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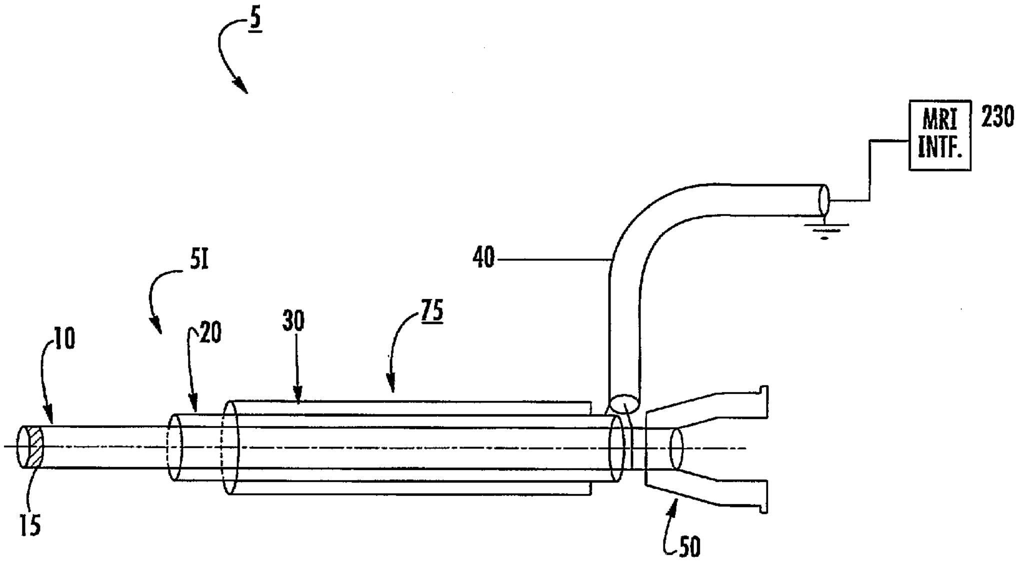
# (54) Title: MRI SYSTEMS HAVING MRI COMPATIBLE UNIVERSAL DELIVERY CANNULAS WITH COOPERATING MRI ANTENNA PROBES AND RELATED SYSTEMS AND METHODS




(57) Abstract: *In vivo* deep brain medical probe systems include: (a) an MRI compatible cannula comprising a plurality of concentric axially extending tubes with a receiving bore; and (b) an elongate antenna member with a conductor and an insulating layer configured to slidably advance through cannula bore to define an MRI receive antenna.

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# MRI SYSTEMS HAVING MRI COMPATIBLE UNIVERSAL DELIVERY CANNULAS WITH COOPERATING MRI ANTENNA PROBES AND RELATED SYSTEMS AND METHODS

## RELATED APPLICATIONS

This application claims the benefit or priority to U.S. Provisional Patent Application Serial No. 60/591,409, filed 7/27/04 and U.S. Provisional Patent Application Serial No. 60/608,232, filed 9/9/2004, the contents of these applications are hereby incorporated by reference as if recited in full herein.

## FIELD OF THE INVENTION

The present invention relates to medical leads and may be particularly suitable for use with MRI compatible medical instruments such as implantable Deep Brain Stimulation ("DBS") leads and/or implantable sympathetic nerve chain stimulation leads.

## BACKGROUND OF THE INVENTION

Deep Brain Stimulation (DBS) is becoming an acceptable therapeutic modality in neurosurgical treatment of patients suffering from various conditions, including, for example, chronic pain, Parkinson's disease, essential tremor, dystonia and other medical conditions. Other electro-stimulation therapies have also been carried out or proposed using internal stimulation of the sympathetic nerve chain and/or spinal cord, etc.

One example of a prior art DBS system is the Activa® system from Medtronic, Inc. The Activa® system includes an implantable pulse generator stimulator that is positioned in the chest cavity of the patient and a lead with axially spaced apart electrodes that is implanted with the electrodes disposed in neural tissue. The lead is tunneled subsurface from the brain to the chest cavity connecting the electrodes with the pulse generator. These leads can have multiple exposed electrodes at the distal end that are connected to conductors which run along the length of the lead and connect to the pulse generator placed in the chest cavity.

Generally described, electrostimulation is carried out by delivering a pulse of desired frequency and amplitude in the target cranial tissue, typically using an implanted lead system. These lead systems have electrodes that are exposed at a distal end to contact the target cranial/neuronal tissue. The lead systems are connected to an implanted pulse generator at the other opposing end (proximal end). The distal end of the lead system is implanted in the desired cranial anatomy by stereotactic surgical procedures. In this procedure, a microelectrode system is advanced in the cranial tissue, typically based on MRI, CT or PET images acquired prior to the procedure. The target location for lead implantation in the cranial anatomy may be determined by measuring the electrical signal (EPG) signature of the specific anatomy using a microelectrode system. Typically these procedures are long and there is a clinical need for real time imaging guidance.

Notwithstanding the above, there remains a need for alternative MRI compatible medical lead configurations.

## SUMMARY OF EMBODIMENTS OF THE INVENTION

Embodiments of the present invention provide MRI compatible imaging systems comprising an MRI compatible cannula and a cooperating microelectrode system that provide an internal MRI antenna. Certain embodiments are particularly suitable for identifying deep brain target locations for implanting stimulation devices. The systems may be used to access various parts of the cranial tissue using substantially real-time MRI for guiding an implantation and/or interventional procedure. These devices can obtain MRI signals environment to obtain MRI images of the local surrounding anatomy and may be used to detect and/or measure the electrical pulses of the cranial tissue.

Certain embodiments are directed to *in vivo* deep brain medical probe systems include: (a) an MRI compatible cannula comprising a plurality of concentric axially extending tubes with a receiving bore; and (b) an elongate antenna member with a conductor (which may be a center conductor) and an insulating layer configured to slidably advance through cannula bore to define an MRI receive antenna.

Other embodiments are directed to MRI compatible deep brain imaging and recording probe systems that include: (a) a flexible elongate inner member body having opposing proximal and distal portions, the inner member body comprising at least one recording electrode disposed on the distal portion, the inner member comprising at least one axially extending conductor disposed in a core of the inner member body and an axially extending insulating layer surrounding the conductor for at least a major portion of the length of the conductor; (b) a cannula member having increased ridility relative to the inner member and sized and configured to slidably receive the flexible inner member therethrough, wherein, the inner member and cannula cooperate to define an MRI antenna; (c) an RF transmit decoupling circuit in communication with the inner member with the decoupler circuit configured to decouple the MRI antenna during an MRI RF excitation transmission; and (d) a splitter circuit in communication with the inner member to electrically isolate a recording circuit from an MRI imaging circuit.

Other embodiments are directed a medical kit include: (a) an elongate sterilized bio and MRI compatible internal MRI-antenna probe member having opposing distal and proximal portions, the probe comprising a core with a center conductor and at least one recording electrode in communication with the conductor on the distal portion; and (b) a generally rigid cannula comprising at least two concentric tubular members sized and configured to slidably receive the elongate MRI antenna probe therein. In operation, the MRI antenna probe lead cooperates with the cannula to define an internal MRI antenna.

The kit can also include an implantable flexible elongate stimulation probe sized and configured to slidably extend through an axially extending bore of the cannula.

Still other embodiments are directed to MRI antenna and recording electrode probe systems that include: (a) an MRI compatible cannula having an axially extending bore; (b) an elongate flexible probe having at least one recording electrode held by a distal portion of the probe; and (c) an elongate MRI antenna probe. The probe is configured to slidably extend through the cannula bore, and, in operation, the cannula and antenna probe cooperate to define components of at least one deep brain MRI receive antenna.

Other embodiments are directed to computer program products for operating a multi-purpose MRI compatible recording probe with MRI antenna. The computer program product includes a computer readable storage medium having computer readable program code embodied in the medium. The computer-readable program code includes computer readable program code that controllably engages a first or second operational mode for a MRI compatible recording probe with at least one recording electrode and an MRI antenna. The first operational mode having a first transmission path connecting the MRI antenna with an MRI scanner and decoupling the electrode during MRI operation and the second operational mode having a second transmission path connecting the electrode with a recording source during electrical stimulation or recording.

The computer readable program code may be configured to time the selection of the operational mode to occur proximate in time but after an MRI signal acquisition by the MRI antenna in the first operational mode. The computer readable program code may be configured to obtain microrecordings of local tissue in substantially real time proximate in time to an MRI signal acquisition by the MRI antenna in the first operational mode. The computer readable program code may be configured to obtain a plurality of MRI signals of local neural tissue proximate the MRI antenna in substantially real time, then obtain a plurality of microrecordings of the local neural tissue to allow a clinician to track placement of the probe using both MRI data and audio data.

In some embodiments, the cannula is configured to cooperate with the MRI antenna probe to define an MRI receive antenna when the MRI antenna probe is held inside the cannula. In particular embodiments, the cannula comprises a conductive shielding layer that cooperates with the MRI antenna probe to define an MRI receive antenna during positioning in a body used to obtain MRI signals for MRI positional guidance. In operation, the antenna probe can remain in placed and guide the stimulation probe into position or be removed from the cannula and replaced with the stimulation probe, which is then inserted to the same target location identified by the antenna probe.

Other embodiments are directed to MRI compatible deep brain imaging and probe systems. The systems include: (a) a flexible elongate inner member having opposing proximal and distal portions, the inner member comprising at least one optic fiber in a core of the inner member; (b) a cannula member having increased rigidity relative to the inner member and sized and configured to slidably receive the flexible inner member therethrough, wherein, the inner member and cannula cooperate to define an MRI antenna; and (c) an RF transmit decoupling circuit in communication with the inner member, wherein the decoupler circuit is configured to decouple the MRI antenna during an MRI RF excitation transmission.

These and other embodiments will be described further below.

BRIEF DESCRIPTION OF THE DRAWINGS

**Figure 1** is a schematic illustration of an MRI assembly with a cannula and elongate internal MRI antenna probe according to embodiments of the present invention.

**Figure 2** is an exploded schematic view of certain components of the assembly shown in **Figure 1**.

**Figure 3A** is a sectional view of the device shown in **Figure 2**, with the three components assembled together according to embodiments of the present invention.

