

Medical electrical equipment —

Part 3: Particular requirements for performance —

Section 3.12 Method of declaring parameters for lung ventilators

Committees responsible for this British Standard

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- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health Care Industries
- Association of Veterinary Anaesthetists of Great Britain and Ireland
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Paediatric Association
- Department of Health
- Electro Medical Trade Association Limited
- Industrial Safety (Protection Equipment) Manufacturers' Association
- Intensive Care Society
- Medical Sterile Products Association

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Publication(s) referred to	Inside back cover

Foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. This standard, together with BS 5724-2.12, constitutes a revision of BS 3806:1964, which is withdrawn. Attention is drawn to BS 5724-2.13, which specifies requirements for the safety of anaesthetic machines that incorporate lung ventilators and of lung ventilators intended for use with inhalational anaesthetic agents.

This standard describes a method of declaring the performance parameters to be declared by the manufacturer of lung ventilators to provide purchasing authorities and users with the information necessary to compare lung ventilators made by different manufacturers.

Terms defined in this standard and in BS 5724-1 are written in capitals.

NOTE Throughout this standard the unit of pressure used is the kilopascal (kPa).
1 kPa = 10.1972 cm H₂O.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i to vi, pages 1 to 80, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Section 1. General

1 Scope

This standard describes a method of declaring the performance parameters to be stated in documents accompanying a LUNG VENTILATOR, together with test methods to be used to measure the parameters. It does not cover parameters resulting from recent developments such as jet and very high FREQUENCY ventilation and oscillation.

Motive power units for LUNG VENTILATORS together with RESUSCITATORS, RESPIRATORY THERAPY VENTILATORS, EXTERNAL BODY VENTILATORS, ROCKING APPARATUS and ELECTROSTIMULATORS are outside the scope of this standard.

The object of this standard is to permit the direct comparison of LUNG VENTILATORS of different manufacture, and to standardize methods for the determination of compliance with the manufacturer's declared performance.

NOTE The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

NOTE Manufacturers should use these terms in their literature.

For the purposes of this British Standard, the definitions given in BS 5724-1 apply, together with the following.

2.1

alveolar pressure (P_A)

the pressure in the alveoli

NOTE In the test apparatus this is represented by the pressure in the COMPLIANCE unit. For reasons given in note 1 to 3.3.4, this differs somewhat from true ALVEOLAR PRESSURE and is therefore referred to as "ALVEOLAR" PRESSURE ($P_{A''}$).

2.2

cardiogenic-pulsation-equivalent pressure (P_{card})

that waveform of pressure which, if it were applied to the outside of the PATIENT'S thoracic cage with the respiratory muscles paralysed, would produce the same waveforms of pressure and flow within the PATIENT'S lungs as are actually produced by the beating of the PATIENT'S heart

NOTE In performance tests in this standard, the waveform of P_{card} is fixed in shape, amplitude and FREQUENCY. It is that waveform which, when applied to a test apparatus with appropriate COMPLIANCE and resistance, produces a sine wave approximation to the waveform of flow at the mouth typically found in some PATIENTS with hyperdynamic hearts.

2.3

compliance

volume added per unit pressure increase when gas is added to an enclosed space and the added volume is expressed at the temperature and humidity in that enclosed space and at ambient atmospheric pressure

2.4

continuous mandatory ventilation (CMV)

ventilation of the PATIENT'S lungs with regular inflations by the LUNG VENTILATOR and with little or no respiratory effort by the PATIENT

2.5

continuous negative airway pressure (CNAP)

negative MOUTH PRESSURE which is applied continuously throughout the spontaneous ventilation cycle

2.6

continuous positive airway pressure (CPAP)

positive MOUTH PRESSURE which is applied continuously throughout the spontaneous ventilation cycle

2.7

delivered total ventilation (V_{DEL})

volume of gas per minute delivered through the PATIENT CONNECTION PORT during the INSPIRATORY PHASES

2.8

delivered volume ($V_{T,DEL}$)

volume of gas delivered through the PATIENT CONNECTION PORT during an INSPIRATORY PHASE

2.9

driving gas

gas which powers the LUNG VENTILATOR but is not delivered to the PATIENT

2.10

electrostimulator

apparatus which induces activity in the respiratory musculature by means of electrical impulses acting upon the corresponding nerves or muscles

2.11

emergency air intake port

dedicated GAS INTAKE PORT through which ambient air may be drawn when the supply of FRESH GAS and/or INFLATING GAS is insufficient

2.12

expiratory phase

interval from the start of expiratory flow to the start of inspiratory flow

2.13

expiratory time (T_E)

duration of the EXPIRATORY PHASE

2.14

external body ventilator

machine intended to augment or provide the PATIENT'S ventilation by means of the application of intermittent or alternating pressure to the trunk

2.15**frequency (/)**

the number of ventilatory cycles per minute
(in breaths/min)

NOTE The term may be applied to machine ventilation and to spontaneous ventilation simulated by the test apparatus.

2.16**fresh gas**

respirable gas supplied to the VENTILATOR BREATHING SYSTEM and intended to be delivered to the PATIENT

NOTE Fresh gas includes gas entering the VENTILATOR BREATHING SYSTEM as follows:

- a) continuously, at a steady flow from a flowmeter, to the FRESH GAS INPUT PORT;
- b) intermittently, from some reservoir, which may be an integral part of the LUNG VENTILATOR or may be attached externally to the FRESH GAS INTAKE PORT;
- c) intermittently, from a demand valve.

It excludes the following:

- 1) air entering intermittently through the FRESH GAS INTAKE PORT with no reservoir, other than the atmosphere, attached to it;
- 2) air drawn in through the EMERGENCY AIR INTAKE PORT;
- 3) air drawn in through leaks in the VENTILATOR BREATHING SYSTEM;
- 4) expired gas from the PATIENT.

2.17**fresh gas inlet**

any port of a breathing attachment through which FRESH GAS enters the VENTILATOR BREATHING SYSTEM

2.18**fresh gas input port**

GAS INPUT PORT to which FRESH GAS is supplied

NOTE There may be more than one FRESH GAS INPUT PORT.

2.19**fresh gas intake port**

GAS INTAKE PORT, other than the EMERGENCY AIR INTAKE PORT, through which FRESH GAS may be drawn into the VENTILATOR BREATHING SYSTEM by the LUNG VENTILATOR or the PATIENT

2.20**gas exhaust port**

the port of the LUNG VENTILATOR from which gas is discharged to the atmosphere either directly or via an anaesthetic gas scavenging system

2.21**gas input port**

the port to which gas is supplied under pressure and through which the gas is driven by this pressure

NOTE 1 The gas may be supplied either at a controlled pressure or at a controlled flow.

NOTE 2 See also GAS INTAKE PORT (2.22).

2.22**gas intake port**

the port through which gas is drawn into the VENTILATOR BREATHING SYSTEM by the LUNG VENTILATOR or the PATIENT

NOTE 1 Gas may be supplied to the port at or about ambient atmospheric or end-expiratory pressure, or the port may simply be left open to the atmosphere.

NOTE 2 In a VENTILATOR BREATHING SYSTEM, energy is required to reduce the pressure below that of the atmosphere. Therefore, when gas is supplied at or about atmospheric pressure to a GAS INTAKE PORT, work has to be done, either by the LUNG VENTILATOR (using energy from, for example, an electrical supply or a DRIVING GAS supply) or by the PATIENT in order to lower the breathing system pressure sufficiently for gas to flow in through the GAS INTAKE PORT. In this sense, gas is "drawn" into the breathing system. A similar argument applies, even if gas is supplied to the GAS INTAKE PORT at a small POSITIVE PRESSURE to compensate for the use of POSITIVE END-EXPIRATORY PRESSURE.

NOTE 3 See also GAS INPUT PORT (2.21).

2.23**gas output port**

the port of the LUNG VENTILATOR through which gas is delivered at RESPIRATORY PRESSURES through a tube to the PATIENT CONNECTION PORT

2.24**gas return port**

the port of the LUNG VENTILATOR through which gas is returned at RESPIRATORY PRESSURES through a tube from the PATIENT CONNECTION PORT

2.25**high pressure gas input port**

GAS INPUT PORT to which gas is supplied at a pressure not exceeding 500 kPa

2.26**inflating gas**

FRESH GAS which powers the LUNG VENTILATOR and is supplied to the PATIENT

2.27**inspiratory : expiratory time ratio (I : E ratio)**

ratio of the INSPIRATORY TIME to the EXPIRATORY TIME

2.28**inspiratory pause**

interval from the end of inspiratory flow to the start of expiratory flow

2.29**inspiratory pause time (T_{IP})**

duration of the INSPIRATORY PAUSE

2.30**inspiratory phase**

interval from the start of inspiratory flow to the start of expiratory flow

2.31**inspiratory time (T_I)**

duration of the INSPIRATORY PHASE

2.32**inspiratory time per cent ($T_{I(\%)}$)**

INSPIRATORY TIME expressed as a percentage of the VENTILATORY PERIOD

2.33**intermittent mandatory ventilation (IMV)**

the combination of spontaneous breathing with periodic ventilator-induced inflations

2.34**low pressure gas input port**

GAS INPUT PORT to which gas is supplied at a pressure not exceeding 100 kPa

2.35**lung ventilator**

an automatic device which is intended to augment or provide ventilation of the PATIENT's lungs when connected to the PATIENT'S airway

2.36**maximum steady relief pressure ($P_{RS,max}$)**

highest pressure which can exist for more than 300 ms (100 ms in the case of neonatal use) at the PATIENT CONNECTION PORT with any pressure-limiting relief devices operating normally, whether or not other components of the LUNG VENTILATOR are operating normally

NOTE Components of a LUNG VENTILATOR are operating normally when individually they operate as the manufacturer intended, even though particular combinations of settings of controls and of the compliance and resistance of the PATIENT'S respiratory tract (or of the test apparatus) may lead to an inappropriate pattern of ventilation.

