APPARATUS AND METHOD FOR MONITORING AN AIRWAY DEVICE SUCH AS AN ENDOTRACHEAL TUBE

The present invention relates to the monitoring of an airway device, such as an endotracheal tube or other pharyngeal/laryngeal device for maintaining an open airway in an animal or human patient.

An endotracheal tube, or similar airway device, is used to maintain a clear airway in a patient, e.g. for artificial ventilation during surgery. Typically, the device includes an inflatable cuff, which is inflated when in position in a patient's airway. The inflated cuff forms a seal, between the airway device and the tissues surrounding the airway, to thereby maintain the device in position in a patient's airway, and to prevent leakage of infected oropharyngeal secretions into the patient's lungs.

WO-A-99/33508 describes an apparatus that includes a monitoring system for monitoring pressure in the cuff of a laryngeal mask airway device, and for maintaining the inflated cuff at a preset pressure, within narrow tolerances. In particular, the apparatus periodically measures the pressure within a closed system incorporating the inflated cuff and compares the measured pressure with a preset pressure, to determine a difference and its polarity. The apparatus then controls the pressure within the closed system to reduce the difference to zero. The disclosure of WO-A-99/33508 is incorporated herein, by reference.

The present invention seeks to provide improvements over the existing apparatus described in WO-A-99/33508.

According to a first aspect, the present invention provides a method for monitoring a pressure of an inflatable seal of an airway device, the method comprising: periodically receiving a pressure value indicative of the pressure

of the inflatable seal; comparing the received pressure value with a preselected, desired pressure value, and, if a difference between the received pressure value and the preselected pressure value is greater than a predefined tolerance, changing the pressure of the inflatable seal, to reduce the difference, characterised in that the step of changing the pressure is carried out at a rate dependent upon a difference between the received pressure value and the desired pressure value.

In prior art techniques, it is typical to respond quickly to correct pressure deviations from a set point. However, cyclic pressure changes in the inflatable seal occur as a result of intra-thoracic and intra-tracheal pressure from the patient's airway during the breathing cycle. In certain circumstances, responding instantaneously to correct pressure deviations resulting from normal cyclic changes may reduce the inflation pressure to below a minimum required to create a seal with the airway. This may lead to leakage of secretions past the seal into the patient's lungs, and increase the risk that the airway device may be dislodged.

Accordingly, the present invention minimises this problem, by controlling the rate at which the pressure is changed in response to a detected deviation or change in pressure from the desired pressure. Thus, instead of making an instantaneous change in pressure to correct for the deviation, the pressure is adjusted at a rate dependent upon the deviation of the measured pressure value from the desired pressure value. The rate of adjustment may be further limited by a threshold value. By controlling the rate of pressure adjustment, the time taken to correct for the deviation from the desired value is delayed. Typically, the rate of adjustment produces a delay for a period that corresponds to, or is greater than, a normal time period for inspiration or expiration, which represents the greatest deviation in pressure associated with the breathing cycle.

In one embodiment, the rate of change of pressure is dependent on the square of the difference between the measured pressure value and the desired value.

For example, in an embodiment in which a piston is utilised to change the volume, and hence the pressure, in a closed volume system, the piston is moved at a rate N that is defined by the equation:

$$N = \frac{((P_1 - S)^2 * S)}{(R)}$$

Where: P_1 is the actual measured pressure
S is the set point or desired pressure
* is the multiplier operation
R is a regulation constant

In one embodiment, the rate N is a speed that corresponds to the number of steps per second moved by a stepper motor driving the piston.

The rate N may be subject to a predetermined maximum threshold speed. Thus, if the calculated rate N is greater that the threshold, the piston is controlled to move at the threshold rate.

Typically, if the measured pressure is higher than the set-point/desired pressure, the motor drives the piston backward at rate N in order to reduce pressure, and if the measured pressure is lower than set-point motor drives the piston forward at rate N in order to increase pressure.

In one embodiment, the measured pressure value is received at periodic time intervals, for example time intervals in the range of 0.1 to 2.5 seconds, and the rate of change of volume, and thus pressure, recalculated and adjusted. In one embodiment, the rate is recalculated every 0.5 seconds.

According to the second aspect, the present invention provides a method for detecting a change in position of an airway device with an inflatable seal, the

CLAIMS:

1. A method for monitoring a pressure of an inflatable seal of an airway device, the method comprising the steps of:

receiving a pressure value indicative of the pressure of the inflatable seal;

comparing the received pressure value with a preselected, desired pressure value, and

if a difference between the received pressure value and the preselected pressure value is greater than a predefined tolerance, changing the pressure of the inflatable seal, to reduce the difference;

wherein the step of changing the pressure is carried out at a rate dependent upon a difference between the received pressure value and the desired pressure value; and

said rate change is delayed for a period that corresponds to, or is greater than, a normal time period for inspiration or expiration.

