

Guidance and Considerations for General Purpose Textile Face Coverings: Adult

1. Foreword

1.1 Given the COVID-19 pandemic and related government recommendations of face covering use in public settings, this guidance was developed by a group of industry stakeholders to provide information to manufacturers. Considerations and recommendations are intended to help manufacturers more efficiently design and produce face coverings for general purpose (non-medical) use. This document contains voluntary guidance and practical considerations for:

- Regulatory Considerations
- Fit and Sizing Considerations
- Material and Construction Considerations
- Particle Filtration Considerations
- Breathing Resistance Considerations
- Laundering and Service Life Considerations
- Tie and Ear Loop Considerations
- Product Labeling and Marking Considerations

2. Purpose and Scope

2.1 This monograph contains voluntary guidance for design, construction and labeling of general-purpose, reusable textile face coverings for adults.

2.2 Guidance in this document applies to general-purpose face coverings intended for daily use by asymptomatic individuals.

2.3 Face coverings described in this document are intended for adult-use only.

2.4 Face coverings described in this document are not medical devices per the US Food and Drug Administration (FDA) or Health Canada; they are not personal protective equipment (PPE) as defined by the National Institute for Occupational Safety and Health (NIOSH).

3. Referenced Documents

NOTE: Use current versions of all publications unless otherwise specified.

3.1 Industry Methods:

3.1.1 AATCC LP1 Laboratory Procedure for Home Laundering: Machine Washing (see 19.1).

3.1.2 ASTM D3938 Standard Guide for Determining or Confirming Care Instructions for Apparel and Other Textile Products.

3.1.3 ASTM D4964 Standard Test

Method for Tension and Elongation of Elastic Fabrics (Constant Rate-of-Extension Type Tensile Testing Machine).

3.1.4 ASTM D5034 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test).

3.1.5 ASTM F2100 Standard Specification for Performance of Materials Used in Medical Face Masks.

3.1.6 ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres.

3.1.7 ASTM D737 Standard Test Method for Air Permeability of Textile Fabrics.

3.1.8 EN 14683 Medical face masks—Requirements and test methods.

3.1.9 ISO 9237 Textiles—Determination of the permeability of fabrics to air.

3.2 US Regulations:

3.2.1 16 CFR 300 Rules and Regulations under the Wool Products Labeling Act of 1939

3.2.2 16 CFR 303 Rules and Regulations under the Textile Fiber Products Identification Act

3.2.3 16 CFR 423 Care Labeling of Textile Wearing Apparel and Certain Piece Goods

3.2.4 16 CFR 1610 Standard for the Flammability of Clothing Textiles

3.3 Canada Regulations:

3.3.1 Canada Consumer Product Safety Act (S.C. 2010, c. 21)

3.3.2 Textile Flammability Regulations (SOR/2016-194)

3.3.3 Textile Labelling Act (R.S.C., 1985, c. T-10)

3.3.4 Textile Labelling and Advertising Regulations (C.R.C., c. 1551)

4. Terminology

4.1 **breathing resistance**, n.—the differential pressure required to draw air through a measured surface area at a constant air flow rate. *Source*: EN 14683, an FDA-recognized consensus method for surgical masks.

NOTE: The term “breathability” is also associated with this definition, but due to possible confusion with vapor permeability, it is not used in this document. Fabrics designed to specifically allow escape of perspiration in the form of vapor are *not* typically suitable for face coverings.

4.2 **face covering**, n.—an item of clothing designed to reduce distribution of the wearer’s respiratory droplets (e.g., from breathing, coughing and/or sneezing). (Compare *medical face mask*.)

NOTE: For the purpose of this guidance, face coverings specifically:

- Fully cover user’s nose and mouth.
- Fit snugly against the sides of the face so there are no gaps.
- Do not cause difficulty breathing while wearing.

