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(54) MEDICAL WORKFLOW SYSTEM AND METHOD

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A61B 8/12 (2006.01)

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

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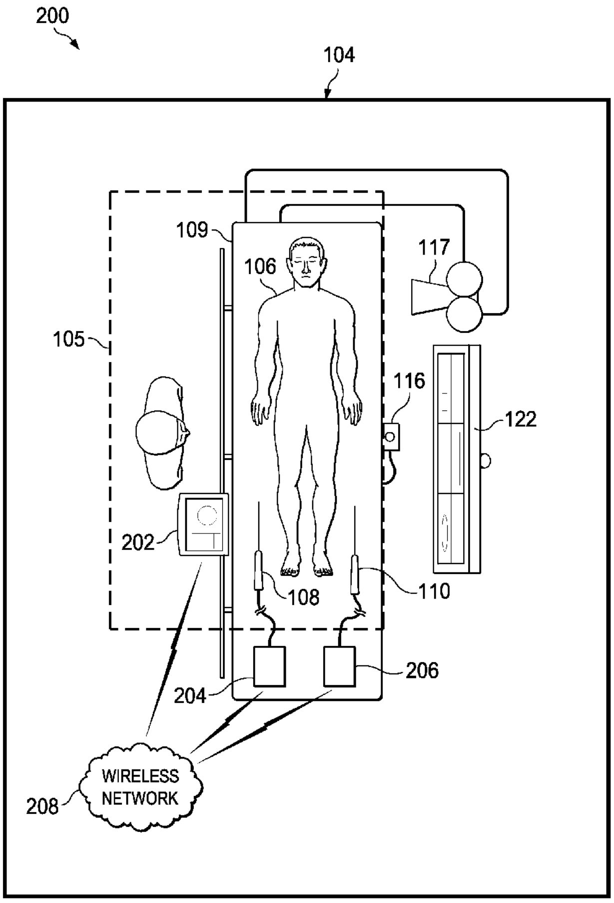
USPC **600/427**; 600/407; 600/463; 600/425; 600/431

(57) **ABSTRACT**

A method of conducting a medical workflow with a touch-sensitive bedside controller is disclosed. The method includes initiating a medical workflow using a graphical user interface on the bedside controller, positioning an imaging tool within a patient's body based on images captured by the imaging tools and displayed on the bedside controller, controlling the commencement and termination of a recordation of images captured by the imaging tool using the graphical user interface on the bedside controller, navigating through the recorded images to identify an image of interest using the graphical user interface on the bedside controller, and performing measurements on the image of interest using the graphical user interface on the bedside controller.



