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Heim, Patrick

Date

08.05.2024

Reference
244303 r28/aml

OPPO 01

Application No./Patent No.
20195922.8 - 1113 / 3766408

Applicant/Proprietor
Abbott Diabetes Care, Inc.

BRIEF COMMUNICATION

Subject: ☐ Your letter of
☐ Our telephone conversation of
☐ Communication of
☐

Enclosure(s): ☐ Letter from the proprietor of the patent of
☐ Letter from the opponent of
☒ Copy (copies) Decision revoking the European Patent (Art. 101(2) and 101 (3)
(b) EPC)

Communication:

All annexes to the letter as well as the consolidated list of all opposition citations are available for inspection via the European Patent Register at **www.epo.org/register**. Should you wish to receive these documents in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (OJ EPO 2022, A28).

☐

For the Opposition Division



☒ **Registered letter**

EPO Form 2911O 04.22 (03/05/24)

DEXCOM EXHIBIT 1270
DexCom v. Abbott Diabetes Care
IPR2024-00520

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Application No. / Patent No. 20 195 922.8 - 1113 / 3 766 408 / 01	Ref. 244303 r28/aml	Date 08.05.2024
Proprietor Abbott Diabetes Care, Inc.		

Decision revoking the European Patent (Art. 101(2) and 101(3)(b) EPC)

The Opposition Division - at the oral proceedings dated 15.04.2024 - has decided:

European Patent No. EP-B- 3 766 408 is revoked.

The reasons for the decision are enclosed.

Possibility of appeal

This decision is open to appeal. Attention is drawn to the attached text of Articles 106 to 108 and Rules 97 to 98 EPC.

Opposition Division:

Chairman: Knüpling, Moritz
2nd Examiner: Trattner, Barbara
1st Examiner: Kaden, Malte



Heim, Patrick
Formalities Officer
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Enclosure(s): 17 page(s) reasons for the decision (Form 2916)
Wording of Articles 106 - 108 and Rules 97-98 EPC (Form 2019)
Minutes of oral proceedings
Consolidated list

Claims of the Main Request; Auxiliary Requests 1-38 and 40

to EPO postal service: 03.05.24

Facts and submissions

- I. European patent No. 3 766 408 is based upon European patent application No. 20 195 922.8 filed on 24-03-2011, which is a third generation divisional application of the ultimate root application EP 11 760 268 (published as WO 2011/119896).

It claims priority of US 61/317,243 filed on 24-03-2010, of US 61/345,562 filed on 17-05-2010, of US 61/361,374 filed on 02-07-2010, and of US 61/411,262 filed on 08-11-2010.

The mention of the grant of the patent has been published in European Patent Bulletin 2022/17 of 27-04-2022.

Proprietor of the patent is:

Abbott Diabetes Care, Inc.
1360 South Loop Road
Alameda, CA 94502
US

- II. Notice of opposition has been filed on 26-01-2023 by:

Opponent 1:
Dexcom, Inc.
6340 Sequence Drive
San Diego, CA 92121
US

- III. An intervention has been filed on 13-06-2023 by:

Opponent 2:
Dexcom Deutschland GmbH
Haifa-Allee 2
55128 Mainz
DE

- IV. Documents **D1-D20** have been submitted within the opposition period by Opponent 1; Opponent 2 submitted documents **D21-D24** with the intervention; see the annexed consolidated list.

- V. With the notice of opposition, Opponent 1 requests revocation of the patent in its entirety based on Articles 100(a), 100(b) and 100(c) EPC. The Opponent auxiliary requests oral proceedings to be held.

Opponent 1 argues that the subject-matter of all granted claims involves an extension of subject-matter (Article 100(c) and 76(1) EPC) and is insufficiently disclosed (Article 100(b) EPC).

According to Opponent 1, the priority claim of the patent is invalid.

With regard to Articles 100(a) and 56 EPC, Opponent 1 argues that claim 1 lacks an inventive step in view of D1 in combination with any of common general knowledge, D5-D9; in view of D10 in combination with any of common general knowledge, D6, D11, D7-D9; in view of D14 in combination with any of D1, D10, D15-D18; or in view of the prior art acknowledged in the patent, in combination with any of D10, D1, common general knowledge.

VI. With letter of 12-04-2023, Opponent 1 requests acceleration of the opposition proceedings due to pending infringement proceedings.

VII. With the notice of intervention filed on 13-06-2023, Opponent 2 requests the patent to be revoked in its entirety, and oral proceedings to be held as an auxiliary measure.

Opponent 2 adopts the arguments of Opponent 1 that the patent's priority claim is invalid, and that the claimed subject-matter involves an extension of subject-matter and is not sufficiently disclosed. The inventive step objections of Opponent 1 are likewise endorsed.

Opponent 2 further argues that claim 1 lacks an inventive step in view of D14 in combination with D21.

VIII. On 19-06-2023 the Proprietor is invited to file within a period of two months their observations on the intervention.

IX. With letter of 20-06-2023, the Proprietor requests rejection of the opposition and maintenance of the patent as granted. The Proprietor auxiliary requests maintenance of the patent in amended form based on the 31 auxiliary requests filed with the letter. Furthermore, oral proceedings are auxiliary requested.

The Proprietor additionally requests neither to admit into the proceedings the ground of opposition under Article 100(b) EPC nor the objections against the dependent claims under Article 100(c) and 100(a) EPC; according to the Proprietor, these objections are not sufficiently substantiated.

X. On 21-08-2023, Opponent 1 submits further arguments with respect to extension of subject-matter, insufficient disclosure, and lack of inventive step. Document **D25** is filed with the letter, see the annexed consolidated list.

Opponent 1 raises a new inventive step objection in view of D1 in combination with D14.

- XI. In a letter of 25-08-2023, the Proprietor argues that the submissions by Opponent 1 filed on 21-08-2023 could and should have been made within the opposition period, and asks a period of four months to file their reply, before any preliminary opinion by the Opposition Division. According to the Proprietor, the conduct of Opponent 1 makes the request for accelerated proceedings unjustified. Additionally, the Proprietor requests a period of at least six months between any preliminary opinion and the date for oral proceedings to be observed.
- XII. On 29-08-2023, the Proprietor files a response to the intervention and argues that claim 1 is inventive in view of D14 in combination with D21.
- XIII. In a letter of 07-09-2023, Opponent 1 provides counter arguments to the the Proprietor's letter of 25-08-2023.
- XIV. With letter of 12-09-2023, Opponent 2 endorses the arguments provided by Opponent 1.
- XV. On 21-09-2023, the parties are summoned to attend oral proceedings scheduled for 15 and 16 April 2024. In its preliminary opinion, the Opposition Division considers claims 1 and 21 to involve an extension of subject-matter. The division further considers the patent to meet the requirement of sufficiency of disclosure, the priority to be invalid, and the requirement of inventive step to be met.
- XVI. With letter of 23-10-2023, the Proprietor submits Auxiliary Requests 4, 5, and 6. The previous Auxiliary Requests are maintained, but changed in their order as indicated in the letter.
- XVII. With letter of 12-12-2023, Opponent 1 provides further arguments with regard to the requests on file, and submits documents **D26-D28** (see the annexed consolidated list) which are relied on in inventive step objections against some of the Auxiliary Requests.
- XVIII. With letter of 12-12-2023, Opponent 2 endorses the arguments and submissions made by Opponent 1.
- XIX. In a letter of 09-02-204, Opponent 1 submits that D26 was published before the priority date of the contested patent.
- XX. On 15-02-2024, the Proprietor submits Auxiliary Requests 35-38 and replies to the objections raised against the requests on file.
- XXI. With letter of 15-03-2024, Opponent 1 submits further arguments with regard to added matter in the contested patent.

- XXII. With letter of 09-04-2024, Opponent 2 endorses the arguments and submissions made by Opponent 1.
- XXIII. On 15-04-2024, oral proceedings take place in the presence of the parties. The Opposition Division decides to admit the ground of opposition of Article 100(b) EPC, but comes to the conclusion that the patent is sufficient in disclosure. Granted claim 1 is found to involve an extension of subject-matter. The Proprietor files a new Auxiliary Request 1 and a new Auxiliary Request 2, which are likewise found to involve an extension of subject-matter. The Opposition Division further concludes that the 38 auxiliary requests filed during the written proceedings do not overcome the added matter objection. The patent is revoked.
- XXIV. The decision is based on the following requests.
- Main Request: maintenance as granted
 - Auxiliary Requests 1, 2: filed during oral proceedings on 15-04-2024
 - Auxiliary Requests 3-5: filed as Auxiliary Requests 1, 4, 9 on 20-06-2023
 - Auxiliary Requests 6-8: filed as Auxiliary Requests 4-6 on 23-10-2023
 - Auxiliary Requests 9-36: filed as Auxiliary Requests 2, 3, 5-8, 10-31 on 20-06-2023
 - Auxiliary Requests 37-40: filed as Auxiliary Requests 35-38 on 15-02-2024

The claims under consideration are annexed to this decision. No copy of Auxiliary Request 39 is annexed, as this request concerns deletion of figures 1, 16, and 17, and no formal copy was provided (see Auxiliary Request 37 of 15-02-2024).

Reasons for the decision

1 Admissibility of the opposition and intervention

The opposition is admissible because it meets all the requirements of Articles 99(1) and 100 EPC and Rules 3(1) and 76(1)(2) EPC.

The intervention is admissible because it meets the requirements of Article 105 EPC and Rule 89 EPC.

2 Admissibility of the ground of opposition under Article 100(b) EPC

The Proprietor requests the ground of opposition under Article 100(b) EPC not to be admitted into the proceedings, because it is not sufficiently substantiated.

The Opposition Division is, however, of the opinion that it is clear from the notice of opposition of Opponent 1 (see page 20) what the objection of insufficient disclosure consists in. In essence, Opponent 1 argues that the claimed subject-matter is not sufficiently disclosed over the whole scope of claim 1 due to the broad functional language used in the claim. The argument made by Opponent 1 can thus be understood without difficulty.

As set out in Guidelines F-III-1, an objection of insufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts. This is, however, a matter of substance, not admissibility. The Opposition Division is therefore of the opinion that the ground of opposition under Article 100(b) EPC is admissible.

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

Opponent 1 argues that claim 1 is not enabled over its whole scope as several functional features are used in the claim, without defining any relevant structure of the invention.

The Opposition Division, however, notes that the patent discloses several embodiments of an inserter configured to insert a portion of a glucose sensor into a subject, for advancing the on-body unit and the sharp to a distal position, and for retracting the sharp from the distal position. At least one way of engaging the gripping arms with recesses on the on-body unit is disclosed (inserter 3700). Whether a broad field is sufficiently exemplified by a limited number of examples depends on the case (Guidelines F-III, 1). In the present case, the Opposition Division sees no reason to doubt that the embodiments disclosed in the patent enable the skilled person to put the invention as claimed into practice over the whole scope of the claim. No reasons are provided why the skilled person would be unable to implement alternative means for implementing the claimed assembly, beyond the concrete example given in the patent. An objection of lack of sufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts (Guidelines F-III, 1); the Opposition Division is of the opinion that no such doubts have been substantiated. The use of functional features is not in itself a reason to conclude that there is insufficient disclosure (see also Guidelines F-IV, 6.5).

The ground of opposition of Article 100(b) EPC therefore does not prejudice maintenance of the patent as granted.

4 **Extension of subject-matter (Articles 100(c) and 76(1) EPC)**

4.1 Claim 1 as granted relates to a glucose monitoring assembly comprising an inserter and an on-body electronics unit. The inserter comprises, inter alia, a carrier having a plurality of gripping arms for detachably engaging recesses of the on-body electronics unit housing. The on-body electronics unit comprises a glucose sensor and wireless communication circuitry

According to the Proprietor, a general basis for claim 1 as granted is provided by claims 1, 3, 13, 14, 19, and 20 of the original application (published as WO 2011/119896). The Opposition Division, however, considers that said claims of the original application alone do not provide a basis for granted claim 1.

The apparatus according to original claims 1 and 13 comprises several features that are not part of the assembly according to granted claim 1, namely:

- a sheath defining a distal surface for placement on the skin of the subject;
- a sharp support extending through a portion of the device support (the device support corresponding to the carrier of granted claim 1);
- the device support comprising a first engagement member for releasably coupling the device support to the sharp support;
- a handle movable between a proximal position and a distal position relative to the sheath, and adapted to urge the device support and the sharp support from a proximal portion to a distal portion; and
- a driver for advancing the sharp support towards the proximal portion when the sharp support reaches the distal position.

Claim 1 as granted, on the other hand, requires features that have no basis in original claims 1, 3, 13, 14, 19, and 20, in particular:

- an on-body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon;
- a glucose sensor;
- on-body electronics coupled with the glucose sensor and disposed within the body-electronics unit housing, wherein the on-body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level.

It is thus necessary to also take into consideration the description and figures of the original application.

- 4.2 The claimed interaction between the gripping arms of the carrier and the recesses on the on-body electronics unit housing is disclosed in two embodiments: that of fig. 109-134 and that of fig. 135-136.

The Proprietor argues that fig. 30, 45, 79, 80, 98, and 108 also show gripping arms and that fig. 1, 16 and 17 show recesses on the on-body housing (122). The Opposition Division agrees that fig. 30, 45, 79, 80, 98, and 108 may show arms similar to arms 3762 and 3762' in fig. 122 and fig. 135-136, but notes that the claimed engagement of the arms with recesses on the on-body housing is not shown in the figures, nor described in the corresponding description.

The Opposition Division further agrees with Opponent 1 that the original drawings of the PCT application (submitted as D25 in the present proceedings) do not show recesses on the on-body housing in fig. 1, 16, and 17. The recesses shown in fig 1, 16, and 17 of WO 2011/119896 were introduced with replacement sheets filed at a date later than the filing date of the original application.

The claimed engagement of the gripping arms with recesses on the on-body electronics unit housing is thus disclosed only in the context of the embodiments of fig. 109-134 and of fig. 135-136. Paragraph [0258] discloses that the gripping arms serve to hold the on-body housing (322) in place; engagement of the recesses (3766) with the gripping arms (3762) maintains the proper height location of the on-body housing (322). Ribs (3768) or other projections on the interior surface of the sheath 3708 hold the gripping arms securely in place against the on body housing while the sheath is fully extended. When the medical device carrier (3730) advances along the sheath (3708) to reach the proximal position during use, the gripping arms (3762) are no longer supported by the sheath (3708) and the force of the adhesive skin patch (318) overcomes the retention force of the gripping arms (3762).

