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(71) Applicant (for DE only): **ROCHE DIAGNOSTICS GMBH** [DE/DE]; Sandhofer Strasse 116, 68305 Mannheim (DE).

(71) Applicant (for all designated States except DE, US): **F.HOFFMANN LA ROCHE AG** [CH/CH]; Grenzacher Strasse 124, 4070 Basel (CH).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **LIST, Hans** [DE/DE]; Siegfriedstrasse 27, 64754 Hesseneck-Kailbach (DE). **HAAR, Hans-Peter** [DE/DE]; Waldstrasse 2, 69168 Wiesloch (DE). **MEACHAM, George Bevan Kirby** [US/US]; 18560 Parkland Drive, Shaker Heights, Ohio 44122 (US).

(74) Agent: **DICK, Alexander**; Isenbruck, Bösl, Hörschler, Wichmann, Huhn, Patentanwälte, Theodor-Heuss-Anlage 12, 68165 Mannheim (DE).

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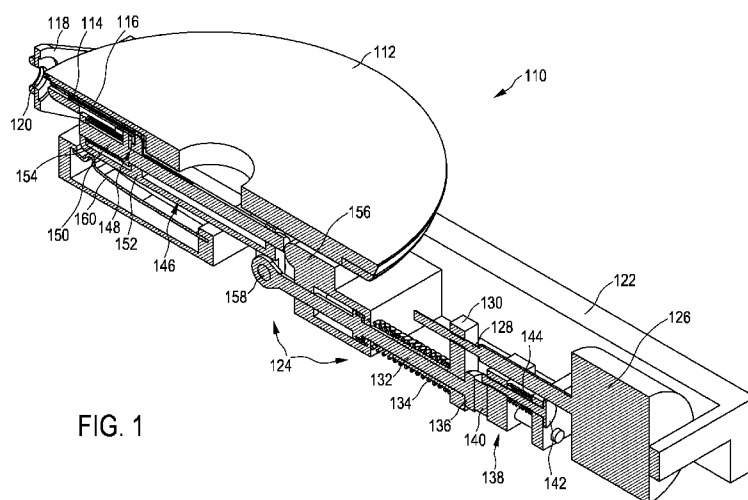


FIG. 1

(57) Abstract: An actuator for driving a test element is proposed. The test element comprises a lancet for perforating a skin portion of a living organism. The actuator comprises an engaging part for engaging and driving the test element to perform a lancing motion. The actuator further comprises a lancing actuator and a lancing spring, wherein the lancing actuator is adapted for biasing the lancing spring by executing a forward movement and thereby exerting a biasing force on the engaging part. The actuator further comprises a latch element, wherein the latch element is a force-sensitive latch element, wherein the latch element is adapted for exerting a retention force holding back the engaging part. The retention force counteracts the biasing force. The latch element is adapted for releasing the engaging part when the biasing force exerted by the lancing actuator exceeds the retention force exerted by the latch element, thereby allowing for the test element to perform the lancing motion.



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Test system for measuring the concentration of an analyte in a body fluid

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Technical field of the invention

The invention discloses an actuator for driving a test element, wherein the test element
10 comprises a lancet for perforating a skin portion of a living organism. In a further aspect,
the invention relates to a test system for measuring the concentration of one or more
constituents in a body fluid of a living organism. In a further aspect, the invention discloses
an opening mechanism for use in a test system for measuring the concentration of one or
more constituents in a body fluid of a living organism. Such actuators, test systems and
15 opening systems may be used to determine the concentration of an analyte in a body fluid
of a patient, such as for determining the blood glucose level and/or the level of other
analytes, such as cholesterol, lactose, hormones, or other constituents or metabolites
comprised in a body fluid.

20 Background of the invention and prior art

Monitoring of the concentration of certain analytes in body fluids, such as blood glucose or
cholesterol, forms an essential part of the daily routine for many patients suffering from
certain diseases, such as diabetes. Thus, in the latter case, the blood glucose level has to be
25 determined several times per day in a fast and reliable way, in order to be able to take
appropriate medical measures.

In order to minimize the interruptions of the daily routine of the patient, in many cases, the
patient uses mobile analytic systems that are easy to transport and to handle. Thus, e.g., the
30 measurement of the blood glucose level may be performed by the patient without leaving
his workplace or during his leisure activities.

Many mobile systems are known to a person skilled in the art and are commercially
available. These systems may function according to several distinct principles of
35 measurement. Therein, e.g., optical and/or electrochemical measurement processes may be
used, in order to determine the concentration of the constituent (i.e. the analyte) of the

body fluid. Thus, e.g., test elements, such as test strips, may be used, which are capable of receiving a sample (e.g. a droplet) of the body fluid to be analyzed. An example of test strips (in this case electrochemical test strips) is given in US 5,286,362. An example of measurement systems using optical analytical methods is given in WO 01/48461. The principles of measurement disclosed in these documents, as well as the chemical substances used therein, may be applied to the invention disclosed below. Nevertheless, other principles and/or substances may be used.

In most cases, the test elements, which are generally designed to be disposable test elements, form an essential part of the test systems described above, especially of portable or mobile test systems. Thus, typically, a diabetic uses five to seven test elements per day. Therein, in most cases, it is essential to keep the test elements clean and stored under dry conditions, in order not to have the measurement affected by ingressing humidity and/or other contaminations. This holds true for test elements such as the test strips mentioned above, as well as for other disposable test elements, such as test elements comprising a lancing system for perforating a skin portion of a living organism, such as of a human patient. For this purpose, WO 03/08834 A1 discloses a device for use with a penetrating member driver to penetrate tissue. The device includes a single disk-shaped cartridge coupled to a plurality of penetrating members and operatively couplable to a penetrating member driver. The penetrating members are movable to extend radially outward from the cartridge to penetrate tissue.

Besides test systems using separate test elements for lancing and for analysis, test systems are known with combined test elements, which are suited for the lancing or sampling action as well as for analysis of the body fluid sample generated by the lancing/sampling action. These test systems, which are commonly known as "get and measure systems" ("GAM-systems"), may be designed as described in WO 2005/084546 A2. Therein, a body fluid sampling device is disclosed, comprising a skin-piercing element having a collection zone for receiving body fluid, wherein the device further comprises a fluid receiving means remote spaced apart from said collection zone, so that body fluid in said collection zone will not contact the fluid receiving means initially. Said collection zone takes up a very small volume of body fluid of about 10 to 500 nanoliters in a very short time period. Said fluid receiving means may have a test zone for performing an analytical reaction. Fluid sample from said collection zone is automatically or manually transported to said fluid receiving means to contact said fluid with said test zone.

For sampling the body fluid in GAM-systems, a controlled movement of the skin-piercing or lancing element has proven to be of importance. Thus, EP 1 709 906 A1 describes a method and a system for sampling of body fluid, wherein a piercing element perforates the skin of a body part in forward movement and collects body fluid using a capillary structure inside the piercing element. The sampling of the body fluid may be optimized by detecting the presence of the body fluid and controlling the penetration depth.

Similarly, WO 2007/045412 A1 describes a test element for use as a disposable article for examining a body fluid, comprising a piercing element for piercing a body part, a collection zone configured thereon for body fluid obtained through the puncture and at least one optical waveguide for carrying out an optical measurement in the collection zone. The collection zone is configured by a collecting aperture of the piercing element, which aperture is elongate in the direction of piercing, and in that the optical waveguide is integrated into the piercing element so as not to be displaced and is arranged with its distal end in a proximal measuring zone of the collecting aperture.

Still, despite of the enormous progress that has been made during the recent years with respect to GAM-systems for piercing a skin portion of a patient and for sampling a body fluid, the precise control of the penetration of the piercing or lancing system remains a major challenge. Thus, a very precise control of the lancing action has to be guaranteed, such as a precise control of the penetration depth, the penetration force and the duration of the lancing movement.

Further, as indicated above, a major challenge resides in the fact that the “get and measure systems” as described above are rather sensitive to environmental conditions and, therefore, in many cases have to be stored in sealed compartments, such as in the system described by WO 03/088834 A1. Before initiating the lancing motion, these compartment seal barriers have to be opened by some mechanism to avoid contact between the lancing system and the compartment seal barriers. This is necessary since the lancing systems for use in GAM-systems in many cases make use of hydrophilic surfaces in order to collect body fluid. These hydrophilic surfaces, however, may deteriorate and lose part of their hydrophilic properties if they come into contact with the seal barriers. Thus, in many cases, a very complicated actuating mechanism will have to be used, which, on the one hand, allows for opening of the compartments of the test element to be used, and which, on the other hand, allows for a simple initiation of the lancing motion.

WO 2006/013045 A1 discloses a blood collection system for collecting blood for diagnostic purposes. Said system comprises an electric motor, which provides energy for propelling a lancet. The blood collection system also comprises a mechanical energy accumulator, in which the electric energy that is converted by the motor is stored in the form of mechanical energy. WO 2006/013045 A1 further discloses the use of a motor for biasing a spring element. The motor current is monitored in order to monitor the compression status of the spring element, and as soon as the compression of the spring element reaches a defined state, the motor is stopped, and the spring element may be released by a separate action, in order to release the mechanical energy and in order to start the lancing motion.

WO 2007/006399 A1 discloses a lancet device by means of which a lancet can be displaced along a puncturing path in order to create a puncture wound on a skin surface, especially to obtain body fluid for diagnostic purposes. Said lancet device comprises a lancet drive with a driving means generating a driving force for a puncturing movement of the lancet along the puncturing path in the direction of the skin surface. The lancet drive is provided with a magnet, with the aid of which a magnetic retaining force can be generated that acts counter to the driving force, as well as triggering means which allow the retaining force to be reduced such that the lancet is accelerated in the direction of the skin surface under the effect of the driving force generated by the driving means.

The systems disclosed by WO 2006/013045 A1 and by WO 2007/006399 A1 provide a significant improvement with regard to the control of the lancing motion. Nevertheless, both in the system disclosed by WO 2006/013045 A1 and in the system disclosed in WO 2007/006399 A1, an active triggering mechanism for triggering the lancing motion is required, which in some cases might increase the complexity of the system. Further, a precise control of the penetration depth of the lancing motion remains a challenge.

Summary of the invention

The present invention therefore provides an actuator for driving a test element, a test system and an opening mechanism which provide solutions for at least some of the drawbacks or challenges of the prior art systems discussed above. Specifically, the actuator allows for a very precise control of the lancing motion and for a precise control of the sampling of body fluid.

In a first aspect of the invention, an actuator is provided for driving a test element, wherein the test element comprises a lancet for perforating a skin portion of a living organism. The lancet may comprise a simple lancing needle or any other means for perforating a skin portion of a human or animal patient, such as a sharp edge etc.

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As described above, the test element may comprise a simple lancet for solely perforating the skin portion, without any further sampling and/or testing means, such as a simple lancing needle without any analytical test portion. Alternatively, the test element may comprise a testing means for detecting a constituent in a fluid sample, without
10 incorporating a lancet. Nevertheless, the test element may preferably be designed to act as a get and measure test element (such as the test elements disclosed in WO 2005/084546 A2 or WO 2007/045412 A1) and, thus, may comprise sampling and/or testing means for sampling a body fluid and for measuring the concentration of one or more constituents (in the following also called “analytes”) in the body fluid, as will be described in further detail
15 below. The sampling means may comprise a capillary structure within a lancing needle. The testing means may comprise a test strip comprising one or more chemical substances for detecting the constituent. The testing means may be physically attached to the needle or may be positioned within the system, separated from the needle. An optical waveguide system may be used for optical detection of the constituent, as will be discussed in more
20 detail below. Further, the test strip may function as sampling means, which may be connected to the needle or which may be arranged separately. Other embodiments of the test element than the embodiments described are possible, as will be obvious to the person skilled in the art.

25 The actuator further comprises an engaging part for engaging and driving the test element to perform a lancing motion. Thus, a plunger may be provided, which is capable of performing a linear motion and which is capable of transferring momentum to the test element, in order to cause the test element to perform the lancing motion. The expression “lancing motion” may comprise a simple perforation (i.e. a unidirectional linear motion of
30 a skin-piercing element), or may comprise further types of motion, such as a cutting motion performed by a sharp edge (e.g. a part of an edge of a knife) or a motion comprising other directional components, such as a rotational motion of a blade or a two-dimensional motion.

