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(54) **INTRAVASCULAR ULTRASOUND PATIENT INTERFACE MODULE (PIM) FOR DISTRIBUTED WIRELESS INTRALUMINAL IMAGING SYSTEMS**

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A61B 8/00 (2006.01)

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CPC ***A61B 8/12*** (2013.01); ***A61B 8/445*** (2013.01); ***A61B 8/4472*** (2013.01); ***A61B 8/461*** (2013.01); ***A61B 8/54*** (2013.01); ***A61B 8/565*** (2013.01)

(58) **Field of Classification Search**
CPC A61B 8/12; A61B 8/445; A61B 8/4472; A61B 8/461; A61B 8/54; A61B 8/565
See application file for complete search history.

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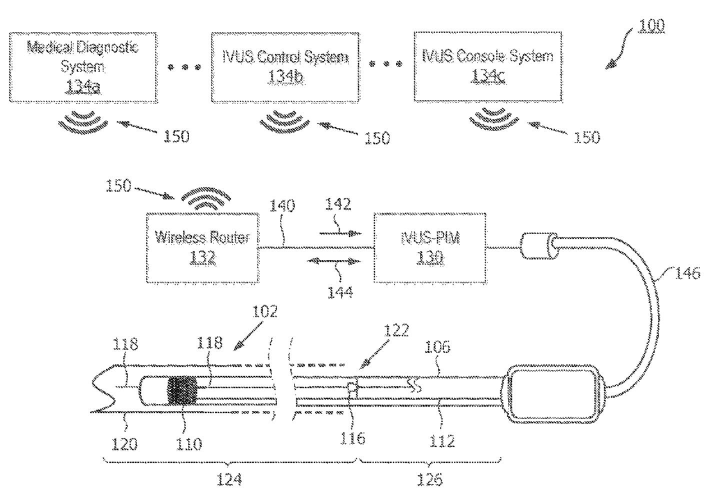
(57) **ABSTRACT**

An intraluminal imaging system is provided. The intraluminal imaging system includes a patient interface module (PIM) in communication with an intraluminal device comprising an ultrasound imaging component and positioned within a body lumen of a patient, a wireless router via an signal link, and a computing device in wireless communication with the wireless router, wherein the PIM comprises a processing component configured to receive an ultrasound echo signal from the ultrasound imaging component; and determine image data based on at least the ultrasound echo signal; and a power and communication component configured to receive power from the signal link; and transmit, to

(Continued)



the computing device via the signal link and the wireless router, the image data.

20 Claims, 6 Drawing Sheets

Related U.S. Application Data

(60) Provisional application No. 62/479,152, filed on Mar. 30, 2017.

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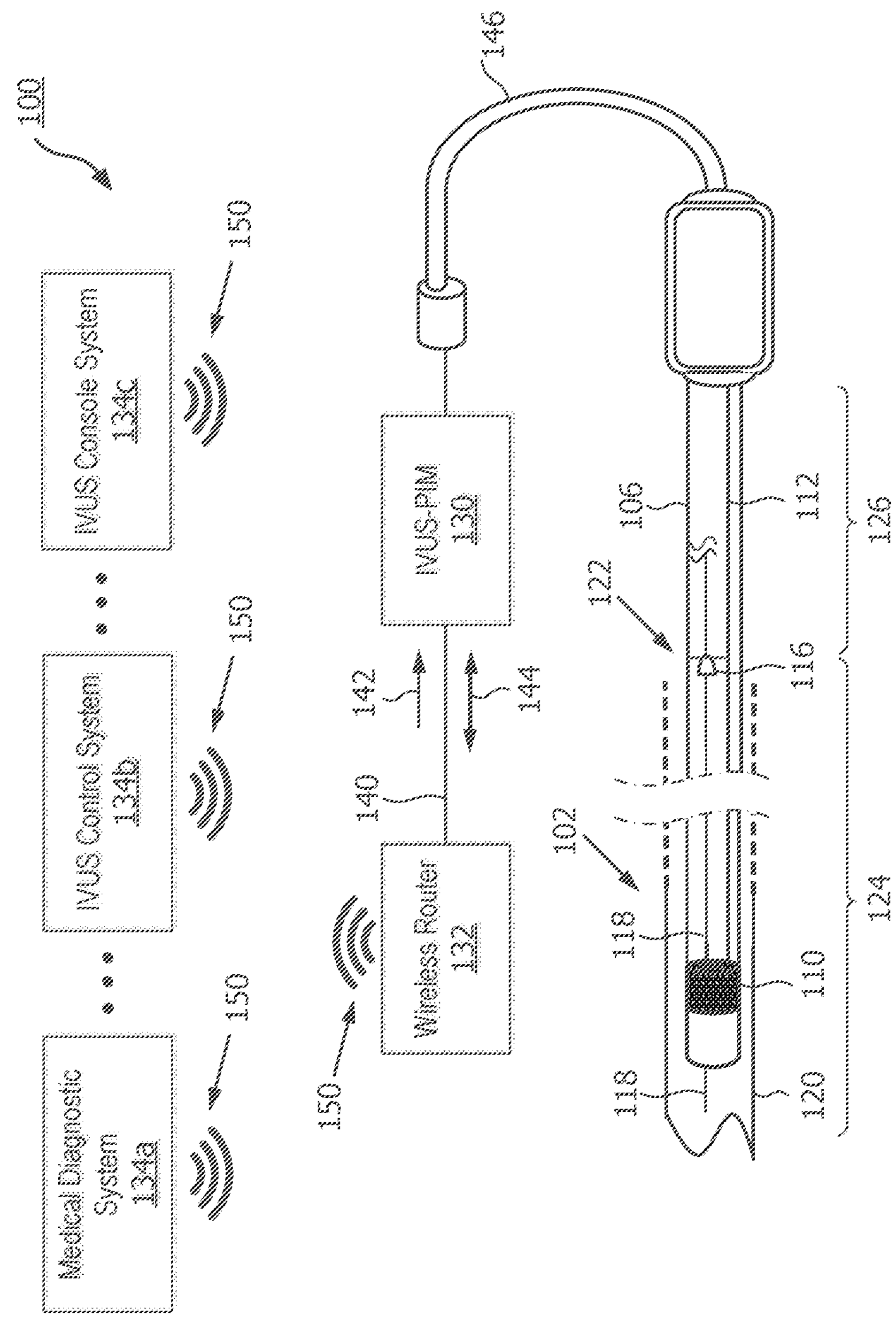
100
Medical Diagnostic System 134a
IVUS Control System 134b
IVUS Console System 134c
150
150
150
150
Wireless Router 132
IVUS-PIM 130
140
142
144
146
102
106
110
112
116
118
118
120
122
124
126

FIG. 1

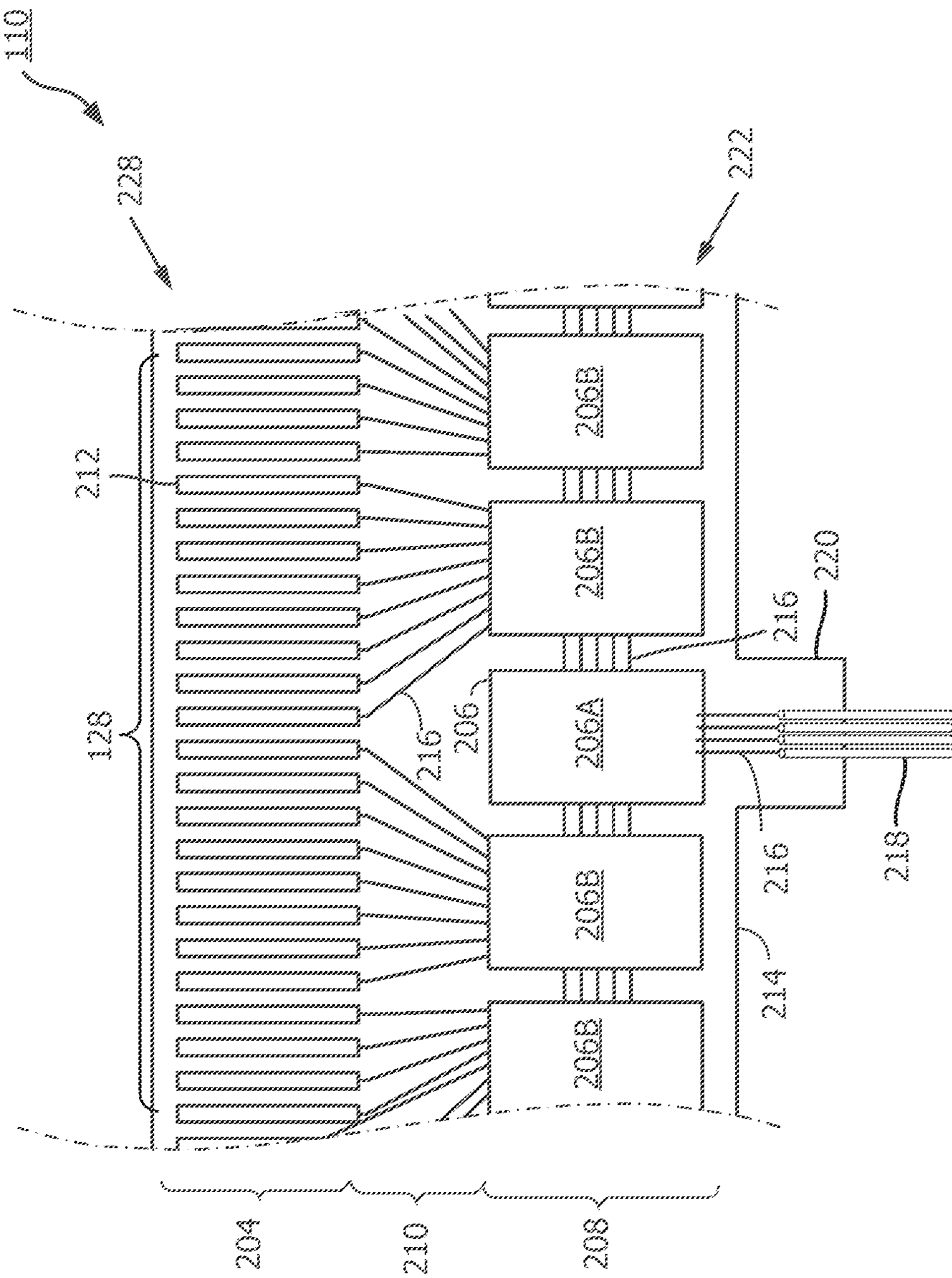
110
228
222
212
128
206B
206B
206A
206
206B
206B
216
216
216
220
112
218
214
204
210
208