The interaction between sheath and gripping arms is thus functionally linked to the engagement between gripping arms and recesses on the on-body housing as claimed. Omission of the sheath, having ribs or other projections on an interior surface, thus involves an extension of subject-matter.

Furthermore, when the original application discloses recesses on the on-body housing, namely in the embodiments of fig. 109-134 and of 135-136, it discloses them in combination with engagement bosses (3764) on the gripping arms (see

paragraph [0258]). There is no disclosure of recesses on the on-body housing without there being engagement bosses on the gripping arms, nor is there any suggestion that the engagement bosses may be omitted.

The embodiment of fig. 109-134 further requires an adhesive skin patch (318), a spring (3746), a sharp carrier (3716), and carrier arms (3732). These features serve to retract the sharp to a retracted, proximal position after the sharp and the on-body housing have been advanced to the distal position. As explained in paragraph [0258], when the medical device carrier (3730) advances along the sheath (3708) to reach the proximal position, the gripping arms (3762) are no longer supported by the sheath and the force of the adhesive skin patch (318) overcomes the retention force of the gripping arms. The retraction of the device carrier is explained, for example, in paragraph [0261]: the carrier arms (3732) are not of sufficient rigidity or bias to counteract the bias of the spring (3746) in order to maintain the sharp carrier in the distal position without support from the sheath; accordingly, the spring (3746) urges the sharp carrier (3716) in the proximal direction thereby displacing the carrier arms (3732).

The sharp carrier (3716) and the carrier arms (3732) are thus functionally linked to the advancing the medical device carrier and the sharp in a distal direction and to the subsequent retraction of the sharp in a proximal direction. These features are also part of the inserter disclosed in its most general form in paragraphs [0007] and [0013] (corresponding to original claims 1 and 13), the sharp carrier 3716 corresponding to the sharp support, and the carrier arms (3732) corresponding to the first engagement member of the device support.

Omission of the sharp carrier and the carrier arms thus involves an extension of subject-matter.

Paragraphs [0007] and [0013] (as well as original claims 1, 13, 20) further require a handle movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position to insert the sharp into the skin of the subject. The embodiment of fig. 109-134, however, does not require a separate handle; rather the housing (3702) is alternatively referred to as handle (see paragraph [0264]) and is used as a handle to move both the device support and the sharp support towards the skin of the patient. While the housing of inserter 3700 acts as a handle, its function of urging both the sharp and the on body unit downwards, by a movement relative to the sheath, has been omitted from claim 1.

The claim specifies that the inserter is configured to advance the on body unit and the sharp from a proximal position to a distal position, but leaves it open by what mechanism the on body unit and the sharp are advanced. The original application, however, discloses only specific mechanisms of advancing the on body unit and the sharp, be by actuating the housing as in the inserter 3700 (see fig. 131-132) or by actuating a separate handle as in inserter 200 (see fig. 7-8), for example.

Omission of the movement of the housing relative to the sheath therefore involves an extension of subject-matter.

Claim 1 as granted further requires a plurality of recesses circumferentially disposed on the on body unit, the plurality of recesses comprising a first recess in a spaced relation to a second recess. That the recesses are circumferentially disposed is not disclosed in the description of the original application. The inserter 3700 is shown in fig. 126, for example, to have recesses on the circumference of the on board unit; this can also be understood from fig. 122, showing corresponding engagement bosses on the gripping arms. The inserter 3700' is shown in fig. 135 to comprise three recesses along the circumference of the on board unit.

Inserters 3700 and 3700' are thus shown in the figures to comprise three recesses disposed circumferentially on a disc-shaped on board unit. Moreover, the recesses are shown to be disposed on the circumference in a rotationally symmetric or equidistant manner.

Paragraph [0258] may provide a disclosure of one or more recesses due to the disclosure of one or more gripping arms ("medical device carrier 3700 further includes one or more housing gripping arms 3762 (e.g., three are depicted in FIGURE 96)"). However, the disposition of the recesses on the circumference of the on body unit is only shown in the figures, which depict a rotationally symmetric arrangement on a disc shaped on body unit.

Granted claim 1, on the other hand, allows the recesses to be disposed on the circumference in any conceivable arrangement. In the opinion of the Opposition Division, there is no direct and unambiguous disclosure in the original application for this feature. Paragraph [0258] discloses that the recesses are provided "on the side walls of the on body housing"; this is, however, not a disclosure of the recesses being circumferentially disposed on the on body housing (the side walls are not limited to the circumference of the on body housing). The Opposition Division therefore considers that omission of the circumferential disposition of the recesses as shown in the figures of inserter 3700 or 3700' involves an extension of subject-matter.

- 4.3 In summary, the Opposition Division considers that claim 1 as granted involves an extension of subject-matter in that it omits the sheath with ribs or projections, the sharp carrier, the carrier arms, engagement bosses on the gripping arms, the relative movement between housing and sheath, and the specific circumferential arrangement of recesses disclosed in the original application.
- 4.4 The Proprietor argues that the subject-matter of claim 1 is directly and unambiguously disclosed in the original application, and that the application as a whole has to be taken into account.

Reading the application as a whole, the skilled person would arrive in a direct and unambiguous way at the subject-matter and recognise that the features mentioned under point 4.3 above are not essential to the invention or presented as optional. According to the Proprietor, there is no requirement to start from a specific embodiment in the analysis of extension of subject-matter.

The Opposition Division cannot agree with this reasoning.

Even reading the original description sequentially from beginning to end as suggested by the Proprietor does not lead in a direct and unambiguous way to the subject-matter of granted claim 1. The original application discloses several embodiments of an inserter (see inserters 200, 300, 400, 2400, 2500, 2700, 3700, 3700') wherein many of the features of the individual inserters are described as optional. According to paragraphs [0152]-[0153], for example, the inserter may include components for advancing a sharp towards the skin of the subject, the sensor and on body electronics may be supported by a support structure, a driver may be provided for advancing the sharp and/or the analyte sensor/support structure towards the skin of the patient; in some embodiments, the force applied to the actuator drives the sharp and/or support structure between a retracted position and an advanced position; in some embodiments, the sensor and on body electronics is maintained in a retracted position prior to installation by contacting projections extending inwardly from a recess in the inserter; the inserter can also include one or more components for retracting the sharp, while allowing the analyte sensor and optional on body electronics to remain on the subject; the components for retracting the sharp can include a retractor, wherein the retractor and the actuator may be the same structure.

Some of these features are part of the assembly according to granted claim 1, while others are not. In order to derive the subject-matter of granted claim 1 from the description, a selection of features has to be made, with no pointer being present as to which features should be selected. The same applies to the specific embodiments. For example, some inserters (inserters 200, 2400) comprise a separate handle or actuator, while other inserters do not (inserters

300, 400, 2500, 2700, 3700, 3700'). The sheath may be described as optional in paragraph [0178] with reference to fig. 7 (inserter 200), whereas according to paragraph [0258] (inserter 3700) the sheath supports, and is thus functionally linked to, the gripping arms. The interaction of recesses on the on body unit with the gripping arms is only described in the context of inserter 3700 (see paragraph [0258]). In the opinion of the Opposition Division, there is thus no pointer to the specific combination of features set out in granted claim 1.

It is true that the original application discloses that features of individual embodiments may be combined with other embodiments. A generic statement to that effect in paragraph [0085], for example, does not however provide a direct and unambiguous pointer towards the claimed combination of features. Paragraph [0113] refers to fig. 1 and the inserter 200, but also indicates that the inserters 300, 400, 2400, 2500, 2700, 3700 may be used in the depicted system. Which features of which inserter may be combined with another inserter is, however, not derivable therefrom.

Paragraph [0161] refers to the embodiment of fig. 7, wherein the on body housing is supported within a recess of carriage 230. As an alternative to the recess, this passage discloses that the carriage may include projections which contact the on body housing and refers to fig. 122 and 135-136, i.e. inserter 3700/3700'. In the opinion of the Opposition Division, this is however not a direct and unambiguous indication that the projections of the inserter 3700/3700' may be incorporated into the inserter 200. Rather, paragraph [0161] merely states that other embodiments use projections, namely those of fig. 122 and 135-136. In these other embodiments, the projections are disclosed in combination with other functionally linked components of the inserter.

Similarly, paragraph [0227] indicates that spring hooks 2542 (see fig. 79-80) serve to support the on body housing when the inserter has not been fired and to release it when the on body housing has been attached to the skin of the user, and refers to fig. 122, 125, 135-140. This does not, however, allow for the conclusion to be drawn that the inserter 2500 comprises recesses on the on body housing, as no such recesses are indicated in the corresponding description or figures (see for example fig. 81-87). Like inserter 3700, inserter 2500 comprises carrier arms (in the form of latches 2538) that interact with a sheath (2512) to support and release the on body housing (see fig. 83-84); it can therefore not be derived from these passages that the carrier arms or the sheath are optional.

The Opposition Division therefore considers that only the inserters 3700 and 3700' are clearly disclosed to comprise gripping arms interacting with recesses on the on body housing.

The Proprietor argues that also the inserters shown in fig. 6, 24, 39, and 149 comprise such recesses.

The Opposition Division cannot agree. Figures 6, 24 and 39 may show gripping arms engaging the on body housing; it is, however, not possible to derive from these drawings whether the on body housing comprises recesses. Projections on the gripping arms could simply hold the on body housing on its bottom wall, without there being any recesses; and no recesses are mentioned in the corresponding description.

According to the Proprietor, fig. 149 shows two recesses on the mounting unit (3980) of the on body housing. The Opposition Division notes, however, that the figure shows three recesses on the mounting unit, and their purpose is not derivable from the figure, nor explained in the corresponding description (see paragraph [0272]).

The Opposition Division is furthermore not convinced by the Proprietor's argumentation that the features listed in paragraph 4.3 above are presented as optional in the original application.

With reference to paragraph [0178] the Proprietor argues that the sheath is optional ("an optional sheath 242 is positioned within housing 202"). This passage refers, however, to fig. 7 and inserter 200. This does not imply that the sheath of inserter 3700 is optional, too; the more so since there is a functional relationship between the sheath and the gripping arms of inserter 3700: according to paragraph [0258], when the medical device carrier 3730 advances along the sheath 3708 to reach the proximal position during use, the gripping arms 3762 are no longer supported by the sheath 3708 and the force of the adhesive skin patch 318 overcomes the retention force of the gripping arms 3762.

The statement in paragraph [0203] that the needle carrier and the carriage are spaced apart from the sheath likewise does not provide a basis to conclude that the sheath is optional in inserter 3700.

Paragraph [0258] mentions a retention force of the gripping arms, but this does not imply that the gripping arms provide a retention force on their own, without the presence of a sheath; according to the last sentence of paragraph [0258],

the retention force of the gripping arms is overcome when the gripping arms are no longer supported by the sheath. In other words, the sheath is necessary to provide the retention force.

Furthermore (see paragraph [0258]), ribs or projections on an interior surface of the sheath hold the gripping arms securely in place while the sheath is fully extended. A sheath having internal ribs and the carrier arms are thus functionally linked.

Regarding the sharp support, the Proprietor argues that the inserter is disclosed without limitations to a sharp support and refers to paragraphs [0148], [0152], [0153]. Furthermore, paragraph [0162] discloses that the needle support member 234 can be omitted. The sharp support is thus neither essential nor indispensable to the function of the invention.

Generic statements such as in paragraphs [0148] and [0152]-[0153], however, do not allow to conclude that the sharp support of inserter 3700 is optional, in particular since the sharp support (3716) is functionally interlinked with other components, e.g. the driver (3746), sheath (3708), and carrier arms (3732), see for example paragraph [0261] and fig. 127-128. Omission of the sharp support requires modifications to make up for the change.

According to paragraph [0162], the support member 234 can be omitted and needle hub 236 can be secured to the actuator 214 directly. Inserter 3700, however, does not comprise an actuator separate from the housing. It is thus not clear how this teaching should be applied to the inserter 3700.

The Opposition Division does not agree with the Proprietor that the carrier arms are not required by any independent claim as filed. Original claim 1 requires a first engagement member for coupling the device support to the sharp support, and original claim 20 requires the device support to include a feature adapted to engage the sharp support. Independent claim 13 may not explicitly require such engagement features, but the claim is directed at a method instead of an insertion apparatus or system. It can therefore not be concluded from claim 13 that the carrier arms of the inserter 3700 are optional or not functionally linked with other components of the inserter.

Regarding the engagement boss, the Proprietor argues that paragraph [0258] describes this feature as optional, and further refers to original claims 3 and 19. Paragraph [0258], however, describes the combination of engagement boss and recesses as optional, not the engagement boss alone ("In some embodiments, gripping arms 3762 are provided with engagement boss 3764 which are configured to engage with corresponding recesses 3766"). When the original application discloses recesses on the on-body housing, there are also

engagement bosses on the gripping arms (see inserters 3700, 3700'). Original claims 3 and 19 refer to movable arms engaging the device, not to movable arms engaging recesses on the device.

Regarding the relative movement between handle and sheath, the Proprietor refers to paragraph [0184] and argues that this feature is optional. While said paragraph states that "in some embodiments, handle 302 is advanced relative to sheath 342", this does not provide an indication how the inserter 3700 would operate without such relative movement.

- 4.5 The Opposition Division is therefore of the opinion that claim 1 as granted involves an extension of subject-matter (Articles 100(c) and 76(1) EPC).

5 **Auxiliary Request 1**

Claim 1 of Auxiliary Request 1 has been amended inter alia to require the plurality of recess to be "circumferentially and symmetrically disposed" on the on body housing.

- 5.1 Claim 1 leaves it open relative to what plane, axis or point the plurality of recesses is symmetric to. Furthermore, the kind of symmetry (e.g. rotational symmetry or reflectional symmetry about a plane or a point) is undefined. It is therefore unclear what symmetric disposition is intended to be covered by claim 1 as amended. Claim 1 therefore does not meet the requirements of Article 84 EPC.

Additionally, there is no direct and unambiguous disclosure in the original application of a general symmetric disposition of the recesses. The description does not mention any symmetry in the arrangement of the recesses, and while the figures (see for example fig. 135) show a rotationally symmetric arrangement of three recesses, a symmetric disposition defined as generally as in claim 1 is not derivable from them. Claim 1 therefore does not meet the requirements of Article 76(1) EPC.

