ConMed Corp.

Smoke Plume Testing Project

CU Boulder Team:

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Introduction & Project Scope

The CU team has designed and manufactured a testing chamber built to replicate the environment of an operating room during an electrosurgical procedure. This will enable ConMed, a surgical and medical device manufacturing company, to test if their ViroVac smoke plume evacuation system meets one of the requirements within ISO 16571- an international standard established in 2014 to set guidelines for equipment that removes plume generated by medical devices. Smoke plume negatively impacts operating room staff, such that it hinders the vision of the surgeon, produces an unpleasant odor, and releases hazardous chemicals that include mutagens and carcinogens into the air. These particles are small enough to pass through surgical masks and deposit directly into the lung tissue of the staff, causing long-term health issues and, potentially, disease transmission. ConMed completing such a test, along with others, will allow integration of their evacuation system to improve the safety of healthcare workers and advance smoke plume evacuation within the industry.

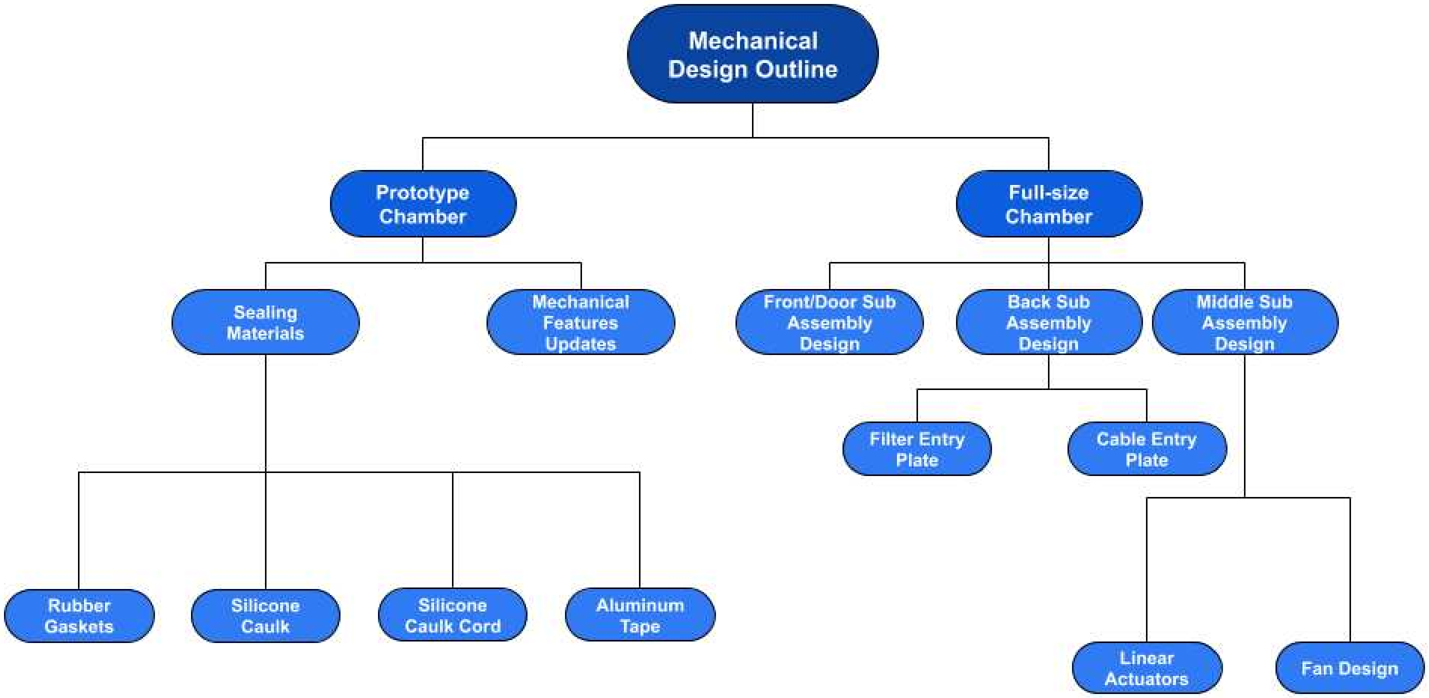
ConMed's ViroVac's evacuation system that would follow the ISO 16571 standard, 90% smoke removal, to ensure medical personnel's safety.

