
Method of controlling the functionality of an analytical system

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Technical Field

10 The present invention refers to a method of controlling the functionality of an analytical system. The invention further relates to an analytical system and to a computer program and a computer-readable storage medium for performing the method according to the present invention. The method, the analytical system, the computer program and the storage medium may be used in medical diagnostics, in order to for example qualitatively and/or quantitatively determine one or more parameters of a patient, specifically of a bodily fluid of a patient, such as for qualitatively and/or quantitatively determining the concentration of one or more analytes in one or more bodily fluids, such as for detecting glucose in blood and/or interstitial fluid or other parameters as outlined further below. Other fields of application of the present invention, however, are feasible.

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Background art

In the field of medical diagnostics, in many cases, one or more parameters of a patient are measured. As example, one or more analytes have to be detected in samples of a bodily fluid, such as blood, interstitial fluid, urine, saliva, or other types of body fluids. Examples of analytes to be detected are glucose, triglycerides, lactate, cholesterol, cardiac parameters (e.g. Troponin T, NT-proBNP and/or D-Dimer), sepsis parameters (e.g. PCT) and/or traumatic brain injury parameters and/or other types of analytes typically present in these body fluids. According to the concentration and/or the presence of the analyte, an appropriate treatment may be chosen, if necessary. As an example and without narrowing the scope, the invention may specifically be described with respect to blood glucose measurements. However, all features and/or embodiments may expressly apply in to the measurement principles of other parameters (specifically but not limited to: triglycerides, lactate, cholesterol, cardiac parameters (e.g. Troponin T, NT-proBNP and/or D-Dimer), sepsis parameters (e.g. PCT)

and/or traumatic brain injury parameters). Therefore, the present invention may also be used in the context of the measurement of analytes and/or other types of analytical measurements using test elements.

- 5 Generally, devices and methods known to the skilled person make use of test elements comprising one or more test chemicals, which, in presence of the analyte to be detected, are capable of performing one or more detectable detection reactions.

10 US 2011/0244558 A1 describes a sample analyzer and a method of writing information on a recording medium attached to a reagent container. The sample analyzer comprises: a reagent container set section for setting a reagent container; a reader/writer configured to read out an information from the recording medium attached to the reagent container set in the reagent container set section and configured to write an information on the recording medium; a writing instruction section configured to issue an instruction to write the information on
15 the recording medium; and a controller configured to control the reader/writer to write the information on the recording medium attached to the reagent container set in the reagent container set section if the kind information read out from the recording medium indicates the specific reagent and the writing instruction section has issued the writing instruction.

20 In order to verify the functionality of analytical devices and systems, a control fluid may be used for performing a control measurement. The control fluid has predetermined properties, such as a known concentration of a control analyte to be detected, and can, thus, be used for performing a control measurement.

25 With regard to these analytical control measurements, one technical challenge resides in the surveillance of the control fluid. As an example, the date of first use of the control fluid is not monitored by the analytical system. This implies the risk of using a control fluid with expired in-use stability. By today, a user of the control fluid typically notes the date of first use, such as the date of opening, by hand on a small label on the container of the control
30 fluid.

The method of manual recording of important information involves several technical challenges. Specifically, the usability of the manual method is poor and further, the writing may be not wiping resistant. A major challenge relies in the fact that it is not guaranteed that a
35 user will take attention to this noted date or will write the date onto the label. Thus, there is a need for more reliable means of recording.

Summary of the invention

It is therefore desirable to provide methods and devices which address the above-mentioned technical challenges of controlling the functionality of an analytical system using a control
5 fluid. Specifically, methods and devices shall be proposed which overcome the need for manual recording of important information, such as expiry information of control fluids.

This problem is addressed by a method for controlling the functionality of an analytical system with the features of the independent claims. Advantageous embodiments which might
10 be realized in an isolated fashion or in any arbitrary combinations are listed in the dependent claims.

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
15 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,
20 besides B, one or more further elements are present in entity A, such as element C, elements C and D or even further elements.

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
25 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, notwithstanding the fact that the respective feature or element may be present once or more than once.

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
35 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.

In a first aspect of the invention, a method of controlling the functionality of an analytical system is disclosed, the analytical system comprising at least one analytical device for determining an analyte concentration in a sample of a bodily fluid. The method comprises the following steps which, as an example, may be performed in the given order. It shall be noted, however, that a different order is also possible. Further, it is also possible to perform one or more of the method steps once or repeatedly. Further, it is possible to perform two or more of the method steps simultaneously or in a timely overlapping fashion. The method may comprise further method steps which are not listed.

The method further comprises:

- a. providing at least one container containing at least one control fluid, the container comprising at least one identifier, wherein the identifier comprises at least one identification number of the container;
- b. reading the identifier of the container by using at least one reading device of the analytical system; and
- c. performing a database query in a database of the analytical system, the database containing database entries for a plurality of known containers comprising identification numbers of the known containers and assigned expiry information for the respective known containers, the database query comprising checking if the container already has a database entry in the database.

The method may specifically be performed at least half-automated or even fully-automated. Automated steps may be performed and/or initiated by a processor, a machine and/or a controller. The term “half-automated” 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 process or method comprising multiple steps or actions, wherein a part but not all of the steps or actions are performed, supported and/or initiated by a processor, a machine and/or a controller. The term “fully-automated”, also referred to as “automatically”, 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 process or method comprising multiple steps or actions, wherein all of the steps or actions are performed, supported and/or initiated by a processor, a machine and/or a controller. Regarding step a., the container may for example

be provided by a user or, alternatively, the container may be transported to the analytical system by a machine or a conveyor, such as a conveyor belt, which can hence be considered an automated step. Method steps b. and/or c. may be performed automatically. In more detail, the container may automatically be positioned in a spot where the identifier of the container
5 can be read by the reading device. The reading device may then be triggered by a processor to read the identifier. The information comprising the identification number retrieved by reading the identifier may then be automatically linked to one or more database entries when performing a database query.

10 The term “controlling the functionality of an analytical 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 may specifically refer, without limitation, to one or more of checking, assessing, verifying, maintaining or setting at least one functionality of an analytical system. The term “functionality”, as the
15 skilled person will understand, also is a broad term and may specifically refer to the ability and/or the degree of capability of a system of performing at least one function. Thus, as an example, the at least one function may be or may comprise an analytical function, such as the function of measuring at least one medical parameter of a patient and/or the function of qualitatively or quantitatively determining at least one analyte in a bodily fluid. As an exam-
20 ple, the term “controlling the functionality of an analytical system” may, thus, refer to a method by which the capability of the analytical system of performing the at least analytical function is qualitatively or quantitatively determined and/or to a method by which the capability of the analytical system of performing the at least analytical function is set or main-
25 tained, such as by calibrating the analytical system. The term “controlling the functionality of an analytical system” may specifically refer to a method of assessing the usability of a control fluid, whereby the control fluid may be used for verifying the functionality of the analytical system. Other options are feasible.

The term “analytical device” as used herein is a broad term and is to be given its ordinary
30 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 an arbitrary device configured for an analytical examination of the sample. Specifically, the analytical device may be configured for conducting at least one analytical measurement, such as for determining at least one analytical parameter, e.g. for qualitatively and/or quan-
35 titatively determining the concentration of at least one analyte in a sample, such as a sample of a bodily fluid. Thus, the analytical device may specifically be or may comprise at least one measurement device for measuring the at least one parameter, such as a blood glucose

measurement device. Other options are feasible. As an example, the analytical device may be a handheld device configured for a mobile analytical measurement. Alternatively, however, the analytical device may be or may comprise a laboratory device. The analytical device may further comprise a display and/or a screen, specifically a touchscreen, which is
5 configured for interacting with a user of the analytical device. For example, the display of the analytical device may be configured for displaying the result of the analytical measurement.

