



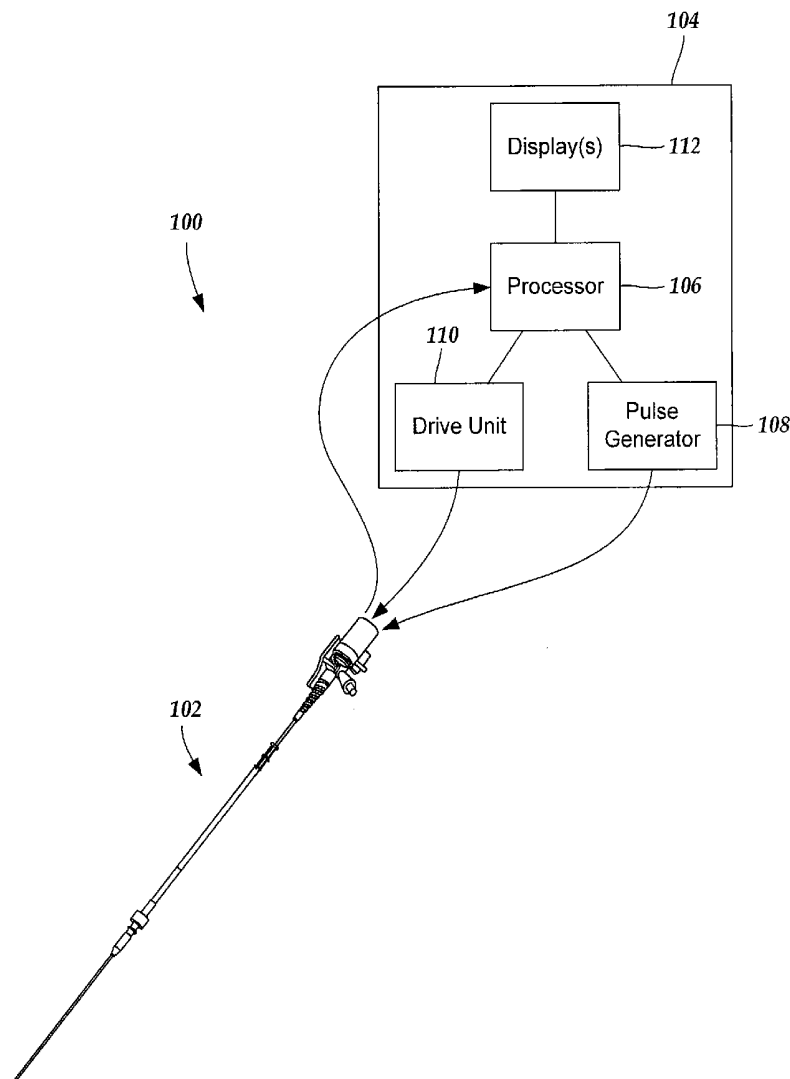
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(19) **United States**(12) **Patent Application Publication**
Hastings et al.(10) **Pub. No.: US 2010/0249603 A1**(43) **Pub. Date: Sep. 30, 2010**(54) **SYSTEMS AND METHODS FOR MAKING
AND USING A MOTOR
DISTALLY-POSITIONED WITHIN A
CATHETER OF AN INTRAVASCULAR
ULTRASOUND IMAGING SYSTEM**(75) Inventors: **Roger N. Hastings**, Maple Grove,
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Maple Grove, MN (US)(21) Appl. No.: **12/415,724**(22) Filed: **Mar. 31, 2009****Publication Classification**(51) **Int. Cl.**
A61B 8/14 (2006.01)(52) **U.S. Cl.** **600/467**(57) **ABSTRACT**

A catheter assembly for an intravascular ultrasound system includes an imaging core configured and arranged for inserting into a distal end of a lumen of a catheter. The imaging core includes at least one transducer mounted to a driveshaft and configured and arranged for transforming applied electrical signals to acoustic signals and also for transforming received echo signals to electrical signals. A motor is coupled to the driveshaft between the one or more transducers and the transformer. The motor includes a rotatable magnet and at least two magnetic field windings disposed around at least a portion of the magnet.



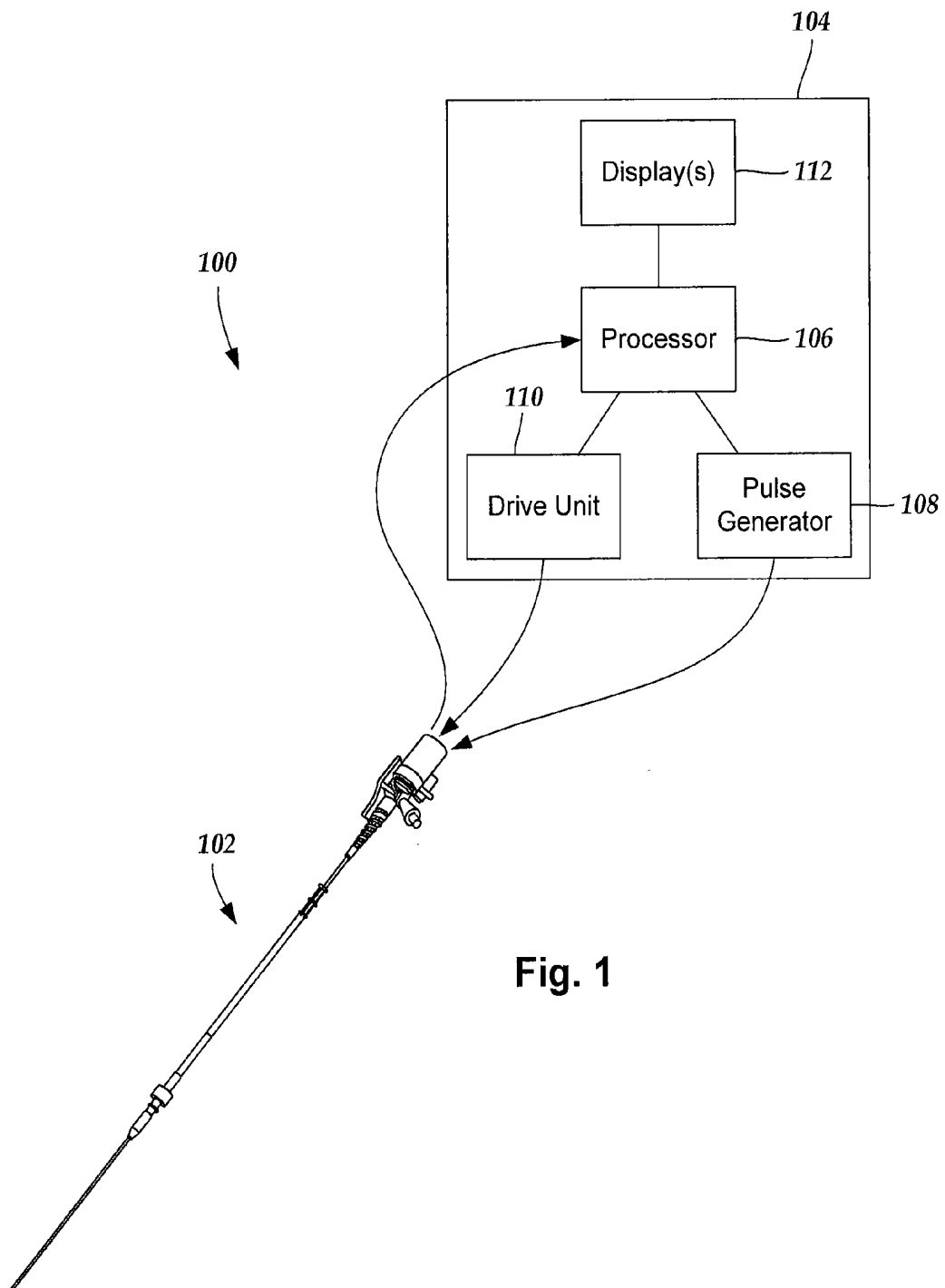
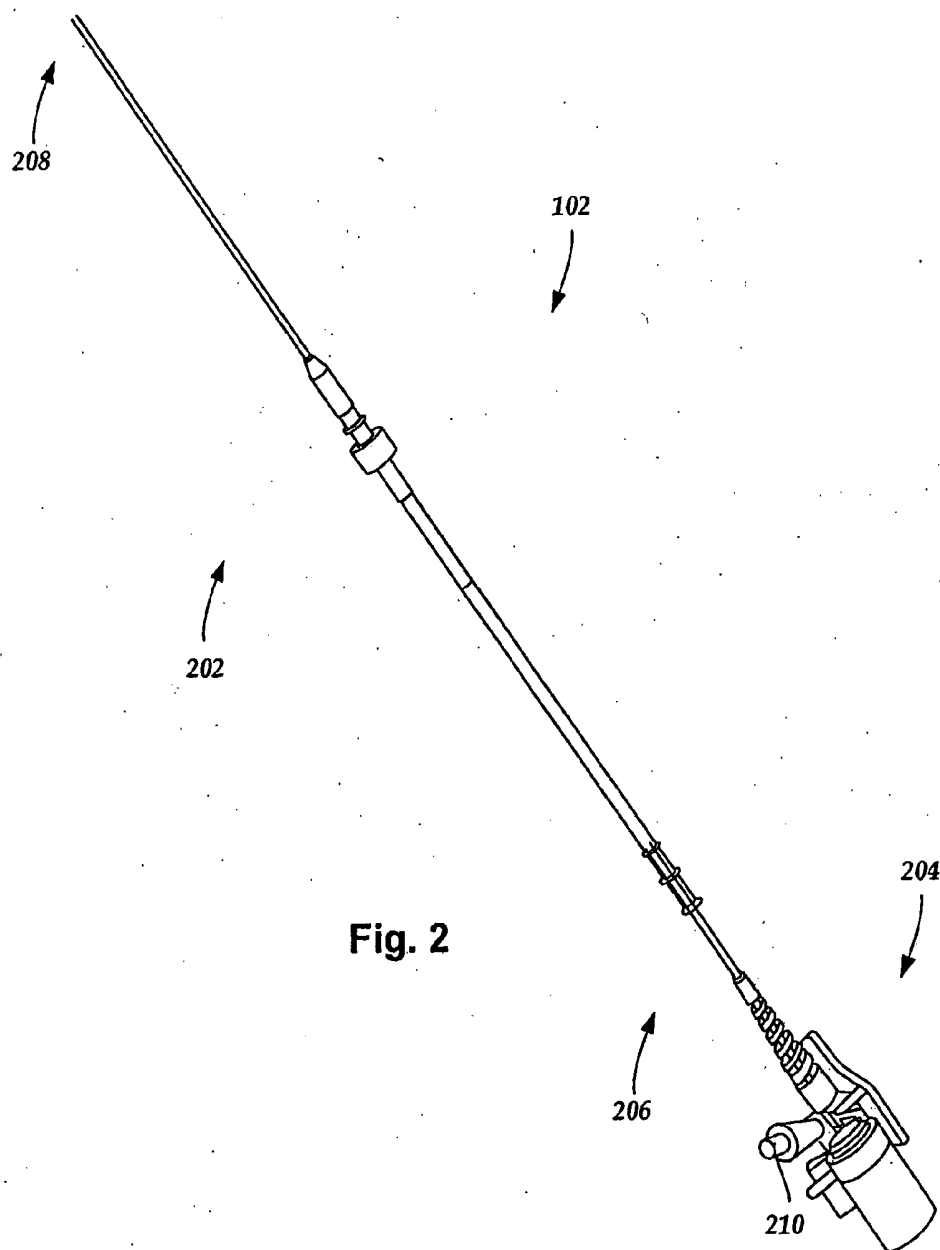


