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Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities¹

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^{ε1} NOTE—Reapproved with the editorial removal of year dates from referenced documents in May 2013.

INTRODUCTION

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.

Healthcare workers can be exposed to biological fluids capable of transmitting disease. 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.

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 the healthcare facilities. Four levels of barrier properties for surgical gowns are specified in 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—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.

1.2 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*

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responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

2.1 ASTM Standards:²

- D751 Test Methods for Coated Fabrics
- D1683 Test Method for Failure in Sewn Seams of Woven Apparel Fabrics
- D1776 Practice for Conditioning and Testing Textiles
- D5034 Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- D5587 Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
- D5733 Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure (Withdrawn 2008)³
- D6701 Test Method for Determining Water Vapor Transmission Rates Through Nonwoven and Plastic Barriers (Withdrawn 2008)³
- F1494 Terminology Relating to Protective Clothing
- F1671 Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
- F1868 Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate

2.2 AAMI Documents:⁴

- AAMI PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities
- AAMI ST65 Processing of multiple-use surgical textiles for use in health care facilities
- AAMI TIR11 Selection of Surgical Gowns and Drapes in Healthcare Facilities
- AAMI/ANSI BE78 Biological Evaluation of Medical Devices, Part 10: Test for Irritation and Sensitization

2.3 AATCC Standards:⁵

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

2.4 ANSI/ASQC Standard:⁶

- ANSI/ASQC Z1.4 Sampling Procedures and Tables for Inspection by Attributes

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 non-conforming

- ISO 9073 Part 10 Textiles—Test methods for nonwovens—Part 10: Lint and other particles generation in the dry state
- ISO 10993-10 Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity

- 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

- ISO 13683 Sterilization of healthcare products—Requirements for validation and routine control of moist heat sterilization in healthcare facilities

2.6 Federal Standards:⁷

- 16 CFR 1610 Standard for the Flammability of Clothing Textiles, Federal Register, Vol. 40, No. 59891, Dec. 30, 1975
- 21 CFR Parts 801.437 and 878.4040 Surgical Apparel, Federal Register, Vol. 63, No. 318, Nov. 12, 1998, pp. 63247.
- 29 CFR Part 1910.1030 Occupational Exposure to Blood-borne Pathogens: Final Rule, Federal Register, Vol. 66, No. 12 / Thursday, January 18, 2001.

3. Terminology

3.1 Definitions:

3.1.1 *bloodborne pathogen, n*—an infectious bacterium or virus, or other disease-inducing microbe carried in blood or other potentially infectious body fluids.

3.1.1.1 *Discussion*—For the purpose of this test method, the primary blood-borne pathogens include Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Other microorganisms must be considered on a case-by-case basis.

3.1.2 *body fluid, n*—any liquid produced, secreted, or excreted by the human body.

3.1.2.1 *Discussion*—In this specification, body fluids include liquids potentially infected with blood-borne pathogens, including, but not limited to, blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid and peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids (see 29 CFR Part 1910.1030).

3.1.3 *critical zone(s), n*—area of a gown where direct contact with blood, body fluids, and other potentially infectious materials is most likely to occur.

3.1.3.1 *Discussion*—Annex B of AAMI PB70 provides examples of barrier classification for surgical gowns based on the critical zone(s). The critical zone can encompass multiple parts of the garment.

⁷ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

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 The last approved version of this historical standard is referenced on www.astm.org.

⁴ Available from the Association for the Advancement of Medical Instrumentation, 110 North Glebe Road, Suite 220, Arlington, VA 22201.

⁵ Available from American Association of Textile Chemists and Colorists (AATCC), One Davis Dr., P.O. Box 12215, Research Triangle Park, NC 27709-2215.

⁶ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

3.1.4 *critical zone component, n*—any element, constituent, or item incorporated into the critical zone, including the materials, seams and attachments.

3.1.4.1 *Discussion*—Seams at the boundary between the critical and non-critical zones are not considered parts of the critical zone(s).

3.1.5 *flammability, n*—those characteristics of a material that pertain to its ignition and support of combustion.

3.1.6 *healthcare protective clothing, n*—protective clothing used in a healthcare setting.

3.1.7 *multiple-use, adj*—refers to an item of protective clothing that is intended to be used several times with appropriate care of the protective clothing item between use.

3.1.7.1 *Discussion*—In this specification, multiple-use protective clothing is subject to cleaning (laundering) and sterilization between each use.