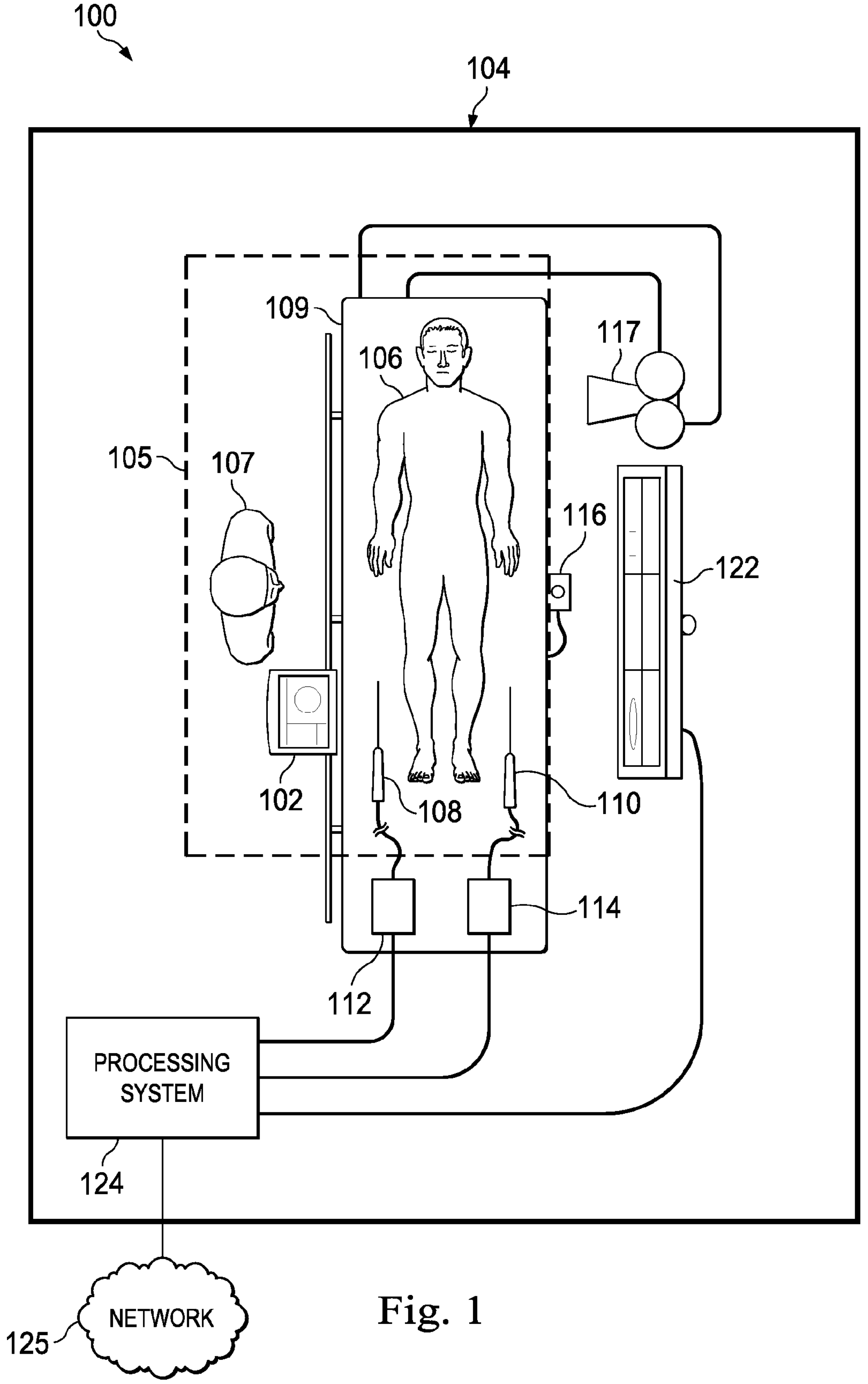

100
104
109
106
117
105
107
116
122
102
108
110
114
112
PROCESSING SYSTEM
124
NETWORK
125

Fig. 1

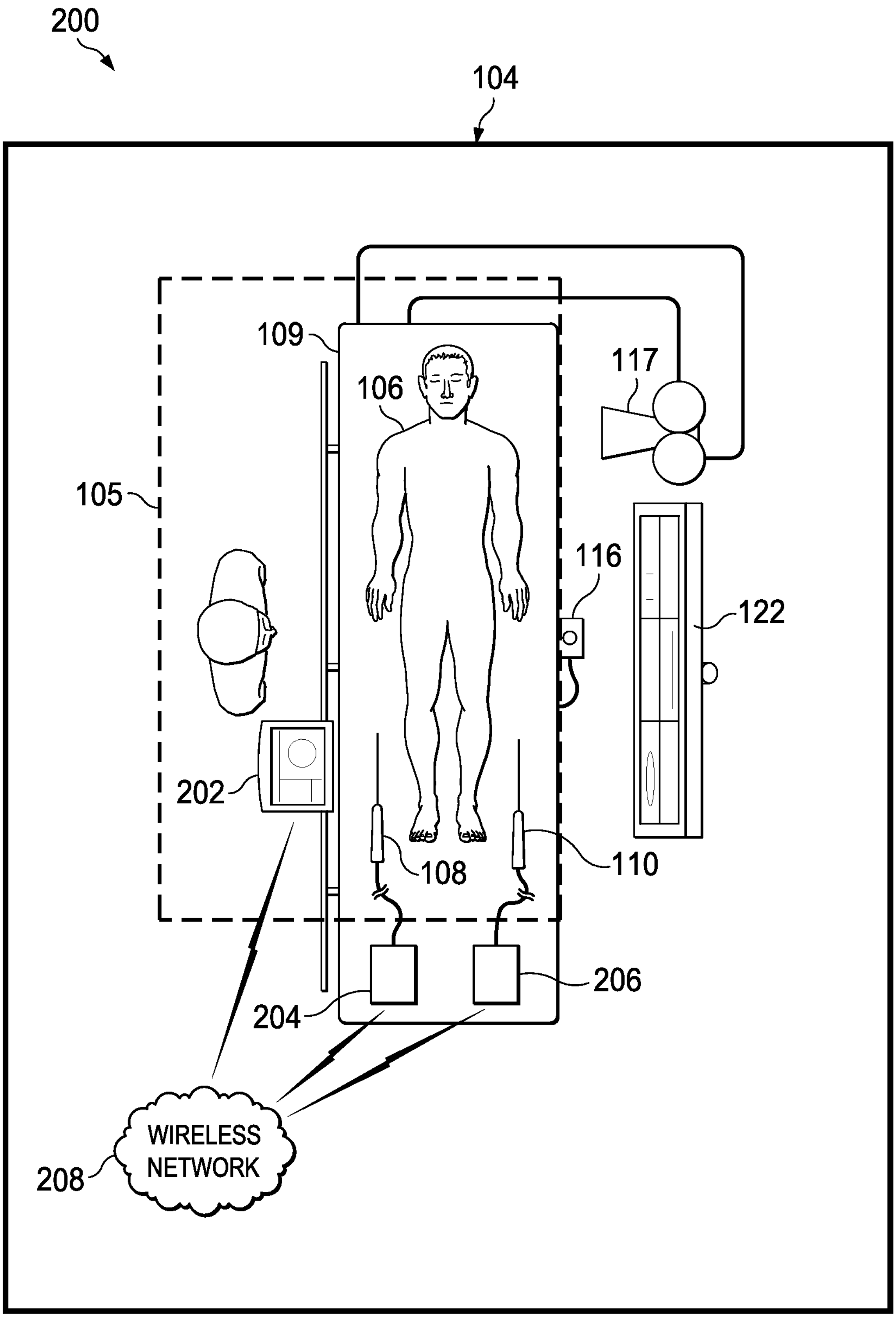

200
104
109
106
117
105
116
122
202
108
110
206
204
WIRELESS NETWORK
208

Fig. 2

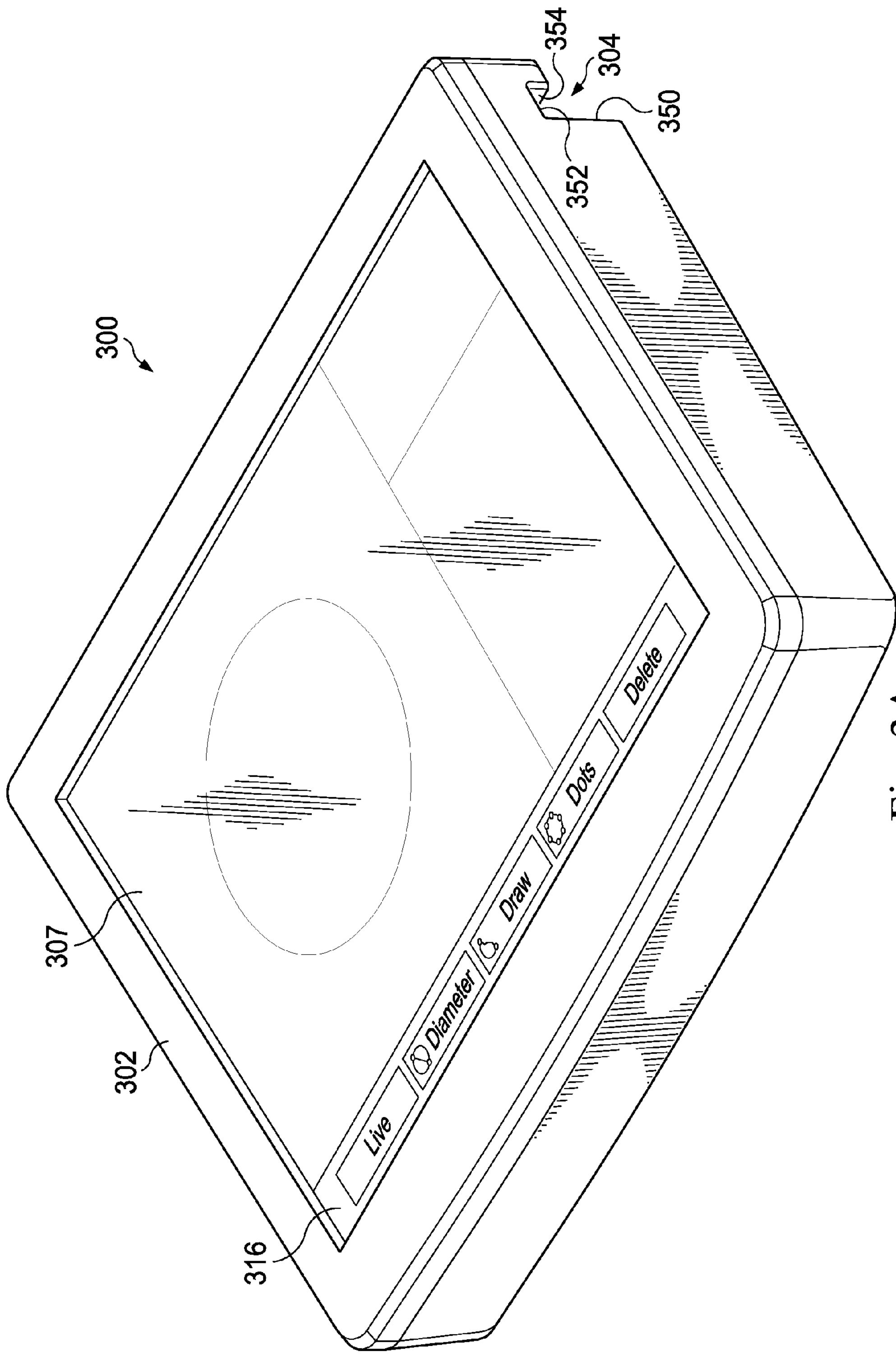

354
304
350
352
300
307
302
316
Live
Diameter
Draw
Dots
Delete

Fig. 3A

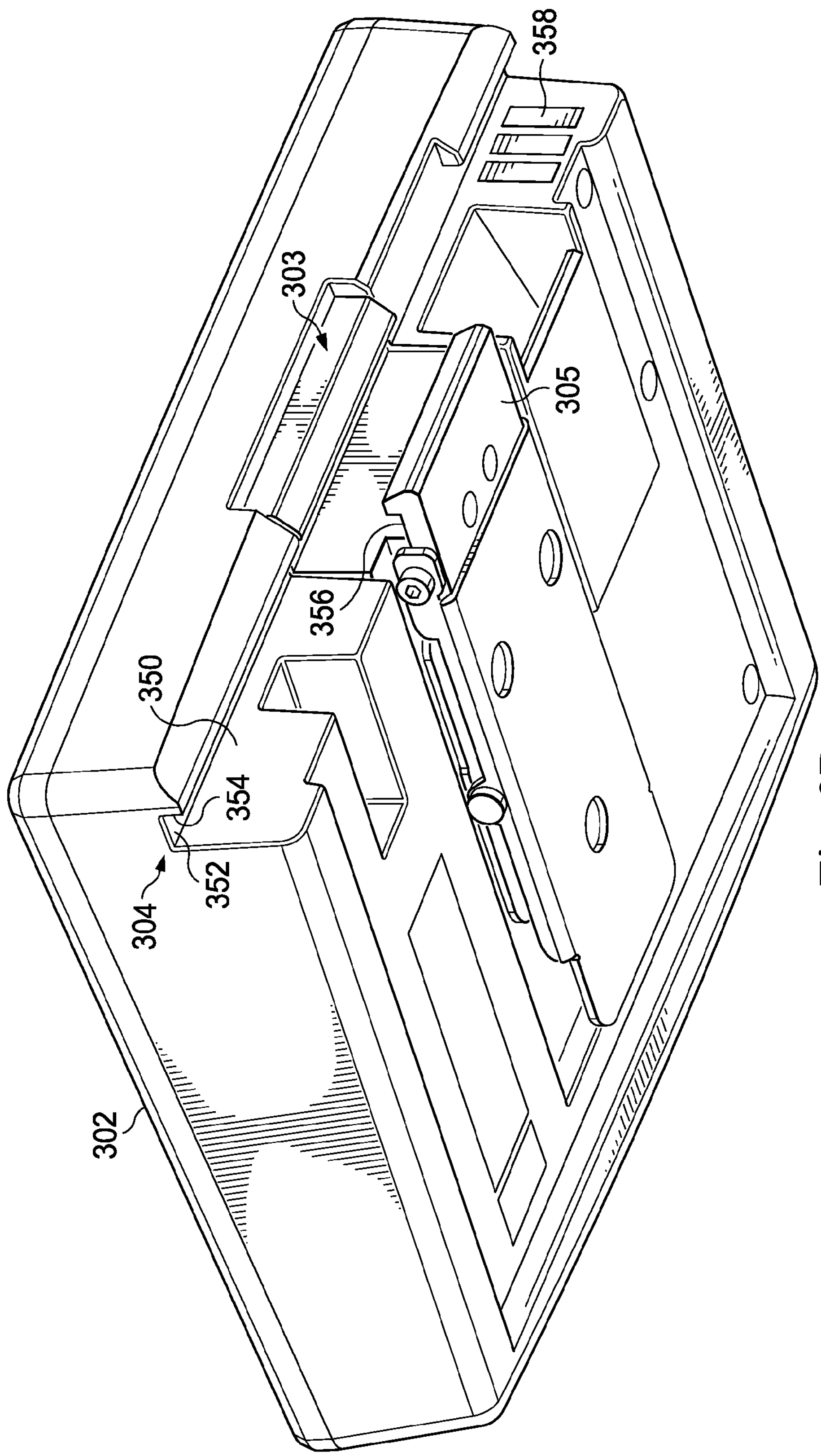


Fig. 3B

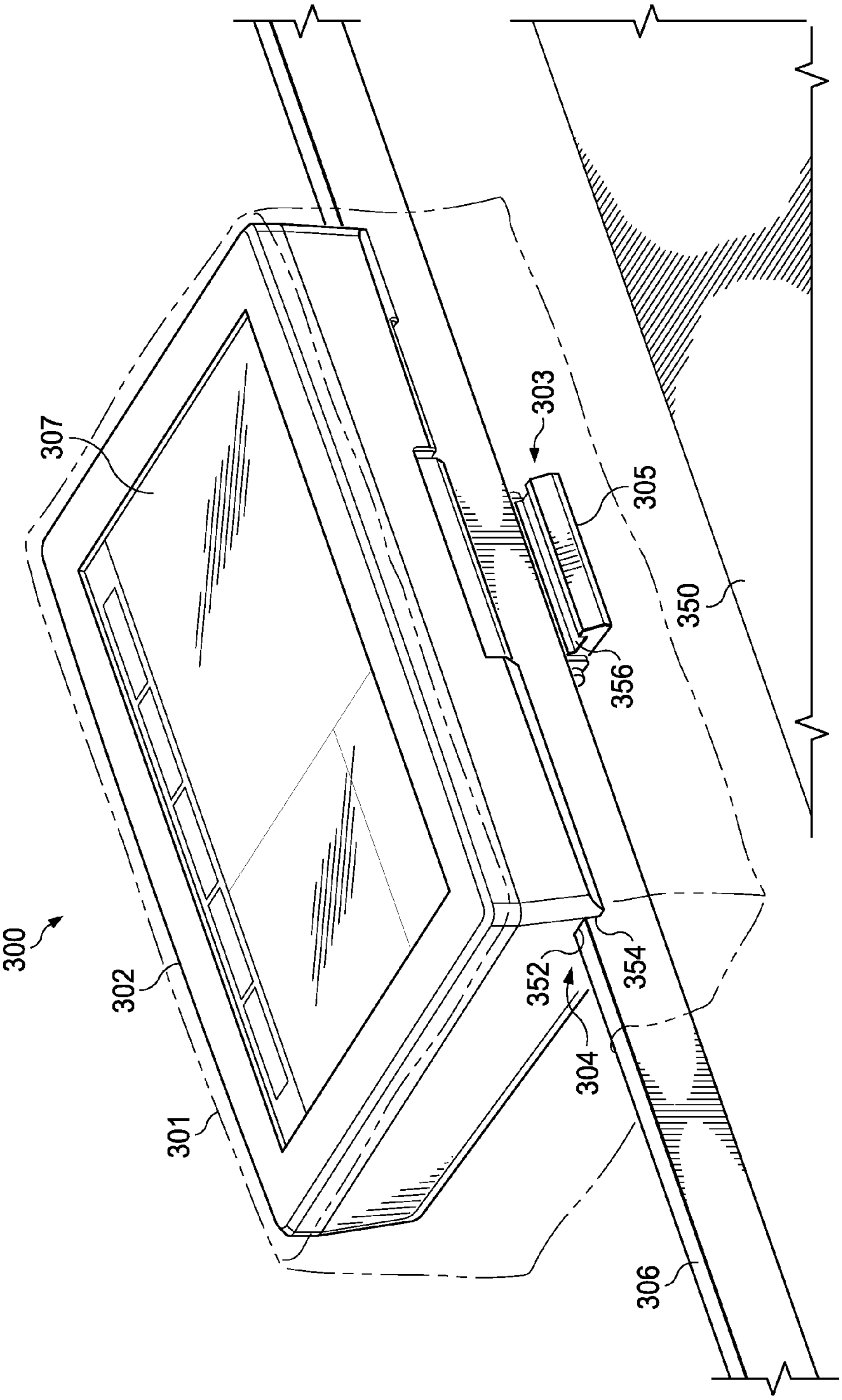


Fig. 3C