- 5.2 The Proprietor refers to fig. 6, 24, 30, 45, 79, 80, 122, 126, 135, 136 and 149 as also showing circumferentially and symmetrically disposed recesses on the on body housing. Reading claim 1 with a mind willing to understand, one would realise that the claim refers to a rotationally symmetric arrangement of recesses. Furthermore, it would be clear to the skilled person that the symmetric arrangement of recesses shown in the figures fulfils the function disclosed in paragraph [0258] of maintaining proper height location of the on body housing. Claim 1 thus meets the requirements of both Article 84 and 76(1) EPC.

The Opposition Division cannot agree.

Claim 1 merely states that the recesses are circumferentially and symmetrically disposed on the on body housing. The recesses may thus be disposed on the circumference in, for example, either a rotationally symmetric or reflectional symmetric arrangement. The reference to the circumferential disposition does not necessarily mean that the recesses are arranged in a rotationally symmetric way. Nor is the on body housing required to be circular.

Paragraph [0258] mentions maintaining proper height location of the on body housing. However, if the skilled person understands from this passage and the figures that the symmetric arrangement of recesses shown in the figures serves to achieve this goal, it is also clear that not every symmetric arrangement can be said to maintain proper height location.

With respect to fig. 149, it is noted that the recesses shown on the mounting unit (3980) are not directly and unambiguously disclosed as recesses to be engaged by gripping arms.

The Opposition Division therefore considers claim 1 of Auxiliary Request 1 not to meet the requirements of Article 84 and 76(1) EPC.

6 **Auxiliary Request 2**

According to claim 1 of Auxiliary Request 2, the recesses are equidistantly spaced around the circumference of the on body electronics unit housing.

6.1 The Opposition Division is of the opinion that claim 1 is ambiguous due to the formulation used in the claim.

According to claim 1, the on body electronics unit housing comprises "the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, the recesses being equidistantly spaced around the circumference of the on body electronics unit housing" (emphasis added by the division). The underlined occurrence of the recesses can refer either to the plurality of recesses or to the first and second recess. It is thus ambiguous whether all recesses of the plurality of recesses are to be spaced equidistantly around the circumference or if only two of the recesses are required to be spaced equidistantly. In the latter case, the two recesses may, for example, be located on opposite points on the circumference of a circular on body housing, while the remaining recesses can be located on any points of the circumference.

Claim 1 therefore does not meet the requirements of Article 84 EPC.

Additionally, there is no direct and unambiguous disclosure of equidistantly spaced recesses on the on body housing. Figure 135, for example, may show three recesses arranged equidistantly on the on body housing, but this only in combination with a disc shaped on body housing. Claim 1, however, leaves the shape of the on body housing undefined. Non-circular on body housings are foreseen in the original application, see for example fig. 149, but there is no indication how recesses on non-circular housings should be distributed.

Claim 1 therefore does not meet the requirements of Article 76(1) EPC.

- 6.2 According to the Proprietor, the skilled person would understand from claim 1 that the plurality of recesses are spaced equidistantly. This is also clear from paragraph [0258], which discloses maintaining the proper height location. Furthermore, figure 149 discloses a square-shaped on body housing with equidistantly spaced recesses. Claim 1 thus meets the requirements of both Article 84 and 76(1) EPC.

The Opposition Division does not agree.

With respect to the spacing of the recesses, claim 1 can be read in two ways, both of which are technically sensible. The Opposition Division therefore sees no indication which interpretation should be followed.

In fig. 135, for example, the recesses are shown to be equidistantly spaced on the circumference of a circular on body housing. How recesses on an on body housing having a different shape (e.g. an oval) should be distributed is not evident. It is conceivable that the spacing for other shapes should also be equidistant, but the arrangement of recesses could also be equiangular. Both arrangements are the same for a circular on body housing, but may differ for other shapes.

Figure 149 shows a square shaped on body housing, but there is no indication what purpose the recesses serve or which of the recesses are intended for engagement with gripping arms (the Proprietor argues that fig. 149 shows two recesses for engaging the gripping arms, but the figure shows three recesses in total).

The Opposition Division therefore considers claim 1 of Auxiliary Request 2 not to meet the requirements of Article 84 and 76(1) EPC.

7 **Auxiliary Requests 3-40**

According to claim 1 of each of Auxiliary Requests 3-40, the plurality of recesses is circumferentially disposed on the on body housing. The reasoning under point 4.2, last four paragraphs, therefore applies to each of these requests.

Consequently, Auxiliary Requests 3-40 do not meet the requirements of Article 76(1) EPC.

Decision

European patent 3 766 408 is revoked on the ground of Article 100(c) EPC and in view of Article 76(1) EPC, taking account of the amendments made by the patent proprietor during opposition proceedings (Articles 101(2) and 101(3)(b) EPC).

Article 106
Decisions subject to appeal

- (1) An appeal shall lie from decisions of the Receiving Section, Examining Divisions, Opposition Divisions and the Legal Division. It shall have suspensive effect.
- (2) A decision which does not terminate proceedings as regards one of the parties can only be appealed together with the final decision, unless the decision allows a separate appeal.
- (3) The right to file an appeal against decisions relating to the apportionment or fixing of costs in opposition proceedings may be restricted in the Implementing Regulations.

Rule 97
Appeal against apportionment and fixing of costs

- (1) The apportionment of costs of opposition proceedings cannot be the sole subject of an appeal.
- (2) A decision fixing the amount of costs of opposition proceedings cannot be appealed unless the amount exceeds that of the fee for appeal.

Rule 98
Surrender or lapse of the patent

The decision of an Opposition Division may be appealed even if the European patent has been surrendered in all the designated Contracting States or has lapsed in all those States.

Article 107
Persons entitled to appeal and to be parties to appeal proceedings

Any party to proceedings adversely affected by a decision may appeal. Any other parties to the proceedings shall be parties to the appeal proceedings as of right.

Article 108
Time limit and form

Notice of appeal shall be filed, in accordance with the Implementing Regulations, at the European Patent Office within **two months** of notification of the decision. Notice of appeal shall not be deemed to have been filed until the fee for appeal has been paid. Within **four months** of notification of the decision, a statement setting out the grounds of appeal shall be filed in accordance with the Implementing Regulations.

Further information concerning the filing of an appeal

- (a) Notice of appeal can be filed in accordance with Rule 1 and Rule 2(1) EPC, by delivery by hand, by post, or by technical means of communication. The filing has to comply with the details and conditions and, where appropriate, any special formal or technical requirements laid down by the President of the European Patent Office (R. 99(3) EPC).
- (b) The addresses of the filing offices of the European Patent Office are as follows:

(i) European Patent Office D-80298 Munich Germany	(ii) European Patent Office Postbus 5818 NL-2280 HV Rijswijk (ZH) The Netherlands	(iii) European Patent Office D-10958 Berlin Germany
Fax: +49 89 2399-4465	Fax: +31 70 340-3016	Fax: +49 30 259 01-840

- (c) The notice of appeal must contain the name and address of the appellant in accordance with the provisions of Rule 41(2)(c) EPC, an indication of the decision impugned, and a request defining the subject of the appeal. In the statement of grounds of appeal the appellant shall indicate the reasons for setting aside the decision impugned, or the extent to which it is to be amended, and the facts and evidence on which the appeal is based (R. 99(1) and (2) EPC). The notice of appeal and any subsequent submissions stating the grounds for appeal must be signed (R. 50(3) EPC).
- (d) The fee for appeal is laid down in the Rules relating to Fees. The schedule of fees and expenses of the EPO or a reference to the current version is regularly published in the Official Journal of the European Patent Office under the heading "Guidance for the payment of fees, expenses and prices". Fee information is also published on the EPO website under www.epo.org/fees.



20195922.8

CONSOLIDATED LIST - KONSOLIDIERTE LISTE - LISTE RÉCAPITULATIVE**P:** Abbott Diabetes Care, Inc.**1:** Dexcom, Inc.**2:** Dexcom Deutschland GmbH

	CITATIONS – ENTGEGENHALTUNGEN - CITATIONS	P	1	2
D1	US 2004/0002682 A1		D1	
D2	US 5,390,671		D2	
D3	US 5,568,806		D3	
D4	US 5,586,553		D4	
D5	US 2009/0292185 A1		D5	
D6	US 2006/0020189 A1		D6	
D7	US 2007/0203407 A1		D7	
D8	US 2008/0097246 A1		D8	
D9	US 7,344,500 B2		D9	
D10	US 2009/0124979 A1		D10	
D11	US 2008/0269683 A1		D11	
D12	US 7,585,287		D12	
D13	US 6,602,268		D13	
D14	WO 2010/091005 A1		D14	
D15	WO 2009/016638 A1		D15	
D16	WO 2004/098684 A2		D16	
D17	WO 2008/115409 A1		D17	
D18	US 2008/0243051 A1		D18	
D19	Review article Klonoff D, Diabetes Techn. & Therap. Vol. 7, No. 5, 2005		D19	
D20	Review article De Block et al. Current Diabetes Reviews, 2008,4,159-168		D20	
D21	US 2007/0135774 A1			D21
D22	Copy of complaint from German infringement proceedings;			D22
D23	English translation of complaint from German infringement proceedings			D23
D24	Copy of official confirmation of service of German proceedings			D24
D25	Original drawings of PCT/US2011/029881 obtained from PATENTSCOPE		D25	
D26	US 60/587787		D26	
D27	US 6,560,471 B1		D27	
D28	WO 2011/025549 A1		D28	

into the skin of the user and the attachment of the housing unit 4020 to the skin of the user. In FIGURE 151, the cap 3704 is removed. In FIGURES 152-153, the housing unit 4020 is positioned in the housing support 3731, for example, by use of adhesive patch 4028. In FIGURE 154, the sharp carrier 3716 is advanced distally, thereby advancing the sensor hub 4022 distally and into engagement with the housing unit 4020. In FIGURE 155, the sharp carrier 3716 is released, thereby allowing the sharp carrier 3716 to move proximally. The inserter 3700 is removed, leaving the sensor hub 4022 coupled to the housing unit 4020, as illustrated in FIGURE 156.

[0208] In some embodiments, the housing unit 4020 and the adhesive patch 4028 are stored in a sealed compartment 4100 as shown in FIGURE 157. The compartment 4100 includes a lower cap portion 4104 and a cover portion 4102, manufactured from a flexible material such as metal foil or plastic. As shown in FIGURE 158, the lower cap portion 4104 stores the sterilized housing unit 4020 and adhesive patch 4028 therein until ready for use. In some embodiments, the adhesive patch 4028 includes adhesive on both sides.

[0209] In some embodiments, on body housing 4200 includes housing unit 4220 and sensor hub 4222 as illustrated in FIGURE 159. The sensor may be insert molded with mechanical contacts. The PCB in the housing unit 4220 may include leaf spring contacts 4230. The sensor hub 4222 may be mechanically attached to the housing unit 4220, e.g., the electrical contacts may function as mechanical snaps. Sealing may be provided by an elastomeric gasket. The housing unit 4220 may be macromelt or injection molded.

[0210] In some embodiments, on body housing 4300 includes housing unit 4320 and sensor hub 4322 as illustrated in FIGURE 160. The sensor may have insert molded contacts. The PCB in housing unit 4320 may include exposed pads. Mechanical attachment of the housing unit and sensor hub may be accomplished by molded snaps. The needle guide may be injection molded or overmolded macromelt of TPE (thermoplastic elastomer). The housing unit 4320 may be macromelt or injection molded.

[0211] In some embodiments, on body housing 4400 includes housing unit 4420 and sensor hub 4422 as illustrated in FIGURE 161. The sensor may have exposed pads on the flag or contact portion of the sensor. The PCB in housing unit 4420 may include a SMT ZIF connector, or similar 4430. Mechanical attachment of the housing unit and sensor hub may be accomplished by molded snaps. The needle guide may be injection molded plastic with elastomer overmold. The housing unit 4320 may be macromelt overmold.

[0212] In some embodiments, a clamshell type arrangement 4500 is provided which includes a needle guide 4550 having a living hinge arrangement 4552. The sensor may include bent metal contacts that are inserted after molding. The PCB may include PCB pads. The mechanical attachment is performed by adhesive of me-

chanical snap to PCB. The transponder housing, not shown, may be injection molded, UV or ultrasonic bonded.

[0213] In some embodiments, on body housing 4600 includes housing unit 4620 and sensor hub 4622 as illustrated in FIGURE 163. The sensor 14 may have exposed pads on the flag or contact portion of the sensor. The PCB in housing unit 4620 may include concentric exposed pads 4690. Mechanical attachment of the housing unit and sensor hub may be accomplished by molded snaps or PSA. The needle guide may be injection molded plastic with elastomer overmold. The housing unit 4620 may be macromelt overmold.

[0214] In some embodiments, on body housing 4700 includes housing unit 4720 and sensor hub 4722 as illustrated in FIGURE 164. The sensor may have exposed pads on the flag and may also include a compressed anisotropic zebra, conductive elastomeric or similar. The PCB in housing unit 4720 may include exposed pads. Mechanical attachment of the housing unit and sensor hub may be accomplished by snaps. The needle guide may overmold macromelt or TPE. The housing unit 4720 may be macromelt overmold.

[0215] It is understood that the subject matter described herein is not limited to particular embodiments described, as such may, of course, vary. It is also understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present subject matter is limited only by the appended claims.

Claims

1. A glucose monitoring assembly, the assembly comprising:

(1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:

an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);

a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');

(2) an on body electronics unit (1100), comprising:

the on body electronics unit housing comprising the plurality of recesses circumfer-

- entially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess; the glucose sensor; and
on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
- wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,
- wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and
- wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
 3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
 4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
 5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
 6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
 7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
 8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
 9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
 10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
 11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
 12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
 13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
 14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
 15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed

within the first interior space.

16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722),
 wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48),
 wherein the distal sensor portion is configured to sense a glucose level of the subject,
 wherein the proximal sensor portion is engaged with the sensor hub, and
 wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.
19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin

surface of the subject.

