Designation: F 1246 – 91 (Reapproved 2005)

Standard Specification for Electrically Powered Home Care Ventilators, Part 1—Positive-Pressure Ventilators and Ventilator Circuits[1]

This standard is issued under the fixed designation F 1246; 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 This specification covers all electrically powered lung ventilators and ventilator circuits specifically intended for use in the home environment, and marketed after the final date of approval for this specification. Breathing circuits intended specifically for use with home care ventilators are also included within the scope of this specification. The application of critical care ventilators, anesthesia ventilators, emergency care transport ventilators, and resuscitators in the home environment is not covered by this specification. As well, this specification does not cover high frequency ventilators or external body ventilators. Part 1 of this specification addresses positive pressure ventilators, and Part 2 addresses negative pressure ventilators. (See also X1.1.1.)

1.2 The values stated in SI units are to be regarded as standard.

1.3 The following precautionary caveat pertains to the test method 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:* [2]

F 1054 Specification for Conical Fittings[3]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *breathing system*—gas pathways in direct connection with the patient through which intermittent or reciprocating gas flow occurs and into which a mixture of controlled composition may be dispensed.

3.1.2 *end-expiratory pressure*—pressure in the breathing system at the end of the expiratory phase time, prior to the beginning of the inspiratory phase time.

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

3.1.4 *home care ventilator*—ventilator intended for use in the home environment.

3.1.5 *home environment*—the patient's place of residence outside the hospital. This usually refers to the patient's home, but may include nursing homes, and personal or other means of transportation.

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

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

3.1.7.1 *Discussion*—This term has not been changed in accordance with ISO 4135, however, the text is identical. The ISO term is "maximum safety pressure."

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

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

3.1.9 *patient connection port*—that opening at the patient end of an expiratory valve unit; a *Y*-piece fitting or a unidirectional valve to which may be connected either a tracheal tube adaptor or a face mask angle piece.

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

3.1.11 *peak pressure*—the maximum gage pressure achieved during the inspiratory phase time, with all pressure limiting mechanisms functioning.

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

[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.14 on Ventilators.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Withdrawn.

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

3.1.14 *ventilator*—a device capable of automatically main taining or replacing a patient's entire pulmonary ventilation.

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

3.2 *Descriptions of Abbreviations Specific to This Standard:*

3.2.1 *C*—indicates 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*—indicates resistance to flow in units of kPa/L/s (or cm H_2O/L/s), for example, R5 = 0.5 kPa/L/s (5 cm H_2O/L/s).

NOTE 1—In the interest of brevity and clarity, all other abbreviations have been provided in parentheses following the related term in 3.1.

4. Performance Requirements

4.1 *Power Sources*:

4.1.1 *Electrical*—The ventilator shall continue to function within the manufacturer's specifications at any control setting throughout a line voltage range of 90 to 130-V a-c, rms, and throughout a frequency range of 50 to 70 Hz. Testing shall be in accordance with 6.1.1 and 6.1.2.

4.1.2 An integral battery power source shall be provided that will activate automatically when line voltage conditions fall below the range specified by the manufacturer. This power source shall maintain the performance of the ventilator within the requirements of this specification for no less than 15 min. Testing shall be in accordance with 6.1.2. (See also X1.2.2.)

4.1.2.1 Battery use event alarm (see 4.12.3).

4.1.2.2 External battery connections (if supplied) shall be for a nominal 12-V d-c supply. (See also 5.1.7.)

4.2 *Accuracy of Controls, Indicators, and Pressure Relief Devices*:

4.2.1 *Calibrated Controls and Indicators*—All calibrated controls and indicators shall be accurate to within ±10 %.

4.2.2 *Pressure Controls, (calibrated, or uncalibrated with independent indicators)*—The actual pressure at the sensing site (see 5.1.8) shall agree with the control setting within ±5 cm H_2O up to 30 cm H_2O and ±10 cm H_2O over 30 cm H_2O. Testing shall be in accordance with 6.2.1. (See also X1.2.3.)

4.2.3 *Limited Pressure Relief Controls*—If the pressure in the breathing circuit reaches a level greater than the usual operator adjusted peak pressure, a pressure reduction mechanism shall activate within 3 s. This pressure reduction mechanism shall bring the breathing circuit to a predetermined baseline pressure equal to or less than the end-expiratory pressure, but in no case shall this pressure be subatmospheric. Alternately, the limited pressure relief mechanism may 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. Testing shall be in accordance with 6.2.2. (See also X1.2.4.)

4.3 *Volume Controls*—The actual minute or tidal volume delivered at the patient outlet of the ventilator shall be within± 10 % of the control setting for calibrated controls or indicated setting for uncalibrated controls. If both a calibrated control and indicator are used, both shall meet this requirement. Testing shall be in accordance with 6.2.3, Table 1, and Annex A1. (See also X1.2.5.)

4.3.1 *Volume Stability*—The volume delivered by the ventilator shall not vary by more than ±10 % of the set tidal volume or by more than ±10 % of the expired volume when tested as outlined in 6.2.3 and Annex A1 using all power sources as supplied by the manufacturer. (See also 5.1.10.)

4.3.2 *Exhaled Volume Measurement Devices, (if provided)*—See 5.1.11.

4.3.3 *Delivered Volume*—Interdependence of controls, see 5.1.12.

4.4 *Frequency*:

4.4.1 Devices controlling ventilator frequency shall be accurate to within one breath per minute or ±10 % of the setting, whichever is greater. Testing shall be in accordance with 6.2.3 and Annex A1. (See also 5.1.14 and X1.2.7.)

4.4.2 *Stability of Control Setting*—The ventilator controls shall not vary more than ±10 % of the set value. Testing shall be in accordance with 6.2.3 and Annex A1. (See also 5.1.15 and X1.2.7.)

4.4.3 *Frequency Controls*—Interdependence of control functions, see 5.1.16.

4.5 *Accuracy of Inspiratory Time Controls Calibrated or Uncalibrated with Associated Indicators, (if provided)*—Inspiratory time controls shall be accurate to within± 10 % of the set or indicated value. Testing shall be in accordance with 6.2.4.

