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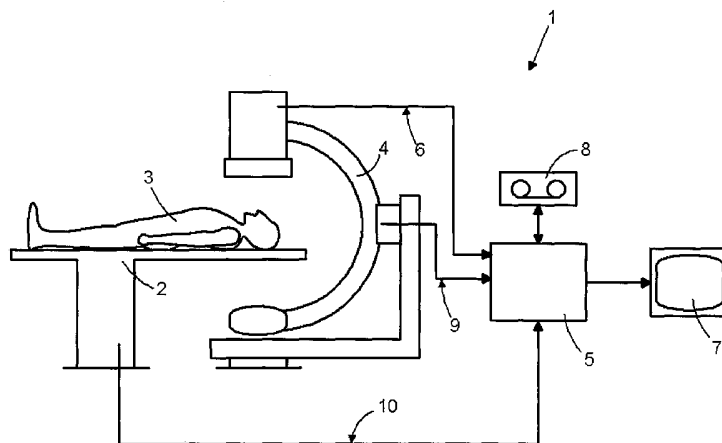
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[Continued on next page]

(54) Title: APPARATUS AND METHOD OF NAVIGATING AN INSTRUMENT



(57) Abstract: An apparatus to be used with navigating an instrument in a vascular tree of a patient, comprises a patient's examination table, a C-arm, mounted to which is an X-ray source and an image recorder for registering first X-ray images of the patient, obtained by the use of the X-ray source, and a processing unit connected with the image recorder for processing the images of the first images registered by the image recorder, as well as a monitor optionally connectable with the processing unit for displaying the image, wherein the processing unit is designed for combining the first X-ray images of the patient with second image data relating to at least a portion of the patient's vascular tree, wherein the processing unit is designed for, with respect to an adjustable projection orientation, deriving a two-dimensional projection image from threedimensional image data concerning the vascular tree of the patient, wherein the projection orientation depends on the information regarding the situation and/or position of the patient's examination table and/or the C-arm.



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 of navigating an instrument

The invention relates to a method and apparatus for navigating an instrument in a vascular tree of a patient, wherein in an adjustable X-ray orientation first X-ray images of the patient are obtained on which the instrument is visible, and wherein said first X-ray images are combined with second image data relating to at least a portion of the patient's vascular tree.

Such a method and apparatus are known from the practice of neurovascular interventions.

With neurovascular interventions, a long flexible instrument (catheter/guide wire) is passed into the blood vessels of a patient. Via branches in the vascular tree, the tip of the instrument has to be guided to the site intended for treatment. To assist the navigation of the instrument, use is made of projection images obtained by X-ray, in which the instrument in the patient's body is visible. The X-ray source and the image enhancer are mounted on a so-called C-arm that can be rotated around the patient to facilitate the taking of pictures from different angles. Also, the patient's examination table can be moved so as to bring a different part of the body into vision. The blood vessels themselves are not visible in the X-ray images.

When navigating the instrument, the interventionist using the instrument usually orientates himself by X-ray images on which the current position of the catheter/guide wire is visible. These images are two-dimensional projections, providing only limited insight concerning the true three-dimensional position of the instrument. The fact that the vessels themselves are not visible in these images renders navigation more difficult. The interventionist is required to mentally relate the X-ray image to possibly previously made images, such as an angiogram, of the vessels. Finding this relationship is rendered more difficult because the previously made images are not necessarily taken from the same point of sight and projection geometry as the X-ray bringing the instrument into vision.

A known manner of visualising the vessels and the catheter/guide wire simultaneously in one single image is by making a so-called road map. To this end, first contrast pictures relating to the blood vessels are taken. Subsequently, during X-raying, these previously made contrast pictures are subtracted from the X-ray image. The result is an image in which the vessels are visible in negative (white) with the catheter/guide wire therein being visible in positive (black). A serious restriction is, however, that the C-arm, the patient's examination table and the patient are not allowed to move during the making and use of the road map. It is therefore not possible to change the point of sight while the road map is being used. Moreover, the making of the road map requires extra operations, and both radiation and contrast fluid have to be used. Owing to these drawbacks the road map has a limited usefulness.

The above-mentioned limitations not only create an extra load on the interventionist, but they also limit the precision and efficiency of the navigation. Furthermore, said limitations increase the load of radiation and contrast medium for the patient, and they raise the variable costs of the procedure because of the additional consumption of contrast medium.

The object of the invention is to combat the above-mentioned drawbacks and problems.

To this end the invention proposes an apparatus and a method, which is characterised by one or several of the appended claims.

The method according to the invention is characterised in that the second image data are obtained by - in a projection orientation that corresponds with the X-ray orientation of the patient - deriving a projection image from three-dimensional image information relating to the vascular tree of the patient, and by combining this projection image with the first X-ray images.

Correspondingly, the apparatus according to the invention is characterised in that the processing unit is designed for, with respect to an adjustable projection orientation, deriving a two-dimensional projection image from three-dimensional image data concerning the vascular tree of

the patient, wherein the projection orientation depends on the information regarding the situation and/or position of the patient's patient's examination table and/or the C-arm.

Desirably, the projection image is derived from the
5 three-dimensional image information with a magnification of the image that is equal to the magnification of the first X-ray images.

The invention provides a method and apparatus,
wherein a projection image of the vessels that is derived from
10 three-dimensional image information obtained by, for example, previous rotation angiography, and the current X-ray image on which the catheter/guide wire is visible, are combined to one single image. Thus in this image, both the catheter/guide wire and the vessels are visible simultaneously and in the correct
15 position in relation to one another. One of the advantages afforded by the invention is that during X-raying, the C-arm and the patient's patient's examination table are permitted to move so that the point of sight for the visualisation may be chosen freely. The method and apparatus according to the in-
20 vention allow the interventionist during navigation to observe the position of the catheter/guide wire in the blood vessels directly and continuously. This renders the injection of contrast medium for the purpose of locating the catheter/guide wire superfluous, which also reduces the load on the patient.
25 Since, in addition, the X-ray image does not need to contain any anatomical reference points, a smaller angle of view may be chosen for the X-ray, which considerably reduces radiation. The interventionist is able to rotate the C-arm and move the patient's patient's examination table freely so as to augment
30 his three-dimensional insight in the situation and to choose an optimal point of sight.

The invention is also embodied in a computer program which, after being loaded into the computer of the processing unit for the image data, is able to collaborate with these to
35 implement the method according to the invention. The invention is also embodied in a data carrier comprising the computer program.

Hereinbelow the invention will be further elucidated by way of a non-limiting exemplary embodiment and with refer-
40 ence to the drawing.

In the drawing, one single figure illustrates the apparatus according to the invention. The apparatus is generally designated by reference numeral 1 and comprises a patient's examination table 2 for the patient 3 to be examined, as well
5 as a C-arm 4, mounted to which is an X-ray source and an image recorder for registering X-ray images of the patient 3, obtained by the use of the X-ray source. The manner of operating and implementing such an apparatus 1 that is useful and is used for navigation of an instrument in a vascular tree of the
10 patient 3, is completely known to the person skilled in the art so that a further explanation is not necessary.

In a manner also known to the person skilled in the art, a processing unit 5 is connected to the image recorder (not shown). The image recorder provides the respective vision
15 signals via a vision signal line indicated with reference numeral 6. As a rule, an image display unit 7 is connected with the processing unit 5 for the visualisation of the X-ray images. The processing unit 5 usually also possesses a memory 8 wherein the image information can be stored, and fetched again
20 into the computer of the processing unit 5.

Before the catheter and/or guide wire is passed into the patient 3, the patient 3 is fixed to the examination table 2. Preferably both the patient's examination table 2 and the C-arm 4 have sensors, by means of which via signal lines 9 and
25 10 information regarding the position and situation of the patient's examination table 2 and the C-arm 4 can be supplied to the processing unit 5.

Preceding the navigation procedure, it is customary to obtain three-dimensional image information regarding the
30 vascular tree of the patient 3, using a three-dimensional rotation angiography method, which is known in itself.

While the instrument navigates through the vascular tree of the patient 3, the processing unit 5 derives a two-dimensional image from this three-dimensional image information, wherein said two-dimensional image forms a virtual
35 projection image of the vascular structure of the patient 3 in a projection orientation that corresponds with the current X-ray orientation of the patient 3. The data required for this are fed to the processing unit 5 with the aid of the above-
40 mentioned sensors, which via the signal lines 9 and 10 pass

the information regarding the situation and position of the patient's examination table 2 and the C-arm 4 to the processing unit 5.

By the above described manner, the two-dimensional projection image obtained of the vascular structure of the patient 3, and the current X-ray image in which the instrument, i.e. the catheter and/or guide wire that is passed into the vascular tree is visible, can be shown combined into one single image. This may be realised, for example, by averaging the corresponding pixels of the two images. The single image obtained in accordance with the invention can then be displayed on the monitor 7.

If the interventionist navigating the instrument considers it necessary or desirable to change the situation or position of the patient's examination table 2 or the C-arm 4, a new two-dimensional projection image is automatically and continuously formed from the previously obtained three-dimensional image information relating to the vascular structure of the patient 3. In this manner, the current X-ray image can be continuously combined with these adapted two-dimensional image data relating to the vascular structure, so as to facilitate the navigation of the instrument.

In addition to the advantages mentioned above, the apparatus and method according to the invention offer the further advantage that even without X-ray, the image of the vascular structure can be visualised on the monitor 7. This makes it possible for the interventionist to choose an optimal point of sight and viewing direction by rotating the C-arm 4 or moving the patient's examination table 2, without the necessity of involving X-ray.

CLAIMS

1. An apparatus (1) to be used with navigating an instrument in a vascular tree of a patient (3), comprises a patient's examination table (2), a C-arm (4), mounted to which is an X-ray source and an image recorder for registering first X-ray images of the patient 3, obtained by the use of the X-ray source, and a processing unit (5) connected with the image recorder for processing the images of the first images registered by the image recorder, as well as a monitor (7) optionally connectable with the processing unit (5) for displaying the image, wherein the processing unit (5) is designed for combining the first X-ray images of the patient (3) with second image data relating to at least a portion of the patient's (3) vascular tree, **characterised** in that the processing unit (5) is designed for, with respect to an adjustable projection orientation, deriving a two-dimensional projection image from three-dimensional image data concerning the vascular tree of the patient (3), wherein the projection orientation depends on the information regarding the situation and/or position of the patient's examination table (2) and/or the C-arm (4).

2. An apparatus according to claim 1, **characterised** in that the three-dimensional image information concerning the vascular tree of the patient (3) is stored in a memory (8) of the processing unit (5).

3. An apparatus according to claim 1 or 2, **characterised** in that the patient's examination table (2) and/or the C-arm (4) are provided with position and/or situation sensors that are coupled to pass signals to the processing unit 5.

4. A method for navigating an instrument in a vascular tree of a patient (3), wherein in an adjustable X-ray orientation first X-ray images of the patient (3) are obtained on which the instrument is visible, and wherein said first X-ray images are combined with second image data relating to at least a portion of the patient's (3) vascular tree, **characterised** in that the second image data are obtained by - in a projection orientation that corresponds

with the X-ray orientation of the patient (3) - deriving a projection image from three-dimensional image information relating to the vascular tree of the patient (3), and by combining this projection image with the first X-ray images.

5 5. A method according to claim 4, **characterised** in that the projection image is derived from the three-dimensional image information with a magnification of the image that is equal to the magnification of the first X-ray images.

