Designation: F 1208 – 89 (Reapproved 2005)

Standard Specification for Minimum Performance and Safety Requirements for Anesthesia Breathing Systems[1]

This standard is issued under the fixed designation F 1208; 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 breathing systems and components employed with anesthesia gas machines for humans. This specification considers the circle system as a whole and some of its components individually. A particular emphasis is placed upon component arrangement in the circle absorber-type system, and submits a system of standard description and notation. Excluded are ventilators for use during anesthesia, Mapelson nonrebreathing type systems, as well as breathing systems and related components of dental *analgesia* machines. (For rationale, see Appendix X1.)

1.2 *This standard does not purport to address all of the safety concerns, if any, 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.*

1.3 This specification is arranged as follows:

2. Referenced Documents

2.1 *ASTM Standards:* [2]

F 1054 Specification for Conical Fittings[3]

F 1204 Specification for Anesthesia Reservoir Bags[3]

F 1205 Specification for Anesthesia Breathing Tubes

2.2 *ANSI/ASME Standard:*

ANSI/ASME B40.1M-1985 Standard for Pressure Gauge[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *absorber assembly*—a container(s) for CO_2 absorbent, and may include, but need not be limited to, the inspiratory and expiratory unidirectional valves, APL valve, and bag mount.

3.1.2 *adjustable pressure limiting valve* (APL valve)—a user-adjustable valve which releases gas and is intended to provide control of the breathing system pressure.

3.1.3 *breathing system*—a gas pathway in direct connection with the patient through which gas flows occur at respiratory

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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.

[4] Available from the American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

pressures, in which directional valves may be present, and into which a mixture of controlled composition may be dispensed.

3.1.4 *circle breathing system*—a breathing system in which circular gas flow (through separate inspiratory and expiratory pathways) is determined by unidirectional valves.

3.1.5 *common gas outlet*—that port through which the mixture dispensed from the anesthesia gas machine is delivered to the breathing system.

3.1.6 *compliance*—the change of volume per unit change in pressure within a closed system. Units of compliance are: L/kPa or L/cm H_2O (litres per kilopascal or litres per centimetre of water).

3.1.7 *expiratory pathway*—that portion of the gas pathway through which expired gases flow at respiratory pressures.

3.1.8 *fresh gas inlet*—that port on breathing systems to which the fresh gas supply is attached.

3.1.9 *fresh gas supply tube (or hose)*—that conduit conveying gases from the common gas outlet, or other gas source, to the fresh gas inlet of the breathing system.

3.1.10 *inspiratory pathway*—that portion of the gas pathway through which inspiratory gases flow at respiratory pressures.

3.1.11 *kilopascal (kPa)—SI unit of pressure*, 1 kPa approximates 10 cm of H_2O.

3.1.12 *labeling*—information and literature accompanying the device (for example, brochure, package insert, manual, etc.).

3.1.13 *marking*—information directly on a device.

3.1.14 *may*—denotes an optional feature or consideration.

3.1.15 *resistance*—the pressure difference from inlet to outlet of the device per unit of flow, expressed in kPa/L/s (kilopascals per litre per second). For the purposes of this specification, pressure drops are noted at flows of 0.5 L/s and 1.0 L/s.

3.1.16 *room temperature and pressure, dry gas* (rtpd)—*forthe purposes of this specification*, 20 ± 3°C, at ambient barometric pressure.

3.1.17 *shall*—denotes a mandatory feature or consideration.

3.1.18 *should*—denotes a desirable but not mandatory feature or consideration.

4. System Classification

4.1 Symbols were devised, diagramatic rules established, and a standard method of notation utilized. In addition, these symbols, diagramatic rules, and method of notation may be used in labeling and marking.

4.1.1 *Notation*—The method of notation consists of two parts: that of graphic notation (see Fig. 1), and that of numeric designation of functional segments of the circle system (see section 3.2 and Fig. 2).

4.1.1.1 *Diagramatic Rules*:

(1) Gas flow in circuit proceeds in counter-clockwise direction.

(2) Patient end symbol is on the right side of circle.

(3) Reservoir bag symbol is on the left side of circle opposite the patient symbol.

4.1.2 *Functional Divisions of the Circle System—Segmentation*—The circle system is divided into four segments (see Fig. 2) to illustrate specific functional characteristics. These segments include the following areas where components may be located, or in some cases, shall be located.

Segment 1—From patient to expiratory valve.

Segment 2—From expiratory valve to reservoir bag.

Segment 3—From reservoir bag to inspiratory valve.

Segment 4—From inspiratory valve to patient.

An example of the use of these symbols in a circle system is shown in Fig. 3 and is presented *for illustrative purposes only.*

5. Test Procedures

5.1 *General*—The test methods are included after each requirement (and each requirement will be referenced by section number in parentheses) to provide a means to substantiate compliance with the requirement. Other test methods may be employed if they can be shown to be equivalent.

5.1.1 *Accuracy*—Unless otherwise specified, accuracy shall be ±5 % of reading for each variable to be measured, and flow meters shall be compensated for pressure.

5.1.2 *Environmental Conditions*—Run all tests at rtpd except where otherwise stated.

5.1.3 *Test Gases*—All tests shall be performed with dry oxygen, or dry medical air, or dry nitrogen, unless otherwise specified in a particular test method.

6. Sterilization

6.1 *Disassembly*—The reuseable components of the breathing system, including the absorber and valves, shall be capable of being disassembled as required for cleaning and sterilization.

6.1.1 *Methods*—The manufacturer shall state suitable means of sterilization. The reuseable components of the breathing system should be sterilizable by autoclaving.

6.2 *Test Procedure*:

6.2.1 Disassemble according to instructions in the labeling.

6.2.2 Verify by reading the appropriate instructions in the labeling.

7. Systems

7.1 *Requirements*—The requirements of this section refer to breathing system assemblies as supplied complete by the manufacturer, that is, absorber, inspiratory and expiratory valves, APL valve, breathing tubes, Y-piece, and right angle connector (but excluding the reservoir bag and other components). Any component accessory to the breathing system which permits only unidirectional flow (such as some Peep valves and cascade humidifiers) or any device whose correct function depends upon the direction of gas flow through it shall be marked with an arrow indicating the proper directional flow, or the words “inlet” and “outlet,” or both.

7.1.1 *Leakage of Breathing System*—The maximum leakage of the breathing system as described above, shall not exceed 300 mL/min when pressurized to 3.0 kPa (30 cm H_2O).

7.1.1.1 The maximum leakage of a Y-piece and right-angle connector, with two breathing tubes shall not exceed 75 mL/min when pressurized to 3 kPa (30 cm H_2O).

7.1.1.2 The maximum leakage of that portion of the breathing system not specified in 7.1.1.1 shall not exceed 225 mL/min when pressurized to 3.0 kPa (30 cm H_2O).

