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(54) **Title:** BRAGG GRATED FIBER OPTIC FLUCTUATION SENSING AND MONITORING SYSTEM

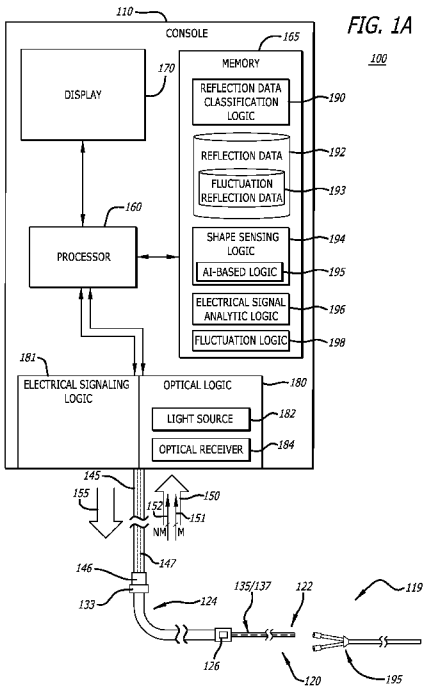


FIG. 1A

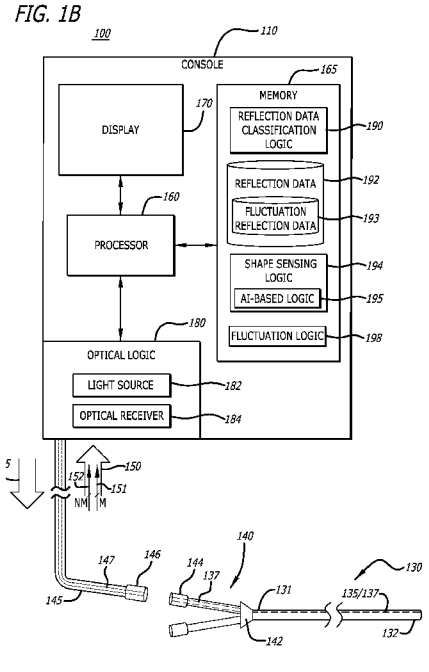


FIG. 1B

(57) **Abstract:** Disclosed herein is a system, apparatus and method directed to detecting damage to an optical fiber of a medical device. The optical fiber includes core fibers including a plurality of sensors configured to (i) reflect a light signal based on received incident light, and (ii) change a characteristic of the reflected light signal based on experienced strain. The system also includes a console having memory storing logic that, when executed, causes operations of providing receiving reflected light signals of different spectral widths of the broadband incident light by one or more of the plurality of sensors, processing the reflected light signals to detect fluctuations of a portion of the optical fiber, and determining a location of the portion of the optical fiber or a defect affecting a vessel in which the portion is disposed based on the detected fluctuations. The portion may be a distal tip of the optical fiber.

WO 2022/031613 A1

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# BRAGG GRATED FIBER OPTIC FLUCTUATION SENSING AND MONITORING SYSTEM

## PRIORITY

**[0001]** This application claims the benefit of priority to U.S. Provisional Application No. 63/060,533, filed August 3, 2020, which is incorporated by reference in its entirety into this application.

## BACKGROUND

**[0002]** In the past, certain intravascular guidance of medical devices, such as guidewires and catheters for example, have used fluoroscopic methods for tracking tips of the medical devices and determining whether distal tips are appropriately localized in their target anatomical structures. However, such fluoroscopic methods expose patients and their attending clinicians to harmful X-ray radiation. Moreover, in some cases, the patients are exposed to potentially harmful contrast media needed for the fluoroscopic methods.

**[0003]** More recently, electromagnetic tracking systems have been used involving stylets. Generally, electromagnetic tracking systems feature three components: a field generator, a sensor unit and control unit. The field generator uses several coils to generate a position-varying magnetic field, which is used to establish a coordinate space. Attached to the stylet, such as near a distal end (tip) of the stylet for example, the sensor unit includes small coils in which current is induced via the magnetic field. Based on the electrical properties of each coil, the position and orientation of the medical device may be determined within the coordinate space. The control unit controls the field generator and captures data from the sensor unit.

**[0004]** Although electromagnetic tracking systems avoid line-of-sight reliance in tracking the tip of a stylet while obviating radiation exposure and potentially harmful contrast media associated with fluoroscopic methods, electromagnetic tracking systems are prone to interference. More specifically, since electromagnetic tracking systems depend on the measurement of magnetic fields produced by the field generator, these systems are subject to electromagnetic field interference, which may be caused by the presence of many different types of consumer electronics such as cellular telephones. Additionally, electromagnetic

tracking systems are subject to signal drop out, depend on an external sensor, and are defined to a limited depth range.

**[0005]** Disclosed herein is a fiber optic shape sensing system and methods performed thereby where the system is configured to provide confirmation of tip placement, tracking information and/or vessel defect detection using optical fiber technology. Further, the system is configured to detect fluctuations of a portion of a body of implementation through one or more core fibers, and confirm a location within the vasculature of the patient and/or detect a defect affecting a blood vessel (e.g., vessel constriction, vasospasm, vessel occlusion, etc.). In some embodiments, the portion of the optical fiber may be the distal tip. Some embodiments combine the fiber optic shape sensing functionality with one or more of intravascular electrocardiogram (ECG) monitoring, impedance/conductance sensing, blood flow directional detection, etc.

## SUMMARY

**[0006]** Briefly summarized, embodiments disclosed herein are directed to systems, apparatus and methods for obtaining measurements indicating fluctuations of a distal tip of a medical instrument (also referred to as a body of implementation), such as a catheter, a guidewire, or a stylet, via a fiber optic core during advancement through a vasculature of a patient. The systems, apparatus and methods may then further include correlation of the tip fluctuation measurements to stored data (e.g., experiential knowledge of previously measured tip fluctuations) in order to confirm a location of the distal tip of the medical device or detect a defect affecting a blood vessel. Although embodiments primarily discuss obtaining measurements indicating fluctuations of a distal tip of the medical device, the disclosure is not intended to be limited to such a particular portion of the medical device. Instead, the embodiments and methodologies described herein with respect to the distal tip may be applied to other portions of the medical device.

**[0007]** More particularly, in some embodiments, the medical instrument includes optical fiber core configured with an array of sensors (reflective gratings), which are spatially distributed over a prescribed length of the core fiber to generally sense external strain on those regions of the core fiber occupied by the sensor. The optical fiber core is configured to receive broadband light from a console during advancement through the vasculature of a patient, where the broadband light propagates along at least a partial distance of the optical fiber core toward the distal end. Given that each sensor positioned along the optical fiber core

is configured to reflect light of a different, specific spectral width, the array of sensors enables distributed measurements throughout the prescribed length of the multi-core optical fiber. These distributed measurements may include wavelength shifts having a correlation with strain experienced by the sensor.

**[0008]** The reflected light from the sensors (reflective gratings) within the optical fiber core is returned from the medical instrument for processing by the console. The physical state of the medical instrument may be ascertained based on analytics of the wavelength shifts of the reflected light. For example, the strain caused through bending of the medical instrument, and hence angular modification of the optical fiber core, causes different degrees of deformation. The different degrees of deformation alter the shape of the sensors (reflective grating) positioned on the optical fiber core, which may cause variations (shifts) in the wavelength of the reflected light from the sensors positioned on the optical fiber core. The optical fiber core may comprise a single optical fiber, or a plurality of optical fibers (in which case, the optical fiber core is referred to as a "multi-core optical fiber").

**[0009]** As used herein, the term "core fiber," generally refers to a single optical fiber core disposed within a medical device. Thus, discussion of a core fiber refers to single optical fiber core and discussion of a multi-core optical fiber refers to a plurality of core fibers. Various embodiments discussed below to detection of the health (and particularly the damage) that occurs in each of an optical fiber core of medical device including (i) a single core fiber, and (ii) a plurality of core fibers.

**[00010]** Specific embodiments of the disclosure include utilization of a medical instrument, such as a stylet, featuring a multi-core optical fiber and a conductive medium that collectively operate for tracking placement with a body of a patient of the stylet or another medical device (such as a catheter) in which the stylet is disposed. In lieu of a stylet, a guidewire may be utilized. For convenience, embodiments are generally discussed where the optical fiber core is disposed within a stylet; however, the disclosure is not intended to be so limited as the functionality involving detection of the health of an optical fiber core disclosed herein may be implemented regardless of the medical device in which the optical fiber core is disposed.

**[00011]** In some embodiments, the optical fiber core of a stylet is configured to return information for use in identifying its physical state (e.g., shape length, shape, and/or form) of

(i) a portion of the stylet (e.g., tip, segment of stylet, etc.) or a portion of a catheter inclusive of at least a portion of the stylet (e.g., tip, segment of catheter, etc.) or (ii) the entirety or a substantial portion of the stylet or catheter within the body of a patient (hereinafter, described as the "physical state of the stylet" or the "physical state of the catheter"). According to one embodiment of the disclosure, the returned information may be obtained from reflected light signals of different spectral widths, where each reflected light signal corresponds to a portion of broadband incident light propagating along a core of the multi-core optical fiber (hereinafter, "core fiber") that is reflected back over the core fiber by a particular sensor located on the core fiber. One illustrative example of the returned information may pertain to a change in signal characteristics of the reflected light signal returned from the sensor, where wavelength shift is correlated to (mechanical) strain on the core fiber.

**[00012]** In some embodiments, the core fiber utilizes a plurality of sensors and each sensor is configured to reflect a different spectral range of the incident light (e.g., different light frequency range). Based on the type and degree of strain asserted on each core fiber, the sensors associated with that core fiber may alter (shift) the wavelength of the reflected light to convey the type and degree of stain on that core fiber at those locations of the stylet occupied by the sensors. The sensors are spatially distributed at various locations of the core fiber between a proximal end and a distal end of the stylet so that shape sensing of the stylet may be conducted based on analytics of the wavelength shifts. Herein, the shape sensing functionality is paired with the ability to simultaneously pass an electrical signal through the same member (stylet) through conductive medium included as part of the stylet.

**[00013]** More specifically, in some embodiments each core fiber of the multi-core optical fiber is configured with an array of sensors, which are spatially distributed over a prescribed length of the core fiber to generally sense external strain those regions of the core fiber occupied by the sensor. Given that each sensor positioned along the same core fiber is configured to reflect light of a different, specific spectral width, the array of sensors enables distributed measurements throughout the prescribed length of the multi-core optical fiber. These distributed measurements may include wavelength shifts having a correlation with strain experienced by the sensor.

**[00014]** According to one embodiment of the disclosure, each sensor may operate as a reflective grating such as a fiber Bragg grating (FBG), namely an intrinsic sensor corresponding to a permanent, periodic refractive index change inscribed into the core fiber.

Stated differently, the sensor operates as a light reflective mirror for a specific spectral width (e.g., a specific wavelength or specific range of wavelengths). As a result, as broadband incident light is supplied by an optical light source and propagates through a particular core fiber, upon reaching a first sensor of the distributed array of sensors for that core fiber, light of a prescribed spectral width associated with the first sensor is reflected back to an optical receiver within a console, including a display and the optical light source. The remaining spectrum of the incident light continues propagation through the core fiber toward a distal end of the stylet. The remaining spectrum of the incident light may encounter other sensors from the distributed array of sensors, where each of these sensors is fabricated to reflect light with different specific spectral widths to provide distributed measurements, as described above.

**[00015]** During operation, multiple light reflections (also referred to as "reflected light signals") are returned to the console from each of the plurality of core fibers of the multi-core optical fiber. Each reflected light signal may be uniquely associated with a different spectral width. Information associated with the reflected light signals may be used to determine a three-dimensional representation of the physical state of the stylet within the body of a patient. Herein, the core fibers are spatially separated with the cladding of the multi-mode optical fiber and each core fiber is configured to separately return light of different spectral widths (e.g., specific light wavelength or a range of light wavelengths) reflected from the distributed array of sensors fabricated in each of the core fibers. A comparison of detected shifts in wavelength of the reflected light returned by a center core fiber (operating as a reference) and the surrounding, periphery core fibers may be used to determine the physical state of the stylet.

**[00016]** During vasculature insertion and advancement of the catheter, the clinician may rely on the console to visualize a current physical state (e.g., shape) of a catheter guided by the stylet to avoid potential path deviations. As the periphery core fibers reside at spatially different locations within the cladding of the multi-mode optical fiber, changes in angular orientation (such as bending with respect to the center core fiber, etc.) of the stylet imposes different types (e.g., compression or tension) and degrees of strain on each of the periphery core fibers as well as the center core fiber. The different types and/or degree of strain may cause the sensors of the core fibers to apply different wavelength shifts, which can be measured to extrapolate the physical state of the stylet (catheter).

**[00017]** Embodiments of the disclosure may include a combination of one or more of the methodologies to determine the location of a distal tip of a body of implementation (e.g., an introducer wire, a guidewire, a stylet within a needle, a needle with fiber optic inlayed into the cannula, a stylet configured for use with a catheter, an optical fiber between a needle and a catheter, and/or an optical fiber integrated into a catheter) and/or various defects of a vessel of a patient through which the body of implementation is advancing. For example, some embodiments are directed to detection of the distal tip of the body of implementation advancing through the Super Vena Cava (SVC) toward the right atrium of the patient's heart, where the detection may be based at least in part on detecting fluctuations in the tip of the body of implementation and correlated against expected fluctuations caused by the rhythm of the heart. Other embodiments are directed to detection of defects in a vessel through which the body of implementation is advancing through detection of tip fluctuations of the body of implementation and correlating such expected fluctuations for the location of the tip of the body of implementation and/or known fluctuations for certain defects. Examples of defects that may be detected through embodiments discussed herein include, but are not limited or restricted to, vessel constriction, a vasospasm, and an occlusion in the vessel.

**[00018]** For instance, certain embodiments include the logic configured to perform run-time analytics, heuristics and/or machine-learning techniques to correlate detected fluctuations of the distal tip of the body of implementation with previously detected tip fluctuations (e.g., experiential knowledge).

**[00019]** Further embodiments of the disclosure may include integration with any combination of the following, as will be discussed below: electrocardiogram (ECG) signaling systems, ultrasound systems, fiber optic shape sensing techniques, tip location techniques, tip confirmation techniques, impedance/conductance sensing, confirmation of catheter advancement techniques (e.g., a fluctuating body of implementation stops/changes in fluctuation as catheter tip is advanced over this body), blood pressure, and/or blood flow direction identification. It should be noted that embodiments containing an optical fiber core either advancing in, or integrated with, a body of implementation and void of other detection systems may be compatible for use with a magnetic resonance imaging system.

**[00020]** In some embodiments, as an optic fiber is relatively flexible, the body of implementation may be reinforced through, for example, one or more layers of reinforcing or layering material, where such reinforcement may provide a degree of stiffness to the length of

the body of implementation. In some such embodiments, the amount of reinforcement may vary along the length of the body of implementation such that degree of stiffness varies accordingly. For example, in one exemplary embodiment, the amount of reinforcement provided may be a first amount for a first portion of the body of implementation and a second, less amount of a second portion (e.g., where the second portion is the distal tip). In such an example, the level of stiffness would be less at the distal tip than for the remaining length of the body of implementation. Such an embodiment would provide for greater flexibility at the distal tip thereby enabling a greater range of motion motivated by blood flow, turbulence, etc. The greater range of motion may be measured by the optic fiber or other sensors as described herein. As a result, such an exemplary embodiment may be better suited to measure movement at the distal tip of the body of implementation than embodiments having a uniform stiffness along the length of the body of implementation.

**[00021]** Additionally, the body of implementation may include one or more protrusions that extend from the body of implementation that are configured to amplify the forces being experienced by the body of implementation. In some embodiments, the protrusions may be deployable during advancement of the body of implementation in the vasculature of the patient. For instance, logic of the console may be configured to receive user input initiating deployment such that, in response, the logic transmits a signal that causes deployment (e.g., a flap may be extended from body of implementation in a direction substantially perpendicular to the direction of the anticipated (or detected) force or motion. In such embodiments, the protrusions may experience greater fluctuations with each passing volume of blood, vessel spasm, etc., as compared to a body of implementation without such protrusions.

**[00022]** Some embodiments of the disclosure are directed to a medical device system for detecting fluctuation using optical fiber technology of a medical device. The system may comprise the medical device comprising an optical fiber having one or more of core fibers, each of the one or more core fibers including a plurality of sensors distributed along a longitudinal length of a corresponding core fiber and each sensor of the plurality of sensors being configured to (i) reflect a light signal of a different spectral width based on received incident light, and (ii) change a characteristic of the reflected light signal based on strain experienced by the optical fiber. The system may further comprise a console including one or more processors and a non-transitory computer-readable medium having stored thereon logic, when executed by the one or more processors, causes operations including providing a

broadband incident light signal to the optical fiber, receiving reflected light signals of different spectral widths of the broadband incident light by one or more of the plurality of sensors, processing the reflected light signals associated with the one or more of core fibers to detect fluctuations of a distal tip of the optical fiber, and determining a location of the distal tip of the optical fiber or a defect affecting a vessel in which the distal tip is disposed based on the detected fluctuations.

