

(10) **Patent No.:** US 10,383,596 B2
(45) **Date of Patent:** Aug. 20, 2019

- ## OTHER PUBLICATIONS

- International Search Report and The Written Opinion received in Patent Cooperation Treaty Application No. PCT/US2009/068724, dated Jul. 20, 2010, 4 pages.

(Continued)

US 2015/0182188 A1 Jul. 2, 2015

Related U.S. Application Data

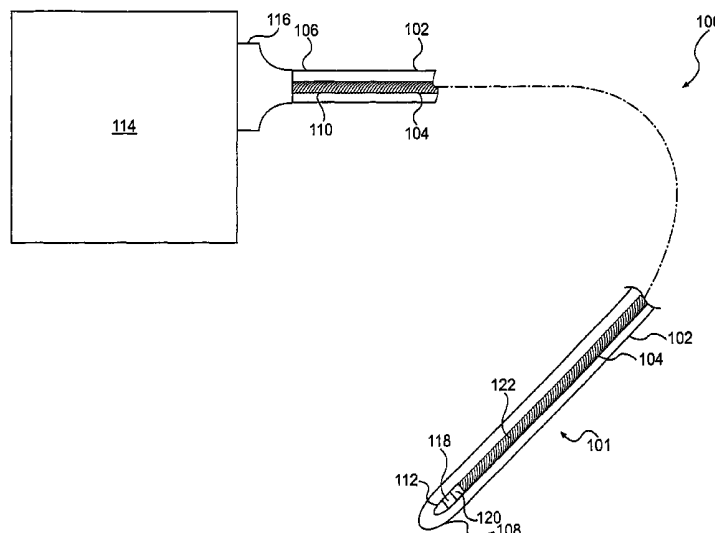
Primary Examiner — Elmer M Chao

- (63) Continuation of application No. 13/849,945, filed on Mar. 25, 2013, now Pat. No. 8,961,425, which is a
(Continued)
- (51) **Int. Cl.**
A61B 8/00 (2006.01)
A61B 8/12 (2006.01)
(Continued)
- (52) **U.S. Cl.**
CPC *A61B 8/12* (2013.01); *A61B 8/445*
(2013.01); *A61B 8/4461* (2013.01);
(Continued)
- (58) **Field of Classification Search**
CPC A61B 8/12; A61B 8/445; A61B 8/4461;
A61B 8/54; A61B 8/52; A61B 8/56;
(Continued)

(57) **ABSTRACT**

An intravascular ultrasound probe is disclosed, incorporating features for utilizing an advanced transducer technology on a rotating transducer shaft. In particular, the probe accommodates the transmission of the multitude of signals across the boundary between the rotary and stationary components of the probe required to support an advanced transducer technology. These advanced transducer technologies offer the potential for increased bandwidth, improved beam profiles, better signal to noise ratio, reduced manufacturing costs, advanced tissue characterization algorithms, and other desirable features. Furthermore, the inclusion of electronic components on the spinning side of the probe can be highly advantageous in terms of preserving maximum signal to noise ratio and signal fidelity, along with other performance benefits.

15 Claims, 6 Drawing Sheets



Related U.S. Application Data

continuation of application No. 12/402,278, filed on
Mar. 11, 2009, now Pat. No. 8,403,856.

(51) Int. Cl.

G10K 11/35 (2006.01)

A61B 8/08 (2006.01)

(52) U.S. Cl.

CPC **A61B 8/4483** (2013.01); **A61B 8/4488**
(2013.01); **A61B 8/52** (2013.01); **A61B 8/54**
(2013.01); **A61B 8/56** (2013.01); **G10K 11/355**
(2013.01); **A61B 8/4472** (2013.01)

(58) Field of Classification Search

CPC ... A61B 8/4483; A61B 8/4488; A61B 8/4472;
G10K 11/355

See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

4,763,663 A	8/1988	Uphold et al.
4,803,992 A	2/1989	Lemelson
5,115,809 A	5/1992	Saitoh et al.
5,176,140 A	1/1993	Kami et al.
5,209,235 A	5/1993	Brisken et al.
5,271,402 A	12/1993	Yeung et al.
5,313,950 A	5/1994	Ishikawa et al.
5,485,846 A	1/1996	Weber et al.
5,596,991 A	1/1997	Tanaka
5,810,009 A	9/1998	Mine et al.
5,810,733 A	9/1998	Van Creveld et al.
5,827,313 A	10/1998	Ream
5,846,205 A	12/1998	Curley et al.
5,989,191 A *	11/1999	Scampini A61B 8/12 600/453
6,004,273 A	12/1999	Sakamoto et al.
6,017,311 A	1/2000	Sakamoto
6,017,312 A	1/2000	Masters
6,149,599 A	11/2000	Schlesinger et al.
6,325,760 B1	12/2001	Takanori et al.
6,709,396 B2	3/2004	Flesch et al.
6,709,397 B2	3/2004	Taylor
6,758,818 B2	7/2004	Pantages et al.
7,396,332 B2	7/2008	Taimisto et al.

2003/0100834 A1	5/2003	Umeda et al.
2003/0208119 A1	11/2003	Crowley
2004/0199047 A1	10/2004	Taimisto
2006/0084875 A1	4/2006	Knight
2006/0173337 A1	8/2006	Chen et al.
2006/0173350 A1	8/2006	Yuan et al.
2007/0167813 A1	7/2007	Lee et al.
2007/0178768 A1	7/2007	Harshman et al.
2008/0161696 A1	7/2008	Schmitt et al.
2008/0177183 A1	7/2008	Courtney et al.
2009/0221958 A1	9/2009	Beyar et al.

FOREIGN PATENT DOCUMENTS

JP	08-191835	7/1996
JP	2001-327502	11/2001
JP	2002501809 A	1/2002
JP	2008526437	7/2008
WO	WO 99/39640	8/1999
WO	WO 03/103501	12/2003
WO	WO 2006/076428	7/2006
WO	WO2008/086356	7/2008
WO	WO 2008/086613	7/2008

OTHER PUBLICATIONS

Supplementary European Search Report received in European Patent Application No. 09837988.6, dated Apr. 4, 2013, 9 pages.

Supplementary European Search Report received in European Patent Application No. 10751228.7, dated Feb. 18, 2013, 8 pages.

Japanese Office Action and translation received in Japanese Application No. 2011-554100, dated Jan. 14, 2014, 7 pages.

Japanese Office Action and translation received in Japanese Application No. 2011-542485, dated Jan. 15, 2014, 4 pages.

Korean Intellectual Property Office, "Notification of Transmittal of the International Search Report and The Written Opinion of the International Search Authority, or the Declaration" for PCT/US2010/026491, dated Sep. 28, 2010, 8 pages.

European Patent Office, "Examination Report" for Application No. 10751228.7, dated Sep. 29, 2016, 7 pages.

Japanese Patent Office, Japanese Office Action dated Sep. 1, 2015, Application No. 2011-554100. Translation included 2 pages.

European Patent Office, "Examination Report" for Application No. 1075122.7-1657, dated May 19, 2017, 4 pages.

