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(71) Applicant: **IOI AURANAE KFT** [HU/HU]; Városligeti fasor 34-36., 1068-Budapest (HU).

(72) Inventor: **KŐNTŐS, Zoltán**; Nevegy utca 16. fszt. 1., 1112 Budapest (HU).

(74) Agent: **SBGK PATENT AND LAW OFFICES**; P.O. Box 360, H-1369 Budapest (HU).

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(54) **Title:** DEVICE AND METHOD FOR THE AUTOMATIC DETERMINATION OF ANION AND CATION LEVELS FROM URINE

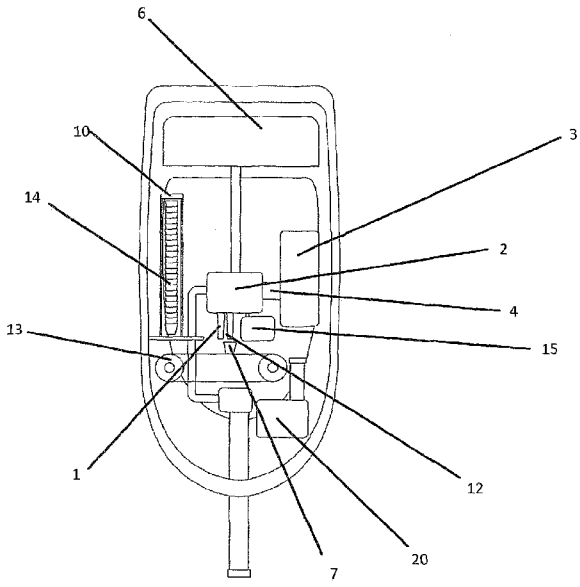


Figure 1b

(57) **Abstract:** The device for automatic determination of anion and/or cation levels in urine, which comprises: a) at least one sampling unit, b) at least one turbidity measuring unit, c) at least one reagent solution storage unit, said reagent solution is suitable for detecting anions and/or cations by selective precipitation reaction, d) at least a pump for delivering a reagent solution corresponding to the precipitation reaction with the specific ion, e) at least one unit for collecting and transmitting data, and f) at least one control unit, g) a housing for mounting it to a vertical supporting structure, enclosing the units and designed for urine collection, characterized in that - further comprising a human machine interface, i.e. HMI, and - the sampling unit contains at least one electromechanical unit enabling the horizontal and vertical movements of the sample vessels, and where the anion and/or cation detected in the urine is selected from Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, $P04^{3-}$ ions, and where the automatic detection is not based on enzymatic reactions, but is a urine analysis method based on precipitation.

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Device and method for the automatic determination of anion and cation levels from urine

BACKGROUND OF THE INVENTION

1. Technical Field of the invention

The invention relates to a device and a method for the automatic determination of anion and cation levels from urine. Urine analysis may provide a wide range of data of clinical significance not only regarding kidney function but also various metabolic processes, organ and cell system functions. The majority of the end products of metabolic processes are removed by the kidneys through urine.

Minerals are involved in the structure and the vital functions of the body. Almost all minerals are needed to build up the cells. A complete lack of minerals or lack of certain minerals will cause illness in the body, however, even they are found in traces in the nutrition, it will cover the functional needs. Minerals can be supplemented for the body in the form of food and sufficient amount of liquid (water), or in the form of nutritional supplements.

The mineral sodium is a cation of the body whose main function is to maintain the salt-water balance of the body. Sodium ions in the body are mainly present in the extracellular space, while the intracellular space contains a small amount of sodium ions. The mineral sodium is primarily excreted via the urine and this excretion is controlled by the body's needs (ADH hormone, aldosterone). Abnormal loss of the sodium minerals most likely to occur in adrenal or renal diseases. Abnormal accumulation of sodium minerals may develop in circulatory failure due to the weakness in the right part of the heart and in renal diseases with protein loss, which may lead to edema (swelling) after rapid increase in body weight.

The potassium ion, an ion exists in the body is the major cationic component of the intracellular space, while it is present only in very small amounts in the extracellular space. The levels of the Na^+ and K^+ and the ion exchange are closely related to each other, providing the proper osmotic pressure conditions between cells. The average daily potassium need of an adult human is 2-3 g (based on RDA-OÉTI), which is provided by balanced and mixed diet. Typical symptom of potassium deficiency is myasthenia and the intestinal atony (balky bowels). Extreme increases in potassium levels (for example, due to renal failure or excessive potassium intake) can lead to cardiac conduction disturbances (blocks), or even to cardiac arrest. Potassium is one of the macronutrients, i.e. is a mineral that the body needs in hundreds of milligrams or grams per day. Potassium plays an important role in maintaining fluid balance and gastro-intestinal tract balance,

as well as in transmitting electrical impulses between nerve and muscle. It is of great importance that the transport of the hydrogen ions is also dependent on the presence of potassium, therefore, potassium plays an essential role also in maintaining the acid-base balance, as it can affect the changes of the pH in a favorable way for the body.

Calcium ion as a cation plays a key role in the function of many cells. Thus, for example, the calcium mineral plays a role in coupling of the stimulus and contraction in muscle cells, coupling of the stimulus and excretion in endocrine and exocrine glands and in blood coagulation. In addition to calcium, bones and the dentition also contain a large amounts of phosphate ions. It is found in the bones in the form of calcium phosphate. It also plays an important role in the energy-supply of the body, in the metabolism of the nutrients and in maintaining the acid-base balance.

The magnesium mineral as a cation contributes in the structure of teeth and bones in the body and plays a role in the transmission of stimuli, including nerve and muscle function. Magnesium is involved in about 300 different biochemical processes in the body. The amount of magnesium needed depends on a number of factors, such as age, gender, or whether a woman is pregnant or nursing. Magnesium plays a major role in the proper functioning of the muscles, inter alia by influencing the utilization of calcium and potassium. Magnesium also plays a major role in the proper functioning of cardiac muscles and neurotransmitting system. Depression, bad mood, lethargy, anxiety, nervousness and also hearing deficiency can also result from magnesium deficiency. The magnesium mineral is excreted mainly via the urine from the body.

Iodine is a mineral that becomes a constituent of thyroid hormones (as iodine), i.e. thyroxine and triiodothyronine and therefore plays an important role in metabolic processes, growth, and functioning of the nervous system, as thyroid hormones play a central role in the regulating cellular life and metabolism.

The primary role of selenium mineral in the body is the stabilization of the cell membrane and act as an antioxidant, i.e. it is effective in neutralizing free radicals. The lack of selenium minerals can cause skeletal muscle degeneration and muscle degeneration, resulting in disruption of the leg, improper gait and posture. The concentration of selenium minerals in the body can be detected in blood, urine, hair and nails. Selenium is an essential microelement with antioxidant activity and is a component of many enzymes. Lack of it can cause a variety of health problems in the function of the liver, thyroid, brain, testicles and ovaries.