4.5.1 *Stability of Inspiratory Time Controls, (if provided)*—The inspiratory time controls shall be stable to ±10 % of the set value. Testing shall be in accordance with 6.2.5 and Annex A1. (See also 5.1.17 and X1.2.9.)

4.6 *Inspiratory Flow Control*:

4.6.1 *Accuracy*—If provided, peak inspiratory flow shall be accurate to within ±10 % of the set value over the range as specified by the manufacturer. Testing shall be in accordance with 6.2.3 and Annex A1. (See also 5.1.18 and X1.2.10.)

4.6.2 *Stability*—If provided, inspiratory peak flow shall be stable to within ±10 % of the set value over the range as specified by the manufacturer. Testing shall be in accordance with 6.2.3 and Annex A1. (See also 5.1.18 and X1.2.10.)

4.7 *Intermittent Deep Breath (Sigh) Volume*—If provided, this feature shall be accurate to ±10 % of the set value. Testing shall be in accordance with 6.2.6. (See also 5.1.19.)

4.8 *Human Factors Requirements*:

4.8.1 The markings of all controls and indicators shall be legible from a distance of 1 m by an operator with 20/20 vision (corrected if necessary), in an illuminance level of 215 lx.

4.8.2 All controls shall be provided with some means to minimize the possibility of inadvertent control manipulation.

4.9 *Fittings*:

TABLE 1 Lung Model and Ventilator Settings For Use in Testing

Compliance	Resistance	V^t Set, mL	Frequency Set	I:E Set
C 1	R 50	50	30	1:2
C 3	R 20	100	30	1:2
C 10	R 20	300	20	1:2
C 20	R 20	500	20	1:2
C 50	R 5	1000	15	1:2

4.9.1 Fittings provided by the ventilator manufacturer, or the breathing system manufacturer (if different).

4.9.1.1 For flow direction sensitive devices, the direction of flow shall be permanently marked on the fitting. The fitting should be designed so that it cannot be installed in the reverse direction. Testing shall be in accordance with 6.3.1. (See also X1.3.1.)

4.9.2 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 designed such that it cannot be connected with the breathing tubes. (See also X1.3.2.)

4.9.3 If an ambient air inlet is fitted to the ventilator it shall not be a 15- or 22-mm male or female cone as defined in Specification F 1054, and it shall be clearly marked as "air inlet." Testing shall be in accordance with 6.3.2. (See also X1.3.3.)

4.9.4 If an expired gas outlet (other than an outlet for a spirometer) is fitted to the machine, it shall be designed in such a way that it cannot be easily connected to either 22-, 15-, or 30-mm cones or sockets, or 22-mm internal diameter tubing. Testing shall be in accordance with 6.3.3. (See also X1.3.4.)

4.9.5 *Gas Connections for Pressurized Gases*—If the device has a threaded connector on a pressurized gas connection, it shall be gas specific and non-interchangeable. If the ventilator is capable of being independently connected to a gas piping system or cylinder, it shall have a permanently attached CGA[4] nut and gland No. 1240 (oxygen) fitting, if intended to be supplied with oxygen, or a CGA[4] nut and gland No. 1160 (air) fitting, if intended to be supplied with compressed air, or both fittings if both gases are used. Testing shall be in accordance with 6.3.4.

4.9.5.1 Small tubing connections, for example, 3- to 6-mm (⅛- to 3⁄16-in.) inside diameter (ID) tubing for powering an exhalation valve and for proximal sampling of respired gases, if provided, shall be so designed as to be non-interchangeable and the connection point shall be clearly marked as to its intended purpose. Testing shall be in accordance with 6.3.5. (See also X1.3.5.)

4.10 *Breathing Circuits, General*—In addition to the relevant requirements set forth in 4.9 and 5.1.20, breathing circuits and breathing circuit components either supplied by the manufacturer or recommended for use with a home care ventilator shall comply with the following requirements:

4.10.1 *Expiratory Resistance*—In the absence of expiratory resistors or positive end-expiratory pressure devices, the pressure drop at the patient connection port shall not exceed 5 cm H_2O at a flow of 50 L/min when spirometer or breathing attachments specified by the manufacturer, or both, are used. Testing shall be in accordance with 6.4.1. (See also X1.4.1.)

4.10.2 *Kinking and Occlusion of Tubing*:

4.10.2.1 *Kinking*—Tubing shall be sufficiently rigid (for example, wire guarded or wound) or so constructed (for example, corrugated) as to minimize the possibility of kinking. Testing shall be in accordance with 6.4.2. (See also X1.4.2.)

4.10.2.2 *Occlusion*—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. Testing shall be in accordance with 6.4.3. (See also X1.4.3.) The test is passed if ΔP is less than 10 cm H_2O.

4.10.3 All patient circuit components that are flow direction sensitive shall be permanently marked with the direction of flow and should be designed to minimize the risk of misassembly. Testing shall be in accordance with 6.4.4. (See also X1.4.4.)

4.10.4 All breathing circuits complying with the requirements as outlined in this specification should be either marked or labeled as complying with ASTM Specification F 1246.

4.11 *Provisions for Supplemental Oxygen*—The ventilator shall be capable of being provided with supplemental oxygen. (See also 5.1.21.)

4.12 *Alarms*—The following alarms shall be provided on all home care ventilators:

4.12.1 *Breathing Circuit Alarm*—The breathing circuit alarm(s) shall respond within 15 s or two complete breath cycles of the ventilator if the breathing circuit is compromised by disconnection. This alarm shall be activated within ±20 % of the control setting. A means shall be provided to silence the audible portion of this alarm. This period of audible alarm silencing shall not exceed 60 s. (During this period of time the visual alarm shall remain activated.) (See also 5.1.22 and X1.5.1.)

4.12.2 *High Airway Pressure*—Alarms for high airway pressure shall be provided. This alarm may function in any of the following three ways:

4.12.2.1 Upon reaching a preset pressure the ventilator may plateau at that pressure or "dump" to ambient pressure, and then alarm on the next breath that meets or exceeds a preset value,

4.12.2.2 The ventilator may alarm on the second breath where the preset value has been met or exceeded, or

4.12.2.3 The ventilator may alarm on each breath where the preset value has been met or exceeded. (See Fig. 1 and X1.5.2.)

