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(54) ROTATIONAL INTRAVASCULAR ULTRASOUND PROBE WITH AN ACTIVE SPINNING ELEMENT

(71) Applicant: **Volcano Corporation**, San Diego, CA (US)

(72) Inventor: **Paul Douglas Corl**, Palo Alto, CA (US)

(73) Assignee: **VOLCANO CORPORATION**, San Diego, CA (US)

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A61B 8/12 (2006.01)

(Continued)

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CPC ***A61B 8/12*** (2013.01); ***A61B 8/445*** (2013.01); ***A61B 8/4461*** (2013.01);

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(58) **Field of Classification Search**

CPC A61B 8/12; A61B 8/445; A61B 8/4461; A61B 8/54; A61B 8/52; A61B 8/56;

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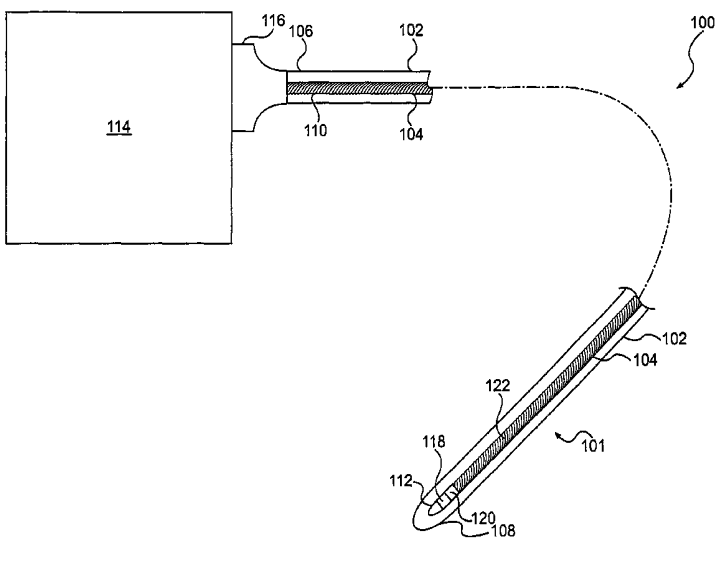
Primary Examiner — Elmer M Chao

(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.

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G10K 11/35 (2006.01)
A61B 8/08 (2006.01)

