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(54) **MALPOSITION DETECTION SYSTEM**

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CPC ***A61B 34/20*** (2016.02); ***A61B 5/068*** (2013.01); ***G01D 5/3538*** (2013.01); ***G02B 6/02042*** (2013.01); *A61B 2034/2061* (2016.02)

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CPC . A61B 34/20; A61B 5/068; A61B 2034/2061; G01D 5/3538; G02B 6/02042
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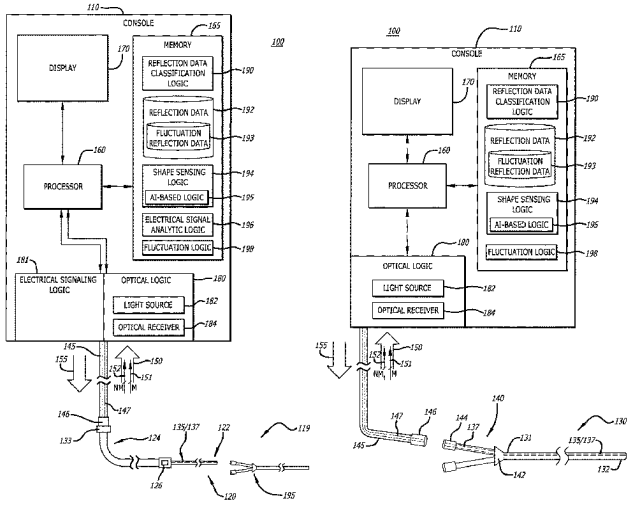
(57) **ABSTRACT**

A system, apparatus and method directed to detecting malposition of a medical device within a vessel of a patient, such as an Azygos vein. The medical device can include a multi-core optical fiber including a plurality of core fibers, where each of the plurality of core fibers includes a plurality of sensors is configured to reflect a light signal based on received incident light, and change a characteristic of the reflected light signal for use in determining a physical state of the multi-core optical fiber. The system can include a console having non-transitory computer-readable medium storing logic that, when executed, causes operations of providing a broadband incident light signal to the multi-core optical fiber, receiving reflected light signals, processing the reflected light signals, and determining whether the medical device has entered the Azygos vein of the patient based on the reflected light signals.

12 Claims, 14 Drawing Sheets



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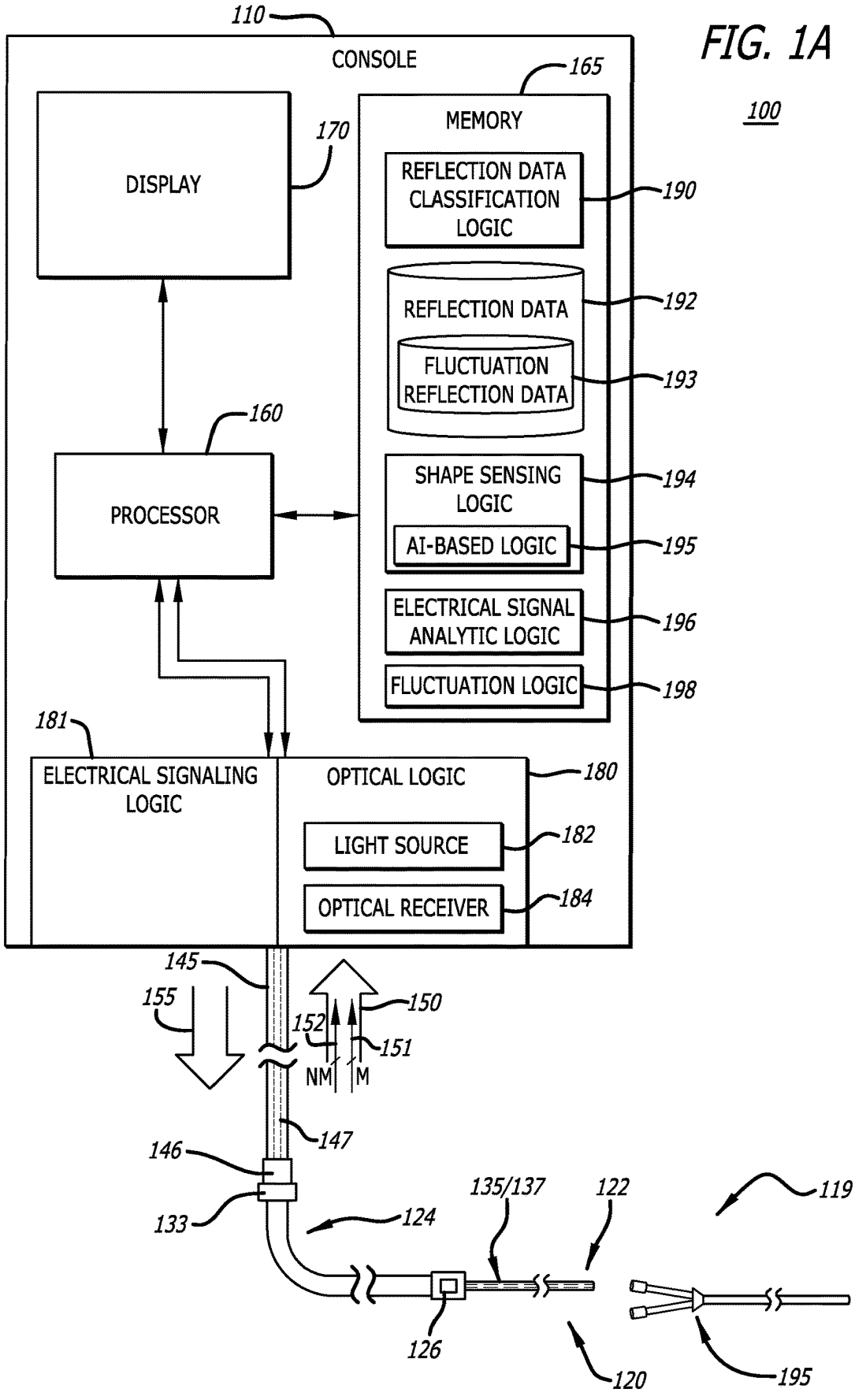
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MEMORY
DISPLAY
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REFLECTION DATA CLASSIFICATION LOGIC
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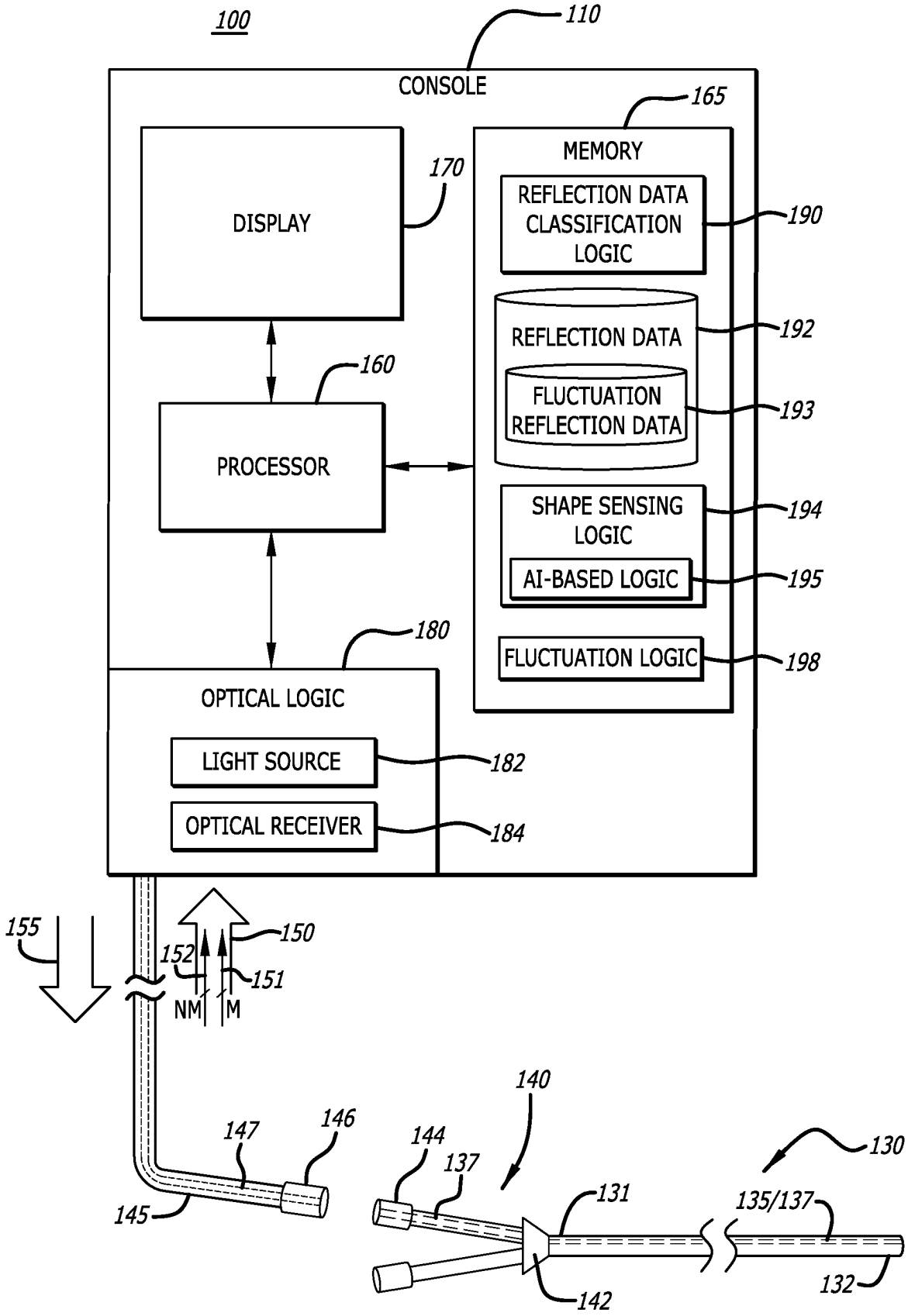
REFLECTION DATA
192
FLUCTUATION REFLECTION DATA
193
160
PROCESSOR
SHAPE SENSING LOGIC
194
AI-BASED LOGIC
195
ELECTRICAL SIGNAL ANALYTIC LOGIC
196
FLUCTUATION LOGIC
198
181
ELECTRICAL SIGNALING LOGIC
OPTICAL LOGIC
180
LIGHT SOURCE
182
OPTICAL RECEIVER
184
145
155
150
152
151
NM
M
147
146
133
124
135/137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

FIG. 1A

100

FIG. 1B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OPTICAL LOGIC
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135/137
145
142
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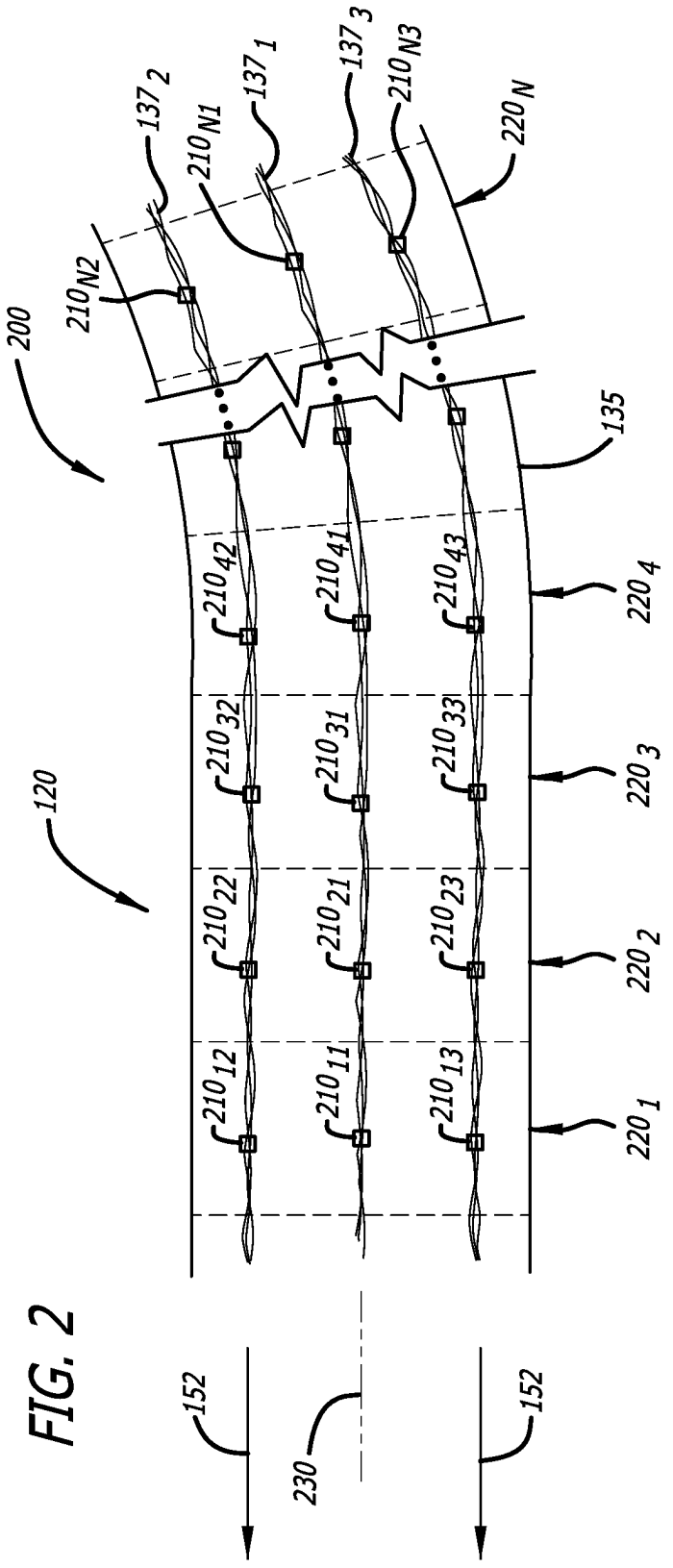
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120
135
152
230
152
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210_{N1}
137_1
137_3
210_{N3}
220_N
210_{N2}
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210_{41}
210_{43}
220_4
210_{32}
210_{31}
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210_{12}
210_{11}
210_{13}
220_1

