

**Barrier Performance According to AAMI PB70**

Medical Textiles Network and Biocomplexity Workshop  
University of California, Davis  
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P. Brown, W. L. Gore & Associates, Inc.

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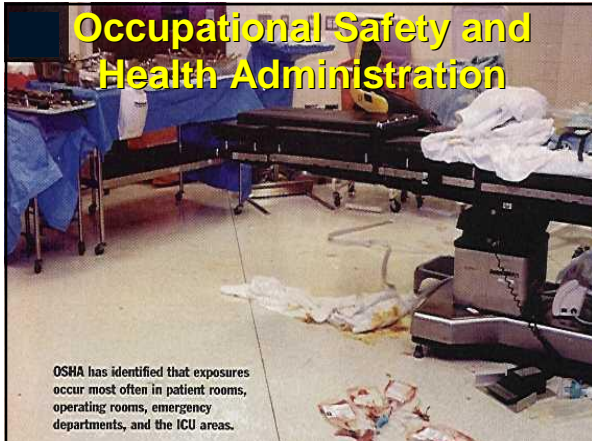
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**Occupational Safety and Health Administration**

OSHA has identified that exposures occur most often in patient rooms, operating rooms, emergency departments, and the ICU areas.

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**FDA**

**Medical Device Regulations**

- ✦ AAMI PB70 is formally recognized by FDA
- ✦ AAMI PB70 is the basis for new barrier claims/labeling

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## Standards and Recommended Practices

- ✦ Endorsed by AORN & included in recommended practices
- ✦ Endorsed by APIC

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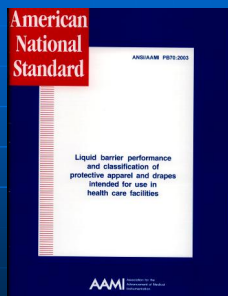
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## AAMI PB70



*Voluntary Standard*

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## Purpose

- ✦ Establish minimum performance requirements with a uniform classification system to help end-users select the most appropriate protective barrier products for the intended application

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## AAMI PB70

- ▶ Reusable & Disposable
- ▶ Drapes and Protective Apparel With Barrier Claims
- ▶ Minimum Barrier, Classification, & Labeling Requirements
- ▶ Four Barrier Performance Classifications
- ▶ Classification Based on Weakest Critical Zone Component
- ▶ Acceptable Quality Level = 4%
- ▶ End-of-life Is Predetermined for Reusable Products

## AAMI PB70 Barrier Properties

**barrier properties:** Ability of a protective product to resist the penetration of liquids and liquidborne microorganisms. For purposes of this standard, levels of barrier performance are defined and classified according to the barrier properties of the critical zone. (See Table 1.)

Level	Test	Result
1	AATOC 42:2000	≤ 4.6 g
2	AATOC 42:2000 AATOC 127:1998	≤ 1.0 g ≥ 20 cm
3	AATOC 42:2000 AATOC 127:1998	≤ 1.0 g ≥ 50 cm
4	ASTM F1971:2002 (surgical gowns and other protective apparel) ASTM F1970:2002 (surgical drapes and drape accessories)	Pass

## AAMI PB70 Critical Zone

**critical zone:** Area of protective apparel or surgical drape where direct contact with blood, body fluids, and OPIM is most likely to occur.

**critical zone component:** Element, constituent, or item incorporated into the critical zone, including the materials, seams, and points of attachment.

## Design Requirements

[illegible]

The critical zone of a surgical gown or other protective apparel (excluding isolation gowns) shall, at a minimum, comprise the front area of the gown from chest to knees and the sleeves from the cuff to above the elbow. The manufacturer shall define the exact dimensions of the critical zone and shall, as specified in 4.1.3(a), provide detailed information on the barrier performance of each critical zone component. As specified in 4.1.3(b), the manufacturer also shall provide detailed information on the barrier performance of areas outside the critical zone.

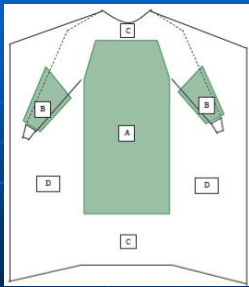
## Classification and Labeling

Surgical gowns, other protective apparel, surgical drapes, and drape accessories shall be classified and labeled according to the barrier performance properties of their critical zones. The barrier performance of all critical zone components, including seams and points of attachments, shall be determined. The classification of the product shall be a number denoting the performance of the critical zone component having the lowest barrier performance.

