Emergency N95 Mask Retrofit Proposal

PREPARED FOR

John Wilczynski

America Makes

PREPARED BY

Darrell Wallace, Brian Vuksanovich, and Eric MacDonald

EXECUTIVE SUMMARY

As a readily-available substitute for N95 face masks immediately required by the medical community on the front line during the pandemic, retrofit N95 filtration cartridges that can be used with commercially available 3M paint masks or CPAP masks (intended for sleep apnea) can be printed and assembled with filtration performance that **meets or exceeds FDA-required levels.** The retrofit cartridges were co-developed by Youngstown State University with guidance from ER doctors employed by **Mercy Health.** The principal advantage of this approach is leveraging existing and commercially-available materials and manufacturing processes to build low-to-medium volumes with 3D printing and then scale to large quantities with a design readily promoted to traditional injection molding with inexpensive tooling.

Problem: N95 masks are in short supply during the pandemic. N95 masks **must filter** 95% of 300nm particles and **resist** penetration of bodily fluids. Fit to the face is critical and masks require fit tests to ensure tight seal. Leakage defeats the purpose of the mask.

Mask Option A: Industrial respirator face shields / chemical filters (3M paint half-face face masks) are readily available. The masks as purchased are not effective for viruses. The chemical filter cartridge can be replaced with a retrofit structure that can house N95 or HEPA filter media, some of which may be readily available. 3M paint respirators are within the community as donations. These masks are reusable and can be easily sanitized (no surface roughness or porosity often associated with 3D printing).

Mask Option B: CPAP mask are available at hospital and community. The masks have no filtration without attached pump. The hose connection can be a connection point for a filter cartridge. CPAP masks are available within the community as donations.
These masks are reusable and can be easily sanitized (no surface roughness or porosity often associated with 3D printing).

Cartridge Design for either mask (A or B): A single-design respirator cartridge

- Cartridges can be used in pairs for 3M mask and alone on CPAP masks.
- Cartridges do not touch the face or affect fit.
- Easy to sanitize and replace filter media.

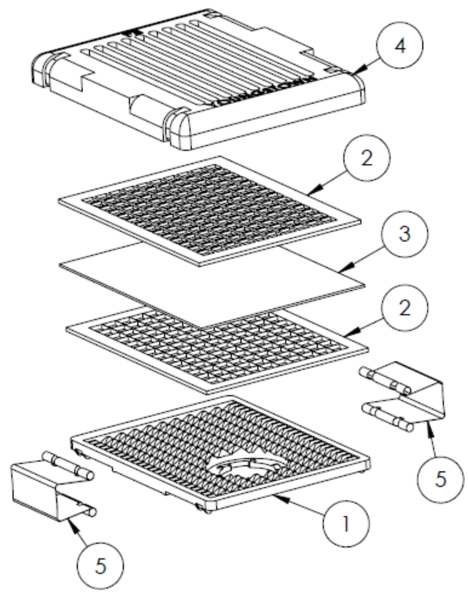
Low volumes and remote production immediately by 3D printed. Higher volume production with same design in injection molding. Cartridge can be used in pairs with 3M half face masks or as a single filter in a CPAP mask.

Overview

N95 respirators are in critically short supply in response to the COVID-19 pandemic. There are insufficient resources to meet the increased demand. The proposed concept addresses this need in three ways:

- **Use of commercially produced reusable facepiece for critical fit** - 3D printed filter cartridges (filter media holders) are adapted to existing, tight-fitting, commercially-produced reusable facepieces are used as reusable devices.
    - Cartridge portion is standardized
    - Interface to masks is easily customized to fit various widely-available mask types.
- **Versatile Filter Media** - Best-available filter media can be used efficiently
    - N95, HEPA, or other appropriate filter materials as available
    - Media are cut into 3”x4” sections with virtually no wasted media
- **Scalable production** – Can be effectively produced at many production volumes.
    - Design has been demonstrated to be effective when printed on mid-range consumer desktop printer (Lulzbot Taz 5 FDM), desktop vat photopolymerization (Formlabs)
    - Designed to be compatible with rapidly tooled high-volume production (injection molding)

Figure 1: Modular filter prototype attached to a 3M 600 series facepiece



1	Filter Base
2	Filter Support
1	N95 Filter Material
1	Filter Cover
2	Medium Binder Clip
4	Binder Clip Key (Not Shown)

Figure 2: Modular retrofit filter system

Concept

The proposed concept is intended to provide a highly versatile solution that can be adapted to the mask facepieces, filter media, and production options that are available at each region or location. Components are highly interchangeable between design variants, regardless of production method.

Design Versatility

The basic designs share a common filter cartridge, which is comprised of:

- **Cover** – louvred outer shell of the cartridge
- **Filter Supports (2)** – structural support for the filter media
- **Filter Media** – N95, HEPA, or best-available filtration media (3” x 4” patch)
- **Base** – back plate of the filter cartridge; this is the component that is modified to accommodate each specific mask.
- **Binder Clips** – Provide reliable clamping force and ease of media replacement
- **Gasket (not pictured)** – if the base is printed on a low-quality printer, an elastomeric gasket is inserted between the base and the adjacent filter support.
    - This is not necessary if filter supports are printed from elastomeric material (preferred)
    - Alternatively, the base and adjacent filter support can be glued together with RTV silicone or other suitable adhesive to achieve air-tight seal.

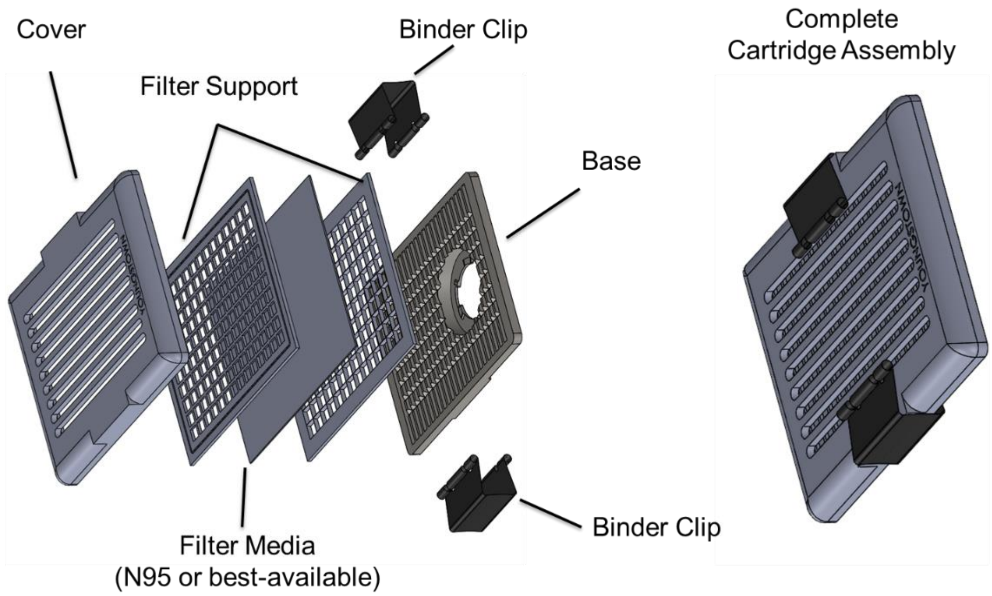


Figure 3: Cartridge filter design (solid model)