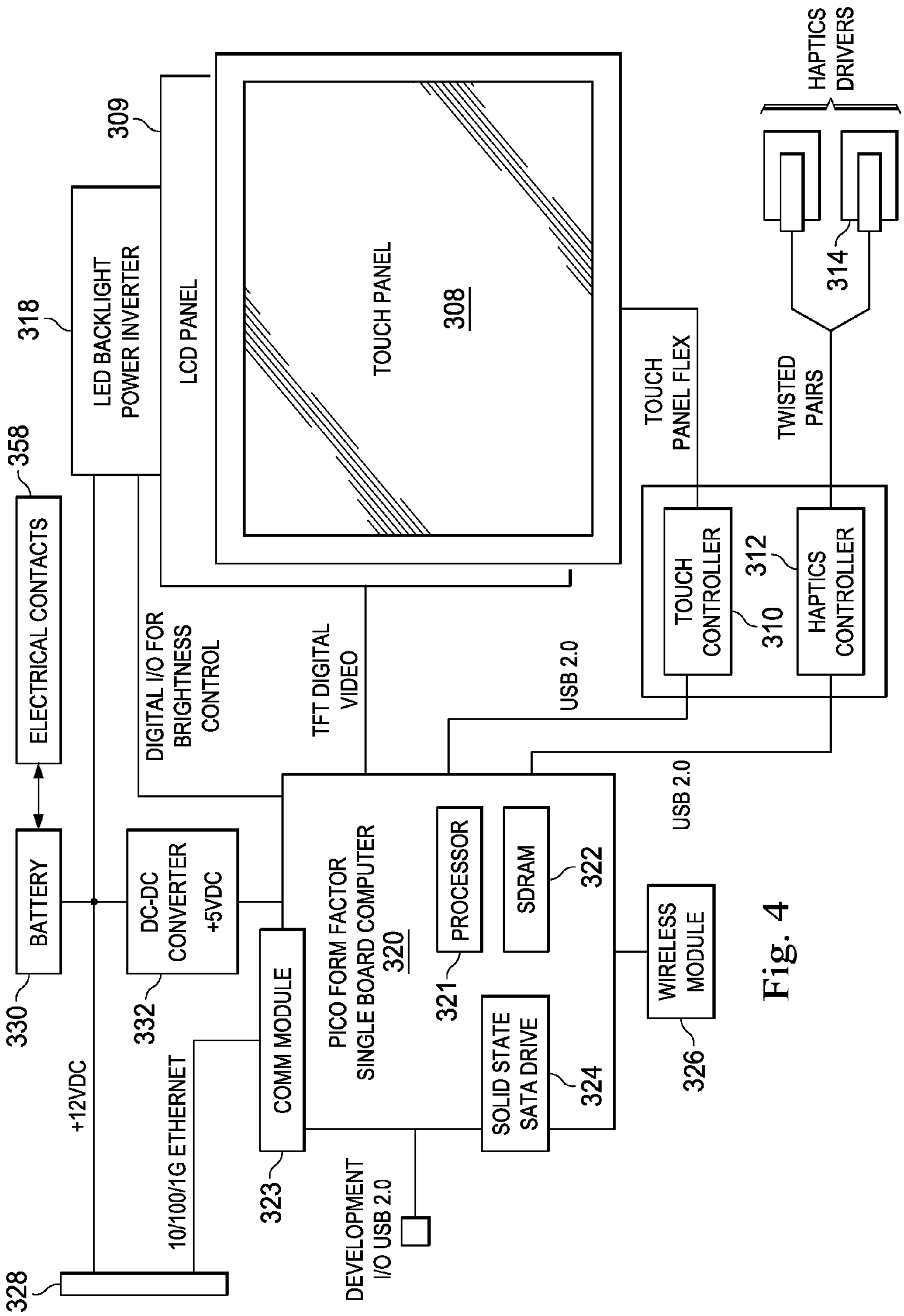

LED BACKLIGHT POWER INVERTER
318
LCD PANEL
309
TOUCH PANEL
308
HAPTICS DRIVERS
314
TOUCH PANEL FLEX
TWISTED PAIRS
ELECTRICAL CONTACTS
358
BATTERY
330
DC-DC CONVERTER +5VDC
332
+12VDC
DIGITAL I/O FOR BRIGHTNESS CONTROL
TFT DIGITAL VIDEO
USB 2.0
TOUCH CONTROLLER
310
HAPTICS CONTROLLER
312
USB 2.0
PICO FORM FACTOR SINGLE BOARD COMPUTER
320
PROCESSOR
321
SDRAM
322
SOLID STATE SATA DRIVE
324
COMM MODULE
323
WIRELESS MODULE
326
10/100/1G ETHERNET
DEVELOPMENT I/O USB 2.0
328

