Designation: F 1100 – 90

Standard Specification for Ventilators Intended for Use in Critical Care[1]

This standard is issued under the fixed designation F 1100; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 *General*—This specification establishes minimum performance and safety requirements for all ventilators and ventilator circuits intended for use with adult, child, or infant patients in critical care within the hospital and introduced for sale after the acceptance date of this specification, except as noted below. Definitions, performance requirements, test methods, and rationale are included. Several definitions have been included in Section 3.1 and Appendix X1 that are not used in the text of this specification. This material has been included for the sake of completeness, and for any possible educational benefit that may be served.

1.2 *Exclusions*—This specification does not apply to body ventilators such as the tank ventilator or the chest cuirass nor does it apply to ventilators utilizing the Sanders technique or "jet" ventilation, (venturi effect type) high frequency ventilators (greater than 2.5 Hz), or anesthesia ventilators. This specification does not apply to ventilators intended for use in transport applications or home care, nor does it apply to those ventilators developed for veterinary applications. The application of critical care ventilators in the home environment is not covered by this specification nor is the hospital use of transport or home care ventilators. (See also X2.1.)

1.3 The following precautionary caveat pertains to the test methods portion only, Section 6, of this specification: *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

F 1054 Specification for Conical Fittings of 15-mm and 22-mm Sizes[2]

2.2 *ANSI Standards:*

ANSI Z-79.9, 1978, Humidifiers and Nebulizers for Medical Use[3]

ANSI Z-79.10, 1979, Requirements for Oxygen Analyzers for Monitoring Patient Breathing Mixtures[3]

2.3 *ISO Standards:*

ISO 4135 Anesthesiology Vocabulary[4]

ISO 5356 Anesthetic and Respiratory Equipment Conical Connectors[4]

2.4 *Other Standards:*

CGA V-5 Specifications for DISS Connections[5]

MDS 201 Electromagnetic Compatibility Standard for Medical Devices[6]

3. Terminology

3.1 *Descriptions of Terms*—For the purposes of this specification the definitions in 3.1.1-3.1.49 shall apply.

3.1.1 *airway pressure (P_{aw})*—pressure at a specified point in the patient's airway. The site and conditions under which measurements are made should be given.

3.1.2 *alarm*—a means of alerting the operator that a particular condition exists.

3.1.3 *alveolar pressure (P_A)*—pressure in the alveoli. In the case of the lung model, this is represented by the pressure in the compliance chamber.

3.1.4 *apparatus internal compliance*—volume/pressure relationship, expressed in millilitres per kilopascal (or millilitres per centimetre H_2O) of those portions of the patient system that are pressurized during the inspiratory phase time (see also 8.1).

3.1.5 *continuous positive airway pressure* (CPAP)—P_{aw} maintained above ambient.

3.1.5.1 *Discussion*—Common usage of this term references spontaneous ventilation.

3.1.6 *control*—a means available to the operator of directly adjusting a ventilator function.

3.1.7 *cycling pressure*—that pressure which, when reached in the patient system, causes the ventilator to cycle from inspiratory to expiratory phase or from expiratory to inspiratory phase.

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[2] *Annual Book of ASTM Standards*, Vol 13.01.

[3] Available from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

[4] Available from the International Standards Organization, 1, Rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland.

[5] Available from the Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.

[6] Available from the National Technical Information Service (NTIS), Accession #PB271635, 5285 Port Royal Road, Springfield, VA 22161.

3.1.8 *differential inspiratory triggering pressure* (ΔP_{tr})—changes in airway pressure at the patient connection port which must be generated by the patient to initiate the ventilator inspiratory phase.

3.1.8.1 *Discussion*—Pressure shall be expressed in terms of gage pressure in units of kilopascals (or centimetres H_2O) to follow the kilopascal units.

3.1.9 *expiratory pause time* (T_{EP})—interval from the end of expiratory flow to the start of inspiratory flow.

3.1.10 *expiratory phase time* (T_E)—interval from the start of expiratory flow to the start of inspiratory flow.

3.1.11 *expiratory positive airway pressure* (EPAP)—P_{aw} above ambient during the expiratory phase, generally approximated by P_{ps}.

3.1.12 *expiratory (sub-atmospheric) sub-ambient pressure*—pressure lower than ambient, during the expiratory phase time.

3.1.12.1 *Discussion*—Sub-ambient pressure may be constant throughout the expiratory phase time or it may vary through the phase time, depending upon the method by which such pressure is generated.

3.1.13 *frequency (ventilatory) (f)*—number of breathing cycles per minute.

3.1.14 *heat and moisture exchanger* (HME)—a passive device which is designed to conserve some of the patient's exhaled moisture and heat, and to release heat and moisture to the patient's airway during inspiration.

3.1.15 *inspiratory-expiratory phase time ratio (I:E ratio)*—ratio of the inspiratory phase time to the expiratory phase time.

3.1.16 *inspiratory minute volume* ($\dot{V}_I$)—volume of gas inspired per minute by the patient, measured by litres (L).

3.1.17 *inspiratory pause time* (T_{IP})—interval from the end of inspiratory flow to the start of expiratory flow.

3.1.18 *inspiratory phase time* (T_I)—interval from the start of inspiratory flow to the start of expiratory flow.

3.1.19 *inspiratory positive airway pressure* (IPAP)—P_{aw} above ambient during the inspiratory phase of CPAP, generally approximated by P_{ps}.

3.1.20 *inspiratory relief valve*—unidirectional valve designed to admit air to the patient system when the patient inspires spontaneously and the supply of inspiratory gases from the ventilator is inadequate.

3.1.21 *inspiratory relief valve resistance*—pressure difference across the inspiratory relief valve at a constant flow of 30 L/min.

3.1.22 *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.

3.1.23 *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.

3.1.24 *inspiratory triggering response time* (T_{tr})—time delay between the satisfaction of the inspiratory triggering pressure or flow, or both, volume requirements, and the start of inspiratory flow.

3.1.25 *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.

3.1.25.1 *Discussion*—In some devices there exists a complex relationship between the multiple parameters as defined in 3.1.22-3.1.25.

3.1.26 *intermittent mandatory ventilation* (IMV)—a mode of operation of the ventilator that permits spontaneous breathing of a controlled inspiratory gas mixture between the predetermined ventilator-derived breaths, using the same inspiratory gas mixture.

3.1.27 *maximum limited pressure* ($P_{L\,max}$)—the highest gage pressure which can be attained in the patient system during malfunction of the ventilator but with functioning safety mechanisms.

3.1.27.1 *Discussion*—The title of this definition is different from the title given in ISO 4135. However, the text is identical to that in ISO 4135. The title of the ISO definition is *maximum safety pressure*.

3.1.28 *maximum working pressure* ($P_{w\,max}$)—the highest gage pressure which can be attained in the patient system during the inspiratory phase when the ventilator is functioning normally.

3.1.28.1 *Discussion*—This may be limited by a controllable ventilator mechanism to less than $P_{L\,max}$.

3.1.29 *minimum limited pressure* ($P_{L\,min}$)—the highest numerical value of sub-atmospheric gage pressure which can be attained in the patient system during malfunction of the ventilator but with functioning safety mechanisms.

3.1.29.1 *Discussion*—The title of this definition is different from the title given in ISO 4135. However, the text is identical to that in ISO 4135. The title of the definition in ISO 4135 is *minimum safety pressure*.

3.1.30 *minimum working pressure* ($P_{w\,min}$)—highest numerical value of sub-atmospheric gage pressure which can be attained in the patient system during the expiratory phase when the ventilator is functioning normally.

3.1.30.1 *Discussion*—This may be limited by a controllable ventilator mechanism to a sub-atmospheric pressure that is numerically smaller than $P_{L\,min}$.

3.1.31 *minute volume* ($\dot{V}$)—volume of gas, expressed in litres per minute entering or leaving the patient or lung model. The physical conditions under which measuring was made should be given.

3.1.32 *monitor (indicator display)*—a means of informing the operator of the status or numerical value of ventilation or a ventilator.

