CoVid-19 Medical Face Shield Design Guidance Document

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Executive Summary

The individual and industrial response to the current Personal Protective Equipment (PPE) shortage due to the COVID-19 global pandemic has been unprecedented. In the days following the emergence of the pandemic, many face shield designs were made available on the internet to download and manufacture. In many cases, the requirements for each design solution were not clearly articulated and, consequently, the relative performance of each design varies for the intended use. The purpose of this document is to provide necessary background information, functional performance and usability requirements for the design and fabrication of Face Shields to address the Personal Protective Equipment (PPE) shortages resulting the Covid-19 pandemic. This document provides an overview of the following:

- Medical Face Shield Device Use Case
- Medical Face Shield Canadian Regulatory Authorization Requirements
- Medical Face Shield Design Requirements
- Considerations when employing manufacturing processes using 3d printing

The race to meet the perceived demand for PPE meant that many face shield designs were made available without establishing clearly articulated product design requirements. Without a defined set of requirements, the performance of each design may not be suitable for the intended use. A checklist has been included in Appendix 1 for those wishing to assess potential face shield designs against the requirements in order determine suitability prior to manufacture.

Disclaimer

The information shared in this whitepaper is not all-encompassing or comprehensive and does not in any way intend to create or put into implicit effect any elements of a contractual relationship. The primary purpose of this whitepaper is to provide readers with pertinent information in order for them to reasonably analyse the necessary information for a medical face shield design and or fabrication project and make an informed decision about the relative suitability of a design for the intended use.

Introduction

The individual and industrial response to the current Personal Protective Equipment (PPE) shortage due to the COVID-19 global pandemic has been unprecedented. Never before have small and medium sized enterprises had the ability to generate the output required to meet the increased demand brought on by any preceding circumstance. Much of this capacity has been created by the now almost ubiquitous presence of 3d printing technology. This technology has made it possible for almost anyone to manufacture PPE sub assemblies for items such as face shields requiring only a Computer Aided Design (CAD) file and a 3d printer. In the days following the emergence of the pandemic, many face shield designs were made available on the internet to download and manufacture. In many cases, the requirements for each design solution were not clearly articulated and, consequently, the relative performance of each design varies for the intended use.

The purpose of this document is to provide necessary background information, functional performance and usability requirements for the design and fabrication of Face Shields to address the Personal Protective Equipment (PPE) shortages resulting the Covid-19 pandemic. A checklist has been included in Appendix 1 at the end of this document for those wishing to assess potential face shield designs against these requirements in order to assist in determining design efficacy prior to manufacture.

Definitions

PPE: Personal Protective Equipment
Visor: face shield subsystem that is designed to create a barrier between the user and the environment.
Frame: face shield subsystem that is designed to secure the visor to the suspension mechanism
Suspension Mechanism: face shield subsystem that is designed to secure the face shield to the head
Intended Use: What the device is intended to be used for
Indications for Use: reasons or situations in which someone would use the device
Contraindications for Use: reasons or situations in which someone would not use the device
3d Printing: a method making a physical object from a three-dimensional digital model, typically by laying down many thin layers of a material in succession.

Background

The following is a summary of the intended use of medical PPE face shields along with when they should and should not be used[1]:

- **Intended Use:** Face shields are personal protective equipment devices that are used for protection of the facial area and associated mucous membranes (eyes, nose, mouth and possibly ears) from splashes, sprays, and spatter of body fluids.
- **Indications for Use:** Face shields are to be used in conjunction with other protective equipment and are therefore classified as adjunctive personal protective equipment.
- **Contraindications for Use:** Use of a face shield alone for eye, face, and mucous membrane protection from contamination by body fluids is insufficient. Face shields are not meant to

[1] Health Canada. (2020a). *3D printing and other manufacturing of personal protective equipment in response to COVID-19* [cited 22 Apr 2020]. Retrieved from https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19-unconventional-manufacturing-personal-protective-equipment.html

function as primary respiratory protection and should not be used alone because aerosols can flow behind.

