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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Breathing machines for medical use — Lung ventilators

Respirateurs médicaux — Ventilateurs pulmonaires

Reference number
ISO 5369 : 1987 (E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5369 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment.*

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Breathing machines for medical use — Lung ventilators

0 Introduction

The main purpose in the preparation of this International Standard was to specify minimum requirements for the design and construction of lung ventilators for medical use. The aim was to ensure that machines designed for this purpose should be safe and be compatible with other apparatus used in similar applications throughout the world. Since lung ventilators have different capabilities, test procedures were developed to provide information concerning their behaviour when used to ventilate lungs with different characteristics.

Progress in this field has been rapid and is still continuing. For this reason no attempt has been made in section two to specify the characteristics of an ideal ventilator. It was considered that any such specification would soon be outdated and that it might also inhibit further developments in this field. However it is intended to include further developments dealing with safety and performance of lung ventilators. These developments may incorporate new functions and ventilatory patterns. In view of the known effects of lung ventilator characteristics on the patient's circulatory and respiratory function, it was considered important that the manufacturers should provide as much information as possible for the use of the prospective purchaser. To facilitate this exchange of information a test procedure has been devised utilizing an example of a test lung with a number of different, but standardized, impedances to lung ventilator output. It is intended that information derived from tests on this model should supplement other information customarily provided by the manufacturer.

Test methods are given in annex A and test data for constant-flow generators are given in annex B : both annexes form an integral part of this International Standard. Respiratory data for normal children are given, for information purposes, in annex C.

1 Scope and field of application

This International Standard specifies basic requirements for lung ventilators for medical use.

Section one defines the main classes of breathing machines used in medical practice and indicates how these may be further subdivided according to their mode of action.

Section two gives definitions of the terms used in the field of lung ventilators designed for adult, paediatric and neonatal patients. Characteristics for lung ventilators are also specified.

2 References

ISO 5356, *Anaesthetic and respiratory equipment — Conical connectors —*

Part 1 : Cones and sockets.

Part 2 : Screw-threaded weight-bearing connectors.

ISO 8185, *Humidifiers for medical use — Safety requirements.*

IEC Publication 601-1, *Safety of medical electrical equipment — Part 1 : General requirements.*

IEC Publication 601-2-12, *Medical electrical equipment — Part 2: Particular requirements for the safety of lung ventilators.* [1)]

IEC Publication 601-2-13, *Medical electrical equipment — Part 2: Particular requirements for the safety of anaesthetic machines.* [1)]

1) At present at the stage of draft.

Section one : Breathing machines — General

3 Classification and definitions of types of breathing machines

Class of equipment	Classification and definition
3.1 Lung ventilator	Automatic device which is connected to the patient's airway and is designed to augment or provide the patient's ventilation. The types of lung ventilators are as follows : **3.1.1 controller** : Apparatus which inflates the patient's lungs independently of the patient's inspiratory effort. **3.1.2 assistor** : Device designed to augment the patient's inspirations synchronously with his inspiratory effort. **3.1.3 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.
3.2 Resuscitator	Portable device used in emergency situations to provide lung ventilation to individuals whose breathing is inadequate. Resuscitators are classified according to their prime movers as follows : a) operator-powered; b) gas-powered; c) electrically powered.
3.3 Respiratory therapy ventilator	Device which is connected to the patient's airway and is primarily designed to deliver an aerosol and/or augment ventilation.
3.4 External body ventilator	Machine designed to augment or replace the patient's ventilation by means of the application of intermittent or alternating pressures to the trunk. External body ventilators are classified as follows : **3.4.1 tank or cabinet** : External body ventilator in which the patient is enclosed to his neck in a rigid airtight chamber. **3.4.2 cuirass** : External body ventilator in which all or part of the trunk is in an airtight enclosure, forming or incorporating a rigid frame. **3.4.3 belt** : External body ventilator consisting of a flexible airtight bag wrapped around the patient's trunk. When inflated the bag produces forced expiration followed by inspiration upon deflation.
3.5 Rocking apparatus	Device used to produce or aid ventilation by using the weight of the abdominal contents to move the diaphragm.
3.6 Electrostimulator	Apparatus in which activity of the respiratory musculature is induced by electric impulses acting on the corresponding nerves or muscles.

Section two : Lung ventilators

4 Definitions related to the performance of lung ventilators

For the purposes of this International Standard, the following definitions apply.

4.1 (ventilatory) frequency, f : The number of breathing cycles per minute (bpm).

4.2 tidal volume, V_t : Volume of gas, expressed in millilitres, entering or leaving the patient (or the test lung) during the inspiratory or expiratory phase time. The physical conditions under which measurements are made should be given.

4.3 minute volume, $\dot{V}_E$: Volume of gas, expressed in litres in 1 min, entering or leaving the patient (or the test lung). The physical conditions under which measurements are made should be given.

4.4 volumetric displacement : That volume, expressed in millilitres, passed per cycle, during the inspiratory phase through the patient connection port when the pressures at the intake to the ventilator and at the outlet from the patient connection port are equal to the atmospheric pressure. (Such a volume may or may not be equal to the patient's tidal volume.)