FIG. 2

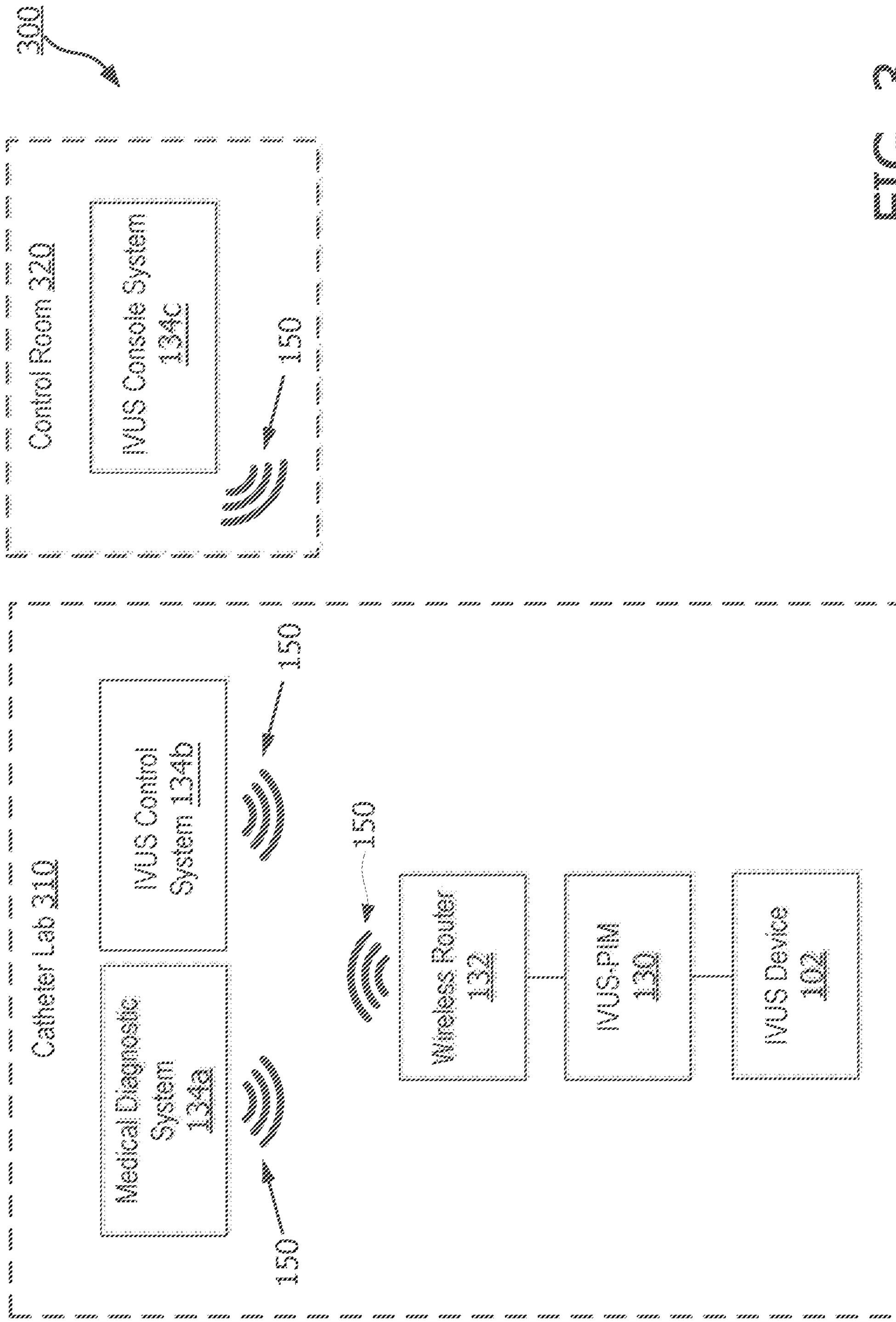
300
Control Room 320
IVUS Console System
134c
150
Catheter Lab 310
Medical Diagnostic
System
134a
150
IVUS Control
System 134b
150
150
Wireless Router
132
IVUS-PIM
130
IVUS Device
102

FIG. 3

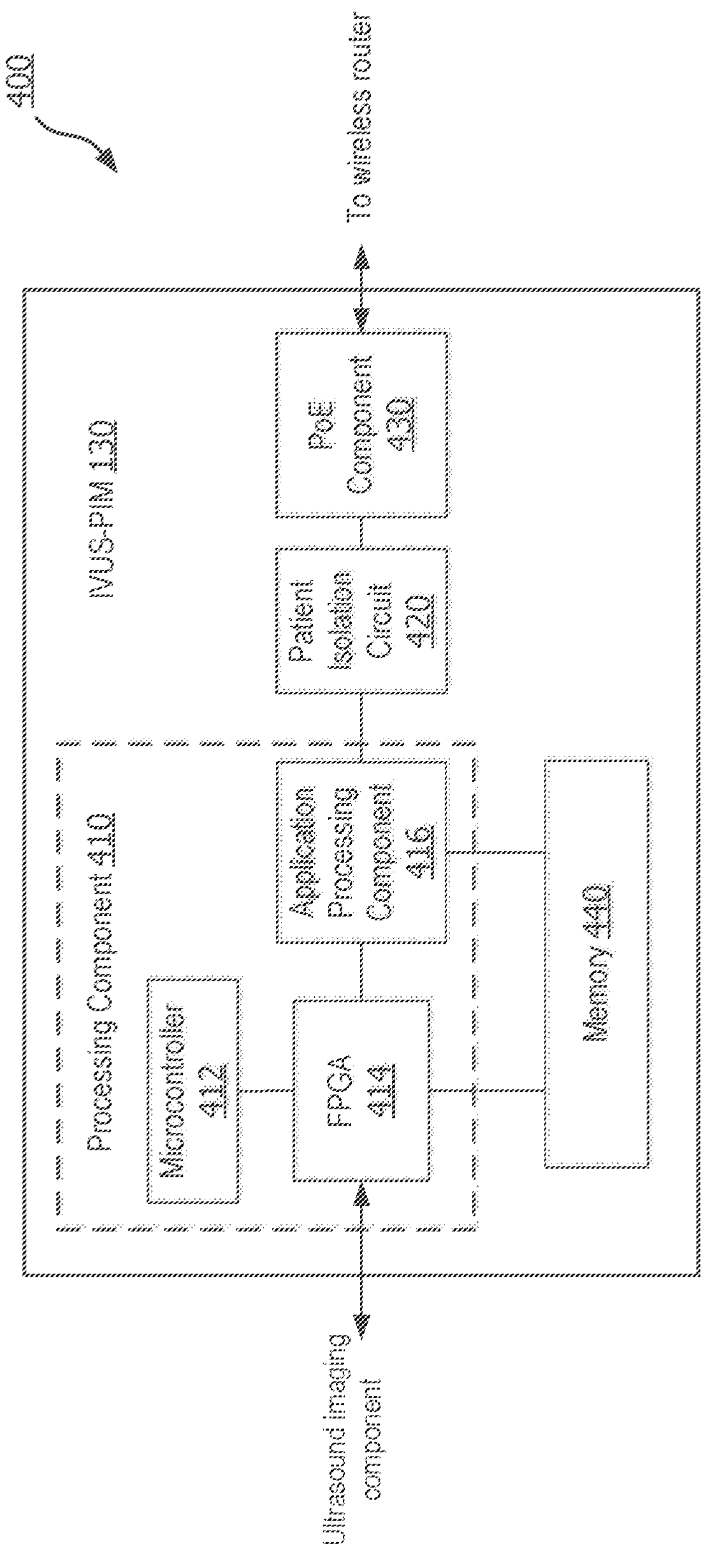
400
To wireless router
IVUS-PIM 130
Processing Component 410
Microcontroller 412
FPGA 414
Application Processing Component 416
Patient Isolation Circuit 420
PoE Component 430
Memory 440
Ultrasound imaging component