Mechanical Design Overview

The team's designs began with the initial purpose of building a chamber that would:

1. Produce surgical smoke in a repeatable manner
2. Include a door for easy access and cleaning
3. Evacuate the smoke from the chamber
4. Integrate wiring while maintaining the sealing
5. Mix the smoke evenly
6. Incorporate a particle counter for testing the smoke amount
7. Include a filtered port to eliminate negative pressure during evacuation
8. Maintain relative sealing of the chamber throughout testing

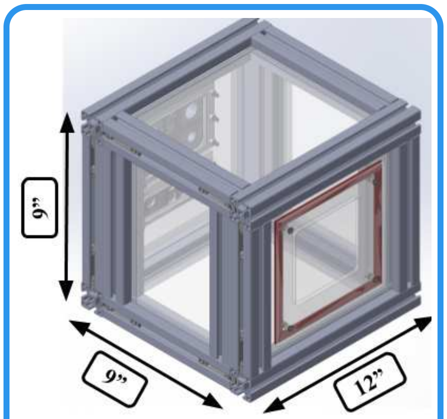
This project is split into two phases. The first phase is a scaled down prototype for the initial testing of the sealing methods and sealable components, as well as determining the effectiveness of materials used. Phase two, the full-sized version, includes feedback from the scaled-down prototype and incorporates all electrical components.



Prototype Chamber: Mechanical Design

Prototype's Objective

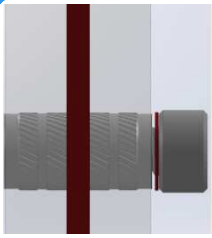
The objective of the first phase within the smoke plume test project is conducting sealing tests on a small scale version of the actual design in order to verify the validity of different design features in terms of the sealing. Based on results of prototype testing, changes were implemented to improve the sealing of the chamber, specifically regarding threaded inserts and rubber adhesive.

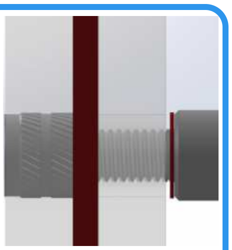


The updated mechanical design based on test results.

Threaded Inserts Test

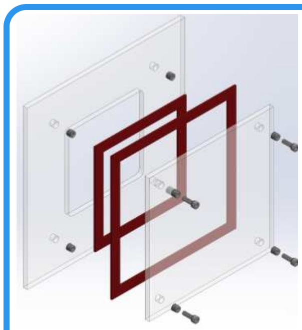
The sealing test verified the effectiveness of a single threaded insert along with a clearance hole in comparison to two threaded inserts, as the misalignment of the two threaded inserts lead to leakage. This caused the sheets to be under bending stress, thus, a major gap between the sheets was created.

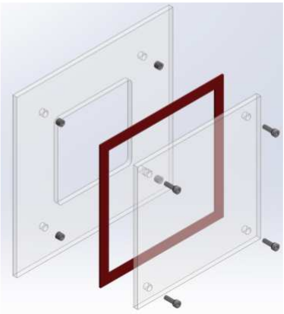

First threaded insert design, which was ineffective.


Updated threaded insert design, which proved to achieve adequate sealing.

Rubber Adhesive Test

The sealing test verified the effectiveness of rubber adhesive only around the sheet cover, as opposed to rubber adhesive around both the sheet cover and the front sheet's opening. Using the rubber on both caused the sheets to be under bending stress, thus a major gap between the sheets was formed.

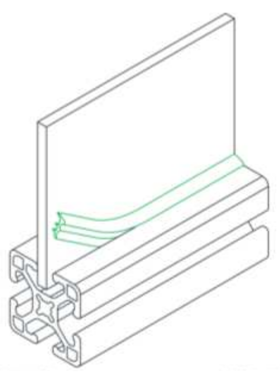

Ineffective adhesive rubber design.


Updated and effective adhesive rubber design.

Prototype Chamber: Sealants & Accessibility Testing

Sealant Test

Rubber gaskets, permanent silicone caulk, removable silicone caulk cord, and aluminum tape were all tested. The results revealed that both the aluminum tape and silicone caulk cord passed the water test.



Rubber gaskets produced ineffective sealing.

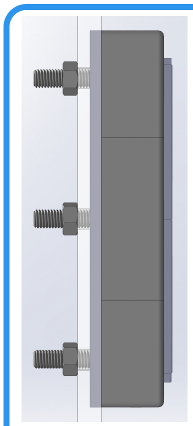
Permanent silicon caulk passed the sealing test.

Removable silicone caulk provided effective sealing.

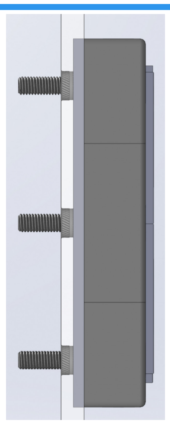
Aluminum tape produced effective sealing.

Accessibility Test

The use of threaded inserts with screws instead of bolts and nuts would ensure easier accessibility within the chamber for the user. Therefore, the attach-ability of the cable entry plate design was improved due to how frequently the user would attach/detach the cable entry plate.



The use of bolts and nuts to attach the cable entry plate.



The use of threaded inserts to attach the cable entry plate.

