US 20190125302A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2019/0125302 A1**

Clark (43) **Pub. Date: May 2, 2019**

(54) **ACCELEROMETER IN HANDLE FOR ULTRASOUND MEDICAL IMAGING DEVICE**

(71) Applicant: **KONINKLIJKE PHILIPS N.V.**, Einhoven (NL)

(72) Inventor: **David Wesley Clark**, Derry, NH (US)

(21) Appl. No.: **16/165,604**

(22) Filed: **Oct. 19, 2018**

Related U.S. Application Data

(60) Provisional application No. 62/579,336, filed on Oct. 31, 2017.

Publication Classification

(51) **Int. Cl.**

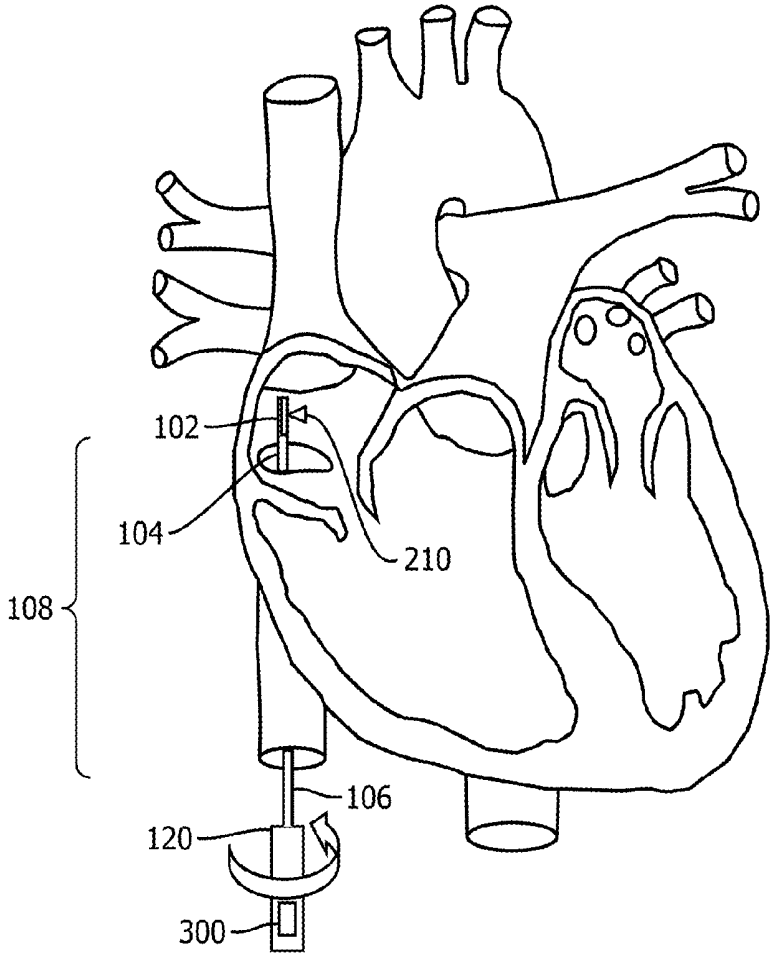
A61B 8/00	(2006.01)
A61B 8/12	(2006.01)
A61B 8/08	(2006.01)

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

CPC ***A61B 8/4254*** (2013.01); ***A61B 8/12*** (2013.01); ***A61B 8/463*** (2013.01); ***A61B 8/0883*** (2013.01); ***A61B 8/445*** (2013.01); ***A61B 8/4466*** (2013.01); ***A61B 8/5238*** (2013.01); ***A61B 8/4488*** (2013.01)

(57) **ABSTRACT**

Ultrasound imaging devices, systems and methods are provided. In some embodiments, the ultrasound imaging devices include a flexible elongate member including a proximal portion and a distal portion, the distal portion configured to be positioned within a body of a patient, an ultrasound imaging element disposed at the distal portion of the flexible elongate member and configured to obtain imaging data from within the body of the patient; and a handle coupled to the proximal portion of the flexible elongate member. The handle includes an accelerometer configured to determine an orientation of the ultrasound imaging element.



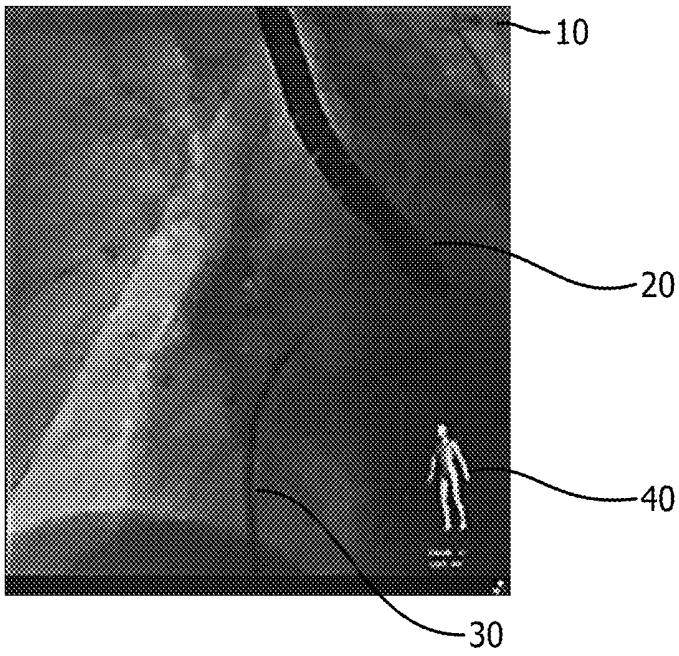


FIG. 1

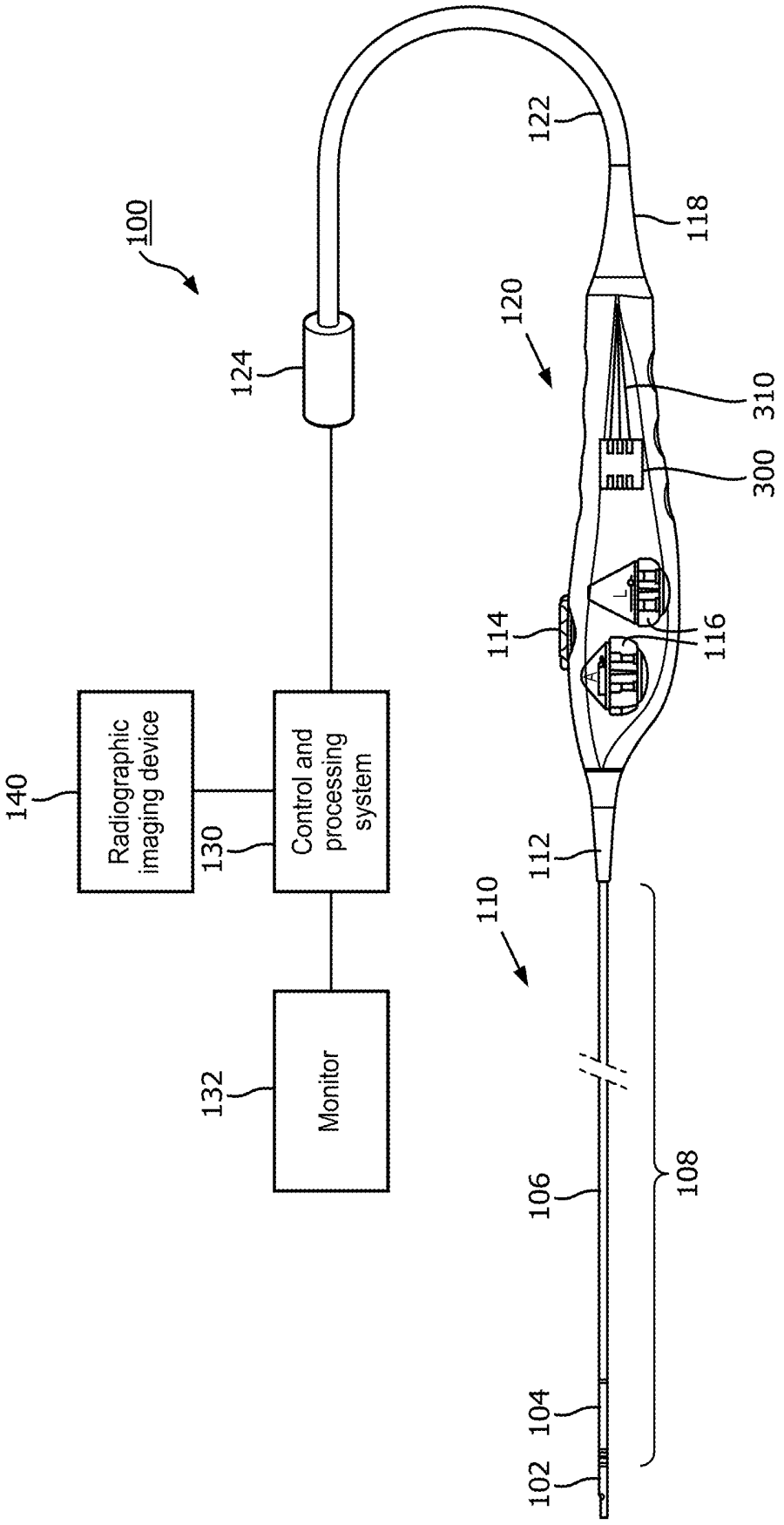

100
122
118
120
124
310
300
114
116
140
Radiographic imaging device
130
Control and processing system
112
110
132
Monitor
106
108
104
102

FIG. 2

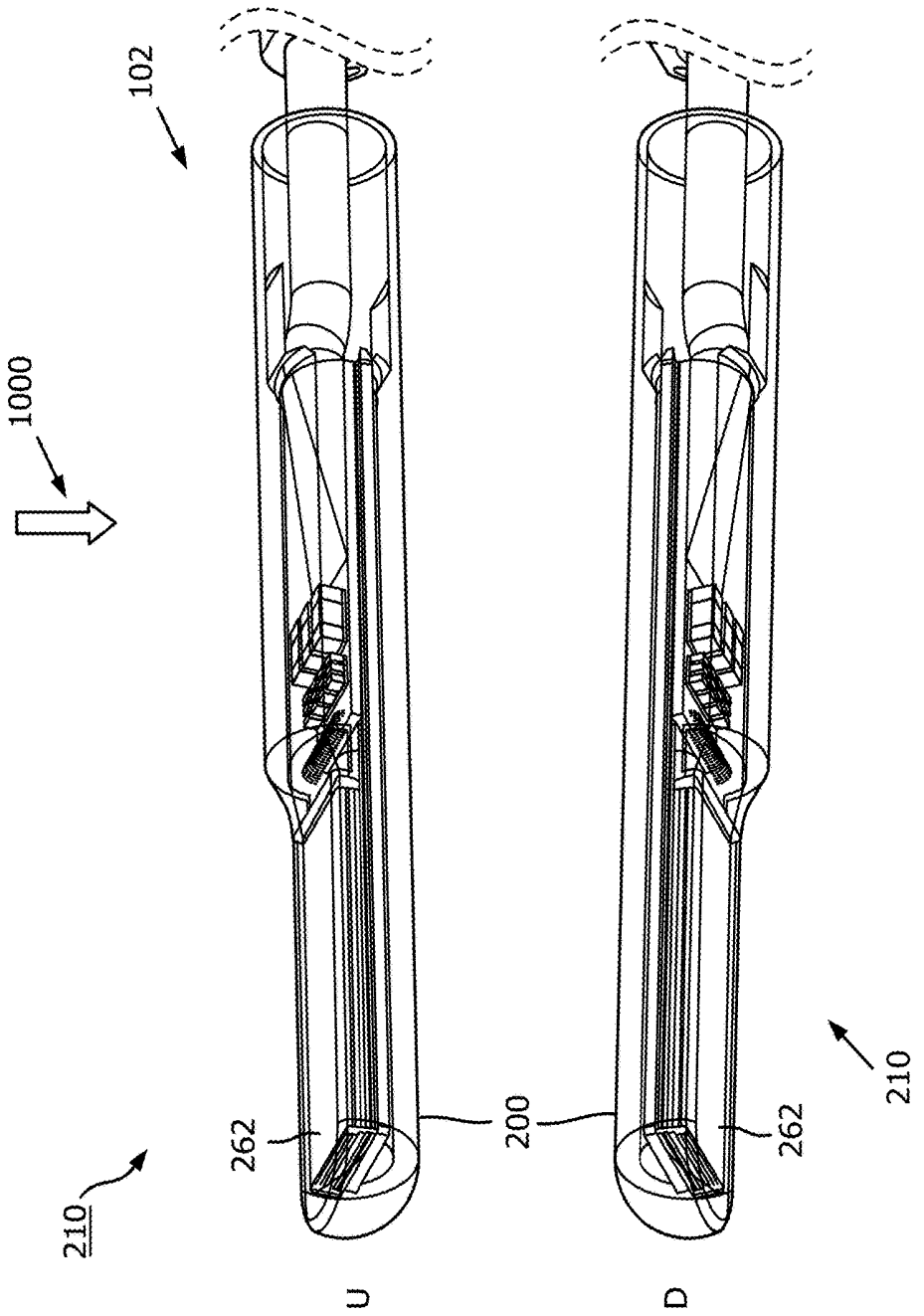


FIG. 3

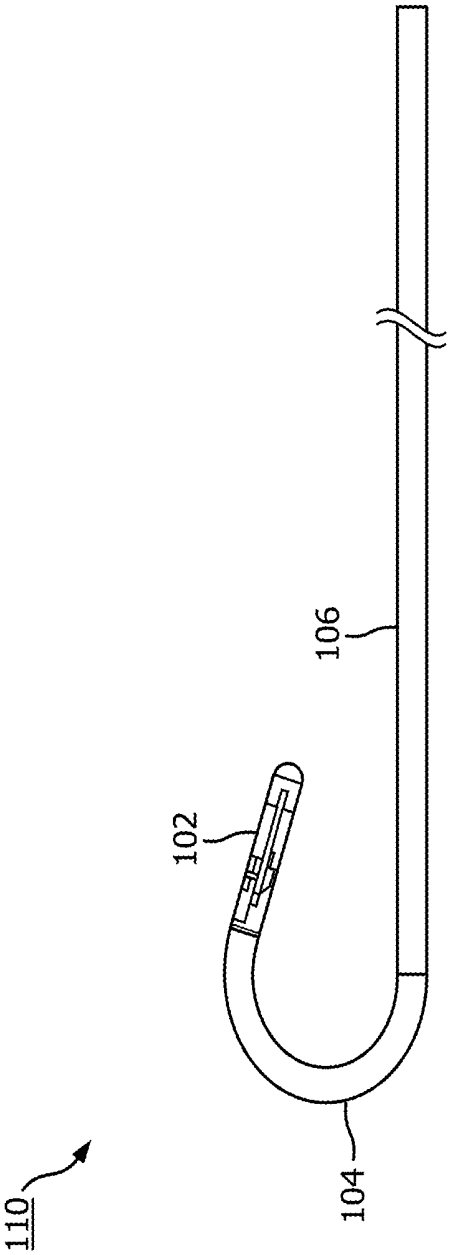


FIG. 4

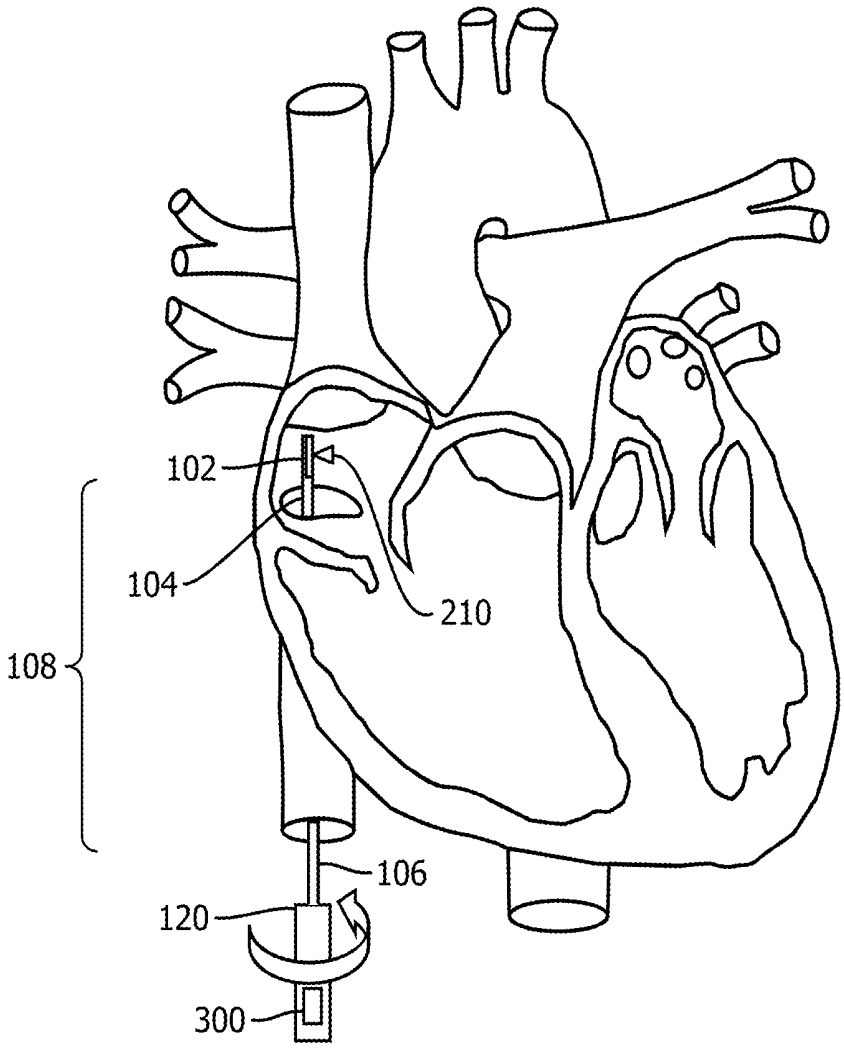


FIG. 5

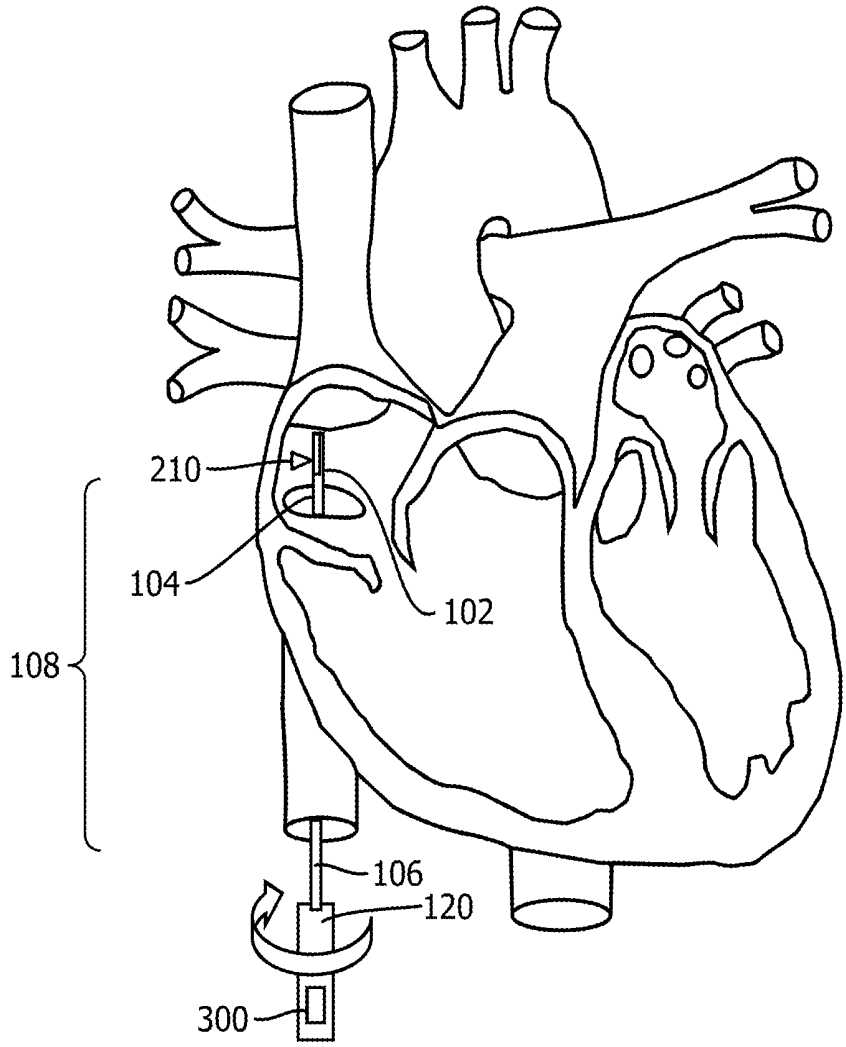


FIG. 6

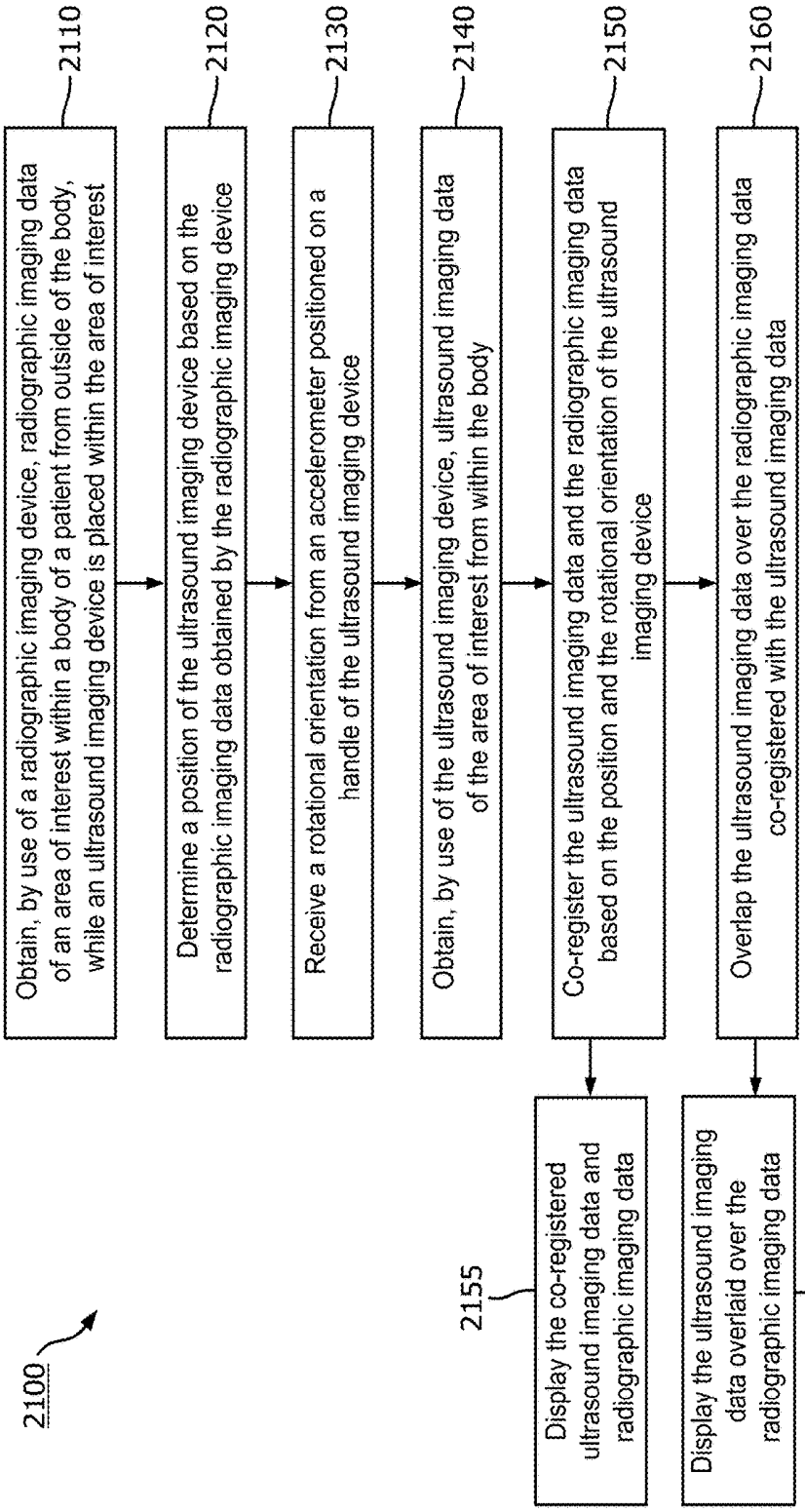

2100
2110
Obtain, by use of a radiographic imaging device, radiographic imaging data of an area of interest within a body of a patient from outside of the body, while an ultrasound imaging device is placed within the area of interest
2120
Determine a position of the ultrasound imaging device based on the radiographic imaging data obtained by the radiographic imaging device
2130
Receive a rotational orientation from an accelerometer positioned on a handle of the ultrasound imaging device
2140
Obtain, by use of the ultrasound imaging device, ultrasound imaging data of the area of interest from within the body
2150
Co-register the ultrasound imaging data and the radiographic imaging data based on the position and the rotational orientation of the ultrasound imaging device
2160
Overlap the ultrasound imaging data over the radiographic imaging data co-registered with the ultrasound imaging data
2155
Display the co-registered ultrasound imaging data and radiographic imaging data
2165
Display the ultrasound imaging data overlaid over the radiographic imaging data

FIG. 7

ACCELEROMETER IN HANDLE FOR ULTRASOUND MEDICAL IMAGING DEVICE

RELATED APPLICATION

[0001] This application claims the benefit of and priority to U.S. Provisional Application No. 62/579,336, filed Oct. 31, 2017, which is incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present disclosure relates generally to ultrasound imaging devices and systems. In particular, the present disclosure provides an ultrasound imaging device with an accelerometer-embedded handle that determines orientation of the ultrasound transducer.

BACKGROUND

[0003] Diagnostic and therapeutic ultrasound catheters have been designed for use inside many areas of the human body. For example, a trans-esophageal echocardiography (TEE) probe can be inserted into an esophagus of a patient and image the patient's heart with high frequency ultrasound waves. Another common diagnostic ultrasound method is intra-cardiac echocardiography (ICE), where a single rotating transducer or an array of transducer elements (sometimes referred to as a transducer array) is threaded through a patient's femoral vein or jugular vein and enters his or her heart to take images. Transducers on TEE probes and ICE catheters transmit ultrasound waves and receive echoes from the tissue. A signal generated from the echoes is transferred to a console which allows for the processing, storing, display, or manipulation of the ultrasound-related data.

[0004] TEE probes and ICE catheters are usually used along with a radiographic imaging device, such as a fluoroscopy system, to guide and facilitate medical procedures, such as transseptal lumen punctures, left atrial appendage closures, atrial fibrillation ablation, and valve repairs. In order to co-register the ultrasound images from a TEE probe or an ICE catheter and radiographic images, a computer system has to identify the position and orientation of the ultrasound transducer. In case of TEE, because the diameter of a TEE probe can be as large as 13 mm, the TEE probe and its internal structure can be discerned by the computer system in the radiographic images. However, in case of a mini TEE probe or an ICE catheter that can have a diameter of about 3 mm, while the computer system can determine its position, its rotational orientation may not be detectable with adequate precision in the radiographic images. Without reliable information of the orientation, co-registration may fail or lose fidelity.

SUMMARY

[0005] Embodiments of the present disclosure provide an ultrasound imaging system having a handle containing an accelerometer. For example, the ultrasound imaging system can be an intracardiac echocardiography (ICE) catheter that obtains ultrasound images from within the chambers of the heart or any other suitable ultrasound device. An ultrasound imaging element is positioned at the distal portion of the imaging device, which is disposed within the body of the patient to obtain ultrasound images. The handle is positioned at the proximal portion of the imaging device. A doctor controls where the ultrasound images are obtained using the handle. For example, the doctor can rotate the handle to correspondingly rotate the imaging element. The accelerometer monitors the orientation of the handle, and thus the corresponding orientation