3.1.33 *nebulizing humidifier*—device designed to add water to the inspired gas in the form of droplets.

3.1.34 *negative end expiratory pressure* (NEEP)—the P_{ps} at the end of expiration, below ambient.

3.1.35 *patient system*—that part of the gas system of a ventilator through which respired gas travels at appropriate respiratory pressures.

3.1.36 *patient system compliance*—volume/pressure relationship, expressed in mL/kPa (or mL/cm H_2O), of those portions of the patient system that are pressurized during the inspiratory phase time.

3.1.37 *positive end-expiratory pressure* (PEEP)—P_{ps} at the end of expiration, above ambient.

3.1.38 *pressure, patient system (P_{ps})*—pressure at a specified point in the patient system.

3.1.38.1 *Discussion*—Conditions under which measurements are made shall be given.

3.1.39 *pressure support*—a ventilator mode designed to augment the patient's ventilation synchronously with his inspiratory effort until a preset pressure is met.

3.1.40 *sigh (ventilator)*—deliberate increase in tidal volume for one or more breaths at intervals.

3.1.41 *spirometer*—device designed to measure a volume of gas.

3.1.42 *synchronous intermittent mandatory ventilation (SIMV) or assisted ventilation*—a ventilator mode which provides a mechanism for synchronizing the ventilator-delivered breaths with a patient's inspiration, as detected by the ventilator.

3.1.43 *tidal volume (V_T)*—volume of gas, expressed in millilitres (mL), entering or leaving the patient or the lung model during the inspiratory or expiratory phase time. The physical conditions under which gas volumes are measured should be given.

3.1.44 *time constant*—time in which an exponential process is 63 % complete.

3.1.45 *vaporizing humidifier*—device designed to add water to the inspired gas in the form of vapor.

3.1.46 *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 kPa (or cm H_2O) referred to a flow of 0.5 L/s.

3.1.47 *ventilator pressure (P_{vent})*—pressure at a specified point in the ventilator. The site and conditions under which measurements are made should be given.

3.1.48 *ventilators intended for use with anesthesia*—ventilator designed to be used with or integral to an anesthesia breathing system.

3.1.49 *volumetric displacement*—that volume, under specific conditions and expressed in millilitres, passed per cycle during the inspiratory phase through the patient connection port when the pressure at the intake to the ventilator and the outlet from the patient's connection port is equal to the atmospheric pressure.

3.2 *Symbols:Symbols:*

3.2.1 *C*—compliance in units of mL/kPa (or mL/cm H_2O), for example, *C*20 = 2.0 mL/kPa (20 mL/cm H_2O).

3.2.2 *R*—resistance to flow in units of kPa/L/s (or cm H_2O/L/s), for example, *R*5 = 0.5 kPa/L/s (5 cm H_2O/L/s).

3.2.2.1 *Discussion*—In the interest of brevity and clarity, all other abbreviations have been provided in parentheses following the related term in Section 3.

4. Materials and Manufacture

4.1 Components of a spirometer that come in direct contact with the patient's exhaled gas shall be capable of being sterilized or disinfected or shall be labelled for single use only, or isolated in some manner from the respired gas in the patient breathing circuit. (See also X2.2.)

5. Performance Requirements

5.1 *Determination of Ventilator Endurance, Wave-form, and Volume Characteristics—General*—Compliance with the requirements given in 5.2-5.4 shall be determined with one or more samples of production ventilators with the assurance that the results, which shall be made available to customers, are representative of all production ventilators of that type.

NOTE 1—The requirements given in 5.2-5.4 and the tests described in 6.3 delineate first article or design qualification tests and are not intended to be lot sampling tests. The disclosure of information referred to in 6.3 is intended to include periodic maintenance necessary during the endurance test and the results of work performed.

5.2 *Ventilator Endurance*—Each ventilator (as described in 5.1) shall be tested for endurance as described in 6.3.1 with respect to each group of patients for which its use is recommended, that is, for adults, for children, and for infants. The ventilator shall run for 2000 h against the appropriate conditions as shown in Table 1. A separate machine may be used for each group or the period of tests may be divided equally between groups. If the ventilator is provided with an assist mechanism, the mechanism shall be part of the test. If IMV or SIMV is provided, that mechanism shall be a part of the test. Data resulting from these tests shall be available on request from the manufacturer.

5.3 *Wave-form Performance*—The ventilator shall be tested as described in 6.3.2 with each of the compliance and resistance combinations appropriate to its intended use (that is, for adults, for children, or for infants), in the order shown in Table 2.

5.4 *Volume Performance*—The ventilator shall be tested against the combinations of compliance (*C*) and resistance (*R*) appropriate to its sphere of use, as shown in Table 3. The manufacturer shall determine the range of tidal volumes that the ventilator is capable of delivering to the lung at the specified frequencies with an inspiratory/expiratory phase time ratio as close to 1:2 as possible. Further measurements at different frequencies and with different compliance and resistance combinations may be included if desired. All results shall be expressed in the form of a table or a diagram similar to Fig. 1. The conditions under which the tests are carried out shall be stated (see 6.3.2 and 6.3.2.1).

5.5 *Power Sources*:

5.5.1 *Electrical*—The ventilator shall continue to function within the manufacturer's specifications at any control setting throughout a range of ±10 % fluctuation of the stated nominal voltage and ±1 % fluctuation of the stated frequency for electrical power sources.

5.5.2 *Pneumatic*—When tested according to the methods outlined in 6.5, the ventilator shall continue to function within the manufacturer's specifications at any control setting

TABLE 1 Endurance Test

Group	Minute Volume V_E, L	Ventilatory Frequency, f, breaths/min[A]	Compliance	Resistance
Adult	10	20	*C*50	*R*20 or R_p20
Child	4.5	30	*C*20	*R*50 or R_p50
Infant	0.8	60	*C*3	*R*200 or R_p200

[A] Or nearest possible.

TABLE 2 Procedure for Performance Test—Waveform[A]

Test Number[B]	Compliance	Resistance		Tidal Volume V_t ± 5 %, mL	Ventilation Frequency *f*, ± 5 % (breaths/min)	Sample Time Constant, s	Ventilation Pressure Limit, cm H_2O[C]
		Linear	Parabolic				
Adult							
[1]	*C*50	*R*5	R_p5	500	20	0.25	12.5
2	*C*50	*R*20	R_p20	500	20	1.0	20.0
3	*C*20	*R*5	R_p5	500	20	0.1	27.5
4	*C*20	*R*20	R_p20	500	20	0.4	35.0
Children							
[1]	*C*20	*R*20	R_p20	300	20	0.4	21.0
2	*C*20	*R*50	R_p50	300	20	1.0	30.0
3	*C*10	*R*20	R_p20	300	20	0.2	36.0
4	*C*10	*R*50	R_p50	300	20	0.5	45.0
[5]	*C*3	*R*20	R_p20	50	30	0.06	18.5
6	*C*3	*R*50	R_p50	50	30	0.15	20.8
7	*C*3	*R*200	R_p200	50	30	0.6	32.0
Infant							
[1]	*C*3	*R*50	R_p50	30	30	0.15	12.3
2	*C*3	*R*200	R_p200	30	30	0.6	19.0
3	*C*1	*R*50	R_p50	30	30	0.05	32.3
4	*C*1	*R*200	R_p200	30	30	0.2	39.0
[5]	*C*1	*R*200	R_p200	15	60	0.2	24.0

[A] Inspiratory/expiratory phase time ratio as close to 1:2 as possible; see 6.3.2.

[B] The ventilator controls shall be reset to suit the chosen standard conditions (bracketed) before undertaking each subsequent test. 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.

[C] Ventilation Pressure Limit = Calculated pressure applied by constant-flow generators at the machine side of the airway resistance to achieve the required tidal volume during the set inspiratory time. These pressures will be in excess of the corresponding lung pressure that will be developed by the end of the inspiratory phase.