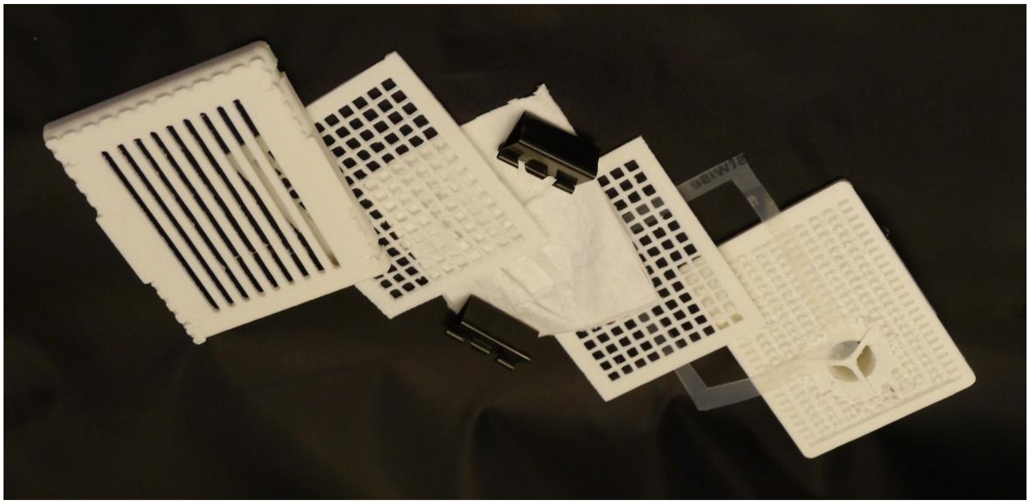


Figure 4: Cartridge filter design printed in ABS (with gasket and binder clips)

Customization for Mask Types

The strategy of this design is to leverage the many types of high-quality, tight-fitting, commercially available masks that may be suitable for use in this application. The sealing of the mask to the wearer's face is critical and is the most difficult feature to reliably print.

Figure 5: Examples of compatible masks (left to right): AMBU / anaesthesia style mask, CPAP/BIPAP mask, industrial respirator

In general, the design can be adapted for use with any number of commercially produced masks. These include:

- Industrial ventilator masks (various brands with different cartridge attachments)
- Medical facemasks:
  - AMBU / anaesthesia masks
  - CPAP/BIPAP
  - Ventilator masks
- Full-face snorkel / scuba masks

The design concept has been successfully demonstrated and tested with 3D printed cartridges attached to two different commercial masks:

- **3M 6000- / 7000-series cartridge respirator mask** – one of the most popular models of industrial cartridge respirator (
- **CPAP / BIPAP mask** – readily available in hospital inventory and possibly able to be reclaimed, sanitized, and reused

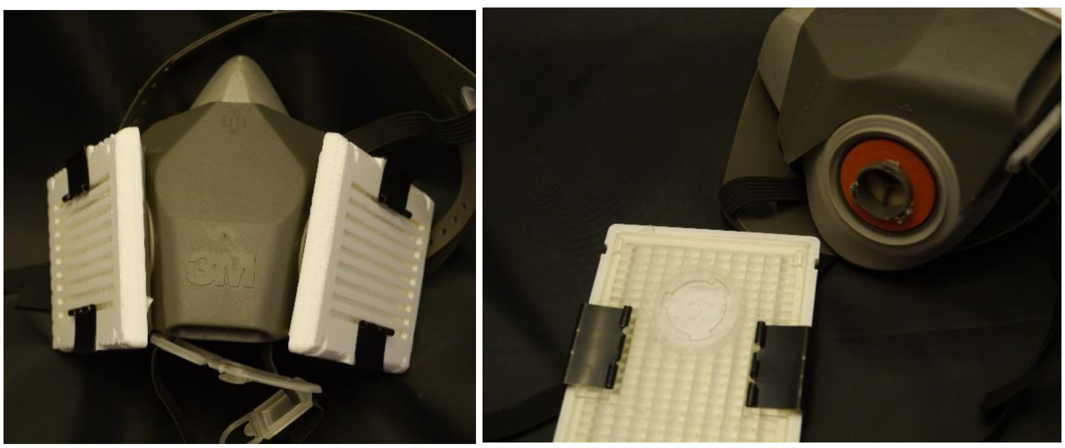


Figure 6: Left: Filter cartridges adapted to 3M industrial mask; Right – cartridge base plate with bayonet fitting to mate with 3M mask

Figure 7: Cartridge base with 3M bayonet fitting attached to mask (clear resin printed on Formlabs 2 printer)