4.12.3 The audible portion of this alarm may automatically reset, or may require manual resetting. However, the visual portion of this alarm shall only be provided with a manual resetting mechanism.

4.12.4 *Battery Use Event Alarm*—A coupled, audible (cancellable), and visual event alarm shall be provided to indicate when the ventilator has switched to the integral battery power source. The visual alarm shall be automatically resetting only with restoration of external power. A non-cancellable audible advisory indicator other than the event alarm shall be periodically activated throughout the duration of integral battery power supply use. A low battery audible and visual indicator shall be enabled at all times. Testing shall be in accordance with 6.5.1. (See also X1.5.3.)

4.13 *Anti-Asphyxia Valves and Negative Pressure Relief Valves*—If an anti-asphyxia valve or a negative pressure relief valve is provided separate from the spontaneous breathing inlet valve, the ventilator or breathing circuit, or both, shall provide a means for the patient to inhale ambient air in the event of ventilator failure. The cracking pressure of this valve shall be

[4] Available from Compressed Gas Association (CGA), 1725 Jefferson Davis Hwy., Suite 1004, Arlington, VA 22202-4102.

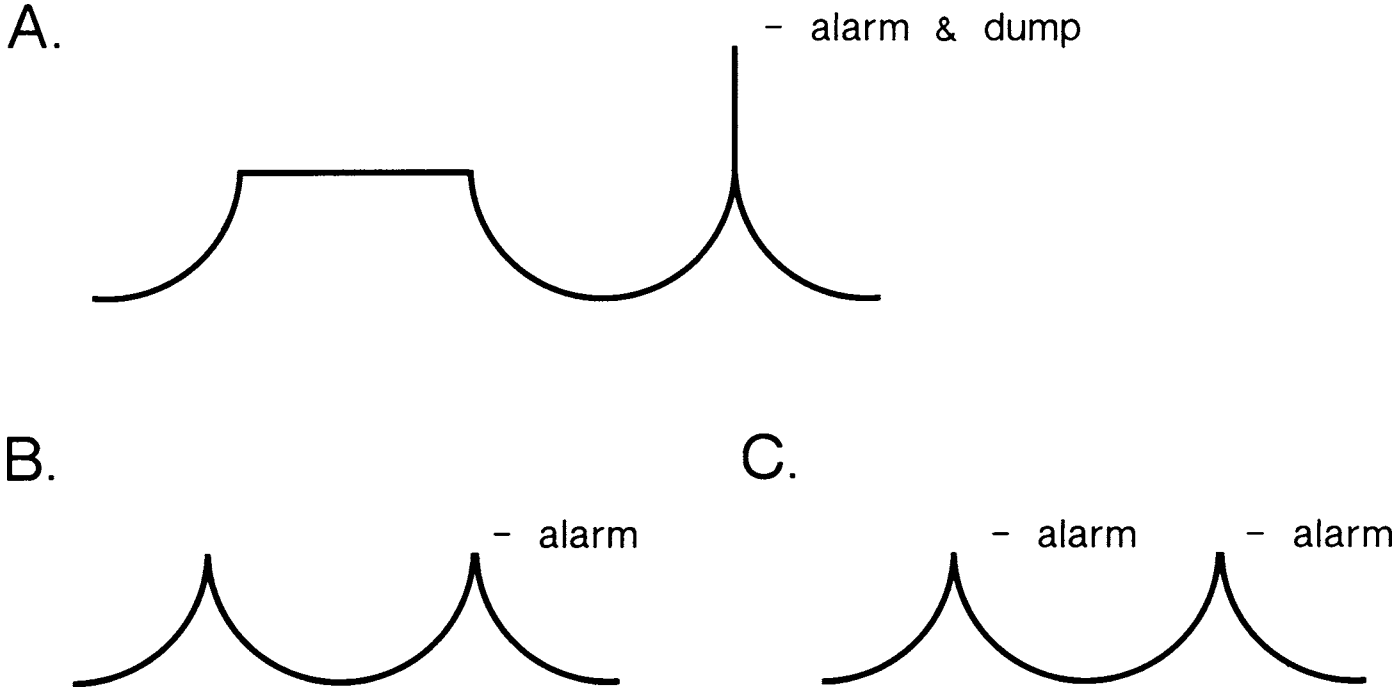

FIG. 1 Three Different Pressure Patterns That May Activate the Airway Overpressure Alarm

no less than 3 cm of H_2O and no greater than 10 cm of H_2O. The resistance to flow shall not exceed 10 cm of H_2O per L/sec (measured at the patient connection port). The function of the anti-asphyxia or negative pressure relief valve shall not be compromised by the state of the power supply of the ventilator. Testing shall be in accordance with 6.6.1. (See also X1.6.1.)

4.14 *Electrical Safety*:

4.14.1 *Accessory Outlets, (if provided)*—Accessory outlets shall be separately fused in a circuit parallel to the circuit providing the ventilator power.

4.14.2 *Battery Charging Systems*—See 5.1.23.

4.14.3 *Electromagnetic Interference*—The ventilator should meet the requirements of MDS-201.[5] (See also X1.7.1.)

4.14.3.1 *Electrostatic Discharge*—The ventilator should continue to function within the manufacturer's specifications at any control setting following exposure to contact electrostatic discharges between 2 and 8 kV and air discharges between 2 and 15 kV applied using a probe that simulates electrostatic discharges from humans. The test discharges should be applied to the area of the ventilator most likely to conduct the discharge into the ventilator electric circuitry, for example, front panel controls or other conductive parts exposed to contact by the user. (See also X1.7.2.)

5. Labeling and Product Marking

5.1 The manufacturer shall provide the following information:

5.1.1 Intended environments for use (and recommended power supply or power supply limitations).

5.1.2 A recommended checklist for use in determining that the ventilator is functioning within the manufacturer's specifications following changes in ventilator settings or reassembly of the breathing circuit.

