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(54) Title: METHOD OF DEMAGNETIZING AND REMAGNETISING A MAGNETIC ELEMENT IN AN IMPLANT DURING MAGNETIC RESONANCE IMAGING

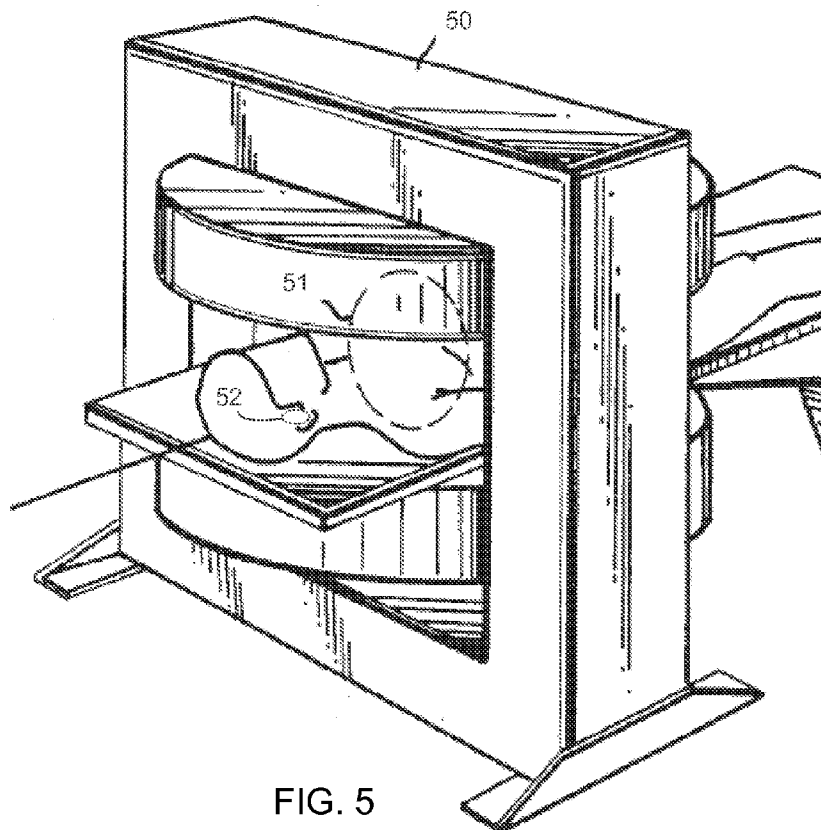


FIG. 5

(57) Abstract: There is disclosed a method of operating a magnetic resonance imaging (MRI) system, the method comprising demagnetizing a magnetic element in an implanted medical device by exposing it to an external demagnetizing magnetic field; performing magnetic resonance imaging of the patient; and remagnetizing the magnetic element without removing it from the implanted medical device by exposing the magnetic element to an external remagnetizing magnetic field.

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METHOD OF DEMAGNETIZING AND REMAGNETISING A MAGNETIC ELEMENT IN AN IMPLANT DURING MAGNETIC RESONANCE IMAGING

[0001] This application claims priority from U.S. Provisional Patent Application 60/949,560, filed July 13, 2007, which is hereby incorporated by reference.

Field of the Invention

[0002] The present invention relates to implantable medical devices, and specifically, to demagnetization and remagnetization of magnetic elements in such devices to allow for magnetic resonance imaging.

Background Art

[0003] Some implantable medical devices use magnets to hold internal and external pieces in proper position. For example, as shown in Fig. 1, an idealized cochlear implant system may include a receiving coil **108** located under the skin **103** and embedded in or just on top of the bone **104**. An implanted internal magnet **106** is contained in the center of the receiving coil **108**. An external transmitter housing **101** includes an external magnet **105** that is positioned over the internal magnet **106** so that the external transmitter housing **101** is held in place in an optimum position adjacent to the receiving coil assembly **102**. When such an optimal position is maintained, an external transmitting coil **107** within the transmitter housing **101** can use inductive coupling to transmit a transcutaneous data and/or power signal to the receiving coil **108**.