FIG. 2

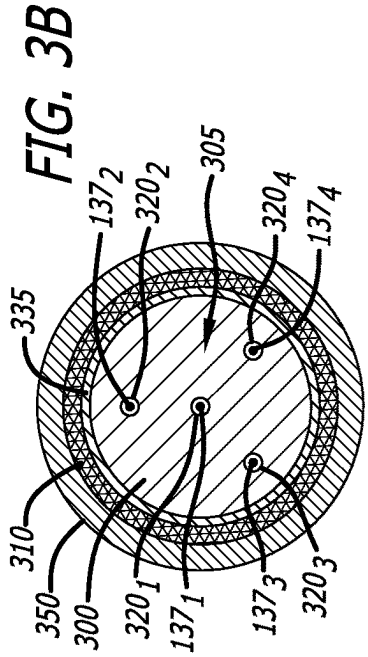


FIG. 3B

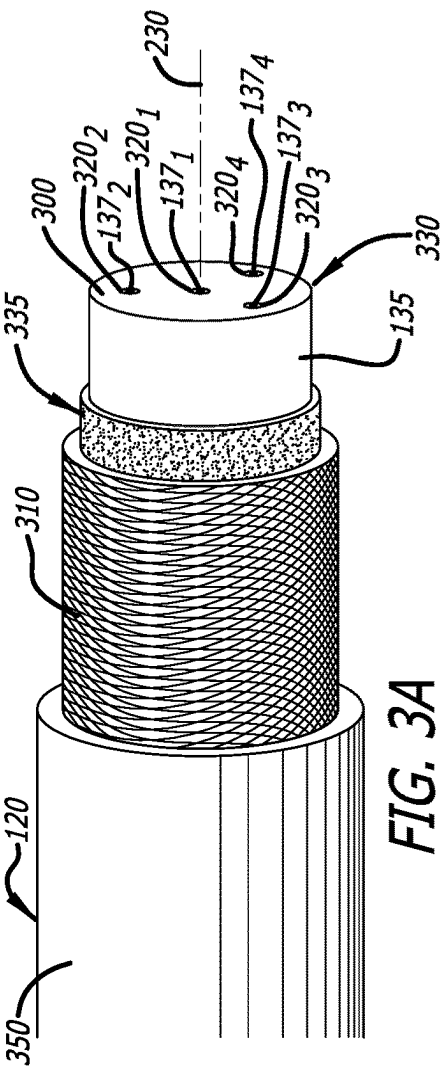


FIG. 3A

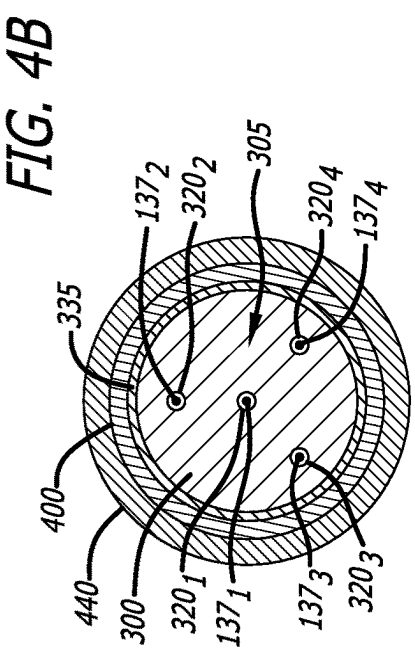


FIG. 4B

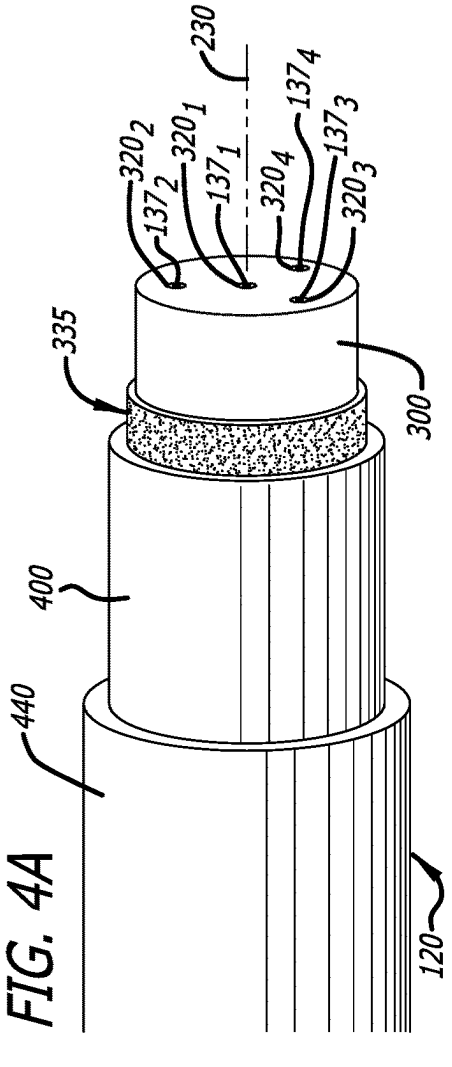
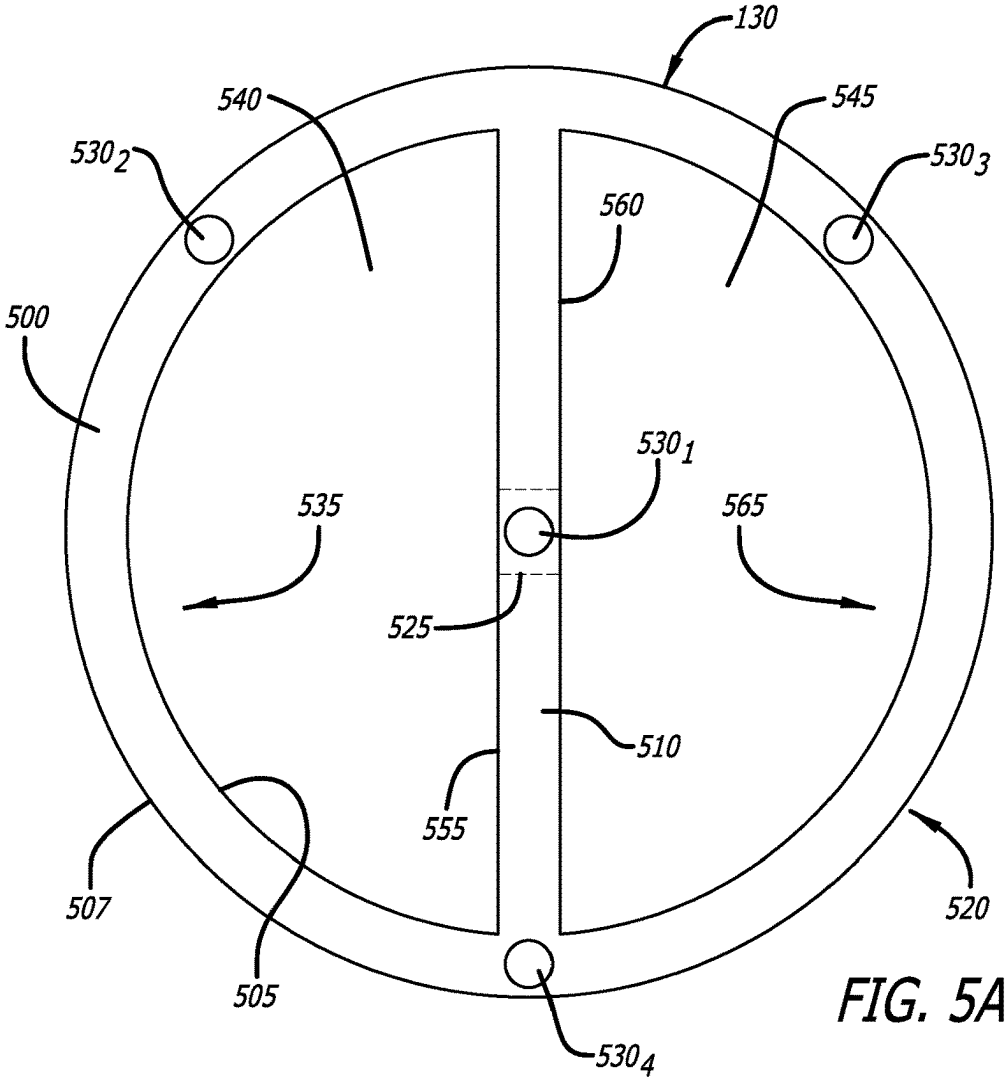


FIG. 4A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540
545
530_2
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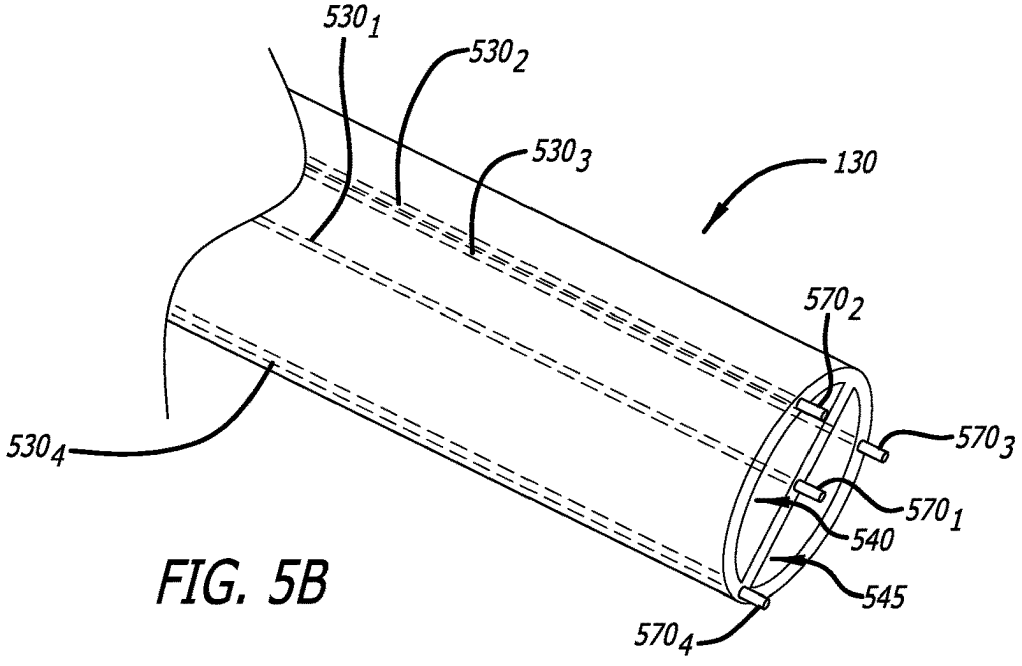
500
530_1
535
565
525
510
555
507
520
505
530_4

