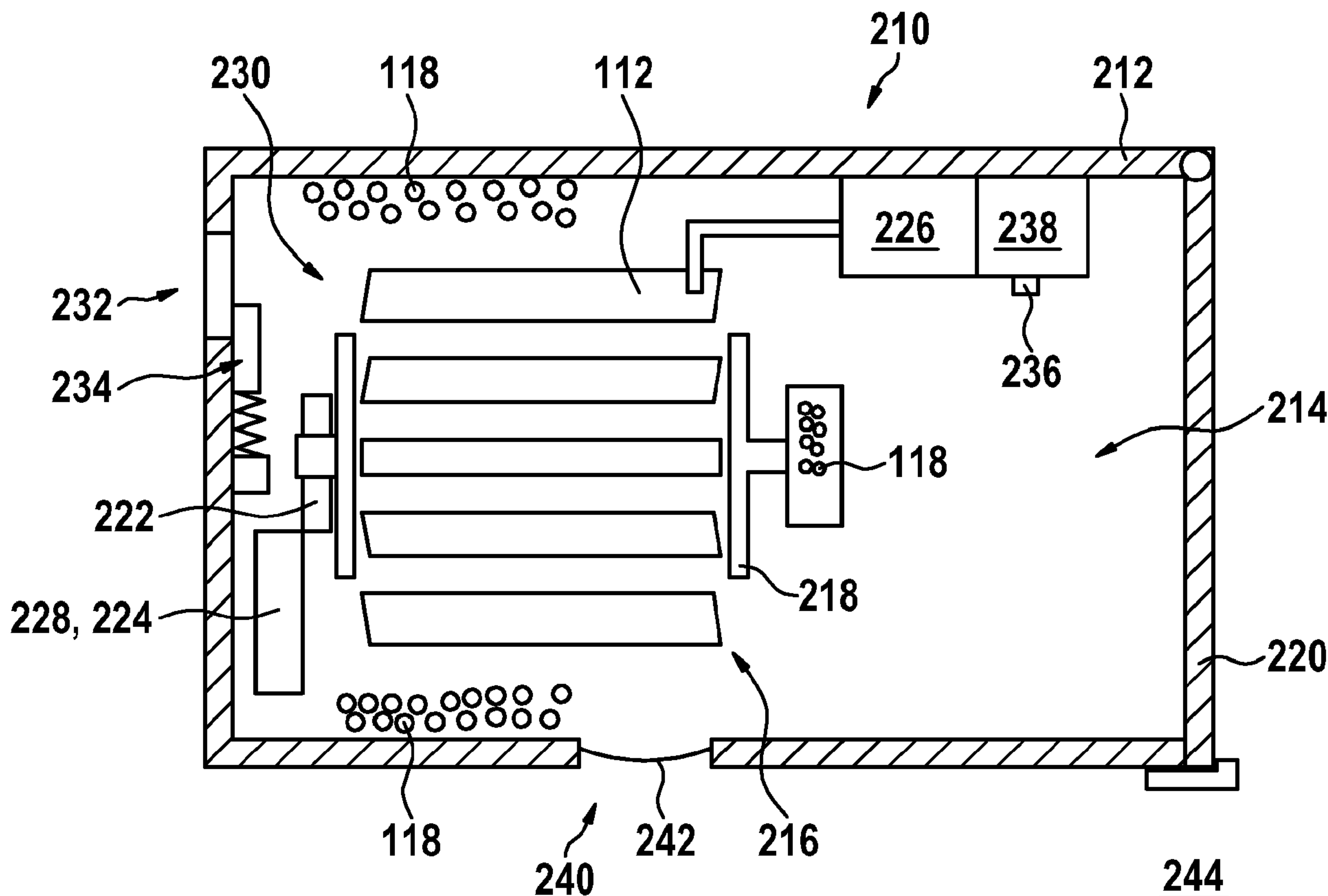




(86) Date de dépôt PCT/PCT Filing Date: 2007/07/10
(87) Date publication PCT/PCT Publication Date: 2008/01/24
(45) Date de délivrance/Issue Date: 2012/06/19
(85) Entrée phase nationale/National Entry: 2009/01/08
(86) N° demande PCT/PCT Application No.: EP 2007/057023
(87) N° publication PCT/PCT Publication No.: 2008/009585
(30) Priorité/Priority: 2006/07/18 (EP06117422.3)

(51) Cl.Int./Int.Cl. *G01N 33/487* (2006.01),
A61B 5/00 (2006.01)
(72) Inventeur/Inventor:
HONES, JOACHIM, DE
(73) Propriétaire/Owner:
F. HOFFMANN-LA ROCHE AG, CH
(74) Agent: NORTON ROSE CANADA
S.E.N.C.R.L., S.R.L./LLP

(54) Titre : SYSTEME DE MESURE PORTATIF D'ENCOMBREMENT OPTIMAL
(54) Title: PORTABLE MEASURING SYSTEM HAVING AN OPTIMIZED ASSEMBLY SPACE



(57) Abrégé/Abstract:

A portable measuring system (210) is proposed which is used to analyze a liquid sample for at least one analyte contained therein. The portable measuring system (210) has a moisture-proof housing (212) with an internal atmosphere (214). The moisture-proof housing (212) prevents air moisture and/or water vapor from penetrating into the internal atmosphere (214) of the housing. The



(57) **Abrégé(suite)/Abstract(continued):**

portable measuring system (210) also has at least one test element support (216) inserted into the internal atmosphere (214) of the housing. The at least one test element support (216) is equipped with at least one retaining structure (218) and at least one test element (112) that is supported by the at least one retaining structure (218). The at least one test element support (216) is designed in such a way that, after insertion into the internal atmosphere (214) of the housing, the at least one test element (112) is exposed to said internal atmosphere (214). A release mechanism (228) is also provided which can convey at least one test element (112) into an application position (230) within the internal atmosphere (214) of the housing. In this application position (230), the liquid sample can be applied to the at least one test element (112).

