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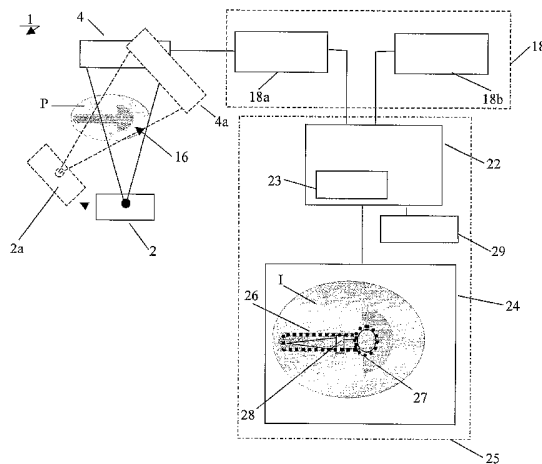
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(54) Title: A METHOD, A SYSTEM AND A COMPUTER PROGRAM FOR VALIDATION OF GEOMETRICAL MATCHING IN A MEDICAL ENVIRONMENT



(57) Abstract: A method, a system and a computer program for geometrical matching between an anatomical site and an object. A first data set (18a), representative of the anatomical site, is obtained by means of a suitable imaging using a medical diagnostic apparatus (2). The second data set (18b) comprises a geometric description of the object or its image obtained by means of a medical diagnostic unit. The system (1) comprises processing means (22) to retrieve the first data set (18a) and the second data set (18b) in order to produce a superimposed image (I) comprising the image (26) based on the first data set (18a) and an image (28), based on the second data set (18b). Images (26) and (28) are visualized on a display (24) using the same magnification factor and substantially the same orientation in space. The system (1) comprises automatic delineation means (23), and image manipulation means.

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A method, a system and a computer program for validation of geometrical matching in a medical environment

The invention relates to a method of validation of matching between geometry of an anatomical site and geometry of an object conceived to be positioned within said anatomical site.

The invention further relates to a system for enabling a validation of matching  
5 between geometry of an anatomical site and geometry of an object conceived to be positioned within said anatomical site.

The invention still further relates to a computer program.

An embodiment of a method as is set forth in the opening paragraph is known from US 6,424,332. The known method is suitable for comparing a digitized image of a joint  
10 implant with a medical image representative of geometry of a human joint, said medical image being provided on a hard-copy carrier. The known hard-copy carrier comprises an X-ray film transparency, which is mountable in front of a suitable display means where to the digitized image of the implant is projected. The known digitized image of the implant can be provided as a digital graphical model of the implant or, alternatively, it can be provided as  
15 another suitable image.

The known method is suitable for practicing a preparative step for a clinical intervention, for example for selecting a correct implant conceived to be inserted into a target area of a patient. The clinician, provided with a medical transparency, which is fixed in front of the digitized image of the implant, can check whether the implant fits to the target area. In  
20 case the clinician is certain that a proper implant is selected, he can start the intervention.

It is a disadvantage of the known method that a measure of a spatial conformance between geometry of the anatomical site and geometry of the implant can not be quantitatively assessed.

It is an object of the invention to provide a method of validation of matching  
25 between geometry of an anatomical site and geometry of an object, whereby a quantitative assessment of said matching is enabled.

To this end the method according to the invention comprises the steps of:

- obtaining a first data set representative of geometry of the anatomical site by means of a diagnostic medical apparatus;

- obtaining a second data set representative of geometry of the object,
- superimposing the first data set and the second data set using a processing means.

