ANNEX A TO THE STATEMENT OF GROUNDS (EP 418)

EP 418 CONDITIONAL AMENDMENT 1

CLAIMS

1. An integrated analyte monitoring device assembly (110, 211), comprising:

an analyte sensor (101, 250, 540, 1020) for transcutaneous positioning through a skin layer (210) and maintained in fluid contact with an interstitial fluid under the skin layer during a predetermined time period, the analyte sensor having a proximal portion and a distal portion;

an insertion device (1200); and

sensor electronics (102, 1030) coupled to the analyte sensor, the sensor electronics comprising:

a circuit board (1310) having a conductive layer (801) and a sensor antenna disposed on the conductive layer;

one or more electrical contacts (1360) provided on the circuit board and coupled with the proximal portion of the analyte sensor to maintain continuous electrical communication; and

a data processing component (610, 950) including an application specific integrated circuit (ASIC) provided on the circuit board and in signal communication with the analyte sensor, the data processing component configured to execute one or more routines for processing analyte related signals received from the analyte sensor, the data processing component configured to control the transmission of the data associated with the analyte related signals received from the analyte sensor to a remote location (220) using the sensor antenna only in response to a request signal received from the remote location;

wherein:

the analyte sensor is coupled with the sensor electronics and provided to the user within an on-body housing (1010) prior to positioning the distal portion of the analyte sensor through the skin layer, the on-body housing being configured for positioning on the skin layer; and

the coupled analyte sensor and sensor electronics are positioned entirely within an insertion device housing (1210) of the insertion device (1200) prior to positioning the distal portion of the analyte sensor through the skin layer.

2. The assembly (110, 211) of claim 1 wherein the proximal portion of the analyte sensor (101, 250, 540) and the circuit board (1310) are encapsulated.

3. The assembly (110, 211) of claim 2 wherein the proximal portion of the analyte sensor (101, 250, 540, 1020) and the circuit board (1310) are encapsulated with a potting material.

4. The assembly (110, 211) of claim 1 wherein the circuit board (1310) includes an upper layer and a lower layer, where the conductive layer (801) is disposed between the upper layer and the lower layer

5. The assembly (110, 211) of claim 1 wherein the antenna includes a loop antenna or a dipole antenna.

6. The assembly (110, 211) of claim 1 including a power supply (1120) to provide power to the sensor electronics.

7. The assembly (110, 211) of claim 1 wherein the data processing component includes a state machine.

8. The assembly (110, 211) of claim 7 wherein the state machine is configured to execute one or more programmed or programmable logic for processing the signals data associated with the analyte related signals received from the analyte sensor (101, 250, 540, 1020).

9. The assembly (110, 211) of claim 1 wherein the data processing component (610, 950) is configured to transition from an inactive state to an active state upon detection of RF power from the remote location (220), and wherein the request signal for the data associated with the analyte related signals received from the remote location includes a radio frequency (RF) control signal.

10. The assembly (110, 211) of claim 9 wherein the RF power and the RF control signal are both received on a same carrier signal from the remote location (220).

11. The assembly (110, 211) of claim 10 wherein the sensor antenna is tuned such that when the data processing component (610, 950) transitions from the inactive state to the active state upon detection of the RF power from the remote location (220), the data

associated with the analyte related signals is transmitted as a reflected backscatter signal to the remote location.

12. The assembly (110, 211) of claim 1 wherein the analyte sensor (101, 250, 540, 1020) includes a bent configuration, whereby at least the proximal portion of the body of the analyte sensor is maintained in a direction substantially planar to the surface of the skin.

CLAIMS

1. An integrated analyte monitoring device assembly (110, 211), comprising:

an analyte sensor (101, 250, 540, 1020) for transcutaneous positioning through a skin layer (210) and maintained in fluid contact with an interstitial fluid under the skin layer during a predetermined time period, the analyte sensor having a proximal portion and a distal portion;

an insertion device (1200); and

sensor electronics (102, 1030) coupled to the analyte sensor, the sensor electronics comprising:

a circuit board (1310) having a conductive layer (801) and a sensor antenna disposed on the conductive layer;

one or more electrical contacts (1360) provided on the circuit board and coupled with the proximal portion of the analyte sensor to maintain continuous electrical communication; and

a data processing component (610, 950) including an application specific integrated circuit (ASIC) provided on the circuit board and in signal communication with the analyte sensor, the data processing component configured to execute one or more routines for processing analyte related signals received from the analyte sensor, the data processing component configured to control the transmission of the data associated with the analyte related signals received from the analyte sensor to a remote location (220) using the sensor antenna only in response to a request signal received from the remote location;

wherein:

the analyte sensor is coupled with the sensor electronics and provided to the user within an on-body housing (1010) prior to positioning the distal portion of the analyte sensor through the skin layer, the on-body housing being configured for positioning on the skin layer;

the coupled analyte sensor and sensor electronics are positioned at a first position entirely within an insertion device housing (1210) of the insertion device (1200) prior to positioning the distal portion of the analyte sensor through the skin layer; and

the insertion device is configured to move the coupled analyte sensor and sensor electronics in a direction substantially perpendicular to the skin layer to a second, inserted position.

2. The assembly (110, 211) of claim 1 wherein the proximal portion of the analyte sensor (101, 250, 540) and the circuit board (1310) are encapsulated.

3. The assembly (110, 211) of claim 2 wherein the proximal portion of the analyte sensor (101, 250, 540, 1020) and the circuit board (1310) are encapsulated with a potting material.

4. The assembly (110, 211) of claim 1 wherein the circuit board (1310) includes an upper layer and a lower layer, where the conductive layer (801) is disposed between the upper layer and the lower layer

5. The assembly (110, 211) of claim 1 wherein the antenna includes a loop antenna or a dipole antenna.

6. The assembly (110, 211) of claim 1 including a power supply (1120) to provide power to the sensor electronics.

7. The assembly (110, 211) of claim 1 wherein the data processing component includes a state machine.

8. The assembly (110, 211) of claim 7 wherein the state machine is configured to execute one or more programmed or programmable logic for processing the signals data associated with the analyte related signals received from the analyte sensor (101, 250, 540, 1020).

9. The assembly (110, 211) of claim 1 wherein the data processing component (610, 950) is configured to transition from an inactive state to an active state upon detection of RF power from the remote location (220), and wherein the request signal for the data associated with the analyte related signals received from the remote location includes a radio frequency (RF) control signal.

10. The assembly (110, 211) of claim 9 wherein the RF power and the RF control signal are both received on a same carrier signal from the remote location (220).

11. The assembly (110, 211) of claim 10 wherein the sensor antenna is tuned such that when the data processing component (610, 950) transitions from the inactive state to the active state upon detection of the RF power from the remote location (220), the data associated with the analyte related signals is transmitted as a reflected backscatter signal to the remote location.

12. The assembly (110, 211) of claim 1 wherein the analyte sensor (101, 250, 540, 1020) includes a bent configuration, whereby at least the proximal portion of the body of the analyte sensor is maintained in a direction substantially planar to the surface of the skin.

CLAIMS

1. An integrated analyte monitoring device assembly (110, 211), comprising:

an analyte sensor (101, 250, 540, 1020) for transcutaneous positioning through a skin layer (210) and maintained in fluid contact with an interstitial fluid under the skin layer during a predetermined time period, the analyte sensor having a proximal portion and a distal portion;

an insertion device (1200) comprising an insertion device housing (1210) and an introducer (1260) coupled to the insertion device housing, the introducer configured to move in a direction substantially perpendicular to the skin layer between a first position and a second position; and

sensor electronics (102, 1030) coupled to the analyte sensor, the sensor electronics comprising:

a circuit board (1310) having a conductive layer (801) and a sensor antenna disposed on the conductive layer;

one or more electrical contacts (1360) provided on the circuit board and coupled with the proximal portion of the analyte sensor to maintain continuous electrical communication; and

a data processing component (610, 950) including an application specific integrated circuit (ASIC) provided on the circuit board and in signal communication with the analyte sensor, the data processing component configured to execute one or more routines for processing analyte related signals received from the analyte sensor, the data processing component configured to control the transmission of the data associated with the analyte related signals received from the analyte sensor to a remote location (220) using the sensor antenna only in response to a request signal received from the remote location;

wherein:

the analyte sensor is coupled with the sensor electronics and provided to the user within an on-body housing (1010) prior to positioning the distal portion of the analyte sensor through the skin layer, the on-body housing being configured for positioning on the skin layer;

the coupled analyte sensor and sensor electronics are positioned entirely within the insertion device housing (1210) prior to positioning the distal portion of the analyte sensor through the skin layer; and

the insertion device is further configured such that the coupled analyte sensor and sensor electronics are configured to move in the same direction as the introducer along with the movement of the introducer to position the on-body unit on the skin layer.

2. The assembly (110, 211) of claim 1 wherein the proximal portion of the analyte sensor (101, 250, 540) and the circuit board (1310) are encapsulated.

3. The assembly (110, 211) of claim 2 wherein the proximal portion of the analyte sensor (101, 250, 540, 1020) and the circuit board (1310) are encapsulated with a potting material.

4. The assembly (110, 211) of claim 1 wherein the circuit board (1310) includes an upper layer and a lower layer, where the conductive layer (801) is disposed between the upper layer and the lower layer

5. The assembly (110, 211) of claim 1 wherein the antenna includes a loop antenna or a dipole antenna.

6. The assembly (110, 211) of claim 1 including a power supply (1120) to provide power to the sensor electronics.

7. The assembly (110, 211) of claim 1 wherein the data processing component includes a state machine.

8. The assembly (110, 211) of claim 7 wherein the state machine is configured to execute one or more programmed or programmable logic for processing the signals data associated with the analyte related signals received from the analyte sensor (101, 250, 540, 1020).

9. The assembly (110, 211) of claim 1 wherein the data processing component (610, 950) is configured to transition from an inactive state to an active state upon detection of RF power from the remote location (220), and wherein the request signal for the data associated with the analyte related signals received from the remote location includes a radio frequency (RF) control signal.

10. The assembly (110, 211) of claim 9 wherein the RF power and the RF control signal are both received on a same carrier signal from the remote location (220).

11. The assembly (110, 211) of claim 10 wherein the sensor antenna is tuned such that when the data processing component (610, 950) transitions from the inactive state to the active state upon detection of the RF power from the remote location (220), the data associated with the analyte related signals is transmitted as a reflected backscatter signal to the remote location.

12. The assembly (110, 211) of claim 1 wherein the analyte sensor (101, 250, 540, 1020) includes a bent configuration, whereby at least the proximal portion of the body of the analyte sensor is maintained in a direction substantially planar to the surface of the skin.