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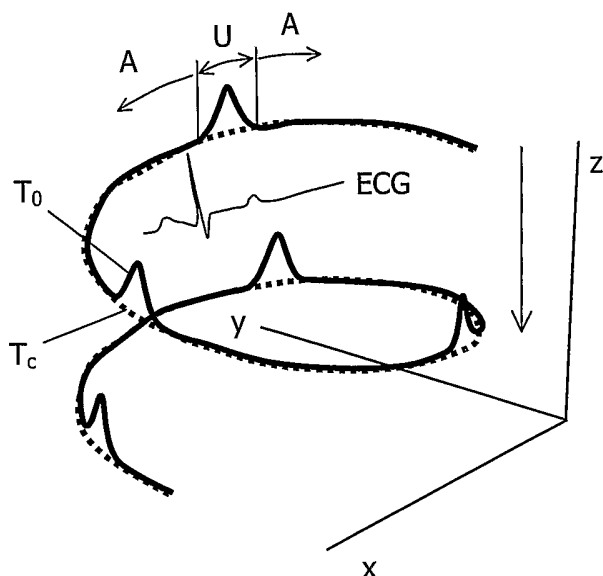
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(54) Title: APPARATUS AND METHOD FOR NAVIGATING A CATHETER



(57) Abstract: The invention relates to a navigation system for guiding a catheter in a patient's vascular system, where the spatial position of the catheter and its orientation are continually measured by a locating device. The resulting trajectory ( $T_0$ ) of the catheter contains movement artefacts on account of the heartbeat. In order to suppress said movement artefacts, the electrocardiogram (ECG) is recorded in parallel, and the position and orientation signals are suppressed during phases of strong heart movement (QRS peak). Preferably, extrapolation of the compensated trajectory ( $T_c$ ) is carried out in the gaps arising as a result of signal suppression.

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## Apparatus and method for navigating a catheter

The invention relates to a navigation system and a method for navigating a catheter in a vascular system which is subject to a cyclic intrinsic movement.

During a catheter examination carried out for diagnostic or therapeutic purposes, it is extremely important for the treating physician to know the current position of the instrument (catheter tip, guidewire, etc.) in the patient's vascular system in as precise a manner as possible. In clinical practice, this aim is usually achieved in that the movement of the catheter in the patient's body is subject to X-ray monitoring, wherein possibly radio-opaque markers are applied to the catheter. In order to have on the X-ray images also a best possible representation of the course of the vessel, an X-ray contrast agent is moreover injected from time to time. However, this procedure has the disadvantage of being a relatively high strain on the patient on account of the X-ray radiation and the contrast agent and – in terms of the X-ray radiation – also on the medical staff.

For the reasons given above, a catheter navigation is desired in which only a few X-ray images of the vascular system have to be taken with administration of a contrast agent and the catheter is then monitored on these static images or "road maps". The current spatial position and orientation of the catheter must in this case be determined by suitable methods such as, for example, location by means of a magnetic field. However, such a procedure using static road maps runs into problems when the monitored body volume moves and therefore no longer geometrically coincides with the static road maps. An overall movement of the patient may in this connection be practically ruled out as a cause of error by measures such as careful instruction, steady positioning and sedation of the patient. However, cyclic intrinsic movements of the organs of the body by breathing and heartbeat cannot be avoided. These movements are obviously particularly disruptive during examinations of organs in the chest area, such as the coronary vessels.

In this respect, DE 199 46 948 A1 discloses a method which tries to achieve better position accuracy by using a number of road maps which are taken at different phases of a cyclic intrinsic movement of the body. In this case, an image database comprising a number of three-dimensional images of a periodically moving organ of the body, such as the heart for example, is generated prior to a catheter examination, with a movement signal

(ECG, breathing signal) being recorded at the same time as the images. During the subsequent medical intervention, the spatial position of the instrument and also of a reference probe are determined by means of a locating device and the movement signal is recorded at the same time. By means of the movement signal, the relevant 3D image in terms of the movement phase of the organ of the body can then be selected from the image database and used for display purposes. One disadvantage of the known method is in particular the high outlay associated therewith.