Fig. 1



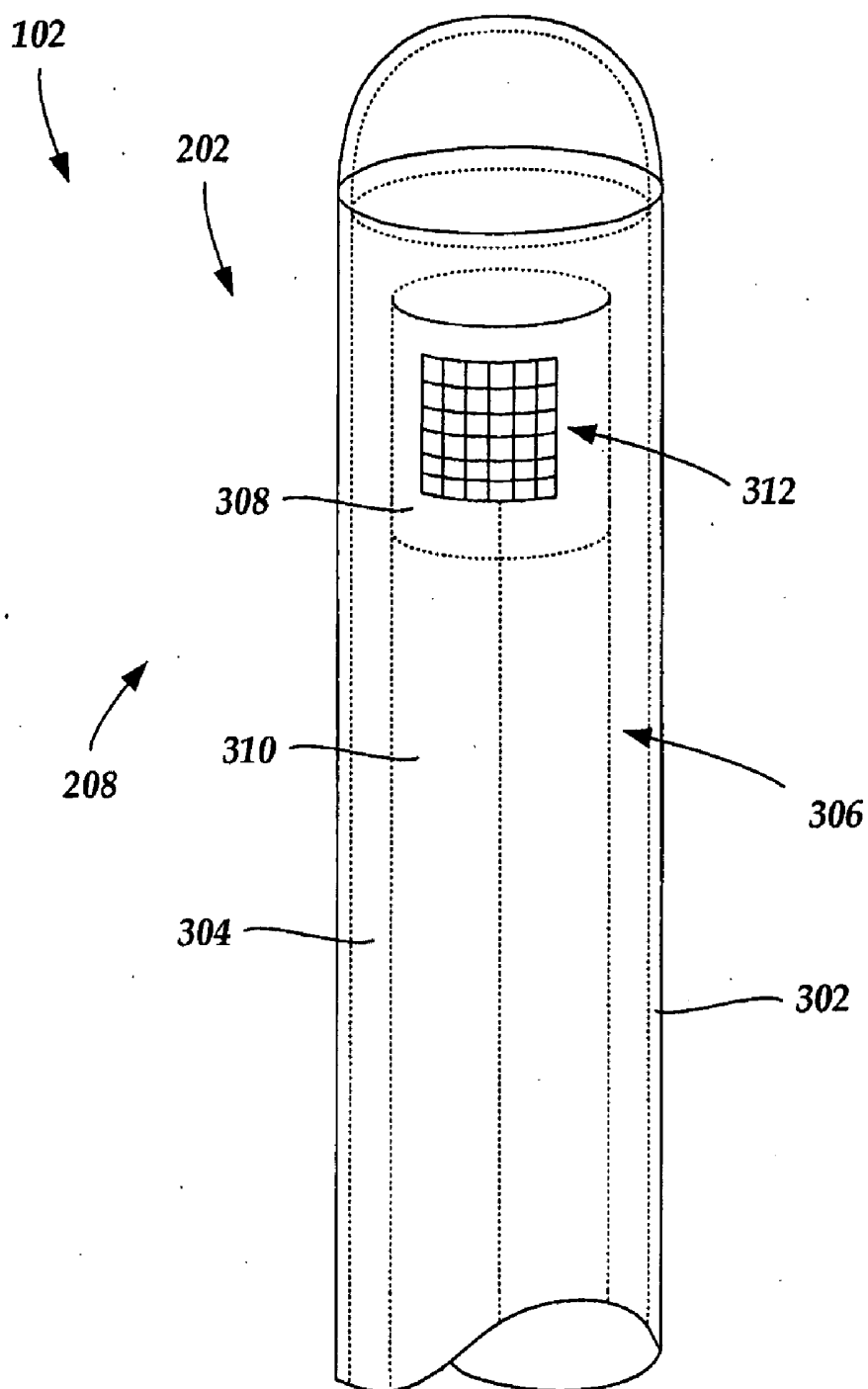


Fig. 3

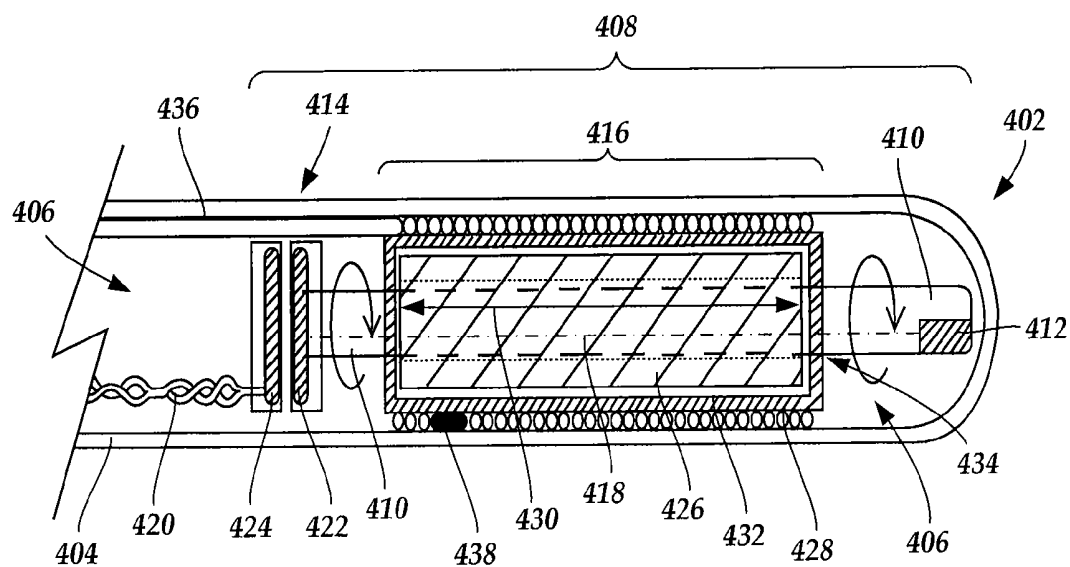


Fig. 4

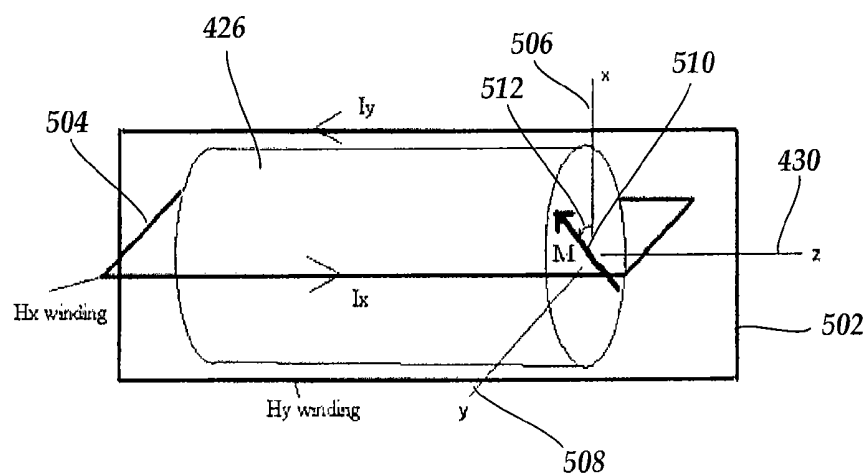


Fig. 5

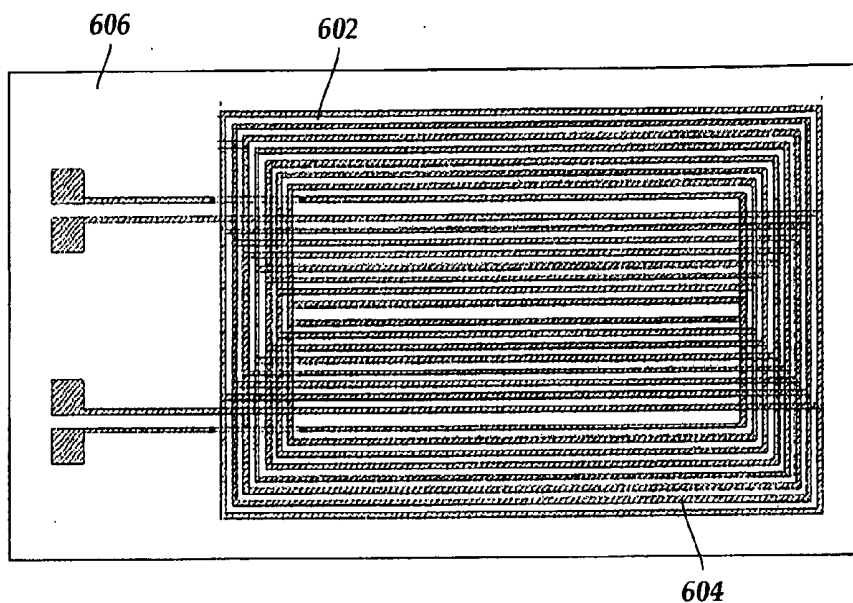


Fig. 6

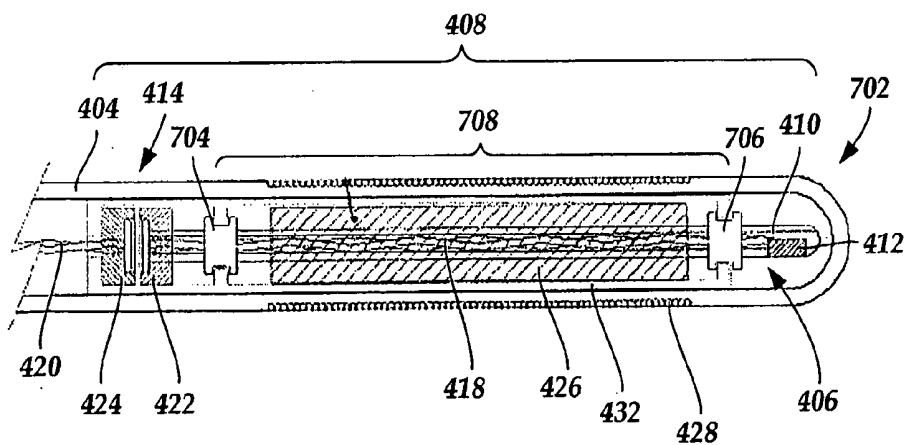


Fig. 7

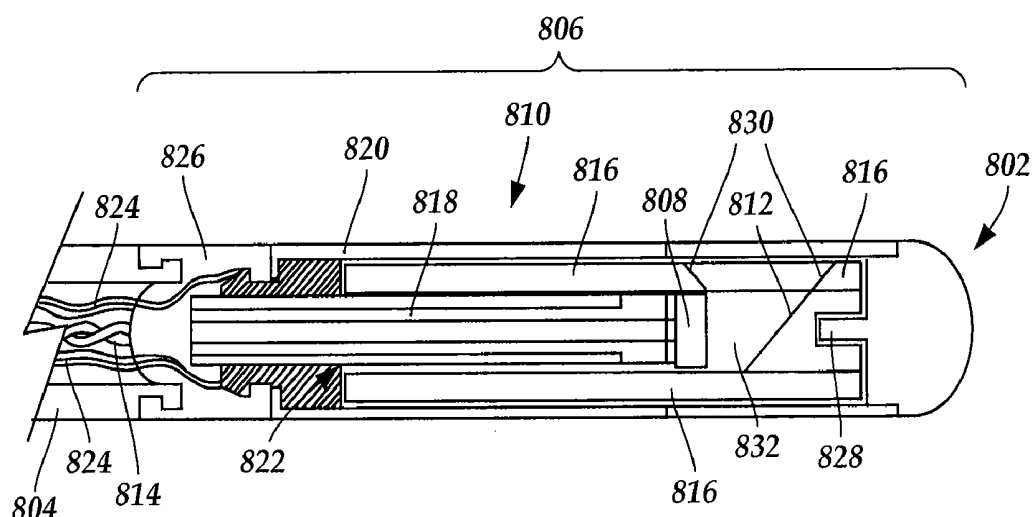


Fig. 8

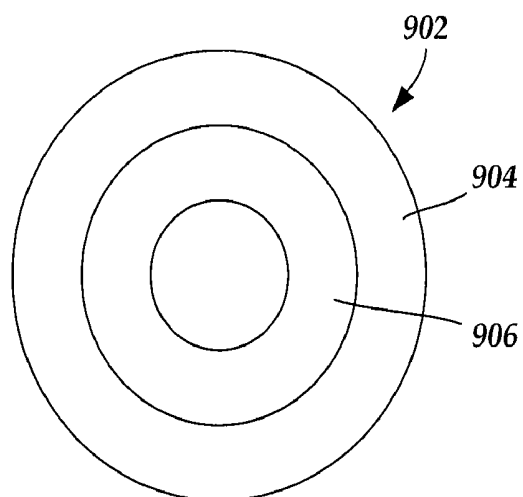


Fig. 9

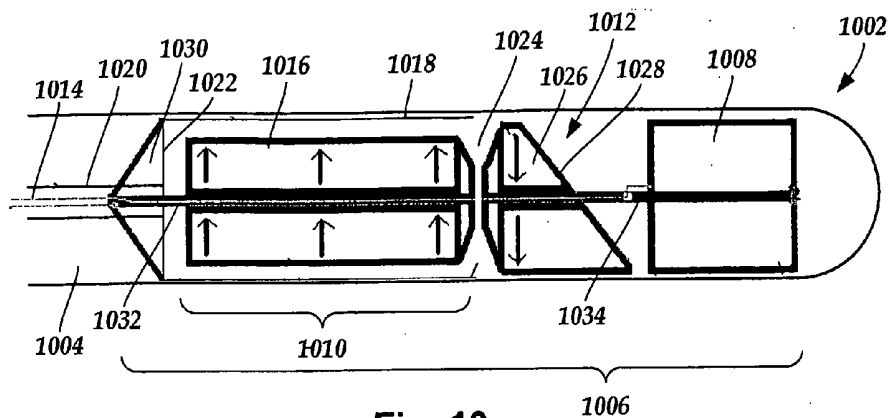


Fig. 10

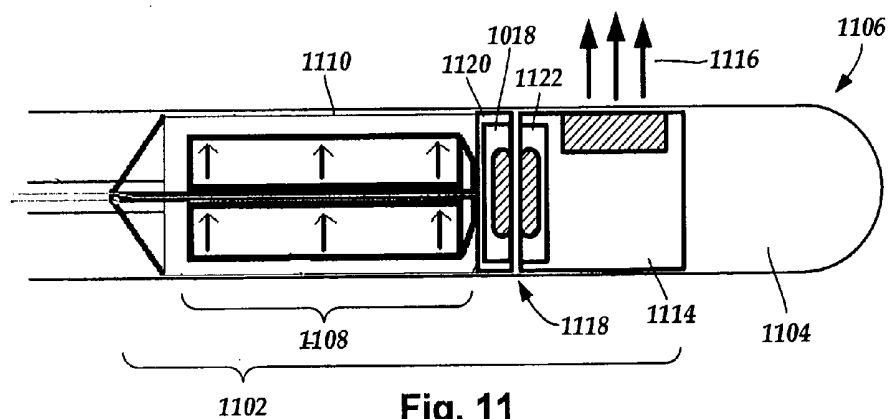


Fig. 11

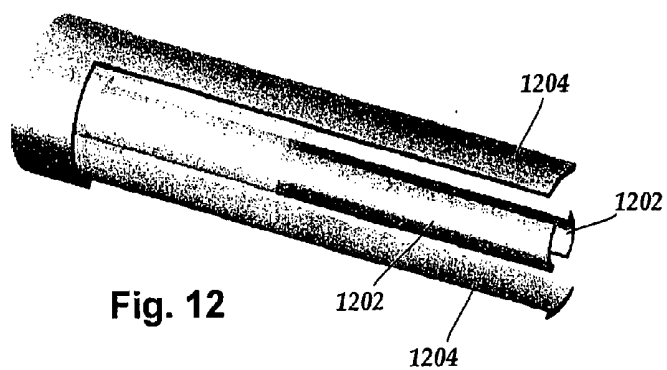


Fig. 12

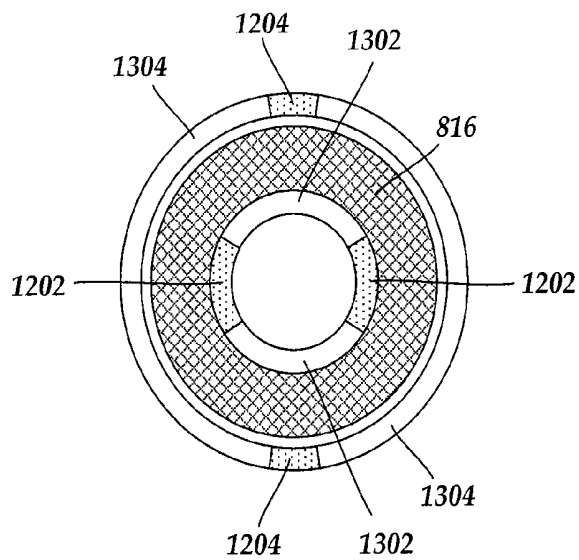


Fig. 13

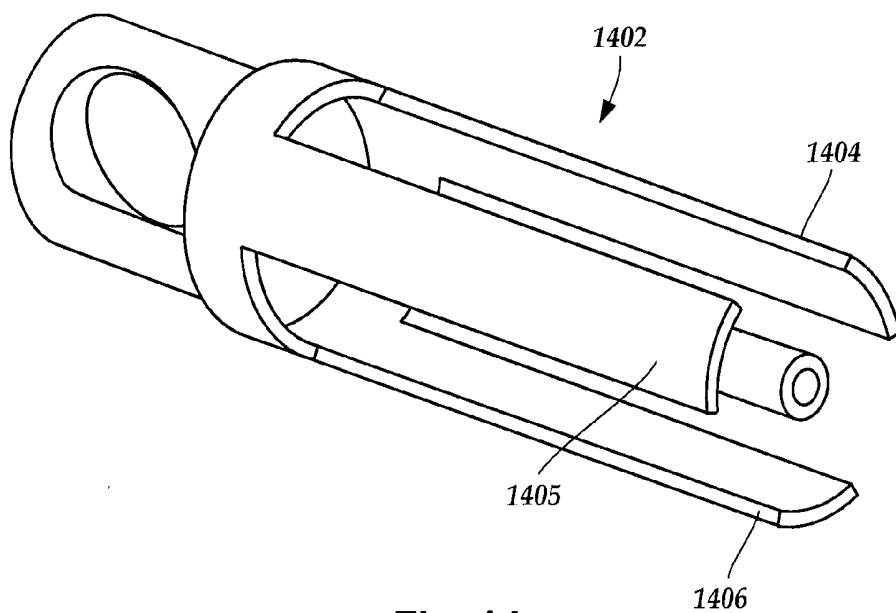


Fig. 14

**SYSTEMS AND METHODS FOR MAKING
AND USING A MOTOR
DISTALLY-POSITIONED WITHIN A
CATHETER OF AN INTRAVASCULAR
ULTRASOUND IMAGING SYSTEM**

TECHNICAL FIELD

[0001] The present invention is directed to the area of intravascular ultrasound imaging systems and methods of making and using the systems. The present invention is also directed to intravascular ultrasound systems that include imaging cores distally positioned within catheters, the imaging cores including rotational motors, as well as methods of making and using the imaging cores, motors, and intravascular ultrasound systems.

BACKGROUND

[0002] Intravascular ultrasound (“IVUS”) imaging systems have proven diagnostic capabilities for a variety of diseases and disorders. For example, IVUS imaging systems have been used as an imaging modality for diagnosing blocked blood vessels and providing information to aid medical practitioners in selecting and placing stents and other devices to restore or increase blood flow. IVUS imaging systems have been used to diagnose atheromatous plaque build-up at particular locations within blood vessels. IVUS imaging systems can be used to determine the existence of an intravascular obstruction or stenosis, as well as the nature and degree of the obstruction or stenosis. IVUS imaging systems can be used to visualize segments of a vascular system that may be difficult to visualize using other intravascular imaging techniques, such as angiography, due to, for example, movement (e.g., a beating heart) or obstruction by one or more structures (e.g., one or more blood vessels not desired to be imaged). IVUS imaging systems can be used to monitor or assess ongoing intravascular treatments, such as angiography and stent placement in real (or almost real) time. Moreover, IVUS imaging systems can be used to monitor one or more heart chambers.

[0003] IVUS imaging systems have been developed to provide a diagnostic tool for visualizing a variety of diseases or disorders. An IVUS imaging system can include a control module (with a pulse generator, an image processor, and a monitor), a catheter, and one or more transducers disposed in the catheter. The transducer-containing catheter can be positioned in a lumen or cavity within, or in proximity to, a region to be imaged, such as a blood vessel wall or patient tissue in proximity to a blood vessel wall. The pulse generator in the control module generates electrical pulses that are delivered to the one or more transducers and transformed to acoustic pulses that are transmitted through patient tissue. Reflected pulses of the transmitted acoustic pulses are absorbed by the one or more transducers and transformed to electric pulses. The transformed electric pulses are delivered to the image processor and converted to an image displayable on the monitor.

BRIEF SUMMARY

[0004] In one embodiment, a catheter assembly for an intravascular ultrasound system includes a catheter, an imaging core, at least one catheter conductor, and at least one motor conductor. The catheter has a longitudinal length, a distal end, and a proximal end. The catheter includes a lumen extending

along the longitudinal length of the catheter from the proximal end to the distal end. The imaging core has a longitudinal length that is substantially less than the longitudinal length of the catheter. The imaging core is configured and arranged for inserting into the lumen to the distal end of the catheter. The imaging core includes a rotatable driveshaft, at least one transducer, a transformer, at least one imaging core, and a motor. The rotatable driveshaft has a distal end and a proximal end. The at least one transducer is mounted to the distal end of the driveshaft and is configured and arranged for transforming applied electrical signals to, acoustic signals and also for transforming received echo signals to electrical signals. The transformer is disposed at the proximal end of the driveshaft. The at least one imaging core conductor couples the at least one transducer to the transformer. The motor is coupled to the driveshaft between the one or more transducers and the transformer. The motor includes a rotatable magnet and at least two magnetic field windings disposed around at least a portion of the magnet. The magnet has a longitudinal axis and an aperture defined along the longitudinal axis of the magnet. The at least one catheter conductor is electrically coupled to the transformer and extends to the proximal end of the catheter. The at least one motor conductor is electrically coupled to the magnetic field windings and extends to the proximal end of the catheter.