Fig. 4

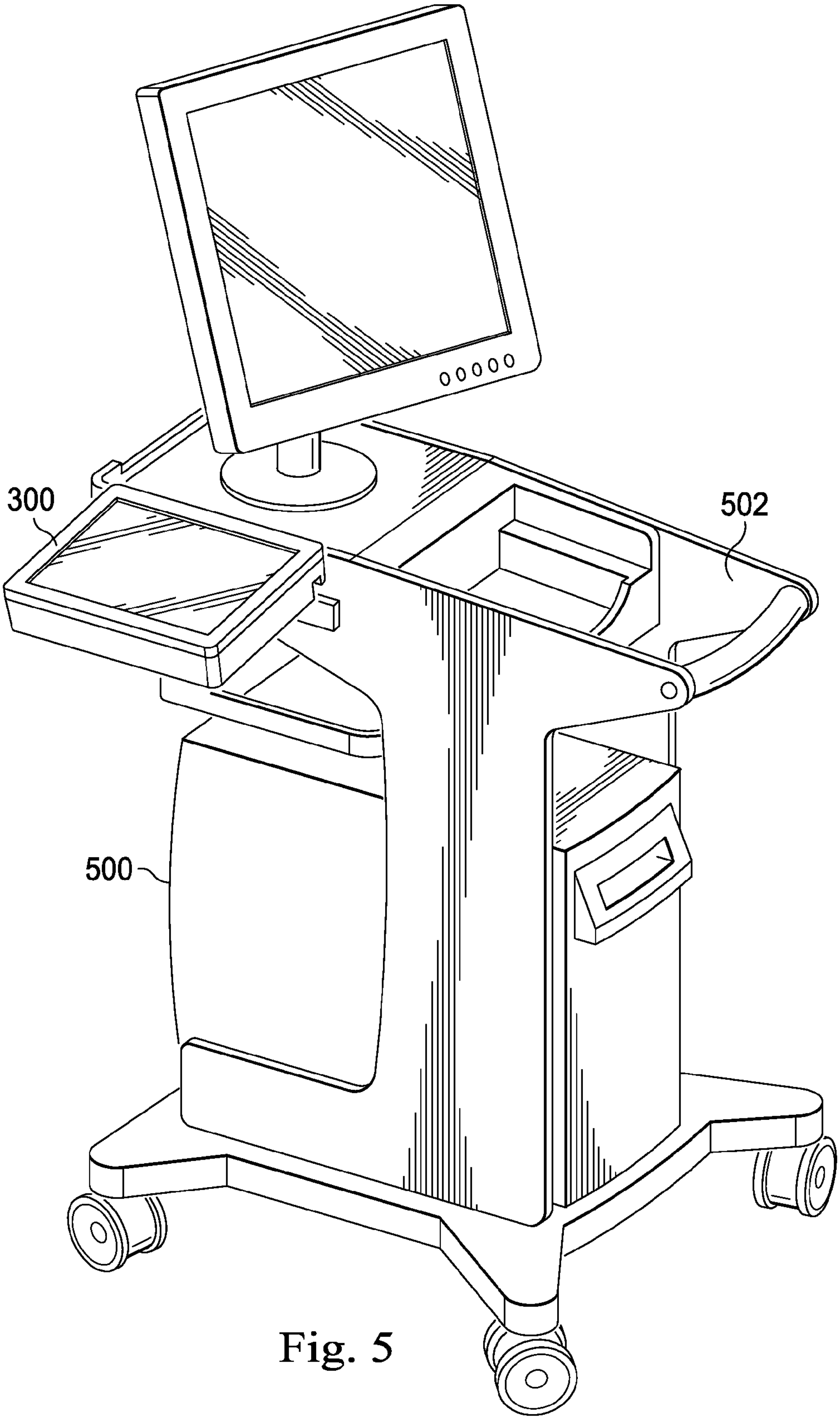


Fig. 5

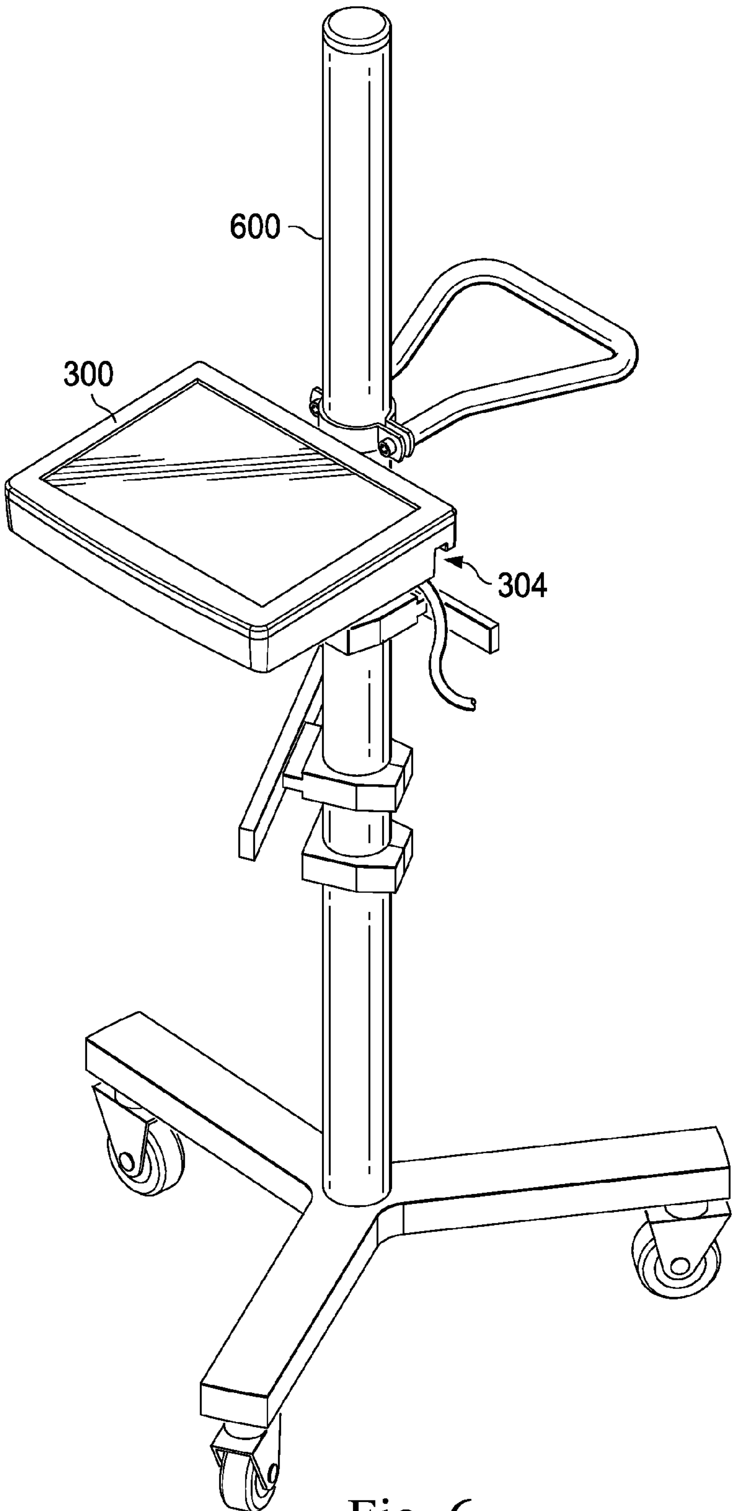


Fig. 6

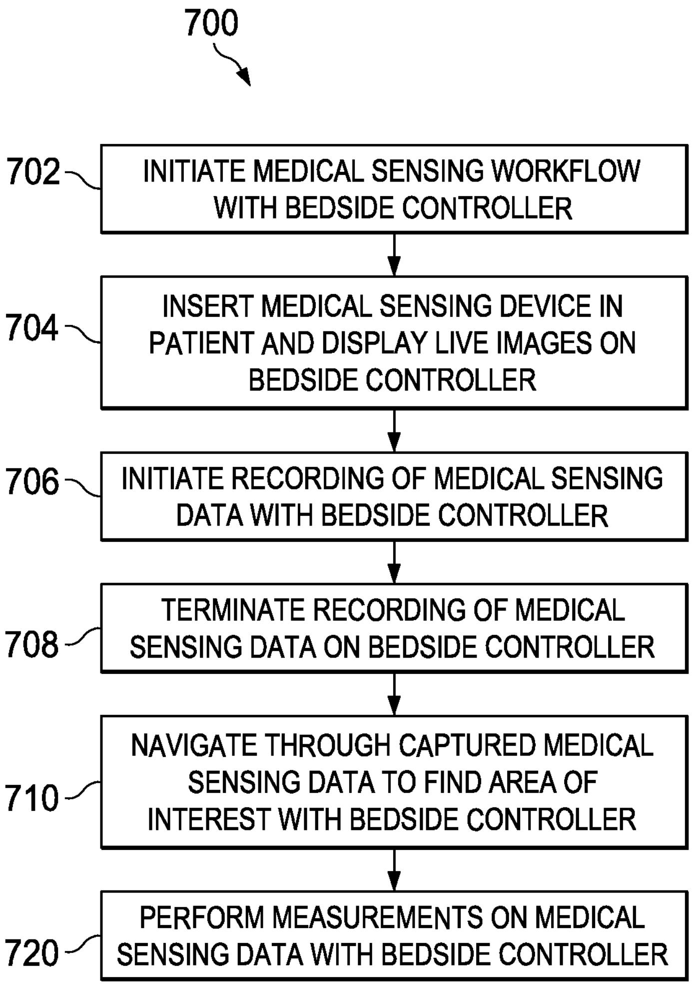

700
702
INITIATE MEDICAL SENSING WORKFLOW WITH BEDSIDE CONTROLLER
704
INSERT MEDICAL SENSING DEVICE IN PATIENT AND DISPLAY LIVE IMAGES ON BEDSIDE CONTROLLER
706
INITIATE RECORDING OF MEDICAL SENSING DATA WITH BEDSIDE CONTROLLER
708
TERMINATE RECORDING OF MEDICAL SENSING DATA ON BEDSIDE CONTROLLER
710
NAVIGATE THROUGH CAPTURED MEDICAL SENSING DATA TO FIND AREA OF INTEREST WITH BEDSIDE CONTROLLER
720
PERFORM MEASUREMENTS ON MEDICAL SENSING DATA WITH BEDSIDE CONTROLLER

Fig. 7

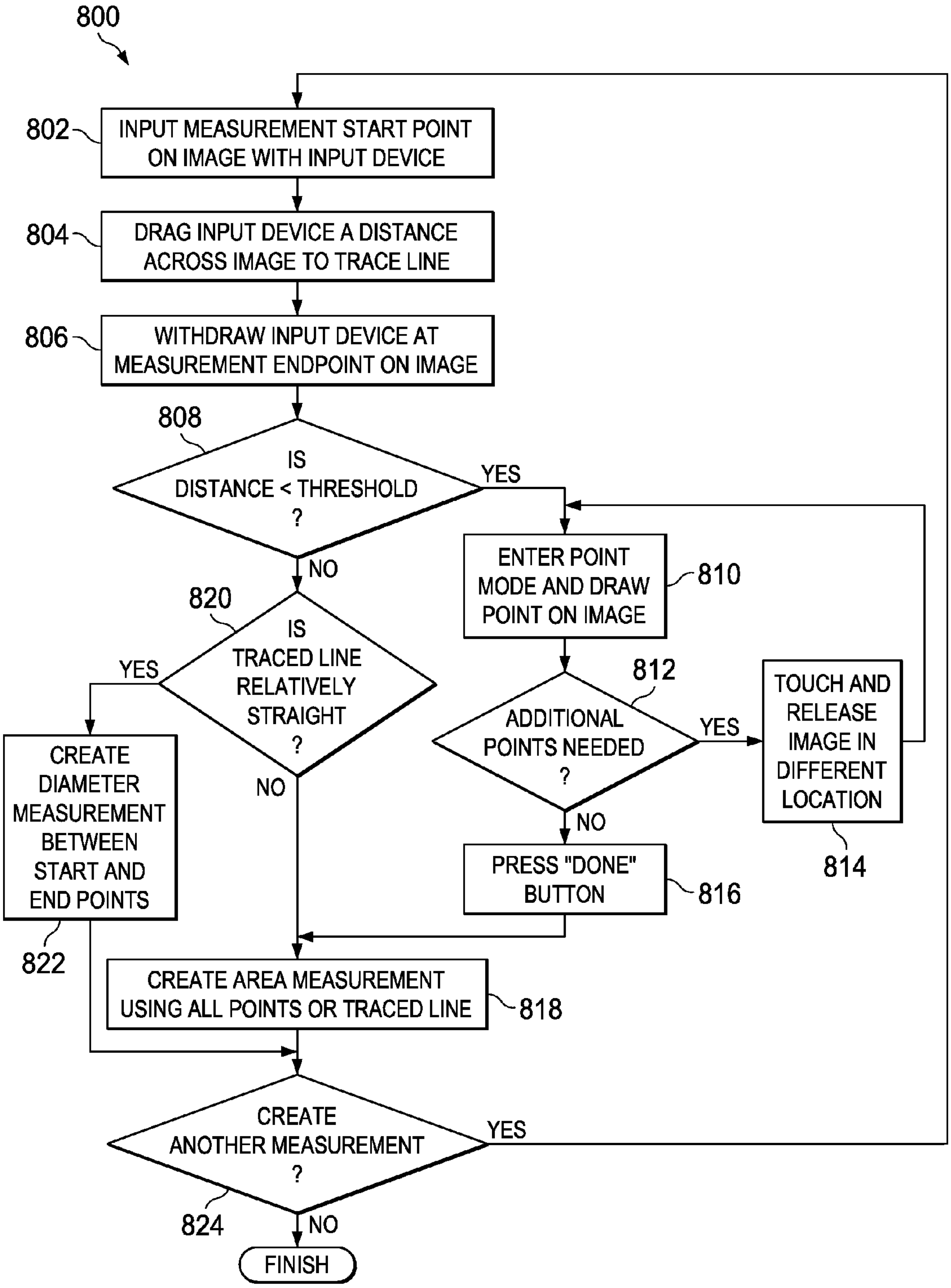

800
802
INPUT MEASUREMENT START POINT ON IMAGE WITH INPUT DEVICE
804
DRAG INPUT DEVICE A DISTANCE ACROSS IMAGE TO TRACE LINE
806
WITHDRAW INPUT DEVICE AT MEASUREMENT ENDPOINT ON IMAGE
808
IS DISTANCE < THRESHOLD ?
YES
NO
810
ENTER POINT MODE AND DRAW POINT ON IMAGE
820
IS TRACED LINE RELATIVELY STRAIGHT ?
YES
NO
812
ADDITIONAL POINTS NEEDED ?
YES
NO
TOUCH AND RELEASE IMAGE IN DIFFERENT LOCATION
814
CREATE DIAMETER MEASUREMENT BETWEEN START AND END POINTS
822
PRESS "DONE" BUTTON
816
CREATE AREA MEASUREMENT USING ALL POINTS OR TRACED LINE
818
CREATE ANOTHER MEASUREMENT ?
YES
824
NO
FINISH

