Understanding the New ASTM F3502-21 Specification on Barrier Face Coverings

Promotional Products Association International Webinar

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About the Development of the Standard

- ASTM International was approached as an appropriate standards development organization for this product
  - F23 on Protective Clothing & Equipment/F23.65 on Respiratory Protection
- Need for standard was identified in late May at COVID-19 PPE related ASTM meeting (support was provided by INDA)
  - Task group was established at ASTM F23 meeting in late June 2020
  - Initial task group activity began in early July and concluded in November 2020 with a draft that was sent out for voting
  - Two and half months were required to resolve ballot negatives and comments
  - A great deal of compromise was required to get to the current specification

Scope of the Specification

- A specification format was chosen to set mandatory requirements that are primarily performance based and with requirements for labeling
- “Barrier face coverings” (BFCs) are primarily for source control (protect others) but also defines a level of inhalation protection (protect wearer)
- Specification established limited design criteria, performance criteria, test methods, labeling and user information, and a minimum conformity assessment (compliance) process
  - Standard is comprehensive in its coverage of the product

Recognizing Product Differences

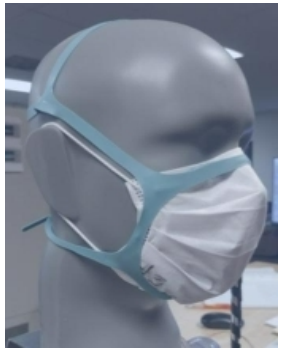
Respirators	Medical Face Masks	Barrier Face Coverings
Personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous atmospheres	an item of protective clothing designed to protect portions of the wearer's face, including the mucous membrane areas of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures	a product worn on the face specifically covering at least the wearer's nose and mouth with the primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter

Limitations of the Standard

- Does not address:
  - Additional performance attributes of barrier face coverings that exist for certain applications (e.g., flame/heat hazard work environments)
  - Use of antimicrobial or antiviral materials, finishes, or mechanisms
  - Requirements for Medical Face Masks (covered in ASTM F2100)
  - Requirements for respirators (instead, per 29 CFR 1910.134 or 42 CFR Part 84)
- Does not imply:
  - BFCs should be placed on very young children (< 2 years), anyone who has trouble breathing, or anyone who is unconscious, incapacitated or otherwise unable to remove barrier face coverings without assistance
- Does not address all the safety concerns associated with its use

Design Criteria

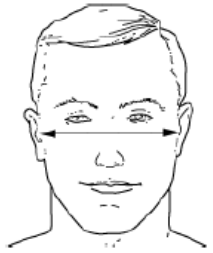
- Kept to a minimum to permit product type flexibility
  - Not be made of irritating or toxic materials
  - Not pose a flammability hazard
  - Cover at least nose and mouth
  - Fit snugly against the wearers face
  - Have a means of head retention
  - Not employ exhaust valves or open vents
  - Be permitted to be available in a universal or multiple sizes
- Manufacturer required to conduct a “design analysis” to assess leakage around edges of BFCs on intended user population

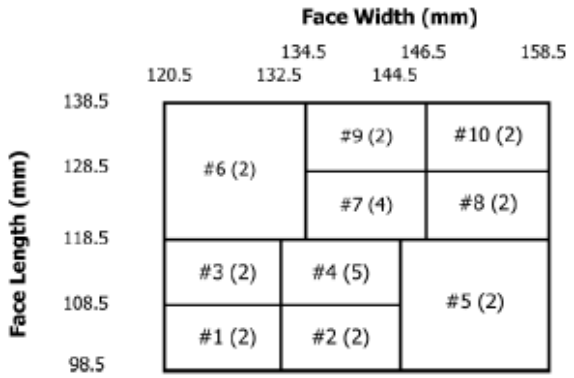


Optional Quantitative Leakage Test

- Allows measuring BFC leakage
  - Around edges and through material
- Can be performed to support design analysis
- References ASTM F3407 with changes:
  - Smaller test subject panel
  - No specific passing criteria

