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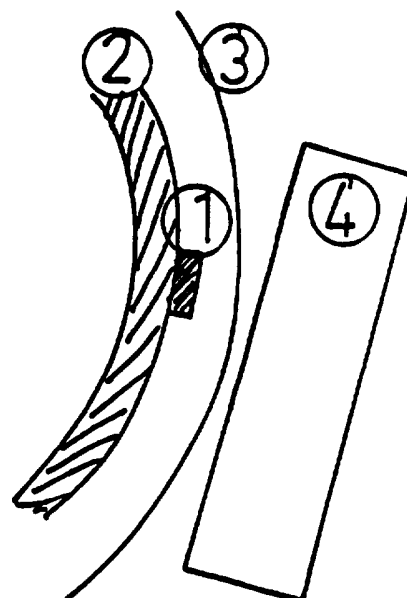
*Before the expiration of the time limit for amending the
claims and to be republished in the event of the receipt of
amendments.*

In English translation (filed in Swedish).

(54) Title: USE OF IMPLANT WITH MAGNETIC PROPERTIES TO DETERMINE THE POSITION OF A PATIENT

(57) Abstract

Use of an implant having magnetic properties for reproducible determination of the position of a patient in time in relation to external treatment equipment, and an apparatus for reproducibly determining the position of a patient in relation to external treatment equipment. The apparatus comprises at least one magnetic device (1) which is so designed that it can be attached to a body part, the position in relation to the intended treatment target is substantially constant, and at least one sensor means (4) which is capable of detecting magnetic fields and/or changes of magnetic fields for determining the position of the patient in the space based thereon.



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Use of implant with magnetic properties to determine the position of a patient.

Technical Field

The present invention relates to the determination of the position of special points or areas on or in live creatures. The term live creatures relates to both humans and animals and they will in the following specification and claims, for simplicity reasons, jointly be called "patients".

Background of the Invention

In medicine it is common to make diagnoses, perform other investigations and treat patients by means of external equipments such as x-ray apparatuses, radiation treatment apparatuses and other types of apparatuses. For simplicity reasons such external diagnosis, other investigation or treatment will in the following jointly be referred to as "treatment". In many cases it is necessary to be able to reproduce the position of the patient in relation to the external equipment as accurately as possible in all space dimensions from one treatment to another. This is in particular true when the treatment might cause damages on surrounding organs, tissue etc., like in, for example, the case with radiation treatment.

Disclosure of Prior Art

The presently most common method for determining the position of a patient in relation to the external treatment-equipment from one treatment to another, is to make markings on the skin of the patient, for example in the form of "crosses" or the like. This procedure is not very reliable since the skin moves in relation to the internal organs, tissues, etc. which are to be treated. There is, therefore, a great chance that the treatment, in particular if it is radiation treatment, damages healthy internal organs, tissues, etc. in the patient. There is therefore a great need of being able to accurately and in a reproducible manner be able to align a patient in relation to the external equipment from one treatment to another.

It is also previously known to use magnetic implants for various purposes. One example is US-A-4,978,323 which discloses systems and methods in which magnets are used for preventing opturation of such body channels, especially the air ducts, in which gas or liquid has to be able to flow. A combination of implanted and external permanent magnets, or only implanted magnets, are used in order to keep the body channel in question open. As an alternative to implanted

magnets, for the same purpose, there are disclosed magnets which are swallowed by the patient as a "pill". An electronic system such as a Hall element can be used for e.g. checking that the magnets fulfil their function to keep the body channel in question open. Also disclosed is the use of magnets for keeping
5 prostheses or endotracheal tubes in place.

US-A-5,125,888 discloses a method for transporting, by means of an electromagnetic field, a drug with attached magnetic object to a desired location in the body, especially the brain, for administration of the drug to that spot, and retraction of the magnetic object.

10 SU-A-1,338,154 discloses a method of matching the radiation parameters in proton therapy, wherein detectors interrupt the treatment if permitted radiation parameters are exceeded.

FI,B,79458 discloses a method and a device for eliminating errors which are caused by the patient's movements in a treatment situation, wherein a mark is
15 made on the skin in the very treatment area. The momentaneous position of this mark is followed by continuously determining the position coordinates of the mark, and treatment is started when the position coordinates of the mark correspond to pre-determined comparison coordinates.

WO,A1,93/00039 discloses a device for detecting and localizing, by means
20 of an electromagnetic field, a metallic object which has been penetrated or implanted into a human or animal body.

There are also a number of publications which make use of similar methods and devices for detecting objects in a human and animal body, e.g. SE 0314231, SE 0193509, US-A-4,987,309, US-A-4,502,147, JP 63-286170, US-A-4,618,980, US-
25 A-4,445,501 and FI 81012.

In summary it is true that the above indicated documents make use of magnets as implants in connection with medical treatment, but none of said documents neither indicate or intimate the use of magnetic implants for solving the above mentioned problems with reproducible determination of the position
30 of a patient on different occasions.