* cited by examiner

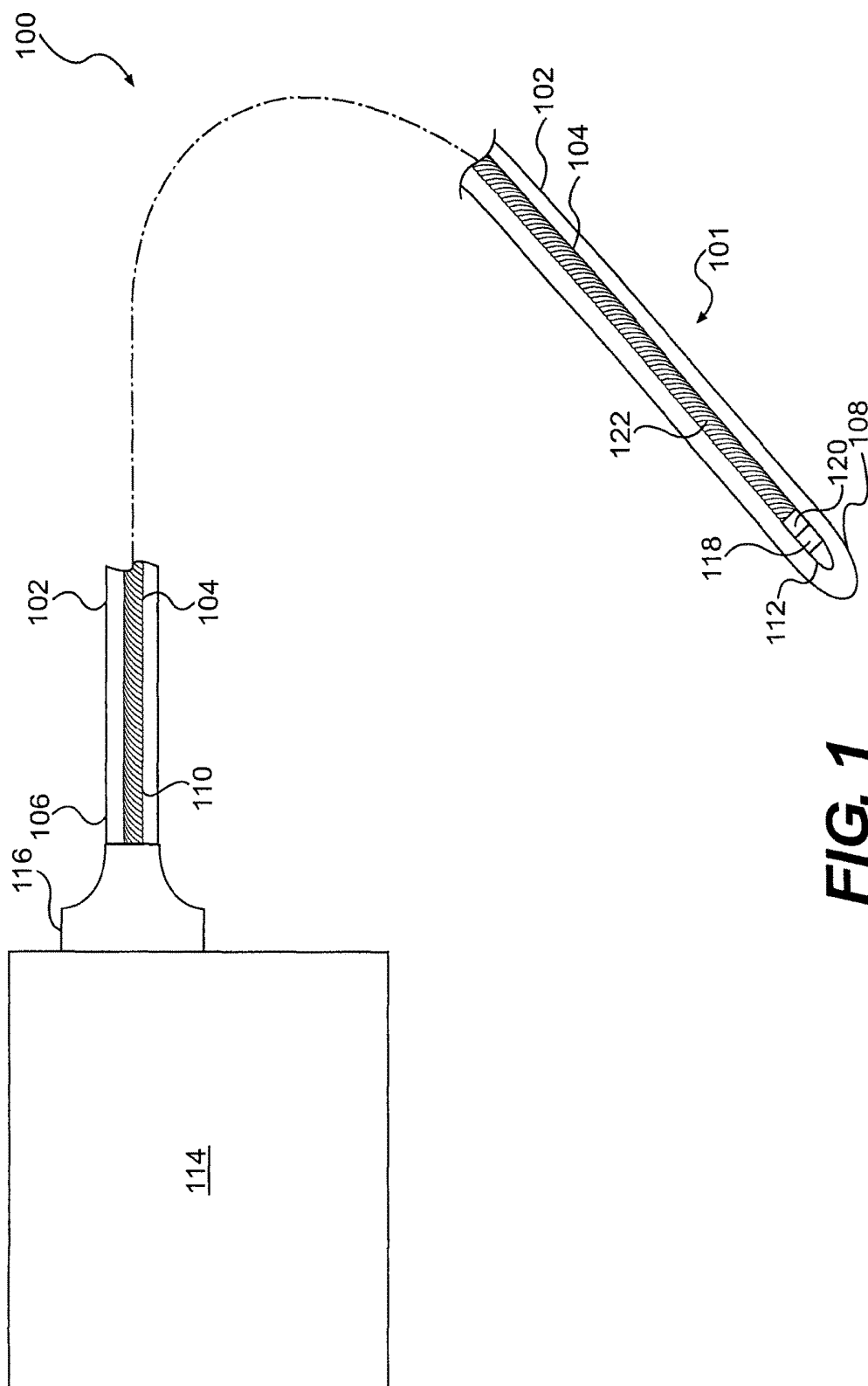


FIG. 1

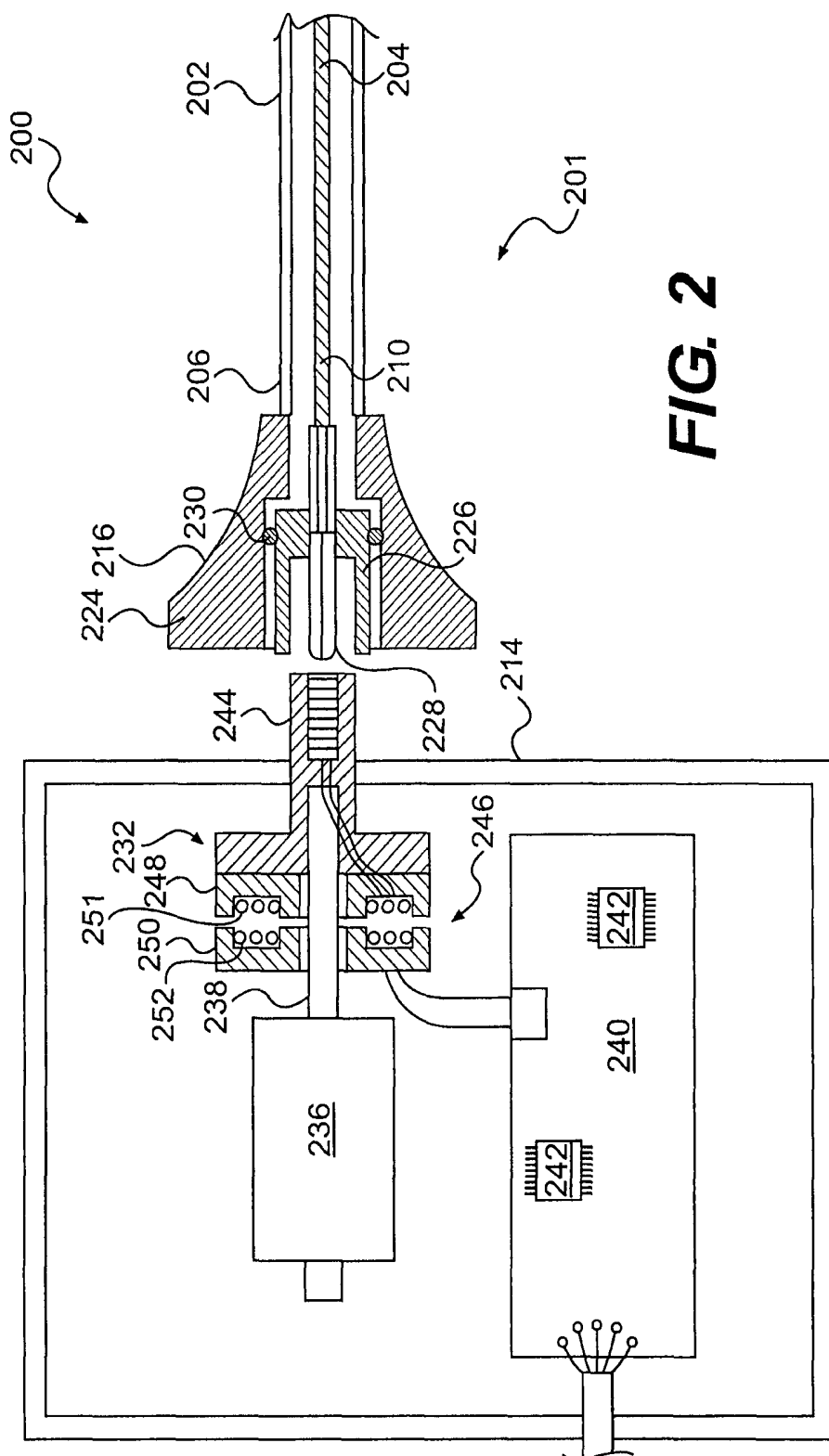


FIG. 2

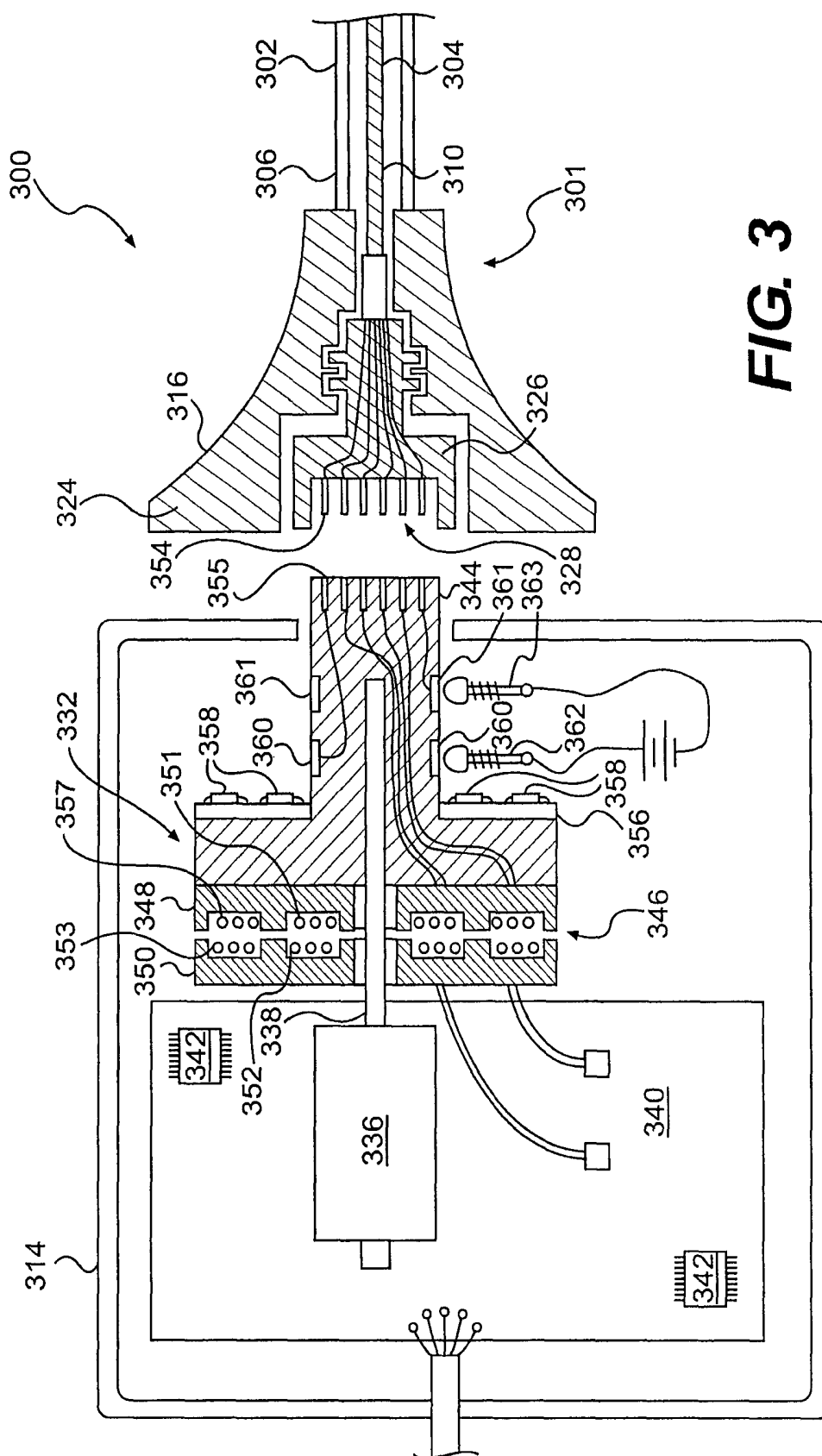


FIG. 3

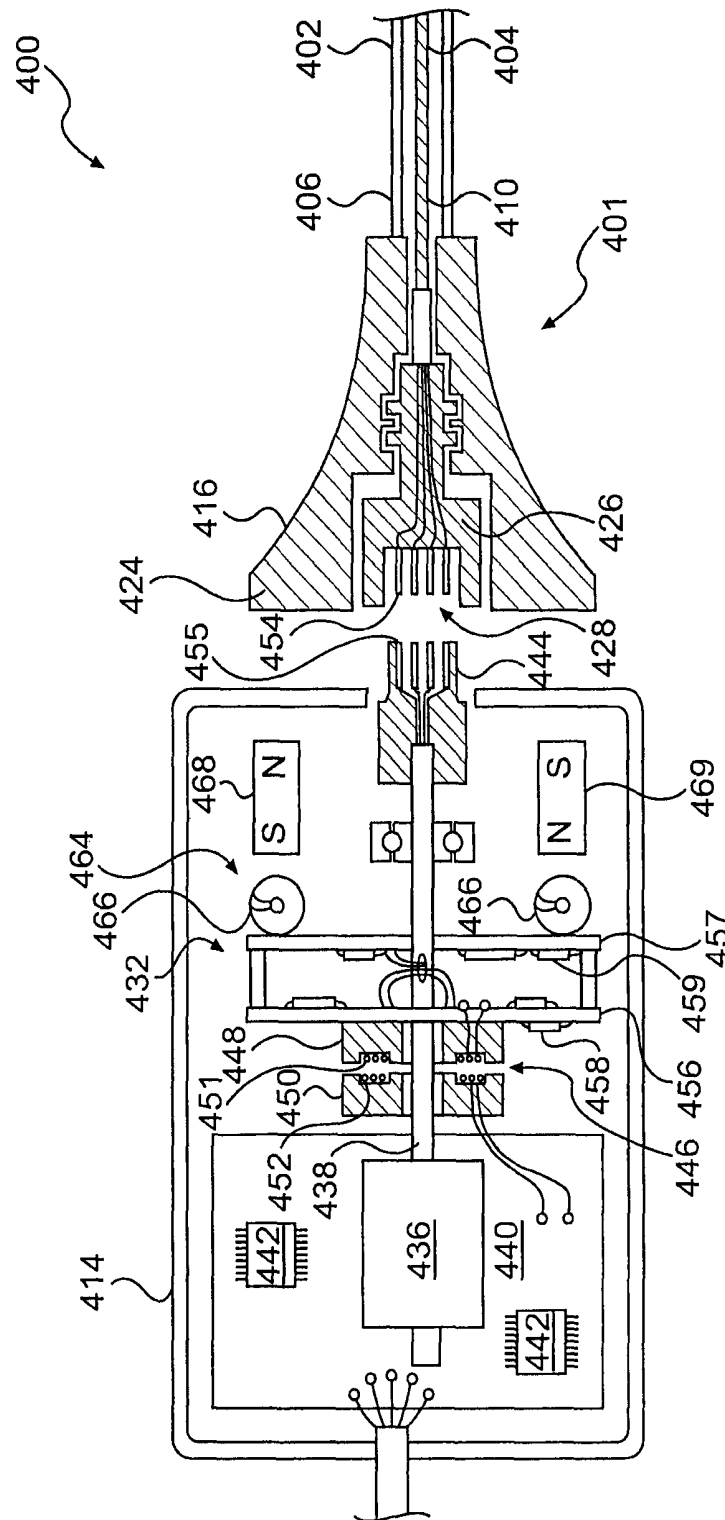


FIG. 4

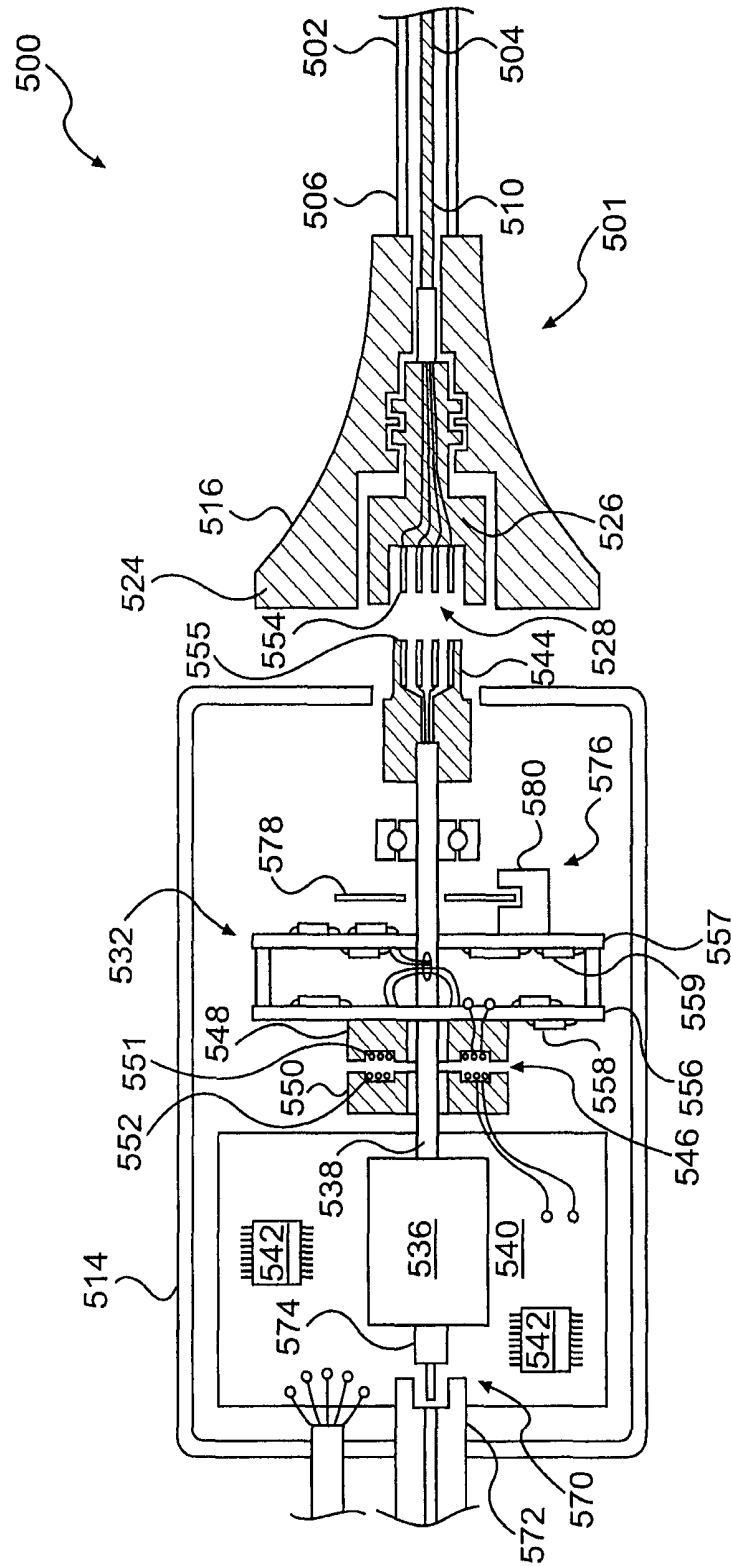


FIG. 5

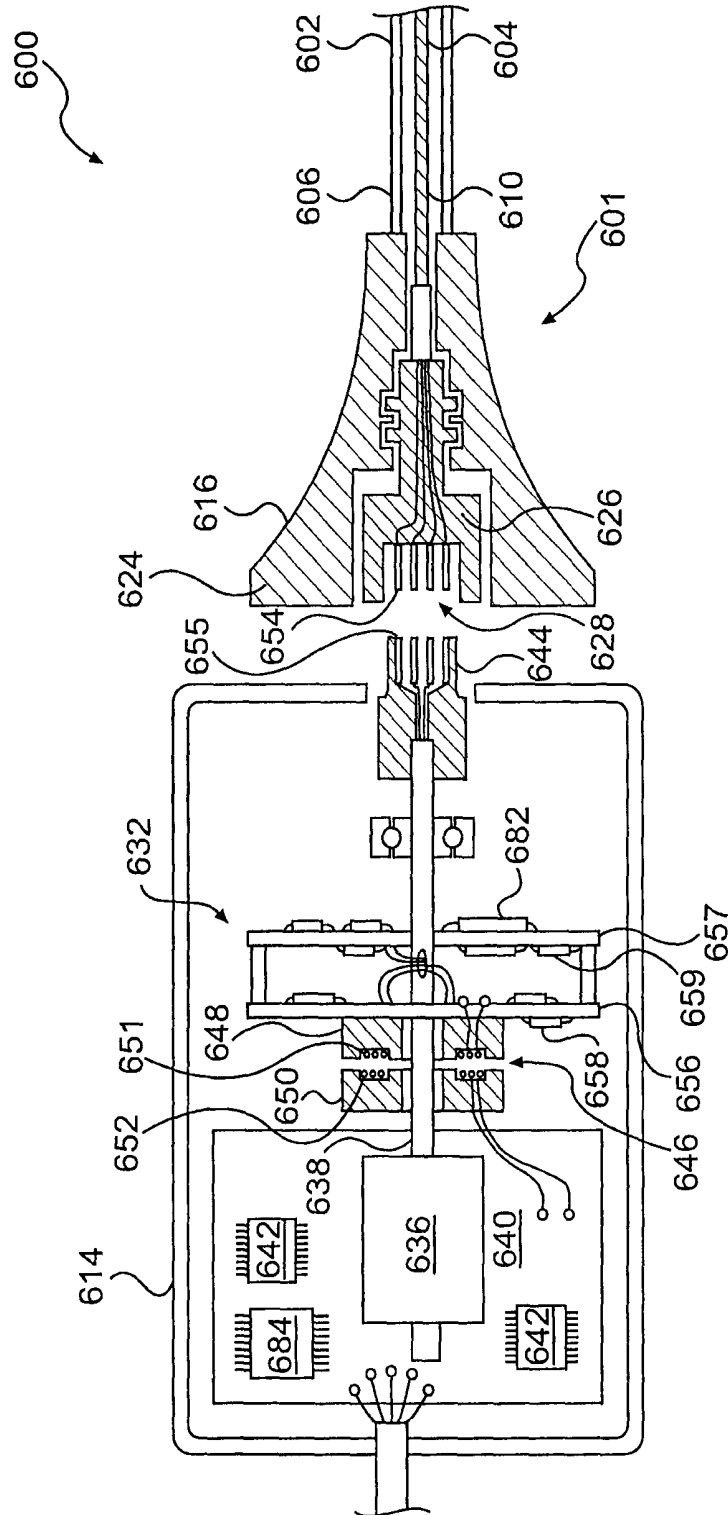


FIG. 6

ROTATIONAL INTRAVASCULAR ULTRASOUND PROBE WITH AN ACTIVE SPINNING ELEMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 13/849,945, filed Mar. 25, 2013, which is a continuation of U.S. patent application Ser. No. 12/402,278 filed on Mar. 11, 2009, now U.S. Pat. No. 8,403,856, each of which is hereby incorporated by reference in its entirety.

BACKGROUND

Intravascular Ultrasound (IVUS) has become an important interventional diagnostic procedure for imaging atherosclerosis and other vessel diseases and defects. In the procedure, an IVUS catheter is threaded over a guidewire into a blood vessel of interest, and images are acquired of the atherosclerotic plaque and surrounding area using ultrasonic echoes. This information is much more descriptive than the traditional standard of angiography, which shows only a two-dimensional shadow of the vessel lumen. Some of the key applications of IVUS include: determining a correct diameter and length of a stent to choose for dilating an arterial stenosis, verifying that a post-stenting diameter and luminal cross-section area are adequate, verifying that a stent is well apposed against a vessel wall to minimize thrombosis and optimize drug delivery (in the case of a drug eluting stent) and identifying an exact location of side-branch vessels. In addition, new techniques such as virtual histology (RF signal-based tissue characterization) show promise of aiding identification of vulnerable plaque (i.e., plaque which is prone to rupture and lead to onset of a heart attack).

There are two types of IVUS catheters commonly in use: mechanical/rotational IVUS catheters and solid state catheters. In a rotational IVUS catheter, a single transducer consisting of a piezoelectric crystal is rotated at approximately 1800 revolutions per minute while the element is intermittently excited with an electrical pulse. This excitation causes the element to vibrate at a frequency dependent upon the particulars of the transducer design. Depending on the dimensions and characteristics of the transducer, this operating frequency is typically in the range of 8 to 50 MHz. In general terms, a higher frequency of operation provides better resolution and a smaller catheter, but at the expense of reduced depth of penetration and increased echoes from the blood (making the image more difficult to interpret). A lower frequency of operation is more suitable for IVUS imaging in larger vessels or within the chambers of the heart.