The technical measure of the invention is based on the insight that by obtaining the data set representative of geometry of the anatomical site by means of a suitable diagnostic medical apparatus, said data set can be made available for further analysis e.g. in a digital form. For example, the data set can be obtained by recording of suitable signals from the medical diagnostic apparatus. The signals can be provided as electronic signals or as optical signals. Also, wireless communication using Blue Tooth standard or any other suitable carrier, like an infra-red carrier is contemplated. By superimposing the first data set and the second data set using suitable processing means, an accurate assessment of the spatial conformance between the anatomical site and the object is enabled. For example, using one of per se known calculation algorithms, it is possible to establish a quantitative measure of a degree of conformance between the object and the anatomical site. Additionally, by providing information about geometry of the anatomical site and the implant in a computerized way, viewing in multiple projections can be enabled, in contrast to the known method. This increases the degree of certainty of matching between the geometry of the anatomical site and the geometry of the object. In a most simple elaboration of the method according to the invention for the second data set it is sufficient to select a suitable geometric description of the object. Preferably, the geometric description is not limited to two-dimensional representation, but comprises a full three-dimensional description of the geometry of the object. For purposes of superimposing the first data set with the second data set a view of a cross-section of the geometric description can be generated using suitable calculation means while keeping a magnification factor for the object the same as for the anatomical site. The spatial orientation of the cross-section is selected in accordance with a direction of a projection of the first data set. Preferably, the first data set is corrected for geometric distortions using per se known corrective measures.

In addition to advantages as are set forth above, the method according to the invention improves the workflow. Namely, using the method of the invention, it is possible to create an own customized library of useful objects. For example, this library can comprise saved superimposed images for certain standard views (for example, lateral, frontal, etc.) and/or for some useful customized views. Next to this, it is possible to save a plurality of objects of the same type, but having different sizes in one file, which can be loaded later for purposes of inspection. It is also possible, provided a library of the useful objects, to write a subroutine operating a suitable computer, which is arranged to load an object from the library

and to perform geometrical matching thereof to the pre-selected anatomical site in an automatic way. The subroutine can be arranged to investigate as many available useful objects as possible for selecting the best match. The best match can be subsequently saved in a further file. The medical specialist has to simply investigate the further file and to confirm  
5 the selected object.

In an embodiment of the method according to the invention, wherein the first data set comprises a first plurality of imaging projections, the second data set comprises a second plurality of projections, the method further comprises the steps of:

- reconstructing a first three-dimensional image representative of the anatomical site  
10 using the first plurality of imaging projections;
- reconstructing a second three-dimensional image representative of the object using the second plurality of imaging projections;
- using the first three-dimensional image and the second three-dimensional image for superimposing.

15 It is found to be particularly advantageous to superimpose the three-dimensional images representative of the geometry of the anatomical site and of the object, respectively. For practicing the current technical measure, for purposes of reconstruction of three-dimensional images, it is sufficient to use at least two sets of two orthogonal projections, one set for the anatomical site and the other set for the object. The process of the  
20 three-dimensional reconstruction is known per se in the art and will not be explained in detail here. According to this technical measure, it is possible to verify the geometrical matching of the implant to the anatomical site in all projections simultaneously, thus increasing the confidence level of the match.

It is advantageous to acquire the second data set using the same medical  
25 diagnostic apparatus as was used for acquisition of the first data set. This technical measure is based on an understanding of the following technical problem. Even for a calibrated medical diagnostic unit, for example, for an X-ray unit, respective readings of the meters, registering a signal representative for a particular spatial orientation of the X-ray source, may have some off-set, leading to discrepancies between the actual spatial orientation of the imaging  
30 projection and the reported position of the X-ray source. The reported position of the X-ray source is used to construct a correspondingly oriented cross-section of the object. Therefore, when this cross-section is superimposed on the medical image of the target area, a minor rotation of one image with respect to the other can be caused. Due to the fact that contemporary interventional procedures pose serious requirements for positioning accuracy it

is advantageous to avoid these minor errors by acquiring the second data set using the same apparatus as for the first data set.

Thus, when the second data set is acquired using the same imaging modality and for substantially the same imaging geometry, one can be confident that a comparison is made for the same imaging projection of both the anatomical site and the object, leading to a minimization of possible positioning error. Moreover, by applying this technical measure a surprising additional effect is reached. In case two images are obtained using the same apparatus, and for the same focus-object distance, geometric distortion of the image, normally caused by the image acquisition system, is cancelled out, leading to a further improvement of accuracy of geometrical matching.

In a further embodiment of the method according to the invention the method comprises the steps of:

- carrying out an automatic delineation of a volume of interest within the first three-dimensional image;
- carrying out an automatic fitting of the second three-dimensional image to the volume of interest.