[0005] In another embodiment, a catheter assembly for an intravascular ultrasound system includes a catheter, an imaging core, at least one catheter conductor, and at least one motor conductor. The catheter has a longitudinal length, a distal end, and a proximal end. The catheter includes a lumen extending along the longitudinal length of the catheter from the proximal end to the distal end. The imaging core has a longitudinal length that is substantially less than the longitudinal length of the catheter and is configured and arranged for inserting into the lumen to the distal end of the catheter. The imaging core includes a motor, at least one transducer, and a mirror. The motor includes a rotatable magnet and at least two magnetic field windings disposed around at least a portion of the magnet. The magnet has a longitudinal axis and an aperture defined along the longitudinal axis of the magnet. The at least one transducer is disposed in the imaging core. The at least one transducer is configured and arranged for transforming applied electrical signals to acoustic signals and also for transforming received echo signals to electrical signals. The at least one transducer is fixed in position such that the at least one transducer does not rotate with the magnet. The mirror is positioned distal to the at least one transducer and is tilted at an angle such that when an acoustic beam is emitted from the at least one transducer to the mirror, the acoustic beam is redirected in a direction that is not parallel the longitudinal axis of the magnet. The rotation of the magnet causes the mirror to rotate. The at least one catheter conductor is electrically coupled to the one or more transducers and extends to the proximal end of the catheter. The at least one motor conductor is electrically coupled to the magnetic field windings and extends to the proximal end of the catheter.

[0006] In yet another embodiment, a method for imaging a patient using an intravascular ultrasound imaging system includes inserting a catheter into patient vasculature. The catheter includes an imaging core disposed in a distal portion of a lumen defined in the catheter. The imaging core is electrically coupled to a control module by at least one conductor. The imaging core has a longitudinal axis and includes at least one transducer and a magnet that rotates by application of a

current from the control module to at least two magnetic field windings wrapped around at least a portion of the magnet. The rotation of the magnet causes rotation of the at least one transducer. The imaging core is positioned in a region to be imaged. At least one electrical signal is transmitted from the control module to the at least one transducer. At least one electrical signal is transmitted from the control module to the at least two magnetic field windings. At least one acoustic signal is transmitted from the at least one transducer to patient tissue in a direction that is not parallel to the longitudinal axis of the imaging core. At least one echo signal is received from a tissue-boundary between adjacent imaged patient tissue by the imaging core. At least one transformed echo signal is transmitted from the at least one transducer to the control module for processing.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Non-limiting and non-exhaustive embodiments of the present invention are described with reference to the following drawings. In the drawings, like reference numerals refer to like parts throughout the various figures unless otherwise specified.

[0008] For a better understanding of the present invention, reference will be made to the following Detailed Description, which is to be read in association with the accompanying drawings, wherein:

[0009] FIG. 1 is a schematic view of one embodiment of an intravascular ultrasound imaging system, according to the invention;

[0010] FIG. 2 is a schematic side view of one embodiment of a catheter of an intravascular ultrasound imaging system, according to the invention;

[0011] FIG. 3 is a schematic perspective view of one embodiment of a distal end of the catheter shown in FIG. 2 with an imaging core disposed in a lumen defined in the catheter, according to the invention;

[0012] FIG. 4 is a schematic longitudinal cross-sectional view of one embodiment of a distal end of a catheter, the distal end of the catheter including an imaging core with a motor, a transformer, and one or more rotating transducers, according to the invention;

[0013] FIG. 5 is a schematic perspective view of one embodiment of a rotating magnet and associated windings, according to the invention;

[0014] FIG. 6 is a schematic top view of one embodiment of windings disposed on a thin film, according to the invention;

[0015] FIG. 7 is a schematic longitudinal cross-sectional view of another embodiment of a distal end of a catheter, the distal end of the catheter including an imaging core with a motor and drag-reducing elements disposed on either end of the motor, according to the invention;

[0016] FIG. 8 is a schematic longitudinal cross-sectional view of yet another embodiment of a distal end of a catheter, the distal end of the catheter including an imaging core with a motor, one or more stationary transducers, and a rotating mirror, according to the invention;

[0017] FIG. 9 is a schematic transverse cross-sectional view of one embodiment of a transducer, according to the invention;

[0018] FIG. 10 is a schematic longitudinal cross-sectional view of another embodiment of a distal end of a catheter, the distal end of the catheter including an imaging core with a motor, one or more stationary transducers, and a rotating mirror, according to the invention;

[0019] FIG. 11 is a schematic longitudinal cross-sectional view of yet another embodiment of a distal end of a catheter, the distal end of the catheter including an imaging core with a motor, one or more rotating transducers, and a transformer, according to the invention;

[0020] FIG. 12 is a schematic perspective view of one embodiment of a two-phase winding geometry configured and arranged for forming a rotating magnetic field around a motor, according to the invention;

[0021] FIG. 13 is a schematic transverse cross-sectional view of one embodiment of the two single-turn windings of FIG. 12 disposed around a motor, according to the invention; and

[0022] FIG. 14 is a schematic perspective view of one embodiment of a three-phase winding geometry configured and arranged for forming a rotating magnetic field around a motor, according to the invention.