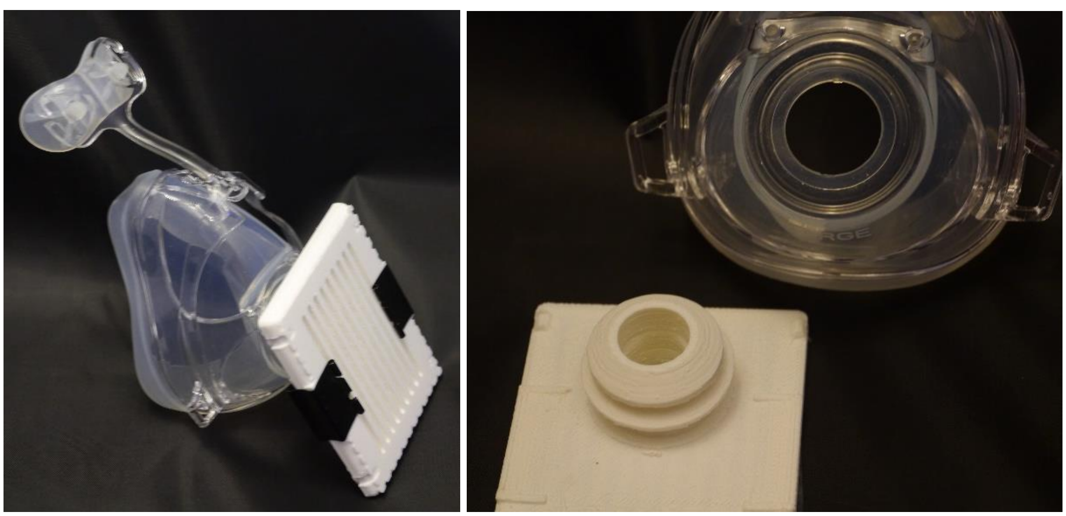


Figure 8: Left: Filter cartridge adapted to BIPAP mask; Right – cartridge base plate with barb fitting to mate with BIPAP mask

Scalable Manufacturing Pathways

These prototypes have been designed so that they can be easily produced in low quantities on desktop 3D printers and can be scaled up in a matter of hours to mass production using 3D printed injection molding tooling. The Following materials and manufacturing methods have been considered, though many others are applicable. Options shown in bold text have been demonstrated.

Components	Process / Material
Cover, Filter support (rigid), Base	• Material Extrusion: ○ **ABS** ○ Nylon ○ Polycarbonate • Vat Photopolymerization: ○ **Standard rigid resin (Formlabs 2)** ○ High-strength resin • SLS / Multijet Fusion ○ Nylon • Injection molding ○ ABS ○ Polycarbonate ○ Nylon • Reaction Injection Molding (RIM) ○ Polyurethane
Gasket / Filter Support (flexible)	• Material Extrusion: ○ **Thermoplastic Elastomer (TPE)** ○ Thermoplastic Urethane (TPU) • Vat Photopolymerization: ○ **Flexible resin (Formlabs 2)** • SLS / Multijet Fusion ○ EVA Foam (e.g. Duraform) • Reaction Injection Molding ○ Polyurethane (low durometer)

We are currently able to produce useable cartridge assemblies at a rate of approximately 4/day per desktop printer. On production-class 3D printers, those numbers could be increased to dozens per printer. We believe that a manufacturer could have useable injection molds produced and operational within 72 hours and, with them, could produce completed filter assemblies at a rate of approximately 2,500 completed mask assemblies per day per injection molding machine. (This assumes 3-shift production at 20 seconds / cycle, one mold for each component, two to 4 cavities per mold). **This does not include provisions for acquiring the replaceable 3” x 4” filtration media patches.**

Flexible Filtration Media

Concept Validation and Testing

Throughout the design process, feedback from medical professionals on the project team has been included. These professionals include emergency room physicians, respiratory therapists, and occupational health and safety experts.

To validate the efficacy of the design, the two mask designs were tested according to the fit testing procedure as dictated by 29CFR1910.134-App A. All filter cartridges were loaded with N-95 filter media extracted from certified respirator masks. The rationale for this testing was that if it can be shown that our design passes the fit test, it confirms that there are no leaks occurring within the cartridge assembly. Therefore, the filtration medium is able to work effectively in this apparatus.

The fit tests were conducted by Julie Gentile, Director of Environmental and Occupational Safety and Health at Youngstown State University. The masks were fitted to Mary Yacavone, Professor of Respiratory Care at Youngstown State. The tests were conducted using a 3M model FT-10 Qualitative Fit Test Apparatus as shown below in Figure 9.

