Spring 2023

Mouthpiece for Patients with Neuromuscular Disorders

Rebekah Starkey
The University of Akron, rks48@uakron.edu

Carissa Thompson
The University of Akron, cnt26@uakron.edu

Michael Dickens
The University of Akron, mad225@uakron.edu

Andrew Pero
The University of Akron, amp307@uakron.edu

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Michael Dickens
Biomedical Engineering Student, The University of Akron, mad225@uakron.edu

Rebekah Starkey
Biomedical Engineering Student, The University of Akron, rks48@uakron.edu

Dr. Christopher Newey, Cleveland Clinic - Cerebrovascular Center

The University of Akron

Biomedical Engineering Design II 001

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Andrew Pero
Biomedical Engineering Student, The University of Akron
Akron, United States
amp307@uakron.edu

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Biomedical Engineering Student, The University of Akron
Akron, United States
cnt26@uakron.edu

Michael Dickens
Biomedical Engineering Student, The University of Akron
Akron, United States
mad225@uakron.edu

Rebekah Starkey
Biomedical Engineering Student, The University of Akron
Akron, United States
rks48@uakron.edu

***Abstract*— Neuromuscular Disorders (NMDs) impact people throughout the world. An early hallmark of these disorders includes some degree of facial muscle weakness. Respiratory testing is important to evaluate the progression of these patients' NMDs. However, these tests require that the patient purses their lips around a mouthpiece to create a tight seal. This is a difficult task for one with facial muscle degeneration. This often leads to results that fail to reflect the patient's true respiratory ability and prevents their physician from providing the appropriate degree of care. The objective of this project was to develop a face mask or mouthpiece for Negative Inspiratory Force (NIF) testing to allow these users to create a proper seal without use of their facial muscles. Through the engineering design process, a 3D printed prototype was designed to interface with NIF testing equipment. This proposed design uses bite force to create a tight seal, allowing for accurate test results, enhanced comfort, and better patient outcomes.**

Keywords— Neuromuscular Disorder, respiratory testing, Negative Inspiratory Force, Guillain-Barre, Myasthenia Gravis

I. INTRODUCTION

Mouthpiece for Patients with Neuromuscular Disorders is a project focused on addressing negative inspiratory force (NIF) and vital capacity (VC) measurement system ergonomics to increase the ease of use and the validity of tests for patients with neuromuscular disorders. Over 141.8 million Americans require NIF and VC testing [3]. NIF and VC are used for many conditions, such as Guillain-Barre Syndrome (GBS) and Myasthenia Gravis (MG). Patients with these conditions often experience difficulty and discomfort when interfacing with standardized NIF mouthpieces. Several patented and commonly used devices exist, including the AirLife® Misty Max by Vyaire Medical Inc. and the ComfitTM Rubber Mouthpieces by SDI Diagnostics [1, 4]. Despite being used by many individuals across all age groups and disease states, the mouthpieces have a standard size and require patients to create a tight seal by pursing their lips over the mouthpiece – because patients with NMDs often have some degree of facial muscle degeneration, their respiratory testing results can be unreliable. This may lead to an improper elevation of respiratory care, which can cause undue stress and discomfort for these patients. Through interviews and research, it became clear that the current mouthpieces used for this testing have serious shortcomings – thus, Mouthpieces for Patients with Neuromuscular Disorders aimed to create a NIF mouthpiece that uses bite force to allow users with facial muscle weakness to have a safe and comfortable fit during these vital diagnostic tests. This project followed the standard steps of the FDA Waterfall Process (Appendix 1). The progression of the design was documented by a Gantt chart (Appendix 2). This report serves to document and detail the development process for this adapted mouthpiece design.

II. USER NEEDS

After gaining an understanding of the relevant anatomy and physiology of GBS and MG, market research helped identify specific shortcomings of the currently implemented solutions for performing respiratory testing on NMD patients. A list of interview questions was developed (Appendix 3) and posed to practicing physicians, clinicians, and respiratory therapists to better understand unmet needs from the voice of the customer (VOC). The answers provided in the interviews were used to narrow the scope of the project by forming a list of eight user needs (Appendix 4), which were weighted based on their importance to the interviewees and focused on cost, compatibility with current equipment, and providing results reflective of patients' true abilities.

