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D E C I S I O N
of 20 November 1997

Case Number: T 0646/95 - 3.2.2

Application Number: 88403160.0

Publication Number: 0326768

IPC: A61B 19/00

Language of the proceedings: EN

Title of invention:
Computer-aided surgery apparatus

Applicant:
FARO MEDICAL TECHNOLOGIES INC.

Opponent:

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Headword:

-

Relevant legal provisions:
EPC Art. 84, 123(2)

Keyword:
"Claims - clarity and support by description (no)"
"Amendments - added subject-matter (confirmed)"

Decisions cited:

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Catchword:

-



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Case Number: T 0646/95 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 20 November 1997

Appellant: FARO MEDICAL TECHNOLOGIES INC.
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Quebec H4S 1M9 (CA)

Representative: Bloch, Gérard
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 29 March 1995
refusing European patent application
No. 88 403 160.0 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: M. G. Noël
J. C. M. De Preter

Summary of Facts and Submissions

- I. By decision of 29 March 1995 the Examining Division refused European patent application No. 88 403 160.0 (publication No. 0 326 768) on the grounds that, in particular, the requirements of Articles 84 and 123(2) EPC were not fulfilled having regard to independent method claim 1 and device claim 12.
- II. Among the many reasons given by the first instance:
- The step of "constantly sensing the position and orientation of the patient portion" has not been disclosed in the application as originally filed. What is constantly calculated by the computer is the position of the operating portion of the surgical instrument, but not the position of the patient portion, as recited in the preamble of claim 1.
 - The subject-matter of claim 1 is not restricted (as it should be) by the step of fixedly attaching the patient portion to the measurement arm holding the instrument according to the mentioned preferred aspect of the method (cf. e.g. page 8, lines 18 to 30 of the application as filed).
 - The terminology of "actual" position and "actual" orientation of the portion of the patient as defined in the characterising portion of either claim 1 or 12 also introduces subject-matter which extends beyond the content of the application as filed.

III. The appellant lodged an appeal against the first instance's decision on 26 May 1995. A statement of grounds was filed on 17 July 1995 and the appeal fee paid in due time.

The appellant requested that the decision under appeal be set aside and the application granted on the basis of the latest submissions.

IV. In response to the above reasons for refusal by the Examining Division, the appellant's arguments were as follows:

- It is clear from the patent application that the portion of the patient is fixedly linked to the reference block so that the block follows the movements of this portion. On the other hand it is obvious that the position and orientation of the reference block is continuously monitored in order to continuously determine the position and orientation of the surgical instrument which is supported from the reference block by the electrogoniometer. Therefore, the position and orientation of the portion of the patient is also continuously monitored.

- There is no reason why claim 1 should be restricted to the step of fixedly attaching the patient portion to the measurement arm holding the instrument, ie to a step that the Examining Division itself considers only as a preferred aspect of the method and not as an essential characteristic. There are other methods for constantly sensing the position or the orientation of the portion of the patient, than fixedly attaching this portion to the reference block.

- The "actual" position and orientation of the patient portion is correctly supported by the application as filed.

V. Independent claims 1 and 12 in suit read as follows:

"1. Method for computer-aided surgery wherein a medical practitioner is assisted in employing a surgical instrument or implant during a surgical procedure being performed on a portion of a patient, wherein the position and orientation of said instrument or implant is determined in a three-dimensional co-ordinate system relative to a reference point and the position and orientation of said portion is determined in said three-dimensional co-ordinate system relative to said reference point, said reference point being disposed outside of and apart from said patient;

said method comprising:

constantly sensing, the position and orientation of said portion in said three-dimensional co-ordinate system to obtain three-dimensional target data of the position and orientation of said portion in said three dimensional co-ordinate system relative to said reference point;

converting said target data to target signals for presenting the position and orientation of said portion on a display device (19);

providing said target signals to said display device (19) whereby a target display of the position and orientation of said portion is presented on said display device (19);

constantly sensing the position and orientation of said surgical instrument or implant in said three-dimensional co-ordinate system to obtain three-dimensional instrument data of the position and orientation of said instrument or implant in said three-dimensional co-ordinate system relative to said reference point;

