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Personal Protective Equipment

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Protection Always On

Face Mask Comparison Table

Surgical Face Mask | **FPM20UN**

Ties • Anti-Fog Foam

Procedure Face Mask | **FPM21UN**

Ear Loops

Surgical Face Mask | **FPM30UN**

Ties • Anti Fog Foam

Surgical Face Mask | **FPM33UN**

Ties • Anti Fog Foam

Procedure Face Mask | **FPM34UN**

Ear Loops • Anti Fog Foam

ASTM Fluid Resistant level:

L2 120mmHg L3 160mmHg

Table 1.

Product Code	Artemis Surgical Face Mask **FPM20UN**	Artemis Procedure Face Mask **FPM21UN**	Athena Surgical Face Mask **FPM30UN**	Athena Surgical Face Mask **FPM33UN**	Athena Procedure Face Mask **FPM34UN**
Ties	✓		✓	✓	
Ear Loops		✓			✓
Anti-fog foam	✓		✓	✓	✓
Latex Free	✓	✓	✓	✓	✓
Colour	White	White	Blue	White	Blue
Australia Standard AS4381-2015	Level 2	Level 2	Level 3	Level 3	Level 3
Fluid Resistant (mmHg)	120	120	160	160	160
Performance BFE ≥99%	✓	✓	✓	✓	✓
ΔP < 5.0 mm H20/cm²	✓	✓	✓	✓	✓
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/cm²	< 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.

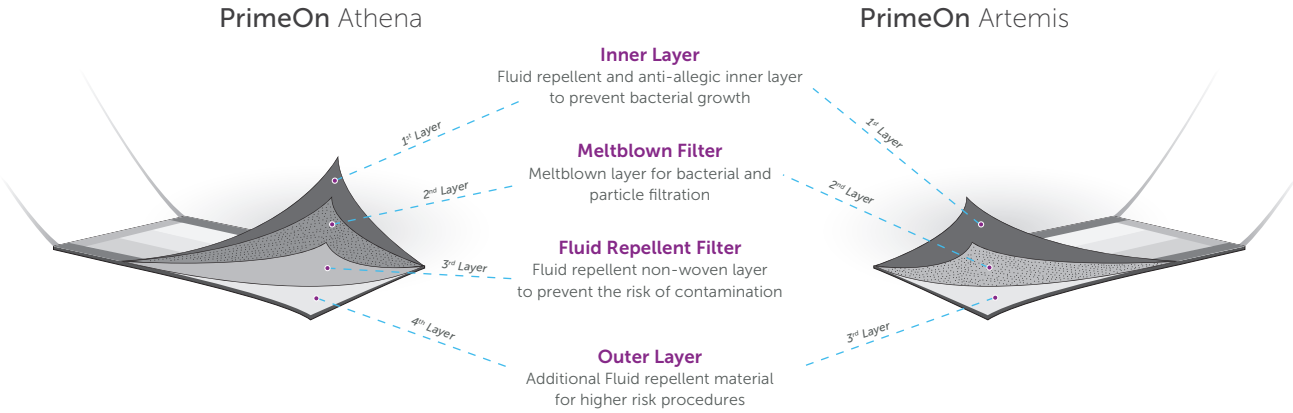


Figure 1.

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

P2 Respirators Comparison Table

Trifold / 3-Panel | **FPR10UN**

Standard Headstrap • Anti-Fog Foam

Trifold / 3-Panel | **FPR11UN**

Relaxed Headstrap • Anti-Fog Foam

Flatfold / 2-Panel | **FPR20UN**

Standard Headstrap

Duckbill | **FPR30UN**

Standard Headstrap

Table 2.

Product Code	Trifold 3-Panel P2 Respirator **FPR10UN**	Trifold 3-Panel P2 Respirator **FPR11UN**	Flatfold 2-Panel P2 Respirator **FPR20UN**	Duckbill P2 Respirator **FPR30UN**
Standard-Fit Headstrap	✓		✓	✓
Relaxed-Fit Headstrap		✓		
Anti-Fog Foam	✓	✓		
Individually Sealed Packaging	✓	✓	✓	✓
Colour	White w/Blue Headstraps	White w/White Headstraps	White w/White Headstraps	Orange w/White Headstraps
Australian/NZ Standard AS/NZS 1716 Classification	Class P2	Class P2	Class P2	Class P2
Maximum Total Inward Leakage (TIL)	≤ 8 %	≤ 8%	≤ 8%	≤ 8%
Particulate Filtration Efficieny (PFE)	≥ 95%	≥ 95%	≥ 95%	≥ 95%
Maximum Pressure Drop: Inhalation/ Exhalation	Inhalation: ≤ 70 Pa (@ 30 L/min) ≤ 240 Pa (@ 95 L/min) Exhalation: ≤ 120 Pa (@ 85 L/min)	Inhalation: ≤ 70 Pa (@ 30 L/min) ≤ 240 Pa (@ 95 L/min) Exhalation: ≤ 120 Pa (@ 85 L/min)	Inhalation: ≤ 70 Pa (@ 30 L/min) ≤ 240 Pa (@ 95 L/min) Exhalation: ≤ 120 Pa (@ 85 L/min)	Inhalation: ≤ 70 Pa (@ 30 L/min) ≤ 240 Pa (@ 95 L/min) Exhalation: ≤ 120 Pa (@ 85 L/min)
Packaging	20 pcs per box 28 boxes per carton	20 pcs per box 28 boxes per carton	25 pcs per box 24 boxes per carton	20 pcs per box 10 boxes per carton