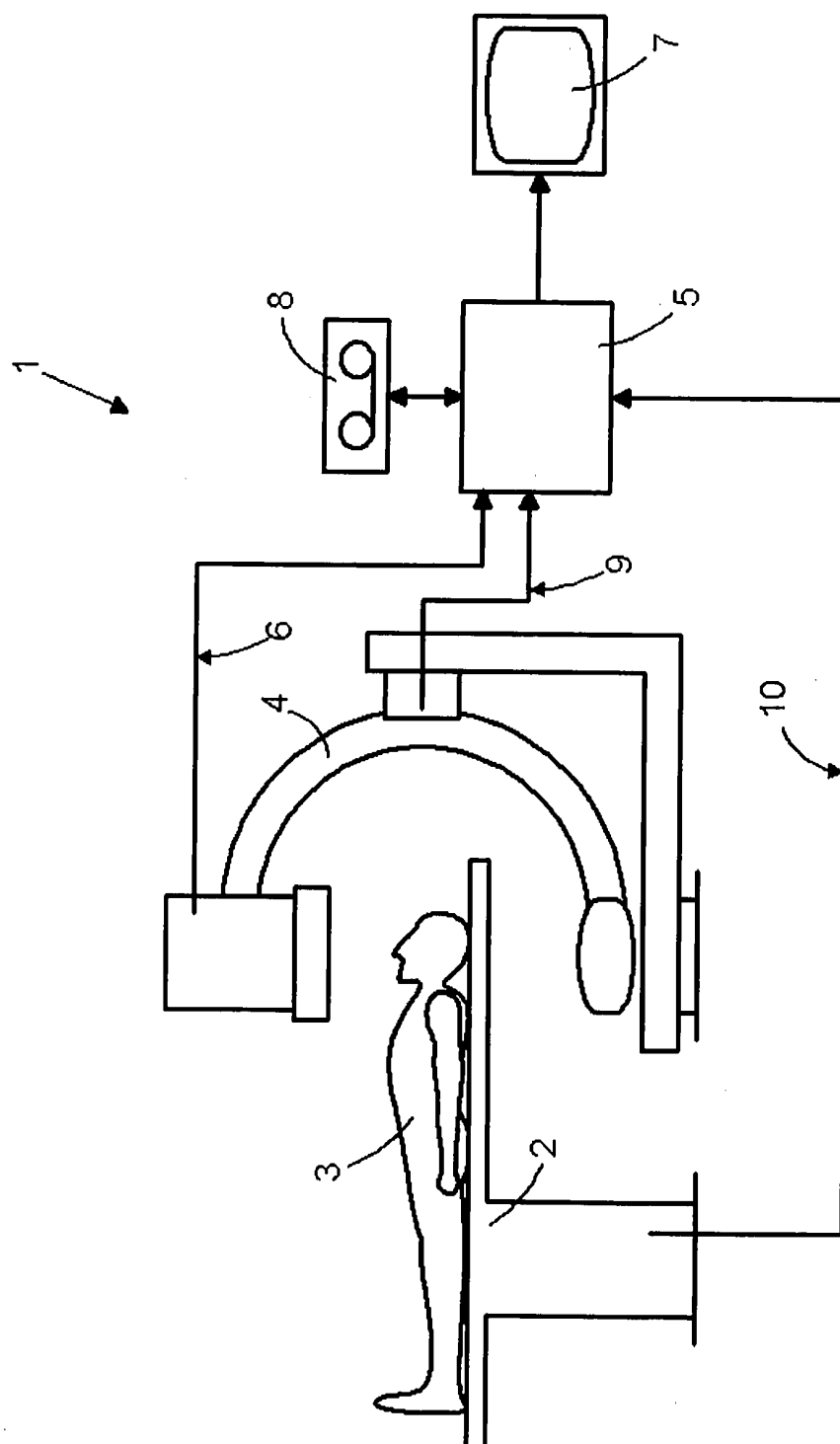
10 6. A method according to claim 4 or 5, **characterised** in that the three-dimensional image information is obtained prior to obtaining the first X-ray images.

15 7. A method according to one of the claims 4-6, **characterised** in that during the navigation of the instrument the direction of X-raying is varied, and that the direction of the projection varies correspondingly.

20 8. A computer program for collaborating with the processing unit (5) forming part of the apparatus (11) according to one of the claims 1-3 for implementing the method in accordance with one of the claims 4-7.

 9. A data carrier loaded with a computer program according to claim 8.

1/1

Fig. 1

INTERNATIONAL SEARCH REPORT

International Application No
T/NL2004/000360

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B19/00 A61B6/00 A61B6/12		
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		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 100 47 314 A (SIEMENS CORP RES INC) 5 April 2001 (2001-04-05) column 3, line 38 - column 4, line 39; figures 3-5	1-3,8,9
X	US 2001/029334 A1 (GRAUMANN RAINER ET AL) 11 October 2001 (2001-10-11) page 3, paragraph 22 - paragraph 26 page 4, paragraph 29 - paragraph 31; figures 1,2	1-3,8,9
A	US 5 852 646 A (KOPPE REINER H ET AL) 22 December 1998 (1998-12-22) abstract; figure 1	1
☐ 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. *G* document member of the same patent family		
Date of the actual completion of the international search 2 September 2004		Date of mailing of the international search report 09/09/2004
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 Moers, R

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NL2004/000360

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.: 4-7
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

International Application No

/NL2004/000360

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