The term “determining an analyte concentration in a sample of a bodily fluid”, also referred
10 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 quantitative and/or qualitative determination of at least one analyte in an arbitrary sample or aliquot of bodily fluid. For example, the bodily fluid may comprise one or more
15 of blood, interstitial fluid, urine, saliva or other types of body fluids. The result of the determining of the concentration, as an example, may be a concentration of the analyte and/or the presence or absence of the analyte to be determined. Specifically, as an example, the analytical measurement may be a blood glucose measurement, thus the result of the analytical measurement may for example be a blood glucose concentration. In particular, an analytical
20 measurement result value may be determined by the analytical measurement. Consequently, the term “analytical measurement result value”, also referred to as an “analyte concentration value”, 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 numerical indication of an
25 analyte concentration in a sample. The at least one analyte, as an example, may be or may comprise one or more specific chemical compounds and/or other parameters. The analyte may be or may comprise one or more of glucose, triglycerides, lactate, cholesterol, cardiac parameters, e.g. Troponin T, NT-proBNP and/or D-Dimer, sepsis parameters, e.g. PCT, and/or traumatic brain injury parameters. As an example, one or more analytes may be de-
30 termined which take part in metabolism, such as blood glucose. Additionally or alternatively, other types of analytes or parameters may be determined, e.g. a pH value.

The term “container” 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
35 customized meaning. The term may specifically refer, without limitation, to an arbitrary enclosure for holding at least one material, such as one or more of a liquid material, a solid material or a gaseous material. The container, as an example, may comprise at least one

container wall and, optionally, at least one opening for removing at least a part of the content from an interior of the container. The opening, as an example, may be sealed or sealable, such as by at least one closure, e.g. a cap, a stopper, a breakable seal or the like. As an example, the container may comprise at least one of the following: a vial, a bottle, a blister, a flask, a pouch, a syringe, a bottle, a tube, a capillary container, a needle, a glass container, a plastic container. In general, the container may be formed and/or filled by a blow-mold technology in one specific embodiment. Specifically, the container may be configured for storing at least one fluid, such as a control fluid, e.g. a control fluid having a well-defined concentration of at least one analyte. Further, the container may be configured to be closed reversibly, thereby protecting the fluid stored inside the vial from the environment outside the vial. The container may be configured to release the fluid stored inside the container in the form of drops, such as with a volume of no more than 1 ml.

The term “control 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 containing at least one analyte, e.g. a control analyte, such as one or more of a solution of the analyte, a dispersion of the analyte, a re-constituted lyophilisate and/or an emulsion of the analyte, e.g. a liquid containing at least one solvent, wherein the liquid has one or more predetermined properties, e.g. a predetermined concentration of the at least one analyte. For example, the control fluid for a blood glucose measurement may comprise glucose as a control analyte dissolved in an aqueous buffer solution. The concentration of the glucose may be set to a predetermined level. Thus, the control fluid may have a known and predetermined concentration of glucose. The control fluid may further comprise additional ingredients such as one or more of a buffer, a biological salt, a preservative and/or other nonreactive ingredients. The control fluid may be used to verify the functionality of the analytical system. Therein, for verifying the functionality of the analytical system, one, or more than one control fluids may be used.

The term “identifier” 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 an element or a combination of elements configured for storing one or more items of information identifying the container and/or at least one content of the container, such as in a readable fashion, specifically in a machine-readable fashion. The identifier may comprise at least one of an optical identifier, an electronic identifier, such as for example an RFID tag, a magnetic identifier

and/or a mechanical identifier. As an example, the identifier, specifically the optical identifier, may be or may comprise at least one of: a one- or two-dimensional code and/or a readable information tag, such as one or more of a barcode, specifically a one- or two-dimensional barcode, a QR code or another type of code directly or indirectly attached to the container, such as by being applied directly to the container and/or by being attached to the container via at least one label or tag. Further embodiments or options of the identifier will be described in detail below. The information stored in the identifier may be read using an appropriate reading device.

10 The at least one item of information stored by the identifier may identify one or more of the container or the content of the container. For identifying the container and/or its content, various options are feasible, as generally known to the skilled person. Thus, as an example, the at least one item of information may specifically comprise at least one identification number of the container and/or the content of the container, such as the control fluid. The
15 term “identification number” 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 one or more of an array or a sequence of numbers and/or letters encoding the identification information of a specific container. The identification number may be unique for a specific
20 container. Thus, it may be possible to identify a specific container according to the respective identification number. The identifier may specifically encode an identification number for identifying the container or any other information related to the content of the container or the container itself, such as the container volume and/or the date of opening the container, for example.

25 The term “comprising at least one identifier, wherein the identifier comprises at least one identification number” 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 situation in
30 which the identifier is comprised by at least one device or object, wherein the at least one identifier encodes at least one identification number on the object or device.

The term “reading” 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
35 customized meaning. The term may specifically refer, without limitation, to the process of retrieving at least one item of information, such as the at least one item of information stored in the identifier, such as in an electronic format. The reading may specifically take place

electronically. The process of reading may depend on the type of identifier. Thus, the reading may comprise an optical reading in case the identifier comprises an optical identifier, such as a bar code and/or a QR code, e.g. by optical scanning. In case the identifier comprises an electronic identifier, such as an RFID code, the reading may comprise an electronic reading, such as a reading by near field communication (NFC). Other options are feasible. The reading may specifically comprise the capturing of the optical information and the decoding thereof to retrieve the encoded information and to identify the container, in particular. Specifically, reading the identifier of the container by using at least one reading device of the analytical system may comprise decoding the identifier of the container by using the at least one reading device and/or at least one decoding device of the analytical system.

The term “reading 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 device configured to perform the reading process as defined above, such as to a device configured to read the information stored by the identifier. Specifically, the reading device may be or may comprise at least one of: a one- or two-dimensional scanner, a camera and/or a radio frequency reading device, such as a NFC reader. The reading device may be integrated into the analytical device. Alternatively or additionally, the reading device may be a separate device, independent from the analytical device. The reading device may further be configured to communicate with the analytical system. Specifically, the reading device may be configured to transfer the identification number of the container to the analytical system, such as to a processor of the analytical system. The reading device may comprise an optical unit which is configured to capture the optical code and a processor for processing, particularly decoding, the captured optical code, specifically an image thereof. Alternatively or in addition, the reading device may be connectable or connected to such a processor, which processes the captured optical code.

The term “database” 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 an organized collection of data, generally stored and accessed electronically from a computer or computer system. The database may comprise or may be comprised by a data storage device, as will be outlined in further detail below. The database may comprise at least one database management system, comprising a software running on a computer or computer system, the software allowing for interaction with one or more or a user, an application or the database itself, such as in order to capture and analyze the data contained in the database. The database

management system may further encompass facilities to administer the database. The database, containing the data, may, thus, be comprised by a database system which, besides the data, comprises one or more associated applications. Specifically, the database may contain information about the container and/or its content, such as the identification number and/or
5 the expiry information.

The database may contain a plurality of database entries. The term “database entry” 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
10 may specifically refer, without limitation, to at least one item of information stored in the database, in an organized fashion. Thus, as an example, each database entry may comprise at least one package of information, wherein a plurality of packages of information may be related or linked to each other in the database. Thus, as an example, the database entries may comprise the respective identification number and related information linked to that identi-
15 fication number, such as the respective expiry information linked to the information number of a specific container, as will be outlined in further detail below.

The information in the database may be read by performing a database query. The term “database query” as used herein is a broad term and is to be given its ordinary and customary
20 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 the process of accessing the database, such as performing a search in the database with regard to specific information. As an example, a database query may contain a search for a specific identification number of the container and/or a search for further information associated with the identification number of the container in the database.
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The term “expiry information” 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 numerical value indicating the maximum time limit of use of the control fluid stored in the container. Specifically, the expiry information may contain an expiry date, such as an absolute date until which the control fluid may be used safely. Additionally or alternatively, the expiry information may contain an in-use stability date, such as an allowed time period of use of the control fluid stored in the container, the time period starting from a first day of
30 opening of the container. Thus, the expiry information may comprise one or both of an absolute expiry information containing an absolute date and/or time, and/or a relative expiry information defined by a time span to be calculated from a specific date or time, such as
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from a specific event, e.g. the first opening of the container. Further, the expiry information may contain a combination of both, the expiry date and the in-use stability date of the container.

