Designation: F 965 – 99

Standard Specification for Rigid Laryngoscopes for Tracheal Intubation—Hook-On Fittings for Laryngoscope Handles and Blades with Lamps [1]

This standard is issued under the fixed designation F 965; 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.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope

1.1 This specification covers critical dimensions and considerations for the junction of any blade and any handle of a hook-on type laryngoscope to allow engagement, lamp illumination, and disengagement through multiple cycles. An electrical lamp is fixed to the blade and supplied with energy through the handle.

1.2 This standard does not cover: (*1*) the blade form or handle design beyond the interchangeability aspects of the connection between the blade and the handle; (*2*) the measurement and specificiation of the lamp illumination intensity; and (*3*) disposable, flexible, or fiber-illuminated laryngoscopes designed for surgery.

1.3 The state-of-the-art of laryngoscope performance does not permit sufficient reproducibility to allow inclusion of mandatory force values in this standard; therefore, only recommended values have been provided.

1.4 The values stated in SI units are to be regarded as the standard.

2. Referenced Documents

2.1 *ANSI Standard:*

ANSI Y14.5 Dimensions and Tolerances[2]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *blade*—a separate rigid device to provide direct vision of the larynx, incorporating a hook-on base and a socket connection for a laryngoscope lamp and an electrical connection to the hook-on end.

3.1.2 *contacts*—conductive components of the hook-on fittings, both handle and blade, which come together to make an electrical circuit when the handle and blade are in the locked, operating position.

3.1.3 *engagement*—the blade and handle are engaged when the hinge pin is positioned against the closed end of the hinge slot, and remains coupled in all positions.

3.1.4 *folded position*—the position of the engaged blade when the tip of the blade is as close as possible to the handle.

3.1.5 *handle*—a separate, rigid device which is held in the hand during use, containing the hook-on connection that retains the blade and supplies electrical energy for the lamp.

3.1.6 *hinge*—the mechanical feature of the handle and blade that allows them to be engaged and disengaged. The hinge also allows the blade to be placed into the operating, folded, and all intermediate positions while engaged.

3.1.7 *hinge pin*—the component of the handle that inserts into the blade hinge slot.

3.1.8 *hinge slot*—the surfaces of the blade hook-on fitting that engage the hinge pin.

3.1.9 *locking mechanism*—the feature that retains the blade hook-on fitting in the operating position.

3.1.10 *locking slots*—the surfaces of the handle hook-on fitting that accept the locking surfaces of the blade hook-on fitting.

3.1.11 *locking surfaces*—the components of the blade locking mechanism that fit into the locking slots to resist the blade displacement from the normal operating position.

3.1.12 *operating position*—the position of the engaged blade and handle when the lamp is lit and the instrument is ready for use.

3.1.13 *retainer*—the surface, component, or feature of the blade hinge slot that retains the blade hook-on fitting to the handle hinge pin. The retainer maintains the engagement of the blade in the operating, folded, and all intermediate positions.

3.1.14 *seating surfaces*—the surface or surfaces of the blade hook-on fitting that contact the handle hook-on fitting to support the blade in the locked operating position.

4. Significance and Use

4.1 The primary objective of this specification is to ensure interchangeability concerning mechanical fit and electrical contact between the hook-on type handle and laryngoscope blade by specifying only the critical dimensions of the handle

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

hook-on fitting that affect interchangeability, and by designating the minimum performance requirements.

4.2 The secondary objective is to provide test procedures and values for performance.

5. Performance Requirements

5.1 *Hook-on Blade and Handle Fittings*—Detachable hook-on blade and handle combinations that engage shall lock and the lamp will light when in the operating position.

NOTE 1—For rationale statements for the performance requirements, see Appendix X1.