DETAILED DESCRIPTION

[0023] The present invention is directed to the area of intravascular ultrasound imaging systems and methods of making and using the systems. The present invention is also directed to intravascular ultrasound systems that include imaging cores distally positioned within catheters, the imaging cores including rotational motors, as well as methods of making and using the imaging cores, motors, and intravascular ultrasound systems.

[0024] Suitable intravascular ultrasound (“IVUS”) imaging systems include, but are not limited to, one or more transducers disposed on a distal end of a catheter configured and arranged for percutaneous insertion into a patient. Examples of IVUS imaging systems with catheters are found in, for example, U.S. Pat. Nos. 7,306,561; and 6,945,938; as well as U.S. Patent Application Publication Nos. 20060253028; 20070016054; 20070038111; 20060173350; and 20060100522, all of which are incorporated by reference.

[0025] FIG. 1 illustrates schematically one embodiment of an IVUS imaging system 100. The IVUS imaging system 100 includes a catheter 102 that is coupleable to a control module 104. The control module 104 may include, for example, a processor 106, a pulse generator 108, a drive unit 110, and one or more displays 112. In at least some embodiments, the pulse generator 108 forms electric pulses that may be input to one or more transducers (312 in FIG. 3) disposed in the catheter 102. In at least some embodiments, mechanical energy from a pullback motor disposed within the drive unit 110 may be used to provide translational movement of an imaging core (306 in FIG. 3) disposed in the catheter 102.

[0026] In at least some embodiments, electric pulses transmitted from the one or more transducers (312 in FIG. 3) may be input to the processor 106 for processing. In at least some embodiments, the processed electric pulses from the one or more transducers (312 in FIG. 3) may be displayed as one or more images on the one or more displays 112. In at least some embodiments, the processor 106 may also be used to control the functioning of one or more of the other components of the control module 104. For example, the processor 106 may be used to control at least one of the frequency or duration of the electrical pulses transmitted from the pulse generator 108, the rotation rate of the imaging core (306 in FIG. 3) by the drive unit 110, the velocity or length of the pullback of the imaging core (306 in FIG. 3) by the drive unit 110, or one or more properties of one or more images formed on the one or more displays 112.

[0027] FIG. 2 is a schematic side view of one embodiment of the catheter 102 of the IVUS imaging system (100 in FIG. 1). The catheter 102 includes an elongated member 202 and a hub 204. The elongated member 202 includes a proximal end 206 and a distal end 208. In FIG. 2, the proximal end 206 of the elongated member 202 is coupled to the catheter hub 204 and the distal end 208 of the elongated member is configured and arranged for percutaneous insertion into a patient. In at least some embodiments, the catheter 102 defines at least one flush port, such as flush port 210. In at least some embodiments, the flush port 210 is defined in the hub 204. In at least some embodiments, the hub 204 is configured and arranged to couple to the control module (104 in FIG. 1). In some embodiments, the elongated member 202 and the hub 204 are formed as a unitary body. In other embodiments, the elongated member 202 and the catheter hub 204 are formed separately and subsequently assembled together.

[0028] FIG. 3 is a schematic perspective view of one embodiment of the distal end 208 of the elongated member 202 of the catheter 102. The elongated member 202 includes a sheath 302 and a lumen 304. An imaging core 306 is disposed in the lumen 304. The imaging core 306 includes an imaging device 308 coupled to a distal end of a rotatable driveshaft 310.

[0029] The sheath 302 may be formed from any flexible, biocompatible material suitable for insertion into a patient. Examples of suitable materials include, for example, polyethylene, polyurethane, plastic, spiral-cut stainless steel, nitinol hypotube, and the like or combinations thereof.

[0030] One or more transducers 312 may be mounted to the imaging device 308 and employed to transmit and receive acoustic pulses. In a preferred embodiment (as shown in FIG. 3), an array of transducers 312 are mounted to the imaging device 308. In other embodiments, a single transducer may be employed. In yet other embodiments, multiple transducers in an irregular-array may be employed. Any number of transducers 312 can be used. For example, there can be two, three, four, five, six, seven, eight, nine, ten, twelve, fifteen, sixteen, twenty, twenty-five, fifty, one hundred, five hundred, one thousand, or more transducers. As will be recognized, other numbers of transducers may also be used.

[0031] The one or more transducers 312 may be formed from one or more known materials capable of transforming applied electrical pulses to pressure distortions on the surface of the one or more transducers 312, and vice versa. Examples of suitable materials include piezoelectric ceramic materials, piezocomposite materials, piezoelectric plastics, barium titanates, lead zirconate titanates, lead metaniobates, polyvinylidene fluorides, and the like.

[0032] The pressure distortions on the surface of the one or more transducers 312 form acoustic pulses of a frequency based on the resonant frequencies of the one or more transducers 312. The resonant frequencies of the one or more transducers 312 may be affected by the size, shape, and material used to form the one or more transducers 312. The one or more transducers 312 may be formed in any shape suitable for positioning within the catheter 102 and for propagating acoustic pulses of a desired frequency in one or more selected directions. For example, transducers may be disc-shaped, block-shaped, rectangular-shaped, oval-shaped, and the like. The one or more transducers may be formed in the desired shape by any process including, for example, dicing, dice and fill, machining, microfabrication, and the like.

[0033] As an example, each of the one or more transducers 312 may include a layer of piezoelectric material sandwiched between a conductive acoustic lens and a conductive backing material formed from an acoustically absorbent material (e.g., an epoxy substrate with tungsten particles). During operation, the piezoelectric layer may be electrically excited by both the backing material and the acoustic lens to cause the emission of acoustic pulses.

[0034] In at least some embodiments, the one or more transducers 312 can be used to form a radial cross-sectional image of a surrounding space. Thus, for example, when the one or more transducers 312 are disposed in the catheter 102 and inserted into a blood vessel of a patient, the one or more transducers 312 may be used to form an image of the walls of the blood vessel and tissue surrounding the blood vessel.

[0035] In at least some embodiments, the imaging core 306 may be rotated about a longitudinal axis of the catheter 102. As the imaging core 306 rotates, the one or more transducers 312 emit acoustic pulses in different radial directions. When an emitted acoustic pulse with sufficient energy encounters one or more medium boundaries, such as one or more tissue boundaries, a portion of the emitted acoustic pulse is reflected back to the emitting transducer as an echo pulse. Each echo pulse that reaches a transducer with sufficient energy to be detected is transformed to an electrical signal in the receiving transducer. The one or more transformed electrical signals are transmitted to the control module (104 in FIG. 1) where the processor 106 processes the electrical-signal characteristics to form a displayable image of the imaged region based, at least in part, on a collection of information from each of the acoustic pulses transmitted and the echo pulses received.

[0036] As the one or more transducers 312 rotate about the longitudinal axis of the catheter 102 emitting acoustic pulses, a plurality of images are formed that collectively form a radial cross-sectional image of a portion of the region surrounding the one or more transducers 312, such as the walls of a blood vessel of interest and the tissue surrounding the blood vessel. In at least some embodiments, the radial cross-sectional image can be displayed on one or more displays (112 in FIG. 1).

[0037] In at least some embodiments, the drive unit (110 in FIG. 1) is used to provide translational movement to the imaging core 306 within the lumen of the catheter 102 while the catheter 102 remains stationary. For example, the imaging core 306 may be advanced (moved towards the distal end of the catheter 102) or retracted/pulled back (moved towards the proximal end of the catheter 102) within the lumen 304 of the catheter 102 while the catheter 102 remains in a fixed location within patient vasculature (e.g., blood vessels, the heart, and the like). During longitudinal movement (e.g., pullback) of the imaging core 306, an imaging procedure may be performed, wherein a plurality of cross-sectional images are formed along a longitudinal length of patient vasculature.

[0038] In at least some embodiments, the pullback distance of the imaging core is at least 5 cm. In at least some embodiments, the pullback distance of the imaging core is at least 10 cm. In at least some embodiments, the pullback distance of the imaging core is at least 15 cm. In at least some embodiments, the pullback distance of the imaging core is at least 20 cm. In at least some embodiments, the pullback distance of the imaging core is at least 25 cm.

[0039] The quality of an image produced at different depths from the one or more transducers 312 may be affected by one or more factors including, for example, bandwidth, trans-

ducer focus, beam pattern, as well as the frequency of the acoustic pulse. The frequency of the acoustic pulse output from the one or more transducers 312 may also affect the penetration depth of the acoustic pulse output from the one or more transducers 312. In general, as the frequency of an acoustic pulse is lowered, the depth of the penetration of the acoustic pulse within patient tissue increases. In at least some embodiments, the IVUS imaging system 100 operates within a frequency range of 5 MHz to 60 MHz.

[0040] In at least some embodiments, the catheter 102 with one or more transducers 312 mounted to the distal end 208 of the imaging core 306 may be inserted percutaneously into a patient via an accessible blood vessel, such as the femoral artery, at a site remote from the selected portion of the selected region, such as a blood vessel, to be imaged. The catheter 102 may then be advanced through the blood vessels of the patient to the selected imaging site, such as a portion of a selected blood vessel.

[0041] It is desirable to have uniform rotation of the imaging core 306 during operation. When the catheter 102 is advanced through blood vessels of the patient, the catheter 102 may navigate one or more tortuous regions or one or more narrow regions which may press against one or more portions of the catheter 102 and cause a non-uniform rotation (e.g., a wobble, a vibration, or the like) of the imaging core 306 during operation. Non-uniform rotation may lead to the distortion of a subsequently-generated IVUS image. For example, the subsequently-generated IVUS image may be blurred.

[0042] In conventional systems, a rotational motor is disposed in a proximal portion of the catheter 302 or in a unit to which the proximal portion of the catheter is attached. Due to the distance between a proximally-positioned rotational motor and an imaging core and the tortuous nature of the vasculature into which the distal end of the catheter is positioned during operation, non-uniform rotation can be difficult to prevent.

[0043] A motor disposed on the imaging core and positioned in a distal portion of the catheter is described. The imaging core has a longitudinal length that is substantially less than a longitudinal length of the catheter. The imaging core also includes one or more transducers. In at least some embodiments, disposing the motor in the imaging core may reduce, or even eliminate non-uniform rotation caused by one or more off-axis forces (e.g., blood vessel walls pressing against portions of the catheter). In at least some embodiments, the motor includes a rotor formed from a permanent magnet. In at least some embodiments, the catheter has a diameter that is no greater than one millimeter.

[0044] It may be the case that the distal end of the catheter 102 is disposed in patient vasculature without having any information regarding the precise location or orientation of the one or more transducers. In at least some embodiments, a sensing device may be disposed in the imaging core for sensing the location or orientation of the one or more transducers. In at least some embodiments, the sensing device includes one or more magnetic sensors. In some embodiments, the sensing device includes a plurality of magnetic sensors located external to the patient. In other embodiments, one or more sensors are positioned within the patient, and a plurality of sensors are positioned external to the patient.

[0045] Additionally or alternatively, in at least some embodiments, the sensing device measures the amplitude or orientation of the rotating magnet magnetization vector pro-

duced by the motor. In at least some embodiments, data from the magnetic sensing device may be input to a drive circuit to provide controlled and uniform rotation of the imaging core (e.g., through a feedback loop). In at least some embodiments, data from the sensing device may also be used to make corrections to data collected during non-uniform rotation of the imaging core.

