

MECHANICAL RESPIRATORY REGULATION UNIT

Cross-Reference to Related Application

5 This application claims priority to co-pending U.S. Provisional Application Serial Number 63/007,856, filed April 9, 2019, which is hereby incorporated by reference herein in its entirety.

Background

10 The COVID-19 crisis led to a tremendous need for low-cost, easy to manufacture ventilators. One of the main components of a ventilator is the inspiratory valve, which is opened for a given period of time to enable inspiration and then closed for a given period of time (possibly of different length) to enable expiration. For a typical respiratory rate of 10 to 20 breaths per minute, the
15 inspiratory valve must open and close 10 to 20 times per minute. Therefore, over the useful life of a ventilator, which is normally several years, the inspiratory valve must operate through millions of cycles. To ensure that it will last that long, most ventilator inspiratory valves comprise solenoid valves that are designed to withstand over 100 million cycles. Unfortunately, such robust solenoid valves are expensive.

Notably, the inspiratory valve is not by itself sufficient to control the respiratory process as it only controls the inspiratory portion of the respiratory cycle. Therefore, an expiratory valve is also required to control expiration. Moreover, an electronic control unit is typically needed to control the inspiratory/expiratory valves and, therefore, the inhalation/exhalation process, its rate, and the inhalation/exhalation timing ratio (I:E ratio), among other parameters. The additional need for an expiratory valve and the electronic control unit further increases the cost of the ventilator and, therefore, creates challenges to producing low-cost ventilators.

In view of the above discussion, it can be appreciated that it would be desirable to have alternative, less expensive means for controlling the respiratory process of a ventilator.

Brief Description of the Drawings

The present disclosure may be better understood with reference to the following figures. Matching reference numerals designate corresponding parts throughout the figures, which are not necessarily drawn to scale.

Fig. 1 is a front view of an embodiment of a respiratory regulation unit.

Fig. 2 is an exploded perspective view of the respiratory regulation unit of Fig. 1.

Fig. 3 is a horizontal cross-sectional view taken through a pinching case of the respiratory regulation unit of Fig. 1.

Fig. 4 is a perspective view of a cylindrical drum of the respiratory regulation unit of Fig. 1.

Fig. 5 is a vertical cross-sectional view taken through the pinching caes of the respiratory regulation unit of Fig. 1.

Detailed Description

As identified above, it would be desirable to have less expensive means for controlling the respiratory process of a ventilator than those that are currently used in existing ventilators. Disclosed herein is an example of such means. More particularly, disclosed is a mechanical respiratory regulation unit that is robust but utilizes a simple mechanical design that enables the unit to operate without the need for expensive solenoid valves or an electronic control unit. The respiratory regulation unit receives high-pressure gas, in the form of air or air mixed with oxygen, and alternately opens and closes an inspiration line and an expiration line that both lead to a patient's airway to control the patient's respiratory cycle. In some embodiments, the respiratory regulation unit achieves this by alternately pinching closed the inspiration line and the expiration line. In some embodiments, this pinching is achieved using a rotatable drum that is driven by an electric motor. The drum includes a pinch roller that alternately rolls along the inspiration and expiration lines to pinch them closed for period of time. Instead of requiring an electronic control unit, the duration of the inspiration and expiration portions of the respiratory cycle are controlled by simply changing the speed at which the drum rotates.

In the following disclosure, various specific embodiments are described. It is to be understood that those embodiments are example implementations of the disclosed inventions and that alternative embodiments are possible. Such alternative embodiments include hybrid embodiments that include features from different disclosed embodiments. All such embodiments are intended to fall within the scope of this disclosure.

Figs. 1-3 illustrate an example embodiment for a mechanical respiratory regulation unit 10. As shown in these figures, the respiratory regulation unit 10 is

configured as a small rectangular box that is defined by an outer housing 12. As is apparent from Fig. 2, the housing 12 comprises a first or bottom member 14, a second or top member 16, and a cover plate 18. Each of those three components can be secured together using conventional threaded fasteners, such as screws or
5 bolts.