Against this background, it is an object of the present invention to provide means for the simpler navigation of an instrument in a vascular system, with compensation of cyclic intrinsic movements of the body.

This object is achieved by a navigation system having the features of claim 1 and by a method having the features of claim 10. Advantageous refinements are contained in the dependent claims.

The navigation system according to the invention is used to navigate a catheter in a vascular system which is subject to a cyclic intrinsic movement caused by the heartbeat. In this case, the term "catheter" is to be understood in a broad sense and hereinafter encompasses any instrument which is to be moved in a controlled manner through the vascular system of a patient. The navigation system comprises the following components:

a) A locating device which is designed to record a temporal sequence of position signals, with each of the position signals indicating the spatial position of the catheter at the associated measurement time. In this connection, the term "position of the catheter" is to be understood to mean the spatial position  $r$ , expressed for example by Cartesian coordinates, of at least one selected point of the catheter, with the term "position" possibly also encompassing the orientation of the catheter expressed for example by three angles. Furthermore, the term "temporal sequence" refers to the fact that for each position signal the associated measurement time  $t$  is known as a temporal coordinate. The sequence therefore typically consists of spatial-temporal coordinates  $(r, t)$ .

b) A measuring system for recording an electrocardiogram. The measuring system typically contains at least two electrodes by means of which the excitation potential of the heart can be derived. The electrodes may be attached externally to the body of the patient or be integrated in the catheter.

c) A data processing device which is coupled to the locating device and the measuring system and is designed to generate a compensated trajectory from the sequence of position signals, the compensated trajectory being obtained from the sequence by changing

position signals that have been recorded during a predefined phase of the electrocardiogram. The change in a position signal may in particular consist in removing the latter or in replacing the latter by one or more replacement signals. Depending on the technical implementation of the navigation, a position signal can be "removed" by the obtaining thereof being suppressed  
5 during the predefined ECG phase. The predefined phase of the electrocardiogram is typically defined such that it corresponds to a strong spatial movement of the heart. In particular, the predefined phase of the ECG may therefore correspond to the systoles of the heartbeat.

By changing position signals during phases of a strong movement of the heart, the navigation system can generate a compensated trajectory which describes the position of  
10 the catheter without the disruptive influence of a heart movement. The compensated trajectory can therefore be used in particular to show the position of the catheter on a static road map which has been recorded during a heart phase outside the predefined signal change phases. The calculation of an informative compensated trajectory is therefore particularly possible because the spatial movement of the heart is essentially limited to phases of the heart  
15 cycle that can be clearly determined. Typically, a change of position signals must therefore take place approximately during 70% of the duration of a trajectory, whereas the trajectory can be used unchanged the rest of the time.

In the simplest case, the position signals are removed without being replaced during the predefined phases of the electrocardiogram. The compensated trajectory then  
20 contains gaps during which there are no position signals. Preferably, these gaps in the compensated trajectory are filled by interpolating and/or extrapolating retained position signals. An interpolation can be used if the compensated trajectory contains retained position signals before and after, in time terms, a gap that is to be filled. In the simplest case, the gap can in this case be closed by a linear interpolation between the last position signal before the  
25 gap and the first position signal after the gap. In many applications, this will primarily involve displaying, in real time, a currently measured trajectory for the treating physician. If the trajectory is therefore in a phase of the heart cycle in which its position signals are suppressed, no interpolation is possible since the continuation of the trajectory after the end of the suppression phase is (as yet) unknown. Thus, in order to be able to provide the treating  
30 physician with a current representation of the (approximate) catheter position, in these cases an extrapolation of the recorded trajectory in the gap will be carried out. This means that the profile of the trajectory in the gap is predicted on the basis of previous trajectory values.

A Kalman filter is preferably used for the abovementioned extrapolation of the trajectory. The Kalman filter allows the ideal prediction of the trajectory on the basis of a

model on which the filter is based, the parameters of which are continuously adapted to the movement at any given time. It can be calculated relatively simply at the same time.

As mentioned above, the heartbeat and breathing are the most important cyclic intrinsic movements of the body which make navigation of a catheter more difficult. The trajectory generated by the navigation system, which has been compensated with respect to the heartbeat, thus usually still contains disruptions on account of breathing. The data processing device is therefore preferably also designed to correct the compensated trajectory with respect to an intrinsic movement of the vascular system caused by breathing.

In this respect, in the event of an optional type of breathing correction the data processing device is designed to carry out the following steps:

a) Calculation of a movement pattern caused by breathing from part-sections of the compensated trajectory in which there has been no movement (no advance or retreat) of the catheter relative to the vascular system. If required, the compensated trajectory is characterized in that the movement parts caused by the heartbeat are already eliminated. In one part-section – that is to say a group of temporally successive position signals – of the compensated trajectory in which it is known that there has been no relative movement of the catheter in the vascular system, any location change in the compensated trajectory must therefore be caused by the breathing movement. Such part-sections are therefore suitable for recognizing the movement pattern present at the associated location of the vascular system and caused by breathing. The movement pattern can in this case be described for example by periodically time-dependent difference vectors which on the basis of a spatially constant reference point allocate each point in time to a predefined point of the vascular system on the compensated trajectory. Part-sections of the compensated trajectory in which there is no relative movement of the catheter are preferably detected by an additional device in the navigation system, which additional device records for example an advance or a retreat of the catheter in the vascular system and provides this information in addition to the recorded sequence of the position signals.

b) Correction of the compensated trajectory by subtracting the movement pattern calculated in step a).

According to one variant for correcting the breathing movement, the data processing device is designed to correct the compensated trajectory by applying a spatial extrapolation filter (e.g. Kalman filter) on the basis of a previously determined movement pattern.

According to another development of the navigation system, the latter may comprise a breathing sensor that is coupled to the data processing device. A breathing sensor supplies a signal which represents a characteristic point in time of the breathing cycle and/or the phase profile of the breathing cycle. With the aid of this signal, the breathing correction  
5 of the trajectory can be compared and thus made even more precise, or alternative methods for correcting breathing movements may be used.

The invention furthermore relates to a method of navigating a catheter in a vascular system which is subject to a cyclic intrinsic movement caused by the heartbeat. The method comprises the following steps:

- 10 a) Recording of a temporal sequence of position signals which indicate the respective spatial position (position and possibly orientation) of the catheter.
- b) Recording of an electrocardiogram in parallel, in time terms, with the sequence of position signals according to step a).
- c) Determination of a predefined phase of the electrocardiogram. This may be  
15 in particular the phase of a systole which corresponds to a relatively strong movement of the heart.
- d) Generation of a compensated trajectory from the temporal sequence of position signals recorded in step a), by changing in this sequence those position signals which have been recorded during the predefined phase of the electrocardiogram determined in step  
20 c).

The method comprises in a general manner the steps that can be carried out by the navigation system described above. For details regarding the refinement, advantages and developments of the method, reference should therefore be made to the explanations regarding the navigation system.

25 The compensated trajectory is continued during the predefined phases of the electrocardiogram preferably by means of an interpolation or extrapolation. In this way, the gaps resulting from the removal of position signals can be at least more or less closed, so that a continually updated position of the catheter is available to the treating physician.

30

The invention will be further described with reference to examples of embodiments shown in the drawings to which, however, the invention is not restricted.

Fig. 1 schematically shows the use of a navigation system according to the invention in a catheter examination of coronary vessels.

Fig. 2 shows a spatial representation of a measured catheter trajectory  $T_0$  and of a trajectory  $T_c$  that has been compensated with respect to the heartbeat, and also as an inset the parallel profile of the electrocardiogram.

Fig. 3 shows the profile of a typical electrocardiogram with the phases in  
5 which position signals are to be suppressed.