2.37**maximum working pressure ($P_{W,max}$)**

highest pressure which can be attained at the PATIENT CONNECTION PORT during the INSPIRATORY PHASE, irrespective of the setting of controls other than any control intended to adjust this pressure, with the LUNG VENTILATOR working normally

NOTE 1 Even if not adjustable, this maximum may be less than the MAXIMUM STEADY RELIEF PRESSURE.

NOTE 2 See the note to 2.36.

2.38**minimum mandatory ventilation (MMV)**

predetermined DELIVERED TOTAL VENTILATION of which, if only a proportion is achieved by spontaneous breathing, the balance will be delivered by the LUNG VENTILATOR

NOTE This includes those circumstances in which the DELIVERED TOTAL VENTILATION, although predetermined in the steady state, may be subject to transient changes, even prolonged ones, after a change in spontaneous breathing.

2.39**minimum steady relief pressure ($P_{RS,min}$)**

lowest (most negative) pressure which can exist for more than 300 ms (100 ms in the case of neonatal use) at the PATIENT CONNECTION PORT with any pressure-limiting relief devices operating normally, whether or not other components of the LUNG VENTILATOR are operating normally

NOTE See note to 2.36.

2.40**minimum working pressure ($P_{W,min}$)**

lowest (most negative) pressure which can be attained at the PATIENT CONNECTION PORT during the EXPIRATORY PHASE, irrespective of the setting of controls other than any control intended to adjust this pressure, with the LUNG VENTILATOR working normally

NOTE 1 Even if not adjustable, this minimum may be less negative than the MINIMUM STEADY RELIEF PRESSURE.

NOTE 2 See note to 2.36.

2.41**mouth pressure (P_{Mo})**

lateral pressure at the point in the PATIENT'S airway or test apparatus to which the PATIENT CONNECTION PORT of the LUNG VENTILATOR is connected

2.42**negative end-expiratory pressure (NEEP)**

negative MOUTH PRESSURE at the end of the EXPIRATORY PHASE

2.43**negative pressure**

pressure less than that of the ambient atmosphere, expressed as a difference from ambient atmospheric pressure

2.44**patient connection port (of the ventilator breathing system)**

the port of the VENTILATOR BREATHING SYSTEM to which the PATIENT or test apparatus may be connected

2.45**positive end-expiratory pressure (PEEP)**

positive MOUTH PRESSURE at the end of the EXPIRATORY PHASE

2.46**positive pressure**

pressure greater than that of the ambient atmosphere, expressed as a difference from ambient atmospheric pressure

2.47**pressure assistance**

a facility intended for use when the PATIENT is breathing spontaneously to make the MOUTH PRESSURE more positive during the INSPIRATORY PHASE of the spontaneous ventilatory cycle than during the EXPIRATORY PHASE

NOTE It may be capable of continuous variation into PRESSURE HINDRANCE.

2.48**pressure hindrance**

a condition in which the MOUTH PRESSURE of the spontaneously breathing PATIENT during the EXPIRATORY PHASE of the spontaneous ventilatory cycle is more positive than during the INSPIRATORY PHASE as a result of pressure generated by the LUNG VENTILATOR

NOTE PRESSURE HINDRANCE is the result of pressure generated by the LUNG VENTILATOR as opposed to resistance within the VENTILATOR BREATHING SYSTEM, i.e. the reverse of PRESSURE ASSISTANCE.

2.49**respiratory-muscle-equivalent pressure (P_{mus})**

that waveform of (negative) pressure which, if it were applied to the outside of the PATIENT'S thoracic cage, with the respiratory muscles paralysed, would produce the same waveforms of pressure and flow within the PATIENT'S lungs as are actually produced by the PATIENT'S respiratory muscles

NOTE In performance tests in this standard, the waveform of P_{mus} is generally fixed in shape but variable in amplitude and FREQUENCY. It is that waveform which, when applied at the appropriate amplitude and FREQUENCY to a test apparatus with appropriate COMPLIANCE and resistance, produces the same waveforms of pressure and flow in the test apparatus as actually occur in the lungs of average healthy humans.

2.50**respiratory pressure**

any level of pressure between the MINIMUM WORKING PRESSURE and the MAXIMUM WORKING PRESSURE (see 2.37 and 2.40)

2.51**respiratory therapy ventilator**

device which is connected to the PATIENT'S airway and is intended primarily to deliver an aerosol and/or augment ventilation of the lungs

2.52**resuscitator**

portable device used in emergency situations to provide ventilation of the lungs of individuals whose breathing is inadequate

2.53**rocking apparatus**

device intended to augment or provide ventilation by using the weight of the abdominal contents to move the diaphragm

2.54**synchronized intermittent mandatory ventilation (SIMV)**

INTERMITTENT MANDATORY VENTILATION in which inflation of the lungs is initiated only when a specified characteristic of the PATIENT'S spontaneous breathing is present

NOTE Examples of such characteristics are inspiratory flow greater than some threshold, and expiratory flow not greater than some threshold.

2.55**total ventilation (V)**

volume of gas per minute entering or leaving the PATIENT'S lungs or the test apparatus

2.56**triggering**

the initiation of an INSPIRATORY PHASE of the LUNG VENTILATOR by the inspiratory effort of the PATIENT

NOTE When a LUNG VENTILATOR is set for TRIGGERING some combinations of circumstance can lead to self-TRIGGERING, i.e. the LUNG VENTILATOR starts an INSPIRATORY PHASE without any inspiratory effort by the PATIENT.

2.57**triggering pressure (P_{Tr})**

MOUTH PRESSURE required for TRIGGERING

2.58**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

2.59**VBS pressure (P_{VBS})**

pressure at a specified point in the VENTILATOR BREATHING SYSTEM

2.60**VBS expiratory resistance**

the magnitude of $(P_{\text{highE}} - P_{\text{lowE}})/\dot{v}_{\text{highE}}$ where

$\dot{v}_{\text{highE}}$ is the relevant "high" flow given in Table 1;

P_{highE} is the MOUTH PRESSURE when the expiratory flow has fallen to $\dot{v}_{\text{highE}}$;

P_{lowE} is the VBS EXPIRATORY RESISTANCE REFERENCE PRESSURE (see Figure 1).

Table 1 — “High” and “low” flows for resistance tests

Intended use	“High” flow	“Low” flow
	L/min	L/min
Adult or adult and paediatric	50	2.5
Paediatric or paediatric and neonatal	15	0.75
Neonatal	5	0.25

2.61

VBS expiratory resistance reference pressure (P_{lowE})

the MOUTH PRESSURE when expiratory flow has fallen to the relevant “low” flow given in Table 1 (see Figure 1)

2.62

VBS inspiratory resistance

the magnitude of $(P_{\text{highI}} - P_{\text{lowI}})/\dot{v}_{\text{highI}}$

where

$\dot{v}_{\text{highI}}$ is the relevant “high” flow given in Table 1;

P_{highI} is the MOUTH PRESSURE when the inspiratory flow has increased to $\dot{v}_{\text{highI}}$;

P_{lowI} is the VBS INSPIRATORY RESISTANCE REFERENCE PRESSURE (see Figure 1).

2.63

VBS inspiratory resistance reference pressure (P_{lowI})

the MOUTH PRESSURE when spontaneous inspiratory flow has increased to the relevant “low” flow of Table 1, neglecting any transient fall in pressure at the start of inspiration (see Figure 1)

2.64

ventilator breathing system (VBS)

a breathing system bounded by the LOW PRESSURE GAS INPUT PORT(S), the GAS INTAKE PORT(S) and the PATIENT CONNECTION PORT together with the FRESH GAS INLET and GAS EXHAUST PORT(S), if these are provided

NOTE 1 Closed VENTILATOR BREATHING SYSTEMS, including circle and other absorption systems, may have only GAS OUTPUT PORTS, GAS RETURN PORTS, an EMERGENCY AIR INTAKE PORT and FRESH GAS INLET(S) admitting gas supplied via a FRESH GAS INPUT PORT or ports, i.e. no GAS EXHAUST PORT may be necessary unless a flow of FRESH GAS is permitted in excess of that required for uptake by the PATIENT.

NOTE 2 Attention is drawn to the definition of a breathing system in BS 6015.

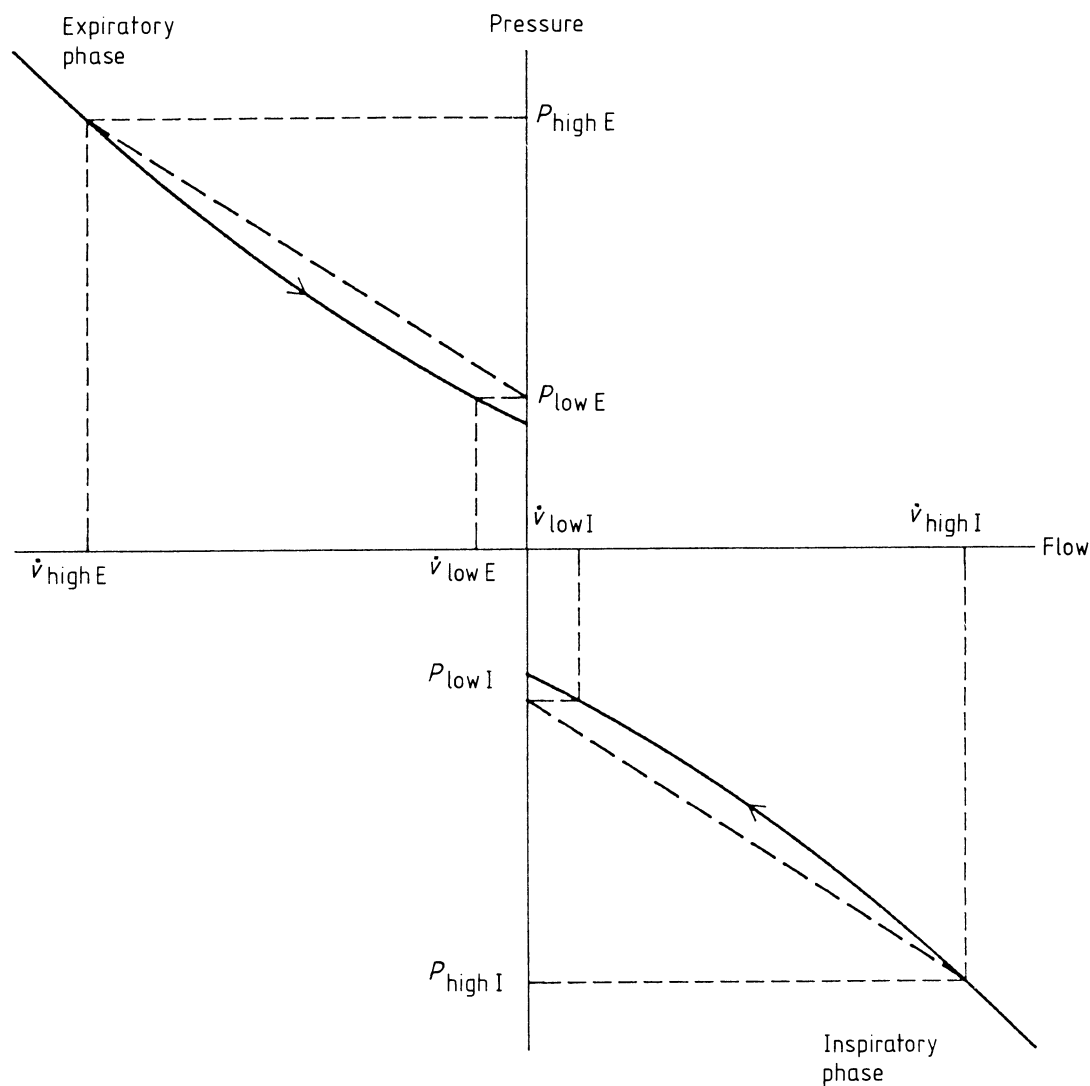
NOTE 3 Gas supplied to the LUNG VENTILATOR at any GAS INPUT PORT may enter the VENTILATOR BREATHING SYSTEM at any point.

NOTE 4 Valves may be placed anywhere in relation to ports and, indeed, anywhere in the VENTILATOR BREATHING SYSTEM, provided the requirements of this standard are met.

2.65

ventilatory period (T)

the duration of one ventilatory cycle



NOTE The curve in the lower-right quadrant is a plot of pressure at the PATIENT CONNECTION PORT against flow through that port during the period of increasing inspiratory flow of a spontaneous breath. The curve in the upper-left quadrant is a plot of pressure at the PATIENT CONNECTION PORT against flow through that port during the period of decreasing expiratory flow of any breath. The magnitude of the flow $v_{high I}$ is equal to that of $v_{high E}$ and is the appropriate "high" flow given in Table 1. The magnitude of the flow $v_{low I}$ is equal to that of $v_{low E}$ and is the appropriate "low" flow given in Table 1.

Figure 1 — Illustration of the definitions of VBS EXPIRATORY RESISTANCE and VBS INSPIRATORY RESISTANCE and of the corresponding reference pressures

Section 2. Test and operating conditions

3 Test conditions

3.1 General

3.1.1 Tests shall be carried out on one LUNG VENTILATOR representative of production ventilators. Routine maintenance and replacement of parts shall be carried out during the tests, as recommended by the manufacturer, and details shall be included in the ACCOMPANYING DOCUMENTS.

NOTE In the case of a LUNG VENTILATOR that requires an anaesthetic machine for its operation, an appropriate anaesthetic machine will be needed for the tests.

3.1.2 The LUNG VENTILATOR to be tested shall be fitted only with VENTILATOR BREATHING SYSTEM components either supplied or recommended by the manufacturer. The VENTILATOR BREATHING SYSTEM components used shall be the same for all tests except that if the LUNG VENTILATOR is recommended for more than one intended use, e.g. adult, paediatric or neonatal, the VENTILATOR BREATHING SYSTEM used for the tests shall be that appropriate to the intended use. The manufacturer shall state the set of components to be used in the tests. If amongst the VENTILATOR BREATHING SYSTEMS supplied or recommended by the manufacturer for clinical use there are any which the manufacturer states are non-rebreathing systems, the set of components stated for use in the tests shall be those that form such a system. The ACCOMPANYING DOCUMENTS shall include details of which VENTILATOR BREATHING SYSTEM components were used, which of the following were included and where they were positioned:

- a) spirometer;
- b) humidifier or heat and moisture exchanger;
- c) tubing heater inside the breathing system tubing;
- d) water trap(s);
- e) filter(s);
- f) in-line sensor(s).

If a humidifier is included, it shall be dry and unheated but, if it has a water container or reservoir in continuity with the VENTILATOR BREATHING SYSTEM, either the water shall be replaced by an equivalent volume of a solid or liquid having a low vapour pressure or the humidifier shall be replaced by a device which has the same COMPLIANCE when empty as the recommended humidifier fully charged with water.

3.1.3 If the LUNG VENTILATOR requires a supply of gas at a constant pressure, the pressure shall be maintained at that recommended by the manufacturer or, if the manufacturer defines a range of acceptable pressures, at the centre of that range.

3.1.4 If the LUNG VENTILATOR requires an electrical supply, the supply voltage shall be maintained within the range specified in BS 5724-1.

3.1.5 Tests shall be carried out at an ambient temperature of 23 ± 2 °C and an ambient barometric pressure of 100 ± 5 kPa.

3.1.6 During the tests, the LUNG VENTILATOR shall be supplied with gas of a quality and composition recommended by the manufacturer. Except for the pre-test running (see 5.2), the gas delivered to the VENTILATOR BREATHING SYSTEM shall be air or a gas having a composition as close to that of air as possible.

3.1.7 For most tests, three sets of values for various parameters are specified to be used when testing LUNG VENTILATORS intended for adult, paediatric or neonatal use. Unless otherwise specified, each test shall be carried out for each intended use recommended by the manufacturer. If the manufacturer recommends ranges of use expressed in terms of the age or body mass of the PATIENT, LUNG VENTILATORS for use with PATIENTS older than 7 years or having a body mass greater than 23 kg shall be regarded as adult ventilators, those for use with PATIENTS less than 6 months old or having a body mass less than 7 kg shall be regarded as neonatal ventilators and all others shall be regarded as paediatric ventilators.

NOTE The boundaries between adult and paediatric (and between paediatric and neonatal) are derived by calculating the geometric mean of the relevant DELIVERED VOLUMES given in Table 11 and using the values in Appendix A to estimate corresponding age and body mass.

If the manufacturer's recommendations for operating the LUNG VENTILATOR require a knowledge of the PATIENT'S body mass, values of 70 kg, 13 kg and 3 kg shall be used for tests relating to adult, paediatric and neonatal use respectively.

3.1.8 If a LUNG VENTILATOR has more than one mode of operation (see Appendix B) for any of the following functions, for each function, the manufacturer shall state one of the following modes as being the "basic" mode and three others (or such lesser number as may be available in the LUNG VENTILATOR), in order of priority as "additional" modes:

- a) the delivery of mandatory breaths in CONTINUOUS MANDATORY VENTILATION (CMV) and triggered CMV;
- b) the delivery of mandatory breaths in INTERMITTENT MANDATORY VENTILATION (IMV);
- c) the delivery of mandatory breaths in MINIMUM MANDATORY VENTILATION (MMV);
- d) directly controlled PRESSURE ASSISTANCE of spontaneous breathing;

- e) PRESSURE ASSISTANCE as a means of providing MMV;
- f) PRESSURE HINDRANCE of spontaneous ventilation;
- g) TRIGGERING and windowing in triggered CMV, SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION (SIMV), MMV and PRESSURE ASSISTANCE (see **B.5.2**).

NOTE The manufacturer may specify different modes as basic or additional for the different functions.

The basic and additional modes for any function shall constitute the “selected” set of modes for the particular function except that, for paediatric tests, the additional modes shall be omitted from the selected set unless the LUNG VENTILATOR is recommended only for paediatric use. Unless otherwise specified, all tests shall be performed in all relevant selected modes.

NOTE If the manufacturer wishes to report the results of more than four modes of operation, these may be included in an appendix to the results given in the ACCOMPANYING DOCUMENTS.

3.2 Accuracy of measurements

3.2.1 The accuracy of measurements of the parameters covered by this standard shall be as given in Table 2.

3.2.2 Measurements of INSPIRATORY : EXPIRATORY TIME RATIO (I : E RATIO) shall be made in terms of INSPIRATORY TIME PER CENT ($T_{I(\%)}$) to the accuracy given in Table 2 and then converted to I : E RATIO (T_I/T_E) from the following equation:

$$\frac{T_I}{T_E} = \frac{T_{I(\%)}}{100 - T_{I(\%)}}$$

3.2.3 For the recording of waveforms and for the resistance tests, the 90 % response time of the complete recording system to a step change shall be less than 5 ms for pressure and less than 50 ms for flow and volume.

