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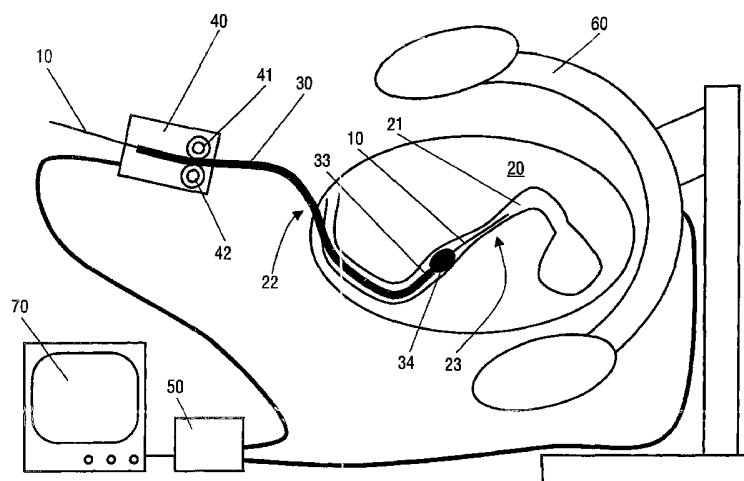
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ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: METHOD FOR TRANSCUTANEOUS CATHETER GUIDING



(57) Abstract: The invention relates to a method of determining the position of a catheter introduced along a guide wire inserted into a body, in which method an image of the guide wire and the body region at the area of the guide wire is acquired by means of an imaging method, the distance traveled by the catheter on the guide wire is measured and the position of the catheter in the body is determined on the basis of the measured distance. The invention also relates to a device for determining the position of a catheter introduced along a guide wire inserted into a body, which device includes sensor means for measuring the distance traveled by the catheter on the guide wire and means for determining the position of the catheter on the basis of the measured distance.



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Method for transcutaneous catheter guiding

The invention relates to a method of determining the position of a catheter introduced along a guide wire inserted into a body, in which method an image of the guide wire and the body region at the area of the guide wire is acquired by means of an imaging method.

5 In order to determine the position of the catheter in known methods of the kind set forth, an imaging method is regularly carried out in order to acquire images of the relevant body regions with the inserted guide wire and the catheter introduced along this guide wire, thus enabling determination of the position of the catheter. Depending on the requirements imposed as regards the accuracy of the positioning of the catheter, or the tip of
10 the catheter, several image acquisition procedures have to be carried out so as to enable repeated checking of the position of the catheter. Such repeated image acquisition is a costly procedure. Furthermore, notably when an X-ray imaging method (fluoroscopy) is used, the repeated image acquisitions lead to a substantial radiation load for the patient as well as for the medical staff.

15 It is an object of the invention to provide a method which enables a simplified determination of the catheter position and reduces the radiation load.

The object is achieved in accordance with the invention by measuring the distance traveled by the catheter on the guide wire and by determining the position of the catheter in the body on the basis of the measured distance.

20 Because the catheter is fed forwards on the guide wire, the catheter or the catheter tip can only be situated along the guide wire. When the position of the guide wire relative to the lesion is known, therefore, the position of the catheter can be determined as a function of the distance traveled by the catheter or the tip of the catheter on the guide wire. As a result, after the position of the guide wire in relation to the lesion in the body and the
25 body region around the guide wire have been determined once, the position of the catheter or the tip of the catheter in the body region can be determined at any instant by measuring how far the catheter has traveled on the guide wire. The determination of the position of the catheter thus requires only a single acquisition of an image of the body region and the guide wire, so that the radiation load caused by the repeated image acquisitions can be avoided.

Furthermore, the position of the catheter or the catheter tip can be determined permanently and in real time, whereas according to the known method the position of the catheter or the catheter tip can be determined only at given instants, that is, the instants of image acquisition. The method in accordance with the invention thus enables a reduction of the radiation load, a simplified determination of the position of the catheter/the tip of the catheter, and a permanent and real-time determination and display of the position of the catheter.

In accordance with a first advantageous version of the method in accordance with the invention an image of the body region is acquired and the position of the catheter is displayed in this image. This image can be acquired before, during or after the determination of the position of the catheter.

The body region, and possibly the guide wire introduced into this body region, can then be determined from the image data previously acquired by means of the imaging method, the position of the catheter can be determined, as described before, on the basis of the measured distance and be displayed in the image of the body region. In this preferred version imaging can take place at regular intervals, for example, at instants specified by the user, or a plurality of images can be formed in rapid succession, thus enabling permanent real-time observation of the catheter/the tip of the catheter and hence of the progress of the catheter.

In accordance with a further advantageous version the imaging of the body region and the guide wire is realized by means of a two-dimensional or three-dimensional imaging method. All types of medical imaging methods can be used for this purpose. Use can advantageously be made of X-ray imaging methods, that is, two-dimensional X-ray projections or computed tomography X-ray imaging methods. For the visualization of vascular systems, a contrast medium can then be advantageously administered so as to be imaged by the imaging method. Customary methods in this respect are angiography methods, in particular fluoroscopic angiography.

For the above version of the method in accordance with the invention the body region and the guide wire can be advantageously imaged by way of two essentially orthogonal projections, a three-dimensional image of the body region being formed from such projections by way of modeling. Modeling is performed by means of numerical calculation from the image data acquired by way of the projections. The modeling notably enables the formation of a coronary roadmap. Customary methods can be used for the modeling operation. The projections can be acquired either simultaneously by means of a

two-plane system or successively by means of a mono-plane system. In the case of temporally successive projections it is advantageous to acquire the projections in the same cardiac phase when the method in accordance with the invention is used for the imaging of the vascular system, notably in the region of the heart.

5 It can be advantageously arranged in particular that the acquisition of the image data is realized by means of images of the body regions which have been shifted in time and triggered on the basis of the cardiac frequency. The successively acquired image data can be compared and possibly superposed in this manner. Furthermore, if the image data from images of the same cardiac phase is available, a three-dimensional image can be
10 modeled from such image data without it being necessary to carry out any complex reconstruction methods, distortion correction methods and/or image data allocation operations.

 In a further advantageous version of the method in accordance with the invention an image of the body region with the guide wire and the inserted catheter is
15 acquired and displayed after the determination of the position of the catheter. This postponed acquisition of image data serves to compare the calculated (virtual) image data on the position of the catheter with the actual position of the catheter. This approach serves to check the calculated catheter position. It can then be arranged, for example, to perform an image data acquisition at given time intervals and to compare the catheter position visualized from
20 this image acquisition with the numerically calculated catheter position at the relevant instant and to perform, if necessary, a correction of the calculation data. It may also be arranged to couple the image acquisition means to the sensor means so as to carry out an image data acquisition operation for given traveled distances, notably when the target position or a region around the target position is reached.

25 The invention also relates to a device for determining the position of a catheter introduced along a guide wire inserted into a body, which device includes sensor means for measuring the distance traveled by the catheter on the guide wire and means for determining the position of the catheter on the basis of the measured distance.

 In a very simple embodiment of the invention it is possible to predetermine
30 merely a desired position of the catheter and to calculate the distance of travel of the catheter on the guide wire which is necessary for this position of the catheter. Subsequently, the catheter is displaced on the guide wire until the desired distance has been traveled, said distance being determined by means of simple measuring means such as, for example, a centimeter tape, a caliper gage or the like.

Furthermore, sensors which are known for the purpose of length sensing, for example, inductive or potentiometric distance sensors, can be used to determine the distance. Such distance sensors may be coupled to display or signal means which indicate the relevant distance of travel and/or trigger a signal, for example, an optical or acoustic signal, when a given reference distance is reached.

The device in accordance with the invention may also include image acquisition means which are arranged to acquire an image of the inserted guide wire and the body region of the guide wire. Such image acquisition means can also be constructed so as to co-operate with the sensor means, thus forming image data describing the position of the catheter.

A further advantageous embodiment of the device in accordance with the invention includes imaging means for displaying the body region at the area of the guide wire, as well as for displaying the inserted guide wire itself and/or the inserted catheter. The imaging means may be capable of forming a two-dimensional image or also a three-dimensional image for display in a customary manner, for example, by means of a display screen.

