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D E C I S I O N
of 11 May 2006

Case Number: T 0310/04 - 3.2.02

Application Number: 97203409.4

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IPC: A61M 1/28

Language of the proceedings: EN

Title of invention:
Automated peritoneal dialysis system

Patentee:
DEKA PRODUCTS LIMITED PARTNERSHIP

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step - confirmed"

Decisions cited:
-

Catchword:
-



Case Number: T 0310/04 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 11 May 2006

Appellant: Fresenius Medical Care Deutschland GmbH
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 2 February 2004
rejecting the opposition filed against European
patent No. 0829266 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: T. Kriner
Members: M. Noël
E. Dufrasne

Summary of Facts and Submissions

I. Following an opposition filed by the appellant (opponent) against European patent No. 0 829 266, the opposition division decided on 13 January 2004 (posted 2 February 2004) to reject the opposition and to maintain the patent as granted.

In the decision the opposition division held that the grounds for opposition cited by the appellant (Article 100(a) EPC) did not prejudice the maintenance of the patent.

II. The appellant lodged an appeal, by notice received at the EPO on 25 February 2004 and paid the appeal fee on the same day. A statement setting out the grounds of appeal was filed on 14 June 2004.

III. Oral proceedings were held on 11 May 2006, 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 European patent No. 0 829 266 be revoked.

The respondent (patentee) requested that the appeal be dismissed or, in the alternative, that the patent be maintained on the basis of the auxiliary requests 1 to 5 filed with letter dated 27 October 2004.

IV. Documents referred to in the present decision:

D1: EP-A1-0 402 505

D2: DE-A-1 964 733

D3: US-A-4 277 226

D4: WO-A1-91/12830

D6: EP-A1-0 311 709

V. Claim 1 as granted (main request) reads as follows:

"An automated peritoneal dialysis system including means (34,35) for establishing flow communication with a patient's peritoneal cavity catheter through a pumping mechanism (P1, PA1), control means (16) for operating the pumping mechanism to emulate gravity flow conditions independent of head height conditions to drain spent peritoneal dialysis liquid from the catheter and infuse fresh dialysis liquid from a source (20) to the catheter, the control means (16) being operable to conduct a peritoneal dialysis modality, and means for monitoring system operation including means for generating a first alarm signal when system operation fails to satisfy a first predetermined set of criteria, means for suspending system operation in response to the first alarm signal; and requiring user intervention to resume system operation, and means for generating a second alarm signal when system operation fails to satisfy a second predetermined set of criteria different than the first set of criteria, characterised by:

means for (i) continuing system operation for a predetermined time period in response to the second alarm signal; (ii) cancelling the second alarm condition without user intervention when, after the

predetermined time period, system operation satisfies the second set of criteria; and (iii) initiating a first alarm condition when, after the predetermined time period, system operation fails to satisfy the second set of criteria."

VI. At the oral proceedings and in their written submissions the parties argued as follows:

(i) The appellant:

D1 disclosed a peritoneal dialysis system comprising all features contained in claim 1 in suit with the exception of the production of a predetermined time period in response to a second alarm signal. Instead, a predetermined number of abnormal volume cycles occurring in a row was detected so as to activate an alarm circuit and stop the process. When the detected volume cycles were of the same duration, the counting of violation signals that occurred in sequence was functionally equivalent to the setting of a predetermined time period. In both cases inopportune user intervention was avoided in less hazardous alarm situations. The replacement of one measure by the other was obvious for a person skilled in the art. Therefore, the subject-matter of claim 1 was not inventive over the disclosure of D1 and the general knowledge of the skilled person.

D6 disclosed an automated haemodialysis control based upon patient blood pressure and heart rate, in particular to prevent hypotension. According to

the blood pressure alarm subroutine described in reference to Figure 4, the production of a low alarm signal indicating onset of a hypotension episode did not immediately stop the operation of the system. Rather it was continued for a predetermined time period (10 min) until the blood pressure was tested again. The skilled person would thus have found in D6 an alternative to D1 for replacing the counting of abnormal volume cycles in order to avoid intervention by the dialysis personnel. The subject-matter of claim 1, therefore, did not involve an inventive step with respect to the combination of D1 and D6.

D3 disclosed a volumetric infusion pump for intravenous administration of fluids from a supply bag to a patient. When the bag became empty or when an occlusion occurred in the supply line, the pump was stopped by a pump control and an alarm was produced after a predetermined time period based on the charge of a capacitor. Although this document was concerned with a different technical field, it was nevertheless relevant and should have been considered in combination with D1, in view of similar problems of management of alarm conditions in order to avoid dispensable intervention of the medical personnel.

D4 was concerned with the dissolution of gallstones and subsequent removal of fragments from the gallbladder. The alarm system described on page 30 in reference to Figure 12c mentioned two alarm conditions of different importance, resulting from pressure measurements and producing

two alarm signals. In the most hazardous condition (alarm (0)) a first alarm signal was produced and both aspiration pumps were brought to a stop by operator intervention, whereas in a less acute condition (alarm (1)) a second alarm signal undergoing a predetermined time period was generated. If after a predetermined maximum aspiration time the second alarm condition were not returned to normality, i.e. should the system be unable to come to the proper pressure operating range within said predetermined time period, the system initiated, again, a first alarm condition (alarm (0)), in conformity with the characterising features of claim 1 at issue. Its subject-matter, therefore, was suggested by the combination of documents D1 and D4.

D2 disclosed an automated peritoneal dialysis apparatus comprising all features of the precharacterising portion of claim 1, including means for generating alarm signals in response to critical situations, which caused the apparatus to shut off. Since the production of a second alarm system undergoing a predetermined time period was well known from either of documents D3, D4 or D6, the consideration of one of them in combination with D2 taken as a starting point led in an obvious manner to the subject-matter of claim 1.

(ii) The respondent

D1 disclosed a continuous cyclic peritoneal dialysis system having alarm means different to those of the present invention. In D1, if the

volume of fluid which was filled and drained to and from the patient was not within predetermined limits, a violation signal was registered but no alarm signal was generated. Only if a number of violations occurred in a row, was an alarm circuit activated and the process stopped. However, the system operation continued since drain was further initiated.

Faced with the problem of providing a peritoneal dialysis system having improved monitoring functions, the skilled person would have had no reason to modify the system of D1 to refer to a predetermined time period rather than a cycle-dependent checking of fill/drain volumes. There was no hint in D1 that the described system, which had already improved monitoring functions, should be abandoned in favour of a second time-delayed alarm system which would actually generate a signal as soon as a violation was detected. Therefore, the subject-matter of claim 1 was inventive over D1.

D6 was concerned with monitoring physiological parameters of a patient, in contrast to the claims of the present patent which instead were related to operating an automated peritoneal dialysis system. D6 was particularly concerned with monitoring low blood pressure of patients. If low pressure was detected, remedial therapeutic action was undertaken. Should the remedial action fail to raise the blood pressure, then the treatment was terminated. The skilled person, therefore, would clearly have been taught towards the monitoring of

patient's physiological conditions along with the provision of associated medical treatments, i.e. away from the subject-matter of claim 1.

D3 was not concerned with dialysis at all. It disclosed nothing concerning the use of a two-level alarm system. Instead, it disclosed an electro-mechanical device, which was used to avoid mechanical errors in the detection of the draining of a supply bag. The person skilled in the art would not have considered this document which did not even relate to the problem of performing peritoneal dialysis having improved monitoring functions and did not disclose how to arrive at the subject-matter of claim 1 in suit.

D4 was even more remote than D3 from the present patent, since it was related to removal of gallstones. There was nothing in this document to suggest that its teaching could be applied to systems for peritoneal dialysis and its alarm system was based on a different concept. D4 disclosed a system in which an alarm was generated after an abnormal pressure condition was present continuously and for a predetermined time period within the gallbladder. If the condition ceased before the predetermined time period had expired, no alarm was generated. Thus D4 did not suggest an alarm system as defined in claim 1 of the present patent.