For the purpose of this guidance, face coverings specifically are not:

- Medical Devices.
- Personal Protective Equipment (PPE)
- Intended for use by healthcare personnel

4.3 **fit**, for face coverings, n.—the ability to cover the user’s nose and mouth while making consistent and snug contact with user’s face at the perimeter (see Fig. 1).

4.4 **healthcare personnel (HCP)**, n.—all persons, paid and unpaid, working in healthcare settings whose activities place them at risk for transmission of respiratory infections from patients. *Source*: CDC.

NOTE: Examples of such activities include those that require direct contact with patients and/or exposure to the patient care environment, including being in the patient room or in a triage or examination room or other potentially contaminated areas, and handling blood, body fluids, secretions, or excretions (except sweat) or soiled medical supplies, equipment or environmental surfaces.

4.5 **healthcare setting**, n.—a place where healthcare is delivered. (Compare *public setting*.) *Source*: FDA.

NOTE: Healthcare settings include, but are not limited to, acute-care hospitals; long-term care facilities, such as nursing homes and skilled nursing facilities; physicians’ offices; urgent-care centers; outpatient clinics; home healthcare (i.e., care provided at home by professional healthcare providers), and emergency medical services. Settings include specific sites within non-healthcare settings where healthcare is routinely delivered (e.g., a medical clinic embedded within a workplace or school).

4.6 **medical device**, n.—any item intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.



Fig. 1—Face covering covers the user's nose and mouth and makes contact at perimeter (dotted line).

Source: FDA

4.7 **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. (Compare *face covering*.) Source: ASTM F2100.

4.8 **particle filtration efficiency**, n.—the efficiency of the filter material in capturing aerosolized particles, expressed as the percentage of a known number of particles that does not pass the medical face covering material at a given flow rate. Source: ASTM F2299, the FDA recognized consensus standard for surgical masks.

4.9 **personal protective equipment (PPE)**, medical, n.—clothing, helmets, gloves, face shields, goggles, face coverings and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness. Source: FDA.

4.10 **public setting**, n. —a venue in which people may be in close proximity to others outside their immediate family or household. (Compare *healthcare setting*.)

NOTE: Public settings include (but are not limited to) grocery stores, pharmacies, parks, public transportation, and office environments.

4.11 **service life**, for *textiles*, n.—the maximum number of laundering cycles that can be performed before an item can no longer perform its intended end use.

NOTE: The properties defining service life for a face covering are:

- User Fit
- Particle filtration
- Breathing resistance
- Ear loop or tie attachment
- Ear loop or tie elastic recovery (if applicable)

5. Safety Precautions

5.1 The safety precautions specified in the monograph are not intended to be all inclusive.

5.2 It is the user's responsibility to reference applicable safety data sheets, use safe and proper techniques, and wear appropriate personal protective equipment when required.

5.3 Users MUST consult manufacturers for specific details such as safety data sheets, equipment operating instructions, and other recommendations. Consult and follow all applicable health and safety regulations (e.g., OSHA standards and rules).

6. Limitations

6.1 This guidance does not address all aspects of textile face covering design and performance.

6.2 Barrier and breathability properties apply to fabric only and may not be representative of complete face covering properties. This document does not include detailed protocols for evaluating complete face coverings.

6.3 This guidance does not apply to regulated respiratory protection. Refer to applicable regulations and standards for guidance on these items.

7. Regulatory Considerations

7.1 Follow all applicable national and local regulations. The list below is NOT intended to be comprehensive. Addi-

tional testing and/or certifications may be necessary.

7.2 For the United States:

7.2.1 Review US Consumer Products Safety Commission (CPSC) flammability guidance regarding 16 CFR 1610. Some fabrics may be exempt from testing based on weight/construction and/or fiber content.

7.2.2 Review US Federal Trade Commission (FTC) guidance regarding fiber labeling, country of origin, and manufacturer identification according to 16 CFR 303 and 16 CFR 300. Non-wool face coverings may be exempt from labeling requirements if they do not cover any part of the neck or shoulders.

7.2.3 Review FTC care label guidance regarding 16 CFR 423. Care labels are typically required to be permanently affixed to the apparel item, but it may be possible to apply for an exemption.

7.3 For Canada:

7.3.1 Review SOR/2016-194 for flammability guidance.

7.3.2 Review the Textile Labelling Act & the Textile Labelling and Advertising Regulations to ensure product includes all applicable labeling, fiber content, and claims requirements.

7.4 Labels should generally be "conspicuous and accessible" whether they are affixed to the face covering or the packaging. Label information should also be conspicuous and accessible in online, print media or other sales channels.

8. Fit and Sizing Considerations

8.1 Size face coverings to sufficiently cover the user's nose and mouth.

8.1.1 See Appendix 1 for CDC's and Health Canada sizing recommendations for homemade face coverings.

8.2 Design face covering so they do not obscure the wearer's visibility.

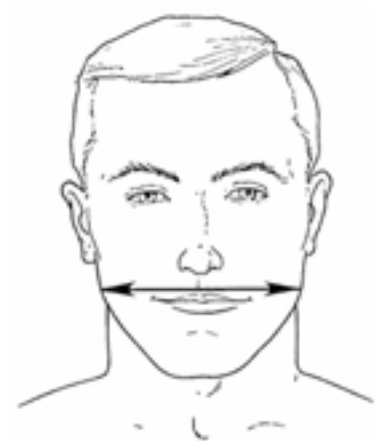
8.3 Design perimeter of face covering to make consistent and snug contact with user's face (and under chin), maximize airflow through covering material and minimize side leakage (see Fig. 1).

8.4 See Fig. 2 for key facial measurements to consider when sizing covering.

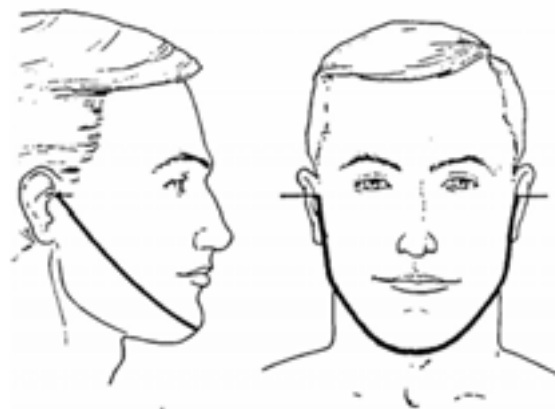
8.4.1 For specific measurements one may consult NIOSH's survey on anthropometric head and face data of respirator users. (www.nap.edu/resource/11815/Anthrotech_report.pdf)

9. Materials and Construction Considerations

9.1 This section is not intended to be design restrictive, but to provide practical options to manufacturers as to which fabrics and processing techniques have demonstrated promise, and those that have not.



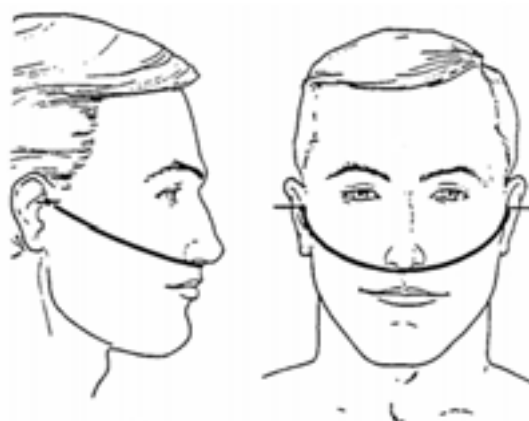
BIGONIAL BREADTH



BITRAGION CHIN ARC



BIZYGOMATIC BREADTH



BITRAGION SUBNASALE ARC



INTERPUPILLARY BREADTH



MENTON-SELLION LENGTH

Fig. 2—Facial measurements to consider for sizing.