Abstract

A portable measuring system (210) is proposed which is used to analyze a liquid sample for at least one analyte contained therein. The portable measuring system (210) has a moisture-proof housing (212) with an internal atmosphere (214). The moisture-proof housing (212) prevents air moisture and/or water vapor from penetrating into the internal atmosphere (214) of the housing. The portable measuring system (210) also has at least one test element support (216) inserted into the internal atmosphere (214) of the housing. The at least one test element support (216) is equipped with at least one retaining structure (218) and at least one test element (112) that is supported by the at least one retaining structure (218). The at least one test element support (216) is designed in such a way that, after insertion into the internal atmosphere (214) of the housing, the at least one test element (112) is exposed to said internal atmosphere (214). A release mechanism (228) is also provided which can convey at least one test element (112) into an application position (230) within the internal atmosphere (214) of the housing. In this application position (230), the liquid sample can be applied to the at least one test element (112).

(Figure 2)

Portable measuring system having an optimized assembly space5 Field of the invention

The invention relates to a portable measuring system with a small assembly space that can be used to analyze a liquid sample for at least one analyte contained therein. Measuring systems of this kind are used in particular in the field of
10 medicine, for example for blood glucose monitoring, or in the field of chemical or biological analysis, for example environmental analysis.

Prior art

15 The monitoring of blood glucose concentration is an essential part of the daily routine of diabetics. The blood glucose concentration has to be determined quickly and reliably several times a day in order, if appropriate, to be able to take suitable medical measures. So as not to restrict the diabetic's daily routine any more than is necessary, suitable portable devices are often employed which are intended to be
20 easy to carry around and to operate such that the blood glucose concentration can be measured, for example, at the workplace or even during leisure time.

Various portable devices are presently available on the market, some of them functioning according to different measurement methods. Various diagnostic
25 methods are used in these devices, for example optical or even electrochemical measurement methods. An example of a frequently employed measurement method utilizes a special kind of electrochemical test strips. These test strips are, for example, configured such that a predetermined quantity of blood is conveyed to an electrode system via a capillary system on the test strip. For modern test strips,
30 a quantity of blood of ca. 1.5 μl is sufficient, sometimes even quantities of blood of less than 1 μl . The electrode system may, for example, involve gold electrodes that are provided with a coating. The coating in most cases contains different enzymes and so-called mediators and has the effect that charge carriers (for example in the form of redox molecules) form within the sample on the electrodes, the
35 concentration of these charge carriers being dependent on the blood glucose concentration. The concentration of these charge carriers can be determined by means of the gold electrodes and a suitable measurement system, for example by means of a current-voltage measurement, and from this concentration it is possible, finally, to calculate the blood glucose concentration. An example of

electrochemical test strips of this kind is set out in US 5,286,362.

As an alternative to the described electrochemical measurement method, other measurement principles can also be used. Thus, for example, WO 01/48461 describes a test strip with light guides for examining a sample, in particular of a body fluid, in which a reagent system, upon reaction with the sample, leads to a characteristic and optically measurable change in a detection zone. By way of light guides that are let into the test strip, this change can be evaluated by an evaluation device.

The test strips thus form an important element of portable diagnostic systems. Typically, about 5 to 7 such test strips are needed each day by a diabetic. It is essential that the test strips are stored in a clean and dry condition, to ensure that the measurement of the blood glucose concentration is not rendered inaccurate by contamination or by the effect of moisture.

For this purpose, the test strips are usually stored in suitable containers in order then to be removed by the user from the test strip container for a measurement and fitted into a corresponding measuring device. Such measuring devices, for example measuring devices for electrochemical or optical determination of the blood glucose concentration, are known to persons skilled in the art and described, for example, in US 2002/0170823 A1.

For storing and dispensing the test strips, magazine systems are also known. For example, US 2003/0116583 A1, EP 0 640 393 B1 and US 4,911,344 describe suitable storage systems in which several test strips are stored in a magazine. EP 1 488 736 A1 also describes a system which contains, instead of individual test strips, a tape cassette composed of a long individual test strip with a plurality of test fields.

In addition to systems in which the test strip magazine and measuring device are used as separate units, integrated systems also exist which not only comprise several test strips stored in one magazine, but also afford the possibility of evaluation of these test strips. Examples of systems of this kind are to be found in US 5,489,414, US 6,093,156, WO 02/18940 A2, WO 02/055008 or WO 03/083469 A2. Some of these systems, for example the system described in US 6,093,156 or WO 03/083469 A2, already comprise an integrated lancet system too, which makes it possible to perforate the skin to generate a blood droplet and then permits analysis of the blood droplet using one and the same measuring system.

However, in the systems known from the prior art, the problem surrounding the moisture sensitivity of the test strips has as yet been solved only partially. Thus, for example, DE 103 32 488 A1 and US 2005/0033196 A1 each disclose test systems with integrated lancet system and test strips, in which blood droplets are applied directly to test strips. In these cases, however, the test strips are largely unprotected and thus exposed to the air moisture.

Air moisture, especially at elevated temperatures and over long periods of time, can affect the sensitivity of the test strips and thus render the measurement inaccurate. To avoid this, the systems disclosed in WO 03/083469 A2 or WO 02/055008 A2, for example, contain separate, exchangeable, airtight test strip magazines, which are inserted into the actual measuring device. However, this requires a dual packaging of the test strips, which requires considerable assembly space, since the test strips are now surrounded by the actual magazine wall as primary packaging and in addition by the wall of the measuring device. Analogously, WO 2006/047135 A1 also describes a complex test strip dispenser with a test strip "cartridge". Here, a device housing encloses a magazine (cartridge), which for its part has an outer envelope and an inner envelope. The test strips are stored in a moisture-proof manner in the magazine. Since optimization of size is a crucial factor for portable medical measuring devices, the disadvantage of the dual packaging of the systems known from the prior art is in some cases critically important when it comes to the patient's acceptance of the measuring device.

Other systems, for example the system disclosed in US 5,489,414, are based on individually sealed test elements. These test elements can be designed, for example, as multi-use test elements with individually sealed test areas. A disadvantage of these, however, is that the seal of the test elements has to be removed before use, which has to be done by additional mechanical action, for example, or by manual action on the part of the patient. Automatic removal of the seal, for example by perforation of the seal, requires additional mechanical elements and drive elements inside the measuring device, which in turn greatly increase the assembly space and/or the energy requirement of the systems.

These examples show that it has not hitherto been possible to entirely solve the problems of, on the one hand, ensuring that disposable test elements for reloading of the measuring devices can be transported to the measuring device in an airtight package or seal (for example commercially) and, on the other hand, of ensuring that these sealed test elements can then be used in the measuring device itself with

removal of the seal.