Short Description of the Drawing

An example of the presently preferred embodiment of the invention is illustrated in the enclosed drawings, in which

Figure 1 is a diagrammatic sectional view showing a patient having a
35 magnetic implant and an external sensor, and

Figure 2 is a schematic elevational view showing an example of external equipment for recordal and presentation of the position of the implant in the body.

Description of the Invention and Preferred Embodiments

5 In Figure 1 the reference numeral 1 shows a magnetic implant which e.g. may be an implanted permanent magnet. It is, however, within the scope of the invention possible to choose an arbitrary implant having the ability to produce, as such or in combination with any other material, produce detectable magnetic fields (including electromagnetic fields) and/or changes of magnetic fields, etc.

10 In accordance with the invention the implant 1 is attached to a suitable body part 2 which, in contrast to the skin, has a comparatively constant position in the body. In the shown embodiment the body part is a bone in the body. Reference numeral 3 represents the skin of the patient. It is preferred to position the implant as close as possible to the respective area of treatment, but outside
15 the same. It can also often be suitable to encapsulate the implant in a more tissue-friendly material. The implant is also preferably provided with devices and/or materials which are known per se and makes an accurate securing of the implant in bones possible, for example screws, plates, orthopedical supports and the like.

20 In an alternative embodiment the implant can be an "explant", i.e. be located in a corresponding position outside the body, preferably in the vicinity of, and positionally connected to, underneath parts, e.g. a bone.

The schematically shown device 4, which is located outside the patient, represents one or more sensors detecting magnetic fields and/or changes of
25 magnetic fields, e.g. from the implant 1 and/or another device cooperating therewith.

The number and the type of sensors, implants and detection method will be chosen with regard to i.a. the desired accuracy. Thus, the magnetic field can be generated in any manner which fulfil the indicated purpose, for example by
30 means of permanent magnets, induction with in-operated spool and power source in or outside the body. It is also possible, by induction to build up a voltage in the implant which subsequently can provide a magnetic field through a spool. It is not necessary for the implant as such to generate a magnetic field, but it can be so designed that its magnetic properties will change the applied magnetic field
35 (for example a steel plate), and this change will be detected by the sensor. Thus

the implant as such does not have to provide a magnetic field but only provide a change of a magnetic field, applied from the outside. In this case the implant has magnetic properties which can be detected by the sensor. It is also possible to combine an outer magnetic field with a magnetic field which is generated by the
5 implant in an optional manner.

Since the implant does not have to be magnetic as such, but is capable of acting by induction, it will be possible to use e.g. magnetically insensitive spools of copper which do not interfere with investigations using magnetic resonance tomography.

10 Since the position of the sensor 4 is known, the position of the implant/explant 1 can be calculated in a simple manner. Since the position of the implant in the patient is known, as is also its relation to the target of the treatment such as a radiation target, it is also possible to determine the positions for the patient and the target of the treatment.

15 The design of the sensors 4 can be varied as needed in the individual case, from a simple spool to more advanced elements which are sensitive to magnetic fields, e.g. Hall instruments, magnetic resistive sensors or the like which together build up a sensor. Such a sensor may contain one or more elements of the same or different type which are sensitive to magnetic fields. The elements may be
20 grouped into different configurations (circular, in rows, etc.). The sensors may be movable or stationary. The elements of the sensors can also be immobile or movable in order to increase the area in which the magnetic field is detected. This is technique which is well known as such and which a person skilled in the art can apply on the present invention without any further description.

25 Figure 2 shows a sensor 4 built-up from 25 analogous Hall sensors which are arranged in 5 rows of 5 sensors each. By reading the signals from the sensors into a computer 6, using an analogue-to-digital converter 5, each sensor can be read rapidly. Each sensor provides a voltage which is proportional to the magnetic field in which it is located. The magnets which are located closer to the center of
30 the magnetic field provide the maximum deflection. By using this device the center of the magnetic field can be determined accurately in two directions and the accuracy increases when using more devices.

The invention is not intended to be restricted to the embodiments which have been described and/or shown, but many modifications and variations are
35 possible within the scope of the appended claims.

CLAIMS

1. Use of an implant having magnetic properties for in time reproducible determination of the position of a patient in relation to external treatment equipment.
- 5 2. Use according to claim 1,
characterized in that the implant comprises a permanent magnet.
3. Use according to claim 1,
characterized in that the implant comprises at least one material which, in co-
operation with at least one external material, producing a magnetic field by
10 means of which the position of the patient in the space can be determined.
4. Use according to any one of claims 1 to 3,
characterized in that the implant is attached to a body part whose position in
relation to an intended treatment target is substantially constant.
5. Use according to any one of claims 1 to 4,
15 **characterized in that** the body part is a bone in the body.
6. Use according to any one of claims 1 to 5,
characterized in that the implant is an explant.
7. A device for in time reproducible determination of the position of a patient
in relation to external treatment equipment,
20 **characterized in that** it comprises
 - a) at least one device (1) which has magnetic properties and is so designed
that it can be attached to a body part, the position of which is substantially
constant in relation to an intended treatment target,
 - b) at least one sensor device (4) being capable of detecting a magnetic field
25 and/or changes of a magnetic field and, based thereon, determine the position of
the patient in the space.