5.1.3 The recommendation that an alternative means of ventilation be available and the procedures to be followed if the ventilator ceases to function properly.

5.1.4 If the ventilator is intended for use during patient transport via ambulance, it shall be marked with instructions to use the 12-V d-c power supply rather than the 115-V a-c power supply.

5.1.5 The ventilator shall be marked with the following: **Warning**—Portable (external 115-V a-c) power supplies should not be used to power the ventilator unless it is known by the user that the voltage variations from such a power supply are within the operating limits recommended by the manufacturer.

5.1.6 The periodicity of the integral power source use indicator, (see 4.1.2.1).

5.1.7 The exact range of voltages over which the ventilator will operate.

5.1.8 Where in the ventilator breathing circuit the pressure for each pressure control is sensed, (for example, ventilator output, patient, etc.).

5.1.9 Volume performance of the ventilator when tested in accordance with 6.3.

5.1.10 The period of time during which the ventilator meets the volume control accuracy requirements of 4.3. The manufacturer shall disclose upon request the method of statistical analysis used to support the disclosed value.

5.1.11 The accuracy of any exhaled volume measurement devices, if provided with the ventilator, and the gas conditions during the accuracy testing shall be referenced.

[5] MDS-201 "Electromagnetic Compatibility Standard for Medical Devices," is available as Accession No. PB271635 from the National Technical Information Service, (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

5.1.12 The limits of frequency, inspiratory time, or I:E ratio, or combination thereof, beyond which the interdependence of control functions may cause the tidal volume specification not to be met. (See also X1.8.1.)

5.1.13 The tidal volume and minute volume range for which the ventilator is intended to function.

5.1.14 The period of time (utilizing both internal and external power supplies) during which the ventilator is capable of meeting the frequency control requirements of 4.4.1. The manufacturer shall disclose upon request the method of statistical analysis used to support the disclosed value.

5.1.15 The period of time during which the ventilator controls meet the requirements in 4.4.2. (See also X1.2.7.) The manufacturer shall disclose upon request the method of statistical analysis used to support the disclosed value.

5.1.16 The limits of inspiratory time, volume, and I:E ratio control interdependence that may cause the frequency requirements in 4.4.1 not to be met.

5.1.17 The period of time during which the inspiratory time controls, if provided, meet the requirements in 4.5.1. The manufacturer shall disclose upon request the method of statistical analysis used to support the disclosed value.

5.1.18 The period of time during which the ventilator will meet the requirements in 4.6.1 and 4.6.2. The manufacturer shall disclose upon request the method of statistical analysis used to support the disclosed value.

5.1.19 The range for sigh rate and sigh volume, if provided.

5.1.20 The tubing circuit manufacturer shall disclose the recommended continuous duration of use for "single patient use" or "disposable" circuits. (See also X1.8.2.)

5.1.21 The expected FiO_2 for various oxygen flows and ventilator settings. (See also X1.8.3.)

5.1.22 A test method for compliance with the requirements in 4.12.1.

5.1.23 Information concerning the input/output characteristics of the battery charging systems.

6. Test Methods

6.1 *Test Method for Power Source Requirements*:

6.1.1 While performing the tests for requirements 4.2-4.7 through , vary the supply voltage from 90 to 130-V a-c, and vary the frequency from 50 to 70 Hz.

6.1.2 Lower the line power to a point below the minimum specified by the manufacturer and verify that the ventilator switches to the integral battery power supply and continues to operate without degradation of performance. Next, configure the ventilator in such a manner as to create the maximum power consumption within the manufacturer's recommended operating range, and ensure that the integral battery powers the ventilator adequately to meet the requirements of this specification for no less than 15 min.

6.2 *Test Method for Accuracy of Controls, Indicators, and Pressure Relief Devices*:

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

6.2.2 Configure the ventilator for use as recommended by the manufacturer. Fill the humidifier to the recommended level. Make pressure measurements at the patient connection port using an electronic transducer and record the pressure waves using a strip chart recorder. Set the pressure relief controls at 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 activates within 3 s of reaching the maximum limiting pressure.

6.2.3 Test the ventilator against the parameters outlined in Table 1 using the general methods, etc. prescribed in Annex A1 as applicable, and record the volume control accuracy. The results of testing under this requirement, shall be made available by the manufacturer on request, and the values disclosed as the mean of the tests performed plus or minus the standard deviation.

NOTE 2—See Annex A1 for additional details.

6.2.4 Test the inspiratory time controls at the minimum, mid, and maximum inspiratory time against the conditions as outlined in 6.2.3 with the methods described in Annex A1.

6.2.5 Test the ventilator under the conditions as outlined in 6.2.3 and with the methods described in Annex A1 utilizing both the internal and external power sources and record the duration of time where the controls remain within the limits set in 4.5.1.

6.2.6 Activate the sigh mechanism as recommended by the manufacturer, repeat through five cycles, and determine the rate and volume. (See also 5.1.19.)

6.3 *Test Method for Human Factors Requirements*:

6.3.1 Visually inspect the connector for the appropriate markings under the conditions outlined in 4.8.1, and attempt to change the fitting direction.

6.3.2 Attempt to fit a 15- or 22-mm male or female cone into the ambient air inlet.

6.3.3 Attempt to connect 22-, 15-, and 30-mm cones and sockets, and 22-mm internal diameter tubing to the expired gas outlet.

6.3.4 Check the connectors to establish that the appropriate CGA[4] designated fitting has been supplied. Disconnect the hose(s) from the ventilator and connect the two ends of the hose together to verify that the connectors on both ends of the hose are for the same type of gas.

6.3.5 Inspect the connection point for markings under the conditions outlined in 4.8.1 and attempt to cross-connect or interchange the fittings or tubing.

6.4 *Tests for Breathing Circuit Requirements*:

6.4.1 Generate a 50 L/min gas flow through the patient breathing system with no PEEP. Measure the pressure drop from the patient connection port to ambient.

6.4.2 Condition all tubing at 42°C and 100 % relative humidity with gas flowing through the tubing for 1 h prior to testing as outlined as follows: 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 (ID) that is intended for use with infants and neonates) through the tubing and measure the

pressure above atmospheric pressure (ΔP) necessary to drive the flow through the tubing. The test is passed if ΔP is less than 10 cm H_2O.

