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(54) Title: MRI PROBE

(57) Abstract: A dual mode probe, comprising: (a) a probe body having a proximal end and a distal end at opposite ends of a probe axis; (b) a first imaging module operable in an MRI imaging modality and including a main field magnet located on the probe body; and (c) a second imaging module operable in a second imaging modality and located on the body at a fixed relative position and orientation with respect to the first imaging module; wherein a field of view of the first imaging module and a field of view of the second imaging module are at a known rotational and/or axial displacement from one another.



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MRI PROBE

RELATED APPLICATIONS

The present application claims benefit under 35 USC 119(e) from US
5 provisional patent applications 60/960,212, and 60/960,213, both filed on September 20,
2007. This application is related to two PCT applications filed on even date, by
applicants Topspin, et. al, the first titled "MRI Magnet and Coil Configurations," having
attorney docket number 44841, and the second titled "Data Reconstruction Methods for
MRI Probes," having attorney docket number 38140. The disclosures of all of these
10 applications are incorporated herein by reference.

The present application is related to the following applications: U.S. Patent
Application No. 10/597,325 filed July 20, 2006 and entitled "MRI Probe for Prostate
Imaging"; PCT Patent Application No. PCT/IL2005/000074 filed January 20, 2005,
entitled "MRI Probe for Prostate Imaging" and published as WO 2005/067392; and U.S.
15 Provisional Patent Application No. 60/537,030 filed January 20, 2004 and entitled "MRI
Probe for Prostate Imaging". The disclosures of the above applications are each fully
incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to intrabody medical probes with two imaging
20 modules and an optional tissue sampling/therapeutic module. For example, a single
probe can be configured for US and MRI imaging and tool guidance (e.g. biopsy,
brachytherapy, HIFU or external radiation).

BACKGROUND OF THE INVENTION

Early detection of prostate cancer is important for successful treatment. The
25 most common methods of screening for prostate cancer, manual examination and blood
tests for PSA, can give false positive and false negative results and can not be used as a
reliable basis for interventional treatment. Biopsy is a definitive way of detecting a
tumor and evaluating how dangerous it is. Biopsy usually employs a small point
sampling by sharp long syringe and is considered as a "gold standard" with no false
30 positives. However, biopsies often miss a tumor because blood tests and manual exams
give only a poor indication of where in the prostate a tumor is located. This may result

in false negative diagnosis based upon biopsy results. To avoid missing a tumor, multiple biopsies may be made in different parts of the prostate. However, multiple biopsies can cause greater patient discomfort, and may still miss a small or diffuse tumor.

5 Various medical imaging technologies have been used or suggested for detecting and precisely locating prostate cancer, as well as for guiding biopsies, and for treatment of prostate cancer, for example by radiation, including implantation of radioactive sources in the prostate, and by thermal ablation using radio waves, microwaves, or ultrasound. See, for example, US patents 6,371,903; 5,404,881 to Cathaud et al;
10 6,425,867 to Vaezy et al; 6,432,067; 6,402,742 to Blewett et al; 6,311,084; and 6,129,670, the disclosures of which are incorporated herein by reference. Ultrasound imaging (US) is typically inexpensive and can be done with a transrectal ultrasound (TRUS) probe, which is brought close to the prostate, however ultrasound imaging is poor at distinguishing normal from malignant tissue.

15 Conventional MRI, in which the patient is placed within the bore of a large magnet, is better at distinguishing between different types of soft tissue, including normal and malignant prostate tissue, but is expensive, and may preclude or make difficult certain procedures, such as image guided biopsy and working with implants such as radioactive seeds. This is also true if the MRI receiver is located in a rectal
20 probe close to the prostate (because a large magnet, transmit and gradient coils are generally required), in order to improve the signal to noise ratio (SNR), as described, for example, in US patents 5,170,789; 6,549,800 to Atalar et al; 6,470,204 to Uzgiris et al; and 5,451,232, the disclosures of which are incorporated herein by reference.

 US patent 5,810,007, to Holupka, the disclosure of which is incorporated herein
25 by reference, describes software for fusing an ultrasound image of the prostate, obtained with a rectal probe, and a conventional MRI image of the prostate. The fused image incorporates information from both images, and is particularly useful for monitoring treatment of the prostate.

 US patent 5,572,132, to Pulyer, describes a self-contained MRI probe, including
30 a permanent magnet and an RF coil used for transmitting MRI pulses as well as for receiving MRI signals. Such a probe can be used in the rectum for prostate imaging, as

well as in other body cavities, and would be much less expensive than conventional MRI. However, the requirement that this kind of probe have a relatively homogeneous static magnetic field in the imaging region, limits the magnetic field strength that can be obtained in the imaging region, and hence limits the SNR or the resolution. The disclosure of this patent is incorporated herein by reference.

Blank et al, in PCT publication WO 02/39132, describes a self-contained MRI probe which employs pulse sequences that do not require such great magnetic field homogeneity in the imaging region, and hence may be capable of better spatial resolution for a given SNR and image acquisition time. The disclosure of this publication is incorporated herein by reference.

US patent publication 2006/0004274 by Hawman describes registering two images made with different imaging modalities, where the images differ by a rigid displacement and rotation. Hawman describes registration of images where at least one of the images is acquired using an external imaging device. The disclosure of this publication is incorporated herein by reference.

US 4,819,650 to Goldstein, describes an intrabody probe with first and second ultrasound transducer arrays which produce images in different planes oriented in different directions (e.g. 90 degrees apart). Goldstein describes translating the transducers a fixed amount axially, while keeping the probe in place, so that the first transducer is brought to the same axial position previously occupied by the second transducer. The disclosure of this patent is incorporated herein by reference.

US 6,709,397, and US 7,066,889 to Taylor describe a rectal probe with a single rotatable ultrasound transducer. The disclosures of these patents are incorporated herein by reference.

US 5,201,908 to Jones describes an endoscope with a sheath including multiple channels which can be used for putting an instrument through.

US patent 6,443,902 describes biopsy needle conduits in a rectal probe.

"Target Scan" is a commercially available imaging/biopsy system designed for prostate available from Envisioneering Medical Technologies (St Louis MO, USA).

Civco Medical Instruments (Bedfordshire, UK) produces equipment for stabilizing and/or manipulating medical tools in step-wise increments (e.g. the SeeDos series of products).

SUMMARY OF THE INVENTION

5 The present invention, in some embodiments thereof, relates to intrabody medical probes and methods of use thereof. In an exemplary embodiment of the invention, the probes are equipped with two imaging modules which operate in different imaging modalities, for example, MRI and ultrasound. In an exemplary embodiment of the invention, the probes are used for imaging (suspected) prostate cancer and optionally
10 for guiding and/or performing biopsy and/or treatment thereof. Optionally or alternatively, such a probe is used in other applications, such as vascular applications or intra-abdominally (e.g., through a keyhole surgical approach, laparoscope, natural orifice surgery, such as via a uterus or an open surgical approach).

In accordance with exemplary embodiments of the invention there are provided
15 features which are optionally provided in such probes, including, but not limited to: expandable probe designs, probe anchoring, guide sheath designs and use for positioning and registration, probe alignment, image fusion, probe magnet and biopsy needle design, RF interference control, temperature control and disposable elements. In some embodiments, such options and/or features are used in single-modality probes, for
20 example, MRI probes or ultrasound probes.

There is provided in accordance with an exemplary embodiment of the invention, an imaging probe system, the probe comprising:

- (a) a probe body having a proximal end and a distal end at opposite ends of a probe axis;
- (b) a first imaging module operable in a first imaging modality, including a magnet to be used for MRI imaging and located on the probe body; and
- (c) a second imaging module operable in a second imaging modality and located on the body at a fixed relative position and orientation with respect to the first imaging module;

wherein a field of view of the first imaging module and a field of view of the second imaging module are at a known rotational and/or axial displacement from one another.

In an exemplary embodiment of the invention, there is provided a system including:

- (a) a probe system as described herein; and
- (b) an image processor designed and configured to:
 - (i) receive a first output signal from the first imaging module;
 - (ii) receive a second output signal from the second imaging module; and
 - 10 (iii) register the first and second output signals to produce a registered composite image. Optionally, the system comprises at least one position sensor adapted for generating a signal indicating relative movement between uses of said imaging modules and wherein said processor is configured to dynamically register a signal from said sensor and using said known displacement.

15 In an exemplary embodiment of the invention, said first imaging module comprises a self contained MRI imaging device.

In an exemplary embodiment of the invention, the first imaging module is characterized by sufficient resolution to identify a tumor with a volume of 0.5cc or more.

20 In an exemplary embodiment of the invention, the second imaging module comprises an ultrasound imaging device.

In an exemplary embodiment of the invention, the system comprises an external shell, the imaging modules rotatable within the shell.

25 In an exemplary embodiment of the invention, the probe body is adapted for rectal insertion. Optionally, the system is adapted for prostate imaging.

In an exemplary embodiment of the invention, the system comprises a biopsy tool. Optionally or alternatively, the system comprises an insertion tool.

In an exemplary embodiment of the invention, the system comprises an inflatable body adapted to surround at least a portion of the probe body.

30 In an exemplary embodiment of the invention, the system comprises a separate sheath adapted for rectal insertion and adapted to receive said probe body therein.

Optionally, said sheath has at least one fixing balloon mounting thereon. Optionally or alternatively, said sheath has at least one MRI coil mounted thereon.

In an exemplary embodiment of the invention, the system comprises at least one MRI coil mounted in a manner deployable relative to said probe.

5 In an exemplary embodiment of the invention, the system comprises a cooling system for cooling said MRI imaging module.

In an exemplary embodiment of the invention, the system comprises a stabilizer which maintains a position of said probe body relative to a patient and allows relative movement therebetween.

10 There is provided in accordance with an exemplary embodiment of the invention, a method for imaging an area of interest, the method comprising:

- (a) providing a probe body and an ultrasound imaging module and an MRI imaging module, the two imaging modules at a fixed relative position and orientation with respect to one another so that a field of view of the first imaging module and a field of view of the second imaging module are at a known rotational and axial displacement from one another;
- (b) acquiring image data of an area of interest using one of the imaging modules;
- (c) rotating and/or axially moving the probe body through the known rotational and/or axial displacements so that the field of view of the other imaging module includes the area of interest;
- (d) acquiring image data of the area of interest using the other imaging module;
- (e) registering image data of the area of interest from the two imaging modules to produce a composite image of the area of interest.

25 In an exemplary embodiment of the invention, the method comprises monitoring a relative position of said probe during said acquisitions and registering said image data from said modules in real time based on said monitoring.

In an exemplary embodiment of the invention, the area of interest comprises at least a portion of a prostate gland. Optionally, the at least a portion of the prostate gland comprises a peripheral zone (PZ).

30 In an exemplary embodiment of the invention, providing includes rectal insertion.

In an exemplary embodiment of the invention, the method comprises:

(f) rotating the probe body back through the known angular displacement so that the ultrasound imaging module is aimed towards the area of interest. Optionally, the method comprises:

5 (g) acquiring ultrasound image data as a biopsy tool is advanced towards the area of interest. Optionally, the method comprises:

(h) registering the ultrasound image data and the MRI image data of the area of interest to produce a composite image of the area of interest which depicts the biopsy tool.

10 There is provided in accordance with an exemplary embodiment of the invention, a probe control apparatus, the apparatus comprising:

(a) a probe body comprising a first imaging module and a second imaging module at a known rotational displacement from the first imaging module;

(b) a rotation mechanism operable to track a rotation of the probe; -

15 (c) control circuitry adapted to track the rotation of the probe body through the known rotational displacement and generate an indication when rotated. Optionally, the control circuitry is adapted to rotate the probe body through the known rotational displacement.

In an exemplary embodiment of the invention, the apparatus comprises:

20 (d) image processing circuitry adapted to resolve images acquired by the first imaging module and the second imaging module to produce a composite image. Optionally, the apparatus comprises:

(e) a display configured to display the composite image.

In an exemplary embodiment of the invention, the apparatus comprises:

25 (e) a rotatable probe sheath with at least one channel at an acute angle to an axis of the probe body; and

(f) alignment circuitry adapted to calculate an alignment between an opening of at least one of the at least one channels and a target in the composite image. Optionally, the apparatus comprises:

30 (g) an alignment mechanism adapted to receive an output comprising the calculated alignment from the alignment circuitry and to output a signal responsive thereto.

Optionally, said output causes activation of an actuator. Optionally or alternatively, said output generates a human perceptible indication.

In an exemplary embodiment of the invention, the alignment mechanism generates a signal with respect to axial alignment.

5 In an exemplary embodiment of the invention, the alignment mechanism generates a signal with respect to a rotational alignment.

In an exemplary embodiment of the invention, the apparatus comprises:

(h) a tool deployment mechanism adapted to deploy a tool from the opening of the at least one of the at least one channels so that a distal portion of the tool approaches the
10 target.

There is provided in accordance with an exemplary embodiment of the invention, a probe sheath for an intra-rectal probe, the sheath characterized by at least one channel at an acute angle to an axis of a body of the intra-rectal probe. Optionally, the sheath is adapted for axial translation with respect to the body of the probe.

15 In an exemplary embodiment of the invention, the sheath is adapted for rotational translation with respect to the body of the probe.

There is provided in accordance with an exemplary embodiment of the invention, a method of MRI imaging, comprising:

(a) surrounding a patient with a temporary flexible RF shield;
20 (b) imaging at least part of the patient using a portable probe of a diameter smaller than 10 cm.

There is provided in accordance with an exemplary embodiment of the invention, a method of MRI imaging, comprising:

(a) inserting an MRI imaging probe into a body;
25 (b) powering said probe inside said body for at least 30 seconds;
(c) extracting heat from said probe using a cooling system during said powering.

Optionally, said cooling system extracts heat to outside of said body. Optionally or alternatively, said cooling system uses a heat sink inside said body.

There is provided in accordance with an exemplary embodiment of the
30 invention, a sheath, comprising:

(a) a hollow body having a diameter suitable for insertion into the body;

(b) at least one MRI coil mounted on the body. Optionally, said coil comprises a gradient coil. Optionally or alternatively, the sheath comprises a balloon adapted to increase an outside diameter of said sheath, over only part of a length thereof.

There is provided in accordance with an exemplary embodiment of the invention, an MRI probe, comprising:

(a) a body sized to be inserted into a body;

(b) an MRI magnet within said body; and

(c) at least one movable element having an MRI coil mounted thereon.

Optionally, said movable element is mounted to said body using a hinge. Optionally or alternatively, said movable element is mounted on an inflatable element.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

Implementation of the method and/or system of embodiments of the invention can involve performing or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of embodiments of the method and/or system of the invention, several selected tasks could be implemented by hardware, by software or by firmware or by a combination thereof using an operating system.

For example, hardware for performing selected tasks according to embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to exemplary embodiments of method and/or system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or

data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Exemplary non-limiting embodiments of the invention described in the following description, read with reference to the figures attached hereto. In the figures, identical and similar structures, elements or parts thereof that appear in more than one figure are generally labeled with the same or similar references in the figures in which they appear. Dimensions of components and features shown in the figures are chosen primarily for convenience and clarity of presentation and are not necessarily to scale. The attached figures are:

10

FIG. 1 is a simplified flow diagram of a method according to an exemplary embodiment of the invention;

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FIG. 2A is an axial (sagittal) cross section of a probe according to an exemplary embodiment of the invention;

FIG's. 2B, 2C and 2D are transverse cross sections of the probe of the exemplary embodiment of FIG. 2A through line A-A;

20

FIG. 2E is a traverse (coronal) cross section of the probe of the exemplary embodiment of FIG. 2A through line B-B;

FIG. 3A side view of an exemplary rotating collar with channels applied to a probe according to an exemplary embodiment of the invention depicted in line with an organ including a target;

25

FIG. 3B is a cross sectional view of an exemplary isolation mechanism through line D-D in FIG. 3A;

FIG's. 4A and 4B illustrate imaging planes of an ultrasound imaging module and an MRI imaging module of a probe according to an exemplary embodiment of the invention respectively;

30

FIG. 4C illustrates the imaging planes of FIG's. 4A and 4B superimposed on one another according to an exemplary embodiment of the invention;

FIG's. 4D and 4E depict exemplary image as they appear on a display screen according to an exemplary embodiment of the invention;

FIG. 5 is a perspective view of an exemplary tool delivery mechanism depicted separately from the probe body for clarity;

5 FIG. 6 is a schematic representation of a control system according to an exemplary embodiment of the invention;

FIG's. 7A shows an axial cross-sectional view of a probe including an MRI sensor and an ultrasound sensor diametrically opposite thereof, and including a placement balloon in accordance with an exemplary embodiment of the invention;

10 FIG. 7B shows a side cross-sectional view of the probe of FIG. 7A, inserted into a rectum, in accordance with an exemplary embodiment of the invention;

FIG. 7C is a side view of a wire diagram of a probe in accordance with an exemplary embodiment of the invention;

15 FIG. 8A is an axial cross-sectional view of a probe including rigid extendable flaps for MRI coils, in accordance with an exemplary embodiment of the invention;

FIG. 8B is an axial view of the probe of FIG. 8A, in a closed configuration, in accordance with an exemplary embodiment of the invention;

FIG. 8C is a top view of a probe including rigid extendable flaps for MRI coils, in accordance with an exemplary embodiment of the invention;

20 FIG. 8D is an axial cross-sectional view of a probe including rigid extendable flaps for MRI coils, which rotate with an MRI probe, in accordance with an exemplary embodiment of the invention;

25 FIG. 8E is an axial cross-sectional view of a probe including MRI coils mounted on an expandable balloon, with an optional second balloon, in accordance with an exemplary embodiment of the invention;

FIG. 9A is an axial cross-sectional view of a probe sheath including MRI coils mounted thereon, in accordance with an exemplary embodiment of the invention;

FIG. 9B is a sidecross-sectional view of a probe sheath including MRI coils mounted thereon, in accordance with an exemplary embodiment of the invention;

30 FIG's. 10A-10D illustrate MRI probes including cooling and/or insulation systems, in accordance with an exemplary embodiment of the invention;

FIG. 11A is a side cross-sectional view of a probe inserted inside the body inside a sheath, in accordance with an exemplary embodiment of the invention;

FIG. 11B is a side-cross-sectional view of a probe inside a sheath, in accordance with an exemplary embodiment of the invention;

5 FIG. 12 is a flowchart of a method of using a sheath with replaceable probes, in accordance with an exemplary embodiment of the invention;

FIG's. 13A-13C illustrate exemplary magnet designs for a dual modality MRI probe, in accordance with an exemplary embodiment of the invention;

10 FIG's. 14A-14B illustrate MRI probes with one or more biopsy channels formed therein, in accordance with an exemplary embodiments of the invention;

FIG. 15 illustrates an MRI sensor design including a magnet and multiple coils, in accordance with an exemplary embodiment of the invention; and

FIG. 16 illustrates a probe guide including axial and rotational positioning elements, in accordance with an exemplary embodiment of the invention.

15 **DESCRIPTION OF EXEMPLARY EMBODIMENTS**

An aspect of some embodiments of the invention relates to a transrectal imaging probe comprising two imaging modules whose fields of view are separated by a known angular displacement and that rely upon different imaging modalities. Optionally, the imaging modules are located at a same, or similar, axial position with respect to the probe. In an exemplary embodiment of the invention, the known angular displacement is 180 degrees. In another exemplary embodiment of the invention, the known angular displacement is zero degrees and the imaging modules are axially displaced with respect to one another. In an exemplary embodiment of the invention, the imaging modules comprise an ultrasound imaging module and a self-contained Magnetic resonance imaging (MRI) module.

In an exemplary embodiment of the invention, the MRI module includes one or more recesses to receive the ultrasonic imager. Optionally, two imagers are provided, a longitudinal imager and a transverse imager. Optionally, most of the probe adjacent an imaging zone thereof is filled with an MRI magnet.

30 In an exemplary embodiment of the invention, the magnet of the MRI module fills one sector of the probe and an ultrasonic imager fills an opposing sector of the

probe. In an exemplary embodiment of the invention, at least 30%, 40%, 50%, 60%, 70% or more of a volume of a magnet section of a probe is filled with a magnet. The section being considered extends between two axial extents of the magnet. Optionally, the magnet is 6 cm long, field of view is 5 cm long, 120 degrees wide and 2.5 cm deep.

5 In an exemplary embodiment of the invention, the MRI magnet is longer than the ultrasonic imager. For example, the magnet has an axial extent greater than that of a transverse US sensor by a factor of at least 5, 6, 8, 10, 12 or intermediate amounts and/or greater by a factor of 1.5, 2, 3, 4, 5 or intermediate amounts than that of a longitudinal probe. Optionally, the US probe is substantially centered with respect to the
10 MRI probe and/or magnet, however, this is not essential. Optionally, this increases a B0 and or a uniformity in Z direction, over a shorter magnet.

In an exemplary embodiment of the invention, one or more ultrasound images are rapidly acquired until an image showing boundaries of the prostate is achieved. At this stage (or before), the probe is subject to a known displacement (optionally angular
15 displacement) to align the MRI module with the prostate. In an exemplary embodiment of the invention, the two imaging modules are installed so that their fields of view have a known angular displacement and/or known axial displacement with respect to one another. Optionally, the ultrasonic imager is rotated and/or moved axially to form the image. Optionally, the alignment mechanism is used to align acquired US slices. In an
20 exemplary embodiment of the invention, a longitudinal US sensor is stepwise rotated between ~ 100 to 260 deg and a Transverse US sensor is rotated 180 deg and scanned axially stepwise.

Optionally, image acquisition by MRI takes longer than image acquisition by ultrasound. Optionally, MRI is characterized by a greater ability to distinguish tumors
25 from normal prostate tissue than ultrasound. In an exemplary embodiment of the invention, using the US imaging module to precisely locate the prostate, contributes to an ability to use the MRI to scan a smaller field of view. Optionally, the smaller field of view includes a specific area of interest. Optionally, MRI provides lower spatial resolution than ultrasound. Optionally, using the MRI module to scan a smaller field of
30 view contributes to a reduction in total imaging time. In an exemplary embodiment of the invention, the smaller field of view is the peripheral zone (PZ) of the prostate.

Optionally, a small depth of penetration contributes to a reduction in size of the field of view.

Alternatively or additionally, after an MRI image showing the location of a tumor, relative to a known reference, is acquired, the probe can be subjected to the
5 known displacement (e.g. angular displacement) and used to guide a medical procedure (e.g. biopsy and/or cryotherapy and/or implantation of brachytherapy seeds) or an external treatment, such as aiming radiation beams.

In some exemplary embodiments of the invention, the US module is operated first and the MRI module is operated afterwards, optionally, the US module is operated
10 again for tool guidance.

In some exemplary embodiments of the invention, the MRI module is operated first and the US module is operated afterwards.

In an exemplary embodiment of the invention, an image is produced by registering ultrasound and MRI data. In an exemplary embodiment of the invention, the
15 known angular and/or axial displacement contributes to simplification of registration. In an exemplary embodiment of the invention, the probe rotates without disturbing its surroundings, so that the probe stays in the same position relative to the prostate. Optionally, the part of the probe inserted into the rectal cavity has rotationally symmetric exterior. Optionally, the probe comprises an external shell which does not
20 rotate, and the imaging modules rotate within the external shell.

An aspect of some embodiments of the invention relates to a transrectal imaging probe with a single or multiple channels for biopsy instruments (e.g. needles).

In an exemplary embodiment of the invention, the channels are provided in the probe itself. Optionally, each channel has an exit characterized by a known axial
25 position on the probe, a known azimuthal angle relative to an axis of the probe and a known rotational position on the probe. In an exemplary embodiment of the invention, the exits can be registered with respect to the combined ultrasound MRI image so that a channel with an exit aligned with a tumor can be selected.

In an exemplary embodiment of the invention, one or more such channels is
30 provided within a groove or tunnel formed in the MRI magnet. Optionally or

alternatively, one or more such channels are provided in a gap or gaps between component parts of an MRI magnet that is made of multiple components.

An aspect of some embodiments of the invention relates to at least one channel, optionally a plurality of channels, for instruments (e.g. biopsy needles) provided in a rotatable probe sheath. Optionally, the probe sheath is axially translatable with respect to the probe. In an exemplary embodiment of the invention, a biopsy needle is advanced through a channel until it is visible in the combined ultrasound MRI image. Optionally, channel position is adjusted using ultrasound feedback. In an exemplary embodiment of the invention, adjustment can be made via axial translation and/or via rotation of the sheath with respect to the probe and/or the probe with respect to the sheath.

An aspect of some embodiments of the invention relates to a probe control apparatus configured to operate a transrectal imaging probe comprising two imaging modules. In an exemplary embodiment of the invention, the apparatus also aligns channels with targets identified in images acquired by the probe. Optionally, the aligned channels are used to guide tools (e.g. biopsy tools or brachytherapy implantation tools) so that they approach the target. In some embodiments, the probe apparatus is used to align two separate probes, at least one of which including an imaging ability. Optionally or alternatively, the control apparatus is used to align ultrasonic images with an MRI image acquired using the same or similar apparatus and/or probe. Optionally, such aligned images are overlaid.

In an exemplary embodiment of the invention, the probe control apparatus supports axial scanning using an MRI imaging modality. Optionally, averaging is performed on body portions which are viewed at two axial positions of the probe.

In an exemplary embodiment of the invention, the apparatus comprises a sheath which is shaped to receive a plurality of matching probes.

In an exemplary embodiment of the invention, the probe control apparatus includes means for attaching the probe to a patient or a bed and prevent relative movement between the probe and an imaged object.

In an exemplary embodiment of the invention, the probe control apparatus include an axial position encoder and/or a rotational position encoder for determining relative position and/or rotation of a probe relative to the control apparatus. In an

exemplary embodiment of the invention, the positions are monitored as a probe is moved, so, for example, the system is aware of what is being aimed-at/viewed at any time and a live US image can be enhanced with the relevant MRI markings or other position based data. Optionally or alternatively, a signal is provided when the probe is at
5 a correct position (e.g., for needle aiming). Optionally, one or more motorized means are provided to automatically move the probe to a desired position (axial and/or rotational).

An aspect of some embodiments of the invention relates to a probe or probe sheath including a positioning inflatable element, which positions the probe/sheath, fixes the probe sheath and/or urges the probe sheath against an object to be imaged, such
10 as a prostate. Optionally, the inflatable element is used for cooling the probe. Optionally the inflatable element stabilizes one or more of the rectal cavity, the abdominal cavity and the prostate and/or prevents or reduces motion of the rectal cavity walls.

An aspect of some embodiments of the invention relates to a probe sheath (e.g., for rectal use) which is disposable. Optionally, the sheath includes an expandable
15 fixating element, such as a balloon. Optionally or alternatively, the sheath includes one or more RF or magnetic elements used as part of an MRI imaging process and designed to cooperate with an MRI probe inserted into the sheath. In an exemplary embodiment of the invention, the probe sheath is rigid.

An aspect of some embodiments of the invention relates to an expandable probe.
20 In an exemplary embodiment of the invention, the probe includes one or more coils that reposition during expansion. In some embodiments, the coils are mounted on an associated device, such as a sheath, which is physically proximate but structurally separate from the probe. Optionally, the one or more coils include an RF transmit and/or receive coil. Optionally or alternatively, the one or more coils include a gradient coil. In
25 an exemplary embodiment of the invention, the coils are mechanically coupled to the probe in a manner which prevents their relative motion once positioned, even under forces of several Kg (e.g., 1, 4, 8, 10, 15, 20, 30 or intermediate numbers of Kg).

In an exemplary embodiment of the invention, the coils are curved when
30 deployed. Optionally or alternatively, the coils extend towards an imaged object and apply force on a surrounding tissue.

Optionally, the coils include both a positioning mechanism and a locking-in place mechanism to prevent their movement once positioned. Optionally, the positioning mechanism includes one or more balloons.

5 An aspect of some embodiments of the invention relates to an MRI-probe includes a temperature control mechanism, which may reduce pain and/or tissue damage to surrounding tissue. In an exemplary embodiment of the invention, the probe or a surrounding sheath includes one or more thermally insulating sections. Optionally or alternatively, an active cooling system including gas cooling and/or water cooling is provided adjacent elements of the probe that heat up. Optionally or alternatively, a
10 balloon used for stabilizing the probe is used as a heat sink for heat generated by the probe and is optionally further cooled. Optionally or alternatively, a magnet of the probe is used as a heat sink and is optionally further cooled. Optionally or alternatively to a heat sink, part of the probe or inflation fluid comprises a phase change material which changes phase when a target temperature is reached, thereby absorbing heat energy and
15 preventing further temperature rise.

In an exemplary embodiment of the invention, the probe includes heat conducting elements, such as metal elements or heat pipes, to conduct heat from a heat forming element to a cooling element and/or heat sink.

In an exemplary embodiment of the invention, the probe includes a temperature
20 sensors, for example, in a cooling fluid or on the probe, which sensor is used to decide on reducing heat, for example, by turning heating elements off, reducing power to heating elements and/or changing duty cycles or other properties of heating elements and/or activate cooling, for example, if a target temperature is reached or approaches. Optionally, reducing heat generation and/or turning off parts of the probe are
25 communicated to the data collection so the image reconstruction can take such pauses or changes into account (e.g., change duty cycle). Optionally, decision making circuitry is provided integral to the probe. Optionally or alternatively, such circuitry is part of a programming of the probe control system.

30 Optionally, the target temperatures are selected taking into account residual heat of heating elements and/or residual heat sink capacity of heat sink elements. Optionally, heat conveying ability of surrounding tissue is also taken into account.

An aspect of some embodiments of the invention relates to reducing RF interference by surrounding a patient having a probe therein with an RF blocking element. Optionally, the element comprises a conducting blanket, which is foldable. Optionally or alternatively, the blocking element comprises a layer of paint or metal mesh placed on walls of a room used for MRI imaging. Optionally, an RF shielding tent is used, for example, an RF blocking fabric body mounted on a metal frame, for example, as in http://www.ramayes.com/EMI_Shielded_Tent_PVC_Frame.htm, the disclosure of which is incorporated herein by reference. Exemplary dimensions of such a frame/tent are 2x2x2 meters, but smaller and larger sizes may be used. Optionally, such a tent is used with other portable and/or hand-held MRI probes. Optionally, such a tent is used which includes a covering capable of reducing interference by at least 50%, 80%, 90%, 95% or 98%.

Overview of description

Exemplary embodiments of the invention relate to intrabody medical probes and methods of use thereof. In an exemplary embodiment of the invention, the probes are equipped with two imaging modules which operate in different imaging modalities. Optionally, the probes are additionally configured to perform a medical procedure, for example a biopsy, for example the probes are configured for both imaging and biopsy.

Fig. 1 is a simplified flow diagram illustrating an exemplary method according to the invention. The other FIG's. generally depict various embodiments and/or optional features of the intrabody medical probes.

Exemplary Method

FIG. 1 illustrates an exemplary method 100 of using a composite image comprising image data acquired in two different imaging modes to guide a biopsy.

At 102 a probe with two imaging modules is deployed. In an exemplary embodiment of the invention, a first imaging module is an ultrasound imaging module and a second imaging module is an MRI imaging module. In an exemplary embodiment of the invention, each imaging module is fully contained in the probe, although one or more of the modules can be powered by an external power source.

At 104 a scan is performed using the first imaging module. Optionally, the scan is performed to locate an organ. In an exemplary embodiment of the invention, the probe is an intra-rectal probe and the organ is a prostate gland.

At 106 a first image of the organ is acquired using the first imaging module. In an exemplary embodiment of the invention, the first image is an ultrasound image. Optionally, organ borders are visible in the first image, but tumors, especially small tumors, are not discernible.

At 108 the probe is rotated through a known angle to aim a second imaging module at the organ. Optionally, the second imaging module acquires image data more slowly than the first imaging module.

At 110 an additional image of the organ is acquired using the second imaging module. In an exemplary embodiment of the invention, a target (e.g. tumor) is visible within the organ in the additional image.

At 112 the probe is rotated through a known angle to aim the first imaging module at the organ (optionally to aim the first imaging module at the organ again).

At 114 images from first module and second module are registered with respect to one another. Acts 112 and 114 may be, for example, switched.

At 116 a tool (e.g. biopsy tool) is guided to the target in the organ using image data from the first imaging module. In an exemplary embodiment of the invention, the target is visible during the guiding.

After the tool has performed a desired medical procedure, the tool and the probe (and the optional sheath, if present) are withdrawn.

Exemplary Probe

FIG. 2A is an axial cross section of a probe 200 according to an exemplary embodiment of the invention. Probe 200 comprises a body 210 with a distal end 214 adapted for intrabody (e.g. intra-rectal) insertion and a proximal end 212. Optionally, proximal end 212 remains outside the body during use. In the depicted embodiment, a cable 216 is shown attached to proximal end 212 of probe 200. Optionally, cable 216 transmits electric power and/or data between probe 200 and an external device (e.g. power source or data processor). In an exemplary embodiment of the invention, probe

200 comprises a self contained power source (e.g. battery) and/or is provided with a cordless data transfer capability (e.g. RF or Bluetooth).

In an exemplary embodiment of the invention, probe 200 comprises a first imaging module 220 and a second imaging module 230. In an exemplary embodiment of the invention, first imaging module 220 and a second imaging module 230 rely upon different imaging modalities. Optionally, module 220 acquires imaging data based upon ultrasound reflectance and/or module 230 acquires imaging data based upon MRI. In an exemplary embodiment of the invention, modules 220 and 230 and/or their respective fields of view are separated by a known angle. Optionally, rotation of probe body 200 through the known angle serves to switch an imaging modality applied to a desired target as described above in the context of method 100. In an exemplary embodiment of the invention, each of imaging modules 220 and 230 is aimed radially outward from an axis B-B of body 210 of probe 200. Optionally, imaging modules 220 and 230 are placed at a similar axial location on probe body 210.

Also visible in FIG. 2A is a tool channel module 260 comprising at least one, optionally a plurality of, channel(s) 270. In an exemplary embodiment of the invention, each channel 270 is provided at an acute angle with respect to axis B-B of probe body 210. In the depicted embodiment proximal openings 274 of channels 270 are below distal openings 272 of channels 270. In an exemplary embodiment of the invention, each channel 270 is adapted for passage of a tool (e.g. biopsy tool or brachtherapy delivery tool) therethrough.

Although channels 270 are depicted as parallel, in some exemplary embodiments of the invention they are non-parallel. A potential advantage of using non-parallel channels is that they may provide more options for directing a needle or other tool to a suspected tumor, at different angles of approach. A potential advantage of having parallel channels is that it may be easier for the operator to choose which channel to use.

In an exemplary embodiment of the invention, probe 200 can be manipulated either axially or rotationally from a position used to acquire MR image data where the prostate center is coincident with the center of the MRI field. A biopsy is performed using these two degrees of freedom (linear movement in/out of the rectum, and angular

rotation of probe 200) to direct the biopsy needle to a desired target, as in conventional ultrasound biopsy probes that do not have self-contained MRI modules.

In FIG. 2A and other figures, multiple channels 270 are depicted. In an exemplary embodiment of the invention, multiple channels 270 are replaced or
5 augmented by an axial translation mechanism, rotational mechanism and/or tilting mechanism for one or more channels.

FIG's. 2B, 2C and 2D are transverse cross sections of probe 200 of the exemplary embodiment of FIG. 2A through line A-A.

Referring now to FIG.2A, probe body 210 can be moved in order to scan (104)
10 using first imaging module 220 until at least a portion of an organ 250 (e.g. prostate) is in field of view 222. In an exemplary embodiment of the invention, imaging module 220 is an ultrasound imaging device which is capable of resolving borders 252 of organ 250. In an exemplary embodiment of the invention, once an image of organ 250 has been acquired (106), movement of probe body 210 is stopped and probe's body 210 is rotated
15 (108) through an angle θ to bring the second imaging module 230 into alignment with organ 250. Optionally, angle θ can be 0, 30, 45, 60, 90, 120 or 180 degrees or lesser or intermediate number of degrees. In the depicted embodiment, θ is 180 degrees.

FIG. 2C is an additional transverse cross sections of probe 200 through line A-A after rotation (108). Field of view 232 of probe 230 is now aligned with organ 250 and
20 can acquire (110) additional image data. Optionally, imaging module 230 is an MRI device adapted for resolving one or more targets (e.g. tumors 254) within organ 250 or on borders 252 of organ 250. In an exemplary embodiment of the invention, an ultrasound module 220 operates more quickly than an MRI module 230 and is used to rapidly locate organ 250. Optionally, slower MRI module 230 can then be employed to
25 provide additional detail (e.g. tumor location and/or dimensions) pertaining to organ 250. In an exemplary embodiment of the invention, use of modules 220 and 230 which rely upon different imaging modalities contributes to a shortening of overall procedure time. Optionally, obtaining morphological information quickly in a "rapid" imaging mode and subsequently obtaining tissue characterization information with the second
30 (slower) imaging mode contributes to the shortening of overall procedure time.

In an exemplary embodiment of the invention, image data from modules 220 and 230 is registered (114) to provide a composite image depicting both borders 250 and target(s) 254 within or on organ 250.

FIG. 2D is an additional transverse cross sections of probe 200 through line A-A after re-rotation (112) of body 210 of probe 200 to bring field of view 222 back into alignment with organ 200. This FIG. illustrates that imaging module 220 with a rapid response time can be used to guide a tool towards one or more of targets 254 in the composite image.

Exemplary channels and their use in exemplary medical procedures

FIG. 2E is a transverse cross section of probe 200 through line B-B from above. In the depicted embodiment, distal openings 272 of eight channels 270 are visible. Channels 270 are as described above in the context of FIG. 2A. Organ 250 is superimposed above imaging module 220. In the depicted embodiment, channels 270 are provided in two rows on opposite sides of axis B-B of body 210 of probe 200. In other embodiments shown below, one or more parallel rows (or otherwise arranged channels) are provided; which channels may transverse a magnet.

FIG. 3A is side view of an exemplary probe 300 fitted with a rotating sheath 260 with channels 270 applied to a probe body 210 according to an exemplary embodiment of the invention depicted in line with organ 250 including a target 254. Line C-C represents a border between a body of a subject and the ambient environment. Portions of the FIGure to the left of C-C are within the body of the subject and portions to the right of C-C are outside the body.

In the depicted embodiment, rotating sheath 260 is coupled to probe body 210 via rotation mechanism 310 and rotational translation of sheath 260 is accomplished by motion of sheath 260 with respect to probe body 210. One of ordinary skill in the art will be capable of incorporating commercially available rotation mechanisms into the context of the invention. One example of such a commercially available rotation mechanism is the SeeDos stepper (Civco Medical Instruments; Bedfordshire, UK).

In an exemplary embodiment of the invention, rotation mechanism 310 includes a precise stepper controlling relative rotational motion between groove 310 on body 210 of probe 200 and protrusions 520 (FIG. 5) of sheath 260.

Optionally, operation of rotation mechanism 310 can be manual or automated. In an exemplary embodiment of the invention, rotation mechanism 310 advances in discrete increments, for example increments determined by arcuate teeth and/or a step motor.

5 In FIG. 3A, a tool 320 is depicted passing from a proximal aperture 274 of one of channels 270 to a distal aperture 272 of the same channel 270. As seen in the figure, as tool 320 extends from channel 270, it comes into proximity with, and optionally contacts, target 272.

10 FIG. 3B is a transverse cross sectional view of an exemplary isolation mechanism 390 adapted to contribute to a reduction in patient discomfort as probe body 210 is rotated within a rectum 370. The depicted section is through line D-D of FIG. 3A. The depicted exemplary rotation mechanism optionally relies upon an external shell 350 and/or an inflatable body 380.

15 In some exemplary embodiments of the invention external shell 350, optionally a rigid shell, covers a portion of probe body 210. Shell 350 contributes to an isolation between probe body 210 and rectal wall 370. In an exemplary embodiment of the invention, this isolation reduces patient discomfort. Relative rotational motion of probe body 210 within shell 350 can be controlled manually and/or by a mechanical mechanism (not pictured for clarity). According to various exemplary embodiments of
20 the invention, the mechanical mechanism can comprise one or more of arcuate teeth, gears, belts, pulleys, rollers and bearings. In an exemplary embodiment of the invention, the mechanical mechanism is controlled by a stepper, for example of the type described above. Optionally, shell 350 and sleeve 260 are subject to the control of a single stepper or separate steppers.

25 Alternatively, or additionally, an inflatable body 380 contributes to isolation of probe body 210 from rectal wall 370. In an exemplary embodiment of the invention, inflatable body 380 comprises an elastic material, e.g. latex, which can be filled to a desired volume with an inert material (e.g. air, saline or a biologically neutral gel). In an exemplary embodiment of the invention, body 380 is filled with a conductant gel which
30 contributes to an efficiency of transmission of an ultrasound signal from ultrasound module 220 to target 250 (e.g. a prostate gland). In an exemplary embodiment of the

invention, inflation of body 380 contributes to a stabilization of probe 210 within rectum 370. Optionally, a degree of stabilization is sufficient to preserve an orientation of shell 350 with respect to target 250 as probe body 210 rotates therein.

Optionally, probe body 210 can be subject to axial translation within shell 350.

5 This axial translation can be instead of, or in addition to, rotation.

FIG 5 illustrates an exemplary tool delivery mechanism 500 detached from probe 200. Depicted exemplary mechanism 500 includes rotating sheath 260 with channels 270 and a tool holder 530 through which tool 320 can be passed. Optionally, tool 320 is fitted with a handle 540. In an exemplary embodiment of the invention, handle 540
10 contributes to ease of manipulation of tool 320 with respect to holder 530 and/or channels 270 of sheath 260. In the depicted exemplary embodiment, engagement protrusions 520 are adapted for insertion in, and motion with respect to, rotation mechanism 310 (FIG. 3A) of probe body 210.

In an exemplary embodiment of the invention, tool 320 is a biopsy tool which
15 contacts target 254 and removes a sample therefrom. Removal can be, for example, via aspiration through a needle.

In an exemplary embodiment of the invention, tool 320 is a brachytherapy seed placement tool which approaches target 254 and places one or more brachytherapy seed(s) in proximity thereto. Placement can be, for example, via ejection through a
20 needle. Ejection can be accomplished, for example, using a biologically compatible fluid (e.g. normal saline) under pressure.

In an exemplary embodiment of the invention, an ability of tool 320 to approach target 254 varies with a particular channel 270 in which the tool is inserted. In an exemplary embodiment of the invention, a user of the invention is provided with
25 information pertaining to which channel 270 to select and/or information pertaining to how to position sheath 260 with respect to body 210 of probe 200. Optionally, the user is notified when a correct position/angle is reached and/or when a correct position is left.

In other exemplary embodiments of the invention, a channel 270 is selected automatically and/or sheath 260 is positioned automatically with respect to body 210 of
30 probe 200.

Channel selection sheath positioning are described in greater detail below in sections entitled "Exemplary Controller" and "Exemplary Alignment Algorithm".

Exemplary Registration of Image Data from Different Modalities

FIG's. 4A and 4B illustrate imaging planes of an ultrasound imaging module 220 and an MRI imaging module 230 respectively of probe 200 according to an exemplary embodiment of the invention.

In FIG. 4A intersection 410 of an ultrasound transverse section 412 and an ultrasound sagittal section 414 is with organ 250 superimposed. While only one transverse section 412 and one sagittal section 414 is depicted for clarity, an ultrasound imaging module typically provides numerous sections in each of the sagittal and transverse orientations. Optionally, additional sections are provided by axially translation and/or rotating the ultrasound transducer or by using a transducer with an internal phase array mechanism. Ultrasound imaging of this type is described, for example, in US patent application 2004/0152986 A1 by Gutierrez, the disclosure of which is fully incorporated herein by reference.

FIG. 4B illustrates coronal sections 422 produced by an MRI imaging module intersecting organ 250. In an exemplary embodiment of the invention, each coronal section 422 spans an angle 424. Optionally, angle 424 can be 60, 90, 120 or 150 degrees or lesser or intermediate or greater numbers of degrees. In an exemplary embodiment of the invention, a total radial depth of coronal sections 422 is 10, 20, 30, 40 or 50 mm or lesser or intermediate or greater depths. Optionally, each coronal section 422 has a radial depth of 3, 5, 7, 10, 12 or 15 mm or lesser or intermediate or greater depths. Optionally, two or more coronal sections 422 each with a radial depth of about 10 mm are employed.

FIG. 4C illustrates the ultrasound transverse section 412 and ultrasound sagittal section 414 of FIG. 4A and the MRI coronal sections 424 of FIG. 4B superimposed on one another according to an exemplary embodiment of the invention.

In an exemplary embodiment of the invention, use of transverse section 412 and sagittal section 414 and coronal section 424 is sufficient for determination of location coordinates of a target in X, Y and Z dimensions. In an exemplary embodiment of the invention, the combined image produced by superimposition includes the low resolution

(e.g. about 10 mm) MRI data superimposed on the high resolution US image (e.g. about 1 mm resolution).

In an exemplary embodiment of the invention, the combined image is characterized by sufficient resolution to detect tumors characterized by a volume of 0.5 cc or more, at least 95% of the time. This volume is generally considered a threshold for clinical significance, and 95% probability of detection is a typical standard. Such tumors have diameter slightly less than 1 cm. In an exemplary embodiment of the invention, a voxel size of less than 1x1x1cm, provides sufficient resolution.

Relationship between voxel size, contrast, and sensitivity

In accordance with some embodiments of the invention, if the tumor volume is V_t , and the voxel volume is V_v , the probability of detecting a tumor may be found from

$$P = \frac{1}{2} + \frac{1}{2V_v} \int dx \int dy \int dz \operatorname{erf} \left[\frac{V_t}{\sqrt{2V_v}} f(x, y, z) \cdot \operatorname{CNR} \right]$$

Here, $\operatorname{erf}(x)$ is an error function (the integral of a normalized gaussian distribution from 0 to x), and CNR is the contrast to noise ratio for cancerous vs. normal tissue, which depends on the MRI weighting (T_1 , T_2 and/or diffusion weighting), as well as on the voxel size, the acquisition time, the RF power, and the gradient fields. The function $f(x,y,z)$ is the fraction of the tumor that will be inside the voxel volume, if the center of the tumor is located at a position (x,y,z) relative to the center of the voxel, and the integration is over the voxel volume. For example, if the tumor is a sphere, and the voxel is a cube of equal diameter, then $V_t/V_v = \pi/6$, and $f(x,y,z)$ has a maximum value of 1 at the center of the voxel, falling off to 1/2 at the center of each face of the voxel, to 1/4 at the center of each edge, and falling to a minimum value of 1/8 at each corner. For a spherical tumor much smaller in diameter than a voxel, for any shape voxel, $f(x,y,z)$ will be 1 over most of the volume of the voxel, and fall to lower values close to the boundaries of the voxel. Then the probability P will be $\frac{1}{2} + \frac{1}{2} \operatorname{erf}(\operatorname{CNR} \cdot V_t / \sqrt{2V_v})$, and $P = 0.95$ when CNR is approximately $2V_v/V_t$. If the tumor diameter is sufficiently great compared to the voxel dimensions, for example at least $2\sqrt{3}$ times the voxel diameter in the case of cubic voxels, then $f(x,y,z) = V_v/V_t$ everywhere in the voxel, because the tumor will extend over the whole voxel if its center is anywhere in the voxel, and the probability P will be $\frac{1}{2} + \frac{1}{2} \operatorname{erf}(\operatorname{CNR} / \sqrt{2})$. In this case, $P = 0.95$ when CNR is

approximately 2. Because CNR is lower, for a given RF power and gradient field, and a given acquisition time, when the voxel volume is smaller, a good choice of voxel volume may be about twice the tumor volume, i.e. tumor diameter approximately equal to voxel diameter in the case of cubic voxels, and in this case a CNR somewhat greater than 4, for example greater than 5 or greater than 6, or greater than 8, may be needed to obtain $P = 0.95$. Alternatively, the voxel volume is about equal to the tumor volume, or about half the tumor volume, or about 4 times the tumor volume, or about 8 times the tumor volume, or higher or lower than these values.

The voxels in general may be different shapes and sizes, and need not all be the same size and shape. A number of factors may be considered in choosing the voxel volumes and shapes, alternatively or additionally to physical limitations. In some embodiments of the invention, the goal is to maximize the probability that a physician will succeed in putting a biopsy needle through any tumor of sufficient size that is present, for example any tumor that is a sphere at least 1 cm in diameter. Another consideration may be avoiding too many false positives, due to too high a noise level, for example. The contrast obtained, on average, between a voxel that includes at least part of a tumor, and other voxels that include only normal tissue, is one factor that affects the probability of success. Another factor is the positions of the voxels relative to the locations at which a biopsy needle can be inserted, so that once a voxel is identified as including at least part of a tumor, this knowledge will allow the physician to insert a biopsy needle that will pass through the tumor. There may be constraints on the acquisition time, governed for example by patient comfort, and there may be safety constraints on heating of tissue from RF fields and from RF and gradient coils, all of which may put constraints on the achievable CNR. The choice of voxel positions and shapes may be governed as well by the image reconstruction algorithm. The US provisional application entitled "MRI Probe with Extended Radial Field of View," and corresponding co-filed PCT application, for example, describe how the shapes and positions of voxels may be chosen according to the curved contours of field amplitude for nominally y-gradient and z-gradient coils, in order to improve resolution.

In some cases, probability of detection is varied by changing the detection threshold, which also changes the probabilities of expected false alarms. Optionally,

however, the above is applied for commonly used fixed detection ratios. In some applications, a detection threshold may be varies based on the seriousness of the various failure modes of detection (false negative, false positive).

FIG. 4D depicts exemplary outputs of transverse image plane 412 and sagittal image plane 414 of prostate target 250 as they appear on a display screen according to an exemplary embodiment of the invention. Reference 416 indicates an MRI image, with the color of each pixel/voxel indicating a degree of suspicion of abnormality. Line 418 indicates an outline of a prostate. Depending on the imaging method, the image may be a 3D image. The resolution of the MRI image displayed is 5x4 pixels but can be improved, for example, by changing imaging time. Optionally, the image is interpolated from several slices in different depths, for example, if the plane imaged by the ultrasound is not aligned with the slices imaged by the MRI. Optionally, the overlay uses a color lookup table used to transform the MRI image gray level into color markings. Optionally, this table is changed as a result of clinical studies and/or may be selected based on patient information, such as PSA, age and medical history.

FIG. 4E depicts an exemplary composite image 450 output as they appear on a display screen according to an exemplary embodiment of the invention. Visible in the depicted example are prostate border 252, peripheral zone 480, MRI enhanced region 460 (corresponding to coronal sections 422 in FIG. 4B) and suspicious area 470.

FIG. 6 depicts an exemplary control system 600. In an exemplary embodiment of the invention, system 600 includes a controller 610 and one or more of a display 650 and at least one user input device (e.g. mouse 662 and/or keyboard 660).

In the depicted exemplary embodiment of the invention, first imaging module 220 of probe 200 provides image data as an output to image processor 620 which is optionally an ultrasound image processor.

In the depicted exemplary embodiment of the invention, second imaging module 230 of probe 200 provides image data as an output to image processor 630 which is optionally an MRI image processor.

In an exemplary embodiment of the invention, image processors 620 and 630 each provide image data output to a registration module 640. Optionally, registration module produces a composite image including, for example, ultrasound and MRI image

data acquired by separate imaging modules (e.g. 220 and 230) which is spatially aligned. In FIG. 6 a composite image including organ 250 and tumor target 254 is presented on display 254.

5 Optionally, rotation of probe body 210 to switch between imaging modules 220 and 230 is performed manually.

In an exemplary embodiment of the invention, registration module 640 provides three dimensional location coordinates to a tool control module 670.

10 In an exemplary embodiment of the invention, tool control module translates the three dimensional location coordinates into operating instructions 675 for rotation mechanism 310 and/or tool 320.