The microelement lithium is very likely to influence a person's psychological mood. Lithium salts are used to treat manic depression (should not be given to a pregnant woman during

pregnancy). Its deficiency affects the development of cardiac and circulatory diseases. Low intake reduces the reproductivity rate and affects the weight of the embryo.

The urine sample best reflects the body's recent mineral levels. Urine analysis is painless, and is one of the so-called non-invasive methods, and is therefore very common in everyday practice.

According to the present state of the art the rapid test and test strip applications are the most commonly used urine test methods for routine use, which methods are based typically on yes/no answers, i.e. are not suitable for quantitative analysis but for qualitative analysis only. Their function is based typically on the visible physiochemical changes resulting from the interaction with the component to be analyzed. The test stripe assay provides false positive and false negative results in high percentage. They are not capable of quantifying anions and cations.

Urine analysis can sometimes be time consuming and/or difficult to perform, if urinary stimulation is not present at the time of analysis. This is often why clinicians overlook this laboratory diagnostic method, which provides important information during clinical measures.

2. Description of the Prior Art

There are many solutions available in the prior art to assist with urine testing at home. Hungarian Patent No. 220777 relates to a solid state device for performing multi-analyte assays comprising a substrate and a multiple discrete reaction sites each containing a ligand covalently bonded to the substrate, wherein the surface of the substrate in the device is inert between the reaction sites with respect to analyte, and the analytes are selected from the group consisting of antibiotics, hormones, cardiac damage markers, infection markers, allergy markers, narcotics, enzymes, viruses, nucleotides and peptides. The samples to be analyzed in the device are whole blood, serum, plasma, urine, faeces, bile, tissue or nutritive. The multi-analyte analysing system comprises a device as disclosed above, a translation work surface, a sample dosing system, a liquid reagent delivery system, a tempered black box, a CCD camera and an image processing device. The disclosed solution can be used for simultaneous automatized detection of multiple substances, however, the compounds to be analyzed and the assay method differ from that of the present invention. Preparation of the substrate containing the biological ligands and analytic methodology thereof are extremely expensive and is not applicable for the determination of anion and cation levels and is most suitable for the detection of the presence of macromolecules.

International Publication No. WO 2018/122403 relates to a reusable device which is capable of quantifying at least one substance in the urine, such as a compound or a chemical

component and the device can be mounted on the toilet bowl, especially on its rim. The device described includes a mounting part, a boxed electrical unit, an urine receiving area with at least one electrochemical sensor, a wireless connector capable of transmitting data to a remote central computer, wherein the electrochemical sensor comprises at least an ion sensitive Field Effect Transistor (ISFET) configured to be able to the detect the levels of one or more physiological ions. The obtained device is easy to use and easy to mount at home, even more than once. The electrochemical sensor can be set to measure the concentration of one or more substances selected from the group consisting of H^+, Na^+, K^+, Ca^{2+}, Mg^{2+}, Cl^-, H_2O_2, glucose, nitrites, proteins, estrogens, lutein hormone, beta-HCG hormone (hormone indicating pregnancy) and creatinine. The invention provides a solution for simple and rapid quantitative measurement of urine components at home, simple data processing and storage on IT devices. However, the disadvantage of the ISFET electrochemical sensor is that it can only be used within a narrow measuring range and therefore cannot be used to measure certain ions. In addition, for hygienic reasons, the attachable device is not suitable for multiple use. Conversely, frequent replacement of the device does not make the continuous monitoring cost effective on the basis of repeated measurements a day.

International Publication Nos. WO 2008/072112, WO 2017/160399 and WO 2017/058806 disclose urine analysis methods, however, their use relate to specific measurements and devices which are different from the solution of the present invention, they have limited applicability, and they are not suitable for cheap anion and cation level detection at home.

US2017022536 (A1) relates to a portable device for analyzing the presence of metabolites in urine, said device comprising a sampling unit, a reagent container, a unit for determining the quantity of metabolites and an electronic communication unit. The amount of the metabolites is measured by the color change after mixing the reagent with the urine sample. The analyte to be measured is glucose, nitrite, proteins, etc. The disclosed portable device can be mounted on the toilet bowl, thus, the hygienic problems mentioned above are present in this case as well, and the range of the metabolites to be analyzed do not cover the analytes that can be analyzed by the present invention, i.e. cations and anions.

The obvious disadvantage of the methods used so far is the ability to automate, that is, to perform serial measurements which give satisfactory results in quality, but the result is available in a much shorter time than at present. The cost of automated measurements is even lower than the cost of individual tests, so there is significant time, logistical and life-saving benefits of the proposed methods compared to currently available. A further advantage of the solution is that it

allows the approximate determination of the amount of multiple anions and cations in the urine using a single device.

SUMMARY OF THE INVENTION

It was an object of the present invention to provide a device for overcoming the above-mentioned problems which allows to sample from urine and to determine the level of anion and cation detectable in the urine in a hygienic way.

A further object was to provide a device capable of continuously monitoring the levels of a given anion and/or cation for several days through urine analysis, thereby providing an overview of the anion and/or cation supply of the body. Based on these measurements, the subject is able to decide which anion and/or cation needs additional intake or has to be abandoned. This allows the subject to prevent certain diseases associated with low or too high anion or cation levels in the body.

It has been recognized that there is an urgent need for a method and device for determining the anion and cation levels of urine in a rapid, yet relatively accurate measurement at home. Moreover, with proper use of modern devices, the values obtained allow continuous monitoring of the anion and cation levels of urine. The values thus obtained can assist in proper diagnosis of diseases by tracking inadequate amount of anion and cation for self-determining of the intake or abandonment of the corresponding anion and cation, thereby preventing the onset of certain diseases.

It has also been recognized that, due to its multi-purpose nature, up to 5 or 6 analysis can be performed on a single urine sample, depending on its volume, so that the proportion of individual anions and/or cations can be determined side by side. By measuring some cation and anion groups together, we can infer the physical state or the performance of the body.

The results of the analysis performed with the device can be shared electronically with experts, physicians, so a diagnosis can be made in a very short time without any travel waiting time and a possible intervention can be initiated. Intervention is also possible in places where so far, typically due to the duration of the analysis, it has not been possible to intervene meaningfully, such as in the case of athletes or heavy workers, since the device located at the workplace is capable of continuously monitoring the ion levels, thus maintaining the appropriate level of performance.

DETAILED DESCRIPTION OF THE INVENTION

To solve the above objects, it has surprisingly been found that the determination of the amount of anions and cations can be accomplished by precipitation reactions that allow the reagent specific to a given ion to react selectively with only one component in a multiionic environment. The method is thus based on whether a particular anion or cation forms a precipitate with a reagent specific to it. The assay is carried out by adding said reagent to a suitably selected volume of urine until the selective precipitation begins, so that the amount of reagent is proportional to the concentration of the anion or cation dissolved in the urine.