of the imaging element, and where in the patient's anatomy the ultrasound images are being obtained. The orientation data from the accelerometer can be used, e.g., together with an X-ray image of the patient's anatomy, to identify which part of the anatomy is shown in the ultrasound images. Advantageously, the accelerometer can provide orientation data when the ultrasound imaging element is small such that its orientation cannot be determined precisely enough by looking at the X-ray image itself. The medical imaging systems described herein reliably determine the orientation of the imaging element of the ultrasound imaging device. The orientation data is particularly advantageous when registering internal imaging data with external imaging data, such as angiograms or x-ray imaging data.

[0006] In one embodiment, an ultrasound imaging system is provided. The ultrasound imaging system includes a flexible elongate member having a proximal portion and a distal portion, the distal portion configured to be positioned within a body of a patient, an ultrasound imaging element disposed at the distal portion of the flexible elongate member and configured to obtain imaging data from within the body of the patient; and a handle coupled to the proximal portion of the flexible elongate member. The handle includes an accelerometer configured to determine an orientation of the ultrasound imaging element. The system may further include a computing device in communication with the handle and the ultrasound imaging element, wherein the computing device is configured to receive the ultrasound and orientation data and co-register the received data to radiographic imaging data.

[0007] In some implementations, the accelerometer is a dual-axis accelerometer. In some instances, the ultrasound imaging element includes a transducer array. In some embodiments, the handle of the ultrasound imaging device includes a first actuator, which, upon activation, is configured to deflect the distal portion of the flexible elongate member along a first plane. In still some embodiments, the handle of the ultrasound imaging device includes a second actuator, which, upon activation, is configured to deflect the distal portion of the flexible elongate member along a second plane not parallel to the first plane

[0008] In another embodiment, a medical imaging system is provided. The method includes an ultrasound imaging device configured to obtain ultrasound imaging data of an area of interest within a body of a patient and a computing device in communication with the ultrasound imaging device and a radiographic imaging device. The ultrasound imaging device includes a flexible elongate member and a handle. A distal portion of the flexible elongate member is sized and shaped to be inserted into the body and placed in the area of interest. The handle includes an accelerometer configured to determine an orientation of the flexible elongate member. The computing device is configured to receive radiographic imaging data of the area of interest from the radiographic imaging device; determine a position of the ultrasound imaging device using the radiographic imaging data; receive the orientation of the flexible elongate member from the accelerometer; receive ultrasound imaging data from the ultrasound imaging device; co-register the ultrasound imaging data and the radiographic imaging data; and output the co-registered ultrasound imaging data and radio-

graphic imaging data to a display. In some embodiments, the computing device is further configured to control the ultrasound imaging device and the radiographic imaging device. In some implementations, the computing device is further configured to overlay the ultrasound imaging data over the radiographic imaging data co-registered with the ultrasound imaging data and output to the display the ultrasound imaging data overlaid over the radiographic imaging data co-registered with the ultrasound imaging device. In some instances, the medical imaging system further includes the radiographic imaging device. In some implementations, the medical imaging system further includes the display. In some embodiments, the ultrasound imaging device is intracardiac echocardiography (ICE) device. In some other embodiments, the ultrasound imaging device is a transesophageal echocardiography (TEE) device. In still other embodiments, the ultrasound imaging device is an intravascular ultrasound (IVUS) device. In some instances, the accelerometer is a dual-axis accelerometer. In some other instances, the accelerometer is a triple-axis accelerometer.