15 Optionally, tool 310 is deployed manually and operating instructions 675 are displayed on display 650. According to some exemplary embodiments of the invention, a user of system 600 manually implements instructions 675. Optionally, instructions 675 include one or more of a rotation direction for sleeve 260 (e.g. clockwise or anticlockwise), a number of rotational units (e.g. clicks) for sleeve 260 and a channel 270 into which tool 320 should be inserted.

It will be appreciated that only channels 270 with a proximal aperture 274 outside the subject's body (i.e. to the right of C-C in FIG. 3A) are actually available for use in manual embodiments of the invention.

20 Optionally, tool 310 is deployed automatically by tool control module 670. According to some exemplary embodiments of the invention, controller 610 implements instructions 675 without active intervention of a user of system 600. Optionally, the user of system 600 can manually override or abort implementation of instructions 675 by controller 610. Optionally, instructions 675 include one or more of a rotation direction 25 for sleeve 260 (e.g. clockwise or anticlockwise), a number of rotational units (e.g. clicks) for sleeve 260 and a channel 270 from which tool 320 should be ejected.

Ejection or deployment of tool 310 can be, for example, by means of a pressurized fluid, a mechanical mechanism or a magnetic field. For purposes of clarity, any or all of these mechanisms are schematically represented by tool control module 670. In an exemplary 30 embodiment of the invention, channels 270 are axially translatable by an axial

translation mechanism which is also schematically represented by tool control module 670.

In an exemplary embodiment of the invention, each of channels 270 is fitted with a similar tool 320, and only one tool 320 is deployed according to instructions 675.

5 According to this automatic exemplary embodiment of the invention, all channels 270, including those with a proximal aperture 274 inside the subjects body (i.e. to the left of C-C in FIG. 3A) are available for use.

Optionally, tool control module 670 also rotates probe body 210 to switch between imaging modules 220 and 230.

10 Exemplary Alignment Algorithm

In an exemplary embodiment of the invention, one or more MRI images are obtained, in the YZ plane, at one or more different values of X, corresponding to different MRI resonance frequencies. Optionally, the X, Y, Z coordinates are not Cartesian coordinates, and surfaces of constant X are not planar, but are curved
15 somewhat, for example in the same direction as surfaces of constant radial distance from the probe axis. Optionally, the Y coordinate approximately represents an azimuthal direction from the probe axis. If a suspected tumor is detected in an MRI image at a voxel with coordinates (Y, Z), then one of the channels 270 is chosen, which corresponds to the Z coordinate of the suspected tumor, and sheath 260 is rotated to a
20 position which corresponds to the Y coordinate of the suspected tumor. In some embodiments of the invention, there is a direct correspondence between the Z coordinate of the voxel in the MRI image, and the channel 270 that is used, i.e. each channel corresponds to a different row of voxels, and rotating sleeve 260 clicks into a different discrete position for each column of voxels, regardless of the value of X for that image.
25 In other embodiments of the invention, the spacing of voxels in Y and Z does not correspond respectively to the different channels 270 and the different discrete positions of sleeve 260, and/or the correspondence is different for different values of X. In this case, optionally, a look-up table, consulted manually or by control software running on controller 610, converts from the Y and Z coordinates, and optionally the X coordinate,
30 of the suspicious voxel in the MRI image, to the channel 270 and the position of rotating sleeve 260 to be used. Once the channel is chosen and rotating sleeve 260 is positioned,

tool 320 is inserted through the chosen channel 270, for example to obtain a biopsy sample, or to deliver brachytherapy or some other form of therapy, optionally guided in real time by ultrasound imaging in the sagittal (XZ) plane.

In some embodiments, the software is executed on a general purpose computer, such as a Pentium based PC (desktop, laptop or embedded) executing the windows operating system.

Exemplary diagnostic mode

In an exemplary embodiment of the invention, imaging modules 220 and 230 are used to determine a clinical status of a target 254 (e.g. tumor). Optionally, a size of target 254 is accurately determined. Alternatively or additionally, a degree of invasiveness of a tumor target 254 is assessed from the imaging data. In an exemplary embodiment of the invention, a decision pertaining to whether to biopsy and/or treat target 254 is made in accord with the size measurement and/or degree of invasiveness assessment. In an exemplary embodiment of the invention, a prostate tumor with a volume of 0.5 cc or less is not indicative of a need to biopsy and/or treat.

In an exemplary embodiment of the invention, imaging modules 220 and 230 are employed repeatedly over time to monitor a clinical progression of a target 254. In an exemplary embodiment of the invention, a growth rate of target 254 is an important clinical indicator.

Additional Exemplary dual-imaging probe

FIG's. 7A-7C show an alternative configuration 700 where an MRI probe is on an opposite side from an ultrasound probe, optimally configured for imaging prostate 250. FIG. 7A shows an axial cross-sectional view of a probe 711 (along dashed line in 7B) including an MRI sensor including a magnet 710 and coils 716 and an ultrasound sensor 712 diametrically opposite thereof, and including an optional placement balloon 702 in accordance with an exemplary embodiment of the invention. Optionally, balloon 702 is expanded, for example using saline 708. Optionally or alternatively, a different expandable structure is used, for example, a mechanical hinged structure. In an exemplary embodiment of the invention, rotation is in the direction of an arrow 714. Optionally, the direction of rotation is maintained, to avoid backlash. Alternatively,

there is a restriction on number of rotations in a certain direction, for example, due to cable-length.

Also shown in FIG. 7A is an outer layer 704 of balloon 702. Optionally, layer 704 is compliant. Optionally or alternatively, layer 704 is designed to have a maximum inflation diameter, for example, by being non-compliant and/or including one or more expansion limiting elements (such as radial fibers). Optionally or alternatively, layer 740 has formed thereon one or more protrusions and/or one or more rigid regions, to assist in anchoring balloon 702 to rectal wall 370. In an exemplary embodiment of the invention, the balloon is formed of expanding silicone and is 12 cm long and a 6 cm long inflatable section, with a final diameter of 4.5 cm. Optionally, ultrasonic imaging is carried out with balloon 702 deflated, to allow more manual manipulation of the probe. Alternatively, at least for acquiring images to be registered to MRI images, balloon 702 is inflated.

In an exemplary embodiment of the invention, an inner layer 706 of balloon 702 is non-compliant and/or is rigid and supports the insertion and/or rotation of probe 711. Optionally, space between probe 711 and inner layer 704 is filled with ultrasound coupling gel and/or oil. Optionally, a separate rigid and/or non-compliant inner layer 704 is glued to balloon 702, for example in contact with the inside of the balloon or its outside. Alternatively, balloon 702 is sealed by layer 704, for example, by welding or gluing thereto.

FIG. 7B shows a side cross-sectional view of configuration 700, inserted into a rectum, in accordance with an exemplary embodiment of the invention. As shown, in an exemplary embodiment of the invention, balloon 702 is located on the opposite of the probe from the prostate. Balloon 702 is optionally used for one or more of fixing the probe in place and/or urging the probe against the prostate. Also shown is an optional inflation tube 724 for inflation and/or deflation of balloon 702. Also visible in FIG. 7B are the optional location of coils 716 within recesses in magnet 710.

Optionally, a sheath 726 is provided and on which balloon 702 is mounted and within which probe 711 may fit. Optionally or alternatively, a condom like flexible sheath is provided on probe 711 and/or balloon 702.

In an exemplary embodiment of the invention, probe 711 includes a handle 720 which extends outwards through an anus 721, for holding by hand or by machine (e.g., as described below).

FIG. 7C is a partially transparent view of probe system 700, in one exemplary implementation thereof. As shown, ultrasound transducer 712 optionally comprises a longitudinal array 736 and a circumferential (transverse) array 734. Also shown is an exemplary position for MRI RF transmit/receive coils. Optionally, an extension 730 of handle 720 is of a greater diameter than handle 720 (which may lie in the anal canal) and/or may include electronics therein, for example, preamplifiers. Optionally or alternatively, handle 720 includes electronics. Optionally, a cable 732 conveys electronic signals from and to probe system 700. The probe shown does not illustrate gradient coils and thus images a single voxel using MRI. However, as in other embodiments described herein, Z and/or y gradient coils are optionally provided and multiple voxels are images, for example, 2, 4, 6, 10, 20, 40 or intermediate or greater numbers.

It should be noted that while probe 711 is described as being rotated to switch between ultrasonic and MRI modes, other movements may be supported. In one example, ultrasonic array 712 is axially displaced from the MRI module (especially magnet 710). Optionally, handle 720/730 is mounted in a holder that can mechanically move the probe so that alternately the MRI and ultrasound imaging modality are in a correct position. Optionally or alternatively, a sensor is provided and the system merely indicates to a user when the probe is moved correctly for a desired alignment between MRI and ultrasonic images. Optionally, such indication is by sound or light. Alternatively, such indication is by display on a screen of one image overlaid with another image or fields of view. Optionally, data acquired when the probe is not in a correct axial position is ignored and/or binned according to position. In some embodiments, axial motion is used for generating an MRI image by axially scanning a plurality of adjacent and optionally contiguous regions using axial motion of the probe to shift an MRI ROI. Optionally, rotational locking is provided to avoid undesired rotation of the probe during axial motion.

In an exemplary embodiment of the invention, probe 711 is mounted within balloon 702, for example, balloon 702 and/or sheath 726 being narrower at a more proximal portion than the probe is at a more distal portion. However, in some embodiments, for example, as described below, the sheath allows the probe to be fully retracted and/or the sheath is disposable.

Optionally, the sheath is marked with a bar-code (or other code) that is used by the system for authentication and cannot be reused.

Extending coils

FIG's. 8A-8E show schematically various methods of allowing one or more coils of the MRI probe to deploy after insertion and thus take up more space than available for insertion (generally the rectum has a greater allowable inner diameter than the anal canal). Optionally, such deployment is used to approximate the coils to the prostate and/or to mechanically distort the prostate. Some embodiments described below deploy rigid wings, on which coils are mounted. Optionally, the wings are hinged (e.g., using a living hinge) so that they can fold out and generate a form other than an arc, for example, each wing can fold and define a concave shape. Some embodiments described below utilize flexible coils. It should be noted that some MRI coils (e.g., gradient coils) experience significant forces during use, such as one to several Kg. Optionally, such coils are deployed and/or held in place relatively rigidly.

Various embodiments described below include, where the coils are mounted on a balloon, where the coils are mounted on a sheath, where the coils are mounted on a probe, where the coils rotate with the probe and/or where the coils do not rotate with the probe.

In an exemplary embodiment of the invention, the coils are RF transmit and/or receive coils. Optionally or alternatively, the coils are Phi gradient coils. Optionally or alternatively, the coils are Z-gradient coils. Generally, gradient coils need to be fixed in place and/or located at a known position, to reduce imaging artifacts. Optionally, a sensor (not shown, possible provided as 803, below) is provided to report on the actual position of the deployed coil and/or report if the coils are completely deployed. Such positional information may be taken into account during reconstruction.

The selection of which coil to deploy may also depend on temperature control issues, for example, in a particular pulse design, RF coils may heat up more than gradient coils and therefore need to be mounted in a manner compatible with cooling and/or incompatible with heat transfer to tissue.

5 In an exemplary embodiment of the invention, one or more of the following mechanism is used to deploy the coils:

(a) Individual balloon(s) for each coil. Optionally, such balloons are non-compliant and include a separate high pressure inflation lumen (not shown). Optionally, a plurality of balloons are provided along the length of a single coil.

10 (b) A single balloon for moving a plurality of coils and/or on which the coils are mounted. Optionally, at least the part of the balloon on which the coils are mounted, is made non- or less flexible and/or elastic. Optionally or alternatively, the entire balloon is made non-compliant.

(c) Telescoping element (e.g., a piston that extends out of the probe body or out
15 of a tube, or a series of co-axial extending tubes), optionally activated by hydraulic or pneumatic means.

(d) Linear actuators, operated with electricity.

(e) A screw mechanism, optionally a no-backdrive screw, optionally powered by
a DC motor.

20 (f) A mechanical wedge inserted into the probe at a hinge from outside the body.

(g) An arm that unfolds and optionally locks when straight. Such an arm may be activated, for example, using any of the mechanism described herein.

(h) A pneumatic piston (e.g., for each flap) that pushes out the flap with the coil.
Optionally, a spring (now shown) is provide din this or other embodiments, optionally at
25 the hinge, to fold the flaps after use.

In an exemplary embodiment of the invention, a separate mechanism is provided for keeping the coils deployed.

FIG. 8A is an axial cross-sectional view of a probe 800 including rigid extendable flaps for MRI coils 824, in accordance with an exemplary embodiment of the
30 invention. In the example shown, a probe 811 is configured to rotate within an inner sleeve 806 of a balloon 802 with an outer layer 804. Probe 811 optionally includes a

magnet 810 and an ultrasonic imager 812. Optionally, an ultrasonic window 828 is provided in balloon 702 and/or layer 806 to support ultrasonic imaging there through. In an exemplary embodiment of the invention, coils 824 are formed as rigid wings and/or mounted on rigid frames. Optionally, the coils are attached to inner sleeve 806 using one or more hinges 826 (e.g., living hinges or pin-based hinges).

In the embodiment depicted, individual deployment balloons 822 are used for deploying the coils. Optionally or alternatively, balloons 822 serve to maintaining the coils in place if, for example, deployed by inflation of balloon 802. Optionally or alternatively, coils 824 can move within the volume of balloon 802. Alternatively, the coils are attached to layer 804 and optionally distort the layer based on force applied by balloons 822.

FIG. 8B is an axial cross sectional view of probe 800, in a closed configuration, in which, for example, both balloons 822 and 802 are deflated.

FIG. 8C is a top view of probe 800. In an exemplary embodiment of the invention, coils 824 are mounted on or embedded in flaps 825. Optionally, a plurality of separate hinge elements are provided for each flap. Optionally or alternatively, a plurality of flap moving mechanisms 803, optionally axially arranged, are provided for each flap. Optionally, one or more of elements 803 serves as a deployment sensor indicating the angular position of its respective flap 825. With respect to movement/locking elements 803, it is noted that removing small parts of the magnet can have a relatively small effect on the field strength, uniformity and/or shape. In an exemplary embodiment of the invention, 1%, 3%, 5%, 10%, 20% or intermediate percentages of magnet volume are removed and/or not provided (e.g., relative to a regular convex shape such as a blunt cylinder) without substantial effect. Optionally, the removal is at multiple locations in the magnet, for example, 2, 4, 5, 10 or intermediate numbers.

In an exemplary embodiment of the invention and as shown, the edges of flaps 825 are rounded. Optionally, flaps 825 have a generally ovoid or rounded-corner rectangle shape. Optionally, the flaps are planar. Alternatively, the flaps are curved. Alternatively the flaps can fold or distort out of their original plane. Optionally, the flaps can flatten against the prostate shape.

Also shown in FIG. 8C is an inflation tube 824 for inflating/deflating balloon 802.

As an alternative mechanism for opening and/or locking flaps 825 in place, there is depicted a plurality of rods 830 which are inserted from outside the body and lock hinges 826 in an open position. Optionally, the rods are conveyed along a handle 820 in grooves defined therein (not shown). Optionally or alternatively, the rods are used to rotate an eccentric element and/or a screw which then deploys the flaps/coils.

FIG. 8D is an axial cross-sectional view of a probe 832 including rigid extendable flaps for MRI coils 824, which rotate with an MRI probe, optionally inside balloon 802, if any. Optionally, the probes and the flap are attached to the balloon using rings within which the probe is held, with the rings being at axial locations other than of the flaps. In alternative embodiments, the flaps are mounted on a sleeve, within which sleeve the probe rotates.

FIG. 8E is an axial cross-sectional view of a probe 840 including MRI coils 842 (e.g., RF transmit coils) mounted on an expandable balloon 844. Optionally, balloon 844 is formed of a non-stretching material. Optionally, separate balloons are used for deployment and for fixating the probe and a second balloon 846 bordering with balloon 844, performs the regular functions of balloon 802. As shown probe 811 can rotate within an inner layer/sleeve 804. Optionally, balloon 844 serves as a separate sheath, for example, as described below.

While the above has generally described each flap as having separate coils, optionally, a single coil spans two flaps and is made of a material flexible enough to behind at the hinges 826. Alternatively, a single coil may be split into two or more coils and each such coil be on a separate flap. This may be less efficient as part of one coil cancels out the field from a corresponding part of the other coil where current flow is opposite, however, the heat caused by current flow is still dissipated. Optionally or alternatively, three coils are provided (or one large coil) with some coil function being provided on each flap and some in a central, non-moving section. A coil may be provided between the flaps for other purposes as well.

Sheath with coils

In an exemplary embodiment of the invention, the probe is provided with a sheath into which it can be inserted and/or removed. Optionally, at least some MRI functions are integrated into the sheath, for example, RF transmit and/or receive coils and/or gradient coils. Optionally, the probe together with the sheath operate as a complete MRI imager.

In an exemplary embodiment of the invention, a sheath for a dual-mode probe sheath is made of a rigid material, for example, plastic, of thickness 0.3-0.5 mm for example and rigid enough to withstand forces applied by the anal canal, peristaltic motion, probe manipulation and/or magnetic forces caused by operation of the MRI probe. Optionally or alternatively, the sheath is made flexible or semi-rigid, optionally non-elastic. In an exemplary embodiment of the invention, the sheath is formed of a material and has a thickness and finish which does not substantially block or distort or reflect ultrasonic radiation passing therethrough, for example, TPX plastic or a material which has an ultrasonic index similar to that of the rectal wall. Optionally or alternatively, the sheath includes a window or aperture for ultrasonic imaging. Optionally, the window is long enough and wide enough to allow imaging through it of the prostate (or other target organ) and without moving the sheath. Optionally or alternatively, a biopsy needle window or aperture is provided, optionally sharing the same window as for ultrasound, through which window a biopsy needle can pass. Optionally, the window is formed of a material (e.g., rubber optionally reinforced with fabric) which splits when a needle contacts it, rather than crumble.

In an exemplary embodiment of the invention, the sheath is non-conducting and/or otherwise does not interfere with MRI sensing, for example, being formed of silicone, rubber and/or plastic materials.

FIG. 9A is an axial cross-sectional view of a configuration 900 including a probe 902 mounted in a probe sheath 910 that includes one or more MRI coils 908 mounted thereon, in accordance with an exemplary embodiment of the invention. In the example shown, probe 902 has a shell/housing 915 and can rotate in an inner rigid sleeve 904 of a balloon 912 which is also part of the sheath. Optionally or alternatively, the balloon is provided as a separate sheath element. In an exemplary embodiment of the invention,

probe 910 reads its axial and/or rotational position off of sleeve 904 using a sensor (not shown) such as an optical position encoder. Optionally or alternatively, external measuring means are used, for example, as described below. Optionally, ultrasonic gel or oil 906 is used to help couple the ultrasonic imaging of probe 902 to the prostate.

5 FIG. 9B is a side cross-sectional view of configuration 900. As shown, coil(s) 908 use separate power/data lines 920 than line(s) 922 used for the rest of probe 902. Optionally, lines 920 and 922 share a plug 918. Optionally or alternatively, line(s) 920 are embedded in the sheath matrix.

Also shown is an optional inflation lumen 914 for inflating/deflating balloon
10 912. Also shown is an optional positional encoder/sensor 930, shown for example as being mounted on the sheath, but which may also be mounted on the probe inside the body or outside thereof, which indicates the relative insertion depth of the probe. Optionally, this information is used to determine an alignment between the probe magnet and the coils.

15 In an alternative embodiment, electrical contacts (not shown) are provided on the inside of sheath 910 (e.g., sleeve 904) and match contacts on the outside of probe housing 915. Such contacts are optionally used to convey power from probe 902 to coils 908.

Optionally, coils 908 are rigidly mounted to sheath 910. Alternatively, one or
20 more of the above deployment mechanism are used to extend advance or otherwise deploy coils 908.

Temperature control

MRI probes often dissipate considerable power; often with better SNR/shorter
25 imaging times being achievable if higher power is dissipated. Some of the power is dissipated as heat, which may cause pain or damage to surrounding tissue. In an exemplary embodiment of the invention, such pain/damage is avoided by temperature control. Optionally, temperature control includes reducing or stopping power if certain allowed values are exceeded. Optionally or alternatively, temperature control comprises actively cooling a heating element of the probe. Optionally or alternatively, temperature
30 control comprises passively cooling a heating element. Optionally or alternatively, temperature control comprises insulating a heating element from surrounding tissue.

In an exemplary embodiment of the invention, heat transfer is achieved using flowing fluid, heat pipes or conducting materials. Optionally, heat is transferred to a location where cooling is easier and/or a heat sink (such as saline or a magnet) is available. Optionally or alternatively, a cooling system, for example, a gas expander is provided. 5
Optionally or alternatively, a phase changing material is used, which absorbs heat energy as a change in its specific heat.

In an exemplary embodiment of the invention, the amount of cooling comprises conveying 10-50 watts (e.g., 20, 30, 40 or other intermediate values) away from sensitive tissue. Optionally or alternatively, the cooling comprises absorbing between 1
10 and 40 Watthours heat energy by the probe and/or associated structures, without a dangerous and/or painful increase in temperature remaining (e.g., maintaining parts in contact with body below 36, 37, 39, 40, 41 or 42 degrees Celsius). In general, the power rating and total energy depend on the sequence used and/or other imaging parameters, as well as probe design and/or efficiency.

In an exemplary embodiment of the invention, temperature control utilizes one
15 or more sensors or estimators of heat dissipation (e.g., calculated based on power provided and time). Optionally, if it is determined that the temperature is too high, power provision is stopped and/or reduced. Optionally, such determination takes into account an existing heat absorption capacity of the system. Optionally, such a sensor is
20 provided near a heating element, optionally near the probe surface (optionally each heating element).

FIG's. 10A-10D illustrate MRI probes including cooling and/or insulation systems, in accordance with an exemplary embodiment of the invention.

FIG. 10A shows a probe 1000 in which an insulating layer 1006 insulates an RF
25 coil 1004 from a body. Optionally, insulation 1006 is provided as part of a shell 1002 of probe 1000. Optionally, heat from coil 1004 is coupled to a heat sink, for example, a magnet 1016, optionally using a heat guide/coupler 1008. Optionally, a heat pipe is used for such coupling, for example, a linear heat pipe and/or a flat heat pipe. Optionally or alternatively, the saline in the balloon is used for heat coupling. Optionally, a stirring
30 motor or circulation pump (not shown) is used for heat evening. Also shown is a power

wire 1010 used to convey power from a PCB 1012 to coil 1004 and an optional ultrasonic sensor 1014.

FIG. 10B shows a probe 1020, in which an active cooling system is used to cool coil 1004 and/or magnet 1016 and/or other heating elements (e.g., one or more gradient coils 1018). As shown, cold fluid flows through a conduit 1024 to a cooling location 1026 (of which there may be several and which may include a heat-exchanger design with one or more large surface elements) and back out via a conduit 1022. Optionally, an external heat pump or other source of cool fluid is provided (not shown). Optionally or alternatively, a cooling system is provided on the probe, for example, a system based on gas expansion (e.g., with expansion at 1026).

FIG. 10C is an axial cross-sectional view of a probe 1040 which illustrates features from both probes 1000 and 1020. In particular, insulating material 1006 is shown on one side of coils 1004 and heat conducting material 1008 on its other side. In proximity to the heat conducting material and/or magnet 1016 are shown cooling conduits 1022, 1024. Optionally, additional gradient coils 1042 (e.g., Z gradient coils) are cooled by direct contact with magnet 1016. Optionally, a layer of ultrasonic coupling gel 1044 and/or an ultrasonic array 1014 serve to thermally insulate some components of the MRI probe from the body.

Also shown are exemplary temperature sensors, for example, an optional sensor 1046 near a heat source and/or an optional sensor 1048 in the body of the probe and/or near the heat sink (magnet 1016).

FIG. 10D shows a configuration 1050 having a probe 1062 in thermal contact with a cooled saline balloon 1058. In an exemplary embodiment of the invention, balloon 1058 is inflated via an inflation channel 1056 and deflated via a deflation channel 1057. The channels optionally pass through a handle 1054. Optionally, if the cooling channel has very cold fluid, it is insulated from the body of the handle surrounding it. Optionally, these channels are also used to circulate cooled fluid in the balloon. In an exemplary embodiment of the invention, an external heat sink or cooler is used, for example, a thermoelectric cooler. Optionally, the heat sink is designed as a pipe or pipes with a plurality of fins (or other radiator or heat exchanger design), which fins are dipped in a substantial volume (e.g., 5-10 liters) of water.

Optionally, the speed of a water circulation pump used to move the cooling fluid, depends on the fluid temperature, sink temperature and/or a desired target temperature. In an alternative configuration, a separate inflation/deflation channel is used and a closed loop pressured system is used to extract, cool and return fluid to balloon 1058.

5 Optionally, a sensor 1070 is provided in the saline and connected (not shown) to logic which controls the cooling and/or circulation of fluid in balloon 1058.

In an exemplary embodiment of the invention, heating elements are coupled to the saline (or other fluid) in balloon 1058, for example, using a heat pipe. Optionally or alternatively, the coupling is first to magnet 1016 which is itself coupled to the balloon.

10 Optionally or alternatively, cooling for RF coils that are mounted inside the balloon and/or float inside the balloon, is provided by substantially direct contact with the cooled saline.

In an exemplary embodiment of the invention, saline and/or magnet are pre-cooled, so as to extend their usefulness as heat sinks. Optionally, they are maintained in thermally insulated or cold conditions until use.

Sheath and exemplary utilization thereof

In an exemplary embodiment of the invention, the probe is not inserted directly into the body. Rather a sheath is inserted into the anal canal and the probe is guided by the sheath. In an exemplary embodiment of the invention, the sheath is fixed to the patient and/or bed, so that it can be used to ascertain a relative position of a probe and the prostate, even with probe replacements and/or movements. Optionally, the patient is sedated and/or tied to a bed, to reduce movements of the patient.

