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DESCRIPTION

Description

Technical Field

[0001] The invention relates to a medical system and to a method of manufacturing a medical system. The medical system specifically may be used for detecting at least one analyte in a body fluid, such as a body fluid contained in a body tissue. The medical system specifically may be used for inserting an analyte sensor contained in the system into the body tissue of the user. The medical system may be applied both in the field of home care and in the field of professional care, such as in hospitals. Other applications are feasible.

Background art

[0002] Monitoring certain body functions, more particularly monitoring one or more concentrations of at least one analyte concentration such as at least one metabolite concentration in a body fluid plays an important role in the prevention and treatment of various diseases. Such analytes can include by way of example, but not exclusively, blood glucose, lactate, cholesterol or other types of analytes and metabolites. Without restricting further possible applications, the invention will be described in the following text with reference to blood-glucose monitoring. However, additionally or alternatively, the invention can also be applied to other types of analytes, such as the analytes mentioned above.

[0003] For monitoring these body functions, specifically for monitoring the concentration of at least one analyte, over a period of time, specifically, electrochemical sensors are used which transcutaneously are inserted into the body tissue of the user. The sensors typically comprise an elongated flexible substrate onto which a plurality of electrodes, including one or more working electrodes and one or more further electrodes such as one or more counter electrodes and/or one or more reference electrodes are applied.

[0004] As an example, US 2010/0200538 A1 discloses methods for fabricating analyte sensor components, using IC- or MEMs-based fabrication techniques and sensors prepared therefrom. Fabrication of the analyte sensor component comprises providing an inorganic substrate having deposited thereon a release layer, a first flexible dielectric layer and a second flexible dielectric layer insulating there between electrodes, contact pads and traces connecting the electrodes and the contact pads of a plurality of sensors. Openings are provided in one of the dielectric layers over one or more of the electrodes to receive an analyte sensing

membrane for the detection of an analyte of interest and for electrical connection with external electronics. The plurality of fabricated sensor components are lifted off the inorganic substrate.

[0005] As a further example, EP 2348964 B1 discloses an electrode system for measuring the concentration of an analyte under in-vivo conditions. The electrode system comprises a counter-electrode having an electrical conductor, a working electrode having an electrical conductor on which an enzyme layer containing immobilized enzyme molecules for catalytic conversion of the analyte is arranged, and a diffusion barrier that slows the diffusion of the analyte from body fluid surrounding the electrode system to enzyme molecules down. The invention provides the enzyme layer in the form of multiple fields that are arranged on the conductor of the working electrode at a distance from each other.

[0006] Several challenges in the field of continuous monitoring systems have to be addressed. Firstly, one challenge resides in appropriate devices for inserting the analyte sensor into the body tissue. A further challenge resides in the fact that, in many systems, the analyte sensor has to be electrically connected to an electronics unit disposed on the surface of the skin of the user. Further challenges reside in the overall handling of the medical system which, in many cases, has to be performed by untrained users including children and elderly people, which generally requires easy handling procedures with as little steps as possible.

[0007] WO 2016/012482 A1 discloses an insertion device for inserting an analyte sensor into a body tissue, the insertion device having an insertion needle holder and a drive mechanism for linearly driving the insertion needle holder in a longitudinal direction. The drive mechanism comprises at least one actuator for actuating the drive mechanism. The actuator comprises at least one actuator arm which is pivotable about at least one axle in order to actuate the drive mechanism. The insertion device further comprises at least one protection against reuse including at least one locking mechanism. The locking mechanism is adapted to at least partially prevent a back-pivoting of the actuator arm in a direction reversing the actuation direction once the actuator arm has been pivoted by at least one threshold angle.

[0008] Similarly, WO 2016/012497 A1 discloses an insertion device for inserting an analyte sensor into a body tissue. The insertion device comprises an insertion needle holder and a drive mechanism for driving the insertion needle holder in a longitudinal direction. The drive mechanism comprises at least one actuator for actuating the drive mechanism. The drive mechanism comprises a rotor adapted to transform an actuation motion of the actuator into a motion of the insertion needle holder in the longitudinal direction. The insertion device further comprises at least one safety lock. The safety lock, in a locked position, is adapted to at least partially block a rotation of the rotor. In an unlocked position, the safety lock is adapted to permit the rotation of the rotor.

[0009] Further, disposable systems for long-term monitoring of an analyte as well as corresponding insertion devices for analyte sensors are known. WO 2017/037191 A1 discloses a kit for determining a concentration of at least one analyte in a body fluid of a user, comprising: a) a sensor module comprising i. at least one sensor element adapted to

determine the concentration of the analyte, wherein the sensor element is at least partly implantable into a body tissue of the user; ii. at least one control device connected to the sensor element, wherein the control device comprises at least one data collection device adapted to collect measurement data acquired by using the sensor element, wherein the control device further comprises at least one wireless near-field communication device adapted to transmit measurement data, wherein the sensor module comprises a sensor module mechanical interface; b) at least one data reader module adapted to receive measurement data transmitted by the sensor module via wireless near-field communication, wherein the data reader module comprises at least one data storage device and is adapted to store the measurement data; c) at least one data transmission module adapted to receive measurement data transmitted by the sensor module via wireless near-field communication, wherein the data transmission module comprises at least one wireless far-field communication device, wherein the wireless far-field communication device is adapted to transmit at least part of the measurement data to an external device via wireless far-field communication. The data reader module and the data transmission module each comprise a mechanical interface adapted to reversibly engage the sensor module mechanical interface, thereby alternatively generating a fixed spatial relationship between the sensor module and the data reader module or the sensor module and the data transmission module.

[0010] Further, in EP 2 991 552 A1 systems, devices, and methods are described for changing the power state of a sensor control device in an in vivo analyte monitoring system in various manners, such as through the use of external stimuli (light, magnetics) and RF transmissions.

[0011] WO 2011/119896 A1 describes an apparatus for insertion of a medical device in the skin of a subject, as well as methods of inserting medical devices. Said apparatus includes a sheath, a device support movable between a proximal and distal position, a sharp support movable between a proximal and distal position, a handle movable between a proximal and distal position, and a driver.

[0012] US 2010/286714 A1 describes an inserter device for inserting a medical device into the subcutaneous or intramuscular area of a patient. More specifically, an inserter device is described comprising means for providing a controlled and defined acceleration and deceleration of a penetrating member. The inserter device according to the invention comprises a housing (encompassing said penetrating member, a rotating member and driving means for rotating the rotating member around a rotating axis. The rotating member comprises transformation means transforming the rotational movement into a longitudinal movement of the penetrating member in the direction of insertion and the transformation means comprises controlling means providing a controlled variation of the velocity of the penetrating member in the direction of insertion.

[0013] US 2007/202488 A1 describes method for determining the relative benefits of products which affect animal epithelial tissue. Also provided is a method for evaluating quantitative changes on one or more affected surfaces of epithelial tissue of a subject caused by a test product.

[0014] US 2016/331284 A1 describes compact medical device inserters, systems incorporating the same, and related methods of use. The inserters can include a housing, a sharp support, a sharp body, and a shroud, and can apply a sensor control device to a recipient with a sensor implanted in the recipient's body. The shroud can extend from the sensor control device in a position that covers or protects the sensor and a sharp, and can be retracted by pressure placed upon the inserter against the recipient's body to cause the sharp and sensor to penetrate the body, after which the sharp can be automatically withdrawn with the aid of a biasing element.

[0015] Despite the advantages achieved by the above-mentioned devices, several technical challenges remain. Specifically, reliably connecting the analyte sensor to the electronics unit remains a challenge. Further, the trend for miniaturization generally encourages the use of disposable electronics, with a battery included. These devices, however, generally should be switched off during storage and transport and should be switched on after insertion of the analyte sensor into the body tissue. The switching, however, generally requires an additional step to be performed by the user. Further, protecting the analyte sensor and the electronics during storage, transport and use, specifically against humidity and mechanical shocks, remains to be an issue.

Problem to be solved

[0016] It is therefore desirable to provide devices and methods which address the above-mentioned technical challenges. Specifically, a medical system is desirable which allows for easy and user-friendly insertion of an analyte sensor into a body tissue, with few handling steps and with a high degree of protection against detrimental mechanical and environmental influences.

Summary

[0017] This problem is addressed by a medical system and a method of manufacturing thereof, with the features of the independent claims. The present invention is defined in the claims. Advantageous embodiments which might be realized in an isolated fashion or in any arbitrary combinations are listed in the dependent claims.

[0018] As used in the following, the terms "have", "comprise" or "include" or any arbitrary grammatical variations thereof are used in a non-exclusive way. Thus, these terms may both refer to a situation in which, besides the feature introduced by these terms, no further features are present in the entity described in this context and to a situation in which one or more further features are present. As an example, the expressions "A has B", "A comprises B" and "A includes B" may both refer to a situation in which, besides B, no other element is present in A (i.e. a situation in which A solely and exclusively consists of B) and to a situation in which,

besides B, one or more further elements are present in entity A, such as element C, elements C and D or even further elements.

[0019] Further, it shall be noted that the terms "at least one", "one or more" or similar expressions indicating that a feature or element may be present once or more than once typically will be used only once when introducing the respective feature or element. In the following, in most cases, when referring to the respective feature or element, the expressions "at least one" or "one or more" will not be repeated, non-withstanding the fact that the respective feature or element may be present once or more than once.

[0020] Further, as used in the following, the terms "preferably", "more preferably", "particularly", "more particularly", "specifically", "more specifically" or similar terms are used in conjunction with optional features, without restricting alternative possibilities. Thus, features introduced by these terms are optional features and are not intended to restrict the scope of the claims in any way. The invention may, as the skilled person will recognize, be performed by using alternative features. Similarly, features introduced by "in an embodiment of the invention" or similar expressions are intended to be optional features, without any restriction regarding alternative embodiments of the invention, without any restrictions regarding the scope of the invention and without any restriction regarding the possibility of combining the features introduced in such way with other optional or non-optional features of the invention.

[0021] In a first aspect of the present invention, a medical system is disclosed. The system specifically may be configured for and used for qualitatively and/or quantitatively detecting at least one analyte in a body fluid, such as one or more of the analyte listed above.