FIG. 4

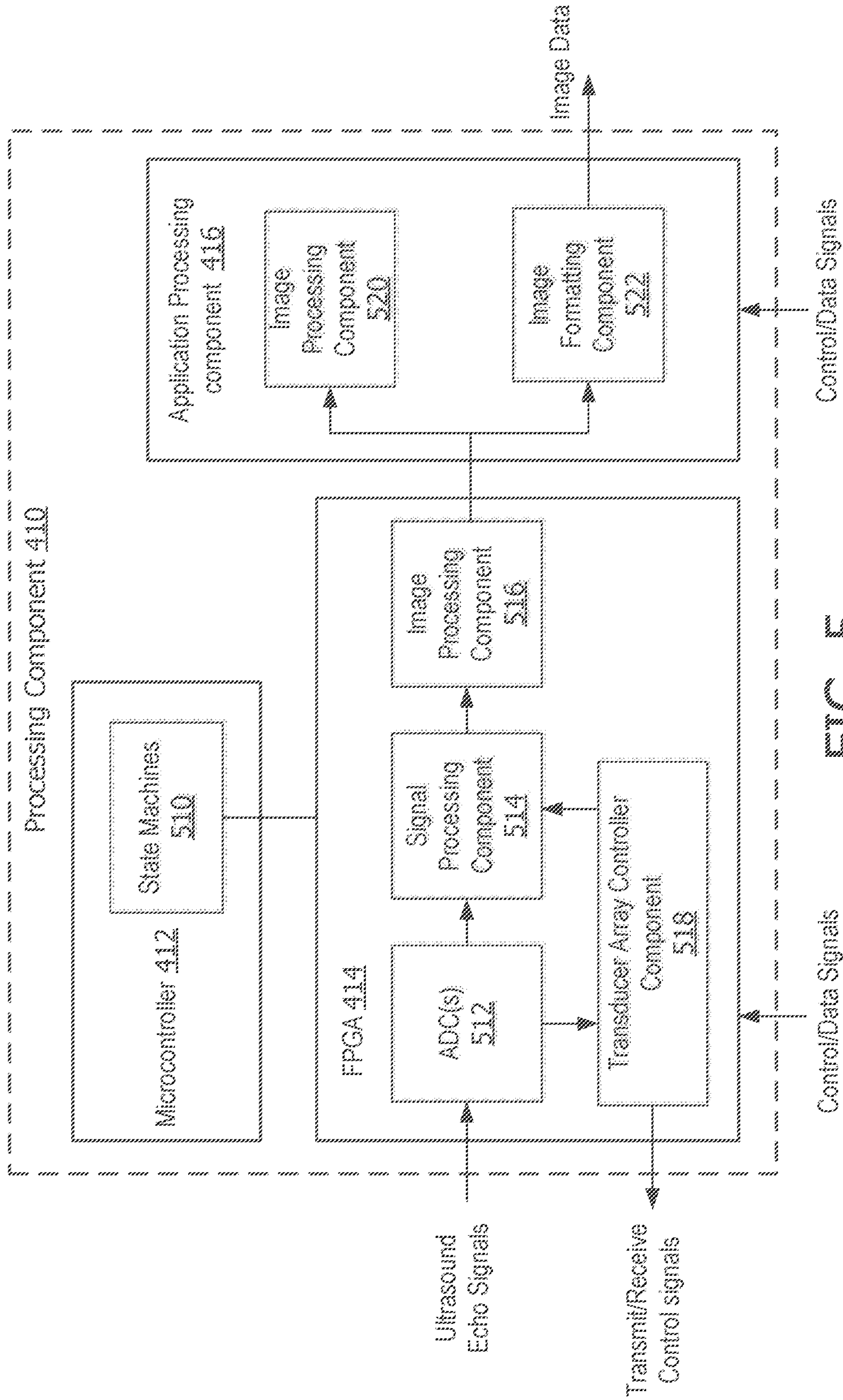
Processing Component 410
Microcontroller 412
State Machines 510
FPGA 414
ADC(s) 512
Signal Processing Component 514
Image Processing Component 516
Transducer Array Controller Component 518
Application Processing component 416
Image Processing Component 520
Image Formatting Component 522
Image Data
Control/Data Signals
Control/Data Signals
Ultrasound Echo Signals
Transmit/Receive Control signals

FIG. 5

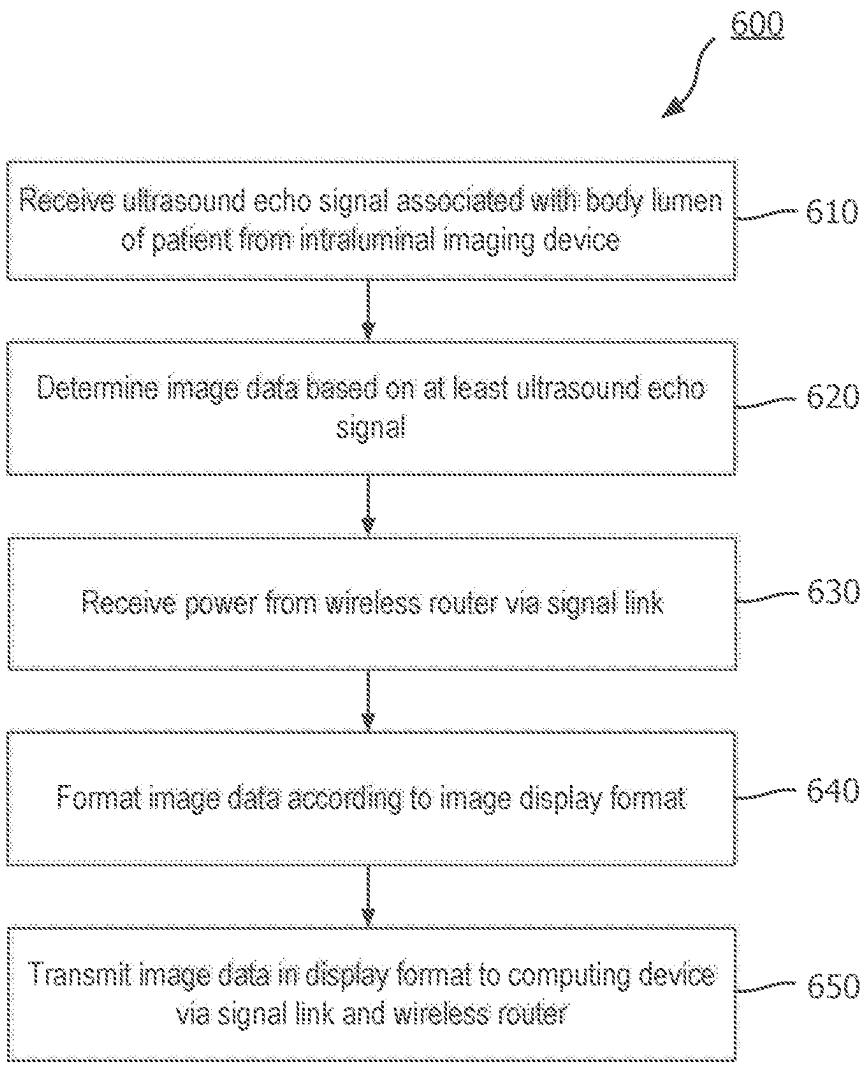
600
Receive ultrasound echo signal associated with body lumen of patient from intraluminal imaging device
610
Determine image data based on at least ultrasound echo signal
620
Receive power from wireless router via signal link
630
Format image data according to image display format
640
Transmit image data in display format to computing device via signal link and wireless router
650

FIG. 6

INTRAVASCULAR ULTRASOUND PATIENT INTERFACE MODULE (PIM) FOR DISTRIBUTED WIRELESS INTRALUMINAL IMAGING SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 16/496,095, filed Sep. 20, 2019, now U.S. Pat. No. 11,950,954, which is the national stage entry of International Application No. PCT/EP2018/055361, filed Mar. 5, 2018, which claims priority to and the benefit of U.S. Provisional Application No. 62/479,152, filed Mar. 30, 2017, each of which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

The present disclosure relates generally to intraluminal imaging and, in particular, to decoupling image processing and image generation from control and display by generating image data at an intravascular ultrasound (IVUS)-patient interface module (PIM) and distributing the image data wirelessly to multiple diagnostic console and/or control systems via a wireless router.