III. DESIGN INPUTS

The qualitative customer requirements were translated into quantifiable engineering requirements to help design a well-rounded device (Appendix 5). Within these requirements, it was important to follow the

specific standards which are listed in the table in Appendix 5. A quality function deployment (QFD) chart was utilized to help to further visualize the weight given to each engineering requirement during the design and fabrication stages of this mouthpiece (Appendix 6). An extension of this is minimizing the potential for failure in the device – as biomedical engineers, it is of the utmost importance to create devices that will improve patient outcomes. Thus, it is biomedical engineers' ethical obligation to be proactive in anticipating and mitigating risks that may cause serious harm. In order to do this, a preliminary failure modes effect analysis (FMEA) was developed to evaluate potential failure points (Appendix 7). This was vital in device manufacturing to minimize risks and maximize patient safety. Risks (for example, the device splintering into small pieces and becoming a choking hazard) were identified and rated on a 1-5 scale in three categories: severity, likelihood of occurrence, and probability of detection. These three numbers were then multiplied together to return a risk priority number (RPN) for each failure mode, indicating the degree of care and attention needed for each during the design output and testing stages. A risk mitigation plan was later developed and implemented to ensure the safety of the patients that will interface with the device.

IV. DESIGN PROCESS

Three different conceptual configurations were developed, each with a different modality for creating the seal and affixing the device to the patient's face (Appendix 10). The first configuration (Concept 1) was an external cushion designed to fit around the outside curvature of the patient's mouth. Severe facial weakness in NMD patients often leads to a permanent frown, and it was this shape that was taken into consideration when detailing the first concept. Also, this concepts featured straps that wrapped around the patient's head to secure the device in place. The other two concepts were intraorally focused and utilized bite force as the primary affixion mechanism, since the masseter (jaw) muscle is often unaffected by NMDs. These concepts relied on the patient's bite to hold the device in place, with the seal created by sidewalls that sat flush with either the inside (Concept 2) or the outside (Concept 3) of the patient's mouth. All three concepts featured an external tube that fits into the three-way valve adapter that is currently used in clinical NIF testing.

Using a down selection matrix (Appendix 11) in tandem with the QFD, each design concept was evaluated for its ability to meet the engineering requirements and for its feasibility given the time and budgetary constraints inherent to this project. The results indicated the intraoral mouthpiece with an internal seal was the best concept, as it demonstrated the most promise to maximize efficacy and simplicity while minimizing patient discomfort. In the interest of ease, the design would be a one-size-fits-most model with a focus on compatibility with the average adult population. After finalizing the concept, a design FMEA (Appendix 7) was created to shape future risk mitigation and verification activity.

V. DESIGN OUTPUTS

Each mouthpiece prototype was virtually modeled using SolidWorks and printed using a Formlabs 3D resin printer. The SolidWorks models and drawing are found in Appendix 15. The mouthpiece is intended to be produced as one uniform unit to enhance manufacturing and marketability potential, and to reduce the number of component interfaces where failure can occur.

The design takes inspiration from football mouthguards and snorkeling breathing pieces. It consists of the following aspects: wide tapered flanges, upon which the patient bites to secure the device into place and create enough separation for airflow into the testing machine; rounded sidewalls, which extend from the flanges, sit between the patient's teeth and lips, and serve to form a complete seal upon inspiration; and the tube, which protrudes from the patient's mouth and is designed to fit into the existing NIF equipment.

In detailing the specifications of this mouthpiece, the primary goal was to strike the perfect balance between safety, efficacy, patient comfort, and compatibility. For instance, the thickness of the bite pieces needed to be thick enough to ensure the bite force would not tear the material, but not so thick as to cause undue jaw pain. Dimensions of each team member's bite - specifically tooth width, bite depth, and inter-molar distances - were averaged and used to guide dimensions of the device. With each successive prototype print, aspects of the design were added and refined to better meet the engineering requirements.

Another decision matrix was employed to select the material, with a focus on balancing biocompatibility,

stability, and manufacturing cost (Appendix 12). Though the prototype would be 3D printed using Formlabs 80A resin due to the constraints of this project, the material that achieved the highest score was an injection-moldable thermoplastic polyurethane (TPU). A bill of materials (BOM, Appendix 13) was created to track the parts used and resources spent. All components were printed by the Biomedical Engineering Department at The University of Akron.

VI. DESIGN VERIFICATION

Design verification testing was completed during the Design Outputs stage and was used to ensure that the design outputs met the criteria of the design inputs. This was completed by testing the alpha and beta prototypes against the engineering requirements. Ten design specifications (Appendix 5) were developed to ensure the success of the device and verification methods were used to ensure the adherence of the device to the specifications. The device was modeled using ANSYS (Appendix 16) to verify if the device could withstand 160 PSI, the maximum bite force of a human jaw [5]. Thermoplastic polyurethane, with a sheer modulus of 862.2 N/mm^2 and a Poisson's ratio of 0.3897, was chosen as the material to model the deformation and stress behavior of the device [2]. A uniform pressure of 160 PSI was applied to the flanges of the model, which highlighted areas of deformation and high stress at potential failure points along the mouthguard. Revisions were made to the prototype to ensure these points had the proper support to withstand the applied load.

