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(54) MULTI-MODE CAPACITIVE MICROMACHINED ULTRASOUND TRANSDUCER AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS

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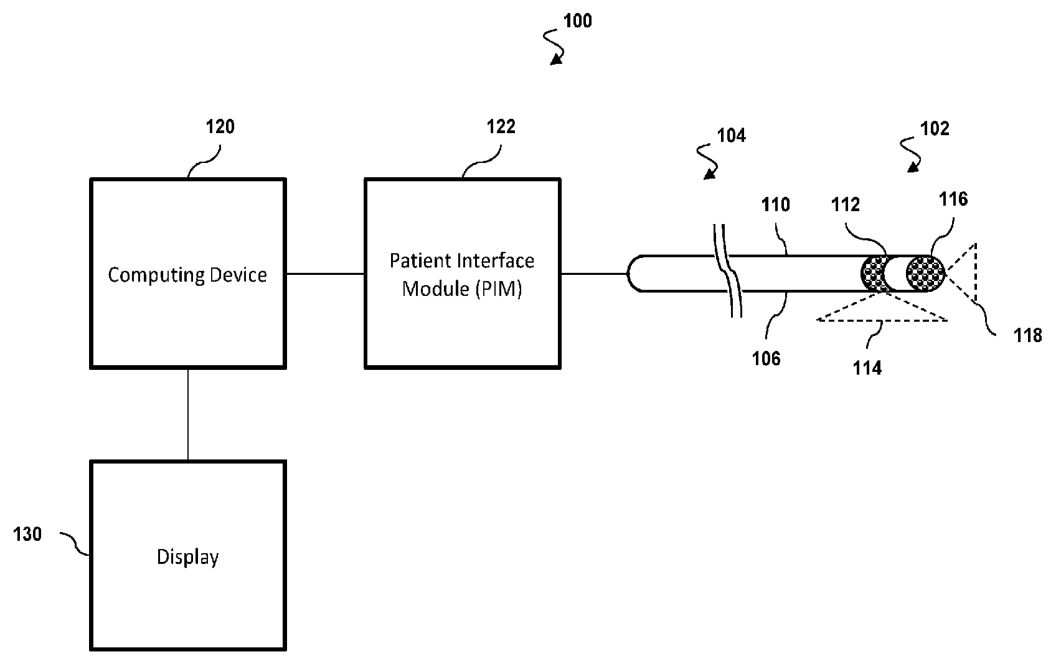
(57) ABSTRACT

Multi-mode capacitive micromachined ultrasound transducer (CMUT) and associated devices systems, and methods are provided. In an embodiment, an intravascular device includes a flexible elongate member having a proximal portion and a distal portion; and a first sensor assembly disposed at the distal portion of the flexible elongate member, the first sensor assembly comprising a first array of capacitive micromachined ultrasonic transducers (CMUTs); wherein the first sensor assembly comprises at least two of a pressure sensor, a flow sensor, or an imaging sensor. In some embodiments, the intravascular device further includes a second sensor assembly comprising a second array of CMUTs.



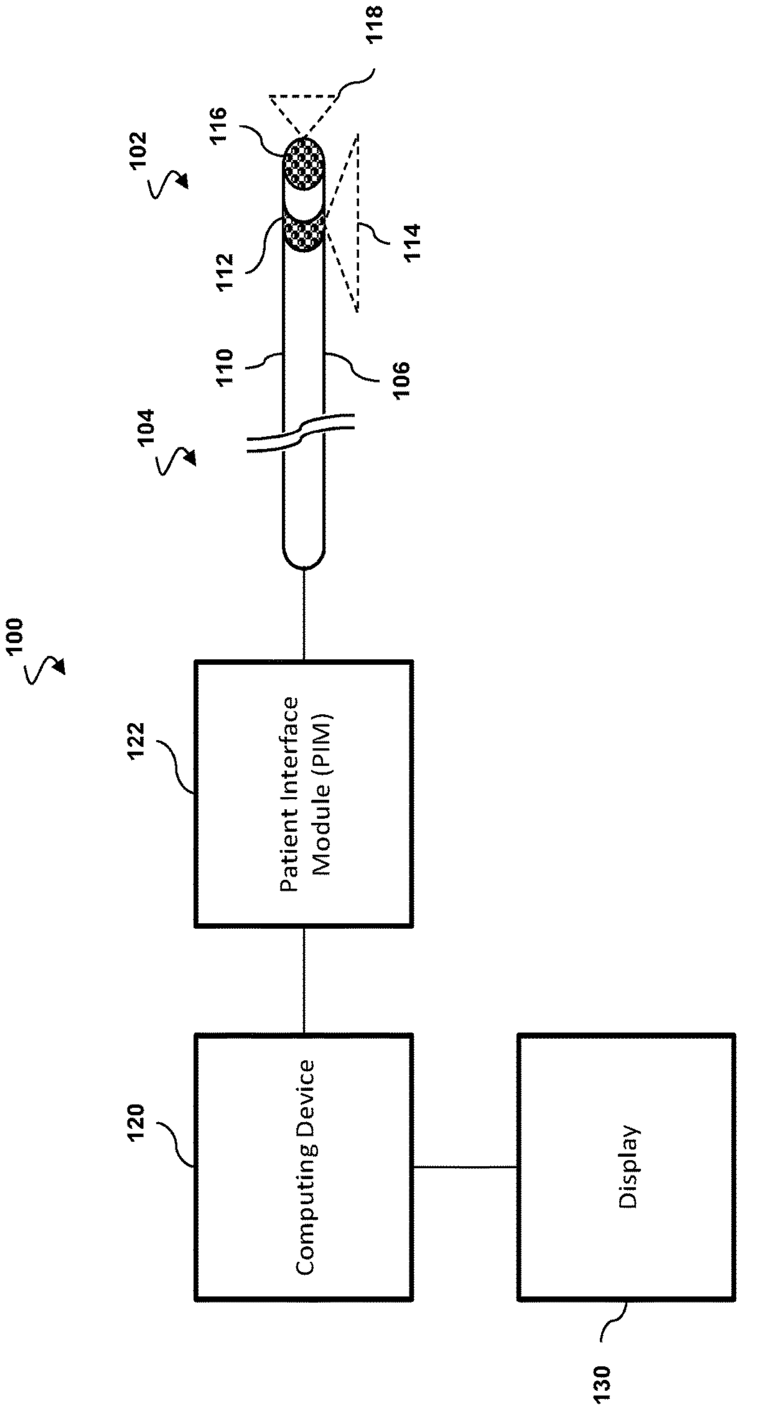

100
102
104
106
110
112
114
116
118
122
Patient Interface Module (PIM)
120
Computing Device
Display
130

FIG. 1

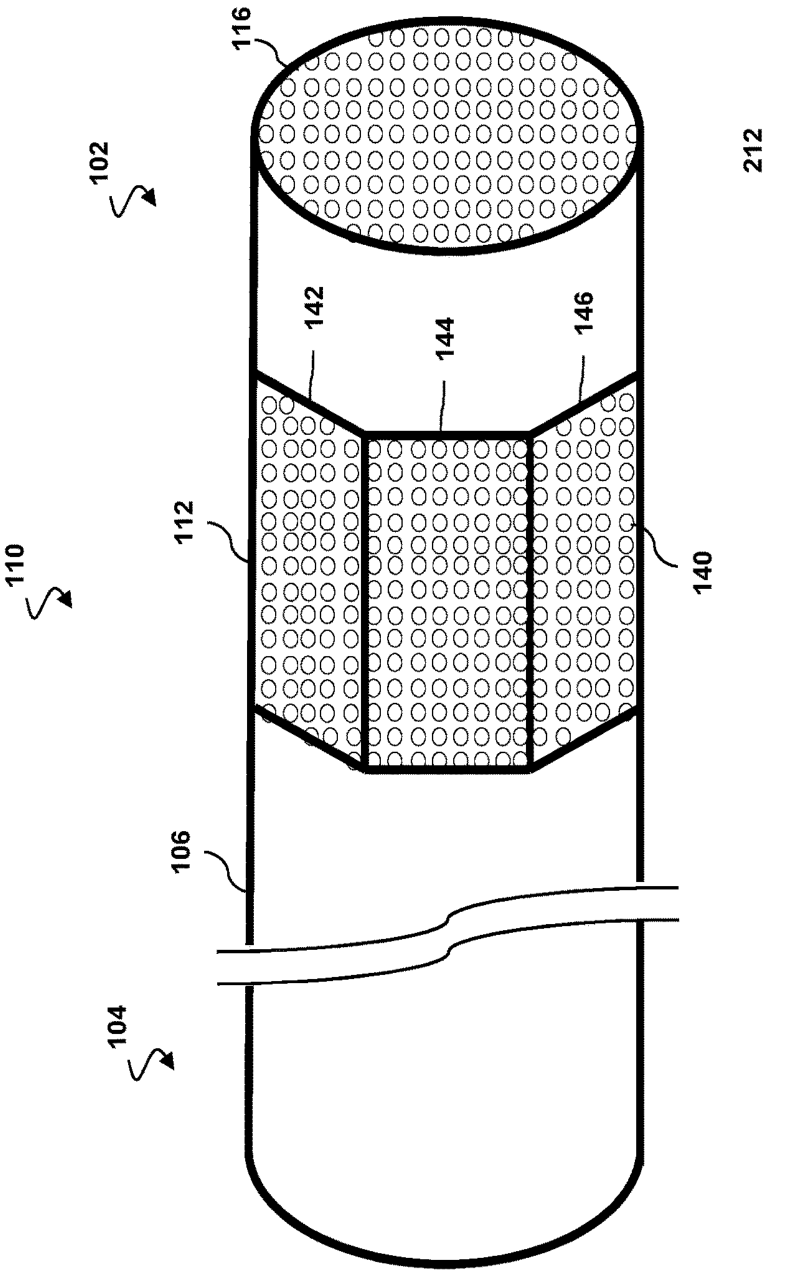


FIG. 2

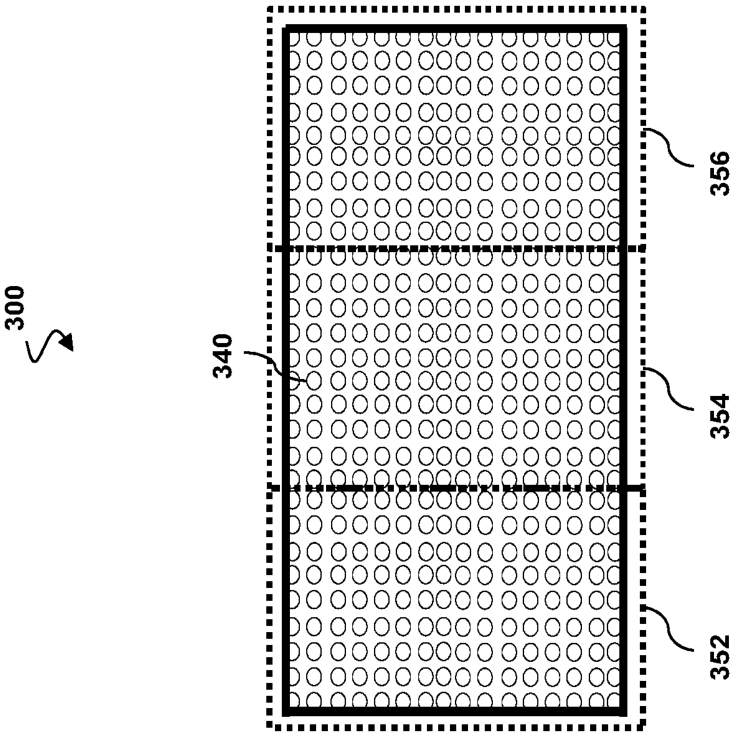


FIG. 3

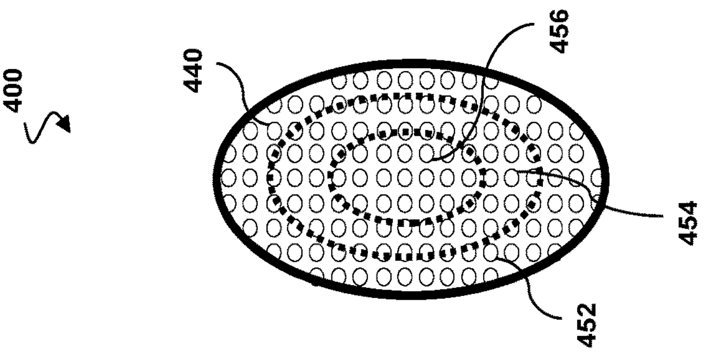


FIG. 4

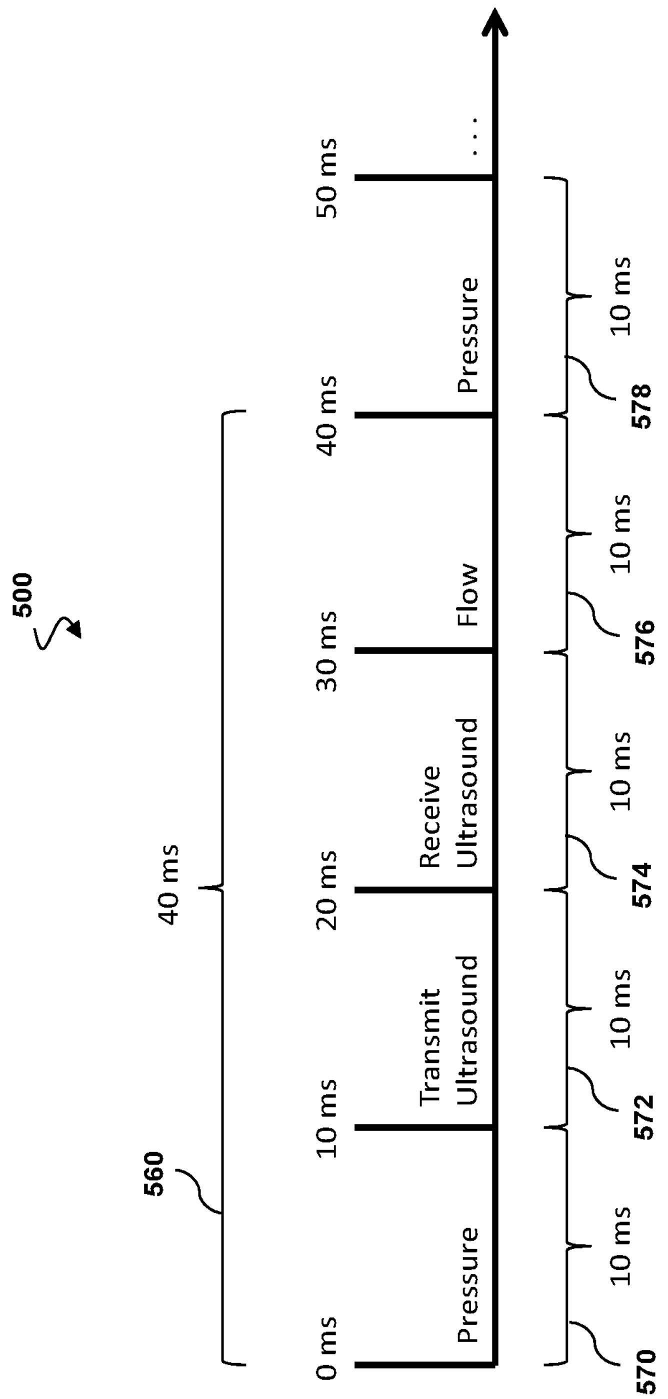

500
560
40 ms
0 ms
10 ms
20 ms
30 ms
40 ms
50 ms
Pressure
Transmit Ultrasound
Receive Ultrasound
Flow
Pressure
. . .
10 ms
10 ms
10 ms
10 ms
10 ms
570
572
574
576
578

FIG. 5

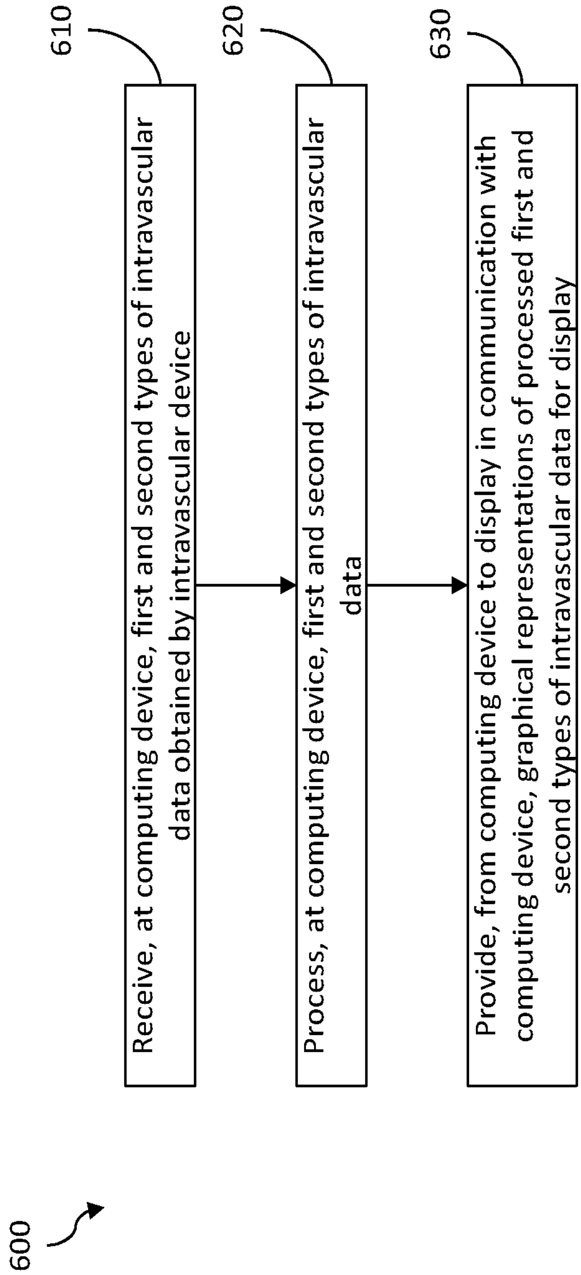

600
610
Receive, at computing device, first and second types of intravascular data obtained by intravascular device
620
Process, at computing device, first and second types of intravascular data
630
Provide, from computing device to display in communication with computing device, graphical representations of processed first and second types of intravascular data for display

Fig. 6

MULTI-MODE CAPACITIVE MICROMACHINED ULTRASOUND TRANSDUCER AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims priority to and the benefit of U.S. Provisional Patent Application No. 62/188,222, filed Jul. 2, 2015, which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present disclosure relates generally to intravascular sensing and, in particular, to sensing different modalities using capacitive micromachined ultrasound transducers (CMUTs). For example, some embodiments of the present disclosure provide an intravascular device with a CMUT sensor assembly operable to obtain pressure, flow, and/or imaging data within vasculature of a patient.

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, single-photon emission computed tomography (SPECT), 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, Instant Wave-Free Ratio™ (iFR®) determination, a coronary flow reserve (CFR) determination, optical coherence tomography (OCT), trans-esophageal echocardiography, and image-guided therapy.

[0004] Commercial sensors usually implement lead-zirconate-titanate (PZT) or piezoelectric micro-machined ultrasound transducers (PMUTs) to acquire imaging, flow, pressure, and other types of intravascular data. While PZT and PMUT sensors have been satisfactory in most respects, CMUT sensors are being considered more recently as an alternative technology. CMUT sensors operate on the principle of detecting capacitance changes when a membrane is deflected. Extant intravascular devices with CMUT sensors, however, are usually limited to one sensing modality, such as ultrasound imaging.

[0005] Thus, there remains a need for intravascular sensing system that provides multi-mode sensing capabilities.

SUMMARY

[0006] Embodiments of the present disclosure provide an improved intravascular device for sensing multiple types of intravascular data with capacitive micromachined ultrasound transducers (CMUTs). In some circumstances, the CMUTs can be divided or organized into zones. Each zone can obtain data corresponding to a different intravascular data type (e.g., pressure, flow, imaging, etc.). In other circumstances, the CMUTs can be cycle through different operations (e.g., pressure, flow, and imaging, etc.) so that the same CMUTs obtain data corresponding to the different intravascular data types at various times.

[0007] In an exemplary aspect, the present disclosure is directed to an intravascular device. The intravascular device includes a flexible elongate member having a proximal portion and a distal portion; and a first sensor assembly disposed at the distal portion of the flexible elongate member, the first sensor assembly comprising a first array of capacitive micromachined ultrasonic transducers (CMUTs); wherein the first sensor assembly comprises at least two of a pressure sensor, a flow sensor, or an imaging sensor.

[0008] In some embodiments, the first sensor assembly is disposed in an annular configuration about the flexible elongate member. In some embodiments, the first sensor assembly is disposed at a distal end of the flexible elongate member. In some embodiments, the first sensor assembly is disposed in at least one of a side-looking or forward-looking orientation. In some embodiments, the intravascular device further includes a second sensor assembly comprising a second array of CMUTs. In some embodiments, the first sensor assembly is disposed in one of a side-looking or forward-looking orientation, and wherein the second sensor assembly is disposed in the other of a side-looking or forward-looking orientation. In some embodiments, the flexible elongate member comprises a guide wire or a catheter. In some embodiments, the first array of CMUTs is arranged in a planar or non-planar configuration. In some embodiments, different portions of the first array of CMUTs comprise the pressure sensor, the flow sensor, or the imaging sensor. In some embodiments, the first sensor assembly comprises the pressure sensor, the flow sensor, or the imaging sensor at different times.

[0009] In an exemplary aspect, the present disclosure is directed to an intravascular system. The system includes an intravascular device configured to be inserted into vasculature of a patient, the intravascular device comprising: a flexible elongate member having a proximal portion and a distal portion, a sensor assembly disposed at the distal portion of the flexible elongate member, the sensor assembly comprising an array of capacitive micromachined ultrasonic transducers (CMUTs); wherein the sensor assembly comprises at least two of a pressure sensor, a flow sensor, or an imaging sensor; and a computing device in communication with the intravascular device and configured to receive intravascular data obtained by the sensor assembly.

[0010] In some embodiments, the intravascular system further includes a patient interface module (PIM) in communication with the intravascular device and the computing device. In some embodiments, the intravascular system further includes a display in communication with the computing device and configured to display graphical representations of the intravascular data. In some embodiments, different portions of the array of CMUTs comprise the pressure sensor, the flow sensor, or the imaging sensor. In some embodiments, the computing device is configured to receive pressure data, flow data, or imaging data obtained by the respective different portions of the array of CMUTs. In some embodiments, the computing device is configured to control the respective different portions of the array of CMUTs to obtain pressure data, flow data, or imaging data. In some embodiments, the sensor assembly comprises the pressure sensor, the flow sensor, or the imaging sensor at different times. In some embodiments, the computing device is configured to receive pressure data, flow data, or imaging data obtained by the sensor assembly at the respective different times. In some embodiments, the computing device configured to control the sensor assembly to obtain pressure data, flow data, or imaging data at the respective different times.

[0011] In an exemplary aspect, the present disclosure is directed to a method of obtaining intravascular data. The method includes receiving, at a computing device, first and second intravascular data associated with different modalities and obtained by an intravascular device inserted into the vasculature of a patient and in communication with the computing device, the intravascular device comprising: a flexible elongate member having a proximal portion and a distal portion, a sensor assembly disposed at the distal portion of the flexible elongate member, the sensor assembly comprising an array of capacitive micromachined ultrasonic transducers (CMUTs); wherein the sensor assembly comprises at least two of a pressure sensor, a flow sensor, or an imaging sensor; processing, at the computing device, the first and second intravascular data; and providing, from the computing device to a display in communication with the computing device, graphical representations of the processed first and second types of intravascular data for display.

[0012] In some embodiments, the first and second intravascular data are simultaneously obtained by the intravascular device. In some embodiments, different portions of the array of CMUTs comprise the pressure sensor, the flow sensor, or the imaging sensor. In some embodiments, the method further includes controlling the respective different portions of the array of CMUTs to obtain pressure data, flow data, or imaging data. In some embodiments, the first and second intravascular data are obtained by the intravascular device at different times. In some embodiments, the sensor assembly comprises the pressure sensor, the flow sensor, or the imaging sensor at different times. In some embodiments, the method further includes controlling the sensor assembly to obtain pressure data, flow data, or imaging data at the respective different times.

[0013] Additional aspects, features, and advantages of the present disclosure will become apparent from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Illustrative embodiments of the present disclosure will be described with reference to the accompanying drawings, of which:

[0015] FIG. **1** is a diagrammatic schematic view of an intravascular sensing system according to aspects of the present disclosure.

[0016] FIG. **2** is a diagrammatic side view of an intravascular device according to aspects of the present disclosure.

[0017] FIG. **3** is a diagrammatic top view of an array of CMUTs according to aspects of the present disclosure.

[0018] FIG. **4** is a diagrammatic top view of an array of CMUTs according to aspects of the present disclosure.

[0019] FIG. **5** is a diagrammatic illustration of an intravascular data acquisition protocol according to aspects of the present disclosure.

[0020] FIG. **6** is a flow diagram of a method of obtaining intravascular data according to aspects of the present disclosure.

DETAILED DESCRIPTION

[0021] For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the implementations illustrated in the drawings and specific language will be used to describe them. It will nevertheless be understood that no limitation of the scope of the disclosure is intended. Any alterations and further modifications to the described devices, instruments, methods, and any further application of the principles of the present disclosure are fully 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 or more implementations may be combined with the features, components, and/or steps described with respect to other implementations of the present disclosure. For simplicity, in some instances the same reference numbers are used throughout the drawings to refer to the same or like parts.

[0022] The present disclosure relates generally to intravascular sensing devices, systems and methods having a CMUT array operable to obtain data associated with multiple, different intravascular modalities. In some embodiments, the different portions of the CMUT array are operable as different ones of a pressure sensor, a flow sensor, an imaging sensor, etc. In some embodiments, the CMUT array is operable as the pressure sensor, the flow sensor, the imaging sensor, etc., at different times. Multiple CMUT arrays may be provided on the intravascular device. The positioning and orientation each CMUT array can be selected to optimize collection of data associated with a particular intravascular modality.

[0023] The intravascular sensing devices, systems and methods of the present disclosure provide multiple advantages. For example, utilizing a CMUT array may result in fewer conductors extending along the length of the intravascular device. For example, a CMUT includes two conductors extending respectively to two electrodes. The capacitance changes between the electrodes can be representative of the obtained intravascular data. A CMUT array also advantageously utilizes multiple individual CMUTs that are in communication. In that regard, individual CMUTs and/or zones within CMUT array can be individually addressed and/or otherwise controlled. A CMUT array may also advantageously reduce processing carried out by a processor and/or data stored on a memory because detecting capacitance changes are less process/memory intensive. The CMUT array also allows for smaller, minimally invasive sensors and intravascular devices.

[0024] Referring to FIG. **1**, shown therein is an intravascular sensing system **100**. The system **100** includes an intravascular device **110** having a sensor assemblies **112** and **116**, a computing device **120**, a patient interface module (PIM) **122**, and a display **130**. The intravascular sensing system **100** can be implemented, for example, in a catheterization lab of a hospital or other medical services provider. The intravascular device **110** is also illustrated in more detail in FIG. **2**.

[0025] Referring to both FIGS. **1** and **2**, the intravascular device **110** includes flexible elongate member **106** and sensor assemblies **112**, **116**. The intravascular device **110** is configured to be inserted into a patient's vasculature by a user, such as a surgeon or other medical profession, during an intravascular sensing procedure. In that regard, the intravascular device **110** can be a catheter, guide wire, or guide catheter. The flexible elongate member **106** has a distal portion **102** and a proximal portion **104**. The dimensions of the flexible elongate member **106**, including the length and diameter, can vary in different embodiments. For example, the flexible elongate member **106** can be sized and shaped for use in the coronary arteries, peripheral vessels, heart, and/or other areas of the patient's vasculature.

[0026] In different embodiments, the intravascular device **110** can include one, two, three, four, or more sensor assemblies coupled to the flexible elongate member **106**. FIGS. **1** and **2** illustrate two sensor assemblies **112**, **116** disposed at the distal portion **102** of the intravascular device **110**. Each sensor assembly **112**, **116** includes an array or plurality of CMUTs. In that regard, each array can be arranged in a planar, non-planar, and/or other suitable configuration. For example, an array can include CMUTs laid out substantially in two dimensions (as shown, e.g., in FIG. **4**). An array can also be arranged in a non-planar configuration. For example, an array with CMUTs laid out substantially in two dimensions can be arranged in a cylindrical or non-planar configuration when wrapped around an intravascular device (e.g., sensor assembly **112** of FIGS. **1** and **2**). It is understood that a CMUT array can be described as two-dimensional or three-dimensional. In that regard, an array with CMUTs laid out substantially in two dimensions (x and y) extends at least some value in the third dimension (z). Other suitable two-dimensional or three-dimensional configurations are also contemplated.

[0027] An outermost of layer of each CMUT is visible in FIGS. **1** and **2**. For example, each CMUT includes a sensor membrane or diaphragm **140** that is configured to be deflected upon application of voltage to create a pressure wave (e.g., to transmit an ultrasound signal) or detect/measure pressure that is electronically sensed as a change in capacitance (e.g., upon receipt of an ultrasound echo). The CMUTs can be similar to those described in U.S. Pat. No. 8,203,912, titled "CMUTs with a high-k dielectric," and issued Jun. 19, 2012; U.S. Pat. No. 6,632,178, titled "Fabrication of capacitive micromachined ultrasonic transducers by micro-stereolithography," and issued Oct. 14, 2003; U.S. Pat. No. 8,327,521, titled "Method for production and using a capacitive micro-machined ultrasonic transducer," and issued Dec. 11, 2012; U.S. Pat. No. 6,443,901, titled "Capacitive micromachined ultrasonic transducers," and issued Jun. 15, 2000; U.S. Pat. No. 6,659,954, titled "Micromachined ultrasound transducer and method for fabricating same," and issued Dec. 9, 2003; U.S. application Ser. No. 14/382,560, titled "Capacitive micro-machined ultrasound transducer device with charging voltage source," and filed Sep. 3, 2014; U.S. application Ser. No. 14/125,958, titled "Ultrasound transducer assembly and method of manufacturing the same," and filed Dec. 13, 2013; U.S. application Ser. No. 14/365,647, titled "Ultrasound transducer device and method of manufacturing the same," and filed Jun. 16, 2014; U.S. application Ser. No. 14/370,110, titled "Capacitive micro-machined transducer and method of manufacturing the same," and filed Jul. 1, 2014; U.S. application Ser. No. 14/369,341, titled "Capacitive micro-machined transducer and method of manufacturing the same," and filed Jun. 27, 2014; U.S. application Ser. No. 13/062,744, titled "Capacitive micromachine ultrasound transducer," and filed Mar. 8, 2011; U.S. application Ser. No. 13/885,791, titled "Catheter comprising capacitive micromachined ultrasonic transducers with an adjustable focus," and filed Sep. 3, 2013; U.S. application Ser. No. 14/000,891, titled "Ultrasonic CMUT with suppressed acoustic coupling to the substrate," and filed Mar. 13, 2012; and U.S. application Ser. No. 14/365,647, titled "Ultrasound transducer device and method of manufacturing the same," and filed Jun. 16, 2014, the entireties of which are incorporated by reference herein.

[0028] The sensor assemblies **112**, **116** can be positioned, arranged, oriented, and/or otherwise disposed on the flexible elongate member **106** in any desired manner. For example, the sensor assemblies **112**, **116** can be positioned at any point along the length of the flexible elongate member **106**. The sensor assemblies **112**, **116** can include a linear, rectangular, circular, elliptical, annular, and/otherwise suitably shaped array of CMUTs. The sensor assemblies **112**, **116** may be coupled to the flexible elongate member **106** in a side-looking, forward-looking, other suitable orientation, and/or combinations thereof. In the illustrated embodiment, the sensor assembly **112** is disposed in an annular configuration around or about the flexible elongate member **106**. The sensor assembly **112** can be disposed in a side-looking orientation that covers the field of view **114**, for example. In that regard, the sensor assembly **112** may be advantageously positioned for obtaining intravascular imaging and/or pressure data. The sensor assembly **116** is disposed at the distal end of the flexible elongate member **106**. The sensor assembly **116** is disposed in a forward-looking orientation that covers the field of view **118**, for example. In that regard, the sensor assembly **116** may be advantageously positioned for obtaining intravascular imaging, pressure data, and/or flow data. In some instances, two or more sensor assemblies can be coupled to the flexible elongate member **106** with known separation distance(s) (e.g., 10 cm, 20 cm, etc.). For example, in an embodiment with three sensor assemblies, the first and second sensor assemblies can be separated by a first distance, and the first and third sensor assemblies can be separated by a second distance. In such an embodiment, the sensor assemblies may be advantageously utilized for sensing pressure to compute one or more pressure quantities (iFR, FFR, Pd/Pa, etc.). For example, a first sensor assembly can be positioned at a location proximal to a lesion (e.g. at or near the aorta, with a coronary artery, etc.), and the second and third sensor assemblies can be positioned at locations distal to the lesion. The sensor assemblies can thus measure a proximal pressure (e.g., Pa) and two distal pressures (e.g., Pd_1, Pd_2, at different distances from the proximal pressure measurement location), for example, while the intravascular device is held stationary within the vasculature.