3.1.8 *other potentially infectious materials, n*—any materials, other than blood or body fluids, containing blood-borne pathogens or materials that have been linked with the potential transmission of infectious disease.

3.1.9 *protective clothing, n*—an item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard; or isolating the external environment from contamination by the wearer of the clothing.

3.1.9.1 *Discussion*—Examples of protective clothing include surgical gowns, isolation gowns, decontamination garments, aprons, sleeve protectors, and certain types of laboratory coats. The primary purpose of the protective clothing is to act as a barrier between the wearer and a hazard. However, the product may also offer protection as a barrier, which prevents the body from being a source of contamination.

3.1.10 *single use, adj*—refers to an item of protective clothing that is intended to be used once and then disposed.

3.1.10.1 *Discussion*—In this specification, single use protective clothing is subject to sterilization prior to use per the manufacturer's instructions.

3.1.11 *surgical gown, n*—protective clothing that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate matter.

3.1.11.1 *Discussion*—This definition is consistent with the definition provided by the U.S. Food and Drug Administration (21 CFR 878.4040) except that the word “device” is used instead of protective clothing.

3.2 For definitions of other protective clothing-related terms used in this test method refer to Terminology **F1494**.

4. Significance and Use

4.1 This specification provides requirements for surgical gowns used for protection of healthcare workers where the potential for exposure to blood, body fluids, and other potentially infectious materials exists. The specification requires barrier testing based on the system of classifying gowns established in AAMI PB70 and sets general safety require-

ments for surgical gowns based on biocompatibility, sterility assurance, and flame spread. Documentation and reporting requirements are set for important physical properties including tensile strength, tear resistance, seam strength, linting resistance, evaporative resistance testing, and water vapor transmission rate.

4.2 This specification does not address protective clothing used for non-surgical applications, such as isolation gowns or decontamination gowns; protective clothing for the hands, such as surgical gloves, patient examination gloves, or other medical gloves; protective clothing for the head, such as goggles or face shields, surgical caps or hoods, surgical masks, or respirators; protective clothing for the feet, such as operating room shoes, shoe covers, or surgical boots; or other types of protective clothing and equipment worn by health care providers.

4.3 Surgical gowns are either multiple-use or single-use products as designated by the manufacturer. This specification is intended to provide the basis for manufacturer claims for surgical gown performance and efficacy. For multiple-use gowns, this specification takes into account the anticipated care and maintenance of these products, by examining test requirements for surgical gown materials both before and after the maximum expected number of cycles for laundering and sterilization.

4.4 Additional information on the processing of multiple-use surgical gowns is provided in AAMI ST65.

4.5 While surgical gowns are classified for barrier performance as specified in AAMI PB70, this specification establishes certain other physical performance and documentation requirements for surgical gowns and their materials. Design requirements and recommendations are also provided for surgical gowns.

4.6 Additional information for the testing, selection, and use of surgical gowns is provided in AAMI TIR11.

NOTE 3—Information on barrier classes in AAMI TIR11 does not currently match the levels established in AAMI PB70. However, AAMI TIR11 provides other useful information that is intended to aid in the selection and use of surgical gowns.

5. Design Requirements

5.1 Surgical gowns shall be designed to comply with the barrier performance requirements of AAMI PB70.

5.2 Surgical gowns which are intended for reuse shall have affixed or attached a means for marking or recording the number of laundering and sterilization cycles to which the specific item has been subjected.

5.3 The sizes of the critical zone(s) of a surgical gown shall be defined by anatomical reference in accordance with AAMI PB70.

6. General Safety and Performance Requirements

6.1 Biocompatibility

6.1.1 Materials used in the construction of surgical gowns shall be classified as external devices that contact breached or compromised surfaces for limited exposures and shall pass the

appropriate evaluations in accordance with AAMI/ANSI BE78. Alternatively, ISO 10993-10 is permitted to be used.

6.2 Sterility assurance level

6.2.1 The selected sterilization process for surgical gowns shall have a sterility assurance level of at least 10⁻⁶.

NOTE 4—Appropriate sterilization processes include those specified in ISO 11134 for moist heat, ISO 11135 for EtO, ISO 11137 for Gamma or ISO 13683 also for moist heat.

6.3 Flame spread

6.3.1 Materials used in the construction of surgical gowns shall meet the requirements for Class 1 “normal flammability” in accordance with 16 CFR Part 1610 before and after the conditioning specified in Section 9.

6.4 Natural Rubber Latex

6.4.1 Gowns that contain natural rubber latex should include the latex caution statement CFR 801.437, “THIS PRODUCT CONTAINS NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTION.” (See 11.2.1 Labeling requirements)

7. Barrier and Physical Property Requirements

7.1 The barrier performance of the critical zone(s) of the surgical gown shall be tested and classified as specified in AAMI PB70. (See Table 1.)

7.2 The physical properties of the critical zone(s) of the surgical gown shall be tested and reported as specified in Table 2.

8. Sampling

8.1 Sample size shall be sufficient to establish an acceptable statistical confidence interval for the property being measured.

NOTE 5—Examples of acceptable sampling plans are found in references such as ANSI/ASQC Z1.4, ISO 2859-1 and ISO 3951.

8.2 Material specimens shall be removed from manufactured surgical gowns and conditioned in accordance with Section 9.

8.2.1 Specimens for testing may be performed on material roll goods or fabricated seam samples if it can be demonstrated that the samples are representative of the actual finished gowns.

9. Conditioning

9.1 *General Requirements*—Testing used for demonstrating performance of surgical gowns shall be conducted after ambient conditioning on both single and multiple-use products as specified in 9.2. For surgical gowns where the manufacturer is claiming continued barrier performance after multiple uses, or

if laundering/sterilization is required before use, then testing shall also be conducted after the maximum number of cycles of washing/drying (9.3) and sterilization (9.4) specified by the manufacturer.

9.2 *Ambient Conditioning*—All specimens shall be conditioned at a temperature of 21 ± 3°C [70 ± 5°F] and relative humidity of 65 ± 5 % for at least 24 h in accordance with Practice D1776, unless otherwise specified by the selected test method.

9.3 *Laundering Conditioning*—Specimens from multiple-use surgical gowns shall be laundered using the manufacturer’s recommended washing and drying procedures. These procedures shall conform to AAMI ST65. The total number of washing and drying cycles specified in the manufacturer’s claims shall be used.

9.4 *Sterilization*—If specimens are not removed from sterile surgical gowns, specimens from surgical gowns shall be sterilized using the manufacturer’s recommended sterilization process and specific sterilization cycle parameters (for example, time, temperature, sterilant concentration, humidity, etc.). If surgical gowns also require laundering, sterilization of specimen surgical gowns shall be performed following each laundering cycle as specified in 9.3. The total number of sterilization cycles specified in the manufacturer’s claims shall be followed.

10. Test Methods (Refer to Table 2)

10.1 *Barrier Performance*—Determine the barrier performance in accordance with AAMI PB70.

10.2 *Tensile Strength*—Determine the tensile strength of each material in the critical zone(s), except for fastening elements (for example, hook and loop closure tape, snaps, belts, ties, and cuffs), used in the construction of the surgical gown as specified in Test Method D5034, following the conditioning specified in Section 9. Where multiple, separable layers of materials are used in the construction of surgical gowns, the combination of all material layers shall be tested. Report the average tensile strength for each material direction.

10.3 *Tear Resistance*—Determine the tear resistance of each material in the critical zone(s), except for fastening elements (for example, hook and loop closure tape, snaps, belts, ties, and cuffs), used in the construction of the surgical gown as specified in Test Method D5587 (woven) using Option 1 to calculate the tearing force, or Test Method D5733 (nonwovens), following the conditioning specified in Section 9. Where multiple, separable layers of materials are used in the construction of surgical gowns, the combination of all material layers shall be tested. Report the average tear resistance for each material direction.

TABLE 1 Classification of Surgical Gown Barrier Performance based on AAMI PB70

Barrier Performance	Test Method	AAMI PB70 Barrier Classification			
		Level 1	Level 2	Level 3	Level 4
Impact Penetration	AATCC 42	<4.5 g AQL 4.0	<1.0 g AQL 4.0	<1.0 g AQL 4.0	^A
Hydrostatic Resistance	AATCC 127	^A	>20 cm AQL 4.0	>50 cm AQL 4.0	^A
Viral Penetration Resistance	ASTM F1671	^A	^A	^A	Pass AQL 4.0

^ANot required for this level.

