Medical device for detecting at least one analyte in a body fluid

The present disclosure relates to a medical device for detecting at least one analyte in a body fluid, comprising a base body that is configured for reversibly attaching the medical device to a patient's body; an insertable analyte sensor comprising an insertable portion that is configured for being at least partially inserted into body tissue of a user; and an electronics unit that is operably connected to the insertable analyte sensor, wherein the insertable analyte sensor comprises a first electrode and a second electrode, both, forming part of the insertable portion, wherein the first electrode comprises a first free end and a second end, wherein the second end of the first electrode is electrically connected to a first electric conductor electrically connecting the first electrode of the insertable analyte sensor to the electronics unit, wherein the second electrode comprises a first free end and a second end, wherein the second end of the second electrode is electrically connected to a second electric conductor electrically connecting the second electrode of the insertable analyte sensor to the electronics unit, and wherein the first electrode extending from the second end towards its first free end and the second electrode extending from the second end towards its first free end are configured to be, during use of the medical device, at least partially in electric contact with the body tissue of a user.

A hitherto known medical device for detecting at least one analyte in a body fluid is, during use, removably attached to a user's body, wherein the insertable analyte sensor is inserted into the body tissue of the user. Accordingly, the first electrode and the second electrode are in direct contact with the body tissue, and electrically connected to the electronics unit. Thus, failure of the electronics unit, such a short circuit, may result in a high electric current flowing into the user's body via the first electrode and the second electrode. Therefore, in order increase the user's safety known medical devices comprises redundant electronic components such that a failure of an electronic component does not result in a high electric current flowing into the user's body, but is compensated by the respective redundant component. However, the number of extra, redundant electric components increase the production costs and results in a larger size of the medical device.

Accordingly, it is an object of the present disclosure to provide a medical device for detecting at least one analyte in a body fluid which avoid at least one disadvantage of hitherto known medical devices. In particular, it is an object of the present disclosure to provide a medical device for detecting at least one analyte in a body fluid mitigating a risk of a high current flowing into the body tissue of a user while allowing for lower production costs.

At least one of the above objects is solved by the provision of the subject matter disclosed in the claims and throughout the specification.

According to an aspect, a medical device for detecting at least one analyte in a body fluid, is provided, the medical device comprising a base body that is configured for reversibly attaching the medical device to a patient's body; an insertable analyte sensor comprising an insertable portion that is configured for being at least partially inserted into body tissue of a user; and an electronics unit that is operably connected to the insertable analyte sensor, wherein the insertable analyte sensor comprises a first electrode and a second electrode, both, forming part of the insertable portion, wherein the first electrode comprises a first free end and a second end, wherein the second end of the first electrode is electrically connected to a first electric conductor electrically connecting the first electrode of the insertable analyte sensor to the electronics unit, wherein the second electrode comprises a first free end and a second end, wherein the second end of the second electrode is electrically connected to a second electric conductor electrically connecting the second electrode of the insertable analyte sensor to the electronics unit, and wherein the first electrode extending from the second end towards its first free end and the second electrode extending from the second end towards its first free end are configured to be, during use of the medical device, at least partially in electric contact with the body tissue of a user, wherein the electrical resistance of the first electric conductor and the electrical resistance of the second electric conductor is higher than the electrical resistance of the first electrode and the electrical resistance of the second electrode.

The medical device for detecting at least one analyte in a body fluid can be removably attached to a user's body. For instance, the base body can be adhered to a user's skin. For example, the base body can comprise an adhesive layer or can comprise a patch comprising an adhesive that is configured for removably adhering the medical device to a user's body.

When being attached to a user's body, the insertable portion of the insertable analyte sensor is inserted into the body tissue of the user, wherein the first electrode and the second electrode are in electric contact with the body tissue and in electric contact with the electronics unit via the first conductor and the second conductor, respectively. Presence of an analyte in the body tissue will affect an electric current flowing between the first electrode and the second electrode. The change in electric current can be evaluated by the electronics unit so to allow a detection of the respective analyte. By way of example, only, the electronics unit can be a printed circuit board.