Object of the invention

- 5 The object of the present invention is therefore to make available a portable measuring system for analysis of a liquid sample, in particular for use in medicine, which system has a small assembly space and yet permits substantially airtight storage of test elements in the measuring device.

10 Description of the invention

According to a broad aspect of the present invention, there is provided a portable measuring system which is used to analyze a liquid sample for at least one analyte contained therein, comprising: a moisture-proof housing with an internal atmosphere, said moisture-proof
15 housing preventing air moisture and/or water vapor from penetrating into the internal atmosphere of the housing; at least one test element support which can be inserted into the internal atmosphere of the housing, the at least one test element support having at least one retaining structure and a plurality of test elements that supported by the at least one retaining structure and that is used to analyze the liquid sample, the at least one test element
20 support being designed in such a way that, after insertion into the internal atmosphere of the housing, the test elements are exposed to said internal atmosphere; and wherein the liquid sample can be applied to the test elements within the internal atmosphere of the housing, and at least one application opening is provided which has at least one of the following sealing elements: a sealing lip; a sealing ring; a sealing slide; an application flap; a movable
25 sealing element; and a two-component plastic structure with at least one rigid and at least one flexible housing component.

A portable measuring system is proposed which is used to analyze a liquid sample for at least one analyte contained therein. The portable measuring system can, in particular, be a
30 system for glucose measurement, in particular blood glucose measurement, and/or for cholesterol measurement and/or coagulation measurement. Alternatively or in addition, however, other analytes can also be determined, for example for their concentration or presence, or corresponding other analyses can be performed, for example pH measurements or similar chemical analyses. It is also possible, for example, to perform immunology
35 measurements or similar measurements using the test device. The sample will in particular be a liquid sample, for example blood, urine, saliva or stools. However, other kinds of samples are also conceivable, for example gaseous samples.

- 4a -

5 The analysis is based on the use of test elements, for example optical and/or electrochemical test elements, as are known from the prior art. For example, these test elements can be in the form of test strips.

10 The portable measuring system comprises a measuring device that has a moisture-proof housing with an internal atmosphere. The moisture-proof housing prevents air moisture and/or water vapor from penetrating into the internal atmosphere of the housing when the moisture-proof housing is in its closed state. This can be achieved, for example, by suitable sealing elements and/or production methods known from the prior art.

The portable measuring system also has at least one test element support which can be inserted into the internal atmosphere of the housing and which has at least one retaining structure and at least one test element that is supported by the at least one retaining structure and that is used to analyze the liquid sample. The at least one
5 test element support is designed in such a way that, after insertion of the test element support into the internal atmosphere of the housing, the at least one test element is exposed to said internal atmosphere.

To this extent, the proposed system has similarities to the magazine system
10 disclosed in US 6,908,008 B2, for example. In contrast to the system known from US 6,908,008 B2, in which a test strip has to be dispensed from the airtight magazine for application of the liquid sample, an underlying concept of the present invention is that the liquid sample can be applied to a test element to be used within the internal atmosphere of the housing itself.

15 For this purpose, the proposed portable measuring system can preferably have a release mechanism designed to convey at least one test element into an application position within the internal atmosphere of the housing. The liquid sample can be applied to the at least one test element in the application position.

20 The proposed portable measuring system therefore does without an airtight primary packaging around the test elements, which packaging would have to be removed prior to application of the liquid sample, or from which packaging the test elements would have to be withdrawn prior to application of the liquid sample. In
25 this way, the assembly space of the portable measuring system can be considerably reduced.

The at least one test element support can be sold and stored in a removable package, for example in what is called a blister pack. In this package, the test
30 elements are protected against air moisture and other atmospheric influences. To use them, the patient opens the package and inserts the test element support into the internal atmosphere of the housing, for which purpose the moisture-proof housing can be flipped open, pushed open or unscrewed, for example. Only during this brief insertion time are the test elements exposed to the ambient air. Then,
35 after the housing has been closed, the test elements are stored directly in the internal atmosphere of the housing without any additional sealing. The outward seal is now effected by the measuring device itself. For this purpose, all or part of the housing of the measuring device is designed to be moisture-proof, in such a way that the internal atmosphere of the housing is protected.

In addition, a desiccant can be received in the internal atmosphere of the housing. Alternatively or in addition, a desiccant can also be connected to the at least one test element support, such that a new, unused desiccant is inserted into the internal atmosphere of the housing each time a test element support is replaced. The amount of desiccant is preferably to be chosen such that the desiccant is able to bind the moisture that penetrates through the housing walls by diffusion and by passing through microscopic leaks during the desired storage period, and preferably, in addition, the moisture that is introduced when applying the sample into the internal atmosphere of the housing.

10

The possibility of air moisture penetrating into the internal atmosphere of the housing exists only for the brief time in which the liquid sample is being applied to the at least one test element to be used. For application of the liquid sample, the housing has an application opening. This application opening is equipped with at least one sealing element. This at least one sealing element can have a sealing lip, a sealing slide, an application flap, a movable sealing element and/or a two-component plastic structure with at least one rigid and at least one flexible housing component. This application opening and the at least one sealing element connected thereto are in principle required only once per measurement system, such that assembly space can be cut down and no complicated sealing constructions for several openings are needed.

20

The liquid sample can be applied, for example, by a procedure in which a patient, for example using a lancet system, generates a blood droplet on the skin surface, for example of a finger pad, and then opens the application opening by pressing or sliding it with the finger pad or with another finger. In this way, the blood droplet can then be applied to the at least one test element within the internal atmosphere of the housing.

25

After the measurement, the sample on the test element is dried by the dry environment within the internal atmosphere of the housing. For this purpose, it is possible (see above) to provide a suitable excess of desiccant. For example, in order to dry a liquid sample, an amount of approximately 10 mg of a desiccant with a capacity of approximately 10% by weight is usually required for every 1 microliter of sample volume.

35

To improve the sealing function of the at least one sealing element, a pressure-equalizing structure can also be provided in the portable measuring system. This pressure-equalizing structure prevents penetration of water vapor and/or moisture

when a pressure of the internal atmosphere of the housing changes relative to the air pressure outside the internal atmosphere of the housing. Such pressure fluctuations occur, for example, upon cooling or heating of the portable measuring system, which processes are associated with a change in the volume of the air in the internal atmosphere of the housing and thus with a pressure fluctuation. This pressure-equalizing structure can, for example, comprise a flexible volume-modifying element, in particular a pressure-equalizing membrane. Other possibilities are also conceivable.