**[00023]** In some embodiments, the optical fiber is a single-core optical fiber. In alternative embodiments, the optical fiber is a multi-core optical fiber including a plurality of core fibers. In some embodiments, the defect is one of a constriction of the vessel, a vasospasm of the vessel, or an occlusion in the vessel.

**[00024]** In certain embodiments, the determining performed by the logic includes correlating the reflected light signals with previously obtained reflected light signals to identify the location of the distal tip of the optical fiber or the defect affecting a vessel, and determining whether a correlation result is above a first threshold. In some embodiments, the correlating is performed through machine-learning techniques. In certain embodiments, determining the location of the distal tip of the optical fiber includes obtaining electrocardiogram (ECG) signals, correlating the ECG signals with the detected fluctuations to identify whether the detected fluctuations include movements in accordance with a rhythmic pattern of the ECG signals, and determining whether a correlation result is above a first threshold.

**[00025]** In some embodiments, the medical device is one of an introducer wire, a guidewire, a stylet, a stylet within a needle, a needle with the optical fiber inlayed into a cannula of the needle or a catheter with the optical fiber inlayed into one or more walls of the catheter. Further, in some embodiments, each of the plurality of sensors is a reflective grating, where each reflective grating alters its reflected light signal by applying a wavelength shift dependent on a strain experienced by the reflective grating. Some embodiments may include logic that, when executed by the one or more processors, causes further operations including generating an alert indicating an existence of the defect. In certain embodiments, the alert includes an indication of a location of the defect.

**[00026]** Some embodiments of the disclosure are directed to a method for placing a medical device into a body of a patient, the method comprising providing a broadband

incident light signal to an optical fiber included within the medical device, wherein the optical fiber includes a one or more of core fibers, each of the one or more of core fibers including a plurality of reflective gratings distributed along a longitudinal length of a corresponding core fiber and each of the plurality of reflective gratings being configured to (i) reflect a light signal of a different spectral width based on received incident light, and (ii) change a characteristic of the reflected light signal based on strain experienced by the optical fiber, receiving reflected light signals of different spectral widths of the broadband incident light by one or more of the plurality of sensors, processing the reflected light signals associated with the one or more of core fibers to detect fluctuations of a distal tip of the optical fiber, and determining a location of the distal tip of the optical fiber or a defect affecting a vessel in which the distal tip is disposed based on the detected fluctuations.

**[00027]** In some embodiments, the optical fiber is a single-core optical fiber. In alternative embodiments, the optical fiber is a multi-core optical fiber including a plurality of core fibers. In some embodiments, the defect is one of a constriction of the vessel, a vasospasm of the vessel, or an occlusion in the vessel.

**[00028]** In certain embodiments, the determining performed by the logic includes correlating the reflected light signals with previously obtained reflected light signals to identify the location of the distal tip of the optical fiber or the defect affecting a vessel, and determining whether a correlation result is above a first threshold. In some embodiments, the correlating is performed through machine-learning techniques. In certain embodiments, determining the location of the distal tip of the optical fiber includes obtaining electrocardiogram (ECG) signals, correlating the ECG signals with the detected fluctuations to identify whether the detected fluctuations include movements in accordance with a rhythmic pattern of the ECG signals, and determining whether a correlation result is above a first threshold.

**[00029]** In some embodiments, the medical device is one of an introducer wire, a guidewire, a stylet, a stylet within a needle, a needle with the optical fiber inlayed into a cannula of the needle or a catheter with the optical fiber inlayed into one or more walls of the catheter. Further, in some embodiments, each of the plurality of sensors is a reflective grating, where each reflective grating alters its reflected light signal by applying a wavelength shift dependent on a strain experienced by the reflective grating. Some embodiments may include logic that, when executed by the one or more processors, causes further operations

including generating an alert indicating an existence of the defect. In certain embodiments, the alert includes an indication of a location of the defect.

**[00030]** Yet other embodiments of the disclosure are directed a non-transitory computer-readable medium having stored thereon logic that, when executed by one or more processors, causes operations including providing a broadband incident light signal to an optical fiber included within the medical device, wherein the optical fiber includes a one or more of core fibers, each of the one or more of core fibers including a plurality of reflective gratings distributed along a longitudinal length of a corresponding core fiber and each of the plurality of reflective gratings being configured to (i) reflect a light signal of a different spectral width based on received incident light, and (ii) change a characteristic of the reflected light signal based on strain experienced by the optical fiber, receiving reflected light signals of different spectral widths of the broadband incident light by one or more of the plurality of sensors, processing the reflected light signals associated with the one or more of core fibers to detect fluctuations of a distal tip of the optical fiber, and determining a location of the distal tip of the optical fiber or a defect affecting a vessel in which the distal tip is disposed based on the detected fluctuations.

**[00031]** In some embodiments, the optical fiber is a single-core optical fiber. In alternative embodiments, the optical fiber is a multi-core optical fiber including a plurality of core fibers. In some embodiments, the defect is one of a constriction of the vessel, a vasospasm of the vessel, or an occlusion in the vessel.

**[00032]** In certain embodiments, the determining performed by the logic includes correlating the reflected light signals with previously obtained reflected light signals to identify the location of the distal tip of the optical fiber or the defect affecting a vessel, and determining whether a correlation result is above a first threshold. In some embodiments, the correlating is performed through machine-learning techniques. In certain embodiments, determining the location of the distal tip of the optical fiber includes obtaining electrocardiogram (ECG) signals, correlating the ECG signals with the detected fluctuations to identify whether the detected fluctuations include movements in accordance with a rhythmic pattern of the ECG signals, and determining whether a correlation result is above a first threshold.

**[00033]** In some embodiments, the medical device is one of an introducer wire, a

guidewire, a stylet, a stylet within a needle, a needle with the optical fiber inlayed into a cannula of the needle or a catheter with the optical fiber inlayed into one or more walls of the catheter. Further, in some embodiments, each of the plurality of sensors is a reflective grating, where each reflective grating alters its reflected light signal by applying a wavelength shift dependent on a strain experienced by the reflective grating. Some embodiments may include logic that, when executed by the one or more processors, causes further operations including generating an alert indicating an existence of the defect. In certain embodiments, the alert includes an indication of a location of the defect.

**[00034]** These and other features of the concepts provided herein will become more apparent to those of skill in the art in view of the accompanying drawings and following description, which disclose particular embodiments of such concepts in greater detail.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[00035]** Embodiments of the disclosure are illustrated by way of example and not by way of limitation in the figures of the accompanying drawings, in which like references indicate similar elements and in which:

**[00036]** FIG. 1A is an illustrative embodiment of a medical instrument monitoring system including a medical instrument with optic shape sensing and fiber optic-based oximetry capabilities in accordance with some embodiments;

**[00037]** FIG. 1B is an alternative illustrative embodiment of the medical instrument monitoring system 100 in accordance with some embodiments;

**[00038]** FIG. 2 is an exemplary embodiment of a structure of a section of the multi-core optical fiber included within the stylet 120 of FIG. 1A in accordance with some embodiments;

**[00039]** FIG. 3A is a first exemplary embodiment of the stylet of FIG. 1A supporting both an optical and electrical signaling in accordance with some embodiments;

**[00040]** FIG. 3B is a cross sectional view of the stylet of FIG. 3A in accordance with some embodiments;

**[00041]** FIG. 4A is a second exemplary embodiment of the stylet of FIG. 1B in accordance with some embodiments;

**[00042]** FIG. 4B is a cross sectional view of the stylet of FIG. 4A in accordance with some embodiments;

**[00043]** FIG. 5A is an elevation view of a first illustrative embodiment of a catheter including integrated tubing, a diametrically disposed septum, and micro-lumens formed within the tubing and septum in accordance with some embodiments;

**[00044]** FIG. 5B is a perspective view of the first illustrative embodiment of the catheter of FIG. 5A including core fibers installed within the micro-lumens in accordance with some embodiments;

**[00045]** FIGS. 6A-6B are flowcharts of the methods of operations conducted by the medical instrument monitoring system of FIGS. 1A-1B to achieve optic 3D shape sensing in accordance with some embodiments;

**[00046]** FIG. 7 is an exemplary embodiment of the medical instrument monitoring system of FIG. 1A during operation and insertion of the catheter into a patient in accordance with some embodiments;

**[00047]** FIG. 8A is a detailed view of a stylet disposed within the Superior Vena Cava (SVC) advancing toward the right atrium of a patient in accordance with some embodiments;

**[00048]** FIG. 8B is side elevation view of a stylet advancing through a vessel of the vasculature of a patient toward a point of constriction in the vessel in accordance with some embodiments;

**[00049]** FIG. 8C is side elevation view of a stylet advancing through a vessel of the vasculature of a patient toward a vasospasm affecting the vessel in accordance with some embodiments; and

**[00050]** FIG. 8D is side elevation view of a stylet advancing through a vessel of the vasculature of a patient toward an occlusion in the vessel in accordance with some embodiments.

## DETAILED DESCRIPTION

**[00051]** Before some particular embodiments are disclosed in greater detail, the particular embodiments disclosed herein do not limit the scope of the concepts provided herein. It

should also be understood that a particular embodiment disclosed herein can have features that can be readily separated from the particular embodiment and optionally combined with or substituted for features of any of a number of other embodiments disclosed herein.

**[00052]** Regarding terms used herein, it should also be understood the terms are for the purpose of describing some particular embodiments, and the terms do not limit the scope of the concepts provided herein. Ordinal numbers (e.g., first, second, third, etc.) are generally used to distinguish or identify different features or steps in a group of features or steps, and do not supply a serial or numerical limitation. For example, "first," "second," and "third" features or steps need not necessarily appear in that order, and the particular embodiments including such features or steps need not necessarily be limited to the three features or steps. Labels such as "left," "right," "top," "bottom," "front," "back," and the like are used for convenience and are not intended to imply, for example, any particular fixed location, orientation, or direction. Instead, such labels are used to reflect, for example, relative location, orientation, or directions. Singular forms of "a," "an," and "the" include plural references unless the context clearly dictates otherwise.

**[00053]** With respect to "proximal," a "proximal portion" or a "proximal end portion" of, for example, a probe disclosed herein includes a portion of the probe intended to be near a clinician when the probe is used on a patient. Likewise, a "proximal length" of, for example, the probe includes a length of the probe intended to be near the clinician when the probe is used on the patient. A "proximal end" of, for example, the probe includes an end of the probe intended to be near the clinician when the probe is used on the patient. The proximal portion, the proximal end portion, or the proximal length of the probe can include the proximal end of the probe; however, the proximal portion, the proximal end portion, or the proximal length of the probe need not include the proximal end of the probe. That is, unless context suggests otherwise, the proximal portion, the proximal end portion, or the proximal length of the probe is not a terminal portion or terminal length of the probe.

**[00054]** With respect to "distal," a "distal portion" or a "distal end portion" of, for example, a probe disclosed herein includes a portion of the probe intended to be near or in a patient when the probe is used on the patient. Likewise, a "distal length" of, for example, the probe includes a length of the probe intended to be near or in the patient when the probe is used on the patient. A "distal end" of, for example, the probe includes an end of the probe intended to be near or in the patient when the probe is used on the patient. The distal portion,

the distal end portion, or the distal length of the probe can include the distal end of the probe; however, the distal portion, the distal end portion, or the distal length of the probe need not include the distal end of the probe. That is, unless context suggests otherwise, the distal portion, the distal end portion, or the distal length of the probe is not a terminal portion or terminal length of the probe.

**[00055]** The term "logic" may be representative of hardware, firmware or software that is configured to perform one or more functions. As hardware, the term logic may refer to or include circuitry having data processing and/or storage functionality. Examples of such circuitry may include, but are not limited or restricted to a hardware processor (e.g., microprocessor, one or more processor cores, a digital signal processor, a programmable gate array, a microcontroller, an application specific integrated circuit "ASIC", etc.), a semiconductor memory, or combinatorial elements.

**[00056]** Additionally, or in the alternative, the term logic may refer to or include software such as one or more processes, one or more instances, Application Programming Interface(s) (API), subroutine(s), function(s), applet(s), servlet(s), routine(s), source code, object code, shared library/dynamic link library (dll), or even one or more instructions. This software may be stored in any type of a suitable non-transitory storage medium, or transitory storage medium (e.g., electrical, optical, acoustical or other form of propagated signals such as carrier waves, infrared signals, or digital signals). Examples of a non-transitory storage medium may include, but are not limited or restricted to a programmable circuit; non-persistent storage such as volatile memory (e.g., any type of random-access memory "RAM"); or persistent storage such as non-volatile memory (e.g., read-only memory "ROM", power-backed RAM, flash memory, phase-change memory, etc.), a solid-state drive, hard disk drive, an optical disc drive, or a portable memory device. As firmware, the logic may be stored in persistent storage.

**[00057]** Referring to FIG. 1A, an illustrative embodiment of a medical instrument monitoring system including a medical instrument with optic shape sensing and fiber optic-based oximetry capabilities is shown in accordance with some embodiments. As shown, the system 100 generally includes a console 110 and a stylet assembly 119 communicatively coupled to the console 110. For this embodiment, the stylet assembly 119 includes an elongate probe (e.g., stylet) 120 on its distal end 122 and a console connector 133 on its proximal end 124, where the stylet 120 is configured to advance within a patient vasculature

either through, or in conjunction with, a catheter 195. The console connector 133 enables the stylet assembly 119 to be operably connected to the console 110 via an interconnect 145 including one or more optical fibers 147 (hereinafter, "optical fiber(s)") and a conductive medium terminated by a single optical/electric connector 146 (or terminated by dual connectors). Herein, the connector 146 is configured to engage (mate) with the console connector 133 to allow for the propagation of light between the console 110 and the stylet assembly 119 as well as the propagation of electrical signals from the stylet 120 to the console 110.

**[00058]** An exemplary implementation of the console 110 includes a processor 160, a memory 165, a display 170 and optical logic 180, although it is appreciated that the console 110 can take one of a variety of forms and may include additional components (e.g., power supplies, ports, interfaces, etc.) that are not directed to aspects of the disclosure. An illustrative example of the console 110 is illustrated in U.S. Publication No. 2019/0237902, the entire contents of which are incorporated by reference herein. The processor 160, with access to the memory 165 (e.g., non-volatile memory or non-transitory, computer-readable medium), is included to control functionality of the console 110 during operation. As shown, the display 170 may be a liquid crystal diode (LCD) display integrated into the console 110 and employed as a user interface to display information to the clinician, especially during a catheter placement procedure (e.g., cardiac catheterization). In another embodiment, the display 170 may be separate from the console 110. Although not shown, a user interface is configured to provide user control of the console 110.

**[00059]** For both embodiments, the content depicted by the display 170 may change according to which mode the stylet 120 is configured to operate: optical, TLS, ECG, or another modality. In TLS mode, the content rendered by the display 170 may constitute a two-dimensional (2D) or three-dimensional (3D) representation of the physical state (e.g., length, shape, form, and/or orientation) of the stylet 120 computed from characteristics of reflected light signals 150 returned to the console 110. The reflected light signals 150 constitute light of a specific spectral width of broadband incident light 155 reflected back to the console 110. According to one embodiment of the disclosure, the reflected light signals 150 may pertain to various discrete portions (e.g., specific spectral widths) of broadband incident light 155 transmitted from and sourced by the optical logic 180, as described below

**[00060]** According to one embodiment of the disclosure, an activation control 126, included on the stylet assembly 119, may be used to set the stylet 120 into a desired operating mode and selectively alter operability of the display 170 by the clinician to assist in medical device placement. For example, based on the modality of the stylet 120, the display 170 of the console 110 can be employed for optical modality-based guidance during catheter advancement through the vasculature or TLS modality to determine the physical state (e.g., length, form, shape, orientation, etc.) of the stylet 120. In one embodiment, information from multiple modes, such as optical, TLS or ECG for example, may be displayed concurrently (e.g., at least partially overlapping in time).

**[00061]** Referring still to FIG. 1A, the optical logic 180 is configured to support operability of the stylet assembly 119 and enable the return of information to the console 110, which may be used to determine the physical state associated with the stylet 120 along with monitored electrical signals such as ECG signaling via an electrical signaling logic 181 that supports receipt and processing of the received electrical signals from the stylet 120 (e.g., ports, analog-to-digital conversion logic, etc.). The physical state of the stylet 120 may be based on changes in characteristics of the reflected light signals 150 received at the console 110 from the stylet 120. The characteristics may include shifts in wavelength caused by strain on certain regions of the core fibers integrated within an optical fiber core 135 positioned within or operating as the stylet 120, as shown below. As discussed herein, the optical fiber core 135 may be comprised of core fibers $137_1$-$137_M$ (M=1 for a single core, and $M \geq 2$ for a multi-core), where the core fibers $137_1$-$137_M$ may collectively be referred to as core fiber(s) 137. Unless otherwise specified or the instant embodiment requires an alternative interpretation, embodiments discussed herein will refer to a multi-core optical fiber 135. From information associated with the reflected light signals 150, the console 110 may determine (through computation or extrapolation of the wavelength shifts) the physical state of the stylet 120, and that of the catheter 195 configured to receive the stylet 120.

