



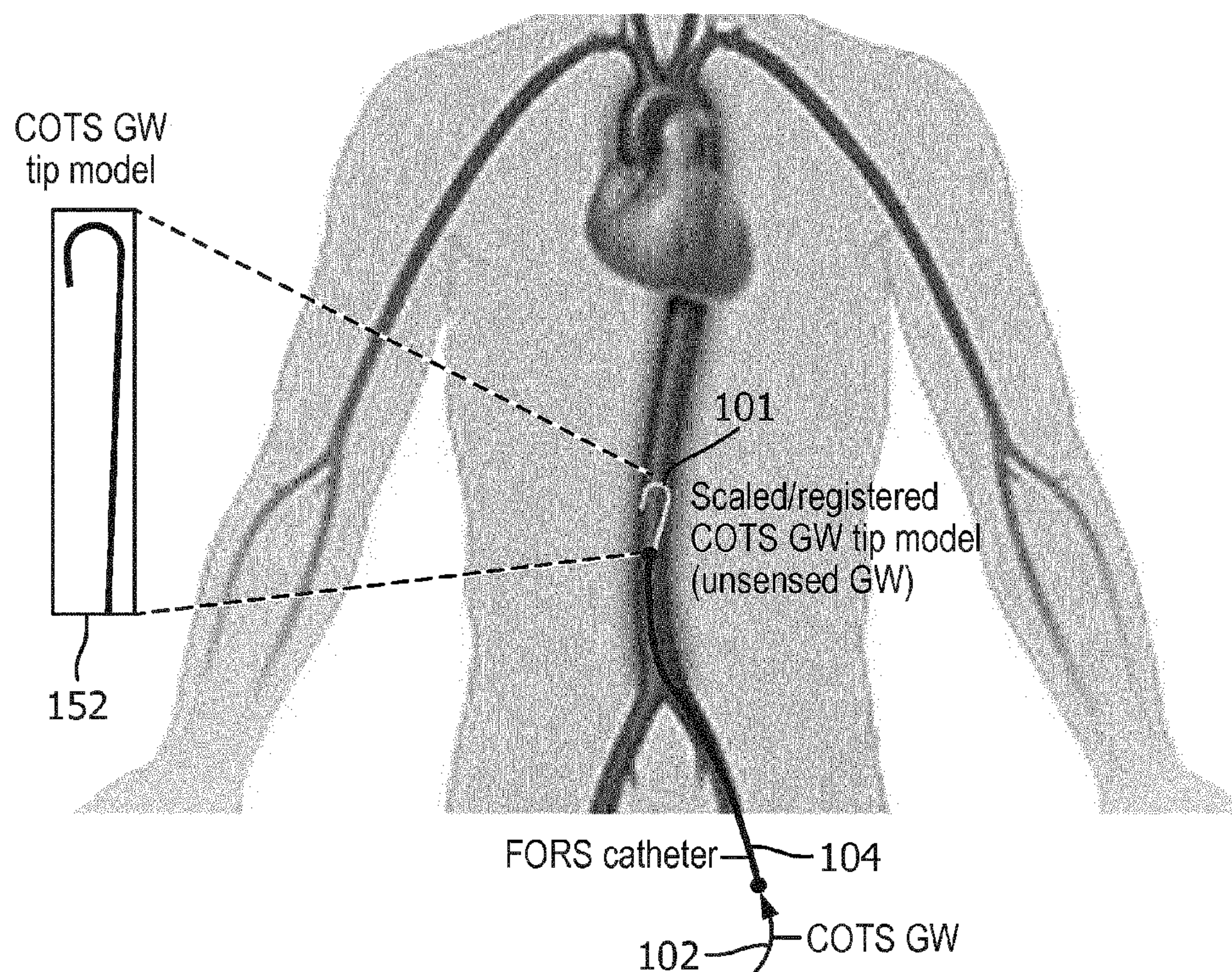
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(19) **United States**(12) **Patent Application Publication**
THIENPHRAPA et al.(10) **Pub. No.: US 2019/0313940 A1**(43) **Pub. Date: Oct. 17, 2019**(54) **SYSTEMS AND METHODS FOR
DETERMINING THE POSITION OF A
NON-SHAPE-SENSED GUIDEWIRE WITH A
SHAPE-SENSED CATHETER AND FOR
VISUALIZING THE GUIDEWIRE**(71) Applicant: **KONINKLIJKE PHILIPS N.V.**,
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(2013.01); **A61B 2034/2061** (2016.02); **A61B**
90/39 (2016.02); **G01L 1/246** (2013.01); **A61B**
5/066 (2013.01)(57) **ABSTRACT**

A system and method for determining the position of a non-shape-sensed guidewire (102) and for visualizing the guidewire. The system includes a shape-sensed catheter (104) having a lumen (103) that is configured to receive the non-shape-sensed guidewire. A measurement module (122) is configured to measure a distance that the non-shape-sensed guidewire moves. The measurement module may receive signals from a sensor (124) associated with a measurement assembly that is configured to receive at least a portion of the non-shape-sensed guidewire and/or the shape-sensed catheter. A location module (126) is configured to determine a position of the non-shape-sensed guidewire. The system is configured to generate a virtual image (101) of the guidewire. The system is configured to generate a virtual image (101) of the guidewire, including a portion of the non-shape-sensed guidewire that does not extend along a shape-sensing optical fiber.