Face Shield Device Clinical Environment Use Case

In response to COVID-19, face shields are in use by "front line" physicians, nurses, first responders and support personnel in a primary care setting such as a hospital or extended care facility. The device is be worn as part of a Personal Protective Equipment (PPE) protocol that is designed to minimize exposure to pathogens and as such will be an adjunct piece of equipment that is used in conjunction with protective clothing, gloves, head covers, eyewear and respiration equipment. The device is employed as a necessary piece of equipment but may be treated as somewhat of an inconvenience by users. As a result, depending on the design, it may be donned and doffed several times during a shift[2]. It also, may need to be cleaned after exposure and possibly repurposed and or recycled if availability of replacements run low. The device may be exposed to a variety of temperature and humidity conditions depending on the type, location and nature of care facilities and or device applications. It may also be exposed to chemical and or abrasions (cleaning, collisions with hard surfaces and or medical equipment) either during cleaning and or intended use. The device will also be used in a variety of lighting conditions depending on the location and type of treatment facility.

Regulatory Authorization

In Canada, most PPE, including face shields, are Class I medical devices if they are represented for use for medical purposes[3]. Health Canada advises manufacturers of face shields to adhere to the following standards:

- ANSI/ISEA Z.87.1 (2015) - American National Standard For Occupational And Educational Personal Eye And Face Protection Devices
- CSA Z94.3 (2020) - Eye and face protectors
- CSA Z94.3.1 (2016) - Guideline For Selection, Use, And Care Of Eye And Face Protectors

Health Canada has created two regulatory pathways that allow for the distribution and sale of 3D printed Class I devices. **Note that a sale generally requires the transfer of ownership of a device from one party to another and does not necessitate any transfer of money**. The two pathways are:

1. The manufacturer must hold an authorization under the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19[4];or

[2] Prestero, T. (2020). *DtM-v3.1 Face Shield PPE, 3D printable headband NO LOGO*. [cited 22 Apr 2020] Retrieved from https://3dprint.nih.gov/discover/3dpx-013359

[3] Health Canada. (2020a). *3D printing and other manufacturing of personal protective equipment in response to COVID-19*. [cited 22 Apr 2020] Retrieved from https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19-unconventional-manufacturing-personal-protective-equipment.html

[4] Health Canada. (2020b). *Interim order respecting the importation and sale of medical devices for use in relation to COVID-19*. Government of Canada [cited 22 Apr 2020]Retrieved from https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.html

2. The manufacturer must hold a valid Medical Device Establishment Licence (MDEL)

Face Shield Design Requirement Guidance

For the purposes of this document, the face shield as a system is comprised of three subassemblies: the Visor, Frame and Suspension Mechanism (SM). The following sections describe a set of "system" level requirements and then goes into more detail about each individual subassembly.

High Level System Level Requirements

The US National Institutes of Health 3D Print Exchange states the following requirements[5]:

- **Core Performance:** A face shield is intended to limit aerosol and splatter exposure to the face (some distance above the forehead to below the chin and ideally past the ears)
- **Useful Life:** if the device is intended to be re-usable, it should be able survive multiple daily washes using cleaning and disinfecting agents commonly found in the clinical environment.
- **Fabrication:** The face shield should require little or no specialized equipment to fabricate (i.e. no complex supply chains or production bottlenecks)
- **Assembly:** The face shield should require little or no specialized expertise and equipment to assemble.
- **Usability:** The face shield should be is easy to put on (don) (as it will be put on dozens of times in a twelve-hour shift)
- **Usability:** The face shield should be comfortable to wear and remain in place during use
- **Usability:** The face shield should be is easy to take off (doff) (as it maybe taken off dozens of times in a twelve-hour shift)

It is conceivable that any design may incorporate a feature from one subassembly into another and that some requirements are more readily verifiable than others. This information can be used to assist those designing and or fabricating these devices and will hopefully result in products that safely and effectively meet the needs of users.