**[00062]** According to one embodiment of the disclosure, as shown in FIG. 1A, the optical logic 180 may include a light source 182 and an optical receiver 184. The light source 182 is configured to transmit the incident light 155 (e.g., broadband) for propagation over the optical fiber(s) 147 included in the interconnect 145, which are optically connected to the multi-core optical fiber core 135 within the stylet 120. In one embodiment, the light source

182 is a tunable swept laser, although other suitable light sources can also be employed in addition to a laser, including semi-coherent light sources, LED light sources, etc.

**[00063]** The optical receiver 184 is configured to: (i) receive returned optical signals, namely reflected light signals 150 received from optical fiber-based reflective gratings (sensors) fabricated within each core fiber of the multi-core optical fiber 135 deployed within the stylet 120, and (ii) translate the reflected light signals 150 into reflection data (from repository 192), namely data in the form of electrical signals representative of the reflected light signals including wavelength shifts caused by strain. The reflected light signals 150 associated with different spectral widths may include reflected light signals 151 provided from sensors positioned in the center core fiber (reference) of the multi-core optical fiber 135 and reflected light signals 152 provided from sensors positioned in the periphery core fibers of the multi-core optical fiber 135, as described below. Herein, the optical receiver 184 may be implemented as a photodetector, such as a positive-intrinsic-negative "PIN" photodiode, avalanche photodiode, or the like.

**[00064]** As shown, both the light source 182 and the optical receiver 184 are operably connected to the processor 160, which governs their operation. Also, the optical receiver 184 is operably coupled to provide the reflection data (from repository 192) to the memory 165 for storage and processing by reflection data classification logic 190. The reflection data classification logic 190 may be configured to: (i) identify which core fibers pertain to which of the received reflection data (from repository 192) and (ii) segregate the reflection data stored with a repository 192 provided from reflected light signals 150 pertaining to similar regions of the stylet 120 or spectral widths into analysis groups. The reflection data for each analysis group is made available to shape sensing logic 194 for analytics.

**[00065]** According to one embodiment of the disclosure, the shape sensing logic 194 is configured to compare wavelength shifts measured by sensors deployed in each periphery core fiber at the same measurement region of the stylet 120 (or same spectral width) to the wavelength shift at a center core fiber of the multi-core optical fiber 135 positioned along central axis and operating as a neutral axis of bending. From these analytics, the shape sensing logic 194 may determine the shape the core fibers have taken in 3D space and may further determine the current physical state of the catheter 195 in 3D space for rendering on the display 170.

**[00066]** According to one embodiment of the disclosure, the shape sensing logic 194 may generate a rendering of the current physical state of the stylet 120 (and potentially the catheter 195), based on heuristics or run-time analytics. For example, the shape sensing logic 194 may be configured in accordance with machine-learning techniques to access a data store (library) with pre-stored data (e.g., images, etc.) pertaining to different regions of the stylet 120 (or catheter 195) in which reflected light from core fibers have previously experienced similar or identical wavelength shifts. From the pre-stored data, the current physical state of the stylet 120 (or catheter 195) may be rendered. Alternatively, as another example, the shape sensing logic 194 may be configured to determine, during run-time, changes in the physical state of each region of the multi-core optical fiber 135 based on at least: (i) resultant wavelength shifts experienced by different core fibers within the optical fiber 135, and (ii) the relationship of these wavelength shifts generated by sensors positioned along different periphery core fibers at the same cross-sectional region of the multi-core optical fiber 135 to the wavelength shift generated by a sensor of the center core fiber at the same cross-sectional region. It is contemplated that other processes and procedures may be performed to utilize the wavelength shifts as measured by sensors along each of the core fibers within the multi-core optical fiber 135 to render appropriate changes in the physical state of the stylet 120 (and/or catheter 195), especially to enable guidance of the stylet 120, when positioned at a distal tip of the catheter 195, within the vasculature of the patient and at a desired destination within the body.

**[00067]** The console 110 may further include electrical signaling logic 181, which is positioned to receive one or more electrical signals from the stylet 120. The stylet 120 is configured to support both optical connectivity as well as electrical connectivity. The electrical signaling logic 181 receives the electrical signals (e.g., ECG signals) from the stylet 120 via the conductive medium. The electrical signals may be processed by electrical signal logic 196, executed by the processor 160, to determine ECG waveforms for display.

**[00068]** Additionally, the console 110 includes a fluctuation logic 198 that is configured to analyze at least a subset of the wavelength shifts measured by sensors deployed in each of the core fibers 137. In particular, the fluctuation logic 198 is configured to analyze wavelength shifts measured by sensors of core fibers 137, where such corresponds to an analysis of the fluctuation of the distal tip of the stylet 120 (or “tip fluctuation analysis”). In some embodiments, the fluctuation logic 198 analyzes the wavelength shifts measured by

sensors at a distal end of the core fibers 137. The tip fluctuation analysis includes at least a correlation of detected movements of the distal tip of the stylet 120 (or other medical device or instrument) with experiential knowledge comprising previously detected movements (fluctuations), and optionally, other current measurements such as ECG signals. The experiential knowledge may include previously detected movements in various locations within the vasculature (e.g., SVC, Inferior Vena Cava (IVC), right atrium, azygos vein, other blood vessels such as arteries and veins) under normal, healthy conditions and in the presence of defects (e.g., vessel constriction, vasospasm, vessel occlusion, etc.). Thus, the tip fluctuation analysis may result in a confirmation of tip location and/or detection of a defect affecting a blood vessel.

**[00069]** It should be noted that the fluctuation logic 198 need not perform the same analyses as the shape sensing logic 194. For instance, the shape sensing logic 194 determines a 3D shape of the stylet 120 by comparing wavelength shifts in outer core fibers of a multi-core optical fiber to a center, reference core fiber. The fluctuation logic 198 may instead correlate the wavelength shifts to previously measured wavelength shifts and optionally other current measurements without distinguishing between wavelength shifts of outer core fibers and a center, reference core fiber as the tip fluctuation analysis need not consider direction or shape within a 3D space.

**[00070]** In some embodiments, e.g., those directed at tip location confirmation, the analysis of the fluctuation logic 198 may utilize electrical signals (e.g., ECG signals) measured by the electrical signaling logic 181. For example, the fluctuation logic 198 may compare the movements of a subsection of the stylet 120 (e.g., the distal tip) with electrical signals indicating impulses of the heart (e.g., the heartbeat). Such a comparison may reveal whether the distal tip is within the SVC or the right atrium based on how closely the movements correspond to a rhythmic heartbeat.

**[00071]** In various embodiments, a display and/or alert may be generated based on the fluctuation analysis. For instance, the fluctuation logic 198 may generate a graphic illustrating the detected fluctuation compared to previously detected tip fluctuations and/or the anatomical movements of the patient body such as rhythmic pulses of the heart and/or expanding and contracting of the lungs. In one embodiment, such a graphic may include a dynamic visualization of the present medical device moving in accordance with the detected fluctuations adjacent to a secondary medical device moving in accordance with previously

detected tip fluctuations. In some embodiments, the location of a subsection of the medical device may be obtained from the shape sensing logic 194 and the dynamic visualization may be location-specific (e.g., such that the previously detected fluctuations illustrate expected fluctuations for the current location of the subsection). In alternative embodiments, the dynamic visualization may illustrate a comparison of the dynamic movements of the subsection to one or more subsections moving in accordance with previously detected fluctuations of one or more defects affecting the blood vessel.

**[00072]** According to one embodiment of the disclosure, the fluctuation logic 198 may determine whether movements of one or more subsections of the stylet 120 indicate a location of a particular subsection of the stylet 120 or a defect affecting a blood vessel and, as a result, of the catheter 195, based on heuristics or run-time analytics. For example, the fluctuation logic 198 may be configured in accordance with machine-learning techniques to access a data store (library) with pre-stored data (e.g., experiential knowledge of previously detected tip fluctuation data, etc.) pertaining to different regions (subsections) of the stylet 120. Specifically, such an embodiment may include processing of a machine-learning model trained using the experiential knowledge, where the detected fluctuations serve as input to the trained model and processing of the trained model results in a determination as to how closely the detected fluctuations correlate to one or more locations within the vasculature of the patient and/or one or more defects affecting a blood vessel.

**[00073]** In some embodiments, the fluctuation logic 198 may be configured to determine, during run-time, whether movements of one or more subsections of the stylet 120 (and the catheter 195) indicate a location of a particular subsection of the stylet 120 or a defect affecting a blood vessel, based on at least (i) resultant wavelength shifts experienced by the core fibers 137 within the one or more subsections, and (ii) the correlation of these wavelength shifts generated by sensors positioned along different core fibers at the same cross-sectional region of the stylet 120 (or the catheter 195) to previously detected wavelength shifts generated by corresponding sensors in a core fiber at the same cross-sectional region. It is contemplated that other processes and procedures may be performed to utilize the wavelength shifts as measured by sensors along each of the core fibers 137 to render appropriate movements in the distal tip of the stylet 120 and/or the catheter 195.

**[00074]** Referring to FIG. 1B, an alternative exemplary embodiment of a medical instrument monitoring system 100 is shown. Herein, the medical instrument monitoring

system 100 features a console 110 and a medical instrument 130 communicatively coupled to the console 110. For this embodiment, the medical instrument 130 corresponds to a catheter, which features an integrated tubing with two or more lumen extending between a proximal end 131 and a distal end 132 of the integrated tubing. The integrated tubing (sometimes referred to as "catheter tubing") is in communication with one or more extension legs 140 via a bifurcation hub 142. An optical-based catheter connector 144 may be included on a proximal end of at least one of the extension legs 140 to enable the catheter 130 to operably connect to the console 110 via an interconnect 145 or another suitable component. Herein, the interconnect 145 may include a connector 146 that, when coupled to the optical-based catheter connector 144, establishes optical connectivity between one or more optical fibers 147 (hereinafter, "optical fiber(s)") included as part of the interconnect 145 and core fibers 137 deployed within the catheter 130 and integrated into the tubing. Alternatively, a different combination of connectors, including one or more adapters, may be used to optically connect the optical fiber(s) 147 to the core fibers 137 within the catheter 130. The core fibers 137 deployed within the catheter 130 as illustrated in FIG. 1B include the same characteristics and perform the same functionalities as the core fibers 137 deployed within the stylet 120 of FIG. 1A.

**[00075]** The optical logic 180 is configured to support graphical rendering of the catheter 130, most notably the integrated tubing of the catheter 130, based on characteristics of the reflected light signals 150 received from the catheter 130. The characteristics may include shifts in wavelength caused by strain on certain regions of the core fibers 137 integrated within (or along) a wall of the integrated tubing, which may be used to determine (through computation or extrapolation of the wavelength shifts) the physical state of the catheter 130, notably its integrated tubing or a portion of the integrated tubing such as a tip or distal end of the tubing to read fluctuations (real-time movement) of the tip (or distal end).

**[00076]** More specifically, the optical logic 180 includes a light source 182. The light source 182 is configured to transmit the broadband incident light 155 for propagation over the optical fiber(s) 147 included in the interconnect 145, which are optically connected to multiple core fibers 137 within the catheter tubing. Herein, the optical receiver 184 is configured to: (i) receive returned optical signals, namely reflected light signals 150 received from optical fiber-based reflective gratings (sensors) fabricated within each of the core fibers 137 deployed within the catheter 130, and (ii) translate the reflected light signals 150 into

reflection data (from repository 192), namely data in the form of electrical signals representative of the reflected light signals including wavelength shifts caused by strain. The reflected light signals 150 associated with different spectral widths include reflected light signals 151 provided from sensors positioned in the center core fiber (reference) of the catheter 130 and reflected light signals 152 provided from sensors positioned in the outer core fibers of the catheter 130, as described below.

**[00077]** As noted above, the shape sensing logic 194 is configured to compare wavelength shifts measured by sensors deployed in each outer core fiber at the same measurement region of the catheter (or same spectral width) to the wavelength shift at the center core fiber positioned along central axis and operating as a neutral axis of bending. From these analytics, the shape sensing logic 190 may determine the shape the core fibers have taken in 3D space and may further determine the current physical state of the catheter 130 in 3D space for rendering on the display 170.

**[00078]** According to one embodiment of the disclosure, the shape sensing logic 194 may generate a rendering of the current physical state of the catheter 130, especially the integrated tubing, based on heuristics or run-time analytics. For example, the shape sensing logic 194 may be configured in accordance with machine-learning techniques to access a data store (library) with pre-stored data (e.g., images, etc.) pertaining to different regions of the catheter 130 in which the core fibers 137 experienced similar or identical wavelength shifts. From the pre-stored data, the current physical state of the catheter 130 may be rendered. Alternatively, as another example, the shape sensing logic 194 may be configured to determine, during run-time, changes in the physical state of each region of the catheter 130, notably the tubing, based on at least (i) resultant wavelength shifts experienced by the core fibers 137 and (ii) the relationship of these wavelength shifts generated by sensors positioned along different outer core fibers at the same cross-sectional region of the catheter 130 to the wavelength shift generated by a sensor of the center core fiber at the same cross-sectional region. It is contemplated that other processes and procedures may be performed to utilize the wavelength shifts as measured by sensors along each of the core fibers 137 to render appropriate changes in the physical state of the catheter 130.

**[00079]** Referring to FIG. 2, an exemplary embodiment of a structure of a section of the multi-core optical fiber included within the stylet 120 of FIG. 1A is shown in accordance with some embodiments. The multi-core optical fiber section 200 of the multi-core optical

fiber 135 depicts certain core fibers $137_1$-$137_M$ ($M \geq 2$, $M=4$ as shown, see FIG. 3A) along with the spatial relationship between sensors (e.g., reflective gratings) $210_{11}$-$210_{NM}$ ($N \geq 2$; $M \geq 2$) present within the core fibers $137_1$-$137_M$, respectively. As noted above, the core fibers $137_1$-$137_M$ may be collectively referred to as "the core fibers 137."

**[00080]** As shown, the section 200 is subdivided into a plurality of cross-sectional regions $220_1$-$220_N$, where each cross-sectional region $220_1$-$220_N$ corresponds to reflective gratings $210_{11}$-$210_{14}$...$210_{N1}$-$210_{N4}$. Some or all of the cross-sectional regions $220_1$...$220_N$ may be static (e.g., prescribed length) or may be dynamic (e.g., vary in size among the regions $220_1$...$220_N$). A first core fiber $137_1$ is positioned substantially along a center (neutral) axis 230 while core fiber $137_2$ may be oriented within the cladding of the multi-core optical fiber 135, from a cross-sectional, front-facing perspective, to be position on "top" the first core fiber $137_1$. In this deployment, the core fibers $137_3$ and $137_4$ may be positioned "bottom left" and "bottom right" of the first core fiber $137_1$. As examples, FIGS. 3A-4B provides illustrations of such.

**[00081]** Referencing the first core fiber $137_1$ as an illustrative example, when the stylet 120 is operative, each of the reflective gratings $210_1$-$210_N$ reflects light for a different spectral width. As shown, each of the gratings $210_{1i}$-$210_{Ni}$ ($1 \leq i \leq M$) is associated with a different, specific spectral width, which would be represented by different center frequencies of $f_1 \ldots f_N$, where neighboring spectral widths reflected by neighboring gratings are non-overlapping according to one embodiment of the disclosure.

**[00082]** Herein, positioned in different core fibers $137_2$-$137_3$ but along at the same cross-sectional regions 220-$220_N$ of the multi-core optical fiber 135, the gratings $210_{12}$-$210_{N2}$ and $210_{13}$-$210_{N3}$ are configured to reflect incoming light at same (or substantially similar) center frequency. As a result, the reflected light returns information that allows for a determination of the physical state of the optical fibers 137 (and the stylet 120) based on wavelength shifts measured from the returned, reflected light. In particular, strain (e.g., compression or tension) applied to the multi-core optical fiber 135 (e.g., at least core fibers $137_2$-$137_3$) results in wavelength shifts associated with the returned, reflected light. Based on different locations, the core fibers $137_1$-$137_4$ experience different types and degree of strain based on angular path changes as the stylet 120 advances in the patient.

**[00083]** For example, with respect to the multi-core optical fiber section 200 of FIG. 2, in response to angular (e.g., radial) movement of the stylet 120 is in the left-veering direction, the fourth core fiber $137_4$ (see FIG. 3A) of the multi-core optical fiber 135 with the shortest radius during movement (e.g., core fiber closest to a direction of angular change) would exhibit compression (e.g., forces to shorten length). At the same time, the third core fiber $137_3$ with the longest radius during movement (e.g., core fiber furthest from the direction of angular change) would exhibit tension (e.g., forces to increase length). As these forces are different and unequal, the reflected light from reflective gratings $210_{N2}$ and $210_{N3}$ associated with the core fibers $137_2$ and $137_3$ will exhibit different changes in wavelength. The differences in wavelength shift of the reflected light signals 150 can be used to extrapolate the physical configuration of the stylet 120 by determining the degrees of wavelength change caused by compression/tension for each of the periphery fibers (e.g., the second core fiber $137_2$ and the third core fiber $137_3$) in comparison to the wavelength of the reference core fiber (e.g., first core fiber $137_1$) located along the neutral axis 230 of the multi-core optical fiber 135. These degrees of wavelength change may be used to extrapolate the physical state of the stylet 120. The reflected light signals 150 are reflected back to the console 110 via individual paths over a particular core fiber $137_1$-$137_M$.

**[00084]** Referring to FIG. 3A, a first exemplary embodiment of the stylet of FIG. 1A supporting both an optical and electrical signaling is shown in accordance with some embodiments. Herein, the stylet 120 features a centrally located multi-core optical fiber 135, which includes a cladding 300 and a plurality of core fibers $137_1$-$137_M$ ($M \geq 2$; $M=4$) residing within a corresponding plurality of lumens $320_1$-$320_M$. While the multi-core optical fiber 135 is illustrated within four (4) core fibers $137_1$-$137_4$, a greater number of core fibers $137_1$-$137_M$ ($M>4$) may be deployed to provide a more detailed three-dimensional sensing of the physical state (e.g., shape, etc.) of the multi-core optical fiber 135 and the stylet 120 deploying the optical fiber 135.

**[00085]** For this embodiment of the disclosure, the multi-core optical fiber 135 is encapsulated within a concentric braided tubing 310 positioned over a low coefficient of friction layer 335. The braided tubing 310 may feature a "mesh" construction, in which the spacing between the intersecting conductive elements is selected based on the degree of rigidity desired for the stylet 120, as a greater spacing may provide a lesser rigidity, and thereby, a more pliable stylet 120.

**[00086]** According to this embodiment of the disclosure, as shown in FIGS. 3A-3B, the core fibers $137_1$-$137_4$ include (i) a central core fiber $137_1$ and (ii) a plurality of periphery core fibers $137_2$-$137_4$, which are maintained within lumens $320_1$-$320_4$ formed in the cladding 300. According to one embodiment of the disclosure, one or more of the lumens $320_1$-$320_4$ may be configured with a diameter sized to be greater than the diameter of the core fibers $137_1$-$137_4$. By avoiding a majority of the surface area of the core fibers $137_1$-$137_4$ from being in direct physical contact with a wall surface of the lumens $320_1$-$320_4$, the wavelength changes to the incident light are caused by angular deviations in the multi-core optical fiber 135 thereby reducing influence of compression and tension forces being applied to the walls of the lumens $320_1$-$320_M$, not the core fibers $137_1$-$137_M$ themselves.

**[00087]** As further shown in FIGS. 3A-3B, the core fibers $137_1$-$137_4$ may include central core fiber $137_1$ residing within a first lumen $320_1$ formed along the first neutral axis 230 and a plurality of core fibers $137_2$-$137_4$ residing within lumens $320_2$-$320_4$ each formed within different areas of the cladding 300 radiating from the first neutral axis 230. In general, the core fibers $137_2$-$137_4$, exclusive of the central core fiber $137_1$, may be positioned at different areas within a cross-sectional area 305 of the cladding 300 to provide sufficient separation to enable three-dimensional sensing of the multi-core optical fiber 135 based on changes in wavelength of incident light propagating through the core fibers $137_2$-$137_4$ and reflected back to the console for analysis.

**[00088]** For example, where the cladding 300 features a circular cross-sectional area 305 as shown in FIG. 3B, the core fibers $137_2$-$137_4$ may be positioned substantially equidistant from each other as measured along a perimeter of the cladding 300, such as at "top" (12 o'clock), "bottom-left" (8 o'clock) and "bottom-right" (4 o'clock) locations as shown. Hence, in general terms, the core fibers $137_2$-$137_4$ may be positioned within different segments of the cross-sectional area 305. Where the cross-sectional area 305 of the cladding 300 has a distal tip 330 and features a polygon cross-sectional shape (e.g., triangular, square, rectangular, pentagon, hexagon, octagon, etc.), the central core fiber $137_1$ may be located at or near a center of the polygon shape, while the remaining core fibers $137_2$-$137_M$ may be located proximate to angles between intersecting sides of the polygon shape.

**[00089]** Referring still to FIGS. 3A-3B, operating as the conductive medium for the stylet 120, the braided tubing 310 provides mechanical integrity to the multi-core optical fiber 135 and operates as a conductive pathway for electrical signals. For example, the braided tubing

310 may be exposed to a distal tip of the stylet 120. The cladding 300 and the braided tubing 310, which is positioned concentrically surrounding a circumference of the cladding 300, are contained within the same insulating layer 350. The insulating layer 350 may be a sheath or conduit made of protective, insulating (e.g., non-conductive) material that encapsulates both for the cladding 300 and the braided tubing 310, as shown.

**[00090]** Referring to FIG. 4A, a second exemplary embodiment of the stylet of FIG. 1A is shown in accordance with some embodiments. Referring now to FIG. 4A, a second exemplary embodiment of the stylet 120 of FIG. 1A supporting both an optical and electrical signaling is shown. Herein, the stylet 120 features the multi-core optical fiber 135 described above and shown in FIG. 3A, which includes the cladding 300 and the first plurality of core fibers $137_1$-$137_M$ ($M \geq 3$; $M=4$ for embodiment) residing within the corresponding plurality of lumens $320_1$-$320_M$. For this embodiment of the disclosure, the multi-core optical fiber 135 includes the central core fiber $137_1$ residing within the first lumen $320_1$ formed along the first neutral axis 230 and the second plurality of core fibers $137_2$-$137_4$ residing within corresponding lumens $320_2$-$320_4$ positioned in different segments within the cross-sectional area 305 of the cladding 300. Herein, the multi-core optical fiber 135 is encapsulated within a conductive tubing 400. The conductive tubing 400 may feature a "hollow" conductive cylindrical member concentrically encapsulating the multi-core optical fiber 135.

**[00091]** Referring to FIGS. 4A-4B, operating as a conductive medium for the stylet 120 in the transfer of electrical signals (e.g., ECG signals) to the console, the conductive tubing 400 may be exposed up to a tip 410 of the stylet 120. For this embodiment of the disclosure, a conductive epoxy 420 (e.g., metal-based epoxy such as a silver epoxy) may be affixed to the tip 410 and similarly joined with a termination/connection point created at a proximal end 430 of the stylet 120. The cladding 300 and the conductive tubing 400, which is positioned concentrically surrounding a circumference of the cladding 300, are contained within the same insulating layer 440. The insulating layer 440 may be a protective conduit encapsulating both for the cladding 300 and the conductive tubing 400, as shown.

**[00092]** Referring to FIG. 5A, an elevation view of a first illustrative embodiment of a catheter including integrated tubing, a diametrically disposed septum, and micro-lumens formed within the tubing and septum is shown in accordance with some embodiments. Herein, the catheter 130 includes integrated tubing, the diametrically disposed septum 510, and the plurality of micro-lumens $530_1$-$530_4$ which, for this embodiment, are fabricated to

reside within the wall 500 of the integrated tubing of the catheter 130 and within the septum 510. In particular, the septum 510 separates a single lumen, formed by the inner surface 505 of the wall 500 of the catheter 130, into multiple lumens, namely two lumens 540 and 545 as shown. Herein, the first lumen 540 is formed between a first arc-shaped portion 535 of the inner surface 505 of the wall 500 forming the catheter 130 and a first outer surface 555 of the septum 510 extending longitudinally within the catheter 130. The second lumen 545 is formed between a second arc-shaped portion 565 of the inner surface 505 of the wall 500 forming the catheter 130 and a second outer surfaces 560 of the septum 510.

**[00093]** According to one embodiment of the disclosure, the two lumens 540 and 545 have approximately the same volume. However, the septum 510 need not separate the tubing into two equal lumens. For example, instead of the septum 510 extending vertically (12 o'clock to 6 o'clock) from a front-facing, cross-sectional perspective of the tubing, the septum 510 could extend horizontally (3 o'clock to 9 o'clock), diagonally (1 o'clock to 7 o'clock; 10 o'clock to 4 o'clock) or angularly (2 o'clock to 10 o'clock). In the later configuration, each of the lumens 540 and 545 of the catheter 130 would have a different volume.

**[00094]** With respect to the plurality of micro-lumens $530_1$-$530_4$, the first micro-lumen $530_1$ is fabricated within the septum 510 at or near the cross-sectional center 525 of the integrated tubing. For this embodiment, three micro-lumens $530_2$-$530_4$ are fabricated to reside within the wall 500 of the catheter 130. In particular, a second micro-lumen $530_2$ is fabricated within the wall 500 of the catheter 130, namely between the inner surface 505 and outer surface 507 of the first arc-shaped portion 535 of the wall 500. Similarly, the third micro-lumen $530_3$ is also fabricated within the wall 500 of the catheter 130, namely between the inner and outer surfaces 505/507 of the second arc-shaped portion 555 of the wall 500. The fourth micro-lumen $530_4$ is also fabricated within the inner and outer surfaces 505/507 of the wall 500 that are aligned with the septum 510.

**[00095]** According to one embodiment of the disclosure, as shown in FIG. 5A, the micro-lumens $530_2$-$530_4$ are positioned in accordance with a "top-left" (10 o'clock), "top-right" (2 o'clock) and "bottom" (6 o'clock) layout from a front-facing, cross-sectional perspective. Of course, the micro-lumens $530_2$-$530_4$ may be positioned differently, provided that the micro-lumens $530_2$-$530_4$ are spatially separated along the circumference 520 of the catheter 130 to ensure a more robust collection of reflected light signals from the outer core fibers $570_2$-$570_4$ when installed. For example, two or more of micro-lumens (e.g., micro-lumens $530_2$ and

$530_4$) may be positioned at different quadrants along the circumference 520 of the catheter wall 500.

**[00096]** Referring to FIG. 5B, a perspective view of the first illustrative embodiment of the catheter of FIG. 5A including core fibers installed within the micro-lumens is shown in accordance with some embodiments. According to one embodiment of the disclosure, the second plurality of micro-lumens $530_2$-$530_4$ are sized to retain corresponding outer core fibers $570_2$-$570_4$, where the diameter of each of the second plurality of micro-lumens $530_2$-$530_4$ may be sized just larger than the diameters of the outer core fibers $570_2$-$570_4$. The size differences between a diameter of a single core fiber and a diameter of any of the micro-lumen $530_1$-$530_4$ may range between 0.001 micrometers (μm) and 1000 μm, for example. As a result, the cross-sectional areas of the outer core fibers $570_2$-$570_4$ would be less than the cross-sectional areas of the corresponding micro-lumens $530_2$-$530_4$. A "larger" micro-lumen (e.g., micro-lumen $530_2$) may better isolate external strain being applied to the outer core fiber $570_2$ from strain directly applied to the catheter 130 itself. Similarly, the first micro-lumen $530_1$ may be sized to retain the center core fiber $570_1$, where the diameter of the first micro-lumen $530_1$ may be sized just larger than the diameter of the center core fiber $570_1$.

**[00097]** As an alternative embodiment of the disclosure, one or more of the micro-lumens $530_1$-$530_4$ may be sized with a diameter that exceeds the diameter of the corresponding one or more core fibers $570_1$-$570_4$. However, at least one of the micro-lumens $530_1$-$530_4$ is sized to fixedly retain their corresponding core fiber (e.g., core fiber retained with no spacing between its lateral surface and the interior wall surface of its corresponding micro-lumen). As yet another alternative embodiment of the disclosure, all the micro-lumens $530_1$-$530_4$ are sized with a diameter to fixedly retain the core fibers $570_1$-$570_4$.

**[00098]** Referring to FIGS. 6A-6B, flowcharts of methods of operations conducted by the medical instrument monitoring system of FIGS. 1A-1B to achieve optic 3D shape sensing are shown in accordance with some embodiments. Herein, the catheter includes at least one septum spanning across a diameter of the tubing wall and continuing longitudinally to subdivide the tubing wall. The medial portion of the septum is fabricated with a first micro-lumen, where the first micro-lumen is coaxial with the central axis of the catheter tubing. The first micro-lumen is configured to retain a center core fiber. Two or more micro-lumen, other than the first micro-lumen, are positioned at different locations circumferentially spaced along the wall of the catheter tubing. For example, two or more of the second plurality of

micro-lumens may be positioned at different quadrants along the circumference of the catheter wall.

**[00099]** Furthermore, each core fiber includes a plurality of sensors spatially distributed along its length between at least the proximal and distal ends of the catheter tubing. This array of sensors is distributed to position sensors at different regions of the core fiber to enable distributed measurements of strain throughout the entire length or a selected portion of the catheter tubing. These distributed measurements may be conveyed through reflected light of different spectral widths (e.g., specific wavelength or specific wavelength ranges) that undergoes certain wavelength shifts based on the type and degree of strain.

**[000100]** According to one embodiment of the disclosure, as shown in FIG. 6A, for each core fiber, broadband incident light is supplied to propagate through a particular core fiber (block 600). Unless discharged, upon the incident light reaching a sensor of a distributed array of sensors measuring strain on a particular core fiber, light of a prescribed spectral width associated with the first sensor is to be reflected back to an optical receiver within a console (blocks 605-610). Herein, the sensor alters characteristics of the reflected light signal to identify the type and degree of strain on the particular core fiber as measured by the first sensor (blocks 615-620). According to one embodiment of the disclosure, the alteration in characteristics of the reflected light signal may signify a change (shift) in the wavelength of the reflected light signal from the wavelength of the incident light signal associated with the prescribed spectral width. The sensor returns the reflected light signal over the core fiber and the remaining spectrum of the incident light continues propagation through the core fiber toward a distal end of the catheter tubing (blocks 625-630). The remaining spectrum of the incident light may encounter other sensors of the distributed array of sensors, where each of these sensors would operate as set forth in blocks 605-630 until the last sensor of the distributed array of sensors returns the reflected light signal associated with its assigned spectral width and the remaining spectrum is discharged as illumination.

**[000101]** Referring now to FIG. 6B, during operation, multiple reflected light signals are returned to the console from each of the plurality of core fibers residing within the corresponding plurality of micro-lumens formed within a catheter, such as the catheter of FIG. 1B. In particular, the optical receiver receives reflected light signals from the distributed arrays of sensors located on the center core fiber and the outer core fibers and translates the reflected light signals into reflection data, namely electrical signals representative of the

reflected light signals including wavelength shifts caused by strain (blocks 650-655). The reflection data classification logic is configured to identify which core fibers pertain to which reflection data and segregate reflection data provided from reflected light signals pertaining to a particular measurement region (or similar spectral width) into analysis groups (block 660-665).

**[000102]** Each analysis group of reflection data is provided to shape sensing logic for analytics (block 670). Herein, the shape sensing logic compares wavelength shifts at each outer core fiber with the wavelength shift at the center core fiber positioned along central axis and operating as a neutral axis of bending (block 675). From these analytics, on all analytic groups (e.g., reflected light signals from sensors in all or most of the core fibers), the shape sensing logic may determine the shape the core fibers have taken in three-dimensional space, from which the shape sensing logic can determine the current physical state of the catheter in three-dimension space (blocks 680-685).

**[000103]** Referring to FIG. 7, an exemplary embodiment of the medical instrument monitoring system of FIG. 1A during operation and insertion of the catheter into a patient are shown in accordance with some embodiments. Herein, the catheter 195 generally includes integrated tubing with a proximal portion 720 that generally remains exterior to the patient 700 and a distal portion 730 that generally resides within the patient vasculature after placement is complete, where the catheter 195 enters the vasculature at insertion site 710. The stylet 120 may be advanced through the catheter 195 to a desired position within the patient vasculature such that a distal end (or tip) 735 of the stylet 120 (and hence a distal end of the catheter 195) is proximate the patient's heart, such as in the lower one-third (1/3) portion of the Superior Vena Cava ("SVC") for example. For this embodiment, various instruments may be placed at the distal end 735 of the stylet 120 and/or the catheter 195 to measure pressure of blood in a certain heart chamber and in the blood vessels, view an interior of blood vessels, or the like.

**[000104]** The console connector 133 enables the stylet 120 to be operably connected to the console 110 via the interconnect 145 (FIG. 1A). Herein, the connector 146 is configured to engage (mate) with the console connector 133 to allow for the propagation of light between the console 110 and the stylet assembly 119 (particularly the stylet 120) as well as the propagation of electrical signals from the stylet 120 to the console 110

**[000105]** During advancement of the stylet 120, the distal tip 735 typically fluctuates due to, among other factors, blood flow and blood pressure within the blood vessel. These fluctuations may be movements by a distal portion of the stylet 120in any direction. Typically, the movements are relatively minor compared to the overall advancement of the stylet 120 (and the catheter 195); however, such movements are detectable by the sensors of the core fibers integrated into the stylet 120.

**[000106]** The fluctuations may vary based on the blood vessel in which the stylet 120 (and catheter 195) is advancing due to one or more of the physical properties of the blood vessel, the location of the blood vessel (and its proximity to the patient's heart), and any defects affecting the blood vessel (e.g., vessel constriction, vasospasm, occlusion, etc.). As will be discussed in further detail below, the volume of the blood vessel may affect the fluctuations (e.g., a larger diameter may provide for greater fluctuation). Similarly, the turbulence of the blood flow generally affects the fluctuations (e.g., higher turbulence typically equates to greater fluctuation). Relatedly, the proximity of the distal tip 735 to the patient's heart may affect the fluctuations due to the turbulent blood flow emanating from the right atrium of the heart and flowing through the SVC (see FIG. 8A). The blood pressure within the blood vessel may also affect tip fluctuations. Further, various defects may affect the fluctuations of the distal tip 735 and cause fluctuations that vary from those expected when the stylet 120 is advancing through a healthy blood vessel. FIGS. 8B-8D provide examples of the stylet 120 advancing toward various defects.

**[000107]** Referring now to FIG. 8A, a detailed view of a stylet disposed within the Superior Vena Cava (SVC) advancing toward the right atrium of a patient is shown in accordance with some embodiments. FIG. 8A illustrates a detailed perspective of the vasculature proximate to the heart 803 of a patient as well as the anatomy of the heart 803. Specifically, as the stylet 120 approaches the right atrium 804 through the SVC 800, the stylet 120 may either advance into the right atrium 804 or into the azygos vein 802. The stylet 120 is often used to locate a particular point in the vasculature at which point the catheter 195 may be used to administer a medical procedure or medicament, where this point may be referred to as the "target site" 805.

**[000108]** In some embodiments, the tip fluctuation logic 198 is configured to confirm the location of the distal tip 735 of the stylet 120 (which, in turn, corresponds to the distal tip of the catheter 195, within a predetermined distance such as approximately 1-2 cm) as the

catheter 195 and the stylet 120 advance through a patient's vasculature toward a target site 805. According to one embodiment of the disclosure, the tip fluctuation logic 198 is configured to analyze a subset of the wavelength shifts measured by sensors deployed in each of the core fibers 137, for example, the sensors included in the distal portion 801 of the stylet 120. In some embodiments, the distal portion 801 includes a plurality of sensors such as 50, 30, 10, 5, 3, etc. It should be noted that the disclosure is not limited to the recited number of sensors and such a recitation should be understood to merely provide exemplary examples. Further, in some embodiments, the number of sensors included in the distal portion 501 and thus utilized by the tip fluctuation logic 198 may be dynamically configurable during run-time. Thus, a user may provide user input to the console 110 to adjust the number of sensors utilized by the tip fluctuation logic 198. As a result, a user may alter the specificity of the analysis performed by the tip fluctuation logic 198 during run-time (e.g., where utilization of a fewer number of sensors may correspond to an analysis that is more specific as to fluctuation at the distal tip 735).

**[000109]** In particular, the tip fluctuation logic 198 is configured to analyze wavelength shifts measured by the sensors of core fibers 137 located within the distal portion 801, where such corresponds to a tip fluctuation analysis as discussed above. With reference to FIG. 8A, as the distal tip 735 of the stylet 120 advances through the SVC 800 toward the target site 805 within the right atrium 804, the sensors within the distal portion 801 may detect an increase in movements, corresponding to an increase in tip fluctuations. The increase in tip fluctuations may be caused by the turbulence of the blood flow exiting the right atrium and entering the SVC (thus, the stylet 120 is advancing in a direction opposing the blood flow). Thus, the increase in fluctuations may provide the tip fluctuation logic 198 one indication that the distal tip 735 is approaching the right atrium 804.

**[000110]** In one embodiment, the tip fluctuation logic 198 may be configured to correlate the wavelength shifts received from the sensors within the distal portion 801 with data from the experiential knowledge repository 193 corresponding to previously detected wavelength shifts received from sensors within a similar distal portion of a stylet. Based on the correlation, the tip fluctuation logic 198 may determine the distal tip 735 is within the SVC 800, within a certain distance to the right atrium 804 or the target site 805, or within the right atrium 804. In one instance, the determination may be based on whether the correlation results indicate that the correlation between the detected wavelength shifts and any of the

previously detected wavelength shifts corresponding to the SVC 800, the target site 805 or the right atrium 804 is greater than or equal to a threshold.

**[000111]** In other embodiments, the detected wavelength shifts received from the sensors within the distal portion 801 may be utilized by the tip fluctuation logic 198 as input to a trained machine-learning model that, upon processing, provides a correlation to one or more of previously detected fluctuations corresponding to the SVC 800, the target site 805 or the right atrium 804. A similar threshold determination may then be made by the tip fluctuation logic 198 as referenced above.

**[000112]** In embodiments in which ECG signals may be obtained by the stylet 120 (or the catheter 195), the ECG signals may provide an indication as to the rhythmic pulses of the heart 803. The tip fluctuation logic 198 may compare the rhythmic pulses as indicated by the ECG signals to the detected wavelength shifts received from the sensors within the distal portion 801 to determine whether the detected wavelength shifts indicate movement that correlates to the rhythmic pulses by at least a threshold.

**[000113]** In some embodiments, the tip confirmation may be used in combination with the shape sensing functionality discussed above in which the shape sensing logic 194 determines the current physical state of the stylet 120 (and hence the catheter 195) in 3D space for rendering on the display 170. Further, in some embodiments, the catheter 195 and/or the stylet 120 may incorporate a pressure sensor configured to detect the blood pressure within the blood vessel (or heart chamber) in which the distal tip 735 is placed. The detected blood pressure may also be utilized in the correlations discussed herein such that the tip fluctuation logic 198 may correlate the detected blood pressure with previously detected blood pressures to aid in the determination of the placement of the distal tip 735 and/or detection of a defect affecting the blood vessel.

**[000114]** In some embodiments, the tip fluctuation logic 198 may detect, or provide data for detection of, placement of the distal tip 735 in the Azygos vein 802. For instance, the tip fluctuation logic 198 may detect fluctuations correlating to placement within the SVC 800 and subsequently detect a decrease in fluctuations such that the detected fluctuations no longer correlate to placement with the SVC 800 but instead correlate to placement within the Azygos vein 802. For example, upon detection of a decrease in fluctuations, the tip fluctuation logic 198 may perform a correlation between the detected fluctuations and

previously detected fluctuations known to correspond to the Azygos vein. The decrease in fluctuations of the distal tip 735 within the Azygos vein compared to the within the SVC 800 may be due to the smaller diameter of the Azygos vein 802, and less turbulent blood flow within the Azygos vein 802. This detection may be optionally confirmed through detection of the direction of blood flow. Specifically, if the distal tip 735 of the stylet 120 advances into the Azygos vein 802, the stylet 120 will be advancing in the direction of blood flow indicating that the stylet 120 has deviated from the SVC 800.

**[000115]** In some embodiments, the tip fluctuation logic 198 may generate a graphic illustrating the detected tip fluctuation compared to previously detected tip fluctuations and/or the rhythmic impulses of the heart. In one embodiment, such a graphic may include a dynamic visualization of the present distal tip moving in accordance with the detected tip fluctuations adjacent to a distal tip moving in accordance with previously detected tip fluctuations.

**[000116]** Referring to FIGS. 8B-8D, diagrams are provided illustrating the stylet 120 advancing through a vessel of the vasculature of a patient and encountering a defect affecting the vessel. The stylet 120 may be advancing through the vessel within the catheter 195 (not shown for purposes of clarity). Referring specifically to FIG. 8B, a side elevation of the stylet 120 advancing through a vessel of the vasculature of a patient toward a point of constriction in the vessel is shown in accordance with some embodiments. The stylet 120 is shown advancing through the vessel 814 toward a point of constriction 815, which may be a vasoconstriction, e.g., the constriction of capillaries or arterioles. In some embodiments, the vasoconstriction may result in elevated blood pressure levels.

**[000117]** As the stylet 120 advances through the vessel 814, the console 110 receives reflected light from sensors located along the core fibers 137. As discussed above, the tip fluctuation logic 198 may perform an analysis on the wavelength shifts detected by a subset of the sensors, particularly those disposed in a distal portion of the stylet 120 (such as those disposed in the distal portion 801 of FIG. 8A). As the stylet 120 advances toward the point of constriction 815, the fluctuations of the distal tip 735 change due to properties of the blood vessel such as a narrowing diameter and a decrease in blood flow. Thus, by monitoring the tip fluctuations of the distal tip 735 during advancement, the tip fluctuation logic 198 may detect an unexpected change (decrease) in the tip fluctuations (e.g., a change not based on entrance into a new vessel). The tip fluctuation logic 198 may then correlate the detected wavelength

shifts corresponding to the decrease in fluctuations with previously detected wavelength shifts for various defects that affect blood vessels (e.g., the defect being a vasoconstriction in FIG. 8B). The correlation may be performed in any manner as discussed herein including, for example, via a machine-learning model.

**[000118]** When the tip fluctuation logic 198 determines the result of the correlation is above a threshold, an alert or notification may be generated and provided to the user. The alert or notification may audible or visual, and may be displayed on the display 170 of the console 110. In some embodiments, the shape sensing functionalities of the shape sensing logic 194 discussed above may be combined with the correlation performed by the tip fluctuation logic 198 to provide an indication of a location of the point of constriction 815 (or other defect discussed below) to the user.

**[000119]** Referring to FIG. 8C, side elevation of a stylet advancing through a vessel of the vasculature of a patient toward a vasospasm affecting the vessel is shown in accordance with some embodiments. The stylet 120 is shown advancing through the vessel 816 toward a vasospasm 817, which may be due to an arterial spasm. As the stylet 120 advances through the vessel 816, the console 110 receives reflected light from sensors located along the core fibers 137. As the stylet 120 advances toward the vasospasm 817, the fluctuations of the distal tip 735 change due to properties of the blood vessel such as a narrowing diameter and a decrease in blood flow therein. Thus, by monitoring the tip fluctuations of the distal tip 735 during advancement, the tip fluctuation logic 198 may detect an unexpected change (increase due to the spasm, e.g., contractions, of the walls of the vessel) in the tip fluctuations (e.g., a change not based on entrance into a new vessel). The tip fluctuation logic 198 may then correlate the detected wavelength shifts corresponding to the decrease in fluctuations with previously detected wavelength shifts for various defects that affect blood vessels (e.g., the defect being a vasospasm in FIG. 8C). The correlation may be performed in any manner as discussed herein including, for example, via a machine-learning model. Alerts or notifications may be generated in a similar manner as discussed above.

**[000120]** Referring to FIG. 8D, a side elevation of a stylet advancing through a vessel of the vasculature of a patient toward an occlusion in the vessel is shown in accordance with some embodiments. The stylet 120 is shown advancing through the vessel 818 toward an occlusion 819, e.g., a blockage or clot due to plague build-up, a blood clot, etc. As the stylet 120 advances through the vessel 818, the console 110 receives reflected light from sensors located

along the core fibers 137. As the stylet 120 advances toward the occlusion 819, the fluctuations of the distal tip 735 change due to properties of the blood vessel such as a narrowing diameter and a decrease in blood flow therein. Thus, by monitoring the tip fluctuations of the distal tip 735 during advancement, the tip fluctuation logic 198 may detect an unexpected change (decrease) in the tip fluctuations (e.g., a change not based on entrance into a new vessel). The tip fluctuation logic 198 may then correlate the detected wavelength shifts corresponding to the decrease in fluctuations with previously detected wavelength shifts for various defects that affect blood vessels (e.g., the defect being an occlusion in FIG. 8D). The correlation may be performed in any manner as discussed herein including, for example, via a machine-learning model. Additionally, with respect to advancement of the stylet 120 toward the occlusion 819, the distal tip 735 may come into contact with the occlusion 819 thereby causing the fluctuations to cease. Therefore, detection that fluctuations have ceased may be a factor in the correlation performed by the tip fluctuation logic 198. Alerts or notifications may be generated in a similar manner as discussed above.

**[000121]** While some particular embodiments have been disclosed herein, and while the particular embodiments have been disclosed in some detail, it is not the intention for the particular embodiments to limit the scope of the concepts provided herein. Additional adaptations and/or modifications can appear to those of ordinary skill in the art, and, in broader aspects, these adaptations and/or modifications are encompassed as well. Accordingly, departures may be made from the particular embodiments disclosed herein without departing from the scope of the concepts provided herein.

# CLAIMS

What is claimed is:

1. A medical device system for detecting fluctuation using optical fiber technology of a medical device, the system comprising:

the medical device comprising an optical fiber having one or more of core fibers, each of the one or more core fibers including a plurality of sensors distributed along a longitudinal length of a corresponding core fiber and each sensor of the plurality of sensors being configured to (i) reflect a light signal of a different spectral width based on received incident light, and (ii) change a characteristic of the reflected light signal based on strain experienced by the optical fiber; and

a console including one or more processors and a non-transitory computer-readable medium having stored thereon logic, when executed by the one or more processors, causes operations including:

providing a broadband incident light signal to the optical fiber;

receiving reflected light signals of different spectral widths of the broadband incident light by one or more of the plurality of sensors;

processing the reflected light signals associated with the one or more of core fibers to detect fluctuations of a portion of the optical fiber; and

determining a location of the portion of the optical fiber or a defect affecting a vessel in which the portion is disposed based on the detected fluctuations.

2. The system of claim 1, wherein the portion of the optical fiber is a distal tip.

3. The system of either claim 1 or 2, wherein the optical fiber is a multi-core optical fiber including a plurality of core fibers.

4. The system of any of claims 1-3, wherein the defect is selected from the group consisting of a constriction of the vessel, a vasospasm of the vessel, and an occlusion in the vessel.

5. The system of any of claims 1-4, wherein the determining includes:

correlating the reflected light signals with previously obtained reflected light signals to identify the location of the portion of the optical fiber or the defect affecting a vessel, and

determining whether a correlation result is above a first threshold.

6. The system of claim 5, wherein the correlating is performed through machine-learning techniques.

7. The system of any of claims 1-6, wherein determining the location of the portion of the optical fiber includes

obtaining electrocardiogram (ECG) signals,

correlating the ECG signals with the detected fluctuations to identify whether the detected fluctuations include movements in accordance with a rhythmic pattern of the ECG signals, and

determining whether a correlation result is above a first threshold.

8. The system of any of claims 1-7, wherein the medical device is one of an introducer wire, a guidewire, a stylet, a stylet within a needle, a needle with the optical fiber inlayed into a cannula of the needle or a catheter with the optical fiber inlayed into one or more walls of the catheter.

9. The system of any of claims 1-8, wherein each of the plurality of sensors is a reflective grating, where each reflective grating alters its reflected light signal by applying a wavelength shift dependent on a strain experienced by the reflective grating.

10. The system of any of claims 1-9, wherein the logic, when executed by the one or more processors, causes further operations including generating an alert indicating an existence of the defect.

11. The system of claim 10, wherein the alert includes an indication of a location of the defect.

12. A method for placing a medical device into a body of a patient, the method comprising:

providing a broadband incident light signal to an optical fiber included within the medical device, wherein the optical fiber includes a one or more of core fibers, each of the one or more of core fibers including a plurality of reflective gratings distributed along a longitudinal length of a corresponding core fiber and each of the plurality of reflective gratings being configured to (i) reflect a light signal of a different spectral width based on received incident light, and (ii) change a characteristic of the reflected light signal based on strain experienced by the optical fiber;

receiving reflected light signals of different spectral widths of the broadband incident light by one or more of the plurality of sensors;

processing the reflected light signals associated with the one or more of core fibers to detect fluctuations of a portion of the optical fiber; and

determining a location of the portion of the optical fiber or a defect affecting a vessel in which the portion is disposed based on the detected fluctuations.

13. The method of claim 12, wherein the portion of the optical fiber is a distal tip.

14. The method of either claim 12 or 13, wherein the optical fiber is a multi-core optical fiber including a plurality of core fibers.

15. The method of any of claims 12-14, wherein the defect is selected from the group consisting of a constriction of the vessel, a vasospasm of the vessel, and an occlusion in the vessel.

16. The method of any of claims 12-15, wherein the determining includes:

correlating the reflected light signals with previously obtained reflected light signals to identify the location of the portion of the optical fiber or the defect affecting a vessel; and

determining whether a correlation result is above a first threshold.