4.5 breathing system : Those gas pathways continuously or intermittently in communication with the patient's respiratory tract during any form of ventilation.

4.6 apparatus internal compliance : Volume/pressure relationship of gases in those portions of the breathing system which are pressurized during the inspiratory phase time (see clause 12).

4.7 ventilator pressure, p_{vent} : Pressure of gas at a specified point in the ventilator. The site and conditions under which measurements are made should be given.

4.8 airway pressure, p_{aw} : Pressure of gas at a specified point in the patient's airway. The site and conditions under which measurements are made should be given.

4.9 alveolar pressure, p_A : Pressure of gases in the alveoli. In the case of the test lung this is represented by the pressure in the compliance chamber.

4.10 sub-atmospheric pressure; sub-ambient pressure : Pressure of gas in the breathing system lower than ambient, developed by the ventilator during the expiratory phase time.

4.11 maximum safety pressure, $p_{s,max}$: Highest gauge pressure which can be attained in the breathing system during malfunction of the ventilator but with functioning safety mechanisms.

4.12 minimum safety pressure, $p_{s,min}$: Highest numerical value of sub-atmospheric gauge pressure which can be attained in the breathing system during malfunction of the ventilator but with functioning safety mechanisms.

4.13 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.

4.14 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.

4.15 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.

4.16 differential inspiratory triggering pressure, Δp_{tr} : Change in airway pressure at the patient connection port which must be generated by the patient to initiate the ventilator inspiratory phase.

4.17 inspiratory triggering flow, $\dot{V}_{tr}$: Flow which must be generated by the patient at the patient connection port to initiate the ventilator inspiratory phase.

4.18 inspiratory triggering volume, V_{tr} : Volume measured at the patient connection port which must be moved by the patient to initiate the ventilator inspiratory phase.

4.19 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.

4.20 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.

4.21 inspiratory relief valve resistance : Pressure difference across the inspiratory relief valve measured at a specified flow.

4.22 ventilator failure safety mechanism : Device which permits the patient to breathe ambient air during malfunction of the ventilator or failure of its gas or power supplies.

4.23 inspiratory phase time, T_I : Interval from the start of inspiratory flow to the start of expiratory flow.

4.24 expiratory phase time, T_E : Interval from the start of expiratory flow to the start of inspiratory flow.

4.25 inspiratory pause time, T_{IP} : Interval from the end of inspiratory flow to the start of expiratory flow.

4.26 expiratory pause time, T_{EP} : Interval from the end of expiratory flow to the start of inspiratory flow.

4.27 inspiratory-expiratory phase time ratio (I:E ratio) : Ratio of the inspiratory phase time to the expiratory phase time.

4.28 sigh (ventilator) : Deliberate increase in tidal volume for one or more breaths at intervals.

4.29 work (ventilator), W : Work performed by the ventilator on the patient, expressed in joules.

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

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

4.30 power (ventilator), $P\ (= \dot{W})$: Rate of work performed by the ventilator on the patient, expressed in watts.

$$P = \dot{W} = p_{aw} \times \dot{V}$$

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

4.31 ventilator 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 the patient system to atmosphere. This is expressed in conventional centimetres of water referred to a flow of 0,5 l/s.

NOTE — The suggested test flows are 1 l/s and 0,5 l/s for the adult model, 0,3 l/s for the paediatric model and 0,03 l/s for the neonatal model.

4.32 time constant, T_c : Time in which an exponential change is approximately 63 % complete.

4.33 spirometer : Device designed to measure a volume of gas.

5 Lung ventilator characteristics

The characteristics, listed in 5.1 to 5.8, some of which apply to all ventilators, determine the performance of the ventilator.

5.1 Modes of operation during the inspiratory or expiratory phase

a) As a flow generator.

b) As a pressure generator.

c) As a combined flow and pressure generator.

5.2 Volume control

a) Pressure pre-set.

b) Volume pre-set :
   1) tidal;
   2) minute.

c) A combination of pressure and volume pre-set.

5.3 Cycling control

a) Inspiration to expiration :
   1) volume;
   2) pressure;
   3) time;
   4) flow;
   5) combined;
   6) manual cycling;
   7) other.

b) Expiration to inspiration :
   1) pressure;
   2) time;
   3) flow;
   4) combined;
   5) patient;
   6) manual override;
   7) other.

5.4 Types of safety limit

a) Volume.

b) Pressure.

c) Time.

d) Other.

5.5 Types of pressure pattern

a) Positive — atmospheric.

b) Positive — sub-atmospheric.

c) Positive — positive.

5.6 Source of power

a) Pneumatic.

b) Electrical.

c) Other.

5.7 Power transmission

a) Direct.

b) Indirect.

5.8 Source of inspired gas

a) Driving gas.

b) Fresh gas.

c) Mixed.

6 Test lung and method for testing performance of lung ventilators

6.1 Test equipment

6.1.1 Test lung

The requirements for the test lung have not precluded the development of more sophisticated test lungs with the same ranges of compliance and linear or non-linear resistances. The test lung serves a similar purpose to those developed by the French Laboratoire National d'Essais. The French test lung system uses parabolic resistances. If these non-linear resistances are used, their characteristics should be stated.