The analyte can be one or more analytes, preferably metabolites such as glucose, lactate, triglycerides, cholesterol or analytes in bodily fluids, such as for example blood or interstitial fluid or other bodily fluids. For instance, the insertable analyte sensor can be an electrochemical sensor that is configured for detecting at least one analyte, wherein the first electrode is configured as a working electrode and is used as transducer, and the second electrode is configured as a counter electrode.

The medical device can comprise a power supply that is configured for providing electric power to the electronics unit. The power supply can be a battery or a rechargeable battery that is configured for providing electric power to the electronics unit. By way of example, only, the battery can be configured to provide an electric power of 3.4 V.

In order to mitigate a risk of an uncontrolled electric current flowing into the user's body in case of a failure of the electronics unit or a component thereof, the electrical resistance of the first conductor and the electrical resistance of the second conductor is higher than the electrical resistance of the first electrode and the electrical resistance of the second electrode. During use, an electric current is flowing between the first electrode and the second electrode, the first electric conductor and the second electric conductor together with the first electrode and the second electrode form a potentiometer. The higher electrical resistance of the first conductor and the second conductor limits the electric current flowing through the first conductor and the second conductor, so that the electric current that is flowing through the first electrode and the second electrode is limited, too. Consequently, there is no need for redundant electric components that would limit the electric current flowing through the first electrode and the second electrode in case of a failure of the electronics unit or parts thereof. Without the need of redundant electric components the overall number of electronic components of the electronics unit can be reduced, such that the medical device can be of smaller size and with lower production costs.

According to an example, the sum of the electrical resistance of first electric conductor and the electrical resistance of the second electric conductor is higher than the sum of the electrical resistance of the first electrode and the electrical resistance of the second electrode. For instance, the sum of the electrical resistance of the first electrode and the electrical resistance of the second electrode can be 9 kOhm, while the sum of the electrical resistance of the first electrical conductor and the electrical resistance of the second electrical conductor can be 90 kOhm.

The electrical resistance of the first electrode and the electrical resistance of the second electrode can be equally high, and/or that the electrical resistance of the first electric conductor and the electrical resistance of the second electric conductor can be equally high. For the ease of its production, and for obtaining a symmetric potentiometer, it is beneficial that the electrical resistance of the first electrode is equal to the electrical resistance of the second electrode. Likewise, the electrical resistance of the first conductor is equal to the electrical resistance of the second conductor. In the meaning of the present disclosure, equal means identical measurement values that, however, may deviate by a common measuring inaccuracy and production inaccuracy.

In an example, the electrical resistance of the first electric conductor and the electrical resistance of the second electric conductor is at least 2-times, at least 4-times, at least 5-times or at least 10-

times higher than the electrical resistance of the first electrode and the electrical resistance of the second electrode. For instance, the electrical resistance of the first electrode and electrical resistance of the second electrode each can be 9 kOhm, while the electrical resistance of the first electric conductor and the electrical resistance of the second electric conductor each can be 90 kOhm.

In case of a failure of the electronics unit or parts thereof, an electric current that is uncontrolled flowing via the first electrode and the second electrode into body tissue, may harm the body tissue if the current exceeds 50 µA. Therefore, the electrical resistance of the first electric conductor and the electrical resistance of the second electric conductor, that during use limit a maximum electric current flowing through the first electrode and the second electrode, are selected so that the voltage of the power supply divided by the sum of the electrical resistance of the first electrical conductor and the electrical resistance of the second electric conductor is smaller than or equal to 50 µA. By knowing the voltage of the power supply, e.g. the voltage of a battery, the electrical resistance of the first electric conductor and the electrical resistance of the second electric conductor can be determined so to limit the maximum electric current flowing through the first electrode and the second electrode. The sum of the electrical resistance of the first electric conductor and the electrical resistance of the second electric conductor can be equal to the voltage of the power supply divided by the maximum allowed electric current, here: 50 µA.

In an example, the first electrode from its second towards its first free end and the second electrode from its second end towards its first free end are, over its respective length, configured to be during use of the medical device in electric contact with the body tissue. When being inserted, the first electrode and the second electrode forming at least part of the insertable portion, are in electric contact with the body tissue. At least one side of the respective first and second electrode, there is no electric isolation shielding the first and second electrode against the body tissue. On the other hand, the first electric conductor and the second electric conductor can be, over its respective length, configured to be during use of the medical device electrically isolated against the body tissue. Since, during use of the medical device, the first electric conductor and the second electric conductor limit the maximum electric current flowing through the first electrode and the second electrode, the first electric conductor and the second electric conductor should not be in direct electric contact with the body tissue.

