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(54) **DEVICES AND METHODS FOR DETERMINING BLOOD FLOW AROUND A BODY LUMEN**

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(52) **U.S. Cl.**

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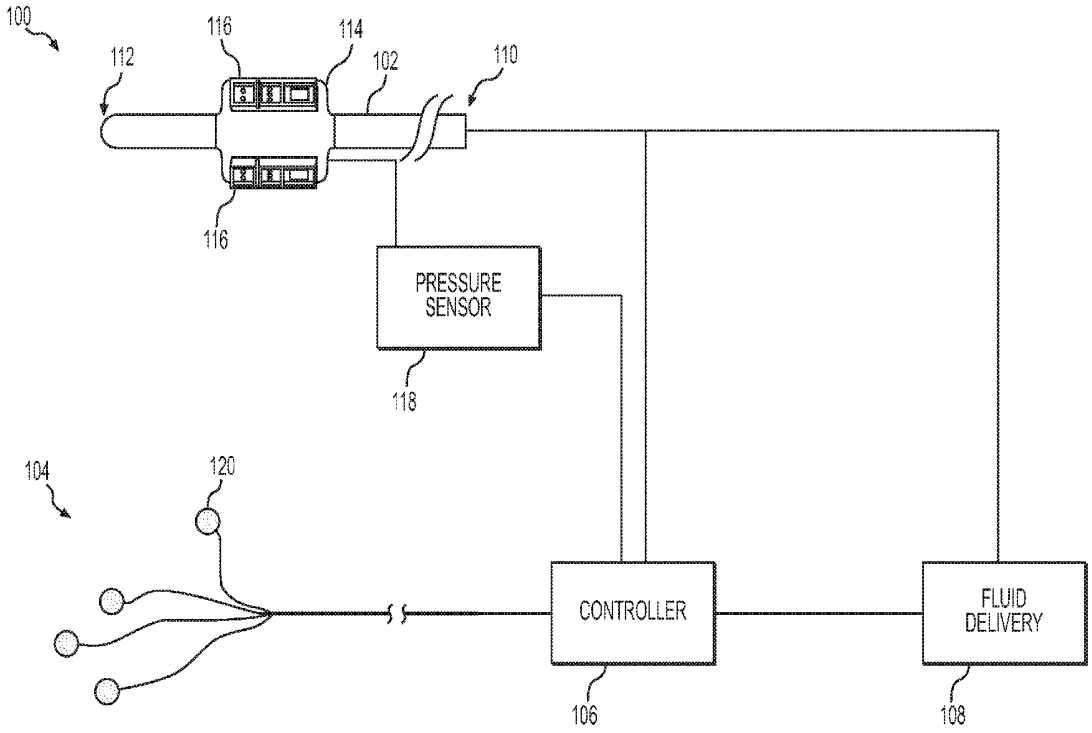
(57) **ABSTRACT**

A system may include an expandable member, and a plurality of sensors disposed on an outer surface of the expandable member and circumferentially spaced apart from one another, wherein each of the plurality of sensors includes a first emitter configured to emit light of a first wavelength, and a detector configured to detect light, and a controller coupled to the plurality of sensors.



