

# prime<sup>en</sup>

Personal Protective Equipment

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Protection Always On

# Face Mask & Face Shield Comparison Table

Table 1.



ASTM Fluid Resistant level:

L2 120mmHg    L3 160mmHg

Product Code	Artemis Surgical Face Mask	Artemis Procedure Face Mask	Artemis Procedure Face Mask	Athena Surgical Face Mask	Athena Surgical Face Mask
	FPM20UN	FPM21UN	FPM24UN	FPM30UN	FPM33UN
Ties	✓			✓	✓
Ear Loops		✓	✓		
Anti-fog foam	✓			✓	✓
Latex Free	✓	✓	✓	✓	✓
Color	White	White	Yellow	Blue	White
Australia Standard AS4381-2015	Level 2	Level 2	Level 2	Level 3	Level 3
Fluid Resistant (mmHg)	120	120	120	160	160
Performance BFE ≥99%	✓	✓	✓	✓	✓
ΔP < 5.0 mm H2O/cm <sup>2</sup>	✓	✓	✓	✓	✓
Packaging	50 masks per box 6 boxes per carton	50 masks per box 6 boxes per carton	50 masks per box 6 boxes per carton	50 masks per box 6 boxes per carton	50 masks per box 6 boxes per carton

# Face Mask

PrimeOn face masks are designed to meet industry standards and regulations, such as AS 4381-2015 and ASTM F2101 for specific clinical applications, and all PrimeOn masks are manufactured under ISO 13485. The materials and donning attachments are sonically bonded, and all PrimeOn face masks have enclosed nosepieces to assist in conforming to the contours of the face.

See **Table 1.** for performance data by category and code.

According to the Australia Standard for Single-use Face Masks for Use in Health Care (AS 4381:2015), face masks are categorised based on the level of protection – Level 1, Level 2 & Level 3. See **Table 2.**

Table 2. AS 4381-2015 single use face mask for use in health care

Characteristics	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial Filtration Efficiency (BFE%)	≥ 95%	≥ 98%	≥ 98%
Differential Pressure (ΔP), mmH2O/cm <sup>2</sup>	< 4.0	< 5.0	< 5.0
Resistance to penetration by synthetic blood, minimum pressure in mmHg	80 mmHg	120 mmHg	160 mmHg
Application	For general purpose medical procedures where there is no risk of exposure to blood or body fluid splash	For use in emergency department, dentistry, endoscopy or wound dressing where minimal blood or body fluid droplet exposure may possibly occur	For all surgical procedures and major trauma first aid or in any environment where the risk of exposure to blood or body fluid splash are high

It is critical for the wearer to wear the right mask for the right task to ensure they are being protected while they care for their patients. All PrimeOn masks are made of materials that are able to withstand storage and usage in the environments likely to be encountered. Materials which are in contact with the skin are non-staining, soft, pliable and not likely to cause any skin irritation. The mask material used for manufacturing the PrimeOn face masks are hazard and latex free.

PrimeOn face mask range have been tested to ensure they will not disintegrate, split or tear when used for its intended purpose. These masks will maintain integrity, breathability and function throughout the use of the procedure. Each design has additional features such as wrap around shield and anti-fog device to enhance the mask's performance, user's experience and protection according to the user's needs.

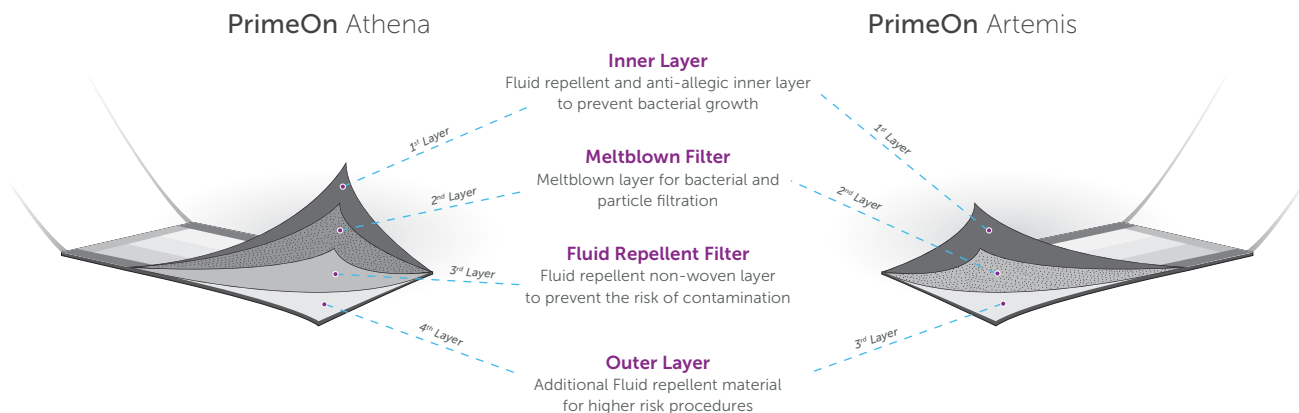


Figure 1.