BACKGROUND

Intravascular ultrasound (IVUS) imaging is widely used in interventional cardiology as a diagnostic tool for assessing a diseased vessel, such as an artery, within the human body to determine the need for treatment, to guide the intervention, and/or to assess its effectiveness. An IVUS device including one or more ultrasound transducers is passed into the vessel and guided to the area to be imaged. The transducers emit ultrasonic energy in order to create an image of the vessel of interest. Ultrasonic waves are partially reflected by discontinuities arising from tissue structures (such as the various layers of the vessel wall), red blood cells, and other features of interest. Echoes from the reflected waves are received by the transducer and passed along to an IVUS imaging system. The imaging system processes the received ultrasound echoes to produce a cross-sectional image of the vessel where the device is placed. IVUS imaging can provide detailed and accurate measurements of lumen and vessel sizes, plaque areas and volumes, and location of key anatomical landmarks. IVUS imaging allows physicians to evaluate the size of a lesion, select a treatment device (e.g., a stent) based on the evaluated lesion size, and subsequently evaluate the treatment success.

There are two types of IVUS catheters commonly in use today: rotational and solid-state. For a typical rotational IVUS catheter, a single ultrasound transducer element is located at the tip of a flexible driveshaft that spins inside a plastic sheath inserted into the vessel of interest. The transducer element is oriented such that the ultrasound beam propagates generally perpendicular to the axis of the device. The fluid-filled sheath protects the vessel tissue from the spinning transducer and driveshaft while permitting ultrasound signals to propagate from the transducer into the tissue and back. As the driveshaft rotates, the transducer is periodically excited with a high voltage pulse to emit a short burst of ultrasound. The same transducer then listens for the returning echoes reflected from various tissue structures. The IVUS imaging system assembles a two dimensional display of the vessel cross-section from a sequence of pulse/acquisition cycles occurring during a single revolution of the transducer.

Solid-state IVUS catheters carry an ultrasound imaging assembly that includes an array of ultrasound transducers distributed around its circumference along with one or more integrated circuit controller chips mounted adjacent to the transducer array. The solid-state IVUS catheters are also referred to as phased array IVUS transducers or phased array IVUS devices. The controllers select individual transducer elements (or groups of elements) for transmitting an ultrasound pulse and for receiving the ultrasound echo signal. By stepping through a sequence of transmit-receive pairs, the solid-state IVUS system can synthesize the effect of a mechanically scanned ultrasound transducer but without moving parts (hence the solid-state designation). Since there is no rotating mechanical element, the transducer array can be placed in direct contact with the blood and vessel tissue with minimal risk of vessel trauma.

In operation, an IVUS device may be connected to a number of cables, for example, a power cable and a communication cable. The IVUS device may receive power from the power cable for operating an ultrasound imaging assembly included in the IVUS device. The IVUS device may communicate with a console or processing system over the communication cable for controlling the operations of the ultrasound imaging assembly and reading out measurements (e.g., ultrasound echo signals) collected by the ultrasound imaging assembly, analyzing and processing the images for display.

IVUS procedures are typically performed in a catheter lab. The use of the IVUS device in the catheter lab increases the number of cables in the catheter lab and may clutter the workspace of the catheter lab. In some instances, it may be desirable to output image data to multiple diagnostic systems for various aspects of a workflow, which further increasing the amount of cabling. These conditions can make a physician's ability to gather medical images and/or data for patient diagnosis more challenging.

SUMMARY

While existing intraluminal imaging systems have proved useful, there remains a need for improved systems and techniques for reducing the amount of cabling between intraluminal imaging devices and systems in catheter labs. Embodiments of the present disclosure provide an IVUS-PIM that determines image data based on ultrasound echo signals collected from an ultrasound imaging component and distributes the image data wirelessly to multiple systems via a power over Ethernet (PoE) connection to a wireless router. For example, the IVUS-PIM is coupled to an intraluminal imaging device including an ultrasound imaging component and a wireless router via an Ethernet cable. The IVUS-PIM includes a processing component coupled to the ultrasound imaging component and a PoE component coupled to the Ethernet cable. The PoE component receives power from the Ethernet cable to power the IVUS-PIM and the intraluminal imaging device. During a medical procedure, the intraluminal imaging device can be inserted into a vessel of a patient and the ultrasound imaging component can emit ultrasound signals and receive ultrasound echo signal reflected from the structure of the vessel. The processing component receives the ultrasound echo signals and applies imaging algorithms to determine image data from the received ultrasound echo signals. The processing component formats the image data into a suitable image display format. The PoE component transmits and distributes the image data to one or more diagnostic systems that are in wireless communication with the wireless router. The PoE component can also receive control and/or data signals from one or more diagnostic systems for imaging and image processing and generation.

In one embodiment, an intraluminal imaging system is provided. The intraluminal imaging system includes a patient interface module (PIM) in communication with an intraluminal device comprising an ultrasound imaging component and positioned within a body lumen of a patient, a wireless router via a signal link, and a computing device in wireless communication with the wireless router, wherein the PIM comprises a processing component configured to receive an ultrasound echo signal from the ultrasound imaging component; and determine image data based on at least the ultrasound echo signal; and a power and communication component configured to receive power from the signal link; and transmit, to the computing device via the signal link and the wireless router, the image data.

In some embodiments, the power and communication component is further configured to receive a control signal from the computing device via the signal link and the wireless router, and wherein the processing component is further configured to receive the ultrasound echo signal based on at least the control signal. In some embodiments, the power and communication component is further configured to receive a control signal from the computing device via the signal link and the wireless router, wherein the processing component is further configured to transmit an ultrasound signal transmission trigger to the ultrasound imaging component based on at least the control signal, and wherein the ultrasound echo signal is associated with the ultrasound signal transmission trigger. In some embodiments, the power and communication component is further configured to receive a control signal from the computing device via the signal link and the wireless router, and wherein the processing component is further configured to determine the image data based on the control signal. In some embodiments, the power and communication component is further configured to provide the power received from the signal link to the ultrasound imaging component of the intraluminal device. In some embodiments, the power and communication component is further configured to provide the power received from the signal link to the processing component. In some embodiments, the PIM further includes a memory coupled to the processing component and configured to store the image data. In some embodiments, the power and communication component is further configured to receive, from a medical diagnostic system via the signal link and the wireless router, an image border line, and wherein the processing component is further configured to determine the image data further according to the image border line. In some embodiments, the intraluminal system further comprises the intraluminal device. In some embodiments, the ultrasound imaging component comprises one or more ultrasound transducers. In some embodiments, the PIM further comprises a patient isolation circuit coupled between the power and communication component and the processing component. In some embodiments, the processing component is further configured to format the image data according to an image display format usable by the computing device to display the image data, and wherein the power and communication component is further configured to transmit the image data by transmitting the image data in the image display format usable by the computing device to display the image data. In some embodiments, the PIM is in communication with a second computing device in wireless communication with the wireless router, and wherein the power and communication component is further configured to transmit, to the second computing device via the signal link and the wireless router, the image data.

In one embodiment, a method of performing intraluminal imaging includes receiving, by a patient interface module (PIM) from an intraluminal imaging device, an ultrasound echo signal associated with a body lumen of a patient; determining, by the PIM, image data based on at least the ultrasound echo signal; receiving, by the PIM, power from a wireless router via a signal link; and transmitting, by the PIM to a computing device via the signal link and the wireless router, the image data.

In some embodiments, the method further includes receiving, by the PIM from the computing device via the signal link and the wireless router, a control signal, wherein the receiving the ultrasound echo signal includes receiving the ultrasound echo signal based on at least the control signal. In some embodiments, the method further includes receiving, by the PIM from the computing device via the signal link and the wireless router, a control signal; and transmitting, by the PIM to the intraluminal imaging device, an ultrasound signal transmission trigger based on at least the control signal, wherein the ultrasound echo signal is associated with the ultrasound signal transmission trigger. In some embodiments, the method further includes receiving, by the PIM from the computing device via the signal link and the wireless router, a control signal, wherein the determining the image data includes determining the image data further based on at least the control signal. In some embodiments, the method further includes receiving, by the PIM from a medical diagnostic system via the signal link and the wireless router, an image border line, wherein the determining the image data includes determining the image data according to the image border line. In some embodiments, the method further includes formatting, by the PIM, the image data according to an image display format of the computing device, wherein the transmitting the image data includes transmitting the image data in the image display format of the computing device. In some embodiments, the method further includes transmitting, by the PIM to a second computing device via the signal link and the wireless router, the image data.