The test lung is designed to simulate the impedances to ventilator output which may be found in both normal and diseased states. The impedances to ventilator output are lung elastance and airflow resistance : these shall be simulated in the test lung by a compliance and a resistance connected in series (see figure 1). The various combinations of compliances and resistances used in the test procedures are given in table 3.

6.1.2 Compliances

The required compliances shall be as given in table 1.

Table 1 — Required compliances

Classification	Compliance C ml/kPa	Compliance C ml/cmH_2O
C 50	4,9 ± 0,245	50 ± 2,5
C 20	1,96 ± 0,098	20 ± 1
C 10	0,98 ± 0,049	10 ± 0,5
C 3	0,294 ± 0,015	3 ± 0,15
C 1	0,098 ± 0,005	1 ± 0,05

The volume/pressure characteristics of the compliances shall be measured at ambient pressure and temperature and throughout a range of gauge pressure changes from − 1,96 to + 3,92 kPa (− 20 to + 40 cmH_2O) for adults, from − 1,96 to + 4,9 kPa (− 20 to + 50 cmH_2O) for paediatrics and from − 1,96 to + 7,85 kPa (− 20 to + 80 cmH_2O) for neonates, and throughout a range of inspiratory phase times of 0,1 to 6 s.

NOTE — Suitable methods of constructing such compliances are described in annex A.

6.1.3 Resistances

The required resistances shall be as given in table 2.

Table 2 — Required resistances

Classification	Resistance R ± 20 % kPa/(l/s)	Resistance R ± 20 % cmH_2O/(l/s)	Range of air flow l/s
R 5	0,49	5	0 to 2
R 20	1,96	20	0 to 1
R 50	4,9	50	0 to 0,5
R 200	19,6	200	0 to 0,1
R 500	49	500	0 to 0,075
R 1 000	98	1 000	0 to 0,05

NOTE — The values above relate to dry air at ambient pressure and at 20 °C. They include the resistance of the flow-measuring device. Methods of constructing and testing suitable resistances are given in annex A. When using non-linear resistances, the values should be tested at flows as given in clause 11.

6.2 Measurements

Measurements of pressure, flow and volume shall be made using apparatus as shown in figure 1, and shall be accurate to within ± 2,5 % of the reading; an additional tolerance of ± 2,5 % of the full scale shall be allowed. Measurements of power and work shall be accurate to within ± 5 % of the reading and ± 5 % of the peak reading. This accuracy shall be maintained at frequencies up to 10 Hz.

The total compliance of the pressure-measuring devices, connecting tubes, flow-measuring device and resistance, shall not exceed 4 % of the model compliance.

6.3 Type tests

6.3.1 General

The test procedures described in 6.3.2 to 6.3.4 shall be carried out by the manufacturer on one or more samples of production ventilators, representative of all production ventilators of that type; a test report giving the results shall be provided to purchasers. These test procedures include one for endurance and two for performance. The endurance test shall be performed first and the performance tests after. Routine maintenance as specified by the manufacturer may be carried out during these tests, but details of all such maintenance shall be included in the test report.