Patentansprüche

1. Glucoseüberwachungsanordnung, wobei die Anordnung umfasst:

(1) einen Einführer (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), umfassend:

ein Einführergehäuse (202, 302, 402, 2402, 2502, 2702, 3702);

eine Lanzette (224, 324, 424, 2404, 2550), wobei die Lanzette ausgestaltet ist, um einen Anteil eines Glucosesensors (14) in ein Subjekt einzuführen; und

einen Träger (230, 330, 430, 2730, 3730), der abnehmbar mit einer Vielzahl von Aussparungen (3766, 3766') eines am Körper getragenen Elektronikeinheitgehäuses (122, 322, 3800, 4200) in Eingriff ist, wobei der Träger (230, 330, 430, 2730, 3730) eine Vielzahl von Greifarmen (3762, 3762') umfasst;

(2) eine am Körper getragene Elektronikeinheit (1100), umfassend:

das am Körper getragene Elektronikeinheitgehäuse, umfassend die Vielzahl von Aussparungen, die im Umfang darauf angeordnet sind, wobei die Vielzahl der Aussparungen eine erste Aussparung in einer beabstandeten Beziehung zu einer zweiten Aussparung umfasst;

den Glucosesensor; und

am Körper getragene Elektronik, die mit dem Glucosesensor gekoppelt ist, wobei die am Körper getragene Elektronik innerhalb des am Körper getragenen Elektronikeinheitgehäuses angeordnet ist, und wobei die am Körper getragene Elektronik einen Prozessor, Speicher, eine Energieversorgung und drahtlose Kommunikationsschaltung(en) einschließt, die ausgestaltet ist/sind, um drahtlos Daten zu kommunizieren, die einen Glucosespiegel angeben;

wobei der Einführer ausgestaltet ist, um die am Körper getragene Elektronikeinheit und die Lanzette aus einer proximalen Position, die vollständig innerhalb des Einführers liegt, zu einer distalen Position vorzuschieben, wobei jeder Greifarm von der Vielzahl der Greifarme (3762, 3762') ausgestaltet ist, um in Eingriff mit einer entspre-

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - ~~a sheath defining a distal surface for placement on the skin of the subject;~~
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; ~~and~~
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'); ~~and~~
 - a sharp support adapted to support the sharp extending through a portion of the carrier, wherein the carrier includes at least one feature adapted to operatively engage the sharp support;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially and symmetrically disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
 - wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) such that the inserter is configured to advance the on body electronics unit, the sharp support, and the sharp from a proximal position entirely within the inserter to a distal position,
 - wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position;

wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position; and

wherein the inserter is further configured to retract the sharp support and the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
- ~~5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~
- ~~6-5. The glucose monitoring assembly of claim 51, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.~~
- ~~7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses~~

~~(3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~

~~8.6.~~ The glucose monitoring assembly of any preceding claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').

~~9.7.~~ The glucose monitoring assembly of any preceding claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.

~~10.8.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

~~11.9.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~12.10.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~13.11.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~14.12.~~ The glucose monitoring assembly of claim 1123, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~15.13.~~ The glucose monitoring assembly of claim 1123 or 1234, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~16.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end

~~configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~

~~17.14.~~ The glucose monitoring assembly of claim ~~1356~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18.15.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19.16.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~ The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21.17.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22.18.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - ~~a sheath defining a distal surface for placement on the skin of the subject;~~
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; ~~and~~
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'); ~~and~~
 - a sharp support adapted to support the sharp extending through a portion of the carrier, wherein the carrier includes at least one feature adapted to operatively engage the sharp support;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, the recesses being equidistantly spaced around the circumference of the on body electronics unit housing;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
 - wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) such that the inserter is configured to advance the on body electronics unit, the sharp support, and the sharp from a proximal position entirely within the inserter to a distal position,
 - wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position;

wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position; and

wherein the inserter is further configured to retract the sharp support and the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
- ~~5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~
- ~~6-5. The glucose monitoring assembly of claim 51, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.~~
- ~~7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses~~

~~(3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~

8.6. The glucose monitoring assembly of any preceding claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').

9.7. The glucose monitoring assembly of any preceding claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.

10.8. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11.9. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12.10. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

13.11. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

14.12. The glucose monitoring assembly of claim 1123, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

15.13. The glucose monitoring assembly of claim 1123 or 1234, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

16. ~~The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end~~

~~configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~

~~17.14.~~ The glucose monitoring assembly of claim ~~1356~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18.15.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19.16.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~ The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21.17.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22.18.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - a sheath defining a distal surface for placement on the skin of the subject;
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into thea subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, ~~wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
- ~~20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).~~
- ~~21.~~20. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
- ~~22.~~21. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - a sharp support adapted to support the sharp extending through a portion of the carrier;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit, the sharp support, and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp support and the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the

subject,

wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
- ~~7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~
- ~~8-7.~~ The glucose monitoring assembly of any preceding claim-7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
- ~~9-8.~~ The glucose monitoring assembly of any preceding claim-7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
- ~~10-9.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

~~41.10.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~42.11.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~43.12.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~44.13.~~ The glucose monitoring assembly of claim ~~1213~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~45.14.~~ The glucose monitoring assembly of claim ~~1213~~ or ~~1314~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~46.15.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~47.16.~~ The glucose monitoring assembly of claim ~~1516~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~48.17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722),

wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48),
wherein the distal sensor portion is configured to sense a glucose level of the subject,
wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-19.~~ The glucose monitoring assembly of claims 1 to ~~1445~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-20.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-21.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sheath defining a distal surface for placement on the skin of the subject;
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into thea subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'); and
 - a sharp support adapted to support the sharp extending through a portion of the carrier;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit, the sharp support, and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position; and

wherein the inserter is further configured to retract the sharp support and the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
- ~~7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~
- 8.7. The glucose monitoring assembly of any preceding claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
- 9.8. The glucose monitoring assembly of any preceding claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.

~~10.9.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

~~11.10.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~12.11.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~13.12.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~14.13.~~ The glucose monitoring assembly of claim ~~12~~3, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~15.14.~~ The glucose monitoring assembly of claim ~~12~~3 or ~~13~~4, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~16.15.~~ The glucose monitoring assembly of any preceding claim, ~~wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~

~~17.16.~~ The glucose monitoring assembly of claim ~~15~~6, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~ The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on-body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-19.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-20.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - a driver for retracting the sharp;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp by the driver from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the ~~inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700')~~ further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) is disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), and wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sheath defining a distal surface for placement on the skin of the subject;
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into thea subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'); and
 - a sharp support adapted to support the sharp extending through a portion of the carrier, wherein the carrier includes carrier arms for releasably coupling the carrier to the sharp support;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
- wherein the inserter is configured to advance the on body electronics unit, the sharp support, and the sharp from a proximal position entirely within the inserter to a distal position,
- wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,
- wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position; and

wherein the inserter is further configured to retract the sharp support and the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
- ~~7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~
- ~~8.7. The glucose monitoring assembly of any preceding claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').~~
- ~~9.8. The glucose monitoring assembly of any preceding claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.~~

~~40-9.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

~~41-10.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~42-11.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~43-12.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~44-13.~~ The glucose monitoring assembly of claim ~~123~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~45-14.~~ The glucose monitoring assembly of claim ~~123~~ or ~~134~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~46-15.~~ The glucose monitoring assembly of any preceding claim, ~~wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~

~~47-16.~~ The glucose monitoring assembly of claim ~~156~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in

response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18.~~17. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19.~~18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~ The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21.~~19. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22.~~20. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - a sheath defining a distal surface for placement on the skin of the subject;
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) movable relative to the sheath;
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into thea subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, ~~wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the

subject,

wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
- ~~20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).~~
- ~~21.~~20. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
- ~~22.~~21. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a device carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446,

- 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
 14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
 15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
 16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
 17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
 18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sheath defining a distal surface for placement on the skin of the subject;
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into thea subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'); and
 - a sharp support adapted to support the sharp extending through a portion of the carrier, wherein the carrier includes at least one feature adapted to operatively engage the sharp support;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
- wherein the inserter is configured to advance the on body electronics unit, the sharp support, and the sharp from a proximal position entirely within the inserter to a distal position,
- wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,
- wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position; and

wherein the inserter is further configured to retract the sharp support and the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
- ~~7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~
- ~~8.7. The glucose monitoring assembly of any preceding claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').~~
- ~~9.8. The glucose monitoring assembly of any preceding claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.~~

~~40.9.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

~~41.10.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~42.11.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~43.12.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~44.13.~~ The glucose monitoring assembly of claim ~~123~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~45.14.~~ The glucose monitoring assembly of claim ~~123~~ or ~~134~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~46.15.~~ The glucose monitoring assembly of any preceding claim, ~~wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~

~~47.16.~~ The glucose monitoring assembly of claim ~~156~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in

response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18.~~17. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19.~~18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~ The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21.~~19. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22.~~20. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of movable gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each movable gripping arm of the plurality of movable gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and wherein the movable gripping arms displace radially outwardly to release the on body electronics unit housing. and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of movable gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of movable gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of movable gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of movable gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding movable gripping arm of the plurality of movable gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each movable gripping arm of the plurality of movable gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the movable gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200);
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
 - wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,
 - wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and
 - wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
- ~~11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).~~

~~42-11.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~43-12.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~44-13.~~ The glucose monitoring assembly of claim ~~12~~~~13~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~45-14.~~ The glucose monitoring assembly of claim ~~12~~~~13~~ or ~~13~~~~14~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~46-15.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~47-16.~~ The glucose monitoring assembly of claim ~~15~~~~16~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~48-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the

subject,
wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-19.~~ The glucose monitoring assembly of claims 1 to ~~1415~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-20.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-21.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') provided on side walls of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
- ~~11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).~~
- ~~12.~~11. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446,

2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~13-12.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~14-13.~~ The glucose monitoring assembly of claim ~~12~~~~13~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~15-14.~~ The glucose monitoring assembly of claim ~~12~~~~13~~ or ~~13~~~~14~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~16-15.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~17-16.~~ The glucose monitoring assembly of claim ~~15~~~~16~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-19.~~ The glucose monitoring assembly of claims 1 to ~~1415~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-20.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-21.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein ~~each recess of the~~ plurality of recesses (3766, 3766') is disposed on ~~a~~ side walls of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446,

- 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
 14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
 15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
 16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
 17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
 18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446,

2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') for maintaining a sterile environment for the on body electronics unit and the sharp housed therein.
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446,

- 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
 14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
 15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
 16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
 17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
 18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit housing comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics unit housing.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'), wherein the gripping arms are movable to release the on body electronics unit housing;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'), wherein the gripping arms engage radially inwardly on the on body electronics unit housing;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position; and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
- ~~4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.~~
- ~~5.4.~~ The glucose monitoring assembly of any of claims 1-~~34~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
- ~~6.5.~~ The glucose monitoring assembly of claim ~~45~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
- ~~7.6.~~ The glucose monitoring assembly of any of claims 1-~~56~~, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
- ~~8.7.~~ The glucose monitoring assembly of claim ~~67~~, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
- ~~9.8.~~ The glucose monitoring assembly of claim ~~67~~ or ~~78~~, wherein the engagement boss (3764, 3764') comprises a conical shape.
- ~~10.9.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
- ~~11.10.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~42-11.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~43-12.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~44-13.~~ The glucose monitoring assembly of claim ~~12~~~~13~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~45-14.~~ The glucose monitoring assembly of claim ~~12~~~~13~~ or ~~13~~~~14~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~46-15.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~47-16.~~ The glucose monitoring assembly of claim ~~15~~~~16~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~48-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the

subject,
wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-19.~~ The glucose monitoring assembly of claims 1 to ~~1415~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-20.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-21.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position;

wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position; and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

~~2.~~ The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

~~3.2.~~ The glucose monitoring assembly of claim 1 ~~or 2~~, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

~~4.~~ The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.

~~5.3.~~ The glucose monitoring assembly of ~~any of claims 1 or 2-4~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.

~~6.4.~~ The glucose monitoring assembly of claim ~~35~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.

~~7.5.~~ The glucose monitoring assembly of any of claims 1-~~46~~, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.

~~8.6.~~ The glucose monitoring assembly of claim ~~57~~, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').

~~9.7.~~ The glucose monitoring assembly of claim ~~57~~ or ~~68~~, wherein the engagement boss (3764, 3764') comprises a conical shape.

~~10.8.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

~~41-9.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~42-10.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~43-11.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~44-12.~~ The glucose monitoring assembly of claim ~~11~~~~13~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~45-13.~~ The glucose monitoring assembly of claim ~~11~~~~13~~ or ~~12~~~~14~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~46-14.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~47-15.~~ The glucose monitoring assembly of claim ~~14~~~~16~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-16.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-18.~~ The glucose monitoring assembly of claims 1 to ~~13-15~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-19.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-20.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss ~~is~~ configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
- ~~7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~
- ~~8.7.~~ The glucose monitoring assembly of any preceding claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
- ~~9.8.~~ The glucose monitoring assembly of any preceding claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
- ~~10.9.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
- ~~11.10.~~ The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~12-11.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

~~13-12.~~ The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~14-13.~~ The glucose monitoring assembly of claim ~~1213~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~15-14.~~ The glucose monitoring assembly of claim ~~1213~~ or ~~1314~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~16-15.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~17-16.~~ The glucose monitoring assembly of claim ~~1516~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-19.~~ The glucose monitoring assembly of claims 1 to ~~1415~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-20.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-21.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'), wherein the plurality of gripping arms comprises three gripping arms;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, ~~and~~

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter;

further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject;

wherein the securing force of the adhesive portion is configured to overcome the retention force of the gripping arms.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.
19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
- ~~22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.~~

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, ~~and~~

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter; and

wherein the inserter includes an actuator and wherein depression of the actuator causes the advancement from the proximal position to the distal position.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the

subject,

wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, ~~and~~

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter; and

wherein the inserter is configured to activate the on body electronics.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of a subject;
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
 - wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,
 - wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and
 - wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
- ~~16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~
- ~~17.~~ 16. The glucose monitoring assembly of any preceding claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~ The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-19.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-20.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sheath defining a distal surface for placement on the skin of a subject, the sheath having at least one biased retention feature;
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into thea subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
 - wherein the inserter housing is configured to advance distally relative to the sheath, wherein advancing the inserter housing distally comprises applying a minimum force to overcome the at least one biased retention feature to allow distal movement of the inserter housing relative to the sheath; and
 - wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position;
 - wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and
 - wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
- ~~16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~
- ~~17.~~ 16. The glucose monitoring assembly of any preceding claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of the minimum force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~ ~~The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).~~