TABLE 3 Volume Performance Test

Type of Ventilator	Compliance	Resistance		Ventilatory Frequencies
		Linear	Parabolic	
Adult	*C*20	*R*20	R_p20	10, 15, 20, 30
Child	*C*10	*R*50	R_p50	15, 20, 30, 40
	*C*3	*R*200	R_p200	15, 20, 30, 40
Infant	*C*1	*R*200	R_p200	20, 30, 40, 60

Tidal Volume, V_T (ml)	Ventilatory Frequency, *f* (bpm)			
	10	15	20	30
Max	—	—	—	—
Min	—	—	—	—

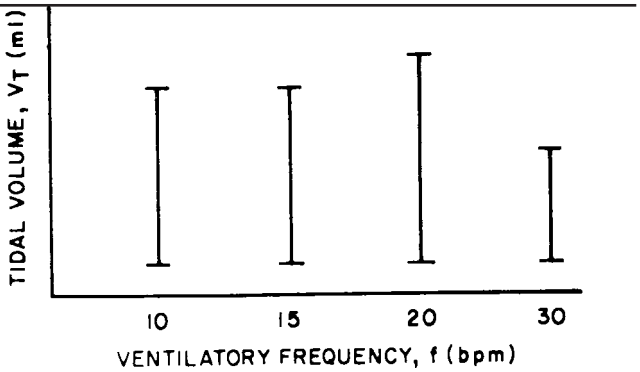

FIG. 1 Suggested Format for Volume Performance Test Report Form

throughout a range of supply pressures of 379 kPa (55 psig) +20 %, −25 %. (See also Appendix X3.3.2.)

5.5.2.1 The ventilator's gas connection(s) shall be non-interchangeable. If the device has a threaded connection, it shall conform to the appropriate CGA V-5 1978 specification for DISS connections. If the ventilator is capable of being independently connected to the gas piping system it shall have permanently attached a Nut and Gland Fitting No. 1240 (oxygen), if intended to be powered by oxygen, or a Nut and Gland Fitting No. 1160 (air), if intended to be powered by air, or both fittings if both gases are used. (See also Appendix X3.3.2.1.)

5.6 *Accuracy of Calibrated Controls, Indicators, and Pressure Relief Devices*:

5.6.1 *Calibrated Controls*—When tested according to the methods outlined in 6.6.1, controls for $P_{w\,max}$ on infant ventilators shall be accurate to within ±0.196 kPa (±2 cm H_2O) over the entire range. Controls for $P_{w\,max}$ in all other ventilators shall be accurate to within ±0.49 kPa (±5 cm H_2O) up to 2.94 kPa (30 cm H_2O) and± 0.98 kPa (±10 cm H_2O) for settings above 30 cm H_2O. All other calibrated controls, when working at nominal power inputs, should be accurate to within ±10 % of the setting. (See also X2.3.3.1.)

5.6.1.1 *Maximum Working Pressure*—If provided in the patient breathing circuit, positive pressure control devices shall restrict the airway pressure to within ±0.49 kPa (±5 cm H_2O) up to a point of 2.94 kPa (30 cm H_2O) and to within ±0.98 kPa (±10 cm H_2O) for settings above 30 cm H_2O, when tested by the methods described in 6.6.2. (See also X2.3.3.2.)

5.6.2 *Indicators*—All other indicators should be accurate to within ±10 % of the reading.

5.6.3 *Limited Pressure Relief Controls*—If the pressure in the breathing circuit reaches a level greater than the usual operator adjusted peak pressure, the device (ventilator) shall activate a pressure reduction mechanism within 3 s when tested as outlined in 6.6.3. This pressure reduction mechanism shall bring the breathing circuit to a predetermined baseline pressure equal to or less than the end-expiratory pressure. The limited pressure relief mechanism may also be activated without delay when the preset maximum limiting pressure is reached. A

coupled visual/audible alarm shall be activated in this event. The visual signal shall be retained when the pressure is reduced and shall require a manual reset. (See also X2.3.3.3.)

5.6.4 When tested by the methods described in 6.6.4, devices indicating ventilatory frequency shall be accurate to one breath per minute or 10 % of the setting, whichever is greater.

5.6.4.1 When tested by the methods described in 6.6.4, devices controlling ventilator frequency shall be accurate to within one breath per minute or 10 % of the setting, whichever is greater. (See also X2.3.3.4.)

5.7 *Spirometers and Other Devices for Indication of Ventilator Function Integral to the Ventilator*:

NOTE 2—Continuous flow ventilators are exempt from the requirements of 5.7.

5.7.1 Provision shall be made for connection of a spirometer or other device for the measurement of expired volume if not provided as an integral part of the ventilator. The fitting for the attachment of this spirometer shall be a standard 30-mm conical male connector.

5.7.2 When tested as described in 6.7, any spirometer integral with the ventilator shall be accurate to within ±10 % of the reading over the flow ranges specified by the manufacturer. The pressure drop with a steady gas flow of 50 L/min shall not exceed 0.196 kPa (2.0 cm H_2O). Conditions of calibration shall be disclosed. (See also X2.3.4.1.)

5.7.3 When tested as described in 6.7.2, the spirometer shall continue to function within the limits of accuracy delineated in 5.7.2 whatever the humidity and within the temperature range of 20 to 37°C (due allowance being made for the difference between gas temperature and humidity in the spirometer and the temperature and humidity at which the spirometer was calibrated). Spirometers should be designed in such a manner that they cannot become obstructed by secretions from the patient. (See also X2.3.4.2.)

5.8 *Accuracy of Gas Mixture Controls*:

5.8.1 When tested as described in 6.8, ventilators that incorporate as a primary control an inspiratory gas mixture control shall provide a mean delivered oxygen concentration within ±10 % of the set oxygen concentration or 3 % oxygen, whichever is greater, throughout the range of pressures, frequencies, and tidal volumes for which the ventilator is capable. At a given setting of the ventilator, the mean delivered oxygen concentration shall be within ±3 % oxygen for at least one hour. (See also X2.3.5.)

5.9 *Expiratory Resistance*:

5.9.1 *Adult and Child Ventilators*—When tested in accordance with the methods described in 6.9, and in the absence of expiratory resistors or positive end expiratory pressure devices, the pressure at the patient connection port for adult and child ventilators shall not exceed 0.49 kPa (5 cm H_2O) at a flow of 50 LPM when spirometer or breathing attachments, or both, as specified by the manufacturer are used. (See also X2.3.6.)

5.9.2 *Constant Flow Infant Ventilators*—When tested according to the methods described in 6.9, positive end-expiratory pressure inherent in the design of constant flow infant ventilators shall not exceed 0.29 kPa (3 cm H_2O) at a constant machine flow of 20 L/min, 60 breaths per minute, 1:1 I:E ratio, $R = 4.9$ kPa/L/s (50 cm H_2O/L/s), and $C = 3$ mL/0.29 kPa (3 mL/cm H_2O). If expiratory assistance is necessary to comply with this requirement, it shall be so stated. (See also Appendix X2.6.)

5.10 *Fittings Connecting Adult Ventilator, Patient, and Spirometer*—The patient connection port shall be a 15⁄22 mm conical coaxial fitting in accordance with Specification F 1054.

5.10.1 For flow direction-sensitive devices, the direction of flow shall be permanently marked on the connector, and the connector should be designed so that it cannot be installed in the reverse direction. (See also X2.3.7.1.)

5.10.2 If a connector for a bag for manual ventilation is provided on the ventilator, it shall face downward and shall be situated away from the connectors for the patient breathing tubes. The bag mount should provide a secure connection. The term *bag* shall be marked on the connector. (See also X2.3.7.2.)

5.10.3 If there is a separate outlet for the spirometer on the breathing tubes or the machine, the gas outlet leading to the spirometer should be a 30-mm male cone in accordance with ISO 5356. In any case, it shall not be compatible with a 15, 19, or 22-mm fitting. (See also 6.10.3 and X2.3.7.3.)

5.10.4 If an ambient air inlet is fitted to the ventilator, it shall not be a 19, 22, 15, or 30-mm male cone and shall be clearly marked as *air inlet*. (See also 6.10.4 and X2.3.7.4.)