The invention also relates to a computer program with program means for making a computer carry out the method in accordance with the invention when the program is executed on a computer.

A preferred embodiment of the method and the device in accordance with the invention will be described in detail hereinafter with reference to the Figures. Therein:

Fig. 1 is a diagrammatic representation of an embodiment of the device in accordance with the invention with a guide wire introduced into a body,

Fig. 2 shows a flow chart of a version of the method in accordance with the invention, and

Fig. 3 is a diagrammatic representation of the lengths of the guide wire and a catheter arranged thereon.

In Fig. 1 a guide wire 10 has been introduced into a vascular system 21 of a body 20 via a body opening 22. The guide wire 10 has been slid into the vascular system 21 so far that from the opening 22 it extends beyond a constriction 23 in the vascular system 21.

A catheter 30 has been threaded on the guide wire. The catheter 30 has been advanced through the vascular system 21, along the guide wire 10, so far that the end 31 of the catheter 30 within the vascular system 21 is situated just in front of the constriction 23. To the end 33 situated within the vascular system there is attached a dilatation bulb 34. The dilatation bulb 34 is merely an example and may be replaced by other known catheter-guided treatment devices.

The catheter 30 and the guide wire 10 pass through a feed device 40. The feed device includes feed wheels 41, 42. The feed wheels 41, 42 are situated at a distance from one another. The catheter 30 passes between the feed wheels 41, 42 and is frictionally engaged thereby.

Because of the frictional contact between the feed wheels 41, 42 and the catheter 30, the wheels 41, 42 rotate when the catheter 30 is manually advanced on the guide wire 10. Furthermore, the catheter 30 can be advanced on the guide wire 10 by driving the feed wheels 41, 42.

The feed wheels 41, 42 (or at least one of these feed wheels) are connected to sensor means (not shown) which measure the rotation of the feed wheels and hence measure the distance of travel of the catheter 30. The rotation sensor means are connected to a computer 50 and apply the measured distance to the computer.

Fig. 1 also shows an X-ray C-arm 60. This apparatus is of a known type as used for many medical imaging applications. The X-ray C-arm is arranged in such a manner that it is capable of imaging the body 20, that is, at least the body region in which the constriction 23 is situated. The X-ray C-arm 60 is also connected to the computer 50 and applies the image data to the computer.

The computer 50 calculates the position of the catheter 30, notably the position of the dilatation bulb 34 at the end 33 of the catheter 30, from the image data of the X-ray C-arm 60 and the distance of travel as presented by the rotation sensors of the feed device 40.

The computer 50 is connected to a monitor 70 which serves to display the body region around the constriction 23, the guide wire 10 at the area of this constriction and the catheter 30, that is, notably the end 33 thereof and the dilatation bulb 34 attached thereto.

Referring to Fig. 2, the method in accordance with the invention commences with an image acquisition step S1 in which an image R1 is acquired of the relevant body region and the guide wire.

In a next step S2 a coronary roadmap is formed from said image R1. Subsequently (S3), the guide wire is displayed in the coronary roadmap. As a result (R2) of

this display, the 3D co-ordinates $F(x,y)$ can be displayed separately in dependence on a parameter l . The parameter l denotes the distance between the guide wire segment to be displayed and the end of the guide wire.

During a next step S4 the distance traveled by the catheter on the guide wire is
5 determined. This results in a traveled distance s (R3).

In order to determine the position in which the tip of the catheter is situated within the body, the traveled distance s can be used to determine the 3D co-ordinates of the tip of the catheter, the overall length of the guide wire and of the catheter 30 being known.

Referring to Fig. 3, the length L_0 of the guide wire and the length C_0 of the
10 catheter being known, the distance D searched between the tip of the catheter and the front end of the guide wire can be simply determined in dependence on the traveled distance s by calculating D in conformity with the formula

$$D=L_0-C_0-s.$$

Similarly, in particular when a two-dimensional imaging method is used, a
15 marker may be provided on the guide wire, the distance between said marker and the extracorporal end of the guide wire being known. This marker is placed in relation to the lesion (for example, centrally with respect to the lesion, exactly behind the lesion or exactly in front of the lesion) by means of the imaging method. The catheter can then be exactly positioned by relating it to the extracorporal end of the guide wire.

20 Again referring to Fig. 2, after the determination of the position of the catheter or the tip of the catheter in dependence on the traveled distance s (S5), the catheter can be displayed (S6) and, using the previously acquired image with the body region and the guide wire R1, an image R4 can be formed which shows the body region, the guide wire and the catheter.

CLAIMS:

1. A method of determining the position of a catheter (30) introduced along a guide wire (10) inserted into a body (20), in which method an image of the guide wire and the body region at the area of the guide wire is acquired by means of an imaging method (S1, S2, S3), characterized in that the distance traveled by the catheter (30) on the guide wire (10) is measured (S4) and the position of the catheter in the body (20) is determined on the basis of the measured distance (S5).

2. A method as claimed in claim 1, characterized in that an image is acquired of the body region, the position of the catheter being displayed in said image (S6).

3. A method as claimed in claim 1, characterized in that the acquisition (S1) of the image of the body region and the guide wire is performed by means of a two-dimensional or three-dimensional imaging method, preferably being an X-ray imaging method.

4. A method as claimed in claim 3, characterized in that the body region and the guide wire are imaged by way of two essentially orthogonal projections (S1) and that a three-dimensional image of the body region is formed from said projections by way of modeling.

5. A method as claimed in claim 1, characterized in that the acquisition (S1) of the images is performed by means of images of the body regions which have been shifted in time and triggered on the basis of the cardiac frequency.

6. A method as claimed in claim 1, characterized in that an image of the body region with the guide wire and the inserted catheter is acquired and displayed after the determination of the position of the catheter.

7. A method as claimed in claim 1, characterized in that the catheter is advanced by means of a drive device which measures the advancement of the catheter.

8. A method as claimed in claim 7, characterized in that an acoustic and/or optical signal is generated and/or an image acquisition is performed when the catheter reaches the target position.

5 9. A device for determining the position of a catheter (30) introduced along a guide wire (10) inserted into a body (20), characterized in that it includes sensor means for measuring the distance traveled by the catheter on the guide wire and means for determining the position of the catheter on the basis of the measured distance.

10 10. A device as claimed in claim 9, characterized in that it includes image acquisition means (60) for the acquisition of an image of the inserted guide wire and the body region at the area of the guide wire.

11. A device as claimed in claim 10, characterized in that it includes image
15 display means (70) for displaying the image of the inserted guide wire, the introduced catheter and/or the body region at the area of the guide wire.

12. A device as claimed in claim 10, characterized in that it includes drive means
20 for displacing the catheter on the guide wire, which drive means are coupled to the sensor means.

13. A computer program with program means for making a computer carry out the method claimed in claim 1 when the computer program is executed on a computer.