~~21-19.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-20.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700');
 - wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
 - wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,
 - wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and
 - wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
- ~~13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').~~
- ~~14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.~~
- ~~15-13.~~ The glucose monitoring assembly of any preceding claim ~~13 or 14~~, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
- ~~16-14.~~ The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
- ~~17-15.~~ The glucose monitoring assembly of claim ~~14~~16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-16.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-18.~~ The glucose monitoring assembly of claims 1 to ~~13-15~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-19.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-20.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position; and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.~~

~~13.~~12. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~14.~~13. The glucose monitoring assembly of claim ~~12~~13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~15.~~14. The glucose monitoring assembly of claim ~~12~~13 or ~~13~~14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~16.~~15. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~17.~~16. The glucose monitoring assembly of claim ~~15~~16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-19.~~ The glucose monitoring assembly of claims 1 to ~~1415~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-20.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-21.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position; and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter, while allowing the on body electronics unit to remain on the subject.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.~~

~~13.~~ 12. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~14.~~ 13. The glucose monitoring assembly of claim ~~12~~13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~15.~~ 14. The glucose monitoring assembly of claim ~~12~~13 or ~~13~~14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~16.~~ 15. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~17.~~ 16. The glucose monitoring assembly of claim ~~15~~16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-19.~~ The glucose monitoring assembly of claims 1 to ~~1415~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-20.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-21.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position;

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter; and

wherein the driver is configured to automatically withdraw the sharp without further user interaction after actuation of insertion.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

~~12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.~~

~~13.~~12. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

~~14.~~13. The glucose monitoring assembly of claim ~~12~~13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

~~15.~~14. The glucose monitoring assembly of claim ~~12~~13 or ~~13~~14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

~~16.~~15. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~17.~~16. The glucose monitoring assembly of claim ~~15~~16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18-17.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19-18.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20-19.~~ The glucose monitoring assembly of claims 1 to ~~1415~~, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21-20.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22-21.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position;

wherein the sharp extends longitudinally within the inserter and the portion of the glucose sensor that is inserted into the subject is substantially aligned with the longitudinal axis of the inserter and substantially perpendicular to the skin surface prior to insertion; and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the

subject,

wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position;

wherein the sensor is configured to bend such that it is positioned in two substantially perpendicular, intersecting planes; and

wherein the portion of the glucose sensor that is inserted into the subject is substantially vertically aligned with the longitudinal axis of the inserter and substantially perpendicular to the skin surface of the subject prior to insertion; and

wherein a contact portion is oriented in a substantially horizontal configuration and in electrical contact with the on body electronics; and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.
19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,
wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,
wherein the portion of the glucose sensor is positioned within the sharp and the sharp has a substantially U, C, or V shaped profile; and
wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the

subject,

wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.
22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

wherein the on body electronics comprises an aperture and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics; and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the

subject,
wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~19. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21.~~20. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22.~~21. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

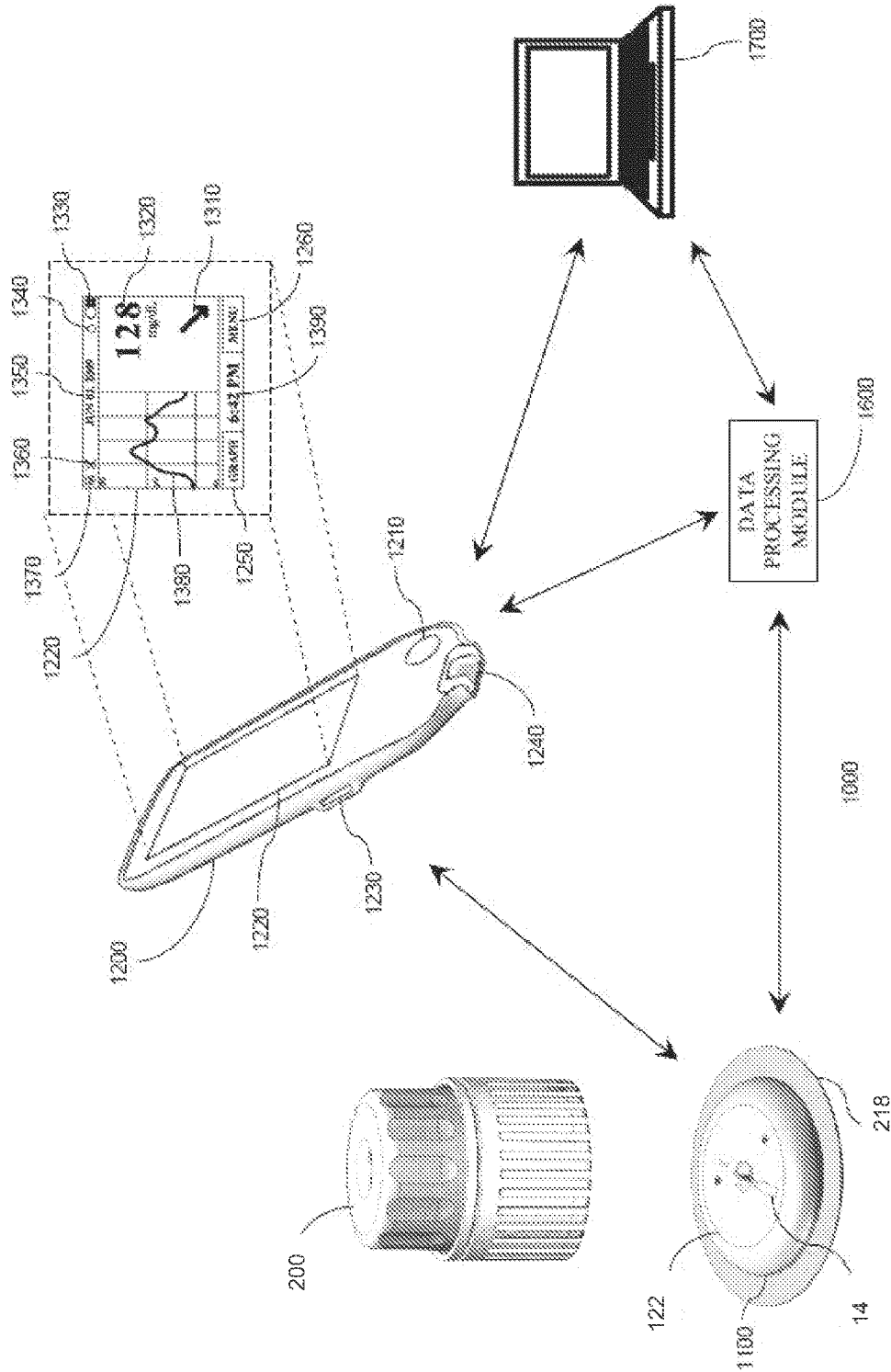


FIG.1

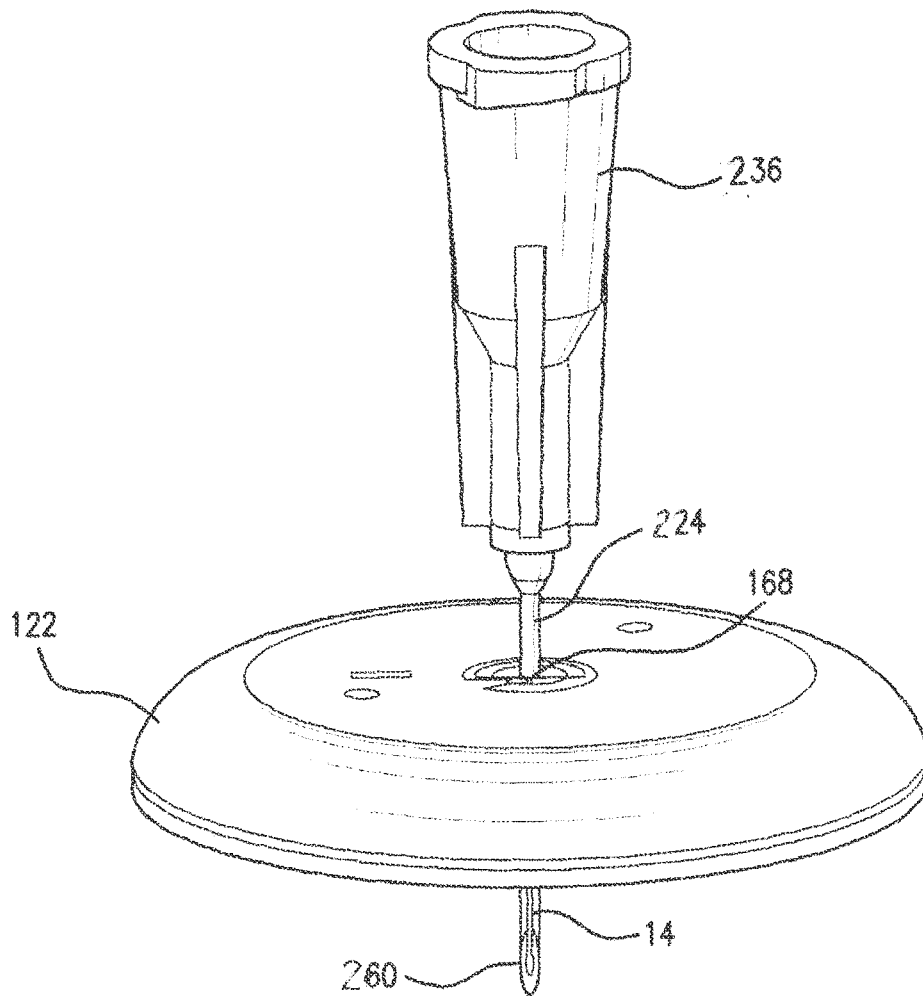


FIG. 16

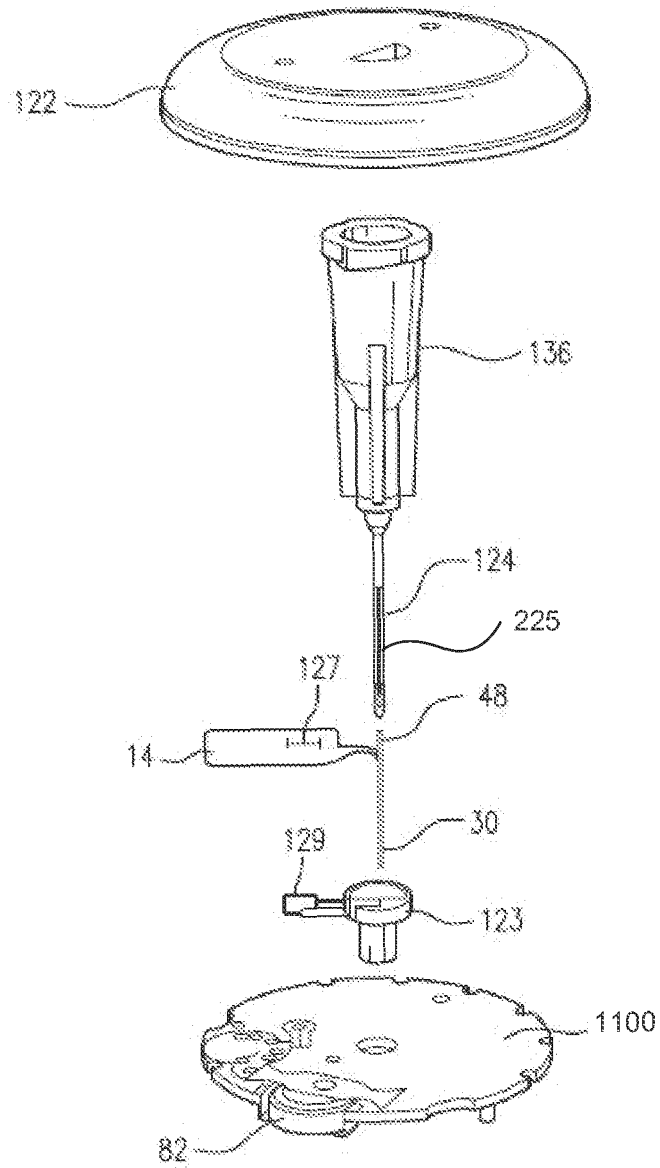
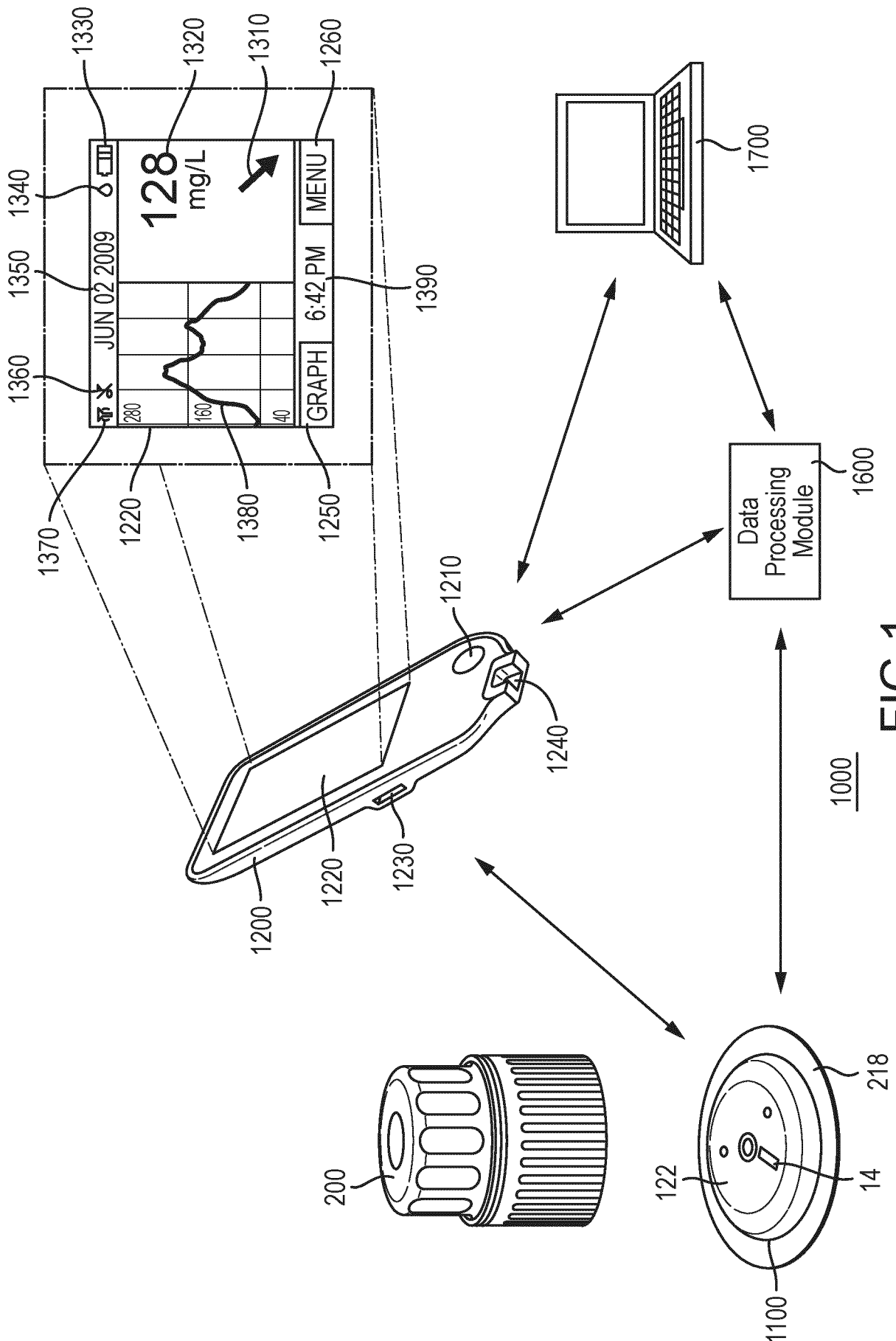