For example, magnesium ions can be selectively detected in the form of hydroxide precipitate, well distinguished from the calcium ions, because under the conditions used, $Mg(OH)_2$ precipitates, while $Ca(OH)_2$ remains in solution, which is determined by their solubility. The amount of the reagent is proportional to the concentration of the Mg ions in the urine.

Calcium ions can be selectively detected in the form of a white oxalate precipitate, well distinguishable from other ions, since oxalate ions do not react with other ions under the conditions used, and thus, the low solubility of calcium oxalate allows the determination.

Potassium ions can be selectively detected in a precipitation reaction in the form of a yellow precipitate with sodium hexanitrito cobaltate[III] reagent, well distinguished from other ions.

Sodium ions can be selectively detected in a precipitation reaction in the form of a white precipitate with potassium hexahydroxy antimonate [V] reagent, well distinguished from other ions.

Lithium ions can be selectively detected in a precipitation reaction in the form of a white precipitate with potassium hydrogen phosphate reagent, well distinguished from other ions.

Iodide ions can be selectively detected in a precipitation reaction by reacting with IOI Blue® 0,5 reagent (copper nitrate), well distinguished from other anions.

Selenate ions can be selectively detected in the form of a color reaction in a hydrochloric acid medium with thiourea reagent, well distinguished from other ions, giving a purple color reaction where the color depth is proportional to the concentration of the selenate ions.

Phosphate ions can be selectively detected in a precipitation reaction in the form of a white precipitate with lithium hydroxide reagent, well distinguished from other ions.

The basic criteria for performing each assay are 20 ml urine sample and 15 minutes assay time. Adjusted to the concentration of each ion to be tested, a set of reagents were selected to provide the precipitation phenomenon and detection from 20 ml urine in 15 minutes.

The invention relates to a device for automatic determination of anion and/or cation levels in urine, comprising:

a) at least one sampling unit,
b) at least one turbidity measuring unit,
c) at least one reagent solution storage unit,
d) at least a pump for transferring the reagent solution,
e) at least one Human Machine Interface (HMI),
f) at least one unit for collecting and transmitting data, and
g) at least one control unit,

said units are arranged in a frame adapted to receive urine sample.

The invention further relates to a device for automatic determination of anion and/or cation levels in urine, comprising:

a) at least one sampling unit,
b) at least one turbidity measuring unit,
c) at least one reagent solution storage unit, said reagent solution suitable for detecting anions and/or cations by a selective precipitation reaction,
d) at least a pump for delivering a reagent solution suitable for the precipitation reaction of the ion to be detected,
e) at least one Human Machine Interface (HMI),
f) at least one unit for collecting and transmitting data, and
g) at least one control unit,

which units are arranged in a properly designed frame.

The invention further relates to a device for carrying out a urine test method based on a precipitation reaction. In order to detect the precipitation, the automatic turbidity test unit contains at least one turbidity detector unit that uses UV, IR or IR-LED light source. The device according to the invention may further comprise measuring units for determining the temperature, conductivity and pH of the urine, such as, but not limited to, an ISFET pH sensor or a temperature sensor.

The device of the present invention measures the anion and cation levels of the urine, in particular Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, PO_4^{3-} ions. The storage unit of the reagent solutions suitable for detecting the anion and cation levels by selective precipitation reaction contains in particular the following reagent solutions: calcium hydroxide, oxalate salts, sodium hexanitritocobaltate[III], potassium hexahydroxy antimonate[V], potassium hydrogen phosphate, copper nitrate, thiourea dissolved in hydrochloric acid medium, and lithium hydroxide. Each of these reagent solutions can be used to detect a particular anion or cation.

The invention further relates to a device suitable for the testing one or even more anions and/or cations or other parameters simultaneously.

The present invention relates to a device wherein the turbidity sensor is connected to the sample storage compartment through a horizontal and a vertical sample forwarding unit, which, together with sample storage compartment, are designed to be controlled by a logic control, said logic control includes the plurality of IT elements computing the test results (such as the number of drops of the specific reagent solution) and sets of units transmitting the said test results to the unit for collecting and transmitting the data.

The present invention relates to a device wherein the sampling unit comprising a flowmeter with sensor for separating 1 to 100 ml, preferably 10 to 20 ml of urine sample to the sample holder. The sampling unit is designed to be capable of sampling one or more samples.

The invention further relates to a device wherein the sampling unit comprises at least one electromechanical unit for delivering the sample holders in horizontal and vertical direction. In the device of the present invention the reagent solution is added into the sampling vessel via an element having a dropping needle.

The present invention relates to a device further comprising, within its active range, an adjustable inner parameter storing unit and a built-in radio frequency communication transceiver for the detection of the proximity of IT devices, preferably smart devices having the similarly configured parameters and an ioFIT identifier.

The present invention further relates to a device further comprising a radio frequency transceiver, an antenna, a mechanical unit for fixing the said device, wherein the active range of the radio frequency transceiver can be variably set to specific values, and the inner parameter storage unit has a fix selection template preset to the parameters stored in it, wherein said selection template can be broadened or modified.

The invention further relates to a device having a digital accounting system associated with measurements for offsetting each test service in which, when a measurement is made, the transaction value in internal accounting unit [Rz] is subtracted from the internal accounting units [Rz] of the smart device having the same ioFIT identifier.

The present invention further relates to a device which further comprising a smart contract storage unit wherein by accepting the said smart contract, after sending the measured parameter and recording said measured parameter from the informatic device with ioFIT identifier the unit automatically charges a predetermined internal accounting unit on the internal account having the

ioFIT identifier identical with the ioFIT identifier of the informatic device from which the urine test request was sent and thereby the agreement will be executed.

The present invention relates to a method for the automatic determination of anion and/or cation levels in urine, comprising the steps of:

a) providing a device according to the present invention,

b) selecting the ion to be tested in the urine via the human machine interface (5) or via the IT device being in connection with the device of the present invention by the subject requiring the test,

c) urine sampling by the sampling unit (1) of the device after urination,

d) adding a reagent solution specific for the detection of the selected ion and delivered by the pump (4) to the sample volume of urine to be analyzed until the turbidity caused by the precipitation is detected,

e) recording the drop number of the reagent solution in the unit for collecting and transmitting the data (6), wherein said drop number is proportional to the concentration of the urine anion and/or cation, and

f) calculating and displaying the measured data on the human machine interface of the device and/or on the smart device of the subject.

The invention further relates to a method for determination of anion and/or cation levels in urine, in particular Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, PO_4^{3-}. In the method of the invention the reagent solutions used for the selective precipitation reactions for detecting the anions and/or cations are the following: calcium hydroxide, oxalate salts, sodium hexanitritocobaltate[III], potassium hexahydroxy antimonite[V], potassium hydrogen phosphate, copper nitrate, thiourea dissolved in hydrochloric acid medium, and lithium hydroxide.