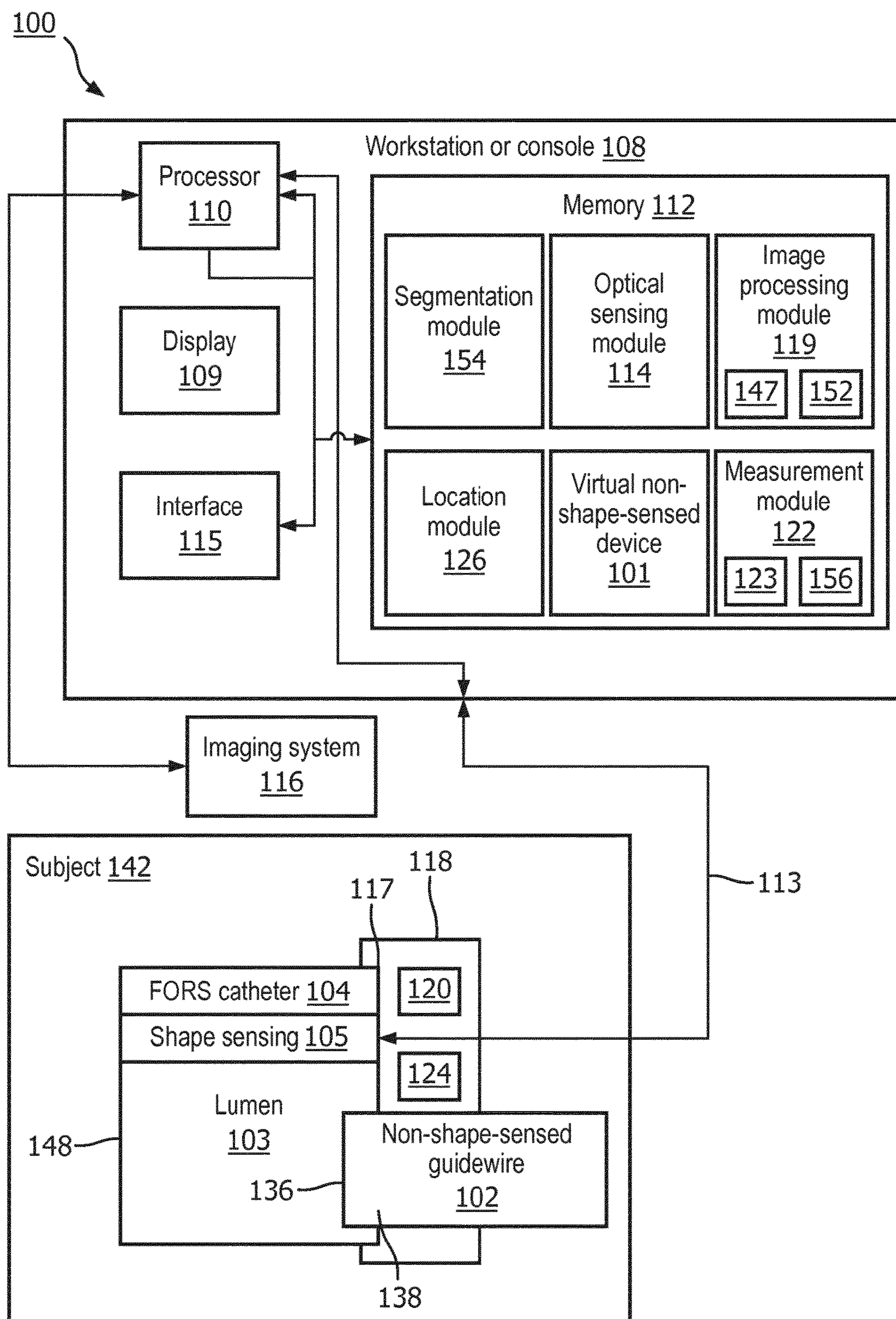


FIG. 1

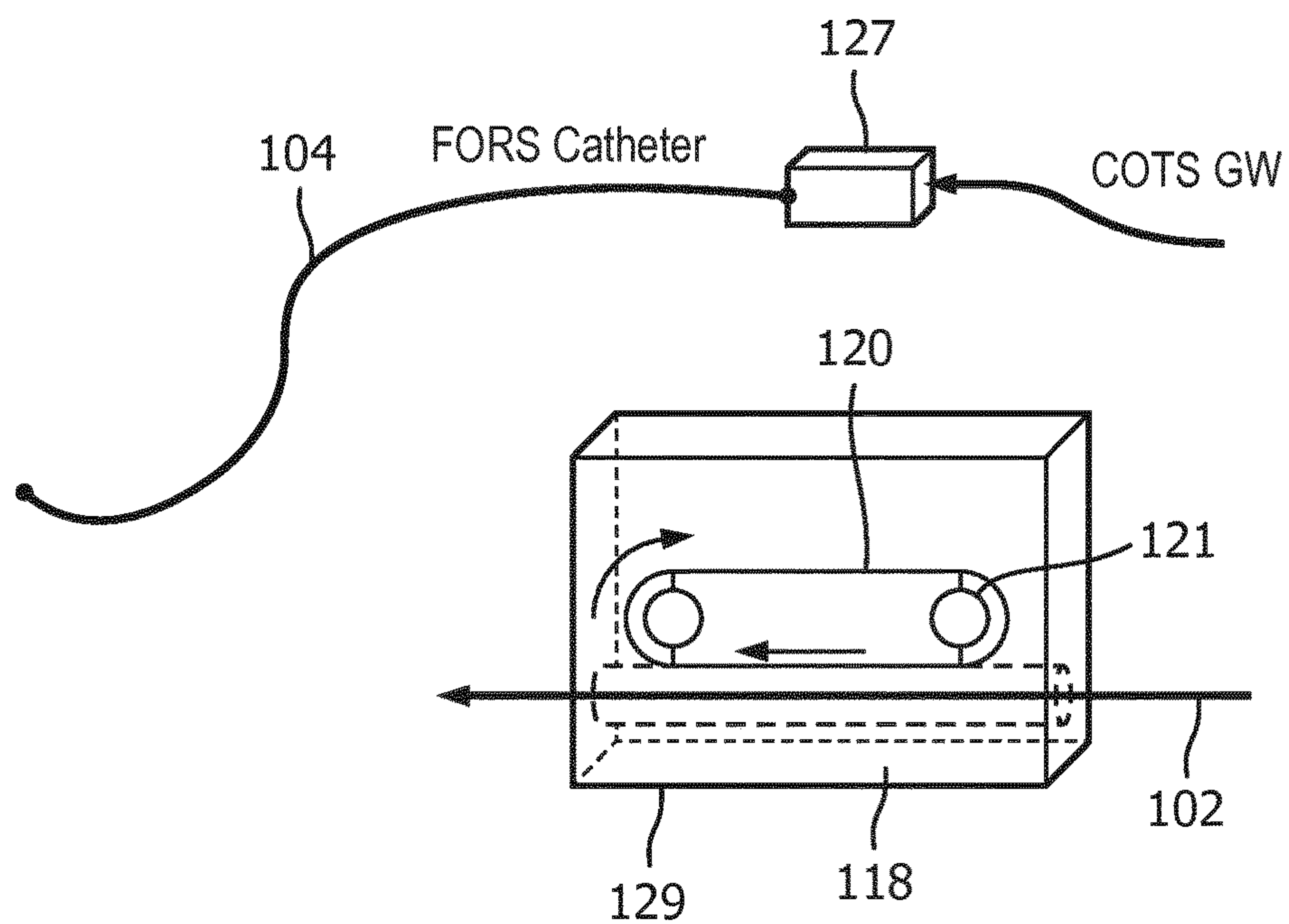


FIG. 2

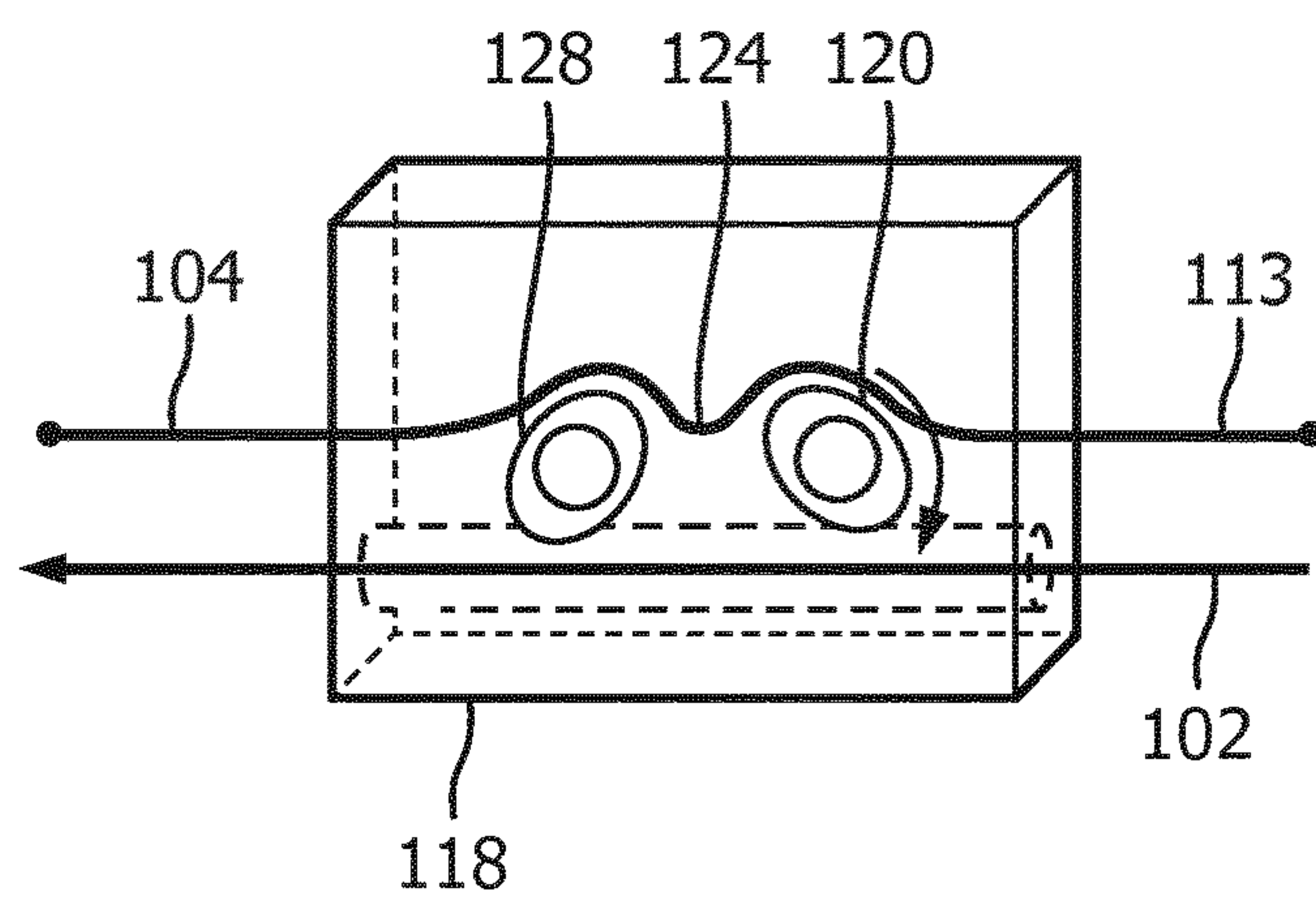


FIG. 3

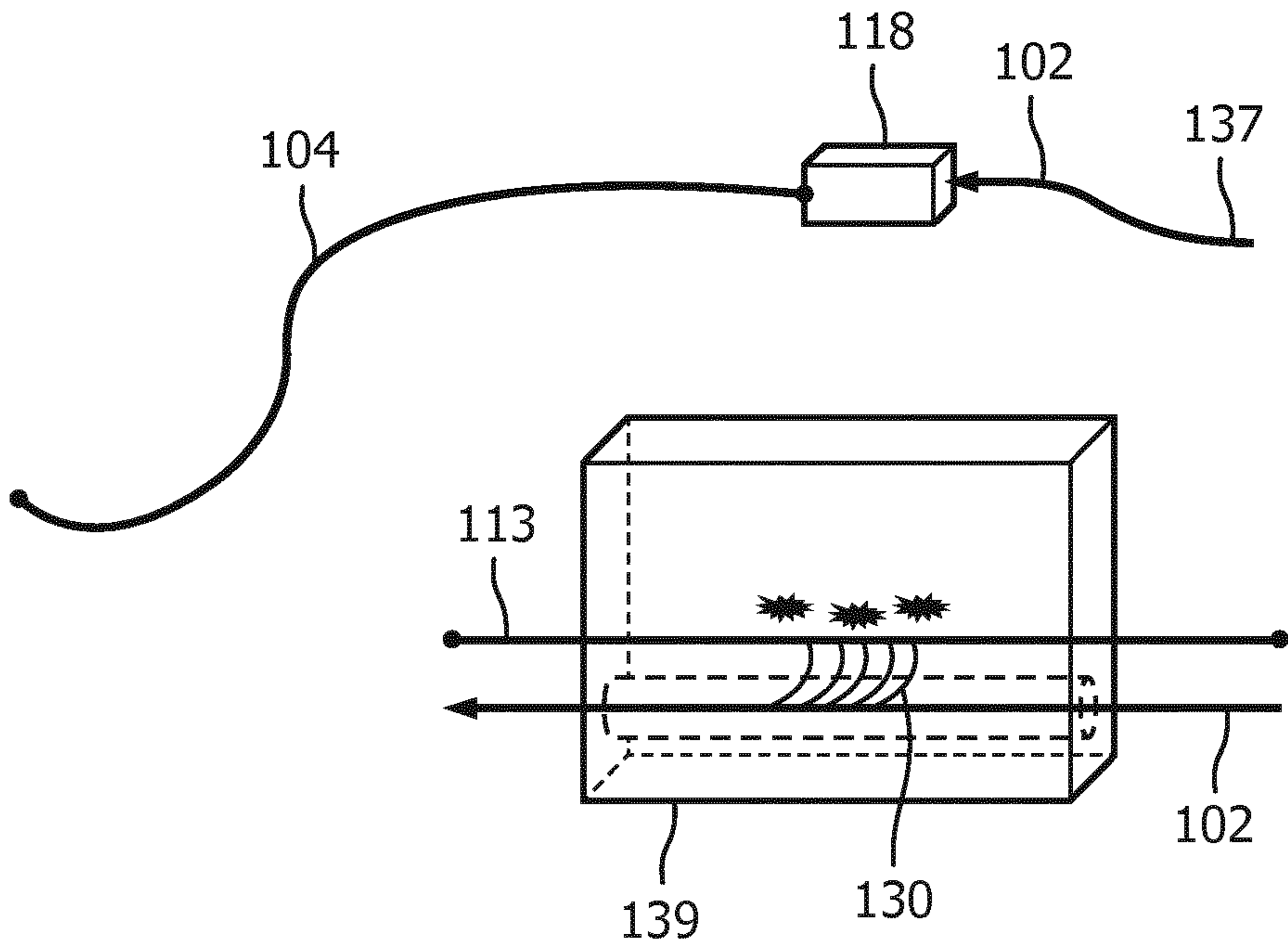


FIG. 4

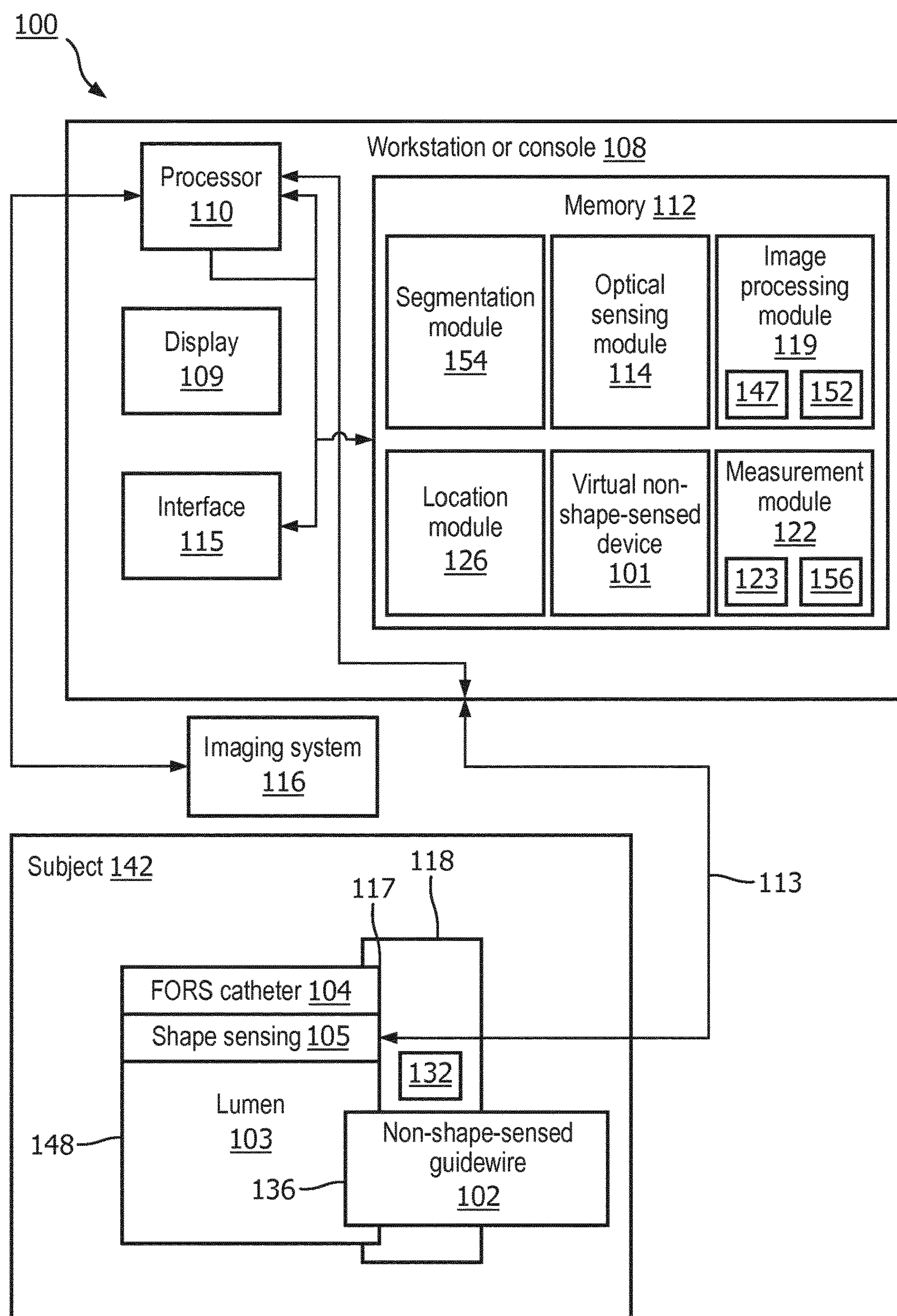
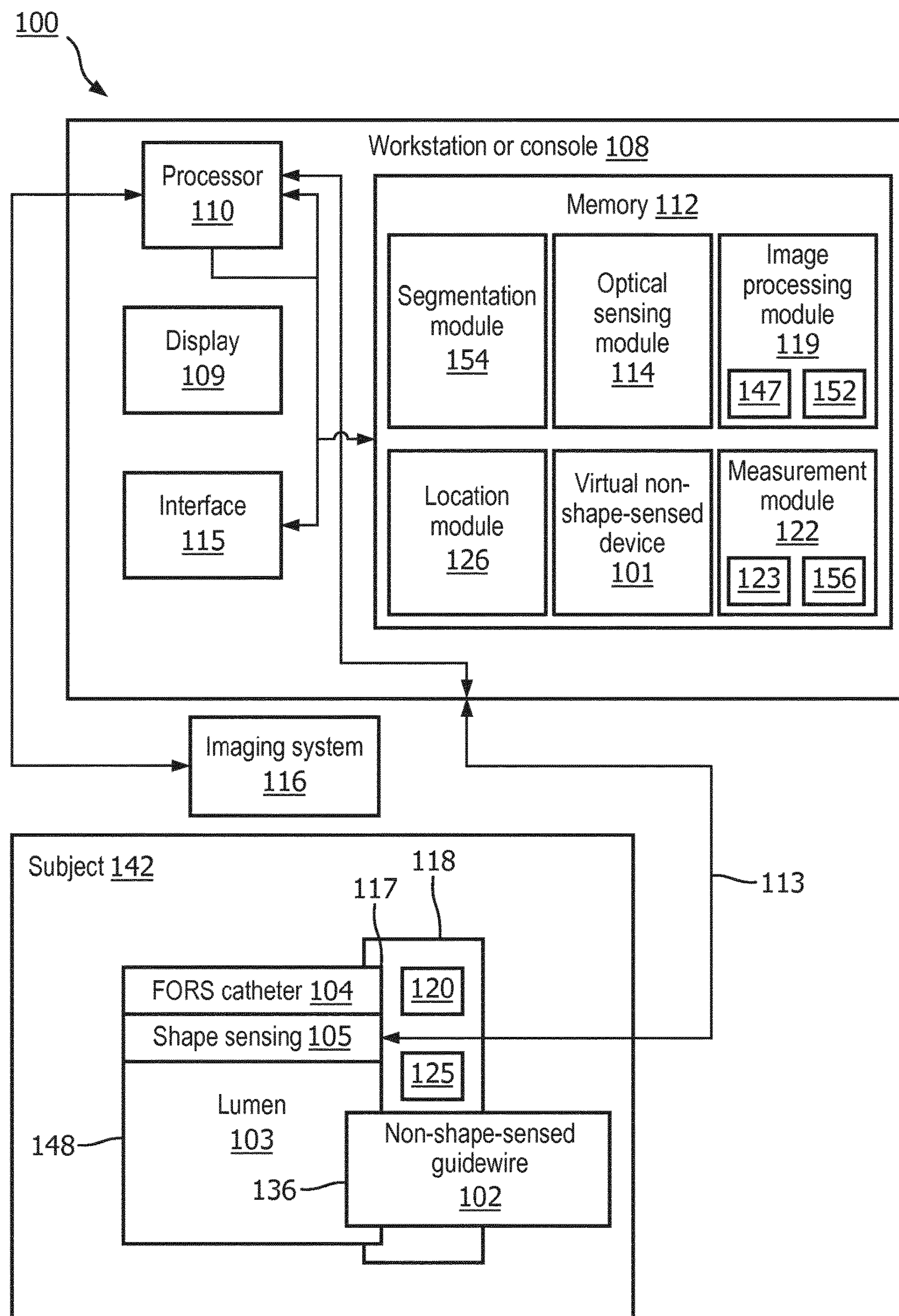