[0009] In another embodiment, a method for displaying ultrasound imaging data and radiographic imaging data with respect to an area of interest within a body of a patient is provided. The method includes obtaining the radiographic imaging data of the area of interest from outside of the body by a radiographic imaging device while an ultrasound imaging device is placed within the area of interest; determining a position of the catheter based on the radiographic imaging data; receiving the orientation of the ultrasound imaging device from the accelerometer; obtaining, by the ultrasound imaging device, the ultrasound imaging data of the area of interest from within the body; co-registering the ultrasound imaging data and the radiographic imaging data based on the position and rotational orientation of the ultrasound imaging device; and displaying the co-registered ultrasound imaging data and radiographic imaging data on a display. The ultrasound imaging device includes a handle that includes an accelerometer configured to determine an orientation of the ultrasound imaging device. In some embodiments, the method further includes overlaying ultrasound imaging data over the radiographic imaging data co-registered with the ultrasound imaging data. In some implementations, the method further includes displaying the ultrasound imaging data overlaid over the radiographic imaging data co-registered with the ultrasound imaging data.

[0010] Additional aspects, features, and advantages of the present disclosure will become apparent from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Illustrative embodiments of the present disclosure will be described with reference to the accompanying drawings, of which:

[0012] FIG. **1** is a picture of a radiographic image showing a TEE probe and a catheter within a patient's body.

[0013] FIG. **2** is a schematic diagram of a medical imaging system according to embodiments of the present disclosure.

[0014] FIG. **3** is a perspective view of an imaging assembly of an ultrasound imaging device in two substantially opposing orientations.

[0015] FIG. **4** is a schematic diagram illustrating a portion of an ultrasound imaging device under deflection according to embodiments of the present disclosure.

[0016] FIG. **5** is a schematic diagram illustrating an ultrasound imaging device with an imaging assembly positioned on a distal portion thereof inserted into a heart in a first orientation and a proximal portion thereof coupled to a handle, according to embodiments of the present disclosure.

[0017] FIG. **6** is a schematic diagram illustrating the ultrasound imaging device with the imaging assembly inserted into a heart in a second orientation different from the first direction and the proximal portion coupled to the handle, according to embodiments of the present disclosure.

[0018] FIG. **7** is a flow diagram of a method for displaying ultrasound imaging data and radiographic imaging data with respect to an area of interest within a body of a patient, according to aspects of the disclosure.

DETAILED DESCRIPTION

[0019] For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It is nevertheless understood that no limitation to the scope of the disclosure is intended. Any alterations and further modifications to the described devices, systems, and methods, and any further application of the principles of the present disclosure are fully contemplated and included within the present disclosure as would normally occur to one skilled in the art to which the disclosure relates. For example, while the ICE system is described in terms of intraluminal imaging, it is understood that it is not intended to be limited to this application. In particular, it is fully contemplated that the features, components, and/or steps described with respect to one embodiment may be combined with the features, components, and/or steps described with respect to other embodiments of the present disclosure. For the sake of brevity, however, the numerous iterations of these combinations will not be described separately.

[0020] FIG. **1** is a picture of a radiographic image **10** showing a TEE probe **20** and a catheter **30** within a patient's body to image an area of interest. In this case, the area of interest is within the patient's heart. In some instances, the radiographic image **10** is captured by a radiography imaging device, such as a fluoroscopy system and is displayed on a display device. The TEE probe **20** is inserted into the patient's esophagus through the patient's mouth. Sometimes, if the circumstances require, the TEE probe **20** can be inserted all the way into the patient's stomach to image the patient's heart at a preferable angle. A catheter **30** enters the patient's body through his or her femoral or jugular vein and is threaded to the patient's heart. When a catheter such as catheter **30** enters the patient's body through his/her jugular vein, the catheter **30** is advanced downward into the patient's heart through the superior vena cava. However, when catheter **30** enters the patient's body through his/her femoral vein, the catheter would be advanced upward into the patient's heart through the inferior vena cava.

[0021] As illustrated in FIG. **1**, the radiographic imaging device that captures the radiographic image **10** is directed at the area of interest from outside of the patient's body while the TEE probe **20** and the catheter **30** is positioned adjacent to or within the patient's heart. Due to the difference in dimensions of the esophagus and vein that allow passage of a regular TEE probe, such as the TEE probe **20**, and catheter **30**, the TEE probe **20** has a diameter substantially larger than that of the catheter **30**. External characteristics of the TEE

probe **20** can be readily identified by a computer system that processes radiographic images from the radiographic imaging device. In some implementations, X-ray from the radiographic imaging device penetrates certain outer radiolucent features of the TEE probe **20** and allows the computer system to discern inner radiopaque structures of the TEE probe **20**. Because the computer system can identify features and characteristics of the TEE probe **20**, the computer system can determine a position and an orientation of the TEE probe **20**. The same cannot be said for the catheter **30**. Given the resolution of the radiographic imaging data, while the position of catheter **30** is readily identifiable, the smaller dimensions of catheter **30** may not provide enough discernible features and characteristics for the computer system to determine the orientation of catheter **30**. In some instances, the orientation refers to the rotational orientation around a longitudinal direction along the length of catheter **30**. For example, the silhouette of the catheter **30** in the radiographic image **10** provides little details. In contrast, the silhouette of the TEE probe **20** reveals much more details, including the gaps between vertebrae embedded within a polymer jacket. In some examples, a figurine icon **40** is also displayed to indicate the imaging plane of the displayed radiographic image relative to the patient's body.

[0022] FIG. **2** shows a schematic diagram of a medical imaging system **100** according to embodiments of the present disclosure. The system **100** can include an ultrasound imaging device **110**, a connector **124**, a control and processing system **130** (for example, a console and a computer), and a monitor **132**. In some embodiments, the ultrasound imaging device **110** is an ICE catheter. The ultrasound imaging device **110** includes an imaging assembly **102** at the tip of a flexible elongate member **108**, and a handle **120**. The flexible elongate member **108** includes a distal portion **104** and a proximal portion **106**. The distal end of the distal portion **104** is attached to the imaging assembly **102**. The proximal end of the proximal portion **106** is attached to the handle **120**, for example, by a resilient strain reliever **112**. The handle **120** may be used for manipulation of the ultrasound imaging device **110** and manual control of the ultrasound imaging device **110**. The imaging assembly **102** can include an imaging core with ultrasound transducer elements and associated circuitry. The handle **120** can include actuators **116**, a clutch **114**, and other steering control components for steering the ultrasound imaging device **110**. The steering may include deflecting the imaging assembly **102** and the distal portion **104** along different planes, as described in greater details herein.

[0023] The handle **120** is connected to the connector **124** via another strain reliever **118** and a connection cable **122**. The connector **124** may be configured to provide suitable configurations for interconnecting the control and processing system **130** and the monitor **132** to the imaging assembly **102**. The control and processing system **130** may be used for processing, storing, analyzing, and manipulating data, and the monitor **132** may be used for displaying obtained signals generated by the imaging assembly **102**. The control and processing system **130** can include one or more processors, memory, one or more input devices, such as keyboards and any suitable command control interface device. The control and processing system **130** can be operable to facilitate the features of the medical imaging system **100** described herein. For example, a processor can execute computer readable instructions stored on the non-transitory tangible computer readable medium. The monitor **132** can be any suitable display device, such as liquid-crystal display (LCD) panel or the like.