**Figure 3B** is an alternate sectional view of the device shown in **Figure 2**, with a hollow core, according to embodiments of the present invention.

**Figure 4** is a schematic illustration of an internal MRI antenna having a loopless antenna configuration according to embodiments of the present invention.

**Figure 5** is a schematic illustration of a matching tuning decoupling circuit and an RF-recording electrode splitter circuit that is operatively associated with an MRI probe assembly according to embodiments of the present invention.

**Figure 6** is a schematic illustration of an MRI probe assembly used for deep brain procedures with an MRI system according to embodiments of the present invention.

**Figure 7A** is a schematic illustration of an MRI probe assembly having a cannula sized to receive both an MRI antenna probe and a stimulation probe according to embodiments of the present invention.

**Figure 7B** is a schematic illustration of a medical kit that can provide an MRI compatible cannula and the stimulation and antenna probe shown in **Figure 7A**.

**Figure 7C** is a schematic illustration of a combination NIR optic and MRI antenna tissue imaging and/or tissue data collection system according to embodiments of the present invention.

**Figures 8A-8D** are digital photographs of a cannula and imaging antenna assembly with interface connectors according to embodiments of the present invention.

**Figure 9** is a block diagram of a data processing system according to embodiments of the present invention.

**Figure 10** is a digital image of the device shown in **Figures 8A-8D** in a primate during an investigational study.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like numbers refer to like elements throughout. It will be appreciated that although discussed with respect to a certain antenna embodiment, features or operation of one lead system embodiment can apply to others.

In the drawings, the thickness of lines, layers, features, components and/or regions may be exaggerated for clarity and broken lines illustrate optional features or operations, unless specified otherwise. In addition, the sequence of operations (or steps) is not limited to the order presented in the claims unless specifically indicated otherwise. It will be understood that when a feature, such as a layer, region or substrate, is referred to as being "on" another feature or element, it can be directly on the other element or intervening elements may also be present. In contrast, when an element is referred to as being "directly on" another feature or element, there are no intervening elements present. It will also be understood that, when a feature or element is referred to as being "connected" or "coupled" to another feature or element, it can be directly connected to the other element or intervening elements may be present. In contrast, when a feature or element is referred to as being "directly connected" or "directly coupled" to another element, there are no intervening elements present. Although described or shown with respect to one embodiment, the features so described or shown can apply to other embodiments.

Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and this application and should not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

Probe embodiments of the present invention can be configured to image, record and/or stimulate any desired internal region of the body or object. The object can be any object, and may be particularly suitable for animal and/or human subjects. Some probe embodiments can be sized and configured for deep brain interrogation. Some probe embodiments can be configured to place interventional devices to treat, such as stimulation electrodes to stimulate a desired region of the brain and/or sympathetic nerve chain. Examples of known stimulation treatments and/or target body regions are described in U.S. Patent Nos. 6,708,064; 6,438,423; 6,356,786; 6,526,318; 6,405,079; 6,167,311; 6539,263; 6,609,030 and 6,050,992, the contents of which are hereby incorporated by reference as if recited in full herein.

**Figure 1** illustrates a first embodiment of an MRI probe assembly **5** that can define an internal MRI antenna **5I** according to the present invention. As shown, the assembly **5** comprises a plurality of generally concentric members, shown as three members **10, 20, 30**. The outer member **30** and/or intermediate member **20** can be a cannula member **75** (**Figures 7A, 7B**) that is configured to remain in position and guide a stimulation lead **100** or other therapeutic device into the target location using data obtained from the MRI antenna. Additional generally concentric members can be used, such as a fourth outermost member, or even more members. Referring again to **Figure 1**, the inner member **10** can include a conductive core which can be hollow or solid. In some embodiments, the core can comprise a relatively thin elongate axially extending insulated lead wire that is insulated over its outer surface along at least a major length of its body. The intermediate member **20** can be insulated from the inner member **10** and may cooperate with the inner member **10** to define a shield for the internal MRI antenna **5I**. The outer member **30** can be connected to the intermediate member **20** at a proximal end portion thereof and may also be insulated along its length. The inner member **10** can be configured to slide through the bore of the intermediate **20** and/or outer member **30** to allow for *in situ* extension beyond the bounds of the intermediate member **20** and/or outer member **30** during a procedure. The intermediate member **20** can be configured to slide through the bore of the outer member **30** or the intermediate member can be affixed to the outer member **30**. Each of the members **10, 20, 30** may comprise concentrically configured tubing (such as NITINOL) of increasing size. The outer member **30** can be more rigid than the inner and/or intermediate members **20, 30**.

**Figure 2** illustrates an exploded view of one embodiment of the assembly **5**. As shown, the inner member **10** can have a first length that is longer than the length of either the intermediate or outer member **20, 30**. The intermediate member can have a length that is less than the inner member **10**, but longer than the outer member **30**. In some particular embodiments, the intermediate member **20** is about 1-3 cm shorter than the inner member **10** and the cannula or outer member **30** can be about 1-4 cm shorter than the intermediate member **20**. In some embodiments (such as for deep placement), the overall length of the inner member **10** can be about 10 inches to about 13 inches. The members **10, 20** and **30** can be provided as differently sized sets that allow for deep or shallow placement. The shallow probe placement can employ lengths that are 1/5-1/3 the length of the deep placement members.

**Figure 3A** illustrates that the members **10, 20, 30** can be sized and configured to snugly abut each other. In other embodiments, the members **10, 20, 30** may have relatively small radial air gap spaces. Biocompatible anti-friction coatings may be used to facilitate *in situ* adjustment (extension and/or retraction of the inner member **10**) during a procedure. **Figure 3A** also illustrates that the inner member core **10c** can be solid. **Figure 3B** illustrates that the inner member core **10c** can be open, allowing for additional interventional probes to be guided/inserted therethrough without removing the inner member **10**.

**Figure 4** illustrates that in some embodiments, the assembly **5** can be configured to define a loopless MRI antenna **5I**. The inner member **10** can include a core that is plated with a conductive material or coating for improved conductivity and an outer layer of a thin dielectric **11**. The dielectric can terminate to expose the distal end or tip. The outer tubing layer **30** can define a shield. The intermediate member **20** can include a dielectric layer **23** that may be coated for improved conductivity. A distal section of the outer tube **30** can be coiled **30c** to improve loading. The proximal portion of the body of the assembly **5** can connect to a micro BNC connector **52**, as shown.

**Figure 1** illustrates that a coaxial cable **40** can electrically connect to the inner member **10** and the intermediate member **20**. The inner member **10** can merge into a connector **50** at its proximal end portion. The coaxial cable **40** can connect to an MRI scanner interface **230** and the connector **50** can communicate with a recorder (*see, e.g.*, **Figure 5**).

In some embodiments, as shown in **Figure 1**, the inner member **10** can include at least one recording electrode **15** on a distal portion thereof. For neural uses, different regions in the brain provide different "signature signals" with intensities, frequencies and/or pitches (typically readings of between about 1-4 microvolts) which can be sensed or recorded and are identifiable.

In this embodiment, the conductive core **10c** can connect to the electrode **15** and the insulating layer on the inner member **10** can be configured to expose the electrode **15** (*i.e.*, the insulating layer or material can provide a gap or terminate at the location of the electrode). The electrode **15** can be generally cylindrical or configured in any desired configuration. In this embodiment, the assembly **5** can define a bimodal device that provides both a microelectrode recording operational mode as well as an internal MRI antenna receive mode (typically electrically isolated so that each mode is not concurrently operative).

Generally stated, the assembly **5** can be configured so that components of the cannula **75** and microelectrode **15** system form one or more internal MRI RF antennas **5I** that can be matched and tuned at the MRI frequency of interest. The assembly **5** can include or be in communication with a matching/tuning and RF decoupling circuit **124** (**Figure 5**) as well as a splitter circuit **125** (**Figure 5**). The matching/tuning and RF decoupling circuit **124** is configured to decouple the probe during RF excitation so as to inhibit operation during active RF transmission (activating the antenna to receive MRI signals after RF excitation). The splitter circuit **125** can be configured to electrically isolate the probe or separate the operation of the MRI RF signal(s) from the microelectric recording (EPG) signal(s). The splitter circuit **125** can include either a high pass and/or a low pass filter. Additional components of the antennas can be implemented as RF chokes as described for example, in U.S. Patent No. 6,284,971, the contents of which are hereby incorporated by reference as if recited in full herein. The term "RF chokes" refers to a shielding layer configuration that provides an electrical length of less than or equal to $\lambda/4$ (from the perspective of external electromagnetic waves) to inhibit the formation and/or propagation of RF induced current or standing waves in an AC (alternating current, *e.g.*, diathermy applications) or RF exposure environment. The physical length that provides the electrical wavelength may vary depending on the materials used in fabricating the probe (such as dielectric constant) and the magnetic field in which it is used.

In some embodiments, a typical system **5** may comprise two discrete members, a cannula **75** and an inner tubular member **10,** that may be an insulated wire, that can be termed an MRI antenna probe **10**. The cannula **75** can comprise two or more concentric tubes, each insulated from the other and arranged to form an MRI antenna **5I**, namely a loopless/dipole antenna (**Figure 4**). If two concentric tubes, insulated from each other, are used, the inner tube **10** forms the core of the loopless antenna and the outer tube forms the shield. In case of more than two tubes, *e.g.*, three tubes, the tubes can be arranged so that the innermost tube **10** forms the core, the intermediate **20** the shield/ground and the outermost **30** can be connected to the intermediate tubing at the proximal end to form an RF choke as shown in **Figure 1**.

An internal member **10** can cooperate with the cannula **75** and act as an MRI antenna **5I** (an RF antenna), which is advanced in the cannula **75** and used to obtain an MRI image of the surrounding anatomy. A recording electrode **15** thereon can be used to obtain and/or measure microelectric signals from the intracranial tissue. The MRI image data and microrecording data can facilitate more exact identification of target cranial anatomy for placement of an implantable DBS lead systems.

As shown in **Figure 5**, the shield **30c** can be coiled in the distal section to reduce the overall loading length. The entire length of the inner member **10** may be insulated with a polymeric dielectric, except for the distal tip of the inner member **10** and, in some embodiments, the distal tip of the shielding **11**. This is to allow measurement of the EPG or EEG signal from the cranial tissue. If the EPG measurement is not a desired feature, the entire length of the inner member **10** may be insulated to prevent contact with biological fluids. At the proximal end of the inner member **10a** micro-BNC connector **52** facilitates connecting to a matching/tuning and decoupling circuit and/or a RF-EPG signal splitter circuit, as shown in **Figure 5**.

The system **5** may be used with an MRI scanner as shown in **Figure 6**. Once the MRI antenna **5I** and/or micro-electrode system is used to identify the intracranial location to implant the lead systems, the inner member **10** (and as appropriate, the intermediate tubing **20**) can be removed and a lead system or other interventional device can be introduced (and implanted as desired) using the cannula **75** as shown in **Figure 7A**. Alternatively, the lead system or other interventional device can be positioned with the inner member **10** in place where the inner member comprises a hollow core as shown in **Figure 3B**.

In some embodiments, the inner member **10** and the cannula **75** can be made to work in conjunction with each other, where the function of the cannula tubings can be dependent on the length of the member **10** in the cannula **75**. In a typical procedure, the cannula **75** will be advanced in the cranial anatomy, and the imaging coil will be advanced in the cannula and into the tissue. When the antenna probe member **10** is partially outside the distal end of the cannula **75**, the probe **10** acts as the core **10c** of the loopless antenna **5I** and the cannula **75** as the shield of the loopless antenna. When the antenna probe **10** is outside the cannula **75** to a desired length, the cannula **75** ceases to act as the shield but acts as an RF choke to the inner member **10**. This mechanism can be built in into the handle section of the inner member **10**.

In other embodiments the cannula can be configured to define all or a portion of an inductor loop antenna configuration, a multiple inductor loop configuration, an opposed solenoid coil, etc. The inner imaging antenna probe may be configured in other manners, such as, but not limited to an inductor loop coil, a quadrature loop coil, etc.

It is also noted that the RF splitter circuit **125** (**Figure 5**) may be implemented in the ground circuitry, if the distal end of the coiled shield **30c** is used to obtain or measure micro recording or EP signals.

In another embodiment, the concentric tubings **20, 30** of the cannula **75** system **5** are not permanently connected to each other and are able to slide inside the other as noted above. Depending on their relative positions, the components perform different electrical functions. For example, the cannula **75** can include two concentric tubings, which slide relative to each other and can be removed as desired or appropriate during the procedure. When the inner tubing **10** extends out of the intermediate tubing **20**, it can act as the core of the loopless antenna. The inner member **10** can also include one or two or more concentric (which may be slidable) tubes, all insulated from each other, and with an innermost wire. Thus, when extended or advanced, the innermost wire forms the core of the loopless antenna, and the outer tubings can form the shield and/or the balun. Also the cannula related tubings can form a part of the shield or the RF choke balun, depending on the location of the inner coils with respect to the cannula tubings.

The cannula **75** can be configured with a generally rigid body and/or a body that has increased rigidity relative to at least the inner member **10**. The cannula **75** can be configured to slidably receive at least the distal and intermediate portions of the inner member **10** and/or probe body **100** (**Figure** 7A) to guide the inner member **10** into position. The cannula **75** and/or associated members **10, 20, 30** can be single-use and disposable and provided as a sterilized component in a medical kit, or it may be re-used as a standard component and sterilized by the user/clinic. The cannula **75** can be configured according to a desired body entry location; *e.g.*, for oral entry, the cannula **75** can be formed into a bite block, nasal cavity or ear plug member, and for non-neural uses, such as placement in the spinal column, no cannula may be required.

For MRI compatible uses, the cannula **75**, the members **10**, **20**, **30**, an MRI interface cable and connectors **40, 50** can comprise non-magnetic MRI compatible material(s). In some embodiments, the kit can include an implantable pulse generator **50** as well as the implantable stimulation lead **100** which may also comprise MRI compatible materials to allow post-placement MRI interrogation of the subject. As described above, the stimulation lead **100** can be configured to be guided through the same cannula **75** as the antenna **5I**. In some embodiments, the antenna core **10** is removed after a desired location is determined, then the stimulation lead or other device is guided through the cannula **75** to the target location. In other embodiments, the core remains in position and the interventional device guided therethrough as noted above.

The MRI antenna **5I** is configured to pick-up MRI signals internally from local tissue during an MRI procedure. In some embodiments, the antenna **5I** has a focal length or signal-receiving length of between about 1-5 cm, and typically is configured to have a viewing length to receive MRI signals from local tissue of between about 1-2.5 cm. The MRI antenna **5I** can be a loopless antenna such as shown in **Figure 4**. However, other antenna configurations can be used, such as, for example, a whip antenna, a coil antenna, and/or a looped antenna. *See, e.g.*, U.S. Patent Nos. 5,699,801; 5,928,145; 6,263,229; 6,606,513; 6,628,980; 6,284,971; 6,675,033; and 6,701,176, the contents of which are hereby incorporated by reference as if recited in full herein. *See also* U.S. Patent Application Publication Nos. US 2003/0050557; US 2004/0046557; and 2003/0028095, the contents of which are also hereby incorporated by reference as if recited in full herein. The antenna may be used to guide placement of interventional probes and are not necessarily used to generate images of local structure.

It is contemplated that the electrode(s) of the antenna **5I** and/or the stimulation lead **100** can be sized and configured to "fit" the desired internal target, which may be a relatively small region, such as less than about 1-3 mm. Typically, as shown in **Figure 1**, the electrode(s) **15** can be held on a distal portion of the probe body.

Generally stated, the assembly has two primary operational modes with different electric transmission paths, which are electrically directed using the splitter circuit **125 (Figure 5)**. In operation, during an MRI procedure, an RF excitation pulse is transmitted to a subject. The MRI antenna is decoupled during RF transmission, then operative during a receive cycle to receive signal from local tissue. The recording electrode(s) **15** is typically isolated via the splitter circuit **125** so that only the MRI antenna is active. The MRI interface communicates with the MRI scanner.

During MRI guided clinical implantation of the probe can first be used as an MRI antenna **5I** to provide high resolution imaging of the target internal anatomy (such as neural tissue) and to locate the position of the electrode **15** in the body by obtaining MRI signals and hence, images, that are acquired by the external coils and/or internal MRI antenna. The electrodes **15** can also be used to assess location via acquiring or sensing electrical signals from the target (neural) anatomy.

**Figures 7A** and **7B** illustrate a dual probe system according to other embodiments of the present invention. In this embodiment, an MRI antenna probe **120a** and a stimulation probe **120b** can be sized and configured to serially enter a common cannula **75**. The antenna probe **120a** and/or the stimulation probe **120b** can each include at least one sensing electrode. Each probe **120a, 120b** can have a graduated scale or coordinate system that allows the antenna probe **120a** to be used to obtain MRI imaging data used to locate the target *in vivo* location. The cannula **75** can include MRI fiducial markers (not shown). The antenna probe **120a** can then be removed and replaced with the stimulation probe **120b** that can be automatically advanced in the same trajectory to the same position based on the data provided by the antenna probe **120a** and the controlled insertion to the location defined by the antenna probe **120a**, typically to a high degree of precision. The two probes **120a, 120b** can be sized and configured to have substantially the same cross-sectional area. In some embodiments, a non-conductive elastomeric sleeve (not shown), coating or other configuration can be used to size the probes **120a, 120b** to snugly fit the cannula **75** as desired. In other embodiments, an insert can be used to adjust the size of the cannula **75** to correspond to that of the probe in use (also not shown).

**Figure 7B** illustrates that a kit **80** can comprise the two probes **120a, 120b** and, optionally, the cannula **75**. The antenna probe **120a** can be configured to connect with the MRI interface while the stimulation probe **120b** can be configured to connect to the implantable pulse generator, each of which (along with respective leads) may also form part of the medical kit **80**.

The cannula **75** may be sized and configured to be a universal delivery system cannula **75** that can slidably serially receive selectable different elongate probes, such as the microelectrode and stimulation electrode probes discussed above. For example, the universal system cannula **75** can be configured to selectably receive different elongate members, such as, but not limited to, at least two of the following MRI compatible devices: an MRI antenna probe, an optic probe, a depth probe, an EEG probe, a stimulation probe (which may be implantable), a biopsy probe, an ablation probe, and a drug and/or fluid delivery and/or extraction probe (catheter, shunt and the like). The MRI antenna probe may be a standalone MRI antenna probe that cooperates with the cannula **75**, or may be combined with any of the other probe functions. For example, the probe **5** can be configured to provide a combination biopsy needle and MRI antenna probe when positioned in the cannula **75**. An example of a needle antenna is described in U.S. Patent 6,606,513, the contents of which are hereby incorporated by reference as if recited in full herein.

As such, the cannula **75** can have an ID (inner diameter) that allows different selected probes to be guided therethrough, or one or more of the tubes (such as the intermediate tube **20** in a three tube configuration) can be removed when the cannula **75** is used with larger probes. That is, one or more of the cannula tubes can act a removable sleeve for certain probes. In other embodiments, the cannula **75** has a fixed ID, and the different probes have a substantially similar OD (outer diameter), or one or more of the different probes can use sleeves to provide the desired size that allow them to be guided reliably into location with the same cannula **75**. The OD of the different selectable inner members, usable with a universal cannula **75**, can be between about 0.5-3 mm, and in some embodiments is about 1.5 mm or less, typically about 1.3 mm or less, and more typically between about 1.27-1.3 mm. The OD of the cannula **75** may be about 2 mm. The members **10, 20** and **30** can be provided as differently sized sets that allow for deep or shallow placement. The shallow probe placement can employ lengths that are 1/5-1/3 the length of the deep placement members described above.

The cannula **75** and probe members can be provided as differently sized sets that allow for deep or shallow *in vivo* placement and/or for use with about a 1.5T or about a 3.0T MRI System. For brain applications, the shallow probe placement can employ lengths that are at least about 3 cm, typically about 3 cm. The deep placement members can be at least about 7 cm long, typically between about 7-8 cm long. Different French size probes and/or different length probes may generate different loads and tuning may be adjusted accordingly. The antenna probes can be tuned remotely so that substantially the entire length or a selected portion thereof is active.