35 Instead of a plunger, many other means of engaging the test element and transferring momentum to the test element may be used. Further, the engaging part may comprise, as outlined above, a special connection for engaging an adapted portion of the test element, in

order to optimize the transfer of momentum, such as grippers, hooks, lugs, or similar means. Further, the engaging part may comprise an appropriate contact or port to the test element, in order to allow for a direct measurement of the analyte within the body fluid, as soon as a sample of the body fluid has been taken. Further examples of this engaging part
5 will be described in more detail below.

Further, the actuator comprises a lancing actuator and a lancing spring, wherein the lancing actuator is adapted for biasing the lancing spring, e.g. during a biasing phase, by executing a forward movement and thereby exerting a biasing force on the engaging part. Thus, the
10 lancing actuator may comprise a motor, such as a servo motor and/or a stepper motor. Nevertheless, other types of lancing actuators may be used.

The expression “spring” as used hereinafter (such as in “lancing spring”, “coupling spring”, “latch bias spring” or “lift spring”) basically may comprise any means for storing
15 mechanical energy. Thus, the lancing spring may comprise a coil spring or any other type of spring capable of exerting a lancing force on the engaging part when compressed, such as a plate spring or a leaf spring or an elastic element, such as a rubber band or any other type of elastomeric material, or even a hydraulic or pneumatic energy storage. Combinations of various kinds of springs are possible. Similarly, the other kinds of springs
20 mentioned hereinafter may comprise one or more of a number of various means for storing mechanical energy.

As outlined above, the expression “linear” actuator may include other types of actuation than simple unidirectional actuations, such as two- or even three-dimensional actuations or
25 rotational movements.

Further, the actuator comprises a latch element, which is a force-sensitive latch element and which is adapted for exerting a retention force holding back the engaging part, e.g. during the biasing phase. Thus, the holding force at least partly is counteracting the biasing
30 force. The latch element further is adapted for releasing the engaging part, e.g. during a lancing phase, when the biasing force exerted by the lancing actuator exceeds the retention force exerted by the latch element, thereby allowing for the test element to perform the lancing motion. In other words, the latch is adapted for triggering the lancing motion of the test element. Thus, the linear actuator may be adapted for biasing the lancing spring during
35 a biasing phase by executing a forward movement and thereby exerting a relatively low force on the engaging means, wherein the force-sensitive latch element holds back the engaging means during the relatively low force biasing phase, and then may release the

engaging means when a higher force is generated, e.g. by direct contact between the linear actuator and the engaging means, such that the lancing spring may accelerate the engaging means in a forward direction during a lancing phase and thereby may allow the test element to perform the lancing motion.

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Thus, the latch element according to the present invention may allow for an automatic or “passive” triggering of the lancing motion without any further triggering control or triggering action, such as an electronic or manual triggering. The triggering may simply occur as soon as the biasing force exceeds the retention force, which allows for a rather simple and cost-effective construction of the actuator. The biasing of the lancing spring and the triggering of the lancing motion may be part of one and the same motion of the lancing actuator, without any stopping of the lancing actuator, or without the need of switching the lancing actuator from a “biasing state” into a “triggering state”. Thus, as compared to e.g. WO 2006/013045 A1, the control of the actuator may be simplified significantly, allowing for a more simple design.

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The latch element may comprise a switchable magnet, such as an electromagnetic element capable of being switched on and off by appropriate electric signals (e.g. an electromagnet), or, alternatively or additionally, may comprise a permanent magnetic element, such as one or more permanent magnets. In the latter case, the holding force of the permanent magnetic element may be counteracted by a second force, and the triggering of the lancing motion may be initiated by causing the second force to exceed the magnetic holding force. Further examples of possible embodiments of the magnetic switch element will be given below. More generally, the latch element may be any of a number of mechanisms, (e.g. a mechanical detent) that restrains the test element below a set holding force and releases the test element when this set holding force is exceeded. Additionally, the latch element may be any of a number of mechanisms, (e.g. a solenoid-actuated mechanical latch) that restrains the test element until a release signal is received from a control device.

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In one embodiment of the present invention, the engaging part may comprise a fast shuttle element and a slow shuttle element, wherein the fast shuttle element may be adapted for engaging the test element, wherein the lancing actuator may engage the slow shuttle element, and wherein the lancing spring may extend between the fast shuttle element and the slow shuttle element. The magnetic switch is adapted for holding back the fast shuttle element. Thus, in this embodiment, the biasing force is transferred from the lancing actuator onto the lancing spring indirectly, via the slow shuttle element. The magnetic

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switch element on the other hand directly controls the fast shuttle element, thereby allowing for a precise control of the triggering of the lancing motion.

5 In another embodiment, the magnetic switch element comprises a magnetic element exerting an attractive magnetic force on the engaging part, wherein the release of the engaging part is initiated as soon as the lancing force exceeds the attractive magnetic force. In this embodiment, which is technically simple to realize, the magnetic switch element is a “passive” magnetic switch element, and the triggering of the lancing motion may simply be performed by adjusting the relative position of the magnetic element and the lancing
10 actuator.

In a further embodiment of the invention, the position of the magnetic switch element in the direction of the lancing force is adjustable, allowing for a penetration depth of the lancing motion of the test element to be adjusted. Thus, in a preferred embodiment, a
15 stroke adjustment screw may be provided, in order to allow for adjustment of the position of the magnetic switch element.

In a further embodiment of the invention, the engaging part comprises a gripper for gripping a portion of the test element. The actuator may be adapted for at least partly
20 transforming a linear motion of the lancing actuator into a gripping motion of the gripper. Thus, in a preferred embodiment, the gripper comprises a first gripper element and a second gripper element, wherein the first and second gripper elements are biased by a coupling spring to exert a clamping force onto the portion of the test element. The actuator may further comprise an abutment portion, wherein the actuator is adapted to dislocate the
25 first and second gripper elements by retracting the gripper and pressing one of the grippers against the abutment portion, thereby compressing the coupling spring and opening the gripper. Nevertheless, other mechanisms for opening and/or closing a gripper for engaging the portion of the test element may be provided. The actuator may be adapted to close the gripper by a forward movement of the lancing actuator.

30 In a further embodiment of the invention, the engaging part comprises a pivotable portion, wherein the pivotable portion comprises the gripper and wherein the actuator is adapted to pivot the gripper into engagement with the test element by a forward movement of the lancing actuator and to pivot the gripper out of engagement with a test element by a
35 rearward movement of the lancing actuator. Therein, in a preferred embodiment, the pivotable portion is biased into engagement with the test element by a lift spring.

Generally, in a preferred embodiment, the actuator may be adapted for at least partly transforming a first linear motion of the lancing actuator into a second linear motion of the gripper, wherein the second linear motion of the gripper at least contains a directional component perpendicular to the first linear motion.

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In a further embodiment of the invention, the engaging part comprises an optical fiber connection for optically contacting the test element. Thus, in a preferred embodiment, the optical fiber connection comprises an optical fiber for providing an optical excitation signal to the test element and an optical fiber for reading out an optical signal from the test
10 element. Thus, the test element may comprise one or more substances capable of changing optical properties when in contact with a body fluid comprising the analyte. Other embodiments may be used, such as an embodiment using one or more read-out fibers but not additional excitation fibers. The expression “fiber” may comprise any element capable of guiding electromagnetic radiation, such as visible light and/or ultraviolet light and/or
15 infrared light, from one place to another place. Thus, flexible glass fibers, flexible plastic fibers, rigid plastic or glass waveguides or any other wave guide element or combination of wave guides may be used. Further details and possible embodiments of the engaging part will be described below.

20 Additionally or alternatively, in a further embodiment of the invention, the engaging part comprises an electrical connection for electrically contacting the test element. These may comprise electrical elements, such as electrical ports (e.g. electrical clamps, pin-connectors, contact pads or any other contacting means) and/or electrical connectors, such as cables, wires, or other connecting means or combinations thereof may be comprised.
25 Thus, the test element may be adapted for performing electrochemical analysis of the body fluid sample, which will be described in further detail below.

In a further embodiment of the invention, the actuator is adapted to perform a retraction movement of the engaging part, thereby causing the test element to retract from a
30 perforated skin portion. Thus, in this embodiment, the lancing motion described above may be supplemented and/or followed by the retraction movement. A sequence of lancing/retraction movements may be used. In a preferred embodiment, during the retraction movement, the test element may sample body fluid from the living organism, e.g. by capillary forces. Additionally or alternatively, other types of sampling may be used,
35 such as passive or active pump- or suction actions for sampling a body fluid, such as blood.

In a further embodiment, the actuator may be adapted for detecting if a first lancing motion resulted in a successful acquisition of a body fluid sample from the living organism. Additionally, the actuator may be adapted for re-iterating the lancing motion with an increased penetration depth if no or insufficient body fluid is acquired. This embodiment of the invention may preferably be combined with the sampling of body fluid during the retraction movement by capillary forces, as outlined above.

In a further aspect of the present invention, a test system for measuring the concentration of one or more constituents (analytes) in a body fluid of a living organism is provided. Therein, the test system, which may be designed as an integrated test system for sampling and analyzing, the test system may comprise an actuator according to one of the embodiments described above and at least one test element according to one of the embodiments described above. The test element comprises a lancet for perforating a skin portion of a living organism. The definitions and potential embodiments described above may be applied.

In a further embodiment of the invention, the test element further comprises a capillary transport system for acquiring a body fluid sample from the living organism. This capillary transport system may comprise one or more bores, or, alternatively or additionally, the capillary transport system may comprise one or more grooves being capable of exerting a capillary force onto the body fluid sample and thereby extracting the body fluid sample from the living organism. Alternatively or additionally, instead of using "passive" capillary forces, the capillary transport system may comprise active extraction means, such as a pump, in order to actively draw the body fluid sample from the living organism and to support the capillary forces.

In a further embodiment of the present invention, the test element further comprises a substance that changes at least one chemical or physical property as a function of a concentration of a constituent of a body fluid in contact with the substance. Thus, the substance e.g. may comprise one or more enzymes, such as gluconolactone. Examples of chemical substances which may be used within the present invention are described in US 5,286,362 or in WO 01/48461. The chemical or physical property may change as a result of the simple presence of the constituent, or it may change gradually, e.g. increasingly with increasing concentration of the constituent. The chemical property, which changes with the concentration of the constituent, may comprise an electrochemical property, such as in US 5,286,362, which may be detected electronically, or, additionally or alternatively, it may comprise an optical property, such as described in WO 01/48461, such as a color reaction,

a change of reflectivity, a change in fluorescence and/or phosphorescence properties or similar optical properties.

5 In a further embodiment, the test system further comprises a magazine, wherein the magazine comprises at least one test element. In a preferred embodiment, the magazine comprises at least one compartment, wherein the at least one compartment comprises at least one test element. The compartment may comprise at least one barrier, in order to preserve sterility of the at least one test element and to exclude environmental contaminants. Thus, the barrier may comprise a plastic foil and/or a metal foil, such as an
10 aluminum foil, which may be used to seal the at least one compartment.

In a preferred embodiment, the test system further comprises an opening mechanism to open the barrier of the compartment of the test element prior to perforating the skin portion of the living organism. This opening mechanism may, e.g., be designed as described in
15 WO 03/088834 and may, preferably, prevent the test element, especially the lancet of the test element, from contacting the barrier and thereby taking risk of losing its properties, such as a potential hydrophilic property of the test element.

In a preferred embodiment, the opening mechanism is actuated by the lancing actuator,
20 which allows for the opening motion and the driving of the test element to be performed by the same lancing actuator, thereby allowing for a simplification of the test system.

In a preferred embodiment, the opening mechanism is adapted for opening the barrier in at least one lancing portion, allowing for the test element to perform the lancing motion
25 without contacting the barrier. Thus, the opening of the barrier in the at least one lancing portion may comprise a perforation and/or crumbling (folding) of the barrier, in order to create an opening that provides a passage for the lancet.

In a further embodiment, the opening mechanism may further be adapted for opening the
30 barrier in at least one engagement portion. The engagement portion may allow for the engaging part of the actuator to engage the test element, such as by the types of engagement described above.

