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(71) Applicant *(for all designated States except US)*: **NOVO NORDISK A/S** [DK/DK]; Novo Allé, DK-2880 Bagsværd (DK).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **PEDERSEN, Bennie, Peder, Smiszek** [DK/DK]; Mosevang 8, DK-4690 Haslev (DK). **HANSEN, Michael, Ejstrup** [DK/DK]; Sasserod 41, DK-5462 Morud (DK). **KLITMOSE, Lars, Peter** [DK/DK]; NOVO NORDISK A/S, Novo Allé, DK-2880 Bagsværd (DK). **HANSEN, Kim, Ejholm** [DK/DK]; NOVO NORDISK A/S, Novo Allé, DK-2880 Bagsværd (DK). **HANSEN, Denis, B.** [DK/DK]; NOVO NORDISK A/S, Novo Allé, DK-2880 Bagsværd (DK).

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[Continued on next page]

(54) **Title**: INJECTION DEVICE INCORPORATING DOSE MONITORING

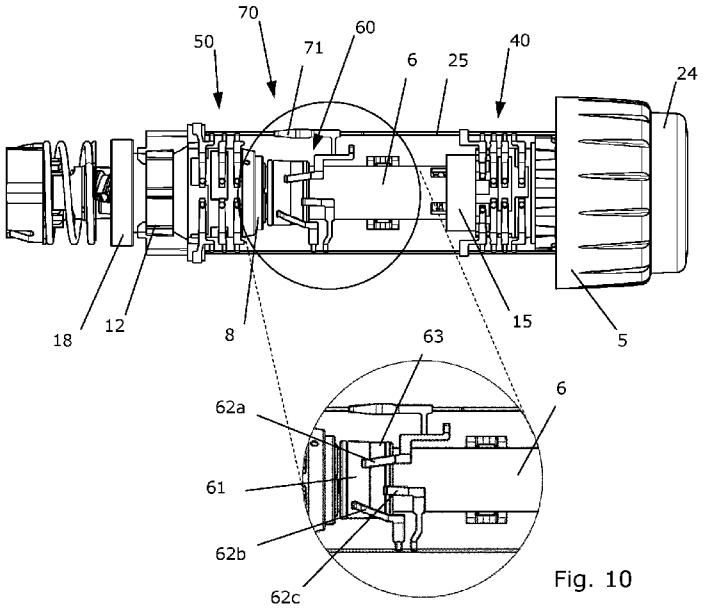

Fig. 10

(57) **Abstract**: The present invention relates to an electronically assisted injection device adapted to inject doses of a drug from a held cartridge. The injection device may include a first rotational sensor (40) coupled to a driver (6) for sensing a dose setting and a second rotational sensor (50) coupled to a dosing member (8) for sensing an expelled dose. A third axial sensor (60) provides information relating to the axial position of the driver (6). A control circuit is adapted to determine the end of dosed state based on data from the first, the second and the third sensor s (40, 50, 60). The injection device may also include an arrangement for determining fluid ingress into the interior of the injection device. The arrangement includes an electrically non-conductive surface portion (63) disposed on a first component (6) and an electrode assembly (62a, 62b, 62c) disposed on a second component (80) wherein the first component (6) and the second component (80) moves relative to each other during operation.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

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30 May 2013

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2012/056598

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/056598

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/24 A61M5/315 A61M5/20
ADD. A61M5/31

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2010/142598 A2 (NOVO NORDISK AS [DK]; JESPERSEN SOEREN KRAGH [DK]; BUSCHARDT CLAUS VAL) 16 December 2010 (2010-12-16)	12-15
A	page 13, line 5 - page 20, line 23; figures 1-6	1-11

A	WO 2008/116766 A1 (NOVO NORDISK AS [DK]; MOELLER CLAUS SCHMIDT [DK]) 2 October 2008 (2008-10-02) cited in the application the whole document	1-11

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search	Date of mailing of the international search report
4 April 2013	12/04/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Knaus-Reinbold, S

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	DE 10 2004 063650 A1 (TECPHARMA LICENSING AG [CH]) 20 July 2006 (2006-07-20) the whole document	1-11
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A	US 2002/198483 A1 (WARIAR RAMESH [US] ET AL) 26 December 2002 (2002-12-26) paragraph [0053] - paragraph [0076]; figures 1-3	12-15

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Information on patent family members

International application No
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-11

Injection device for setting and expelling set doses of a drug from a drug-filled cartridge, the injection device comprising a housing, a piston rod, a dosing member, a driver coupled to the piston rod and a first, second and third sensors associated with the driver and the dosing member and a control circuit coupled to the first, second and third sensors, the control circuit being adapted to determine an amount of a set dose and/or an amount of an expelled dose and the state wherein the driver is in an initial rotational position relative to the dosing member based on data from the first, second and third sensors.

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2. claims: 12-15

Injection device for setting and expelling set doses of a drug from a drug-filled cartridge, the injection device comprising a housing with a housing component forming an opening and a dose setting and injection mechanism operable to set a dose and to expel a set dose, the dose setting and injection mechanism defining a first component and a second component that move relative to each other during operation of the dose setting and injection mechanism, wherein an electrically non-conductive surface portion is disposed on the first component and wherein an electrode assembly comprising at least a first electrode and a second electrode is disposed on the second component, wherein the electrode assembly and the electrically non-conductive surface portion are configured to move relatively and next to each other during operation of the dose setting and injection mechanism, and wherein a control circuit is coupled to the electrode assembly, the control circuit being configured to sense an electrical characteristic associated with the electrode assembly to determine the presence of a fluid on the electrically non-conductive surface portion.