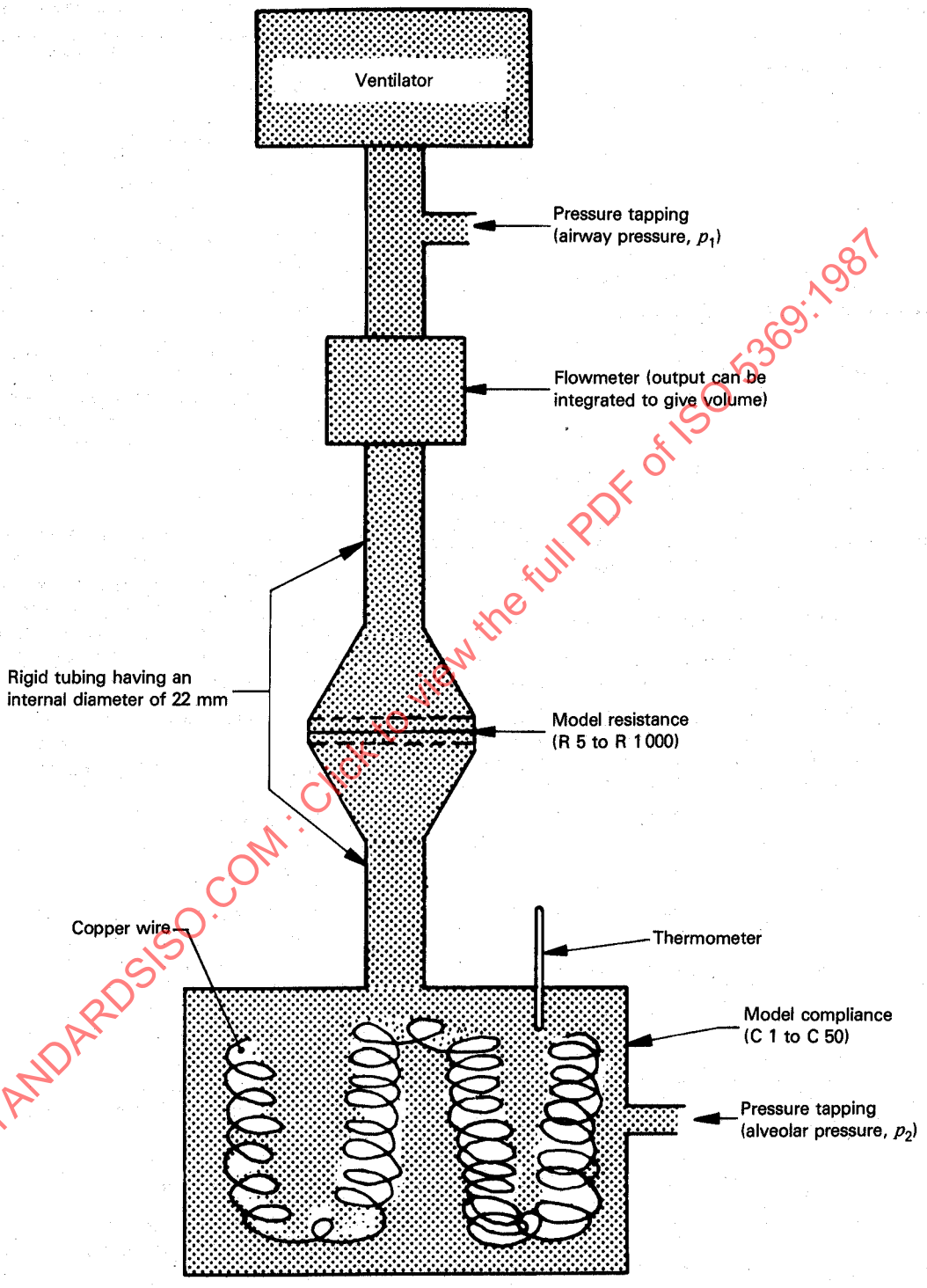
6.3.2 Endurance test

Each ventilator (as described in 6.3.1) shall be tested for endurance in respect of each group of patients for which it is recommended to be used, i.e. adult, paediatric or neonatal.

NOTE — A separate machine may be used for each group or the period of test may be divided equally between groups.

The inspiratory-expiratory phase time ratio (I : E ratio) shall be as close to 1:2 as possible and the ventilator run for 2 000 h against the appropriate conditions given in table 4.

The test shall be run continuously except for necessary maintenance as described in 6.3.1.



NOTE — Output may be separately calibrated for each compliance to give volume.

Figure 1 — Schematic diagram of an example of a test lung that may be used for the testing of ventilators

Table 3 — Procedure for performance test — Waveforms

[I : E ratio as close to 1:2 as possible (see 6.3.3)]

Test number	Compliance classification	Resistance classification	Tidal volume V_t	Frequency f	Time constant* T_c	p_{peak}**	
			ml	bpm (± 5 %)	s	kPa	cmH_2O
Adult							
①	C 50	R 5	500	20	0,25	1,22	12,5
2	C 50	R 20	500	20	1	1,96	20
3	C 20	R 5	500	20	0,1	2,69	27,5
4	C 20	R 20	500	20	0,4	3,43	35
Paediatric							
①	C 20	R 20	300	20	0,4	2,05	21
2	C 20	R 50	300	20	1	2,94	30
3	C 10	R 20	300	20	0,2	3,53	36
4	C 10	R 50	300	20	0,5	4,41	45
⑤	C 3	R 20	50	30	0,06	1,81	18,5
6	C 3	R 50	50	30	0,15	2,04	20,8
7	C 3	R 200	50	30	0,6	3,14	32
Neonatal							
①	C 3	R 50	30	30	0,15	1,21	12,3
2	C 3	R 200	30	30	0,6	1,86	19
3	C 1	R 50	30	30	0,05	3,17	32,3
4	C 1	R 200	30	30	0,2	3,82	39
5	C 1	R 500	30	30	0,5	5,15	52,5
6	C 1	R 1 000	30	30	1	7,35	75
⑦	C 1	R 200	15	60	0,2	2,35	24

NOTE — The ventilator controls shall be reset to suit the appropriate standard conditions (circled) before each subsequent test is undertaken. Thus the order of recordings obtained on adults would be test ①, test 2 (controls unchanged), test 2 (controls adjusted if necessary), controls reset to satisfy test ① conditions, test 3 (controls unchanged), test ③ (controls readjusted if necessary), etc.

* For information only.

** p_{peak} = calculated peak airway pressure for constant flow generators

Additional information relating to peak pressures developed by constant flow generators is given in annex B.

Table 4 — Conditions for endurance test

Group	Minute volume $\dot{V}_E$	Frequency (or nearest possible) f	Compliance classification	Resistance classification
	l/min	bpm		
Adult	10	20	C 50	R 20
Paediatric	4,5	30	C 20	R 50
Neonatal	0,8	40	C 3	R 200

6.3.3 Waveform performance test

The ventilator shall be connected in turn to each of the compliance and resistance combinations appropriate to its sphere of intended use (i.e. adult, paediatric or neonatal), in the order shown in table 3. At the beginning of the test, the ventilator controls shall be adjusted to obtain the required frequency and tidal volume at an I : E ratio which is as close to 1:2 as possible. The ventilator settings required to obtain these conditions shall be recorded. If it is necessary to reset the ventilator controls to match the ventilator to a new set of conditions, this shall be noted in the results. In such an event, records shall be obtained before and after resetting the ventilator controls. The ventilator shall always be reset to the standard conditions appropriate to a given tidal volume (as indicated in table 3) before each subsequent test.

