

# Surgical drape and gown barrier classifications

## Overview of AAMI PB70:2003

### Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities

For a complete copy of AAMI PB70:2003, visit [www.aami.org](http://www.aami.org).

As established by the Association for the Advancement of Medical Instrumentation

FDA recognized as of October 1, 2004

This standard establishes a classification system and associated minimum requirements for protective apparel and drapes used in healthcare facilities based on their liquid barrier performance.

By specifying a consistent basis for testing and labeling protective apparel and drapes, and providing a common understanding of barrier properties (e.g., efficacy against liquid or liquidborne microorganism penetration), this new classification system should assist healthcare personnel in determining the most appropriate product for the anticipated task.<sup>1</sup>

Surgical gowns, surgical drapes, drape accessories and other protective apparel are devices intended to promote infection control practices and help protect patients and healthcare personnel. Barrier efficacy has long been recognized as important in helping to prevent infections and is now mandated by Occupational Safety and Health Administration (OSHA) regulations limiting occupational exposure to bloodborne pathogens (29 CFR 1910.1030). The CDC *Guideline For Prevention of Surgical Site Infection* also sets forth the recommendation that drapes and gowns be impermeable to liquids and viruses.<sup>2</sup>

The level of barrier protection needed depends primarily on the potential for exposure to blood, body fluids and OPIM. The classification of barrier performance associated with this standard is based on the hierarchy of risks associated with the anticipated blood, body fluid, OPIM or other liquid volume involved in the type and duration of procedure or activity being performed.



# Classification levels of barrier performance

## Level 1 Gowns and Drapes

Describes surgical gowns, other protective apparel, surgical drapes and drape accessories that demonstrate the ability to resist liquid penetration in a laboratory test, AATCC 42 (Water resistance: Impact penetration test).

## Level 2 Gowns and Drapes

Describes surgical gowns, other protective apparel, surgical drapes and drape accessories that demonstrate the ability to resist liquid penetration in two laboratory tests, AATCC 42 (Water resistance: Impact penetration test) and AATCC 127 (Water resistance: Hydrostatic pressure test).

## Level 3 Gowns and Drapes

Describes surgical gowns, other protective apparel, surgical drapes and drape accessories that demonstrate the ability to resist liquid penetration in two laboratory tests, AATCC 42 (Water resistance: Impact penetration test) and AATCC 127 (Water resistance: Hydrostatic pressure test). For Level 3, the test criterion for AATCC 127 performance is set at a higher value than for Level 2.

## Level 4 Gowns

Describes surgical gowns and protective apparel that demonstrate the ability to resist liquid and viral penetration in a laboratory test, ASTM F1671 (Standard 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).

## Level 4 Drapes

Describes surgical drapes and drape accessories that demonstrate the ability to resist liquid penetration in a laboratory test, ASTM F1670 (Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood).

Level	Test	Result
1	AATCC 42 Water Impact (WI)	≤ 4.5g
2	AATCC 42, WI AATCC 127 Hydro Head (HH)	≤ 1.0g ≥ 20cm
3	AATCC 42, WI AATCC 127, HH	≤ 1.0g ≥ 50cm
4	ASTM F1671, Gowns ASTM F1670, Drapes	Pass Pass

**Table 1: Classification of barrier performance of surgical gowns, other protective apparel, surgical drapes and drape accessories.**

The more stringent tests of this standard, ASTM F1670 and ASTM F1671, involve the use of body fluid and bloodborne pathogens simulants according to time and pressure protocols that have been found to discriminate a higher level barrier performance in the laboratory setting.

The less stringent tests, AATCC 42 and AATCC 127, involve the use of indirect (splash or spray) and direct contact with water according to time and pressure protocols.

**Note:** This classification system is intended to set a common foundation for the different levels of barrier protection available but does not take into account potential variations in specific procedures and techniques used in healthcare facilities. The end user is the ultimate judge of the appropriateness of the barrier level required, based on experience and the potential or known exposure risks.

