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Standard Specification for Ventilators Intended for Use During Anesthesia¹

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1. Scope

1.1 This specification applies to all ventilators specifically introduced for sale following acceptance of this specification and intended for use during the administration of anesthesia. Definitions, performance requirements, test methods, and a rationale for all mandatory requirements are included.

1.2 The anesthesia ventilator cannot protect against malfunctions within the anesthesia machine, nor can it protect against inappropriate or inadvertent use of the oxygen flush valve, and therefore, no attempt has been made to address problems that may arise from malfunctions with these devices in this specification. (See also X3.1.)

1.3 Several definitions have been included in Section 2 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. Appendix X1 also outlines various characteristics of ventilators intended for use during anesthesia and defines the main classes of breathing machines that may be used in medical practice and indicates how these may be subdivided according to their mode of action.

1.4 The following precautionary caveat pertains to the test methods portion, 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 concerns 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.* For an additional safety precaution, see Note 6.

2. Referenced Documents

2.1 ASTM Standards:

F 1054 Specification for Conical Fittings of 15-mm and 22-mm Sizes²

F 1161 Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines²

2.2 ANSI Standards:

Z-79.10 Standard for Oxygen Analyzers³

Z-79.11 Standard for Scavenging Systems for Excess for Anesthetic Gases³

2.3 ISO Standard:

ISO 4135 Anesthesiology Vocabulary⁴

2.4 Other Standards:

IEC 601-1 Safety of Medical Electrical Equipment⁵

CGA V-5, 1978 Specifications for DISS Connections⁶

3. Terminology

3.1 **Definitions**—For the purposes of this specification, the definitions in 3.1.1-3.1.51 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 H₂O) of those portions of the patient system that are pressurized during the inspiratory phase time (see also 5.8 and 3.1.36).

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

3.1.5.1 **Discussion**—Common usage of the 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.

3.1.8 **differential inspiratory triggering pressure (ΔP_{tr})**—change in airway pressure at the patient connection port which

¹ This specification is under the jurisdiction of ASTM Committee F-29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.10 on Anesthesia Workstations.

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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 International Standards Organization, 1, Rue de Varembe, Case postale 56, CH-1211.

⁵ Available from International Electrotechnical Commission, 3 rue de Varembe, 1211 Geneva 20, Switzerland.

⁶ Available from Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.