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Totally TubulAir - Adjustable Nasal Cannula

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***Abstract*—Many individuals require short-term and long-term oxygen therapy. These users experience discomfort and problems with the standard nasal cannula that are compounded by issues with oxygen sources being heavy with limited supply and tubing getting tangled, kinked, or not providing enough mobility. The objective of this project was to address ergonomic issues with oxygen therapy devices to increase the ease of use for healthcare workers, patients, and families. By following the engineering design process, a prototype was developed for a nasal cannula with interchangeable prongs. The new design allows users to select a prong size that is more comfortable for them.**

Keywords—oxygen therapy, design process, ergonomics

I. Introduction

Totally TubulAir is a project focused on addressing oxygen therapy system ergonomics in order to increase ease of use for patients, patients' families, and healthcare employees. Over 1.5 million Americans use oxygen therapy and many experience significant discomfort with their nasal cannulas [1]. Oxygen therapy is used for many conditions, such as Chronic Obstructive Pulmonary Disease and Cystic Fibrosis. Patients with these conditions use their devices constantly [2]. There are several patented and commonly used devices, including Venturi masks and nasal cannulas, but cannulas are the most preferred device for prolonged use [3]. Despite being used by many individuals across all age groups, cannulas have a standard size with either a straight or curved prong. This limitation makes them highly uncomfortable for the wide variety of nasal anatomy and inconvenient for users that need their cannulas daily. Through interviews and research, it became clear that oxygen therapy users often have a serious issue with the discomfort of nasal cannulas and the problems associated with the issue. These problems include skin irritation and the cannula slipping out which is a safety concern. Totally TubulAir aimed to create nasal cannulas that are size adjustable so that users can have a safe and comfortable cannula fit. The steps of the FDA Waterfall Process (user needs, design inputs, design process, design outputs, and the medical device stage, along with verification and validation) were followed and the progress of the design was kept in a Gantt chart (Appendix 1). This process will be explained in the report, detailing how the Totally TubulAir adjustable nasal cannula device was developed.

II. User Needs

By researching oxygen therapy devices, why and how they are used, and existing devices and patents, an understanding of the current solutions to oxygen therapy problems and unfulfilled needs areas was gained. To narrow down the project's focus, a list of questions was developed (Appendix 2) to ask stakeholders, including registered nurses, an oxygen therapy caretaker, respiratory therapists, physicians, sales representatives, manufacturers, and an Emergency Medical Technician. From the answers collected in the interviews, specific user needs were compiled based on the most prevalent concerns. Nine user needs were developed to focus on safety, ease of use, and cost (Appendix 3).

III. Design Inputs

With the user needs in mind, a preliminary quality functional deployment (QFD) plan was made (Appendix 4) to evaluate and translate the user needs and into measurable engineering requirements (Appendix 5). The preliminary QFD also helped to understand the relation of the customer and engineering requirements to target values and competitive products. The target values used were derived from the interviews and research on materials, anatomy, and capabilities of current devices. While current devices successfully deliver oxygen, they often lack in comfort, size variation, and frequently slip out of the nasal cavity. A risk management plan was created to evaluate the success and risk level of the device ideas and relevant components. By establishing rankings for how severe failures could be, the probability of their occurrence, and how easy it would be to detect them, a risk priority number could be calculated based on the risk priority number table (Appendix

6). A concept failure mode and effects analysis (FMEA) was created for concept components. Then, risk assessment numbers were assigned to each potential failure that could occur within components. For each failure, the causes were listed, and most importantly, ways to mitigate the failures and verify that the success of mitigations were listed. These important steps confirmed that all concepts could be successful devices if pursued and recommended actions were in place to handle any failures that the future device could experience.

IV. Design Process

The design process began by developing five design concepts related to oxygen therapy need areas: a hosing reel, width extensions, interchangeable bulb & prong attachments, ear attachments, and a nose clip (detailed concepts in Appendix 7). The concepts were influenced by current devices and patents and intended to address unmet needs. To down select, the QFD (Appendix 8) was updated to measure the concepts against the engineering requirements and see which concepts were feasible within the parameters of the project, specifically time and budget. Decision matrices were also made to help down select the concepts by using the weighted engineering requirements to rank them (Appendix 9). The results ranked the interchangeable prong design concepts as the best design concept to pursue. A design FMEA (Appendix 10) was created to assess the risks of the design components and ensure the concepts were safe and reasonable before starting the beta prototyping phase. Clay alpha prototypes were made to further prove the potential success of the interchangeable prong design with varying sizes to improve user comfort and safety by superior fitting anatomy to existing devices. (Appendix 7). To prepare for the next phase, a parts design matrix was made along with preliminary design specifications to make sure engineering requirements and target values could be reached based on potential device specifications (Appendix 11). The last step was to set up mitigations for potential risk and verification plans to ensure that the device met the developed engineering requirements. In addition to designing the cannula itself, a drying rack for the interchangeable prongs was modeled in SolidWorks, and 3D printed with polylactic acid material (PLA) through the University of Akron's Bierce Library.

V. Design Outputs

After deciding to pursue an interchangeable prong nasal cannula design, three versions of the concept were modeled in SolidWorks. Two models were made with snap connections and one was made for a lock and key connection. A decision matrix (Appendix 12) was made to determine which connection method would be best. Based on the feasibility of the designs, specifically manufacturability, the decision matrix results determined that the snap connection design would be used. The SolidWorks design was fabricated in three separate pieces using 3D printing via a Formlabs 3B resin printer. The base piece was modeled after standard cannulas but with ridged nasal pieces to connect to the prongs. Then, a prong was made with internal ridged connection components and shaped to mimic standard cannulas (SolidWorks parts and drawings in Appendix 13). The base piece will interface to standard tubing and a prong piece will attach to each of the two connection points. Once the components were modeled, material selection was considered. Another decision matrix (Appendix 14) was made to determine which material would be most appropriate. The materials evaluated were based on standard cannula materials and compatibility with the available 3D printer. Once the decision matrix was completed, the results led to selecting 80A resin for the base piece and 50A resin for the prong pieces. This ensures that the device is soft enough to be comfortable but stable enough to support the snap connection. A bill of materials (BOM) (Appendix 15) was made to record the parts used, including the printed parts, a 3D printed PLA drying rack for the components, and the standard tubing used to connect the device to. From this point, the components were printed by in Biomedical Engineering Department of The University of Akron to complete verification.

VI. Design Verification

Fourteen device specifications (Appendix 16) were developed to ensure the success of the device and verification methods were used to ensure the adherence of the device to the specifications. First, the device was modeled in COMSOL to ensure that it could withstand the highest possible flow rate of air, 6 L/min, which is the highest prescribed flow for oxygen delivery systems. Velocity, streamlines, and pressure were modeled and confirmed that the Totally TubulAir device could withstand maximum flow. The pressure model also highlighted areas of high pressure at sharp internal edges. Thus, the components were revised to have rounded edges and avoid high pressure areas. The model results are shown in Appendix 17.

Several tests were completed on the printed prototype, including inspection testing, fit testing, and dimensional measurements to ensure the prototype matched the modeled dimensions. Some dimensions initially failed and necessitated four new revisions to the drawings. Cycle testing was completed at the snap connection zone to determine if the components could withstand being interchanged. This test consisted of attaching and detaching the prongs a number of times to replicate the actions of a user. The user would likely change their prongs no more than once daily and the prongs are replaced every 30 days with a new set. Therefore, the number of cycles is a maximized value to ensure the device lasts beyond expected use. Again, the first version had failures, but the verified revisions passed inspection. The cycle test was failed initially but a risk assessment was performed to justify an alternative number of cycles, in which case the device passed. Next, a pull gauge was used to determine the maximum force a cannula would experience during normal use, resulting in 1 N. Tensile testing was completed on assemblies to confirm they could withstand over 1 N of force. To ensure the device does not leak air, flow testing was performed on the device. This was done by attaching the base of the cannula to a pressure gage and blocking the prong airways. An air pump was used to push air into the device and the gauge was observed to make sure there was no pressure drop until the airways were unblocked. Passing

this test ensured that the device does not leak air. Throughout the verification process, improvements to the design were made as well as making it more stable for 3D printing. The first revision of the device was thinner, with a wall thickness of 0.63 mm. The second revision had an increased wall thickness, but the thickness was accompanied by stiffer components that failed during cycling. A third revision was made that was a medium thickness between the two, at 1.87 mm. All verification testing is summarized in a table in Appendix 18. The third revision for the prongs was used in the final assembly. The base was revised a fourth and final time to round the edges at the snap connection points for an easier connection. The final revisions passed all verification and met all device specifications, meaning the device met the engineering requirements.

VII. Medical Device

The revision 03 device has a cannula base printed with 80A resin and interchangeable prongs printed with 50A resin. The tubing components were purchased preassembled, and our device was substituted in for the existing standard design (Figure 1).

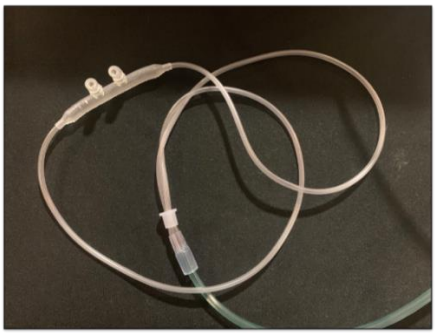

Figure 1. Totally TubulAir Beta Prototype Rev. 03

Throughout the revisions, material thickness was adjusted to find what would be the most secure and comfortable for a patient to use. Due to 3D printing constraints, there is room for improvement of the thickness and the design of the tubing. Regardless, it is anticipated that this version of the device will outperform the standard cannula per the identified customer requirements applicable to the design.

VIII. Validation Testing

In order to assess the success of the design to meet the customer requirements, four tests were performed: Fit Testing, Inspection and Size Analysis, Compatibility and Connections, and Sanitization-Wear. The Fit Testing involved volunteers wearing both a standard cannula and the Totally TubulAir device for extended periods of time while performing daily tasks. At the conclusion of the test, the volunteers filled out surveys for both cannulas and then these results were analyzed. The survey asked for ratings on comfortability, impact on activities, slippage, pinching, claustrophobia, and visual appearance. For each surveyed question, the Totally TubulAir cannula performed better than the standard cannula. These questions created a point of comparison between the standard cannula and the Totally TubulAir prototype based on the customer needs determined during the interview process. Inspection and Size Analysis involved assessing the developed sizes of prongs by the team against research and ranges established to ensure that multiple sizes are available for a variety of age groups. Three size options were developed for adults, one size for children, one size for infants and one size for neonates were developed. The models were assessed against the size ranges and all were within the acceptable range so this test was passed. Compatibility and Connections demonstrated that the prototype successfully interfaces with standard extension tubing provided to patients and interfaces with oxygen concentrators and oxygen tanks. The prototype was connected securely to extension tubing and an oxygen tank so this constituted as a pass. A concentrator was not readily available for trial, but the connection point is the same so it is assumed that the prototype would also interface well. Finally, Sanitization-Wear demonstrated that the device can withstand cleaning in a simulated at-home setting by a patient or caretaker. The prongs withstood cleaning with soap and water for 60 cycles and dried on the rack developed for it. It was noted that the current devices get bloody or can have mucus build up so being able to clean a device quickly and easily is important. The validation plan is in Appendix 19, and the results of validation testing are in Appendix 20. In addition to testing, some stakeholders were interviewed again to determine if the prototype would be something use themselves or recommend and what feedback they had. Two surveys have been conducted, both yielding positive feedback regarding the concept meeting a need that does not currently have similar options and that the feature of cleanability was a major plus as it allows for cleaner devices and potential cost savings on replacing the larger cannula piece.

IX. Risk Mitigation Process

The risk assessment process throughout the design was primarily done with failure modes and effects analysis (FMEA). Once prototypes were developed, the design FMEA (dFMEA) was used to identify potential failure points and identify mitigations for the theoretical or experienced failures during initial testing. The biggest risk area was regarding the prong attachments: (i) lack of proper fit with the patient nasal cavity, allowing more oxygen leakage than it should, or (ii) the prong material ripping at the connection point, making it not useable by the patient. The mitigation for sizes is providing multiple sizes for various ages so that patients can find what works better for them, and for the material ripping, the wall thickness of the prototype prongs was increased. Additionally, the connection point on the base was filleted in order to make it smoother to place the prong on. Originally, it was believed that an 80A base would be ideal, but after testing, it was found that a 50A resin base provides a softer, more flexible base which makes prong connections effortless. The final revision with the 50A resin base and prong attachments is pictured below (Figure 2).

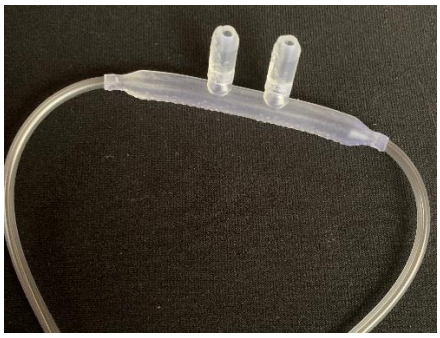

Figure 2. Totally TubulAir Final Beta Prototype

Another large risk with the cannula was that the tubing components could become kinked during use, compromising air flow. It was decided to use pre-made cannula tubing rather than redesign it. This tubing base has sturdy tubing that should not easily kink during normal movements. This is an area that can be explored further to find a sturdier material or a coating that prevents the tubing from kinking. This is a low risk and is easily detected at the cannula level. The Risk Summary Table, in Appendix 21, contains all identified risks with explanations. The benefits of this device outweigh the residual risks as it provides a more ergonomic, customizable option to patients to help increase their comfort. With a transition to injection molding from 3D printing, it is expected that the observed failures will be further mitigated. Throughout the life of the device, risk will be continuously monitored. Once on a manufacturable scale, a process FMEA would be established to ensure good manufacturing processes were followed and potential risks were mitigated. Additionally, an application FMEA would be beneficial for determining risk associated with use outside of failures demonstrated through the dFMEA. These assessments would be performed at the later stages of the device's development.

X. Marketing and Manufacturing Considerations

In the United States alone, over 1.5 million people use oxygen therapy [1]. It has been also estimated that the global oxygen therapy market will reach 4.6 billion dollars by 2026 [4]. People around the world require these devices, especially since the beginning of the pandemic. It has been estimated that the cost of a standard cannula can range from $20-$50 depending on how much tubing comes with it, but it is usually covered by insurance [5]. There are several companies that manufacture nasal cannulas that are similar, making the market competitive.

To produce this product, 3D printing would be costly and time consuming. For large scale production, this device would be best made using injection molding. The current 3D printed device sales price to end user was estimated to be $18.40, but cost $4.60 to produce since equipment was readily available. By pursuing the course of injection molding, this device should be competitive with current products although the production cost is higher due to the addition of the changeable prongs.

XI. Summary Feasibility Discussion

The design satisfies the targeted need area of a more ergonomic cannula setup for oxygen therapy users. The product that we have developed is a 3D printed prototype, but it would be best classified as proof-of-principal for large scale manufacturing via injection molding.

XII. Discussion, Lessons Learned, and Conclusions

Medical device creation relies on following a specific process, including the development of user needs, design inputs, design process, and design outputs to lead to a device. The Totally TubulAir project provides insight into this process. By successfully completing all steps and validating and verifying them, a complete device was made. Although all steps were completed, some setbacks and obstacles were lessons for the project. The timeline had to be adjusted at multiple points and the project had to adapt. Also, 3D printing was a keystone of this project and while it had many positives, it had some pitfalls as well. With the structure of the device, it required many supports when printing and although the supports were cut off, they made the device surface irregular and often compromised in the beginning prototype revisions. Initially, injection molding was considered for device design; however, 3D printing was a more efficient, cost-effective option for the timeline of this project. Recreating molds would have taken more time, but it may also have eliminated some issues experienced with the location of supports and the capabilities of the printer. Determining the sizing prior to creation of molds would be critical to cost savings during product development. For the purpose of this project as a proof-of-concept, 3D printing was an effective option, and injection molding could be an option in the future if this project is continued after determining the ideal sizes for the prongs and base. The Totally TubulAir device is a representation of the design process and its success because the product is an innovative solution to a medical need that many face.

XIII. Future Work

The consideration for future work would be transferring the production process from 3D printing resin to injection molding. More material research or options should also be considered if a budget and time allows for it so that a biocompatible, soft material can be selected. An issue with our design was the limitation between wall thickness and 3D printing capabilities. With injection molding being the mode of large-scale manufacturing, a new design should have thinner walls than the last iteration of our device to make the material more flexible and comfortable. While a variety of sizes are offered, it would be worth conducting more research about the optimal curvature of the prong for oxygen delivery. A curvature similar to existing cannulas was used in our design, but as research indicates, there are a variety of nasal cavity sizes. Additionally, both stakeholder surveys during the validation stage indicated that a straight option for each size should also be offered so this is something that can be developed. Although the device still has some risks associated with it, patient comfort outweighs the possibility of product failure. The child, infant, and neonate size options were only modeled during the project so these options would need to undergo testing to ensure that the prototypes perform as specified.

While this design does address issues revolving around lack of customization for patients, there are still several need areas that need addressed with oxygen therapy as a whole. There remain issues regarding hose/tubing management and improving the oxygen sources supplied to patients. Additionally, the standard masks and cannulas could be further modified to offer more sizes and increase patient comfort. With a growing market, there is room for improvements to current devices.

XIV. Individual Roles and Responsibilities

Angelina Marchio was the primary lead on competitive products, material, and anatomical research for the project. Angeline participated in concept generation. She also was responsible for the QFD target rationale. She modeled an alpha concept in SolidWorks. She was primary author on device specifications and verification test methods. She was the lead on determining cannula sizes and writing the verification report. She assisted in testing.

Emily McGrath is the primary for creating meeting agendas and taking meeting minutes. She is also the owner of the DHF and responsible for making revisions and ensuring all documents are properly formatted. She is one of the two primary document authors for the team and responsible for coordinating testing. She participated in concept generation and SolidWorks modeling for alpha prototype. She was responsible for risk management planning and reporting, verification test methods, validation plans, validation procedures, and the risk mitigation summary. She assisted in all testing. Emily was a co-author of all Honors College submissions.

Megan Bruns is one of the two primary document authors. She is also responsible for all SolidWorks modeling for all beta prototype revisions and coordinating 3D printing of the device. Megan is also the primary for device drawings. She was the lead for patent research, the concept FMEA, the concept decision matrix, the design FMEA, and the parts design matrix. She assisted in editing and reviewing all documents. She assisted in all testing and was responsible for the pull gage DOE to determine force values. Megan was a co-author of all Honors College submissions and submission to IdeaExchange.

Olivia Renkel acted as the team project manager. Her primary contributions include maintaining the Gantt Chart and preparing the QFD. She assisted in concept generation. She was the lead on analytical modeling, the budget, the purchase requests, and the BOM. She assisted with prototype testing.

XV. Professional and Ethical Responsibilities

The design has considered global, economic, environmental, and societal contexts. Oxygen therapy is used on a global scale and the goal is for the product to be used in place of existing standard cannulas. By planning to use injection molding for large-scale manufacturing, large quantities of product can be quickly produced to meet demand. As this product should be accessible to all oxygen therapy patients, we tried to utilize existing parts in order to keep the cost of the device low so that it could be covered by insurance in economic and societal contexts. While there is the added component of the prongs being removeable, the environmental impact is only marginally larger than that of existing devices.

XVI. Acknowledgements

We'd like to thank Dr. Hossein Tavana for being our project mentor, Dr. Chen Ling for reading and advising, Steve Patterson for 3D print help, Dr. Audrey Nguyen for testing assistance, Dr. James Keszenheimer for project advice, and Pouria Rafsanjani Nejad for COMSOL training and assistance. We'd also like to thank the AeroCare team in Akron for their assistance with training and access to oxygen therapy equipment, as well as all who interviewed with us to provide insight onto this need area.

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Appendix 1 – Gantt Chart

WBS	Task	Lead	Support	Start	End	Cal Days	% Done	Work Days	Days Done	Days Left
1	Gate 1	All		Tue 8/31/21	Tue 9/28/21	29	100%	21	29	0
1.1	Introduction	All		Tue 8/31/21	Tue 9/07/21	8	100%	6	8	0
1.1.1	Get acquainted	All		Tue 8/31/21	Tue 8/31/21	1	100%	1	1	0
1.1.2	Investigate project parameters	All		Tue 8/31/21	Thu 9/02/21	3	100%	3	3	0
1.1.3	Assign roles	All		Tue 8/31/21	Tue 9/07/21	8	100%	6	8	0
1.2	Research	All		Thu 9/02/21	Tue 9/28/21	27	100%	19	27	0
1.2.1	Research potential problems	All		Thu 9/02/21	Tue 9/28/21	27	100%	19	27	0
1.2.2	Research current solutions	All		Thu 9/02/21	Tue 9/28/21	27	100%	19	27	0
1.2.3	Draft problem statement	All		Thu 9/02/21	Tue 9/28/21	27	100%	19	27	0
1.3	Interviews	All		Tue 9/07/21	Tue 9/28/21	22	100%	16	22	0
1.3.1	Prepare stakeholder questions	All		Tue 9/07/21	Mon 9/13/21	7	100%	5	7	0
1.3.2	Determine potential interviewees	All		Tue 9/07/21	Fri 9/10/21	4	100%	4	4	0
1.3.3	Collect baseline feedback	All		Fri 9/10/21	Tue 9/28/21	19	100%	13	19	0
1.3.4	Contact potential interviewees	All		Fri 9/10/21	Tue 9/28/21	19	100%	13	19	0
1.3.5	Schedule Interviews	All		Fri 9/10/21	Tue 9/21/21	12	100%	8	12	0
1.3.6	Conduct Interviews	All		Mon 9/13/21	Fri 9/17/21	5	100%	5	5	0
1.3.7	Document interview takeaways	All		Mon 9/13/21	Fri 9/24/21	12	100%	10	12	0
1.3.8	Prepare user needs	All		Mon 9/13/21	Fri 9/24/21	12	100%	10	12	0
1.3.9	Write finalized problem statement	All		Tue 9/14/21	Tue 9/14/21	1	100%	1	1	0
1.4	Gate 1 Presentation	All		Tue 9/21/21	Tue 9/28/21	8	100%	6	8	0
1.4.1	Create presentation slides	All		Tue 9/21/21	Thu 9/23/21	3	100%	3	3	0
1.4.2	Create Gantt chart	All		Tue 9/21/21	Fri 9/24/21	4	100%	4	4	0
1.4.3	Practice Presentation	All		Thu 9/23/21	Tue 9/28/21	6	100%	4	6	0
1.4.4	Finalize Presentation	All		Fri 9/24/21	Tue 9/28/21	5	100%	3	5	0
1.5	Honors Proposal	All		Tue 9/21/21	Tue 9/28/21	8	100%	6	8	0
1.5.1	Write proposal	All		Tue 9/21/21	Thu 9/23/21	3	100%	3	3	0
1.5.2	Determine 3rd reader	All		Tue 9/21/21	Tue 9/21/21	1	100%	1	1	0
1.5.3	Edit proposal	All		Thu 9/23/21	Thu 9/23/21	1	100%	1	1	0
1.5.4	Distribute proposal to readers	All		Thu 9/23/21	Thu 9/23/21	1	100%	1	1	0
1.5.5	Receive feedback	All		Thu 9/23/21	Thu 9/23/21	1	100%	1	1	0
1.5.6	Revise proposal	All		Mon 9/27/21	Mon 9/27/21	1	100%	1	1	0
1.5.7	Get signatures	All		Tue 9/28/21	Tue 9/28/21	1	100%	1	1	0
1.5.8	Submit to Honors College	All		Tue 9/28/21	Tue 9/28/21	1	100%	1	1	0
2	**Design Inputs**	All		Wed 9/29/21	Tue 11/02/21	35	100%	25	35	0
2.1	**Engineering Requirements**	All		Thu 10/07/21	Thu 10/14/21	8	100%	6	8	0
2.1.1	Identify/Down-select problem	All		Thu 10/07/21	Tue 10/12/21	6	100%	2	6	0
2.1.2	Translate user requirements into engineering requirements	All		Tue 10/12/21	Thu 10/14/21	3	100%	3	3	0
2.2	**QFD**	Olivia		Thu 10/07/21	Thu 10/28/21	22	100%	16	22	0
2.2.1	Moving User Requirements into QFD	Olivia	Angie	Thu 10/07/21	Thu 10/28/21	22	100%	16	22	0
2.2.2	Move engineering requirements into QFD	Olivia	Angie	Thu 10/14/21	Tue 10/19/21	6	100%	4	6	0
2.2.3	Identify relationships in QFD	Olivia	Angie	Tue 10/19/21	Thu 10/21/21	3	100%	3	3	0
2.2.4	Finalize QFD	Olivia	Angie	Thu 10/21/21	Thu 10/28/21	8	100%	6	8	0
2.3	**Risk Management Plan**	All		Thu 10/07/21	Thu 10/21/21	15	100%	11	15	0
2.3.1	Finalize Roles	All		Thu 10/07/21	Sun 10/10/21	4	100%	2	4	0
2.3.2	Determine Risks	All		Sun 10/10/21	Tue 10/12/21	3	100%	2	3	0

2.3.3	Initial Draft	Emily		Tue 10/12/21	Thu 10/21/21	10	100%	8	10	0
2.4	**FMEA**	Megan		Thu 10/21/21	Thu 10/28/21	8	100%	6	8	0
2.4.1	Create Initial Revision	Megan		Thu 10/21/21	Thu 10/28/21	8	100%	6	8	0
2.5	**Honors Proposal First Draft**	Emily	Megan	Thu 10/07/21	Thu 10/28/21	22	100%	16	22	0
2.5.1	Draft Proposal	Emily	Megan	Thu 10/07/21	Thu 10/28/21	22	100%	16	22	0
2.6	**Gantt Chart**	Olivia		Thu 10/07/21	Thu 10/28/21	22	100%	16	22	0
2.6.1	Establish Action Items	Olivia	Megan	Thu 10/07/21	Fri 10/08/21	2	100%	2	2	0
2.6.2	Update	Olivia		Thu 10/07/21	Thu 10/28/21	22	100%	16	22	0
2.5	**Gate 2 Review**	All		Thu 10/21/21	Tue 11/02/21	13	100%	9	13	0
2.5.1	Create Presentation Slides	All		Thu 10/21/21	Thu 10/28/21	8	100%	6	8	0
2.5.2	Practice Presentation	All		Thu 10/28/21	Tue 11/02/21	6	100%	4	6	0
2.5.3	Finalize Presentation	All		Thu 10/28/21	Tue 11/02/21	6	100%	4	6	0
3	**Design Process**	All		Wed 11/03/21	Tue 12/07/21	35	75%	25	26	9
3.1	**Honors Proposal**	Emily	Megan	Wed 11/03/21	Tue 11/30/21	28	100%	20	28	0
3.1.1	Finalized Proposal	Emily	Megan	Wed 11/03/21	Mon 11/22/21	20	100%	14	20	0
3.1.2	Submit to Honors College	Megan	All	Mon 11/22/21	Tue 11/30/21	9	100%	7	9	0
3.2	**Gantt Chart**	Olivia	All	Wed 11/03/21	Tue 11/09/21	7	100%	5	7	0
3.2.1	Establish Action Items	Olivia	Megan	Wed 11/03/21	Fri 11/05/21	3	100%	3	3	0
3.2.2	Update	Olivia	All	Fri 11/05/21	Tue 11/09/21	5	100%	3	5	0
3.3	**Concept Generation**	All		Wed 11/03/21	Wed 11/17/21	15	100%	11	15	0
3.3.1	Brainstorming	All		Wed 11/03/21	Wed 11/10/21	8	100%	6	8	0
3.3.2	Alpha prototype creation	All		Wed 11/10/21	Wed 11/17/21	8	100%	6	8	0
3.3.3	Bench top testing	All		Mon 11/29/21	Fri 12/03/21	5	0%	5	0	5
3.4	**Design Reviews**	All		Thu 11/18/21	Tue 11/23/21	6	100%	4	6	0
3.4.1	Create Decision Matrix (Delivery)	Olivia	Angie	Thu 11/18/21	Tue 11/23/21	6	100%	4	6	0
3.4.2	Create Decision Matrix (Tubing)	Olivia	Angie	Thu 11/18/21	Tue 11/23/21	6	100%	4	6	0
3.5	**Down-selection of topics**	Angie	All	Thu 11/18/21	Tue 11/30/21	13	50%	9	6	7
3.5.1	Prepare QFD	All		Thu 11/18/21	Tue 11/23/21	6	50%	4	3	3
3.5.2	Prepare FMEA	Megan	All	Thu 11/18/21	Tue 11/23/21	6	50%	4	3	3
3.6	**Risk Management Plan**	Emily	Megan	Thu 11/18/21	Tue 11/30/21	1	90%	9	0	1
3.6.1	Determine updated risk information	Emily	Megan	Thu 11/18/21	Tue 11/23/21	1	100%	4	1	0
3.6.2	Update documentation	Emily	Megan	Tue 11/23/21	Fri 11/26/21	1	100%	4	1	0
3.6.3	Finalize Risk Management Plan	Emily	All	Fri 11/26/21	Tue 11/30/21	1	75%	3	0	1
3.7	**Gate 3 Review**	All		Tue 11/30/21	Tue 12/07/21	8	25%	6	2	6
3.7.1	Create Presentation Slides	All		Tue 11/30/21	Fri 12/03/21	4	50%	4	2	2
3.7.2	Practice Presentation	All		Fri 12/03/21	Mon 12/06/21	4	25%	2	1	3
3.7.3	Finalize Presentation	All		Mon 12/06/21	Tue 12/07/21	2	0%	2	0	2
4	**Design Outputs**	All		Wed 1/12/22	Wed 2/16/22	36		26		
4.1	**CAD prototype development**	All		Wed 1/12/22	Mon 1/17/22	6	100%	4	6	0
4.1.1	Create initial models of snap connection	Megan	Angie	Wed 1/12/22	Sat 1/15/22	4	100%	3	4	0
4.1.1.1	Review snap connection models	Emily	Olivia	Sat 1/15/22	Sun 1/16/22	2	100%	0	2	0
4.1.1.2	Finalize models	Angie	Megan	Sun 1/16/22	Mon 1/17/22	2	100%	1	2	0
4.1.1.3	Order materials	Olivia		Sun 1/16/22	Mon 1/17/22	2	100%	1	2	0
4.1.1.4	Send out models for printing	Olivia		Sun 1/16/22	Mon 1/17/22	2	100%	1	2	0
4.1.2	Create initial models of lock and key connection	Emily	Olivia	Wed 1/12/22	Sat 1/15/22	4	100%	3	4	0

4.1.2.1	Review lock and key connection models	Megan	Angie	Sat 1/15/22	Sun 1/16/22	2	100%	0	2	0
4.1.2.2	Order materials	Olivia		Sun 1/16/22	Mon 1/17/22	2	100%	1	2	0
4.1.2.3	Finalize models	Angie	Megan	Sun 1/16/22	Mon 1/17/22	2	100%	1	2	0
4.1.2.4	Send out models for printing	Olivia		Sun 1/16/22	Mon 1/17/22	2	100%	1	2	0
4.1.3	Drawings	All		Mon 1/17/22	Fri 1/21/22	5	100%	5	5	0
4.2	**CAD prototype analysis**	All		Wed 1/12/22	Mon 1/17/22	6	100%	4	6	0
4.2.1	Determine cavity size	Angie		Wed 1/12/22	Sat 1/15/22	4	100%	3	4	0
4.2.2	Decide which prototype to go forward with	All		Wed 1/12/22	Sat 1/15/22	4	100%	3	4	0
4.2.3	Order extra prototypes to be printed	Olivia		Wed 1/12/22	Wed 2/02/22	22	100%	16	22	0
4.3	Testing	All		Mon 1/17/22	Mon 2/14/22	29	75%	21	21	8
4.3.1	Design test methods	All		Mon 1/17/22	Fri 1/21/22	5	100%	5	5	0
4.3.2	Bench top testing	All		Fri 1/21/22	Mon 1/24/22	4	50%	2	2	2
4.3.2.1	Create bench top testing plans	Angie		Mon 1/17/22	Tue 1/18/22	2	100%	2	2	0
4.3.3	Verification testing	Emily		Tue 1/18/22	Mon 1/24/22	7	50%	5	3	4
4.3.3.1	Determine verification plans	Olivia		Fri 1/21/22	Mon 1/24/22	4	100%	2	4	0
4.4	Risk Assessment	Megan		Mon 1/24/22	Mon 1/31/22	8	100%	6	8	0
4.4.1	DFMEA	Megan		Mon 1/24/22	Mon 1/31/22	8	100%	6	8	0
4.4.2	Risk Management Report update	Emily		Mon 1/24/22	Mon 1/31/22	8	100%	6	8	0
4.5	Analytical Modeling	All		Mon 1/31/22	Mon 2/07/22	8	50%	6	4	4
4.5.1	Comsol	Olivia		Mon 2/07/22	Mon 2/14/22	8	0%	6	0	8
4.5.2	Hand calculations	Emily		Mon 2/07/22	Mon 2/14/22	8	100%	6	8	0
4.6	Documentation			Wed 1/19/22	Wed 2/16/22	29	100%	21	29	0
4.6.1	BOM	Olivia	Emily	Wed 1/26/22	Wed 2/09/22	15	100%	11	15	0
4.6.2	Decision matrix	Megan	All	Wed 1/19/22	Wed 1/26/22	8	100%	6	8	0
4.7	Gate 4 Review	All		Wed 2/09/22	Wed 2/16/22	8	67%	6	5	3
4.7.1	Create Presentation Slides	All		Tue 2/08/22	Wed 2/09/22	2	75%	2	1	1
4.7.2	Practice Presentation	All		Wed 2/09/22	Mon 2/14/22	6	75%	4	4	2
4.7.3	Finalize Presentation	All		Mon 2/14/22	Wed 2/16/22	3	50%	3	1	2
5	Medical Device	All		Wed 2/23/22	Wed 3/23/22	29	75%	21		
5.1	Documentation	All		Wed 2/23/22	Thu 2/24/22	2	100%	2	2	0
5.1.1	Update Test Method Document (New sterilization & Update Inspection)	Angie	Emily	Wed 2/23/22	Wed 2/23/22	1	100%	1	1	0
5.2	Validation Wrap-up	Olivia	Megan	Fri 3/04/22	Fri 3/18/22	15	100%	11	15	0
5.2.1	Complete final validation tests with new prototypes	Olivia	Emily	Fri 3/04/22	Sat 3/12/22	9	100%	6	9	0
5.2.2	Complete surveys and input into documentation	Angie	Emily	Sat 3/12/22	Fri 3/18/22	7	100%	5	7	0
5.3	Honors Proposal	Emily	Megan	Wed 2/23/22	Wed 3/23/22	29	75%	21	21	8
5.3.1	Complete First Draft of Honors Proposal and send to readings	Emily	Megan	Wed 2/23/22	Fri 3/18/22	24	100%	18	24	0
5.3.2	Implement Honors report feedback	Megan	Emily	Sat 3/26/22	Fri 4/22/22	28	75%	20	21	7
5.3.3	Finals Honors Report	Megan	Emily	Sat 3/26/22	Fri 4/22/22	28	50%	20	14	14
5.4	Capstone Day	All		Wed 4/13/22	Fri 4/22/22	10	50%	8	5	5
5.4.1	Capstone poster	Megan	Olivia	Sat 3/26/22	Fri 4/22/22	28	90%	20	25	3
5.4.2	Gather materials for capstone day	Megan	Emily	Sat 3/26/22	Fri 4/22/22	28	75%	20	21	7
5.5	Video	All		Wed 4/13/22	Fri 4/22/22	10	33%	8	3	7

5.5.1	Create script	All		Wed 2/23/22	Wed 3/30/22	36	100%	26	36	0
5.5.2	Film video	All		Wed 4/13/22	Fri 4/22/22	10	0%	8	0	10
5.5.3	Edit and finalize video	All		Mon 2/14/22	Wed 2/16/22	3	0%	3	0	3
5.6	NEOvations Poster	All		Wed 4/13/22	Fri 4/22/22	10	50%	8	5	5
5.7	Gate 4 Review	All		Wed 2/23/22	Wed 4/13/22	50	100%	36	50	0
5.7.1	Create Presentation Slides	All		Mon 4/04/22	Mon 4/11/22	8	100%	6	8	0
5.7.2	Practice Presentation	All		Fri 4/08/22	Tue 4/12/22	5	100%	3	5	0
5.7.3	Finalize Presentation	All		Fri 4/08/22	Tue 4/12/22	5	100%	3	5	0

Appendix 2 – Interview Questions

Customer/User Interview Questions

1. Can you tell us a little bit about your exposure to oxygen therapy?
2. What are some common complaints that you have heard or experienced relating to portable oxygen devices?
3. Can you recall a specific scenario where you witnessed or experienced a major issue with a portable oxygen system?
a. What happened?
b. How did you fix it or did the user fix it?
4. How much assistance does insurance generally provide?
5. What common/known symptoms of patients that have respiratory dysfunction do you think make handling oxygen therapy difficult?
a. What do you do to get around these?
b. What else could be done to get around these issues?
6. What keeps you up at night concerning oxygen delivery?
7. What makes your day (better/brighter) concerning oxygen delivery?
a. Why? Does it happen often/rarely?
8. If you could make your ideal oxygen therapy device, what would be the first thing that you would change?
9. What demographics (i.e. young, old, male, female, etc) do you typically think of when you think about those who need oxygen therapy?
10. Do you feel that health care providers are sufficiently training those who receive oxygen therapy on their devices and equipment?
11. Do you think that the cannulas could be made to be more comfortable and functional for patients?
12. Are you concerned about flammability/burn risks?

Health Care Worker Focused

1. How do you know what the oxygen rate should be adjusted too? Is there a typical rage depending on type of person, age, active life, weight, disease, etc.?
2. What problems do you run into relating to application of cannulas/masks on patients?
3. How often do you have to change or clean the mask or nasal cannula?
4. What is the biggest inconvenience you face when it comes to oxygen delivery setup?
5. If (you/ your patient/ client) were wanting to do a specific task, what setbacks from the oxygen delivery system hold them back from doing said activities?

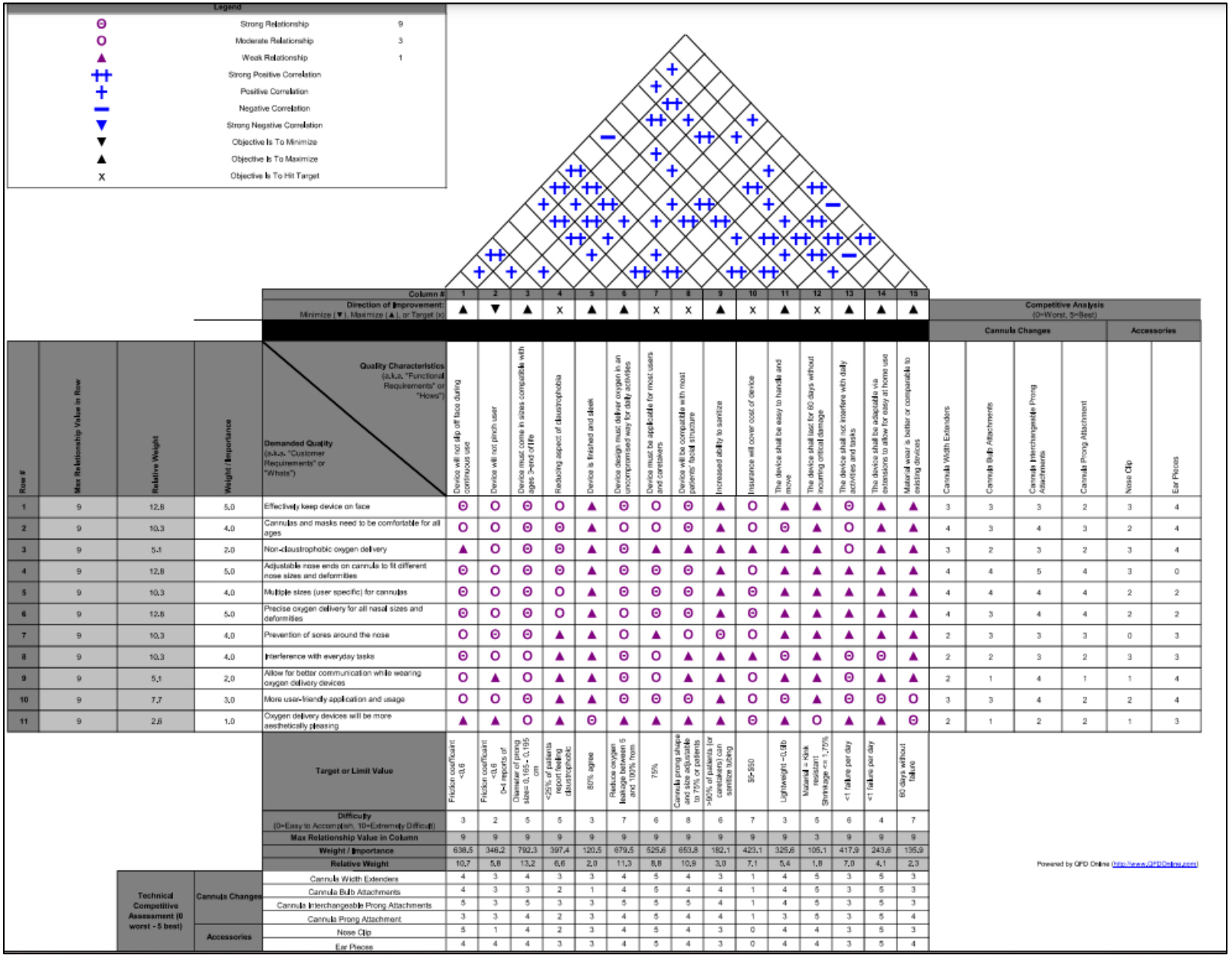
Device Specific/Manufacturing/Retailer Focused Questions

1. What specific masks and/or nasal cannula do you produce/manufacture?
2. Do you use a humidifier device in conjunction with the oxygen delivery systems?
3. What is the biggest inconvenience you face when it comes to your oxygen delivery setup?
4. With the delivery set up in mention, what does it do that creates a better life for (you, your patient/ client) in functionality terms? (make sure to have name or type of system recorded)
5. Since conserver devices deliver oxygen in pulses or bursts and is not recommended for everyone, what about the patient telling you if they should use a conserver device in conjunction with their oxygen therapy?
6. What is the most restrictive guideline that you must meet in device design?
7. If an oxygen concentrator is used instead of tanks for home care set-ups, what about these machines allows for the best and or worst delivery of oxygen?
8. How do you account for flammability risks?

Appendix 3 - User Needs

1. Effectively keep device on face
2. Cannula is comfortable for all ages
3. Non-claustrophobic oxygen delivery
4. Cannula can fit different nose sizes and potential deformities
5. Multiple sizes offered
6. Minimize interference with everyday tasks
7. User friendly application and usage
8. Oxygen delivery devices more aesthetically pleasing
9. Device can be cleaned

Appendix 4 – Preliminary QFD



Legend		
⊖	Strong Relationship	9
O	Moderate Relationship	3
▲	Weak Relationship	1
++	Strong Positive Correlation	
+	Positive Correlation	
−	Negative Correlation	
▼	Strong Negative Correlation	
▼	Objective Is To Minimize	
▲	Objective Is To Maximize	
X	Objective Is To Hit Target	

Row #	Max Relationship Value in Row	Relative Weight	Weight / Importance	Demanded Quality (a.k.a. "Customer Requirements" or "Whats") \ Quality Characteristics (a.k.a. "Functional Requirements" or "Hows")	Column #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Competitive Analysis (0=Worst, 5=Best)					
					Direction of Improvement: Minimize (▼), Maximize (▲), or Target (x)	▲	▼	▲	x	▲	▲	x	x	▲	x	▲	x	▲	▲	▲	Cannula Changes				Accessories	
						Device will not slip off face during continuous use	Device will not pinch user	Device must come in sizes compatible with ages 3-end of life	Reducing aspect of claustrophobia	Device is finished and sleek	Device design must deliver oxygen in an uncompromised way for daily activities	Device must be applicable for most users and caretakers	Device will be compatible with most patients' facial structure	Increased ability to sanitize	Insurance will cover cost of device	The device shall be easy to handle and move	The device shall last for 60 days without incurring critical damage	The device shall not interfere with daily activities and tasks	This device shall be adaptable via extensions to allow for easy at home use	Material wear is better or comparable to existing devices	Cannula Width Extenders	Cannula Bulb Attachments	Cannula Interchangeable Prong Attachments	Cannula Prong Attachment	Nose Clip	Ear Pieces
1	9	12.8	5.0	Effectively keep device on face		⊖	O	⊖	O	▲	⊖	O	⊖	▲	O	▲	▲	⊖	▲	▲	3	3	3	2	3	4
2	9	10.3	4.0	Cannulas and masks need to be comfortable for all ages		O	O	⊖	⊖	▲	O	O	⊖	▲	O	⊖	▲	O	▲	▲	4	3	4	3	2	4
3	9	5.1	2.0	Non-claustrophobic oxygen delivery		▲	O	⊖	⊖	▲	⊖	▲	▲	▲	▲	▲	▲	O	▲	▲	3	2	3	2	3	4
4	9	12.8	5.0	Adjustable nose ends on cannula to fit different nose sizes and deformities		⊖	O	⊖	⊖	▲	⊖	⊖	⊖	▲	O	▲	▲	▲	▲	▲	4	4	5	4	3	0
5	9	10.3	4.0	Multiple sizes (user specific) for cannulas		⊖	O	⊖	O	▲	⊖	⊖	⊖	▲	⊖	▲	▲	▲	▲	▲	4	4	4	4	2	2
6	9	12.8	5.0	Precise oxygen delivery for all nasal sizes and deformities		⊖	O	⊖	O	▲	O	⊖	⊖	▲	⊖	▲	▲	▲	▲	▲	4	3	4	4	2	2
7	9	10.3	4.0	Prevention of sores around the nose		O	⊖	⊖	▲	▲	O	▲	O	⊖	O	▲	▲	▲	▲	▲	2	3	3	3	0	3
8	9	10.3	4.0	Interference with everyday tasks		⊖	O	O	▲	▲	⊖	O	▲	▲	▲	⊖	▲	⊖	⊖	▲	2	2	3	2	3	3
9	9	5.1	2.0	Allow for better communication while wearing oxygen delivery devices		O	▲	O	▲	▲	⊖	O	▲	▲	O	▲	▲	⊖	▲	▲	2	1	4	1	1	4
10	9	7.7	3.0	More user-friendly application and usage		O	O	⊖	▲	▲	⊖	⊖	⊖	▲	O	⊖	▲	⊖	⊖	O	3	3	4	2	2	4
11	9	2.6	1.0	Oxygen delivery devices will be more aesthetically pleasing		▲	▲	O	▲	⊖	▲	▲	▲	▲	⊖	▲	O	▲	▲	⊖	2	1	2	2	1	3
				Target or Limit Value		Friction coefficient <0.6	Friction coefficient <0.6 (0-4 reports of discomfort)	Diameter of prong size= 0.165 - 0.195 cm	<25% of patients report feeling claustrophobic	80% agree	Reduce oxygen leakage between 5 and 100% from	75%	Cannula prong shape and size compatible to 75% of patients	>90% of patients can easily sanitize tubing	50-500	Lightweight ~0.4lb	Material = Kink Resistant Shrinkage <= 1.75%	<1 failure per day	<1 failure per day	90 days without failure						
				Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)		3	2	5	5	3	7	6	8	6	7	3	5	6	4	7						
				Max Relationship Value in Column		9	9	9	9	9	9	9	9	9	9	9	3	9	9	9						
				Weight / Importance		638.5	346.2	792.3	397.4	120.5	679.5	525.6	653.8	182.1	423.1	325.6	105.1	417.9	243.6	135.9						
				Relative Weight		10.7	5.8	13.2	6.6	2.0	11.3	8.8	10.9	3.0	7.1	5.4	1.8	7.0	4.1	2.3						
Technical Competitive Assessment (0 worst - 5 best)		Cannula Changes		Cannula Width Extenders		4	3	4	3	3	4	5	4	3	1	4	5	3	5	3						
				Cannula Bulb Attachments		4	3	3	2	1	4	5	4	4	1	4	5	3	5	3						
				Cannula Interchangeable Prong Attachments		5	3	5	3	3	5	5	5	4	1	4	5	3	5	3						
				Cannula Prong Attachment		3	3	4	2	3	4	5	4	4	1	3	5	3	5	4						
		Accessories		Nose Clip		5	1	4	2	3	4	5	4	3	0	4	4	3	5	3						
				Ear Pieces		4	4	4	3	3	4	5	4	3	0	4	4	3	5	4						

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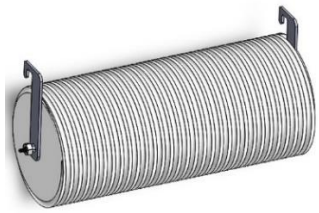
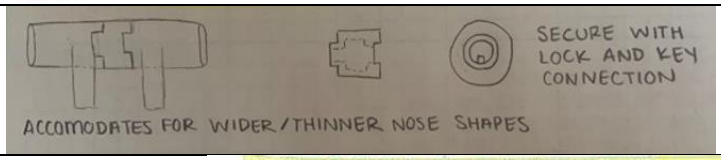
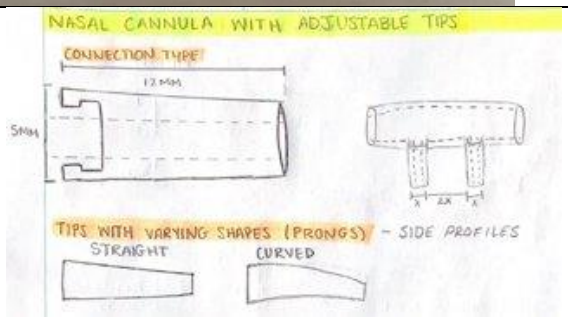
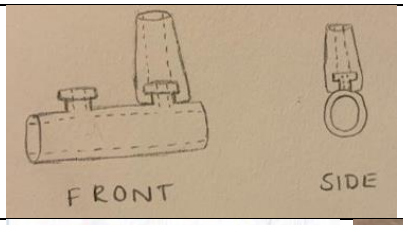
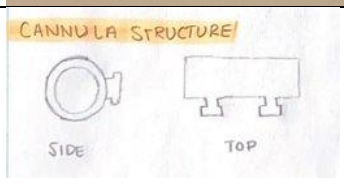
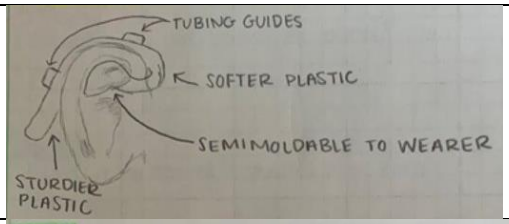
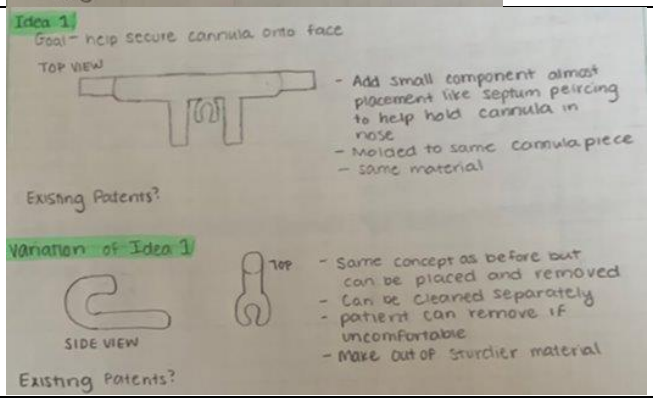
Appendix 5 – Preliminary Engineering Requirements (Further developed in Appendix 16)

1. Device will not slip off face during continuous use
2. Device will not pinch user
3. Device must come in sizes compatible with ages 3-end of life
4. Reducing aspect of claustrophobia
5. Device is finished and sleek
6. Device design must deliver oxygen in an uncompromised way for daily activities
7. Device must be applicable for most users and caretakers
8. Device will be compatible with most patients' facial structure
9. Increased ability to clean
10. Insurance will cover cost of device
11. The device shall be easy to handle and move
12. The device shall last for 60 days without incurring critical damage
13. The device shall not interfere with daily activities and tasks
14. The device shall be adaptable via extensions to allow for easy at home use
15. Material wear is better or comparable to existing devices

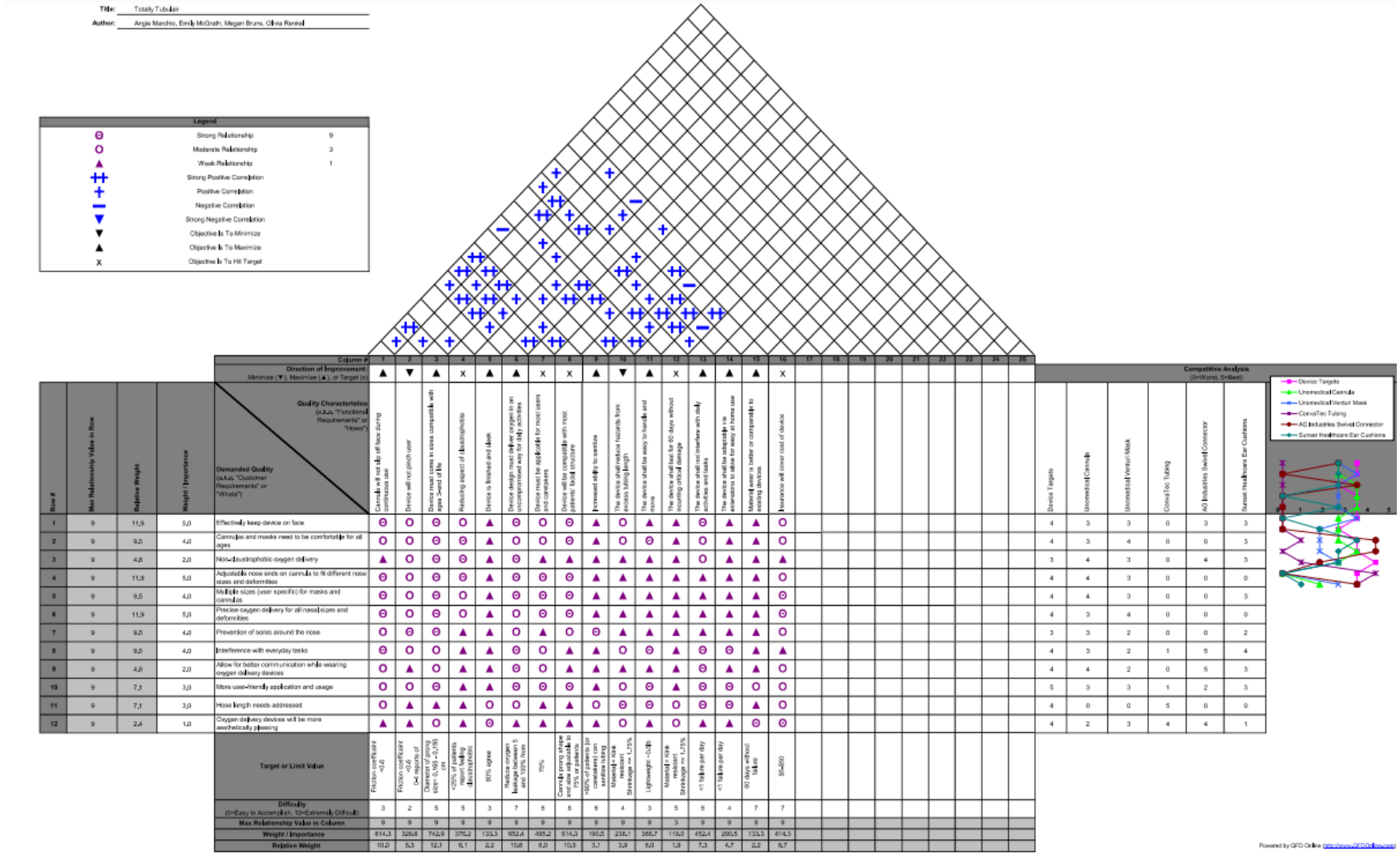
Appendix 6 – Risk Priority Number Table

		Risk Priority Number							
Severity	S-5	0	25	50	75	100	150	5	Detection
	S-4	0	16	32	48	64	80	4	
	S-3	0	9	18	27	36	45	3	
	S-2	0	4	8	12	16	20	2	
	S-1	0	1	2	3	4	5	1	
		0	1	2	3	4	5		
		Probability							

Appendix 7 - Team Concepts

Concept 1 – Hosing Reel	
Concept 2 – Width Extensions	
Concept 3 – Interchangeable Bulb & Prong Attachments	 
Concept 3a – Snap Connection	
Concept 3b – Lock and Key Connection	 
Concept 4 – Ear Attachments	
Concept 5 – Nose Clip	

Appendix 8 – QFD



Appendix 9 – Concept Down Selection Matrices

Idea	System	Device will not slip off face during continuous use	Device will not pinch user	Device must come in sizes compatible with ages 3-end of life	Reducing aspect of claustrophobia	Device is finished and sleek	Device design must deliver oxygen in an uncompromised way for daily activities	Device must be applicable for most users and caretakers	Device will be compatible with most patients' facial structure	Increased ability to sanitize	The device shall be easy to handle and move	The device shall last for 60 days without incurring critical damage	The device shall not interfere with daily activities and tasks	Material wear is better or comparable to existing devices	Insurance will cover cost of device	Weighted Score	Rank	Is this something we can complete in time?	Is this something we can complete with cost constraints	Do we need to do more research to understand and complete this design?	What software will this require	What mechanical knowledge will this require?	Is different material stressed for this design?
Weight	/100	10.63	6.25	6.25	5.00	5.00	10.63	6.25	10.63	5.00	6.25	6.25	10.63	5.00	6.25	/10							
Cannula Width Extenders	Delivery	7	6	8	5	5	8	9	8	5	7	9	5	6	2	6.59	2	Yes	Yes	Yes	Solidworks	Injection Molding	Potentially
Cannula Bulb Attachments	Delivery	8	6	6	3	2	8	9	8	7	7	9	5	6	2	6.42	4	Yes	Yes	Yes	Solidworks	Injection Molding	Potentially
Cannula Interchangable Prong Attachmer	Delivery	9	6	9	5	5	9	9	9	7	7	9	5	6	2	7.18	1	Yes	Yes	Yes	Solidworks	Injection Molding	Potentially
Ear Pieces	Delivery	8	7	8	6	6	7	9	7	5	7	8	5	7	1	6.57	3	Yes	Yes	Yes	Solidworks	Injection Molding	Potentially
Cannula Nose Clip	Delivery	9	1	7	4	5	8	9	7	5	7	8	5	6	2	6.21	5	Yes	Yes	No	Solidworks	Injection Molding	Potentially
Cannula prong attachment	Delivery	6	5	8	3	4	7	9	7	7	6	9	5	8	2	6.19	6	Yes	Yes	Yes	Solidworks	Injection Molding	Potentially

Idea	System	Reducing aspect of claustrophobia	Device is finished and sleek	Device design must deliver oxygen in an uncompromised way for daily activities	Device must be applicable for most users and caretakers	Increased ability to sanitize	The device shall reduce hazards from excess tubing length	The device shall be easy to handle and move	The device shall last for 60 days without incurring critical damage	The device shall not interfere with daily activities and tasks	The device shall be adaptable to allow for easy at home use	Material wear is better or comparable to existing devices	Insurance will cover cost of device			Weighted Score	Rank	Is this something we can complete in time?	Is this something we can complete with cost constraints	Do we need to do more research to understand and complete this design?	What software will this require	What mechanical knowledge will this require?	Is different material stressed for this design?
Weight	/100	5.00	5.00	12.50	7.50	7.50	7.50	12.50	5.00	12.50	7.50	5.00	12.50			/10							
Horizontal Tube Coil	Tubing	7	7	6	8	1	9	9	9	5	6	7	1			5.65	1	Yes	Maybe	Yes	Solidworks	ign for stationary, rotary dev	No
Vertical Tube Coil	Tubing	8	8	6	8	1	9	9	9	4	6	7	1			5.77	2	Yes	Maybe	Yes	Solidworks	3d Printing, Hardware	No
Tubing Sleeve	Tubing	5	4	6	8	1	9	8	8	6	2	6	1			4.82	3	Yes	No	Yes	No	rial knowledge, Tensile Testir	Yes
"Pig Tail" Tubing	Tubing	6	9	7	8	1	4	5	7	5	4	4	1			4.43	4	Yes	Maybe	Yes	No	Material knowledge	Yes

Appendix 10 – Design FMEA

No	Component/Part	Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) Mechanism(s) of Failure	OCC	CN	DET	RPN	Current Mitigations	Verification	Suggested Mitigations	SEV	DET	OCC	RPN
1	Prong Attachment	Delivers oxygen to patient with good fit to patient	Attachment comes off in patient nose	Patient inhales attachment into nasal cavity	4	Prong to cannula connection can't withstand adequate force	1	4	1	4	Tight tolerances for connection point	Tensile testing	Develop secure attachment with strong and applicable material	1	2	1	2
			Oxygen leakage	Patient does not recieve adequate oxygen supply	4	Improper fit	2	8	4	32	Various sizes so patient can select best fit	Test multiple sizes on different nasal shapes and sizes	Develop leak resistant attachment	2	2	1	4
			Attachment falls off prior to use	Patient unable to use device	2	Poor attachment connection	1	2	1	2	Tight tolerances for connection point	Tensile testing	Develop secure attchment and provide sufficent backups	2	1	1	2
			Attachment clogged with mucus or debris	Patient does not recieve adequate oxygen supply	2	Device does not prevent clogging; device not able to easily be cleaned	2	4	2	8	Device easy to clean	Test cleaning time and drying time	Develop prong with adequate sized openings for oxygen flow	1	2	2	4
			Attachment pinches user	Minor skin abrasion/discomfort	1	Device design has improper tolerances that allow for skin to catch	2	2	1	2	Various sizes so patient can select best fit	Test multiple sizes on different nasal shapes and sizes	Device designed with tolerances and techniques to decrease potential for pinch points	1	1	2	2
			Attachment causes sores in nose	Patient discomfort; if untreated, potential for infection	2	Material issue	3	6	2	12	Material should cause low friction and interference with skin	Survey comfort	Design device with most skin friendly tubing; limit contact of prong in nasal cavity	2	2	3	12
			Attachment doesn't connect to cannula	Patient unable to use device	3	ID of Prong Attachment is incorrect	1	3	2	6	Tight tolerances for connection point	Sampling production lots to ensure devices meets specifications	Assure effective manufacturing processes & validations	2	2	1	4
			Attachment rips at connection point	Patient unable to use device	4	Material/design issue	4	16	1	16	Design tolerances	Cycle Testing	Increasing wall thickness of prongs; creating fillet around base connection	4	1	3	12
			Attachment does not fit user	Patient does not recieve adequate oxygen supply	3	Improper fit	1	3	2	6	Various sizes so patient can select best fit	Test multiple sizes on different nasal shapes and sizes	Assure effective manufacturing processes & validations	2	1	1	2
2	Connection Point on Cannula for Prongs	Secure attachment point for prong attachments	Prong Attachment does not connect well allowing oxygen leakage	Patient does not recieve adequate oxygen supply	4	Connection point too small for prong attachment	1	4	1	4	Tight tolerances for connection point	Sampling production lots to ensure devices meets specifications	Assure effective manufacturing processes & validations	1	1	1	1
			Prong Attachment does not connect	Patient unable to use device	3	Connection point too large for prong attachment	1	3	1	3	Tight tolerances for connection point	Sampling production lots to ensure devices meets specifications	Assure effective manufacturing processes & validations	2	1	1	2
			Connection point breaks	Patient unable to use device	4	Improper dimensions or material	1	4	1	4	Tight tolerances for connection point	Sampling production lots to ensure devices meets specifications	Assure effective manufacturing processes & validations	2	1	1	2
			Connection point becomes clogged with debris	Patient does not recieve adequate oxygen supply	4	Device does not prevent clogging	1	4	2	8	Device easy to clean	Device can be cleaned of all debris with soap and water	Provide multiple replacements and cleaning instructions	1	2	1	2
3	Cannula Tubing (Applicable to both larger and split tubing segments)	Provides path for oxygen flow to nasal piece and prongs for patient	Tubing irritates patient's skin	Patient develops sores	2	Material issue	3	6	2	12	Various sizes so patient can select best fit	Test multiple sizes on different nasal shapes and sizes	Design device with most skin friendly tubing; limit contact of prong in nasal cavity	1	2	3	6
			Tubing kinks	Patient does not recieve adequate oxygen supply	4	Material prone to kinking	2	8	3	24	Use material that resists kinking	Observe standard use during 2hour period to ensure less than 2 instances of kinking occurs	Design device with firm tubing that allows for motion	1	3	2	6
			Tubing cracks	Patient does not recieve oxygen due to leak	4	Matieral unable to withstand forces of everyday use	1	4	2	8	Material able to withstand use	Post--use inspection	Provide multiple replacements	2	1	1	2
			Tubing cracks	Patient does not recieve oxygen due to leak	4	Matieral exceeded lifespan	1	4	2	8	Replacements to be provided	Set of 3 or more parts provided to user per month	Provide multiple replacements	2	2	1	4
4	Cannula Connection to Tubing Extension or Oxygen Source	Allows user to get additional length of tubing or direct connection to oxygen source	Connection does not interface with extension tubing	Patient reach from oxygen source is limited	3	Connection manufactured with improper dimensions	1	3	1	3	Tight tolerances for connection point	Test and compare with current connction dimensions and preform multiple mechanical tests and connections to multiple delievery devices	Develop design with proper dimensions with reasonable tolerances	1	1	1	1
			Connection does not interface with oxygen source	Patient unable to use device	3	Connection manufactured with improper dimensions	2	6	1	6	Tight tolerances for connection point	Test and compare with current connction dimensions and preform multiple mechanical tests and connections to multiple delievery devices	Develop design with proper dimensions with reasonable tolerances	1	1	2	2
			Connection breaks	Patient unable to use device	4	Connection material wore out	1	4	1	4	Tight tolerances for connection point	Preform mechanical tests for material being considered	Develop design that uses applicable and wear-proof material	2	1	1	2
			Connection breaks	Patient unable to use device	4	Connection not able to withstand everyday forces	1	4	1	4	Tight tolerances for connection point	Preform excessive rounds of mechanical tests and multiple trial runs with connecting to delievery device. Tensile testing	Develop design that provides a secure connection	2	1	1	2
5	Connection Point for Tubing Split	Larger tubing of cannula connects to two thinner softer segments that carry oxygen to nose	Thinner tubing pulls free (either side)	Patient unable to use device	4	Connection not able to withstand everyday forces	1	4	1	4	Larger tubing overmolded onto smaller	Tensile testing	Inspections during production to ensure overmold does not contain defects and tubing is secure	4	1	0	0
			Thinner tubing collapsed in overmold	Patient unable to use device	4	Failure during manufacturing; not captured in screening	1	4	1	4	Inspection during manufacturing	Visual Inspection; proof of air flow through device prior to packaging	Operators inspect each device once overmold is complete	4	1	0	0

Appendix 11 – Parts Design Matrix & Preliminary Design Specifications

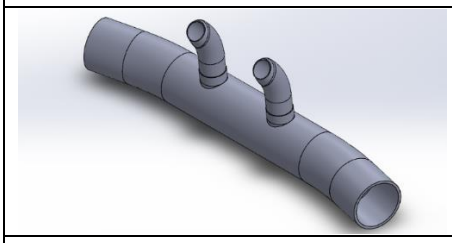
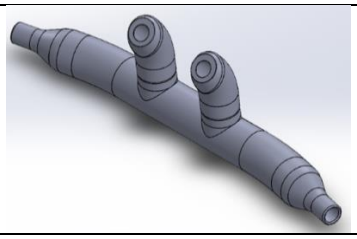
Green=Positive Correlation
White=Neutral/No Correlation
Blue=Negative Correlation

Component Name	Prong Attachment									Cannula Attachment					Tubing			
Design Specifications / Engineering Reqs	Length	Width	Weight	Shape	Flexibility	Sterility	Material Life	Material	Appearance	Material	Weight	Appearance	Diameter	Length	Material	Weight	Flexibility	Material Life
Not slip off face during continuous use																		
Not pinch user																		
Sizes compatible with ages 3-end of life																		
Reducing aspect of claustrophobia																		
Finished and sleek																		
Uncompromised delivery																		
Applicable for most users																		
Facial structure compatibility																		
Increased ability to sanitize																		
Insurance will cover cost of device																		
Easy to handle and move																		
60 day life																		
Not interfere with daily activities and tasks																		
Adaptable via extensions for ease of use																		
Material wear is better or comparable																		
	8	6	-2	8	2	3	2	4	1	3	-2	1	1	4	4	-1	2	1
Target Values	Fit Average Nasal Cavity for Defined Age Groups	Fit Average Nasal Cavity for Defined Age Groups	Less than 0.5 lbs	Fit Average Nasal Cavity for Defined Age Groups	60-90A Durometer	>90% of patients (or caretakers) can sanitize tubing	60 days	60-90A Durometer	80% Agree	60-90A Durometer	Less than 0.5 lbs	80% Agree	Size appropriate for prong attachment within ±0.05	Fit Average Nasal Cavity for Defined Age Groups	60-90A Durometer	Less than 0.5 lbs	60-90A Durometer	60 days

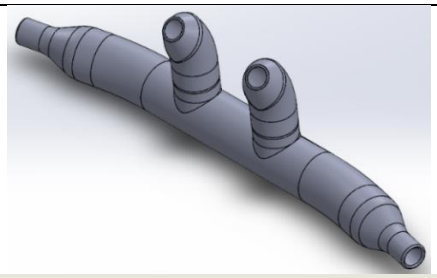
Appendix 12 – Connection Method Decision Matrix

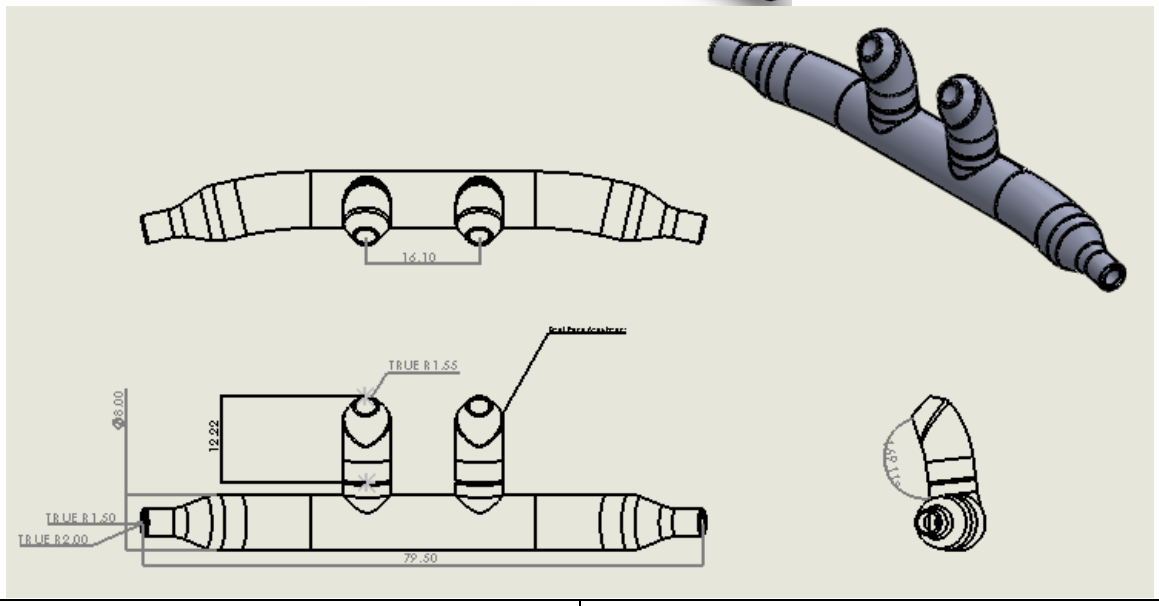
Method	Quick Connection	Interchangeable	Does not add excessive bulk to cannula	Fits in Nostril	Comfortable	Material must deliver oxygen in an uncompromised way for daily activities	Able to be Sanitized	Does not disconnect easily	Ability to be manufactured	Weighted Score	Rank
Weight (/100)	5.60	11.10	5.60	16.70	16.70	16.70	5.60	11.10	11.10	/10	
Snap Connection	8	6	6	8	8	8	6	5	7	7.13	1
Lock and Key	4	8	5	8	8	8	4	7	3	6.73	2

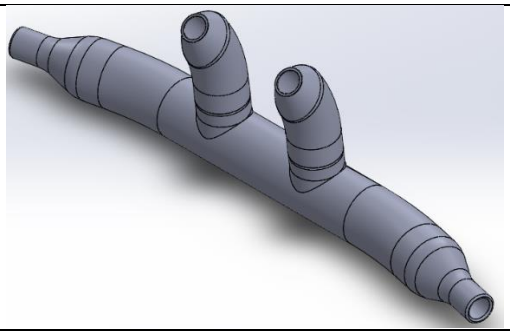
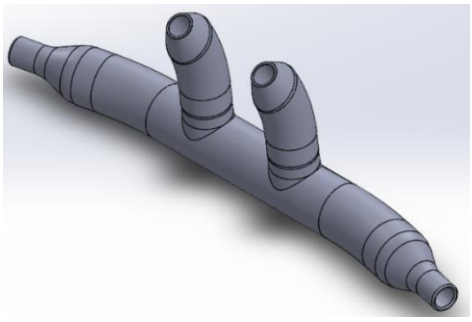
Appendix 13 - SolidWorks Parts and Drawings

Revision 1	Revision 2
	

Revision 3 Small





Revision 3 Medium	Revision 3 Large
	

Appendix 14 – Material Decision Matrix

Material	Compatible with 3D Printing	Light Weight	Pliable in Nose	Comfortable on Skin	Able to be Sanitized	Material must deliver oxygen in an uncompromised way for daily activities	Material shall last for 60 days without incurring critical damage	Affordable	Weighted Score	Rank
Weight	21.40	7.10	14.30	14.30	7.10	21.40	7.10	7.10	/10	
50A	10	8	8	8	5	7	6	5	7.63	1
80A	10	8	6	7	6	8	7	5	4.21	2
Soft PVC	1	8	7	6	6	8	7	6	3.37	3
Super Soft	1	8	6	7	5	7	6	6	3.13	4
LLDPE	1	8	7	6	5	8	7	6	3.08	5

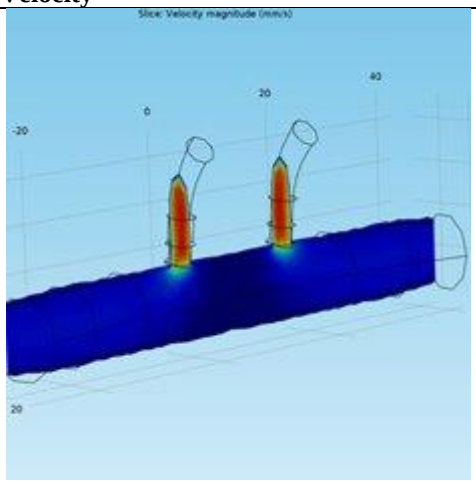
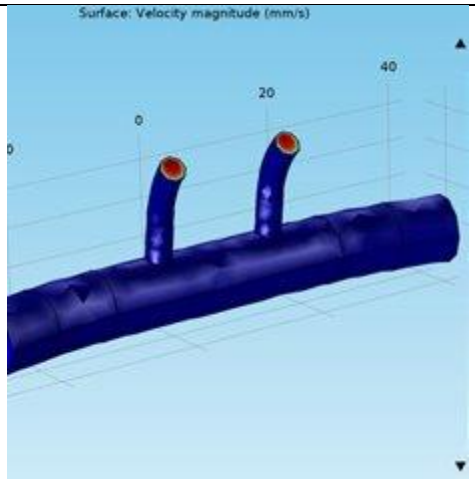
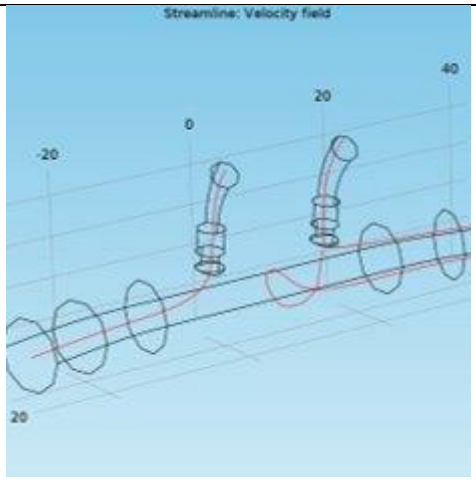
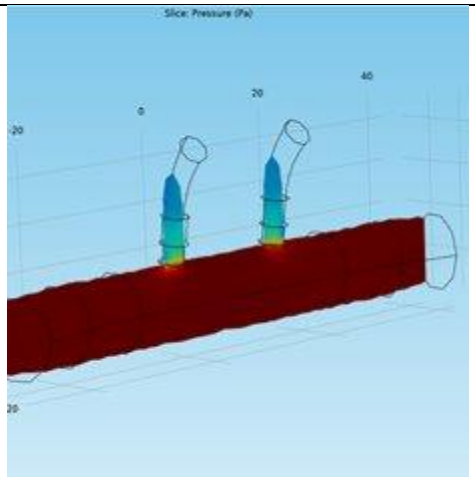
Appendix 15 – Bill of Materials (BOM)

Item #	Part #	Part Name	Quantity	Vendor Part #	Vendor Part Name	Material	Vendor	Cost per Part	Lead Time
1	B1-50A	Base	1	RS-F2-ELCL-01	Flexible Resin 50A 1L	50A Resin	FormLabs	$1.10	1 week
2	P2-50A	Prong	2	RS-F2-ELCL-01	Flexible Resin 50A 1L	50A Resin	FormLabs	$0.50	1 week
3	C1	Cannula Base	1	B08R1SM155	Adult Oxygen Tubing Nasal Cannula	PVC	Amazon	$2.00	1 week
4	DR-1	Drying Rack	1	N/A	3D Print	PLA	Bierce Library	$0.00	3 Days

Appendix 16 – Device Specifications

Spec #	Design Specification	Impacted Parts of Device	Rationale	Test Method	Test Target
1	Weight of device is under 32(+2/-7) g	Entire device	- Lighter than iPhone - Comparable to existing cannula (32g from measurement) - Does not cause user fatigue from wear - Comfortable fit for continuous use	-Weigh on scale and compare with standard cannula	32(+2/-7) g
2	Cannula Prong fills less than or equal to 60% of user's nasal cavity	Prong & Base	-Doesn't cause claustrophobia -Better fit for patient -Allows patient to exhale through nostril	-Caliper measurement -Fit Test	Prong Outer Diameter: Adult: 2.7mm - 7.15 mm Children: 1.5 mm - 4 mm
3	Material/connections last for 60 days	Entire Device	-Material lasts daily use for a month (recommended change out by providers)	-Cycle Testing	120 cycles can be withstood
4	Material Hardness – Prongs Between 45-65 duro	Prongs	-Soft for user -Flexible in nose	N/A - Research Based Information	Material selection 45-55 duro
5	Material Hardness – Base between 65-95 duro	Base	-Sturdy for prongs -Soft to not cause discomfort	N/A - Research Based Information	Material Selection 75-85 duro
6	Uncompromised Air Flow	Entire Device	-Patient should receive uncompromised flow from the device to their nostrils for proper device function	-Flow Test -Analytical Model -Design	Comparable to current models 6L/min Less than 30% leakage
7	Withstand Sterilization	Prongs	-Patient/caretaker should be able to clean prongs is build up occurs -Not feasible with current devices	-Cleaning Test (Cannula drying rack)	Functions properly with secure connections after 60 cleans
8	Appearance	Entire Device	-General population satisfied with appearance during use	-Fit Testing Survey	80% agree
9	Useable for a variety of age ranges	Prongs & Base	-Applicable to general population	-Fit Testing Survey -Dimension Analysis	Provide 3 sizes for children Provide 3 sizes for adults
10	Device withstands average forces	Prong & Base	-Device doesn't detach	-Tensile Test -Material Selection -Design	Withstand 3.1 N amount of force
11	Prongs withstand lateral force	Prong	-Prong can withstand lateral forces -Prong does not detach during use	-Gauge DOE	Withstand minimum lateral force of 1lb
12	Cannula Joints Force Req	Cannula Joints	-Cannula does not break from daily forces	-Tensile Test	Withstand 3.1 N of force
13	Leakage at cannula joints	Cannula Joints	-Uncompromised flow through device to patient	-Flow Test	No leakage at cannula joints
14	Device shall interface with standard oxygen sources	Cannula Source Connection	-Good interface for ubiquitous device use	-Compatibility Test	Usable with standard device

Appendix 17 – COMSOL Analytical Modeling of Velocity, Streamlines, & Pressure

Velocity	
	
Streamlines	**Pressure**
	

Appendix 18 – Verification Results

Table 1: Beta Prototype Rev. 01 Results

Test Method	Prototype #	Criteria for Success	Pass/Fail	Comments	Initial(s) of Tester	Date
Inspection	1	Prong attaches both sides	Pass		EM	2/11/22
	2		Pass		EM	2/11/22
	3		Pass		EM	2/11/22
	4		Pass		EM	2/11/22
	1	Caliper measurements- ± 0.3mm from SW drawing	Pass		EM	2/11/22
	2		Fail	Oversized prong OD	AM	2/11/22
	3		Fail	Oversized distance between prongs, oversized prong OD	OR	2/11/22
	4		Pass		MB	2/11/22
Cycle	1	120 cycles of attaching the prongs on base can be completed	Pass		OR and MB	2/11/22
	3		Fail	100 cycles completed and broke on bottom of prong	AM and EM	2/11/22
Tensile	2	Max Tensile Value is more than 1N force it takes to pull prongs off from base	Pass		EM	2/15/22
Tensile	4		Pass		EM	2/15/22

Table 2: Beta Prototype Rev. 02 Results

Test Method	Prototype #	Criteria for Success	Pass/Fail	Comments	Initial(s) of Tester	Date
Inspection	1	Caliper measurements ± 0.3mm from SW drawing	Fail	Distance between prongs was 0.4mm too small	EM	2/28/22
	2		Pass			
	3		Pass			
	4		Fail	ID of base was 0.6mm to large		
	3	Prong and cannula attach	Pass			03/01/22
Tension	3	Max Tensile Value is more than 1N force it takes to pull prongs off from base	Pass		MB and EM	03/01/22
	4		Pass			

Table 3: Beta Prototype Rev. 03 Results

Test Method	Prototype #	Criteria for Success	Pass/Fail	Comments	Initials(s) of Tester	Date
Inspection	1	Prong attaches both sides	Pass		EM	3/14/22
	2		Pass		EM	3/14/22
	3		Pass		EM	3/14/22
	4		Pass		EM	3/14/22
	1	Caliper measurements- ± 0.3mm from SW drawing	Pass		EM	3/14/22
	2		Pass		EM	3/14/22
	3		Pass		EM	3/14/22
	4		Pass		EM	3/14/22
	1	Weight 32(+2/-7) g	Pass		AM	3/16/22
	2		Pass		AM	3/16/22
	3		Pass		AM	3/16/22
	4		Pass		AM	3/16/22
	1	Dimensional Analysis Distance Between Prongs (15 – 18.5) mm Prong OD Result (2.7 – 7.15) mm Prong ID Result (1.7 -6.15) mm	Pass		EM	3/16/22
	2		Pass		EM	3/16/22
	3		Pass		EM	3/16/22
	4		Pass		EM	3/16/22
Flow	1	No leakage, withstands constant pressure	Pass		OR/MB	3/14/22
	2		Pass		OR/MB	3/14/22
	3		Pass		MB/OR	3/14/22
	4		Pass		MB/OR	3/14/22
Cycle	4	Withstand 120 cycles	Fail	See Risk Assessment Document (714.00)	OR/MB	3/14/22
	2		Fail		MB/OR	3/14/22
	1		Fail		MB/OR	3/14/22

Appendix 19 – Validation Plan

Customer Requirement Number	Customer Requirement	Validation Method	Validation Test Name	Validation Procedure Number
1	Effectively keep device on face	• Testing	• Fit Testing	• 1
2	Cannula is comfortable for all ages	• Testing • Analysis	• Fit Testing • Inspection and Size Analysis	• 1 • 2
3	Non-claustrophobic oxygen delivery	• Testing	• Fit Testing	• 1
4	Cannula can fit different nose sizes and potential deformities	• Testing • Analysis	• Fit Testing • Inspection and Size Analysis	• 1 • 2
5	Multiple sizes offered	• Analysis	• Inspection and Size Analysis	• 1 • 2
6	Minimize interference with everyday tasks	• Testing	• Fit Testing	• 1
7	User friendly application and usage	• Testing • Demonstration	• Fit Testing • Compatibility and Connections	• 1 • 3
8	Oxygen delivery devices more aesthetically pleasing	• Testing	• Fit Testing	• 1
9	Device can be cleaned	• Testing	• Sanitization- Wear	• 4

Appendix 20 – Validation Testing Results

Prototype Number	Validation Procedure Number	Validation Name	Pass/Fail	Comments	Tester
R3P4S R3P4S R3P4M R3P4M R3P4L	1	Fit Testing	Pass	N/A	MB
N/A	2	Inspection and Size Analysis	Pass	N/A	EM
R3P4L	3	Compatibility and Connections	Pass	N/A	EM
R3P4S R3P4M R3P4L	4	Sanitization-Wear	Pass	N/A	OR \ MB

Appendix 21 – Risk Summary Table

Risk	Summary of Risk	RPN	Risk Level	Mitigations
Prong Attachment Oxygen Leakage	Patient does not receive adequate oxygen supply as oxygen leaks from improper fit	32	Medium	Provide multiple sizes so that patients can choose a size that fits best.
Cannula Tubing Kink	Tubing kinks prevent patient from receiving an adequate oxygen supply.	24	Medium	Device made with tubing sturdy enough to avoid easy kinks.
Prong Attachment Connection Rip	Prong rips at its base which is the connection point. A new prong is needed.	16	Medium	Patients provided with backups; material wall thickness increased; fillet added to base connection point for smooth putting on.
Prong Attachment Causes Sores	Material and device can cause sores in nose creating patient discomfort, and if untreated, potential for infection.	12	Low	Choice of soft material with lower friction than other available printing options.
Tubing Causes Sores	Tubing causes skin irritation and patients can develop sores.	12	Low	Use current tubing that should be minimally irritating to patient's skin.
Prong Attachment Clogged	Attachment becomes clogged with mucus or debris and patients don't receive adequate oxygen supply	8	Low	Prongs can be removed and cleaned with soap and water. Backups will be provided while the other set dries.
Prong to Cannula Attachment Point Clogs	Connection points collect debris and patients do not receive adequate oxygen supply.	8	Low	Prong can be removed, and debris can be removed from connection point.
Cannula Tubing Cracks	Tubing cracks due to material not being able to withstand force or exceed its lifespan. This would be a device failure.	8	Low	Durable material selected and new cannula provided every 30 days, so material does not exceed life.
Prong Attachment doesn't Connect	The prong doesn't attach, and the patient is unable to use the device.	6	Low	Tight design tolerances and ensure effective manufacturing practices.
Cannula doesn't Interface	Cannula doesn't interface with oxygen source, and patients are unable to use devices.	6	Low	Tight tolerances, use premanufacturing cannula parts, proper dimensions.
Prong Detaches during Use	Prong comes off during use and may be inhaled.	4	Low	Tight tolerances and secure attachment between prong and base.
Prong Attachment Not Secure	Prong Attachment does not connect well allowing oxygen leakage which disrupts patient's oxygen flow.	4	Low	Tight tolerances for connection point and assure effective manufacturing processes.
Cannula to Prong Connection Point Breaks	Connection point on cannula for attaching prongs, and patient is unable to use device.	4	Low	Tight tolerances for connection point and assure effective manufacturing processes. Sturdy enough material selected.
Cannula Connection to Extension Tubing/Oxygen Source Breaks	Connection breaks and patient is unable to use device. Break is caused by material wear or material is not able to withstand daily use.	4	Low	Tight tolerances for connection; develop design that uses applicable and wear-proof material. New cannula every 30 days.

Connection Point for Tubing Split Pulls Free	Thinner tubing pulls free at connection point and patient is unable to use device.	4	Low	Secure tubing over mold; inspections during production; pre-established assembly used.
Thinner Tubing Collapse	Thinner tubing collapses in over mold and the patient is unable to use device.	4	Low	Inspection during manufacturing.
Cannula Connection Interface with Extension Tubing	Connection interfaces with oxygen source but not extension tubing so patient has limited mobility.	3	Low	Ensure proper tolerance and ensure good manufacturing practices.
Prong Attachment Falls Off	Attachments fall off prior to use so the patient is not able to use the device.	2	Low	Secure attachment and backups provided in instance of failure.
Prong Pinches User	Prong pinches the user at cannula connection points and causes minor skin discomfort.	2	Low	Various sizes for best fit and designing so minimum potential for pinch point. Soft material used.