The rotational IVUS catheter has a drive shaft disposed within the catheter body. The transducer is attached to the distal end of the drive shaft. The typical single element piezoelectric transducer requires only two electrical leads, with this pair of leads serving two separate purposes: (1) delivering the intermittent electrical transmit pulses to the transducer, and (2) delivering the received electrical echo signals from the transducer to the receiver amplifier (during the intervals between transmit pulses). The IVUS catheter is removably coupled to an interface module, which controls the rotation of the drive shaft within the catheter body and contains the transmitter and receiver circuitry for the transducer. Because the transducer is on a rotating drive shaft and the transmitter and receiver circuitry is stationary, a device

must be utilized to carry the transmit pulse and received echo across a rotating interface. This can be accomplished via a rotary transformer, which comprises two halves, separated by a narrow air gap that permits electrical coupling between the primary and secondary windings of the transformer while allowing relative motion (rotation) between the two halves. The spinning element (transducer, electrical leads, and driveshaft) is attached to the spinning portion of the rotary transformer, while the stationary transmitter and receiver circuitry contained in the interface module are attached to the stationary portion of the rotary transformer.

The other type of IVUS catheter is a solid state (or phased array) catheter. This catheter has no rotating parts, but instead includes an array of transducer elements (for example 64 elements), arrayed in a cylinder around the circumference of the catheter body. The individual elements are fired in a specific sequence under the control of several small integrated circuits mounted in the tip of the catheter, adjacent to the transducer array. The sequence of transmit pulses interspersed with receipt of the echo signals provides the ultrasound data required to reconstruct a complete cross-sectional image of the vessel, similar in nature to that provided by a rotational IVUS device.

Currently, most IVUS systems rely on conventional piezoelectric transducers, built from piezoelectric ceramic (commonly referred to as the crystal) and covered by one or more matching layers (typically thin layers of epoxy composites or polymers). Two advanced transducer technologies that have shown promise for replacing conventional piezoelectric devices are the PMUT (Piezoelectric Micromachined Ultrasonic Transducer) and CMUT (Capacitive Micromachined Ultrasonic Transducer). PMUT and CMUT transducers may provide improved image quality over that provided by the conventional piezoelectric transducer, but these technologies have not been adopted for rotational IVUS applications due to the larger number of electrical leads they require, among other factors.