With particular reference to Fig. 1, the cover plate 18 includes a respiratory cycle indicator 20 that includes indicia 22 and 24 that respectively identify the inhalation and exhalation portions of the respiratory cycle, as well as an indicator
10 needle 26 that rotates as the respiratory regulation unit 10 is operated and identifies the portion of the cycle that the respiratory regulation unit is regulating at any given time during such operation. As described below, the needle 26 is driven by a motor of the respiratory regulation unit 10 that also drives a rotatable drum that controls the opening and closing of inspiration and respiration lines that pass through the
15 respiratory regulation unit. Extending through the cover plate 18 are first and second rotatable controls 28 and 30 that can be rotated by an operator (e.g., a medical professional) to control the pressure of the gas that is delivered to the patient and the rate of respiration, respectively.

As is further shown in Fig. 1, an inspiration line 32 and an expiration line 34, each comprising a flexible polymeric tube, pass through the respiratory regulation
20 unit 10 to enable the it to control the opening and closing of the lines. Referring to Figs. 2 and 3, the inspiration and expiration lines 32, 34 enter and exit the top member 16 of the housing 12 through openings 36 that are formed through opposed ends of the member. As is most clearly illustrated in Fig. 3, each line 32, 34 passes through a pinching case 38. More particularly, each line 32, 34 passes through a
25 cylindrical cavity 40 formed within the pinching case 38. The cavity 40 is defined by

opposed arcuate walls 42 and 44 along which the lines 32, 34 respectively follow. In the illustrated embodiment, the inspiration line 32 follows the arcuate wall 42 while the expiration line 34 follows the arcuate wall 44.

As shown in Figs. 2 and 3, also provided within the cylindrical cavity 40 of the punching case 38 is a cylindrical, rotatable drum 46 that is located between the inspiration line 32 and the expiration line 34. As shown in greater detail in Fig. 4, the drum 46 comprises a continuous peripheral groove 48 that is formed along a central portion of the circular outer periphery of the drum between two opposed circular flanges 50. The groove 48 is configured to receive and provide space for the portions of the inspiration and expiration lines 32, 34 that pass through the cavity 40.

As shown in the cross-section of Fig. 3, the distances between the center of the groove 48 and each opposed arcuate wall 42, 44 of the cavity 40 is approximately the same dimension as the outer diameter of the inspiration and expiration lines 32, 34. Accordingly, the groove 48 provides just enough space for the lines 32, 34 so that they are not pinched by the rotatable drum 46. However, as shown Fig. 4, the drum 46 also comprises a cylindrical pinch roller 52 that is rotatably mounted at each end to one of the flanges 50 and positioned within (and, therefore, occupies a portion of) the groove 48 at a particular angular position along the outer periphery of the drum. In some embodiments, the roller 52 is sized and positioned so that its outer surface extends a small distance beyond the outer peripheries of the flanges 50 (see Fig. 5 below).

As the pinch roller 52 has an axis of rotation that is parallel with an axis of rotation of the drum 46, as the drum 46 rotates within the cavity 40, the pinch roller can roll along the portions of the inspiration and expiration lines 32, 34 that pass through the cavity. However, as the pinch roller 52 is positioned within the groove 48,

which provides just enough space for the lines 32, 34 to occupy, the pinch roller pinches the lines closed whenever it comes into contact with the lines.

An example of the above-described functionality is depicted in Fig. 5, which is a vertical cross-sectional view taken through the center of the cylindrical cavity 40 of the pinching case 38. As shown in that figure, the expiration line 34 (on the left side) is positioned within the groove 48 of the drum 46. As the distance between the center of the groove 48 and the arcuate wall 44 of the cavity 40 is approximately the same as the outer diameter of the expiration line 34, the expiration line is not pinched and exhaled gas can flow freely through the line during the expiratory portion of the respiratory cycle. On the opposite side of the cavity 40, however, the pinch roller 52 is shown rolling over the inspiration line 32 so as to pinch the line closed to prevent gas from being delivered to the patient's airway while the patient exhales. During the inspiratory portion of the respiratory cycle, however, the opposite situation occurs in which the inspiration line 32 is unaffected by the pinch roller 52 and is, therefore, wide open, while the expiration line 34 is pinched closed by the pinch roller.