FIG. 5A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530_2
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570_2
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570_3
570_1
540
545
570_4

FIG. 5B

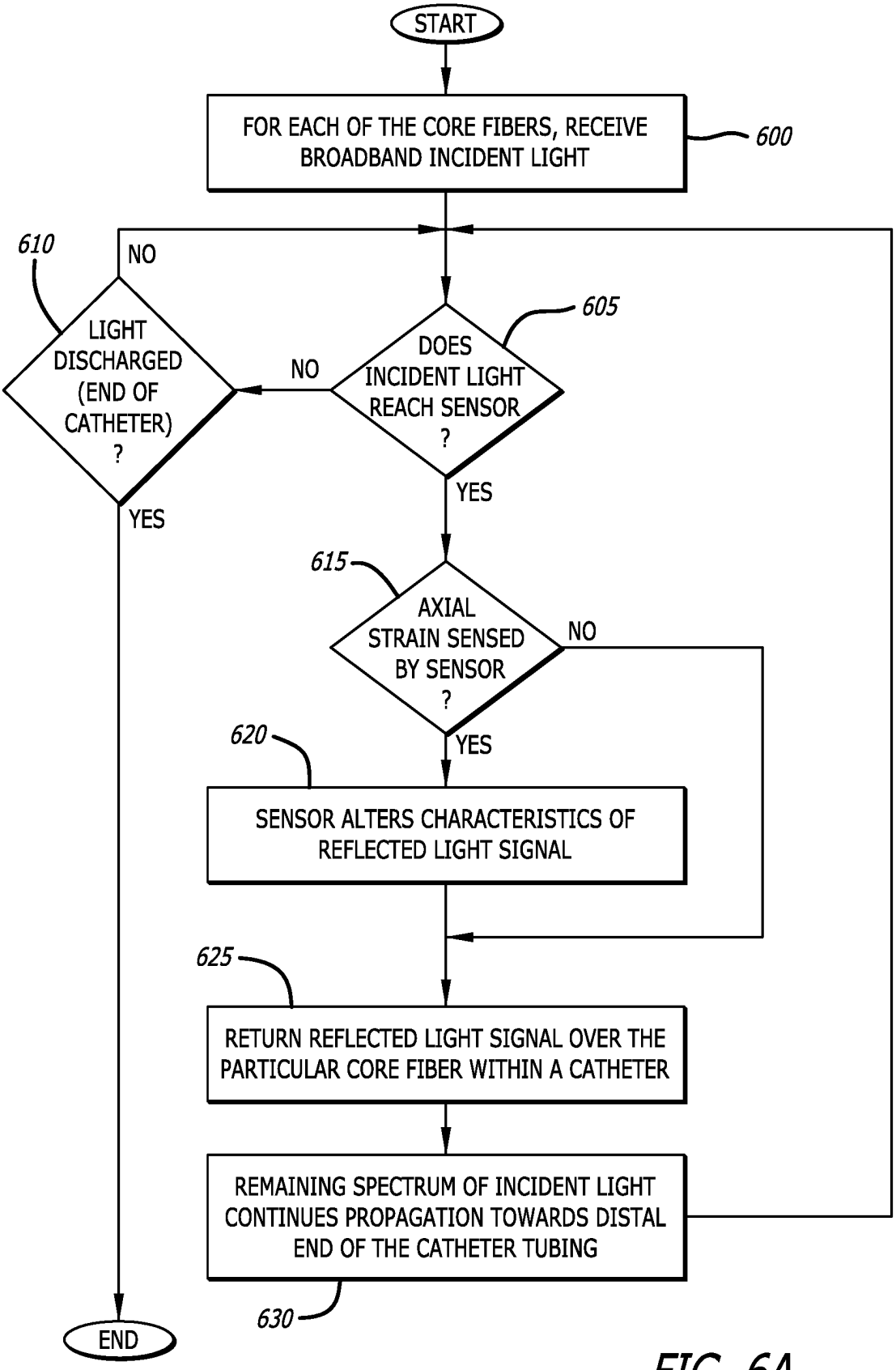

START
FOR EACH OF THE CORE FIBERS, RECEIVE BROADBAND INCIDENT LIGHT
600
605
DOES INCIDENT LIGHT REACH SENSOR ?
NO
YES
610
LIGHT DISCHARGED (END OF CATHETER) ?
NO
YES
615
AXIAL STRAIN SENSED BY SENSOR ?
NO
YES
620
SENSOR ALTERS CHARACTERISTICS OF REFLECTED LIGHT SIGNAL
625
RETURN REFLECTED LIGHT SIGNAL 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

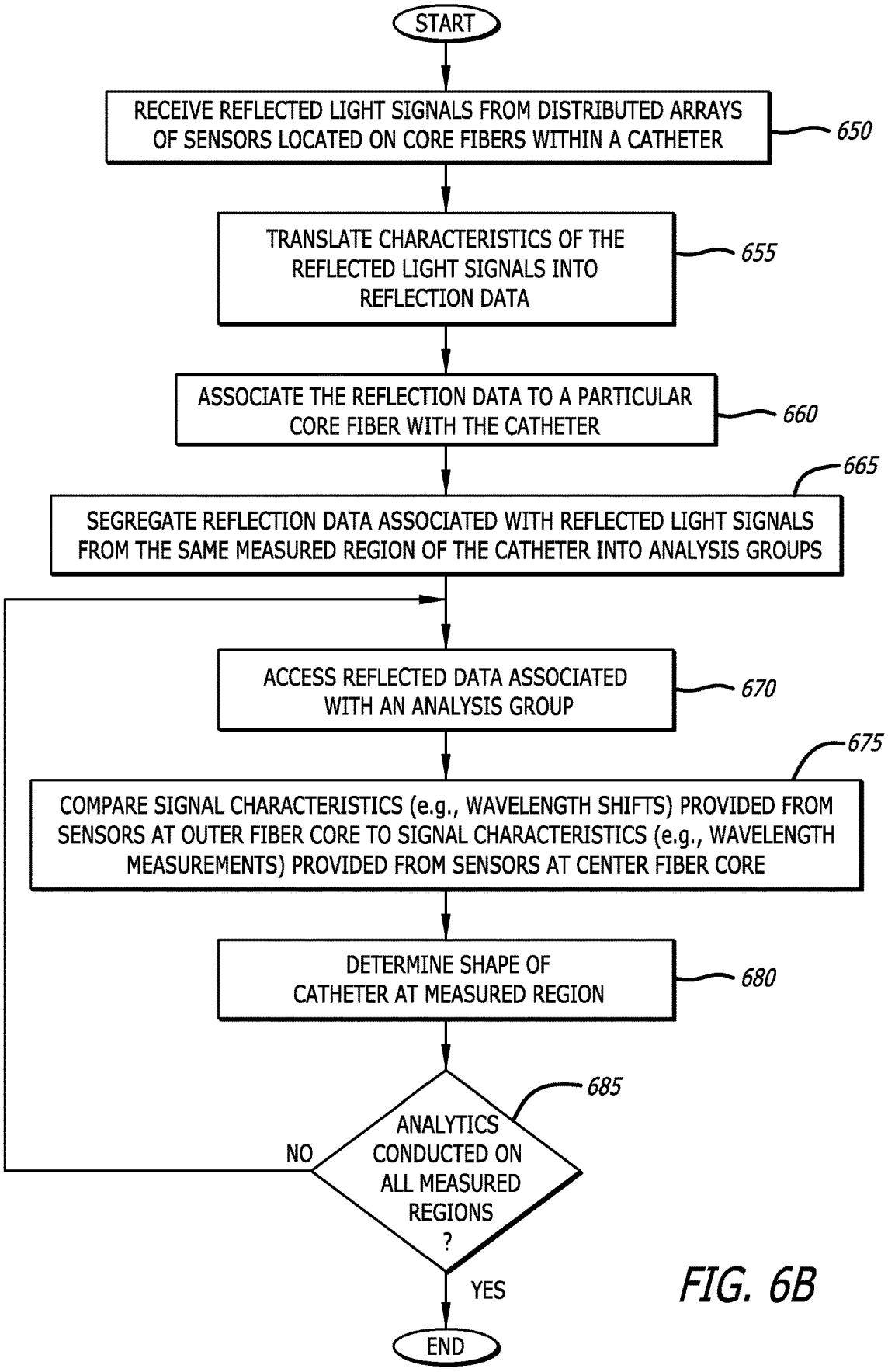
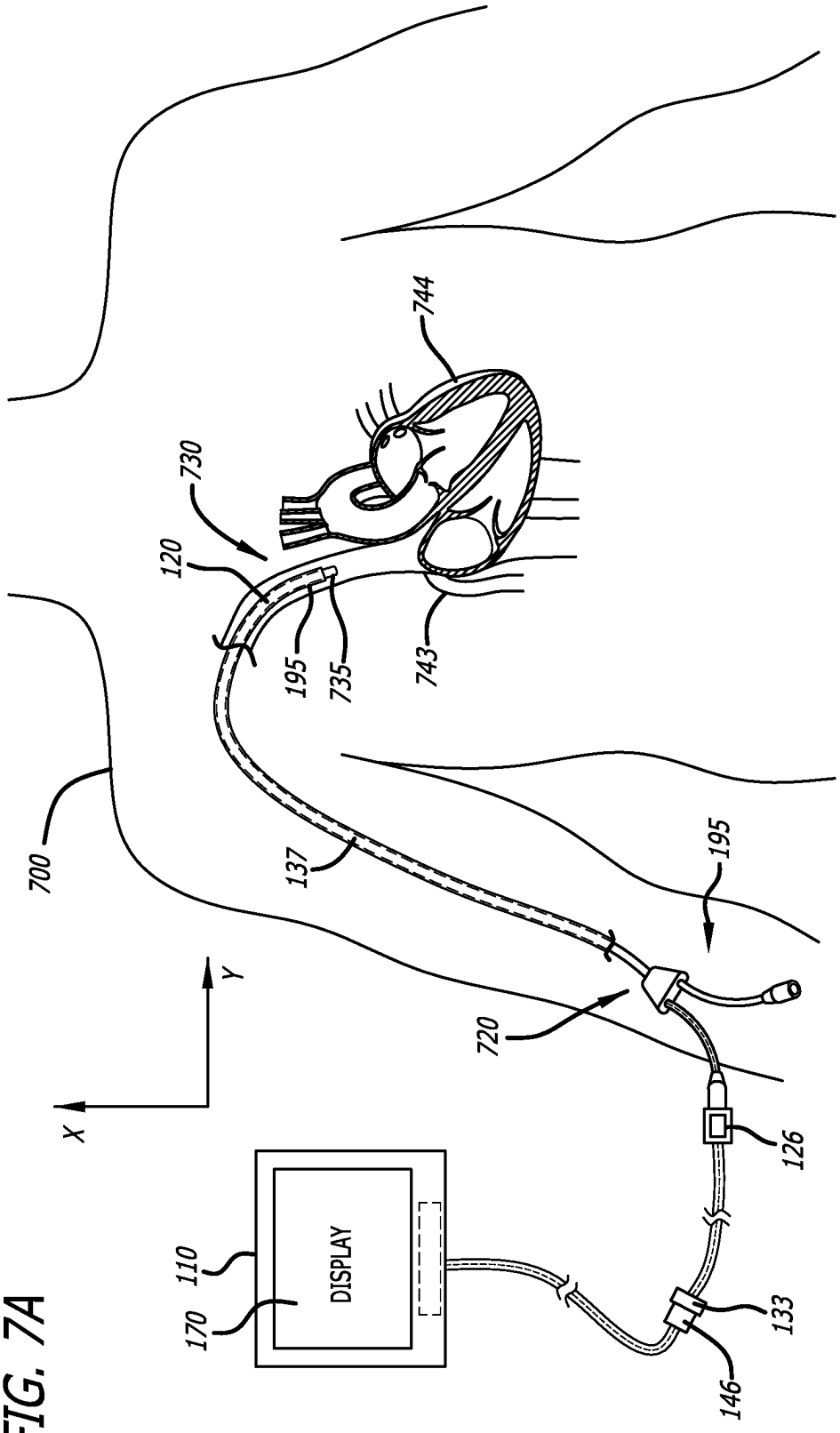