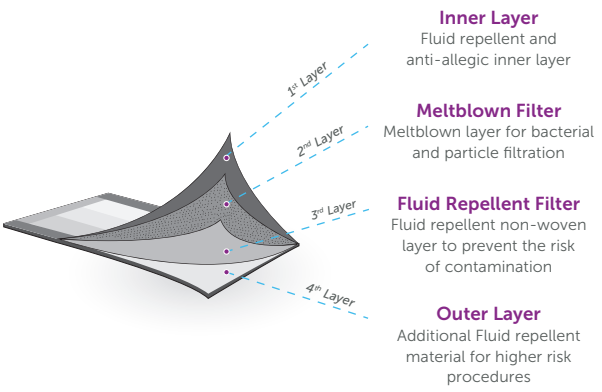
AS/NZS 1716-2012 P2 Respirators

PrimeOn P2 Respirators are designed to protect against droplet and airborne pathogens and meet the stringent requirements of Australian/New Zealand Standard for Respiratory Protective Devices against Particulates, AS/NZS 1716-2012 Class P2. Featuring latex-free elastic headstrap fastening the respirators are suitable for use in a healthcare setting, and they are available in three different facepiece designs - Trifold, Flatfold, and Duckbill - to ensure the optimal fit for all wearers. All PrimeOn P2 Respirators are proudly manufactured in Australia, under the strict requirements of ISO 13485-2016 Medical Device Quality Management Systems.

It is worth noting that other equivalent international standards for particulate respirators are in common use, most notably the **NIOSH N95** standard from the USA and the **KN95** standard from China. While these standards are accepted by many Australian institutions, the AS/NZS 1716-2012 standard is developed locally to suit Australian conditions, with unique requirements that are not necessarily covered or matched by other global standards, and is the most accepted standard across Australia and New Zealand.

See *Table 2.* for performance data by product code.

Figure 1.



Each PrimeOn P2 Respirator's facepiece is constructed of 4 layers of non-woven polypropylene fibre

Table 1. lists the key performance parameters specified by AS/NZS 1716-2012

Characteristics	AS/NZS 1716-2012 Class P2
Particulate Filtration Efficiency (PFE%)	≥ 94% (@ 95 L/min)
Total Inward Leakage (TIL)	≤ 8% leakage
Inhalation Resistance - Max Pressure Drop	≤ 70 Pa (@ 30 L/min) ≤ 240 Pa (@ 95 L/min)
Exhalation Resistance - Max Pressure Drop	≤ 120 Pa (@ 85 L/min)

Choosing the Right P2 Respirator

In order to achieve optimal protection against airborne and droplet pathogens, it is crucial that a good seal is maintained against the face of the user while remaining comfortable in use for extended periods. To achieve this goal, three facepiece designs are offered:

(i) Trifold/3-Panel - Divided between top, middle and bottom sections, this design is compact in size for storage and portability, is collapse-resistant with extended use while still offering excellent filtration performance and facial-fit, available in two headstrap elastic strengths: Standard-Fit or Relaxed-Fit.

(ii) Flatfold/2-Panel - Divided between the left and right sections, the flatfold design is easy to don and doff, with an acceptable level of fitment and suited for general use while offering moderate levels of comfort.

(iii) Duckbill - with a distinct shape when unfolded and worn, this design has a front panel that tapers down towards the chin and cheek area, and a horizontal seam down the middle of the respirator. The larger internal volume of the duckbill respirator offers greater airflow and positions the respirator material further from the face for greater comfort.

The PrimeOn P2 Respirator range has been tested to ensure they will maintain an acceptable seal against the face, not disintegrate, split or tear when used for its intended purpose. These respirators will maintain integrity, breathability and function throughout the use of the procedure.

It is essential that the best facial fit is achieved when selecting a P2 respirator - there is no one-size-fits-all. Therefore fit-testing may be required (and mandated by some institutions) to find the most form-fitting design. Please contact Mun Australia for further details, including professional fit testing services in Australia.

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Sterile Dental Surgical Packs

Comprehensive

Infection prevention and control is never more important than when performing surgical procedures so patients experience better outcomes and recovery post-surgery. That is why it is essential to have all the necessary components on hand when setting up your sterile fields for an aseptic environment.

The PrimeOn Comprehensive Sterile Dental Surgical Pack allows you to successfully prepare for surgical procedures and create asepsis around your patient and their surrounds.

Every component in this pack is sterilised with ethylene oxide and sealed together in a headed bag with a sterilisation indicator label. This pack is recommended for procedures including but not limited to implant surgery, extractions, maxillofacial surgery, orthognathic surgery, TMJ surgery, cleft-palate, mandibular surgery and facial aesthetics.

Pack Components

Component		Quantity	Component		Quantity
	Trolley/Back Table Cover	1		Adhesive Film	3
	¾ Surgical Patient Drape, U-shaped With Velcro Tube Management	1		Head Bar Drape With Adhesive	1
	AAMI Level 2 Surgical Gowns	2		White & Blue Tube Adaptor	1
	Spunlace Hand Towel	4		Suction Tube	1
	Mayo Stand Cover	1		Saliva Ejector	1
	Quick Drill Sleeve With Applicator	2		Fine Aspiration Handle With Control Vent	1
	X-ray Detectable Gauze	10		Biohazard Waste Bag	1

Sterile Dental Surgical Packs

Comprehensive

Code	DSP20UN
Dimension	D43 cm x W30 cm x H15 cm
Product Description	Dental Surgical Packs - Comprehensive
Packaging	6 packs per carton

- Sterile

Sterile Dental Surgical Packs

Basic

Common surgical procedures carried out in a dental chair require the same need for an aseptic environment as other more involved surgical procedures. By providing this environment patients are well protected from the risk of infection and poor recovery from cross contamination.

The PrimeOn Basic Sterile Dental Surgical Pack carries all the necessary medical consumables required to create sterile fields for yourself and your patients when seated in a dental chair.

Components of the pack are sterilised using ethylene oxide and placed in a headed bag featuring a sterilisation indicator sticker. This dental surgical pack can be used with procedures such as teeth extractions, dental implants, veneers, crowns, tooth exposure, bone grafting and the removal of foreign tissue and fragments.

Pack Components

Component		Quantity	Component		Quantity
	¾ Surgical Patient Drape, U-shaped With Velcro Tube Management	1		Surgical Drape (90 x 120cm)	1
	Trolley/Back Table Cover	1		Quick Drill Sleeve With Applicator	2
	Adhesive Film	4		X-ray Detectable Gauze	16
	Surgical Drape (75 x 90cm)	1		Biohazard Waste Bag	1

Sterile Dental Surgical Packs

Basic

Code	DSP10UN
Dimension	D35 cm x W30 cm x H6 cm
Product Description	Dental Surgical Packs - Basic
Packaging	12 packs per carton

- Sterile

Protective Apparel Range

Head Wear

Colour: White

Code	AHW10UN
Size	Universal
Product Description	Bouffant Cap
Packaging	50 pieces/bag, 20 bags/carton

- Latex Free

Colour: Blue

Code	AHW11UN
Size	Universal
Product Description	Bouffant Cap
Packaging	50 pieces/bag, 20 bags/carton

- Latex Free

Protective Apparel Range

Footwear

Colour: Blue

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

• Latex Free • Non-skid design

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Protective Apparel Range

Gowns

Colour: Blue

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

• Latex Free • Packed in an Easy Dispensing Box

Colour: Yellow

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

• Latex Free • Lightweight Spunbond Fabric with Laminate

Colour: Yellow

Code	AGO41RR
Size	Regular
Product Description	Specialised Impervious Gown
Packaging	10 pieces/pack, 5 packs/carton

• Latex Free • Lightweight Spunbond Fabric with Laminate

Colour: Blue

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

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

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Protective Apparel Range

Gowns

Colour: Blue

Code	AGO52UN
Size	Universal
Product Description	Procedure AAMI Level 2 Gown
Packaging	10 pieces/bag, 10 bags/carton

• Spunbond Fabric with Laminate • AAMI Level 2

Colour: Dark Blue

Code	AGO20UN
Size	Universal
Product Description	Sleeveless Gown
Packaging	10 pieces/bag, 10 bags/carton

• Latex Free • Lightweight Spunbond Polypropylene Material

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).*[1]

Factors to consider[2]

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.[3]

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

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[3, 8]

Chemotherapy Testing

Healthcare workers responsible for administering cancer treatments to patients are at risk of being exposed to toxic productschemicals, 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.
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