[0046] FIG. 4 is a schematic longitudinal cross-sectional view of one embodiment of a distal end of a catheter 402. The catheter 402 includes a sheath 404 and a lumen 406. A rotatable imaging core 408 is disposed in the lumen 406 at the distal end of the catheter 402. The imaging core 408 includes a rotatable driveshaft 410 with one or more transducers 412 coupled to a distal end of the driveshaft 410 and a transformer 414 coupled to a proximal end of the driveshaft 410. The imaging core 408 also includes a motor 416 coupled to the driveshaft 410. One or more imaging core conductors 418 electrically couple the one or more transducers 412 to the transformer 414. In at least some embodiments, the one or more imaging core conductors 418 extend within the driveshaft 410. One or more catheter conductors 420 electrically couple the transformer 414 to the control module (104 in FIG. 1). In at least some embodiments, the one or more of the catheter conductors 420 may extend along at least a portion of the longitudinal length of the catheter 402 as shielded electrical cables, such as a coaxial cable, or a twisted pair cable, or the like.

[0047] When the catheter 402 employs one or more rotatable transducers 412, the transformer 414 is typically used to electrically couple the stationary portions of the system (e.g., the control module (104 in FIG. 1)) with the rotating portions of the system (e.g., the one or more transducers 412). In conventional systems employing a rotating transducer, the transformer is positioned at a proximal end of a catheter (such as catheter hub 204 in FIG. 2). Typically, the transformer 414 employs inductive coupling between a rotating component and a stationary component (e.g., a rotor and a stator, or a rotating pancake coil and a stationary pancake coil, or the like). Pulses of current from the control module (104 in FIG. 1) may be induced in the rotating component, via the stationary component. The induced current may transmit to the one or more transducers and may be transformed to an acoustic signal and emitted as one or more acoustic pulses. Echo pulses received by the one or more transducers may be transformed to electrical signals and transmitted to the rotating component. A voltage may be induced in the stationary component by the electrical signal in the rotating component. In at least some embodiments, the voltage may be input to the control module (104 in FIG. 1) for processing.

[0048] The transformer 414 is disposed on the imaging core 408. In at least some embodiments, the transformer 414 includes a rotating component 422 coupled to the driveshaft 410 and a stationary component 424 disposed spaced apart from the rotating component 414. In some embodiments, the stationary part 424 is proximal to, and immediately adjacent to, the rotating component 422. The rotating component 422 is electrically coupled to the one or more transducers 412 via the one or more imaging core conductors 418 disposed in the imaging core 408. The stationary component 416 is electrically coupled to the control module (104 in FIG. 1) via one or more conductors 420 disposed in the lumen 406. Current is inductively passed between the rotating component 422 and

the stationary component **424** (e.g., a rotor and a stator, or a rotating pancake coil and a stationary pancake coil, or the like).

[0049] In at least some embodiments, the transformer **414** is positioned at a proximal end of the imaging core **408**. In at least some embodiments, the components **422** and **424** of the transformer **414** are disposed in a ferrite form. In at least some embodiments, the components **422** and **424** are smaller in size than components conventionally positioned at the proximal end of the catheter. Additionally, the diameter of the wire **418** used to form the components **422** and **424** may be smaller in size than the diameter of wire used in conventional components. In at least some embodiments, the diameter of wire **418** is no greater than 0.004 inches (0.010 cm). In at least some embodiments, the diameter of the wire is no greater than 0.003 inches (0.008 cm). In at least some embodiments, the diameter of the wire is no greater than 0.002 inches (0.005 cm).

[0050] Additionally, the length of the wire **418** used to couple the rotating component **422** to the one or more transducers **412** may be less than for conventional components because the component **422** is typically positioned in closer proximity to the one or more transducers **412** than with conventional systems. Thus, the resistance of the wire **418** used to form the rotating component **422** and to couple to the one or more transducers **412** may be less than for conventional systems. Accordingly, the inductance and mutual inductance of the components **422** and **424** may need to be adjusted by increasing the number of turns of the components **422** and **424** compared to conventional coils.

[0051] The motor **416** includes a rotor **426** and a stator **428**. In at least some embodiments, the rotor **426** is a permanent magnet with a longitudinal axis, indicated by a two-headed arrow **430**, which is coaxial with the longitudinal axis of the imaging core **408** and the driveshaft **410**. The magnet **426** may be formed from many different magnetic materials suitable for implantation including, for example, neodymium-iron-boron, or the like. One example of a suitable neodymium-iron-boron magnet is available through Hitachi Metals America Ltd, San Jose, Calif.

[0052] In at least some embodiments, the magnet **426** is cylindrical. In at least some embodiments, the magnet **426** has a magnetization *M* of no less than 1.4 T. In at least some embodiments, the magnet **426** has a magnetization *M* of no less than 1.5 T. In at least some embodiments, the magnet **426** has a magnetization *M* of no less than 1.6 T. In at least some embodiments, the magnet **426** has a magnetization vector that is perpendicular to the longitudinal axis of the magnet **426**. In at least some embodiments, the magnet **426** is disposed in a housing **432**.

[0053] In at least some embodiments, the magnet **426** is coupled to the driveshaft **410** and is configured and arranged to rotate the driveshaft **410** during operation. In at least some embodiments, the magnet **426** defines an aperture **434** along the longitudinal axis **430** of the magnet **426**. In at least some embodiments, the driveshaft **410** and the one or more imaging core conductors **418** extend through the aperture **434**. In at least some other embodiments, the drive shaft **410** is discontinuous and, for example, couples to the magnet **426** at opposing ends of the magnet **426**. In which case, the one or more imaging core conductors **418** still extend through the aperture **434**. In at least some embodiments, the magnet **426** is, coupled to the driveshaft **410** by an adhesive. Alternatively, in some embodiments the driveshaft **410** and the magnet **426**

can be machined from a single block of magnetic material with the aperture **434** drilled down a length of the driveshaft **410** for receiving the imaging core conductors **418**.

[0054] In at least some embodiments, the stator **428** includes two perpendicularly-oriented magnetic field windings (**502** and **504** in FIG. 5) which provide a rotating magnetic field to produce torque causing rotation of the magnet **426**. The stator **428** is provided with power from the control module (**104** in FIG. 1) via one or more motor conductors **436**.

[0055] In at least some embodiments, a sensing device **438** is disposed on the imaging core **408**. In at least some embodiments, the sensing device **438** is coupled on the housing **432**. In at least some embodiments, the sensing device **438** is configured and arranged to measure the amplitude of the magnetic field in a particular direction. In at least some embodiments, the sensing device **438** uses at least some of the measured information to sense the angular position of the magnet **426**. In at least some embodiments, at least some of the measured information obtained by the sensing device **438** is used to control the current provided to the stator **428** by the one or more motor conductors **436**.

[0056] In at least some embodiments, the diameter of the catheter **402** is no greater than 0.042 inches (0.11 cm). In at least some embodiments, the diameter of the catheter **402** is no greater than 0.040 inches (0.11 cm). In at least some embodiments, the diameter of the catheter **402** is no greater than 0.038 inches (0.10 cm). In at least some embodiments, the diameter of the catheter **402** is no greater than 0.036 inches (0.09 cm). In at least some embodiments, the diameter of the catheter **402** is no greater than 0.034 inches (0.09 cm). In at least some embodiments, the diameter of the catheter **402** is sized to accommodate intracardiac echocardiography systems.

[0057] In at least some embodiments, the diameter of the magnet **426** is no greater than 0.025 inches (0.06 cm). In at least some embodiments, the diameter of the magnet **426** is no greater than 0.022 inches (0.06 cm). In at least some embodiments, the diameter of the magnet **426** is no greater than 0.019 inches (0.05 cm). In at least some embodiments, the diameter of the aperture **434** is no greater than 0.010 inches (0.03 cm). In at least some embodiments, the diameter of the aperture **434** is no greater than 0.009 inches (0.02 cm). In at least some embodiments, the diameter of the aperture **434** is no greater than 0.008 inches (0.02 cm). In at least some embodiments, the longitudinal length of the magnet **426** is no greater than 0.13 inches (0.33 cm). In at least some embodiments, the longitudinal length of the magnet **426** is no greater than 0.12 inches (0.30 cm). In at least some embodiments, the longitudinal length of the magnet **426** is no greater than 0.11 inches (0.28 cm).

[0058] In at least some embodiments, the motor **416** provides enough torque to rotate the one or more transducers **412** at a frequency of at least 15 Hz. In at least some embodiments, the motor **416** provides enough torque to rotate the one or more transducers **412** at a frequency of at least 20 Hz. In at least some embodiments, the motor **416** provides enough torque to rotate the one or more transducers **412** at a frequency of at least 25 Hz. In at least some embodiments, the motor **416** provides enough torque to rotate the one or more transducers **412** at a frequency of at least 30 Hz. In at least some embodiments, the motor **416** provides enough torque to rotate the one or more transducers **412** at a frequency of at least 35 Hz. In at least some embodiments, the motor **416**

provides enough torque to rotate the one or more transducers **412** at a frequency of at least 40 Hz.

[0059] In a preferred embodiment, the torque is about the longitudinal axis **430** of the magnet **426** so that the magnet **426** rotates. In order for the torque of the magnet **426** to be about the longitudinal axis **430**, the magnetic field of the magnetic field windings (i.e., coils of the stator) lies in the plane perpendicular to the longitudinal axis **430**, with the field vector rotating about the longitudinal axis **430**.

[0060] As discussed above, the stator **428** provides a rotating magnetic field to produce a torque the rotor **426**. The stator **428** may comprise two perpendicularly-oriented magnetic field windings ("windings") that wrap around the magnet **426** as one or more turns to form a rotating magnetic field. FIG. 5 is a schematic perspective view of one embodiment of the rotating magnet **426** and windings, represented as orthogonal rectangular boxes **502** and **504**. Although the windings **502** and **504** are shown as two orthogonal rectangles, it will be understood that each of the windings **502** and **504** may represent multiple turns of wire which may be spread out to minimize an increase in the diameter of the catheter (**402** in FIG. 4). When the windings **502** and **504** are spread out, a band of current may be generated instead of the lines of current shown in FIG. 5.

[0061] In at least some embodiments, the diameter of the wire used to form the windings **502** and **504** is no greater than 0.004 inches (0.010 cm). In at least some embodiments, the diameter of the wire is no greater than 0.003 inches (0.008 cm). In at least some embodiments, the diameter of the wire is no greater than 0.002 inches (0.005 cm).

[0062] In order for the magnet **426** to rotate about the longitudinal axis **430**, the torque must be about the longitudinal axis **430**. Therefore, the magnetic field generated by the windings **502** and **504** must lie in a plane perpendicular to the longitudinal axis **430** with a magnetic field vector **H** for the windings **502** and **504** rotating about the longitudinal (z) axis **430** to torque and rotate the magnet **426**. FIG. 5 also shows an x-axis **506** and a y-axis **508** that are orthogonal to each other and to the longitudinal axis **430**. As shown in FIG. 5, the magnetization vector **M** **510** of the magnet **402** is in an x-y plane that is perpendicular to the longitudinal axis **430**.

[0063] The winding **502** produces a magnetic field at the center of the winding **502** that is parallel to the y-axis **508**. The winding **504** produces a magnetic field at the center of the winding **504** that is parallel to the x-axis **506**. The combined magnetic field vector **H** for the windings **502** and **504** is given by:

$$H = H_x x' + H_y y',$$

where x' and y' are unit vectors in the x and y directions, respectively. The magnetization vector **M** rotates through the angle **512**, which is equal to the angular velocity of the magnet **426** times the elapsed time for uniform rotation. Thus, the magnetization vector **M** is given by:

$$M = M(\cos(\omega t)x' + \sin(\omega t)y').$$

[0064] The magnetic moment vector **m** is given by:

$$m = MV;$$

where **M**=magnetization vector of the magnet **426** in Tesla; and **V**=the magnet **426** volume in m^3 .

[0065] The torque τ exerted on the magnet **426** is given by:

$$\tau = m \times H;$$

where τ =the torque vector in N-m; **m**=the magnetic moment vector in Tesla- m^3 ; **H**=the magnetic field vector of the windings **502** and **504** in amp/m; and \times =the vector cross product.

[0066] The vector cross product can be evaluated:

$$\tau = MV(H_y \cos(\omega t) - H_x \sin(\omega t))z'.$$

[0067] The vector cross product verifies that the torque produced by the windings **502** and **504** on the magnetic moment vector **m** is indeed about the longitudinal axis **430**. Moreover, the torque will be uniform and independent of time if the magnetic fields generated by the field windings **502** and **504** are given by:

$$H_x = -H \sin(\omega t);$$

$$H_y = H \cos(\omega t);$$

thereby yielding a torque τ given by:

$$\tau = MVH z'.$$

The torque is uniform because the magnetic field is uniformly rotating, since $H^2 = H_x^2 + H_y^2$ is independent of time, and the H_x and H_y components describe clockwise rotation of the winding magnetic field vector **H** about the z' axis. The resulting uniform torque on a symmetric magnet having the magnetization vector **M** in the x-y plane is an inherent expression of a rotating field electric motor.

[0068] Thus, the orthogonal fields produce a magnetic field that uniformly rotates about the longitudinal axis **430** at angular speed ω . Under operational conditions, the magnetization vector **M** of the magnet **426** will follow the winding magnetic field vector **H** of the windings **502** and **504** with a slip angle that is determined by a system drag torque. When the angular speed ω is increased, the drag torque (and the slip angle) increases until the magnet **426** can no longer rotate fast enough to keep up with the magnetic field.

[0069] A changing slip angle may potentially lead to non-uniform rotation. In at least some embodiments, the sensing device **438** facilitates maintaining uniform rotation of the magnet **426** by maintaining a uniformly rotating magnetic field. In at least some embodiments, the sensing device **438** controls the currents that produce H_x and H_y by feedback from measured values for M_x and M_y components. The relationship between H_x and H_y and M_x and M_y is given by:

$$H_x \propto I_x \propto -M_y; \text{ and}$$

$$H_y \propto I_y \propto M_x;$$

[0070] where I_x =the current in amps producing the magnetic field component H_x ; and I_y =the current in amps producing the magnetic field component H_y .

[0071] In at least some embodiments, the sensing device **438** may be implemented in digital form. In at least some embodiments, digitally processed data output from the sensing device **438** is used to compute the currents at each point in time to maintain uniform rotation. In at least some embodiments, the digital sensing device **438** may measure more than one component of the magnetic field of the magnet **426** at a given point to fully determine the currents for a given rotational direction.

[0072] In at least some other embodiments, the sensing device **438** may be implemented in analog form. In at least some embodiments, the analog sensing device **438** includes two magnetic sensors placed 90 degrees apart on the housing (**432** in FIG. 4) or elsewhere on the imaging core (**408** in FIG. 4). Generally, the magnetic field generated by the magnet **426**

is substantially larger than the magnetic field generated by the windings 502 and 504. Thus, the sensors of the sensing device 438 measure the perpendicular components of the magnetization vector **M** in the x-y plane, relative to the axes passing from the center of the magnet 426 to the sensors. The measured signals can be amplified and fed back to the currents in the windings 502 and 504. If, as shown in the previous equations, the x current is inverted, the magnet 426 rotates clockwise. If the y current is inverted, the magnet 426 rotates counterclockwise.

[0073] In at least some embodiments, the sensing device 438 includes at least some magnetic sensors located external to the patient. For example, two tri-axial magnetic sensors, including six individual sensors, may measure the x, y, and z components of a rotating magnetic field of the magnet 426 at two locations external to the patient. In at least some embodiments, magnetic field sensing of the rotating magnet 426 is facilitated by sensing only magnetic fields that rotate in phase with the magnet winding drive currents. Data from the external sensors may be inverted to find the x, y, and z coordinates of the rotating magnet (and IVUS transducer), and the spatial orientation of the magnet 426. This data can be used to form a three dimensional image of surrounding tissue (e.g., bends in an artery) during pull back imaging.

[0074] In at least some embodiments, one or more sensors may be positioned in proximity to the rotating magnet 426 and implantable into the patient, while a plurality of sensors remain external to the patient. The implantable sensor may identify the angular orientation of the rotating magnet 426, and this data may be used to accept only data from the external sensors that have the proper frequency and proper phase angle of the rotating magnet while rejecting data obtained from external sensors with an improper frequency and phase angle, thereby further increasing the signal-to-noise ratio in the external sensor data.

[0075] The amount of magnetic torque that may be generated by the motor 416 may be limited by the amount of current that may be passed through the windings 502 and 504 without generating excessive heat in the catheter (402 in FIG. 4). Heat is generated in the windings 502 and 504 by Joule heating at a rate given by:

$$P=I^2R;$$

[0076] where **P**=the power dissipated as heat in watts; **R**=the resistance of the windings 502 and 504; and **I**=the amplitude of the current in amps.

[0077] The value for **P** is divided by two because sinusoidal current is employed. However the value for **P** is also multiplied by two because there are two windings 502 and 504. In at least one experiment, it has been estimated that up to 300 mW of heat is readily dissipated in blood or tissue without perceptibly increasing the temperature of the motor (416 in FIG. 4). In at least one experiment, it has been estimated that heat dissipation increases to several watts when blood is flowing.

[0078] The magnetic field **H** of the windings 502 and 504 having **N** turns and inputting current **I** may be computed. The result follows from the formula for the magnetic field generated by a current-carrying line segment. Typically, the lengths of the long ends of the rectangular-shaped windings 502 and 504 parallel with the longitudinal axis 430 are substantially greater than the lengths of the short ends of the windings 502 and 504. Accordingly, the short ends may not significantly

contribute to the magnetic torque. The magnetic field **H** of the windings 502 and 504 having **N** turns and inputting current **I** is given by:

$$H=2NI/(\pi D\sqrt{1+(D/L)^2});$$

where **N**=the number of turns of the windings 502 and 504; **D**=the winding width in meters (typically the diameter of the housing (432 in FIG. 4); and **L**=the length of the windings 502 and 504 in meters. **NI** can be analyzed in terms of the power dissipated in the windings 502 and 504. Although theoretical optimization of all parameters is possible, safety limits may be incorporated into design implementation.

[0079] In one exemplary embodiment, rectangular windings 502 and 504 have 8 turns of silver wire with a 2.7 inches (6.86 cm) length, a 0.002 inch (0.005 cm) diameter, and a resistance of 0.5 Ohms. A magnet 426 has a cylindrical shape with an outer diameter of 0.022 inches (0.056 cm), an inner diameter of 0.009 inches (0.022 cm), and a longitudinal length of 0.132 inches (0.34 cm). The magnetization **M**=1.4 for the magnet 426 having the above-mentioned dimensions formed from neodymium-iron-boron. The maximum power **P** is equal to 0.3 watts, the maximum current amplitude is 0.77 amps, and the quantity **NI** is 6.2 amps. Using the above-mentioned values, the torque on the magnet 426 is given by:

$$\tau=2MV(NI)/(\pi D\sqrt{1+(D/L)^2}).$$

[0080] Inserting the above-mentioned values gives a torque of 4 μ N-m=0.4 gm-mm, which is approximately four times larger than an estimated maximum frictional drag on the magnet 426. The corresponding force is about 0.1 gram, or about 30 times the weight of the magnet 426. Although torque may be increased by increasing the magnet radius, it is desirable that the catheter (402 in FIG. 4) be small enough to be disposed in a wide variety of patient vasculature. Additional considerations for insertion of the catheter into patient vasculature may be considered including, for example, the length of the imaging core (408 in FIG. 4) (because the relative stiffness of the imaging core (408 in FIG. 4) may affect maneuverability of the catheter), heat generation, the resistivity of metals at room temperature, and the strength of the materials used to form the magnet 426.

[0081] It may be difficult to form the windings 502 and 504. For example, it may be difficult to wind a wire of 0.002 inch (0.005 cm) diameter around a cylindrical surface of a housing (432 in FIG. 4). In at least some embodiments, the windings 502 and 504 are deposited onto a thin film (e.g., a polyimide film, or the like), which is then disposed onto the housing (432 in FIG. 4). For example, one or more types of metals (e.g., copper, silver, gold, or other metals or metal alloys) are deposited onto the thin film, and the thin film is disposed onto the housing (e.g., using one or more adhesives or other types of suitable coupling methods). In alternate embodiments, the housing (432 in FIG. 4) is formed from a ceramic cylinder or extruded polyimide tube, or other material that is suitable for deposition of metal strip lines. A three-dimensional lithography process may be used to deposit and define the windings 502 and 504 on the cylinder. For example, a metal film may be deposited uniformly on an outer surface of the cylinder and a laser may be used to remove undesired metal film from the outer surface of the cylinder, thereby defining the windings 502 and 504.

[0082] FIG. 6 is a schematic top view of one embodiment of the windings 602 and 604 disposed on a thin film 606. In at least some embodiments, the windings 602 and 604 are dis-

posed on both sides of the thin film 606. In at least some embodiments, the winding 602 is disposed on a first side of the thin film 606 and the winding 604 is disposed on a second side of the thin film 606. In preferred embodiments, the windings 602 and 604 are disposed on the thin film 606 such that when the thin film 606 is disposed around the magnet 426 (or the housing 432), the windings 602 and 604 are offset from one another by 90 degrees.

[0083] It is undesirable to have rotating portions of the imaging core directly contacting stationary portions of the distal end of the catheter. Relative motion between rotating portions of the imaging core (e.g., the rotating driveshaft, the magnet, and the like) and the stationary components of the distal end of the catheter (e.g., the stator, the housing, and the like) may produce a frictional drag. FIG. 7 is a schematic longitudinal cross-sectional view of another embodiment of a distal end of a catheter 702. The catheter 702 includes drag reducing elements 704 and 706 disposed on each end of a motor 708. The drag reducing elements 704 and 706 may include any suitable device for reducing drag including, for example, one or more bushings, one or more bearings, or the like or combinations thereof.

[0084] Other drag reducing techniques may also be employed instead of, or in addition to, the drag reducing elements 704 and 706. For example, in at least some embodiments, the housing (432 in FIG. 4) is formed, at least in part, from a conductive material (e.g., carbon fiber and the like). In at least some embodiments, the rotation of the magnet (426 in FIG. 4) produces eddy currents which may increase as the angular velocity of the magnet increases. Once a critical angular velocity is met or exceeded, the eddy currents may cause the magnet to levitate. In a preferred embodiment, the conductive material of the housing has conductivity high enough to levitate the magnet (426 in FIG. 4) to a position equidistant from opposing sides of the housing, yet low enough to not shield the magnet (426 in FIG. 4) from the magnetic field produced by the windings (602 and 604 of FIG. 6).

[0085] As another example of a drag reducing technique, a space between the magnet 426 and the housing 432 may be filled with a ferrofluid (e.g., a suspension of magnetic nanoparticles, such as available from the Ferrotec Corp., Santa Clara, Calif.). The ferrofluid is attracted to the magnet 426 and remains positioned at an outer surface of the magnet 426 as the magnet 426 rotates. The fluid shears near the walls of non-rotating surfaces, such that the rotating magnet 426 does not physically contact these non-rotating surfaces. The resulting viscous drag torque on the magnet 426 increases in proportion to the rotation frequency of the magnet 426, and may be reduced relative to a non-lubricated design.

[0086] In at least some embodiments, the one or more transducers are stationary within the imaging core and direct an acoustic signal onto a rotating mirror. Employing a fixed transducer and a rotating mirror may eliminate the need for a transformer. Transformers have several disadvantages including, for example, a loss in energy amplitude through inductance between components, phase-shifting IVUS waveforms, financial expense, and manufacturing difficulty. Additionally, eliminating the transformer may have several advantages. For example, the imaging core may be shorter in length than an imaging core with a transformer. As discussed above, the portion of the catheter in which the imaging core is disposed is typically stiffer than other portions of the catheter. Thus,

reducing the length of the imaging core may allow the catheter to navigate through sharper turns in patient vasculature.

[0087] In at least some embodiments, the rotatable mirror is positioned distal to the one or more fixed transducers. FIG. 8 is a schematic longitudinal cross-sectional view of yet another embodiment of a distal end of a catheter 802. The catheter 802 defines a lumen 804 within which an imaging core 806 is disposed. The imaging core 806 includes one or more fixed transducers 808, a motor 810, and a rotating mirror 812 distal to the one or more transducers 808. The one or more transducers 808 are electrically coupled to the control module (104 in FIG. 1) via one or more transducer conductors 814.

[0088] The motor 810 includes a rotating magnet 816 and two inner windings 818, or two outer windings 820, or one inner winding 818 and one outer winding 820. The magnet 816 may be formed from many different magnetic materials suitable for implantation including, for example, neodymium-iron-boron, or the like. In at least some embodiments, the magnet 816 is cylindrical. In at least some embodiments, the magnet 816 defines an aperture 822. In at least some embodiments, the magnet 816 has a magnetization vector that is perpendicular to the longitudinal axis of the magnet 816.

[0089] In at least some embodiments, the windings 818 or 820 include two perpendicularly-oriented windings (see e.g., 502 and 504 in FIG. 5) which provide a rotating magnetic field to torque the magnet 816. The windings 818 or 820 are provided with power from the control module (104 in FIG. 1) via one or more motor conductors 824. In at least some embodiments, a support hub 826 is positioned at a proximal end of the imaging core 806. In at least some embodiments, at least one of the windings 818 and 820 or the one or more transducers 808 are cantilevered from the support hub 826.

