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Datasheet for the decision of 12 February 2014

Case Number: T 0978/10 - 3.2.02

05012193.8 Application Number:

Publication Number: 1568345

IPC: A61H31/00, G07C9/00, G06F1/00,

A61B19/00

Language of the proceedings: ΕN

Title of invention:

Public Access CPR and AED Device

Applicant:

Revivant Corporation

Headword:

Relevant legal provisions:

EPC Art. 76(1), 84, 52(1), 54(1), 54(2) EPC R. 43(2), 115(2) RPBA Art. 15(3)

Keyword:

Divisional application - subject-matter extends beyond content of earlier application (yes) Claims - conciseness (no) Novelty - (no) Oral proceedings - held in absence of appellant

Decisions cited:

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 0978/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 February 2014

Appellant: Revivant Corporation
(Applicant) 775 Palomar Avenue

Sunnyvale, CA 94086 (US)

Representative: Nordic Patent Service A/S

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1200 Copenhagen K (DK)

Decision under appeal: Decision of the Examining Division of the

European Patent Office posted on

28 December 2009 refusing European patent application No. 05012193.8 pursuant to

Article 97(2) EPC.

Composition of the Board:

M. Stern

- 1 - T 0978/10

Summary of Facts and Submissions

I. The applicant has appealed the Examining Division's decision, dispatched on 28 December 2009, to refuse European patent application No. 05 012 193.8, which is a divisional application of European patent application No. 00 913 721.7.

II. The impugned decision was based on a main and first to third auxiliary requests. In the reasons for the decision, the Examining Division considered in particular the following documents:

D2: DE-A-196 30 951; D8: WO-A-99/09929.

The Examining Division held that the subject-matter of claims 1 and 2 of all requests extended beyond the content of the parent application as originally filed, was not clear and lacked novelty over the disclosure of each of documents D2 and D8. Furthermore, the presence of two independent claims in the same category in the main request and the second auxiliary request was held not to meet the requirements of Article 84 EPC in combination with Rule 43(2) EPC.

- III. The notice of appeal was received on 26 February 2010 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 23 April 2010.
- IV. The Board summoned the appellant to oral proceedings and provided its provisional opinion by a communication dated 26 November 2013.

- 2 - T 0978/10

- V. The appellant informed the Board that it would not be present at the oral proceedings. These were held on 12 February 2014 in the appellant's absence.
- VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 and 2 according to the main request or, in the alternative, of claims 1 and 2 according to one of the first to third auxiliary requests, all requests having formed the basis of the impugned decision.
- VII. The claims of the appellant's requests are reported below.
 - a) Claim 1 of the main request reads as follows (compared to independent claim 6 of the parent application as originally filed, additions are underlined, deletions are struck through):

"A medical treatment system for treatment of a patient, wherein said medical treatment system which is intended to be used in an environment wherein the device may be removed from a secure storage device and deployed upon the patient by a first operator pending arrival of a second operator, said medical treatment system comprising:

- a plurality of medical devices (2, 7L & 7R, 8L & 8R, 9L & 9R, 10i & 10s, 11);
- means (12, 24) for controlling physical access to
 the plurality of medical devices,;
- means (12, 25) for controlling functional enablement of a medical device included within

- 3 - T 0978/10

the plurality of medical devices;

- means (14, 15, 16, 17, 22, 23) for identifying the first operator and means (24) for permitting physical access to a medical device by the first operator while prohibiting functional enablement of the medical device to the first operator;
- means (14, 15, 16, 17, 22, 23) for identifying the second operator and means (25) for permitting functional enablement of a medical treatment device included within the plurality of medical devices upon identification of the second operator;
- wherein the means (24) for controlling physical access is operable to permit physical access to a medical treatment device included within the plurality of medical devices depending upon the identity of the first operator; and
- the means (25) for controlling function<u>al</u>
 enablement is operable to permit functional
 enablement of a medical device included within
 the plurality of medical devices depending
 upon the identity of the second operator;
- wherein at least one of the medical devices

 amongst the plurality of medical devices is

 capable of both diagnosis and treatment of a

 condition of the patient, and the controller

 permits the first operator to operate the at

 least one medical device in diagnosis of the

 patient while prohibiting the first operator

- 4 - T 0978/10

from operating the at least one medical device
in therapeutic treatment of the patient."

b) Claim 2 of the main request reads as follows (compared to independent claim 6 of the parent application as originally filed, additions are underlined, deletions are struck through):