Symbols

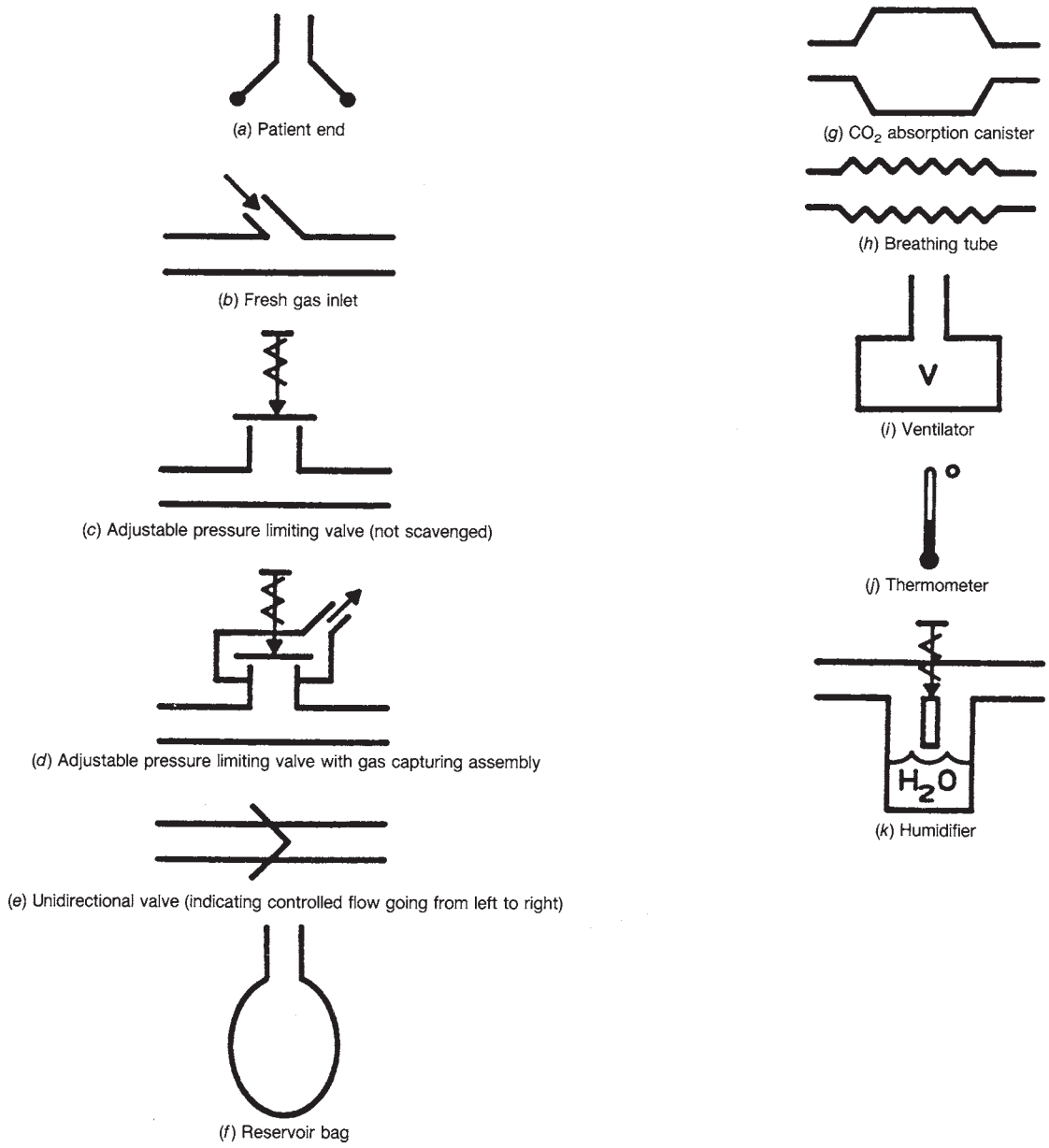

FIG. 1 Symbols

7.1.1.3 Manufacturers shall disclose in their labeling conformance with 7.1.1.

7.1.2 *Resistance of Breathing Systems (see 7.2.2)*—Manufacturers shall disclose in their labeling the typical pressure drops due to inspiratory and expiratory gas flow in their breathing system at reference flows of 0.5 and 1.0 L/s. For pediatric systems resistance at appropriately lower flow rates should be disclosed.

7.1.2.1 *Expiratory Pathway Resistance*:

(1) The maximum expiratory pathway resistance shall not exceed 0.65 kPa (6.5 cm H_2O) at a flow of 1.0 L/s from the patient connection port to the reservoir bag mount, with the APL valve closed.

(2) The maximum resistance of an expiratory tube plus Y-piece or T-piece, with right-angle connector shall not exceed 0.15 kPa (1.5 cm H_2O) per metre length, at a flow of 1.0 L/s.

7.1.2.2 *Inspiratory Pathway Resistance*—The maximum inspiratory pathway resistance shall not exceed 0.65 kPa (6.5 cm