

JIS

JAPANESE INDUSTRIAL STANDARD

**Lung Ventilators for
Medical Use**

JIS T 7204—1989

Translated and Published

by

Japanese Standards Association

Printed in Japan

In the event of any doubt arising,
the original Standard in Japanese is to be final authority.

JAPANESE INDUSTRIAL STANDARD

J I S

Lung Ventilators for Medical Use

T 7204-1989

1. Scope

This Japanese Industrial Standard specifies lung ventilators for adults, children, or newborns for medical use (hereafter referred to as the "lung ventilators"). These lung ventilators include those used exclusively for anesthesia.

Remarks: In this Standard the units and numerical values shown in { } are in accordance with the traditional units and are appended for informative reference.

2. Definitions

For the purposes of this Standard the following definitions apply. Those in () of definitions indicate the symbols.

- (1) lung ventilator The automatic ventilation apparatus designed so as to be connected with the patient's airway in order to regulate or augment the patient's ventilation.
- (2) breathing controller The apparatus which inflates the patient's lungs independent of the patient's inspiratory effort.

Applicable Standards:

JIS T 1001-General Requirements for Safety of Medical Electrical Equipment

JIS T 1005-Style Manual for Instruction Manuals

JIS T 7201-Anesthetic Machines

Corresponding International Standards:

ISO 5369 Breathing machines for medical use - Lung ventilators

ISO 8185 Humidifiers for medical use - Safety requirements

Relating laws and regulations: The Drugs, Cosmetics and Medical Instruments Act

- (3) breathing assistor The device designed to augment the patient's inspirations synchronously with the patient's inspiratory effort.
- (4) assistor-controller Apparatus which is designed to function either as an assistor or a controller and which may, in default of the patient's inspiratory effort, automatically function as a controller.
- (5) ventilatory frequency (f) The number of breathing cycles per minute.
- (6) tidal volume (V_T) Volume of gas (to be expressed by ml) entering or leaving the patient or the test lung during the inspiratory or expiratory phase time.
- (7) minute volume ($\dot{V}_E$) Volume of gas (to be expressed by l) entering or leaving the patient in 1 min.
- (8) breathing system Parts of gas system of lung ventilator where the breathing gas passes at breathing pressure.
- (9) apparatus internal compliance Volume/pressure relationship of gases in those portions of the breathing system or entering the composing parts which are pressurized during the inspiratory phase (to be expressed by ml/kPa {ml/cm H₂O}).
- (10) ventilator pressure (P_{vent}) Pressure of gas at a specified point in the breathing system of lung ventilator.
- (11) airway pressure (P_{aw}) Pressure of gas at a specified point in the patient's airway.
- (12) alveolar pressure (P_A) Pressure of gases in the alveolar. In the case of the test lung this is expressed by the pressure in the compliance model.
- (13) sub-atmospheric pressure; sub-ambient pressure Pressure of gas in the breathing system lower than the ambient, developed by the ventilator during the expiratory phase time.
- (14) maximum safety pressure ($P_{s, max}$) Highest gauge pressure which can be attained in the breathing system restricted with safety mechanism.
- (15) minimum safety pressure ($P_{s, min}$) Highest numerical value of sub-atmospheric gauge pressure which can be attained in the breathing system of lung ventilator restricted with a safety mechanism.

- (16) maximum working pressure ($P_{w, \max}$) Highest numerical value of pressure which can be attained in the breathing system during the inspiratory phase when the ventilator is functioning normally. This value does not exceed the maximum safety pressure according to the mechanism of a ventilator capable of being controlled.
- (17) minimum working pressure ($P_{w, \min}$) Highest numerical value of sub-atmospheric gauge pressure which can be attained in the breathing system during the expiratory phase when the ventilator is functioning normally. This value does not exceed the minimum safety pressure according to the mechanism of ventilator capable of being controlled.
- (18) inspiratory triggering pressure (P_{tr}) Airway pressure at the patient connection port which must be generated by the patient to initiate the ventilator inspiratory phase.
- (19) inspiratory triggering flow ($\dot{V}_{tr}$) Gas flow which must be generated by the patient at the patient connection port to initiate the ventilator inspiratory phase.
- (20) inspiratory triggering volume (V_{tr}) Gas volume measured at the patient connection port which must be moved by the patient to initiate the ventilator inspiratory phase.
- (21) inspiratory triggering response time (T_{tr}) Time delay between the attainment of the inspiratory triggering pressure, flow or volume requirements and the start of inspiratory flow.
- (22) inspiratory relief valve Unidirectional valve designed to admit air to the breathing system when the patient inspires spontaneously and the supply of inspiratory gases from the ventilator is inadequate.
- (23) inspiratory relief valve resistance Pressure difference across the inspiratory relief valve measured at a specified flow (for adult, 30 l/min).
- (24) inspiratory phase time (T_I) Interval from the start of inspiratory flow to the start of expiratory flow.
- (25) expiratory phase time (T_E) Interval from the start of expiratory flow to the start of inspiratory flow.
- (26) inspiratory pause time (T_{IP}) Interval from the end of inspiratory flow to the start of expiratory flow.
- (27) expiratory pause time (T_{EP}) Interval from the end of expiratory flow to the start of inspiratory flow.
- (28) inspiratory/expiratory phase time ratio ($I:E$ ratio) Ratio of the inspiratory phase time to the expiratory phase time.