According to an example, the first electric conductor comprises a first cable cross-sectional area, the second electric conductor comprises a second cable cross-sectional area, the first electrode comprises a third cable cross-sectional area, and the second electrode comprises a fourth cable cross-sectional area, wherein the first cable cross-sectional area and the second cable cross-sectional area are smaller than the third cable cross-sectional area and the fourth cable cross-sectional area. The electrical resistance of the respective electric conductor or electrode is inter alia dependent on the cross-sectional area, wherein a smaller cross-sectional area provides a higher electrical resistance

than a larger cross-sectional area of the same material. For instance, the cross-sectional area of the first electrode and the second electrode can be reduced by laser ablation.

The first cable cross-sectional area can be smaller than the third cable cross-sectional area, and the second cable cross-sectional area can be smaller than the fourth cable cross-sectional area. For instance, the first cable cross-sectional area and the second cable cross-sectional area are of equal size, and/or the third cable cross-sectional area and the fourth cable cross-sectional area are of equal size.

The first cable cross-sectional area and the second cable cross-sectional area can be at least 2-times, at least 4-times, at least 5-times, or at least 10-times smaller than the third cable cross-sectional area and the fourth cable cross-sectional area.

According to an example, the base body comprises a bushing, wherein the electronics unit is arranged on a first side of the bushing and the insertable portion of the insertable analyte sensor is arranged on a second side of the bushing opposite to the first side, wherein the second end of the first electrode electrically connected to the first electric conductor, and the second end of the second electrode electrically connected to the second electric conductor are both located within the bushing or at the first side of the bushing comprising the electronics unit or at the second side of the bushing comprising the insertable portion of the insertable analyte sensor. The bushing has a first side and second side, and provides a channel for the first and second electric conductors and/or the first and second electrode which are electrically connected to the electronics unit. For instance, when being located on the first side or within the bushing, a contact point between the first electrode and the first electric conductor as well as a contact point between the second electrode and the second electric conductor, i.e. the second end of the first electrode and/or the second end of the second electrode, is protected by the base body or the bushing. According to an example, the bushing can be a through hole or duct in the base body allowing the first and second electric conductors and/or the first and second electrode to pass into and out of the base body. Like the base body, the bushing can be made from an electrical isolating material.

Further advantages, features and technical effects of the present invention are apparent from the following description of embodiments and the accompanying figures.

Figure 1 shows a schematic view of a medical device for detecting at least one analyte in a body fluid according to an embodiment,

Figure 2 shows a schematic view of a medical device for detecting at least one analyte in a body fluid according to another embodiment, and

Figure 3 shows a schematic view of a medical device for detecting at least one analyte in a body fluid according to yet another embodiment.

Claims

1. A medical device (1) for detecting at least one analyte in a body fluid, comprising:
   - a base body (2) that is configured for reversibly attaching the medical device (1) to a patient's body;
   - an insertable analyte sensor (3) comprising an insertable portion (4) that is configured for being at least partially inserted into body tissue of a user; and
   - an electronics unit (5) that is operably connected to the insertable analyte sensor (3),
   - wherein the insertable analyte sensor (5) comprises a first electrode (6) and a second electrode (7), both, forming part of the insertable portion (4),
   - wherein the first electrode (6) comprises a first free end (6a) and a second end (6b), wherein the second end (6b) of the first electrode (6) is electrically connected to a first electric conductor (8) electrically connecting the first electrode (6) of the insertable analyte sensor (3) to the electronics unit (5),
   - wherein the second electrode (7) comprises a first free end (7a) and a second end (7b), wherein the second end (7b) of the second electrode (7) is electrically connected to a second electric conductor (9) electrically connecting the second electrode (7) of the insertable analyte sensor (3) to the electronics unit (5),
   - wherein the first electrode (6) extending from the second end (6b) towards its first free end (6a) and the second electrode (7) extending from the second end (7b) towards its first free end (7a) are configured to be, during use of the medical device (1), at least partially in electric contact with the body tissue of a user, and
   - wherein the electrical resistance of the first electric conductor (8) and the electrical resistance of the second electric conductor (9) is higher than the electrical resistance of the first electrode (6) and the electrical resistance of the second electrode (7).