[5] Prestero, T. (2020). *DtM-v3.1 Face Shield PPE, 3D printable headband NO LOGO*. [cited 22 Apr 2020] Retrieved from https://3dprint.nih.gov/discover/3dpx-013359

Subassembly Requirements

Face Shield Visor:

The visor is arguably the most important component of the device because it creates a protective barrier between user and the environment. It is also a piece of optical equipment as it is necessary for the user to look through the visor while conducting their work activities. Visors that are constructed of poor quality materials or ones that exhibit physical material defects such as haze or other light distortion properties can promote eye strain and headaches for the user. Excessive curvature of the visor design may also cause image distortion. In addition to headaches and eyestrain, it is possible that material defects could result in medical and or treatment errors during use. The following design requirements are relevant to visors:

Minimum specifications in urgent manufacturing scenarios as specified by Health Canada

In the event that **urgent** production of face shields is required in Canada, the following minimum specifications would be incorporated into the design and verification to ensure safe and effective face shields[6]:

- Device must provide adequate coverage (CSA Z94.3 Sections 10.2.1/10.2.2/10.3/10.4).
- Device should made of optically clear, distortion free, lightweight materials (refer to CSA Standard Z94.3.1-16 and)

[6] Health Canada. (2020a). *3D printing and other manufacturing of personal protective equipment in response to COVID-19*. [cited 22 Apr 2020] Retrieved from https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19-unconventional-manufacturing-personal-protective-equipment.html

- Device should be free of visible defects or flaws that would impede vision (ANSI Z87.1 Section 9.4)
- Device should withstand impact from sharp or fast projectiles (ANSI Z87.1 Section 9.2 and 9.3, CSA Z94.3 Section 10.1)
- If available, device should display anti-fog behavior on inside and outside of shield. (CSA Standard Z94.3.1-16)
- Eye and face PPE shall be distinctly marked to facilitate identification of the manufacturer.

Face shield Visor Materials: Performance Comparison[7]

a. Acetate visors are used in chemical applications where optical clarity is needed. Cellulose acetate is a plant-based plastic that is hypoallergenic. Acetate was first used for eyewear in the late 1940s because of the brittleness and other problems encountered with previously used plastics. Acetate face shields offer the following benefits:

   - It is well-suited for applications requiring good optical clarity and rigidity
   - It does not become limp or distorted under normal temperatures
   - It offers high impact resistance and withstands crazing or cracking over a wide range of temperatures under normal stress
   - It is an excellent shield for grease and oils
   - It maintains flexibility over long periods

b. PETG is a thermoplastic polyester that provides excellent toughness, chemical resistance, and is easily die-cut for face shield use. PETG offers excellent protection at a competitive price point. PETG is suitable for face shields because:
   - It incredibly durable
   - It is highly impact-resistant
   - It can be sterilized

c. Polycarbonate is naturally transparent, amorphous thermoplastic with applications beyond eyewear lenses. Polycarbonate has numerous benefits that make it a particularly great choice for safety eyewear:
   - It is able to internally transmit light almost as effectively as glass
   - It is lighter than glass
   - It possesses a natural UV filter
   - It can withstand impacts far greater than many other commonly used plastics

[7] Webb, A. (2019, 12 Dec 2019). Fundamentals of Face Shields. [cited 22 Apr 2020] Retrieved from https://www.mcrsafety.com/blog/fundamentals-of-face-shields

Visor Material Properties Comparison Reference

	Acetate	PETG	Polycarbonate
Impact Resistance	Good	Best	Better
Heat Resistance	*****	****	****
Chemical Resistance	Best	Good	Better
Optical Quality	Best – 190°F	Better – 180°F	Good – 170°F
Scratch Resistance	*****	****	****
Material Cost	Highest	Mid	Lowest

Additional Visor Design Considerations:

Based on additional product requirements and research, we believe the following considerations should be taken into consideration.

- Visors should not deform during reasonable foreseeable use.
- Visors should be non-permeable and not have any exposed holes or gaps (that could be necessary either for fitment or adjustment) that may expose the user to pathogenic materials when not in use after initial fitment.
- Visor materials that are treated with anti scratch and or antimicrobial coatings are desirable as they may enhance the useful life and anti-infection performance of the visor. Visors that have anti fog coatings may limit the useful of the visor as it may be removed by washing. In some cases Pledge Brand furniture polish may be used as an effective treatment to restore anti fog performance[8].
- Visors should be generally be sized so they extend beyond the users chin by as much as is practical so as to provide maximum protection but not restrict mobility.
- Visors should extend beyond the eyebrow line as much as possible and or practical to be sufficiently protective.
- The method of attachment of the visor to the frame should not cause stress concentrations that may lead to failure of the visor during use or shorten the useful life of the device.
- Visors and or associated coatings should be resistant to chemicals such as bleach in concentrations that are reasonably foreseeable to be used in a clinical environment.
- Visor materials should be tolerant of a range of indoor / outdoor temperature and humidity levels that could be anticipated during use.
- Visors should not degrade appreciably with repeated exposure to sunlight

[8] Sears, D. (2018, 26 Apr 2018). Hockey Cage and Visor Guide. *New to Hockey.* [cited 22 Apr 2020] Retrieved from http://newtohockey.com/hockey-cage-visor-guide/

Face Shield Frame:

The frame is another important component of the device as it acts as the physical interface between the head and the visor.

