

STERILIZATION ASSEMBLY OF CONTINUOUS GLUCOSE MONITOR AND STERILIZATION METHOD

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to Chinese Patent Application No. 202211555748.9, titled “STERILIZATION ASSEMBLY OF CONTINUOUS GLUCOSE MONITOR AND STERILIZATION METHOD”, and filed with China National Intellectual Property Administration on December 06, 2022, the entire disclosure of which is incorporated herein by reference.

FIELD

[0002] The present disclosure belongs to the field of medical device technologies, and more particularly, to a sterilization assembly of a continuous glucose monitor and a sterilization method.

BACKGROUND

[0003] A biosensor is an instrument that is sensitive to bioactive substances and converts a concentration of sensed bioactive substances into an electrical signal for a detection. A glucose sensor is a relatively common type of biosensor. Continuous Glucose Monitoring, CGM, is a technical means to indirectly reflect a blood glucose level by continuously monitoring a glucose concentration of interstitial fluid under a skin through the glucose sensor. In testing of blood glucose with a CGM product, a puncture needle and a sensor pin are needed to pierce a human skin; an electrochemical reaction occurs between a biological enzyme on the sensor and the interstitial fluid under the skin, and is converted into an electrical signal; and the electrical signal is converted into a blood glucose reading for a user. Since the product has a part that pierces the human skin, the product needs to be sterilized

before leaving factory to avoid a risk of infection to the user caused by pathogenic bacteria on the product.

[0004] A monitoring assembly generally includes a sensor and an electronic unit (transmitter), both of which typically require different sterilization methods. For the transmitter, gas sterilization, such as with ethylene oxide gas, is typically adopted. Since the biological enzyme on the sensor chemically reacts with gas such as ethylene oxide, which affects activity of the biological enzyme and consequently accuracy of monitoring, the sensor cannot be sterilized through the gas sterilization, but instead through radiation sterilization. However, the radiation sterilization can easily affect a circuit of the transmitter. Therefore, the sensor and the transmitter need to be sterilized separately.

[0005] In the related art, the monitoring assembly is typically assembled before the sterilization, and then the two different sterilization methods are performed separately. During the sterilization, since the radiation sterilization and the gas sterilization utilize radiation and gas for the sterilization, respectively, it is often difficult to effectively isolate the radiation and the gas, resulting in varying degrees of damage to the biological enzyme on the sensor and the circuit of the transmitter; or the sensor and the transmitter are sterilized separately, and when used, the user manually installs the transmitter to electrically connect the transmitter to the sensor, which increases complexity of the user's operation.

[0006] In addition, the CGM product has higher sterilization requirements for front-end components that are in direct contact with the skin (e.g., the skin fixing portion, semi-sided needle, etc.), and lower sterilization requirements for a rear-end propelling assembly, etc. However, in the related art, the CGM product is typically assembled and then sterilized as a whole, which leads to a relatively poor sterilization effect on the front-end components. Moreover, sterilization cost is relatively high due to a large size of the whole machine.

[0007] Therefore, how to effectively sterilize the front-end parts of the CGM product and ensure that the sensor and the transmitter are not affected by the two sterilization methods has become a technical problem urgently to be solved in the art.

SUMMARY

[0008] The present disclosure provides a sterilization assembly of a continuous glucose monitor and a sterilization method to solve at least one of the above technical problems.

[0009] Technical solutions adopted in the present disclosure are as follows.

5 **[0010]** A sterilization assembly of a continuous glucose monitor is provided. The sterilization assembly includes a sensor, a skin fixing portion, a cap, and a connection base. The skin fixing portion has a through hole. The cap is engaged with a lower part of the skin fixing portion to form a closed chamber. The sensor has an end fixed to the skin fixing portion and another end extending downwards into the closed chamber through the through hole of
10 the skin fixing portion. The connection base has a skin fixing portion mounting cavity. The connection base further has a mounting opening to mount a sensor electronics unit at the skin fixing portion.

[0011] An engagement site is provided at an outer side of the connection base and/or an inner side of the cap to engage the cap with the connection base and fix the cap to the
15 connection base.

[0012] The sterilization assembly further includes an insertion assembly. The connection base is further provided with a hook to connect the connection base with the insertion assembly.

[0013] The sterilization assembly further includes a retraction assembly including a
20 needle body and a needle base. The needle body extends downwards into the enclosed chamber through the through hole, and the sensor is at least partially nested inside the needle body.

[0014] The connection base and/or the needle base is provided with a first seal portion configured to seal the through hole.

25 **[0015]** The cap includes an outer shell and an inner shell that are nested with each other. The inner shell is disposed at the lower part of the skin fixing portion, and a second seal portion is provided between the inner shell and the skin fixing portion.

[0016] The outer shell at least partially surrounds an outer periphery of the connection base; one of the outer shell and the connection base is provided with a fixing protrusion; and

another one of the outer shell and the connection base is provided with an engagement site having a guide section and a locking section that are connected to each other to allow the outer shell and the connection base to be rotatably engaged with each other.

[0017] The connection base is provided with a plurality of resilient ribs at a side wall of the connection base. The cap is abutted against the plurality of resilient ribs when the cap is fixed at the connection base, to move the plurality of resilient ribs towards the skin fixing portion to clamp the skin fixing portion.

[0018] The outer shell is further provided with a support post configured to be abutted with the lower part of the skin fixing portion.

[0019] The sterilization assembly further includes a sensor electronics unit including a coupling portion located in the mounting opening. The coupling portion is provided with a first contact, and the sensor electronics unit is provided with a second contact couplable with the first contact.

[0020] The present disclosure also discloses a sterilization method for a continuous glucose monitor. The sterilization method includes: performing first sterilization treatment on a first sterilization unit, in which the first sterilization unit includes: a cap, a connection base having a mounting cavity, a sensor and a skin fixing portion being mounted in the mounting cavity, the connection base further having a mounting opening, the skin fixing portion being engaged with the cap to form a closed chamber, the skin fixing portion having a through hole, and the sensor having an end fixed to the skin fixing portion and another end extending downwards into the enclosed chamber through the through hole, and a retraction assembly at least partially extending downwards into the enclosed chamber through the through hole, the sensor being at least partially nested inside the retraction assembly; and performing second sterilization treatment on a second sterilization unit, in which the second sterilization unit includes the first sterilization unit and a sensor electronics unit, the sensor electronics unit being mounted at the skin fixing portion through the mounting opening.

[0021] The second sterilization unit further includes an insertion assembly connected to the connection base.

[0022] Since the above technical solutions are adopted, the present disclosure can provide the following advantageous effects.