Fig. 8

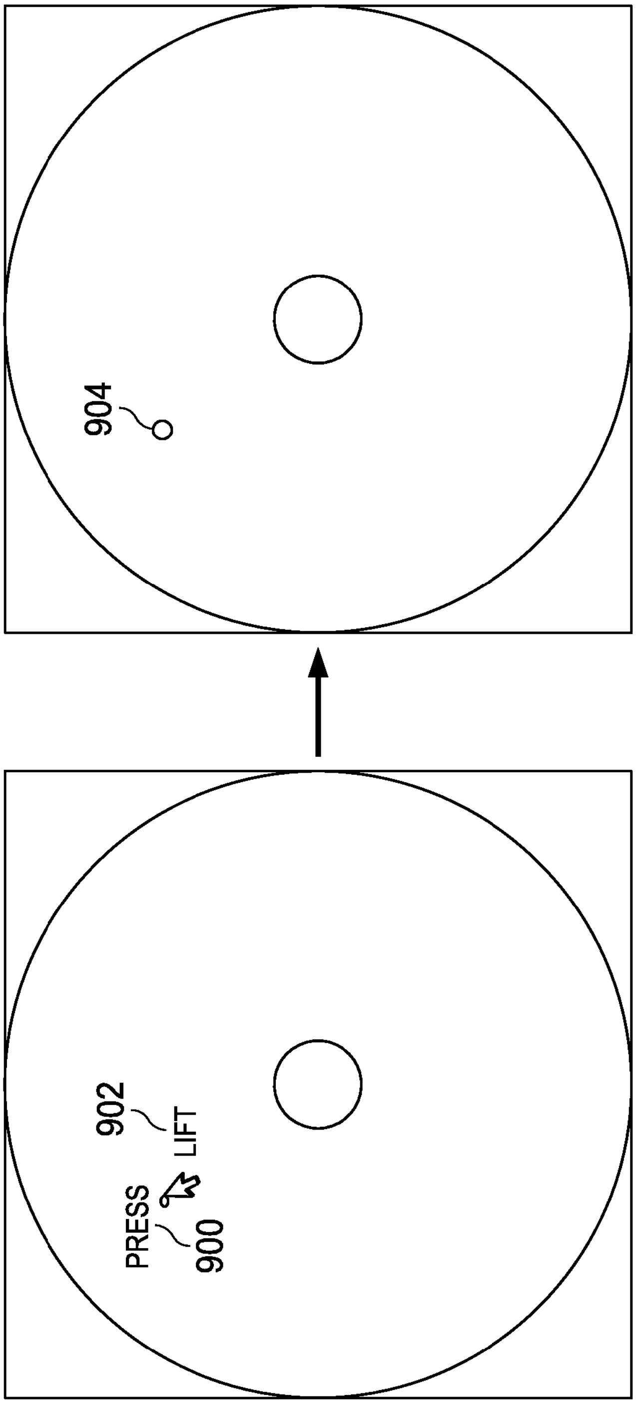


Fig. 9

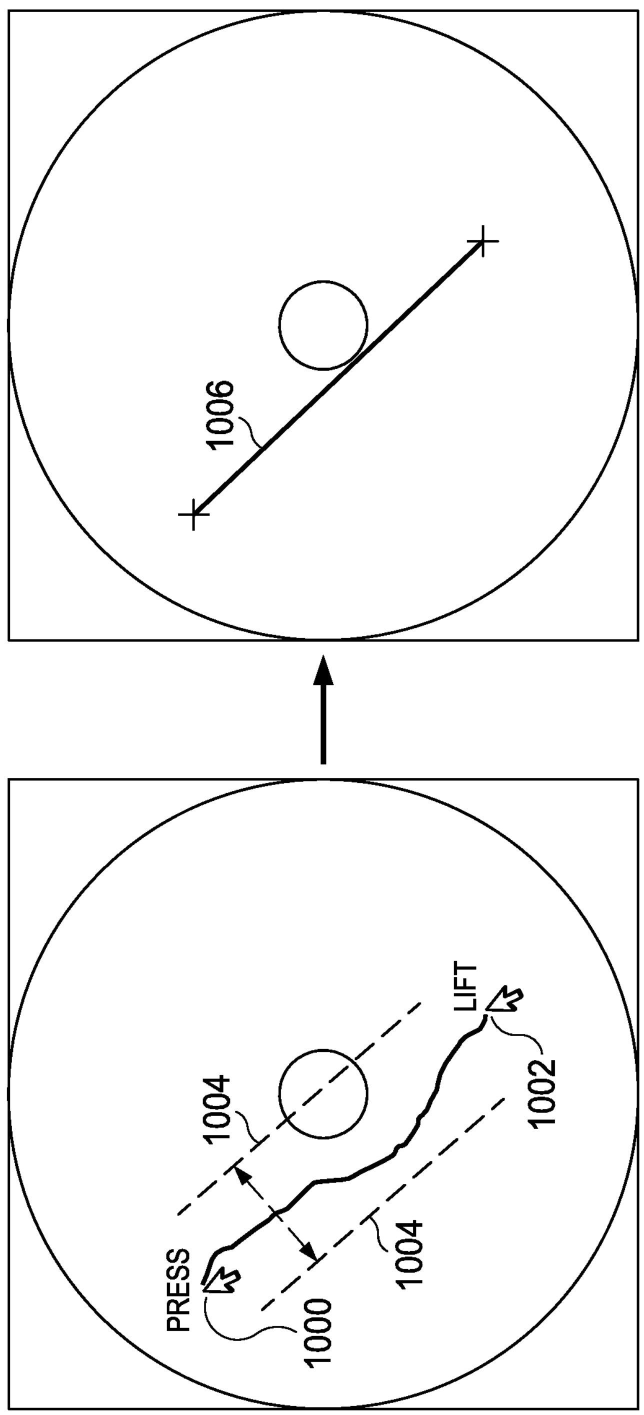


Fig. 10

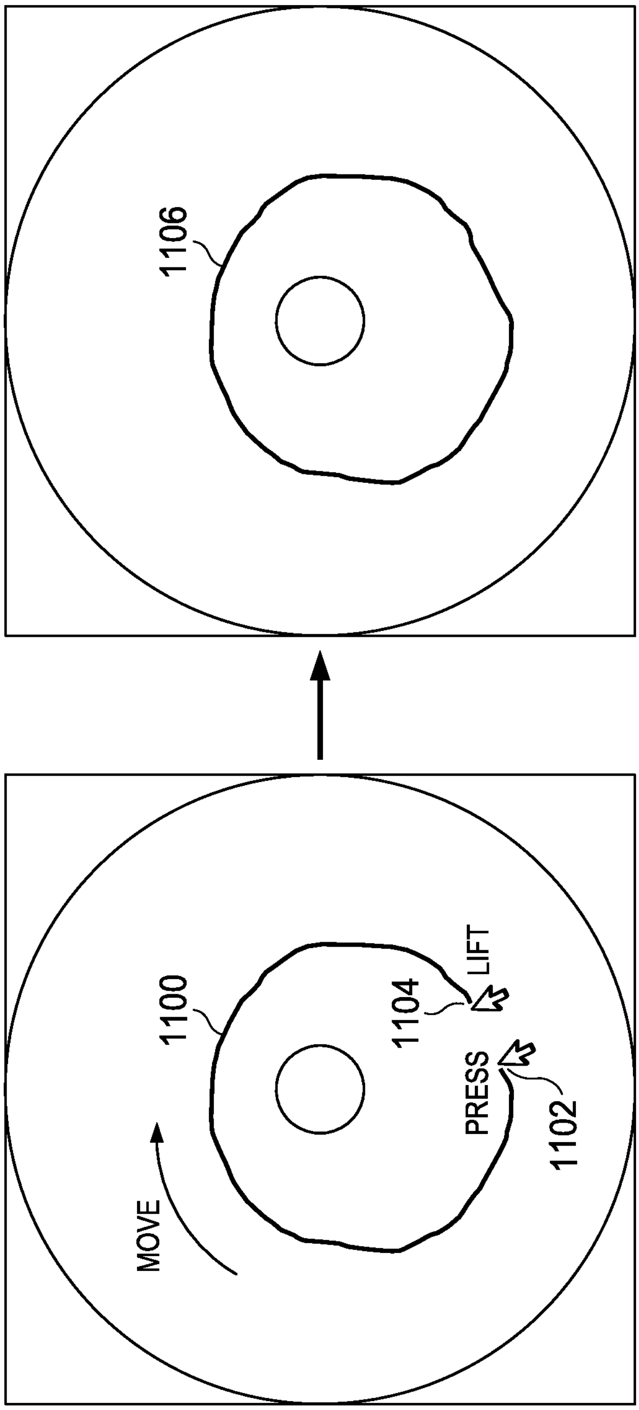


Fig. 11

MEDICAL WORKFLOW SYSTEM AND METHOD

[0001] This application claims the benefit of U.S. provisional patent application 61/560,677, filed Nov. 16, 2011, entitled "MEDICAL SENSING CONTROL SYSTEM AND METHOD," the entirety of which is incorporated by reference herein.

TECHNICAL FIELD

[0002] Embodiments of the present disclosure relate generally to the field of medical devices and, more particularly, to a medical workflow system and associated methods of use.

BACKGROUND

[0003] Innovations in diagnosing and verifying the level of success of treatment of disease have progressed from solely external imaging processes to include internal diagnostic processes. In addition to traditional external image techniques such as X-ray, MRI, CT scans, fluoroscopy, and angiography, small sensors may now be placed directly in the body. For example, diagnostic equipment and processes have been developed for diagnosing vasculature blockages and other vasculature disease by means of ultra-miniature sensors placed upon the distal end of a flexible elongate member such as a catheter, or a guide wire used for catheterization procedures. For example, known medical sensing techniques include intravascular ultrasound (IVUS), forward looking IVUS (FL-IVUS), fractional flow reserve (FFR) determination, a coronary flow reserve (CFR) determination, optical coherence tomography (OCT), trans-esophageal echocardiography, and image-guided therapy. Traditionally, many of these procedures are carried out by a multitude of physicians and clinicians, where each performs an assigned task. For example, a physician may stand next to a patient in the sterile field and guide the insertion and pull back of an imaging catheter. A clinician near the physician may control the procedure workflow with a controller, for example by starting and stopping the capture of images. Further, after images have been captured, a second clinician in an adjacent control room working at a desktop computer may select the images of interest and make measurements on them. Typically, the physician in the catheter lab must instruct the clinician in the control room on how to make such measurements. This may lengthen the time of the procedure, increase the cost of the procedure, and may lead to measurement errors due to miscommunication or clinician inexperience. Further, when making measurements on medical sensing images, a clinician may typically have to select a measurement mode prior to making any measurements, reducing the efficiency of the medical sensing workflow.

[0004] Accordingly, while the existing devices and methods for conducting medical sensing workflows have been generally adequate for their intended purposes, they have not been entirely satisfactory in all respects.

SUMMARY

[0005] In one exemplary aspect, the present disclosure is directed to a method of conducting a medical workflow with a touch-sensitive bedside controller. The method includes initiating a medical workflow using a graphical user interface on the bedside controller, positioning an imaging tool within a patient's body based on images captured by the imaging tools and displayed on the bedside controller, controlling the commencement and termination of a recordation of images captured by the imaging tool using the graphical user interface on the bedside controller, navigating through the recorded images to identify an image of interest using the graphical user interface on the bedside controller, and performing measurements on the image of interest using the graphical user interface on the bedside controller.

[0006] In some instances, the performing measurements may include touching and releasing portions of the image of interest as it is displayed on the bedside controller to make one of an area measurement and a diameter measurement.

[0007] In another exemplary aspect, the present disclosure is directed to a bedside controller. The bedside controller include a housing, a touch-sensitive display disposed within a surface of the housing and configured to display images and receive user input on the surface, and a processor disposed within the housing. The bedside controller also includes a communication module disposed within the housing, communicatively coupled to the processor, and configured to transmit and receive medical data and a non-transitory computer readable storage module disposed within the housing, communicatively coupled to the processor, and including a plurality of instructions stored therein and executable by the processor. The plurality of instructions include instructions for rendering a graphical user interface (GUI) on the touch-sensitive display, instructions for displaying images of a patient as they are being captured by an imaging tool disposed within the patient's body, and instructions for initiating and terminating a recordation of the images based on user input to the GUI. The plurality of instructions also include instructions for displaying the recorded images within the GUI so that a user may identify an image of interest and instructions for making a measurement on the image of interest based on a user measurement input to the GUI.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. **1** is a schematic drawing depicting a medical sensing system including a bedside controller according to one embodiment of the present disclosure.

[0009] FIG. **2** is a schematic drawing depicting a medical sensing system including a wireless bedside controller according to another embodiment of the present disclosure.

[0010] FIG. **3**A is a diagrammatic perspective view of a bedside controller.

[0011] FIG. **3**B is a diagrammatic rear perspective view of the bedside controller of FIG. **3**A.

[0012] FIG. **3**C is a diagrammatic perspective view of the bedside controller of FIG. **3**A mounted to a bed rail.

[0013] FIG. **4** is a functional block diagram of the bedside controller of FIGS. **3**A and **3**B according to aspects of the present disclosure.

[0014] FIG. **5** is a diagrammatic perspective view of a multi-modality mobile processing system with the bedside controller of FIGS. **3**A and **3**B attached thereto.

[0015] FIG. **6** is a diagrammatic perspective view of the bedside controller of FIGS. **3**A and **3**B releasably mounted on an IV pole.

[0016] FIG. **7** is a high-level flowchart illustrating a method of conducting a medical sensing workflow with a bedside controller according to various aspects of the present disclosure.

[0017] FIG. **8** is high-level flowchart of a method that describes a measurement workflow conducted on a bedside controller according to various aspects of the present disclosure.

[0018] FIGS. **9-11** are partial screen images illustrating various aspects of the method of FIG. **8**.

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 will nevertheless be understood that no limitation of the scope of the disclosure is intended. Any alterations and further modifications in the described devices, instruments, methods, and any further application of the principles of the disclosure as described herein are contemplated as would normally occur to one skilled in the art to which the disclosure relates. 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.

[0020] FIG. **1** is a schematic drawing depicting a medical sensing system **100** including a bedside controller **102** according to one embodiment of the present disclosure. In general, the medical sensing system **100** provides for coherent integration and consolidation of multiple forms of acquisition and processing elements designed to be sensitive to a variety of methods used to acquire and interpret human biological physiology and morphological information. More specifically, in system **100**, the bedside controller **102** is a touch-enabled, integrated computing device for the acquisition, control, interpretation, measurement, and display of multi-modality medical sensing data. In the illustrated embodiment, the bedside controller **102** is a tablet-style touch-sensitive computer that provides user controls and diagnostic images on a single surface. In the medical sensing system **100**, the bedside controller **102** is operable to present workflow control options and patient image data via graphical user interfaces (GUIs) corresponding to a plurality of medical sensing modalities. The bedside controller **102** will be described in greater detail in association with FIGS. **3**A, **3**B, and **4**.