FIG. 17



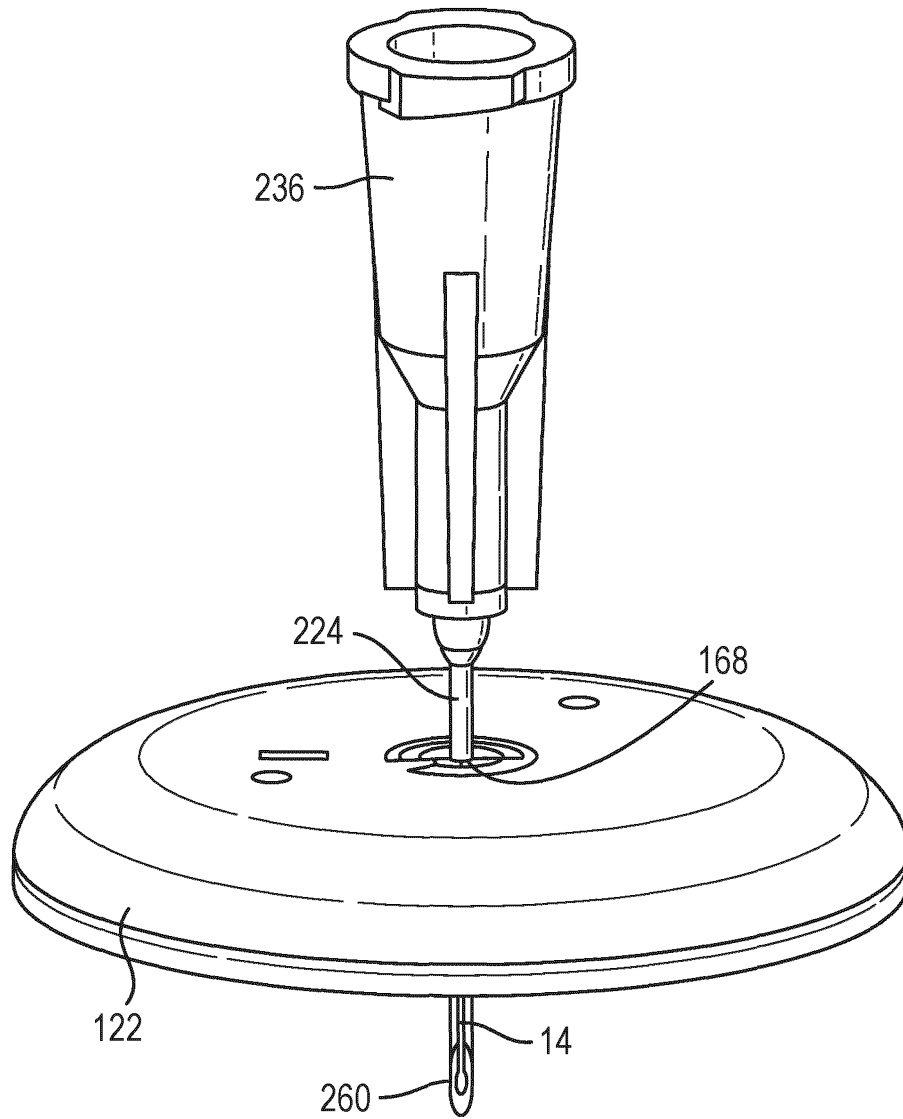


FIG. 16

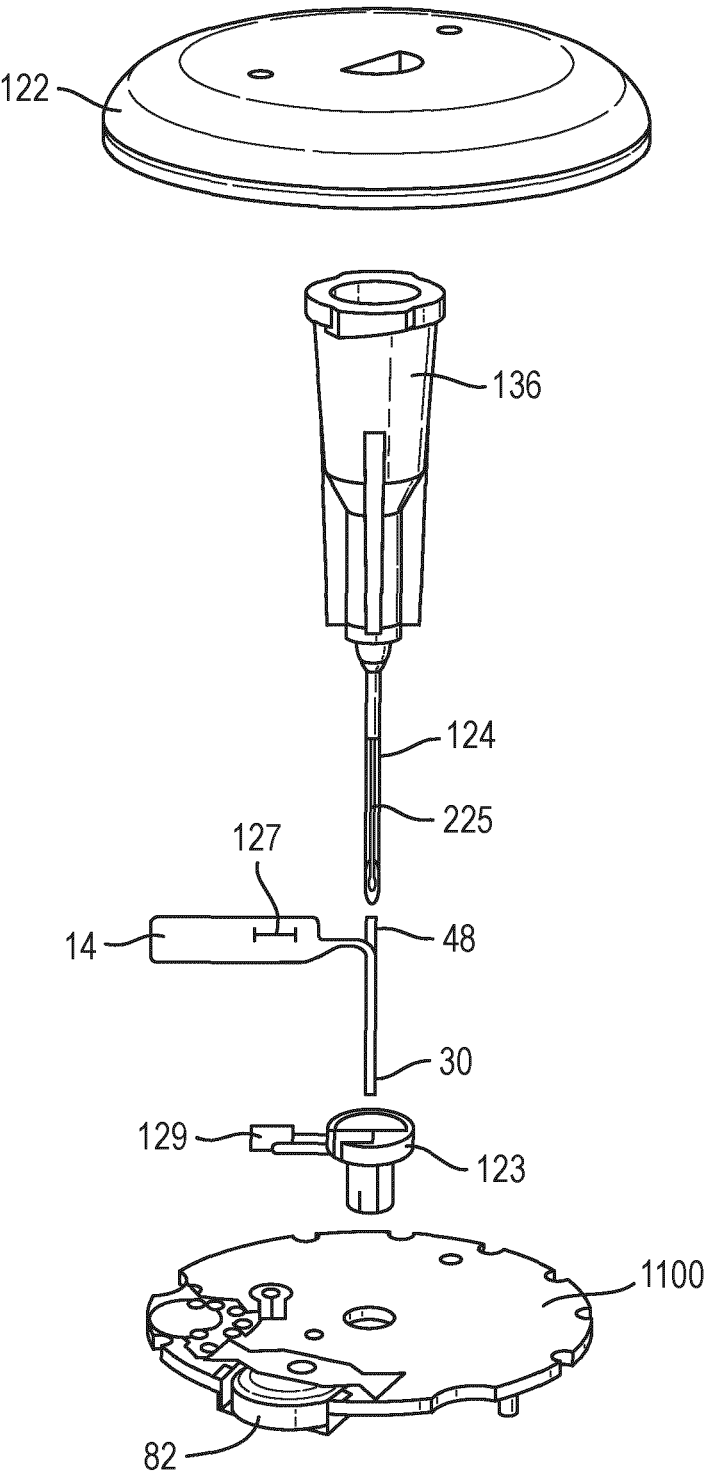


FIG. 17

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; and
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762');
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.
2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.

4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
6. The glucose monitoring assembly of claim 5, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.
7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.
8. The glucose monitoring assembly of claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').
9. The glucose monitoring assembly of claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.
10. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.
11. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).
12. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446,

- 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.
13. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').
 14. The glucose monitoring assembly of claim 13, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.
 15. The glucose monitoring assembly of claim 13 or 14, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.
 16. The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
 17. The glucose monitoring assembly of claim 16, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).
 18. The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

19. The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.
20. The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).
- ~~21. The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.~~
- ~~22.~~21. The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.



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Application No. / Patent No. 20 195 922.8 - 1122 / 3 766 408 / 01	Ref. 244303 r28/aml	Date 08.05.2024
Proprietor Abbott Diabetes Care, Inc.		

Provision of a copy of the minutes in accordance with Rule 124(4) EPC

The attached copy of the minutes of the oral proceedings is sent to you in accordance with Rule 124(4) EPC.



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Enclosure(s): Copy of the minutes (Form 2309)

Application No.:

20 195 922.8

Patent No.:

EP-B-3 766 408

Minutes of the oral proceedings before the OPPOSITION DIVISION

The proceedings were public.

Proceedings opened on 15.04.2024 at 09:04 hours

Present as members of the opposition division:

Chairman:	Knüpling, Moritz
1st member:	Kaden, Malte
2nd member:	Trattner, Barbara
Minute writer:	Trattner, Barbara

Present as or for the party or parties:

- For the Proprietor(s): Abbott Diabetes Care, Inc.
Ms. Dr. Catherine L Booth, Ms. Caroline Warren and Mr Leonard Wright as representatives of the proprietor
- For the Opponent 1: Dexcom, Inc.
Mr. Dr. Mark Jones as representative
- For the Opponent 2: Dexcom Deutschland GmbH
Ms. Anne Katrin Schön and Mr. Dr. Peter Klusmann as representatives

The identity of the person/s (as well as, if applicable, that of the witness or witnesses) and, where necessary, the authorisation to represent/authority to act were checked.

Essentials of the oral proceedings and relevant statements of the parties:

The chairman opened the oral proceedings at 09:04.

Contact details between the Opposition Division (**OD**) and the parties were exchanged. The Proprietor (**PR**) and the Opponents (**OP1** and **OP2**) confirmed the receipt of the OD's contact details.

The chairman informed the parties and the public that the recording of these oral proceedings was not allowed.

OP1 and OP2 confirmed that they requested revocation of the patent in full. PR indicated that they request maintenance of the patent in full or based on any one of auxiliary requests (AUX) 1-38.

MAIN REQUEST

Discussion regarding compliance with regard to Article 100(b) EPC

The chairman invited the discussion of Article 83 EPC of the main request.

The PR indicated that they relied on their arguments provided during the written procedure and that they followed the preliminary opinion of the OD as expressed in the Summons to attend oral proceedings.

OP1 and OP2 also rested on their arguments of the written submissions.

The chairman pronounced the intermediate conclusion that the requirements of Article 83 EPC were met.

Discussion regarding compliance with regard to Article 100(c) EPC

The chairman invited discussion on Article 100(c) EPC and summarised the division's preliminary opinion as expressed in the Summons to attend oral proceedings.

The **PR** started their argumentation by outlining the concept of the gold standard. They argued that the whole application should be read in its context and that rather than looking only at the embodiment of the inserter 3700 and 3700', one should look at the many other references to inserters in the entire application as filed. The earlier application as a whole disclosed in their view in a great level of generality the concept of how the on-body unit (OBU) is retained and advanced. In this context paragraph [0085] of the earlier application was cited to emphasise that discrete components may be separated from embodiments and combined or incorporated in other embodiments. According to the PR, the general idea of an OBU with sensor electronics and a sharp as well as an inserter was outlined in paragraphs [0087], [0091], [0094] and [0112] of the

earlier application. In their view, the inserter of figure 1 represented a general inserter and it was emphasised that in their view any inserter could be used for any OBU. Further reference was made to paragraphs [0138], [0141] and [0148] of the earlier application which outlined the specifics of the sensors and the general teaching of the insertion assembly.

According to the PR, the key parts of system related to the sharp, the inserter and the sensor, while the other features were optional. In this regard, reference was made to paragraph [0152] of the earlier application which in their view outlined that the sharp advancer is optional and to paragraph [0153] of the earlier application, outlining that the driver was optional. Then, reference was made to the inserter 200 as depicted by figure 1 and in paragraphs [0156], [0160]-[0162]. With regard to paragraph [0161] it was emphasised that figure 7 also illustrated inserter 200 and provided in the PR's view an explicit cross-reference to include the arms of inserter 3700 into the inserter 200, by referring to the carriage including projections which contact and/or advance the on body housing and a reference to figures 122 and 135-136. With regard to paragraph [0178] it was argued that the sheath for the inserter 200 was optional. It was according to the PR neither essential nor inextricably linked to the remaining features of the embodiment. The PR continued by outlining the embodiment of inserter 300 which showed the arms, by referring to paragraphs [0183] and [0184] onwards as well as figure 30. With regard to paragraph [0184] of the earlier application the PR emphasised that in their view the advancement of the housing relative to the sheath was optional.

Further reference was made to the embodiment of inserter 400 and figure 45 as well as to paragraph [0203], with regard to which the PR argued that the contact of sheath and arms was non-essential in their view. The PR further cited paragraphs [0222] and [0227] in combination with figures 79 and 80, emphasising that latches of the carrier were optional, but that it was a spring hook which provided support. The PR further stressed that this passage provided another explicit cross-reference to the embodiment with arms by referring to figures 122, 125 and 135-140.

The PR continued their argumentation by outlining the embodiment of inserter 2700 and by referring to paragraph [0240] of the earlier application and they pointed out that in their view it was either the ribs of the sheath or a spring which introduced a natural bias that prevented the OBU from falling out of the inserter.

Further reference was made to figures 109-122 in context of paragraphs [0249] and [0250] of the earlier application. It was pointed out that paragraph [0252] again provided in the PR's view an explicit cross-reference to the embodiment with arms by referring to figure 122 onwards. In the PR's view this passage also demonstrated that the sheath was an optional feature, as the sheath holds the arms but when the arms are no longer supported they have their own retention force.

