

AS 4381: 2015

UNDERSTANDING THE NEW AUSTRALIAN MASK STANDARDS

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.

OLD STANDARD (AS) 4381:2002:

(AS) 4381: 2002 SINGLE USE FACE MASKS				
CHARACTERISTICS	GENERAL PURPOSE	SUBMICRON	FLUID RESISTANT	TEST METHOD
	For general purpose medical procedures, where the wearer is not at risk of blood or bodily fluid splash	For tasks where the health care worker is not at risk of blood or bodily fluid splash, and requires a mask with submicron filter efficiencies	For all surgical procedures, or in any area where the health care worker is at risk of blood or bodily fluid splash, and requires a fluid resistant mask with submicron filter efficiencies	
Bacterial Filtration Efficiency (BFE) % (3 µm)	95% (min)	98% (min)	98% (min)	AS4381
Particulate Filtration Efficiency (PFE) % (0.1 µm)	Not Required	98% (min)	98% (min)	AS4381
Differential Pressure (Delta P) mm H ₂ O	5.0 (max)	5.0 (max)	5.0 (max)	AS4381
Resistance to penetration by synthetic blood (fluid resistance) at 16.0 kPa pressure	Not Required	Not Required	No evidence of blood reaching the inner layer of material	AS4381

NEW STANDARD (AS) 4381:2015: RED INDICATES CHANGE

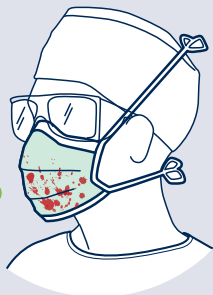
(AS) 4381: 2015 SINGLE USE FACE MASKS				
CHARACTERISTICS	LEVEL 1	LEVEL 2	LEVEL 3	TEST METHOD
	Level 1 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood at the minimum velocity specified in Table 2, bacterial filtration efficiency and differential pressure. 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)	Level 2 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood at the middle velocity specified in Table 2, bacterial filtration efficiency and differential pressure. 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)	Level 3 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood at the maximum velocity specified in Table 2, bacterial filtration efficiency and differential pressure. 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)	
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
PLUS: Requires Instructions For Use, "The masks should be packed such that each mask can be removed without becoming entangled in another"				

AS 4381: 2015 NEW FACE MASK STANDARD

PROBLEM

Studies show fluid strikes the face area of OR staff on average

45–51% of the time¹



45% of masks used in Australia are not fluid resistant²

There is a **high cost** associated with infections which may include:



chronic disabilities



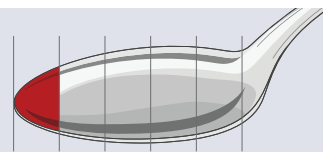
emotional stress



loss of income and/or employment

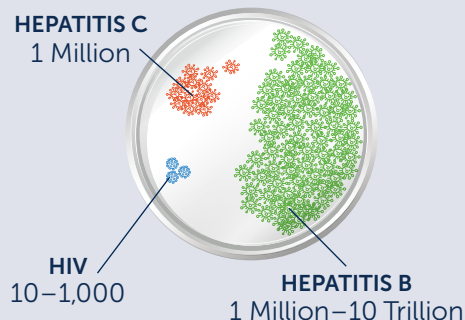


facility cost



1 millilitre of blood = 1/5 of a teaspoon

Just **1 millilitre** of blood can contain virus counts that range from:³



THE NEW STANDARD

AS 4381: 2015 is the new standard for single-use face masks, revised in December 2015. The Respiratory Standard (AS/NSZ 1715 Selection, use and maintenance of respiratory protective equipment) is separate and remains unchanged.

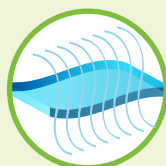
Single-use masks are now measured on **3 performance metrics:**



Bacterial Filtration (BFE)



Fluid Resistance



Breathability

MASKS ARE RATED ACCORDING TO PERFORMANCE LEVELS:

1

80 mm Hg

LOW

2

120 mm Hg

MODERATE

3

160 mm Hg

HIGH

Fluid Exposure

SOLUTION

All HALYARD* FLUIDSHIELD* Surgical and Procedure Masks are available in Levels 1, 2, and 3 and are fluid-resistant.



QUESTION YOUR PROTECTION

Ensure your masks comply with **AS 4381: 2015.**

Contact your Halyard Account Manager to simplify compliance today.

1. CG Davies et al, Ann R Coll Surg Engl 2007 89(8): 770–772; S Endo et al, Jour Hospital Infection 2007 (67) 1: 56–61; DC Berridge et al, Br J Surg 1993 80 (11): 1379–80.
2. Scott N & Jones H, ACA Research, Understanding the implications of changing face mask standards 2015.
3. Morgan, David R. Mission to the Point: A Review of Needlestick Injury and Occupational Risks From BloodBorne Viruses. Journal of American Biological Safety Association. 2001

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