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(21) International Application Number: PCT/DK92/00212 (22) International Filing Date: 2 July 1992 (02.07.92) (30) Priority data: 1346/91 12 July 1991 (12.07.91) DK (71) Applicant (for all designated States except US): NOVO NORDISK A/S [DK/DK]; Novo Allé, DK-2880 Bagsvaerd (DK). (72) Inventors; and (75) Inventors/Applicants (for US only) : BONNICHSEN, Frits, Frydendal [DK/DK]; Hoejdevej 31, DK-3540 Lyngø (DK). JØRGENSEN, Peter, Nissen [DK/DK]; Valloevvej 5, DK-2700 Boenshoej (DK). (74) Agent: NOVO NORDISK A/S; Patent Department, EiT, Novo Allé, DK-2880 Bagsvaerd (DK).		(81) Designated States: AU, BB, BG, BR, CA, CS, FI, HU, JP, KP, KR, LK, MG, MN, MW, NO, PL, RO, RU, SD, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: SYRINGE SYSTEM (57) Abstract An insulin injection system comprises a pen shaped syringe with a cartridge containing insulin, and an injection needle. The needle is a G 30 needle and the insulin is a type which may freely flow through a G 30 needle. When the insulin is the type comprising suspended crystals the maximal dimension of any crystal is 15 µm.		

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SYRINGE SYSTEM

The invention relates to syringes for injecting insulin and more specified pen-shaped syringes administering insulin doses from a cartridge in the pen syringe.

5 Diabetes is usually treated by the patient frequently injecting himself with an insulin dose which he adjusts each time according to his immediate need.

To make it less straining to the patient to prick himself several times a day, it is aspired to make the injections as painless as possible and to reduce the psychical malaise many people will feel if they have to pass a needle into their
10 own body.

As the malaise seems to grow with the length and the thickness of the needle and the sensation of pain seems to be reduced when the needle is made thinner, a passable way seems to be to make the needle thinner and shorter. This line may, of course, only be followed to a certain extent, as the
15 needle must have a length permitting the subcutaneous injection of the insulin and a thickness allowing the insulin to pass through the needle.

Whereas the acceptable minimum length of the needle is well defined, the lower limit for the thickness of the needle is more fluid. With a thinner needle it becomes more difficult to press the insulin out through the needle and
20 the injections will take more time. A more relevant lower limit is set by the fact that by injecting insulin types appearing as suspended crystals, a sieving of the suspension may occur, and the suspension injected may consequently have a lower concentration than expected.

The thicknesses of needles are indicated by a "G" and a gauge
25 number increasing with thinner needles. Thus, the outer diameter of a G 27 needle is 0.4 mm, of a G 28 needle 0.36 mm, and of a G 30 needle 0.3 mm. The wall thickness of the needles is typically 0.075 mm, so that a G 27 needle has a bore of 0.25 mm, whereas the bore of a G 30 needle is 0.15 mm.

Commonly, G 27 needles are used. However, according to Diabetes
30 Forecast 1976; 29 page 27 problems are observed when G 27 needles and even thicker needles are used for injecting an insulin containing suspended crystals.

The problem is a clogging of the needle during injection, which clogging is due to the fact that crystals of e.g. Lente insulin having a size of 20 - 40 μm have a tendency to align themselves across the inside of the needle. This clogging is observed during injection, especially if this injection is carried out too slowly. It must
5 be presumed that a similar clogging occurs during the filling of the syringe thus making the filling impossible or at least having the effect that some of the crystals are retained with the consequence that the suspension sucked into the syringe has a lower concentration than expected.

Whereas the trend goes towards the use of G 28 needles this is
10 seen as close to the limit of what is possible. G 29 needles are seen as needles for disposable syringes for insulin, but G 30 needles have so far been deemed unusable for injection of an insulin suspension.

The present invention is based on the surprising recognition that needles thinner than G 29 may be used for injecting insulin.

15 The present invention is, thus, related to an insulin injection system comprising a pen shaped syringe having a cartridge with insulin and an injection needle, the system being characterized in that the needle is a G 30 needle and the cartridge contains an insulin type which may flow freely through a G 30 needle.

20 By the use of a pen shaped syringe with a cartridge the insulin will only have to pass the needle once, which in itself halves the risk of sieving. Further, the use of suspensions of insulin types having very short and needle shaped crystals totally eliminates the risk of bridging in a G 30 needle when no dimension of the insulin crystals exceeds 15 μm .

25 By closely binding a G 30 needle to a system further comprising a pen-shaped syringe, it may be ensured that a pen syringe equipped with a G 30 needle will always contain insulin of a type which may pass through the needle without any sieving effect.

The pen syringe may either be manufactured as a disposable
30 device which is sold prefilled with the insulin or it may appear as a durable pen syringe so designed that it can only receive cartridges with insulin which may pass freely through a G 30 needle.

The needle may have attaching means cooperating with attaching means on the pen syringe for mounting the needle on the pen syringe, whereby the needle hub may be designed to only match with pen syringes of the system. Such attaching means may be a needle hub having a thread cooperating with a
5 corresponding thread on the syringe.

The needle hub may have a central protrusion covering part of the length of the needle. Thereby, the length of the injection part of the needle is made shorter, which is advantageous as well from a psychological point of view as from a mechanical one. The protrusion makes visible only the part which
10 should be inserted and it supports the thin and consequently more fragile needle.

With an injection part of the needle of 8 - 12 mm, it is avoided that the injections become intermuscular instead of subcutaneous. The needles may be manufactured in the same length as usual for thicker needles and the shorter injection part may be obtained by the hub protrusion covering a larger part than
15 usual for the needle.

CLAIMS

1. An insulin injection system comprising a pen shaped syringe comprising a cartridge with insulin and an injection needle, characterized in that the needle is a G 30 needle and the cartridge contains an insulin type which may
5 freely flow through a G 30 needle.

2. An insulin injection system according to claim 1, characterized in that the insulin in the cartridge has a maximal crystals size of 15 μm .

3. An insulin injection system according to claim 1 or 2, characterized in that the pen syringe is a disposable device prefilled with insulin.

10 4. An insulin injection system according to claim 1 or 2, characterized in that the pen syringe is a durable device designed to receive only cartridges containing insulin which may pass freely through a G 30 needle.

5. An insulin injection system according to any of the preceding claims, characterized in that the needle has attaching means for cooperation with
15 attaching means on the pen syringe.

6. An insulin injection system according to claim 5, characterized in that the needle attaching means is a needle hub having a thread cooperating with a corresponding thread on the pen syringe.

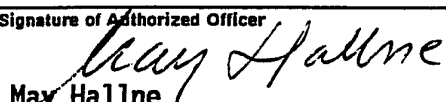
7. An insulin injection system according to claim 6, characterized in
20 that the needle hub has a central protrusion covering part of the length of the needle.

8. An insulin injection system according to claim 7, characterized in

that the length of the injection part of the needle is 8 - 12 mm.

INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 92/00212

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC5: A 61 M 5/32, 5/158		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC5	A 61 M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched ⁸		
SE,DK,FI,NO classes as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category *	Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	EP, A2, 0265214 (NOVO INDUSTRI A/S) 27 April 1988, see page 3, line 14 - line 18; table I-III --	1-8
Y	WO, A1, 8903698 (BUTLER, J.H.A.) 5 May 1989, see page 1, line 3 - line 4 --	1-3,5-8
Y	CH, A5, 675078 (NOSTA AG) 31 August 1990, see column 1, line 23 - line 25 --	1-2,4-8
A	EP, A1, 0368191 (KIRCHNER & WILHELM GMBH & CO) 16 May 1990, see the whole document -- -----	1-8
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
2nd October 1992	14 -10- 1992	
International Searching Authority	Signature of Authorized Officer	
SWEDISH PATENT OFFICE	 May Hallne	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.PCT/DK 92/00212**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on 28/08/92. The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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