The PR then referred to paragraph [0258] of the earlier application which introduces the recesses and the sharp support. Paragraph [0227] of the earlier application in their view

explicitly adds the recesses to the inserter 2500 by the cross-reference to figures 122, 125 and 135-140.

With reference to paragraphs [0266] and [0267] the PR argued that the embodiments of 3700 and 3700' were substantially identical but that the provision of a sheath was clearly optional in the embodiment 3700' due to the natural retention force of the arms of this embodiment.

The PR then referred to original claims 1, 3, 4, 5, 13 and 19 of the earlier application and argued that while claim 1 comprised a sheath, its function was irrelevant and thus the feature non-essential. They furthermore argued that also the first engagement member and the sharp support was non-essential for the independent claim but became only relevant in the dependent claim of the earlier application. In the PR's view these features did not serve a purpose in claim 1. The PR argued that in their view there was ample basis to omit these features. They further argued that OBU recesses were found in many embodiments and not only in the inserter 3700, such as in figures 145-149 and 161, and that these features could be extracted.

The **OP1** started their argumentation also by referring to the gold standard and emphasised that the features have to be disclosed together in combination in the same level of generality as claimed. They further stressed that no benefit of doubt should be given to the PR.

With regard to the PR's argumentation they stated that from the paragraphs cited by the PR there was no clear pointer to a particular selection and therefore no basis for the claimed feature combination, in their opinion. They further argued that in their view there was no direct and unambiguous disclosure for the feature omission and re-combining of other features with the remaining features. They stressed that original claims 1 and 13 of the earlier application referred to a sheath, device support, sharp support, handle and driver, which were all omitted. While in their view original claim 20 of the earlier application related to a different concept and was thus not considered a helpful starting point, it still included the features of the handle, sheath and sharp support.

They argued that in contrast to the original claims of the earlier application, present claim 1 additionally provided an inserter housing, recesses on the OBU, arms engaging recesses and advancement and retraction of the inserter, which in their opinion represented a considerable shift in scope. The OP1 stressed that a direct and unambiguous disclosure should be plain and immediate and free from vagueness and other alternatives. In the OP1's view there was no disclosure of the precise feature combination as claimed.

To assess the compliance with Article 76(1) EPC the OP1 suggested to start with the embodiment of the inserters 3700 and 3700' and assess how far it can be generalised. In the OP1's view the omitted sheath, carrier arms and sharp carrier of this embodiment are linked to other elements of the embodiment. Similarly, in their opinion, the handle and the consequence of the handle motion as disclosed in the embodiment of 3700 in

paragraphs [0262]-[0264] are essential to the embodiment, as well as the movement and engagement of the sharp carrier, which was outlined with reference to paragraphs [0256]-[0257] and [0263]-[0264].

They further argued that claim 1 of the granted patent defined a particular arrangement of recesses which represented in their view an improper generalisation of the recesses. They referred to figures 122 and 126 in this context and argued that also the geometry of the bosses and the device carrier were relevant.

With regard to the omitted feature of the handle, they referred to original claim 1 as well as paragraphs [0253], [0262] and [0263] of the earlier application and argued that in their opinion the handle and its particular configuration were structurally and functionally linked to the remaining features of the embodiment and no alternatives to this handle were disclosed.

With regard to the feature of the engagement of carriers, the OP1 referred to paragraphs [0263], [0264] and figure 133 of the earlier application and argued that the sharp carrier and the carrier arms are functionally linked and coupled during advancement and retraction and that in their view no alternative structure or function was disclosed.

With regard to the feature of the gripping arms, reference was made to paragraph [0258] of the earlier application and the OP1 argued that the gripping arms were held by ribs on the sheath and without these projections in their view the engagement was insecure.

With regard to the features of the bosses, the OP1 argued that they were of essential nature in connection with recesses and they referred to page 70, lines 21 and 24 and stated that the recesses were corresponding to the bosses rather than to the arms and that such engagement between bosses and recesses maintained the proper height location of the OBU.

The OP1 further argued that there was no literal disclosure of the arrangement of recesses in a circumferential spacing as defined by granted claim 1. In their opinion the only circumferential recess was disclosed in a different context in paragraph [0178], which outlines an annular recess housing a spring. This disclosure in their view does not correspond to figures 122 and 135, where arms find recesses along defined points. The OP1 stressed that in their view there was no general disclosure of circumferentially spaced recesses at the claimed level of generality but rather only a particular arrangement of three recesses according to a tripod system, which has the effect of maintaining a proper height location. In their view the omission of a particular recess necessitates a change to other elements.

The OP1 then provided an outline of the different inserter embodiments. With regard to inserter 2400 as outlined in paragraph [0207] they argued that this embodiment was very different in that all the other embodiments define the handle, device carrier, sharp carriers and needle carriers. They argued that no other configuration of three distinct

recesses with bosses an a particular spacing was disclosed. The OP1 requested great care when interpreting the drawings. The OP1 then referred to inserter 3700 in paragraph [0266], which outlines that the arms are radially spaced apart. With regard to inserter 2700 the OP1 referred to paragraph [0238] and figures 7, 8 and 22 arguing that this inserter comprises a distinct housing with a sheath. They referred to paragraphs [0011] and [0181] to outline further features such as the handle with a button and flanges engaging the fingers, which represent analogous features to the carrier arms. With regard to the inserter 300, the OP1 referred to figures 25, 26 and 34 as well as to paragraphs [0184], [0147] and [0194] in combination with figure 48 to outline the specifics of this embodiment. With regard to the operation of the inserter 400, the OP1 referred to figure 60 and paragraphs [0202], [0199], [0205] and [0206]. Turning to the inserter 2500, the OP1 cited figure 84 as well as paragraphs [0227], [0232] and [0225]. With reference to the inserter 2700, they cited figure 101 and paragraphs [0247], [0249] and [0240].

Turning to the general part of the disclosure, the OP1 argued that all features were presented as optional and that therefore this passage did not provide any hint on how to specifically modify an embodiment. They referred to paragraphs [0148] and [0152] as indicated by the PR and argued that these passages outline that all features are optional and provide a very general and vague disclosure rather than giving a precise disclosure of the specifically claimed embodiment. They further referred to paragraphs [0113], [0139] and [0153] of the earlier application and argued that in their view these passages did not provide a disclosure for the claimed feature combination. With continued reference to paragraphs [0160], [0184], [0203] and [0255] they argued that in their opinion features were picked and chosen from various embodiments. They summarised that these passages neither indicated the modification of the claimed embodiment in its generalisation and nor the omission of the features as outlined.

OP2 argued that they did not receive an explanation from the PR as to why the functionalities of the omitted features need not to be included into the subject-matter of the claim. They referred to the EPC Guidelines, section H-V.3.1 and summarised the three criteria which must be met if a feature of an original claim is removed or replaced by another feature.

With regard to the omitted feature of the sheath, they argued that in view of paragraph [0007] of the earlier application, said sheath was essential for the function beyond its effect on the arms, since it also provided a distal surface for placement on the skin of a subject and moreover, as the handle moves relative to the sheath from a proximal to a distal direction, it provided a reference point for the handle as well as for the directions, i.e. what is proximal and what is distal. They further referred to paragraph [0178] of the earlier application and stated that while the sheath may be optional, its function is not. They argued that in their view the sheath was optional to the extent that it interacted with the spring. The housing could act as a sheath but its function must still be there,

according to the OP2's view.

With regard to the omitted feature of the handle, they argued that the handle must be movable between a proximal-distal direction relative to the sheath and urge the sharp support to insert the sharp into the skin of the subject. In their view the handle was essential since it was the only element which caused the insertion of the sharp into the skin. They referred to figure 7 with regard to inserter 200, figures 34 and 36 with regard to inserter 400, figures 48 and 49 with regard to inserter 400, figures 81-84 with regard to inserter 2500 and figures 91-108 with regard to inserter 2700 and argued that in all these embodiments the handle was indispensable as otherwise no insertion was possible.

The OP2 referred to the bridging section on pages 8 and 9 of the Summons to attend oral proceedings and agreed with the preliminary opinion of the OD that the omission of the sharp carrier and the carrier arms involve an extension of subject-matter. In this regard, they also referred to [0264], [0184], [0148], [0152] as well as figure 130 of the earlier application.

The OP2 further argued that in relation to the gold standard that the combination of the features of the granted claim was very specific and while many of the features thereof may be disclosed as optional, it was relevant whether these features were disclosed together. This was not the case, according to the OP2's view. They further referred to the cross-reference as pointed out by the PR in paragraph [0161] to figures 122, 135 and 136 and argued that the bosses are in their view the projections mentioned in this paragraph and thus a necessary component.

The **PR** counter argued that in paragraph [0161] the bosses are disclosed together with the recesses and that paragraph [0227] provided an explicit cross-reference to incorporate specific features.

With reference to the 10th edition of the Case Law Book of the Board of Appeal, section II-F.2.1.1, they argued that a skilled person would read the whole disclosure and understand that a sheath was optional. With regard to paragraph [0152] of the earlier application, in their opinion, a skilled person would read this using common knowledge and understand which features are optional, non-essential and non-extrically linked. In the PR's view the invention lies within the disclosure of paragraph [0161], where it is explicitly stated that the sheath can be omitted. In their opinion, a skilled person would combine the inserter 200 only with the arms based on the explicit cross reference to figures 122, 135 and 136 in this paragraph.

They moreover argued that the housing of granted claim 1 clearly could be handled and therefore represented a handle.

With regard to the reference to the EPC Guidelines section H-V.3.1. by the OP2 earlier in the discussion, the PR argued that one does not have to start at the claim, but that a skilled person would start at the beginning of the application and read through it.

The **OP1** argued that with regard to the totality of the application all features were presented as optional and that the granted claim represented the extraction of a subset of optional features in an undirected manner. They expressed the opinion that the claimed combination of the granted claim 1 was not directly and unambiguously derivable from the earlier application as filed. In their view, paragraph [0161] of the earlier application provided no basis for an undirected modification of the inserter 200 with only the gripping arms. Rather, to find out, how the gripping arms work, the skilled person would - in the opinion of OP1 - implement the particular mechanism of the gripping arms explicitly outlined by the embodiments of 3700 and 3700'. There was, in the opinion of OP1, no generalisation of features disclosed and the skilled person would take into account all interacting elements.

The **OP2** stated that they had no further comments.

The chairman asked the PR for further basis with regard to the claim language of the circumferentially spaced recesses. In this respect, the **PR** referred to figure 149 which disclosed in their view OBUs with recesses spaced apart and around the OBU, as well as figure 45 in relation to the inserter 400 and further to figures 159, 146, 145 and 155. They argued that in view of paragraph [0258] which discloses the presence of one or more arms, implying the presence of one or more recesses, and further in view of figure 149, which in the PR's view discloses two recesses, there was no requirement to define three recesses in the claim.

The oral proceedings were paused at 12:05 for deliberation of the division on Article 76(1) EPC of claim 1 of the granted patent.

The oral proceedings were resumed at 12.45.

The chairman announced the intermediate conclusion that the granted claim 1 does not meet the requirements of Article 76(1) EPC. He outlined that a starting point for a claim from the earlier application was needed and that at least the omission of the sheath and its ribs, the sharp carrier, the carrier arms, the relative movement of the housing to the sheath as well as the wording of the circumferentially spaced recesses did not comply with the requirements of Article 76(1) EPC.

The **PR** requested a break of 1 hour to prepare another request.

The oral proceedings were paused at 12:50.

At 13:50 the **PR** requested another 30 min to prepare their request.

The chairman granted the request and resumed the oral proceedings at 14:27.

NEW AUXILIARY REQUEST 1 (AUX1)

The **PR** filed a new AUX1 at 14:22 by e-mail to the OD. The new AUX1 was forwarded to OP1 and OP2 by the second member of the OD. The **OP1** and **OP2** confirmed the receipt of the AUX1 by email.

The **PR** explained that the new AUX1 corresponded to previous AUX5 with additional changes introduced into the granted claims. In this respect they referred to granted claims 4, 5 and 16 as a basis for the additional features. The basis for the term of a "symmetric" disposal of the recesses around the circumference, was provided to be from the figures of the earlier application.

The **OP1** and **OP2** requested a break of 45 min to analyse the new AUX1.

The oral proceedings were paused at 14:35.

The oral proceedings were resumed at 15:20.

The chairperson invited the discussion on Article 76(1) EPC on the newly added feature of a symmetrical disposal of the recesses of claim 1 of the new AUX1.

The **PR** referred to figure 30, and outlined that three arms engage the circumference of the OBU. They further referred to figures 6, 24, 79, 80 and 122 and argued with reference to paragraph [0258] of the earlier application which referred to figure 122, that one or more gripping arms, e.g. 3, were disclosed. They pointed out that in their opinion figure 149 discloses 2 recesses which are again symmetrically spaced.

Upon request from the chairman for a basis for circumferential symmetry, they argued that a skilled person would understand how to implement a symmetrical arrangement. Since the precise number of three recesses was optional from paragraph [0258] and figure 149 in their opinion shows 2 recesses, in the PR's view a skilled person would use their common general knowledge to embody the claim.

The **OP1** argued that in their view the feature of symmetrical disposal as defined in claim 1 of AUX 1 violated Article 84 EPC, since symmetry needs a reference and it is not understood, with reference to which entity the recesses are symmetrically disposed. With regard to Article 76(1) EPC they argued that all arm configurations disclosed by the application are identical and show a precise configuration of the recesses. In their view, figure 149 does not assist, since there is no explanation about this figure regarding the figure elements and potential recesses. Only figures 135 and 136 of the earlier application disclose in the OP1's view a particular configuration of three equidistant, equilateral recesses on a round disk. In their view paragraph [0258] refers only to the gripping arms but does not at all relate to recesses in a spaced relation which are circumferentially and symmetrically disposed. In the OP1's view this feature represents a generalisation far beyond what the skilled person would derive.

The **OP2** argued that with regard to Article 84 EPC the type of symmetry was unclear, since there is point symmetry, line symmetry or rotational symmetry. They further argued that it was unclear how the symmetry and the circumference are related and whether the claimed spacing was part of the symmetry.

With regard to Article 76(1) EPC they argued there was no general disclosure of any potential symmetrical arrangement from the drawings. They referred to figures 30 and 122 and stated that these only show very specific symmetries. With regard to paragraph [0258] they argued that the engagement and thus the symmetry had to be such that the proper height location of the OBU was maintained.