Due to the fact that the anatomical site frequently comprises irregular shapes, it is advantageous to automatically create a volume of interest within the anatomical site whereto the object is to be fitted. The procedure of an automatic delineation of the volume of interest is per se known in the art, and can, for example, be carried out based on grey-scale values within the first three-dimensional image. As a result, all not essential information within the first three-dimensional image is discarded and the targeted fit is carried out. Preferably, the shape of the volume of interest is smoothed and geometrically described using suitable functions. During matching of the well defined structure, like the second three-dimensional image, with geometrically described volume of interest, it is possible to obtain further quantitative information about the degree of conformance between two images with further improved accuracy. This further quantitative information can be used to further elaborate a selection process of a suitable object to be positioned within the anatomical site.

A system according to the invention comprises:

- storage means arranged to store a first data set representative of geometry of the anatomical site and a second data set representative of geometry of the object,
- processing means arranged to retrieve the first data set and the second data set from the storage means, said processing means being further arranged to superimpose the first data set and the second data set to yield a superimposed image;

- display means arranged to visualize the superimposed image.

According to the technical measure of the invention, the user of the system according to the invention is enabled to select one or more computerized images of the anatomical site and one or more computerized images of the object or of different objects simultaneously on-line, even immediately before the planned intervention commences. By superimposing these images and by further displaying the superimposed image, the user can effectively and accurately carry out the task of selection of a proper object, matching geometry of the anatomical site. Any data set can be obtained by recording of suitable signals from the medical diagnostic apparatus. The signals can be provided as electronic signals or as optical signals. Also, wireless communication using Blue Tooth standard or any other suitable carrier, like an infra-red carrier is contemplated.

It is further possible to compile a database comprising available objects, for example comprising superimposed images created for different viewing angles. Additionally, in this database comments or other relevant alpha-numerical information can be stored, for example, results of a follow-up study for a particular patient group. This additional information can be used as an additional criterion during future process of the object selection for a different anatomical site belonging to the same patient group.

In an embodiment of the system according to the invention, the system comprises a medical diagnostic apparatus arranged for obtaining the first data set.

This technical measure is of particular importance when the selection process takes place immediately before the intervention. Preferably, the second data set is acquired using the same imaging apparatus, for example an X-ray device. In this case, all acquired data is obtained for the same acquisition geometry, thus improving the accuracy of comparison between respective images. Additionally, image distortion caused by the read-out components of the imaging device is cancelled out still further improving the accuracy of the comparison.

In a further embodiment of the system according to the invention, whereby the first data set comprises a first plurality of imaging projections and the second data set comprises a second plurality of imaging projections, the system further comprises:

- reconstruction means arranged to reconstruct:
- a first three-dimensional image representative of the anatomical site using the first plurality of imaging projections;
- a second three-dimensional image representative of the object using the second plurality of imaging projections;

whereby the processing means is further arranged to superimpose the first three-dimensional image and the second three-dimensional image to yield a further superimposed image, the display means being further arranged to visualize the further superimposed image.

It is found to be particularly advantageous to enable a three-dimensional  
5 investigation of geometrical matching between the object and the anatomical site. Using a suitable graphical representation, like a transparency mode or a specific color-wash for reconstructed images, it is easy to comprehend the degree of three-dimensional conformance between the anatomical site and the object, thus further improving the accuracy of the selection. Using per-se known calculation algorithms it is possible to compute the degree of  
10 spatial conformance between the object and the anatomical site.

In a still further embodiment of the system according to the invention, the system further comprises:

- automatic delineation means arranged to delineate a volume of interest within a  
second three-dimensional image of the anatomical site, the processing means being  
15 further arranged to carry out an automatic fit between the second three-dimensional image and the volume of interest.

This technical measure is based on the insight that an accuracy of the matching is increased when two geometrically well defined shapes are compared. The object, usually being a mechanical structure, has a well defined shape. The anatomical site usually has a well  
20 defined volume of interest wherein the object is to be positioned. Therefore, by carrying out an automatic delineation of the volume of interest within the first three-dimensional image of the anatomical site, the accuracy of comparison of the volume of interest with the three-dimensional image of object is further improved. Preferably, the delineated volume of interest is subjected to a smoothing operation prior to the comparison. This technical measure  
25 has an additional advantage, namely, when the volume of interest is geometrically described using suitable functions determining its spatial shape, it is possible to perform a further quantitative analysis of the degree of conformance between the volume of interest and the object. These quantitative data can be further used as a parameter for the object selection, or for reporting purposes, or for purposes of further analysis, like a patient follow-up.

