APPARATUS AND METHOD FOR NAVIGATING AN INSTRUMENT THROUGH AN ANATOMICAL STRUCTURE

Apparatus for navigating an instrument through an anatomical structure of a patient’s body volume, comprising a table for supporting the patient and at least a first C-arm having a first X-ray source and a first X-ray detector for acquiring a first series of 2D-images of the instrument whilst manoeuvring through said anatomical structure, and further comprising a processing unit for the images which unit connects to a memory device, whereby the memory device holds pre-determined 3D-images of the patient’s anatomical structure, and the processing unit is arranged for processing the 2D-images of the instrument and the 3D-images of the anatomical structure so as to provide merged 3D-images of the instrument that in use manoeuvres through said anatomical structure.

Published:
— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
Apparatus and method for navigating an instrument through an anatomical structure

The invention relates to an apparatus and method for navigating an instrument through an anatomical structure of a patient's body volume, comprising a table for supporting the patient and at least a first C-arm having a X-ray source and a X-ray detector for acquiring a first series of 2D-images of the instrument whilst manoeuvering through said anatomical structure, and further comprising a processing unit for the images which unit connects to a memory device, whereby the memory device holds pre-determined 3D-images of the patient's anatomical structure, and the processing unit is arranged for processing the 2D-images of the instrument and the 3D-images of the anatomical structure so as to provide merged 3D-images of the instrument that in use manoeuvers through said anatomical structure.

Such an apparatus and method are known from US-B-6 351 513.

In the known apparatus and method 3D-images of a patient's anatomical structure, in particular the patient's vascular structure are obtained by 3D-angiography, magnetic resonance imaging or computer tomography imaging. These 3D-images are of comparatively high resolution and quality.

To alleviate navigational difficulties that the radiologist experiences when a medical instrument such as a catheter is pushed through said vascular structure to a region of interest, US-B-6 351 513 teaches to apply real time 2D imaging of the instrument whilst manoeuvering through the vascular structure and merging the 2D-image of the instrument with the predetermined 3D-images of the vascular structure. Since the catheter is moving through a vessel the catheter must according to US-B-6 351 513 actually lie in 3D space, somewhere on a "sheaf" which is a surface formed by taking a line (a catheter) and keep sweeping along the length of the catheter. This generates a surface and the catheter can be anywhere on that surface. Since we know that the catheter is moving through the vessel which is a 3D structure, the intersection of this surface with the pre-stored 3D reconstruction data, gives the location of the catheter. US-B-6 351 513 teaches: if the 3D reconstruction of the vessels is known (i.e. from the 3D-angiography reconstruction) the position of the catheter is also known since it is confined within the reconstructed vessels.

Several problems attach to the method and apparatus according to US-B-6 351 513. As a first problem the known art does not take into account that the position of the C-
arm is not always calibrated, causing that inaccuracies occur and correspondence is lacking between the priorly acquired 3D-images of the vascular structure and the later acquired 2D-images of the instrument.

A second problem is that during imaging the patient may intentionally or unintentionally move. Even movement due to beating of the heart and breathing may give rise to unacceptable inaccuracies.

A third problem is that the radiologist may elect to move the table on which the patient is laying in an effort to improve his view at the instrument during manoeuvring.

All said problems may result in discrepancies in the merged images of the instrument and the vascular structure making same unreliable. Although hereabove and also hereafter at some places reference is made to a patient’s vascular structure, the invention is not restricted to this application but applies in general to a patient’s anatomical structure. The reference to the vascular structure is however particularly useful in understanding the invention.

With the apparatus and method according to the invention it is aimed to reduce or circumvent the above-mentioned problems.

To this end the apparatus according to the invention is characterized in that the processing unit is arranged to carry out a 2D-3D registration to relate the coordinates of the 2D-images of the instrument to the coordinates of the 3D-images of the anatomical structure prior to providing the merged 3D-images of the instrument and the anatomical structure. It is to be noted that although usually the images of the anatomical structure are obtained prior to the imaging of the instrument, the 3D-images of the anatomical structure may also be obtained during the intervention with the instrument. In the first situation, i.e. when the acquisition of images of the anatomical structure has been done prior to the imaging of the instrument, it is desirable to immediately precede the imaging of the instrument by a short imaging of the anatomical structure. This allows for registering the images taken during this session with the coordinates of the earlier recorded 3D-images of the anatomical structure.

A first preferred embodiment of the apparatus according to the invention is characterized it comprises a second C-arm with a X-ray source and a X-ray detector for acquiring a second series of 2D-images simultaneously with the first series of 2D-images, and that the processing unit is arranged to carry out the 2D-3D registration on both the first series and the second series of 2D-images of the instrument, and that the processing unit is arranged to derive thereafter a 3D-image of the instrument based on said first and second series of 2D-images and to merge said 3D-image of the instrument with the 3D-images of the
anatomical structure. This embodiment provides the advantage that the 3D-image of the instrument and in particular its location within the patient's body volume can be established independently from the priori established 3D-image of the patient's anatomical structure. This results in higher accuracy of the instrument's actual positioning in the patient's body.

Consistent with the above the method according to the invention is characterized in that the 2D-images of the instrument are registered with the 3D-images of the anatomical structure prior to providing the merged 3D-images of the instrument and the anatomical structure, and that in a preferred embodiment a second series of 2D-images is acquired simultaneously with the first series of 2D-images of the instrument but from a different angle, whereby both the first series and the second series of 2D-images of the instrument are registered with the 3D-images of the anatomical structure followed by deriving from the first and second series of 2D-images a series of 3D-images of the instrument, and that the 3D-images of the instrument are merged with the 3D-images of the anatomical structure.

A second more preferred embodiment of the apparatus according to the invention is characterized in that the memory device holds a pre-determined 3D-model representation of the instrument and that the processing unit is arranged to carry out a 2D-3D registration to relate the coordinates of the 3D-model representation with the coordinates of the 2D-images of the instrument, and that the processing unit is further arranged to calculate 2D-model images of the instrument corresponding to the acquired 2D-images of the instrument, and to modify the 3D-model representation into an adapted 3D-model representation in order to optimize matching of the 2D-model images to the acquired 2D-images of the instrument, and that the processing unit is further arranged to merge the adapted 3D-model representation of the instrument with the 3D-images of the anatomical structure.

This provides the advantage of increased accuracy and reliability with respect to the 3D-images of the instrument that are merged with the 3D-images of the anatomical structure. By application of the 3D-model representation of the instrument it is furthermore possible to take into account instrument characteristics such as the rigidity of the instrument in different directions.

Also in this second preferred embodiment the accuracy and reliability of the combined images of instrument and anatomical structure can be further enhanced by application of the feature that the apparatus comprises a second C-arm with a second X-ray source and a second X-ray detector for acquiring a second series of 2D-images.
simultaneously with the first series of 2D-images, and that the processing unit is arranged to carry out the registration of the coordinates of the 3D-model representation in respect of both the first series and the second series of 2D-images of the instrument, and that the processing unit is arranged to derive thereafter an adapted 3D-model representation of the instrument based on both the first series and the second series of 2D-images of the instrument, and to merge this adapted 3D-model representation with the 3D-images of the anatomical structure.

Consistent with the above, the method according to the invention is in a second preferred embodiment characterized in that a 3D-model representation of the instrument is acquired and is registered with the 2D-images of the instrument, and in that 2D-model images of the instrument are derived from said 3D-model representation corresponding to the acquired 2D-images of the instrument, and that said 3D-model representation is adapted to optimize the matching of the 2D-model images with the acquired images of the instrument prior to merging the adapted 3D-model representation of the instrument with the 3D anatomical structure.

A further detailed embodiment thereof is characterized in that a second series of 2D-images is acquired simultaneously with the first series of 2D-images of the instrument but from a different angle, and that a registration is carried out of the coordinates of the 3D-model representation of the instrument in respect of both the first series and the second series of 2D-images of the instrument, whereafter the 3D-model representation of the instrument is adapted to optimize the matching of said first series and second series of images of the instrument with 2D-model images of the instrument derived from said 3D-model representation, and that thereafter the adapted 3D-model representation of the instrument is merged with the 3D anatomical structure.

The invention is further embodied in software for a computer which is characterized by coding that is arranged for implementing the just mentioned method. The invention is also embodied in a data carrier comprising such software.

The invention will hereafter be further elucidated with reference to a non-limiting example of the apparatus and method according to the invention and with reference to the drawing.

In the drawing

Figure 1 shows schematically the apparatus according to the invention.
Figure 2 shows schematically the acquisition of a 2D-image with the aid of the apparatus according to figure 1.

Figure 3 schematically shows the merger of a 3D-image from the instrument and a predetermined 3D-image of a patient's vascular structure.

Figures 4, 5, 6 and 7 show a series of real time 3D-images of an instrument manoeuvring through the vascular structure.

With reference first to figure 1 an apparatus 1 is shown for navigating an instrument through a vascular structure of a body volume of a patient 2. The apparatus 1 comprises a table 3 for supporting the patient 2 and in the shown preferred embodiment it comprises a first C-arm 4 with a X-ray source 5 and an image intensifier 6 for acquiring a first series of 2D-images. It further comprises a second C-arm 7 having a X-ray source 8 and an image intensifier 9 for acquiring a second series of 2D-images. Both image intensifiers are connected with a processing unit 10 (a computer) which connects to a memory device 11 and a display unit 12.

Initially in a manner well known in the art 3D-images of the patient's 2 vascular structure are acquired and stored in the memory device 11.

When a medical instrument such as a guide wire, a catheter, a stent or otherwise is manoeuvred through the vascular structure of the patient 2 at least one of the C-arms 4, 7 but preferably both arms are used to acquire 2D-images of the instrument. For one C-arm 4 or 7 this is schematically shown in figure 2 indicating with 'F' the X-ray source, the patient's body volume shown in the middle whereby the patient's vascular structure is recognizable, and below the patient's body volume a detector for acquiring a 2D-image of the body volume under examination. When the instrument is maneuvered through the vascular structure the X-ray source operates in real time however on a low energy level, which suffices to provide images of the medical instrument.

Figure 3 relates to biplane imaging of the instrument making use of both C-arms 4 and 7. The middle of the figure shows schematically the vascular structure of the patient in the form of a 3D-image, which is acquired prior to navigating the instrument through the vascular structure.

Making use of both C-arms 4 and 7 a first series of 2D-images of the instrument and a second series of 2D-images of the instrument are acquired simultaneously which is represented by pictures A and B respectively. Picture A represents one image of a
first series of images by using X-ray source Fa, picture B represents one image of the second
series of images making use of X-ray source Fb. Both the first series and the second series of
2D-images of the instrument are processed by the processing unit 10 to carry out a 2D/3D
registration to relate the coordinates of the 2D-images of the instrument, to the coordinates of
the 3D-image of the vascular structure. In a first embodiment the 2D-images of the
instrument are acquired simultaneously with the images of the vascular structure. In a second
more usual embodiment the 3D-images of the anatomical structure are, however, acquired
prior to the intervention with the instrument. In this situation it is desirable to immediately
precede the imaging of the instrument by a short imaging of the anatomical structure in order
to register the images taken during the intervention with the coordinates of the earlier
recorded 3D-images of the anatomical structure. This applies to both the first series of 2D-
images and the second series of 2D-images of the instrument. Figure 3 symbolizes that
thereafter the two series of 2D-images, which are taken from a different angle, are combined
and construed into a 3D representation of the instrument, following which the 3D-image of
the instrument is merged with the 3D-image of the vascular structure.

As mentioned hereabove the merger of the 3D-image of the instrument and the
3D-image of the vascular structure can be based both on a single series of images acquired by
use of only one C-arm. It is preferred however to make use of both C-arms in order to
improve the spatial accuracy and reliability of the 3D-image of the instrument in relation to
the 3D-image of the vascular structure.

Also, otherwise a further improvement of the spatial reliability and accuracy
of the combined images is obtainable, as will be explained hereafter. In a first embodiment as
elucidated hereabove the acquired 2D-images of the instrument are applied directly to derive
3D-images thereof, which are then merged with the 3D-images of the vascular structure.

In a second and more preferred embodiment of the invention the memory
device 11 shown in Figure 1 also holds a pre-determined 3D-model representation of the
instrument. This 3D-model representation of the instrument is used by the processing unit 10
in combination with the 2D-images of the instrument that are obtained with either a single C-
arm or both C-arms 4 and 7.

To this end the coordinates of the 3D-model representation are registered with
the acquired 2D-images of the instrument and subsequently the processing unit 10 carries out
calculated projections in relation to the 3D-model representation of the instrument resulting
in 2D-model images of the instrument corresponding to the acquired 2D-images of the
instrument.
The 3D-model representation is then adapted, usually in an iterative procedure, in order to optimize the matching of the calculated 2D-model images to the acquired 2D-images of the instrument. The eventual 3D-model representation as adapted can then be directly merged with the earlier acquired 3D-images of the vascular structure of the patient. A particularly reliable and accurate reconstruction of the combined images of instrument and vascular structure can thus be obtained.

By executing the method and operating the apparatus according to the invention in real time, a series of 3D-images is acquired as shown in figures 4 to 7.

Figure 4 shows the tip of a guide wire at the entrance portion of the vascular structure of an patient's body volume under examination. Figure 5 shows same when the guide wire has progressed a little and figures 6 and 7 show same in even further progressed positions.

