

AAMI Guidelines: Know More to Protect Better

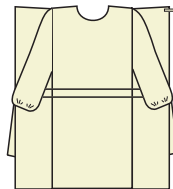
Information in this document is based on ANSI/AAMI PB70:2003, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for use in Health Care Facilities. These new performance guidelines can help healthcare workers safeguard themselves and their patients by choosing the most protective apparel. Learn more about this important industry standard.



Announcing AAMI Liquid Barrier Protection Classifications: Kimberly-Clark Wants You to Know More

An objective benchmark in barrier protection is now available. It's a system of classification for protective apparel and drapes used in healthcare settings based on liquid barrier performance. The guidelines were developed by the Association for the Advancement of Medical Instrumentation (AAMI). They specify a consistent basis for testing protective apparel and provide a common understanding of barrier properties, such as efficacy against strike-through of blood and fluids. There are four tests that must be performed in order to establish the final AAMI classification: Spray Impact Penetration Test; Hydrostatic Head Test; ASTM F1670; ASTM F1671. The Spray Impact Test is performed to determine if the product is protective or nonprotective. The Hydrostatic Pressure Test result indicates the level of protection from 1-3. Finally, for those products that are required to be fully impervious, the ASTM F1670 and ASTM F1671 are to be performed.

The AAMI guidelines provide a reliable benchmark to help determine the types of protection most appropriate for a particular task or clinical situation. As such, it can help purchasers make more objective decisions, and may increase compliance with OSHA Bloodborne Pathogen and other relevant regulations.



The entire isolation gown, including seams but excluding cuffs, hems and bindings, is required to have a barrier performance of at least Level 1.



**Below Level 1
is considered
non-protective.**

**Most
Protective**

Spray Impact Penetration Test Results

The Spray Impact Penetration Test measures the resistance of fabrics to liquid penetration by water spray impact. Results help predict barrier performance of the isolation gown's critical zones and indicate how well the gown will perform when fluids fall or splash onto it. Although every area on an isolation gown is considered a critical zone, the seams are typically the weakest point. When analyzing results from this test, higher numbers indicate lower fluid resistance.²

PRODUCTS TESTED:

3 lots each of the following product lines:

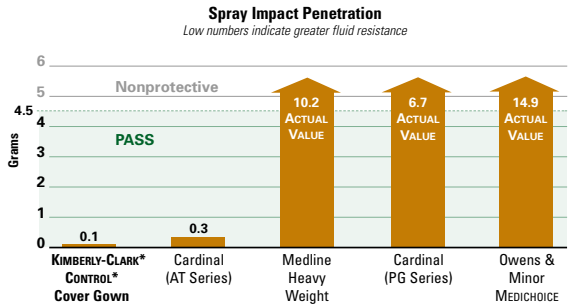
- KIMBERLY-CLARK* CONTROL* Cover Gown
- Cardinal SMS Isolation Gowns (AT Series), SMS
- Medline Heavy Weight SMS Isolation Gown
- Cardinal Fluid-resistant tri-layer SMS cover gowns (PG Series)
- Owens & Minor MEDICHOICE Heavier Weight SMS Gowns

WHY IS THIS TEST IMPORTANT?

This test is important because it simulates resistance to pressure spray or splash of fluids in a clinical setting. This type of "arterial spurting" is often seen when an artery of a blood vessel is inadvertently compromised or damaged during tasks such as blood draw, I.V. changes and injections.

CONCLUSIONS:

For the best protection against the danger of high pressure fluid spraying, choose an isolation gown with the highest fluid resistant properties. It is imperative that both the gown fabric and seams provide high fluid resistance. **Out of all the products tested, KIMBERLY-CLARK CONTROL Cover Gowns performed the best in the Spray Impact Penetration Test. KIMBERLY-CLARK CONTROL Cover Gowns were the only isolation gown that had the highest fluid resistance in both gown fabric and gown sleeve seams.**



Spray Impact Penetration
Test Results

KIMBERLY-CLARK* CONTROL* Cover Gown	PASS
Cardinal (AT Series)	PASS
Medline Heavy Weight	Nonprotective
Cardinal (PG Series)	Nonprotective
Owens & Minor MEDICHOICE	Nonprotective

Hydrostatic Head Test Results

The Hydrostatic Head Test measures the resistance of fabrics to liquid penetration by water under constantly increasing hydrostatic pressure. Results help predict barrier performance properties of the isolation gown's critical zones and indicate how well the gown will perform when fluid pressure is applied to it. Although every area of an isolation gown is a critical zone, the seams are the area of most concern. When analyzing results from this test, a higher millibar value indicates greater resistance to water penetration.²

PRODUCTS TESTED:

3 lots each of the following product lines:

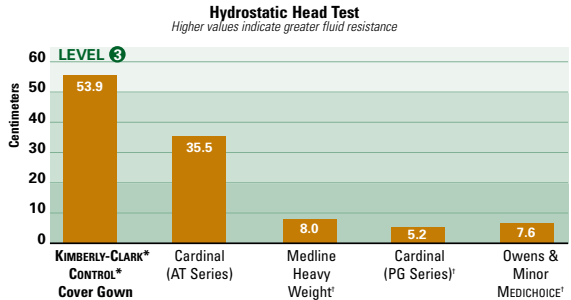
- KIMBERLY-CLARK* CONTROL* Cover Gown
- Cardinal SMS Isolation Gowns (AT Series), SMS
- Medline Heavy Weight SMS Isolation Gown
- Cardinal Fluid-resistant tri-layer SMS cover gowns (PG Series)
- Owens & Minor MEDICHOICE Heavier Weight SMS Gowns

WHY IS THIS TEST IMPORTANT?

This test is important because it simulates resistance to liquid penetration in a clinical setting. Many procedures involve irrigation fluids, tissue fluids, or other liquids. An isolation gown with high fluid resistance will provide barrier protection against the fluids even when pressure is applied. For example, the healthcare worker's arm or torso may lean or rest against contaminated fluids during a procedure.

CONCLUSIONS:

For the best protection against the danger of fluid penetration, choose an isolation gown with the highest fluid resistant properties. It is imperative that both the gown fabric and seams provide high fluid resistance. **Out of all the products tested, KIMBERLY-CLARK CONTROL Cover Gowns performed the best in the Hydrostatic Head Test. KIMBERLY-CLARK CONTROL Cover Gowns were the only isolation gown that had the highest fluid resistance in both gown fabric and gown sleeve seams.**



Hydrostatic Head Test

AAMI Rating

KIMBERLY-CLARK* CONTROL* Cover Gown	Level 3
Cardinal (AT Series)	Level 2
Medline Heavy Weight	Nonprotective [†]
Cardinal (PG Series)	Nonprotective [†]
Owens & Minor MEDICHOICE	Nonprotective [†]

[†] Does not pass the Spray Impact Penetration Test.

AAMI Classifications

Four classification levels have been established.

Within each category, standardized test methods and minimum performance levels have been determined for gowns, drapes and other protective apparel.

Level 1: When tested for impact penetration, critical zone components must have a blotter weight gain of no more than 4.5 grams.

Level 2: When tested for impact penetration and hydrostatic pressure, critical zone components must have a blotter weight gain of no more than 1.0 grams and a hydrostatic resistance of at least 20 cm.

Level 3: When tested for impact penetration and hydrostatic pressure, critical zone components must have a blotter weight gain of no more than 1.0 grams and a hydrostatic resistance of at least 50 cm.

Level 4: When tested for resistance to Bacteriophage Phi-X174, critical zone components must show an AQL of 4%.

Level	Test	Result
1	AATCC 42 (Spray Impact Test)	≤ 4.5g
2	AATCC 42 AATCC 127 (Hydrostatic Pressure Test)	≤ 1.0g ≥ 20cm
3	AATCC 42 AATCC 127	≤ 1.0g ≥ 50cm
4	ASTM F1670 <i>(Synthetic Blood Test for Drapes and Drape Accessories Only)</i>	Pass
	ASTM F1671 <i>(Bacteriophage Test for Surgical Gowns and Other Protective Apparel)</i>	Pass

Key Points

1. These levels apply to the product's Critical Zones.
2. The entire isolation gown, including seams but excluding cuffs, hems and bindings, is required to have a barrier performance of at least Level 1.
3. Products that are not at least Level 1 are considered non protective.

REFERENCE LIST:

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
2. **AMERICAN ASSOCIATION OF TEXTILE CHEMISTS AND COLORISTS.** Water resistance: Impact penetration test. AATCC 42. Research Triangle Park (NC): AATCC, 2000.
2. **AMERICAN ASSOCIATION OF TEXTILE CHEMISTS AND COLORISTS.** Water resistance: Hydrostatic pressure test. AATCC 127. Research Triangle Park (NC): AATCC, 1998.

DEFINITIONS:

Critical zone – Area of protective apparel where direct contact with blood, bodily fluids, and OPIM is most likely to occur.

Hydrostatic pressure – Pressure exerted by water at rest.

Millibar – A unit of atmospheric pressure equal to 1/1000 bar (1 mbar) and equal to 1.02 centimeters.

Other potentially infectious materials (OPIM) – Any materials, other than blood or bodily fluids, containing bloodborne pathogens or materials that have been linked with the potential transmission of infectious disease.

Penetration – Movement of matter, on a nonmolecular level, through porous materials, closures, seams, or imperfections (e.g., pinholes) in a protective product.

Seam – Area at which two or more pieces of material are joined together. NOTE: Many types of seams can be formed, including conventional needle-and-thread, adhesive, welded, and “false” seams.

Standard deviation - A statistic used as a measure of the dispersion or variation in a distribution, equal to the square root of the arithmetic mean of the squares of the deviations from the arithmetic mean.



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