All tests shall be performed without a sub-atmospheric phase unless this is an integral feature of the ventilator mechanism.

The following traces shall be recorded simultaneously during the tests and displayed in the order shown :

a) pressure at the patient end of the ventilator tubes (p_1 in figure 1);

b) pressure in the chamber (= alveolar pressure, p_2 in figure 1);

c) flow;

d) volume;

NOTE — Power and work may be calculated from the above data.

NOTES

1 To ensure that rebreathing is not occurring an additional volume-measuring device should be inserted into the expiratory line. This should substantially confirm the volume recorded by the pneumotachograph or other measuring device.

2 If desired, additional recordings may be appended to illustrate special characteristics of the ventilator.

The scale and clarity of the records shall be such that a change of 5 % of the peak reading can be detected. All records shall be inscribed with the appropriate scales, time base, and details of the test. These shall include the following:

a) Ambient temperature and pressure, together with the temperature, composition and humidity of the inspired gas.

b) The nature and dimensions of the breathing tubes connecting the ventilator to the test lung and whether other apparatus (e.g. humidifier, spirometer or water traps) was included in the part of the system which is pressurized during inspiration. If such apparatus was included, the type and position of connection shall be specified.

If a humidifier is included, it shall be filled to the "full" water level with gelatin or other relatively non-compressible substance. If this is not practicable, the humidifier shall be replaced with an equivalent compliance and resistance.

c) All settings of the controls shall be listed if possible.

d) Any other relevant information (e.g. source and pressure of driving gas, use of special circuits, type of humidifier).

6.3.4 Volume performance test

The ventilator shall be tested against the combinations of compliance and resistance appropriate to its use as detailed in table 5.

Table 5 — Combinations of compliance and resistance for the volume performance test

Group	Compliance classification	Resistance classification	Frequencies f bpm
Adult	C 20	R 20	10, 15, 20, 30
Paediatric	C 10 / C 3	R 50 / R 200	15, 20, 30, 40
Neonatal	C 1	R 200	20, 30, 40, 60

The manufacturer shall determine the range of tidal volume which the ventilator is capable of delivering to the lung at the specified frequencies with an I:E ratio as close to 1:2 as possible. Further measurements at different frequencies and with different compliance/resistance combinations may be included. All results shall be expressed in the form of a table or diagram, as in figure 2. The conditions under which the tests are carried out shall be stated as for the waveform performance test (see 6.3.3).

Tidal volume V_t ml	Frequency, f bpm			
	10	15	20	30
Maximum				
Minimum				

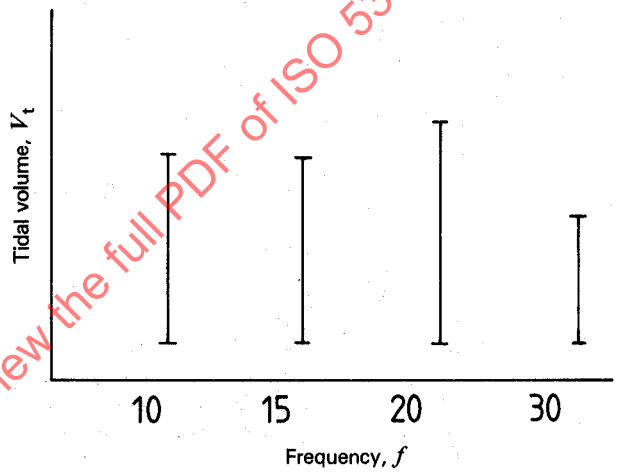


Figure 2 — Suggested format of table and/or diagram used to illustrate volume performance test

7 Power sources

The ventilator shall function correctly at any control setting with a variation of not more than ± 10 % of minute and tidal volumes throughout the range of voltage fluctuation not exceeding ± 10 % of the nominal rated voltage, and from 105 % of the maximum to 95 % of the minimum rated driving gas pressure.

8 Accuracy of controls, indications and pressure-relief valves

8.1 Pressure-relief valves

Calibrated positive or sub-atmospheric pressure-relief valves shall restrict the airway pressure to within ± 0,49 kPa (± 5 cmH_2O) or ± 20 % of the set value (whichever is the greater) for all settings of other controls and in the case of total respiratory obstruction.

NOTE — Transient increases in pressure in the system may cause these limits to be exceeded. Valves should be designed to minimize this effect.

8.2 Pressure gauges

Pressure gauges shall comply with the following requirements :

a) the scale range shall be from at least − 0,98 kPa to + 9,8 kPa (− 10 cmH_2O to + 100 cmH_2O) for adults;

b) the gauge shall have zero adjustment, where necessary;

c) under conditions of dynamic testing, readings shall be subject to a tolerance of ± (2 % of the full scale reading + 4 % of the reading).

d) the indicator, scale graduations and numbering shall be legible to an operator having a visual acuity (corrected if necessary) of at least 1,25 when seated or standing in front of the ventilator at an illuminance of 215 lx.

