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Datasheet for the decision of 1 October 2013

Case Number: T 0664/10 - 3.5.02

Application Number: 03251013.3

Publication Number: 1353305

IPC: G08B 21/02

Language of the proceedings: EN

Title of invention:
Non-hand contact alarm silence system for infant care apparatus

Applicant:
Datex-Ohmeda, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - problem and solution approach - real-life problem (no), objective problem (yes)

Decisions cited:
-

Catchword:
-

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Case Number: T 0664/10 - 3.5.02

D E C I S I O N
of the Technical Board of Appeal 3.5.02
of 1 October 2013

Appellant: (Applicant)
Datex-Ohmeda, Inc.
3030 Ohmeda Drive
Madison, WI 53718 (US)

Representative:
Copsey, Timothy Graham
Kilburn & Strode LLP
20 Red Lion Street
London WC1R 4PJ (GB)

Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 22 September 2009 refusing European patent application No. 03251013.3 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: M. Ruggiu
Members: M. Léouffre
W. Ungler

Summary of Facts and Submissions

I. The applicant appealed against the decision of the examining division to refuse European patent application No. 03 251 013.3.

II. The reason given for the refusal was that the subject-matter of claims 1 and 6 did not involve an inventive step (Article 56 EPC) having regard to the combined teachings of

D1: US 6 350 228 B1; and
D5: JP 8 103 437 A with its EPODOC abstract in English; or
D2: US 6 161 655 A.

III. With the grounds of appeal, received on 22 January 2010, the appellant indicated that the present invention had been incorporated into the "Panda iRes™" and "Giraffe™" infant warmers, which received a Gold Award at the Medical Design Excellence Awards of 2008 as reported by a press release titled: GE Healthcare "Panda" and "Giraffe" Infant Warmers Win Medical Design Excellence Award. Together with the grounds of appeal, the appellant also filed a declaration from Karen Starr, a neonatal nurse practitioner. Mrs Starr is a Clinical Product Surveillance Specialist employed by GE Healthcare, and is in contact with medical practitioners to obtain feedback on the Applicant's products, including the "Panda" and "Giraffe" infant warmers.

IV. In an annex to the summons to oral proceedings, the board expressed the preliminary opinion that the

subject-matter of claim 1, filed with letter of 20 June 2007, and of claim 6, filed with the grounds of appeal of 22 January 2010, did not appear to involve an inventive step in the sense of Article 56 EPC, having regard to the combination of D1 and D2 or D5.

V. At the oral proceedings of 1st October 2013 before the board, the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 4 filed with letter dated 20 June 2007 and claims 5 to 7 filed with letter dated 22 January 2010 (main request), or if that was not possible, on the basis of claims 1 and 2 of the auxiliary request filed during the oral proceedings of 1st October 2013.

VI. Claim 1 of the main request reads as follows:

"A patient care apparatus for use with a patient, said patient care apparatus comprising a means to sense an alarm condition (46), an audible alarm sounding device (40, 48), means responsive to the sensed alarm condition to cause said audible alarm sounding device to produce an audible sound, and an alarm silence switch operable by a care provider for silencing the alarm sounding device, characterized in that the alarm silence switch is a non-contact switch (42, 50) which is activatable without physical contact by a care provider."

Claims 2 to 5 are dependent on claim 1.

Claim 6 of the main request reads as follows:

"A method of silencing an audible alarm on a patient care apparatus. e.g. an infant care apparatus, said audible alarm (40, 48) being responsive to a predetermined condition associated with a patient or a function of the medical apparatus to produce an audible alarm and said patient care apparatus havingan [sic] alarm silence switch (42, 50) activatable to silence the audible sound emanating from the audible alarm device,

characterized in that the alarm silence switch (42, 50) is a non-contact switch and the method comprises activating the alarm silence switch to silence the audible sound by an action of a user without physically touching the alarm silence switch by a care provider."

Claim 7 is dependent on claim 6.

VII. Claim 1 of the auxiliary request is based on claim 6 of the main request wherein the characterising part has been amended as follows:

"characterized in that the alarm silence switch (42, 50) is a non-contact switch and the method comprises a care provider wearing sterile gloves activating the non-contact alarm silence switch to silence the audible sound by an action of the care provider without physically touching the alarm silence switch by the care provider."

Claim 2 is dependent on claim 1.

VIII. The appellant essentially argued as follows:

Modern patient care apparatuses were often linked to alarms provided with a silence switch. An apparatus according to the preamble of claims 1 and 6 was disclosed in D1 which was considered as implicitly comprising a silence switch.

Alarms of patient care apparatuses could be irritating and could disturb the caregiver when he had to concentrate on the patient. The caregiver had therefore to silence the alarm. However pressing the alarm silence button could lead to infective agents being transferred from a caregiver to the button and from the button to another caregiver who could transmit them to the patient. The caregiver might have been wearing sterile gloves in order to prevent infection from passing from the caregiver to the patient. The caregiver had then to remove his/her glove, press the alarm silence button and replace his/her glove on his/her hand. This procedure was time consuming and distracted the caregiver.

Alarms of infant care apparatuses were frequent and irritating and needed to be regularly silenced by the caregiver who had to un-glove and re-glove frequently. The problem of maintaining sterility was solved by the procedure of un-gloving, activating the silence switch of the alarm and re-gloving. The un-gloving and re-gloving procedure was the real-life problem to be solved. This real-life problem could be defined as how to silence an alarm effectively without undergoing the un-gloving and re-gloving procedure while maintaining

sterility for the patient (cf. grounds of appeal, page 3, penultimate paragraph).

The solution was a non-contact alarm silence switch.

D2 related to a non-contact elevator call button and D5 related to a medical image diagnostic system operated with a contactless switch. Neither D2 nor D5 taught about the issue of silencing an alarm, in particular silencing alarms of patient care apparatuses. None of the prior art was concerned with the real-life problem of un-gloving and re-gloving to silence an alarm of a patient care apparatus while maintaining sterility. D2 and D5 would not have been found when searching for a solution to the problem of un-gloving and re-gloving to silence an alarm in a patient care apparatus while maintaining sterility, if the examining division had not used an ex-post facto analysis to formulate the problem. Any formulation of the problem should have comprised the terms un-gloving and re-gloving.

Claim 1 of the auxiliary request was filed as an attempt to better relate the solution to the problem. It specified "a care provider wearing sterile gloves activating the non-contact alarm silence switch". It did not raise any further issue and was based on section [0022] of the application as published.

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty (Article 54 EPC)*

The preambles of claim 1 as filed with letter of 20 June 2007 and of claim 6 as filed with letter of 22 January 2010 have been drafted on the basis of document D1 (cf. grounds of appeal at page 3, item 3). D1 discloses indeed a patient care apparatus for use with a patient (cf. column 3, lines 24 to 26 and figure 1). Said patient care apparatus comprises a means to sense an alarm condition (cf. column 4, lines 53 to 60), an audible alarm sounding device 56, means responsive to the sensed alarm condition to cause said audible alarm sounding device to produce an audible sound (cf. column 5, lines 22 to 30), and implicitly an alarm silence switch operable by a care provider for silencing the alarm sounding device as admitted by the appellant (cf. grounds of appeal at page 3, item 3).

Thus, claims 1 and 6 of the main request differ from D1 respectively in that

"the alarm silence switch is a non-contact switch (42, 50) which is activatable without physical contact by a care provider"; and in that

"the alarm silence switch (42, 50) is a non-contact switch and the method comprises activating the alarm silence switch to silence the audible sound by an action of a user without physically touching the alarm silence switch by a care provider".

Claims 1 and 6 are therefore both novel in the sense of Article 54 EPC.

3. *Main request - Inventive step (Article 56 EPC)*

3.1 Patient care apparatuses having an audible alarm sound device require the care provider to manually push the alarm silence button on or near the particular apparatus to silence that alarm so as to take some action in response to the alarm condition (cf. description of published application, section [0003]). In many instances, the care provider "is wearing gloves that must be maintained in sterile condition. In such instances, the sterile environment is maintained by the caregiver wearing a gown and with gloves that overlap the sleeves of the gown so that almost the entire upper body of the caregiver is maintained in sterile conditions. Thus any touching of an alarm silence button by any portion of the caregivers upper body, that is, any portion of the body above the waist, can destroy the sterility of the caregiver" (cf. section [0004]). Therefore the caregiver "must remove the sterile gloves, push the alarm silence switch or button, and then re-glove to return to attending to the patient then in the birthing process, or undergoing some other procedure requiring the sterile conditions" (cf. section [0005]).

3.2 The appellant considers that the removing of the sterile gloves and the re-gloving is the real-life problem faced by the caregivers that should be considered in the assessment of inventive step in accordance with the problem/solution approach.

3.3 Actually, as admitted by the appellant in his grounds of appeal (cf. page 2, paragraph 2), "Procedures that are conducted in patient care apparatus require the caregiver to wear sterile gloves in order to prevent infections from passing from the caregiver to the patient, who is vulnerable to infections." Nevertheless infective agents may pass from a caregiver to the button of an alarm switch and then to another person activating the switch, who might transmit the germs to the patient. The appellant admits in his grounds of appeal, that "In order to overcome this problem, a procedure was devised for the caregiver to remove his/her glove, press the alarm silence button and replace the glove on his/her hand. This has become established and is a perfectly satisfactory procedure to prevent infections spreading from the alarm silence button to the patient".

3.4 Hence the real-life problem identified by the appellant, namely undergoing un-gloving and re-gloving, is a procedure aiming at solving the problem of avoiding spreading contaminants from the button of the alarm silence switch to the patient.

3.5 The invention replaces the alarm silence switch by a non-contact alarm silence switch. The immediate effect of the non-contact switch is that the germs or contaminants present on the button of the switch cannot be transmitted to the caregiver and then to the patient. The consequence is that while sterility is maintained, the caregiver does not need to undergo the un-gloving and re-gloving procedure and may keep his gloves when approaching the non-contact switch. Starting from D1, the non-contact switch and the devised procedure of un-

gloving and re-gloving appear as two alternative solutions to the problem of avoiding spreading the germs or contaminants from the alarm switch, which constitutes the objective problem. The above shows that objective criteria must be used to determine the technical problem which is decisive for the assessment whether claimed subject-matter fulfils the requirement of Article 56 EPC (cf. Case Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, I.D.4.5. page 180 and I.D.4.4.1, page 178, paragraphs 2, 3 and 4.).

3.6 A caregiver, well aware of the devised procedure or even applying the devised procedure, might perceive the said procedure as a real-life problem because it leads to a waste of time, and increases the risk of distraction (cf. grounds of appeal, page 2, paragraph 2). However the procedure is not the objective problem solved but a solution to that problem implying a succession of actions causing distraction and waste of time. Seeking a solution to the subjective problem of reducing waste of time and distraction due to the procedure, the caregiver might have looked for other procedures, like for example assistance of another person, using the elbow or other objects to switch off the alarm (cf. grounds of appeal, page 2, last sentence of paragraph 2). Alternatively, the caregiver, aware of the objective cause that led to the devised procedure, namely the contaminants on the alarm silence switch, might have presented the subjective problem of waste of time and distraction and its objective cause to the technician who developed the patient care apparatus of D1.

3.7 A technician made aware of the subjective problem and its cause, namely the contaminants on the switch of a patient care apparatus, would immediately focus on the objective problem, namely the transmission of contaminants from and to the switch. A solution to the objective problem, involving a non-contact switch is a straightforward solution, since the advantages of a non-contact switch with respect to the transmission of bacteria were well known at the priority date of the application (cf. D2, column 2, lines 18 to 64 or the abstract of D5).

The non-contact call button of D2 is an elevator call button which may be used in "doctor's offices and hospitals, as well as in factories where dirty work is performed, since bacteria and filth may be passed from one passenger to the button and hence to other passengers" (cf. column 1, lines 20 to 24), and an operator of a medical image diagnostic system, which is provided with a non-contact switch, can, according to D5, "easily perform the switch operation in the non-contact fashion as [sic] maintaining the hand in a disinfected state" (cf. last line of the translated abstract).

It would therefore be a straightforward solution for a technician to apply the teaching of D5 or D2 to the patient care apparatus of D1 and to replace the alarm silence switch of D1 by a contactless switch according to D5 or D2.

Hence, the subject-matter of claims 1 and 6 appears to the board as obvious and the conditions of Article 56 EPC are not met.

4. *Auxiliary request - Inventive step (Article 56 EPC)*

In an attempt to link the solution to the real-life problem that a caregiver was facing, namely un-gloving and re-gloving to switch off the alarm of a patient care apparatus, the applicant amended the characterising part of claim 1 of the auxiliary request to read: "the method comprises a care provider wearing sterile gloves activating the non-contact alarm silence switch to silence the audible sound by an action of the care provider without physically touching the alarm silence switch by the care provider."

The objective problem remains however to avoid transmitting contaminants to the user, or from the user to the switch, even when the user is wearing gloves. The person of ordinary skill is however aware of D2 that recites that non-contact switches may be adjusted to sense the presence of users as much as 8 cm distant from the button, whereby much less filth, bacteria and mechanical stress is transferred to the button, and work with infra-red radiation which can be reflected from gloves (cf. D2, column 2, lines 51 to 64). Aware of the caregivers wearing gloves, a technician of ordinary skill would have obviously solved the objective problem of avoiding contaminants to be transmitted from one caregiver to the button of the alarm silence switch and from the button itself to another caregiver who could transmit it to the patient, by replacing the alarm switch of the patient care apparatus of D1 by a non-contact alarm silence switch according to D2, i.e. a non-contact switch responsive to users wearing gloves.

Thus the subject-matter of claim 1 of the auxiliary request is also obvious in the light of documents D1 and D2. The conditions of Article 56 EPC are therefore not met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

U. Bultmann M. Ruggiu