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

FIG. **1** is a schematic diagram of a distributed wireless intraluminal imaging system, according to aspects of the present disclosure.

FIG. **2** is a top view of a portion of an ultrasound imaging assembly, according to aspects of the present disclosure.

FIG. **3** illustrates a use case scenario for a distributed wireless intraluminal imaging system, according to aspects of the present disclosure.

FIG. **4** is a schematic diagram illustrating an architecture of an IVUS-patient interface module (PIM), according to aspects of the present disclosure.

FIG. **5** is a schematic diagram illustrating functional blocks of an IVUS-PIM, according to aspects of the present disclosure.

FIG. **6** is a flow diagram of a method of performing ultrasound imaging, according to aspects of the present disclosure.

DETAILED DESCRIPTION

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

FIG. **1** is a schematic diagram of a distributed wireless intraluminal imaging system **100**, according to aspects of the present disclosure. The system **100** may include an IVUS device **102**, an IVUS-PIM **130**, a wireless router **132**, a plurality of distributed systems **134**, for example, including a medical diagnostic system **134***a*, an IVUS control system **134***b*, and an IVUS console system **134***c*. The IVUS-PIM **130** is in communication with the IVUS device **102** and the wireless router **132**. The IVUS-PIM **130** is connected to the wireless router **132** via an Ethernet cable **140**. The Ethernet cable **140** functions as a signal link or PoE link delivering power to the IVUS-PIM **130** and the IVUS device **102** as shown by the arrow **142** and transporting data between the IVUS-PIM **130** and the wireless router **132** as shown by the arrow **144**. The wireless router **132** is in wireless communication with the systems **134** as shown by the radio frequency (RF) signals **150**. Thus, the IVUS-PIM **130** can communicate with one or more of the systems **134** via the wireless router **132**.

The IVUS device **102** may include a flexible elongate member **106**, which may be a catheter, a guide wire, or a guide catheter. The IVUS device **102** may further include an ultrasound imaging assembly **110**. The ultrasound imaging assembly **110** may be mounted at a distal portion **124** near a distal end of the flexible elongate member **106**.

The IVUS-PIM **130** is coupled to a proximal end of the flexible elongate member **106**. The IVUS device **102** further includes an electrical cable **112** extending along the flexible elongate member **106** between the ultrasound imaging assembly **110** and the IVUS-PIM **130**. The electrical cable **112** may carry control signals, echo data, and/or power between the IVUS-PIM **130** and the IVUS device **102**.

At a high level, the IVUS device **102** can be inserted into a vessel **120** of a patient. The IVUS device **102** emits ultrasonic energy from a transducer array included in the ultrasound imaging assembly **110**. The ultrasonic energy is reflected by tissue structures of the vessel **120** surrounding the ultrasound imaging assembly **110**, and the ultrasound echo signals are received by the transducer array in the ultrasound imaging assembly **110**. The electrical cable **112** transfers the ultrasound echo signals to the IVUS-PIM **130**.

The vessel **120** may represent fluid filled or surrounded structures, both natural and man-made. The vessel **120** may be within a body of a patient. The vessel **120** may be a blood vessel, as an artery or a vein of a patient's vascular system, including cardiac vasculature, peripheral vasculature, neural vasculature, renal vasculature, and/or or any other suitable lumen inside the body. For example, the IVUS device **102** may be used to examine any number of anatomical locations and tissue types, including without limitation, organs including the liver, heart, kidneys, gall bladder, pancreas, lungs; ducts; intestines; nervous system structures including the brain, dural sac, spinal cord and peripheral nerves; the urinary tract; as well as valves within the blood, chambers or other parts of the heart, and/or other systems of the body. In addition to natural structures, the IVUS device **102** may be used to examine man-made structures such as, but without limitation, heart valves, stents, shunts, filters and other devices.

The IVUS-PIM **130** includes a processing component (a processing component **410** shown in FIGS. **4** and **5**), which may include hardware and/or software, configured to determine image data based on the ultrasound echo signals, for example, by applying image processing algorithms and/or image analytic algorithms to the ultrasound echo signals. For example, the IVUS-PIM **130** can generate image data for a cross-sectional view of the vessel **120**.

In an embodiment, the IVUS device **102** further includes a guide wire exit port **116** disposed near a junction **122** at which a distal portion **124** is coupled to a proximal portion **126**. Accordingly, in some instances the IVUS device **102** is a rapid-exchange catheter. The guide wire exit port **116** allows a guide wire **118** to be inserted towards the distal end in order to direct the IVUS device **102** through the vessel **120**.

The IVUS-PIM **130** further includes a power and communication component (a PoE component **430** shown in FIG. **4**) coupled to the wireless router **132** by the Ethernet cable **140**. The wireless router **132** functions as a power sourcing equipment and the IVUS-PIM **130** function as a power device. For example, the power and communication component of the IVUS-PIM **130** draws power from the wireless router **132** and provides the power to the ultrasound imaging assembly **110** over the electrical cable **112**. Electrical signals can be transmitted between the IVUS-PIM **130** and the IVUS device **102** via a cable **146**.

The Ethernet cable **140** includes multiple twisted pairs. The Ethernet cable **140** can transport power and data over different twisted pairs or the same twisted pairs as described in Institute of Electrical and Electronics Engineers (IEEE) 802.3 standards. The internal components of the IVUS-PIM **130** are described in greater detail herein with respect to FIGS. **4** and **5**. The IVUS-PIM **130** communicates the image data to the wireless router **132** via the Ethernet cable **140**.

The wireless router **132** may be any wireless communication device or access point configured with support for transporting data and power (e.g., PoE support). The wireless router **132** may include transceivers and antennas configured to communicate with the systems **134** according to any suitable wireless communication protocols, such as IEEE 802.11 (WiFi) standards, fifth generation (5G) wireless communication protocols, or any advanced wireless communication protocol. For example, the wireless router **132** may forward signals received from the systems **134** to the IVUS-PIM **130**. In a reverse direction, the wireless router **132** may forward signals received from the IVUS-PIM **130** to the systems **134**. The wireless router **132** may include a power and communication component configured to deliver power to the IVUS-PIM **130** and to transport data via the Ethernet cable **140**, for example, according to the IEEE 802.3 standards.

The systems **134** may include computing devices including hardware and/or software, consoles, keyboards, display monitors, and/or touchscreens for controlling and/or monitoring physiologic assessments and measurements. The systems **134** may further include wireless communication devices including transceivers and antennas for wireless communication with the wireless router **132**. The wireless communication devices may implement a similar wireless communication protocol as the wireless router **132** for communication with the wireless router **132**. Thus, in some embodiments, the systems **134** may be wireless computer workstations, wireless tablets, and/or any mobile devices.

The IVUS control system **134***b* can send control signals carrying commands for performing medical imaging using the IVUS device **102** and the wireless router **132** can forward the control signals to the IVUS-PIM **130**. For example, the IVUS control system **134***b* may function similar to a bedside controller. The IVUS-PIM **130** can control the ultrasound imaging assembly **110** and/or generate image data according to the control commands. For example, during a medical imaging procedure, a clinician may operate the IVUS control system **134***b* by sending a start command to begin imaging and generate image data, a recording command to record generated image data, a stop command to stop the acquisition, and/or sending ultrasound signal transmission and/or reception triggers to obtain certain imaging views.

The IVUS-PIM **130** may send the generated image data to the IVUS control system **134***b* for display via the Ethernet cable **140** and the wireless router **132**. In some embodiments, the IVUS-PIM **130** may simultaneously send the generated image data to the IVUS control system **134***b*, the IVUS console system **134***c*, and/or the medical diagnostic system **134***a* for display via the wireless router **132**. In some embodiments, the IVUS console system **134***c* may function as another controller performing different aspects of the workflow than the IVUS control system **134***b*.

The medical diagnostic system **134***a* can perform medical measurements and analysis and facilitate medical imaging. For example, the medical system **134***a* may include instruments or may communicate with instruments performing optical coherence tomography (OCT), electrophysiology (EP) mapping, pressure measurements, flow measurements, and/or electrocardiography (ECG) measurements. The medical diagnostic system **134***a* can display image data generated by the IVUS-PIM **130** in conjunction with the other medical measurements. The medical diagnostic system **134***a* may include user interfaces to enable physicians to request other imaging views and/or further computations based on initial image data generated by the IVUS-PIM **130**. The medical diagnostic system **134***a* may send further requests and/or controls to the IVUS-PIM **130** via the wireless router **132**, as described in greater detail herein.

