ANNEX A TO THE STATEMENT OF GROUNDS (EP 918)

EP 918 CONDITIONAL AMENDMENT 1

CLAIMS

1. An apparatus (200) (300) (400) (2400) (2500) (2700) (3700) for inserting an integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ (14) into the skin of a subject, which comprises:

a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface for placement on a skin surface;

a device support (430) (3702) movable between a proximal position and a distal position that is closer to the skin surface, and adapted to support an integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~;

a sharp support movable between the proximal position and the distal position that is closer to the skin surface and adapted to support a sharp (224) (324) (424) (2404) (2550) for inserting a portion of the in vivo analyte sensor of the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ under the skin surface and extending through a portion of the device support;

a handle (302) (402) (2502) (2702) (3702) movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from the proximal position to the distal position to insert the sharp under the skin surface; and

a driver (246) (346) (446) (2406) (2544) for advancing the sharp support towards the proximal position when the sharp support reaches the distal position;
wherein the device support (430) (3702) includes a first engagement member (474) (475) for releasably coupling the device support to the sharp support (428) (434) (436) and a second engagement member (3727) (3732) for engaging the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~;

~~and further characterised in that~~ wherein: the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726); and

advancing the handle (302) (402) (2502) (2702) (3702) from the proximal position to the distal position comprises applying a minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and a force applied to the handle moves the sheath into the handle and moves the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ from the proximal position to the distal position and inserts the sharp and the portion of the in vivo analyte sensor under the skin surface.

ANNEX A TO THE STATEMENT OF GROUNDS (EP 918)

EP 918 CONDITIONAL AMENDMENT 1

2. The apparatus of claim 1, wherein the handle and sheath comprise an interlocking configuration (328) (351) which prevents relative movement of the handle with respect to the sheath which is overcome by a force applied to the handle.

3. The apparatus of claim 1 or 2, wherein the second engagement member (3727) (3732) comprises one or more movable arms (3732) for engaging the integrated in vivo analyte sensor and on-body electronics assembly ~~device~~ (14), preferably wherein the one or more movable arms are normally biased in a position spaced apart from the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~.

4. The apparatus of claim 3, wherein the one or more movable arms (3732) are maintained in engagement with the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) when the device support (430) (3702) is in the proximal position, or wherein the one or more movable arms are permitted to return to the configuration spaced apart from the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ when the device support is in the distal position.

5. The apparatus of any of the preceding claims 1-4, wherein the first engagement member (474) (475) is released from the sharp support (428) (434) (436) when the device support (430) (3702) reaches a distal position, preferably wherein the first engagement member is maintained in engagement with the sharp support by a portion of the sheath (242) (342) (442) (2512) (2708) (3708).

6. The apparatus of any of the preceding claims 1-5, further comprising a stop to maintain the device support (430) (3702) in the proximal position such that it protects the user from accessing the retracted sharp (224) (324) (424) (2404) (2550).

~~7. The apparatus of any of the preceding claims, wherein the medical device (14) is an analyte sensor.~~

~~7~~8. A method for using an integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) comprising:

providing an apparatus comprising a sheath (242) (342) (442) (2512) (2708)

(3708) defining a distal surface, a device support (430) (3702) adapted to support an integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14), a sharp support (428) (434) (436) adapted to support a sharp (224) (324) (424) (2404) (2550) extending through a portion of the device support, a handle (302) (402) (2502) (2702) (3702) movable relative to the sheath, and a driver (246) (346) (446) (2406) (2544) for displacing the sharp support;

disposing the distal surface of the sheath on a skin surface (S);

displacing the handle in a first longitudinal direction such that the sheath moves into the handle;

displacing the sharp support in the first longitudinal direction, the sharp support displacing the sharp and the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~;

inserting the sharp and a portion of the in vivo analyte sensor of the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ under the skin surface;

releasing the driver; and

displacing the sharp in a second longitudinal direction by the driver;

~~characterised in that~~ wherein:

the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726); and

displacing the handle (302) (402) (2502) (2702) (3702) in the first longitudinal direction comprises applying a minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and displacing the handle in the first longitudinal direction displaces the device support in the first longitudinal direction and inserts the sharp and the portion of the in vivo analyte sensor of the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ under the skin surface.