[0022] The medical system comprises:

1. a. a housing;
2. b. a preassembled functional module received in the housing, the preassembled functional module comprising

   b1. an analytical sensor for detecting at least one analyte in a body fluid of a user;

   b2. an electronics unit electrically connected to the analytical sensor;

   b3. an insertion component for inserting the analytical sensor into a body tissue of the user; and

   b4. at least one sterility cap at least partially surrounding the insertion component;

3. c. at least one removable protective cap connected to the housing, covering the preassembled functional module;

wherein the protective cap is removable from the housing by pulling off the protective cap from the housing, wherein the housing comprises at least one guiding surface for guiding the protective cap during pulling off the protective cap, wherein the preassembled functional

module comprises at least one guiding surface for guiding the sterility cap during pulling off the sterility cap from the insertion component, wherein a length of the guiding surface of the housing exceeds a length of the guiding surface for the sterility cap by at least a factor of 2 such that the sterility cap is fully pulled off from the insertion component before the guiding by the guiding surface of the housing ends when the protective cap is pulled off from the housing.

[0023] In a further aspect of the present invention, a medical system is disclosed. The medical system comprises:

1. a. a housing;
2. b. a preassembled functional module received in the housing, the preassembled functional module comprising

   b1. an analytical sensor for detecting at least one analyte in a body fluid of a user;

   b2. an electronics unit electrically connected to the analytical sensor;

   b3. an insertion component for inserting the analytical sensor into a body tissue of the user; and

   b4. at least one sterility cap at least partially surrounding the insertion component;

3. c. at least one removable protective cap connected to the housing, covering the preassembled functional module, wherein the sterility cap is distinct from the protective cap;

wherein the protective cap is removable from the housing by pulling off the protective cap from the housing, wherein the housing comprises at least one guiding surface for guiding the protective cap during pulling off the protective cap, wherein the preassembled functional module comprises at least one guiding surface for guiding the sterility cap during pulling off the sterility cap from the insertion component, wherein a length of the guiding surface of the housing exceeds a length of the guiding surface for the sterility cap.

[0024] In a further aspect of the present invention, a medical system is disclosed. The medical system comprises:

1. a. a housing;
2. b. a preassembled functional module received in the housing, the preassembled functional module comprising

   b1. an analytical sensor for detecting at least one analyte in a body fluid of a user;

   b2. an electronics unit electrically connected to the analytical sensor;

   b3. an insertion component for inserting the analytical sensor into a body tissue of the user; and

   b4. at least one sterility cap at least partially surrounding the insertion component;

3. c. at least one removable protective cap connected to the housing, covering the preassembled functional module;

wherein the protective cap is removable from the housing by pulling off the protective cap from the housing, wherein the housing comprises at least one guiding surface for guiding the protective cap during pulling off the protective cap, wherein the preassembled functional module comprises at least one guiding surface for guiding the sterility cap during pulling off the sterility cap from the insertion component, wherein a length of the guiding surface of the housing exceeds a length of the guiding surface for the sterility cap,

[0025] wherein the housing has a front face which is configured for being disposed on a skin of the user, wherein the front face has a rim with an opening enclosed by the rim, wherein the rim is configured for tightening the skin for application of the analytical sensor.

[0026] In a further aspect of the present invention, a medical system is disclosed. The medical system comprises:

1. a. a housing;
2. b. a preassembled functional module received in the housing, the preassembled functional module comprising

   b1. an analytical sensor for detecting at least one analyte in a body fluid of a user;

   b2. an electronics unit electrically connected to the analytical sensor;

   b3. an insertion component for inserting the analytical sensor into a body tissue of the user; and

   b4. at least one sterility cap at least partially surrounding the insertion component;

3. c. at least one removable protective cap connected to the housing, covering the preassembled functional module;

wherein the protective cap is removable from the housing by pulling off the protective cap from the housing, wherein the housing comprises at least one guiding surface for guiding the protective cap during pulling off the protective cap, wherein the preassembled functional module comprises at least one guiding surface for guiding the sterility cap during pulling off the sterility cap from the insertion component, wherein a length of the guiding surface of the housing exceeds a length of the guiding surface for the sterility cap,

wherein the electronics unit is already electrically connected to the analytical sensor when the preassembled functional module is received in the housing, with the protective cap being connected to the housing.

[0027] In a further aspect of the present invention, a medical system is disclosed. The medical

system comprises:

1. a. a housing;
2. b. a preassembled functional module received in the housing, the preassembled functional module comprising

   b1. an analytical sensor for detecting at least one analyte in a body fluid of a user;

   b2. an electronics unit electrically connected to the analytical sensor;

   b3. an insertion component for inserting the analytical sensor into a body tissue of the user; and

   b4. at least one sterility cap at least partially surrounding the insertion component;

3. c. at least one removable protective cap connected to the housing, covering the preassembled functional module;

wherein the protective cap is removable from the housing by pulling off the protective cap from the housing, wherein the housing comprises at least one guiding surface for guiding the protective cap during pulling off the protective cap, wherein the preassembled functional module comprises at least one guiding surface for guiding the sterility cap during pulling off the sterility cap from the insertion component, wherein the guiding surface of the housing provides at least a rotational component when the protective cap is pulled off from the housing, wherein the sterility cap is connected to the preassembled functional module by at least one connection, wherein, by the rotational component, the connection is untightened and the sterility cap is removable from the preassembled functional module.

[0028] In a further aspect of the present invention, a medical system is disclosed. The medical system comprises:

1. a. a housing;
2. b. a preassembled functional module received in the housing, the preassembled functional module comprising

   b1. an analytical sensor for detecting at least one analyte in a body fluid of a user;

   b2. an electronics unit electrically connected to the analytical sensor;

   b3. an insertion component for inserting the analytical sensor into a body tissue of the user, wherein the insertion component comprises at least one insertion cannula, with the analytical sensor partially received therein, wherein the insertion component further comprises at least one holder for the insertion cannula; and

   b4. at least one sterility cap at least partially surrounding the insertion component;

3. c. at least one removable protective cap connected to the housing, covering the preassembled functional module;

wherein the holder, the insertion cannula and the sterility cap form components of a sterile container for the analytical sensor,

wherein the protective cap is removable from the housing by pulling off the protective cap from the housing, wherein the housing comprises at least one guiding surface for guiding the protective cap during pulling off the protective cap, wherein the preassembled functional module comprises at least one guiding surface for guiding the sterility cap during pulling off the sterility cap from the insertion component.

[0029] Components a., b., and c. as listed above specifically may be pre-assembled, such as to form a pre-assembled module, a pre-assembled single unit, a single factory-assembled module. This pre-assembled module or unit, specifically, may be packaged, as will be outlined in further detail below, e.g. in a blister pack.

[0030] The term "medical system" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to a system configured for performing at least one medical function. Specifically, as outlined above, the medical system may be configured for qualitatively and/or quantitatively detecting at least one analyte in a body fluid, such as in a body fluid contained in a body tissue of a user. The medical system specifically may be configured for performing at least two actions, which are the action of inserting an analytical sensor into the body tissue and to the action of detecting the analyte in the body fluid by using the analytical sensor. The medical system specifically may be, in a basic state before use, a unitary system which may be handled as one single piece. After use, which is after insertion of the analyte sensor into the body tissue, the medical system may disassemble into a disposable handling component including an inserter in a used state, and into an analyte sensor unit, with a body mount and the analyte sensor, wherein the body mount may be attached to the skin of the user and wherein the analyte sensor may protrude from the analyte sensor unit into the body tissue.

[0031] As further used herein, the term "housing" is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to a basically arbitrary element which is configured for fully or partially enclosing one or more components and for providing protection for these one or more components, such as against mechanical influence and/or humidity. The housing, specifically, may be or may comprise a rigid housing, such as a rigid housing made of one or more of a plastic material, a metallic material or a cardboard material. The housing may have a front face which is configured for being disposed on the skin of the user, such as an essentially flat front face. The front face, as an example, may have a rim, with an opening enclosed by the rim, wherein the rim, as an example, is configured for tightening the skin for application of the analyte sensor. The housing, as will be explained in further detail below, may comprise, may contain or may encase one or more further components, such as an insertion actuator.

[0032] As further used herein, the term "functional module" is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to a module, such as a unitary module made of one or more components, specifically a plurality of interconnected components, which are configured for interacting for performing at least one function, specifically at least one medical function. In the present case, the functional module specifically may be a medical functional module configured for performing at least one medical function, such as for qualitatively and/or quantitatively detecting at least one analyte in a body fluid.

[0033] As further used herein, the term "preassembled" generally refers to the fact that an assembly process has already taken place. Thus, as claimed, the medical system comprises the functional module as defined above in a preassembled state, which means the components of the functional module already being assembled, such as by being mechanically and/or electrically interconnected, thereby being ready for use for the at least one function, such as the at least one medical function, e.g. for the at least one analytical function. The preassembling specifically may take place in a factory, thereby rendering the preassembled functional module a factory-assembled functional module. Specifically, the medical system may be configured such that the at least one preassembled functional module is fully covered by the combination of the housing and the protective cap, such that the user may not see or manipulate the preassembled functional module without opening the medical device, e.g. without removing the protective cap.

[0034] As further used herein, the term "received in the housing" generally refers to the fact that the preassembled functional module is fully or partially surrounded by the housing. As outlined above, specifically, the housing may comprise at least one receptacle for receiving the preassembled functional module. The receptacle, as an example, may be located in a front face of the housing, wherein the receptacle may fully or partially be surrounded by a frame formed e.g. by the housing. The receptacle may be covered by the protective cap, such that, when the protective cap is removed from the housing, the functional module is accessible and may be placed on the skin of the user.

[0035] The term "sensor" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to an arbitrary element or device configured for detecting at least one condition or for measuring at least one measurement variable. The sensor specifically may be or may comprise an analyte sensor for at least partial implantation into a body tissue of a user, more specifically an analyte sensor for continuous monitoring of the analyte. The sensor specifically may be a monolithic sensor element.

[0036] Consequently and as further used herein, the term "analytical sensor" is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art

and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to a sensor according to the definition given above, which is configured for being used for analytical purposes. Specifically, the analytical sensor may be configured for qualitatively and/or quantitatively detecting at least one analyte in a body fluid of the user, such as one or more of the analytes listed above, more specifically glucose. The body fluid, as an example, may be or may contain one or more of blood or interstitial fluid. The analytical sensor specifically may be configured for long-term monitoring of the analyte. The analytical sensor, as an example, may be configured for being placed into the body tissue and for remaining therein for at least one week, by providing measurement data over this period of use. The analytical sensor specifically may be or may comprise an electrochemical analytical sensor, as will be described in further detail below.