[0024] In some embodiments, the handle **120** includes an accelerometer **300** coupled to a plurality of electrical wires **310**. In some instances, the accelerometer **300** is a dual-axis accelerometer. In some other examples, the accelerometer **300** is a triple-axis accelerometer. As compared to a dual-axis accelerometer that measures acceleration along an X and a Y axes, a three-axis or triple-axis accelerometer measures acceleration along an additional Z axis. In embodiments where a triple-axis accelerometer is used and its Z-axis is aligned with the longitudinal direction of the handle **120**, the tilting movement of the handle **120** can be measured. In some embodiments, the accelerometer **300** is a micro-machined accelerometer that is integrated with a signal conditioning circuit. The accelerometer **300** is positioned inside of handle **120** to measure accelerations along at least two axes of the handle **120** relative to the vertical force of earth's gravity. This way, the accelerometer **300** is able to detect and measure rotational orientation of the handle **120** for a dual-axis accelerometer, and also tilting for a triple-axis accelerometer. In some instances, as the flexible elongate member **108** is torsionally stiff and attached to the handle **120**, the rotational orientation of the handle **120** assumes a one-to-one correlation with the rotational orientation of the flexible elongate member **108**. Because the imaging assembly **102** is attached to the distal portion **104** of the flexible elongate member **108**, the rotational orientation of the imaging assembly **102** also assumes a one-to-one correlation with the rotation orientation of the handle **120**. As a result, in some embodiments, the accelerometer **300** measures and determines the rotational orientation of the imaging assembly **102** by measuring and determining the rotational orientation of the handle **120**. The accelerometer **300** transmits orientation data, including the rotational orientation of the handle **120** and the imaging assembly **102**, to the control and processing system **130** by way of electrical wires **310**.

[0025] In some embodiments, a dual-axis accelerometer **300** can be replaced by two single-axis accelerometers. Similarly, a triple-axis accelerometer **300** can be replaced by two dual-axis accelerometers or three single-axis accelerometers. Further, in some other embodiments, the accelerometer **300** can be replaced by a gyroscope. The gyroscope can be a single-axis, a dual-axis or a triple-axis gyroscope. In some embodiments, one or both of an accelerometer or a gyroscope can be implemented in the handle **120**. A gyroscope positioned inside the handle **120** can measure the rotational orientation of the handle **120** and the rotational orientation of the imaging assembly **102**, provided that the flexible elongate member **108** connecting the handle **120** and the imaging assembly **102** is torsionally stiff

[0026] The electrical wires **310** have distal ends and proximal ends. In some embodiments, the distal ends of the electrical wires **310** are bonded to bond pads on the accelerometer **300** or bond pads on a substrate on which the accelerometer **300** is mounted; and the proximal ends of the electrical wires **310** are connected to the control and processing system **130** by way of the connection cable **122** and the connector **124**. In some instances, the accelerometer **300** or the substrate, on which the accelerometer **300** is mounted, is mounted or coupled to the interior of the handle **120**. Arranged in that fashion, each of the actuators **116** is

attached to one or more distally-extending pull wires that are threaded through the flexible elongate member **108** and anchored to the distal portion **104**; and the accelerometer **300** is bonded to the plurality of electrical wires **310** that extend proximally and enter the connection cable **122**.

[0027] In operation, a physician or a clinician may advance the flexible elongate member **108** into a vessel within a heart anatomy. By controlling the actuators **116** and the clutch **114** on the handle **120**, the physician or clinician can steer the flexible elongate member **108** to a position near the area of interest to be imaged. For example, one actuator **116** may deflect the imaging assembly **102** and the distal portion **104** in along a first plane and the other actuator **116** may deflect the imaging assembly **102** and the distal portion **104** along a second plane not parallel to the first plane. In some embodiments, the first plane has a normal direction perpendicular to the normal direction of the second plane. The clutch **114** provides a locking mechanism to lock the positions of the actuators **116** and in effect lock the deflection of the flexible elongate member while imaging the area of interest. Embodiments of the present disclosure can include steering mechanism features similar to those described in U.S. Provisional App. No. 62/402,483, filed Sep. 30, 2016, the entirety of which is hereby incorporated by reference herein. Additionally, embodiments of the present disclosure can include features similar to those described in U.S. Provisional App. No. 62/403,479, filed Oct. 3, 2016, U.S. Provisional App. No. 62/434,517, filed Dec. 15, 2016, U.S. Provisional App. No. 62/403,311, filed Oct. 3, 2016, U.S. Provisional App. No. 62/437,778, filed Dec. 22, 2016, U.S. Provisional App. No. 62/401,464, filed Oct. 29, 2016, U.S. Provisional App. No. 62/401,686, filed Oct. 29, 2016, and/or U.S. Provisional App. No. 62/401,525, filed Oct. 29, 2017, the entireties of which are hereby incorporated by reference herein.

[0028] The imaging process may include activating the ultrasound transducer elements on the imaging assembly **102** to produce ultrasonic energy. A portion of the ultrasonic energy is reflected or scattered by the area of interest and the surrounding anatomy, and the ultrasound echo signals are received by the ultrasound transducer elements. The connector **124** transfers the received echo signals in the form of ultrasound imaging data to the control and processing system **130** where the ultrasound image is reconstructed and displayed on the monitor **132**. In some embodiments, the control and processing system **130** can control the activation of the ultrasound transducer elements and the reception of the echo signals. In some embodiments, the control and processing system **130** and the monitor **132** may be part of a same system. In some instances, the ultrasound image can be further displayed in a different monitor (not shown in FIG. **2**) to be viewed by a physician or clinician.

[0029] The system **100** may be utilized in a variety of applications such as trans-septal punctures, left atrial appendage closures, atrial fibrillation ablation, and valve repairs and can be used to image vessels and structures within a living body. In some examples, the device **110** can be sized and shaped, structurally arranged, and/or otherwise configured to be positioned within any suitable anatomy and/or body lumen of a patient. For example, the device **110** can be an intraluminal device. Although the system **100** is described in the context of intraluminal imaging procedures, the system **100** is suitable for use with any catheterization procedure, e.g., ICE, mini TEE, or intravascular ultrasound (IVUS). More generally speaking, the system is suitable for use with any medical imaging procedures where the angular and/or rotational orientation of an imaging element is of interest and bears a pre-determined relationship with the angular and/or rotational orientation of a handle connected directly or indirectly to the imaging element. An example of such a medical imaging procedure includes external ultrasound examination where an external ultrasound imaging device is used. For example, disclosure described herein can be implemented for any ultrasound transducer with an accelerometer in the handle to determine orientation. In addition, the imaging assembly **102** may include any suitable physiological sensor or component for diagnostic, treatment, and/or therapy. For example, the imaging assembly can include an imaging component, an ablation component, a cutting component, a morcellation component, a pressure-sensing component, a flow-sensing component, a temperature-sensing component, and/or combinations thereof.

[0030] In some embodiment, the ultrasound imaging device **110** includes a flexible elongate member **108** that can be positioned within a vessel, such as a femoral vein or a jugular vein. The flexible elongate member **108** may have a distal portion **104** and a proximal portion **106**. The ultrasound imaging device **110** includes an imaging assembly **102** that is mounted within the distal portion **104** of the flexible elongate member **108**.

[0031] In some embodiments, the medical imaging system **100** is used for generating 2D and 3D images. In some examples, the medical imaging system **100** is used for generating multi-plane images in two or more different planes at some non-zero angle or distance to each other.

[0032] In some embodiments, the control and processing system **130** is in communication with a radiographic imaging device **140**. In some embodiments, the radiographic imaging device **140** is a fluoroscopy system. In some other embodiments, the radiographic imaging device **140** is an X-ray imaging device other than a fluoroscopy system. The control and processing system **130** can be used to activate, operate, and control the radiographic imaging device **140**. In some embodiments, the control and processing system **130** may be used for processing, storing, analyzing, and manipulating radiographic imaging data received from the radiographic imaging device **140**, and the monitor **132** may be used for displaying obtained radiographic imaging data generated by the radiographic imaging device **140**. The control and processing system **130** can include one or more processors, memory, one or more input devices, such as keyboards and any suitable command control interface device. The control and processing system **130** can be operable to facilitate the features of the medical imaging system **100** described herein. For example, a processor can execute computer readable instructions stored on the non-transitory tangible computer readable medium.

[0033] In some embodiments, the control and processing system **130** outputs both ultrasound imaging data received from the ultrasound imaging device **110** and the radiographic imaging data received from the radiographic imaging device **140**, to the monitor **132** for simultaneous display of the ultrasound imaging data and the radiographic imaging data. In some instances, the ultrasound imaging data and the radiographic imaging data are displayed on the monitor **132**

in real time while the ultrasound imaging device **110** and the radiographic imaging device **140** are capturing them within the patient's body.

[0034] In some embodiments, the ultrasound imaging data and the radiographic imaging data are co-registered before they are displayed on the monitor. To co-register the ultrasound imaging data and the radiographic imaging data, the control and processing system **130** has to identify the position and orientation of the ultrasound imaging device **110** and the radiographic imaging device **140**. The orientation, field of view, and position of the radiographic imaging device **140** is readily available to the control and processing system **130** as the movement of the radiographic imaging device **140** is controlled through the control and processing system **130**. In some embodiments where fluoroscopy system is used, the radiographic imaging element orbits around the patient's body along a C-shaped arm (C-arm) and the orbiting is controlled through the control and processing system **130**.

[0035] With respect to the position of the ultrasound imaging device **110**, the control and processing system **130** can determine the position of the imaging assembly **102** based on radiographic imaging data obtained by the radiographic imaging device **140**. To achieve that, the radiographic imaging device **140** is directed at the area of interest from outside of the patient's body while the imaging assembly **102** of the ultrasound imaging device **110** is advanced into and positioned within the area of interest. In some examples, the area of interest is the patient's heart. The foregoing arrangement allows the radiographic imaging device **140** to obtain radiographic imaging data that contain information of the position of the imaging assembly **102**. For example, such information includes distances between the imaging assembly **102** and two reference points adjacent to the area of interest within the patient's body. Oftentimes the imaging assembly **102** is too small for the control and processing system **130** to reliably determine the orientation of the imaging assembly **102**. In some instances, the control and processing system **130** determines the orientation (for example, the rotational orientation) of the imaging assembly **102** based on orientation data from the accelerometer **300**. Having obtained or received positions and orientations of the ultrasound imaging device **110** and the radiographic imaging device **140**, the control and processing system **130** can co-register the ultrasound imaging data and the radiographic imaging data and output the co-registered imaging data to the monitor **132** for display. When displayed on the monitored **132**, the co-registered imaging data are displayed such that the ultrasound image and the radiographic image share substantially the same field of view. In some embodiments, the control and processing system **130** can overlay the ultrasound image on top of the radiographic image to provide a more intuitive view for a physician or clinician performing the catheterization.

[0036] FIG. **3** is a perspective view of the imaging assembly **102** of the ultrasound imaging device **110** in two substantially opposing orientations. The imaging assembly **102** may include an imaging core **262** that is positioned within a tip member **200**. In some embodiments, the tip member **200** is substantially cylindrical in shape except for the portion that houses the imaging core **262**, which may be flat. In some embodiments, the imaging core **262** has a directional field of view **210**. FIG. **3** shows the imaging assembly **102** in a "U" orientation where the imaging core **262** faces upward with an upward field of view **210** and another imaging assembly **102** in a "D" orientation where the imaging core **262** faces downward with a downward field of view **210**. When being imaged along a direction **1000** by a radiographic imaging device such as the radiographic imaging device **140**, because the tip member is cylindrical in shape and of a small diameter, the radiographic imaging data do not contain enough information for the control and processing system **130** to determine the rotational orientation of the imaging assembly **102** precisely enough to adequate co-register the images. Sometimes the small dimensions of the imaging assembly **102** can make it more difficult for the control and processing system **130** to distinguish the "U" and "D" orientations or any intermediate orientations. This makes it unreliable for the control and processing system **130** to determine the orientation of the imaging assembly **102** by the radiographic imaging data alone. Advantageously, the accelerometer **300** described in the present disclosure eliminates the unreliable orientation determination by radiographic imaging data and introduces fidelity in the orientation determination, thereby facilitating accurate and fast co-registration of the ultrasound imaging data and the radiographic imaging data.

[0037] FIG. **4** is a schematic diagram illustrating a portion of the ultrasound imaging device **110** under deflection according to embodiments of the present disclosure. For example, the flexible elongate member **108** shown in FIG. **2** is referred to as a neutral position. In FIG. **4**, the imaging assembly **102** and the distal portion **104** of the flexible elongate member **108** are deflected from the neutral position. As described above, the deflection is controlled by the actuators **116**. The capability of the imaging assembly **102** to deflect allows the ultrasound imaging device **110** to obtain ultrasound imaging data of the area of interest from more directions. The deflection of the imaging assembly **102** is readily discernible by the control and processing system **130** from the radiographic imaging data obtained by the radiographic imaging device **140**.

[0038] Reference is now made to FIGS. **5** and **6**. FIG. **5** is a schematic diagram illustrating the ultrasound imaging device **110** with imaging assembly **102** positioned on distal portion **104** inserted into a heart of a patient in a first orientation and proximal portion **106** coupled to handle **120**, according to embodiments of the present disclosure. When the imaging assembly **102** is in the first orientation, the field of view **210** of the imaging assembly **102** is pointed to the right of FIG. **5**. FIG. **6** is a schematic diagram illustrating imaging assembly **102** being inserted into the heart in a second orientation different from the first orientation. When the imaging assembly **102** is in the second orientation, the field of view **210** of the imaging assembly **102** is pointed to the left of FIG. **6**. As described above, because the flexible elongate member **108** is torsionally stiff, the flexible elongate member **108** and the imaging assembly **102** rotate with the handle **120**. That is, by rotating the handle **120**, the imaging assembly **102** can be rotated between the first orientation shown in FIG. **5** and the second orientation shown in FIG. **6**. In some embodiments, the accelerometer **300** is mounted inside of the handle **120** and the accelerometer **300** determines the orientation of the handle **120**, thereby determining the orientation of the flexible elongate member **108** and the imaging assembly **102**. FIGS. **5** and **6** show that the imaging assembly **102** enters into the heart via the inferior vena cava, suggesting that the imaging assembly

102 is inserted into the patient's body through the femoral vein. In some other examples, the imaging assembly 102 can enter into the heart via the superior vena cava and the imaging assembly 102 is inserted into the patient's body through the jugular vein.

[0039] FIG. 7 is a flow diagram of a method 2100 for displaying ultrasound imaging data and radiographic imaging data with respect to the area of interest within a body of a patient, according to aspects of the disclosure. As illustrated, the method 2100 includes a number of enumerated steps, but embodiments of the method 2100 may include additional steps before, after, and in between the enumerated steps. In some embodiments, one or more of the enumerated steps may be omitted, performed in a different order, or performed concurrently. The method 2100 can be performed with reference to FIGS. 2, 5 and 6. At step 2110, radiographic imaging data of an area of interest within a body of a patient from outside of the body is obtained by the radiographic imaging device 140, while the imaging assembly 102 of the ultrasound imaging device 110 is placed within the area of interest. At this step, the radiographic imaging device 140 is directed at the area of interest from outside of the patient's body. Consequently, the radiographic imaging device 140 not only obtains radiographic imaging data of the area of interest, but also of the imaging assembly 102 within the area of interest. Therefore, the radiographic imaging data captured by the radiographic imaging device 140 contains imaging data about the position of the imaging assembly 102. In some embodiments, the flexible elongate member 108 is inserted into the patient's body and advanced into the patient's heart with assistance of another monitor separate from the monitor 132. In those embodiments, before the imaging assembly 102 is in position within the area of interest, the monitor 132 displays the radiographic imaging data obtained by the radiographic imaging device 140 and the other monitor displays the ultrasound imaging data obtained by the ultrasound imaging device 110.