6.4.3 Condition all tubing at 42°C and 100 % relative humidity with gas flowing through the tubing for 1 h prior to testing as outlined as follows: place a 2.5-kg weight on a 5-cm segment in the middle of a 1-m length of tubing; establish a 75 L/min flow (25 L/min for tubing smaller than 22-mm inside diameter (ID) that is intended for use with infants and neonates) through the breathing system, and use on an ambient air inlet could lead to misconnection of breathing circuit components to the ambient air inlet.

6.4.4 Visually inspect the circuit components under the conditions outlined in 4.8.1, and attempt to change connector direction.

6.5 *Test Methods for Alarm Requirements*:

6.5.1 During performance of the tests for compliance with 4.4.1, check to ensure that the audible and visual event alarms sound as the transition from line power to battery power occurs, and that the periodic audible advisory indicator functions, annunciating at the interval outlined by the manufacturer in the accompanying documents.

6.6 *Test Method for Anti-Asphyxia Valve and Negative Pressure Relief Valves Requirements*—Configure the ventilator and breathing system as it is when connected to the patient. Measure pressure and flow at the patient connection port of the breathing system. Generate a breath at the minimum recommended tidal volume and record the opening pressure of the valve and the resistance to flow. Repeat the test at the maximum recommended tidal volume. Record the opening ("cracking") pressure and resistance to flow at both tidal volume settings.

ANNEX

(Mandatory Information)

A1. GENERAL TEST CONDITIONS, APPARATUS AND METHODS

A1.1 *General Test Conditions*—All tests shall be conducted at NTPD (20°C, 760 mm Hg, 0 % RH) or corrected to NTPD with the ventilator configured for use as recommended by the manufacturer.

A1.2 *Test Apparatus:*

A1.2.1 *Lung Models, Compliances and Resistances*—The lung models illustrated in Figs. A1.1 and A1.2 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.

A1.2.1.1 *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, that can be simulated in the lung models by compliance and a resistance connected in series (see Figs. A1.1 and A1.2). The various combinations of compliances and resistances used in the test procedures are given in Table 1.

A1.2.1.2 *Compliances*—The required compliances are given in Table 1. These compliances shall include the compliances of all components of the lung model system. The volume-pressure characteristics of the model compliances, including connections, shall be determined at ambient pressure and temperature, and shall be determined as in 6.1.2 and shall be within ±5 % of the required compliance values shown in Table 1.

A1.2.1.3 *Resistances*—The required resistances are given in Table 1. These values relate to measurements at NTPD. They include the resistance of the flow measuring device.

A1.3 *General Methods of Testing Performance of Lung Ventilators*—Measurements of pressure, flow, and volume shall be made as shown in Figs. A1.1 and A1.2 and shall be accurate to within ±2.5 % of the reading. An additional tolerance of ±2.5 % of the full scale reading shall be allowed. The reading accuracy of the recording device shall be maintained at frequencies up to 10 Hz. Ambient conditions shall be recorded, and all results are to be reported at NTPD (20°C, 760 mm Hg, and 0 % RH) even though other conditions may exist during actual testing. Dry air, unless otherwise specified in an individual requirement, is to be the test gas.