In a further embodiment, the magazine comprises a magazine disk of essentially round
35 shape, wherein the disk comprises a plurality of test elements in an essentially radial arrangement, such that the lancet of the test element are pointing towards the outer diameter of the disk. The test system may further comprise a rotating unit for rotating the

magazine disk into a sampling position with respect to a pre-selected test element, wherein in the sampling position the test system is adapted for driving the actuator, in order to perform the lancing motion of the preselected test element. Preferably, the test system may be adapted to use a new test element for each test.

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In a further aspect of the present invention, an opening mechanism for use in a test system for measuring the concentration of one or more constituents in a body fluid of a living organism is provided. Therein, the test system comprises a test element, wherein the test element comprises a lancet for perforating a skin portion of the living organism. The test system further comprises a magazine including at least one compartment, wherein the at least one compartment comprises at least one test element. The at least one compartment further comprises at least one barrier to preserve sterility of the test element and to exclude environmental contaminants, wherein the opening mechanism comprises a first opening element for opening the barrier in at least one lancing portion, allowing for the test element to perform the lancing motion without contacting the barrier. Further, the opening mechanism comprises a second opening element for opening the shielding in at least one engagement portion, wherein the engagement portion allows for engaging part of the test system to engage the test element. The opening mechanism is adapted to simultaneously actuate the first and second opening elements.

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In a further embodiment of the present invention, the first and second opening elements of the opening mechanism are made of one piece. Thus, the first and second opening elements may comprise a plastic or metal piece of the opening mechanism.

25 In a further embodiment, the first and second opening elements are formed by edges of a pivotable opening arm. The first opening element may be arranged at a protrusion at the tip of the pivotable arm, and the second opening element may be arranged at a long side of the pivotable arm. The expression "pivotable" may comprise rotational movements and/or one- or more dimensional linear movements of the arm, and may be read as "moveable".

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In a further aspect of the present invention, a test system is provided, which may be designed according to one of the embodiments of a test system described above. The test system further comprises an opening mechanism according to one or more of the embodiments disclosed above.

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The actuator, the test system and the opening mechanism according to one or more of the embodiments disclosed above provide a large number of advantages over actuators, test

systems and opening mechanisms as known from prior art. Thus, for lancing, sampling and preparation of measurements in get and measure systems, one simple common operation may be provided and may be sufficient for obtaining a measurement result. This operation may be realized by actuators and combined motions, wherein the switching between
5 different motions may be provided by a latch element, in particular the magnetic switch element (magnetic latch). Further, the test system and the actuator according to one or more of the embodiments outlined above, may allow for a precise control of the lancing and/or perforation depth. The invention further may allow for repetition of the lancing and/or measurement. Further, the test system and/or the actuator may allow for a
10 “conventional” application of the body fluid sample (e.g. a blood droplet) onto the test element.

The test system may preferably be designed as a compact, self-contained hand-held device. The test system may comprise a housing accommodating the system components. The test
15 system may further comprise means for measurement, such as electronical and/or computer components, in order to perform a measurement of the concentration of the constituent or analyte within the body fluid. Further, input and/or output means may be provided, such as a display, keys for operating the test system, an interface for interfacing the test system with one or more computers for the purpose of control of the measurement and/or a data
20 exchange, as well as other appropriate controls of test systems, as known from prior art systems. Further, the test system may comprise one or more energy storage elements, such as batteries, accumulators, supercapacitors and/or similar elements. Additionally or alternatively, the test system may comprise an external power supply.

25 A further understanding of the nature and advantages of the invention will become apparent by reference to the following portions of the specification and to the drawings. The invention, however, is not limited to the exemplary embodiments shown in the drawings.

30 Brief description of the drawings

In the drawings

Figure 1 shows a perspective view of a preferred embodiment of a test system for
35 measuring the concentration of one or more constituents in a body fluid;

Figure 2 shows an exploded view of a magazine comprising test elements;

Figure 3 shows an embodiment of a test element;

Figure 4 shows a side view of the magazine according to Figure 2, comprising a test
5 element;

Figure 5 shows an enlarged view of the test element within the magazine;

Figure 6 shows a top view of the magazine according to Figure 2;

Figure 7 shows a first step of interaction between an opening mechanism and the
10 magazine according to Figure 2;

Figure 8 shows a second step of interaction between the opening mechanism and the
15 magazine;

Figure 9 shows a third step of interaction between the opening mechanism and the
magazine; and

Figures 10 to 17 show several steps of an operating cycle of the test system according to
20 Figure 1 in a sectional view.

Detailed description of the embodiments

25 The figures show an exemplary embodiment of a preferred test system for measuring the concentration of one or more constituents in a body fluid of a living organism. In Figure 1, a perspective sectional view of the test system 110 is shown. The test system 110 uses a flat disk magazine 112 comprising fifty test elements 114, wherein each test element is housed in a separate compartment 116. The test elements 114 each comprise a lancet and a
30 measurement chemistry, wherein the magazine 112 and the test elements 114 will be described in more detail below. The test system 110 comprises a housing 118 including a structural base 122.

35 The test system 110 further comprises an actuator 124 for driving the test elements 114. The actuator 124 comprises a lancing actuator 126, which, in this exemplary embodiment,

is formed by a servo motor 126 comprising a linear drive screw 128. The linear drive screw 128 interacts with a threaded hole of a slow shuttle 130.

Further, the actuator 124 of the test system 110 according to Figure 1 comprises a fast shuttle 132, which is biased against the slow shuttle 130 by a lancing spring 134. A head 136 of the fast shuttle 132 interacts with a magnetic switch element 138, the magnetic switch element 138 comprising a permanent magnet 140. The position of the magnetic switch element 138 may be adjusted by a stroke adjustment screw 142, which is biased by a latch bias spring 144.

The fast shuttle 132 comprises an engagement member 146 for engaging the test element 114. The engaging part comprises a gripper 148 having a first gripper element 150, and a second gripper element 152. The first and second gripper elements 150, 152 are biased by a coupling spring 154 exerting a clamping force between the grippers 150, 152.

Further, the structural base 122 comprises an abutment portion 156, which, by pressing against the first gripper element 150, may dislocate the first and second gripper elements 150, 152, thereby opening the gripper 158 against the clamping force of the coupling spring 154.

The engagement member 146, in the exemplary embodiment shown in Figure 1, is designed to be a pivotable portion, being connected to the remainder of the fast shuttle 132 by a pivot 158. Thus, the pivot 158 allows for an up- or down-movement of the engagement member 146 comprising the gripper 158. The engagement member 146 is biased against the disk magazine 112 by a lift spring 160.

Further details of the operation of the test system 110 will be described below, with reference to Figures 10 to 17.

In Figure 2, an exploded view of the disk magazine 112 is shown. In this exemplary embodiment, the magazine 112 comprises a body 162, formed by a plastic molding with radial pockets or compartments 116, comprising fifty disposable test elements 114. The disk body 162 may comprise a plastic material containing a desiccant that maintains a low moisture storage environment for the measurement chemistry film (see below) of the test elements 114.

The magazine 112 further comprises a cover ring 164, which also may be formed by a plastic molding. Further, the magazine 112 comprises a cup-shaped foil barrier 166, which is bonded to the bottom and the outer edge of the disk body 162 and the cover ring 164, so that each radial compartment 160 forms a separate sealed volume that protects each disposable test element 114 from moisture and preserves its sterility. The foil may be formed by a metal, such as soft aluminum or copper, so that when it is deformed, it does not spring back. Other types of foils may be used, such as plastic foils. The disk magazine 112 and its contents may be sterilized by a penetrating process, such as an E-beam sterilization after it is sealed.

It has to be noted that the exploded view of the disk magazine 112 in Figure 2 shows the magazine 112 in an upside down view as compared to the disk magazine 112 shown in the test system 110 according to Figure 1.

In Figure 3, two test elements 114 are depicted in a perspective view. Therein, the upper test element 114 is depicted in an exploded view, in order to demonstrate the construction of the test element 114.

The test elements 114 each comprise a lancet 168, which, in this embodiment, is formed by a slotted steel needle which may be used to penetrate the skin of a patient and to collect a small quantity of a body fluid, such as blood, in the slot, and to transport this small quantity of body fluid, driven by capillary forces, to an active surface of a glucose measurement film 170. This glucose measurement film 170 comprises a substance, which, in this embodiment, changes its color in accordance to the concentration of the constituent of the body fluid, such as blood glucose. The slot 172 within the lancet 168 extends to the rear end of the lancet 168, so that the lancet consists of two parallel slides joined at the sharp tip of the lancet 168.

The test element 114 further comprises a test element body 174, which serves several functions and which may be formed by a plastic material. As a first function, the test element body 174 allows for an engagement of the gripper 148 of the actuator 124, and, therefore, comprises an engagement portion formed by gripper notches 176 near the rear end of the test element body. These gripper notches 176 are designed to leave a rear end protrusion 178, which may be engaged by the gripper 148.

Further, as a second function, the test element body 174 is designed to be an optical fiber slider, comprising several optical fibers, which will be outlined in more detail with

reference to Figure 5. Thus, the test element body 174 comprises three optical fibers 180, accessible by an optical port 182 at the rear end of the test element body 174. Thereof, two of the optical fibers 180 are optical excitation fibers 184, wherein the third optical fiber functions as a readout fiber 186, which may be used to detect light emitted by the measurement film 170. In this embodiment, as will be shown in more detail below, the engagement member 146 therefore does not only include means for mechanical engagement of the test element 114, but also optical engagement means for optically contacting the optical port 182 at the rear end of the test element 114.

In Figures 4 and 5, an enlarged sectional side view of the magazine 112 is shown. Thereof, Figure 5 shows an enlarged view of a single compartment 116 for receiving the test elements 114.

As can be seen, the disk magazine 112 comprises a central circular opening 188. A rotating unit of the test system 110 (not depicted in Figure 1) may be used in order to engage the magazine 112 by engaging the central opening 188 and thereby rotating the disk magazine 112 into a desired position, around a rotating axis 190 of the magazine 112.

The magazine compartments 116 containing the test elements 114 each comprise a lancing portion 192 and an engagement portion 194. The lancing and engagement portions 192, 194 both are sealed by the foil barrier 166. The lancing portion 192 allows for the test element 114 and the lancet 168 to leave the compartment 116, wherein the engagement portion 194 allows for the engagement member 146 and the gripper 148 to engage the test element 114. Further, the lancing portion 192 comprises a foil storage pocket 196 for accommodating the crumbled or folded portion of the foil barrier 166 after performing the opening process (see Fig. 8 below). The lancing portion 192 and the engagement portion 194 are separated by the cover ring 164. Further details of the lancing and engagement portions 192, 194 and their purposes will be explained with reference to Figures 7 through 9 below.

In Figure 6, a sectional top view of the magazine 112 is depicted. This sectional top view again shows, in addition to the perspective view in Figure 2, the pie slice-type arrangement of the compartments 116 and the test elements 114 accommodated therein. Further, it can be seen that the lancing portion 192 of the compartments 116 is formed to be slightly enlarged in width, as compared to the remainder of the compartments 116.

In Figures 7 through 9, a simplified view of an opening mechanism 198 is depicted, which may be used in combination with the magazine 112 in the test system 110 according to Figure 1. Thus, the opening mechanism 198 may be used in combination with the actuator 124 depicted in Figure 1, and may even be driven by the actuator 124 itself. The opening mechanism 198 is used for opening one specific compartment 116 of the disk magazine 112, in order to allow for a lancing movement of the test element 114 by moving the test element 114 linearly through the lancing portion 192 of the compartment 116 and through the opening 120 within the housing 118 in Figure 1, by avoiding the tip of the lancet 168 touching the foil barrier 166. For this purpose, besides the sampling position of the test element 114 to be used, as depicted in Figure 1, a separate opening position may be provided, in which the opening mechanism 198 opens the foil barrier 166 of the compartment 116 containing the test element 114 to be used in an upcoming sampling step.

