



Designation: F3502 – 21

## Standard Specification for Barrier Face Coverings<sup>1</sup>

This standard is issued under the fixed designation F3502; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

### INTRODUCTION

This is the first ASTM standard to address this type of product. The standard was primarily established in response to the global COVID-19 pandemic beginning in 2019 to address a product that is neither a medical face mask per ASTM Specification F2100 for providing source control, nor a respirator for providing inhalation protection as defined by regulatory requirements specified in the United States under 42 CFR Part 84.

This specification is intended to establish a national standard baseline for a source control device. This standard brings value by specifying minimum design, performance, and testing requirements and allowing comparison of products by end users where current guidelines have been limited. Evolving literature suggests that barrier face coverings could reduce the potential for disease transmission, as well as offering a reduction of inhalation particulate matter by the wearer. The focus of this specification is to identify how the device should perform in terms of source control/protection, comfort, and re-use potential. The level of source control/protection depends on how well particles are blocked from going through the barrier face covering and minimizing the amount of leakage that may occur around the perimeter of the barrier face covering. The specific performance property for filtration efficiency provides a greater challenge than most other particulate filtration tests, including BFE, based on the use of smaller particles and more rigorous test conditions. Barrier face coverings must be comfortable enough for individuals to be willing to wear them for long periods of time. Requirements for breathing resistance were incorporated into the specification. The final performance criterion was the potential for re-use of the barrier face covering, so the possibility of re-use was identified in the specification.

Users of this standard are directed to Section 1 (Scope) and Section 4 (Significance and Use) to understand the specific areas addressed by this standard and its limitations, along with the reasons for choice of specific requirements. Users of this standard are further directed to the specific caveats for this standard that are included in 1.3 – 1.11. The subcommittee responsible for this standard intends to further evolve this specification for addressing new knowledge about disease transmission reduction and barrier face covering design, performance, labeling, conformity assessment, and other aspects of these products' safety, health, and environmental impact as this information becomes available.

### 1. Scope

1.1 This specification is primarily intended to help ensure barrier face coverings meeting the stated requirements provide (1) a means of source control for individual wearers by reducing the number of expelled droplets and aerosols from the wearer's nose and mouth into the air; and (2) to potentially

offer a degree of particulate filtration to reduce the amount of inhaled particulate matter by the wearer.

NOTE 1—The source control/protection provided by barrier face coverings depends on several factors not considered in this specification, such as material degradation from wearer challenges including perspiration, talking, sneezing, and the length of time the barrier face covering is worn. Further research is needed to expand the evidence base for the protective effect of face coverings and, in particular, to identify the combinations of materials that maximize both their blocking and filtering effectiveness, as well as fit, comfort, durability, and consumer appeal. (<https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html>.)

NOTE 2—There are currently no established methods for measuring outward leakage from a barrier face covering, medical mask, or respirator.

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Nothing in this standard addresses or implies a quantitative assessment of outward leakage and no claims can be made about the degree to which a barrier face covering reduces emission of human-generated particles.

1.2 This specification establishes minimum design, performance (testing), labeling, user instruction, reporting and classification, and conformity assessment requirements for barrier face coverings.

1.2.1 Design criteria include setting minimum areas of face coverage over the wearer's nose and mouth, prohibiting open vents or valves, requiring a means for retaining the barrier face covering on the wearer's head, and providing a representation of product sizing. Manufacturers are further required to perform a design analysis for assessing leakage of exhaled air from the barrier face covering. Manufacturers are permitted to conduct quantitative testing as specified in this standard to supplement the design analysis.

1.2.2 Performance and testing criteria define minimum barrier face covering filtration efficiency and airflow resistance performance properties. Sub-micron particulate filtration efficiency represents the ability to capture and reduce respirable droplets and aerosols that potentially contain viruses and bacteria. Airflow resistance represents the wearer's ease of breathing or breathability while wearing the barrier face covering. The impact of repeated cleaning or laundering on continued performance is applied for measuring performance properties for those barrier face coverings that are intended to be reusable. Manufacturers are permitted to also provide test results for bacterial filtration efficiency (BFE) as supplemental information to the mandatory performance measurement of sub-micron particulate filtration efficiency.

NOTE 3—The principal performance criteria for barrier face covering determined by testing are sub-micron particle filtration efficiency and airflow resistance. Quantitative leakage assessment testing is optional for information purposes and is not required. This testing is not likely to be representative of outward leakage from the barrier face covering and should not be claimed to represent the amount of source control offered by the face covering. Bacterial filtration efficiency testing is also optional and not required. It is significantly different than sub-micron filtration efficiency, and the results of BFE testing cannot be interchanged or directly compared. The scope of this standard does not include accessories to barrier face coverings.

1.2.3 Labelling requirements specify the minimum content for labels that appear on the barrier face covering, its immediate packaging, and if different, point-of-sale packaging.

1.2.4 User instructions are required to guide selection and sizing, proper use (positioning and adjustment), and care including cleaning or laundering if product reuse is intended; inform on product cautions and limitations; and describe product replacement and disposal procedures.

1.2.5 Conformity assessment is demonstrated following Guide **F3050**, Annex A3, Model A to issue a declaration of conformity indicating that each barrier face covering labelled as compliant has met all of the requirements of this standard specification including design criteria, performance criteria, test methods, labelling, and user information. Additionally, conformance to this standard requires that sub-micron particulate filtration efficiency and airflow resistance tests have been performed by a laboratory accredited for conducting these tests.

1.3 This specification addresses all barrier face coverings and only barrier face coverings that are intended for either a single use (disposable) or multiple uses (reusable).

1.4 This specification does not address the unique additional performance attributes of barrier face coverings that exist for certain applications, such as flame-resistant apparel used in environments where there are flame, high heat, electrical arc, or related hazards, but does recommend that barrier face coverings also conform to other standards as applicable.

1.5 This specification does not address the use of antimicrobial or antiviral materials, finishes, or mechanisms.

NOTE 4—The use of antimicrobial materials, finishes, or mechanisms is generally subject to regulatory oversight by government agencies, including the U.S. Environmental Protection Agency and U.S. Food and Drug Administration in the United States, which applies additional safety and efficacy requirements to these products. See 5.1.2 for the requirement of nontoxic and non-irritating materials used in the construction of barrier face coverings.

1.6 This specification does not address requirements for medical face masks, which are covered in Specification **F2100**.

1.7 Nothing in this specification is intended to contradict or replace criteria that are established in 42 CFR Part 84 for air-purifying respirators or requirements for use of respirators in accordance with 29 CFR 1910.134.

1.8 Nothing in this specification is intended to imply that barrier face coverings qualify as approved respiratory protection devices or have FDA clearance for use in a healthcare setting.

1.9 Nothing in this specification is intended to imply that barrier face coverings 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.

1.10 The values stated in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.

1.11 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.12 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 2. Referenced Documents

### 2.1 ASTM Standards:<sup>2</sup>

<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

- D3938** Guide for Determining or Confirming Care Instructions for Apparel and Other Textile Products
- D5489** Guide for Care Symbols for Care Instructions on Textile Products
- F1494** Terminology Relating to Protective Clothing
- F1506** Performance Specification for Flame Resistant and Electric Arc Rated Protective Clothing Worn by Workers Exposed to Flames and Electric Arcs
- F2100** Specification for Performance of Materials Used in Medical Face Masks
- F2101** Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*
- F2302** Performance Specification for Labeling Protective Clothing Which Provides Resistance to Incidental Exposures to Heat or Open Flame
- F3050** Guide for Conformity Assessment of Personal Protective Clothing and Equipment
- F3407** Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators
- 2.2 *AATCC Monograph*:<sup>3</sup>
- M14** Guidance and Considerations for General Purpose Textile Face Coverings: Adult
- 2.3 *ANSI/ASQC Standard*:<sup>4</sup>
- ANSI/ASQC Z1.4** Sampling Procedures and Tables for Inspection by Attributes
- 2.4 *ISO Standards*:<sup>5</sup>
- ISO 2859-1** Sampling Procedures for Inspection by Attributes—Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-Lot Inspection
- ISO/ANSI/AAMI 10993-5** Biological Evaluation of Medical Devices—Part 5: Tests for In Vitro Cytotoxicity
- ISO/ANSI/AAMI 10993-10** Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Skin Sensitization
- ISO/IEC 17025** General Requirements for the Competence of Testing and Calibration Laboratories
- 2.5 *Federal Regulations*:<sup>6</sup>
- 16 CFR Part 1610** Standard for the Flammability of Clothing Textiles
- 16 CFR Part 303** Rules and Regulations Under the Textile Fiber Products Identification Act
- 16 CFR Part 423** Care Labeling of Textile Wearing Apparel and Certain Piece Goods as Amended
- 29 CFR 1910.134** Respiratory Protection
- 42 CFR Part 84** Approval of Respiratory Protective Devices

2.6 *NPPTL Standard Test Procedure*:<sup>7</sup>

**TEB-APR-STP-0059** Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators

2.7 *NFPA Standard*:<sup>8</sup>

**NFPA 2112** Standard on Flame-Resistant Clothing for Protection of Industrial Personnel Against Short-Duration Thermal Exposures from Fire

### 3. Terminology

#### 3.1 *Definitions*:

3.1.1 *airflow resistance, n*—in the testing of a barrier face covering, the degree to which a product worn over the wearer's nose and mouth restricts the ability of the wearer to inhale and exhale (also referred to as breathing resistance).

3.1.1.1 *Discussion*—This specification requires the measurement of airflow resistance of the barrier face covering during inhalation. The performance requirement is set to reduce the restriction of inhaling and exhaling as much as possible.

3.1.2 *bacterial filtration efficiency (BFE), n*—the effectiveness of a material in preventing the passage of aerosolized bacteria, expressed as the percentage of a known quantity that does not pass through the barrier face covering at a given aerosol flow rate.

3.1.2.1 *Discussion*—In this specification, BFE is only an optional reported test and not part of the requirements. BFE testing primarily involves the evaluation of larger sized particles and lower exposure conditions as compared to sub-micron particulate filtration efficiency.

3.1.3 *barrier face covering, n*—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.

3.1.3.1 *Discussion*—In this specification, barrier face coverings are assessed for airflow resistance; filtration performance using sub-micron particulate filtration efficiency testing; and the degree of face coverage per a leakage assessment using a product design analysis that can be supplemented by quantitative testing using test subjects.

3.1.4 *design analysis, n*—a process applied to represent the coverage and potential leakage pathways in the design of a barrier face covering as worn by an individual.

3.1.4.1 *Discussion*—In this specification, a design analysis is used for assessing the leakage associated with a barrier face covering when worn by the general user population.

3.1.5 *flammability, n*—a quality of a product related to its rate of flame spread when contacted by a flame source.

3.1.5.1 *Discussion*—In this specification, flammability applies to barrier face coverings as determined by 16 CFR Part 1610 as part of the Consumer Product Safety Commission

<sup>3</sup> Available from American Association of Textile Chemists and Colorists (AATCC), P.O. Box 12215, Research Triangle Park, NC 27709-2215, <http://www.aatcc.org>.

<sup>4</sup> Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

<sup>5</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

<sup>6</sup> Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, <http://www.access.gpo.gov>.

<sup>7</sup> Available from National Personal Protective Technology Laboratory (NPPTL), <https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf>.

<sup>8</sup> Available from National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169-7471, <http://www.nfpa.org>.

regulations for wearing apparel. However, products that comply with these regulations by having Class 1 or 2 flammability are considered not flame resistant when exposed to flame, high heat, electrical arc, or other thermal hazards.

3.1.6 *leakage assessment, n*—the evaluation of a barrier face covering for its potential to fit snugly to the wearer’s face at least over their nose and mouth and to reduce the likelihood of leakage of unfiltered air from the wearer to the outside environment.

3.1.6.1 *Discussion*—In this specification, the leakage assessment addresses particulates passing through the barrier face covering and around the perimeter of the barrier face covering. When quantitative testing is performed, the leakage assessment is permitted to be presented as the ratio of the particulate level upstream (outside) of a barrier face covering to the level downstream (inside) of the barrier face covering on test subjects.

NOTE 5—The leakage assessment represents the total inward leakage likely to occur during wear. Whether measured quantitatively or assessed qualitatively, the leakage assessment does not represent the likely outward leakage of particles generated by the wearer. This is because there are currently no specific accepted techniques that are available to measure outward leakage from a barrier face covering or other products. Thus, no claims may be made with respect to the degree of source control offered by the barrier face covering based on the leakage assessment.

NOTE 6—Leakage assessment, if measured quantitatively on a barrier face covering that rests closely on the face and thus has minimal inward volume, may not be representative of true inward leakage or particles that come through or around the barrier face covering.

3.1.7 *medical face mask, n*—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.

3.1.7.1 *Discussion*—Medical face masks include surgical masks, procedure masks, isolation masks, laser masks, dental masks, and patient care masks. Isolation masks, laser masks, dental masks, and patient care masks are considered isolation masks. For many user groups, the term “mask” has become synonymous with any product worn on the wearer’s face that offers a level of filtration efficiency; however, in the context of this specification, “mask” refers only to medical face masks that are different from barrier face coverings. Requirements for medical face masks are provided in Specification **F2100**. This standard is not intended to address regulatory requirements.

3.1.8 *respirator, n*—personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous contaminants.

3.1.8.1 *Discussion*—Barrier face coverings are not designed to meet the performance requirements of NIOSH-approved respirators. For the purpose of this specification, healthcare workers are typically instructed to wear filtering facepiece respirators with N95 or higher levels of filtration efficiency as defined in 42 CFR Part 84 that are intended to protect the wearer from exposure to pathogenic biological airborne particulates. See also the definition for *surgical N95 respirators*.

3.1.9 *reusable, adj*—referring to the ability of a product to be used and laundered or cleaned multiple times and maintain its specified performance characteristics.

3.1.9.1 *Discussion*—The use of the term “reusable” in this specification is intended to distinguish types of barrier face coverings that are durable and that can be further subjected to laundering or cleaning which permits their use multiple times until they are damaged, cannot be effectively cleaned, or have surpassed the expiration date or are beyond the manufacturer’s designated service life.

3.1.10 *service life, n*—in the specification of barrier face coverings, the maximum number of use and laundering or cleaning cycles that barrier face coverings can undergo and still maintain their performance properties.

3.1.10.1 *Discussion*—For the purpose of this specification, the service life is the maximum number of cleaning or laundering cycles that can be applied to a reusable barrier face covering as specified by the manufacturer.

3.1.11 *shelf life, n*—in the specification of barrier face coverings, the length of time after the date of manufacture that a barrier face covering can be stored as specified by the manufacturer.

3.1.12 *source control, n*—the use of a barrier face covering over the wearer’s nose and mouth that is intended to contain the wearer’s respiratory secretions, including droplets and aerosols, to help prevent the transmission from infected individuals who may or may not have symptoms of a specific respiratory disease.

3.1.12.1 *Discussion*—When worn properly, barrier face coverings meeting the requirements of this specification provide a level of source control.

3.1.13 *sub-micron particulate filtration efficiency, n*—a measure of the ability of a barrier face covering to capture aerosolized particles smaller than one micron, expressed as a percentage of a known number of particles that do not pass the barrier face covering at a given face velocity for flat samples or flow rate for whole article testing.

3.1.13.1 *Discussion*—In this specification, a specific form of sub-micron particulate efficiency testing is performed as described in **8.1**.

3.1.14 *surgical N95 respirator, n*—a respirator that has both NIOSH approval as an N95 filtering facepiece respirator per 42 CFR Part 84 and FDA clearance as a Class II medical device under 21 CFR Section 878.4040.

3.1.14.1 *Discussion*—Surgical N95 respirators are N95 filtering facepiece respirators that are approved under 42 CFR Part 84 criteria and meet additional performance criteria for material biocompatibility, fluid resistance, and flammability required by the FDA.

3.2 For definitions of other protective clothing-related terms used in this standard, refer to Terminology **F1494**.

## 4. Significance and Use

4.1 Barrier face coverings are worn over at least the nose and mouth with the primary purpose of providing source control and to potentially reduce inhaled particulates. It is expected that a range of barrier face covering products with different configurations, designs, and materials of construction can be developed and qualified in accordance with this specification. For this reason, a limited number of principal

performance evaluations are applied. The principal performance requirements in this specification for barrier face coverings include sub-micron particle filtration efficiency and airflow (breathing) resistance, with a separate design criterion for leakage assessment.

4.1.1 Minimum requirements are set for sub-micron particulate filtration efficiency for the purpose of source control. The test for sub-micron particulate filtration efficiency is based on 42 CFR Part 84 (Subpart K), with further detail in NIOSH Standard Test Procedure TEB-APR-STP-0059. These procedures are typically applied to air-purifying respirators with filters. The test is performed using poly-disperse sodium chloride (NaCl) aerosols with a count median diameter of  $75 \pm 20$  nm electrical mobile diameter and a geometric standard deviation of  $\leq 1.86$  to give a mass median aerodynamic diameter of  $0.3 \mu\text{m}$ . Testing is performed on full products or, for certain products, the area of the product that fully covers the wearer's nose and mouth. Testing to this method yields a percentage reduction that can range from 0 % (no sub-micron filtration capability) to 99.97 % (practically all sub-micron particles are blocked by the product). For the purpose of this specification, a minimum 20 % requirement is set. This specific performance property provides a greater challenge than most other particulate filtration tests, including BFE, based on the use of smaller particles and more rigorous test conditions.

4.1.2 As filtration efficiency for a barrier face covering increases, airflow resistance (breathing resistance) also increases, making it more difficult to breathe. Consequently, a maximum airflow resistance for barrier face coverings is established. Measurements of airflow resistance are made with the same equipment that is used to measure sub-micron particulate filtration efficiency. This testing yields airflow resistance values in millimeters of water gauge pressure ( $\text{mm H}_2\text{O}$ ), where lower pressures indicate easier breathing. In this standard, the airflow resistance must be at 15  $\text{mm H}_2\text{O}$  or below. The value of 15  $\text{mm H}_2\text{O}$  was chosen as this level is a lower breathing resistance than required for filtering facepiece respirators and is not expected to require a pre-use medical evaluation for the general user population.

4.1.3 Sub-micron particulate filtration efficiency and airflow resistance do not account for the leakage of air around the perimeter of the barrier face covering. A leakage assessment using a design analysis of the product is required to assess the ability of the barrier face covering design to provide appropriate coverage for a range of wearer faces of different dimensions. The design analysis can be conducted by the manufacturer in a number of different ways. The standard also permits the supplemental use of quantitative information obtained from a modified form of Test Method F3407 using test subjects. This test yields a reportable ratio of outside particulate concentration to the concentration of particles in the wearer's breathing zone. Thus, a leakage ratio of 1.0 indicates the outside and inside environments are equal and that particulates flow through gaps in the barrier face covering (in addition to any particulates that pass through the filtration materials of the product).

4.1.4 Additional testing requirements are included in this specification for barrier face coverings that are intended to be laundered or cleaned and reused. These tests evaluate the impact of multiple cycles of cleaning or laundering on sub-micron particulate filtration efficiency, airflow resistance, and leakage assessment. This requirement is included in this specification because it is known that certain products may shrink, stretch, become distorted, or are otherwise negatively affected in their capabilities for source control and their potential for reducing the inhalation of particulate matter. For the purposes of this specification, defined performance requirements for sub-micron particulate filtration efficiency and airflow resistance in addition to the leakage assessment design analysis requirements must be met after the maximum number of laundering and cleaning cycles specified by the manufacturer.

4.1.5 A system for reporting the key performance properties is established in this specification where compliant product performance above the minimum levels is classified into two different levels that indicate differences of performance. The purpose of this classification system is to allow end users to differentiate products among the mandatory performance properties—sub-micron particulate filtration efficiency and airflow resistance. While the higher level indicates better performance for the individual property, these levels do not imply specific protection levels or applications since there is currently insufficient information to characterize how barrier face covering performance relates to all conditions of use. It is also possible for a product to have high performance for one property (sub-micron particulate filtration efficiency or airflow resistance) and low performance for the other property.

4.2 Design criteria are established in this specification to ensure the barrier face covering stays over the wearer's nose and mouth, as well as to limit the use of features that would compromise the effectiveness of the barrier face covering from providing source control and reducing the inhalation of particulate matter. For example, the incorporation of vents, valves, or other features that allow for airflow to bypass the filtration elements of the barrier face covering during exhalation are prohibited.

4.3 Minimum requirements are established for labelling of barrier face coverings and for information provided by the manufacturer to the end user. The intent of these requirements is to deliver products that are clearly identified as meeting this specification and that additional pertinent information and instructions are provided to the end user.

4.4 The conformity assessment requirements for barrier face coverings in this specification have been established to provide confidence that the products labeled as compliant meet all applicable criteria of this specification. Performance requirements in Section 6 must be performed by competent laboratories accredited to ISO/IEC 17025, and the testing performed must be within the scope of the laboratory's ISO/IEC 17025 accreditation. The manufacturer must also meet all of the Model A requirements in Guide F3050 for other aspects of conformity assessment that address testing/inspection facilities, a quality management system, records retention, ongoing conformity, recalls and safety alerts, and marking. The

manufacturer is required to determine compliance with all design, performance, reporting, labeling, user information, and conformity assessment requirements in this specification and provide a declaration of conformation that indicates that their product(s) fulfills all of these requirements.

4.5 It is the responsibility of the user of this standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

4.6 A number of recommendations are provided through notes to aid in the clarification of requirements or suggestions to address other areas of compliance with this specification.

## 5. Design Requirements

### 5.1 *General Construction:*

5.1.1 The barrier face covering shall be designed to cover at least the wearer's nose and mouth and fit snugly where the product contacts the wearer's face to reduce gaps, as determined by the product design analysis in 5.4.

NOTE 7—A leakage assessment design analysis is provided in 5.4 to ascertain the extent of possible leakage through or around the barrier face covering through a product design self-declaration that can be supplemented by reporting the results of quantitative testing specified in 8.3.

5.1.2 Portions of the barrier face covering materials that contact the wearer's skin shall be made of non-irritating and nontoxic materials.

NOTE 8—It is possible to assess these characteristics of barrier face covering materials by performing dermal irritation and skin sensitization tests according to procedures provided in ISO/ANSI/AAMI 10993-10 and by performing cytotoxicity testing per ISO/ANSI/AAMI 10993-5. This note does not imply a requirement to use any of the listed tests or any particular test for determining that the product does not irritate the wearer. It is further possible that the use of materials already evaluated to these standards satisfies this requirement.

5.1.3 Barrier face coverings shall not be made of materials that pose a flammability hazard.

5.1.3.1 Where barrier face coverings are used in applications where flame, high heat, electrical arc, or other thermal hazards are present, barrier face coverings shall be qualified to the respective applicable standards, as appropriate.

NOTE 9—Barrier face coverings made of textile fabrics are considered wearing apparel and are subject to 16 CFR 1610 requirements for the measurement of textile material flammability. The application of this federal regulation is intended to limit the use of potentially dangerous, flammable materials, where acceptable performance is judged by the respective materials being classified as Class 1, "Normal Flammability," Class 2, "Intermediate Flammability," or exempt from testing. Specific standards related to flame, high heat, electrical arc, and other thermal hazard exposures include, but are not limited to: Specification F1506, Specification F2302, and NFPA 2112.

5.1.4 Barrier face coverings shall be free of any sharp edges, sharp points, or burrs.

5.1.5 Barrier face coverings shall be permitted to be either disposable (single use) or reusable (multiple uses).

5.1.5.1 Barrier face coverings shall be constructed of materials and designed such that they will not be damaged by ordinary handling, donning, and doffing.

5.1.5.2 Barrier face coverings that are intended to be reusable shall be constructed of materials and designed such that they will not be damaged by ordinary handling, donning, and doffing after being repeatedly subjected to laundering or cleaning as specified by the manufacturer.

NOTE 10—Section 6 has specific requirements for evaluating the performance of reusable barrier face coverings for their continued performance following the manufacturer's recommended maximum number of laundering (or cleaning) cycles when using the manufacturer's recommended laundering or cleaning procedures.

5.1.6 Barrier face coverings shall be designed, shaped, or have features that aid in minimizing the flow of air around the perimeter of the product.

5.1.7 Barrier face coverings shall not have vents, valves, or other open pathways as part of their design.

NOTE 11—The use of exhalation valves or other features that bypass the filtration of the product are not allowed because these features potentially diminish source control and increase the likelihood of unfiltered air to pass through into the environment.

5.1.8 Barrier face coverings with replaceable filters shall have means for preventing the improper placement of the filters.

5.1.9 Barrier face coverings that include transparent materials for the purpose of allowing others to view the wearer's lips shall afford sufficient filtration material to provide the function of source control.

### 5.2 *Retention System:*

5.2.1 Barrier face coverings shall have a means for keeping the barrier face covering over the wearer's nose and mouth for the expected period of use and range of activities.

NOTE 12—Examples of retention systems include, but are not limited to: ties, elastic ear loops, and head harnesses. In some cases where the retention system is integrated with the filtering area, such as tubular neck garments (sometimes referred to as gaiters), the area intended to cover the wearer's nose and mouth must be clearly identifiable and proper orientation described in the user instructions. The effectiveness of these systems for keeping the barrier face covering on the wearer's head and maintaining coverage of wearer's nose and mouth varies with the type of retention system in combination with the materials of construction and the overall design. Subsection 5.4 includes an assessment as a degree for how well the barrier face covering fits on individuals' faces. For adult products, the use of plastic toggles or slides is permitted but should not be able to release from the tie or free end (thus leaving the ability of the mask to fall open).

5.2.2 Where the barrier face covering uses a head harness, the head harness shall provide for adjustment to allow proper fit on the wearer's head. When the head harness is made from elastic materials, the elasticity of the harness material is considered adequate adjustability for proper use.

### 5.3 *Sizing:*

5.3.1 Where intended to be worn by a range of individuals, multiple sizes shall be permitted, but not required, to allow a single model to fit a wide variety of the end user population, excluding very young children (<2 years).

5.3.2 Barrier face coverings shall be permitted to be offered in single sizes for the general population and for specific population groups such as children.

NOTE 13—Anthropometric data from the National Institute for Occupational Safety and Health are available as a resource for product size development.<sup>9</sup>

5.4 Leakage Assessment:

5.4.1 The leakage assessment shall be reported by the manufacturer through a product design analysis self-declaration.

5.4.2 The required self-declaration shall report that the product reduces leakage around the perimeter or other areas of the product based upon an analysis of the product design. This statement is included on any self-declaration required as part of Guide F3050, under Section 12 of this specification.

5.4.2.1 The manufacturer is permitted to conduct quantitative testing to supplement its product design analysis self-declaration. When used, the leakage ratio shall be determined using Test Method F3407, with the modifications specified in 8.3.

5.4.3 Where barrier face coverings are reusable and intended for laundering or cleaning, the product design analysis shall be applied to barrier face coverings both in a new condition and after the maximum number of laundering or cleaning cycles as specified by the manufacturer according to the manufacturer’s care instructions.

NOTE 14—Examples of means to accomplish a leakage assessment could include dimensional analysis, computer modeling, placement of barrier face coverings on standardized head or head/torso forms and judging their respective areas of coverage and conformity to the head or head-torso form face showing conformance to the fit and sizing characterizations of AATCC M14-2020, or performing a quantitative analysis.<sup>10</sup>

6. Performance Requirements

6.1 Barrier face coverings shall meet the requirements specified in Table 1.

6.2 Where the barrier face covering is reusable and intended to be laundered or cleaned, barrier face coverings shall meet each of the requirements in Table 1, both in a new condition and after the maximum number of laundering or cleaning cycles specified for the product in accordance with 7.3.

7. Sampling and Conditioning

7.1 Type of Samples—Testing shall be performed on complete barrier face coverings or materials as specified in each individual test method in Section 8.

<sup>9</sup> The report, “A Head-and-Face Anthropometric Survey of U.S. Respirator Users,” is available from *Journal of Occupational and Environmental Hygiene*, Vol 2, No. 11, 2005, pp. 567–76. DOI: 10.1080/15459620500324727. [https://www.nap.edu/resource/11815/Anthrotech\\_report.pdf](https://www.nap.edu/resource/11815/Anthrotech_report.pdf). This report provides key facial dimensions for persons aged 18 to 55.

<sup>10</sup> Digital files for solid headform models are available at <https://www.cdc.gov/niosh/data/datasets/rd-10130-2020-0/default.html>.

TABLE 1 Barrier Face Covering Minimum Performance Requirements

Performance Property	Criteria	Test Method Section
Sub-micron particulate filtration efficiency	≥20 %	8.1
Airflow resistance, inhalation	≤15 mm H <sub>2</sub> O	8.2

7.1.1 Where materials are specified as the samples in the individual test method, these samples shall be taken from complete barrier face coverings unless the nature of the testing requires larger samples than what can be obtained from any particular finished product.

7.1.2 The number of barrier face coverings or material samples shall be as specified in the individual test method.

7.2 Choice of Samples—The specific barrier face covering samples to be tested shall be representative of the barrier face coverings being manufactured.

NOTE 15—The use of a sampling plan for choosing specific representative samples of barrier face coverings for evaluation in accordance with this specification is recommended but not required. Examples of acceptable sampling plans are found in ANSI/ASQC Z1.4 and ISO 2859-1.

7.3 Conditioning:

7.3.1 Prior to testing, specimens shall be conditioned to the environmental conditions specified in each test method in Section 8.

7.3.2 Reusable barrier face coverings shall be further subjected to testing after the maximum number of laundering or cleaning cycles specified by the manufacturer as required in Section 11.

7.3.2.1 If the manufacturer specifies that their reusable barrier face covering is to be cleaned or laundered before use, then the barrier face covering shall be tested initially following a single cleaning or laundering cycle in lieu of testing in a new condition.

7.3.2.2 Laundering or cleaning for reuse shall be performed as specified by the manufacturer as required in Section 11.

8. Test Methods

8.1 Sub-Micron Particulate Filtration Efficiency—Sub-micron particulate filtration efficiency shall be measured as specified in Subpart K of 42 CFR Part 84, using an initial efficiency (no preloading) and the following modifications:

NOTE 16—Additional useful information on the performance of this testing is provided in TEB-APR-STP-0059, particularly for the generation of the sodium chloride salt aerosol.

NOTE 17—Both sub-micron particulate filtration efficiency and airflow resistance are performed using the same equipment and can be conducted on the same set of samples. It is recommended that the procedures for measuring airflow resistance described in 8.2 be measured first without the use of the challenge aerosol.

8.1.1 Specimens:

8.1.1.1 A total of ten (10) specimens shall be tested.

8.1.1.2 Where barrier face coverings are reusable, an additional set of specimens shall be tested after the maximum number of laundering and cleaning cycles specified by the manufacturer, according to manufacturer care instructions (ten specimens tested in each condition for a total of 20 samples).

8.1.1.3 Specimens shall include the entire product unless the style of product extends beyond the ordinary shape of a product that normally just covers the wearer’s nose and mouth, such as a tubular product (for example, gaiter), in which case the specimen should include at least the portion of the product that covers the wearer’s nose and mouth and be representative of the final, finished manufacturer product.

8.1.1.4 For products with filter inserts smaller than the specimen area, the area around the filter insert shall be included in the specimen area to be tested.

8.1.1.5 Specimens shall be pre-conditioned at  $85 \pm 5\%$  relative humidity and  $38 \pm 2.5\text{ }^\circ\text{C}$  for  $25 \pm 1\text{ h}$ . After conditioning, the filters shall be sealed in an airtight, non-hygroscopic container and tested within 10 h.

8.1.2 *Specimen Mounting and Test Setup:*

8.1.2.1 In cases where the specimen lays flat against the filter holder in the test equipment, a mesh screen, wire frame, or similar device with at least 70 % open area shall support specimen products.

NOTE 18—The use of a mesh screen, wire frame, or similar device is intended to prevent the collapse of the product into the equipment, which can potentially affect test results and approximate at least the anatomy/area of the nose and mouth when used.

8.1.2.2 Where a mesh screen, wire frame, or similar device is used, the laboratory shall ensure that the type of support device used does not adversely affect the results of the test.

8.1.2.3 A face velocity of  $10 \pm 0.5\text{ cm/s}$  shall be used with the flow rate not exceeding 85 Lpm as specified in 8.1.3.5.

NOTE 19—The use of a specified face velocity affects the challenge flow rate. For example, with a filter that has an area of  $100\text{ cm}^2$ , the challenge flow rate would be approximately 60 Lpm to achieve the face velocity of  $10\text{ cm/s}$ .

8.1.2.4 The specimen shall be mounted and sealed on an adapter plate to prevent leakage, including leakage that may occur between multiple layers of the product. The specimen shall be sealed using hot melt glue, beeswax, rope caulk (for large gaps), or another appropriate sealant onto the adapter plate.

NOTE 20—Rope caulk is useful to help seal large gaps, if necessary. Beeswax has been found to better seal the perimeter of multilayered products. It is recommended to use a method of sealing that ensures that leakage does not occur through any areas of attachment, particularly for products that have irregular sealing surfaces, multiple layers, or other aspects of their design that make sealing on the test apparatus difficult. The provision of photographs from the laboratory of the specimen setup are useful for documenting how the specimen is mounted.

8.1.2.5 A small chamber shall be created by placing a container around the device and placing a cover (with a large inlet hole) over the chamber (see Fig. 1 for an example). Gasket material shall be used to seal the chamber to the plates.

NOTE 21—This step is not necessary if the specimen cannot be mounted and instead will be tested directly in the filter holder of the testing equipment.

8.1.3 *Procedures:*

8.1.3.1 The NaCl aerosol shall have a particle size distribution with count median diameter of  $75 \pm 20\text{ nm}$  and a standard geometric deviation not exceeding 1.86 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

8.1.3.2 The test shall be conducted at  $25 \pm 5\text{ }^\circ\text{C}$  and a relative humidity of  $30 \pm 10\%$  and the particles shall be neutralized to the Boltzmann equilibrium state. Each specimen will be challenged with a concentration not exceeding  $200\text{ mg/m}^3$ .

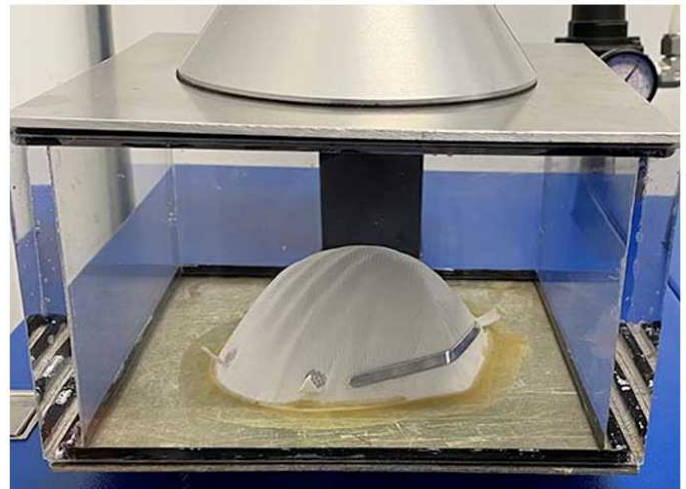


FIG. 1 Example of a Filter Holder Adapter

8.1.3.3 The efficiency of the specimen will be determined by using a forward-light-scattering photometer or equivalent.

8.1.3.4 If the specimen is mounted and secured into a chamber, perform a test setup with the empty chamber to account for any loss of particles caused by the chamber.

8.1.3.5 The specimens shall be tested at a flow rate of  $85 \pm 4\text{ Lpm}$ . If the specimen lays flat in the filter holder, adjust the flow rate to achieve a face velocity of  $10 \pm 0.5\text{ cm/s}$  (see Note 19).

8.1.3.6 The stabilization time for the test shall be a minimum of 6 s to have stable concentrations upstream and downstream before measurement data is collected.

NOTE 22—Larger chambers around the barrier face covering take a longer time to stabilize and it is necessary to increase the stabilization time accordingly. This is determined by first installing the mounting fixture and observing changes in the signal for a period of time to determine how much time is needed for stabilization.

8.1.3.7 The measurement time should be a minimum of 4 s to average out aerosol concentration fluctuation. Measurement times shall not exceed 15 s so as to minimize loading of the specimen.

8.1.4 *Calculation and Interpretation of Results:*

8.1.4.1 The percent filtration efficiency shall be calculated for each specimen as 100 minus the percent penetration.

8.1.4.2 The lowest measured filtration efficiency of all specimens (including specimens subjected to laundering and cleaning) rounded to the lowest integer shall be used to determine compliance with this specification, the classification of sub-micron particulate filtration efficiency as specified in Table 2, and for the purpose of the manufacturer reporting their results.

8.2 *Airflow Resistance:*

8.2.1 Airflow resistance for inhalation shall be determined using the specimen requirements in 8.1.1 and specimen mounting and test setup requirements in 8.1.2.

8.2.2 Airflow resistance of an empty fixture (chamber without a specimen installed) or screen if tested in the filter tester holder shall be measured at a flow rate of  $85 \pm 4\text{ Lpm}$  (or other flow rate to achieve  $10 \pm 0.5\text{ cm/s}$  for flat specimens) to



**TABLE 2 Separate Classification of Barrier Face Covering Performance Properties<sup>A,B</sup>**

Performance Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)
Sub-micron particulate filtration efficiency <sup>C</sup> (Effectiveness of barrier face covering for capturing small particles; larger percentages indicate higher performance)	≥20 %	≥50 %
Airflow resistance (Indicative of ease of breathing while wearing barrier face covering; lower resistances indicate more breathable products)	≤15 mm H <sub>2</sub> O <sup>D</sup>	≤5 mm H <sub>2</sub> O

<sup>A</sup> Each performance property is classified separately; there are four possible sets of classifications. A barrier face covering can have:

- (1) Level 1 performance for both properties,
- (2) Level 1 performance in sub-micron particulate filtration efficiency and Level 2 performance in airflow resistance,
- (3) Level 2 performance in sub-micron particulate filtration efficiency and Level 1 performance in airflow resistance, and
- (4) Level 2 performance for both properties.