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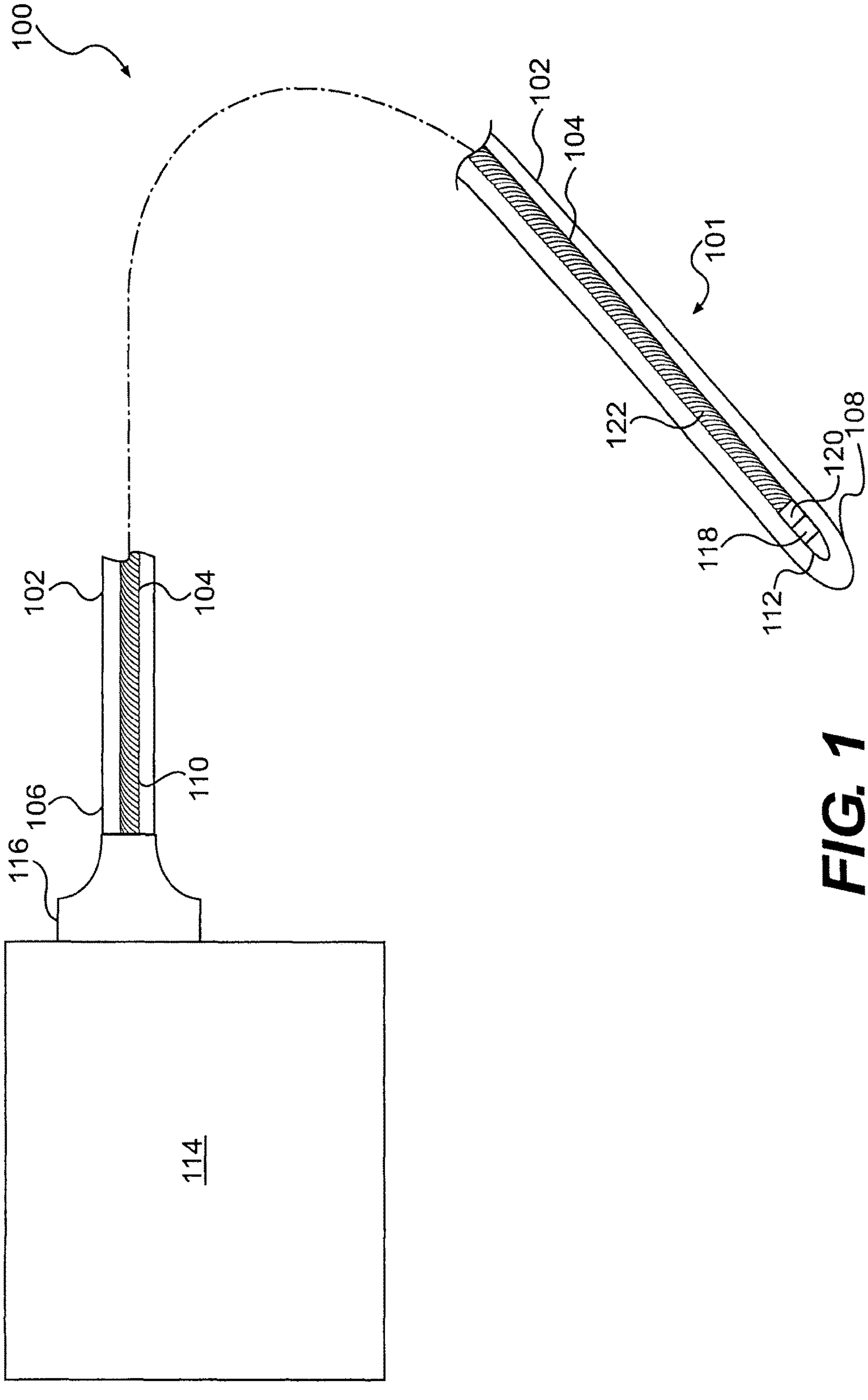

FIG. 1

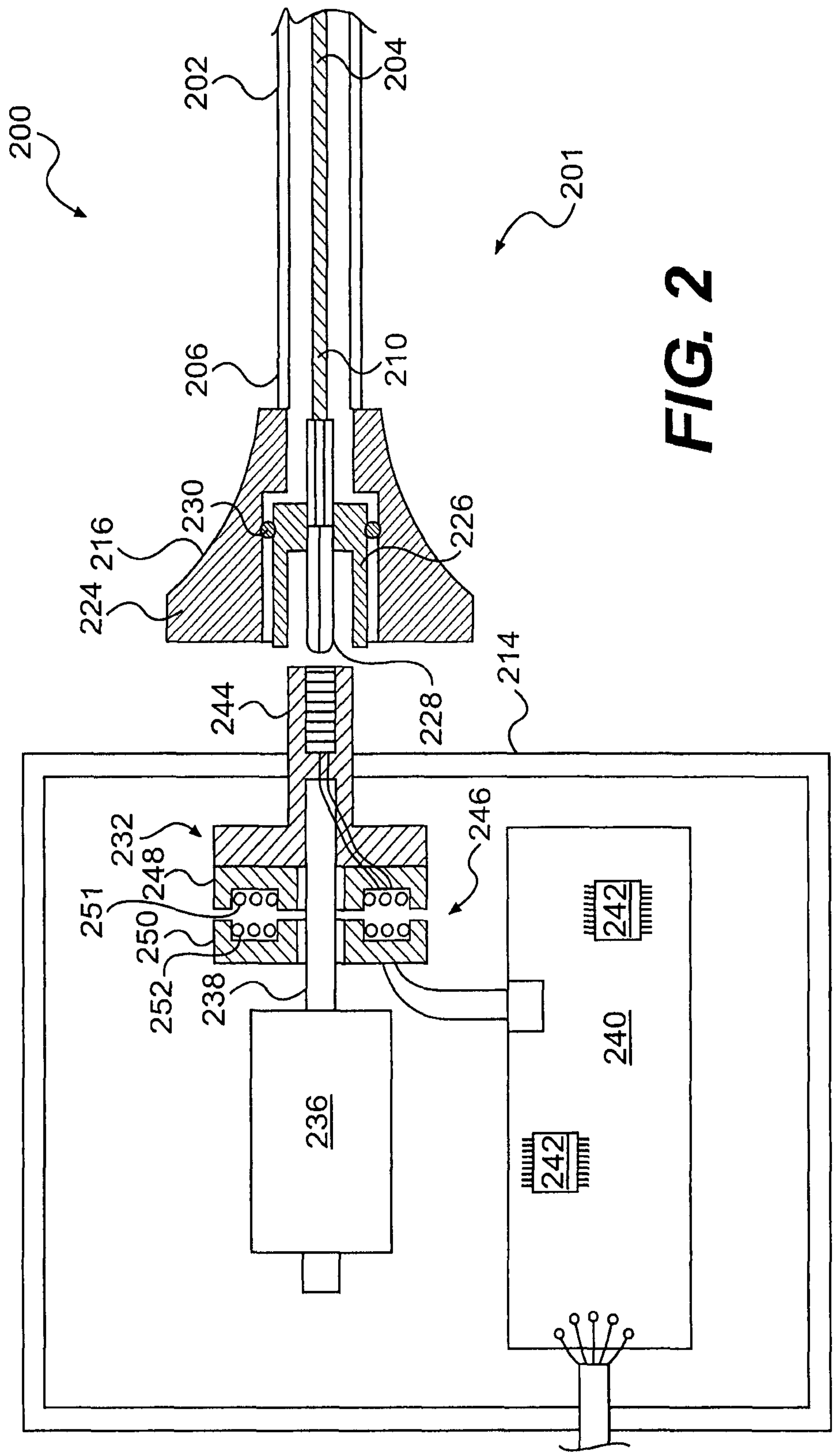
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FIG. 2