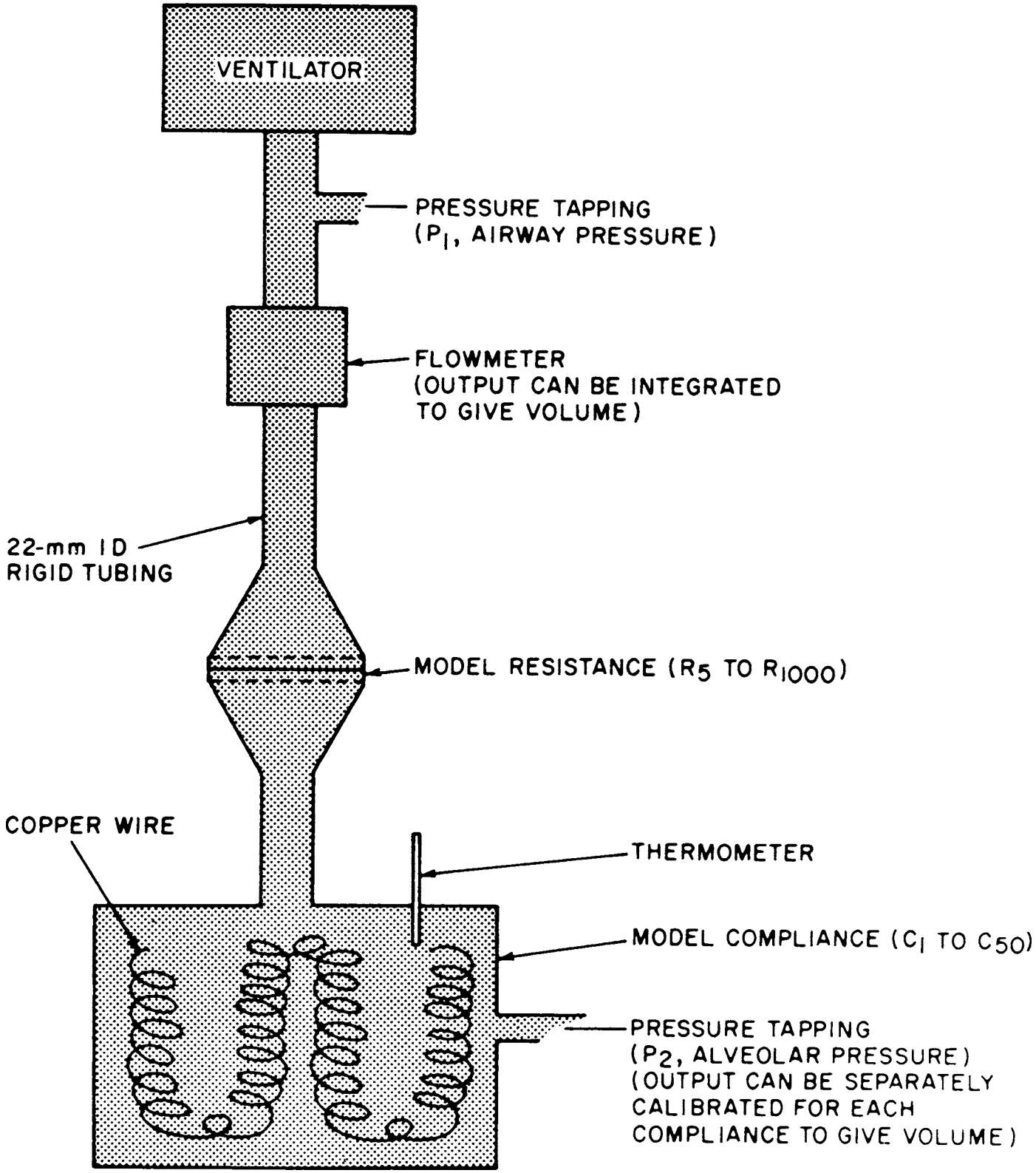

FIG. A1.1 Representative Passive Lung Model

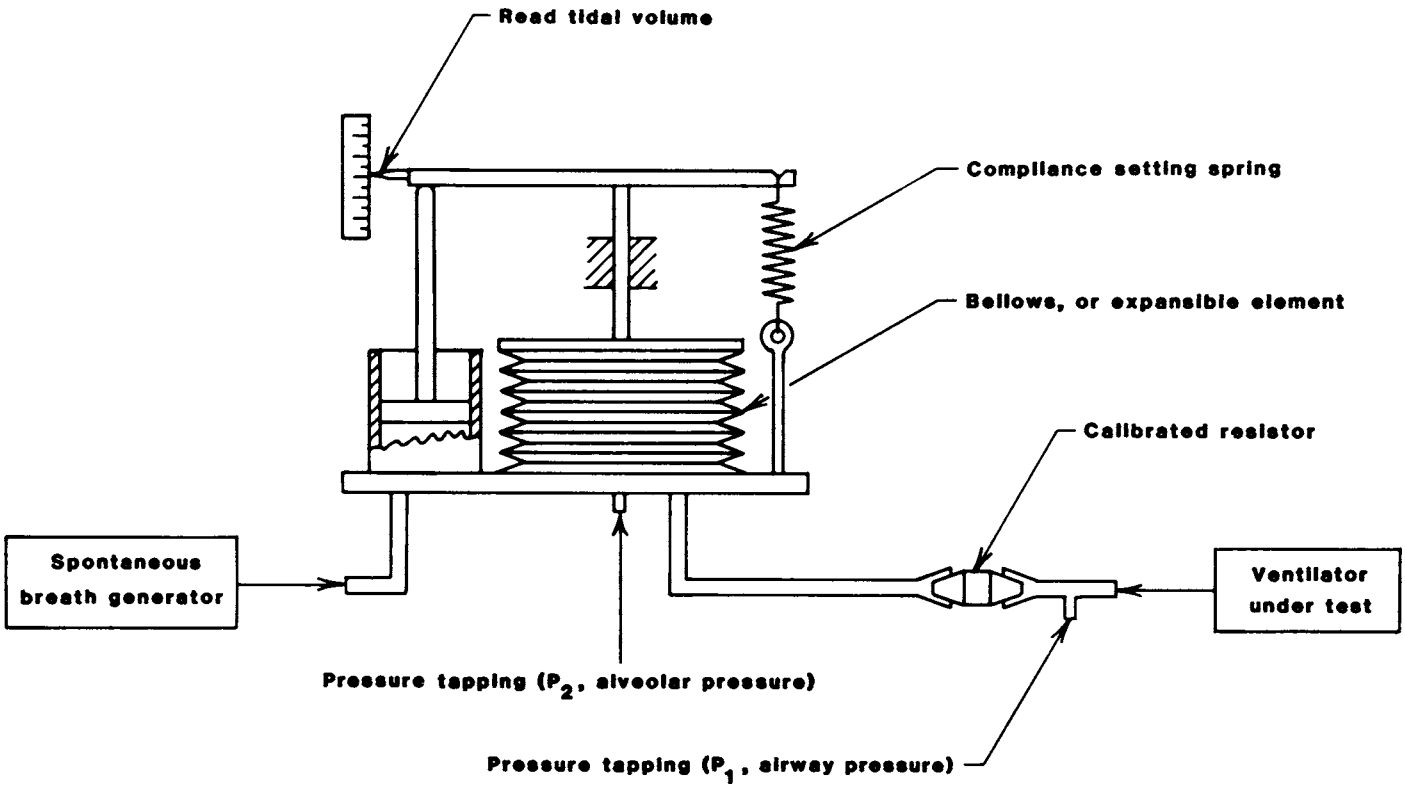

FIG. A1.2 Representative Active Lung Model

APPENDIX

(Nonmandatory Information)

X1. STATEMENTS OF RATIONALE FOR THIS SPECIFICATION

NOTE X1.1—The rationales for many of the requirements of this specification are given in this Appendix. For the sake of clarity, the paragraph to which each rationale applies is given in italics at the beginning of each subsection.

X1.1 Rationale for Scope

X1.1.1 *Paragraph 1.1*—The scope of this specification is limited to home care ventilators because the operating environment for home care ventilators is considerably different from that found in the hospital. Examples of these environmental differences are: the training of personnel, difference in power supplies, extremes in power supply variation, control of temperature and humidity, and the need to secure controls to prevent inadvertent movement and tampering by other individuals in the home environment. Requirements for critical care ventilators and ventilators intended for use during anesthesia have been addressed in other specifications.

X1.2 Rationale for Performance Requirements

X1.2.1 *Paragraph 4.1.1*—Fluctuation within the ranges specified in 4.1.1 is known to occur in electrical power supplies. The causes for such variations may be outside the control of the ventilator user. For example, a decrease in the voltage in the power supply by the local electric utility, or the variations that may result from demands for power by such equipment as washing machines, freezer motors, and air conditioning apparatus. If a gasoline powered portable generator is used as an emergency power supply for a home care ventilator, this may cause fluctuation in voltage or frequency from that normally supplied by the local utility, or both.