17. The method of claim 16, wherein the correlating is performed through machine-learning techniques.

18. The method of any of claims 12-17, wherein determining the location of the portion of the optical fiber includes:

obtaining electrocardiogram (ECG) signals;

correlating the ECG signals with the detected fluctuations to identify whether the detected fluctuations include movements in accordance with a rhythmic pattern of the ECG signals; and

determining whether a correlation result is above a first threshold.

19. The method of any of claims 12-18, wherein the medical device is one of an introducer wire, a guidewire, a stylet, a stylet within a needle, a needle with the optical fiber inlayed into a cannula of the needle or a catheter with the optical fiber inlayed into one or more walls of the catheter.

20. The method of any of claims 12-19, wherein each of the plurality of sensors is a reflective grating, where each reflective grating alters its reflected light signal by applying a wavelength shift dependent on a strain experienced by the reflective grating.

21. The method of any of claims 12-20, wherein the logic, when executed by the one or more processors, causes further operations including generating an alert indicating an existence of the defect.

22. The method of claim 21, wherein the alert includes an indication of a location of the defect.

23. A non-transitory computer-readable medium having stored thereon logic that, when executed by one or more processors, causes operations including:

providing a broadband incident light signal to an optical fiber included within the medical device, wherein the optical fiber includes a one or more of core fibers, each of the one or more of core fibers including a plurality of reflective gratings distributed along a longitudinal length of a corresponding core fiber and each of the plurality of reflective gratings being configured to (i) reflect a light signal of a different spectral width based on received incident light, and (ii) change a characteristic of the reflected light signal based on strain experienced by the optical fiber;

receiving reflected light signals of different spectral widths of the broadband incident light by one or more of the plurality of sensors;

processing the reflected light signals associated with the one or more of core fibers to detect fluctuations of a portion of the optical fiber; and

determining a location of the portion of the optical fiber or a defect affecting a vessel in which the portion is disposed based on the detected fluctuations.

24. The non-transitory, computer-readable medium of claim 23, wherein the portion of the optical fiber is a distal tip.

25. The non-transitory, computer-readable medium of either claim 23 or 24, wherein the optical fiber is a multi-core optical fiber including a plurality of core fibers.

26. The non-transitory, computer-readable medium of any of claims 23-25, wherein the defect is selected from the group consisting of a constriction of the vessel, a vasospasm of the vessel, and an occlusion in the vessel.

27. The non-transitory, computer-readable medium of any of claims 23-26, wherein the determining includes:

correlating the reflected light signals with previously obtained reflected light signals to identify the location of the portion of the optical fiber or the defect affecting a vessel; and

determining whether a correlation result is above a first threshold.

28. The non-transitory, computer-readable medium of claim 27, wherein the correlating is performed through machine-learning techniques.

29. The non-transitory, computer-readable medium of any of claims 23-28, wherein determining the location of the portion of the optical fiber includes:

obtaining electrocardiogram (ECG) signals;

correlating the ECG signals with the detected fluctuations to identify whether the detected fluctuations include movements in accordance with a rhythmic pattern of the ECG signals; and

determining whether a correlation result is above a first threshold.

30. The non-transitory, computer-readable medium of any of claims 23-29, wherein the medical device is one of an introducer wire, a guidewire, a stylet, a stylet within

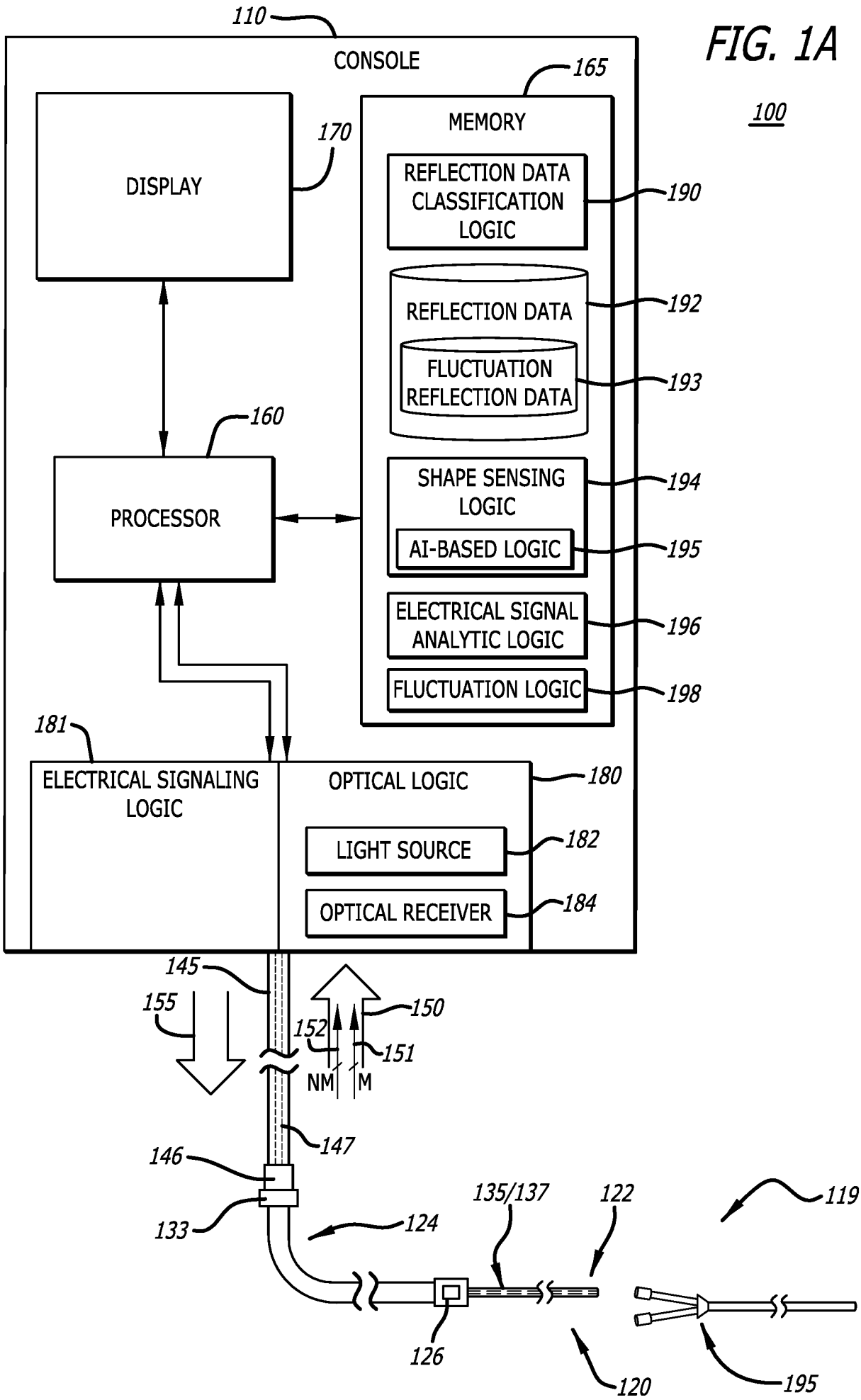
a needle, a needle with the optical fiber inlayed into a cannula of the needle or a catheter with the optical fiber inlayed into one or more walls of the catheter.

31. The non-transitory, computer-readable medium of any of claims 23-30, wherein each of the plurality of sensors is a reflective grating, where each reflective grating alters its reflected light signal by applying a wavelength shift dependent on a strain experienced by the reflective grating.

32. The non-transitory, computer-readable medium of any of claims 23-31, wherein the logic, when executed by the one or more processors, causes further operations including generating an alert indicating an existence of the defect.

33. The non-transitory, computer-readable medium of any of claims 23-32, wherein the alert includes an indication of a location of the defect.

FIG. 1A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CONSOLE
165
MEMORY
170
DISPLAY
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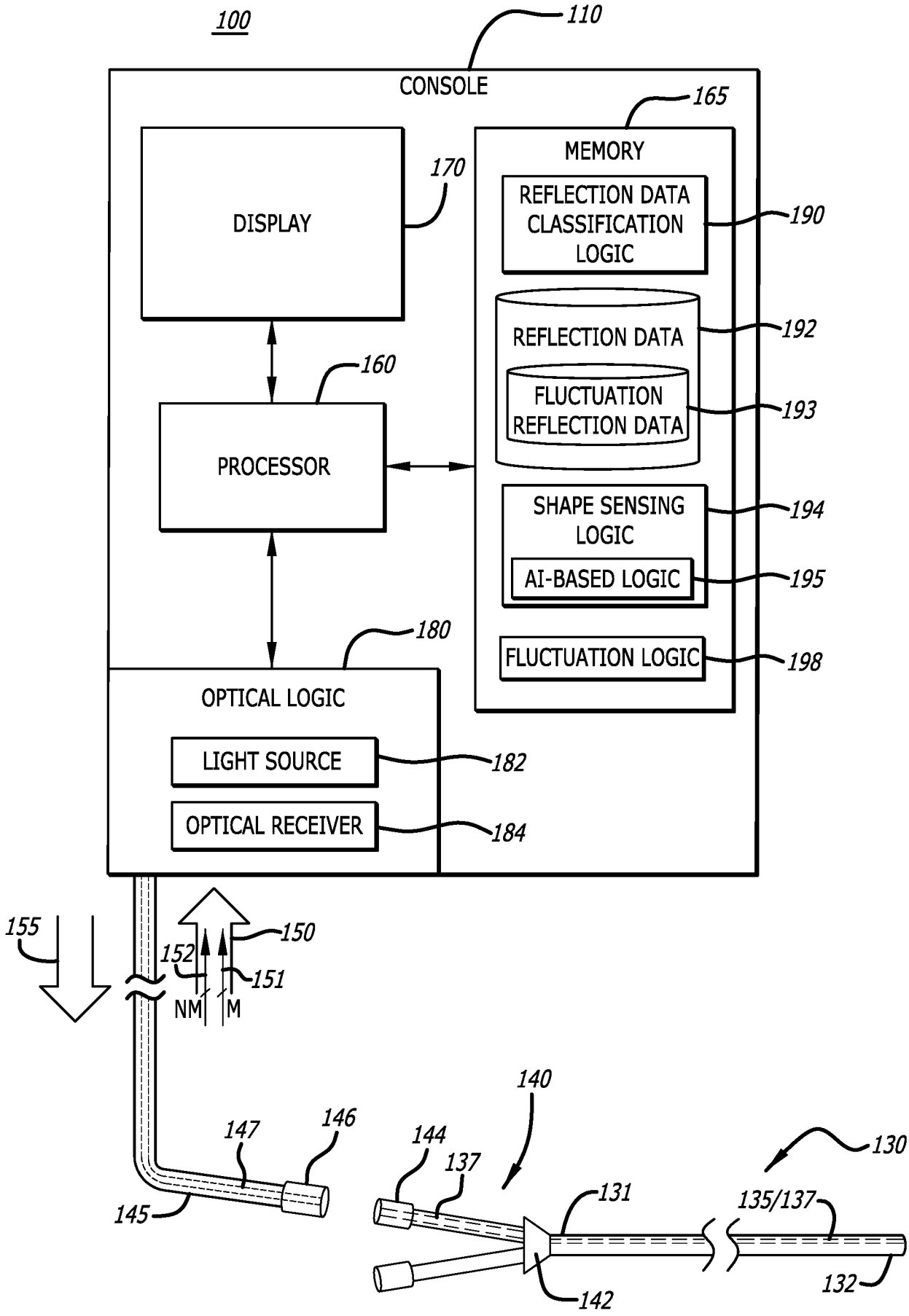
190
REFLECTION DATA
192
FLUCTUATION REFLECTION DATA
193
160
PROCESSOR
SHAPE SENSING LOGIC
194
AI-BASED LOGIC
195
ELECTRICAL SIGNAL ANALYTIC LOGIC
196
FLUCTUATION LOGIC
198
181
ELECTRICAL SIGNALING LOGIC
OPTICAL LOGIC
180
LIGHT SOURCE
182
OPTICAL RECEIVER
184
145
155
150
152
151
NM
M
147
146
133
124
135/137
122
119
126
120
195

FIG. 1B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160
PROCESSOR
SHAPE SENSING LOGIC
194
AI-BASED LOGIC
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180
FLUCTUATION LOGIC
198
OPTICAL LOGIC
LIGHT SOURCE
182
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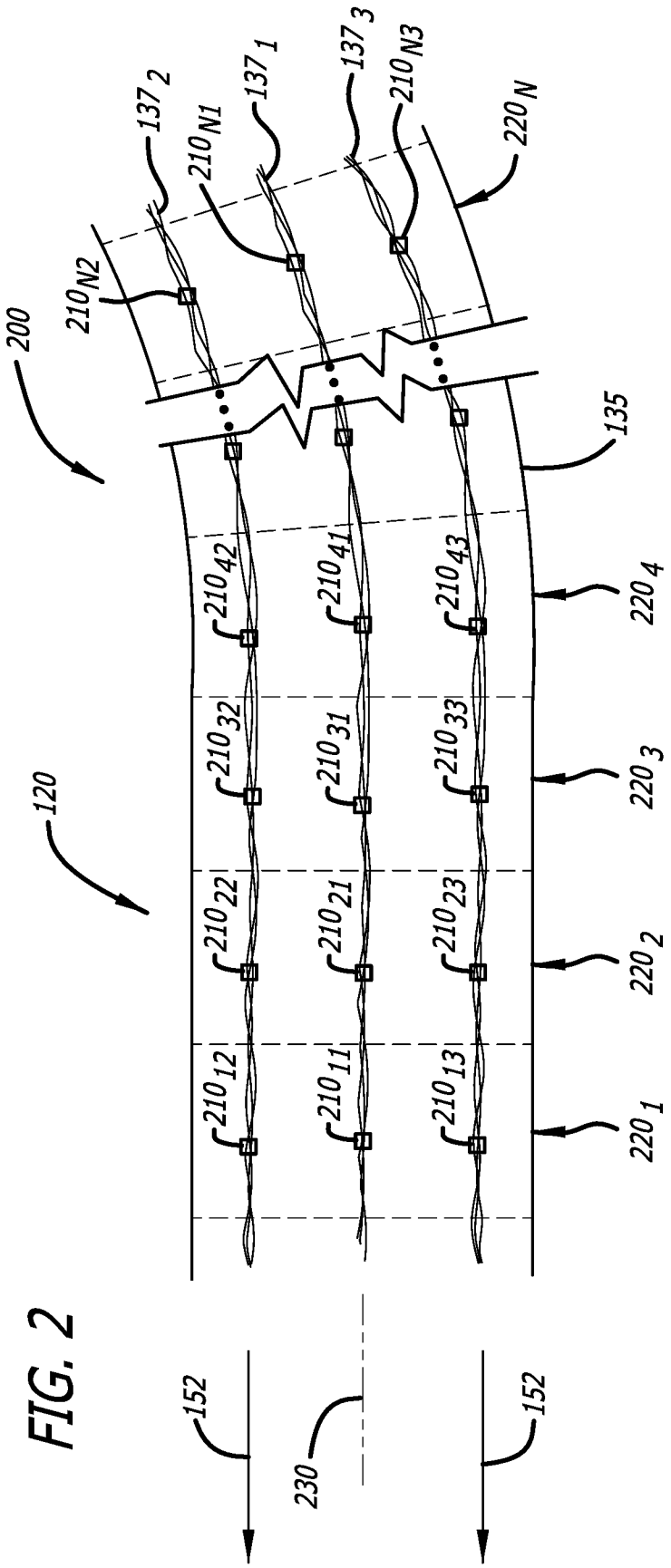
145
142
132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120
135
152
230
152
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$210_{N1}$
$137_1$
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$220_N$
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$220_3$
$210_{22}$
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$210_{23}$
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$210_{12}$
$210_{11}$
$210_{13}$
$220_1$

