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Calibration Specification for Ventilators

呼吸机校准规范

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1 Scope

This Specification is applicable to the calibration of invasive ventilator (hereinafter referred to as ventilator).

This Specification is inapplicable to non-invasive ventilator, high-frequency jet ventilator, high-frequency oscillatory ventilator or emergency ventilator; nor is it applicable to equipment merely used to increase patients' ventilatory capacity in hospitals.

2 References

This Specification takes the following documents as references:

GB/T 8982-2009 *Oxygen Supplies for Medicine and Aircraft Breathing*

GB 9706.28-2006 *Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators*

YY 0600.3-2007 *Lung Ventilators for Medical Use - Particular Requirements for Basic Safety and Essential Performance - Part 3: Emergency and Transport Ventilators*

YY 0601-2009 *Medical Electrical Equipment - Particular Requirements for Basic Safety and Essential Performance of Respiratory Gas Monitors*

Pharmacopoeia of the People's Republic of China (Version 2015)

In terms of references with a specified date, only versions with a specified date are applicable to this Specification. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this Specification.

3 Terms and Definitions

3.1 Ventilators

Ventilator refers to an automatic device designed to increase or provide ventilation for patients.

3.2 Ventilation Mode

Ventilation mode refers to the mechanical ventilation treatment method of ventilator,

Positive end-expiratory pressure refers to the pressure value of end-expiratory airway. It is expressed in (kPa).

3.12 Test Lung

Test lung refers to a mechanical ventilation load that simulates a patient's chest and lung characteristics (pulmonary compliance and airway resistance parameters are fixed, graded or adjustable), including test lung for adults, test lung for infants, or hybrid test lung.

3.13 Lung Compliance, *C*

Lung compliance refers to within a unit pressure, the volume of gas that lung can hold. It is expressed in (mL/kPa).

3.14 Airway Resistance, *R*

Airway resistance refers to within a unit flow, the pressure value that airway can generate. It is expressed in [kPa/(L•s^{-1})].

NOTE: 1 kPa = 10 mbar = 10 cmH_2O = 10 hPa.

4 Overview

Ventilator is a kind of ventilation equipment for clinical treatment of patients with respiratory insufficiency or respiratory failure. The fundamental principle of ventilator is to mix medical air and oxygen, and in accordance with certain ventilation mode and respiratory airway mechanical parameters (tidal volume, respiratory frequency, I:E, airway peak pressure, positive end-expiratory pressure and inspiration flow oxygen concentration, etc.), through patient's circuit, deliver the air-oxygen mixed gas to the patient, so as to force or assist the patient to breathe, thereby, maintaining the patient's respiratory function.

5 Metrological Characteristics

5.1 Tidal Volume

In terms of ventilator whose delivered tidal volume (V_T) > 100 mL, or, whose minute volume > 3 L/min, the relative indication error shall not exceed ± 15%. In terms of ventilator whose delivered tidal volume (V_T) ≤ 100 mL, or, whose minute volume ≤ 3 L/min, it shall satisfy relevant requirements of the instruction for use.

5.2 Respiratory Frequency

The maximum permissible error of respiratory frequency (*f*): ± 10% of set value or ± 1 number of times / minutes. The greater absolute value between them shall prevail.

1. The compatibility of gas flow measurement: air, oxygen and air-oxygen mixed gas.

2. Reference or compensation standard of gas flow measurement: equipped with the compensation capability in ambient temperature, ambient atmospheric pressure (ATP); standard temperature (0 °C or 21 °C), standard atmospheric pressure (101.325 kPa) (STP); body temperature, ambient atmospheric pressure, saturated with water vapor (BTPS), etc.

6.2.2 Test lung

a) Volume of test lung: (0 ~ 300) mL and (0 ~ 1,000) mL;

b) Lung compliance: 50 mL/kPa, 100 mL/kPa, 200 mL/kPa and 500 mL/kPa; may be selected in accordance with demands;

c) Airway resistance: 0.5 kPa / (L•s^{-1}), 2 kPa / (L•s^{-1}) and 5 kPa / (L•s^{-1}); may be selected in accordance with demands.

6.2.3 Calibration medium

Medical oxygen and medical compressed air used for the calibration of ventilator shall comply with the requirements of GB/T 8982-2009 *Oxygen Supplies for Medicine and Aircraft Breathing* and *Pharmacopoeia of the People's Republic of China* (Version 2015).