The system **100** may use any of a variety of ultrasonic imaging technologies. Accordingly, in some embodiments of the present disclosure, the system **100** is a solid-state IVUS imaging system incorporating an array of piezoelectric transducers fabricated from lead-zirconate-titanate (PZT) ceramic. In some embodiments, the system **100** incorporates capacitive micromachined ultrasonic transducers (CMUTs), or piezoelectric micromachined ultrasound transducers (PMUTs).

In some embodiments, the system **100** includes some features similar to s solid-state IVUS system, such as the EagleEye® catheter available from Volcano Corporation and those disclosed in U.S. Pat. No. 7,846,101 hereby incorporated by reference in its entirety. For example, the IVUS device **102** includes the ultrasound imaging assembly **110** near a distal end of the IVUS device **102** and an electrical cable **112** extending along the longitudinal body of the IVUS device **102**. The cable **112** is a transmission line bundle including a plurality of conductors. It is understood that any suitable gauge wire can be used for the conductors **218**. In an embodiment, the cable **112** can include a four-conductor transmission line arrangement with, e.g., 41 American wire gauge (AWG) wires. In some embodiments, the system **100** can include features similar a rotational IVUS system, such as the Revolution® catheter available from Volcano Corporation and features disclosed in U.S. Pat. Nos. 5,601,082 and 6,381,350.

FIG. **2** is a top view of a portion of the solid state or phased array ultrasound imaging assembly **110**, according to aspects of the present disclosure. While FIG. **2** describes a solid state or phased array IVUS imaging assembly, it is understand that features of the present disclosure can be implemented with a rotational IVUS imaging assembly. FIG. **2** illustrates the ultrasound imaging assembly **110** in a flat configuration. The ultrasound imaging assembly **110** includes the transducer array **128** formed in a transducer region **204** and transducer control logic dies **206** (including dies **206**A and **206**B) formed in a control region **208**, with a transition region **210** disposed therein between. The transducer array **128** includes an array of transducers **212**. The transducer control logic dies **206** and the transducers **212** are mounted on a flex circuit **214** in a flat form prior to assembling into a final rolled form as shown in FIG. **1**. The transducer array **128** is a non-limiting example of a medical sensor element and/or a medical sensor element array. The transducer control logic dies **206** is a non-limiting example of a control circuit. While the ultrasound imaging assembly **110** is described as including a flex circuit, it is understood that the transducers and/or controllers may be arranged to form the ultrasound imaging assembly **110** in other configurations, including those omitting a flex circuit.

The transducer array **128** can include any number and type of ultrasound transducers **212**, although for clarity only a limited number of ultrasound transducers are illustrated in FIG. **2**. In an embodiment, the transducer array **128** includes 32 individual ultrasound transducers **212**. In another embodiment, the transducer array **128** includes 64 ultrasound transducers **212**. In another embodiment, the transducer array **128** includes 96 ultrasound transducers **212**. In yet another embodiment, the transducer array **128** includes 128 ultrasound transducers **212**. Other numbers are both contemplated and provided for. With respect to the types of transducers, in an embodiment, the ultrasound transducers **212** are piezoelectric micromachined ultrasound transducers (PMUTs) fabricated on a microelectromechanical system (MEMS) substrate using a polymer piezoelectric material, for example as disclosed in U.S. Pat. No. 6,641,540, which is hereby incorporated by reference in its entirety. In alternate embodiments, the transducer array **128** includes PZT transducers such as bulk PZT transducers, capacitive micromachined ultrasound transducers (cMUTs), single crystal piezoelectric materials, other suitable ultrasound transmitters and receivers, and/or combinations thereof. While FIG. **2** illustrates the ultrasound transducers **212** arranged in a single row, for example, for two-dimensional (2D) imaging, in some embodiments, the ultrasound transducers **212** can be alternatively arranged in multiple rows forming a matrix of ultrasound transducers **212**, for example, for three-dimensional (3D) imaging.

The ultrasound imaging assembly **110** may include various transducer control logic, which in the illustrated embodiment is divided into discrete control logic dies **206**. In various examples, the control logic of the ultrasound imaging assembly **110** performs: decoding control signals sent by the IVUS-PIM **130** across the cable **112**, driving one or more transducers **212** to emit an ultrasonic signal, selecting one or more transducers **212** to receive a reflected echo of the ultrasonic signal, amplifying a signal representing the received echo, and/or transmitting the signal to the IVUS-PIM **130** across the cable **112**. In some embodiments, when the transducer array **128** includes cMUTs, the control logic may further include biasing circuitries to optimize the cMUTs for transmit and/or receive. In the illustrated embodiment, an ultrasound imaging assembly **110** having 64 ultrasound transducers **212** divides the control logic across nine control logic dies **206**, of which five are shown in FIG. **2**. Designs incorporating other numbers of control logic dies **206** including 8, 9, 16, 17 and more are utilized in other embodiments. In general, the control logic dies **206** are characterized by the number of transducers they are capable of driving, and exemplary control logic dies **206** drive **4**, **8**, and/or **16** transducers.

The control logic dies **206** are not necessarily homogenous. In some embodiments, a single controller is designated a master control logic die **206**A and contains the communication interface for the cable **112**. Accordingly, the master control circuit may include control logic that decodes control signals received over the cable **112**, transmits control responses over the cable **112**, amplifies echo signals, and/or transmits the echo signals over the cable **112**. The remaining controllers are slave controllers **206**B. The slave controllers **206**B may include control logic that drives a transducer **212** to emit an ultrasonic signal and selects a transducer **212** to receive an echo. In the depicted embodiment, the master controller **206**A does not directly control any transducers **212**. In other embodiments, the master controller **206**A drives the same number of transducers **212** as the slave controllers **206**B or drives a reduced set of transducers **212** as compared to the slave controllers **206**B. In an exemplary embodiment, a single master controller **206**A and eight slave controllers **206**B are provided with eight transducers assigned to each slave controller **206**B.

To electrically interconnect the control logic dies **206** and the transducers **212**, in an embodiment, the flex circuit **214** further includes conductive traces **216** that carry signals between the control logic dies **206** and the transducers **212**. In particular, the conductive traces **216** providing communication between the control logic dies **206** and the transducers **212** extend along the flex circuit **214** within a transition region **210** between the transducer region **204** and the control region **208**. In some instances, the conductive traces **216** can also facilitate electrical communication between the master controller **206**A and the slave controllers **206**B. The conductive traces **216** can also provide a set of conductive pads that contact the conductors **218** of cable **112** when the conductors **218** of the cable **112** are mechanically and electrically coupled to the flex circuit **214**.

FIG. **3** illustrates a use case scenario **300** for the distributed wireless intraluminal imaging system **100**, according to aspects of the present disclosure. The scenario **300** includes a catheter lab **310** and a control room **320**. The catheter lab **310** is an examination room in a hospital or clinic where a physician or a clinician may perform a medical treatment or diagnostic procedure on a patient, for example, using the IVUS device **102**. The control room **320** may be another room in the hospital or clinic where anther physician or clinician may monitor the image data obtained from the medical procedure during the procedure. For example, the IVUS device **102**, the IVUS-PIM **130**, the wireless router **132**, the medical diagnostic system **134***a*, and the IVUS control system **134***b* are located in the catheter lab **310**, while the IVUS console system **134***c* is located in the control room **320**.

During a medical procedure, a physician may insert the IVUS device **102** into a patient vessel (e.g., the vessel **120**) of interest. The physician may normalize and/or calibrate the IVUS device **102** by operating the IVUS control system **134***b* and/or the medical diagnostic system **134***a* prior to the insertion. The physician may operate the IVUS control system **134***b* for performing the medical procedure. For example, the physician may start, record, and/or stop image data acquisition. The physician may press a start button, for example, via a graphical user interface (GUI) display on the IVUS control system **134**, to begin image data acquisition. The IVUS control system **134** sends a control signal carrying a start command to the wireless router **132**. The wireless router **132** forwards the control signal to the IVUS-PIM **130**. The IVUS-PIM **130** begins to collect ultrasound echo signals from the ultrasound imaging assembly **110** on the IVUS device **102**. The IVUS-PIM **130** computes image data according to the received ultrasound echo signals. The IVUS-PIM **130** transmits the image data to the IVUS control system **134***b*, the medical diagnostic system **134***a*, and/or the IVUS console system **134***c* for display. The physician may also initiate recording and/or stopping the image data acquisition using similar mechanisms as the starting of the data acquisition.

