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Docket No.: 75760

DECLARATION FOR PATENT APPLICATION AND ASSIGNMENT

Title of the Invention: **EXHALATION VALVE, INHALATION VALVE, VENTILATOR AND METHOD FOR CONTROLLING VENTILATION**

As a below named inventor, I hereby declare that:

This declaration is directed to:

- ☒ The attached application, or
☐ United States application or PCT international application number

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

WHEREAS, **Drägerwerk AG & Co. KGaA**

(hereinafter referred to as Assignee) having a place of business at: **Meislinger Allee 53-55, 23558 Lübeck, GERMANY**

is desirous of acquiring the entire right, title and interest to said invention and in the Letters Patent to be obtained therefor from the United States;

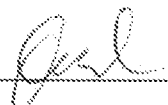
NOW THEREFORE, be it known by all whom it may concern, that for and in consideration of the sum of One Dollar (\$1.00) (or the equivalent thereof in foreign currency) and other valuable consideration, the receipt of which is hereby acknowledged, I have assigned, sold and set over and by these presents do assign, sell and set over unto the said Assignee for the territory of the United States of America and not elsewhere, the full and exclusive right, title and interest in and to the said invention, said invention, application and Letters Patent to be held and enjoyed by the said Assignee for its own use and behoof and for the use and behoof of its successors and assigns to the full end of the term for which said Letters Patent is granted, as fully and entirely as the same would have been held by me had this Assignment and sale not been made.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than (5) years, or both.

LEGAL NAME OF INVENTOR

INVENTOR: **Thorsten DUNKEL**

Inventor's signature



Date 10-17-01-06

McGLEW & TUTTLE, P.C., Box 9227 Scarborough Station, Scarborough N.Y. 10510-9227 U.S.A

Docket No.: 75760

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The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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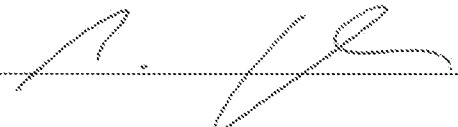
is desirous of acquiring the entire right, title and interest to said invention and in the Letters Patent to be obtained therefor from the United States;

NOW THEREFORE, be it known by all whom it may concern, that for and in consideration of the sum of One Dollar (\$1.00) (or the equivalent thereof in foreign currency) and other valuable consideration, the receipt of which is hereby acknowledged, I have assigned, sold and set over and by these presents do assign, sell and set over unto the said Assignee for the territory of the United States of America and not elsewhere, the full and exclusive right, title and interest in and to the said invention, said invention, application and Letters Patent to be held and enjoyed by the said Assignee for its own use and behoof and for the use and behoof of its successors and assigns to the full end of the term for which said Letters Patent is granted, as fully and entirely as the same would have been held by me had this Assignment and sale not been made.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than (5) years, or both.

LEGAL NAME OF INVENTOR

INVENTOR: **Andreas JUNK**

Inventor's signature  Date 13.01.2017

McGLEW & TUTTLE, P.C., Box 9227 Scarborough Station, Scarborough N.Y. 10510-9227 U.S.A

Docket #75760

EXHALATION VALVE, INHALATION VALVE, VENTILATOR AND METHOD FOR CONTROLLING VENTILATION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority under 35 U.S.C. §119 of German Application 10 2016 001140.8 filed February 3, 2016, the entire contents of which are incorporated herein by reference.

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FIELD OF THE INVENTION

[0002] The present invention pertains to an exhalation valve, to an inhalation valve, to a ventilator and to a method for controlling ventilation, and especially but not exclusively to a concept for an improved control of a valve for a ventilator.

BACKGROUND OF THE INVENTION

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[0003] Valves and valve systems are used in the field of medicine and especially in

automated patient supply. For example, diaphragms are employed in mechanical ventilation and are often indispensable elements there. A diaphragm is an elastic or partially elastic element or membrane, which can be acted on with a force or a displacement, by which force or displacement a deformation of the geometry becomes established. For example, an opening is closed or
5 opened by the deformation.

[0004] Diaphragms are used, for example, in exhalation valves, and the respiratory phases of patients are controlled by means of them during active, mechanical ventilation. The diaphragm undergoes a great, dynamic change during the exhalation. The diaphragm is not infrequently induced to vibrate due to the controlling force and the opposing force of the gas
10 mixture (also called "Durchfluss" in German or "flow" in English). These vibrations may have an adverse effect on the flow and pressure measurement through the ventilator. Furthermore, the comfort of the patient may be compromised by vibrations during the ventilation, or the vibrations may be so pronounced that they are in the audible range and are perceived as an acoustic nuisance for the user and the patient.

15 **[0005]** Vibrations, which may have an unfavorable effect, are often observed in existing systems in case of a high positive end-expiratory pressure (PEEP), positive residual pressure at the end of expiration).

SUMMARY OF THE INVENTION

[0006] Therefore, there is a need for developing an improved configuration for

ventilating patients.

[0007] This need is met by exemplary embodiments of an exhalation valve or inhalation valve according to the invention, a ventilator according to the invention and a method according to the invention.

5 **[0008]** This is accomplished by using exhalation valves or inhalation valves (hereinafter also called valves for short) that make possible an improved control of the flow through more controlled opening and closing characteristics. Therefore, measures are taken on the valve, which measures permit complete opening, controllable or defined partial closing and complete closing, particularly, the valve includes means for complete opening, controllable or defined
10 partial closing and complete closing. Exemplary embodiments can thus reduce the vibrations of the diaphragm, which develop, for example, due to an undefined closing of the "zero gap" (e.g., contact between a crater (also known a valve seat or valve seat crater) and a diaphragm) on one side and high local, flow-induced forces on the other side.