~~89~~. The method of claim ~~78~~, having one or more of the following:

wherein the first longitudinal direction is from a proximal to distal position, and the second longitudinal direction is from a distal to proximal position,

wherein the sharp (224) (324) (424) (2404) (2550) is displaced towards the proximal direction when the sharp support (428) (434) (436) reaches the distal position,

wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support is displaced to the proximal position,

wherein displacing the handle in the first longitudinal direction comprises overcoming an interlocking configuration between the handle and the sheath (242) (342) (442) (2512) (2708) (3708) by applying a predetermined force.

910. The method of claims 78 or 89, wherein delivering the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) to the subject comprises releasing the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ from the device support (430) (3702), preferably wherein releasing the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ from the device support comprises allowing one or more movable arms (3762) (3762') on the device support to displace radially outwardly.

1011. The apparatus of claim 1, wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support (428) (434) (436) is advanced to the proximal position.

1112. The apparatus of claim 5, wherein the first engagement member is released from the sharp support when the device support reaches the distal position for a now proximal movement of the sharp support and sharp relative to the device support.

EP 918 CONDITIONAL AMENDMENT 2

CLAIMS

1. An apparatus (200) (300) (400) (2400) (2500) (2700) (3700) for inserting an integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ (14) into the skin of a subject, which comprises:

a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface for placement on a skin surface;

a device support (430) (3702) movable between a proximal position and a distal position that is closer to the skin surface, and adapted to support an integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~;

a sharp support movable between the proximal position and the distal position that is closer to the skin surface and adapted to support a sharp (224) (324) (424) (2404) (2550) for inserting a portion of the in vivo analyte sensor of the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ under the skin surface and extending through a portion of the device support;

a handle (302) (402) (2502) (2702) (3702) movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from the proximal position to the distal position to insert the sharp under the skin surface; and

a driver (246) (346) (446) (2406) (2544) for advancing the sharp support towards the proximal position when the sharp support reaches the distal position;

wherein the device support (430) (3702) includes a first engagement member (474) (475) for releasably coupling the device support to the sharp support (428) (434) (436) and a second engagement member (3727) (3732) for engaging the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~;

~~and further characterised in that~~ wherein: the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726);

advancing the handle (302) (402) (2502) (2702) (3702) from the proximal position to the distal position comprises applying a minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and a force applied to the handle moves the sheath into the handle and moves the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ from the proximal position to the distal position and inserts the sharp and the portion of the in vivo analyte sensor under the skin surface; and

the apparatus is configured to activate the on-body electronics of the integrated in vivo analyte sensor on-body electronics assembly.

2. The apparatus of claim 1, wherein the handle and sheath comprise an interlocking configuration (328) (351) which prevents relative movement of the handle with respect to the sheath which is overcome by a force applied to the handle.

3. The apparatus of claim 1 or 2, wherein the second engagement member (3727) (3732) comprises one or more movable arms (3732) for engaging the integrated in vivo analyte sensor and on-body electronics assembly ~~device~~ (14), preferably wherein the one or more movable arms are normally biased in a position spaced apart from the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~.

4. The apparatus of claim 3, wherein the one or more movable arms (3732) are maintained in engagement with the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) when the device support (430) (3702) is in the proximal position, or wherein the one or more movable arms are permitted to return to the configuration spaced apart from the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ when the device support is in the distal position.

5. The apparatus of any of the preceding claims 1-4, wherein the first engagement member (474) (475) is released from the sharp support (428) (434) (436) when the device support (430) (3702) reaches a distal position, preferably wherein the first engagement member is maintained in engagement with the sharp support by a portion of the sheath (242) (342) (442) (2512) (2708) (3708).

6. The apparatus of any of the preceding claims 1-5, further comprising a stop to maintain the device support (430) (3702) in the proximal position such that it protects the user from accessing the retracted sharp (224) (324) (424) (2404) (2550).

~~7. The apparatus of any of the preceding claims, wherein the medical device (14) is an analyte sensor.~~

78. A method for using an integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) comprising:

providing an apparatus comprising a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface, a device support (430) (3702) adapted to support an integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14), a sharp support (428) (434) (436) adapted to support a sharp (224) (324) (424) (2404) (2550) extending through a portion of the device support, a handle (302) (402) (2502) (2702) (3702) movable relative to the sheath, and a driver (246) (346) (446) (2406) (2544) for displacing the sharp support;

disposing the distal surface of the sheath on a skin surface (S);

displacing the handle in a first longitudinal direction such that the sheath moves into the handle;

displacing the sharp support in the first longitudinal direction, the sharp support displacing the sharp and the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~;

inserting the sharp and a portion of the in vivo analyte sensor of the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ under the skin surface;

releasing the driver; and

displacing the sharp in a second longitudinal direction by the driver;

~~characterised in that~~ wherein:

the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726); ~~and~~

displacing the handle (302) (402) (2502) (2702) (3702) in the first longitudinal direction comprises applying a minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and displacing the handle in the first longitudinal direction displaces the device support in the first longitudinal direction and inserts the sharp and the portion of the in vivo analyte sensor of the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ under the skin surface; and

the method further comprises activating the on-body electronics of the integrated in vivo analyte sensor and on-body electronics assembly by the apparatus.

89. The method of claim 78, having one or more of the following:

wherein the first longitudinal direction is from a proximal to distal position, and the second longitudinal direction is from a distal to proximal position,

wherein the sharp (224) (324) (424) (2404) (2550) is displaced towards the proximal direction when the sharp support (428) (434) (436) reaches the distal position,

wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support is displaced to the proximal position,

wherein displacing the handle in the first longitudinal direction comprises overcoming an interlocking configuration between the handle and the sheath (242) (342) (442) (2512) (2708) (3708) by applying a predetermined force.

910. The method of claims 78 or 89, wherein delivering the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) to the subject comprises releasing the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ from the device support (430) (3702), preferably wherein releasing the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ from the device support comprises allowing one or more movable arms (3762) (3762') on the device support to displace radially outwardly.

1011. The apparatus of claim 1, wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support (428) (434) (436) is advanced to the proximal position.

1112. The apparatus of claim 5, wherein the first engagement member is released from the sharp support when the device support reaches the distal position for a now proximal movement of the sharp support and sharp relative to the device support.

EP 918 CONDITIONAL AMENDMENT 3

CLAIMS

1. An apparatus (200) (300) (400) (2400) (2500) (2700) (3700) for inserting a medical device (14) into the skin of a subject, which comprises:

a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface for placement on a skin surface;

a device support (430) (3702) movable between a proximal position and a distal position that is closer to the skin surface, and adapted to support a medical device;

a sharp support movable between the proximal position and the distal position that is closer to the skin surface and adapted to support a sharp (224) (324) (424) (2404) (2550) for inserting the medical device under the skin surface and extending through a portion of the device support;

a handle (302) (402) (2502) (2702) (3702) movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from the proximal position to the distal position to insert the sharp under the skin surface; and

a driver (246) (346) (446) (2406) (2544) for advancing the sharp support towards the proximal position when the sharp support reaches the distal position;

wherein the device support (430) (3702) includes a first engagement member (474) (475) for releasably coupling the device support to the sharp support (428) (434) (436) and a second engagement member (3727) (3732) for engaging the medical device;

and further characterised in that the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726) that is a part of the sheath and that is biased against the handle and that is configured to prevent the handle from moving relative to the sheath until a minimum force has been applied in a distal direction to the handle; and

advancing the handle (302) (402) (2502) (2702) (3702) from the proximal position to the distal position comprises applying a the minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and a force applied to the handle moves the sheath into the handle and moves the medical device from the proximal position to the distal position and inserts the sharp under the skin surface.

2. The apparatus of claim 1, wherein the handle and sheath comprise an interlocking configuration (328) (351) which prevents relative movement of the handle with respect to the sheath which is overcome by a force applied to the handle.

3. The apparatus of claim 1 or 2, wherein the second engagement member (3727) (3732) comprises one or more movable arms (3732) for engaging the device (14), preferably wherein the one or more movable arms are normally biased in a position spaced apart from the medical device.

4. The apparatus of claim 3, wherein the one or more movable arms (3732) are maintained in engagement with the medical device (14) when the device support (430) (3702) is in the proximal position, or wherein the one or more movable arms are permitted to return to the configuration spaced apart from the medical device when the device support is in the distal position.

5. The apparatus of any of the preceding claims 1-4, wherein the first engagement member (474) (475) is released from the sharp support (428) (434) (436) when the device support (430) (3702) reaches a distal position, preferably wherein the first engagement member is maintained in engagement with the sharp support by a portion of the sheath (242) (342) (442) (2512) (2708) (3708).

6. The apparatus of any of the preceding claims 1-5, further comprising a stop to maintain the device support (430) (3702) in the proximal position such that it protects the user from accessing the retracted sharp (224) (324) (424) (2404) (2550).

7. The apparatus of any of the preceding claims, wherein the medical device (14) is an analyte sensor.

8. A method for using a medical device (14) comprising:

providing an apparatus comprising a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface, a device support (430) (3702) adapted to support a medical device (14), a sharp support (428) (434) (436) adapted to support a sharp (224) (324) (424) (2404) (2550) extending through a portion of the device support, a handle (302) (402) (2502) (2702) (3702) movable relative to the sheath, and a driver (246) (346)

(446) (2406) (2544) for displacing the sharp support;

disposing the distal surface of the sheath on a skin surface (S);

displacing the handle in a first longitudinal direction such that the sheath moves into the handle;

displacing the sharp support in the first longitudinal direction, the sharp support displacing the sharp and the medical device;

inserting the sharp and the medical device under the skin surface;

releasing the driver; and

displacing the sharp in a second longitudinal direction by the driver;

characterised in that the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726) that is a part of the sheath and that is biased against the handle and that is configured to prevent the handle from moving relative to the sheath until a minimum force has been applied in a distal direction to the handle; and displacing the handle (302) (402) (2502) (2702) (3702) in the first longitudinal direction comprises applying ~~a~~ the minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and displacing the handle in the first longitudinal direction displaces the device support in the first longitudinal direction and inserts the sharp and the medical device under the skin surface.

9. The method of claim 8, having one or more of the following:

wherein the first longitudinal direction is from a proximal to distal position, and the second longitudinal direction is from a distal to proximal position,

wherein the sharp (224) (324) (424) (2404) (2550) is displaced towards the proximal direction when the sharp support (428) (434) (436) reaches the distal position,

wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support is displaced to the proximal position,

wherein displacing the handle in the first longitudinal direction comprises overcoming an interlocking configuration between the handle and the sheath (242) (342) (442) (2512) (2708) (3708) by applying a predetermined force.

10. The method of claims 8 or 9, wherein delivering the medical device (14) to the subject comprises releasing the medical device from the device support (430) (3702), preferably wherein releasing the medical device from the device support comprises

allowing one or more movable arms (3762) (3762') on the device support to displace radially outwardly.

11. The apparatus of claim 1, wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support (428) (434) (436) is advanced to the proximal position.

12. The apparatus of claim 5, wherein the first engagement member is released from the sharp support when the device support reaches the distal position for a now proximal movement of the sharp support and sharp relative to the device support.

EP 918 CONDITIONAL AMENDMENT 4

CLAIMS

1. An apparatus (200) (300) (400) (2400) (2500) (2700) (3700) for inserting an integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ (14) into the skin of a subject, which comprises:

a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface for placement on a skin surface;

a device support (430) (3702) movable between a proximal position and a distal position that is closer to the skin surface, and adapted to support an integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~;

a sharp support movable between the proximal position and the distal position that is closer to the skin surface and adapted to support a sharp (224) (324) (424) (2404) (2550) for inserting a portion of the in vivo analyte sensor of the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ under the skin surface and extending through a portion of the device support;

a handle (302) (402) (2502) (2702) (3702) movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from the proximal position to the distal position to insert the sharp under the skin surface; and

a driver (246) (346) (446) (2406) (2544) for advancing the sharp support towards the proximal position when the sharp support reaches the distal position;

wherein the device support (430) (3702) includes a first engagement member (474) (475) for releasably coupling the device support to the sharp support (428) (434) (436) and a second engagement member (3727) (3732) for engaging the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~;

~~and further characterised in that~~ wherein: the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726) that is a part of the sheath and that is biased against the handle and that is configured to prevent the handle from moving relative to the sheath until a minimum force has been applied in a distal direction to the handle; and

advancing the handle (302) (402) (2502) (2702) (3702) from the proximal position to the distal position comprises applying ~~a~~ the minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and a force applied to the handle moves the sheath into the handle and moves the integrated in vivo analyte sensor on-body electronics assembly ~~medical~~

~~device~~ from the proximal position to the distal position and inserts the sharp and the portion of the in vivo analyte sensor under the skin surface.

2. The apparatus of claim 1, wherein the handle and sheath comprise an interlocking configuration (328) (351) which prevents relative movement of the handle with respect to the sheath which is overcome by a force applied to the handle.

3. The apparatus of claim 1 or 2, wherein the second engagement member (3727) (3732) comprises one or more movable arms (3732) for engaging the integrated in vivo analyte sensor and on-body electronics assembly ~~device~~ (14), preferably wherein the one or more movable arms are normally biased in a position spaced apart from the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~.

4. The apparatus of claim 3, wherein the one or more movable arms (3732) are maintained in engagement with the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) when the device support (430) (3702) is in the proximal position, or wherein the one or more movable arms are permitted to return to the configuration spaced apart from the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ when the device support is in the distal position.

5. The apparatus of any of the preceding claims 1-4, wherein the first engagement member (474) (475) is released from the sharp support (428) (434) (436) when the device support (430) (3702) reaches a distal position, preferably wherein the first engagement member is maintained in engagement with the sharp support by a portion of the sheath (242) (342) (442) (2512) (2708) (3708).

6. The apparatus of any of the preceding claims 1-5, further comprising a stop to maintain the device support (430) (3702) in the proximal position such that it protects the user from accessing the retracted sharp (224) (324) (424) (2404) (2550).

~~7. The apparatus of any of the preceding claims, wherein the medical device (14) is an analyte sensor.~~

78. A method for using an integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) comprising:

providing an apparatus comprising a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface, a device support (430) (3702) adapted to support an integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14), a sharp support (428) (434) (436) adapted to support a sharp (224) (324) (424) (2404) (2550) extending through a portion of the device support, a handle (302) (402) (2502) (2702) (3702) movable relative to the sheath, and a driver (246) (346) (446) (2406) (2544) for displacing the sharp support;

disposing the distal surface of the sheath on a skin surface (S);

displacing the handle in a first longitudinal direction such that the sheath moves into the handle;

displacing the sharp support in the first longitudinal direction, the sharp support displacing the sharp and the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~;

inserting the sharp and a portion of the in vivo analyte sensor of the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ under the skin surface;

releasing the driver; and

displacing the sharp in a second longitudinal direction by the driver;

~~characterised in that~~ wherein:

the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726) that is a part of the sheath and that is biased against the handle and that is configured to prevent the handle from moving relative to the sheath until a minimum force has been applied in a distal direction to the handle; and

displacing the handle (302) (402) (2502) (2702) (3702) in the first longitudinal direction comprises applying ~~a~~ the minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and displacing the handle in the first longitudinal direction displaces the device support in the first longitudinal direction and inserts the sharp and the portion of the in vivo analyte sensor of the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ under the skin surface.

~~89~~. The method of claim ~~78~~, having one or more of the following:

wherein the first longitudinal direction is from a proximal to distal position, and the second longitudinal direction is from a distal to proximal position,

wherein the sharp (224) (324) (424) (2404) (2550) is displaced towards the proximal direction when the sharp support (428) (434) (436) reaches the distal position,

wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support is displaced to the proximal position,

wherein displacing the handle in the first longitudinal direction comprises overcoming an interlocking configuration between the handle and the sheath (242) (342) (442) (2512) (2708) (3708) by applying a predetermined force.

~~910~~. The method of claims ~~78~~ or ~~89~~, wherein delivering the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) to the subject comprises releasing the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ from the device support (430) (3702), preferably wherein releasing the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ from the device support comprises allowing one or more movable arms (3762) (3762') on the device support to displace radially outwardly.

~~1011~~. The apparatus of claim 1, wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support (428) (434) (436) is advanced to the proximal position.

~~1112~~. The apparatus of claim 5, wherein the first engagement member is released from the sharp support when the device support reaches the distal position for a now proximal movement of the sharp support and sharp relative to the device support.

EP 918 CONDITIONAL AMENDMENT 5

CLAIMS

1. An apparatus (200) (300) (400) (2400) (2500) (2700) (3700) for inserting an integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ (14) into the skin of a subject, which comprises:

a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface for placement on a skin surface;

a device support (430) (3702) movable between a proximal position and a distal position that is closer to the skin surface, and adapted to support an integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~;

a sharp support movable between the proximal position and the distal position that is closer to the skin surface and adapted to support a sharp (224) (324) (424) (2404) (2550) for inserting a portion of the in vivo analyte sensor of the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~ under the skin surface and extending through a portion of the device support;

a handle (302) (402) (2502) (2702) (3702) movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from the proximal position to the distal position to insert the sharp under the skin surface; and

a driver (246) (346) (446) (2406) (2544) for advancing the sharp support towards the proximal position when the sharp support reaches the distal position;

wherein the device support (430) (3702) includes a first engagement member (474) (475) for releasably coupling the device support to the sharp support (428) (434) (436) and a second engagement member (3727) (3732) for engaging the integrated in vivo analyte sensor on-body electronics assembly ~~medical device~~;

~~and further characterised in that~~ wherein: the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726) that is a part of the sheath and that is biased against the handle and that is configured to prevent the handle from moving relative to the sheath until a minimum force has been applied in a distal direction to the handle;

advancing the handle (302) (402) (2502) (2702) (3702) from the proximal position to the distal position comprises applying ~~a~~ the minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and a force applied to the handle moves the sheath into the handle and moves the integrated in vivo analyte sensor on-body electronics assembly ~~medical~~

~~device~~ from the proximal position to the distal position and inserts the sharp and the portion of the in vivo analyte sensor under the skin surface; and

the apparatus is configured to activate the on-body electronics of the integrated in vivo analyte sensor on-body electronics assembly.

2. The apparatus of claim 1, wherein the handle and sheath comprise an interlocking configuration (328) (351) which prevents relative movement of the handle with respect to the sheath which is overcome by a force applied to the handle.

3. The apparatus of claim 1 or 2, wherein the second engagement member (3727) (3732) comprises one or more movable arms (3732) for engaging the integrated in vivo analyte sensor and on-body electronics assembly ~~device~~ (14), preferably wherein the one or more movable arms are normally biased in a position spaced apart from the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~.

4. The apparatus of claim 3, wherein the one or more movable arms (3732) are maintained in engagement with the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) when the device support (430) (3702) is in the proximal position, or wherein the one or more movable arms are permitted to return to the configuration spaced apart from the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ when the device support is in the distal position.

5. The apparatus of any of the preceding claims 1-4, wherein the first engagement member (474) (475) is released from the sharp support (428) (434) (436) when the device support (430) (3702) reaches a distal position, preferably wherein the first engagement member is maintained in engagement with the sharp support by a portion of the sheath (242) (342) (442) (2512) (2708) (3708).

6. The apparatus of any of the preceding claims 1-5, further comprising a stop to maintain the device support (430) (3702) in the proximal position such that it protects the user from accessing the retracted sharp (224) (324) (424) (2404) (2550).

~~7. The apparatus of any of the preceding claims, wherein the medical device (14) is an analyte sensor.~~

78. A method for using an integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) comprising:

providing an apparatus comprising a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface, a device support (430) (3702) adapted to support an integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14), a sharp support (428) (434) (436) adapted to support a sharp (224) (324) (424) (2404) (2550) extending through a portion of the device support, a handle (302) (402) (2502) (2702) (3702) movable relative to the sheath, and a driver (246) (346) (446) (2406) (2544) for displacing the sharp support;

disposing the distal surface of the sheath on a skin surface (S);

displacing the handle in a first longitudinal direction such that the sheath moves into the handle;

displacing the sharp support in the first longitudinal direction, the sharp support displacing the sharp and the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~;

inserting the sharp and a portion of the in vivo analyte sensor of the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ under the skin surface;

releasing the driver; and

displacing the sharp in a second longitudinal direction by the driver;

~~characterised in that~~ wherein:

the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726) that is a part of the sheath and that is biased against the handle and that is configured to prevent the handle from moving relative to the sheath until a minimum force has been applied in a distal direction to the handle; ~~and~~

displacing the handle (302) (402) (2502) (2702) (3702) in the first longitudinal direction comprises applying ~~a~~ the minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and displacing the handle in the first longitudinal direction displaces the device support in the first longitudinal direction and inserts the sharp and the portion of the in vivo analyte sensor of the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ under the skin surface; and

the method further comprises activating the on-body electronics of the integrated in vivo analyte sensor and on-body electronics assembly by the apparatus.

89. The method of claim 78, having one or more of the following:

wherein the first longitudinal direction is from a proximal to distal position, and the second longitudinal direction is from a distal to proximal position,

wherein the sharp (224) (324) (424) (2404) (2550) is displaced towards the proximal direction when the sharp support (428) (434) (436) reaches the distal position,

wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support is displaced to the proximal position,

wherein displacing the handle in the first longitudinal direction comprises overcoming an interlocking configuration between the handle and the sheath (242) (342) (442) (2512) (2708) (3708) by applying a predetermined force.

910. The method of claims 78 or 89, wherein delivering the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ (14) to the subject comprises releasing the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ from the device support (430) (3702), preferably wherein releasing the integrated in vivo analyte sensor and on-body electronics assembly ~~medical device~~ from the device support comprises allowing one or more movable arms (3762) (3762') on the device support to displace radially outwardly.

1011. The apparatus of claim 1, wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support (428) (434) (436) is advanced to the proximal position.

1112. The apparatus of claim 5, wherein the first engagement member is released from the sharp support when the device support reaches the distal position for a now proximal movement of the sharp support and sharp relative to the device support.