

ing at least one second color channel of the color space, wherein the second item of information is concentration-dependent wherein the estimating of the concentration of the analyte in the bodily fluid further takes into account the point in time of sample application estimated in step i);
5 a refining step, comprising one or both of assessing a plausibility of the estimated analyte concentration determined in step ii) by means of the first item of information, or improving an accuracy of the estimated analyte concentration determined in step ii) by means of the first item of information

10 wherein, further, at least one of the following is realized:

- the second item of information is time-dependent, wherein, in step ii), the concentration of the analyte in the bodily fluid is estimated by using an assumed time span elapsed since the application of the bodily fluid to the test field, wherein the first item of information, in addition to being time-dependent, additionally is dependent on the analyte concentration, where-
15 in, in step e), the dependency of the first item of information on the concentration is eliminated by assuming the concentration of the analyte in the bodily fluid estimated in step ii), thereby deriving a probable time span elapsed since the application of the bodily fluid to the test field from the first item of information, wherein the probable time span elapsed since the application of the bodily fluid to the test field is compared with the assumed time span elapsed since the application of the bodily fluid to the test field; and/or
20
- step e) comprises applying a correction to the estimated analyte concentration, wherein the correction comprises one or both of applying a correction factor to the estimated analyte concentration and applying an off-
25 set to the estimated analyte concentration, wherein the correction to the estimated analyte concentration is a function of a time variable, the time variable characterizing a time span elapsed between the application of the drop of bodily fluid to the test field and the capturing of the image of the
30 test field with the test field having the drop of bodily fluid applied there-
to.

The disclosed method of determining a concentration of an analyte in a bodily fluid by
35 using a mobile device having a camera comprising the steps just described may also be referred to as the method of determining a concentration of an analyte in a bodily fluid.

The term “analyte” 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 arbitrary chemical or biological substance or species, such as a molecule or a chemical compound, e.g. glucose, triglycerides, lactate or cholesterol.

The term “determining a concentration of an analyte”, which may also be referred to as an analytical measurement, 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 may specifically refer, without limitation, to a qualitative and/or quantitative determination of at least one analyte in a sample. The result of the analytical measurement, as an example, may be the concentration of the analyte and/or the presence or absence of the analyte to be determined. blood, interstitial fluid, urine, saliva or the like.

The term “bodily fluid” 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 may specifically refer, without limitation, to a liquid sample comprising at least one bodily fluid, such as blood, interstitial fluid, urine, saliva or the like.

The term “mobile device” 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 may specifically refer, without limitation, to a mobile electronics device, more specifically to a mobile communication device such as a cell phone or smartphone. Additionally or alternatively, as will be outlined in further detail below, the mobile device may also refer to a tablet computer or another type of portable computer having at least one camera.

Claims

1. A method of determining a concentration of an analyte in a bodily fluid by using a mobile device having a camera, the method comprising:
 - a) prompting a user to one or more of
 - apply a drop of bodily fluid to at least one test field of an optical test strip, or
 - confirm an application of a drop of bodily fluid to at least one test field of an optical test strip;
 - b) waiting for a predetermined minimum amount of waiting time;
 - c) capturing at least one image of at least one part of the test field, with the test field having the drop of bodily fluid applied thereto, by using the camera; and
 - d) determining the concentration of the analyte in the bodily fluid based on the image captured in step c), comprising:
 - i) estimating a point in time of sample application to the test field, by taking into account at least one first item of information derived from the image captured in step c) by using at least one first color channel of a color space, wherein the first item of information is time-dependent; and
 - ii) estimating the concentration of the analyte in the bodily fluid, by taking into account at least one second item of information derived from the image by using at least one second color channel of the color space, wherein the second item of information is concentration-dependent, wherein the estimating of the concentration of the analyte in the bodily fluid further takes into account the point in time of sample application estimated in step i);
 - e) a refining step, comprising one or both of assessing a plausibility of the estimated analyte concentration determined in step ii) by means of the first item of information, or improving an accuracy of the estimated analyte concentration determined in step ii) by means of the first item of informationwherein, further, at least one of the following is realized:
 - the second item of information is time-dependent, wherein, in step ii), the concentration of the analyte in the bodily fluid is estimated by using an assumed time span elapsed since the application of the bodily fluid to the test field, wherein the first item of information, in addition to being time-dependent, additionally is dependent on the analyte concentration, wherein, in step e), the

