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**Datasheet for the decision
of 17 July 2019**

Case Number: T 2185/15 - 3.2.02

Application Number: 11180924.0

Publication Number: 2402046

IPC: A61M1/14

Language of the proceedings: EN

Title of invention:

Medical device

Patent Proprietor:

Nikkiso Company Limited

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:

EPC Art. 100(b), 54(1), 56
EPC R. 124(1)

Keyword:

Sufficiency of disclosure (yes)

Novelty (yes)

Inventive step (yes)

Request to record a statement in the minutes of oral proceedings (refused)

Decisions cited:

T 1453/14

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2185/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 17 July 2019

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 28 September
2015 rejecting the opposition filed against
European patent No. 2402046 pursuant to Article
101(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: M. Stern
D. Ceccarelli

Summary of Facts and Submissions

- I. The opponent lodged an appeal against the decision of the Opposition Division, posted on 28 September 2015, rejecting the opposition against European patent No. 2 402 046.
- II. Notice of appeal was filed on 24 November 2015, and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 8 February 2016.
- III. The following documents are cited in the present decision:
- D1: WO-A-96/41 292
 - D2: US-A-6 251 113
 - D3: WO-A-03/011 128
 - D4: DE-A-197 42 637
 - D7: EP-A-1 088 523
 - D8: WO-A-01/49 369
 - D9: DE-A-197 47 353
 - D10: WO-A-94/24 929
 - D11: DE-A-199 03 079
 - D13: DE-A-197 42 633
- IV. Oral proceedings were held on 17 July 2019 at the same time as the oral proceedings for case T 1453/14 concerning the patent granted for parent application 03 749 98.4.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the patent be maintained on the basis of one of auxiliary request 1, filed with letter dated 10 June 2016, and auxiliary request 2, filed with letter dated 16 July 2019.

- V. Claim 1 of the patent (**main request**) reads as follows (feature numbering in square brackets added by the Board):

"[1] A medical device (1) comprising:
an operation input unit (12) for an operator to enter instructions;
[2] an operation unit (20) for performing prescribed operations required for medical treatment based on input from said operation input unit (12);
[3] a human body detection means (18) for detecting the operator's presence in the vicinity of said operation input unit (12); and
[4] a control unit (19) that provides control a function [sic] for allowing said input operation unit (12) to instruct said operation unit's (20) operations, or
[5] allowing the operation unit (20) to operate based on the input entered into said operation input unit (12), only when said human body detection means (18) is detecting the operator;
characterized in that
[6] said control function provided by said control unit (19) can be cancelled."

Claims 2 to 6 are dependent claims.

- VI. The arguments of the appellant which are relevant for the present decision may be summarised as follows:

- *Sufficiency of disclosure*

The patent did not provide the reader with enough information to devise the human body detection means of dependent claim 6. The detection means could not differentiate between an operator trained to use the device and a patient detected in the vicinity of the operation input unit. Furthermore, when measuring the operator's presence with light it would not be possible to differentiate whether a person or, for example, an insect had crossed the light path.

- *Novelty*

Each of documents D7, D8, D9 and D3 anticipated the subject-matter of claim 1.

D7 disclosed that the energy supply of the entire medical device was turned off in response to a signal from the photo-sensor for detecting the presence of the operator. Moreover, in column 4, lines 20 to 26, D7 disclosed that the mode changing switch 2a allowed to switch between a laser irradiation enabled state (ready mode) and a laser irradiation disabled state (a wait or standby mode). Therefore, feature [6] of claim 1 was anticipated.

In D8, a user identification system authorised access to medical devices, particularly implanted medical devices. The identification process included the detection of a fingerprint, an image or an iris scan. If a match with stored data was confirmed, user access to the device was allowed. Figure 5 showed a flow chart of the user identification and authorisation process which ended at step 530. This was equivalent to a

cancellation of the identification and authorisation process. Moreover, page 9, lines 6 to 14 described a special override function or emergency situation in which the identification and authorisation process was cancelled.

D9 concerned a patient treatment monitoring system with several patient terminals which required treating personnel to be identified by fingerprint detection or face recognition. Access to a patient terminal was only allowed if the identification means detected the authorised operator. The identification means could be decoupled from the patient terminal, whereby the terminal was brought back to its initial state. Therefore, feature [6] of claim 1 was disclosed.

D3 disclosed a bedside patient monitor for monitoring patient parameters when a clinician was in the room or approaching it. The patient monitor had a local input interface, such as a keyboard. When no clinician was in the area of the patient monitor, the display and alarms were suspended, dimmed or lowered, or the patient monitor was put in power-save mode. These conditions were equivalent to a cancellation of the control functions of the device.

- Inventive step

The subject-matter of claim 1 was rendered obvious by each of the following combinations of documents:
D1 in combination with either D7, D10, D11, D13 or D4;
D2 in combination with D7;
D7 in combination with either D10 or D11;
D8 in combination with either D10 or D11;
D9 in combination with either D10, D11, D13 or D4;
D7 by itself.

Document D1 disclosed a dialysis device comprising a touch screen (130) for inputting data. The touch screen enabled, moreover, the detection of the operator's presence in the vicinity of the device and a control unit (112, 118, 122) that provides a control function allowing the input operation unit to instruct the operation unit's operation or allowing the operation unit to operate, only when human body detection means was detecting the operator. Even if D1 was considered not to disclose the capability of cancelling the aforementioned control functions, as defined in feature [6] of claim 1, such cancelling was known from documents D7, D10, D11, D13 and D4. The skilled person would readily incorporate such an improvement into the device of D1 as well.

D2 disclosed an ophthalmic surgery system comprising a touch-responsive screen which was a human body detection means for detecting the operator's presence in the vicinity of an operation input unit provided by the foot control assembly (15). The cancelling of the control function of control unit (3), which was not disclosed in D2, was nevertheless known from D7. It was hence obvious to incorporate this aspect into the device of D2 as well.

If documents D7, D8 and D9 were not considered to anticipate the subject-matter claimed, the skilled person would consider implementing the capability of cancelling of control functions, as defined in feature [6] of claim 1, in view of the teaching of documents D10, D11, D13 and D4. Moreover, paragraph [0003] of D7 mentioned problems of erroneously applying laser irradiation. For example, while a laser treatment apparatus was placed in the

ready mode, a third party may accidentally or erroneously input the irradiation instruction signal, performing undesired laser irradiation. Alternatively, the operator himself may unintentionally perform the laser irradiation even though he is not observing the affected part. It was hence obvious to the skilled person to implement the device with the capability of cancelling the control functions as claimed.

VII. The arguments of the respondent that are relevant for the present decision are essentially those on which the reasons set out below are based.

Reasons for the Decision

1. The appeal is admissible.

2. *The invention*

The invention relates to a medical device which comprises an operation unit (20), an operation input unit (12) for an operator to enter instructions, a control unit (19) and a human body detection means (18) for detecting the operator's presence in the vicinity of the device's operating input unit, the control unit providing a control function for allowing:

(a) the input operation unit to instruct an operation unit's operation or

(b) the operation unit (20) to operate based on the input entered,

only when said human body detection means (18) is detecting the operator.

According to the characterising part of claim 1 of the granted patent, the control function provided by the

control unit only when the human body detection means is detecting the operator can be cancelled.

The human body detection means prevent the medical device being operated due to a malfunction of the operation input unit or an external noise while in fact the operator is not operating the device (paragraphs [0005] and [0006] of the patent).

As explained in column 10, lines 29 to 39 of the patent, the possibility of cancelling the aforementioned control function, allows the operation unit to operate based on input information entered into the input unit for example, regardless of whether the operator is detected by the human body detection means or not. This improves the ease of operation of the medical device.

3. *Sufficiency of disclosure (Article 100(b) EPC)*

The appellant objected that the patent did not provide the reader with enough information to devise the human body detection means of dependent claim 6. The detection means could not differentiate between an operator trained to use the device and a patient detected in the vicinity of the operation input unit. Furthermore, when measuring the operator's presence with light, it would not be possible to differentiate whether a person or an insect had crossed the light path.

The Board finds these objections unconvincing. Claim 6 appended to claim 1 calls for a device capable of detecting a human body in the vicinity of the operation input unit. It is within the normal engineering capability of a person skilled in the art to provide

filtering means for enhancing detection selectivity and eliminating spurious signals, if this should become necessary, particularly to differentiate signals originating from other sources, for example, an insect.

Also claim 6 does not require the device to carry out any differentiation between a person trained to operate the device and other persons such as a patient, children or cleaning personnel. The operator in the context of the present invention is not limited to a person authorised to carry out the treatment.

The Board therefore comes to the conclusion that the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

4. *Novelty*

- 4.1 Document D7 discloses a laser photocoagulation apparatus for ophthalmic treatment (paragraph [0020]; Figure 1). The apparatus of D7 comprises a control board (2) for inputting irradiation conditions (paragraph [0021]) and a joystick (6) for moving a slit lamp delivery (3) and for allowing the operator to perform sighting (alignment) with respect to the affected part (column 4, lines 37 to 40; column 7, lines 8 to 11). Hence, the control board (2) and the joystick (6) form an "operation input unit" as defined in feature [1] of claim 1. The apparatus of D7 comprises, moreover, a controller (60) controlling a laser source (10) in accordance with the irradiation conditions and mode set with the control board (paragraph [0031]). The laser source (10) is thus an "operation unit" as defined in feature [2] of claim 1.

The apparatus further comprises an infrared photo-sensor (57) comprising an infrared emitter and detector which detects whether the operator is observing the patient's eye (E) through the eyepieces (3a) (paragraphs [0030] and [0036]). Alternatively, the photo-sensor (57) may be disposed on the joystick (6) (paragraph [0038]). Hence, the photo-sensor (57) on the joystick (6) is "a human body detection means for detecting the operator's presence in the vicinity of said operation input", as defined in feature [3] of claim 1.

According to paragraph [0031], a control unit (controller 60) controls the laser source (10) in accordance with the presence/absence signal from the photo-sensor (57). Laser irradiation is enabled when the control unit (60) continuously receives a detection signal from the photo-sensor (57) and is disabled when no detection signal is received (paragraphs [0035] and [0036]). Hence, the control unit (60) "provides a control function for allowing the operation unit (laser source 10) to operate based on the input entered into said operation input unit (control board 2 and joystick 6) only when the human body detection means (photo-sensor 57) is detecting the operator", as defined in feature [5] of claim 1.

4.2 D7 does not disclose, however, that the control function provided by said control unit according to feature [5] may be cancelled, as recited in characterising feature [6].

In particular, column 8, lines 13 to 16 which the appellant referred to, does not disclose this feature. This passage of D7 explains that the power supply of the whole apparatus or part of it may be controlled in

accordance with the detection signal from the photo-sensor (57). This means that when the operator is detected as not looking through the eyepieces or not holding the joystick, the control function actively shuts down the apparatus or a part of it. Hence, the control function of enabling the operation of the operation unit only when the operator is being detected is still active, i.e. not cancelled at all.

Moreover, the disclosure on column 4, lines 20 to 26, which the appellant additionally referred to, concerns the capability of the operator to switch, using switch 2a, between two modes, one in which laser irradiation is enabled (ready mode) and another in which laser irradiation is disabled (a wait or standby mode), even if the irradiation instruction signal is input (paragraph [0006], in particular column 2, lines 13 to 15). As in the latter mode there is no laser irradiation whatsoever, the entire control unit is disabled and does not allow the operation unit (laser source 10) to operate based on the input entered into the operation input unit. In contrast, according to feature [6], what is disabled is the specific control function allowing the operation unit to operate based on the input entered into the operation input unit only when the human body detection means is detecting the operator. That is, feature [6] allows the operation unit to operate based on input information entered into the input unit, regardless of whether the operator is detected by the human body detection means or not.

It follows that D7 does not anticipate the claimed subject-matter.

4.3 Document D8 discloses a user identification system for providing authorised access to operational hardware and software tools in medical devices, particularly implanted medical devices (page 1, lines 4 to 7 and 20 to 21; claim 1). The identification process disclosed includes the detection of a fingerprint, an image or an iris scan of the user (page 8, lines 13 to 17). If a match with stored data is confirmed, user access to the device is allowed on the basis of the authorization level (page 8, lines 17 to 20). The identification only occurs at a certain time, after which access is allowed or denied. Figure 5 shows a flow chart of the user identification and authorisation process 500 (page 8, line 13 to 17) which ends in step 530 (page 9, lines 5 to 6). This is not equivalent to a cancellation of the identification and authorisation process. Moreover, page 9, lines 6 to 14 describes a special override function or emergency situation in which after a first denial of user access (at step 504 in Figure 5) the user obtains authentication and authorisation (step 524) when queried (at step 507). Also in this situation the identification and authorisation process is still active and not cancelled.

In contrast to D8, features [4] and [5] of claim 1 require that the control unit allows the operation unit to be instructed or to operate "only when said human body detection means is detecting the operator", in other words, while it is detecting the operator. A fortiori, feature [6] is not disclosed in D8 either.

Hence, D8 does not anticipate the claimed subject-matter.

4.4 Document D9 discloses a patient treatment monitoring system with several patient terminals which requires

treating personnel to be identified by fingerprint detection or face recognition (column 3, lines 13 to 18). In this respect, as in D8, the identification only occurs at a certain time, after which access is allowed or denied. Thus, also D9 fails to disclose a control unit which allows the operation unit to be instructed or to operate "only when said human body detection means is detecting the operator" (as defined in features [4] and [5] of claim 1), in other words, while it is detecting the operator. Since D9 does not disclose the control unit with the aforementioned control functions, the cancellation of these control functions, as defined in feature [6] of claim 1, is not disclosed in D9 either.

Moreover, it is noted that column 8, lines 32 to 34 and 58 to 60, mentioned by the appellant, states that the identification device may be decoupled from the patient terminal, whereby the terminal is brought back to its initial state. In its initial state the patient terminal is equipped with a medical personnel identification capability (column 5, lines 58 to 61). There is no disclosure of cancelling the control function of enabling operation of the operation unit only when the operator is being detected. In fact, column 8, lines 32 to 34 is followed by a reference to the authorisation process as being still active (column 8, lines 34 to 38).

Hence, D9 does not anticipate the claimed subject-matter.

- 4.5 Document D3, which is prior art under Article 54(3) EPC, discloses a bed-side patient monitor which monitors patient parameters when a clinician is in the room or approaching it (page 2, lines 30 to 34). The

patient monitor has a local input interface, such as a keyboard (page 6, lines 27 to 28). However, feature [6] of claim 1 is not anticipated by D3, in particular not on page 8, lines 31 to 34 mentioned by the appellant. The cited passage indicates that when no clinician is in the local area of the patient monitor, the display and alarms are suspended, dimmed, or lowered, or the patient monitor is put in power-save mode. In this condition, only the display and the alarms are deactivated. However, the control function of enabling the operation of the operation unit only when the operator is being detected is still active and has not been cancelled. It is active in the sense that when an operator is detected again the operation unit (e.g., the display and the alarms) will be reset to be operable again.

Hence, D3 does not anticipate the claimed subject-matter.

4.6 The Board therefore concludes that the subject-matter of claim 1 is novel within the meaning of Article 54(1) EPC.

5. *Inventive step*

5.1 *D1 in combination with either D7, D10, D11, D13 or D4*

5.1.1 Document D1 discloses a dialysis device comprising means for entering and validating information from an operator, such as a touch screen (130) (page 2, lines 22 to 26; page 3, lines 25 to 28; page 30, lines 14 to 23; Figure 3). Such means constitute an operation input unit as defined in feature 1 of claim 1. The input entered into the device is validated by safety microcontroller 122 (Figure 3; paragraph

bridging pages 15 and 16). As a result, the operator is less likely to make mistakes arising from boredom or inattention (page 30, lines 7 to 23).

The appellant considered that touch screen 130 was a means for detecting the operator's presence in the vicinity of the operation input unit as recited in feature [3] of claim 1. The Board notes, however, that touch screen 130 has already been identified as the operation input unit according to feature [1]. As a consequence, in D1 there are no separate means additional to the operation input unit for detecting the operator's presence in the vicinity of the operation input unit as defined in feature [3]. Consequently, D1 also lacks a control unit as defined in features [4] and [5] of claim 1, i.e. a control unit that provides a control function for allowing the input operation unit to instruct the operation unit's operation or allowing the operation unit to operate, only when human body detection means is detecting the operator. A fortiori, there is no disclosure in D1 about cancelling the aforementioned control functions.

- 5.1.2 Moreover, none of documents D7, D10, D11, D13 and D4 cited by the appellant in combination with the closest prior art D1 discloses the capability defined in feature [6] of cancelling the aforementioned control functions either:

Concerning D7, see points 4.1 and 4.2 above.

Document D10 discloses a patient monitor having a cancel key which allows to end a started patient monitoring session (page 41, lines 17 to 23; page 42, lines 1 to 4). By ending patient monitoring no control functions as recited in features [4] and [5] are being

cancelled, namely the control functions of allowing the input operation unit to instruct an operation unit's operation or allowing the operation unit to operate based on the input entered, only when said human body detection means is detecting the operator.

Document D11 discloses a patient monitoring system having a button which allows to cancel an alarm state (column 3, lines 36 to 41). An alarm state does not anticipate control functions as recited in features [4] and [5], namely the control functions of allowing the input operation unit to instruct an operation unit's operation or allowing the operation unit to operate based on the input entered, only when said human body detection means is detecting the operator.

Document D13 discloses a dialysis device with a touch screen which can be deactivated to avoid its accidental operation (column 1, lines 34 to 41; column 3, lines 31 to 34 and 55 to 58; column 4, lines 58 to 66; column 5, lines 5 to 16). The deactivation of a touch screen does not anticipate the cancelling of the control functions as recited in features [4] and [5], namely the control functions of allowing the input operation unit to instruct an operation unit's operation or allowing the operation unit to operate based on the input entered, only when said human body detection means is detecting the operator.

Document D4 is essentially similar to D13 (column 3, lines 41 to 48).

Since none of documents D7, D10, D11, D13 and D4 discloses the capability recited in feature [6] of cancelling the aforementioned control functions according to features [4] and [5], the combination of

D1 with any of these documents does not lead the skilled person to the subject-matter claimed.

5.2 *D2 in combination with D7*

Document D2 discloses an ophthalmic surgery system comprising a touch-responsive screen (column 13, lines 39 to 43 column 14, line 57 to column 15, line 4). This touch screen was considered by the appellant as human body detection means for detecting the operator's presence in the vicinity of an operation input unit, which the appellant identified to be foot control assembly 15 (column 6, lines 37 to 42; Figure 1). The appellant did not identify any disclosure in D2 of feature [6], i.e. the cancelling of the control functions defined in features [4] and [5].

Since D7 does not disclose either the capability defined in feature [6] of cancelling the aforementioned control functions according to features [4] and [5], as explained above, the combination of D2 with D7 does not lead the skilled person to the subject-matter claimed.

5.3 *D7 or D8 in combination with either D10 or D11;
D9 in combination with either D10, D11, D13 or D4*

As explained above, none of documents D7, D8 or D9 discloses the capability defined in feature [6] of cancelling the control functions according to features [4] and [5]. These distinguishing features are also not known from any of documents D10, D11, D13 and D4 as indicated above. Hence, the aforementioned combinations of documents do not lead the skilled person to the subject-matter claimed.

5.4 *D7 by itself*

The appellant argued at oral proceedings that paragraph [0003] of D7 mentioned problems of erroneously applying laser irradiation. For example, while a laser treatment apparatus was placed in the ready mode, a third party may accidentally or erroneously input the irradiation instruction signal, performing undesired laser irradiation. Alternatively, the operator himself may unintentionally perform the laser irradiation even though he is not observing the affected part. It would hence be obvious to the skilled person to implement the device with the capability of cancelling of the control functions of features [4] and [5].

The Board does not find this argument convincing. Paragraph [0003] cited by the appellant describes the problems encountered in the prior art which the invention of D7 sets out to solve (paragraph [0004]). D7 presents a complete solution to these problems in the form of a device comprising features [1] to [5] as explained above, without including feature [6], i.e. the cancelling of the control functions of features [4] and [5]. Hence, on the basis of D7 alone, without the benefit of knowledge of the present invention, the skilled person would not be led to search for further solutions to the problems of paragraph [0003].

5.5 For the above reasons, the Board comes to the conclusion that claim 1 of the patent as granted satisfies the requirements of an inventive step within the meaning of Article 56 EPC. This applies a fortiori to the preferred embodiments defined in dependent claims 2 to 6.

6. Hence, none of the grounds raised prejudices the maintenance of the patent as granted.
7. *Request to include a statement in the minutes of oral proceedings*
 - 7.1 During oral proceedings, the opponent requested that the Board states in the minutes of oral proceedings that the Board intended to accept the patent proprietor's argument that a control unit which allows the operation unit to be instructed or to operate "only when said human body detection means is detecting the operator" (as defined in features [4] and [5] of claim 1) was equivalent to a control unit allowing the operation unit to be instructed or to operate while the human body detection means was detecting the operator.
 - 7.2 Pursuant to Rule 124(1) EPC, the minutes of oral proceedings must contain the essentials of these proceedings and the relevant statements made by the parties. As is common practice in the Boards of Appeal, it is not the function of the minutes to record statements - such as the one in question - which a party considers to be possibly relevant. It is, instead, left to the discretion of the Board to decide what it considered "essential" or "relevant" in this respect. In the present case, the Board does not consider the statement in question to be more essential or relevant just because one of the parties requested it to be recorded in the minutes. At the same time the Board does not recognise that the statement in question should be any more essential or relevant than other statements made during the oral proceedings which were not requested to be included in the minutes. The

statement is incorporated into the reasoning given above, under points 4.2 to 4.4, 5.1.1 and 5.1.2.

7.3 The Board consequently decides that the statement is not a proper subject for the minutes according to Rule 124(1) EPC, and the appellant's request to include the statement in the minutes is therefore refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated