US012514547B1

(12) **United States Patent**
Jovanov et al.

(10) **Patent No.: US 12,514,547 B1**
(45) **Date of Patent: Jan. 6, 2026**

(54) **MULTI-MODAL HEART DIAGNOSTIC SYSTEM AND METHOD**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **18/404,499**

(22) Filed: **Jan. 4, 2024**

Related U.S. Application Data

(63) Continuation of application No. 17/187,172, filed on Feb. 26, 2021, now Pat. No. 11,872,080.
(Continued)

(51) **Int. Cl.**

A61B 8/00	(2006.01)
A61B 5/00	(2006.01)
A61B 5/0205	(2006.01)
A61B 5/11	(2006.01)
A61B 5/318	(2021.01)

(Continued)

(52) **U.S. Cl.**
CPC ***A61B 8/4263*** (2013.01); ***A61B 5/0205*** (2013.01); ***A61B 5/7267*** (2013.01); ***A61B 8/0883*** (2013.01); ***A61B 8/4254*** (2013.01); ***A61B 8/461*** (2013.01); ***G05B 13/0265*** (2013.01); *A61B 5/1102* (2013.01); *A61B 5/318* (2021.01); *A61B 7/04* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 8/4263; A61B 2034/2051; A61B 2034/2048; A61B 6/0407; A61B 8/4245; A61B 8/4254; A61B 8/42; A61B 8/4227; A61B 34/20; A61B 8/4209; A61N 7/00
See application file for complete search history.

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Primary Examiner — Keith M Raymond
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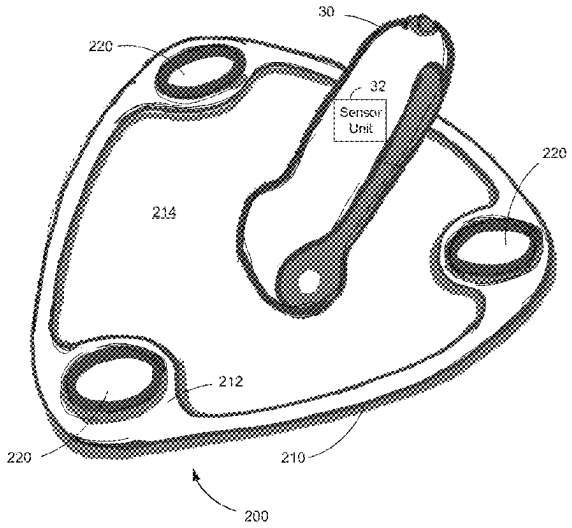
(57) **ABSTRACT**

A multi-modal heart diagnostic system is provided. The diagnostic system can monitor heart activity and assists a user or operator in performing echocardiography. The system can include a positioning device that is placed on a patient's chest. The positioning device can incorporate several multi-modal sensors. The multi-modal sensors can measure different parameters associated with an assessment of heart activity. The multi-modal sensors can also be used to provide information that can assist an operator in positioning the probe within the positioning device to capture an echocardiogram.

18 Claims, 10 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 62/981,893, filed on Feb. 26, 2020.

(51) **Int. Cl.**

A61B 7/04	(2006.01)
A61B 8/08	(2006.01)
G05B 13/02	(2006.01)

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

CPC *A61B 2562/0219* (2013.01); *A61B 2562/0223* (2013.01)

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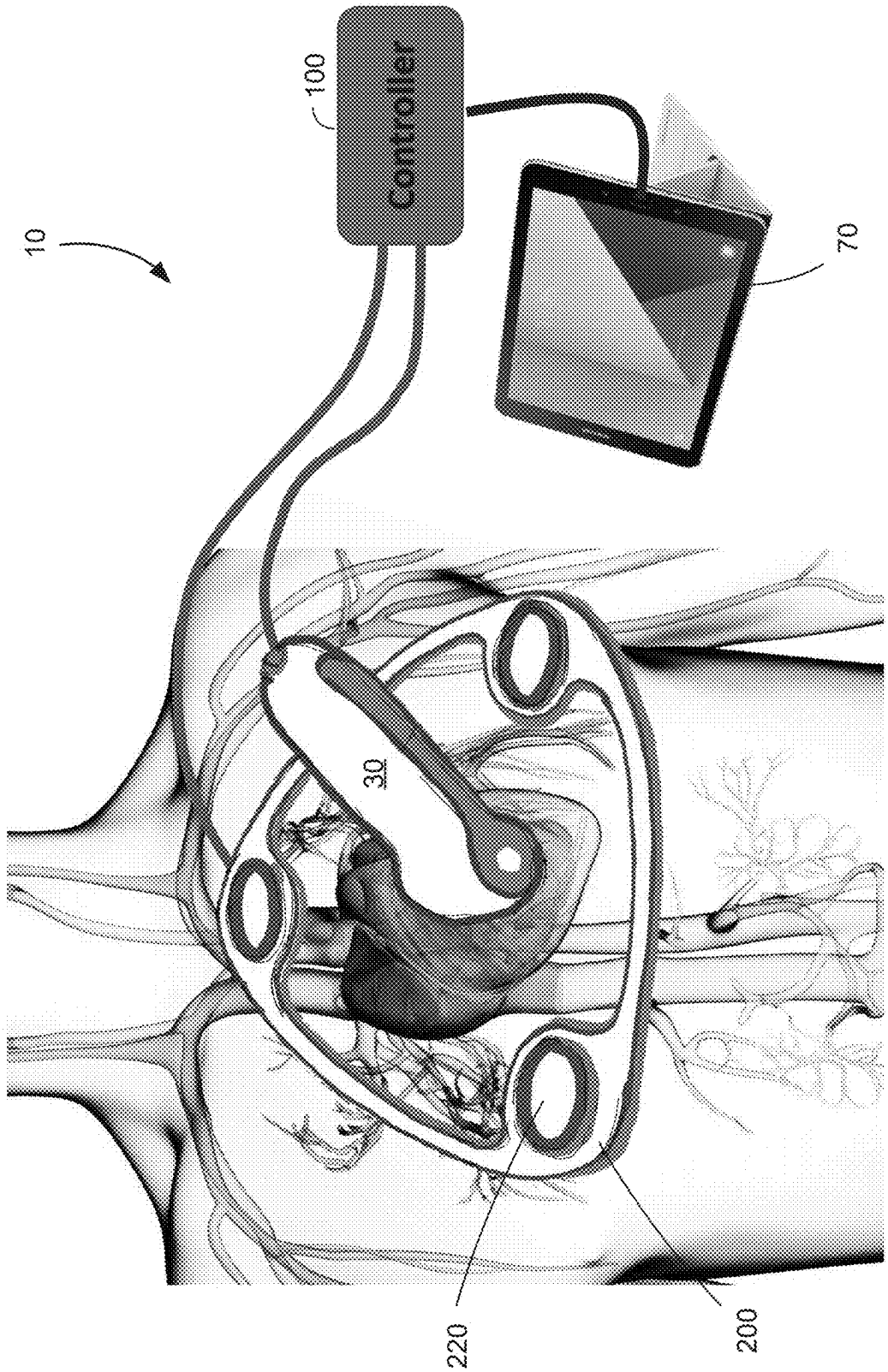

FIG. 1

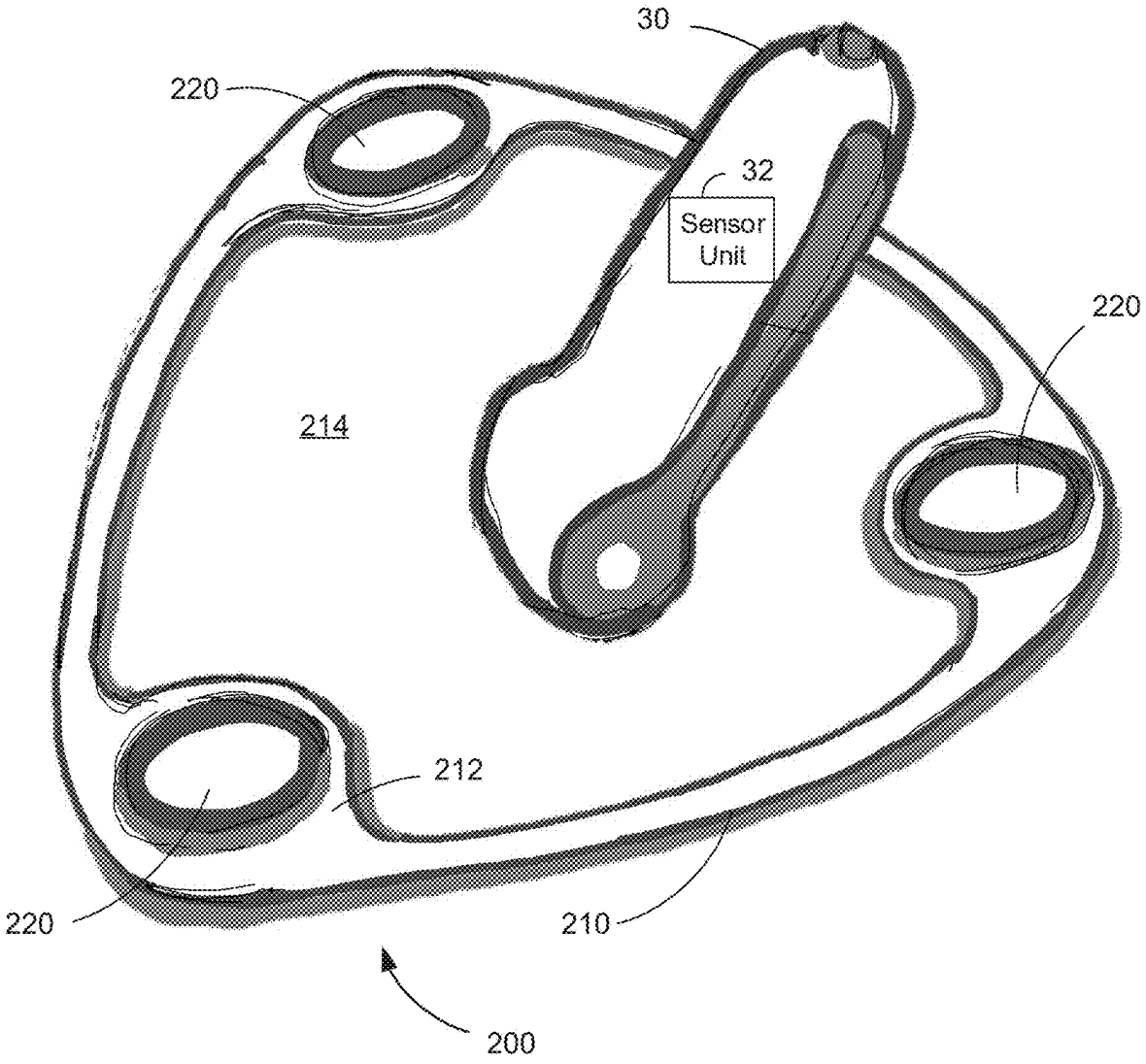

FIG. 2

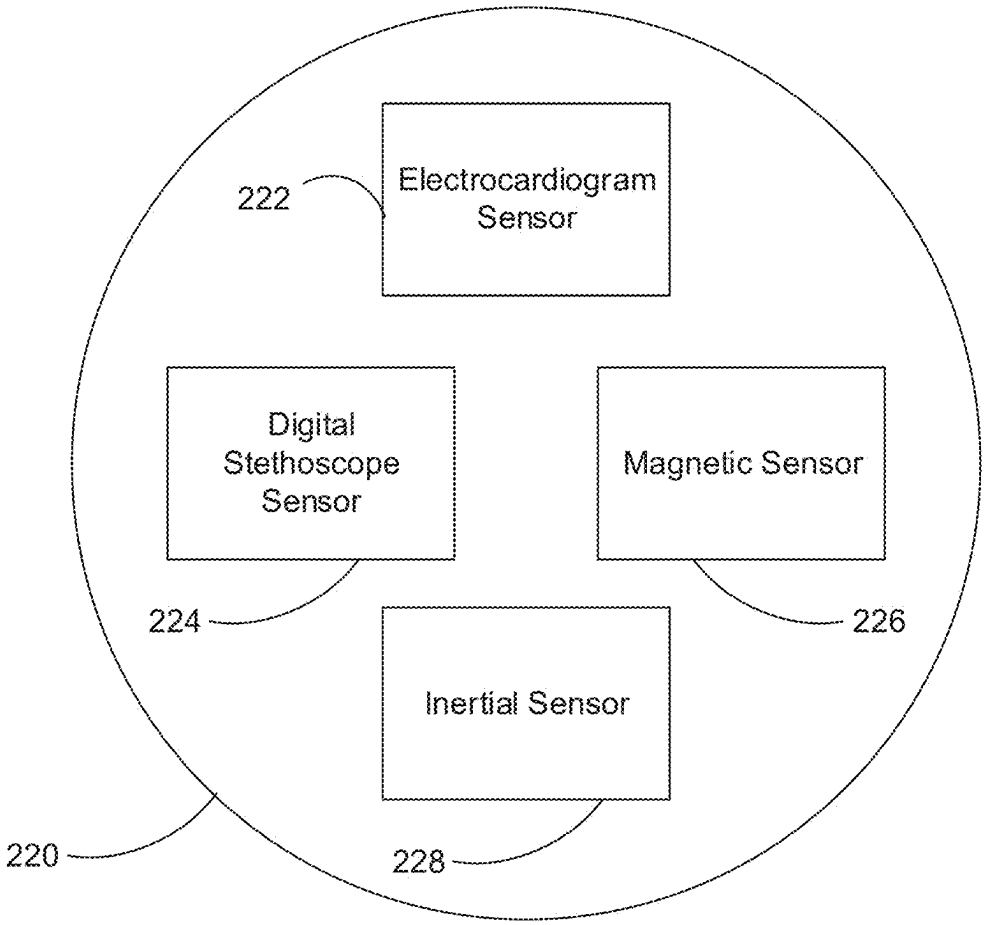
Electrocardiogram Sensor
222
Digital Stethoscope Sensor
Magnetic Sensor
224
226
Inertial Sensor
220
228

FIG. 3

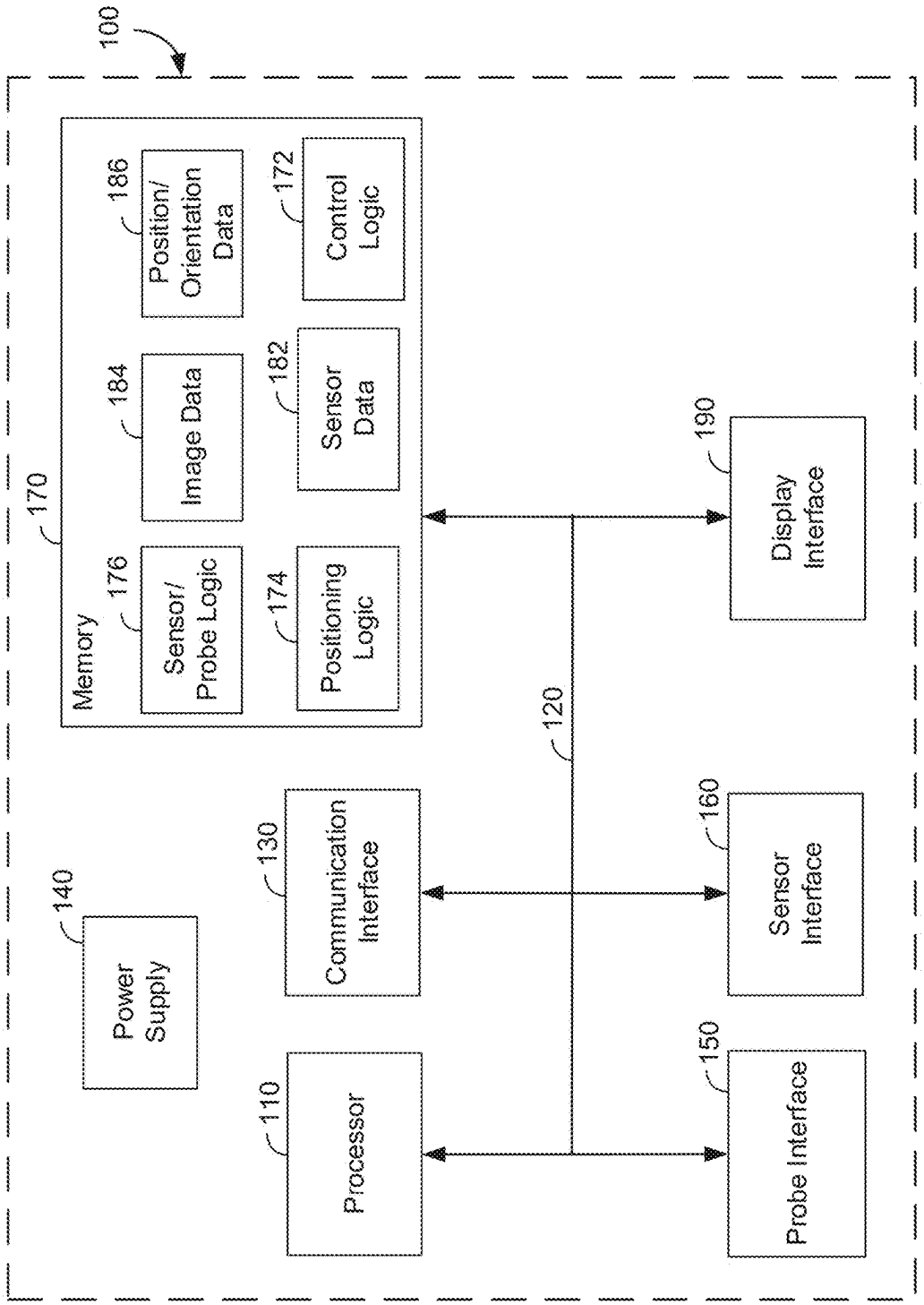
100
170
Memory
176
Sensor/
Probe Logic
174
Positioning
Logic
184
Image Data
182
Sensor
Data
186
Position/
Orientation
Data
172
Control
Logic
120
140
Power
Supply
130
Communication
Interface
160
Sensor
Interface
190
Display
Interface
110
Processor
150
Probe Interface

FIG. 4

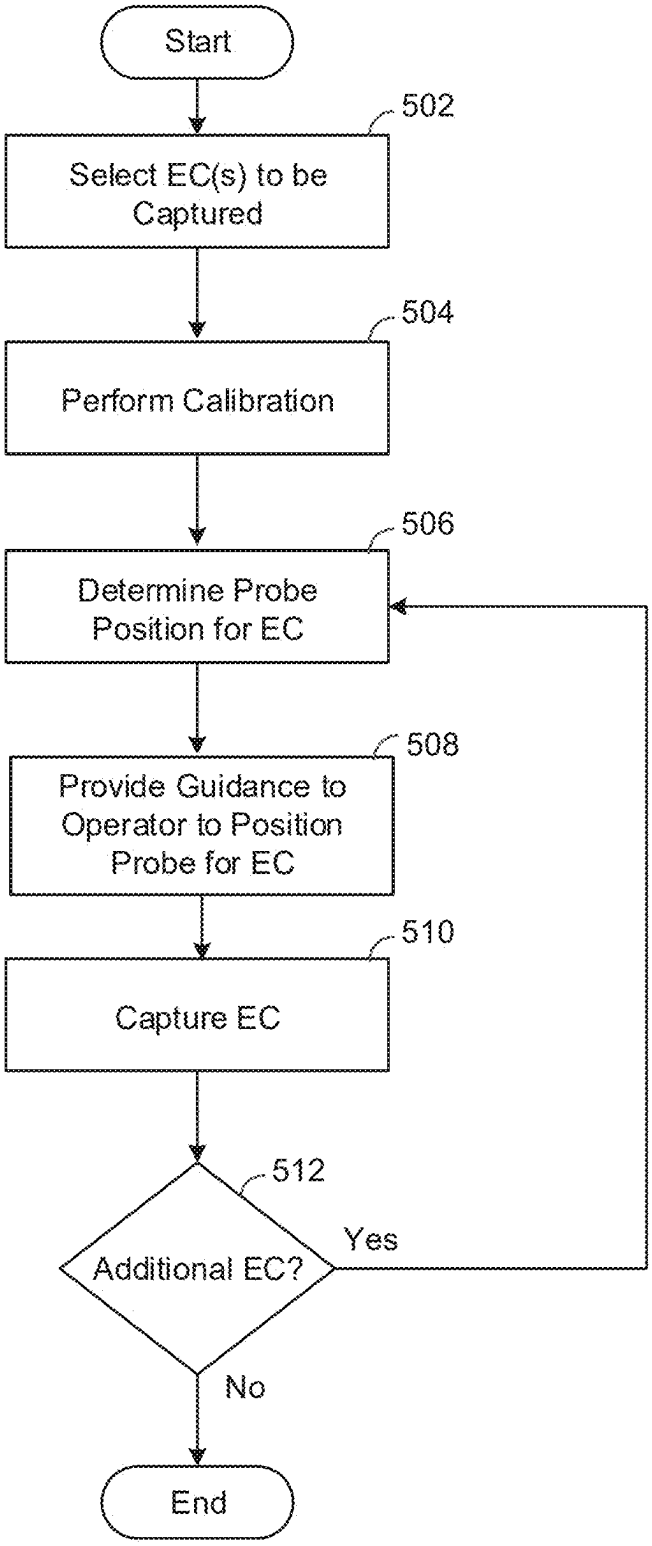
Start
502
Select EC(s) to be Captured
504
Perform Calibration
506
Determine Probe Position for EC
508
Provide Guidance to Operator to Position Probe for EC
510
Capture EC
512
Additional EC?
Yes
No
End

FIG. 5

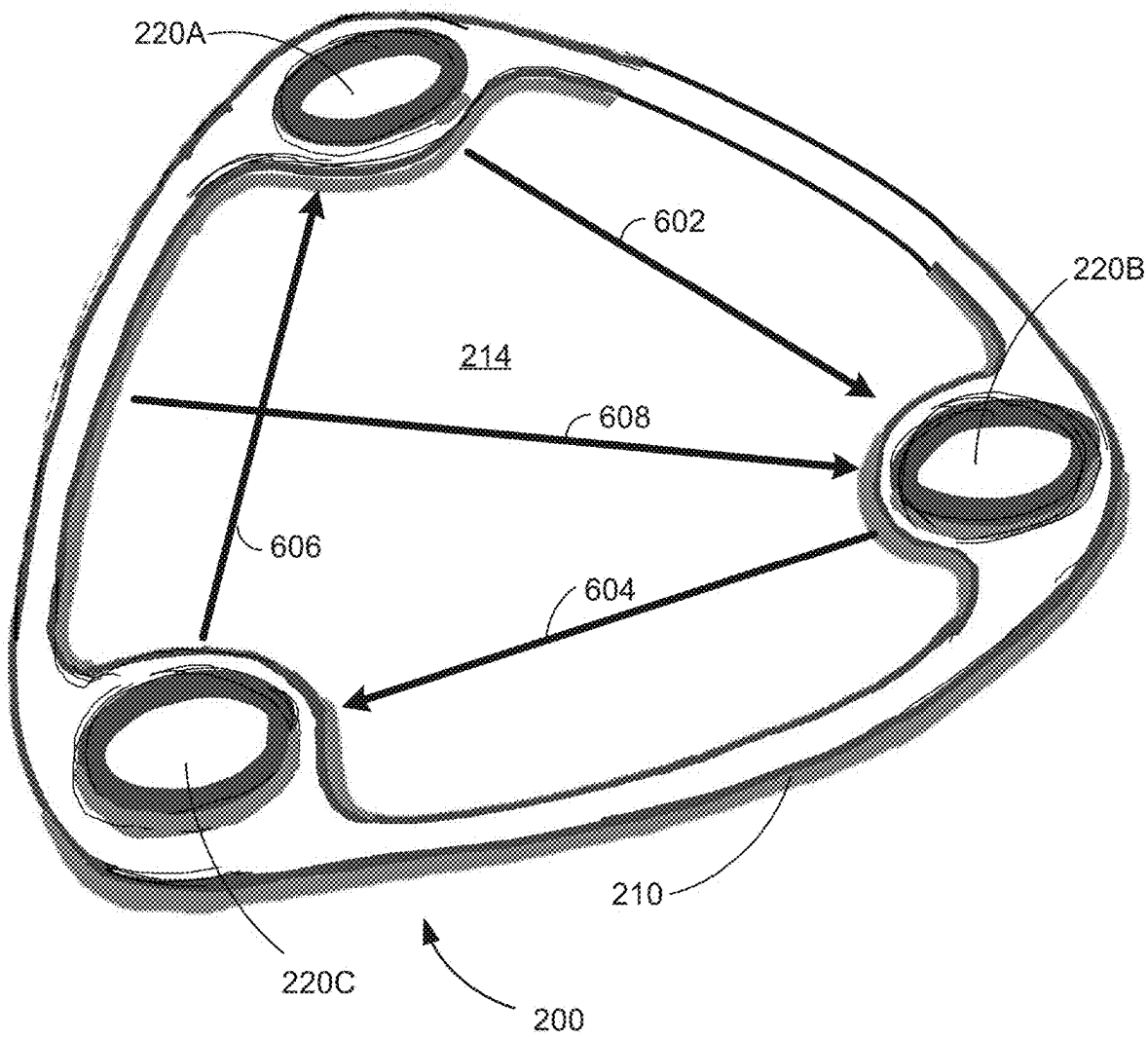

FIG. 6

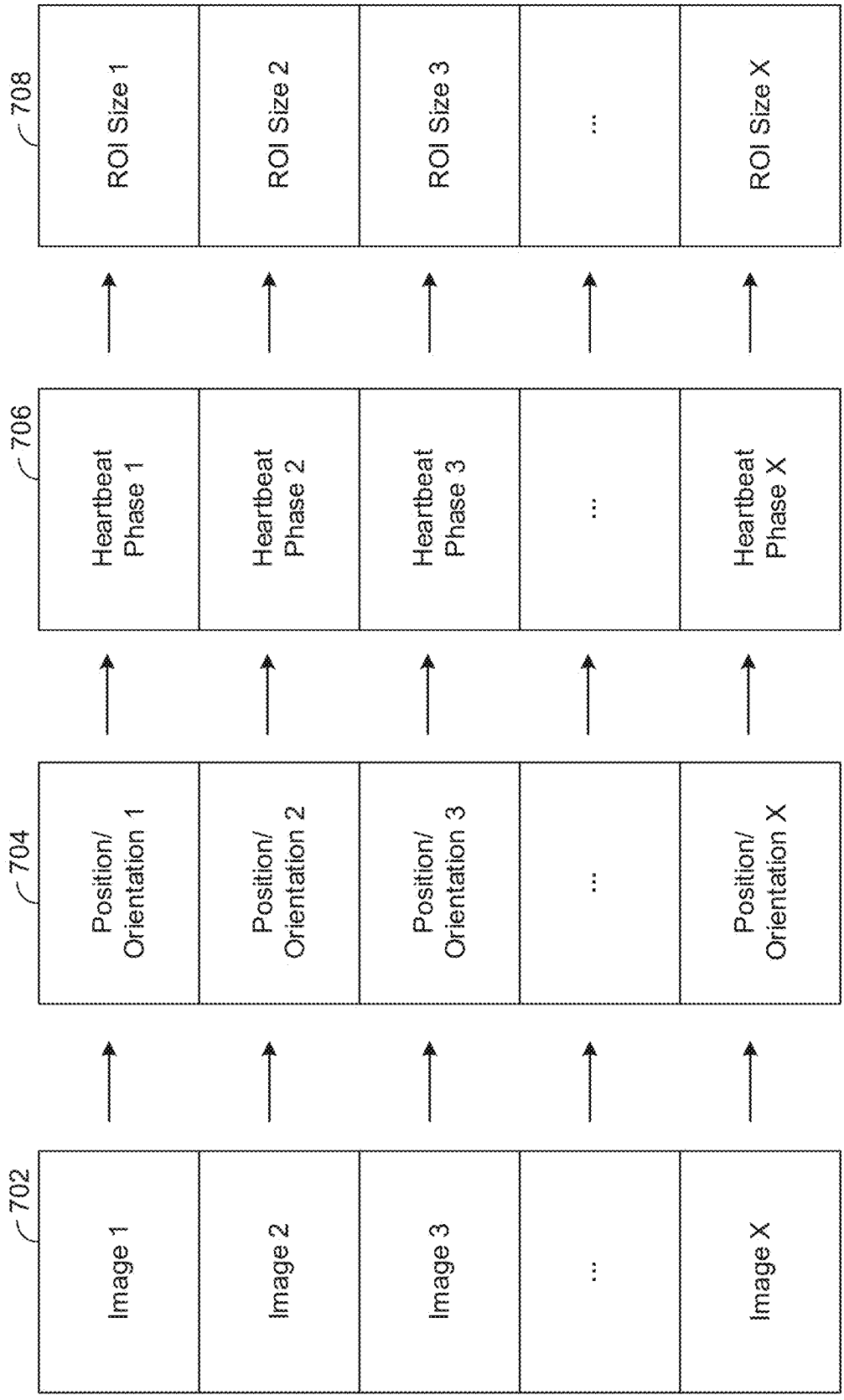
702
Image 1
Image 2
Image 3
...
Image X
704
Position/ Orientation 1
Position/ Orientation 2
Position/ Orientation 3
...
Position/ Orientation X
706
Heartbeat Phase 1
Heartbeat Phase 2
Heartbeat Phase 3
...
Heartbeat Phase X
708
ROI Size 1
ROI Size 2
ROI Size 3
...
ROI Size X

FIG. 7

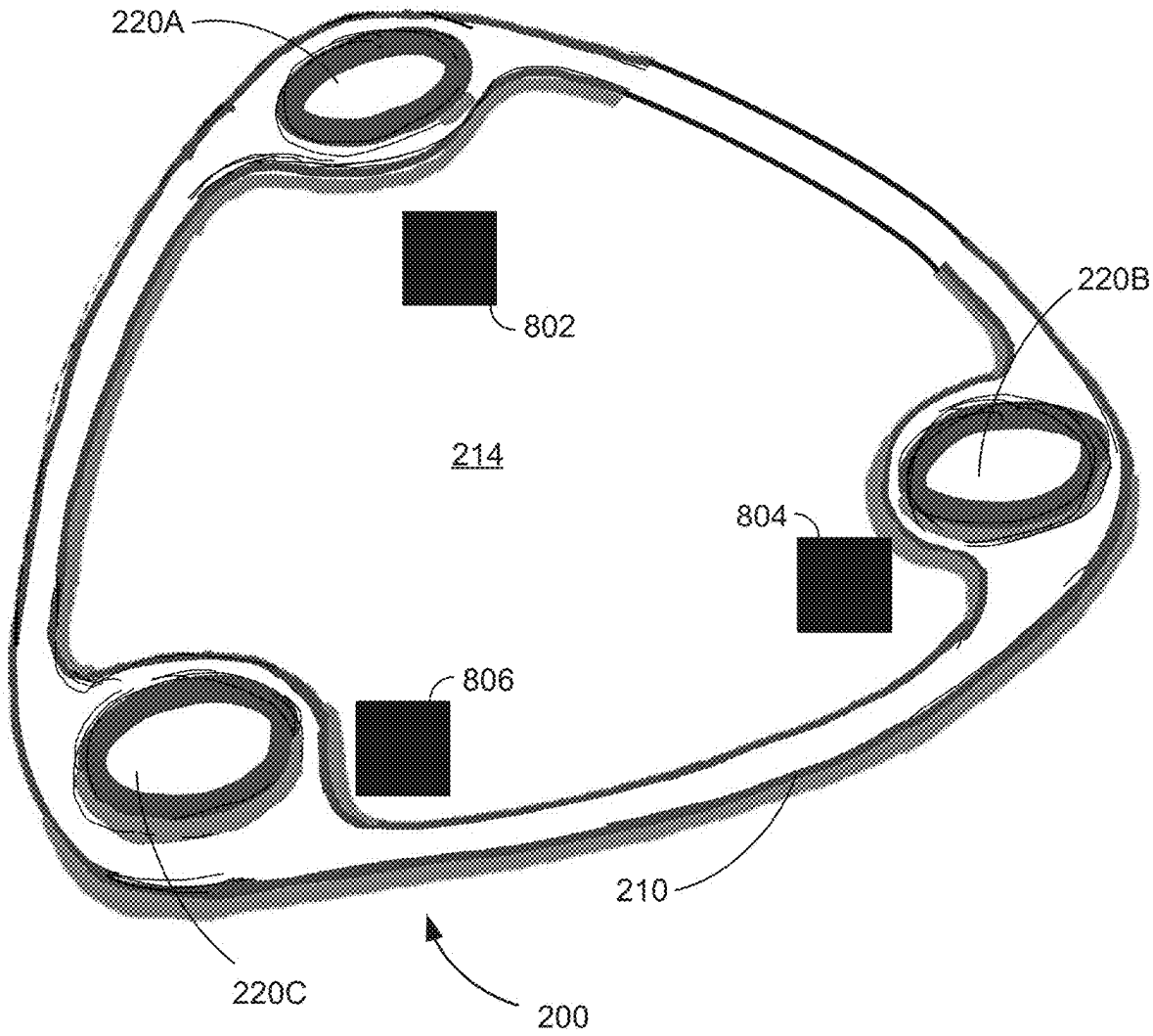

FIG. 8

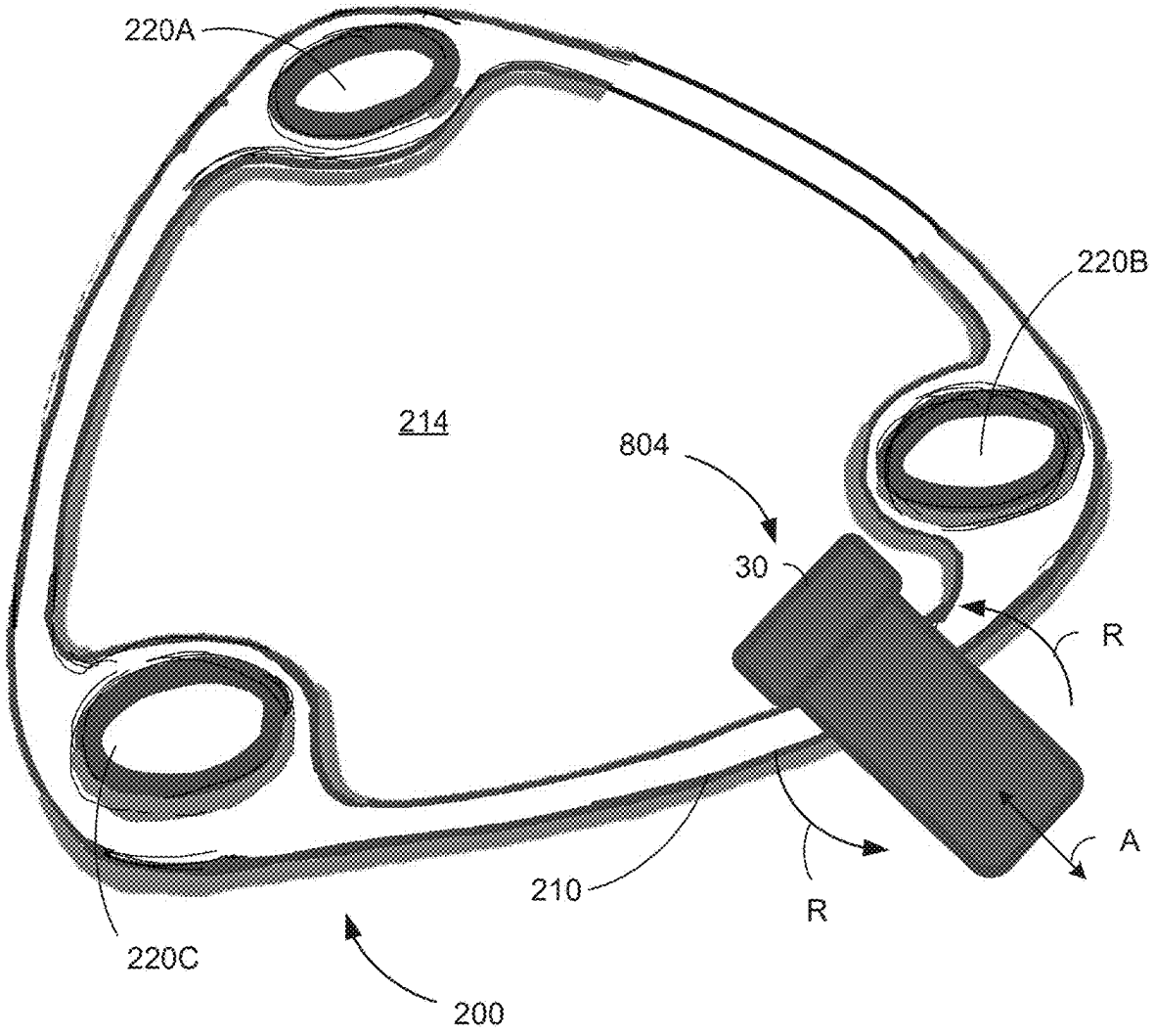

FIG. 9

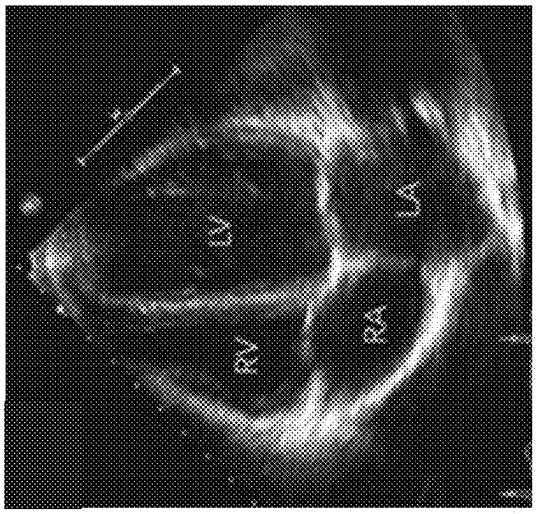

FIG. 10B

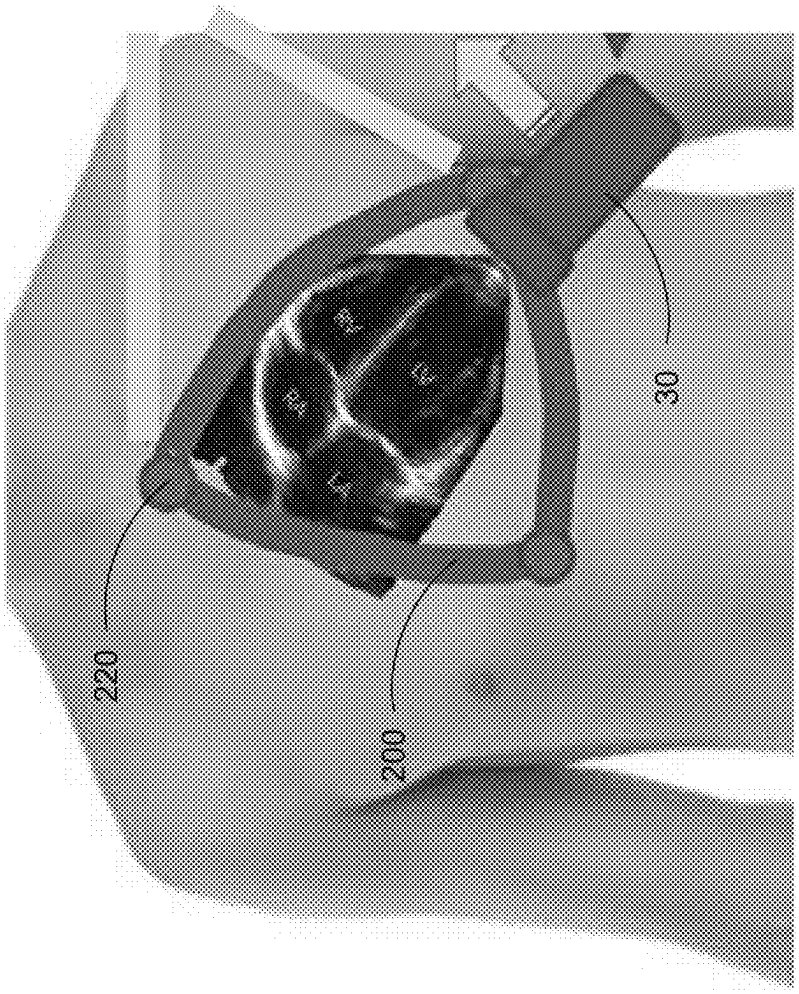

FIG. 10A

MULTI-MODAL HEART DIAGNOSTIC SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Pat. No. 11,872,080, entitled "Multi-Modal Heart Diagnostic System and Method" and filed on Feb. 26, 2021, which is incorporated herein by reference. U.S. Pat. No. 11,872,080 claims the benefit of U.S. Provisional Patent Application No. 62/981,893, entitled "Multi Modal Heart Activity Sensor," filed on Feb. 26, 2020, which incorporated herein by reference.

BACKGROUND

The present disclosure generally relates to a system and method that provides for monitoring of heart activity and assists a user in performing diagnostic procedures of the heart.

The heart function of a person can be assessed using multiple sensors (or modalities) and diagnostic procedures that are appropriate for evaluating different heart conditions. Some diagnostic procedures, which involve complex setups and are typically performed in medical facilities such as hospitals, can include magnetic resonance imaging (MRI) scans, positron emission tomography (PET) scans, computerized tomography (CT) or computerized axial tomography (CAT) scans, etc.

Other diagnostic procedures can include an electrocardiogram (ECG), auscultation and/or an echocardiogram (EC). ECGs can provide information about the heart's electrical activity. In addition to the monitoring of heart rhythms, ECGs can be used to diagnose myocardial ischemia and even localize part of the heart affected by the ischemic event. Auscultation, defined as listening to the heart sound, can be performed using acoustic sensors (e.g., a stethoscope) or electronically with a digital stethoscope (DS). Auscultation can be an important method for the early diagnosis of cardiac dysfunction. Traditional auscultation requires substantial clinical experience and good listening skills, while the DS has paved the way for a new field of computer-aided auscultation. An EC shows the shape and movement of heart valves, the size of heart chambers and their operation, and can be used to assess heart conditions, such as murmurs or damage to the heart due to prior heart attack or infection. During echocardiography, ultrasound (high-frequency sound waves) from a hand-held probe (also referred to as a wand or transducer) placed on a person's chest provides pictures of the heart's valves and chambers. While ECs can provide useful information for diagnosis, prognosis, and clinical and therapeutic management, the proper placement of the probe by the operator in order to obtain medically useful images can be time-consuming and uncomfortable to the person undergoing the procedure. In addition, traditional cardiac ultrasound (echocardiography) training requires a very long training period (e.g., 14 months of a full-time training program) to develop the necessary skills and experience to obtain medically useful images. Due to the long training period, the training of less experienced staff (e.g., nurses) to record diagnostic images typically does not occur. Therefore, a system to assist an operator (including less experienced operators) in the placement of the probe during an EC to acquire high quality diagnostic images would be beneficial.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure can be better understood with reference to the following drawings. The elements of the drawings are not necessarily to scale relative to each other, emphasis instead being placed upon clearly illustrating the principles of the disclosure. Furthermore, like reference numerals designate corresponding parts throughout the several views.

FIG. **1** is a diagram showing an embodiment of a multi-modal heart diagnostic system.

FIG. **2** is a diagram showing an embodiment of the positioning device and probe of FIG. **1**.

FIG. **3** is a block diagram showing an embodiment of the multi-modal sensor of FIG. **2**.

FIG. **4** is a block diagram showing an embodiment of a controller of FIG. **1**.

FIG. **5** is a flow diagram of an embodiment of a process for capturing an echocardiogram with the probe.

FIG. **6** is a diagram showing an embodiment of probe sweeps within the positioning device to calibrate the diagnostic system.

FIG. **7** is a diagram showing the relationship between images and

position/orientation information obtained during a probe sweep.

FIG. **8** is a diagram showing an embodiment of appropriate positions for the probe for capturing different echocardiograms.

FIG. **9** is a diagram showing an embodiment of the positioning of the probe for capturing an echocardiogram.

FIG. **10**A is a diagram showing an embodiment of an orientation of an echocardiogram image that may be presented to an operator.

FIG. **10**B is a diagram showing a traditional orientation of an echocardiogram image that may be presented to an operator.

DETAILED DESCRIPTION

The present disclosure generally pertains to a system that provides for monitoring of heart activity and assists a user in performing diagnostic procedures of the heart. The system can include a positioning device that is placed on a person's (or patient's) chest. The positioning device can incorporate several multi-modal sensors and be used to assist an operator in positioning the probe for an echocardiogram (EC). The multi-modal sensors can measure different parameters associated with an assessment of heart activity. The multi-modal sensors can also be used to provide information that can assist an operator (including a non-expert operator) in positioning the probe for an EC. The use of the multi-modal sensors and the probe during a calibration procedure provides image information, position data, orientation data and other information that permits the system to determine an appropriate position for the probe for an EC and to provide subsequent guidance information to the operator of the system to enable the operator to position the probe in the appropriate position for the optimal EC diagnostic images. By having several multi-modal sensors and multiple sensing modalities, the system can provide improved signal quality and robustness of the monitoring of heart activity, as well as unique information obtained from the synergy of information from multiple sensing modalities. In addition, the system can implement real-time processing of information and artificial intelligence methods to provide further information and guidance to the operator to facilitate better diagnostic procedures and analysis.

In an embodiment, the system can include an integrated multi-node, multi-modal sensor setup that can be used to collect multiple sensory signals and the relative position of sensors in relation to organs and anatomical structures of the

person. The system also has a method of presentation/rendering of EC images from the probe that are placed on a physically accurate location on the body relative to the probe and the multi-modal sensor nodes. The system can represent an anatomically accurate physical location and view of underlying organs of the person in real time, as the position and orientation of the probe changes in time. The system also provides an integrated system that processes multi-modal signals and EC images to guide operators (or users) toward an optimal position and orientation of the probe that can produce quality diagnostic images and videos.

The system of the present disclosure can provide better and faster training of operators in obtaining diagnostic EC images and videos. The system also allows non-experts to take expert quality diagnostic images and videos. In addition, the system can provide automatic guidance to operators in order to optimize data collection using real-time processing of changes that may not be visible to the operator. A significant reduction of test duration can be provided by the system because of the faster sensor setup of already integrated multi-modal sensors and faster image/data acquisition using an automated expert system that provides guidance to the operator. The system can provide simultaneous acquisition and processing of multiple sensor modalities (e.g., electrical, sound, mechanical motion and ultrasound images) and can provide automatic calibration and adjustment according to the anatomy of individual patients.

FIG. **1** shows an embodiment of a system to monitor heart activity and assist medical personnel in performing diagnostic procedures of the heart. The system **10** includes a positioning/reference device **200** with several multi-modal sensors (also referred to as sensor units) **220**. The positioning device **200** of FIG. **1** shows three multi-modal sensors **220**, but fewer multi-modal sensors **220** or additional multi-modal sensors can be used in other embodiments. The positioning device **200** can be in communication with (either by a wired or wireless connection) a controller **100** to permit the controller **100** to receive signals and/or data from the multi-modal sensors **220** of the positioning device **200** and to synchronize the data from the multi-modal sensors **220** as needed. In another embodiment, the individual multi-modal sensors **220** may be individually in communication with the controller **100**. The system **10** includes a hand-held probe **30** for performing echocardiography. The probe **30** can be in communication with (either by a wired or wireless connection) the controller **100** to permit the controller **100** to receive signals and/or data from the probe **30**. The controller **100** can be in communication with (either by a wired or wireless connection) a display **70** in order for the controller **100** to provide the information obtained from the probe **30** and the multi-modal sensors **220** to the user of the system **100**. In addition, the display **70** may include a user interface (e.g., a touch panel) to permit the operator to input information and/or instructions to the controller **100**. In an embodiment, the display **70** may be a liquid crystal display (LCD) but may be a desktop, laptop or tablet computer or a hand-held device, such as a cellular telephone (e.g., smartphone), in other embodiments. In another embodiment, the display **70** can be a thin flexible display that can be placed directly on the chest of the person (or patient) to represent anatomical structures of the person located beneath the flexible display.

FIG. **2** shows an embodiment of the positioning system **200** and probe **30**. The positioning system **200** can include a support structure **210** having a generally curvilinear triangle (or a Reuleaux triangle) shape. While a curvilinear triangle shape for the support structure **210** is shown in FIG. **2**, the support structure **210** can have other geometric shapes (e.g., circular) and non-geometric shapes in other embodiments. In one embodiment, the support structure **210** can be a soft, flexible material, but may be a rigid or semi-rigid material in other embodiments. The support structure **210** can have a hollow or open interior portion **214** (i.e., an open space or cavity) that permits the probe **30** to move within the support structure **210** and along a person's body when the support structure **210** is placed on the person. However, in other embodiments, the interior portion **214** may be formed from the same material as the other portions of the support structure **210** (i.e., the support structure **210** is a solid piece without an open space) or may incorporate a different material (e.g., a film-like material) different from the other portions of the support structure **210** that may facilitate movement of the probe **30** within the support structure **210** and along the person. In addition, the support structure **210** can incorporate expanded portions **212** at each of the "corners" of the curvilinear triangle shape to hold a multi-modal sensor **220**. The expanded portions **212** can be located in the support structure **210** to provide a fixed distance between the multi-modal sensors **220** and to maintain the relative position of the multi-modal sensors **220** in the support structure **210**.

In an embodiment, the support structure **210** may provide either printed signs or other indicia that can assist the operator in positioning the support structure **210** on the person undergoing the procedure or in positioning the probe **30** relative to the multi-modal sensors **220** on the body of the person. In another embodiment, display **70** or LED indicators on the support structure **210** can be used to guide the operator during positioning of the support structure **210** to obtain optimal performance of the multi-modal sensors **220**. In still another embodiment, artificial intelligence or machine learning algorithms can be used to automatically determine optimal positioning of the support structure **210** and multi-modal sensors **220**. The display **70** or LED indicators on the support structure **210** can be used to guide the operator during positioning of the support structure **210** as determined by the artificial intelligence or machine learning algorithm. In an embodiment, after being positioned on the person's body, the support structure **210** may be fastened to the person's body using chemical (e.g., a disposable adhesive similar to that used with standard ECG electrodes) or mechanical (e.g., suction cup) techniques to maintain the position of the support structure **210** on the person's body.

FIG. **3** shows an embodiment of the multi-modal sensor **220**. As shown in FIG. **3**, the multi-modal sensor **220** can include an electrocardiogram sensor (or electrode) **222** that can be used for capturing an electrocardiogram, a digital stethoscope (DS) sensor **224** that can be used for performing electronic auscultation, a magnetic sensor **226** (e.g., a magnetometer) and an inertial sensor **228** (e.g., an accelerometer). In one embodiment, the inertial sensor **228** can provide dynamic information about the motion and orientation of an object and can be used to measure heart induced motion using ballistocardiography (BCG). While the multi-modal sensor **220** of FIG. **3** is shown with 4 sensors, the multi-modal sensor **220** could include additional sensors, fewer sensors or different sensors in other embodiments. For example, the multi-modal sensor **220** may utilize other motion sensors, such as gyroscopes or proximity sensors, or any other suitable sensor for determining position or orientation either in place of or in addition to inertial sensors **228** and magnetic sensors **226**. In other embodiments, other

suitable techniques and devices (e.g., RF and/or NFC positioning techniques and devices) for determining position and orientation may be used.

The three multi-modal sensors **220** of the support structure **210** can provide the controller **100** with three (3) channels of ECG readings (e.g., between the ECG electrodes **222** of the first and second multi-modal sensors, between the ECG electrodes **222** of the second and third multi-modal sensors and between the ECG electrodes **222** of the third and first multi-modal sensors). Each ECG electrode **222** provides a contact for the differential bioamplifier used in generating the ECG. In another embodiment using a solid support structure **210**, a reference electrode for the ECG can be placed in the center of the support structure **210** that can create 3 additional ECG channels between the reference electrode and the ECG electrodes **222** of the multi-modal sensors **220**. The multi-modal sensors **220** can also provide the controller **100** with 3 audio signals (1 from each DS sensor **224**), 3 BCG signals (1 from each inertial (or BCG) sensor **228**) and 3 3D orientation signals (1 from each magnetic sensor **226**). In addition, the controller **100** can receive ultrasound images from the probe **30** and a position and/or orientation of the probe **30** from a sensor unit **32** (see FIG. **2**) located in or on the probe **30**. The probe **30** can either incorporate the sensor unit **32** within the body of the probe **30** or the sensor unit **32** can be attached to the exterior of a conventional probe. In an embodiment, the sensor unit **32** can include one or more motion sensors such as inertial sensors (e.g., accelerometers), gyroscopes, magnetic sensors (e.g., magnetometers), proximity sensors, any other suitable sensor for determining position or orientation, or any combination thereof. In other embodiments, other suitable techniques and devices (e.g., RF and/or NFC positioning techniques and devices) for determining the position and orientation of the probe **30** may be used.

FIG. **4** shows an embodiment of the controller **100**. The controller **100** shown by FIG. **4** can include logic **172**, referred to herein as "control logic," for generally controlling the operation of the controller **100**. The controller **100** also includes logic **174**, referred to herein as "positioning logic," and logic **176**, referred to herein as "sensor/probe logic." The positioning logic **174** can be used for calibrating operation of the probe **30** in the positioning system **200** and for providing guidance or feedback to the operator of the probe in order to permit the operator to position the probe **30** within the positioning system **200** for an EC. The sensor/probe logic **176** can be used to process signals, images, data, etc. received from the probe **30** and the multi-modal sensors **220**. In other embodiments, the positioning logic **174** and/or the sensor/probe logic **176** can be combined with the control logic **172** or with one another. The control logic **172**, the positioning logic **174** and the sensor/probe logic **176** may be implemented in software, firmware, hardware, or any combination thereof. In FIG. **4**, control logic **172**, the positioning logic **174** and the sensor/probe logic **176** are implemented in software and stored in memory **170**. However, other configurations of the control logic **172**, the positioning logic **174** and the sensor/probe logic **176** are possible in other embodiments.

Note that the control logic **172**, the positioning logic **174** and the sensor/probe logic **176**, when implemented in software, can be stored and transported on any computer-readable medium for use by or in connection with an instruction execution apparatus that can fetch and execute instructions. In the context of this document, a "computer-readable medium" can be any non-transitory means that can contain or store code for use by or in connection with the instruction execution apparatus.

The controller **100** may include at least one conventional processor **110**, which includes processing hardware for executing instructions stored in the memory **170**. As an example, the processor **110** may include a central processing unit (CPU) or a digital signal processor (DSP). The processor **110** communicates to and drives the other elements within the controller **100** via a local interface **120**, which can include at least one bus. When the control logic **172**, the positioning logic **174** and the sensor/probe logic **176** and are implemented in software, the processor **110** may execute instructions of the control logic **172**, the positioning logic **174** and the sensor/probe logic **176** to perform the functions ascribed herein to the control logic **172**, the positioning logic **174** and the sensor/probe logic **176**.

The controller **100** also has a communication interface **130**. The communication interface **130** includes a radio frequency (RF) radio or other device for communicating wirelessly and corresponding connection ports for wired communications (e.g., Ethernet). Using the communication interface **130**, the controller **100** may communicate with other devices, systems (e.g., the electronic medical record (EMR) software of a medical facility) and/or networks (e.g., the Internet).

The controller **100** can have a power supply **140**, which provides electrical power to the components of the controller **100** and possibly to the probe **30** and/or the multi-modal sensors **220** of the positioning system **200** in an embodiment. In one embodiment, the power supply **140** has an interface that allows it to plug into or otherwise interface with an external component, such as a wall outlet or battery, and receive electrical power from such external component. If desired, the power supply **140** may incorporate one or more batteries to permit the controller **100** to be independent of the external power component.

The controller **100** can include a probe interface **150**, a sensor interface **160** and a display interface **190**. In one embodiment, the probe interface **150** and the sensor interface **160** may be combined into a single interface. The probe interface **150** enables the controller **100** to exchange (e.g., send and receive) signals and data with the probe **30**. For example, the probe **30** can provide image data to the controller **100** during a procedure that is then stored in image data **184**. In addition, the inertial sensor and the magnetic sensor of the probe **30** can provide position and orientation information that is stored in position/orientation data **186**. The sensor interface **160** enables the controller **100** to exchange (e.g., send and receive) signals and data with the multi-modal sensors **220** of the positioning device **200**. For example, the multi-modal sensors **220** can provide data from individual sensors to the controller **100** that is then stored in sensor data **182**. The display interface **190** enables the controller **100** to exchange (e.g., send and receive) data and information with the display **70**. For example, the controller **100** may provide image data **184** from the probe **30** to the display **70** via the display interface **190** for viewing by the operator. Each of the probe interface **150**, sensor interface **160** and the display interface **190** may include any suitable interfaces for providing signals and data between processor **110** and the corresponding component connected to the interface. The interfaces may include communication busses such as I2C, SPI, USB, UART, and GPIO. In some embodiments, the sensor interface **160** may also include connections such that signals from the multi-modal sensors **220** (e.g., measured analog signals) may be provided to processor **110**.

The sensor/probe logic **176** of the controller **100** can extract different types of information from the set of signals and/or data received from the multi-modal sensors **220** and stored as sensor data **182**. The sensor/probe logic **176** can determine a common component of all sensors of the same type (e.g., ECG sensors **222**, DS sensors **224**, or inertial (or BCG) sensors **228**). The sensor/probe logic **176** can also determine the latency of individual signals of the same kind (e.g., between different ECG sensors **222**) or between different signals of the same multi-modal sensor **220** (e.g., between an ECG sensor **222** and an inertial (or BCG) sensor **228**) or, more specifically, as a time delay between different signals of different multi-modal sensors **220** (e.g., between a first ECG sensor **222** and a second inertial (or BCG) sensor **228**).

Further, the sensor/probe logic **176** can determine the total power of individual signals or event related energy of the signals. For the DS sensors **224**, the sensor/probe logic **176** can determine the PDSx—the power of an individual DS sensor **224**, or the power during the heart beat events, for example, sounds S1 (PDS1 for a first DS sensor **224**) and S2 (PDS2 for a second DS sensor **224**). For the ECG sensors **222**, the sensor/probe logic **176** can determine the total power or event related power (e.g., ECGP—the power of the P-wave, or other events of interest, such as Q, R, S and T waves). In addition, the sensor/probe logic **176** can calculate a related power estimate for each event as the maximum amplitude during the event, or as an average value during the event (e.g., an RMS value of the signal). In an embodiment, each event related energy can be calculated as integral of the signal (or signal squared) over event time. The sensor/probe logic **176** can also be used to detect turbulent flow (i.e., recirculation of fluids) in the heart that may be a result of stenosis (and possibly determine a location of the stenosis) using the signals from the DS sensors **224** and the ECG sensors **222**. In an embodiment, the sensor/probe logic **176** can perform a pre-ejection analysis (e.g., ECG to BCG/accelerometer→electrical signal to mechanical motion latency) having a better signal to noise ratio (common component ICA of signals of the same type from different sensors)).

The use of the positioning device **200** for different diagnostic conditions may result in the positioning device **200** having different optimal positions. In one embodiment, the optimal position for the positioning device **200** can be determined by the sensor/probe logic **176** using the relative weights of individual signals for the multi-modal sensors **220**. For example, some condition may require positioning of the positioning device **200** that results in the signal with 60% contribution from the first ECG sensor **222**, 25% contribution from the second ECG sensor **222**, and 15% contribution from the third ECG sensor **222**. The controller **100** may guide the operator to move the positioning device **200** until the maximum value of the desired composite signals is achieved. Guidance of the operator can be performed through the display **70** or indicators on the positioning device **200** itself indicating the desired direction of the motion and the desired rotational position for the positioning device **200** needed to place the positioning device **200** in the optimum position.

The positioning logic **174** can be used to provide guidance to an operator of the system **10** in placing the probe **30** on the person's body in an appropriate (or optimal) position to capture a desired EC once the positioning device **200** is in the desired position. FIG. **5** shows an embodiment of a process executed by the positioning logic **174** to determine an appropriate position for the probe **30** in the positioning device **200** to capture a desired EC. The process begins by the operator of the system **10** selecting one or more ECs to capture (step **502**). In one embodiment, the ECs that may be captured can include a parasternal view (long axis and/or short axis), a subxiphoid view and/or an apical view.

Once the operator has selected the ECs to be captured, the operator has to calibrate the system **10** (step **504**). The calibration of the system **10** involves the movement of the probe **30** within the positioning device **200** to obtain information for the positioning logic **174** to determine the appropriate position for the probe **30** in the positioning device **200** for the selected ECs to be captured. The operator can perform several sweeps of the probe **30** within the positioning device **200** during calibration. FIG. **6** shows a first path **602** for the sweep of the probe **30** within the positioning device **200** that extends between multi-modal sensor **220**A and multi-modal sensor **220**B, a second path **604** for the sweep of the probe **30** within the positioning device **200** that extends between multi-modal sensor **220**B and multi-modal sensor **220**C, a third path **606** for the sweep of the probe **30** within the positioning device **200** that extends between multi-modal sensor **220**C and multi-modal sensor **220**A, and a fourth path **608** for the sweep of the probe **30** within the positioning device **200** that extends from a point midway between multi-modal sensor **220**A and multi-modal sensor **220**C to multi-modal sensor **220**B and typically corresponds to the preliminary movement of the probe **30** by an expert in a typical EC procedure.

During each sweep of the probe **30** in the positioning device **200**, a series of images can be captured from the probe **30** along with corresponding location information regarding the probe **30**, and a relative phase of the heartbeat as determined using ECG, BCG and sound information captured by multi-modal sensors **220**. The sweep of the probe **30** can capture several heartbeats in order to determine when the ventricles are open (as opposed to contracted), which facilitates a better view of the ventricles. The same method can be applied for the atrium, which corresponds to the different phase of the heartbeat. As shown in FIG. **7**, each captured image from the sweep of the probe can be stored in an image set **702** and corresponding location information of the probe for each captured image can be stored in a position/orientation data set **704**, and the relative phase of the heartbeat, which is generated from the sensor data **182**, can be stored in heartbeat phase data set **706**. The image set **702** from each sweep of the probe **30** can be stored in image data **184** and the position/orientation data set **704** from each sweep of the probe **30** can be stored in position/orientation data **186**. The position/orientation data set **704** can include, for each captured image in image set **702**, an x-y position of the center of the probe **30** relative to the positioning device **200** (e.g., as determined by triangulation using 3D orientation signals in one embodiment), a rotational orientation of the probe **30** about the center and an angular orientation of the probe **30** relative to the plane of the positioning device **200**. A size of the region of interest (e.g., an area of cross section of the heart) can be calculated and stored in the region of interest (ROI) size data set **708**. In an embodiment, the relative angle of the probe **30** can be determined from the absolute 3D angle of the probe **30** (as determined by a 3D orientation signal from the magnetic sensor in the probe **30**) and from 3D orientation signals from the individual sensors (e.g., magnetic sensors **226**) in the multi-modal sensors **220**. The position/orientation data associated with each captured image can be obtained from the inertial sensor and magnetic sensor of the probe **30** and/or the multi-modal sensors **220** (including inertial sensors **228** and magnetic sensors **226**).

However, in another embodiment, the position/orientation data associated with each captured image can be obtained only from the inertial sensor and the magnetic sensor of the probe **30**. The position/orientation data can be defined relative to reference points of the support structure **210** corresponding, in one embodiment, to the location of the multi-modal sensors **220**.

After the image set **702**, the position/orientation data set **704**, the heartbeat phase data set **706**, and the ROI size data set **708** is captured for each sweep of the probe **30** during calibration, the positioning logic **174** can determine an appropriate location for the probe **30** within the positioning device **200** and relative to the multi-modal sensors **220** (or reference points) for a selected EC to be captured (step **506**). The positioning logic **174** can then use the image sets **702**, the position/orientation data sets **704**, heartbeat phase data set **706**, and the ROI size data set **708** from each of the sweeps of the calibration process to determine an optimal position and orientation of the probe **30** for capturing the desired view of the EC (e.g., the cross section of the ventricles). The positioning logic **174** can use information from the image sets **702** and the relative phase of the heartbeat from heartbeat phase data set **706** to determine the location of the heart in the person's chest and then use the approximate location of the heart to determine the position of the probe **30** relative to the location of the heart needed to capture the desired view of the echocardiogram. In an embodiment, the positioning logic **174** can use the image sets **702**, the relative phase of the heartbeat from heartbeat phase data set **706** and the ROI size data set **708** to create a three-dimensional (3D) model of the heart in the person's chest with respect to the reference points of the positioning device **200**. The positioning logic **174** can then use the 3D model of the heart in determining where to locate the probe **30** for the desired EC. In one embodiment, the positioning logic **174** can use a machine learning or artificial intelligence algorithm with the image sets **702** and the position/orientation data sets **704** from the calibration process to determine the appropriate position. The positioning logic **174** can include a training set that includes prior image sets **702** and position/orientation data sets **704** along with the position chosen for the desired EC to train the machine learning or artificial intelligence algorithm.

As known in the art, "machine learning" generally refers to neural computing techniques or artificial intelligence whereby a computer effectively "learns" relationships between inputs and outputs. In one embodiment, the positioning logic **174** employs an appropriate algorithm (e.g., random forest, support vector machines, Bayes, logistic regression, etc.) in order to determine an optimal position and orientation for the probe **30** that results in an optimal EC. In learning the optimal position and orientation of the probe **30**, the positioning logic **174** performs an analysis on the image data **184**, the position/orientation data **186**, and the relative phase of the heartbeat generated from sensor data **182** in order to define relationships between the position and orientation of the probe **30** as indicated by the position/orientation data **186** and the desired output (e.g., a captured EC) as indicated by the image data **184**. Then, as the image sets **702**, the position/orientation data sets **704** and the heartbeat phase data sets **706** are received during the calibration process, the positioning logic **174** can use the defined relationships to determine the optimal position and orientation of the probe **30** to obtain the desired EC.

In another embodiment, the positioning logic **174** can use information from the multi-modal sensors **220** (e.g., information from the electrocardiogram sensors **222**, the digital stethoscope sensors **224** and the inertial sensors **228**) to determine an approximate location of the person's heart in the person's chest. The positioning logic **174** can then use the information regarding the approximate location of the heart from the multi-modal sensors **220** along with the image sets **702**, the position/orientation data sets **704**, heartbeat phase data set **706**, and ROI size data set **708** to determine a location for the probe **30** that coincides with the expected location of the features of the heart that are of interest to the operator.

Once the appropriate position for the probe has been determined, the system **10** can provide guidance to the operator in locating the probe **30** in the positioning device **200** for the desired EC (step **508**) using the multi-modal sensors **220** (and their corresponding signals) to provide points of reference. FIG. **8** shows the appropriate positions for the probe **30** in the positioning device **200** for several different ECs. The probe **30** can be positioned at location **802** for a parasternal view, at position **806** for a subxiphoid view, and at position **804** for an apical view. In one embodiment, the positioning logic **174** can provide information to the display **70** (e.g., a computer generated representation of the probe **30** relative to the positioning device **200**) to assist the operator in moving the probe **30** into the appropriate position for the desired EC. In another embodiment, LED indicators on the support structure **210** can be used to guide the operator during positioning of the probe **30**.

After the probe **30** is in the appropriate position, the positioning logic **174** can provide further information to the display **70** (or on the support structure **210**) to assist the operator in obtaining the appropriate rotational and angular orientation of the probe **30**. For example, as shown in FIG. **9**, once the probe **30** is positioned in position **804**, the positioning logic **174** can provide additional guidance to the operator on the display **70** to appropriately orient the probe **30** to obtain the desired EC. The positioning logic **174** may have the operator adjust the rotational position of the probe **30** as shown by arrows R (i.e., turn the probe **30** either clockwise or counterclockwise about the center of the probe **30**) and/or adjust the angular position of the probe **30** as shown by arrow A (i.e., tilt the probe **30** either toward the operator or away from the operator). In another embodiment, once the probe **30** is at the position and orientation determined by the positioning logic **174**, the positioning logic **174** can perform an image analysis of an image captured by the probe **30** at that position and then provide the operator with instructions to make incremental position and/or orientation changes to the probe **30** to improve the quality of the captured image from the probe **30**. The incremental changes to the position and/or orientation of the probe **30** can be repeated until an optimal image is obtained from the probe **30**. Optimization might include processing of images to calculate the size of the region of interest for the given phase of the heartbeat. Automatic image processing can generate better accuracy in calculating features of interest than the user would be able to perceive.

After the probe **30** is at the proper position and orientation in the positioning device **200**, the operator can capture the desired EC (step **510**). Next, a determination is made if additional ECs need to be captured (step **512**). If no additional ECs are needed, the process ends. However, if additional ECs are required, the process returns to step **506** to determine the probe position for the next EC and the process continues as discussed above until all of the desired ECs have been captured.

The controller can present the captured EC image from the probe **30** to the operator on the display **70**. The view of

the EC image can be presented relative to the probe **30** being located at the top of the image, as shown in FIG. **10**B. The operator then has to mentally rotate the EC image to place it on the physical body of the patient and modify position of the probe **30** in order to achieve the best diagnostic quality of the EC image. In an embodiment, the controller **100** can update the 3D orientation of each multi-modal sensor **220** and relative orientation of the probe **30** such that the EC image from the probe **30** is rendered relative to the probe **30** and multi-modal sensors **220** as shown in FIG. **10**A. The controller **100** can provide the operator with the option to select (and switch) between the traditional view of the EC image (as shown in FIG. **10**B), the alternate view of the EC image (as shown in FIG. **10**A), or both views for presentation on the display **70**.

In an embodiment, the selected EC image or view can be made static to permit rendering of the probe position only relative to the reference point and patient's body. In that mode, the controller **100** can simulate an "X-ray view" of organs beneath the current position of the probe **30** to permit the operator to more easily find anatomical structures of interest for specific diagnostic procedures. Moreover, the controller **100** can guide the operator to modify the position of the probe **30**, while providing the results of the processing and selection of diagnostically optimal images and videos. For example, small changes in the position of the probe **30** might provide better image of the ventricles and automatic calculation of the size of ventricles may provide guidance for the optimal position based on small changes of the area in the EC image that might not be observable by looking at the EC image. Suggested motion for the probe **30** can be visualized as shown in FIG. **10**A as an arrow in the direction of the suggested motion. The feedback provided by the controller can be particularly important for non-expert operators, and permit acquisition of expert quality EC images and videos from non-expert operators. The reference points (i.e., the multimodal sensors **220**) don't need extremely accurate positioning on the patient's body as the organs can be visualized relative to the reference points, and operator guidance is suggested in relation to the same reference points.

In an embodiment, the multi-modal sensors **220** have magnetic sensors **226** (e.g., a magnetometer) and inertial sensors **228** (e.g., an accelerometer) that permit the sensor/probe logic **176** to determine an absolute orientation of each multi-modal sensor **220**. Since, the probe **30** also has a magnetometer and accelerometer as described above, an absolute orientation of the probe **30**, as well as an orientation of the probe **30** relative to each multi-modal sensor can be determined by the positioning logic **174**. The multi-modal sensors **220** can be placed at defined physical locations on the body of the patient, as shown in FIG. **1**, thus the relative orientation of the probe **30** in relation to the physical location of multi-modal sensors **220** can be visualized and rendered for the operator on the display **70** to facilitate guidance of the probe **30** to the optimal recording position and orientation.

In another embodiment, the probe **30** can be equipped with a small magnet with strength significantly larger than Earth's magnetic field. In that case, the 3D vector of magnetic field of each multi-modal sensor **220** would point toward the magnet on the probe **30**. By using triangulation of vectors from at least three multi-modal sensors **220**, the absolute position of the probe **30** relative to the multi-modal sensors **220**, which are used as reference points, can be determined.

In a further embodiment, a reference magnet can be implemented as dynamic electromagnetic coil in the probe that can be turned on to produce an electro-magnetic field only when determining the relative position of the probe **30**. By using this approach, the controller **100** can have the individual multi-modal sensors **220** measure both a 3D vector of Earth's magnetic field (for accurate orientation of the sensors) and the 3D vector of the reference field on the probe **30** (for accurate positioning of the probe **30**), and provide the information to the controller **100** for subsequent use by the controller **100**.

Although the figures herein may show a specific order of method steps, the order of the steps may differ from what is depicted. Also, two or more steps may be performed concurrently or with partial concurrence. Variations in step performance can depend on the software and hardware systems chosen and on designer choice. All such variations are within the scope of the application. Software implementations could be accomplished with standard programming techniques, with rule-based logic and other logic to accomplish the various connection steps, processing steps, comparison steps and decision steps.

It should be understood that the identified embodiments are offered by way of example only. Other substitutions, modifications, changes and omissions may be made in the design, operating conditions and arrangement of the embodiments without departing from the scope of the present application. Accordingly, the present application is not limited to a particular embodiment, but extends to various modifications that nevertheless fall within the scope of the application. It should also be understood that the phraseology and terminology employed herein is for the purpose of description only and should not be regarded as limiting.

What is claimed is:

1. A system for positioning a probe to capture an echocardiogram of a patient, the system comprising:

a positioning device to be placed on a patient, the positioning device comprising a support structure defining an open interior space and a plurality of reference points around the open interior space, wherein the support structure comprises a plurality of sensor units, each sensor unit of the plurality of sensor units having at least one sensor for sensing heart activity of the patient and providing sensor data indicative of the heart activity;

a probe configured to capture a plurality of echocardiogram images while positioned within the open interior space of the support structure, the probe comprising at least one motion sensor; and

a controller configured to receive the sensor data from the plurality of sensor units and motion data from the motion sensor, the controller configured to determine, based on the heart activity indicated by the sensor data and at least one of the plurality of echocardiogram images, a desired position for the probe in the open interior space of the support structure with respect to the plurality of reference points and signals from the at least one motion sensor of the probe to capture an echocardiogram image, the controller further configured to provide guidance to an operator to move the probe to the desired position determined by the controller.

2. The system of claim **1**, wherein the support structure comprises a plurality of sensor units, each sensor unit of the plurality of sensor units being located at a corresponding reference point of the plurality of reference points, each

sensor unit of the plurality of sensor units comprises an inertial sensor and a magnetic sensor.

3. The system of claim **2**, wherein the controller is connected to the plurality of sensor units to receive signals from the inertial sensors and magnetic sensors of the plurality of sensor units and the controller is configured to determine a position for the probe in the open interior space of the support structure using the received signals from the inertial sensors and magnetic sensors of the plurality of sensor units.

4. The system of claim **1**, further comprising a display connected to the controller, wherein the controller is configured to provide guidance on the display to an operator to move the probe to the desired position determined by the controller.

5. The system of claim **1**, wherein the controller is further configured to present the echocardiogram image on the display relative to a location of the probe and a location of the plurality of reference points.

6. The system of claim **1**, wherein the controller is configured to determine one or more of a rotational orientation or an angular orientation for the probe at the desired position for the probe.

7. The system of claim **1**, wherein the controller is configured to receive a plurality of data sets prior to the determination of the desired position of the probe, wherein each data set of the plurality of data sets corresponds to a position and orientation of the probe within the support structure when a respective echocardiogram image of the plurality of echocardiogram images is captured, and wherein the controller is configured to use the plurality of data sets to determine the desired position for the probe in the support structure.

8. The system of claim **1**, wherein the controller is configured to create a 3D model of the heart based the plurality of echocardiogram images.

9. The system of claim **1**, wherein the support structure has a substantially curvilinear triangle shape, and the plurality of reference points correspond to points of the curvilinear triangle shape.

10. The system of claim **1**, wherein the sensor data includes heartbeat phase data, and wherein the controller is configured to determine the desired position for the probe based on the heartbeat phase data.

11. The system of claim **1**, wherein the at least one sensor includes an inertial sensor for sensing heartbeats of the patient.

12. A method for positioning a probe to capture an echocardiogram of a patient, the method comprising:

placing a positioning device on a patient, the positioning device comprising a support structure defining an open interior space and a plurality of reference points around the open interior space, wherein the support structure comprises a plurality of sensor units;

sensing heart activity of the patient with the plurality of sensor units;

providing, by the plurality of sensor units, sensor data indicative of the heart activity;

capturing a plurality of echocardiogram images with a probe positioned within the open interior space;

receiving the sensor data at a controller;

receiving the plurality of echocardiogram images at the controller;

determining, by the controller based on the heart activity indicated by the sensor data and at least one of the plurality of echocardiogram images, a desired position for the probe in the open interior space of the support structure to capture an echocardiogram image;

guiding an operator to move the probe within the open interior space of the support structure to the desired position determined by the controller; and

capturing an echocardiogram image with the probe while the probe is at the desired position.

13. The method of claim **12**, wherein guiding an operator to move the probe within the open interior space includes providing information to an operator on a display.

14. The method of claim **12**, further comprising presenting the echocardiogram image on a display.

15. The method of claim **12**, wherein positioning the probe at the determined position includes setting one or more of a rotational orientation or an angular orientation for the probe at the desired position for the probe.

16. The method of claim **12**, wherein:

the support structure comprises a plurality of sensor units, each sensor unit of the plurality of sensor units being located at a corresponding reference point of the plurality of reference points, each sensor unit of the plurality of sensor units comprises an inertial sensor and a magnetic sensor;

the probe comprises an inertial sensor and a magnetic sensor; and

capturing the plurality of data sets associated with the probe includes determining the position and orientation of the probe based on signals from the inertial sensor and magnetic sensor of the probe and signals from the inertial sensors and magnetic sensors of the plurality of sensor units.

17. The method of claim **12**, further comprising creating a 3D model of the heart based on the plurality of echocardiogram images.

18. The method of claim **12**, wherein the sensor data includes heartbeat phase data, and wherein determining a desired position for the probe is based on the heartbeat phase data.

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