Full Scale Chamber: Design Overview

Chamber's Objective

The CU Boulder team's goal was to create a larger testing chamber that would give ConMed the ability to test for 90% smoke removal for their line of ViroVac evacuators. The full-scale testing chamber is comprised of the following sub-assemblies:

Door/Front Subassembly

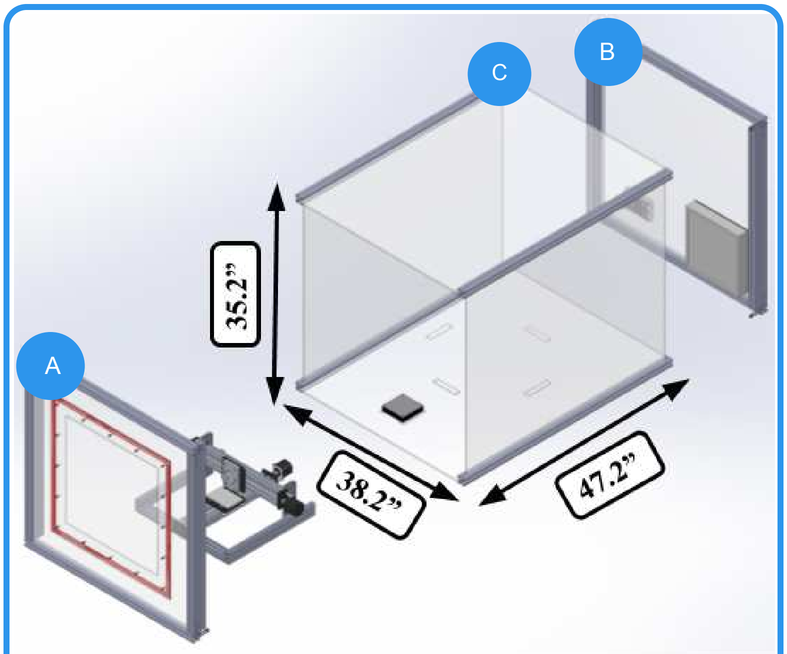
The door/front subassembly (A) design provides a sealable access panel for repeatable testing and cleaning.

Back Subassembly

The back subassembly (B) design includes two entry plates. A cable entry plate ensures cable/tube sealable accessibility and a filter entry plate filters particles in/out of the chamber while also eliminating negative pressure and maintaining sealing.

Middle Subassembly

The middle subassembly (C) design includes a linear actuator, which makes repetitive automated cuts, as well as a fan to ensure even mixing of smoke.



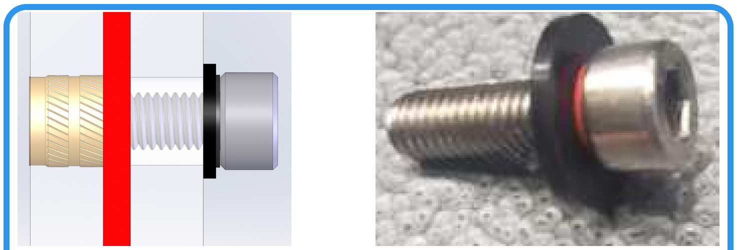
The updated mechanical design based on test results from the prototype, which highlights the overall chamber's subassembly.

An overview of the updated mechanical design of the Full size chamber

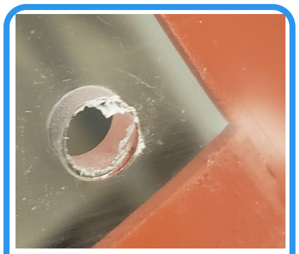
Full Scale Chamber: Sub-Assembly Features

Door/Front Design

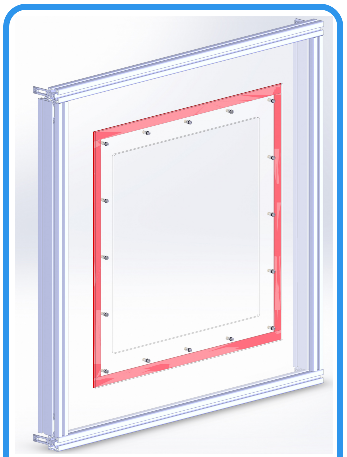
The door/front subassembly provides a sealable access panel for repeatable testing and cleaning. The large opening along with the cover guarantees accessibility to the samples, repeatable testing, and mechanical features that would ensure that the door is sealed. The following are essential features:



The prototype results revealed that gaps were present on the attachment holes due to machining finishes from the water jet. In order to accommodate this, the team used a clearance hole, threaded inserts, and added sealing rubber washers. This proved to seal adequately.



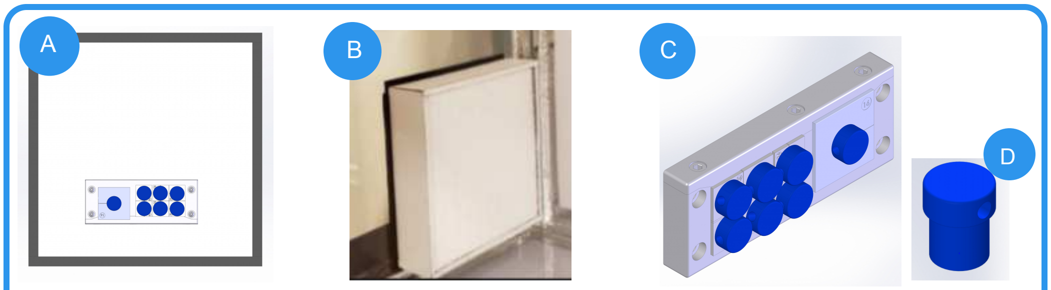
Attachment hole's water jet finishes before post processing.