## Classification and Labeling of Multiple-use

... The classification of multiple-use products shall be based on their performance at the end of the labeled use-life (i.e., after being processed in the manner recommended by the manufacturer for the number of processings claimed).

## PB70 Critical Zones



### Surgical Gowns

- Entire front - Area A, B, and C are at least Level 1.
- Critical zone - At least area A and B; level defined by the lower performing area.
- Back of gown may be nonprotective but it must have a warning label.

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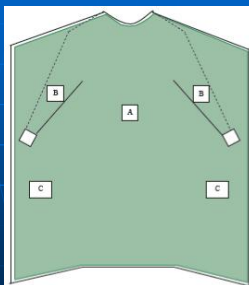
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## PB70 Critical Zones



### Isolation Gowns

- Entire gown, including seams but excluding cuffs, hems, and bindings, is required to be at least Level 1.
- Critical Zone - Entire gown.

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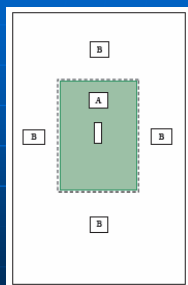
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## PB70 Critical Zones



### Surgical Drapes

- Entire drape is required to be at least Level 1.
- Critical zone - At least area A.
- Seams between two areas must have at least barrier performance of lower performing area.

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# AAMI PB70

## Determining the End-of-Life

4.1.3 Technical information

c) 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;

d) for multiple-use products, instructions on inspections that can be performed by processors to verify the continued safety and effectiveness of the product; and

e) for multiple-use products, an instruction to processors that if the labeled barrier performance of the product cannot be verified or the product has reached the end of its labeled use life, the product should be downgraded to a nonprotective category of use rather than a lower level of barrier performance.

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# Test Methods

Test Methods	AAMI PB70
AATCC 42	Level 1, 2, 3
AATCC 127	Level 1, 2, 3
ASTM F1670	Level 4 - Drapes
ASTM F1671	Level 4 - Apparel

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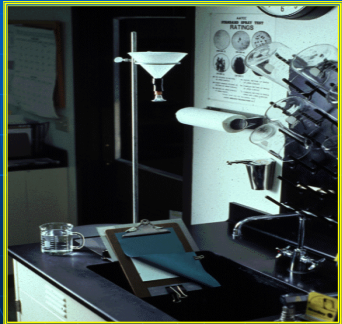
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# AATCC 42

## Water Resistance: Impact Penetration



Set Up

Reusable  
Untreated  
vs. Treated

Seam

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# AATCC 127

## Water Resistance: Hydrostatic Pressure Test

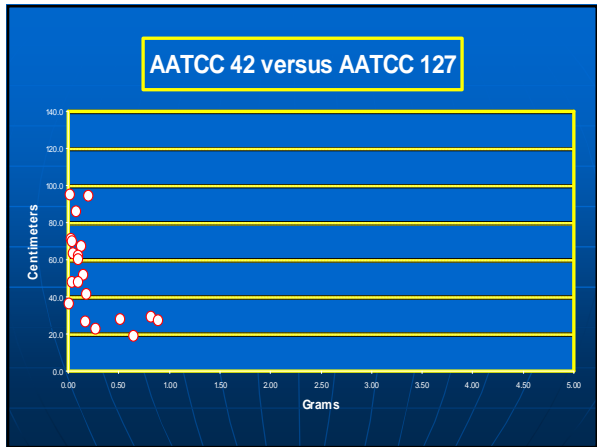


The image shows a laboratory setup for the AATCC 127 Hydrostatic Pressure Test. A white digital pressure controller with a red display and several buttons is mounted on a black base. A clear cylindrical chamber is positioned on top of the base. A black cable connects the controller to a power source. A small orange cap is visible on the side of the controller. The setup is placed on a light-colored surface against a white wall.

Set Up

Disposable  
With and  
Without  
Seam

## Disposable With and Without Seam



# Modeling Blood & Body Fluids

Repellent  
Contact Angle  $> 90^\circ$  = Hydrophobic

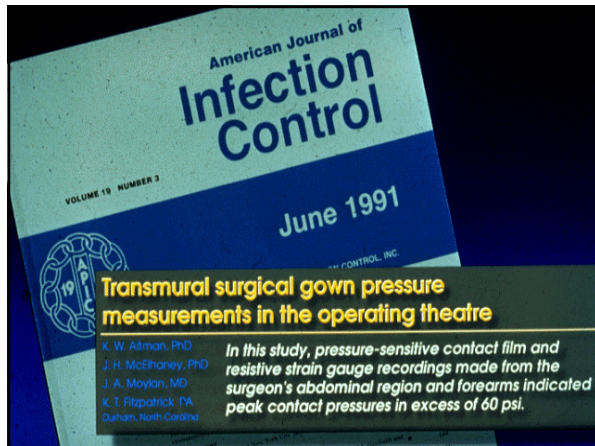
- Surface Tension
- Chemistry
- Viscosity

