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Datasheet for the decision of 28 January 2010

Case Number: T 1165/07 - 3.2.02

Application Number: 00992182.6

Publication Number: 1237590

IPC: A61M 1/00

Language of the proceedings: EN

Title of invention:
Improved security infusion pump with bar code reader

Applicant:
B. Braun Medical, Inc.

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 54, 56

Keyword:
"Novelty (yes) after amendments"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1165/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 28 January 2010

Appellant: B. Braun Medical, Inc.
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Representative: UEXKÜLL & STOLBERG
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 8 January 2007 refusing European patent application No. 00992182.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: M. Noel
Members: P. L. P. Weber
M. J. Vogel

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division dated 08 January 2007 to refuse the application because of lack of novelty of the subject-matter of claim 1 over D1: WO-A-99/10029.

The notice of appeal was filed on 16 March 2007 and the appeal fee paid on the same day.
The statement setting out the grounds of appeal was filed on 18 May 2007 together with an amended set of claims.

II. In a communication dated 19 October 2009, the Board drew the attention of the appellant to still existing formal objections and informed the appellant that in the even these formal objections were dealt with, a patent could be granted.

III. With letter dated 15 November 2009, the appellant filed a new main request and an auxiliary request and requested that a patent be granted on the basis of one of these requests and the amended description and figures already on file.

IV. Claim 1 according to the main request reads as follows:

A medical infusion pump with a bar code reading system of the type having:

(a) a pump mechanism (10) with a housing (11), a display screen (34), and control software for operating the infusion pump according to input infusion data (162, 162a, 162b);

(b) a bar code scanner (62) operatively coupled to said pump mechanism housing (11) and operatively attached to communicate scanned infusion data (74, 76, 78, 80) to said pump display screen (34) and to the control software;

(c) a bar code scanning program (136, 148, 156) incorporated with the pump and operatively connected through circuitry in said pump mechanism (10), for activating said bar code scanner (62) to scan for an authorization code (94) from an authorized user (90), for an authorized user ID code (92) from said authorized user (90), for a patient ID code (98) from a patient (96), and for the infusion data (74, 76, 78, 80) and a patient ID code (72) from a medicinal fluid (70) container (12) label (66), wherein the medicinal fluid container label (66) comprises a bar code and the scanned infusion data includes parameters provided for operating the infusion pump (10);

(d) a confirmation program (138, 159) requiring scanning (136, 148, 156) of the authorized user ID code (92), the patient ID code (98) from the patient, and the patient ID code (72) from the medicinal fluid (70) container (12) label (66), to confirm a match (159)of the patient ID codes (72, 98) before operating (172) the pump mechanism (10) according to the scanned infusion data (74, 76, 78, 80), wherein the confirmation program (138, 159) requires scanning (136) of the authorization code (94) and the authorized user ID code (92) before permitting (146) scanning of the patient ID code (98) from the patient (96) and the

patient ID code (72) from the medicinal fluid container label (66); and

(e) a program for displaying (40) the scanned infusion data (74,76,78,80) and further requiring manual keypad (58) confirmation by the authorized user (90) of the displayed required pump mechanism operating infusion data (74,76,78,80) prior to activating said pump mechanism (10) to infuse fluids according to the scanned infusion data (74,76,78,80).

V. The following documents were cited in the international search report or in the supplementary european search report :

D1: WO-A-99/10029
D2 : US-A-5378231
D3 : WO-A-93/12828
D4 : US-A-4573994
D5 : US-A-5735263
D6 : US-A-5871465
D7 : US-A-4706207

Reasons for the Decision

1. The appeal is admissible.

2. Support for the amendments

Claim 1 according to the main request is based on the originally filed application documents as follows:
feature (a): claim 1 feature a)
feature (b): page 3, lines 13, 14 and claim 1 feature b)

feature (c): claim 1 feature c) and claim 3
feature (d): claim 1 feature d), page 2, line 29 to page 3, line 3, page 11, lines 9 to 12.
feature (e): claim 1 feature e), page 12, lines 8-11.

Therefore the amended claim complies with the requirement of Art. 123(2) EPC.

3. Novelty

Document D1 discloses a system for preparing and infusing a medicament to a patient with a mixing and delivery device which is interconnected with a central computer or databases in order to make several checks prior to infusion (for instance if the patient has some allergies incompatible with the prescribed medicament) and/or various updates of databases. For instance Figures 3, 4, 17 and the corresponding parts of the description give an overview of the system architecture and purpose.

In the embodiment shown in Figures 5A, 5B and 7 which is described in most detail and is the most relevant with regard to the present invention, the following remarks are made regarding the security features:

The identity of the patient is checked by scanning a bar code on for instance a wrist band (see page 17 lines 20 to 30, page 28, lines 24 to 30) but the identity of the patient is not checked on the label of the medicinal fluid container as required by feature (c) of present claim 1.
Consequently there is also no check that the patient ID on the patient label is the same as the one on the

medicinal fluid container as required by feature (d) of claim 1. In the device of D1 this seems also not necessary as the device is connected with a central database in which it is checked whether the scanned medicine is compatible with the patient and corresponds to the prescription, see page 28 lines 30 to 37, Figure 6, box 100.

It is further disclosed that the identity of the clinician is scanned (see page 28 lines 24 to 30, page 29 lines 36, 37) and that a password or authorisation is entered. However there is no order imposed for the different scannings as required by feature (d) of present claim 1 according to which the confirmation program requires an authorised user ID code and an authorisation code be entered before the scanning of the patient ID from the patient and from the medicinal fluid container is permitted. According to the flow diagram of Figure 6 of D1, showing one embodiment of the invention, it is, on the contrary, the patient ID which is scanned before the clinician ID is scanned.

Moreover there is no mentioning in D1 of a requirement for the clinician to positively authorise the infusion by manual keypad confirmation as required by feature (e) of present claim 1.

The other documents on file are less relevant than D1.

Therefore the subject-matter of claim 1 of the main request is novel and complies with Article 54 EPC.

4. Inventive step

D1 discloses the closest prior art. Starting from this document the problem is as set out in the application, namely to reduce the complexity of the system and at the same time improve its human accountability.

The solution is given by the order of the scannings imposed by feature (d) which guaranties that no further scanning can take place unless it is done by an authorised user. By then checking the match between the patient ID and the patient ID on the label of the medicinal fluid container it is guarantied that the medicinal fluid is for the right patient and this check can be done locally without the need for connection to a central computer as it simply amounts to comparing two scannings. By finally requiring, in feature (e), a positive action (manual keypad confirmation) of the clinician to authorise the infusion in accordance with the displayed infusion data, it is guarantied that the clinician makes a final check of the infusion data before authorising it.

There is no suggestion in the prior art cited in the search report to provide and scan patient information on the medical fluid container in order to make sure that the medicine is for the right patient. Neither is there any suggestion to require the healthcare professional to confirm positively the infusion data after they have been displayed on the screen of the pump.
There is further no suggestion whatsoever to integrate all the features in a "local" pump, thus avoiding the complexity of a centralised system.

The only information which is clearly scanned in the device according to D2 is from the drug vial (see col. 3 lines 41 to 45) for identifying the drug. The system then prompts the user to enter delivery information (see col. 5, lines 54 to 62). User information can also be stored in the system (col. 9, lines 5 to 19). However no user ID scanning or access code scanning is required.

The other documents are not more relevant.

For these reasons, the Board is satisfied that the subject-matter of claim 1 of the main request also involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision is set aside.

2. The case is remitted to the first instance department with the order to grant a patent on the basis of following application documents:

Description, Pages:
1,3-8, 10,11, 15,16 as published
9, 12-14 as filed with entry into the regional phase before the EPO
2, 2a received on 29 December 2005 with letter of 28 December 2005

Claims, Numbers:
1 received on 16 November 2009 with letter of 15 November 2009

Drawings, Sheets
1/6-6/6 filed with entry into the regional phase before the EPO

The Registrar: The Chairman:

D. Sauter M. Noël