To monitor the internal atmosphere of the housing, a moisture sensor and/or a temperature sensor can also be provided. The moisture sensor measures the moisture in the internal atmosphere of the housing, and the temperature sensor measures the temperature. In this way, for example, a warning system can emit a warning to a user if the moisture in the internal atmosphere of the housing and/or the temperature of the internal atmosphere of the housing exceeds a predefined threshold value (or in each case one or more threshold values). Other types of measurements are also conceivable, for example monitoring a "total dose" (for example a time integral of the moisture and temperature) to which the test elements have thus far been subjected in the internal atmosphere of the housing such that, for example when they have been subjected to a maximum extent, a warning can be generated to tell the user that new test elements ought to be used. It is thus possible, for example, to monitor a "climate integrator", which represents a time integral over temperature and moisture for example, and accordingly to generate a warning when a threshold value is exceeded.

The at least one retaining structure can be designed in various ways. For example, it can be a drum with peripheral receiving slits for strip-shaped test elements. This drum can be a simple injection-molded part, for example. Test element tapes with a plurality of measurement areas can also be used, in which case, for example, an unwinding mechanism can be provided. Moreover, the at least one retaining structure can have, for example, at least one retaining rotor that is able to rotate in the moisture-proof housing.

The portable measuring system can also have an electronic evaluation device for determining the presence and/or concentration of the at least one analyte. This electronic evaluation device is in this case preferably adapted to the nature and function of the at least one test element. Thus, for example, an evaluation device can be provided for electrochemical measurements by means of electrochemical test elements. Alternatively or in addition, an optical evaluation is also

conceivable.

5 The at least one test element preferably has at least one reagent layer, which is designed to change at least one property, in particular an optical and/or electro-chemical property, upon contact with the at least one analyte to be detected. With the test element support inserted into the internal atmosphere of the housing, the at least one reagent layer of each test element is preferably exposed directly to the internal atmosphere of the housing. "Directly" can also be understood as meaning a connection of the reagent layer to the internal atmosphere of the housing via a
10 capillary. In contrast to the prior art, for example US 5,489,414, a sealing, in particular an individual sealing, of the test elements is not required.

It is also preferable if the portable measuring system as such already has at least one integrated lancet system for perforating an area of skin. This integrated lancet
15 system is also preferably received in the moisture-proof housing. It is thus possible to first carry out a perforation procedure via the application opening and immediately thereafter, i.e. without changing the position of the area of skin to be perforated, to generate a blood droplet, with subsequent direct application of this blood droplet to a test element. This minimizes the number of times the housing is
20 opened and during which air moisture could penetrate into the internal atmosphere of the housing. Moreover, as has been discussed above, only a single application opening is needed in principle. In this way, the assembly space of the proposed portable measuring system can be made very small. Such a construction can be achieved only with difficulty when using the magazine solutions known from the
25 prior art or the systems in which the test elements are sealed individually. The integrated lancet system can have a plurality of disposable lancets for example, such that a fresh, unused lancet can be used for each perforation.

Further details and features of the invention will become clear from the following
30 description of preferred illustrative embodiments in conjunction with the dependent claims. Here, the respective features can be embodied either singly or in several combinations with one another. The invention is not limited to the illustrative embodiments.

35 The illustrative embodiments are shown schematically in the figures. Identical reference numbers in the individual figures designate elements which are identical or whose functions are identical, or which correspond to one another in terms of their function.

In the drawing:

Figure 1 shows a portable measuring system corresponding to the prior art, with dual enclosure of test elements;

5

Figure 2 shows a portable measuring system according to the invention without primary packaging of the test elements;

10

Figure 3 shows a fully integrated portable measuring system according to the invention in a sectional plan view; and

Figure 4 shows the portable measuring system according to the invention from Figure 3 in a sectional side view.

15

Figure 1 is a schematic representation of a portable measuring system 110 corresponding to the prior art 1, for example corresponding to the system disclosed in US 6,908,008. In this case, the portable measuring system 110 is designed as a simple storing and dispensing system (dispenser) for test elements 112 in the form of test strips. An electronic evaluation device is not provided in this example.

20

The portable measuring system 110 in Figure 1 has a housing 114 which, in this example, is not necessarily designed to be moisture-proof. Instead, the test elements 112 are stored in a moisture-proof primary packaging 116. Moreover, a desiccant 118 is also accommodated in this primary packaging 116. Such desiccants are known to persons skilled in the art. For example, these desiccants can be silica gel, a molecular sieve and/or other chemicals that absorb air moisture.

25

To use the portable measuring system according to Figure 1, the primary packaging 116 is inserted into the housing 114. A test element 112 can be dispensed through a dispensing opening 117 of the primary packaging 116 and through an opening 120 of the housing 114 by means of a dispensing mechanism (not shown here). To prevent air moisture from penetrating into the primary packaging 116 during this dispensing procedure, an individual seal (for example a sealing film) of the test element 112 can be punctured during the dispensing procedure. Other configurations are also known, for example closable dispensing slits or the like in the area of the dispensing opening 117.

35

A disadvantage of the known portable measuring system 110 according to Figure 1 is, as has been explained above, the assembly space needed for the dual packaging

of the test elements 112.

In contrast to the device according to Figure 1, a first illustrative embodiment of a portable measuring system 210 according to the invention is shown in Figure 2. In this illustrative embodiment, it is assumed that the portable measuring system 210 is used to determine blood glucose concentrations. As has been explained above, however, other possible uses are also conceivable. For this purpose, the portable measuring system 210 in this example has a moisture-proof housing 212, which encloses an internal atmosphere 214 of the housing.

The “internal atmosphere of the housing” designates the cavity enclosed by the moisture-proof housing 212 and at the same time also the atmosphere, that is to say the properties of the gas (generally air) in the cavity. In the simplified depiction according to Figure 2, the moisture-proof housing 212 has a single cavity, although other configurations are also conceivable. For example, it is not absolutely necessary for the whole of the moisture-proof housing to be moisture-proof as such. All that is required is that the moisture-proof housing 212 encloses in a moisture-proof manner the area in which test elements 112 are received (internal atmosphere 214 of the housing).