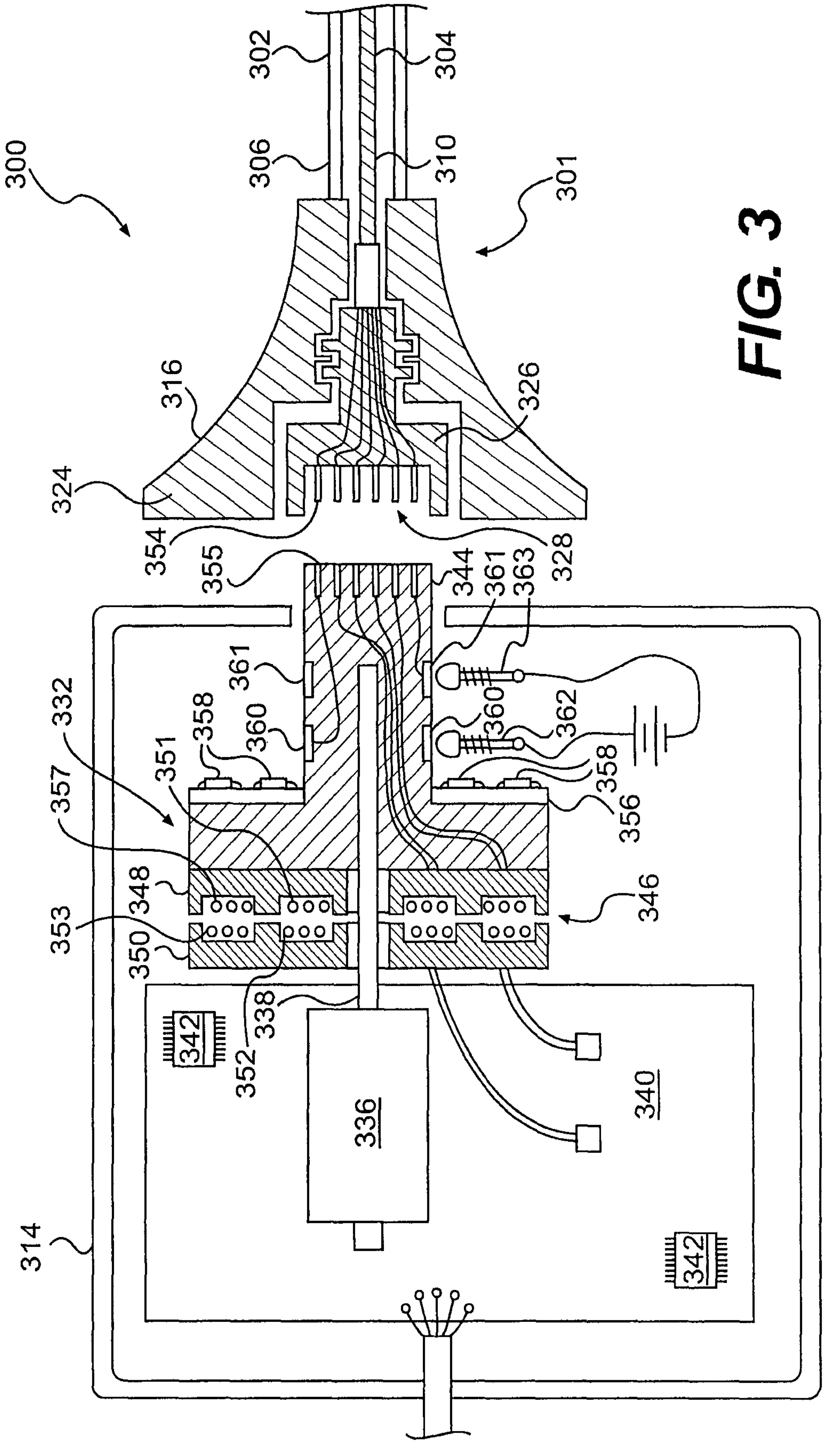
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FIG. 3

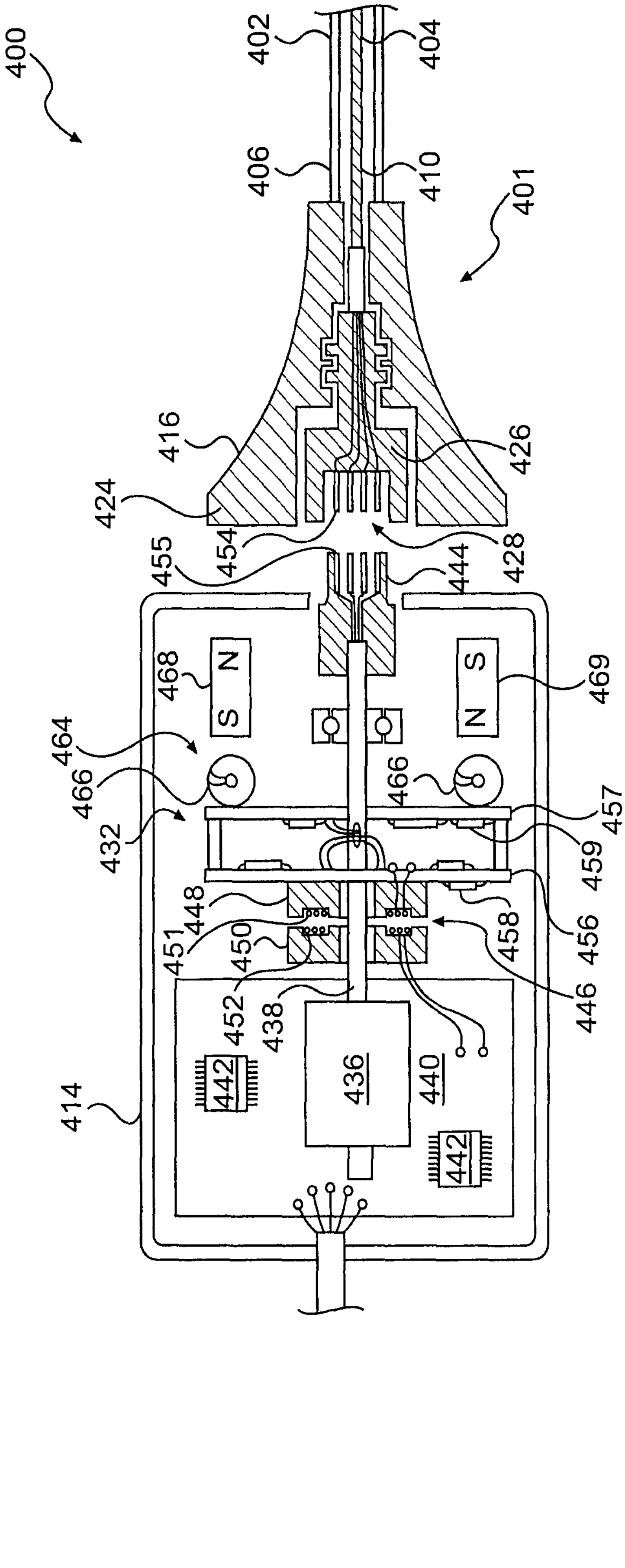
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FIG. 4

