

(e.g. carrying out a glucose level measurement by drawing blood or measuring drug levels after insertion of the drug). However, this leads to the need of additional devices for this check and is tedious for the user. Additionally, such an improper placement may also happen after even a correct insertion of the flexible insertion piece and after a check has been carried out, e.g. due to the flexible insertion piece moving when the skin moves, in particular when the skin moves such that the insertion piece's position in the skin depth changes and/or the axial position of the attached device. In such cases, the deformation of the flexible insertion piece may not be detected and lead to erroneous results, which may harm the user's health.

10 Such improper functioning may be caused or indicated by a deformation of the flexible insertion piece.

Thus, there is a need for improved means and methods for determining proper insertion of a flexible insertion piece during and after its insertion into the skin that avoids the drawbacks of the prior art. This problem is solved by the means and methods provided by the present invention as specified in the claims and herein below.

Hence, an aspect of the invention provides a device for transcutaneous insertion, in particular e.g. a device for transcutaneous delivery of a drug or for transcutaneous measurement of a physical parameter such as an analyte concentration, comprising a flexible insertion piece for transcutaneous insertion (also called insertion piece in the following), which comprises a deformation measurement device for detecting one or more deformation signals.

In particular, the one or more deformation signals that may allow determining whether a deformation is present in the deformation measurement device, and thus in at least a part of the insertion piece.

25 In particular, the deformation measurement device may be triggered, e.g. by one or more start signals, e.g. application of a voltage or current, or may be connected to a start signal, e.g. a voltage, continuously. From the deformation measurement device, one or more deformation signals may be received in response to the triggering. These one or more deformation signals may e.g. comprise a voltage, a current or a resistance.

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From the one or more deformation signals, a deformation value may then be determined. The deformation value may in particular correspond to a value measured from the deformation signals, e.g. a measured voltage, current or resistance, or may be derived therefrom, e.g. be calculated using information from the one or more deformation signals.

be configured to cover at least part of a patch or other fixing aid when the device for transcutaneous insertion is inserted into a user's skin.

5 A deformation measurement device may, for example, comprise (micro-)conductors with predetermined breaking points, which break if a bending of the flexible insertion piece exceeds a certain threshold bending.

10 A deformation measurement device may alternatively or additionally comprise two or more markings on the flexible insertion piece, the position of which may be visually checked (e.g. by the user himself or using a camera). If the distance of the positions deviates from a known distance of the marks (reference value) more than a certain threshold, this indicates an adverse deformation of the flexible insertion piece.

15 Such a deformation measurement device according to embodiments of the invention may in particular comprise a strain measurement device, e.g. for detecting a bending of the insertion piece. Strain measurement devices as such are known and for example available from HBM Deutschland, Hottinger Brüel & Kjaer GmbH, Darmstadt, Germany. Strain measurement devices according to embodiments of the invention may for example correspond to strain measurement devices used in strain gauges. A strain measurement  
20 device according to embodiments of the invention may e.g. comprise a meander-shaped pattern of a conductor on an insulating layer or some other arrangement of a conductor in a particular direction on an insulating layer.

25 This meander-shaped pattern or other arrangement of a conductor may, in the following, also be referred to as "measurement grid".

30 A meander-shaped pattern of a conductor according to embodiments of the invention may be arranged along a certain direction. When stretching the layer comprising the conductor into that direction, the resistance of the conductor increases, while on the other hand, when compressing the layer comprising the conductor into that direction, the resistance of the conductor decreases. A deformation value may hence be the resistance of the strain measurement device.

35 Particular patterns, which may be used for strain gauges can, with proper size adjusting (i.e. typically miniaturization), be mounted on or in a flexible insertion piece according to

embodiments of the invention. Other patterns which may be used in embodiments of the present invention can be any patterns having repeated parallel lines of a continuous conductor arranged parallel to each other with the same height, or at least approximately parallel to each other (deviation from parallel e.g. not more than 10°, or not more than 20°).

- 5 Such arrangements may, in particular, allow recognizing a change of resistance when the conductor is deformed.

