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Breathing machines for medical use — Lung ventilators

Respirateurs médicaux — Ventilateurs pulmonaires

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Foreword

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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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Contents

Page

0 Introduction 1

1 Scope and field of application 1

2 References 1

Section one : Breathing machines — General

3 Classification and definitions of types of breathing machines 2

Section two : Lung ventilators

4 Definitions related to the performance of lung ventilators 3

5 Lung ventilator characteristics 4

6 Test lung and method for testing performance of lung ventilators 5

7 Power sources 8

8 Accuracy of controls, indications and pressure-relief valves 8

9 Spirometer and other devices for indication of ventilator function 9

10 Characteristics of delivered gas 9

11 Expiratory resistance 9

12 Internal compliance of apparatus 9

13 Fittings connecting the adult ventilator, patient and the spirometer 11

14 Alarms 11

15 Humidifiers 12

16 Methods of cleaning, desinfection or sterilization 12

17 Electrical safety requirements 12

18 Information to be provided by the manufacturer 12

19 Marking 13

20 Bibliography 13

Annexes

A Test methods 15

B Peak airway pressures developed by constant flow generators in tests specified in table 3 17

C Respiratory data on normal children compiled from available literature 18

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.

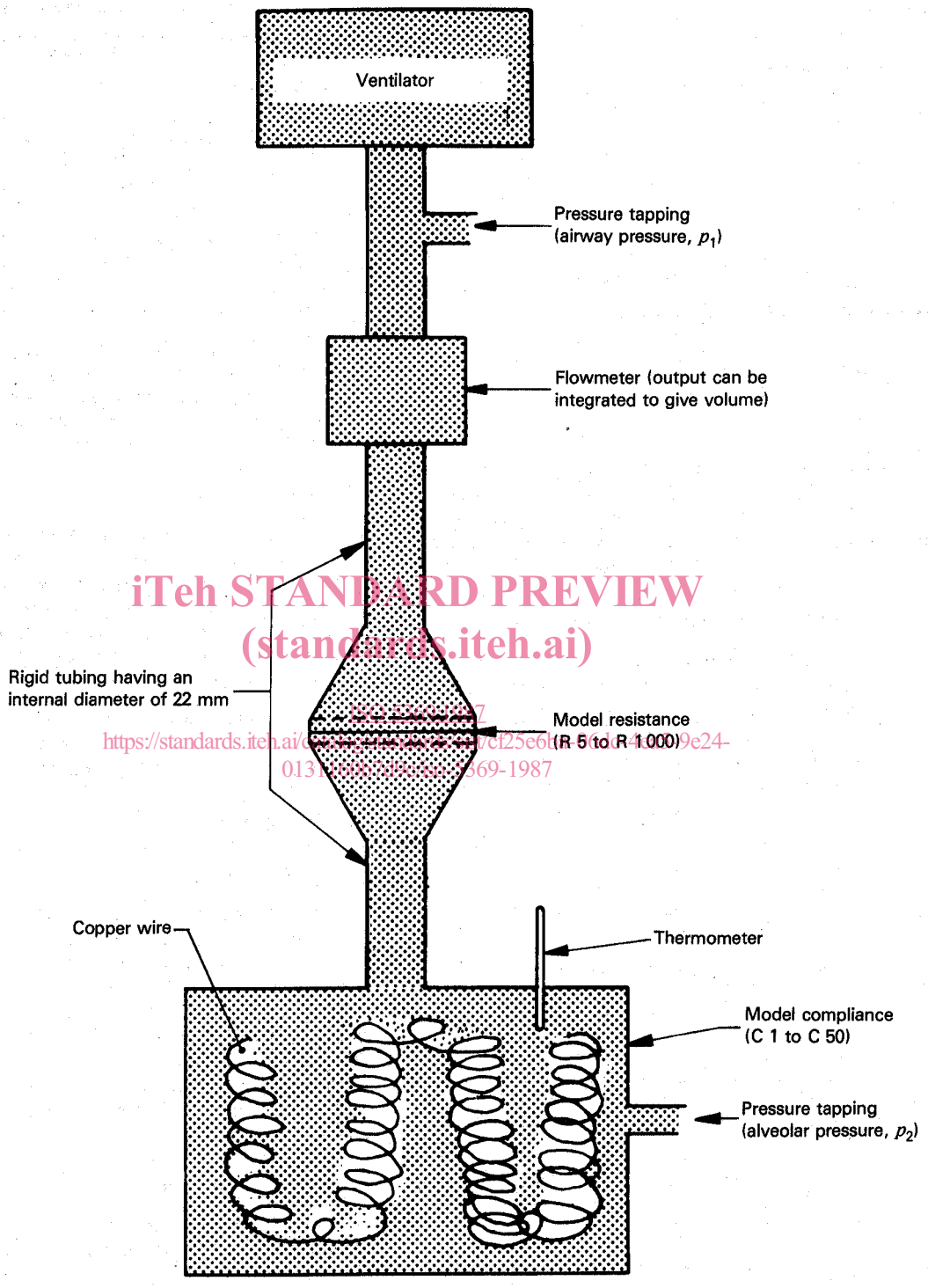
6.3.2 Endurance test

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.