5.2 *Handle Fittings (Hook-On)*:

5.2.1 *Critical Dimensions*—Measurements shall be made with the accuracy and precision necessary to determine conformance with the dimensions specified in Fig. 1. The measurements shall be taken from datum plane A, datum B, and the hinge pin centerline. The total clearance between the width of the handle slot and the width of the blade hook-on fitting shall not exceed 0.011 in. (0.28 mm). Dimensions and configurations not shown shall be at the discretion of the manufacturer to ensure strength and safe operation. The method of dimensioning is in accordance with ANSI Y14.5.

5.2.2 *Electrical Contact*—The insulated central contact shall press against the central contact on the blade to maintain conductivity and ensure lamp illumination while in the operating position (see 5.9).

5.3 *Blade Fittings (Hook-On)*—Blade hook-on fittings shall engage the handle hook-on fitting as specified in Fig. 1 and 5.9. Typical blade hook-on fittings are shown in Fig. 2.

5.4 *Engagement, Hinge Slot*—The slot and hinge pin should engage when a force between 10 N and 45 N is applied. This force should be applied along the axis shown in Fig. 3 (Note 2).

5.5 *Blade Retention*—The retainer shall secure the hinge pin to the closed end of the blade hinge slot in all positions when the blade is in the engaged, folded position (see 5.10).

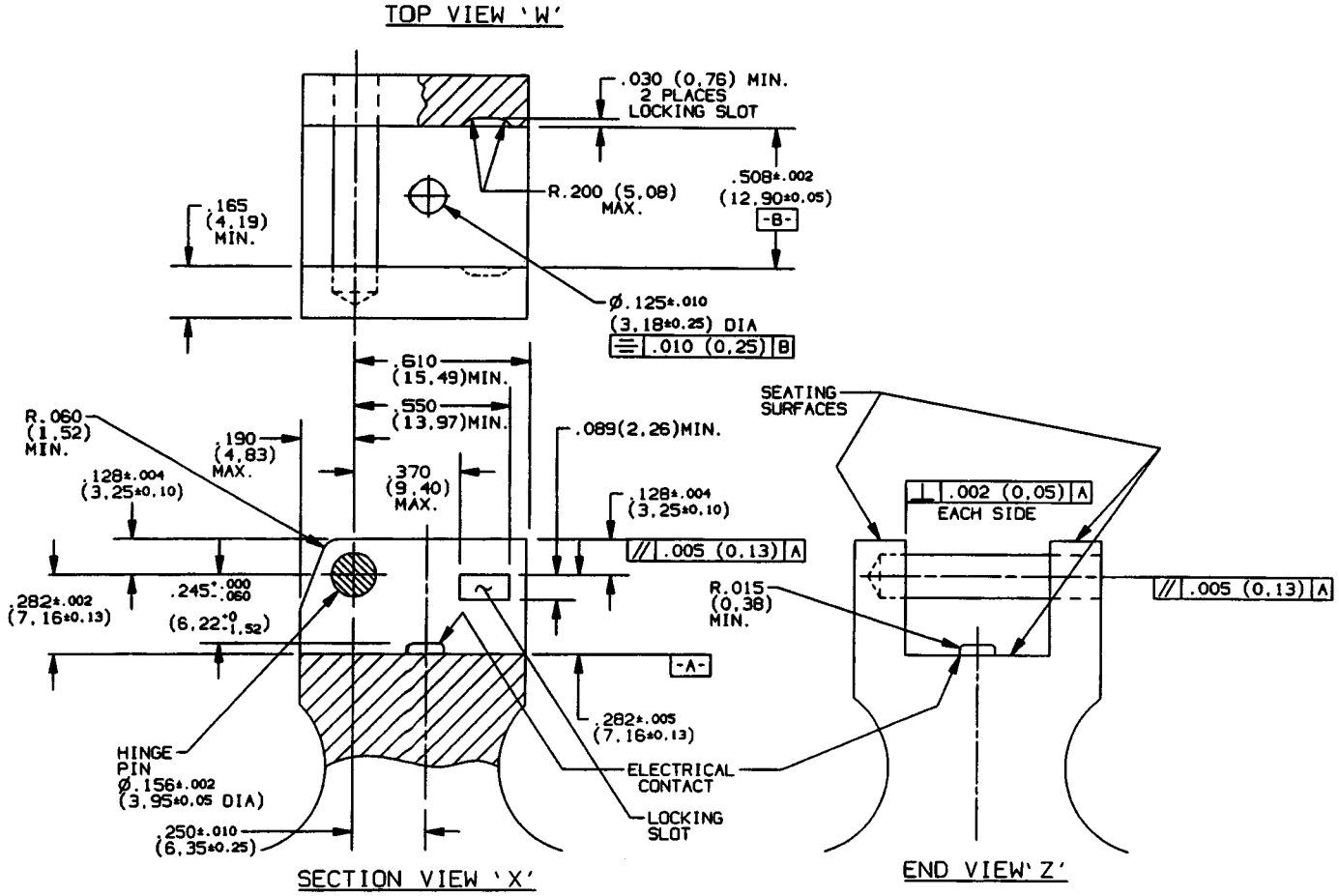
5.6 *Operating Position*:

5.6.1 *Locking*—Locking of the folded blade into the operating position should occur when a torque between 0.35 N · m and 1.35 N · m is applied to the blade.

5.6.2 *Unlocking*—Unlocking of the blade from the operating position to the folded position should occur when a torque between 0.25 N · m and 1.35 N · m is applied to the blade.

5.7 *Disengagement, Hinge Slot*—Disengagement of the folded blade from the handle and hinge pin should occur when a force between 10 N and 45 N is applied.

NOTE 2—The laboratory of the Defense Logistics Agency, Defense Personnel Support Center, Philadelphia, PA, constitutes the source for the data specified. Testing included components from various manufacturers,



NOTE 1—(*1*) Dimensions are in inches. Dimensions in parenthesis [( )] are in millimetres, (*2*) Datum A is the plane of the handle slot seating surfaces, and (*3*) Datum B is the width of the handle slot.

FIG. 1 Handle Hook-On Fitting

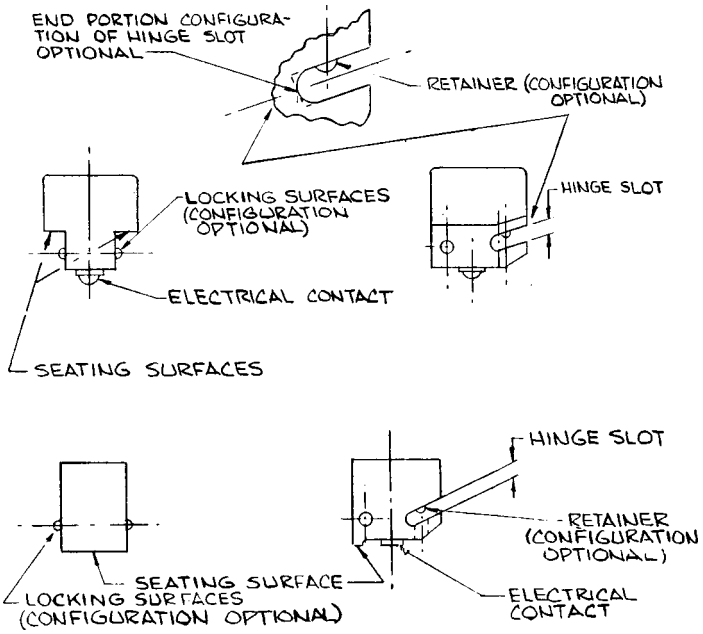


FIG. 2 Typical Blade Hook-On Fitting Configurations

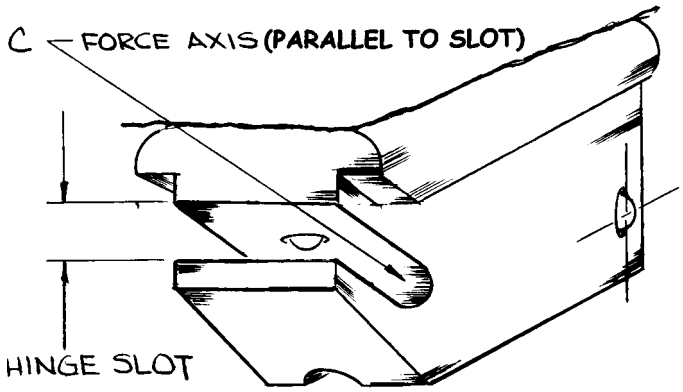


FIG. 3 Typical Blade Engagement/Disengagement Force Axis

totalling 25 blades of three types and two handles of different manufacture. Measurements were obtained by the use of a 60 g load cell with 10 lb adapter and universal transducer readout. The laboratory results were verified with a calibrated spring gage. Results showed that the slot and hinge pin should engage when a force of less than 44.5 N is applied, locking of the blade into operating position should occur when a force of 6.8 to 27.0 N (1.5 to 6.0 lbf) is applied to the blade at a distance of 4.5 to 5.0 cm from the centerline of the hinge pin, unlocking the blade from operating position should occur when a force of 4.5 to 27.0 N (1.0 to 6.0 lbf) applied to the blade at a distance of 4.5 to 5.0 cm from the centerline of the hinge pin, and disengagement of the folded blade from the handle and hinge pin should occur when a force of less than 44.5 N is applied.

5.8 *Corrosion Resistance*—Components should resist corrosion under conditions of normal use, including cleaning and disinfecting procedures as specified by the manufacturer.

5.9 *Hook-On Blade and Handle Fittings and Electrical Contacts*—The lamp shall light when the blade is placed into the operating position. Recommended engagement and locking values are specified in 5.3, 5.4, and 5.6.