START
RECEIVE REFLECTED LIGHT SIGNALS FROM DISTRIBUTED ARRAYS OF SENSORS LOCATED ON CORE FIBERS WITHIN A CATHETER
650
TRANSLATE CHARACTERISTICS OF THE REFLECTED LIGHT SIGNALS INTO REFLECTION DATA
655
ASSOCIATE THE REFLECTION DATA TO A PARTICULAR CORE FIBER WITH THE CATHETER
660
665
SEGREGATE REFLECTION 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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DISPLAY
X
Y

FIG. 7A

FIG. 7B

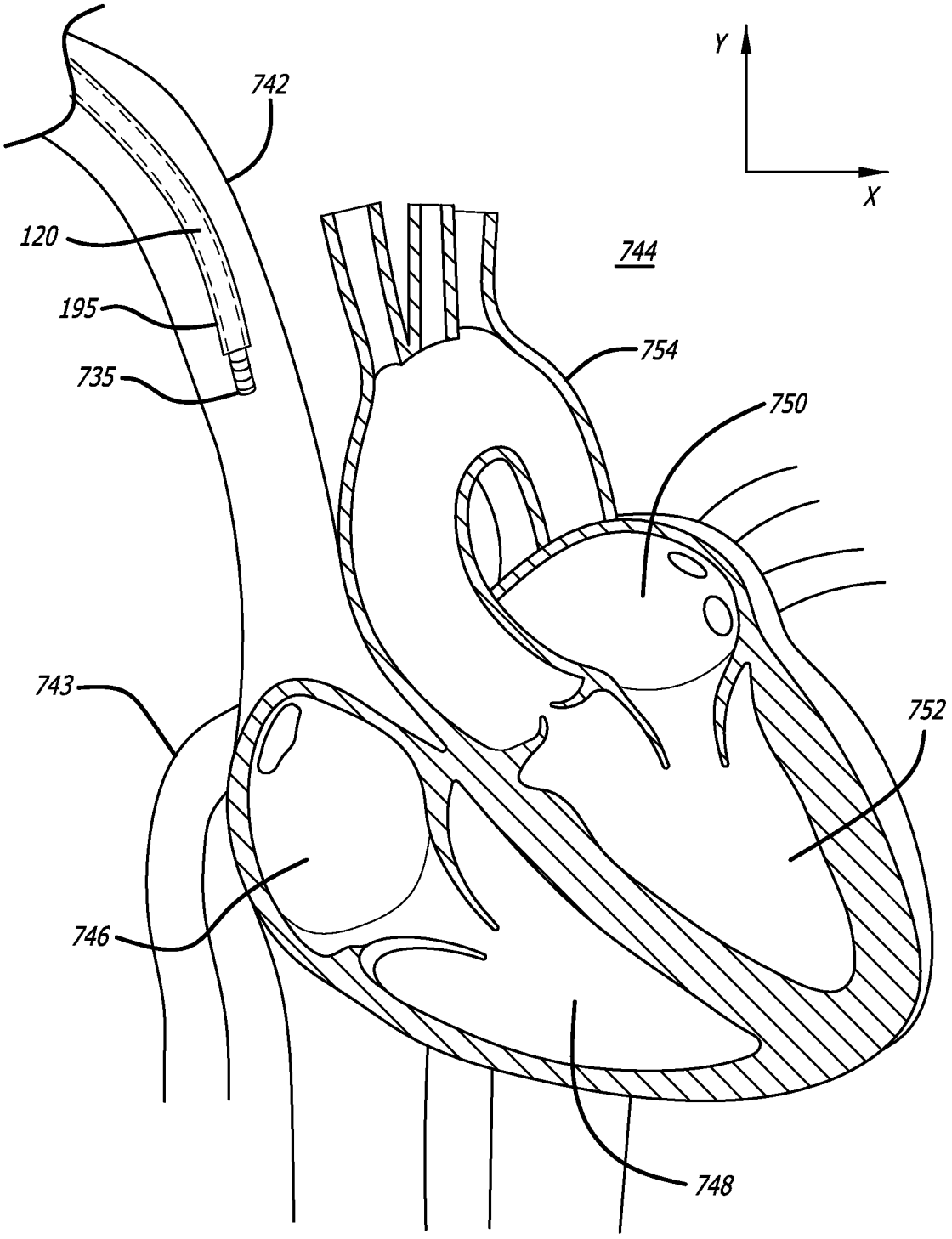


FIG. 8

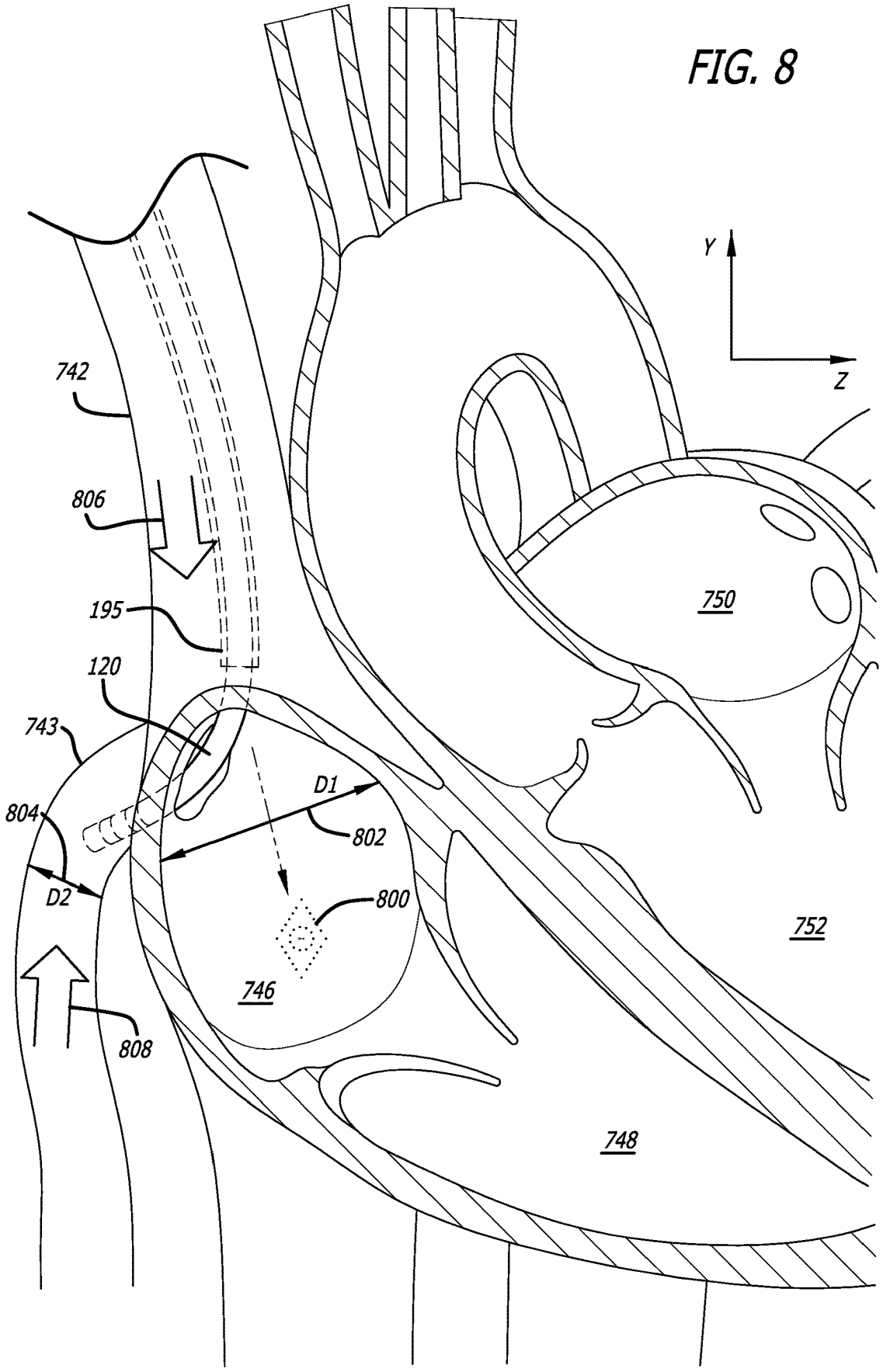
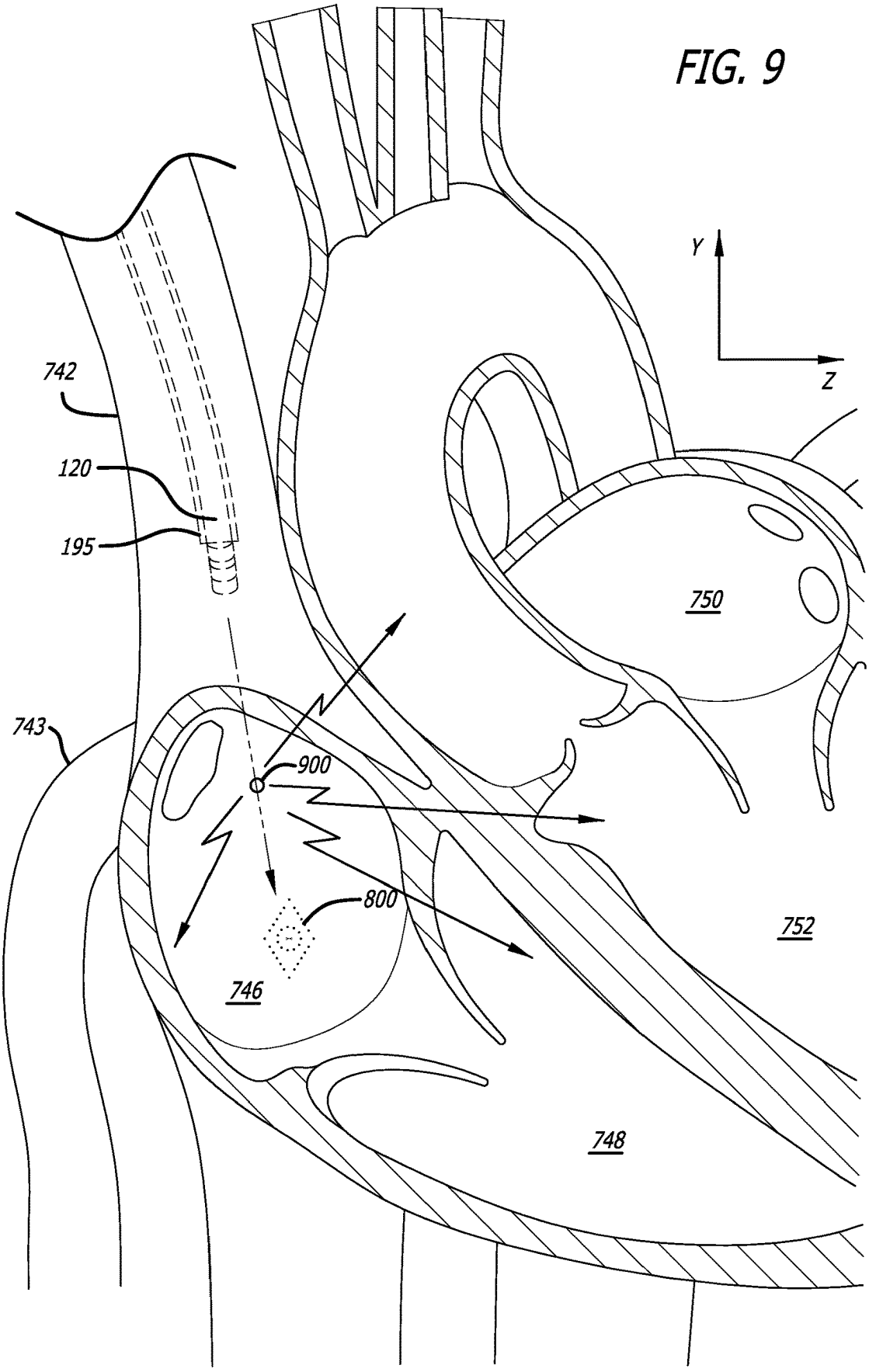