Optionally, the sheath provides additional functions such as one or more of: sterility (e.g., the sheath is sealed from the anal canal and not open at its distal end), guiding biopsy needles (e.g., including one or more channels), include MRI coils, thermal insulation, heat sink ability and/or include at least a part of a cooling system (e.g., pipes for cooling fluid, gas expansion and/or heat pipe). In various embodiments of the invention, elements which would otherwise be in the probe, are provided as part of the sheath. In an exemplary embodiment of the invention, the sheath is constructed to be disposable. Optionally, the sheath and/or the probe and/or a holding apparatus onto

which the sheath mounts (if any) include a position sensor such as an encoder to determine the relative positions of the sheath and the inserted probe.

In an exemplary embodiment of the invention, the sheath supports replacement of probes during a treatment, e.g., has a fixed diameter. Optionally or alternatively, the sheath is collapsible at the area designed to be at the anal canal, for example by pleating
5 or crumpling or by being flexible or elastic on one or more sides thereof. Optionally, expanding sections, such as coils and/or balloons are provided on the sheath and not on the probe. In an exemplary embodiment of the invention, the sheath includes at least one alignment protrusion which matches a groove in the probe (or vice versa) which assists
10 in axial and/or rotational alignment between the sheath and the probe. Optionally or alternatively, the probe is inserted using a lock so it does not axially move relative to the sheath unless desired. Optionally or alternatively, friction is used to reduce undesired relative movement. Optionally or alternatively, the inside of the sheath includes a plurality of protrusions that engage the outside of the probe, or vice versa.

15 Optionally, the sheath, even if rigid includes a non-rigid ultrasound window, for example, formed of rubber, through which ultrasonic imaging can be carried out.

FIG. 11A is a side cross-sectional view of a configuration 1100 including a probe 1104 inserted inside the body inside a sheath 1102, in accordance with an exemplary embodiment of the invention. An optional fixation balloon 1106, with an
20 optionally flexible outer wall 1122 is optionally part of the sheath. Probe 1104 can be of any type, for example, be a dual-mode probe with an MRI imaging module/sensor 1108 and an ultrasonic sensor 1112.

In an exemplary embodiment of the invention, sheath 1102 defines a rigid sleeve 1110 in which probe 1104 rides. Optionally, ultrasonic coupling gel or oil is injected
25 into the sheath before insertion of probe 1104 thereto. Optionally or alternatively, the probe includes a port for elution of gel/oil into the surrounding sheath. Optionally or alternatively, the probe and/or sheath include one or more grooves for conveyance of oil/gel therealong.

In the example shown, probe 1104 is used even when it is not pushed all the way
30 into sheath 1102. Optionally, this allows for axial scanning using the probe and/or for more flexibility in sheath placement. In an exemplary embodiment of the invention,

axial and/or rotational position are used for calculating image effects and/or aligning imaging modalities. Various image processing and/or alignment functions are optionally provided by a controller 1114. Optionally, one or more position encoder or position marking 1116 are provided on the sheath, probe (e.g., handle) and/or sheath holding apparatus. Various encoders and position and rotation sensors are known in the art and may be used, including sensors that are wholly on one part of the system and sensors that are provided on multiple parts of the system which cooperate together.

Optionally, a bed fixation device 1120 is used to directly hold sheath 1102 (e.g., the sheath is rigid and strong enough to be held or includes a suitable reinforcing element such as a metal or plastic ring) or an intermediate adjustable mechanism is used. Optionally, such apparatus (see FIG. 16) may hold both the probe and the sheath, or hold only the probe.

Optionally, a biopsy channel 1118 is provided in the sheath and/or the probe. Optionally, the sheath includes a window (optionally the same as used for imaging) through which a needle can pass. Optionally, a plurality of channels 118 are provided, at different positions and/or angles.

FIG. 11B is a side-cross-sectional view of configuration 1100, showing an exemplary relative positioning of the elements shown in FIG. 11A.

Replaceable probes

FIG. 12 is a flowchart of a method 1200 of using a sheath with replaceable probes, in accordance with an exemplary embodiment of the invention.

At 1202, a sheath is inserted and positioned.

At 1204, a first probe is inserted, for example, an ultrasonic imaging probe or a dual ultrasound-MRI probe. Optionally, the probe is a standard ultrasonic probe. Optionally, a tubular adaptor may be used to match the diameters of the probe and the sheath.

At 1206, the first probe is used to locate a target, for example, a prostate. The probes axial and/or rotational position are optionally noted.

At 1208, the first probe is removed (or rotated) and a second probe with a different modality, such as MRI is inserted. Using the above noted position, the probe is optionally aligned to point at the target.

At 1210, the target is imaged. For MRI, this may take several minutes. Optionally, prior to imaging, a display is made on the image form the first probe to indicate where an MRI region of interest and/or different quality parts, might be. Such display may be used to position the MRI imager.

5 At 1212, the target is optionally scanned (imaged at several locations successively). Optionally, the probe includes a plurality of spaced apart MRI imagers, optionally which share a magnetic field source, for example, a chain of magnets or a single long magnet.

10 At 1214, the second probe is removed (or rotated) and the first probe (or other imaging probe) is inserted.

At 1216, the first probe is used for imaging and/or scanning.

At 1218, the images from the various probes are overlaid, optionally in real-time. Optionally, as a probe is moved relative to a body target, the overlay is updated, for example, to indicate a change in distance and/or orientation relative to a tumor.

15 Optionally, part of the process is repeated, for example, acquiring an MRI image with different parameters, based on ultrasonic imaging or based on a narrowing of a region of interest.

At 1220, biopsy needle and/or treatment devices, optionally on separate probes, are inserted using the above noted registrations between the probes and images. 20 Optionally, each probe is known to the system with respect to relative offsets and/or can be calibrated using a calibration procedure. Optionally, the linear encoding of position is used to allow a same probe to include axially separate biopsy needles and imagers and the probe is axially moved after an image is acquired so as to aim a biopsy needle at a desired location.

25 Optionally, one or both of the probe and sheath are covered with a condom-like layer, for sterility.

Exemplary space filling magnet designs

In an exemplary embodiment of the invention, the magnet part of the MRI probe is made as space filling as possible, for example, filling 50% of a volume of the probe 30 between the reaches of the axial extent of the magnet. In one embodiment, the magnet is made longer (e.g., a factor of 1.5, 2, 3, 4, 5, 6, 8, or intermediate values or more of the

depth of the effective viewing field). In another, the magnet includes recesses for various functional elements, such as ultrasonic imager(s), biopsy needle and/or coils. Optionally or alternatively, such functional elements are provided between parts of the magnet, for a multi-component magnet. Optionally, such a magnet is formed of
5 components with substantially equal sizes.

In an exemplary embodiment of the invention, the extra magnet volume supports a greater B_0 and/or may allow a more uniform B_0 (in the Z direction). Potential advantages of forming the magnet from parts, include one or more of reduction of noise, reduction in eddy currents, better control over field and/or manufacture process, reduced
10 manufacture cost and/or allow different parts of magnet to have different magnetization directions. In accordance with an exemplary embodiment of the invention, it is noted that removing parts of a magnet (or otherwise providing a non-cylindrical magnet), while possibly affecting the general field shape have a lesser effect on total field strength and/or allow useful imaging using non-uniform fields as provided for in some
15 embodiments of the invention.

FIG's. 13A-13C illustrates exemplary magnet designs for a dual modality MRI probe, in accordance with an exemplary embodiment of the invention.

FIG. 13A shows a probe design 1300 in which a longer magnet 1304 is provided, side by side with an ultrasonic imager 1306. In an exemplary embodiment of
20 the invention, the transverse US sensor is 1 cm long, the longitudinal sensor is 6 cm long (e.g., as long as a prostate) and the magnet is 10-15 cm long (e.g., a factor of 1.5, 2, 4 or intermediate or more of the length of the prostate). Both the magnet and the imager are contained in a shell 1302. Optionally, a cable 1310 connects imager 1306 to an external controller. In an exemplary embodiment of the invention, one or more biopsy
25 needle guides 1308 are provided. As the magnet is long, the guides may need to pass through the magnet.

FIG. 13B shows a probe design 1320 in which imager 1306 sits in a recess 1324 of a magnet 1322.

FIG. 13C shows a top view and multiple cross-sections of a probe 1320' which
30 includes both a longitudinal ultrasonic array 1306 and a transverse array 1307, both of which optionally sit in grooves. The cross-sectional views show how at different parts of

the magnet, different amounts of material are missing. Optionally, the arrangement of missing sections is symmetric, for example, to within 10%, 5%, 1% (with respect to what percentage of a part of the probe exactly mirrors an opposite part).

Exemplary Additional biopsy guides

5 In an exemplary embodiment of the invention, non-trivial biopsy needle conduits are provided. In one example, the conduits pass through a magnet portion of the MRI probe. Optionally, the magnet is composed of parts or a channel or groove is milled through it. In another example, the conduits are external to the probe. In another example, a plurality of conduits are provided, at multiple angles and/or positions. In an
10 exemplary embodiment of the invention, the spatial density of the conduits is selected to match the MRI resolution, so that for a suspected MRI voxel, at least one of a plurality of needle conduits is guaranteed to guide a needle to transect a tumor having a size which is if interested and detectable using MRI, for example, between 5-8 mm in diameter or larger.

15 In an exemplary embodiment of the invention, the conduit includes a section that passes through the optional fixing balloon. Alternatively, the balloon is at least partially self-sealing or puncture resistant (e.g., has a fabric layer), so that the needle damage sit but does not cause a catastrophic leakage of its contents.

In an exemplary embodiment of the invention, a surround sheath includes a
20 window for passing of biopsy needles and/or includes the conduits. Optionally, the needles pass through any surrounding condom layer.

FIG's. 14A-14B illustrate MRI probes with one or more biopsy channels formed therein, in accordance with an exemplary embodiments of the invention.

25 FIG. 14A shows a probe 1400, including a shell 1406 within which are found, for example, an RF coil 1404, a gradient coil 1408, a magnet 1402 and an ultrasonic imager 1410.

In an exemplary embodiment of the invention, a separate channel 1412 is provided for passage of an elastic or super-elastic needle 1414. Optionally, the biopsy needle is formed of Nitinol. Optionally, the needle is one manufactured by
30 Envisoneering, USA.

FIG. 14B shows a probe 1420, in which a bore 1424 is formed in a magnet 1426 and serves as part of a biopsy needle conduit 1422. Optionally, conduit 1422 is used with rigid biopsy needles. Optionally or alternatively, a plurality of conduits are provided. Optionally, instead of or in addition to a bore, a groove is formed on a magnet part or a space is provided between magnet parts. Also shown is a PCB 1428 which may include an aperture for passage of conduit 1422, between electronic components.

Exemplary MRI probe design

FIG. 15 illustrates an MRI sensor probe design 1500 including a magnet assembly 1510 and multiple coils 1504, 1506 and 1508, encased in a housing 1502, in accordance with an exemplary embodiment of the invention.

Self-contained MRI probes of other sizes, and not necessarily to scale, may be used for other parts of the body, for example a probe of 2 mm or less in diameter is optionally used for intravascular MRI. Optionally, the magnets in magnet assembly 1510 are composed of magnetically hard permanent magnet material with high energy product, such as NdFeB, or any other such material known in the art. Such magnets have the potential advantages that they do not demagnetize easily, and that the magnetic field they produce in the imaging region will be about as strong as possible, for a given geometry of the probe and imaging region. In an exemplary embodiment of the invention, probe 1500 has a longitudinal axis in the z-direction, an imaging region centered in the +x-direction, and magnet assembly 1510 produces a magnetic field in the imaging region that is predominantly in the -y-direction, with magnets that are magnetized at angles that center around the +y-direction.

One RF coil is provided which faces the imaging region in the +x-direction, which excites nuclei in the imaging region, and receives NMR signals from the excited nuclei. Optionally an RF shield(not shown), made for example of aluminum foil, is located between the RF coil and the magnet assembly, optionally completely surrounding the magnet assembly, to prevent magneto-acoustic ringing in the magnet assembly from the RF fields. Optionally, a pair of phi-gradient coils, overlapping and to the sides of the RF coil, produce a phi-gradient field, optionally substantially parallel to the static magnetic field in the imaging region and anti-symmetric in ϕ , that provides phase encoding in the ϕ direction, which corresponds nearly to the y-direction in the

imaging region. As used herein, “y-gradient” is synonymous with “phi-gradient” and “ ϕ -gradient.” Optionally, a set of three z-gradient coils at the +z end of the probe, and a similar set of three z-gradient coils at the -z end of the probe, produce a z-gradient field, optionally substantially parallel to the static magnetic field in the imaging region and anti-symmetric in z, that provides phase encoding in the z-direction.

In an exemplary embodiment of the invention, magnet assembly 1510 for a self-contained MRI probe, with a longitudinal axis in the z direction, using a Cartesian x-y-z coordinate system, has an imaging region that includes the positive x direction. Optionally, the magnet assembly is not uniformly magnetized, but includes a portion at $y < 0$ with positive y component and negative x component of magnetization, and a portion at $y > 0$ with positive y component and positive x component of magnetization.

In an exemplary embodiment of the invention, the magnets of magnet assembly 1510 are Vacodym 722 NdFeB magnets, sold by Vacuumschmelze, in Germany. The magnet assembly has a semi-circular cross-section 30 mm in diameter, and is 60 mm long. Optionally, assembly 1510 comprises a center part, and end parts. Optionally, assembly 1510 has a semi-circular cross-section, to allow room for the ultrasound module. In an exemplary embodiment of the invention, the center part comprises four magnets. The end parts each comprises two magnets. Optionally, the direction of magnetization of the different magnets is about 25 degrees from the +y-direction, in the x-y plane, either toward the +x or -x direction, or at another angle, not necessarily the same angle for all of the magnets, between 20 and 30 degrees from the +y-direction, or between 15 and 35 degrees from the +y-direction.

In an exemplary embodiment of the invention, the plot of static magnetic field strength vs. distance from surface of magnet assembly 1510, along the x-axis in the +x direction, which is the center of the imaging region, is as follows. In an exemplary embodiment of the invention, the distance of 5 mm to a distance of 20 mm from the edge of the probe, is approximately (a little broader than) the imaging region. For the RF coil and phi-gradient coils pushed against the rectal wall, this imaging region, which also extends from $y = +25$ mm to -25 mm, covers most of the peripheral zone of the prostate, where most cancers occur and where needle biopsies are performed. The field varies from 0.21 tesla down to 0.045 tesla in this region, and the imaging region is

considered to range from 0.20 tesla down to 0.048 tesla, a factor of 4.2. In an exemplary embodiment of the invention, the RF coil is capable of transmitting power and receiving signals over the corresponding range of nuclear magnetic resonance frequencies, ranging from 8.5 MHz down to 2.0 MHz.

5 Optionally, to achieve a fall-off in RF magnetic field of only a factor of 4 over the imaging region, ranging from 5 to 20 mm from the edge of the probe, RF coil 204 extends over 36 mm in z , and over 28 mm in ϕ , is curved with a radius of 22.5 mm, generally comparable to a typical radius of curvature of the inner surface of the rectal wall (noting however, such a coil could be mounted on a balloon and/or hinges and/or
10 otherwise deploy and directly conform to colon shape), and is located just outside the probe edge, centered on the x -axis, facing the imaging region. In an exemplary embodiment of the invention, B_1 falls from about 0.96×10^{-3} tesla at 5 mm from the probe edge, to 0.24×10^{-3} tesla at 20 mm from the probe edge, for 1 amp of current in the transmitting coil.

15 The six z -gradient coils are optionally each a rectangular coil made of 0.35 mm diameter copper magnet wire, with 40 windings around a $13.6 \times 7 \times 2$ mm rectangular core. Optionally, the coils have their centers at $z = +25$ mm (and optionally connected in series), and at $z = -25$ mm (and optionally connected in series). Optionally, the two sets
20 of coils are connected in parallel, anti-symmetrically, and have, for example, total inductance of 22.6 μH and resistance of 0.8 Ω . In this arrangement, the NI through each of the six coils is equal in magnitude. Other arrangements are optionally made if different NI is to be used in different coils within each set, for example driving different coils separately at different voltages, or driving two or more coils in series but having
25 different numbers of turns in different coils. Optionally, to make the z -gradient field anti-symmetric with respect to z and symmetric with respect to y , the four coils in the y - z plane all have the same NI, and the two coils in the x - z plane both have the same NI. The predominant component of the z -gradient fields, like the static magnetic fields, is generally the ϕ component (or y component) in the imaging region, so the z -gradient
30 fields add to or subtract from the static magnetic fields in the imaging region.

In an exemplary embodiment of the invention, the two phi-gradient coils are optionally located with their centers at $\pm 65^\circ$ from the x-axis, at a radius of 45 mm, when they are deployed. Optionally, they are located closer to the probe when it is inserted, and expand away from the probe, closer to the rectal wall, when the probe is in use.

5 Each coil is optionally made of 0.7mm diameter copper wire, with 28 windings (2 layers of 14 windings each) around a $32 \times 16 \times 2$ mm rectangular core. Each coil has a height of approximately 42 mm in the z direction and 26 mm in the ϕ direction, and is about 1.4 mm thick radially. In practice, these dimensions may be a little bigger if the windings are not perfectly packed. If the two coils are connected in parallel, they have a total

10 inductance of 16.2 μH and resistance of 0.15 Ω . Whether they are wired in parallel or in series, the two coils are wired so that the phi-gradient field they produce has a ϕ component that is anti-symmetric in ϕ . Like the static magnetic field, the predominant component of the phi-gradient field in the imaging region is optionally the ϕ or y component, so that the phi-gradient field adds to or subtracts from the strength of the

15 static magnetic field.

When used in a non-prostate probe (or even in the prostate), the above dimensions maybe be larger or smaller and/or a different imaging volume may be desired. For example, the probe diameter can vary over the range 1 mm-100 mm, for example, between 20 mm and 40 mm. The probe length may be, for example, between

20 10 mm and 200 mm.

Exemplary probe holder design

FIG. 16 illustrates a probe guide 1600 including axial and rotational positioning elements, in accordance with an exemplary embodiment of the invention. In an exemplary embodiment of the invention, guide 1600 serves to move a probe that is not

25 within a sheath. Alternatively, a sheath 1602 is provided which does not move with the probe and has a fixed position relative to guide 1600. Optionally, element 161 (described below) includes an inner lip which engages the sheath. In an alternative design, the sheath fits over element 1611. Optionally, the sheath includes a non-rotationally symmetric portion (e.g., a protrusion) which engages guide 1600 (e.g., a

30 groove) to prevent rotational and/or axial motion. Optionally or alternatively, an adjustable pressure ring (not shown) is used to attach the sheath to the guide.

In guide 1600 as shown, a bed fixing element 1604 is used to fix the guide relative to a bed on which the patient is located. Optionally, the patient is tied to the bed. A probe handle 1612 optionally serves for manual manipulation thereof. Optionally or alternatively, motorized manipulations are provided. Optionally, a Civco “multi purpose workstation”, such as described in www.civco.com/urology/accucare_stabilizers/m-p_workstation/, is used

In an exemplary embodiment of the invention, element 1604 is coupled to the bed via an adjustable stabilizer 1630 which allows several degrees of motion (translation and/or orientation), for example, 3, 4, 5 or 6 of guide 1600 relative to the bed. Optionally, the stabilizer comprises a plurality of elongate elements connected by lockable or high friction joints.

In the embodiment depicted, a linear movement element 1610 is used to axially move the probe. Optionally or alternatively, a rotational element 1611 is used to rotate the probe, e.g., using a bearing.

In an exemplary embodiment of the invention, a rotational position sensor 1608 indicates a rotational position of the code, for example, comprising an optical encoder which reads markings off the probe or off of guide 1600 (e.g., if guide 1600 has a fixed and predetermined or known relationship to the probe). Optionally or alternatively, a linear position sensor 1606 such as a linear encoder indicates an axial position. Optionally, guide 1600 includes a reader which reads a code off the probe which indicates, for example, its length.

In an exemplary embodiment of the invention, the encoders provide data using a cable 1622 to a connector 1620, which is separate from a cable 1616 and a connector 1614 of the probe. Optionally, the encoders are integral to the sheath. Alternatively, the encoders are mounted onto the sheath that pre-determined positions adapted for exact registration thereto.

In some embodiments a locking mechanism, such as a locking screw or pressure collar are used to mechanically couple the probe and sheath and prevent undesired relative movement.

Optional RF shielding

In an exemplary embodiment of the invention, noise caused by RF interference (e.g., from generators and ECG machines) is reduced using a portable shield. In one example, the probe itself is shielded except at a reception angle of the coils. Optionally
5 or alternatively, the patient is wrapped in an RF shielding blanket. In one example, such a blanket includes an RF blocking fabric. Optionally or alternatively, a plurality of standing partitions, optionally with fabric covering or fabric on a frame are used. Optionally or alternatively, a tent is provided, optionally mounted on a frame and/or hangable from a ceiling or vertical rod in the room.

Exemplary reduced/Single visit image and treat mode

In an exemplary embodiment of the invention, a dual probe is used to reduce treatment time and/or treatment numbers. In one example, an MRI image is used to guide a biopsy taking to target a tumor, rather than randomly in the prostate. This may allow the biopsy procedure to be shorter and/or less painful and/or less expensive. For
15 example, instead of 12-24 biopsies, a typical number of biopsies using the above described methods may be, for example, 1-4 or 4-10, or 6-12 biopsies.

In another example, with or without physical biopsy, the results of an MRI image are used to immediately provide treatment, for example, in the form of Cryotherapy, RF therapy or Brachytherapy. Such therapy may be guided using the probes and/or needle
20 conduits described above.

Optionally, the therapy is provided not through the probe, for example, HIFU (high intensity focused ultrasound), RF heating and radioactive beams may be aimed using the image and sheath as a reference point. Optionally, such a therapy means is coupled mechanically (or using a position sensor) to the sheath and/or guide 1600.

Exemplary image guided mode

In an exemplary embodiment of the invention, the dual probes provide two imaging modalities which complement each other. Optionally, the images and especially images formed by fusion of the two modalities.

In an exemplary embodiment of the invention, the image(s) are used to guide the
30 insertion of a tool, such as a biopsy needle (e.g., as action 116 in FIG. 1, which may include treatment such as seed insertion). In one example, the images are used for

planning an access direction and/or depth. In another example, the images are acquired in real time to monitor the tool usage. For example, the position of a biopsy needle is detected using ultrasound and matched up to an MRI image which shows suspected pixels. In another example, the biopsy needle includes an MRI marker, such as a small
5 piece of plastic containing gadolinium or a field affecting material such as iron. In another example, the effects of a treatment, for example, location of radioactive seeds (optionally which include an MRI marker) are tracked with one or both imaging modalities.

In an exemplary embodiment of the invention, the system provides guidance to a
10 user as to how far to advance a needle and/or probe and a desired rotation angle. Optionally, such guidance is provided by a user making on an image and the system translating such markings to movement of probe elements.

Exemplary Image acquisition and reconstruction methods

In an exemplary embodiment of the invention, the magnet design and/or pulse
15 sequences used follow what is described in two PCT applications filed on even date with this application by applicant Topspin, et. al, the disclosures of which is incorporated herein by reference.

In an exemplary embodiment of the invention, the MRI probe is moved axially
and/or rotated, as part of a mechanical scanning process. Such scanning may be under
20 computer and/or manual control. Such scanning may be in addition to scanning using gradient coils.

Optionally, after a first MRI image is acquired, a second, detail image of some
point may be desired. Optionally, such a second image is acquired by modifying the
gradients and optionally moving the probe to a new position optimized for the desired
25 second image. Such second image may take longer to acquire due to lower SNR.

Image fusion

In an exemplary embodiment of the invention, the dual mode probe is used to
register images from multiple modalities without using fiduciary markers in the body or
implanted. Optionally, the fusion is carried out during a single procedure and insertion,
30 which may reduce artifacts due to motion of soft tissue in the body.

In an exemplary embodiment of the invention, the merged image can be used to more clearly identify cancer, obstacles and/or sensitive tissue. The following two papers, the disclosures of which are incorporated herein by reference, describe using MRI signals to detect cancer tissue. Optionally, such methods are used to enhance the detectability of cancer on ultrasonic images, for example, by directing the attention of a physician to a particular part of an image or to act as an additional consideration in deciding if a possible indication is of a lesion to be suspected or is an artifact: NMR IN BIOMEDICINE (NMR Biomed. In press) Published online in Wiley InterScience (www.interscience.wiley.com) DOI:10.1002/nbm.1114, "Apparent diffusion coefficient of the prostate in men prior to biopsy: determination of a cut-off value to predict malignancy of the peripheral zone" by Virendra Kumar, N. R. Jagannathan, Rajeev Kumar, S. Thulkar, S. Dutta Gupta, S. N. Dwivedi, A. K. Hemal and N. P. Gupta; and JOURNAL OF MAGNETIC RESONANCE IMAGING 21:258-262 (2005), "Differentiation of Noncancerous Tissue and Cancer Lesions by Apparent Diffusion Coefficient Values in Transition and Peripheral Zones of the Prostate", by Chiho Sato, Shinji Naganawa, Tatsuya Nakamura, Hisashi Kumada, Shunichi Miura, Osamu Takizawa, and Takeo Ishigaki.

In a particular embodiment of the invention, image registration is used to identify what ultrasound slice is imaged with respect to a previously acquired MRI image acquired by the probe. Optionally, if multiple MRI slices are available the appropriate slice will be retrieved and shown. Optionally, multiple ultrasound slices (from same or different probes) are aligned to each other using the probe alignment mechanism. In an exemplary embodiment of the invention, the images are aligned and/or overlaid in real time using the position sensors (described above) and suitable software (e.g., not image processing). Optionally, real-time means faster at least 1, 5, 10, 20 or more images aligned/sec.

