BOZEMAN HEALTH

☑ Talking Points

June 10, 2020

This message is for all leadership within Bozeman Health.

Alternate Personal Protective Equipment – Mask Summary Statement

- In response to global shortages of personal protective equipment (PPE) and other supplies, the Incident Command Team quickly and thoroughly evaluated and continues to evaluate several alternative PPE options. Throughout this innovative and investigative process of alternate PPE design, the Incident Command Team understood that HEPA filters offer equivalent or higher filtration than medical grade surgical masks. As a result, specific HEPA filters were chosen after evaluating different products for breathability and components. When locally sourced and manufactured masks are used with a HEPA filter insert, BH is using them as an isolation mask. Several options for masks were evaluated by the Incident Command Medical Technical Specialists and the below listed masks were selected because they are fully cleanable, have filter material equivalent to or better than a medical grade isolation mask and for some like the 406 mask, they have passed internal fit testing, meaning they sealed tightly to the user's face just as a respirator does. Bozeman Health also conducted a risk assessment on the entire system per department and made recommendations using available guidance on single use, extended use, and reuse.

Detailed Rationale for Alternate PPE Masks

HEPA filter inserts in cloth masks for use as PPE

- **Bacterial and Filtration Efficiency:**
  - HEPA filters remove 99.97% of airborne particles at sub-micron particle size of 0.3 micron (viruses, mold, dust, allergens, pollen, bacteria, dust mites or cigarette smoke, asbestos, various toxic dusts and aerosols from the air, dander).
  - P100 masks have the same filtration efficacy as a HEPA filter. P100 filter will block 99.9% of particles 0.3 microns or larger.
  - Why 0.3 and not 0.1 micron? 0.3 is the most penetrating particle size, meaning that 0.3 micron particles are actually *more* difficult to filter than smaller particles. As particles become smaller than 0.3 microns, the effects of Brownian motion make them fly around in a zigzag pattern in a way that they end up hitting filter fibers and get stuck.
- **Differential pressure** has not been tested in Kirby vacuum bag
  - Kirby HEPA vacuum bags were found through user testing to be the easiest to breathe through of all the options evaluated
  - IC has been in touch with MSU and MT Tech to pursue testing on particulate filtration and transmission/source filtering capabilities.
- **Flame Spread**
  - Flame Spread is not tested in the Kirby vacuum bag filter product or cloth masks
  - Do not use in settings with high fire risk (e.g. surgery, due to high O_2 concentrations, low humidity, and heat source (i.e. Bovie)

- **Splash Resistance**
  - Has not been tested in Kirby vacuum bag
  - Instructions for using a cloth mask with filter include wearing it in combination with full face shield if splash is potential or fully anticipated.
- **Microbial cleanliness** is not tested in cloth masks, however, these are laundered per healthcare industry standards (equivalent standards to scrubs that are laundered for use in surgical settings).
- **Safety**
  - Kirby Vacuum bags do not contain fiberglass or other hazardous materials, they are made from polypropylene. HEPA vacuum cleaner bags are made from a melt-blown material. The melt-blown process is the same process that is used to make N95 respirator masks. Melt-blown is the most efficient way to make a highly efficient media filter. Thermo-plastic synthetic material is melted and moved through a large number of tiny nozzles. Once the filaments leave the tiny nozzles, they are blown by hot air in the same direction to create endless fibers.
  - BH has a dedicated altered-operations position that inspects every mask that is laundered and will repair and replace when indicated.

406 Masks

- Plastic injection molded face piece can be disinfected between uses and fits tightly to the face, provides more protection from fluid splash
- Filter material is not rated for fluid resistance, flammability, or microbial cleanliness
- Filter material is AFI MBN95
  - BFE Rating of 95%
  - Meets criteria for surgical mask material
    - Manufacturer clams it meets standards of N95 mask material. This statement this has not been confirmed, however BH is collaborating with MSU to conduct confirmatory testing.

406 Mask filter specifications

FILTRATION GRADE: BFE 95		
Basis Weight	25 to 30 g/m²	
Material	100% Virgin Polypropylene	
BFE Rating	95%	
BFE Test Method	ASTM F2101-19	EN 14683:2019
Delta P	3.2 - 3.5 mmH2o/cm²	31 - 34 Pa/cm²
Delta P Flow Rate	8 Liters per Minute	
Delta P Test Area	~40cm²	

BOZEMAN HEALTH

Medical Grade Mask Standards

Mask standards vary by country, Europe uses the EN 14683 standard and the US uses the ASTM F2100 standard. Details about filtration efficiency and other performance capabilities are outlined below.