[0009] Therefore, exemplary embodiments create an exhalation valve or inhalation valve
15 for a medical ventilator for controlling a flow of a fluid. The fluid is especially a breathing gas. The valve comprises an inlet and an outlet for the fluid. Between the inlet and the outlet, the valve has further a crater (also known as a valve seat or valve seat crater) and a diaphragm movable relative to the valve seat crater for influencing the flow through the valve seat crater. The valve seat crater and the diaphragm are arranged such that the valve seat crater can partially

be sealed by means of the diaphragm, and the diaphragm and the valve seat crater are not closed all over during the initial contact. The non-all-over closing and the partial sealability associated herewith can be used to stabilize the diaphragm position and to reduce vibrations. The valve seat crater can be sealed in a partially and fully controlled manner by means of the diaphragm in
5 exemplary embodiments. Exemplary embodiments can thus make possible a full range of control, controlled opening, controlled partial opening or closing and controlled complete closing. This may lead to increased comfort especially in case of use in ventilators.

[0010] In exemplary embodiments, the diaphragm may have an elastic material and at least one damping element. The damping element may represent a simple structural measure in
10 order to achieve the above-described controllability or partial closability. For example, the damping element may comprise a reinforcement of the diaphragm on one side. The reinforcement on one side can make possible a non-uniform yielding of the diaphragm and hence a controllable partial closing or opening. In some exemplary embodiments, the diaphragm and the valve seat crater may have a defined contact point or a defined, limited contact surface, at
15 which or on which the diaphragm and the valve seat crater first touch one another during a closing of the valve. An opening and/or closing characteristic of a mechanical nature can thus be predefined by the defined contact point and the contact surface, and a flow characteristic will, in turn, become controllable based on the geometry of these opening and closing characteristics at given pressure differences.

[0011] In some exemplary embodiments, the valve seat crater may have a sealing contour

for sealing with a sealing surface of the diaphragm. The valve seat crater and the diaphragm may be configured to form a sealing gap between the sealing contour and the sealing surface. The sealing gap may, in this case, be configured such that the sealing contour touches the sealing surface at a defined first point in the course of a closing and that the sealing gap assumes a defined dimension at a defined second point, at which the sealing contour and the sealing surface do not touch each other. Such an arrangement may likewise make possible a controllable behavior of the valve based on the corresponding geometric conditions. The flow of the fluid through the sealing gap can then be correspondingly controllable. In further exemplary embodiments, the diaphragm may have a lateral extension, for example, a diameter in case of a diaphragm with a lateral extension, for example, a diameter in case of a diaphragm with a round cross section, a semiaxis in case of an elliptical cross section, length or width in case of other shapes. When the sealing contour and the sealing surface touch each other at the defined first point, the dimension of the sealing gap at the defined second point may then exceed, for example, a percentage of the lateral extension of the diaphragm. Due to such defined geometric conditions, exemplary embodiments can make it possible to infer other variables, for example, flowthrough, flow, volume flow, pressure, pressure difference, vibration intensity, vibration damping, etc., from a degree of opening or closing of the valve.

[0012] The damping element may be configured in other exemplary embodiments to deflect the diaphragm asymmetrically or symmetrically under the action of a force. The sealing surface can partially touch the sealing contour when the diaphragm partially seals the valve seat crater. In addition or as an alternative, the diaphragm may be configured such that an

asymmetrical distribution of forces becomes established between the sealing surface and the sealing contour under the action of a force. The diaphragm can thus be controlled by corresponding means, e.g., pneumatically and/or by means of a plunger, and the asymmetrical deflection and/or force distribution then permits a corresponding control and/or vibration damping.

[0013] The diaphragm and the damping element may have a one-piece configuration in some exemplary embodiments. The damping element may now be arranged inside or outside the diaphragm, and many different possible applications and implementations are made possible hereby and exemplary embodiments can thus be adapted in this respect to the particular application. For example, the damping element may comprise an elastic structure and/or a compacted structure. The controllable partial closability can thus be achieved by means of corresponding structures. The sealing surface and the sealing contour may form an angle with one another. The oblique closing thus made possible may represent a simple implementation of the partial closability or opening of the valve. The sealing surface and/or the sealing contour may be beveled in relation to a longitudinal axis of the valve seat crater, which can lead to a similar effect and to a simple implementation.

[0014] In some exemplary embodiments, the sealing surface and/or the sealing contour may have one or more defined unevennesses, which form one or more defined residual openings between the sealing surface and the sealing contour when a predefined force acts on the diaphragm. The residual openings can then cause a defined flow, so that a controllable or

defined state of the valve is achieved. The one or more residual openings can then be closable in some other exemplary embodiments by the action of another, stronger force on the diaphragm, so that the valve can then also be closed completely.

[0015] Moreover, exemplary embodiments provide a ventilator with an exhalation valve or inhalation valve according to the above description.

[0016] Exemplary embodiments also create a method for controlling ventilation by means of a flow of a fluid, especially of a breathing gas, through an exhalation valve or inhalation valve having an inlet and an outlet for the fluid. The valve has further, between the inlet and the outlet, a valve seat crater and a diaphragm movable relative to the valve seat crater for influencing the flow through the valve seat crater. The method for controlling the flow comprises a partial sealing of the valve seat crater with the diaphragm and a non-complete closing of the diaphragm and valve seat crater upon initial contact.

[0017] Further advantageous embodiments will be described in more detail below on the basis of the exemplary embodiments shown in the drawings, but, on the whole, the present invention is not limited, in general, to these exemplary embodiments. The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects attained by its uses, reference is made to the accompanying drawings and descriptive matter in which preferred embodiments of the invention are illustrated.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] In the drawings:

[0019] Figure 1 is a schematic view showing an exemplary embodiment of an exhalation valve or inhalation valve;

5 **[0020]** Figure 2 is a sectional view of a valve in a ventilator;

[0021] Figure 3 is a pressure curve over time as well as a volume curve over time in the course of an inhalation and an exhalation;

[0022] Figure 4 is a pressure curve over time as well as a volume curve over time within the framework of a pressure-assisted ventilation, which takes place within the framework of
10 spontaneous breathing attempts of a patient;

[0023] Figure 5 is a schematic view showing an exemplary embodiment of a ventilator;