In some embodiments, the medical diagnostic system **134***a* may facilitate image generation at the IVUS-PIM **130**. As described above, the medical diagnostic system **134***a* can include instruments or communicate with instruments operating in other medical diagnostic modalities. For example, a physician operating the medical diagnostic system **134***a* can collect images and/or medical data from the instruments as well as images from the IVUS-PIM **130**. The physician may determine that more detailed images and/or images of certain areas are required. Thus, the physician may request additional images or images at different resolutions and/or different depths and/or provide additional data to the IVUS-PIM **130** for image generation via the medical diagnostic system **134***a*, for example, via a GUI on the medical diagnostic system **134***a*. In an embodiment, a physician may select a border surrounding an area or a structure of interest based on the received images. The medical diagnostic system **134***a* may send a data signal including the selected border to the IVUS-PIM **130**. Upon receiving the data signal, the IVUS-PIM **130** may re-compute image data according to the selected border and/or requests the IVUS device **102** to collect additional ultrasound echo signals for image generation.

FIG. **4** is a schematic diagram illustrating an architecture of the IVUS-PIM **130**, according to aspects of the present disclosure. FIG. **5** is a schematic diagram illustrating functional blocks of the IVUS-PIM **130**, according to aspects of the present disclosure. The IVUS-PIM **130** includes a processing component **410**, a patient isolation circuit **420**, a PoE component **430**, and a memory **440** encased in a housing **400**. The housing **400** may be constructed from a rigid material, such as plastic and/or metal. The processing component **410** is coupled to the memory **440**, and the ultrasound imaging assembly **110** of the IVUS device **102**. The processing component **410** includes a microcontroller **412**, a field programmable gate array (FPGA) **414**, and an application processing component **416**. The patient isolation circuit **420** couples the PoE component **430** to the processing component **410**.

The PoE component **430** is a power and communication component configured to draw power and communicate data via the Ethernet cable **140**. For example, the PoE component **430** may include a PoE controller, an Ethernet device, a direct current (DC)/DC converter. The PoE controller draws or requests power from the wireless router **132** via the Ethernet cable **140**. The PoE device controller may also handle signaling required for PoE communication. The DC/DC converter converts input voltage received from the wireless router **132** into a suitable voltage level for operating the processing component **410** and the ultrasound imaging assembly **110**. For example, the PoE component **430** is coupled to the power circuitry within the IVUS-PIM **130** and the electrical cable **112** of the IVUS device **102**. The Ethernet device may include transceivers and medium access control (MAC) processors configured to communicate data with the wireless router **132** according to an Ethernet protocol. The transportations of the data and power may be over the same twisted pair or different twisted pairs.

The patient isolation circuit **420** includes circuitry configured to provide electrical isolation between the PoE component **430** and the IVUS device **102**, which is in contact with a patient body when in use. For example, in an event where a short or electrical malfunction occurs, the patient isolation circuit **420** may restrict the line voltage from passing from the PoE component **430** to the patient undergoing an intraluminal imaging procedure. The patient isolation circuit **420** may also restrict the amount of low-level RF signals that may be passed to the patient body.

The memory **440** may include volatile memory and non-volatile memory of any suitable memory types, including random access memory (RAM), read-only memory (ROM), programmable read-only memory (PROM), erasable programmable read-only memory (EPROM), electrically erasable programmable read-only memory (EEPROM), dynamic random-access memory (DRAM), static random-access memory (SRAM), and combinations thereof. The memory **440** is configured to store image data generated by the processing component **410**.

As shown in FIG. **5**, the FPGA **414** includes one or more analog-to-digital converters (ADCs) **512**, a signal processing component **514**, an image processing component **516**, and a transducer array controller component **518**. The ADCs **512** includes circuitry configured to receive analog ultrasound echo signals from the ultrasound imaging component (e.g., the transducer array **128**) on the ultrasound imaging assembly **110** and convert the analog ultrasound echo signals into digital signals. The signal processing component **514** is coupled to the ADCs **512**. The signal processing component **514** is configured to perform signal conditioning on the digital signals. Signal conditioning may include amplification, filtering, and quadrature demodulation.

The transducer array controller component **518** is coupled to the ultrasound imaging assembly **110**, the ADCs **512**, and the signal processing component **514**. The transducer array controller component **518** includes circuitry configured to control the transducer array **128** for ultrasound signal transmissions and/or receptions of reflected ultrasound echo signals. The transducer array controller component **518** may receive control and/or data signals for operating the transducer array **128** from the systems **134** via the Ethernet cable **140** and the wireless router **132**. For example, the transducer array controller component **518** may be in communication with the control logic dies **206** shown in FIG. **2** and may send trigger signals to initiate ultrasound signal transmissions and/or ultrasound echo receptions. In some embodiments, the transducer array controller component **518** may further include circuitry implementing some of the operations of the control logic dies **206**. In some embodiments, the transducer array controller component **518** may further include circuitry configured to perform beamforming by combining ultrasound echo signals or responses received from the transducer array **128** and providing the combined or beamformed signals to the signal processing component **514**.

The image processing component **516** is coupled to the signal processing component **514**. The image processing component **516** includes circuitry configured to perform image processing. The image processing component **516** may function as an accelerator or engine for processing complex, computationally intensive image processing algorithms. In an embodiment, the image processing component **516** may perform noise reduction and/or image enhancement. For example, the image processing component **516** can perform clutter suppression, where clutters or imaging artifacts can be identified and removed. Alternatively, the image processing component **516** can perform ringdown subtraction, where ringdown artifacts at a range close to an excitation source (e.g., the transducers **212**) are identified and removed.

In an embodiment, the image processing component **516** can transform the conditioned echo signals into other domains for image analysis. For example, the image processing component **516** can apply a fast Fourier transform (FFT) on the conditioned echoed signals for analysis in the frequency or spectral domain. For example, the image processing component **516** can identify a border line or a wall of a vessel (e.g., the vessel **120**) and superimpose the border on a cross-sectional view of the vessel.

In an embodiment, the image processing component **516** may generate Doppler data by processing the conditioned echo signals into Doppler power or velocity information. The image processing component **516** may also generate B-mode data by applying envelope detection and logarithmic compression on the conditioned echo signals. The image processing component **516** can further generate images in various views, such as 2D and/or 3D views, based on the Doppler data or the B-mode data. The image processing component **516** can also perform various analyses and/or assessments. For example, the image processing component **516** can apply virtual histology (VH) techniques, for example, to analyze or assess plaques within a vessel (e.g., the vessel **120**). The images can be generated to display a reconstructed color-coded tissue map of plaque composition superimposed on a cross-sectional view of the vessel.

In an embodiment, the image processing component **516** can apply a blood flow detection algorithm (e.g., ChromaFlo®) to determine the movement of blood flow, for example, by acquiring image data of a target region (e.g., the vessel **120**) repeatedly and determining the movement of the blood flow from the image data. The blood flow detection algorithm operates based on the principle that signals measured from vascular tissue are relatively static from acquisition to acquisition, whereas signals measured from blood flow vary at a characteristic rate corresponding to the flow rate. As such, the blood flow detection algorithm may determine movements of blood flow based on variations in signals measured from the target region between repeated acquisitions. To acquire the image data repeatedly, the transducer array controller component **518** can configure the transducer array **128** to transmit repeated pulses on the same aperture.

In an embodiment, the image processing component **516** can apply a border detection algorithm to automatically detect intraluminal vessel wall from the collected image signals by optimizing signals from the vascular tissue and characterize features of the intraluminal vessel wall.

The microcontroller **412** is coupled to the FPGA **414**. For example, a control firmware may be stored on the memory **440** and executed by the microcontroller **412**. The control firmware may include state machines **510** configured to control the operations of the FPGA **414**. For example, the state machines **510** may control the starting and ending of a particular signal processing and/or image processing circuitry. While the microcontroller **412** is illustrated as a separate component from the FPGA **414**, in some embodiments, the microcontroller **412** can be implemented as part of the FPGA **414**.

The application processing component **416** is coupled to the FPGA **414**. The application processing component **416** can include hardware and/or software. In some embodiments, the application processing component **416** may include a general purpose processor, a digital signal processor, and/or an application-specific integrated circuit (ASIC). The application processing component **416** is configured to generate image data from the conditioned echo signals. The application processing component **416** includes an image processing component **520** and an image formatting component **522**. The image processing component **520** may implement image processing algorithms that are less computational intensive and/or require more flexibility or programmability compared to the image processing algorithms performed at the image processing component **516**. For example, the image processing component **520** may perform contrast enhancement. Contrast enhancement changes the histogram of an image, for example, by representing areas of a target region of interest with more intensity levels and representing areas of the target region of less interest with less intensity levels. The change in the histogram may be achieved via a sigmoid-like curve, represented by a function $h:[0,1]\rightarrow[0,1]$. The curve may be configured to optimize image contrast for maximum clinical utility.