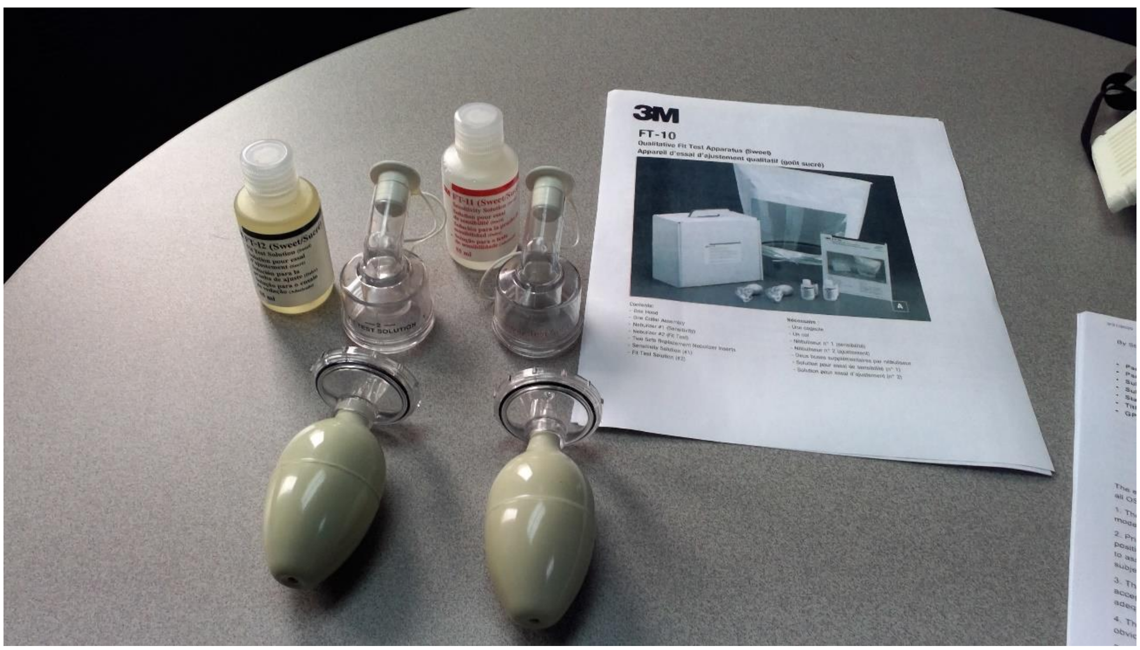


Figure 9: 3M Model FT-10 Qualitative Fit Test Apparatus

(a)

(b)

Figure 10: Fit-testing of mask and cartridge system. (a) BIPAP system with single cartridge adapter; (b) fit test procedure

During the testing procedure, the wearer was exposed to a sweet substance, which was successfully filtered out by the mask and filter system (Figure 10). To separate out the performance of the cartridge system from the seal of the mask on the wearer's face, a test was conducted with the cartridge system fully enclosed in a plastic bag. This occluded the cartridges and verified the integrity of the mask-to-face seal, which speaks to the fit of the mask on the wearer and does not speak to the efficacy of the cartridge design.

It should be acknowledged that the mask facepiece did not fit tightly to the wearer's face under all conditions (such as lateral motion of the head). The leakage that occurred was related to poor fit of this particular facemask size / design to the wearer's face. Under the current time constraints and social distancing provisions, it was not practical to try additional combinations of masks and wearers.

Upon concluding the testing, both professionals concurred that the efficacy of the filter adapter had been successfully demonstrated. The wearer was not able to detect the test scent if the mask was securely seated on her face. This means that no air was allowed to pass unfiltered. The cartridge will allow any installed filter medium to function up to its rated performance. Additionally, she confirmed that the breathing resistance was qualitatively acceptable based on her experience with respirators.

Design and Manufacturing Notes

The versatility of the manufacturing processes requires that the manufacturer make process- and material-specific adjustments to accommodate the performance requirements of the design.

3D Printed Components

For the 3D-printed components, this requires that the manufacturer understand good manufacturing practices for their material and process combination, and that they choose appropriate build orientations, infill densities, support strategies, and post-processing steps. These requirements are generally well understood by qualified 3D printing companies and should pose no significant barriers to producing effective components by 3D printing.

The tested prototypes were produced by the lowest quality printers considered. These printers, hobby-grade machines, were able to produce components that performed as-expected. This confirms that higher quality manufacturing methods should be able to consistently achieve acceptable results. The demonstration also confirms that emergency crowdsourcing of these components may be a viable consideration if no better alternatives exist.