The invention further relates to the use of a device for the automatic determination of anion and/or cation levels in urine. By analyzing of successive urine samples, it allows continuous monitoring of specific anion and/or cation levels for several days, thus providing an overview of the measured anion and/or cation supply in the body. Based on these measurements the subject can decide which cation and/or anion needs additional intake or, in case of high levels, to leave foods containing that cation and/or anion in their diet. This allows the subject to prevent certain diseases associated either low or too high anion and/or cation levels in the body.

Preferred embodiments of the urine testing device of the present invention will now be described in more detail with reference to the accompanying Figures.

Figure 1a. shows the front view of the automated device for the detection and analysis of individual urine cations and anions, and Figure 1b. shows the internal structure of the urinal version of the device.

EXAMPLES

Example 1. Automatic anion and cation level detection in urine

The device for carrying out the urine analysis method by precipitation according to the present invention, comprises the following components:

a) at least one sampling unit 1,
b) at least one automated turbidity measuring unit 2,
c) at least one reagent solution storage unit 3 for the selective precipitation reaction,
d) at least one pump 4 for delivering the reagent solution suitable for the precipitation reaction of the ion to be detected,
e) at least one human machine interface (HMI) 5,
f) at least one unit for collecting and transmitting data 6, and
g) at least one central control 15 for controlling the process,

which components are arranged in a properly designed frame 16.

During the method for the automated analysis of cations and anions [ions] of the urine, the ions from the urine are analyzed in an automated turbidity measuring unit 2 connected to at least one sampling unit 1, such that the aqueous solutions of metal ions are used as analytical reagent, wherein said solutions are added automatically and dropwise to the sample to be analyzed with the pump 4, wherein the appearance of precipitates forming upon interaction of said solution with urine indicate the end point of the analysis/detection. When the end point is reached, the number of reagent liquid droplets indicates the result of the measurement, which is processed digitally stored and electronically by the unit for collecting and transmitting data 6. The measurement data is transmitted by the unit for collecting and transmitting data 6 to the IT device having ioFIT identifier of the subject, said IT device is subjected to identification and authorization steps prior to the sampling step. The sample containing sampling vessel 7 is connected directly or indirectly to the turbidity measuring unit 2 containing the measuring instrument, while the measuring instrument is connected to the unit for collecting and transmitting data 6.

In one aspect of the present invention, there is provided a method of detecting and analyzing particular urine cations and anions comprising measuring the parameters, preferably quantitative parameters, of the ionic components from a urine sample. In a further aspect, further parameters can also be determined during the method. In addition to the at least one automated measuring unit 2 suitable for measuring turbidity, additional measuring instruments may be included to determine additional parameters in the method. Examples of such urine analyzing methods include, but are not limited to, methods for measuring urine temperature and pH. For the automated turbidity measuring unit 2, UV and IR detection methods, among others, wherein the infrared [IR] detection methods are suitable for detection of carboxyl group containing organic anions, among others, and the ultraviolet detection methods are suitable for detection of gold complexes. The turbidity detector may be complemented by, but not limited to, IR and UV detectors.

The essence of the method of the present invention is to prepare the particular urine cations and anions [ions] for the automated analysis and measurement in aqueous solution by sampling directly from the urine [if necessary, through a suitably selected filter surface] by transferring it into a sampling vessel 7 using a suitably selected valve, said sampling vessel 7 is designed to have an opening-closing element on its upper surface, preferably an inlet valve and an opening-closing inlet element having reagent-dosing inlet, preferably having an inlet valve which can be sealed tightly. According to one aspect of the device for analyzing urine samples is suitable for sampling a clean [free from suspended substances] urine sample, wherein the sampling vessel 7 is sealed by a cap, wherein said vessel can preferably be filled or emptied without removing the cap.

In one aspect the invention relates to a method for automated turbidity detection of a sample by automatically adding a reagent solution to a sample until its turbidity reaches a predetermined value, which is the end of the detection. The drop number of the reagent added to the sample is proportional to the amount of the ion to be detected.

The device according to the invention comprises a reagent solution storage unit 3 and dispensing unit, reagent dosing valves, a turbidity measuring unit 2 comprising a sensor capable of measuring turbidity during reagent dosing in a given volume of sample in the sample compartment, and a unit for data collecting and transmitting 6, wherein these units are suitably arranged in a housing 16 suitable for urination. In the device, the turbidity sensor is connected to the sample vessel storage unit 10 through the horizontal and vertical sample forwarding unit 13,14, which are arranged with the sample vessel storage unit 10 under common logical control, which comprising a set of the IT elements for computing the measurement result (the drop number the

corresponding reagent solution), and elements which collecting and transmitting the results to the unit for collecting and transmitting data 6.

In the sampling vessel storage unit 10 comprised by the device according to the invention there are sampling vessels 7 are arranged, which are rotated by a stepping mechanism. The sampling vessels 7 are preferably cylindrical and have a positioning element. The sampling vessel storage unit 10 comprises at least one electromechanical unit for forwarding the sampling vessel 7 horizontally and vertically. The stepping mechanism may move freely through a vertical sample forwarding unit 14. The sampling vessel storage unit 10 further comprises a horizontal sample forwarding unit 13 by means of which the collected urine sample is placed horizontally in various positions for measurements towards measuring instruments for performing the selected measurements and finally towards the disposal vessel 20.

The reagent solution is introduced into the sampling vessel 7 via element provided with dropping needle 12. The sampling unit 1 includes a flow sensor and flow meter for separating 20 ml of urine sample into the sampling vessel 7. The sampling unit 1 further includes a flow direction changing valve for disposing the excess urine after the 20 ml of urine sample is transferred into the sampling vessel 7. The control unit 15 is coupled with a distance sensor arranged outside the frame or separated from the frame in order to detect the subject who would like to perform the measurement and accordingly, to activate the HMI 5 interface panel.

The determination of the cation and anion levels of the urine sample is performed by an electronically controlled turbidity measuring unit 2 which detects the end points of the precipitation reached by dropwise addition of a reagent solution to the sample which sample has a predetermined volume and originates from the urine to be tested, said reagent solution is delivered by pump 4, and the cation and anion levels are determined by means of detecting the turbidity generated in the sample having a predetermined volume. The device according to the invention comprises a sample analysing system, wherein the sampling vessel 7 containing the urine sample are arranged so that they move horizontally from the last position of the sample vessel storage to sample analysis site and after the analysis it is delivered to disposal vessel 20. The sampling vessels 7 are preferably cylindrical and have a positioning element. The stepping mechanism is free to move horizontally.

The pump 4 is a material delivering unit connecting the sampling vessel 7 with the reagent solution storage unit 3.

Turbidity is measured by a turbidity measuring detector unit. The device according to the invention further comprises a unit for data collecting and transmitting 6, which includes a

horizontal sample forwarding unit 13, a vertical sample forwarding unit 14 and the controlling ports of the unit for data collecting and transmitting 6, which are connected to the central control unit 15.