- (29) sigh (S_{igh}) Deliberate increase in tidal volume for one or more breaths at specified intervals.
- (30) work (W) Work performed by the ventilator on the patient [to be expressed in joules (J)].

$$W = \int (P_{\text{aw}} \times \dot{V}) dt$$

where, $\dot{V} = \frac{dV}{dt}$

- (31) power ($P = \dot{W}$) Rate of work performed by ventilator on the patient [expressed in watts (W)].

$$P = \dot{W} = P_{\text{aw}} \times \dot{V}$$

where, $\dot{V} = \frac{dV}{dt}$

- (32) expiratory resistance For ventilators in which expiration is not assisted, the total resistance to gas flow from the patient connection port through the expiratory port of ventilator to atmosphere. (This is expressed conventionally by cm H₂O.).
- (33) time constant Time in which an exponential change is approximately 63 % complete.
- (34) PEEP (positive end expiratory pressure) In expiratory phase the pressure when the positive pressure is retained until its end time.
- (35) CPAP (continuous positive airway pressure) The method to add continuous positive pressure at end expiration time of spontaneous breathing.
- (36) IMV (intermittent mandatory ventilation) The method to carry out the positive airway pressure with ventilator intermittently during spontaneous breathing. The ventilation synchronous with inspiration is called SIMV (synchronized intermittent mandatory ventilation).
- (37) spirometer (breathing volume meter) Device designed to measure a volume of gas to be expired or inspired by breathing.
- (38) nebulizer (spray humidifier) Device to add medical liquid or water in the form of micro particles to inspiratory gas.
- (39) vaporizing humidifier Device to add medical liquid or water in the form of vapor to inspiratory gas.
- (40) humidifier Generic name of nebulizer and vaporizing humidifier.

- (41) test lung The simulated lung to be used for performance test of ventilator, usual function check, etc., by connecting with patient's connecting end of ventilator.

3. Structure and performance

3.1 Power source The power source, in the range from the maximum rated voltage 105 % to the minimum rated voltage 90 % or from the maximum rated operating gas pressure 105 % to the minimum rated operating gas pressure 90 %, shall continue the effective function at any adjusting set, and, be ± 10 % in error or variation of tidal volume or minute volume.

3.2 Accuracy of controller, indicator and pressure relief valve

3.2.1 Graduated controller and indicator When actuating at rated input power, the accuracy of all graduated controller and indicator shall be ± 10 % of the maximum graduation.

3.2.2 Airway pressure The graduated positive pressure (expiration) control valve, sub-atmospheric pressure (inspiration) control valve, and relief valve shall, in cases of the other control setting or in the case of a completely clogged airway, be limited to ± 0.49 kPa [± 5 cm H₂O] of set value or ± 20 % of set value (whichever is the larger) in airway pressure. At the time of rapid variation of breathing system, it may exceed this controlling value temporarily, but the relief valve shall function so this influence remains at the minimum limit.

3.2.3 Airway pressure gauge and breathing system pressure gauge
The airway pressure gauge and breathing system pressure gauge shall comply with the following conditions:

- (1) The scale has the width of at least from -0.98 kPa [-10 cm H₂O] up to $+9.8$ kPa [$+100$ cm H₂O].
- (2) If required, the zero-point control can be performed.
- (3) The reading values are within the error range of $\pm$ (the sum of 2 % of full scale width and 4 % of read out value).
- (4) The indicating scale can be read out at a distance of 1 m apart from the lung ventilator under the illumination of 215 lx (20 feet candle-power) by a person having normal visual power (completed with rectification).

Remarks: The normal visual power means, in the case of naked eyes or in the case of weak naked eyes where those are rectified suitably with lenses, the visual power of 1.0 or more by both eyes.

3.3 Spirometer The spirometer shall comply with the following conditions.

- (1) The accuracy of the spirometer shall, in the range of specified capacity and flow rate, be $\pm 10\%$ of read-out value.

Further, the resistance to be generated by passing the spirometer at the normal flow rate of 30 l per min does not exceed 0.098 kPa {1.0 cm H₂O}.

- (2) The spirometer, even under any humidity conditions and even in the range of 10 to 37°C, can maintain the function in the error range specified in (1).

The differences of gas temperature and humidity in the spirometer and those at the corrected time are to be taken into consideration. The spirometer to be set nearby the patient is to be of such structure that it is not clogged by secretion of patient.

- (3) The spirometer, except in the case of one time use, is capable of disinfecting and sterilizing [Refer to 7.(8)].

Remarks: The lung ventilator without a built-in apparatus to measure the expiratory gas should preferably be a structure capable of connecting a spirometer to it.