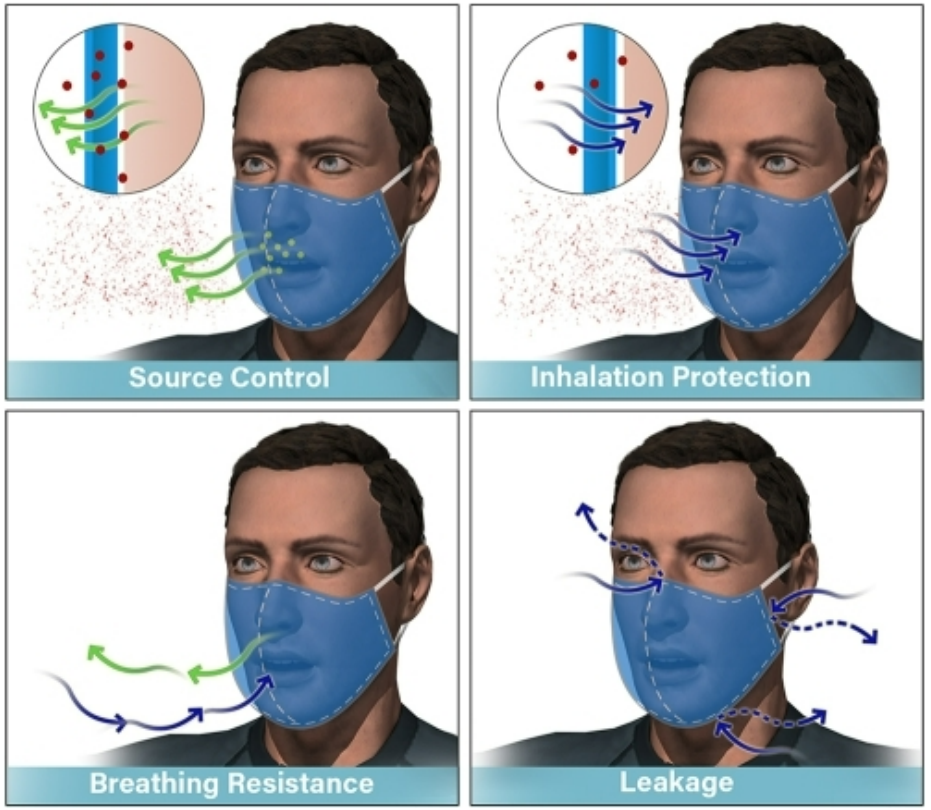
TABLE X1.1 Measured Face Dimensions

Description	Definition	Diagram
Bizygomatic Breadth (face width)	Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches	
Menton-Sellion Length (face length)	Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark	



Mandatory Performance Requirements

- Sub-micron particulate filtration efficiency
  - Establishes % particles blocked by product
  - Higher values are better
- Airflow resistance (inhalation)
  - Measures resistance to air passing through product
  - Lower values are better
- Applies to single use and reusable products
  - Reusable products are evaluated before and after maximum number of cycles for manufacturer specified laundering/cleaning procedures



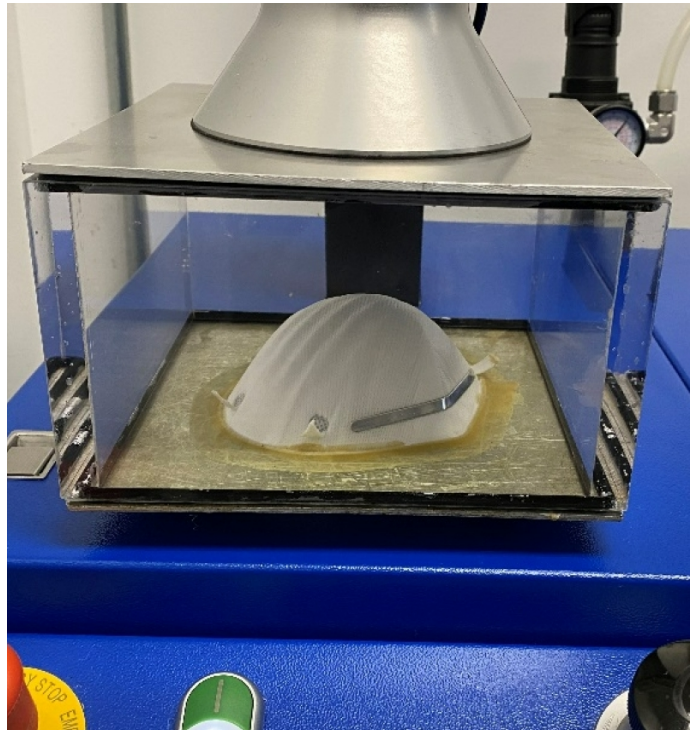
Sub-Micron Particulate Filtration Efficiency

- Test method based on 42 CFR Part 84 (Subpart K)
  - Other details provided in NIOSH TEB-APR-STP-0059 (same test method used to measure performance of N95 respirators)
  - Uses poly-disperse sodium chloride particles
  - Count medium diameter of 75 nm diameter
  - Mass median aerodynamic diameter of 0.3 microns
  - Airflow rate of 85 Liters/min adjusted to face velocity of 10 cm/s
- Evaluates full product (not just material)
- Utilizes holder to position face covering test sample on test apparatus
- Provides greater challenge than other filtration tests (much better at discriminating filtration performance)
  - **Minimum performance is ≥ 20%**

Photograph courtesy of NIOSH/NPPTL

Airflow Resistance

- Test performed on same equipment and sample as filtration efficiency test
  - Airflow resistance measured before filtration efficiency
- Test apparatus calculates initial resistance (ΔP) for air being pulled through face covering
- Airflow resistance relies of test sample being mounted on test platform to seal around its edges and evaluate entire product
  - **Maximum airflow is ≤ 15 mm H_2O**



Photograph courtesy of NIOSH/NPPTL

Performance Classification

- ASTM F3502 sets two separate classifications of both sub-micron particulate filtration efficiency and airflow resistance
  - Each property is separately classified
  - Intended to differentiate products among mandatory performance properties
  - Products may have mixed performance
- Performance levels do not imply specific protection levels or applications

Performance Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)
Sub-micron particulate filtration efficiency (Effectiveness of barrier face covering for capturing small particles; larger percentages indicate higher performance)	≥ 20%	≥ 50%
Air flow resistance (Indicative of ease of breathing while wearing barrier face covering; lower resistances indicate more breathable products)	≤ 15 mm H_2O	≤ 5 mm H_2O

Reporting of Results

- Documentation of results/test information
- Provides
  - Manufacturer name
  - Product name or model number
  - Laboratory name/address
  - Laboratory accreditation info.
  - Specific test values
  - Laundering method & # cycles, if reusable
  - Other test documentation
  - Performance classifications

REPORT OF TESTING AND OTHER INFORMATION REQUIRED BY ASTM F3502-21 SPECIFICATION ON BARRIER FACE COVERINGS											
Manufacturer Name											
Product Name or Model number											
Laboratory Name/Address											
Laboratory Accreditation Credentials											
Sub-micron Particulate Filtration Efficiency (Section 8.1)						Date of Testing					
Test Values (%) by Specimen											
Condition	1	2	3	4	5	6	7	8	9	10	Report Value†
Pristine*											
After Wash**											
Air Flow Resistance (Section 8.2)						Date of Testing					
Test Values (mm H_2O) by Specimen											
Condition	1	2	3	4	5	6	7	8	9	10	Report Value†
Pristine*											
After Wash**											
* Description of Condition if Other than Pristine (identify where performed)											
** Description of Laundering or Cleaning Conditions Applied (identify where performed)											
Description of Approach Applied as Part of Product Design Analysis (provide supporting documentation, as needed)											
Results of quantitative leakage assessment with leakage ratio (if applicable – document full findings in separate report)											
PERFORMANCE CLASSIFICATION***				Sub-micron Particulate Filtration Efficiency				Air Flow Resistance			

Product Labeling

- Product label
  - Manufacturer name
  - Product name or model
  - “MEETS ASTM F3502”
- Package label (smallest unit/package)
  - Product performance property classes
  - Materials of constructions
  - Month/year of manufacture
  - Lot or trace number (if applicable)
  - Indication of single use or reusable
  - Expiration date (if applicable)

MEETS ASTM F3502, SPECIFICATION ON BARRIER FACE COVERINGS.

THIS PRODUCT IS PRIMARILY INTENDED AS A MEANS OF SOURCE CONTROL FOR MINIMIZING THE PROJECTION OF THE EXPELLED MATERIALS FROM THE WEARER’S NOSE AND MOUTH.

WARNING: THIS FACE BARRIER COVERING IS NOT A MEDICAL FACE MASK AS DEFINED IN ASTM F2100, IS NOT INTENDED FOR USE IN MEDICAL PROCEDURES, AND IS NOT A RESPIRATOR

Full Compliance Statement

Visual Rating Methods – Part 1

Suggested Schemes for Indicating Face Covering Performance – Tabular

Option 1

Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)	"My Mask"
Filtration Efficiency	≥ 20%	≥ 50%	Level 2: 60%
Breathability	≤ 15 mm H_2O	≤ 5 mm H_2O	Level 1: 8 mm H_2O

Option 2

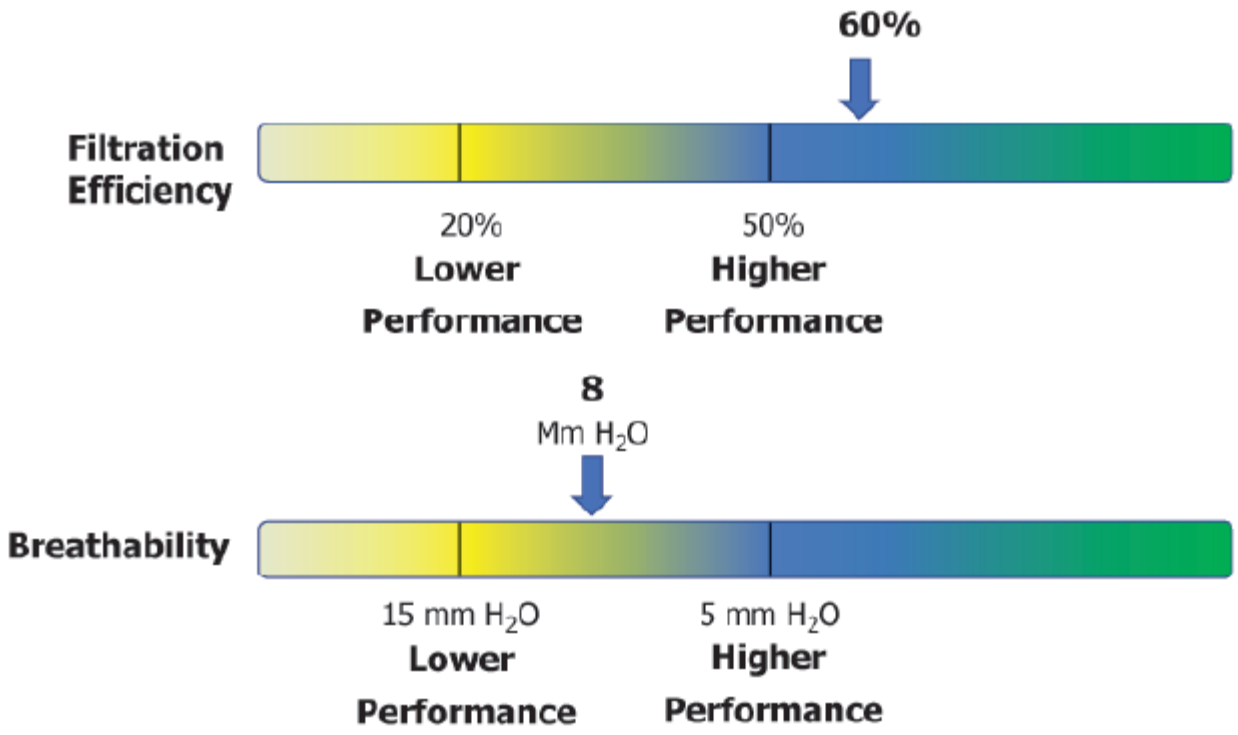
Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)	"My Mask"
Filtration Efficiency	≥ 20% F1	≥ 50% F2	F2
Breathability	≤ 15 mm H_2O B1	≤ 5 mm H_2O B2	B1

Option 3

Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)
Filtration Efficiency	F1	F2
Breathability	B1	B2

Visual Rating Methods – Part 2

- Suggested Scheme for Indicating Face Covering Performance – Continuum



User Instructions

- User instructions required for smallest saleable unit/package
- Content
  - Repeat of label information
  - Information on how to select correct size or make adjustments (if applicable)
  - How sizes are defined
  - How to put on and take off barrier face covering including proper orientation
  - If reusable, laundering or cleaning instructions
  - Maximum number of laundering and cleaning cycles
- Content (continued)
  - Other cautions and limitations (e.g., products not suitable for young children, products with metal should not be worn during MRI procedures)
  - Conditions of storage and shelf life
  - When to replace face covering
  - Procedures for disposal follow use

Manufacturers are encouraged to use diagrams, images, or video to convey correct use

Conformity Assessment

- Conformity assessment encompasses how a manufacturer product meets the ASTM F3502 standard
- BFC manufacturer must apply “Model A” criteria of ASTM F3050-17
  - Requirements has manufacturer self-declare conformance, set the frequency of testing, and address product quality
- Filtration efficiency and airflow resistance must be performed by laboratory accredited to ISO 17025
  - Quantitative leakage testing is not subject to this requirement
- Manufacturers are permitted to meet more rigorous requirements (e.g., 3rd party certification organization)

Future Changes to the Standard

- Intent is to evolve standard immediately as new information becomes available [work effort has already commenced]
- Separate effort to develop a separate test method for filter efficiency and air flow resistance
- Research and approach to develop a test method for measuring outward leakage (compared with inward leakage)
- New work group to address comments provided during the balloting process, initially focusing on clarifications and minor changes

Other ASTM Resources

- Recorded separate ASTM Webinar from 22 February
- ASTM to develop separate training package geared toward:
  - Manufacturers
  - End users
- ASTM has prepared a FAQ document that will be released soon
- NIOSH has developed a blog about the standard
- Discussions with different organizations for identifying a database associated with listing conforming products

Potential Enforcement Approaches

- OSHA is responsible for enforcement in the workplace and could consider adopting the standard
- Federal agencies who have jurisdictions not covered by OSHA should consider adopting the ASTM standard for workers under their jurisdiction
- FDA could consider dual certification of a facemask for medical use compliant with the ASTM Standard [FDA does recognized F3502]
- Options for the general public could be defined
- NIOSH or another agency should list the information on a trusted source website
- PPE purchases for barrier face coverings (e.g., Strategic National Stockpile) could adopt the ASTM standard