In another aspect of the invention, the device may include further measuring instruments in addition to at least one turbidity measuring unit 2. These include, but are not limited to, UV detectors or IR detectors which are used to measure additional physical and/or chemical properties of the urine. These measuring instruments are also properly connected to the central control unit 15 and to the unit for collecting and transmitting data 6.

The device according to the invention comprises within its active range an adjustable inner parameter storing unit capable of active communication, an integrated radio frequency communication transceiver for the detecting the proximity of IT devices, preferably smart devices having similarly adjusted parameters and having an ioFIT identifier, said device further comprises a 6 unit for collecting and transmitting data and at least one human machine interface (HMI) 5 and have an individual device identifier [MID]. The device according to the invention further comprises a power source, electronic memory chip and a radio frequency communication transceiver, antenna, a mechanical fixing unit and a housing 16 enclosing them. The active range of the radio frequency communication transceiver can be variably set to specific values and the inner parameter storage unit comprises a preset, scalable and modifiable, fix selection template for the parameters stored therein.

The human machine interface (HMI) 5 unit of the device according to the invention may also include a proximity sensor that turns on the device in the vicinity of the subject intending to perform the analysis.

The device according to the invention further comprises a unit for collecting and transmitting data 6 which is suitable for collecting reagent drop number data and/or other urine physical parameter data [temperature, conductivity], wherein the unit for collecting and transmitting data 6 comprises a processing unit for processing the data it collects, the automated dropper connects to said unit for collecting and transmitting data, and a display unit, as well as, a unit for transmitting the reagent solution drop number data and/or the urine physical parameter data to the unit for collecting and transmitting data 6 and/or to the display or to the IT device of the subject in a suitable displayable form for the subject, a primer data collecting module for monitoring reagent drop number data provided by the automatic dropper and/or a second data collecting module for collecting other urine physical parameter data [temperature, conductivity], and/or a third data collecting module for monitoring the usage data of the whole device.

The device according to the invention is provided with a dual function structure for operability by which in the first step analyses the urine sample and in the second step transmits results to the nearby IT device, preferably a smart device having an ioFIT identifier by unit for collecting and transmitting data 6, while an auto-executable smart contract stored on the mass storage device is activated and the value of the above transaction for the analysis in internal accounting unit [Rz] is subtracted from the internal accounting units [Rz] belonging to the IT device, preferably a smart device having the same ioFIT identifier. The value of the above transaction will be charged in internal accounting units [Rz] to the account of the IT device having the same MID identifier.

The present invention also relates to the implementation of a digital coin insertion in connection with device and analyzing method, according to the principle of the present coin inserting devices whereby, if an internal accounting unit account belonging to a specific ioFIT identifier is electronically chargeable and the authorizing instruction is issued [before executing the smart contract] the cost of the analysis may be offset with Rz internal accounting unit which corresponds to the "insertion" of an electronic coin.

According to another approach of the invention, the measurement data and the payment and accounting processes may be stored in a blockchain structure.

During the implementation of the present invention, it automatically performs predefined method steps, such as sampling, analysis, rinsing, result transmitting. It is a multifunctional application since it is able to measure multiple cations and anions in one procedure.

In another aspect of the present invention, the device also comprises a housing 16 enclosing an interior space and being capable for displaying an interactive advertisement, said housing 16 includes electronic and non-electronic advertising space on it. In a further aspect of the present invention the device also includes a central control unit 15 arranged inside the housing 16 wherein the central control unit 15 has one or more communication ports for signal transmission and at least one communication port for the central control unit 15 is in connection with the unit for collecting and transmitting data 6. This part of the device according to the present invention may contain advertisements and may be used for advertising purposes.

The device of the present invention also includes a smart contract on a storage unit, and when a request is received from the IT device with an ioFIT identifier for a urine test to the device with a specific MID identifier, upon transmitting the parameter [drop number] presenting the result of the analysis to the IT device with the ioFIT identifier [simultaneously saving the data in the IT device], the account of the same ioFIT identifier is automatically debited with an [Rz] internal

accounting unit amount predefined in the smart contract [which will be credited to the MID account of the party performing the measurement], and thereby the contract is executed. The subject of the contract is the analysis to be performed and the settlement of its offset in internal accounting units according to the fee schedule. The contracting parties are the owner of the IT device with the ioFIT identifier, preferably a smart device and the business organization operating the devices according to the invention.

Different embodiments of the invention may be provided with different designs. Thus, for example, the design of the housing 16 may differ from that urinal design shown on Figures 1a. and 1b. In another aspect of the device according to the present invention can be used as a conventional toilet solution regardless of gender, while the urinal design is male-only. Of course, we do not intend to limit the scope of the invention to the following embodiments, so that further embodiments and arrangements within the scope of the invention may be provided.

In the following, a preferred embodiment of the device and method of the present invention will be described in detail, but it is not intended to limit the scope of the invention to the embodiment illustrated herein.

Example 2. Detection of iodide ions in urine with $Cu(NO_3)_2$ solution by means of a urinal design of the device of the invention

A subject with smart device having an ioFIT identifier requiring the automatic determination of [iodide ion] anion and cation levels in urine was initiated the detection by selecting the corresponding ion(s) to be analyzed via the human machine interface (HMI) 5 on the device housing or via a suitable IT device, preferably on a smart device, through a suitable data transmitting connection. 20 ml of urine was sampled and transferred to the sampling vessel 7 by the sampling unit 1 inside the device of the present invention. The subject with a smart device having an ioFIT identifier was detected by the proximity sensor of the HMI 5.

Inside the sampling unit 1 the urine sample was sampled by means of a flow reserving valve controlled by the central control unit 15 allowing the accurate sampling of 20 ml of sample. The 20 ml urine sample was placed into the sampling vessel 7, while in the lack of the need of additional sampling the remaining urine was disposed by closing the valve and was discharged from the device through the drain pipe by using known methods available also from the prior art. After the measurement, the device was flushed with a liquid that provides good hygiene, such as clear water or a liquid containing a disinfectant.

Basically, the urine in the plastic sampling vessel 7 is a transparent liquid having various shades of yellow. In order to eliminate the turbidity or incomplete transparency of the sample, it was filtered by a filter placed in the sampling vessel 7 and was allowed to sediment for a few minutes before the analysis. After sampling, the sampling vessel 7 was moved forward on a horizontal conveyor belt in three determined positions:

1. the sampling vessel 7 was placed under the urine dosing tube and 20 ml of clear urine was introduced into the sampling vessel 7.

2. at the second position [measurement point], the dropping of the reagent solution was started from the reagent solution storage unit 3 according to a predetermined protocol corresponding to the selected analysis, as a result of which the change in the turbidity of the urine was monitored by the turbidity meter placed in the turbidity measuring unit 2.

3. at the third, last position, the content of the sampling vessel 7 filled with urine was placed into the disposal container 20.