[0037] The term "electronics unit" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to a unit, such as a unit which may be handled as a single piece, which is configured for performing at least one electronic function. Specifically, the electronics unit may have at least one interface for being connected to the analytical sensor, wherein the electronics unit may provide at least one electronic function interacting with the analytical sensor, such as at least one measurement function. As will be outlined in further detail below, the electronics unit specifically may be configured for measuring at least one voltage and/or for measuring at least one current, thereby interacting with the analytical sensor, specifically the electrochemical analytical sensor. The electronics unit specifically may comprise at least one electronics unit housing, wherein the analytical sensor, e.g. with a proximal end, may protrude into the housing and may be electrically connected with at least one electronic component within the housing. As an example, the proximal end and/or at least one contact portion of the electrochemical sensor may protrude into the housing and, therein, may be electrically connected to at least one electronic component, such as to at least one printed circuit board and/or at least one contact portion of the electronics unit, e.g. by one or more of a soldering connection, a bonding connection, a plug, a clamping connection or the like. The electronics unit, as will be outlined in further detail below, specifically may be used as a transmitter for transmitting measurement data to at least one external device, such as to at least one receiver, e.g. wirelessly.

[0038] The electronics unit is electrically connected to the analytical sensor. Thus, an electrical connection exists between the analytical sensor and the electronics unit. Via this electrical connection, the electronics unit may interact with the analytical sensor for performing at least one electrochemical measurement. The electrical connection specifically, as outlined above, may be established by at least one connection portion of the analytical sensor protruding into a housing of the electronics unit. The functional module may be preassembled in the sense that, the electronics unit is already electrically connected to the analytical sensor when the functional module is received in the housing, with the protective cap being connected to the housing. Specifically, the electronics unit may be irreversibly electrically connected to the analytical sensor. Thus, specifically, no need for assembly of the electronics unit and the analytical sensor is given, since, in the preassembled functional module, the electronics unit and the

analytical sensor are already connected, electrically and optionally also mechanically.

[0039] The term "insertion component" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to an element or a combination of elements which are configured for inserting at least one component into a body tissue of a user, e.g. transcutaneously or subcutaneously. Thus, specifically, the at least one insertion component may be or may comprise at least one insertion cannula, with a tip or sharp configured for piercing the skin of the user and further, optionally, with at least one slot configured for receiving at least a part of the analytical sensor. The insertion component may comprise further elements, such as at least one holder for manipulating or holding the insertion component such as the insertion cannula.

[0040] The electronics unit specifically may have an opening there through, through which the insertion component may protrude. Thus, as an example, the electronics unit may have an upper side and a lower side, with the lower side facing towards the skin of the user and with the upper side facing towards the housing, such as towards an insertion actuator. The insertion actuator may drive the insertion component, such as the insertion cannula, through the opening, such as through a through hole in in a housing of the electronics unit.

[0041] The term "protective cap" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to an element configured for partially covering at least one other device, component or element, thereby providing at least partial protection against mechanical and/or environmental influences. The protective cap specifically may be fully or partially made of at least one rigid material, such as of at least one plastic material and/or at least one metal. The protective cap specifically may have an opening which is configured to be directed towards the housing of the medical system. The protective cap specifically may be made essentially rotationally symmetric, e.g. by having an axial rotational symmetry about an axis such as a cylinder axis. The protective cap, as an example, may be designed as a cylinder, a hemisphere or as a dome.

[0042] The protective cap, as an example, may be connected to the housing by at least one of a form-fit or a force-fit connection. Specifically, a rim of the protective cap may be pushed over a rim of the housing or vice a versa. Thus, as an example, the protective cap may have a circular, oval or polygonal rim which fits tightly over the rim of the housing having a corresponding shape, or vice a versa. There may be an overlap region in the connected state, in which the protective cap overlaps with the housing or vice a versa.

[0043] As outlined above, the housing specifically may comprise at least one receptacle for receiving the electronics unit, the receptacle being open towards an end of the housing covered by the protective cap. Therein, as an example, the receptacle may comprise at least one open space, being open towards the front face of the housing, wherein the electronics unit

is received within the open space. The electronics unit may be held in the receptacle by at least one holding means, such as by at least one hook or the like, which may free the electronics unit once applied to the skin of the user, e.g. after insertion of the analytical sensor into the body tissue.

[0044] As outlined above, the electronics unit specifically may comprise at least one electronics component. Specifically, the electronics unit may comprise at least one of a measurement device for providing electrochemical measurement values, specifically at least one of an amperometric or a potentiostatic measurement device; a transmitter for transmitting measurement values to at least one external receiver; an integrated data storage device; an integrated battery. These electronic components generally are known in the art of long-term monitoring one or more analytes, such as in from one or more of the above-mentioned prior art documents.

[0045] As outlined above, specifically in an assembled state of the analytical system and prior to removal of the protective cap, the analytical sensor is fixedly electrically connected to the electronics unit. Thus, as opposed to systems in which the analytical sensor is connected to an electronics unit during insertion, in the present case, the analytical sensor specifically may be electrically connected to electronics unit prior to insertion. Thus, the analytical sensor and the electronics unit may form part of a disposable unit.

[0046] The analytical sensor specifically may be an electrochemical analytical sensor. Thus, the electrochemical analytical sensor specifically may have at least one working electrode and at least one further electrode selected from the group consisting of a counter electrode and a reference electrode. As an example, the at least one working electrode may comprise at least one chemical reagent for detecting the at least one analyte, such as at least one chemical reagent containing at least one enzyme. The at least one working electrode and the at least one further electrode specifically may be connected to the electronics unit via at least two electrical leads.

[0047] The preassembled functional module may further comprise at least one sterility cap at least partially surrounding the insertion component.

[0048] The term "sterility cap" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to an element such as a cover which is configured for maintaining a sterile atmosphere in a space fully or partially surrounded by the element. The sterility cap, as an example, may be a rigid sterility cap, e.g. made of a rigid plastic material and/or a metal. The sterility cap, as an example, may have a rotational symmetry about an axis which, as an example, may be identical to a rotational symmetry axis of the protective cap and/or of a rotational symmetry axis of the housing. The sterility cap, as an example, may have an elongated shape, with a length exceeding its diameter or equivalent diameter by at least a factor of 2, more preferably by at least a factor of five. The sterility cap, as an example, may have a length of 5 to 20 mm,

e.g. a length of 10 to 15 mm.

[0049] As outlined above, the insertion component specifically may comprise at least one insertion cannula. The insertion cannula may fully or partially be received in the sterility cap. The sterility cap, as an example, may have an elongated shape, with a closed end and an open end, with the insertion cannula protruding from the open end into the sterility cap, with the tip of the insertion cannula facing the closed end. The analytical sensor may partially be received in the insertion cannula, such as in a slot of the insertion cannula. The insertion component may further comprise at least one holder for the insertion cannula, wherein the holder, the insertion cannula and the sterility cap form components of a sterile container for the analytical sensor. The holder, as an example, may comprise a rigid component connected to a proximal end of the insertion cannula, i.e. to an end of the insertion cannula opposing the tip of the insertion cannula. The insertion cannula, as an example, may be connected to the holder by gluing and/or by injection molding and/or e.g. by other means of material engagement. The holder, as an example, may have a cylindrical shape.

[0050] The protective cap specifically may be removable from the housing by pulling off the protective cap from the housing. Thus, as outlined above, the protective cap may, in a stage connected to the housing, overlap with the housing or vice a versa. The protective cap specifically may be stuck onto the housing in a tight fashion. The housing specifically may comprise at least one guiding surface for guiding the protective cap during pulling off the protective cap, specifically a circumferential guiding surface. Thus, the guiding surface may be an outer surface of the housing, such as an outer surface having one of a circular cross-section, and oval cross-section or a polygonal cross-section. In the connected state, the protective cap may overlap with the housing within the guiding surface. When being pulled off from the housing, the protective cap, such as an inner surface of the protective cap, may slide over the guiding surface.

[0051] The sterility cap specifically may be fixedly connected to the protective cap. Thus, the sterility cap may be configured for being pulled off from the insertion component when the protective cap is pulled off from the housing. Still, the sterility cap may be distinct from the protective cap. Thus, even though the sterility cap may be received within the protective cap, the wall of the sterility cap should be different from the wall of the protective cap.

[0052] The sterility cap, however, may be connected to the protective cap at a distal end of the sterility cap, e.g. by one or more of a form-fit connection, a force-fit connection or a connection by material engagement such as a gluing or a connection by injection molding. The protective cap and the sterility cap specifically may be made of different materials.

[0053] The option of connecting the action of removing the protective cap from the housing with the action of pulling off the sterility cap from the insertion component provides a plurality of further options and advantages. Thus, as an example, the preassembled functional module may comprise at least one guiding surface for guiding the sterility cap during pulling off the sterility cap from the insertion component. A length of the guiding surface of the housing may

exceed a length of the guiding surface for the sterility cap, specifically by at least a factor of 2, more specifically by at least a factor of 5 or by at least a factor of 10. Additionally or alternatively, a length of the guiding surface of the housing may exceed a length of the sterility cap, specifically such that the sterility cap is fully pulled off from the insertion component before the guiding by the guiding surface of the housing ends when the protective cap is pulled off from the housing. Thus, in other words, by coupling the action of removing the protective cap from the housing, e.g. by pulling off the protective cap from the housing, with the action of removing the sterility cap from the insertion component, e.g. from the insertion cannula, provides the option of guiding the sterility cap via guiding the protective cap by the housing, such that the sterility cap performs a well-defined movement until the insertion component, e.g. the insertion cannula, is fully free and until the sterility cap is fully removed from the insertion component. Thus, the risk of mechanically damaging the insertion component, e.g. the insertion cannula, during removal of the sterility cap may be significantly reduced, since the movement of the sterility cap is well-defined and may be directed precisely along a longitudinal axis of the insertion component, e.g. the insertion cannula, specifically over the full length of the insertion cannula.

