

Stopgap Face Mask (SFM) - Test report

Risk Element: Inadequate fluid resistance

Guidance document suggests the following: ASTM F1862/F1862M-17

Test Results:

We attempted to acquire or compound our own synthetic blood as the compounding formula and technique are listed in ASTM F1862. We were unable to locate a commercial source for the thickening agent specified in the standard, contacted the manufacturer of the thickening agent (DOW chemical), and found that the thickening agent is only sold in the Pacific Rim countries.

Fluid resistance testing was performed using whole Milk at room temperature (substitute for Synthetic blood specified in ASTM F1862 with a surface tension 61 dynes +/-1 dyne). 2 ml of liquid in a 10 ml syringe with a ½" long 18 gauge needle was dispensed over 0.5 seconds at a distance of 12" from the mask. The device passed the challenge condition.

Risk Element: Inadequate barrier for bacteria

Guidance document suggests the following: ASTM F1215-89

Test Results:

Verified that the portions of the mask that we believed to be non-conducting and therefore not available for gas exchange are non-conducting. Have not tested coupons from the surgical mask used as those materials have already undergone the 510(k) review process.

Risk Element: Inadequate air exchange (differential pressure)

Guidance document suggests the following: MIL-M-36945C 4.4.1.1.1

Test Results:

Validated the adequacy of air exchange in our design using two individuals: one male, one female each performing continuous CPR chest compressions on a mannequin for a period of 2 minutes.

Risk Element: Flammability

Guidance document suggests using one of the following:

CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles

Test Results:

Flame did not climb to the top of the test coupon in 3.5 seconds. Device met the requirements of the standard.

Risk Element: Evaluation of Bio-Compatibility

Listing skin contacting components as described in plan.