It is emphasized that the invention can advantageously use any known form of 2D/3D registration to relate the coordinates of the 2D-images of the instrument to the coordinates of the 3D-images of the vascular or any other anatomical structure. For this purpose one could select one of the methods described in the article "A Comparison of Similarity Measures for use in 2D/3D Image Registration" by Graeme P. Penney et al., IEEE Transactions On Medical Imaging, Vol. 17, No. 4, August 1998, pages 586 to 595.
CLAIMS:

1. Apparatus for navigating an instrument through an anatomical structure of a patient's body volume, comprising a table for supporting the patient and at least a first C-arm having a first X-ray source and a first X-ray detector for acquiring a first series of 2D-images of the instrument whilst manoeuvring through said anatomical structure, and further comprising a processing unit for the images which unit connects to a memory device, whereby the memory device function is to hold pre-determined 3D-images of the patient's anatomical structure, and the processing unit is arranged for processing the 2D-images of the instrument and the 3D-images of the anatomical structure so as to provide merged 3D-images of the instrument that in use manoeuvres through said anatomical structure, characterized in that, the processing unit is arranged to carry out a 2D-3D registration to relate the coordinates of the 2D-images of the instrument to the coordinates of the 3D-images of the anatomical structure prior to providing the merged 3D-images of the instrument and the anatomical structure.

2. Apparatus according to claim 1, characterized in that, it comprises a second C-arm with a second X-ray source and a second X-ray detector for acquiring a second series of 2D-images simultaneously with the first series of 2D-images, and that the processing unit is arranged to carry out the 2D-3D registration on both the first series and the second series of 2D-images of the instrument, and that the processing unit is arranged to derive thereafter a 3D-image of the instrument based on said first and second series of 2D-images, and to merge said 3D-image of the instrument with the 3D-images of the anatomical structure.

3. Apparatus according to claim 1, characterized in that the memory device holds a pre-determined 3D-model representation of the instrument and that the processing unit is arranged to carry out a 2D-3D registration to relate the coordinates of the 3D-model representation with the coordinates of the 2D-images of the instrument, and that the processing unit is further arranged to calculate 2D-model images of the instrument corresponding to the acquired 2D-images of the instrument, and to modify the 3D-model representation into an adapted 3D-model representation in order to optimize matching of the
2D-model images to the acquired 2D-images of the instrument, and that the processing unit is further arranged to merge the adapted 3D-model representation of the instrument with the 3D-images of the anatomical structure.

5. Apparatus according to claim 3, characterized in that it comprises a second C-arm with a second X-ray source and a second X-ray detector for acquiring a second series of 2D-images simultaneously with the first series of 2D-images, and that the processing unit is arranged to carry out the registration of the coordinates of the 3D-model representation in respect of both the first series and the second series of 2D-images of the instrument, and that the processing unit is arranged to derive thereafter an adapted 3D-model representation of the instrument based on both the first series and the second series of 2D-images of the instrument, and to merge this adapted 3D-model representation with the 3D-images of the anatomical structure.

15. Method for navigating an instrument through a anatomical structure of a patient's body volume comprising the steps of
- having available 3D-images of the patient's anatomical structure
- acquiring a first series of 2D-images of the instrument whilst manoeuvering through the anatomical structure
- processing the 2D-images of the instrument and the 3D-images of the anatomical structure for providing merged 3D-images of the instrument manoeuvering through the anatomical structure characterized in that, the 2D-images of the instrument are registered with the 3D-images of the anatomical structure prior to providing the merged 3D-images of the instrument and the anatomical structure.

6. Method according to claim 5, characterized in that, a second series of 2D-images is acquired simultaneously with the first series of 2D-images of the instrument but from a different angle, that both the first series and the second series of 2D-images of the instrument are registered with the 3D-images of the anatomical structure followed by deriving from the first and second series of 2D-images a series of 3D-images of the instrument, and that the 3D-images of the instrument are merged with the 3D-images of the anatomical structure.
7. Method according to claim 5, characterized in that a 3D-model representation of the instrument is acquired and is registered with the 2D-images of the instrument, and in that 2D-model images of the instrument are derived from said 3D-model representation corresponding to the acquired 2D-images of the instrument, and that said 3D-model representation is adapted to optimize the matching of the 2D-model images with the acquired images of the instrument prior to merging the adapted 3D-model representation of the instrument with the 3D anatomical structure.