- dependency of the first item of information on the concentration is eliminated by assuming the concentration of the analyte in the bodily fluid estimated in step ii), thereby deriving a probable time span elapsed since the application of the bodily fluid to the test field from the first item of information, wherein the probable time span elapsed since the application of the bodily fluid to the test field is compared with the assumed time span elapsed since the application of the bodily fluid to the test field; and/or
- 5
- step e) comprises applying a correction to the estimated analyte concentration, wherein the correction comprises one or both of applying a correction factor to the estimated analyte concentration and applying an offset to the estimated analyte concentration, wherein the correction to the estimated analyte concentration is a function of a time variable, the time variable characterizing a time span elapsed between the application of the drop of bodily fluid to the test field and the capturing of the image of the test field with the test field having the drop of bodily fluid applied thereto.
- 10
- 15
2. The method according to claim 1, wherein the minimum amount of waiting time is determined by using a method selected from the group consisting of:
- a time span is chosen for the minimum amount of waiting time, wherein the time span is known to be sufficient for a detection reaction in the test field for samples having a concentration of the analyte within a predetermined concentration range to have reached a steady state;
- 20
- a predetermined time span is chosen for the minimum amount of waiting time;
 - a time span confirmed by the user in step a) is chosen for the minimum amount of waiting time.
- 25
3. The method according to any one of the preceding claims, wherein the estimated analyte concentration in step ii) is determined by determining the concentration of the analyte corresponding to the second item of information by means of a correlation between the analyte concentration and the second item of information and by using an assumed time span elapsed since the application of the bodily fluid to the test field.
- 30
4. The method according to any one of the preceding claims, wherein the refining step is performed in an iterative manner.
- 35

5. The method according to any one of the preceding claims, wherein step e) comprises at least one of the following options:
- α) selecting at least one correlation from a predetermined set of correlations, wherein each correlation describes a relationship between the first item of information and the analyte concentration for a specific time span elapsed since the application of the bodily fluid to the test field;
 - β) selecting at least one correlation from a predetermined set of correlations, wherein each correlation describes a relationship between the first item of information and the time elapsed since the application of the bodily fluid to the test field for a specific analyte concentration,
- wherein step e) further comprises determining an expected first item of information corresponding to the estimated analyte concentration determined in step ii) by means of the correlation selected in step e), wherein step e) further comprises comparing the determined expected first item of information with the first item of information derived from the image captured in step c), wherein the estimated analyte concentration determined in step d) is classified as plausible if a difference between the expected first item of information and the first item of information derived in step i) from the image captured in step c) is equal to or smaller than a predetermined threshold value, wherein the estimated analyte concentration determined in step d) is classified as implausible if the difference between the expected first item of information and the first item of information derived in step i) is greater than the predetermined threshold value.
6. The method according to any one of the preceding claims, wherein the first color channel comprises a blue color channel, and wherein the second color channel comprises at least one element selected from the group consisting of: a red color channel; a green color channel.
7. The method according to any one of the preceding claims, wherein the method further comprises capturing at least one dry image of the at least one part of the test field, with the test field not having the drop of bodily fluid applied thereto, by using the camera.
8. The method according to any one of the preceding claims, wherein step d) further comprises deriving at least one reference information from at least one reference part of the optical test strip outside the test field.

9. The method according to any one of the preceding claims, wherein in step c) at least two images are captured, wherein the method further comprises step f), wherein step f) is carried out between step c) and step d):
f) comparing the second items of information of the at least two images.
- 5
10. A computer program including computer-executable instructions for performing the method according to any one of the preceding claims when the program is executed on a computer or computer network.
- 10 11. A mobile device having a camera, the mobile device being configured for determining a concentration of an analyte in a bodily fluid by using the method of determining a concentration of an analyte in a bodily fluid according to any one of the preceding method claims.
- 15 12. A kit for determining a concentration of an analyte in a bodily fluid, the kit comprising:
- at least one mobile device according to claim 11; and
- at least one optical test strip having at least one test field.