The opening mechanism 198 comprises a pivotable opening arm 200, which, in this preferred embodiment, is formed as single piece, but which may as well be formed by two separate pieces. The opening arm 200 comprises a first opening element 202 for opening the foil barrier 166 in the region of the lancing portion 192, and a second opening element 204 for simultaneously opening the foil barrier 166 in the range of the engagement portion 194. The first opening element 202 is formed by a sharp edge of a protrusion 206 at the front end of the opening arm 200. The second opening element 204 is formed by edges in a linear portion of the pivotable opening arm 200.

In Figure 8, the opening action exerted by the opening mechanism 198 is shown. For this purpose, the pivotable opening arm 200 performs an upward movement, towards the interior of the compartment 116. Thus, from Figure 8, it is clear that the expression “pivotable” is not limited to pure pivoting movements, but may also comprise other movements, such as the linear movement shown in Figure 8.

During the upward movement, which, in Figure 8, is referred to by referential 208, in one single movement, the foil barrier 166 is opened more or less simultaneously in the lancing portion 192 and in the engagement portion 194. Therein, in the lancing portion 192, the foil barrier 166 is cut and crumpled in the foil storage pocket 196, leaving a more or less rectangular opening in the foil barrier 166 at the front end of the test element 114, allowing for the lancet 168 to leave the compartment 116 without touching the foil barrier 166. Thus, since no contact between the lancet 168 and the foil barrier 166 occurs during a lancing motion of the test element 114, no detrimental effects such as a deterioration of the hydrophilic properties of the lancet 168 may occur.

The opening of the foil barrier 166 in the range of the engagement portion 194, forming a long rectangular or slit-like opening, allows for the engagement member 146 to engage the test element 114. The rectangular area foil barrier is cut on the two short sides and one long side so that an attached flap is formed. The flap is then folded to one side to provide free access to the engagement portion 194 of the test element 114.

After performing the opening procedure, the opening arm 200 performs, as can be seen in Figure 9, a downward movement 210, allowing for the rotating mechanism to rotate the freshly opened compartment 116 into a sampling position, as depicted in Figure 1.

In Figures 10 through 17, a number of sectional side views of the test system 110 in Figure 1 is shown in different steps of operation, which will be used in order to explain the functioning of the test system 110 and the actuator 124.

In Figure 10, the test system 110 is depicted with the compartment 116 of the test element 114 to be used in the sampling position, with the lancet 168 pointing towards the opening 120 in the housing 118. The opening 120 is surrounded by a rubber ring 212. The test element 114 to be used in the upcoming process may be moved by a rotating unit (not depicted) into the position depicted in Figure 10 after performing the opening process depicted in Figures 7 through 9.

In the reset position depicted in Figure 10, the lancing actuator 126 pulls back the slow shuttle 130 and, by force of the lancing spring 134, the fast shuttle 132. The direction of this rearward movement is referred to by referential 214 in Figure 10.

By this rearward movement, the rear end of the first gripper element 150 of the pivotable engagement member 146 is pressed against the abutment portion 156. Thereby, a torque is exerted on the pivotable engagement member 146, and a downward movement 216 of the front end of the engagement member 146 occurs by pivoting around the pivot 158, against the spring force of the lift spring 160. Simultaneously, the relative position of the first and second gripper elements 150, 152 is changed by pressing the first gripper element 150 against the abutment portion 156, thereby opening the gripper 148. In this reset position depicted in Figure 10, the disk magazine 112 may be rotated, in order to transport the test element 114 to be used into the sampling position.

In a second process step, as depicted in Figure 11, the test system 110 is in an engaged position. For this purpose, the lancing actuator 126 performs a forward movement 218, thereby pivoting the gripper 148 into the compartment 116 of the test element 114. The upward movement of the gripper 148 is supported by the lift spring 160. Further, by relaxation of the coupling spring 154, the gripper 148 is closed, whereby a mechanical engagement between the rear end protrusion 178 of the test element 114 (see Figure 3) and the gripper 148 is provided. Further, the second gripper element 152 comprises a fiber port 220, which, in the engaged position depicted in Figure 11, provides an optical contact to the optical port 182 at the rear end of the test element 114 (see Figure 3), allowing for an optical readout of the measurement film 170 within the test element 114.

In Figure 12, a cocked position of the test system 110 and the actuator 124 is depicted. In order to reach this cocked position, the lancing actuator 126 pushes, by force of the linear drive screw 128, the slow shuttle 130 into a forward direction (in Figure 12 referred to by referential 222). The fast shuttle 138 on the other hand is held back by the magnet 140, exerting a magnetic force onto the head 136 of the fast shuttle 132. Thus, by the relative movement of the slow shuttle 130 and the fast shuttle 132, the lancing spring 134 is compressed.

When the lancing spring 134 is fully compressed, the slow shuttle 130 contacts the fast shuttle 132 and pushes it out of engagement with the magnet 140. This releases the fast shuttle 132 and starts the lancing action.

Thus, by the position of the magnetic switch element 138 and the magnet 140, the triggering point of the lancing action of the test system 110 and, thus, the penetration depth of the lancet 168 of the test element 114 may be controlled. This position may be adjusted by the stroke adjustment screw 142.

In Figure 13, the lancing action is shown in progress. Therein, the lancing spring 134 expands and accelerates the fast shuttle 132. Thus, the fast shuttle 132 performs a fast forward movement, which is referred to in Figure 13 by referential 224. Since the test element 114 is engaged by the engagement member 146, the fast forward movement 224 of the fast shuttle 132 is transferred to the test element 114, which therefore performs the lancing movement, allowing for the lancet 168 to leave the housing 118 through the opening 120, in order to penetrate a skin portion of the patient.

In Figure 14, the test system 110 is shown with the test element 114 and the lancet 168 in fully extended position. The lancet 168 extends to the desired penetration depth set by the stroke adjustment screw 142. By moving the magnetic switch element 138 rearward (towards the lancing actuator 126), the penetration depth can be lowered, whereas by moving the magnetic switch element 138 forward, i.e. away from the lancing actuator 126, the penetration depth of the lancet 168 can be increased. The movement of the fast shuttle 134 may be stopped by contact with the slow shuttle 130. An optical sensor, a motor current sensor or other means may be used to detect the lancet release and stop the advancement of the lancing actuator 126 during or shortly after the fast shuttle 134 hits the slow shuttle 130. Thus, in the position depicted in Figure 14, a first penetration of the skin is achieved.

In Figure 15, a withdrawal of the lancet 168 from the perforated skin portion is depicted. Therefore, the lancing actuator 126 performs a rearward movement 226 of the linear drive screw 128, thereby causing the slow shuttle 130 to perform a rearward movement as well. The lancing actuator 126 controls the position of the lancet 168 after maximum penetration and enables a variety of retraction programs. A slow retraction and a detection light pulse at a sample collection position with the lancet 168 still partially in the skin is only one possibility.

During this retraction movement of the lancet 168, blood or a similar body fluid is collected through the slot 172 in the lancet 168. If no blood is detected by an optical detector in contact with the fiber port 220, the lancing actuator 126 may advance the slow shuttle 130 again, in order to re-cock the lancing spring 134.

A mechanism (not shown) may be used to change the penetration adjustment screw 142, in order to increase the lancet penetration depth on a following, second lancing action. As before, the fast shuttle 132 is held back by the magnet 136 of the magnetic switch element 138. When the lancing spring 134 is fully compressed, the slow shuttle 130 again contacts the fast shuttle 132 and pushes it out of engagement with the magnet 136. This releases the fast shuttle 132 and starts a second, deeper lancing action. This second cocked position is depicted in Figure 16, which more or less corresponds to Figure 12, but with the magnet 136 and the magnetic switch element 138 moved further to the left (compare Figures 12 and 16).

In Figure 17, the second, optional penetration, which may be performed if no blood is detected by the test system 110, is depicted. This view more or less corresponds to the

situation depicted in Figure 14, except for the position of the magnetic switch element 138, which, according to the increased penetration depth, is moved forward, i.e. to the left in Figure 17, in order to increase the penetration depth. After penetration, the lancet 168 is then retracted by the lancing actuator 126, and the mechanism is returned to the engaged position shown in Figure 11. If no blood is detected, then the lancet 168 may be extended slowly for manual sample collection. After the measurement is complete, the lancing actuator 126 may return the mechanism to the reset position shown in Figure 10.

The test system 110 depicted in Figure 1 may further comprise one or more evaluation elements for evaluating the measurement and/or for controlling the operation of the overall test system 110. Thus, the test system 110 may comprise one or more electronic components as well as one or more computer systems, for providing excitation signals to the optical port 182, as well as reading out detection signals from the optical fibers 180. Further functions may be performed by this system. Further, the movement of the overall actuator 124, specifically of the lancing actuator 126, may be controlled. Thus, the lancing actuator 126 may be driven to move the slow shuttle 130 at speeds up to 0.1 m/s. For the lancing movement of the lancet 168, driven by the lancing spring 134, velocities of approximately 1.0 m/s may be achieved.

The test system 110 may further comprise one or more energy storage devices, such as batteries, accumulators or similar devices. Thus, e.g., a lithium primary battery may be used, such as a battery used in digital cameras. Other solutions for providing the energy required for operating the actuator 124 and/or the measurements may be used, as described above.

Further, instead of the servo motor, other types of lancing actuators 126 may be used, which may provide for a controlled forward and/or backward movement of the slow shuttle 130. The combination of the energy storage by the lancing spring 134 with the slow movement of the lancing actuator 126 provides a fast penetration motion, despite of the potential use of a slower motor that cocks the energy storage spring 134 prior to the fast penetration motion, wherein the lancing actuator controls the test element position during subsequent sample collection and measurement steps.

The test system 110 may further comprise one or more light sources, such as light emitting diodes (LEDs) or laser diodes. These light sources may be located on a stationary structure, such as a printed circuit board, e.g. in contact with or affixed to the structural base 122. Further, one or more light detectors may be used, which may also be located inside the test

system 110, e.g. on the same printed circuit board, in order to provide for the required signals for the determination of the concentration of the analyte. Light signals may be provided to the fiber port 220 and the optical port 182 via flexible optical fibers, which are denoted by referential 228 in Figures 10 and 11, and which are only schematically depicted. Other types of flexible light guides may be used instead of optical fibers, as described above. The optical light sources may be located on the moving optical coupling in the measuring instrument, and electrical power may be supplied from the stationary portion of the test system 110 through flexible electrical conductors. Similarly, the optical light detectors may be located on the moving optical coupling, whereas the electrical power and signal connections are made to the stationary portion of the test system 110 through flexible electrical conductors. In a further embodiment, the optical light sources may be located on a stationary structure in the test system 110, and the light may be conveyed from the moving test element through flexible light guides.

Reference numbers

110	test system	176	gripper notches
112	magazine	178	rear end protrusion
114	test element	180	optical fibers
116	compartment	182	optical port
118	housing	184	optical excitation fibers
120	opening	186	readout fiber
122	structural base	188	central opening
124	actuator	190	axis
126	lancing actuator	192	lancing portion
128	linear drive screw	194	engagement portion
130	slow shuttle	196	foil storage pocket
132	fast shuttle	198	opening mechanism
134	lancing spring	200	opening arm
136	head of fast shuttle	202	first opening element
138	magnetic switch element	204	second opening element
140	permanent magnet	206	protrusion
142	stroke adjustment screw	208	upward movement
144	latch bias spring	210	downward movement
146	engagement member	212	rubber ring
148	gripper	214	rearward movement
150	first gripper element	216	downward movement
152	second gripper element	218	forward movement
154	coupling spring	220	fiber port
156	abutment portion	222	forward movement of slow shuttle
158	pivot	224	fast forward movement of fast shuttle
160	lift spring	226	rearward movement
162	body	228	flexible optical fibers
164	cover ring		
166	foil barrier		
168	lancet		
170	glucose measurement film		
172	slot		
174	test element body		

Claims

1. An actuator for driving a test element, wherein the test element comprises a lancet for perforating a skin portion of a living organism, wherein the actuator comprises an engaging part for engaging and driving the test element to perform a lancing motion,
5 wherein the actuator further comprises a lancing actuator and a lancing spring, wherein the lancing actuator is adapted for biasing the lancing spring by executing a forward movement and thereby exerting a biasing force on the engaging part, wherein the actuator further comprises a latch element, wherein the latch element is a
10 force-sensitive latch element, wherein the latch element is adapted for exerting a retention force holding back the engaging part, wherein the retention force counteracts the biasing force, and wherein the latch element is adapted for releasing the engaging part when the biasing force exerted by the lancing actuator exceeds the retention force exerted by the latch element, thereby allowing for the test element to
15 perform the lancing motion.
2. The actuator according to claim 1, wherein the latch element comprises a magnetic switch element.
- 20 3. The actuator according to claim 1, wherein the latch element comprises a mechanical detent.
4. The actuator according to claim 1, wherein the engaging part comprises a fast shuttle element and slow shuttle element, wherein the fast shuttle element is adapted for
25 engaging the test element, wherein the lancing actuator engages the slow shuttle element, wherein the lancing spring extends between the fast shuttle element and the slow shuttle element, and wherein the latch element is adapted for holding back the fast shuttle element.
- 30 5. The actuator according to claim 2, wherein the magnetic switch element comprises a magnetic element exerting an attractive magnetic force on the engaging part, wherein the release of the engaging part is initiated as soon as the lancing force exceeds the attractive magnetic force.
- 35 6. The actuator according to claim 1, wherein the position of the latch element in the direction of the lancing force is adjustable, allowing for a penetration depth of the lancing motion of the test element to be adjusted.