8. Method according to claim 7, characterized in that a second series of 2D-images is acquired simultaneously with the first series of 2D-images of the instrument but from a different angle, and that a registration is carried out of the coordinates of the 3D-model representation of the instrument in respect of both the first series and the second series of 2D-images of the instrument, whereafter the 3D-model representation of the instrument is adapted to optimize the matching of said first series and second series of images of the instrument with 2D-model images of the instrument derived from said 3D-model representation, and that thereafter the adapted 3D-model representation of the instrument is merged with the 3D anatomical structure.

9. Software for a computer in an apparatus for navigating an instrument through an anatomical structure of a patient’s body volume, which apparatus is arranged to implement the steps of:
- accessing 3D-images of the patient’s anatomical structure
- acquiring a first series of 2D-images of the instrument whilst manoeuvring through the anatomical structure, wherein execution of the software causes the computer to
- process the 2D-images of the instrument and the 3D-images of the anatomical structure for providing merged 3D-images of the instrument manoeuvring through the anatomical structure characterized in that, executing said software causes the computer to register the 2D-images of the instrument with the 3D-images of the anatomical structure prior to providing the merged 3D-images of the instrument and the anatomical structure.

10. Software according to claim 9, arranged for processing a first series of 2D-images and a second series of 2D-images of the instrument, that are acquired simultaneously but from different angles, characterized in that executing the software causes the computer to register both the first series and the second series of 2D-images of the instrument with the
3D-images of the anatomical structure, and thereafter to derive from the first and the second series of 2D-images a series of 3D-images of the instrument, and to merge the 3D-images of the instrument with the 3D-images of the anatomical structure.

11. Software according to claim 9, characterized in that execution thereof causes the computer to register an acquired 3D-model representation of the instrument with the 2D-images of the instrument, to derive 2D-model images of the instrument from said 3D-model representation corresponding to the acquired 2D-images of the instrument, and to adapt said 3D-model representation in order to optimize the matching of the 2D-model images with the acquired images of the instrument prior to merging the adapted 3D-model representation of the instrument with the 3D anatomical structure.

12. Software according to claim 11, arranged for processing a first series of 2D-images and a second series of 2D-images of the instrument that are acquired simultaneously, but from a different angle, characterized in that execution thereof causes the computer to carry out a registration of the coordinates of the 3D-model representation of the instrument in respect of both the first series and the second series of 2D-images of the instrument, and to subsequently adapt the 3D-model representation of the instrument in order to optimize the matching of said first series and second series of images of the instrument with 2D-model images of the instrument derived from said 3D-model representation, and to merge thereafter the adapted 3D-model representation of the instrument with the 3D anatomical structure.

13. Data carrier carrying software for a computer in an apparatus for navigating an instrument through an anatomical structure of a patient’s body volume, which is arranged to implement the steps of:
- acquiring 3D-images of the patient’s anatomical structure
- acquiring a first series of 2D-images of the instrument whilst manoeuvring through the anatomical structure, wherein execution of the software causes the computer to
- process the 2D-images of the instrument and the 3D-images of the anatomical structure for providing merged 3D-images of the instrument manoeuvring through the anatomical structure characterized in that, executing said software causes the computer to register the 2D-images of the instrument with the 3D-images of the anatomical structure prior to providing the merged 3D-images of the instrument and the anatomical structure.
FIG. 2
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B6/12 A61B6/00 A61B19/00

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

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbol)
IPC 7 A61B

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

Electronic database consulted during the international search (name of database and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Category</th>
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<th>Relevant to claim No.</th>
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<td>X</td>
<td>US 6 542 770 B2 (ZYLKA WALDEMAR ET AL) 1 April 2003 (2003-04-01) the whole document</td>
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<td>Y</td>
<td>US 6 144 759 A (WEESER JUERGEN ET AL) 7 November 2000 (2000-11-07) column 5, line 10 - line 48 column 11, line 21 - line 40; figure 1</td>
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<td>X</td>
<td>US 5 274 551 A (CORBY JR NELSON R) 28 December 1993 (1993-12-28) column 3, line 8 - column 5, line 27 column 9, line 28 - column 11, line 22; figures 1, 2</td>
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[X] Further documents are listed in the continuation of box C.  [X] 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
*Y 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
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Date of the actual completion of the international search 12 October 2004

Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk
Tel. +31-70 540-2040, Tx. 51 681 epo nl, Fax: +31-70 540-3016

Authorized officer Artikis, T

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**INTERNATIONAL SEARCH REPORT**

**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. **X** Claims Nos.: 5-8 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.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2004)
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