Minimum specifications in urgent manufacturing scenarios

In the event that **urgent** production of face shields is required in Canada, the following minimum specifications would be incorporated into the design and verification to ensure safe and effective face shields[9]:

- The device should allow adequate space between the wearer's face and the inner surface of the visor to allow for the use of ancillary equipment (medical/surgical mask, respirator, eyewear, etc.)
- Eye and face PPE shall be distinctly marked to facilitate identification of the manufacturer.

Additional Frame Design Considerations

Based on additional product requirements and research, we believe the following considerations should be taken into account.

- The frame should be made of low cost materials
- Based on existing commercial designs, the frame should be designed to be lightweight (less than 150 grams), durable enough for the intended use and comfortable (evenly distribute pressure) for the user to wear.

[9] Health Canada. (2020a). *3D printing and other manufacturing of personal protective equipment in response to COVID-19*. [cited 22 Apr 2020] Retrieved from https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19-unconventional-manufacturing-personal-protective-equipment.html

- The frame should be able to withstand compressive and tension and or torsional forces that are reasonably foreseeable during use.
- The frame should not have any sharp edges and or pinch points that may impact the safety of the user.
- The frame design should incorporate a method of attachment for the visor that is secure, reliable and enables the replacement of visors as required by the user.
- The frame may enable the vertical and or horizontal position adjustment of the visor depending on the type, size and availability of replacement parts.
- The frame could incorporate a feature that enables the visor to be rotated into another position when not in use.
- Ideally, no special tools should be required for visor replacement and it should be compatible with other replaceable visor designs.
- The frame also establishes the visor offset which is defined as the distance between the visor and the forehead. This visor offset should be sufficient to facilitate air circulation to reduce fogging and also accommodate N95 respirators and protective eyewear.
- The size specifications of protective eyewear and respirators vary but a reasonable guideline is that the visor offset should be a minimum of 38mm (1.5 inches) from the forehead.
- Frames should be able to accommodate a range of head sizes as many users of different gender and body type will be required to use them.
- Additional splash protection may be incorporated into the frame above the visor connection point.
- Frames should be resistant to chemicals such as bleach in concentrations that are reasonably foreseeable to be used in a clinical environment.
- Frame materials should be tolerant of a range of indoor / outdoor temperature and humidity levels that could be anticipated during use.
- Frames should not degrade appreciably with repeated exposure to sunlight

Face Shield Suspension Mechanism (SM):

The suspension mechanism is the component of the device that facilitates secure fixation of the device to the user's head. The following are some basic recommendations for the requirements of this subsystem.

Minimum specifications in urgent manufacturing scenarios (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19-unconventional-manufacturing-personal-protective-equipment.html)

In the event that urgent production of face shields is required in Canada, the following minimum specifications would be incorporated into the design and verification to ensure safe and effective face shields:

- Device should fit snugly to afford a good seal to the forehead area and to prevent slippage of the device.
- User contacting materials should provide adequate material biocompatibility (skin sensitivity and cytotoxic testing) (ISO 10993-5, 10)

Additional Suspension Mechanism (SM) Design Considerations
Based on additional product requirements and research, we believe the following considerations should be taken into account.

- The SM should facilitate secure fitment to the head
- Should be intuitive to fit and adjust when used in conjunction with existing PPE
- Should not require readjustment or repositioning after initial fitting
- Should be intuitive put on before use when used in conjunction with other PPE
- Should not require excessive pressure to ensure secure fixation
- Should distribute fixation pressure evenly across the head
- Should be simple to remove when used in conjunction with other PPE
- Should accommodate a range of head sizes: 2.5 percentile female to 97.5 percentile male[10]
- Ideally should be made of non-absorbent materials
- SM's should be resistant to chemicals such as bleach in concentrations that are reasonably foreseeable to be used in a clinical environment.
- SM materials should be tolerant of a range of indoor / outdoor temperature and humidity levels that could be anticipated during use.
- SM's should not degrade appreciably with repeated exposure to sunlight.