D2 did not come closer than D1 to the subject-matter of claim 1, so that its consideration in combination with either one of the preceding documents would not change the above conclusions.

Reasons for the Decision

1. The appeal is admissible.

2. *Closest prior art*

2.1 D1 represents the closest prior art document. It discloses (see Figures 1 and 2) an automated peritoneal dialysis system including means for establishing flow communication with a patient's peritoneal cavity catheter 26 through a pumping mechanism B, C, a control means A for operating the pumping mechanism to drain peritoneal dialysis liquid from the catheter and infuse fresh dialysis liquid from a source 12, 16 to the catheter. Means for monitoring the system operation are provided, including means for generating a first alarm or violation signal when the system operation fails to satisfy a first predetermined set of criteria (signals from the dialysate proportioning unit 14 (DPU) and from the reverse osmosis unit 10 (ROU), see column 11, lines 17 to 32) and means (abnormal cycle counter 94) for generating a second alarm or violation signal when the system operation fails to satisfy a second predetermined set of criteria (fill or drain volumes of each cycle not being in tolerance with respect to predetermined maximum or minimum volumes set in cycle monitor 92).

Moreover, D1 discloses means for suspending the system operation in response to the various alarm signals, i.e. in situations requiring user intervention to resume the system operation (see column 8, lines 30 to 33). This monitoring system is thus comparable to the system described in the present patent with reference to paragraphs [314] and [315], in which an alarm 1 situation suspends the therapy session and requires user intervention to correct, using an alarm menu.

It results therefrom that all features contained in the preamble of claim 1 of the present patent are known from D1.

- 2.2 According to D1 the number of those violation signals which indicate a fill or drain volume per half-cycle being out of tolerance, is totalized in counter 94. However, since the time of their occurrence and registration is not fixed and then possibly unpredictable, the abnormal cycle count limit which is set in counter 94 is reached within essentially variable time periods, the more so since the violations are taken into account only if they occur in a row. The continuation of the system operation according to D1, therefore, is not functionally equivalent to the continuation of the system operation for a predetermined, fixed time period as claimed which is completely independent from fill and drain volume measurements.

Since the features (i) to (iii) of claim 1 all refer to said "predetermined time period", the subject-matter of claim 1 as granted differs from the disclosure of D1 by its characterising features.

3. *Problem and solution*

With respect to the disclosure of D1 the technical problem underlying the present patent is to provide a system for performing peritoneal dialysis which does not immediately lead to alarm situations which cause termination of the system operation and necessitate user intervention, having improved monitoring functions, in particular safer and more flexible alarm functions.

The solution is given by the characterising features of claim 1 as granted, according to which a first alarm condition (the most hazardous situation) is initiated only if the second set of criteria (the less hazardous situation) which generates the second alarm signal, persists over a predetermined time period. Within this time period the operation of the dialysis system is continued until the monitoring system checks the situation again.

4. *Inventive step*

- 4.1 The object of D1 is principally to control the volume of the dialysate in the peritoneal cavity so as to monitor the osmolality and, hence, the concentration of the fluid in response to the amount of fluid removed from the patient. Monitoring the volume of dialysate in the cavity certainly represents a situation at risk, which is sufficiently relevant to justify stopping the dialysis process in case of a failure (alarm 1 situation). This is performed in D1 by activating the

alarm circuit 96 after counting successive violation signals in counter 94, as mentioned above.

However, the person skilled in the art would not have considered to replace the counting of incorrect volume signals by the setting of a predetermined time period since there is no suggestion for such a replacement. Moreover, this could lead to a reduced safety of the system operation, which is principally based on the monitoring of a predetermined number of violation signals occurring in a row. A single non-violating signal in a fill/drain cycle would reset the system and prevent an alarm from being generated. Contrarily, in the present invention, the monitoring system checks the situation again (second set of criteria) after a predetermined time period.

Furthermore, the precited violation signals (DPU, ROU, abnormal cycle count limit) are simultaneously applied to the alarm circuit 96 as shown in Figure 2. Thus, although these alarm signals correspond to different sets of criteria, in accordance with claim 1 at issue, D1 does not make any gradual distinction between their relevance. In every instance an alarm signal is received by circuit 96, an audible alarm is triggered and the system is shut off. It can only be restarted after user intervention, i.e. by pressing a reset button 98a (see column 8, lines 30 to 33 and column 11, lines 27 to 32).

The teaching of document D1 alone, therefore, would not have allowed the skilled person to arrive at the solution as claimed, which is based on two distinct and hierarchical alarm situations generated by criteria

independent from the volumes of fluid and which uses a predetermined time period in response to the second alarm signal, i.e. in situations that require minimum or no user intervention.

- 4.2 Document D6 relates to an automated haemodialysis control which is based on patient blood pressure and heart rate, in particular for continuously monitoring the patient blood pressure at variable intervals during haemodialysis in order to prevent hypotension.

Prima facie, the person skilled in the art would hardly have considered D6 which is not concerned with peritoneal dialysis and which aims at monitoring parameters of a patient and not, as in the present patent, dialysis machine parameters such as supply of fluid, low fluid flow or an occluded line. But even if the skilled person would have tried to combine this document with the teaching of D1, he still would not have arrived at the subject-matter of claim 1 as demonstrated hereafter.

In D6 (see flow diagram of Figure 4 and columns 7 and 8) the means for monitoring the system operation comprises two alarm systems, namely a deviation-type alarm and a limit-type alarm.

A first alarm signal (deviation alarm) is generated when the system operation fails to satisfy a first set of criteria (readings deviating from the initial patient readings), in which case the monitoring cycle duration is reduced but the system operation is not suspended.

A second alarm signal (high/low alarm) is generated when the system operation fails to satisfy a second set of criteria (readings reaching high blood pressure limit or onset of a hypotension episode). A therapeutic intervention is immediately initiated by decreasing the ultra-filtration rate (DROP UFR) and by increasing the sodium concentration (NA-180) for a predetermined time period (3,5 min). Thereafter, the blood pressure is tested again for a low alarm condition, as shown at the bottom of Figure 4.

If the blood pressure has increased above the low alarm limit following therapeutic intervention, the system operation is continued for a predetermined time period (10 min) in response to the low alarm signal still being within acceptable values. After that period, if the system operation satisfies the second set of criteria (blood pressure above the low alarm level) the ultra-filtration rate is increased up to its desired value and the system operation is continued. Therefore, features (i) and (ii) of claim 1 at issue are disclosed by D6.

However, if the low alarm level persists and still fails to satisfy the second set of criteria, the dialysis operation comes to an end and the staff is alerted but the monitoring system does not return to the first alarm condition, contrary to feature (iii) as claimed.

The monitoring system of D6, therefore, is not compatible with the system of D1, in view of different control parameters and a different monitoring concept.

4.3 Document D3 discloses a volumetric infusion pump useful in intravenous feeding, including a detector which provides an alarm when a supply bag or reservoir becomes empty or when an occlusion occurs between the bag and the pump. When the head pressure of fluid supplied to the pump inlet decreases below a predetermined level, an alarm condition results and the pump is stopped. To this end, if an electrical contact between two cam followers is broken for a period of time, sufficient for a capacitor to charge to a predetermined level, the pump control 58 produces an alarm which stops motor 56.

Although D3, therefore, discloses means for continuing the system operation for a predetermined time period, the skilled person would not have considered this teaching for the dialysis system according to D1, since it concerns a different application in a different technical field. The disclosure of D3, therefore, is insufficient to suggest the subject-matter of claim 1, when starting from the prior art according to D1.

4.4 Document D4 discloses an apparatus for chemical contact dissolution of gallstones, wherein a solvent is delivered and removed at a rate sufficient to effect gallstone dissolution and fragmentation. Then, aspiration of insoluble fragments is performed. Referring to Figures 10 and 12, a microprocessor 100 monitors the pressure values produced by a transducer and controls the infusion and aspiration pumps 14, 18, respectively, in response to pressure measurements. A module stored in the system memory determines the proper response to various pressure measurements and checks a number of criteria. If these criteria are not

satisfied, an alarm condition results, which causes a pump control to set maximal continuous aspiration for both pumps and to trigger an alarm.

When the main program used to determine the proper response is executed for the first time, a subroutine (Figure 12a and text referred to from page 27) has first to determine which pump should be started. If the system is unable to come to the proper pressure operating range within a predetermined time period (maximum aspiration (MAXASP) or infusion (MAXINF) time), an alarm (0) condition results (condition so hazardous that normal operation should not be resumed) and the operator is notified to stop the operation.

The flow diagram of Figure 12c shows two alarm conditions depending upon whether an abnormal pressure condition is recoverable (alarm (1)) or not (alarm (0) referred to above). But whatever the alarm condition considered, the first priority is to aspirate fluid from both catheter lumen to reduce the pressure. If a severe alarm (0) condition is entered, a tone is set at step 266 and aspiration is continued until the pumps are stopped by operator intervention at step 270 (see page 30, lines 28 to 30). Therefore, unlike the first alarm situation in the present patent, there is no means in D4 for automatically suspending the system operation in response to a hazardous alarm (0) condition.

The alarm (1) routine of Figure 12c presents some similarities with the second alarm situation according to the present patent, in that a predetermined period of time (t_{ALMASP} = maximum time allowable at maximum

aspiration) is set for continuing the system operation in response to an alarm (1) condition and for initiating further an alarm (0) condition when the predetermined time period has elapsed. However, when an alarm (1) condition is entered, both pumps continue to aspirate at maximum rate until they are stopped by manual intervention (see page 31, lines 8 to 11). This working, again, differs from that of the monitoring system of the present patent, in which the system operation is suspended in response to the first alarm signal.

As a consequence, the alarm system disclosed by D4, which is particularly concerned with the dissolution of gallstones and is based on continuously monitoring operating pressures, could not be combined with the teaching of D1 which serves a different purpose and is based on the different concept of counting incorrect volumes.

4.5 It follows from the above considerations that neither from D1 nor from any of D6, D3 or D4, was it suggested to modify the system according to D1 by specifically replacing in one of two alarm levels of a system the monitoring of a predetermined number of violation signals occurring in a row by the monitoring of a time period.

4.6 Document D2 does not come closer to the subject-matter of claim 1 than does D1. Nevertheless D2 discloses in the preamble of claim 1 as well, in particular (see Figures 1 and 7) an automated peritoneal dialysis system in which a dialysis solution is injected into and taken from a patient cavity 53 by means of

volumetric pumps 12, 73 under the control of a control unit 16. An alarm system is provided for detecting and warning the user in case of occlusion, leakage of liquid or presence of air in the tubing circuit, in order to avoid contamination and sterility problems. The detection of a failure causes the dialysis machine to shut down immediately by action of the control unit. (see page 4, lines 8 to 13; page 9, lines 8 to 11 and from page 26, line 7 to page 27, line 20).

However D2, like D1 (see point 4 above) does not establish any priority or hierarchical system between the different alarm situations or alarm signals. Therefore D2 does not contain means for generating a second alarm signal within the meaning of the present patent. Moreover, like D1, the alarm system of D2 does not provide a predetermined time period for the system operation to continue until a new test of the situation is made and a decision is taken. Consequently, the same reasoning as for D1 applies to document D2, considered alone or in combination with documents D3, D4 and D6

- 4.7 As a result, the subject-matter of claim 1 involves an inventive step vis-à-vis the state of the art, in accordance with the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner