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Standard Specification for Barrier Face Coverings¹

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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 reuse 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 reuse of the barrier face covering, so the possibility of reuse 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 intended to help ensure barrier face coverings meeting the stated requirements provide (1) a means of source control for individual wearers by reducing expelled aerosols from the wearer's nose and mouth into the air; and (2)

a degree of particulate filtration that potentially reduces the amount of aerosols inhaled by the wearer.

¹ This specification is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.65 on Respiratory.

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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.

Nothing in this specification 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 expired human-generated aerosols.

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 where the general approach is described in the product report. Manufacturers are permitted to conduct quantitative testing as specified in this specification to supplement the design analysis. Accessories, such as braces or other devices that allow the barrier face covering to better conform to the wearer's face, are addressed as part of this specification if used for the purpose of reducing leakage.

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 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 for reuse. 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.

1.2.3 Labeling 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 with a Supplier Declaration of Conformity (SDOC) following Guide **F3050**, Annex A3, Model A. The SDOC states that each barrier face covering labeled as compliant has met all of the requirements of this specification including design criteria, performance criteria, test methods, labeling, and user information. Additionally, conformance to this specification requires that

sub-micron particulate filtration efficiency and airflow resistance tests have been performed by a laboratory accredited for conducting these tests.

NOTE 4—This specification does not provide for any form of provisional, limited, or partial conformance of barrier face coverings since their compliance with this specification is a function of meeting all performance requirements, including specific filtration efficiency and breathability requirements, as well as all applicable design, labeling, reporting, and user information requirements.

1.3 This specification addresses barrier face coverings that are either disposable or 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, nor the use of drugs, biologics, or nanoparticles in barrier face coverings. This specification also does not address the efficacy of cleaning agents or other chemicals for cleaning, disinfecting, or sanitizing barrier face coverings.

NOTE 5—Claims made about the use of antimicrobial materials, finishes, or mechanisms; or the use of drugs, biologics, or nanoparticles in any product subject the manufacturer to regulatory oversight by government agencies, including the 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.

NOTE 6—There are several aspects that relate to the material composition and design of barrier face coverings that are not addressed in this specification but warrant attention relative to their safety, health effects, and impact on the environment, including but not limited to: leaching of potentially toxic finishes, inhalable toxic substances from materials, and bioburden inhibitors subject to regulatory oversight.

1.11 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the*