[0024] Figure 6 is a schematic view showing an exemplary embodiment of an exhalation valve or inhalation valve with a reinforcement within the diaphragm;

[0025] Figure 7 is a schematic view showing an exemplary embodiment of an exhalation

valve or inhalation valve with a reinforcement outside the diaphragm;

[0026] Figure 8 is a schematic view showing another exemplary embodiment of an exhalation valve or inhalation valve with a reinforcement outside the diaphragm;

[0027] Figure 9 is a schematic view showing an exemplary embodiment of an exhalation
5 valve or inhalation valve with a reinforcement or weighting of the diaphragm on one side;

[0028] Figure 10 is a schematic view showing a hinge principle in some exemplary embodiments;

[0029] Figure 11 is a schematic view showing an exemplary embodiment of an exhalation valve or inhalation valve with an angle between the diaphragm and the valve seat
10 crater;

[0030] Figure 12 is a schematic view showing an exemplary embodiment of an exhalation valve or inhalation valve with a beveled valve seat crater;

[0031] Figure 13 is a schematic view showing an exemplary embodiment of an exhalation valve or inhalation valve with a beveled diaphragm;

[0032] Figure 14 is a schematic view showing an exemplary embodiment of an
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exhalation valve or inhalation valve with a defined unevenness in the valve seat crater;

[0033] Figure 15 is a schematic view showing an exemplary embodiment of an exhalation valve or inhalation valve with a defined unevenness in the diaphragm; and

[0034] Figure 16 is a block diagram of a flow chart of an exemplary embodiment of a method for controlling ventilation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0035] Referring to the drawings, various exemplary embodiments will now be described in more detail with reference to the attached drawings, in which some exemplary embodiments are shown.

[0036] Identical reference numbers can designate identical or comparable components in the following description of the attached figures, which show only some exemplary embodiments. Further, summary reference numbers may be used for components and objects that appear several times in an exemplary embodiment or in a drawing, but are described together with respect to one or more features. Components or objects that are described with the same reference number or with a summary reference number may have an identical configuration but optionally also different configurations with respect to individual features, a plurality of features or all features, for example, their dimensioning, unless something different appears explicitly or implicitly from the description. Optional components are indicated by broken lines or arrows in

the figures.

[0037] Even though exemplary embodiments may be modified and varied in different ways, exemplary embodiments are shown in the figures as examples and will be described herein in detail. It shall, however, be clarified that exemplary embodiments are not intended to be limited to the particular forms being disclosed, but exemplary embodiments shall rather cover all functional and/or structural modifications, equivalents and alternatives, which are within the scope of the present invention. Identical reference numbers designate identical or similar elements in the entire description of the figures.

[0038] It should be noted that an element that is referred to as being "connected" or "coupled" with another element may be connected or coupled directly with the other element or elements located in between may be present. If, by contrast, an element is referred to as being "directly connected" or "directly coupled" with another element, no elements located in between may be present. Other terms, which are used to describe the relation between elements should be interpreted in a similar manner (e.g., "between" versus "directly in between," "adjoining" versus "directly adjoining," etc.).

[0039] Unless specified otherwise, all the terms being used here (including technical and scientific terms) have the same meaning that is attached to them by a person of average skill in the field to which the exemplary embodiments belong. It shall further be clarified that terms, e.g., those that are defined in generally used dictionaries, are to be interpreted such that they have

the meaning that is consistent with their meaning in the context of the relevant technique and are not to be interpreted in an idealized or excessively formal sense, unless this is expressly defined herein.

[0040] Figure 1 shows an exemplary embodiment of an exhalation valve 10 or inhalation valve 10. The exhalation valve 10 or inhalation valve 10 shown in Figure 1 is suitable, for example, for a medical ventilator for controlling a flow of a fluid, especially a breathing gas, which will be explained in more detail on the basis of the following figures. As is shown in Figure 1, the valve 10 comprises an inlet 12 and an outlet 14 for the fluid. The flow direction may possibly also be different in exemplary embodiments and the inlet 12 and the outlet 14 are transposed in this case. The flow direction shown in Figure 1 will be maintained in the following figures, but another flow direction or a transposition of the inlet and outlet is also possible.

[0041] Further, the valve 10 has, between the inlet 12 and the outlet 14, a valve seat (also referred to as a crater or valve seat crater) 16 and a diaphragm 18 movable relative to the valve seat crater for influencing the flow through the valve seat crater 16. The valve seat crater 16 and the diaphragm 18 are configured and arranged to provide an initial partial contact means wherein the valve seat crater 16 is partially sealed by the diaphragm 18, with the diaphragm 18 and the valve seat crater 16 not closing all over (not fully closing) during the initial contact. This incomplete closing can be achieved based on the different initial partial contact means explained in more detail below. For example, the initial partial contact means may be provided based on features in the area 20, which is shown in Figure 1, and/or a sealing gap 22, which is located

between the diaphragm 18 and the valve seat crater 16, may correspondingly be modified. A selection of concrete initial partial contact means features will be explained in detail below.

[0042] Figure 1 schematically shows the valve 10, in which the gap 22 between the diaphragm 18 and the valve seat crater 16 is still open. If the opposing force 24 acts on the diaphragm, the gap 22 becomes larger or smaller. The flow shown (volume flow of the breathing gas indicated by the bent arrow) can thus be dispensed in a smaller quantity and finally stopped altogether. The time and the rapidity of respiratory phases are thus controlled with the diaphragm 18 during mechanical ventilation and the value of the pressure level during the respiratory phases is controlled by varying the gap width. Figure 2 shows an exemplary embodiment of an exhalation valve 10 or inhalation valve 10 as it can be used, for example, in a ventilator. Figure 2 shows three views: a perspective view of a diaphragm 18 on the left-hand side, a sectional view of the valve 10 in the center and a perspective view of the corresponding valve seat crater 16 on the right-hand side. The sealing surface 26, which seals with a sealing contour 28 of the valve seat crater if a sufficient force 24 is applied to the diaphragm 18, can be seen in the view on the left-hand side. The diaphragm 18 has a disk-shaped configuration in this embodiment, and the sealing surface 26 is located in the center of the diaphragm 18 and is coupled with a fastening ring surrounding the diaphragm 18 concentrically via an elastic bead or a rebate. The diaphragm 18 may be formed in one piece from an elastic material. These components are also shown in the center of Figure 2, where the sealing gap 22 is open. The flow is shown by an arrow drawn in broken line and it extends in the view from right to left and then downward; consequently, the inlet 12 for the fluid is arranged on the right and the outlet 14 is

arranged on the left in this exemplary embodiment. Moreover, the views in the center and on the right show fastening components of the valve seat crater 16, which are used for fastening in a ventilator, which will be explained below. The right side of Figure 2 shows the valve seat crater 16, which has a fixing device 29 for the diaphragm 18, this fixing device being configured as a ring-shaped groove here. The valve seat crater 16 has a sleeve-like or cylindrical configuration, so that a circular sealing contour 28 is obtained.

[0043] The course of ventilation as well as a ventilator shall be described in more detail based on the following Figures 3 through 5, using an exemplary embodiment of a valve. Figure 3 shows a pressure curve over time as well as a volume flow curve over time in the course of an inhalation and an exhalation. Figure 4 shows a pressure curve over time as well as a volume flow curve over time within the framework of pressure-assisted ventilation, which takes place in connection with spontaneous breathing attempts of a patient. Figures 3 and 4 show curves on the basis of which a pressure-controlled ventilation will be explained as an example.

[0044] To illustrate a ventilation with trigger control, Figure 3 shows a pressure curve of a pressure value P over time, and a curve of a volume flow \dot{V} over time can be seen as well. If a patient is ventilated by a ventilating device, the pressure is controlled such that the pressure is regulated before an inhalation phase INP to a minimum end-expiratory pressure PEEP (Positive End Expiratory Pressure in English). If the patient makes an attempt at breathing spontaneously, this leads to the volume flow \dot{V} being exceeded based on a so-called trigger threshold or flow

trigger threshold FT at the time ZP. If the threshold is exceeded, the pressure P is then adjusted such that the pressure P is adjusted to a maximum pressure Pmax, and this maximum pressure Pmax is above the minimum pressure PEEP by a differential pressure ΔP. A duration T_IP is usually preset for an inhalation phase, so that the exhalation phase EXP, during which pressure P is again lowered to the minimum pressure PEEP, is then started after the end of the duration T_IP. A negative volume flow \dot{V} is thus obtained during the exhalation phase based on the outflow of the volume flow \dot{V} from the patient.

[0045] Such a trigger-controlled ventilation is carried out, for example, within the framework of a pressure-assisted ventilation, as it is shown once again in Figure 4.

[0046] Figure 5 shows an exemplary embodiment of a ventilator 30 or of a ventilating device BV for the automated ventilation of a patient PT. The ventilating device BV has an inhalation port IP and an exhalation port EP, to which a ventilation tube BS, which faces the patient PT, can be connected. A breathing gas is fed to the patient via this ventilation tube BS and then removed from the patient towards the ventilating device BV. The feed takes place via the inhalation port IP and the removal via the exhalation port EP. The ventilation tube BS merges the connections of the ports EP, IP at a so-called Y-piece YS, which then usually ends at a tube, which is inserted into the patient PT in order to ventilate him via his lungs LU.

[0047] The ventilating device BV further has a breathing gas delivery unit AGF. The

breathing gas delivery unit AGF is preferably a piston unit KE, in which a piston KO can be moved forward and backward by a motor M.

[0048] The ventilating device BV has at least one volume flow sensor VS to detect a volume flow of the breathing gas. The volume flow sensor VS can provide a volume flow signal VSS to a computer R. The computer R is at least one computer, which may also be embodied by a network of a plurality of computers. The ventilating device BV further has a pressure sensor DS for detecting a pressure of the breathing gas. The pressure sensor DS provides a pressure sensor signal DSS for the computer R. The computer R is configured to actuate the breathing gas delivery unit AGF via an actuating signal ANS. The computer R preferably accesses a memory unit MEM in order to carry out the method according to the present invention. A minimum pressure PEEP is preferably brought about by an exhalation valve PV, which corresponds to an exemplary embodiment of the valve 10 described and which is preferably located in the area of the exhalation port EP.

[0049] Further, there is an inhalation valve IV, which likewise corresponds to the valve 10 described, which controls the feed of breathing air from the ventilating device to the patient PT. In case the ventilating device BV is an anesthesia ventilating device, the ventilating device BV preferably has a carbon dioxide adsorber CA as well as an anesthetic gas mixing unit NG. A gas mixture necessary for the anesthesia can then be introduced into the breathing circuit via the anesthetic gas mixing unit NG. The ventilating device BV further has as the anesthesia ventilating device an anesthetic gas discharge line ANF and a connection to an anesthetic gas

discharge line ANF. The gas flow within the ventilating device BV is controlled by nonreturn valves RV. The computer R preferably controls the anesthetic gas mixing unit NG by means of a control signal NGAS.

[0050] As is shown in Figures 3-5, there are inhalation and exhalation phases for the mechanical ventilation of a patient. The two phases can be controlled by inhalation valves and exhalation valves 10. Exemplary embodiments of the valves 10 reduce vibrations, which may occur in various situations and thus the valves 10 can favorably affect the patient's ventilation comfort. Vibrations may occur, for example, during the breathing air feed (inhalation) when the inhalation pressure plateau is reached or during the removal of breathing air (exhalation) when the end-expiratory pressure plateau (PEEP) is reached. Exemplary embodiments of the valves 10 may generally be used in ventilators, i.e., for example, in the area of anesthesia, intensive care and emergency ventilation. For example, the vibrations occurring can be distinguished according to frequency ranges of, for example, $0 < f < 20 \text{ Hz}$, $20 \text{ Hz} < f < 50 \text{ Hz}$, $50 \text{ Hz} < f < 200 \text{ Hz}$, $200 \text{ Hz} < f < 2 \text{ kHz}$, $2 \text{ kHz} < f < 20 \text{ kHz}$, and a plurality of frequencies may also occur simultaneously.

