Designation: F 1246 – 91 (Reapproved 1999)

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:*

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

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.

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.

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

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