[0090] In at least some embodiments, the rotating mirror 812 is disposed in the aperture 822, with the one or more fixed transducers 808 disposed either proximal to the magnet 816 or in the aperture 822. In at least some embodiments, the rotating mirror 812 is disposed distally from the magnet 816, with the one or more fixed transducers 808 disposed either proximal to the magnet 816, inside the aperture 822 of the magnet 816, or distal to the magnet 816. In at least some embodiments, the rotating mirror 812 is coupled to an inner surface of the magnet 816. In at least some embodiments, the rotating mirror 812 is fixedly coupled to the magnet 816 such that the mirror 812 rotates with the magnet 816. In at least some embodiments, the mirror 812 is held in position by one or more supports 828 positioned distally from the mirror 812. In at least some embodiments, the mirror 812 is held in position such that a reflective surface of the mirror 812 is not obstructed by either the magnet 816 or the one or more supports 828 as the mirror 812 rotates during operation.

[0091] In at least some embodiments, acoustic signals may be emitted from the one or more fixed transducers 808 towards the rotating mirror 812 and be redirected to an angle that is not parallel to the longitudinal axis of the magnet 816. In at least some embodiments, acoustic signals are redirected to a plurality of angles that are within a 120 degree range with respect to the transverse axis of the magnet 816. In at least some embodiments, acoustic signals are redirected to a plurality of angles that are within a 90 degree range with respect to the transverse axis of the magnet 816. In at least some embodiments, acoustic signals are redirected to a plurality of angles that are within a 120 degree range with respect to the transverse axis of the magnet 816 such that the plurality of angles are centered on an angle that is perpendicular to the

longitudinal axis of the magnet **816**. In at least some embodiments, acoustic signals are redirected to a single angle that is perpendicular to the longitudinal axis of the magnet **816**. In at least some embodiments, acoustic signals are redirected to a single angle that is not perpendicular to the longitudinal axis of the magnet **816**. In at least some embodiments, a notch (or window, fenestration, or the like) with side walls **830** is formed in the magnet **816** to provide an acoustic opening through which acoustic signals may be transmitted from the catheter **802**. In at least some embodiments, an acoustically transparent membrane may be disposed across the notch so that a region **832** between the one or more transducers **808** and the mirror **812** is fluidtight.

[0092] In at least some embodiments, the region **832** between the one or more transducers **808** and the mirror **812** is filled with an airless fluid with impedance that matches tissue or fluid surrounding the distal end of the catheter **802**. In at least some embodiments, the region **832** between the one or more transducers **808** and the mirror **812** is filled with a ferrofluid. In at least some embodiments, in addition to the region **832**, one or more spaces may be formed along at least a portion of the surface area of the magnet **816** when the magnet **816** is disposed in the catheter **802**. In at least some embodiments, the one or more spaces surrounding at least a portion of the surface area of the magnet **816** are filled with ferrofluid. It may be an advantage to surround the magnet with ferrofluid because the ferrofluid is attracted to the magnet **816**. If enough of the surface area of the magnet **816** is accessible by the ferrofluid, the ferrofluid may cause the magnet **816** to float, thereby potentially reducing friction between the magnet **816** and other contacting surfaces which may not rotate with the magnet **816** during operation.

[0093] In at least some embodiments, the mirror **812** includes a reflective surface that is non-planar. In at least some embodiments, the reflective surface of the mirror **812** is concave. It may be an advantage to employ a concaved reflective surface to improve focusing, thereby improving lateral resolution of acoustic pulses emitted from the catheter **802**. In at least some embodiments, the reflective surface of the mirror **812** is convex. In at least some embodiments, the shape of the reflective surface of the mirror **812** is adjustable. It may be an advantage to have an adjustable reflective surface to adjust the focus or depth of field for imaging tissues at variable distances from the mirror **812**. In at least some embodiments, the mirror **812** is a coated membrane stretched over a space that contains air or other compressible substance. When the fluid pressure of the region **832** between the one or more transducers **808** and the mirror **812** increases, the reflective surface of the mirror **812** may deflect to produce a concave surface.

[0094] In at least some embodiments, the one or more transducers include a plurality of annuli. In at least some embodiments, at least one of the annuli resonates at a frequency that is different from at least one of the remaining annuli. FIG. 9 is a schematic transverse cross-sectional view of one embodiment of a transducer **902** with a plurality of annuli, such as annulus **904** and annulus **906**. In at least some embodiments, the annulus **904** resonates at a different frequency than the annulus **906**.

[0095] In at least some embodiments, the rotatable mirror is positioned proximal to the one or more fixed transducers. FIG. 10 is a schematic longitudinal cross-sectional view of another embodiment of a distal end of a catheter **1002**. The catheter **1002** defines a lumen **1004** within which an imaging

core **1006** is disposed. The imaging core **1006** includes one or more fixed transducers **1008**, a motor **1010**, and a rotating mirror **1012** proximal to the one or more transducers **1008**. The one or more transducers **1008** are electrically coupled to the control module (**104** in FIG. 1) via one or more transducer conductors **1014**.

[0096] The motor **1010** includes a rotating motor magnet **1016** and windings **1018**. In at least some embodiments, the motor magnet **1016** is cylindrical. In at least some embodiments, the motor magnet **1016** is formed from neodymium-iron-boron. The windings **1018** are provided with power from the control module (**104** in FIG. 1) via one or more motor conductors **1020**. The motor **1010** is disposed in a housing **1022** with a distal end cap **1024**. In at least some embodiments, space around the motor **1010** is evacuated to reduce friction. In at least some embodiments, space around the motor **1010** is filled with one or more gases to reduce friction. Many different gases may be used including, for example, nitrogen, carbon dioxide, oxygen, or the like or combinations thereof. In at least some embodiments, space around the motor **1010** includes one or more gases and is partially evacuated.

[0097] The mirror **1012** includes a magnet **1026** and a tilted reflective surface **1028**. In at least some embodiments, the mirror **1012** is configured and arranged to rotate with the motor magnet **1016**. In at least some embodiments, the mirror **1012** is not coupled to the end cap **1024**. In at least some embodiments, the mirror magnet **1026** has an opposing magnetization direction from the motor magnet **1016**, as shown in FIG. 10 by the directions of arrows on the motor magnet **1016** and the mirror magnet **1026**. The motor magnet **1016** is magnetically coupled to the mirror **1012** through the end cap **1024**.

[0098] The end cap **1024** can be formed from a rigid or semi-rigid material (e.g., one or more metals, alloys, plastics, composites, or the like). In at least some embodiments, the end cap **1024** is coated with a slick material (e.g., polytetrafluoroethylene, or the like) to reduce friction between the end cap **1024** and the rotating motor magnet **1016** and mirror **1012**. In at least some embodiments, at least one of the motor magnet **1016** or the mirror **1012** has a tapered end contacting the end cap **1024** to reduce friction during rotation.

[0099] In at least some embodiments, the imaging core **1006** includes a support hub **1030** disposed at a distal end of the imaging core **1006**. In at least some embodiments, the windings **1018** are supported on one end by the support hub **1030** and on the opposite end by the end cap **1024**. In at least some embodiments, the motor **1010** includes a motor shaft **1032** providing a longitudinal axis about which the motor magnet **1016** rotates. In at least some embodiments, the motor shaft **1032** is coupled on one end by the support hub **1030** and on the opposite end by the end cap **1024**. In at least some embodiments, the one or more transducers **1008** are coupled to a transducer shaft **1034** extending distally from the end cap **1024**. In at least some embodiments, the mirror **1012** defines an aperture through which the transducer shaft **1034** extends. In at least some embodiments, the one or more transducer conductors **1014** are at least partially disposed in the transducer shaft **1034**. In at least some embodiments, the one or more transducer conductors **1014** are at least partially disposed in the motor shaft **1032**. In alternate embodiments, the one or more transducer conductors **1014** extend around an outer surface of one or more of the motor **1010** or the mirror **1012**.

[0100] In at least some embodiments, acoustic signals may be emitted from the one or more transducers 1008 towards the mirror 1012 and be redirected to an angle that is not parallel to the longitudinal axis of the motor magnet 1016. In at least some embodiments, acoustic signals are redirected to a plurality of angles that are within a 120 degree range with respect to the transverse axis of the motor magnet 1016. In at least some embodiments, acoustic signals are redirected to a plurality of angles that are within a 90 degree range with respect to the transverse axis of the motor magnet 1016. In at least some embodiments, acoustic signals are redirected to a plurality of angles that are within a 120 degree range with respect to the transverse axis of the motor magnet 1016 such that the plurality of angles are centered on an angle that is perpendicular to the longitudinal axis of the motor magnet 1016. In at least some embodiments, acoustic signals are redirected to a single angle that is perpendicular to the longitudinal axis of the motor magnet 1016. In at least some embodiments, acoustic signals are redirected to a single angle that is not perpendicular to the transverse axis of the motor magnet 1016.

[0101] In alternate embodiments, the imaging core described above can be implemented using one or more rotating transducers and a transformer without using a mirror. FIG. 11 shows a longitudinal cross-sectional view of one embodiment of an imaging core 1102 disposed in a distal end of a lumen 1104 of a catheter 1106. The imaging core 1102 includes a motor 1108 disposed in a housing 1110 with an end cap 1112 that may be rigid or semi-rigid. The imaging core 1102 also includes one or more transducers 1114 disposed distal to the motor 1108. In at least some embodiments, a magnet is attached to the one or more transducers 1114. The one or more transducers 1114 (via the attached magnet) are magnetically coupled to the motor 1108 through the end cap 1112. In at least some embodiments, the one or more transducers 1114 are positioned such that the acoustic signals output from the one or more transducers 1114 are directed at angles that are not parallel with to the longitudinal axis of the motor 1108, as shown by arrows 1116. In at least some embodiments, a transformer 1118 with a stationary component 1120 and a rotating component 1122 is used to power the one or more transducers 1114. In at least some embodiments, the stationary component 1120 is disposed within the end cap 1112 and the rotating component 1122 is disposed within the one or more transducers 1114.

[0102] In at least some embodiments, the windings include a single turn of wire. As shown above, the torque on the motor (e.g., 810 in FIG. 8) is given by:

$$\tau = 2MV(NI)/(\pi DV \sqrt{1+(D/L)^2});$$

wherein the only dependence of torque on the windings is through the product NI . For example, the same result is obtained regardless of whether 0.77 amps flow through windings with 8 turns, or 6.2 amps flow through windings with 1 turn. Heat generation will be the same as long as the total cross-sectional area of the windings is the same. For example, one line two mills high and sixteen mills wide heats equivalent to eight lines two mills high and two mills wide. Accordingly, in at least some embodiments, each winding includes a single turn.

[0103] FIG. 12 is a schematic perspective view of one embodiment of a portion of a first single-turn winding 1202 and a second single-turn winding 1204 configured and arranged for disposing around the magnet (816 in FIG. 8). In at least some embodiments, the first single-turn winding 1202

and the second single-turn winding 1204 are configured and arranged for disposing on separate surfaces of the magnet (816 in FIG. 8). For example, in at least some embodiments, the first single-turn winding 1202 is configured and arranged to be disposed along an inner surface of the magnet (816 in FIG. 8) and the second single-turn winding 1204 is configured and arranged to be disposed along an outer surface of the magnet (816 in FIG. 8). The single-turn windings 1204 and 1206 may be formed from any type of conductive material suitable for implantation into a patient. It may be an advantage to employ single-turn windings, and disposing the first single-turn winding 1202 and the second single-turn winding 1204 along separate surfaces in order to eliminate crossovers from the top and bottom side of the winding circuit.

[0104] FIG. 13 is a schematic transverse cross-sectional view of one embodiment of the first and second single-turn windings 1202 and 1204, respectively, disposed around the magnet (816 in FIG. 8). The single-turn windings 1202 and 1204 may be disposed directly along the magnet 816. In at least some embodiments, the single-turn windings 1202 and 1204 may be imbedded in non-conductive tubing in order to maintain a relative thickness of the catheter (802 in FIG. 8) along a transverse axis of the catheter (802 in FIG. 8). For example, the first single-turn winding 1202 is shown in FIG. 13 as being imbedded in a non-conductive tube 1302 which is disposed along an inner side of the magnet 816. Similarly, the second single-turn winding 1204 is shown in FIG. 13 as being imbedded in a non-conductive tubing 1304 disposed along an outer side of the magnet 816.

[0105] The second single-turn winding 1204 may exert more torque than the first single-turn winding 1202 because the second single-turn winding 1204 has a larger diameter than the first single-turn winding 1202. Thus, the second single-turn winding 1204 may not need to input as much current as the first single-turn winding 1202 during operation. Accordingly, in at least some embodiments, the second single-turn winding 1204 is not as thick as the first single-turn winding 1202.

