



Designation: F2407/F2407M – 23a

Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities¹

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INTRODUCTION

Healthcare workers can be exposed to biological fluids capable of transmitting diseases. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne pathogens, such as Hepatitis (Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)) and Human Immunodeficiency Virus (HIV). Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential of direct skin contact with microorganisms, body fluids, and other potentially infectious materials through the use of protective apparel.

Healthcare protective clothing, including surgical gowns, is worn by healthcare workers to protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and other contaminants from one person to another.

This specification addresses the performance of surgical gowns designed to preserve the sterile field and/or protect against exposure of healthcare workers to blood, body fluids, and other potentially infectious materials during surgery and other healthcare procedures.

This specification establishes uniform testing and reporting requirements for surgical gown manufacturers in order to provide information to end users that can be used in making informed decisions in the selection and purchase of surgical gowns according to the anticipated exposures. This information is also useful for helping end users comply with the Occupational Safety and Health Administration's blood-borne pathogen standard (29 CFR 1910.1030).

1. Scope

1.1 This specification establishes requirements for the performance, documentation, and labeling of surgical gowns used in healthcare facilities. Four levels of barrier properties for surgical gowns are specified in ANSI/AAMI PB70 and are included in this specification for reference purposes.

NOTE 1—Some properties require minimum performance and others are for documentation only.

NOTE 2—ANSI/AAMI PB70 evaluates the barrier properties of surgical gown fabrics using water only in Levels 1, 2, and 3. Since surgical gowns are exposed to blood and other fluids with different surface tensions, the performance of additional testing to identify the barrier levels to simulated biological fluids is required for a Level 4 gown.

¹ This specification is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.40 on Biological.

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1.2 This specification does not cover all the requirements that a healthcare facility deems necessary to select a product, nor does it address criteria for evaluating experimental products.

1.3 This specification is not intended to serve as a detailed manufacturing or purchase specification, but can be referenced in purchase specifications as the basis for selecting test requirements.

1.4 The values stated in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.

1.5 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

- D751 Test Methods for Coated Fabrics
- D1683/D1683M Test Method for Failure in Sewn Seams of Woven Fabrics
- D1776/D1776M Practice for Conditioning and Testing Textiles
- D4966 Test Method for Abrasion Resistance of Textile Fabrics (Martindale Abrasion Tester Method)
- D5034 Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- D5587 Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
- D6701 Test Method for Determining Water Vapor Transmission Rates Through Nonwoven and Plastic Barriers
- E96/E96M Test Methods for Gravimetric Determination of Water Vapor Transmission Rate of Materials
- F1154 Practices for Evaluating the Comfort, Fit, Function, and Durability of Protective Ensembles, Ensemble Elements, and Other Components
- F1494 Terminology Relating to Protective Clothing
- F1868 Test Method for Thermal Resistance, Evaporative Resistance, and Total Heat Loss Measurements of Clothing Materials Using a Sweating Hot Plate
- F3050 Guide for Conformity Assessment of Personal Protective Clothing and Equipment
- F3352/F3352M Specification for Isolation Gowns Intended for Use in Healthcare Facilities

2.2 AAMI Documents:³

- ANSI/AAMI PB70 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Healthcare Facilities
- ANSI/AAMI ST65 Processing of Multiple-Use Surgical Textiles for Use in Healthcare Facilities
- AAMI TIR11 Selection of Surgical Gowns and Drapes in Healthcare Facilities
- ANSI/AAMI BE78 Biological Evaluation of Medical Devices, Part 10: Test for Irritation and Sensitization

2.3 AATCC Standards:⁴

- AATCC 42 Water Penetration Resistance: Impact Penetration Test
- AATCC 127 Water Resistance: Hydrostatic Pressure Test

2.4 ANSI/ASQ Standards:⁵

- ANSI/ASQ Z1.4 Sampling Procedures and Tables for Inspection by Attributes
- ANSI/ASQ Z1.9 Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming

2.5 ISO Standards:⁶

- ISO 2859-1 Sampling Plans for Inspection by Attributes
- ISO 3951 Sampling Procedures and Charts for Inspection by Variables for Percent Nonconforming
- ISO 9001 Quality Management Systems—Requirements
- ISO 9073-10 Textiles—Test Methods for Nonwovens—Part 10: Lint and Other Particles Generation in the Dry State
- ISO 10993-5 Biological Evaluation of Medical Devices—Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-7 Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-10 Biological Evaluation of Medical Devices—Part 10: Tests for Skin Sensitization
- ISO 10993-23 Biological Evaluation of Medical Devices—Part 23: Tests for Irritation
- ISO 11134 Sterilization of Healthcare Products—Requirements for Validation and Routine Control—Industrial Moist Heat Sterilization
- ISO 11135 Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization
- ISO 11137 Sterilization of Healthcare Products—Requirements for Validation and Routine Control—Radiation Sterilization
- ANSI/AAMI/ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes
- ISO 13683 Sterilization of Healthcare Products—Requirements for Validation and Routine Control of Moist Heat Sterilization in Healthcare Facilities
- ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories
- ISO/IEC 17026 Conformity Assessment—Example of a Certification Scheme for Tangible Products

2.6 Federal Standards:

- 16 CFR 1610 Standard for the Flammability of Clothing Textiles, Federal Register, Vol 40, No. 59891, Dec. 30, 1975⁷
- 16 CFR 1611 Standard for the Flammability of Vinyl Plastic Film, Federal Register, Vol 40, No. 59891, Dec. 30, 1975⁸
- 21 CFR 801.437 User Labeling for Devices That Contain Natural Rubber⁹
- 21 CFR 820 Subpart K Labeling and Packaging Control,

⁵ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁶ Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, <http://www.iso.org>.

⁷ Available at <https://www.ecfr.gov/current/title-16/chapter-II/subchapter-D/part-1610>.

⁸ Available at <https://www.ecfr.gov/current/title-16/chapter-II/subchapter-D/part-1611>.

⁹ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.437>.

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 Available from the Association for the Advancement of Medical Instrumentation, 110 North Glebe Road, Suite 220, Arlington, VA 22201.

⁴ Available from American Association of Textile Chemists and Colorists (AATCC), One Davis Dr., P.O. Box 12215, Research Triangle Park, NC 27709-2215.