Fig. 1 schematically shows the components of a navigation system according to the invention, by means of which a catheter 3 can be guided in the vascular system 10 of a  
10 patient in order for example to examine the coronary vessels of the heart 11. At the tip of the catheter 3 there is a magnetic field probe 2 which can be used to measure the strength and direction of a magnetic field 1 impressed on the space by a field generator (not shown). The resulting measured signal is forwarded to a data processing device 5 (computer), where information about the current absolute spatial position of the probe 2 and hence of the  
15 catheter 3 can be obtained from the measured signals. The probe 2 is thus a locating device which supplies a temporal sequence of position signals relating to the current position  $\underline{r}(t) = (x(t), y(t), z(t))$  and orientation  $\phi(t) = (\alpha(t), \beta(t), \gamma(t))$  ( $\alpha$  = yaw angle,  $\beta$  = angle of inclination,  $\gamma$  = roll angle,  $t$  = time) of the catheter 3. Instead of the position determination with the aid of a magnetic field 1 which is shown by way of example, other methods could of  
20 course also be used to determine the current position and possibly orientation of the catheter 3.

The navigation system furthermore comprises electrodes 6, 7 for recording an electrocardiogram and also a breathing sensor 8 which monitors for example the movement of the diaphragm 9. The signals from these sensors are likewise passed to the data processing  
25 device 5.

In order to minimize the exposure of the patient to X-ray radiation and contrast agent injections, it is endeavored that the movement of the catheter 3 be monitored on a few static X-ray images of the vascular system 10, known as "road maps". In this case, however, the intrinsic movement of the vascular system 10 in the thorax cavity 4 caused by the  
30 heartbeat and by breathing must be taken into account and compensated. In this respect, Fig. 2 shows the profile of a trajectory  $T_0$  in a spatial coordinate system with the axes  $x$ ,  $y$  and  $z$ , said trajectory being formed from the sequence of position signals  $\underline{r}(t)$  supplied by the magnetic sensor 2. The trajectory  $T_0$  shows, in the center, a movement running in the direction of the arrow which corresponds to the advance of the catheter along the vessel, this

advance being performed by the physician. However, deflections caused by the heartbeat are superposed on this movement (these being shown in the figure as transverse deflections relative to the vessel).

For part of the trajectory  $T_0$ , Fig. 2 shows in parallel the electrocardiogram (“ECG”) recorded at the same time. Deflections of the catheter which are caused not as a result of an advance of the catheter along the vessel but rather by the heartbeat are essentially restricted to the systolic phases of the heartbeat.

Fig. 3 shows an electrocardiogram in greater detail. The characteristic points of the ECG are denoted by the letters P, Q, R, S and T in the conventional manner. The systole  $Sy$  of the heart corresponds to the RST region, whereas the diastole  $Di$  encompasses the points P and Q. From empirical investigations, the ECG phases can be correlated with the resulting heart movement (cf. Y. Wang, E. Vidan, G.W. Bergman: “Cardiac Motion of Coronary Arteries: Variability in the Rest Period and Implications for Coronary MR Angiography”, *Radiology*, 213:751-758, 1999; S. Achenbach, D. Ropers, J. Holle, et al.: “In-Plane Coronary Arterial Motion Velocity: Measurement with Electron Beam CT”, *Radiology*, 216:457-463, 2000). In this way, it is possible to determine a phase U of the ECG during which data of the trajectory  $T_0$  of Fig. 2 are to be removed or suppressed since they contain movement artefacts on account of a strong movement of the heart. As shown in Fig. 3, this phase U of signal suppression contains in particular points Q, R and S of the electrocardiogram. On the other hand, during the remaining phases, denoted “A”, the position signals of the trajectory  $T_0$  are retained unchanged. To analyze the profile of the electrocardiogram, use may be made for example of the methods described in the literature (cf. B.-U. Köhler, C. Hennig, R. Orglmeister: “The Principles of Software QRS Detection”, *IEEE Engineering in Medicine and Biology*, pages 42-57 (2002)).

In the event of the trajectory generated by signal suppression in the phases U of the ECG being displayed directly in real time on a static road map, the catheter position appears frozen during a heart contraction (phase U) since no current position signals are available. As a result, there may be a certain discrepancy between the actual catheter position and the catheter position displayed for example on a monitor. In order to minimize this discrepancy, the profile of the trajectory is preferably extrapolated in the signal suppression gaps. Such an extrapolation may take place for example by means of a Kalman filter (R.E. Kalman, “A New Approach to Linear Filtering and Prediction Problems”, *Transactions of the ASME – Journal of Basic Engineering*, 82 (Series D), 35-45, 1960; P.S. Maybeck: “Stochastic models, estimation, and control, Vol. I”, Academic Press, 1979). The

compensated trajectory obtained by signal suppression in the phases U and subsequent extrapolation is shown in dashed line in Fig. 2 and denoted  $T_c$ .