## Critical Zones

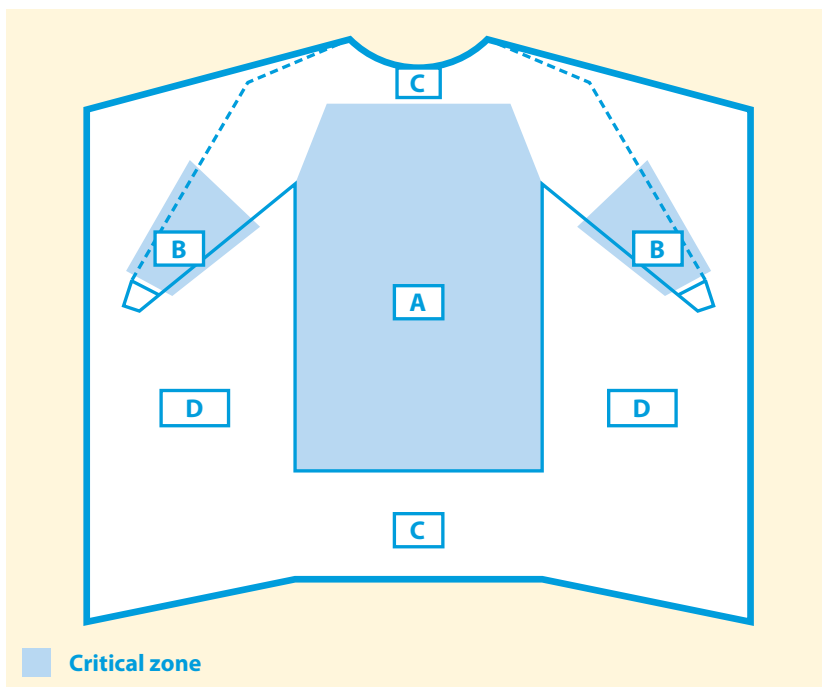
The barrier requirements for the design and construction of surgical gowns, other protective apparel, surgical drapes and drape accessories are based on the anticipated location and degree of liquid contact, given the expected conditions of use. The critical zones include those areas where direct contact with blood, body fluids and OPIM is most likely to occur, although areas outside of the critical zones can inadvertently be splashed or sprayed as well.

### Surgical Gowns

The entire front of a gown (areas A, B and C), including the seam and other components, is required to meet the minimum level of barrier performance (Level 1). Since the back of a gown (area D) is expected to stay dry, there is no liquid barrier performance requirement for that area. The critical zone of the surgical gown is comprised of at least areas A and B. The classification of the surgical gown is based on the lower performing component of the two.

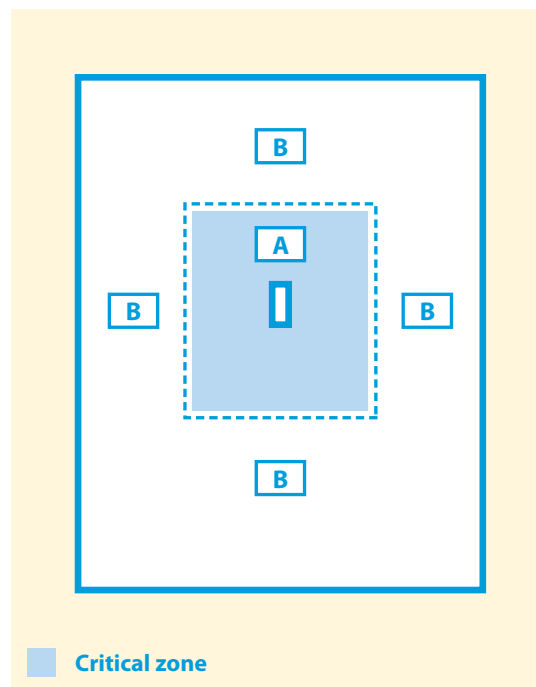
### Surgical Drapes

Because of the variation in patient size, patient positioning and draping technique, as well as the possible expansion of the surgical site or field during the procedure, the entire drape (areas A and B) is required to meet at least the minimum level of barrier performance (Level 1). The critical zone of a surgical drape is comprised of area A.



**Example of a surgical gown intended for surgical applications**

**A: Critical Zone – front**  
**B: Critical Zone – sleeve**  
**C: Front**  
**D: Back**



**Example of a surgical drape**

**A: Critical Zone**  
**B: Body**

- 1 *Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*, Association for the Advancement of Medical Instrumentation, ANSI/AAMI PB70:2003.
- 2 Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention (1999); Mangram, et. al. (1999). *Guideline for Prevention of Surgical Site Infection*, 1999. *Infection Control and Hospital Epidemiology*, Volume 20, Number 4, 247-278.

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Cardinal Health  
Clinician Apparel and Patient Protection  
1500 Waukegan Road  
McGaw Park, IL 60085

[cardinalhealth.com](http://cardinalhealth.com)