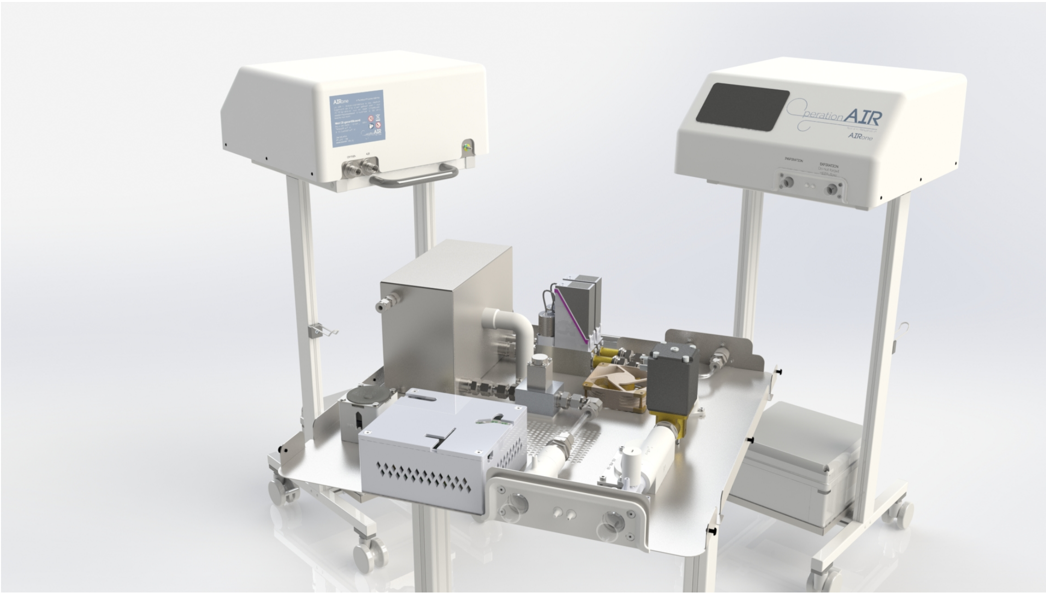


AIRone - 3D printing

Tomas Gast

Version 1.1, April 29, 2020

⚠ WARNING:
The device should only be used
by trained users and these
instructions should be thoroughly
read before use.

Contents

1 Introduction

1.1 Why 3D printing?

3D printing enabled us to rapidly manufacture numerous complex parts, helped us to iterate quickly and provides a good quality, easy to setup end product. The overall design had the tendency to change on a daily basis at the beginning of our project. The only way to keep all parts connected was by 3D printing all types of connectors. Over time, these connectors grew to more mature parts that remained in the full scale design. These parts are either difficult to manufacture, or could easily be integrated in other 3D printing parts.

1.2 Functional and safety requirements

We break the requirements down into two parts: airflow or housing related 3D printed parts. The airflow related parts are subjected to much heavier requirements, since they are in contact with high oxygen concentrations, pressure and the patient. In the list below, these requirements are stated.

- White finish to easily see contamination.
- Smooth surface finish to minimise the disruption of the airflow.
- Airtight up to +120 mbar for 10 minutes.
- Structurally safe.
- No sharp corners.
- Biocompatible material.
- No internal support because their remains might break off and reach the patient.
- No support on connecting faces, because the quality of the connection can otherwise not be guaranteed.
- Highly consistent manufacturing to guarantee the airtighness at connections.
- Doesn't degrade after being exposed to high levels of oxygen.
- Absolute minimum life span of 30 days.
- The parts don't contain any grease or oils.

The housing related parts are merely used to connected other parts to each other or the bottom plate, so they don't have nearly as many requirements:

- White finish, to easily see contamination.
- Structurally safe.
- No sharp corners.
- Absolute minimum life span of 30 days.

1.3 3D printing and manufacturing quantity

3D printing is typically not suited for mass production as shown in figure 1, and mostly shines during the prototyping phase. This hasn't been different in this project, but the pace of the project has. And setting up a traditional manufacturing line for these parts is time consuming. The production of our parts often started hours after we settled on a certain final design, leaving no room for the design and manufacturing of molds. Additionally, we created offsets on conical faces to ensure an airtight connection, which would likely have to be retested for a different manufacturing process.
So although 3D is not the optimal technique for mass production, we ended up choosing it for our limited edition of 80 devices. Luckily we had a readily available network to print up to 20 devices worth of parts per day.