[0029] Sensor assemblies **112**, **116** can be substantially unitary components or formed of constituent elements. For example, the sensor assembly **116** can be a single component. For example, the sensor assembly **112** can include a plurality of panels **142**, **144**, **146**. The sensor assembly **112** can include other panels on the side of the intravascular device **110** that is not visible in FIGS. **1** and **2**. The panels **142**, **144**, **146** are shown to be generally rectangular, though they may be otherwise shaped in different embodiments. The sensor assembly **112** can be manufactured with the panels **142**, **144**, **146** in the planar configuration. During assembly of the intravascular device **110**, the panels **142**, **144**, **146** can be folded into an annular configuration. In that regard, the sensor assembly **116** may be operated in a similar manner as a solid-state or phased array piezoelectric transducer array if so desired by the user. For example, individual panels may be activated one at a time in a sweeping manner (e.g., to transmit ultrasound signal, to receive ultrasound signal, etc.).

[0030] The sensor assemblies **112**, **116** are configured to sense, collect, and/or otherwise obtain imaging data, pressure data, Doppler or velocity flow data, volume or mass flow data, temperature data, other diagnostic data, and/or combinations thereof. In some embodiments, the sensor assembly **112** and the sensor assembly **116** are operable to obtain different types or modalities of intravascular data. For example, the sensor assembly **112** obtains pressure data while the sensor assembly **116** obtains flow data. In some embodiments, the sensor assembly **112** and/or the sensor assembly **116** may each be fixedly configured to obtain one type of intravascular data. In that regard, the sensor assembly **112** and/or the sensor assembly **116** can be optimized, e.g., during manufacture, to obtain data associated with a particular intravascular modality. In some embodiments, the sensor assemblies **112**, **116** are operable to obtain data associated with the same intravascular modality.

[0031] In some embodiments, the sensor assembly **112** and/or the sensor assembly may be variably configured to obtain data associated with different intravascular modalities. In that regard, the sensor assemblies **112**, **116** are operable to obtain any one or more intravascular sensing modalities. For example, the sensor assembly **112** can obtain pressure data and later obtain flow data. Such an embodiment is described in greater detail with respect to FIG. **5**. In other embodiments, the data type obtained by the sensor assemblies **112**, **116** can be selected and controlled by a user (e.g., before and/or during the intravascular sensing procedure). In some embodiments, one of the sensor assembly **112** and/or the sensor assembly **116** is fixedly configured to obtain one type of intravascular data while the other of the sensor assembly **112** and/or the sensor assembly **116** is variably configured to obtain different types of intravascular data.

[0032] In some embodiments, different portions of the array of CMUTs forming the sensor assembly (e.g., sensor assembly **112**, the sensor assembly **116**, etc.) are operable to obtain intravascular data associated with different modalities. As described in greater detail with respect to FIGS. **3** and **4**, a portion of the CMUT array can be configured to obtain imaging data, a portion can be configured to obtain pressure data, a portion may be configured to obtain flow data, etc. In some embodiments, the different portions of the sensor assembly can each be fixedly configured to obtain one type of intravascular data. In that regard, the different portions may be optimized, e.g., during manufacture, to obtain the respective data type. In some embodiments, the different portions of the CMUT array can each variably configured to obtain different types of intravascular data. For example, a first portion of the CMUT array can obtain pressure data and later obtain flow data. In other embodiments, the data type obtained by different portions of the CMUT array can be selected and controlled by a user (e.g., before and/or during the intravascular sensing procedure).

[0033] The intravascular device **110** can include various other components to facilitate transmission of signals between the sensor assemblies **112**, **116**, the computing device **120**, and/or the PIM **122**. For example, the intravascular device **110** can include conductors that electrically couple the sensor assemblies **112**, **116**, the computing device **120**, and/or the PIM **122**. In that regard, the conductors may be in contact with electrodes of the CMUT, a particular portion of the CMUT array, and/or the sensor assemblies **112**, **116**. The intravascular device **110** can also include integrated circuit controller chips(s) or application-specific integrated circuit(s) configured to control the sensor assemblies **112**, **116** and/or particular portions thereof. For example the controller chip(s) may activate transmitter circuitry to generate an electrical pulse to excite the CMUT array element(s) and to accept amplified echo signals received from the CMUT array element(s) via amplifiers included on the controller chip(s). The controller chip(s) can also provide to signals to the sensor assemblies **112**, **116** and/or portions thereof to obtain data associated with particular intravascular sensing modalities. In that regard, controller chip(s) may be configured to perform pre-processing on the obtained data to determine the modality associated therewith. In some instances, controller chip(s) can perform digital signal processing functions, amplifier functions, wireless functions, as described, e.g., in U.S. application Ser. No. 14/133,331, titled "Intravascular Devices Having Information Stored Thereon And/Or Wireless Communication Functionality, Including Associated Devices, Systems, And Methods," and filed Dec. 18, 2013, which is incorporated by reference herein in its entirety.

[0034] Referring again to FIG. **1**, the intravascular device **110** and/or the sensor assemblies **112**, **116** are in communication the computing device **120** and/or the PIM **122**. For example, the computing device **120** receives the intravascular data obtained by the intravascular device **110** and processes the intravascular data to generate a graphical representation of the obtained data. For example, the computing device **120** can receive pressure data from the sensor assembly **112** and/or the sensor assembly **116** by way of the PIM **122**. The computing device **120** can process the data to compute one or more pressure quantities (e.g., FFR, iFR, etc.). In some embodiments, the computing device **120** can co-register the obtained data with a fluoroscopic/angiographic image of the vessel. The computing device **120** can output a graphical representation of the processed data, such as the pressure quantities overlaid on the image of the vessel to the display **130**. As another example, the computing device **120** can receive imaging data representative of ultrasound echoes from the sensor assembly **112** and/or the sensor assembly **116**. The computing device **120** can process the data to reconstruct an image of the tissue structures in the medium surrounding the sensor assembly **112** and/or the sensor assembly **116**. The image provided to and displayed on the display **130** can be similar to a B-scan image representative of the two-dimensional anatomical structure of the tissue in a plane perpendicular to the longitudinal axis of intravascular device **110**, with brightness at any point of the image representing of the strength of the echo signal received from the corresponding location within the tissue. In some embodiments, the imaging data obtained by the intravascular device **110** is used for lumen mapping. The computing device **120** can receive and process the imaging data to generate an image illustrating the contours of a lumen of the patient's vasculature. As yet another example, the computing device **120** can receive and process flow data to generate a visual representation of movement of elements in the medium surrounding the sensor assembly **112** and/or the sensor assembly **116**, such as blood flow. In some embodiments, the computing device **120** may carry out one or more functions described above with respect to the controller chip(s). For example, the computing device **120** can generate and provide signals to the sensor assemblies **112**, **116** and/or portions thereof to obtain data associated with particular intravascular sensing modalities.