FIG. 5



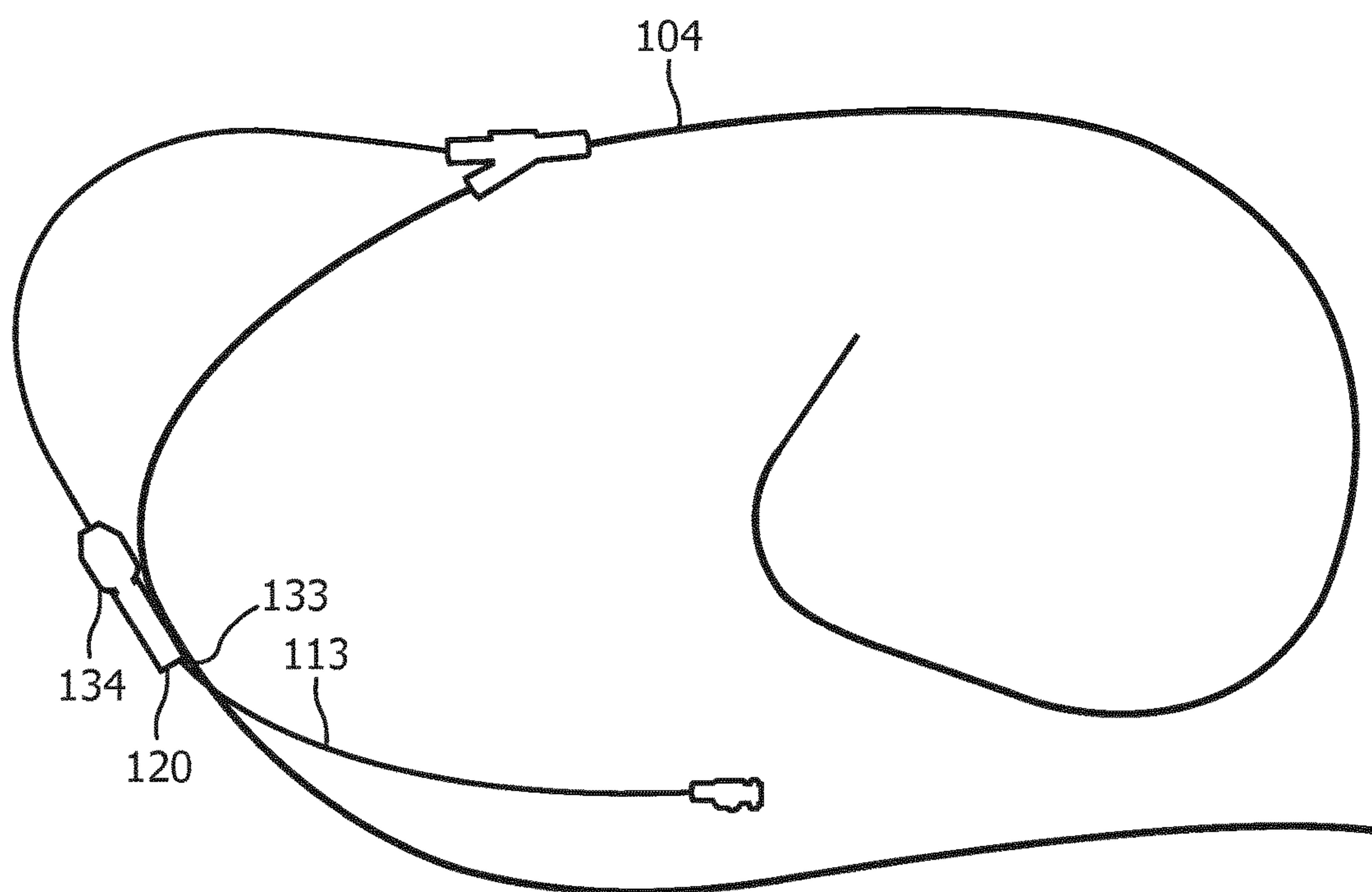


FIG. 7

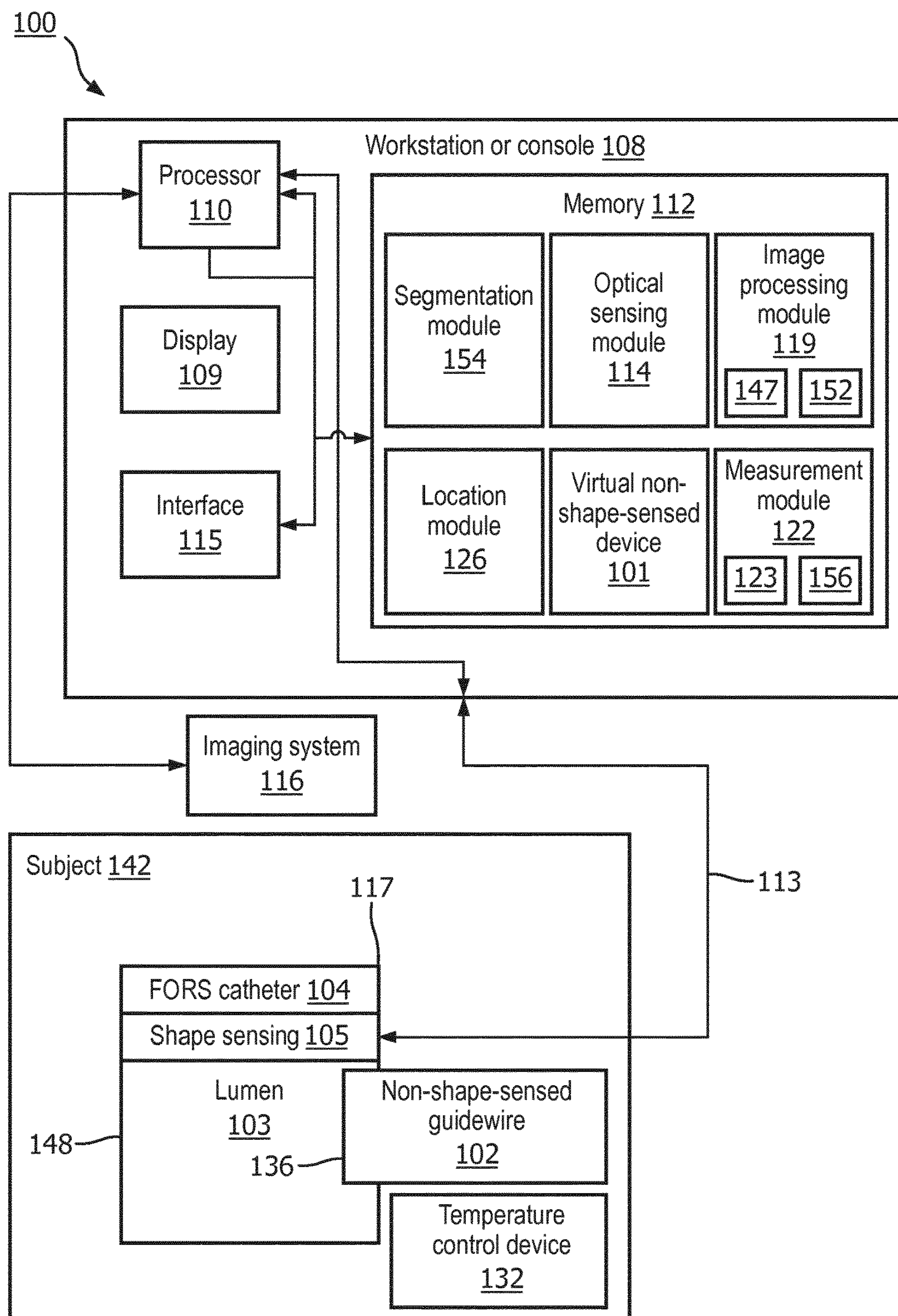


FIG. 8

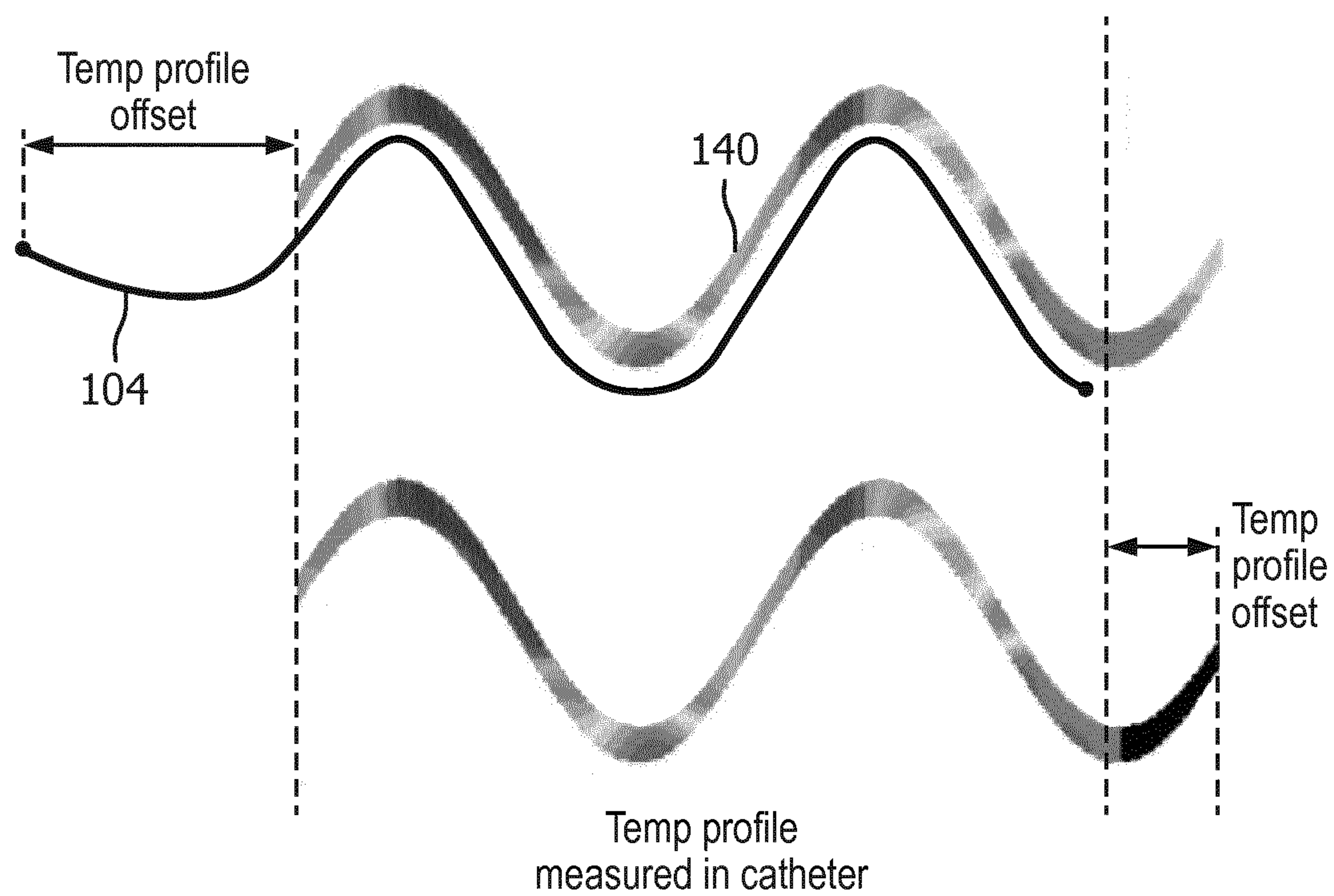


FIG. 9

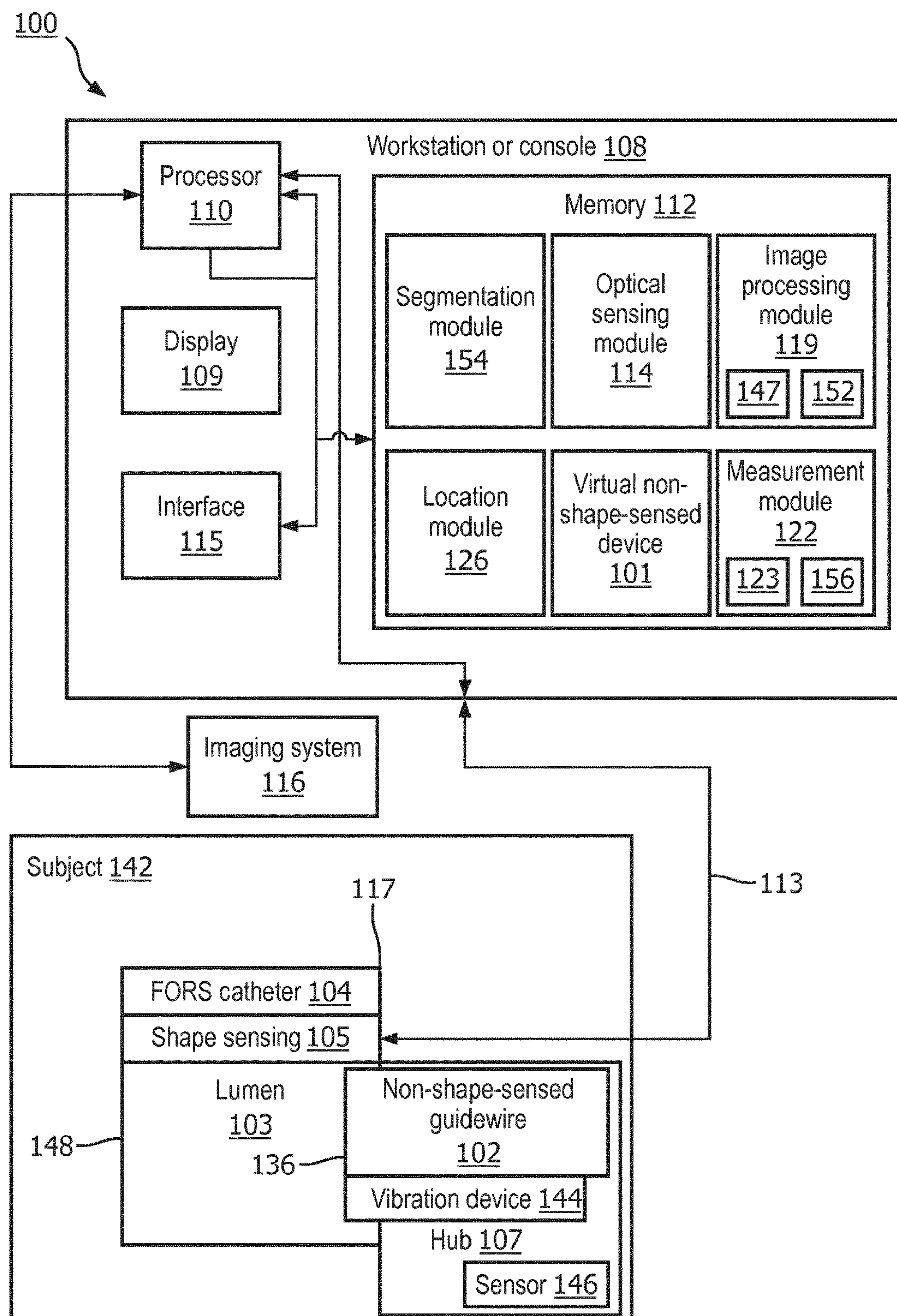


FIG. 10

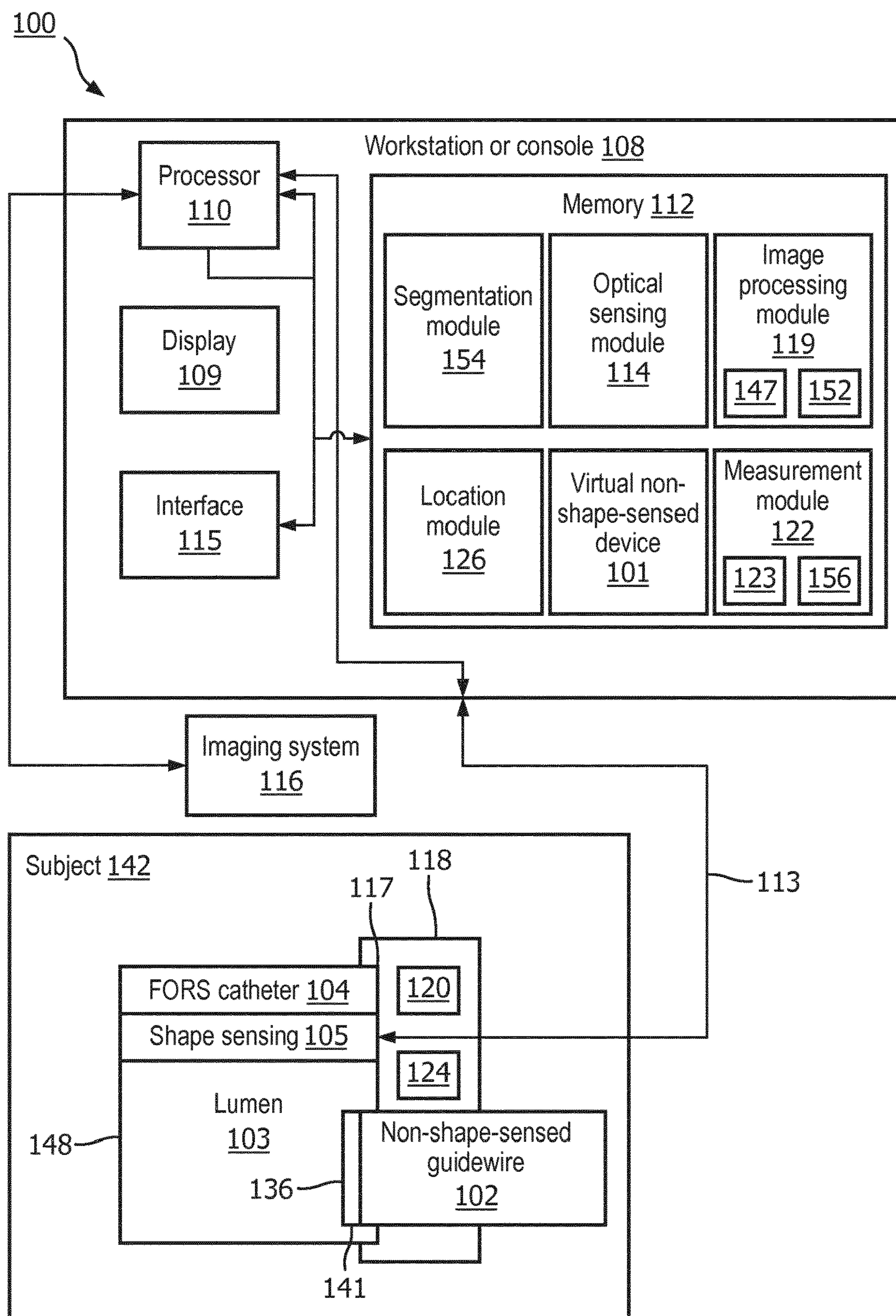


FIG. 11

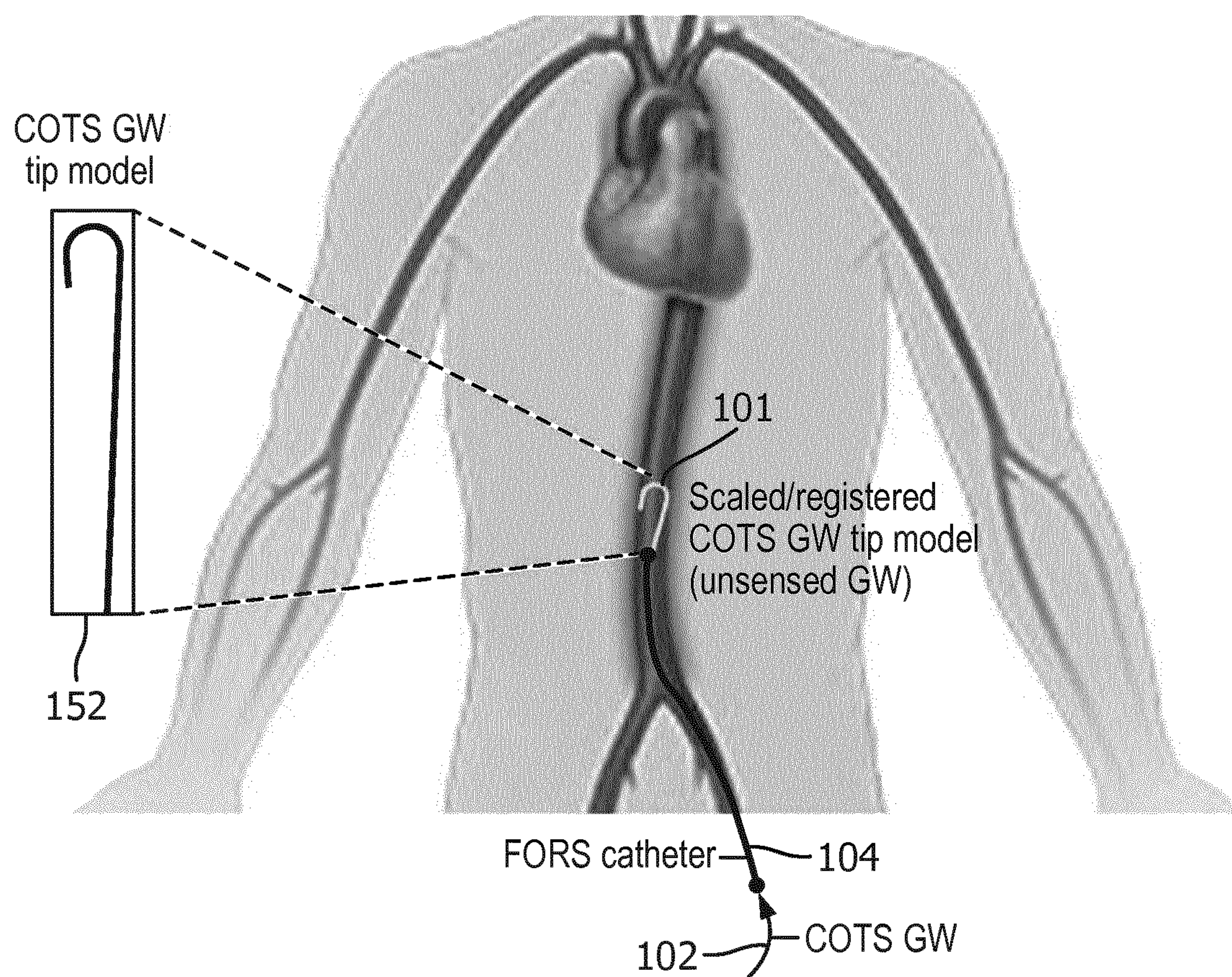


FIG. 12

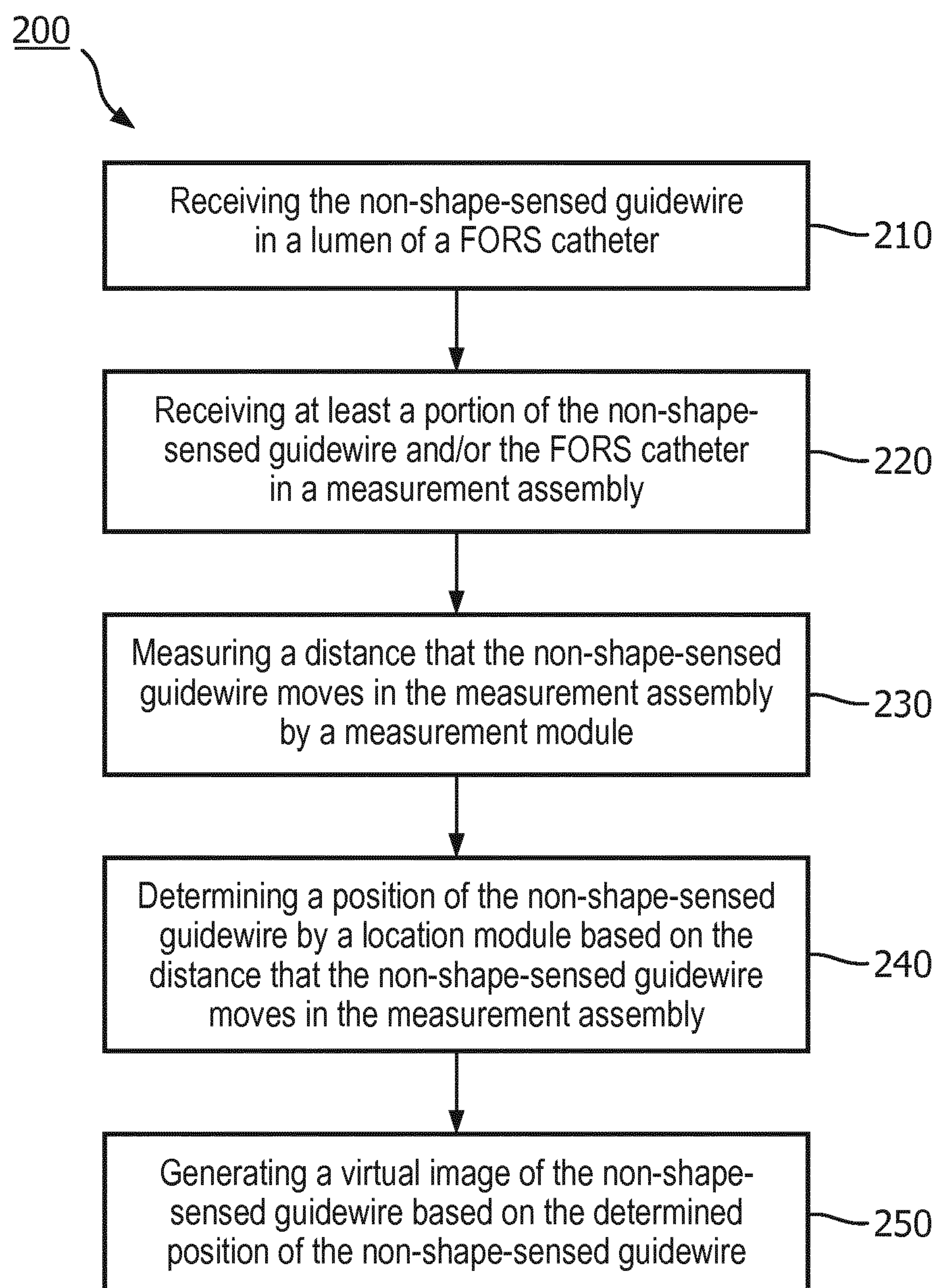


FIG. 13

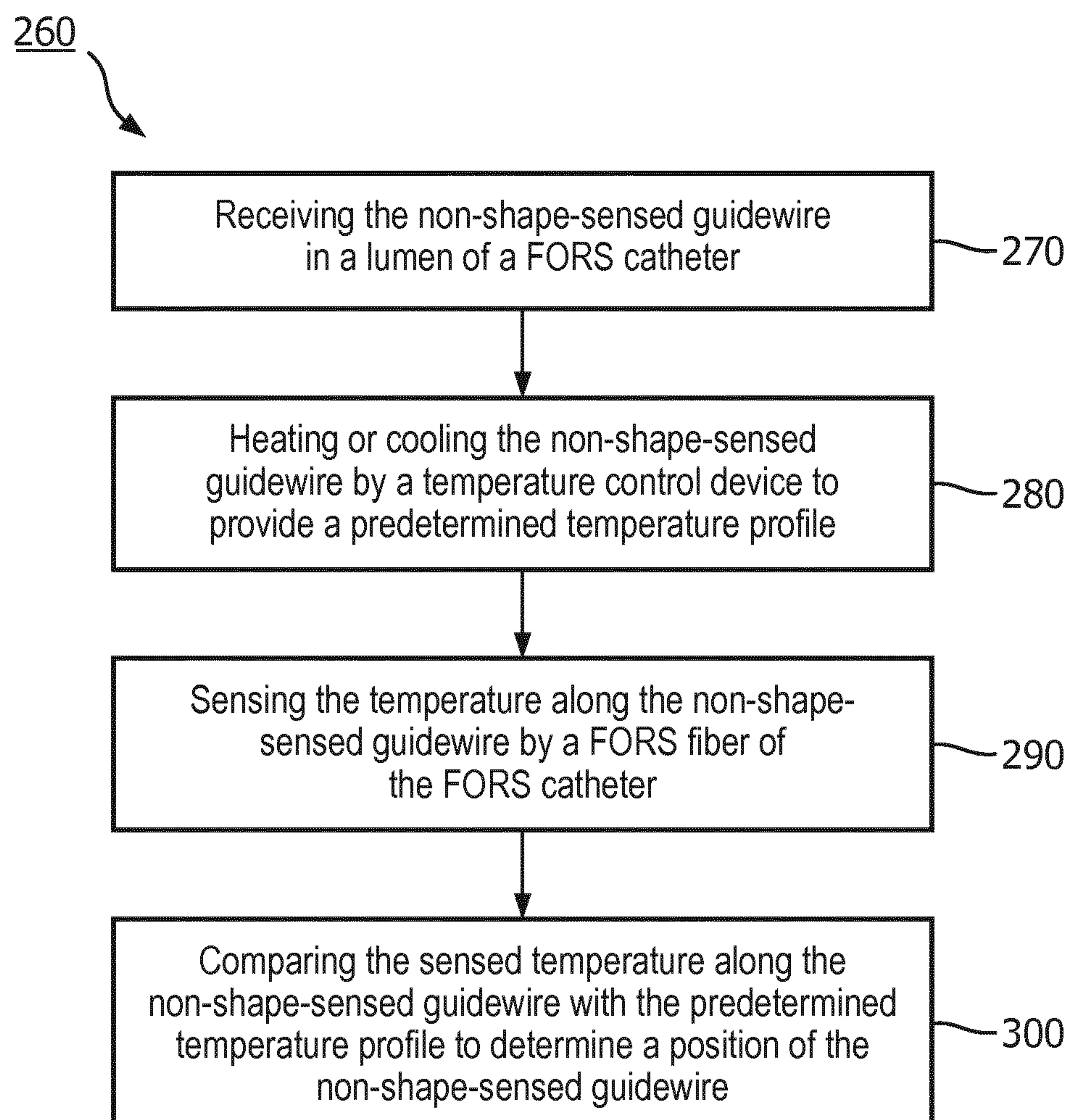


FIG. 14

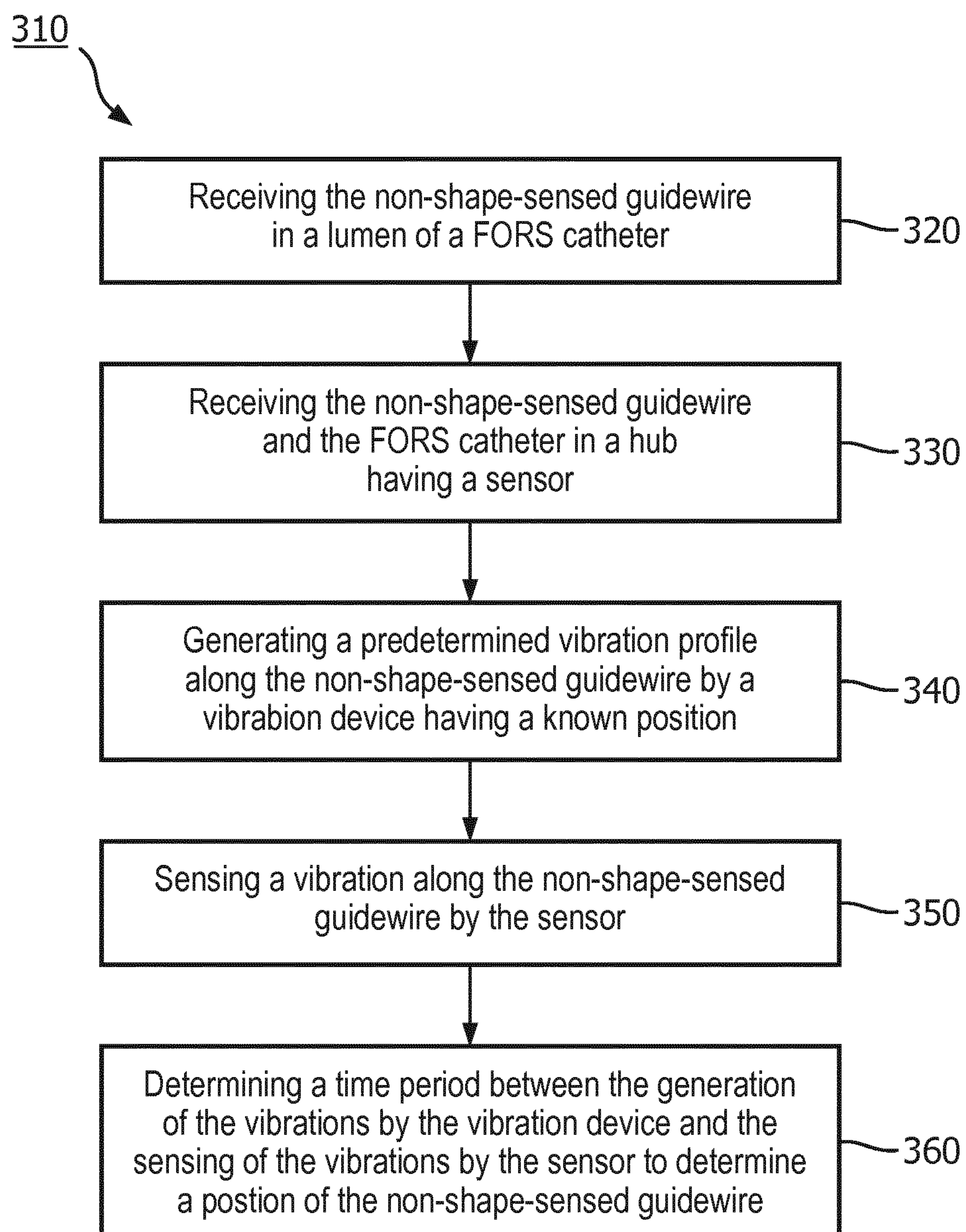


FIG. 15

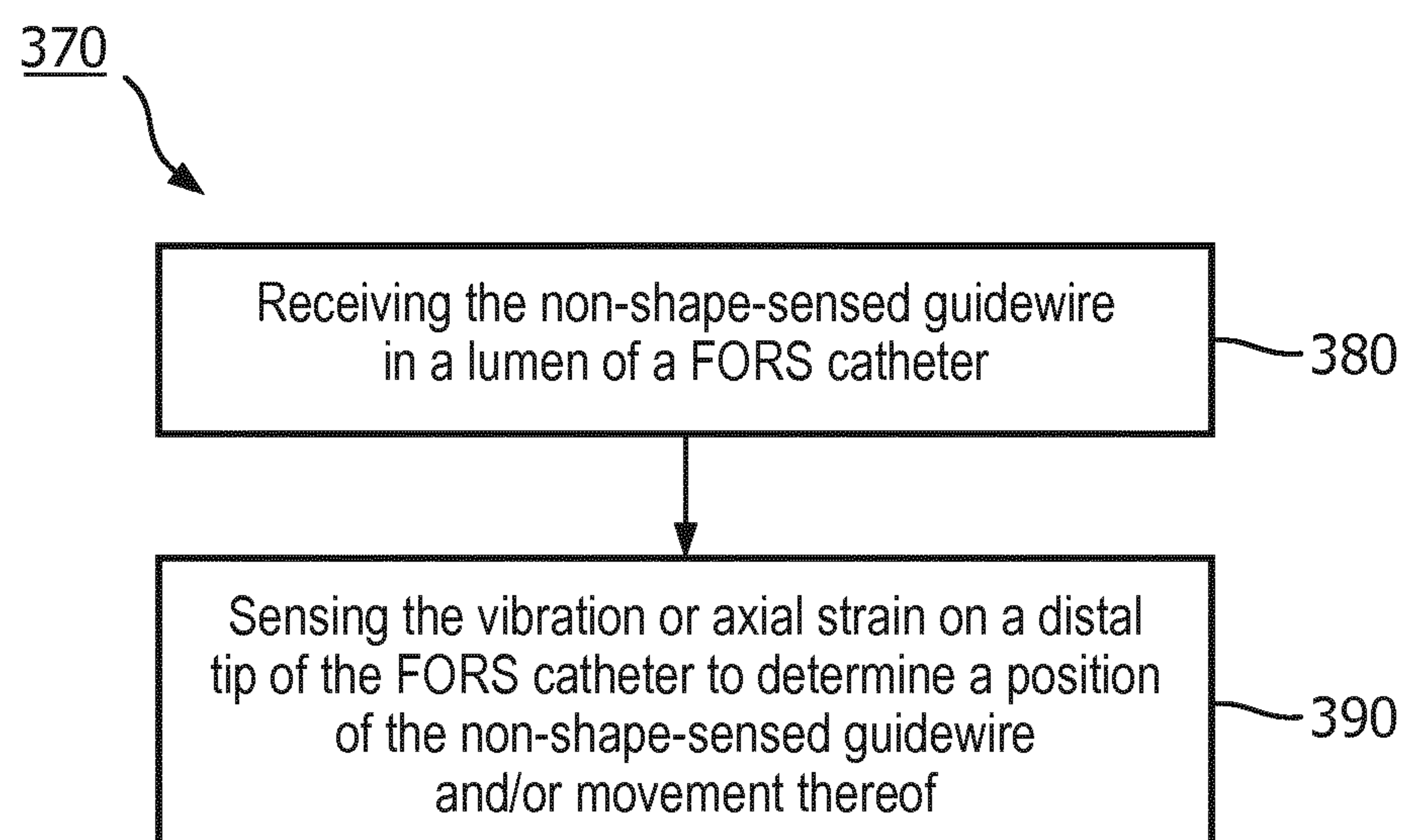


FIG. 16

SYSTEMS AND METHODS FOR DETERMINING THE POSITION OF A NON-SHAPE-SENSED GUIDEWIRE WITH A SHAPE-SENSED CATHETER AND FOR VISUALIZING THE GUIDEWIRE

BACKGROUND

Technical Field

[0001] This disclosure relates to medical instruments and more particularly to systems having shape sensing optical fibers in catheters for determining the position of a non-shape-sensed guidewire and visualizing the guidewire.

Description of the Related Art

[0002] A medical device may be enabled with shape sensing by embedding an optical fiber(s) within the device. Optical shape sensing (OSS) or Fiber-Optical RealShape™ (hereinafter, “FORST™”) employs light along an optical fiber for device localization and navigation during surgical intervention. One principle involved makes use of distributed strain measurement in the optical fiber using characteristic Rayleigh backscatter or controlled grating patterns. Multiple optical fibers can be used together to reconstruct a 3D shape, or a single optical fiber with multiple