FIG. 9



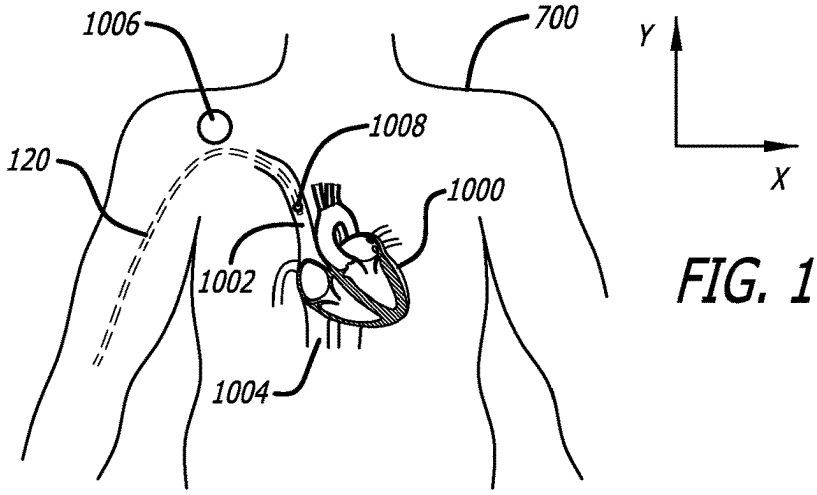


FIG. 10A

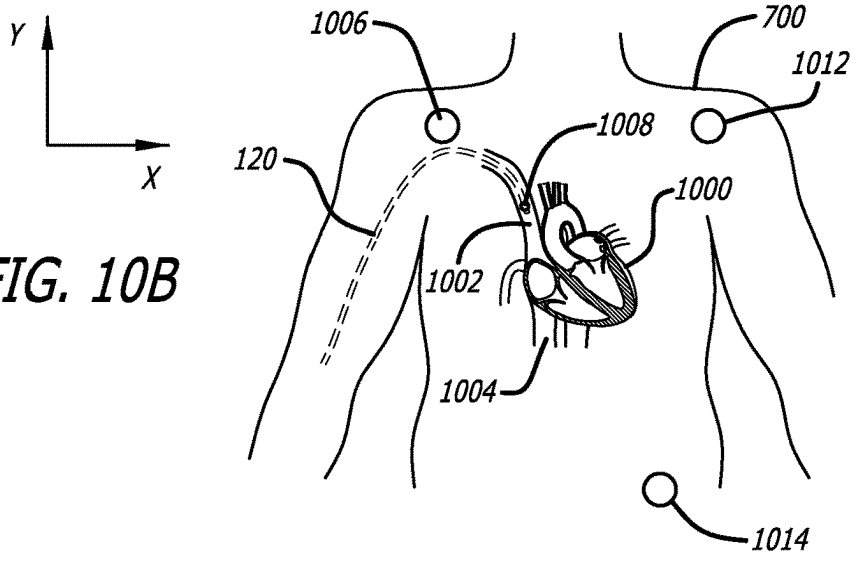


FIG. 10B

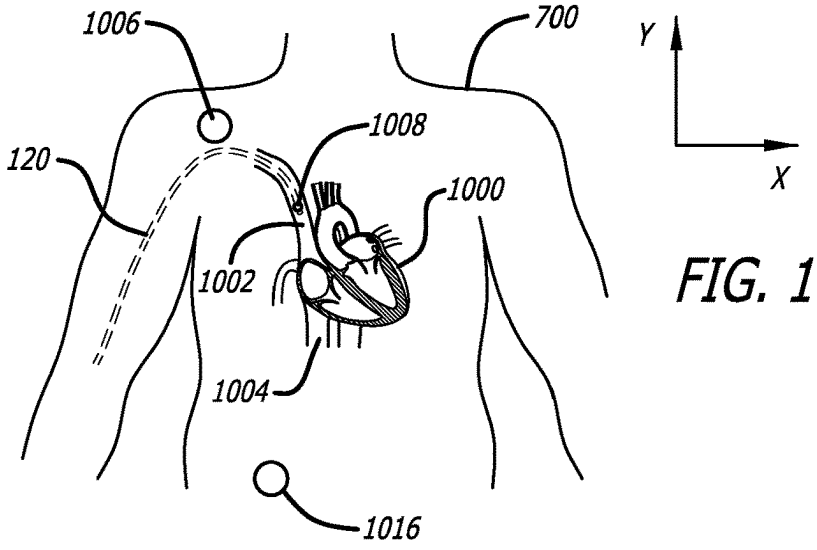


FIG. 10C

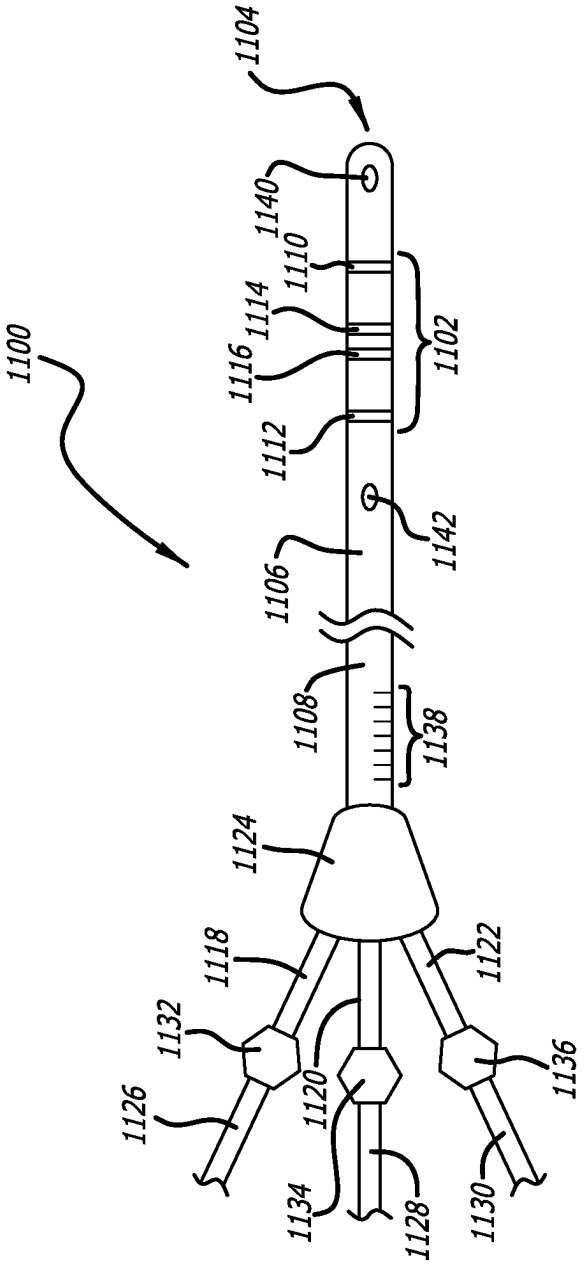

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FIG. 11

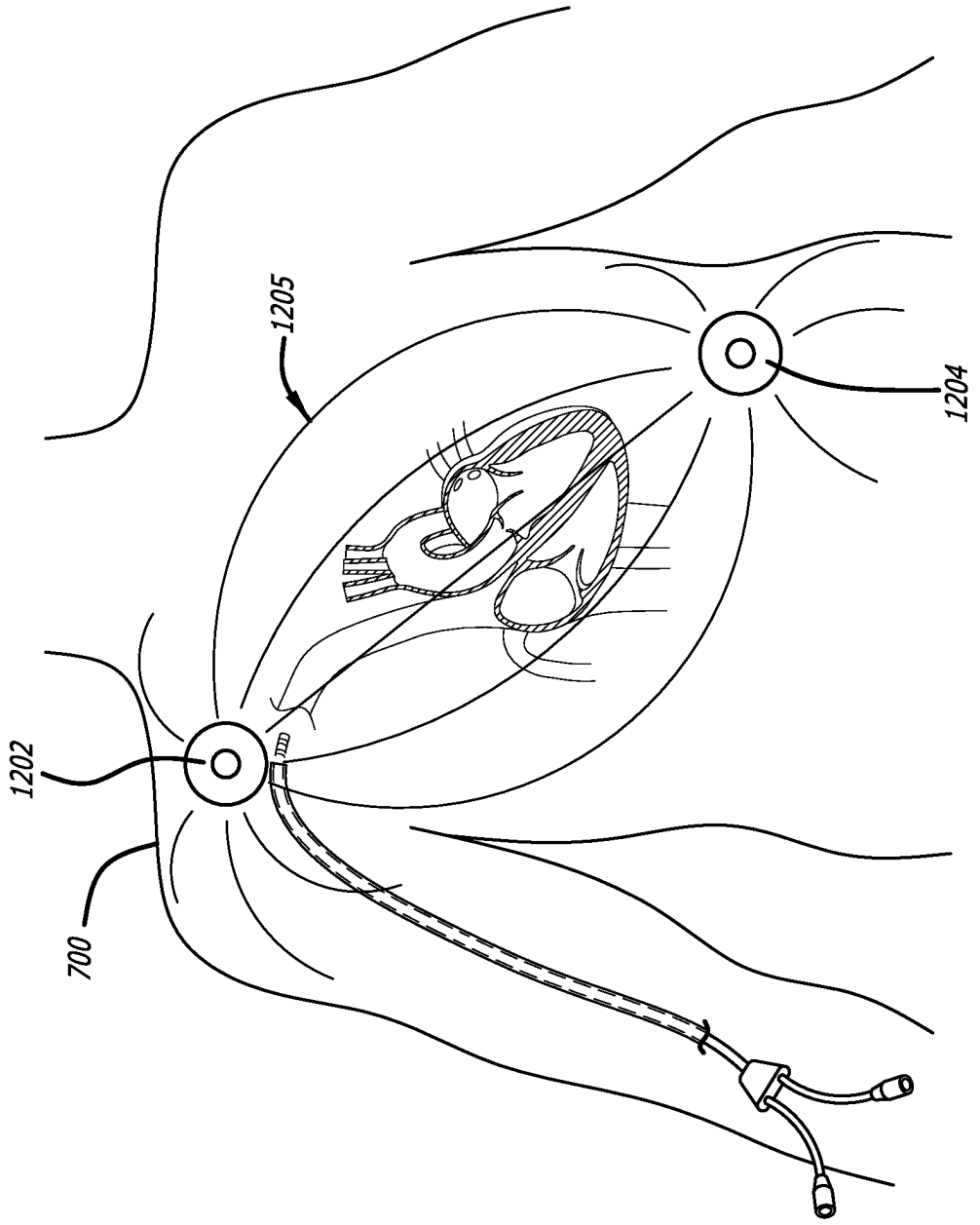

FIG. 12

MALPOSITION DETECTION SYSTEM

PRIORITY

This application is a division of U.S. patent application Ser. No. 17/357,561, filed Jun. 24, 2021, now U.S. Pat. No. 11,622,816, which claims the benefit of priority to U.S. Provisional Application No. 63/044,911, filed Jun. 26, 2020, each of which is incorporated by reference in its entirety into this application.

BACKGROUND

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.

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.

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.

Disclosed herein is a system and method for determining whether a medical device inserted into a patient has deviated from a target advancement path and has entered the vessel of the patient based on one or more signals from the medical device.

SUMMARY

Briefly summarized, some embodiments disclosed herein are directed to systems, apparatuses and methods for obtaining three-dimensional (3D) information (reflected light) corresponding to a trajectory and/or shape of a medical instrument, such as a catheter, a guidewire, or a stylet, during advancement through a vasculature of a patient, and determining malposition of the medical instrument within a vessel of the patient, such as the Azygos vein. In some embodiments, the system is a fiber optic shape sensing system and methods thereof, configured to provide confirmation of tip placement or information passed/interpreted as an electrical signal. Some embodiments combine the fiber optic shape sensing functionality with one or more of intravascular electrocardiogram (ECG) monitoring, impedance/conductance sensing and blood flow directional detection. Although the examples herein are with respect to malposition into the Azygos vein, the invention described herein is not so limited. It should be appreciated that the invention described herein can be used to detect malposition of a medical device in any number of vessels and locations in a patient, and is not intended to be specific to malposition into the Azygos vein.

More particularly, in some embodiments, the medical instrument includes a multi-core optical fiber, with each core fiber of the multi-core optical fiber is 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 multi-core optical fiber 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 multi-core optical fiber toward the distal end. 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 enable 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.

The reflected light from the sensors (reflective gratings) within each core fiber of the multi-core optical fiber 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 each core fiber, causes different degrees of deformation. The different degrees of deformation alters the shape of the sensors (reflective grating) positioned on the core fiber, which may cause variations (shifts) in the wavelength of the reflected light from the sensors positioned on each core fiber within the multi-core optical fiber, as shown in FIGS. **2**-**5**B and **7**A-**13**.

Specific embodiments of the disclosure include utilization of a stylet featuring a multi-core optical fiber and a conductive medium that collectively operate for tracking placement of a catheter or other medical device within a body of a patient. The 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.

In some embodiments in which the stylet includes a multi-core optical fiber, each 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.

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 enable 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.

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.