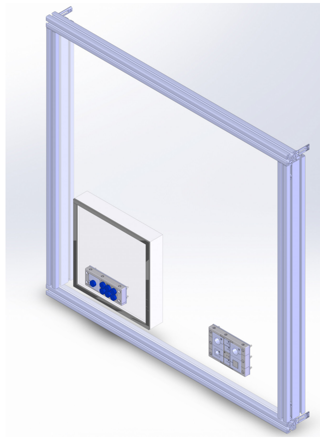
The door/front subassembly showing sealing features.

Back Design

The back subassembly design includes a cable entry plate and filter entry plate, which ensures sealable accessibility and filtering during evacuation. The following are important subassembly features:

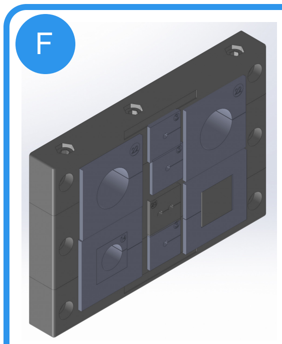


The filter entry plate (A) equilibrates the pressure and filters both remaining toxic smoke particles inside the chamber and other particles outside the chamber, which ensures consistent particle counts generated from the electrosurgical pencil. It includes seven openings along with a ULPA filter (B) and removable 3D-printed PLA plugs (C&D).

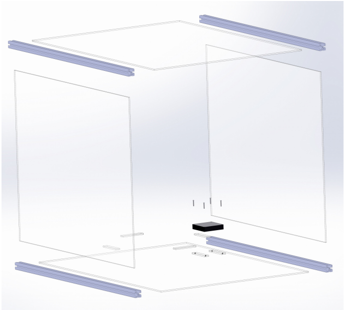


The back subassembly of the chamber showing sealing and accessibility features.

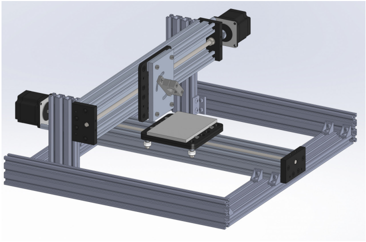
Full Scale Chamber: Sub-Assembly Features



The cable/port entry plate includes openings for cable and tube access while maintaining the design's adequate sealing. Grommets are the parts providing both cable/tube accessibility while accommodating for different diametral sizes, depicted in G.



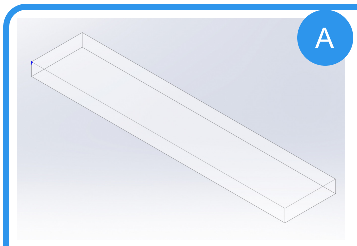
The middle subassembly with a fan.

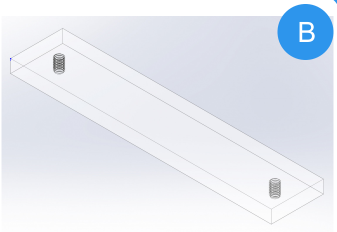


The linear actuator's design highlights the automation cutting mechanism.

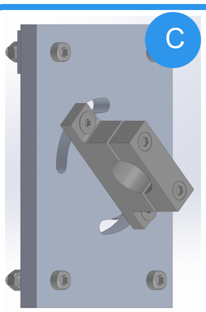
Middle Design

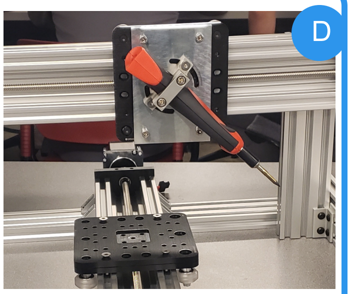
The middle subassembly design includes an automated cutting mechanism for repeated cutting and a fan, which evenly mixes fluid (air) in the chamber. Motion is facilitated by two linear actuators. Key features include:





Within the middle subassembly, both the fan and linear actuator structures are fixed via the use of polycarbonate blocks. These are fused on the chamber's polycarbonate sheet, where they would restrain the x and y movement of the linear actuator's structure. This attachment methodology minimizes leakage by eliminating the use of drilled holes and fasteners for fixturing.