The **PR** stated that paragraph [0258] was a key disclosure which defined one or more gripping arms and a plurality of recesses which maintain a proper height location. The plurality of recesses was already defined in the claim. With regard to the question of the reference for the symmetry, a skilled person would understand that the symmetry is around the axis of the OBU around its circumference, since they would read the claim with a mind willing to understand.

They emphasised that there was no requirement for exactly three or equidistantly spaced recesses and referred to figures 149, 141, 145, 146 and 148 as well as paragraphs [0268] and [0271]. With regard to figure 149 they stressed that in their view the mounting unit clearly shows two symmetric recesses. They further pointed to figure 150 and paragraphs [0274], [0273] and [0258] and outlined that a skilled person would have no doubt of a basis of at least 2 symmetrically placed recesses from these passages.

The **OP1** argued that in their view the AUX1 was an attempt to remedy one undisclosed feature by adding another undisclosed feature. They maintained that in their opinion the feature of symmetric disposal was unclear and not disclosed by the earlier application. They indicated that also an example of two recesses symmetrical along a line through a round OBU would fall under the scope of claim 1 of AUX1. With regard to figure 149 and paragraph [0272] they argued that these passages were not disclosing general symmetry of recesses as claimed but related to another embodiment.

The **OP2** referred again to figure 149 and paragraph [0268] and [0272] and argued that this passage relates to the assembly of the OBU and cannot tell how recesses interact with the arms, and that actually 3 recesses are disclosed, rather than 2 and that these are not symmetrical in their opinion.

The **PR** indicated that they have no further comments.

The oral proceedings were paused at 15:59 for deliberation of the division on Articles 84 and 76(1) EPC for the feature of "symmetrical" disposal of the recesses as claimed by claim 1 of AUX1.

The oral proceedings were resumed at 16:14.

The chairman announced the intermediate conclusion that claim 1 of AUX1 does not meet the requirements of Articles 84 and 76(1) EPC. The chairperson asked the PR on how they wish to proceed. The PR requested a break of 20 min, which was granted by the chairman.

The oral proceedings were paused at 16:16.

The PR requested another 5 min of break, which was granted by the chairman.

The oral proceedings were resumed at 16:47.

NEW AUXILIARY REQUEST 2 (AUX2)

The **PR** filed a new AUX2 at 16:43 by e-mail to the OD. The new AUX2 was forwarded to OP1 and OP2 by the second member of the OD. The **OP1** and **OP2** confirmed the receipt of AUX2 by email.

The **PR** confirmed that the AUX1-AUX38, which were filed before the oral proceedings, should be re-numbered to AUX3-AUX40.

The **OP1** and **OP2** requested 20 min break to analyse the new AUX2, which was granted by the chairman.

The oral proceedings were paused at 16:48.

The oral proceedings were resumed at 17:06.

The chairperson invited the discussion on Articles 84 and 76(1) EPC on the newly added feature of "the recesses being equidistantly spaced around the circumference of the on body electronics unit housing" of claim 1 of AUX2.

The **OP1** argued that in their view this feature was unclear, as it was not clear, whether "the recesses" which are equidistantly spaced refer to the first and second recesses or to the plurality of recesses defined in the claim. Furthermore, in their opinion, it was not clear with regard to which other entity they are equidistantly spaced, i.e. with regard to each other or with regard to something else. They furthermore provided examples demonstrating cases whether the distance between recesses is different, but nevertheless the angle is identical as the symmetry requirement has been removed from the claim. They argued that the claim was not restricted to circular OBUs and that therefore the three fold symmetry on a round disk of the original disclosure was totally lost. They also argued that there was in their view no basis for the term "equidistant", since the earlier application disclosed only a very precise arrangement and it was not obvious from this earlier application that distances are at the heart of the disclosure.

The **OP2** shared the concerns regarding Articles 84 and 76(1) EPC expressed by the OP1 and added that it was not understood how two recesses can be equidistantly spaced and that this would need a symmetrical housing which was no longer required by the claim language. They further emphasised that there was no disclosure of 2 diametrically placed recesses by the earlier application as filed.

The **PR** referred again to paragraph [0258] and argued that this passage provided in their view an explicit plurality of arms and recesses to maintain the proper height adjustment. Figure 149 in their view also disclosed two equidistantly spaced recesses. They argued that the skilled person would use common general knowledge to work the claim and that the examples provided by the OP1 would in their opinion purposefully misconstrue the claimed subject-matter, whereas the skilled person would use common knowledge and apply the application as a whole to interpret the claims.

The **OP1** counter argued that they did not understand why oval OBUs, which would demonstrate the relation of angles and distances referred to earlier in the discussion, should not be within the scope of the arrangement since this did not relate to an unreasonable shape in their view. The same applied in their opinion to 4 recesses on an OBU located beside each other with equal distances between the recesses 1-2, 2-3 and 3-4. They again posed the question, where the basis in the application lied for focussing on equi-distances rather than on equi-angles and stressed that the point of ambiguity had not been addressed.

The **OP2** emphasised that in their opinion figure 149 cannot support this claim as it shows a different embodiment and the electronics unit does not cooperate with the inserter. In the OP2's opinion this figure also shows three recesses rather than two and it is not evident that the distances between them are equal.

The **PR** argued that the point that figure 149 did not disclose an OBU was irrelevant in light of the claim, since this figure 149 discloses in their opinion 2 equidistantly spaced recesses.

The **OP1** posed the question, how in light of figure 149 the spaces between the recesses should even be determined, i.e. end-end of recesses or centre-centre of recesses.

The **PR** stated that in their opinion a skilled person can determine from figure 149 that the recesses are equidistant from either centre-centre or end-end of the recesses.

The oral proceedings were paused at 17:27 for deliberation of the OD with regard to Articles 84 and 76(1) EPC of the feature of equidistant recesses according to claim 1 of AUX2.

The oral proceedings were resumed at 17:43.

The chairman announced the intermediate conclusion that the subject-matter of claim 1 of AUX2 violates the requirements of Articles 84 and 76(1) EPC.

AUXILIARY REQUESTS 3-40

The chairman announced the intermediate conclusion that the wording of the circumferentially spaced recesses in claims 1 of the 3rd-40th auxiliary requests did not comply with the requirements of Article 76(1) EPC.

DECISION

The chairman announced the decision that the patent is revoked under Article 101(2) and 101(3)(b) EPC.

The oral proceedings were closed at 17:44.

After deliberation of the opposition division,

- the chairman announced the following **decision** :

The patent is revoked under Article 101(2) and 101(3)(b) EPC.

Regarding the reasons for the decision, the chairman referred to:

Article 101(2) EPC, first sentence: the following ground(s) for opposition mentioned in Article 100 EPC prejudice(s) the maintenance of the patent as granted.

The division's opinion is that, even taking into consideration the amendments made by the proprietor of the patent during the opposition proceedings, the patent does **not** meet the requirements of the Convention (Article 101(3)(b)EPC)

Claim 1 of the patent as granted (main request) and claims 1 of the 1st-40th auxiliary request do not meet the requirements of Article 76(1) EPC in view of the earlier application as filed. Therefore Article 100(c) EPC prejudices the maintenance of the patent. Furthermore, claims 1 of the 1st and 2nd auxiliary request do not meet the requirements of Article 84 EPC.

The party/parties was/were informed that the minutes of the oral proceedings and a written reasoned decision (including an indication of the possibility of appeal) will be notified to him/them as soon as possible.

The chairman **closed the oral proceedings** on 15.04.2024 at 17:44 hours.

signed:

Knüpling, Moritz

.....
Chairman

Enclosure(s):

NewAR1.pdf, NewAR2.pdf



signed:

Trattner, Barbara

.....
Minute Writer

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - ~~a sheath defining a distal surface for placement on the skin of the subject;~~
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; ~~and~~
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'); ~~and~~
 - a sharp support adapted to support the sharp extending through a portion of the carrier, wherein the carrier includes at least one feature adapted to operatively engage the sharp support;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially and symmetrically disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
 - wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) such that the inserter is configured to advance the on body electronics unit, the sharp support, and the sharp from a proximal position entirely within the inserter to a distal position,
 - wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position;

wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position; and

wherein the inserter is further configured to retract the sharp support and the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
- ~~5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~
- ~~6-5. The glucose monitoring assembly of claim 51, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.~~
- ~~7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses~~

~~(3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~

8.6. The glucose monitoring assembly of any preceding claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').

9.7. The glucose monitoring assembly of any preceding claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.

10.8. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11.9. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12.10. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

13.11. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

14.12. The glucose monitoring assembly of claim 1123, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

15.13. The glucose monitoring assembly of claim 1123 or 1234, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

16. ~~The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end~~

~~configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~

~~17.14.~~ The glucose monitoring assembly of claim ~~1356~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18.15.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19.16.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~ The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21.17.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22.18.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.

Claims:

1. A glucose monitoring assembly, the assembly comprising:
 - (1) an inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700'), comprising:
 - an inserter housing (202, 302, 402, 2402, 2502, 2702, 3702);
 - ~~a sheath defining a distal surface for placement on the skin of the subject;~~
 - a sharp (224, 324, 424, 2404, 2550), wherein the sharp is configured to insert a portion of a glucose sensor (14) into a subject; ~~and~~
 - a carrier (230, 330, 430, 2730, 3730) detachably engaged with a plurality of recesses (3766, 3766') of an on body electronics unit housing (122, 322, 3800, 4200), wherein the carrier (230, 330, 430, 2730, 3730) comprises a plurality of gripping arms (3762, 3762'); ~~and~~
 - a sharp support adapted to support the sharp extending through a portion of the carrier, wherein the carrier includes at least one feature adapted to operatively engage the sharp support;
 - (2) an on body electronics unit (1100), comprising:
 - the on body electronics unit housing comprising the plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, the recesses being equidistantly spaced around the circumference of the on body electronics unit housing;
 - the glucose sensor; and
 - on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level;
 - wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) such that the inserter is configured to advance the on body electronics unit, the sharp support, and the sharp from a proximal position entirely within the inserter to a distal position,
 - wherein each gripping arm of the plurality of gripping arms (3762, 3762') is configured to be engaged with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing when the on body electronics unit is in the proximal position,

wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position;

wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position; and

wherein the inserter is further configured to retract the sharp support and the sharp from the distal position to a retracted position entirely within the inserter.

2. The glucose monitoring assembly of claim 1, wherein the plurality of gripping arms are configured to be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.
3. The glucose monitoring assembly of claim 1 or 2, wherein the plurality of gripping arms (3762, 3762') are biased in an outward direction.
4. The glucose monitoring assembly of claim 1, 2 or 3, wherein the plurality of gripping arms (3762, 3762') are configured to deflect in an outward direction after the on body electronics unit (1100) advances from the proximal position.
- ~~5. The glucose monitoring assembly of any of claims 1-4, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises one or more interior surfaces configured to hold the plurality of gripping arms against the plurality of recesses (3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~
- ~~6-5. The glucose monitoring assembly of claim 51, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') is further configured such that the one or more interior surfaces are not in contact with the corresponding gripping arm of the plurality of gripping arms (3762, 3762') when the on body electronics unit (1100) is in the distal position.~~
- ~~7. The glucose monitoring assembly of any of claims 1-6, wherein each gripping arm of the plurality of gripping arms (3762, 3762') comprises an engagement boss (3764, 3764') configured to engage with a corresponding recess of the plurality of recesses~~

~~(3766, 3766') of the on body electronics unit housing (122, 322, 3800, 4200) when the on body electronics unit (1100) is in the proximal position.~~

8.6. The glucose monitoring assembly of any preceding claim 7, wherein the engagement boss (3764, 3764') is disposed on a tip portion of the gripping arm (3762, 3762').

9.7. The glucose monitoring assembly of any preceding claim 7 or 8, wherein the engagement boss (3764, 3764') comprises a conical shape.

10.8. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') comprises a concave portion.

11.9. The glucose monitoring assembly of any preceding claim, wherein each recess of the plurality of recesses (3766, 3766') is disposed on a side wall of the on body electronics unit housing (122, 322, 3800, 4200).

12.10. The glucose monitoring assembly of any preceding claim, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a driver (246, 346, 446, 2406, 2544, 2746, 3746) disposed in the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702), wherein the driver is configured to apply a force that retracts the sharp (224, 324, 424, 2404, 2550) after the sharp reaches the distal position.

13.11. The glucose monitoring assembly of any preceding claim, further comprising a cap (204, 304, 404, 2412, 2504, 2704, 3704) removably attached to a distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700').

14.12. The glucose monitoring assembly of claim 1123, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) is removably attached to the distal portion of the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') by a plurality of threads.

15.13. The glucose monitoring assembly of claim 1123 or 1234, wherein the cap (204, 304, 404, 2412, 2504, 2704, 3704) includes a first interior space, and wherein a section of the glucose sensor (14) and a section of the sharp (224, 324, 424, 2404, 2550) are housed within the first interior space.

16. ~~The glucose monitoring assembly of any preceding claim, wherein the inserter further comprises a sheath (242, 342, 442, 2512, 2708, 3708) having a distal sheath end~~

~~configured to be placed on a skin surface of the subject, and wherein the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702) is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).~~

~~17.14.~~ The glucose monitoring assembly of claim ~~1356~~, wherein the sheath (242, 342, 442, 2512, 2708, 3708) is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing (202, 302, 402, 2402, 2502, 2702, 3702).

~~18.15.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics unit (1100) further comprises a sensor hub (123, 4022, 4422, 4722), wherein the glucose sensor (14) comprises a distal sensor portion (30) and a proximal sensor portion (48), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

~~19.16.~~ The glucose monitoring assembly of any preceding claim, wherein the on body electronics comprises an aperture, and wherein the sharp (224, 324, 424, 2404, 2550) extends through the aperture of the on body electronics.

~~20.~~ The glucose monitoring assembly of claims 1 to 15, wherein the inserter (200, 300, 400, 2400, 2500, 2700, 3700, 3700') further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit (1100) and the sharp (224, 324, 424, 2404, 2550).

~~21.17.~~ The glucose monitoring assembly of any preceding claim, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit (1100) is in the proximal position.

~~22.18.~~ The glucose monitoring assembly of claim 1, further comprising an adhesive portion (118, 218, 318, 418, 2718, 4028) configured to secure the on body electronics unit housing (122, 322, 3800, 4200) to a skin surface of the subject.