7 Calibration Items and Calibration Methods

7.1 Appearance and Functionality Inspection

7.1.1 The equipment to be calibrated shall be intact in structure, and free of defects and mechanical damages that would affect the normal operation and hinder the reading.

7.1.2 The power switch of the equipment to be calibrated shall be reliably installed; the on-off status shall be obvious; the control button shall be clearly marked and easy to control.

7.1.3 The equipment to be calibrated shall be marked with the name of instrument, manufacturer, model and exit-factory No.

7.1.4 The equipment to be calibrated shall work normally after being turned on.

7.2 Tidal Volume

7.2.1 As it is shown in Figure 1, correctly connect the ventilator to be calibrated, the ventilator tester and the test lung. In addition, in accordance with the requirements of the instruction for use, start the pre-heating of related equipment.

$\bar{p}_0$--- arithmetic mean value of 3 monitored values of airway peak pressure of calibrated ventilator, expressed in (kPa);

$\bar{p}_m$---arithmetic mean value of 3 measured values of tester, expressed in (kPa).

NOTE: when the calibrated instrument does not have the airway peak pressure monitoring function, $\bar{p}_0$ in Formula (3) refers to the set value of airway peak pressure of the calibrated ventilator.

7.5 Positive End-expiratory Pressure

7.5.1 In accordance with Figure 1, connect the calibrated ventilator, the ventilator tester and the test lung. Then, under the condition: PCV mode or VCV mode, and IPL = 2.0 kPa or V_T = 400 mL; f = 15 times/min; I:E = 1:2; F_iO_2 = 40%, respectively calibrate the calibration point of 0.2 kPa, 0.5 kPa, 1.0 kPa, 1.5 kPa and 2.0 kPa positive end-expiratory pressure. For each calibration point, respectively record for 3 times the monitored value of positive end-expiratory pressure of ventilator and the measured value of positive end-expiratory pressure of tester.

7.5.2 The calculation of indication error of positive end-expiratory pressure shall take 7.4.2 as a reference.

7.6 Inspiration Flow Oxygen Concentration

7.6.1 In accordance with Figure 1, connect the calibrated ventilator, the ventilator tester and the test lung. Then, under the condition: VCV mode, and V_T = 400 mL; f = 15 times/min; I:E = 1:2; PEEP = 0.2 kPa, respectively calibrate the calibration point of 21%, 40%, 60%, 80% and 100% inspiration flow oxygen concentration. For each calibration point, respectively record for 3 times the monitored value of inspiration flow oxygen concentration of ventilator and the measured value of inspiration flow oxygen concentration of tester.

7.6.2 Indication error of inspiration flow oxygen concentration shall be calculated in accordance with Formula (4).

$$\delta = \bar{m}_0 - \bar{m}_m \qquad (4)$$

Where,

δ---indication error of inspiration flow oxygen concentration of calibrated ventilator, expressed in (%);

$\bar{m}_0$ ---arithmetic mean value of 3 monitored values of inspiration flow oxygen concentration of calibrated ventilator, expressed in (%);

$\bar{m}_m$---arithmetic mean value of 3 measured values of tester, expressed in (%).

NOTE:

1. When the calibrated instrument does not have the inspiration flow oxygen concentration monitoring function, $\overline{m}_0$ in Formula (4) refers to the set value of inspiration flow oxygen concentration of the calibrated ventilator.

2. The calibration method of respiratory frequency, airway peak pressure, positive end-expiratory pressure and inspiration flow oxygen concentration of pediatric ventilator is the same as the calibration method of adult ventilator. The calibration condition may select: infant's test lung; tidal volume shall be set as 150 mL; I:E shall be set as 1:1.5; other conditions may remain the same.

8 Expression and Processing of Calibration Result

8.1 Calibration Record

Please refer to Appendix A for the format of calibration record.

8.2 Processing of Calibration Result

Please refer to Appendix B for the format of inside page of calibration certificate. The calibration certificate shall at least include the following content:

a) Title, for example, "calibration certificate";

b) Name and address of laboratory;

c) Location of calibration (if calibration is not conducted in laboratory);

d) Unique identification of certificate or report (for example, certificate No.), identification of each page and total pages;

e) Name and address of client;

f) Description and clear identification of calibrated ventilator (such as model and product No., etc.);

g) Date of calibration or effective date of calibration certificate;

h) Identification of technical specification, on which, calibration is based, including name and code;

i) Description of traceability and validity of measurement standards used for calibration;

j) Description of calibration environment;

k) Description of calibration result and measurement uncertainty;

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