Designation: F 1218 – 89 (Reapproved 1999)

Standard Specification for Bronchoscopes (Rigid) [1]

This standard is issued under the fixed designation F 1218; 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 definitions and requirements for rigid bronchoscopes and certain bronchoscopic accessories used in the practice of medicine.

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:*

3.1.1 *bronchoscopes (rigid)*—a medical instrument having viewing means, with or without optics, introduced into the larynx or tracheobronchial airway, or both, through a natural or surgically created body opening for examination, diagnosis, or therapy, and intended to be unyielding to natural or surgically created body cavities.

3.1.2 *optical endoscope*—a medical instrument with optics, having viewing means, which may be introduced into a body cavity through a bronchoscope, or through a naturally or surgically created body opening for examination, diagnosis, or therapy. An optical endoscope may be of rigid or flexible design.

3.1.3 *endoscopic accessory*—a medical instrument inserted through a bronchoscope for diagnosis or therapy.

3.1.3.1 *rigid accessory*—an accessory whose insertion portion is intended to be unyielding to natural or surgically created body cavities or instrument lumens.

3.1.3.2 *flexible accessory*—an accessory whose insertion portion is intended to conform to natural or surgically created body cavities or instrument lumens.

3.1.3.3 *Discussion*—The intent is to include forceps, snares, electrodes, and other such instruments which can be passed through a bronchoscope or with a bronchoscope through another accessory. The intent is also to exclude certain instruments, such as electrosurgical units, light sources, other such instruments, and ventilation systems external to the bronchoscope.

3.1.4 *distal*—the location of that portion of a bronchoscope or endoscopic accessory which is farther from the user than some reference point.

3.1.4.1 *Discussion*—The terms given in 3.1.4 and 3.1.5, commonly used in endoscopy, are defined in their most general form to avoid the need for such definitions as “distal tip,” “distal end,”“ area proximal to ...,” “X cm distal to the ... .”

3.1.5 *proximal*—the location of that portion of a bronchoscope or endoscopic accessory which is closer to the user than some reference point.

3.1.5.1 See 3.1.4.

3.1.6 *insertion portion*—that portion of a bronchoscope or endoscopic accessory which is intended to be inserted into a natural or surgically created body opening; or which is intended to be inserted into the lumen of a bronchoscope or endoscopic accessory.

3.1.6.1 *Discussion*—Although the term defined seems self-explanatory, different expressions for the same portion of the instrument are used by different manufacturers.

3.1.7 *maximum insertion portion width*—the maximum external width of a bronchoscope or endoscopic accessory throughout the length of the insertion portion.

3.1.7.1 *Discussion*—By defining external sizes as maxima and internal sizes as minima, sufficient instrument information for selection of an instrument will be provided to users.

3.1.8 *minimum lumen width*—the minimum internal width of a bronchoscope or endoscopic accessory through which a bronchoscope or endoscopic accessory is intended to pass.

3.1.8.1 See 3.1.7.

3.1.9 *working length*—the maximum length of the insertion portion.

3.1.10 *overall length*—the distance between the proximal and distal ends of a rigid bronchoscope or bronchoscopic accessory, expressed in metric units.

3.1.11 *field of view*—the size of the object field viewed through an optical endoscope and stated by the vertex angle (in degrees) of the cone whose vertex is at the distal window surface of the instrument.

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[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.13 on Laryngoscopes and Bronchoscopes .

Current edition approved March 31, 1989. Published July 1989.

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

3.1.11.1 *Discussion*—The endoscope is not intended to be in contact with the object. (See Fig. 1.)

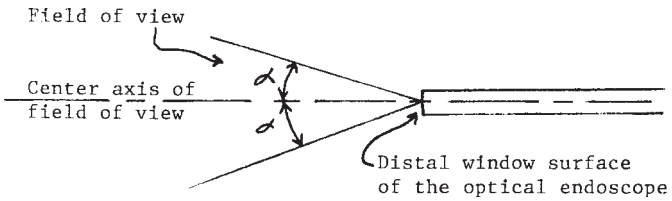

FIG. 1 Field of View

3.1.11.2 *Discussion*—The definitions given in 3.1.11 and 3.1.12, as illustrated, describe characteristics of optical endoscopes paramount for effective use, thereby allowing the user to select instruments of specific values for particular medical purposes.

3.1.12 *direction of view*—the location of the center of the object field relative to the normal axis of the optical endoscope, and stated as the angle (in degrees) between the normal axis of the optical endoscope and the center of the field of view. (See Fig. 2.)

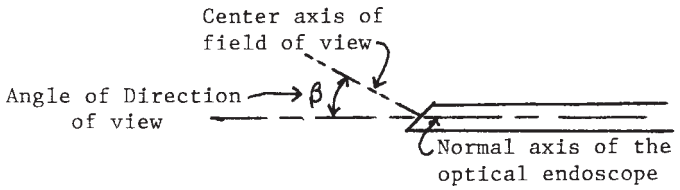

FIG. 2 Direction of View

3.1.12.1 See 3.1.11.

3.1.13 *controllable portion*—that part of the insertion portion of an optical endoscope whose motion is intended to be remotely controlled by the user.

3.1.13.1 Many optical endoscopes incorporate provisions for remote control of the motion of the distal tip by the user. The mechanisms for these controls vary widely, and are obviously of interest to the user. In order to avoid constraint of future designs, control characteristics are defined in the most general terms.