"A medical treatment system for treatment of a patient, wherein said medical treatment system which is intended to be used in an environment wherein the device may be removed from a secure storage device and deployed upon the patient by a first operator pending arrival of a second operator, said medical treatment system comprising;

- a plurality of medical devices (2, 7L & 7R, 8L & 8R, 9L & 9R, 10i & 10s, 11);
- means (12, 24) for controlling physical access to
 the plurality of medical devices;
- means (12, 25) for controlling functional enablement of a medical device included within the plurality of medical devices;
- means (14, 15, 16, 17, 22, 23) for identifying the first operator and means (24) for permitting physical access to a medical device by the first operator while prohibiting functional enablement of the medical device to the first operator;
- means (14, 15, 16, 17, 22, 23) for identifying the second operator and means (25) for

- 5 - T 0978/10

permitting functional enablement of a medical treatment device included within the plurality of medical devices upon identification of the second operator;

- wherein the means (24) for controlling physical access is operable to permit physical access to a medical treatment device included within the plurality of medical devices depending upon the identity of the first operator; and
- the means (25) for controlling function<u>al</u> enablement is operable to permit functional enablement of a medical device included within the plurality of medical devices depending upon the identity of the second operator;
- wherein the at least one medical device is an automatic external defibrillator, and the controller permits access to the automatic external defibrillator to the first operator, thereby allowing the first operator to install the automatic external defibrillator on the patient, but the system prohibits the first operator from operating the automatic external defibrillator to apply defibrillating shock to the patient, and the system permits the second operator to operate the automatic external defibrillator to apply defibrillating shock to the patient."
- c) Claim 1 of the first auxiliary request is identical to claim 1 of the main request.

- 6 - T 0978/10

d) Claim 2 of the first auxiliary request reads as follows:

"A medical treatment device of claim 1 wherein: the at least one medical device is an automatic external defibrillator, and the controller permits access to the automatic external defibrillator to the first operator, thereby allowing the first operator to install the automatic external defibrillator on the patient, but the system prohibits the first operator from operating the automatic external defibrillator to apply defibrillating shock to the patient, and the system permits the second operator to operate the automatic external defibrillator to apply defibrillating shock to the patient."

e) Claim 1 of the second auxiliary request reads as follows (compared to claim 1 of the main request, additions are underlined):

"A medical treatment system for treatment of a patient, wherein said medical treatment system is intended to be used in an environment wherein the device may be removed from a secure storage device and deployed upon the patient by a first operator pending arrival of a second operator, said medical treatment system comprising:

a plurality of medical devices (2, 7L & 7R, 8L & 8R, 9L & 9R, 10i & 10s, 11);

means (12, 24) for controlling physical access to the plurality of medical devices, ;

- 7 - T 0978/10

- means (12, 25) for controlling functional enablement of a medical device included within the plurality of medical devices;
- means (14, 15, 16, 17, 22, 23) for identifying the first operator as having a first level of training and means (24) for permitting physical access to a medical device by the first operator while prohibiting functional enablement of the medical device to the first operator;
- means (14, 15, 16, 17, 22, 23) for identifying the second operator as having a second level of training and means (25) for permitting functional enablement of a medical device included within the plurality of medical devices upon identification of the second operator;
- wherein the means (24) for controlling physical access is operable to permit physical access to a medical device included within the plurality of medical devices depending upon the identity of the first operator; and
- the means (25) for controlling functional enablement is operable to permit functional enablement of a medical device included within the plurality of medical devices depending upon the identity of the second operator;
- wherein at least one of the medical devices amongst the plurality of medical devices is capable of both diagnosis and treatment of a condition of the patient, and the controller

-8- T 0978/10

permits the first operator to operate the at least one medical device in diagnosis of the patient while prohibiting the first operator from operating the at least one medical device in therapeutic treatment of the patient."

f) Claim 2 of the second auxiliary request reads as follows (compared to claim 2 of the main request, additions are underlined):

"A medical treatment system for treatment of a patient, wherein said medical treatment system is intended to be used in an environment wherein the device may be removed from a secure storage device and deployed upon the patient by a first operator pending arrival of a second operator, said medical treatment system comprising;

- a plurality of medical devices (2, 7L & 7R, 8L & 8R, 9L & 9R, 10i & 10s, 11);
- means (12, 24) for controlling physical access to the plurality of medical devices;
- means (12, 25) for controlling functional enablement of a medical device included within the plurality of medical devices;
- means (14, 15, 16, 17, 22, 23) for identifying the first operator as having a first level of training and means (24) for permitting physical access to a medical device by the first operator while prohibiting functional enablement of the medical device to the first operator;