Absorbent  
Contact Angle  $< 90^\circ$  = Hydrophilic

The diagram illustrates the concept of contact angle in the context of modeling blood and body fluids. It features a blue background with a grid of white lines. On the right side, there are three horizontal green bars representing surfaces. Above the top bar, a blue droplet is shown with a contact angle greater than 90 degrees, indicating a hydrophobic interaction. A white line and an arc indicate the contact angle. Above the middle bar, a red droplet is shown with a contact angle greater than 90 degrees, also indicating a hydrophobic interaction. A white line and an arc indicate the contact angle. Above the bottom bar, a cyan droplet is shown with a contact angle less than 90 degrees, indicating a hydrophilic interaction. A white line and an arc indicate the contact angle. On the left side, the text 'Repellent' and 'Contact Angle  $> 90^\circ$  = Hydrophobic' is displayed. Below this, a bulleted list contains 'Surface Tension', 'Chemistry', and 'Viscosity'. At the bottom left, the text 'Absorbent' and 'Contact Angle  $< 90^\circ$  = Hydrophilic' is displayed.

- Surface Tension
- Chemistry
- Viscosity

**Absorbent**  
**Contact Angle  $< 90^\circ$  = Hydrophilic**



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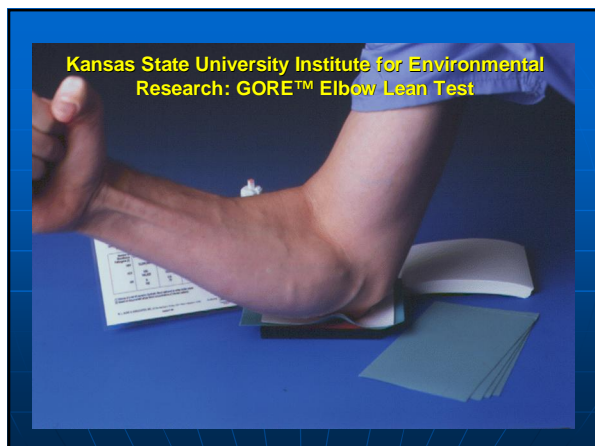
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## KSU Report Correlation Coefficients

KCC Test	KCC Test NA	AATCC 42	Mason Jar	ASTM 1 psi	ASTM 2 psi	GORE™ Elbow Lean
AATCC 42	.92*					
Mason Jar	.69	.75				
ASTM 1 psi	.38	.25	.54			
ASTM 2 psi	.60	.49	.37	.59		
AATCC 127	.92*	.75	.56	.63	.74	
GORE™ Elbow Lean	.61	.50	.38	.60	.98*	.75

KSU IER Report #90-07A

\* Significant @ 0.01 Level

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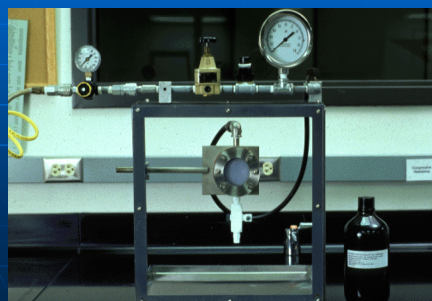
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## ASTM F1670

### Resistance to Penetration by Synthetic Blood



Set Up

Disposable  
Procedure A

Disposable  
Procedure B

Reusable  
Procedure A  
With &  
Without Seam

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## Detecting Strike-through

Volume of Strike-through (1) Actual Size	100 µL	10 µL	1 µL	0.1 µL
Number of Bloodborne Pathogens (2)				
HBV	10,000,000	1,000,000	100,000	10,000
HCV	100-100,000	10-10,000	1-1,000	0.1-100
HIV	6-700	0.6-70	0.06-7	0.006-0.7

(1) Volume of a red 40 dyne/cm Synthetic Blood delivered to white blotter paper.

(2) Based on documented whole blood concentrations of infected patients.