“Moisture-proof” is understood here not only as protection against splash water or rain, but also protection against water vapor and air moisture. Complete watertightness can also be provided. It should be noted, however, that one hundred percent protection against air moisture is in most cases not technically feasible, with the result that “moisture-proof” is also to be understood as meaning that penetration of air moisture is merely delayed. The moisture penetrating through the walls of the housing 114 as a result of diffusion is bound by the desiccant 118. For example, with penetration of 1 mg of air moisture per day, a supply of desiccant 118 of 1 g with 10% by weight binding capacity ensures a storage period of about 100 days.

The portable measuring system according to the illustrative embodiment in Figure 1 is based on measurement by means of test elements 112, which can be designed according to the prior art. For example, these can be electrochemical test strips, for example capillary-gap test elements and/or optical test strips.

The test elements 112 are held on a test element support 216 which can be inserted into the internal atmosphere 214 of the housing and which in turn has a retaining structure 218. This retaining structure 218 can, as in Figure 2, be designed in the

- 11 -

form of a drum, for example, on which the test elements 112 are received peripherally in radial longitudinal slits. In contrast to Figure 1, a primary packaging 116 is not used, which means that the test elements 112 are exposed directly to the internal atmosphere 214 of the housing. The moisture-proof housing 212 thus replaces the primary packaging 116 and so takes over the functions of the elements 114 and 116 according to Figure 1.

The test element support 216 can be removed from the moisture-proof housing 212 via an insertion opening 220, closable in a moisture-proof manner (for example a lockable flap sealed off by an O-ring), and can be replaced by a test element support 216 which is equipped with unused test elements 112 and which, for this purpose, is taken from a blister pack, for example. When inserted, the test element support 216 engages in a receiving seat 222, in which it is mounted so as to rotate by means of a drive 224.

A desiccant 118 is also received in the internal atmosphere of the housing. Alternatively or in addition, a desiccant 118 can be received on and/or in the test element support 216, such that this desiccant 118 is also renewed each time a test element support 216 is replaced.

In this example, the drive 224 acts as a release mechanism 228. By means of this release mechanism 228, a test element 112 to be used is conveyed into an application position 230. In this application position 230, a liquid sample can be applied to the test element 112 in the moisture-proof housing 212 via an application opening 232. For this purpose, the application opening 232 has a sealing element 234. In this illustrative embodiment, this sealing element 234 according to Figure 2 is designed as a sealing slide which can be pushed aside, for example by a patient's finger, such that the application opening 232 is freed. A blood droplet present on the finger can then be applied to the test element 112 to be used in the application position 230. For this purpose, the test element 112 to be used can also be pushed by a mechanism (not shown here) nearer to the application opening 232.

In the illustrative embodiment according to Figure 2, it is assumed hereinbelow that the test elements 112 are electrochemical test elements, for example test elements in the form of capillary gap test elements. Accordingly, an electronic evaluation device 226 is provided which electrically contacts the test element 112 located in the application position 230 and generates a corresponding measured value. For this purpose, the electronic evaluation device 226 can comprise, for

example, a microcomputer, evaluation electronics, operating elements (e.g. pushbuttons, switches, keys, etc.), acoustic and/or optical output elements (e.g. one or more displays), data memories and other elements. Electronic evaluation devices 226 of this kind are known from the prior art. The electronic evaluation
5 device 226 can, for example, also control the release mechanism 228.

Moreover, in the illustrative embodiment according to Figure 2, a moisture sensor 236 (it can alternatively or additionally be a temperature sensor) and a warning system 238 are provided in the internal atmosphere 214 of the housing. For
10 example, the warning system 238 can be a component part of the electronic evaluation device 226. The warning system can be designed, for example, in such a way that it emits an acoustic and/or optical warning to a user as soon as the air moisture in the internal atmosphere 214 of the housing exceeds a predetermined threshold value. As has been described above, another mode of operation is also
15 conceivable, for example an integration of the air moisture over time. This can also be done taking into account a measured temperature in the internal atmosphere 214 of the housing.

The moisture-proof housing 214 is designed, for example, as a one-part or multi-
20 part injection molded component. Methods for making injection-molded housings of this kind moisture-proof are known to persons skilled in the art. For this purpose, suitable plastics with low permeability for air moisture and oxygen and/or suitable sealing devices (e.g. sealing rings) can be used, for example. Accordingly, the sealing element 234 can also be configured in various ways. As has been
25 described above, one or more sealing lips can be used as an alternative to or in addition to the spring-mounted sealing slide shown in Figure 2. Such sealing elements can be produced, for example, by means of multi-component injection molding and/or by encapsulation of suitable sealing elements (for example rubber lips) in a suitable injection molding tool. The sealing element or sealing elements
30 can be opened (alternatively or cumulatively) either by the patient (e.g. via manual slides, etc.) or automatically by a dedicated drive mechanism.

Moreover, the moisture-proof housing 212 in the illustrative embodiment according to Figure 2 has a pressure-equalizing structure 240. In this illustrative
35 embodiment, this pressure-equalizing structure 240 is designed as a pressure-equalizing membrane 242 which is integrated into the moisture-proof housing 212 (again by encapsulation, for example). This pressure-equalizing membrane 242 prevents penetration of air moisture into the internal atmosphere 214 of the housing and permits pressure equalization between the internal atmosphere 214 of

the housing and the external atmosphere 244. This prevents "breathing" of the portable measuring system 210 during which, for example as a result of temperature fluctuations, air exchange could take place through the application opening 232.

5

The moisture-proof housing 212 as a whole can be designed in such a way that air moisture is kept away from the internal atmosphere 214 of the housing. The moisture-proof housing 212 can also provide protection against entry of splash water or even ensure that the whole portable measuring system 210 is waterproof.

10

This also allows the portable measuring system 210 to be cleaned with aggressive cleaning agents. The moisture introduced into the internal atmosphere 214 of the housing by application of the liquid sample via the application opening 232 can generally be absorbed without any problem by the desiccant 118.

15

Instead of the test element support 216 with the drum-shaped retaining structure 218 shown by way of example in Figure 2, other structures can also be easily used, for example arrangements in the form of stacks, disks, rows and or zigzags. Figures 2 and 3 show a further example in which the test element support 216 is designed with a circular disk shape in the form of a test strip wheel.

20

The portable measuring system 210 according to the illustrative embodiment in Figures 2 and 3 also contains an integrated lancet system 310 in the form of a multi-tipped lancet wheel mounted so as to be rotated by a drive 312.