[0021] In the illustrated embodiment, the medical sensing system **100** is deployed in a catheter lab **104**. The catheter lab **104** may be used to perform on a patient **106** any number of medical sensing procedures alone or in combination such as, by way of example and not limitation, angiography, intravascular ultrasound (IVUS), virtual histology (VH), forward looking IVUS (FL-IVUS), intravascular photoacoustic (IVPA) imaging, fractional flow reserve (FFR) determination, coronary flow reserve (CFR) determination, optical coherence tomography (OCT), computed tomography, intracardiac echocardiography (ICE), forward-looking ICE (FLICE), intravascular palpography, transesophageal ultrasound, or any other medical sensing modalities known in the art. In addition to controlling medical sensing systems, the bedside controller may be used to cooperate with and control medical treatment systems such as, for example but without limitation, those used for stent placement, coil embolism, ablation therapy, kidney stone treatments, basket placement in a cystoscopy, tumor removal, and chemical therapies. The catheter lab **104** further includes a sterile field **105** that encompasses the portions of the catheter lab surrounding the patient **106** on a procedure table **109** and a clinician **107**, who may perform any number of medical sensing procedures or treatments. As shown in FIG. **1**, the bedside controller **102** may be positioned within the sterile field **105** and may be utilized by the clinician **107** to control a workflow of a medical sensing procedure or treatment being performed on the patient **106**. For example, the clinician **107** may initiate the procedure workflow, watch real-time IVUS images captured during the procedure, and make measurements on the IVUS images all using the bedside controller **102** inside of the sterile field **105**. In alternative embodiments, the bedside controller **102** may be utilized outside of the sterile field **105**, for instance, in other locations within the catheter lab **104** or in a control room adjacent to the catheter lab. A method of utilizing the bedside controller **102** to control a medical sensing workflow or treatment workflow will be discussed in greater detail in association with FIGS. **7** and **8**.

[0022] In the embodiment illustrated in FIG. **1**, the medical sensing system **100** additionally includes a number of interconnected medical sensing-related tools in the catheter lab **104** to facilitate a multi-modality workflow procedure, such as an IVUS catheter **108**, an IVUS patient isolation module (PIM) **112**, an OCT catheter **110**, and OCT PIM **114**, an electrocardiogram (ECG) device **116**, an angiogram system **117**, a boom display **122**, and a multi-modality processing system **124**. The bedside controller **102**, PIMs **112** and **114**, ECG device **116**, angiography system **117**, and boom display **122** are communicatively coupled to the processing system **124**. In one embodiment, the processing system **124** is a computer workstation with the hardware and software to acquire, process, and display multi-modality medical sensing data, but in other embodiments, the processing system may be any other type of computing system operable to process medical sensing data. For example, during an IVUS workflow, the processing system **124** is operable to accept raw IVUS data from the IVUS PIM **112**, transform it into IVUS images, and make the images available to the bedside controller **124**, so that they may be displayed to the clinician **107** for analysis. In the embodiments in which the processing system **124** is a computer workstation, the system includes at least a processor such as a microcontroller or a dedicated central processing unit (CPU), a non-transitory computer-readable storage medium such as a hard drive, random access memory (RAM), and/or compact disk read only memory (CD-ROM), a video controller such as a graphics processing unit (GPU), and a network communication device such as an Ethernet controller. Further, the multi-modality processing system **124** is communicatively coupled to a data network **125**. In the illustrated embodiment, the data network **125** is a TCP/IP-based local area network (LAN), however in other embodiments, it may utilize a different protocol such as Synchronous Optical Networking (SONET), or may be a wide area network (WAN). The processing system **124** may connect to various resources via the network **125**, such as a Digital Imaging and Communications in Medicine (DICOM) system, a Picture Archiving and Communication System (PACS), and a Hospital Information System. U.S. Patent Application No. 61/473,570, entitled "MULTI-MODALITY MEDICAL SENSING SYSTEM AND METHOD" and filed on Apr. 8, 2011, discloses a multi-modality processing system that processes medical sensing data and is hereby incorporated by reference in its entirety.

[0023] In the medical sensing system **100**, the IVUS PIM **112** and OCT PIM **114** are operable to respectively receive medical sensing data collected from the patient **106** by the IVUS catheter **108** and OCT catheter **110** and are operable to transmit the received data to the processing system **124**. In one embodiment, the IVUS PIM **112** and OCT PIM **114** transmit the medical sensing data over a Peripheral Component Interconnect Express (PCIe) data bus connection, but, in other embodiments, they may transmit data over a USB connection, a Thunderbolt connection, a FireWire connection, or some other high-speed data bus connection. Additionally, the ECG device **116** is operable to transmit electrocardiogram signals or other hemodynamic data from patient **106** to the processing system **124**. To aid the clinician in data capture, the bedside controller **102** is operable to display the ECG data along side medical sensing data. Further, in some embodiments, the processing system **124** may be operable to synchronize data collection with the catheters **108** and **110** using ECG signals from the ECG **116**. Further, the angiogram system **117** is operable to collect x-ray, computed tomography (CT), or magnetic resonance images (MRI) of the patient **106** and transmit them to the processing system **124**. After the x-ray, CT, or MRI data has been processed into human-readable images by the processing system **124**, the clinician **107** may navigate the GUI on the bedside controller **124** to retrieve the images from the processing system **124** and display them on the controller. In some embodiments, the processing system **124** may co-register image data from angiogram system **117** (e.g. x-ray data, MRI data, CT data, etc.) with sensing data from the IVUS and OCT catheters **108** and **110**. As one aspect of this, the co-registration may be performed to generate three-dimensional images with the sensing data. Such co-registered 3-D images data may be viewable on the bedside controller **124**. In one embodiment, a clinician may rotate, zoom, and otherwise manipulate such 3-D images on the bedside controller **102** using simultaneous touch inputs (i.e. multitouch) and gestures.

[0024] Additionally, in the illustrated embodiment of FIG. **1**, medical sensing tools in system **100**, are communicatively coupled to the processing system **124** via a wired connection such as a standard copper link or a fiber optic link. Specifically, the bedside controller **124** may be communicatively and/or electrically coupled to the processing system **124** via a Universal Serial Bus (USB) connection, a Power-over-Ethernet connection, a Thunderbolt connection, a FireWire connection, or some other high-speed data bus connection.

[0025] However, in an alternative embodiment, such as that shown in FIG. **2**, the medical sensing tools may communicate wirelessly. In that regard, FIG. **2** is a schematic drawing depicting a medical sensing system **200** including a wireless bedside controller **202** according to another embodiment of the present disclosure. The medical sensing system **200** is similar to the system **100** of FIG. **1** but the medical sensing tools including the wireless bedside controller **202**, a wireless IVUS PIM **204**, and a wireless OCT PIM **206** communicate with a wireless network **208** via wireless networking protocols. For example, the bedside controller **202** may send and receive workflow control parameters, medical sensing images, and measurement data to and from a remote processing system via IEEE 802.11 Wi-Fi standards, Ultra Wide-Band (UWB) standards, wireless FireWire, wireless USB, Bluetooth, or another high-speed wireless networking standard. Such wireless capability allows the clinician **107** to more freely position the bedside controller **202** inside or outside of the sterile field **105** for better workflow management.

[0026] With reference now to FIGS. **3**A, **3**B, **3**C and **4**, FIG. **3**A is a diagrammatic perspective view of a bedside controller **300**, FIG. 3B is a diagrammatic rear perspective view of the bedside controller, FIG. **3**C is a diagrammatic perspective view of the bedside controller mounted to a bed rail, and FIG. **4** is a functional block diagram of the bedside controller **300** according to aspects of the present disclosure. The bedside controller **300** is similar to the bedside controllers **102** and **202** in medical sensing systems **100** and **200**, and is operable to, among other things, initiate a medical sensing or treatment procedure workflow, display real-time images captured during the procedure, accept measurement input on the images from a clinician. The bedside controller **300** generally improves system control available to a clinician working at a patient table. For instance, giving a clinician both workflow control and measurement capability within the sterile field reduces errors and improves workflow efficiency.

[0027] As show in FIG. 3A, the bedside controller **300** includes an integrally formed housing **302** that is easy to grasp and move around a catheter lab or other medical setting. In one embodiment, the integrally formed housing **302** may be seamlessly molded from materials such as thermoplastic or thermosetting plastic or moldable metal. In other embodiments, the integrally formed housing **302** may comprise a plurality of housing portions fixedly bonded in a substantially permanent manner to form an integral housing. The housing **302** is resistant to fluids, and, in one embodiment, may have a rating of IPX4 against fluid ingress as defined by the International Electrotechnical Commission (IEC) standard 60529. In other embodiments in which the housing **302** may be used in different environments, the hub may have a different fluid ingress rating. In the illustrated embodiment, the housing **302** is about 10.5 inches in width, about 8.25 inches in height, and has as thickness of about 2.75 inches. In alternative embodiments, the housing may have a different width, height, or thickness that is similarly conducive to portability.

[0028] As shown in FIG. 3B, the housing **302** further includes self-contained mounting structure **303** disposed on the housing. In the illustrated embodiment, the mounting structure is disposed near an outer edge of the housing. The mounting structure **303** allows the bedside controller **300** to be releasably mounted in a variety of places in and out of a catheter lab in a self-contained manner. That is, the bedside controller **300** may be directly secured to another object without the use of a separate external mount. In the illustrated embodiment, the mounting structure **303** includes a mounting channel **304** and a retaining clamp **305** that pivots over the mounting channel to secure a mounting platform therewithin. The mounting channel **304** is defined by a longer front wall **350**, a top wall **352**, and a shorter back wall **354**, and the retaining clamp includes a slot **356** that extends through the clamp in a manner generally parallel to the mounting channel. The front wall **350** and the back wall **354** are generally perpendicular to a touch-sensitive display **307** in the housing **302**, and the top wall **352** is generally parallel to the display **307**. In the illustrated embodiment, the retaining clamp is spring-loaded and releasably exerts pressure on objects situated in the mounting channel. In alternative embodiments, the retaining clamp may be configured differently and exert force via mechanisms other than springs.

[0029] As shown in FIG. **3**C, in operation, the bedside controller **300** may be releasably secured to a mounting platform, for example a bed rail **306**, by pivoting the mounting clamp **305** to an open position, positioning the controller such that the rail extends through the length of the channel **304**, and releasing the clamp such that it secures the rail within the channel. When the rail **306** is positioned in the mounting channel **304** and the clamp **305** is holding it therein, three surfaces of the rail are respectively engaged by the front wall **350**, the top wall **352**, and the back wall **354**, and a fourth surface of the rail extends through the slot **356** in the clamp **305**. In this manner, the mounting structure **303** may maintain the bedside controller **300** in a position generally parallel to a procedure table **350** associated with the bed rail **306**, as shown in FIG. **3**B. Described differently, the mounting structure **303** is a cantilevered mounting structure in that it secures one end of the controller to an object while the majority of the controller extends away from the object in an unsupported manner. Such a cantilevered position allows for a display of the controller to be both readable and at a comfortable input angle for an operator. Further, the self-contained mounting structure **303** allows the bedside controller **300** to be quickly released from the bed rail **306** and reattached to an IV pole, a cart on which a processing system is deployed, or other location in or out of the sterile field to allow for convenient workflow control and image analysis. In alternative embodiments the mounting structure **303** of the bedside controller may vary from the design illustrated in FIGS. **3**A and **3**B and include additional and/or different components to allow for self-contained mounting.

