

LEVEL 3

DISPOSABLE SURGICAL GOWN

WE FOLLOW HIGH QUALITY STANDARDS.

The ANSI/AAMI PB70 standard includes four standard tests to evaluate the barrier effectiveness of surgical gowns, etc. Based on the results of these standardized tests, four levels of barrier performance are defined, with Level 1 being the lowest level of protection, and Level 4 being the highest level of protection.



**AAMI Level
Protection**



AAMI LEVEL 3 Surgical Gown

Recommended for: Arterial blood draw, Inserting an IV, Emergency Room, Trauma.

Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure).

Used in MODERATE risk situation:

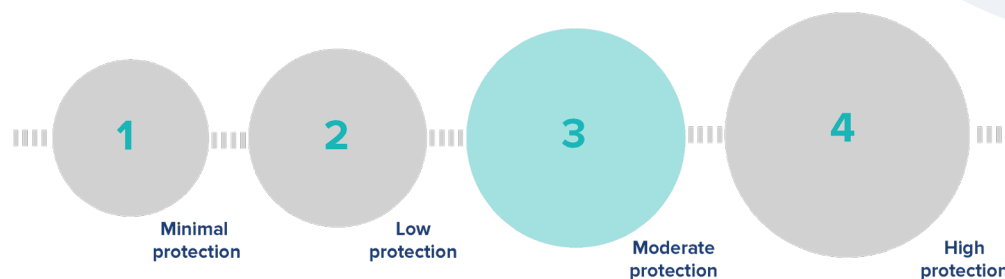
- Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2.
- Two tests are conducted to test barrier protection performance:
 1. Water impacting the surface of the gown material.
 2. Pressurizing the material.

Medical polysedden recorded film:

| | |
|-----------------------|-------------------------------|
| Core | 3" |
| Teatry | On the engraved side |
| Type of material used | Poly silk medical low density |
| Type of film used | Flat |
| Way to deal with it | Total |
| Color | Yellow, Blue, White |



| Characteristics | Method | Unit | Standard | Minimum | Maximum |
|-------------------------------------|-----------|-------------------|----------|---------|---------|
| Base weight | Intern | GR/M ² | 50 | 47 | 55 |
| Width of the film | Intern | CM | 140 | 139.5 | 140.5 |
| Wight per roll | Intern | KG | 50 | 40 | 60 |
| Treatment | Intern | CM | 38 | 36 | 40 |
| Tension machine sense | ASTM D882 | KGF | 2,400 | 1,800 | 3,000 |
| Tension transverse sense | ASTM D882 | KGF | 2,100 | 1,600 | 2,700 |
| Elongations machine sense | ASTM D882 | % | 650 | 450 | 850 |
| Elongations transverse sense | ASTM D882 | % | 700 | 500 | 900 |
| Coefficient of friction PEL-PEL-LG | ASTM 1894 | GF | 0.450 | 0.300 | 0.600 |
| Coefficient of friction PEL-PEL-LNG | ASTM 1894 | GF | 0.653 | 0.400 | 0.900 |



AAMI Level 3

Determined per ANSI/AAMI PB:2012

Disposable Surgical Gown **Level 3**



**Water
Resistance**





AAMI PB70 Liquid Barrier Performance and Classification

Test Article: Blue Plastic Toucan

A total of thirty-two (32) specimens were tested from ten (10) test articles. Specimens were chosen from the critical zones as described in AAMI PB70 for an isolation gown. Test specimens were subjected to the following tests:

AATCC 42 Water Resistance: Impact Penetration Test

AATCC 127 Water Resistance: Hydrostatic Pressure Test.

Based on the results of the testing as summarized in the attached reports, numbers 2004287 and 2004288, the product listed above was classified as **AAMI PB70 Level 3**.

Record Storage: All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by

A handwritten signature in black ink, appearing to read "Gerald M. Alalae", written over a horizontal line.

Date

A handwritten date "6-12-20" in black ink, written over a horizontal line.



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Test Article: Blue Plastic Touacan
Part # N/A Lot # N/A Batch # N/A**AATCC 42 Water Resistance: Impact Penetration Test**Test article received: 6/4/2020
Test start date: 6/8/2020
Test termination date: 6/9/2020
SOP No. (current version): LEXLP-074

Procedure: Thirty-two (32) sections each measuring 178 x 330 mm were cut from 30 products from areas representing the critical zones as described in AAMI PB 70 for an isolation gown. The test specimens and one (1) blotter sheet for each were preconditioned at $65 \pm 2\%$ rh and $21 \pm 1^\circ\text{C}$ for a minimum of 4 hours. Test samples were then clamped to the incline stand of an Impact Tester. Blotter paper was weighed and inserted beneath the test sample. Deionized Water (DIW) heated to $27 \pm 1^\circ\text{C}$ was poured into the funnel and the water sprayed onto the test article. The blotter paper was removed and re-weighed.

The post-weight for each specimen was used to determine the AAMI PB70 Level met based on the following criteria:

| Post -Weight Gain Acceptance Criteria | | |
|---------------------------------------|-----------------------|-----------------------|
| Level 1 | Level 2 | Level 3 |
| $\leq 4.5 \text{ gm}$ | $\leq 1.0 \text{ gm}$ | $\leq 1.0 \text{ gm}$ |

Results: A total of 32 / 32 specimens had a weight gain of $\leq 1.0 \text{ gm}$.

Conclusion: Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 3.

Record Storage: All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by  Tech: AP/GP Date 

Test Article: Blue Plastic Touacan
Part # N/A Lot # N/A Batch # N/A**AATCC 127 Water Resistance: Hydrostatic Pressure Test**Test article received: 6/4/2020
Test start date: 6/8/2020
Test termination date: 6/9/2020

Procedure: Thirty-two (32) sections each measuring 200 mm x 200 mm were cut from 30 products from areas representing the critical zones as described in AAMI PB 70 for an isolation gown. The test specimens were preconditioned at $65 \pm 2\%$ rh and $21 \pm 1^\circ\text{C}$ for a minimum of 4 hours. Individual specimens were clamped into the Hydrostatic Tester and analyzed.

The hydrostatic pressure required for water penetration for each specimen was used to determine the AAMI PB70 Level met based on the following criteria:

| Hydrostatic Pressure Acceptance Criteria | |
|---|---------------------------------|
| Level 2 | Level 3 |
| $\geq 20 \text{ cmH}_2\text{O}$ | $\geq 50 \text{ cmH}_2\text{O}$ |

Results: A total of 32 / 32 specimens had a hydrostatic pressure for water penetration of $\geq 50 \text{ cmH}_2\text{O}$.

Conclusion: Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 3.

Record Storage: All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by  Tech: AP/GP Date 6-11-20