In an exemplary embodiment of the invention, the images are registered using a probe that is not rotated. In one example, an MRI probe is switch with an ultrasound probe. In one example, the imagers are offset axially (e.g., the ultrasonic imager all positioned axially of the MRI imager), so axial motion is used instead of or in addition to rotation. Alternatively, the fields of view of the two probes overlap. In another

example, the two sensors lie side by side and both image the same field of view. As with rotation, these methods can allow two images of the prostate to be aligned, in real time and without image processing methods. Optionally, a previous calibration process is carried out to determine what processing, if any, should be used to match the images, for example, geometric distortion or selective amplification. Optionally, one or more of the gradients, B₀ and RF distribution are mapped and used during reconstruction for improving image quality. In an exemplary embodiment of the invention, the following process is used:

- (a) locate the probe using an ultrasound image, to be below the prostate center;
- 10 (b) lock the stabilizer (1630, FIG. 16);
- (c) US scan along Z and/or at 90 degrees in either direction (depending on sensor type)
- (d) (optionally) axially (or rotationally) lock the probe;
- (e) (optionally) rotate (or axially move) the probe so the MRI sensor is aimed at
15 the prostate;
- (f) (optionally) lock any motion of the probe;
- (g) MRI image;
- (h) roam through the combined MRI and US data and mark biopsy locations, etc;
- (i) select one or more locations to interact with;
- 20 (i) move the probe towards the direction where treatment/biopsy is to be carried out, until the system indicates the probe is positioned and oriented such that the interaction would be with the selected location. Optionally, the system indicates which of a plurality of biopsy channels to use. Optionally or alternatively, the system indicates one indication when one of axial and rotation positions are correct and a second when a
25 second one is correct.

Optionally, and possibly alternatively to using encoders, the probe may include one or more accelerometers, which generate a signal indicating the amount and/or direction of motion of the probe between uses. Optionally or alternatively, a position sensor is used, for example, a magnetic position sensor, optionally using a transmitter
30 outside the body and a receiver on the coil. Optionally, a receiver, e.g., for calibration, is provided on the body.

General

While the above describe features and options mainly with respect to dual-mode probes, it should be appreciated that many of the above described features may also be applied to single modality probes. Similarly, while the above has focused on biopsy taking, the above probes can be used for therapy as well, for example, based on acquired image(s).

In an exemplary embodiment of the invention, a dual mode imaging probe of the type described hereinabove can be provided for about one tenth of the cost of a conventional MRI device. Optionally, the lower cost contributes to a likelihood that imaging and/or biopsy can be performed in a urologist's clinic. In an exemplary embodiment of the invention, an ability to perform a procedure at the urologist's clinic contributes to a degree of willingness of the patient to undergo the procedure.

A variety of numerical indicators have been utilized to describe probe dimensions or distances and times. It should be understood that these numerical indicators could vary even further based upon a variety of engineering principles, materials, intended use and designs incorporated into the invention.

It should be further understood that the individual features described herein can be used together, in the exemplary combinations described above, or in other combinations or sub-combinations. Alternatively, each of the features can be used separately, for example, by being added to other available probes.

Additionally, components or processes described or depicted as a single item can optionally be replaced by a larger number of components or processes which provide the described or depicted function.

Conversely, components or processes described or depicted as a multiple items can optionally be replaced by a smaller number of components or processes which provide the described or depicted function.

All embodiments described above are exemplary in nature and are not intended to limit the scope of the invention which is defined solely by the following claims.

The word "exemplary" is used herein to mean "serving as an example, instance or illustration". Any embodiment described as "exemplary" is not necessarily to be

construed as preferred or advantageous over other embodiments and/or to exclude the incorporation of features from other embodiments.

The word "optionally" is used herein to mean "is provided in some embodiments and not provided in other embodiments". Any particular embodiment of the invention
5 may include a plurality of "optional" features unless such features conflict.

As used herein the term "about" refers to $\pm 10\%$.

The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean "including but not limited to". This term encompasses the terms "consisting of" and "consisting essentially of".

10 The phrase "consisting essentially of" means that the composition or method may include additional ingredients and/or steps, but only if the additional ingredients and/or steps do not materially alter the basic and novel characteristics of the claimed composition or method.

As used herein, the singular form "a", "an" and "the" include plural references
15 unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

Throughout this application, various embodiments of this invention may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible
20 limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as
25 as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral) within the indicated range. The phrases "ranging/ranges
30 between" a first indicate number and a second indicate number and "ranging/ranges from" a first indicate number "to" a second indicate number are used herein

interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals therebetween.

As used herein the term "method" refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known
5 manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and medical arts.

As used herein, the term "treating" includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical
10 or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination
- in a single embodiment. Conversely, various features of the invention, which are, for
15 brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various
embodiments are not to be considered essential features of those embodiments, unless
the embodiment is inoperative without those elements.

20 Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

25 All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or
identification of any reference in this application shall not be construed as an admission
30 that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

CLAIMS

1. An imaging probe system, the probe comprising:
 - (a) a probe body having a proximal end and a distal end at opposite ends of a probe axis;
 - (b) a first imaging module operable in a first imaging modality, including a magnet to be used for MRI imaging and located on the probe body; and
 - (c) a second imaging module operable in a second imaging modality and located on the body at a fixed relative position and orientation with respect to the first imaging module;wherein a field of view of the first imaging module and a field of view of the second imaging module are at a known rotational and/or axial displacement from one another.
2. A system for medical imaging, the system comprising:
 - (a) a probe system according to claim 1; and
 - (b) an image processor designed and configured to:
 - (i) receive a first output signal from the first imaging module;
 - (ii) receive a second output signal from the second imaging module; and
 - (iii) register the first and second output signals to produce a registered composite image.
3. A system according to claim 2, comprising at least one position sensor adapted for generating a signal indicating relative movement between uses of said imaging modules and wherein said processor is configured to dynamically register a signal from said sensor and using said known displacement.
4. A system according to any of claims 1-3, wherein said first imaging module comprises a self contained MRI imaging device.

5. A system according to any of claims 1-4, wherein the first imaging module is characterized by sufficient resolution to identify a tumor with a volume of 0.5cc or more.
6. A system according to any of claims 1-5, wherein the second imaging module comprises an ultrasound imaging device.
7. A system according to any of claims 1-6, comprising an external shell, the imaging modules rotateable within the shell.
8. A system according to any of claims 1-7, the probe body is adapted for rectal insertion.
9. A system according to claim 8, adapted for prostate imaging.
10. A system according to any of claims 1-9, comprising a biopsy tool.
11. A system according to any of claims 1-10, comprising an insertion tool.
12. A system according to any of claims 1-11, comprising an inflatable body adapted to surround at least a portion of the probe body.
13. A system according to any of claims 1-12, comprising a separate sheath adapted for rectal insertion and adapted to receive said probe body therein.
14. A system according to claim 13, wherein said sheath has at least one fixing balloon mounting thereon.
15. A system according to claim 13 or claim 14, wherein said sheath has at least one MRI coil mounted thereon.

16. A system according to any of claims 1-15, comprising at least one MRI coil mounted in a manner deployable relative to said probe.

17. A system according to any of claims 1-16, comprising a cooling system for cooling said MRI imaging module.

18. A system according to any of claims 1-17, comprising a stabilizer which maintains a position of said probe body relative to a patient and allows relative movement therebetween.

19. A method for imaging an area of interest, the method comprising:

(a) providing a probe body and an ultrasound imaging module and an MRI imaging module, the two imaging modules at a fixed relative position and orientation with respect to one another so that a field of view of the first imaging module and a field of view of the second imaging module are at a known rotational and axial displacement from one another;

(b) acquiring image data of an area of interest using one of the imaging modules;

(c) moving and/or rotating the probe body through the known rotational and/or axial displacement so that the field of view of the other imaging module includes the area of interest;

(d) acquiring image data of the area of interest using the other imaging module;

(e) registering image data of the area of interest from the two imaging modules to produce a composite image of the area of interest.

20. A method according to claim 19, comprising monitoring a relative position of said probe during said acquisitions and registering said image data from said modules in real time based on said monitoring.

21. A method according to claim 19 or claim 20, wherein the area of interest comprises at least a portion of a prostate gland.

22. A method according to claim 21, wherein the at least a portion of the prostate gland comprises a peripheral zone (PZ).
23. A method according to any of claims 19-22, wherein providing includes rectal insertion.
24. A method according to any of claims 19-23, comprising:
(f) rotating the probe body back through the known angular displacement so that the ultrasound imaging module is aimed towards the area of interest.
25. A method according to claim 24, comprising:
(g) acquiring ultrasound image data as a biopsy tool is advanced towards the area of interest.
26. A method according to claim 25, comprising:
(h) registering the ultrasound image data and the MRI image data of the area of interest to produce a composite image of the area of interest which depicts the biopsy tool.
27. A probe control apparatus, the apparatus comprising:
(a) a probe body comprising a first imaging module and a second imaging module at a known rotational displacement from the first imaging module;
(b) a rotation mechanism operable to track a rotation of the probe;
(c) control circuitry adapted to track the rotation of the probe body through the known rotational displacement and generate an indication when rotated.
28. Apparatus according to claim 27, wherein the control circuitry is adapted to rotate the probe body through the known rotational displacement.
29. Apparatus according to claim 27 or claim 28, comprising:

(d) image processing circuitry adapted to resolve images acquired by the first imaging module and the second imaging module to produce a composite image.

30. Apparatus according to claim 29, comprising:

(e) a display configured to display the composite image.

31. Apparatus according to any of claims 27-30, comprising:

(e) a rotatable probe sheath with at least one channel at an acute angle to an axis of the probe body; and

(f) alignment circuitry adapted to calculate an alignment between an opening of at least one of the at least one channels and a target in the composite image.

32. Apparatus according to claim 31, comprising:

(g) an-alignment mechanism adapted to receive an output comprising the calculated alignment from the alignment circuitry and to output a signal responsive thereto.

33. Apparatus according to claim 32, wherein said output causes activation of an actuator.

34. Apparatus according to claim 32, wherein said output generates a human perceptible indication.

35. Apparatus according to any of claims 32-34, wherein the alignment mechanism generates a signal with respect to axial alignment.

36. Apparatus according to any of claims 32-35, wherein the alignment mechanism generates a signal with respect to a rotational alignment.

37. Apparatus according to any of claims 32-36, comprising:

(h) a tool deployment mechanism adapted to deploy a tool from the opening of the at least one of the at least one channels so that a distal portion of the tool approaches the target.

38. A probe sheath for an intra-rectal probe, the sheath characterized by at least one channel at an acute angle to an axis of a body of the intra-rectal probe.

39. A sheath according to claim 38, wherein the sheath is adapted for axial translation with respect to the body of the probe.

40. A sheath according to claim 38, wherein the sheath is adapted for rotational translation with respect to the body of the probe.

41. A method of MRI imaging, comprising:

(a) surrounding a patient with a temporary flexible RF shield;

(b) imaging at least part of the patient using a portable probe of a diameter smaller than 10 cm.

42. A method of MRI imaging, comprising:

(a) inserting an MRI imaging probe into a body;

(b) powering said probe inside said body for at least 30 seconds;

(c) extracting heat from said probe using a cooling system during said powering.

43. A method according to claim 42, wherein said cooling system extracts heat to outside of said body.

44. A method according to claim 42, wherein said cooling system uses a heat sink inside said body.

45. A sheath, comprising:

(a) a hollow body having a diameter suitable for insertion into the body;

(b) at least one MRI coil mounted on the body.

46. A sheath according to claim 45, wherein said coil comprises a gradient coil.
47. A sheath according to claim 45 or claim 46, comprising a balloon adapted to increase an outside diameter of said sheath, over only part of a length thereof.
48. An MRI probe, comprising:
- (a) a body sized to be inserted into a body;
 - (b) an MRI magnet within said body; and
 - (c) at least one movable element having an MRI coil mounted thereon.
49. A probe according to claim 48, wherein said movable element is mounted to said body using a hinge.
50. A probe according to claim 48 or claim 49, wherein said movable element is mounted on an inflatable element.

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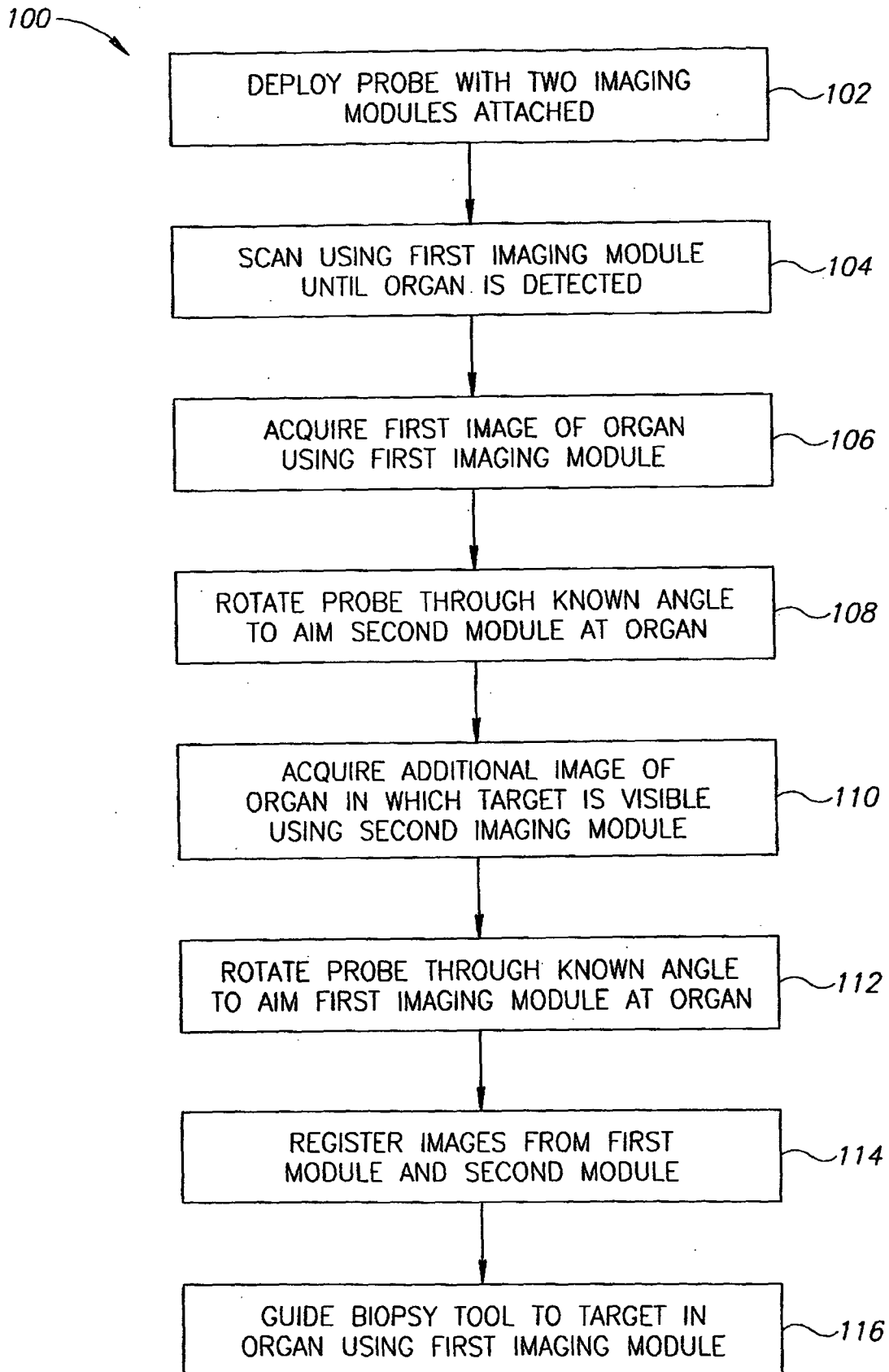