Post-processing of the 3D printed components requires due care to ensure all loose particles are removed from air passages. Commercial printers with soluble supports or non-fragmenting supports are preferred to mitigate this risk. Parts should be cleaned thoroughly prior to assembly.

Molded Components

In cases where filter base configurations require complicated undercuts, 3D printing may remain the best near-term option for production. For all other components, production rates and costs will be far more favorable while also providing more consistent part quality. For these reasons, wherever practical, molding of the components is preferred.

Assembly

There are two critical interfaces in this design. The first is the interface between the cartridge base and the mask. That interface depends upon the gasket at that interface and the quality of the surface of the printed base component. The other interface, and the one that is more difficult to control, is the interface between the base and filter media.

Several assembly configurations have been explored. Which option is most effective depends on several factors:

- Material / process used to create the components
- Filter medium
- Sanitation procedures to be used

If permissible, the most reliable sealing method will be to bond the base-side filter support to the base with a flexible adhesive gasket (e.g. RTV silicone). This will seal that air gap and reduce the number of loose components.

Alternatively, the filter support may be molded or printed from a compliant, flexible material, such as silicone, polyurethane, or thermoplastic elastomer. In that case, the filter support serves the functions of both supporting the filter medium and sealing the air gap between the cartridge base and the filter.

The last option is to use a rigid filter support and seal the gap between the filter support and the base with a compliant gasket material. This gasket can be cut from a thin sheet of silicone (as was done in the filters tested here). It may also be printed or molded.

Continued Development

The project team continues to evolve the design concept to enhance reliability, reduce production cost / time, and adapt the design to fit the widest possible range of available facepieces.

Appendix A - Project Team Qualifications

Design

- **Darrell Wallace – Professor and Program Coordinator, Manufacturing Engineering, Youngstown State University** – 30 years experience in manufacturing and process design
- **Brian Vuksanovich – Associate Professor, Mechanical Engineering Technology, Youngstown State University** – 30 years of engineering, product design, and manufacturing experience