[0054] The guiding surface of the housing specifically may provide for at least one movement selected from the group consisting of a translational movement of the protective cap and the sterility cap when the protective cap is pulled off from the housing; a rotational movement of the protective cap and the sterility cap when the protective cap is pulled off from the housing; both a translational and a rotational movement of the protective cap and the sterility cap when the protective cap is pulled off from the housing. Thus, several movements are possible and may even be combined. As an example, when pulling off the protective cap, the protective cap may only perform a translational movement, e.g. along a longitudinal axis of the medical system. However, rotational movements may be introduced additionally or alternatively. As an example, the at least one guiding surface may provide for one or more spiral-shaped guiding elements or guiding surfaces, thereby introducing a rotational movement. The rotational movement specifically may also be used for blocking or unlocking actions. Thus, as an example, the guiding surface of the housing may provide at least a rotational component when the protective cap is pulled off from the housing. The sterility cap may be connected to the preassembled functional module by at least one bayonet connection, wherein, by the rotational component, the bayonet connection may be untightened and the sterility cap may be removable from the preassembled functional module.

[0055] The medical system may further comprise at least one indicator seal connected to the protective cap and the housing. As used herein, the term "indicator seal" specifically may refer to an element which is visible to a user and which indicates whether the medical system has been used before, specifically whether the protective cap has already been removed from the housing before. Thus, the indicator seal may also be referred to as an originality seal. The medical system may comprise one or more tamper-evident closure means and the indicator seal may be part of the tamper-evident closure means. The indicator seal, as an example, may be configured to be broken when the protective cap is removed from the housing. The indicator seal specifically may comprise one of a sealing foil and a sealing tape. The indicator

seal may exemplarily be an originality closure.

[0056] The indicator seal may provide further functionality to the medical system. Thus, the indicator seal may also provide sealing properties, such as against ingression of humidity into the housing and/or into the protective cap. Additionally or alternatively, the indicator seal may be light-tight. This option is specifically useful in connection with the option of the electronics unit being activated by an optical switch, which will be explained in further detail below.

[0057] Thus, generally, the medical system may be configured such that the electronics unit is switched on when the protective cap is removed from the housing. The electronics unit specifically may be switched on by at least one switching mechanism selected from the group consisting of: a mechanical switch connected to the cap, wherein the mechanical switch is switched on when the protective cap is removed from the housing; a light-sensitive switch, wherein the light-sensitive switch is switched on by ambient light when the protective cap is removed from the housing; a liner covering a battery of the electronics unit, wherein the liner is pulled off when the protective cap is removed from the housing. Thus, as an example, the protective cap may comprise a pin or a ribbon which is connected to the electronics unit. By removing the protective cap, e.g. by pulling off the protective cap, the pin or the ribbon may set free a switch within the electronics unit, thereby switching on the electronics unit. Additionally or alternatively, the electronics unit may comprise a photodiode, a phototransistor or another light-sensitive element which is configured for detecting the removal of the protective cap and ambient light shining on to the electronics unit, the electronics unit being configured for being switched on by the detection of the light. Additionally or alternatively, the light-sensitive element may generate a photocurrent or a photovoltage sufficient for switching on the electronics unit.

[0058] The medical system may further comprise at least one adhesive plaster for attaching the electronics unit to a skin surface of a user. The adhesive plaster may be attached directly or indirectly to the electronics unit or to a part which, e.g. during insertion of the analytical sensor, is connected to the electronics unit. The adhesive plaster may be or may comprise an adhesive surface, e.g. an adhesive surface of a rigid part or of a flexible bandage. The adhesive plaster, in an initial state of the medical system with the protective cap being connected to the housing, may be covered by at least one removable liner. The liner may be connected to the protective cap, e.g. directly by attaching the liner or a part thereof such as a ribbon or a latch of the liner to the protective cap, or indirectly, e.g. by connecting the protective cap and the liner by using a ribbon, a protrusion of the protective cap or the like. By these means or other means, the liner thus may be configured for being pulled off from the adhesive plaster when the protective cap is removed from the housing.

[0059] The medical system may further comprise at least one insertion actuator. The term "insertion actuator" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to an arbitrary device which is configured for directly or indirectly inserting at least one insertable element into a body tissue. The insertion actuator may comprise at least one mechanical device which is configured

for driving forward the insertable element or the insertion component such as the insertion cannula into the body tissue. The insertion actuator, as an example, may comprise at least one slider connected to the insertion component or the holder for the insertion component and configured for performing a forward linear motion in an insertion direction and, optionally, a backward linear motion in an opposite direction. As an example, the slider may be driven by at least one spring element, which may be pre-tensioned or biased in the forward direction or in the backward direction. Additionally or alternatively, the slider may be connected to at least one actuation button which may be pushed by the user, thereby driving the slider in the forward direction. The insertion actuator, thus, may be configured for driving the insertion component into the body tissue and, optionally, backwards again after insertion of the insertable analytical sensor. The backward motion, as an example, for retracting the insertion component such as the insertion cannula from the body tissue, may be driven by a return spring or by a motion inverter. The insertion actuation by the insertion actuator may further initiate or provide other actions, such as an assembly of components of the body mount, such as components providing a shell for the electronics unit, and/or an attachment of a body mount to the skin of the user. Inserting actuators configured for driving an insertion motion as known to the skilled person may also be used in the context of the present invention. As an example, reference may be made to the actuators disclosed in the above-mentioned documents WO 2016/012482 A1, WO 2016/012497 A1 or WO 2017/037191 A1 and the prior art cited therein. These insertion actuators may also be used in the context of the present invention, directly or with contextspecific modifications. Generally, the insertion actuator may be configured for advancing the insertion component after removal of the protective cap from the housing and for inserting the analytical sensor into the body tissue.

[0060] As indicated above, the medical system may comprise a body mount. The term "body mount" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to an analytical component interacting with the analytical sensor configured for being mounted to the skin of the user. The body mount may comprise the adhesive plaster and a cradle attached to the adhesive plaster and configured for receiving the electronics unit, as well as, fully or partially, the electronics unit. Further, optionally, the body mount may comprise an upper shell covering the electronics unit, wherein, as an example, the upper shell may be connected to the cradle, thereby forming a shell fully or partially enclosing the electronics unit. The analytical sensor, in an inserted state with the body mount attached to the skin, may protrude from a lower side of the electronics unit, through an opening in the cradle and an opening in the adhesive plaster, into the body tissue.

[0061] In an initial state, before removing the protective cap from the housing, the body mount may be received in the housing. Therein, the body mount may be received in the housing in an assembled state or in a disassembled state, wherein, in the latter case, an assembly may take place during insertion or after insertion of the analytical sensor into the body tissue. Thus, generally, the body mount may comprise at least one cradle for attachment to the skin of the user and at least one upper shell, wherein the electronics unit is received in the upper shell.

The cradle and the upper shell may be disassembled before actuation of the insertion actuator. The medical system, specifically the cradle and the upper shell, may be configured for being assembled when the insertion actuator is actuated. Thus, as an example, when the insertion actuator moves forward towards the skin of the user, the adhesive plaster and/or the cradle may reach the skin and, thereby, a forward movement of these components may be stopped, wherein the electronics unit with the analytical sensor connected thereto and, optionally, the upper shell still may move forward towards the skin. Thereby, firstly, the electronics unit may be inserted into the cradle. Secondly, afterwards, the upper shell may be put on top and may be locked to the electronics unit and/or to the cradle, thereby forming a casing or shell for the electronics unit. Simultaneously, during the forward motion, the insertion component may be driven into the body tissue, thereby inserting the analytical sensor into the body tissue. Afterwards, the insertion component may be retracted from the body tissue, with the analytical sensor remaining in the body tissue.

[0062] As outlined above, the insertion actuator specifically may comprise at least one pushbutton. The pushbutton, as an example, may comprise a linearly slidable pushbutton which may be pushed in a linear direction, such as perpendicular to the skin of the user. The insertion actuator, specifically the pushbutton, may be comprised in the housing, may be attached to the housing or may be integrated into the housing. As further outlined above, the insertion actuator further may be configured for retracting the insertion component from the body tissue after insertion of the analytical sensor.

[0063] The protective cap, in addition or as an alternative to one or more of the above-mentioned functions, may provide further functionality. Thus, as an example, the protective cap may also provide functions for keeping the level of humidity within the closed medical system, before removal of the protective cap, low. Thus, specifically, the protective cap may comprise a plurality of chambers at least partially filled with a desiccant such as silica gel. As an example, on one or more inner surfaces facing towards the housing, the protective cap may comprise one or more separating walls protruding from the at least one in the surface into an interior of the protective cap, thereby forming the chambers, which, as an example, may be open towards the housing. The chambers may fully or partially be filled with the at least one desiccant.

[0064] As a further, additional or alternative measure for protecting the analytical sensor and/or the electronics unit in the medical system from humidity, the medical system may further comprise at least one humidity seal received in between the protective cap and the housing. Thus, as outlined above, the protective cap may overlap with the housing in an overlap region, which may also provide the at least one guiding surface. Within this overlap region, at least one humidity seal may be provided, such as by providing O-ring and/or by providing a line of glue, such as a circumferential line. The humidity seal may be broken when the protective cap is removed from the housing.

[0065] The medical system may further comprise at least one package. The package specifically may be an airtight and/or a humidity-tight package such as a blister pack. The

remaining components of the medical system may be enclosed in the closed package, specifically in the blister pack. Thus, the housing, the preassembled functional module and the removable protective cap connected to the housing may form a single, closed unit of the medical system which may be enclosed in the closed package, with the preassembled functional module, e.g. preassembled by factory assembly, enclosed in the housing with the protective cap attached thereto. Thus, once the user opens the closed package, taking out the unit, the unit may be ready to use.

[0066] In a further general aspect, not covered by the present invention, a method of manufacturing a medical system, specifically of a medical system as disclosed above or as disclosed in further detail below, is proposed. The method comprises the steps disclosed in the following. The steps specifically may be performed in the given order. Still, a different order is possible. The method may comprise additional steps which are not mentioned. It is further possible to perform one or more of the method steps repeatedly. Further, two or more of the method steps may be performed in a timely overlapping fashion or simultaneously.

[0067] The method steps comprised by the method of manufacturing the medical system are:

1. i. providing a housing;
2. ii. preassembling a functional module, the preassembled functional module comprising
    - an analytical sensor for detecting at least one analyte in a body fluid of a user;
    - an electronics unit electrically connected to the analytical sensor; and
    - an insertion component for inserting the analytical sensor into the body tissue;
3. iii. receiving the preassembled functional module in the housing;
4. iv. connecting at least one removable protective cap to the housing, thereby covering the preassembled functional module.

[0068] As indicated above, the method specifically may be used for manufacturing the medical system as proposed therein, such as according to any one of the embodiments disclosed above and/or according to any one of the embodiments disclosed in further detail below.

[0069] Further proposed but not being part of the present invention is a method of using the medical system according to the present invention, such as the medical system according to any one of the embodiments disclosed above or according to any one of the embodiments disclosed in further detail below. The method may comprise the following steps, preferably in the given order. A different order, however, may also be feasible. Further, again, one, more than one or even all of the method steps may be performed repeatedly. Further, two or more of the method steps may also be performed fully or partially simultaneously. The method may comprise further steps.

[0070] The method comprises:

1. I. providing the medical system,

2. II. removing the protective cap from the housing,
3. III. placing the housing against the skin of the user, and
4. IV. inserting the analytical sensor into the body tissue of the user.

[0071] Method step I. may also include removing a unit of the medical system, comprising the housing, the protective cap and the preassembled functional module, from a closed package, such as from a blister pack.

[0072] Method step II. may comprise a plurality of sub-steps, which may be initiated by removing the protective cap from the housing. One or more of the sub-steps disclosed in the following may be comprised. Thus, as indicated above, the steps may comprise switching on the electronics unit. Additionally or alternatively, the step may comprise removing a sterility cap from the insertion component. Additionally or alternatively, the step may also comprise breaking an indicator seal. Additionally or alternatively, the step may also comprise removing a liner from an adhesive plaster.

[0073] Method step III. may comprise attaching an adhesive plaster to the skin and, further, optionally, placing a cradle onto the skin and adhering the cradle to the skin with the adhesive plaster.

[0074] Similarly, method step IV. may comprise one or more of the following sub-steps. Thus, as an example, the method step may comprise the step of initiating the insertion by activating an insertion actuator, such as by pushing a pushbutton. The step may also comprise an assembly of a body mount, e.g. by assembling the adhesive plaster, the cradle and the electronics unit as well as, optionally, an upper shell to form a single unit.

[0075] The medical system and the method according to the present invention provide a large number of advantages over known methods and devices. Thus, specifically, the above-mentioned technical challenges of known inserting devices, specifically for continuous monitoring sensors, are addressed.

[0076] Specifically, the medical system may provide for a fully disposable continuous monitoring system, such as a fully disposable continuous glucose monitoring system. The functional module may be preassembled, such that the body mount, the electronics unit and the analytical sensor are already in an assembled state. The functional module in combination with the housing and the removable protective cap may also form a preassembled module and may be delivered to the customer in such a preassembled fashion. Thus, no further assembling steps generally needs to be performed by the user. The preassembled module may comprise the housing, the functional module and the protective cap. The protective cap may combine different functionalities in one element. Such functionalities may include one or more of ensuring a sterile and safe environment, providing a simple user handling for removal of the protective cap, providing for a sterile barrier of the analytical sensor compartment,

initializing of medical system, providing for tamper-evident closure means such as the indicator seal or further functionalities. The protective cap specifically may ensure, in a simple and cost efficient fashion, a high robustness, and easy system initialization, as well as easy handling steps, in one system element. The medical system may provide for a sensor system for monitoring an analyte concentration, comprising an assembly of the analytical sensor, an inserter and an electronics unit. The analytical sensor, the inserter and the electronics unit may be preassembled prior to application of the analytical sensor. This pre-assembly specifically may be a factory pre-assembly, prior to unpacking the system by a user. The assembly may further comprise the protective cap which may fix the inserter, the analytical sensor and the electronics unit in place and, upon removal of the protective cap, may allow for insertion of the analytical sensor into subcutaneous tissue. as outlined above, the protective cap may be part of an initialization concept for the medical system, e.g. by the electronics unit comprising at least one photosensitive element which detects ambient light once the protective cap is removed, thereby initiating the electronics unit in connection with the analytical sensor. Additionally or alternatively, the protective cap may incorporate guiding means for simpler user handling on removal of the protective cap, e.g. via a screw that also may be used as seal. Additionally or alternatively, the protective cap may include a tamper-evident closure, which may also aid as a barrier for liquid or humidity.

[0077] Thus, the protective cap specifically may provide multiple functions and multiple solutions for the technical challenges. Thus, as indicated above, by providing a protection against humidity, the protective cap may protect sensitive components of the analytical sensor, such as the substrate, enzymes or the like. Thereby, the storage lifetime may be increased. No additional desiccant in an outer packaging, including the requirement for additional space, is generally required. The desiccant may be placed in the protective cap, e.g. by placing the desiccant directly into the protective cap and/or by implementing one or more packages of desiccant into the protective cap, e.g. by material engagement such as gluing and/or by formfitting connection. The amount of desiccant may be adapted to the desired storage lifetime of the medical system.

[0078] The protective cap may further, as indicated above, be used as a switch for switching on the electrical unit, such as the transmitter. Thus, as outlined above, several functionalities and/or switching concepts may be implemented. As an example, optical switches such as one or more phototransistors may be used, wherein, when removing the protective cap from the housing, ambient light may switch on the electronics unit. The protective cap generally may be designed by using a light-tight material, in order to avoid unintentionally switching on the electronics unit and in order to provide a light barrier which is broken immediately before use of the medical system by the user. An appropriate geometry of the protective cap may be chosen.

[0079] The protective cap may further provide mechanical protection. Thus, an additional mechanical protection for the entire medical system is provided. Thus, by appropriate and/or flexible design of the protective cap or of parts thereof, the protective cap alone or in conjunction with the housing may absorb or reduce mechanical influences and shocks. Thus, as an example, without the protective cap, the medical system may be dropped onto a sterility

cap covering the insertion component such as the insertion cannula and thereby inducing damages to the insertion component. Without the protective cap, other constructive protective measures would be required.

[0080] Further, as outlined above, the sterility cap and the removal of the same impose further technical challenges onto typical medical systems. Due to the length of the insertion component, such as the length of the insertion cannula, pulling off the sterility cap typically requires a minimum length of guiding, such as a minimum length of 10 mm, in order to safely remove the sterility cap from the insertion component and in order to avoid damaging of the insertion component by the sterility cap during removal. By connecting the sterility cap to the protective cap, the guiding of the sterility cap during removal may be increased and improved. Thus, as an example, the protective cap may be guided by the housing when removing the protective cap from the housing, wherein a guiding length or guiding distance increases the length of the insertion component and/or the length of the protective cap. Thus, by this increased guiding, as an example, transversal movements may be possible only after the sterility cap has safely cleared the insertion component such as the cannula.

[0081] The protective cap may further be used for preparing the body mount for attachment to the skin of the user. Thus, as outlined above, the removal of the protective cap from the housing may also be used for removing a liner from an adhesive plaster.

[0082] The protective cap may further be used in connection with an indicator seal, such as the originality closure, and/or with a humidity barrier. Thus, in between the protective cap and the housing, the indicator seal may be provided, such as by providing a visible adhesive tape which clearly indicates whether the medical system has been opened and/or damaged. The indicator seal may also provide an additional barrier against humidity and, thus, may render an additional package obsolete. Additionally or alternatively, a humidity barrier may be provided in between the protective cap and the housing or the pushbutton of the actuator.

[0083] Further, as outlined above, when removing the protective cap from the housing, various movements are feasible. Thus, purely translational movements as well as combinations with rotational movements are feasible. Further, the movement of the protective cap may be translated into an appropriate movement of the sterility cap. Thus, even if the protective cap performs a purely translational movement, this translational movement may be translated into a rotational component of the sterility cap or vice a versa. For transforming a movement of the protective cap into a desired movement of the sterility cap, the sterility cap may be connected to the protective cap via one or more guiding elements, such as one or more cam controls. Thereby, the sterility cap may be unlocked from one or more of the insertion component, the electronics unit, the holder or the preassembled functional module, e.g. by a bayonet lock. Generally, by making use of one or more of these options, the geometry of the medical system, such as the geometry of the insertion actuator, may be separated from the geometry of other components of the medical system and, generally, may be chosen freely. The insertion actuator not necessarily has to have a round cross-section, and the electronics unit may be optimized onto a small area. Generally, the geometry may be chosen independent from the

functions of the components, such as of the transmitter.

Short description of the Figure

[0084] Further optional features and embodiments will be disclosed in more detail in the subsequent description of embodiments, preferably in conjunction with the dependent claims. Therein, the respective optional features may be realized in an isolated fashion as well as in any arbitrary feasible combination, as the skilled person will realize. The scope of the invention is not restricted by the preferred embodiments. The embodiments are schematically depicted in the Figure. Therein, identical reference numbers in the Figure refer to identical or functionally comparable elements.

[0085] In the Figure:

Figure 1
shows a cross-sectional view of an embodiment of a medical system.

Detailed description of the embodiment

[0086] In Figure 1, a cross-sectional view of an embodiment of a medical system 110 is shown. The medical system comprises a housing 112 which, as an example, may be made of a plastic material. The housing 112 may comprise one component or a plurality of components.

[0087] Within the housing 112, in this exemplary embodiment, an insertion actuator 114 is comprised, which, as an example, may comprise a pushbutton 116. As an example for potential details of the insertion actuator, reference may be made to the above-mentioned prior art documents, such as to WO 2017/037191 A1 as well as the prior art cited therein. It shall be noted, however, that other insertion mechanisms are feasible.

[0088] Further received within the housing 112 is a preassembled functional module 118. Thus, as an example, the housing 112 may comprise a receptacle 122 in which the preassembled functional module 118 is received. The preassembled functional module 118 comprises an analytical sensor 120 which is not visible in this figure and which is received within a sterility cap 124. The preassembled functional module 118 further comprises at least one electronics unit 126, such as at least one transmitter 128. Further, the preassembled functional module 118 comprises at least one insertion component 130, which also is not visible in this figure. The insertion component 130, as an example, may comprise at least one insertion cannula 132, e.g. an insertion cannula 132 having a slot with the analytical sensor 120 received therein.

[0089] The medical system 110 further comprises at least one protective cap 134. The protective cap 134, in the closed state as shown in Figure 1, which is the state before use of the medical system 110, is connected to the housing 112. Thus, as an example, the protective cap 134 may overlap with the housing 112 in an overlap region 136. Thus, a circumferential rim 138 of the protective cap 134 may snugly fit on a circumferential guiding surface 140 on an upper outer side of the housing 112. The protective cap 134, for disconnecting from the housing 112, may be pulled off from the housing 112, wherein the guiding surface 140 may have a length L in the direction of pulling off the protective cap 134.

[0090] When pulling off the protective cap 134 from the housing 112, various functions may be initiated. Thus, as an example, the sterility cap 124 may be connected to the protective cap 134 by a connection 142. Thus, when pulling off the protective cap 134 from the housing 112, the sterility cap 124 may be pulled off from the insertion component 130. Therein, a length l of the sterility cap 124 may be smaller than the guiding length L, such that the sterility cap 124 fully clears the insertion component 130 before the guiding of the protective cap 134 by the guiding surface 140 ends. Thereby, a misplacement of the sterility cap 124 in relation to the insertion component 130 is avoided, which might lead to a damaging of the insertion component 130. Consequently, the connection between the sterility cap 124 and the protective cap 134 may lead to a safe removal of the sterility cap 124 from the insertion component 130.

[0091] The sterility cap 124, the insertion component 130 and a holder 144 for the insertion component 130 may form a miniaturized sterile container 146 for the analytical sensor 120. This sterile container 146 may be disassembled, by removing the sterility cap 124, when the protective cap 134 is removed from the housing 112.

[0092] The medical system 110 may further comprise a body mount 148. The body mount 148, which may also be placed in the receptacle 122, may contain a cradle 150 which may be placed against the skin of the user once the protective cap 134 is removed. The body mount 148 may further comprise an adhesive plaster 152 on top of the cradle 150, for adhering the cradle 150 onto the skin. The adhesive plaster 152 may be protected by a liner 154 which, e.g. via one or more protrusions 156 of the protective cap 134, may be connected to the protective cap 134. Thus, when the protective cap 134 is removed from the housing 112, the protective cap 134 may also remove the liner 154 from the adhesive plaster 152.

[0093] The cradle 150 may be configured for receiving the electronics unit 126. Thus, the electronics unit 126 may also fully or partially be part of the body mount 148. The electronics unit 126, in this exemplary embodiment, may be received in an upper shell 158, which may also form part of the body mount 148 and which may interact with the cradle 150 for providing a cover for the electronics unit 126.

[0094] The medical system 110 may further comprise at least one desiccant 160. The desiccant 160 may be comprised in the protective cap 134, specifically in a plurality of chambers 162 provided by the protective cap 134.

[0095] The medical system 110 may further comprise at least one indicator seal 164, such as at least one clearly visible tape, at a transition between the protective cap 134 and the housing 112. The indicator seal 164, firstly, may clearly indicate whether the medical system 110 has been used or not and may be broken when removing the protective cap 134 from the housing 112. The indicator seal 164 may provide further functionality, such as by providing a humidity barrier and by preventing or reducing the ingression of humidity into the protective cap 134 and/or into the housing 112. Further, the indicator seal 164 may provide a light barrier and may be rendered light-tight. This is specifically useful in connection with an optical switching mechanism.

[0096] Thus, the electronics unit 126 may comprise an optical switch, such as an optical switch having a photodiode or a phototransistor. The protective cap 134 may be light-tight. When removing the protective cap 134 from the housing 112 for the first time, the photosensitive element of the electronics unit 126 may register the ambient light and may switch on the electronics unit 126. Other switches connected to the movement and removal of the protective cap 134 are feasible, such as mechanical switches. Thus, generally, the electronics unit 126 may be configured for being switched on when the protective cap 134 is removed from the housing 112.

[0097] For providing further humidity protection, at least one humidity seal 166 may be provided in between the protective cap 134 and the housing. Thus, as an example, one or more lines of glue may be provided on the guiding surface 140.

[0098] For use of the medical system 110 according to Figure 1, the protective cap 134 may be removed from the housing 112. Thereby, as outlined above, the sterility cap 124 may be removed from the insertion component 130. The removal of the sterility cap 124 may take place by purely translational movement, such as in an axial direction in Figure 1. Additionally or alternatively, the removal of the sterility cap 124 may also imply a rotational movement, e.g. by transforming a translational movement of the protective cap 134 into a rotational movement of the sterility cap 124. Thus, as an example, a connection between the protective cap 134 and the sterility cap 124 may provide for an appropriate motion transformation, e.g. by providing one or more cams.

[0099] Further, as outlined above, by removal of the protective cap 134, the liner 154 may be removed, and the electronics unit 126 may be switched on. Subsequent to the removal of the protective cap 134, the housing 112 may be placed onto the desired skin side. Thereby, by the adhesive plaster 152, the cradle 150 is adhered to the skin.

[0100] Subsequently, by pushing the push button 116, the insertion component 130, e.g. the insertion cannula 132, is driven into the body tissue, thereby placing the analytical sensor 120 into the body tissue. Once the insertion has taken place, the insertion component 130 is retracted from the body tissue, back into the housing 112, remaining therein and preventing injuries. Further, during the insertion motion initiated by the insertion actuator 114, the body mount 148 is assembled. Thus, the upper shell 158 is connected to the cradle 150, safely

placing the electronics unit 126 in between. It shall be noted, however, that the analytical sensor 120 is already electrically connected to the electronics unit 126 in the unused state as shown in Figure 1, since the functional module 118 is preassembled. Thus, during insertion, no electrical connection between the analytical sensor 120 and the electronics unit 126 has to take place, thereby reducing the complexity of the insertion motion and reducing the risk of electrical failure during the connection. Thus, the electronics unit 126, with the analytical sensor 120 fixedly connected thereto, may fully be designed as a disposable unit, without reusable parts. By providing a battery and by providing a switching mechanism, e.g. triggered by the removal of the protective cap 134, the number of handling steps may significantly be reduced, leading to a simplified operating procedure which can be managed even by elderly people and children.

[0101] After insertion of the analytical sensor 120 into the body tissue and placement of the body mount 148 onto the skin, the remaining parts of the medical system 110, specifically the housing 112 and the insertion actuator 114, may be removed and may be disposed of. No further handling steps are required for the user, e.g. no further handling steps such as connecting electronic components to the analytical sensor 120 and/or the body mount 148 or the electronics unit 126. Thus, after performing the above-mentioned steps, without further steps, the analytical sensor 120 and the electronics unit 126 may provide measurement values. The measurement values, as an example, may be transmitted wirelessly to a receiver, such as a medical data management system.

List of reference numbers

[0102]

110 medical system
112 housing
114 insertion actuator
116 pushbutton
118 preassembled functional module
120 analytical sensor
122 receptacle
124 sterility cap
126

electronics unit

128

transmitter

130

insertion component

132

insertion cannula

134

protective cap

136

overlap region

138

rim

140

guiding surface

142

connection

144

holder

146

sterile container

148

body mount

150

cradle

152

adhesive plaster

154

liner

156

protrusion

158

upper shell

160

desiccant

162

chamber

164

indicator seal

166

humidity seal

REFERENCES CITED IN THE DESCRIPTION

Cited references

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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PATENTKRAV

1. Medicinsk system (110), der omfatter

a. et hus (112),

b. et formonteret funktionsmodul (118), der er optaget i huset (112), hvilket formonteret funktionsmodul (118) omfatter

b1. en analysesensor (120) til at påvise mindst én analyt i en kropsvæske hos en bruger,

b2. en elektronikenhed (126), der er elektrisk forbundet med analysesensoren (120),

b3. en indføringskomponent (130) til at indføre analysesensoren (120) i et kropsvæv hos brugeren, og

b4. mindst én sterilitetshætte (124), der mindst delvist omgiver indføringskomponenten (130),

c. mindst én aftagelig beskyttelseshætte (134), der er forbundet med huset (112), der dækker det formonterede funktionsmodul (118),

hvor beskyttelseshætten (134) kan aftages fra huset (112) ved at trække beskyttelseshætten (134) af huset (112), hvor huset (112) omfatter mindst én styreflade (140) til at styre beskyttelseshætten (134), når beskyttelseshætten (134) trækkes af, hvor det formonterede funktionsmodul (118) omfatter mindst én styreflade til at styre sterilitetshætten (124), når sterilitetshætten (124) trækkes af indføringskomponenten (130), hvor en længde af husets (112) styreflade (140) er længere end en længde af styrefladen til sterilitetshætten (124) med mindst en faktor 2, således at sterilitetshætten (124) trækkes helt af indføringskomponenten (130), før styringen ved hjælp af husets (112) styreflade (140) slutter, når beskyttelseshætten (134) trækkes af huset (112).

2. Medicinsk system (110) ifølge det foregående krav, hvor husets (112) styreflade (140) tilvejebringer mindst én bevægelse, der er valgt fra gruppen bestående af: en translationsbevægelse af beskyttelseshætten (134) og sterilitetshætten (124), når beskyttelseshætten (134) trækkes af huset (112), en rotationsbevægelse af beskyttelseshætten (134) og sterilitetshætten (124), når beskyttelseshætten (134) trækkes af huset (112), både en translations- og en rotationsbevægelse af beskyttelseshætten (134)

og sterilitetshætten (124), når beskyttelseshætten (134) trækkes af huset (112).

3. Medicinsk system (110) ifølge det foregående krav, hvor husets (112) styreflade (140) tilvejebringer mindst én rotationskomponent, når beskyttelseshætten (134) trækkes af huset (112), hvor sterilitetshætten (124) er forbundet med det formonterede funktionsmodul (118) med mindst én forbindelse, hvor forbindelsen løsnes med rotationskomponenten, og sterilitetshætten (124) kan aftages fra det formonterede funktionsmodul (118).

4. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor sterilitetshætten (124) er konfigureret til at blive trukket af indføringskomponenten (130), når beskyttelseshætten (134) trækkes af huset (112), hvor sterilitetshætten (124) er forbundet med beskyttelseshætten (134) ved en distal ende af sterilitetshætten (124) med én eller flere af en formtilpasningsforbindelse, en tvangstilpasningsforbindelse, en materialeindgrebsforbindelse eller en sprøjtestøbningsforbindelse.

5. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor beskyttelseshætten (134) og sterilitetshætten (124) er fremstillet af forskellige materialer.

6. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor indføringskomponenten (130) omfatter mindst én indføringskanyle (132) med analysesensoren (120) delvist optaget deri.