TABLE 2 Physical Property Documentation Requirements (Documentation Only)^A

Performance Property	Test Method	Section	Reported Data
Tensile strength ^B	ASTM D5034	11.3	Average tensile strength each material direction ^C
Tear resistance ^B	ASTM D5587 (woven); ASTM D5733 (non-woven)	11.4	Average tearing force each material direction ^C
Seam Strength	ASTM D751 (stretch woven or knit)	11.5	Average seam strength for each seam type in the critical zone(s)
Lint Generation ^D	ISO 9073 Part 10	11.6	Particle count for each side, unless material is the same on each side
Evaporative resistance ^E or	ASTM F1868 , Part B	11.7	Average evaporative resistance for both critical and non-critical zone(s)
Water vapor transmission rate ^E	ASTM D6701 (nonwoven and plastic barrier materials)	11.8	Average water vapor transmission rate for both critical and non-critical zone(s)

^AAppendix X1 provides a description of each method, its intended application, and limitations.

^BMeasurement of tensile and tear strength properties may not be indicative of snag or puncture resistance. There are no generally accepted test methods for snag or puncture resistance available at this time.

^CThis specification follows industry practice for reporting strength properties in both material directions (warp and fill, machine and cross-machine, or wales and course as specified by the manufacturer) to provide the end user with a comparison of material performance because a material may have different strengths associated with each direction of its manufacture.

^DResults from lint testing are highly operator and equipment dependent. It is recommended that data be collected using a single piece of equipment, using a single operator, and on the same day to minimize variability.

^EThis specification permits reporting either evaporative resistance or water vapor transmission rate. Appendix X1 provides a comparison of the two methods with their respective procedures, application, and limitations. Garment comfort is a function of several factors, including but not limited to, fabric “breathability,” garment design, weight, fabric stiffness, the degree of garment fit on the individual wearer, and other possible individual wearer preferences (for example, noise, odor). Due to the complexity of these factors the best assessment of overall gown comfort can be made through actual wear tests. Measuring the breathability of the fabrics used to construct surgical gowns is one method of predicting thermal comfort. Those gowns that are designed and constructed of materials which more freely allow evaporation of perspiration and body heat transfer provide better thermal comfort. When gowns are constructed or reinforced with different materials in the critical and non-critical zones then testing the breathability of all the materials is important to help gain an understanding of the impact of overall garment design on thermal comfort. Comparisons of breathability between different surgical gowns (or gown materials) should only be made using the same test method. Also included in Appendix X1 are other potential factors that can affect comfort.

10.4 Seam Strength—Determine the seam strength of surgical gown woven or nonwoven materials, and materials that incorporate woven or nonwoven fabric layers, as specified in Test Method **D1683** following the conditioning specified in Section 9. Determine the seam strength of surgical gown knit or stretch woven materials as specified in Test Method **D751**, using the tension testing machine with ring clamp, following the conditioning specified in Section 9. Where multiple, separable layers of materials are used in the construction of surgical gowns, the combination of all material layers shall be tested. Report the average seam strength for each type of seam used in the critical zone of the surgical gown.

10.5 Lint Generation—Determine the lint generation of each side of each material used in the construction of the surgical gowns as specified in ISO 9073 Part 10, using a 5-min test time, following the conditioning specified in Section 9. If the surface for each side of the material is the same, it shall be permitted to test only one side.

10.6 Evaporative Resistance—Determine evaporative resistance of the materials or composites in the critical zone and non-critical zone, exclusive of cuffs and attachments, as specified in Test Method **F1868**, Part B. Where multiple, separable layers of materials are used in the construction of surgical gowns, the combination of all material layers shall be tested. When multiple, separable layers of materials are used in the construction of surgical gowns, the combination of all material layers shall be tested. Separately report the average evaporative resistance for critical zone and non-critical zone materials or composites.

10.7 Water Vapor Transmission Rate—Determine the water vapor transmission rate of materials or composites in the critical zone and non-critical zone, exclusive of cuffs and attachments, as specified in Test Method **D6701**. When multiple, separable layers of materials are used in the construction

of surgical gowns, the combination of all material layers shall be tested. Separately report the average water vapor transmission rate for the critical zone and non-critical zone materials or composites.

NOTE 6—Either evaporative resistance (10.6) or water vapor transmission rate (10.7) are tested.

11. Labeling Requirements

11.1 Product Labeling—Each surgical gown item shall be prominently labeled with the following information:

11.1.1 Manufacturer name.

11.1.2 Product or style name.

11.1.3 The barrier performance level for the surgical gown as classified by AAMI PB70.

11.1.4 Product lot or serial number.

NOTE 7—The product lot or serial number applies to either individually manufactured surgical gowns or to groups or lots of manufactured surgical gowns, and serves as a means for tracing the manufacture of products.