There are many potential advantages of these advanced transducer technologies, some of which are enumerated here. Both PMUT and CMUT technologies promise reduced manufacturing costs by virtue of the fact that these transducers are built using wafer fabrication techniques to mass produce thousands of devices on a single silicon wafer. This is an important factor for a disposable medical device such as an IVUS catheter. These advanced transducer technologies provide broad bandwidth (>100%) in many cases compared to the 30-50% bandwidth available from the typical piezoelectric transducer. This broader bandwidth translates into improved depth resolution in the IVUS image, and it may also facilitate multi-frequency operation or harmonic imaging, either of which can help to improve image quality and/or enable improved algorithms for tissue characterization, blood speckle reduction, and border detection. Advanced transducer technologies also offer the potential for improved beam characteristics, either by providing a focused transducer aperture (instead of the planar, unfocused aperture commonly used), or by implementing dynamically variable focus with an array of transducer elements (in place of the traditional single transducer element).

BRIEF SUMMARY

The present invention provides the enabling technology allowing advanced transducer technology to be introduced into a rotational IVUS catheter. This in turn will provide improved image quality and support advanced signal processing to facilitate more accurate diagnosis of the medical

3

condition within the vessel. All of this can be achieved in a cost-effective way, possibly at a lower cost than the conventional technology.

Embodiments of an intravascular ultrasound probe are disclosed herein. The probe has features for utilizing an advanced transducer technology on a rotating transducer shaft. In particular, the probe accommodates the transmission of the multitude of signals across the boundary between the rotary and stationary components of the probe required to support an advanced transducer technology. These advanced transducer technologies offer the potential for increased bandwidth, improved beam profiles, better signal to noise ratio, reduced manufacturing costs, advanced tissue characterization algorithms, and other desirable features. Furthermore, the inclusion of electronic components on the spinning side of the probe can be highly advantageous in terms of preserving maximum signal to noise ratio and signal fidelity, along with other performance benefits.

In a disclosed embodiment, a rotational intravascular ultrasound probe for insertion into a vasculature is described. The rotational intravascular ultrasound probe can comprise an elongate catheter, an elongate transducer shaft, a spinning element, and a motor. The elongate catheter can have a flexible body. The elongate transducer shaft can be disposed within the flexible body and can have a drive cable and a transducer coupled to the drive cable. The spinning element can be coupled to the transducer shaft and can have an electronic component coupled thereto that is in electrical contact with the transducer. A motor may be coupled to the spinning element for rotating the spinning element and the transducer shaft.

In another disclosed embodiment, an interface module for a rotational intravascular ultrasound probe for insertion into a vasculature is described. The interface module can comprise a connector, a spinning element, and a motor. The connector can be used for attachment to a catheter having a transducer shaft with a transducer. The spinning element can be coupled to the connector and can have an electronic component coupled thereto that is in electrical contact with the connector. A motor may be coupled to the spinning element for rotating the spinning element.

In yet another disclosed embodiment, an interface module for a rotational intravascular ultrasound probe for insertion into a vasculature is described. The interface module can comprise a printed circuit board, a connector, a spinning element, and a motor. The connector can be used for attachment to a catheter having a transducer shaft with a transducer. The spinning element can be coupled to the connector. The spinning element has more than two signal pathways electrically connecting the spinning element to the connector. A motor may be coupled to the spinning element for rotating the spinning element.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a simplified fragmentary diagrammatic view of a rotational IVUS probe;

FIG. 2 is a simplified fragmentary diagrammatic view of an interface module and catheter for the rotational IVUS probe of FIG. 1 incorporating basic ultrasound transducer technology;

FIG. 3 is a simplified fragmentary diagrammatic view of an embodiment of an interface module and catheter for the rotational IVUS probe of FIG. 1 incorporating an advanced ultrasound transducer technology;

FIG. 4 is a simplified fragmentary diagrammatic view of another embodiment of an interface module and catheter for

4

the rotational IVUS probe of FIG. 1 incorporating an advanced ultrasound transducer technology;

FIG. 5 is a simplified fragmentary diagrammatic view of another embodiment of an interface module and catheter for the rotational IVUS probe of FIG. 1 incorporating an advanced ultrasound transducer technology; and

FIG. 6 is a simplified fragmentary diagrammatic view of another embodiment of an interface module and catheter for the rotational IVUS probe of FIG. 1 incorporating an advanced ultrasound transducer technology.

DETAILED DESCRIPTION

Turning to the figures, representative illustrations of rotational intravascular ultrasound (IVUS) probes, some of which include active spinning elements, are shown therein. An active spinning element can increase the number of signal paths available for the operation of the transducer so that advanced transducer technologies, such as PMUT (Piezoelectric Micromachined Ultrasonic Transducer) and CMUT (Capacitive Micromachined Ultrasonic Transducer), can be utilized with a rotational IVUS probe. In addition, an active spinning element can include active electronics on the rotary side of the probe.

Referring specifically to FIG. 1, a rotational intravascular ultrasound probe **100** for insertion into a patient for diagnostic imaging is shown. The probe **100** comprises a catheter **101** having a catheter body **102** and a transducer shaft **104**. The catheter body **102** is flexible and has both a proximal end portion **106** and a distal end portion **108**. The catheter body **102** is a sheath surrounding the transducer shaft **104**. For explanatory purposes, the catheter body **102** in FIG. 1 is illustrated as visually transparent such that the transducer shaft **104** disposed therein can be seen, although it will be appreciated that the catheter body **102** may or may not be visually transparent. The transducer shaft **104** is flushed with a sterile fluid, such as saline, within the catheter body **102**. The fluid serves to eliminate the presence of air pockets around the transducer shaft **104** that adversely affect image quality. The fluid can also act as a lubricant. The transducer shaft **104** has a proximal end portion **110** disposed within the proximal end portion **106** of the catheter body **102** and a distal end portion **112** disposed within the distal end portion **108** of the catheter body **102**.

The distal end portion **108** of the catheter body **102** and the distal end portion **112** of the transducer shaft **104** are inserted into a patient during the operation of the probe **100**. The usable length of the probe **100** (the portion that can be inserted into a patient) can be any suitable length and can be varied depending upon the application. The distal end portion **112** of the transducer shaft **104** includes a transducer subassembly **118**.

The proximal end portion **106** of the catheter body **102** and the proximal end portion **110** of the transducer shaft **104** are connected to an interface module **114** (sometimes referred to as a patient interface module or PIM). The proximal end portions **106**, **110** are fitted with a catheter hub **116** that is removably connected to the interface module **114**.

The rotation of the transducer shaft **104** within the catheter body **102** is controlled by the interface module **114**, which provides a plurality of user interface controls that can be manipulated by a user. The interface module **114** also communicates with the transducer subassembly **118** by sending and receiving electrical signals to and from the transducer subassembly **118** via wires within the transducer shaft **104**. The interface module **114** can receive, analyze, and/or display information received through the transducer

shaft 104. It will be appreciated that any suitable functionality, controls, information processing and analysis, and display can be incorporated into the interface module 114.

The transducer shaft 104 includes a transducer subassembly 118, a transducer housing 120, and a drive cable 122. The transducer subassembly 118 is coupled to the transducer housing 120. The transducer housing 120 is attached to the drive cable 122 at the distal end portion 112 of the transducer shaft 104. The drive cable 122 is rotated within the catheter body 102 via the interface module 114 to rotate the transducer housing 120 and the transducer subassembly 118. The transducer subassembly 118 can be of any suitable type, including but not limited to one or more advanced transducer technologies such as PMUT or CMUT. The transducer subassembly 118 can include either a single transducer or an array.

FIG. 2 shows a rotational IVUS probe 200 utilizing a common spinning element 232. The probe 200 has a catheter 201 with a catheter body 202 and a transducer shaft 204. As shown, the catheter hub 216 is near the proximal end portion 206 of the catheter body 202 and the proximal end portion 210 of the transducer shaft 204. The catheter hub 216 includes a stationary hub housing 224, a dog 226, a connector 228, and bearings 230. The dog 226 mates with a spinning element 232 for alignment of the hub 216 with the interface module 214 and torque transmission to the transducer shaft 204. The dog 226 rotates within the hub housing 224 utilizing the bearings 230. The connector 228 in this figure is coaxial. The connector 228 rotates with the spinning element 232, described further herein.

As shown, the interior of the interface module 214 includes a motor 236, a motor shaft 238, a printed circuit board (PCB) 240, the spinning element 232, and any other suitable components for the operation of the IVUS probe 200. The motor 236 is connected to the motor shaft 238 to rotate the spinning element 232. The printed circuit board 240 can have any suitable number and type of electronic components 242, including but not limited to the transmitter and the receiver for the transducer.

The spinning element 232 has a complimentary connector 244 for mating with the connector 228 on the catheter hub 216. As shown, the spinning element 232 is coupled to a rotary portion 248 of a rotary transformer 246. The rotary portion 248 of the transformer 246 passes the signals to and from a stationary portion 250 of the transformer 246. The stationary portion 250 of the transformer 246 is wired to the transmitter and receiver circuitry on the printed circuit board 240.

The transformer includes an insulating wire that is layered into an annular groove to form a two- or three-turn winding. Each of the rotary portion 250 and the stationary portion 248 has a set of windings, such as 251 and 252 respectively. Transformer performance can be improved through both minimizing the gap between the stationary portion 250 and the rotary portion 248 of the transformer 246 and also by placing the windings 251, 252 as close as possible to each other.

Advanced transducer technologies can require more than the two conductive signal lines that a single piezoelectric transducer utilizes on a conventional rotational IVUS probe. For example, in addition to signal pathways for ultrasound information communicated with the transducer, certain advanced transducer technologies also require a power supply in order to operate. In order to pass the necessary multiple of signals between the advanced transducer technology and the interface module, a suitable structure may be needed to transmit ultrasound signals, power, and any other

suitable signals across the boundary between the rotating and stationary mechanical components. Particularly for ultrasound signals, the mode of transmission must also maintain reliable signal quality, without excess noise, sufficient for the interface module to form a reliable image of the target tissue from the sensitive ultrasound signals. It will be appreciated that any suitable signals can be communicated across the boundary between the rotating and stationary mechanical components including, but not limited to, A-scan RF data, power transmit pulses, low amplitude receive signals, DC power and/or bias, AC power, and/or various control signals. The signal transfer across the boundary between the rotating and stationary mechanical components can have high frequency capability and broadband response.

Multiple signal transfer pathways are presented herein for communicating signals across the boundary of the rotating and stationary parts. Each of these pathways are explained in further detail herein, and for purposes of discussion and explanation, certain pathways may be shown in combination with one another. It will be appreciated, however, that any of these pathways may be utilized in any suitable combination with one another to permit any suitable number of total signal pathways. Furthermore, as will be explained in further detail below, certain signal transfer pathways can be more conducive to transmitting either power or other signals, such as ultrasound signals.