3.4 Gas characteristics The characteristics of gas to be fed in the patient shall be as follows:

- (1) The gas temperature at the patient side end of breathing tube can be so maintained that it does not become lower by 5°C or more than the environmental temperature and does not exceed 41°C [Refer to 3.8(13)].
- (2) In the case where the lung ventilator is assembled with a inspiration gas mixing controller, the concentration of oxygen to be fed-in, in the set range of ventilatory frequency and tidal volume of the lung ventilator, is to be $\pm 10\%$ of the set value.

Further, the oxygen concentration is stabilized at $\pm 3\%$. In case where this condition is not satisfied, this lung ventilator must be marked with the purport that the correct control of concentration of oxygen to be fed-in the patient is impossible.

Remarks: In the case of such system that two or more kind pressure gases are introduced into the inspiratory gas mixing controller, the reverse flow preventive valves should preferably be provided at respective gas inlets.

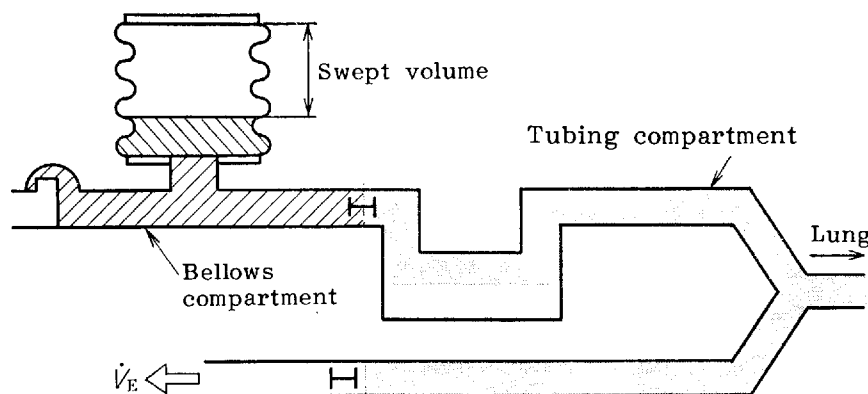
3.5 Expiration resistance In the case of no expiratory resistor nor positive end expiratory pressure apparatus or when it is not used, even in the case where the breathing accessories and spirometer recommended by the manufacturer are used, the pressure at the patient connection port at the expiration flow rate of 0.5 l per second for adult use, 0.25 l per second for children and 0.83 l per second for newborn infant shall not exceed 0.49 kPa {5 cm H₂O}.

Further, for following these requirements, in the case of requiring expiratory accessory, the effect shall be described in the handling instruction manual.

3.6 Apparatus internal compliance The lung ventilator internal compliance, hereafter referred to as the "internal compliance", shall comply with the following conditions.

- (1) For the lung ventilator attached with the tidal volume scale at the bellows part, the internal compliance is to be divided into the following two components (Refer to Fig. 1).
 - (a) Breathing system part in the lung ventilator from the gas inlet to inspiratory valve (Bellows part).
 - (b) The part in the breathing tube from inspiratory valve to expiratory valve (Tubing compartment).

Fig. 1. Internal compliance



- (2) The tubing compartment may include humidifier and water traps if desired. The manufacturer must state in the instruction manual which components are to be found in the breathing system during the test and the probable variations in compliance due to manufacturing tolerances or variations in humidifier water level.

- (3) The matters to influence to the expired gas volume measurement such cases where a part of gas compressed in the bellows compartment is discharged to atmosphere passing through the expiratory valve, and this gas volume is a part of gas volume to be measured in the tubing compartment, where the expired gas augments by a continuous nebulizer indicating the likely error in expired gas volume measurement, etc., are to be described in the handling instruction manual.
- (4) In the case where the volume/pressure relationship of two compartments of bellows and tubing is non-linear, the volume/pressure diagram covering a range of end-inspiratory pressures up to 5.88 kPa {60 cm H₂O} in internal compliance or to the maximum safety pressure of lung ventilator, whichever is the lower is to be described in the handling manual.

- Remarks 1. During mechanical ventilation, between the set value of tidal volume, the gas volume to be fed in lung and the gas volume to be discharged from inspiratory system, a difference may be generated. These differences are due to fresh gas added to the system in the inspiratory phase, compression of gas in the breathing system, elasticity or leakage of bellows or wall of connecting breathing tube or the like. The gas volume to be compressed in breathing system varies by breathing system internal pressure at inspiratory end, but it is determined by internal compliance.
2. Due to internal compliance of the bellows compartment, the difference between the tidal volume setting and the gas volume passing the inspiratory valve is generated. In most lung ventilators this gas volume remains in the lung ventilator, and does not affect with the gas volume to be measured by spirometer at the expiratory port. The gas volume recorded at expiratory port by the internal compliance of tubing compartment may become larger than the gas volume fed in the lung.

3.7 Alarm system The alarm system shall comply with the following conditions.

- (1) The alarm system provides warning of ventilator malfunction, and actuates due to abnormal changes of inspired gas composition or temperature, leakage or clogging in the breathing system (abnormal change in flow rate and pressure), abnormalities of power source, etc.
- (2) The alarm system actuates even independently upon all main mechanisms of the lung ventilator.