**3.27 Strike-through: Passage of a liquid that could contain microorganisms through a barrier product (including it's seams and/or points of attachment).**

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## ASTM F1671

### Resistance to Penetration by Phi-X174 Bacteriophage






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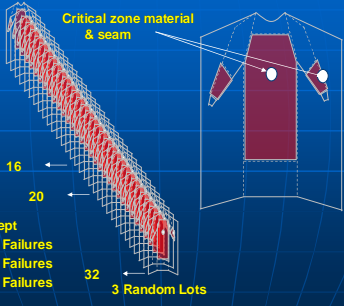
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## PB70 Level 4 Sampling Plan



**Critical zone material  
& seam**

16  
20  
32

Accept  
0/16 Failures  
1/20 Failures  
3/32 Failures

3 Random Lots

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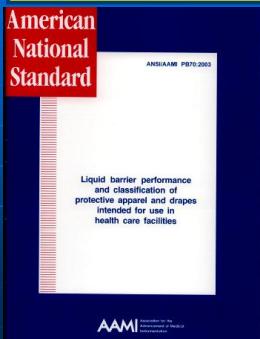
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## AAMI PB70

### Weakest Critical Zone Component



- ▶ **Level 1**
  - AATCC 42 ( $\leq 4.5$  g)
- ▶ **Level 2**
  - AATCC 42 ( $\leq 1.0$  g)
  - AATCC 127 ( $\geq 20$  cm)
- ▶ **Level 3**
  - AATCC 42 ( $\leq 1.0$  g)
  - AATCC 127 ( $\geq 50$  cm)
- ▶ **Level 4**
  - Drapes - ASTM F1670 (Pass)
  - Gowns - ASTM F1671 (Pass)

*\* Statistical Requirement: AQL 4%*

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## Advantages of AAMI PB70

- ▶ Requires Identical Labeling for Reusable and Disposable Products
- ▶ Addresses All Critical Zone Components
- ▶ Test Methods & Limits Provide More Discrimination in Barrier Performance
- ▶ Establishes Higher Statistical Confidence
- ▶ Helps Prevent Reuse Beyond Defined Life

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## AAMI TIR 11:2005 Selection and Use of Protective Apparel and Drapes in Health Care Facilities

Table 3 – General relationships between barrier performance and anticipated exposure risks

ANSI/AAMI PB70 Barrier Performance	Anticipated Risk of Exposure			Examples of Procedures with Anticipated Exposure Risks
	Fluid Amount	Fluid Spray or Splash	Pressure on Gown or Drape	
Level 1	Minimal	Minimal	Minimal	Simple/excisional biopsies Excision of "lumps and bumps" Ophthalmological procedures Simple eye, nose, & throat (ENT) procedures
Level 2	Low	Low	Low	Tonsillectomies & adenoidectomies Endoscopic gastrointestinal procedures Simple orthopedic procedures with tourniquets Open hernia repair Minimally invasive surgery
Level 3	Moderate	Moderate	Moderate	Mastectomies Arthroscopic orthopedic procedures Endoscopic urological procedures (e.g. transurethral prostate resections) Open gastro/urological procedures
Level 4	High	High	High	Any procedure with surgeon's hands & arms in a body cavity Orthopedic procedures without a tourniquet Cardiovascular / thoracic procedures Trauma procedures Caesarean sections

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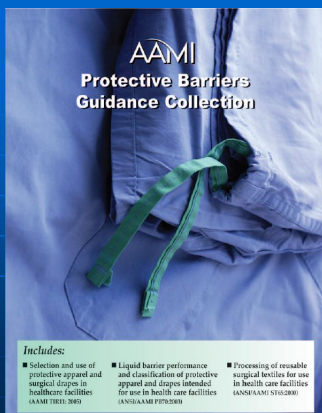
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## AAMI Protective Barriers Resource Bundle

LIST PRICE: \$235  
MEMBER DISCOUNT PRICE: \$125




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## Impact/Long Term View

- ✦ PB70 standard puts compliant reusable and disposable products on an even playing field
- ✦ Reusable manufacturers/processors must invest in PB70 compliant products, processes, & quality systems to succeed
- ✦ PB70 will become the "standard of care" and impact the development of other national & international standards

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## Other Important Factors

- |                    |                               |
|--------------------|-------------------------------|
| ■ Protection       | ■ Comfort                     |
| • Good barrier     | • <u>Cool gowns</u>           |
| • Good design      | • Warm drapes                 |
| • Strong / durable | • Soft & light                |
| ■ General S&E      | ■ Cost                        |
| • Biocompatible    | • Compliance                  |
| • Sterile          | • Acceptable quality          |
| • Flame resistant  | • <u>Environmental impact</u> |
| • Lint resistant   | • Minimize waste              |

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