While in the following, meander-shaped patterns are discussed as a particular example for strain measurement devices according to embodiments of the invention, it is understood that other patterns serving the same purpose mentioned above, and also for example a more complex combination of more than one meander-shaped or similar pattern, e.g. as  
5 used in a membrane rosette strain gauge, may be used in embodiments of the present invention.

Typically, the strain measurement device according to embodiments of the invention can be positioned in the area of the flexible insertion piece in which a deformation would be of particular interest or harmful to the functioning of the device. In particular, this typically  
10 comprises or consists of the region of the flexible insertion piece inserted into the skin and the region adjacent to it, which is not supposed to be inserted. The strain measurement device according to embodiments of the invention may alternatively or additionally be positioned in the region of the flexible insertion piece which is intended to bend during insertion or which is bent before and/or after insertion of the flexible insertion piece.

Typically, such a flexible insertion piece for transcutaneous insertion comprises an insertion area configured to extend from a tip inserted into the skin to the surface of the skin, a connection area and an attachment area. The tip is the part of the flexible insertion piece which is intended to be inserted into the skin deepest in use. It may comprise an, optionally  
15 electronic, analyte measurement arrangement of an analyte sensor and/or an opening, e.g. the opening may be used or usable for administering a drug into the skin. The device for transcutaneous insertion may be configured such that, when inserted into the skin, the tip is placed subcutaneously.  
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The attachment area is arranged on the opposite end of the tip of the flexible insertion piece. Optionally, the attachment area is configured to be attached to electronics and/or a drug reservoir, e.g. the electronics allowing sending to and receiving signals from the flexible  
25 insertion piece, in particular the deformation measurement device and/or the drug reservoir allowing delivering of a drug. The attachment area may comprise contact regions for electrical connections, e.g. for connecting it to contacts within a housing or a patch, and/or one or more connection regions or points for connecting to a drug reservoir.

The connection area connects the insertion area with the attachment area. It may, in particular, be configured to be bent to allow attaching the flexible insertion piece, in particular in the attachment area and/or connection area, along the surface of the user's skin. Typically, the regions of interest for which deformation, in particular a deformation  
30 value, is of most interest are the insertion area and/or the connection area. Typically,  
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therefore, the deformation measurement device is arranged such as to allow detecting deformation signals of the insertion area and/or the connection area. In particular, the deformation measurement device may be mounted on or in the insertion area and/or the connection area.

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Once the flexible insertion piece has been inserted, the tip usually is not bent as it is already inside the skin. However, movement of the skin or external force applied to the skin and/or to the device for transcutaneous insertion may lead to deformation of the insertion area and/or the connection area of the flexible insertion piece. The attachment area may be less likely to be affected by the force though it is possible that it is deformed as well as, when it is in use, it is usually attached to the user's skin such that this area may not be deformed easily.

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In particular, the deformation measurement device according to embodiments of the invention may be arranged such that it allows detecting one or more deformation signals in at least half of the flexible insertion piece, half of the flexible insertion piece or less than half of the flexible insertion piece, in particular in the half or less than half of the flexible insertion piece configured for transcutaneous insertion and immediately adjacent to the part of the flexible insertion piece configured for transcutaneous insertion, in particular in the insertion and/or connection area.

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The signals received from the strain measurement device according to embodiments of the invention may represent electrical resistance which can for example be measured using a Wheatstone Bridge or any other resistance measurement device. The resistance measurement device, in particular a Wheatstone Bridge, may be located in the insertion device for transcutaneous insertion, e.g. integrated into a patch which attaches the flexible insertion piece to the user's skin, or integrated into other electronics, e.g. in a housing or drug infusion pump.

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According to embodiments of the invention, such a strain measurement device, e.g. in a pattern as is known to be used on a strain gauge, can, in particular after proper size adjusting, i.e. typically a miniaturization, be mounted in or on a flexible insertion piece, in particular on an insulating layer of the flexible insertion piece and/or below a protective, e.g. biocompatibility, layer, e.g. in the case of the flexible insertion piece comprising an analyte sensor or a flexible cannula for drug delivery.