- 5 The method, the analytical system, the computer program and the storage medium may be used in medical diagnostics, in order to for example qualitatively and/or quantitatively determine one or more parameters of a patient, specifically of a bodily fluid of a patient, such as for qualitatively and/or quantitatively determining the concentration of one or more analytes in one or more bodily fluids, such as for detecting glucose, cardiac parameters, e.g.
- 10 Troponin T, NT-proBNP and/or D-Dimer, sepsis parameters, e.g. PCT, and/or traumatic brain injury parameters in blood and/or interstitial fluid or other parameters as outlined further below.

- As outlined above, the method comprises in step a. and b. using at least one identifier comprising at least one identification number of the container. The identifier may comprise at least one of: a bar code; a QR code; an RFID tag. The identifier may specifically comprise more than one bar code, e.g. two, three, or even more than three bar codes, more than one QR code, e.g. two, three, or even more QR codes and/or more than one RFID tag, e.g. two, three, or even more RFID tags. The identifier may comprise a combination of one or more
- 15 bar codes, one or more QR codes and/or one or more RFID tags.
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- Further, the identifier may comprise, besides the at least one identification number of the container, at least one further item of information. The at least one further item of information may be selected from the group consisting of: an item of type information providing information on the type of the control fluid; an item of kit information, the kit information providing information on a kit comprising at least one analytical test element and the control fluid; a level information, the level information providing information on a level of at least one control analyte being comprised in the control fluid; a lot number; a shelf life; an expiration date; a date of manufacturing; a version number of code content and/or a layout; a kit type; a level type; a bottle ID; a time period of in-use stability; a target value (lot specific).
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- The term "bar code" 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 binary optical information, such as to a binary sequence of optical information, such as a sequence of parallel lines having different widths, the binary sequence encoding information such as a number and/or an array of numbers and/or letters. Thus, the bar code may be a sequence of single
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colored lines having a high contrast compared to a background. Specifically, the bar code may comprise black lines on a white background.

5 The term “QR code” 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 quadratic matrix of binary pixels, the matrix encoding information such as a number and/or an array of numbers and/or letters. The pixels of the quadratic matrix may have a high contrast compared to a background. Specifically, the pixels of the matrix may comprise black squares arranged
10 on a white background. Further, the QR code may comprise an indication of orientation enabling the reading device of the QR code to align the matrix.

The term “RFID tag” 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
15 or customized meaning. The term may specifically refer, without limitation, to a label configured for exchanging data information with a reading device by using radio-frequency electromagnetic radiation, such as by using the NFC standard. The RFID tag may further comprise an antenna configured to receive and to emit a radio-frequency signal and an electronic chip such as a microchip configured to store the data information. Specifically, the
20 RFID tag may be a flexible substrate having an electronic conducting coil and optionally at least one microchip.

The at least one item of information, as may be contained by the identifier, may specifically comprise at least one arbitrary characteristic describing one or more of the appearance, the
25 state or the functionality of the container and/or its content. Specifically, the item of information may comprise at least one item selected from the group consisting of: an item of type information; an item of kit information; a level information; a lot number. The item of type information may provide information on the type of the control fluid. For example, the type of the control fluid may refer to a hypoglycemic range or a hyperglycemic range for which
30 the control fluid is used. As another example, the item of information may provide information on a kit, the kit may be comprised of at least one analytical test element and the control fluid. Further, the item of information may refer to a level information, the level information providing information on a level of the at least one analyte being comprised in the control fluid. The item of information may also refer to a lot number of the container,
35 the lot number describing a batch of the container. Thus, a specific container containing a control fluid may be uniquely identified by combining the information of at least one identification number and at least one further item of information.

The method according to the present invention may further comprise comparing a current date with the expiry information, specifically an automated step of comparing a current date with the expiry information performed by a processor, a machine or a controller. If the comparing of the current date with the expiry information indicates that the control fluid in the container has expired, the method may comprise triggering and/or taking at least one expiry action, such as at least one action which is predefined for the case that the control fluid in the container has expired. Further, the expiry action may comprise at least one action selected from the group consisting of: providing indication to a user that the control fluid in the container has expired; displaying a warning; providing at least one electronic information indicating that the control fluid in the container has expired; preventing further use of the control fluid in the container.

However, if the comparing of the current date with the expiry information indicates that the control fluid in the container has not expired, the method may include taking at least one confirmation action, such as at least one action which is predefined for the case that the control fluid in the container has not expired. The confirmation action may comprise at least one action selected from the group consisting of: providing indication to a user that the control fluid in the container has not expired; displaying a clearance indication for the control fluid; providing at least one electronic information indicating that the control fluid in the container has not expired; allowing for further use of the control fluid in the container.

Further, the expiry action and/or the confirmation action may be provided to the user via the analytical device. The analytical device may be configured to provide information to the user via at least one interface, specifically via at least one display of the analytical device. It shall be noted that other options are also feasible. As an example, the expiry action and/or the confirmation action may also, additionally or alternatively, be brought to the user's attention by other means, such as by audio means and/or haptic means. The method may also comprise outputting a sign, specifically a warning sign and/or a clearance indication, such as one or more of a visual warning and/or clearance indication, an audio warning and/or a clearance indication or a haptic warning and/or a clearance indication.

In case the comparing of the current date with the expiry information indicates that the control fluid in the container has not expired, the method according to the present invention may further comprise the following step:

- d. determining the analyte concentration of the control fluid contained in the container by using the analytical device.

Step d. may also be referred to as a control measurement or may be part of a control measurement. Step d. may be performed automatically. In more detail, step d. may be performed and/or initiated by a processor, a controller and/or a machine. The control measurement may, as an example, be used for adjusting the settings of the analytical system and/or of the analytical device and/or for interpreting the readings of the analytical system and/or of the analytical device. Additionally or alternatively, the control measurement may also be used for one or more of calibrating one or both of the analytical system and/or of the analytical device and/or for verifying the integrity of one or both of the analytical system and/or of the analytical device and/or of an analytical measurement. This analytical measurement of the control fluid may result in an analyte concentration value. The determined analyte concentration value may further be compared with the level information of the control fluid. Thus, the comparison may indicate a correct functionality of the analytical system if the determined analyte concentration value lies within a predetermined acceptable range.

As outlined above, the method may include comparing the current date with the expiry information of the container. The expiry information may comprise at least one of: an expiry date, the expiry date indicating an absolute date of expiration of the control fluid; an in-use stability date, the in-use stability date indicating a date calculated by determining the end of a predetermined in-use stability period calculated from a date of first opening of the container.

The term “current date” 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 numerical value indicating a day according to the calendar on which the container is currently in use. Specifically, the use of the container may be registered by the action of reading the identifier of the container.

The term “expiry date” 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 numerical value indicating a day according to the calendar on which the approved usability of the control fluid stored in the container ends. The expiry date of the control fluid may indicate an absolute date of expiration of the control fluid. Specifically, the stability of the control fluid may be guaranteed only until the expiry date. At a point in time after the expiry date, the

control solution may have altered properties and thus, can lead to a deviation of the analyte measurement.