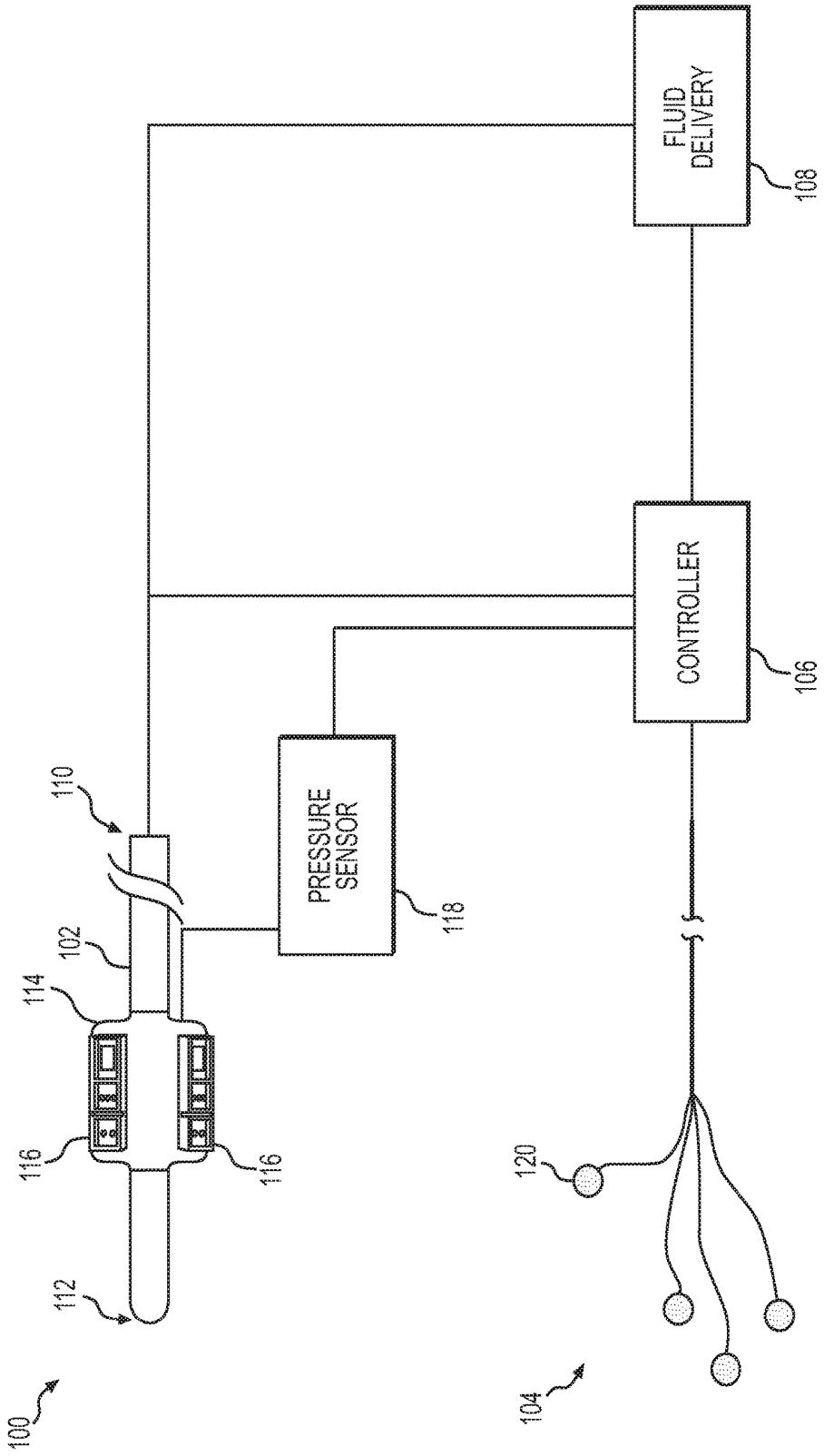

FLUID DELIVERY
108
CONTROLLER
106
PRESSURE SENSOR
118
110
102
114
116
116
112
120
100
104

FIG. 1

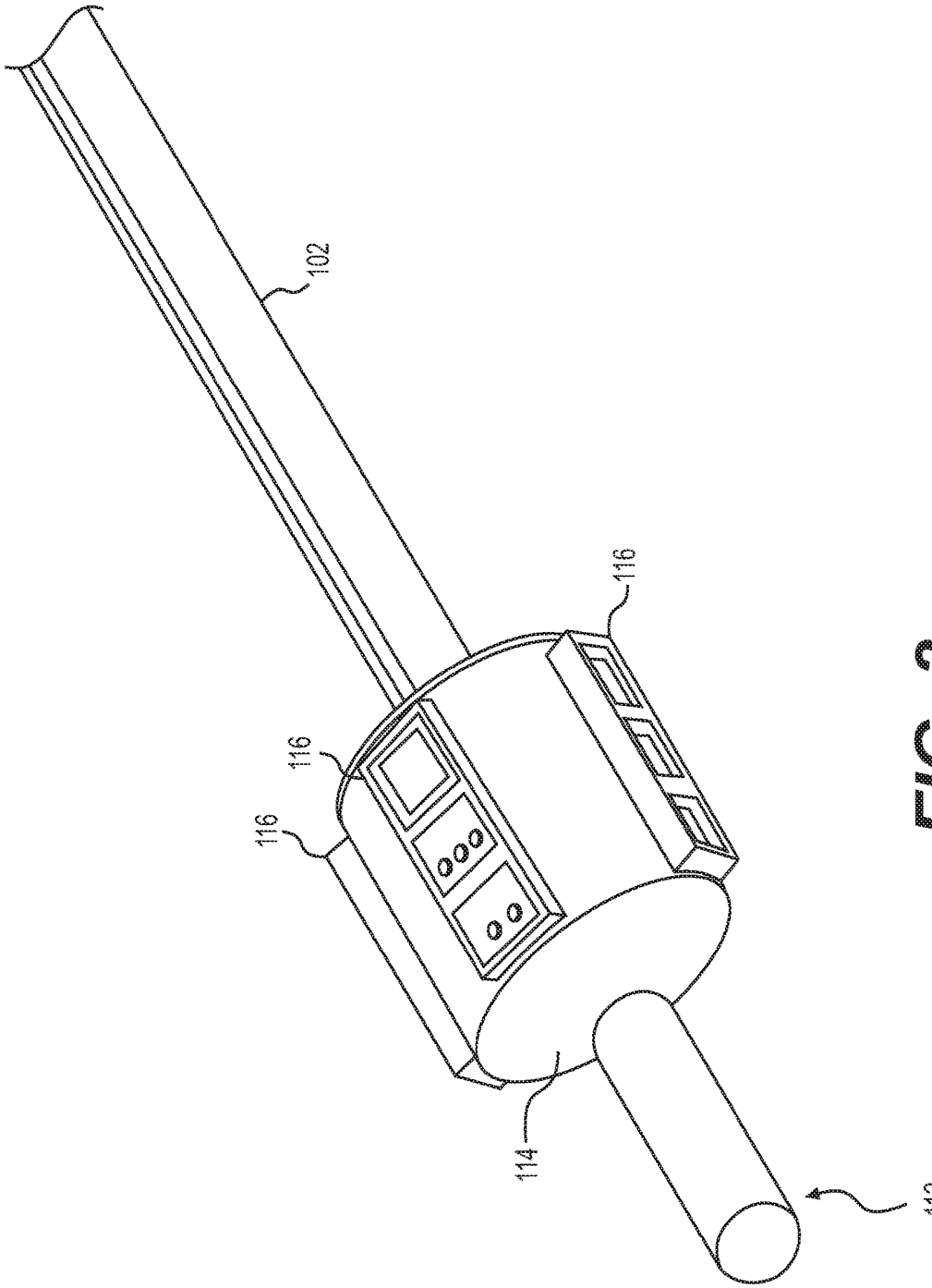


FIG. 2

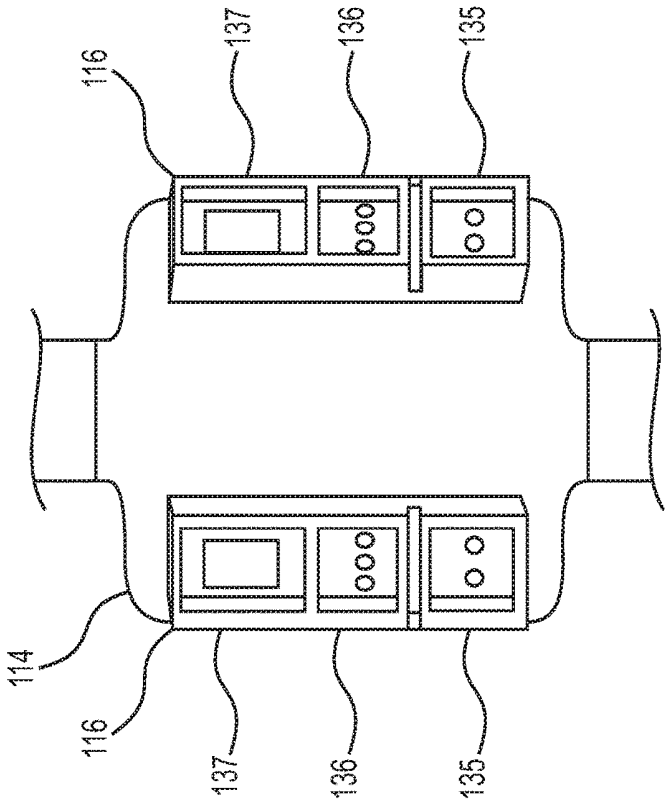


FIG. 4

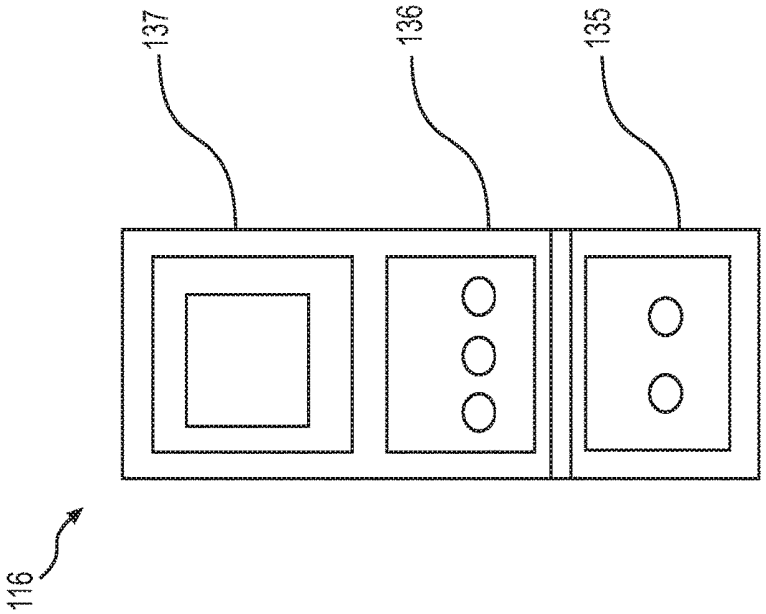


FIG. 3

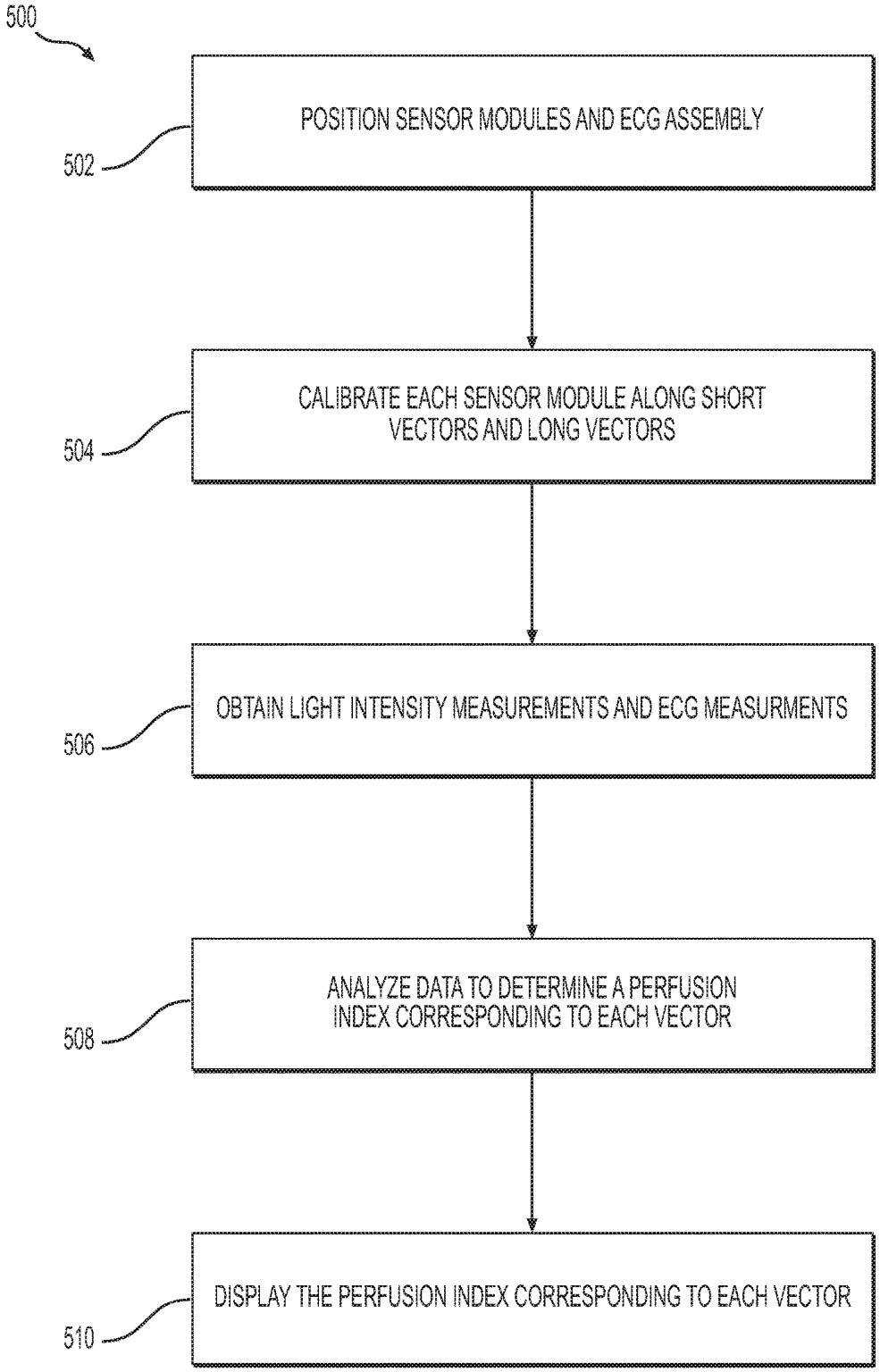

500
POSITION SENSOR MODULES AND ECG ASSEMBLY
502
CALIBRATE EACH SENSOR MODULE ALONG SHORT VECTORS AND LONG VECTORS
504
OBTAIN LIGHT INTENSITY MEASUREMENTS AND ECG MEASURMENTS
506
ANALYZE DATA TO DETERMINE A PERFUSION INDEX CORRESPONDING TO EACH VECTOR
508
DISPLAY THE PERFUSION INDEX CORRESPONDING TO EACH VECTOR
510