[0051] Some additional exemplary embodiments of valves, especially different configurations of the diaphragm 18 and of the valve seat crater 16, which may be adapted to one or more, optionally also all frequency ranges, will be described below. For example, the closing characteristic of the diaphragm 18 with respect to a first contact point on the valve seat crater 16 up to complete closing can be configured in a defined manner and vibrations can thus directly be

reduced or entirely eliminated. The valve seat crater 16 can in this case be able to be sealed partially and completely in a controlled manner by means of the diaphragm 18. A plurality of options are conceivable for defining a first contact point, as this will schematically be shown in the following figures.

5 **[0052]** Figure 6 shows an exemplary embodiment of an exhalation valve 10 or inhalation valve 10 with a reinforcement within the diaphragm 18. The valve 10 may consequently comprise a damping element 32 and the diaphragm 18 may be formed from an elastic material. The damping element 32 may comprise, as is shown, for example, in Figure 6, a reinforcement of the diaphragm 18 on one side. Figure 6 further shows the sealing contour 28 of the valve seat
10 crater 16, which faces the sealing surface 26 of the diaphragm 18.

[0053] Diaphragm elastomers may generally be used as the material for the diaphragm 18 in exemplary embodiments. Examples are hyperelastic materials, most of which are approved for medical applications (biocompatibility), e.g., silicones and thermoplastic elastomers (TPE). For example, metals approved for medical applications or plastics approved for medical
15 applications, e.g., titanium, brass, polypropylene (PP), polyethylene (PE), poly(aryl)sulfone (PSU), acrylonitrile-butadiene-styrene (ABS), polystyrene (PS), etc., may be used for the damping element 32 and the diaphragm reinforcement. For example, plastics approved for medical applications or metals approved for medical applications, e.g., PP, PE, PSU, ABS, PS, titanium, brass, etc., may be used for the valve seat crater 16. Figure 6 shows the damping
20 element within the diaphragm 18, Figure 7 shows an exemplary embodiment of an exhalation

valve 10 or inhalation valve 10 with a reinforcement or with a damping element 32 outside the diaphragm 18. Another exemplary embodiment of an exhalation valve 10 or inhalation valve 10 with a reinforcement or with a damping element 32 outside the diaphragm 18 is shown in Figure 8.

5 **[0054]** The damping element 32 is shown in Figures 6-8 in a simplified manner as a spring symbol, which may, in turn, correspond to different implementations in exemplary embodiments. Examples are ribs, webs, straps, compactions, thickenings, which may each be formed from the same material or a material other than the material of the diaphragm 18. Figure 9 shows an exemplary embodiment of an exhalation valve 10 or inhalation valve 10 with a compaction or weighting 34 of the diaphragm on one side. In the exemplary embodiments according to Figures 6-9, the damping elements 32 or the weighting 34 lead to a static/dynamic change in the angle of the axes of rotation of the valve seat crater 16 and the diaphragm 18 during the operation. A kind of hinge is formed. This hinge principle shall be explained in more detail for some exemplary embodiments on the basis of Figure 10. Figure 10 shows a closing operation of the valve 10 in one exemplary embodiment in a characteristic sequence: Open - partially closed - completely closed. Not all reference numbers are repeated again in Figure 10 for the sake of clarity; the components shown correspond to those in the other figures.

15 **[0055]** The valve 10 is shown in the opened state in the top part of Figure 10. Figure 10 shows in the center that during the closing operation, the diaphragm 18 and the valve seat crater 16 form a defined contact point or a defined limited contact surface, at or on which the

diaphragm 18 and the valve seat crater 16 will first touch one another during the closing of the valve 10. The view in the bottom part of Figure 10 now shows the valve 10 in the completely closed state. The asymmetry shown in the center of Figure 10 can be achieved, for example, by the above-described damping elements 32 or the weighting 34.

5 **[0056]** As was already explained on the basis of the above-described views, the valve seat crater 16 has a sealing contour 28 for sealing with a sealing surface 26 of the diaphragm 18. The valve seat crater 16 and the diaphragm 18 are configured in this case to form a sealing gap 22 between the sealing contour 28 and the sealing surface 26. The sealing gap 22 is configured, in turn, such that when the sealing contour 28 and the sealing surface 26 touch each other and the
10 sealing gap 22 is consequently closed at a defined first point (on the left in the view shown in the center of Figure 10), the sealing gap 22 assumes a defined dimension at a defined second point (on the right in the view shown in the center of Figure 10), at which the sealing contour 28 and the sealing surface 26 do not touch each other. In some other exemplary embodiments, the flow of the fluid through the sealing gap 22 thus becomes able to be controlled. In other words, the
15 sealing gap 22 is formed such that the sealing contour 28 touches the sealing surface 26 at a defined first point in the course of the closing of the sealing gap 22, and that the sealing gap 22 assumes a defined dimension at a defined second point, at which the sealing contour 28 and the sealing surface 26 do not touch each other.