5 The terms “the control fluid has expired” and “the control fluid has not expired”, respectively, as used herein, are broad terms and are to be given their ordinary and customary meaning to a person of ordinary skill in the art and are not to be limited to a special or customized meaning. The terms may specifically refer, without limitation, to a present condition of the control fluid, be it a real present condition or an assumed present condition, specifically an age of the control fluid and/or a duration of exposure of the control fluid to ambient air. Specifically, the control fluid may have expired if the current date is later than 10 the expiry date. Further, the control fluid may have not expired if the current date is before the expiry date or equals the expiry date. Thus, an expired control fluid may have lost its predetermined properties or may be assumed to have lost its predetermined properties, specifically the predetermined level of the control analyte, and may therefore not be suitable for use as a control fluid. Consequently, a control fluid which has not expired may maintain its 15 predetermined properties and is therefore suitable for use as a control fluid.

The term “in-use stability period” 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 20 to a special or customized meaning. The term may specifically refer, without limitation, to a maximum time period of safe use of the control fluid starting from a first opening of the container or, in case of a re-constituted lyophilisate, from the time-point of re-constitution. Specifically, the safe use of the control fluid may be established in case the control fluid is stable against a change in properties.

25 The term “in-use stability date” 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 numerical value indicating a day according to the calendar on which the in-use stability time period ends. The in-use stability date may be calculated by determining the end of the predetermined in-use stability period calculated from a date of first opening of the container. 30 The date of first opening may indicate a current date of first use of the container and may be recorded in step e. of the method according to the present invention, as will be described in further detail below.

35 The term “expiry action” 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 an action taken by the analytical system, a processor, a machine and/or a controller related to the analytical system in the event that the comparison of the current date with the expiry information has resulted in the conclusion that the control fluid stored in the container has expired. Consequently, the term “confirmation action” 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 an action taken by the analytical system in the event that the comparison of the current date with the expiry information has resulted in the conclusion that the control fluid stored in the container has not expired.

The term “user” 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 human being independent from the fact that the human being may be in healthy condition or may suffer from one or more diseases. As an example, the human being may be a patient suffering from diabetes and/or other diseases. However, the user may also be a medical trained person examining a patient suffering from diabetes and/or other diseases. Specifically, the user may be or may comprise a medical healthcare person, specifically in point-of-care applications. The user, however, may also be the patient himself or herself, specifically in homecare applications. The user may specifically be a person handling one or more of the analytical system, the analytical device, the container or the control fluid.

The method according to the present invention may further comprise the following step:

e. if the container does not yet have a database entry in the database, creating a new database entry for the container, the new database entry comprising the identification number of the container and assigned expiry information for the container.

Step e. may be performed and/or initiated automatically by a controller, a machine and/or a processor and may therefore be automated. The expiry information of the new database entry may comprise at least one of: an expiry date, the expiry date indicating an absolute date of expiration of the control fluid; a date of the creating of the new database entry; a date of first opening of the respective container; an in-use stability date, the in-use stability date indicating a date calculated by determining the end of a predetermined in-use stability period calculated from a date of first opening of the container.

As outlined above, the method comprises reading the identifier of the container by using at least one reading device. The reading device may be selected from the group consisting of: a reading device integrated into the analytical device, which means in particular that the reading device is coupled to and/or contained in the housing of the analytical device, specifically in a substantially fixed position; a reading device being separate from the analytical device, specifically an independent bar code scanner. Specifically, the reading device may comprise at least one of a bar code scanner, a QR code scanner, a camera or an RFID reader. Specifically, in many analytical devices for point-of-care applications, but also in many other analytical devices, reading devices are integrated as components, such as components of a handheld device. As an example, one or more of an integrated barcode scanner, a QR code scanner or an NFC reader may be present, or an integrated camera may be used as a reading device, such as for reading barcodes and/or QR codes. If the reading device is separate from the analytical device, it may have a wireless connection with the analytical device. Alternatively, the reading device may be coupled to the analytical device by a cable and/or a wire.

15 The term “bar code scanner” 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 device configured to read barcodes. Specifically, the bar code scanner may be configured to capture the barcode optically and further to determine the information contained in the barcode. As an example, the bar code scanner may comprise at least one light emitting device and at least one light sensitive detector. The light emitting device may be configured to emit light in the optical and/or in the infrared range and further to focus the emitted light onto the barcode. The light sensitive detector may be configured to detect the reflected light from the barcode and to convert the optical signal into an electronic signal. Further, the barcode scanner may be configured to determine from the converted electronic signal the information contained in the barcode.

30 The term “QR code scanner” 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 device configured to read the two-dimensional binary matrix of a QR code. The QR code scanner may further be configured to translate the binary matrix into the information stored by the QR code. As an example, the QR code scanner may be a camera.

35 The term “camera” 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 device having at least one imaging element configured for recording or capturing spatially resolved one-dimensional, two-dimensional or even three-dimensional optical data or information. As an example, the camera may comprise at least one camera chip, such as at least one CCD chip and/or at least one CMOS chip configured for recording images.

The term “image” 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 data recorded and/or captured by using a camera, such as a plurality of electronic readings from the imaging device, such as the pixels of the camera chip. Thus, the image may be or may comprise at least one array of information values, such as an array of grey scale values and/or color information values. The image may be a single color image or a multi-color or colored image.

The camera, besides the at least one camera chip or imaging chip, may comprise further elements, such as one or more optical elements, e.g. one or more lenses. As an example, the camera may be a fix-focus camera, having at least one lens which is fixedly adjusted with respect to the camera. Alternatively, however, the camera may also comprise one or more variable lenses which may be adjusted, automatically or manually. The invention specifically shall be applicable to cameras as usually used in mobile applications such as notebook computers, tablets or, specifically, cell phones such as smartphones. Thus, specifically, the camera may be part of a mobile device which, besides the at least one camera, comprises one or more data processing devices such as one or more data processors. Other cameras, however, are feasible.

The term “RFID reader” 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 device configured to read an RFID tag by using radio-frequency electromagnetic radiation. Specifically, the RFID reader may be configured to read the information stored in a RFID tag by decoding the radio-frequency signal. The RFID reader, as an example, may comprise an NFC standard communication interface or NFC reader.

As outlined above, the analytical system according to the present invention comprises at least one analytical device for determining an analyte concentration in a sample of a bodily fluid. The analytical system may further comprise at least one test element, the test element

comprising at least one test chemical, specifically at least one test chemical of a diagnostic test and/or at least one test chemical within an immunological test setup. The test chemical may be configured for performing at least one detection reaction in the presence of the analyte, wherein the analytical device may be configured for determining the analyte concentration by using the test element. As an example, the test element may comprise at least one test strip. Therefore, the analytical device may comprise at least one test strip port configured for receiving the test strip. Alternatively or additionally, the test element may comprise at least one test device, such as at least one test device comprising one or more of a cartridge, a fluidic system, a sensor unit and the like. In this example, the analytical device may comprise at least one port of the test device. The display of the analytical device may further be configured to provide information about the analytical measurement to the user.

The term “analytical test element”, also referred to as “test element”, 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 an arbitrary device which is capable of detecting the analyte in the sample or of determining the parameter of the sample. The test element may specifically be a strip-shaped test element. As used herein, the term “strip-shaped” refers to an element having an elongated shape and a thickness, wherein an extension of the element in a lateral dimension exceeds the thickness of the element, such as by at least a factor of 2, preferably by at least a factor of 5, more preferably by at least a factor of 10 and most preferably by at least a factor of 20 or even at least a factor of 30. Thus, the test element may also be referred to as “test strip”.

The term “test chemical”, often also referred to as a “test chemistry”, 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 an arbitrary material or a composition of materials adapted to change at least one detectable property in the presence of the analyte. Generally, this property may be selected from an electrochemically detectable property and/or an optically detectable property, such as a color change and/or a change in remissive properties. Specifically, the test chemical may be a highly selective test chemical, which only changes the property if the analyte is present in the sample of the body fluid applied to the test element, whereas no change occurs if the analyte is not present. More preferably, the degree or change of the property may be dependent on the concentration of the analyte in the body fluid, in order to allow for a quantitative detection of the analyte. The change of property of the test chemical in presence of the analyte may also be referred to as “detection reaction”.