FIG. 5

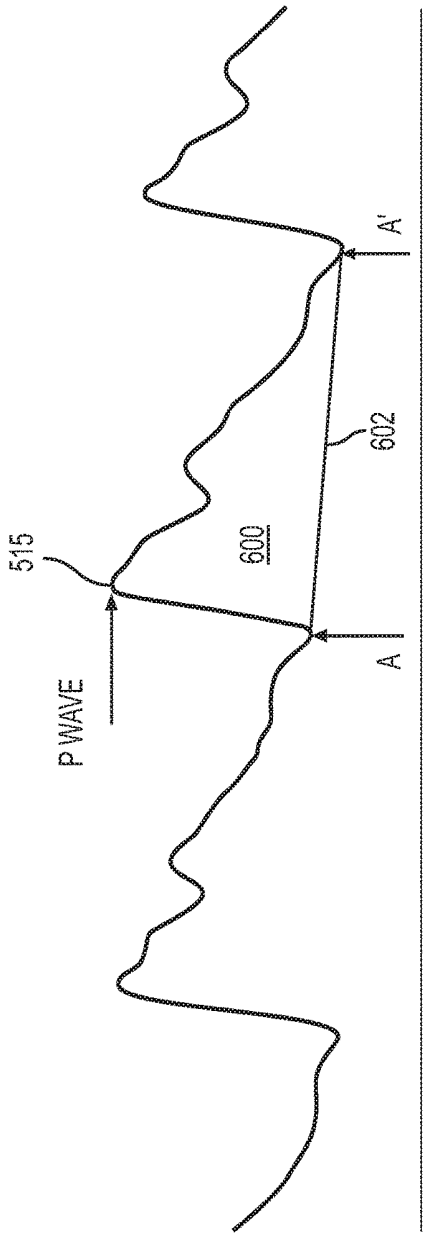


FIG. 6A

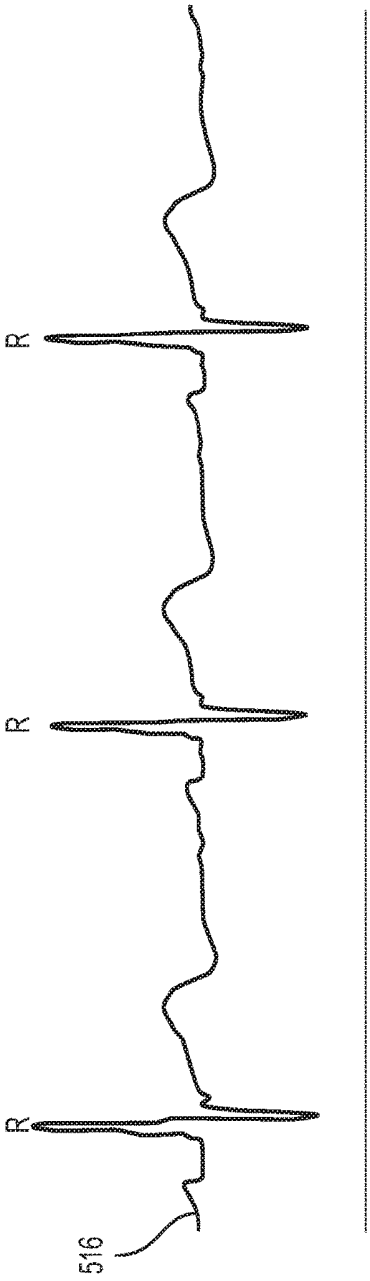


FIG. 6B

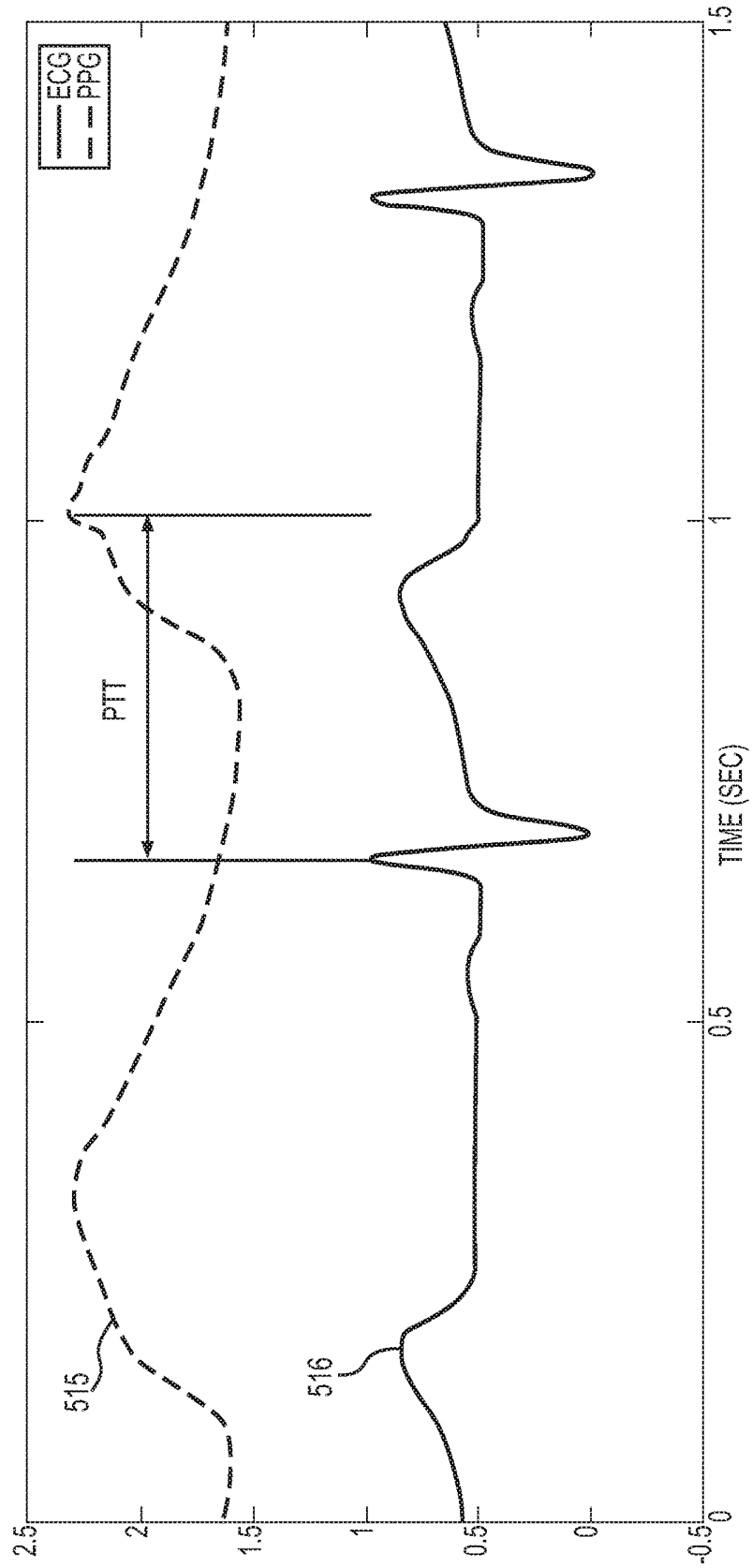


FIG. 7

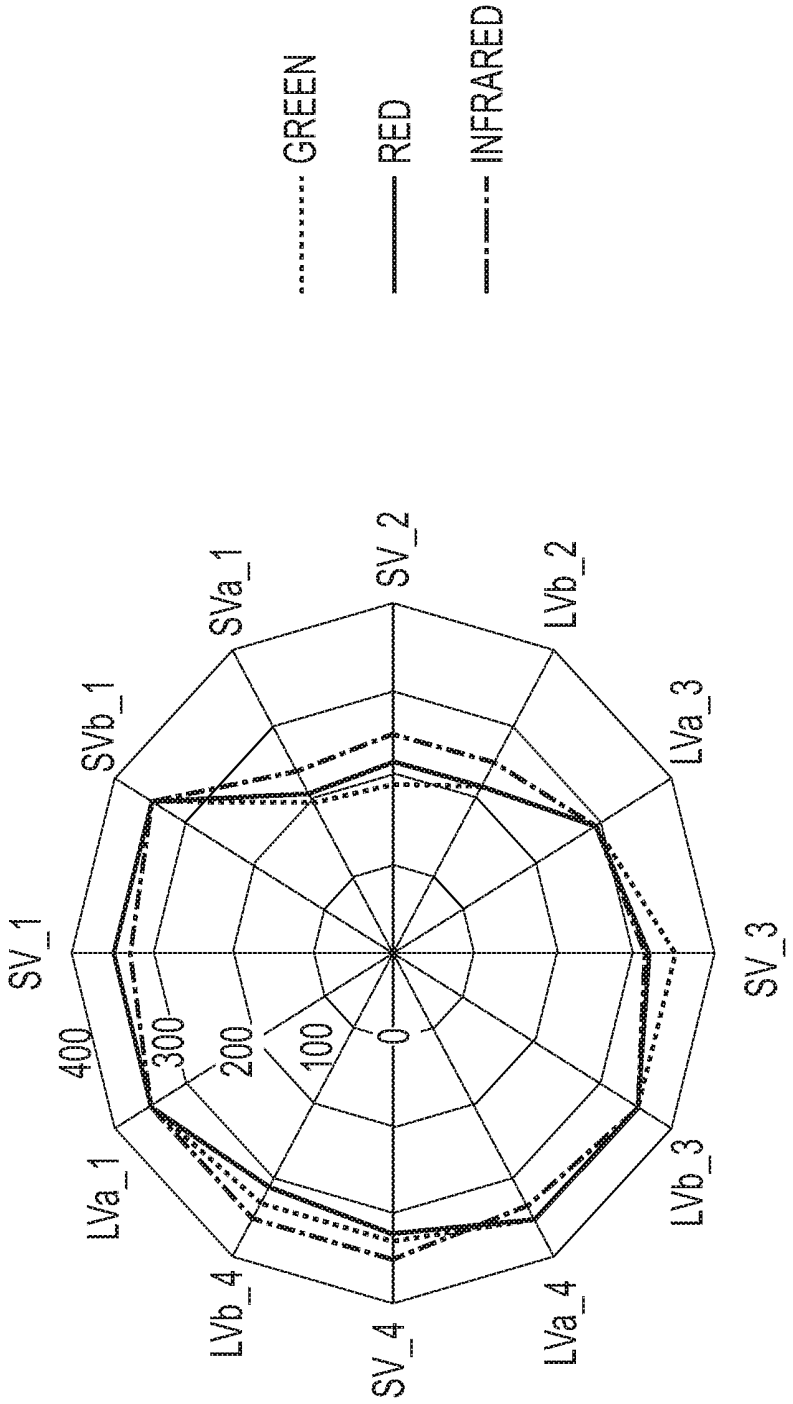

GREEN
RED
INFRARED
SV_1
SVa_1
SV_2
LVb_2
LVa_3
SV_3
LVb_3
LVa_4
SV_4
LVb_4
LVa_1
SVb_1
400
300
200
100
0

FIG. 8

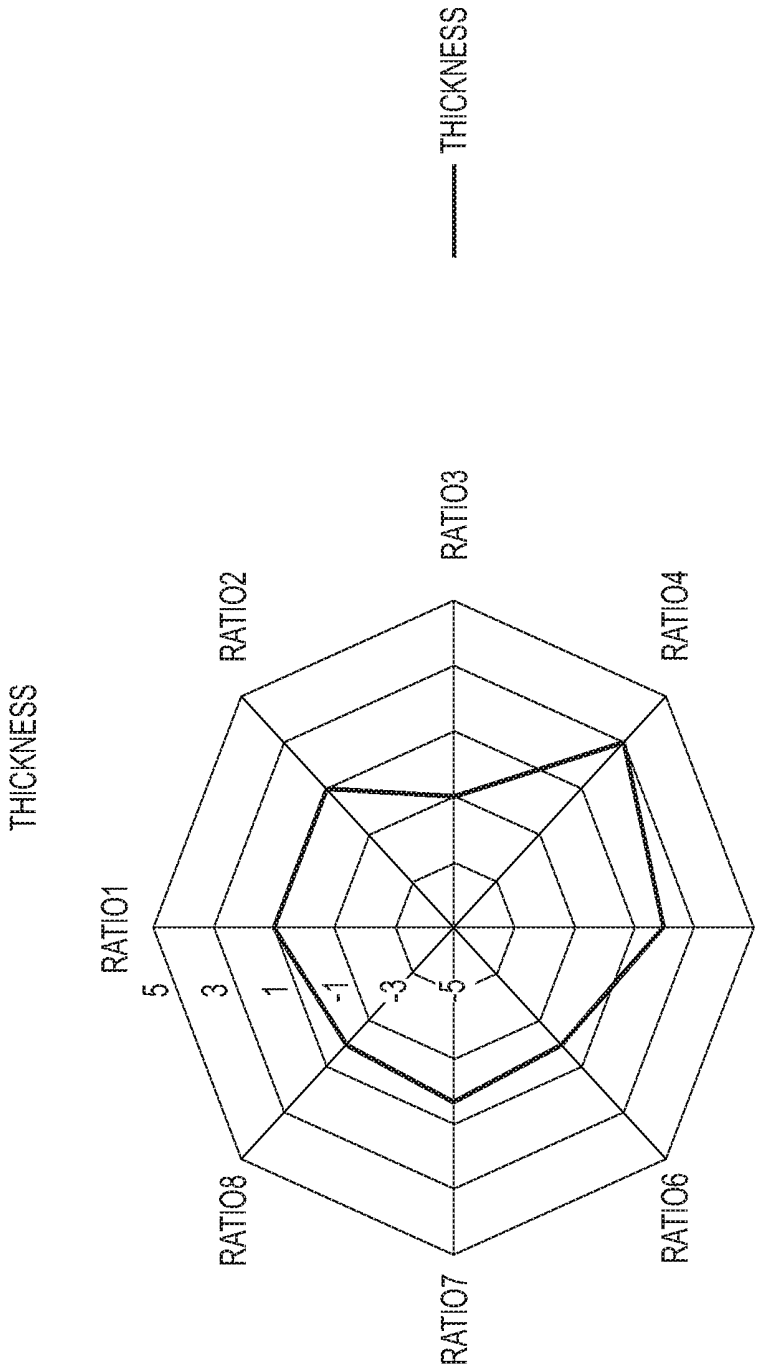

THICKNESS
RATIO3
RATIO2
RATIO4
THICKNESS
RATIO1
RATIO5
5
3
1
-1
-3
-5
RATIO8
RATIO6
RATIO7

FIG. 9

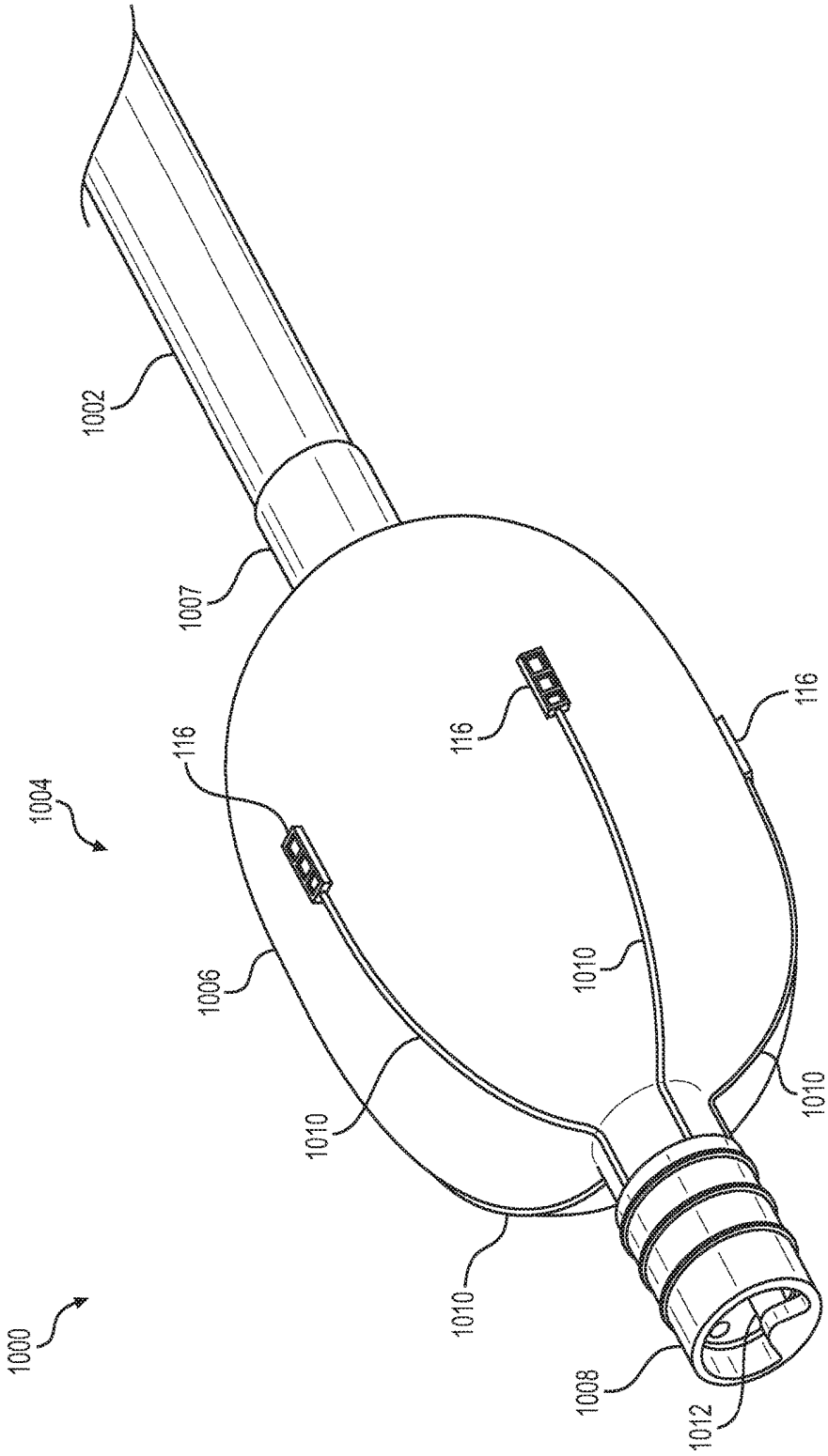