Referring to FIG. 3, an embodiment of a rotational IVUS probe 300 having an interface module 314 and catheter 301 suitable for use with an advanced transducer technology is represented. As shown, the probe 300 has a catheter body 302, a transducer shaft 304, and a catheter hub 316. The catheter body 302 has a proximal end 306 and the transducer shaft 304 has a proximal end 310. The catheter hub 316 includes a stationary exterior housing 324, a dog 326, and a connector 328. The connector 328 is represented with six conductive lines 354 shown in this embodiment. It will be appreciated, however, that any suitable number of conductive lines can be utilized.

As shown, the interior of the interface module 314 can include a motor 336, a motor shaft 338, a main printed circuit board (PCB) 340, a spinning element 332, and any other suitable components for the operation of the IVUS probe 300. The motor 336 is connected to the motor shaft 338 to rotate the spinning element 332. The printed circuit board 340 can have any suitable number and type of electronic components 342.

The spinning element 332 has a complimentary connector 344 for mating with the connector 328 on the catheter hub 316. The connector 344 can have conductive lines, such as 355, that contact the conductive lines, such as 354, on the connector 328. As shown, the spinning element 332 is coupled to a rotary portion 348 of a rotary transformer 346. The rotary portion 348 of the transformer 346 passes the signals to and from a stationary portion 350 of the transformer 346. The stationary portion 350 of the transformer 346 is electrically connected to the printed circuit board 340.

In this embodiment, the transformer 346 has multiple sets of windings for transmitting multiple signals across the transformer 346. Specifically, as shown, the rotary portion 348 and the stationary portion 350 of the transformer 346 each have two sets of windings, such as windings 352, 353 on the stationary portion 350 and windings 351, 357 on the rotary portion 348, to transmit two signals across the transformer 346. In this way, more signal pathways are available for a probe 300 utilizing an advanced transducer technology. It will be appreciated that any suitable number of windings

may be used to transmit any suitable number of signals across the transformer 346. In alternative embodiments, planar flex circuits can be used in place of the windings in the transformer. The planar flex circuits can be placed very close to one another to enhance signal quality.

Another consideration for advanced transducer technologies is that the probe 300 can benefit from the utilization of certain active electronic components and circuitry in order to facilitate and/or complement the operation of the transducer. Through active electronic components and circuitry on the spinning element 332, more complex electrical communication can take place between the interface module 314 and the transducer. Furthermore, by handling certain signal processing functions on the spinning element 332, the number of signals that need to pass across the spinning element 332 can, in some embodiments, be reduced.

As shown, a printed circuit board 356 can be coupled to the spinning element 332. The printed circuit board 356 can have any suitable number of electronic components 358 coupled thereto. Any suitable number of printed circuit boards 356 having any suitable number and type of electronic components 358 can be utilized on the spinning element 332. The electronic components on the spinning element 332 allow for signal processing to take place on the spinning side of the probe 300 before the signal is communicated across the rotary/stationary boundary.

Typically, advanced transducer technologies require a DC power source. To provide DC power to the transducer, the spinning element 332 can be fitted with contacts, such as slip ring contacts 360, 361, which are respectively engaged by stationary brushes 362, 363 within the interface module 314. Each of the slip rings 360, 361 is coupled to a respective conductive line, such as 355, in the connector 344.

In other embodiments, the transducer can be powered by an AC power source. For example, instead of using brushes and contacts, AC power can be transmitted through a set of windings in the transformer 346. Once the power has passed across from the stationary portion 350 of the transformer 346 to the rotary portion 348 of the transformer 346, it can be passed to a power supply circuit, such as a diode rectifier, on the spinning element 332 that rectifies the AC power into DC power. The rectifier can be coupled to the printed circuit board 356 on the spinning element 332 as one of the electronic components 358. After the AC power is converted to DC power, the DC power can be used to power the transducer, as well as the other electronic components 358 included on printed circuit board 356.

Turning to FIG. 4, an embodiment of a rotational IVUS probe 400 having an interface module 414 and catheter 401 suitable for use with an advanced transducer technology is represented. As shown, the probe 400 has a catheter body 402, a transducer shaft 404, and a catheter hub 416. The catheter body 402 has a proximal end portion 406, and the transducer shaft 404 has a proximal end portion 410. The catheter hub 416 includes a stationary exterior housing 424, a dog 426, and a connector 428. The connector 428 is represented with four conductive lines 454 shown in this embodiment. It will be appreciated, however, that any suitable number of conductive lines can be utilized.

As shown, the interior of the interface module 414 can include a motor 436, a motor shaft 438, a main printed circuit board (PCB) 440, a spinning element 432, and any other suitable components for the operation of the IVUS probe 400. The motor 436 is connected to the motor shaft 438 to rotate the spinning element 432. The printed circuit board 440 can have any suitable number and type of electronic components 442.

The spinning element 432 has a complimentary connector 444 for mating with the connector 428 on the catheter hub 416. The connector 444 can have conductive lines, such as 455, that contact the conductive lines, such as 454, on the connector 428. As shown, the spinning element 432 is coupled to a rotary portion 448 of a rotary transformer 446. The rotary portion 448 of the transformer 446 passes the signals to and from a stationary portion 450 of the transformer. The stationary portion 450 of the transformer 446 is electrically connected to the printed circuit board 440.

As shown, the rotary portion 448 and the stationary portion 450 of the transformer 446 each have a set of windings 451, 452 to transmit a signal across the transformer 446. It will be appreciated that any suitable number of windings may be used to transmit any suitable number of signals across the transformer 446. In this embodiment, the transformer 446 can be used to transfer the ultrasound signal. It will also be appreciated that a planar flex circuit may be used in place of one or more of the sets of windings as previously described.

The probe 400 can benefit from the utilization of certain electronic components and circuitry in order to facilitate and/or complement the operation of the transducer. As shown, one or more printed circuit boards 456, 457 can be coupled to the spinning element 432. The printed circuit boards 456, 457 can have any suitable number of electronic components, such as 458 and 459, coupled thereto. It will be appreciated that any suitable number of printed circuit boards 456, 457 having any suitable number and type of electronic components 458, 459 can be utilized on the spinning element 432. Electronic components on the spinning element 432 allow for signal processing to take place on the spinning side of the probe 400 before the signal is communicated across the rotary/stationary boundary.

In this embodiment, power is provided to the transducer using a generator mechanism 464 to generate power locally. As illustrated in the figure, the generator mechanism 464 includes a generator coil 466 and a plurality of stator magnets 468, 469. The generator coil 466 can be attached to the spinning element 432 to rotate with the spinning element 432 and generate power. The power generated is AC power, so a power supply circuit, such as a diode rectifier, can be used to convert the AC power into DC power. The rectifier can be coupled to the printed circuit boards 456, 457 on the spinning element 432. After rectification, the DC power can be used to power the transducer as well as the other electronic components 458, 459 included on the printed circuit boards 456, 457. It will be appreciated that any suitable generator can be utilized to provide power to the transducer.

Another embodiment of a rotational IVUS probe 500 having an interface module 514 and catheter 501 suitable for use with an advanced transducer technology is represented in FIG. 5. As shown, the probe has a catheter body 502, a transducer shaft 504, and a catheter hub 516. The catheter body 502 has a proximal end portion 506, and the transducer shaft 504 has a proximal end portion 510. The catheter hub 516 includes a stationary exterior housing 524, a dog 526, and a connector 528. The connector 528 is represented with four conductive lines 554 shown in this embodiment. It will be appreciated, however, that any suitable number of conductive lines can be utilized.

As shown, the interior of the interface module 514 can include a motor 536, a motor shaft 538, a main printed circuit board (PCB) 540, a spinning element 532, and any other suitable components for the operation of the IVUS probe 500. The motor 536 is connected to the motor shaft

538 to rotate the spinning element **532**. The printed circuit board **540** can have any suitable number and type of electronic components **542**.

The spinning element **532** has a complimentary connector **544** for mating with the connector on the catheter hub **516**. The connector **544** can have conductive lines, such as **555**, that contact the conductive lines, such as **554**, on the connector **528**. As shown, the spinning element **532** is coupled to a rotary portion **548** of a rotary transformer **546**. The rotary portion **548** of the transformer **546** passes the signals to and from the stationary portion **550** of the transformer **546**. The stationary portion **550** of the transformer **546** is electrically connected to the printed circuit board **540**.

As shown, the rotary portion **548** and the stationary portion **550** of the transformer **546** each have one set of windings **551**, **552** to transmit a signal across the transformer **546**. It will be appreciated that any suitable number of windings **551**, **552** may be used to transmit any suitable number of signals across the transformer **546**. In this embodiment, the transformer **546** is used to transfer AC power. Once the power has passed across from the stationary portion **550** of the transformer **546** to the rotary portion **548** of the transformer **546**, it can be passed to a power supply circuit, such as a diode rectifier, on the spinning element **532** that rectifies the AC power into DC power. The rectifier can be coupled to the printed circuit boards **556**, **557** on the spinning element **532**. After the AC power is converted to DC power, the DC power can be used to power the transducer as well as the other electronic components **558**, **559** included on the printed circuit boards **556**, **557**. It will also be appreciated that a planar flex circuit may be used in place of one or more of the sets of windings as previously described.