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.

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).

Embodiments of the disclosure may include a combination of one or more of the methodologies to determine when a body of implementation (e.g., catheter, guidewire, and/or stylet) has deviated from its target trajectory (e.g., into the right atrium) and instead into an undesired location (e.g., the Azygos vein). Certain embodiments of the disclosure pertain to distal tip location detection using fiber optic shape sensing such that deviation of the body of implementation into the negative-Z plane (dorsal movement of the body of implementation) can be detected and identified using analysis of reflected light through a multi-core optical fiber as discussed below. For example, the use of fiber optic shape sensing may analyze the reflected light in comparison to predetermined anatomical angles, deviation from an identified reference plane (with identified anterior/posterior orientation), and/or deviation from a predetermined anatomical frame.

Further embodiments of the disclosure pertain to the use of fiber optic shape sensing to detect fluctuation of the body of implementation. For example, deviation of the advancement of the body of implementation out of the SVC into the Azygos vein is identified via a reduction in fluctuations in the body of implementation. Additionally, intravascular ECG monitoring may be combined with either or both of the fiber optic shape sensing methodologies referenced above to detect deviation of the advancement of the body of implementation into the Azygos vein as the detected P-wave of the intravascular ECG decreases in slightly in amplitude even as the body of implementation is advanced towards the sinoatrial (SA) node. Additionally, or in the alternative, impedance/conductance sensing may be combined with either or both of the fiber optic shape sensing methodologies and, optionally, the ECG intravascular ECG monitoring to detect deviation of the advancement of the body of implementation into the Azygos vein. For instance, as the body of implementation deviates into the Azygos vein the smaller diameter vessel is characterized by a varied impedance/conductance.

In yet other embodiments, the direction of the blood flow may be utilized in combination with any of the fiber optic shape sensing methodologies, intravascular ECG monitoring and/or impedance/conductance sensing referenced above. For instance, as the body of implementation deviates into the Azygos vein, the flow of blood will change from in-line with the advancement of the body of implementation to against the advancement of the body of implementation, which may be detected using pulse oximetry and/or blood flow Doppler. For instance, detection using pulse oximetry includes measurement and analysis of the oxygen levels within the blood as the body of implementation advances through the vasculature. Specifically, analysis of the oxygen

levels may vary from vessel to vessel such that detection of deviation of the distal tip of the body of implementation into the Azygos vein may be detected when the measured oxygen level decreases when the distal tip is in the heart. Specifically, the oxygen level may decrease as the distal tip of the body of implementation advances from a larger vessel (SVC) to a smaller vessel (Azygos vein).

Some embodiments herein disclose a medical device system for detecting malposition of a medical device within a vessel of a patient, such as an Azygos vein, the system including the medical device comprising a multi-core optical fiber having a plurality of core fibers, each of the plurality of 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 for use in determining a physical state of the multi-core optical fiber and a console. The console includes 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 multi-core optical fiber, receiving reflected light signals of different spectral widths of the broadband incident light reflected by each of the plurality of sensors, processing the reflected light signals associated with the plurality of core fibers, and determining whether the medical device has entered the Azygos vein of the patient based on the reflected light signals.

In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on a shape of the medical device indicated by the reflected light signals. In some embodiments, the shape of the medical device is indicated by the reflected light signals is utilized as input to a machine-learning configured to process the input and provide a result indicating a confidence level as to whether the shape of the medical device indicates entry into the Azygos vein of the patient. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based a result of heuristics performed on the shape of the medical device indicated by the reflected light signals. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on an amount of fluctuation of the medical device indicated by the reflected light signals.

In particular embodiments, the amount of fluctuation of the medical device is an amount of fluctuation at a distal tip of the medical device. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and impedance sensing of advancement of the medical device through a vasculature of the patient. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on (i) the shape of the medical device indicated by the reflected light signals, (ii) electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient, and (iii) impedance sensing of the advancement of the medical device through the vasculature of the patient.

In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and detection of a direction of blood flow within a portion of a vasculature of the patient in which the medical device is currently disposed. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and one or more of (i) electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient, (ii) impedance sensing of the advancement of the medical device through the vasculature of the patient, or (iii) detection of a direction of blood flow within a portion of the vasculature of the patient in which the medical device is currently disposed.

In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on (i) the shape of the medical device indicated by the reflected light signals, (ii) electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient, (iii) impedance sensing of the advancement of the medical device through the vasculature of the patient, and (iv) detection of a direction of blood flow within a portion of the vasculature of the patient in which the medical device is currently disposed.

In particular embodiments, the different types of strain include compression and tension. In other embodiments, the medical device includes an elongated shape and is inserted into a vasculature of the body of the patient. In some embodiments, the medical device is a stylet removably inserted into a lumen of a catheter assembly for placement of a distal tip of the catheter assembly in a superior vena cava of the vasculature. In yet other embodiments, at least two of the plurality of core fibers to experience different types of strain in response to changes in an orientation of the multi-core optical fiber. In yet further 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.

Further embodiments relate to a method for placing a medical device into a body of a patient, the method comprising providing a broadband incident light signal to a multi-core optical fiber included within the medical device, wherein the multi-core optical fiber includes a plurality of core fibers, each of the plurality 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 for use in determining a physical state of the multi-core optical fiber, receiving reflected light signals of different spectral widths of the broadband incident light reflected by each of a plurality of reflective gratings, processing the reflected light signals associated with the plurality of core fibers, and determining whether the medical device has entered the Azygos vein of the patient based on the reflected light signals.

In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on a shape of the medical device indicated by the reflected light signals. In some embodiments, the shape of the medical device is indicated by the reflected light

signals is utilized as input to a machine-learning configured to process the input and provide a result indicating a confidence level as to whether the shape of the medical device indicates entry into the Azygos vein of the patient. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based a result of heuristics performed on the shape of the medical device indicated by the reflected light signals. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on an amount of fluctuation of the medical device indicated by the reflected light signals.

In particular embodiments, the amount of fluctuation of the medical device is an amount of fluctuation at a distal tip of the medical device. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and impedance sensing of advancement of the medical device through a vasculature of the patient. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on (i) the shape of the medical device indicated by the reflected light signals, (ii) electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient, and (iii) impedance sensing of the advancement of the medical device through the vasculature of the patient.

In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and detection of a direction of blood flow within a portion of a vasculature of the patient in which the medical device is currently disposed. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and one or more of (i) electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient, (ii) impedance sensing of the advancement of the medical device through the vasculature of the patient, or (iii) detection of a direction of blood flow within a portion of the vasculature of the patient in which the medical device is currently disposed.

In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on (i) the shape of the medical device indicated by the reflected light signals, (ii) electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient, (iii) impedance sensing of the advancement of the medical device through the vasculature of the patient, and (iv) detection of a direction of blood flow within a portion of the vasculature of the patient in which the medical device is currently disposed.

In particular embodiments, the different types of strain include compression and tension. In other embodiments, the medical device includes an elongated shape and is inserted into a vasculature of the body of the patient. In some embodiments, the medical device is a stylet removably inserted into a lumen of a catheter assembly for placement of a distal tip of the catheter assembly in a superior vena cava of the vasculature. In yet other embodiments, at least two of the plurality of core fibers to experience different types of strain in response to changes in an orientation of the multi-core optical fiber. In yet further 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 of disclose a non-transitory computer-readable medium having stored thereon logic that, when executed by the one or more processors, causes operations. The operations include providing a broadband incident light signal to a multi-core optical fiber included within the medical device, wherein the multi-core optical fiber includes a plurality of core fibers, each of the plurality of core fibers including a plurality of reflective gratings distributed along a longitudinal length of a corresponding core fiber and each reflective grating 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 for use in determining a physical state of the multi-core optical fiber, receiving reflected light signals of different spectral widths of the broadband incident reflected each of the plurality of reflective gratings, processing the reflected light signals associated with the plurality of core fibers, and determining whether the medical device has entered the Azygos vein of the patient based on the reflected light signals.

In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on a shape of the medical device indicated by the reflected light signals. In some embodiments, the shape of the medical device is indicated by the reflected light signals is utilized as input to a machine-learning configured to process the input and provide a result indicating a confidence level as to whether the shape of the medical device indicates entry into the Azygos vein of the patient. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based a result of heuristics performed on the shape of the medical device indicated by the reflected light signals. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on an amount of fluctuation of the medical device indicated by the reflected light signals.

In particular embodiments, the amount of fluctuation of the medical device is an amount of fluctuation at a distal tip of the medical device. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and impedance sensing of advancement of the medical device through a vasculature of the patient. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on (i) the shape of the medical device indicated by the reflected light signals, (ii) electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient, and (iii) impedance sensing of the advancement of the medical device through the vasculature of the patient.

In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and detection of a direction of blood flow within a portion of a vasculature of the patient in which the medical device is currently disposed. In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on the shape of the medical device indicated by the reflected light signals and one or more of (i) electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient, (ii) impedance sensing of the advancement of the medical device through the vasculature of the patient, or (iii) detection of a direction of blood flow within a portion of the vasculature of the patient in which the medical device is currently disposed.

In some embodiments, the determining operation determines whether the medical device has entered the Azygos vein is based on (i) the shape of the medical device indicated by the reflected light signals, (ii) electrocardiogram (ECG) monitoring of advancement of the medical device through a vasculature of the patient, (iii) impedance sensing of the advancement of the medical device through the vasculature of the patient, and (iv) detection of a direction of blood flow within a portion of the vasculature of the patient in which the medical device is currently disposed.

In particular embodiments, the different types of strain include compression and tension. In other embodiments, the medical device includes an elongated shape and is inserted into a vasculature of the body of the patient. In some embodiments, the medical device is a stylet removably inserted into a lumen of a catheter assembly for placement of a distal tip of the catheter assembly in a superior vena cava of the vasculature. In yet other embodiments, at least two of the plurality of core fibers to experience different types of strain in response to changes in an orientation of the multi-core optical fiber. In yet further 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.

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

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:

FIG. **1**A 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;

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

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. **1**A in accordance with some embodiments;

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

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

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

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

FIG. **5**A 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;

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

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

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

FIG. **7**B is a detailed view of the stylet of FIG. **7**A in the Superior Vena Cava (SVC) advancing toward the right atrium of the patient in accordance with some embodiments;

FIG. **8** is a first illustration of a stylet advancing through a patient's vasculature toward the right atrium of the patient's heart in accordance with some embodiments;

FIG. **9** is a second illustration of a stylet advancing through a patient's vasculature toward the right atrium of the patient's heart in accordance with some embodiments;

FIGS. **10**A-**10**C are illustrations depicting an electrode configuration that provides for acquisition of endovascular ECG data in accordance some embodiments;

FIG. **11** is an illustration of an exemplary peripherally inserted central catheter in accordance with some embodiments; and

FIG. **12** is an illustration of a system utilizing a second embodiment of a peripherally inserted central in conjunction with two electrode pads in accordance with some embodiments.

DETAILED DESCRIPTION

Before some particular embodiments are disclosed in greater detail, it should be understood that 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.

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.

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.

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.

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.

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.

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**.

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. Pat. No. 10,992,078, 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**.

For both of these 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

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).

Referring still to FIG. **1**A, 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 $\mathbf{137}_1$-$\mathbf{137}_M$ (M=1 for a single core, and M≥2 for a multi-core), where the core fibers $\mathbf{137}_1$-$\mathbf{137}_M$ 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 also that of the catheter **195** configured to receive the stylet **120**.

According to one embodiment of the disclosure, as shown in FIG. **1**A, 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.

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.

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.

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**.

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.

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.

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** measures 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.

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.

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.

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.

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.

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**.

Referring to FIG. **1**B, 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. **1**B include the same characteristics and perform the same functionalities as the core fibers **137** deployed within the stylet **120** of FIG. **1**A.

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).

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.

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**.

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**.

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

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

Referencing the first core fiber $\mathbf{137}_1$ as an illustrative example, when the stylet **120** is operative, each of the reflective gratings $\mathbf{210}_1$-$\mathbf{210}_N$ reflects light for a different spectral width. As shown, each of the gratings $\mathbf{210}_{11}$-$\mathbf{210}_{Ni}$ (1≤i≤M) is associated with a different, specific spectral width, which would be represented by different center frequencies of f_1 . . . f_N, where neighboring spectral widths reflected by neighboring gratings are non-overlapping according to one embodiment of the disclosure.