5.10.5 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 when tested as outlined in 6.10.5 it cannot easily be connected to either 22, 15, or 30-mm cones or sockets, or to 22-mm internal diameter tubing. (See also X2.3.7.5.)

5.11 *Alarm Systems*:

5.11.1 *General*—The alarm system shall provide a warning signal(s) if the function of the ventilator deviates from the control settings by more than preset levels as specified in the appropriate sections of this draft standard or in the instructions for use. Signal(s) shall be appropriate to the nature of the response expected from the operator. In general, if an immediate response is required of the operator, an audible and a visual signal shall be provided. If a less than immediate response is required, a lower priority visible signal may be used. This may be coupled with an audible signal so long as it is distinctly different from any audible signal requiring immediate operator response. Monitoring functions (for example, *ventilator on*) should not have coupled audible and visual alarms. Alarm signal outputs shall be provided.

5.11.2 *Testing of Alarm Function*—A means shall be provided to test the audible and visual annunciation of all alarms.

5.11.3 *Required Alarms*—The following alarms shall be provided on all critical care ventilators:

5.11.3.1 *Loss of Main Power Supply*—A loss of main power alarm shall be provided, and when tested as described in 6.11, shall have a duration of at least two min at a constant sound pressure level. A means shall be provided for silencing this alarm following disconnection from the main power supply. This means of silencing the alarm shall not be remote from the ventilator, and the alarm silencing mechanism shall automatically reset when the main power is restored. (See also X2.3.8.1.)

5.11.3.2 *Breathing Circuit Integrity*—When tested in accordance with the manufacturer's instructions, the breathing circuit integrity alarm(s) shall respond within 15 s or one complex cycle of the ventilator if the breathing circuit is compromised by disconnection or leakage. This alarm shall be activated within ±20 % of the control setting. The manufacturer shall disclose a method for complying with this requirement. A means shall be provided to silence the audible portion of this alarm. This period of audible alarm silencing shall not exceed 2 min. (During this period of time the visible alarm shall still be activated.) Means should be provided to remote the audible disconnect alarm's silencing mechanism a minimum of 4 ft and a maximum of 8 ft from the ventilator control panel. Monitoring of breathing circuit integrity may be accomplished utilizing any of several different technologies. The manufacturer shall disclose how breathing circuit integrity is monitored. (See also X2.3.8.2.)

5.11.3.3 *High Airway Pressure*—Alarms for high airway pressure shall be provided. This alarm may either sound immediately when the high alarm pressure limit set point is reached, or at the end of 3 s (see 5.6.3). The audible portion of this alarm may either automatically reset, or may require manual resetting. However, the visual portion of this alarm shall only be provided with a manual resetting mechanism. (See also X2.3.8.3.)

5.11.4 *Alarm Battery Power Supplies*—If any alarm incorporates a battery power supply, the battery should be of a type readily obtainable and the system shall include a means whereby the use may, with a simple operation, determine that the battery needs to be replaced or recharged.

5.11.5 *Alarm Operating Instructions* (see 7.2 and 8.3).

5.12 *Humidification (where applicable)*—Humidifiers that are integral to or recommended for use with critical care ventilators shall comply with the requirements of ANSI Z-79.9, 1978.

5.13 *Electromagnetic Interference*—MDS-201 may be used as a guide during the design and development of mechanical ventilators. This material was developed following a study of specific hospital environments in several areas of the United States (see section 2.4).

5.14 *Kinking and Occlusion of Breathing Tubing*:

5.14.1 *Kinking*—When preconditioned as described in 6.12.1, and tested as outlined in 6.12.2, tubing shall be sufficiently rigid (for example, wire guarded or wound) or so constructed (for example, corrugated) as to minimize the possibility of kinking. (See also X2.3.9.1.)

5.14.2 *Occlusion*—When preconditioned as described in 6.12.1, and tested as outlined in 6.12.3, the tubing shall be designed so as to prevent occlusion when a 2.5-kg weight bears on a 5-cm segment in the middle of a 1 m length of tubing. (See also X2.3.9.2.)

5.15 *Measurement of Oxygen Concentration*—The manufacturer shall either provide an oxygen monitor with the ventilator or shall recommend a monitor for use with the ventilator. If no oxygen monitor is provided with the ventilator, the manufacturer shall make provisions to facilitate the mounting of an oxygen analyzer on the ventilator and for the connection of an oxygen analyzer in the ventilator circuit.

5.15.1 If provided with the ventilator or recommended for use with a ventilator, the oxygen analyzer shall comply with the requirements of ANSI Z-79.10, 1979.

6. Test Methods

6.1 *General*—Measurements of pressure, flow, and volume shall be made as shown in Figs. 1 and 2, and shall be accurate to within ±2.5 % of the reading plus ±2.5 % of the full scale reading. The reading accuracy of the recording device shall be maintained at frequencies up to 10 Hz. Ambient conditions shall be recorded and converted to NTPD (20°C, 760 mm Hg, 0 % relative humidity). Dry air shall be used as the test gas unless specified otherwise in the individual test method.

6.2 *Test Equipment*:

6.2.1 *Lung Models*—Lung models are designed to provide impedances to the ventilator output that simulate both normal and diseased lung states. The impedances to ventilator output are lung elastance and airflow resistance, which can be simulated in the lung models by a compliance and a resistance connected in series (see Figs. 1 and 2). The various combinations of compliances and resistances used in the test procedures are given in Table 2. The passive lung model in Fig. 2 is intended for the testing of the controlled ventilation mode (see Appendix X1) only. Fig. 3 illustrates an active test system for the testing of IMV modes and other ventilator functions. These lung models do not preclude the development of different or more sophisticated lung models with the same ranges of compliance and linear or nonlinear resistances. If nonlinear resistances are used, their characteristics must be specified.

6.2.2 *Compliances*—The required compliances are given in Table 4. These compliances shall include the compliances of all