cores that may also be helixed for a lower-profile sensor. The shape along the optical fiber begins at a specific point along the sensor, known as the launch or $z=0$, and the subsequent shape position and orientation are relative to that point. FORST™ fibers can be integrated into medical devices to provide live guidance of the devices during minimally invasive procedures.

[0003] The inclusion of a FORST™ shape sensing device permits the determination of the shape of the device and a visualization of a virtual device without requiring an imaging device such as an x-ray imaging device. However, the shape sensing device requires customizing a mechanical design of the device to add an additional lumen for the fiber. Adding the fiber also adds cost to the device and necessitates the use of an additional shape sensing system.

[0004] The shape of a non-shape-sensed device, such as a guidewire that is received in a catheter having FORST™ shape sensing, will be defined by the shape of the catheter for the length over which the devices overlap. It would be advantageous to utilize the FORST™ catheter to determine a position of the non-shape-sensed guidewire in the catheter and to accurately visualize the non-shape-sensed guidewire. Furthermore, it would be advantageous to visualize the portion of the non-shape-sensed guidewire that does not overlap with the FORST™ catheter.

SUMMARY

[0005] In accordance with the present principles, a system for determining a position of a non-shape-sensed guidewire is provided. The system includes a non-shape-sensed guidewire. The system also includes a shape-sensing catheter having a lumen, wherein the non-shape-sensed guidewire is received in the lumen. A measurement assembly is configured to receive at least a portion of the non-shape-sensed guidewire and/or the shape-sensing catheter. A measurement module is configured to measure a distance that the non-shape-sensed guidewire moves in the measurement assembly. A location module is configured to determine a position

of the non-shape-sensed guidewire based on the distance that the non-shape-sensed guidewire moves determined by the measurement module.

[0006] In another embodiment, a system for determining a position of a non-shape-sensed guidewire includes a non-shape-sensed guidewire. A temperature control device associated with the non-shape-sensed guidewire is configured to heat or cool the non-shape-sensed guidewire to provide a predetermined temperature profile along the non-shape-sensed guidewire. A shape-sensing catheter having a lumen receives the non-shape-sensed guidewire in the lumen, the shape-sensing catheter has a shape-sensing optical fiber that is configured to sense temperature along the non-shape-sensed guidewire. A location module is configured to receive signals from the shape-sensing optical fiber concerning the temperature along the non-shape-sensed guidewire and compare a sensed temperature profile to the predetermined temperature profile to determine a position of the non-shape-sensed guidewire.

[0007] In another embodiment, a system for determining a position of a non-shape-sensed guidewire includes a non-shape-sensed guidewire. A vibration device associated with the non-shape-sensed guidewire is configured to generate a predetermined vibration profile along the non-shape-sensed guidewire. The vibration device has a known position. A shape-sensing catheter having a lumen receives the non-shape-sensed guidewire in the lumen. A hub is configured to receive the shape-sensing catheter and secure a position of the shape-sensing catheter. The hub includes a sensor having a known position that is configured to sense the vibration along the non-shape-sensed guidewire. A location module is configured to receive signals from the sensor concerning the vibrations and determine a time period between the generation of vibrations by the vibration device to a sensing of the vibrations by the sensor to determine a position of the non-shape-sensed guidewire.

[0008] In another embodiment, a system for determining the position of a non-shape-sensed guidewire includes a non-shape-sensed guidewire. A shape-sensing catheter having a lumen, receives the non-shape-sensed guidewire in the lumen. A measurement module is configured to detect the vibration, shape, or axial strain on a distal tip of the shape-sensing catheter to determine the position of the non-shape-sensed guidewire and/or movement thereof.

[0009] In another embodiment, a method for determining the position of a non-shape-sensed guidewire is provided. The method includes the steps of receiving the non-shape-sensed guidewire in a lumen of a shape-sensing catheter; receiving at least a portion of the non-shape-sensed guidewire and/or the shape-sensing catheter in a measurement assembly; measuring a distance that the non-shape-sensed guidewire moves in the measurement assembly by a measurement module; and determining a position of the non-shape-sensed guidewire by a location module based on the distance that the non-shape-sensed guidewire moves in the measurement assembly.

[0010] In another embodiment, a method for determining the position of a non-shape-sensed guidewire is provided. The method includes the steps of receiving the non-shape-sensed guidewire in a lumen of a shape-sensing catheter; heating or cooling the non-shape-sensed guidewire by a temperature control device to provide a predetermined temperature profile along the non-shape-sensed guidewire; sensing a temperature along the non-shape-sensed guidewire by

a shape-sensing optical fiber of the shape-sensing catheter; and comparing a sensed temperature along the non-shape-sensed guidewire with the predetermined temperature profile to determine a position of the non-shape-sensed guidewire.

[0011] In another embodiment, a method for determining the position of a non-shape-sensed guidewire is provided. The method includes the steps of receiving the non-shape-sensed guidewire in a lumen of a shape-sensing catheter; receiving the shape-sensing catheter and the non-shape-sensed guidewire in a hub having a sensor; generating a predetermined 20 vibration profile along the non-shape-sensed guidewire by a vibration device having a known position; sensing the vibration along the non-shape-sensed guidewire by the sensor; and determining a time period between the generation of the vibrations by the vibration device and the sensing of the vibrations by the sensor to determine a position of the non-shape-sensed guidewire.

[0012] In another embodiment, a method for determining the position of a non-shape-sensed guidewire is provided. The method includes the steps of receiving the non-shape-sensed guidewire in a lumen of a shape-sensing catheter; and sensing vibration, shape, or axial strain on a distal tip of the shape-sensing catheter to determine the position of the non-shape-sensed guidewire and/or movement thereof.

[0013] These and other objects, features and advantages of the present disclosure will become apparent from the following detailed description of illustrative embodiments thereof, which is to be read in connection with the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

[0014] This disclosure will present in detail the following description of preferred embodiments with reference to the following figures wherein:

[0015] FIG. 1 is a block/flow diagram showing a system for determining the position of a non-shape-sensed guidewire in accordance with one embodiment;

[0016] FIG. 2 shows images of the system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring a rotating belt;

[0017] FIG. 3 shows images of the system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring cams;

[0018] FIG. 4 shows images of a system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring a vibration device in the measurement assembly;

[0019] FIG. 5 shows a block/flow diagram showing a system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring a temperature control device in the measurement assembly;

[0020] FIG. 6 shows a block/flow diagram showing a system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring an optical tracking device in the measurement assembly;

[0021] FIG. 7 shows images of the system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring a torquer having a FORS™ fiber;

[0022] FIG. 8 shows a block/flow diagram showing a system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring a temperature control device;

[0023] FIG. 9 shows images for the system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring a temperature control device;

[0024] FIG. 10 shows a block/flow diagram showing a system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring a vibration device;

[0025] FIG. 11 shows a block/flow diagram showing a system for determining the position of a non-shape-sensed guidewire in accordance with an embodiment featuring mechanical features on the non-shape-sensed guidewire;

[0026] FIG. 12 shows images for the system for determining the position of a non-shape-sensed guidewire in accordance with one embodiment which generates a virtual guidewire utilizing a model;

[0027] FIG. 13 is a flow diagram showing a method for determining the position of a non-shape-sensed guidewire in accordance with one embodiment;

[0028] FIG. 14 is a flow diagram showing a method for determining the position of a non-shape-sensed guidewire in accordance with another embodiment;

[0029] FIG. 15 is a flow diagram showing a method for determining the position of a non-shape-sensed guidewire in accordance with another embodiment; and

[0030] FIG. 16 is a flow diagram showing a method for determining the position of a non-shape-sensed guidewire in accordance with another embodiment.

DETAILED DESCRIPTION OF EMBODIMENTS

[0031] In accordance with the present principles, a system for determining the position of a non-shape-sensed guidewire utilizing a FORS™ catheter and for visualizing the non-shape-sensed guidewire is provided. The system is configured to determine the position of the non-shape-sensed guidewire by utilizing a FORS™ catheter which has a lumen that is configured to receive the non-shape-sensed guidewire. The system may include a measurement assembly which is configured to receive at least a portion of the non-shape-sensed guidewire and/or the FORS™ catheter. A measurement module is configured to measure a distance that the non-shape-sensed guidewire moves in the measurement assembly. A location module is configured to determine a position of the non-shape-sensed guidewire based on the distance that the non-shape-sensed guidewire moves that is determined by the measurement module.

[0032] The system is also configured to detect the presence of the guidewire within the proximal end of the FORS™ catheter, detect the presence of the non-shape-sensed guidewire within other portions of the FORS™ catheter and to detect and measure the distance that the non-shape-sensed guidewire moves. The system may provide feedback to the user concerning the detection and/or measurement of the guidewire's movement and position.

[0033] The system provides improvements for the visualization of the non-shape-sensed guidewire during an interventional procedure by the generation of a virtual guidewire. The virtual guidewire that is generated by the system also includes a portion of the non-shape-sensed guidewire that does not extend along a FORS™ fiber, such as the portion that protrudes from a distal tip of the FORS™ catheter.

[0034] The system permits the guidewire to be a conventional commercial over the counter guidewire which does not require a FORS™ shape sensing system to be incorpo-

rated in the device in order for its shape, position and orientation to be tracked and visualized. It should be understood that the present invention will be described in terms of medical instruments; however, the teachings of the present invention are much broader and are applicable to any fiber optic instruments. In some embodiments, the present principles are employed in tracking or analyzing complex biological or mechanical systems. In particular, the present principles are applicable to internal tracking procedures of biological systems and procedures in all areas of the body such as the lungs, gastro-intestinal tract, excretory organs, blood vessels, etc. The elements depicted in the FIGS. may be implemented in various combinations of hardware and software and provide functions which may be combined in a single element or multiple elements.

[0035] The functions of the various elements shown in the FIGS. can be provided through the use of dedicated hardware as well as hardware capable of executing software in association with appropriate software. When provided by a processor, the functions can be provided by a single dedicated processor, by a single shared processor, or by a plurality of individual processors, some of which can be shared. Moreover, explicit use of the term “processor” or “controller” should not be construed to refer exclusively to hardware capable of executing software, and can implicitly include, without limitation, digital signal processor (“DSP”) hardware, read-only memory (“ROM”) for storing software, random access memory (“RAM”), non-volatile storage, etc.

[0036] Moreover, all statements herein reciting principles, aspects, and embodiments of the invention, as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents as well as equivalents developed in the future (i.e., any elements developed that perform the same function, regardless of structure). Thus, for example, it will be appreciated by those skilled in the art that the block diagrams presented herein represent conceptual views of illustrative system components and/or circuitry embodying the principles of the invention. Similarly, it will be appreciated that any flow charts, flow diagrams and the like represent various processes which may be substantially represented in computer readable storage media and so executed by a computer or processor, whether or not such computer or processor is explicitly shown.

[0037] Furthermore, embodiments of the present invention can take the form of a computer program product accessible from a computer-usable or computer-readable storage medium providing program code for use by or in connection with a computer or any instruction execution system. For the purposes of this description, a computer-usable or computer readable storage medium can be any apparatus that may include, store, communicate, propagate, or transport the program for use by or in connection with the instruction execution system, apparatus, or device. The medium can be an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system (or apparatus or device) or a propagation medium. Examples of a computer-readable medium include a semiconductor or solid state memory, magnetic tape, a removable computer diskette, a random access memory (RAM), a read-only memory (ROM), a rigid magnetic disk and an optical disk. Current

examples of optical disks include compact disk—read only memory (CD-ROM), compact disk—read/write (CD-R/W), Blu-Ray™ and DVD.

[0038] Reference in the specification to “one embodiment” or “an embodiment” of the present principles, as well as other variations thereof, means that a particular feature, structure, characteristic, and so forth described in connection with the embodiment is included in at least one embodiment of the present principles. Thus, the appearances of the phrase “in one embodiment” or “in an embodiment”, as well any other variations, appearing in various places throughout the specification are not necessarily all referring to the same embodiment.

[0039] It is to be appreciated that the use of any of the following “/”, “and/or”, and “at least one of”, for example, in the cases of “A/B”, “A and/or B” and “at least one of A and B”, is intended to encompass the selection of the first listed option (A) only, or the selection of the second listed option (B) only, or the selection of both options (A and B). As a further example, in the cases of “A, B, and/or C” and “at least one of A, B, and C”, such phrasing is intended to encompass the selection of the first listed option (A) only, or the selection of the second listed option (B) only, or the selection of the third listed option (C) only, or the selection of the first and the second listed options (A and B) only, or the selection of the first and third listed options (A and C) only, or the selection of the second and third listed options (B and C) only, or the selection of all three options (A and B and C). This may be extended, as readily apparent by one of ordinary skill in this and related arts, for as many items listed.

[0040] It will also be understood that when an element such as a layer, region or material is referred to as being “on” or “over” another element, it can be directly on the other element or intervening elements may also be present. In contrast, when an element is referred to as being “directly on” or “directly over” another element, there are no intervening elements present. It will also be understood that when an element is referred to as being “connected” or “coupled” to another element, it can be directly connected or coupled to the other element or intervening elements may be present. In contrast, when an element is referred to as being “directly connected” or “directly coupled” to another element, there are no intervening elements present.

[0041] Referring now to the drawings in which like numerals represent the same or similar elements and initially to FIG. 1, a system 100 for determining the position of a non-shape-sensed guidewire 102 that is received by a shape-sensing catheter 104, such as a FORST™ catheter, is illustratively shown in accordance with one embodiment. While the non-shape-sensed interventional device is illustratively described as being a guidewire 102, in other embodiments, the device may be any medical device that is configured to be received in the lumen of another medical device. For example, the non-shape-sensed device may be a k-wire, a syringe tip, suture thread, or other such component. Additionally, while the FORST™ device is illustratively described as being a FORST™ catheter 104, the FORST™ device may be any other FORST™ device that includes a lumen 103 which may receive a guidewire or other device configured to be received in a lumen. For example, the FORST™ device may be any “over-the-wire” device having a lumen, such as a sheath, a probe, an endograft deployment device, a robot, an electrode, a filter device, a balloon device, a graft, a stent, a

drill, and awl, a screwdriver or other similar component. The devices may be robotically or manually controlled.

[0042] System 100 may include a workstation or console 108 from which a procedure is supervised and/or managed. Workstation 108 preferably includes one or more processors 110 and memory 112 for storing programs and applications. Memory 112 may store an optical sensing module 114 configured to interpret optical feedback signals from a shape sensing device or FORST™ system 105. The FORST™ catheter 104 is configured to receive the FORST™ system 105 therethrough. The optical sensing module 114 is configured to use the optical signal feedback (and any other feedback) to reconstruct deformations, deflections and other changes associated with shape sensed devices.

[0043] The shape sensing system 105 includes one or more optical fibers 113 which may be arranged in a set pattern or patterns. The optical fibers 113 connect to the workstation 108 through cabling. The cabling may include fiber optics, electrical connections, other instrumentation, etc., as needed.

[0044] System 105 with fiber optics may be based on fiber optic Bragg grating sensors, Rayleigh scattering, or other types of scattering. Inherent backscatter in conventional optical fiber can be exploited, such as Raleigh, Raman, Brillouin or fluorescence scattering. One such approach is to use Rayleigh scatter in standard single-mode communications fiber. Rayleigh scatter occurs as a result of random fluctuations of the index of refraction in the fiber core. These random fluctuations can be modeled as a Bragg grating with a random variation of amplitude and phase along the grating length. By using this effect in three or more cores running within a single length of multi-core fiber, or in multiple single-core fibers arranged together, the 3D shape and dynamics of the surface of interest can be followed.

[0045] A fiber optic Bragg grating (FBG) system may also be employed for system 105. FBG is a short segment of optical fiber that reflects particular wavelengths of light and transmits all others. This is achieved by adding a periodic variation of the refractive index in the fiber core, which generates a wavelength-specific dielectric mirror. A fiber Bragg grating can therefore be used as an inline optical filter to block certain wavelengths, or as a wavelength-specific reflector.

[0046] Fresnel reflection at each of the interfaces where the refractive index is changing is measured. For some wavelengths, the reflected light of the various periods is in phase so that constructive interference exists for reflection and, consequently, destructive interference for transmission. The Bragg wavelength is sensitive to strain as well as to temperature. This means that Bragg gratings can be used as sensing elements in fiber optical sensors.

[0047] Incorporating three or more cores permits a three dimensional form of such a structure to be precisely determined. From the strain measurement, the curvature of the structure can be inferred at that position. From the multitude of measured positions, the total three-dimensional form is determined. A similar technique can be used for multiple single-core fibers configured in a known structure or geometry.

[0048] The workstation 108 includes a display 109 for viewing internal images of a subject 142 or volume. The workstation 108 includes an image processing module 119 that is configured to generate a virtual representation 101 of the non-shape-sensed guidewire as an overlay on medical

images such as x-ray images, computed tomography (CT) images, magnetic resonance images (MRI), real-time internal video images or other images as collected by an imaging system 116 in advance or concurrently. The imaging system 116 may be an x-ray imaging device or other known imaging device. The imaging device is configured to acquire images of the subject 142.

[0049] Display 109 may also permit a user to interact with the workstation 108 and its components and functions, or any other element within the system 100. This is further facilitated by an interface 115 which may include a keyboard, mouse, a joystick, a haptic device, or any other peripheral or control to permit user feedback from and interaction with the workstation 108.

[0050] In a preferred embodiment, as shown in FIG. 1, the system 100 includes a FORST™ catheter 104 which has a non-shape-sensed guidewire 102 passing therethrough. As shown in FIG. 1, in one embodiment, the system 100 includes a measurement assembly 118 that is configured to receive at least a portion of the non-shape-sensed guidewire 102 and/or the FORST™ catheter 104. In a preferred embodiment, the measurement assembly 118 is positioned adjacent to, or over, a proximal portion of the FORST™ catheter.

[0051] In one embodiment, the measurement assembly 118 includes a plurality of movable elements 120 that are configured to contact the non-shape-sensed guidewire 102 and move when the guidewire is advanced or retracted in the lumen 103 of the FORST™ catheter. For example, in the embodiment shown in FIG. 2, the measurement assembly includes a rotating belt 121 which is configured to rotate as the guidewire is advanced or retracted in the lumen 103 of the FORST™ catheter. Image 127 in FIG. 2 shows an overview of the system 100 in this embodiment. Image 129 shows a close up view of the measurement assembly 118 in accordance with this embodiment. The rotating belt 121 preferably functions as a passive conveyor belt which only moves as the non-shape-sensed guidewire is advanced or retracted in the lumen 103 of the FORST™ catheter. In one embodiment, the rotating belt 121 may have an increased length to increase the accuracy of measuring the movement of the belt.

[0052] In alternative embodiments, movable elements 120 such as wheels, rollers or balls or other known movable elements may be used instead of a rotating belt 121. Additionally, in certain embodiments, the measurement assembly 118 may include a second set of movable elements (not shown) which are configured to bias the non-shape-sensed guidewire 102 against the movable elements 120 to ensure sufficient contact between the movable elements and the non-shape-sensed guidewire and to minimize friction applied to the non-shape-sensed guidewire.

[0053] The measurement assembly 118 also includes a sensor 124 which is associated with the movable elements 120 and is configured to sense movement of the movable elements and send signals concerning the movement that it senses. For example, in the embodiment shown in FIG. 2, the sensor is associated with the rotating belt 121 and senses rotation of the belt in a clockwise and/or counter-clockwise direction.

[0054] FIG. 3 shows another embodiment of the system 100 in which the movable elements 120 of the measurement assembly 118 are a pair of rotating cams 128. The cams 128 contact the non-shape-sensed guidewire 102 and are configured to rotate as the guidewire is advanced or retreated. In

this embodiment, the sensor **124** comprises a FORSTTM fiber which is configured to be deflected as the cams **128** are rotated. In the embodiment shown in FIG. 3, the measurement assembly **118** is configured to receive the FORSTTM catheter **104** and at least one of the optical fibers **113** of the FORSTTM catheter is configured to be deflected as the cams **128** are rotated. The at least one optical fiber **113** of the FORSTTM catheter that is deflected is preferably positioned along the proximal section of the FORSTTM catheter **104**. However, in alternative embodiments, the measurement assembly **118** may include a second FORSTTM fiber that is not part of the FORSTTM catheter which is configured to be deflected as the cams **128** are rotated.

[0055] The system **100** also includes a measurement module **122** which is configured to receive signals from the sensor **124** and analyze the signals to detect the presence of the guidewire into the proximal end of the FORSTTM catheter **104**, detect the presence of the non-shape-sensed guidewire within the FORSTTM catheter and to detect and measure the distance that the non-shape-sensed guidewire **102** moves.

[0056] The movable elements **120** are preferably encoded so that a specific amount of movement of the guidewire **102** results in a specific amount of movement of the movable elements **120**. In one embodiment, the measurement module **122** may include conversion data **123** which converts a specific amount of movement of the non-shape-sensed guidewire **102** with a specific degree of movement of the movable elements **120**. The conversion data **123** may be obtained in a calibration phase or may be predetermined by the manufacturer. For example, the rotating belt **121** may be configured to rotate a full revolution for every 1 millimeter that a guidewire is advanced or retracted. Images **137** and **139** in FIG. 4 show another embodiment of the system **100** in which the measurement assembly **118** includes a vibration mechanism **130** which is configured to interact with the non-shape-sensed guidewire **102** as the guidewire is advanced or retracted in the FORSTTM catheter **104**. The vibration mechanism **130** is configured to vibrate the FORSTTM catheter **104** when the vibration mechanism interacts with the non-shape-sensed guidewire **102**.

[0057] In this embodiment, the sensor may comprise a FORSTTM fiber which is configured to be vibrated by the vibration mechanism **130**. A FORSTTM system detects the vibration of the FORSTTM fiber when it is vibrated and the signal is sent to the measurement module **122**. In the embodiment shown in FIG. 4, the measurement assembly **118** is configured to receive the FORSTTM catheter **104** and at least one of the optical fibers **113** of the FORSTTM catheter is configured to sense vibration caused by the vibration mechanism **130**. However, in alternative embodiments, the measurement assembly **118** may include a second FORSTTM fiber that is not part of the FORSTTM catheter which is configured to sense vibrations by the vibration device **130**.

[0058] FIG. 5 shows another embodiment of the system **100** in which the measurement assembly **118** includes a temperature control device **132** that is configured to heat or cool the non-shape-sensed guidewire **102** when the guidewire is advanced or retracted a predetermined distance. For example, the temperature control device **132** may include a motion sensor which is configured to trigger the temperature control device to cool or heat the non-shape-sensed guidewire **102** when the non-shape-sensed guidewire **102** is advanced or retracted 1 millimeter. In this embodiment, the sensor **124** may comprise a FORSTTM fiber which is config-

ured to sense temperature-induced strain as the guidewire temperature changes. The FORSTTM system **105** is configured to detect the temperature-induced strain of the FORSTTM fiber as it is heated or cooled. In the embodiment shown in FIG. 5, the measurement assembly **118** is configured to receive the FORSTTM catheter **104** and at least one of the optical fibers **113** of the FORSTTM catheter is the FORSTTM fiber that is configured to sense temperature-induced strain. However, in alternative embodiments, the measurement assembly **118** may include a second FORSTTM fiber that is not part of the FORSTTM catheter which is configured to sense temperature-induced strain.

[0059] In another embodiment, shown in FIG. 6, the measurement assembly **118** may include a sensor comprising an optical tracking device **125** that is configured to monitor movement of the non-shape-sensed guidewire and send signals concerning the movement to the measurement module **122**. The optical tracking device **125** may be used to read an existing pattern on the non-shape-sensed guidewire **102**, or, a retrofit attachment sticker or sleeve could be applied to the guidewire to assist the optical tracking device with monitoring movement. The markers may also serve to calibrate the optical tracking device.

[0060] In the embodiment shown in FIG. 7, the measurement assembly **118** is a torquer **134** that is configured to receive the non-shape-sensed guidewire **102** and to be releasably secured to a position **133** of the guidewire. The torquer **134** includes a FORSTTM fiber **113**. A location module **126** is configured to receive signals from the FORSTTM fiber **113** of the torquer and from the FORSTTM fiber of the FORSTTM catheter and provide a determination of a position and orientation of the torquer **134** relative to the FORSTTM catheter **104**. In one embodiment, the torquer **134** is configured to receive the FORSTTM catheter **104** and the optical fiber **113** of the FORSTTM catheter is the optical fiber which provides a determination of a position and orientation of the torquer relative to the FORSTTM catheter. However, in alternative embodiments, the measurement assembly **118** may include a second FORSTTM fiber that is not part of the FORSTTM catheter which is configured to determine the position and orientation of the torquer **134** relative to the FORSTTM catheter. The second FORSTTM fiber may be detachably secured to the torquer **134**. In other embodiments, a tracking device, such as an optical tracking device, electromagnetic tracking device or other known tracking device may be associated with the torquer **134** and configured to track the position and orientation of the torquer. The FORSTTM catheter may include a similar tracking device so that the tracked position of the torquer **134** may be determined relative to the FORSTTM catheter **104**.

[0061] In one embodiment, the location module **126** is configured to determine the position of the torquer **134** with respect to the FORSTTM catheter **104** by assuming a straight path distance between the torquer and the FORSTTM catheter. In other embodiments, the location module **126** is configured to utilize the five degree of freedom positions and orientations of the torquer **134** and FORSTTM catheter **104** to determine the position of the torquer.

[0062] The length of the non-shape-sensed guidewire **102** which extends from the fixed position **133** of the guidewire where the torquer **134** is secured may be predetermined. Therefore, the position of the distal tip **136** of the non-shape-sensed guidewire may be determined by the location module **126** using the determined position of the torquer **134** and the

predetermined length of the guidewire **102** which extends past the torquer. The stiffness or other mechanical properties of the non-shape-sensed guidewire **102** may be adjusted to provide an improved estimate of the path from the guidewire from the torquer **134** to the FORSTTM catheter **104**. In the case where the position of the torquer along the guidewire is not predetermined, a registration step can be used. The registration step may include aligning the tip of the two devices and capturing the length or using imaging (x-ray, CT, MRI, ultrasound, etc) to define the distance from the torquer to the tip of the guidewire.

[0063] FIGS. 8-9 show another embodiment of the system **100** which includes a temperature control device **132**. In this embodiment, the temperature control device **132** is configured to heat or cool at least a portion of the non-shape-sensed guidewire **102** to provide a predetermined temperature profile **140** along the length of the non-shape-sensed guidewire. The FORSTTM fibers **113** of the FORSTTM catheter **104** are configured to sense the temperature along the length of the FORSTTM catheter based on temperature-induced strain thereon. The location module **126** is configured to receive signals from the FORSTTM system **105** and determine whether there is a match between the measured temperature profile and the predetermined temperature profile. The location module **126** may perform the comparison based on cross correlation or other known matching methods. A matching temperature profile provides a determination of the longitudinal position of the non-shape-sensed guidewire **102** relative to the FORSTTM catheter **104**.

[0064] FIG. 10 shows another embodiment of the system **100** which includes a vibration device **144** that is associated with the non-shape-sensed guidewire **102**. For example, the vibration device **144** may be incorporated in, or mounted on, the non-shape-sensed guidewire **102**. In this embodiment, the vibration device **144** is configured to generate a predetermined vibration profile along the non-shape-sensed guidewire **102**. The system also includes a hub **107** that is configured to receive the FORSTTM catheter **104** and the non-shape-sensed guidewire **102** and secure a position of the FORSTTM catheter and the non-shape-sensed guidewire. The hub includes a sensor **146** having a known position that is configured to sense the vibration along the non-shape-sensed guidewire **102**. The location module **126** is configured to receive signals from the sensor **146** concerning the vibrations and determine the time differential between the generation of vibrations by the vibration device **144** and the sensing of the vibrations by the sensor. The location module **126** is configured to analyze the time difference between the generation of the vibrations and the sensing of the vibrations to determine the position of the non-shape-sensed guidewire. The vibration profile created by the vibration device **144** is preferably a distinctive profile to permit the vibrations to be distinguished from ambient noise/vibrations.

[0065] In another embodiment, the vibration device is disposed within the measurement assembly **118**. The measurement assembly **118** is configured to receive the non-shape-sensed guidewire **102**. The measurement assembly **118** also includes a vibration device **144** that is triggered to vibrate as the guidewire passes through the measurement assembly. The vibration created by the vibration device **144** is modulated to correspond to the motion of the non-shape-sensed guidewire **102**. The optical fiber(s) **113** of the FORSTTM catheter is/are configured to sense the vibration and send the signal to the measurement module **122** to determine

a distance that the non-shape-sensed guidewire **102** moves in the measurement assembly.

[0066] In another embodiment shown in FIG. 11, the non-shape-sensed guidewire **102** includes mechanical features **141** which are configured to create a distinct vibration or axial strain on a distal tip **148** of the FORSTTM catheter as the guidewire is extended or retracted from the distal tip of the FORSTTM catheter. For example, the emergence of the non-shape-sensed guidewire **102** from the distal tip **148** of the FORSTTM catheter may cause lateral deflection on the distal end of the FORSTTM catheter while the catheter remains in a stationary position in the longitudinal direction. The measurement module **122** is configured to receive the signals from the shape sensing system **105** of the FORSTTM catheter **104** due to vibration or axial strain on the distal tip **148** of the FORSTTM catheter to detect the presence of the non-shape-sensed guidewire or the movement of the guidewire. For example, the sensing of vibration or axial strain on the distal tip **148** of the FORSTTM catheter may indicate the emergence of the non-shape-sensed guidewire **102** from the distal tip **148** of the FORSTTM catheter. The mechanical features **141** may be any mating elements, frictional elements or other mechanical elements providing characteristic interactions with each other as generally known in the art.

[0067] The location module **126** is configured to receive the measured distance that the non-shape-sensed guidewire **102** moves determined by the measurement module **122** and determine a position of the non-shape-sensed guidewire. The location module **126** is configured to send this position to the image processing module **119** which is configured to generate a virtual non-shape-sensed device **101** on the display **109**. The measurement module **122** and the location module **126** are also configured to send feedback to the user concerning the sensed position or movement of the guidewire **102**. The feedback may be a visual signal, aural signal, haptic feedback or other feedback known in the art. For example, the location module **126** may be configured to have the system **100** generate a visual signal on the display **109** that the non-shape-sensed guidewire **102** is within the FORSTTM catheter **104** when it receives signals from the FORSTTM system indicating the presence of the guidewire within the catheter.

[0068] While the system utilizes a FORSTTM system **105** to measure a portion of the non-shape-sensed guidewire **102** that extends along a FORSTTM fiber **113** which enables the determination of the position of the non-shape-sensed guidewire it would also be advantageous to specifically determine the position and orientation of a portion of the non-shape-sensed guidewire that does not extend along a FORSTTM fiber. For example, for an embodiment of the system **100** that utilizes shape sensing data from the FORSTTM fiber **113** of the FORSTTM catheter to measure a position of the non-shape-sensed device, it would be advantageous to measure the position of the non-shape-sensed guidewire which protrudes outside the distal tip **148** of the FORSTTM catheter.

[0069] As shown in FIG. 12, in one embodiment, the image processing module **119** is configured to store a model **152** of the non-shape-sensed guidewire based on known dimensions of the device. The image processing module **119** is configured to generate the virtual guidewire **101** utilizing the model. In one embodiment, the image processing module **119** is configured to receive the most distal position of the non-shape-sensed guidewire that is detected by the location module **126** or the measurement module **122** and

position the distal tip of the virtual guidewire **101** in that location. The image processing module **119** is also configured to receive updated positions of the guidewire from the location module **126** based on information sensed by the FORSTTM system **105**, such as the insertion depth measured by the measurement module **122**. The image processing module **119** may also receive information concerning the surrounding anatomical region and the mechanical properties of the guidewire **102** and the FORSTTM catheter **104** to further deform the model **152** and the displayed virtual guidewire **101**.

[0070] In another embodiment, the imaging system **116** is configured to acquire images of the FORSTTM catheter **104** and the non-shape-sensed guidewire **102**. A segmentation module **154** is configured to segment a portion of the image. For example, the imaging system **116** may be an x-ray imaging system that is configured to acquire 2D fluoroscopy images. The segmentation module **154** is configured to segment a 2D fluoroscopy image of the portion of the non-shape-sensed guidewire which protrudes from the distal tip **148** of the FORSTTM catheter. The image processing module **119** is configured to acquire the segmented data and utilize the segmented data in combination with 3D knowledge of the FORSTTM catheter tip, to generate a virtual guidewire **101** for the portion of the guidewire **102** that is not shape sensed by the system.

[0071] In another embodiment, the system **100** is configured to utilize vibration or axial strain sensed on the distal tip **148** of the FORSTTM catheter to determine the position of the non-shape-sensed guidewire **102**. For example, the measurement module **122** may include predetermined data **156** concerning the characteristic strain exhibited by different portions of the guidewire on the distal tip **148** of the FORSTTM catheter. In one embodiment, the data **156** pertains to lateral motion exhibited by the distal tip **148** of the FORSTTM catheter as different portions of the guidewire protrude through the distal tip. The measurement module **122** is configured to analyze the vibration or axial strain on the distal tip **148** of the FORSTTM catheter with respect to the predetermined data **156** to determine the portion of the guidewire at the distal tip. The image processing module **119** is configured to generate the virtual guidewire **101** at the position determined by the measurement module **122** based on the determined characteristic strain sensed at the distal tip **148** of the FORSTTM catheter.

[0072] The distal portion **138** of the non-shape-sensed guidewire may have a distinct shape and mechanical properties which cause characteristic strain or shape deformation on the distal tip **148** of the FORSTTM catheter as it emerges from the lumen **103** depending on the orientation of the distal tip of the guidewire as it emerges. The predetermined data **156** may include data concerning the characteristic strain/shape on the distal tip **148** of the FORSTTM catheter based on the orientation of the distal portion **138** of the guidewire. The measurement module **122** is configured to determine the orientation of the distal tip **148** of the FORSTTM catheter as it emerges from the lumen **103** based on the detected strain at the distal tip.

[0073] Furthermore, the location of the strain and shape change detected along the FORSTTM catheter may indicate the position of the non-shape-sensed guidewire **102** which protrudes from the catheter. For example, if the portion of the non-shape-sensed guidewire that protrudes from the distal tip **148** of the catheter is bent to the left, more force will be

exerted on the right wall of the FORSTTM catheter. The image processing module **119** is configured to analyze the shape sensing of the FORSTTM catheter **104** determined by the shape sensing system **105** to determine the position of the guidewire that protrudes from the distal tip **148** of the catheter and provide a more accurate positioning of the virtual guidewire **101**.

[0074] In another embodiment, the image processing module **119** is configured to generate a probabilistic map **147** that extends from the distal tip **148** of the FORSTTM catheter based upon the known device length, mechanical properties, x-ray fluoroscopy or other inputs received by the system. The probabilistic map **147** may be a point cloud, a color-coded map, a cone of possible guidewire locations, etc.

[0075] Referring to FIG. **13**, methods **200** for determining the position of a non-shape-sensed guidewire, are illustratively shown in accordance with the present principles. In block **210**, the non-shape-sensed guidewire is received in a lumen of a FORSTTM catheter. In block **220**, at least a portion of the non-shape-sensed guidewire and/or the FORSTTM catheter is received in a measurement assembly. In block **230** a distance that the non-shape-sensed guidewire moves in the measurement assembly is measured by a measurement module. In block **240**, a position of the non-shape-sensed guidewire is determined by a location module based on the distance that the non-shape-sensed guidewire moves in the measurement assembly.

[0076] As previously described, the method may include the further step in block **250** of generating a virtual image of the non-shape-sensed guidewire based on the determined position of the non-shape-sensed guidewire. The generating of a virtual image also includes generating a portion of the non-shape-sensed guidewire that does not extend along a FORSTTM fiber as previously described. As previously described, the measurement assembly may include movable elements, such as a rotating belt, wheels, rollers, balls, or at least one cam along with an associated sensor. Alternatively, the measurement assembly may include a vibration device that interacts with the non-shape-sensed guidewire and is configured to generate vibrations on the FORSTTM catheter that are sensed by a FORSTTM fiber.

[0077] In another embodiment, the measurement assembly may include a temperature control device that is configured to heat or cool the non-shape-sensed guidewire and the temperature change is sensed by a FORSTTM fiber. In a further embodiment, the measurement assembly comprises a torquer that is secured to a fixed position on the non-shape-sensed guidewire and the torquer includes a FORSTTM fiber. The position and orientation of the torquer are determined relative to the FORSTTM catheter by analyzing shape sensing information from the FORSTTM fiber and the FORSTTM catheter.

[0078] Referring to FIG. **14**, another embodiment for a method **260** for determining the position of a non-shape-sensed guidewire is illustratively shown in accordance with the present principles. In block **270**, the non-shape-sensed guidewire is received in a lumen of a FORSTTM catheter. In block **280**, the non-shape-sensed guidewire is heated or cooled by a temperature control device to provide a predetermined temperature profile along the non-shape-sensed guidewire. In block **290**, the temperature is sensed by a FORSTTM fiber of the FORSTTM catheter along the non-shape-sensed guidewire. In block **300**, the sensed temperature along the non-shape-sensed guidewire is compared with a

predetermined temperature profile to determine a position of the non-shape-sensed guidewire.

[0079] Referring to FIG. 15, another embodiment for a method 310 for determining the position of a non-shape-sensed guidewire is illustratively shown in accordance with the present principles. In block 320, the non-shape-sensed guidewire is received in a lumen of a FORSTTM catheter. In block 330, the FORSTTM catheter and non-shape-sensed guidewire are received in a hub having a sensor. In block 340, a predetermined vibration profile is generated along the non-shape-sensed guidewire by a vibration device having a known position. In block 350, the vibration is sensed along the non-shape-sensed guidewire by the sensor. In block 360, the time period between the generation of the vibrations by the vibration device and the sensing of the vibrations by the sensor is determined to determine a position of the non-shape-sensed guidewire.

[0080] Referring to FIG. 16, another embodiment for a method 370 for determining the position of a non-shape-sensed guidewire is illustratively shown in accordance with the present principles. In block 380, the non-shape-sensed guidewire is received in a lumen of a FORSTTM catheter. In block 390, vibration or axial strain on a distal tip of the FORSTTM catheter is sensed to determine a position of the non-shape-sensed guidewire and/or movement thereof.

[0081] In interpreting the appended claims, it should be understood that:

[0082] a) the word “comprising” does not exclude the presence of other elements or acts than those listed in a given claim;

[0083] b) the word “a” or “an” preceding an element does not exclude the presence of a plurality of such elements;

[0084] c) any reference signs in the claims do not limit their scope;

[0085] d) several “means” may be represented by the same item or hardware or software implemented structure or function; and

[0086] e) no specific sequence of acts is intended to be required unless specifically indicated.

[0087] Having described preferred embodiments for systems and methods for determining the position of a non-shape-sensed guidewire with a FORSTTM catheter and for visualizing the guidewire (which are intended to be illustrative and not limiting), it is noted that modifications and variations can be made by persons skilled in the art in light of the above teachings. It is therefore to be understood that changes may be made in the particular embodiments of the disclosure disclosed which are within the scope of the embodiments disclosed herein as outlined by the appended claims. Having thus described the details and particularity required by the patent laws, what is claimed and desired protected by Letters Patent is set forth in the appended claims.

1. A system for determining a position of a non-shape-sensed guidewire, comprising:

- a guidewire;
- a catheter including a shape sensing optical fiber and having a lumen, wherein said guidewire is received in the lumen;
- a measurement assembly configured to receive at least a portion of the guidewire and/or the catheter;

a measurement module configured to measure a distance that the guidewire moves in the measurement assembly; and

a location module configured to determine a position of the guidewire based on the distance that the guidewire moves determined by the measurement module.

2. The system as recited in claim 1, wherein the system includes:

an image processing module that is configured to process information for generation of a virtual image of the guidewire based on the position determined by the location module.

3. The system as recited in claim 1, wherein the measurement assembly comprises:

a plurality of movable elements that are configured to move when the guidewire is advanced or retracted in the shape-sensed catheter; and

a sensor that is associated with the movable elements which is configured to send signals concerning the movement of the movable elements to the measurement module to measure movement of the non-shape-sensed guidewire.

4. The system as recited in claim 3, wherein the plurality of movable elements comprise at least one of a rotating belt, wheels, rollers or balls.

5. The system as recited in claim 3, wherein the plurality of movable elements comprise at least one cam and the sensor comprises a shape-sensing optical fiber which is configured to be deflected by the at least one cam when the guidewire is advanced or retracted in the shape-sensed catheter; and

the measurement module receives signals from the shape-sensing optical fiber concerning deflections of the shape-sensing optical fiber by the at least one cam to measure movement of the guidewire.

6. The system as recited in claim 5, wherein:

the measurement assembly is configured to receive the shape-sensed catheter; and

a shape-sensing optical fiber of the shape-sensed catheter comprises the shape-sensing optical fiber that is configured to be deflected by the guidewire when the guidewire is advanced or retracted in the shape-sensed catheter.

7. (canceled)

8. (canceled)

9. The system as recited in claim 1, wherein:

the measurement assembly comprises a torquer that is configured to be secured to a fixed position on the guidewire, said torquer including a shape-sensing optical fiber; and

the location module is configured to receive shape sensing information from the shape-sensing optical fiber and the shape-sensed catheter and determine a position and orientation of the torquer relative to the shape-sensed catheter.

10. The system as recited in claim 1, wherein:

the measurement assembly comprises a torquer that is configured to be secured to a fixed position on the guidewire; and

at least one tracking device associated with the torquer and the shape-sensed catheter is configured to track a position and orientation of the torquer and the shape-sensed catheter to determine a position and orientation of the torquer relative to the shape-sensed catheter.

11. The system as recited in claim 1, wherein the measurement assembly includes an optical tracking device that is configured to monitor movement of the guidewire and send signals to the measurement module concerning movement of the guidewire.

12. The system as recited in claim 11, wherein the guidewire includes markers and the optical tracking device is configured to read the markers to monitor movement of the guidewire and/or to calibrate the optical tracking device.

13. The system as recited in claim 2, wherein:

the image processing module is configured to store a model of the guidewire and generate the virtual image based on the model;

the image processing module is configured to position the virtual image by placing a distal tip of the model at a most distal position of the guidewire that is detected by the location module; and

the image processing module is further configured to update the position based on the distance that the guidewire moves in the measurement assembly.

14. The system as recited in claim 2, wherein:

the system further includes an imaging system that is configured to acquire images of the shape-sensed catheter and the guidewire;

a segmentation module that is configured to segment an image of a portion of the guidewire that protrudes from a distal tip of the shape-sensed catheter to provide segmented data; and

the image processing module is configured to generate a portion of the virtual guidewire that protrudes from the distal tip of the shape-sensed catheter based on the segmented data and 3D knowledge of the distal tip of the shape-sensed catheter.

15. The system as recited in claim 2 wherein the image processing module is configured to display a probabilistic map for a portion of the virtual guidewire that protrudes from the distal tip of the shape-sensed catheter.

16. (canceled)

17. (canceled)

18. (canceled)

19. (canceled)

20. (canceled)

21. A method for determining the position of a guidewire, comprising the steps of:

receiving the guidewire in a lumen of a catheter including a shape sensing optical fiber;

receiving at least a portion of the guidewire and/or the catheter in a measurement assembly;

measuring a distance that the guidewire moves in the measurement assembly by a measurement module; and

determining a position of the non shape sensed guidewire by a location module based on the distance that the guidewire moves in the measurement assembly.

22. (canceled)

23. (canceled)

24. (canceled)

25. The method recited in claim 1, further comprising the step of processing information for generation of a virtual image of the guidewire based on a determined position of the guidewire and the step of displaying a probabilistic map for a portion of the virtual guidewire that protrudes from the distal tip of the catheter.

26. (canceled)

27. (canceled)

28. (canceled)

29. (canceled)

30. (canceled)

31. (canceled)

32. (canceled)

33. (canceled)

34. (canceled)

35. (canceled)

36. (canceled)

37. (canceled)

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