NOTE — It is recommended that the pressure gauges should be statically tested *in situ* on the ventilator at intervals not exceeding six months.

8.3 Devices indicating ventilatory frequency

Devices indicating ventilatory frequency shall be accurate to ± 10 % of the full scale reading.

8.4 Other calibrated controls

When working at nominal power inputs, all other calibrated controls shall be accurate to within ± 10 % of the full scale reading.

9 Spirometer and other devices for indication of ventilator function

9.1 If a device for measuring exhaled gas is not incorporated in the lung ventilator, provision shall be made for connection of a spirometer.

9.2 The spirometer shall be accurate to within ± 10 % of the readings over the volume and flow-rate ranges specified by the manufacturer. The pressure drop with a steady gas flow of 0,5 l/s shall not exceed 0,098 kPa (1 cmH_2O).

9.3 Re-usable spirometers shall be capable of being disinfected or sterilized (see clause 16).

NOTE — Spirometers should continue to function within the limits of accuracy specified in 9.2 whatever the humidity and within the temperature range from 10 to 37 °C (due allowance having been made for the difference between gas temperature and humidity in the spirometer and the temperature and humidity at which the spirometer was calibrated). Spirometers designed to be positioned close to the patient should be designed in such a manner that they cannot become obstructed by secretions from the patient.

10 Characteristics of delivered gas

10.1 The gas temperature at the patient end of the breathing tubes should neither exceed 41 °C nor fall more than 5 °C below ambient temperature.

10.2 When ventilators have incorporated an inspiratory gas mixture control, the accuracy of the mean delivered oxygen concentration shall be within ± 10 % of the set oxygen concentration throughout the range of pressures, frequencies and tidal volumes of which the ventilator is capable. At a given setting of the ventilator the delivered oxygen percentage shall be stable within ± 3 % oxygen.

11 Expiratory resistance

NOTE — In the absence of expiratory resistors or positive end-expiratory devices the pressure at the patient connection port should not exceed 0,49 kPa (5 cmH_2O) at an expiratory flow of 0,5 l/s for equipment for adult use, at 0,25 l/s for paediatric equipment and at 0,083 l/s for neonatal equipment, when breathing attachments and spirometer as specified by the manufacturer are used. If expiratory assistance is necessary to comply with these requirements it should be stated in the accompanying documents.

12 Internal compliance of apparatus

NOTE — During mechanical ventilation there may be differences between the tidal volume setting, the volume of gas delivered to the lungs and the volume of gas leaving the expiratory limb of the breathing system. These differences are due to the addition of fresh gas to the system during the inspiratory phase, to compression of gas within the system, to the elasticity of the walls of the positive pressure bellows or connecting tubing and to leaks. The volume of gas compressed within the breathing system depends on the pressure in the system at the end of inspiration and is dependent on the internal compliance.

12.1 In ventilators with a graduated tidal volume scale the internal compliance (see figure 3) shall be separated into two components :

a) that part of the breathing system within the ventilator from the intake valve to the inspiratory valve (the "bellows compartment");

b) that within the tubing from the inspiratory valve to the expiratory valve (the "tubing compartment").

The latter may include the humidifier and water traps if desired. The manufacturer shall state which components are to be found in the system during the test and the probable variations in compliance due to manufacturing tolerances or variations in humidifier water level.

The internal compliance of the bellows compartment results in a difference between the tidal volume setting on the ventilator and the volume of gas passing through the inspiratory valve. In most ventilators this volume of gas remains within the ventilator and does not contribute to the volume of gas measured by a spirometer at the expiratory port.

The internal compliance of the tubing compartment results in the volume of gas recorded at the expiratory port being larger than that delivered to the lungs.

In some ventilators part of the gas composed in the bellows compartment discharges to the atmosphere through the