According to the commands of the central control unit 15, for the detection of anions and/or cations, like iodide ions in this case by selective precipitation reaction, 0,5 mol/l $Cu(NO_3)_2$ solution was added dropwise by means of a pump 4 from the reagent solution storage unit 3 until otherwise clear urine began to opalesce and a brownish cloudy precipitate was observed and was determined by means of the turbidity meter in the turbidity measuring unit 2. After each drop the urine sample was shaken mechanically and there was a waiting tine of 10 seconds before the next drop was added. Already after the first drop has been added, a colour change occured and the originally yellow urine started to turn green. The color change did not affect the measurement, only the formation of a cloudy, brownish precipitate is measured by the turbidity meter. After the urine began to cloud, but the precipitate had not yet precipitate, one single drop was needed for detecting the precipitate, which indicated the end of the measurement. The iodide ion concentration in the urine is given by the number of the drops after which a brownish cloudy precipitate was observed. The more drops needed, the less iodide ions were secreted by the body. In this case, the reagent solution is added to the urine by an automated pump 4. The central control unit 15 transmitted the measurement results, i.e. the number of droplets used to the unit for collecting and transmitting data 6 through a data transmitting channel. The unit collecting and transmitting data 6 associated the obtained measurement result with the assigned ioFIT identifier at the beginning of the measurement; during data transmission data was also sent to the Rz accounter which charged the same ioFIT Rz account [smart contract]. Upon transmitting the parameter [drop number] presenting the result of the analysis to the IT device with the ioFIT identifier [simultaneously

saving the data in the IT device], the account of the same ioFIT identifier was automatically debited with an [Rz] internal accounting unit amount predefined in the smart contract [which was credited to the MID account of the party performing the measurement], and thereby the contract was executed.

The analysis of the precipitate showed that the solution contained CuI as a precipitate. Therefore, the copper nitrate solution was suitable for the selective detection of iodide ions in urine.

The evaluation can be carried out according to Table 1 below.

Table 1.: Correlation of iodide ion concentration ranges and the drop number of the suitably selected reagent solution.

Iodide ion concentration	Iodine deficiency status	Solution amount needed for formation of brownish cloudy precipitate
〉 99 microgram/liter	optimal	1-2 drops
50-99 microgram/liter	light iodine deficiency	3-5 drops
49,8-20 microgram/liter	medium iodine deficiency	6-7 drops
〈 20 microgram/liter	severe iodine deficiency	over 8 drops

3. Reference example for detecting iodide ion concentration

During calibration of the drop numbers the concentration of the iodide ions of the same urine sample was determined in mg/L with ICP-MS method, in five parallel measurements, on basis of which the theoretical amount of the copper solution was calculated on basis of the solubility product, thereby determining the necessary concentration. By the copper concentration used, the consumption was proportional to the concentration of the iodide ions. The fact that the precipitate was copper(I) iodide was acknowledged by ICP-MS.

REFERENCES

1	sampling unit
2	turbidity measuring unit
3	reagent solution storage unit
4	pump
5	human machine interface (HMI)
6	unit for collecting and transmitting data
7	sampling vessel
10	sampling vessel storage unit
12	dropping needle
13	horizontal sample forwarding unit
14	vertical sample forwarding unit
15	control unit
16	housing
20	disposal vessel

CLAIMS

1. A device for automatic determination of anion and/or cation levels in urine which comprises:

a) at least one sampling unit,
b) at least one turbidity measuring unit,
c) at least one reagent solution storage unit,
d) at least a pump for delivering the reagent solution,
e) at least one unit for data collecting and transmitting,
f) at least one control unit, and
g) a housing for mounting it to a vertical supporting structure, enclosing the units and designed for urine collection

characterized in that

- further comprising a human machine interface, i.e. HMI, and
- the sampling unit contains at least one electromechanical unit enabling the horizontal and vertical movements of the sample vessels, and

where the anion and/or cation detected in the urine is selected from Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, PO_4^{3-} ions, and where the automatic detection is not based on enzymatic reactions, but is a urine analysis method based on precipitation.

2. The device for automatic determination of anion and/or cation levels in urine according to claim 1, which comprises:

a) at least one sampling unit (1),
b) at least one turbidity measuring unit (2),
c) at least one reagent solution storage unit (3), said reagent solution is suitable for detecting anions and/or cations by selective precipitation reaction,
d) at least a pump (4) for delivering a reagent solution corresponding to the precipitation reaction with the specific ion,
e) at least one unit for collecting and transmitting data (6), and
f) at least one control unit (15),
g) a housing (16) for mounting it to a vertical supporting structure, enclosing the units and designed for urine collection,

characterized in that

- further comprising a human machine interface, i.e. HMI, and
- the sampling unit contains at least one electromechanical unit enabling the horizontal and vertical movements of the sample vessels, and

where the anion and/or cation detected in the urine is selected from Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, PO_4^{3-} ions, and where the automatic detection is not based on enzymatic reactions, but is a urine analysis method based on precipitation.

3. The device according to any of claims 1 to 2, wherein the turbidity measuring unit (2) comprises at least one turbidity measuring detector unit with UV, IR or IR-LED light source.

4. The device according to claim 3 further comprising measuring means for determining the temperature, conductivity and pH of the urine, preferably ISFET pH sensor or temperature sensor.

5. The device according to any of claims 1 to 4 wherein the reagent solution storage unit (3) contains the following reagent solutions: sodium hydroxide, sodium hexanitrito cobaltate[III], potassium hexahydroxy antimonate[V], potassium hydrogen phosphate, copper nitrate, thiourea dissolved in hydrochloric acid medium, and lithium hydroxide.

6. The device according to any of claims 1 to 5 wherein one or more urine anions and/or cations or other urine parameters can be measured simultaneously.

7. The device according to any of claims 1 to 6 wherein the turbidity sensor is in connection with the sampling unit (10) through the horizontal and vertical sample forwarding unit, which are arranged under common logical control with the sampling unit (10), wherein said control includes set of IT elements for computing the measurement result i.e. the number of the droplets of the used reagent solution, and elements transmitting the same to the unit for collecting and transmitting data (6).

8. The device according to any of claims 1 to 7 wherein the reagent solution are introduced into the sampling vessel (7) via a unit fitted with a dropping needle (12).

9. The device according to any of claims 1 to 8 wherein the sampling unit (1) comprises a flow detector and flow meter for separating 1-100 ml of urine, preferably 10-20 ml of urine into a sampling vessel (7).

10. The device according to any of claims 1 to 9 further comprising, within its active range, an adjustable inner parameter storing unit and a built-in radio frequency communication transceiver for the detection of the proximity of IT devices, preferably smart devices having the similarly configured parameters and an identifier.

11. The device according to any of claims 1 to 10 further comprising a radio frequency transceiver, an antenna, a mechanical unit for fixing the said device, wherein the active range of the radio frequency transceiver can be variably set to specific values, and the inner parameter storage unit has a fix selection template preset to the to the parameters stored in it, wherein said selection template can be broadened or modified.