FIG.1

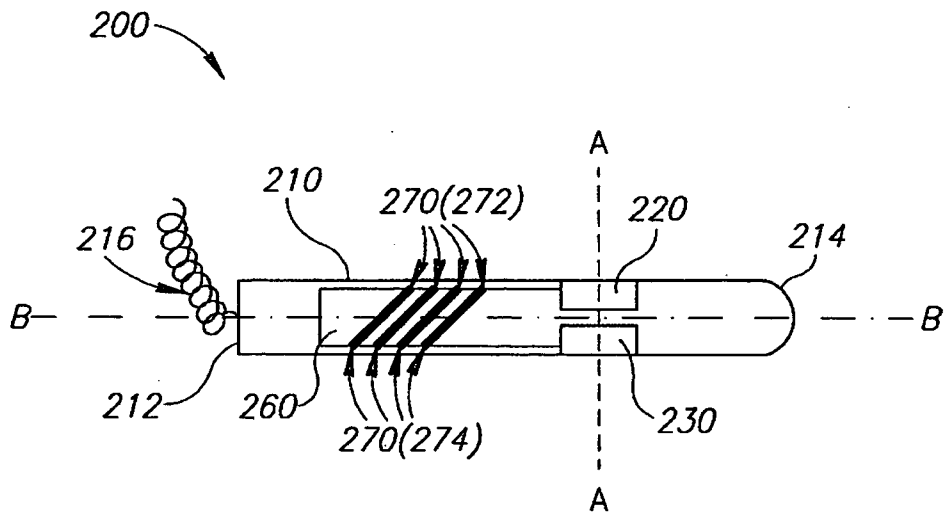


FIG. 2A

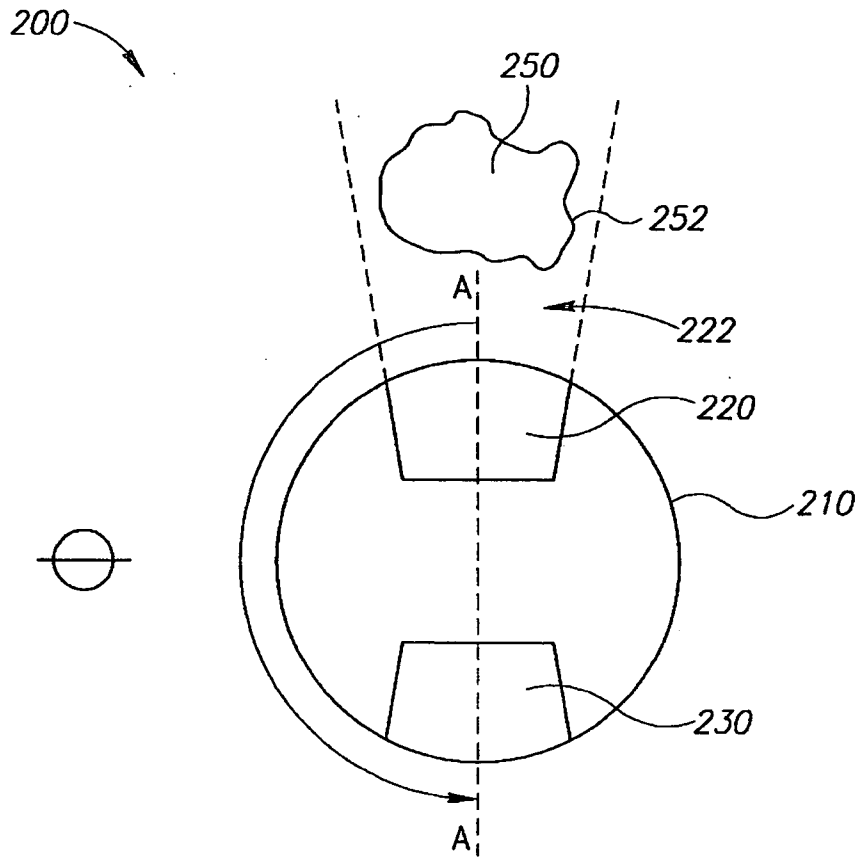


FIG. 2B

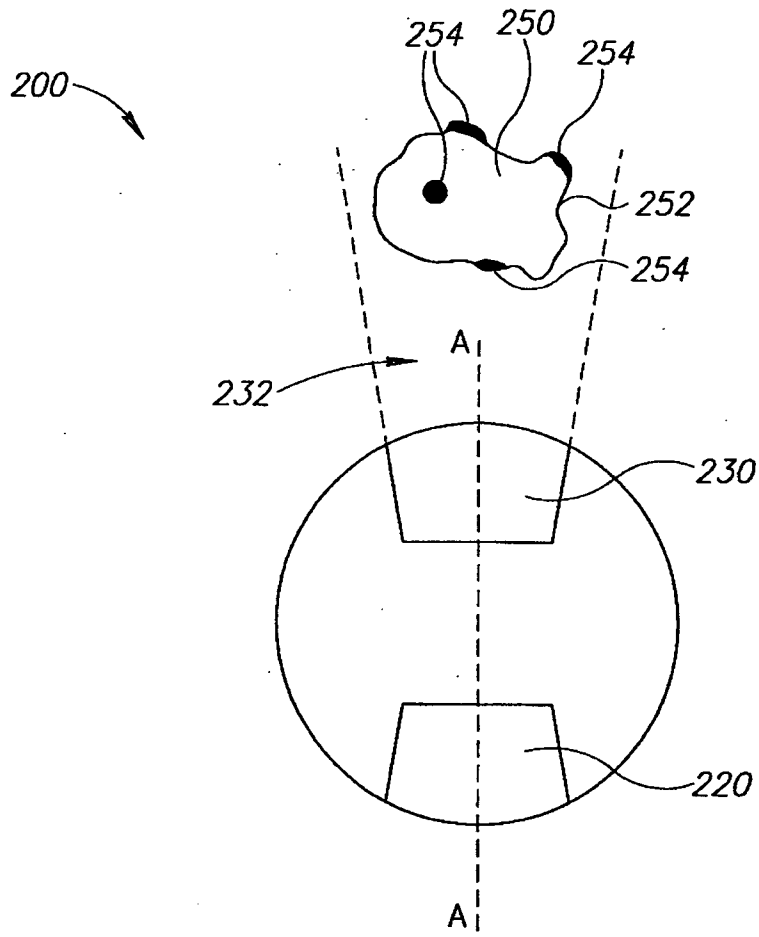


FIG. 2C

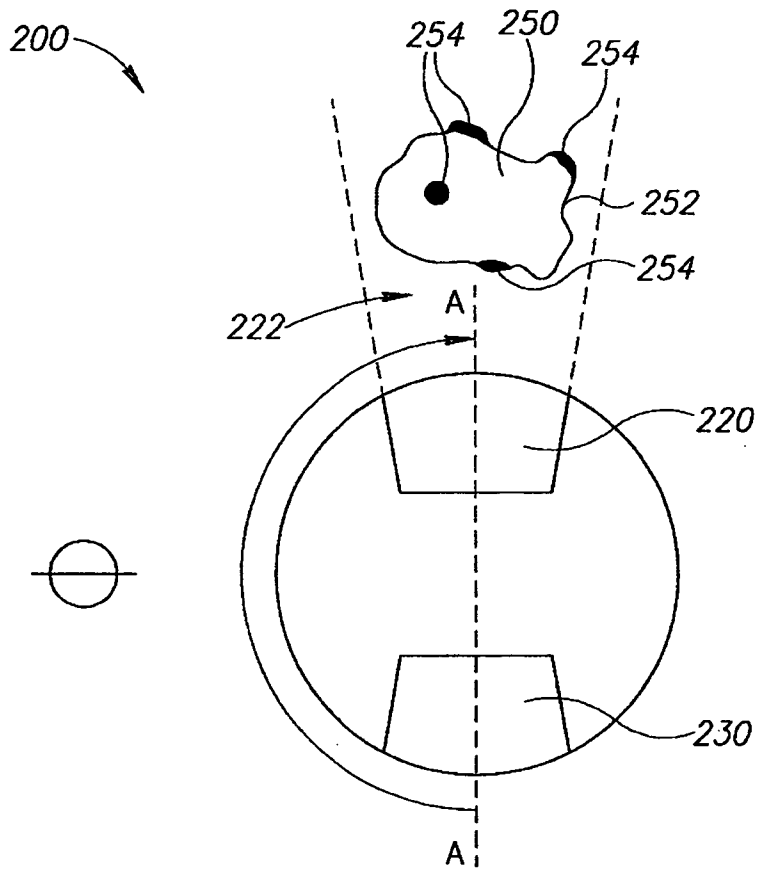


FIG. 2D

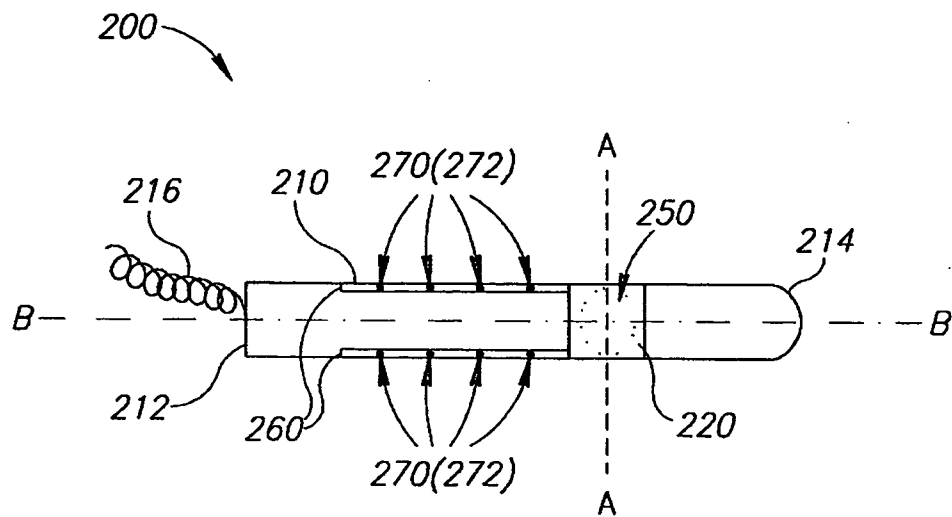


FIG. 2E

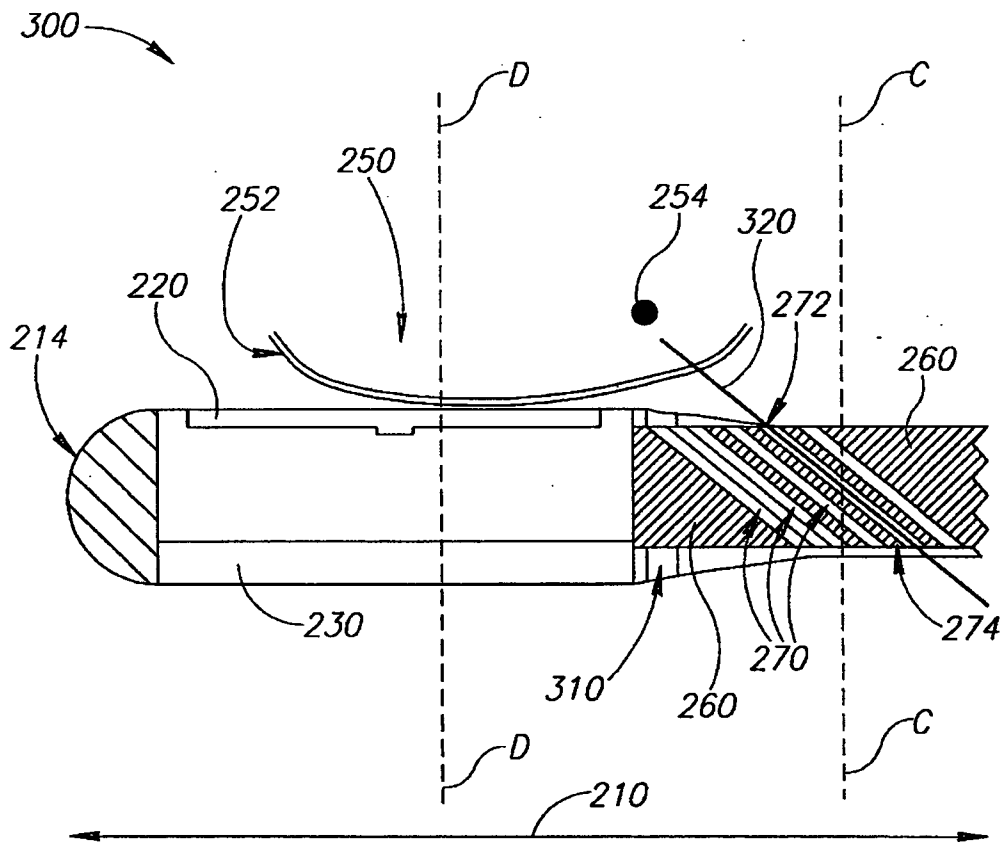


FIG.3A

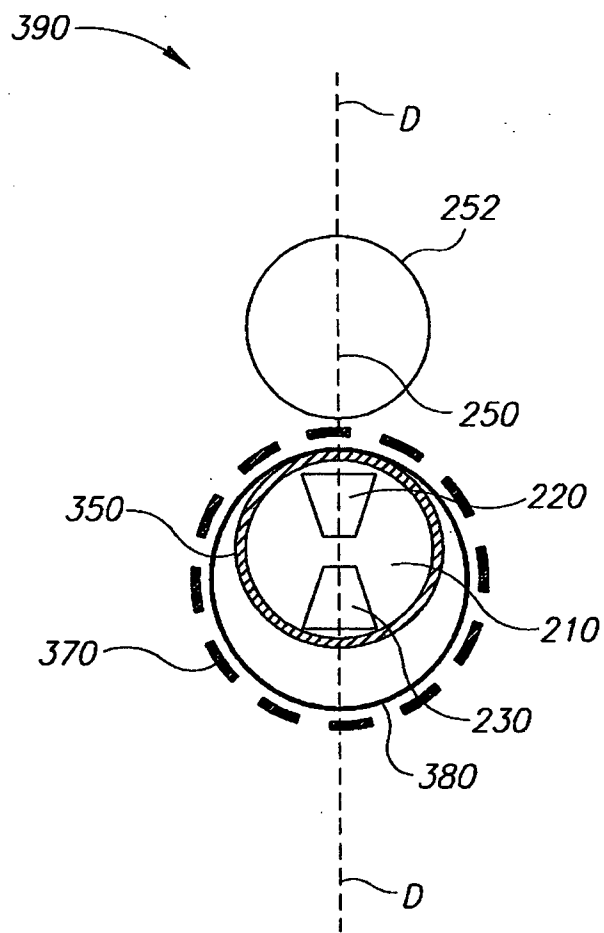


FIG.3B

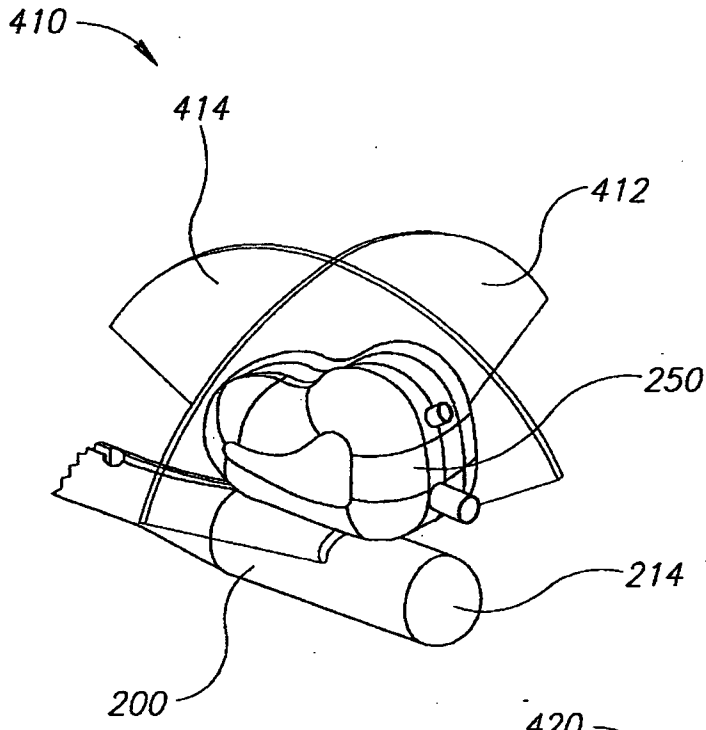


FIG. 4A

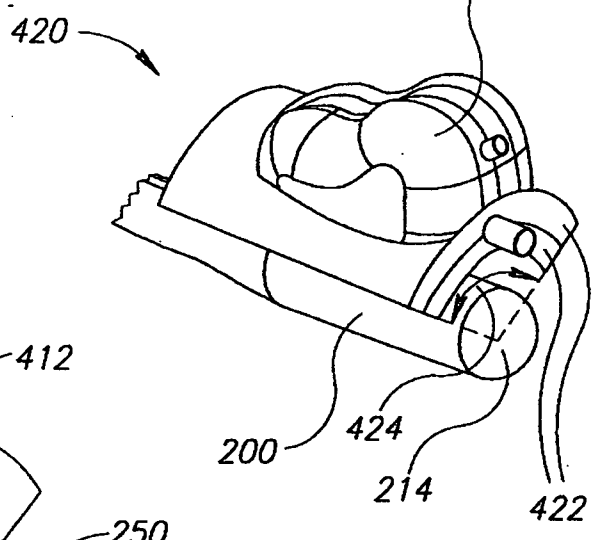


FIG. 4B

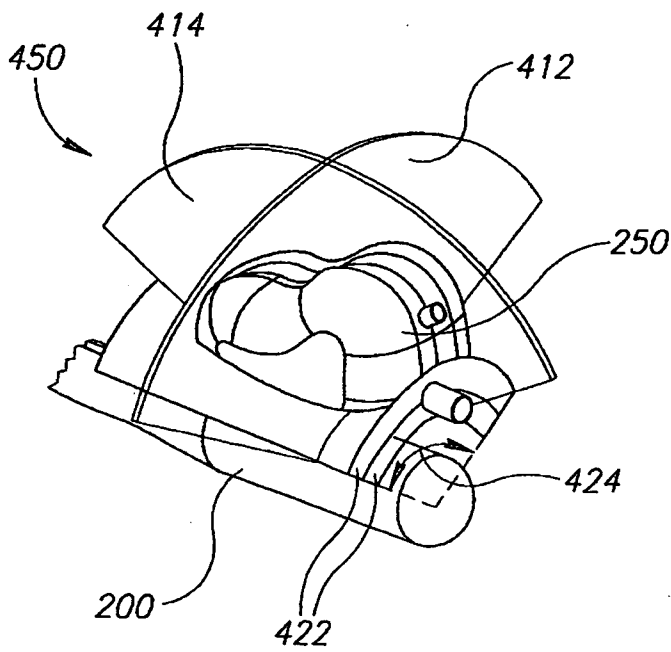
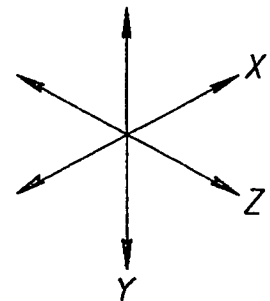


FIG. 4C



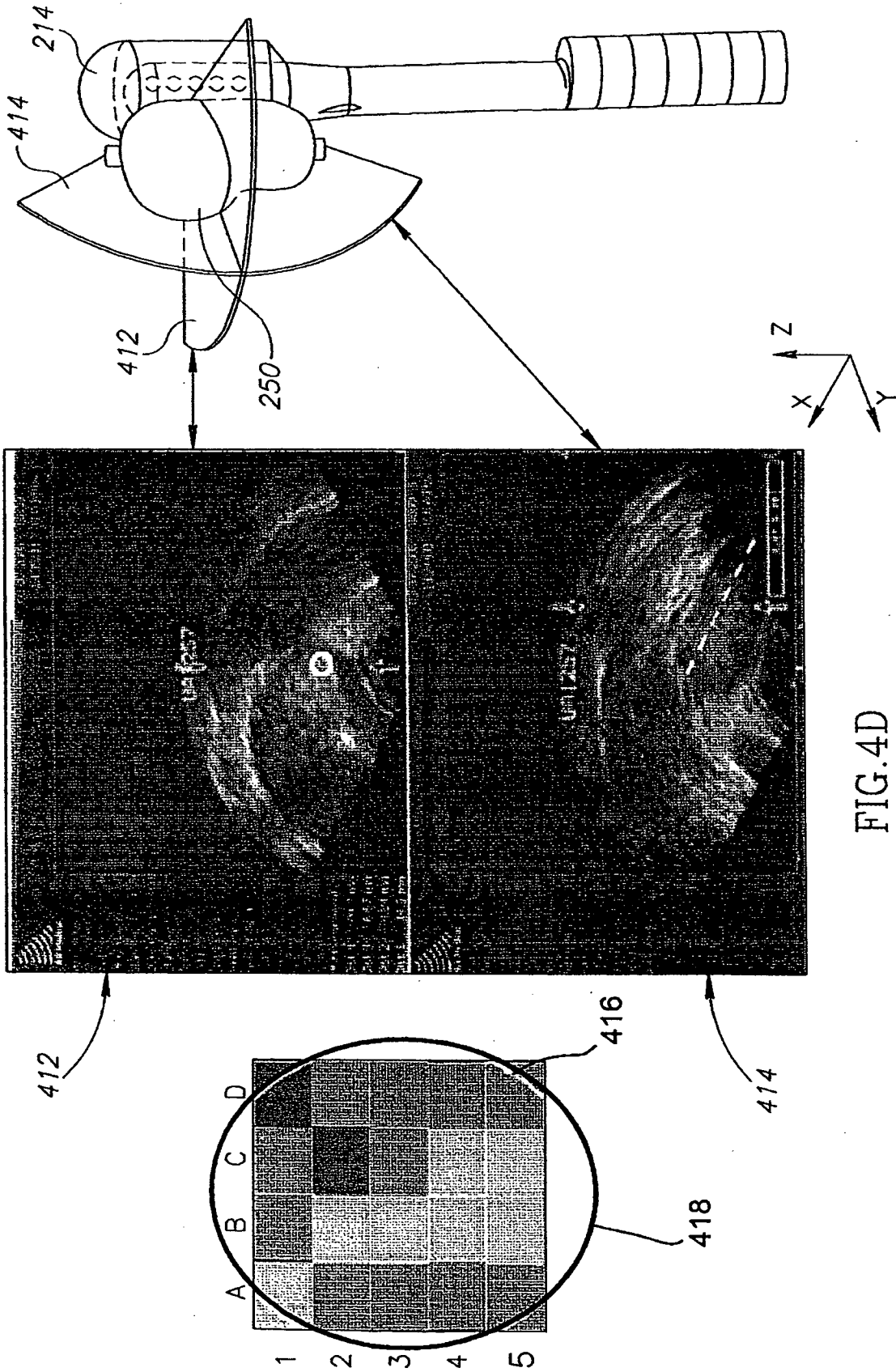


FIG.4D

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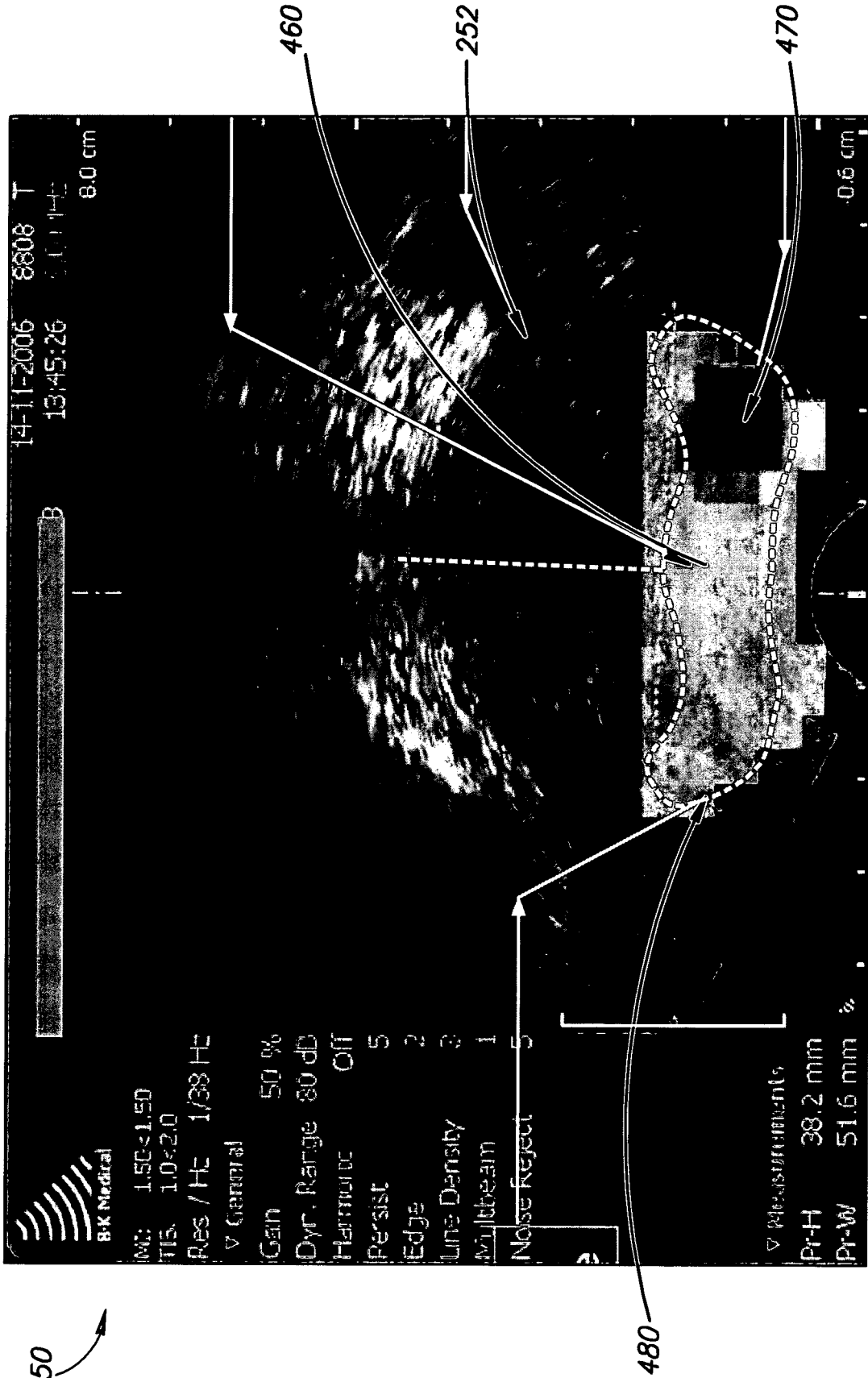


FIG.4E

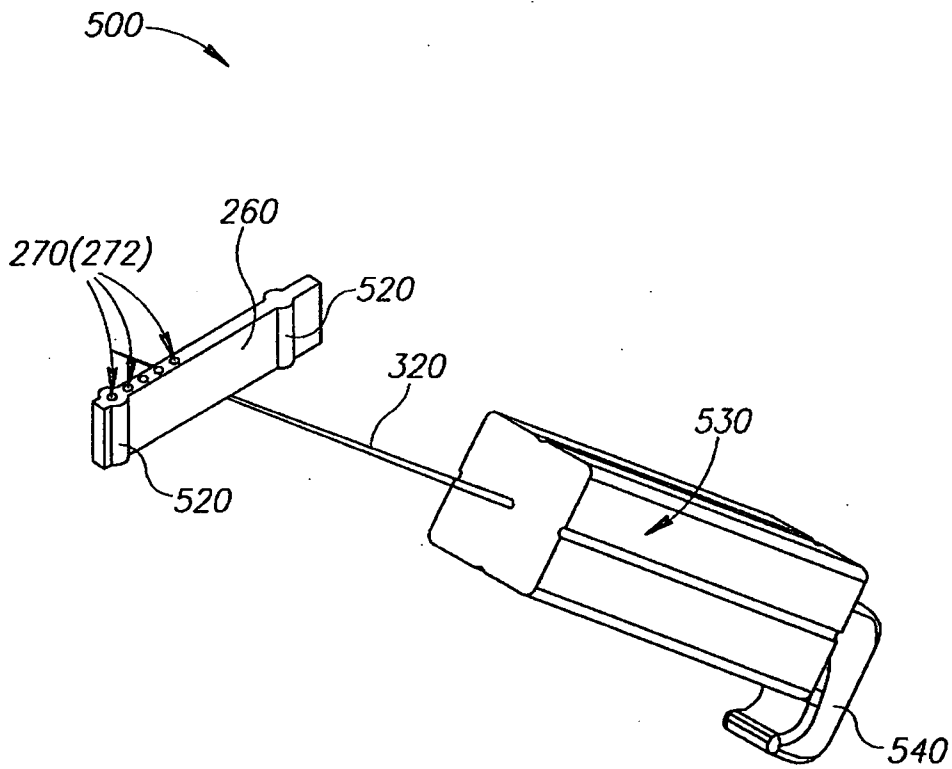


FIG.5

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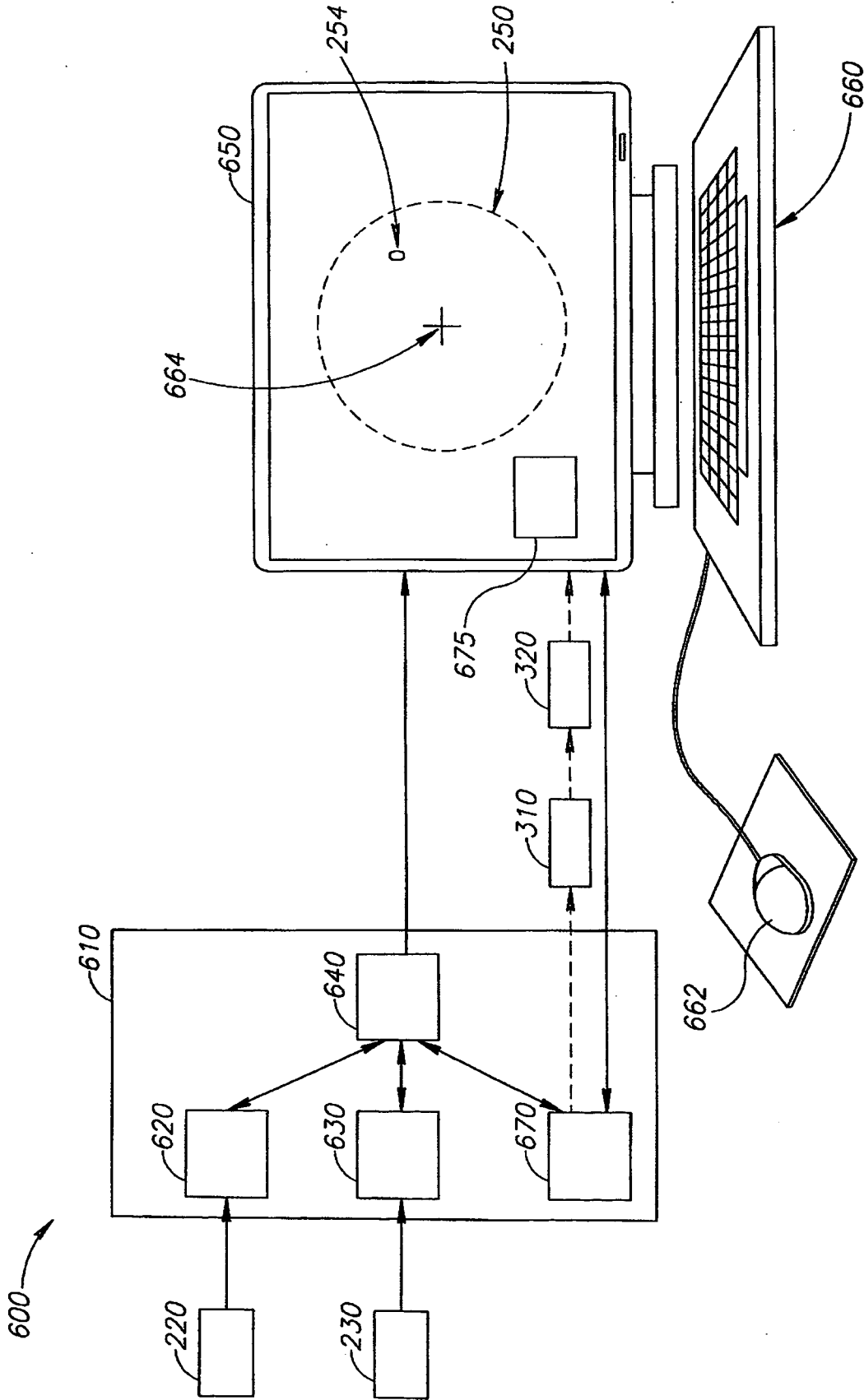


FIG. 6

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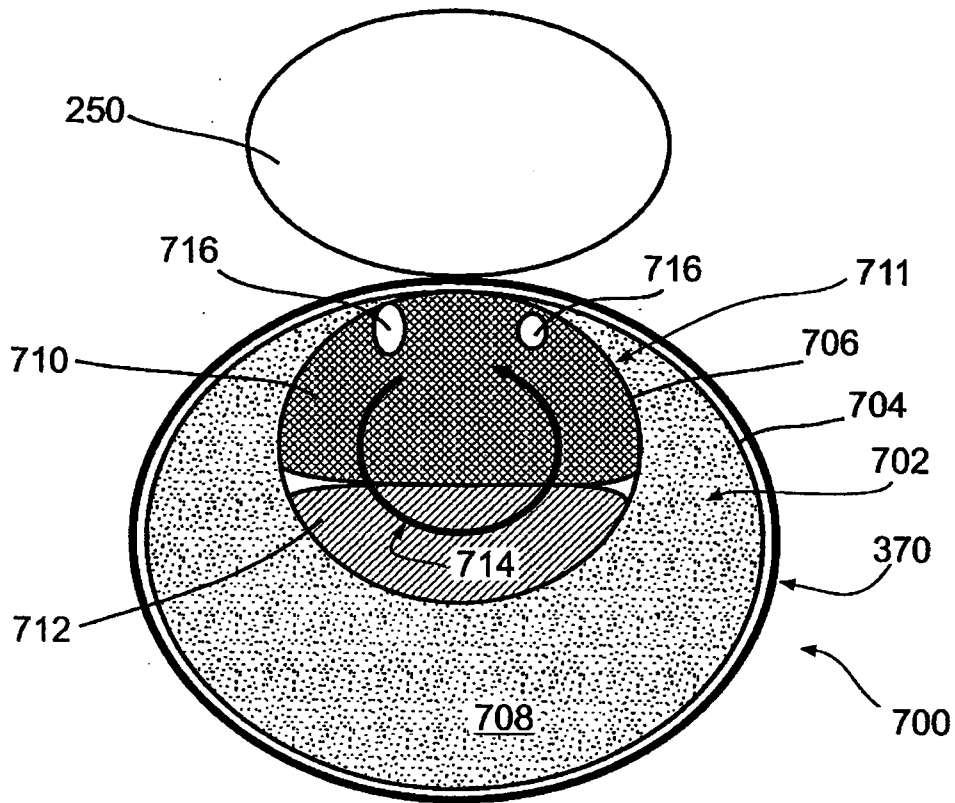