3D Printing Fabrication Considerations

Many Covid-19 face shields employ 3d printing as a method of manufacture of the frame and or suspension mechanism. It is important to note that although 3d printing is a useful technology, it also has certain important limitations that may impact the performance of device while in clinical use. It is recommended that designers consider a variety of ways to fabricate their designs in as simple and low cost manner as possible. Also, it is recommended that designers attempt to access non standard material supply chains as conventional supply chains may be inadequate to meet demand. That said, many designers will employ 3d printing as their preferred method of manufacture of certain face shield

[10] Alvin, R. T., Henry Dreyfuss, A., & with an introduction by Stephen, B. W. (2002). *The measure of man and woman : human factors in design*: Revised edition. New York : Wiley, [2002] ©2002.

components. Therefore, the following guidance is intended to inform readers of some of the limitations of this technology.

In general, 3d printing is used as a method of evaluating the functionality, ergonomics and performance of designs during the prototype development phase. Once proven, other technologies are employed that enable higher volume, lower cost and consistent quality between parts. As 3d printing is intended to be used for small volume manufacturing, we believe the following considerations should be taken into account.

- **Health Risks to Fabricators**: sustained, repeated exposure to volatile organic compounds and or Nano-particulates may pose a risk to those using home 3d printers to print large volumes of parts[11]. It is therefore recommended that adequate ventilation provided in the fabrication environment.
- **Relatively High Cost**: Generally, parts made using 3d printing have a high per unit cost because it is still a relatively slow process and can require additional post processing after completion of the build.
- **Relatively Slow speed**: It has been our experience that 3d printing is relatively slow and may cause production bottlenecks during manufacture. The dimensions of structure to be printed can also slow down the number of units produced. It is recommend the use of 3d printed components be minimized in any design so as to maximize functional effectiveness of the technology and increase the batch build density.
- **Material Strength**: it has been our experience that depending on the type of 3d printing technology that is employed, the design may not be as durable as intended and therefore may pose a hazard to users. Also, 3d printed materials may be negatively impacted by chemicals used in the clinical environment. Sufficient testing should be conducted on designs to ensure they are safe to use.
- **Build Quality**: it has been our experience that the quality and consistency of 3d printed parts can vary based on the temperature and humidity variation within the build envelope, build material temperature, thickness and deposition rate. As fabricators try to increase throughput, the risk of inconsistent build quality may increase. It is recommended that some type if batch testing or inspection procedures be employed to ensure quality and consistency of materials.
- **Resolution**: sometimes variation in layer thickness may change cure time and adhesion properties between layers which may result in inconsistent build quality or weaknesses in critical components.
- **Durability**: It has been our experience that 3d printed parts are less durable than “production” quality parts and steps should be taken to determine the effective useful life of the parts prior to release. This information should also be clearly communicated to users in terms of the intended useful life of the product. It is helpful to delineate between disposable and re-useable devices based on their durability.
- **Supply Chain**: as the demand for 3d printing materials increases, availability of input materials may decrease. It is therefore, recommended that designs employ as little 3d printing as possible in order to maximize the effective utilization of this technology.

Conclusion

3d printing technology has made it possible to manufacture PPE such as face shields requiring only a Computer Aided Design (CAD) file and 3d printer. The race to meet the perceived demand for PPE meant that many face shield designs were made available on the internet without clearly articulated design requirements. Without a clearly defined set of requirements, the performance of each design may not be suitable for the intended use. The information contained within this document is intended to inform fabricators about the functional, performance, safety and usability requirements of medical face shields and to ensure that the resulting outputs are as safe and effective as possible. Lastly, a checklist has been included as Appendix 1 for those wishing to assess potential face shield designs against the requirements in order determine suitability prior to manufacture.