In some embodiments, as shown in **Figure 7C**, the inner member **10** (or one of the selectable inner member probes) can be configured as an NIR (near infrared imaging) optic probe **220**. *See* Giller et al., *Validation of a near-infrared probe for detection of thin intracranial white matter structures*, J. Neurosurg 98: 1299-1306 (2003) and U.S. Patent 6,567,690, the contents of which are hereby incorporated by reference as if recited in full herein. In particular embodiments, the inner member **10** can be configured as a combination NIR optic probe and to provide an MRI antenna as shown in **Figure 7C**. For example, the probe **220** can comprise an elongate fiberoptic fiber or fiber bundle **220f** that can be cladded (meaning the fiber optic(s) encased) with a desired MRI compatible conductive material, such as gold. The cladding or casing layer may terminate before the distal end of the member **220** (exposing the outer surface(s) of the optic fiber). Placing the cladded fiber optic package in the cannula **75** allows the combination probe **220** to cooperate with the cannula **75** and/or define independently, both an MRI antenna and an NIR imaging device. The probe **220** can be in communication with a light source **222** (typically a broad band light source) and a spectrometer **225** (typically a CCD array spectrometer) via the fiber(s) **220f.** The spectrometer can provide tissue data **225d** such as wavelength versus photon output based on local tissue characteristics (*i.e.*, such as reflectance or other desired optical property). The light source **222** and/or the spectrometer **225** can be placed in or out of the MRI suite to avoid MRI interference and/or can be configured with MRI compatible components and materials. As shown, the system can also include an MRI interface **230** electrically connected to the probe **220** via (coaxial) cable **221**. The fiber(s) **220f** can comprise a splitter **220s** at a proximal end portion to provide separate light input and output paths **220i, 220e**.

The coaxial cable **40** can be in electrical communication with the cladding of the probe **220** as well as the intermediate cannula member **20**, as described for the embodiment shown in **Figure 1**. Similarly, the MRI antenna or probe can be in communication with an RF decoupler circuit **124** (**Figure 5**). An optional light and

MRI timer **240** can be used to facilitate concurrent signal acquisition (registration) of a common region. The NIR probe function allows forward views (typically about 1-1.5 mm in front of the probe tip) while the MRI antenna can gather signal data of tissue proximate a distal end portion of the probe.

**Figure 9** is a block diagram of exemplary embodiments of data processing systems that illustrates systems, methods, and computer program products in accordance with embodiments of the present invention. The data processing systems may be incorporated in a digital signal processor in either the implantable pulse generator and/or MRI scanner interface and/or be in communication therewith. The processor **410** communicates with the memory **414** via an address/data bus **448**. The processor **410** can be any commercially available or custom microprocessor. The memory **414** is representative of the overall hierarchy of memory devices containing the software and data used to implement the functionality of the data processing system. The memory **414** can include, but is not limited to, the following types of devices: cache, ROM, PROM, EPROM, EEPROM, flash memory, SRAM, and DRAM.

As shown in **Figure 9**, the memory **414** may include several categories of software and data used in the data processing system: the operating system **452**; the application programs **454**; the input/output (I/O) device drivers **458**; the MRI Antenna operation or Electrode Operation Module **450**; and data **456**.

As will be appreciated by those of skill in the art, the operating system **452** may be any operating system suitable for use with a data processing system, such as OS/2, AIX, DOS, OS/390 or System390 from International Business Machines Corporation, Armonk, NY, Windows CE, Windows NT, Windows95, Windows98, Windows2000 or other Windows versions from Microsoft Corporation, Redmond, WA, Unix or Linux or FreeBSD, Palm OS from Palm, Inc., Mac OS from Apple Computer, LabView, or proprietary operating systems. The I/O device drivers **458** typically include software routines accessed through the operating system **452** by the application programs **454** to communicate with devices such as I/O data port(s), data storage **456** and certain memory **414** components. The application programs **454** are illustrative of the programs that implement the various features of the data processing system and can include at least one application, which supports operations according to embodiments of the present invention. Finally, the data **456** represents the static and dynamic data used by the application programs **454**, the operating system **452**, the

I/O device drivers **458**, and other software programs that may reside in the memory **414.**

While the present invention is illustrated, for example, with reference to the Module **450** being an application program in **Figure 9**, as will be appreciated by those of skill in the art, other configurations may also be utilized while still benefiting from the teachings of the present invention. For example, the Module **450** may also be incorporated into the operating system **452**, the I/O device drivers **458** or other such logical division of the data processing system. Thus, the present invention should not be construed as limited to the configuration of **Figure 9** which is intended to encompass any configuration capable of carrying out the operations described herein. Further, the Module **450** can communicate with other components, such as an MRI scanner.

The I/O data port can be used to transfer information between the data processing system or another computer system or a network (*e.g.*, the Internet) or to other devices controlled by the processor. These components may be conventional components such as those used in many conventional data processing systems, which may be configured in accordance with the present invention to operate as described herein.

The computer-readable program code can include computer readable program code that controllably engages a first or second operational mode for a MRI compatible antenna and recording probe with at least one electrode and an MRI antenna. The first operational mode having a first transmission path connecting the MRI antenna with an MRI scanner and decoupling the electrode during MRI operation and the second operational mode having a second transmission path connecting the electrode with a recording source during electrical recording.

The computer readable program code may be configured to time the selection of the operational mode to occur proximate in time but after an MRI signal acquisition in the first operational mode. The computer readable program code may be configured to operate the second mode to obtain microrecordings of local tissue in substantially real time proximate in time to an MRI signal acquisition by the MRI antenna in the first operational mode. The computer readable program code may be configured to obtain a plurality of MRI signals of local neural tissue proximate the MRI antenna in substantially real time, then obtain a plurality of microrecordings of the local neural tissue to allow a clinician to track placement of the probe using both MRI data and audio data.

The flowcharts and block diagrams of certain of the figures herein illustrate the architecture, functionality, and operation of possible implementations of the present invention. In this regard, each block in the flow charts or block diagrams represents a module, segment, or portion of code, which comprises one or more executable instructions for implementing the specified logical function(s). It should also be noted that in some alternative implementations, the functions noted in the blocks may occur out of the order noted in the figures. For example, two blocks shown in succession may in fact be executed substantially concurrently or the blocks may sometimes be executed in the reverse order, depending upon the functionality involved.

The present invention is explained further in the following non-limiting Example.

## EXAMPLE 1

**Figures 8A-8D** illustrate a prototype configuration of a cannula **75** with MRI antenna **5I** formed by the inner member **10** and cannula **75** that was used to obtain the image of the primate shown in **Figure 10**. The MRI compatible cannula and microelectrode configuration was used *in vivo* with a Siemens Allegra® 2.9T scanner. A 2 mm outer diameter cannula included three concentric insulated tubes from Nitinol configured to define a loopless RF antenna. The innermost tube (1.5 mm inner diameter) formed the core of the loopless antenna and provided a conduit to advance an additional MRI-antenna/microelectrode component. The intermediate tube formed the shield of the antenna with the outermost tube connected to the intermediate tubeat a proximal end to form a RF choke. The inner diameter of the cannula and the outer surfaces were coated with a thin polyurethane insulation and the entire cannula part of the assembly was insulated by a 0.001 inch polyimide tube.

The micro-electrode loopless antenna member was fabricated from Nitinol tube with an insulated gold-plated wire inside the Nitinol tube forming the core of the antenna. The dipole end portion of the antenna was about 1.5 cm and was not insulated at the outermost end portion for about 1 mm to permit EEG measurements. The shield of the antenna was coiled at the distal end portion to reduce the overall loading length to about 3 cm. The member was insulated by a 500 micron polyester layer (except for the distal tip of the member to permit EEG measurements as noted above). The cannula and microelectrode antenna member were matched and tuned to about 123.2MHz and decoupled from pick-up during MRI excitation via a decoupling circuit/switch similar to that described in Ocali et al., *Intravascular magnetic resonance imaging using a loopless catheter antenna*, Magn Reson Med, 1997; 37:pp.112-118.

MRI testing of the cannula and antenna/microelectrode member were performed on the 2.9T Siemen's Allegra® scanner. RF power deposition safety testing was carried out in a polyacrylamide gel phantom of conductivity 0.9 S/m. A nominal 4W/kg SAR (head) MRI sequence was applied for 3.4 minutes. The cannula and the microelectrode/antenna member were placed about 1 cm from the edge of the phantom and the local temperature was measured directly using FISO fiber-optic temperature probes. Actual SAR was calculated from the rate of the initial temperature rise and the specific heat of the gel. The MRI signal to noise ratio (SNR) of the microlectrode/antenna and cannula system was tested in a saline phantom with variable depths of insertion (3 cm and 10 cm) to simulate some clinical conditions.

The feasibility of using the cannula and microelectrode/antenna system for MRI-guided access to the brain (deep brain), such as the STN (subthalamic nucleus), was tested in a primate with protocols approved by the appropriate Animal Care and Use committee. Preoperative MRI and CT images were obtained to locate a head mount and determined a trajectory for microelectrode advancement. The animal was anesthesized, a burr hole prepared, a head mount assembly fixed to the skull and the cannula/antenna system advanced under real-time MRI guidance to the location of the STN. To increase SNR and field-of-view, images obtained from the scanner's external head coil and the internal antenna probe were combined using a phased array adapter.

The cannula/loopless antenna and coaxial cable had an impedance of about 25 ohms. The RF choke created between the primary and secondary shielding had an isolation of about 550 ohms when the antenna/cannula was loaded up to about 4 cm in the saline phantom. The coaxial cable of the microelectrode/antenna member had an impedance of about 32 ohms. The SNR profile of the antenna demonstrated about a 50% improvement over the external head coil in a circular region of about 5 mm radius around the distal end portion of the antenna/microelectrode member. In the primate study, the signal from the scanner's had coil depicts the overall cranial anatomy while the local SNR enhancement provided by the cooperating MRI compatible cannula and microelectrode/antenna member as the coil advanced into the STN is shown in **Figure 10**.

The experiment demonstrated that a cooperating MRI compatible cannula and microelectrode/antenna member suitable for intra-cranial interventions can be fabricated and provide substantial local SNR improvements. The local SNR improvement can provide enhanced local spatial registration for precise anatomical guidance/positioning

In the drawings and specification, there have been disclosed embodiments of the invention and, although specific terms are employed, they are used in a generic and descriptive sense only and not for purposes of limitation, the scope of the invention being set forth in the following claims. Thus, the foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims. In the claims, means-plus-function clauses, where used, are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. Therefore, it is to be understood that the foregoing is illustrative of the present invention and is not to be construed as limited to the specific embodiments disclosed, and that modifications to the disclosed embodiments, as well as other embodiments, are intended to be included within the scope of the appended claims. The invention is defined by the following claims, with equivalents of the claims to be included therein.

THAT WHICH IS CLAIMED IS:

1. An *in vivo* deep brain medical probe system, comprising:

an MRI compatible cannula comprising a plurality of generally concentric axially extending tubes with a receiving bore; and

an elongate antenna member with a core comprising a conductor and an insulating layer configured to slidably advance through the cannula bore to cooperate with the cannula to define an MRI receive antenna.

2. A probe system according to Claim 1, wherein the elongate antenna member comprises a center conductor and at least one recording electrode disposed on a distal portion thereof.

3. A probe system according to Claim 2, wherein the probe system has at least two operational modes, including a first MRI signal operational mode wherein the antenna member receives MRI signals from local tissue and a second operational recording signal mode wherein the recording electrode obtains electrical signals from local target tissue.

4. A probe system according to Claim 3, further comprising a RF decoupling circuit configured to isolate the MRI receive antenna during an MRI excitation RF transmission and a recording splitter circuit to decouple the MRI receive antenna during the recording mode.

5. A probe system according to Claim 1, further comprising an MRI compatible interventional probe member configured to slidably extend through the MRI compatible cannula.

6. A probe system according to Claim 2, wherein the antenna member electrically cooperates with the cannula to define a loopless MRI antenna.

7. A probe system according to Claim 1, wherein the cannula comprises an intermediate tubular member and an outer member that generally encases at least a major length of the intermediate member.

8. A probe system according to Claim 7, wherein the antenna member has a first length, the intermediate member has a second length, and the outer member has a third length, the first length being longer than the second and third lengths, and the second length being longer than the third length.

9. A probe system according to Claim 1, in combination with an implantable stimulation lead that is sized and configured to slidably extend through the bore of the cannula after the antenna member is removed therefrom.

10. A probe system according to Claim 1, wherein the antenna member comprises a hollow core and is configured to slidably receive selected interventional devices therethrough.

11. An MRI compatible deep brain guiding and recording probe system comprising:

a flexible elongate inner member body having opposing proximal and distal portions, the inner member body comprising at least one recording electrode disposed on the distal portion, the inner member comprising at least one axially extending conductor disposed in a core of the inner member body and an axially extending insulating layer having a length that extends for at least a major portion of the length of the conductor;

a cannula member having increased rigidity relative to the inner member and sized and configured to slidably receive the flexible inner member therethrough, wherein, the inner member and cannula cooperate to define an MRI antenna;

an RF transmit decoupling circuit in communication with the inner member with the decoupler circuit configured to decouple the MRI antenna during an MRI RF excitation transmission; and

a splitter circuit in communication with the inner member to electrically isolate a recording circuit from an MRI imaging circuit.

12. A system according to Claim 11, wherein the system is configured to attach to an MRI scanner and a recording circuit for selectively operating the recording electrode or the MRI antenna.

13. A system according to Claim 11, wherein the decoupler circuit comprises a matching and tuning decoupling circuit that engages an MRI scanner and decouples the antenna during RF transmission.

14. A system according to Claim 11, wherein the system has selective operative first and second electrical transmission paths associated with first and second operational modes, the first transmission path connecting the MRI antenna with an MRI scanner and decoupling the electrode during MRI operation and the second transmission path connecting the electrode with a recording source during electrical recording, respectively.

15. A system according to Claim 11, wherein the elongate member has a hollow core.

16. A system according to Claim 11, wherein the elongate member has a generally solid core, and wherein the conductor is substantially centrally held in the core.

17. A medical kit, comprising:

(a) an elongate sterilized bio and MRI compatible internal MRI-antenna probe member having opposing distal and proximal portions, the probe comprising a core with a conductor; and

(b) a generally rigid cannula comprising at least two generally concentric tubular members sized and configured to slidably receive the elongate MRI antenna probe therein,

wherein, in operation, the MRI antenna probe lead cooperates with the cannula to define an internal MRI antenna.

18. A kit according to Claim 17, wherein the antenna probe member comprises and at least one recording electrode in communication with the conductor and residing on the distal portion of the probe.

19. A kit according to Claim 18, wherein the conductor resides substantially in a center of the core of the inner member.

20. A kit according to Claim 17, wherein the core of the antenna member is hollow.

21. A kit according to Claim 17, further comprising an implantable flexible elongate stimulation probe sized and configured to slidably extend through an axially extending bore of the cannula.

22. A computer program product for operating a multi-purpose MRI compatible recording probe and MRI antenna, the computer program product comprising:

a computer readable storage medium having computer readable program code embodied in said medium, said computer-readable program code comprising:

computer readable program code that controllably engages a first or second operational mode for an MRI-compatible probe with at least one recording electrode and an MRI antenna, the first operational mode having a first transmission path connecting the MRI antenna with an MRI scanner and the second operational mode having a second transmission path connecting the electrode with a recording source during electrical stimulation or recording.

23. A computer program product according to Claim 22, wherein the computer readable program code is configured to time the selection of the first operational mode to occur proximate in time but after an MRI excitation signal.

24. A computer program product according to Claim 22, further comprising computer readable program code that is configured to obtain a plurality of MRI signals of local neural tissue proximate the MRI antenna in substantially real time, then obtain a plurality of microrecordings of the local neural tissue to allow a clinician to track placement of the probe.

25. An MRI antenna and recording electrode probe system, comprising:

an MRI compatible cannula having an axially extending bore;

an elongate flexible antenna probe having at least one recording electrode held by a distal portion of the probe;

wherein the probe is configured to slidably extend through the cannula bore, and wherein, in operation, the cannula and antenna probe electrically cooperate to define components of at least one deep brain MRI receive antenna.

26. An MRI antenna probe system according to Claim 25, wherein the cannula is configured to be inserted into a burr hole placed in a patient's skull, and wherein the recording probe and MRI antenna probe are configured for deep brain placement.

27. An MRI antenna probe system according to Claim 25, wherein the MRI antenna probe and the cannula define a plurality of generally concentric tubular members configured to define an axially extending shield disposed over an inner conductive core, with the shield and core being insulated from each other.

28. An MRI antenna probe system according to Claim 25, wherein the cannula comprises a conductive shielding layer that cooperates with the MRI antenna probe to define an MRI receive antenna configured to obtain MRI signals for MRI positional guidance, and wherein, in operation, the antenna probe is removed from the cannula and replaced with a stimulation probe which is then inserted to the same location as the antenna probe.

29. An MRI compatible deep brain probe system comprising:

a flexible elongate inner member having opposing proximal and distal portions, the inner member comprising at least one optic fiber in a core of the inner member;

a cannula member having increased rigidity relative to the inner member and sized and configured to slidably receive the flexible inner member therethrough, wherein, the inner member and cannula cooperate to define an MRI antenna; and

an RF transmit decoupling circuit in communication with the inner member, wherein the decoupler circuit is configured to decouple the MRI antenna during an MRI RF excitation transmission.

30. An MRI compatible system according to Claim 29, wherein the core is encased in an MRI compatible conductive material.

31. An MRI compatible system according to Claim 29, wherein the optic fiber defines the core, and wherein the optic fiber is coated with an MRI compatible conductive material.

32. An MRI compatible system according to Claim 29, further comprising a fiber optic splitter disposed at a proximal portion of the inner member that separates the fiber optic core into two light paths, an input path that is adapted to connect to an input light source and an output path that is adapted to connect to a spectrometer.

33. An MRI compatible system according to Claim 29, wherein the elongate inner member cooperates with the cannula and provides an MRI receive antenna and an NIR imaging member.

34. An MRI compatible system according to Claim 29, wherein the core is generally solid.

35. An MRI compatible system according to Claim 29, wherein the core is generally hollow.

36. An MRI compatible system according to Claim 29, wherein the cannula comprises a plurality of generally concentric tubular members.

37. An MRI compatible system according to Claim 36, wherein the plurality of generally concentric tubular members are configured to snugly abut each other.

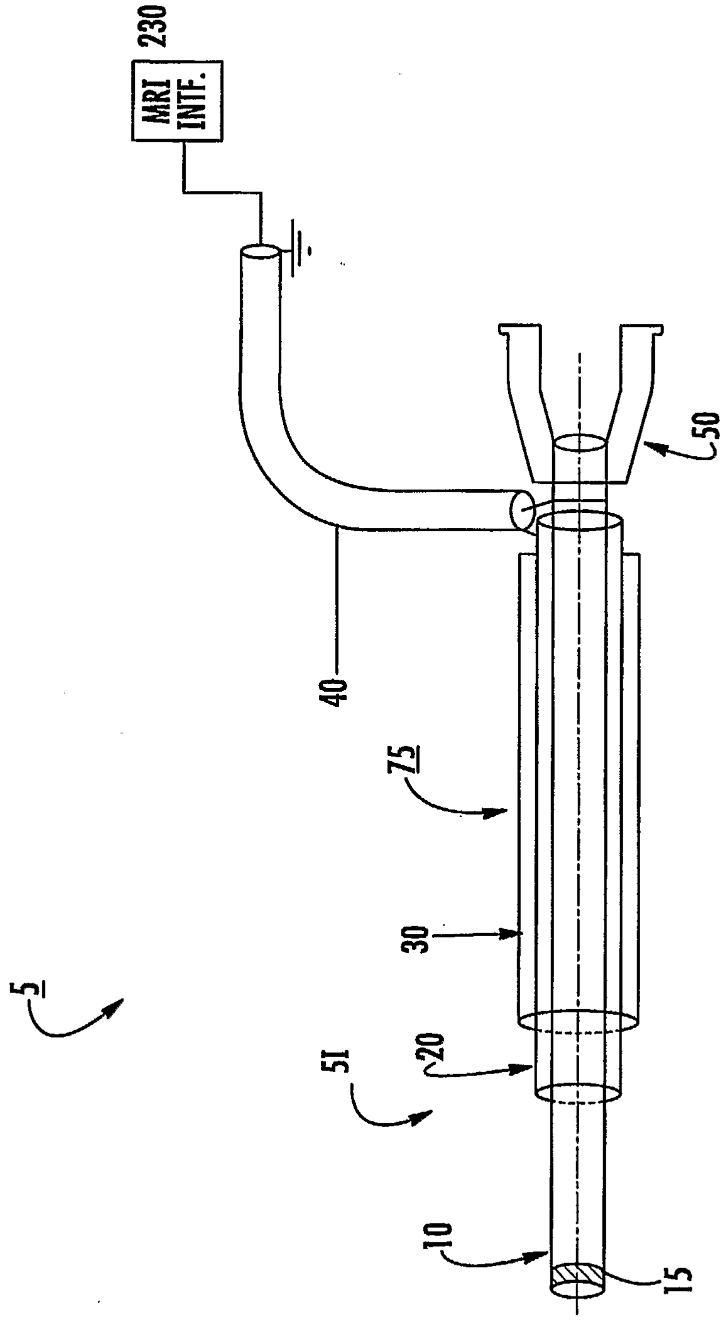



FIG. 1

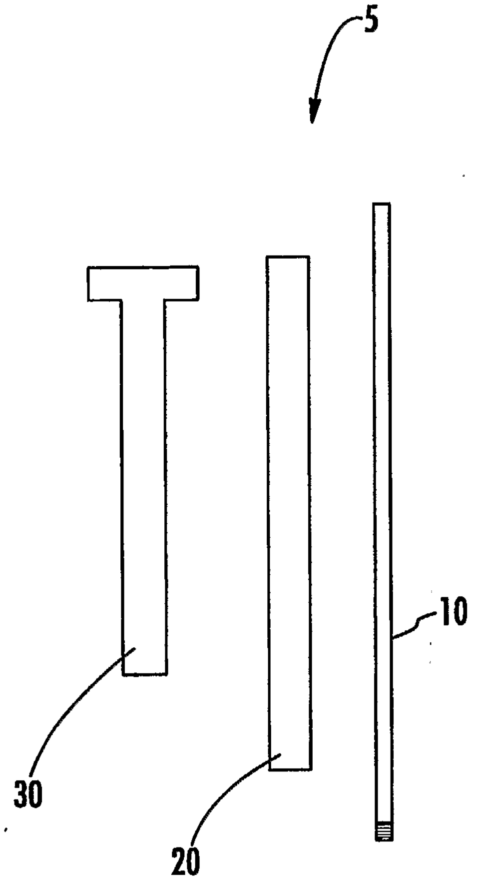



FIG. 2

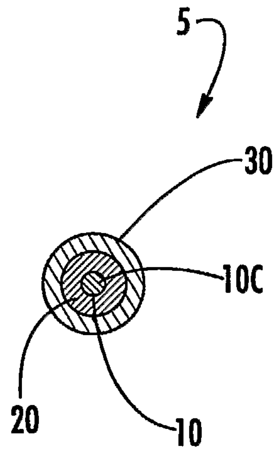



FIG. 3A

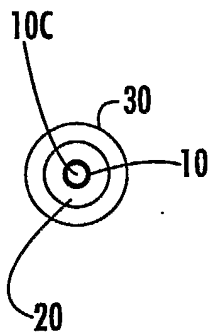



FIG. 3B

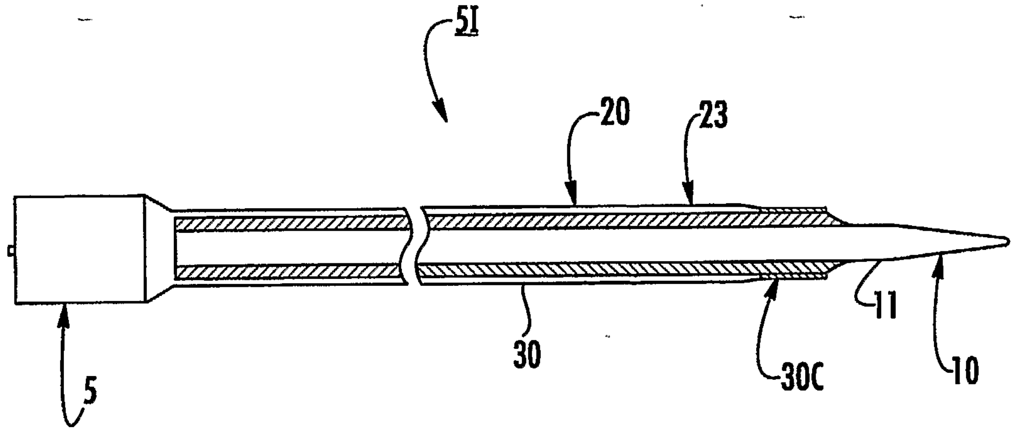

5I
20
23
30
30C
11
10
5

FIG. 4

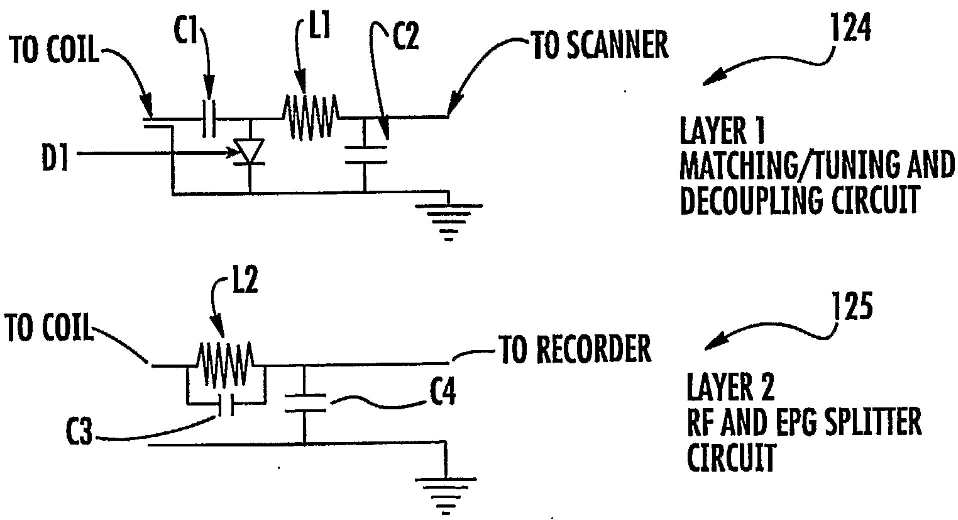

TO COIL
C1
L1
C2
TO SCANNER
124
D1
LAYER 1
MATCHING/TUNING AND
DECOUPLING CIRCUIT
L2
TO COIL
TO RECORDER
125
C4
C3
LAYER 2
RF AND EPG SPLITTER
CIRCUIT

FIG. 5

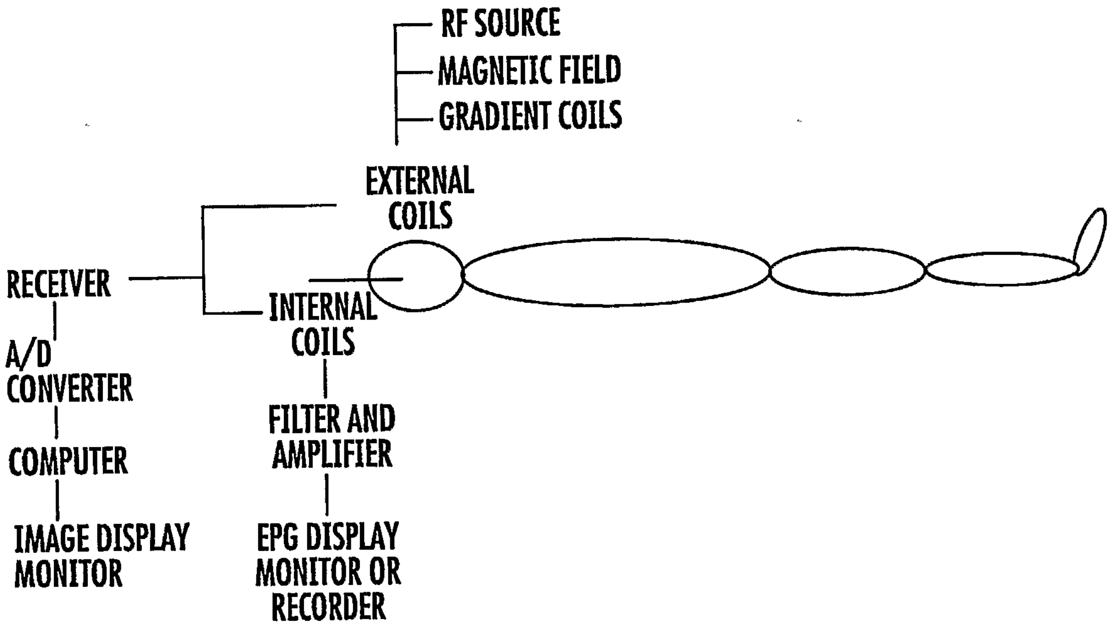

RF SOURCE
MAGNETIC FIELD
GRADIENT COILS
EXTERNAL COILS
RECEIVER
INTERNAL COILS
A/D CONVERTER
COMPUTER
IMAGE DISPLAY MONITOR
FILTER AND AMPLIFIER
EPG DISPLAY MONITOR OR RECORDER

FIG. 6

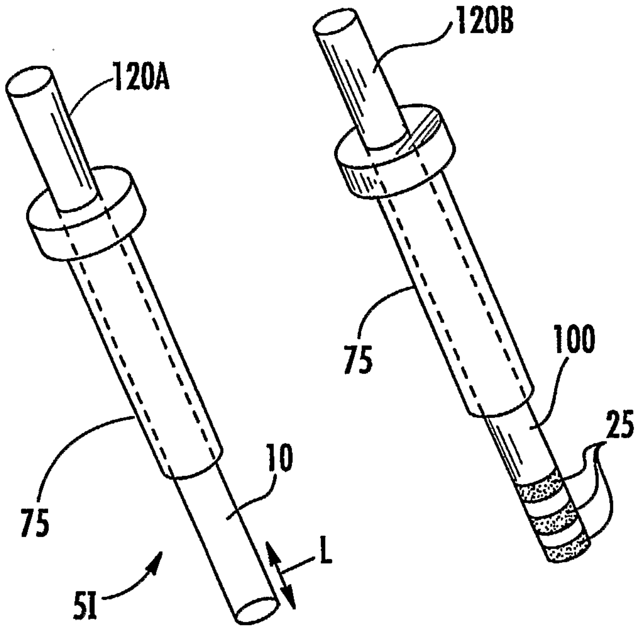



FIG. 7A

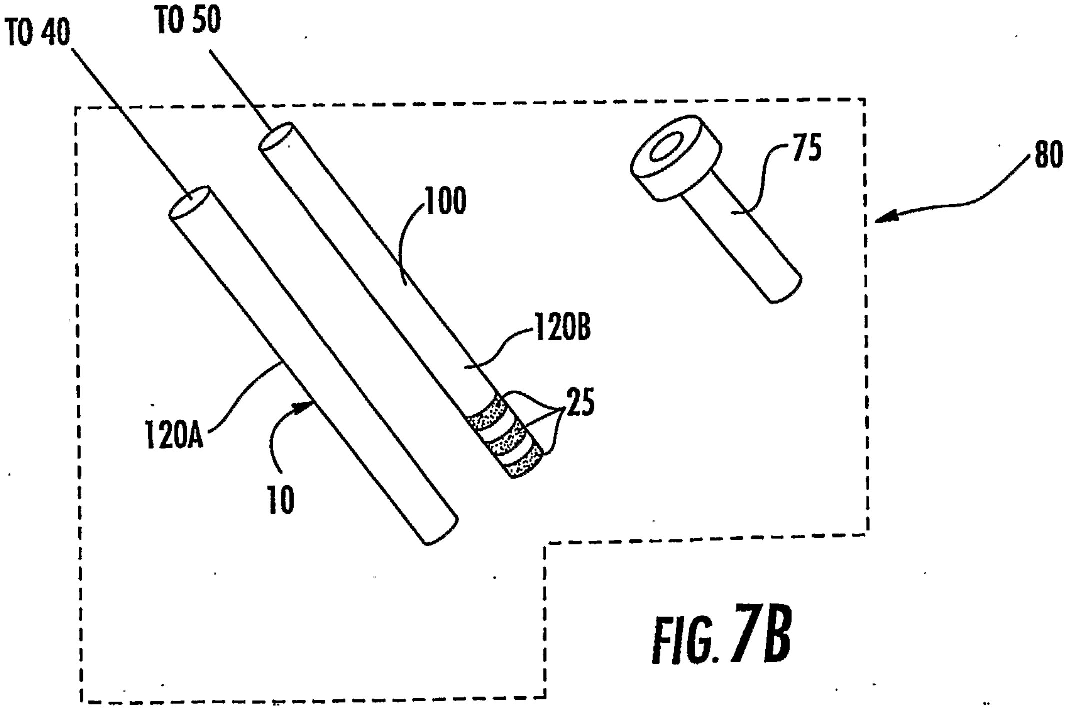
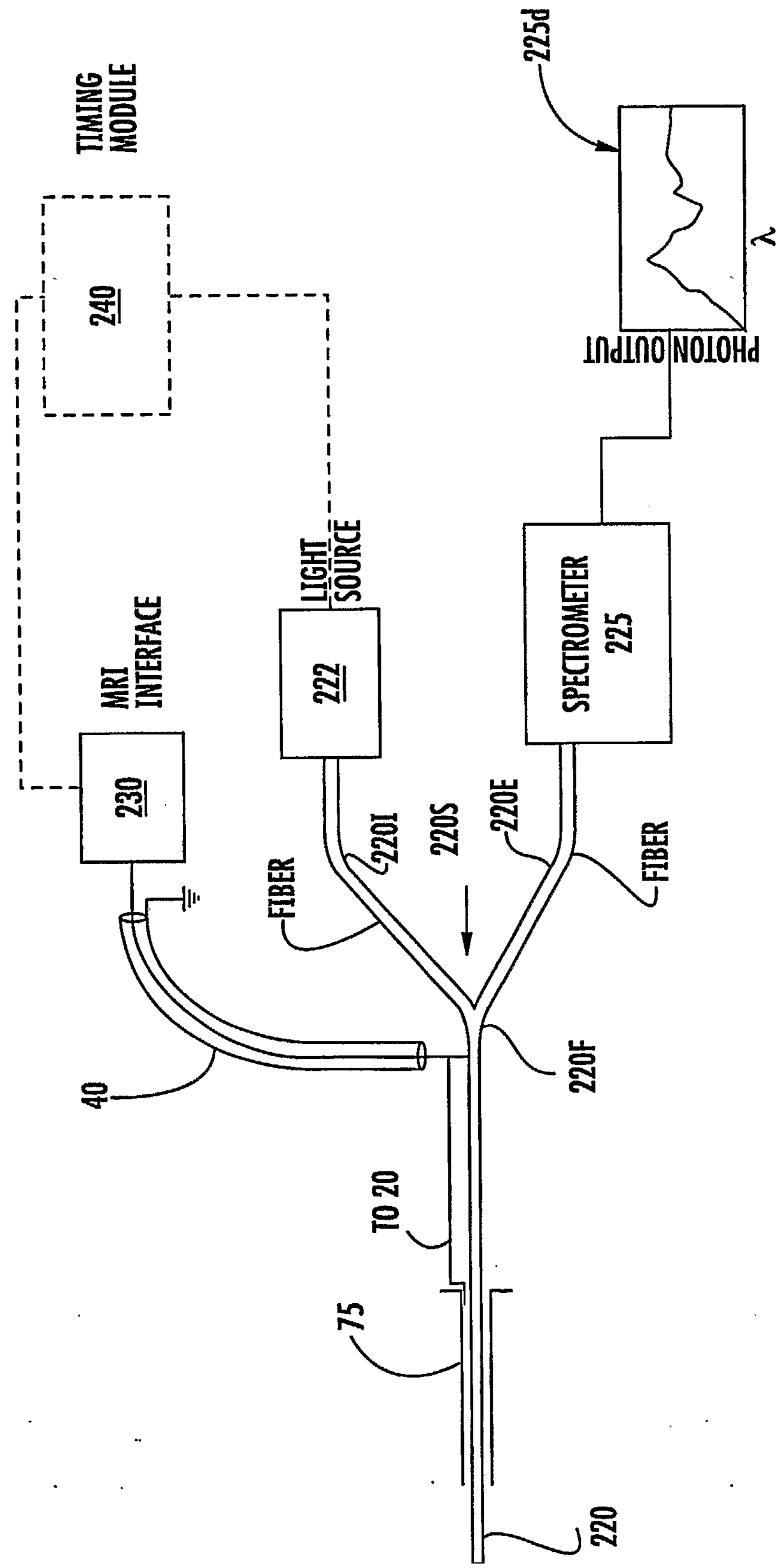



FIG. 7B

FIG. 7C


TIMING MODULE
240
MRI INTERFACE
230
LIGHT SOURCE
222
SPECTROMETER 225
225d
PHOTON OUTPUT
λ
FIBER
220I
220S
220E
FIBER
220F
40
TO 20
75
220

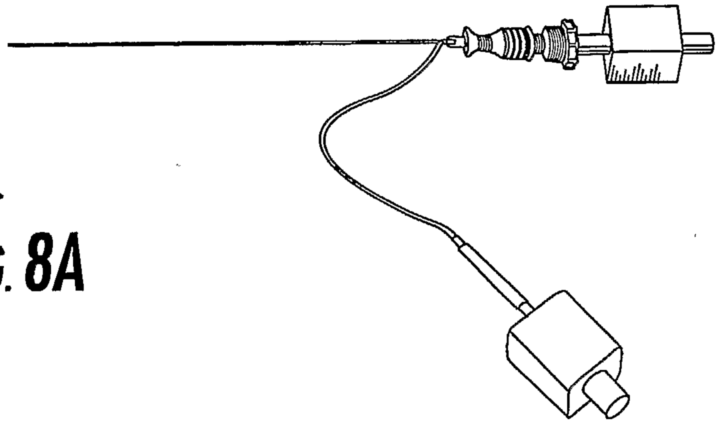


FIG. 8A

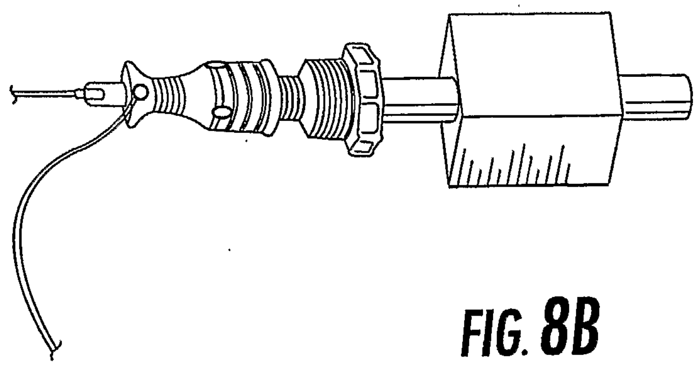


FIG. 8B

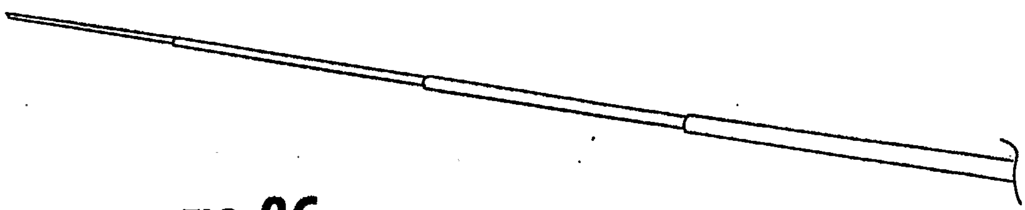


FIG. 8C

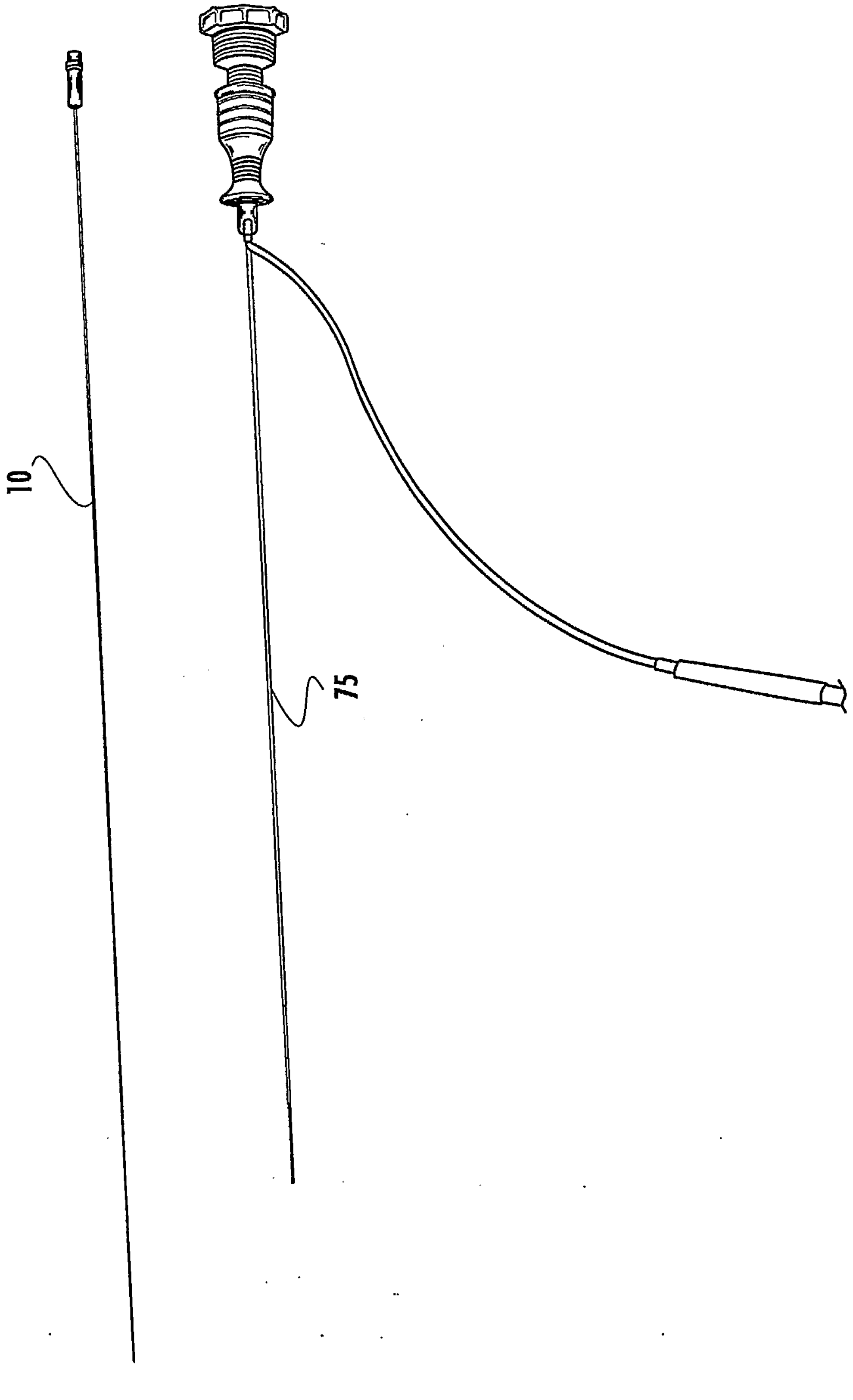



FIG. 8D

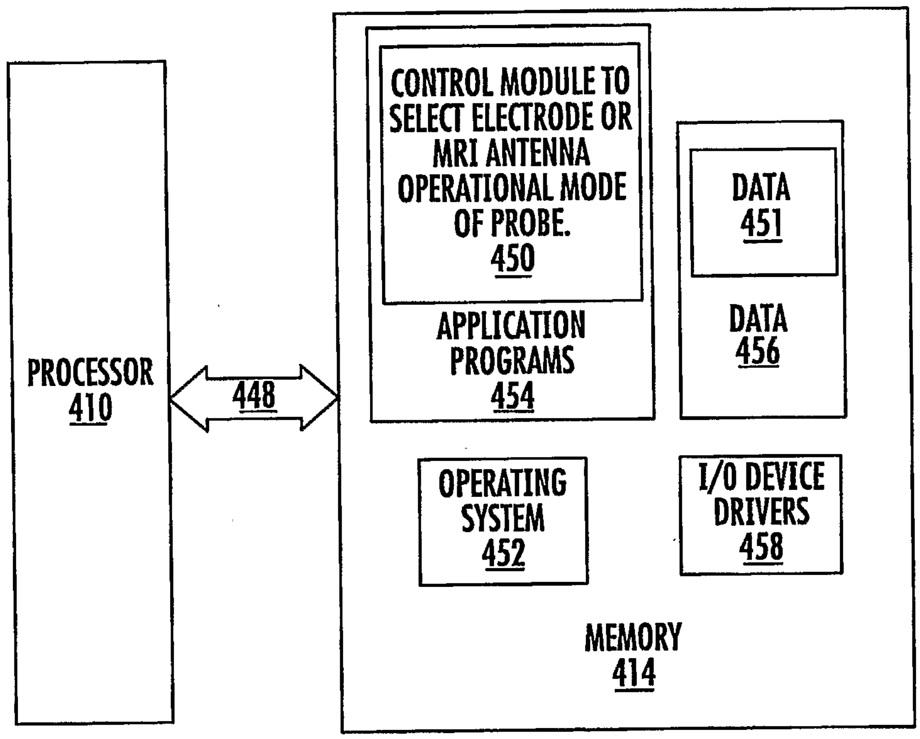

CONTROL MODULE TO SELECT ELECTRODE OR MRI ANTENNA OPERATIONAL MODE OF PROBE.
450
APPLICATION PROGRAMS
454
DATA
451
DATA
456
PROCESSOR
410
448
OPERATING SYSTEM
452
I/O DEVICE DRIVERS
458
MEMORY
414

FIG. 9

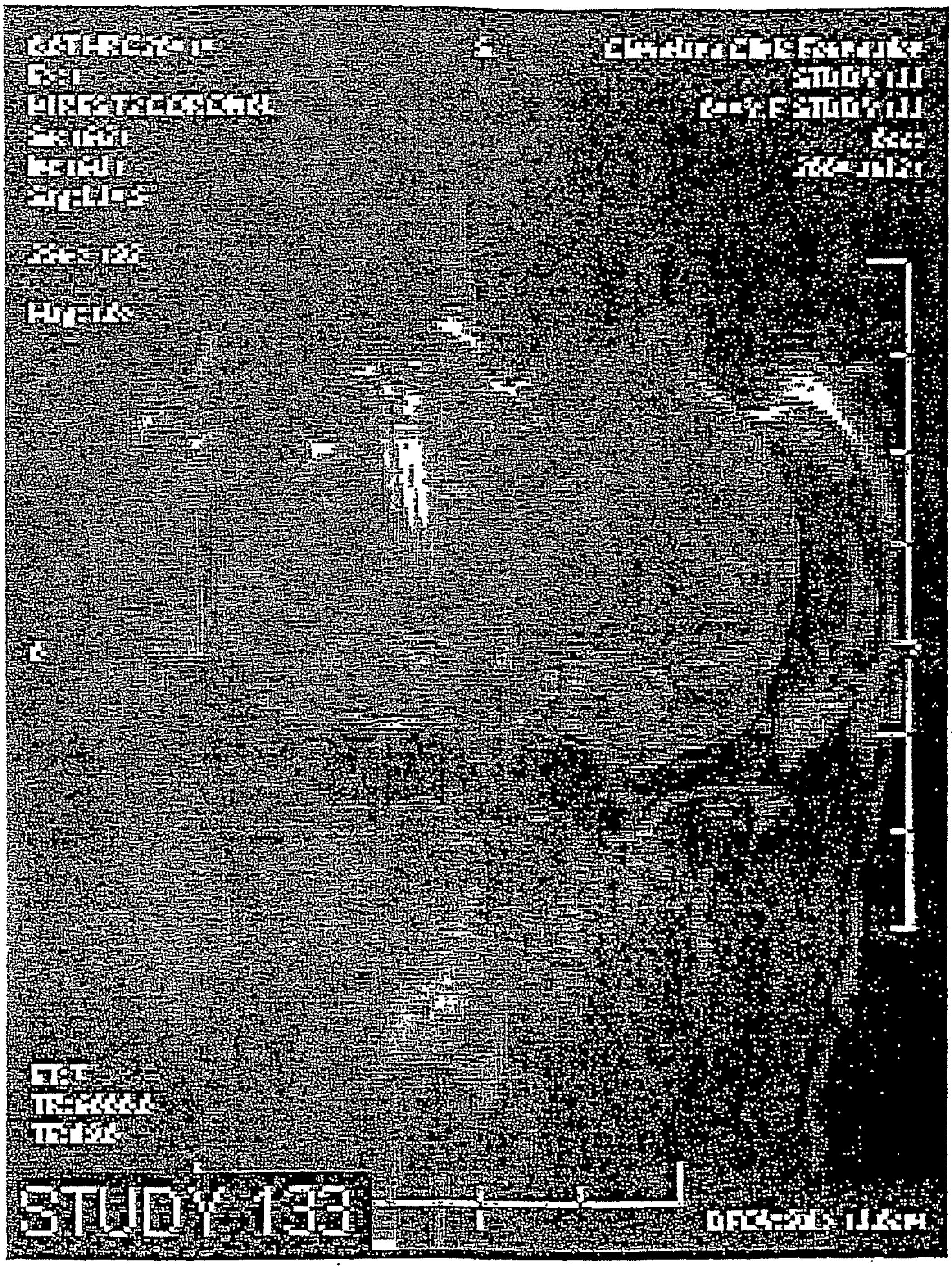



FIG. 10