12. The device according to any of claims 1 to 11 having a digital accounting system associated with measurements for offsetting each test service in which, when a measurement is made, the transaction value in internal accounting unit is subtracted from the internal accounting units of the smart device having the same identifier.

13. The device according to any of claims 1 to 12 which contains further a smart contract storage unit wherein by accepting the said smart contract, after sending the measured parameter and recording said measured parameter from the informatic device with identifier the unit automatically charges a predetermined internal accounting unit on the internal account having the identifier identical with the identifier of the informatic device from which the urine test request was sent and thereby the agreement will be executed.

14. Method for automated determination of anion and/or cation levels in urine, comprising the following steps:

a) providing a device according to any of claims 1 to 13,
b) selecting the ion to be measured in the urine through the human-machine interface or the IT device being in connection with the device by the subject needing the analysis,
c) urine sampling in the sampling unit of the device after urination,

d) adding a reagent solution suitable for the detection of the selected ion forwarded by the pump drop by drop to the sample of a predetermined volume taken from the urine to be analyzed, until the turbidity caused by the precipitation can be detected,

e) recording the data of drop number of the reagent solution being proportional with the anion and/or cation concentration of the urine, said data being recorded in the unit for collecting and transmitting data, and

f) calculating the concentration data by the device and/or on the smart device of the subject,

wherein the anion and/or cation detected in the urine is selected from Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, PO_4^{3-} ions, and wherein the automatic detection is not based on enzymatic reactions, but is a urine analysis method based on precipitation.

15. Method according to claim 14 wherein the reagent solutions suitable for detecting anions and/or cations through selective precipitation reaction are the following: sodium hydroxide, sodium hexanitrito cobaltate[III], potassium hexahydroxy antimonate[V], potassium hydrogen phosphate, copper nitrate, thiourea dissolved in hydrochloric acidic medium, and lithium hydroxide.

16. Use of the device of any of the claims 1 to 13 for automatic determination of anion and/or cation levels in urine wherein the anion and/or cation detected in the urine is selected from Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, PO_4^{3-} ions, and where the automatic detection is not based on enzymatic reactions, but is a urine analysis method including precipitation.

17. The use according to claim 16, wherein from the analyses of the sequential urine samples the given anion and/or cation levels can be monitored continuously for more days.

18. Use according to any of claims 16-17 suitable for determining the necessity of intake

or abandonment of certain anions and/or cations, allowing thereby for the prevention of certain diseases.

AMENDED CLAIMS
received by the International Bureau on 10 June 2020 (10.06.20)

CLAIMS

1. A device for automatic determination of anion and/or cation levels in urine, which comprises:

a) at least one sampling unit (1),

b) at least one turbidity measuring unit (2),

c) at least one reagent solution storage unit (3), said reagent solution is suitable for detecting anions and/or cations by selective precipitation reaction,

d) at least a pump (4) for delivering a reagent solution corresponding to the precipitation reaction with the specific ion,

e) at least one unit for collecting and transmitting data (6),

f) at least one control unit (15), and

g) a housing (16) for mounting it to a vertical supporting structure, enclosing the units and designed for urine collection,

characterized in that

- further comprising a human machine interface, i.e. HMI,
- further comprising a unit fitted with a dropping needle (12) and
- the sampling unit contains at least one electromechanical unit enabling the horizontal and vertical movements of the sample vessels, and

wherein the anion and/or cation detected in the urine is selected from Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, PO_4^{3-} ions, and wherein the precipitation is caused by reagents other than enzymes, and

wherein the design of the housing is urinal design or toilet.

2. The device according to claim 1, wherein the turbidity measuring unit (2) comprises at least one turbidity measuring detector unit with UV, IR or IR-LED light source.

3. The device according to claim 2 further comprising measuring means for determining the temperature, conductivity and pH of the urine, preferably ISFET pH sensor or temperature sensor.

4. The device according to any of claims 1 to 3 wherein the reagent solution storage unit (3) contains the following reagent solutions: sodium hydroxide, sodium hexanitrito cobaltate[III], potassium hexahydroxy antimonate[V], potassium hydrogen phosphate, copper nitrate, thiourea dissolved in hydrochloric acid medium, and lithium hydroxide.

5. The device according to any of claims 1 to 4 wherein one or more urine anions and/or cations or other urine parameters can be measured simultaneously.

6. The device according to any of claims 1 to 5 wherein the turbidity sensor is in connection with the sampling vessel storage unit (10) through the horizontal and vertical sample forwarding unit, which are arranged under common logical control with the sampling vessel storage unit (10), wherein said control includes set of IT elements for computing the measurement result i.e. the number of the droplets of the used reagent solution, and elements transmitting the same to the unit for collecting and transmitting data (6).

7. The device according to any of claims 1 to 6 wherein the reagent solution areintroduced into the sampling vessel (7) via a unit fitted with a dropping needle (12).

8. The device according to any of claims 1 to 7 wherein the sampling unit (1) comprises a flow detector and flow meter for separating 1-100 ml of urine, preferably 10-20 ml of urine into a sampling vessel (7).

9. The device according to any of claims 1 to 8 further comprising, within its active range, an adjustable inner parameter storing unit and a built-in radio frequency communication transceiver for the detection of the proximity of IT devices, preferably smart devices having the similarly configured parameters and an identifier.

10. The device according to any of claims 9 further comprising a radio frequency transceiver, an antenna, a mechanical unit for fixing the said device, wherein the active range of the radio frequency transceiver can be variably set to specific values, and the inner parameter storage unit has a fix selection template preset to the to the parameters stored in it, wherein said selection template can be broadened or modified.

11. The device according to any of claims 1 to 10 having a digital accounting system associated with measurements for offsetting each test service in which, when a measurement is made, the transaction value in internal accounting unit is subtracted from the internal accounting units of the smart device having the same identifier.

12. Method for automated determination of anion and/or cation levels in urine, comprising the following steps:

a) providing a device according to any of claims 1 to 11,
b) selecting the ion to be measured in the urine through the human-machine interface or the IT device being in connection with the device by the subject needing the analysis,
c) urine sampling in the sampling unit of the device after urination,
d) adding a reagent solution suitable for the detection of the selected ion forwarded by the pump drop by drop to the sample of a predetermined volume taken from the urine to be analyzed, until the turbidity caused by the precipitation can be detected,
e) recording the data of drop number of the reagent solution being proportional with the anion and/or cation concentration of the urine, said data being recorded in the unit for collecting and transmitting data, and
f) calculating the concentration data by the device and/or on the smart device of the subject,

wherein the anion and/or cation detected in the urine is selected from Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, PO_4^{3-} ions, and wherein the precipitation is caused by reagents other than enzymes.

13. Method according to claim 12 wherein the reagent solutions suitable for detecting anions and/or cations through selective precipitation reaction are the following: sodium hydroxide, sodium hexanitrito cobaltate[III], potassium hexahydroxy antimonate[V], potassium hydrogen phosphate, copper nitrate, thiourea dissolved in hydrochloric acidic medium, and lithium hydroxide.