<sup>B</sup> As noted in 8.1.4.2 and 8.2.4, the performance properties are calculated from the lowest measured filtration efficiency and highest measured airflow resistance of all test specimens (including specimens subjected to the maximum number of laundering and cleaning cycles, as specified by the manufacturer).

<sup>C</sup> Testing results per procedures in 8.1 based on Subpart K of 42 CFR Part 84.

<sup>D</sup> Airflow resistance in range of 5 to 15 mm H<sub>2</sub>O can be perceived as difficult for long-term wearing by some individuals, including children or adults that have specific medical conditions that cause difficulty in breathing.

determine if the fixture contributes an offset which can be subtracted from the measured resistance when testing a barrier face covering.

8.2.3 Each specimen will be tested at a challenge flow rate of 85 ± 4 Lpm to determine the airflow resistance (in mm H<sub>2</sub>O) with the aerosol challenge turned off, if possible. If the specimen lays flat in the filter holder, adjust the flow rate to achieve a face velocity of 10 ± 0.5 cm/s.

8.2.4 The highest measured resistance to airflow for all specimens (including specimens subjected to laundering and cleaning) rounded to the nearest integer shall be used to determine compliance with this specification and the classification of airflow resistance as specified in Table 2, and for the purpose of the manufacturer reporting their results.

8.3 *Quantitative Leakage Assessment Testing*—If the manufacturer chooses to conduct quantitative testing, the leakage assessment shall be evaluated using Test Method F3407 with the additional modifications specified in the following paragraphs:

NOTE 23—For the purpose of this testing, a leakage ratio replaces respirator fit capability referred to in Test Method F3407.

8.3.1 *Interferences*—A determination shall be made if the wearing of safety glasses or prescription glasses or other items such as ear muffs and helmets worn by the test subject creates an interference with the proper fit of the barrier face covering.

8.3.1.1 If it is determined that the wearing of different items on the test subject's head requires special adjustments of the barrier face covering during a specific quantitative test, then that test subject shall wear the respective items during the testing.

8.3.2 *Conditioning*—Where barrier face coverings are reusable and intended for laundering or cleaning, each test subject shall be evaluated with both a new barrier face covering and a barrier face covering that is laundered or cleaned as specified in 7.3.

8.3.3 *Modified NIOSH Bivariate Panel:*

8.3.3.1 Barrier face coverings manufactured in one size as a universal fit shall be evaluated using the most common population-representative cells of the NIOSH Bivariate Panel that is specified in Test Method F3407 that includes Cells 4 and 7, and then Cells 1, 3, 5, 8, and 10 if additional data are needed.

The leakage ratio shall be determined by averaging the results of ten subjects from any of these cells.

8.3.3.2 Testing shall be permitted to be performed on other definable subgroups.

NOTE 24—For example, quantitative leakage assessment testing of an extra small barrier face covering would include Cell 1 and a range narrower and shorter than that defined by the NIOSH Bivariate Panel provided in Appendix X1.

NOTE 25—When applied, quantitative leakage assessment testing involves at least ten test subjects.

8.3.3.3 The evaluation of size small barrier face coverings shall include subjects meeting the facial dimensions of Cells 1, 2, 3, 4, and 6. Where quantitative testing is performed, the leakage ratio shall be determined by averaging the results of ten subjects from any of these cells.

8.3.3.4 The evaluation of size medium barrier face coverings shall include subjects meeting the facial dimensions of Cells 2, 3, 4, 5, 6, 7, and 9. Where quantitative testing is performed, the leakage ratio shall be determined by averaging the results of ten subjects from any of these cells.

8.3.3.5 The evaluation of size large barrier face coverings shall include subjects meeting the facial dimensions of Cells 5, 7, 8, 9, and 10. Where quantitative testing is performed, the leakage ratio shall be determined by averaging the results of ten subjects from any of these cells.

8.3.3.6 The evaluation of size extra-large barrier face coverings shall include subjects meeting the facial dimensions of Cells 8, 9, and 10. Where quantitative testing is performed, the leakage ratio shall be determined by averaging the results of ten subjects from any of these cells.

8.3.3.7 A size designation other than small, medium, and large shall include at least two subjects from the extended range.

8.3.3.8 All test subjects shall be tested.

8.3.3.9 A test subject shall be permitted to repeat the test one additional time with the same barrier face coverings. In this case, the best result shall be used for the calculations.

8.3.4 *Test Equipment:*

8.3.4.1 If a condensation nuclei counter is used, testing shall be performed in an area of sufficient size and with at least 2000 particles per cubic centimeter as determined by the condensation nuclei counter.

8.3.4.2 If a condensation nuclei counter is used, testing shall be done with a condensation nuclei counter operating in the N99 mode only.

8.3.4.3 If a condensation nuclei counter is used and equipped with a classifier, the N95 mode shall not be used for testing.<sup>11</sup>

8.3.4.4 Additional modifications to Test Method F3407 shall be permitted to allow for the attachment of in-facepiece sampling apparatus that is used to sample the breathing zone of the test subject, as long as the type of equipment used provides measurement of particulate concentrations in the same areas as specified in Test Method F3407.

#### 8.3.5 Procedures:

8.3.5.1 Test subjects shall receive donning and doffing training only from reading the user instructions or watching video versions of the instructions as provided by the manufacturer in accordance with Section 11.

8.3.5.2 Test subjects shall don the barrier face covering sample without assistance from the test coordinator.

#### 8.3.6 Modifications to Calculation or Interpretation of Results:

8.3.6.1 Test subjects that are unable to complete the test for any reason other than fit shall be excluded from the calculations.

8.3.6.2 Where used to supplement the manufacturer's design analysis as part of their leakage assessment, the average leakage ratio for all cells and all subjects for the respective size of barrier face covering offered by the manufacturer shall be reported.

8.3.6.3 The average of all final leakage ratio measurements for subjects used in the panel composition defined in 8.3.3 shall be calculated and rounded down to the nearest 0.5 increment, unless the value is above 1.0 and below 1.5.

8.3.6.4 If the average leakage ratio calculated in 8.3.6.2 is above 1.0 and below 1.5, the leakage ratio shall be rounded to the nearest 0.1 increment where the lowest reportable value above 1.0 shall be 1.1.

8.3.6.5 For reusable barrier face covers where leakage ratio is measured for both new barrier face coverings and for barrier face coverings after the maximum number of laundering or cleaning cycles, the lowest average leakage ratio shall be reported.

8.3.6.6 If a specific barrier face covering evaluated to these requirements shows differences when worn with eyewear or other items, additional warnings or limitations shall be provided as part of the package labelling specified in 10.2.

## 9. Reporting and Classification

9.1 A test report shall be prepared that includes the following information:

NOTE 26—A sample recommended report for providing test results is provided in Appendix X2.

9.1.1 The manufacturer's name.

9.1.2 The product name or model number.

9.1.3 The test laboratory name and accreditation credentials.

<sup>11</sup> For example, the N95-Companion Technology would not be used with the TSI PortaCount Models 8038 or 8048.

9.1.4 The specific test and referenced section within this specification for each test.

9.1.5 The date(s) of testing and individual replicate test values, calculations, and other reportable information required by each test performed in Section 8.

9.1.6 For the product design analysis, the report shall include a description of the specific approach that was used by the manufacturer to make a determination of the product areas of coverage and ability of the barrier face covering to reduce leakage around the wearer's face.

9.1.7 Manufacturers shall be permitted to report the average bacterial filtration efficiency (BFE) of barrier face coverings when tested in accordance with Test Method F2101.

NOTE 27—Manufacturers are cautioned that BFE measurements are not required and generally provide substantially higher efficiencies compared to the mandatory sub-micron particulate filtration efficiencies specified in this standard, since BFE involves the evaluation of larger aerosols and less severe test conditions. In addition, BFE measurements are often only provided for the material and not the overall product.

9.1.8 For quantitative leakage assessment testing, the report shall include each subject's identification number, the size of the barrier face covering worn by the subject, the corresponding bivariate panel cell number, and the leakage ratio measurement in addition to the average leakage ratio provided for each size and for the overall barrier face covering.

9.2 For the purposes of this specification, both sub-micron particulate filtration efficiency and airflow resistance performance results shall be separately classified as specified in Table 2.

NOTE 28—The use of this classification system is intended to aid in understanding potential trade-offs for higher levels of filtration efficiency with airflow (breathing) resistance where a product may have a high filtration efficiency but high airflow resistance indicating difficulty in breathing through barrier face covering. Conversely, it is possible to also have a barrier face covering with low airflow resistance that allows easy breathing but low filtration efficiency. This classification system is not to be used to define the overall actual performance of the barrier face covering when worn by an individual as either a means of source control or in reducing the amount of inhaled particulate matter. It is recognized that the relative coverage and manner for how the product fits on the individual wearer's face are additional factors that define performance.

## 10. Labeling Requirements

10.1 Each barrier face covering shall be labeled.

NOTE 29—Additional or different labeling can be required to comply with applicable regulatory requirements.

10.1.1 The barrier face covering label shall have, at a minimum: (1) the manufacturer's name, identification, designation, or logo; (2) the barrier face covering model or style; and (3) the following statement: "MEETS ASTM F3502."

10.1.2 The label information provided in 10.1.1 shall be printed anywhere on the product or on a permanently affixed tag. The label information shall be accessible without damaging the product.

10.2 The packaging containing the smallest saleable unit/package from which the user withdraws the product for use shall provide the following statement:

“MEETS ASTM F3502, SPECIFICATION FOR BARRIER FACE COVERINGS. THIS PRODUCT IS PRIMARILY INTENDED AS A MEANS OF SOURCE CONTROL FOR MINIMIZING THE PROJECTION OF EXPELLED MATERIALS FROM THE WEARER’S NOSE AND MOUTH. WARNING: THIS BARRIER FACE 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.”

10.2.1 The statement in 10.2 shall be printed on the package where the point-of-sale user may view it in its entirety.

10.2.2 The above warning shall be permitted to exclude references to medical face masks if the product also meets Specification F2100.

10.2.3 The above warning shall be permitted to exclude references to respirators if the product is a respiratory protective device that is also approved under 42 CFR Part 84 and is listed in the NIOSH Certified Equipment List.

10.2.4 The separate classifications of product performance in terms of sub-micron particulate filtration efficiency and airflow resistance shall be provided as specified in 9.2.

NOTE 30—A visual rating scheme is one means to convey the performance classifications of the barrier face covering. Recommendations for these visual schemes include tabular or continuum presentations such as those provided in Appendix X3. Other visual rating schemes are possible. An additional recommended caution is, “Sub-micron particulate efficiency and airflow resistance do not account for leakage of air around the perimeter of the barrier face coverage. Air leakage can significantly affect overall product filtration efficiency.”

10.2.5 The following information shall also be printed legibly on the product packaging:

10.2.5.1 Manufacturer’s name, identification, or designation.

10.2.5.2 Manufacturer’s address.

10.2.5.3 Country of manufacture.

10.2.5.4 Barrier face covering model or style.

10.2.5.5 Primary materials of construction.

NOTE 31—Primary materials of construction include the materials and lists the fiber content for textiles (for example, 100 % cotton, 65 % polyester/35 % cotton, etc.) consistent with regulations found in 16 CFR Part 303. It is permissible to indicate other materials such as ties and loops, and particularly if these materials include latex rubber in addition to metal components that can be hazardous when worn during MRI procedures.

10.2.5.6 Month and year of manufacture, not coded.

10.2.5.7 Lot or trace number, if applicable.

10.2.5.8 Size, if applicable.

10.2.5.9 An indication if the product is for single use or can be reused if cleaned or laundered.

10.2.5.10 Expiration date, if applicable.

10.2.5.11 Manufacturers shall be permitted to include certain variable information, including the manufacturer and year of manufacture, lot or trace number, and size on the label that appears on the barrier face covering instead of the packaging.

## 11. User Instructions

11.1 A set of use instructions shall be provided with the package containing the smallest saleable unit/package from

which the user withdraws the product that includes the following information or statements:

11.1.1 The manufacturer, product, and compliance information, and warning statements provided in 10.2.

11.1.2 Information on how to select the correct size and make adjustments in the fit (if applicable).

11.1.2.1 If applicable, sizing information shall include manufacturer information on how individual sizes of barrier face coverings are specified.

NOTE 32—One approach to establishing sizes is in terms of measured facial dimensions, such as the dimensions described in Appendix X1 that include bizygomatic breadth (face width) and menton-sellion length (face length) where the dimensions covered in Cells 1, 2, 3, 4, and 6 are considered size small; the dimensions covered in Cells 2, 3, 4, 5, 6, 7, and 9 are considered size medium; the dimensions covered in Cells 5, 7, 8, 9, and 10 are considered size large; and the dimensions covered in Cells 8, 9, and 10 are considered size extra-large. It is noted that the dimensions in these size ranges overlap. It is further recommended that if specific dimensions are used, manufacturers provide instructions for how these dimensions are measured. Sizing information is not required to be based on these or other measurements. It is permissible to also use graphic guidance based on general size and shape of individuals’ faces. It is up to the manufacturer to determine the best way to communicate sizing information that can include graphic guidance or measurements that do not include face width or height, or both, or any combination of graphics and measurements.

11.1.3 Procedures for donning (how to put on) and doffing (how to take off).

11.1.3.1 Where the product can be donned in more than one orientation such that the filter does not cover the nose and mouth as intended by the manufacturer, the donning procedures shall instruct the wearer how to identify the proper orientation and filter placement.

NOTE 33—These additional procedures are intended for cases in which the proper orientation of the barrier face covering is not obvious and can be inadvertently donned upside down or with the filtration area on the rear or side of the head.

11.1.4 If the product is reusable then inspection, use, and care instructions, including laundering or cleaning and the service life (maximum number of laundering or cleaning cycles), or specific details regarding when the barrier face covering should be discarded, shall be included.

NOTE 34—Requirements for clear care instructions for reusable barrier face coverings are addressed in 16 CFR Part 423. Guidance for creating care instructions is also provided in Guide D3938; symbols indicating specific care instructions are provided in Guide D5489.

11.1.5 Any other cautions and limitations.

NOTE 35—Examples of cautions and limitations include: (1) barrier face coverings should not be placed on very young children (<2 years) or anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the barrier face covering without assistance, etc.; (2) that barrier face coverings with Level 1 airflow resistance may not be suitable for children or for adults that have difficulty breathing and a barrier face covering with Level 2 airflow resistance is recommended; and (3) the barrier face covering contains metal and should not be worn during MRI procedures.

11.1.6 Conditions of storage and the shelf life, if applicable or known (if stored without use).

11.1.7 How to tell when the barrier face covering has reached the end of its useful life (that is, when it should be replaced).

### 11.1.8 Procedures for disposal of product following use.

NOTE 36—Diagrams with images of the barrier face covering showing specific features and procedures are useful for conveying some of the above information. Video instructions are also recommended for products particularly for donning, adjustment, and doffing. It is further helpful to include instructions for how the barrier face covering should be properly worn to minimize areas of leakage and its fit on the wearer's face.

## 12. Conformity Assessment

12.1 Barrier face coverings that are declared to be compliant with this standard specification shall meet or exceed all Model A requirements for conformity assessment specified in Annex A3 of Guide F3050, with the following additions:

12.1.1 For the purposes of claiming that a product meets this specification, testing for sub-micron particulate filtration efficiency and airflow resistance as specified in Section 8 shall be performed by a laboratory that is accredited in accordance with the requirements of ISO/IEC 17025, where the laboratory's scope of accreditation encompasses the specific tests within this specification.

12.1.1.1 In the evaluation of sample sets, laboratories shall not exclude any specimens with anomalous results unless a root cause analysis has been made by either the laboratory or the manufacturer to explain the reasons for the anomalous results and a corrective action has been implemented either for the preparation of the product by the manufacturer or in the conduct of the test as performed by the laboratory.

12.1.2 As part of the Model A conformity assessment requirements in Guide F3050, manufacturers of compliant

barrier face coverings shall issue a declaration of conformity that the specific product meets the applicable requirements of this specification.

12.2 Manufacturers shall be permitted to meet the more rigorous conformity assessment requirements of Model B, C, or D of Guide F3050 that include additional requirements in independent oversight, quality management system, and other conformity requirements.

## 13. Precision and Bias

13.1 *Precision*—It is not possible to specify the precision of the procedures described in 8.1 and 8.2 of this specification at this time because of the urgent need for the provision of a specification on barrier face coverings and due to the fact that the cited test method is a U.S. government regulations-based test requirement that has already been subjected to government oversight and interlaboratory review. The precision of these test methods is being determined and is expected to be available on or before 2022.

13.2 *Bias*—No information can be presented on the bias of the procedures described in 8.1 and 8.2 of this specification for measuring sub-micron particulate filtration efficiency and airflow resistance because no products having accepted reference values are available.

## 14. Keywords

14.1 airflow resistance; barrier face coverings; breathing resistance; leakage assessment; sub-micron filtration efficiency

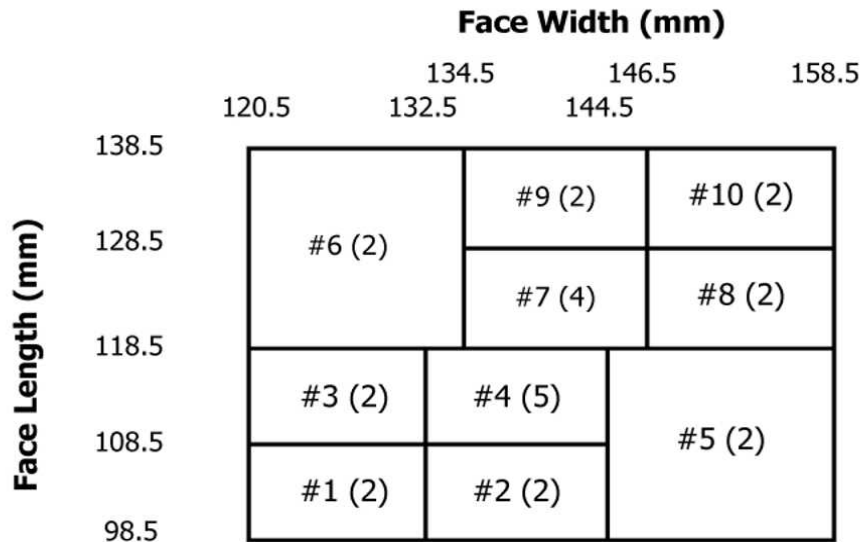
## APPENDIXES

### (Nonmandatory Information)

#### X1. MODIFIED NIOSH BIVARIATE PANEL

X1.1 The NIOSH Bivariate Panel represents approximately 98 % of the U.S. worker population. Cell number and the number of test subjects from a 25-subject panel representing the percentage of the total BFC wearing population having the facial dimensions represented by that cell are indicated in each cell (highlighted in Fig. X1.1). The cell numbers are for the

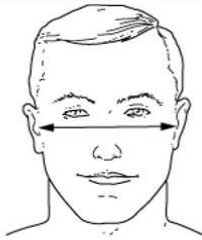
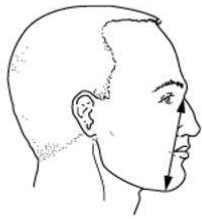
sole purpose of obtaining a panel representative of the population of BFC wearers. Since the panel is two dimensional, meaning it includes bizygomatic breadth (face width) and menton-sellion length (face length), it is not fully descriptive of face size and shape but is a tool for laboratory testing. See Table X1.1.



NOTE 1—The cells are numbered 1 to 10 and the numbers in parentheses indicate the number of test subjects to be sampled from each cell per Test Method F3407. When the test subject’s face length or face width falls on the boundaries, the test subject is classified into the higher number cells with greater face dimensions.

FIG. X1.1 NIOSH Panel Based on Face Length and Width

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	

## X2. SAMPLE REPORT FORM

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

† Report the lowest value of filtration efficiencies measured

‡ Report the highest value of air flow resistances measured

 \*\*\* Base performance classification on lowest sub-micron particulate filtration efficiency value for all conditions evaluated ( $\geq 20\%$  = Lower performance;  $\geq 50\%$  = higher performance). Base performance classification on highest air flow resistance for all conditions evaluated ( $\leq 15$  mm H<sub>2</sub>O = Lower performance;  $\leq 5$  mm H<sub>2</sub>O = Higher performance).

**X3. POSSIBLE VISUAL RATING SCHEMES FOR SHOWING PERFORMANCE CLASSIFICATIONS OF BARRIER FACE COVERINGS**

X3.1 See Figs. X3.1 and X3.2.

	Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)	"My Mask"
Option 1	Filtration Efficiency	≥ 20%	≥ 50%	Level 2: 60%
	Breathability	≤ 15 mm H <sub>2</sub> O	≤ 5 mm H <sub>2</sub> O	Level 1: 8 mm H <sub>2</sub> O
	Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)	"My Mask"
Option 2	Filtration Efficiency	≥ 20% F1	≥ 50% F2	F2
	Breathability	≤ 15 mm H <sub>2</sub> O B1	≤ 5 mm H <sub>2</sub> O B2	B1
	Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)	
Option 3	Filtration Efficiency	F1	F2	
	Breathability	B1	B2	

FIG. X3.1 Package Label—Tabular Options

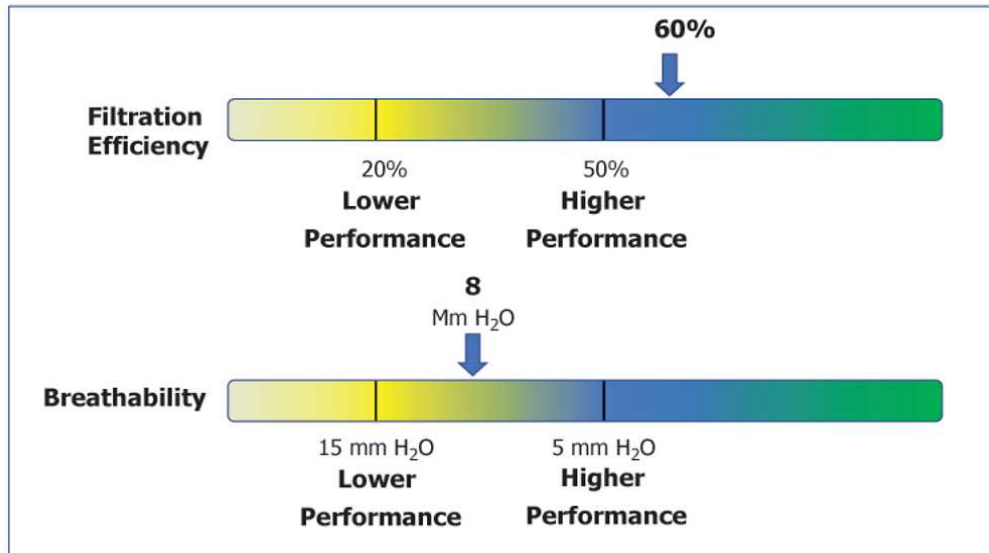


FIG. X3.2 Package Label—Continuum Option

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