2. The medical device (1) according to claim 1, wherein the sum of the electrical resistance of first electric conductor (8) and the electrical resistance of the second electric conductor (9) is higher than the sum of the electrical resistance of the first electrode (6) and the electrical resistance of the second electrode (7).

3. The medical device (1) according to claim 1 or 2, wherein the electrical resistance of the first electrode (6) and the electrical resistance of the second electrode (7) are equally high, and/or that the electrical resistance of the first electric conductor (8) and the electrical resistance of the second electric conductor (9) are equally high.

4. The medical device (1) according to any one of claims 1 to 3, wherein the electrical resistance of the first electric conductor (8) and the electrical resistance of the second electric conductor (9) is at least 2-times, at least 4-times, at least 5-times or at least 10-times higher than the

electrical resistance of the first electrode (6) and the electrical resistance of the second electrode (7).

5. The medical device (1) according to any one of claims 1 to 4, wherein the first electric conductor (8) comprises a first cable cross-sectional area, the second electric conductor (9) comprises a second cable cross-sectional area, the first electrode (6) comprises a third cable cross-sectional area, and the second electrode (7) comprises a fourth cable cross-sectional area, wherein the first cable cross-sectional area and the second cable cross-sectional area are smaller than the third cable cross-sectional area and the fourth cable cross-sectional area.

6. The medical device (1) according to claim 5, wherein first cable cross-sectional area is smaller than the third cable cross-sectional area, and the second cable cross-sectional area is smaller than the fourth cable cross-sectional area.

7. The medical device (1) according to claim 5 or 6, wherein the first cable cross-sectional area and the second cable cross-sectional area are of equal size, and/or the third cable cross-sectional area and the fourth cable cross-sectional area are of equal size.

8. The medical device (1) according to any one of claims 5 to 7, wherein the first cable cross-sectional area and the second cable cross-sectional area are at least 2-times, at least 4-times, at least 5-times, or at least 10-times smaller than the third cable cross-sectional area and the fourth cable cross-sectional area.

9. The medical device (1) according to any one of claims 1 to 8, wherein the base body (2) comprises a bushing (10), wherein the electronics unit (5) is arranged on a first side (10a) of the bushing (10) and the insertable portion (4) of the insertable analyte sensor (3) is arranged on a second side (10b) of the bushing (10) opposite to the first side (10a), wherein the second end (6b) of the first electrode (6) electrically connected to the first electric conductor (8), and the second end (7b) of the second electrode (7) electrically connected to the second electric conductor (9) are both located within the bushing (10) or at the first side (10a) of the bushing (10) comprising the electronics unit (5) or at the second side (10b) of the bushing (10) comprising the insertable portion (4) of the insertable analyte sensor (3).

10. The medical device (1) according to any one of 1 to 9, wherein the first electrode (6) from its second end (6b) towards its first free end (6a) and the second electrode (7) from its second end (7b) towards its first free end (7a) are, over its respective length, configured to be during use of the medical device (1) in electric contact with the body tissue.

11. The medical device (1) according to any one of claims 1 to 10, wherein the first electric conductor (8) and the second electric conductor (9) are, over its respective length, configured to be during use of the medical device (1) electrically isolated against the body tissue.

12. The medical device (1) according to any one of claims 1 to 11, wherein the medical device (1) comprises a power supply (11) that is configured for providing electric power to the electronics unit (5).

13. The medical device (1) according to claim 12, wherein the electrical resistance of the first electric conductor (8) and the electrical resistance of the second electric conductor (9) are selected so that the voltage of the power supply (11) divided by the sum of the electrical resistance of the first electrical conductor (8) and the electrical resistance of the second electric conductor (9) is smaller than or equal to 50 µA.

14. The medical device (1) according to any one of claims 1 to 13, wherein the insertable portion (4) of the insertable analyte sensor (3) comprises a carrier (12) that is configured for carrying the first electrode (6) and the second electrode (7).

15. The medical device (1) according to any one of claims 1 to 14, wherein the base body (2) comprises a patch (13), wherein the patch (13) comprises an adhesive that is configured for adhering the medical device (1) to a user’s body.