## CLAIMS:

1. A navigation system for navigating a catheter (3) in a vascular system (10) which is subject to a cyclic intrinsic movement caused by the heartbeat, comprising
- a) a locating device (2) for recording a temporal sequence ( $T_0$ ) of position signals which indicate the respective spatial position of the catheter (3);
  - 5 b) a measuring system (6, 7) for recording an electrocardiogram (ECG);
  - c) a data processing device (5) which is coupled to the locating device (2) and the measuring system (6, 7) and is designed to generate a compensated trajectory ( $T_c$ ) from the sequence ( $T_0$ ) by changing position signals that have been recorded during a predefined phase (U) of the electrocardiogram (ECG).
- 10
2. A navigation system as claimed in claim 1, characterized in that the predefined phase (U) of the electrocardiogram (E) corresponds to the systole (Sy) of the heartbeat.
3. A navigation system as claimed in claim 1, characterized in that the data
- 15 processing device (5) is designed to carry out the change in the position signals by interpolation and/or extrapolation.
4. A navigation system as claimed in claim 3, characterized in that the extrapolation takes place with the aid of a Kalman filter.
- 20
5. A navigation system as claimed in claim 1, characterized in that the data processing device (5) is designed to correct the compensated trajectory ( $T_c$ ) with respect to an intrinsic movement of the vascular system (10) that is caused by breathing.
- 25
6. A navigation system as claimed in claim 5, characterized in that the data processing device (5) is designed to carry out the following steps:
- a) calculation of a movement pattern caused by breathing from part-sections of the compensated trajectory ( $T_c$ ) in which there has been no movement of the catheter (3) relative to the vascular system (10);

b) correction of the compensated trajectory ( $T_c$ ) by subtracting the calculated movement pattern.

7. A navigation system as claimed in claim 5, characterized in that the data processing device (5) is designed to correct the compensated trajectory ( $T_c$ ) by applying an extrapolation filter on the basis of a previously determined movement pattern.

8. A navigation system as claimed in claim 1, characterized in that it has a breathing sensor (8) that is coupled to the data processing device (5).

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9. A method of navigating a catheter (3) in a vascular system (10) which is subject to a cyclic intrinsic movement caused by the heartbeat, comprising the steps:

a) recording of a temporal sequence ( $T_0$ ) of position signals which indicate the respective spatial position of the catheter (3);

15 b) recording of an electrocardiogram (ECG) in parallel with the sequence of position signals;

c) determination of a predefined phase (U) of the electrocardiogram;

20 d) generation of a compensated trajectory ( $T_c$ ) by changing, in the sequence ( $T_0$ ) of position signals, position signals which have been recorded during the predefined phase (U) of the electrocardiogram.

10. A method as claimed in claim 9, characterized in that the compensated trajectory ( $T_c$ ) is continued during the predefined phase (U) of the electrocardiogram (ECG) by means of interpolation and/or extrapolation.

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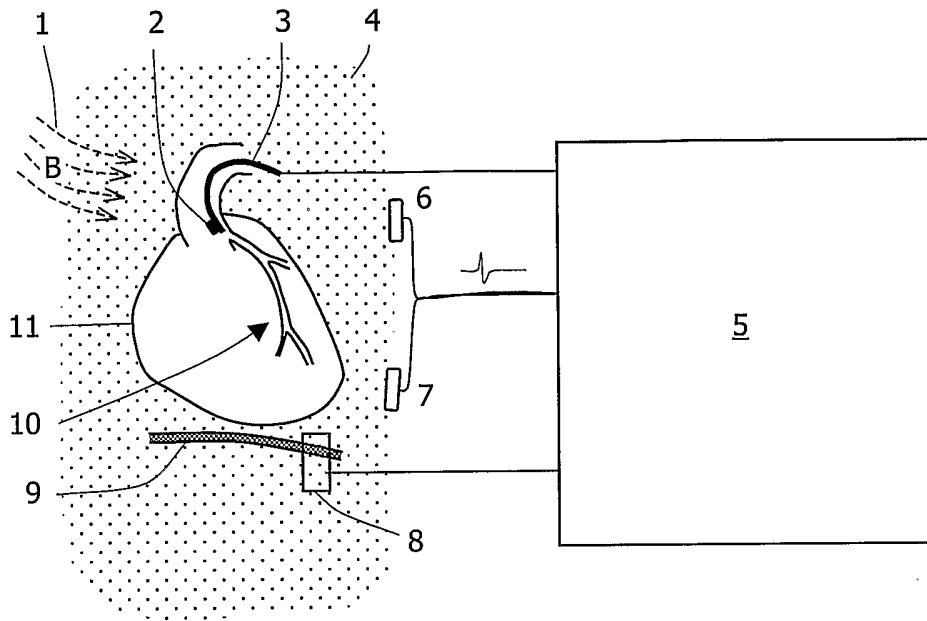