[0004] The receiving coil **108** may, for example, be encapsulated within some tissue-compatible organic material such as silicone or epoxy, forming a receiving coil assembly **102**. In such an arrangement, the receiver coil assembly **102** is connected to receiver electronic circuits within a metal or ceramic case which is hermetically sealed from the surrounding tissue. Or, in another approach, the internal magnet **106**, receiving coil **108** and the receiver electronic circuits are all contained within a common hermetic case. In any such arrangement, the internal magnet **106** is a permanently integrated part of the implant structure.

[0005] One problem arises when the patient undergoes Magnetic Resonance Imaging (MRI) examination. Interactions occur between the receiver magnet and the applied external magnetic field for the MRI. As shown in Fig. 2, the external magnetic field \vec{B} from the MRI may create a torque \vec{T} on an implanted internal magnet **202**, which may displace the internal magnet **202** or the whole coil assembly **201** out of proper position. Among other things, this may damage the adjacent tissue in the patient. In addition, the external magnetic field \vec{B} from the MRI may reduce or remove the magnetization \vec{m} of the internal magnet **202**. As a result, the demagnetized internal magnet **202** may no longer be strong enough after exposure to the external magnetic field \vec{B} of the MRI to hold the external transmitter housing in proper position. The implanted internal magnet **202** may also cause imaging artifacts in the MRI image, there may be induced voltages in the receiving coil, and hearing artifacts due to the interaction of the external magnetic field \vec{B} of the MRI with the implanted device.

[0006] Therefore, implants with removable magnets have been developed. Fig. 3 shows a portion of a typical implant system using magnets according to one approach used in the prior art. An external transmitter housing **301** includes transmitting coils **302** and an external magnet **303**. The external magnet **303** has a conventional coin-shape and north and south magnetic poles as shown which produce external magnetic field lines **304**. Implanted under the patient's skin is a corresponding receiver assembly **305** having similar receiving coils **306** and an implanted internal magnet **307**. The internal magnet **307** also has a coin-shape and north and south magnetic poles as shown which produce internal magnetic field lines **308**. The internal receiver housing **305** is surgically implanted and fixed in place within the patient's body. The external transmitter housing **301** is placed in proper position over the skin covering the internal receiver assembly **305** and held in place by interaction between the internal magnetic field lines **308** and the external magnetic field lines **304**. Rf signals from the transmitter coils **302** couple data and/or power to the receiving coil **306** which is in communication with an implanted processor module (not shown).

[0007] The arrangement in Fig. 3 differs from the earlier prior art in that the implant is designed so that the internal magnet 307 is removable by a first pre-MRI surgery. This eliminates the problems of torque, demagnetization, and image artifacts caused by the magnet during the MRI procedure. Then, after the MRI, a second post-MRI surgery is necessary to replace the internal magnetic 307. While this arrangement allows implant users to receive MRI's when necessary, the requirement for two surgeries raises issues and problems of its own.

Summary of the Invention

[0008] Embodiments of the present invention are directed to a method of operating a magnetic resonance imaging (MRI) system. A magnetic element in an implanted medical device is demagnetized by exposing it to an external demagnetizing magnetic field. Magnetic resonance imaging of the patient is performed. Then the magnetic element is remagnetized without removing it from the implanted medical device by exposing the magnetic element to an external remagnetizing magnetic field.

[0009] In various specific embodiments, the magnetic resonance imaging may be performed after or while generating the demagnetizing magnetic field. The MRI system may be a high field MRI system, for example, a 3T or 6T MRI system. In some embodiments, the implanted medical device may be a cochlear implant system.

[0010] Embodiments of the present invention also include an implanted medical device processed by any of the above methods.

Brief Description of the Drawings

[0011] Fig. 1 shows a portion of a typical idealized cochlear implant which may be used in embodiments of the present invention.

[0012] Fig. 2 shows effects of an external magnetic field on an implanted portion of an implanted device which may be used in embodiments of the present invention.

[0013] Fig. 3 shows a portion of a typical implant system using magnets according to embodiments of the present invention.

[0014] Fig. 4 shows a portion of a typical implant system using a low-torque magnet according to embodiments of the present invention.

[0015] Fig. 5 shows an example of an implantable medical device and an MRI system suitable for use with a method according to an embodiment of the present invention.

Detailed Description of Specific Embodiments

[0016] Embodiments of the present invention are directed to techniques for magnetic resonance imaging which reduce the torque exerted on magnet elements of implanted medical devices, reduce MRI imaging artifacts produced by magnetic field distortions related to the implanted magnetic elements, and also reduce linear force created on such implanted magnetic elements. This is accomplished without first removing the magnet element (or any other part of the implanted medical device) before the MRI scan is performed.

[0017] Some MRI related problems recently have been addressed by using an implanted magnet structured to avoid producing torque in an MRI field. One example of such an arrangement is shown in Fig. 4, which is based on the disclosure of U.S. Patent Publication 20060244560, the contents of which are incorporated herein by reference. The external transmitter housing **401** is basically the same as in Fig. 3, with transmitting coils **402** and an external magnet **403**. The implanted receiver assembly **404** has corresponding receiving coils **405** and an implanted internal magnet **406**, as well as connecting wiring **407** to a separate processor module. But in Fig. 4, the internal magnet **406** has a cylindrical or spherical shape. A ball-shaped welded case **408** (e.g., of titanium or niobium) hermetically encapsulates and isolates the internal magnet **406** from the body tissues (otherwise, it might rapidly corrode). As a result, the internal magnet **406** is able to rotate to re-align itself to an external MRI magnetic field without producing a torque, becoming demagnetized, or creating induced voltages, etc. This avoids many of the problems of the earlier arrangement shown in Fig. 3. Typically, a patient having an implant as shown in

Fig. 4 may undergo MRI without surgeries to remove and replace the internal magnet **406**. But even in this arrangement, there may still be imaging artifacts due to the internal magnet **406**, especially in the nearby region adjacent to the magnet.

[0018] Embodiments of the present invention may be used in conjunction with an implanted medical device such as the structures shown in Figs. 1-4 while avoiding some of the problems described above. With reference for example to Figure 4, a magnetic element in an implanted medical device, such the internal magnet **406** in the implanted receiver assembly **404**, is demagnetized by exposing it to an external demagnetizing magnetic field. Magnetic resonance imaging of the patient is performed. Then the magnetic element is remagnetized without removing it from the implanted medical device by exposing the magnetic element to an external remagnetizing magnetic field.

[0019] Depending on various factors, the magnetic element may be demagnetized either before or while performing the magnetic resonance imaging. As shown in Fig. 5, before the MRI scan, the magnetic element **52** in an implanted medical device may be demagnetized by the magnetic field **51** of the MRI scanner **50**. For example, it has been demonstrated with a 6T-MRI scanner that pre-scan demagnetization can be accomplished by correctly orienting the head of the patient in front of the bore of the scanner **50** and applying the magnetic field **51**. Then, the patient's head can be reoriented as desired for correct MRI imaging and the patient may full enter the bore of the scanner **50** for normal MRI imaging. Post-imaging, remagnetization of the magnetic element **52** can be performed by correctly re-orienting the head of the patient in front of the bore of the scanner **50** and reapplying the magnetic field **51**.

[0020] In an alternative embodiment, if the imaging artifacts are of lesser concern, the demagnetization of the magnetic element **52** can be allowed to occur during the normal MRI scanning, and only the remagnetization part of the procedure might be needed. For example, this could be applied as a standard procedure with 3T MRI-scanners which will be used more and more in the future. If reducing imaging artifacts is of greater importance, e.g., in neurofibromatosis II patients where one is concerned with tumor regrowth after surgical removal (especially in the vicinity of the magnetic element such as a cochlear

implant structure), the demagnetization may be preferred to be more pronounced, and so a demagnetization process may use a high field MRI-machine (e.g., 6T or higher) before the actual imaging scan, and, of course, a remagnetization process afterwards.

[0021] Although various exemplary embodiments of the invention have been disclosed, it should be apparent to those skilled in the art that various changes and modifications can be made which will achieve some of the advantages of the invention without departing from the true scope of the invention.

What is claimed is:

1. A method of operating a magnetic resonance imaging (MRI) system, the method comprising:
 - demagnetizing a magnetic element in an implanted medical device by exposing it to an external demagnetizing magnetic field;
 - performing magnetic resonance imaging of the patient; and
 - remagnetizing the magnetic element without removing it from the implanted medical device by exposing the magnetic element to an external remagnetizing magnetic field.
2. A method according to claim 1, wherein the magnetic resonance imaging is performed after exposing the magnetic element to the demagnetizing magnetic field.
3. A method according to claim 1, wherein the magnetic resonance imaging is performed while exposing the magnetic element to the demagnetizing magnetic field.
4. A method according to claim 1, wherein the MRI system is a high field MRI system.
5. A method according to claim 4, wherein the high field MRI system is at least a 3T MRI system.
6. A method according to claim 4, wherein the high field MRI system is at least a 6T MRI system.
7. A method according to claim 1, wherein the implanted medical device is a cochlear implant system.
8. An implanted medical device processed by a method according to any of claims 1-7.

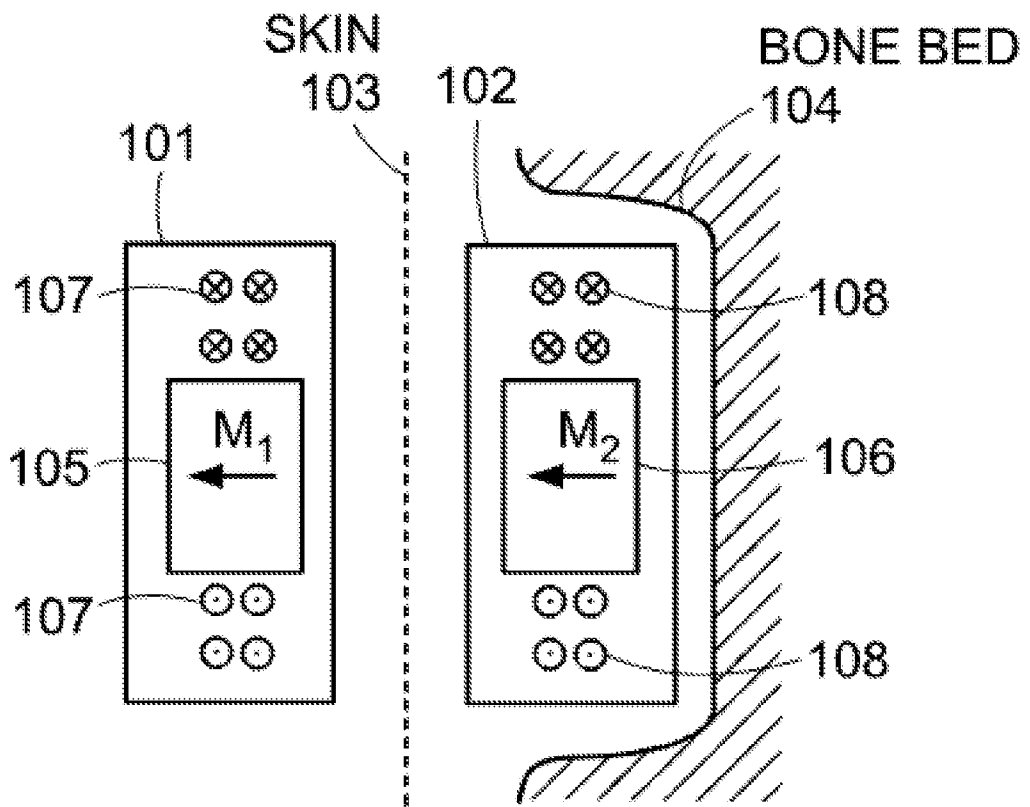


FIG. 1

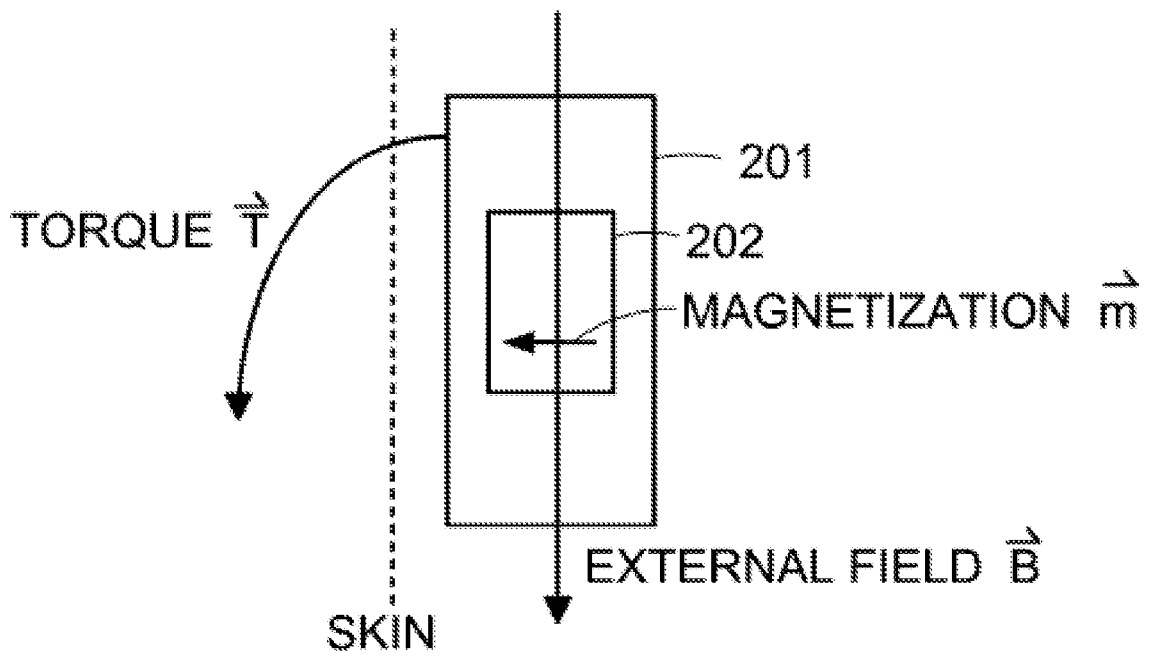


FIG. 2