30 In a still further embodiment of the system according to the invention the system comprises means for manipulating the superimposed image and the further superimposed image.

For enabling a good comprehension of geometry of the anatomical site and of geometry of the object, it is found to be advantageous to enable manipulation of the



superimposed image. This manipulation is preferably arranged to spatially manipulate each of the components of the superimposed image, it being the first data set, the second data set, or, alternatively, the first three-dimensional image, the second three-dimensional image and the volume of interest, where applicable. This functionality of the system enables the operator thereof to carry out a manual fit of the object to the anatomical site. The envisaged spatial manipulation comprises operations of move, rotate or any other displacing.

The computer program according to the invention comprises instructions to:

- transfer a first data set representative of geometry of an anatomical site between a storage means and a processing means;
- 10 - transfer a second data set representative of geometry of an object between the storage means and the processing means;
- superimpose the first data set and the second data set to yield a superimposed dataset;
- transfer the superimposed dataset to a display means.

The computer program according to the invention is in particular suitable to operate a system arranged for enabling a validation of matching between geometry of the anatomical site and geometry of the object, said object being conceived to be positioned within said anatomical site, said system comprising the storage means arranged to store the first data set and the second data set, said system further comprising processing means arranged to retrieve said first data set and said second data set, said system still further comprising the display means. When the computer program is executing its set of instructions, the first data set and the second data set are loaded from the storage means according to a first set of instructions. The first set of instructions comprises, for example an input/output operation between suitable hardware units of a computer. Alternatively or additionally, the first set of instructions may comprise a downloading instruction from a remote computer or a remote source of data, like intranet or internet. Subsequently, in accordance with a second set of instructions, the first data set is superimposed on the second data set to yield the superimposed dataset. The second set of instructions may comprise an image processing step arranged to produce corresponding imaging projections from images contained in the first data set and the second data set, respectively. Next, the superimposed image is made available to an operator on the display means according to the third set of instructions. The third set of instructions may comprise a further image processing, including, for example a suitable sizing of the corresponding images. An executable code of the computer program can be stored within a piece of hardware of a computer, or it can be stored on an exchangeable carrier, like a hard disk, a CD-ROM, or the like. Optionally, the

executable code can be arranged to be downloadable from a remote site, like a web page on the internet.

In an embodiment of the computer program according to the invention, the computer program is arranged to operate a user-interface arranged for visualization of the superimposed dataset.

Preferably, the computer program comprises a further set of instructions arranged to enable an interactive manipulation of the superimposed dataset. For example, the further set of instructions may comprise commands arranged to re-size images, carry out zoom-in or zoom-out operations and to perform translation and/or rotation of the superimposed dataset, build-up three-dimensional images from the respective datasets, and the like. This technical feature enables the operator to obtain a better insight into respective geometries of the medical site and the object and to validate matching of said geometries with high degree of confidence.

15

These and other aspects of the invention will be further discussed with reference to figures.

Figure 1 presents a schematic view of an embodiment of the system according to the invention.

Figure 2 presents a schematic view of an embodiment of a data acquisition system for the object.

Figure 3 presents a schematic view of an embodiment of a method according to the invention.

25

Figure 1 presents a schematic view of an embodiment of the system according to the invention. The system 1 for enabling a validation of matching between geometry of a anatomical site and geometry of an object conceived to be positioned within said anatomical site, according to the invention, operates using respective data sets representative of the anatomical site and of the object.

The first data set 18a, representative of the anatomical site, is obtained by means of a suitable imaging using a medical diagnostic apparatus 2. Figure 1 shows in a simplified way an embodiment of an X-ray unit, which is suitable for obtaining data set 18a representative of the anatomical site of a patient P. In this embodiment a joint 16 is shown as

the anatomical site. In order to enable spatial matching between the anatomical site 16 and the object conceived to be positioned within said site, for example a joint implant, the anatomical site 16 is examined for at least two projections using an X-ray source 2. For this purpose the X-ray source 2 and the X-ray detector 4 are rotated around the patient P. The  
5 corresponding transmission images are detected by means of an X-ray detector at its respective positions 4, 4a. The resulting images are stored in the storage means 18. In spite of the fact that Figure 1 schematically illustrates one common storage means 18, it is also possible that the respective images are stored in physically separate storage units (not shown), which can be accessed from a remote location.