As previously mentioned, the probe **500** can benefit from the utilization of certain electronic components and circuitry in order to facilitate and/or complement the operation of the transducer. As shown, one or more printed circuit boards **556**, **557** can be coupled to the spinning element **532**. The printed circuit boards **556**, **557** can have any suitable number of electronic components, such as **558** and **559**, coupled thereto. It will be appreciated that any suitable number of printed circuit boards **556**, **557** having any suitable number and type of electronic components **558**, **559** can be utilized on the spinning element **532**. Electronic components **558**, **559** on the spinning element **532** allow for signal processing to take place on the spinning side of the probe **500** before the signal is communicated across the rotary/stationary boundary.

In this embodiment, an optical coupler **570** is used to transmit the ultrasound signal. It will be appreciated that any suitable optical coupler may be used. The optical coupler can have a first end **572** and a second end **574**. The first end **572** can be stationary and receive optical signals from the second end **574**, which can be coupled directly or indirectly to the spinning element **532**. The ultrasound signal can be transmitted to circuitry on the printed circuit board **540** or can be carried external to the interface module **514**.

One illustrative example of how the ultrasound signal could be communicated over this optical path is that the printed circuit boards **556**, **557** could include a high speed analog to digital converter (ADC) among electronic components **558**, **559**. This ADC would be used to digitize the ultrasound echo signal and convert the resultant digital data into a serial bit stream. This serial data would then be provided to an optical transmitter, such as a laser diode circuit, also included on printed circuit boards **558**, **559** to transmit the high-speed serial bit stream over the rotating

optical coupler **570** to an optical receiver circuit included on printed circuit board **540** or located remotely from the interface module **514**.

As shown, a structure may be provided that can provide feedback as to the angular position of the transducer. For example, an optical device **576** may be provided that includes a stationary encoder wheel **578** and an optical detector **580**. The optical detector **580** can be attached to a printed circuit board **557** on the spinning element **532**.

Another embodiment of a rotational IVUS probe **600** having an interface module **614** and catheter **601** suitable for use with an advanced transducer technology is represented in FIG. 6. As shown, the probe **600** has a catheter body **602**, a transducer shaft **604**, and a catheter hub **616**. The catheter body **602** has a proximal end portion **606**, and the transducer shaft **604** has a proximal end portion **610**. The catheter hub **616** includes a stationary exterior housing **624**, a dog **626**, and a connector **628**. The connector is represented with four conductive lines, such as **654**, shown in this embodiment. It will be appreciated, however, that any suitable number of conductive lines **654** can be utilized.

As shown, the interior of the interface module **614** can include a motor **636**, a motor shaft **638**, a main printed circuit board (PCB) **640**, a spinning element **632**, and any other suitable components for the operation of the IV US probe **600**. The motor **636** is connected to the motor shaft **638** to rotate the spinning element **632**. The main printed circuit board **640** can have any suitable number and type of electronic components **642** including but not limited to the transmitter and the receiver for the transducer.

The spinning element **632** has a complimentary connector **644** for mating with the connector **628** on the catheter hub **616**. The connector **644** can have conductive lines, such as **655**, that contact the conductive lines, such as **654**, on the connector **628**. As shown, the spinning element **632** is coupled to a rotary portion **648** of a rotary transformer **646**. The rotary portion **648** of the transformer **646** passes the signals to and from the stationary portion **650** of the transformer **646**. The stationary portion **650** of the transformer **646** is electrically connected to the printed circuit board **640**.

As shown, the rotary portion **648** and the stationary portion **650** of the transformer **646** each have a set of windings **651**, **652** to transmit a signal across the transformer **646**. It will be appreciated that any suitable number of windings may be used to transmit any suitable number of signals across the transformer **646**. In this embodiment, the transformer **646** is used to transfer AC power. Once the power has passed across from the stationary portion **650** of the transformer **646** to the rotary portion **648** of the transformer **646**, it can be passed to a power supply circuit, such as a diode rectifier, on the spinning element **632** that rectifies the AC power into DC power. The rectifier can be coupled to printed circuit boards **656**, **657** on the spinning element **632**. After the AC power is converted to DC power, the DC power can be used to power the transducer as well as the other electronic components **658**, **659** included on the printed circuit boards **656**, **657**. It will also be appreciated that a planar flex circuit may be used in place of one or more of the sets of windings as previously described.

As previously mentioned, the probe can benefit from the utilization of certain electronic components and circuitry in order to facilitate and/or complement the operation of the transducer. As shown, one or more printed circuit boards **656**, **657** can be coupled to the spinning element **632**. The printed circuit boards **656**, **657** can have any suitable number of electronic components, such as **658** and **659**, coupled thereto. It will be appreciated that any suitable number of

printed circuit boards **656**, **657** having any suitable number and type of electronic components **658**, **659** can be utilized on the spinning element **632**. Electronic components **658**, **659** on the spinning element **632** allow for signal processing to take place on the spinning side of the probe **600** before the signal is communicated across the rotary/stationary boundary.

In this embodiment, a wireless communication mechanism is used to transmit the ultrasound signal. Any suitable wireless communication mechanism may be used including, but not limited to, wireless mechanisms utilizing radio frequency or infrared. As shown, the wireless communication mechanism includes transmitter and/or receiver components **682** and **684**. The transmitter and/or receiver component **682** can be attached to any suitable location such as the printed circuit board **657** on the spinning element **632**. The transmitter and/or receiver component **684** can likewise be placed in any suitable location including the main printed circuit board **640** in the interface module **614**.

Therefore, it will be appreciated that signals can be carried across the rotating and stationary mechanical components via any suitable mechanism including, but not limited to, a transformer, an optical coupler, a wireless communication mechanism, a generator, and/or brushes/contacts. In certain embodiments, a transformer, an optical coupler, and/or a wireless communication mechanism can be utilized to carry signals such as an ultrasound signal. In certain embodiments, a transformer, a power generator, and/or brushes/contacts can be utilized to convey power to the transducer.

Furthermore, the spinning element can have one or more printed circuit boards with a suitable number and type of active electronic components and circuitry, thus making the spinning element an active spinning element. Examples of electronic components that can be utilized with the active spinning element include, but are not limited to, power supply circuits (such as a generator, rectifier, regulator, high voltage step-up converter, etc.), transmitters (including tripolar transmitters), time-gain-control (TGC) amplifiers, amplitude and/or phase detectors, ADC converters, optical transceivers, encoder circuits, wireless communication components, microcontrollers, and any other suitable components. In addition, the spinning element can include encoder and timing logic such that it can internally generate the transmit triggers, and thus, eliminate the need to communicate a timing signal across the spinning element. Through the embodiments described herein, excellent image quality is possible including wide bandwidth, frequency-agility, low ringdown, focused beam (including dynamically focused beam), and harmonic capability.

As mentioned, any suitable advanced transducer technology may be used, including but not limited to PMUT and CMUT transducers, either as single transducers or arrays. As an example, a PMUT transducer can be formed by depositing a piezoelectric polymer (such as polyvinylidene fluoride—PVDF) onto a micromachined silicon substrate. The silicon substrate can include an amplifier and protection circuit to buffer the signal from the PVDF transducer. It can be important to include the amplifier immediately adjacent to the PVDF element because the capacitance of the electrical cables can dampen the signal from the high impedance PVDF transducer. The amplifier typically requires DC power, transmit input(s), and amplifier output connections. The PVDF transducer can be a focused transducer to provide excellent resolution.

As mentioned above, having an active spinning element, such as is described herein, permits the utilization of an

advanced transducer technology on a rotational IVUS probe. In addition, having an active spinning element can facilitate certain advanced operations of the probe. The enhanced bandwidth of the probe utilizing the active spinner permits the probe to obtain information at a plurality of different frequencies. By way of example and not limitation, the probe can be utilized to obtain ultrasound information taken at two diverse frequencies, such as 20 MHz and 40 MHz. It will be appreciated that any suitable frequency and any suitable quantity of frequencies may be used.

Generally, lower frequency information facilitates a tissue versus blood classification scheme due to the strong frequency dependence of the backscatter coefficient of the blood. Higher frequency information generally provides better resolution at the expense of poor differentiation between blood speckle and tissue, which can make it difficult to identify the lumen border. Thus, if information is obtained at a lower frequency and a higher frequency, then an algorithm can be utilized to interleave and display the two data sets to obtain frequency-diverse information that is closely aligned in time and space. In result, a high resolution ultrasound image can be produced with clear differentiation between blood and tissue and accurate delineation of vessel borders.

The typical **512** A-lines that compose a single frame of an image can be interspersed into alternating high and low frequency A-lines. As an example, a 20 MHz image can show the blood as black and the tissue as gray, while the 40 MHz image can show the blood and tissue as gray and barely, if at all, distinguishable from one another. It can be recognized through a provided algorithm that black in 20 MHz and gray at 40 MHz is blood, gray at both frequencies is tissue, and black at both frequencies is clear fluid. The broadband capability of advanced transducer technologies, such as PMUT, facilitated by the active spinning element, can allow for closely interleaved A-lines of two or more different center frequencies, possibly including pulse-inversion A-line pairs to generate harmonic as well as fundamental information, which is then combined to provide a robust classification scheme for tissue versus blood.