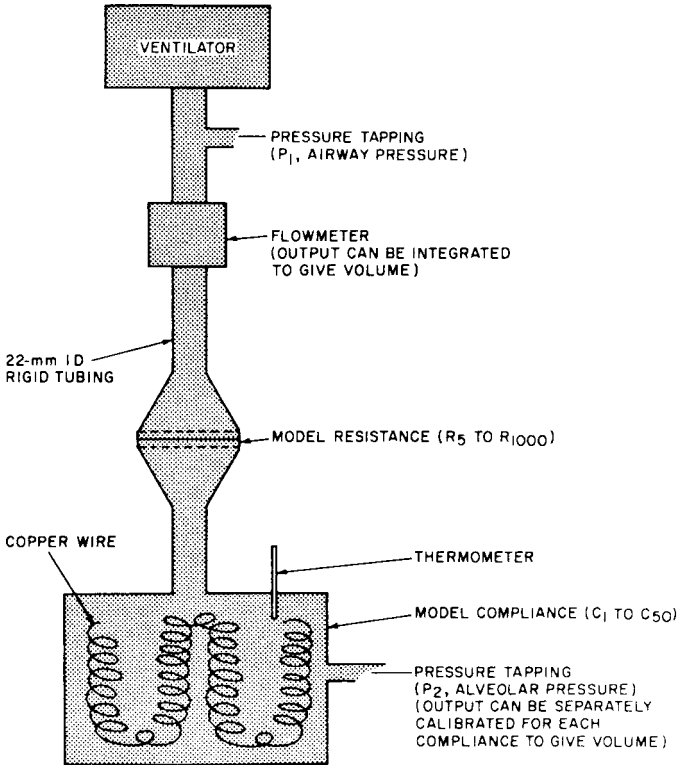

FIG. 2 Representative Passive Lung Model

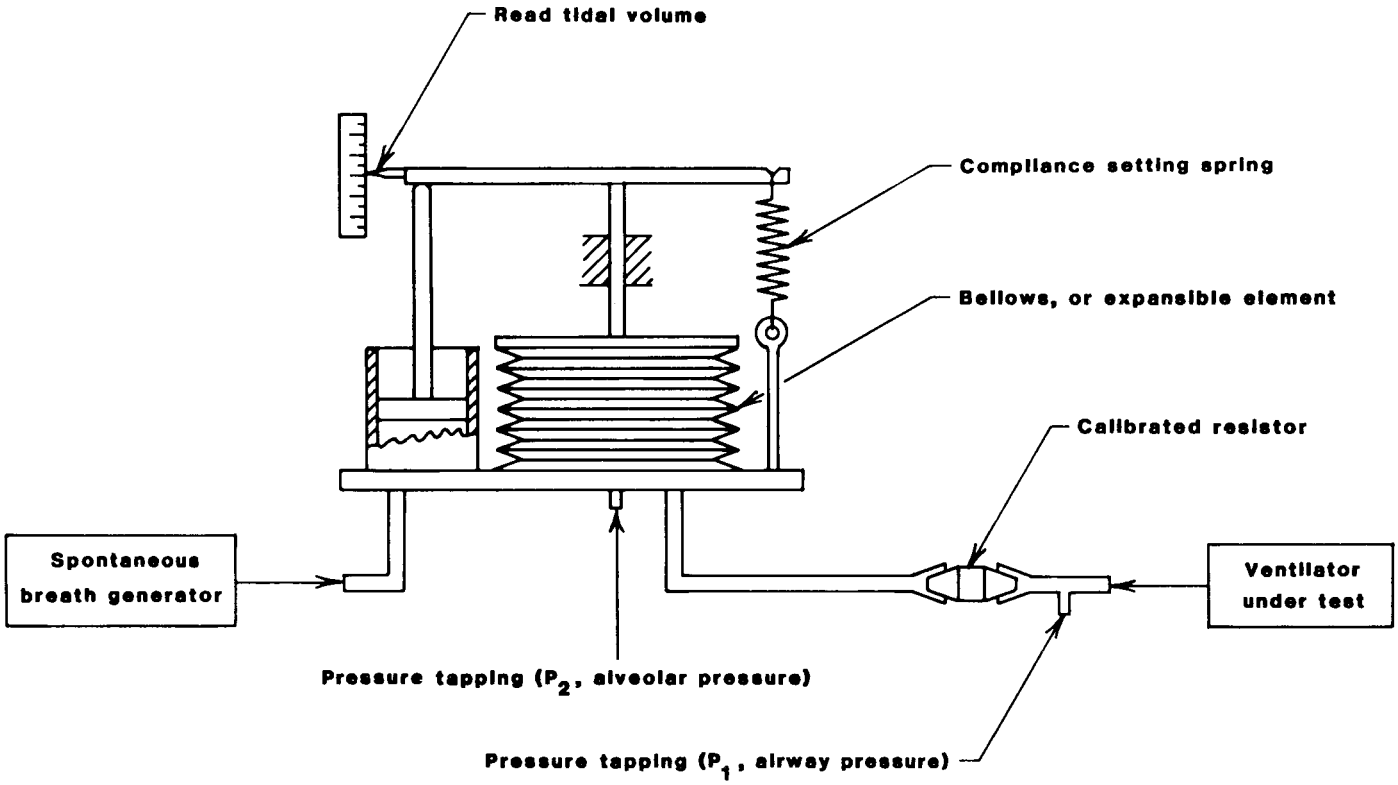

FIG. 3 Representative Active Lung Model

TABLE 4 Required Compliances

Compliance	Value	
	mL/kPa	(mL/cm H_2O)
*C*50	510	(50)
*C*20	204	(20)
*C*10	102	(10)
*C*3	30.6	(3)
*C*1	10.2	(1)

components of the lung model system. The volume-pressure characteristics of the model compliances including connections shall be determined as in 6.1 and shall be within ±5 % of the required compliance values shown in Table 4 throughout a range of inspiratory gage pressures from − 1.96 to + 9.80 kPa (−20 to + 100 cm H_2O) and throughout a range of inspiratory phase times as specified by the manufacturer.

6.2.3 *Resistances*—The required resistances are given in Tables 5 and 6. These values relate to dry air at ambient pressure and at 20*C*. They include the resistance of the flow measuring device.

6.3 *Test Procedures—General*—This section includes one test for endurance and two tests for performance. Perform the endurance test first and the performance tests immediately thereafter. Routine maintenance as specified by the manufacturer may be carried out during these tests, but include details of all such maintenance in the test report.

TABLE 5 Required Resistances (Linear)

Resistance	Value in Flow Range		Range of Airflow (L/s)
	±20 % kPa/L/s	(cm H_2O/L/s)	
*R*5	0.49	(5)	0 to 2.0
*R*20	1.96	(20)	0 to 1.0
*R*50	4.90	(50)	0 to 0.5
*R*200	19.6	(200)	0 to 0.1
*R*500	49.0	(500)	0 to 0.075
*R*1000	98.1	(1000)	0 to 0.05

TABLE 6 Required Resistances (Parabolic)[A]

$\Delta P = K \dot{V}^2$ cm H_2O ($\dot{V}$ = L/s)					
Parabolic Resistor	K ± 10 %	Pressure Drop		@	Flow (L/s)
		kPa	(cm H_2O)		
R_p5	2.70	0.26	(2.70)	@	1.0
		1.06	(10.80)	@	2.0
R_p20	17.61	0.43	(4.40)	@	0.5
		1.73	(17.60)	@	1.0
R_p50	108.70	0.67	(6.79)	@	0.25
		2.67	(27.20)	@	0.5
R_p200	2440.00	0.60	(6.10)	@	0.05
		2.39	(24.40)	@	0.1

[A] Linear and parabolic resistances may be used interchangeably. Representative test lungs and the appropriate parabolic resistances available from Michigan Instruments, Inc., 6300 28th Street, SE, Grand Rapids, MI 49506; BioTek Instruments, Highland Park, Winooski, VT 05404; or Hyco-Anlas Ganthier, S.A., Bureau a Paris, 13, rue Guyton-de-Morveau, 75013 Paris, France, or their equivalents have been found satisfactory for this purpose. Resistances will have different performance values, depending on the manufacturer and the individual resistor configuration. The ventilator manufacturer shall supply data on the resistors used during testing upon request.

6.3.1 *Endurance Test*—Make the inspiratory/expiratory phase time ratio as close to 1:2 as possible, and run the ventilator for 2000 h against the appropriate condition shown in Table 1. If provided, run IMV or SIMV functions at ten breaths per minute, with an additional ten breaths being provided by the machine. Otherwise the frequency of ventilation shall be as listed in Table 1.

6.3.2 *Wave-form Performance Test*—At the beginning of the

test, adjust the ventilator controls to obtain the desired frequency and tidal volume at an inspiratory/expiratory ratio that is as close to 1:2 as possible. Record the ventilator control positions required to obtain these settings. If it is necessary to reset the ventilator controls to match the ventilator to the new set of conditions, note this in the results. In such an event, obtain records before and after resetting the ventilator controls. Always reset the ventilator to the standard conditions appropriate to a given tidal volume (as indicated in Table 2), before each subsequent test. Perform all tests without a sub-ambient phase unless this is an integral feature of the ventilator mechanism.

6.3.2.1 Record the following traces during the tests and display in the order shown:

(*a*) Pressure at the patient end of the ventilator tubes, P_1(see Fig. 1),

(*b*) Pressure in the chamber (equals alveolar pressure P_2, see Fig. 1),

(*c*) Flow at ventilator output, and

(*d*) Volume.

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

6.3.2.2 Reproduce the scale and clarity of the records such that a change of ±2.5 % of the peak reading can be detected easily. Inscribe all records with the appropriate scales, time base, and details of the test. Include the following details:

(*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 (for example, humidifier, spirometer, or water traps) were included in the part of the circuit which is pressurized during inspiration. If such apparatus is included, the type and position shall be specified. If a humidifier is included it shall be filled to the "full" water level with a relatively noncompressible substance. If this is not practicable, the humidifier shall be replaced with an equivalent compliance and resistance.