3.1.14 *French (Charriere) size (Fr)*—a measure of the size of certain endoscopic accessories of circular and noncircular cross-section. The measure has several definitions:

$$Fr = 3 \times u/3.1416 \text{ (pi) for noncircular cross-section}$$

where u is the perimeter of the cross-section, mm.

$$Fr = 3.1416(pi) \times d \text{ for circular cross-section}$$

where d is the diameter of the cross-section, mm.

$$Fr = 3.0 \times d \text{ for circular cross-section}^3$$

where d is the diameter of the cross-section, mm.

3.1.14.1 *Discussion*—This measure of size enjoys worldwide favor in many branches of medicine. In usage, the measurement is imprecise, as shown in 3.1.14. The user should be provided with the manufacturer's definition if the term is to be of any value. Metric measures appear to be more precise.

[3] Commonly used by many manufacturers of endoscopic accessories.

4. Significance and Use

4.1 This specification applies to rigid bronchoscopes, those endoscopic accessories through which rigid bronchoscopes are used, those accessories which are passed through rigid bronchoscopes in use, and those associated accessories which are inserted into the body.

5. Required Characteristics

5.1 *Critical Dimensions*:

5.1.1 The maximum insertion portion width shall not exceed that stated by the manufacturer. (See Note 1.)

NOTE 1—These sizes are given to help the user to select the instruments for a given procedure. Compatibility of instruments in combination requires certain clearances between the insertion portion width and the lumen width; the clearance required depends upon the configuration and dimensions of the instruments. There is no guarantee that the instruments selected solely by these criteria will be compatible in combination.

5.1.2 The minimum lumen width shall not be less than that marked on the bronchoscope. (See Note 1.)

5.1.3 The overall length shall not exceed that marked on the bronchoscope.

5.1.4 The working length shall not be less than that marked on the bronchoscope.

5.2 *Ventilation Connectors*—Ventilation connectors shall meet the requirements of Specification F 1054 or shall be provided with an adaptor to connect with the 15/22-mm connector.

6. Marking, Labeling, and Packaging

6.1 *Marking*:

6.1.1 *Instrument Marking* (see Note 2)—Dimensions shall be given in metric units. Each individual bronchoscope and endoscopic accessory shall have, as a minimum, the following markings:

NOTE 2—The identification of the instrument and markings listed in 6.1.1 are sufficient to permit the user to select the appropriate instrument when necessary.

6.1.1.1 A catalog number and other mark sufficient to identify the instrument and its manufacturer,

6.1.1.2 Maximum insertion portion width, minimum lumen width, overall length, and working length for rigid bronchoscope, and

6.1.1.3 Maximum insertion portion width, working length, field of view, and direction of view of the optical endoscope.

6.1.2 *Marking Legibility* (see Note 3)—The marking required in 6.1.1 shall remain legible throughout the expected life of the instrument when it is used, cleaned, disinfected, sterilized, and stored in accordance with the manufacturer's instructions.

NOTE 3—The primary requirement of instrument marking is that it be legible. Any more detailed requirements on marking methods, materials, sizes, and other characteristics could inhibit design and process innovation.

6.1.3 *Marking Exceptions* (see Note 4)—When the marking required in 6.1.1 and 6.1.2 is impossible to achieve due to

instrument size or configuration, the required markings shall accompany the instrument.

NOTE 4—Design innovation in the trend towards smaller endoscopes and endoscopic accessories would be seriously inhibited without this marking exception.

6.2 *Information to Be Supplied by the Manufacturer* (see Note 5)—The manufacturer of rigid bronchoscopes or endoscopic accessories shall provide the user with at least the following information:

NOTE 5—A significant number of hazards and performance problems of endoscopes and endoscopic accessories are best addressed by education of the user. The objective of 6.2 is to provide a part of the educational process without engaging in the practice of medicine.

6.2.1 A statement of intended uses of the instrument and directions for proper assembly for each use,

6.2.2 Instructions for proper maintenance of the instrument,

6.2.3 An annotated illustration of the instrument, if necessary, to identify pertinent parts and characteristics of the instrument which are referenced in the information supplied, and

6.2.4 The specifications of the instrument, including the following:

6.2.4.1 The name and address of the manufacturer, or supplier, or both,

6.2.4.2 The catalog number and name of the instrument,

6.2.4.3 The dimensional characteristics specified in 6.1.1,

6.2.4.4 If applicable, the field of view and the direction of view,

6.2.4.5 If applicable, the remote controls and associated controllable portion positions available to the user,

6.2.4.6 An identification of any parts replacable by the user and instructions for their replacement, and

6.2.4.7 A listing of the names and addresses of authorized service agents.

6.2.5 Instructions for assembling the instrument for its intended uses and for the dismantling and reassembly of the instrument after cleaning, disinfection or sterilization, or combination thereof,

6.2.6 Precautions and other instructions applicable to the intended uses of the instrument, including those related to electrical, electronic, electro-optical, electrosurgical, or ventilatory apparatus intended to be used with the instrument,

6.2.7 Inspection instructions to provide assurance that the instrument is in working order,

6.2.8 Instructions for the cleaning of reusable instruments, including recommended cleaning agents and equipment,

6.2.9 Details of disinfection and sterilization environments which the instrument can withstand without damage, and

6.2.10 Recommended procedures for the storage of the instrument prior to use, and, for reusable instruments, between uses.

6.3 *Packaging*.

NOTE 6—Problems due to improper packaging have been reported. Rather than impose innovation-limiting design requirements on the manufacturer, we believe that the disclosure approach cited above is more appropriate.

NOTE 7—The manufacturer should package the instrument in a manner to protect the instrument from the adverse effects of shipping environments.

7. Keywords

7.1 bronchoscope; bronchoscopy; endoscope; endoscopy; optical endoscope