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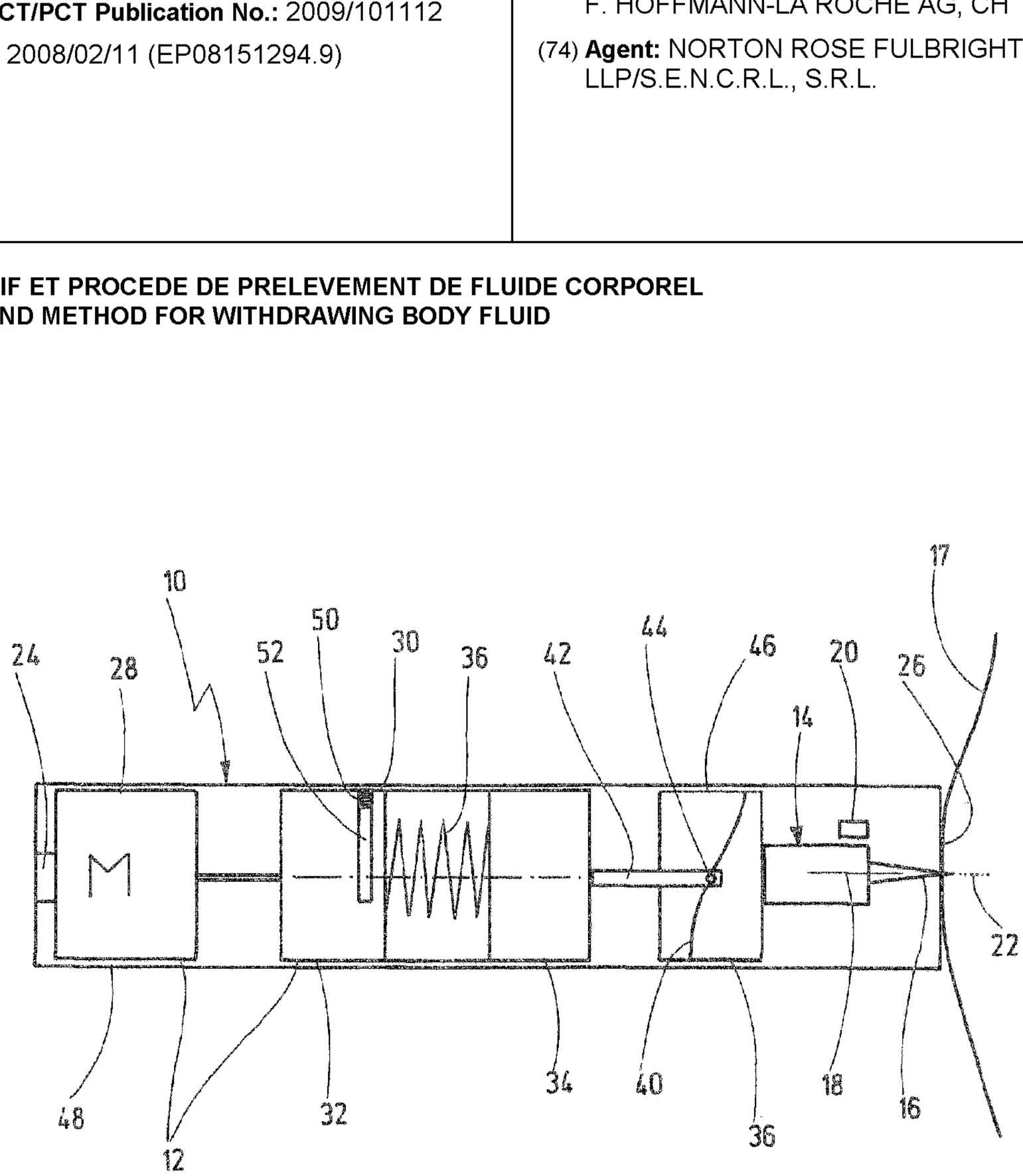
(72) **Inventeurs/Inventors:**
LIST, HANS, DE;
RODEL, WOLFGANG, DE;
HOERAUF, CHRISTIAN, DE

(73) **Propriétaire/Owner:**
F. HOFFMANN-LA ROCHE AG, CH

(74) **Agent:** NORTON ROSE FULBRIGHT CANADA LLP/S.E.N.C.R.L., S.R.L.

(54) **Titre : DISPOSITIF ET PROCEDE DE PRELEVEMENT DE FLUIDE CORPOREL**
(54) **Title: DEVICE AND METHOD FOR WITHDRAWING BODY FLUID**



(57) **Abrégé/Abstract:**
The invention concerns a device for withdrawing body fluid with a lancing element (14) that can puncture the skin of a body part (17) which has a receiving structure (18) for body fluid obtained from the skin puncture, and a lancing drive (12) for a forward and retracting movement of the lancing element (14), wherein the duration of the retracting movement is longer than the duration of the forward movement. According to the invention the lancing drive (12) is designed such that the lancing element (14) is moved in a first retraction phase (R1) of the retraction movement at a maximum retraction speed of more than 0.02 m/s.

Abstract

The invention concerns a device for withdrawing body fluid with a lancing element (14) that can puncture the skin of a body part (17) which has a receiving structure (18) for body fluid obtained from the skin puncture, and a lancing drive (12) for a forward and retracting movement of the lancing element (14), wherein the duration of the retracting movement is longer than the duration of the forward movement. According to the invention the lancing drive (12) is designed such that the lancing element (14) is moved in a first retraction phase (R1) of the retraction movement at a maximum retraction speed of more than 0.02 m/s.

Device and method for withdrawing body fluid

Description

The invention concerns a device for withdrawing body fluid with a lancing element that can puncture the skin of a body part which has a receiving structure (in particular one which acts as a capillary) for body fluid obtained from the skin puncture, and a lancing drive for a forward and retracting movement of the lancing element wherein the duration of the retracting movement is longer (preferably many times longer) than the duration of the forward movement. The invention additionally concerns a corresponding method for withdrawing body fluid.

For blood sugar tests it has already been proposed that an automatic withdrawal of sample from the skin by puncture with a lancing element can be accomplished by carrying out the retraction movement considerably more slowly than the forward movement so that an adequate amount of sample for the test can be reliably collected. In doing so the position of the transition from rapid to slower movement should be at only such a depth in the tissue that a receiving structure incorporated into the lancing element still makes a reliable contact with the escaping liquid. A lancing system is described in WO 2007/073870 which allows the transition position to be kept constant despite a variable lancing depth but with a considerable technical complexity.

Starting from this the object of the invention is to further improve the systems and methods proposed in the prior art and to ensure a reliable sample collection with limited constructional complexity and in doing so also to reduce the painfulness of the procedure.

The invention is based on the idea of placing the start of collection at an intermediate position under the skin which can be reached at a very high speed and which is situated at a fixed retraction distance behind the selected deepest puncture position. In this connection it is provided that the lancing element is moved in a first retraction phase of the rectracting movement at a maximum retraction speed of more than 0.02 m/s. This measure allows the maximum lancing depth to be selected according to the individual skin properties in such a manner that sufficient blood capillaries are opened by the puncture while this particularly pain-intensive phase is reduced to a minimum by the rapid first return movement. The collection process then only takes place in the subsequent second retraction phase which is designed so that body fluid flows into the receiving structure. For this purpose the duration of the skin puncture should be long enough to enable uptake of the required amount of sample. However, it has surprisingly turned out that an excessively slow movement of the lancing element impedes blood uptake. Furthermore, the collecting phase should be completed within a defined time interval in order to also suffice the boundary conditions for the lancing depth. Accordingly it is proposed according to the invention that the lancing drive is designed to retract the lancing element from the skin during a second retraction phase for collecting body fluid into the receiving structure which follows the first retraction phase in such a manner that the retraction speed is between 0.6 and 2 mm/s and/or the collecting period is in a range between 0.3 and 0.8 s.

According to a preferred embodiment the lancing element is pulled back during the first retraction phase by a defined first partial distance preferably of up to 0.5 mm from the deepest puncture position into an intermediate position situated under the skin surface. In this connection the skin surface can be determined by the device by

means of an appropriate reference position for example by a positioning for the body part or a skin detector or a predetermined lancing depth. Furthermore, the constant first retraction distance enables one to dispense with a technically complicated movement control thus enabling a harmonious motion sequence in the region where the direction of the needle is reversed without vibration-critical stop structures.

The return movement of the lancing element preferably takes place in such a manner that the receiving structure can at least be substantially filled with body fluid during the collecting period while the lancing element still projects into the skin. In this connection it should be noted that an appreciable uptake of body fluid released into the puncture wound does not take place until after the first rapid retraction phase.

It is particularly advantageous when the duration of the forward movement and of the first retraction phase is between 0.3 to 3 ms, preferably 0.3 to 0.7 ms thus enabling a harmonious motion sequence for the initial puncture process.

The collection period for taking up body fluid into the receiving structure should advantageously be between 0.4 and 0.5 s. In this connection it is also particularly advantageous when the mean retraction speed of the lancing element during the second retraction phase is in a range of 1 to 1.5 mm/s.

