



Standard Specification for Rigid Laryngoscopes for Tracheal Intubation—Hook on Fittings for Fiberilluminated Blades and Handles¹

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INTRODUCTION

In clinical anesthesia and resuscitation a variety of laryngoscopes are used. Because there is a clinical need for a variety of blade forms, they are manufactured as detachable blade and handle units. In the interest of patient safety, defined dimensions and performance standards are necessary. The aim of this specification is to ensure compatibility of rigid, folding, fiber-illuminated blades and handles within a given system without restricting innovation or design.

1. Scope

1.1 The purpose of this specification is to ensure that reusable, detachable fiber-illuminated hook-on blade and handle combinations that engage shall lock and illuminate when in the operating position.

1.2 Dimensions and tolerances of fiber-illuminated systems shall be provided.

1.3 This specification provides methods of identifying by color the various fiber-illuminated systems and compatible blades and handles within the system.

1.4 This specification covers reusable handles and blades. It does not cover disposable components or systems.

1.5 Nonfiber-illuminated blades and handles with the lamp in the blade shall conform to Specification F 965.

2. Referenced Documents

2.1 ASTM Standards:

F 965 Specification for Rigid Laryngoscopes for Tracheal Intubation—Hook-On Fittings for Laryngoscope Handles and Blades with Lamps²

2.2 Federal Standard:

FED-STD-595A Colors³

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

³ Available from the Naval Publications and Forms Center, 5801 Tabor Ave., Philadelphia, PA 19120.

3. Terminology

3.1 *Descriptions of Terms*—In addition to the terms defined in Specification F 965, the following terms are defined:

3.1.1 *fiber-illuminated laryngoscope blade, n*—a blade which utilizes optical fibers to transmit light from a source in the handle.

3.1.2 *fiber-illumination handle, n*—a hand-held rigid device which provides a power source for illumination of a fiber-illuminated blade. It shall include the light source.

3.1.3 *contact/switch, n*—components of the hook-on fittings, both handle and blade, which come in contact to energize the light source when the blade and handle are in the locked, operating position.

3.1.4 *engagement, n*—the blade and handle are engaged when mechanically attached and the blade remains coupled to the handle in all positions.

3.1.5 *operating position, n*—the position of the engaged blade and handle when illumination is produced and the instrument is ready for use.

4. Performance Requirements

4.1 *Blade and Handle Fittings*—Detachable fiber-illuminated blade and handle combinations that engage shall lock and illuminate when in the operating position, and shall have the same color identification (see Section 7).

4.2 *Mechanical Restrictions*—Fiber-illuminated blades shall be mechanically incompatible with nonfiber-illuminated handles to prevent engagement (see Specification F 965).

4.3 *Blade Retention*—The blade shall be retained on the handle in all attitudes when engaged.

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

4.5 *Critical Dimensions*—All handle hook-on fittings shall conform to the dimensions of one of the systems described by Fig. 1 and Fig. 2. The hook-on blade fitting must engage, lock, and operate at any tolerance specified within any one of the Fig. 1 and Fig. 2. The total clearance between the width of the handle slot and the blade hook-on fitting shall not exceed 0.011 in. (0.28 mm).

4.6 *Component Compatibility*—A handle and blade hook-on fitting which engage shall lock and illuminate. This feature shall also apply to handles which engage either nonfiber-illuminated or fiber-illuminated blades.

5. Marking and Labeling

5.1 All markings shall be legible and durable.

5.2 The name or trademark of the manufacturer shall be marked on the blade fitting and on the handle in an area not less than 10 mm². In addition, the blade shall be marked with its size, type, country of origin, and either s/s, or stainless, if made of stainless steel.

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

5.4 Any removable fiber-optic components should be marked to indicate type and size.

6. Test Methods and Values

6.1 *Illumination*—The blade shall illuminate whenever placed in the operating position.

6.2 *Engagement and Locking*—Engagement and locking values are specified in Appendix X2.

6.3 *Blade Retention*—The engaged blade shall not disengage from the handle in any position because of its mass.

6.4 *Locking-Operating Position*—Locking of the blade into the operating position should occur when a reasonable force is applied (see Test Methods, Appendix X2.1).

6.5 *Unlocking—Operating Position*—Unlocking of the blade from the operating position should occur when a reasonable force is applied (see Test Methods, Appendix X2.2).