Manufacturability and Project Support

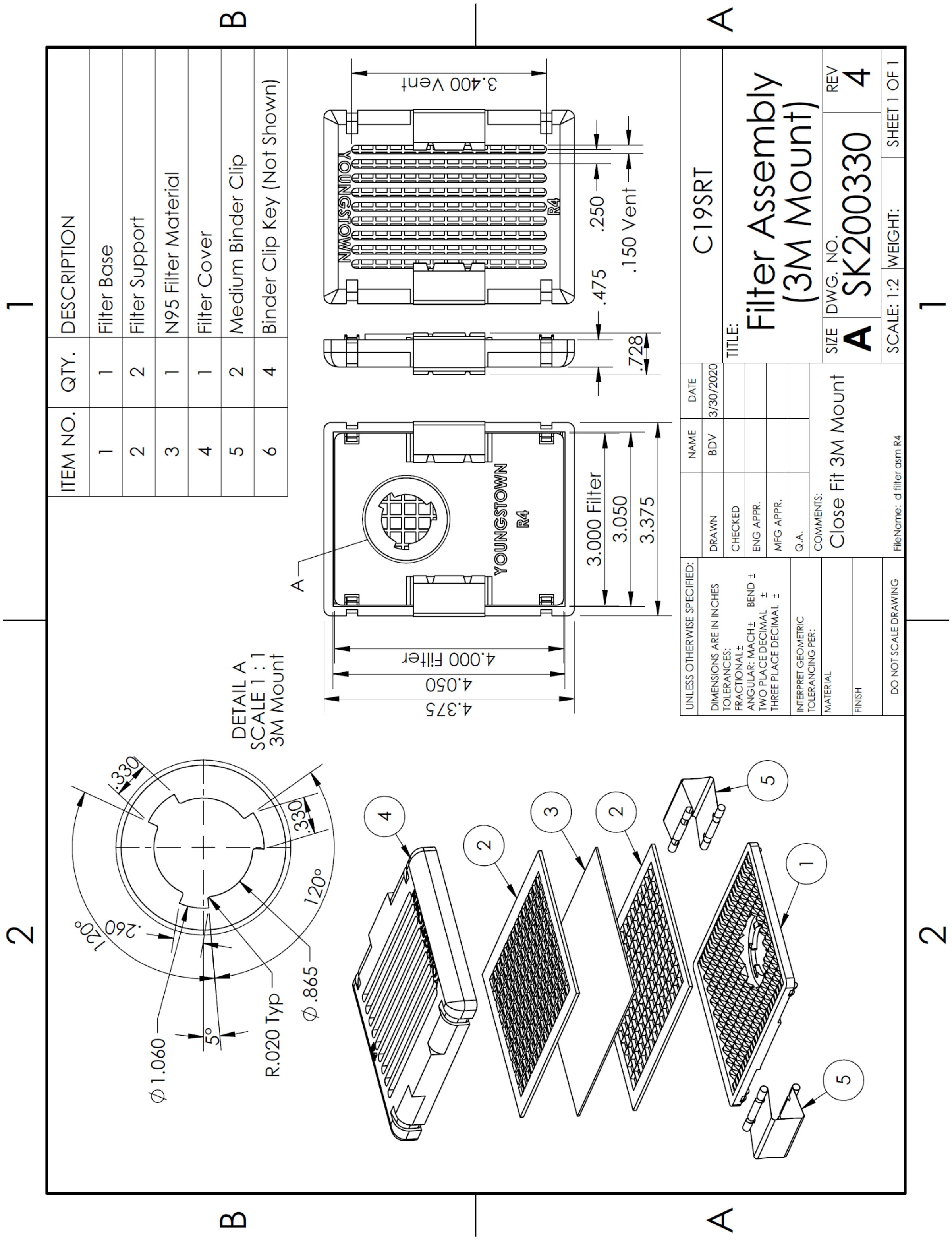
- **Dr. Eric MacDonald – Professor and Friedman Chair for Manufacturing, Electrical Engineering, Youngstown State University –** 3D printing, smart materials, embedded sensing and electronics
- **Dr. Jason Walker – Assistant Professor, Manufacturing Engineering, Youngstown State University** –biomedical engineering, manufacturing processes, and 3D printing
- **Dr. Pedro Cortes – Associate Professor, Chemical Engineering, Youngstown State University** – polymers, smart materials, ceramics, composites, and 3D printing
- **Dr. Taci Turel, Associate Professor, Human Ecology** –textiles and textile manufacturing
- **Mr. John Martin – Assistant Professor, Mechanical Engineering Technology – Youngstown State University** – manufacturing processes
- **Ms. Shena Hinds** – Project Management and research