1002
1007
116
116
116
1004
1006
1010
1010
1010
1010
1003
1000
1008
1012

FIG. 10

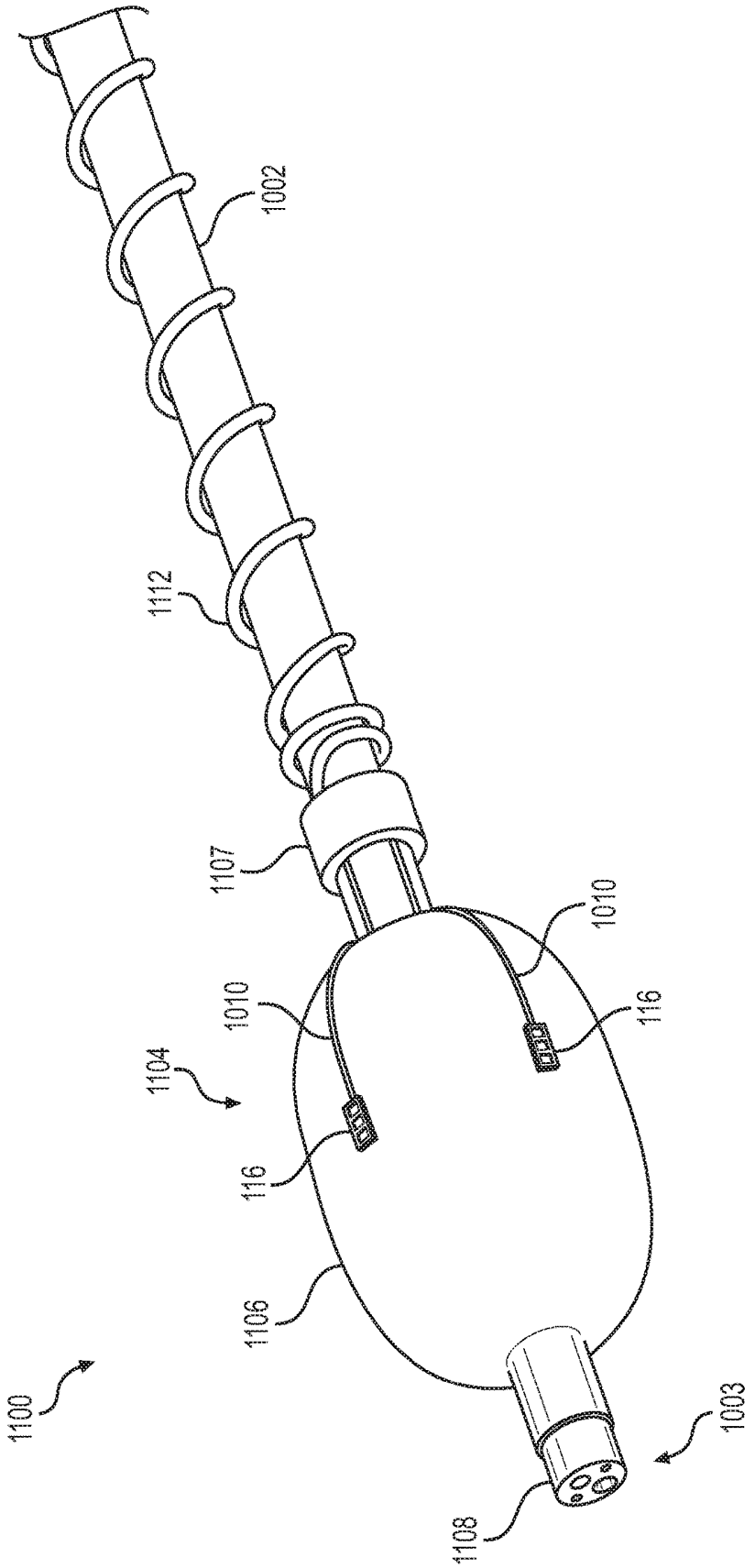


FIG. 11

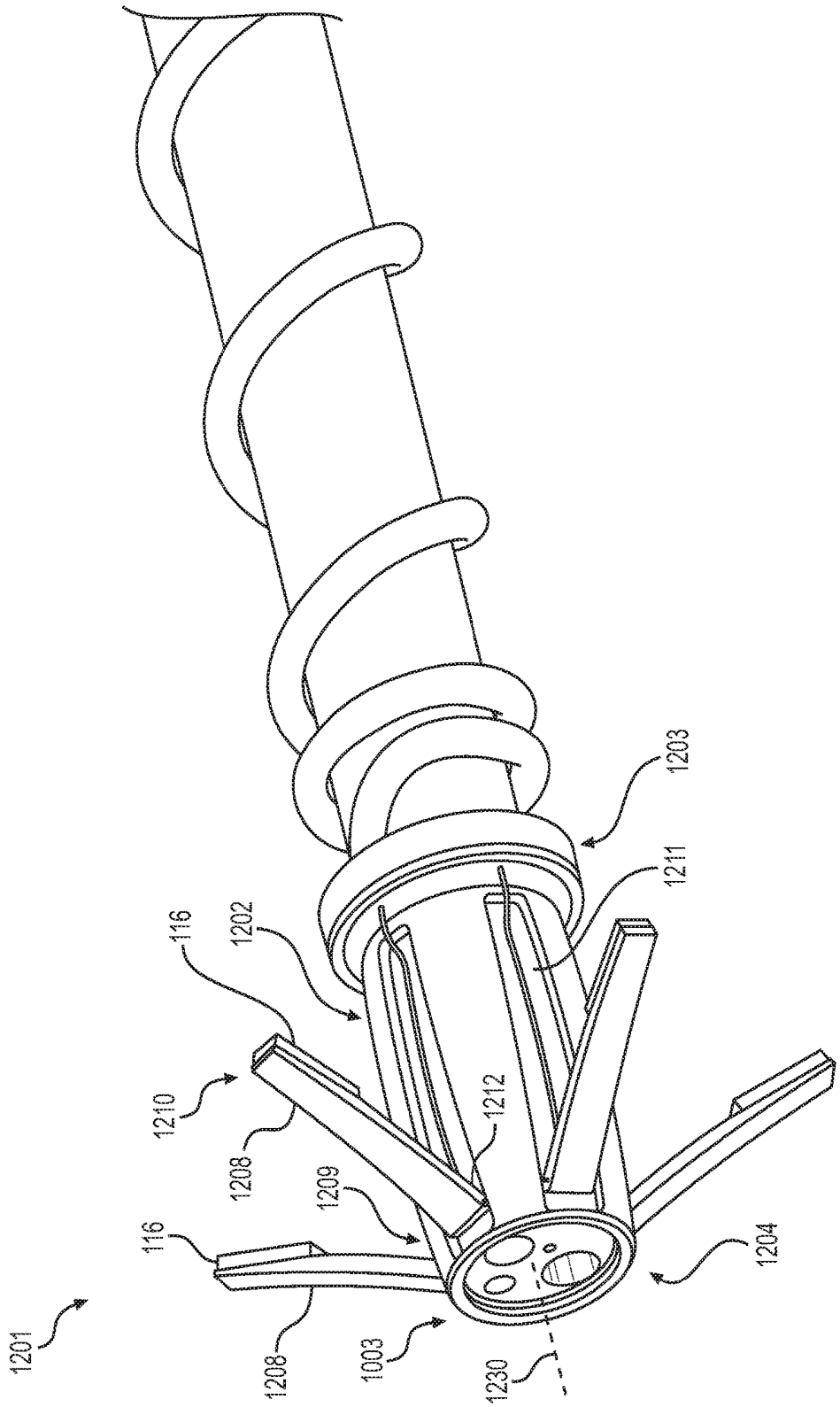

1201
1208
1003
1230
1208
116
1209
1210
1212
1204
116
1202
1211
1203

FIG. 12

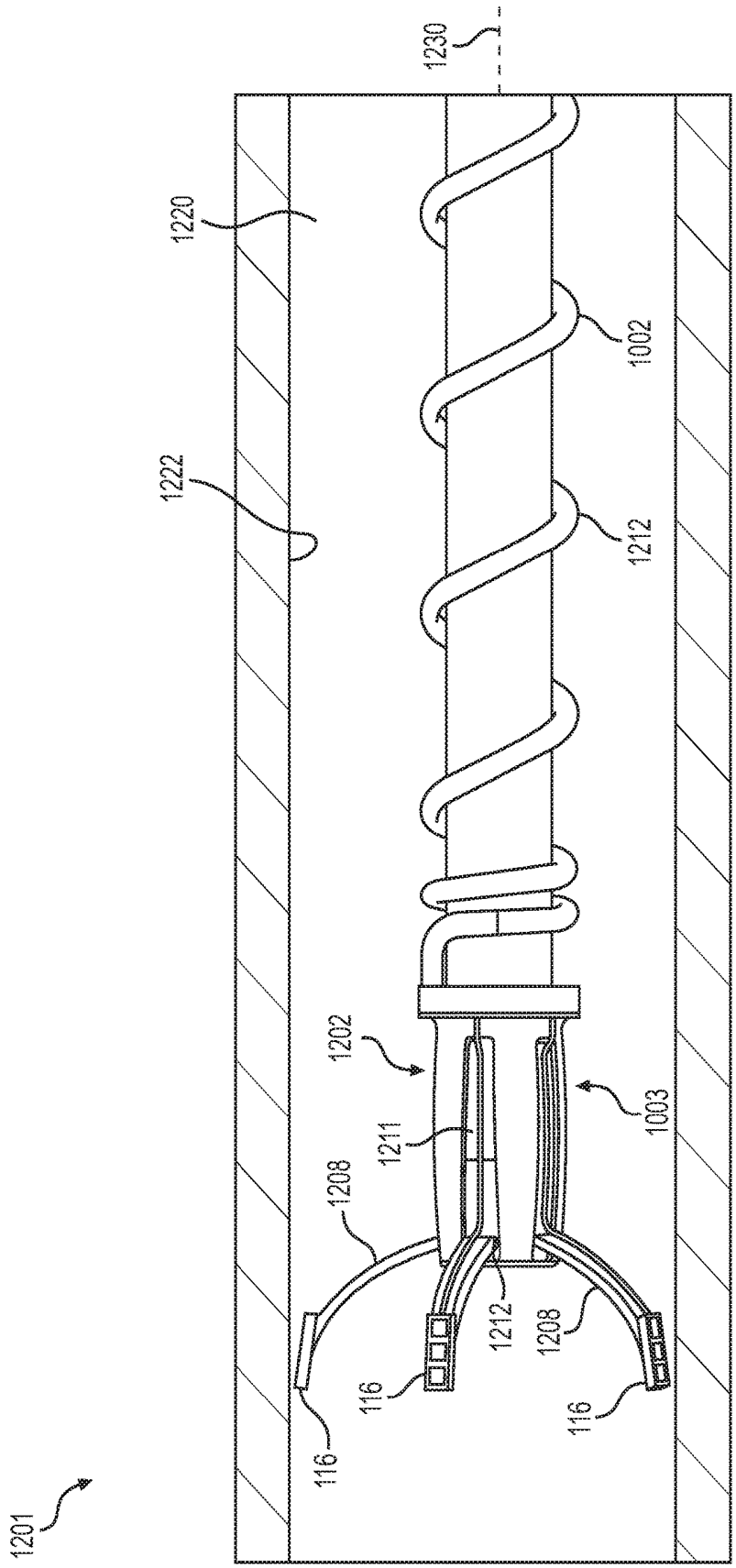

1230
1220
1002
1222
1212
1202
1003
1211
1208
1212
1208
116
116
116
1201

FIG. 13

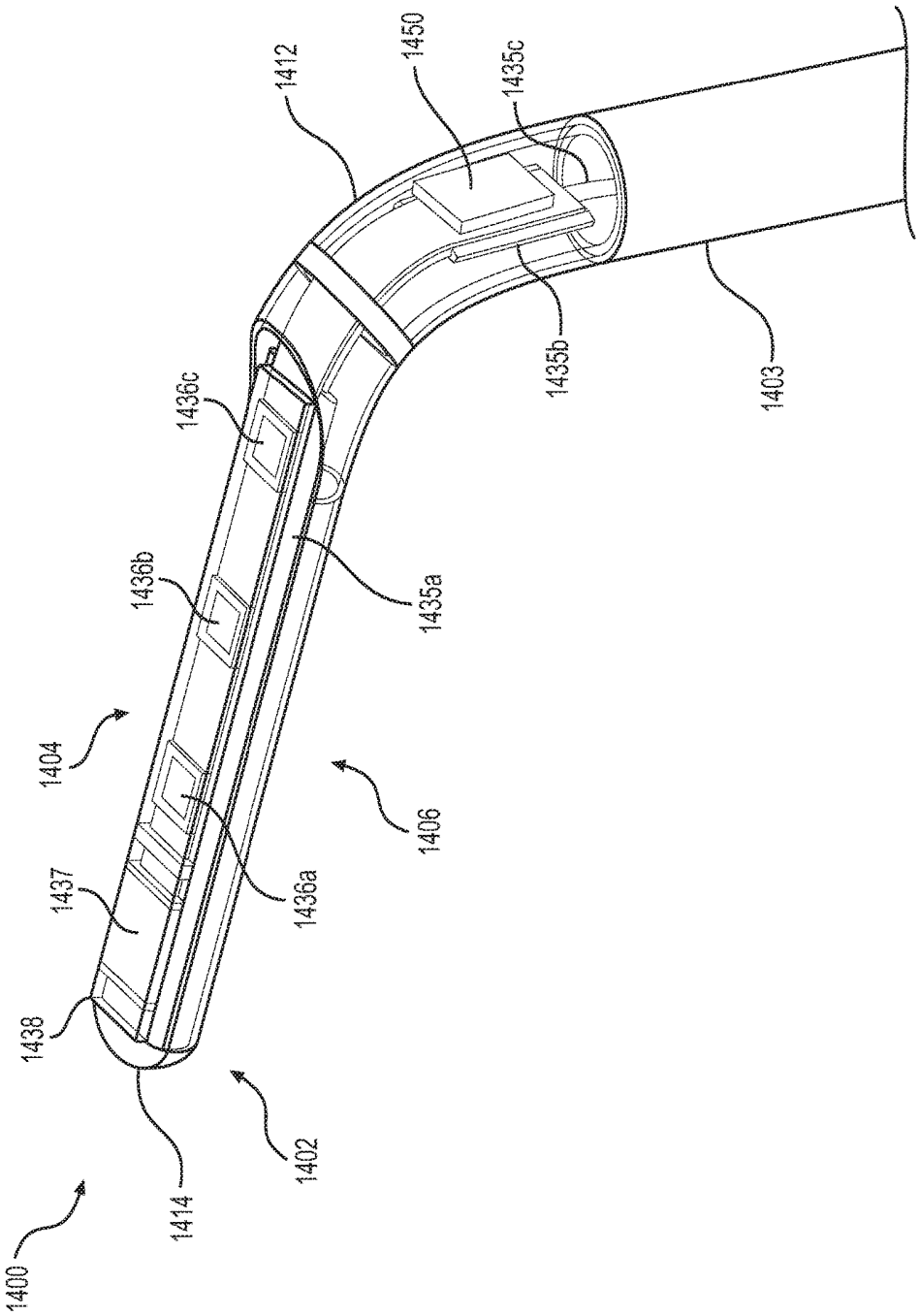

1412
1450
1435c
1435b
1403
1436c
1436b
1435a
1404
1406
1437
1436a
1438
1402
1414
1400