The image formatting component **522** is configured to format the image data according to image display formats suitable for display on the systems **134**. For example, the image formatting component **522** can format the image data generated by the image processing components **516** and **520** according to a display frame rate and/or an available transmission bandwidth. The image formatting component **522** can also packetize the image data for transmission to the systems **134** via the wireless router **132**. While the application processing component **416** is illustrated as a separate component from the FPGA **414**, in some embodiments, the application processing component **416** can be implemented as part of the FPGA **414** and can be controlled by a firmware executing on the microcontroller **412** to provide flexibility. The image data generated by the image processing components **516** and **520** and/or formatted by the image formatting component **522** may be recorded and stored in the memory **440**.

By implementing image processing and image formatting in the IVUS-PIM **130**, the processed image data can be advantageously distributed in a format for display by any suitable display of the systems **134**. In prior configurations, conditioned echo signals from a PIM would be transmitted to the particular computing device (e.g., a console) where the images would be generated. According to the present disclose, the image data are generated at the IVUS-PIM **130** without being transmitted to a particular system, and the image data can be transmitted in a display format to any number of systems **134**. For example, image processing and image formatting can be completed entirely within the PIM **130** and the data for display can be transmitted from the PIM to any suitable computer/monitor for display. In this manner, the image processing and image formatting can be decoupled from larger, bulky computer systems and completed within relatively smaller, lighter, and more mobile PIM **130**.

In some embodiments, the IVUS-PIM **130** may receive a control signal carrying control commands, such as start, stop, and/or record, for example, from IVUS control system **134*b***, and the processing component **410** may control the ultrasound imaging assembly **110** and/or image generations accordingly. In some embodiments, the IVUS-PIM **130** may receive a data signal indicating a border of an image, for example, from the medical diagnostic system **134*a***, and the processing component **410** may generate or re-compute the image data according to the received image border.

FIG. **6** is a flow diagram of a method **600** of performing ultrasound imaging, according to aspects of the present disclosure. Steps of the method **600** can be executed by a computing device (e.g., a processor, processing circuit, and/or other suitable component) of a PIM such as the IVUS-PIM **130**. The method **600** may employ similar mechanisms as described with respect to FIGS. **3**, **4**, and **5**. As illustrated, the method **600** includes a number of enumerated steps, but embodiments of the method **600** may include additional steps before, after, and in between the enumerated steps. In some embodiments, one or more of the enumerated steps may be omitted or performed in a different order.

At step **610**, the method **600** includes receiving an ultrasound echo signal associated with a body lumen of a patient from an intraluminal imaging device (e.g., the IVUS device **102**). Then ultrasound echo signal may correspond to an ultrasound signal emitted by a transducer array (e.g., the transducer array **128**) and reflected by surrounding tissues of a vessel (e.g., the vessel **120**).

At step **620**, the method **600** includes determining image data (e.g., image frames of a cross-sectional area of the vessel or a volume of an anatomical structure) based on at least the ultrasound echo signal.

At step **630**, the method **600** includes receiving power (e.g., the power signal shown by the arrow **142**) from a wireless router (e.g., the wireless router **132**) via a signal link (e.g., the Ethernet cable **140**).

At step **640**, the method **600** includes formatting the image data according to an image display format of a computing device (e.g., the systems **134**).

At step **650**, the method **600** includes transmitting the image data in the image display format to the computing device (e.g., the systems **134**) via the signal link and the wireless router.

Aspects of the present disclosure may provide several benefits. For example, the use of the PoE link for both power and data communications can reduce the amount of cabling that is typically required in an intraluminal system. The coupling of the PoE link to a wireless router enables the distribution of image data to multiple systems without additional cable connections. In addition, computing the image data at the IVUS-PIM can offload image processing and analytic algorithms that are typically computed at a target system with a direct wired connection to the IVUS device. Further, formatting the image data at the IVUS-PIM according to image display formats of the display systems allow the display systems to be light-weight, low-cost wireless devices and systems.

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

What is claimed is:

1. An apparatus, comprising:
- an intravascular imaging catheter configured to obtain an imaging signal while the intravascular imaging catheter is positioned within a blood vessel of a patient;
- a first system comprising a first display; and
- a patient interface module (PIM),
- wherein the PIM is configured for:
  - communication with the intravascular imaging catheter via a first cable;
  - communication with a wireless router, wherein the communication between the PIM and the wireless router is via a signal link; and
  - communication with the first system and a second system via the signal link and the wireless router,
- wherein the PIM comprises:
  - a single housing;
  - a processing component disposed within the housing and configured to:
    - receive the imaging signal from the intravascular imaging catheter;
    - determine intravascular image data based on the imaging signal such that the intravascular image data is determined within the PIM and not the first system or the second system; and
    - format the intravascular image data into a format usable by both the first system and the second system to display the intravascular image data; and
  - a communication component disposed within the housing and configured to transmit the formatted intravascular image data to the first system and the second system via the signal link and the wireless router,
- wherein the PIM is communicatively positioned:
  - between the first system and the intravascular imaging catheter; and
  - between the second system and the intravascular imaging catheter, and
- wherein the first system is configured to display the formatted intravascular image data received from the PIM on the first display.

2. The apparatus of claim 1, wherein the first system is configured to:
- provide a user interface to control the intravascular imaging catheter to provide the imaging signal; and
- transmit, via the PIM, a control signal to the intravascular imaging catheter in response to a user input received at the user interface.

3. The apparatus of claim 2,
- wherein the communication component is further configured to receive the control signal from the first system via the signal link and the wireless router, and
- wherein the processing component is further configured to receive the imaging signal based on at least the control signal.

4. The apparatus of claim 2,
- wherein the communication component is further configured to receive the control signal from the first system via the signal link and the wireless router, and
- wherein the processing component is further configured to determine the intravascular image data based on the control signal.

5. The apparatus of claim 1,
- further comprising the signal link,
- wherein the signal link comprises a second cable configured to carry power from the wireless router to the PIM.

6. The apparatus of claim 5, wherein the communication component is further configured to provide the power received from the signal link to the intravascular imaging catheter.

7. The apparatus of claim 6, wherein the communication component is further configured to provide the power received from the signal link to the processing component.

8. The apparatus of claim 1, wherein the PIM further includes a memory coupled to the processing component and configured to store the intravascular imaging data.

9. The apparatus of claim 1, further comprising the second system.

10. The apparatus of claim 9,
- wherein the second system comprises a second display, and
- wherein the second system is configured to display the formatted intravascular image data received from the PIM on the second display.

11. The apparatus of claim 9, wherein the first system and the second system each comprise a different one of:
- a control system;
- a console system; or
- a diagnostic system.

12. The apparatus of claim 1, wherein the intravascular imaging catheter comprises an intravascular ultrasound (IVUS) catheter.

13. The apparatus of claim 1, wherein the PIM further comprises a patient isolation circuit coupled between the communication component and the processing component.

14. The apparatus of claim 1,
- further comprising the first cable and the signal link,
- wherein the signal link comprises a second cable,
- wherein the PIM and the intravascular imaging catheter are configured to be directly connected via the first cable such that the intravascular imaging signal is transmitted from the intravascular imaging catheter to the PIM by wired communication,
- wherein the PIM and the wireless router are configured to be directly connected via the second cable such that the intravascular imaging signal is transmitted from the PIM to the wireless router by wired communication, and
- wherein the PIM is configured to be indirectly in communication with the first system via the second cable and the wireless router such that the intravascular imaging signal is transmitted from the PIM to the first

system by wired communication from the PIM to wireless router and by wireless communication from the wireless router to the first system.

15. The apparatus of claim **1**, wherein the processing component comprises a field programmable gate array (FPGA).

16. The apparatus of claim **15**,

wherein the PIM further comprises a microcontroller coupled to the FPGA,

wherein the microcontroller is configured to execute control firmware stored in a memory,

wherein the FPGA includes one or more analog-to-digital converters (ADCs),

wherein the intravascular imaging signal comprises an analog signal,

wherein the ADCs are configured to receive the analog signal and convert the analog signal to a digital signal, and

wherein the FPGA is configured to perform signal conditioning on the digital signal to generate a conditioned signal.

17. The apparatus of claim **16**,

wherein the PIM further comprises a processor coupled to the FPGA, and

wherein the processor is configured to generate the intravascular imaging data from the conditioned signal.

18. The apparatus of claim **1**,

wherein the processing component is configured to perform signal conditioning on the intravascular imaging signal to generate a conditioned signal,

wherein the signal conditioning comprises at least one of signal amplification, filtering, or noise reduction, and

wherein the processing component is configured to determine the intravascular imaging data based on the conditioned signal such that the determination of the intravascular imaging data is different than the signal conditioning.

19. The apparatus of claim **9**,

wherein the first system and the second system do not format the intravascular imaging data, and

wherein the intravascular imaging data is generated and formatted entirely within the PIM and not within the first system and the second system.

20. The apparatus of claim **1**, further comprising the wireless router.

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