7. Identification of Compatible Systems

7.1 Compatible system components shall be identified by identical colors (see Appendix X3).

7.2 *Handle Identification*—Handles for fiber-illuminated systems shall be identified by a circumferential band of a color distinct from the handle. The band shall be located between the hook-on fitting and the midpoint of the handle. The width shall be 0.197 ± 0.079 (5 mm ± 2 mm).

7.3 *Blade Identification*—Blades shall be color coded by means of a mark on the heel of the blade or on light guide as specified in Appendix X3 (see Fig. 3). The mark shall be clearly visible when the rigid laryngoscope is in the operating

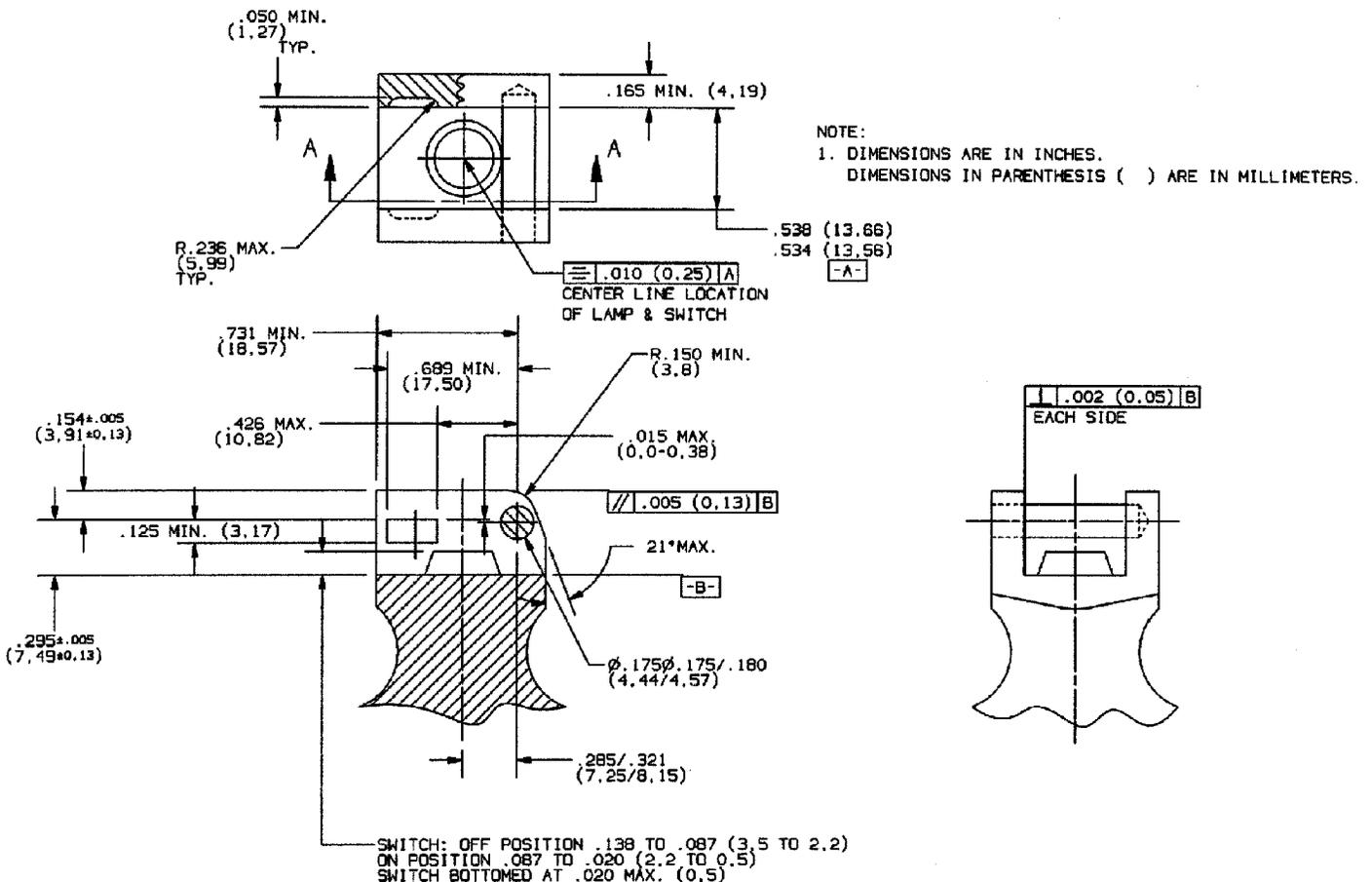
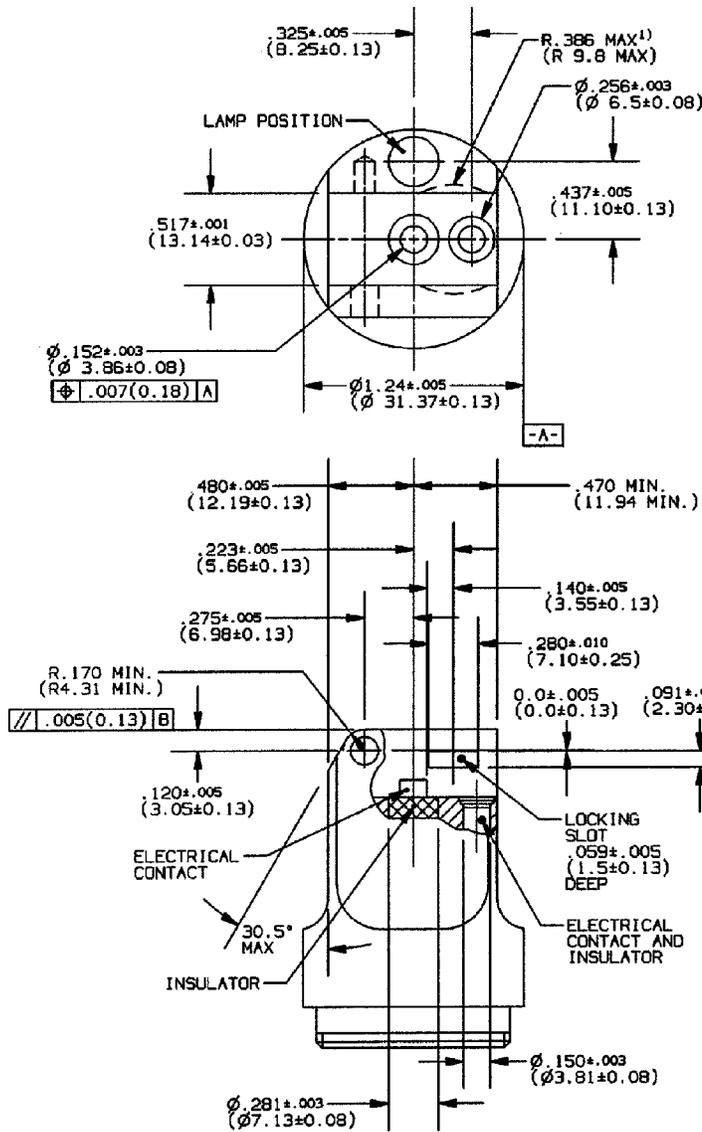
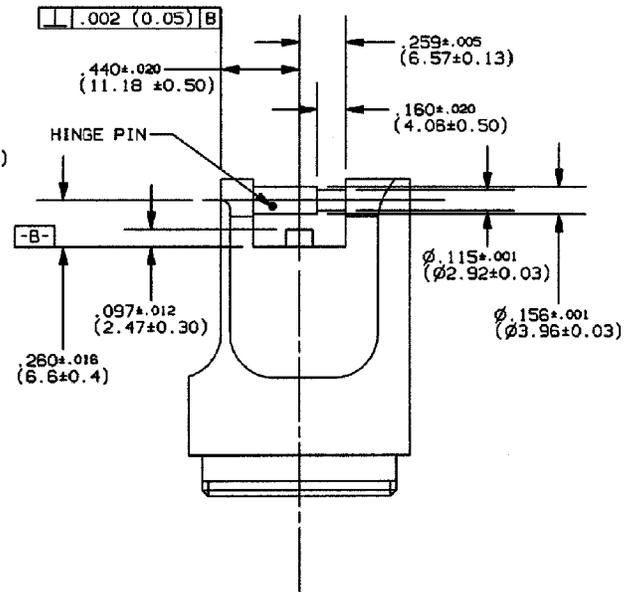


FIG. 1 Handle Hook-on Configuration for Green System



NOTE:
1. DIMENSIONS ARE IN INCHES.
DIMENSIONS IN PARENTHESIS () ARE IN MILLIMETERS.



1) SHAPE OF SLOT TO SUIT

FIG. 2 Handle Hook-on Configuration for Blue System

position. The size of the mark shall not be less than 10 mm². In addition to the marking on the blade, if the fiber-illuminated component is detachable, it shall also be color marked, and such color marking should be visible when the laryngoscope is in the operating position.