[0035] The computing device **120** can be generally representative of any device suitable for performing the processing and analysis techniques discussed within the present disclosure. In some embodiments, the computing device **120** includes a processor, random access memory, and a storage medium. The computing device **120** is operable to execute steps associated with the data acquisition and analysis described herein. Accordingly, it is understood that any steps related to data acquisition, data processing, instrument control, and/or other processing or control aspects of the present disclosure may be implemented by the computing device using corresponding instructions stored on or in a non-transitory computer readable medium accessible by the computing device. In some instances, the computing device **120** is a console device. In some particular instances, the computing device **120** is similar to the s5™ Imaging System or the s5i™ Imaging System, each available from Volcano Corporation. In some instances, the computing device **120** is portable (e.g., handheld, on a rolling cart, etc.). Further, it is understood that in some instances the computing device **120** comprises a plurality of computing devices. In that regard, it is particularly understood that the different processing and/or control aspects of the present disclosure may be implemented separately or within predefined groupings using a plurality of computing devices. Any divisions and/or combinations of the processing and/or control aspects described below across multiple computing devices are within the scope of the present disclosure.

[0036] The PIM **122** that facilitates communication of signals between the computing device **120** and the sensor assemblies **112**, **116** of the intravascular device **110**. In some embodiments, the PIM **122** performs preliminary processing of the obtained intravascular data prior to relaying the data to the computing device **120**. In examples of such embodiments, the PIM **122** performs amplification, filtering, and/or aggregating of the data. In an embodiment, the PIM **122** also supplies high- and low-voltage DC power to support operation of the intravascular device **110** including circuitry within the sensor assemblies **112**, **116**. The PIM **122** transfers the received intravascular data to the computing device **120** where, among other things, a graphical presentation of the processed data is generated displayed on the display **130**. In some embodiments, the PIM **122** is configured to perform wireless functions related to, e.g., the transmission and receipt of intravascular data. An exemplary PIM is described, for example, in U.S. application Ser. No. 14/133,406, titled "Wireless Interface Devices, Systems, and Methods for Use with Intravascular Pressure Monitoring Devices," and filed Dec. 18, 2013, the entirety of which is incorporated by reference herein.

[0037] Referring to FIG. **3**, shown therein is a top view of a CMUT array **300**. In that regard, the array **300** can comprise an entire or partial sensor assembly. For example, the CMUT array **300** may be the sensor assembly **112** or an individual panel **142**, **144**, **146** (FIG. **2**). The CMUT array **300** includes a plurality of sensor membranes **340**. In that regard, the size of the sensor membranes **340** is not necessarily to scale in the drawings. In some embodiments, the diameter of each of the sensor membranes **340** can be between approximately 1 μm and approximately 200 μm, between approximately 10 μm and approximately 200 μm, between approximately 20 μm and approximately 200 μm, and/or other suitable values both larger and smaller.

[0038] In some embodiments, different portions or zones of the CMUT array **300** are operable to obtain data associated with different intravascular modalities. For example, zone **352** can be configured to obtain pressure data, zone **354** can be configured to obtain flow data, and zone **356** can be configured to obtain imaging data. That is, different portions of the CMUT array **300** comprise the pressure sensor, the flow sensor, and/or the imaging sensor. While the zones **352**, **354**, **356** are shown to be similarly sized and shaped, it is understood that the zones may be sized and shaped differently from one another. Similarly, the illustrated embodiment illustrates rectangular zones. In various embodiments, other shapes, such as circles, ellipses, polygons, etc. are used to define the zones. In some embodiments, individual CMUTs and/or zones that perform the same function are arranged continuously or continuously in an array. In other embodiments, individual CMUTs and/or zones that are spaced from one another (e.g., discontinuous or discontinuous) in an array perform the same function. For example, a computing device can process the intravascular data collected at different zones to generate a composite. In some instances, the individual zones can be described as individual pressure sensors, flow sensors, and/or imaging sensors.

[0039] Referring to FIG. **4**, shown therein is a top view of a CMUT array **400**. CMUT array **400** is similarly in manner respects to the CMUT array **300** (FIG. **3**). In that regard, the array **400** can comprise an entire or partial sensor assembly. For example, the CMUT array **300** may be the sensor assembly **116** (FIG. **2**). The CMUT array **400** includes a plurality of sensor membranes **440**. In some embodiments, different portions or zones of the CMUT array **400** are operable to obtain data associated different intravascular modalities. For example, zone **452** can be configured to obtain pressure data, zone **454** can be configured to obtain flow data, and zone **456** can be configured to obtain imaging data. That is, different portions of the CMUT array **400** comprise the pressure sensor, the flow sensor, or the imaging sensor. In the illustrated embodiment, the zone **456** is circular while the zones **452** and **454** are annular, ring, or donut shaped. The zones **452**, **454**, **456** are also concentric. It is understood that the zones may be sized and shaped differently in various embodiments.

[0040] Referring to FIG. **5**, shown therein is an illustration representative of an intravascular data collection protocol **500**. Generally, the protocol **500** is representative of one sensor assembly comprising the pressure sensor, the flow sensor, and/or the imaging sensor at different times. By rapidly cycling through different functions of the sensor assembly, the same sensor assembly can be utilized to obtain data associated with multiple intravascular modalities. For example, the protocol **500** may be implemented using the sensor assembly **112** and/or the sensor assembly **116** (FIGS. **1** and **2**).

[0041] The protocol **500** includes intervals **570**, **572**, **574**, **576**, **578** during which the sensor assembly performs different functions. The intervals **570**, **572**, **574**, **576**, **578** are shown to each be 10 ms in the illustrated embodiment. It is understood that the duration of the intervals **570**, **572**, **574**, **576**, **578** may be different in other embodiments. Similarly, it is understand that one or more intervals **570**, **572**, **574**, 576, 578 can have a duration that is longer or shorter than one or more other intervals 570, 572, 574, 576, 578. For example, during the interval 570, the sensor assembly is operable to obtain pressure data. The intervals 572, 574 can be associated with imaging data. In particular, during the interval 572, the sensor assembly is operable to transmit ultrasound waves, and during the interval 574, the sensor assembly is operable to receive ultrasound echoes reflected from tissues structures within the patient's vascular. During the interval 576, the sensor assembly is operable to obtain flow data. The cycle 560 can repeat multiple times for the total duration of the sensing procedure.