As shown in Fig. 5, the cylindrical drum 46 is mounted to a vertical shaft 54 that is driven by an electric (e.g., direct current (DC)) motor 56. Extending upward from the drum 46 is a further vertical shaft 58 upon which the indicator needle 26 is mounted. As is also shown in Fig. 5, the needle 26 points in the direction of the pinch roller 52. With such an arrangement, the needle 26 rotates in unison with the drum 46 and at all times indicates to the operator the location of the pinch roller 52 during operation of the respiratory regulation unit 10. With further reference to Fig. 5, the pinch roller 52 is mounted to yet another vertical shaft 60 and can freely rotate about that shaft due to the provision of bearings 62 provided at both ends of the shaft.

As described above, the durations of the inspiratory and expiratory portions of the patient's respiratory cycle can be controlled by adjusting the speed at which the drum 46 is rotated. Notably, however, the inspiratory-to-expiratory (I:E) ratio of the respiratory cycle (which is a measure of the relative time for inspiration and expiration) is controlled by the relative lengths of the inspiration and expiration lines 32, 34. Assuming the drum 46 is rotated at a constant speed, the longer the portion of a given line 32, 34 within the cavity 40 is, the longer line is pinched closed and, therefore, the smaller the associated portion of the respiratory cycle will be. As shown in Fig. 3, the inspiration line 32 traverses a greater angular distance (e.g., approximately 135°) than the angular distance traversed by the expiration line 34 (e.g., approximately 115°). Accordingly, the inspiratory portion of the respiratory cycle will be shorter than the expiratory portion of the respiratory cycle and the I:E ratio will be less than 1 (again, assuming the drum 46 is rotated at a constant speed).

The above-described respiratory regulation unit is less expensive than existing systems, easy to manufacture, and even more reliable and robust than the regulation systems of commercially available ventilators. In some embodiments, the respiratory regulation unit can be operated through a nearly infinite number of cycles with much less cost as compared to systems that use multiple expensive solenoid valves. Instead of requiring such valves, the respiratory regulation unit functions as a simple dual-action mechanical valve (controlling both inspiration and expiration) that can be easily manufactured in the critical time of a pandemic crisis (such as MERS, SARS, COVID-19 family).

In addition, the respiratory regulation unit enables control over not only the respiration rate but also the pressure of the gas delivered to the patient. Although

other low-cost ventilators have been proposed for pandemic crises, most have no means of controlling the gas pressure. It is further noted that the respiratory regulation unit is modular. So, while the respiratory regulation unit can be connected to a fixed source of high-pressure gas (e.g., air, oxygen, or both) at a hospital, it can
5 also be connected to portable sources of pressurized gas, such as an electric air pump of the type typically used to inflate inflatable mattresses. Accordingly, the respiratory regulation unit can be used as part of a portable and/or makeshift ventilator.

The speed of the motor, and, therefore, the drum, can be controlled by a
10 potentiometer or another electronic speed controller, hence allowing control of the respiratory rate. In particular, the motor speed can be adjusted by varying the voltage (directly or via pulse-width modulation (PWM)) during the respiratory cycle, thereby enabling control of I:E ratio. The peak inspiratory pressure (PIP) can be manually controlled using a throttling valve or via an electronically controlled valve
15 (e.g., servo valve) on the inspiration line upstream of the respiratory regulation unit or by controlling the rpm of the compression unit. The positive end expiratory pressure (PEEP) can similarly controlled by another valve (manual throttling or electronically-controlled) on the expiration line downstream of the respiratory regulation unit. Hence, the respiratory regulation unit can be used to control the PIP,
20 PEEP, respiratory rate, and the I:E ratio. Air volume can also be monitored and electronically adjusted using feedback control.