converting said instrument data to instrument signals for presenting the position and orientation of said instrument or implant on said display device (19);

providing said instrument signals to said display device (19) whereby an instrument display of the position and orientation of said instrument or implant is presented on said display device;

wherein, as the instrument or implant is manipulated by said medical practitioner, said instrument data changes in accordance with changes in the position and orientation of said instrument, and said instrument display changes in accordance with the changes in said instrument data;

whereby, the position and orientation of said instrument or implant, relative to said portion, is dynamically displayed on said display device (19); said method being **characterized** in that it comprises the step of:

displaying on said display device (19) a relationship between the position and orientation of said surgical instrument or implant and surgical instrument or implant and the actual position and the actual orientation of the portion of the patient on which said procedure is to be carried out which corresponds identically to the actual physical relationship between

the position and orientation of said surgical instrument or implant and the position and orientation of said portion of the patient."

"12. A computer-aided surgical device, having an associated three dimensional co-ordinate reference system, for aiding a medical practitioner in positioning a surgical instrument or implant when performing surgery on, or examining, portions in or on said patient defined either by physical measurement of the positions and orientations, in said co-ordinate reference system, of said portions using said device, or by communication to said device, from an external 2- or 3-dimensional imaging information source, of the positions and orientations, in said co-ordinate reference system, of said portions, said measurement of said communication defining two- or three-dimensional patient data of the position and orientation of said portions in said coordinate system;

whereby, said patient data, identifies the position and orientation of said portions to which surgical procedures, or examinations, are to be applied;

said device comprising:

a reference means (9) having a referenced point in the reference co-ordinate system thereon;

said reference means and said reference point being disposed outside of and apart from said patient;

means (79-87) for determining the position and orientation of said portion on said patient in said co-ordinate reference system relative to said reference point and for developing two- or three-dimensional patient display data proportional to said position and orientation of said portion;

instrument position determining means (7) including sensing means for sensing the position and orientation of said instrument or implant in said co-ordinate reference system relative to said reference point and for developing two- or three-dimensional instrument data proportional to said position and orientation of said instrument;

a display means (19);

means (23) for converting said patient display data to objective signals for presenting an objective display on said display means,

means for converting said instrument data to instrument signals for presenting the position and orientation of said instrument or implant on said display means;

characterised in that it comprises means for presenting on said display a relationship between the position and orientation of said surgical instrument or implant and the actual position and the actual orientation of the portion on the patient on which a procedure is to be carried out which corresponds identically to the actual physical relationship between the position and orientation of said surgical instrument or implant and the position and orientation of said portion of the patient."

In apparatus claim 12 (line 5) a clerical error (deletion of the terms "of a orientation" between "portions" and "in or on") was rectified on the appellant's request and further minor and obvious clerical errors were corrected by the Board, on its own motion:

- in line 3, "is" is replaced by "in"
- in line 13, "commutation" is replaced by "communication"
- in lines 14 and 16, "date" is replaced by "data".

Reasons for the Decision

1. The appeal is admissible.
2. *The invention*

The main problem upon which the invention is based is to assist a surgeon in accurately positioning surgical instruments for performing surgical procedures on a patient.

As shown on Figures 1 and 2 the instrument to be positioned and oriented is fixedly connected to the free end 7A of an arm 7 of an electrogoniometer whereas the other end of it is linked to a reference block 9 which, in turn, is connected to a post 13 supporting a monitor 19 (display). The purpose of the reference block is to determine the position, orientation and length of the instrument (cf. patent application, page 7, lines 25 to 29). The position of the surgical instrument relative to the reference block is constantly calculated by a computer 23, and this position is continuously displayed on the monitor (page 8, lines 1 to 17).

As the position and orientation of the instrument now displayed is determined in relation to the reference block, by establishing and maintaining a fixed relationship between the position of a portion of the

patient on which surgical operating procedures are to be performed and the reference block, the displayed information will necessarily show the actual position and orientation of the instrument relative to the patient portion. Thus, any motion imparted to the patient portion during a surgical procedure will be imparted to both the reference block and the electrogoniometer, so that the position and orientation of the reference plane at the site of operation will remain unchanged (cf. page 8, lines 18 to 30 and from page 11, line 27 to page 12, line 6).