[0023] 1. In the present disclosure, since the skin fixing portion is fixed in the connection base, the cap is engaged with the skin fixing portion to form the closed chamber, and the mounting opening is defined at the connection base, the sensor and the sensor electronics unit can be mounted at the skin fixing portion separately. Thus, step-by-step sterilization can be realized. In a practical operation, the sensor may be fixed in the skin fixing portion first, and the radiation sterilization is performed on the sensor. At this time, a circuit of the sensor electronics unit cannot be affected by the radiation, for the sensor electronics unit has not been mounted at the skin fixing portion. Then, the cap is fixed at the connection base. At this time, the cap is engaged with the skin fixing portion to form the closed chamber. The sensor has a contact pin located in the closed chamber, and the closed chamber is isolated from an external environment. At this time, the sensor electronics unit is mounted at the skin fixing portion through the mounting opening, and then gas sterilization is performed on the sensor electronics unit. At this time, since the contact pin of the sensor is located in the closed chamber, and the gas cannot enter the closed chamber, a biological enzyme on the contact pin of the sensor cannot be affected.

[0024] Furthermore, in the present disclosure, the components with high sterilization requirements, such as the skin fixing portion and the sensor, are connected into a single assembly by means of the connection base, and therefore during the sterilization, only the assembly needs to be sent into a sterilization chamber for the sterilization, without sterilizing a rear-end component such as the monitor. Thus, a size of the sterilization assembly is greatly reduced, and sterilization cost is saved. In this way, sterilization sufficiency and sterilization effect are improved.

[0025] 2. As a preferred embodiment of the present disclosure, the engagement site is provided at an outer side of the connection base and/or an inner side of the cap to engage the cap with the connection base and fix the cap to the connection base. The cap can not only be engaged with the skin fixing portion to enclose an end of the sensor in the closed chamber to provide a sterile environment therefor, but also support the skin fixing portion to enable the skin fixing portion more secure and prevent the skin fixing portion from disengaging before implantation. Furthermore, the cap can also limit a position of a moving component inside the monitor, in such a manner that when the cap has not been disassembled, the position of the

moving component is limited and the moving component cannot move. Thus, an anti-misoperation function is realized. Before use, a user removes the cap, which simultaneously unlocks the moving component inside the monitor. In this way, use reliability is improved. Meanwhile, the cap is more easily and conveniently disassembled through
5 engaging with and fixing to the connection base, which reduces operation difficulty and improves use experience.

[0026] 3. As a preferred embodiment of the present disclosure, the outer shell at least partially surrounds the outer periphery of the connection base; the fixing protrusion is disposed at the one of the outer shell and the connection base; and the engagement site is
10 formed at the other one of the outer shell and the connection base, which has the guide section and the locking section that are connected to each other to allow the outer shell and the connection base to be rotatably engaged with each other. In practice, an overall size of a CGM product tends to be smaller, and therefore it is more convenient for the user to apply a force through a rotation control, which improves use convenience.

[0027] 4. As a preferred embodiment of the present disclosure, the plurality of resilient ribs is arranged at the side wall of the connection base, and the cap is abutted against the plurality of resilient ribs when the cap is fixed at the connection base, moving the plurality of resilient ribs towards the skin fixing portion to clamp the skin fixing portion. The cap at least partially surrounds the outer periphery of the skin fixing portion. When the cap is not
20 disassembled, the plurality of resilient ribs of the connection base moves inwards under the action of the cap, thereby squeezing the skin fixing portion to clamp and fix the skin fixing portion. In this way, connection stability of the skin fixing portion is improved to prevent the skin fixing portion from disengaging. When the user performs an implantation operation, the cap is disassembled. In this case, the plurality of resilient ribs is not squeezed and reset, i.e.,
25 expanding outwards to release the skin fixing portion. At this time, the skin fixing portion can be detached from the connection base under the action of a bonding force of a human skin and remain on a skin surface. The present disclosure realizes the unlocking of the skin fixing portion while disassembling the cap, which further simplifies the operation steps and improves the use experience.

[0028] 5. The present disclosure also discloses the sterilization method for the continuous

glucose monitor, in which the sterilization assembly is divided into two sterilization units, and the two sterilization units are sequentially sterilized in two different methods. In a first sterilization unit, only the sensor is mounted at the skin fixing portion, and no sensor electronics unit is mounted. At this time, radiation sterilization is performed on the first
5 sterilization unit, and the sensor is sterilized. Since no sensor electronics unit is mounted at the skin fixing portion, the circuit of the sensor electronics unit naturally cannot be affected by the radiation sterilization. After the first sterilization unit is sterilized, the contact pin of the sensor is enclosed in the closed chamber, and the chamber is isolated from the external environment. Then, the sensor electronics unit is mounted at the skin fixing portion. At this
10 time, a second sterilization step is performed, such as the gas sterilization. Since the closed chamber is isolated, the gas cannot enter the closed chamber and affect the biological enzyme on the contact pin of the sensor. In this way, through the mounting and the sterilization of the sensor and the sensor electronics unit step by step, the sterilization effect is greatly improved, and adverse effects of the different sterilization methods on the sensor and the sensor
15 electronics unit are avoided to a great extent. As a result, a yield rate of the monitor as well as monitoring accuracy are improved, and product performance is ensured.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] The accompanying drawings described here are used to provide a further understanding of the present disclosure and constitute a part of the present disclosure.
20 Exemplary embodiments of the present disclosure and description thereof are used to explain the present disclosure, and do not constitute an improper limitation of the present disclosure. In the accompanying drawings:

[0030] FIG. 1 is a schematic structural view of a sterilization assembly according to an embodiment of the present disclosure.

25 **[0031]** FIG. 2 is a schematic structural view of a sterilization assembly according to another embodiment of the present disclosure.

[0032] FIG. 3 is a cross-sectional view of the sterilization assembly in FIG. 2.

[0033] FIG. 4 is a schematic structural view of a skin fixing portion according to an

embodiment of the present disclosure.

[0034] FIG. 5 is a schematic structural view of a skin fixing portion according to another embodiment of the present disclosure.

[0035] FIG. 6 is a schematic structural view of an interior of a skin fixing portion according to an embodiment of the present disclosure.

[0036] FIG. 7 is a schematic view of an internal structure of a skin fixing portion according to another embodiment of the present disclosure.

[0037] FIG. 8 is a schematic view of a bottom structure of a skin fixing portion according to an embodiment of the present disclosure.

[0038] FIG. 9 is a schematic view of a bottom structure of a skin fixing portion according to another embodiment of the present disclosure.

[0039] FIG. 10 is a schematic structural view of a cap according to an embodiment of the present disclosure.

[0040] FIG. 11 is a schematic structural view of a cap according to another embodiment of the present disclosure.

[0041] FIG. 12 is a schematic structural view of a connection base according to an embodiment of the present disclosure.

[0042] FIG. 13 is a schematic structural view of a connection base according to another embodiment of the present disclosure.

[0043] FIG. 14 is a schematic structural view of a limit structure according to an embodiment of the present disclosure.

[0044] FIG. 15 is a schematic structural view of a limit structure according to another embodiment of the present disclosure.

[0045] FIG. 16 is a schematic structural view of a retraction assembly according to an embodiment of the present disclosure.

[0046] FIG. 17 is a schematic structural view of a retraction assembly according to another embodiment of the present disclosure.

[0047] FIG. 18 is a schematic view of an internal structure of a monitor according to an embodiment of the present disclosure.

[0048] FIG. 19 is a schematic structural view of the monitor in FIG. 18.

