

Let AAMI Be Your Guide to Better Protection.

This document is based on ANSI/AAMI PB70:2003 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for use in Health Care Facilities. This guideline assists health care workers select the appropriate protective apparel for a particular task. To learn more and read a full copy of the standard, visit the AAMI website at: www.aami.org.

What is AAMI?

The Association for the Advancement of Medical Instrumentation (AAMI) is a unique alliance of professionals and organizations dedicated to the understanding and beneficial use of medical device technology. AAMI members include health care institutions, research and teaching facilities, government agencies, manufacturers, test houses, trade associations and individual health care professionals.

AAMI and its members have assumed an important leadership responsibility in medical device standards worldwide and often set the standards of practice. Standards of practice are developed to prevent and minimize injury or death to patients by providing clear, universally accepted guidelines for safe use of equipment, medical devices, instruments or processes.

AAMI PB70:2003, “Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.”

The AAMI Protective Barriers Committee recently established standard PB70, “Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.” This standard creates a system of classification and minimum requirements based on liquid barrier performance for protective apparel and drapes used in health care facilities. The guideline specifies a reliable method for testing and labeling protective apparel and provides an understanding of barrier properties to assist health care personnel select the appropriate product for a particular task. Four laboratory tests are used to identify and understand liquid barrier properties: Spray Impact Penetration Test, Hydrostatic Head Test, ASTM F1670 and ASTM F1671.

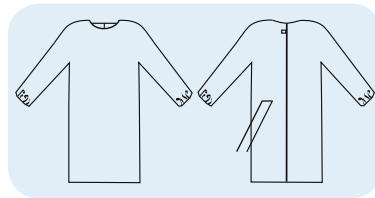
This classification system is intended to set a common foundation for the different levels of barrier protection available but does not take into account variations in procedures and techniques used in health care facilities. The end-user must determine the barrier level required for a procedure based on experience and the potential exposure risk.¹

1. Association for the Advancement of Medical Instrumentation (AAMI). Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Arlington, VA:AAMI, 2003.

AAMI Classification Levels of Barrier Performance

The AAMI PB70:2003 standard establishes four levels of barrier performance and the testing required for each level. An isolation gown that is not classified as Level 1 or higher is deemed non-protective. The entire isolation gown, including the front, back, sleeves and seams are considered critical zones.

Level	Test	Result	Exposure Risk
1	Spray Impact Penetration	≤ 4.5 g	Low
2	Spray Impact Penetration Hydrostatic Pressure	≤ 1.0 g ≥ 20 cm	↕
3	Spray Impact Penetration Hydrostatic Pressure	≤ 1.0 g ≥ 50 cm	
4	ASTM F1671 (Gowns) ASTM F1670 (Drapes)	Pass Pass	High



CRITICAL ZONES: Front, Back, Sleeves, Seams

Tests

AATCC 42 - Impact Penetration Test

The Spray Impact Penetration Test measures the resistance of fabrics to liquid penetration by water spray impact. These test results predict barrier performance of an isolation gown, including critical zones, when fluids spray or splash onto it.

AATCC 127 - Hydrostatic Pressure Test

The Hydrostatic Head Pressure Test measures the resistance of fabrics to liquid penetration by water under constantly increasing hydrostatic pressure.

ASTM F1670 - Synthetic Blood Test for Surgical Drapes and Drape Accessories

ASTM F1670 standard test method for resistance of materials to penetration of synthetic blood.

ASTM F1671 - Bacteriophage Test for Surgical Gowns and Other Protective Apparel

ASTM F1671 standard test method for resistance of materials to penetration of synthetic blood and blood-borne pathogens using PHI-X174 bacteriophage.

Critical Zones

Protective apparel and drapes shall be classified and labeled according to the barrier performance of their critical zones. A critical zone is an area where direct contact with blood, body fluids and other potentially infectious materials (OPIM) is most likely to occur. **For isolation gowns, the entire gown including the front, back, sleeves and seams is considered the critical zone and must have a barrier performance of at least Level 1.** This requirement is due to the unpredictable nature of potential contact with blood, body fluids and OPIM in isolation applications.

Encompass Medical offers two isolation gowns that meet AAMI Level 1 performance testing: 46969-087 and 46969-187.



Gowns: 46969-187 and 46969-087

Catalog #	Description	Material	Coverage	Impact Penetration AATCC 42
46969-087	Isolation Gown, Yellow	Tri-Layer Composite	Fluid Resistant	< 4.5 g
46969-187	Isolation Gown, Blue	Tri-Layer Composite	Fluid Resistant	< 4.5 g