For example, the test chemical may be or may comprise at least one test chemical of a diagnostic test, such as of a blood glucose test. Alternatively or additionally, the test chemical may be or may comprise at least one test chemical within an immunological test setup, such as within a urine test, an allergy test, a pregnancy test or the like.

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The analytical system may further comprise at least one backbone server, the backbone server being configured for exchanging information with the analytical device. The backbone server may be configured for storing the database. Further, the analytical system may comprise a plurality of analytical devices.

10

The term “backbone server” 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 device, specifically a server device, which is capable of performing one or more operations with the data to be processed. Specifically, the server may comprise at least one processor, which may be programmed, by appropriate software, for performing one or more operations with the data to be processed. Further, the backbone server may be configured for data exchange, specifically for exchanging information with the analytical device. The backbone server may also be configured to store data. As an example, the backbone server may be configured for storing the database. The backbone server may comprise at least one data interface for exchange of one or both of data or commands with the at least one analytical device and/or with further devices. The at least one data interface may be or may comprise at least one of a wire-bound or a wireless interface. The backbone server may also, fully or partially, be embodied as a cloud server device.

25

As already mentioned above, the method according to the present invention may be at least partially automated and/or computer implemented, specifically at least one of steps b., c. and optionally d. and e. as described in more detail below.

30 In a further aspect of the present invention, an analytical system is disclosed. The analytical system comprises:

- A. at least one analytical device for determining an analyte concentration in a sample of a bodily fluid;
- B. at least one reading device, the reading device being configured for reading at least one identifier of a container containing at least one control fluid, the identifier comprising at least one identification number of the container;

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- C. at least one database containing database entries for a plurality of known containers comprising identification numbers of the known containers and assigned expiry information for the respective known containers; and
- D. at least one processor configured for performing at least one database query, the database query comprising checking if the container already has a database entry in the database.

The analytical system may further comprise the at least one container containing the at least one control fluid or may be configured for use with the at least one container. Specifically, the analytical system may be configured for performing the method according to the present invention and/or for being used in the method according to the present invention. For definitions of the features of the analytical systems and for optional features of the analytical system, reference may be made to one or more of the embodiments of the method as disclosed above or as disclosed in further detail below.

The term “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 may specifically refer, without limitation, to an arbitrary set of interacting or interdependent components parts forming a whole. Specifically, the components may interact with each other in order to fulfill at least one common function. The at least two components may be handled independently or may be coupled or connectable. Thus, the term “analytical system” generally refers to a group of at least two elements or components which are capable of interacting in order to perform at least one analytical measurement by interacting with an arbitrary test element, specifically at least one analytical measurement of at least one analyte of the sample. The analytical system may generally also be referred to as a test element analysis system, an analytical kit, a sensor system or a measurement system. The analytical system may be an apparatus, specifically comprising at least two components.

The term “processor” as generally 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 an arbitrary logic circuitry configured for performing basic operations of a computer or system, and/or, generally, to a device which is configured for performing calculations or logic operations. In particular, the processor may be configured for processing basic instructions that drive the computer or system. As an example, the processor may comprise at least one arithmetic logic unit (ALU), at least one floating-point unit (FPU), such as a math co-processor

or a numeric coprocessor, a plurality of registers, specifically registers configured for supplying operands to the ALU and storing results of operations, and a memory, such as an L1 and L2 cache memory. In particular, the processor may be a multi-core processor. Specifically, the processor may be or may comprise a central processing unit (CPU). Additionally, 5 or alternatively, the processor may be or may comprise a microprocessor, thus specifically the processor's elements may be contained in one single integrated circuitry (IC) chip. Additionally or alternatively, the processor may be or may comprise one or more application-specific integrated circuits (ASICs) and/or one or more field-programmable gate arrays (FPGAs) or the like. The processor may specifically be configured, such as by software programming, 10 for performing one or more evaluation operations.

In a further aspect of the present invention, a computer program is disclosed, the computer program comprising instructions which, when the program is executed by the analytical system according to the present invention, such as according to any one of the embodiments 15 disclosed above and/or according to any one of the embodiments disclosed in further detail below, cause the analytical system to carry out at least steps b. and c. and optionally e. of the method according to the present invention, 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. For the steps which are not computer-implemented or computer-implementable, the 20 computer program may imply a prompting of the user to perform specific acts or trigger an element of the analytical system to perform and/or initiate these steps. Thus, as an example, the computer program may comprise instructions which, when executed, prompt the user to one or more of providing at least one container, i.e. for performing step a. of the method. Additionally or alternatively, the computer program may comprise instructions which, when 25 executed, prompt the user to read the identifier of the container by using the at least one reading device of the analytical system, such as by scanning the barcode and/or the QR code. The prompting, as an example, may take place by visually displaying instructions, e.g. on a display of the analytical device, and/or by other means, such as by providing audible instructions. Step c., however, may be fully computer-implemented by the computer program, as 30 well as, optionally, step e. of the method. Thus, the computer program may comprise instructions which, when the program is executed by the analytical system according to the present invention, cause the analytical system to prompt the user to perform step a., to optionally prompt the user to assist in performing step b. and, further, to automatically read the identifier, and, to carry out at least step c. automatically.

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Similarly, a computer-readable storage medium is disclosed, comprising instructions which, when executed by the analytical system according to the present invention, 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, cause the analytical system to carry out at least steps b. and c. and optionally e. of the method according to the present invention, 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. For the options of prompting the user to assist in some of the method steps, specifically in step a., reference is made to the description of the computer program.

As used herein, the term “computer-readable storage medium” may specifically refer to a non-transitory data storage means, such as a hardware storage medium having stored thereon computer-executable instructions. The computer-readable data carrier or storage medium may specifically be or may comprise a storage medium such as a random-access memory (RAM) and/or a read-only memory (ROM).

The computer program may also be embodied as a computer program product. As used herein, a computer program product may refer to the program as a tradable product. The product may generally exist in an arbitrary format, such as in a paper format, or on a computer-readable data carrier and/or on a computer-readable storage medium. Specifically, the computer program product may be distributed over a data network.

The methods and devices according to the present invention may provide a large number of advantages over similar methods and devices known in the art. Specifically, the method and devices as described herein may increase the usability of a control fluid. Thus, the method according to the present invention enables the analytical system to recognize and/or identify the individual container of a control fluid on the date of first use by reading out the identifier. This enables the analytical system, specifically the analytical device, to monitor the allowed time period of use of this individual control fluid after opening the respective container.

Further, the method and devices according to the present invention allow for an automatic recording of the date of first use of a control fluid. Therefore, the need for a manual recording the first date of use becomes obsolete. The risk of wiping the information noted on the container is avoided as well. Thus, a loss of this information is prevented by using the method according to the present invention.

Moreover, the method described herein ensures that the date of first use of a control fluid is recorded correctly. Further, the user’s attention will be drawn to the status of the control fluid, since the status will be brought to the user automatically via the at least one interface

of the analytical device. It is therefore no longer possible to use a control fluid with expired in-use stability.

5 The analytical system can hence avoid the application of outdated control material which cannot be guaranteed to serve its purpose in view of the control function of the analytical system. It may be possible that a result obtained from a control made with outdated control material is not accepted by the analytical system and only a result obtained from a control made with control material in the qualified range (e.g. by shelf life studies) will be accepted for use by the analytical system.

10

Summarizing and without excluding further possible embodiments, the following embodiments may be envisaged:

15 Embodiment 1: A method of controlling the functionality of an analytical system, the analytical system comprising at least one analytical device for determining an analyte concentration in a sample of a bodily fluid, the method comprising:

- a. providing at least one container containing at least one control fluid, the container comprising at least one identifier, wherein the identifier comprises at least one identification number of the container;
- 20 b. reading the identifier of the container by using at least one reading device of the analytical system; and
- c. performing a database query in a database of the analytical system, the database containing database entries for a plurality of known containers comprising identification numbers of the known containers and assigned expiry information for
25 the respective known containers, the database query comprising checking if the container already has a database entry in the database.