25

During operation, a lancet 314 to be used is first rotated to a kinking station 316. In this kinking station 316, the lancet 314 to be used is kinked upward by 90° (in Figure 3) by means of a spring mechanism 318. Thereafter, the lancet wheel is rotated through 180° by means of the drive 312, until the upwardly kinked lancet is below the application opening 232 in the housing 212. In this illustrative

30

embodiment, the application opening 232 is designed as a cone and is again closed by a sealing element 234. The sealing element 234 can be pushed aside by the finger 320 of the patient, thus exposing the application opening 232. At the same time, the finger 320 closes this application opening 232. By pressing the finger 320 onto the application opening 232, the skin of the finger 320 in the area of the application opening 232 forms a bulge curving into the interior of the housing 212.

35

When the portable measuring system 210 is triggered, a lancet spring mechanism 322 ensures that the lancet 314, which is located below the application opening 232 and is bent upward, is accelerated and perforates the skin of the finger 320 within the application opening 232. A blood droplet 324 is thus formed.

The test element support 216 designed in this illustrative embodiment according to Figures 3 and 4 as a circular disk is divided into circular disk sectors 326. Each of these circular disk sectors 326 forms a test element 112. Each of these test elements 112 has a reagent layer 328 which, as has been described above, reacts to the presence and/or concentration of the analyte in the liquid sample (blood droplet 324). In this illustrative embodiment according to Figures 3 and 4, this reagent layer 328 is, for example, a reagent layer 328 for a color reaction in the presence of glucose, i.e. a reagent layer 328 which, by reaction with glucose, changes its color and/or its fluorescence properties.

After the skin in the area of the application opening 232 has been perforated, a test element spring mechanism 330 briefly bends the test element support 216 upward in the area of the application position below the application opening 232, even as far as the application opening 232. In this way, the blood droplet 324 is applied to the reagent layer 328 of the test element 112 located in the application position 230, and the described reaction can take place.

The release mechanism 228 then turns the test element support 216 through 180° such that the test element 112 on which the blood droplet 324 has been applied is placed above or below an optical reader 332. This optical reader 332 carries out a simple optical measurement, for example, or a measurement of fluorescence excitation. The optical reader 332 is connected to the electronic evaluation device 226, which can be designed analogously to Figure 2 and can, for example, comprise a microprocessor, operating elements, displays, data memories or the like.

The fully integrated portable measuring system 210 according to the illustrative embodiment in Figures 3 and 4 shows particularly clearly the advantages of the solution according to the invention. According to the invention, the reagent layer 328 is exposed directly to the internal atmosphere 214 of the housing. A separate sealing of the individual test elements 112 is neither necessary nor desirable. If a seal first had to be removed from the individual reagent layers 328, this would require additional mechanical outlay, which in turn would be disadvantageous in terms of the energy requirement and the assembly space, since further mechanical devices and actuating elements would be needed. Once again, for example, a desiccant 118 (not shown in Figure 3 or Figure 4) can be integrated in the test element support 216 designed here in the form of a circular disk.

List of reference numbers

110	portable measuring system (prior art)
112	test element
114	housing
116	primary packaging
117	dispensing opening
118	desiccant
120	opening
210	portable measuring system
212	moisture-proof housing
214	internal atmosphere of housing
216	test element support
218	retaining structure
220	insertion opening
222	receiving seat
224	drive
226	electronic evaluation device
228	release mechanism
230	application position
232	application opening
234	sealing element
236	moisture sensor
238	warning system
240	pressure-equalizing structure
242	pressure-equalizing membrane
244	external atmosphere
310	integrated lancet system
312	drive
314	lancet
316	kinking station
318	spring mechanism
320	finger
322	spring mechanism for lancets
324	blood droplet
326	sectors of circular disk
328	reagent layer
330	spring mechanism for test element
332	optical reader

CLAIMS:

1. A portable measuring system which is used to analyze a liquid sample for at least one analyte contained therein, comprising:
a moisture-proof housing with an internal atmosphere, said moisture-proof housing preventing air moisture and/or water vapor from penetrating into the internal atmosphere of the housing;
at least one test element support which can be inserted into the internal atmosphere of the housing, the at least one test element support having at least one retaining structure and a plurality of test elements that supported by the at least one retaining structure and that is used to analyze the liquid sample, the at least one test element support being designed in such a way that, after insertion into the internal atmosphere of the housing, the test elements are exposed to said internal atmosphere; and
wherein the liquid sample can be applied to the test elements within the internal atmosphere of the housing, and at least one application opening is provided which has at least one of the following sealing elements: a sealing lip; a sealing ring; a sealing slide; an application flap; a movable sealing element; and a two-component plastic structure with at least one rigid and at least one flexible housing component.
2. The portable measuring system as claimed in claim 1, further comprising a release mechanism, said release mechanism being designed to convey the test elements into an application position within the internal atmosphere of the housing, the liquid sample being able to be applied to the test elements in the application position.
3. The portable measuring system as claimed in claim 1 or 2, wherein a desiccant is received in the internal atmosphere of the housing.
4. The portable measuring system as claimed in any one of claims 1 to 3, further comprising a pressure-equalizing structure for preventing penetration of water vapor and/or moisture when a pressure of the internal atmosphere of the housing changes relative to the air pressure outside the internal atmosphere of the housing.

5. The portable measuring system as claimed in claim 4, further comprising a flexible volume-modifying element.
6. The portable measuring system as claimed in claim 5, wherein the flexible volume-modifying element is a pressure-equalizing membrane.
7. The portable measuring system as claimed in any one of claims 1 to 6, further comprising a moisture sensor and/or a temperature sensor for measuring the moisture and/or temperature of the internal atmosphere of the housing.
8. The portable measuring system as claimed in claim 7, further comprising a warning system for emitting a warning to a user if at least one of the following values exceeds one or more predefined threshold values: the moisture of the internal atmosphere of the housing; the temperature of the internal atmosphere of the housing; and a climate integrator that takes account of time, moisture and temperature.
9. The portable measuring system as claimed in any one of claims 1 to 8, wherein the at least one retaining structure has at least one retaining rotor and/or drum that is able to rotate in the moisture-proof housing.
10. The portable measuring system as claimed in any one of claims 1 to 9, further comprising a desiccant connected to the test element support.
11. The portable measuring system as claimed in any one of claims 1 to 10, further comprising an electronic evaluation device for determining the presence and/or the concentration of the at least one analyte.
12. The portable measuring system as claimed in any one of claims 1 to 11, further comprising at least one integrated lancet system for perforating an area of skin.
13. The portable measuring system as claimed in claim 12, wherein the at least one integrated lancet system is received in the moisture-proof housing.
14. The portable measuring system as claimed in claim 12 or 13, wherein the at least one integrated lancet system has a plurality of lancets designed as

disposable lancets.

15. The portable measuring system as claimed in any one of claims 1 to 14, wherein the test elements have at least one reagent layer, said at least one reagent layer being designed to change at least one property upon contact with the at least one analyte to be detected, and, with the test element support inserted into the internal atmosphere of the housing, the at least one reagent layer of each test element is exposed to the internal atmosphere of the housing.
16. The portable measuring system as claimed in claim 15, wherein said at least one reagent layer is designed to change an optical and/or electro-chemical property upon contact with the at least one analyte to be detected.

1 / 2

Fig. 1

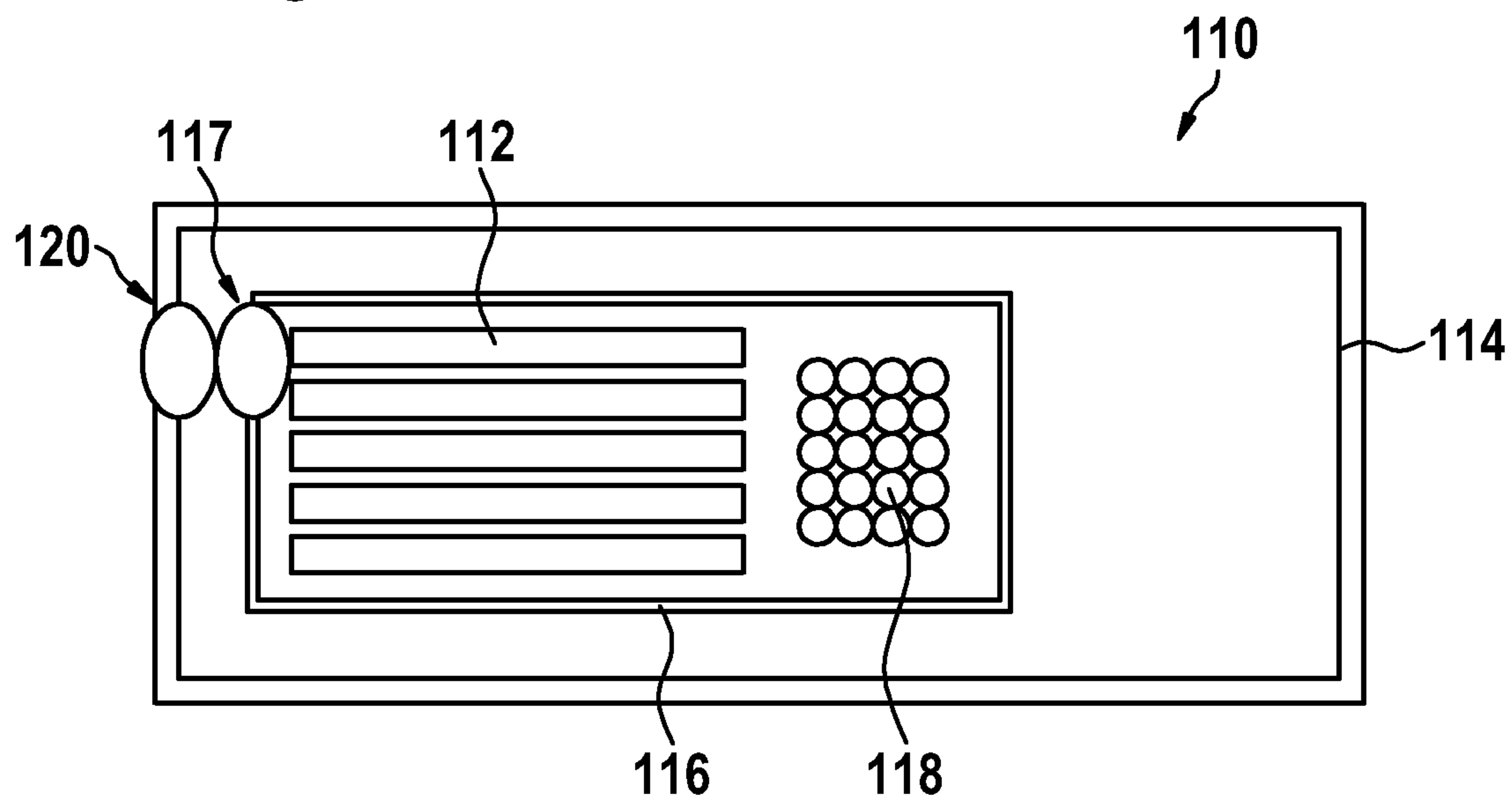
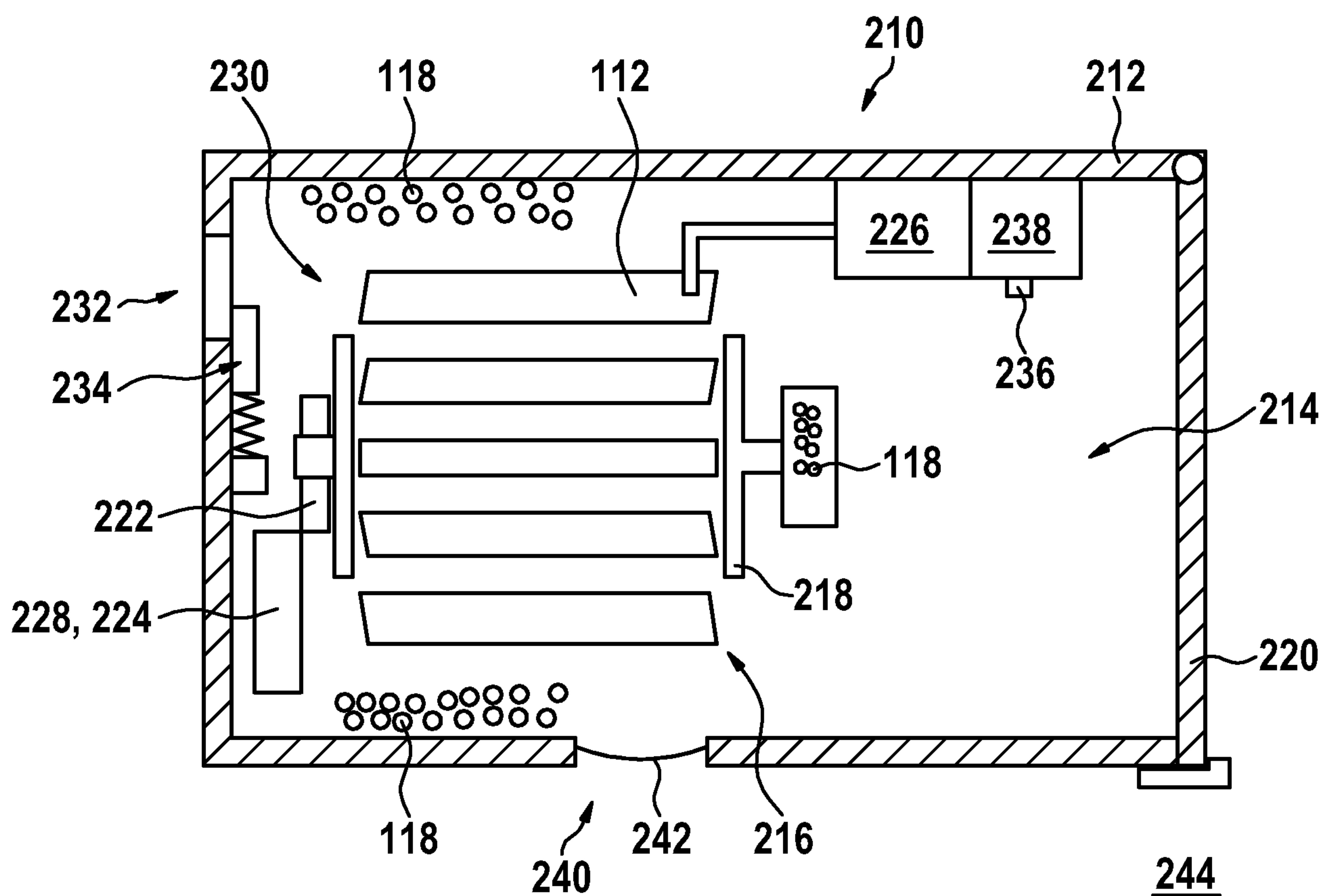


Fig. 2



2 / 2

Fig. 3

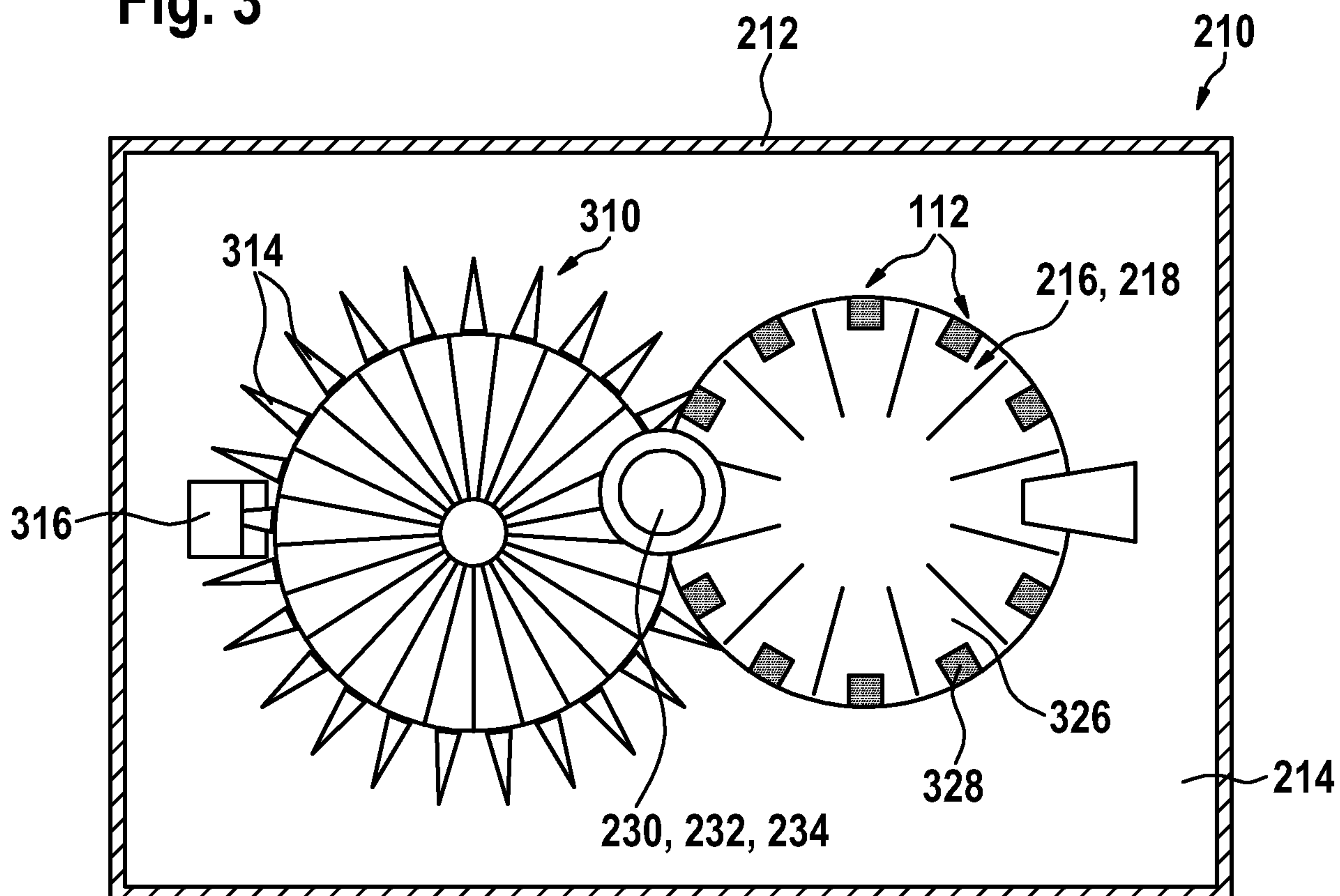


Fig. 4