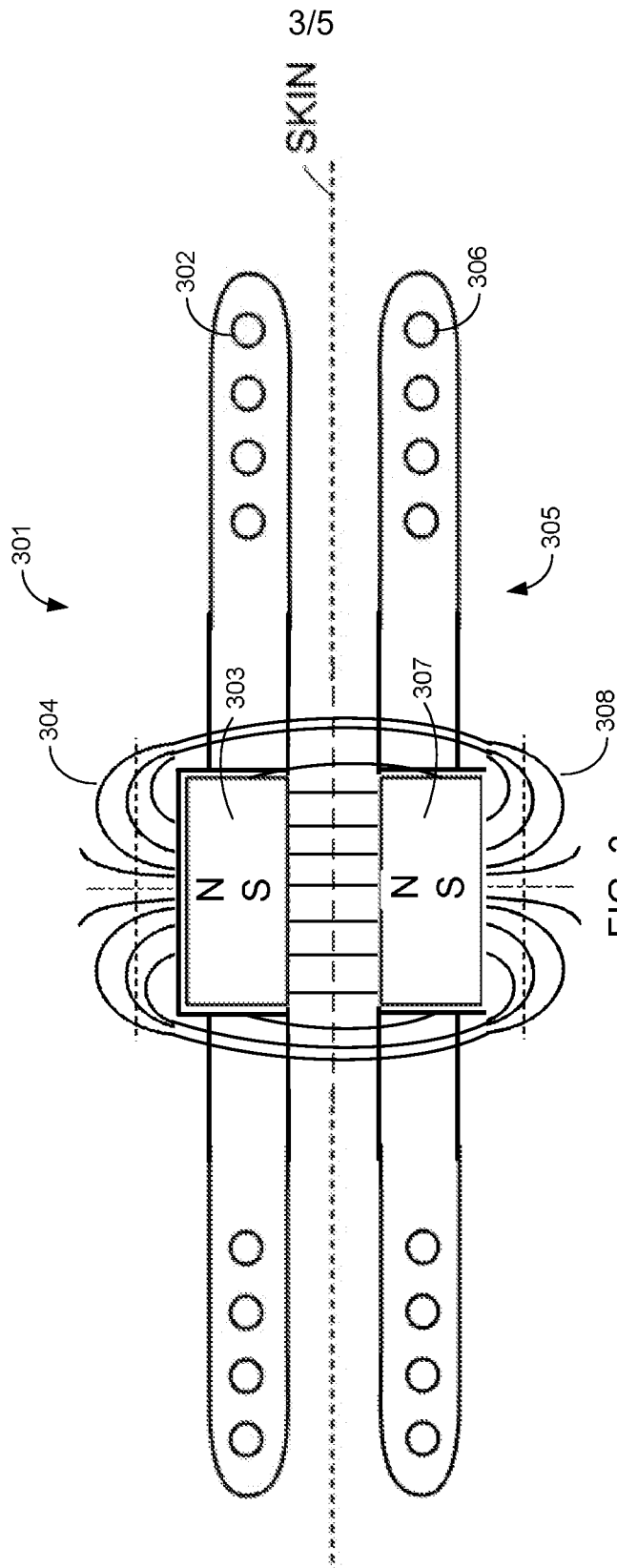


FIG. 3

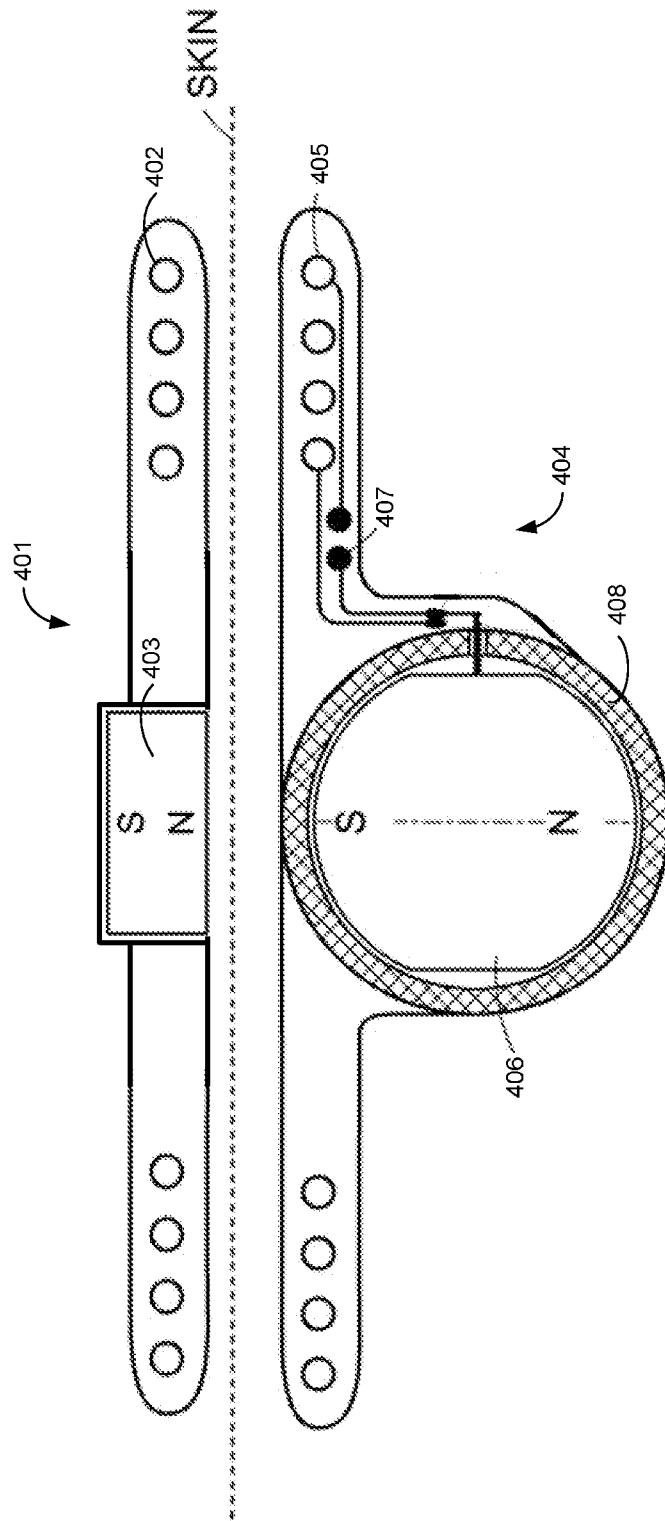