[0030] Embedded into the front of the housing **302** is the touch-sensitive display **307** that comprises both a touch panel **308** and a flat panel display **309**. The touch panel **308** overlays the flat panel display **308** and accepts user input via human touch, stylus touch, or some other analogous input method. In other words, the touch-sensitive display **307** displays images and accepts user input on the same surface. In the current embodiment, the touch panel **308** is a resistive-type panel, but in alternative embodiments it may be a capacitive-type panel, projective-type panel, or some other suitable type of touch enabled input panel. Further, the touch panel **308** is operable to accept multiple inputs simultaneously (multitouch), for instance, to enable rotation of a three-dimensional rendering of a vessel along multiple axes. Additionally, the touch panel **308** is capable of receiving input when a sterile drape **301** is covering the bedside controller **300** and also when a user is gloved. The touch panel **308** is controlled by a touch controller **310** disposed within the housing **302**. Further, when a clinician makes contact with the touch panel **308**, the touch panel is operable to provide haptic feedback via a haptics controller **312** and haptics drivers **314**. This haptic technology is operable to simulate a plurality of sensations on the touch panel **308** by varying the intensity and frequency of vibrations generated when a user contacts the touch panel. In some embodiments, the housing **302** may include a sheath configured to store a stylus therein. Thus, a clinician may remove the stylus from the sheath in the housing to make measurements on the bedside controller and store it when the measurements have been completed.

[0031] Beneath the touch panel **308** is the flat panel display **309** that presents a graphical user interface (GUI) **316** to a user. In the illustrated embodiment, the flat panel display **309** is a LCD display but in alternative embodiments, it may be a different type of display such an LED display or an AMOLED display. In the illustrated embodiment, the flat panel display **309** is illuminated by a LED backlight power inverter **318**. As mentioned above, the GUI **316** not only allows a clinician to control a medical sensing workflow but also make measurements on images captured from a patient in the sterile field. A method of interacting with the GUI **316** to make vessel measurements will be discussed in greater detail in association with FIGS. **8-11**.

[0032] The bedside controller **300** includes a single board processing platform **320** within the housing **302** that is operable to render the GUI **316** and process user input. In the illustrated embodiment, the processing platform has a pico form factor and includes integrated processing components such as a processor **321**, system memory **322**, graphics processing unit (GPU), communications module **323**, and I/O bus controller. In some embodiments, the processor **321** may be a low power processor such as an Intel Atom® processor or a ARM-based processor, and the communications module **323** may be a 10/100/1 Gb Ethernet module. And, the I/O bus controller may be a Universal Serial Bus (USB) controller. The bedside controller **300** further includes a storage module **324** that is a non-transitory computer readable storage medium operable to store an operating system (i.e. software to render and control the GUI), image manipulation software, medical sensing data and images received from a processing system, and other medical sensing-related software. The processor **321** is configured to execute software and instructions stored on the storage module **324**. In the illustrated embodiment, the storage module **324** is a solid state drive (SSD) hard drive communicatively coupled to the processing platform **320** via a SATA connection, but, in alternative embodiments, it may be any other type of non-volatile or temporary storage module. The bedside controller **300** further includes a wireless communications module **326** communicatively coupled to the processing platform **320**. In some embodiments, the wireless communications module is a IEEE 802.11 Wi-Fi module, but in other may be a Ultra Wide-Band (UWB) wireless module, a wireless FireWire module, a wireless USB module, a Bluetooth module, or another high-speed wireless networking module.

[0033] In the illustrated embodiment, the bedside controller **300** is powered via both a wired 12 VDC power-over-Ethernet (PoE) connection **328** and a battery **330** disposed within the housing **302**. In one embodiment, the battery **330** may be sealed within the integrally formed housing **302** and may be recharged through electrical contacts disposed on the exterior of the housing and electrically coupled to the battery. As shown in the embodiment of FIG. **3**B, the front wall **350** may include one or more electrical contacts **358** through which the battery **330** may be charged when the controller is mounted to objects with compatible charging structure. In other embodiments, the housing **302** may include a battery compartment with a removable cover to permit battery replacement. Such a battery compartment cover may be resistant to fluid ingress (e.g., with an IPX4 rating). The beside controller **300** may be coupled to a processing system in the catheter lab via the PoE connection **328**, over which it receives medical sensing images that have been captured from the patient and rendered on the processing system. In operation, when the bedside controller is coupled to the PoE connection **328**, it receives power and communications over the same physical wire. When the bedside controller **300** is disconnected from the PoE connection **328**, it runs on battery power and receives data wirelessly via the wireless communications module **326**. When used wirelessly in a catheter lab, the beside controller may directly communicate with a processing system (i.e. in an ad-hoc wireless mode), or, alternatively, it may communicate with a wireless network that serves a plurality of wireless devices. In alternative embodiments, the bedside controller **300** may receive power and data through different wired connections, or receive data communications through a wired data connection and power from the battery **330**, or receive data communications through the wireless module **326** and power from a wired electrical connection. In some embodiments, the bedside controller **300** may be used in a semi-wireless configuration, in which the battery **330** provides backup power to the controller when the controller is temporarily disconnected from a wired power source. For example, if at the beginning of a procedure, the bedside controller **300** is connected to a PoE connection (or other type of wired connection) and during the procedure the controller must be disconnected from the PoE connection to allow for a cabling adjustment, the battery **330** may keep the controller alive until a PoE connection can be re-established. In this manner, a full power-off and reboot of the controller **300** is avoided during a procedure. As shown in FIG. **4**, a DC-DC power converter **332** converts input voltage to a voltage usable by the processing platform **320**.

[0034] It is understood that although the bedside controller **300** in the illustrated embodiments of FIGS. **3** and **4** includes specific components described herein, the bedside controller may include any number of additional components, for example a charge regulator interposed between the electrical contacts and the battery, and may be configured in any number of alternative arrangements in alternative embodiments.

[0035] With reference now to FIGS. **5** and **6**, illustrated are examples of locations in which the bedside controller **300** may be mounted. FIG. **5** is a diagrammatic perspective view of a multi-modality mobile processing system **500**. The processing system **500** is disposed on a cart **502** that enables the processing system to be easily moved between different locations such as different catheter labs. As shown in FIG. **5**, the bedside controller **300** is mounted to the cart **502** so that it may be transported to catheter labs with the processing system. The bedside controller **300** is releasably secured to the cart via the self-contained mounting structure **303** that is built into the housing **302**. Further, in some embodiments, the cart **502** may include a dock for the bedside controller **300** such that when the controller is docked on the cart its battery is recharged through the electrical contacts **358** disposed on the housing **302**. As shown in FIG. **6**, the bedside controller **300** may also releasably attach to an IV pole **600** via the self-contained mounting structure **303**. When so attached, the bedside controller **300** may be rolled next to a patient in the sterile field and thus within reach of a clinician who may operate the controller with a single hand.

[0036] FIG. **7** is a high-level flowchart illustrating a method **700** of conducting a medical sensing workflow with the bedside controller **300** of FIGS. **3-4** according to various aspects of the present disclosure. The method **700** will be described in the context of an IVUS procedure but may equally apply to any number of medical sensing or treatment procedures, such as an OCT procedure, a FLIVUS procedure, an ICE procedure, etc. The method **700** begins at block **702** where a medical sensing workflow is initiated with the bedside controller **300**. Using an IVUS procedure as an example, a clinician in the sterile field and adjacent a patient may select the "IVUS" option out of a plurality of modes (e.g., OCT, Chromaflow, FLIVUS, etc) on the bedside controller's GUI to begin the IVUS workflow. Next, in block **704**, after an IVUS imaging catheter has been inserted into the patient, the clinician may select a 'Live Images' option on the bedside controller's GUI to receive live images from the catheter. Using the real-time images, the clinician may guide the catheter within the patient to a desired position. In typical embodiments, a processing system may collect raw IVUS data from the catheter and process the data to render IVUS images. The bedside controller retrieves the IVUS images from the processing system and displays them to a user in real-time. Then, in block **706**, after the IVUS catheter has been appropriately positioned in the patient using the live images, the clinician selects a 'Record' option on the bedside controller GUI and begins the catheter pull back. The processing system responds to the record command and begins rendering and storing IVUS images. The method **700** proceeds to block **708** where, after the IVUS catheter pull back has been completed, the clinician terminates the recording of IVUS images via the bedside controller's GUI. Then, in block **710**, the clinician at the bedside recalls the captured IVUS images on the bedside controller and finds the IVUS images associated with the area of interest. Specifically, the bedside controller may present a condensed view of all captured images and the clinician may navigate through them using gestures on the bedside controller's touch panel to find the target area. Finally, in block **720**, the clinician performs measurements on the IVUS images directly on the bedside controller. The user of the bedside controller creates measurements by interacting with an image through a series of presses, moves and releases using a finger or stylus on the controller's touch-sensitive display. These actions are interpreted by the bedside controller's internal processor and converted to measurements on the display. For precise measurements, the clinician may annotate the images using a stylus or another tool compatible with the bedside controller's touch panel. After the appropriate measurements have been completed, the clinician may save the images to the processing system by selecting the appropriate options in the bedside controller GUI. A method of performing measurements on the bedside controller will be described below.

[0037] FIG. **8** is high-level flowchart of a method **800** that describes a measurement workflow on the bedside controller **300** of FIGS. **3A-4**. In one embodiment, the method **800** may be carried out during block **720** of the method **700** in FIG. **7** as part of a medical sensing workflow on intravascular images. Further, in the illustrated embodiment, the method **800** of making measurements on the bedside controller **300** is implemented in measurement software stored in the storage module **324** in the bedside controller. In general, when measuring images, such as intravascular images, a clinician has the option of making different types of measurements such as diameter measurements and area measurements. Typically, when making area measurements, a clinician may either denote the edges of an object by drawings a series of discrete points that are connected in subsequent processing or by drawing a continuous line around the object to the measured. In this regard, the method **800** of performing measurements on images is "smart" in that it does not require a user to select a particular measurement mode prior to interacting with an image on the bedside controller. For instance, when a user performs a series of measurement inputs on the bedside controller, the GUI software interprets the nature (e.g. shape) of a user's measurement inputs, automatically enters either diameter mode, area-point mode or area-draw mode, and outputs the desired measurement on the controller's display.

[0038] In more detail, the method **800** begins at block **802** where an image to be measured is displayed on the bedside controller and a user inputs a measurement start point on the image with an input device. For example, the user may use a finger or stylus to indicate a point on a vessel border from which a measurement will commence. Note that prior to selecting the measurement start point, the measurement software did not require the user to select a measurement mode. Next, in block **804**, the user, without removing the input device from the image after indicating the start point, drags the input device across the image a distance to trace a line. Then, in block **806**, the user withdraws the input device from the image at a measurement end point. The method **800** proceeds to decision block **808** where the measurement software determines whether the distance between the start point and the end point is less than a threshold value. In one embodiment, the threshold value is equivalent to **10** pixels, but, in alternative embodiments, the threshold value may be smaller or larger or measured in different units. Further, in some embodiments, the threshold value is adjustable either manually by a user or automatically based on detected error rates. If the distance is less than the threshold value, the method proceeds to block **810** where the measurement software enters area-point mode and draws a point on the image corresponding to the end point (i.e. where the user lifted the input device from the touch-enabled display). This sequence is illustrated in FIG. **9**. Specifically, when a user presses (**900**) an input device on an image and immediately lifts (**902**) the input device, the input will be interpreted as a point entry and a point **904** will be drawn on the image.