FIG. 7A

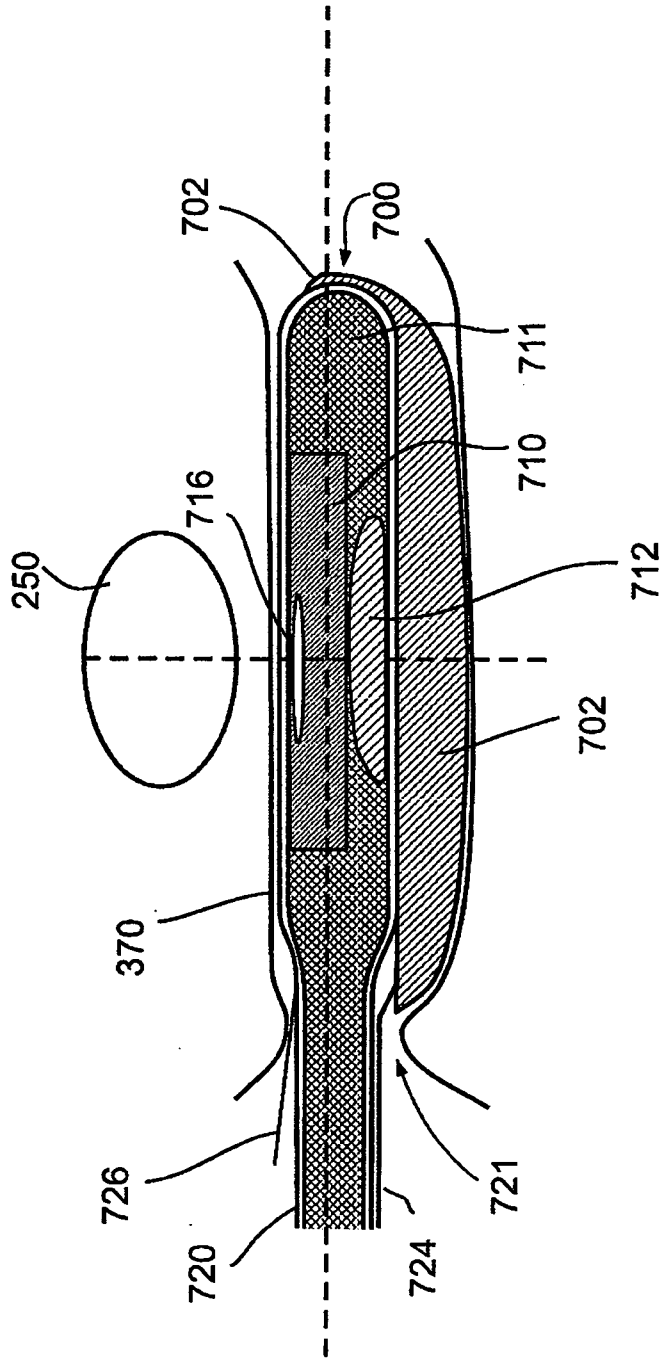


FIG. 7B

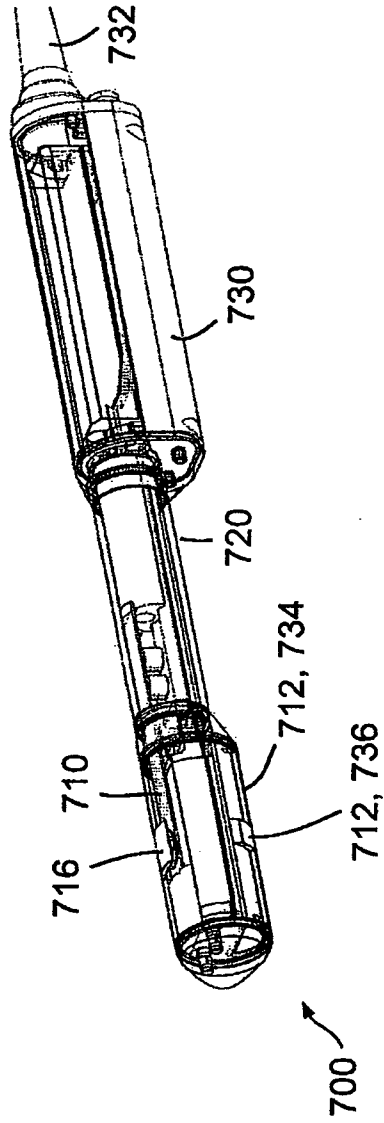


FIG. 7C

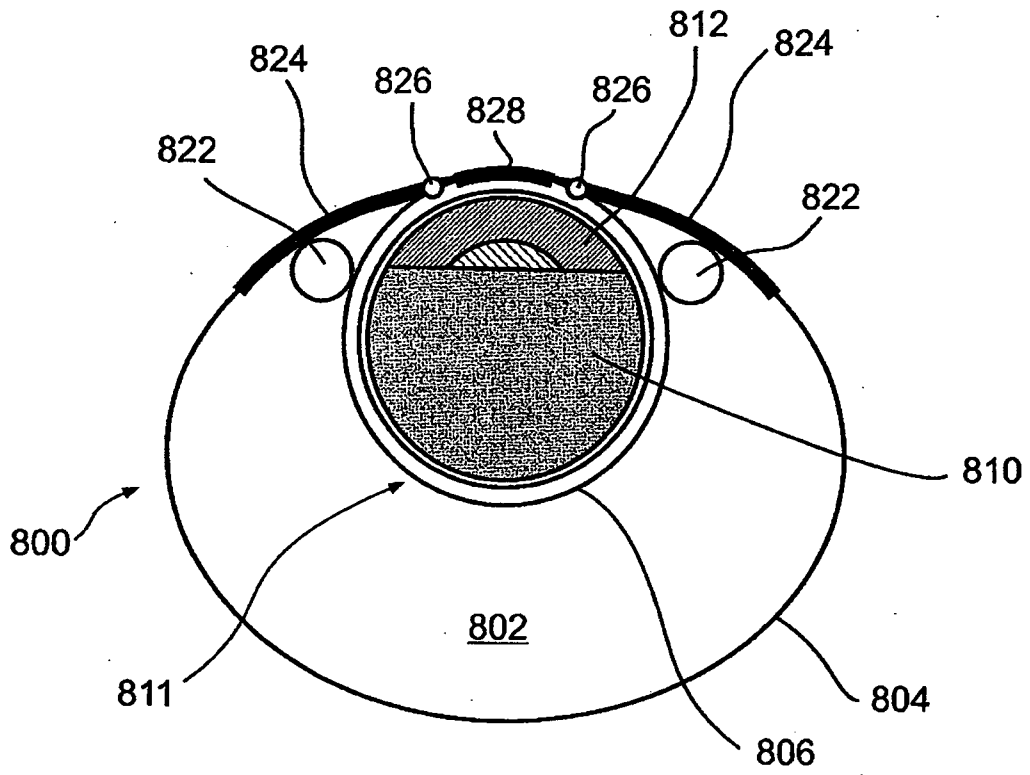


FIG. 8A

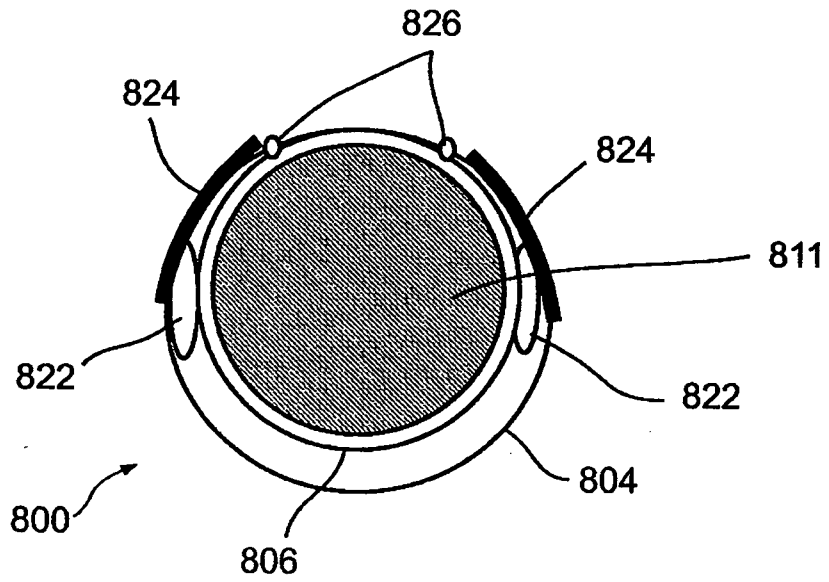


FIG. 8B

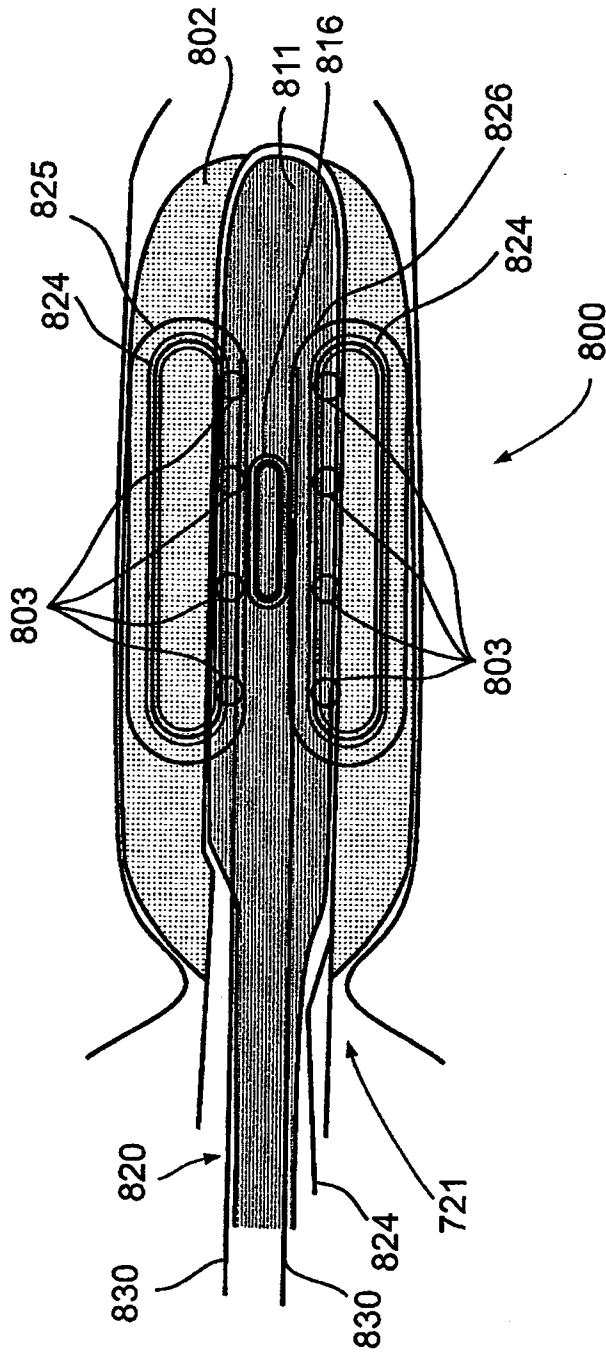
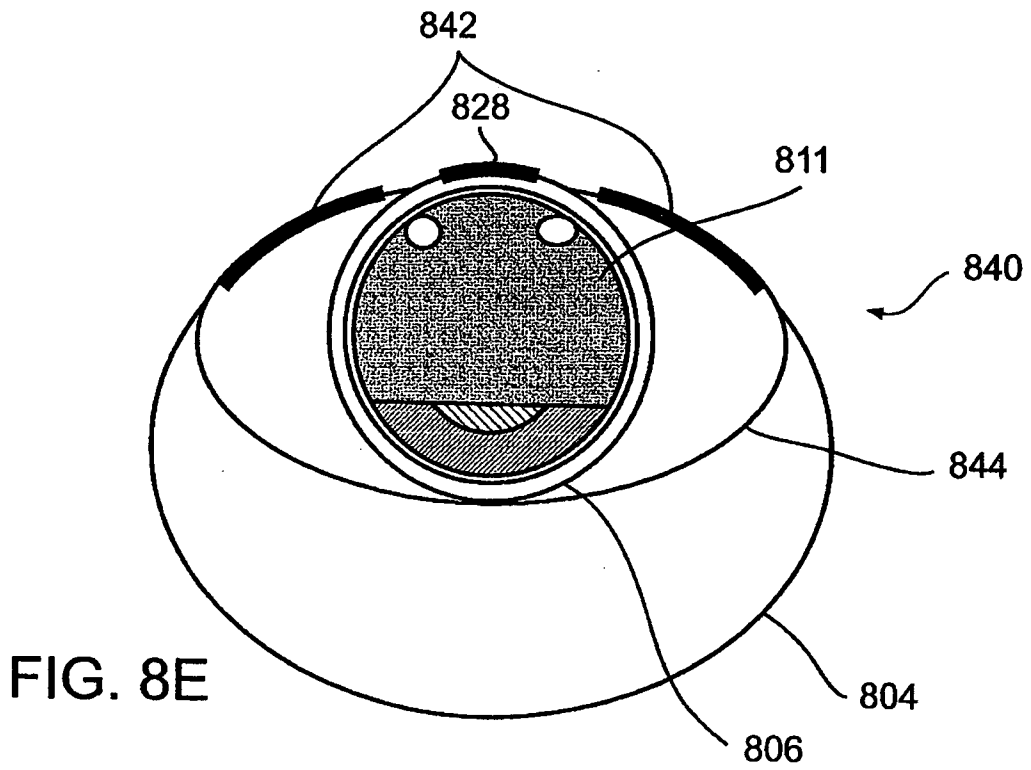
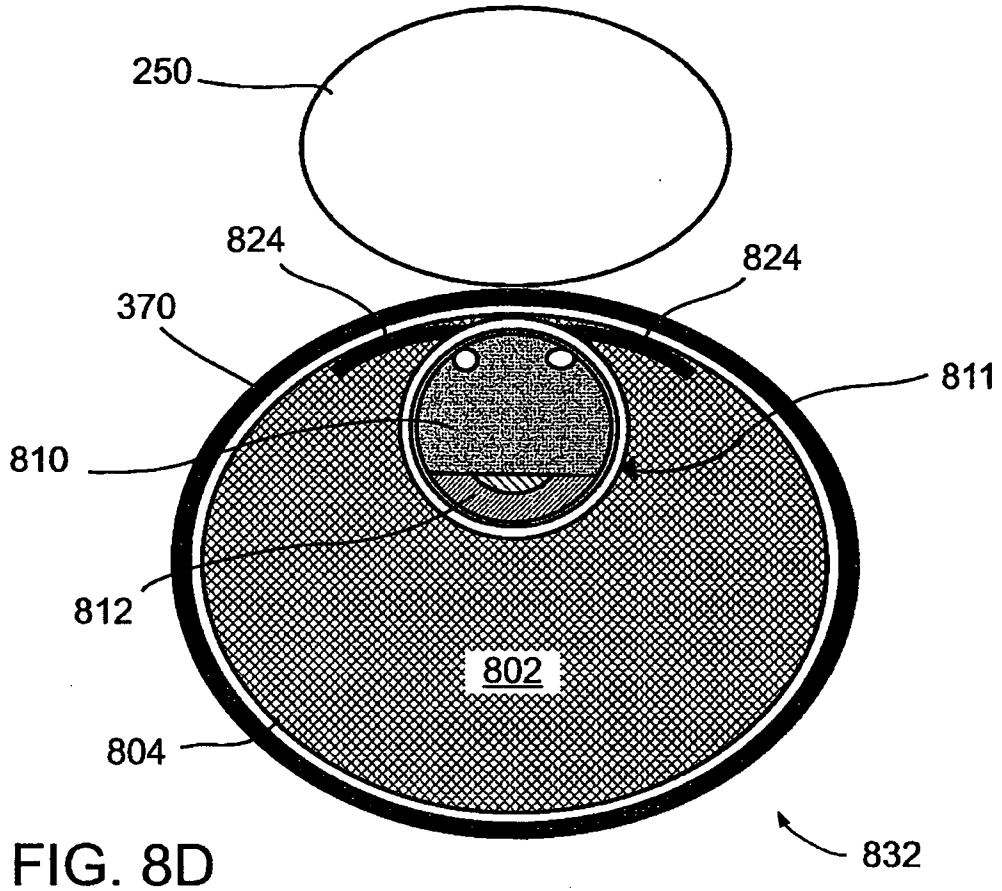