Embodiment 2: The method according to the preceding embodiment, wherein the identifier comprises at least one of: a bar code; a QR code; an RFID tag.

30

Embodiment 3: The method according to any one of the preceding embodiments, wherein the identifier comprises, besides the at least one identification number of the container, at least one further item of information, the at least one further item of information being selected from the group consisting of: an item of type information providing information on
35 the type of the control fluid; an item of kit information, the kit information providing information on a kit comprising at least one analytical test element and the control fluid; a level information, the level information providing information on a level of at least one control

analyte being comprised in the control fluid; a lot number; a shelf life; an expiration date; a date of manufacturing; a version number of code content and/or a layout; a kit type; a level type; a bottle ID; a time period of in-use stability; a target value (lot specific).

- 5 Embodiment 4: The method according to any one of the preceding embodiments, further comprising comparing a current date with the expiry information, specifically an automated step of comparing a current date with the expiry information performed by a processor, a machine or a controller.
- 10 Embodiment 5: The method according to the preceding embodiment, wherein, if the comparing of the current date with the expiry information indicates that the control fluid in the container has expired, the method further comprises triggering and/or taking at least one expiry action.
- 15 Embodiment 6: The method according to the preceding embodiment, wherein the expiry action comprises at least one action selected from the group consisting of: providing indication to a user that the control fluid in the container has expired; displaying a warning; providing at least one electronic information indicating that the control fluid in the container has expired; preventing further use of the control fluid in the container.
- 20 Embodiment 7: The method according to the preceding embodiment, wherein, if the comparing of the current date with the expiry information indicates that the control fluid in the container has not expired, taking at least one confirmation action.
- 25 Embodiment 8: The method according to the preceding embodiment, wherein the confirmation action comprises at least one action selected from the group consisting of: providing indication to a user that the control fluid in the container has not expired; displaying a clearance indication for the control fluid; providing at least one electronic information indicating that the control fluid in the container has not expired; allowing for further use of the control
- 30 fluid in the container.

Embodiment 9: The method according to any one of the two preceding embodiments, further comprising:

- 35 d. determining the analyte concentration of the control fluid contained in the container by using the analytical device.

Embodiment 10: The method according to any one of the preceding embodiments, wherein the expiry information comprises at least one of: an expiry date, the expiry date indicating an absolute date of expiration of the control fluid; an in-use stability date, the in-use stability date indicating a date calculated by determining the end of a predetermined in-use stability period calculated from a date of first opening of the container.

Embodiment 11: The method according to any one of the preceding embodiments, wherein the analytical device is configured to provide information to the user via at least one interface, specifically via at least one display of the analytical device.

Embodiment 12: The method according to any one of the preceding embodiments, further comprising:

- e. if the container does not yet have a database entry in the database, creating a new database entry for the container, the new database entry comprising the identification number of the container and assigned expiry information for the container.

Embodiment 13: The method according to the preceding embodiment, wherein the expiry information of the new database entry comprises at least one of: an expiry date, the expiry date indicating an absolute date of expiration of the control fluid; a date of the creating of the new database entry; a date of first opening of the respective container; an in-use stability date, the in-use stability date indicating a date calculated by determining the end of a predetermined in-use stability period calculated from a date of first opening of the container.

Embodiment 14: The method according to any one of the preceding embodiments, wherein the reading device is selected from the group consisting of: a reading device integrated into the analytical device; a reading device being separate from the analytical device, specifically an independent bar code scanner.

Embodiment 15: The method according to the preceding embodiment, wherein the reading device comprises at least one of a bar code scanner, a QR code scanner, a camera or an RFID reader.

Embodiment 16: The method according to any one of the preceding embodiments, wherein the analytical system further comprises at least one test element, the test element comprising at least one test chemical, specifically at least one test chemical of a diagnostic test and/or at least one test chemical within an immunological test setup, wherein the test chemical is configured for performing at least one detection reaction in the presence of the analyte, wherein

the analytical device is configured for determining the analyte concentration by using the test element.

5 Embodiment 17: The method according to the preceding embodiment, wherein the test element comprises at least one test strip and/or at least one test device, such as at least one test device comprising one or more of a cartridge, a fluidic system, a sensor unit and the like, wherein the analytical device comprises at least one test strip port configured for receiving the test strip and/or at least one port of the test device.

10 Embodiment 18: The method according to any one of the preceding embodiments, wherein the analytical system further comprises at least one backbone server, the backbone server being configured for exchanging information with the analytical device, wherein the backbone server is configured for storing the database.

15 Embodiment 19: The method according to any one of the preceding embodiments, wherein the analytical system comprises a plurality of analytical devices.

Embodiment 20: The method according to any one of the preceding embodiments, wherein the method is at least partially computer implemented, specifically at least one of steps b., c.
20 and optionally d. and e..

Embodiment 21: An analytical system, comprising:

- A. at least one analytical device for determining an analyte concentration in a sample of a bodily fluid;
- 25 B. at least one reading device, the reading device being configured for reading at least one identifier of a container containing at least one control fluid, the identifier comprising at least one identification number of the container;
- C. at least one database containing database entries for a plurality of known containers comprising identification numbers of the known containers and assigned
30 expiry information for the respective known containers; and
- D. at least one processor configured for performing at least one database query, the database query comprising checking if the container already has a database entry in the database.

35 Embodiment 22: The analytical system according to the preceding embodiment, wherein the analytical system is configured for performing the method according to any one of the preceding embodiments referring to a method.

Embodiment 23: A computer program comprising instructions which, when the program is executed by the analytical system according to any one of the preceding embodiments referring to an analytical system, cause the analytical system to carry out at least steps b. and c.
5 and optionally d. and/or e. of the method according to any one of the preceding embodiments referring to a method.

Embodiment 24: A computer-readable storage medium comprising instructions which, when executed by the analytical system according to any one of the preceding embodiments referring to an analytical system, cause the analytical system to carry out at least steps b. and c.
10 and optionally d. and/or e. of the method according to any one of the preceding embodiments referring to a method.

Short description of the Figures

15 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
20 not restricted by the preferred embodiments. The embodiments are schematically depicted in the Figures. Therein, identical reference numbers in these Figures refer to identical or functionally comparable elements.

In the Figures:

25 Figure 1 shows embodiments of an analytical system, an analytical device and a container in a schematic view; and
Figure 2 shows a flow chart of an embodiment of a method for controlling the functionality of an analytical system.
30

Detailed description of the embodiments

In Figure 1, embodiments of an analytical system 110, an analytical device 112 and a container 114 are shown in a schematic view. The analytical system 110 comprises the at least
35 one analytical device 112, which is configured for determining an analyte concentration in a sample of a bodily fluid. The analytical system 110 further comprises at least one reading

device 113 configured for reading at least one identifier 124 of a container 114 containing at least one control fluid. The container 114 may also form part of the analytical system 110. The analytical system 110 further comprises at least one database 116 containing database entries 130 for a plurality of known containers 114, the database entries 130 comprising
5 identification numbers of known containers 114 and assigned expiry information for the respective known containers 114. Further, the analytical system 110 comprises at least one processor 117 configured for performing at least one database query, the database query comprising checking if the container 114 already has a database entry 130 in the database 116. The components of the analytical device 112 and their functions will be explained in
10 the following.

As outlined above, the analytical system 110 comprises the at least one database 116. The at least one database 116 may fully or partially be stored on a backbone server 118 of the analytical system 110, such as in at least one data storage device 119 of the backbone server
15 118. The backbone server 118 may be a stand-alone backbone server 118 or may comprise a plurality of backbone servers 118 and/or may also be embodied as a cloud server. Additionally or alternatively, the database 116 may also fully or partially be stored in at least one data storage device 121 of the at least one analytical device 112.