[0039] The method **800** then proceeds to decision block **812** where it is decided whether additional points are needed to make a measurement on the image. If additional points are needed, the method proceeds to block **814** where a user touches and releases the displayed image at a different location. Note that in this branch of method **800**, the measurement software is in area-point mode so that all entries will be interpreted as points and, when an input is detected, a point will be drawn on the image in block **810** regardless of the distance between a start point and end point of the input. If no additional points are needed to make a measurement in decision block **812**, the method **800** proceeds to block **816**, where a user selects a 'Done' button in the bedside controller GUI to exit area-point mode. In block **818**, the measurement software creates an area measurement using the entered points. For example, in an embodiment directed toward vessel measurement, the measurement software connects the entered points to create a bounding circle at the vessel's outer edge. In one embodiment, the measurement software uses the entered points as seed points to assist edge detection algorithms.

[0040] With reference back to decision block **808**, if the distance between the start point and the end point is greater than or equal to the threshold, the method **800** proceeds to decision block **820** where the measurement software determines whether the drawn line is "relatively straight". That is, it determines whether the user desires to measure a diameter with a line or an area with an enclosed shape. As shown in FIG. **10**, to make such a determination, the measurement software compares intervening points on the traced line between a start point **1000** and an end point **1002** against a boundary threshold **1004**. If all intervening points are within the boundary threshold **1004**, the measurement software determines that the user desires to make a diameter measurement and transforms the traced line into a straight line **1006** extending from the start point to the end point. The diameter measurement is thus based on the length of the straight line **1006**. In alternative embodiments, however, the measurement software may employ different methods for determining whether the user desires to make a diameter measurement or an area measurement, such as detecting whether intervening points between start and end points increase in distance from the start point before decreasing in distance from the start point or detecting whether the traced line extending through the start point, at least one intervening point, and the end point is arcuate past a threshold degree. At decision block **820**, if the user's traced line is relatively straight, the method proceeds to block **822** where the measurement software enters diameter mode and outputs a measurement of the straight line **1006** created between the start and end points. If, however, the traced line is not relatively straight, the method **800** proceeds to **818** where the measurement software enters area-draw mode. As shown in FIG. **11**, the traced line **1100** between start point **1102** and end point **1104** extends outside of a boundary threshold (not shown) and is thus not relatively straight, prompting the measurement software to enter area-draw mode. Once this determination is made, the software connects the start and ends points to create an unbroken bounding line **1006** from which an area may be calculated. After an area measurement has been made in block **818** (either in area-point mode or area-draw mode), the method proceeds to decision block **824** where it is determined if another measurement needs to be done. If so, the method proceeds back to block **802** where a user selects another start point on the image without first selecting a measurement mode. If all measurements have been completed, the method **800** ends.

[0041] It is understood that the methods **700** and **800** illustrated in the flow charts of FIGS. **7** and **8** may, in alternative embodiments, be performed in a different order and may include different and/or additional blocks in some embodiments. For example, workflows for some medical sensing procedure may allow for additional measurement modes, such as volumetric measurements. According to the described aspects of the present disclosure, a user may initiate any such additional measurement modes without first selecting a measurement mode, thus simplifying the workflow. Further, the steps in methods **700** and **800** described above may be completed over the course of more than one patient visit to a catheter lab.

[0042] Although illustrative embodiments have been shown and described, a wide range of modification, change, and substitution is contemplated in the foregoing disclosure and in some instances, some features of the present disclosure may be employed without a corresponding use of the other features. For example, in some embodiments, the touch-enabled integrated bedside controllers **102** and **300** may be used to control and measure non-cardiovascular diagnostic data such as data from cranial or peripheral arteries, as well as data from non-vascular body portions. Further, the controllers **102** and **300** may be used to control an MRI workflow and measure MRI image data, or may be utilized in computer assisted surgery (CAS) applications. Further, the modules described above in association with the bedside controller **300** may be implemented in hardware, software, or a combination of both. And the bedside controller may be designed to enable user control in many different network settings such as ad-hoc networks, local area networks, client-server networks, wide area networks, internets, and the controller may have a number of form factors such as a tablet, a smartphone, a laptop, or any other similar device. It is understood that such variations may be made in 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 scope of the present disclosure.

What is claimed is:

1. A method of conducting a medical workflow with a touch-sensitive bedside controller, the method comprising:
- initiating a medical workflow using a graphical user interface on the bedside controller;
- positioning an imaging tool within a patient's body based on images captured by the imaging tools and displayed on the bedside controller;
- controlling the initiation and termination of a recordation of images by the imaging tool using the graphical user interface on the bedside controller;
- navigating through the recorded images to identify an image of interest using the graphical user interface on the bedside controller; and
- performing measurements on the image of interest using the graphical user interface on the bedside controller.

2. The method of claim **1**, wherein the initiating includes selecting the medical workflow out of a plurality of medical workflows presented as selectable options within the graphical user interface.

3. The method of claim **2**, wherein the plurality of medical workflows includes two or more of an intravascular ultrasound (IVUS) imaging workflow, an intravascular photoacoustic (IVPA) imaging workflow, an optical coherence tomography (OCT) workflow, a forward looking IVUS (FL-IVUS) workflow, a fractional flow reserve (FFR) workflow, a coronary flow reserve (CFR) workflow, and an angiography workflow.

4. The method of claim **1**, wherein the performing measurements includes touching and releasing portions of the image of interest as it is displayed on the bedside controller to make one of an area measurement and a diameter measurement.

5. The method of claim **4**, wherein the touching and releasing includes making one of the area measurement and the diameter measurement without first selecting a measurement mode corresponding one of the area measurement and the diameter measurement.

6. The method of claim **1**, wherein the initiating, positioning, controlling, navigating, and performing are performed on the bedside controller in a sterile field.

7. The method of claim **1**, wherein navigating through the recorded images includes navigating through a condensed view of all of the recorded images.

8. The method of claim **1**, wherein navigating through the recorded images includes performing navigation-type gestures on the touch-sensitive display.

9. The method of claim **1**, wherein performing measurements includes annotating the image of interest with the measurements.

10. The method of claim **9**, further including saving to a processing system the image of interest with the measurement annotations thereon.

11. The method of claim **1**, wherein the imaging tool is a sensor disposed on a catheter within a vessel of the patient.

12. The method of claim **11**, wherein the controlling includes coordinating the recordation with a pullback of the catheter.

13. The method of claim **1**, wherein controlling the initiation and termination includes selecting a record option in the graphical user interface to initiate the recordation.

14. The method of claim **1**, further including receiving haptic feedback in response to performing measurements on the image of interest using the graphical user interface.

15. The method of claim **1**, wherein the images captured by the imaging tool are associated with one of intravascular ultrasound (IVUS), intravascular photoacoustic (IVPA), optical coherence tomography (OCT), forward looking IVUS (FL-IVUS), fractional flow reserve (FFR), coronary flow reserve (CFR), and angiography.

16. A bedside controller, comprising:
- a housing;
- a touch-sensitive display disposed within a surface of the housing and configured to display images and receive user input on the surface;
- a processor disposed within the housing;
- a communication module disposed within the housing, communicatively coupled to the processor, and configured to transmit and receive medical data; and
- a non-transitory computer readable storage module disposed within the housing, communicatively coupled to the processor, and including a plurality of instructions stored therein and executable by the processor, the plurality of instructions including:
  - instructions for rendering a graphical user interface (GUI) on the touch-sensitive display;
  - instructions for displaying images of a patient as they are being captured by an imaging tool disposed within the patient's body;
  - instructions for initiating and terminating a recordation of the images based on user input to the GUI;
  - instructions for displaying the recorded images within the GUI so that a user may identify an image of interest; and
  - instructions for making a measurement on the image of interest based on a user measurement input to the GUI.

17. The bedside controller of claim **16**, wherein the images of the patient are associated with one of intravascular ultrasound (IVUS), intravascular photoacoustic (IVPA), optical coherence tomography (OCT), forward looking IVUS (FL-IVUS), fractional flow reserve (FFR), coronary flow reserve (CFR), and angiography.

18. The bedside controller of claim **16**, wherein the plurality of instructions includes instructions for presenting a plurality of workflow modes selectable by a user through the GUI.

19. The bedside controller of claim **18**, wherein the plurality of instructions includes instructions for receiving a user selection of a workflow mode out of the plurality of workflow modes through the GUI.

20. The bedside controller of claim **18**, wherein the plurality of workflow modes includes two or more of an intravascular ultrasound (IVUS) imaging mode, an intravascular photoacoustic (IVPA) imaging mode, an optical coherence tomography (OCT) mode, a forward looking IVUS (FL-IVUS) mode, a fractional flow reserve (FFR) mode, a coronary flow reserve (CFR) mode, and an angiography mode.

21. The bedside controller of claim **16**, wherein the instructions for displaying the recorded images within the GUI includes instructions for displaying a condensed view of all of the recorded images.

22. The bedside controller of claim **16**, wherein the instructions for displaying the recorded images within the GUI includes instructions for receiving gesture inputs through the touch-sensitive display for navigation through the recorded images.

23. The bedside controller of claim **16**, wherein the plurality of instructions includes instructions for annotating the image of interest with the measurements.

24. The bedside controller of claim **23**, wherein the plurality of instructions includes instructions for saving to a processing system the image of interest with the measurement annotations thereon.

25. The bedside controller of claim **16**, wherein the imaging tool is a sensor disposed on a catheter within a vessel of the patient.

26. The bedside controller of claim **25**, wherein the instructions for initiating and terminating include instructions for coordinating the recordation with a pullback of the catheter.

27. The bedside controller of claim **16**, wherein the instructions for making a measurement include instructions for selecting one of an area measurement mode and a diameter measurement mode based on the user measurement input.

28. The bedside controller of claim **16**, wherein the instructions for rendering a GUI on the touch-sensitive display include instructions for providing haptic feedback in response to touch-based input to the GUI.

29. The bedside controller of claim **16**, wherein the instructions for displaying the recorded images include instructions for displaying a three-dimensional rendering of a portion of the patient's body.

30. The bedside controller of claim **29**, wherein the instructions for displaying a three-dimensional rendering include: instructions for receiving multiple concurrent touch inputs via the touch-sensitive display; and instructions for rotating the three-dimensional rendering about an axis based on the multiple concurrent touch inputs.

* * * * *

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摘要(译)

公开了一种利用触敏床边控制器进行医疗工作流程的方法。该方法包括使用床边控制器上的图形用户界面启动医疗工作流程，基于由成像工具捕获并显示在床边控制器上的图像将成像工具定位在患者体内，控制图像记录的开始和终止由成像工具使用床边控制器上的图形用户界面捕获，使用床边控制器上的图形用户界面导航记录的图像以识别感兴趣的图像，并使用图形用户界面对感兴趣的图像执行测量床边控制器。