- 9 - T 0978/10

- means (14, 15, 16, 17, 22, 23) for identifying the second operator as having a second level of training and means (25) for permitting functional enablement of a medical device included within the plurality of medical devices upon identification of the second operator;
- wherein the means (24) for controlling physical access is operable to permit physical access to a medical device included within the plurality of medical devices depending upon the identity of the first operator; and
- the means (25) for controlling functional enablement is operable to permit functional enablement of a medical device included within the plurality of medical devices depending upon the identity of the second operator;
- wherein the at least one medical device is an automatic external defibrillator, and the controller permits access to the automatic external defibrillator to the first operator, thereby allowing the first operator to install the automatic external defibrillator on the patient, but the system prohibits the first operator from operating the automatic external defibrillator to apply defibrillating shock to the patient, and the system permits the second operator to operate the automatic external defibrillator to apply defibrillating shock to the patient."

- 10 - T 0978/10

- g) Claim 1 of the third auxiliary request is identical to claim 1 of the second auxiliary request.
- h) Claim 2 of the third auxiliary request reads as follows:

"A medical treatment device of claim 1 wherein: the at least one medical device is an automatic external defibrillator, and the controller permits access to the automatic external defibrillator to the first operator, thereby allowing the first operator to install the automatic external defibrillator on the patient, but the system prohibits the first operator from operating the automatic external defibrillator to apply defibrillating shock to the patient, and the system permits the second operator to operate the automatic external defibrillator to apply defibrillating shock to the patient."

VIII. The appellant's arguments are summarised as follows:

a) Main request

i) Added subject-matter with respect to the parent application as originally filed (Article 76(1) EPC)

Figures 3A and 3B of the parent application as originally filed showed four different levels of experience of an operator. These levels were not related to the first and second operators of claims 1 and 2 as such. Rather, no unambiguous correspondence between the levels of experience and the

users needed to be given. A basis for the first and second operators was provided on page 9, lines 17 to 27 and page 18, lines 14 to 28 of the parent application as originally filed. A basis for the prohibition of the functional enablement of the medical device to the first operator was present on page 5, lines 3 to 6 - providing a definition of the term "functional enablement" - and page 5, lines 6 to 8 together with page 10, lines 6 to 8 of the parent application as originally filed. In the light of the meaning of functional enablement as explained throughout the parent application as originally filed, there was also no contradiction between the passage on page 19, lines 25 to 27 of the latter and the present claims.

Page 9, lines 17 to 27 of the parent application as originally filed provided a basis for a first operator installing a medical device prior to the arrival of a second operator. The second operator, arriving on the scene, could enter identification information causing the functional enablement of power-emitting medical devices and permission to physically access advanced equipment, as disclosed on page 17, lines 2 to 12 of the parent application as originally filed.

Page 5, lines 6 to 8, page 10, lines 6 to 8, page 17, lines 2 to 8 and page 19, line 24 to page 20, line 1 of the parent application as originally filed provided a basis for

- 12 - T 0978/10

sensors and monitoring for diagnostic purposes rather than therapeutic treatment. Defibrillators and automatic emergency defibrillators, especially as described on page 18, lines 14 to 28 of the parent application as originally filed, could also operate in a diagnostic or non-therapeutic mode, thus providing support for the language of both claims 1 and 2. As regards the concept in claim 2 of a first operator who might have physical access to the defibrillator to install it on the patient before the second operator arrived, a basis was provided on page 16, lines 13 to 14, page 17, lines 2 to 5, page 18, lines 18 to 23 and in particular on page 9, lines 18 to 24.

ii) Plurality of independent claims in the same category (Rule 43(2) EPC)

Claims 1 and 2 related to different alternatives of an apparatus providing two distinct solutions to the problem of preventing an inexperienced or untrained person from using vital life-saving equipment in an inappropriate manner. They were therefore allowable under Rule 43(2)(c) EPC.

iii) Clarity (Article 84 EPC)

The definition of a first and a second operator in claims 1 and 2 created no ambiguity, since it was clear from the wording of the claims that the first and the

- 13 - T 0978/10

second operator were allowed to perform different actions. The fact that the description referred to four different levels of training was neither in contradiction with the claims, nor introduced other ambiguities. The claims had been drafted at a level of generality to cover situations involving different pairs of users with different levels of training.