FIG. 2

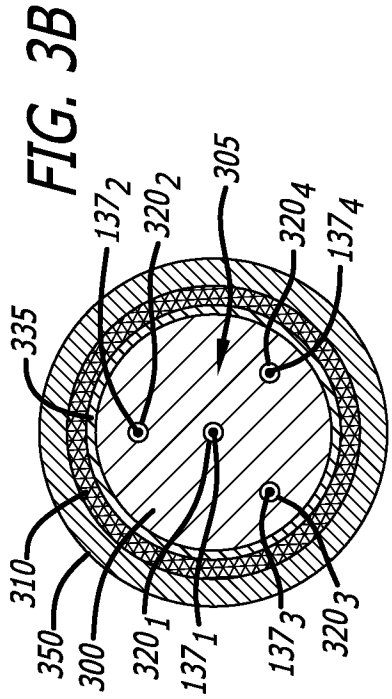



FIG. 3B

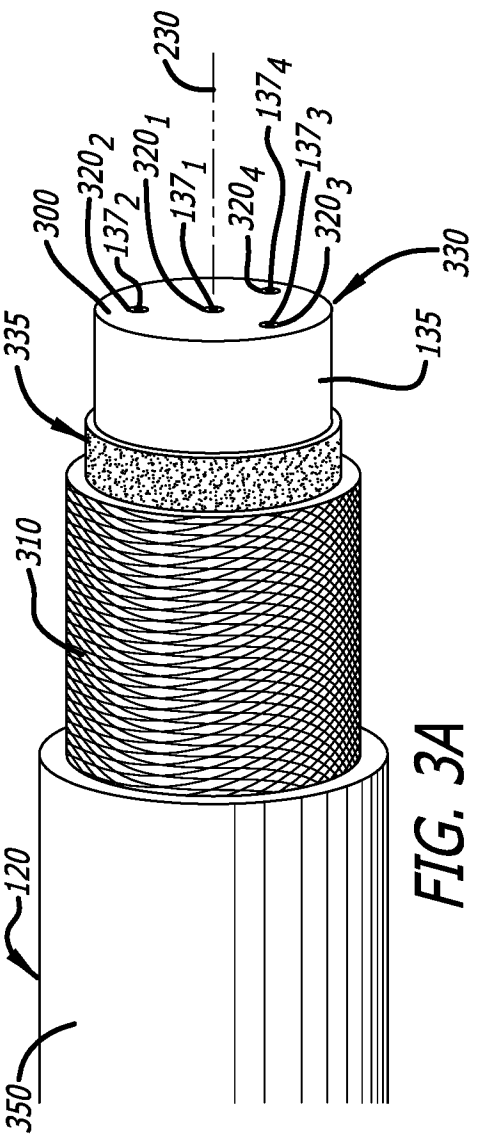



FIG. 3A

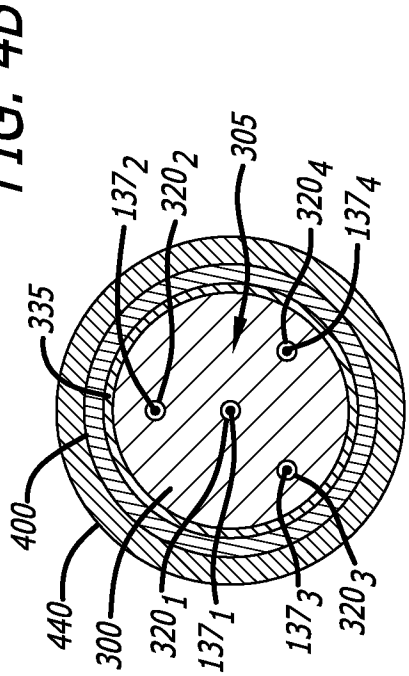



FIG. 4B

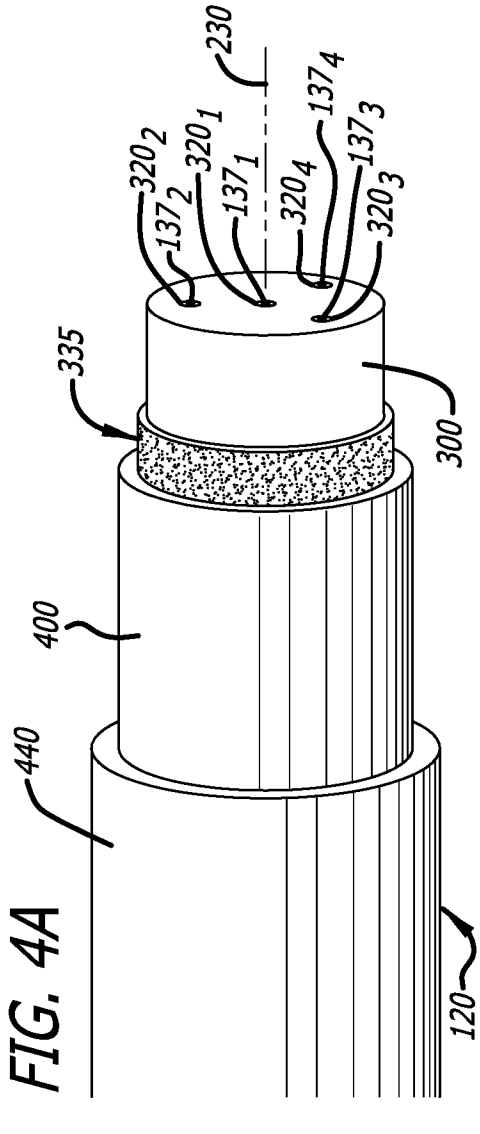
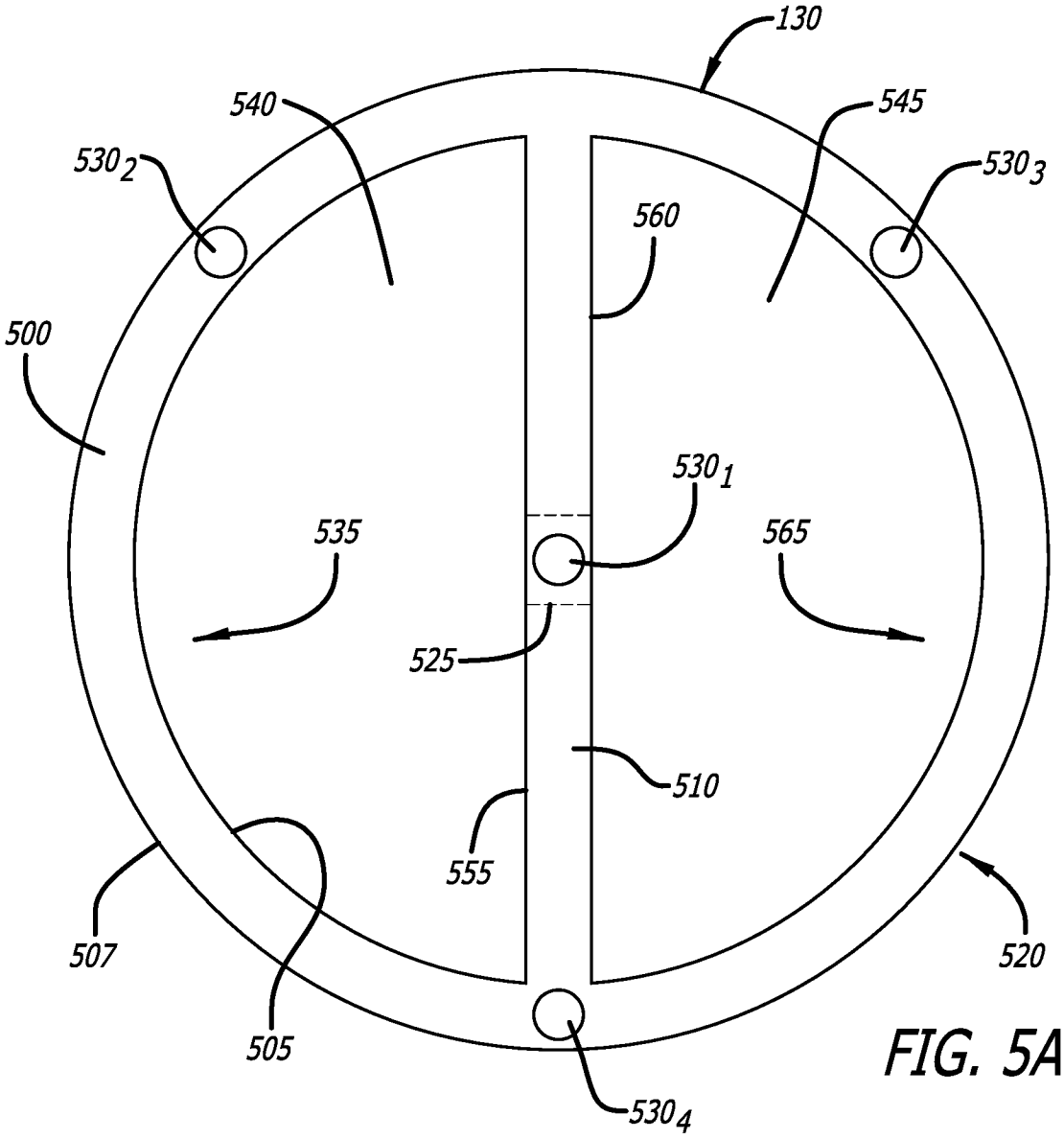



FIG. 4A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545
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$530_3$
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500
$530_1$
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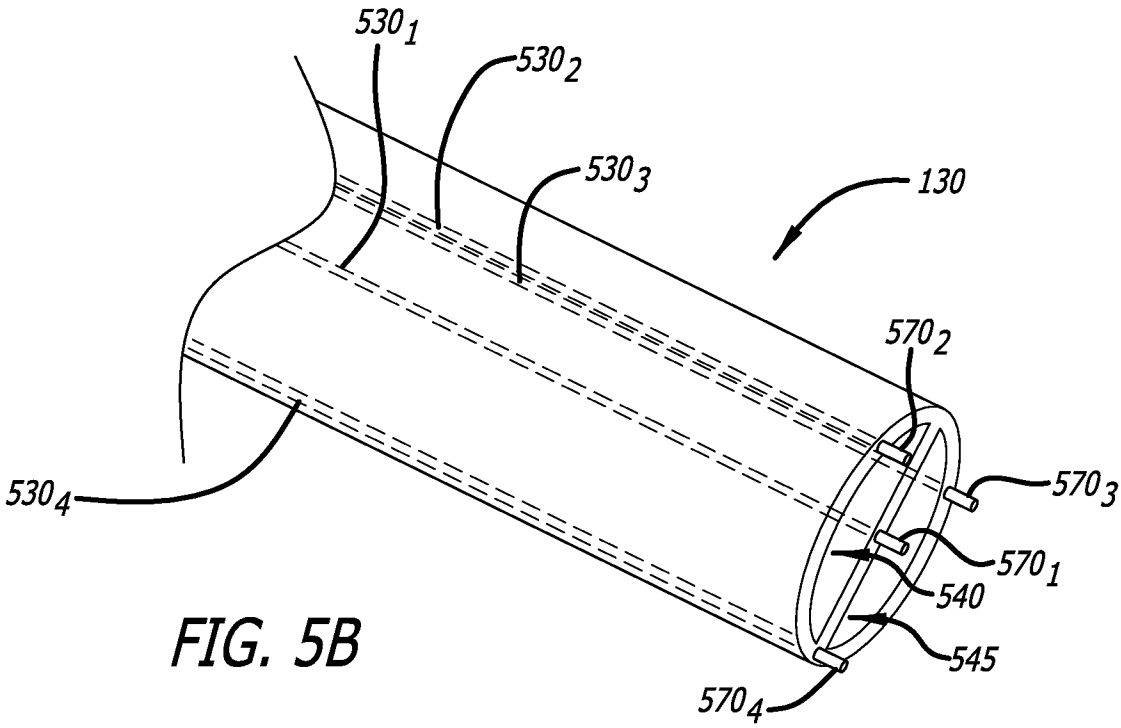
525
510
555
507
520
505
$530_4$

FIG. 5A


$530_1$
$530_2$
$530_3$
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$570_2$
$530_4$
$570_3$
$570_1$
540
545
$570_4$

FIG. 5B

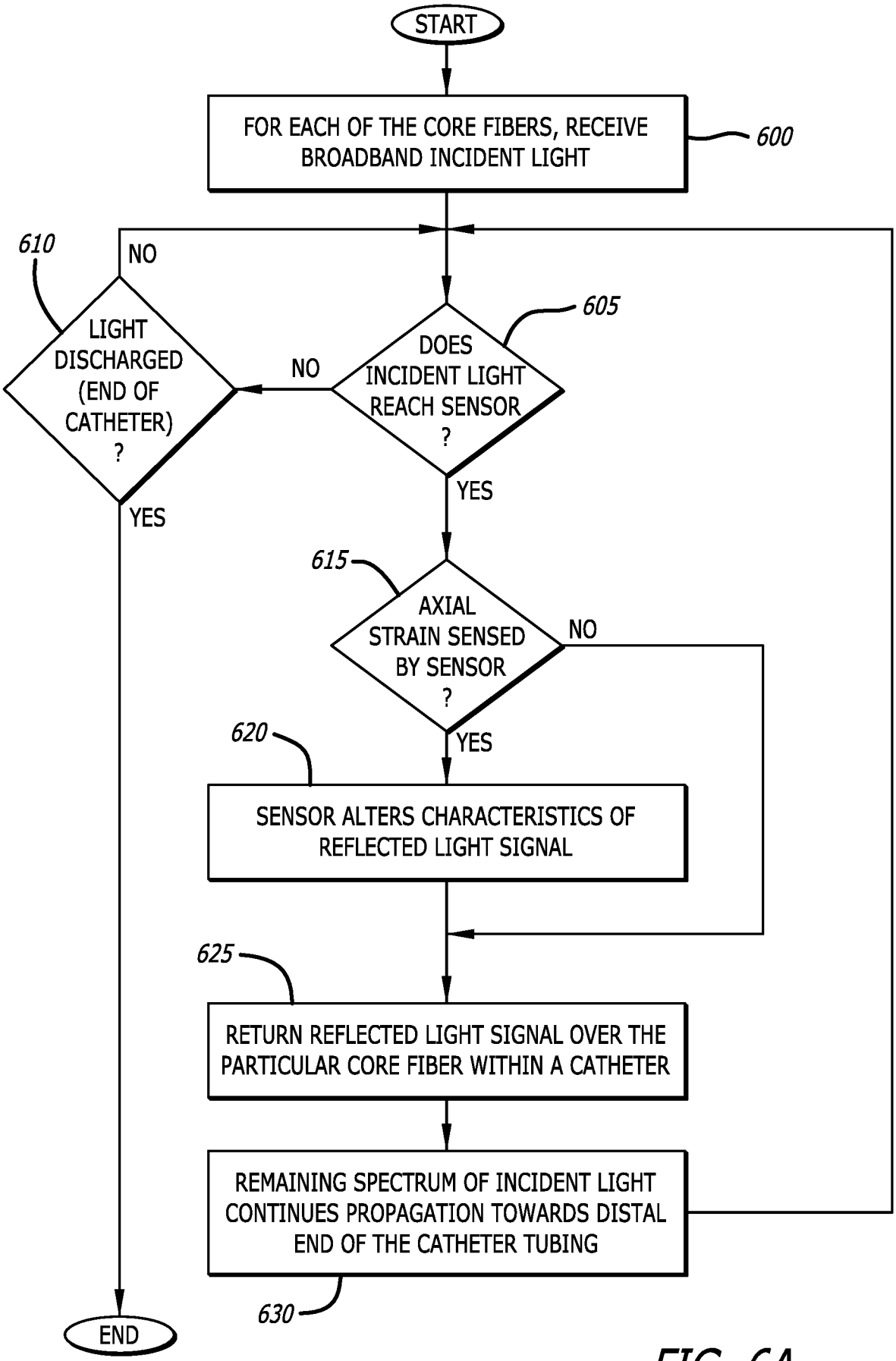

START
FOR EACH OF THE CORE FIBERS, RECEIVE BROADBAND INCIDENT LIGHT
600
610
NO
LIGHT DISCHARGED (END OF CATHETER) ?
605
DOES INCIDENT LIGHT REACH SENSOR ?
NO
YES
YES
615
AXIAL STRAIN SENSED BY SENSOR ?
NO
YES
620
SENSOR ALTERS CHARACTERISTICS OF REFLECTED LIGHT SIGNAL
625
RETURN REFLECTED LIGHT SIGNAL OVER THE PARTICULAR CORE FIBER WITHIN A CATHETER
REMAINING SPECTRUM OF INCIDENT LIGHT CONTINUES PROPAGATION TOWARDS DISTAL END OF THE CATHETER TUBING
630
END