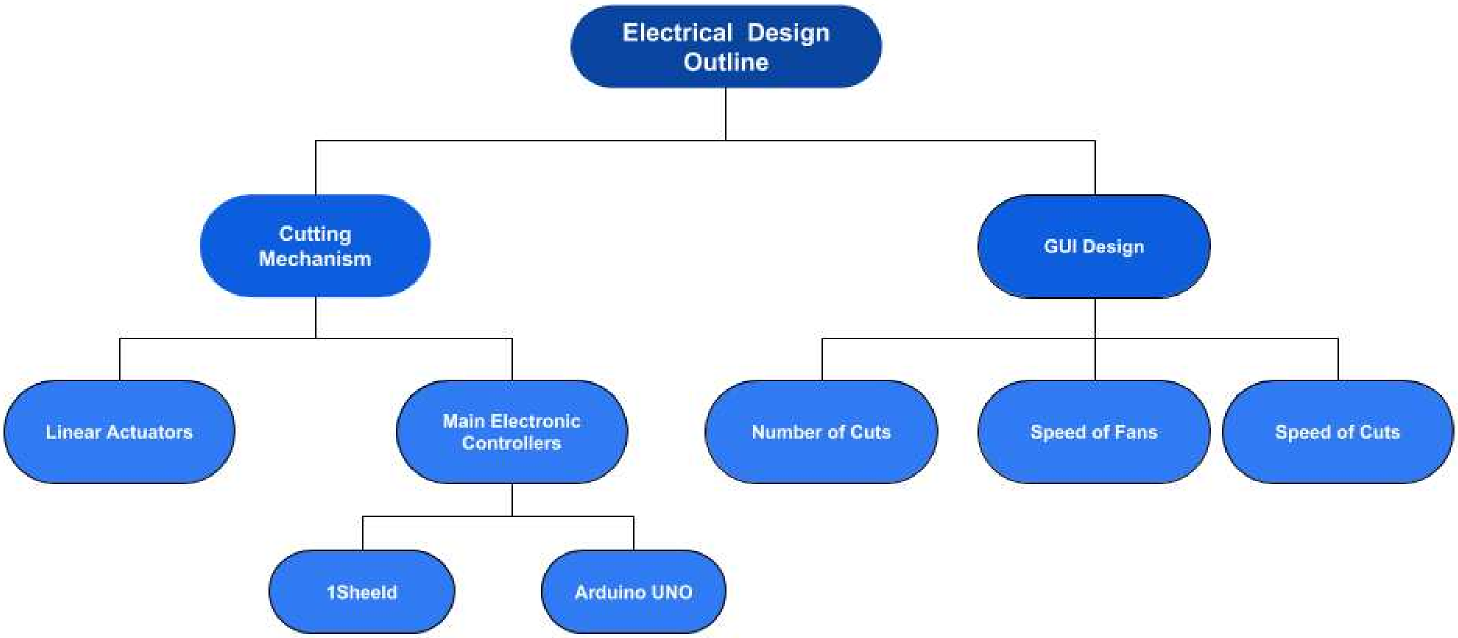


Both C and D highlight the pencil's fixture design that accommodates different cutting angles and the pencil diametral size of 20mm ~ 0.787".

E highlights the fan setup. The fan is fastened onto polycarbonate blocks while the blocks are fastened onto the chamber's polycarbonate sheet.

Electrical Design & GUI Overview

The purpose of the electrical design within this project is to create smoke in a repeatable manner using ConMed's electrosurgical pencil. This includes two linear actuators in order to create multiple cuts on a slice of bologna. These actuators are controlled via the electronics shown in B & C on the following page, which incorporate an Arduino graphical user interface, GUI design D also depicted within the following pages, to specify the inputs of: number of cuts, fan speeds, and speed of cuts.



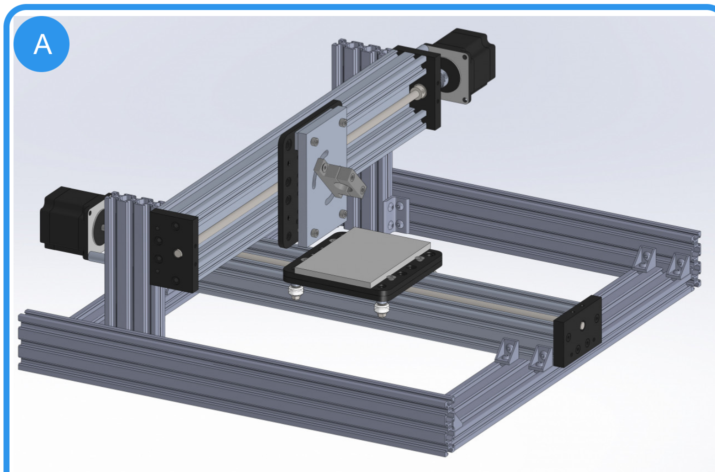
Electrical Design & GUI Overview

Automated Cutting Mechanism

The electrical design of the cutting mechanism includes two linear actuators to create multiple cuts on a slice of bologna. A screw driven linear actuator was chosen because of its accurate positioning, lack of backlash, and easily integrable structure with the v-slotted rails, depicted in A. The motion of the two linear actuators is meant to simulate a surgeon's hand, and thus the pencil moves at an angle, while the lower plate moves to position the cut. Moreover, the motion of these actuators is produced by two bipolar motors, where the direction and input voltage to these motors are controlled by two motor drivers connected to an Arduino micro-controller, shown in B and C. By generating the smoke via the automated cutting mechanism, the P-trak particle counter collects necessary data, discussed within the testing results section.