[0049] FIG. 20 is a schematic structural view of a monitor according to another embodiment of the present disclosure.

[0050] FIG. 21 is a schematic view of an internal structure of the monitor in FIG. 20, in which a cap is not shown;

5 **[0051]** FIG. 22 is a cross-sectional view of the monitor in FIG. 20.

[0052] in which:

[0053] 1 skin fixing portion; 11 sensor; 12 through hole; 13 sensor electronics unit; 131 mounting position; 14 mating slot; 15 isolation portion; 16 annular seal strip; 17 bonding layer; 171 first avoidance region; 172 second avoidance region;

10 **[0054]** 2 cap; 21 inner shell; 211 mounting slot; 212 support post; 213 engagement site; 2131 guide section; 2132 locking section; 22 outer shell; 23 closed chamber; 24 outer cover;

[0055] 3 retraction assembly; 31 needle body; 32 needle base; 321 engagement groove; 322 limit slot; 33 first seal portion;

15 **[0056]** 4 limit structure; 41 limit hole; 411 protrusion structure; 42 toggle lever; 43 guide groove; 44 stop rib; 45 limit member;

[0057] 5 connection base; 51 guide slider; 52 stop protrusion; 53 pressing portion; 54 fixing protrusion; 55 resilient rib; 551 fixing protrusion rib; 56 passage hole; 57 hook; 58 mounting opening;

[0058] 6 housing; 61 triggering structure;

20 **[0059]** 7 insertion assembly.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0060] To explain an overall concept of the present disclosure more clearly, detailed description is made below by way of examples with reference to the accompanying drawings.

25 **[0061]** In the following description, many specific details are provided to facilitate full understanding of the present disclosure. However, the present disclosure can further be implemented in many other ways than those described herein. Therefore, the scope of the present disclosure is not limited by specific embodiments disclosed below.

[0062] In addition, in the description of the present disclosure, it should be understood

that, the orientation or the position indicated by terms such as “top”, “bottom”, “inner”, “outer”, “axial”, and “circumferential” should be construed to refer to the orientation and the position as shown in the drawings, and is only for the convenience of describing the present disclosure and simplifying the description, rather than indicating or implying that the pointed device or element must have a specific orientation, or be constructed and operated in a specific orientation, and therefore cannot be understood as a limitation of the present disclosure.

[0063] In the present disclosure, unless otherwise clearly specified and limited, terms such as “install”, “connect”, “connect to”, “fix”, and the like should be understood in a broad sense.

For example, it may be a fixed connection or a detachable connection or connection as one piece; mechanical connection or electrical connection or communication; direct connection or indirect connection through an intermediate; internal communication of two components or the interaction relationship between two components. For those of ordinary skill in the art, the specific meaning of the above-mentioned terms in the present disclosure can be understood according to specific circumstances.

[0064] In the present disclosure, unless expressly stipulated and defined otherwise, the first feature “on” or “under” the second feature may mean that the first feature is in direct contact with the second feature, or the first and second features are in indirect contact through an intermediate. Reference throughout this specification to “implementation”, “embodiment”, “an embodiment”, “example”, or “a specific example” means that a particular feature, structure, material, or characteristic described in connection with the embodiment or example is included in at least one embodiment or example of the present disclosure. The appearances of the above phrases in various places throughout this specification are not necessarily referring to the same embodiment or example. Further, the particular features, structures, materials, or characteristics may be combined in any suitable manner in one or more embodiments or examples.

[0065] As illustrated in FIGS. 1 to 22, there is provided a sterilization assembly of a continuous glucose monitor. The sterilization assembly includes a sensor 11, a skin fixing portion 1, a cap 2, and a connection base 5. The skin fixing portion 1 has a through hole 12.

The cap 2 is engaged with a lower part of the skin fixing portion 1 to form a closed chamber

23. The sensor 11 has an end fixed to the skin fixing portion 1 and another end extending downwards into the closed chamber 23 through the through hole 12 of the skin fixing portion 1. The connection base 5 has a skin fixing portion mounting cavity. The connection base 5 further has a mounting opening 58 to mount a sensor electronics unit 13 at the skin fixing portion 5.

[0066] In the present disclosure, since the skin fixing portion 1 is fixed in the connection base 5, the cap 2 is engaged with the skin fixing portion 1 to form the closed chamber 23, and the mounting opening 58 is defined at the connection base 5, the sensor 1 and the sensor electronics unit 13 can be sequentially mounted at the skin fixing portion 1. Thus, step-by-step sterilization can be realized. In addition, the sensor 1 and the sensor electronics unit 13 are mounted at the skin fixing portion 1 before delivery to form a one-piece structure, which eliminates a need for the user to assemble the sensor electronics unit 13 after an implantation operation, is thus more convenient and simpler and easy to operate. In this way, use experience of a user is improved.

[0067] Specifically, no limitation is imposed on a shape of the cap 2 in the present disclosure, for example, which may be of a split structure or a one-piece structure, as long as the cap 2 can be engaged with the lower part of the skin fixing portion 1 to form the closed chamber. The cap 2 may be partially connected to an insertion assembly or may not be partially connected thereto.

[0068] For a specific operation, the sensor 11 may be fixed at the skin fixing portion 1 first, and radiation sterilization is performed on the sensor 11. At this time, a circuit of the sensor electronics unit 13 cannot be affected by the radiation, for the sensor electronics unit 13 has not been mounted at the skin fixing portion 1.

[0069] Then, the cap 2 is fixed at the connection base. At this time, the cap 2 is engaged with the skin fixing portion 1 to form the closed chamber 23. The sensor 11 has a contact pin located in the closed chamber 23, and the closed chamber 23 is isolated from an external environment. At this time, the sensor electronics unit 13 is mounted at the skin fixing portion 1 through the mounting opening 58, and then gas sterilization is performed on the sensor electronics unit 13. At this time, since the contact pin of the sensor 11 is located in the closed chamber 23, and gas cannot enter the closed chamber 23, a biological enzyme on the contact

pin of the sensor 11 cannot be affected.

[0070] As illustrated in FIGS. 6 and 7, a mounting position 131 for a mounting of the sensor electronics unit 13 is offset from the through hole 12, the sensor 11 has a free end passing through the through hole 12, and an isolation portion 15 is provided between the through hole 12 and the mounting position 131. Therefore, during the sterilization, two regions of the skin fixing portion 1 can be respectively sterilized in different ways without affecting each other.

[0071] Furthermore, in the present disclosure, the components with high sterilization requirements, such as the skin fixing portion 1 and the sensor 11, are connected into a single assembly by means of the connection base 5, and therefore during the sterilization, only the assembly needs to be sent into a sterilization chamber for the sterilization, without sterilizing a rear-end component of a monitor. Thus, a size of the sterilization assembly is greatly reduced, and sterilization cost is saved. In this way, sterilization efficiency and sterilization effect are improved.

[0072] As a preferred embodiment of the present disclosure, an engagement site is provided at an outer side of the connection base 5 and/or an inner side of the cap 2 to engage the cap 2 with the connection base 5 and fix the cap 2 to the connection base 5.