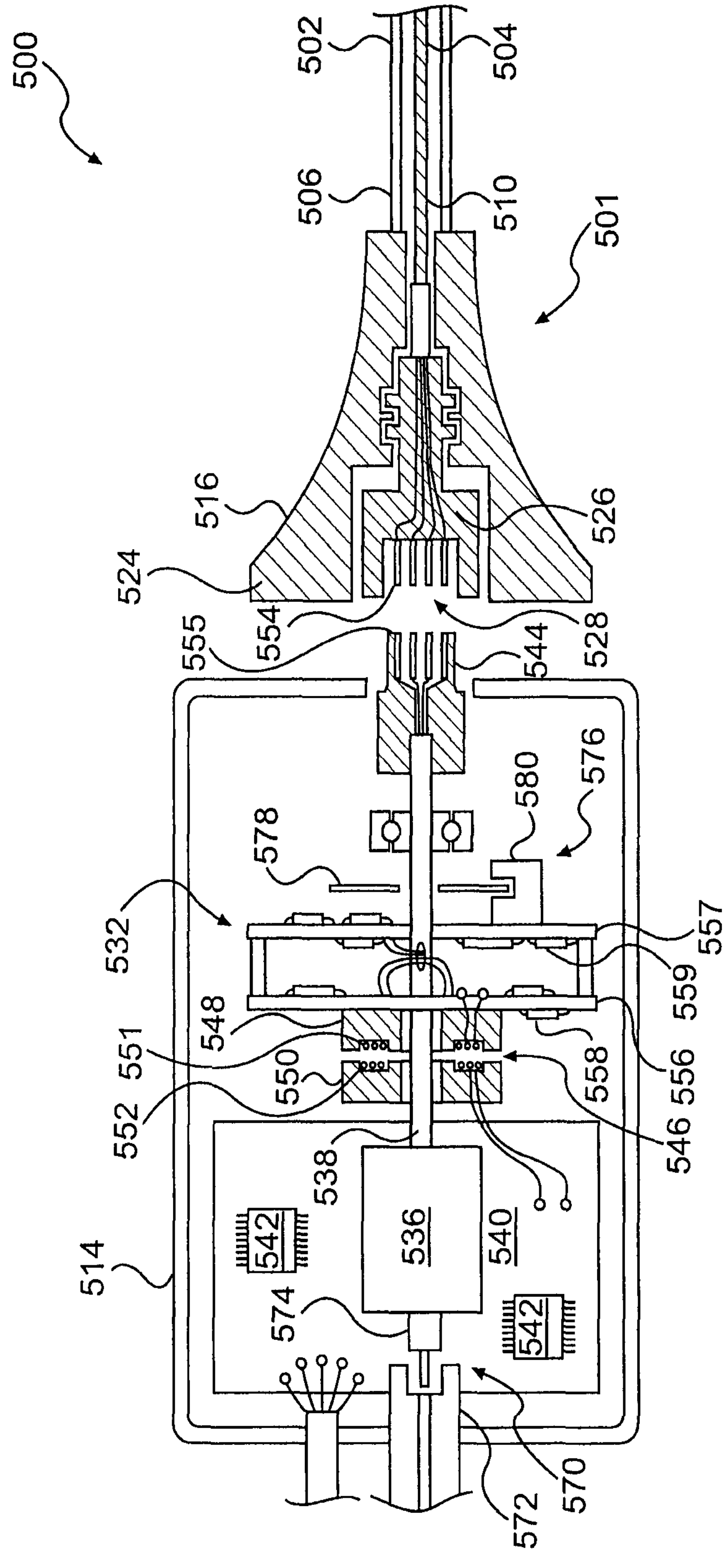
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FIG. 5

