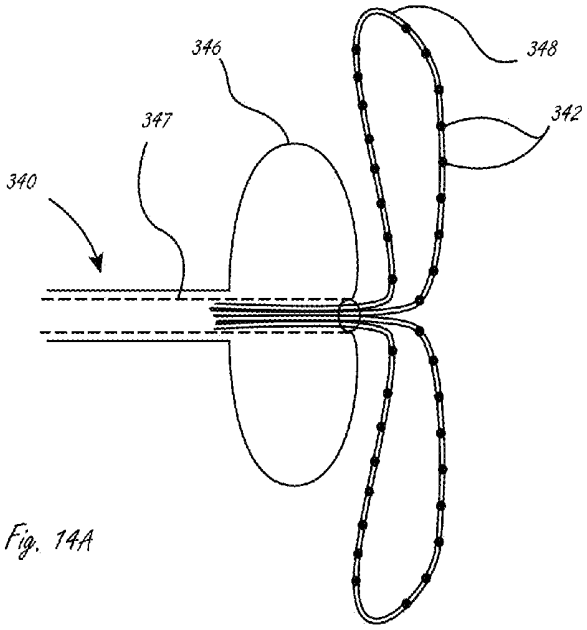

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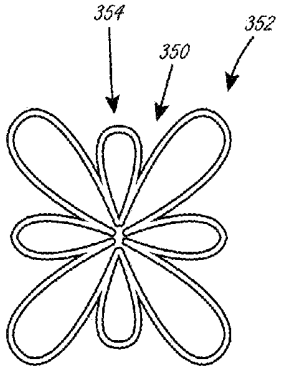

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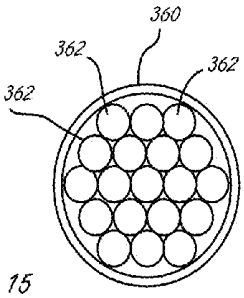
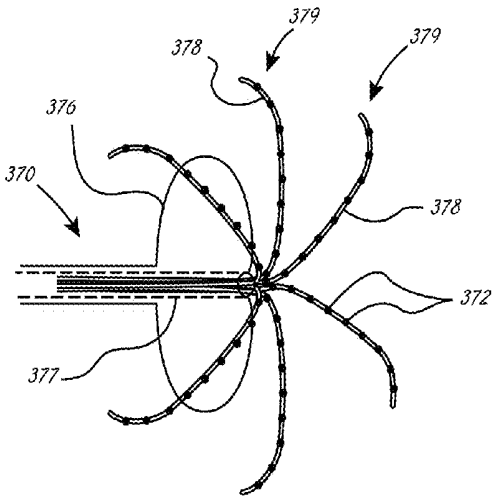


Fig 15



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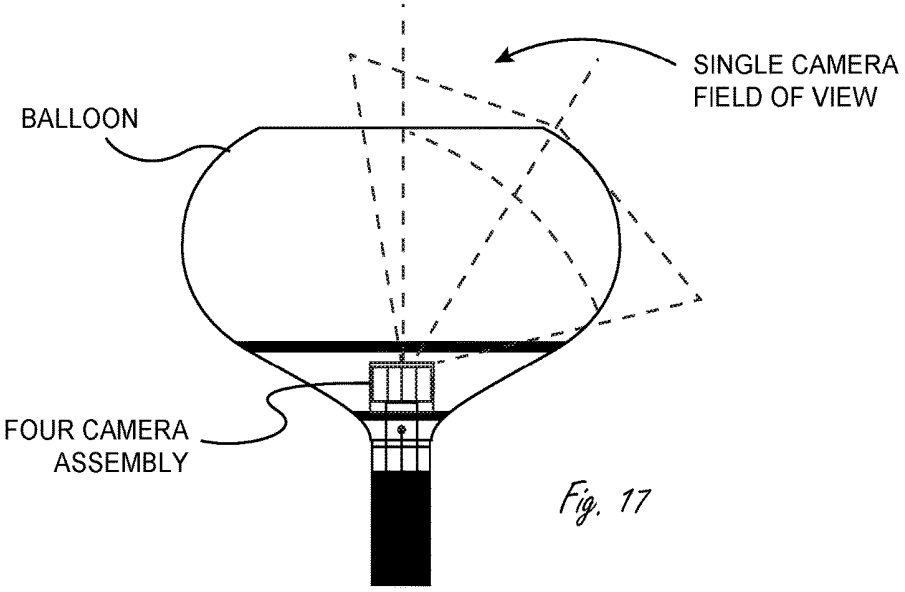

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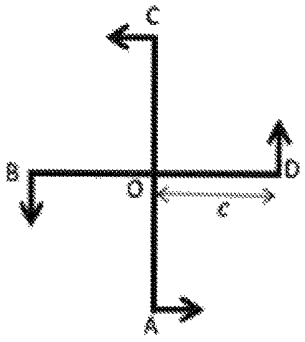

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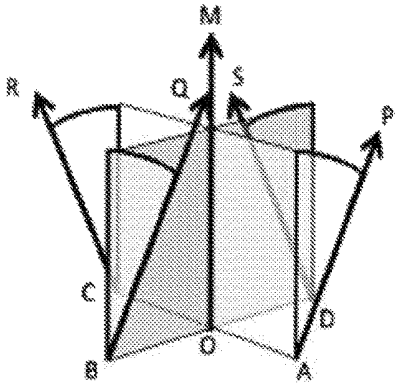

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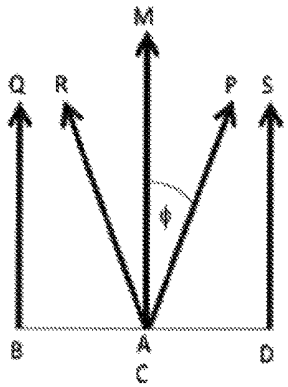

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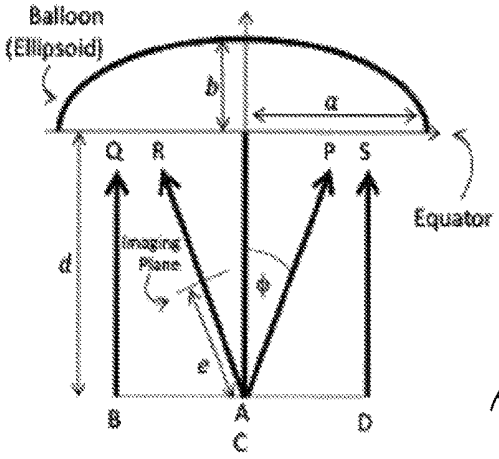

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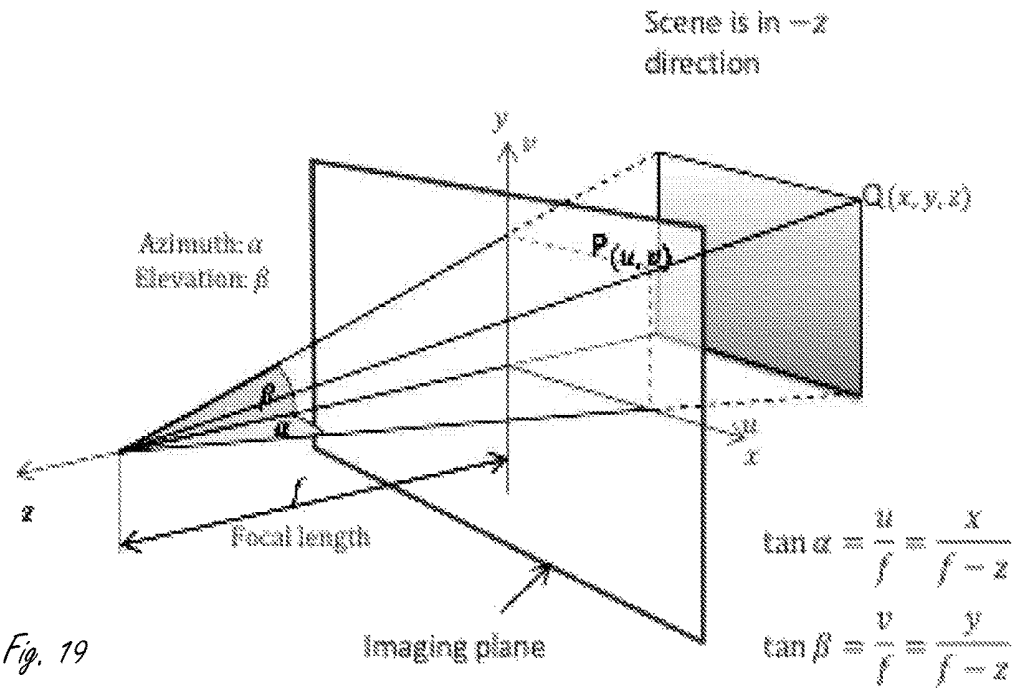
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z
f
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$\tan\beta = \frac{v}{f} = \frac{y}{f-z}$

Fig. 19

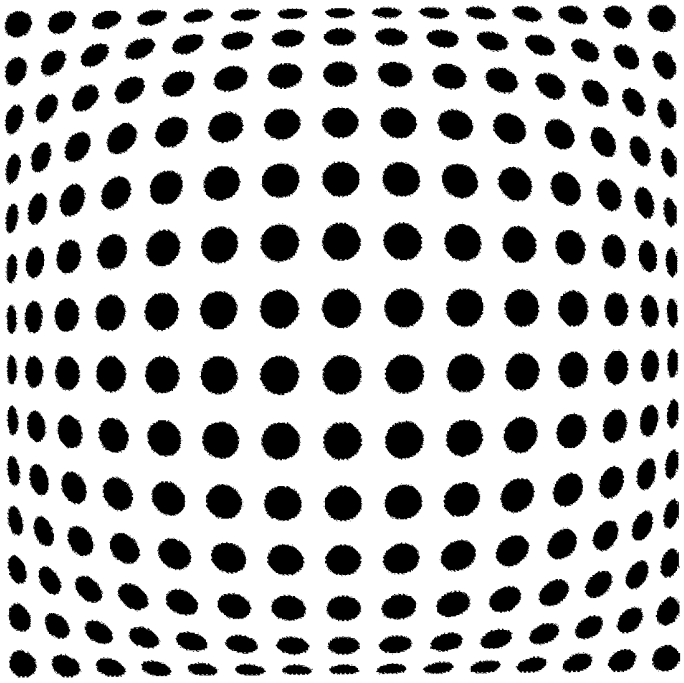

Fig. 20

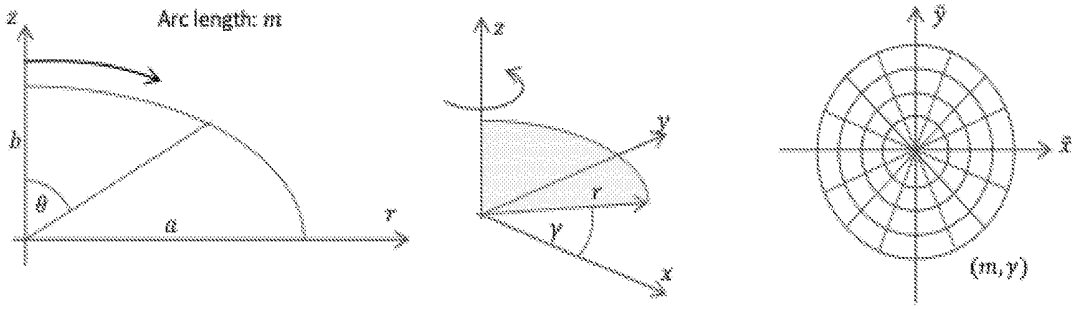

Fig. 21 (A) (B) (C)

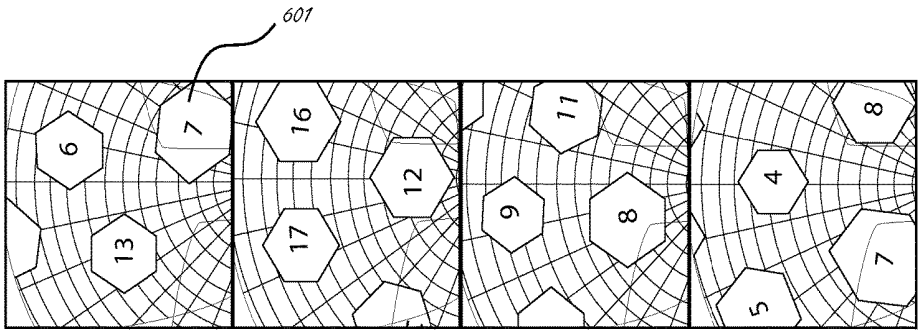

Fig. 22

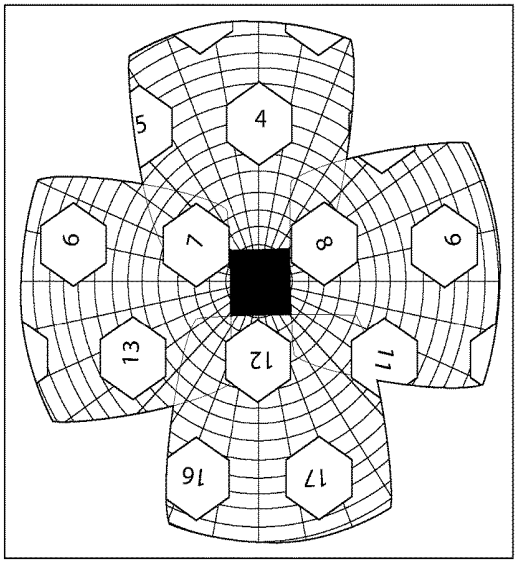

Fig. 23

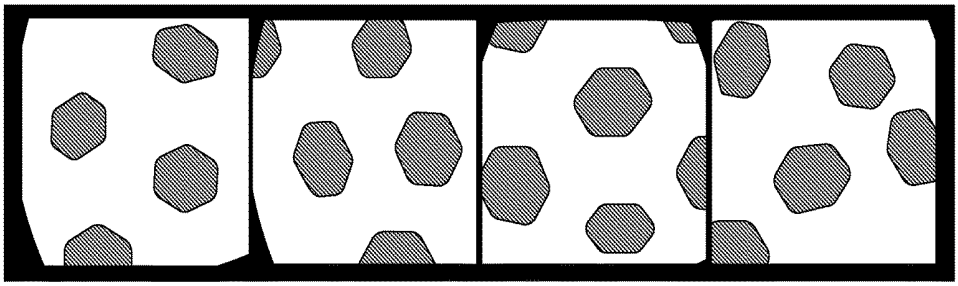

Fig. 24

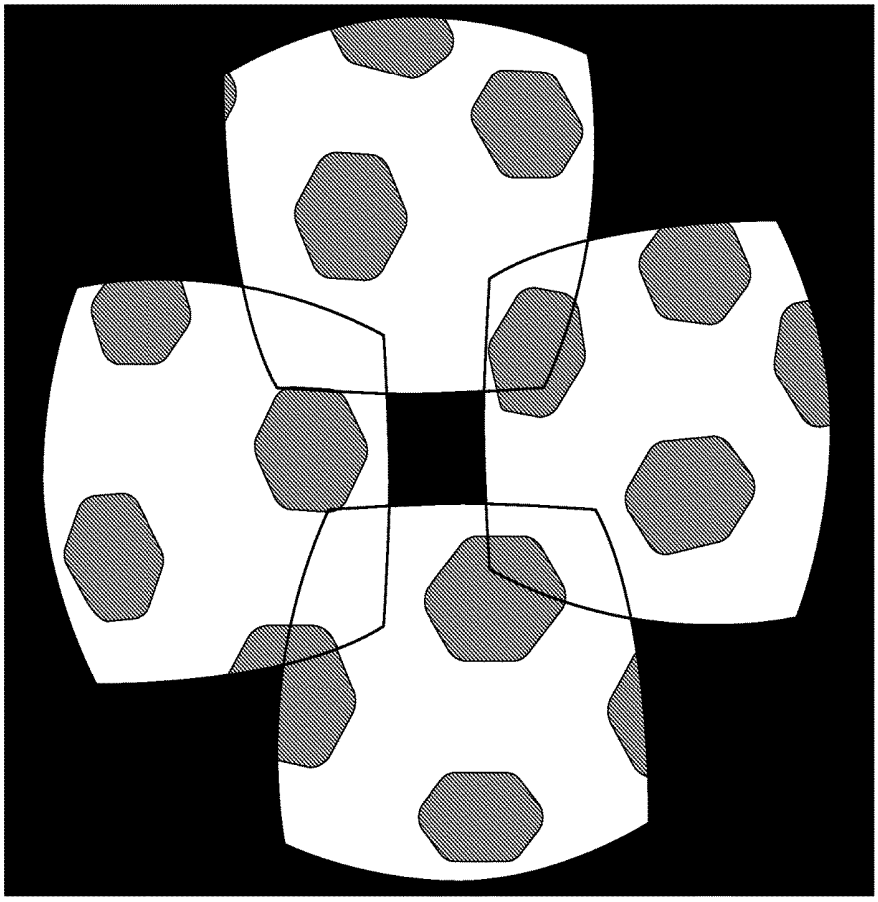

Fig. 25

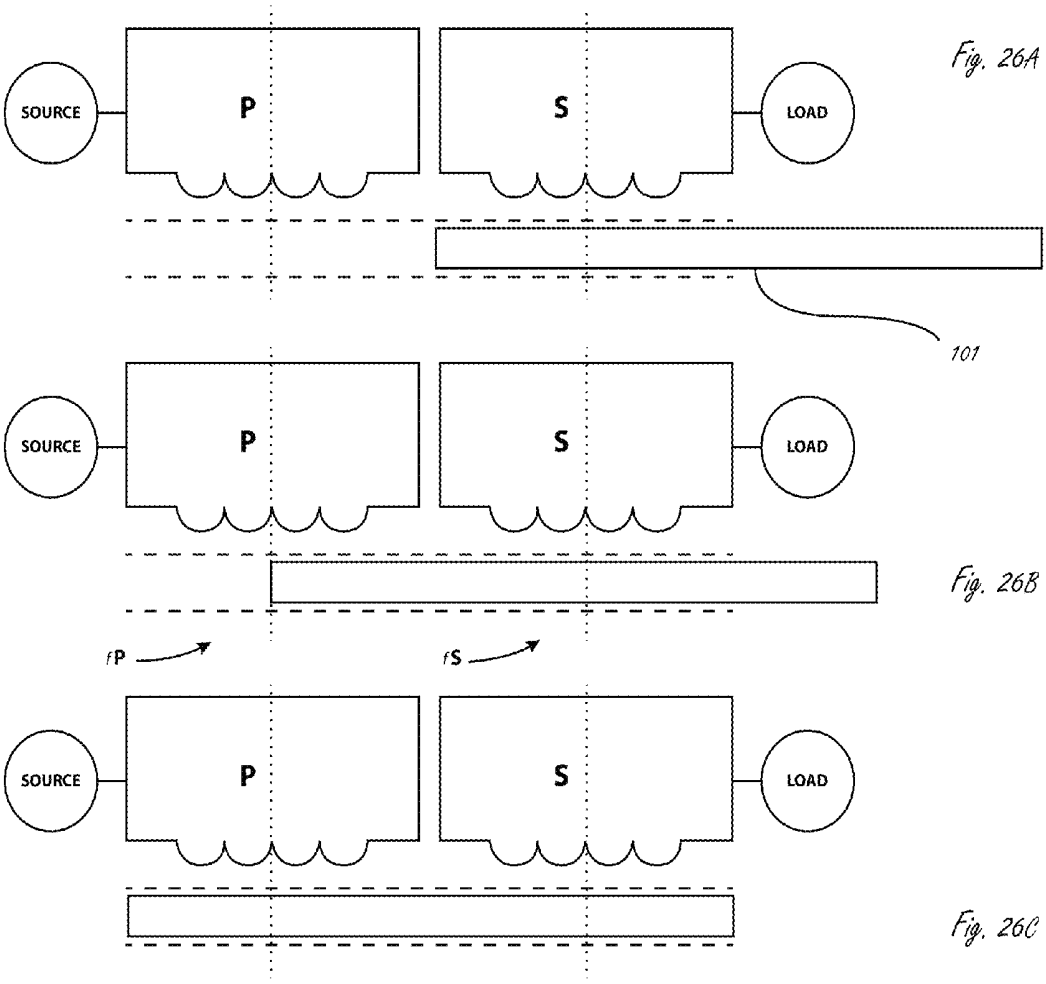

Fig. 26A

Fig. 26B

Fig. 26C

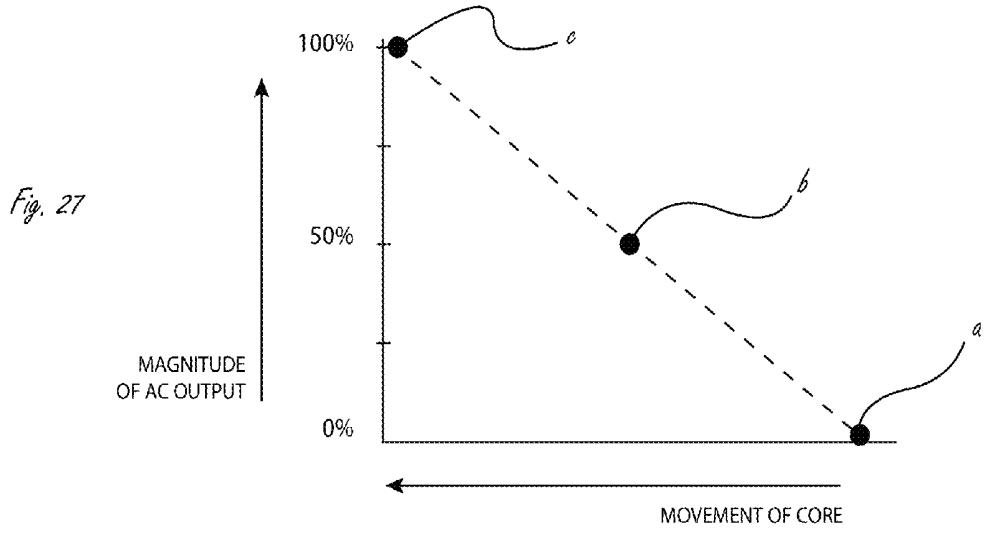

Fig. 27

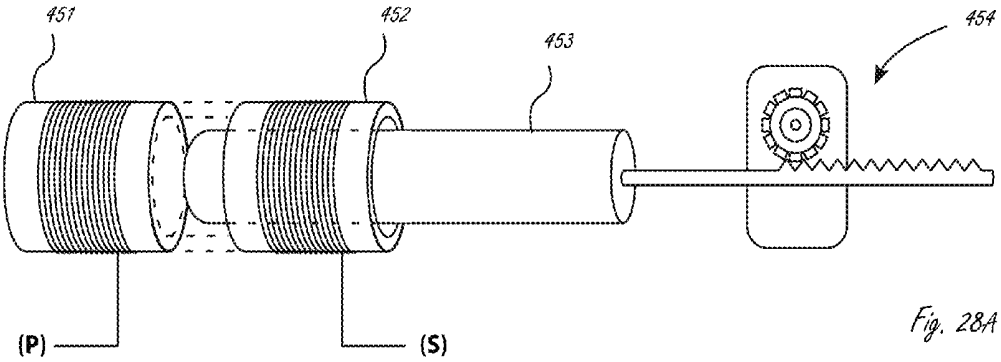

Fig. 28A

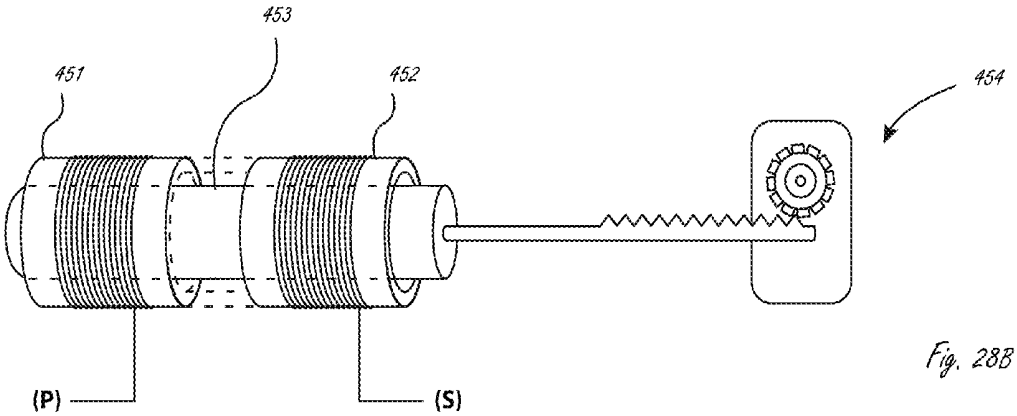

Fig. 28B

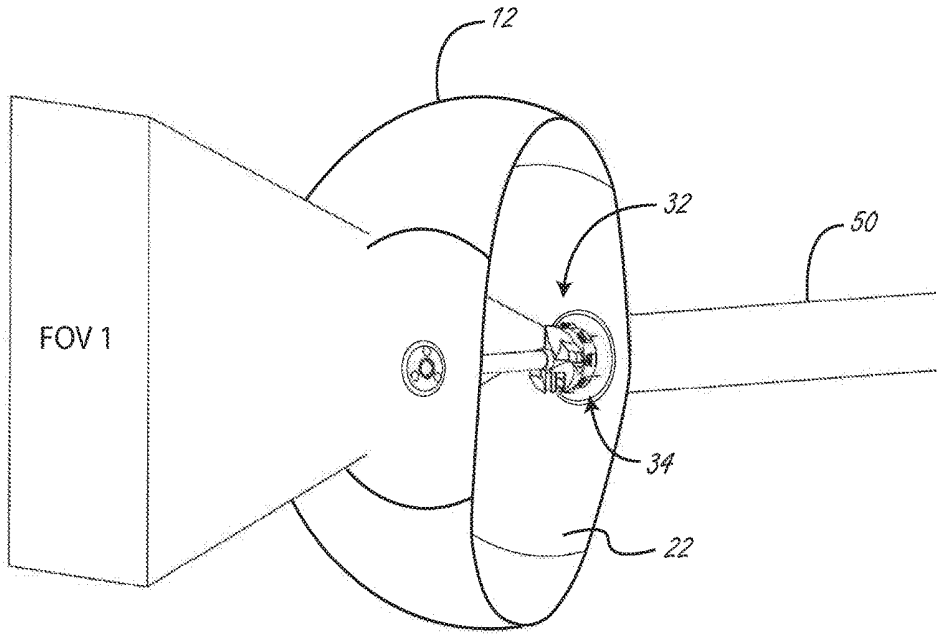

Fig. 29

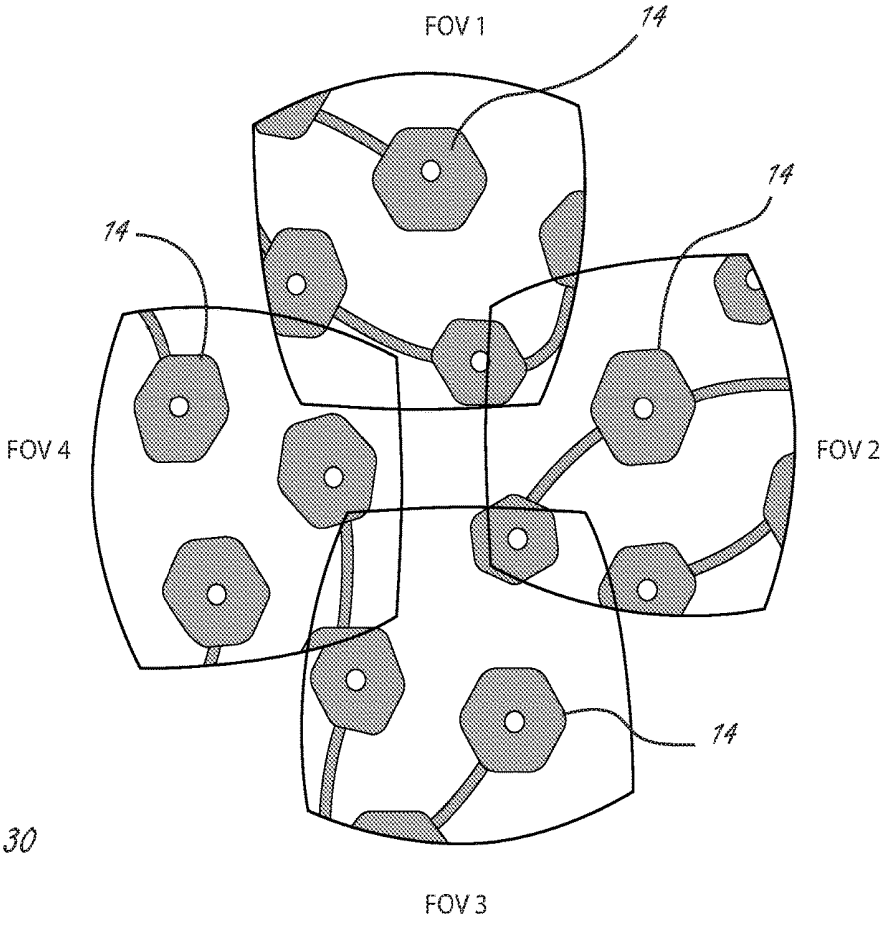

Fig. 30

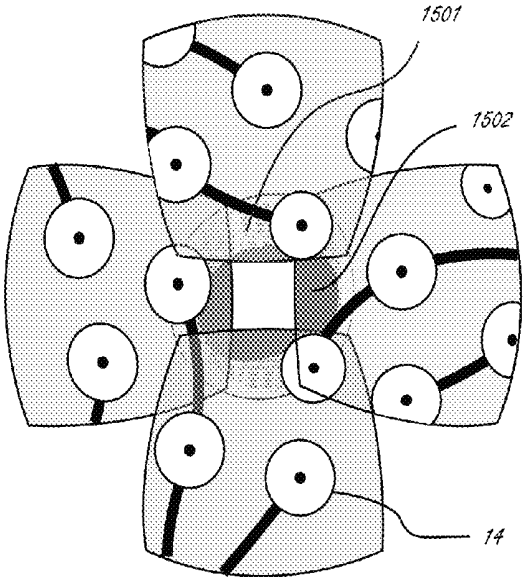

Fig. 31A

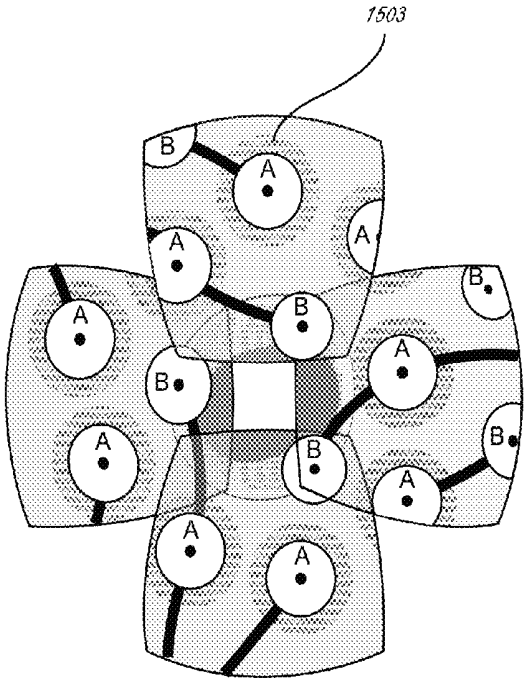

Fig. 31B

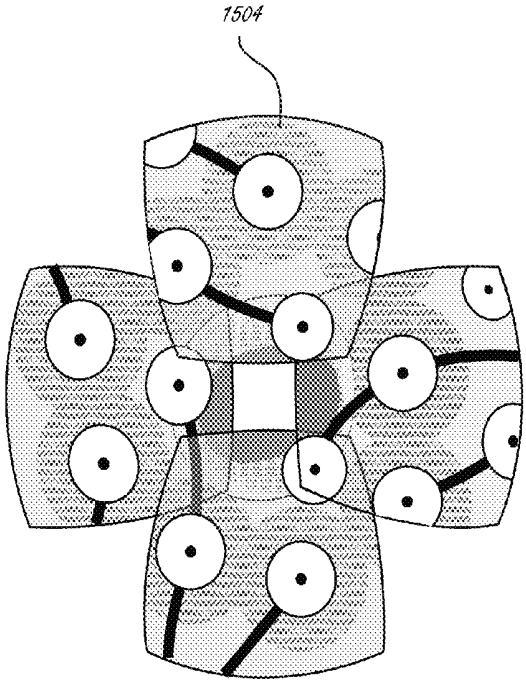

Fig. 31C

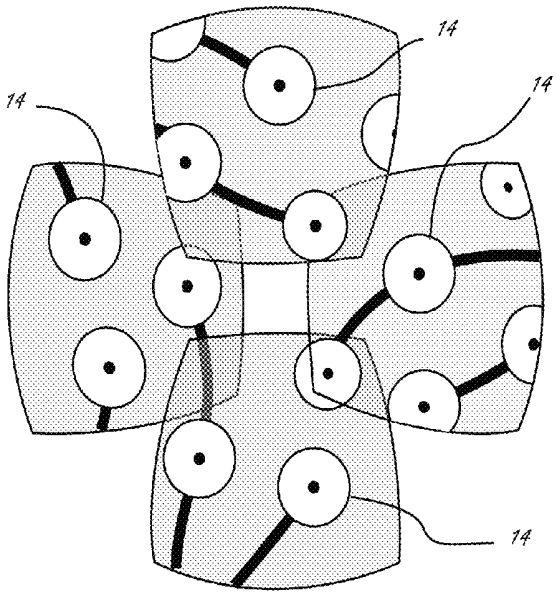

Fig. 32A

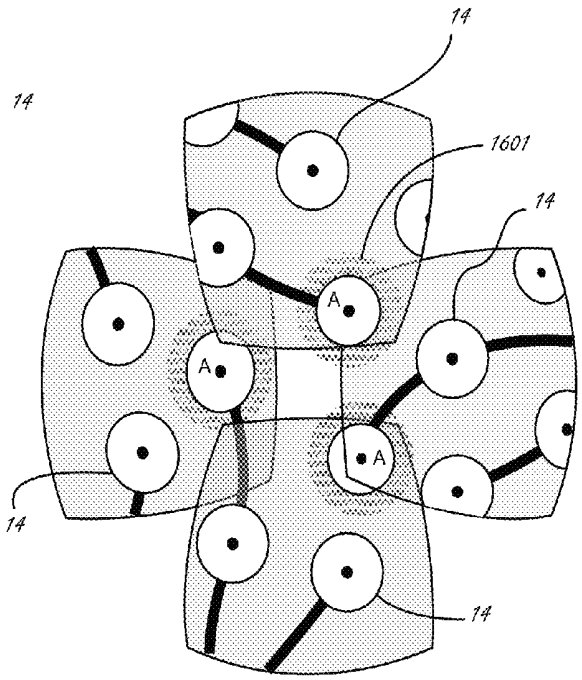

Fig. 32B

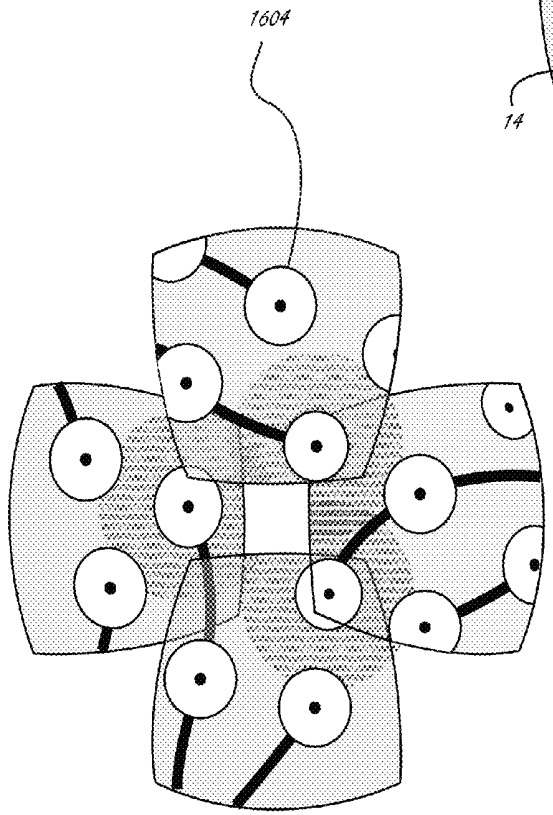

Fig. 32C

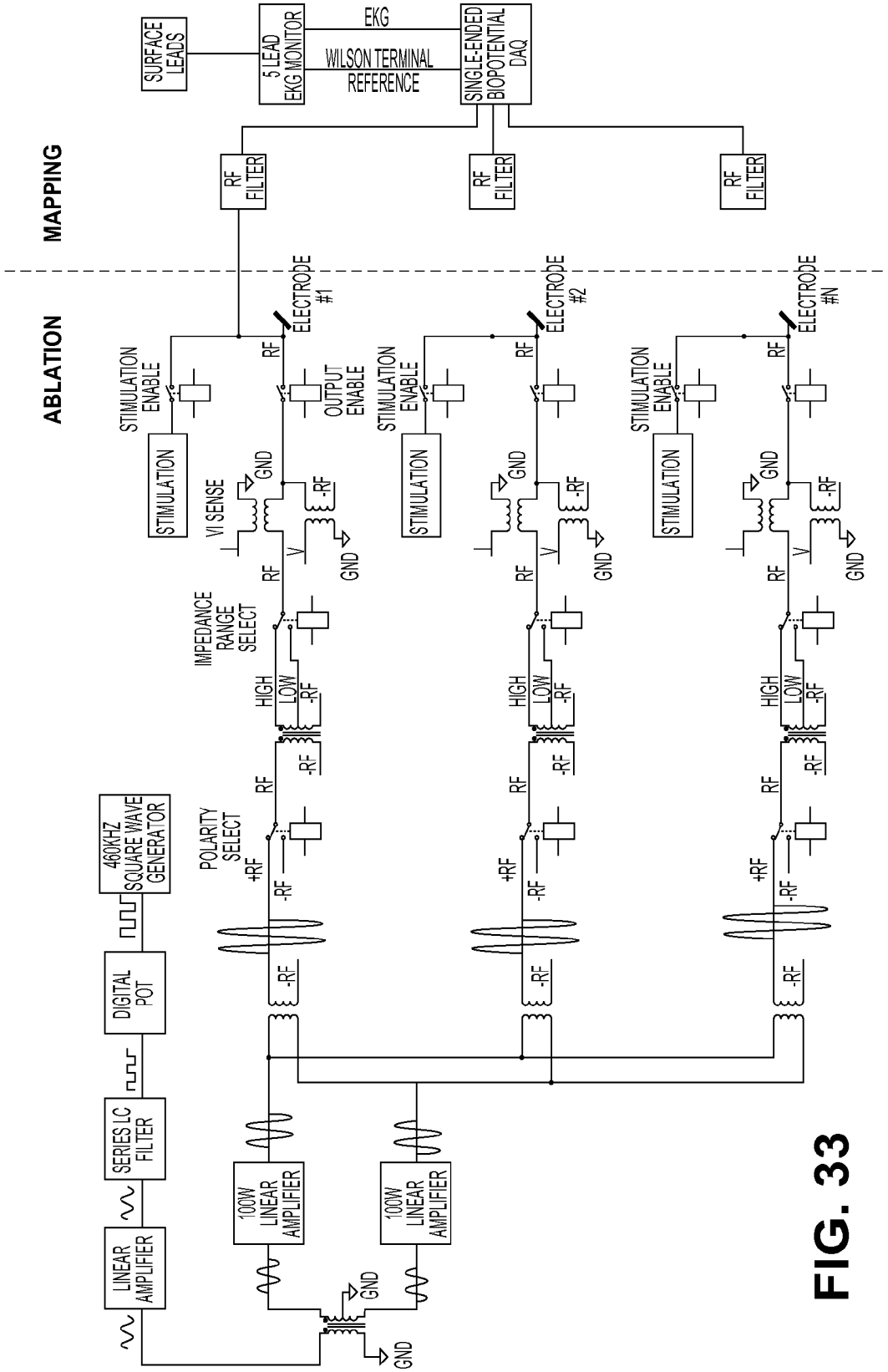
MAPPING
ABLATION
SURFACE LEADS
5 LEAD EKG MONITOR
EKG
WILSON TERMINAL REFERENCE
SINGLE-ENDED BIOPOTENTIAL DAQ
RF FILTER
RF FILTER
RF FILTER
ELECTRODE #1
ELECTRODE #2
ELECTRODE #N
STIMULATION ENABLE
OUTPUT ENABLE
STIMULATION
V/I SENSE
GND
-RF
RF
V
IMPEDANCE RANGE SELECT
HIGH
LOW
POLARITY SELECT
+RF
460KHZ SQUARE WAVE GENERATOR
DIGITAL POT
SERIES LC FILTER
LINEAR AMPLIFIER
100W LINEAR AMPLIFIER
100W LINEAR AMPLIFIER
GND
GND

FIG. 33

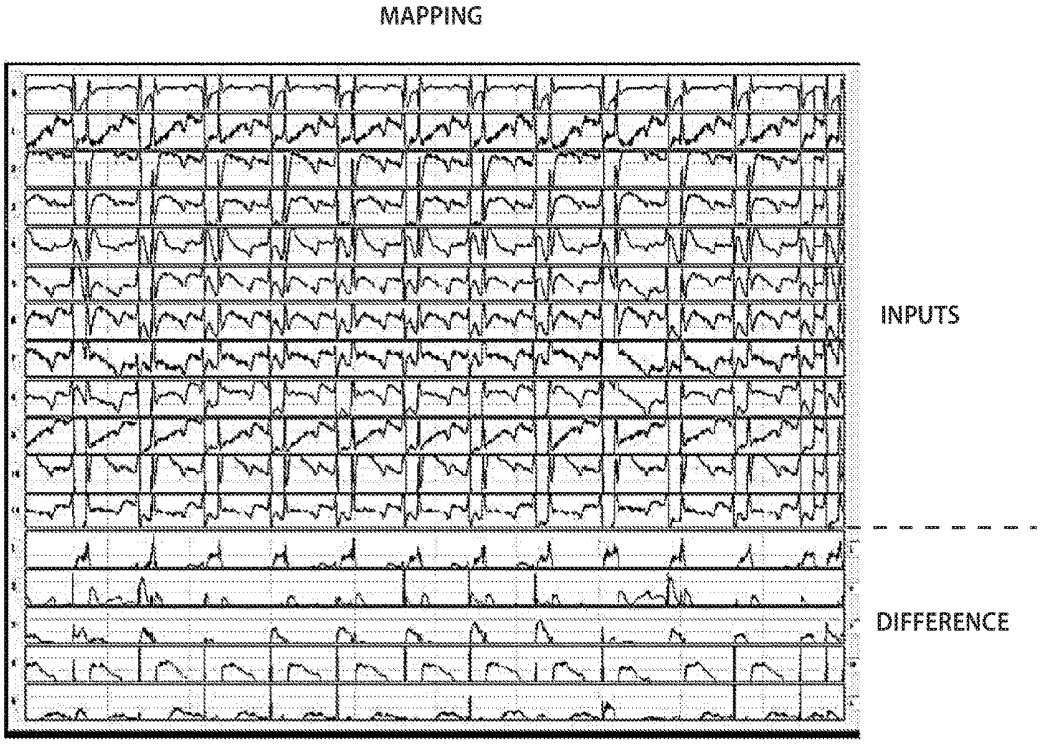

Fig. 34

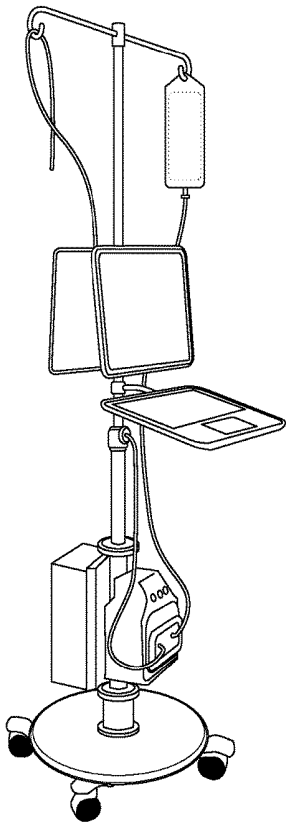

Fig. 35

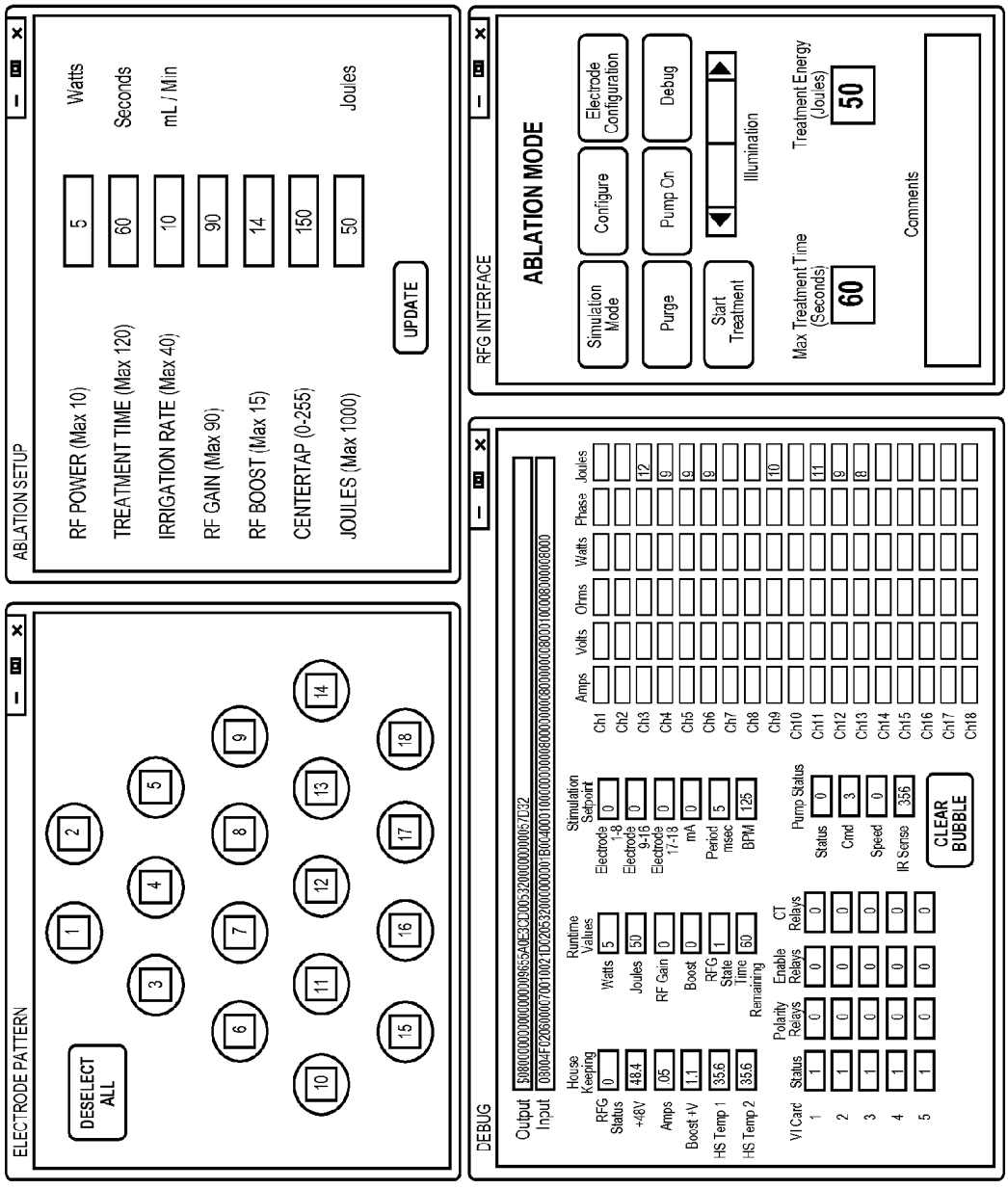
ELECTRODE PATTERN
DESELECT ALL
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
ABLATION SETUP
RF POWER (Max 10)
5
Watts
TREATMENT TIME (Max 120)
60
Seconds
IRRIGATION RATE (Max 40)
10
mL / Min
RF GAIN (Max 90)
90
RF BOOST (Max 15)
14
CENTERTAP (0-255)
150
JOULES (Max 1000)
50
Joules
UPDATE
RFG INTERFACE
ABLATION MODE
Simulation Mode
Configure
Electrode Configuration
Purge
Pump On
Debug
Start Treatment
Illumination
Max Treatment Time (Seconds)
60
Treatment Energy (Joules)
50
Comments
DEBUG
Output
Input
CLEAR BUBBLE

FIG. 36

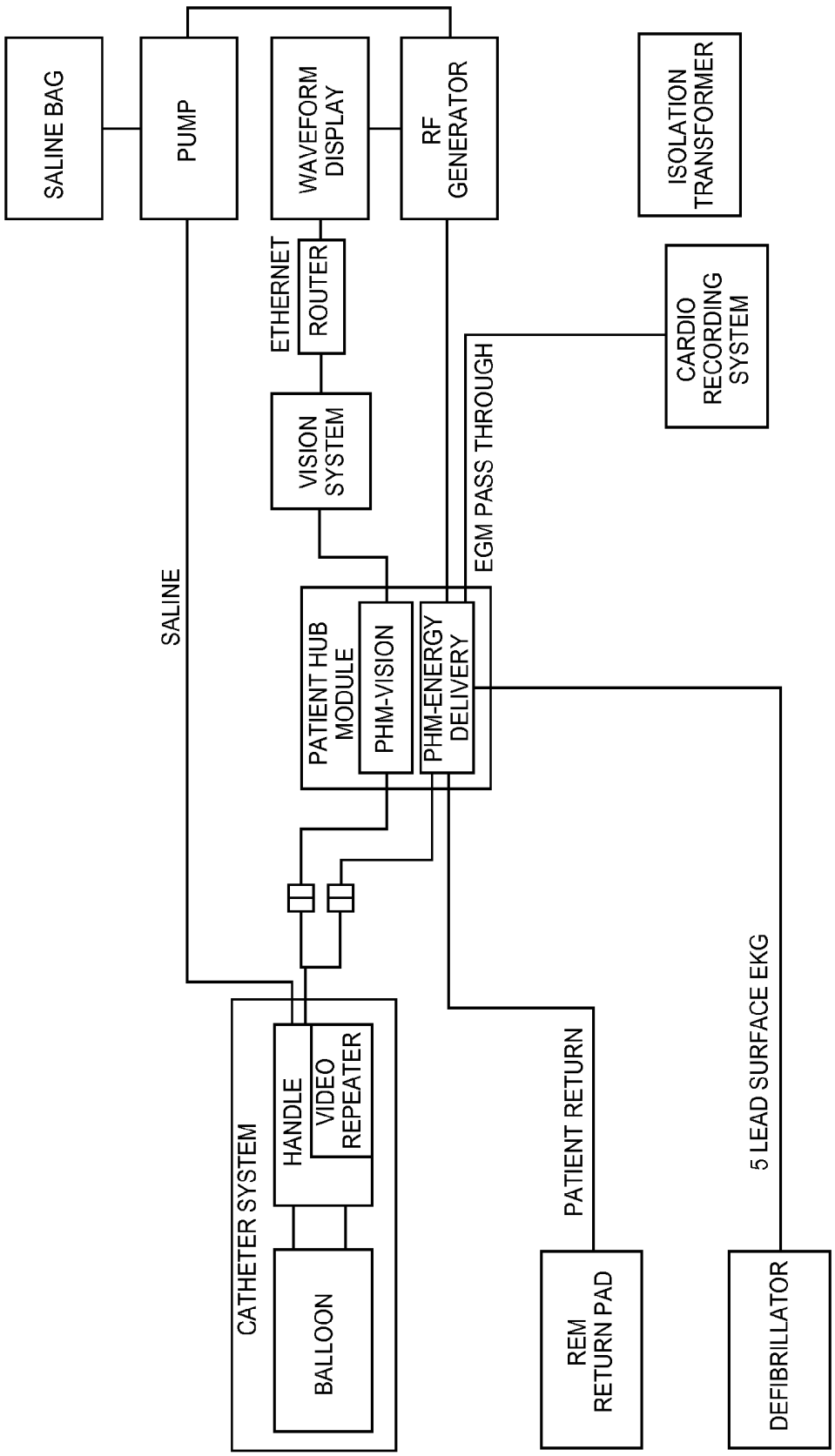
SALINE BAG
PUMP
WAVEFORM DISPLAY
RF GENERATOR
ISOLATION TRANSFORMER
ETHERNET
ROUTER
CARDIO RECORDING SYSTEM
VISION SYSTEM
EGM PASS THROUGH
SALINE
PATIENT HUB MODULE
PHM-VISION
PHM-ENERGY DELIVERY
CATHETER SYSTEM
HANDLE
VIDEO REPEATER
BALLOON
PATIENT RETURN
5 LEAD SURFACE EKG
REM RETURN PAD
DEFIBRILLATOR

FIG. 37

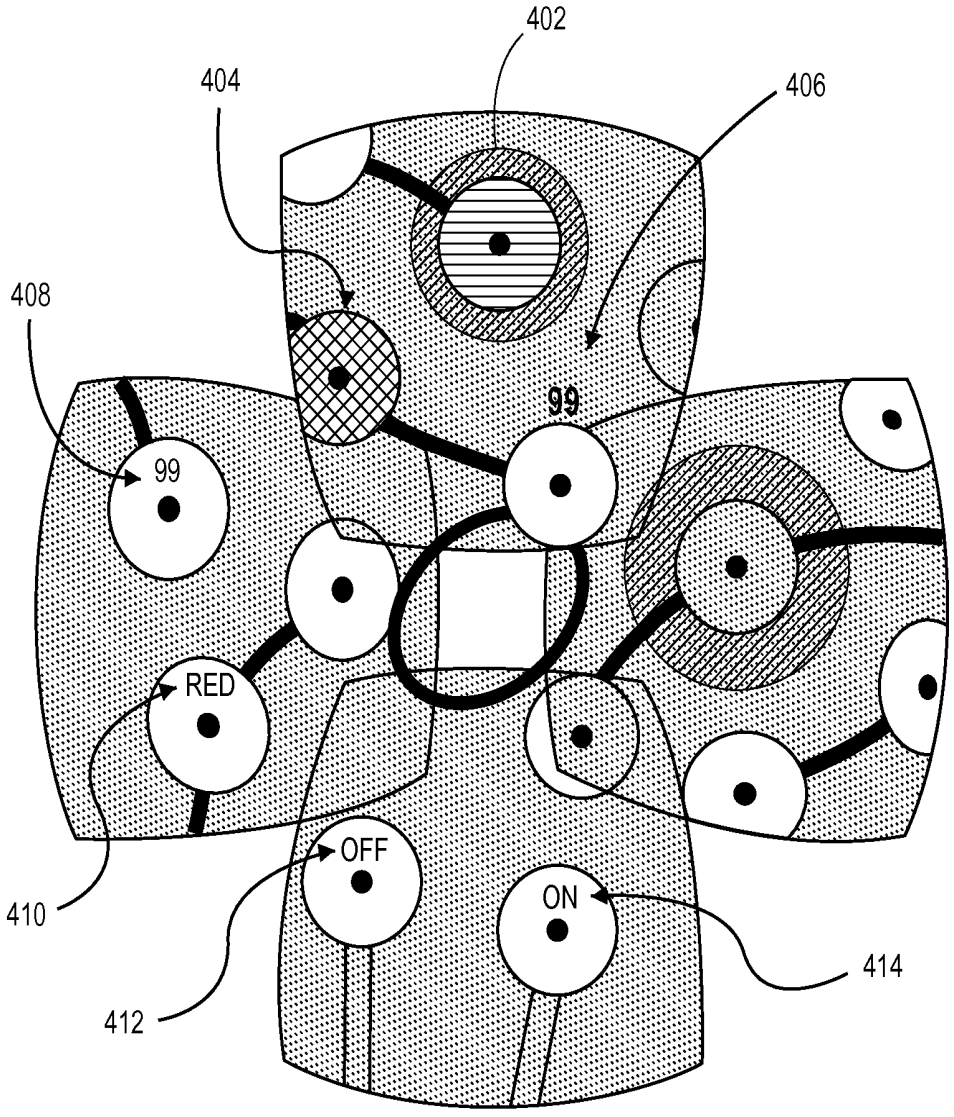

FIG. 38

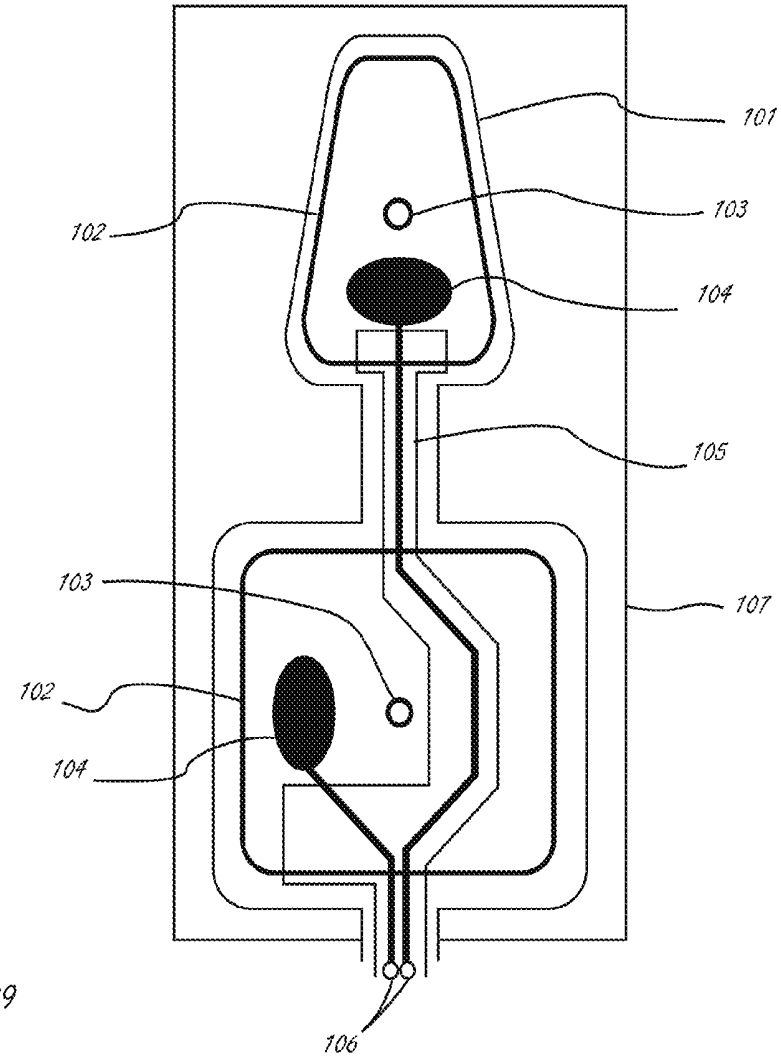

Fig. 39

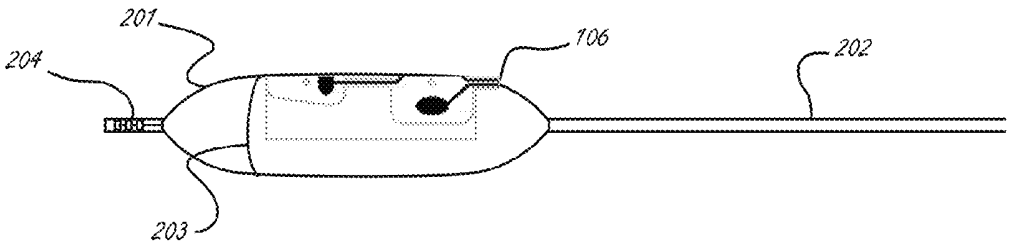

Fig. 40

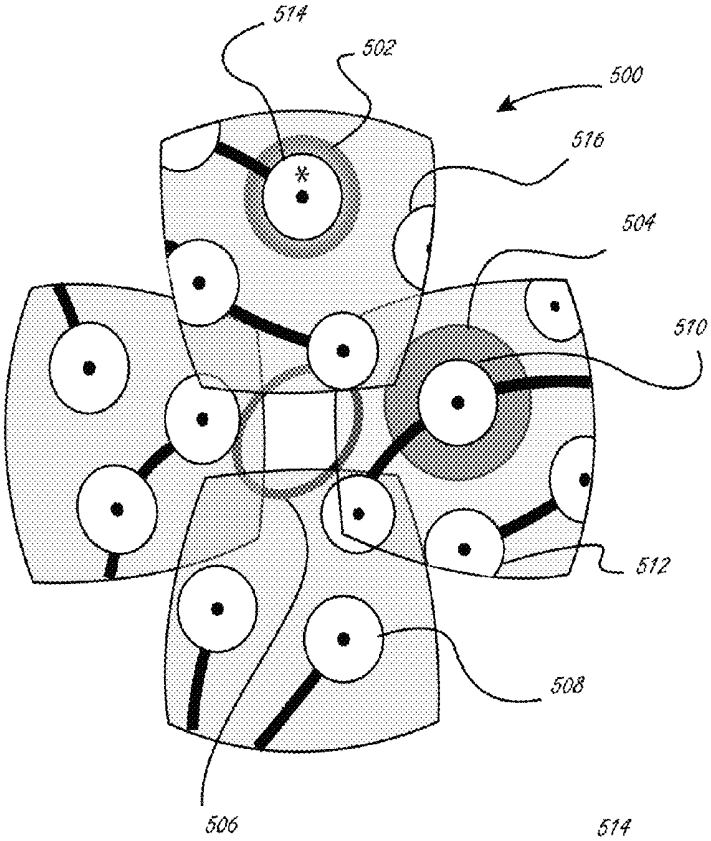

Fig. 41A

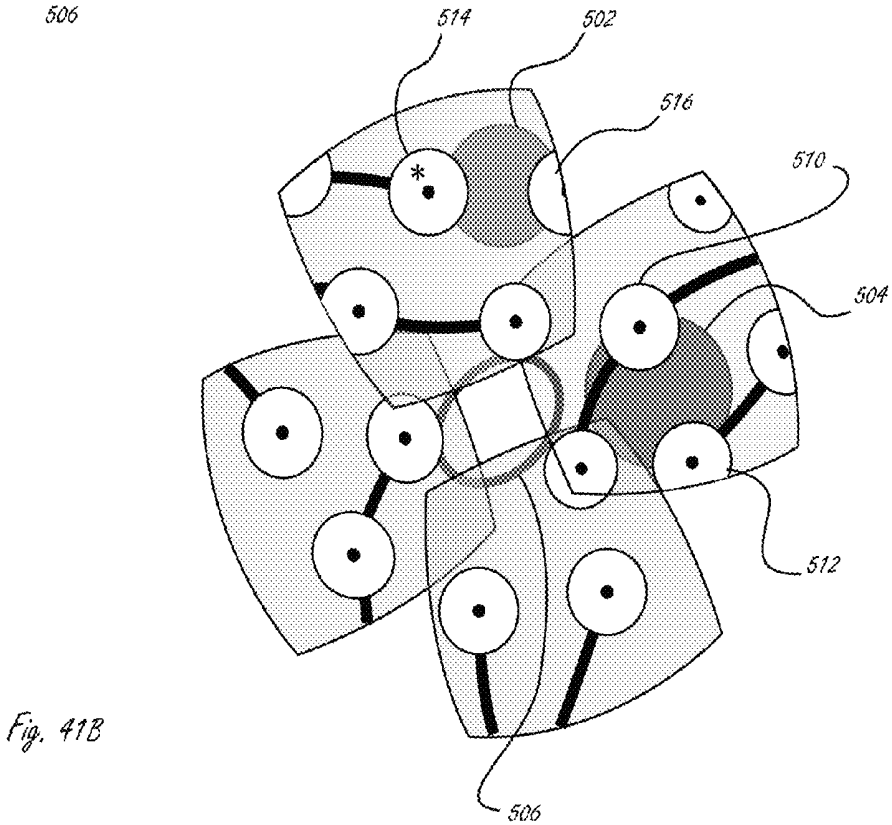

Fig. 41B

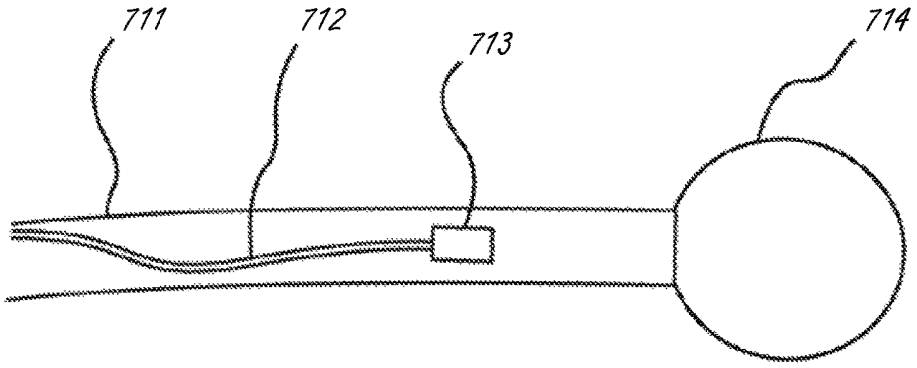

Fig. 42

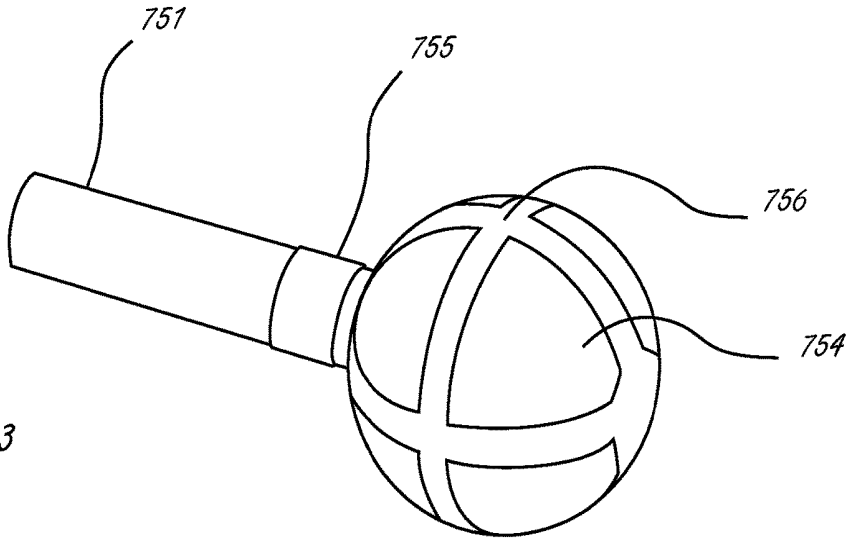

Fig. 43

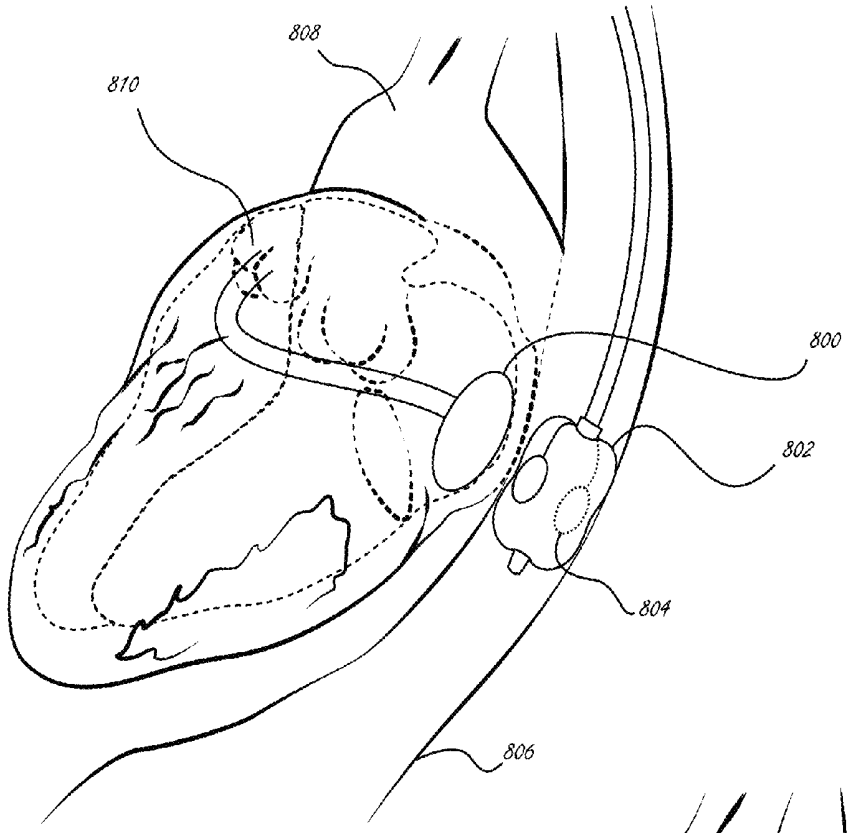

Fig. 44

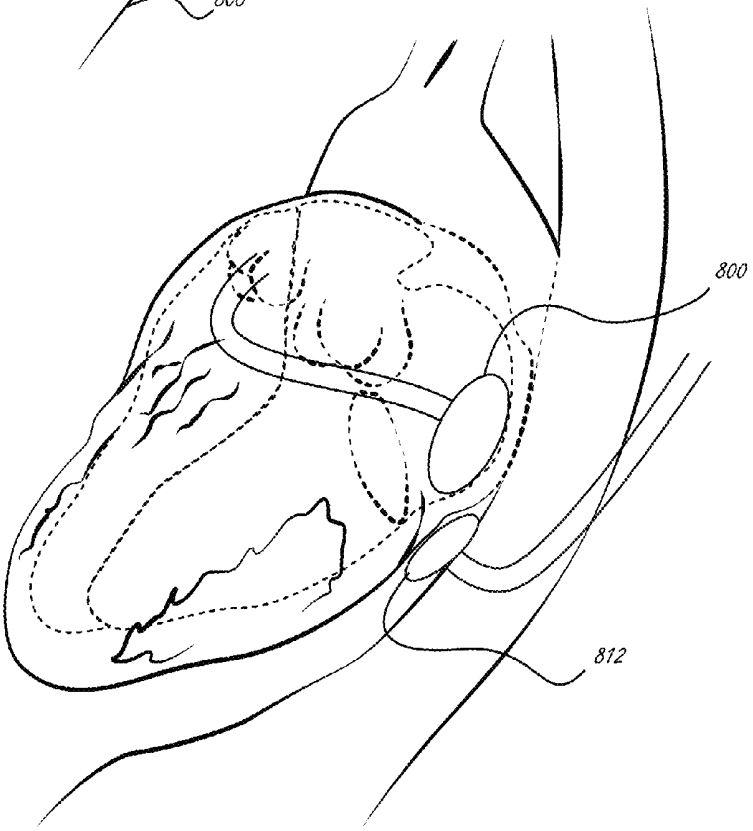

Fig. 45

CARDIAC ABLATION CATHETERS AND METHODS OF USE THEREOF

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of the following fourteen U.S. Provisional Applications, the disclosures of which are incorporated by reference herein: App. No. 61/809,629, filed Apr. 8, 2013; App. No. 61/809,646, filed Apr. 8, 2013; App. No. 61/895,880, filed Oct. 25, 2013; App. No. 61/809,636, filed Apr. 8, 2013; App. No. 61/864,335, filed Aug. 9, 2013; App. No. 61/829,985, filed May 31, 2013; App. No. 61/820,992, filed May 8, 2013; App. No. 61/821,001, filed May 8, 2013; App. No. 61/821,014, filed May 8, 2013; App. No. 61/934,640, filed Jan. 31, 2014, App. No. 61/939,185, filed Feb. 12, 2014; App. No. 61/934,647, filed Jan. 31, 2014; App. No. 61/945,005, filed Feb. 26, 2014, and App. No. 61/947,950, filed Mar. 4, 2014. All of the above-mentioned disclosures are incorporated by reference herein.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND

Energy transmission to tissues can be used to treat a variety of medical conditions. Electrodes can be used to deliver energy to tissues and cells for the purpose of sensing, mapping, ablating, and/or stimulate muscles and/or nerves. Stimulation of muscles and/or nerves can be used to trigger signals to the brain or directly to a specified muscle cell/group. When the treatment requires removing or destroying a target tissue, thermal ablation therapy can be used to heat a target tissue with a surgical instrument such as a needle or probe electrode coupled to an energy source that heats the probe tip, the target tissue, or both. In such cases the thermal energy may be delivered directly by heating or cooling the probe or indirectly by generating energy fields within the tissue which in turn generate heat, or both. Energy fields commonly used to create heat indirectly are RF and acoustic energy fields. The goal for most ablation procedures is to achieve cell death quickly, precisely and with minimal to no collateral damage.

In the case of thermal ablation therapy for terminating destructive cardiac conductive pathways, energy can be delivered to the aberrant cells using minimally-invasive techniques such as an electrode-tip catheter. Pulmonary vein isolation via radio frequency catheter ablation has been demonstrated to be an effective treatment for some patients experiencing atrial fibrillation (AF). The cornerstone of the AF ablation procedures is electrical isolation of relatively large pulmonary vein antra. Ablation of large confluent areas or lines of ablation with older generation AF ablation devices is accomplished by point to point manipulation and RF application with the single electrode tip. The single electrode catheter technique is extremely time-consuming, complex and fraught by subjectivity. Furthermore, efficient and complete mapping of the electrical activity in target tissues often requires the placement of multiple catheters in the left atrium, the use of a 3D-mapping, and/or steering system. It is often desirable to create relatively large surface area lesions with relatively shallow depths of ablation.

Newer larger electrode arrays for "one shot" ablation have been used to improve catheter ablation treatments. These ablation systems have been adopted as a way to provide full contact to tissues having a complex 3-D anatomy and an overall larger lesion area. But known devices incorporate electrodes that are bulky, stiff and limited in their ability to be packed efficiently and effectively into the small space of the treatment catheter. The stiffness of these devices limits conformability against the tissue resulting in the need for additional repositioning and overlapping patterns to ensure uninterrupted lines of ablation.

SUMMARY OF THE DISCLOSURE

One aspect of the disclosure is an ablation catheter comprising: an expandable membrane and a plurality of ablation electrodes secured to the exterior of the expandable membrane; an imaging member disposed within the expandable membrane; a diffuse reflector secured to at least a proximal portion of the expandable membrane; and a light source disposed within the expandable member and positioned to direct light towards the diffuse reflector such that diffuse reflection of the light is directed towards a field of view of the imaging member.

In some embodiments the imaging member is generally distally facing and the light source is generally proximally facing. The imaging member and the light source can be secured to an inner catheter shaft. The imaging member can be a plurality of cameras oriented to provide a 360 degree view around a longitudinal axis of the catheter. The imaging member can be disposed distally relative the light source.

In some embodiments the diffuse reflector does not extend to the distal end of the expandable membrane when in an expanded configuration. The diffuse reflector can extend no further than about half-way along the distal length of the expandable membrane when in an expanded configuration.

In some embodiments the diffuse reflector comprises first and second portions divided by a flex circuit secured to the exterior of the expandable membrane, the flex circuit comprising at least one conductive layer in electrical communication with at least one of the plurality of electrodes.

One aspect of the disclosure is an inflatable assembly adapted to be positioned within a patient, comprising an expandable membrane; an imaging member disposed within the expandable membrane; a diffuse reflector secured to at least a proximal portion of the expandable membrane; and a light source disposed within the expandable member and positioned to direct light towards the diffuse reflector such that diffuse reflection of the light is directed towards a field of view of the imaging member.

One aspect of the disclosure is an ablation catheter, comprising: an expandable membrane and at least one ablation electrode secured to the exterior of the expandable membrane; an imaging member disposed within the expandable membrane, the imaging member having a field of view; a light source disposed within the expandable member adapted to deliver light towards the field of view of the imaging member; and a reflection adjuster adapted to reduce specular reflection of light from at least one of the plurality of ablation electrodes into the field of view of the imaging member. The reflection adjuster can be a light absorber. The reflection adjuster can be adapted to scatter light away from the field of view of the imaging member. The reflection adjuster can be an anti-reflective coating on at least one of an inside of balloon or the at least one electrode.

One aspect of the disclosure is a video display process, comprising receiving a plurality of images from a camera in motion secured to a catheter; calculating a mean rotation of a center of mass of an anatomical feature shown in the images relative to a feature whose position is fixed relative to the camera; and communicating as output images in which the anatomical feature is fixed and the feature whose position is fixed relative to the camera is shown to be moving.

One aspect of the disclosure is a method of stabilizing an image of cardiac tissue while moving a camera positioned within the heart; comprising providing an ablation catheter within a left atrium, the ablation catheter including an expandable membrane, a plurality of electrodes secured to an exterior surface of the expandable membrane, at least one camera positioned within the expandable membrane with a field of view fixed relative to the position of the plurality of electrodes when the expandable membrane is in an expanded configuration, and a light source; and in response to movement of the camera within the left atrium, and, while the camera is being moved, displaying a video of cardiac tissue in which the position of the cardiac tissue is fixed and the plurality of electrodes in the field of view are moving.

One aspect of the disclosure is a method of superimposing an image of cardiac tissue with additional information, comprising positioning an ablation catheter within a left atrium, the ablation catheter including an expandable membrane, a plurality of electrodes secured to an exterior surface of the expandable membrane, at least one camera positioned within the expandable membrane, and a light source; capturing an image with the at least one camera, wherein the image shows at least one of at least one of the plurality of electrodes and the cardiac tissue; obtaining additional information indicative of at least one of a characteristic of the cardiac tissue and a characteristic of the ablation catheter; displaying the image that shows the at least one of at least one of the plurality of electrodes and the cardiac tissue with the with the additional information superimposed thereon.

In some embodiments the additional information comprises an indicator of cardiac tissue adjacent one of the plurality of electrodes. The additional information can comprise temperature of cardiac tissue adjacent one of the plurality of electrodes.

In some embodiments the additional information is a qualitative indicator.

In some embodiments the additional information is a quantitative indicator.

In some embodiments the additional information comprises a state of at least one of the plurality of electrodes, such as on or off.

One aspect of the disclosure is an ablation catheter comprising: an expandable membrane and a plurality of ablation electrodes secured to the exterior of the expandable membrane; at least one imaging member disposed within the expandable membrane, the at least one imaging member having a field of view that include the plurality of ablation electrodes; and an electrode identifier associated with each of the plurality of electrodes and adapted to be visually identifiable in the field of view so that each of the plurality of electrodes can be visually identifiable.

In some embodiments the electrode identifiers comprise alphanumeric characters on or near each of the electrodes.

In some embodiments the electrode identifiers are colors associated with each of the electrodes.

In some embodiments the electrode identifiers are shapes of the electrodes.

In some embodiments the electrode identifiers are a first type of identifier for at least one of the plurality of electrodes, and a second type of identifier for at least a second of the plurality of electrodes.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A-**1**C illustrate an exemplary ablation device in expanded configurations.

FIG. **1**D illustrates an exemplary ablation device in a collapsed configuration.

FIG. **2**A is a side view of an exemplary distal end of an ablation catheter.

FIG. **2**B is a close up side view of the inside of the catheter from FIG. **2**A.

FIG. **3** is a perspective view showing inside the expandable membrane.

FIG. **4** illustrates a camera assembly.

FIG. **5** is a perspective view of a distal end of an ablation catheter, with a cutaway of an expandable member.

FIG. **6** is an exemplary flat view of the LED flex circuit.

FIG. **7** illustrates the distal end of a device incorporating a slideable sheathing tool comprising a sheathing tube.

FIG. **8** is a flat view showing three individual flex circuits that are secured to the exterior of membrane and to electrodes.

FIG. **9**A illustrates a portion of one of the flex circuits and electrodes in FIG. **8**.

FIG. **9**B illustrates the exemplary different layers of the flex circuit from section S-S from FIG. **9**A.

FIG. **10** illustrates each of the three flex circuit tails terminating in terminations extending proximally from the distal end of the balloon and extending proximally within an outer shaft and secured to the outer surface of the proximal end of the balloon and irrigation shaft.

FIGS. **11**A-**16** illustrate exemplary ablation catheter adapted with mapping structures or adapted to be used with mapping structures.

FIG. **17** is a side view of a distal portion of an exemplary visualization catheter.

FIGS. **18**A-**18**D show the orientations of the axes of four cameras in relationship to the longitudinal axis of a catheter shaft.

FIG. **19** shows the geometry of one of the four cameras, and all four have the same geometry.

FIG. **20** shows a picture of a regular grid pattern target taken by a representative camera.

FIGS. **21**A-**21**C show parameterization that can be used to unwrap the 3D surface of the ellipsoidal balloon into a 2D plane.

FIG. **22** shows a set of four camera images simulated using a known pattern, in this case, ablation electrodes painted on the membrane.

FIG. **23** shows the panoramic image generated by projecting the images from FIG. **22** back onto the unwrapped balloon surface using the methods described above.

In FIG. **24** the panoramic image is generated by projecting the component images back onto the unwrapped balloon surface.

FIG. **25** shows tissue images acquired by four cameras using the methods described herein.

FIGS. **26**A-**26**C illustrate an electromechanical device providing for the continuous or semi-continuous adjustment of the transfer of AC power from a source to a load by means of linearly displaceable core.

FIG. **27** shows a graph illustrating movement of the core versus magnitude of AC output.

FIGS. **28**A and **28**B represent one embodiment of where a core is displaced by a micro-stepper motor and screw mechanism.

FIG. **29** illustrates only one of the four fields of view for one of the four cameras in the camera assembly.

FIG. **30** illustrates the four fields of view from the four cameras, each overlaid with at least one other field of view, to give the physician a 360 degree view.

FIGS. **31**A-**31**C illustrate an exemplary method of ablating cardiac tissue.

FIGS. **32**A-**32**C illustrate an exemplary method of ablating cardiac tissue.

FIG. **33** is an exemplary schematic of the electrical aspect of an exemplary embodiment.

FIG. **34** illustrates mapping signals from a plurality of channels.

FIGS. **35** and **36** illustrate aspects of an external console.

FIG. **37** illustrates an exemplary block diagram of a cardiac ablation system.

FIG. **38** illustrates exemplary information and indicators that can be superimposed on the images from the cameras.

FIG. **39** represents an exemplary flexible circuit for application to the outer surface of a balloon.

FIG. **40** shows an assembled flexible circuit affixed to a balloon.

FIGS. **41**A and **41**B illustrate a composite view as described herein from a four camera array as presented to the user on a display.

FIGS. **42** and **43** illustrate an exemplary embodiment of an ablation catheter wherein the balloon is configured for contact (physical) measurements.

FIG. **44** illustrates an ablation balloon in the left atrium and esophageal temperature balloon positioned and inflated in the esophagus.

FIG. **45** illustrates an embodiment that includes an endocardial catheter and an epicardial catheter.

DETAILED DESCRIPTION

The disclosure describes methods of, and systems and devices configured for, diagnosing, preventing, and/or treating cardiac arrhythmias. The disclosure includes methods of and devices configured for ablating cardiac tissue. The disclosure is related to and incorporates by reference the devices and methods described in U.S. Pat. No. 8,295,902, issued Oct. 23, 2012, and U.S. Pub. No. 2012/0071870, published Mar. 22, 2012, the disclosures of which are incorporated by reference herein. Devices herein can incorporate suitable structural features in embodiments in the aforementioned applications even if the disclosure fails to expressly include them. Additionally, the methods of use herein can include suitable method steps in embodiments in the aforementioned applications even if the disclosure fails to expressly include them.

FIGS. **1**A-**1**C illustrate a distal portion of an exemplary cardiac ablation catheter. FIGS. **1**A-**1**C shows expandable member **10** in an expanded configuration. FIG. **1**A is a distal view, FIG. **1**B is a perspective view, and FIG. **1**C is a side view.

The cardiac ablation catheter is configured to deliver ablative energy to tissue such as cardiac tissue and to ablate the tissue. Expandable member **10** includes membrane, or balloon, **12** and a plurality of energy delivery elements **14** secured to the exterior of membrane **12**. In this embodiment energy delivery elements **14** are electrodes configured and positioned to deliver ablative RF energy to tissue when expandable member **10** is inflated and to ablate the tissue, and are in electrical communication with an RF generator (not shown) configured to generate RF energy.

FIG. **1**D illustrates expandable member **10** in a collapsed, or deflated, configuration prior to full inflation.

FIG. **2**A is a side sectional view of the distal portion of the ablation catheter shown in FIGS. **1**A-**1**C. FIG. **2**B is a highlighted side sectional view of components within outer shaft **51**. FIG. **2**A shows membrane **12** expanded at the distal end of outer lumen **50**, which is the annular space between outer shaft **51** and irrigation shaft **55**. The distal end of membrane **12** is secured, such as by press-fit and/or adhesive, to distal hub assembly **20**, between an inner member and an outer member of assembly **20** as shown. The proximal end of membrane **12** is secured to the outer surface of irrigation shaft **55**. Hub **20** is secured to guide wire shaft **54**, which in this embodiment defines guidewire lumen **53** so that the ablation catheter can be advanced over a guidewire (not shown). Guidewire shaft **54** and irrigation shaft **55** are adapted to be axially movable relative to one another, which allows the distal end of membrane **12** to be moved relative to the proximal end of membrane **12**. Relative movement between the two components can allow for the shape of the balloon to be changed. The movement also assists in transitioning expandable member **10** to a collapsed configuration, as shown in FIG. **1**D.

Visualization system **30** includes a camera assembly **32** and illumination sources **35** disposed on the guide wire shaft **54**. The cameras are configured to enable real-time imaging of the procedure from within the expandable member **10** to visualize the membrane and electrodes, cardiac tissue when the membrane/electrodes and cardiac tissue interface, as well as lesion formation during the ablation procedure, as is described in more detail below.

FIG. **2**B shows radially outer shaft **51**, irrigation shaft **55** that defines irrigation lumen **52**, and guide wire shaft **54** that defines guidewire lumen **53**.

The materials of the membranes **12** described herein can vary. Generally, the membrane material is thin, readily foldable into a low profile and refoldable after expansion. The materials can be elastic, inelastic, stretchy, non-stretchy, compliant, semi-compliant, or non-compliant. In an embodiment, membrane **12** has an expandable structure and can be constructed of materials such as those materials used in the construction of balloon catheters known in the art, including, but not limited to polyvinyl chloride (PVC), polyethylene (PE), cross-linked polyethylene, polyolefins, polyolefin copolymer (POC), polyethylene terephthalate (PET), nylon, polymer blends, polyester, polyimide, polyamides, polyurethane, silicone, polydimethylsiloxane (PDMS) and the like. Membrane **12** can be constructed of relatively inelastic polymers such as PE, POC, PET, polyimide or a nylon material. Membrane **12** can be constructed of relatively compliant, elastomeric materials including, but not limited to, a silicone, latex, urethanes, or Mylar elastomers. Membrane **12** can be embedded with other materials such as for example, metal, Kevlar or nylon fibers. Membrane **12** can be constructed of a thin, non-extensible polymer film such as polyester or other flexible thermoplastic or thermosetting polymer film. In one embodiment flexible membrane **12** can be about 0.001" to about 0.002" in thickness to provide sufficient burst strength and allow for foldability. In some embodiments it is preferable to have the electrode mechanical properties as close to the membrane mechanical properties as possible. One way of providing this is to use an inelastic membrane that will not stretch as it is expanded.

This helps secure the branches to the membrane. Membrane **12** has a front, or distal, face that is generally flat but can have other shapes as well.

Expandable member **10** includes what is generally referred to in U.S. Pat. No. 8,295,902, issued Oct. 23, 2012, and U.S. Pub. No. 2012/0071870, published Mar. 22, 2012, as flex circuits. A flex circuit as used herein generally refers to a conductive layer, an insulation layer, and optionally a substrate layer. A flex circuit is in electrical communication with at least one electrode.

FIG. **8** is a flat view showing three individual flex circuits that are secured to the exterior of membrane **12**. Each of the three flex circuits includes six energy delivery elements **14**, and a tail terminating in termination **41** for the six conductive traces, one for each of the six electrodes. The terminations may be in the form of a connector or solder pads or other such suitable interface. The terminations **41** extend proximally from energy delivery elements on the expandable member, one of which can be seen in FIG. **1**D. Each of the tails branch off into three branches **16**, each one of which includes two energy delivery elements. Each of the two side branches **16** extend away from the longitudinal axis of the connector at substantially the same angle and each of two electrodes on a side branch is disposed at the same axial position (in the distal/proximal direction) as the other corresponding electrode on the other side branch. The central branch, however, initially extends along the same general direction as the longitudinal axis of a tail, and the first electrode on the central branch is axially disposed at the same general location as the second electrodes on the right and left branch. The central branch then extends away from the longitudinal axis of the tail, and the second (distal) electrode on the central branch is disposed further distally than the other five electrodes on the flex circuit, and is disposed radially (relative the longitudinal axis of tail) at the same general position as the first (proximal) electrode on one of the other side branches. In FIG. **8**, the six electrodes on one of the flex circuits are labeled A-F. The two side branches of the flex circuit include electrodes A-B and E-F respectively. The central branch includes electrodes C and D. In the flat view, electrode C (the distal electrode of the central branch) is axially disposed at the same general position as electrodes B and F. Electrode D is disposed further distally than the other five electrodes, and is positioned radially in the same general position as electrode A. Electrodes A and E are disposed in the same general axial position, as are electrodes B, C, and F. Each of the three flex circuits is positioned on the expandable member, and the arrangement and size of electrodes provides for eighteen electrodes secured to the expandable member. As can be seen in FIGS. **1**A and **1**B, there are three electrodes closely surrounding hub **20**.