Medical and Safety Experts

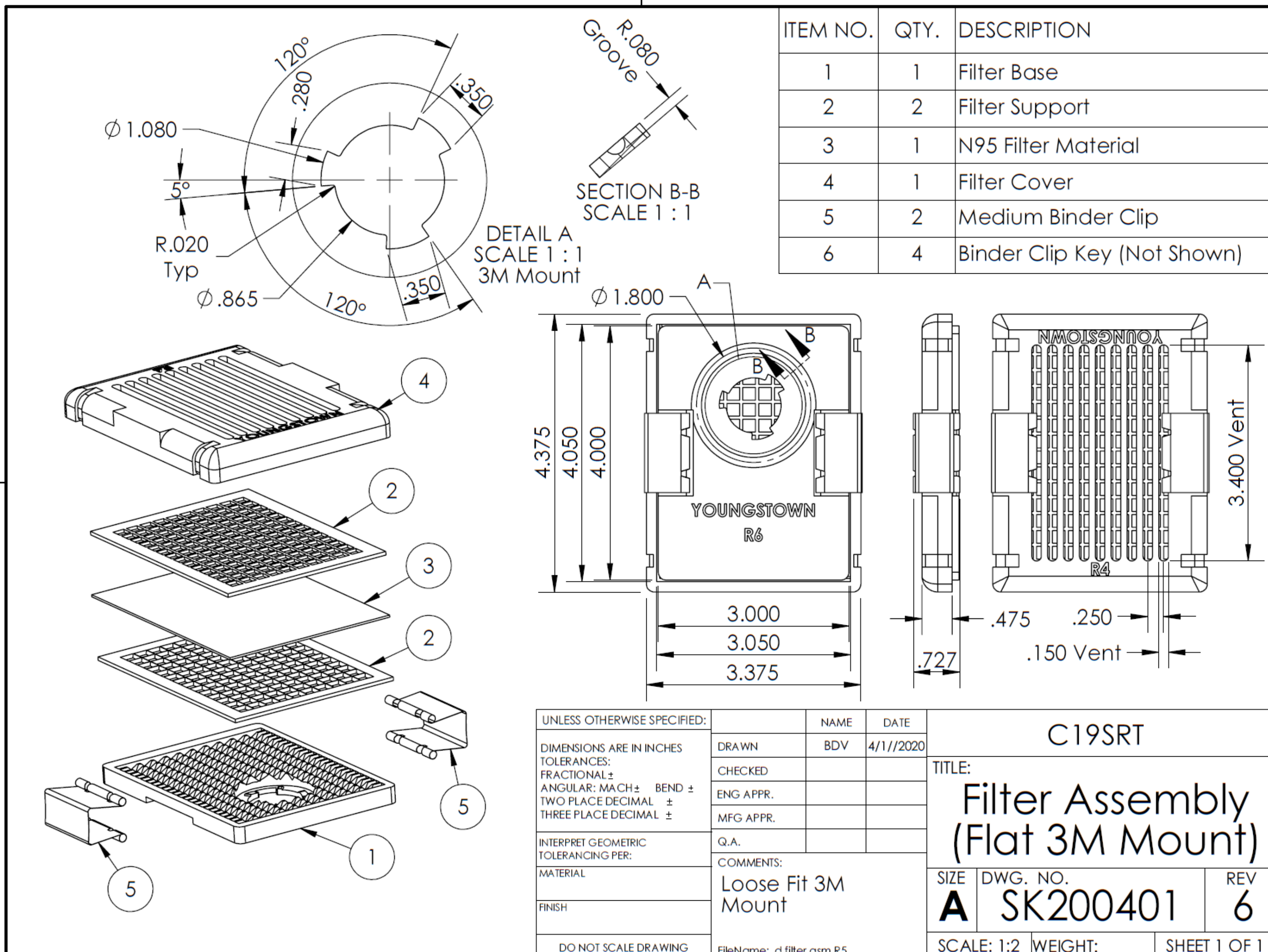
- **Dr. Daniel Hinds, DO – Emergency Medicine Physician, Mercy Health**
- **Dr. Lindsey Smith, MD – Emergency Medicine Resident, Mercy Health**
- **Mary Yacavone, Med, RRT, Professor, Respiratory Care, Youngstown State University**
- **Julie Gentile – Director of Environmental and Occupational Safety and Health, Youngstown State University** - Masters in Industrial Hygiene with over 18 years of health and safety experience. Member of the YSU Emergency Management Team and the universities representative for the Mahoning County LEPC.

Appendix B: Technical Drawings

- **Filter Assembly (3M Mount) – R4** – This is the design revision that was tested and that is being proposed for initial production
- **Filter Assembly (3M Mount) – R6** – This is the current design version under development. It offers improved printability but remains in the design iteration phase.



ITEM NO. | QTY. | DESCRIPTION
1 | 1 | Filter Base
2 | 2 | Filter Support
3 | 1 | N95 Filter Material
4 | 1 | Filter Cover
5 | 2 | Medium Binder Clip
6 | 4 | Binder Clip Key (Not Shown)
3.400 Vent
.475
.250
.150 Vent
.728
3.000 Filter
3.050
3.375
4.000 Filter
4.050
4.375
A
YOUNGSTOWN
R4
DETAIL A
SCALE 1 : 1
3M Mount
.330
.330
120°
120°
.260
5°
Ø1.060
R.020 Typ
Ø.865
1
2
3
4
5
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME DATE
DRAWN BDV 3/30/2020
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
Close Fit 3M Mount
FileName: d filter asm R4
C19SRT
TITLE:
Filter Assembly (3M Mount)
SIZE A
DWG. NO. SK200330
REV 4
SCALE: 1:2
WEIGHT:
SHEET 1 OF 1



ITEM NO.	QTY.	DESCRIPTION
1	1	Filter Base
2	2	Filter Support
3	1	N95 Filter Material
4	1	Filter Cover
5	2	Medium Binder Clip
6	4	Binder Clip Key (Not Shown)

Appendix C – Associated 3D Printing (STL) Files

Appendix D – Letters of Support