For a user-related collecting profile it should be possible to adjust the maximum lancing depth between 1 and 2.5 mm.

The speed time course during the return movement of the lancing element is advantageously adapted in accordance with a variable lancing depth in such a manner that the lancing element remains inserted into the skin for a predetermined

dwell period. This enables an individual adaptation of the puncture depth without constantly changing the cycle durations.

For a simpler movement control it can be advantageous when the speed time course during the retraction movement of the lancing element is preset independently of the lancing depth.

Another improvement with regard to sample collection is achieved by the fact that the speed of the lancing element in the second retraction phase is essentially constant.

A test element to which body fluid can be applied from the receiving structure is provided for a simplified handling in an integrated system.

In order to substantially exclude disadvantageous changes in the samples, the total duration from the start of the retraction movement of the lancing element until loading the test element with the body fluid should be less than 5 s, preferably less than 1 to 2 s.

Another supplementary or alternative aspect of the invention is that a test element designed to detect an analyte in the body fluid is arranged in such a manner that the transfer time for transferring the body fluid from the receiving structure onto the test element (20) is less than 1.5 s, preferably less than 1 s and preferably less than 0.5 s. It has surprisingly turned out that adherence to this time window is particularly important for the test quality. The test element can be directly arranged on the lancing element and optionally be fluidically connected to the receiving structure via a flow path. It is also possible to arrange the test element separately and in particular physically separate from the receiving structure and to transfer the liquid by a

suitable actuation for example with structure deformation. Reference is made in this connection to WO 2005/084530 and WO 2007/025713 as examples.

The lancing element advantageously has a sharp lancing member which penetrates in a low-pain manner into the skin during skin puncture and in particular a single needle tip.

In order to take into consideration possible dents in the skin during puncture, it is possible to register the position of the skin surface by a skin detector and/or to define it for the body part by means of a positioning unit.

Sample collection is considerably simplified by means of the fact that a channel structure and in particular a groove-shaped or slot-shaped channel structure that can be brought into contact with the body fluid at least at a distal end section during skin puncture, is incorporated into the lancing element.

Another advantageous aspect of the invention is the fact that the drive mechanism controls the forward movement and retraction movement during a first retraction phase of the lancing element whereas the drive motor retracts the lancing element from the skin in a second retraction phase of the retraction movement. This allows a favourable movement profile to be achieved by simple technical means. This is particularly important for test devices required in large numbers. The drive mechanism can be effectively designed for the rapid movement and the motor provided for the slow remaining movement can be designed to be compact and energy saving.

The drive motor advantageously supplies the drive mechanism with mechanical energy for automatic movement control.

Another improvement is achieved by means of the fact that the drive motor retracts the drive mechanism together with the lancing element as a combination in the second retraction phase.

A constructionally particularly advantageous embodiment provides that the drive mechanism has a cam control driven by means of a spring.

The invention also concerns a method for withdrawing body fluid in which a forward and retraction movement of a lancing element is controlled by a lancing drive in such a manner that the lancing element is retracted in a first retraction phase of the retraction movement at a maximum retraction speed of more than 0.02 m/s and in which the lancing element is retracted from the skin during a second retraction phase for collecting body fluid in the receiving structure which follows the first retraction phase in such a manner that the collection period is in a range between 0.2 and 0.8 s and/or the retraction speed is between 0.8 and 1.5 mm/s.

In accordance with one aspect of the present invention, there is provided a device for withdrawing body fluid, comprising: a lancing element adapted for puncturing skin of a body part, the lancing element having a receiving structure for collecting the body fluid obtained by capillary action; and a lancing drive for moving the lancing element in forward and return movements; wherein the duration of the return movement is several times longer that the duration of the forward movement, the return movement comprising a first retraction phase during which the lancing drive is configured to move the lancing element at a maximum retraction speed of more than 0.02 m/s, the first retraction phase being followed by a second retraction phase for collecting the body fluid into the receiving structure, the lancing drive being configured to move the lancing element during the second retraction phase for a duration of between 0.3 and 0.8 s and/or a retraction speed of between 0.6 and 2 mm/s.

In accordance with another aspect of the present invention, there is provided a device for withdrawing body fluid, comprising: a lancing element adapted for puncturing skin of a body part, the lancing element having a receiving structure for collecting the body fluid obtained by capillary action; and a lancing drive for moving the lancing element in forward and return movements; a test element for detecting an analyte in the body fluid, the lancing drive being configured to move the lancing element at a speed during the return movement such that a transfer time for transferring the body fluid from the receiving structure onto the test element is less than 1.5 s, wherein the total duration from the start of the return movement of the lancing element until completion of loading the test element with the body fluid is less than 5 s.