Fig. 1

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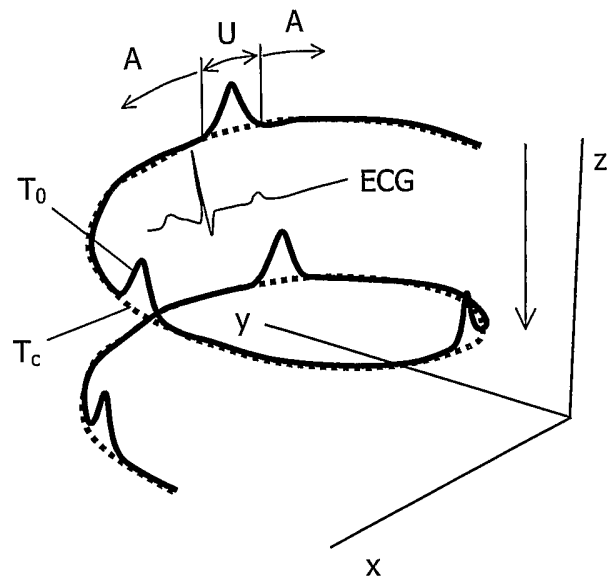


Fig. 2

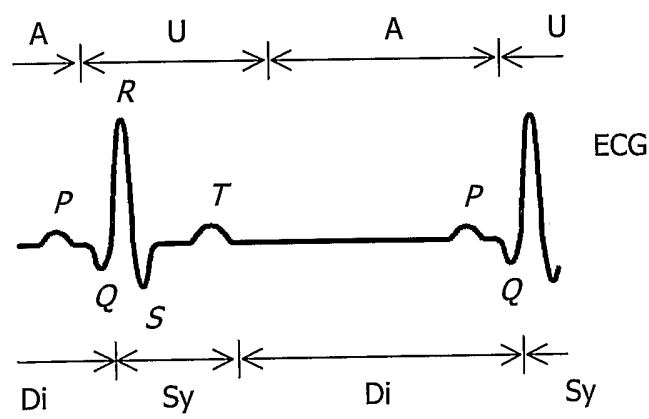


Fig. 3

## INTERNATIONAL SEARCH REPORT

International Application No

F 01/IB2004/050602

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7 A61B5/06		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B		
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, INSPEC, WPI Data		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 473 635 B1 (RASCHE VOLKER) 29 October 2002 (2002-10-29) column 4, line 4 - column 4, line 52 column 6, line 10 - column 6, line 60 column 7, line 15 - column 7, line 39; figure 5	1-8
A	EP 0 775 466 A (MEDTRONIC INC) 28 May 1997 (1997-05-28) column 3, line 51 - column 4, line 5 column 7, line 48 - column 8, line 39; figures 1,2a,2b,2c	1-8
<input type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
° Special categories of cited documents :		
*A* document defining the general state of the art which is not considered to be of particular relevance *E* 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		Date of mailing of the international search report
13 September 2004		20/09/2004
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  Lomme1, A

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IB2004/050602

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 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.: 9, 10  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2.  Claims Nos.:  
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:
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 III Observations where unity of invention is lacking (Continuation of item 3 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

International Application No

PCT/IB2004/050602

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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