3.2.4 For the volume performance tests, the results shall be stated in the ACCOMPANYING DOCUMENTS in terms of volume at ambient temperature and pressure to the accuracy given in column 3 of Table 2.

NOTE In order to meet these accuracy requirements, various corrections to the raw measurements may be necessary.

If a flow or volume measuring device is sensitive to volume of gas rather than mass, correction may be necessary to convert from raw measurements to flow or volume at ambient temperature and pressure. If the composition of the gas differs from that of air (see **3.1.6**), correction may also be necessary for differences in viscosity and/or density with a volume-sensitive device and for differences in density with a mass-sensitive device.

If flow or volume are sensed other than close to point X (see Figure 2), it may be necessary to correct also for the fact that part of the gas entering at point X is sequestered in the COMPLIANCE (of the tubing and any components) between X and the sensing point. For instance, if volume is derived by calculating $C \times P_{A'}$ where C is the COMPLIANCE of the COMPLIANCE unit (see **3.3.2**) and $P_{A'}$ is the “ALVEOLAR” PRESSURE in the COMPLIANCE unit (see note 1 to **3.3.4**), it may be satisfactory simply to set C equal to the COMPLIANCE of the complete system but, if COMPLIANCE C' between X and the resistance element of the resistance unit is too large, it may be necessary to calculate volume from $(C - C')P_{A'} + C'P_{M0}$, where P_{M0} is the MOUTH PRESSURE at point X. Transient effects, resulting for instance from gas going first to C' at the start of the INSPIRATORY PHASE of controlled ventilation, are likely to be complete well within the allowed 90 % response time.

3.3 Test apparatus

NOTE See also **5.2.1** and **5.9.1**.

3.3.1 General

The test apparatus is intended to simulate, in a simplified form, the pneumatic characteristics of the PATIENT'S respiratory system, i.e. its COMPLIANCE and resistance. For some tests, the PATIENT'S spontaneous respiratory activity is simulated by applying to the COMPLIANCE, either directly or indirectly, a waveform of pressure equivalent to the effects of the PATIENT'S respiratory muscles, the RESPIRATORY-MUSCLE-EQUIVALENT PRESSURE P_{mus} . For some tests of TRIGGERING, the effect of the beating of the heart is reproduced by similarly applying a waveform of the CARDIOGENIC-PULSATION-EQUIVALENT PRESSURE P_{card} .

The test apparatus comprises three parts: the passive part (**3.3.2**), the active part (**3.3.3**) and the measurement part (**3.3.4**).

Table 2 — Required accuracies

1	2	3		4	
Parameter	Units	Test apparatus measurements (see 3.2), properties (see 3.3) and target settings (see 3.4.1)		Target settings of the LUNG VENTILATOR (see 3.4.1)	
		Zero error	Sensitivity error	Zero error	Sensitivity error
MOUTH PRESSURE ALVEOLAR PRESSURE Breathing system pressure	kPa	0.02 kPa	1 %	0.05 kPa	5 %
Supply pressure		0 kPa	1 %	0 kPa	2 %
Steady or mean flow, e.g. FRESH GAS flow, V_{DEL}	L/min	0 L/min	2 %	0 L/min	5 %
Instantaneous flow $\left\{ \begin{array}{l} A^a \\ P \\ N \end{array} \right.$		1.0 L/min 0.3 L/min 0.1 L/min	5 %	—	—
DELIVERED VOLUME Tidal volume Total volume (see 5.9)	L or mL	0 mL	5 %	0 mL	5 %
Instantaneous volume $\left\{ \begin{array}{l} A^a \\ P \\ N \end{array} \right.$		10 mL 3 mL 1 mL	5 %	—	—
Time	s	0.01 s	1 %	0.05 s ^b	5 % ^b
INSPIRATORY TIME PER CENT	Percentage of VENTILATORY PERIOD	1 percentage point	0 %	2 percentage points ^c	0 %
FREQUENCY	breaths/min	0 breaths/min	1 %	0 breaths/min	5 % ^d
TOTAL VENTILATION	L/min	0 L/min	5 %	0 L/min	5 %
Delivered oxygen concentration	Percentage (v/v)	0.5 percentage points	0 %	0 percentage points	15 %
COMPLIANCE	mL/kPa	0 mL/kPa	5 %	—	
Resistance	kPa/(L/s)	0 kPa/(L/s)	10 %	—	
Temperature	°C	0.5 °C	0 %	See 3.1.5	
Tracer gas composition in rebreathing test (see 5.9)	Percentage of the smaller of ($F_c - F_a$) and ($F_c - F_v$) (see 5.9)	1 percentage point	0 %	—	

NOTE 1 The term “percentage points” is used where the unit itself includes per cent (e.g. INSPIRATORY TIME PER CENT), to avoid confusion with “% error”.

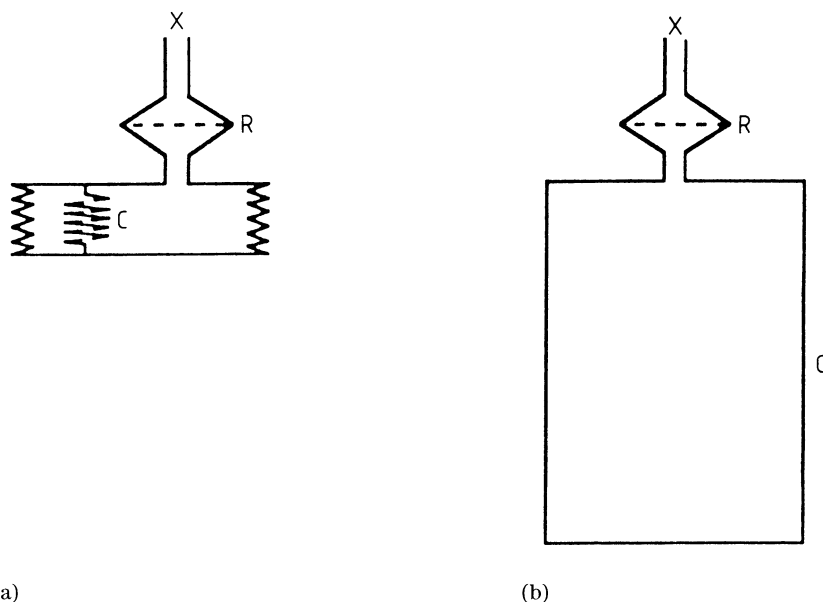
NOTE 2 The accuracies given are expressed in the form of a maximum zero error quoted directly in the appropriate units plus a sensitivity error quoted as a percentage of the reading. A zero error together with a sensitivity error is given if a variable can pass through zero or can, in any one application, cover a range such that the minimum is a small fraction of the maximum.

^a A, Adult; P, Paediatric; N, Neonatal.

^b Applies to INSPIRATORY TIME in seconds.

^c Tolerance increased to 5 percentage points if the LUNG VENTILATOR has no direct control of I : E RATIO (or INSPIRATORY TIME PER CENT) or of INSPIRATORY TIME and EXPIRATORY TIME.

^d Tolerance increased, except for the synchronization test recording (see 5.12.1), to 10 % if the LUNG VENTILATOR has no direct control of FREQUENCY or of INSPIRATORY TIME and EXPIRATORY TIME.



NOTE The PATIENT CONNECTION PORT of the LUNG VENTILATOR under test is connected to point X.

Figure 2 — Illustration of two types of COMPLIANCE unit (C) in series with a resistance unit (R)

3.3.2 Passive part

The passive part of the test apparatus shall comprise a resistance unit in series with a COMPLIANCE unit.

NOTE 1 The resistance and COMPLIANCE of these units correspond to the total respiratory resistance and total respiratory COMPLIANCE of the PATIENT.

NOTE 2 Two types of COMPLIANCE unit are possible. One consists of a distensible container to which suitable elastic properties have been imparted, e.g. a spring-loaded bellows [see Figure 2(a)], and the other consists of a suitably large rigid container in which the COMPLIANCE arises from the compressibility of the contained gas [see Figure 2(b)].

The connection at point X in Figure 2 shall consist of a smooth bore tube that can be securely attached to the PATIENT CONNECTION PORT of the LUNG VENTILATOR and that has a minimum inside diameter of 20 mm, 12.5 mm or 6 mm, when testing LUNG VENTILATORS intended for adult, paediatric or neonatal use respectively. The pressure at point X shall be measured at the side of this tube and at a longitudinal position such that the end of the PATIENT CONNECTION PORT is between 10 mm and 50 mm from the site of pressure measurement. Any component of the test apparatus having an inside diameter of less than 20 mm, 12.5 mm or 6 mm, when testing LUNG VENTILATORS intended for adult, paediatric or neonatal use respectively, shall be at least 10 mm from the site of pressure measurement.

3.3.3 Active part

3.3.3.1 For tests involving simulation of spontaneous respiratory activity by the PATIENT, the effect of the action of the PATIENT'S respiratory muscles shall be reproduced by applying to the COMPLIANCE unit, either directly or indirectly, a waveform of pressure P_{mus} .

NOTE 1 This arrangement permits [1] valid simulation of the interaction between simultaneous spontaneous and ventilator-induced breaths in a way that would be impossible with a test apparatus which merely reproduced the normal flow waveform of spontaneous respiration.

NOTE 2 The method of applying the P_{mus} waveform to the COMPLIANCE unit depends upon the type of unit used. With the distensible-container type, P_{mus} can be applied directly to the outside of the container [see Figure 3(a)]. Alternatively, if the distensible container is a bellows, a force proportional to P_{mus} may be applied to the movable end of the bellows (the arrangement of Lyle and others [2] could be adapted in this way). With the rigid container type, it is necessary [1], to connect a piston pump (or equivalent) to the rigid container [see Figure 3(b)] and drive the piston in such a way that its contained volume V_{pump} is continuously equal to $-C \times P_{\text{mus}}$, where C is the COMPLIANCE in use. Alternatively, gas can be withdrawn from and returned to the rigid container at a flow rate equal to $-C \times P_{\text{mus}}$, where P_{mus} is the rate of change of P_{mus} [1].