FIG. 6A

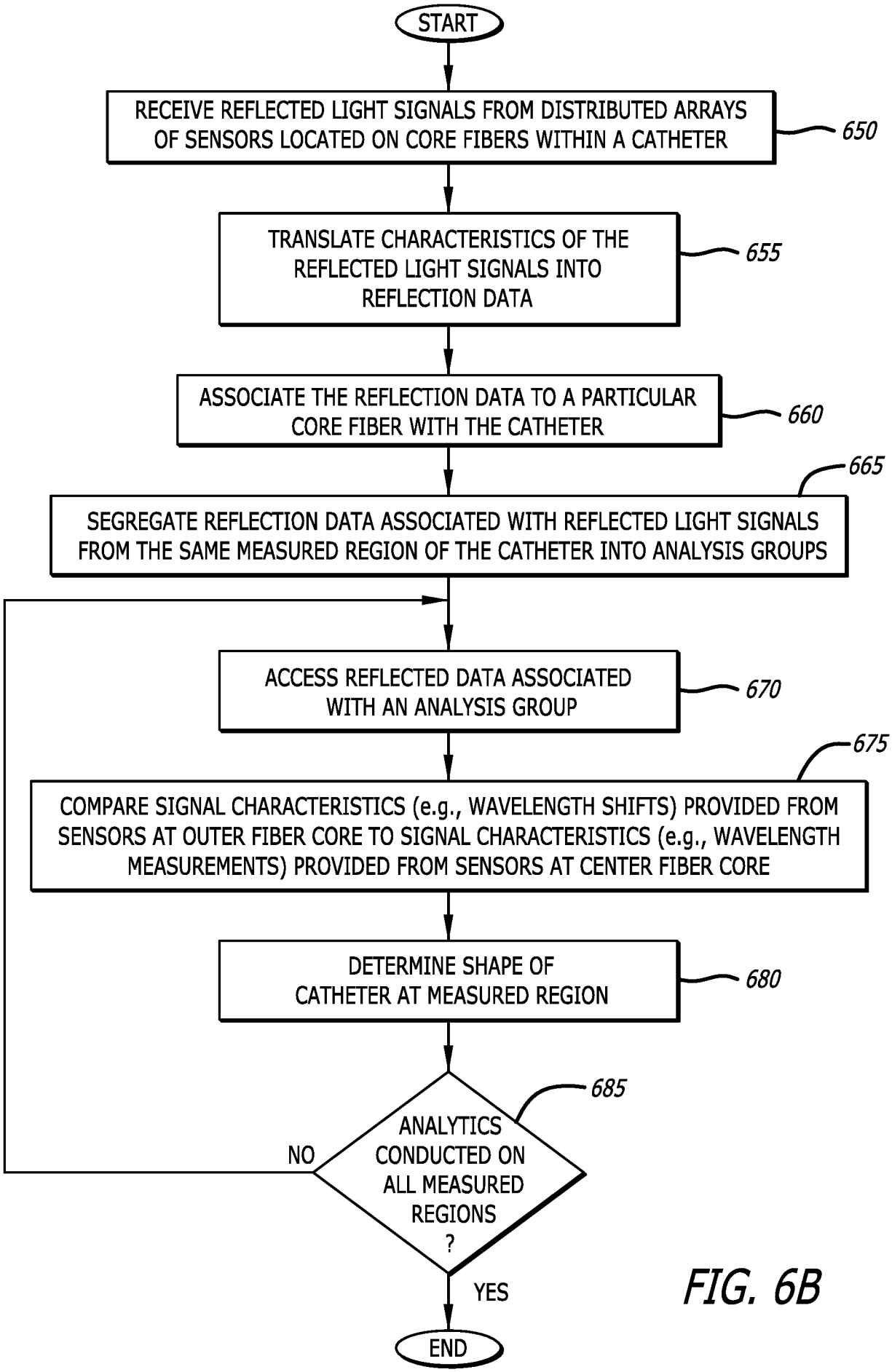

START
RECEIVE REFLECTED LIGHT SIGNALS FROM DISTRIBUTED ARRAYS OF SENSORS LOCATED ON CORE FIBERS WITHIN A CATHETER
650
TRANSLATE CHARACTERISTICS OF THE REFLECTED LIGHT SIGNALS INTO REFLECTION DATA
655
ASSOCIATE THE REFLECTION DATA TO A PARTICULAR CORE FIBER WITH THE CATHETER
660
665
SEGREGATE REFLECTION DATA ASSOCIATED WITH REFLECTED LIGHT SIGNALS FROM THE SAME MEASURED REGION OF THE CATHETER INTO ANALYSIS GROUPS
ACCESS REFLECTED DATA ASSOCIATED WITH AN ANALYSIS GROUP
670
675
COMPARE SIGNAL CHARACTERISTICS (e.g., WAVELENGTH SHIFTS) PROVIDED FROM SENSORS AT OUTER FIBER CORE TO SIGNAL CHARACTERISTICS (e.g., WAVELENGTH MEASUREMENTS) PROVIDED FROM SENSORS AT CENTER FIBER CORE
DETERMINE SHAPE OF CATHETER AT MEASURED REGION
680
685
ANALYTICS CONDUCTED ON ALL MEASURED REGIONS ?
NO
YES
END

FIG. 6B

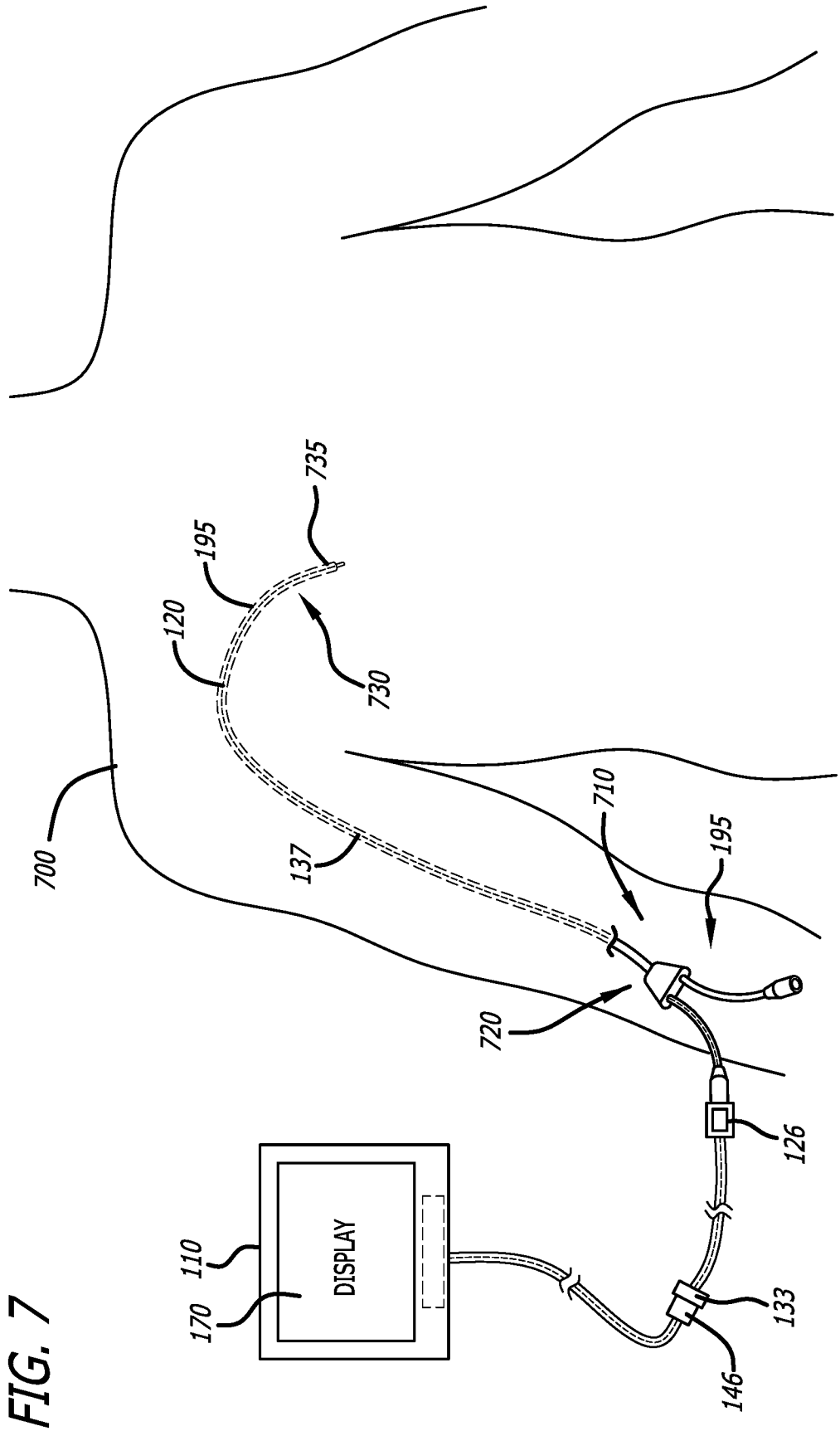
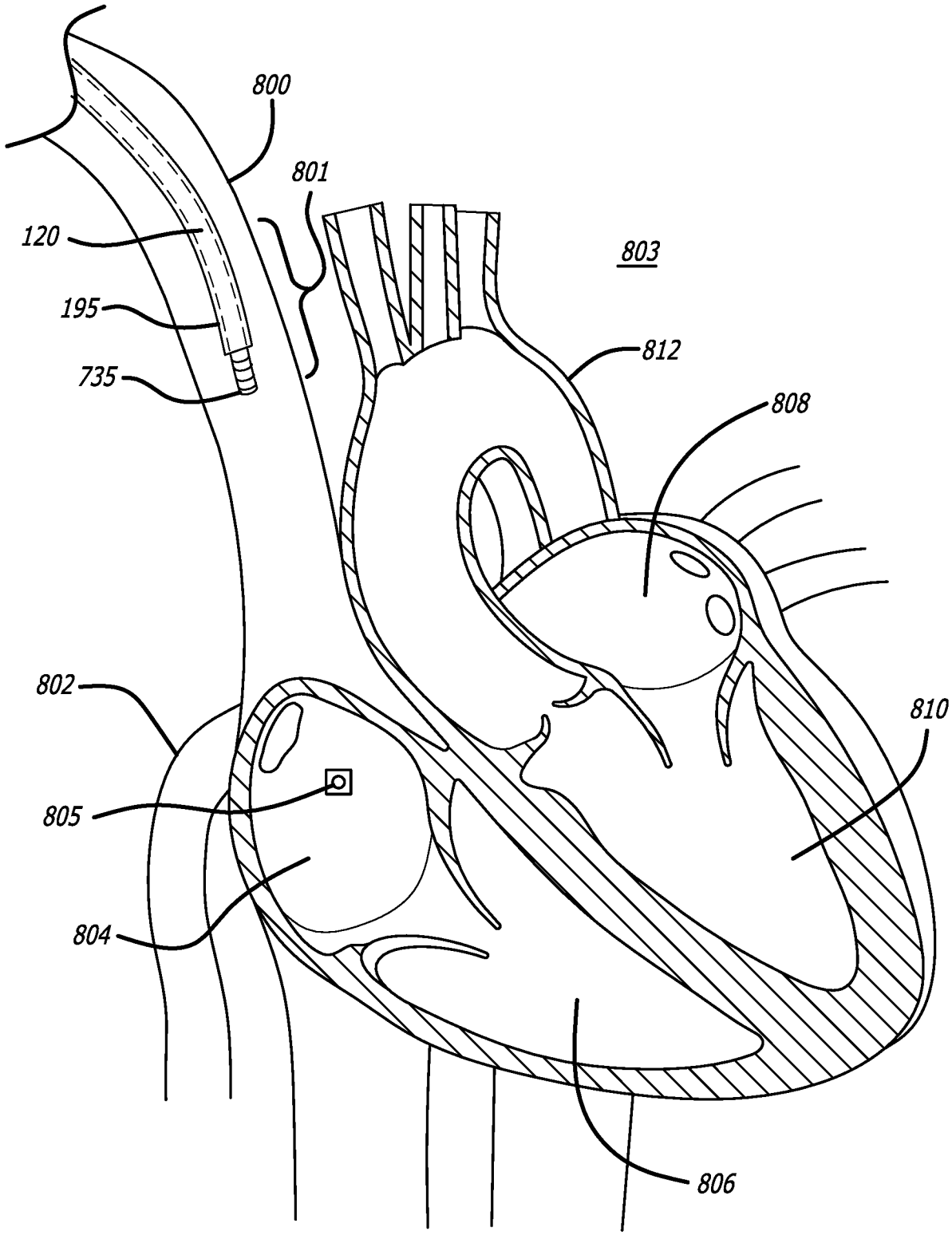



FIG. 7

FIG. 8A



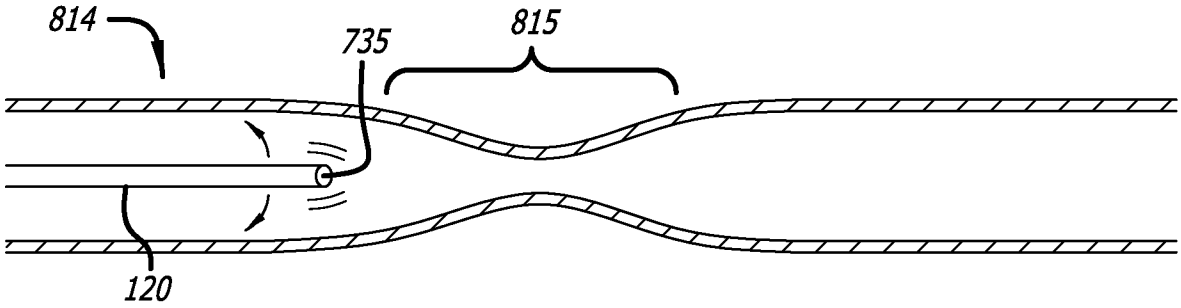



FIG. 8B

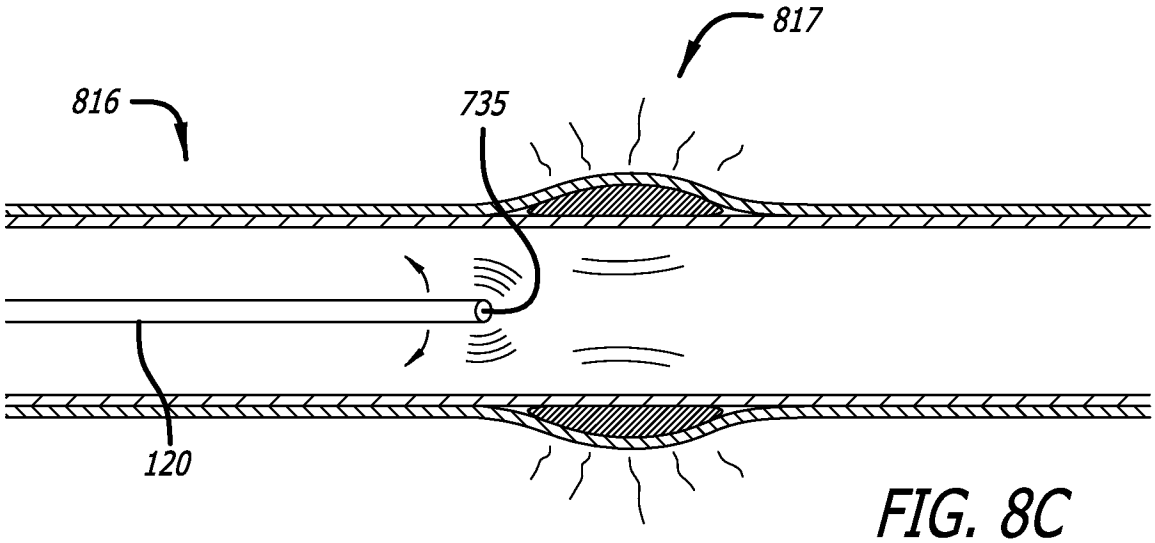



FIG. 8C

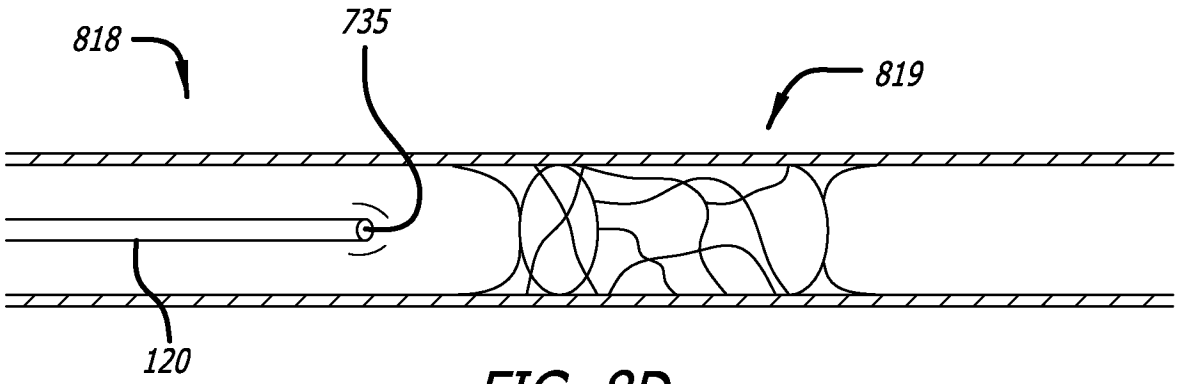



FIG. 8D

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2021/044216

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/06
ADD. G01L1/24 A61B5/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B G01L

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| A | paragraphs [0006], [0021] - [0023], [0029], [0033], [0048], [0051]; claims 10,11 | 7,18,29 |
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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

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

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

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

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 9 November 2021 | 18/11/2021 |

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

3

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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International application No
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Information on patent family members

International application No
PCT/US2021/044216

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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