The invention is further elucidated in the following on the basis of an embodiment example shown schematically in the drawing.

Fig. 1 shows a device for blood sugar tests with a multi-stage lancing drive in a simplified sectional diagram.

Fig. 2 shows a lancing profile when using the device according to fig. 1.

The device shown in fig. 1 enables a user to himself remove a blood sample for analytical purposes and in particular for blood sugar monitoring. The device comprises a hand-held device 10 with a lancing drive 12 for automatically handling a lancing element 14 used as a single-use article for blood withdrawal.

The lancing element 14 is designed as a so-called "microsampler" for collecting a small amount of blood from a body part 17 and in particular from a fingertip. As a monolythic one-piece moulded part it can consist of thin stainless steel sheet and have a distally shaped tip 16 as a lancing member to produce a puncture wound. A groove-shaped or slot-shaped capillary channel 18 whose distal end section extends into the area of the tip 16, enables the uptake of body fluid (blood and/or tissue fluid) from the puncture wound. A test element 20 provided with a test chemistry which can be loaded with body fluid from the receiving structure 18 by making a suitable flow connection after the skin puncture can be used to detect the target substance (glucose) present in the body fluid. Blood glucose detection especially by means of contact-free optical methods is known in the prior art and is therefore not elucidated in more detail here.

The lancing drive 12 enables a controlled forward and retraction movement of the lancing element 14 along a lancing axis 22 where the lancing depth can be advantageously selected by the user in a range between 1 and 2.5 mm for adaptation to various skin types by means of an adjusting unit 24. The position of the skin surface can be optionally predetermined for the body part 17 by means of a positioning unit 26.

For a multiphase motion control the lancing drive 12 comprises an electrical drive motor 28 and a drive mechanism 30 that is pretensioned by the motor and operates purely mechanically. The drive mechanism 30 controls the rapid forward movement and a first rapid phase of the return movement whereas the drive motor 28 slowly retracts the lancing element 14 from the skin via the drive mechanism 30 in a second retraction phase. This allows the collection process to be optimized and made particularly user-friendly.

The mechanical drive mechanism 30 has a tensioning rotor 32 and a drive rotor 34 and the rotors are connected together by a pretensioned torsion spring 36. The drive

mechanism 30 additionally comprises a cam drive or sliding gate drive 38 which translates the rotary motion of the drive rotor 34 into a translatory or lancing motion of the coupled lancing element 14 using a control cam 40. For this purpose the free end of a control arm 42 which extends from the drive rotor 34 engages in the circumferential control cam 40 by means of a cam slider 44. When the drive rotor 34 rotates, a stroke is generated corresponding to the cam slope whereby the cam drive 38 is guided by a linear guide 46 in the device housing 48.

The relative rotation of the two rotors 32, 34 can be mutually limited by stop elements 50, 52 in order to take up the pretension of the spring 36 and to stop the drive rotor 34 in a desired rotation angle position. In a preparatory tensioning phase the drive rotor 34 is locked against rotation with respect to the housing 48 so that the spring 36 can be tensioned by the tensioning rotor 32 by rotating the motor 28 until the stop elements 50, 52 reach their initial position. The lock on the drive rotor 34 is released at a given angular position of the tensioning rotor 32 by a trigger that is not shown so that the drive rotor 34 instantaneously rotates in a spring-driven manner until the stop member 50 on the drive rotor side strikes against the other end of the stop groove 52 on the tensioning rotor side. In this manner it is possible to travel through an angular range of the control cam 40 in order to very rapidly execute the forward movement and the first retraction phase of the retraction movement.

Further details of a suitable drive mechanism are described in EP-A 1 669 028 which in this regard is made a subject matter of the present application by way of reference.

As mentioned the drive side of the drive motor 28 is coupled to the tensioning rotor 32 in order to supply the mechanism 30 with mechanical energy in a preparatory tensioning phase. Another important function of the drive motor 28 is the controlled slow return movement of the lancing element 14 during the second retraction phase.

In this process the stop elements 50, 52 are held in the end position described above by the remaining spring tension. As a result the drive mechanism 30 can be rotated further as a unit in order to travel through the remaining section of the control cam 40 during which the lancing element 14 is retracted at a defined retraction speed. In this phase the lancing member 16 which is still situated under the skin can take up sufficient blood from the partially vacated puncture wound by means of the collecting structure 18. The collected blood is subsequently transferred onto the test element 20 by a suitable actuation within preferably 0.5 s in a transfer step. For this purpose the test element 20 is arranged near enough to the receiving structure so that liquid transport takes place in the specified time taking into account the achievable transport rate.

The lancing profile shown in fig. 2 is particularly advantageous for a blood collection that is as effective and pain-free as possible. In this connection the term "lancing profile" is to be understood as the time course of the lancing movement which is shown as a function of lancing depth over time.

In phase v of the forward movement, the tip 16 of the lancing element 114 strikes the skin at t = 0 at a high speed and penetrates in one movement down to the desired puncture depth d. This depth must be individually optimized in order to extend through the epidermis to reach the dermis containing the blood capillaries. The duration of the forward movement is preferably between 0.3 and 0.7 ms.

Then in the first retraction phase R1 the tip 16 is pulled back by a predetermined distance Δd of about 0.5 mm to an intermediate position situated under the skin surface. This retraction position is preferably in the stratum corneum of the epidermis. This first retraction R1 should take place as rapidly as possible because the lancing element 14 which has been excited to vibrate by the sharp reversal of direction should not execute too many oscillation periods in the blood-carrying and innervated dermis. Hence, the maximum retraction speed reached shortly after the

movement is reversed should not be more than 0.02 m/s. Accordingly the duration of the first retraction phase is limited to a range between 0.3 and 3 ms. As elucidated above a uniform, harmonious sequence of motions is achieved in phases v and R1 by means of the drive mechanism 30.

The retraction of the lancing element 14 is considerably slowed down at the end of the phase R1 so that the collection process can take place during the subsequent second retraction phase R2. In this connection it has surprisingly turned out that the retraction speed should not fall below a minimum value and should still be high enough so that the skin tissue readily releases liquid. On the other hand, the collection period should be sufficiently long to allow the receiving structure or capillary 18 to collect the liquid which can take up to 500 ms taking into consideration production tolerances and aging effects. It must also be borne in mind than an excessive dwell period of the lancing element in the inserted state in the skin will be disagreeable to the user. In order to achieve a sufficient uptake of blood into the receiving structure 18, the speed of the lancing element in the second retraction phase should be essentially constant and a value between 1 and 1.5 mm/s is favourable. Such a relatively slow retraction can be achieved in an energy-saving manner by applying a voltage which is kept constant by simple means to a compact drive motor 28.

The lancing profile can be predefined independently of the lancing depth. In the case of a deeper puncture the curve shown in fig. 2 is then, as it were, shifted upwards without alteration. Alternatively it may be of advantage to adapt the speed time course depending on a selectively changed lancing depth in such a manner that a defined dwell time is reached in the punctured state.

CLAIMS:

1. A device for withdrawing body fluid, comprising:

a lancing element adapted for puncturing skin of a body part, the lancing element having a receiving structure for collecting the body fluid obtained by capillary action; and

a lancing drive for moving the lancing element in forward and return movements;

wherein the duration of the return movement is several times longer that the duration of the forward movement, the return movement comprising a first retraction phase during which the lancing drive is configured to move the lancing element at a maximum retraction speed of more than 0.02 m/s, the first retraction phase being followed by a second retraction phase for collecting the body fluid into the receiving structure, the lancing drive being configured to move the lancing element during the second retraction phase for a duration of between 0.3 and 0.8 s and/or a retraction speed of between 0.6 and 2 mm/s.

2. The device according to claim 1, wherein the lancing element is configured to retract during the first retraction phase by a distance of up to 0.5 mm.

3. The device according to claim 1 or 2, wherein the receiving structure is configured to be filled with the body fluid during a collecting period while the lancing element still projects into the skin.

4. The device according to any one of the claims 1 to 3, wherein the duration of the forward movement is between 0.3 and 3 ms.

5. The device according to claim 4, wherein the duration of the forward movement is between 0.3 and 0.7 ms.

6. The device according to one of the claims 1 to 5, wherein the duration of the first retraction phase is between 0.3 and 3 ms.

7. The device according to any one of the claims 1 to 6, wherein the second retraction phase has a duration of between 0.4 and 0.5 s.

8. The device according to anyone of the claims 1 to 7, wherein the mean retraction speed of the lancing element during the second retraction phase is between 1.0 and 1.5 mm/s.

9. The device according to one of the claims 1 to 8, wherein a maximum lancing depth is adjustable between 1 and 2.5 mm.

10. The device according to any one of the claims 1 to 9, further comprising a variable lancing depth, wherein the speed of the lancing element during the return movement is adapted as a function of the variable lancing depth such that the lancing element is configured to remain inserted into the skin for a predetermined dwell period.

11. The device according to any one of the claims 1 to 9, wherein the speed of the lancing element during the return movement is presettable independently of the lancing depth.

12. The device according to any one of the claims 1 to 11, wherein the speed of the lancing element in the second retraction phase is constant.

13. The device according to any one of the claims 1 to 12, further comprising a test element for detecting an analyte and to which the body fluid from the receiving structure is applicable.

14. The device according to claim 13, wherein the total duration of the return movement of the lancing element is less than 5 s.

15. The device according to claim 14, wherein the total duration of the return

movement of the lancing element is less than 2 s.

16. A device for withdrawing body fluid, comprising:

a lancing element adapted for puncturing skin of a body part, the lancing element having a receiving structure for collecting the body fluid obtained by capillary action; and

a lancing drive for moving the lancing element in forward and return movements;

a test element for detecting an analyte in the body fluid, the lancing drive being configured to move the lancing element at a speed during the return movement such that a transfer time for transferring the body fluid from the receiving structure onto the test element is less than 1.5 s, wherein the total duration from the start of the return movement of the lancing element until completion of loading the test element with the body fluid is less than 5 s.

17. The device according to claim 16, wherein the transfer time for transferring the body fluid from the receiving structure onto the test element is less than 0.5 s.

18. The device according to claim 16 or 17, wherein the total duration from the start of the return movement of the lancing element until completion of loading the test element with the body fluid is less than 2 s.

19. The device according to any one of the claims 1 to 18, wherein the lancing element comprises a channel configured to be brought into contact with the body fluid during skin puncture.

20. The device according to any one of claims 1 to 19, wherein the lancing drive has a drive motor and a mechanical drive mechanism, the drive mechanism configured to control the forward movement and the return movement during a first retraction phase of the lancing element and the drive motor configured to effect the return movement of the lancing element in a second retraction phase.

21. The device according to claim 20, wherein the drive motor is configured to supply the drive mechanism with mechanical energy for automatic movement control.

22. The device according to claim 20 or 21, wherein the drive motor is configured to retract the lancing element in the second retraction phase by means of the drive mechanism.

23. The device according to any one of the claims 20 to 22, wherein the drive mechanism has a spring-driven cam control.

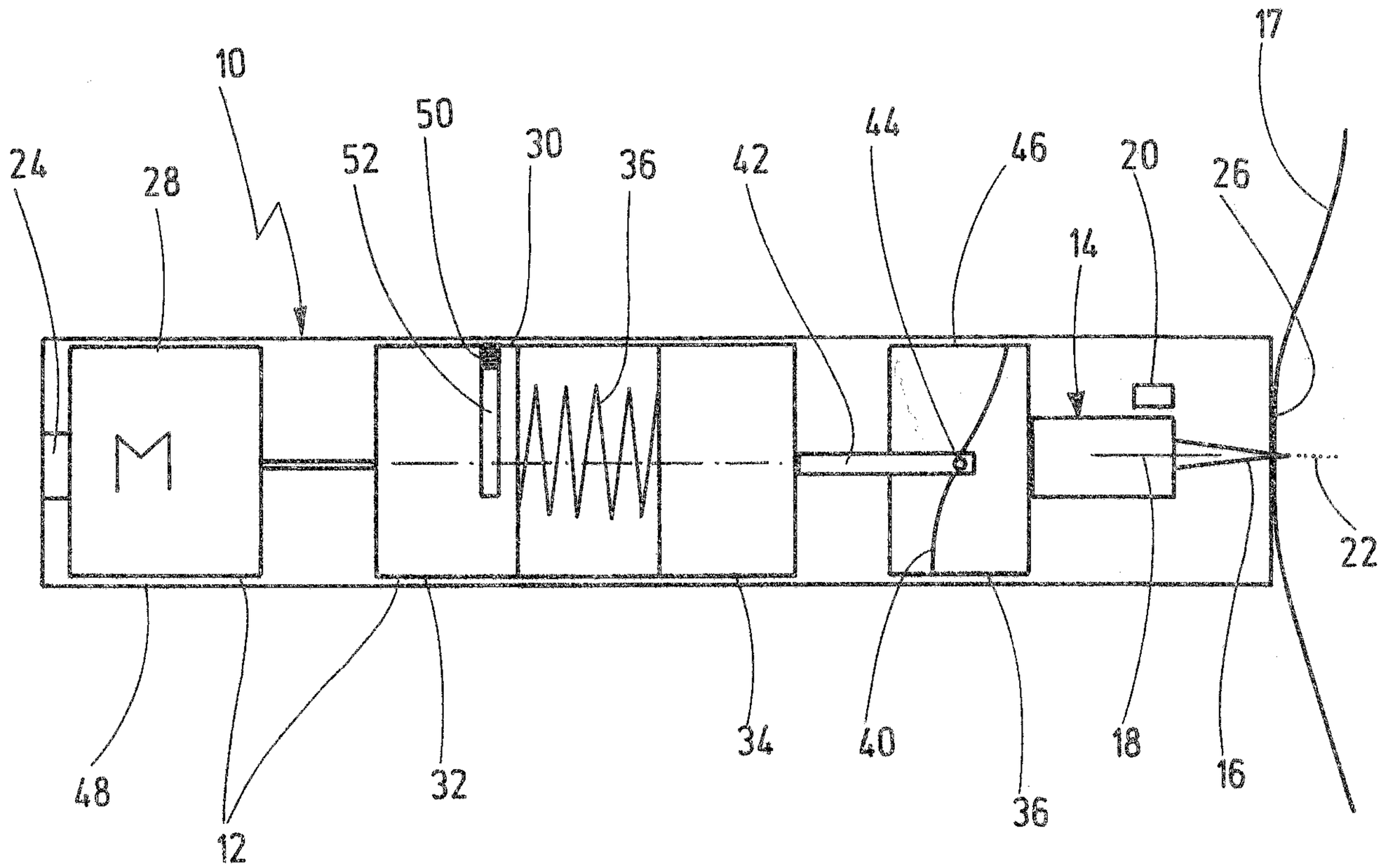

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Fig.1

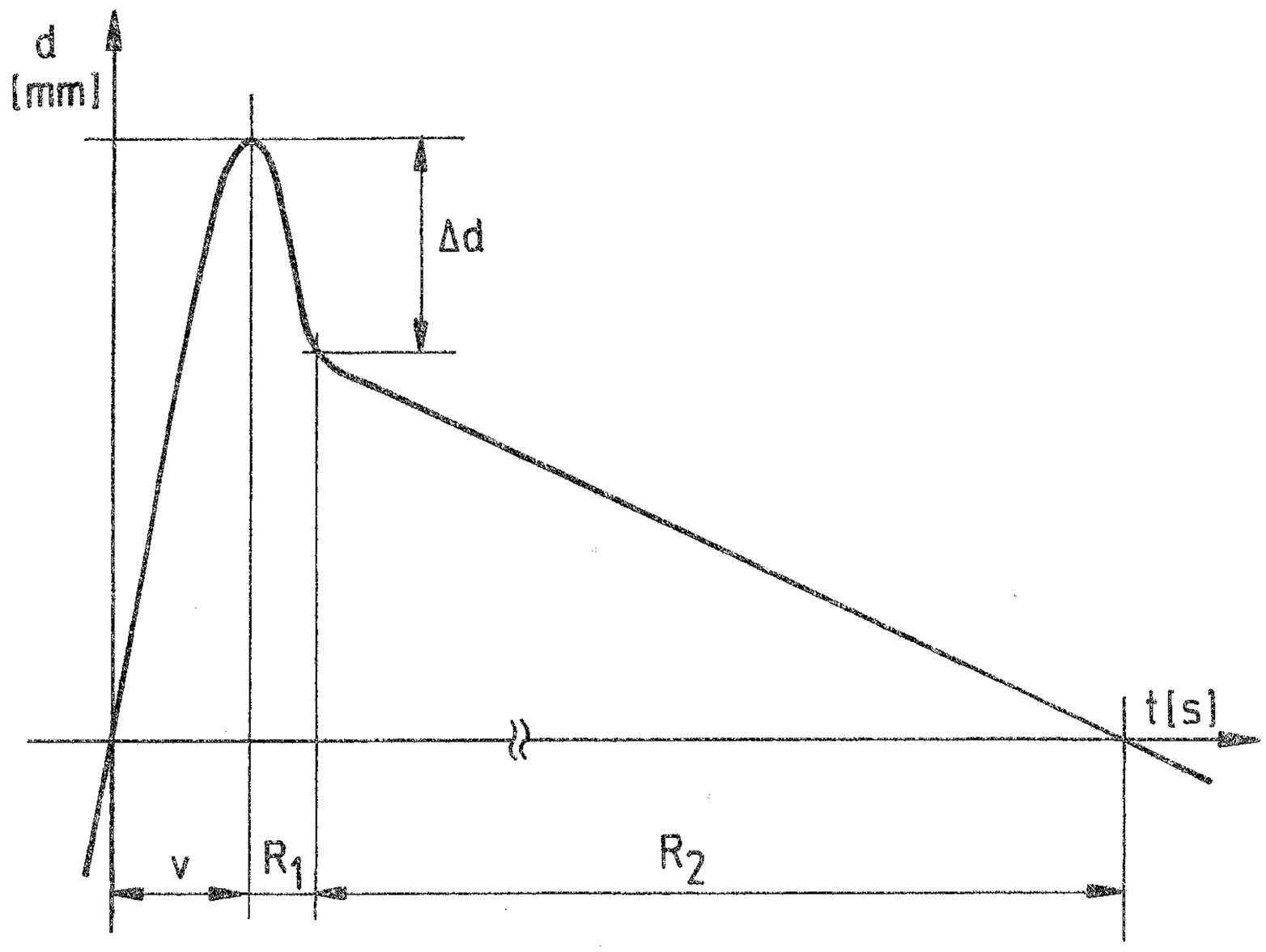
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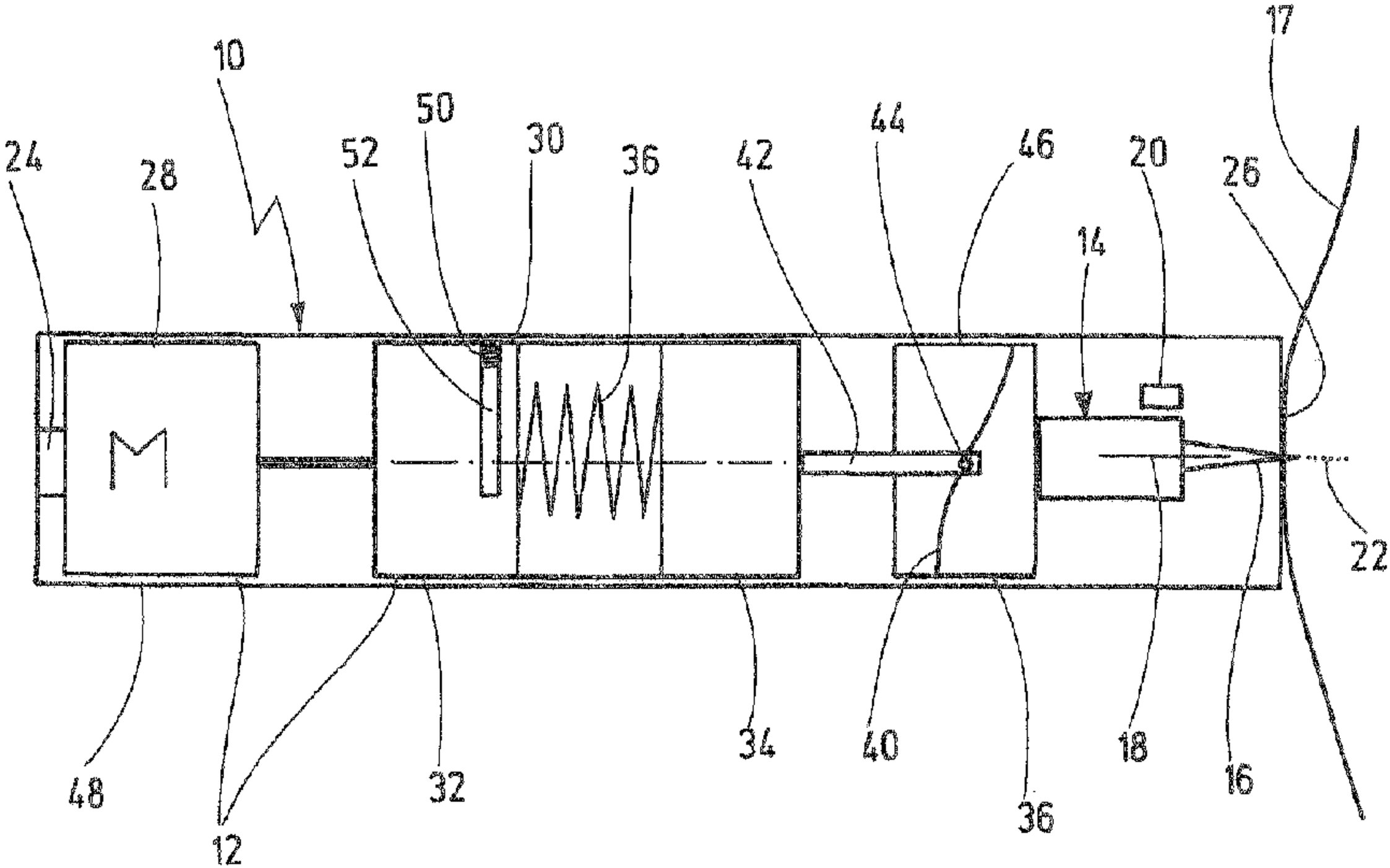
Fig.2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