10 The system 1 further comprises processing means 22 arranged to retrieve the first data set 18a and the second data set 18b in order to produce a superimposed image I comprising the image 26 based on the first data set 18a and an image 28, based on the second data set 18b. Images 26 and 28 are visualized using the same magnification factor and substantially the same orientation in space. The superimposed image I is fed-back to the user  
15 of the system by means of a suitable display screen 24 using a suitable user-interface (not shown). Although two-dimensional images are illustrated in Figure 1, it is possible that the processing means 22 is arranged to produce respective three-dimensional images, which are mutually superimposed and presented as such on the display 24. The system 1 further comprises automatic delineation means 23, which is arranged to carry out an automatic  
20 delineation of the volume of interest within the first three-dimensional image. A projection of the volume of interest on the two-dimensional image I is schematically shown by an area 27. The system 1 further comprises manipulation means 29, arranged to displace the image of the anatomical site 26 and/or the image of the object 28. A suitable example of the manipulation means is a computer mouse, a keyboard cursor, or any other suitable means, including a  
25 voice control. A control signal (not shown) from the manipulation means 29 is received by the processing means 22, after which a corresponding image is displaced. Preferably, the processing means 22 and the display means make part of one computer 25, preferably installed on a data network. An example of a suitable data network is a hospital information system.

30 Figure 2 presents a schematic view of an embodiment of a data acquisition system for the object. It is found to be preferable, to acquire the second data set using the same imaging unit, as was used for purposes of first data set acquisition. The data acquisition system 10 for the object comprises a medical diagnostic apparatus, for example an X-ray unit. For purposes of acquisition of the second data set, the object 6 is positioned between the

X-ray source 2' and the X-ray detector 4', the resulting transmission image being generated by suitable image generation means 8 coupled to the detector 4'. In order to enable a three-dimensional image generation, the X-ray source 2' and the X-ray detector 4' are rotated around the object 6 and a number of transmission images is taken, for example for positions 5 2', 2a'. It is sufficient to register at least two orthogonal images. Upon a generation of the second data set, it is stored in a storage unit 9, which is arranged to be accessible by the processing means (not shown) of the system according to the invention.

Figure 3 presents a schematic view of an embodiment of a method 20 according to the invention. The method according to the invention is suitable to enable a 10 validation of matching between geometry of anatomical site and geometry of an object conceived to be positioned within said site. At step 21 of the method 20 according to the invention, a first data set 23, 25 representative of the anatomical site is obtained. This step can comprise loading of a pre-stored image 23, or a step of acquisition of the image 25. The step of image acquisition is performed in case the method of the invention is practiced 15 immediately prior to the planned intervention. Next, the second data set representative of the object is obtained. This step also includes a plurality of options, namely loading 24 of a pre-stored image of the implant, accessing 26 a remote location, for example a site of a manufacturer to download data comprising geometric description of the object, or, alternatively, carrying out an image acquisition 28 using the same imaging unit and 20 substantially the same imaging geometry, as for acquisition of the first data set 25. It must be noted, that the step 24 of loading a pre-stored image of the implant can comprise loading of a geometrical model of the implant, or loading a pre-stored image obtained using the medical diagnostic apparatus. In the latter case it is preferable that the second data set acquisition is carried out for substantially the same imaging geometry as was used or will be used for 25 acquisition of the first data set.

Upon obtaining of the first data set and the second data set, a superimposing 30 of these data sets is carried out. This step enables the operator visually and quantitatively investigate the degree of matching between the anatomical site and the object. In case three-dimensional images are superimposed, the viewer can study the spatial conformance between the target volume of the anatomical site and the object. Additionally, at step 32 a volume of 30 interest within the three-dimensional image of the anatomical site is delineated and an automatic fit between the volume of interest and the second three-dimensional image is carried out. The results of the fit can be used as a further quantitative parameter for selection purposes. In case the results of a visual or quantitative validation of matching meet an a-

priori defined criterion, the selection procedure of the suitable object is finalized 34.