The different "means for identifying" and "means for controlling" in both claims 1 and 2 were also clearly defined, based on their respective functions.

iv) Novelty and inventive step (Article 52(1) in conjunction with Articles 54 and 56 EPC)

From the impugned decision it was unclear which document should be considered as the closest prior art and which features of the claims were disclosed in this document.

b) First to third auxiliary requests

Amended first to third auxiliary requests were provided should the main request not be accepted. The second and third auxiliary requests further specified that the operators were identified as being of different levels of training. A basis for this amendment could be found on page 10, line 26 to page 11, line 6 of the parent application as originally filed.

- 14 - T 0978/10

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Duly summoned, the appellant had said it did not intend to attend the oral proceedings. The Board decided to continue the proceedings without that party according to Rule 115(2) EPC and to hold the oral proceedings as provided for in Article 15(3) RPBA. Accordingly, the appellant is treated as relying only on its written case.

3. Main request

3.1 Added subject-matter with respect to the parent application as originally filed (Article 76(1) EPC)

Claims 1 and 2 seek their basis mainly in independent claim 6 of the parent application as originally filed, with some deletions and additions.

In the impugned decision the Examining Division considered the following deletions and additions as far as the requirements of Article 76(1) EPC are concerned:

- -) the definition of the means for permitting physical access to a medical device by the first operator while prohibiting functional enablement of the medical device to the first operator in the fifth paragraph of each of claims 1 and 2;
- -) the deletion of the term "treatment" in the sixth and seventh paragraph of each of claims 1 and 2;

- 15 - T 0978/10

-) the introduction of the whole last paragraph of each of claims 1 and 2.

As regards the introduction of the whole last paragraph of claims 1 and 2, the passages of the parent application as originally filed relied upon by the appellant generally disclose sensors for monitoring physiological parameters to diagnose the patient (page 8, line 28 to page 9, line 3) and therapeutic capabilities (page 10, lines 3 to 6). There is however no basis in the parent application as originally filed for a generic single medical device capable of both diagnosis and treatment of the patient or for a generic automatic external defibrillator which can be installed on the patient by a first operator and with which a second operator can apply defibrillation. On the contrary, the parent application as originally filed discloses only a particular kind of medical device comprising at the same time particular kinds of sensors for monitoring physiological parameters to diagnose the patient and particular therapeutic capabilities as defined on page 10, lines 3 to 6. This particular medical device is a cardiopulmonary resuscitation (CPR) and automatic emergency defibrillation (AED) device as described in particular on page 7, lines 2 to 26, with defibrillation electrodes 9L and 9R (figure 1), used also for electrocardiographic (EKG) sensing (page 7, lines 18 to 20). It is only with respect to said particular medical device that the technical significance of having the particular tiered access system as defined in the last paragraph of claims 1 and 2 is explained in the application. The Board therefore concludes that the generalisations introduced in the last paragraph of both claims 1 and 2 comprise subjectmatter extending beyond the content of the parent application as originally filed.

- 16 - T 0978/10

For this reason, the main request does not comply with Article 76(1) EPC.

3.2 Plurality of independent claims in the same category (Article 84 EPC and Rule 43(2) EPC)

Rule 43(2) EPC prescribes that "... a European patent application may contain more than one independent claim in the same category (product, process, apparatus or use) only if the subject-matter of the application involves one of the following:

- (a) a plurality of interrelated products,
- (b) different uses of a product or apparatus,
- (c) alternative solutions to a particular problem, where it is inappropriate to cover these alternatives by a single claim."

Claims 1 and 2 are drafted as independent claims and, as the appellant correctly remarks, they belong to the same category of apparatus claims. Hence, the exceptions under points (a) and (b), which respectively concern interrelated products and use claims, cannot apply.

The Board also fails to see how the subject-matter of the application might involve alternative solutions to a particular problem, which it would be inappropriate to cover by a single claim. When comparing the wording of claims 1 and 2, it is immediately apparent that the claims overlap considerably and are essentially directed to the same object. Moreover, claim 2 specifies an automatic external defibrillator, the

- 17 - T 0978/10

installation of which involves operating in diagnosis of the patient (page 19, line 24 to page 20, line 1), the automatic external defibrillator being a particular medical device capable of both diagnosis and treatment of a condition of the patient as specified in claim 1. It has therefore to be concluded that claim 2 could appropriately be drafted as dependent on claim 1. Hence there is no need within the meaning of Rule 43(2)(c) EPC to have two independent claims.

The Board therefore concludes that the main request does not comply with Rule 43(2) EPC.

3.3 Novelty - Article 52(1) in conjunction with Article 54(1) and (2) EPC

The most relevant piece of prior art is considered to be document D8, which is the only cited document explicitly dealing with a CPR and AED device of the kind described in the present application.