FIG. 8C



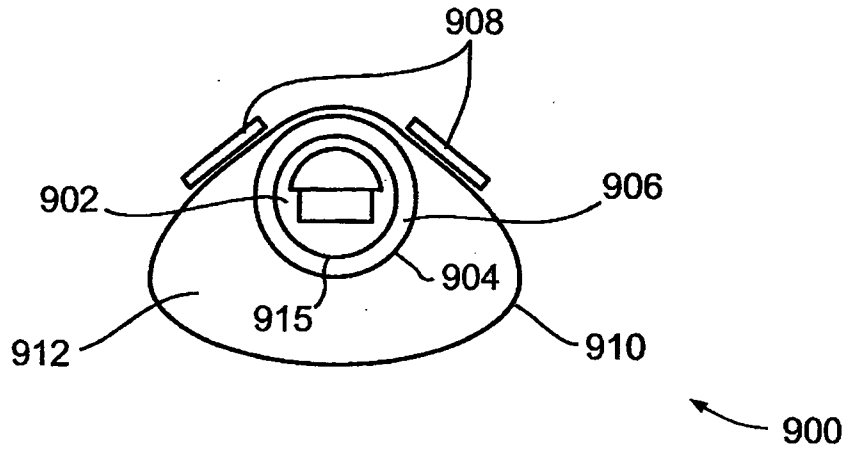


FIG. 9A

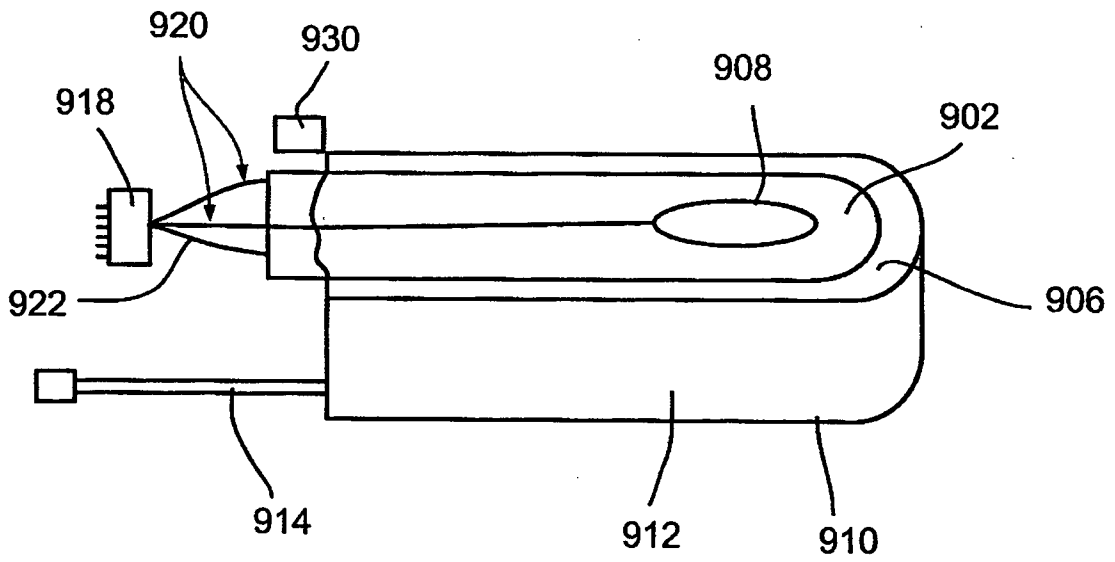


FIG. 9B

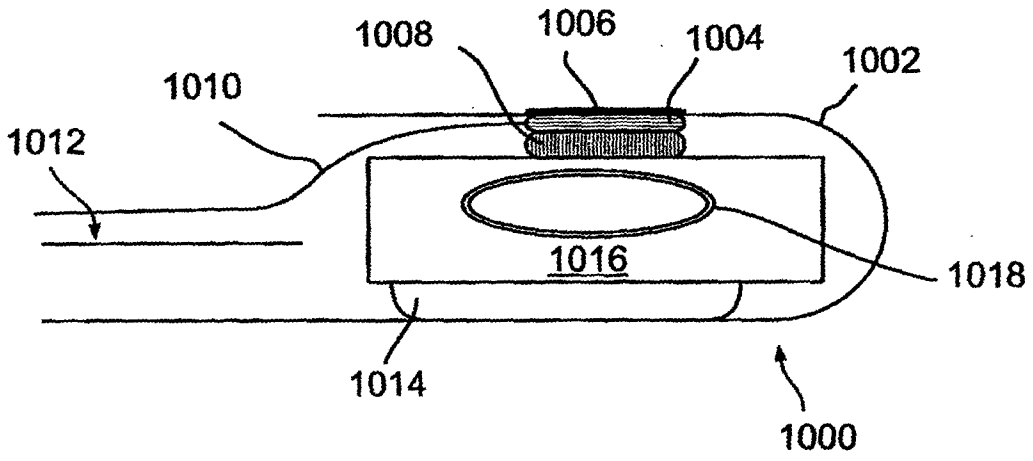


FIG. 10A

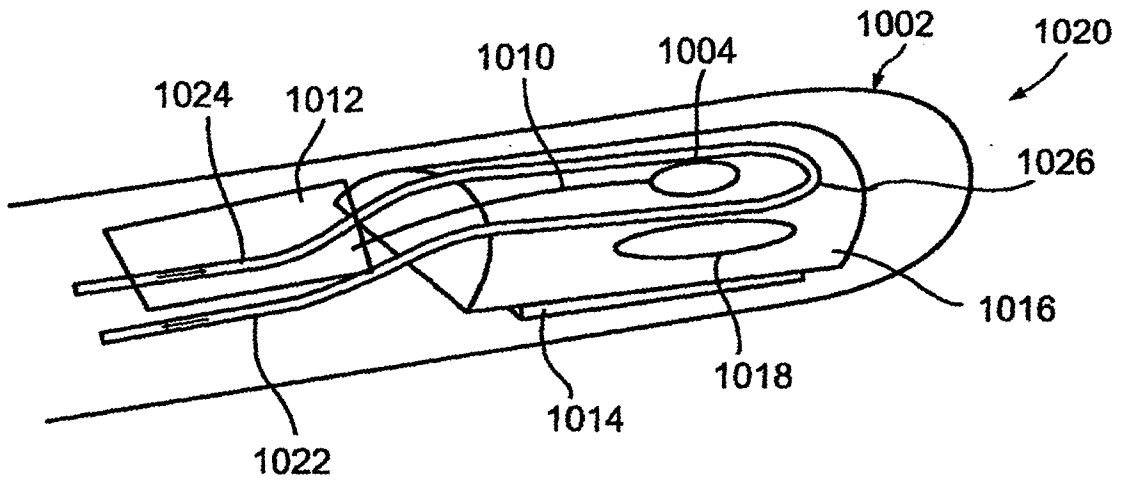


FIG. 10B

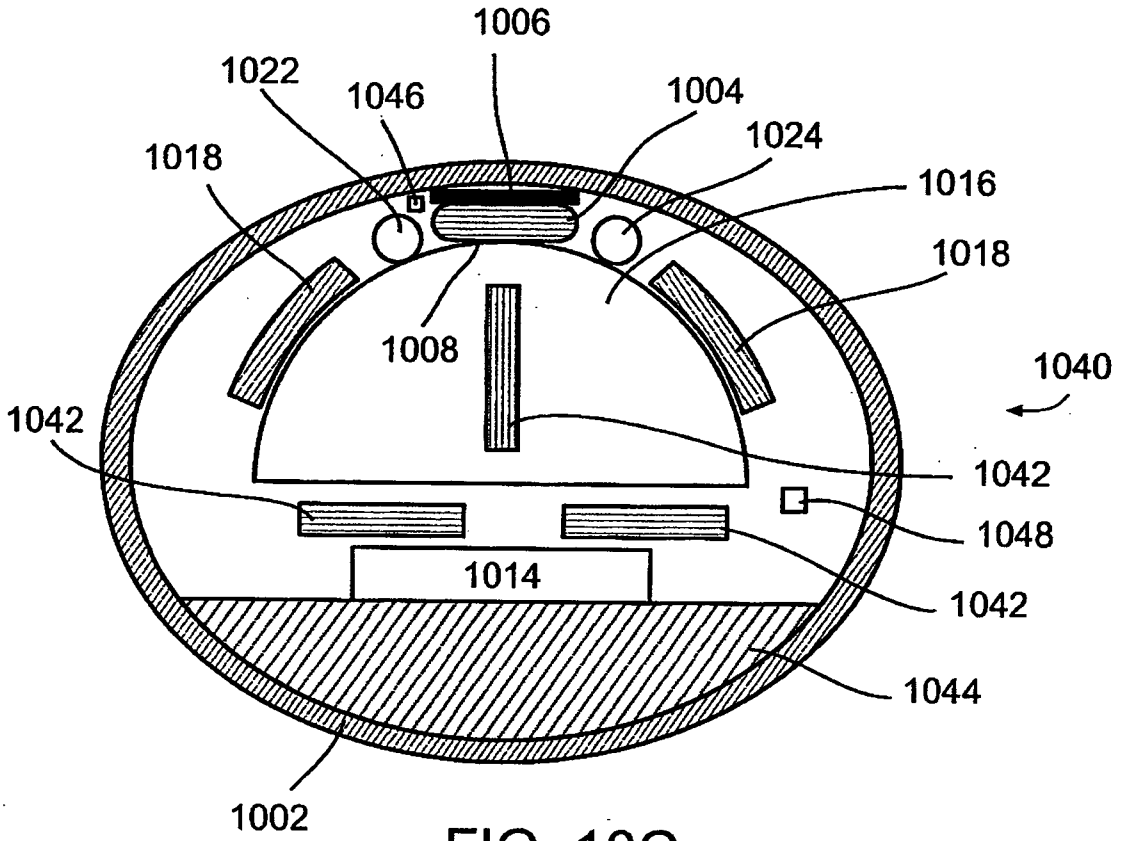


FIG. 10C

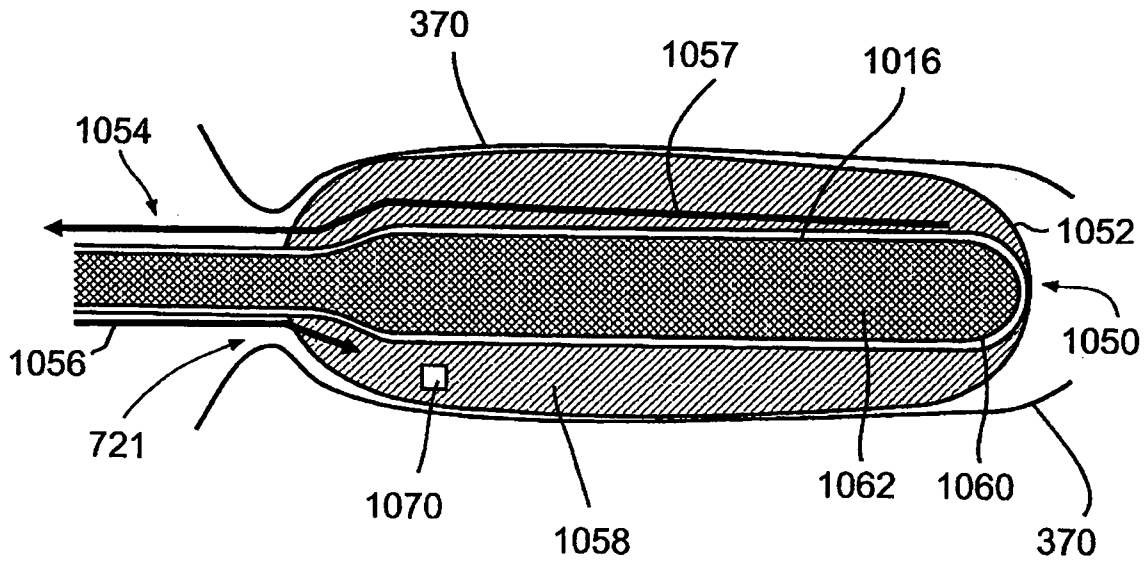


FIG. 10D

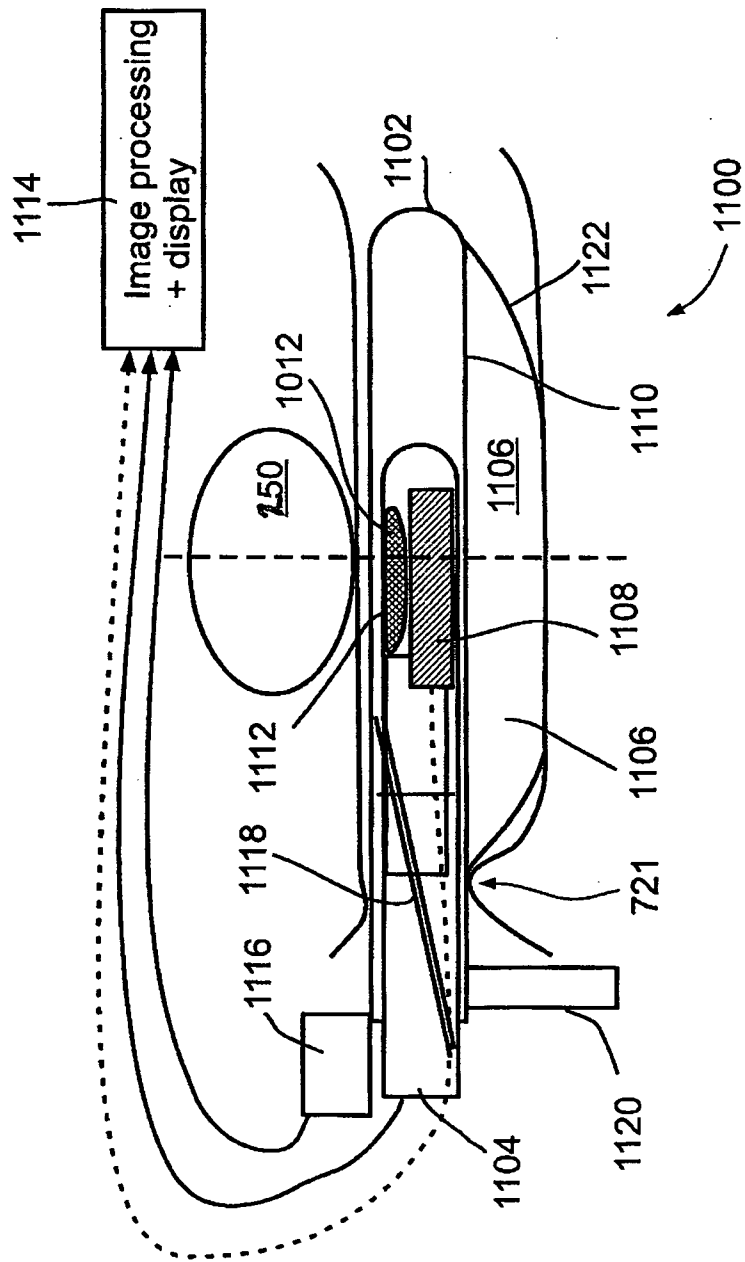


FIG. 11A

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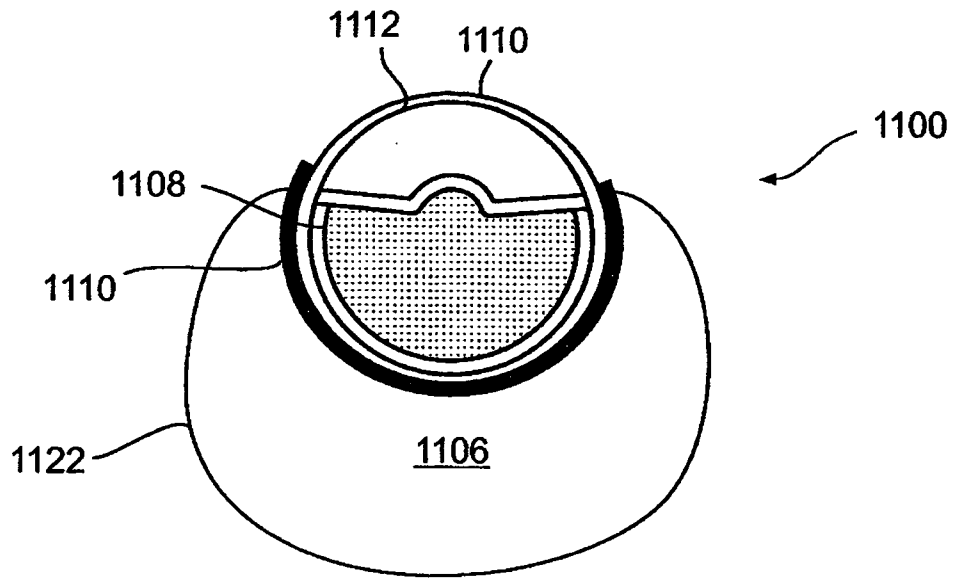


FIG. 11B

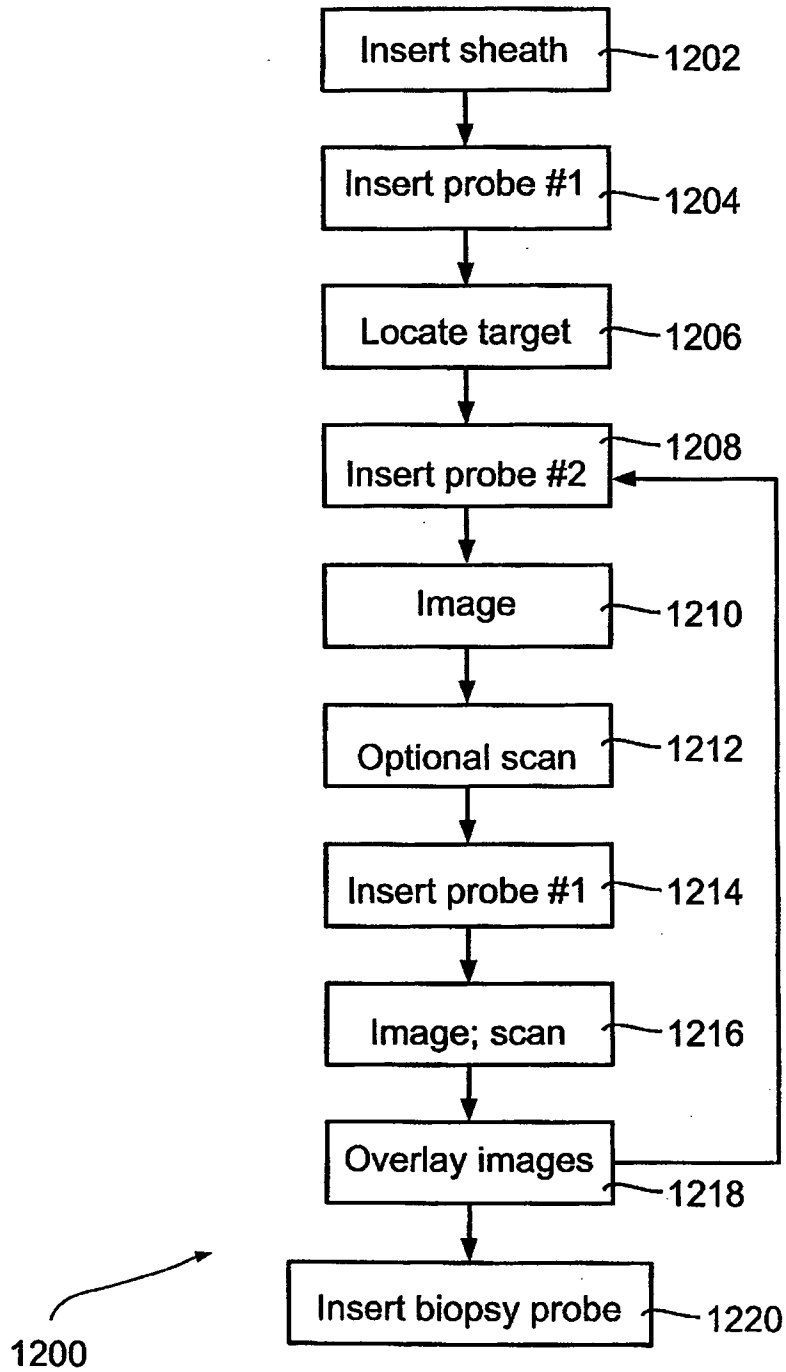


FIG. 12

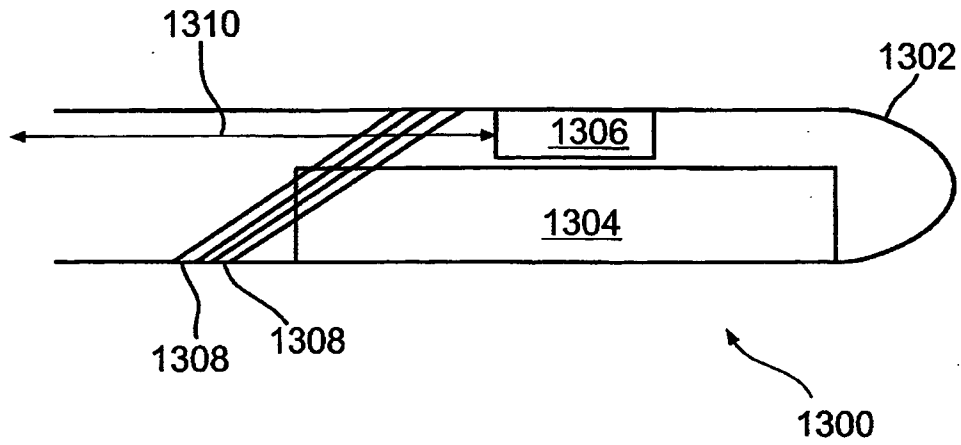


FIG. 13A

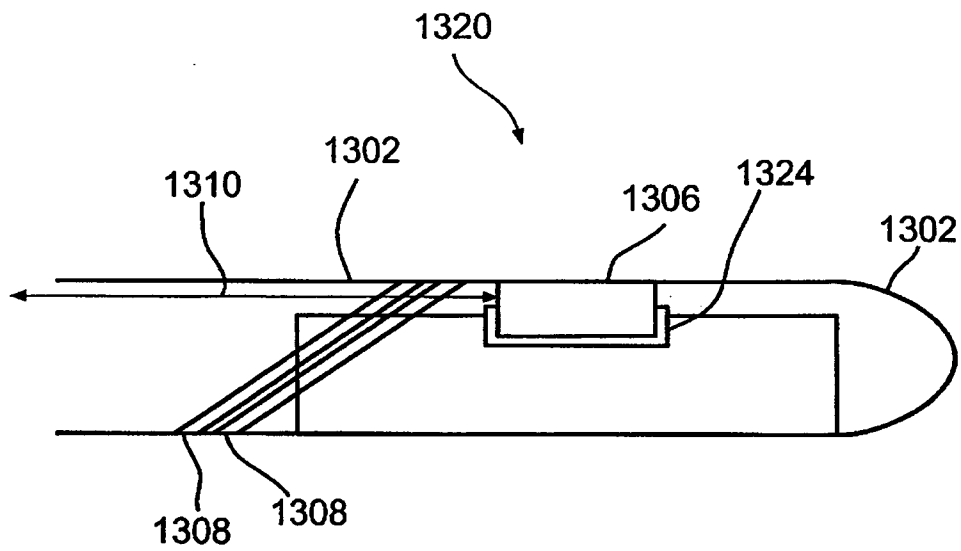


FIG. 13B

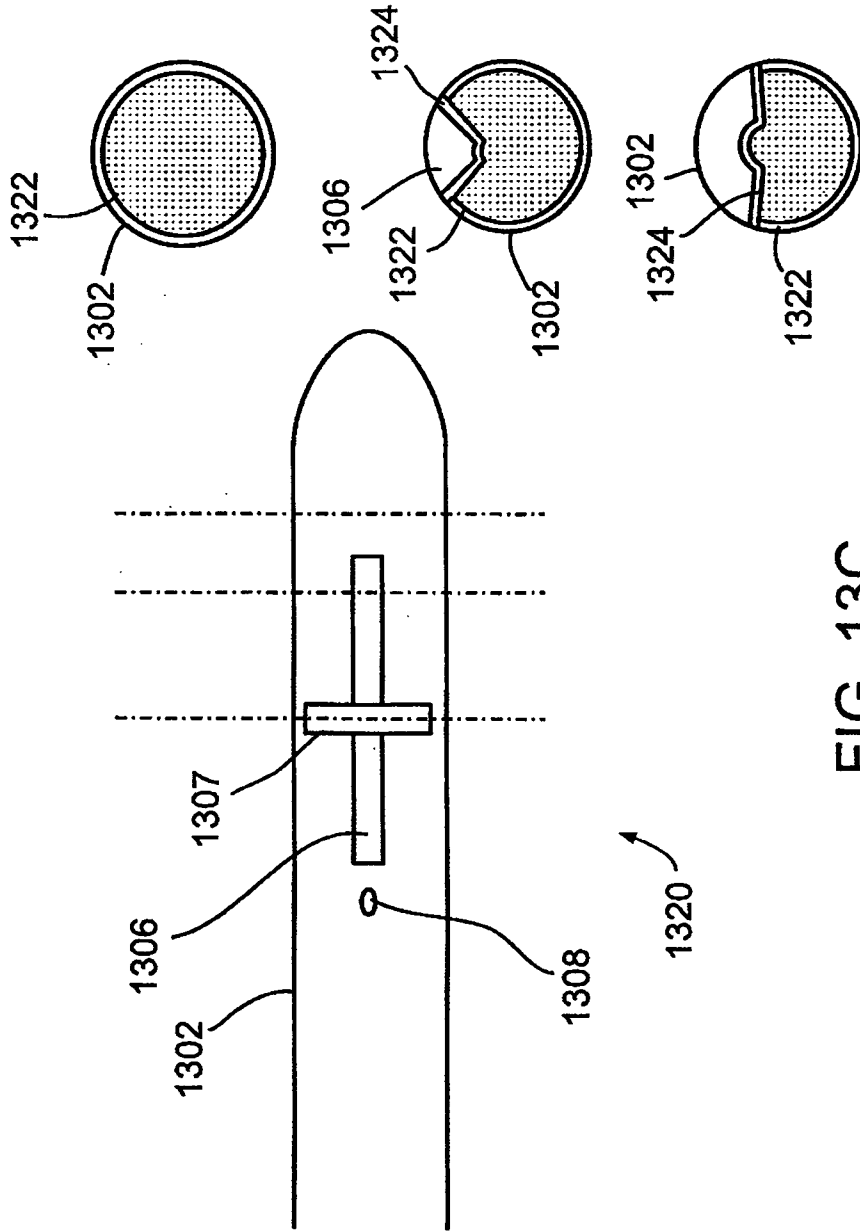


FIG. 13C

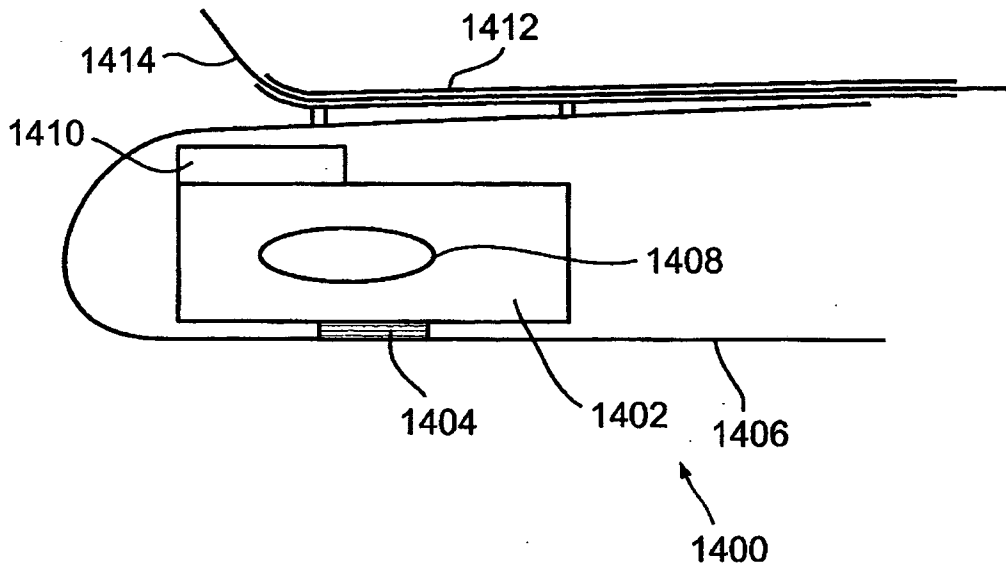


FIG. 14A

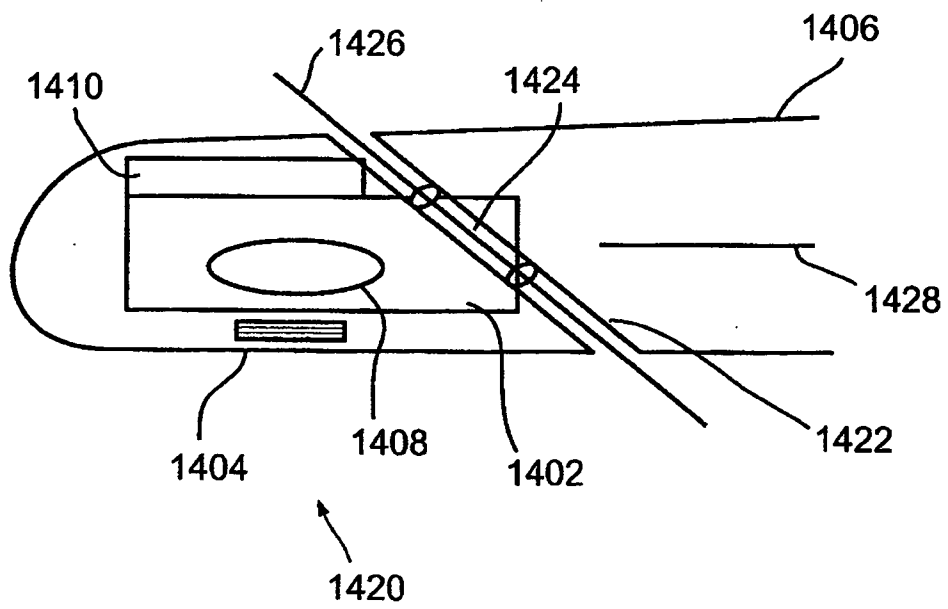


FIG. 14B

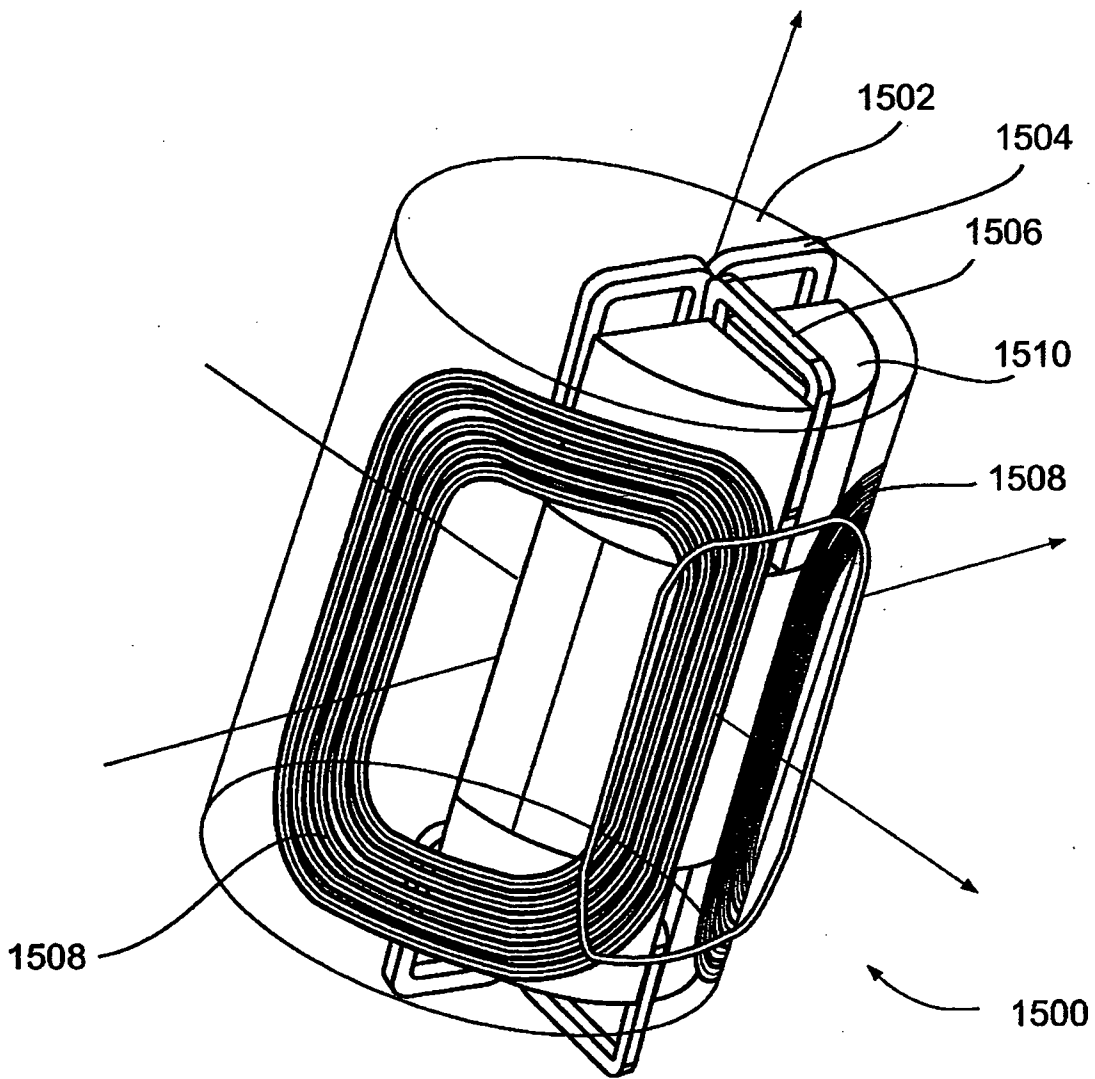


FIG. 15

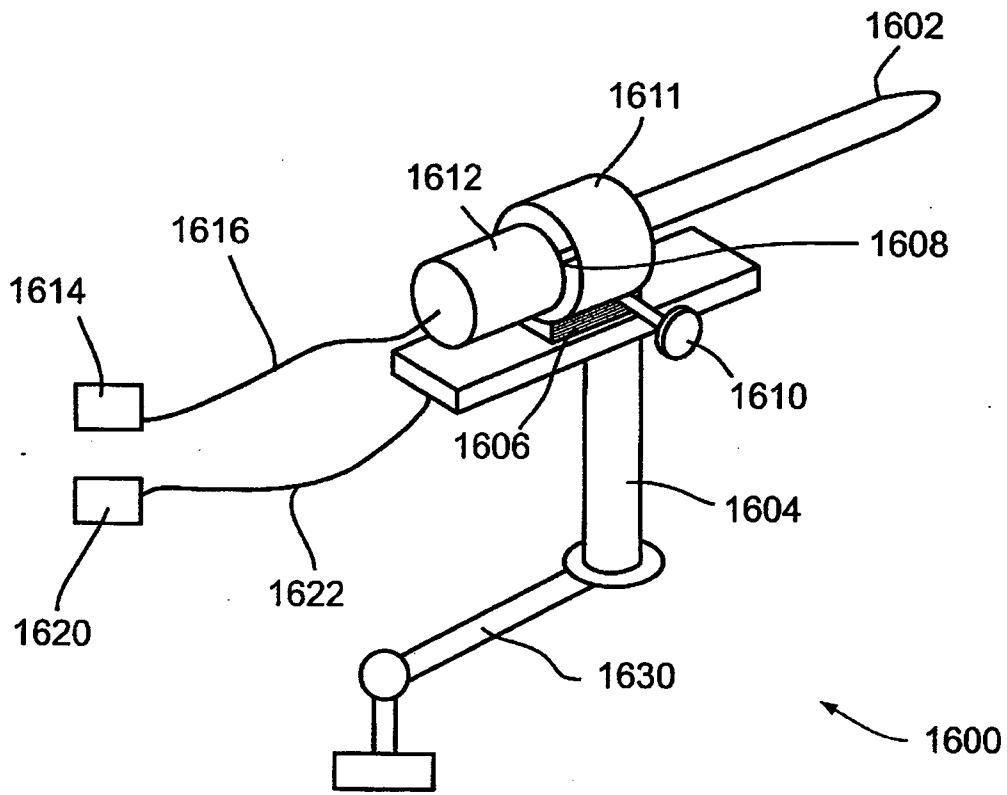


FIG. 16