

# NEW

## MEDICAL FACE MASKS

Breathable Viral Barrier (BVT)

Strong

Soft

Breathable

The best **VIRUS**  
barrier



Perfect balance between PROTECTION AND COMFORT

With Sanitary Registry

## Breathable viral barrier of last generation!

Coronavirus, HIV, Tuberculosis, avian influenza, H1N1, among others greater than 0.027 microns.

This innovative medical face mask is built for the most critical circumstances, keeping health professionals protected and comfortable.

The latest generation of **Breathable Viral Barrier** surgical fabric, takes advantage of decades of experience in the manufacture of products for surgical protection.

The fabric is made up of a LAMINATED TRI-LAYER built to be waterproof, breathable and comfortable.

But above all, it be an infallible BARRIER against viruses and bacteria of all kinds.

The **Breathable Viral Barrier** fabric is strong, soft, highly breathable and provides excellent barrier properties against viruses that cause infectious diseases such as HIV / AIDS (Human Immunodeficiency Virus), H1N1 and Avian Influenza.



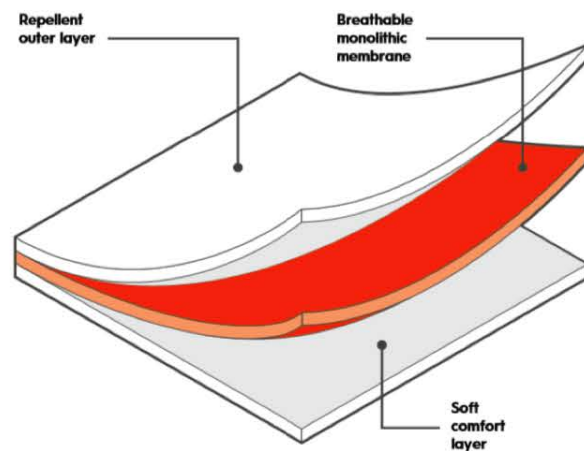
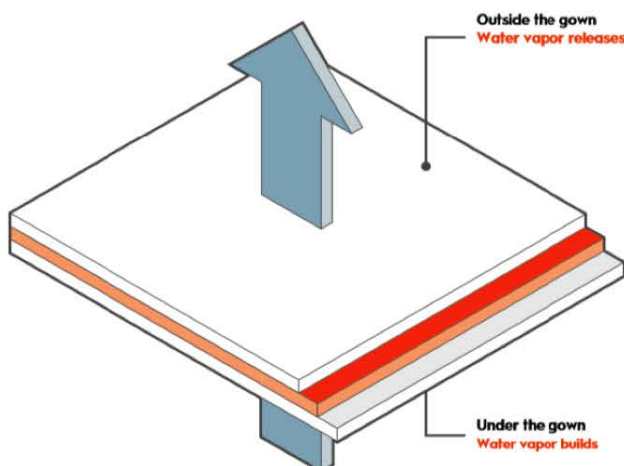
1. The outer layer provides water repellency and resistance.



2. The inner layer is soft and comfortable when used during long surgical procedures.



3. The barrier layer is a membrane that has a non-porous monolithic structure that provides an impermeable barrier, thereby blocking the passage of viruses and bacteria. The structure of the film allows the passage of moisture vapor, which allows the user to remain comfortable while providing the highest level of protection.



Anticipated Risk of Exposure			Examples of procedure with anticipated exposure risks	ANSI/AAMI PB 70 Barrier performance	Test	Result
Fluid amount	Fluid spray or splash	Pressure on gown or drape				
Minimal	Minimal	Minimal	<ul style="list-style-type: none"> <li>- Simple excisional biopsies</li> <li>- Excision of 'lumps and bumps'</li> <li>- Ophthalmological procedures</li> <li>- Simple ear, nose and throat (ENT) procedures</li> </ul>	Level 1 <b>(least protective)</b>	AATCC 42 Water impact (WI)	≤ 4.5 g
Low	Low	Low	<ul style="list-style-type: none"> <li>- Tonsilectomies and adenoidectomies</li> <li>- Endoscopic gastrointestinal procedures</li> <li>- Simple orthopedic procedures with tourniquets</li> <li>- Open hernia repair</li> <li>- Minimally invasive surgery</li> <li>- Interventional radiology or catheter lab procedures</li> </ul>	Level 2	AATCC 42, WI AATCC 127 Hydro Head (HH)	≤ 1.0 g ≥ 20 cm
Moderate	Moderate	Moderate	<ul style="list-style-type: none"> <li>- Mastectomies</li> <li>- Arthroscopic orthopedic procedures</li> <li>- Endoscopic urological procedures (e.g. transurethral prostate resections)</li> <li>- Open gastrointestinal and genito-urinary procedures</li> </ul>	Level 3	AATCC 42, WI AATCC 127, HH	≤ 1.0 g ≥ 50 cm
High	High	High	<ul style="list-style-type: none"> <li>- Any procedure in which the surgeon's hands and arms are in a body cavity</li> <li>- Orthopedic procedures without a tourniquet</li> <li>- Open cardiovascular or thoracic procedures</li> <li>- Trauma procedures</li> <li>- Caesarean sections</li> </ul>	Level 4 <b>BVB</b> <b>(most protective)</b>	ASTM F1671, Gowns ASTM F1670 Drapes	Pass Pass

- Comfort. Thanks to breathability
- Strong, light and with little noise.
- Reliability. Meets the highest international standards
- Without FC (Flourine Chemical)

The Protection and Comfort found in BVT protective masks meet the highest standards of regulatory performance. It is designed to pass the criteria of **AAMI PB 70 Level 4** and high performance critical area gowns in accordance with the European Standard for surgical curtains, gowns and clean air suits EN13795.

ASTM F1671 \* is the standard test method for the resistance of materials used in protective clothing to blood-borne penetration using Phi-X174 bacteriophage penetration as a test system. The test system has been designed to measure the penetration of a microbe substitute for hepatitis (B and C) and human immunodeficiency virus (HIV).

The bacteriophage substitute Phi-X174, used in the test method, is similar to HCV in size and shape, but also serves as a substitute for HBV and HIV. Inferences from other pathogens should be evaluated on a case-by-case basis.

*Source: Annual Standard Book ASTM, vol. 11.03. October 2002.*

International industry standards are used to test and measure the performance of the barrier for blood fluids and pathogens for materials used in protective clothing. This fabric exceeds these strict standards that provide the necessary waterproof protection in the surgical environment.

## Better threat barrier / Excellent breathability

Compared to pleated three-layer masks, the monolithic film provides a significantly better barrier to all fluids in the operating room, including bacteria and viruses.





## Pleated three layer masks

The breathability in the structure of the three layers is formed by adding an intermediate layer made of short fibers, which under tension form micro holes to allow the passage of air. Due to its nature, it could have potential changes in its barrier performance under tension.

## BVT Mouth cover

Breathability is inherent in the membrane, which allows the passage of water vapor. The membranes will not change the barrier performance, even under stressful conditions. It is a complete barrier against fluids and viruses as small as 0.027 microns. (CORONAVIRUS 0.030 microns) which **exceeds the FFP3.**

**WHAT MASKS PROTECT AGAINST THE CORONAVIRUS?**

 FFP1 Filtration of at least 78% of air particles	It protects from non-toxic and non-fibrogenic waste from dust or aerosols. Avoid inhalation of annoying residues and odors.
 FFP2 Filtration of at least 92% of air particles	It Protects from non-toxic waste and fibrogenic elements. It avoids inhalation of toxic fluids of dust, aerosols and smoke.
 N95 Filtration of at least 95% of air particles	Those are recommended by the US health authorities and those demanded by the Chinese community.
 FFP3 Filtration of at least 98% of air particles	It protects against poisonous and toxic types of dust, smoke and aerosols. It protects against bacteria, viruses and fungal spores.

FFP: Filtering Facepiece (normativa europea)

*BVB mouth covers exceeds the FFP3 protection factor*

## Excellent breathability

915/5000

The breathability of a fabric is essential to avoid the sauna effect. It can be measured by its moisture vapor transmission rate, MVTR. The dense and non-porous film used in these masks transports water molecules by molecular diffusion through the polymer matrix, using a difference in the partial pressure of water vapor through the film as the driving force.

In this way, the films or membranes serve to control the relative humidity and temperature in the microclimate adjacent to human skin. Alternatively, microporous films allow vapors through physical micro holes. With a moisture vapor transmission rate of 1300 g / m<sup>2</sup> / day, the monolithic film of BVB masks is highly breathable, while maintaining a complete barrier. A high MVTR eliminates the effect of sauna and reduces user fatigue.

Upright MVTR @ 32C/50% RH		
BVT	Competitor A	Competitor B
1300 g/m <sup>2</sup> /day	1500 g/m <sup>2</sup> /day	1000 g/m <sup>2</sup> /day

## Safety first! Lint free

The fluff is a potential danger. It is essential to minimize the fluff, since it floats and serves as a carrier of bacteria, which can consequently adhere to any surface. Antibodies react to lint and, therefore, could initiate an infection. BVT is made of spun bicomponent continuous fibers that have virtually no lint. Low flammability Due to the high concentration of oxygen in the operating room and the use of lasers or other electrical devices, it is important that single-use fabrics have low flammability and do not light up. The BVB mask has a Class 1 Flammability rating, which means a burning time of 3.5 s or more according to the textile clothing standard.

Flammability, 16 CFR 1610.4

BVT	Competitor A	Competitor B
Class 1	Class 1	Class 1

Materials for gowns and surgical masks should have great strength, including puncture resistance to resist conversion and use in difficult conditions. The strength of the tissues is measured by ASTM tensile, tear and tear strength test methods. BVT is among the toughest tissues available for medical use.

When the non-woven fabric of a mouthpiece or garment gets wet loses its resistance.

Grab Tensile
BVT
9500 g

Trapezoid Tear
BVT
1400 g

Burst Strength
BVT
3100 g/cm <sup>2</sup>

Simple mouth covers should NOT be used for more than one hour.

**BVT mouth covers allow to be used for long periods of time.**

## Viral Penetration ASTM Method F 1671 Final Report

Test Article: Set# 1: Grade WL26403, Run# T31513, Lot# 361800174703  
 Purchase Order: 4500946815  
 Study Number: 869222-S01  
 Study Received Date: 20 Jan 2016  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0062 Rev 14

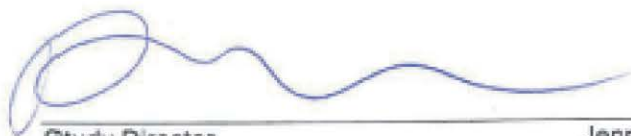
**Summary:** This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at  $21 \pm 5^\circ\text{C}$  and 30-80% relative humidity (RH), and then tested for viral penetration using a  $\Phi\text{X174}$  bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of  $\Phi\text{X174}$  bacteriophage. The viral penetration method complies with ASTM F1671; sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 8  
 Number of Test Articles Passed: 8  
 Test Article Side Tested: Darker Side (Labeled Side)  
 Test Article Preparation: Cut from the Material at Random  
 Test Article Sealed: Paraffin Wax  
 Exposure Procedure: A (No retaining screen)  
 Compatibility Ratio: 1.0 per sponsor  
 Environmental Plate Results: Acceptable

### Results:

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-8	$2.5 \times 10^8$	$3.0 \times 10^8$	$<1^a$	None Seen	Pass
Negative Control	$2.5 \times 10^8$	$3.0 \times 10^8$	$<1^a$	None Seen	Acceptable
Positive Control	$2.5 \times 10^8$	$3.0 \times 10^8$	$1.5 \times 10^2$	Yes	Acceptable

<sup>a</sup> A value of  $<1$  plaque forming unit (PFU)/mL is reported for assay plates showing no plaques.

  
Study Director

for  
Jennifer Jorgenson, B.S.



02 Feb 2016  
Study Completion Date



869222-S01