20 **[0057]** The controllability is thus linked with the geometry of the diaphragm 18. The diaphragm 18 may have a lateral extension and the dimension of the sealing gap 22 at the defined

second point may exceed a percentage of the lateral extension of the diaphragm 18 when the sealing contour 28 and the sealing surface 26 touch each other at a defined first point. The diaphragm 18 is assumed to have a round cross section in Figure 10, so that the height of the gap at the second point in the view shown in the center is greater than a percentage of the diameter of the diaphragm 18. In other exemplary embodiments, the residual gap is, for example, at least 1% of the valve seat crater diameter. Larger initial gap dimensions, e.g., 2%, 3%, 5%, 10%, 20%, etc., are, however, likewise conceivable. An absolute value, e.g., 0.1 mm, 0.2 mm, 1 mm, 2 mm, 5 mm, 10 mm, etc., is also possible in other exemplary embodiments,

[0058] Returning to the exemplary embodiments shown in Figures 6-9, it is possible to use as a damping element 32, for example, a reinforcement of the internal diaphragm geometry (Figure 6), reinforcement of the external diaphragm geometry (Figures 7 and 8), external damping of the diaphragm displacement (Figure 8), as well as an asymmetric change in the diaphragm weight (Figure 9). This will lead to a change in the angle of the axes of rotation of the valve seat crater 16 and diaphragm 18 on actuation. The diaphragm 18 may now be heavier on one side or at a point, for example, due to accumulation of material and external application of material. Figure 10 thus shows an exemplary embodiment in which the damping 32 is formed to asymmetrically deflect the diaphragm 18 upon application of a force. The sealing surface 26 partially touches the sealing contour 28 when the diaphragm 18 partially seals the valve seat crater 16. The diaphragm 18 is configured such that an asymmetric distribution of forces becomes established between the sealing surface 26 and the sealing contour 28 when a force is applied to the diaphragm 18. The force may be applied with various means or mechanisms in

exemplary embodiments, examples being pneumatic, electromechanical, mechanical (e.g., plunger), fluid mechanical-pneumatic, fluid mechanical-(electro)mechanical means or mechanisms, etc.

[0059] In another exemplary embodiment, the diaphragm 18 and the damping element 32

5 are made in one piece, for example, by compaction of material on one side of the diaphragm 18.

The damping element 32 is arranged within or outside the diaphragm. In general, the damping element 32 may comprise an elastic structure and/or a compacted structure. The possibility of

reinforcing the external diaphragm geometry on one side by one or more ribs 36 in the displacement path may be implemented as another exemplary embodiment. Ribs 36 are provided

10 for this, for example, in the area 20, compare Figure 1, as this is indicated by broken lines in

Figure 10. It is conceivable to provide only one rib 36, which will thus define the

above-described second point. However, a plurality of ribs are also conceivable, and they are

arranged along the circumference of the diaphragm 18 and the characteristic shown in Figure 10

is thus obtained as an end result. Webs, straps, brackets, which may be formed in one piece or

15 also as multipart components, are also conceivable as an alternative to the ribs.

[0060] The characteristic resulting herefrom is similar, in principle, to that of a cover

with a hinge, which can move only about the hinge axis during opening and closing. As is

shown in the center of Figure 10, the reinforcement 36 acts as a fixed point, which suppresses the motion in the X direction and markedly limits same in the Z direction. A slight motion is still

20 possible at the fixed point itself in the Y direction (right-hand side of the view in Figure 10),

whereas the greatest and fastest displacements are possible on the opposite side (left-hand side of the view in Figure 10).

[0061] If the entire diaphragm 18 shall in this case form a seal on the valve seat crater 16, the diaphragm 18 and the valve seat crater 16 touch each other at the beginning of the closing operation at first on the surfaces on which the diaphragm 18 has the highest degrees of freedom, namely, opposite the fixed point or at the first point in Figure 10. The rest of the diaphragm 18 follows with a short time delay. A concrete contact point (first point) with defined closing characteristics can thus be obtained on the valve seat crater 16 and the vibration is suppressed or reduced. Figure 10 thus shows an improved or optimized closing operation. The opened diaphragm 18 is shown in the upper view, for example, in the inoperative state. In the view shown in the center, the diaphragm 18 touches the valve seat crater 16 in a defined manner. It then closes further, until it comes fully to lie on the valve seat crater 16, as this is shown in the bottom part of Figure 10. The indicated rib may likewise be configured as an elastic rib.

[0062] The effect shown in Figure 10 can also be achieved by other measures in other exemplary embodiments. For example, a change in the angle of the axes of rotation of the valve seat crater 16 and diaphragm 18 in the static state can be used by varying the valve seat crater 16. Figure 11 shows an exemplary embodiment of an exhalation valve 10 or inhalation valve 10 with an angle α different from zero between the diaphragm 18 and the valve seat crater 16. The diaphragm 18 and the valve seat crater 16 are located opposite each other at an angle $>0^\circ$, so that a closing characteristic similar to that in Figure 10 is obtained. The sealing surface 26 and the

sealing contour 28 form an angle with one another. Figure 12 shows an exemplary embodiment of an exhalation valve 10 or inhalation valve 10 with a beveled valve seat crater 16. The valve seat crater 16 is beveled opposite the diaphragm 18. The inclination does not have to be linear. Figure 13 shows an exemplary embodiment of an exhalation valve 10 or inhalation valve 10 with a beveled or shortened diaphragm 18. Consequently, variations of the diaphragm geometry and/or of the valve seat crater geometry can be embodied in exemplary embodiments. The diaphragm 18 is, for example, shortened on one side. The displacement until closing continues to be made possible by the elasticity of the diaphragm 18, compare Figure 13. The sealing surface 26 and/or the sealing contour 28 is beveled here in relation to the longitudinal axis of the valve seat crater 16. Beveling both components is likewise conceivable.

[0063] Figure 14 shows an exemplary embodiment of an exhalation valve 10 or inhalation valve 10 with a defined unevenness in the valve seat crater 16. This defined unevenness may correspond to a defined or also asymmetric recess, deformation, bulge, structure in the diaphragm and/or valve seat crater surface, so that the sealing gap does not close completely on initial contact between the diaphragm 18 and the valve seat crater 16, but there remains a defined residual gap or a residual opening. The size of the residual opening may correspond, for example, to more than 1%, 2%, 3%, 5%, 10%, 20%, 30%, 50% of the diaphragm or valve seat crater surface. Figure 15 shows an exemplary embodiment of an exhalation valve 10 or inhalation valve 10 with a defined unevenness in the diaphragm 18. Such unevennesses or recesses may be used additionally or as an alternative in additional exemplary embodiments. The valve seat crater 16 may be provided with a recess on one side, Figure 14, in order to guarantee a

defined residual opening in a flatly closed valve 10. As the closing force/closing displacement increases further, this residual gap can be closed in a specific manner. The sealing surface 26 of the diaphragm 18 may be provided with a recess on one side in order to guarantee a defined residual opening in a flatly closed valve 10. This residual gap can be closed in a specific manner
5 as the closing force/closing displacement increases further. The sealing surface 26 and/or the sealing contour 28 may consequently have one or more defined unevennesses in other exemplary embodiments, and these unevennesses form one or more defined residual openings between the sealing surface 26 and the sealing contour 28 when a predefined force acts on the diaphragm 18. The one or more residual openings can then be able to be closed when an additional, stronger
10 force acts on the diaphragm 18.