7. Medicinsk system (110) ifølge det foregående krav, hvor indføringskomponenten (130) yderligere omfatter mindst én holder (144) til indføringskanylen (132), hvor holderen (144), indføringskanylen (132) og sterilitetshætten (124) danner komponenter af en steril beholder til analysesensoren (120).

8. Medicinsk system (110) ifølge det foregående krav, hvor sterilitetshætten (124) er forbundet med beskyttelseshætten (134) via et eller flere styreelementer til at transformere en bevægelse af beskyttelseshætten (134) til en ønsket bevægelse af sterilitetshætten (124), hvor sterilitetshætten (124) kan låses op fra holderen (144) med en bajonetlås.

9. Medicinsk system (110) ifølge et hvilket som helst af de to foregående krav, hvor holderen (144) omfatter en stiv komponent, der er forbundet med en proksimal ende af indføringskanylen (132).

10. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor elektronikenheden (126) omfatter mindst én af: en måleanordning til at tilvejebringe elektrokemiske måleværdier, især mindst én af en amperometrisk eller en potentiostatisk måleanordning, en sender (128) til at sende måleværdier til mindst én ekstern modtager, en integreret datalagringsanordning, et integreret batteri.

11. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor elektronikenheden (126) omfatter mindst ét elektronikenhedshus, hvor analysesensoren (120) rager ind i elektronikenhedhuset og er elektrisk forbundet med mindst én elektronisk komponent i elektronikenhedshuset.

12. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor det medicinske system (110) er konfigureret således, at elektronikenheden (126) tændes ved hjælp af en omskiftningsmekanisme.

13. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor det medicinske system (110) er konfigureret således, at elektronikenheden (126) tændes, efter beskyttelseshætten (134) aftages fra huset (112).

14. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor beskyttelseshætten (134) er forbundet med huset (112) med mindst én af en formtilpasnings- eller en tvangstilpasningsforbindelse.

15. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor huset (112) omfatter mindst én optagelsesdel (122) til at optage det formonterede funktionsmodul (118), hvor optagelsesdelen (122) er placeret i en forside af huset (112), hvor optagelsesdelen (122) er helt eller delvist omgivet af en ramme, der er dannet af huset (112).

16. Medicinsk system (110) ifølge det foregående krav, hvor optagelsesdelen (122) er dækket af beskyttelseshætten (134), således at, når beskyttelseshætten (134) aftages fra huset (112), er det formonterede funktionsmodul (118) tilgængeligt og kan placeres på brugerens hud.

17. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, der yderligere omfatter mindst én indikatorforsegling (164), der er forbundet med beskyttelseshætten (134) og huset (112), hvor indikatorforseglingen (164) er konfigureret til at blive brudt, når beskyttelseshætten (134) aftages fra huset (112).

18. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor det medicinske system (110) yderligere omfatter mindst én indføringsaktuator (114), hvor indføringsaktuatoren (114) omfatter mindst én mekanisk anordning, der er konfigureret til at føre indføringskomponenten (130) frem og ind i et kropsvæv.

19. Medicinsk system (110) ifølge det foregående krav, hvor elektronikenheden (126) har en åbning derigennem, gennem hvilken indføringskomponenten (130) rager frem.

20. Medicinsk system (110) ifølge det foregående krav, hvori indføringsaktuatoren (114) driver indføringskomponenten (130) gennem åbningen.

21. Medicinsk system (110) ifølge et hvilket som helst af de tre foregående krav, hvor indføringsaktuatoren yderligere er konfigureret til at føre indføringskomponenten (130) tilbage igen efter indføring af den indførbare analysesensor (120), hvor en returbevægelse til tilbagetrækning af indføringskomponenten (130) fra kropsvævet drives af en returfjeder.

22. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor huset (112), det formonterede funktionsmodul (118) og den aftagelige beskyttelseshætte (134) danner en formonteret enkelt enhed.

23. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor sterilitetshætten (124) er fast forbundet med beskyttelseshætten (134).

24. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor analysesensoren (120) er en elektrokemisk analysesensor.

25. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor det medicinske system (110) yderligere omfatter mindst én fugttætning (166), der er optaget mellem beskyttelseshætten (134) og huset (112).

26. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor et tørremiddel (160) er placeret i beskyttelseshætten (134).

27. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor sterilitetshætten (124) er forskelligt fra beskyttelseshætten (134).

28. Medicinsk system (110) ifølge det foregående krav, hvor sterilitetshætten (124) optages inden i beskyttelseshætten (134), hvor en væg af sterilitetshætten (124) er forskellig fra en væg af beskyttelseshætten (134).

29. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor huset (112) har en forside, der er konfigureret til at blive anbragt på brugerens hud, hvor forsiden har en kant (138) med en åbning, der er omsluttet af kanten, hvor kanten (138) er konfigureret til at stramme huden til påføring af analysesensoren (120).

30. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor elektronikenheden (126) allerede er elektrisk forbundet med analysesensoren (120), når det formonterede funktionsmodul (118) optages i huset (112), idet beskyttelseshætten (134) er forbundet med huset (112).

31. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor beskyttelseshætten (134) overlapper med huset (112) i et overlapningsområde (136), hvor mindst én fugttætning er tilvejebragt inden i overlapningsområdet (136).

32. Fremgangsmåde til fremstilling af et medicinsk system (110), hvor det medicinske system (110) er et medicinsk system (110) ifølge et hvilket som helst af de foregående krav, hvor fremgangsmåden omfatter:

i. at tilvejebringe et hus (112),

ii. at formontere et funktionsmodul (118), hvilket formonteret funktionsmodul (118) omfatter

- en analysesensor (120) til at påvise mindst én analyt i en kropsvæske hos en bruger,
- en elektronikenhed (126), der er elektrisk forbundet med analysesensoren (120),
- en indføringskomponent (130) til at indføre analysesensoren (120) i kropsvævet og
- mindst én sterilitetshætte (124), der mindst delvist omgiver indføringskomponenten (130),

iii. at optage det formonterede funktionsmodul (118) i huset (112),

iv. at forbinde mindst én aftagelig beskyttelseshætte (134) med huset (112), hvorved det formonterede funktionsmodul (118) dækkes,

hvor beskyttelseshætten (134) kan aftages fra huset (112) ved at trække beskyttelseshætten (134) af huset (112), hvor huset (112) omfatter mindst én styreflade (140) til at styre beskyttelseshætten (134) under aftrækning af beskyttelseshætten (134),

hvor det formonterede funktionsmodul (118) omfatter mindst én styreflade til at styre sterilitetshætten (124) under aftrækning af sterilitetshætten (124) fra indføringskomponenten (130), hvor en længde af husets (112) styreflade (140) er længere end en længde af styrefladen til sterilitetshætten (124).

33. Medicinsk system (110), der omfatter

a. et hus (112),

b. et formonteret funktionsmodul (118), der er optaget i huset (112), hvilket formonteret funktionsmodul (118) omfatter

b1. en analysesensor (120) til at påvise mindst én analyt i en kropsvæske hos en bruger,

b2. en elektronikenhed (126), der er elektrisk forbundet med analysesensoren (120),

b3. en indføringskomponent (130) til at indføre analysesensoren (120) i et kropsvæv hos brugeren, og

b4. mindst én sterilitetshætte (124), der mindst delvist omgiver indføringskomponenten (130),

c. mindst én aftagelig beskyttelseshætte (134), der er forbundet med huset (112), der dækker det formonterede funktionsmodul (118), hvor sterilitetshætten (124) er forskelligt fra beskyttelseshætten (134),

hvor beskyttelseshætten (134) kan aftages fra huset (112) ved at trække beskyttelseshætten (134) af huset (112), hvor huset (112) omfatter mindst én styreflade (140) til at styre beskyttelseshætten (134) under aftrækning af beskyttelseshætten (134), hvor det formonterede funktionsmodul (118) omfatter mindst én styreflade til at styre sterilitetshætten (124) under aftrækning af sterilitetshætten (124) fra indføringskomponenten (130), hvor en længde af husets (112) styreflade (140) er længere end en længde af styrefladen til sterilitetshætten (124).

34. Medicinsk system (110), der omfatter

a. et hus (112),

b. et formonteret funktionsmodul (118), der er optaget i huset (112), hvilket formonteret funktionsmodul (118) omfatter

b1. en analysesensor (120) til at påvise mindst én analyt i en kropsvæske hos

en bruger,

b2. en elektronikenhed (126), der er elektrisk forbundet med analysesensoren (120),

b3. en indføringskomponent (130) til at indføre analysesensoren (120) i et kropsvæv hos brugeren, og

b4. mindst én sterilitetshætte (124), der mindst delvist omgiver indføringskomponenten (130),

c. mindst én aftagelig beskyttelseshætte (134), der er forbundet med huset (112), der dækker det formonterede funktionsmodul (118),

hvor beskyttelseshætten (134) kan aftages fra huset (112) ved at trække beskyttelseshætten (134) af huset (112), hvor huset (112) omfatter mindst én styreflade (140) til at styre beskyttelseshætten (134) under aftrækning af beskyttelseshætten (134), hvor det formonterede funktionsmodul (118) omfatter mindst én styreflade til at styre sterilitetshætten (124) under aftrækning af sterilitetshætten (124) fra indføringskomponenten (130), hvor en længde af husets (112) styreflade (140) er længere end en længde af styrefladen til sterilitetshætten (124).

hvor huset (112) har en forside, der er konfigureret til at blive anbragt på brugerens hud, hvor forsiden har en kant (138) med en åbning, der er omsluttet af kanten, hvor kanten (138) er konfigureret til at stramme huden til påføring af analysesensoren (120).

35. Medicinsk system (110), der omfatter

a. et hus (112),

b. et formonteret funktionsmodul (118), der er optaget i huset (112), hvilket formonteret funktionsmodul (118) omfatter

b1. en analysesensor (120) til at påvise mindst én analyt i en kropsvæske hos en bruger,

b2. en elektronikenhed (126), der er elektrisk forbundet med analysesensoren (120),

b3. en indføringskomponent (130) til at indføre analysesensoren (120) i et kropsvæv hos brugeren, og

b4. mindst én sterilitetshætte (124), der mindst delvist omgiver indføringskomponenten (130),

c. mindst én aftagelig beskyttelseshætte (134), der er forbundet med huset (112), der dækker det formonterede funktionsmodul (118),

hvor beskyttelseshætten (134) kan aftages fra huset (112) ved at trække beskyttelseshætten (134) af huset (112), hvor huset (112) omfatter mindst én styreflade (140) til at styre beskyttelseshætten (134), når beskyttelseshætten (134) trækkes af, hvor det formonterede funktionsmodul (118) omfatter mindst én styreflade til at styre sterilitetshætten (124), når sterilitetshætten (124) trækkes af indføringskomponenten (130), hvor en længde af husets (112) styreflade (140) er længere end en længde af styrefladen til sterilitetshætten (124), hvor elektronikenheden (126) allerede er elektrisk forbundet med analysesensoren (120), når det formonterede funktionsmodul (118) optages i huset (112), idet beskyttelseshætten (134) er forbundet med huset (112).

36. Medicinsk system (110), der omfatter

a. et hus (112),

b. et formonteret funktionsmodul (118), der er optaget i huset (112), hvilket formonteret funktionsmodul (118) omfatter

b1. en analysesensor (120) til at påvise mindst én analyt i en kropsvæske hos en bruger,

b2. en elektronikenhed (126), der er elektrisk forbundet med analysesensoren (120),

b3. en indføringskomponent (130) til at indføre analysesensoren (120) i et kropsvæv hos brugeren, og

b4. mindst én sterilitetshætte (124), der mindst delvist omgiver indføringskomponenten (130),

c. mindst én aftagelig beskyttelseshætte (134), der er forbundet med huset (112), der dækker det formonterede funktionsmodul (118),

hvor beskyttelseshætten (134) kan aftages fra huset (112) ved at trække beskyttelseshætten (134) af huset (112), hvor huset (112) omfatter mindst én styreflade (140) til at styre beskyttelseshætten (134) under aftrækning af beskyttelseshætten (134), hvor det formonterede funktionsmodul (118) omfatter mindst én styreflade til at styre sterilitetshætten (124) under aftrækning af sterilitetshætten (124) fra indføringskomponenten (130), hvor husets (112) styreflade (140) tilvejebringer mindst

en rotationskomponent, når beskyttelseshætten (134) trækkes af huset (112), hvor sterilitetshætten (124) er forbundet med det formonterede funktionsmodul (118) ved hjælp af mindst én forbindelse, hvor forbindelsen løsnes ved hjælp af rotationskomponenten, og sterilitetshætten (124) kan aftages fra det formonterede funktionsmodul (118).

37. Medicinsk system (110), der omfatter

a. et hus (112),

b. et formonteret funktionsmodul (118), der er optaget i huset (112), hvilket formonteret funktionsmodul (118) omfatter

b1. en analysesensor (120) til at påvise mindst én analyt i en kropsvæske hos en bruger,

b2. en elektronikenhed (126), der er elektrisk forbundet med analysesensoren (120),

b3. en indføringskomponent (130) til at indføre analysesensoren (120) i et kropsvæv hos brugeren, hvor indføringskomponenten (130) omfatter mindst én indføringskanyle (132) med analysesensoren (120) delvist optaget deri, hvor indføringskomponenten (130) yderligere omfatter mindst én holder (144) til indføringskanylen (132), og

b4. mindst én sterilitetshætte (124), der mindst delvist omgiver indføringskomponenten (130),

c. mindst én aftagelig beskyttelseshætte (134), der er forbundet med huset (112), der dækker det formonterede funktionsmodul (118),

hvor holderen (144), indføringskanylen (132) og sterilitetshætten (124) danner komponenter i en steril beholder til analysesensoren (120),

hvor beskyttelseshætten (134) kan aftages fra huset (112) ved at trække beskyttelseshætten (134) af huset (112), hvor huset (112) omfatter mindst én styreflade (140) til at styre beskyttelseshætten (134) under aftrækning af beskyttelseshætten (134), hvor det formonterede funktionsmodul (118) omfatter mindst én styreflade til at styre sterilitetshætten (124) under aftrækning af sterilitetshætten (124) fra indføringskomponenten (130).

38. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav

1-2, 3-31, 33, 34, 35 og 37, hvor husets (112) styreflade (140) tilvejebringer mindst en rotationskomponent, når beskyttelseshætten (134) trækkes af huset (112).

39. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav 3, 36 og 38, hvor sterilitetshætten (124) er forbundet med det formonterede funktionsmodul (118) med mindst én bajonetforbindelse, hvor bajonetforbindelsen løsnes med rotationskomponenten, og sterilitetshætten (124) kan aftages fra det formonterede funktionsmodul (118).

40. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav 33, 34, 35 og 36, hvor indføringskomponenten (130) omfatter mindst én indføringskanyle (132) med analysesensoren (120) delvist optaget deri, hvor indføringskomponenten (130) yderligere omfatter mindst én holder (144) til indføringskanylen (132), hvor holderen (144), indføringskanylen (132) og sterilitetshætten (124) danner komponenter i en steril beholder til analysesensoren (120),

41. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav 37 og 40, hvor sterilitetshætten (124) er forbundet med beskyttelseshætten (134) via et eller flere styreelementer til at transformere en bevægelse af beskyttelseshætten (134) til en ønsket bevægelse af sterilitetshætten (124), hvor sterilitetshætten (124) kan låses op fra holderen (144) med en bajonetlås.

42. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav 1 til 31, 33, 34, 35, 36 og 37 til 41, hvor det formonterede funktionsmodul (118) er et fabriksmonteret funktionsmodul.

43. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav 1 til 31, 33, 34, 35, 36 og 37 til 42, hvor funktionsmodulet (118) er formonteret i den forstand, at elektronikenheden (126) allerede er elektrisk forbundet med analysesensoren (120), når funktionsmodulet (118) optages i huset (112), idet beskyttelseshætten (134) er forbundet med huset (112), hvor elektronikenheden (126) er irreversibelt elektrisk forbundet med analysesensoren (120).

44. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav 1 til 31, 33, 34, 35, 36 og 37 til 43, hvor komponenter a., b. og c. som anført i et hvilket som helst af kravene 1, 33, 34, 35, 36 og 37 er formonteret til at danne et formonteret enkelt fabriksmonteret modul, hvor det formonterede enkelte fabriksmonterede modul er

pakket.

45. Medicinsk system (110) ifølge et hvilket som helst af de foregående krav 33, 34, 35, 36 og 37 til 44, hvor det medicinske system (110) yderligere omfatter mindst én indikatorforsegling (164), der er forbundet med beskyttelseshætten (134) og huset (112), hvor indikatorforseglingen (164) er konfigureret til at blive brudt, når beskyttelseshætten (134) aftages fra huset (112).

DRAWINGS

Drawing

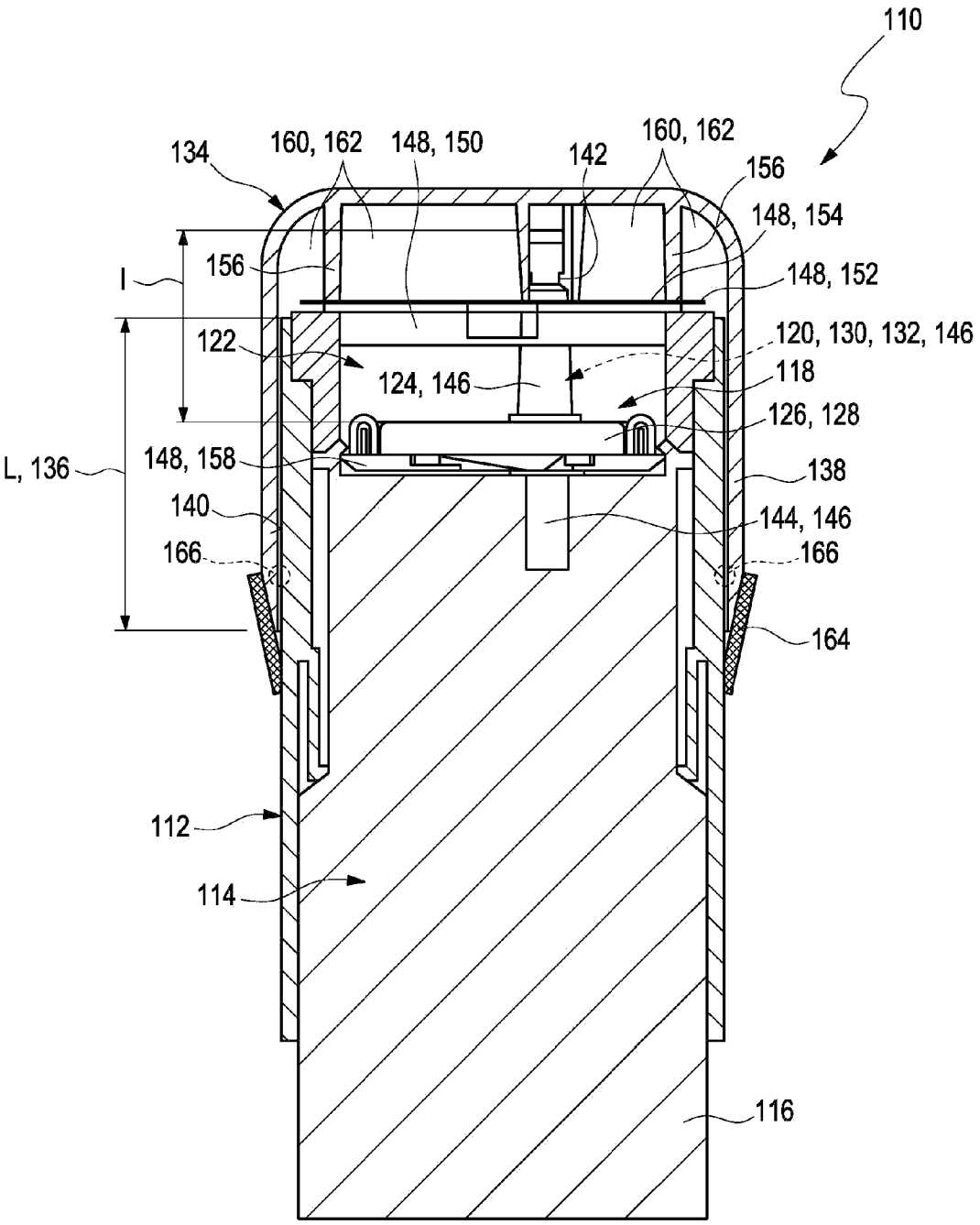


Fig. 1