X1.2.1.1 Although Subcommittee F29.03.09 is aware of specific problems caused by extreme high voltage conditions, particularly in ambulances, it was not felt appropriate for the home care ventilator to be required to function in the grossly aberrant conditions described for some ambulances. The subcommittee is also aware that attempts are currently being made to correct these problems with the manufacturers of generators for ambulances.

X1.2.1.2 Members of Subcommittee F29.03.09 also noted that there were a number of other types of clinical apparatus (for example, apnea monitors, etc.) that were severely damaged or destroyed by the power variations in ambulances, and that this problem would be most appropriately addressed via standards for ambulances.

X1.2.2 *Paragraph 4.1.2*—Subcommittee F29.03.09 members present agreed that for safety purposes it was necessary to mandate that all ventilators intended for home care should have

a power source integral to the ventilator to provide for patient needs in the event of an emergency such as an electrical storm or other such incidents that might interrupt the line power supply to the ventilator. "Integral" is intended to mean as a component part of the ventilator system. This power source may, or may not, be enclosed within the ventilator housing.

X1.2.2.1 Subcommittee F29.03.09 also agreed that the 15 min time period was intended to provide a safety factor so that the patient or the care giver could find an alternative source of power to operate the ventilator, or an alternative source of ventilation for the patient. The subcommittee agreed that it was not intended that the integral battery be used regularly as a power source for the ventilator during movement and transport of the patient.

X1.2.2.2 It was felt that to mandate switching to a battery power source under both low and high voltage conditions would significantly increase the cost of the ventilator while addressing a problem caused in a relatively small part of the ventilator use environment, and that the excessive voltage problem was better addressed by improving the specification for power supplies in ambulances. The subcommittee did note, however, that marking on the ventilator should be provided to the effect that the ventilator should be operated off the 12-V d-c power supply in the ambulance as opposed to the 115-V a-c generator supply.

X1.2.3 *Paragraph 4.2.2*—The limits set forth in 4.2.2 were the minimum acceptable to the subcommittee in order to maintain operator confidence and provide for patient safety.

X1.2.4 *Paragraph 4.2.3*—Subcommittee F29.03.09 felt that the requirement in 4.2.3 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 mech anisms "plateaued" in pressure rather than "dumping" the tidal volume until ambient pressure is reached. The subcommittee also felt for this requirement to be truly effective that a combined test would need to be developed ensuring that tubing met a given level of resistance to crushing and kinking.

X1.2.5 *Paragraph 4.3*—The requirement for disclosure of accuracy if both a calibrated control and indicator are used is intended to address the issue of a coarse gradation on the control and a fine gradation on the indicator that is associated with it. Under these circumstances it is important to clarify for the user which (the control or the indicator) meets the specified accuracy. The compliances and resistances given in the test method, the frequency, and I:E ratio are representative of conditions that would be found during the ventilation of an adult patient with normal pulmonary physiology. The members of the subcommittee felt that the accuracy specified would provide for adequate reproducibility of control movement to ensure effective modification of ventilator function.

X1.2.5.1 The parameters specified in Table 1 include a wide range of resistances, compliances, tidal volumes, and ventilatory rates reflective of the use environment and will provide the user with the necessary information to determine whether or not a particular ventilator is capable of providing for the needs of a specific patient.

X1.2.6 *Paragraph 4.3.1*—A variation of ±10 % of tidal volume or minute volume reflects a possible variation of 7 mm of mercury $PaCO_2$, and this is within acceptable limits for this type of ventilation.

X1.2.7 *Paragraph 4.4.1*—A variation of ±10 % of tidal volume or minute volume reflects a possible variation of 7 mm of mercury $PaCO_2$, and this is within acceptable limits for this type of ventilation.

X1.2.8 *Paragraph 4.5.1*——The required accuracy of inspiratory times will allow the clinician to control ventilation in situations where airway leaks prevent using set volume as the parameter to determine minute ventilation. Errors caused by inaccuracies in inspiratory time settings will also effect impedance of venous return.

X1.2.9 *Paragraph 4.5.1*—Variation in stability of inspiratory time controls will lead to variation in ventilation in cases where airway leak is the determinant of ventilation, and will affect venous return, and may therefore cause injury to the patient if variation outside of the limits stated in 4.5.1 occur.

X1.2.10 *Paragraph 4.6*—Peak flow in some types of ventilators may be the determinant of inspiratory time, and in other types of ventilators it may be the determinant of tidal volume. Therefore, the accuracy and stability need to fall within the specifications of 4.6.1 and 4.6.2 in order for the device to function safely in the clinical environment.

X1.3 Rationale for Human Factors Requirements

X1.3.1 *Paragraph 4.9.1.1*—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.

X1.3.2 *Paragraph 4.9.2*—This requirement is intended to minimize the possibility of inappropriate connection of the ventilator breathing circuit tubing to the spirometer outlet.

X1.3.3 *Paragraph 4.9.3*—In other standards for anesthetic and respiratory care equipment both 19- and 30-mm fittings have been prohibited from use as ambient air inlets. However, for ventilator use in the home environment, it was felt that both of these standard fittings should be allowed. The 19-mm fitting is conventionally used for scavenging anesthetic waste gases, and the 30-mm fitting is designated for use with spirometers. Subcommittee F29.03.09 felt that neither of these applications pertained to use of home care ventilators, and that it would be acceptable to allow the use of the 19- and 30-mm fitting on home care ventilators.

X1.3.4 *Paragraph 4.9.4*—The use of 15- or 22-mm fittings for a ventilator air inlet in these applications is unacceptable because 15- or 22-mm fittings are routinely a part of the requirements of 4.9.4. The requirements given in 4.9.4 will minimize the possibility of inadvertent connection of breathing system components to the expired gas outlet.

X1.3.5 *Paragraph 4.9.5*—These connections are manipulated every time the circuit is changed, and significant problems have been reported with misconnection of these tubings.

X1.4 Rationale for Breathing Circuit Requirements

X1.4.1 *Paragraph 4.10.1*—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 achievable. Patient system configurations, tubing length, connector sizes, and gas flow through the system are factors that may combine to raise end-expiratory pressure to the 5 cm H_2O maximum under certain conditions of ventilation. Device-inherent resistance above the 5 cm H_2O level is not acceptable because of the adverse effect that these levels may have on the patient's respiratory pattern or cardiovascular flow.

X1.4.2 *Paragraph 4.10.2.1*—It is often necessary for ventilator tubing to be placed over the tops of bedrails, over the rails of wheelchairs, over crib railings, and in other places where it may be subject to kinking. The tests outlined for this requirement are intended to simulate these conditions.

X1.4.3 *Paragraph 4.10.2.2*—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 on the tubing, passing of the tubing over a wheelchair arm where it may be occluded by the patient's arm, etc.). Tests for this requirement are intended to simulate this type of occlusion.

X1.4.4 *Paragraph 4.10.3*—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.

X1.5 Rationale for Alarms Requirements

X1.5.1 *Paragraph 4.12.1*—A means of silencing the ventilator breathing circuit alarm is necessary in order to perform procedures such as measuring volumes, suctioning, etc., where the patient is briefly disconnected from the ventilator. The subcommittee felt that the time period of 60 s (rather than the requirement for 2 min that is included in other ventilator specifications) was more appropriate in this specification due to the lower level of supervision that most patients on home care ventilators are subject to.

X1.5.2 *Paragraph 4.12.2*:

X1.5.2.1 *Paragraph 4.12.2.1*—The type of alarm mechanism described in 4.12.2.1 is essential in certain types of ventilation where a variable leak is present, and in the first part of the illustration in Fig. 1 where the leak from the patient is equal to the flow of gas being sent to the patient, a plateau is reached. This type of ventilation is often used for pediatric patients. The portion of Fig. 1 illustrated in (A) defines a situation where a patient is being ventilated by a volume ventilator with a leak, and an obstruction occurs to decrease that leak.

X1.5.2.2 *Paragraph 4.12.2.2*—The type of alarm described in 4.12.2.2 is intended to reduce the number of spurious alarms in the home environment, in a situation where the upper pressure limit is frequently reached on an individual breath during routine ventilation, and may only indicate a malfunction or obstruction on repeated breaths.

X1.5.2.3 *Paragraph 4.12.2.3*—The type of alarm described in 4.12.2.3 is intended to provide the maximum indication of overpressure in applications where any overpressure condition may be injurious to the patient.

X1.5.3 *Paragraph 4.12.3*—Indicators for several different purposes have been addressed in this requirement. The coupled audible and visual event alarm to be activated when the ventilator begins operating on the battery power source was intended to provide notification to both the patient and the care-giver that line power was no longer being provided to the ventilator. The requirement states that the audible portion of this event alarm is manually cancelable, because once the care-giver has attended to the ventilator, the audible portion of the alarm has fulfilled its intended purpose. However, it was felt necessary to maintain the visual portion of the alarm as a reminder that the integral battery power source was still in use, and to provide an audible advisory indicator on a periodic basis (for example, every 4 or 5 min) to additionally remind both the patient and the care-giver that the integral battery power source was in use. The subcommittee felt that this approach to alarms and indicators on the power supply would provide the necessary safety while minimizing the nuisance factor that is inherent in continuously sounding alarms.

X1.6 Rationale for Anti-Asphyxia Valves and Negative Pressure Relief Valve Requirements

X1.6.1 *Paragraph 4.13*—The subcommittee included requirements for the valve to open at no less than 3 cm of H_2O and no greater than 10 cm of H_2O because it was felt that this was the range necessary in order to prevent the anti-asphyxia valve from opening during the initial negative pressure phase of assisted ventilation while still providing for function in the event of ventilator malfunction.

X1.7 Rationale for Electrical Safety Requirements

X1.7.1 *Paragraph 4.14.3*—Electromagnetic interference can cause improper operation of ventilators. There are numerous sources of such interference, including electrical appliances, telemetry transmitters, and nearby radio broadcasting stations. However, several manufacturers of medical devices have experienced field failures caused by conducted or radiated electromagnetic interference in devices that meet the requirements of MDS-201,[5] and further or additional requirements may be necessary in order to address application of home care ventilators in specific environments.

X1.7.2 *Paragraph 4.14.3.1*—Electrostatic discharge can cause improper operation of home care ventilators. Operators of medical devices in the home are likely to become electrostatically charged from contact with synthetic garments and carpets. Discharges to medical equipment from operators is likely, particularly in conditions of low humidity. Ventilators are life support devices, and must therefore continue to function within the manufacturer's specifications.

X1.7.2.1 Although test probes are necessary for effective testing, no accepted standards for electrostatic discharge testing exist at present. The specifications contained in a recent proposed revision of IEC Publication 801-2[6] describe a type of

[6] IEC Publication 801-2 is available from International Electrotechnical Commission, 3 rue de Varembé, CH-1211 Geneva 20, Switzerland.

probe and waveforms that effectively model electrostatic discharges from humans.

X1.8 Rationale for Marking and Labeling Requirements

X1.8.1 *Paragraph 5.1.2*—Unpredictable degradation of performance due to interdependence of controls can seriously affect the ability of the operator to accurately adjust the ventilator's function, and can thus result in jeopardy to the patient.

X1.8.2 *Paragraph 5.1.20*—Although "single patient use" tubing is often changed every 24 to 48 h in the hospital setting, the duration of use in the home care setting may considerably exceed this time period. It is necessary for the user/consumer to know the recommended duration of use so that the tubing can be changed prior to any physical degradation that might compromise performance of the ventilator.

X1.8.3 *Paragraph 5.1.21*—The expected FiO_2 for various flows and settings referenced in this requirement refer to operation during controlled ventilation only. Members of the subcommittee were well aware of the possibility of variation in FiO_2 during the assist mode, but it was agreed that it was not appropriate to mandate the use of such devices as gas blenders, etc. in order to maintain concentration during the assist mode because of the increased expense and complexity involved, and because of the decrease in portability that such equipment would cause.