Herein, positioned in different core fibers $\mathbf{137}_2$-$\mathbf{137}_3$ but along at the same cross-sectional regions **220**-$\mathbf{220}_N$ of the multi-core optical fiber **135**, the gratings $\mathbf{210}_{12}$-$\mathbf{210}_{N2}$ and $\mathbf{210}_{13}$-$\mathbf{210}_{N3}$ 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 $\mathbf{137}_2$-$\mathbf{137}_3$) results in wavelength shifts associated with the returned, reflected light. Based on different locations, the core fibers $\mathbf{137}_1$-$\mathbf{137}_4$ experience different types and degree of strain based on angular path changes as the stylet **120** advances in the patient.

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 $\mathbf{137}_4$ (see FIG. **3**A) 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 $\mathbf{137}_3$ 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 $\mathbf{210}_{N2}$ and $\mathbf{210}_{N3}$ associated with the core fibers $\mathbf{137}_2$ and $\mathbf{137}_3$ 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 $\mathbf{137}_2$ and the third core fiber $\mathbf{137}_3$) in comparison to the wavelength of the reference core fiber (e.g., first core fiber $\mathbf{137}_1$) 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 $\mathbf{137}_1$-$\mathbf{137}_M$.

Referring to FIG. **3**A, a first exemplary embodiment of the stylet of FIG. **1**A supporting both an optical and electrical signaling is shown in accordance with some embodi-

ments. Herein, the stylet **120** features a centrally located multi-core optical fiber **135**, which includes a cladding **300** and a plurality of core fibers $\mathbf{137}_1$-$\mathbf{137}_M$ (M≥2; M=4) residing within a corresponding plurality of lumens $\mathbf{320}_1$-$\mathbf{320}_M$. While the multi-core optical fiber **135** is illustrated within four (4) core fibers **1371-1374**, a greater number of core fibers $\mathbf{137}_1$-$\mathbf{137}_M$ (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**.

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**.

According to this embodiment of the disclosure, as shown in FIGS. **3**A-**3**B, the core fibers $\mathbf{137}_1$-$\mathbf{137}_4$ include (i) a central core fiber $\mathbf{137}_1$ and (ii) a plurality of periphery core fibers $\mathbf{137}_2$-$\mathbf{137}_4$, which are maintained within lumens $\mathbf{320}_1$-$\mathbf{320}_4$ formed in the cladding **300**. According to one embodiment of the disclosure, one or more of the lumen $\mathbf{320}_1$-$\mathbf{320}_4$ may be configured with a diameter sized to be greater than the diameter of the core fibers $\mathbf{137}_1$-$\mathbf{137}_4$. By avoiding a majority of the surface area of the core fibers $\mathbf{137}_1$-$\mathbf{137}_4$ from being in direct physical contact with a wall surface of the lumens $\mathbf{320}_1$-$\mathbf{320}_4$, 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 $\mathbf{320}_1$-$\mathbf{320}_M$, not the core fibers $\mathbf{137}_1$-$\mathbf{137}_M$ themselves.

As further shown in FIGS. **3**A-**3**B, the core fibers $\mathbf{137}_1$-$\mathbf{137}_4$ may include central core fiber $\mathbf{137}_1$ residing within a first lumen $\mathbf{320}_1$ formed along the first neutral axis **230** and a plurality of core fibers $\mathbf{137}_2$-$\mathbf{137}_4$ residing within lumens $\mathbf{320}_2$-$\mathbf{320}_4$ each formed within different areas of the cladding **300** radiating from the first neutral axis **230**. In general, the core fibers $\mathbf{137}_2$-$\mathbf{137}_4$, exclusive of the central core fiber $\mathbf{137}_1$, 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 $\mathbf{137}_2$-$\mathbf{137}_4$ and reflected back to the console for analysis.

For example, where the cladding **300** features a circular cross-sectional area **305** as shown in FIG. **3**B, the core fibers $\mathbf{137}_2$-$\mathbf{137}_4$ 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 $\mathbf{137}_2$-$\mathbf{137}_4$ 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 $\mathbf{137}_1$ may be located at or near a center of the polygon shape, while the remaining core fibers $\mathbf{137}_2$-$\mathbf{137}_M$ may be located proximate to angles between intersecting sides of the polygon shape.

Referring still to FIGS. **3**A-**3**B, 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.

Referring to FIG. **4**A, a second exemplary embodiment of the stylet of FIG. **1**B is shown in accordance with some embodiments. Referring now to FIG. **4**A, a second exemplary embodiment of the stylet **120** of FIG. **1**B 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. **3**A, which includes the cladding **300** and the first plurality of core fibers $\mathbf{137}_1$-$\mathbf{137}_M$ (M≥3; M=4 for embodiment) residing within the corresponding plurality of lumens $\mathbf{320}_1$-$\mathbf{320}_M$. For this embodiment of the disclosure, the multi-core optical fiber **135** includes the central core fiber $\mathbf{137}_1$ residing within the first lumen $\mathbf{320}_1$ formed along the first neutral axis **230** and the second plurality of core fibers $\mathbf{137}_2$-$\mathbf{137}_4$ residing within corresponding lumens $\mathbf{320}_2$-$\mathbf{320}_4$ 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**.

Referring to FIGS. **4**A-**4**B, 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.

Referring to FIG. **5**A, 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 $\mathbf{530}_1$-$\mathbf{530}_4$ 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 lumen, 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**.

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.

With respect to the plurality of micro-lumens $\mathbf{530}_1$-$\mathbf{530}_4$, the first micro-lumen $\mathbf{530}_1$ is fabricated within the septum **510** at or near the cross-sectional center **525** of the integrated tubing. For this embodiment, three micro-lumens $\mathbf{530}_2$-$\mathbf{530}_4$ are fabricated to reside within the wall **500** of the catheter **130**. In particular, a second micro-lumen $\mathbf{530}_2$ 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 $\mathbf{530}_3$ 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 $\mathbf{530}_4$ is also fabricated within the inner and outer surfaces **505/507** of the wall **500** that are aligned with the septum **510**.

According to one embodiment of the disclosure, as shown in FIG. **5**A, the micro-lumens $\mathbf{530}_2$-$\mathbf{530}_4$ 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 $\mathbf{530}_2$-$\mathbf{530}_4$ may be positioned differently, provided that the micro-lumens $\mathbf{530}_2$-$\mathbf{530}_4$ 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 $\mathbf{570}_2$-$\mathbf{570}_4$ when installed. For example, two or more of micro-lumens (e.g., micro-lumens $\mathbf{530}_2$ and $\mathbf{530}_4$) may be positioned at different quadrants along the circumference **520** of the catheter wall **500**.

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

As an alternative embodiment of the disclosure, one or more of the micro-lumens $\mathbf{530}_1$-$\mathbf{530}_4$ may be sized with a diameter that exceeds the diameter of the corresponding one or more core fibers $\mathbf{570}_1$-$\mathbf{570}_4$. However, at least one of the micro-lumens $\mathbf{530}_1$-$\mathbf{530}_4$ 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 $\mathbf{530}_1$-$\mathbf{530}_4$ are sized with a diameter to fixedly retain the core fibers $\mathbf{570}_1$-$\mathbf{570}_4$.

Referring to FIGS. **6**A-**6**B, flowcharts of methods of operations conducted by the medical instrument monitoring system of FIGS. **1**A-**1**B 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.

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.

According to one embodiment of the disclosure, as shown in FIG. **6**A, 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.

Referring now to FIG. **6**B, 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. **1**B. 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**).

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 this 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**).

Referring now to FIG. **7**A, an exemplary embodiment of the medical instrument monitoring system of FIG. **1**A during operation and insertion of the catheter into a patient is 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. 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 (⅓) portion of the Superior Vena Cava ("SVC") for example. For this embodiment, various instruments may be placed at the distal end 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.

During advancement through a patient vasculature, the stylet **120** receives broadband incident light **155** from the console **110** via optical fiber(s) **147** within the interconnect **145**, where the incident light **155** propagates to the core fibers **137** of the stylet **120**. According to one embodiment of the disclosure, the connector **146** of the interconnect **145** terminating the optical fiber(s) **147** may be coupled to the optical-based catheter connector **144**, which may be configured to terminate the core fibers **137** deployed within the stylet **120**. Such coupling optically connects the core fibers **137** of the stylet **120** with the optical fiber(s) **147** within the interconnect **145**. The optical connectivity is needed to propagate the incident light **155** to the core fibers **137** and return the reflected light signals **150** to the optical logic **180** within the console **110** over the interconnect **145**. As described below in detail, the physical state of the stylet **120** and the catheter **195** may be ascertained based on analytics of the wavelength shifts of the reflected light signals **150**.

Referring to FIG. **7**B, a detailed view of the stylet of FIG. **7**A in the Superior Vena Cava (SVC) advancing toward the right atrium of the patient is shown in accordance with some embodiments. FIG. **7**B illustrates a portion of FIG. **7**A providing a detailed perspective of the vasculature proximate to the heart as well as the anatomy of the heart. Specifically, as the stylet **120** approaches the right atrium **746** through the SVC **742**, the stylet **120** may either advance into the right atrium **746** or deviate into the Azygos vein **743**. The stylet **120** is often used to locate a particular point in the vasculature at which point the catheter may be used to administer a medical procedure or medicament, where this point may be referred to as the "target site" (as shown in FIG. **8**). Numerous methodologies for detecting deviation of the stylet **120** into the Azygos vein **743** are disclosed below.

In some embodiments, the shape sensing logic **194** is configured to determine the shape the core fibers have taken in 3D space as the stylet **120** advances through a patient's vasculature and may further determine the current physical state of the stylet **120** (and hence the catheter **195**) in 3D space for rendering on the display **170**. According to one embodiment of the disclosure, the shape sensing logic **194** may generate a rendering of the current physical state of the catheter **195** based on the physical state of the stylet **120** based on heuristics or run-time analytics. For example, the shape sensing logic **196** 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 **195** in which the core fibers **137** experienced similar or identical wavelength shifts.

In some embodiments, a subset of the images included in the pre-stored data (or a separate set of images stored in the Azygos detection data **199**) may depict particular placements of the stylet **120** as its advancement progresses into the Superior Vena Cava (SVC) and nears the right atrium. Specifically, the subset of the images may include both images in which advancement of the stylet **120** is following a desired or expected path through the SVC and into the right atrium (e.g., to a predetermined target site), and images in which advancement of the stylet **120** deviates from the desired or expected path and enters into the Azygos vein. Further, following generation of the physical state of the stylet **120**, such may be compared using heuristics or run-time analytics to the subset of images depicting advancement along desired (expected) and undesired (unexpected) paths in order determine whether the stylet **120** has deviated into the Azygos vein. For example, the analyses performed by the Azygos detection logic **196** may result in a determination indicating whether stylet **120** and/or the catheter **195** have entered the Azygos vein.

Referring to FIG. **8**, a first illustration of a stylet advancing through a patient's vasculature toward the right atrium of the patient's heart is shown in accordance with some embodiments. As seen, the stylet **120** is advancing through the SVC **742** toward a target site **800** within the right atrium **746** but has deviated from a desired path into the Azygos vein **743**. In one embodiment, as the stylet **120** advances toward the Azygos vein **743** the reflected light generated by the sensors (reflective gratings) indicates such a curvature. The Azygos detection logic **198** obtains the generated physical state of the stylet **120** from the shape sensing logic **194** and, through heuristics and/or run-analytics determines the generated physical state of the stylet indicates entry into the Azygos vein **743**. As referenced above, such a determination may be based on, at least in part, comparison through machine-learning tactics (and, optionally, in combination with image recognition algorithms) to a set of pre-stored images. For instance, a trained machine-learning model may provide an indication that the stylet **120** has entered into the Azygos vein **743** with a particular confidence level. As should be understood, the machine-learning model would previously trained using the pre-stored images of both (i) stylets advancing properly toward the right atrium **746** generation of the physical state of the stylet **120** generation of the physical state of the stylet **120** and (ii) stylets deviating into the Azygos vein **743**.

Additionally, or as an alternative, the Azygos detection logic **198** may analyze the reflected light with respect to fluctuations of the stylet **120** during its advancement in order

to determine whether the stylet **120** has deviated into the Azygos vein **743**. For instance, known or expected rates of fluctuation may be pre-stored as part of the Azygos detection data **199** for various areas of the human vasculature. These known rates of fluctuation may be compared to a current rate of fluctuation of the stylet **120** computed by the Azygos detection logic **198** based on the reflected light, which indicates movement of the stylet **120**. The difference in the fluctuations of the stylet **120** between the SVC **742** and the Azygos vein **743** may be a result of one or more several factors including more turbulent blood flow in the SVC **742**, a larger diameter of the SVC **742**, a difference in pulsatility between the SVC **742** and the Azygos vein **743**, and a difference in the volumes of interiors of the SVC **742** and the Azygos vein **743**. The amount or rate of fluctuation of the stylet **120** may be a combination of movement by the stylet **120**, especially the distal tip, in any direction within the particular portion of the vasculature through which the stylet **120** is currently traveling.