According to the invention, essentially, a fixed relationship between the portion of interest on the patient and the reference block is achieved by means of a mechanical linkage such as the link arrangement shown in Figures 1 and 10, including a plurality of clamping members interconnected by shafts.

3. *Amendments to claims 1 and 12*

3.1 In the precharacterising portion of the method claim 1 the step of "constantly sensing the position and orientation of said portion (cf. a patient)" was introduced (in a modified form) for the first time by the appellant, in its letter dated 10 February 1994.

However, according to the application as originally filed (cf. page 8, lines 1 to 17) it is quite clear that only the position and orientation of the surgical instrument relative to the reference block is constantly calculated by the computer and displayed on the monitor.

The position and orientation of the patient portion is generally defined either by a physical measurement, making use of the device, or by communication to the

device from an external imaging information source, so as to define a three-dimensional target data of the patient portion in the co-ordinate system (cf. precharacterising portions of claims 1 or 10 as originally filed). Nowhere in the application as filed are to be found other means for originally defining the position and orientation of the portion of the patient.

Actually, the position of the patient portion needs not be continuously sensed since the purpose of the fixed relationship, ie the mechanical linkage, is precisely to automatically submit the reference system to the movements of the patient, as explained in above point 2. Therefore, the expression "constantly sensing...said portion" added to claim 1 is not only contrary to the concept of the invention but it also extends its subject-matter beyond the content of the application as filed. Therefore, in the Board's judgement, the requirements of Article 123(2) EPC are not satisfied.

- 3.2 The characterising portions of claims 1 and 12 generally refer to a relationship (not even fixed) between the position and orientation of the surgical instrument and the actual position and orientation of the portion of the patient. Although the term "relationship" as such is supported by the application as filed, the broad wording which is used renders the claimed subject-matter as a whole indefinite. In the absence of more specific means such as the mechanical linkage between the patient portion and the reference block, which is considered by the Board as an essential feature of the invention, the main claims do not actually give any concrete solution to the problem addressed in the application. As a consequence, the subject-matter of claims 1 or 12 is neither clear nor complete nor supported by the description, within the meaning of Article 84 and Rule 29(1) and (3) EPC.

3.3 Further, in the absence of more specific means to characterise the relationship, the subject-matter of these claims is not clearly distinguished from the disclosure of the prior art document (1) GB-A-2 094 590, in which there is described (cf. page 4, lines 42 to 74 and page 9, lines 34 to 40) a displayed relationship between the portion of the patient, which is held in a rigid position with respect to the frames of reference of a probe and a scanner, and the surgical instrument (or probe): see also the communication of the Examining Division of 23 February 1994 (points 3 and 4) objecting lack of novelty. In this connection, the Board observes that in the subsequent appellant's reply dated 17 August 1994, the embarrassing objection of the first instance was no more discussed still less removed by the appellant.

3.4 In the statement setting out the grounds of appeal, the appellant maintained its stand in the face of the first instance's objections of lack of clarity and extension of subject-matter, upon which the decision of refusal is principally based.

Since the appellant maintained its view upon the formal questions at issue without filing any amendments to the claims by way of auxiliary requests, and in particular without taking account of the first instance's relevant remark that claim 1 was not sufficiently specified (cf. decision, point 1.5, last sentence: "Thirdly, claim 1 is not restricted by the corresponding step of fixedly attaching the patient portion (via the reference block) to the measurement arm (electrogoniometer) holding the instrument..."), the Board, following in all respects the view of the first instance, is founded to confirm the decision of refusal under appeal without contravening the appellant's right to be heard (Article 113(1) EPC) on the same grounds as those set out by the first instance.

- 3.5 It results therefrom that, in the Board's judgement, the subject-matter of the method claim 1 and the device claim 12 are not acceptable for both lack of clarity (Article 84) and lack of adequate support (Article 123(2) EPC).
4. After the refusal of the independent claims 1 and 12 and considering that a patent cannot be granted partially, examination of the objection raised under Article 52(4) (methods for treatment by surgery or therapy) against the dependent claims 2 to 11 can be dispensed with.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:



S. Fabiani

The Chairman:



H. Seidenschwarz