5.10 *Blade Retention*—The mass of the engaged, unlocked blade shall not cause it to disengage from the hinge pin when the blade is held such that the open end of the hinge slot faces upwards and the hinge slot is vertical.

6. Marking and Labeling

6.1 All markings shall be legible and durable.

6.2 The name or trademark of the manufacturer shall be marked on the blade and on the handle in an area not less than 10 mm.[2] In addition, the size and type shall be marked on the blade (abbreviations shall be permitted).

6.3 Manufacturers shall provide information concerning cleaning and disinfecting procedures in the package.

7. Keywords

7.1 hook-on fitting; laryngoscope; laryngoscope blade; laryngoscope fitting; tracheal intubation

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE FOR PERFORMANCE REQUIREMENTS

X1.1 *Hook-On Blade and Handle Fittings (Section 5.1*)—This is required for patient safety at the time of laryngoscopy.

X1.2 *Critical Dimensions (Section 5.2.1*)—Critical dimensions of the handle hook-on fittings require precise description to allow interchangeability of different manufacturers' blades and handles, and to ensure rigidity and illumination during use.

X1.3 *Electrical Contact (Section 5.2.2*)—To ensure illumination during use, electrical contacts must be maintained.

X1.4 *Blade Fittings (Hook-On) (Section 5.3*)—Engagement is required to allow use of laryngoscope blades. Because a variety of blades and handles made by different manufacturers are used in clinical practice, all blades should engage all handles.

X1.5 *Engagement, Hinge Slot (Section 5.4*)—Repeated engagement and disengagement are required during clinical use.

X1.6 *Blade Retention (Section 5.5*)—In non-operating positions, retention of the slot on the hinge pin must be sufficient to prevent inadvertent disengagement.

X1.7 *Locking, Operating Position (Section 5.6.1*)—The engaged blade and handle should lock in a stable fashion to provide exposure and illumination of the larynx.

X2. RATIONALE FOR TYPICAL BLADE HOOK-ON FITTING CONFIGURATIONS

X2.1 *Fig. 2*—This figure illustrates two types of laryngoscope blade hook-on fittings. The figure is not for manufacturing or design purposes, but illustrates some typical configurations that permit engagement of the blade and handle hook-on fittings.