

AS 4381:2015 – UNDERSTANDING THE NEW AUSTRALIAN MASK STANDARD

In December 2015, Standards Australia published an updated version of the standard for 'Single-use face masks for use in health care'. The objective was to simplify the standard and harmonise with the North American ASTM F2100-11 and European (EN) 14683.

NEW STANDARD AS 4381:2015 (RED INDICATES CHANGE)

AS 4381: 2015 SINGLE-USE FACE MASKS				
CHARACTERISTICS	LEVEL 1 1	LEVEL 2 2	LEVEL 3 3	TEST METHOD
	<p>Level 1 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood, bacterial filtration efficiency and differential pressure, as specified below.</p> <p>APPLICATIONS: For general purpose medical procedures, where the wearer is not at risk of blood or bodily fluid splash or to protect staff and/or the patient from droplet exposure to microorganisms (e.g. patient with upper respiratory tract infection visits GP)</p>	<p>Level 2 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood, bacterial filtration efficiency and differential pressure, as specified below.</p> <p>APPLICATIONS: For use in emergency departments, dentistry, changing dressings on small or healing wounds where minimal blood droplet exposure may possibly occur (e.g. endoscopy procedures)</p>	<p>Level 3 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood, bacterial filtration efficiency and differential pressure, as specified below.</p> <p>APPLICATIONS: For all surgical procedures, major trauma first aid or in any area where the health care worker is at risk of blood or bodily fluid splash (e.g. orthopaedic, cardiovascular procedures)</p>	
Bacterial Filtration Efficiency (BFE) %	≥ 95%	≥ 98%	≥ 98%	ASTM F2101-14 or EN 14683:2014
Particulate Filtration Efficiency (PFE) % (0.1 µm)	Not Required	Not Required	Not Required	N/A
Differential Pressure (Delta P) mm H ₂ O/cm ²	< 4.0	< 5.0	< 5.0	EN 14683:2014
Resistance to penetration by synthetic blood (fluid resistance) min pressure in mm Hg for pass result	80mm Hg	120mm Hg	160mm Hg	ASTM F1862 / F1862M-13 or ISO 22609

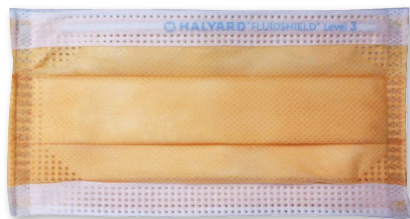
HALYARD* FLUIDSHIELD* PROTECTION



All HALYARD* FLUIDSHIELD* Masks meet the new Australian Standard AS 4381:2015, and are available in Levels 1, 2, and 3.

LEVEL 1	LEVEL 2	LEVEL 3
CODE: 25868 Procedure Mask, SO SOFT*, with Earloops, Lavender	CODE: 28810 Procedure Mask, SO SOFT*, with Earloops, Blue	CODE: 28797 Fog-Free Procedure Mask, SO SOFT*, with Earloops
CODE: 25869 Procedure Mask, with Earloops, Blue	CODE: 28821 Fog-Free Procedure Mask, SO SOFT*, Wraparound Visor, Blue	CODE: 28800 Fog-Free Procedure Mask, SO SOFT*, Wraparound Visor, with Earloops
CODE: 28802 Surgical Mask, SO SOFT*, Blue	CODE: 39123 Surgical Mask, SO SOFT*, Expanded Chamber, with Ties	CODE: 28804 Fog-Free Procedure Mask, SO SOFT*, Wraparound Visor
CODE: 39125 Anti-fog Surgical Mask, SO SOFT*, with Smart Adhesive, Green	CODE: 62113 Fog-Free Surgical Mask, with Ties	CODE: 47107 Fog-Free Procedure Mask, SO SOFT*, with Earloops
	CODE: 62114 Fog-Free Surgical Mask, Wraparound Visor, with Ties	CODE: 47147 Fog-Free Procedure Mask, SO SOFT*, Wraparound Visor, with Earloops
		CODE: 48207 Fog-Free Surgical Mask, SO SOFT*, with Ties
		CODE: 48208 Surgical Mask, SO SOFT*, with Ties
		CODE: 48247 Fog-Free Surgical Mask, SO SOFT*, Wraparound Visor, with Ties
		CODE: 48248 Surgical Mask, SO SOFT*, Wraparound Visor, with Ties
		CODE: 48297 Care Bear Surgical Mask, SO SOFT*, with Ties

With the level of protection clearly labelled on the mask nose piece and on the box, you and your staff can easily identify the right mask for each task.



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Guide to Face Mask Selection and Use

Choose the right mask for the task! Select the mask design, fit and filtration that matches the protection needs for each procedure or risk level. MaskEnomics™ makes it easy to find the level of filtration required, including ASTM Level 3, 2 and 1.

ASTM PERFORMANCE LEVELS

MAXIMUM FILTRATION

NIOSH Approved N95 Particulate Respirator

High Fluid Resistance	160 mmHg
Filtration Efficiency	PFE = 99.9% @ 0.1 micron
Breathability - Delta P	> 5.0 mm H ₂ O/cm ²
Flame Spread	Class 1

N95

Indicated for use when treating patients with airborne diseases such as TB or influenza.*

Meets CE 0121 – In reference to EN 149: 2001 FFP2 NR.

Pictured: Isolator Plus™ N95 Particulate Respirator



ASTM LEVEL 3

High Fluid Resistance	160 mmHg
Filtration Efficiency	BFE ≥ 98% PFE ≥ 98% @ 0.1 micron
Breathability - Delta P	< 5.0 mm H ₂ O/cm ²
Flame Spread	Class 1

LEVEL 3

Ideal for procedures where heavy to moderate amounts of fluid, spray and/or aerosols are produced.

Meets EN14683 Rating – Type IIR Standard.

Pictured: Ultra® Sensitive Earloop with Secure Fit® Mask Technology



ASTM LEVEL 2

Moderate Fluid Resistance	120 mmHg
Filtration Efficiency	BFE ≥ 98% PFE ≥ 98% @ 0.1 micron
Breathability - Delta P	< 5.0 mm H ₂ O/cm ²
Flame Spread	Class 1

LEVEL 2

Ideal for procedures where moderate to light amounts of fluid, spray and/or aerosols are produced.

Meets EN14683 Rating – Type IIR Standard.

Pictured: Procedural Earloop with Secure Fit® Mask Technology



ASTM LEVEL 1

Low Fluid Resistance	80 mmHg
Filtration Efficiency	BFE ≥ 95% PFE ≥ 95% @ 0.1 micron
Breathability - Delta P	< 4.0 mm H ₂ O/cm ²
Flame Spread	Class 1

LEVEL 1

Ideal for procedures where low amounts of fluid, spray and/or aerosols are produced.

Meets EN14683 Rating – Type II Standard.

Pictured: Isofluid® Earloop with Secure Fit® Mask Technology



LOW PERFORMANCE

Surgical Molded Utility Mask
Physical Barrier Only
No LEVEL Performance Level **
Filtration Efficiency N/A

**Unless mask manufacturer certifies mask meets ASTM performance level 1

Ideal as a comfortable substitute for earloop face masks, this mask is a simple physical barrier for exams and visitations or for dry, short procedures that do not produce fluid, spray or aerosols.

Pictured: Surgical Molded



MINIMUM PERFORMANCE

Utility Mask (Tissue/Tissue)
Physical Barrier Only
No LEVEL Performance Level
Filtration Efficiency N/A

Ideal as a simple physical barrier for exams and visitations or for dry, short procedures that do not produce fluid, spray or aerosols.

Pictured: Isolite® Earloop



Understanding ASTM Face Mask Performance Levels

FEATURE	EXPLANATION
Fluid Resistance	Mask resistance to penetration by synthetic blood under pressure (mmHg). Higher fluid resistance = Higher protection.
BFE - Bacterial Filtration Efficiency	Percentage of aerosol particles filtered at a size of 3 microns.
PFE - Submicron Particle Filtration Efficiency	Percentage of submicron particles filtered at 0.1 microns.
Delta P - Differential Pressure	Pressure drop across mask, or resistance to air flow in mmH ₂ O/cm ² . Greater resistance = better filtration but less breathability.
Flame Spread	Measures the flame spread of the mask material.



THE DENTAL ADVISOR
Rated
"Top Mask"
6 YEARS IN A ROW!

SOURCE: American Society for Testing and Materials Standard specification for performance of materials used in medical face masks. F2100-11 Standard.

*Follow CDC Guidelines: Do not treat active TB patients except in approved facilities, meeting all health department, CDC and OSHA standards, in the context of a complete respiratory protection program. CAUTION: The outside of masks and face shields are likely to become contaminated during use. Wash hands after touching any contaminated surfaces. Do not touch outside of the mask with wet or contaminated gloves or hands. Such contamination may compromise mask barrier asepsis by encouraging migration or "wicking" of microbes through the mask.

Crosstex International, Inc. can make no warranties or representations, either expressed or implied, that these products will fully protect the user from exposure to blood or bodily fluids or risk of contracting infectious diseases. OSHA requires the employer to evaluate the anticipated exposure and select the appropriate protective masks to prevent contamination of skin, eyes and respiratory passages. This poster may not be copied in whole or part without the express permission of Crosstex International, Inc. © 2016.

FULL LENGTH FACE SHIELD

- Optically clear, distortion-free wrap-around face shield.
- 1 ½" foam headband holds shield away from face; "floats" lightly on forehead, with no pressure on temples; vented for increased air flow.
- Protects mask and face from direct splatter; may prolong mask life.
- Sonically welded elastic headband for added strength.
- Anti-fog treatment on inside and outside of shield.
- Available in 7" and 9" options



SECURE FIT

Secure Fit® Mask Technology creates a custom fit to reduce your exposure to airborne particulates. Secure Fit® Mask Technology is available in the following Crosstex face masks: Ultra® (ASTM Level 3), Procedural (ASTM Level 2), Isofluid® (ASTM Level 1)



Aluminum nose and chin pieces reduce gapping.

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SELECT THE RIGHT MASK FOR THE TASK

Visit **CROSSTEXLEARNING.COM** to watch an informative **MASKENOMICS™ VIDEO**