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Such a strain measurement device may in particular be mounted, optionally, on an insulating layer, in or on the flexible insertion piece using a stereolithographic or printing process.

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Such a strain measurement device according to embodiments of the invention may in particular allow detecting a bending of the insertion piece as such a bending of the insertion piece typically leads to a strain (stretching or compression) thereof in the bending area. Hence, a bending of the device (and an approximate amount thereof) can be determined  
5 with the strain measurement device according to embodiments of the invention.

In particular, such a strain measurement device may revert to its original properties upon bending and unbending it. In particular, after bending and unbending it once, it may not be damaged, but rather still be usable. It may in particular be possible to detect a deformation (bending), and detect a change back to the original (un-deformed/unbent) state and/or a  
10 change to an even more deformed (bent) state in subsequent measurements.

The strain measurement device may be suitable for continuous measurement, e.g. measurement in certain time intervals during transcutaneous insertion of the flexible insertion piece, in order to recognize changes in the strain, and in particular hence deformation, and through it changes in the positioning of the flexible insertion piece. This  
15 may allow deactivating the device for transcutaneous insertion and/or transmitting a notification, e.g. issuing an alarm or message, to the user or the system, e.g. by transmitting a notification to a display or sending another message, e.g. cautioning the user or system that the positioning of the flexible insertion piece may be improper and that it should be checked.

20 The strain measurement device may in particular be an electronic strain measurement device, which can optionally be attachable to an electronic device (electronics) outside of the flexible insertion piece, e.g. in a patch, in a housing, in particular of an analyte sensor device or in a drug infusion pump.

According to embodiments of the invention, the deformation measurement device may  
25 comprise two, three or more strain measurement devices.

The two, three or more strain measurement devices may be wired each individually, i.e. may be controlled and/or may be monitored separate from each other, or one, two, three or more of them may be wired individually. Alternatively or additionally, two, three, more, or all of the strain measurement devices may be connected in parallel and/or two, three, more or  
30 all of the strain measurement devices may be connected in series.

Connection in series and/or in parallel is associated with the advantage that the number of wires can be reduced to two. However, while such arrangement in series allows

determination of a deformation in at least one of the strain measurement devices, it is not possible to identify the particular strain measurement device where the deformation signal stems from. In contrast, individual wiring is associated with the advantage that it allows for identification of the particular strain measurement device where the deformation signal stems from. On the other hand, the number of wires used to connect all strain measurement devices is increased in comparison to the serial connection arrangement.

The flexible insertion piece according to embodiments of the invention may, in particular in an unbent state, have a longitudinal axis. In a bent state of the flexible insertion piece, the longitudinal axis may be bent as well. This longitudinal axis typically corresponds to the direction along which the flexible insertion piece is to be introduced into the skin. When viewed in a cross section perpendicular to its longitudinal axis, the flexible insertion piece may have one of the following different shapes: a line or very thin rectangle, which corresponds to a flat or strip-formed configuration of the flexible insertion piece, a circular cross section which corresponds to a cylindrical configuration which is also named wire configuration of the flexible insertion piece, an oval shape and a regular or irregular polygonal shape with at least 3 corners which corresponds to a prism shape of the flexible insertion piece.

For a flat flexible insertion piece according to embodiments of the invention, e.g. an insertion piece made up from at least 2 layers in a flat configuration, a strain measurement device may be mounted on a first flat side and another strain measurement device may be mounted on the opposite flat side. For example, when detecting deformation signals, in particular receiving one or more signals, of both of those strain measurement devices, a bending of the flexible insertion piece along the flat side may be recognized by the deformation value determined from the one or more signal(s) of the first strain measurement device indicating a stretching, e.g. an increase in resistance with regard to a reference value, and the deformation value determined from the one or more signal(s) of the second strain measurement device indicating a compression, e.g. a decrease in resistance with regard to a reference value. Hence, a bending of the flexible insertion piece may be distinguished from an overall stretching thereof.

On a flexible insertion piece having a longitudinal axis, two, three or more strain measurement devices may be arranged at different angles around the longitudinal axis of the flexible insertion piece. For example in a flat (strip-formed) flexible insertion piece, they may be arranged under an angle of about 180°, meaning of between 90° and 270°, e.g. between 135° and 225°, e.g. on opposed sides of the flat insertion piece. In another

The analyte measurement arrangement and the deformation measurement device may be arranged on the carrier separate from each other. In particular, they may be mounted on separate layers of the foil or film, or on the same layer in separate areas. The wiring of the analyte measurement arrangement and the deformation measurement device may be  
5 arranged in one layer, which is different from the layer on which the glucose measurement arrangement is mounted and/or which is different from the layer on which the deformation measurement device is mounted. Optionally, the deformation measurement device is further outside than the analyte measurement arrangement, in particular configured to be in use closer to the user's skin and further away from the longitudinal axis, which may also  
10 be called neutral axis, which is not stretched, or the middle of the carrier in a direction perpendicular to the direction of insertion.

The flexible insertion piece comprised by the device for transcutaneous insertion may be or comprise a flexible cannula, e.g. a Teflon or silicone cannula, used for transcutaneous, delivery of a drug. It may have a circular or oval cross section, which may in particular be  
15 measured perpendicular to the longitudinal axis or direction of insertion thereof. It may, in particular, be a flexible cannula of a drug infusion pump or in particular of a body-worn drug infusion patch pump, for example for the infusion of insulin. One end of the flexible cannula may be attachable or attached to a drug infusion pump, a patch or in another manner outside of the skin while the other part of the cannula may be configured to remain inside  
20 the skin of a user, in particular subcutaneously. The deformation measurement device may be mounted on the outside of the cannula, i.e. the wall of the cannula, which – during use – is to be turned towards the skin of the user, and optionally not in contact with the drug delivered through the cannula. The deformation measurement device may be covered by a protective, e.g. biocompatibility, layer on the outside of the cannula, such that – during use  
25 – the deformation measurement device is not in direct contact with the user's skin or other bodily fluids.

Embodiments of the invention further provides a transcutaneous insertion system comprising a device for transcutaneous insertion as described above, an optional display device and a memory. The memory comprises instructions that, when executed, cause one  
30 or more processors to receive one or more signals from the deformation measurement device, determine a deformation value of the flexible insertion piece from the one or more signals and optionally transmit a notification to the display device.

least a portion of the analyte sensor, e.g. the CAM sensor. The housing may additionally or alternatively be adapted for contacting at least a portion of the analyte, e.g. CAM, sensor. Alternatively or additionally, the display device of the system may correspond with an external display device, e.g. a proprietary device, in particular a locked down phone or device, and/or a display device of a mobile device, e.g. a smartphone or tablet, or a consumer electronic device, e.g. a PC, monitor, TV.

The system may comprise a device for transcutaneous insertion and the memory may comprise instructions that, when executed, cause one or more processors to carry out the steps described with regard to the device for transcutaneous insertion above.

Embodiments of the invention further provides a method of detecting deformation of at least a part of the insertion piece of a device for transcutaneous insertion, in particular a device for transcutaneous insertion as previously described. The method comprises receiving one or more signals from a deformation measurement device which may be comprised by, in particular e.g. mounted on or in, a flexible insertion piece for insertion; determining a deformation value of the flexible insertion piece from the one or more signals; and optionally transmitting a notification to a display device. Additional steps may be carried out corresponding to the steps as described above for the system.