[0064] Figure 16 shows a block diagram of a flow chart of an exemplary embodiment of a method for controlling ventilation. The control is effected by means of a flow, through an exhalation valve 10 or inhalation valve 10 having an inlet 12 and an outlet 14 for the fluid, especially a breathing gas, according to the above description, especially Figure 1. The valve 10
15 further comprises between the inlet 12 and the outlet 14 a valve seat crater 16 and a diaphragm 18 movable relative to the valve seat crater for influencing the flow through the valve seat crater 16. The method for controlling the flow comprises a partial sealing 42 of the valve seat crater 16 with the diaphragm 18 and a closing 44 of the diaphragm 18 and valve seat crater 16, which closing does not occur over the entire area, on initial contact. As is shown in Figure 16, the
20 process being shown here begins with an open valve 10 in step 41. The partial sealing 42 is divided here into three substeps, namely, the start of the closing process by the application of

force/displacement 42a, the subsequent reduction of the gap size 42b and the initial contact between the diaphragm 18 and the valve seat crater 16 at a defined point. This is then followed by a controlled sealing 44 of the gap, which does not take place over the entire area. Full contact is then achieved in a next step between the diaphragm 18 and the valve seat crater 16, which leads to complete sealing of the valve 10. The valve 10 can then be opened analogously in the reverse order.

[0065] In summary, the susceptibility to vibration can be reduced and the frequency range of the vibrations can be shifted in at least some exemplary embodiments by an asymmetric distribution of the material hardness and/or of the elasticity of the material of the diaphragm 18 or by asymmetrically changing the displacement path of the diaphragm 18. The embodiment with defined recess in the valve seat crater-valve assembly unit guarantees that the opening of the valve always takes place in a defined controllable and regulatable manner (in the direction of "zero gap") even in case of a high PEEP pressure during the closing of the diaphragm.

[0066] The features disclosed in the above description, in the claims and in the drawings may be significant for the implementation of exemplary embodiments in their different configurations both individually and in any combination and, unless it appears otherwise from the description, they may be combined with one another as desired.

[0067] Even though some aspects were described in connection with a device, it is apparent that these aspects also represent a description of the corresponding method, so that a

block or a component of a device should also be considered to be a corresponding method step or as a feature of a method step. Analogously hereto, aspects that were described in connection with a method step or as a method step also represent a description of a corresponding block or detail or feature of a corresponding device.

5 **[0068]** The above-described exemplary embodiments represent only an illustration of the principles of the present invention. It is apparent that modifications and variations of the devices and details described here will be apparent to other persons skilled in the art. The present invention is therefore intended to be limited only by the scope of protection of the following patent claims rather than by the specific details, which were presented here on the basis of the
10 description and the explanation of the exemplary embodiments.

[0069] While specific embodiments of the invention have been shown and described in detail to illustrate the application of the principles of the invention, it will be understood that the invention may be embodied otherwise without departing from such principles.

WHAT IS CLAIMED IS:

1. A medical ventilator exhalation valve or medical ventilator inhalation valve for controlling a medical ventilator flow of a fluid, the valve comprising:

an inlet;

an outlet;

5 a valve seat crater; and

a diaphragm, the valve seat crater and the diaphragm being disposed between the inlet and the outlet, wherein the diaphragm is movable relative to the valve seat crater for influencing the flow through the valve seat crater, wherein the valve seat crater and the diaphragm are arranged such that the valve seat crater is at least initially only partially sealed by the diaphragm,
10 wherein the diaphragm and the valve seat crater do not close completely on initial contact between the diaphragm and the valve seat crater.

2. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 1, wherein the valve seat crater is partially or completely sealed by the diaphragm and the partial or complete sealing by the diaphragm is controlled.

3. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 1, wherein the diaphragm comprises an elastic material and at least one damping element.

4. A medical ventilator exhalation valve or medical ventilator inhalation valve in

accordance with claim 3, wherein the damping element comprises a reinforcement of the diaphragm on one side.

5. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 1, wherein the diaphragm and the valve seat crater have a defined contact point or a defined limited contact surface, at or on which the diaphragm and the valve seat crater first touch one another during the closing of the valve.

6. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 1, wherein:

the valve seat crater has a sealing contour for sealing with a sealing surface of the diaphragm;

5 the valve seat crater and the diaphragm are configured to form a sealing gap between the sealing contour and the sealing surface;

the sealing gap is formed such that the sealing contour touches the sealing surface at a defined first point during the closing of the sealing gap; and

10 the sealing gap assumes a defined dimension at a defined second point, at which the sealing contour and the sealing surface do not touch each other.

7. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 6, wherein the flow of the fluid through the sealing gap can be controlled.

8. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 6, wherein:

the diaphragm has a lateral extension; and

5 the dimension of the sealing gap at the defined second point exceeds a percentage of the lateral extension of the diaphragm upon the sealing contour initially touching the sealing surface at the defined first point.

9. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 3, wherein:

the valve seat crater has a sealing contour for sealing with a sealing surface of the diaphragm;

5 the damping element is configured to asymmetrically deflect the diaphragm under the action of a force;

the sealing surface partially touches the sealing contour when the diaphragm partially seals the valve seat crater or the diaphragm is configured such that an asymmetric distribution of forces becomes established between the sealing surface and the sealing contour when a force acts
10 on the diaphragm or both the sealing surface partially touches the sealing contour when the diaphragm partially seals the valve seat crater and the diaphragm is configured such that an asymmetric distribution of forces becomes established between the sealing surface and the sealing contour when a force acts on the diaphragm.

10. A medical ventilator exhalation valve or medical ventilator inhalation valve in

accordance with claim 3, wherein:

the diaphragm and the damping element are configured in one piece;

the damping element is arranged on either side of the diaphragm;

5 the damping element comprises an elastic structure or the damping element comprises a compacted structure or the damping element comprises both an elastic structure and a compacted structure.

11. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 1, wherein:

the valve seat crater has a sealing contour for sealing with a sealing surface of the diaphragm; and

5 the sealing surface and the sealing contour form an angle with one another or the sealing surface is beveled in relation to a longitudinal axis of the valve seat crater or the sealing contour is beveled in relation to a longitudinal axis of the valve seat crater or the sealing surface is beveled in relation to a longitudinal axis of the valve seat crater and the sealing contour is beveled in relation to a longitudinal axis of the valve seat crater.

12. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 1, wherein:

the valve seat crater has a sealing contour for sealing with a sealing surface of the diaphragm; and

5 the sealing surface or the sealing contour has or both the the sealing surface and the

sealing contour have one or more defined unevennesses, which at least initially form one or more defined residual openings, between the sealing surface and the sealing contour, when a force acts on the diaphragm.

13. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 12, wherein the one or more residual openings can be closed by an additional, stronger force acting on the diaphragm.

14. A medical ventilator exhalation valve or medical ventilator inhalation valve in accordance with claim 1, wherein the valve seat crater and the diaphragm are disposed and mounted to form an initial partial contact means for the initial contact between the diaphragm and the valve seat crater such that the valve seat crater is at least initially only partially sealed by the diaphragm.

15. A ventilator with a medical ventilator exhalation valve or medical ventilator inhalation valve comprising:

an inlet;

an outlet;

a valve seat crater; and

a diaphragm, the valve seat crater and the diaphragm being disposed between the inlet and the outlet, wherein the diaphragm is movable relative to the valve seat crater for influencing the flow through the valve seat crater, wherein the valve seat crater and the diaphragm are

arranged such that the valve seat crater is at least initially only partially sealed by the diaphragm,
10 wherein the diaphragm and the valve seat crater do not close completely on initial contact
between the diaphragm and the valve seat crater.

16. A ventilator in accordance with claim 15, wherein the valve seat crater and the
diaphragm are disposed and mounted to form an initial partial contact means for the initial
contact between the diaphragm and the valve seat crater such that the valve seat crater is at least
initially only partially sealed by the diaphragm.

17. A method for controlling ventilation by controlling a flow of a breathing gas through
an exhalation valve or through an inhalation valve or through both an exhalation valve and an
inhalation valve, the method comprising the steps of:

5 providing a valve comprising an inlet, an outlet, a valve seat crater and a diaphragm, with
the valve seat crater and the diaphragm being disposed between the inlet and the outlet, with the
diaphragm movable in relation to the valve seat crater for influencing the flow through the valve
seat crater; and

partially closing the valve seat crater with the diaphragm, which is not an all-over closing,
on initial contact.

18. A method according to claim 17, wherein the step of partially closing comprises:
starting of the partially closing with an application of force to the diaphragm or with a
displacement of the diaphragm to reduce a gap between the diaphragm and the valve seat crater;

providing an initial contact between the diaphragm and the valve seat crater at a defined
5 point; and
controlling a non-all-over sealing of the gap.

19. A method according to claim 18, further comprising completely closing the valve
seat crater with the diaphragm with a complete contact between the diaphragm and the valve seat
crater leading to the complete closing.

ABSTRACT OF THE DISCLOSURE

An exhalation valve, an inhalation valve, a ventilator and a method for controlling ventilation are provided. An exhalation valve (10) or inhalation valve (10) for a medical ventilator (30) for controlling a flow of a fluid, especially a breathing gas, has an inlet (12) and an outlet (14) for the fluid. Between the inlet (12) and the outlet (14), a valve seat crater (16) and a diaphragm (18) are provided. The diaphragm (18) is movable relative to the valve seat crater (16) for influencing the flow through the valve seat crater (16). The valve seat crater (16) and the diaphragm (18) are arranged such that the valve seat crater (16) can partially be sealed by means of the diaphragm (18), with the diaphragm (18) and the valve seat crater (16) not closing completely on initial contact of the diaphragm (18) and the valve seat crater (16).

APPENDIX: List of Reference Characters

10	Valve
12	Inlet
14	Outlet
16	Valve seat crater
18	Diaphragm
20	Area
20	Area
22	Sealing gap
24	Force
26	Sealing surface
28	Sealing contour
29	Fixing device
30	Ventilator
32	Damping element
34	Weighting
36	Reinforcement
41, 42, 42a, 42b, 42c, 44, 46	Steps
AGF	Breathing gas delivery unit
ANF	Anesthetic gas discharge line
ANS	Actuating signal
BS	Ventilation tube

BV	Ventilating device
CA	Carbon dioxide adsorber
DS	Pressure sensor
DSS	Pressure sensor signal
EP	Exhalation port
EXP	Exhalation phase
FT	Trigger threshold
INP	Inhalation phase
IP	Inhalation port
IV	Inhalation valve
KE	Piston unit
KO	Piston
LU	Lungs
M	Motor
MEM	Memory unit
NG	Anesthetic gas mixing unit
NGAS	Control signal
P	Pressure
PEEP	Minimum pressure
Pmax	Maximum pressure
PT	Patient
PV	Exhalation valve

R	Computer
RV	Nonreturn valve
T_IP	Duration
	Volume flow
VS	Volume flow sensor
VSS	Volume flow sensor signal
YS	Y-piece
ZP	Time
ΔP	Differential pressure