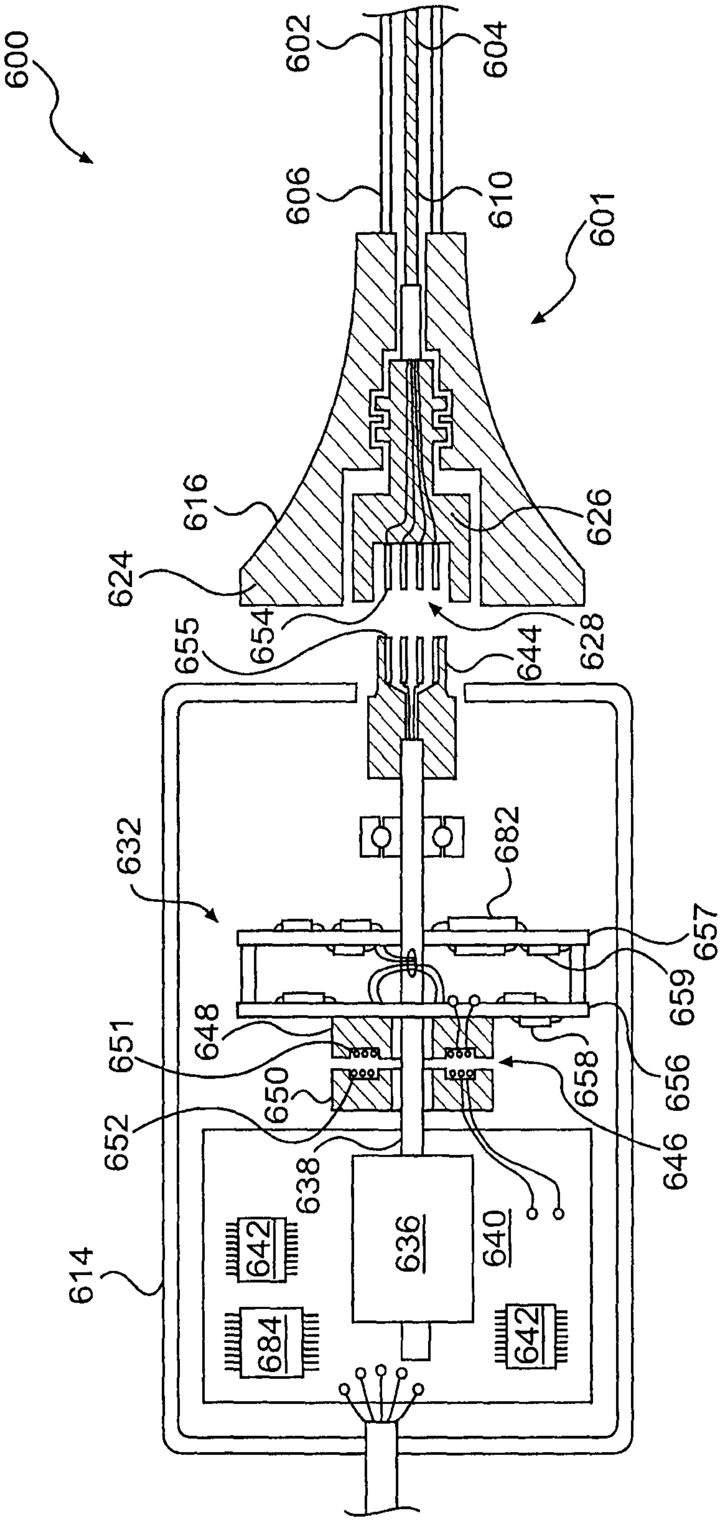
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FIG. 6

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 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 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 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 piezoelectric 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;

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, 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).

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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
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[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		
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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。