Further explanations and examples can be found in the drawings, which are not according to scale. Herein,

Fig. 1a shows part of an exemplary flexible insertion piece for transcutaneous insertion

Fig. 1b shows the positioning of an exemplary flexible insertion piece into the skin

Fig 1c shows an exemplary arrangement of a device for transcutaneous insertion

Fig 1d shows part of an exemplary flexible insertion piece for transcutaneous insertion

Fig. 1e shows a cross-section through the exemplary flexible insertion piece of Fig 1d

Figs. 2a, 2b, 2c show exemplary states of a strain measurement device

Fig. 3a shows an exemplary arrangement of a deformation measurement device in a stack of layers

Fig. 3b shows an exemplary flexible insertion piece

## CLAIMS

1. A device for transcutaneous insertion comprising a flexible insertion piece (1) for transcutaneous insertion, wherein the flexible insertion piece (1) comprises  
  
a deformation measurement device for detecting one or more deformation signals.
- 5 2. The device of claim 1, wherein the deformation measurement device comprises a strain measurement device (3), in particular for detecting a bending of the insertion piece.
3. The device of claim 2, wherein upon bending and unbending the strain measurement device (3) reverts to its original properties.
- 10 4. The device of claims 1-3, wherein the strain measurement device (3) is suitable for continuous measurement and/or an electronic strain measurement device.
5. The device of claims 1-4, wherein the deformation measurement device comprises two, three or more strain measurement devices (3), wherein optionally the two, three or more strain measurement devices (3) are connected in parallel or wherein  
15 optionally the two, three or more strain measurement devices (3) are connected in series.
6. The device of claim 5, wherein two, three or more strain measurement devices (3) are arranged at different angles ( $\beta, \gamma$ ) around a longitudinal axis (L1) of the flexible insertion piece (1).
- 20 7. The device of claims 1- 6, wherein an axis of the deformation measurement device is oriented along a longitudinal axis (L1) of the flexible insertion piece (1) and/or wherein the wiring (3a) attached to the deformation measurement device is oriented along a longitudinal axis (L1) of the flexible insertion piece (1).
8. The device of claims 1-7, wherein the deformation measurement device is arranged  
25 on the outside of the flexible insertion piece (1) or it is arranged on the inside of the flexible insertion piece off-centered.
9. The device of claims 1-8 wherein the device for transcutaneous insertion is a continuous analyte measurement sensor device comprising a transcutaneous

analyte sensor, in particular comprising an electronic analyte measurement arrangement (2).

10. The device of claims 1-8, wherein the flexible insertion piece (1) is a flexible cannula for drug delivery.

- 5 11. A transcutaneous insertion system, comprising

the device for transcutaneous insertion according to claims 1-10,

an optional display device, and

a memory, the memory comprising instructions that, when executed, cause one or more processors to:

10 receive one or more signals from the deformation measurement device;

determine a deformation value of the flexible insertion piece from the one or more signals;

optionally transmit a notification to the display device.

12. The transcutaneous insertion system of claim 11, the memory further comprising  
15 instructions that, when executed, cause one or more processors to:

compare the determined deformation value with a reference value,

if the determined deformation value fulfills a predetermined condition with regard to the reference value, conduct at least one of:

20 a) issue an alarm which is detectable on the device for transcutaneous insertion,

b) issue an alarm which is transmitted to the display device, and

c) deactivate the device for transcutaneous insertion.

13. The transcutaneous insertion system according to claim 11 or 12, wherein the  
25 device for transcutaneous insertion is the device for transcutaneous insertion according to claim 9, wherein the optional display device and the memory is comprised in a housing adapted for placement adjacent to skin of a user.

14. A method of detecting deformation of at least a part of the insertion piece of a device for transcutaneous insertion, in particular the device for transcutaneous insertion according to claims 1-10, the method comprising
- receiving one or more signals from a deformation measurement device;
- 5 determining a deformation value of the flexible insertion piece from the one or more signals;
- optionally transmitting a notification to a display device.
15. The method of detecting deformation according to claim 14, the method comprising
- comparing the determined deformation value with a reference value,
- 10 if the determined deformation value fulfills a predetermined condition with regard to the reference value, conducting at least one of:
- a) issue an alarm which is detectable on the device for transcutaneous insertion,
  - b) issue an alarm which is transmitted to the display device, and
  - 15 c) deactivate the device for transcutaneous insertion.