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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