11.1.5 Size.

11.2 Package Labeling—Each package containing surgical gowns shall be prominently labeled with the same information as required in 11.1 including the lot number, unless the same lot number is used for identifying all products in the package. The following additional information shall be provided on the packaging labeling.

11.2.1 If the gown contains natural rubber latex, it must be labeled with a caution statement (See 6.4). If the gown and its components are composed of materials that are free from natural rubber latex, it is optional for this information to be on a label.

12. Technical Information

12.1 When requested by the purchaser, the following technical information shall be provided:

12.1.1 Manufacturer address and phone number.

12.1.2 Detailed information on the performance of all areas of the critical zone(s).

NOTE 8—Suggested forms of this information are a graphical presentation of the product showing the level of barrier performance of each component, a narrative description of the level of barrier performance of each component or both.

12.1.3 The results of each test used for the performance properties of materials and seams for the surgical gown based on this specification.

12.1.4 For multiple-use products, processing instructions, including a statement of the number of times that the product can be processed and continue to maintain its safety and performance characteristics.

12.1.5 For multiple-use products, instructions on inspections that can be performed by processors to verify the continued safety and effectiveness of the product.

12.1.6 A statement indicating compliance of the surgical gown with this specification, including the number, year or issue, and revision letter.

13. Sizing

13.1 A description of the manufacturer's sizing system indicating the range of wearer dimensions for which the specific size is intended shall be provided.

NOTE 9—An example of a sizing system is the lists of specific surgical gown sizes provided by the manufacturer and the respective range in wearer height and girth that is accommodated by each size.

14. Keywords

14.1 barrier performance; critical zone; healthcare; hydrostatic pressure; impact penetration; physical properties; protective clothing; surgical gown; viral penetration resistance

APPENDIXES

(Nonmandatory Information)

X1. DESCRIPTION, APPLICATION, AND LIMITATIONS OF PHYSICAL PROPERTIES REPORTED FOR DOCUMENTATION PURPOSES

X1.1 **Table X1.1** provides a description, the intended application, and limitations of the physical properties listed in

Table 2 in this specification, which are used for documentation purposes.

TABLE X1.1 Description, Application, and Limitations of Physical Properties Reported for Documentation Purposes