In particular and referring again to FIG. **8**, the SVC **742** is illustrated as having a diameter (D1) **802** and the Azygos vein **743** is illustrated as having a diameter (D2) **804**, where the D2 **804** of the Azygos vein **743** is less than the D1 **802** of the SVC **742**. Thus, the larger diameter of the SVC **742** enables the stylet **120** to have a higher rate of fluctuation over a particular stretch of advancement than does the smaller diameter of the Azygos vein **743**, i.e., the stylet **120** is more limited in its physical movement upon deviating into the Azygos vein **743**.

Additionally, the higher rate of fluctuations may be caused by the contraction of the cardiac muscle of the heart and the actuation of heart valves adjacent to the path of the blood. Specifically, these contractions and actuations interrupt the steady blow flow in the SVC **742**, where the steady blood flow is more broadly observed throughout the rest of the venous vasculature. In the regions immediately adjacent to the heart, e.g., the SVC, vessel properties are unable to flatten and filter these disruptions to steady blood flow resulting in an observable movement (fluctuation) within the stylet **120** when present in this region of the vasculature. Thus, the Azygos detection logic **198** may detect deviation into the Azygos vein **198** based on a lower rate of fluctuation that is at least in part caused by the contractions and actuations discussed above, where the rate of fluctuation is indicated in the reflected light.

In yet other embodiments, the direction of blood flow may be utilized as an indicator that the stylet **120** has deviated into the Azygos vein **743**. Specifically, as illustrated in FIG. **8**, the direction of blood flow in the SVC **742** is illustrated via the arrow **806** (i.e., in-line with the direction of advancement of the stylet **120**) and the direction of blood flow in the Azygos vein **743** is illustrated via the arrow **808** (i.e., against the direction of advancement of the stylet **120**). Thus, utilizing data obtained through pulse oximetry and/or flow Doppler, typically in addition to one or more of the embodiments discussed herein, a directional flow detection logic **199** may determine that the stylet **120** has deviated into the Azygos vein **743**. The directional flow detection logic **199** may be a sub-logic module of the Azygos detection logic **198**. For example, technology implementing pulse oximetry and/or an optical-based Doppler (e.g., Doppler ultrasound) may integrated into the stylet **120** and provide the Azygos detection logic **198** with readings regarding blood oxygen levels and blood flow velocity, which aid the Azygos detection logic **198** in determining whether the distal tip of the body of implementation has deviated into the Azygos vein.

In some embodiments, the stylet **120** and/or the catheter **195** may be operable to perform intravascular ECG monitoring in addition to the fiber optic shape sensing functionality discussed previously. As indicated above, the console **110** may include the electrical signaling logic **181**, which is positioned to receive one or more electrical signals from the stylet **120** and/or catheter **195** when configured to obtain electrical signals, e.g., at a distal tip. Further, the stylet **120** is operable 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 **144**. The electrical signals may be processed by electrical signal analytic logic **196**, executed by the processor **160**, to determine ECG waveforms for display.

Referring to FIG. **9**, a second illustration of a stylet advancing through a patient's vasculature toward the right atrium of the patient's heart is shown in accordance with some embodiments. As is known and illustrated in FIG. **9**, the SA node **900** generates electrical impulses that control the sinus rhythm of the heart. Such as impulses are detectable by, for example, an electrode coupled to a distal tip of the stylet **120**. As the stylet **120** deviates into the Azygos vein **743**, the detected P-wave of the intravascular ECG decreases slightly in amplitude even as the stylet **120** is advanced toward the sinoatrial (SA) node **900**.

Referring to now FIGS. **10**A-**10**C, illustrations depicting an electrode configuration that provides for acquisition of endovascular ECG data are shown in accordance some embodiments. With specific reference to FIG. **10**A, the illustration depicts a single lead configuration with a reference electrode **1006** that is, for example, attached to the patient's skin over the right arm and with a secondary electrode **1008** coupled to the stylet **120** or catheter **195**. It should be noted that the reference electrode **1006** is attached to the skin over the right arm for illustration purposes only with other configurations being possible depending on the type of ECG required. Such a configuration enables ECG data to be obtained from the SVC **1002** and inferior vena cava **1004**.

With reference to FIG. **10**B, the illustration depicts a modified 3-lead configuration, with monitoring and guiding capabilities utilizing four electrodes. In such a configuration, three of the electrodes correspond to standard ECG electrodes: right arm (RA) **1010**, left arm (LA) **1012**, and left leg (LL) **1014** (not shown to proportion), wherein the left leg electrode **1014** is used as reference. The fourth electrode **1016** is attached through to the stylet **120** or catheter **195**. In this configuration, the console **110** and the electrical signal analytic logic **196** may perform two functions simultaneously or concurrently (at least partially overlapping in time): the three standard electrodes (**1010**, **1012**, **1014**) perform a monitoring function of the heart, while the fourth electrode **1016** allows for recording the ECG at the tip of the stylet **120** or catheter **195**. FIG. **10**C provides an illustration depicting a telemetry configuration with a single grounded lead **1018** in addition to the configuration as discussed in FIG. **10**A utilizing electrodes **1006** and **1008**. This configuration can be used to transmit ECGs remotely through a telemetry system configuration.

Referring to now FIG. **11**, an illustration of an exemplary peripherally inserted central catheter is shown in accordance with some embodiments. The device **1100** comprises or is configured as a central venous catheter (CVC), such as, a peripherally inserted central catheter (PICC or PICC line), with a detector **1102** positioned at or near a distal end **1104** of device **1100**. Additionally, the device **1100** is configured

with a multi-core optical fiber, which receives broadband incident light and reflects optical signals (light signals) to a console as discussed above. In some embodiments, the multi-core optical fiber may be integrated into an interior of the device **1100** (e.g., when the device **1100** is a guidewire or a stylet). In other embodiments, the multi-core optical fiber may be integrated into a wall of device **1100** (e.g., when the device **1100** is a catheter).

The device **1100** itself comprises an elongated body **1106** that is made of a material that may permit delivery of device **1100** into a luminal organ (or an access route through another bodily part) of a patient and subsequent withdrawal from the patient without damaging the patient. For example, elongated body **1106** may comprise silicone or one or more other polycarbonates so to prevent device **1100** from "sticking" to the vasculature of the patient during or after insertion. In various device **1100** embodiments, at least one lumen **1108** is defined within elongated body **1106**, and may define multiple lumens **1108**. In other embodiments (such as wire embodiments, for example), device **1100** would not have a lumen therethrough.

The detector **1102** comprises a pair of detection electrodes **1114**, **1116** that are positioned in between a pair of excitation electrodes **1110**, **1112**. The detector **1102** is configured to generate an electric field and also to obtain multiple conductance measurements within the electric field as the detector **1102** is advanced through a patient's vasculature, wherein each of the multiple conductance measurements is indicative of a location of the detector **1102** within the patient's vasculature when the detector **1102** is positioned therein.

Referring now to FIG. **12**, an illustration of a system utilizing a second embodiment of a peripherally inserted central in conjunction with two electrode pads is shown in accordance with some embodiments. In the embodiment shown in FIG. **12**, an electric field is generated by electrodes that are coupled to or positioned on the pads **1202**, **1204**. In such an embodiment, changes in conductance can be obtained using detector **1206**, which includes detection electrodes **1208**, **1210** that are similar to the detection electrodes **1114**, **1116**, for example) as the detector **1206** moves with stylet **1205** through the patient's vasculature.

In such an embodiment, upon activation of distal excitation electrode **110** and proximal excitation electrode **112**, the electric field detectable by detection electrodes **1208**, **1210** of the detector **1206**. As stylet **1205** is advanced through the patient's vasculature, from vessels of smaller diameter/cross-sectional area to larger vessels and ultimately to the heart, stepwise changes (increases) in conductance can be identified, and the anticipated pulsatile nature of voltage change due to the pumping of the heart can also be identified, indicating delivery of a distal end of stylet **1205** to the right atrium.

Specifically, in embodiments in which the pads **1202**, **1204** may themselves serve as the poles or excitation electrodes may be positioned upon the pads **1202**, **1204**, the stylet **1205** need not include excitation electrodes (such as excitation electrodes **1110**, **1112** of FIG. **11**) positioned thereon as the two poles are provided using pads **1202**, **1204** as shown in FIG. **12**. In some embodiments, one or more wires (not shown) may be connected to the pads **1202**, **1204** to transmit a current from an ECG/EKG device (and/or the console **110**), so to generate an electric field detectable by a stylet **1205**.

As shown in FIG. **12**, the pads **1202**, **1034** are each positioned upon the patient's torso. While other locations may be used, the illustrated embodiment includes pad placement whereby the pad **1202** is positioned adjacent to a vein that the stylet **1205** will pass through on the way to the right atrium, and the pad **1204** is positioned adjacent to the right ventricle or the right atrium of the heart (or generally positioned away from the pad **1202**, such as on an opposing arm of a patient, at or near the patient's neck, elsewhere on the torso, etc.).

In an embodiment in which the two pads **1202**, **1204** are poles and generate the electric field, when a detection portion of stylet **1205** is outside the field, conductance is generally high and voltage is very low, and when the detection portion of stylet **1205** moves back into the field, conductance significantly drops, while voltage increases.

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.

What is claimed is:

1. A medical device system for detecting malposition of a medical device within a vasculature of a patient, the system comprising:

the medical device configured for advancement through the vasculature of the patient, wherein the medical device comprises a multi-core optical fiber having a plurality of core fibers, each of the plurality of 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 for use in determining a physical state of the multi-core 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:

receiving one or more signals from the medical device representing one or more parameters indicative of a location of a distal tip of the medical device within the vasculature of the patient, wherein the one or more signals correspond to reflected portions of a propagating light signal;

processing the one or more signals to determine the location of the distal tip, and

determining whether the medical device has deviated from a target advancement path and has entered an Azygos vein of the patient based on the one or more signals.

2. The system of claim **1**, wherein determining whether the medical device has entered the Azygos vein is based on an amount of fluctuation of the medical device indicated by the reflected portions of the propagating light signal.

3. The system of claim **2**, wherein the amount of fluctuation of the medical device is an amount of fluctuation at the distal tip of the medical device.

4. The system of claim **1**, wherein determining whether the medical device has entered the Azygos vein is based on a shape of the medical device indicated by the reflected portions of the propagating light signal.

5. The system of claim 4, wherein the shape of the medical device indicated by the reflected portions of the propagating light signal is utilized as input to a machine-learning model configured to process the input and provide a result indicating a confidence level as to whether the shape of the medical device indicates entry into the Azygos vein of the patient.

6. The system of claim 4, wherein determining whether the medical device has entered the Azygos vein is based on a result of heuristics performed on the shape of the medical device indicated by the reflected portions of the propagating light signal.

7. The system of claim 1, wherein the one or more signals also include electrocardiogram (ECG) signals resulting from ECG monitoring of advancement of the medical device through the vasculature of the patient, and wherein determining whether the medical device has entered the Azygos vein is based at least in part on the ECG signals.

8. The system of claim 1, wherein the one or more signals also include voltage signals representing an impedance measured near the distal tip of the medical device, and wherein determining whether the medical device has entered the Azygos vein is based at least in part on the voltage signals.

9. The system of claim 1, wherein the one or more signals also include an indication of a blood flow direction near the distal tip of the medical device, and wherein determining whether the medical device has entered the Azygos vein is based at least in part on the blood flow direction near the distal tip of the medical device.

10. The system of claim 1, wherein the one or more signals also include an indication of a pulse oximetry reading obtained near the distal tip of the medical device, and wherein determining whether the medical device has entered the Azygos vein is based at least in part on the pulse oximetry reading.

11. The system of claim 1, wherein the one or more signals also include an indication of an optical-based Doppler reading, and wherein determining whether the medical device has entered the Azygos vein is based at least in part on the optical-based Doppler reading.

12. The system of claim 1, wherein the medical device is a stylet removably inserted into a lumen of a catheter assembly for placement of the distal tip of the catheter assembly in a superior vena cava of the vasculature.

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