3.3.3.2 For tests which require only the passive characteristics of the test apparatus (see clause 6 and 8.3), the simulation of spontaneous respiratory activity shall be disabled either by omitting the relevant mechanism, e.g. as in Figure 2, or by maintaining P_{mus} constant at 0 kPa.

NOTE With the arrangement shown in Figure 3(a), unless the container enclosing the bellows has a very low resistance connection to the atmosphere, the use of a special mechanism may be required.

3.3.4 Measurement part

The measurement part of the test apparatus shall enable the following variables to be determined continuously:

- P_{mus} ;
- the lateral pressure at point X in Figure 2, i.e. the MOUTH PRESSURE;
- the pressure in the COMPLIANCE unit of the test apparatus, i.e. the "ALVEOLAR" PRESSURE (P_{A});
- the flow into the test apparatus at point X;
- the volume added to the test apparatus.

NOTE 1 Although the pressure in the COMPLIANCE unit is conventionally referred to as "ALVEOLAR" PRESSURE it does not correspond to the true ALVEOLAR PRESSURE because the COMPLIANCE unit is separated from the "mouth" (point X) by a resistance equal to the total respiratory resistance instead of one equal only to the airway resistance.

NOTE 2 Possible methods of determining volume include integration of flow; calculation according to $C(P_{\text{A}} - P_{\text{mus}})$, where C is the COMPLIANCE of the COMPLIANCE unit; and measurement of the distension of a distensible-container COMPLIANCE unit. Possible methods of determining flow include differentiating measured volume.

NOTE 3 If flow or volume is sensed on the COMPLIANCE side of the resistance unit, some correction may be needed for gas compressed on the side of the resistance element close to point X to achieve the required accuracy (see 3.2).

NOTE 4 With the arrangement shown in Figure 3(b), P_{mus} is best determined indirectly by measuring V_{pump} by means of a displacement transducer.

3.3.5 COMPLIANCE, resistance and P_{mus} and P_{card} waveforms

3.3.5.1 COMPLIANCE and resistance

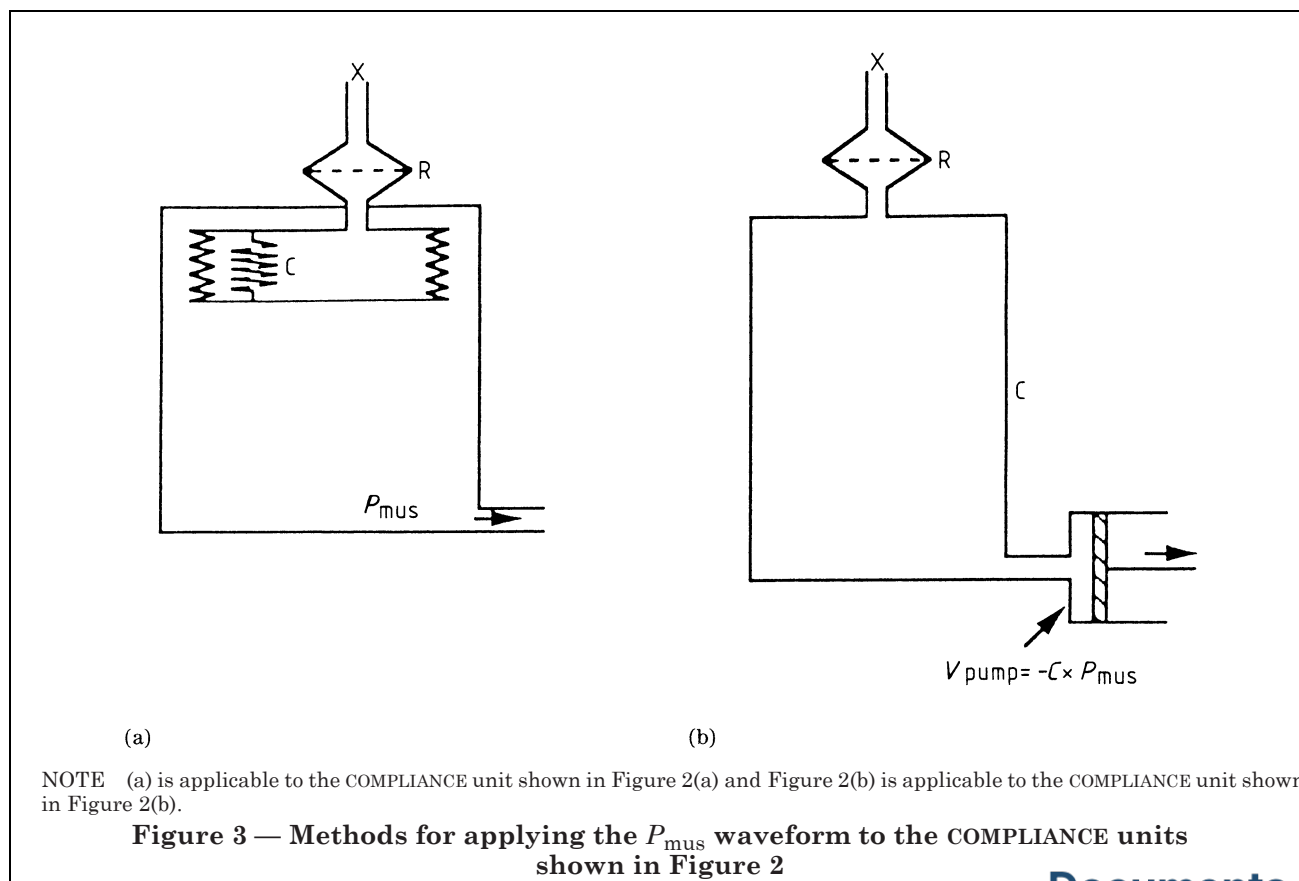
When the test apparatus, including all connecting tubing and measurement devices, is assembled, it shall provide, when measured using dry air at ambient atmospheric pressure and temperature, total COMPLIANCES and resistances as follows.

- COMPLIANCE
(in mL/kPa): 10, 30, 100, 200, 500.
- Resistance [in kPa/(L/s)]: 0.5, 2, 5, 20.

Except for the apparatus used for the pre-test running (see 5.2.1) and, in the case of COMPLIANCE, except for the apparatus used for the rebreathing test (see 5.9.1.3), the total COMPLIANCES and resistances shall have accuracies as given in Table 2.

Except for the pre-test running (see 5.2.1) and the rebreathing test (see 5.9.1.3), the accuracy of the COMPLIANCES shall be maintained:

- throughout the range of "ALVEOLAR" PRESSURE from -2 kPa to 10 kPa; and
- when the volume change occurs over any duration between 0.1 s and 6 s.



NOTE 1 With a distensible-container type of COMPLIANCE unit, item 1) will entail attention being paid to the linearity of the pressure volume characteristic of the unit. Item 2) will entail minimization of the inertia of the unit. The COMPLIANCE of the unit may change with age and ambient temperature.

NOTE 2 With a rigid-container type of COMPLIANCE unit, the relationship of pressure to added volume (ATPD) is inherently linear, but item 2) will entail that the compression of gas in the container be nearly isothermal. This may be achieved by suitably packing the container with heat-absorbing material [3, 4 pp. 182–183]. The COMPLIANCE of this type of unit is inversely proportional to ambient pressure.

The accuracy of the resistances shall be maintained for pressure differences across them of up to 1 kPa for the 0.5 kPa/(L/s) resistance and up to 3 kPa for all other resistances, except for the apparatus used for the pre-test running (see 5.2.1).

NOTE 3 The tolerances on resistance mean that the resistance is nearly linear for flows up to about twice the “high” flows given in Table 1. (Flows of this magnitude may arise in the volume performance test and the I : E RATIO performance test.) Suitable methods of constructing such resistances have been published [5,6]. The resistance of a resistance unit may change with contamination or corrosion.

3.3.5.2 P_{mus} waveform

The ideal P_{mus} waveform is defined by four successive equations, applicable to four successive phases. Except for the pre-test running (see 5.2.1), and for tests in which the specified spontaneous ventilatory FREQUENCY is lower than 10 breaths/min, the durations of the phases, as fractions of the spontaneous VENTILATORY PERIOD shall be as follows.

Phase 1: 0 to 0.34

Phase 2: 0.34 to 0.385

Phase 3: 0.385 to 0.85

Phase 4: 0.85 to 1

The duration of the spontaneous VENTILATORY PERIOD shall be such as to produce the required FREQUENCY in any test. For test in which the specified spontaneous ventilatory FREQUENCY is lower than 10 breaths/min, the durations of the phases shall be as follows.

Phase 1: 0 s to 2.04 s

Phase 2: 2.04 s to 2.31 s

Phase 3: 2.31 s to 5.10 s

Phase 4: 5.10 s to the end of the VENTILATORY PERIOD.

In each phase the P_{mus} shall vary according to the following equations.

$$\text{Phase 1: } P_{\text{mus}} = 0 - 4.951f + 5.938f^2$$

$$\text{Phase 2: } P_{\text{mus}} = 5.383 - 36.712f + 52.788f^2$$

$$\text{Phase 3: } P_{\text{mus}} = -3.097 + 7.287f - 4.287f^2$$

$$\text{Phase 4: } P_{\text{mus}} = 0$$

where

f is the time from the beginning of the spontaneous VENTILATORY PERIOD expressed as a fraction of the period or, if the spontaneous ventilatory FREQUENCY is less than 10 breaths/min, as a fraction of 6 s.

The equivalent equations for the rate of change of P_{mus} (see note 2 to 3.3.3.1) shall be as follows.

$$\text{Phase 1: } \dot{P}_{\text{mus}} = -4.951 + 11.876f$$

$$\text{Phase 2: } \dot{P}_{\text{mus}} = -36.712 + 105.576f$$

$$\text{Phase 3: } \dot{P}_{\text{mus}} = 7.287 - 8.574f$$

$$\text{Phase 4: } \dot{P}_{\text{mus}} = 0$$

Conformity with the ideal waveform of P_{mus} shall be determined by carrying out the following procedure.

- Occlude point X of the test apparatus (see Figure 2).
- Set the active part to produce within the test apparatus [the bellows of Figure 2(a) or the rigid container of Figure 2(b)] a waveform of P_{mus} of an amplitude of 1 kPa at a FREQUENCY of 15 breaths/min.
- Record the waveform of P_{mus} and determine that, at all times throughout the VENTILATORY PERIOD, the actual P_{mus} lies within the following tolerances of the ideal P_{mus} :
 $\pm (0.02 \text{ kPa} + 10 \% \text{ of the ideal value of } P_{\text{mus}} \text{ at any instant})$ (see Figure 4).

NOTE This results in a close time tolerance at the start of contraction ($\pm 20 \text{ ms}$) which is necessary for reliable determination of the TRIGGERING delay (see 5.13).

3.3.5.3 P_{card} waveform

The P_{card} waveform shall be a sine wave having a FREQUENCY of 75 breaths/min, 100 breaths/min or 150 breaths/min for LUNG VENTILATORS intended for adult, paediatric or neonatal use respectively. The amplitude of the waveform shall be such that, when the test apparatus (3.3.2 to 3.3.4) is “breathing” from atmosphere, the volume displacement at point X in Figure 2 shall be 25 mL, 5 mL or 1 mL for LUNG VENTILATORS intended for adult, paediatric or neonatal use respectively. The tolerance for any point on the waveform shall be $\pm 15^\circ$ of the phase angle and $\pm 5 \%$ of the peak amplitude.

3.4 General test procedures, except for the pre-test running described in 5.2

3.4.1 For each test, the test apparatus shall be set to the stated values of COMPLIANCE and resistance. For tests involving simulated spontaneous ventilation, the FREQUENCY and amplitude of the P_{mus} waveform shall be adjusted to obtain the FREQUENCY and tidal volume stated except that, if this would require a peak amplitude more negative than -2 kPa, the test shall be carried out with the peak amplitude of P_{mus} set to -2 kPa. For tests involving machine-induced breaths or pressure assistance, the controls of the LUNG VENTILATOR shall be adjusted in one of the following ways to obtain the stated values of, for example, DELIVERED VOLUME, FREQUENCY and I : E RATIO.

a) Wherever possible, the parameter, as measured in the test apparatus, shall be set within the appropriate tolerance given in Table 2. For I : E RATIO, the corresponding value of INSPIRATORY TIME PER CENT shall be within the appropriate tolerance (see 3.2.2). The stated value of the parameter shall be reported in the ACCOMPANYING DOCUMENTS.

b) If the stated value is not attainable because the parameter can be adjusted only in discrete steps, the parameter shall be set as near as possible to the stated value. The actual value of the parameter and the reason for the difference from the stated value shall be reported in the ACCOMPANYING DOCUMENTS.

c) If the stated value is out of range or is not selectable, the parameter shall be set as near as possible to the stated value. The actual value of the parameter and the reason for the difference from the stated value shall be reported in the ACCOMPANYING DOCUMENTS, except that the test shall not be carried out and the reason shall be reported in the ACCOMPANYING DOCUMENTS if

$$\frac{V_N - V_A}{V_U - V_A} < 0.2$$

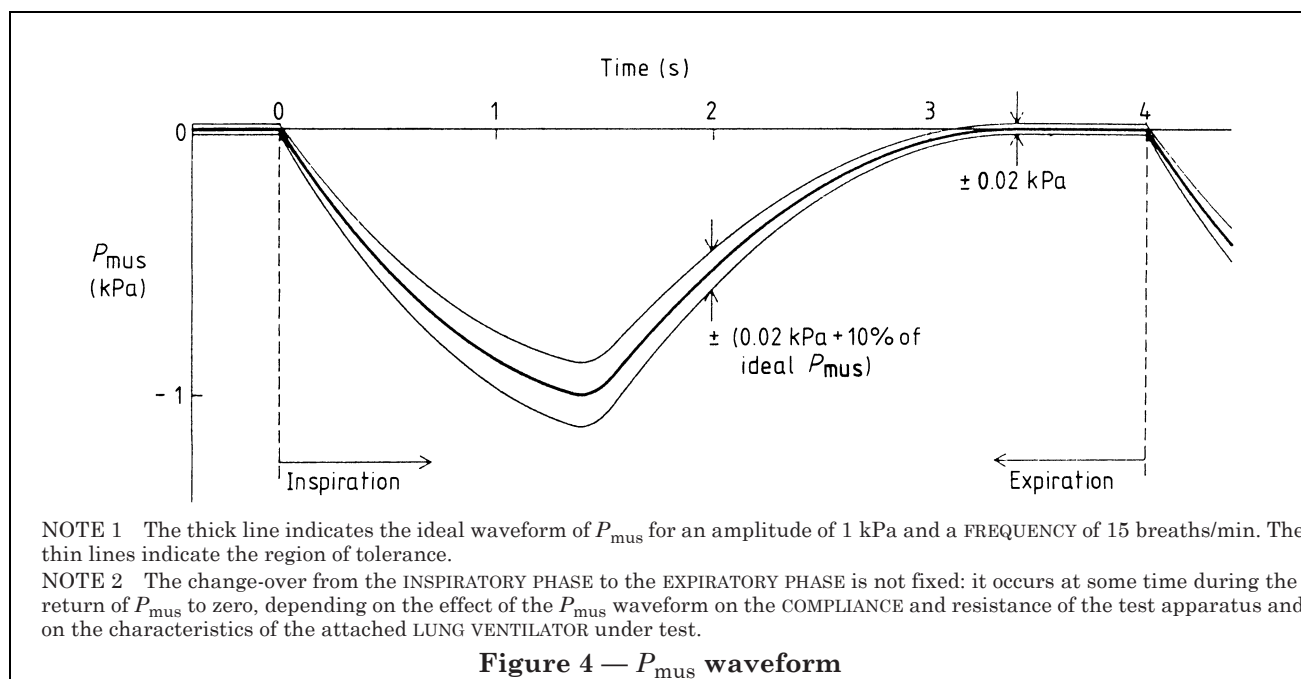
where

V_U is the unattainable stated value;

V_A is the nearest attainable stated value;

V_N is that value that lies between V_A and V_U and is the nearest to V_U that can be attained.

NOTE For some LUNG VENTILATORS, controls are adjusted by entering instructions via a keyboard.



3.4.2 Any external controls, or controls on the anaesthetic machine of which the LUNG VENTILATOR forms a part (e.g. controls of FRESH GAS flow), the setting of which is not specified directly or indirectly in the test procedure, shall be set as recommended by the manufacturer, if necessary using the appropriate body mass specified in **3.1.7**.

NOTE In some LUNG VENTILATORS, the setting of some controls may be specified in an indirect manner. For example, if a test specifies a particular DELIVERED VOLUME and FREQUENCY but the LUNG VENTILATOR has controls for DELIVERED TOTAL VENTILATION and FREQUENCY, the appropriate setting of the DELIVERED TOTAL VENTILATION control will be that required to produce the specified DELIVERED VOLUME.

If the only difference between successive tests is in the settings of the test apparatus, e.g. COMPLIANCE, resistance or the FREQUENCY or amplitude of P_{mus} , the controls of the LUNG VENTILATOR shall not be altered between tests.

3.4.3 If the manufacturer gives specific instructions not to use the LUNG VENTILATOR in the manner stated in any test, e.g. POSITIVE END-EXPIRATORY PRESSURE (PEEP) by POSITIVE PRESSURE cycling from the EXPIRATORY PHASE to the INSPIRATORY PHASE (see item d) in the note to **6.7**), the test shall not be carried out and the reason shall be stated in the ACCOMPANYING DOCUMENTS.

3.5 Reporting of test results in the ACCOMPANYING DOCUMENTS

3.5.1 The results of the tests carried out to measure the parameters to be disclosed, as described in clauses **6**, **7**, **8** and **9**, shall be presented in the form of a test report.

3.5.2 The test report shall state for each test the settings of the test apparatus, the settings of the ventilator controls and of any other relevant controls (see **3.4.2**).

The test report shall also state the following, as appropriate:

- a) the stated value of the parameter [see **3.4.1 a)**]; or
- b) the actual value of the parameter and the reason for the difference from the stated value [see **3.4.1 b)** and c)]; or
- c) the reason for not carrying out a test [see **3.4.1 c)** and **3.4.3**].

3.5.3 The test report shall be structured with the same headings and sub-headings as those in clauses **6**, **7**, **8** and **9**, as appropriate.

NOTE The scale and clarity of reproduction of all graphs should be such that changes of 5 % of the total length of any axis are clearly distinguishable. The labelling and captioning of the graphs and tables of results should be as those given for the appropriate figures and tables in this standard.

If the LUNG VENTILATOR has more than one intended use (adult, paediatric or neonatal), all the results for the tests in clauses **6**, **7**, **8** and **9** shall be reported for one intended use, and then all for the next, and so on. The sequence shall be adult, paediatric, neonatal, except that if the ventilator is intended primarily for neonatal use the sequence shall be reversed.

If a test or tests in a subclause are required to be repeated using more than one mechanism, e.g. for the production of PEEP or NEGATIVE END-EXPIRATORY PRESSURE (NEEP), CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) or CONTINUOUS NEGATIVE AIRWAY PRESSURE (CNAP) or PRESSURE ASSISTANCE or PRESSURE HINDRANCE, or using more than one mode of operation (see Appendix B), unless otherwise stated, the results of all tests using the first mechanism shall be reported first, then all for the second, and so on; and, within each mechanism, all the results for the basic mode of operation shall be reported first, followed by all the results for each additional mode in the order of priority stated by the manufacturer (see **3.1.8**).

For each test carried out, a separate figure or table as appropriate shall be prepared, unless otherwise stated.

If the results of some tests are the same, to within twice the tolerance given in column 4 of Table 2, as those of tests already carried out, the results of the later tests shall be given by reference to the earlier tests.

3.5.4 If the test report includes results giving MOUTH PRESSURES more negative than -1 kPa that have been produced by the LUNG VENTILATOR and not by simulated spontaneous ventilation, alongside the relevant results shall be a warning that the performance of the LUNG VENTILATOR when connected to a PATIENT may be different as a result of narrowing of airways under NEGATIVE PRESSURE.

Section 3. Declaration and measurement of parameters

4 Performance parameters

The following performance parameters shall be presented either in tabulated form or in the form of graphs, as described in clauses 6, 7, 8 and 9, as appropriate, in the ACCOMPANYING DOCUMENTS.

- a) For LUNG VENTILATORS providing CMV:
 - 1) waveform performance;
 - 2) expiratory resistance;
 - 3) volume performance;
 - 4) I : E RATIO performance;
 - 5) rebreathing;
 - 6) actions of controls;
 - 7) TRIGGERING sensitivity and delay, if applicable;
 - 8) TRIGGERING FREQUENCY range, if applicable;
 - 9) over-maximum-FREQUENCY waveform, if applicable.
- b) For LUNG VENTILATORS that allow spontaneous ventilation which is either unsupplemented or supplemented only by PRESSURE ASSISTANCE:
 - 1) waveform performance;
 - 2) resistance;
 - 3) rebreathing;
 - 4) TRIGGERING sensitivity and delay, if applicable;
 - 5) TRIGGERING FREQUENCY range, if applicable;
 - 6) over-maximum-FREQUENCY waveform, if applicable.
- c) For LUNG VENTILATORS providing IMV:
 - 1) waveform performance;
 - 2) volume performance;
 - 3) INSPIRATORY TIME performance;
 - 4) rebreathing;
 - 5) actions of controls;
 - 6) interaction between spontaneous and mandatory FREQUENCIES, if applicable;
 - 7) quality of synchronization, if applicable.
- d) For LUNG VENTILATORS providing MMV:
 - 1) waveform performance;
 - 2) rebreathing;
 - 3) MMV performance;
 - 4) interaction between spontaneous FREQUENCY and MMV;
 - 5) quality of synchronization, if applicable.

NOTE Each of clauses 6, 7, 8 and 9 describes tests on a particular function of the LUNG VENTILATOR (see Appendix B). Any one ventilator may provide all four functions or any subset of the four.

5 Basic test procedures

5.1 General

This clause describes the basic test procedures to be used to produce the information to be disclosed in the ACCOMPANYING DOCUMENTS, as described in clauses 6, 7, 8 and 9. Before carrying out any of the tests, subject the LUNG VENTILATOR to pre-test running as described in 5.2.

5.2 Pre-test running

5.2.1 Test apparatus

The test apparatus described in 3.3 shall be used with the following exceptions.

- a) The total COMPLIANCES and resistances given in 3.3.5.1 shall be accurate to within three times the tolerances given in Table 2.
- b) The accuracy of the COMPLIANCES shall be maintained throughout the range of "ALVEOLAR" PRESSURE from - 1 kPa to 5 kPa and when the volume change occurs over any duration between 0.5 s and 1 s.
- c) The accuracy of the resistances shall be maintained to within the tolerance at the appropriate "high" flow in Table 1.
- d) The P_{mus} waveform (3.3.5.2) required, if any (see 5.2.3), shall be any which permits the DELIVERED VOLUME, FREQUENCY and I : E RATIO used in 5.2.3 to be obtained.

5.2.2 Test conditions

5.2.2.1 The LUNG VENTILATOR shall be supplied with gases of a quality and composition recommended by the manufacturer.

5.2.2.2 The target settings shall be accurate to within three times the tolerances given in column 4 of Table 2.

5.2.2.3 The ambient temperature shall be between 15 °C and 35 °C throughout the test.

5.2.3 Procedure

Set the COMPLIANCE and resistance of the test apparatus to the following values:

- a) for LUNG VENTILATORS intended for adult use, 500 mL/kPa and 0.5 kPa/(L/s), respectively;
- b) for LUNG VENTILATORS intended for paediatric use, 100 mL/kPa and 2 kPa/(L/s), respectively;
- c) for LUNG VENTILATORS intended for neonatal use, 30 mL/kPa and 5 kPa/(L/s), respectively.

Set the amplitude of the P_{mus} waveform to zero. Connect the LUNG VENTILATOR to the test apparatus, adjust the controls and, if necessary, introduce a P_{mus} waveform to give a DELIVERED VOLUME and FREQUENCY as follows at an I : E RATIO of between 1 : 1 and 1 : 3:

- 1) for LUNG VENTILATORS intended for adult use, 500 mL and 15 breaths/min, respectively;
- 2) for LUNG VENTILATORS intended for paediatric use, 100 mL and 20 breaths/min, respectively;
- 3) for LUNG VENTILATORS intended for neonatal use, 20 mL and 30 breaths/min, respectively.

Run the LUNG VENTILATOR for 200 h, for the manufacturer’s recommended service interval or, if the LUNG VENTILATOR is disposable or intended for single use, for the manufacturer’s recommended life, whichever is the shortest.

5.3 Waveform performance test

5.3.1 Procedure

Set the COMPLIANCE, the resistance, and the FREQUENCY and amplitude of the P_{mus} waveform of the test apparatus (see 3.3) and, if applicable, the controls of the LUNG VENTILATOR, as described in clauses 6, 7, 8 and 9, as appropriate. Connect the LUNG VENTILATOR to the test apparatus. When a steady state has been reached, measure the following variables simultaneously:

- a) MOUTH PRESSURE;
- b) “ALVEOLAR” PRESSURE;
- c) flow;
- d) volume.

5.3.2 Presentation of results

5.3.2.1 The variables measured in 5.3.1 shall be displayed in the order given, one above the other, on a common horizontal axis as described in clauses 6, 7, 8 and 9, as appropriate, and as shown in Figure 5(a). The flow waveform shall be displayed with inspiratory flow upwards, i.e. positive. The volume waveform shall be displayed so that zero volume is the state when “ALVEOLAR” PRESSURE and P_{mus} are both zero.

NOTE This corresponds to the functional residual capacity in a PATIENT.

5.3.2.2 For the tests described in any one subclause, the ranges of the horizontal axes shall be as described in clauses 6, 7, 8 and 9, as appropriate. The ranges of the pressure, flow and volume axes may be chosen to suit the circumstances of those tests for the LUNG VENTILATOR under test, but the relative scaling shall be fixed. A unit distance, e.g. 1 cm, in the displayed waveforms shall correspond to the relevant time, pressure, flow and volume given in Table 3, e.g. as shown in Figure 5(b), unless otherwise stated in clauses 6, 7, 8 and 9, as appropriate.

NOTE 1 This will usually be possible on A4 paper with a 1 cm to 2 cm margin and a unit distance of 1 cm, if the results of some tests are displayed landscape instead of portrait.
NOTE 2 The same unit distance should, as far as possible, be used for all displays of results from any one LUNG VENTILATOR and, particularly, for all tests in a group.

Table 3 — Values corresponding to unit distance in displays of waveform performance tests

Intended use	Time	Pressure	Flow	Volume
	s	kPa	L/min	mL
Adult	1	2	45	500
Paediatric	0.75	2	12	100
Neonatal	0.5	2	3.6	20

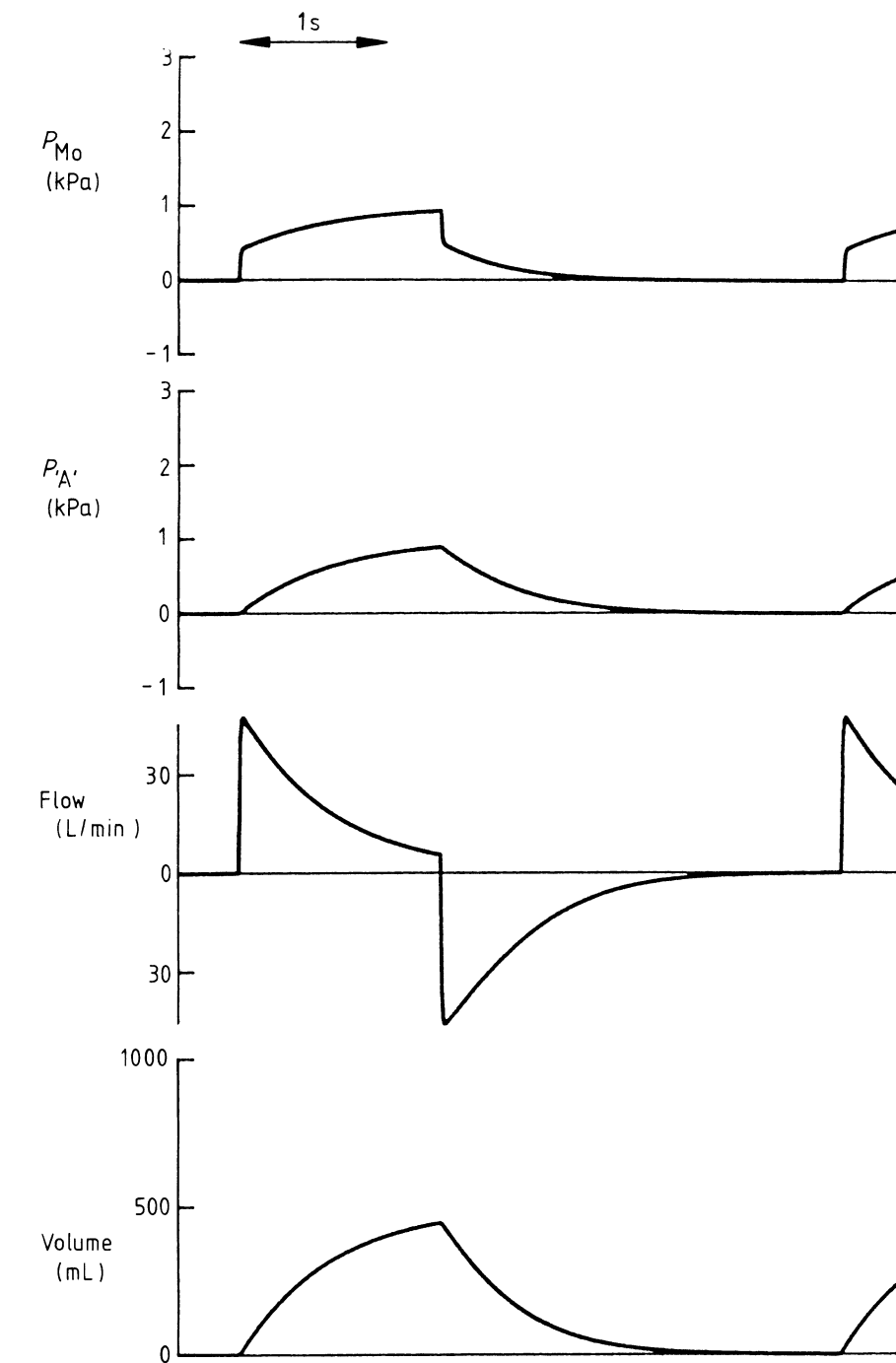
NOTE The relationships between the figures for adult, paediatric and neonatal tests are intended to produce displays of waveforms of approximately the same ratio of amplitude to period in all three cases, that ratio being intended to be roughly optimal for revealing the shape of all waveforms. In addition, the relationships ensure that, in all three cases, if d is the unit distance, $1.5d$ of volume deflection corresponds to an area d^2 under the flow waveform, e.g. in adult use, $1.5d$ corresponds to 750 mL, and an area d^2 under the flow waveform corresponds to 45 L/min (= 0.75 L/s) for 1 s = 750 mL.

5.4 Expiratory resistance test (under CMV)

5.4.1 Procedure

Connect the LUNG VENTILATOR to the test apparatus (3.3). Set the COMPLIANCE and resistance of the test apparatus and the controls of the LUNG VENTILATOR as described in clauses 6, 7, 8 and 9, as appropriate. When a steady state has been reached, measure the following variables simultaneously:

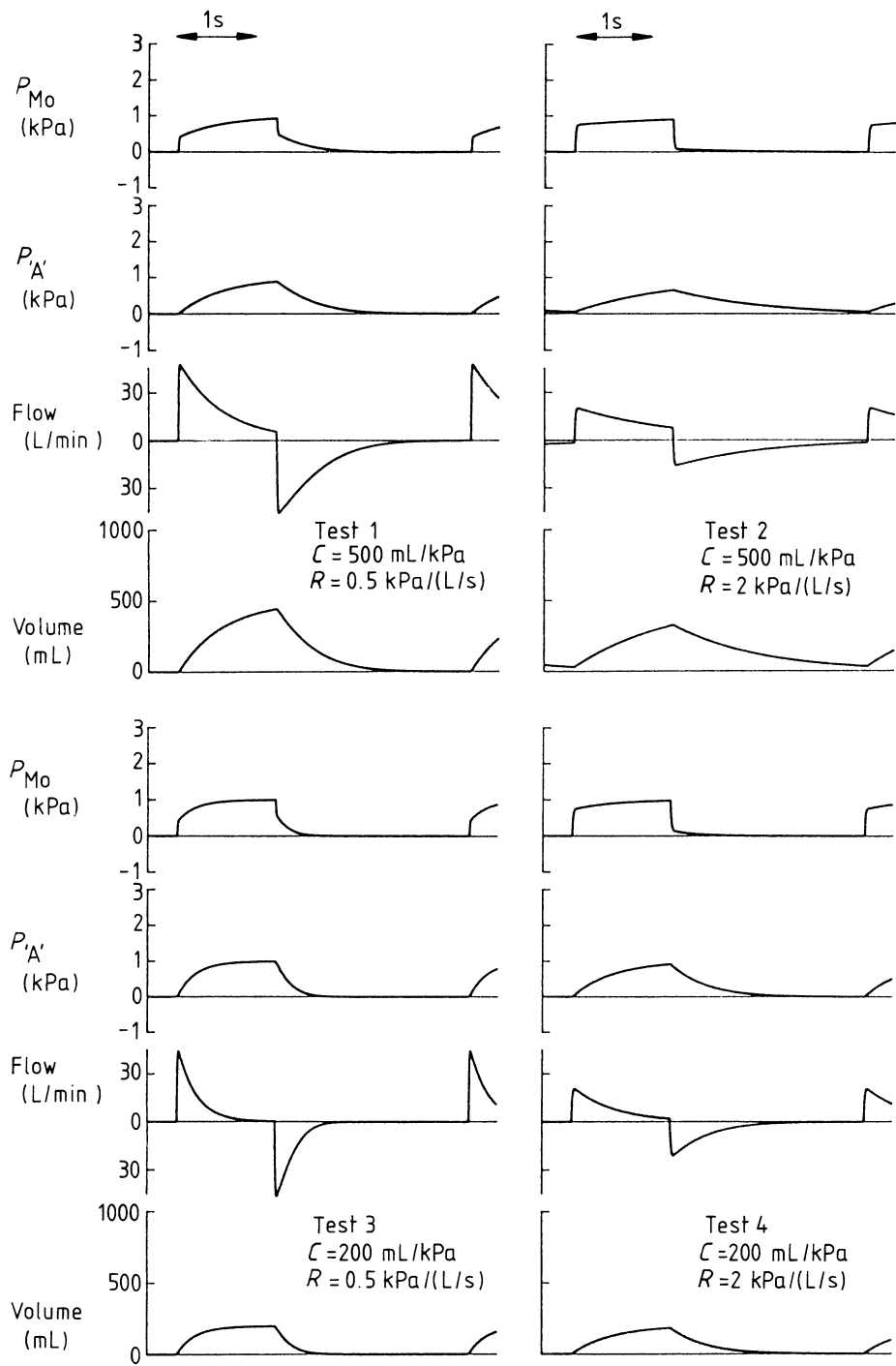
- a) MOUTH PRESSURE; and
- b) flow.



(a)

NOTE The example given in (a) is for a single waveform performance test on a hypothetical adult LUNG VENTILATOR operating as a time-cycled, low constant-pressure generator in CMV under the conditions of test 1 given in Table 11.

Figure 5 — Typical presentation of results of waveform performance tests



(b)

NOTE The example given in (b), for a set waveform performance tests in CMV on a hypothetical adult LUNG VENTILATOR, shows the effects of changes of COMPLIANCE and resistance as given in Table 11 on the waveforms of controlled ventilation in the time-cycled pressure-generation mode of operation.

Figure 5 — Typical presentation of results of waveform performance tests (concluded)

5.4.2 Presentation of results

The MOUTH PRESSURE shall be plotted against flow for only one EXPIRATORY PHASE and only for that part of the phase after the peak expiratory flow. The horizontal axis shall extend from (on the left) 1.2 times the appropriate “high” flow given in Table 1 to (on the right) zero flow. The relative scaling of the horizontal and vertical axes shall be as given in Table 3.

When stated in clauses 6, 7, 8 and 9, as appropriate, the results of tests under different conditions shall be plotted on a single graph, as shown in Figure 6.

5.5 Resistance test (under spontaneous ventilation conditions)

5.5.1 Procedure

Connect the LUNG VENTILATOR to the test apparatus (3.3). Set the COMPLIANCE, the resistance and the FREQUENCY and amplitude of the P_{mus} waveform of the test apparatus, together with the controls of the LUNG VENTILATOR, as described in clauses 6, 7, 8 and 9, as appropriate. When a steady state has been reached, measure the following variables simultaneously:

- MOUTH PRESSURE; and
- flow.

5.5.2 Presentation of results

The MOUTH PRESSURE shall be plotted against flow for one respiratory cycle. If this results in a loop, the direction of the loop, i.e. early inspiration to late inspiration to early expiration to late expiration, shall be indicated by arrows and a note shall be entered against the graph indicating any part of the loop which represents a transient part of the respiratory cycle. Unless otherwise stated in clauses 6, 7, 8 and 9, the horizontal axis shall extend from (on the left) 1.2 times the appropriate “high” expiratory flow to (on the right) 1.2 times the appropriate “high” inspiratory flow given in Table 1. The relative scaling of the horizontal and vertical axes shall be as given in Table 3.

When stated in clauses 6, 7, 8 and 9, as appropriate, the results of tests under different conditions shall be plotted on a single graph, as shown in Figure 7.