FIG. 14

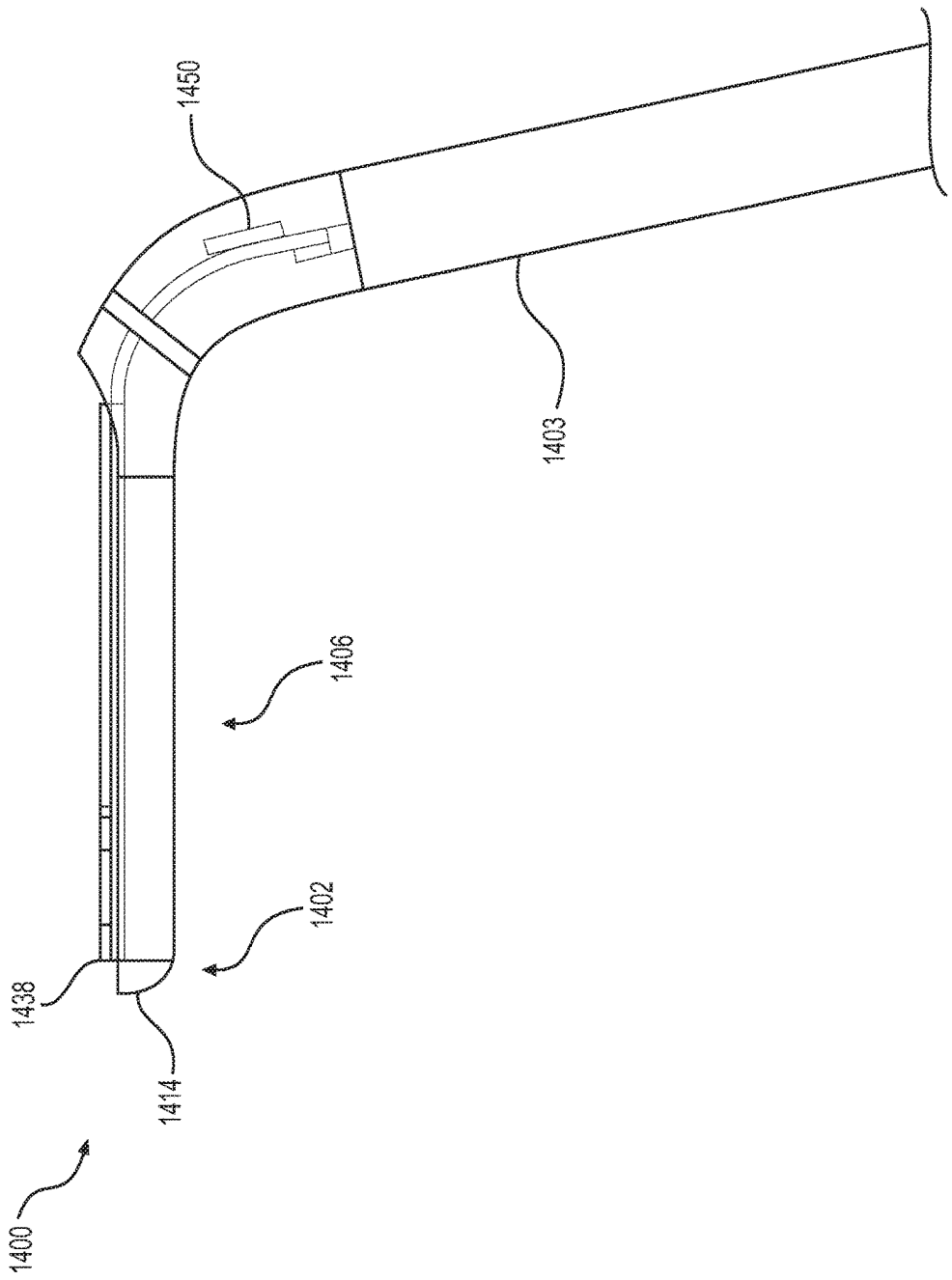


FIG. 15

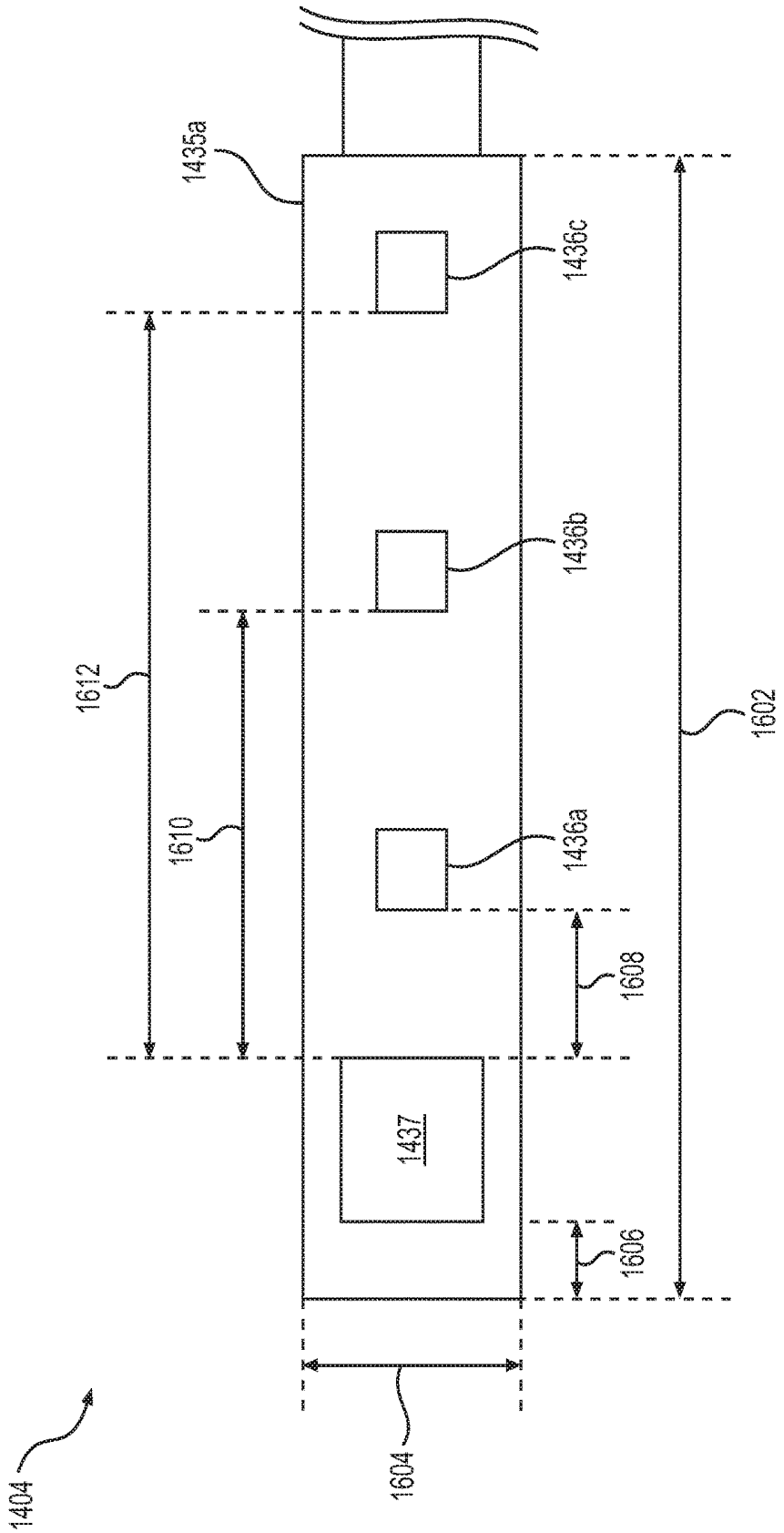

1435a
1436c
1436b
1436a
1612
1610
1602
1608
1437
1606
1604
1404

FIG. 16

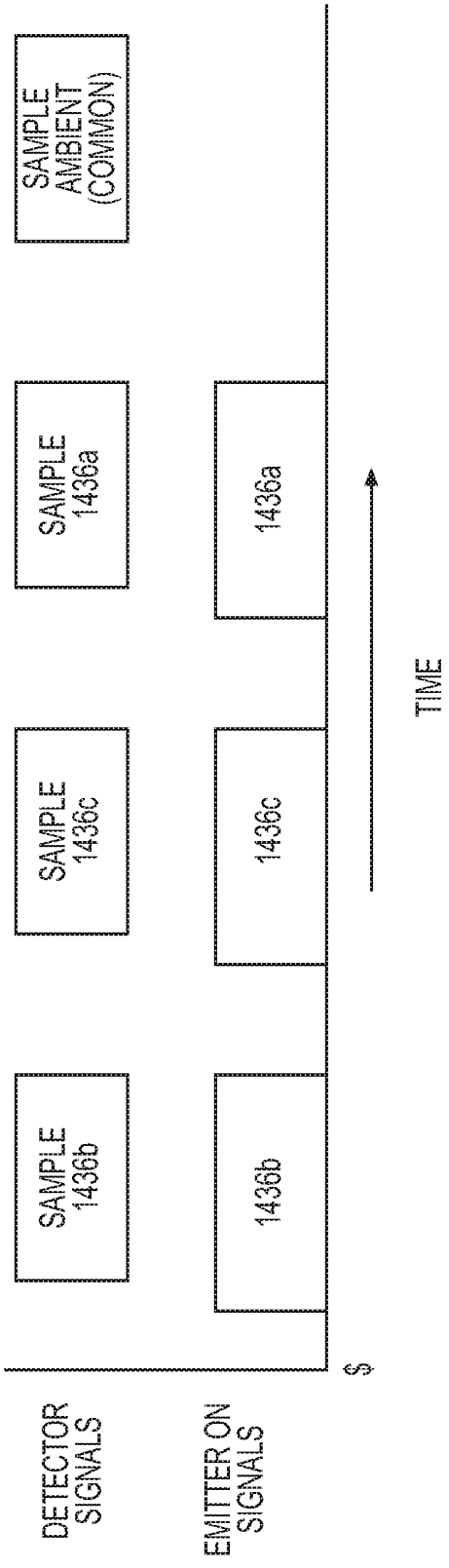

DETECTOR SIGNALS
EMITTER ON SIGNALS
S
SAMPLE 1436b
SAMPLE 1436c
SAMPLE 1436a
SAMPLE AMBIENT (COMMON)
1436b
1436c
1436a
TIME

FIG. 17

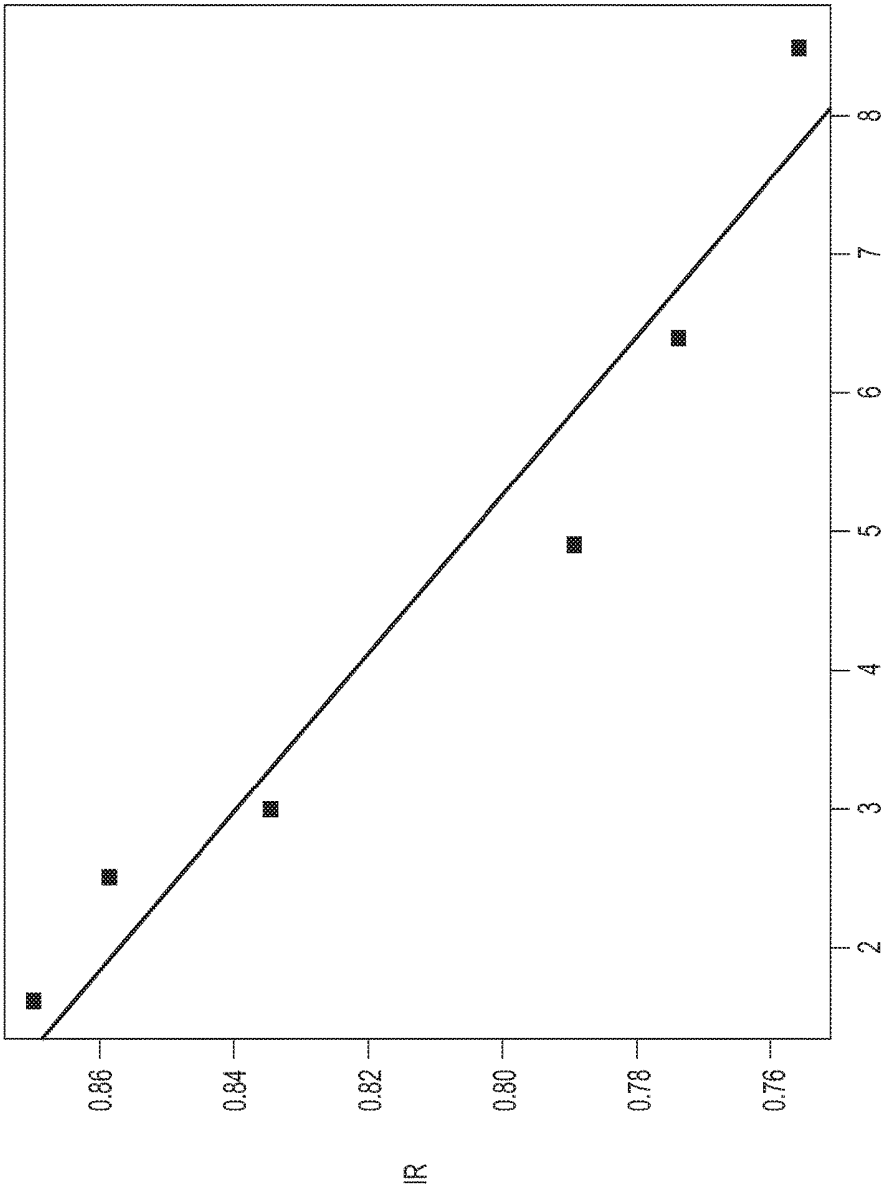


FIG. 18

DEVICES AND METHODS FOR DETERMINING BLOOD FLOW AROUND A BODY LUMEN

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This patent application claims the benefit under 35 U.S.C. § 119 to U.S. Provisional Patent Application No. 62/522,168, filed on Jun. 20, 2017, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] Implementations of the present disclosure relate to devices and methods for determining blood flow around a body lumen, and more specifically, an indicator for identifying inflamed regions of the gastrointestinal tract.

INTRODUCTION

[0003] Inflammatory Bowel Disease (IBD) is a disease that progresses from the mucosal lining of the small bowel or/and colon through the entire bowel/colon wall. Currently, the use of magnetic resonance imaging (MRI) slices as a non-invasive imaging technique for diagnosing IBD is limited by resolution, and does not provide real-time blood flow. Coherence tomography (CT) is another approach, but is not suitable for patients with certain gastrointestinal diseases because the requirement for multiple imaging sessions over time increases the risk of cancer for the patient. Other challenges include subjective severity in scoring from doctor to doctor, diagnosis through elimination, increased patient risk for cancer due to monitoring progression with repetitive CT-scans, and the unavailability of and lack of standardization associated with color enhanced ultrasound.

SUMMARY

[0004] In one implementation, the disclosure is directed to a system including an expandable member, and a plurality of sensors disposed on an outer surface of the expandable member and circumferentially spaced apart from one another, wherein each of the plurality of sensors includes a first emitter configured to emit light of a first wavelength, and a detector configured to detect light, and a controller communicatively coupled to the plurality of sensors. The controller may be configured to, from at least one detector, receive along a first short vector, a measurement of light intensity over time of light, reflected off of body tissue, at the first wavelength and originating from a first emitter from a same sensor; from at least one detector, receive along a first long vector, a measurement of light intensity over time of light, reflected off of body tissue, at the first wavelength and originating from a first emitter from a circumferentially adjacent sensor; calculate separate perfusion indexes corresponding to measured light intensity over time of each first short vector and each first long vector; and initiate the display of the separate perfusion indexes corresponding to measured light intensity over time of each first short vector and each first long vector.

[0005] Each of the plurality of sensors may include a second emitter configured to emit light of a second wavelength that is different than the first wavelength, wherein the controller is further configured to from each detector, receive along a second short vector, a measurement of light intensity over time of light, reflected off of body tissue, at the second wavelength and originating from a second emitter from a same sensor; from each detector, receive along a second long vector, a measurement of light intensity over time of light, reflected off of body tissue, at the second wavelength and originating from a second emitter from a circumferentially adjacent sensor; calculate separate perfusion indexes corresponding to each second short vector and each second long vector; and cause the display of the calculated separate perfusion indexes corresponding to each second short vector and each second long vector. The second emitter may be configured to emit light of a third wavelength different than the first wavelength and the second wavelength, wherein the controller is further configured to: from each detector, receive along a third short vector, a measurement of light intensity over time of light, reflected off of body tissue, at the third wavelength and originating from a second emitter from a same sensor; from each detector, receive along a third long vector, a measurement of light intensity over time of light, reflected off of body tissue, at the third wavelength and originating from a second emitter from a circumferentially adjacent sensor; calculate separate perfusion indexes corresponding to each third short vector and each third long vector; and cause the display of the calculated separate perfusion indexes corresponding to each third short vector and each third long vector. The controller may be further configured to, from each detector, receive along two third long vectors, measurements of light intensity over time of light, reflected off of body tissue, at the third wavelength and originating from second emitters of two different circumferentially adjacent sensors. The third wavelength may be infrared light. The controller may be further configured to, from each detector, receive along two second long vectors, measurements of light intensity over time of light, reflected off of body tissue, at the second wavelength and originating from second emitters of two different circumferentially adjacent sensors. The second wavelength may be visible red light. The controller may be further configured to, from each detector, receive along two first long vectors, measurements of light intensity over time of light, reflected off of body tissue, at the first wavelength and originating from first emitters of two different circumferentially adjacent sensors. The first wavelength may be visible green light. The system may include an ECG assembly coupled to the controller and configured to measure ECG signals. The controller may be further configured to: while calculating each perfusion index, synchronize in time, measured light intensity from each vector with a measurement from the ECG assembly to determine pulse transit time and perfusion intensity; and use the pulse transit time and the perfusion intensity to calculate a respective perfusion index corresponding to each vector. The controller may be configured to receive a measurement of light intensity over time along only one first short vector or first long vector at any given time. The plurality of sensors may include four circumferentially spaced apart sensors. Each detector may be longitudinally aligned with each other detector. Each first emitter may be longitudinally aligned with each other first emitter.

[0006] In another implementation, the disclosure is directed to a method for determining blood flow surrounding a body lumen, the method comprising: receiving, at separate times with a detector: a measurement of light intensity over time of light, reflected off of body tissue, at a first wavelength and originating from an emitter from a sensor cir-

cumferentially aligned with the detector; and a measurement of light intensity over time of light, reflected off of body tissue, at the first wavelength and originating from an emitter from a sensor circumferentially offset from the detector; calculating separate perfusion indexes corresponding to each measurement; and displaying the separate perfusion indexes.

[0007] In yet another implementation, the disclosure is directed to a method for determining blood flow surrounding a body lumen using a plurality of sensors, the method comprising: receiving, with a detector at each sensor, a measurement of light intensity over time of light, reflected off of body tissue, at a first wavelength and originating from a first emitter from a same sensor as the detector; receiving, with a detector at each sensor, a measurement of light intensity over time of light, reflected off of body tissue, at a first wavelength and originating from a first emitter from a sensor circumferentially adjacent to the detector; calculating separate perfusion indexes based on each measurement; and displaying the separate perfusion indexes.

[0008] The body lumen may be in a gastrointestinal tract. Only one measurement may be received at any given time. Each measurement may be taken while the plurality of sensors are in a same location within the body lumen.

[0009] In yet another implementation, the disclosure is directed to a medical device including a catheter; an optical sensor disposed at or adjacent to a distal end of the catheter, the optical sensor including a photodetector and one or more emitters, the photodetector and each of the one or more emitters of the optical sensor being disposed linearly along a longitudinal axis of the catheter; and a controller disposed within the catheter, the controller being configured to determine a thickness of tissue adjacent to the optical sensor based on input from the optical sensor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate various implementations and together with the description, serve to explain the principles of the disclosed implementations.

[0011] FIG. **1** is a schematic view of a perfusion measurement system, according to an implementation of the present disclosure.

[0012] FIG. **2** is a perspective view of an expandable member with a plurality of optical sensors.

[0013] FIG. **3** is a front view of an optical sensor.

[0014] FIG. **4** is a side view of the expandable member of FIG. **2** with a plurality of optical sensors.

[0015] FIG. **5** is a flowchart of a method, according to an implementation of the disclosure.

[0016] FIG. **6**A is illustration of an electrocardiogram measured by the system of FIG. **1**.

[0017] FIG. **6**B is an illustration of a photoplethysmogram measured by the system of FIG. **1**.

[0018] FIG. **7** is a depiction of the electrocardiogram of FIG. **6**A and the photoplethysmogram of FIG. **6**B on common axes.

[0019] FIG. **8** is an illustration of a perfusion index created using optical data measured by the system of FIG. **1**.

[0020] FIG. **9** is an illustration of tissue thickness created using optical data measured by the system of FIG. **1**.

[0021] FIG. **10** is a perspective view of an expandable member and a plurality of sensors, according to another implementation of the present disclosure.

[0022] FIG. **11** is a perspective view of an expandable member and a plurality of sensors, according to yet another implementation of the present disclosure.