PrimeOn Athena facial protection range consist of 4 layers of non-woven materials and PrimeOn Artemis facial protection range consist of 3 layers of non-woven materials



Colour: Blue ●

Code	ASH10UN
Size	Universal
Product Description	Vima Shoe Cover
Packaging	100 pieces/bag, 3 bags/carton

- Latex Free
- Non-skid



<b>Code</b>	<b>AGO40UN</b>
<b>Size</b>	Universal
<b>Product Description</b>	Everyday Impervious Gown
<b>Packaging</b>	10 pieces/pack, 5 packs/carton

- Latex Free
- Lightweight Spunbond Fabric with Laminate



<b>Code</b>	<b>AGO30RR</b>	<b>AGO30XL</b>
<b>Size</b>	Regular	X-Large
<b>Product Description</b>	Impervious Gown - Thumb Hook	
<b>Packaging</b>	15 pieces/box, 5 boxes/carton	

- Latex Free
- Packed in an Easy Dispensing Box



<b>Code</b>	<b>AGO54UN</b>
<b>Size</b>	Universal
<b>Product Description</b>	Surgical Procedure AAMI Level 4 Gown
<b>Packaging</b>	10 pieces/bag, 10 bags/carton

- Chemotherapy tested on ASTM F739 standard
- Spunbond Fabric with Laminate
- AAMI Level 4

# Choosing the Right Gown for the Right Task

The type of gown required depends on the degree of risk, including the anticipated degree of contact with infectious material and the potential for blood and body substances to penetrate through clothes or skin:

## Types of gowns

- **A clean non-sterile gown** is generally adequate to protect skin and prevent soiling of clothing during procedures and/or patient-care activities that are likely to generate splashing or sprays of blood or body substances
- **A fluid-resistant gown** should be worn when there is a risk that clothing may become contaminated with blood, body substances, secretions or excretions (except sweat).<sup>1</sup>

## Factors to consider<sup>2</sup>

Gowns are used to protect the healthcare worker's exposed body areas and prevent contamination of clothing with blood, body substances, and other potentially infectious material. Considerations in choosing the right gown:

- *The volume of body substances likely to be encountered*
- *The extent and type of exposure to blood and body substances*
- *The probable type and route of transmission of infectious agents.*

If a fluid-resistant full body gown is required, it is always worn in combination with gloves, and with other PPE when indicated. Full coverage of the arms and body front, from neck to the mid-thigh or below, ensures that clothing and exposed upper body areas are protected.

At Mun, we offer a vast range of impervious isolation and procedure gowns with your protection and comfort in mind. All our PrimeOn non-sterile impervious gowns are designed for use in applications where light to moderate fluid contact can be expected. With sealed seams, neck ties/Velcro tape, elastic/knitted/thumb-hook cuffs, impervious plastic film or film laminate, PrimeOn isolation and procedure gowns offer worry-free, comprehensive protection from blood and body fluids to help maintain the health and confidence of all healthcare professionals. PrimeOn gowns are ideal for patient contact, isolation, decontamination or general clean-up tasks. (Selected gowns are available in convenient dispenser boxes).



# Gown Protection Levels

The Association for the Advancement of Medical Instrumentation (AAMI) standards are designed to help medical-device companies meet global standards for the safe use of medical devices. AAMI introduced the voluntary standard ANSI/AAMI PB70:2012, *Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*, to determine key identification measures for the appropriate selection of protective apparel and drapes for use in healthcare facilities.<sup>3</sup>

The AAMI gown classification (see Table 3.) stems from four levels of barrier performance, measured accordingly with the following standardised tests:

- AATCC 42-2017: Measures resistance of fabrics to the penetration of water by impact<sup>4</sup>
- AATCC 127-2017: Measures resistance of fabric to the penetration of water under hydrostatic pressure<sup>5</sup>
- ASTM F1670-17: Evaluate resistance of materials used in protective clothing to penetration by synthetic blood under conditions of continuous liquid contact<sup>6</sup>
- ASTM F1671-13: Measure penetration by blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact<sup>7</sup>

Table 3. AAMI level classification based upon set criteria

Barrier Performance	Barrier Protection	Resistance Measures	Test	Test Criteria	Acceptable Quality Level
LEVEL 1	Minimal	Liquid Penetration	AATCC 42	Water Impact ≤4.5g	4%
LEVEL 2	Low	Liquid Penetration	AATCC 42	Spray Impact ≤1.0g	4%
			AATCC 127	Hydrostatic Pressure ≥20cm	4%
LEVEL 3	Moderate	Liquid Penetration	AATCC 42	Spray Impact ≤1.0g	4%
			AATCC 127	Hydrostatic Pressure ≥50cm	4%
LEVEL 4	High	Liquid and Viral Penetration	ASTM F1671	Pass	4%

Defining the best level of protection for the standard ANSI/AAMI PB70:2012 involves an understanding of the critical zones of a gown and what each level of barrier performance entails.

The critical zones of a gown (see Figure 2.) comprise of the front of the gown and the sleeves, which are both primary areas with the greatest risk of exposure to fluids and blood-borne pathogens. As the level increases, so does the need for greater barrier protection for the entire critical zone.

- **Level 1:** Minimal level of fluid barrier protection
- **Level 2:** Low level of fluid barrier protection
- **Level 3:** Moderate level of fluid barrier protection
- **Level 4:** Highest level of fluid and viral barrier protection



Figure 2. AAMI Surgical Gown Classification<sup>8, 9</sup>

# Chemotherapy Testing

Healthcare workers responsible for administering cancer treatments to patients are at risk of being exposed to toxic products/chemicals, including cytotoxic drugs, which must be handled, managed and disposed of with the greatest care. In Australia, recommended policies for best practice in performing chemotherapy and ensuring the safety of healthcare workers have been established in each state with the support of health organisations and government bodies.

Personal protective equipment is a mandatory requirement for the safety of healthcare workers. When determining the appropriate choice of gowns for use with cytotoxic drugs, it is recommended that it is tested against the standard ASTM F739. The PrimeOn AAMI Level 4 surgical procedure gown has been independently tested and shown to have breakthrough detection times as shown in Table 4.

Table 4. Chemotherapy breakthrough detection times for PrimeOn AAMI Level 4 surgical procedure gown

Chemotherapy Drug	Concentration	Average Breakthrough Detection Time (minutes)
Carmustine (BCNU)	3.3mg/ml (3,300 ppm)	386.7
Cyclophosphamide (Cytoxan)	20.0mg/ml (20,000 ppm)	>480
Doxorubicin Hydrochloride	2.0mg/ml (2,000 ppm)	>480
Etoposide (Toposar)	20.0mg/ml (20,000 ppm)	>480
Fluorouracil	50.0mg/ml (50,000 ppm)	>480
Methotrexate	25.0mg/ml (25,000 ppm)	>480
Paclitaxel (Taxol)	6.0mg/ml (6,000 ppm)	>480
Thiotepa	10.0mg/ml (10,000 ppm)	20.0
Vincristine Sulfate	1.0mg/ml (1,000 ppm)	>480

## References

1. NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare, 47.
2. Ibid, 48.
3. Pfiedler Enterprises 2016, *AAMI Levels and Surgical Gowns: Know if You're Protected*, viewed 17 July 2018, <http://www.pfiedler.com/ce/1191/files/assets/common/downloads/AAMI%20Levels%20and%20Surgical%20Gowns.pdf>
4. AATCC TM42-2017, Water Resistance: Impact Penetration Test, American Association of Textile Chemists and Colorists, RTP, NC, USA, 2018, <https://www.aatcc.org/>
5. AATCC TM127-2017, Water Resistance: Hydrostatic Pressure Test, American Association of Textile Chemists and Colorists, RTP, NC, USA, 2017, <https://www.aatcc.org/>
6. ASTM F1670 / F1670M-17a, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood, ASTM International, West Conshohocken, PA, 2017, [www.astm.org](http://www.astm.org)
7. ASTM F1671 / F1671M-13, 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, ASTM International, West Conshohocken, PA, 2013, [www.astm.org](http://www.astm.org)
8. U.S. Food and Drug Administration 2018, *Medical Gowns*, viewed 24 July 2018, <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/PersonalProtectiveEquipment/ucm452775.htm>

All PrimeOn® PPE meet relevant Therapeutic Goods Administration (TGA) criteria for listing on the Australian Register of Therapeutic Goods (ARTG) or equivalent.