FIG. 4

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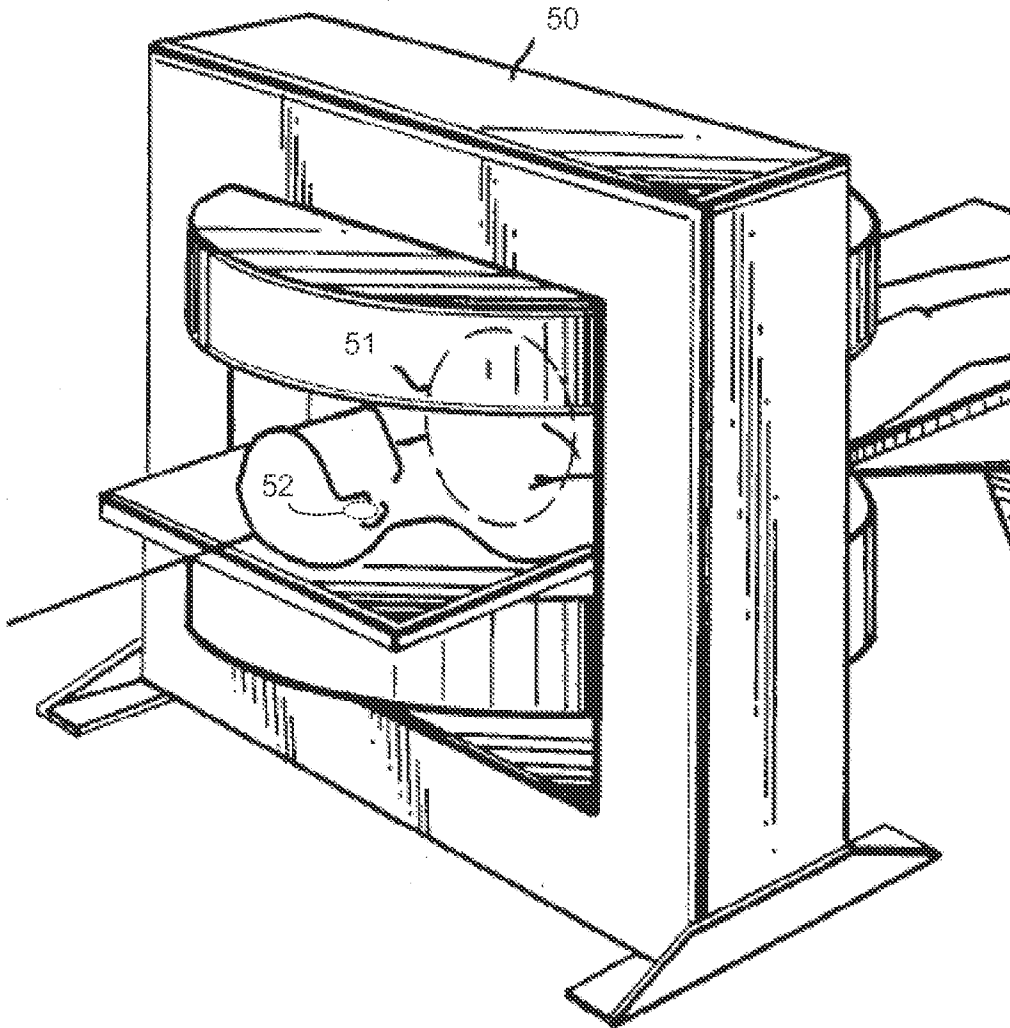