[0023] FIGS. **12** and **13** show un-deployed and deployed configurations, respectively, of an expandable member and a plurality of sensors, according to yet another implementation of the present disclosure.

[0024] FIG. **14** is a perspective view of an optical sensor according to another implementation of the present disclosure.

[0025] FIG. **15** is a side view of the optical sensor of FIG. **14**.

[0026] FIG. **16** is a top view of a portion of the optical sensor of FIG. **14**.

[0027] FIG. **17** is an illustration of a timing sequence of a photodetector and a plurality of emitters from the optical sensor of FIG. **14**.

[0028] FIG. **18** is a fitted line plot regression of an experiment using an optical sensor.

DETAILED DESCRIPTION

[0029] Reference will now be made in detail to implementations of the present disclosure, which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts or components. The term "distal" refers to the direction that is away from the user or operator and into the patient's body. By contrast, the term "proximal" refers to the direction that is closer to the user or operator and away from the patient's body. In the discussion that follows, relative terms such as "about," "substantially," "approximately," etc. are used to indicate a possible variation of ±10% in a stated numeric value.

[0030] Implementations of the present disclosure may provide a low-cost imaging solution for determining the severity of various gastrointestinal diseases. In some implementations, the data collected and displayed to a physician or clinician may be robust enough to enable differentiation of ulcerative colitis from Chrohn's disease.

[0031] Referring to FIG. **1**, a system **100** may include a catheter **102**, an electrocardiogram (ECG) lead assembly **104**, controller **106**, and a fluid delivery device **108**.

[0032] Catheter **102** may extend from a proximal end **110** toward a distal end **112**, and may include an expandable member **114** at or adjacent distal end **112**. Expandable member **114** may be a compliant or semi-compliant balloon configured to inflate and deflate via a fluid conveyed by fluid delivery device **108**. In other implementations, expandable member **114** could be an expandable mesh or an expandable basket with a plurality of radially expandable basket legs. As explained in further detail below, one or more sensors may be coupled to expandable member **114** for measuring blood flow, pressure (e.g., pressure sensor **118**), and/or impedance within a gastrointestinal tract of a patient. Pressure sensor **118** may be configured to measure pressure within expandable member **114**, and to measure intra-abdominal pressure (IAP) within the body lumen when expandable member **114** is deflated. In embodiments where expandable member **114** is a balloon, pressure sensor **118** may be integral or otherwise coupled to an inflating pump. In embodiments where expandable member **114** is a mesh, a miniature integrated

MEMS sensor may be used to measure pressure, and could be placed in the same plane as one or more optical sensors. Controller **106** may evaluate signals from pressure sensor **118** to control inflation and deflation of expandable member **114**, so as not to cause any vascular restriction or accidental occlusion. Pressure sensor **118** also could be used to determine safe placement of stents. Increasing expansion while reading perfusion intensity may result in a temporary and substantial decrease in perfusion. Thus, pressure readings from sensor **118** can be used to reduce expansion in these instances to ensure safe delivery by determining whether expansion of the stent causes a temporary restriction of blood flow.

[0033] ECG lead assembly **104** may be coupled to controller **106**, and may be configured to sense an ECG signal based on electrical activity of the patient's heart sensed by one or more electrodes **120**. While ECG lead assembly **104** is shown in FIG. **1** with four electrodes **120**, any other suitable number of electrodes **120** may be utilized.

[0034] Controller **106** may include a processor that is generally configured to accept information from the system and system components, and process the information according to various algorithms. The processor may be a digital IC processor, analog processor or any other suitable logic or control system that carries out the control algorithms. In some implementations, controller **106** may record treatment parameters such as, e.g., sensor data, so that they may be accessed for concurrent or subsequent analysis. Controller **106** may include software that provides a user interface to components within the system. The software may enable a user (e.g., clinician) to configure, monitor, and control operation of catheter **102**, ECG lead assembly **104**, and control circuitry and pump components within fluid delivery device **108**. As described in further detail below, the software may be configured to process a signal indicative of blood flow within a gastrointestinal tract to calculate an area indicative of a blood flow rate within the gastrointestinal tract.

[0035] Fluid delivery device **108** may include a pump, and may be configured to deliver fluid to and convey fluid from expandable member **114** to inflate and deflate expandable member **114**. Fluid delivery device **108** may be controlled by controller **106**, or another suitable controller. The pump may be any suitable pump, such as, e.g., a peristaltic pump, piston pump, motorized pump, infusion pump, or the like. Fluid delivery device **108** may be powered by electrical power, mechanical power, chemical power, or another suitable mechanism. Fluid delivery device **108** may include a source (e.g., a reservoir of liquid or a canister of gas) used to inflate and deflate the expandable member **114**.

[0036] Referring to FIGS. **1-4**, one or more sensors **116** may be disposed on an outer surface of expandable member **114**. In one implementation, four sensors **116** may be circumferentially spaced about expandable member **114** about 90 degrees from one another, although other numbers of sensors and/or different spacing arrangements also are contemplated. Sensor **116** may be configured to generate a signal that can be used by controller **106** to determine blood flow, e.g., perfusion, within a gastrointestinal tract of a patient. Sensor **116** may include a first emitter **135**, a second emitter **136**, and a detector **137**. First emitter **135** and second emitter **136** each may be configured to emit light, e.g., non-visible infrared light and/or visible light toward body tissue. For example, first emitter **135** and second emitter **136** each may include one or more light emitting diodes (LEDs). In some implementations, first emitter **135** and second emitter **136** may be configured to direct different wavelengths of light at tissue. For example, first emitter **135** may be configured to direct light of a first wavelength (e.g., red light with a wavelength from about 620 nm to about 750 nm) toward body tissue, while second emitter **136** may be configured to direct light of a second wavelength different than the first wavelength (e.g., green light from about 520 nm to about 540 nm, or at about 530 nm) toward body tissue. First emitter **135** and/or second emitter **136** may be configured to separately or simultaneously direct one or more wavelengths of light toward body tissue. For example, first emitter **135** may be configured to direct infrared light (at a wavelength from about 700 nm to about 1 mm) in addition to visible red light. Emitted light may be absorbed by the body based on the blood volume at the absorption location. Absorption occurs when elements in the blood absorb photons and diffuse light passing through the blood. Hemoglobin, for example, is an absorber of light but absorbs different light wavelengths at different rates. Backscatter is the amount of light that is reflected back to the detector and is not absorbed in the blood. Detector **137** may be a photodiode (e.g., a silicon photodiode) that is configured to receive backscattered light reflected from the body.

[0037] Each detector **137** may be longitudinally aligned (e.g., disposed at the same longitudinal location) as each other detector **137**. Similarly, each first emitter **135** may be longitudinally aligned with each other first emitter **135**, and each second emitter **136** may be longitudinally aligned with each other second emitter **136**.

[0038] Referring to FIG. **3**, detector **137** may be configured to measure reflected light that originates from an emitter (e.g., first emitter **135** and/or second emitter **136**). For purposes of discussion herein, a short vector refers to reflected light detected by detector **137** that originated from an emitter on the same sensor **116** as the given detector **137**. Thus, depending on the configuration of emitters on a given sensor, each detector **137** may be configured to detect light along one or more short vectors. In one implementation, where first emitter **135** is configured to emit green light, and second emitter **136** is configured to emit red light and infrared light, each detector **137** may be configured to detect light along three short vectors (green, red, infrared). Different absorption rates in blood and tissue with known correlations can be used to determine various physiological parameters (photoplethysmography), such as, e.g., oxygen saturation, heart rate, perfusion intensity, surrogate blood pressure, and tissue thickness.

[0039] Referring to FIG. **4**, a long vector refers to reflected light detected by detector **137** that originated from an emitter on a circumferentially adjacent emitter. Thus, when a given sensor **116** is disposed circumferentially between two other sensors **116**, the detector **137** of the given sensor **116** may be configured to detect light from one or more long vectors from each of the two adjacent sensors (emitters). In the implementation where first emitter **135** is configured to emit green light, and second emitter **136** is configured to emit red light and infrared light, each detector **137** may be configured to detect light along six long vectors (three long vectors originating from each of the two circumferentially adjacent sensors **116**).

[0040] In one implementation of the disclosure where four sensors **116** are disposed around the circumference of

expandable member **114**, system **100** may record measurements along a total of 36 vectors (12 short vectors and 24 long vectors). Each of the four sensors **116** includes three short vectors, totaling 12 short vectors. Additionally, each of the four sensors **116** includes six long vectors as set forth above, totaling 24 long vectors. Devices with only one optical sensor may have a single vector, which would not enable mapping of the blood vessels around the lumen, the determination of tissue thickness, or the data necessary to size a stent during deployment.

[0041] Referring now to FIG. **5**, an exemplary method **500** is shown. Method **500** may begin at step **502**, where sensors **116** and ECG assembly **104** may be deployed. For example, catheter **102** may be orally inserted into a patient through the nose or mouth and into the gastrointestinal tract through the esophagus and stomach. Using fluoroscopic, ultrasonic, anatomic, or CT guidance, an endoscope (or expandable member **114** alone) may be positioned at a location (region of interest) within the gastrointestinal tract such as the duodenum. The region of interest then may be visualized using an imaging device (e.g., an endoscopic camera), and expandable member **114** may be extended to the region of interest via a working port of the endoscope. Once expandable member **114** is positioned at the location (region of interest), it may be expanded via fluid from fluid delivery device **108**. Before, during, or after insertion of catheter **102** into the body, electrodes **120** of ECG lead assembly **104** may be placed on a suitable site of a patient, such as the patient's chest, to monitor electrical activity of the heart. With expandable member **114** and sensors **116** in position, all other light emitting sources in the body lumen, such as, e.g., a guiding light of an endoscope, may be turned off to avoid interfering with measurements detected by sensor **116**.

[0042] Method **500** may proceed to step **504**, where the system **100** may calibrate sensors **116**. At step **504**, the required gains for detectors **137** and drive currents for the emitters **135** and **136** may be determined. In one implementation, calibration may be accomplished sequentially for each sensor **116**. Calibration for the short vector reflections of each wavelength (e.g., red, infrared, and green) may take place for each sensor **116**. Each of the sensors **116** will be calibrated for each of its short vectors, and the values for the detector gain and current setting for the emitters **135** and **136** may be stored. Then, each sensor **116** may be calibrated for its associated long vectors for each wavelength (e.g., red, infrared, and green) for each circumferentially adjacent sensor.

[0043] The primary purpose of the calibration is to optimize the signal to noise ratio received by detector **137**. The secondary purpose is to obtain the values of the gain and current settings for each vector, which are then used as scoring factors in mapping out the tissue perfusion around the body lumen.

[0044] After calibration, method **500** may proceed to step **506**, where light intensity measurements over time may be made continuously and sequentially for each of the 36 vectors. In some implementations, each detector **137** may be configured to perform more than one measurement at a given time (e.g., pulse, blood oxygen, surrogate blood pressure, mean arterial pressure, perfusion intensity, tissue thickness). Controller **106** may associate a time stamp to each measurement performed, or may otherwise associate the time of day with each waveform collected by each detector **137**. ECG lead assembly **104** may collect ECG data at all times that any detector **137** is collecting optical data.

[0045] After collecting data at step **506**, method **500** may proceed to step **508**, where the collected data may be analysed to generate a perfusion index corresponding to each vector at one or more wavelengths. Perfusion index may be the ratio of the pulsatile blood flow to the non-pulsatile static blood flow. Perfusion index is an indication of pulse strength at the measurement site, and may be indicative of tissue inflammation around the measurement site. The perfusion index may be calculated based on a determined perfusion intensity, which is a measure of blood velocity and its peak amplitude. The perfusion intensity may be determined using a pulse transit time (PTT) and a height of an associated P wave. PTT is the time it takes a pulse pressure (PP) waveform to propagate through a length of an arterial tree. The pulse pressure waveform results from the ejection of blood from the left ventricle and moves with a velocity much greater than the forward movement of the blood itself. The P wave represents atrial depolarization, which may result in atrial contraction.

[0046] The data collected for each vector will be weighed against the calibration values (gain and current), and used to create a perfusion intensity map. Higher gain settings and currents may be flagged as suspected low perfusion regions when looking at P wave heights. The perfusion intensity map then may be manipulated to create a perfusion index map.

[0047] The measured data from sensors **116** may be filtered using a suitable filter, such as a High-Pass Finite Impulse Response (FIR) filter, to remove noise in the data, such as noise caused by distortion created by mechanical ventilation or intestinal peristalsis. For each vector, a PPG signal **515** (FIG. **6**A) and an ECG signal **516** (FIG. **6**B) may synchronized relative to time at a suitable frequency, e.g., 100 Hz. This synchronization is illustrated in FIGS. **6**A and **6**B, which shows the PPG signal **515** over time (FIG. **6**A) for a given vector, and the corresponding ECG signal **516** obtained at the same time.

[0048] The data based on the ECG signal **516** is used to determine an R wave signal. Controller **106** may determine the R wave signal using a derivative based algorithm. Referring to FIG. **6**B, a graph is illustrated depicting ECG signal **516** having determined R waves marked with the letter R. R waves may be used as a trigger to identify PTT. The PTT may be calculated as the time of flight from the R wave of the ECG signal **516** to an associated P wave of PPG signal **515** (see FIGS. **6**A, **6**B, and **7**).

[0049] Referring back to FIG. **6**A, an area **600** under PPG signal **515** may be calculated. This area may represent the volume of pulse as a part of the intensity calculation. The PPG signal **515** is searched between two consecutive R waves, which are used to determine a time window in which to search for a minimum value (shown as "A" in FIG. **6**A) of a segment of the PPG signal **515**. The minimum point A on the PPG signal **515** within the time window after the R wave is used as the starting point of a PPG segment. The ending point of the PPG segment is where the next minimum point of the PPG signal is detected (shown as A' in FIG. **6**A), which is also a starting point for the next PPG segment. To calculate AC area **600**, a boundary line **602** is drawn between minimum points A and A' on the PPG curve. AC area **600** may be the area below PPG signal **515**, above boundary line **602**, and between minimum points A and A'.

[0050] Once area **600** is determined for each vector, a perfusion intensity I_{Perf} may be calculated by dividing the AC area **600** (pulse area) for each vector by the PTT of the same vector. To create the perfusion index, perfusion intensity I_{Perf} may be normalized for all 36 vectors as each may have different gain and current settings. Additionally, it is expected that the 24 long vectors will require higher current and gain settings than the short vectors. Short vector perfusion intensities may be calculated and compared separately from perfusion intensities of the longer vectors. A short vector perfusion index (SV_Index_n) for each of the 12 short vectors may be calculated using the following equation:

$$SV\_Index_n = \frac{I_{Perf_n}}{GAIN_x x I_{LED_n}}$$

I_{LEDn} represents a current associated with a respective LED. A normalization (k) will be made between short and long vectors to create a normalized scoring index. Longer vectors require more current to get a reading that is at an acceptable level above a signal to noise ratio (SNR), and possibly require more gain. k may act as a scaling factor to compensate the larger gain and current settings. Determination of k may require empirical testing in some examples, and may include a balance between the short vector I_Perfn settings with the long vector I_Perf_n settings, for example, where SV_I_PERF=LV_I_PERF. If the resulting intensity measurements are kept the same, k may be the ratio of gain and current setting of long vectors over that of the short vectors.