Performance Property	Description	Application and Limitations
Tensile strength ^{A,B} (ASTM D5034)	A 100-mm [4.0-in.] wide specimen is mounted centrally in 50-mm [2.0-in.] clamps of a tensile testing machine and a force applied until the specimen breaks. Values for the breaking force and the elongation of the test specimen are obtained from machine scales, dials, autographic recording charts, or a computer interfaced with the testing machine.	Tensile strength is reported in pounds force (lbf) or Newtons (N). A higher reported tensile strength indicates a stronger material.
Tear resistance ^{A,B} (ASTM D5587, Option 1 for woven fabrics, and ASTM D5733 for nonwoven fabrics)	An outline of an isosceles trapezoid is marked on a rectangular material specimen. The specimen is slit at the base of the small side of the trapezoid to start the tear. The non-parallel sides of trapezoid marked on the specimen are clamped into parallel grips of a tensile testing machine. The separation of the jaws is continually increased to apply a force to propagate the tear along the specimen. At the same time, the force developed is recorded. The force to continue the tear is calculated from autographic chart recorders or microprocessor data collection systems. Option 1 uses the average of the five highest measured forces as the reported tear resistance. The procedure for testing nonwoven materials is identical except that the maximum recorded force is reported as the tear resistance.	Tear resistance is a measurement of the ease with which a fabric can be torn apart. Tear resistance is reported in pounds force (lbf) or Newtons (N). A higher reported tear resistance indicates a stronger material.
Seam strength (ASTM D1683 for woven and nonwoven materials; ASTM D751 for stretch woven and knit materials)	For woven and nonwoven materials, the strength of a seam is measured in the same way as material tensile strength. The applied force is longitudinal and perpendicular to the seam. A force is applied until seam failure occurs. An observation is made whether the break occurs at the seam or in the material adjacent to the seam. For stretch woven and knit materials, the burst strength is measured. A specimen, with the sewn seam bisecting it, is securely clamped without tension between grooved, circular plates of the ball burst attachment secured to the pulling (movable) jaw for the constant-rate-of-traverse (CRT) testing machine. A force is exerted against the specimen by a polished, hardened steel ball that is attached to the pendulum-actuating (fixed) clamp of the machine, until rupture occurs.	Seam strength is reported in pounds force (lbf) or Newtons (N). A higher reported seam strength indicates stronger seams, that are less likely to separate or break open when garments are strained through use.
Linting (ISO 9073 Part 10)	This test uses a device which subjects a rectangular material specimen to a combined twisting and compression action in a test chamber. During the flexing, air is withdrawn from the chamber and particulates in the air stream are counted and classified in a particle counter. Depending on the choice of counter, the size ranges can fall within the limits of 0.3 or 0.5 to 25 micron particle sizes.	The particles that are counted during the test may be airborne debris (dust) or fragments from fibers, binders or other process treatments. Higher particle counts indicate materials that lint more readily. Reproducibility is only moderate in absolute numbers but rankings are very reproducible, particularly when testing is conducted at the same laboratory for the materials that are being compared. Comparison between materials must be made for the same range of particle size.
Evaporative resistance (ASTM F1868, Part B)	The test involves a guarded hot plate that is heated to skin temperature, saturated with water, and covered with a permeable material that allows vapor to pass through, simulating human sweating. The hot plate and specimen are placed in an atmospheric chamber, where the air temperature, relative humidity, and air velocity are tightly controlled. First, the resistance to evaporation of water vapor is measured for the bare plate. Then a test is conducted with the material specimen on top of the plate. The evaporative resistance is measured by relating the power needed by the plate for maintaining a constant temperature to the difference in water vapor pressure in the atmospheric chamber and the pressure at the plate surface.	Evaporative resistance is intended to be a measurement of material comfort. Test results are reported in pascal meters squared per watt (Pa m ² /W). Lower values of evaporative resistance indicate materials that permit a higher amount of water vapor to go through (under test conditions). This test permits evaluation and discriminates performance among all fabrics, films, coating, and multilayered material systems; however, some extremely lightweight, single layer materials may show artificially high values if the material does not maintain contact with the plate.
Water vapor transmission resistance rate (ASTM D6701)	A dry chamber, guard film, and a wet chamber make up a diffusion cell in which the material is sealed. A first test is made of the water vapor transmission rate of the guard film and air gap between an evaporator assembly that generates 100 % relative humidity. A sensor produces an electrical signal, the amplitude of which is proportional to water vapor concentration. The electrical signal is routed to a computer for processing. The computer calculates the transmission rate of the air gap and guard film and stores the value for further use. The material is then sealed in the test cell and the apparatus started in the test mode. As before, the electrical signal representing the water vapor is sent to the computer which then calculates the transmission rate of the combination of the air gap, the guard film, and the test barrier. The computer then uses this information to calculate the water vapor transmission rate of the material being tested. The computer determines when the measured results indicate that the specimens have reached equilibrium values and when the testing is considered finished.	Water vapor transmission rate is intended to be a measurement of material comfort. Test results are reported in grams of water vapor per square metre of fabric per day (g/m ² /day). Higher water vapor transmission rates indicate materials that allow greater water vapor transfer through the material (under test conditions). This test is generally applied to nonwoven fabrics and plastic barrier materials; however it does not discriminate performance of multilayer material systems.

^AThese properties are reported in the two directions based on the way the material is made—one value represents the direction parallel to the roll (warp or machine direction); the other direction represents the direction perpendicular to the roll (fill or cross machine direction).

^BMeasurement of tensile and tear strength properties may not be indicative of snag or puncture resistance. There are no generally accepted test methods for snag or puncture resistance available at this time.

X2. OTHER IMPORTANT FACTORS

X2.1 The following characteristics are considered important, but there are no tests available for their validation.

X2.1.1 If present on surgical gowns, the neckline closure should close easily and properly in donning, stay secure during wearing and open easily for removal.

X2.1.2 All types of waist closures should remain securely closed during wearing. The tie card assembly should allow easy aseptic transfer, for closure and tying. Ties should allow for ease of gown removal.

X2.1.3 The gown should be folded and packaged in such a way that the size and level of barrier performance is visible and can be picked up and donned aseptically.

X2.1.4 The surgical gown should be constructed with appropriate amount of stitching and construction adhesive so that the gown can be opened up freely and easily donned.

X2.1.5 The surgical gown should have no visible tears, cuts, holes, excessive stains or excessive patches.

X2.1.6 The surgical gown should contain no visible foreign matter such as dirt, grease, extraneous fabric or thread on the surface of the gown or folded into the gown.

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