About the Author

Nigel Halsted has been involved in a variety of aspects of medical, assistive device development and applied research since 1997. He is currently an Applied Research Project Leader for the MAKE+ Group at the British Columbia Institute of Technology where he manages contract medical device development projects for public and private sector clients. Nigel has deep knowledge in product design and development, project management, ISO quality systems, business opportunity assessment, intellectual property management, new product commercialization and organizational development.

Appendix 1: Face Shield Design Requirement Checklist

The following table contains a summary checklist of the design requirements for medical face shields. The table can be used as a reference to assess the relative performance of face shield designs.

Requirement Type	Device Component	Design Requirement	Rationale	Source	Proposed Face Shield Design Meets Requirement? (Yes / No)
Functional	Device	limits aerosol and splatter exposure to the face (some distance above the forehead to below the chin and ideally past the ears)	Purpose of device	US National Institutes of Health 3D Print Exchange	
Functional	Device	provide ventilation through the top the device	reduces fogging	US National Institutes of Health 3D Print Exchange	
Functional	Device	reduces aerosol and splatter exposure on N95 and other face masks	prolongs usable life of mask	US National Institutes of Health 3D Print Exchange	
Performance	Device	if re-usable for a single user: can survive multiple daily washes	will need to be cleaned if soiled	US National Institutes of Health 3D Print Exchange	
Functional	Device	transparent visor can be replaced from readily sourced materials when optical performance is unacceptable	depending on the design, frame may be reusable when visor isn't	US National Institutes of Health 3D Print Exchange	
Fabrication	Device	requires little or no specialized equipment to fabricate (i.e. no complex supply chains or production bottlenecks)	can be made quickly and easily without delay	US National Institutes of Health 3D Print Exchange	

Fabrication	Device	Requires little or no specialized expertise and equipment to assemble.	can be made quickly and easily without delay	US National Institutes of Health 3D Print Exchange	
Usability	Device	is easy to put on (don) (as it will be put on dozens of times in a twelve-hour shift)	visor may not be required in some instances	US National Institutes of Health 3D Print Exchange	
Usability	Device	is comfortable to wear during use	encourages compliance	US National Institutes of Health 3D Print Exchange	
Usability	Device	is easy to take off (doff) (as it maybe taken off dozens of times in a twelve-hour shift)	visor may not be required in some instances	US National Institutes of Health 3D Print Exchange	
Performance	Device	should not have sharp edges	device should not cause injury to user	Research of OTS products	
Performance	Device	should not have pinch points	device should not cause injury to user	Research of OTS products	
Performance	Device	should be constructed of non absorbent materials	device should be cleanable and not harbor pathogenic material	Research of OTS products	
Performance	Visor	should have a luminous transmittance level of greater than 85 percent (if the lens is clear)	material selection criteria	ANSI/ISEA Z87.1-2015	
Performance	Visor	should be free from visible striae	causes visual distortion that leads to eye strain	ANSI/ISEA Z87.1-2015	
Performance	Visor	should be free from visible bubbles	causes visual distortion that	ANSI/ISEA Z87.1-2015	

			leads to eye strain		
Performance	Visor	should be free from visible scratches	causes visual distortion that leads to eye strain	ANSI/ISEA Z87.1-2015	
Performance	Visor	Not exhibit greater than 3 percent haze	material selection criteria	ANSI/ISEA Z87.1-2015	
Performance	Visor	Have luminous transmittance of greater than 97 percent	material selection criteria	ANSI/ISEA Z87.1-2015	
Performance	Visor	Should have high resolving power or resolution and distort image as little as possible	material selection criteria	ANSI/ISEA Z87.1-2015	
Performance	Visor	Must have prismatic power and imbalance of less than 0.37 diopters	material selection criteria	ANSI/ISEA Z87.1-2015	
Performance	Visor	should have a maximum refractive power of (R, L < 0.6 diopters)	material selection criteria	ANSI/ISEA Z87.1-2015	
Performance	Visor	Should have a refractive Error (astigmatism) of no more than 0.06	material selection criteria	ANSI/ISEA Z87.1-2015	
Functional	Visor	Shall provide a continuous physical barrier between the user's face and surrounding environment.	spaces, holes, connection and or attachment points may reduce visor efficacy	ANSI/ISEA Z87.1-2015	
Performance	Visor	Should be impact resistant or fracture in such a way as to not cause injury to the user. (Capable of	Failure of the visor should not cause injury to user. Test may not be relevant in	ANSI/ISEA Z87.1-2015	