[0073] The cap 2 can not only be engaged with the skin fixing portion 1 to enclose an end of the sensor 11 in the closed chamber 23 to provide a sterile environment therefor, but also support the skin fixing portion 1 to enable the skin fixing portion 1 more secure and prevent the skin fixing portion 1 from disengaging before implantation. Furthermore, the cap 2 can also limit a position of a moving component inside the monitor, in such a manner that when the cap 2 has not been disassembled, the position of the moving component is limited and the moving component cannot move. Thus, an anti-misoperation function is realized. Before use, the user removes the cap 2, which simultaneously unlocks the moving component inside the monitor. In this way, use reliability is improved. Meanwhile, the cap 2 is more easily and conveniently disassembled through engaging with and fixing to the connection base 5, which reduces operation difficulty and improves the use experience.

[0074] In a preferred embodiment, as illustrated in FIG. 18, the sterilization assembly further includes an insertion assembly 7, and the connection base 5 is further provided with a

hook 57 to connect the connection base 5 with the insertion assembly 7.

[0075] The connection base 5 is connected to the insertion assembly 7 to allow for a linkage between the connection base 5 and the insertion assembly 7. Upon a trigger by the user, the insertion assembly 7 drives the connection base 5 and moves towards a skin together with the connection base 5, enabling a bottom surface of the skin fixing portion 1 to be in contact with the skin. Preferably, the skin fixing portion 1 is provided with a bonding layer 17 at the bottom surface of the skin fixing portion 1 to bond and fix the skin fixing portion 1 to the skin.

[0076] Meanwhile, after the sensor electronics unit 13 is mounted at the skin fixing portion 1 through the mounting opening 58, the connection base 5 is connected to the insertion assembly 7 by the hook 57, which can reduce assembling difficulty for ease of the operation. It can be understood that a snap slot may be defined at a lower part of the insertion assembly 7 to be engaged with the hook 57.

[0077] In a preferred embodiment, as illustrated in FIGS. 1 to 3, FIG. 16, and FIG. 17, the sterilization assembly further includes a retraction assembly 3. The retraction assembly 3 includes a needle body 31 and a needle base 32. The needle body 31 extends downwards into the closed chamber 23 through the through hole 12, and the sensor 11 is at least partially nested in an interior of the needle body 31.

[0078] During use, since the contact pin of sensor 11 is of a flexible structure that cannot directly pierce the skin to enter the skin, the contact pin of sensor 11 is nested in the interior of needle body 31 by means of the needle body 31, and the contact pin of sensor 11 is implanted into the skin by using the needle body 31 to pierce the skin. After the implantation is completed, the retraction assembly 3 performs a needle withdrawal action to remove the needle from a human body.

[0079] The needle body 31 extends into the closed chamber 23 and is in a closed sterile environment together with the contact pin of the sensor 11, ensuring cleanliness of the needle body 31 and the contact pin of the sensor 11. Preferably, the needle base 32 is connected to the insertion assembly 7 to allow for a linkage between the retraction assembly 3 and the insertion assembly 7. Upon a trigger by the user, the insertion assembly 7 drives the retraction assembly 3 and moves towards the skin together with the retraction assembly 3 to complete

the implantation action, thereby providing power for the retraction assembly 3.

[0080] During the implantation, the insertion assembly 7 moves towards the skin together with the retraction assembly 3, the connection base 5, and the skin fixing portion 1 under an action of a spring, and the contact pin of sensor 11 is implanted into the skin by using the
5 needle to pierce the skin to complete the implantation process. Then, the needle withdrawal action of the retraction assembly 3 is triggered to move the retraction assembly 3 away from the skin and withdraw from the skin, to complete the withdrawal operation. The skin fixing portion 1 is adhered and fixed to the surface of the skin, and the contact pin of the sensor 11 is located under the skin for real-time glucose monitoring.

[0081] The present disclosure does not impose any limitations on the structure of the insertion assembly 7. The existing structure may be used, as long as the connection base 5 is actuated to move towards the skin and the retraction assembly 3 is actuated to perform the needle withdrawal action.

[0082] As illustrated in FIG. 3, the connection base 5 and/or the needle base 32 are
15 provided with a first seal portion 33 configured to seal the through hole 12 to ensure sealing of the closed chamber 23. The first seal portion 33 is of a structure made of an elastomeric material, and when the needle base 32 is abutted against the connection base 5, the first seal portion 33 is squeezed and elastically deformed, thereby sealing a gap between the needle base 32 and the connection base 5.

[0083] As a preferred embodiment of the present disclosure, as illustrated in FIGS. 1 and 2, the connection base 5 is further provided with a limit structure 4 configured to at least restrict the retraction assembly 3 from moving out of the through hole 12.

[0084] The limit structure 4 can limit a position of the retraction assembly 3, to keep the retraction assembly 3 to be firmly connected to the skin fixing portion 1. On the one hand, the
25 retraction assembly 3 blocks and seals the through hole 12, and the connection between the retraction assembly 3 and the skin fixing portion 1 is stable, which facilitates ensuring sealing reliability of the through hole 12, thereby ensuring that the closed chamber 23 is isolated from the external environment and the sensor 11 and the needle body 31 are in the sterile environment. Meanwhile, a risk of disengagement between the retraction assembly 3 and the
30 skin fixing portion 1 is reduced, and a risk of damage to the skin fixing portion 1 is reduced.

On the other hand, the limit structure 3 can restrict the movement of the retraction assembly 3. Thus, the anti-misoperation of the retraction assembly 3 is realized when the cap 2 has not been assembled, and under the restriction of the limit structure 4, the retraction assembly 3 cannot move, thereby cannot perform the implantation action or the withdrawal action. In this way, operation reliability of the monitor is improved, and the cost is saved.

[0085] Specifically, as illustrated in FIGS. 1 and 2, and FIGS. 14 to 17, the limit structure 4 has a limit hole 41. The limit hole 41 and the needle base 32 each have a non-circular structure, and the limit hole 41 is rotatable with the limit structure 4 relative to the needle base 32. When the limit hole 41 rotates until the limit hole 41 coincides with the needle base 32, the limit structure 4 is in an unlocked state. At this time, the limit structure 4 fails to stop the needle base 32, and the retraction assembly 3 can pass through the limit hole 41. When the limit structure 4 rotates until the limit hole 41 is offset from the needle base 32, the limit structure 4 is in a locked state. At this time, the limit structure 4 stops the needle base 32 such that the retraction assembly 3 cannot pass through the limit hole 41.

[0086] In another embodiment, as illustrated in FIG. 15, the limit hole 41 is provided with a protrusion structure 411 at an inner wall of the limit hole 41, and the needle base 32 is correspondingly provided with a slot structure at the outer wall of the needle base 32. When the protrusion structure 411 and the slot structure rotate to be coincided with each other, the needle base 32 is unlocked; and when the protrusion structure 411 and the slot structure are offset from each other, the needle base 32 is locked.