20 The analytical system 110 may comprise a single analytical device 112 or a plurality of analytical devices 112. In the latter case, the analytical devices 112 may specifically be configured for communicating with each other and/or with the backbone server 118. The analytical device 112 is configured for determining an analyte concentration in a sample of a bodily fluid, specifically by using at least one test element 125, such as a test strip 126 and/or
25 a test device, as will be outlined in further detail below. The analytical device 112 may specifically be a handheld analytical device 112, e.g. may be portable with one hand of a user.

The analytical system 110, as outlined above, comprises the at least one reading device 113. The reading device 113 may be or may comprise a stand-alone reading device 113. Additionally or alternatively, the reading device 113 may also fully or partially be integrated into
30 at least one other component, such as into the analytical device 112. Thus, specifically, the analytical device 112 may comprise at least one integrated reading device 113. The reading device 113 may specifically be or may comprise at least one camera 120.

35 As outlined above, the analytical device 112 is configured for determining an analyte concentration in a sample of a bodily fluid. For this purpose, the analytical device 112 may specifically be configured as a portable, handheld measurement device. Thus, the analytical

device 112 may specifically be configured as an electrochemical and/or optical measurement device, configured for using the at least one test element 125, such as the at least one test strip 126 and/or the test device. The test element 125 may specifically be or may comprise at least one of an electrochemical test element or an optical test element. Alternatively or
5 additionally, the test element 125 may comprise the at least one test device, such as at least one test device comprising one or more of a cartridge, a fluidic system, a sensor unit and the like. For interacting with the test element 125, specifically with the test strip 126, the analytical device 112 may comprise at least one test strip port 122, such as for receiving the at least one test element 125. In case the test element 125 may comprise the test device, the
10 analytical device 112 may comprise at least one port of the test device. The analytical device 112 may further comprise at least one user interface, such as a display 123.

As outlined above, the analytical system 110 may further comprise at least one container 114. The container 114 may contain at least one control fluid, the function of which will be
15 outlined in more detail below. The container 114 comprises at least one identifier 124, such as a barcode, a QR code and/or a RFID tag.

As explained above, the test element 125, specifically the test strip 126 and/or the test device, may be used for an analytical measurement of the analyte concentration in a sample of a
20 bodily fluid. The control fluid contained in the container 114 may be used for at least one control measurement by using the analytical device 112, the test element 125 and, instead of the sample of the bodily fluid, an aliquot of the at least one control fluid.

As outlined above, the analytical device 112 comprises the at least one reading device 113,
25 specifically the camera 120. The reading device 113 is configured to read the identifier 124 of the container 114. Thus, as an example, the camera 120 may be used as a barcode reader and/or as a QR code reader. The display 123 of the analytical device 112 may be configured to provide information to a user of the analytical device 112.

30 The backbone server 118 may be connected with the analytical device 112 for unidirectional or bidirectional data exchange, such as via at least one wireless interface 128 of the backbone server 118 communicating with at least one corresponding wireless interface 129 of the analytical device 112, for exchanging information between the backbone server 118 and the analytical device 112.

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The test element 125, specifically the test strip 126 and/or the test device, may comprise at least one test chemical, wherein the test chemical may be configured for performing at least

one detection reaction in the presence of the analyte to be detected. The detection reaction may change an optically detectable property and/or an electrochemically detectable property of the test chemical, specifically of at least one test chemical of a diagnostic test and/or of at least one test chemical within an immunological test setup. The degree of change of the property may be dependent on the analyte concentration of the analyte in the control fluid. Thus, the analytical device 112 may be configured to determine the analyte concentration of the control fluid stored in the container 114 by detecting the change of property of the test chemical on the test strip 126. The result of the analytical measurement may be displayed via the display 123 of the analytical device 112.

The identifier 124 comprises at least one identification number of the container 114. Further, the identifier 124 may comprise also at least one further item of information, specifically one or more further items of information as listed below. The further item of information may be selected from the group consisting of: an item of type information providing information on the type of the control fluid; an item of kit information, the kit information providing information on a kit comprising the at least one analytical test element 125 and the control fluid; a level information, the level information providing information on a level of at least one control analyte being comprised in the control fluid; a lot number; a shelf life; an expiration date; a date of manufacturing; a version number of code content and/or a layout; a kit type; a level type; a bottle ID; a time period of in-use stability; a target value (lot specific). The reading device 113, e.g. the camera 120, may also be configured for reading, besides the at least one identification number, the at least one further item of information from the identifier 124.

The database 116, as outlined above, contains the database entries 130 for a plurality of known containers 114. The database entries 130, as also outlined above, comprise the identification number and assigned expiry information of the known containers 114. The backbone server 118 may be configured for exchanging information with the analytical device 112. Thus, the analytical device 112 and the backbone server 118 may be configured to exchange information, such as the identification number of the container 114 and/or the at least one further item of information.

The analytical system 110 is configured, specifically by software programming, for performing a method of controlling the functionality of the analytical system 110. In Figure 2, a flow chart of an exemplary embodiment of the method is shown, wherein the method is denoted by reference number 132. The method 132 comprises the following steps, which may specifically be performed in the given order. Still, a different order may also be possible. It may

be possible to perform two or more of the method steps fully or partially simultaneously. It may further be possible to perform one, more than one or even all of the method steps once or repeatedly. The method 132 may comprise additional method steps that are not listed.

- 5 The method 132 comprises the following steps:
- a. (denoted by reference number 134) providing the at least one container 114 containing the at least one control fluid, the container 114 comprising the at least one identifier 124, wherein the identifier 124 comprises the at least one identification number of the container 114;
 - 10 b. (denoted by reference number 136) reading the identifier 124 of the container 114 by using the at least one reading device 113 of the analytical system 110; and
 - c. (denoted by reference number 138) performing the database query in the database 116 of the analytical system 110, the database 116 containing the database
15 entries 130 for the plurality of known containers 114 comprising identification numbers of the known containers 114 and assigned expiry information for the respective known containers 114, the database query comprising checking if the container 114 already has a database entry 130 in the database 116.
- 20 In step c. 138, the database entry 130 comprises besides the identification number an assigned expiry information for the respective container 114. The expiry information may comprise an expiry date and/or an in-use stability date. Specifically, the expiry date may indicate an absolute date of expiration of the control fluid. Further, the in-use stability date may indicate a maximum date of use calculated by determining the end of a predetermined
25 in-use stability period calculated from a date of first opening of the container 114. The date of first opening of the container 114 may be registered by a first reading of the identifier 124 of the respective container 114.

The method 132 may further comprise comparing a current date with the expiry information
30 stored in the database entry 130, specifically an automated step of comparing a current date with the expiry information performed by a processor, a machine or a controller. If the comparing of the current date with the expiry information indicates that the control fluid has expired, the method 132 may comprise triggering and/or taking at least one expiry action, such as at least one action which is predefined for the case that the control fluid in the container 114 has expired. However, if the comparing of the current date with the expiry information indicates that the control fluid in the container 114 has not expired, the method 132
35 may include taking at least one confirmation action, such as at least one action which is

predefined for the case that the control fluid in the container 114 has not expired. Further, the expiry action and/or the confirmation action may be provided to the user via at least one interface of the analytical device 112. Specifically, the interface of the analytical device 112 may be at least one display 123 configured to visually provide information to the user, such as the expiry action, the confirmation action or the result of the analytical measurement. It shall be noted that other options are also feasible. Thus, the information may be brought to the user's attention alternatively and/or additionally via audio and/or haptic means.

In case the comparing of the current date with the expiry information indicates that the control fluid in the container 114 has not expired, the method 132 may optionally comprise additional step d. (denoted by reference number 140). The method step d. may comprise:

d. (denoted by reference number 140) determining the analyte concentration of the control fluid contained in the container 114 by using the analytical device 112.