FIG. **9**A illustrates a portion of one of the flex circuits in FIG. **8** (the flex circuit in which termination **41** is at the "6 o'clock" position), including six energy delivery elements **14**. FIG. **9**A shows as alternative embodiment in which the distal electrode on the central branch **16** extends to the right on the page rather than the left, as is shown in FIG. **8**. This arrangement provides the same general arrangement of the eighteen electrodes on the balloon. In the embodiment in FIGS. **1**A-**1**C, there are three of the flex circuits from FIG. **9**A disposed on membrane **12**, and thus eighteen energy delivery elements secured to membrane **12**. FIG. **9**B illustrates the exemplary different layers of the flex circuit from section S-S from FIG. **9**A. Electrically non-conductive substrate layer **13** is deposited on membrane **12**, upon which conductive layers, or traces, **15** are deposited. Insulation layer **17** is deposited on top of conductive layers **15** except where the electrodes **14** are located. For example, to the left in FIG. **9**B, an electrode **14** is disposed on electrically conductive element **15**, thus electrically coupling electrode **14** and conductive layer **15**, which is electrically coupled to an RF generator. On the right side of FIG. **9**B, insulation layer **17** prevents conductor **15** on the right side from being electrically coupled to electrode **14**. Instead, the conductor **15** on the right side will be electrically coupled to the distal electrode on that branch. Each individual conductor **15** is therefore electrically coupled to only one electrode **14**. In the figure shown in **9**A, there are six individual conductive traces **15**, each of which is individually coupled to one electrode. As is described in detail in U.S. Pat. No. 8,295,902, issued Oct. 23, 2012; U.S. Pub. No. 2012/0071870, published Mar. 22, 2012, the electrodes are sized and configured to extend over a portion of the flex circuit and a portion of membrane not covered by the flex circuit. In this manner a large surface area electrode can be deposited onto and secured to the membrane. Each electrode is shown with an irrigation aperture in the middle thereof, as is described herein to irrigate tissue adjacent the electrodes and to prevent the irrigation fluid inside the membrane from becoming too hot and interfering with the tissue ablation.

The conductor or conductive layer **15** can be a material such as, but not limited to, a metal or metal foil of copper, gold, silver, tin, nickel, steel, cupronickel (copper-nickel alloy), KOVAR (nickel-cobalt ferrous alloy) or other material. In an embodiment, more than one conductive material can be used in the conductive layer **15**. In an embodiment, a conductive layer **15** of copper can be plated with a thin layer of an additional conductive material at the conductive pad beneath electrode **14**. In an embodiment, the thin layer of additional conductive material can be gold. The flex circuit and its components can be manufactured using techniques as known in the art.

The materials used to create the electrodes **14** can vary. The electrodes **14** can be a thin film of an electro-conductive or optical ink. The ink can be polymer-based for better adhesion to the membrane. The electrode material can be a biocompatible, low resistance metal such as silver, silver flake, gold, and platinum which are additionally radiopaque. Inks may additionally comprise materials such as carbon and/or graphite in combination with the more conductive materials already described. The addition of carbon and/or graphite can increase the conductivity of the polymer matrix. When incorporated as fibers the carbon and/or graphite add additional structural integrity to the ink electrode. Other fiber materials may be substituted to attain the same end. When the electrode material is not particularly radiopaque, additives such as tantalum and tungsten may be blended with the electrode material to enhance radiopacity. An example of an electro-conductive ink is provided by Engineered Conductive Materials, LLC (ECM) which is a polyurethane-based silver loaded ink. Another example is Creative Materials Inc., which manufactures conductive inks, films, as well as radiopaque inks. As mentioned above, the electrodes **14** can be applied to the membrane **12** and flex circuit using an adhesive. Alternatively, the electrode material can have adhesive properties or be an adhesive-loaded with conductive particles such as silver flakes such that electrodes **14** can adhere the components of the flex circuit to the membrane **12**. If an additional adhesive layer is used to adhere the electrode **14** to the membrane **12** and flex circuit, the adhesive layer can include a conductive or non-conductive material. The electrodes formed with electro-conductive or optical ink or thin metal film can be

visualized under fluoroscopy to provide a general sense of the shape of the membrane and location of the electrode. To enhance visualization under fluoroscopy, radiopaque additives can be included in the electrode material or radiopaque markers laid out next to, on top or below the electrodes as will be discussed in more detail below. Additionally, the bonding layer or substrate will be optimally comprised of a minimally reflective material.

Each of the electrodes is individually addressable, or can be used with any other electrode. The electrodes can operate in monopolar mode or bipolar mode, as is indicated in the exemplary schematic shown in FIG. **34**. Electrodes sets can be chosen such that the lesion is, for example without limitation, linear, a spot, or a hollow circle.

FIG. **3** illustrates the coupling of the distal end of membrane **12** and hub **20**, which can be press fit, adhesive coupling or a combination of both.

To prevent or reduce the likelihood of charring of tissue that is in contact with the energy delivery elements and coagulation of blood adjacent the electrodes, each of the flex circuits at the locations of the electrodes includes an irrigation aperture therethrough, and as shown are in the center of the electrodes. The irrigation apertures also prevent the inflation/irrigation fluid inside the membrane from becoming too hot, which would interfere with the ablation. Irrigation fluid, which is also the fluid that inflates membrane **12** causing it to be reconfigured toward its expanded configuration, is pumped from a fluid source through irrigation lumen **52**, into membrane **12**, through the irrigation apertures (not labeled), and towards the tissue that is in contact with the electrodes to cool the target tissue. One of the drawbacks of previous attempts at cardiac ablation is that the ablation procedures cause blood to coagulate or tissue to char due to lack of a cooling feature. Additionally, since each electrode is individually addressable, and the visualization system allows the operator to identify whether an individual electrode is in contact with tissue, only electrodes in contact with tissue may be turned on. Thus energy is more efficiently coupled to just the sites where ablation is desired and little to no energy is dissipated into the blood.

One of the significant advantages of ablation catheters herein is that, when in use, the ablation procedures can be visualized with an imaging, or visualization, member with a perspective from within the inflatable membrane. In the embodiment in FIGS. **1A-1D**, imaging member **30** includes camera assembly **32** that includes a plurality of cameras **33** and a plurality of illumination, or light, sources, **35** (e.g., LEDs). Expandable member **10** also includes diffuse reflector **22** that is secured to the external surface of membrane **12**. Reflector **22** is a diffuse reflector adapted to create diffuse reflection of light incident upon it from the illumination sources. Reflector **22** is adapted to reflect light in a diffuse manner, as opposed to specular reflection, to better illuminate as much of the camera field of view as possible. If the reflector were adapted for specular reflection rather than diffuse reflection, light from the illumination sources that is reflected from the reflector would appear in the camera's field of view as a localized spot and would not illuminate as much of the field of view as possible.

Illumination sources **35** are configured and positioned to provide illumination generally radially outward towards reflector **22**. Diffuse reflector **22** thus diffusely reflects light forward toward the camera's fields of view. The illumination sources thus provide lighting for the cameras to visualize the procedure, including the tissue, and the lesion formation.

In some embodiments the diffuse reflector is printed on the exterior of the balloon. The diffuse reflector can be comprised of silicone or urethane resins filled with nonconductive white pigment such as TiO, BaO, BaSo4, styrene or other polymer beads, or of metal particles. Optimal materials will be minimally reflective such as a black adhesive.

In this embodiment the diffuse reflector is secured to the membrane such that it does not completely overlap any of the electrodes, and is positioned so that the illumination sources, when activated, emit light towards the reflector. In this embodiment the diffuse reflector, or reflectors, is secured to the membrane at a location that does not extend all the way to the distal end of the membrane. In this embodiment the reflector is secured to the membrane such that it does not extend further distally than the proximal-most electrode. In alternative embodiments, however, the reflector can extend distally to the proximal-most electrode in some locations around the membrane. For example, the distal edge of the reflector can be curved rather than straight, and depending on the electrode layout on the membrane, some portions of the reflector may extend distally relative to the proximal-most electrode. If the membrane in its inflated configuration can be divided in half between the distal most location and proximal most location defining a distal portion and proximal portion, the reflector is disposed at least on the proximal portion. In the embodiment shown in FIGS. **1A-1C**, the reflector is disposed only on the proximal portion.

One aspect of the disclosure is an expandable member that includes a diffuse reflector but does not include any ablation element. For example, medical devices that include an inflatable member and at least one camera and at least one light source therein can benefit from a diffuse reflector even if the device is not used for ablation procedures.

While the reflector herein is described as being a diffuse reflector, there may be some uses in which a reflector that reflects light in a specular manner may be beneficial. Alternatively, a reflector can have portions that reflect light in a diffuse manner and portions that reflect light in a specular manner.

FIG. **4** shows an exemplary camera assembly **32** that includes four cameras **33**, which are disposed within camera hub **37** at an angle relative to the longitudinal axis of the catheter. Camera hub **37** is secured to guide wire shaft **54**, and includes lumen **39** configured to receive guide wire shaft **54** therein.

FIG. **5** is another perspective view of expandable member **10** with a cutaway of the membrane. FIG. **6** is an exemplary flat view of the LED flex circuit, including the LEDs, that is wrapped around the illumination hub proximal to the cameras.

As set forth above, light is reflected from the diffuse reflector to provide illumination in the field of the view of the at least one camera. The field of view of the camera can include the view of an electrode secured to the membrane. As set forth herein, the electrodes can be highly reflective, such as if they are comprised of silver. Reflective electrodes causes light incident upon the electrodes to reflect into the camera field of view, which can cause the electrodes to appear as bright spots on the display, possibly interfering with viewing the procedure. It can thus be beneficial to include in the catheter a reflection adjuster that is adapted to reduce specular reflection of light from at least one of the plurality of ablation electrodes into the field of view of an imaging member.

In some embodiments the reflection adjuster is a light absorber. The light absorber can be positioned between the bottom of the electrodes and the membrane. In some

embodiments the light absorber is a black adhesive that adheres portions of the electrode to the membrane, as well as acts as a light absorber.

In some embodiments the reflection adjuster is an anti-reflective coating. Exemplary anti-reflective coatings include, for example without limitation, a deposited thin layer of TiO2, MgF2, and "moth eye" structures comprised of nanoparticles approximately 200 nm in diameter spaced 300 nm range, random microstructure secured to or created on the interior surface of the membrane that is adapted to reduce reflection. The anti-reflective coating can be adhered to only a portion of the membrane, such as the portion where the electrodes are disposed. For example, an anti-reflective coating could be applied to only the distal portion of the inner membrane.

A reflection adjuster will reduce the amount of reflection from the bottom of the electrodes, creating a clearer image of the membrane and electrodes from within the membrane.

When the images or video provided by the at least camera are displayed on the display, it can be helpful to be able to visually identify the electrodes on the display. For example, a user interface can be used to control delivery parameters for any of the electrodes, and enabling the physician to easily determine and confirm that a given electrode on the video is a particular electrode on the user interface simplifies the procedures and ensures that the correct electrodes are being activated and used as intended.

In some embodiments the catheter includes an electrode identifier associated with at least one of the plurality of electrodes, and is some embodiments the catheter includes an electrode identifier with each of the plurality of electrodes. The electrode identifier need not be unique to each of the electrode, but in some embodiments it is unique to each electrode. The electrode identifier is visually identifiable and allows an individual to visually associate the identifier with an electrode.

In some embodiments the electrode identifier is an alphanumeric characters disposed on or near each of the electrodes. An example of this type of identifier is described and shown below. For example, an alphanumeric character can be printed on the back of an electrode, or the back of a portion of the flex circuit that is associated with an electrode. An alphanumeric character can also be printed on the membrane near the electrode so that the identifier can be easily associated with a particular electrode.

In some embodiments the electrode identifiers are colors associated with one or more of the electrodes. For example, the electrodes can be color-coded so that a user can visually identify each of the electrodes. In some embodiments a group of electrodes can have a particular color, such as all of the electrodes connected to the same flex circuit are all one color. An additional example of an electrode identifier is the shape of the electrode so that the electrode or group of electrodes can be visually identified based on their shape. For example, groups of electrodes can be circular, oval, hexagonal, rectangular, square, etc. Each electrode could have a unique shape to it as well.

An example of electrode identifiers is described below in the context of overlaying field of view images from a plurality of cameras.

FIG. **10** illustrates each of the three flex circuit tails terminating in terminations **41** (one for each flex circuit) extending proximally from the distal end of the balloon and extending proximally within outer shaft **51** and secured to the outer surface of the proximal end of the balloon and irrigation shaft **55**. The proximal aspect of the configuration can also be seen in FIG. **2**B. In FIG. **10**, six conductive wires **18** can be seen extending proximally from one of the terminations **41**, each one of which is in electrical communication with one of the six electrodes in that particular flex circuit. The six wires **18** extend the length of the catheter and are in communication with the RF generator. In an alternate embodiment, not shown, the six conductive traces **15** extend the length of the catheter and are in communication with the RF generator. Camera flex circuit **43** for the visualization system is also shown in FIG. **10**, extending proximally from the visualization system in the catheter.

Exemplary materials for the membrane and flex circuit materials can be found in U.S. Pat. No. 8,295,902, issued Oct. 23, 2012; U.S. Pub. No. 2012/0071870, published Mar. 22, 2012. Additional examples of membrane material include PET, Polyurethane, etc. Exemplary materials for the reflector include metalized paints, silicone or urethane resin filled with nonconductive white pigment such as TiO or BaO or BaSo4, preferably non-conductive. Exemplary materials for the electrodes include silver filled silicone or urethane. Exemplary materials for the conductive traces are conductive metals including copper or other such conductive materials. The insulation layers can be known dielectric materials. Exemplary materials for the substrate include Kapton.

As described herein ablation catheters can include ablation and mapping electrodes secured to the exterior of the membrane. In such embodiments the area of tissue mapped is limited to the area of contact defined by the inflatable structure. The rotors being mapped can, however, be larger than the contact area of the inflatable structure, making it more difficult and time consuming to properly map the atrial chamber for rotors. In some embodiments the ablation catheter includes an inflatable membrane, and is also adapted to increase the area that can be mapped to an area that is greater than that defined by the expandable membrane contact surface.

In some of these embodiments mapping arms when appropriately stiff may provide a way to limit the accidental entry of the ablation elements into the pulmonary arteries thereby minimizing the risk of accidental ablation of the artery wall and consequent risk of subsequent stenosis.

In some embodiments a mapping structure on which at least one mapping electrode is disposed is carried outside of the balloon and collapsed between the wall of the delivery catheter and the outside of the ablation catheter. The mapping structure can be secured to the exterior of the ablation catheter. In some embodiments the one or more mapping structures can be deformable splines, the use of which has been described in the cardiac ablation space. For example, the mapping structures can be made of nitinol and are adapted to deform. The mapping structure can thus expand on release from the delivery catheter and can be collapsed to a collapsed delivery configuration when the delivery catheter is advanced distally relative the ablation catheter

In other embodiments a mapping electrode structure is adapted to be delivered through the guide wire lumen of the ablation catheters herein.

FIGS. **11**A and **11**B depict an exemplary ablation catheter **300** that includes an array of mapping electrodes **302** (only one is labeled for clarity) carried on the surface of a plurality of reconfigurable mapping arms **308**. FIG. **11**A is a side view and FIG. **11**B is a distal view. Arms **308** together have a "basket" configuration and are disposed outside of the inflated membrane **306**. In FIGS. **11**A and **11**B arms **308** are in their expanded configurations, after being released from within the delivery catheter. Arms **308** are collapsed into the space between the delivery catheter and the ablation catheter **300** during delivery and retrieval, and are adapted to self-

expand on release by retraction of the delivery catheter or delivery past the distal end of the delivery catheter. Six arms **408** are shown, each with a plurality of electrodes **302**, but more or fewer arms of the basket can be included. The arms can all be secured to the same mapping basket hub (or made from a single piece of material), or they can be secured independently to the ablation catheter. FIGS. **11**A and **11**B show catheter **300** with arms **308** in retracted positions in with proximal ends of arms **308** are retracted and positioned between the delivery catheter and the ablation catheter. Arms **308** are closer to the surface of expanded membrane **306** than in the expanded configurations shown in FIGS. **11**A and **11**B.

FIG. **13** is a distal view of a distal end of an exemplary ablation catheter **320**. In this embodiment the ablation catheter includes an alternative spiral structure **328** that carries a plurality of mapping electrodes **322** (only three are labeled). The spiral mapping structure can be adapted to be delivered through the guidewire lumen **323**, or it can be adapted to be expanded from between the delivery catheter and ablation catheter shaft, similar to the embodiment in FIGS. **11**A and **11**B. In the embodiment in FIG. **13** in which the spiral structure is adapted to be delivered via a guidewire lumen, the spiral, in a side view, can be in a single plane, or the spiral can have a conical configuration that is adapted to be deformed into a single plane when the spiral is pushed distally into contact with tissue. Ablation electrodes are not labeled on the ablation balloon for clarity on FIGS. **13**-**17**.

FIG. **14**A is a simplified side view illustrating an alternative ablation catheter **340** with a dedicated mapping structure **348** with a plurality of mapping electrodes **342** (only two are labeled) thereon. In this embodiment the two mapping arms **348** have expanded loop configurations as shown and are adapted to be delivered through guidewire lumen **347** as shown. There may be more or fewer than two arms. FIG. **14**B is a distal view of an alternative embodiment in which the mapping structure **350** includes a plurality of loops in their expanded configurations. In this embodiment at least one loop **352** has an expanded "height" (a distance measured from the longitudinal axis of the catheter along a line perpendicular to the axis) greater than a height of a second loop **354**. In particular, there are four arms **352** with a first height greater than a height of four other arms **354**. There can any number of loops of varying height dimension.

FIG. **15** illustrates an exemplary configuration of mapping arms and electrodes **362** in collapsed configurations within guidewire lumen **360**, and is merely illustrative to show how a plurality of arms can be disposed within a guidewire lumen. More or fewer arms can be disposed therein.

FIG. **16** shows a simplified side view of an exemplary ablation catheter **370** in which the mapping arms **378** terminate at their respective distal ends **379**. That is, each arm has a free end. Catheter **370** includes balloon **376**, guidewire lumen **377**, mapping electrodes **372** on arms **378**, similar to other embodiments herein. Any of the described mapping arms may comprise a stiffening member such as NiTi wire such that on release the mapping member takes on a predetermined shape.

Any of the mapping arms that are delivered through the guidewire lumen can alternatively be configured for delivery in the space between the ablation catheter and the delivery catheter, and vice versa.

In yet other embodiments the mapping arms may be woven into a conical braid or braid structure which increases in diameter as it extends distally.

In use, the visualization system allows for real-time visualization of the procedure with a view by one or more cameras disposed within the balloon. The visualization allows for the entire procedure to be visualized, allowing physicians to assess the degree of tissue contact, and see the electrodes, tissue, and lesion formation as it occurs. For clarity, FIG. **29** illustrates only one of the four field of views for one of the four cameras in the camera assembly. FIG. **30** illustrates the four field of views from the four cameras, each overlaid with at least one other field of view, to give the physician a 360 degree view (with the longitudinal axis of the catheter as the reference) of the treatment area. While there is a blind spot shown in the center of the four images, different lensing systems than those used in the current embodiments can allow for elimination of that spot. Since there are electrodes disposed around the entire catheter, the 360 degree view allows the physician to visualize an entire lesion that utilizes electrodes disposed around the catheter. The visualization of the entire procedure including lesion formation at any of the electrode locations is immensely helpful to the physician.

The description herein of overlaying camera field of views is related to the disclosure in U.S. Pub. No. 2012/0071870, in particular FIGS. **38**H-**38**R, and the textual descriptions thereof. One aspect of this disclosure is an exemplary method of generating a panoramic image display using images from a plurality of cameras attached to an endoscopic catheter. In some embodiments a plurality of images captured from a plurality of cameras are overlayed with at least one other image to create the panoramic image around the longitudinal axis of the ablation catheter. Two or more cameras can image various sections of the expandable member (from within the expandable member) and the anatomy, and the geometric relationships between the cameras are either known a priori (by design or measurement), or can be estimated from the images themselves using common anatomical features of the balloon as landmarks.

In general, for each camera, a mapping function that maps a pixel into a virtual unwrapped display screen, e.g. a dome-shaped screen, surrounding the cameras is computed. The images are then projected back to this virtual display screen using inverse projection, i.e., using cameras as projectors. Data in overlapping regions are combined using compositing including blending or some other means.

FIG. **17** is a side view of a distal portion of an exemplary visualization catheter. FIG. **17** shows the geometry of the distal portion, which includes four cameras attached to the distal end of the central shaft of the catheter, surrounded by a membrane filled with saline. Each camera is imaging a section of the closed membrane from within the membrane. The conical shape shown in FIG. **17** represents the field of view of one of the plurality of cameras. In this embodiment, while not shown in FIG. **17**, a plurality of radio frequency electrodes are secured to the exterior of the membrane. When the distal portion is positioned inside a cardiac chamber such as the left atrium, the cameras are able to visualize blood or tissue outside the balloon as well as the inner surface of the balloon. This provides a way to verify that the electrodes are in contact with tissue prior to starting the ablation and the balloon is located properly relative to anatomical landmarks such as a pulmonary vein.

FIGS. **18**A-**18**D show the orientations of the axes of the four cameras in relationship to the longitudinal axis of the catheter shaft. Arrows AP, BQ, CR and DS shown in FIG. **18**C represent the axes of the respective cameras. OM is the longitudinal axis of the catheter shaft. The parameter "c" is the shortest distance between the axis of the catheter shaft OM and an axis of a camera (see FIG. **18**A). The camera axis is also at an angle ϕ relative to the axis of the catheter shaft

OM (see FIG. **18**B). The distal surface of the membrane can be modeled as an elliptical solid of revolution, as shown in the side geometrical view of FIG. **18**D. Parameters a and b define the ellipsoid. The equator of the ellipsoid, as labeled in FIG. **18**D, is at a distance "d" from the point "O" shown in FIG. **18**D. The imaging plane of the camera with the axis CR is at a distance e from C, as shown in FIG. **18**D.

FIG. **19** shows the geometry of one of the four cameras field of view, and all four have the same geometry. A pixel in the imaging plane, P(u, v), is related to a point Q(x, y, z) in space by equations (1) and (2), where f is the focal length of the camera.

$$\frac{u}{f} = \frac{x}{f - z} \tag{1}$$

and

$$\frac{v}{f} = \frac{y}{f - z} \tag{2}$$

Furthermore, the image captured by the camera can have lens barrel aberration. FIG. **20** shows a picture of a regular grid pattern target taken by a representative camera. As can be seen, barrel aberration causes the grid points farther away from center **390** to appear smaller and compressed to each other.

The mapping function that maps the original pixel coordinates, P(u, v), to a distorted pixel coordinate system due to barrel aberration, $\tilde{P}(\tilde{u}, \tilde{v})$, can be determined by using the grid target:

$$\begin{bmatrix} \tilde{u} \\ \tilde{v} \end{bmatrix} = \begin{bmatrix} F(u) \\ G(v) \end{bmatrix} \tag{3}$$

The 3D surface of the ellipsoidal balloon can be unwrapped into a 2D plane using the parameterization shown in FIGS. **21**A-**21**C. In FIG. **21**A, the parameters of a and b describe the balloon as an elliptical solid of revolution. The parameter m corresponds to the arc length along the balloon surface, starting from the zenith. In FIG. **21**B the rotation angle γ describes the azimuthal angle of the solid of revolution. In FIG. **21**C, the unwrapped balloon surface is defined by the parameters (m, γ) in polar coordinates or ($\tilde{x}$, $\tilde{y}$) in rectilinear coordinates.

A point on the balloon surface can be: (x, y, z). A planar unwrapped image can be constructed from the ellipsoidal balloon geometry by unwrapping the balloon surface as follows:

$$\begin{bmatrix} x \\ y \\ z \end{bmatrix} = \begin{bmatrix} a\sin\theta\cos\gamma \\ a\sin\theta\sin\gamma \\ b\cos\gamma \end{bmatrix} \tag{4}$$

Where:

$$\theta = g(m) \tag{5}$$

and g(m) is the well-known "Complete Elliptic Integral of the Second Kind." The unwrapped 2D surface is defined by the polar coordinates: (m, γ) or in rectilinear coordinates, ($\tilde{x}$, $\tilde{y}$), where:

$$\begin{bmatrix} \tilde{x} \\ \tilde{y} \end{bmatrix} = \begin{bmatrix} m\cos\gamma \\ m\sin\gamma \end{bmatrix} \tag{6}$$

In summary, the parameters in Table 1 (below) describe the camera geometry of this multi-camera system.

TABLE 1

	Parameter	Description
1	a	Ellipsoidal balloon geometry
2	b	
3	c	Distance offsets
4	d	
5	e	
6	f	Focal length
7	ϕ	Camera angulation
8	F	Barrel aberration mapping function
	G	

Using the parameters of Table 1, the ($\tilde{x}$, $\tilde{y}$) coordinates of the point on the unwrapped balloon corresponding to each pixel in an image produced by a given camera can be computed. Then the intensity of that pixel can be painted on the unwrapped balloon surface. If more than one camera projects data on to the same location on the unwrapped balloon surface, the data can be combined using any number of exemplary ways, such as blending, maximum value, adaptive blending, alpha blending, weighted averaging, etc. These techniques fall into the general category of "Compositing" as described in Foley et al., "Computer Graphics Principles and Practice", 1990, Addison Wesley, 2nd Edition. ISBN 0-201-12110-7. In the overlapping areas of images from two or more cameras, the underlying anatomical structure may be slightly misaligned even after following the above steps to grossly align the image due to inaccuracies in the geometric model. In this case, a given tissue structure may appear twice in the overlapping area, similar to double vision. To address this problem, images can be locally warped by using feature tracking. See U.S. Pat. No. 6,659,953, issued Dec. 9, 2003 to Sumanaweera et al., titled "morphing diagnostic ultrasound images for perfusion assessment," for a description of an exemplary local warping technique.

FIG. **22** shows a set of four camera images simulated using a known pattern, in this case, ablation electrodes **601** painted on the membrane. Electrodes **601** can be in the pattern of the eighteen electrodes shown in FIGS. **1**A-**1**D. Electrodes **601** also have an identifier associated with them, in this case a unique alphanumeric character.

FIG. **23** shows the panoramic image generated by projecting the images from FIG. **22** back onto the unwrapped balloon surface using the methods described above. FIG. **25** also illustrates exemplary electrode identifiers in the form of numbers printed on each electrode to enable visual identification of each of the electrodes. FIG. **25** also illustrates how the collected images comprise common regions to images that are positioned adjacent to them, and that the common regions are overlapped to create the panoramic image.

In FIG. **24** the panoramic image is generated by projecting the component images back onto the unwrapped balloon surface, but the electrodes **370** do not have electrode identifiers associated with them. FIG. **25** shows tissue images acquired by four cameras using the methods described

above. FIG. **25** shows the panoramic image generated by projecting these images back onto the unwrapped balloon using the present invention.

The exemplary method above acquires an image from each of a plurality of cameras, and combines the images to produce a panoramic image. As set forth above, the images from each camera can be deformed using a geometric transformation. The deforming can comprise information associated with the known geometric relationship between the cameras. The deforming procedure can comprise geometric transformations generated using compositing in the overlapping areas of the images. The procedure can comprise the use of weighted averaging. The procedure comprises alpha blending. The deforming procedure can comprise geometric transformations generated using feature tracking in the overlapping areas of the images. The characterization of the geometric relationship between the cameras can comprise the use of experimentally determined optical targets. The geometric relationship can be determined analytically by geometrically modeling the cameras, the fixture containing the cameras and the balloon. The geometric transformation can include geometric transformations that map the balloon onto a planar surface while maintaining the distance between any arbitrary set of points on the 3D surface.

One aspect of this disclosure is an electromechanical device providing for the continuous or semi-continuous adjustment of the transfer of AC power from a source to a load by means of linearly displaceable core. The electromechanical device can be used with any of the ablation catheters herein. An understanding of the operation of a linear variable differential transformer ("LVDT") assists in the discussion of this aspect of the disclosure. An LVDT is comprised of a primary center coil winding connected to an AC signal source and one or two "secondary" coil windings connected in series to a load. A ferromagnetic core couples the magnetic field at the primary coil to the secondary coil(s) thereby creating a voltage differential across the coils which changes in magnitude with core displacement.

This aspect of the disclosure is a derivative of the LVDT sensor having only a single primary and single secondary coil with a displaceable core. This derivative, called a linear displacement power transformer ("LDPT"), provides a means to transfer power from a primary coil to a secondary coil by means of core position. When the core exists across both coils, maximum (power) coupling occurs between primary ("P") and secondary ("S") coils. As the core is displaced out of the "P" or alternatively out of "S," the coupling is reduced along with the power transfer.

FIGS. **26**A-**26**C provide an illustrated schematic of this aspect. In FIG. **26**A ferromagnetic rod core **101** is aligned with a secondary coil "S" but not a primary coil "P," a decoupled state resulting in minimal current output as charted on the graph of FIG. **27**. FIG. **26**B shows the rod core displaced to partially align with coil "P" at a theoretical halfway point somewhat coupling fields fP and fS to produce a theoretical current output of 50% percent maximum. FIG. **26**C shows the rod core displaced into alignment with coils "P" and "S" fully coupling fields fP and fS providing maximum current output to the load.

FIGS. **28**A and **28**B represent one embodiment of this aspect where core **453** is displaced by a micro-stepper motor and screw mechanism **454**. Primary winding **451** and secondary winding **452** are wound radially along a common axis through which core **453** may be displaced. FIG. **28**A shows the LDPT in a minimal output position and FIG. **28**B shows the LDPT in a maximal output position. The power transfer is electrically noiseless and the use of a ferrite rod core minimizes eddy current loss.

Such a variable transformer is of particular use in a treatment system requiring a multichannel, low noise, linear RF power distribution system. In such linear RF power distribution systems, an LDPT can be comprised in each output channel, a selection of output channels, or alternatively as the power source to all of the channels.

Such treatment systems are of particular use in providing percutaneous ablation treatments such as for the treatment of atrial fibrillation as set forth herein.

One aspect of the disclosure is an assembly that includes a primary winding, secondary winding, a ferromagnetic core, a way to linearly move the ferromagnetic core, where the windings are positioned coaxially, a ferromagnetic rod movable along the coaxial axis, wherein the ferromagnetic rod is adapted such that it can be positioned adjacent to both windings simultaneously, and wherein the ferromagnetic rod is adapted to be positioned adjacent to only one winding. The ferromagnetic core can be displaced by a stepper motor and screw mechanism.

One aspect of the disclosure Is a method of adjusting output power to an RF electrode by moving a ferromagnetic core within a transformer comprised of two windings. One aspect of the disclosure is a method of adjusting power to an RF electrode by moving a ferromagnetic core within a transformer. In either method the RF ablation electrode is percutaneously delivered to a treatment site within a living being.

In an exemplary method of use, the catheter is used to ablate cardiac tissue in the treatment of a cardiac arrhythmia. The catheter is advanced into the left atrium using known access procedures including guide wire and guide catheter techniques. Inflation/irrigation fluid is then pumped from a fluid source down inflation/irrigation lumen **52** to inflate the balloon to the configuration shown in FIGS. **1**A-**1**C within the left atrium. The camera can be activated at any time during the procedure, but generally before inflation so the physician can see if there are any problems with the inflation. At this point the balloon is surrounded by blood, which can be seen. The catheter is advanced distally towards the atrial wall, and as the balloon contacts tissue the blood will be displaced, providing a clear view of the tissue. The physician can then determine if the balloon needs to be moved depending on the desired treatment tissue or desired area to map. An advantage of the visualization system in the devices herein is that the physician can easily see, simply by viewing a display showing the camera field of views, when the balloon is properly positioned. This also simplifies the system in that an analysis of reflected energy need not be performed, as in the case in some previous attempts at cardiac ablation.

Once it has been determined, depending on the visualization information such as proper placement around a pulmonary vein or mapping electrical information, that the balloon has been properly positioned at the treatment site, an external console, generally shown in FIGS. **35** and **36**, is used to activate certain electrodes and control the energy delivery parameters of the procedure. An RF generator generates the RF energy and it is delivered to the electrodes. An exemplary schematic of the electrical aspect of the embodiment shown herein is shown in FIG. **33**. It is understood that eighteen channels are included while only three are shown. Alternate embodiments, not shown, may comprise more or less channels. As shown in FIG. **33**, the mapping capabilities of the system are shown to the right of

the electrode. Each electrode can be used in monopolar or bipolar mode, and impedance and voltage can be measured with each electrode.

The generator is configured such that electrodes can be used to map tissue, ablate tissue, and stimulate tissue, as desired. Ablation of cardiac tissue to treat aberrant signals is described generally herein and known. The generator is also configured, however, to generate and deliver electrical tissue stimulation signals to the electrodes so that the electrodes stimulate the cardiac tissue. The schematic in FIG. **33** illustrates that each electrode can be selected for either ablation or stimulation, while mapping from each electrode occurs continuously. The mapping portion includes filters configured to filter out ablation bandwidths, and other non-essential bandwidths that may be delivered or otherwise present so that mapping can occur continuously. The disclosure herein thus includes a generator configured such that each electrode can be used to both map and ablate tissue at the same time, or stimulate and ablate tissue at the same time. The system is also configured such that ablation, stimulation, and mapping can all be occurring at the same time, although the stimulation and ablation would not be occurring at any given time from the same electrode. These processes in addition can be performed sequentially.

Stimulation of the cardiac tissue can be done for a number of reasons. In an exemplary embodiment stimulation of tissue can be performed during a diagnostics procedure to make sure the electrodes are working. For example, RF energy can be delivered to a first electrode and sensed with another electrode, thereby transferring energy between pairs of electrodes to make sure the pair of electrodes is working. In this exemplary use, the stimulating energy could be delivered before the balloon makes contact with tissue or after it makes contact with tissue, as blood generally has low enough impedance so as not to prevent the diagnostic test. In an alternative embodiment cardiac tissue can be stimulated while tissue is being ablated with other electrodes. For example without limitation, three electrodes could be used to deliver ablation energy to create a lesion between the three electrodes (e.g., a linear ablation), while an electrode on one side of the lesion could be used to deliver stimulating energy to an electrode on another side of the lesion to determine if the tissue is effectively ablated. Exemplary tissue stimulation delivery signal capabilities include currents of 0 to 20 ma, pulse widths of 0 to 100 ms, repetition rates of up to 300 bpm. More preferably 0 to 10 ma, 0 to 10 ms, and up to 180 bpm. Stimulating cardiac tissue in these ways is different than mapping in that mapping measures impedance, while stimulation delivers energy configured to stimulate the cardiac tissue. The disclosure herein therefore includes methods of stimulating cardiac tissue during an ablation procedure, including before the actual ablation, while ablating, or after the ablation has occurred.

FIGS. **31**A-**31**C illustrate an exemplary method of ablating atrial tissue around a pulmonary vein ostia to isolate the pulmonary vein, and show it from the view generated by the four field of views from the camera. FIGS. **31**A-**31**C are meant to be the view the physician would see when using the system. Again, the blind spot in the middle can be removed depending on the camera assembly and arrangement of cameras therein. In FIG. **31**A, the balloon has been advanced into contact with atrial tissue surrounding ostia **1501** of the pulmonary vein lumen **1502**. None of the electrodes have been activated in FIG. **31**A, although mapping procedures could also take place at this stage to assess the conduction of the cardiac tissue. FIG. **31**B show certain electrodes "A" being activated and lesion regions **1503** starting to form in the tissue after the electrodes are making contact and power is applied. Electrodes designated "B" are not being activated in this example. FIG. **31**C shows continued ablation of tissue and formation of lesion region **1504** that generally extends around the pulmonary vein ostia.

FIGS. **32**A-**32**C illustrate an exemplary method of using the system herein to create lesion for treatment of a rotor. FIG. **32**A shows the balloon advanced against cardiac tissue other than an ostia region, where none of the electrodes have been activated. FIG. **32**B shows only electrodes "A" being activated, and ablation lesions **1601** starting to form where the electrodes are in contact with tissue and activated. In this embodiment, electrodes A are the distal most electrodes from each of the three flex circuits. FIG. **32**C shows continued ablation and the formation of lesion region **1604** targeted at a rotor. The blind spot in the middle hides that the lesion extends over tissue that can't be seen. In alternative embodiments of use, more than three electrodes can be used to perform a rotor ablation, such as four or electrodes.

One aspect of the disclosure is a method of superimposing an image or images provided by the camera with information or an image that is an indication of at least one of a characteristic of the cardiac tissue and a characteristic of the ablation catheter. The superimposed images (or superimposed information and image) are presented to the physician in a visual display, such as a monitor, and can be part of a remote user interface. The aspect includes methods and systems adapted to superimpose images. The methods and devices herein are also adapted to obtain the information and superimpose the images.

The information that is being superimposed can be any suitable visual indicator of a characteristic of the cardiac tissue or a characteristic of the ablation catheter.

In some embodiments the information that is superimposed onto the image from the cameras is the electrical activity on the cardiac tissue contacting the expandable member.

In some embodiments the information that is superimposed onto the image from the cameras is the localized impedance of the ablation circuit.

In some embodiments the information that is superimposed onto the image from the cameras is the temperature of the cardiac tissue opposed to the balloon.

In some embodiments the camera comprising CMOS cameras are adapted to be responsive to light in the infrared range. The response can be used to estimate the temperature of the tissue before, during and or after ablation. The response can be interpreted by an algorithm and displayed superimposed to the visual light image from the cameras.

In some embodiments an accelerometer is placed at a location in, on or near the ablation balloon. The accelerometer can be used to detect the orientation of the balloon in relation to gravity. The accelerometer can produce acceleration data that is used to determine the accelerometer position in relation to an initial position. The position can be used to construct a database of locations visited by the balloon and/or information collected by the electrodes on the balloon and/or RF power applied to the balloon electrodes. The collection of information can be used to reconstruct a model to provide guidance to the physician in relation to the locations that are treated and locations that need to be treated.

FIG. **38** illustrates exemplary information and indicators that can be superimposed on the images from the cameras. Indicators **402** and **404** are examples of way to convey temperature of the tissue adjacent an electrode. For example, indicator **402** is a series of lines indicating qualitatively the

temperature, such as "medium." Indicator **404** is a series of intersection lines and can indicate "high" temperature. Any type of visual indicators can thus be used to indicate the qualitative temperature of one or more tissue regions adjacent any of the electrodes.

Superimposed information **406** provides a qualitative indication of tissue temperature, in this example, 99 degrees. Information **406** is next to the image of the electrode, whereas information **408** is information that is on the electrode image. Indicator **410** is a red color superimposed on top of the electrode, providing a qualitative indication of "hot." Information **414** and **416** are superimposed to indicate that the respective electrodes are "on" and "off."

In some embodiments the superimposed information is all the same type of information. For example, each electrode can, at the same time, be superimposed with information indicating the temperature of tissue. In other embodiments, the type of superimposed information can be different for any of the electrodes.

Additional examples of the type of information that can be superimposed include electrical impedance, which can be visualized quantitatively or qualitatively using any of the indicators herein (e.g., color, numbers). Additionally, mapping signals can be superimposed on the camera images as well.

FIG. **39** represents an exemplary flexible circuit for application to the outer surface of a balloon, with a thin polyimide substrate **101** approximately 0.002-0.003" thick and a total structural thickness between 0.004-0.006".

The outline is that of the final ablation pads **102** (only the large square and the triangle). Apertures **103** are for saline flow. Circuit traces **104** terminate in exposed areas on the ablation pads. Conductive silver paint is used to create the ablation pad geometry and the exposed trace provides conductivity.

Alternately, a black adhesive may be used to darken the areas under silver painted ablation pads **102** to prevent reflections inside the balloon, as is described herein. One method of employing polyimide substrate **101** can eliminate the black adhesive providing a thinner and more compliant mounting surface.

A dielectric area **105** is provided to prevent cross talk and conductivity to the blood or other medium. The proximal side of the flex circuit has two small solder pads **106** where the wires are attached.

An assembled flexible circuit as represented in FIG. **39** can be affixed to balloon **201** as shown in FIG. **40**, such balloon being located around a central stem **202**, and such stem having a system to capture the image of the internal surface of the balloon (not shown) and transmit such image to a display outside the patient. An optional long protrusion **203** distal to the triangle pad which wraps around the front of the balloon to create a physical anchor for the circuit.

Additionally an accelerometer **204** is placed at a location in, on or near the ablation balloon, such accelerometer can be used to detect the orientation of the balloon in relation to gravity and to construct treatment relevant data sets as described herein.

When the physician moves the catheters as described herein, more specifically, when the physician rotates the system around the longitudinal axis of the catheter, the image display will show the internal surface of the balloon fixed and everything outside the balloon (e.g., cardiac tissue) moving. This is due to the fact that the cameras, in the embodiments herein, are fixed in relation to the catheter and balloon system.

FIGS. **41**A and **41**B illustrate a composite view as described herein from a four camera array as presented to the user on a display. The images are mapped to a composite image representing the arrangement and orientation of cameras carried by the balloon on the shaft within the balloon. The mapping registration relies on mapping common features within each camera field of view over each other where there are common features within two or more images. As illustrated, one electrode, the orientation registration electrode, is identifiable by a marking in the shape of an asterisk (as shown) which has been printed on the balloon prior to the electrode and is visible to the camera. In other embodiments each electrode may be marked with its own unique identifier or some or all electrodes may have different shapes which help to identify them. The common fixed features (relative to the cameras) include traces, electrodes and other fixed markings. FIG. **41**A illustrates an initial image taken just after burns **502** and **504** created by electrodes **514** and **510** respectively. The balloon is centered around a pulmonary vein **506**. FIG. **41**B illustrates a second image captured by the camera array after the balloon is rotated. Each composite image has been processed such that the fixed features (relative to the cameras) are mapped to the user display in a fashion such that the registration mark (and hence the entire image) is rotated an amount equal and opposite to the rotation measured for the center of mass of one or more of the anatomical features around the center of the composite image such as burns **502** or **504**. By so doing the image of the fixed features will rotate while the portion of the image behind the fixed features will remain fixed as the balloon is manipulated.

Disclosed here therefore is a system to, through image processing, show the internal surface of the balloon rotating while maintaining still, or fixed, the image of everything outside the balloon (e.g., tissue). In this manner, the image of everything that is not part of the catheter will remain fixed, and everything that is part of the catheter will be shown in the video to rotate. In this alternate embodiment, the image that the user views shows the fixed features (e.g., electrodes) being rotated while anatomical features remain still. The anatomical features are the non-fixed features or non-balloon related features in the tissue such as, represented in this view, the pulmonary vein, and the images of burns created by ablation. This is accomplished even though the fixed features move as the camera moves. Keeping the tissue fixed for the user, and having the device components move allows the physician to better control the movement of the device relative to the tissue. To facilitate this procedure the mean rotation of the center of mass of one or more of the key anatomical feature are calculated relative to the location of the fixed features. The mean or other suitable representation of the rotation(s) is then used to rotate the composite image as presented on the user display.

FIG. **37** illustrates an exemplary block diagram of a cardiac ablation system, details of which are described herein. Any of the system components in FIG. **38** can be incorporated and used with any of the individual components described herein.

The number and arrangement of the electrodes disposed on the expandable member, each of which is individually addressable and can be used to deliver energy in either monopolar or bipolar mode, provides for a wide variety of lesion formations without having to remove and insert a separate RF catheter. The exemplary methods shown in FIGS. **31** and **32** are merely exemplary. Linear lesions and arc lesions are additional examples of lesion shapes that can be created depending on the desired ablation procedure. In

the specific example provided herein, there are eighteen individually addressable electrodes disposed on substantially the distal portion of expandable member **10**. Any of them can be energized while others are not, allowing for many different lesion formations to be made in cardiac or other tissue for treating cardiac arrhythmias. Any of the electrodes can be used in bipolar mode with any other electrode as well. Depth and width of lesions may be controlled by choosing and/or varying what combination of electrodes are being used in bipolar and monopolar configurations. Monopolar configuration creates deeper, narrower lesions, and bipolar configuration creates shallower, wider lesions.

One of the advantages of the devices herein is that the number and arrangement of electrodes allow for a wide variety of lesion formations without removing and inserting a new catheter. And the visualization system allows for the entire procedure to be visualized.

FIG. **7** illustrates the distal end of the device incorporating a slideable sheathing tool **100** comprising sheathing tube **102**. In use, balloon **12** is collapsed as previously described and then the sheathing tool is slid over the collapsed balloon. The sheathing tube **102** is then fit into the delivery catheter, not shown. The sheathing fixture is then removed, leaving the collapsed balloon within the deliver catheter ready for advancement to the delivery site.

One aspect of the disclosure is a delivery catheter comprising concentric sheaths as a steering mechanism with a mapping system built into the distal tip, where a mapping basket resides during delivery in the space between the two concentric shafts and on delivery is pushed forward out into the heart chamber. Examples of deployable mapping baskets are described above. An ablation catheter may then be delivered through the delivery catheter with the mapping basket in place. Target locations for ablation can then be identified using the electrodes on the mapping basket and target locations are then ablated with the ablation catheter. The location of the ablation catheter may in addition be identified and verified by the mapping basket.

One aspect of the disclosure is an ablation catheter that includes an electrode structure that is about 1 cm to about 5 cm in diameter and resides on the end of an inflatable or expandable structure and may comprise any of the following: an ablation catheter with a balloon carrying multiple electrodes. In some embodiments the multiple electrodes are used alternatively as a single ablation electrode then as a set of individual impedance sensing electrodes capable of monitoring the inter electrode impedance. Such measurements are useful in characterizing the efficacy of the burn resulting from the ablation and/or mapping the ablated are before or after the burn. In some embodiments contact pressure sensitive electrodes may be incorporated as a means of verifying appropriate contact of the electrode to the cardiac tissue. In many embodiments irrigation is provided as described elsewhere herein, wherein the irrigation system incorporates a pressure sensor. In such embodiments contact pressure may be inferred from changes in pressure within the irrigation system associated with increasing the outflow resistance at the irrigation outflow ports press against tissue. In other embodiments a balloon within a balloon configuration is used such that irrigation pressure may be isolated from inflation pressure. The change in pressure within the inflation system then is directly correlated to the contact pressure. In another alternative cooling may be provided by recirculation within the balloon as opposed to irrigation.

In some embodiments the contact pressure of an electrode is measured by impedance matching. An alternate means of characterizing the quality of lesions is to measure changes in acoustic impedance in the ultrasonic pass band. The acoustic impedance will be changed from that of normal tissue both as a function of temperature and denaturation. In such an embodiment a forward looking US transponder can be incorporated in the balloon or on the surface of the balloon. Such a sensor may be embodied as an array of one or more transponders, an array of one or more transmitters and an array of one or more receivers, or a single transponder.

In an alternate embodiment temperature of the lesion may be monitored by microwave radiometry.

FIGS. **42** and **43** illustrate an exemplary embodiment of an ablation catheter wherein the balloon is configured for contact (physical) measurements. Contact pressure of the balloon and therefore electrodes as characterized by variations in the internal balloon pressure resulting from irrigation holes in the balloon which pass through electrodes being occluded as the electrode is pressed against the tissue. Pressure will increase transiently as the balloon is pressed against the tissue and then reach a new equilibrium associated with any decrease in outflow resistance associated with the occlusion or partial occlusion of irrigation ports. This contact pressure can be mapped by previous experiments to an electrode contact surface area.

A visual contact monitor comprised of a camera within the expandable structure monitors contact as a change in the visual appearance of transparent windows in the balloon. The changes in visual appearance result from differences in the appearance of blood and tissue.

Contact monitoring may be used control power delivery. Measurements of electrode contact obtained by any of the means described herein can be used to mediate the amount of power delivered to an electrode. One control algorithm limits power to an electrode such that the power per area of contact surface is maintained at a constant level.

FIG. **42** illustrates a prototype balloon configured for contact measurement. Balloon **714** is affixed to the end of shaft **711**. Strain gages **713** is affixed to shaft **711** and leads **712** which are interfaced with a strain gage amplifier not shown. There are two additional strain gages affixed to the shaft at plus and minus 120 degrees. FIG. **43** is a representation of a similar device in which all three strain gages are configured in strain gage assemble **755** on shaft **751** which comprises the leads to the strain gage assembly. Balloon **754** comprises electrodes **756**. In alternate embodiments the pressure of enclosed volumes of fluids or gels arranged in cells near the proximal attachment of the balloon may be monitored via one or more pressure sensors. In yet other embodiments the strain gages may be replaced with displacement sensors. As indicated above measurements from such sensing systems can be mapped to an estimate of electrode contact surface. The balloon of FIG. **42** is 2 cm in diameter and that of FIG. **43** may be 1 to 3 cm in diameter. The configuration of electrodes on the device of FIG. **43** comprises eight electrodes. Such a small profile allows small delivery size and precise maneuverability. Such a system is compatible with a single RF generator and may comprise an irrigation system, not shown, to minimize unwanted injury.

The use of RF ablation in the treatment of atrial fibrillation as described herein poses the risk of thermal damage to the esophagus. This disclosure includes systems and methods to measure temperature of the esophageal wall during RF ablation. In some embodiments a balloon is placed in the esophagus and inflated to make contact with the esophageal wall. A pattern of temperature sensitive material deposited

on the balloon measures the temperature change induced by RF ablation. An electronic circuit senses the temperature change to alert the operator.

A thermistor is a type of resistor whose resistance changes with temperature. A negative temperature thermistor (NTC) resistance decreases with temperature due to increased mobility of electrons and subsequent increased ability to conduct current. Commercial NTC thermistors are fabricated from common metal oxides of manganese, nickel, cobalt, iron, copper and titanium using basic ceramics technology. In the basic process, a mixture of a metal oxide powder and suitable binder are sintered in a suitable atmosphere and configuration to achieve the desired temperature coefficient characteristics.

Initial NTC thermistors were fabricated using silver sulfide (Ag_2S) powder. More recently, miniaturized, planar silver ion-specific electrodes based on silver sulfide have been fabricated entirely by screen-printing using low-temperature curing polymer pastes and polyester substrates in the form of flexible foils (Sensors and Actuators B 96, 2003, 482-488). Ostensibly, in addition to sensing silver ions, such constructions may also be sensitive to temperature.

A pattern of temperature-sensitive material is deposited on a flexible balloon which is sized to occlude the esophagus. The pattern includes two flexible thermistors (flextors). The two flextors are used in a battery-powered Wheatstone bridge electrical circuit to measure the differential temperature of the two flextors. When placed in the esophagus, the differential temperature induced by RF heating is sensed. If a temperature differential exceeds a limit, the circuit alerts the operator to modify the RF ablation treatment.

An additional way to improve temperature measurement sensitivity may be possible by the design of the flextor pattern. If the pattern is a loop and the loops are diametrically screened on the balloon, then it may be possible to sense the near field component of the RF field generated by the ablation electrode(s). An electronic circuit is connected to one of the flextors to measure the RF energy picked up by it. At the beginning of RF ablation, the operator rotates the balloon shaft such that the RF signal received by the flextor is maximized. This implies that the flextor is closest to the RF source (ablation electrodes) and subsequently to the tissue being heated. In this alignment, differential sensing is enhanced as one flextor will be in the heating field with the other being on the other side of the balloon and not being heated. FIG. **44** illustrates ablation balloon **500** in the left atrium, esophageal temperature balloon **502** positioned and inflated in the esophagus **506**, temperature sensor **506** that has a loop configuration. Aortic arch **508** and tricuspid valve **510** are also shown for reference.

FIG. **45** illustrates an embodiment that includes an endocardial catheter and an epicardial catheter. The catheters have electrodes on their bodies and/or on their distal ends, such as described herein. The endocardial electrodes are positioned inside a chamber of the heart and the epicardial electrodes are positioned outside such chamber on the epicardium tissue. The electrodes are positioned opposite each other across the wall defining the chamber the heart. The combination of electrodes is energized in such a way that electrical current flows from the epicardial electrode to the endocardium electrode or vice-versa. FIG. **45** illustrates a method of positioning an endocardial catheter and an epicardial catheter.

What is claimed is:

1. An ablation catheter, comprising:

an expandable membrane;

an imaging member disposed within the expandable membrane, the imaging member having a field of view;

a light source disposed within the expandable membrane adapted to deliver light; and

an electrode and a light absorber disposed between the electrode and the expandable membrane, the light absorber adapted to absorb light from the light source and thereby reduce reflection of the light from the electrode to the imaging member, the electrode being in the field of view of the imaging member,

wherein the light absorber is only adhered to a portion of the expandable membrane where the electrode is disposed.

2. The catheter of claim **1**, wherein the electrode is a polymeric material with conductive particles disposed therein.

3. The catheter of claim **1**, further comprising a plurality of electrodes and a plurality of light absorbers, each of the plurality of light absorbers disposed between a respective electrode and the expandable membrane, each of the plurality of light absorbers adapted to absorb light from the light source and thereby reduce reflection of the light from the respective electrode to the imaging member.

4. The catheter of claim **1**, further comprising a flexible circuit carried by the expandable membrane, the flexible circuit in electrical communication with the electrode.

5. The catheter of claim **1**, further comprising:

a camera assembly disposed within the membrane, the camera assembly comprising a plurality of cameras, the imaging member being one of the plurality of cameras; and

a plurality of light sources disposed within the membrane, the plurality of light sources including the light source, wherein the plurality of light sources are disposed proximal to the camera assembly.

6. The catheter of claim **5**, wherein the plurality of cameras and the plurality of light sources are disposed around a lumen extending through the membrane.

7. The catheter of claim **5**, wherein the plurality of light sources are positioned to provide illumination generally radially outward.

* * * * *

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摘要(译)

心脏消融导管和使用方法。包括可膨胀膜的导管，设置在可膨胀膜内的成像构件，具有视场的成像构件，设置在可膨胀构件内的光源，其适于朝向成像构件的视场输送光，以及电极包括外导电层和设置在电极和可膨胀膜之间的内光吸收层，内光吸收层适于吸收来自光源的光，从而减少来自外导电电极的光的反射。