		resisting impact from a 1 in. (25.4mm) diameter steel ball dropped from a height of 50 inches.)	Healthcare context.		
Functional	Visor	should be a minimum of 12 inches in long (97.5 percentile male)	should extend roughly two inches beyond the 97.5 percentile male chin	Measure of Man 2.5 percentile female to 97.5 percentile male	
Functional	Visor	should be a minimum of 8.5 inches in width (97.5 percentile male)	should extend roughly one inch beyond the 97.5 percentile male head width to protect ears	Measure of Man 2.5 percentile female to 97.5 percentile male	
Performance	Visor	should have antimicrobial coating	material selection criteria, nice to have but not required	Research of OTS products	
Performance	Visor	Reusable devices should have anti-scratch coating if possible	extends useful life of visor	Optical Quality Requirements document	
Performance	Visor	Shield material should be impermeable (i.e not have holes which may degrade protection performance)	holes in visor decrease effectiveness	Research of OTS products	
Performance	Visor	Should be able to withstand mechanical stresses when attached to frame during use.	should not fail due to fatigue during use	Research of OTS products	

Functional	Frame	should have a target weight of approximately 100 grams	Users may feel anything more is a burden	Research of OTS products	
Functional	Frame	should accommodate head sizes from 5.2 to 6.5 inches in width	anticipated range of head sizes	Measure of Man 2.5 percentile female to 97.5 percentile male	
Functional	Frame	should be accommodate head sizes from 5.9 to 8.3 inches in length	anticipated range of head sizes	Measure of Man 2.5 percentile female to 97.5 percentile male	
Functional	Frame	should have a sufficient attachment mechanism for a visor	must interface and support visor	Research of OTS products	
Functional	Frame	should protect the face from splashes or overspray coming in from above the face	its reasonably foreseeable that visor may not always be in an optimal position to shield user	Research of OTS products	
Functional	Frame	should enable some movement of air from space between face and the visor	air movement reduces the risk of moisture build up	Research of OTS products	
Performance	Frame	may enable the vertical adjustment of the visor during fitting	one size fits all design may need vertical adjustment for smaller users	Research of OTS products	
Functional	Frame	may enable the replacement of visors as required by users	visor may require replacement	Research of OTS products	
Functional	Frame	Should offset the visor from the face sufficiently	protective equipment is worn in	Research of OTS products	

		to accommodate protective eyewear and N95 respirator masks.	combination with the face shield		
Functional	Frame	Should be able to withstand periodic compressive, tension and or torsional forces	Bending and twisting of frame is reasonably foreseeable during use.	Research of OTS products	
Functional	Frame	Should be able to tolerate foreseeable temperature of 0C to 50C	may be exposed to non temperature controlled environments	Research of OTS products	
Functional	Frame	Should be able to tolerate exposure to humidity range of 50 to 100%	may be exposed to non temperature controlled environments	Research of OTS products	
Functional	Frame	Should be able to resist exposure to UV light	May be left in the sun for extended periods	Research of OTS products	
Functional	Suspension Mechanism	Must facilitate secure fitment to the head	device should feel stable when in use	Research of OTS products	
Functional	Suspension Mechanism	Must not require readjustment or repositioning after fitting	inconvenient to user	Research of OTS products	
Performance	Suspension Mechanism	Must accommodate range of head sizes (2.5 female to 97.5 percentile male)	potential size range of users	Measure of Man	
Performance	Suspension Mechanism	Must be biocompatible for surface contact with skin for beyond 30 days	contact points with head must not employ materials that cause irritation and could be used	ISO 10993	

			continuously beyond 30 days		
Functional	Suspension Mechanism	Should be able to tolerate foreseeable temperature of 0C to 50C	may be exposed to non temperature controlled environments	Research of OTS products	
Functional	Suspension Mechanism	Should be able to tolerate exposure to humidity range of 50 to 100%	may be exposed to non temperature controlled environments	Research of OTS products	
Functional	Suspension Mechanism	Should be able to resist exposure to UV light	May be left in the sun for extended periods	Research of OTS products	