



Designation: F 896 – 90 (Reapproved 1999)

Standard Specification for Flexible Fiberoptic Bronchoscopes¹

This standard is issued under the fixed designation F 896; 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, requirements, and methods of test for flexible fiberoptic bronchoscope and certain endoscopic accessories used in the practice of medicine.

1.2 *Field of Application*—The standard applies to medical flexible fiberoptic bronchoscopes, those endoscopes accessories through which these bronchoscopes are used and those endoscopic accessories which are passed through these bronchoscopes in use.

2. Terminology

2.1 Definitions:

2.1.1 *bronchoscope*—a medical instrument having viewing means with or without optics introduced into the lung for examination, diagnosis, and/or therapy.

2.1.2 *endoscopic accessory*—a medical instrument inserted into a natural or surgically created body opening through which an endoscope is inserted; or a medical instrument inserted through or with an endoscope for examination, diagnosis or therapy.

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

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

2.1.5 *distal*—refers to the location of that portion of an endoscope or endoscopic accessory which is farther from the user than some referenced point.²

2.1.6 *proximal*—refers to the location of that portion of an endoscope or endoscopic accessory which is closer to the user than some referenced point.

2.1.7 *insertion portion*—that portion of an endoscope 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 an endoscope or

endoscopic accessory.³

2.1.8 *maximum insertion portion width*—the maximum external width of endoscopes or endoscopic accessories throughout the length of the insertion portion.

2.1.9 *minimum lumen width*—the minimum internal width at any endoscope or endoscopic accessory lumen through which an endoscope or endoscopic accessory is intended to pass.⁴

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

2.1.11 *field of view*—the size of the object field viewed through a bronchoscope and is stated by the vertex angle (in degrees) of the cone whose vertex is at the distal window surface of the endoscope. (See Fig. 1.) The endoscope is not intended to be in contact with the object.

2.1.12 *Discussion*—These two definitions, (2.1.11 and 2.1.13) as illustrated, describe characteristics of endoscopes paramount for effective use, with the endoscopist selecting instruments of specific values for particular medical purposes. The field of view is not appropriate when the endoscope is intended to be in contact with the object.

2.1.13 *direction of view*—the location of the center of the object field relative to the normal axis of the bronchoscope and stated as the angle in degrees between the normal axis of the endoscope (0) and the center of the field of view. (See Fig. 2 and 2.1.11.)

2.1.14 *controllable portion*—that part of insertion portion of an endoscope or endoscopic accessory whose motion is intended to be remotely controlled by the user.

2.1.15 *Discussion*—Many endoscopes, both rigid and flexible, incorporate provisions for user remote control of the motion of the distal tip. The mechanisms for these controls vary widely; and are obviously of interest to the user. These include, for example, distal tips of flexible endoscopes and elevators of rigid and flexible endoscopes. In order to avoid constraining future designs, control characteristics are defined in the most general terms.

3. Characteristic Requirements

3.1 The maximum insertion portion width shall not be larger

¹ This specification is under the jurisdiction of ASTM Committee F-29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.13 on Laryngoscopes and Bronchoscopes.

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² These terms, 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 the ...”.

³ Although the terms defined seem self-explanatory, different expressions for the same portion of the instrument are used by different manufacturers; hence, the appropriateness of a definition.

⁴ By defining external sizes as maximums and lumen sizes as minimums, sufficient instrument selection information will be provided to practitioners.

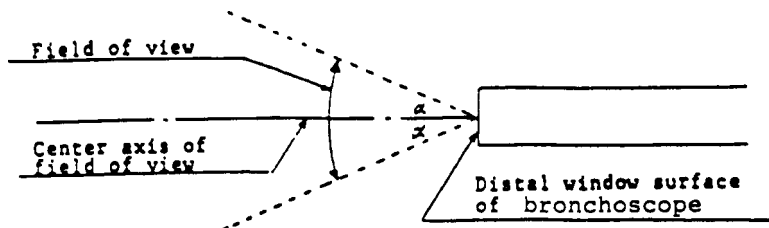


FIG. 1 Field of View

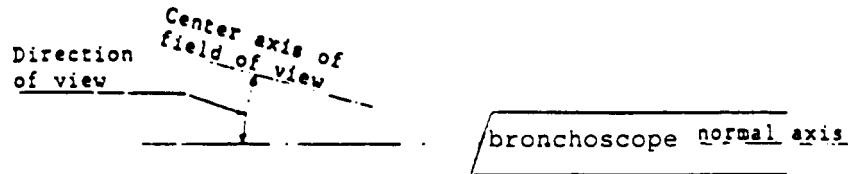


FIG. 2 Direction of View

than that stated by the manufacturer (see Note 1).