NOTE 1—These marks should be resistant to friction, cleaning, handling, and sterilization.

8. Addition of New Systems

8.1 Any system of hook-on fitting which is incompatible with fittings included in this specification, but otherwise

complies with this specification, shall be assigned a color for markings distinct from those previously assigned (see Appendix X3).

9. Keywords

9.1 intubation; laryngoscope; tracheal intubation

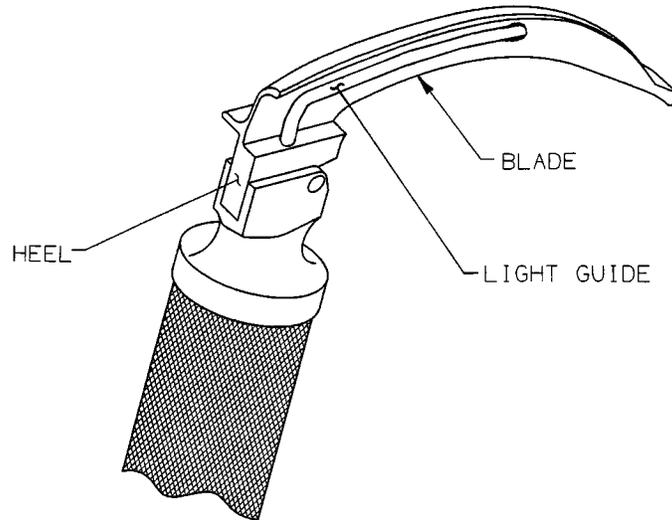


FIG. 3 Schematic Showing Heel of Blade

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 *Blade and Handle Fittings* (4.1)—This is required for patient safety at the time of laryngoscopy.

X1.2 *Mechanical Restrictions* (4.2)—This is required for patient safety at the time of laryngoscopy.

X1.3 *Blade Retention* (4.3)—In nonoperating positions retention of the slot on the hinge pin must be sufficient to prevent inadvertent disengagement.

X1.4 *Corrosion Resistance* (4.4)—Corrosion may cause inadequate electrical and mechanical performance.

X1.5 *Critical Dimensions* (4.5)—The handle hook-on fittings require precise description to ensure compatibility of blades and handles within a given system.

X1.6 *Component Compatibility* (4.6)—In the interest of patient safety, handles and blades which engage should lock and illuminate.

X1.7 *Marking and Labeling* (Section 5)—Legible and durable markings of the manufacturer's trademark, the size, and the type of the blade are necessary to ensure easy identification of the blade by the user. Also, see Section 7. Removable components should be marked to facilitate proper reassembly.

X1.8 *Test Methods and Values* (Section 6)—A major goal of this specification is to ensure that fiber-illuminated components which engage shall lock and illuminate. Further, the components shall engage and disengage with reasonable force in the interest of patient safety at the time of laryngoscopy.

X1.9 *Identification of Compatible Systems* (Section 7)—Identification is necessary to facilitate rapid and accurate recognition of compatible handle and blade components.

X1.10 *Addition of New Systems* (Section 8)—Development of new systems necessitates a mechanism for inclusion in this specification.

X2. TEST METHODS AND VALUES

X2.1 *Locking—Operating Position*—Locking of the 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.

X2.2 *Unlocking—Operating Position*—Unlocking of the blade from the operating position should occur when a torque

between 0.25 N•m and 1.35 N•m is applied to the blade.

X2.3 *Engagement and Disengagement*—Engagement or disengagement of the blade from the handle should occur when a force between 10 N and 45 N is applied (see Fig. X2.1 and Specification F 965).

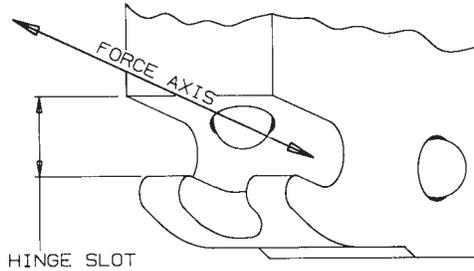


FIG. X2.1 Schematic of Force Axis During Locking and Unlocking

X3. COLOR MARKINGS

X3.1 The systems designated in 7.3 are assigned the following colors:

Fig. 1—green
Fig. 2—blue

X3.2 Color assignment in accordance with FED-STD-595A is as follows:

green—38901
blue—15180

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