Otherwise, an image of another object is selected and steps 30 and further are followed.

Optionally, at step 36 a suitable reporting can be carried out.

## CLAIMS:

1. A method (20) of validation of matching between geometry of an anatomical site and geometry of an object conceived to be positioned within said anatomical site, said method comprising the steps of:
- obtaining (21) a first data set (23,25) representative of geometry of the anatomical site by means of a diagnostic medical apparatus;
  - obtaining (22) a second data set (24,26,28) representative of geometry of the object, superimposing (30) the first data set and the second data set using a processing means.
2. A method according to Claim 1, wherein the first data set comprises a first plurality of imaging projections, the second data set comprises a second plurality of imaging projections, the method further comprising the steps of:
- reconstructing a first three-dimensional image representative of the anatomical site using the first plurality of imaging projections;
  - reconstructing a second three-dimensional image representative of the object using the second plurality of imaging projections;
  - using the first three-dimensional image and the second three-dimensional image for superimposing.
3. A method according to Claim 2, wherein the method comprises the steps of:
- carrying out an automatic delineation of a volume of interest within the first three-dimensional image;
  - carrying out an automatic fitting of the second three-dimensional image to the volume of interest.
4. A system (1) for enabling a validation of matching between geometry of a anatomical site (16) and geometry of an object (6) conceived to be positioned within said anatomical site, said system comprising:

- storage means (18) arranged to store a first data set (18a) representative of geometry of the anatomical site and a second data set (18b) representative of geometry of the object,
  - processing means (22) arranged to retrieve the first data set and the second data set  
5 from the storage means (18), said processing means (22) being further arranged to superimpose the first data set and the second data set to yield a superimposed image (I);
  - display means (24) arranged to visualize the superimposed image.
- 10 5. A system according to Claim 4, wherein the system further comprises a medical diagnostic apparatus (2) arranged for obtaining the first data set (18a).
6. A system according to Claim 5, wherein the medical diagnostic apparatus is further arranged to obtain the second data set.
- 15 7. The system according to Claim 6, wherein the first data set comprises a first plurality of imaging projections (2, 2a), the second data set comprises a second plurality of imaging projections (2', 2a'), the system further comprising:
- reconstruction means (22) arranged to reconstruct:
  - 20 - a first three-dimensional image representative of the anatomical site using the first plurality of imaging projections;
  - a second three-dimensional image representative of the object using the second plurality of imaging projections;
- whereby the processing means (22) is further arranged to superimpose the first three-  
25 dimensional image and the second three-dimensional image to yield a further superimposed image, the display means being further arranged to visualize the further superimposed image.
8. The system according to Claim 7, wherein the system further comprises:
- automatic delineation means (23) arranged to delineate a volume of interest (27)  
30 within the first three dimensional image, the processing means (22) being further arranged to carry out an automatic fit between the second three-dimensional image (28) and the volume of interest (27).

9. A system according to any one of preceding Claim 4-8, wherein the system further comprises:
- means (29) for manipulating the superimposed image and the further superimposed image.
- 5
10. A computer program comprising instructions to
- transfer a first data set (18a) representative of geometry of an anatomical site between a storage means (18) and a processing means (22);
  - transfer a second data set (18b) representative of geometry of an object between the
- 10 storage means and the processing means;
- superimpose (30) the first data set and the second data set to yield a superimposed dataset (I);
  - transfer the superimposed dataset to a display means (24).
- 15
11. A computer program according to Claim 10, being further arranged to operate a user-interface arranged for visualization of the superimposed dataset.