Test	EN 14683			ASTM F2100			BH Alternate	
	Type I	Type II	Type IIR	Level 1	Level 2	Level 3	HEPA	406 Mask
Bacterial filtration efficiency, %	≥95	≥98	≥98	≥95	≥98	≥98	99.97	≥95
Differential pressure, mm H_2O/cm^2 Pa/cm^2	<3.0 <29.4	<3.0 <29.4	<5.0 <49.0	<4.0 <39.2	<5.0 <49.0	<5.0 <49.0	Pending	<3.5 <34
Sub-micron particulate filtration efficiency at 0.1 micron, %	Not Required	Not Required	Not Required	≥95	≥98	≥98	99.97	≥95
Splash Resistance/ Synthetic Blood Resistance, mmHg Pass Result	Not Required	Not Required	120 (16,0 kPa)	80	120	160	Not tested	Not tested
Flame Spread	Not Required	Not Required	Not Required	Class 1	Class 1	Class 1	Not tested	Not tested
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30	Not Required	Not Required	Not Required	Not tested	Not tested

BOZEMAN HEALTH

Guide to Face Mask Selection and Use

Choose the right mask for the task! Select the mask design, fit and filtration that matches the protection needs for each procedure or risk level. The Crosstex® MaskEnomics® filtration guide makes it easy to find the level of filtration required, including ASTM Level 1, 2 and 3.

LEVEL PERFORMANCE LEVELS ▲ ▼

MAXIMUM FILTRATION

NIOSH Approved N95 Particulate Respirator

High Fluid Resistance	160 mmHg
Filtration Efficiency	PFE = 99.9% @ 0.1 micron
Breathability - Delta P	> 5.0 mm H_2O/cm^2
Flame Spread	Class 1

N95

Indicated for use when treating patients with airborne diseases such as TB or influenza.*

Meets CE 0121 – In reference to EN 149: 2001 FFP2 NR.

Pictured: Isolator Plus® N95 Particulate Respirator

ASTM LEVEL 3

High Fluid Resistance	160 mmHg
Filtration Efficiency	BFE ≥ 98% PFE ≥ 98% @ 0.1 micron
Breathability - Delta P	< 5.0 mm H_2O/cm^2
Flame Spread	Class 1

LEVEL 3

Ideal for procedures where heavy to moderate amounts of fluid, spray and/or aerosols are produced.

Meets EN14683 Rating – Type IIR Standard.

Pictured: Ultra™ Sensitive Earloop with SecureFit® Technology

ASTM LEVEL 2

Moderate Fluid Resistance	120 mmHg
Filtration Efficiency	BFE ≥ 98% PFE ≥ 98% @ 0.1 micron
Breathability - Delta P	< 5.0 mm H_2O/cm^2
Flame Spread	Class 1

LEVEL 2

Ideal for procedures where moderate to light amounts of fluid, spray and/or aerosols are produced.

Meets EN14683 Rating – Type IIR Standard.

Pictured: Procedural Earloop with SecureFit® Technology

ASTM LEVEL 1

Low Fluid Resistance	80 mmHg
Filtration Efficiency	BFE ≥ 95% PFE ≥ 95% @ 0.1 micron
Breathability - Delta P	< 4.0 mm H_2O/cm^2
Flame Spread	Class 1

LEVEL 1

Ideal for procedures where low amounts of fluid, spray and/or aerosols are produced.

Meets EN14683 Rating – Type II Standard.

Pictured: Isofluid® Earloop with SecureFit® Technology

LOW PERFORMANCE

Surgical Molded Utility Mask
Physical Barrier Only
No LEVEL Performance Level **
Filtration Efficiency N/A

** Unless mask manufacturer certifies that the mask meets LEVEL performance Level 1

Ideal as a comfortable substitute for earloop face masks, this mask is a simple physical barrier ideal for exams and visitations or for dry, short procedures that do not produce fluid, spray or aerosols.

Pictured: Surgical Molded

MINIMUM PERFORMANCE

Utility Mask (Tissue/Tissue)
Physical Barrier Only
No LEVEL Performance Level
Filtration Efficiency N/A

Ideal as a simple physical barrier for exams and visitations or for dry, short procedures that do not produce fluid, spray or aerosols.

Pictured: Isolite® Earloop

BH only recommends 'unrated' masks for use as source control at this time.

Note: some 'unrated' masks may resemble 'rated' masks.

References:

https://healthcentricadvisors.org/wp-content/uploads/2017/04/3_MaskEnomics_Poster_2012.pdf
https://smartairfilters.com/en/blog/comparison-mask-standards-rating-effectiveness/
https://www.nelsonlabs.com/en14683-harmonizes-bacterial-filtration-efficiency-and-differential-pressure-with-astm-f2100/
https://www.berriman-usa.com/tutorial_2_air_purifiers.htm
https://www.sciencedirect.com/topics/engineering/melt-blown-process
https://indycrafter.com/products/30-replacement-n95-filter-media