2. A method as claimed in claim 1, wherein the step of receiving a pressure value is carried out periodically at predefined time intervals.

3. A method as claimed in claim 2, wherein the predefined time intervals are in the range of 0.1 to 2.0 seconds.

4. A method as claimed in claim 1, 2 or 3, wherein the step of changing the pressure is carried out at a rate that is dependent on the square of the difference between the received pressure value and the preselected pressure value.

5. A method as claimed in any one of claims 1 to 4, wherein the step of changing the pressure is carried out by changing a volume of closed volume pressure system, wherein the change in volume is carried out at a rate that is proportional to:

$$\underline{((P_I - S)^2 * S)}$$

(R)

Where: N is the rate of change of volume
P_1 is the actual measured pressure
S is the set point or desired pressure
* is the multiplier operation
R is a regulation constant.

6. A method as claimed in any preceding claim, wherein the step of changing the pressure is carried out at a rate that is further limited to a predetermined threshold rate.

7. A method as claimed in any preceding claim, wherein a change in position of the airway device with an inflatable seal is detected by, comparing a received pressure value indicative of the pressure of the inflatable seal with a predefined pressure value to determine a difference, and, if the difference is greater than a predetermined amount for a predetermined time period, indicating a detected change in position of the airway device.

8. A method as claimed in claim 7, wherein the predefined pressure value is a previous pressure value that is within predefined tolerances of a preselected, desired pressure value.

9. A method as claimed in claim 7 or claim 8, wherein the predetermined amount is a proportion of the predefined pressure value.

10. A method as claimed in claim 9, wherein the predetermined amount is in the range of 15% and 25% of the predefined pressure value, preferably 20%..

11. A method as claimed in any one of claims 7 to 10, wherein the predetermined time is in the range of 15 seconds to 1 minute.

12. A method as claimed in claim 7, comprising:

receiving a first pressure value indicative of a pressure of the inflatable seal, the pressure value within predefined tolerances of a preselected desired pressure value;

thereafter, periodically receiving further pressure values at predetermined time intervals;

comparing each received pressure value with a predetermined pressure value to determine a difference;

if the difference is greater than a predetermined amount, starting a timer for a predetermined time period, and

if the further, periodically received pressure values are not within the predefined tolerances of the preselected pressure value before the timer has expired, indicating a detected change in position of the airway device.

13. A method as claimed in claim 12, wherein the predetermined pressure value is either the preselected pressure value or the first pressure value.

14. A method as claimed in any preceding claim, wherein a change in position of the airway device with an inflatable seal is detected by, periodically comparing a received pressure value indicative of the pressure of the inflatable seal with a predefined threshold value, and, if the pressure value exceeds the threshold value for a predetermined time period, indicating a detected change in position of the airway device.

15. A method as claimed in any preceding claim, wherein a leak of fluid from an inflatable airway device is detected by

receiving a pressure value for the inflatable airway device;

calculating a statistical average of a values calculated using the received pressure value and a predetermined number of previously received pressure values; and

if the statistical average exceeds a threshold average, indicating a leak of fluid from the airway device.

16. A method as claimed in claim 15, wherein the values calculated using the received and previously received pressure values are values representing a rate of change in volume or pressure of fluid within the inflatable airway device.

17. A method as claimed in any preceding claim, wherein a leak of fluid from an inflatable airway device is detected by periodically receiving a pressure value for the inflatable airway device; comparing the received pressure value with a predetermined, minimum pressure value, and if the received pressure value is less than the predetermined minimum pressure value, indicating a leak of fluid from the airway device.

18. A method as claimed in claim 16, wherein the predefined minimum pressure value is a predetermined proportion of a preselected, desired pressure value, for example 50% of the preselected pressure value.

19. A method as claimed in any preceding claim, wherein a blockage in a pressure system of an inflatable airway device is detected by receiving a pressure value for the inflatable airway device and calculating an average value of deviations in pressure from a desired value , and, if the average value of deviations in pressure from a desired value is below a threshold for activity for a predetermined time period, indicating a blockage in the pressure system of the airway device.

20. A method as claimed in any preceding claim, wherein a blockage in a pressure system of an inflatable airway device is detected by comparing a received pressure value for the inflatable airway device, with a predetermined or average pressure value to calculate a difference; calculating a statistical average of the difference and a predetermined number of differences calculated using previously received pressure values; comparing the statistical

average with a threshold average, and, if the statistical average is less than the threshold for a predetermined time period indicating a blockage in the pressure system of the airway device.

21. A computer readable medium comprising program instructions which, when executed, perform the method of any one or more of claims 1 to 20.

22. An apparatus comprising processor means, configured for carrying out the method of any one or more of claims 1 to 20.