[0087] Further, the limit structure 4 rotates synchronously with the cap 2. The cap 2 is abutted with the skin fixing portion 1 to form the closed chamber 23 before the monitor is used, such that the contact pin of the sensor 11 and the needle body 31 are in the closed sterile environment, and the cap 2 is disassembled through the rotation during the use. At this time, the contact pin of the sensor 11 and the needle body 31 are exposed to facilitate the user to perform the implantation operation. Meanwhile, during the disassembling of the cap 2, the limit structure 4 rotates synchronously with the cap 2, thereby unlocking the retraction assembly 3, which enables the retraction assembly 3 to move to perform the implantation operation. Therefore, synchronous unlocking of the cap 2 and the retraction assembly 3 is realized. The unlocking of the plurality of components in a single step, which simplifies the

operation steps and reduces tediousness of using the product. In this way, the use experience is greatly improved.

[0088] Further, as illustrated in FIGS. 1, 2, 10, 11, and 14, the limit structure 4 includes a toggle lever 42, the cap 2 has a mounting slot 211 located at an open end of the cap 2 and configured to engage with the toggle lever 42, and the cap 2 is configured to rotate the limit structure 4 to change from a locked state to an unlocked state.

[0089] Specifically, as illustrated in FIGS. 1 and 2, the open end of the cap 2 surrounds an outer periphery of the skin fixing portion 1, and the toggle lever 42 is engaged with the mounting slot 211 at the open end of the cap 2 and extends inwards in a radial direction of the cap 2 to cooperate with the retraction assembly 3. The mounting slot 211 has two slot walls located at two sides of the mounting slot 211 in a circumferential direction of the cap 2, to circumferentially limit a position of the toggle lever 42. When the cap 2 rotates, the toggle lever 42 is pushed to synchronically rotate with the cap 2 under an abutment action of a slot wall at a side of the mounting slot 211.

[0090] Further, as illustrated in FIGS. 1, 2, 10, and 11, the mounting slot 211 has an opening facing upwards at a corresponding second position, through which the toggle lever 42 can slide out of the mounting slot 211 to be disengaged from the cap 2 when the user removes the cap 2, allowing the cap 2 to be removed while the toggle lever 42 is retained inside the monitor without affecting operations of internal components.

[0091] As a preferred embodiment of the present disclosure, as illustrated in FIGS. 2, 12, and 14, the sterilization assembly further includes a guide assembly configured to guide the limit structure 4 to rotate. The guide assembly includes a guide groove 43 and a guide slider 51. One of the guide groove 43 and the guide slider 51 is disposed at the limit structure 4, and another one of the guide groove 43 and the guide slider 51 is disposed at the connection base

5.

[0092] Specifically, as illustrated in FIG. 3, the skin fixing portion 1 is located inside the connection base 5, and the limit structure 4 is located at a top surface of the connection base 5. The guide groove 43 is engaged with the guide slider 51 to guide the limit structure 4 to rotate, which improves reliability of the movement of the limit structure 4. As a result, the limit structure 4 moves in a fixed path, thereby ensuring that the limit hole 41 and the needle base

32 coincide with each other and are in an unlocked state, and ensuring that the retraction assembly 3 successfully completes the needle withdrawal action.

[0093] It should be noted that this embodiment does not specifically limit the structure of the guide assembly. In one embodiment, as illustrated in FIGS. 12 and 14, the guide groove 43 is disposed at the limit structure 4, and the guide slider 51 is disposed at the top surface of the connection base 5 and extends in a circumferential direction of the connection base 5 to guide the limit structure 4 to rotate in the circumferential direction of the connection base 5.

[0094] Of course, the guide groove 43 may also be disposed at the connection base 5, and the guide slider 51 is correspondingly disposed in limit structure 4. The guide groove 43 and the guide slider 51 are not specifically limited to these examples.

[0095] Further, as illustrated in FIGS. 2, 12, and 14, the limit structure 4 includes a stop rib 44, and the cap 2 and/or the connection base 5 is provided with a stop protrusion 52. The stop rib 44 is abutted against the stop protrusion 52 when the limit structure 4 rotates to the second position from a first position, restricting the limit structure 4 from rotating towards the first position from the second position.

[0096] The engagement between the stop rib 44 and stop protrusion 52 enables the unlocking movement of the limit structure 4 to be an irreversible operation. Once the limit structure 4 rotates to the unlocking state, under the stop actions of the stop rib 44 and stop protrusion 52, the limit structure 4 is restricted to this position in which the limit structure 4 is in the unlocked state, such that the limit structure 4 cannot rotate back to the locked state, ensuring that the retraction assembly 3 successfully completes the needle withdrawal action, ensuring the use reliability and use safety of the product. The product is avoided from being reused to reduce cross infection.

[0097] In a preferred example, as illustrated in FIG. 12, the connection base 5 is provided with a guide slider 51 at a top surface of the connection base 5, and the guide slider 51 is provided with a stop protrusion 52 to allow for integration of a non-return function and a guide function. The one piece of the multi-purpose improves compactness of a structure inside the monitor and saves the cost.

[0098] Preferably, as illustrated in FIGS. 2, 12, and 14, one of the connection base 5 and the limit structure 4 is provided with a limit member 45, and another one of the connection

base 5 and the limit structure 4 is provided with a blocking member configured to be abutted against the limit member 45 when the limit structure 4 rotates to the second position from the first position, restricting the limit structure 4 from further moving away from the first position.

5 **[0099]** The limit member 45 and the blocking member can limit a rotation angle of the limit structure 4. When the limit structure 4 rotates to the second position, the retraction assembly 3 is unlocked. In this case, the limit structure 4 cannot continue to rotate under stop actions of the limit member 45 and the blocking member. Thus, the limit structure 4 is locked to be kept in the unlocked state, which can avoid once again locking of the retraction
10 assembly 3 due to an excessive rotation of the limit structure 4, to ensure that the retraction assembly 3 successfully completes the needle withdrawal action.

[00100] Preferably, as illustrated in FIGS. 12 and 14, the limit member 45 is a protrusion disposed at the limit structure 4, and the blocking member is disposed at each of two sides of the limit structure 4, and a region between the limit member 45 and the blocking member is a
15 travel of the limit structure 4 to block and limit the limit structure 4 at the two positions.

[00101] In a preferred embodiment of the present disclosure, as illustrated in FIGS. 1, 2, 12, and 13, the sterilization assembly further includes a connection base 5 for a mounting of the skin fixing portion 1. The connection base 5 is provided with a pressing portion 53 cooperating with the connection base 5 to clamp the limit structure 4.

20 **[00102]** The pressing portion 53 forms a downward pressure on the needle base 32 and presses the retraction assembly 3 against the connection base 5 to realize the fixing of the retraction assembly 3. Preferably, the pressing portion 53 is disposed on at least one side of the limit structure 4, and therefore the side wall of the pressing portion 53 can form a stop with the limit structure 4, to restrict the rotation amount of the limit structure 4. That is, the
25 pressing portion 53 constitutes the above-described blocking member.

[00103] In addition, when the cap 2 is disassembled, the limit structure 4 is disengaged from the cap 2. In this case, under the action of the pressing portion 53, the limit structure 4 is still firmly pressed against the connection base 5, thus avoiding the limit structure 4 moving inside the monitor after the limit structure 4 loses its limit function and affecting operations of
30 other components.

[00104] Specifically, as illustrated in FIGS. 12 and 13, the pressing portion 53 is a rib disposed at the top surface of the connection base 5 and extending upwards. The rib is bent at a top of the rib to form a pressing claw. A receiving space is formed between the pressing claw and the top surface of the connection base 5. The limit structure 4 is placed in the receiving space, and the pressing claw forms a downward squeezing pressure on the limit structure 4.

[00105] As a preferred embodiment of the present disclosure, as illustrated in FIG. 3, the cap 2 includes an outer shell 22 and an inner shell 21 nested within the outer shell 22. The inner shell 21 is disposed at the lower portion of the skin fixing portion 1, and a second seal portion is provided between the inner shell 21 and the skin fixing portion 1.

[00106] It can be understood that outer shell 22 and inner shell 21 may or may not be connected to each other.

[00107] The inner shell 21 of the cap 2 is abutted with a bottom surface of the skin fixing portion 1. On the one hand, the inner shell 21 is engaged with the skin fixing portion 1 to form the closed chamber 23, and the second seal portion ensures sealing of the closed chamber 23. On the other hand, the inner shell 21 can provide an upward support force on the skin fixing portion 1, such that the skin fixing portion 1 is fixed more stably to prevent the skin fixing portion 1 from disengaging before the implantation.

[00108] It should be noted that this embodiment does not specifically limit the structure of the second seal portion. In one specific example, as illustrated in FIG. 8, the second seal portion is an annular seal strip 16 disposed at the bottom surface of the skin fixing portion 1, and the inner shell 21 is also of an annular structure to be sealed against the annular seal strip 16, to form the closed chamber 23 inside.

[00109] In another specific example, as illustrated in FIG. 9, the skin fixing portion 1 is provided with a bonding layer 17 located at the bottom surface of the skin fixing portion 1 and provided with a first avoidance region 171. The second seal portion is disposed at the first avoidance region 171, and the inner shell 21 has an abutment end located within the first avoidance region 171.

[00110] It can be understood that the bonding layer 17 is coated with an adhesive such that the bottom surface of skin fixing portion 1 can adhere to a surface of a skin under an action of

a bonding force after the bottom surface of skin fixing portion 1 is in contact with the skin. However, the first avoidance region 171 is free of the adhesive and thus has no stickiness. The inner shell 21 is abutted with the first avoidance region 171, which can not only prevent the inner shell 21 and the bonding layer 17 from adhering to each other, resulting in destruction of the adhesive when the cap 2 is removed, but also prevent the inner shell 21 from rubbing against the adhesive when the cap 2 and the skin fixing portion 1 rotate relative to each other, thus avoiding wrinkling of the bonding layer 17 that affects an adhesion effect.

[00111] Further, as illustrated in FIG. 10, the outer shell 22 is further provided with a support post 212 configured to be abutted with the lower part of the skin fixing portion 1.

[00112] Providing the support post 212 increases a contact area between the cap 2 and the skin fixing portion 1 and improves stability of the support of the cap 2 to the skin fixing portion 1. In an embodiment of the present disclosure, as illustrated in FIG. 10, two support posts 212 are provided, to allow the inner shell 21 and the support post 212 together to abut against the skin fixing portion 1, to form a three-point support for the skin fixing portion 212.

[00113] As illustrated in FIGS. 9 and 10, two support posts 212 are provided. The support post 212 and the inner shell 21 are each eccentric with the cap 2, and lines among the support post 212 and the inner shell 21, and the cap 2 are connected into an approximate isosceles triangle, to further improve the stability of the support of the inner shell 21 and the support post 212 to the skin fixing portion 1 and prevent the skin fixing portion 1 from tilting.

[00114] As a preferred embodiment of the present disclosure, as illustrated in FIGS. 10 to 13, the outer shell 22 at least partially surrounds an outer periphery of the connection base 5; one of the outer shell 22 and the connection base 5 is provided with a fixing protrusion 54; and another one of the outer shell 22 and the connection base 5 is provided with an engagement site 213 having a guide section 2131 and a locking section 2132 that are connected to each other, to allow the outer shell 22 and the connection base 5 to be rotatably engaged with each other.

[00115] Specifically, as illustrated in FIGS. 1 and 2, the outer shell 22 at least partially surrounds an outer periphery of the connection base 5. One of the fixing protrusion 54 and the engagement site 213 is disposed at the outer periphery of the connection base 5, and another one of the fixing protrusion 54 and the engagement site 213 is disposed at an inner wall of the

outer shell 22.

[00116] As illustrated in FIGS. 10 to 13, in one embodiment, the connection base 5 is provided with a fixing protrusion 54 at the outer periphery of the connection base 5; and the outer shell 22 is provided with a fixing groove located at the inner wall of the outer shell 22 and constructed as the engagement site 213. During assembling, the fixing protrusion 54 is inserted into the fixing groove from the guide section, and then the cap 2 is rotated such that the fixing protrusion 54 rotates and slides to the locking section 2132 along the fixing groove, to complete locking of the cap 2 with the connection base 5. Conversely, the fixing protrusion 54 moves to the guide section 2131 by turning the cap 2 in an opposite direction, and then the cap 2 is pulled out in an opening direction of the guide section 2131, that is, the cap 2 is detached.

[00117] Of course, the fixing protrusion 54 may also be disposed at the inner wall of the cap 2, and the engagement site 213 is correspondingly formed at the outer periphery of the connection base 5, which are not specifically limited in the present disclosure.

[00118] Preferably, as illustrated in FIGS. 12 and 13, the connection base 5 is provided with a plurality of resilient ribs 55 at a side wall of the connection base 5. The cap 2 is abutted against the plurality of resilient ribs 55 when the cap 2 is fixed at the connection base 5, moving the plurality of resilient ribs 55 towards the skin fixing portion 1 to clamp the skin fixing portion 1.

[00119] The cap 2 is partially surrounds the outer periphery of the skin fixing portion 1, and when the cap 2 is not disassembled, the resilient ribs 55 of the connection base 5 move inwards under the abutment action of the cap 2, thus squeezing the skin fixing portion 1 to clamp and fix the skin fixing portion 1. In this way, connection stability of the skin fixing portion 1 is improved to prevent the skin fixing portion 1 from disengaging. When the user performs an implantation operation, the cap 2 is disassembled. In this case, the resilient ribs 55 are not squeezed and reset, i.e., expanding outwards to release the skin fixing portion 1. At this time, the skin fixing portion 1 can be detached from the connection base 5 under the action of a bonding force of a human skin and remain on a skin surface. The present disclosure realizes the unlocking of the skin fixing portion 1 while disassembling the cap 2, which further simplifies the operation steps and improves the use experience.

[00120] Preferably, as illustrated in FIGS. 12 and 13, a plurality of resilient ribs 55 is provided and arranged at intervals in a circumferential direction of the connection base 5.

[00121] Further, as illustrated in FIGS. 4, 5, 12, and 13, the resilient rib 55 is provided with a fixing protrusion rib 551 at a side of the resilient rib 55 facing towards the skin fixing portion 1; and the skin fixing portion 1 has a mating slot 14 defined at the outer periphery of the skin fixing portion 1, and the mating slot 14 corresponds to the resilient rib 55. When the resilient rib 55 moves towards the skin fixing portion 1, the fixing protrusion rib 551 extends into the mating slot 14, enabling the connection base 5 to clamp the skin fixing portion 1 more stably, thereby avoiding circumferential rotation of the skin fixing portion 1 caused by vibration or other factors during transportation. When the cap 2 is removed, the resilient rib 55 moves outwards to reset, and the fixing protrusion rib 551 slides out of the mating slot 14.

[00122] In another embodiment of the present disclosure, as illustrated in FIG. 12, the connection base 5 has a passage hole 56 corresponding to the through hole 12, and the needle base 32 is at least partially engaged into the passage hole 56 to restrict the retraction assembly 3 from rotating relative to the connection base 5.

[00123] Specifically, before the implantation, the protrusion structure of the needle base 32 is disposed in the passage hole 56 to restrict the retraction assembly 3 from rotating relative to the connection base 5, and meanwhile, the protrusion structure of the needle base 32 is abutted against the limit structure 4 such that the needle base 32 is in a locked state. After the limit structure 4 is unlocked, the protrusion structure of the needle base 32 is disengaged from the limit structure 4, and the protrusion structure of the needle base 32 can pass through the limit hole 41 when the retraction assembly 3 is retreated, to complete the needle withdrawal action.

[00124] As a preferred embodiment of the present disclosure, as illustrated in FIGS. 3, 5, 6, and 7, the sterilization assembly further includes the sensor electronics unit 13. The sensor 11 includes a coupling portion 18 located in the mounting opening 58. The coupling portion 18 is provided with a first contact 181, and the sensor electronics unit 13 is provided with a second contact couplable with the first contact 181.

[00125] The coupling portion 18 of the sensor 11 is located in the mounting opening 58, such that the sensor electronics unit 13 is mounted at the skin fixing portion 1 through the

mounting opening 58, and then can synchronously complete the coupling between the first contact 181 and the second contact, thereby reducing the operation difficulty. In this way, difficulty in coupling the first contact 181 with the second contact is greatly reduced, and assembling convenience is improved.

5 **[00126]** In one embodiment, as illustrated in FIG. 7, the first contact 181 faces upwards, and the second contact is located at the sensor electronics unit 13 and faces downwards, such that the first contact 181 is coupled with the second contact in an up-down direction when the mounting of the sensor electronics unit 13 is completed.

[00127] In another embodiment, the first contact 181 faces towards one side, and the
10 second contact also faces towards one side and faces towards the first contact 181, such that the first contact 181 is transversely coupled with the second contact when the mounting of the sensor electronics unit 13 is completed.

[00128] As illustrated in FIGS. 18 to 22, the continuous glucose monitor includes a
15 housing 6, an insertion assembly 7 disposed in housing 6, and the sterilization assembly of the continuous glucose monitor described above. The sterilization assembly further includes a retraction assembly 3. The retraction assembly 3 includes a needle body 31 and a needle base 32. The needle base 32 has an engagement groove 321 configured to be connected to the insertion assembly 7 and a limit slot 322 configured to be engaged with the limit structure 4.

[00129] The needle base 32 is connected to the insertion assembly 7 to allow for a linkage
20 between the retraction assembly 3 and the insertion assembly 7. Upon a trigger by the user, the insertion assembly 7 drives the retraction assembly 3 and moves towards the skin together with the retraction assembly 3 to complete the implantation action to provide power for the retraction assembly 3.

[00130] As illustrated in FIGS. 1, 2, and 18, the connection base 5 further has a hook 57
25 configured to be engaged with and fixed to the insertion assembly 7.

[00131] Preferably, as illustrated in FIGS. 1, 2, 3, and 20, the cap 2 includes an outer cover 24, an outer shell 22, and an inner shell 21 that are nested with each other. The housing 6 is connected with the outer shell 22. The inner shell 21 is abutted with a bottom surface of the skin fixing portion 1 to form a closed chamber 23. The outer cover 24 is connected with the
30 housing 6 to enclose all components of the monitor in a chamber formed by the outer cover

24 and the housing 6.

[00132] As illustrated in FIGS. 19 and 22, the housing 6 is provided with a triggering structure 61, and the user can trigger the monitor by operating the triggering structure 61 to complete the entire implantation and needle withdrawal process.

5 **[00133]** The triggering structure 61 may be a button as illustrated in FIG. 19 to be triggered by pressing, or may be a push structure as illustrated in FIG. 22, in which triggering is achieved by pushing down on the structure.

[00134] Before delivery, each of the retraction assembly 3, the skin fixing portion 1, and the connection base 5 of the continuous glucose monitor of the present disclosure is in a
10 locked state, and the user thus cannot trigger the implantation, which greatly reduces a risk of misoperation. An operation method of the continuous glucose monitor of the present disclosure is as follows. The cap 2 is rotated first such that the connection base 5, the skin fixing portion 1, and the insertion assembly 7 synchronously rotate to realize unlocking. Then, the cap 2 is removed. At this time, the contact pin of the sensor 11 and the needle body 31 of
15 the retraction assembly 3 are exposed, and then an open end of the housing 6 is attached to the skin, and the triggering structure 61 is triggered by pressing and the like. At this time, the housing 6 fails to stop the insertion assembly 7, and the insertion assembly 7 drives the retraction assembly 3, the connection base 5, and the skin fixing portion 1 and moves towards the skin together with the retraction assembly 3, the connection base 5, and the skin fixing
20 portion 1 under an action of a spring. The needle pierces the skin, and the contact pin of sensor 11 is implanted under the skin, to complete the implantation process. Then, a needle withdrawal action of the retraction assembly 3 is triggered in such a manner that the retraction assembly 3 moves away from the skin relative to the insertion assembly 7 and withdraws from the skin, to complete the needle withdrawal operation. At this time, the skin fixing
25 portion 1 is adhered and fixed to the surface of the skin. Meanwhile, when other parts of the monitor are removed, the skin fixing portion 1 is disengaged from the connection base 5. In this way, the entire implantation process is completed. After the implantation is completed, only the skin fixing portion 1 is retained on the surface of the skin, and the contact pin of the sensor 11 is located under the skin for real-time monitoring.

30 **[00135]** The present disclosure also discloses a sterilization method for a continuous

glucose monitor. The sterilization method includes the following operations.

[00136] First sterilization treatment is performed on a first sterilization unit. The first sterilization unit includes a cap 2, a connection base 5 and a retraction assembly 3. The connection base 5 has a mounting cavity in which a sensor 11 and a skin fixing portion 1 are mounted. The connection base 5 further has a mounting opening 58. The skin fixing portion 1 is engaged with the cap 2 to form a closed chamber 23. The skin fixing portion 1 has a through hole 12. The sensor 11 has an end fixed to the skin fixing portion 1 and another end extending downwards into the enclosed chamber 23 through the through hole 12. The retraction assembly 3 at least partially extends downwards into the enclosed chamber 23 through the through hole 12. The sensor 11 is at least partially nested in an interior of the retraction assembly 3.

[00137] Second sterilization treatment is performed on a second sterilization unit. The second sterilization unit includes a first sterilization unit and a sensor electronics unit 13. The sensor electronics unit 13 is mounted at the skin fixing portion 1 through the mounting opening 58.

[00138] The sterilization assembly is divided into two sterilization units, and the two sterilization units are sequentially sterilized in two different methods. In the first sterilization unit, only the sensor 11 is mounted at the skin fixing portion 1, and no sensor electronics unit 13 is mounted. At this time, radiation sterilization is performed on the first sterilization unit, and the sensor 11 is sterilized. Since no sensor electronics unit 13 is mounted at the skin fixing portion 1, a circuit of the sensor electronics unit 13 naturally cannot be affected by the radiation sterilization. After the first sterilization unit is sterilized, the contact pin of the sensor 11 is enclosed in the closed chamber 23, and the chamber is isolated from the external environment. Then, the sensor electronics unit 13 is mounted at the skin fixing portion 1. At this time, a second sterilization step is performed, such as through ethylene oxide gas. Since the closed chamber is isolated, gas cannot enter the closed chamber and affect a biological enzyme on the contact pin of the sensor. In this way, through the mounting and the sterilization of the sensor 11 and the sensor electronics unit 13 step by step, the sterilization effect is greatly improved, and adverse effects of the different sterilization methods on the sensor and the sensor electronics unit are avoided to a great extent. As a result, a yield rate of

the monitor as well as monitoring accuracy are improved, and product performance is ensured.

[00139] Preferably, as illustrated in FIG. 18, the second sterilization unit further includes an insertion assembly 7 connected to the connection base 5.

5 **[00140]** The connection base 5 is connected to the insertion assembly 7 such that the insertion assembly 7 can drive the connection base 5 and move towards the skin together with the connection base 5 to perform the implantation action, and the skin fixing portion 1 is fixed at the connection base 5, and therefore the skin fixing portion 1 moves with the connection base 5 correspondingly.

10 **[00141]** Preferably, as illustrated in FIGS. 12, 13, and 18, the connection base 5 is provided with a hook 57 protruding towards the insertion assembly 7, and the insertion assembly 7 has an engagement opening. The hook 57 is snap-fit into the engagement opening to allow the hook 57 and the engagement opening to be fixed in a snap-fit manner. The sensor electronics unit 13 is mounted at the skin fixing portion 1 through the mounting opening 58, and the
15 insertion assembly 7 is connected to the connection base 5 by the hook 57 to form the second sterilization unit for the second sterilization step.

[00142] Of course, the connection base 5 may also be connected to the insertion assembly 7 by other means, such as magnetic suction, which is not specifically limited to this.

20 **[00143]** Any aspects not described in the present disclosure can be realized by adopting or referencing the related art.

[00144] Each embodiment in the specification is described in a progressive manner. The same or similar parts of various embodiments can be referred to each other. Each embodiment focuses on differences from other embodiments.

25 **[00145]** While some embodiments of the present disclosure have been described above, the present disclosure is not limited to these embodiments. It is conceivable for those skilled in the art that various changes and variations can be made to the present disclosure. Any modifications, equivalent replacements, improvements, or the like made within the spirit and the principle of the present disclosure shall equally fall within the scope of the present disclosure as defined by the claims as attached.

CLAIMS

What is claimed is:

1. A sterilization assembly of a continuous glucose monitor, the sterilization assembly comprising:

5 a sensor;

a skin fixing portion having a through hole;

a cap engaged with a lower part of the skin fixing portion to form a closed chamber, the sensor having an end fixed to the skin fixing portion and another end extending downwards into the closed chamber through the through hole of the skin fixing portion; and

10 a connection base having a skin fixing portion mounting cavity, the connection base further having a mounting opening to mount a sensor electronics unit at the skin fixing portion.

2. The sterilization assembly according to claim 1, wherein an engagement site is provided at an outer side of the connection base and/or an inner side of the cap to engage the cap with the connection base and fix the cap to the connection base.

3. The sterilization assembly according to claim 1, further comprising an insertion assembly, wherein the connection base is further provided with a hook to connect the connection base with the insertion assembly.

4. The sterilization assembly according to claim 1, further comprising a retraction assembly comprising a needle body and a needle base, the needle body extending downwards into the enclosed chamber through the through hole, and the sensor being at least partially nested in an interior of the needle body.

5. The sterilization assembly according to claim 4, wherein the connection base and/or the needle base is provided with a first seal portion configured to seal the through hole.

25 6. The sterilization assembly according to claim 1, wherein the cap comprises an outer shell and an inner shell that are nested with each other, the inner shell being disposed at the lower part of the skin fixing portion, and a second seal portion being provided between the inner shell and the skin fixing portion.

7. The sterilization assembly according to claim 6, wherein:

the outer shell at least partially surrounds an outer periphery of the connection base;

one of the outer shell and the connection base is provided with a fixing protrusion; and

another one of the outer shell and the connection base is provided with an engagement

5 site having a guide section and a locking section that are connected to each other to allow the outer shell and the connection base to be rotatably engaged with each other.

8. The sterilization assembly according to claim 6, wherein the connection base is provided with a plurality of resilient ribs at a side wall of the connection base,

wherein the cap is abutted against the plurality of resilient ribs when the cap is fixed at

10 the connection base, to move the plurality of resilient ribs towards the skin fixing portion to clamp the skin fixing portion.

9. The sterilization assembly according to claim 6, wherein the outer shell is further provided with a support post configured to be abutted with the lower part of the skin fixing portion.

15 10. The sterilization assembly according to claim 1, further comprising the sensor electronics unit comprising a coupling portion located in the mounting opening,

wherein the coupling portion is provided with a first contact; and

wherein the sensor electronics unit is provided with a second contact couplable with the first contact.

20 11. A sterilization method for a continuous glucose monitor, the sterilization method comprising:

performing first sterilization treatment on a first sterilization unit, wherein the first sterilization unit comprises:

a cap;

25 a connection base having a mounting cavity, a sensor and a skin fixing portion being mounted in the mounting cavity, the connection base further having a mounting opening, the skin fixing portion being engaged with the cap to form a closed chamber, the skin fixing portion having a through hole, and the sensor having an end fixed to the skin fixing portion and another end extending downwards into the enclosed chamber through the
30 through hole,

a retraction assembly at least partially extending downwards into the enclosed chamber through the through hole, the sensor being at least partially nested in an interior of the retraction assembly; and

5 performing second sterilization treatment on a second sterilization unit, wherein the second sterilization unit comprises the first sterilization unit and a sensor electronics unit, the sensor electronics unit being mounted at the skin fixing portion through the mounting opening.

12. The sterilization method according to claim 11, wherein the second sterilization unit further comprises an insertion assembly connected to the connection base.

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