[0040] At step 2120, the position of the imaging assembly 102 is determined by the control and processing system 130 based on the radiographic imaging data obtained by the radiographic imaging device 140. For example, the control and processing system 130 can determine the position of the imaging assembly 102 by determining the distances between the imaging assembly 102 and at least two reference points adjacent to the area of interest.

[0041] At step 2130, a rotational orientation is received from the accelerometer 300. Because the accelerometer 300 is positioned on the handle 120 of the ultrasound imaging device 110 and the flexible elongate member 108 is torsionally stiff, the rotational orientation from the accelerometer 300 represent not only the orientation of the handle 120, but also the orientation of the flexible elongate member 108 and the imaging assembly 102.

[0042] At step 2140, ultrasound imaging data of the area of interest are obtained by the ultrasound imaging device 110. At step 2150, the ultrasound imaging data obtained by the ultrasound imaging device 110 and the radiographic imaging data obtained by the radiographic imaging device 140 are co-registered based on the position and the rotational orientation of the ultrasound imaging device 110. At step 2155, the co-registered ultrasound imaging data and the radiographic imaging data are displayed on the monitor 132.

[0043] At step 2150, the ultrasound imaging data is overlaid over the radiographic imaging data that are co-registered with the ultrasound imaging data. At step 2165, the ultrasound imaging data overlaid over the radiographic imaging data are displayed on the monitor 132. In some embodiments, the radiographic imaging device 140 is a fluoroscopy system that captures radiographic imaging data in real time. In those embodiments, the method 2100 is a dynamic process where radiographic imaging data are not only obtained in the beginning but also throughout the performance of the method 2100. In fact, in some examples, the radiographic imaging data are displayed at steps 2155 and 2165 are displayed in real time. This allows the physician or clinician to monitor the position and orientation of the imaging assembly 102 in real time, facilitating effective and trouble-free catheterization and intra-cardiac examination procedures.

[0044] Persons skilled in the art will recognize that the apparatus, systems, and methods described above can be modified in various ways. Accordingly, persons of ordinary skill in the art will appreciate that the embodiments encompassed by the present disclosure are not limited to the particular exemplary embodiments described above. In that regard, although illustrative embodiments have been shown and described, a wide range of modification, change, and substitution is contemplated in the foregoing disclosure. It is understood that such variations may be made to the foregoing without departing from the scope of the present disclosure. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the present disclosure.

What is claimed is:

1. An ultrasound imaging system, comprising:
- a flexible elongate member comprising a proximal portion and a distal portion, the distal portion configured to be positioned within a body of a patient,
- an ultrasound imaging element disposed at the distal portion of the flexible elongate member and configured to obtain ultrasound data from within the body of the patient;
- a handle coupled to the proximal portion of the flexible elongate member, wherein the handle comprises an accelerometer configured to generate orientation data corresponding to the ultrasound imaging element; and
- a computing device in communication with the handle and the ultrasound imaging element, wherein the computing device is configured to receive the ultrasound and orientation data and co-register the received data to radiographic imaging data.

2. The ultrasound imaging system of claim 1, wherein the accelerometer is a dual-axis accelerometer.

3. The ultrasound imaging system of claim 1, wherein the ultrasound imaging element comprises a transducer array.

4. The ultrasound imaging system of claim 1, wherein the handle comprises a first actuator, upon activation, configured to deflect the distal portion of the flexible elongate member along a first plane.

5. The ultrasound imaging system of claim 4, wherein the handle further comprises a second actuator, upon actuation, configured to deflect the distal portion of the flexible elongate member along a second plane not parallel to the first plane.

6. A medical imaging system, comprising:
- an ultrasound imaging device configured to obtain ultrasound imaging data of an area of interest within a body of a patient, the ultrasound imaging device including a

flexible elongate member and a handle, wherein a distal portion of the flexible elongate member is sized and shaped to be inserted into the body and placed in the area of interest, wherein the handle includes an accelerometer configured to determine an orientation of the flexible elongate member; and

a computing device in communication with the ultrasound imaging device and a radiographic imaging device, the computing device configured to:

receive radiographic imaging data of the area of interest from the radiographic imaging device;

determine a position of the ultrasound imaging device using the radiographic imaging data;

receive the orientation of the flexible elongate member from the accelerometer;

receive ultrasound imaging data from the ultrasound imaging device;

co-register the ultrasound imaging data and the radiographic imaging data; and

output the co-registered ultrasound imaging data and radiographic imaging data to a display.

7. The medical imaging system of claim **6**, wherein the computing device is further configured to control the ultrasound imaging device and the radiographic imaging device.

8. The medical imaging system of claim **6**, wherein the computing device is further configured to overlay the ultrasound imaging data over the radiographic imaging data co-registered with the ultrasound imaging data and output to the display the ultrasound imaging data overlaid over the radiographic imaging data co-registered with the ultrasound imaging device.

9. The medical imaging system of claim **6**, further comprising the radiographic imaging device.

10. The medical imaging system of claim **6**, further comprising the display.

11. The medical imaging system of claim **6**, wherein the ultrasound imaging device is intra-cardiac echocardiography (ICE) device.

12. The medical imaging system of claim **6**, wherein the ultrasound imaging device is a trans-esophageal echocardiography (TEE) device.

13. The medical imaging system of claim **6**, wherein the ultrasound imaging device is an intravascular ultrasound (IVUS) device.

14. The medical imaging system of claim **6**, wherein the accelerometer is a dual-axis accelerometer.

15. The medical imaging system of claim **6**, wherein the accelerometer is a triple-axis accelerometer.

16. A method for displaying ultrasound imaging data and radiographic imaging data with respect to an area of interest within a body of a patient, comprising:

obtaining the radiographic imaging data of the area of interest from outside of the body by a radiographic imaging device while an ultrasound imaging device is placed within the area of interest, wherein the ultrasound imaging device comprises a handle, the handle including an accelerometer configured to determine a orientation of the ultrasound imaging device;

determining a position of the ultrasound imaging device based on the radiographic imaging data;

receiving the orientation of the ultrasound imaging device from the accelerometer;

obtaining, by the ultrasound imaging device, the ultrasound imaging data of the area of interest from within the body;

co-registering the ultrasound imaging data and the radiographic imaging data based on the position and rotational orientation of the ultrasound imaging device; and

displaying the co-registered ultrasound imaging data and radiographic imaging data on a display.

17. The method of claim **16**, further comprising overlaying ultrasound imaging data over the radiographic imaging data co-registered with the ultrasound imaging data.

18. The method of claim **16**, further comprising displaying the ultrasound imaging data overlaid over the radiographic imaging data co-registered with the ultrasound imaging data.

* * * * *

专利名称(译)	用于超声医学成像设备的手柄中的加速度计		
公开(公告)号	US20190125302A1	公开(公告)日	2019-05-02
申请号	US16/165604	申请日	2018-10-19
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	CLARK DAVID WESLEY		
发明人	CLARK, DAVID WESLEY		
IPC分类号	A61B8/00 A61B8/12 A61B8/08		
CPC分类号	A61B8/4254 A61B8/12 A61B8/463 A61B8/4488 A61B8/445 A61B8/4466 A61B8/5238 A61B8/0883		
优先权	62/579336 2017-10-31 US		
外部链接	Espacenet USPTO		

摘要(译)

提供了超声成像设备，系统和方法。在一些实施例中，超声成像装置包括柔性细长构件，其包括近侧部分和远侧部分，远侧部分构造成定位在患者体内，超声成像元件设置在柔性细长构件的远侧部分处并配置成从患者体内获得成像数据;和连接到柔性细长构件的近端部分的手柄。手柄包括加速计，其被配置为确定超声成像元件的取向。