ANNEX A TO THE STATEMENT OF GROUNDS (EP 045)

EP 045 CONDITIONAL AMENDMENT 1

Claims:

1. A method of operating an inserter (100) comprising a base (142), a spring (146), a sharp (124), and a shuttle (134), the method comprising:

positioning an end of the base of the inserter on a skin surface (S) of a subject, the inserter containing an analyte monitoring assembly including electronics coupled to an analyte sensor (14, 14') and comprising a power source (82), the electronics operable to communicate analyte data;

displacing the shuttle, the analyte monitoring assembly and the sharp from a first position within the inserter to a second position where at least a portion (30) of the analyte sensor of the analyte monitoring assembly is in contact with interstitial fluid under the skin surface; and

automatically retracting the shuttle and the sharp, from the second position to the first position to be entirely retained within ~~and into~~ the inserter, with a force applied by the spring to the shuttle while the end of the base is maintained on the skin surface.

2. The method of claim 1, wherein automatically retracting the shuttle (134) and the sharp (124) comprises automatically retracting the shuttle and the sharp upon the sharp reaching a predetermined distalmost position, optionally further comprising disengaging the shuttle from a retention member (194) upon reaching the predetermined position.

3. The method of any preceding claim, further comprising engaging the analyte monitoring assembly with at least a portion of the sharp (124) within the inserter (100) during displacement between the first position and the second position.

4. The method of any preceding claim, wherein the electronics are activated when the analyte monitoring assembly is at or near the second position.

5. The method of any preceding claim, further comprising positioning a portion of the analyte monitoring assembly on a skin surface (S) at the second position, optionally further comprising activating the analyte monitoring assembly when the portion of the analyte monitoring assembly is positioned on the skin surface.

6. The method of any preceding claim, further comprising providing one or more data associated with a monitored level of an analyte to a remote location (18), optionally, wherein providing the one or more data comprises using one or more of RF communication, infrared communication, Bluetooth communication, Zigbee communication, 802.1x communication, or WiFi communication.

7. The method of claim 6, wherein the remote location (18) includes one or more of a remotely located computing device, a mobile telephone device, a personal digital assistant, or a communication enabled data processing device.

8. The method of any preceding claim, further comprising, prior to positioning the end of the base (142) of the inserter (100), disengaging an end cap (104) from the base of the inserter to expose the interior of the inserter.

9. The method of any preceding claim, further comprising entirely retaining the sharp (124) within the inserter (100) when the sharp is retracted into the inserter, optionally further comprising engaging an end cap (104) with the base (142) of the inserter to enclose the interior of the inserter.

10. An integrated assembly, comprising:

a sensor electronics assembly comprising:

an analyte sensor (14, 14');

a power supply (82); and

a communications circuit for communicating analyte data; and

an insertion device (100), having the sensor electronics assembly therein, and comprising:

a base (142) for positioning on a skin surface of a subject;

a sharp (124);

a spring (146); and

a shuttle (134);

wherein the shuttle, the sensor electronics assembly and the sharp are configured to move between a first position entirely within the insertion device and a second position where at least a portion of the analyte sensor is in contact with interstitial fluid under the skin surface; and

wherein the assembly is configured such that a force applied by the spring to the shuttle automatically retracts the shuttle and the sharp from the second position

to the first position withinand into the insertion device while the end of the base is maintained on the skin surface.

11. The assembly of claim 10, further comprising a retention member configured such that the shuttle (134) and the sharp (124) automatically retract upon the shuttle and the sharp reaching a predetermined distalmost position and disengaging from the retention member.

12. The assembly of claim 10 or 11, wherein the sensor electronics assembly is configured to engage with at least a portion of the sharp (124) within the insertion device (100) during displacement between the first position and the second position.

13. The assembly of any of claims 10 to 12, wherein the sensor electronics assembly is configured to activate when the sensor electronics assembly is at or near the second position, optionally when the sensor electronics assembly is positioned on the skin surface (S).

14. The assembly of any of claims 10 to 13, further comprising a cap (104) configured to mate with the base (142) of the insertion device (100), optionally wherein when the cap is coupled to the insertion device, the interior space of the insertion device is maintained in a substantially contaminant free environment.

15. The method of any of claims 1 to 9, or the assembly of any of claims 10 to 14, wherein the analyte sensor (14, 14') comprises a glucose sensor.

16. The method of any of claims 1 to 9 and 15, wherein the analyte monitoring assembly comprises an on-body unit (16, 122), the on-body unit comprising an aperture (168) that extends from a top surface of the on-body unit to a bottom surface of the on-body unit; wherein:

the sharp (124) extends through the aperture in the on-body unit when the sharp and the analyte monitoring assembly are in the first position; and

automatically retracting the shuttle (134) and the sharp from the second position withdraws the sharp from the aperture in the on-body unit.

17. The assembly of any of claims 10 to 14, wherein the sensor electronics assembly comprises an on-body unit (16, 122), the on-body unit comprising an aperture (168)

that extends from a top surface of the on-body unit to a bottom surface of the on-body unit; wherein the assembly is configured such that:

the sharp (124) extends through the aperture in the on-body unit when the sharp and the sensor electronics assembly are in the first position; and

the sharp is withdrawn from the aperture in the on-body unit in the second position.

18. The method of claim 16 or the assembly of claim 17, further comprising a sensor electronics circuit board (80) within the on-body unit (16, 122), the circuit board having an aperture therethrough, and wherein the sharp (124) also extends through the aperture in the circuit board when the sharp is in the first position.

19. The method of any of claims 1 to 9, 15, 16 or 18, or the assembly of any of claims 10 to 14, 17 or 18, wherein at least a portion of the analyte sensor (14, 14') is positioned within a bore (162) of the sharp (124) when the sharp is in the first position.

20. The method of any of claims 1 to 9, 15, 16, 18 or 19, or the assembly of any of claims 10 to 14 or 17 to 19, wherein the movement from the first position to the second position is in a direction substantially perpendicular to a skin surface of a user.

Claims:

1. A method of operating an inserter (100) comprising a base (142), a spring (146), a sharp (124), and a shuttle (134), the method comprising:

positioning an end of the base of the inserter on a skin surface (S) of a subject, the inserter containing an analyte monitoring assembly including electronics housed in a sensor housing, the electronics coupled to an analyte sensor (14, 14') and comprising a power source (82), the electronics operable to communicate analyte data;

displacing the shuttle, the analyte monitoring assembly and the sharp from a first position within the inserter to a second position where at least a portion (30) of the analyte sensor of the analyte monitoring assembly is in contact with interstitial fluid under the skin surface; and

automatically retracting the shuttle and the sharp from the second position and into the inserter with a force applied by the spring to the shuttle while the end of the base is maintained on the skin surface.

2. The method of claim 1, wherein automatically retracting the shuttle (134) and the sharp (124) comprises automatically retracting the shuttle and the sharp upon the sharp reaching a predetermined distalmost position, optionally further comprising disengaging the shuttle from a retention member (194) upon reaching the predetermined position.

3. The method of any preceding claim, further comprising engaging the analyte monitoring assembly with at least a portion of the sharp (124) within the inserter (100) during displacement between the first position and the second position.

4. The method of any preceding claim, wherein the electronics are activated when the analyte monitoring assembly is at or near the second position.

5. The method of any preceding claim, further comprising positioning a portion of the analyte monitoring assembly on a skin surface (S) at the second position, optionally further comprising activating the analyte monitoring assembly when the portion of the analyte monitoring assembly is positioned on the skin surface.

6. The method of any preceding claim, further comprising providing one or more data associated with a monitored level of an analyte to a remote location (18), optionally,

wherein providing the one or more data comprises using one or more of RF communication, infrared communication, Bluetooth communication, Zigbee communication, 802.1x communication, or WiFi communication.

7. The method of claim 6, wherein the remote location (18) includes one or more of a remotely located computing device, a mobile telephone device, a personal digital assistant, or a communication enabled data processing device.

8. The method of any preceding claim, further comprising, prior to positioning the end of the base (142) of the inserter (100), disengaging an end cap (104) from the base of the inserter to expose the interior of the inserter.

9. The method of any preceding claim, further comprising entirely retaining the sharp (124) within the inserter (100) when the sharp is retracted into the inserter, optionally further comprising engaging an end cap (104) with the base (142) of the inserter to enclose the interior of the inserter.

10. An integrated assembly, comprising:

a sensor electronics assembly comprising:

an analyte sensor (14, 14'); and

a power supply (82); and

a communications circuit for communicating analyte data, housed in a sensor housing; and

an insertion device (100), having the sensor electronics assembly therein, and comprising:

a base (142) for positioning on a skin surface of a subject;

a sharp (124);

a spring (146); and

a shuttle (134);

wherein the shuttle, the sensor electronics assembly and the sharp are configured to move between a first position entirely within the insertion device and a second position where at least a portion of the analyte sensor is in contact with interstitial fluid under the skin surface; and

wherein the assembly is configured such that a force applied by the spring to the shuttle automatically retracts the shuttle and the sharp from the second position and into the insertion device while the end of the base is maintained on the skin surface.

11. The assembly of claim 10, further comprising a retention member configured such that the shuttle (134) and the sharp (124) automatically retract upon the shuttle and the sharp reaching a predetermined distalmost position and disengaging from the retention member.

12. The assembly of claim 10 or 11, wherein the sensor electronics assembly is configured to engage with at least a portion of the sharp (124) within the insertion device (100) during displacement between the first position and the second position.

13. The assembly of any of claims 10 to 12, wherein the sensor electronics assembly is configured to activate when the sensor electronics assembly is at or near the second position, optionally when the sensor electronics assembly is positioned on the skin surface (S).

14. The assembly of any of claims 10 to 13, further comprising a cap (104) configured to mate with the base (142) of the insertion device (100), optionally wherein when the cap is coupled to the insertion device, the interior space of the insertion device is maintained in a substantially contaminant free environment.

15. The method of any of claims 1 to 9, or the assembly of any of claims 10 to 14, wherein the analyte sensor (14, 14') comprises a glucose sensor.

16. The method of any of claims 1 to 9 and 15, wherein the ~~analyte monitoring assembly comprises an on-body unit (16, 122), the on-body unit~~sensor housing compris~~es~~ing an aperture (168) that extends from a top surface of the sensor housing~~on-body unit~~ to a bottom surface of the sensor housing~~on-body unit~~; wherein:

the sharp (124) extends through the aperture in the sensor housing~~on-body unit~~ when the sharp and the analyte monitoring assembly are in the first position; and

automatically retracting the shuttle (134) and the sharp from the second position withdraws the sharp from the aperture in the sensor housing~~on-body unit~~.

17. The assembly of any of claims 10 to 14, wherein the sensor housing~~sensor electronics assembly comprises an on-body unit (16, 122), the on-body unit~~ compris~~es~~ing an aperture (168) that extends from a top surface of the sensor housing~~on-body unit~~ to a bottom surface of the sensor housing~~on-body unit~~; wherein the assembly is configured such that:

the sharp (124) extends through the aperture in the sensor housing~~on-body unit~~ when the sharp and the sensor electronics assembly are in the first position; and

the sharp is withdrawn from the aperture in the sensor housing~~on-body unit~~ in the second position.

18. The method of claim 16 or the assembly of claim 17, further comprising a sensor electronics circuit board (80) within the sensor housing~~on-body unit (16, 122)~~, the circuit board having an aperture therethrough, and wherein the sharp (124) also extends through the aperture in the circuit board when the sharp is in the first position.

19. The method of any of claims 1 to 9, 15, 16 or 18, or the assembly of any of claims 10 to 14, 17 or 18, wherein at least a portion of the analyte sensor (14, 14') is positioned within a bore (162) of the sharp (124) when the sharp is in the first position.

20. The method of any of claims 1 to 9, 15, 16, 18 or 19, or the assembly of any of claims 10 to 14 or 17 to 19, wherein the movement from the first position to the second position is in a direction substantially perpendicular to a skin surface of a user.

Claims:

1. A method of operating an inserter (100) comprising a handle (102), a base (142), a spring (146), a sharp (124), and a shuttle (134), the method comprising:

positioning an end of the base of the inserter on a skin surface (S) of a subject, the inserter containing an analyte monitoring assembly including electronics coupled to an analyte sensor (14, 14') and comprising a power source (82), the electronics operable to communicate analyte data;

prior to positioning the end of the base (142) of the inserter (100), disengaging an end cap (104) from a handle of the inserter to expose the interior of the inserter;

displacing the shuttle, the analyte monitoring assembly and the sharp from a first position within the inserter to a second position where at least a portion (30) of the analyte sensor of the analyte monitoring assembly is in contact with interstitial fluid under the skin surface; and

automatically retracting the shuttle and the sharp from the second position and into the inserter with a force applied by the spring to the shuttle while the end of the base is maintained on the skin surface; and the method further comprising preventing the displacement of the analyte monitoring assembly within the inserter between the first position and the second position when the end cap is engaged with the handle.

2. The method of claim 1, wherein automatically retracting the shuttle (134) and the sharp (124) comprises automatically retracting the shuttle and the sharp upon the sharp reaching a predetermined distalmost position, optionally further comprising disengaging the shuttle from a retention member (194) upon reaching the predetermined position.

3. The method of any preceding claim, further comprising engaging the analyte monitoring assembly with at least a portion of the sharp (124) within the inserter (100) during displacement between the first position and the second position.

4. The method of any preceding claim, wherein the electronics are activated when the analyte monitoring assembly is at or near the second position.

5. The method of any preceding claim, further comprising positioning a portion of the analyte monitoring assembly on a skin surface (S) at the second position, optionally

further comprising activating the analyte monitoring assembly when the portion of the analyte monitoring assembly is positioned on the skin surface.

6. The method of any preceding claim, further comprising providing one or more data associated with a monitored level of an analyte to a remote location (18), optionally, wherein providing the one or more data comprises using one or more of RF communication, infrared communication, Bluetooth communication, Zigbee communication, 802.1x communication, or WiFi communication.

7. The method of claim 6, wherein the remote location (18) includes one or more of a remotely located computing device, a mobile telephone device, a personal digital assistant, or a communication enabled data processing device.

~~8. The method of any preceding claim, further comprising, prior to positioning the end of the base (142) of the inserter (100), disengaging an end cap (104) from the base of the inserter to expose the interior of the inserter.~~

~~9.~~8. The method of any preceding claim, further comprising entirely retaining the sharp (124) within the inserter (100) when the sharp is retracted into the inserter, optionally further comprising engaging thean end cap (104) with the handle~~base (142)~~ of the inserter to enclose the interior of the inserter.

~~10.~~9. An integrated assembly, comprising:

a sensor electronics assembly comprising:

an analyte sensor (14, 14');

a power supply (82); and

a communications circuit for communicating analyte data; and

an insertion device (100), having the sensor electronics assembly therein, and comprising:

a handle (102);

a base (142) for positioning on a skin surface of a subject;

a removable cap (104) configured to mate with the handle;

a sharp (124);

a spring (146); and

a shuttle (134);

wherein the shuttle, the sensor electronics assembly and the sharp are configured to move between a first position entirely within the insertion device and a

second position where at least a portion of the analyte sensor is in contact with interstitial fluid under the skin surface; and

wherein the assembly is configured such that a force applied by the spring to the shuttle automatically retracts the shuttle and the sharp from the second position and into the insertion device while the end of the base is maintained on the skin surface; and

wherein the removable cap is configured to prevent the movement of the sensor electronics assembly between the first position entirely within the insertion device and the second position when the removable cap is mated with the handle.

11.10. The assembly of claim 910, further comprising a retention member configured such that the shuttle (134) and the sharp (124) automatically retract upon the shuttle and the sharp reaching a predetermined distalmost position and disengaging from the retention member.

12.11. The assembly of claim 910 or 101, wherein the sensor electronics assembly is configured to engage with at least a portion of the sharp (124) within the insertion device (100) during displacement between the first position and the second position.

13.12. The assembly of any of claims 910 to 112, wherein the sensor electronics assembly is configured to activate when the sensor electronics assembly is at or near the second position, optionally when the sensor electronics assembly is positioned on the skin surface (S).

14.13. The assembly of any of claims 910 to 123, ~~further comprising a cap (104) configured to mate with the base (142) of the insertion device (100), optionally~~ wherein when the cap is coupled to the insertion device, the interior space of the insertion device is maintained in a substantially contaminant free environment.

15.14. The method of any of claims 1 to 89, or the assembly of any of claims 910 to 134, wherein the analyte sensor (14, 14') comprises a glucose sensor.

16.15. The method of any of claims 1 to 89 and 145, wherein the analyte monitoring assembly comprises an on-body unit (16, 122), the on-body unit comprising an aperture (168) that extends from a top surface of the on-body unit to a bottom surface of the on-body unit; wherein:

the sharp (124) extends through the aperture in the on-body unit when the sharp and the analyte monitoring assembly are in the first position; and

automatically retracting the shuttle (134) and the sharp from the second position withdraws the sharp from the aperture in the on-body unit.

~~17.~~16. The assembly of any of claims ~~9~~10 to 1~~3~~4, wherein the sensor electronics assembly comprises an on-body unit (16, 122), the on-body unit comprising an aperture (168) that extends from a top surface of the on-body unit to a bottom surface of the on-body unit; wherein the assembly is configured such that:

the sharp (124) extends through the aperture in the on-body unit when the sharp and the sensor electronics assembly are in the first position; and

the sharp is withdrawn from the aperture in the on-body unit in the second position.

~~18.~~17. The method of claim 1~~5~~6 or the assembly of claim 1~~6~~7, further comprising a sensor electronics circuit board (80) within the on-body unit (16, 122), the circuit board having an aperture therethrough, and wherein the sharp (124) also extends through the aperture in the circuit board when the sharp is in the first position.

~~19.~~18. The method of any of claims 1 to ~~8~~9, 1~~4~~5, 1~~5~~6 or 1~~7~~8, or the assembly of any of claims ~~9~~10 to 1~~3~~4, 1~~7~~6 or 1~~7~~8, wherein at least a portion of the analyte sensor (14, 14') is positioned within a bore (162) of the sharp (124) when the sharp is in the first position.

~~20.~~19. The method of any of claims 1 to ~~8~~9, 1~~4~~5, 1~~5~~6, 1~~7~~8 or 1~~8~~9, or the assembly of any of claims ~~9~~10 to 1~~3~~4 or 1~~6~~7 to 1~~8~~9, wherein the movement from the first position to the second position is in a direction substantially perpendicular to a skin surface of a user.

Claims:

1. A method of operating an inserter (100) comprising a handle (102), a base (142), a spring (146), a sharp (124), and a shuttle (134), the method comprising:

positioning an end of the base of the inserter on a skin surface (S) of a subject, the inserter containing an analyte monitoring assembly including electronics coupled to an analyte sensor (14, 14') and comprising a power source (82), the electronics operable to communicate analyte data;

prior to positioning the end of the base (142) of the inserter (100), disengaging an end cap (104) from the handle of the inserter to expose the interior of the inserter, the end cap (104) engaged to the handle by one or more threads;

displacing the shuttle, the analyte monitoring assembly and the sharp from a first position within the inserter to a second position where at least a portion (30) of the analyte sensor of the analyte monitoring assembly is in contact with interstitial fluid under the skin surface; and

automatically retracting the shuttle and the sharp from the second position and into the inserter with a force applied by the spring to the shuttle while the end of the base is maintained on the skin surface.

2. The method of claim 1, wherein automatically retracting the shuttle (134) and the sharp (124) comprises automatically retracting the shuttle and the sharp upon the sharp reaching a predetermined distalmost position, optionally further comprising disengaging the shuttle from a retention member (194) upon reaching the predetermined position.

3. The method of any preceding claim, further comprising engaging the analyte monitoring assembly with at least a portion of the sharp (124) within the inserter (100) during displacement between the first position and the second position.

4. The method of any preceding claim, wherein the electronics are activated when the analyte monitoring assembly is at or near the second position.

5. The method of any preceding claim, further comprising positioning a portion of the analyte monitoring assembly on a skin surface (S) at the second position, optionally further comprising activating the analyte monitoring assembly when the portion of the analyte monitoring assembly is positioned on the skin surface.

6. The method of any preceding claim, further comprising providing one or more data associated with a monitored level of an analyte to a remote location (18), optionally, wherein providing the one or more data comprises using one or more of RF communication, infrared communication, Bluetooth communication, Zigbee communication, 802.1x communication, or WiFi communication.

7. The method of claim 6, wherein the remote location (18) includes one or more of a remotely located computing device, a mobile telephone device, a personal digital assistant, or a communication enabled data processing device.

~~8. The method of any preceding claim, further comprising, prior to positioning the end of the base (142) of the inserter (100), disengaging an end cap (104) from the base of the inserter to expose the interior of the inserter.~~

~~9.~~8. The method of any preceding claim, further comprising entirely retaining the sharp (124) within the inserter (100) when the sharp is retracted into the inserter, optionally further comprising engaging thean end cap (104) with the handle~~the base (142)~~ of the inserter to enclose the interior of the inserter.

~~10.~~9. An integrated assembly, comprising:

a sensor electronics assembly comprising:

an analyte sensor (14, 14');

a power supply (82); and

a communications circuit for communicating analyte data; and

an insertion device (100), having the sensor electronics assembly therein, and comprising:

a handle (102)

a base (142) for positioning on a skin surface of a subject;

a removable cap (104) configured to mate with the handle by one or more threads;

a sharp (124);

a spring (146); and

a shuttle (134);

wherein the shuttle, the sensor electronics assembly and the sharp are configured to move between a first position entirely within the insertion device and a second position where at least a portion of the analyte sensor is in contact with interstitial fluid under the skin surface; and

wherein the assembly is configured such that a force applied by the spring to the shuttle automatically retracts the shuttle and the sharp from the second position and into the insertion device while the end of the base is maintained on the skin surface.

~~11.~~10. The assembly of claim ~~9~~10, further comprising a retention member configured such that the shuttle (134) and the sharp (124) automatically retract upon the shuttle and the sharp reaching a predetermined distalmost position and disengaging from the retention member.

~~12.~~11. The assembly of claim ~~9~~10 or 1~~0~~1, wherein the sensor electronics assembly is configured to engage with at least a portion of the sharp (124) within the insertion device (100) during displacement between the first position and the second position.

~~13.~~12. The assembly of any of claims ~~9~~10 to 11~~12~~, wherein the sensor electronics assembly is configured to activate when the sensor electronics assembly is at or near the second position, optionally when the sensor electronics assembly is positioned on the skin surface (S).

~~14.~~13. The assembly of any of claims ~~9~~10 to 1~~3~~3, ~~further comprising a cap (104) configured to mate with the base (142) of the insertion device (100), optionally~~ wherein when the cap is coupled to the insertion device, the interior space of the insertion device is maintained in a substantially contaminant free environment.

~~15.~~14. The method of any of claims 1 to ~~8~~9, or the assembly of any of claims ~~9~~10 to 1~~3~~4, wherein the analyte sensor (14, 14') comprises a glucose sensor.

~~16.~~15. The method of any of claims 1 to ~~8~~9 and 1~~4~~5, wherein the analyte monitoring assembly comprises an on-body unit (16, 122), the on-body unit comprising an aperture (168) that extends from a top surface of the on-body unit to a bottom surface of the on-body unit; wherein:

the sharp (124) extends through the aperture in the on-body unit when the sharp and the analyte monitoring assembly are in the first position; and

automatically retracting the shuttle (134) and the sharp from the second position withdraws the sharp from the aperture in the on-body unit.

~~17.~~16. The assembly of any of claims ~~9~~10 to 1~~3~~4, wherein the sensor electronics assembly comprises an on-body unit (16, 122), the on-body unit comprising an aperture (168) that extends from a top surface of the on-body unit to a bottom surface of the on-body unit; wherein the assembly is configured such that:

the sharp (124) extends through the aperture in the on-body unit when the sharp and the sensor electronics assembly are in the first position; and

the sharp is withdrawn from the aperture in the on-body unit in the second position.

~~18.~~17. The method of claim 1~~5~~6 or the assembly of claim 1~~6~~7, further comprising a sensor electronics circuit board (80) within the on-body unit (16, 122), the circuit board having an aperture therethrough, and wherein the sharp (124) also extends through the aperture in the circuit board when the sharp is in the first position.

~~19.~~18. The method of any of claims 1 to ~~8~~9, 1~~4~~5, 1~~6~~5 or 1~~7~~8, or the assembly of any of claims ~~9~~10 to 1~~3~~4, 1~~6~~7 or 1~~7~~8, wherein at least a portion of the analyte sensor (14, 14') is positioned within a bore (162) of the sharp (124) when the sharp is in the first position.

~~20.~~19. The method of any of claims 1 to ~~8~~9, 1~~4~~5, 1~~5~~6, 1~~7~~8 or 1~~8~~9, or the assembly of any of claims ~~9~~10 to 1~~3~~4 or 1~~6~~7 to 1~~8~~9, wherein the movement from the first position to the second position is in a direction substantially perpendicular to a skin surface of a user.

Claims:

1. A method of operating an inserter (100) comprising a handle (102), a base (142), a spring (146), a sharp (124), and a shuttle (134), the method comprising:

positioning an end of the base of the inserter on a skin surface (S) of a subject, the inserter containing an analyte monitoring assembly including electronics coupled to an analyte sensor (14, 14') and comprising a power source (82), the electronics operable to communicate analyte data;

prior to positioning the end of the base (142) of the inserter (100), disengaging an end cap (104) from the handle of the inserter to expose the interior of the inserter, the end cap (104) engaged to the handle by one or more threads;

displacing the shuttle, the analyte monitoring assembly and the sharp from a first position within the inserter to a second position where at least a portion (30) of the analyte sensor of the analyte monitoring assembly is in contact with interstitial fluid under the skin surface; and

automatically retracting the shuttle and the sharp from the second position and into the inserter with a force applied by the spring to the shuttle while the end of the base is maintained on the skin surface, and the method further comprising preventing the displacement of the analyte monitoring assembly within the inserter between the first position and the second position when the end cap is engaged with the handle.

2. The method of claim 1, wherein automatically retracting the shuttle (134) and the sharp (124) comprises automatically retracting the shuttle and the sharp upon the sharp reaching a predetermined distalmost position, optionally further comprising disengaging the shuttle from a retention member (194) upon reaching the predetermined position.

3. The method of any preceding claim, further comprising engaging the analyte monitoring assembly with at least a portion of the sharp (124) within the inserter (100) during displacement between the first position and the second position.

4. The method of any preceding claim, wherein the electronics are activated when the analyte monitoring assembly is at or near the second position.

5. The method of any preceding claim, further comprising positioning a portion of the analyte monitoring assembly on a skin surface (S) at the second position, optionally

further comprising activating the analyte monitoring assembly when the portion of the analyte monitoring assembly is positioned on the skin surface.

6. The method of any preceding claim, further comprising providing one or more data associated with a monitored level of an analyte to a remote location (18), optionally, wherein providing the one or more data comprises using one or more of RF communication, infrared communication, Bluetooth communication, Zigbee communication, 802.1x communication, or WiFi communication.

7. The method of claim 6, wherein the remote location (18) includes one or more of a remotely located computing device, a mobile telephone device, a personal digital assistant, or a communication enabled data processing device.

~~8. The method of any preceding claim, further comprising, prior to positioning the end of the base (142) of the inserter (100), disengaging an end cap (104) from the base of the inserter to expose the interior of the inserter.~~

~~9.~~8. The method of any preceding claim, further comprising entirely retaining the sharp (124) within the inserter (100) when the sharp is retracted into the inserter, optionally further comprising engaging the~~an~~ end cap (104) with the handle~~the base (142)~~ of the inserter to enclose the interior of the inserter.

~~10.~~9. An integrated assembly, comprising:

a sensor electronics assembly comprising:

an analyte sensor (14, 14');

a power supply (82); and

a communications circuit for communicating analyte data; and

an insertion device (100), having the sensor electronics assembly therein, and comprising:

a handle (102)

a base (142) for positioning on a skin surface of a subject;

a removable cap (104) configured to mate with the handle by one or more threads;

a sharp (124);

a spring (146); and

a shuttle (134);

wherein the shuttle, the sensor electronics assembly and the sharp are configured to move between a first position entirely within the insertion device and a second position where at least a portion of the analyte sensor is in contact with interstitial fluid under the skin surface; ~~and~~

wherein the assembly is configured such that a force applied by the spring to the shuttle automatically retracts the shuttle and the sharp from the second position and into the insertion device while the end of the base is maintained on the skin surface; and

wherein the removable cap is configured to prevent the movement of the sensor electronics assembly between the first position entirely within the insertion device and the second position when the removable cap is mated with the handle.

~~11.~~10. The assembly of claim 9~~10~~, further comprising a retention member configured such that the shuttle (134) and the sharp (124) automatically retract upon the shuttle and the sharp reaching a predetermined distalmost position and disengaging from the retention member.

~~12.~~11. The assembly of claim 9~~10~~ or 10~~1~~, wherein the sensor electronics assembly is configured to engage with at least a portion of the sharp (124) within the insertion device (100) during displacement between the first position and the second position.

~~13.~~12. The assembly of any of claims 9~~10~~ to 11~~12~~, wherein the sensor electronics assembly is configured to activate when the sensor electronics assembly is at or near the second position, optionally when the sensor electronics assembly is positioned on the skin surface (S).

~~14.~~13. The assembly of any of claims 9~~10~~ to 13~~3~~, ~~further comprising a cap (104) configured to mate with the base (142) of the insertion device (100), optionally~~ wherein when the cap is coupled to the insertion device, the interior space of the insertion device is maintained in a substantially contaminant free environment.

~~15.~~14. The method of any of claims 1 to 8~~9~~, or the assembly of any of claims 9~~10~~ to 13~~4~~, wherein the analyte sensor (14, 14') comprises a glucose sensor.

~~16.~~15. The method of any of claims 1 to 8~~9~~ and 14~~5~~, wherein the analyte monitoring assembly comprises an on-body unit (16, 122), the on-body unit comprising an

aperture (168) that extends from a top surface of the on-body unit to a bottom surface of the on-body unit; wherein:

the sharp (124) extends through the aperture in the on-body unit when the sharp and the analyte monitoring assembly are in the first position; and

automatically retracting the shuttle (134) and the sharp from the second position withdraws the sharp from the aperture in the on-body unit.

~~17.~~16. The assembly of any of claims ~~9~~10 to 1~~3~~4, wherein the sensor electronics assembly comprises an on-body unit (16, 122), the on-body unit comprising an aperture (168) that extends from a top surface of the on-body unit to a bottom surface of the on-body unit; wherein the assembly is configured such that:

the sharp (124) extends through the aperture in the on-body unit when the sharp and the sensor electronics assembly are in the first position; and

the sharp is withdrawn from the aperture in the on-body unit in the second position.

~~18.~~17. The method of claim 1~~5~~6 or the assembly of claim 1~~6~~7, further comprising a sensor electronics circuit board (80) within the on-body unit (16, 122), the circuit board having an aperture therethrough, and wherein the sharp (124) also extends through the aperture in the circuit board when the sharp is in the first position.

~~19.~~18. The method of any of claims 1 to ~~8~~9, 1~~4~~5, 1~~6~~5 or 1~~7~~8, or the assembly of any of claims ~~9~~10 to 1~~3~~4, 1~~6~~7 or 1~~7~~8, wherein at least a portion of the analyte sensor (14, 14') is positioned within a bore (162) of the sharp (124) when the sharp is in the first position.

~~20.~~19. The method of any of claims 1 to ~~8~~9, 1~~4~~5, 1~~5~~6, 1~~7~~8 or 1~~8~~9, or the assembly of any of claims ~~9~~10 to 1~~3~~4 or 1~~6~~7 to 1~~8~~9, wherein the movement from the first position to the second position is in a direction substantially perpendicular to a skin surface of a user.