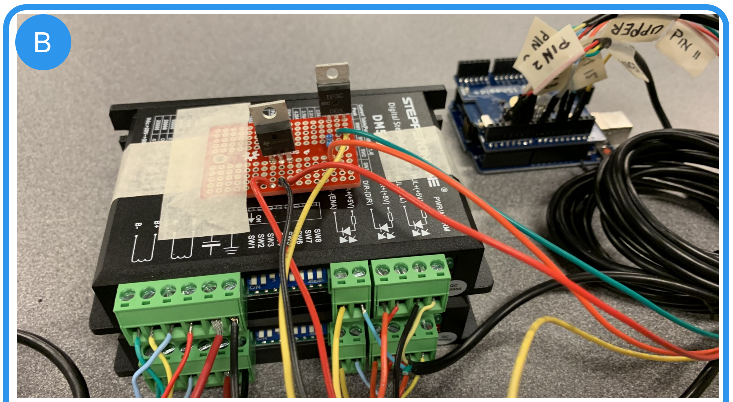
The electrical design requires a DC power source, which in our case splits its voltage between the fan, Arduino UNO, and the motor drivers via the use of a voltage regulator in order to provide the required power to all electrical equipment. The fan's speed is controlled by the Arduino combined with a transistor in order to later on test different fan speeds for the even mixing of the chamber.

A



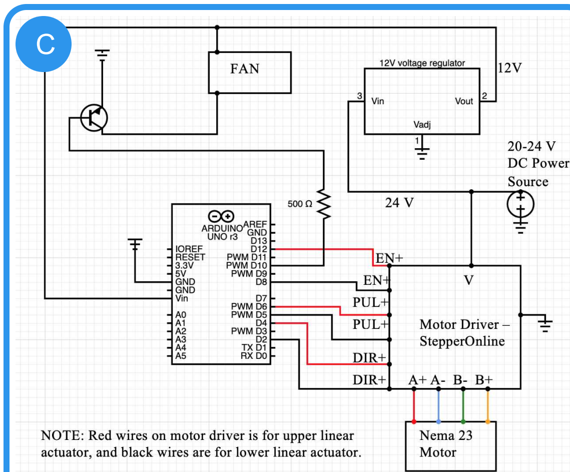
Cutting mechanism structure with two linear actuators.

B



Overall electrical design and controller wiring.

C



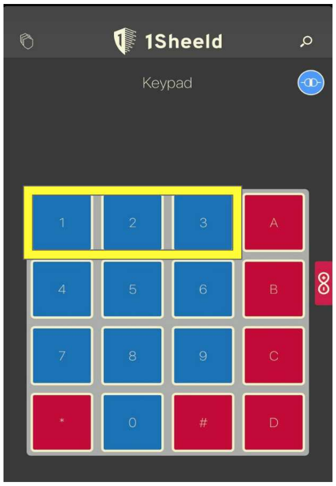
Overall electrical design and controllers schematic highlighting both of the necessary wiring of the fan and motors.

GUI Design

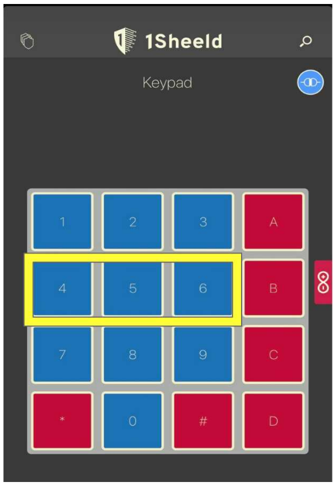
GUI Design

The graphical user interface incorporates a 1Sheeld+, which is an Arduino GUI shield, and an Arduino micro-controller, allowing the user to adjust the important parameters of cutting in an iPhone app. These controllable parameters are shown below:

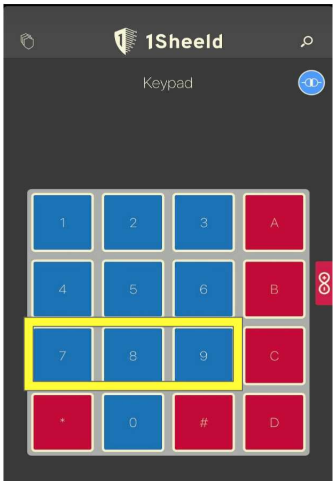
Step 1: Choose number of cuts



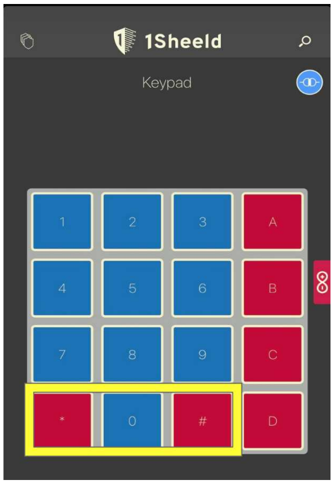
Step 2: Choose speed of fan



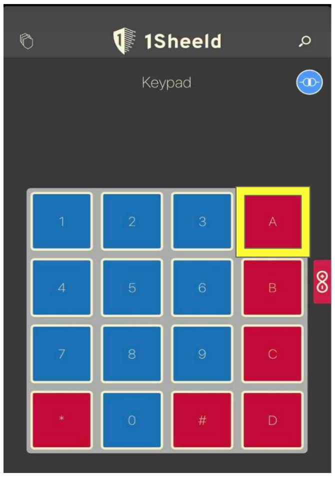
Step 3: Choose speed of cuts



Step 4: Choose angle



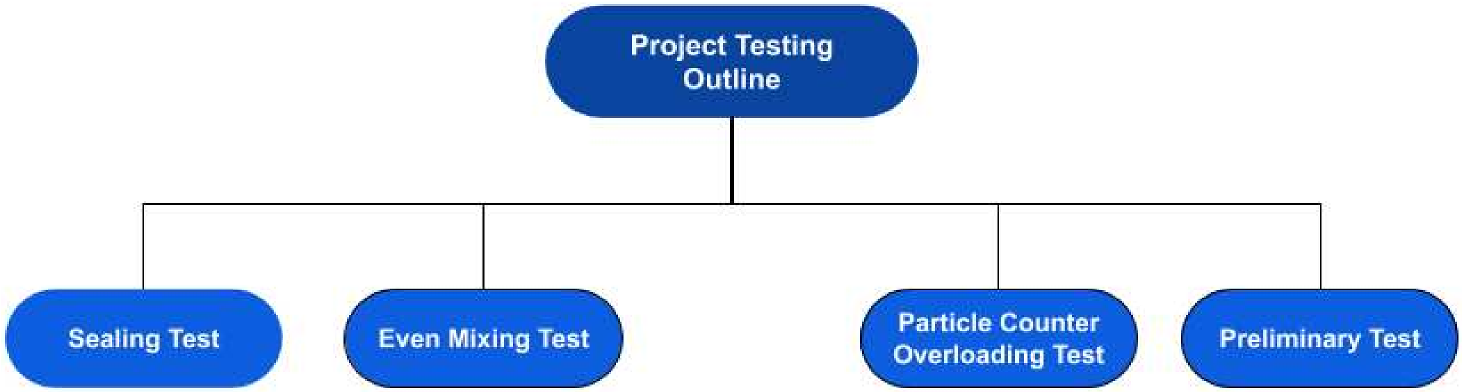
Step 5: Press A to start program



Testing Results

Testing Results

This is a testing based project, which includes various testing procedures to ensure the viability of the overall structure for repeatable preliminary results. The purpose being that the design would allow ConMed in the future to test for 90% particle capture of their line of evacuator products. The outline highlights both conducted and future testings.



Sealing Test Results

The sealing test involved both a water and a fog test to ensure the success of the sealing materials used. Initially, a water test was conducted by filling the prototype with water and testing all sealant methods to find the most effective. Next came the fog test, where a fog machine was placed inside the final chamber along with a particle counter (foobot) in order to check on the consistency of particle measurements over time. Thus, the following was concluded from the collected data:

- Rubber gaskets were ineffective sealants due to large obvious leaks.
- Permanent silicone caulk was partially effective due to corner leaks.
- Permanent silicone caulk and expandable sealing foam was an effective sealant method.
- Aluminum tape was an effective sealant.
- Finally, removable silicone caulk cord was an effective sealant.

Ultimately, we implemented both aluminum tape and removable silicone caulk cord to seal the final chamber. These sealants are able to both seal the chamber and ensure assembly/disassembly of the chamber.

Even Mixing Test

The purpose of the mixing test is to determine the location of the fan/fans within the chamber for the best mixing results, as well as to make sure that the air within the chamber is evenly mixed. This test falls under the category of future testings left to finalize the design before preliminary testings.

Testing Results & Conclusion

Particle Counter Overloading Test

The purpose of the overloading test is to determine the maximum amount of generated smoke from cutting the bologna via varying GUI cutting parameters. The purpose of the test is to ensure the particle counter (P-trak) wouldn't overload. The results would be useful for future testing with the device, and could ultimately change the Arduino coding for speed of cuts, speed of fans, and other parameters. This is future testings that are essential to conduct before preliminary testing.

Preliminary Testing

The purpose of the preliminary testing is to identify the percentage of evacuated smoke plume via the ViroVac system. The success of collecting such data is to ensure ConMed's ability to conduct repeatable tests for other evacuator lines, where they would test the product's viability in meeting the requirements of the ISO 16571 international standard.

Conclusion

Our team achieved the initial goals of the project; we created a method to produce repeatable smoke via two linear actuators. The design included a sealable access door for easy cleaning along with a sealed wiring port for the evacuator, particle counter, and other accessories entering the chamber. Moreover, we included a fan with adjustable speeds for the even mixing test and a functional graphical user interface for specifying the parameters of the speed of cut, number of cuts, and fan speed for mixing of smoke and air. We ensured the elimination of negative pressure during the evacuation stage via a port and an ULPA filter. Finally, we successfully sealed the chamber by utilizing a combination of silicone caulk cord and aluminum tape based on collected data. Thus, these outcomes were concluded to ensure a successful testing chamber for ConMed's future use.

We'd like to highlight some design improvements, which are categorized as mechanical and electrical improvements. For the mechanical side, fixture blocks would be a useful future feature for the door so that one person can manage the attachment method without needing a second person to support the load. Also, the addition of emergency push button (whether mechanical or electrical) and physical keypad feature for user interface would be useful electrical design improvements.

References

Stock Image Gasket:
"2116." Magento Commerce, 8020.net/2116.html.

Stock Image Silicon Caulk Cord:
"Home." Frost King, www.frostking.com/products/weatherstripping/fingertip-rope-caulk.

Stock Image Silicon Caulk:
"Red Devil Silicone Caulk, Clear, 9 Oz." Dollar General, www.dollargeneral.com/red-devil-silicone-caulk-clear-9-oz.html.

Stock Image Aluminum Tape:
"ATP Harness Wrap Aluminum Foil Tape (2' x 60 Yards: 2 Mil) - 24 Rolls." ATP Harness Wrap Aluminum Foil Tape - 2" x 60 Yards, 2 Mil, 24 Rolls, www.rocketindustrial.com/tape/temp-resistant/aluminum/dust-moisture-foil-seal-tape.html.

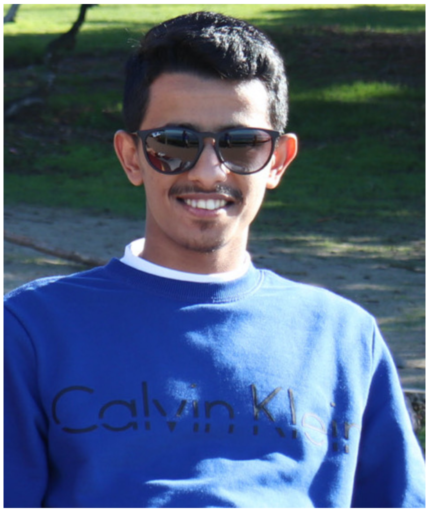
Bios of Team Members

Hussain Alkabah (CAD/Manufacturing Engineer)

Hussain Alkabah has interests in the design sector of the mechanical engineering program. Through his senior year, mechanical and management knowledge have been applied to deliver a biomedical product that meets the requirements of efficiency, cost, and time with his team. He is a sponsored student who would like to explore the industrial world with the leading company in Saudi Arabia, Saudi Aramco, before pursuing a master degree.

Raad Alshamrani (Systems Engineer)

Raad Alshamrani has always been enthusiastic about applying his studies in real life work such as applying mechanical knowledge on real-world problems with the use of mathematical and programming tools. He has also developed communication skills, built and tested parts of a system through senior design. He wishes to pursue a master's degree in Engineering Management as it is helpful to learn how engineers use their engineering skills in management position to be able to run a business or a company.



Isabel Nelson (Test Engineer)

Isabel Nelson has gained an interest in biomedical engineering and mechatronics, and has explored these areas in both internships and working in her lab on campus. Specifically, she has helped work on a variety of medical devices and created and improved research devices for cell stretch in order to research the effects of stress on the cell. She is excited to explore more aspects of engineering, and wants to continue working on projects that will help with health and technical innovation.

Bios of Team Members

Alissa Pearson (Financial Manager)
Alissa Pearson is passionate about combining her engineering degree with her business analytics minor. She enjoys being involved in technical industries, while also bridging the gap between the sciences and business to put an effort towards creating a more holistic and cohesive society. More specifically, the medical industry interests Alissa and she has also put an emphasis on this during her undergraduate career by completing a concentration in Neuroscience while at CU.

Sarah Sadeq (Project Manager)
Sarah Sadeq's interest would mainly be both biomedical and data analysis, where she would integrate her mechanical and electrical backgrounds into the biomedical field. Moreover, data analysis skills were developed via on campus research lab work and leadership skills were developed via her position in senior design and on campus teaching positions. The incorporation of leadership and management would be another avenue she'd pursue in the near future. She is going to pursue her master's degree in mechanical engineering and management as well a year after graduation.

Yuki Wang (Logistics Manager)
With her experience as an intern, lab researcher, project logistics manager, and society of women engineers secretary, Yuki Wang is excited to widen her impact and hopes to pursue a career in the biomedical field. She is picturing herself as a field engineer who works on-site as a technical service provider; becoming the bridge between technology and clinical practice. She is going to pursue her master's degree in applied bioengineering at the University of Washington Seattle right after her graduation from CU.