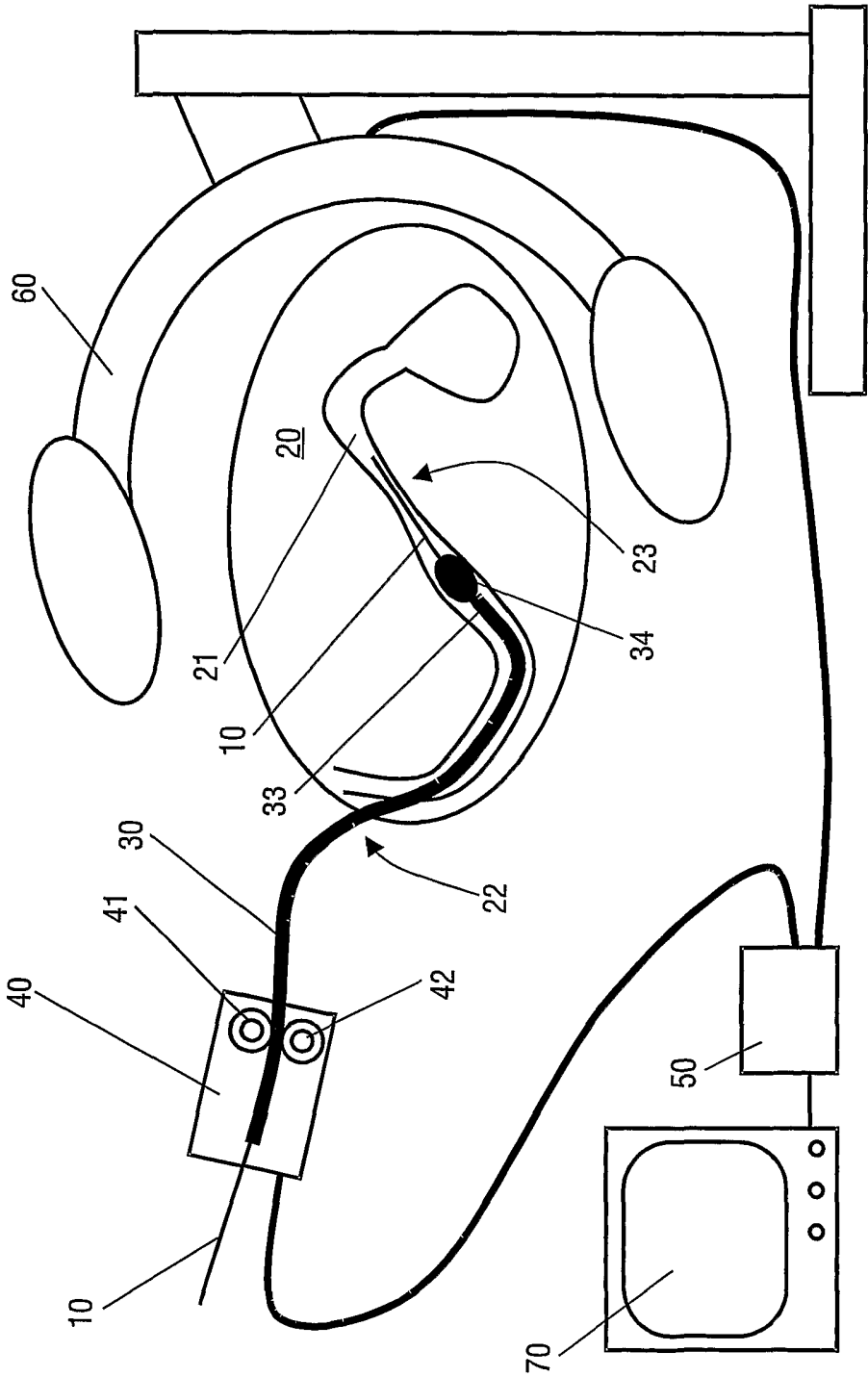


FIG.1

2/2

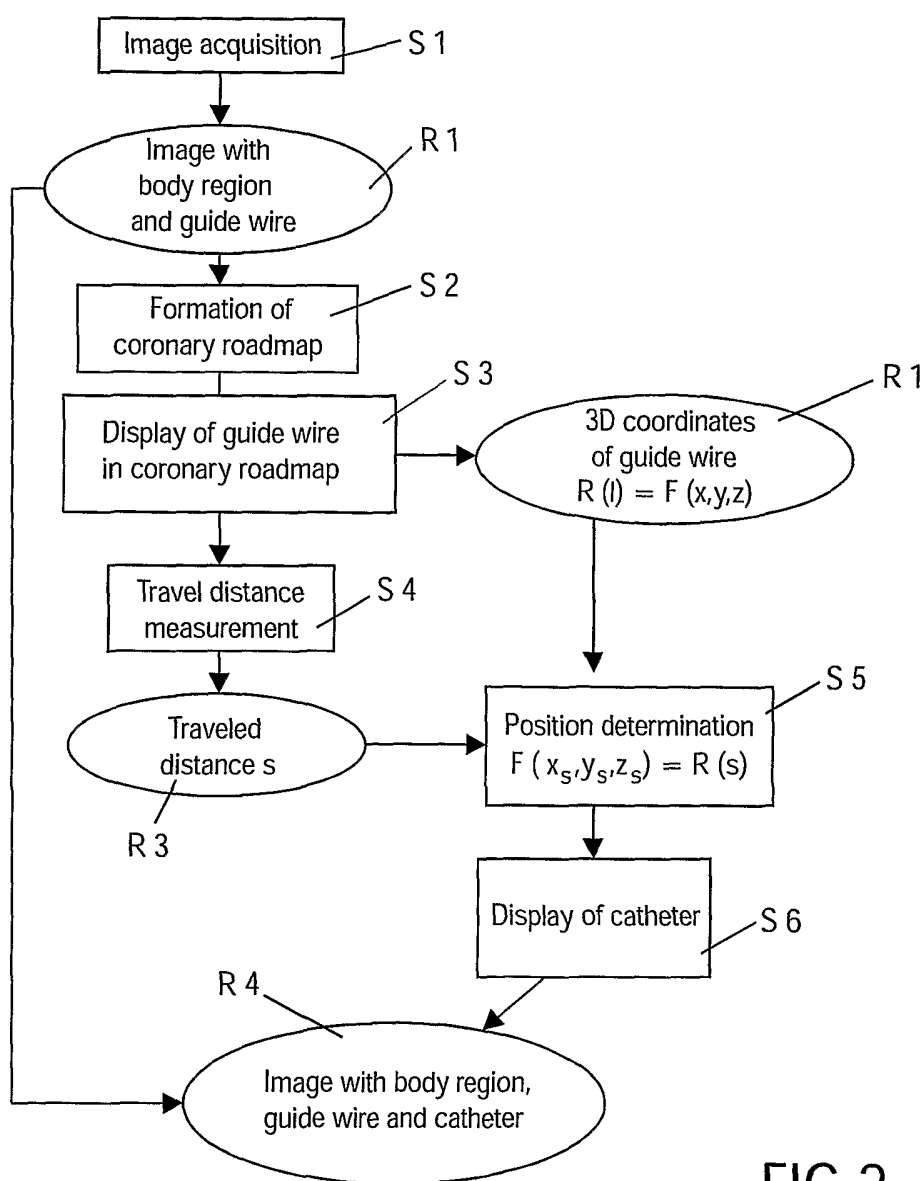


FIG.2

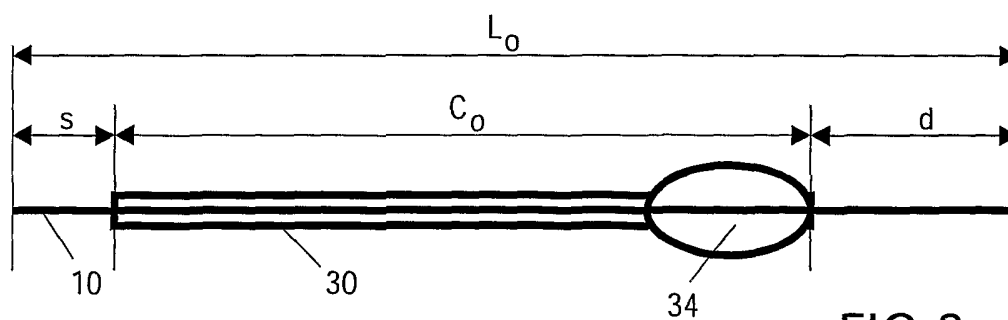


FIG.3

INTERNATIONAL SEARCH REPORT

Internat Application No

PCT/IB 03/01649

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B5/00 A61B6/00

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)

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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01 12093 A (SUPER DIMENSION LTD ; GILBOA PINHAS (IL); FRIEDMAN MARK M (IL)) 22 February 2001 (2001-02-22) page 3, line 13 -page 6, line 10; claim 1 ---	9-12
A	EP 1 088 515 A (BIOSENSE INC) 4 April 2001 (2001-04-04) figure 1 ---	11,12
A	US 6 226 543 B1 (GILBOA PINHAS ET AL) 1 May 2001 (2001-05-01) abstract; figure 1 -----	10



Further documents are listed in the continuation of box C.



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.

Z document member of the same patent family

Date of the actual completion of the international search

28 July 2003

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06/08/2003

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 03/01649

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.: 1-8, 13
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 (advancement of catheter in the body). It is considered that Claim 13 also relates to the method for treatment 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 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

Internat Application No
PCT/JP 03/01649

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