[0042] FIG. 6 illustrates a flowchart of a method 600 of obtaining intravascular data. As illustrated, the method 600 includes a number of enumerated steps, but implementations of the method 600 may include additional steps before, after, and in between the enumerated steps. In some implementations, one or more of the enumerated steps may be omitted or performed in a different order. The steps of the method 600 may be performed by processor, such as the computing device 120 (FIG. 1).

[0043] At step 610, the method 600 includes receiving, at a computing device, first and second intravascular data associated with different modalities. The first and second intravascular data is obtained by an intravascular device inserted into the vasculature of a patient. The intravascular device is in communication with the computing device. The intravascular device may similar to the intravascular device 110 (FIGS. 1 and 2), including a flexible elongate member having a proximal portion and a distal portion, and a sensor assembly disposed at the distal portion of the flexible elongate member. The sensor assembly can include an array of CMUTs. The sensor assembly comprises or is operable to perform the functions of at least two of a pressure sensor, a flow sensor, or an imaging sensor.

[0044] In some embodiments, the first and second intravascular data are simultaneously obtained by the intravascular device. For example, different portions of the array of CMUTs can comprise or operate as different ones of the pressure sensor, the flow sensor, or the imaging sensor. In that regard, the method 600 can include controlling the respective different portions of the array of CMUTs to obtain pressure data, flow data, or imaging data.

[0045] In some embodiments, the first and second intravascular data are obtained by the intravascular device at different times. For example, the sensor assembly can comprise or operate as different ones of the pressure sensor, the flow sensor, or the imaging sensor at different times. In that regard, the method 600 can include controlling the sensor assembly to obtain pressure data, flow data, or imaging data at the respective different times.

[0046] At step 620, the method 600 includes processing, at the computing device, the first and second intravascular data. Processing the first and second intravascular data can include or more computational steps to filter, analyze, and/or otherwise manipulate the obtained data. In that regard, processing the first and second intravascular data can include determining an intravascular modality associated with the first and second intravascular data.

[0047] At step 630, the method 600 includes providing, from the computing device to a display in communication with the computing device, graphical representations of the processed first and second types of intravascular data for display. The graphical representations can include images of the patient's vasculature, quantities, colors, shading, and/or other suitable information representative of the processed data.

[0048] Persons skilled in the art will also 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.

1. An intravascular device, comprising:
a flexible elongate member having a proximal portion and a distal portion; and
a first sensor assembly of a first array of capacitive micromachined ultrasonic transducers (CMUTs) disposed at the distal portion of the flexible elongate member;
wherein the first sensor assembly is operable as at least two of a pressure sensor, a flow sensor, and an imaging sensor; and
wherein the first sensor assembly is configured to be cycled through different operations comprising at least two of a pressure measurement, a flow measurement, and an imaging so that the same first sensor assembly obtains data corresponding to different intravascular data types at various times.

2. The intravascular device of claim 1, wherein the first sensor assembly is disposed in an annular configuration around the flexible elongate member.

3. The intravascular device of claim 1, wherein the first sensor assembly is disposed in at least one of a side-looking or forward-looking orientation.

4. The intravascular device of claim 1, further comprising:
a second sensor assembly comprising a second array of CMUTs.

5. The intravascular device of claim 4, wherein the first sensor assembly is disposed in one of a side-looking or a forward-looking orientation, and wherein the second sensor assembly is disposed in the other of the side-looking or the forward-looking orientation.

6. The intravascular device of claim 1, wherein the flexible elongate member comprises a guide wire or a catheter.

7. The intravascular device of claim 1, wherein the first sensor assembly is arranged in a planar or non-planar configuration.

8. The intravascular device of claim 1, wherein different portions of the first sensor assembly are operable as the pressure sensor, the flow sensor, or the imaging sensor.

9. The intravascular device of claim 1, wherein the first sensor assembly is operable as the pressure sensor, the flow sensor, or the imaging sensor at different times.

10. An intravascular system, comprising:
the intravascular device according to claim 1,
a computing device in communication with the intravascular device and configured to receive intravascular data obtained by the first sensor assembly,

wherein the computing device is configured to cycle through different operations comprising at least two of the pressure measurement, the flow measurement, and the imaging so that through the same first sensor assembly obtains data corresponding to different intravascular data types at various times.

11. The intravascular device system of claim **10**, wherein different portions of the first sensor assembly are operable as the pressure sensor, the flow sensor, or the imaging sensor, and wherein the computing device is configured to control different portions of the first sensor assembly to obtain pressure data, flow data, or imaging data.

12. (canceled)

13. The intravascular system of claim **10**, wherein the first sensor assembly the pressure sensor, the flow sensor, or the imaging sensor at different times, and wherein the computing device is configured to control the sensor assembly to obtain pressure data, flow data, or imaging data at the respective different times.

14. (canceled)

15. A method of obtaining intravascular data, the method comprising:

receiving, at a computing device, first and second intravascular data associated with different modalities and obtained by an intravascular device inserted into vasculature of a patient and in communication with the computing device, the intravascular device comprising:

a flexible elongate member having a proximal portion and a distal portion,

a sensor assembly of an array of capacitive micromachined ultrasonic transducers (CMUTs) disposed at the distal portion of the flexible elongate member;

wherein the sensor assembly is operable as at least two of a pressure sensor, a flow sensor, and an imaging sensor;

wherein the sensor assembly is configured to be cycled through different operations comprising at least two of a pressure measurement, a flow measurement, and an imaging so that the same sensor assembly obtains data corresponding to different intravascular data types at various times,

processing, at the computing device, the first and second intravascular data; and

providing, from the computing device to a display in communication with the computing device, graphical representations of the processed first and second types of intravascular data for display.

16. (canceled)

17. The method of claim **16**, wherein different portions of the sensor assembly are operable the pressure sensor, the flow sensor, or the imaging sensor, further comprising:

controlling the respective different portions of the sensor assembly to obtain pressure data, flow data, or imaging data.

18. (canceled)

19. (canceled)

20. The method of claim **15**, wherein the sensor assembly is operable as the pressure sensor, the flow sensor, or the imaging sensor at different times, further comprising:

controlling the sensor assembly to obtain pressure data, flow data, or imaging data at the respective different times.

21. (canceled)

* * * * *

专利名称(译)	多模式电容微机械超声换能器和相关的装置，系统和方法		
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摘要(译)

提供了多模式电容微机械超声换能器（CMUT）和相关的装置系统以及方法。在一个实施例中，血管内装置包括柔性细长构件，该柔性细长构件具有近端部分和远端部分;第一传感器组件设置在柔性细长构件的远端部分，第一传感器组件包括第一电容微机械超声换能器阵列（CMUT）;其中第一传感器组件包括压力传感器，流量传感器或成像传感器中的至少两个。在一些实施例中，血管内装置还包括第二传感器组件，其包括第二CMUT阵列。