The dual frequency blood classification scheme can be further enhanced by other blood speckle reduction algorithms such as motion algorithms (such as ChromaFlo, Q-Flow, etc.), temporal algorithms, harmonic signal processing, etc. It will be appreciated that any suitable algorithm can be used.

Besides intravascular ultrasound, other types of ultrasound catheters can be made using the teachings provided herein. By way of example and not limitation, other suitable types of catheters include non-intravascular intraluminal ultrasound catheters, intracardiac echo catheters, laparoscopic, and interstitial catheters. In addition, the probe may be used in any suitable anatomy, including, but not limited to, coronary, carotid, neuro, peripheral, or venous.

Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein.

It will be appreciated that like reference numbers and/or like shown features in the figures can represent like features. It will be appreciated that discussions of like reference numbers and/or like shown features in any embodiment may be applicable to any other embodiment.

Any references, including publications, patent applications, and patents, cited herein are hereby incorporated by

13

reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein (including any references contained therein).

Illustrative embodiments of a rotational IVUS probe incorporating an advanced ultrasound transducer technology are described herein. Variations of the disclosed embodiments will be apparent to those of ordinary skill in the art in view of the foregoing illustrative examples. Those skilled in the relevant art will employ such variations as appropriate, and such variations, embodied in alternative embodiments, are contemplated within the scope of the disclosed invention. The invention is therefore not intended to be limited to the examples described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

What is claimed is:

1. A rotational intravascular ultrasound (IVUS) device, the device comprising:

an elongate catheter comprising a flexible body for insertion into a vessel, the flexible body comprising a proximal portion and a distal portion, a flexible drive cable disposed within the flexible body and extending from the proximal portion of the flexible body to the distal portion of the flexible body, and an IVUS transducer assembly coupled to a distal portion of the drive cable, the drive cable configured to be rotated within the flexible body by a motor positioned outside the elongate catheter and coupled to a proximal portion of the drive cable such that the IVUS transducer assembly rotates with the drive cable, wherein the IVUS transducer assembly is configured to obtain imaging data at different frequencies during rotation; and

an electronic component coupled to the drive cable such that the electronic component rotates with the drive cable, the electronic component being in electrical communication with the IVUS transducer assembly to transmit signals to the IVUS transducer assembly or receive signals from the IVUS transducer assembly, wherein the electronic component comprises a printed circuit board including an algorithm stored thereon for interleaving the imaging data at the different frequencies.

2. The rotational IVUS device of claim 1 wherein the electronic component further comprises an active electronic component selected from the group consisting of a transmitter, a time-gain-control amplifier, an amplitude detector, a phase detector, an analog to digital converter, an optical transceiver, an encoder circuit, a wireless communication component, and a microcontroller.

3. The rotational IVUS device of claim 1, further comprising:

a spinning element coupled to the drive cable such that the spinning element rotates with the drive cable, the spinning element configured to be positioned adjacent to and spaced from a stationary element to transmit signals to the stationary element and receive signals from the stationary element.

4. The rotational IVUS device of claim 1 further comprising at least three conductive lines electrically connecting the spinning element to the IVUS transducer assembly.

5. The rotational IVUS device of claim 4 wherein the IVUS transducer assembly includes at least one of a piezo-

14

electric transducer, a Capacitive Micromachined Ultrasonic Transducer (CMUT), or a Piezoelectric Micromachined Ultrasonic Transducer (PMUT).

6. A rotational intravascular ultrasound (IVUS) device, the device comprising:

an elongate catheter comprising a flexible body configured to be inserted into a vessel; and

a rotating assembly extending along a length of the elongate catheter between a proximal portion and a distal portion, the rotating assembly including:

a flexible drive cable disposed within the flexible body of the elongate catheter and extending from the proximal portion to the distal portion, the drive cable configured to be rotated within the flexible body by a motor positioned outside the elongate catheter and coupled to a proximal portion of the drive cable;

an IVUS transducer assembly coupled to a distal portion of the drive cable such that the IVUS transducer assembly rotates with the drive cable, wherein the IVUS transducer assembly is configured to obtain imaging data at different frequencies during rotation; and

an electronic component coupled to the drive cable such that the electronic component rotates with the drive cable, the electronic component being in electrical communication with the IVUS transducer assembly to transmit signals to the IVUS transducer assembly or receive signals from the IVUS transducer assembly, wherein the electronic component comprises a printed circuit board including an algorithm stored thereon for interleaving the imaging data at the different frequencies.

7. The rotational IVUS device of claim 6 wherein the electronic component further comprises an active electronic component selected from the group consisting of a transmitter, a time-gain-control amplifier, an amplitude detector, a phase detector, an analog to digital converter, an optical transceiver, an encoder circuit, a wireless communication component, and a microcontroller.

8. The rotational IVUS device of claim 6 wherein the rotating assembly further includes: a spinning element coupled to the drive cable such that the spinning element rotates with the drive cable, the spinning element configured to be positioned adjacent to and spaced from a stationary element to transmit signals to the stationary element and receive signals from the stationary element.

9. The rotational IVUS device of claim 6 further comprising at least three conductive lines electrically connecting the spinning element to the IVUS transducer assembly.

10. The rotational IVUS device of claim 9 wherein the IVUS transducer assembly includes at least one of a piezoelectric transducer, a Capacitive Micromachined Ultrasonic Transducer (CMUT), or a Piezoelectric Micromachined Ultrasonic Transducer (PMUT).

11. A rotational intravascular ultrasound (IVUS) system, the system comprising:

a motor including a rotating motor shaft;

an elongate catheter including a flexible body for insertion into a vessel, the flexible body comprising a proximal portion and a distal portion, a flexible drive cable disposed within the flexible body and extending from the proximal portion of the flexible body to the distal portion of the flexible body, wherein a proximal portion of the drive cable is coupled to the motor shaft such that the drive cable rotates with the motor shaft, wherein the motor is positioned outside the elongate catheter;

15

an IVUS transducer assembly coupled to a distal portion of the drive cable such that that the IVUS transducer assembly rotates with the motor shaft when the proximal portion of the drive cable is coupled to the motor shaft, wherein the IVUS transducer assembly is configured to obtain imaging data at different frequencies during rotation; and

an electronic component coupled to the motor shaft such that the electronic component rotates with the motor shaft, the electronic component being in electrical communication with the IVUS transducer assembly to transmit signals to the IVUS transducer assembly or receive signals from the IVUS transducer assembly, wherein the electronic component comprises a printed circuit board including an algorithm stored thereon for interleaving the imaging data at the different frequencies.

12. The rotational IVUS system of claim 11 wherein the electronic component further comprises an active electronic component selected from the group consisting of a transmitter, a time-gain-control amplifier, an amplitude detector,

16

a phase detector, an analog to digital converter, an optical transceiver, an encoder circuit, a wireless communication component, and a microcontroller.

13. The rotational IVUS system of claim 11 further comprising:

a spinning element coupled to the motor shaft such that the spinning element rotates with the motor shaft, the spinning element configured to be positioned adjacent to and spaced from a stationary element to transmit signals to the stationary element and receive signals from the stationary element.

14. The rotational IVUS system of claim 11 further comprising at least three conductive lines electrically connecting the spinning element to the IVUS transducer assembly.

15. The rotational IVUS device of claim 14 wherein the IVUS transducer assembly includes at least one of a piezoelectric transducer, a Capacitive Micromachined Ultrasonic Transducer (CMUT), or a Piezoelectric Micromachined Ultrasonic Transducer (PMUT).

* * * * *

专利名称(译)	带有活动纺纱元件的旋转血管内超声探头		
公开(公告)号	US10383596	公开(公告)日	2019-08-20
申请号	US14/628945	申请日	2015-02-23
[标]申请(专利权)人(译)	火山公司		
申请(专利权)人(译)	火山CORPORATION		
当前申请(专利权)人(译)	火山CORPORATION		
[标]发明人	CORL PAUL DOUGLAS		
发明人	CORL, PAUL DOUGLAS		
IPC分类号	A61B8/00 G10K11/35 A61B8/12 A61B8/08		
CPC分类号	A61B8/12 A61B8/445 A61B8/4461 A61B8/4483 A61B8/52 A61B8/54 A61B8/56 G10K11/355 A61B8/4488 A61B8/4472		
其他公开文献	US20150182188A1		
外部链接	Espacenet		

摘要(译)

公开了一种血管内超声探头，其结合了在旋转传感器轴上利用先进的换能器技术的特征。特别地，探头适应跨探头的旋转和固定部件之间的边界的多个信号的传输，这是支持先进的换能器技术所需的。这些先进的传感器技术提供了增加带宽，改善光束轮廓，更好的信噪比，降低制造成本，先进的组织表征算法和其他所需特征的潜力。此外，在保持最大信噪比和信号保真度以及其他性能益处方面，在探针的旋转侧包含电子元件可以是非常有利的。