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/055 H04R25/00 A61N1/372 A61F2/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B G01N A61N H04R A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 178 353 B1 (GRIFFITH GLEN A [US] ET AL) 23 January 2001 (2001-01-23) abstract; figures 3B,8 column 1, line 8 - column 2, line 14	8
A	column 9, line 47 - column 10, line 43	1-7
X	US 2006/244560 A1 (ZIMMERLING MARTIN [AT] ET AL) 2 November 2006 (2006-11-02) cited in the application abstract; figures 1-3 paragraphs [0003] - [0008], [0047] - [0050]	8
A		1-7
A	US 6 348 070 B1 (TEISSL CHRISTIAN [AT] ET AL) 19 February 2002 (2002-02-19) abstract; figure 1 column 1, line 9 - column 4, line 3	1-8
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 Further documents are listed in the continuation of Box C. See patent family annex.

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Date of the actual completion of the international search

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International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,T	WO 2008/014245 A (MED EL ELEKTROMED GERAETE GMBH [US]; HOCHMAIR ERWIN S [AT]; HOCHMAIR I) 31 January 2008 (2008-01-31) paragraphs [0005] - [0007] -----	1-7
T	TEISSL C ET AL: "Magnetic resonance imaging and cochlear implants: compatibility and safety aspects." JOURNAL OF MAGNETIC RESONANCE IMAGING : JMRI JAN 1999, vol. 9, no. 1, January 1999 (1999-01), pages 26-38, XP002503038 ISSN: 1053-1807 abstract pages 27-29, 33 -----	1-7
T	RISI F ET AL: "Magnetic resonance imaging safety of Nucleus(R) 24 cochlear implants at 3.0 T" INTERNATIONAL CONGRESS SERIES, EXCERPTA MEDICA, AMSTERDAM, vol. 1273, 1 November 2004 (2004-11-01), pages 394-398, XP004618864 ISSN: 0531-5131 abstract paragraphs [03.6], [03.7], [0004] -----	1-7

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/069738

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6178353	B1	23-01-2001	NONE	
US 2006244560	A1	02-11-2006	US 2004012470 A1 US 2005062567 A1	22-01-2004 24-03-2005
US 6348070	B1	19-02-2002	NONE	
WO 2008014245	A	31-01-2008	US 2008021518 A1	24-01-2008