1/1

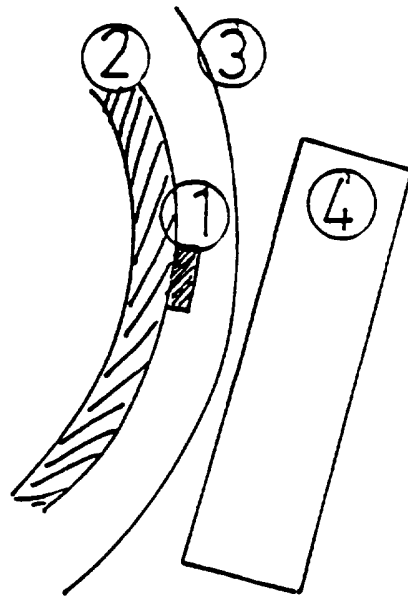


Fig. 1

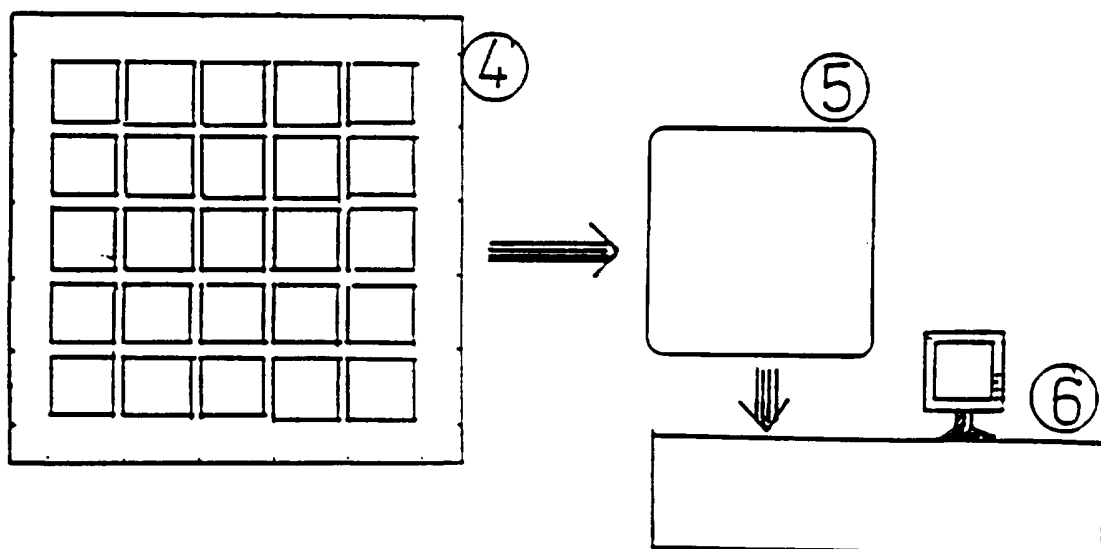


Fig. 2

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 95/01082

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/06

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)

IPC6: A61B, G01V, H03K

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

SE,DK,FI,NO classes as above

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

WPI, CLAIMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FI 79458 B (SEPPO PELTOLA), 29 Sept 1989 (29.09.89), figure 1, abstract	1-5
X	--	7
Y	WO 9300039 A1 (STEINBECK ULRICH), 7 January 1993 (07.01.93), page 3, line 13 - page 4, line 3, figure 1	1-5
A	US 4445501 A (R.G. BRESLER), 1 May 1984 (01.05.84), figure 1, abstract	1-5
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☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "B" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

18 January 1996

Date of mailing of the international search report

19 -01- 1996

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Swedish Patent Office
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 95/01082

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4943770 A (C. ASHLEY-ROLLMAN ET AL.), 24 July 1990 (24.07.90), figure 2, abstract --	1-5
P,A	WO 9424933 A1 (ST. LOUIS UNIVERSITY), 10 November 1994 (10.11.94), page 31, line 1 - page 32, line 10, figures 9-11 -- -----	1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE95/01082

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 6
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Since the term "explant" according to the application is the opposite of the term "implant", claim 6 is contradictory to claim 1. Consequently, claim 6 is so unclear that no search can be carried out (Rule 6.4(b)).

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐

The additional search fees were accompanied by the applicant's protest.

☐

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

11/12/95

International application No.

PCT/SE 95/01082

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
FI-B-	79458	29/09/89	NONE		
WO-A1-	9300039	07/01/93	DE-U-	9107798	10/10/91
US-A-	4445501	01/05/84	CA-A-	1202398	25/03/86
			DE-A-	3217234	16/12/82
			FR-A,B-	2505167	12/11/82
			GB-A,B-	2102127	26/01/83
			JP-A-	58001436	06/01/83
			US-A-	4416289	22/11/83
US-A-	4943770	24/07/90	DE-A-	3813479	10/11/88
			FR-A-	2617395	06/01/89
			GB-A-	2204133	02/11/88
			JP-A-	64002655	06/01/89
WO-A1-	9424933	10/11/94	NONE		