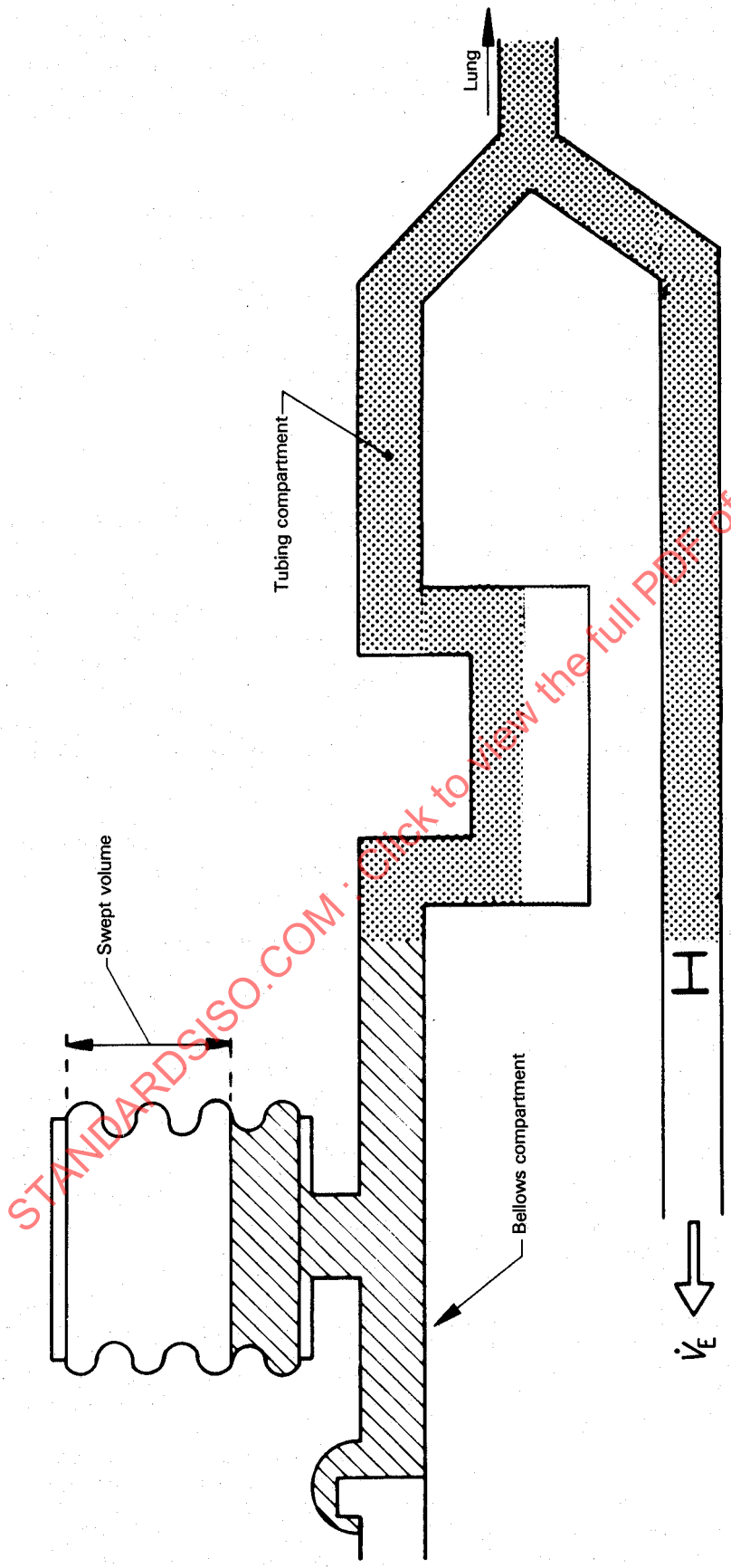


Figure 3 — Internal compliance

expiratory valve during expiration. This gas volume contributes to the measured tubing compartment. In other ventilators the expired gas volume may be augmented by a continuous nebulizer indicating the likely error in expired gas volume measurement.

12.2 The procedures for measuring the internal compliances of these two compartments are given in annex A. The volume/pressure relationship of the two compartments is sometimes non-linear. The compliance shall be expressed in the form of a volume/pressure diagram covering a range of end-inspiratory pressures up to 5,9 kPa (60 cmH_2O) or to the maximum safety pressure of the machine, whichever is the lower.

13 Fittings connecting the adult ventilator, patient and spirometer

13.1 If conical fittings of nominal 22 mm size are used, their design and construction shall be in accordance with ISO 5356-1.

13.2 The patient connection port for adult ventilators shall be 22 mm/15 mm coaxial fittings in accordance with ISO 5356.

NOTE — It is recommended that the patient connection port for paediatric and neonatal ventilators should be 15 mm conical fittings as specified in ISO 5356.

13.3 The connections in the breathing system between the ventilator and patient connection port shall follow a male-female sequence or shall be non-standard.

Non-standard connections shall be chosen so as to minimize the risk of incorrect assembly of the components.

13.4 Conical connections of 22 mm need not follow a specific male-female sequence except in the case of components of which correct functioning is vital to safety and dependent upon direction of gas flow. Such components shall follow the sequence "inlet : female; outlet : male".

13.5 If a connector for a bag for manual ventilation is provided on the ventilator, this shall face downwards and shall be situated away from the connectors for the patient breathing tubes. The bag mount shall be the standard 22 mm male cone with recess and may incorporate a case support for the bag neck. The connector for the bag shall be clearly marked with a symbol together with the word "BAG".

13.6 If provision is made for including a spirometer within an adult patient system (i.e. in the inspiratory or expiratory system or between the patient and the Y-piece), the connection shall be achieved using standard 22 mm cones and sockets.

13.7 If there is a separate outlet for the spirometer on the breathing tubes or on the machine, and it is intended that the air from the spirometer shall be discharged to atmosphere, then the outlet leading to the spirometer shall be a 30 mm male cone.

13.8 If an air inlet is fitted to the ventilator it shall not be a 22 mm, 15 mm or 30 mm male cone and shall be clearly marked as "AIR INLET".

13.9 If an expired gas outlet (other than an outlet for spirometer) is fitted to the machine, it shall be designed in such a way that it cannot easily be connected to 15 mm, 22 mm or 30 mm cones or sockets, or to 22 mm internal diameter tubing.