Said document D8 discloses a medical treatment system for treatment of a patient, wherein said medical treatment system is intended to be used in an environment wherein the device may be removed from a secure storage device and deployed upon the patient by a first operator pending arrival of a second operator (resuscitation device in figures 6 and 7, which can clearly be used as defined), said medical treatment system comprising:

a plurality of medical devices (accessories as mentioned on page 6, lines 10 to 12);

means for controlling physical access to the plurality of medical devices (removal sensor 36, figure 7,

- 18 - T 0978/10

described on page 14, lines 4 to 9);

means for controlling functional enablement of a medical device included within the plurality of medical devices (control unit 54 and communication unit 55, figure 11, described on page 16, lines 7 to 11);

means for identifying the first operator and means for permitting physical access to a medical device by the first operator (by using the communication unit a first operator, who is a bystander normally having access to the resuscitation device, is automatically identified by the system and can be identified by remote medical personnel - page 7, lines 1 to 4) while prohibiting functional enablement of the medical device to the first operator (prohibition of applying defibrillation as disclosed on page 6, lines 20 to 26);

means for identifying the second operator (the communication unit identifies remote medical personnel with more training - page 7, lines 8 to 10) and means for permitting functional enablement of a medical device included within the plurality of medical devices upon identification of the second operator (the remote medical personnel are enabled to perform defibrillation - page 7, lines 10 to 13);

wherein the means for controlling physical access is operable to permit physical access to a medical device included within the plurality of medical devices depending upon the identity of the first operator (in general, bystanders have physical access to the resuscitation device provided they have a minimum of physical skill and basic knowledge of the device - this can be considered dependent on their identity); and

- 19 - T 0978/10

the means for controlling functional enablement is operable to permit functional enablement of a medical device included within the plurality of medical devices depending upon the identity of the second operator (only the remote medical personnel are permitted to decide on functional enablement);

wherein at least one of the medical devices amongst the plurality of medical devices is capable of both diagnosis and treatment of a condition of the patient (the resuscitation device), and the controller permits the first operator to operate the at least one medical device in diagnosis of the patient while prohibiting the first operator from operating the at least one medical device in therapeutic treatment of the patient (page 6, lines 20 to 26), or wherein the at least one medical device is an automatic external defibrillator (page 6, lines 18 to 20), and the controller permits access to the automatic external defibrillator to the first operator, thereby allowing the first operator to install the automatic external defibrillator on the patient, but the system prohibits the first operator from operating the automatic external defibrillator to apply defibrillating shock to the patient, and the system permits the second operator to operate the automatic external defibrillator to apply defibrillating shock to the patient (page 6, lines 20 to 26).

Hence, the disclosure of document D8 is noveltydestroying for the subject-matter of claims 1 and 2.

It follows that claims 1 and 2 do not fulfil the requirements of Article 52(1) EPC in conjunction with Article 54(1) and (2) EPC.

- 20 - T 0978/10

3.4 Thus, the main request is not allowable.

4. First to third auxiliary requests

Claims 1 and 2 of the first auxiliary request differ from respective claims 1 and 2 of the main request only in that claim 2 is drafted as a dependent claim.

Claims 1 and 2 of the second auxiliary request differ from respective claims 1 and 2 of the main request only in the introduction of the levels of training of the first and second operators, for which a basis in the originally filed parent application is present on page 10, line 26 to page 11, line 6.

Claims 1 and 2 of the third auxiliary request combine both differences of the first and second auxiliary requests.

Therefore, the first to third auxiliary requests likewise fail to comply with Article 76(1) EPC, for the reasons explained in point 3.1.

Non-compliance with Rule 43(2) EPC, as explained in point 3.2, also applies to the second auxiliary request.

Non-compliance with Article 52(1) EPC in conjunction with Article 54(1) and (2) EPC, as explained in point 3.3, also applies to the first auxiliary request.

As regards the introduction of the levels of training of the first and second operators in the claims of the second and third auxiliary requests, the Board notes that said levels are not specifically defined and that document D8 also discloses that the first and second

- 21 - T 0978/10

operators have different levels of training (e.g. in order for the second operator to be able to perform defibrillation - page 6, lines 20 to 26). Hence document D8 is also novelty-destroying for the subject-matter of claims 1 and 2 of the second and third auxiliary requests. It follows that claims 1 and 2 of the second and third auxiliary requests do not fulfil the requirements of Article 52(1) EPC in conjunction with Article 54(1) and (2) EPC.

For these reasons, the first to third auxiliary requests are not allowable either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated