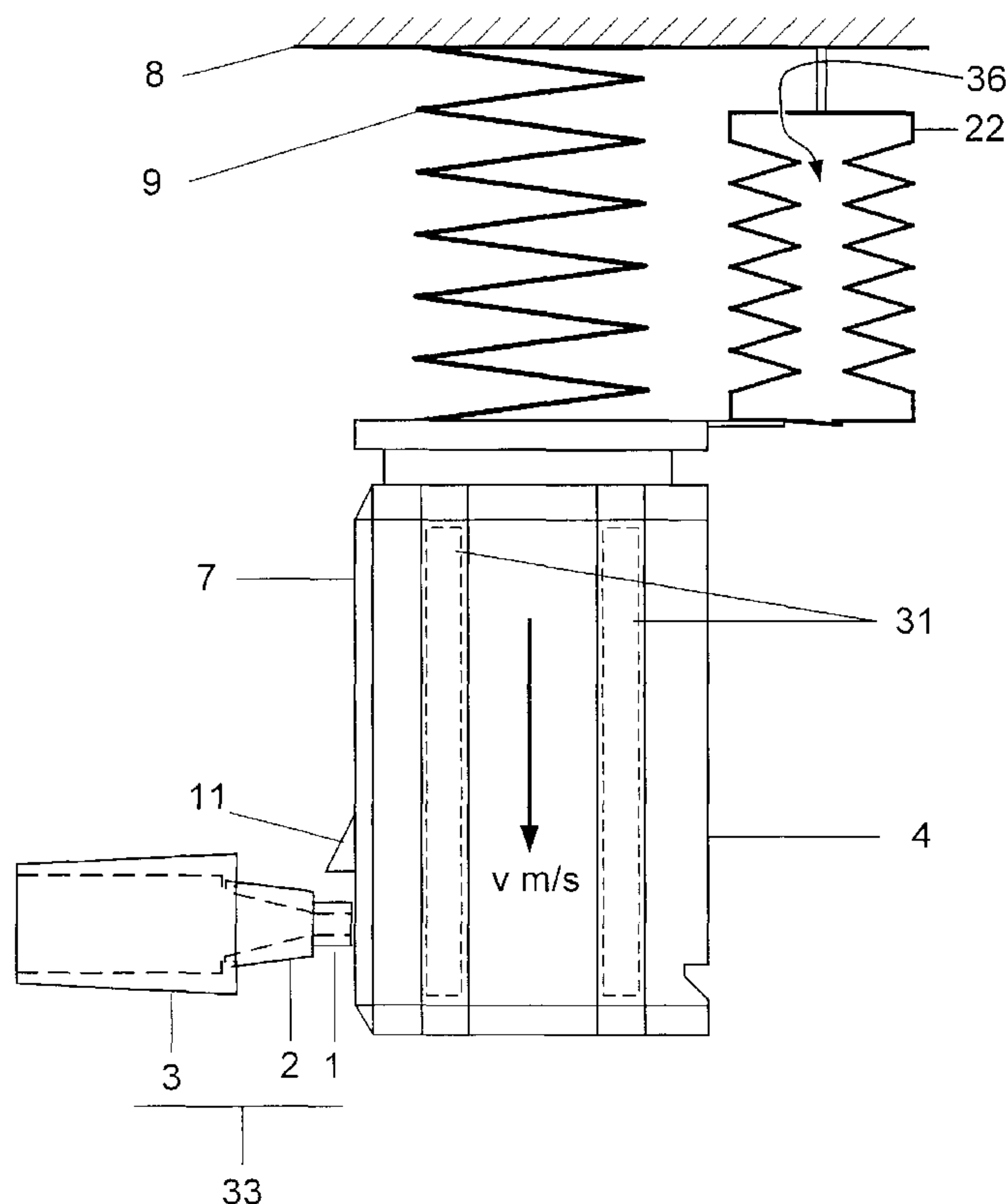




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(57) **Abrégé/Abstract:**

A device is disclosed for controlling the duration of an administration of a prescribed dose of dry powder to a user's lung when inhaling the powder by means of a dry powder inhaler (DPI). The present device controls the speed of a moving cassette (4) carrying medication powder doses to be administered by the DPI one by one to a user. Generally the dose is pre-metered and applied to the cassette in the form of a strip (31) or a series of spots of ready-prepared powder. The present device using the airbrake arrangement (22) prolongs the time during which the pre-metered powder dose is released to the inhalation air.

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

Adjustment means of the airbrake arrangement (22) define leakage of air (36) and thereby motion speed of a spring-loaded cassette (4). During the motion of the cassette the powder dose is sucked from the prepared dose powder strip onto the cassette (4) by a nozzle (1) connected to a mouthpiece used for inhaling medication powder from the dry powder inhaler.

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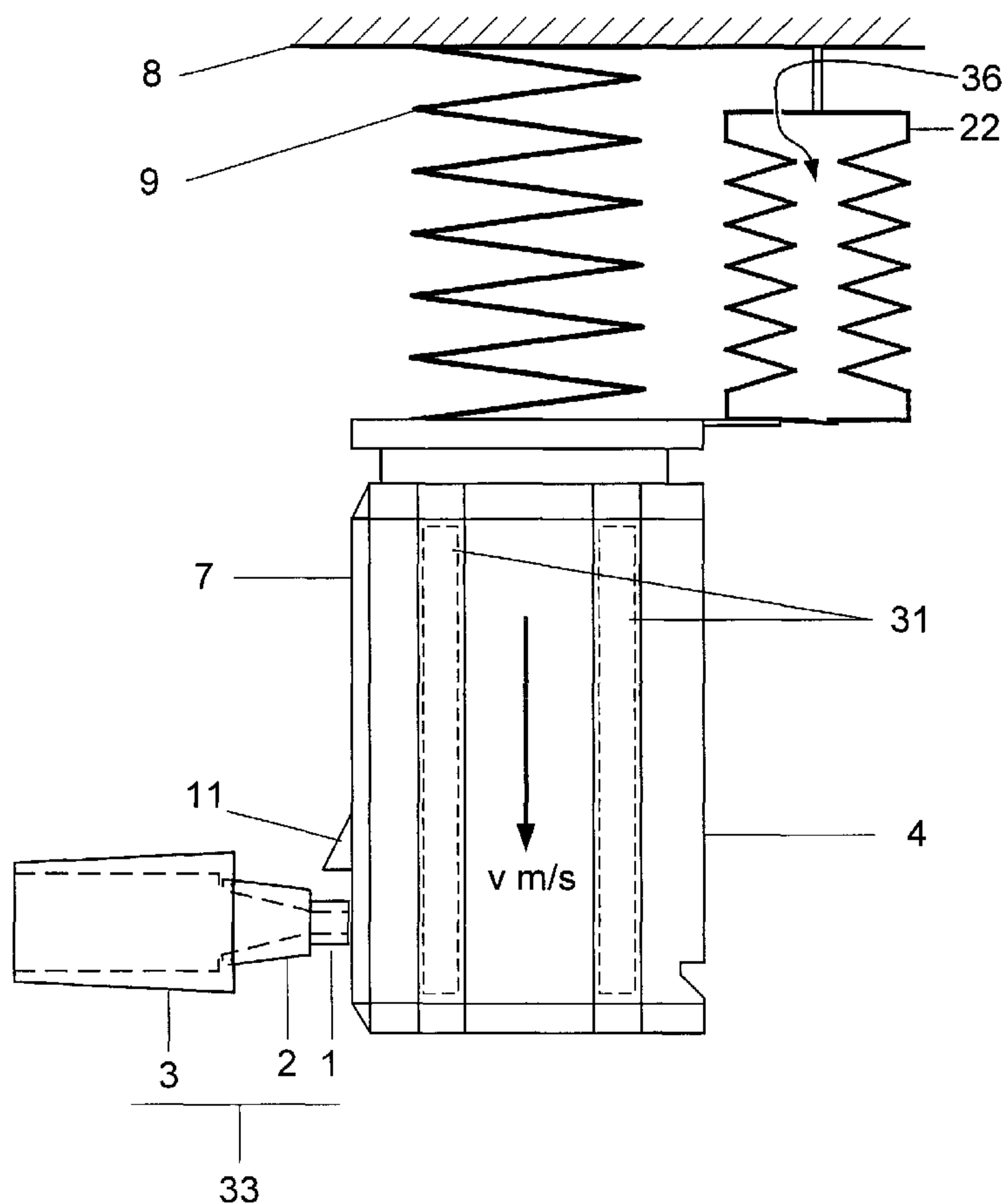
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WO 02/24267 A1

WO 02/24267 A1

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Airbrake**TECHNICAL FIELD**

The present invention relates to a dry powder inhaler for administration of a medication dry powder to the lungs of a user, and more exactly to an
5 airbrake device for prolonging the time for dose delivery upon inhalation.

BACKGROUND

Today supply and distribution of medication powders take place in many different ways. Within health care more and more is focussed on the
10 possibility to dose and distribute powder directly to the lungs of a user by means of an inhaler to obtain an efficient, fast, and user friendly administration of the specific medication substance.

Inhalers have been developed from being very simple to the up-to-date
15 relatively complicated devices. For the up-to-date inhalers some form of dosing process is almost entirely used for preparing the dose to be inhaled. Most often the forming of the dose with the amount to be inhaled takes place industrially in advance in a dose package containing of the order 5-50 doses. The inhaler then is loaded with this dose package as the source of each dose.
20 Other inhalers have a magazine from which the powder is dosed by some device for distribution to the inspiration air. In both cases the powder will generally be strongly agglomerated and therefore must be dispersed.

This dispersion of the agglomerates today mainly takes place by means of
25 techniques in which the energy of the inspiration air is utilized. A normal inhalation takes place during about two seconds and a peaceful inspiration takes 3 - 4 seconds. In such designs, in which only the inhalation air is utilized for the de-agglomeration, only a fraction of the energy of the inhalation air will be utilized, as the dose of powder is given normally during
30 only 0.1 to 0.4 s. Consequently this results in a low exploitation of the available energy which, as a matter of fact, will be present in the inhalation air. As only a small portion of the amount of energy is used it will be too low for a sufficient de-agglomeration to take place. The total respirable dose

therefore becomes very dependent on the occasion and the individual user and thereby very varying from time to time. To improve this condition a number of inhalers include some kind of device against which the powder should collide and thereby transfer energy for de-agglomerating the powder.

5 However, such a collision with a fixed or mechanically moving object involves that a relatively large amount of powder sticks in the device either permanently or some amount thereof gets transported further together with the next dose. In both cases this constitutes a negative factor for the goal of obtaining a high accuracy and quality of the inhaled dose, e.g. an accurate

10 amount of powder having a high portion of very small particles.

In a document WO97/00704 is described an inhaler device in which the substance to be administered is charged electrostatically and the forming of the doses is performed by means of the assistance of a rotating dosing drum

15 attracting the charged particles of the substance. The substance is then emitted from the dosing drum by means of a combination of an additional electric field and the air stream resulting from an inspiration. In advance of a desired dose administration step the substance to be administered is kept in a reservoir, loaded for instance by means of receiving a cartridge containing

20 the substance intended for many operations of the device.

However there is still a demand for simple means for controlling a dose delivery during an inhalation to obtain a full effectiveness of a pre-metered medication powder dose administered to a user's lung.

25

SUMMARY

The present invention discloses a device for controlling the duration of an administration of a prescribed dose of dry powder to a user's lung when inhaling the powder by means of a dry powder inhaler (DPI) one by one. The

30 present device controls the speed and time characteristics of a moving cassette carrying medication powder doses to be administered by the DPI to a user. Generally the dose is pre-metered and applied to the cassette in the form of a strip or a series of spots of ready-prepared powder. An airbrake

device controls the time during which the pre-metered powder dose is released to the inhalation air. Adjustment means of the airbrake device define the motion speed of spring-loaded cassette during which the powder dose is sucked from the prepared dose powder strip onto the cassette by a
5 nozzle connected to a mouthpiece.

A device for controlling dosing speed and timing of an inhaler device is set forth by the independent claim 1, and further embodiments are set forth by the dependent claims 2 to 7.

10

DESCRIPTION OF THE DRAWINGS

The invention will be described in the form of a preferred and illuminating embodiment and by means of the attached drawings wherein like reference numbers indicate like or corresponding elements and wherein:

15

Fig. 1 illustrates a principle sketch of an airbrake in the form of a cylinder;

Fig. 2 illustrates another principle sketch of the airbrake in the form of bellows;

20

Fig. 3 illustrates a principle sketch of the internals of the inhaler with the airbrake illustrated in the form of a bellows and with the relevant parts in their respective positions prior to an inhalation by the user;

25

Fig. 4 illustrates a principle sketch of the internals of the inhaler with the airbrake illustrated in the form of a bellows and with the relevant parts in their respective positions shortly after the inhalation by the user has begun; and

30

Fig. 5 illustrates a principle sketch of the internals of the inhaler with the airbrake illustrated in the form of a bellows and with the relevant parts in their respective positions when the inhalation by the user has ended.

DESCRIPTION OF THE INVENTION

When a user starts to inhale through the mouthpiece of the DPI, the cassette is released from its start position and begins to move propelled by a drive spring. In the preferred embodiment a compression spring is used, but it is equally possible to use a spring working in the expansion mode, indeed the force may come from other sources e.g. hydraulic or pneumatic. The cassette is carrying pre-metered doses preferably in the form of strips of powder. The powder preferably constitutes an electro-powder having well defined electrostatic properties as well as forming a major fine particle fraction with particles of a size preferably between 0.5 and 5 μm .

Referring to Figure 4, the device **22** according to the present invention is coupled to the cassette **4** carrying the prepared doses **31**. The device **22** acts as an airbrake, which controls in an administering process the speed and the timing of the moving cassette **4**. The selected dose to be administered from the cassette is transported from the moving cassette via air sucked by means of a nozzle **1** of the suction tube **33**, comprising besides the nozzle **1** a diffuser **2** and a porous tube **3**, all of which fitted to the mouthpiece (not illustrated). As the flow of inhaled air flows past the dose before going into the nozzle, the powder of the dose is sucked up and dispersed into this air for the length of time it will take for the dose onto the moving cassette to pass by the nozzle **1**. Thus the airbrake controls the delivery of the dose. The delivery can be set from a high concentration in a short time to a low concentration in a long time and anything in between. A continuous administration of the dose is thus made possible. Typically the time span for delivering the dose is of the order of 0.5 - 5 seconds.

The object of designing and including an airbrake as an important part of a dry powder inhaler is to control the particle flow and the time during which the dose is delivered to the user. These are important factors in achieving the overall goal of a continuous dose delivery to the user and in making a local or system delivery possible or a combination thereof. It is easy to adjust the

speed and timing of the cassette and thereby the time it takes to administer the dose by increasing or decreasing the braking action of the airbrake device by changing one or more of its characteristics.

5 The airbrake device is preferably in the form of a variable volume of confined air, which is coupled to the DPI body **8** and the moving cassette **4**. Preferably the airbrake is arranged such, that it is forced to expand or contract when the cassette **4** moves in relation to the body. In the preferred embodiment the confinement can be in the form of a bellows or a cylinder with a piston,
10 but also other embodiments are possible. The continuous braking action, which controls the speed of the cassette **4** is achieved by letting air into or out of the airbrake device through a controlled leakage, e.g. through one or more holes connecting the variable volume with the surrounding atmosphere. In the case of cylinder with piston a small gap between the
15 piston and the cylinder will be another possibility.

In Figures 1 and 2 are presented two illustrative embodiments of an airbrake device **22** enclosing a regulated volume of air **36** in accordance with the present invention.

20

For a better understanding of the mode of operation of the airbrake device only the vital internal parts of an inhaler are illustrated in an illustrative embodiment according to Figures 3, 4 and 5. The airbrake is illustrated as a bellows **22**, but other embodiments of the airbrake are equally possible, e.g.
25 a piston **21** and cylinder **20** arrangement as illustrated in Figure 1, and this and all other alternative embodiments are included as accepted variations of the present invention. Those skilled in the art can no doubt see several possible ways of applying the airbrake in a DPI, but common to all cases is that one end of the airbrake is fixed directly or indirectly to the body **8** of the
30 DPI and the other end is fixed directly or indirectly to a moving dose carrier, also referred to as the cassette **4**. In Figure 3 are shown the relative positions of the vital internal parts of the DPI in the loaded state prior to an inhalation by the user. For the sake of simplicity, the illustrations of Figures 3, 4 and 5

show the cassette member in the form of a cylinder carrying doses **31** arranged on the cylindrical surface in rectangular beds with the long axis parallel to the axis of the cassette. The motion of the cassette while delivering the dose is normally in a straight line along the longitudinal axis, but alternatively a rotation around the axis or a combination of rotation and linear motion will be possible, depending on the geometry of the dose distribution on the cassette member.

Fig. 4 shows the cassette shortly after beginning to inhale, the inhalation releasing the cassette from its loaded ready-to-go state by means of a release mechanism that is not part of the present invention and not illustrated in the figures. The cassette **4** is propelled forward by the drive spring **9** with a speed determined by the force of the spring **9** and the braking action of the air brake **22**. The airbrake **22** then is forced to expand as the cassette moves forward.

Assuming a zero pressure difference between the surrounding atmosphere and the internal volume of the air brake device and provided there is no leakage of air between the surrounding atmosphere and the internal volume of the air brake device, the braking power increases with the distance of travel for the cassette. The reason being that the internal volume of the airbrake is forced to increase as the cassette moves forward, which increases the induced vacuum in the then enlarged but enclosed volume of the airbrake device. This increasing difference in pressure between the internal vacuum and the external atmospheric pressure results in an increasing force, the braking force, which tries to push the airbrake back to its original size. At a certain distance of travel the counteracting forces of the drive spring **9** and the air brake **22** balance each other exactly and the cassette cannot move further.

By introducing a small controlled amount of leakage from the surrounding air to the internal air **36** volume of the airbrake the vacuum and

consequently the braking force will be reduced with time and allowing the cassette to move forward along its path of motion with a controlled speed.

Further the effects of a disturbance of the cassette movement arising for example by some mechanical imperfection or wear have to be accounted for. In these cases the airbrake will automatically help to keep the speed constant, because as the disturbance tries to slow down the moving cassette the braking action by the airbrake is simultaneously reduced, which increases the drive force of the spring that tries to overcome the disturbance.

10

The air thus leaking into the airbrake arrangement is taken from preferably filtered air inside the DPI body, eliminating the risk of dirty air clogging the aperture or apertures leaking air into the airbrake arrangement. Since the speed of the cassette is controlled such that it is repeatable from one dose to the next and if the geometry of the pre-metered dose strip is the same for all doses, the time to deliver a dose will be constant.

15

In another embodiment of the invention it is possible to arrange the air brake device such that the internal volume is forced to contract rather than expand by the moving cassette, creating an over pressure instead of vacuum, but otherwise completely analogue to the principle of operation described in the foregoing.

20

To minimize the power needed from the user to close the inhaler when pushing the cover to the closed position, which tightens the drive spring and forces the airbrake back to its original size, the airbrake has an additional air inlet with a check valve or similar arrangement, which lets air into or out of the variable volume, whichever the case may be, so that the loading operation by the user is made as easy as possible.

25

30

Also illustrated in Figure 4 is a foil cutter **11** cutting open an aluminum foil (not shown) that seals the recess **7** of the cassette surface for protecting the underlying dose **31** on the dose bed in order to make a selected dose

accessible to the air stream upon an inhalation. The cutter is in a fixed position such that when the cassette is pushed past the cutter it cuts through the foil and opens it up just before the nozzle **1**, which is part of the suction tube consisting of a nozzle **1**, a diffuser **2** and a porous tube **3**. Next
5 the dose on the dose bed reaches the point where the nozzle is positioned and as the cassette is pushed past the nozzle, the inhaled air sucks up and disperses the powder of the dose in the stream of air and delivers the dose to the user for the pre-set amount of time.

10 In Figure 5 the cassette has reached the end of its travel, the dosing is completed and the full dose has been delivered to the user.

Particularly the present invention will be of great interest in the design of a new continuous inhaler, which thereby will present a number of advantages
15 in comparison to prior art inhalers found on the market today and which commonly deliver a dose during a very short period of time, often of the order 0.2 to 0.3 seconds.

The present invention has been described by means of an illustrative
20 embodiment for disclosing its operation, but it will be apparent to a person skilled in the art, that there may be performed numerous modification and changes to the present invention without departure from the object and scope thereof, which are defined by the appended claims

CLAIMS

1. A device for a dry powder inhaler for controlling the motion of a cassette member (4) containing pre-metered doses of powder for administration by a dry powder inhaler, **characterized by**

5 a device member (20, 22) enclosing a volume of air (36), which volume will be compressed or expanded by a motion action of the cassette member (4) being propelled by an exerted first force thereby creating an over-pressure or vacuum inside the device member (20, 22) to thereby forming a second force counteracting the first force;

10 an arrangement for letting out or letting in air into the device member (20, 22) at a selected rate, which may vary during an active phase for controlling a motion speed and timing of the cassette member.

2. The device according to claim 1, **characterized in** that the device member forming an airbrake is a cylinder (20) with a piston (21) and provided with an arrangement for controlling a fixed or varying leakage of air between an interior air (36) volume and surrounding atmosphere.

3. The device according to claim 1, **characterized in** that the device member forming an airbrake is a bellows (22) provided with an arrangement for controlling a fixed or varying leakage of air (36) between an interior air volume and surrounding atmosphere.

4. The device according to claim 2 or 3, **characterized in** that the first force is exerted by a loaded spring (9) or corresponding source of force applied to an end surface of the cassette member (4).

5. The device according to claim 4, **characterized in** that the loaded spring (9) is a compression spring between a body (8) of the inhaler device and the end surface of the cassette member (4).

6. The device according to claim 4, **characterized in** that the device member is attached to the same end surface of the cassette member as the

compressing spring, which is loaded when the dry powder inhaler is opened for an inhalation operation.

7. The device according to claim 4, **characterized in** that the
5 arrangement for controlling a leakage of air (36) between an interior air volume and surrounding atmosphere is adjustable for deciding a proper speed of motion and timing of the propelled cassette member (4).

8. The device according to claim 2 or 3, **characterized in** that the
10 arrangement for letting in or letting out air of the device member (20, 22) by means of a check valve or the like when the user closes the dry powder inhaler reducing the energy needed for the operation by the user.

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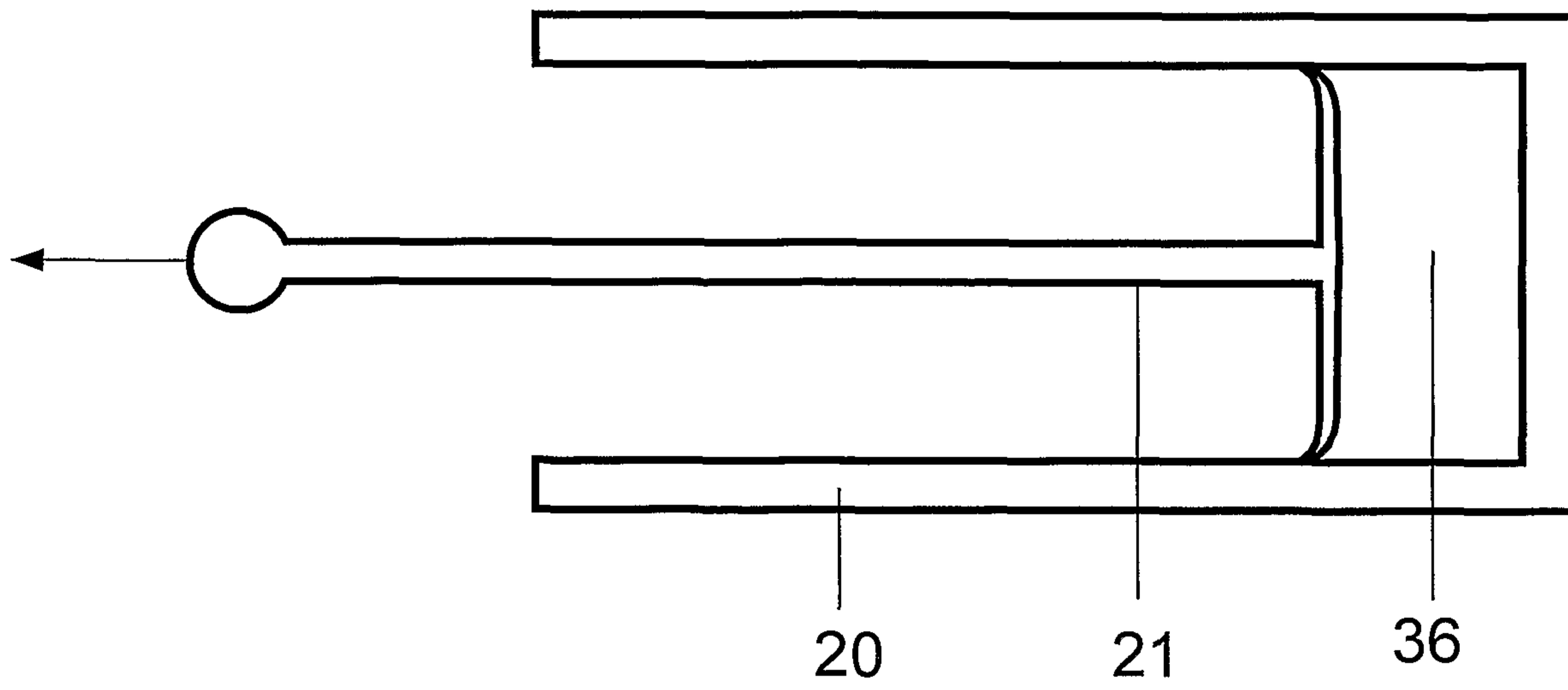


Fig. 1

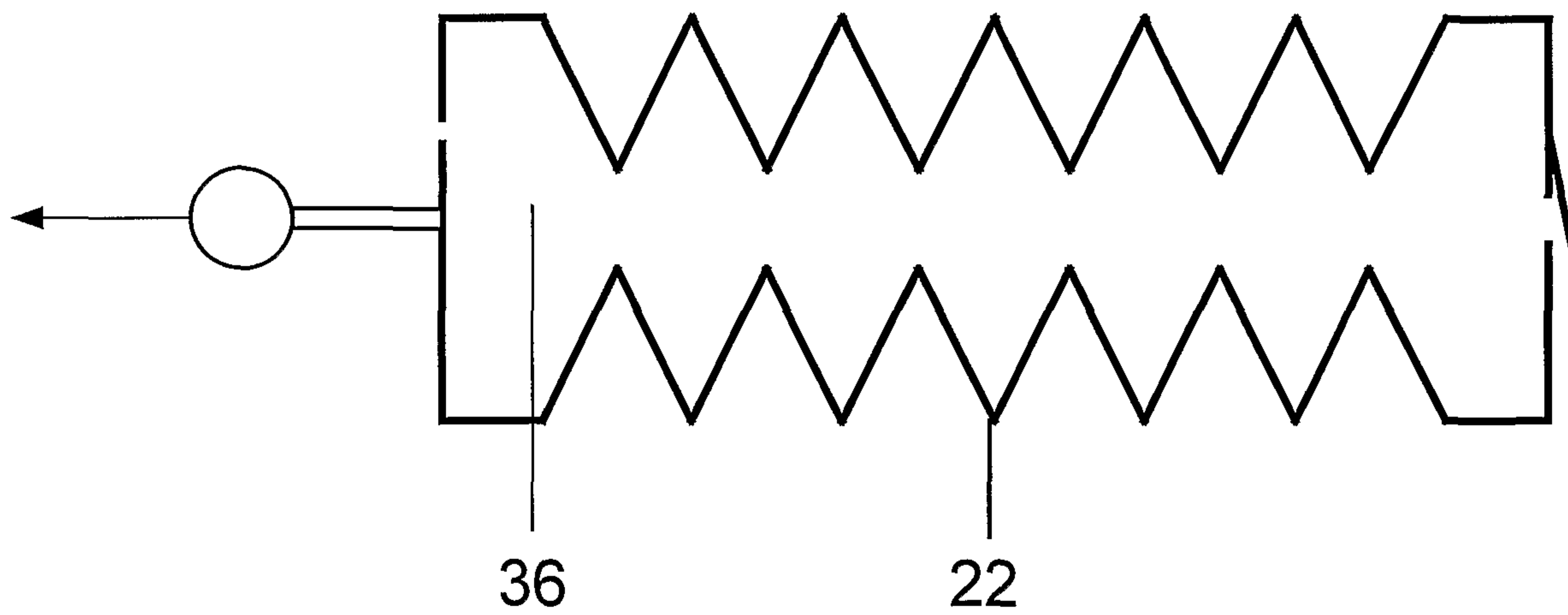


Fig. 2

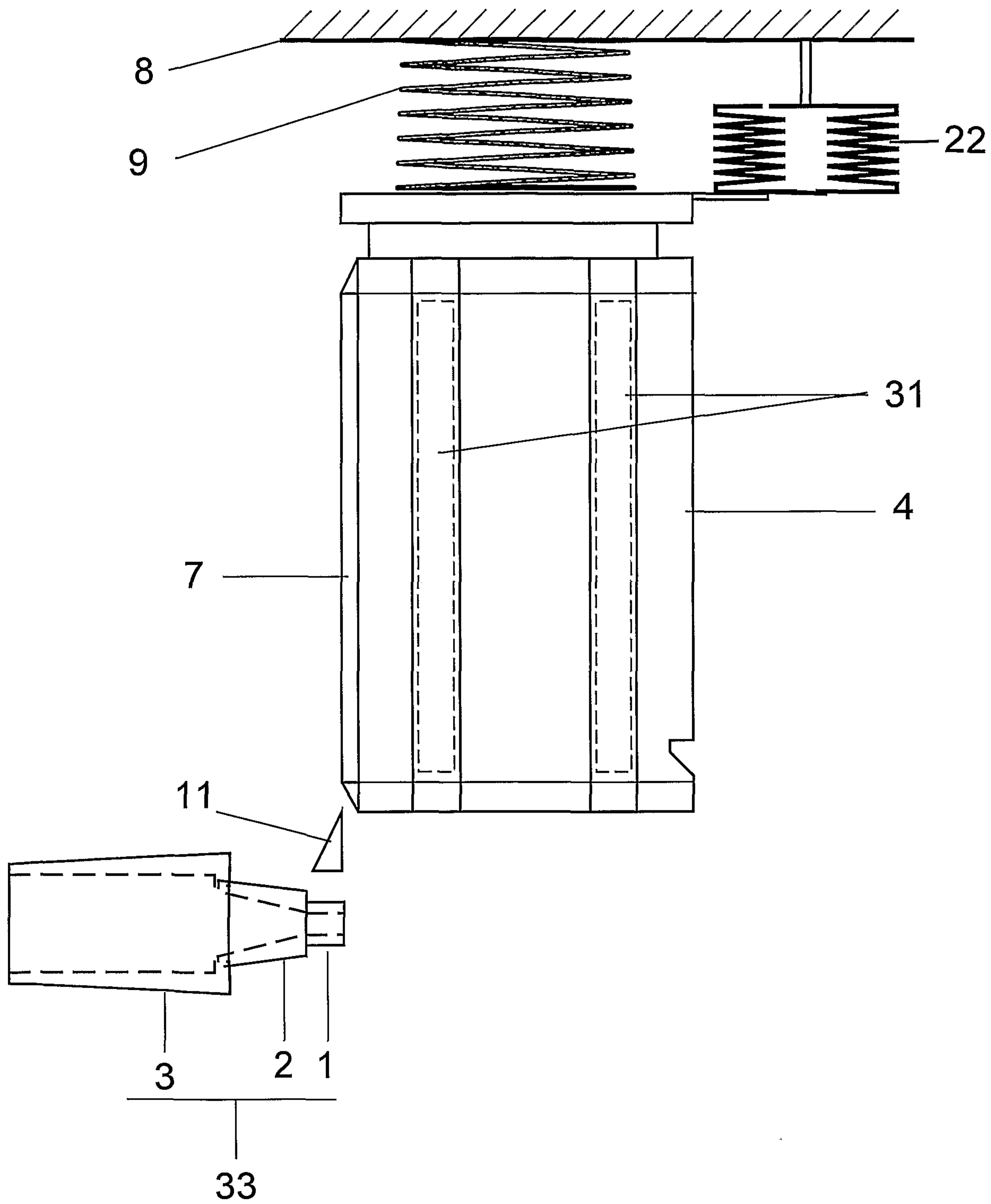


Fig. 3

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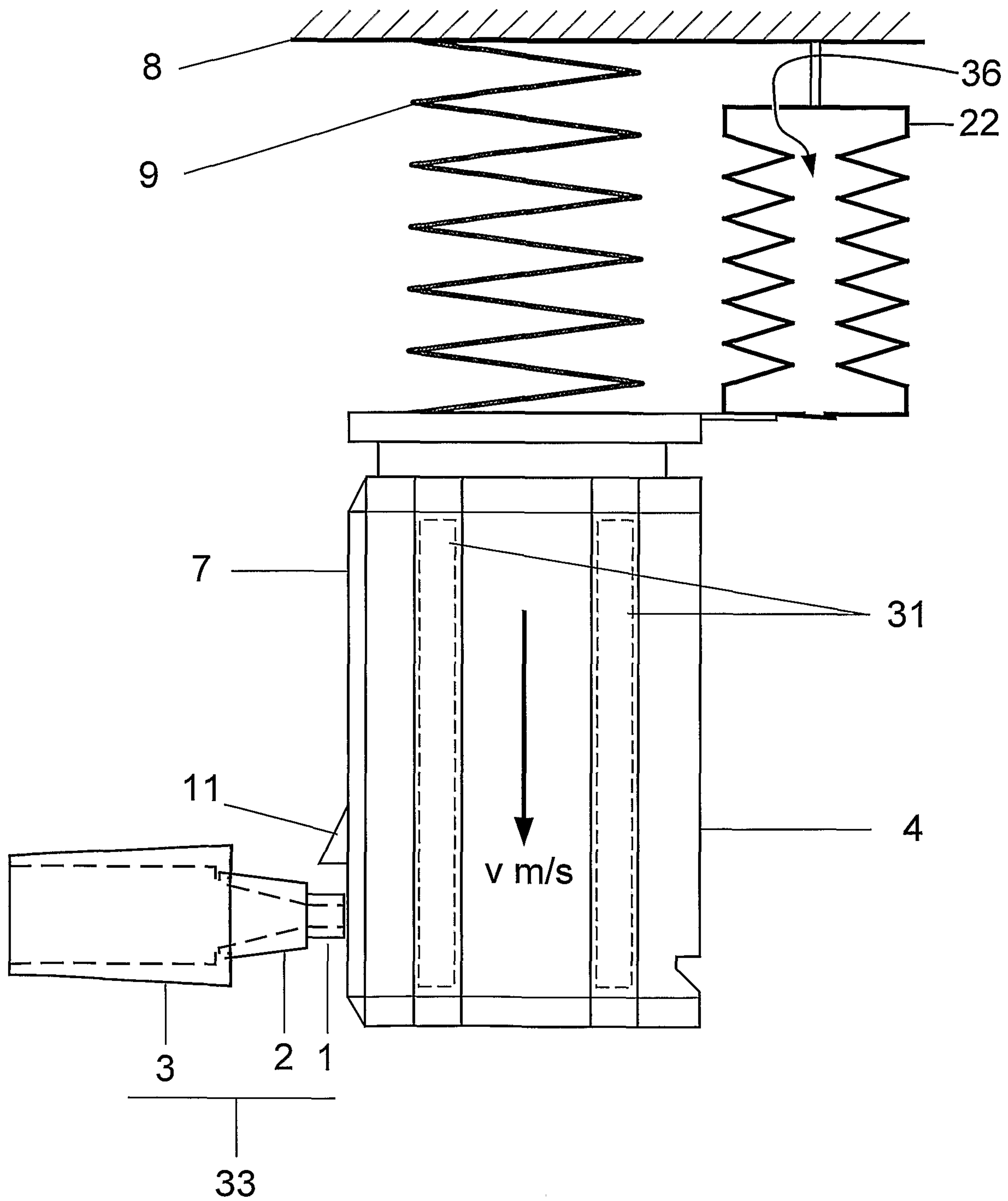


Fig. 4

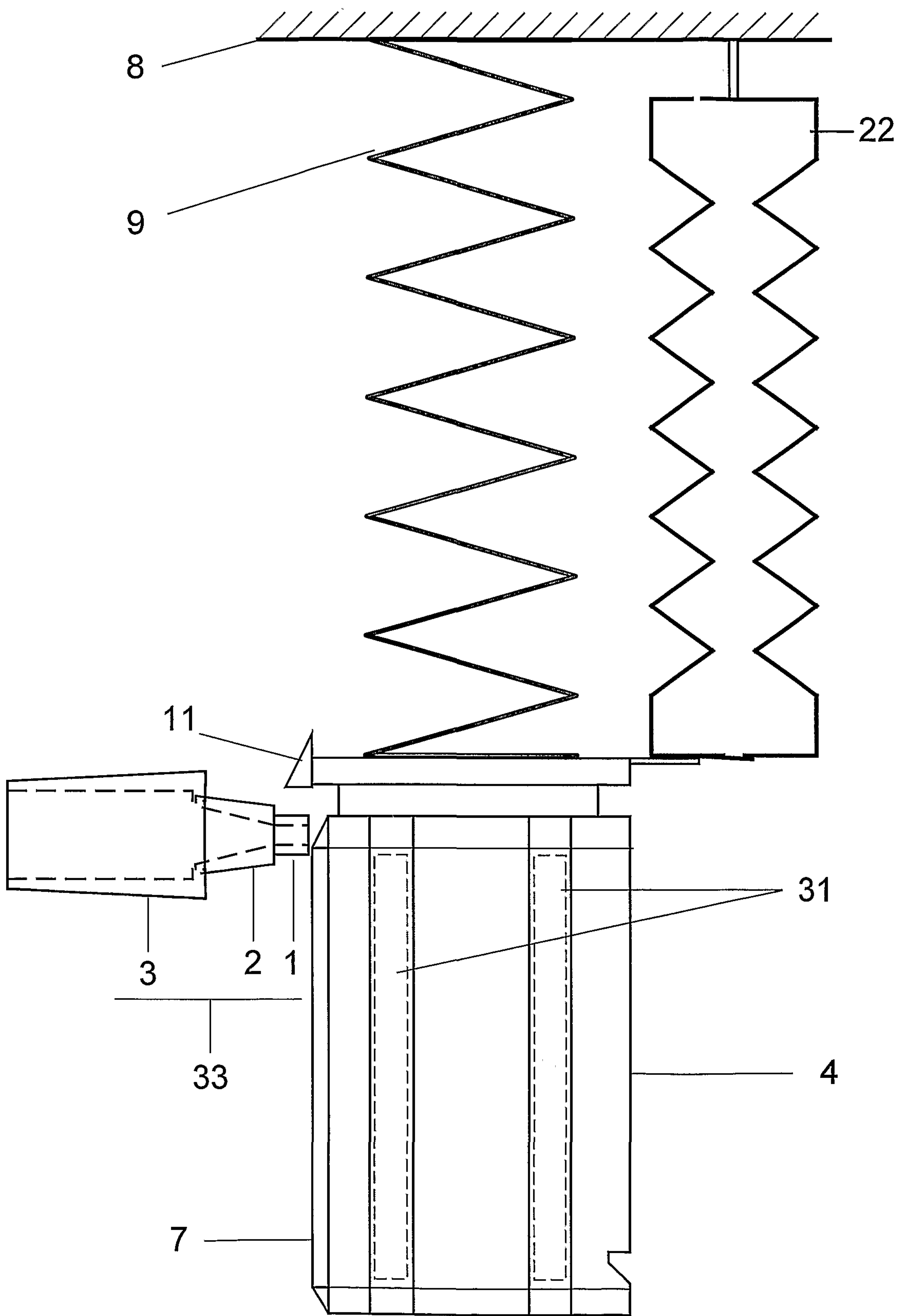


Fig. 5