14 Alarms [1)]

14.1 Alarms shall provide warning of ventilator malfunction and may provide warning of changes in inspired gas composition or temperature, leaks or obstruction in the breathing system and/or changes in the characteristics of the patient's lung. Such alarms may be activated by changes in gas composition or temperature, variations in motive power or changes in pressure, flow or volume in the breathing circuit.

14.2 The alarm signal shall be auditory and visual. Provision should be made for remote extension. If a remote extension is employed, it shall be arranged so that a failure in the external circuit will not affect the correct functioning of the main alarms.

14.3 Simple methods for testing alarms shall be provided.

14.4 If the alarm is activated by a power or gas supply failure, the alarm shall operate without delay for at least 120 s unless reset. All alarm conditions shall be indicated within the range from 15 s to 30 s.

14.5 A self-resetting delay switch shall be provided to inactivate the alarm temporarily but not the visual alarm, for example during aspiration of the trachea. This shall inactivate only the auditory alarm for a duration of not longer than 120 s.

14.6 Any portion of the alarm system which is situated within the breathing system shall be capable of being disinfected or sterilized.

14.7 Indicators used for any visual alarm signal shall be clearly visible under normal operating conditions and shall be suitably protected against mechanical damage.

NOTE — Filament lamps, when used, should be run at 80 % of their rated voltage when the equipment is supplied at the maximum voltage appropriate to a specified voltage range.

1) These requirements are only needed for automatic ventilators intended for use in unattended or only periodically attended areas, i.e. not under constant supervision as in transport.

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Annex A

Test methods

(This annex forms an integral part of the standard.)

A.1 Conditions of test

All tests shall be carried out at 20 ± 2 °C.

A.2 Test lungs

A.2.1 Compliance

The compliances consist of a number of rigid chambers having the volumes as given in table 6.

Table 6 — Compliances and volumes of rigid chambers

Classification	Compliance C		Volume[1]
	ml/kPa	ml/cmH_2O	l
C 50	4,9	50	51,6
C 20	1,96	20	20,6
C 10	0,98	10	10,3
C 3	0,294	3	3,09
C 1	0,098	1	1,03

1) These volumes will give the correct compliance if the container is rigid and contains approximately 2 % wire wool by volume when the atmospheric pressure is at its standard value of 101,3 kPa. Since the compliance of a rigid container is inversely proportional to atmospheric pressure, changes of the latter with the weather (from + 4 to − 5 %) and with altitude, may require some method of adjusting the volume to keep within the specified tolerance of ± 5 %.

The ends of the chamber shall be dished or reinforced to ensure rigidity. In order to ensure that the compression is approximately isothermal, the chamber shall be filled with copper wool or other material with a large surface area and high specific heat. If copper wool is used, the diameter of the threads shall be less than 0,05 mm.

NOTES

1 The chambers are ideally constructed in copper or other material having a high specific heat.

2 Approximately 10 kg of copper wool will be required to ensure isothermal condition with the C 50 compliance; this quantity will occupy approximately 2 % of the volume.

To check that isothermal conditions have been achieved, test each compliance by recording the pressure response to a forced insufflation of the highest tidal volume delivered in the test procedure given in table 3. This tidal volume shall be delivered as rapidly as possible by hand compression of a large syringe. The difference in pressure between the peak and equilibrium values shall be less than 5 % of the peak pressure.

A.2.2 Linear resistances

Linear resistances (see table 7) may be made of sintered glass or other filter material. The cross-sectional area of the filter material is determined by two thin masks with appropriate sized orifices placed between the screens and filter material and the whole assembly is compressed by two elastomeric rings. For resistances in adult test lungs the filter material may be mounted in a container. For paediatric test lungs where the internal volume is critical, smaller mounts may be required.

A.2.3 Connections

If testing a ventilator for adults, pneumotachograph, resistances and compliances shall be connected together with minimal lengths of rigid tubing with an internal diameter of 22 mm. If testing ventilators for paediatric and neonatal patients, narrower rigid tubing shall be used to ensure that the requirements of 6.2 are complied with.

A.3 Suitable measuring apparatus

A.3.1 Flow

A suitable pneumotachograph head for the larger tidal volumes is the Fleisch No. 2 (linear ± 5 %, 0 to 250 l/min). If testing ventilators for paediatric and neonatal patients, a Fleisch No. 1 or 0 head should be substituted.

A.3.2 Pressure

Transducers of the appropriate sensitivity should be connected with minimal lengths of rigid tubing with internal diameters from 1 to 3 mm.

A.3.3 Volume

Baseline drift of an integrated flow signal may be counteracted with a breath-by-breath zero reset or by a backing off voltage. An alternative method for determining volume is to calibrate the pressure p_2 in terms of volume change.

Table 7 — Filter materials for resistance

Classification	Resistance R ± 20 %		Range of air flow
	kPa/(l/s)	cmH_2O/(l/s)	l/s
R 5	0,49	5	0 to 2
R 20	1,96	20	0 to 1
R 50	4,9	50	0 to 0,5
R 200	19,6	200	0 to 1,1
R 500	49	500	0 to 0,075
R 1 000	98	1 000	0 to 0,05