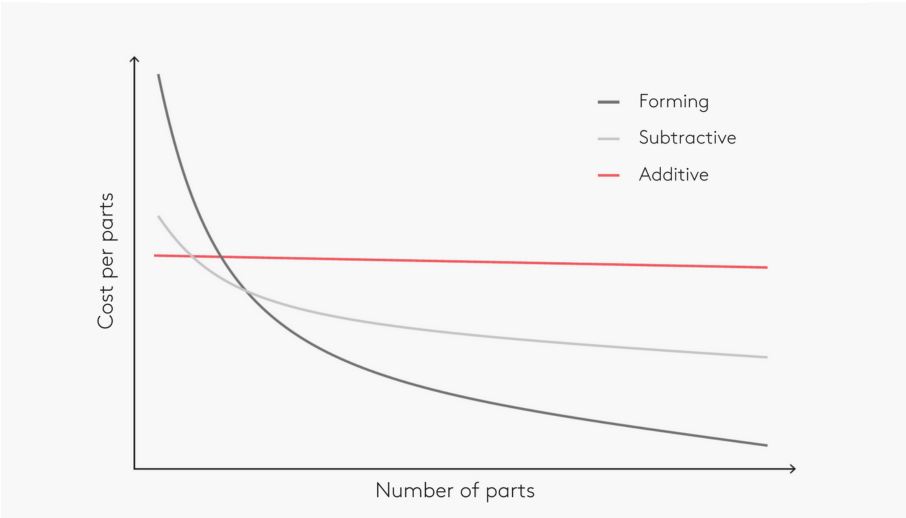
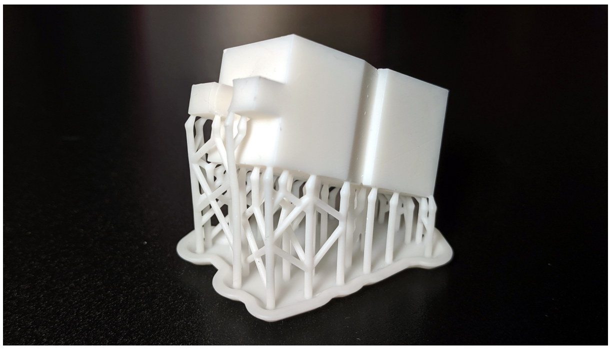


Figure 1: The cost of different manufacturing processes

2 Printing Techniques

Additive manufacturing, the formal name of 3D printing, has truly seen a boom over the last decade. And with that, the different types of printing techniques have also grow steadily. In this chapter, the different techniques that we had to our disposal are compared and our decision explained. Although there are many more options, we only had FDM, SLA and SLS printing available to us.

(a)



(b)

(c)

Figure 2: (a) FDM printing (b) SLA printing (c) SLS printing

2.1 FDM Printing

Due to the widespread availability and the large number of print shops, FDM printing is an easy to apply technique. Unfortunately, none of the materials make it through our airflow related parts safety requirements. Most plastics don't have any special bio-compatibility norm and airtighness cannot be guaranteed. As you can see in figure 2, FDM printing produces a 'tower' of individual lines, that may or may not be fused together. This means that a small (and hard to see) mistake can produce a part with tiny cracks between its lines.
FDM printing is a good option for the housing related parts on the other hand. It's widespread availability means we can easily produce more parts when needed and the other requirements can easily be achieved with most printers:

- White filament is one of the most common types of filament.
- When all wall are chosen to be at least 3mm thick, the parts should be able to withstand more than normal use.
- Sharp corners are avoided by using fillets and chamfers.
- Although PLA (a common filament) is biodegradable, it has been shown to last 15 years under normal, room temperature conditions [1].

Therefore, we chose FDM printing with basic PLA for our housing related parts. The layer height and other setting vary for different parts, which is explained in chapter 3.

2.2 SLA Printing

At the start of the project, we thought about using SLA printing for the airflow related parts but we quickly ran into problems. Firstly, the capacity of a single printer is quite low, meaning you would need a lot of them. Unfortunately, these printers turn out to be hard to find, and even when you do, they are often differently calibrated, making it hard to achieve a consistent result. If you manage to get through this part though, you need to chose the right material. Luckily, bio-compatible materials are available for SLA printing. Fromlabs has a dental product line with bio-compatible materials that are allowed to stay in your mouth for up to 24 hours at a time [2]. Unfortunately, no oxygen related tests have been conducted. And finally, managing the support turned out to be a real issue for some parts that have a conical outer diameter and airflow through its inner diameter. By re-designing these connections, this can most likely be avoided, but this would have been time consuming.
Producing the housing related parts with SLA would have been a good option, was it not for the smaller available capacity.

2.3 SLS Printing

Fortunately, we were approached by an SLS printing company halfway through our design process. This technique, in combination with multiple surface treatments turned out to be our preferred method for producing the airflow related parts. First the whole process is explained, then the impact on the functional and safety requirements are presented:
The printing itself can be done under a ISO 13485 certification, which has been specially developed to allow manufacturers of medical devices to comply with certain medical guidelines [3]. In this printing method, a layer of nylon powder is selectively sintered to create a unique structure. The powder itself can be used as the support material (see figure 2) and parts can be manufactured within other parts (as long as you can take them out). The one major drawback of this technique is the powder that might remain in the pores of the surface. This has to be solved after the printing is done, which is depicted below: When the prints

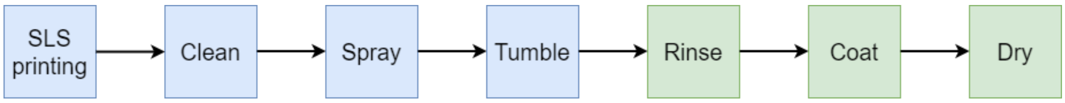


Figure 3: The SLS printing process. The blue processes are done at the printing company, the green ones by our manufacturing company.

leave the machine, the powder has to be cleaned off the parts by hand (with gloves). Then, glass pearls are sprayed against the parts to create a smooth surface, which is much less able to house any remaining dust.The glass pearls also take off any sharp edges. To further smoothen the surface, the parts are tumbled against ceramic particles for 4 hours. To guarantee the glass pearls are removed from the parts, a short rinse is required. The glass pearls are relatively large (0.106 to 0.124 mm) so they cannot get stuck between any remaining pores. Then a food-safe coating named Dichtol WFT 1532, is applied to all parts. This is a polymer based coating for capillary-active impregnation of porosities, micropores and hairline cracks [4]. In other words, the coating significantly helps to improve the airtighness and traps any remaining powder as it hardens. Finally, the parts have to be dried to let the coating evaporate. This process can take up to a day.
All our requirements are influenced accordingly:

- The Nylon we use is polyamide 12, which is white.
- Airtighness has been tested, and no leaks have been detected. In chapter 3, a more detailed description of specific airtight connections is given.
- Again, using a minimum wall thickness of 2 mm ensures structurally safe parts. Note that the device experiences very low values of stress during normal operation.
- Sharp edges are avoided using fillets and chamfers, but the spraying and tumbling processes will mitigate any remaining unsafe edges.
- All materials used are biocompatible.
- The powder functions as support, which is later fully removed.
- All parts are produced by a single machine, for which we carefully selected offsets and tested airtightness.

- Polyamide has shown to be a high barrier for oxygen [5] and has been used in medical devices previously. Furthermore, it has a high oxygen index according to NEN-EN-ISO 15001:2011 [6], which tells us it doesn't combust easily. The polymer based coating is highly restive to most chemicals, but no oxygen specific tests have been conduction. The manufacturer however didn't foresee any issues.
- According to manufacture, parts produced for medical services have a lifespan of at least 2 years.
- The parts don't contain any grease or oils.

3 Parts Overview

3.1 System Overview

In figure 4 an overview of most 3D printed parts is given. The only one missing is the battery switch protector, which is located at the bottom of the cart. Please note that the images here and the STEP files of the assembly can differ slightly as new version are developed. As you can see, a large part of the device is made up of 3D printed parts. So, in this chapter, every part is explained and manufacturing pitfalls are explored.

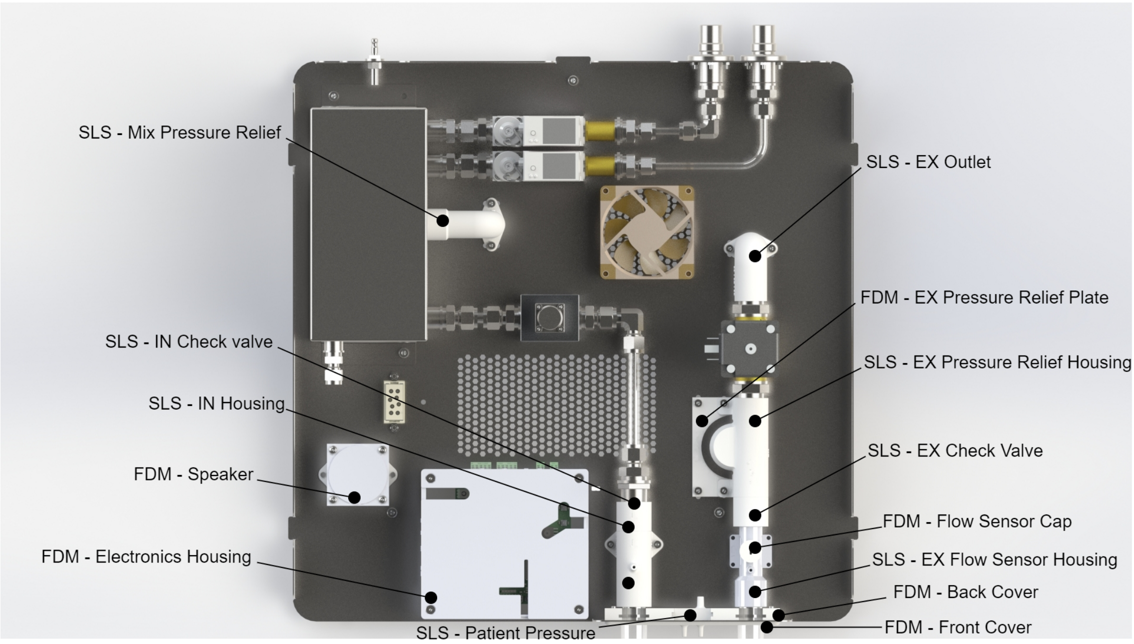


Figure 4: Overview of all 3D printed parts (shown in white).IN and EX stand for inspiratory and expiratory flow respectively.

We kept some things constant, regardless of manufacturing technique or major function: firstly, all parts have their manufacturing dated printed on the part. This has four important functions:

- If the Ventilators ever makes it till the end of lifespan of the 3D printed parts, one needs to know when to replace them.
- During the many iteration, we had to be able to easily differentiate the parts from their previous versions.
- If one of the printers breaks down during the large scale production, and is replaced, one needs to know which part came from which printer. This is because parts from the same print will fit other parts form this printer the best.
- If defects are discovered down the line, one needs to be able to trace them back, perhaps by print date. To easily spot a defective series of prints, it is wise to keep at least one of each unique part of each printing date.

Secondly, to reduce manufacturing complexity, the fastener variety is kept to a minimum. Of course, not all fasteners are the same, but grouping them in some logical fashion is still beneficial:

- All fasteners that connect to the bottom plate are Plastic Metric Socket Head M4 and have a regular M4 nut. Those directly connected to the bottom plate are supported by an A-type M4 washer. Some are countersunk, and some vary in length, but most are 10 mm long. These fasteners are made from plastic to better protect the device against static shocks. During testing, we found that high voltage shocks (8 kV) can enter the 3D printed parts through the metal screw that we used to attach them to the bottom plate.
- All PCB fasteners are M2.5 but in various styles and use star washers for better grounding.

- All Roof on housing connections are ⌀ 4.2 x 15mm self tapping screws.
- Most 3D print to 3D print or retail part connections are snap, click or conical press fits to reduce the number of fasteners needed.

Thirdly, to reduce the amount of SLS printing, some parts consist of a combination of SLS and FDM prints, while this may not be beneficial to the ease of production, the likelihood of defects, the look and the structure of the part. If you have an endless supply of SLS printers, this might not be the best option for you. That being said, this modular design will make the parts easier to replace when they break, or when an improved version becomes available.
And finally, most parts are marked to emphasise flow direction, function or connection type. This might reduce the number of mistakes made during the assembly, and help future maintenance teams.

3.2 SLS parts

As noted before, these parts are all directly in contact with the flow to or from the patient, and are therefore printed using SLS. In the section below, we've split the parts into the Inspiratory flow and the Expiratory flow.

3.2.1 Inspiratory

The Inspiratory air and oxygen enter the Ventilator separately and are mixed according to a pre-specified ratio in the mixing chamber. To make sure the mixing chamber never exceeds a certain maximum pressure, a pressure relief valve is located at the side. When the relief valve is activated, the oxygen rich air shouldn't flow into the ventilator, so a guiding tube is 3D printed.
Here, the tube is pressed to fit over the valve, but no special airtight connection has been made. The

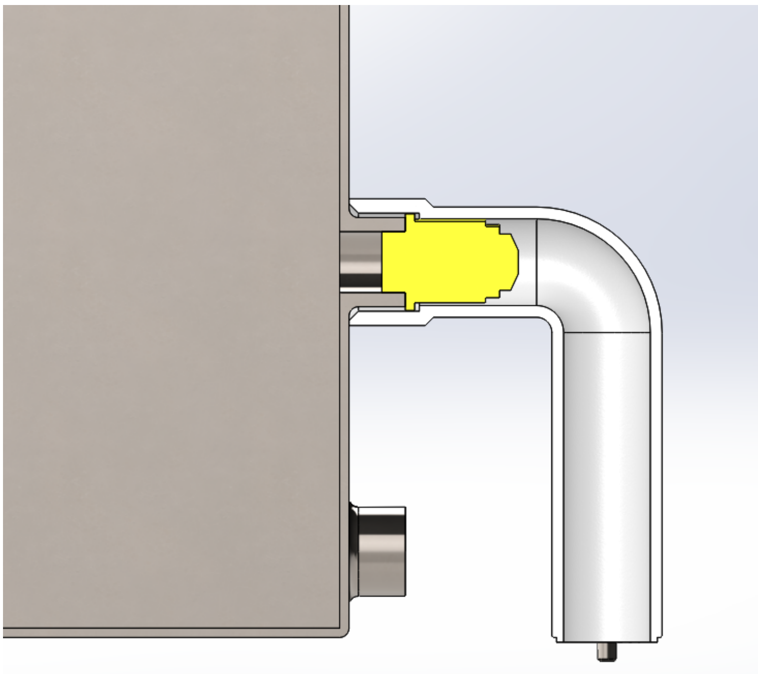


Figure 5: Inspiratory Flow - Pressure Relief. Pressure Relief Valve shown in yellow.

reason for this is that the tube only has to guide away the vast majority of the excess air. The part can easily be sealed with sealant if needed, but this step was left out of the initial design. A small rim is located at the bottom to make sure the air leaves the ventilator.
If the release valve is not triggered, the now mixed air flow through the pressure regulator to the first 3D printed check valve. This valve is placed after all the expensive, hard to come by and hard to clean parts to prevent contamination. 3D printed parts are of course easier to replace.
Lets first discuss the conical connections. We chose to use this interference fit because they provide airtight connection without the need of fasteners and because they are already used in medical tubing. This allows

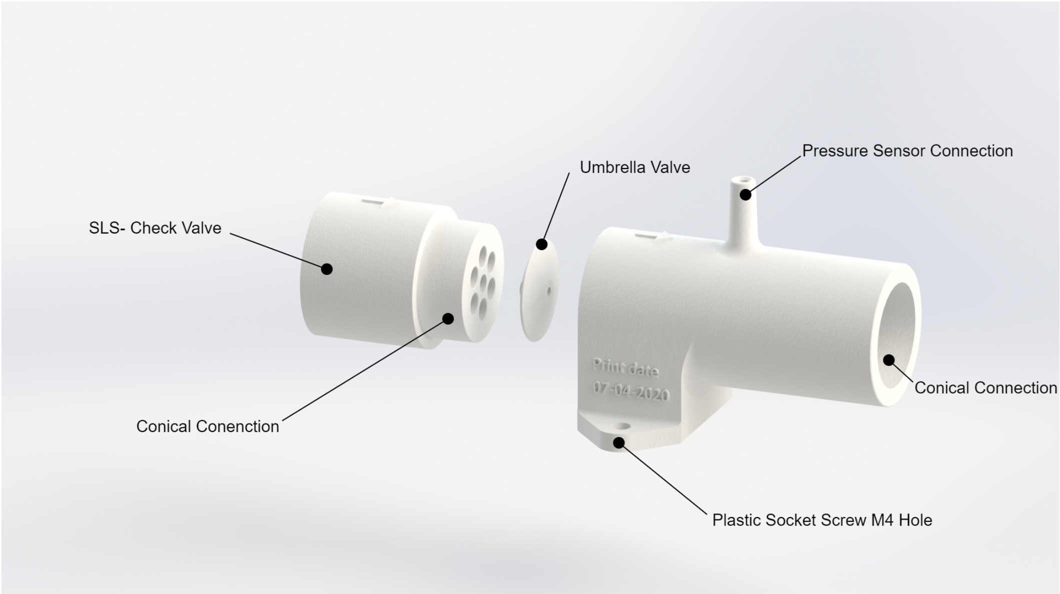


Figure 6: Section view of two Inspiratory parts.

us to use off-the-shelve Male-to-Male connectors as shown in figure 10. As with other press fits, the inner and outer diameter overlap a little and are held together by friction. To create an airtight connection, we experimented with a large range of offsets on the female side of the connection. Varying only one side will make it easier to find your perfect fit. We suggest you print a wide range of different offsets on the first go, since the perfect size depends on your specific printer, material, off-the-shelve parts, conical shape, surface treatments, print orientation, cooling rate, etc. For our prints, we kept the male side true, and reduced the diameter of the female side by 0.2 mm.

The 'IN - Check Valve' is merely a holder for the silicone umbrella valve. The goal of this check valve is to

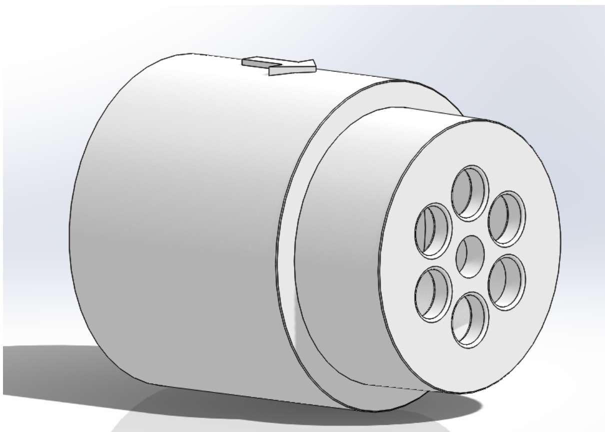


Figure 7: The "IN - Check Valve".

open at the smallest positive pressure, but close at the smallest negative pressure. As the name suggests, its mechanics mimic the flipping motion of an umbrella during a storm. The lower the negative pressure the better the valve seals. This part has the following characteristics:

- A conical connection to the "IN - Housing" part. The reason why this part is separated from the housing is to make the check valve easier to replace or readjust.
- As shown in figure 7, a circular pattern has been extruded from the front of the part. The center cut-out holds the stem of the umbrella and the outer cut-outs let the air flow through. A fillet has been added to the outer cut-outs to eliminate any residual powder that can stick to sharp edges. This is especially important for small holes like these ones, since the tumbling particles may not fully reach

the full surface. The center cut-out on the other hand has no fillet, to more closely resemble the fit provided by the umbrella valve's tech sheet.

- All outer edges have a small chamfer of 0.4 mm to again eliminate any residual powder that can stick to sharp edges.
- The umbrella can be pre-tensioned by sinking the plane on which it sits, relative to the plane of the outer cut-outs. This improves the sealing effect, but also increases the opening pressure (which corresponds to a larger pressure drop in the overall system). We chose not to pre-tension the valve since we had some issues increasing our maximum flow.
- An arrow is placed on top of the part to indicate the flow direction.

The final part in the Inspiratory sub-assembly it the "IN - Housing". This parts connects the check valve to the off-the-shelve male-male connector which functions as output. Additionally, the part incorporates a small pressure sensor connection as close as possible to the off-the-shelve connector. Note that the flow at the pressure sensor shouldn't be disrupted or separated, as this will cause the sensor to misread the true pressure value. So to avoid this, the connector was places far away from any abrupt changes in the diameter. Finally, the housing has a pedestal that, through a bolted connection, maintains the correct height of the part, relative to the not-3D-printed parts.

3.2.2 Expiratory

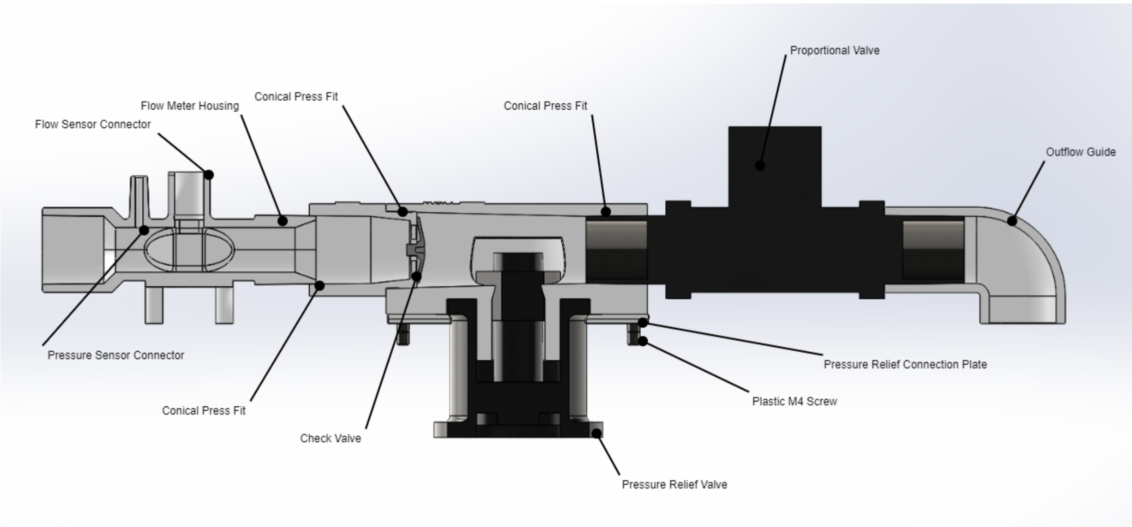


Figure 8: Section view of Expiratory Flow

Once the flow returns, it enters the ventilator through the same male-male connector as we see in figure 10.The flow then enters the first 3D printed part: the Flow Sensor Housing. And as the name suggests, this part's main function is to place a flow sensor in the flow. This part looks quite different since it was designed by an external company. Two thing that are equal to the other parts however are the conical press fits and the pressure sensor connector. Since the flow within these parts is slow compared to other applications, the diameter had to be reduced to obtain better performance from the flow sensor as it uses the cooling rate of a hot wire to calculate the flow. When the flow speed is increased locally, the maximum cooling rate of the wire is increased, and with that the power range of the sensor.

After the Flow Sensor Housing, the flow reaches another Check Valve. This part is exactly the same as the one described above. Keeping both parts identical makes them easier to replace.

The flow then enters the Pressure Relief Housing. As you can see in figure 9, the sub-assembly consists of three parts:

- The housing, which ensures the flow can enter the pressure relief valve and connects airtight to the valve. Since this valve doesn't have a conical face, the end of the faces have to be glued together.

- The Pressure Relief Connection Plate snaps around the valve and fixes it in place with screws. In other words, the Z-movement of the valve is restricted by this plate.
- The valve itself is a simple off-the-shelve valve that opens at a certain pressure. Two faces (one made of Vitton) are pressed together by an adjustable spring. Changing the pre-tension length of the screw will change the opening pressure.

After this section, the housing connects to the Proportional valve using the same conical fit. Note that the male face here is part of a different steel male-male connector. This parts bridges the conical face to the thread size of the proportional valve (this part exists because we didn't manage to print an airtight thread).

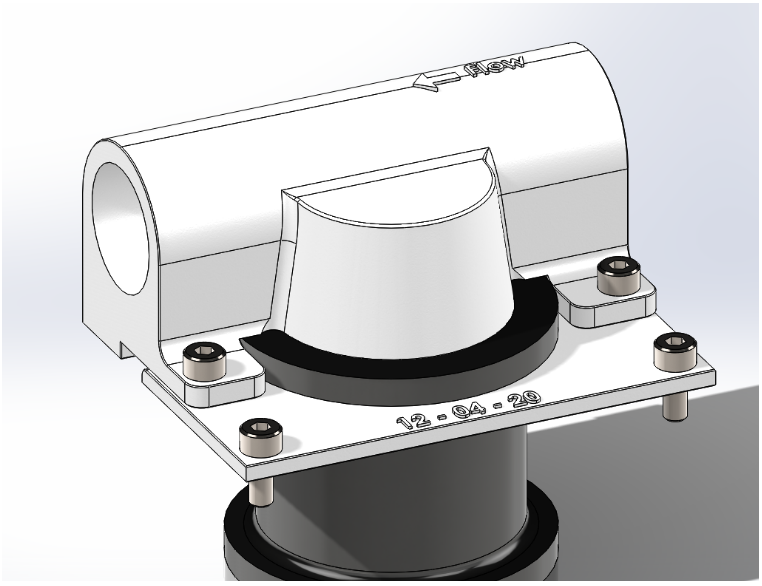


Figure 9: The Pressure Relief Housing with its valve

This same steel male-male connector is also attached to the other side of the proportional valve to create another conical face for the outflow guide. This outflow guide is a simple elbow tube that screws onto the bottom plate. This guide doesn't have a rim at the bottom, unlike the "IN - Pressure Relief" part. This is because the conical face introduce some variation in length across the whole expiratory flow. This is also why some of the holes are replaced by slots in the bottom plate.

3.2.3 Other

One final SLS printed part had been designed that fits exactly between the inspiratory and expiratory flow. This is the "Patient Pressure" connector. This part was designed to more easily introduce a 'weaning' function in the future. This will gradually help the patient regain his or hers breathing capabilities. For this to work, the pressure has to be measured very close to the patient, which is why we created a part that attaches to a pressure tube in advance. In the current version, weaning is not implemented.

3.3 FDM parts

In this section the FDM printed parts are discussed, who serve as protection and attach other parts to the bottom plate. The Pressure Relief Connection Plate was already discussed in the previous section.

3.3.1 Airflow connectors

First we'll take a look at the airflow connectors. These parts have been added to the SLS parts, but don't touch the flow. Making them from PLA allowed us to free up SLS printing capacity in exchange for some extra steps during the assembly. The first part is the Front Cover. This plate can be seen from the outside of the device and (the newer version) fully covers the metal. The screws here are made of plastic and sink into the cover to create a smooth front surface. All sharp corners are removed and replaced with fillets or chamfers.

The male-male connectors are then placed through the larger holes, and slide into the slots of the Outer

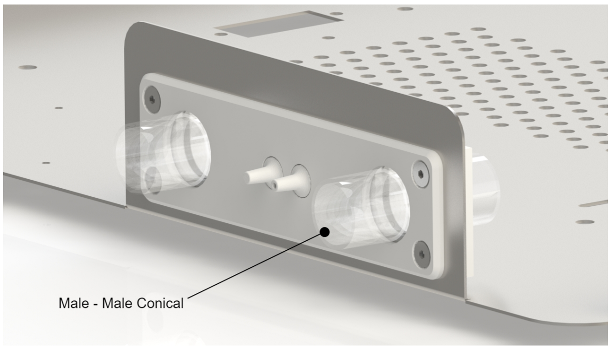


Figure 10: Front Cover

Connection Backside. These slots are chosen such that you need to apply a decent amount of pressure to press the male-male connections into the right position. Additionally, hexagon shaped cuts are made at the back of the part to allow the use of plastic nuts.

Finally, the Flow Sensor Protection Cap is a simple cylinder with a slotted roof that protects the fragile PCB

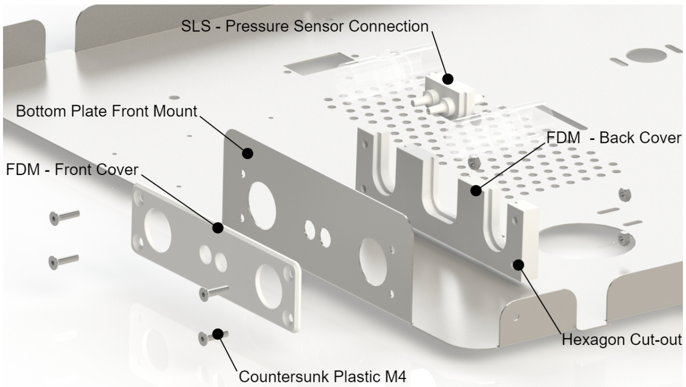


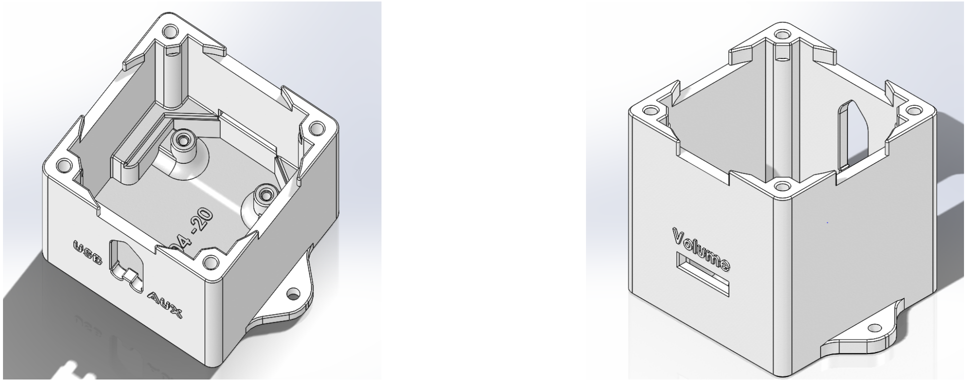
Figure 11: The Outer Connection Backside

of the flow sensor.

3.3.2 Electronics

The second major category of housing related parts are the electronic housings. All these parts have the simple function of housing the electronics and protecting what's inside against external forces and dust.

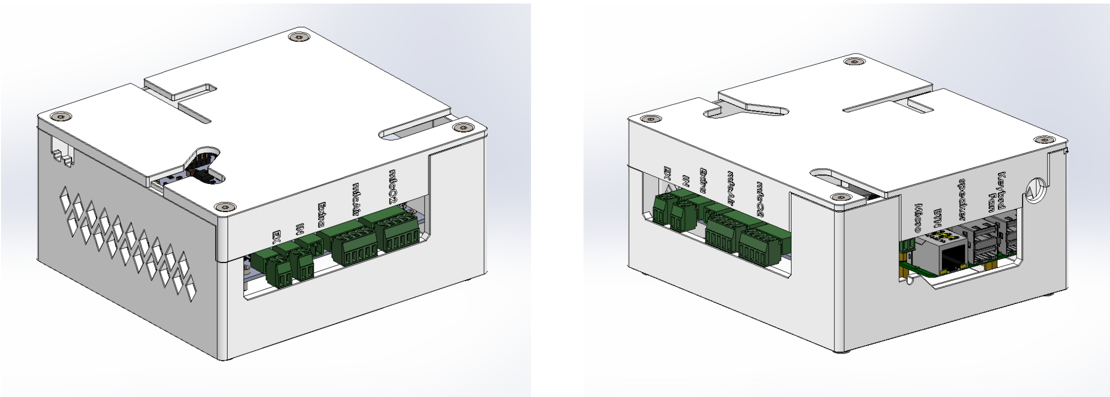
Firstly, the speaker housing makes use of two different self tapping screws that screw directly into the 3D printed material. This creates a secure connection, but makes the parts harder to replace and requires the use of steel screws. On the right image of figure 12, you can see the volume cutout, while on the left you can see the USB and Aux cutouts, that snap over the wires to hold them in place. The size of this cut-out was determined by the size of the USB port. Note that the complex internal shape precisely fits the PCB that is screwed onto the tiny pillars (shown on the left).



(a) (b)

Figure 12: Two views of the Speaker Housing

The second electronics housing was made for the "motherboard" of the ventilator. As you can see in figure 13, the roof has numerous cut-outs to accompany the outgoing tubes and wires. These cut-outs all cut through the sides of the roof, to make the assembly process easier. Additional cut-outs are made on the side of the housing, where text was printed to indicate which wires should be connected. And thirdly, diamond shaped (easy to print without support) cooling holes are made cut out of the side of the base, to allow cool air to enter the housing. The roof itself is screwed onto the the base using self tapping screws.



(a) (b)

Figure 13: Two views of the Electronics Housing, including the PCB and roof.

To ensure the right fit, a rim was applied to the roof, that falls into a side slot on top of the base (see figure 14). These rims aren't placed around the whole side of the roof, but only to two edges. This was done to reduce the required printing accuracy. As you can see, the cut-out on the bottom of the housing fits around the standoffs of the PCB. This was done to improve the grounding of the PCB, since the PLA can act as an capacitor at very high frequency of electromagnetic pulses (we found out about this during a test where 8 kV pulses were applied to the outside of the machine). We therefore decided that the PLA shouldn't touch the PCB and thus decided to screw the tiny M2.5 screws directly onto the steel bottom plate.

3.3.3 Other

One final part that doesn't really fall into the two previous categories is the emergency battery button protection cap as shown in figure 15. Note that this piece doesn't show up on any of the previous images, but is

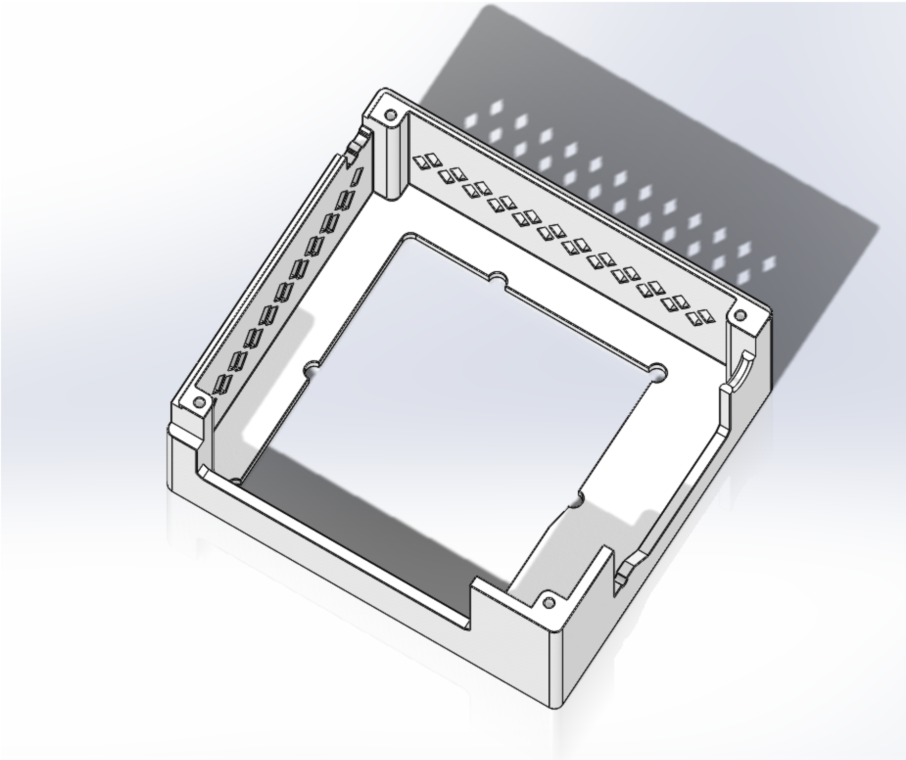


Figure 14: Inside view of the PCB housing

located on the side of the emergency battery. This cap is simply glued onto the plastic of the battery casing and prevents people from accidentally switching the device off.

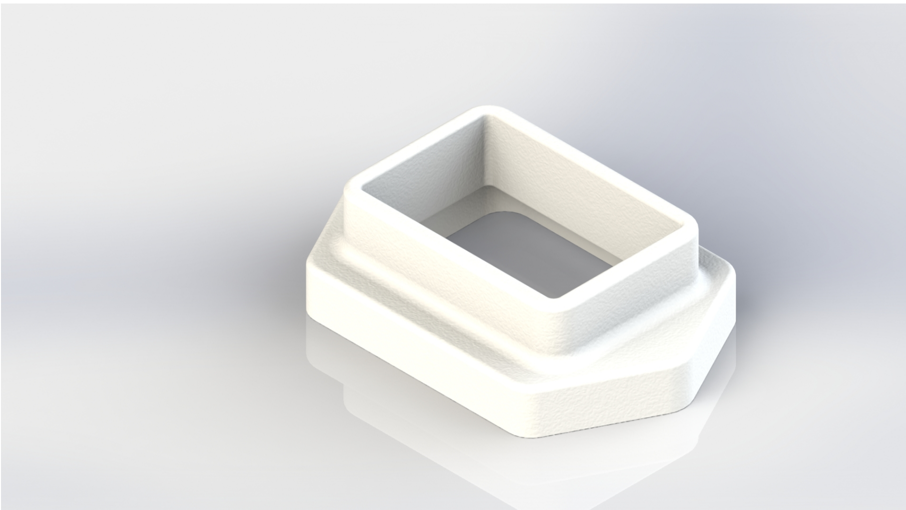


Figure 15: The emergency battery button protection cap

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