7. The actuator according to claim 6, further comprising a stroke adjustment screw allowing for adjustment of the position of the latch element.
- 5 8. The actuator according to claim 1, wherein the engaging part comprises a gripper for gripping a portion of the test element.
9. The actuator according to claim 8, wherein the gripper comprises a first gripper element and a second gripper element, wherein the first and second gripper elements
10 are biased by a coupling spring to exert a clamping force, wherein the actuator further comprises an abutment portion, wherein the actuator is adapted to dislocate the first and second gripper elements by retracting the gripper and pressing one of the grippers against the abutment portion, thereby compressing the coupling spring and opening the gripper.
15
10. The actuator according to claim 9, wherein the actuator is adapted to close the gripper by a forward movement of the lancing actuator.
11. The actuator according to claim 8, wherein the actuator is adapted for at least partly
20 transforming a linear motion of the lancing actuator into a gripping motion of the gripper.
12. The actuator according to claim 8, wherein the engaging part comprises a pivotable portion, wherein the pivotable portion comprises the gripper, and wherein the
25 actuator is adapted to pivot the gripper into engagement with the test element by a forward movement of the lancing actuator and to pivot the gripper out of engagement with the test element by a rearward movement of the lancing actuator.
13. The actuator according to claim 12, wherein the pivotable portion is biased into
30 engagement with the test element by a lift spring.
14. The actuator according to claim 8, wherein the actuator is adapted for at least partly transforming a first linear motion of the lancing actuator into a second linear motion of the gripper, wherein the second linear motion of the gripper at least contains a
35 directional component perpendicular to the first linear motion.

15. The actuator according to claim 1, wherein the engaging part comprises an electrical connection for electrically contacting the test element.
- 5 16. The actuator according to claim 1, wherein the actuator is adapted for detecting if a first lancing motion resulted in acquiring of a body fluid sample from the living organism, wherein the actuator is adapted for re-iterating the lancing motion with an increased penetration depth if no or insufficient body fluid is acquired.
- 10 17. A test system for measuring the concentration of one or more constituents in a body fluid of a living organism, wherein the test system comprises an actuator according to claim 1 and at least one test element, wherein the test element comprises a lancet for perforating a skin portion of a living organism.
- 15 18. The test system according to claim 17, wherein the test element further comprises a capillary transport system for acquiring a body fluid sample from the living organism.
- 20 19. The test system according to claim 17, wherein the test system further comprises a magazine, wherein the magazine comprises at least one test element, wherein the magazine comprises at least one compartment, wherein the at least one compartment comprises a test element, wherein the compartment comprises at least one barrier to preserve sterility of the test element and to exclude environmental contaminants, wherein the test system further comprises an opening mechanism to open the barrier of the compartment of the test element prior to perforating the skin portion of the living organism.
- 25 20. The test system according to claim 19, wherein the opening mechanism is actuated by the lancing actuator.
- 30 21. The test system according to claim 19, wherein the opening mechanism is adapted for opening the barrier in at least one lancing portion, allowing for the test element to perform the lancing motion without getting into contact with the shielding.
- 35 22. The test system according to claim 21, wherein the opening mechanism is further adapted for opening the barrier in at least one engagement portion, wherein the engagement portion allows for the engaging part to engage the test element.

23. The test system according to claim 19, wherein the magazine comprises a magazine disk of an essentially round shape, wherein the disk comprises a plurality of test elements in an essentially radial arrangement, such that the lancet of the test elements are pointing towards the outer diameter of the disk.
- 5
24. The test system according to claim 23, wherein the test system further comprises a rotating unit for rotating the magazine disk into a sampling position with respect to a pre-selected test element, wherein in the sampling position the test system is adapted for driving the actuator, in order to perform the lancing motion of the pre-selected test element.
- 10
25. The test system according to claim 17, wherein the test element comprises at least one hydrophilic coating.
- 15
26. An opening mechanism for use in a test system for measuring the concentration of one or more constituents in a body fluid of a living organism, wherein the test system comprises a test element, wherein the test element comprises a lancet for perforating a skin portion of the living organism, wherein the test system further comprises a magazine including at least one compartment, wherein the at least one compartment comprises at least one test element, wherein the at least one compartment comprises at least one barrier to preserve sterility of the test element and to exclude environmental contaminants, wherein the opening mechanism comprises a first opening element for opening the barrier in at least one lancing portion, allowing for the test element to perform the lancing motion without getting into contact with the barrier, wherein the opening mechanism comprises a second opening element for opening the barrier in at least one engagement portion, wherein the engagement portion allows for engaging part of the test system to engage the test element, and wherein the opening mechanism is adapted to simultaneously actuate the first and second opening elements.
- 20
- 25
- 30
27. The opening mechanism according to claim 26, wherein the first and second opening elements are made of one piece.
- 35
28. The opening mechanism according to claim 26, wherein the first and second opening elements are formed by edges of a pivotable opening arm.

29. The opening mechanism according to claim 28, wherein the first opening element is arranged at a protrusion at the tip of the pivotable arm, and wherein the second opening element is arranged at a long side of the pivotable arm.
- 5 30. The test system according to claim 17, wherein the test system comprises an opening mechanism according to claim 26.

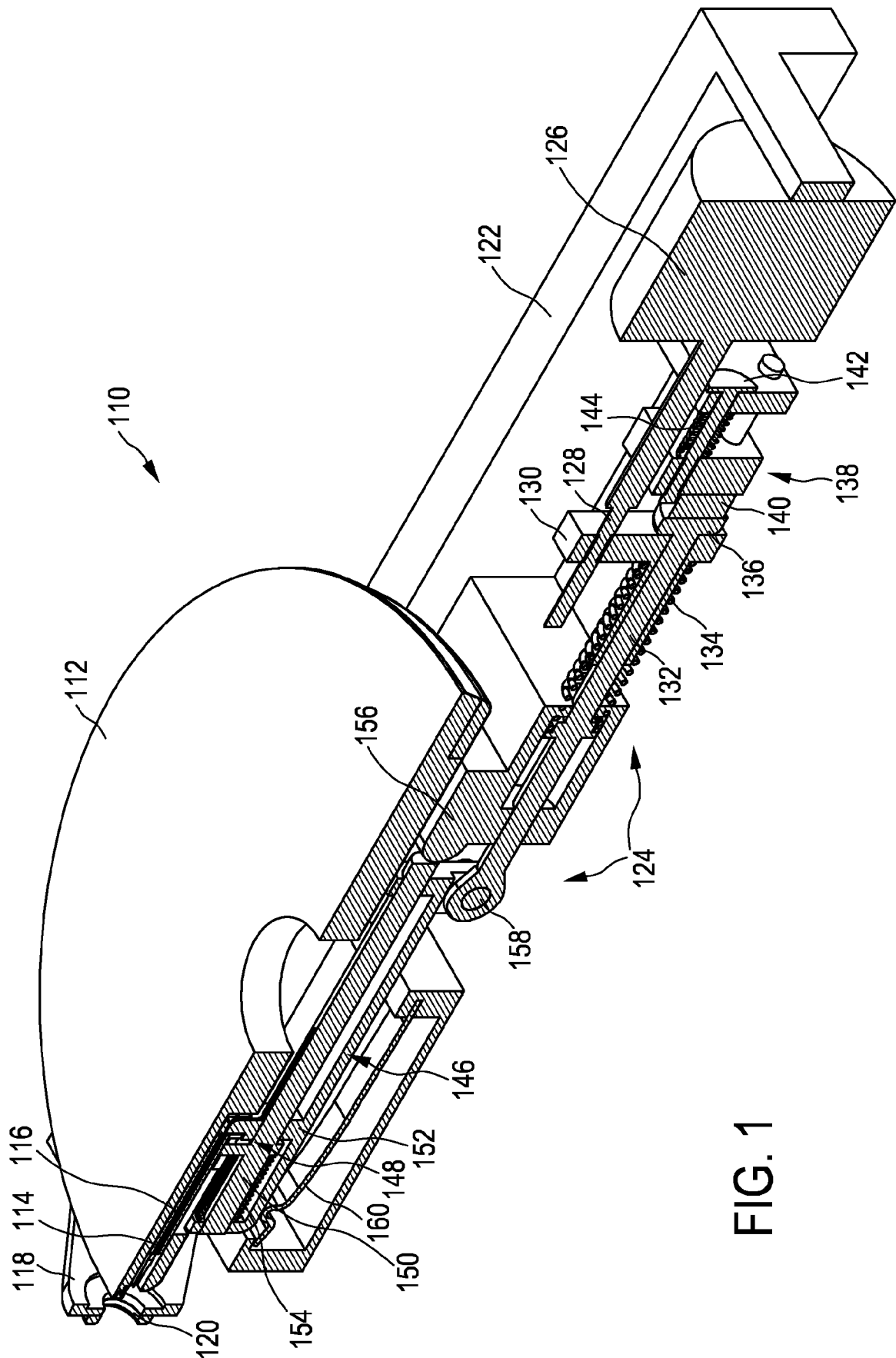


FIG. 1

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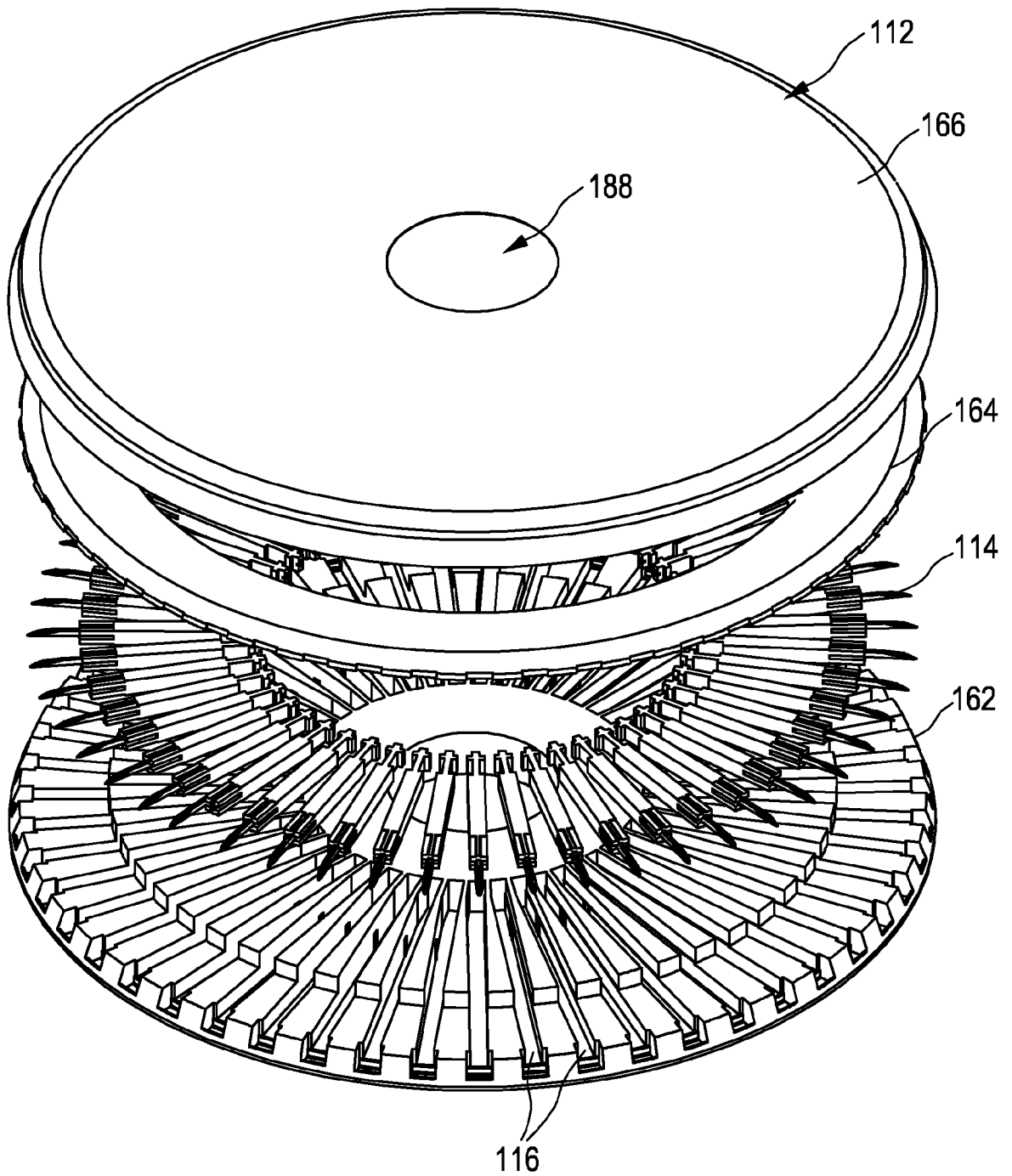


FIG. 2

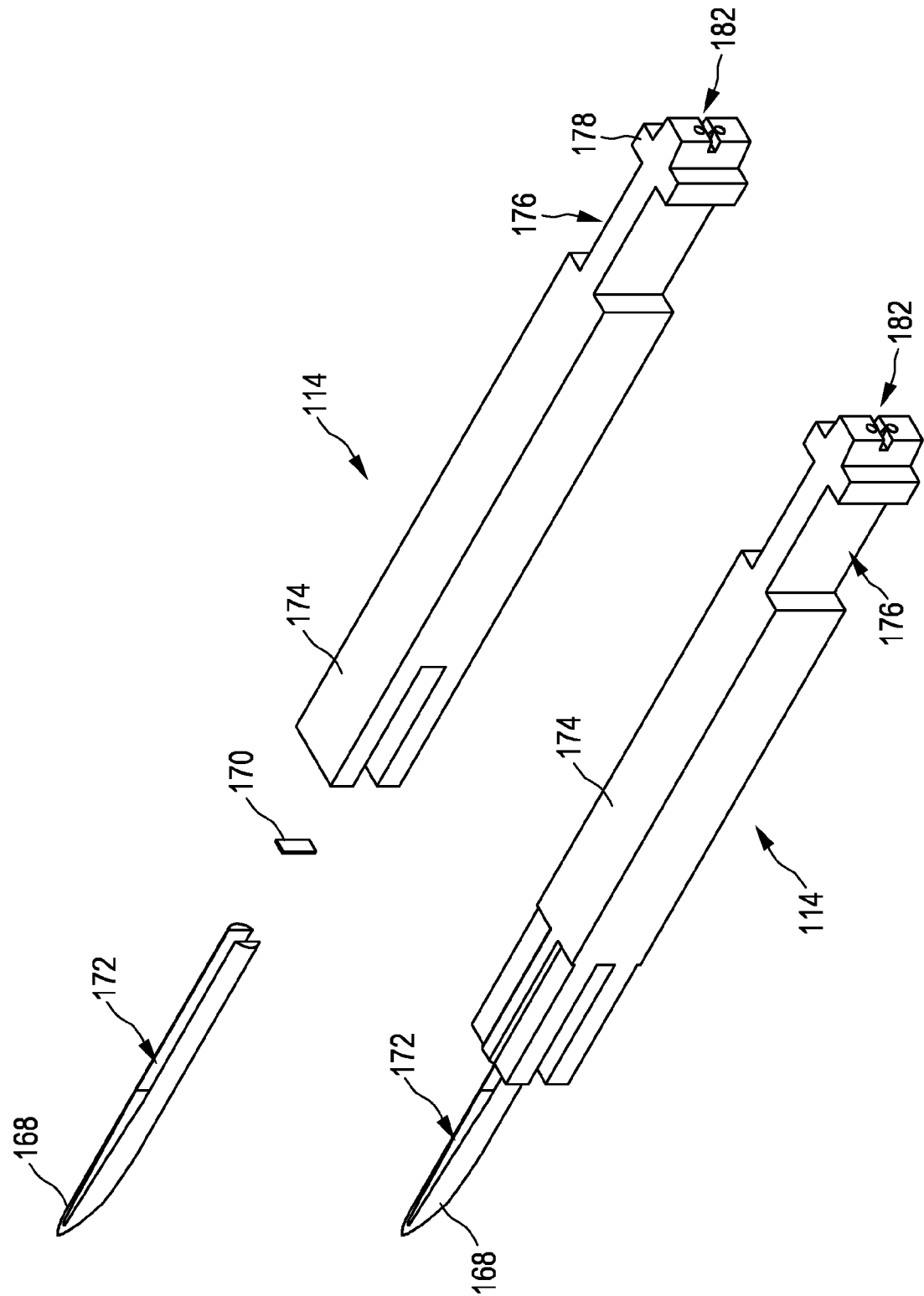


FIG. 3

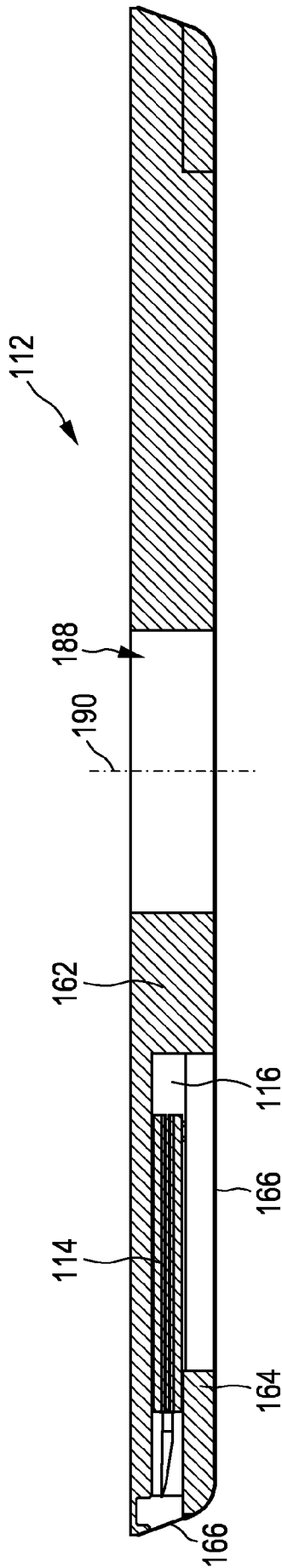


FIG. 4

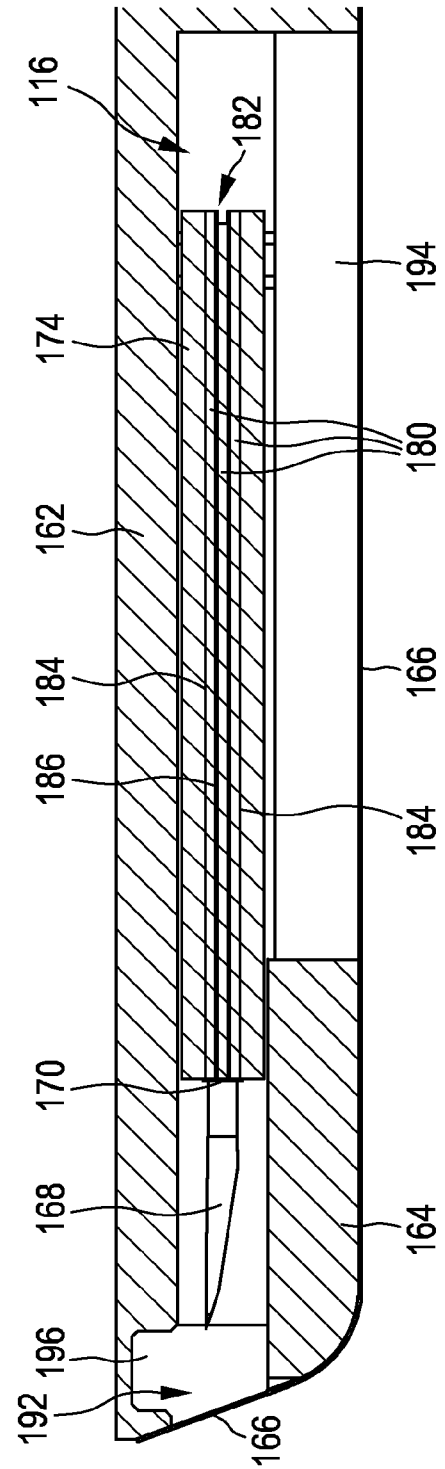


FIG. 5

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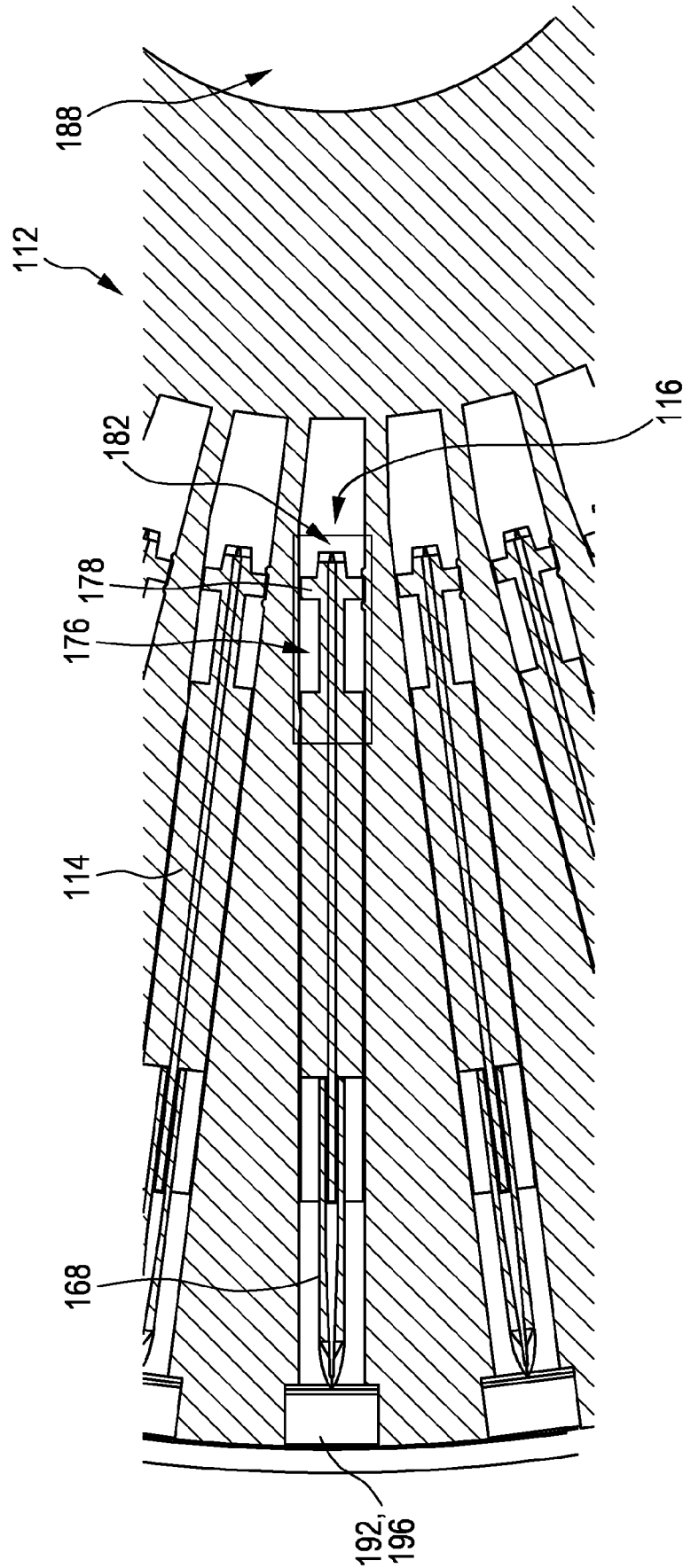


FIG. 6

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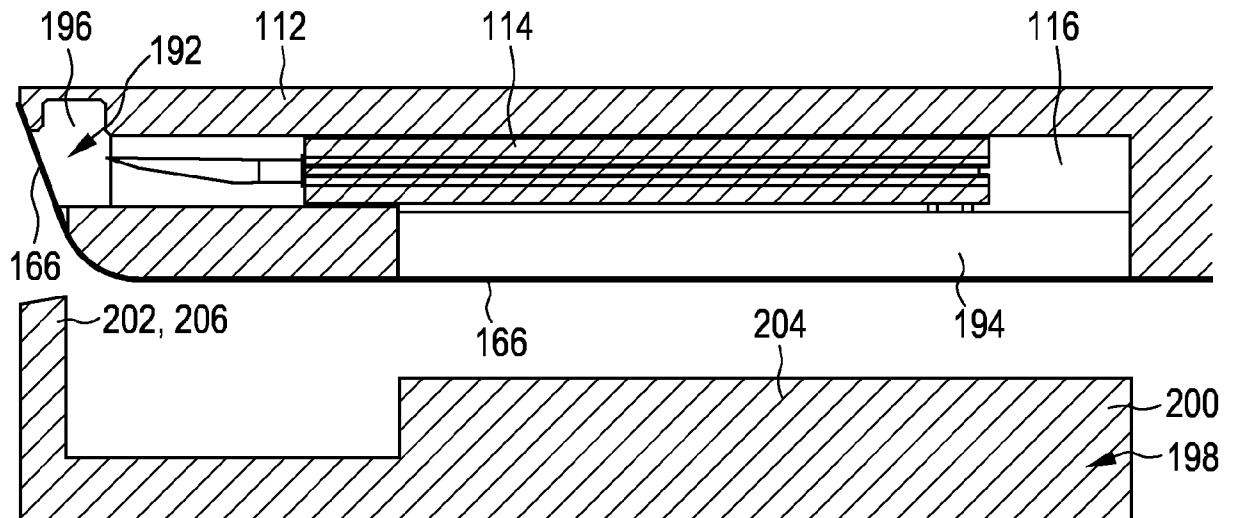


FIG. 7

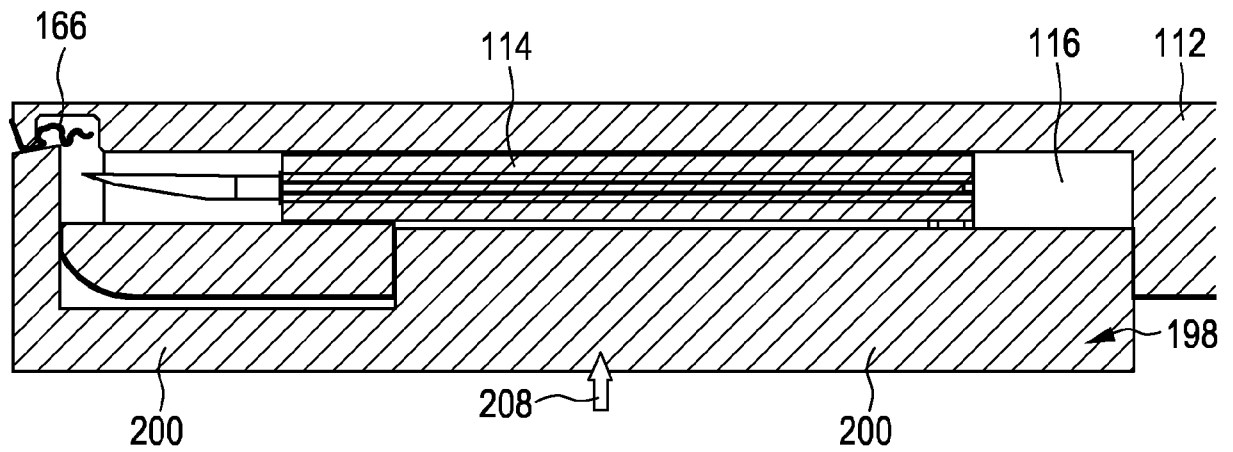


FIG. 8

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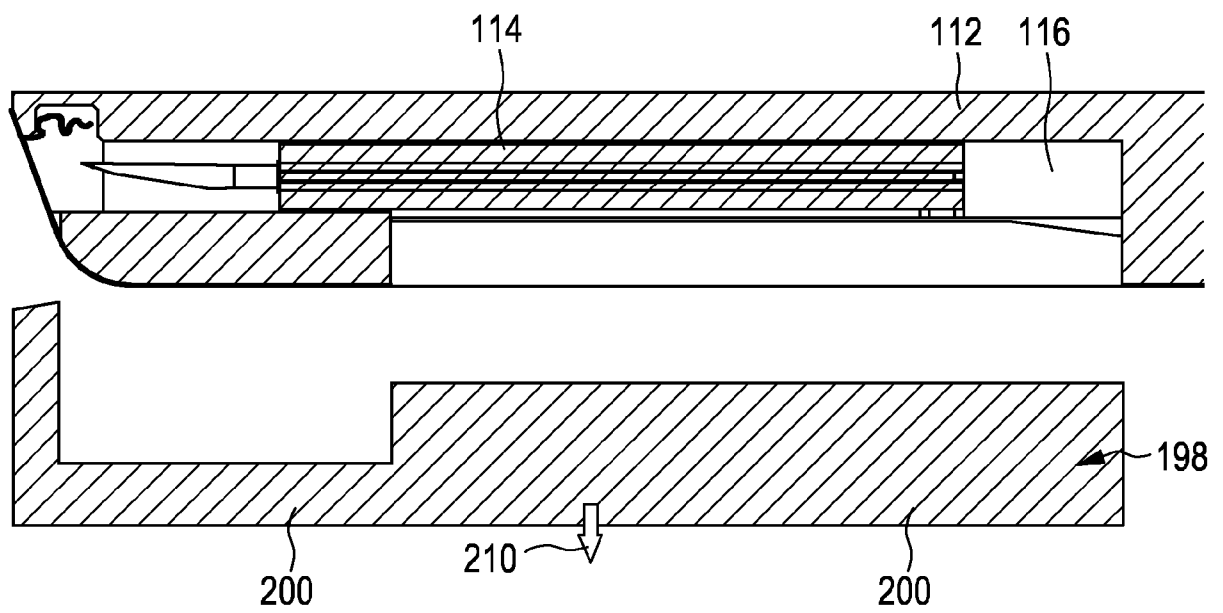


FIG. 9

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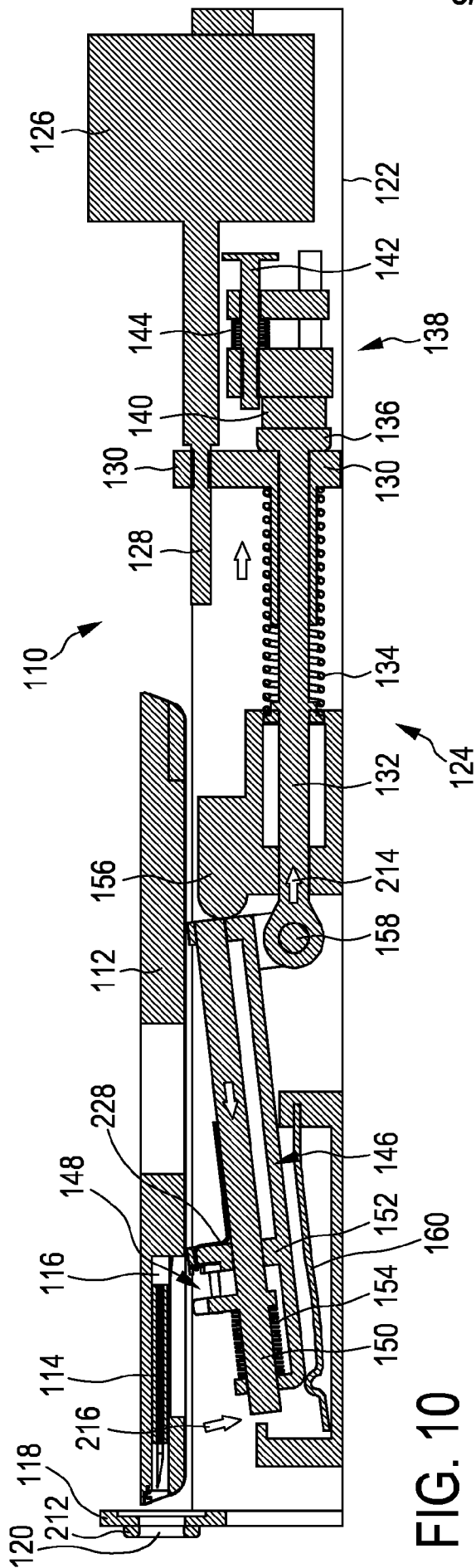


FIG. 10

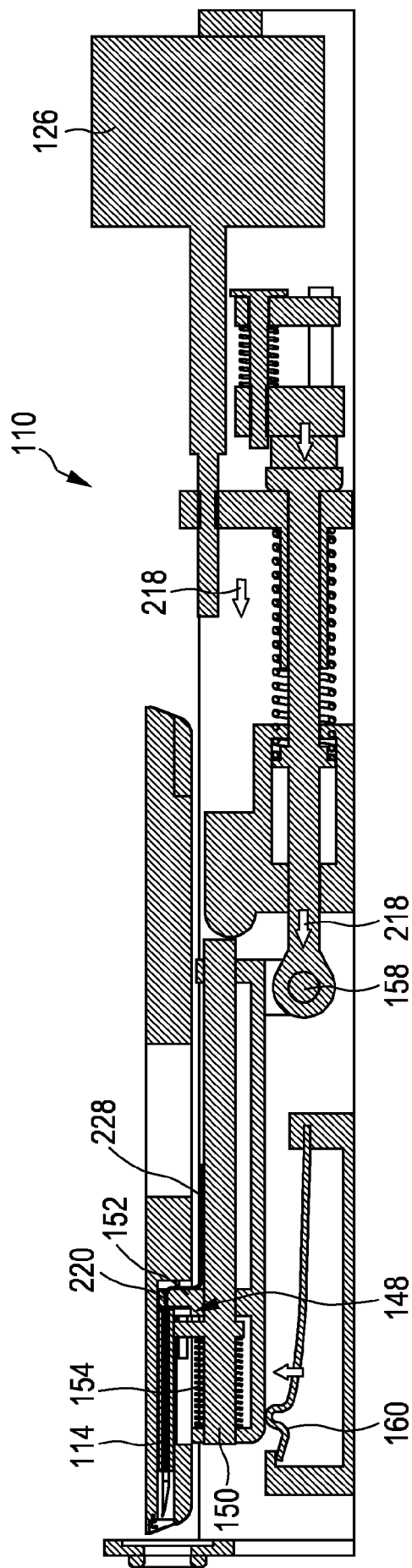
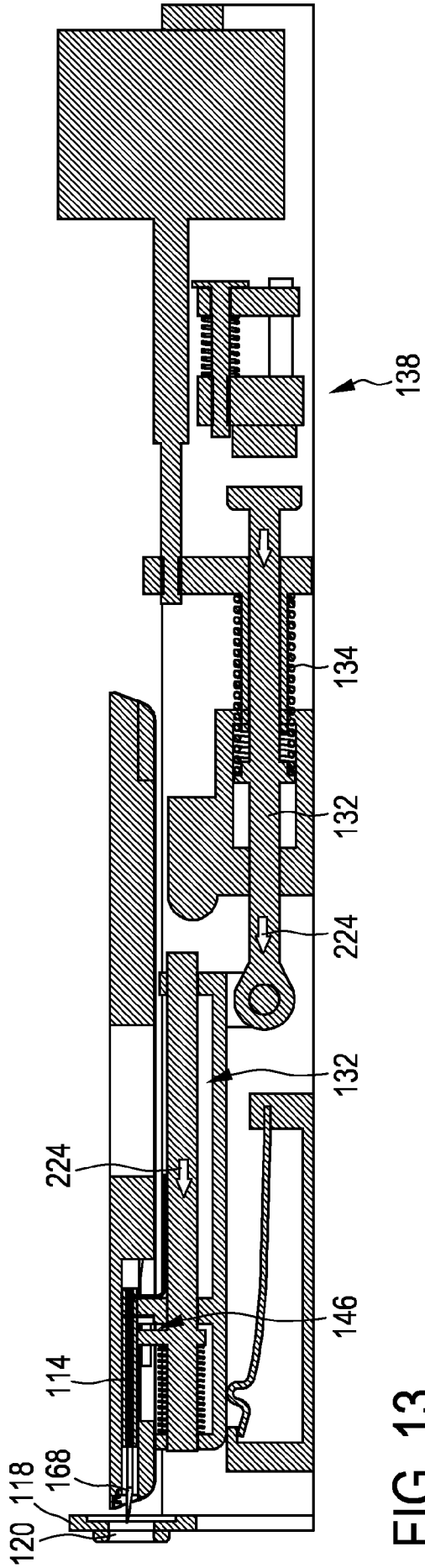
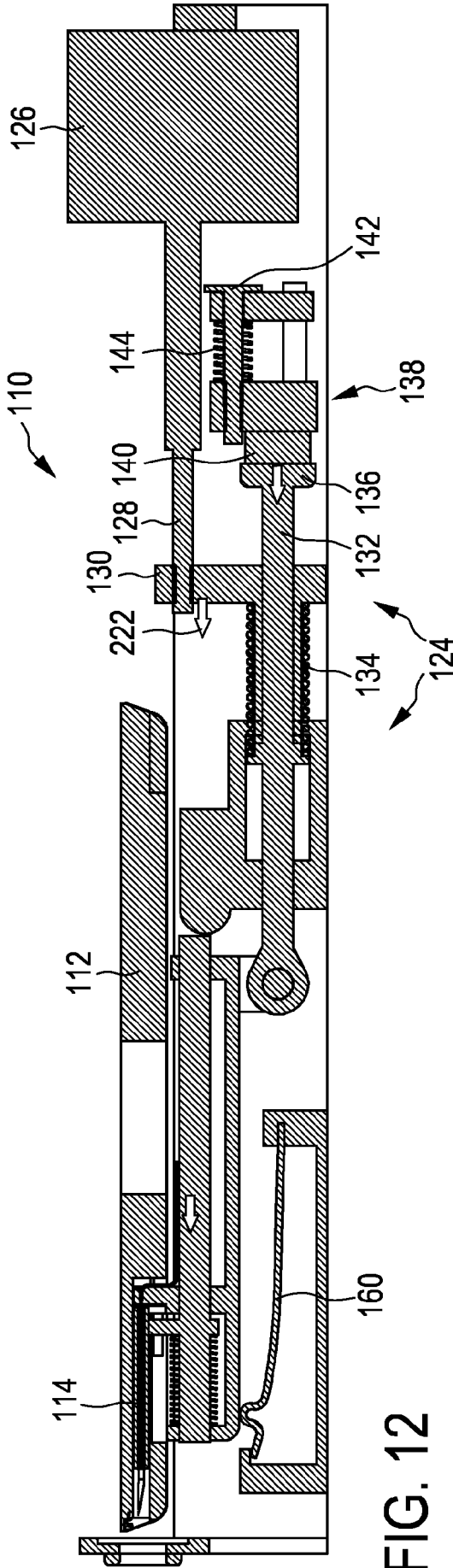
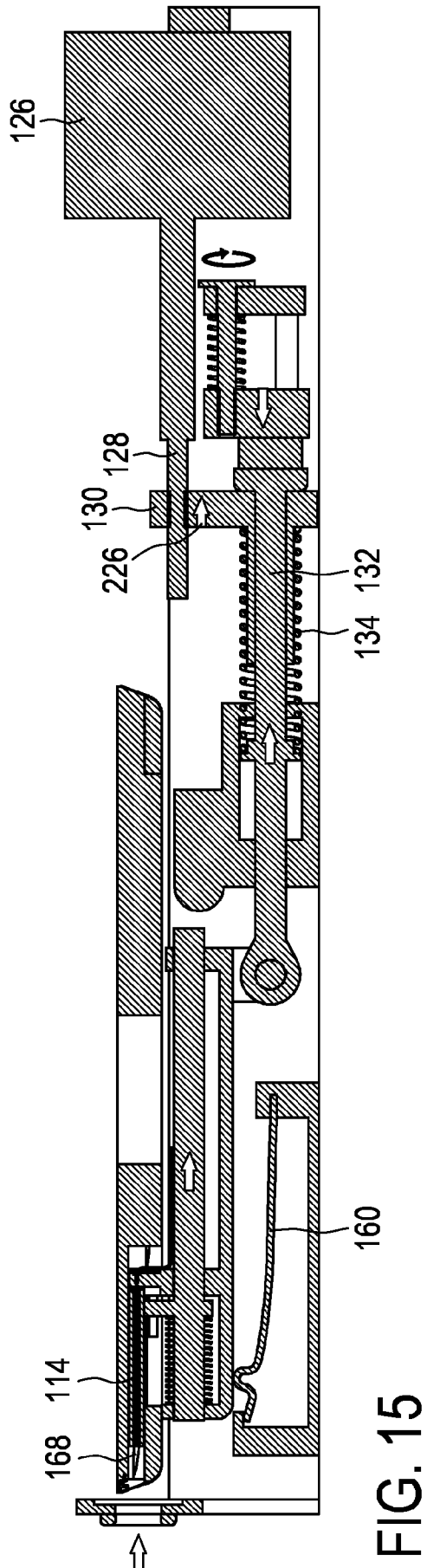
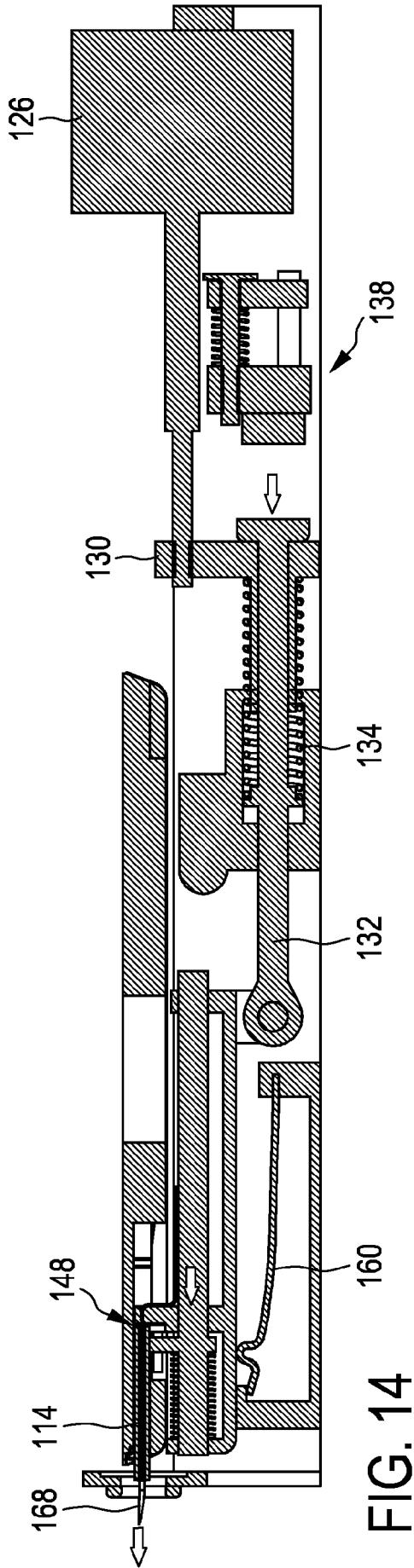


FIG. 11





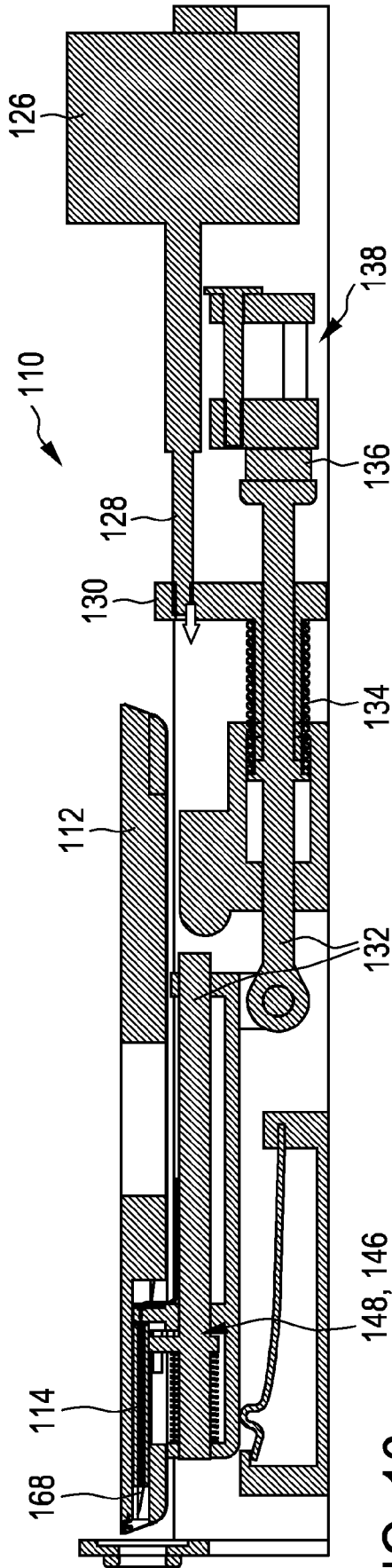


FIG. 16

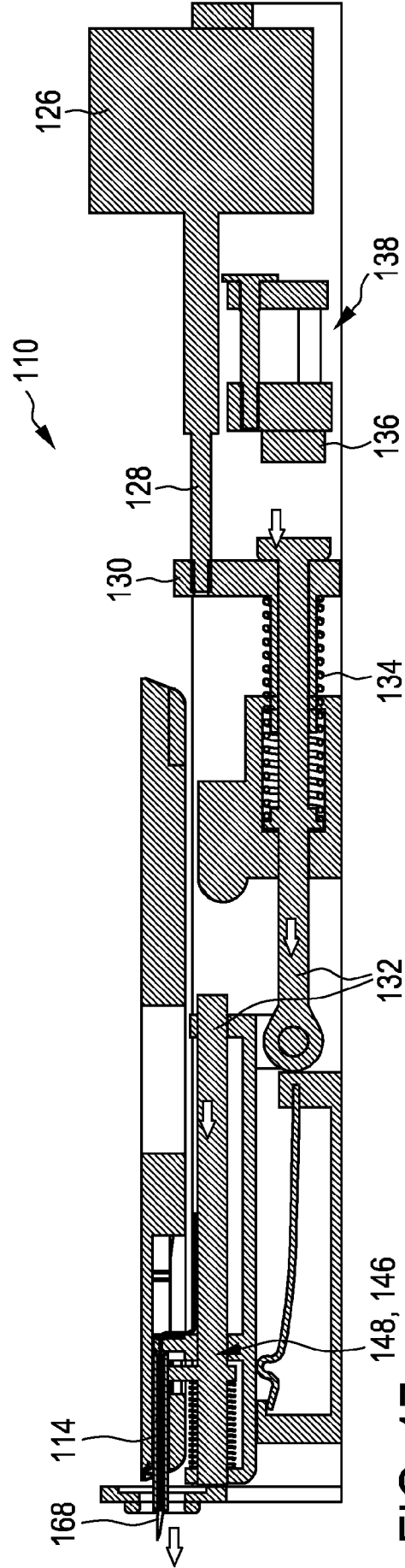


FIG. 17