[0051] The following equation may be used to calculate a long vector index (LV_Index_m), where k is used to scale the result so it is normalized with the short vectors.

$$LV\_Index_m = \frac{I_{Perf_m}}{GAIN_m x I_{LED_m}} k$$

[0052] The indexing score values may be represented as a radial map (see FIG. **8**), which when viewed (method step **510**), gives a visual representation of perfusion index around the body lumen where the measurements were taken with sensors **116**. For illustration, a low perfusion is shown around the SV_**2** portion and adjacent long vectors.

[0053] For two wavelengths (e.g., green and red wavelengths), a variation of the Green's function of a diffusion into a substance can be used with a slope-ratio method to determine tissue wall thickness. The spectral ratio of slopes shown in FIG. **9** represent the difference between short vector perfusion to long vector perfusion of the green wavelength over the difference of the short vector perfusion to long vector perfusion of the red wavelength.

$$\text{Ratio} = \frac{SV\_Index_{green} - LV_{Index_{green}}}{SV\_Index_{red} - LV\_Index_{red}}$$

[0054] This may be evaluated for each position around the sensor array. This ratio may approximate tissue thickness surrounding a body lumen and sensor array. In the example having four optical modules around a circumference of an expandable member, there are two long vectors for each short vector, and thus eight regional ratios. In some examples, slope tomography may be used to determine tissue wall thickness.

[0055] While the slopes used in some examples herein utilize multiple wavelengths of visible light (e.g., green and red), it other examples, combinations of visible and non-visible light may be used to determine tissue wall thickness, such as, e.g., green and IR, or red and IR.

[0056] After step **510**, method **500** may return to step **502** for repositioning of expandable member **114** for additional measurements at different locations in the body.

[0057] More complicated cases of Crohn's Disease, where a stricture may prevent the advancement of a scope/sensor array, may require extra steps of deploying a dilating device to open a passageway, and re-deploying the sensor array. FIGS. **10-13** show various "over-the-scope" devices with sensors **116** that can be used in these more complicated cases. In particular, FIG. **10** shows a system **1000** including an endoscopic device **1002** extending from a proximal end (not shown) to a distal end **1003**. Endoscopic device **1002** may be any suitable endoscopic member, such as, e.g., an endoscope, a ureteroscope, a nephroscope, a colonoscope, a hysteroscope, a uteroscope, a bronchoscope, a cystoscope, a sheath, or a catheter. Endoscopic device **1002** may include one or more additional lumens configured for the passage of a variety of tools and devices, including, but not limited to, imaging devices and tools for irrigation, vacuum suctioning, biopsies, and drug delivery. Endoscopic device **1002** also may include an imaging device, e.g., a camera, at distal end **1003**.

[0058] System **1000** may include a sensor assembly **1004** having an expandable member **1006** disposed between a proximal cuff **1007** and a distal cuff **1008**. Proximal cuff **1007** and distal cuff **1008** each may extend around an exterior surface of endoscopic device **1002**, and may be secured to endoscopic device **1002** by an interference fit or other suitable mechanism. Additionally, in system **1000**, a distalmost end of distal cuff **1008** may be positioned distal to a distalmost end of endoscopic device **1002**.

[0059] One or more sensors **116** may be disposed on an outer surface of expandable member **1006** in a substantially similar manner as described above with respect to sensors **116** and expandable member **114**. In system **1000**, each sensor **116** may be coupled to a control member (e.g., control wire) **1010** that is extended through a working channel of endoscopic device **1002** and connected at its proximal end to controller **106** (shown in FIG. **1**). For example, control members **1010** may be bundled into a sheath **1012**, and sheath **1012** may be extended through the working channel of endoscopic device **1002**. Distal portions of each control member **1010** also may be positioned on an exterior surface of expandable member **1006** and ultimately coupled with a given sensor **116**. Similar to expandable member **114**, expandable member **1006** may be a compliant or semi-compliant balloon configured to inflate and deflate via a fluid conveyed by fluid delivery device **108** (shown only in FIG. **1**). Sheath **1012** also may include a lumen coupled to fluid delivery device **108** to convey fluid to and from expandable member **1006** for inflation and deflation. Alternatively, expandable member **1006** may be coupled to fluid delivery device **108** by another mechanism.

[0060] A system **1100** is shown in FIG. **11**, including a sensor assembly **1104** positioned over endoscopic device **1002** (e.g., the same endoscopic device described with

reference to FIG. **10**). Sensor assembly **1104** may include an expandable member **1106** disposed between a proximal cuff **1107** and a distal cuff **1108**. Proximal cuff **1107** and distal cuff **1108** each may extend around an exterior surface of endoscopic device **1002**, and may be secured to endoscopic device **1002** by an interference fit or other suitable mechanism. Additionally, a distalmost end of distal cuff **1108** may be positioned proximal to a distalmost end of endoscopic device **1002**.

[0061] One or more sensors **116** may be disposed on an outer surface of expandable member **1106**. The arrangement of the sensors **116** on expandable member **1106** may be similar to the arrangement of sensors **116** on expandable member **1006** set forth above, except that control members **1010** may be positioned entirely external to endoscopic device **1002**. For example, control members **1010** may be bundled into a sheath **1112**, and sheath **1112** may extend along the exterior of endoscopic device **1002**. Similar to sheath **1012**, sheath **1112** also may include a lumen coupled to fluid delivery device **108** (shown in FIG. **1**) to convey fluid to and from expandable member **1106** for inflation and deflation.

[0062] A sensor assembly **1201** is shown in FIGS. **12** and **13** in un-deployed and deployed configurations, respectively. Sensor assembly **1201** may be coupled to distal end **1003** of endoscopic device **1002**, and may be configured to position one or more sensors **116** in contact with an inner surface **1222** of a body lumen **1220** (referring to FIG. **13**). Sensor assembly **1201** may include a cuff **1202** having a proximal end **1203** and a distal end **1204**. Cuff **1202** may slide onto distal end **1003** of endoscopic device **1002**. Cuff **1202** may include one or more flexible arms **1208** that are circumferentially spaced apart from one another. Each arm **1208** may include a set curvature. For example, each arm **1208** may have a preset shape in a deployed configuration. As shown in FIGS. **12** and **13**, each arm **1208** may include a concave curvature when viewed from a perspective distal to the arm **1208**, and may include a convex curvature when viewed from a perspective proximal to the arm **1208**. Arms **1208** may be biased into either the un-deployed or deployed configuration.

[0063] Each of the one or more arms **1208** may include a mounted end **1209** and a free end **1210**. Each of the one or more arms **1208** may be at least partially disposed in a corresponding recess **1211** in cuff **1202**. Thus, each recess **1211** may be circumferentially offset from each other recess **1211** of cuff **1202**. Mounted end **1209** of each arm **1208** may form a hinge **1212** with cuff **1202**. Arms **1208** may move from a first, un-deployed position, where free end **1210** is disposed proximally of mounted end **1209**, to a second, deployed position, where free end **1210** is disposed distally of mounted end **1209**. Arms **1208** may be moved between the first and second positions by manipulating endoscopic device **1002** to cause free ends **1210** to engage with tissue. For example, distal movement of endoscopic device **1002** may cause tissue of a body lumen to push proximally against free ends **1210**, moving arms **1208** into the configuration shown in FIG. **12**. On the contrary, proximal movement of endoscopic device **1002** causes tissue of the body lumen to push distally against free ends **1210**, moving arms **1208** into the configuration shown in FIG. **13**. Thus, arms **1208** may be moved between un-deployed and deployed positions by only passive mechanisms without any powered and/or automated components. Alternatively, arms **1208** may be actively moved between the un-deployed and deployed configurations by an active mechanism, such as, e.g., a combination of motors, gears, and actuators. For example, a user may activate an actuator that causes a combination of motors and gears to move arms **1208** between the un-deployed and deployed positions. Furthermore, in one embodiment, each arm **1208** may lie flat/flush within a corresponding recess **1211**, and an actuator may release each arm **1208** when arms **1208** are positioned at a desired tissue site.

[0064] A sensor **116** may be coupled to free end **1210** of each arm **1208**. When arms **1208** are in the first, un-deployed position shown in FIG. **12**, the optical components of sensors **116** may face radially inward toward a central longitudinal axis **1230** of sensor assembly **1201**, and may not be operable. In the second, deployed position shown in FIG. **13**, the optical components of sensors **116** may face radially outward away from central longitudinal axis **1230** and toward surface tissue **1222**. Similar to the device shown in FIG. **11**, control members **1010** may be positioned entirely external to endoscopic device **1002**. For example, control members **1010** may be bundled into a sheath **1212**, and sheath **1212** may extend along the exterior of endoscopic device **1002**.

[0065] The systems shown in FIGS. **10** and **11** may be configured to operate in a similar manner as set forth in step **502** of method **500** (FIG. **5**). For example, the region of interest may be observed using an imaging device (e.g., endoscopic camera). Then, instead of deploying catheter **102** to the region of interest, distal end **1003** of endoscopic device **1002** may be advanced to the region of interest, where a respective expandable member (**1006** or **1106**) is expanded to position sensors **116** in contact with tissue. The system shown in FIGS. **12** and **13** also may operate in a similar manner. For example, after visualization of the region of interest using the system of FIGS. **12** and **13**, distal end **1003** of endoscopic device **1002** may be extended distally of the region of interest, and then pulled proximally to the region of interest to cause arms **1208** to move from the first, un-deployed configuration to the second, deployed configuration.

[0066] The systems shown in FIGS. **10-13** also may stabilize the endoscopic devices on which they are deployed, and centralize the field of view within the lumen being observed. These devices also may be used to stretch out folds within the observed lumen to improve visibility in areas that are difficult to see (e.g., around or within folds in the colon and/or intestinal walls). These effects may improve diagnostic outcomes. Yet another advantage of at least certain embodiments of these devices may be to free up the working port of the endoscopic device, enabling an operator to deploy other medical devices (for, e.g., irrigation, hemostasis stabilization, suturing, tissue sampling, or the like). Devices and methods of the present disclosure may help quantify the severity of tissue damage or healing following treatment, improving diagnostic outcomes by making them less speculative. This may be particularly relevant for inflammatory bowel diseases and ulcerative colitis. Furthermore, at least certain embodiments of devices and methods of the disclosure help improve diagnostic techniques by enabling the measurement of perfusion and thickness in regions of interest. These measurements also help enable physicians to follow the progression of treatment. Furthermore, it is contemplated that any of the inflatable members (e.g., balloons) described herein may be shaped such that, in

one or more inflated configurations (including a fully inflated configuration), the outer surface of the balloon contacts less than an entirety of a body lumen (e.g., 270 degrees or less, 180 degrees or less, 90 degrees or less around the lumen).

[0067] A medical device **1400** is shown in FIGS. **14-16**. Medical device **1400** extends from a proximal end (not shown) toward a distal end **1402**. Medical device **1400** may have a relatively slim profile, and may be used to measure tissue thickness in areas of the body that are not accessible by larger devices. Medical device **1400** may include a diagnostic catheter with at least a two-way steering mechanism. Such a catheter could be made for deployment in a 3.7 mm working port of an endoscope so that it can be visually placed at the region of interest, allowing for tangential tissue measurements.

[0068] Medical device **1400** includes a catheter **1403** and an optical sensor **1404** disposed at or adjacent to distal end **1402**. Catheter **1403** may be a hollow catheter having an open distal portion **1406** in which optical sensor **1404** rests. A majority of catheter **1403** may have a circular cross-section. However, open distal portion **1406** may have a different cross-section, such as, e.g., a half-moon shaped cross-section or another suitable design that enables components of optical sensor **1404** to be placed flush against tissue. Thus, optical components of optical sensor **1404** may face radially outward from a side-facing surface of catheter **1403** (a surface that faces a direction perpendicular to a longitudinal axis of catheter **1403**). Open distal portion **1406** may include a distal and side facing opening of catheter **1403**. The side-facing portion of the opening may extend distally of the distal facing opening.

[0069] Catheter **1403** also may include an articulating joint **1412**. Control cables (not shown) may be connected to a set of control knobs at the proximal end of medical device **1400**, and to articulating joint **1412** to control articulation of articulating joint **1412**. By manipulating the control knobs, an operator may be able to actuate, or bend, articulating joint **1412** during insertion and direct it to a region of interest. Catheter **1403** also may include an atraumatic tip **1414**. For example, tip **1414** may include a soft or flexible material to allow catheter **1403** to navigate and traverse the tortuous pathways of a body in a generally atraumatic manner.

[0070] A substrate **1435***a* may be disposed at open distal portion **1406** of catheter **1403**. Substrate **1435***a* may include a flexible printed circuit board (PCB) that is semi-rigid and that includes a stiffener. Components of optical sensor **1404** may be mounted on to substrate **1435***a*. One or more control wires **1435***c* may extend proximally from optical sensor **1404** to couple optical sensor **1404** to, e.g., power sources, computing devices, and the like.

[0071] Optical sensor **1404** may include a photodetector **1437**, and emitters **1436***a*, **1436***b*, and **1436***c*. Photodetector **1437** and emitters **1436** may be substantially similar to detector **137** and emitters **136** set forth above. Each emitter **1436***a-c* may be configured to radiate infrared light, or another suitable wavelength. For example, some applications may benefit from infrared light, while other applications may benefit from other wavelengths of light. For example, infrared light wavelengths may penetrate deeper into tissue while visible light provides more information regarding surface characteristics. Different wavelengths reflect back de-oxygenated/oxygenated blood differently, and there are known ratios that related to levels of oxygen, carbon dioxide and other characteristics in the tissue. While three emitters are shown in the embodiment of FIGS. **14-16**, any other suitable number may be utilized. Photodetector **1437** and each of emitters **1436***a-c* may be disposed linearly along a same axis, such as, e.g., a longitudinal axis of catheter **1403**. Exemplary dimensions of optical sensor **1404** are shown in FIG. **16**. While certain values for each dimension are discussed below, it is contemplated that alternative dimensions also may be used. Substrate **1435** may have a length **1602** (e.g., 15 mm), and a width **1604** (e.g., 3 mm). A distalmost portion of photodetector **1437** may be disposed a distance **1606** (e.g., 1 mm) from a distalmost end of substrate **1435**. A proximalmost portion of photodetector **1437** may be disposed distances **1608** (2 mm), **1610** (6 mm), and **1612** (10 mm) from distalmost portions of emitters **1436***a*, **1436***b*, and **1436***c*, respectively. It is contemplated that other suitable dimensions also may be utilized.