14. Use of the device of any of the claims 1 to 11 for automatic determination of anion and/or cation levels in urine wherein the anion and/or cation detected in the urine is selected from Na^+, K^+, Ca^+, Mg^{2+}, I^-, Se^{2-}, Li^+, PO_4^{3-} ions, and wherein the precipitation is caused by reagents other than enzymes.

15. The use according to claim 14, wherein from the analysis of the sequential urine samples the given anion and/or cation levels can be monitored continuously for more days.

16. Use according to any of claims 14-15 suitable for determining the necessity of intake or abandonment of certain anions and/or cations, allowing thereby for the prevention of certain diseases.

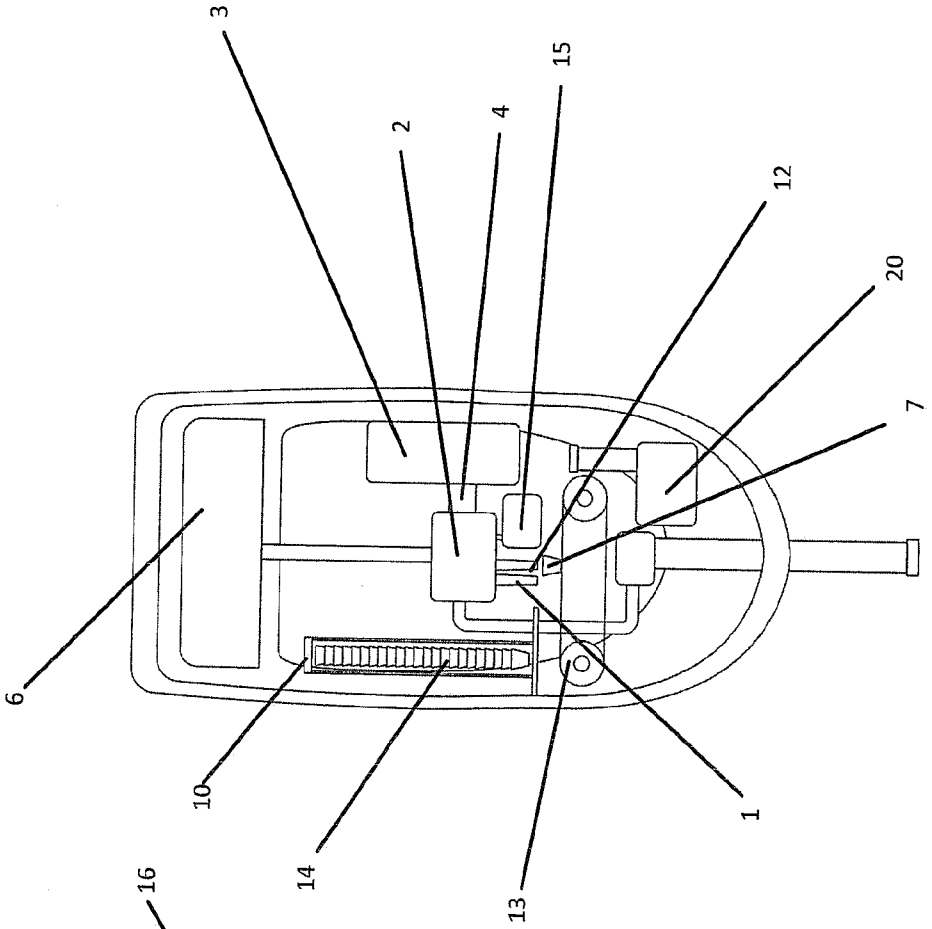


Figure 1b

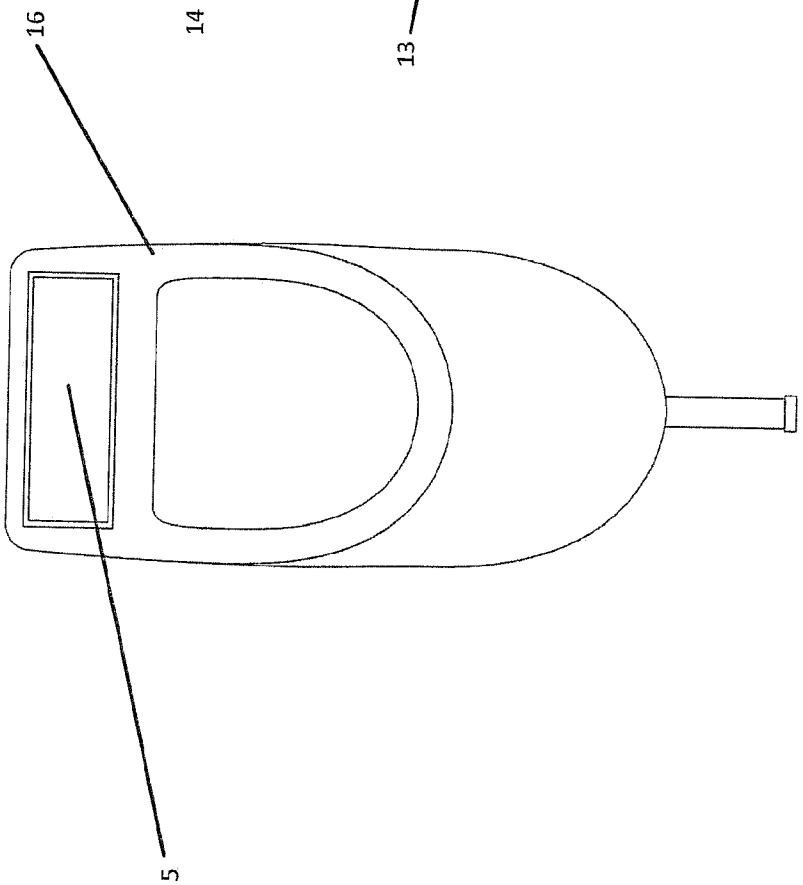


Figure 1a

1/1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/HU2020/000003

A. CLASSIFICATION OF SUBJECT MATTER
A61B 5/20; G01N 21/82; G01N 31/02; G01N 33/493; G01N 33/84; G01N 33/52
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B; G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, EPODOC, PUBCHEM, XPESP, EMBASE, CAPLUS, e-Kutatás

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, D	US 2017/0022536 A1 (Velazquez et al.) 26.01.2017 the whole document, see especially claims, paragraphs 9, 18, 23, 28, 35-37	1-18
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A	US 4,766,080 A (Fleming) 23.08.1988 the whole document, see especially pages 136-140	1-18

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 April 2020 (16.04.2020)	22 April 2020 (22.04.2020)
Name and mailing address of the ISA/ Visegrad Patent Institute/Branch Office HU H-1081 Budapest, II. János Pál pápa tér 7. Hungary Facsimile No.	Authorized officer Dóra Pfenninberger Telephone No.: +361/4745904

INTERNATIONAL SEARCH REPORT
Information on patent family members

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