[0106] In at least some embodiments, up to six amps of current may be utilized by the motor. Thus, in a preferred embodiment, the components of the catheter and imaging core are capable of withstanding up to six amps of current without heating. Low power electronic components are currently available to source six amps of current at low voltage. Additionally, previous studies have shown that flexible stranded leads with an equivalent diameter of approximately 0.015 inches (0.04 cm) can withstand up to six amps of current, while also being capable to fitting through a one-millimeter diameter catheter.

[0107] It will be understood that there are many different multiple-phase winding geometries and current configurations that may be employed to form a rotating magnetic field. For example, a motor may include, for example, a two-phase winding, a three-phase winding, a four-phase winding, a five-phase winding, or more multiple-phase winding geometries. It will be understood that a motor may include many other multiple-phase winding geometries. In a two-phase winding geometry, as discussed above, the currents in the two windings are out of phase by 90°. For a three-phase winding, there are three lines of sinusoidal current that are out of phase by zero, 120°, and 240°, with the three current lines also spaced by 120°, resulting in a uniformly rotating magnetic field that can drive a cylindrical motor magnet magnetized perpendicular to the current lines.

[0108] FIG. 14 is a schematic perspective view of one embodiment of a three-phase winding geometry 1402 configured and arranged for forming a rotating magnetic field around a magnet (see e.g., 816 in FIG. 8). The three-phase winding 1402 includes three windings, or lines, 1404-1406. In at least some embodiments, multiple windings may utilize a single cylindrical surface of the magnet (816 of FIG. 8) with no cross-overs. Such a winding may occupy a minimal volume in an imaging core. Although other geometries may also form a rotating magnetic field, the three-phase geometry 1402 may have the advantages of allowing for a more compact motor construction than other geometries.

[0109] An exceptional property of a three-phase winding geometry 1402 is that only two of the three lines 1404-1406 needs to be driven, while the third line is a common return that mathematically is equal to the third phase of current. This can be verified by noting that:

$$\sin(\omega t) + \sin(\omega t + 120^\circ) = -\sin(\omega t + 240^\circ)$$

[0110] For a three-phase winding geometry 1402, current is driven into two lines with the zero and 120° phase shift of the two terms on the left side of this identity. The sum of the two terms returns on the common line with exactly the correct 240° phase shift on the right side of this equation needed to create the rotating magnetic field. It will be understood that the minus sign indicates that the return current is in the opposite direction of driven current.

[0111] In at least some embodiments, the three unsupported lines 1404-1406 may be supported by a substrate to increase mechanical stability. In at least some embodiments, the lines 1404-1406 are constructed from a solid metal tube, leaving most of the metal in tact, and removing only metal needed to prevent shorting of the lines 1404-1406. In at least some embodiments, the removed portions are backfilled with a non-conductive material.

[0112] The above specification, examples and data provide a description of the manufacture and use of the composition of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention also resides in the claims hereinafter appended.

What is claimed as new and desired to be protected by Letters Patent of the United States is:

1. A catheter assembly for an intravascular ultrasound system, the catheter assembly comprising:

a catheter having a longitudinal length, a distal end, and a proximal end, the catheter comprising a lumen extending along the longitudinal length of the catheter from the proximal end to the distal end;

an imaging core with a longitudinal length that is substantially less than the longitudinal length of the catheter, the imaging core configured and arranged for inserting into the lumen to the distal end of the catheter, the imaging core comprising

a rotatable driveshaft having a distal end and a proximal end,

at least one transducer disposed at the distal end of the driveshaft, the at least one transducer configured and arranged for transforming applied electrical signals to acoustic signals and also for transforming received echo signals to electrical signals,

a transformer disposed at the proximal end of the driveshaft,

at least one imaging core conductor coupling the at least one transducer to the transformer, and

a motor coupled to the driveshaft between the one or more transducers and the transformer, the motor comprising a rotatable magnet and at least two magnetic field windings disposed around at least a portion of the magnet, the magnet having a longitudinal axis and an aperture defined along the longitudinal axis of the magnet;

at least one catheter conductor electrically coupled to the transformer and extending to the proximal end of the catheter; and

at least one motor conductor electrically coupled to the magnetic field windings and extending to the proximal end of the catheter.

2. The catheter assembly of claim 1, wherein the imaging core further comprises a sensing device, the sensing device configured and arranged for sensing the angular position of the magnet.

3. The catheter assembly of claim 2, wherein the sensing device is configured and arranged to control an amount of current applied to the magnetic field windings using the received angular position of the magnet.

4. The catheter assembly of claim 1, wherein the catheter has a transverse diameter that is not greater than one millimeter.

5. The catheter assembly of claim 1, wherein at least one of the at least one imaging core conductor or the driveshaft extends through the aperture of the magnet.

6. The catheter assembly of claim 1, wherein the transformer comprises a rotating component and a stationary component spaced apart from one another, wherein the rotating component is electrically coupled to the at least one imaging core conductor and the stationary component is electrically coupled to the at least one catheter conductor.

7. The catheter assembly of claim 1, wherein the magnet is disposed in a housing.

8. The catheter assembly of claim 7, wherein the housing is formed from a conductive material with conductivity high enough to levitate the magnet when the magnet rotates at an operational angular velocity.

9. The catheter assembly of claim 7, wherein the magnetic field windings are disposed on a thin film.

10. The catheter assembly of claim 9, wherein the thin film is disposed on the housing.

11. An intravascular ultrasound imaging system comprising:

the catheter assembly of claim 1; and

a control module coupled to the imaging core, the control module comprising

a pulse generator configured and arranged for providing electric signals to the at least one transducer, the pulse generator electrically coupled to the at least one transducer via the one or more conductors and the transformer, and

a processor configured and arranged for processing received electrical signals from the at least one transducer to form at least one image, the processor electrically coupled to the at least one transducer via the one or more conductors.

12. A catheter assembly for an intravascular ultrasound system, the catheter assembly comprising:

a catheter having a longitudinal length, a distal end, and a proximal end, the catheter comprising a lumen extend-

- ing along the longitudinal length of the catheter from the proximal end to the distal end;
- an imaging core with a longitudinal length that is substantially less than the longitudinal length of the catheter, the imaging core configured and arranged for inserting into the lumen to the distal end of the catheter, the imaging core comprising
- a motor comprising a rotatable magnet and at least two magnetic field windings disposed around at least a portion of the magnet, the magnet having a longitudinal axis and an aperture defined along the longitudinal axis of the magnet,
 - at least one transducer disposed in the imaging core, wherein the at least one transducer is configured and arranged for transforming applied electrical signals to acoustic signals and also for transforming received echo signals to electrical signals, and wherein the at least one transducer is fixed in position such that the at least one transducer does not rotate with the magnet, and
 - a mirror positioned distal to the at least one transducer, wherein the mirror is tilted at an angle such that when an acoustic beam is emitted from the at least one transducer to the mirror, the acoustic beam is redirected in a direction that is not parallel the longitudinal axis of the magnet, and wherein the rotation of the magnet causes the mirror to rotate;
- at least one catheter conductor electrically coupled to the one or more transducers and extending to the proximal end of the catheter; and
- at least one motor conductor electrically coupled to the magnetic field windings and extending to the proximal end of the catheter.
- 13.** The catheter assembly of claim **12**, wherein the magnetic field windings each comprise a single turn of a conductive material.
- 14.** The catheter assembly of claim **12**, the mirror comprises a non-planar reflective surface.
- 15.** The catheter assembly of claim **12**, wherein the at least one transducer is disposed in the aperture defined in the magnet.
- 16.** The catheter assembly of claim **12**, wherein the at least one transducer comprises a plurality of annuli, at least one annulus configured and arranged to resonate at a frequency that is different from at least one other annulus.
- 17.** The catheter assembly of claim **12**, wherein the mirror is disposed in the aperture defined in the magnet.
- 18.** The catheter assembly of claim **12**, wherein the magnet defines a notch through which an acoustic signal, emitted from the at least one transducer and redirected from the mirror, transmits through.
- 19.** The catheter assembly of claim **12**, wherein the at least one transducer and the mirror are disposed in a fluid-filled region.
- 20.** The catheter assembly of claim **19**, wherein the magnet is at least partially surrounded by a ferrofluid.
- 21.** A catheter assembly for an intravascular ultrasound system, the catheter assembly comprising:
- a catheter having a longitudinal length, a distal end, and a proximal end, the catheter comprising a lumen extending along the longitudinal length of the catheter from the proximal end to the distal end;
 - an imaging core with a longitudinal length that is substantially less than the longitudinal length of the catheter, the imaging core configured and arranged for inserting into the lumen to the distal end of the catheter, the imaging core comprising
- a motor disposed in a housing with a distal end cap, the motor comprising a rotatable magnet and at least two magnetic field windings disposed around at least a portion of the magnet, the magnet having a longitudinal axis along which the magnet rotates,
 - at least one rotatable transducer disposed in the imaging core, the at least one transducer comprising a transducer magnet, wherein the at least one transducer is configured and arranged for transforming applied electrical signals to acoustic signals and also for trans-
- imaging core configured and arranged for inserting into the lumen to the distal end of the catheter, the imaging core comprising
 - a motor disposed in a housing with a distal end cap, the motor comprising a rotatable motor magnet and at least two magnetic field windings disposed around at least a portion of the motor magnet, the magnet having a longitudinal axis and a motor shaft disposed along the longitudinal axis of the motor magnet,
 - at least one transducer disposed in the imaging core, wherein the at least one transducer is configured and arranged for transforming applied electrical signals to acoustic signals and also for transforming received echo signals to electrical signals, and wherein the at least one transducer is fixed in position such that the at least one transducer does not rotate with the motor magnet, and
 - a redirecting mirror comprising a mirror magnet and a reflective surface, the mirror positioned proximal to the at least one transducer, wherein the reflective surface is tilted at an angle such that when an acoustic beam is emitted from the at least one transducer to the reflective surface, the acoustic beam is redirected in a direction that is not parallel the longitudinal axis of the motor magnet, and wherein the mirror magnet and the motor magnet are magnetically coupled together through the end cap such that the rotation of the motor magnet causes the mirror to rotate;
 - at least one transducer conductor electrically coupled to the one or more transducers and extending to the proximal end of the catheter; and
 - at least one motor conductor electrically coupled to the magnetic field windings and extending to the proximal end of the catheter.
- 22.** The catheter assembly of claim **21**, wherein the at least one transducer is coupled to the end cap via a transducer shaft.
- 23.** The catheter assembly of claim **21**, wherein the imaging core further comprises a support hub disposed at a proximal end of the imaging core.
- 24.** The catheter assembly of claim **23**, wherein the motor shaft extends from the support hub to the end cap.
- 25.** The catheter assembly of claim **21**, wherein the housing is at least partially evacuated.
- 26.** A catheter assembly for an intravascular ultrasound system, the catheter assembly comprising:
- a catheter having a longitudinal length, a distal end, and a proximal end, the catheter comprising a lumen extending along the longitudinal length of the catheter from the proximal end to the distal end;
 - an imaging core with a longitudinal length that is substantially less than the longitudinal length of the catheter, the imaging core configured and arranged for inserting into the lumen to the distal end of the catheter, the imaging core comprising
- a motor disposed in a housing with a distal end cap, the motor comprising a rotatable magnet and at least two magnetic field windings disposed around at least a portion of the magnet, the magnet having a longitudinal axis along which the magnet rotates,
 - at least one rotatable transducer disposed in the imaging core, the at least one transducer comprising a transducer magnet, wherein the at least one transducer is configured and arranged for transforming applied electrical signals to acoustic signals and also for trans-

forming received echo signals to electrical signals, and wherein the transducer magnet and the motor magnet are magnetically coupled together through the end cap such that the rotation of the motor magnet causes the at least one transducer to rotate with the motor magnet, and
a transformer electrically coupled to the at least one transducer;
at least one transducer conductor electrically coupled to the transformer and extending to the proximal end of the catheter; and

at least one motor conductor electrically coupled to the magnetic field windings and extending to the proximal end of the catheter.

27. The catheter assembly of claim **26**, wherein the transformer comprises a stationary component and a rotating component spaced apart from one another, and wherein the stationary component is disposed in the end cap and the rotating component is disposed in the at least one transducer.

* * * * *

专利名称(译)	用于制造和使用远端定位在血管内超声成像系统的导管内的马达的系统和方法		
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摘要(译)

一种用于血管内超声系统的导管组件，包括成像芯，该成像芯被配置和布置成插入导管内腔的远端。成像核心包括至少一个换能器，其安装到驱动轴并且被配置和布置用于将所施加的电信号转换为声学信号，并且还用于将接收的回波信号转换成电信号。电动机在一个或多个换能器和变压器之间耦合到驱动轴。电动机包括可旋转的磁体和围绕磁体的至少一部分设置的至少两个磁场绕组。