Step d. may also be referred to as a control measurement or may be part of a control measurement. The control measurement may, as an example, be used for adjusting the settings of the analytical system 110 and/or of the analytical device 112 and/or for interpreting the readings of the analytical system 110 and/or of the analytical device 112. Additionally or alternatively, the control measurement may also be used for one or more of calibrating one or both of the analytical system 110 and/or of the analytical device 112 and/or for verifying the integrity of one or both of the analytical system 110 and/or of the analytical device 112 and/or of an analytical measurement. This analytical measurement of the control fluid may result in an analyte concentration value. The determined analyte concentration value may further be compared with the level information of the control fluid. Thus, the comparison may indicate a correct functionality of the analytical system 110 if the determined analyte concentration value lies within a predetermined acceptable range.

As outlined above, step c. of the method 132 comprises performing a database query. The database query comprises checking if the container 114 already has a database entry 130. Thus, the method 132 may optionally comprise an additional step:

e. (denoted by reference number 142) if the container 114 does not yet have a database entry 130 in the database 116, creating a new database entry for the container 114, the new database entry comprising the identification number of the container 114 and assigned expiry information for the container 114.

The assigned expiry information of the new database entry may comprise at least one of: an expiry date, the expiry date indicating an absolute date of expiration of the control fluid; a

date of the creating of the new database entry; a date of first opening of the respective container 114; an in-use stability date, the in-use stability date indicating a date calculated by determining the end of the predetermined in-use stability period calculated from the date of first opening of the container 114. Specifically, the action of creating the new database entry and the action of first opening of the respective container 114 may take place in a timely manner. Thus, the date of creating of the new database entry and the date of first opening of the container 114 may correspond to each other. The date of first opening of the container 114 may be registered by the action of reading the identifier 124 of the container 114 for the first time and assigning the corresponding current date.

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Further, the method 132 may be at least partially automated and/or computer-implemented, specifically at least step b., step c. and optionally step e. of the method 132 as described above. Thus, the analytical system 110 comprises the at least one processor 117 configured for performing at least one database query, specifically in step c. of the method 132. The at least one processor 117 may fully or partially be comprised by the analytical device 112 and/or by the backbone server 118. The database query may comprise checking if the container 114 already has a database entry 130 in the database 116. For the method steps which are not computer-implemented, the analytical system 110 may be configured, specifically by software programming, to prompt the user to assist in performing the step a. and step d.. The prompting, as an example, may take place by visually displaying instructions, e.g. on the display 123 of the analytical device 112, and/or by other means, such as by providing audible instructions.

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List of reference numerals

110	analytical system
112	analytical device
113	reading device
114	container
116	database
117	processor
118	backbone server
119	data storage device of the backbone server
120	camera
121	data storage device of the analytical device
122	test strip port
123	display
124	identifier
125	test element
126	test strip
128	wireless interface of the backbone server
129	wireless interface of the analytical device
130	database entry
132	controlling method
134	providing at least one container (step a.)
136	reading the identifier (step b.)
138	performing a database query (step c.)
140	determining the analyte concentration of the control fluid contained in the container by using the analytical device (step d.)
142	if the container does not yet have a database entry: creating a new database entry for the container (step e.)

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Claims

1. A method of controlling the functionality of an analytical system (110), the analytical
5 system (110) comprising at least one analytical device (112) for determining an ana-
lyte concentration in a sample of a bodily fluid, the method comprising:
 - a. providing at least one container (114) containing at least one control fluid, the
container (114) comprising at least one identifier (124), wherein the identifier
(124) comprises at least one identification number of the container (114);
 - 10 b. reading the identifier (124) of the container (114) by using at least one reading
device (113) of the analytical system (110); and
 - c. performing a database query in a database (116) of the analytical system (110),
the database (116) containing database entries (130) for a plurality of known
containers (114) comprising identification numbers of the known containers
15 (114) and assigned expiry information for the respective known containers
(114), the database query comprising checking if the container (114) already
has a database entry (130) in the database (116).
2. The method according to the preceding claim, wherein the identifier (124) comprises
20 at least one of: a bar code; a QR code; an RFID tag.
3. The method according to any one of the preceding claims, further comprising com-
paring a current date with the expiry information.
- 25 4. The method according to the preceding claim, wherein, if the comparing of the cur-
rent date with the expiry information indicates that the control fluid in the container
(114) has expired, the method further comprises triggering and/or taking at least one
expiry action.
- 30 5. The method according to the preceding claim, wherein the expiry action comprises at
least one action selected from the group consisting of: providing indication to a user
that the control fluid in the container (114) has expired; displaying a warning;
providing at least one electronic information indicating that the control fluid in the

container (114) has expired; preventing further use of the control fluid in the container (114).

- 5 6. The method according to the preceding claim, wherein, if the comparing of the current date with the expiry information indicates that the control fluid in the container (114) has not expired, taking at least one confirmation action.
- 10 7. The method according to the preceding claim, wherein the confirmation action comprises at least one action selected from the group consisting of: providing indication to a user that the control fluid in the container (114) has not expired; displaying a clearance indication for the control fluid; providing at least one electronic information indicating that the control fluid in the container (114) has not expired; allowing for further use of the control fluid in the container (114).
- 15 8. The method according to any one of the two preceding claims, further comprising:
 - d. determining the analyte concentration of the control fluid contained in the container (114) by using the analytical device (112).
- 20 9. The method according to any one of the preceding claims, wherein the expiry information comprises at least one of: an expiry date, the expiry date indicating an absolute date of expiration of the control fluid; an in-use stability date, the in-use stability date indicating a date calculated by determining the end of a predetermined in-use stability period calculated from a date of first opening of the container (114).
- 25 10. The method according to any one of the preceding claims, further comprising:
 - e. if the container (114) does not yet have a database entry (130) in the database (116), creating a new database entry for the container (114), the new database entry comprising the identification number of the container (114) and assigned expiry information for the container (114).
- 30 11. The method according to the preceding claim, wherein the expiry information of the new database entry comprises at least one of: an expiry date, the expiry date indicating an absolute date of expiration of the control fluid; a date of the creating of the new database entry; a date of first opening of the respective container (114); an in-use stability date, the in-use stability date indicating a date calculated by determining the end of a predetermined in-use stability period calculated from a date of first opening of the container (114).
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12. The method according to any one of the preceding claims, wherein the reading device (113) is selected from the group consisting of: a reading device (113) integrated into the analytical device (112); a reading device (113) being separate from the analytical device (112), specifically an independent bar code scanner.
13. The method according to any one of the preceding claims, wherein the analytical system (110) further comprises at least one backbone server (118), the backbone server (118) being configured for exchanging information with the analytical device (112), wherein the backbone server (118) is configured for storing the database (116).
14. An analytical system (110), comprising:
- A. at least one analytical device (112) for determining an analyte concentration in a sample of a bodily fluid;
 - B. at least one reading device (113), the reading device (113) being configured for reading at least one identifier (124) of a container (114) containing at least one control fluid, the identifier (124) comprising at least one identification number of the container (114);
 - C. at least one database (116) containing database entries (130) for a plurality of known containers (114) comprising identification numbers of the known containers (114) and assigned expiry information for the respective known containers (114); and
 - D. at least one processor (117) configured for performing at least one database query, the database query comprising checking if the container (114) already has a database entry (130) in the database (116).
15. A computer program comprising instructions which, when the program is executed by the analytical system (110) according to any one of the preceding claims referring to an analytical system (110), cause the analytical system (110) to carry out at least steps b. (136) and c. (138) and optionally d. (140) and/or e. (142) of the method according to any one of the preceding claims referring to a method.
16. A computer-readable storage medium comprising instructions which, when executed by the analytical system (110) according to any one of the preceding claims referring to an analytical system (110), cause the analytical system (110) to carry out at least steps b. (136) and c. (138) and optionally d. (140) and/or e. (142) of the method according to any one of the preceding claims referring to a method.