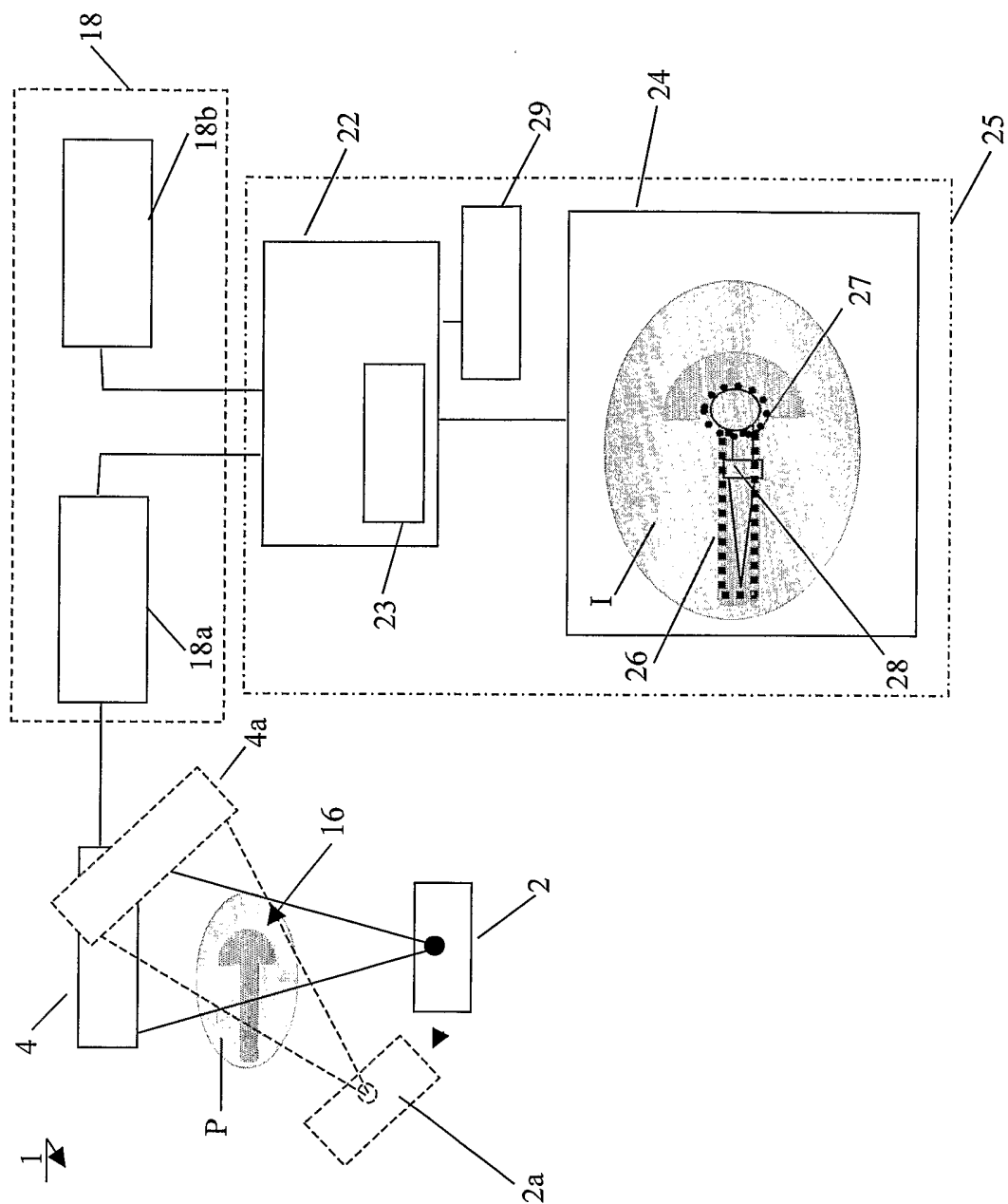


FIG.1

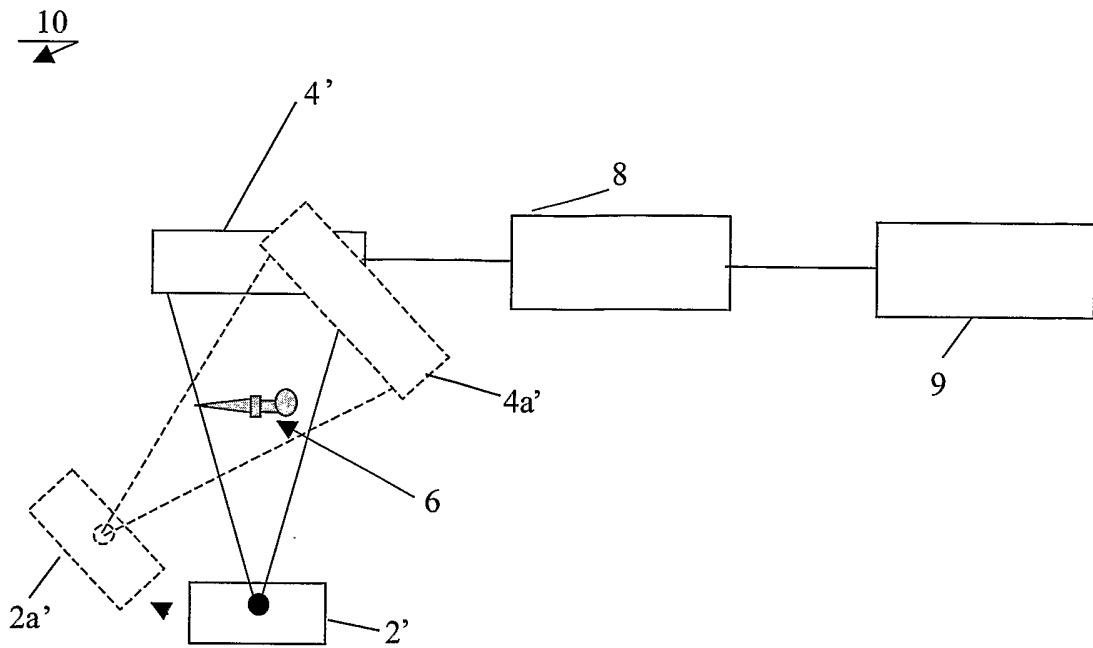


FIG. 2

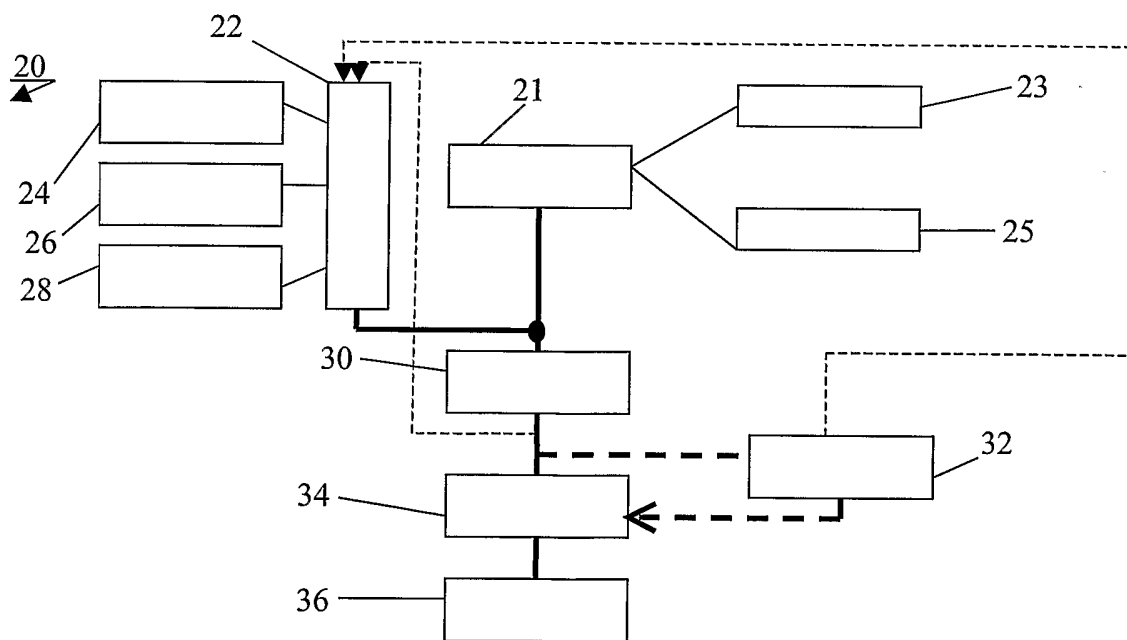


FIG. 3

# INTERNATIONAL SEARCH REPORT

International Application No  
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**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 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 symbols)  
IPC 7 A61B A61F

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, INSPEC

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search

25 April 2005

Date of mailing of the international search report

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## INTERNATIONAL SEARCH REPORT

International Application No  
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