[0072] A lens **1438** may be disposed over optical sensor **1404** (including photodetector **1437** and each emitter **1436***a-c*). Lens **1438** may isolate optical sensor **1404** from tangential back scatter light between emitters **1436** and photodetector **1437** from substrate **1435***a*. Lens **1438** also may provide a barrier between tissue and the optical elements of optical sensor **1404**. The configuration of lens **1438** and optical sensor **1404** may help enable medical device **1400** to determine tissue thickness in the body with a relatively small profile and package. Lens **1438** may be formed from plastic, glass, or another suitable material.

[0073] Photodetector **1437** may be a square-shaped photodetector having sides with a length of 2 mm, although other suitable shapes and dimensions are contemplated. Each emitter **1436** may be a square-shaped emitter having sides with a length of 1 mm, although other suitable shapes and dimensions are contemplated. In some implementations, a length of the flexible substrate is no more than 15 mm. In another embodiment, a length of the flexible substrate is no more than 11 mm.

[0074] Optical sensor **1404** may be coupled to a controller **1450** attached to a substrate **1435***b* that is substantially similar to substrate **1435***a* described above. Controller **1450** may be disposed entirely within a volume contained within catheter **1403**. When controller **1450** is disposed within catheter **1403**, it may have a width less than 3 mm. Alternatively, controller **1450** may be disposed external to medical device **1400**, in which case, the control wires from controller **1450** to optical sensor **1404** may be attached to a flexible extension of the device.

[0075] Controller **1450** may be configured to direct and source constant current for each emitter **1436***a-c* separately, but not simultaneously, as the data acquisition may be time multiplexed during a sampling cycle. In other words, at any given time, only one of emitters **1436***a-c* may emit light. The current setting for each emitter **1436***a-c* may change due to the spatial diversity from photodetector **1437**, and may be adjusted during a calibration process. Photodetector **1437** may require control of an amplification device. Since photodetector **1437** may be mostly capacitive, a trans-impedance amplifier may be used for the analog interface.

[0076] The spatially diverse optical sensor **1404** may be driven through three time division slots to activate each emitter **1436***a-c* separately, with a fourth time slot allowing for data acquisition when none of the emitters **1436***a-c* is activated. This fourth time slot enables the sampling of ambient light. If an operator is confident that the area being

measured has no ambient light, then the fourth time slot may be skipped to reduce procedure time. This sequence is shown in FIG. **17**. The acquisition of samples may be timed sequentially to enable each emitter **1436** a small period of on-ramp to allow for wavelength and temperature stabilization before a measurement is obtained by photodetector **1437**. Suggested sample times could be from 50 microseconds to 200 microseconds per data acquisition. A sample period may include the complete cycle of all four periods, and may impact the overall sample rate of the signal data acquisition.

[0077] For tissue thickness measurements, 50 samples per second may be adequate, allowing for a total sample period of 20 milliseconds. This would allow for 200 microsecond emitter (LED) sampling. In order to increase data fidelity, the sample period may be increased to, e.g., up to 200 samples. In this case, the total sampling period for all four channels is 500 microseconds, allowing for emitter sampling of about 100 microseconds. A longer emitter sampling period allows for a more refined dynamic range of the analog sampling through photodetector **1437** with lower emitter current being supplied (similar to more exposure time in photography for a lower light setting).

[0078] The analog data provided by the amplifier after sampling each emitter may be converted to digital format for further processing. This disclosure contemplates any suitable type of analog to digital converter (ADC). The accuracy of the ADC may be at least comparable to an 8-bit or greater ADC to meet the measurement requirements of the applications contemplated by this disclosure.

[0079] The medical devices described with respect to FIGS. **14-17** can enable the use of emitters using a centroid wavelength of approximately 940 nm (e.g., 930-950 nm) arranged linearly apart from one another to collect a diffusion gradient of reflected and absorbed light in tissue. Evaluation of the gradient makes use of a slopes-ratio method to correlate measurements made by photodetector **1437** with tissue thickness. The ratio comprises three different vectors coming from three LED emitters (e.g., emitters **1436***a-c*) relative to a fixed photodiode (e.g., photodetector **1437**). Considering the distance of the emitters **1436***a-c* from photodetector **1437**, emitter **1436***a* is the closest to photodetector **1437** at a distance of two mm, emitter **1436***b* is mid-range relative to photodetector **1437** at a distance of six mm, and the furthest is emitter **1436***c* at a distance of ten mm relative to photodetector **1437**.

[0080] Tissue thickness may be determined based on data collected by photodetector **1437**. For example, a ratio of slopes method can be used for evaluating the short, mid and long reflective distances as shown in the formula below:

$$T_{ratio} = \frac{1436a - 1436b}{1436a - 1436c}$$

[0081] In the above equation, **1436***a*, **1436***b*, and **1436***c* represent values measured by photodetector **1437** in response to emissions from emitters **1436***a*, **1436***b*, and **1436***c*, respectively. This equation is used further in the linear model described below.

[0082] The use of different wavelengths may provide an ability to measure different skin depths. Infrared light, for example, may provide better skin depth penetration than some of the wavelengths in the visible spectrum. Other wavelengths offer different optical properties in live tissue, and may be used for other characteristics and still provide thickness measurements. Empirical results from a study show slight variations in early results using simulated tissue phantoms. The basis of certain results are from fabricated models. In a lab setup, different wavelengths were evaluated to determine different absorption and reflection patterns.

[0083] A fitted line for linear model statistical regression from data collected with an exemplary device similar to the device described by FIGS. **14-16** is shown below.

[0084] Coefficients:

TABLE 1

Statistical Curve for Collected Data

	Estimate	Standard Error	t value	Pr(>|t|)
Intercept	0.891731	0.011087	80.434	1.43E−07
Thickness	−0.017409	0.002181	−7.982	0.00134

[0085] Table 1 illustrates how well the regression fits in the data. Intercept (b) and thickness (m) estimates are the coefficients for scaling according to the collected data. The significance codes are a function of the R utility to give a approximation of how valid the probability of the null hypothesis tested is. The smaller the Pr value, the higher the significance. When significance is higher, the mathematical outcome being evaluated is higher.

[0086] The residual standard error was 0.0128 on four degrees of freedom. The multiple R-squared was 0.9409, and the adjusted R-squared was 0.9262. The F-statistic was 63.71 on one and four degrees of freedom, and the p-value was 0.001335. The correlation value was −0.9700123, which measures the linear relationship between two variables. In this case, there is a negative correlation between the IR slope value and tissue thickness. As the thickness increases, IR slope value decreases (i.e., they are inversely related to each other). Both of the p-values were below 0.05 thresholds, and thus, this model was statistically significant.

[0087] Model Fitted Values

Thickness	Actual IR Values	Fitted IR Values
1.6	0.869627	0.8638776
2.5	0.858604	0.8482098
3.0	0.834698	0.8395055
4.9	0.789127	0.8064291
6.4	0.773979	0.7803161
8.5	0.756061	0.743758

[0088] Table 2 shows the delta between the real values collected for each thickness measurement and the related curve fit plot.

[0089] Linear Model

$$Y = 0.891731 - 0.017409X$$

[0090] The R-squared value was 0.9409. 94 percent represents the proportion of variation in the response variable. Thus, as tissue thickness increases, the IR slope value decreases.

[0091] The linear model is shown in FIG. **18**, which is a fitted line plot regression analysis of this experiment in an SIG lab with phantom optical equivalent tissue models using slopes ratios methods.

[0092] One example translation with this dataset is:

$$\text{Thickness (mm)} = \frac{R - T_{ratio}}{k}$$

[0093] Where R is the intercept (0.8917 in this example) and k (0.01741 in this example) is the slope (negative) derived from experimental data.

[0094] The relatively slim profile of medical device **1400** also may enable internal placement of medical device **1400** though a scope using direct visualization methods. Medical device **1400** may be used to access many regions of interest in the intestinal tract (e.g., esophagus, stomach, large intestines, duodenum, and parts of the small intestines). In other examples, medical device **1400** may be used to measure thickness in a region of interest, which can then be used as a datapoint to help quantify the severity of healing or inflammation. The data can be part of an index if used with other measurements, such as, e.g., changes in perfusion, temperature, microvascular changes for severity scoring and healing of the tissue of interest. Furthermore, because optical sensor **1404** is flat, it may be used to determine tissue thickness when placed external to a patient, such as, for example, against the skin of a patient.

[0095] Those skilled in the art will understand that the medical devices set out above can be implemented in any suitable body lumen (e.g., blood vessels, the biliary tract, urological tract, gastrointestinal lumens, and the like) without departing from the scope of the disclosure as defined by the claims. In particular, constructional details, including manufacturing techniques and materials, are well within the understanding of those of skill in the art and have not been set out in any detail here. These and other modifications and variations are well within the scope of the present disclosure and can be envisioned and implemented by those of skill in the art.

[0096] Other implementations of the present disclosure will be apparent to those skilled in the art from consideration of the specification and practice of the implementations disclosed herein. It is intended that the specification and implementations be considered as examples only, and departures in form and detail may be made without departing from the scope and spirit of the present disclosure as defined by the following claims.

What is claimed is:

1. A system, comprising:

an expandable member;

a plurality of sensors disposed on an outer surface of the expandable member and circumferentially spaced apart from one another, wherein each of the plurality of sensors includes a first emitter configured to emit light of a first wavelength, and a detector configured to detect light;

a controller communicatively coupled to the plurality of sensors, wherein the controller is configured to:

from at least one detector, receive along a first short vector, a measurement of light intensity over time of light, reflected off of body tissue, at the first wavelength and originating from a first emitter from a same sensor;

from at least one detector, receive along a first long vector, a measurement of light intensity over time of light, reflected off of body tissue, at the first wavelength and originating from a first emitter from a circumferentially adjacent sensor,

calculate separate perfusion indexes corresponding to measured light intensity over time of each first short vector and each first long vector; and

initiate the display of the separate perfusion indexes corresponding to measured light intensity over time of each first short vector and each first long vector.

2. The system of claim **1**, wherein each of the plurality of sensors includes a second emitter configured to emit light of a second wavelength that is different than the first wavelength, wherein the controller is further configured to:

from each detector, receive along a second short vector, a measurement of light intensity over time of light, reflected off of body tissue, at the second wavelength and originating from a second emitter from a same sensor;

from each detector, receive along a second long vector, a measurement of light intensity over time of light, reflected off of body tissue, at the second wavelength and originating from a second emitter from a circumferentially adjacent sensor;

calculate separate perfusion indexes corresponding to each second short vector and each second long vector; and

cause the display of the calculated separate perfusion indexes corresponding to each second short vector and each second long vector.

3. The system of claim **2**, wherein the second emitter is configured to emit light of a third wavelength different than the first wavelength and the second wavelength, wherein the controller is further configured to:

from each detector, receive along a third short vector, a measurement of light intensity over time of light, reflected off of body tissue, at the third wavelength and originating from a second emitter from a same sensor;

from each detector, receive along a third long vector, a measurement of light intensity over time of light, reflected off of body tissue, at the third wavelength and originating from a second emitter from a circumferentially adjacent sensor;

calculate separate perfusion indexes corresponding to each third short vector and each third long vector; and

cause the display of the calculated separate perfusion indexes corresponding to each third short vector and each third long vector.

4. The system of claim **3**, wherein the controller is further configured to, from each detector, receive along two third long vectors, measurements of light intensity over time of light, reflected off of body tissue, at the third wavelength and originating from second emitters of two different circumferentially adjacent sensors.

5. The system of claim **3**, wherein the third wavelength is infrared light.

6. The system of any claim **2**, wherein the controller is further configured to, from each detector, receive along two second long vectors, measurements of light intensity over time of light, reflected off of body tissue, at the second wavelength and originating from second emitters of two different circumferentially adjacent sensors.

7. The system of claim **2**, wherein the second wavelength is visible red light.

8. The system of claim **1**, wherein the controller is further configured to, from each detector, receive along two first

long vectors, measurements of light intensity over time of light, reflected off of body tissue, at the first wavelength and originating from first emitters of two different circumferentially adjacent sensors.

9. The system of claim **1**, wherein the first wavelength is visible green light.

10. The system of claim **1**, further including an ECG assembly coupled to the controller and configured to measure ECG signals.

11. The system of claim **1**, wherein the controller is further configured to:

while calculating each perfusion index, synchronize in time, measured light intensity from each vector with a measurement from the ECG assembly to determine pulse transit time and perfusion intensity; and

use the pulse transit time and the perfusion intensity to calculate a respective perfusion index corresponding to each vector.

12. The system of claim **1**, wherein the controller is configured to receive a measurement of light intensity over time along only one first short vector or first long vector at any given time.

13. The system of claim **1**, wherein the plurality of sensors includes four circumferentially spaced apart sensors.

14. The system of claim **1**, wherein each detector is longitudinally aligned with each other detector.

15. The system of claim **1**, wherein each first emitter is longitudinally aligned with each other first emitter.

16. A method for determining blood flow surrounding a body lumen using a plurality of sensors, the method comprising:

receiving, with a detector at each sensor, a measurement of light intensity over time of light, reflected off of body tissue, at a first wavelength and originating from a first emitter from a same sensor as the detector;

receiving, with a detector at each sensor, a measurement of light intensity over time of light, reflected off of body tissue, at a first wavelength and originating from a first emitter from a sensor circumferentially adjacent to the detector;

calculating separate perfusion indexes based on each measurement; and

displaying the separate perfusion indexes.

17. The method of claim **16**, wherein the body lumen is in a gastrointestinal tract.

18. The method of claim **16**, wherein only one measurement is received at any given time.

19. The method of claim **16**, wherein each measurement is taken while the plurality of sensors are in a same location within the body lumen.

20. A medical device, comprising:

a catheter;

an optical sensor disposed at or adjacent to a distal end of the catheter, the optical sensor including a photodetector and one or more emitters, the photodetector and each of the one or more emitters of the optical sensor being disposed linearly along a longitudinal axis of the catheter; and

a controller disposed within the catheter, the controller being configured to determine a thickness of tissue adjacent to the optical sensor based on input from the optical sensor.

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专利名称(译)	用于确定体腔周围的血流的装置和方法		
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摘要(译)

系统可包括可扩展构件，和设置在可扩展构件的外表面上并且彼此周向间隔开的多个传感器，其中多个传感器中的每一个包括配置成发射第一波长的光的第一发射器，检测器，配置为检测光，以及控制器，连接到多个传感器。