(*c*) A listing of all settings of controls, as applicable.

(*d*) Any other relevant information (for example, source and pressure of driving gas, use of special ventilator circuits, or type of humidifier).

6.4 Inspect the sterilization or disinfection instructions as supplied by the manufacturer.

6.5 Vary the gas supply pressure and electrical supply voltage independently and perform the tests in 6.3.2 under the worst possible conditions. That is, Test No. 4 for adults, children, and infants, respectively. These tests are to be conducted at both the upper and lower extremes as indicated in 5.5.1 and 5.5.2.

6.6 *Accuracy of Calibrated Controls, Indicators, and Pressure Relief Devices*:

6.6.1 Connect the device to a calibrated test apparatus (generally with an accuracy five times greater than the required accuracy), and test the accuracy of the controls over the entire range.

6.6.2 Either set the maximum limited pressure ($P_{L\,max}$) control above the test point for the $P_{w\,max}$ control or temporarily inactivate the $P_{L\,max}$ control. Occlude the ventilator output to the patient system, and verify that the $P_{w\,max}$ control functions within the limits specified in 5.6.1.1 when the ventilator is configured in each of the test modes listed below:

6.6.2.1 Minimum working pressure, minimum rate, and tidal volume,

6.6.2.2 Minimum working pressure, maximum rate, and tidal volume, and

6.6.2.3 Maximum working pressure, maximum rate, and tidal volume.

6.6.3 The tester shall configure the ventilator for use as recommended by the manufacturer. The humidifier shall be filled to the recommended level. Pressure measurements shall be made at the patient connection port using an electronic transducer and the pressure waves shall be recorded using a strip chart recorder. Set the pressure relief controls at 4.90, 6.86, and 9.80 kPa (50, 70, and 100 cm H_2O) or the highest possible setting. If an inspiratory time control is provided, it should be set to the highest setting. Activate the ventilator while totally occluding the patient connection port. Record the pressure and from the recordings determine that the ventilator's pressure reducing mechanism activated within 3 s of reaching the maximum limiting pressure.

6.6.4 Measure the time for at least 100 breaths after a steady state is reached.

6.7 *Spirometers and Other Devices for Indication of Ventilator Function Integral to the Ventilator*:

6.7.1 Measure gas flows with a calibrated flow meter accurate to within 5 % of the reading. Measure the pressure drop with a water column or equivalent accurate to 5 % of the reading. Volume may be calculated by integrating flow over one cycle, or by volumetric measuring device.

6.7.2 Test the spirometer in an ambient environment with the temperature of 20 to 24°C. Set ventilator humidifiers on the maximum output and run the ventilator in a steady state for 8 h with a reservoir bag of at least 1.5 L volume attached to the ventilator outlet. Determine that accuracy requirements of 5.7.2 have been met at the end of the 8-h test.

6.8 *Characteristics of Delivered Gas*—Measure delivered oxygen concentrations at the allowable extremes of pipeline pressures, that is, at 41.2 psig and 66 psig. Also measure concentrations at the extremes of resistance and compliance and before and after all ventilator changes during the *Endurance and Wave Form Performance Tests.* Collect gases from ten breaths and record the reading when the analyzer has reached a steady state.

6.9 *Expiratory Resistance*:

6.9.1 *Adult*:

6.9.1.1 Generate 50 L/min of gas flow through the patient breathing system with no PEEP.

6.9.1.2 Measure the pressure drop from the patient connection port to ambient. Pressure shall not exceed 0.49 kPa (5 cm H_2O).

6.9.2 *Infant*:

6.9.2.1 Generate 20 L/min of gas flow through the patient breathing system with no PEEP.

6.9.2.2 Connect a simulated patient with a resistance of 4.9 kPa/L/s (50 cm H_2O/L/s) and a compliance of 30 mL/kPa (3 mL/cm H_2O) to the circuit.

6.9.2.3 Cycle the ventilator at 60 breaths per minute, 1:1 I:E ratio.

6.9.2.4 Measure the pressure drop from the patient connection to ambient. Pressure shall not exceed 0.29 kPa (3 cm H_2O).

6.10 *Fittings Connecting Adult Ventilator, Patient, and Spirometer*:

6.10.1 Visually inspect the connector and attempt to change connector direction.

6.10.2 Inspect the ventilator in its normal configuration as supplied by the manufacturer.

6.10.3 Attempt to fit a 15, 19, or 22-mm fitting into the spirometer outlet.

6.10.4 Attempt to connect the fittings listed in 5.10.4 to the air inlet. Check the marking to assure that, if provided, the inlet is marked as required in 5.10.4.

6.10.5 Attempt to connect the fittings listed in 5.10.5 to the expired gas outlet. The test is passed if none of the connectors will provide a secure fit.

6.11 *Alarm Systems*—Connect the power supply to the ventilator and run according to the manufacturer's instructions. Then disconnect the ventilator from the main power supply, and determine that the alarm sounds, and maintains a constant sound pressure level ± 3 dBa, for at least 2 min. Repeat the test as outlined above, and silence the loss of main power supply alarm. Reconnect the ventilator main power immediately after silencing the alarm, and then disconnect the ventilator from the main power supply again and determine that the alarm silencing mechanism has reset.

6.12 *Kinking and Occlusion of Breathing Tubing*:

6.12.1 *Preconditioning of Tubing*—Condition all tubing at 42°C and 100 % relative humidity for 1 h prior to testing as outlined below.

6.12.2 *Kinking*—Suspend a length of tubing at least 1 m long over a metal cylinder with a 2.5-cm diameter, all at room temperature. Hang a 0.5-Kg weight on each end, and establish a steady 75 L/min flow (25 L/min for tubing smaller than 22 mm inside diameter which is intended for use with infants and neonates) through the tubing and measure the pressure above atmospheric pressure (Δ P) necessary to drive the flow through the tubing. The test is passed if Δ P is less than 0.98 kPa (10 cm H_2O).

6.12.3 Place a 2.5-Kg weight on a 5-cm segment in the middle of a 1-m length of tubing. Establish a steady 75 L/min flow (25 L/min for tubing smaller than 22 mm inside diameter which is intended for use with infants and neonates) through the tubing and measure the pressure above atmospheric pressure (Δ P) necessary to drive the flow through the tubing. The test is passed if Δ P is less than 0.98 kPa (10 cm H_2O).

7. Warnings and Markings

7.1 If an ambient air inlet is provided, it shall be clearly marked as *air inlet*.

7.2 *Alarm Operating Instructions*—The manufacturer shall provide instructions for testing and setting of the alarms. These instructions (abbreviated if necessary) shall be either permanently marked on or attached to the ventilator or ventilator alarm. (See also X2.3.10.)

8. Operation and Maintenance Manual

8.1 *Apparatus Internal Compliance*—The manufacturer shall disclose the internal compliance of the ventilator and shall provide, upon request, the test methods used to determine the derived values. Manufacturers of ventilator tubing that recommend the use of their tubing with several ventilators, or who do not manufacture ventilators, shall provide the data on tubing compliance on the labeling of their product. (See also X2.3.11.1.)

8.2 *Measurement of Oxygen Concentration*—The manufacturer shall either provide an oxygen monitor with the ventilator or shall recommend a monitor for use with the ventilator.

8.3 *Alarm Operating Instructions*—The manufacturer shall provide instructions for testing and setting of the alarms. These instructions (abbreviated if necessary) shall be either permanently marked on or attached to the ventilator or ventilator alarm. (See also X2.3.11.2.)

8.4 *Assisted Ventilation, or Synchronous Intermittent Mandatory Ventilation*—If the ventilator incorporates a mode of operation where the patient effort initiates a mechanical (for example, assisted, SIMV) breath, then the manufacturer shall disclose the following parameters as applicable: inspiratory triggering pressure, differential inspiratory triggering pressure, inspiratory triggering flow, inspiratory triggering volume, and inspiratory triggering response time.

8.4.1 The manufacturer shall disclose the conditions under which this information was obtained. The manufacturer shall also disclose the recommended patient breathing system (and its characteristics) used in these tests. (See also X2.3.11.3.)

APPENDIXES

(Nonmandatory Information)

X1. CLASSIFICATION AND TYPES OF BREATHING MACHINES

X1.1 *Lung Ventilator*—An automatic device that is connected to the patient's airway and is designed to augment or provide for the patient's ventilation.

X1.1.1 There are four types of lung ventilators:

X1.1.1.1 *Controller*—A device, or mode of operation of a device, that inflates the patient's lungs independently of the patient's inspiratory effort.

X1.1.1.2 *Assister*—A device designed to augment the patient's breathing synchronously with his inspiratory effort.

X1.1.1.3 *Assister-Controller*—An apparatus that is designed to function either as an assister or a controller, and that may, in default of the patient's inspiratory effort, automatically function as a controller.

X1.1.1.4 *Assister-Controller—Spontaneous Breathing*—Those devices that incorporate various modes of operation which allow the patient to breath spontaneously (1) at or above ambient pressure levels or, (2) with or without supplemental mandatory positive pressure breaths.

X1.2 *Resuscitator*—A 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: (1) operator-powdered, (2) gas-powered, or (3) electrically powered. Auxiliary apparatus and methods for use in emergency situations are classified as follows: (1) manual resuscitation, or (2) exhaled air (mouth-to-mouth or mouth-to-nose) resuscitation.

X1.3 *Respiratory Therapy Ventilator*—A device that is connected to the patient's airway and is primarily designed to deliver an aerosol along with augmented ventilation.

X1.4 *External Body Ventilator*—A machine designed to augment or replace the patient's ventilation by means of the application of intermittent or alternating pressures to the trunk.

X1.4.1 External body ventilators are classified as follows:

X1.4.1.1 *Tank or cabinet*—An external body ventilator in which the patient is enclosed to his neck in a rigid airtight chamber.

X1.4.1.2 *Cuirass*—An external body ventilator in which all or part of the patient's trunk is in an airtight enclosure, forming or incorporating a rigid frame.

X1.4.1.3 *Belt*—An external pneumatic body ventilator consisting of a flexible wrapper which contains an airtight bag wrapped around the patient's abdomen. When inflated, the bag produces forced expiration, followed by inspiration upon deflation.

X1.5 *Rocking Apparatus*—A device used to produce or aid ventilation by rocking the patient and using the weight of the abdominal contents to move the diaphgram.

X1.6 *Electrostimulator*—Apparatus in which activity of the respiratory muscles is induced by electric impulses acting on the corresponding nerves or muscles.

X1.7 *High Frequency Ventilators*—Those ventilators that employ a frequency of greater than 2.5 Hz.

X1.8 *Characteristics of Lung Ventilators*—An outline of the modes of operation of lung ventilators is given in 2.1.1 through 2.1.9.[7]

X1.8.1 *Modes of Operation During the Inspiratory or Expiratory Phase*:

X1.8.1.1 Flow Generator
X1.8.1.2 Pressure Generator
X1.8.1.3 Combined Flow and Pressure Generator
X1.8.2 *Volume Control*:
X1.8.2.1 Pressure Preset
X1.8.2.2 Volume Preset
(*a*) Tidal
(*b*) Minute
X1.8.2.3 Combined
X1.8.3 *Cycling Control*:
X1.8.3.1 *Inspiration to Expiration*
(*a*) Volume
(*b*) Pressure
(*c*) Time
(*d*) Flow
(*e*) Combined
(*f*) Manual Override
(*g*) Other
X1.8.3.2 *Expiration to Inspiration*:
(*a*) Pressure
(*b*) Time
(*c*) Flow
(*d*) Combined
(*e*) Patient
(*f*) Manual Override
(*g*) Other
X1.8.3.3 *Types of Safety Limits*:
(*a*) Volume
(*b*) Pressure
(*c*) Time
(*d*) Other
X1.8.3.4 *Types of Pressure Patterns*:
(*a*) Positive-ambient
(*b*) Positive-subambient
(*c*) Positive-positive
X1.8.3.5 *Source of Power*:
(*a*) Pneumatic
(*b*) Electric

[7] See also Mushin, W., Rendell-Baker, L., Thompson, P. W., and Mapleson, W. W., *Automatic Ventilation of the Lungs*, Oxford, England. Blackwell, 1980. (Distributed in the U.S.A. by C.V. Mosby, St. Louis, MO.)

(*c*) Other
X1.8.3.6 *Power Transmission*:
(*a*) Direct
(*b*) Indirect
X1.8.3.7 *Source of Inspired Gas*:
(*a*) Driving gas
(*b*) Fresh gas
(*c*) Mixed
X1.8.3.8 *Type of Control*:
(*a*) Pneumatic
(*b*) Electronic
(*c*) Mechanical
(*d*) Combined

X2. RATIONALE

X2.1 Scope

X2.1.1 The scope of this specification is limited to critical care ventilators intended for use in hospitals because the operating environment outside the hospital is considerably different from that found in most hospitals. It was the opinion of the subcommittee that applications such as transport ventilation and ventilation in the home should be addressed in a separate standard. As well, ventilators intended for use during anesthesia have been addressed in another standard because the conditions of operation and the level of supervision present differ greatly from that found in the critical care environment. It was the opinion of the subcommittee that high frequency or jet ventilation had not as yet reached a point where a standard should be developed for devices used to provide this type of patient support.

X2.2 Although ideally all components in the breathing circuit should be sterilizable, certain types of pressure measuring devices cannot be sterilized with currently available methods without causing damage to the device. The same holds true for certain types of oxygen analyzer sensors. These devices should be capable of being disinfected with a high-level disinfectant[8] or should be isolated from other portions of the patient breathing circuit.

X2.3 *Performance Requirements:*

X2.3.1 *Volume Performance Test*—This test is designed to demonstrate that the ventilator can provide adequate ventilation under relatively severe circumstances, that is, low compliance and high resistance. However, the values given in Table 6 are not considered the worst case. These values are instead considered to be median values.

X2.3.2 *Power Sources*—Fluctuations within the ranges specified in 5.1 are known to occur in both electrical and pneumatic power supply systems in hospitals. The causes for such variation may be outside the control of the ventilator user. For example, a decrease in the power supplied by the local electric utility, or the variation that may result from demand for power caused by equipment such as elevator motors and air-handling apparatus within the hospital will cause these types of fluctuations. The periodic testing of emergency generators may also create this type of variation. Pneumatic power sources may show transient variations as well. The filling of liquid oxygen bulk reservoirs and changes in pressure switch settings on compressed air reservoirs are examples of functional variations that could cause the supply pressure to change. The ranges specified will also accommodate the fluctuations that would be anticipated in adapting equipment to European gas piping systems.

X2.3.2.1 The fittings specified in 5.5.2.1 vary from those presently supplied with critical care ventilators. Nut and gland fittings have been specified for the ventilator so that hoses supplying gas to the ventilator may be checked for the correct fittings by threading the connectors on both ends of the hose together. The subcommittee is aware of problems caused by the fitting of the wrong connector to one end of a hose during repair, and by specifying the nut and gland fitting on the ventilator it has provided a means for testing hoses for the appropriate fitting.

X2.3.3 *Accuracy of Calibrated Controls, Indicators, and Pressure Relief Devices*

X2.3.3.1 These control limits were the minimum that the subcommittee felt were acceptable for maintaining the safety of the ventilator and for maintaining operator confidence in ventilator settings.

X2.3.3.2 Maximum working pressure required for adequate patient ventilation will vary with changes in resistance and compliance. If provided, $P_{w\,max}$ controls provide an additional means for assuring that an injurious overpressure incident does not occur.

X2.3.3.3 The subcommittee felt that the requirement as written would reduce the possibility of barotrauma and would also reduce complications resulting from decreased cardiac output secondary to increased intrathoracic pressure, caused when ventilator pressure relief mechanisms *plateaued* in pressure rather than *dumping* the tidal volume to ambient. The subcommittee also felt for this requirement to be truly effective that a combined test should be performed to measure the performance of the limited pressure relief device during the tubing crush and kink tests.

X2.3.3.4 Limits specified in the requirements in 5.6.4 and 5.6.4.1 encompass the range of accuracy that the members of the subcommittee felt were necessary and appropriate for clinical performance and that were achievable within currently available technology.

X2.3.4 *Spirometers and Other Devices for Indication of Ventilator Function Integral to the Ventilator*

X2.3.4.1 The accuracy specified in this requirement will allow the clinician to adjust the ventilator tidal volume according to the physiologic dead space and carbon dioxide

[8] See Garner, J. S., "CDC Guidelines for the Prevention and Control of Nosocomial Infections-Guideline for Handwashing and Hospital Environmental Control," *American Journal of Infection Control*, 1986, Section 2, pp. 116–129.

production of the patient or for other causes.

X2.3.4.2 Visual indication that the patient is being adequately ventilated is essential feedback provided to the operator by the spirometer. Partial reduction of flow to the spirometer may cause erroneous indication of ventilator malfunction, and complete occlusion of flow to the spirometer will have the same effect. The latter may render the unit inoperative for some period of time. Condensate formation due to temperature variations in the patient system and occlusion of the tubing by patient secretions are known to be potential causes for this type of malfunction. These potential problems should be compensated for in the design of the spirometer and the spirometer/ventilator interface.

X2.3.5 *Characteristics of Delivered Gas*—Maintaining the accuracy of delivered oxygen concentrations throughout the range of ventilator performance is important in order to allow for the rapid and often frequent adjustment of the ventilator without significant variation in the oxygen concentration. The range of accuracy for oxygen analyzers in ANSI Z-79.10[3] is specified as ±3 % oxygen. Limiting the fluctuation to this level at any given ventilator setting is technologically possible, and will minimize the time spent making control adjustments. This should enhance operator confidence in the accuracy of control settings provided on the gas mixing device.

X2.3.6 *Expiratory Resistance:*

X2.3.6.1 *Adult*—Although expiratory resistances of less than 5 cm H_2O at 50 L/min are desirable, the subcommittee realizes that such values may not be uniformly achievable. Patient system configurations, tubing length, connector sizes, and gas flow through the system are all factors that may combine to raise end-expiratory pressure to the 0.49 kPa (5 cm H_2O) maximum under certain ventilator settings. End-expiratory resistance above the 0.49 kPa (5 cm H_2O) level are not acceptable because of the adverse effect they may have on the patient's respiratory pattern or cardiovascular flow.

X2.3.6.2 *Infant*—Positive end-expiratory pressure is inherent in the design of constant flow infant ventilators, and is caused by a combination of three factors: ventilator setting, patient circuit components, and the patient's condition. Ventilator inherent PEEP will increase because of an increase in either the machine flow, the resistance of the patient circuit, or patient expiratory flow. The level of positive end-expiratory pressure will also increase because of a decrease in the expiratory phase time. The increase in positive end-expiratory pressure may be nonlinear with respect to a linear increase in machine flow.

X2.3.7 *Fittings Connecting Adult Ventilator, Patient, and Spirometer*

X2.3.7.1 Flow-direction-sensitive devices such as one-way valves or humidifiers may be caused to malfunction by inadvertent connection in the reverse manner, and it is also possible for injury to the patient to occur if flows of gas are misdirected or humidifier contents are emptied into the breathing circuit as a result of such a misconnection.

X2.3.7.2 The positioning of the connector for a bag mount, if provided, is important so that it is not mistaken for a connector to a patient breathing tube. The marking of the connector is important for the same reason.

X2.3.7.3 This requirement is intended to minimize the possibility of inappropriate connection of the ventilator breathing circuit tubing to the spirometer outlet.

X2.3.7.4 The sizes of fittings outlined in 5.10.4 are commonly used for other types of apparatus on ventilators and should be prevented from being connected to the air inlet. Marking the inlet will also minimize the possibility of this occurring.

X2.3.7.5 The sizes of fittings listed in 5.10.5 are commonly used for other purposes on mechanical ventilators and connection of these tubings of the expired gas port could result in ventilator malfunction.

X2.3.8 *Alarm Systems*

X2.3.8.1 The subcommittee felt that a loss of main power supply alarm with a duration of 2 min was adequate to allow personnel to reach the ventilator and determine the cause of the alarm. The subcommittee also felt that a means for silencing this alarm when main power was disconnected was important in order to minimize the number of spurious alarm signals in the critical care environment. If such a means for silencing an alarm was not provided, every time the ventilator was disconnected to be moved from the patient area, the loss of main power alarm would sound for 2 min, distracting personnel. However, the subcommittee also felt that the means of silencing the loss of main power alarm should not be remote from the ventilator proper, and that when the alarm sounded the operator should be forced to walk to the ventilator to determine the cause of the alarm and correct the situation.

X2.3.8.2 Because breathing circuit disconnection can result in serious injury or death, the alarm used to indicate this event should be of the highest priority. Alarm response within 15 s or one ventilator cycle will allow for appropriate alarm setting when using IMV modes with slow ventilatory rates. The audible alarm should not be capable of being silenced for longer than 2 min because disconnection for longer than this period without an alarm could result in serious patient injury. Activation of the visual alarm during this 2 min audible delay will provide indication that the alarm is still functioning. In many clinical environments it is not possible to position the mechanical ventilator so that the alarm can be silenced from the operator's work position. As well, it may be necessary to silence the alarm for longer than 2 min (repeated activation of the delay) while wearing sterile gloves. Both of these problems have led to disconnect alarms being shut off. The failure to turn the alarm back on and a subsequent disconnection has been reported to have caused injuries and deaths. If an optional means for remoting the alarm silencing mechanism is provided, the user can then determine when this may be necessary, given the clinical environment where the ventilator is to be applied. Because of the various technologies available to provide this type of alarm function, no specification of a particular type of alarm has been made in this draft. The manufacturer should provide the user with a detailed explanation of how this alarm function is accomplished.

X2.3.8.3 Alarms for high airway pressure are necessary to indicate potentially injurious conditions that may be the result of either ventilator malfunction or change in patient pathophysiology. Often these alarms occur intermittently and the

condition creating the alarm will have been cleared by the time the operator reaches the bedside. For this reason, the visual signal indicating that an overpressure condition has occurred should remain for operator information. The 3-s delay is permitted in order to minimize the possibility that transient conditions of short duration will cause spurious alarm signals.

X2.3.9 *Kinking and Occlusion of Tubing*:

X2.3.9.1 It is often necessary for ventilator tubing to be placed over the top of bedrails, or through the top or doors of incubators where the tubing may be subject to kinking. The tests outlined for this requirement are intended to simulate these conditions.

X2.3.9.2 It is often necessary for ventilator tubing to be placed in areas around the patient where it may be occluded (for example, movement of the patient's head onto the tubing, etc.). Tests for requirement 5.14.2 are intended to simulate this type of occlusion.

X2.3.10 *Warnings and Markings*—The permanent marking or attachment of the instructions to the ventilator or ventilator alarm is necessary because often these devices are used where the general instruction manual is not readily available.

X2.3.11 *Operation and Maintenance Manual*:

X2.3.11.1 *Apparatus Internal Compliance*—Increasing internal compliance will (1) decrease the actual volume delivered to the patient from a *set* volume, (2) increase measured volume above the patient's actual minute volume, and (3) decrease the pressure at the patient (both proximal and lung pressures) if not compensated for by the ventilator.

X2.3.11.2 *Alarm Operating Instructions*—The permanent marking or attachment of the instructions to the ventilator or ventilator alarm is necessary because often these devices are used where the general instruction manual is not readily available.

X2.3.11.3 *Assisted Ventilation, or Synchronous Intermittent Mandatory Ventilation*—The information required in 8.4 will allow the clinician to decide whether the ventilator is appropriate for application with a particular patient population, and whether one type of ventilator may be used for several different patient groups, that is, infants and adults.