3.2 The minimum lumen width shall not be smaller than that stated by the manufacturer (see Note 1).

3.3 Insertion portion width and lumen width units shall be millimeters. Working length units shall be metric.

NOTE 1—These sizes are given to help the user to select the procedures which may be carried out with the instrument. Compatibility of instruments combination requires, however a certain clearance between the insertion portion width and the lumen width; the clearance required depending on the form, length and property of the instruments. There is no guarantee that the instruments combination selected solely by this criteria will be compatible.

3.4 Endoscopes and endoscopic accessories shall conform to relevant electrical safety standards.

NOTE 2—Users have reported that shocks and/or burns are a potential hazard when endoscopes and endoscopic accessories are connected to electromedical accessories such as electrosurgical units, pumps and light sources. Although electromedical accessories are beyond the scope of this standard, it is recognized that endoscopes, endoscopic accessories or portions thereof are conductors of or insulators from electrical energy; and, as such, can contribute to the reported hazard. As the need for explicit requirements becomes apparent, such requirements will be proposed for inclusion in subsequent revisions of this standard.

3.5 When tested in accordance with Section 4.2, a solid steel ball bearing, having a diameter equal to the minimum lumen width specified by the bronchoscope manufacturer, shall pass through the entire length of the operating lumen, while the bronchoscope is flexed to the minimum radius or maximum deflection angle specified by the manufacturer, with no applied force other than due to gravity. If any other lumen preconditioning is specified by the manufacturer such preconditioning shall also apply to this test (see Note 3).

NOTE 3—This requirement is intended to assure forceps passage during maximum deflection of the bronchoscope. According to a study performed by the Emergency Care Research Institute, difficulty in passing the forceps is a common problem which can degrade the procedure. (See above reference.) A ball bearing is used, in preference to forceps, because it isolates the effects due to collapse or deformation of the lumen from the effects due to stiffness of the forceps.

4. Test Methods

4.1 Dimensional characteristics:

4.1.1 The dimensional characteristics in 4 shall be verified by measuring instruments whose calibration is traceable to international standards.

NOTE 4—Specific test methods can impose real design constraints; however, test methods must be developed which can evolve over time into viable standard test methods. There must be some traceability of calibration of test instruments to standards in order to resolve issues of dimensional anomalies.

4.2 Forceps passage shall be tested as follows:

4.2.1 Attach the bronchoscope to the test fixture shown in Fig. 3. The bronchoscope should be positioned such that its controllable portion is flexed to the minimum radius or maximum deflection angle specified by the manufacturer.

4.2.2 If any other lumen preconditioning is specified by the manufacturer such preconditioning shall also apply to this test.

4.2.3 Rotate the fixture to the position which directs the proximal portion of the bronchoscope upward.

4.2.4 Place a solid steel ball bearing, having a diameter equal to the minimum lumen width specified by the bronchoscope manufacturer, within the proximal end of the lumen.

4.2.5 Rotate the fixture in the direction which would cause the bearing to pass through the bronchoscope, motivated only

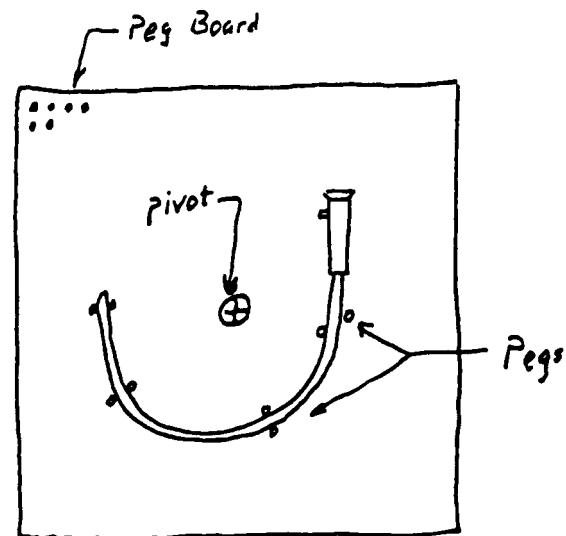


FIG. 3 Text for Forceps Passage