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D E C I S I O N
of 3 December 2003

Case Number: T 0108/01 - 3.2.2

Application Number: 93902133.3

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IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:
Dialysis machine with safety monitoring

Patentee:
GAMBRO HOSPAL (Schweiz) AG

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-



Case Number: T 0108/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 3 December 2003

Appellant: Fresenius Medical Care Deutschland GmbH
(Opponent) Else-Kröner-Strasse 1
D-61352 Bad Homburg (DE)

Representative: Laufhütte, Dieter, Dr.-Ing.
Lorenz-Seidler-Gossel
Widenmayerstrasse 23
D-80538 München (DE)

Respondent: GAMBRO HOSPAL (Schweiz) AG
(Proprietor of the patent) Pfluggässlein 2
CH-4001 Basel (CH)

Representative: Villanova, Massimo
Gambro Dasco S.p.A.
Intellectual Property Department
Via Modenese, 66
I-41036 Medolla (MO) (IT)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 18 December 2000
rejecting the opposition filed against European
patent No. 0581921 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
U. J. Tronser

Summary of Facts and Submissions

I. Following an opposition filed by the appellant against European patent No. 0 581 921, the Opposition Division decided on 18 December 2000 to reject the opposition and hence to maintain the patent as granted after having considered the state of the art represented, in particular, by documents:

E1: DE-A-3 736 712, and

E5: EP-B-0 321 754.

II. In its reasons the Opposition Division found that an inventive step had to be recognized in feature (j) of claim 1, according to which the second group of sensors provided the safety unit not only with information indicative of the actual values of the safety parameters, i.e. parameters indicative of an operating condition of the dialysis machine, but also with parameters indicative of an operative condition of the safety unit, thus providing an additional level of safety by monitoring the safety unit itself.

III. The appellant (opponent) lodged an appeal on 23 January 2001 and contested this decision on the basis of the same prior art documents in a statement of grounds filed on 18 April 2001.

The respondent (patentee) replied without amending the set of claims (version as granted).

IV. Claim 1 in suit reads as follows (identifying letters (a) to (m) introduced for ease of reference):

"A dialysis machine for providing monitored treatment to a patient, comprising:

- (a) a dialysis unit (4) for providing treatment to a patient;
- (b) actuators (6, 8) for the dialysis unit (4);
- (c) sensors (13, 15, 17) for measuring parameters related to the operation of the machine;
- (d) a control unit (2) connected to actuators;
- (e) a safety unit (3) connected to actuators,
- (f) wherein the control unit (2) and the safety unit (3) are connected to each other so as to exchange information;

characterized in that:

the actuators comprise:

- (g) a first group of actuators (6) for carrying out the dialysis treatment;
- (h) a second group of actuators (8) operative for shutting down the machine when the system is set to a general safe condition;

the sensors comprise:

- (i) a first group of sensors (13) connected to the control unit (2) and operative for providing the control unit (2) with information indicative of both the actual values of the safety parameters and treatment progress parameters, wherein at least a subgroup of the first group of sensors (13) provides, through the control unit (2), the actual values of the safety parameters to the safety unit (3);

- (j) a second group of sensors (15) connected to the safety unit (3) and operative for providing the safety unit (3) with information indicative of the actual values of both the safety parameters and parameters indicative of an operative condition of the safety unit (3);
- (k) a third group of sensors (17) connected to the safety unit (3) operative for providing the safety unit (3) with information indicative of an actual operative condition of the first group of actuators (6) when the system is in a safe condition, the third group of sensors being operative for communication with the safety unit (3) in response to the safety unit detecting a patient endangering anomalous situation resulting from inconsistent information detected by one or more sensors of the first group or the second group of sensors (13, 15);
- (l) the control unit (2) is operative for controlling the first group of actuators (6) in accordance with set values of control parameters, set values of safety parameters, and actual values of the safety parameters determined using the first group of sensors (13);
- (m) the safety unit (3) is operative for monitoring at regular intervals actual values of the safety parameters, for selectively setting the system in the safe condition, through the control unit (2), and for selectively setting the system in a

general safe condition by directly
controlling the second group of actuators
(8)."

V. Oral proceedings were held on 3 December 2003, at the end of which the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be revoked;

The respondent requested that the appeal be dismissed.

VI. The parties submitted the following arguments:

- (i) the appellant submitted that claim 1 was drafted with such broad and indefinite terms that its subject-matter could not be distinguished from the state of the art. For example the expressions such as "safe condition"; "general safe condition" and the various functions as claimed of the sensors and actuators, were neither clear nor further explained in the patent specification. Under these circumstances the subject-matter of claim 1 only differed from the disclosure of document E1 by monitoring the system at regular intervals (feature (m)). Besides exchange of information and data between the control units and the safety units, document E1 disclosed turning off the blood pump or bypassing the dialysis fluid through the dialyser, which equated to shutting down the machine. Document E5 also disclosed information exchange between the control unit and the safety unit and the monitoring of safety parameters, this

time at regular intervals, for setting the system either in a safe condition by which small anomalies were corrected or in a general safe condition by shutting down the machine. Therefore, the subject-matter of claim 1 was obvious having regard to the teachings of documents E1 and E5.

(ii) The respondent submitted the following arguments:

The terms used in claim 1 and in the patent specification were explicit enough for the understanding of a skilled person, based on its general knowledge, so that there was no need for a more specific definition of the invention. In particular the group of sensors 13 and 15 were measuring the same safety parameters, the duplication of components aimed at improving the overall safety of the system. In document E1, essentially, the safety unit was not provided with parameters indicative of its operative condition; there was no sensor for providing the safety unit with information indicative of an actual operative condition of the actuators controlled by the control unit for carrying out the dialysis treatment; and the system was not set in a general safe condition by which the machine was shut down by the operation of the safety unit directly controlling its own actuators. Document E5 was concerned with a blood treatment apparatus of a different nature, in which a balance was provided between the amount of ultrafiltrate withdrawn from the ultrafiltration unit and the amount of a substitute solution supplied to the blood circuit of the patient. The teaching of E5, therefore, was incompatible with that of document E1 and their combination inappropriate and irrelevant in an attempt to arrive at the subject-matter of claim 1.

Reasons for the Decision

1. The appeal is admissible.
2. *Closest prior art*

Document E1 represents the closest prior art, as also admitted by the parties. It discloses all the precharacterising features (a) to (f) of claim 1, namely a dialysis machine for providing a monitored treatment to a patient, comprising a dialysis unit 10, actuators for the dialysis unit and sensors for measuring parameters related to the operation of the machine (see Figure 2, actuators and sensors connected from and to the control units 124, 126 and the safety units 130, 132). Both the control and the safety units 124 to 132 are connected to actuators. The subsystem 12 which includes the control unit 122 and the safety unit 128 is less relevant since it relates to the preparation of the dialysate and is not concerned with parameters for controlling the fluids directly on each side of the dialyser 20 and for operating the machine (cf. Figure 1). Further, the control and safety units of each pair are connected to each other so as to exchange information either via a master control unit 134 and a master safety unit 140 in the case of using a plurality of digital control and monitor processors, each pair of processors being assigned to a hydraulic subsystem 12, 14, 16 in the dialysis unit, or directly in the more general and simpler case of using only one digital control processor and one digital monitor processor (cf. column 4, lines 6 to 26).

With respect to the characterising features of claim 1, document E1 discloses (following the same terminology and identifying letters as in claim 1):

- (g) a first group of actuators for carrying out the dialysis treatment, e.g. actuators connected to the ultrafiltration control unit 124.

- (h) a second group of actuators operative for shutting down the machine when the system is set to a general safe condition. In this respect, it should be considered that, according to the present patent (cf. column 5, lines 23 to 35) a general safe condition is generated by the safety unit 3 activating its own safety actuators 8 (second group) whereby causing the shutting down of the machine by initiating one or more of the following actions: preventing the dialysis fluid from flowing through the haemodialysis filter, shutting down the ultrafiltration pump, shutting down the blood module pump and preventing blood from re-entering the vein (cf. patent, column 5, lines 20 to 35).

The same occurs with the monitoring system of document E1, the safety units (monitor processors) of which are also capable of removing the power from the control mechanisms, i.e. to shut down the machine (cf. column 6, lines 54 to 56). For example, if a failure is detected, e.g. a blood leak by blood detector 104, excessive air bubble pressure by bubble detector 118 or a too high transmembrane pressure by sensors 94, 96, 110, 116, the safety unit 132 will block blood flow

from and to the patient by turning off the blood pump 112 and the valve 120 (cf. column 8, lines 33 to 45 and from line 63 to column 9, line 2) or the safety unit 130 will activate the bypass valve 92 on the ultrafiltration side of the dialyser whenever the temperature or the conductivity of the dialysis fluid, sensed by sensors 88 and 90, are outside of a permissible range (cf. column 8, lines 28 to 33). Incidentally, it should be noticed here that in the present patent (column 5, lines 45 to 49) similar parameters are detected and input to the safety unit. It results therefrom that feature (h) is known from E1.

- (i) a first group of sensors connected to the control units (control processors) 124 or 126 (see Figure 2 of E1) and operative for providing the control units with information indicative of both the actual values of the safety parameters and treatment progress parameters. According to the contested patent (column 3, lines 36 to 44 and column 4, lines 41 to 46), this relates to measured values of the parameters of significance to safety (CSS and SRC signals), without any further explanation, as well as measured values of other characteristic parameters such as flow and speed, which determine the progress of a dialysis treatment. Here parameters for controlling the fluids through the dialysis machine are concerned. At the oral proceedings the respondent submitted that the above-mentioned safety parameters were all well known to a person skilled in the art and that, consequently, it was useless entering more specifically into details. It results therefrom

that also document E1 (cf. Figure 2) discloses some groups of sensors (80, 96; 118, 110, 116) directly connected to control units 124, 126 for measuring values which can be regarded as safety parameters within the general meaning given above.

Feature (i) further specifies that at least a subgroup of the first group of sensors provides, through the control unit, the actual values of the safety parameters to the safety unit. In the expression "at least" is included the totality of the group so that also in document E1, the sensors 96 or 118, 110, 116 which are common to the control unit and the corresponding safety unit (cf. column 6, lines 52 to 54 and Figure 2), answer the broad definition as claimed.

- (j) a second group of sensors connected to the safety unit 130 or 132 (see Figure 2 of E1) and operative for providing the safety unit with information indicative of the actual values of both the safety parameters and parameters indicative of an operative condition of the safety unit. As for feature (i), the patent is silent about the nature of the parameters and signals PSS and SRP send to the safety unit (cf. patent, column 3, lines 44 to 52), all supposedly known to the skilled person. As a consequence, similar considerations apply equally to document E1 (cf. column 6, lines 46 to 50), in which the signals detected and the various parameters applied to the safety units 130 and 132 correspond generally to the broad definition given in the patent. Moreover, it is generally admitted that digital processors are designed and

programmed to carry out either control or monitoring functions, which implies necessarily inputting parameters indicative of an operative condition of the processor itself.

- (k) a third group of sensors connected to the safety unit for providing the same with values indicative of the actual operative conditions of the first group of actuators set by the control unit, is not present in document E1. In other words, there is no specific sensor for monitoring the correct operation of the actuators controlled by the control unit.

- (l) the control unit 124 or 126 is operative for controlling the first group of actuators (cf. Figure 2 of E1) in accordance with set values of control parameters, set values of safety parameters and actual values of the safety parameters determined using the first group of sensors (cf. E1, column 7, lines 5 to 9; column 6, lines 46 to 50 and what has been previously said about feature (i)).

- (m) the safety unit of document E1 is operative for monitoring actual values of the safety parameters (see previous remark about feature (j)), however not at regular intervals. Further, the safety unit is operative for selectively setting the system in a general safe condition by directly controlling the second ground of actuators (see feature (h) above).

Furthermore, the safety unit is operative for selectively setting the system in the safe condition, through the control unit. In this respect it should be recalled that, according to the present patent (cf. column 4, line 51 to column 5, line 13) the system is set in the safe condition through the control unit when, following an anomalous situation detected by the safety unit carrying out periodical tests on the basis of all safety relevant parameters and set values input by the operator (cf. column 5, lines 36 to 42), the safety unit sends instructions to the control unit (signals SSR) in order to overcome a situation hazardous to the patient, by the control unit activating its own actuators 6. Similar control is achieved through the system of document E1 since (cf. column 7, line 68 to column 8, line 9), when the parameters sensed by the respective sensors of the safety units reach predetermined limits, the fluids are automatically controlled by control loops carried out by the control units (cf. column 7, lines 5 to 9), so that the machine remains in a safe conditions until the anomaly is corrected.

3. *Problem and solution*

From the foregoing analysis it results that the subject-matter of claim 1 differs from the disclosure of document E1 by providing additional sensors 17 connected to the safety unit, the aim of which is to monitor the proper operation of the actuators 6 controlled by the control unit whenever an inconsistency is detected between the parameter values

sensed by sensors 13 and 15 (feature (k)) and by the safety unit carrying out monitoring tests at regular intervals (feature (m)).

These features, in combination with the known features of claim 1, represent the solution to the problem addressed in the patent in suit, according to which (cf. column 1, lines 50 to 53) the object of the present invention is to provide optimum safety to the dialysis machine at low cost, in particular by reducing to a minimum the number of components involved in the safety monitoring (cf. column 8, lines 15 to 19).

4. *Inventive step*

Document E5 discloses a dialysis machine of the type as claimed comprising, in particular cf. Figure 2, a control unit and a safety unit connected to each other for exchanging information and data via a bi-directional line 98 (cf. column 6, lines 35 to 38; column 9, lines 43 to 47 and claim 5). A sensor 41 (feed-back monitoring means) monitors the operation of an actuator 40 (ultrafiltrate pump) and provides the safety unit 74 with a sensed signal for comparison with a signal from a balancing means 58, transmitted by lines 88 and 100, and a signal value calculated from set parameters entered in device 76 (cf. column 10, lines 8 to 14 and claim 1). In the same manner, an opto-electronic sensor 67 monitors the operation of actuator 66 (substitute pump) and transmits the sensed signal 94 to the safety unit 74. Subsequently, the safety unit calculates the deviation between the amount of fluid removed from the patient via the ultrafiltrate pump 40 and the amount of fluid re-injected to the

patient via the substitute pump 66. If the deviation remains within acceptable limits (± 5 ml) the control unit controls the substitute pump 66 for correcting the deviation (safe condition); but if the deviation reaches 10 ml or more the treatment is interrupted (cf. column 10, lines 43 to 53 and claim 1), in accordance with the general safe condition as defined above (cf. section 2 (h)) and in the patent in suit.

The safety unit is operative for monitoring the above safety parameters at regular intervals since both the control and the safety units exchange their information periodically for comparison (cf. column 6, lines 29 to 38; column 10, lines 21 to 24 and claim 1). It results therefrom that, when the safety unit detects a patient endangering anomalous situation resulting from inconsistent information detected by "one" sensor 58, the safety unit is provided with information indicative of the actual operative condition of actuators 40, 66, via sensors 41 and 67, respectively, and is operative for monitoring at regular intervals actual values of the safety parameters, in accordance with the terminology and meaning of features (k) and (m) of claim 1 at issue.

Having regard to the general wording of claim 1 the skilled person will find in document E5 the parts of the solution and the features which were missing in document E1 and in this obvious manner arrive at the subject-matter of claim 1. A suggestion to combine these documents is to be seen in that document E5 relates to the same technical field and aims at improving the safety of the dialysis system as a whole (cf. column 1, lines 41 to 43 and from column 1,

line 55 to column 2, line 4), while simultaneously providing the control unit and the safety unit with parameters from at least one common sensor (balancing device 58) or with common set parameters (input device 76).

5. In consequence of the above considerations, the subject-matter of claim 1 does not involve an inventive step within the meaning of Article 56 EPC, having regard to the obvious combination of documents E1 and E5.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß