ANNEX A TO THE STATEMENT OF GROUNDS (EP 044)

EP 044 CONDITIONAL AMENDMENT 1

CLAIMS

1. An integrated analyte monitoring assembly, comprising:

a sensor electronics assembly (110, 1270) including:

an analyte sensor (101, 1020, 1280); and

sensor electronics (102, 1030) including a power supply (660) and comprising:

an activation switch (930) operatively coupled to the power supply (660) and the analyte sensor (101, 1020, 1280); and

a controller unit (950) in electrical contact with the analyte sensor and the activation switch having one or more programming instructions stored therein for execution, the controller unit configured to process one or more signals received from the analyte sensor when the activation switch is triggered; and

an insertion device (1200) including:

a housing (1210);

an introducer needle (1260) coupled to the housing configured to move between a first position and a second position; and

a bias mechanism (1250) operatively coupled to the housing and configured to automatically retract the introducer needle from the second position to a retracted position entirely within the insertion device housing,

wherein the sensor electronics assembly is configured for communication with a remote device (104, 105, 106, 222, 260) and is retained entirely within the housing of the insertion device prior to the introducer needle movement from the first position to the second position, and

wherein the sensor electronics assembly (110, 1270) is engaged with the introducer needle (1260) such that the sensor electronics assembly is moved in the same direction as the introducer needle during its movement from the first position to the second position, and further, wherein the introducer needle is configured to disengage from the sensor electronics assembly during its movement from the second position to the retracted position.

2. The integrated analyte monitoring assembly of claim 1, further comprising a cap (1220) configured to mate with an open end of the housing (1210) of the insertion device

(1200), to seal the sensor electronics assembly (110, 1270) therein, optionally wherein the cap is configured to rotatably couple to the end of the housing.

3. The integrated analyte monitoring assembly of claim 2, wherein when the cap (1220) is coupled to the housing (1210) prior to deployment, the interior space of the housing is maintained in a substantially contaminant free and/or sterile environment.

4. The integrated analyte monitoring assembly of claim 2 or 3, wherein the insertion device (1200) and cap (1220) are configured to be coupled during manufacture and sterilized and packaged together.

~~5. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics assembly (110, 1270) is engaged with the introducer needle (1260) such that the sensor electronics assembly is moved in the same direction as the introducer needle during its movement from the first position to the second position, and further, wherein the introducer needle is configured to disengage from the sensor electronics assembly during its movement from the second position to the retracted position.~~

5. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured such that movement of the introducer needle (1260) from the first position to the second position is in response to at least one of a manual force applied on the housing (1210) and a spring biased force.

6. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured to retain the introducer needle (1260) within the insertion device housing (1210) after the bias mechanism (1250) has automatically retracted the introducer needle from the second position to the retracted position entirely within the insertion device housing.

7. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured such that the bias mechanism (1250) is unbiased prior to the introducer needle (1260) movement from the first position to the second position.

8. The integrated analyte monitoring assembly of any preceding claim, wherein the analyte sensor (101, 1020, 1280) includes a glucose sensor.

9. The integrated analyte monitoring assembly of any preceding claim, wherein the bias mechanism (1250) includes a spring.

10. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics (102, 1030) comprises a data processing component (804) provided on a circuit board (1310) and in signal communication with the analyte sensor (101, 1020, 1280), the data processing component configured to execute one or more routines for processing signals received from the analyte sensor, the data processing component configured to control the transmission of data associated with the processed signals received from the analyte sensor to the remote location, optionally in response to a request signal received from the remote location and/or periodically.

11. The integrated analyte monitoring assembly of claim 11, wherein the data processing component is configured to transmit data to the remote location on-demand from a remote device (104, 105, 106, 222, 260) at the remote location, optionally when the remote device is positioned in close proximity to the sensor electronics (102, 1030).

12. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics assembly (110, 1270) includes a housing (1010), optionally having a height of less than approximately 4 mm.

13. The integrated analyte monitoring assembly of any preceding claim, wherein the activation switch (930) is not triggered until the introducer needle (1260) has reached the second position and/or wherein the activation switch is triggered after the introducer needle has reached the second position, and prior to the introducer needle retraction from the second position to the retracted position.

14. The integrated analyte monitoring assembly of any preceding claim, wherein the assembly is configured such that the movement of the introducer needle (1260) between the

first position and the second position is in a direction substantially perpendicular to a skin surface of a user.

CLAIMS

1. An integrated analyte monitoring assembly, comprising:

a sensor electronics assembly (110, 1270) including:

an analyte sensor (101, 1020, 1280); and

sensor electronics (102, 1030) including a power supply (660) and comprising:

an activation switch (930) operatively coupled to the power supply (660) and the analyte sensor (101, 1020, 1280); and

a controller unit (950) in electrical contact with the analyte sensor and the activation switch having one or more programming instructions stored therein for execution, the controller unit configured to process one or more signals received from the analyte sensor when the activation switch is triggered; and

an insertion device (1200) including:

a housing (1210);

an introducer needle (1260) coupled to the housing configured to move between a first position and a second position; and

a bias mechanism (1250) operatively coupled to the housing and configured to automatically retract the introducer needle from the second position to a retracted position entirely within the insertion device housing,

wherein the sensor electronics assembly is configured for communication with a remote device (104, 105, 106, 222, 260) and is retained entirely within the housing of the insertion device prior to the introducer needle movement from the first position to the second position, and

wherein the insertion device is configured such that, when the introducer needle (1260) is in the retracted position entirely within the insertion device housing, the insertion device (1200) is removable from the skin surface while the sensor electronics assembly (110, 1270) is retained on the skin surface and the analyte sensor is maintained in fluid contact with an analyte under the skin surface.

2. The integrated analyte monitoring assembly of claim 1, further comprising a cap (1220) configured to mate with an open end of the housing (1210) of the insertion device

(1200), to seal the sensor electronics assembly (110, 1270) therein, optionally wherein the cap is configured to rotatably couple to the end of the housing.

3. The integrated analyte monitoring assembly of claim 2, wherein when the cap (1220) is coupled to the housing (1210) prior to deployment, the interior space of the housing is maintained in a substantially contaminant free and/or sterile environment.

4. The integrated analyte monitoring assembly of claim 2 or 3, wherein the insertion device (1200) and cap (1220) are configured to be coupled during manufacture and sterilized and packaged together.

5. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics assembly (110, 1270) is engaged with the introducer needle (1260) such that the sensor electronics assembly is moved in the same direction as the introducer needle during its movement from the first position to the second position, and further, wherein the introducer needle is configured to disengage from the sensor electronics assembly during its movement from the second position to the retracted position.

6. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured such that movement of the introducer needle (1260) from the first position to the second position is in response to at least one of a manual force applied on the housing (1210) and a spring biased force.

7. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured to retain the introducer needle (1260) within the insertion device housing (1210) after the bias mechanism (1250) has automatically retracted the introducer needle from the second position to the retracted position entirely within the insertion device housing.

8. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured such that the bias mechanism (1250) is unbiased prior to the introducer needle (1260) movement from the first position to the second position.

9. The integrated analyte monitoring assembly of any preceding claim, wherein the analyte sensor (101, 1020, 1280) includes a glucose sensor.

10. The integrated analyte monitoring assembly of any preceding claim, wherein the bias mechanism (1250) includes a spring.

11. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics (102, 1030) comprises a data processing component (804) provided on a circuit board (1310) and in signal communication with the analyte sensor (101, 1020, 1280), the data processing component configured to execute one or more routines for processing signals received from the analyte sensor, the data processing component configured to control the transmission of data associated with the processed signals received from the analyte sensor to the remote location, optionally in response to a request signal received from the remote location and/or periodically.

12. The integrated analyte monitoring assembly of claim 11, wherein the data processing component is configured to transmit data to the remote location on-demand from a remote device (104, 105, 106, 222, 260) at the remote location, optionally when the remote device is positioned in close proximity to the sensor electronics (102, 1030).

13. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics assembly (110, 1270) includes a housing (1010), optionally having a height of less than approximately 4 mm.

14. The integrated analyte monitoring assembly of any preceding claim, wherein the activation switch (930) is not triggered until the introducer needle (1260) has reached the second position and/or wherein the activation switch is triggered after the introducer needle has reached the second position, and prior to the introducer needle retraction from the second position to the retracted position.

15. The integrated analyte monitoring assembly of any preceding claim, wherein the assembly is configured such that the movement of the introducer needle (1260) between the

first position and the second position is in a direction substantially perpendicular to a skin surface of a user.

CLAIMS

1. An integrated analyte monitoring assembly, comprising:

a sensor electronics assembly (110, 1270) including:

an analyte sensor (101, 1020, 1280); and

sensor electronics (102, 1030) including a power supply (660) and comprising:

an activation switch (930) operatively coupled to the power supply (660) and the analyte sensor (101, 1020, 1280); and

a controller unit (950) in electrical contact with the analyte sensor and the activation switch having one or more programming instructions stored therein for execution, the controller unit configured to process one or more signals received from the analyte sensor when the activation switch is triggered; and

an insertion device (1200) including:

a housing (1210);

an introducer needle (1260) coupled to the housing configured to move between a first position and a second position; and

a bias mechanism (1250) operatively coupled to the housing and configured to automatically retract the introducer needle from the second position to a retracted position entirely within the insertion device housing,

wherein the sensor electronics assembly is configured for communication with a remote device (104, 105, 106, 222, 260) and is retained entirely within the housing of the insertion device prior to the introducer needle movement from the first position to the second position;

wherein the sensor electronics assembly (110, 1270) is engaged with the introducer needle (1260) such that the sensor electronics assembly is moved in the same direction as the introducer needle during its movement from the first position to the second position, and further, wherein the introducer needle is configured to disengage from the sensor electronics assembly during its movement from the second position to the retracted position; and

wherein the insertion device is configured such that, when the introducer needle (1260) is in the retracted position entirely within the insertion device housing, the insertion device (1200) is removable from the skin surface while the sensor electronics assembly (110,

1270) is retained on the skin surface and the analyte sensor is maintained in fluid contact with an analyte under the skin surface.

2. The integrated analyte monitoring assembly of claim 1, further comprising a cap (1220) configured to mate with an open end of the housing (1210) of the insertion device (1200), to seal the sensor electronics assembly (110, 1270) therein, optionally wherein the cap is configured to rotatably couple to the end of the housing.

3. The integrated analyte monitoring assembly of claim 2, wherein when the cap (1220) is coupled to the housing (1210) prior to deployment, the interior space of the housing is maintained in a substantially contaminant free and/or sterile environment.

4. The integrated analyte monitoring assembly of claim 2 or 3, wherein the insertion device (1200) and cap (1220) are configured to be coupled during manufacture and sterilized and packaged together.

~~5. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics assembly (110, 1270) is engaged with the introducer needle (1260) such that the sensor electronics assembly is moved in the same direction as the introducer needle during its movement from the first position to the second position, and further, wherein the introducer needle is configured to disengage from the sensor electronics assembly during its movement from the second position to the retracted position.~~

5. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured such that movement of the introducer needle (1260) from the first position to the second position is in response to at least one of a manual force applied on the housing (1210) and a spring biased force.

6. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured to retain the introducer needle (1260) within the insertion device housing (1210) after the bias mechanism (1250) has automatically retracted the introducer needle from the second position to the retracted position entirely within the insertion device housing.

7. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured such that the bias mechanism (1250) is unbiased prior to the introducer needle (1260) movement from the first position to the second position.

8. The integrated analyte monitoring assembly of any preceding claim, wherein the analyte sensor (101, 1020, 1280) includes a glucose sensor.

9. The integrated analyte monitoring assembly of any preceding claim, wherein the bias mechanism (1250) includes a spring.

10. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics (102, 1030) comprises a data processing component (804) provided on a circuit board (1310) and in signal communication with the analyte sensor (101, 1020, 1280), the data processing component configured to execute one or more routines for processing signals received from the analyte sensor, the data processing component configured to control the transmission of data associated with the processed signals received from the analyte sensor to the remote location, optionally in response to a request signal received from the remote location and/or periodically.

11. The integrated analyte monitoring assembly of claim 11, wherein the data processing component is configured to transmit data to the remote location on-demand from a remote device (104, 105, 106, 222, 260) at the remote location, optionally when the remote device is positioned in close proximity to the sensor electronics (102, 1030).

12. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics assembly (110, 1270) includes a housing (1010), optionally having a height of less than approximately 4 mm.

13. The integrated analyte monitoring assembly of any preceding claim, wherein the activation switch (930) is not triggered until the introducer needle (1260) has reached the second position and/or wherein the activation switch is triggered after the introducer needle

has reached the second position, and prior to the introducer needle retraction from the second position to the retracted position.

14. The integrated analyte monitoring assembly of any preceding claim, wherein the assembly is configured such that the movement of the introducer needle (1260) between the first position and the second position is in a direction substantially perpendicular to a skin surface of a user.

CLAIMS

1. An integrated analyte monitoring assembly, comprising:

a sensor electronics assembly (110, 1270) including:

an analyte sensor (101, 1020, 1280); and

sensor electronics (102, 1030) including a power supply (660) and comprising:

an activation switch (930) operatively coupled to the power supply (660) and the analyte sensor (101, 1020, 1280); and

a controller unit (950) in electrical contact with the analyte sensor and the activation switch having one or more programming instructions stored therein for execution, the controller unit configured to process one or more signals received from the analyte sensor when the activation switch is triggered; and

an insertion device (1200) including:

a housing (1210);

an introducer needle (1260) coupled to the housing configured to move between a first position and a second position; and

a bias mechanism (1250) operatively coupled to the housing and configured to automatically retract the introducer needle from the second position to a retracted position entirely within the insertion device housing,

wherein the sensor electronics assembly is configured for communication with a remote device (104, 105, 106, 222, 260) and is retained entirely within the housing of the insertion device prior to the introducer needle movement from the first position to the second position, and

wherein the activation switch is configured to be triggered semi-automatically in response to activation of the insertion device.

2. The integrated analyte monitoring assembly of claim 1, further comprising a cap (1220) configured to mate with an open end of the housing (1210) of the insertion device (1200), to seal the sensor electronics assembly (110, 1270) therein, optionally wherein the cap is configured to rotatably couple to the end of the housing.

3. The integrated analyte monitoring assembly of claim 2, wherein when the cap (1220) is coupled to the housing (1210) prior to deployment, the interior space of the housing is maintained in a substantially contaminant free and/or sterile environment.

4. The integrated analyte monitoring assembly of claim 2 or 3, wherein the insertion device (1200) and cap (1220) are configured to be coupled during manufacture and sterilized and packaged together.

5. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics assembly (110, 1270) is engaged with the introducer needle (1260) such that the sensor electronics assembly is moved in the same direction as the introducer needle during its movement from the first position to the second position, and further, wherein the introducer needle is configured to disengage from the sensor electronics assembly during its movement from the second position to the retracted position.

6. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured such that movement of the introducer needle (1260) from the first position to the second position is in response to at least one of a manual force applied on the housing (1210) and a spring biased force.

7. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured to retain the introducer needle (1260) within the insertion device housing (1210) after the bias mechanism (1250) has automatically retracted the introducer needle from the second position to the retracted position entirely within the insertion device housing.

8. The integrated analyte monitoring assembly of any preceding claim, wherein the insertion device (1200) is configured such that the bias mechanism (1250) is unbiased prior to the introducer needle (1260) movement from the first position to the second position.

9. The integrated analyte monitoring assembly of any preceding claim, wherein the analyte sensor (101, 1020, 1280) includes a glucose sensor.

10. The integrated analyte monitoring assembly of any preceding claim, wherein the bias mechanism (1250) includes a spring.

11. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics (102, 1030) comprises a data processing component (804) provided on a circuit board (1310) and in signal communication with the analyte sensor (101, 1020, 1280), the data processing component configured to execute one or more routines for processing signals received from the analyte sensor, the data processing component configured to control the transmission of data associated with the processed signals received from the analyte sensor to the remote location, optionally in response to a request signal received from the remote location and/or periodically.

12. The integrated analyte monitoring assembly of claim 11, wherein the data processing component is configured to transmit data to the remote location on-demand from a remote device (104, 105, 106, 222, 260) at the remote location, optionally when the remote device is positioned in close proximity to the sensor electronics (102, 1030).

13. The integrated analyte monitoring assembly of any preceding claim, wherein the sensor electronics assembly (110, 1270) includes a housing (1010), optionally having a height of less than approximately 4 mm.

14. The integrated analyte monitoring assembly of any preceding claim, wherein the activation switch (930) is not triggered until the introducer needle (1260) has reached the second position and/or wherein the activation switch is triggered after the introducer needle has reached the second position, and prior to the introducer needle retraction from the second position to the retracted position.

15. The integrated analyte monitoring assembly of any preceding claim, wherein the assembly is configured such that the movement of the introducer needle (1260) between the first position and the second position is in a direction substantially perpendicular to a skin surface of a user.