Several other tests were performed on the printed prototype – the device was inspected, tested for fit, and its dimensions were analyzed and verified. The prototype material (Formlabs 80A Resin) was analyzed to determine if it met the material properties and biocompatibility requirements for this project. Correspondence with FormLabs suggested that 80A could withstand the necessary bite force but was not biocompatible per ISO 10933-1 standards. Leak testing was performed by attaching the mouthpiece to a manometer and pushing a known volume of air through the assembly and monitoring to make sure there was no pressure loss or air leakage. Multiple revisions and prototypes were made during the verification process to improve the design, including adding structural supports to weak points of the mouthpiece and implementing a tapered angle to the bite region to account for the hinge motion of the jaw. All verification testing is summarized in Appendix 14, and model revisions are contained in Appendix 15.

VII. MEDICAL DEVICE

Multiple rounds of revisions and verification led to the creation of Prototype 4, which was printed on 80A resin and attached to the existing NIF equipment.

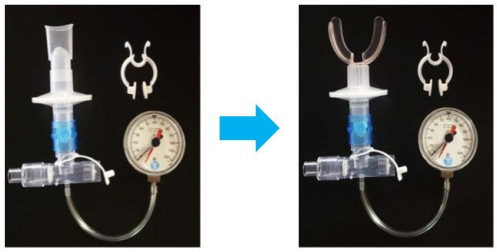

Figure 1. Current NIF equipment (left), Prototype 4 attached to current NIF equipment (right)

Most revisions focused on shortening and rounding the flanges and the sidewalls to maximize the patient's comfort while interfacing with this device. While the prototype was fabricated using resin printing, it is worth noting that the 80A resin used is not rated as biocompatible, and thus would not be used clinically – either medical grade silicone or TPU would be used instead, and would be injection-moldable to minimize costs and maximize efficiency during manufacturing. A NIF test using Prototype 4 was demonstrated to teams of respiratory therapists at both Summa Health Systems and The University of Akron, and both teams indicated this device showed much promise to improve NMD patient outcomes. A link to a video demonstration of this device can be found below.
Click: Demonstration of NIF Testing with Prototype
URL: https://tinyurl.com/UAMP4NMD

VIII. VALIDATION TESTING

Design validation was completed to ensure the device met the customer requirements developed in the User Needs stage. To validate the final prototype created during the Medical Device stage, validation methods were created for each customer requirement (Appendix 4) using a combination of inspection, testing, analysis, and surveying. To test for cost, a comparison with the current methods was conducted to determine if the device was within budget (Appendix 13, III.). To validate the comfort and fit, subjects were asked to use the device to perform the NIF test and rate their comfort level. The validation plans and validation results report are outlined in Appendix 17.

X. RISK MITIGATION PROCESS

To address potential problems or failures with the device, failure mode and effects analysis (FMEA) was done (Appendix 7). With the device being minimally invasive and one solid part, the list of identified risks was inexhaustive and was not altered between design stages. Six potential failure modes were identified relating to the material's biocompatibility, the device's brittleness, compatibility with patients' oral anatomy, edge sharpness, the ability for this device to complete the seal, and the compatibility with current NIF testing equipment. Each potential failure mode was assigned a value on a 1-5 scale (from acceptable to alarming) for its level of severity, occurrence, and probable detection rate (Appendix 9). Risk priority numbers (RPN) for each failure mode were determined by multiplying the assigned severity, occurrence, and detection scores together. A risk matrix was used to identify the acceptability of each failure mode (Appendix 8). RPN values falling in the range of 1-30 were deemed as acceptable, values from 31-60 called for further investigation, while values above 61 were considered unacceptable. Only one failure mode was not deemed "acceptable" – incompatibility with the patient' oral anatomy called for further investigation (RPN 32). To mitigate the risk, the dimensions of each team member's bite were averaged and used to guide the design specifications. This, in tandem with input from clinicians and dentists, lowered the occurrence value from a 4 to a 2 and lowered this mode's RPN value to 16, well within the range of acceptable values.

Residual risks were further mitigated by ensuring that the selected material met ISO biocompatibility standards. ANSYS modeling software was used to ensure that the device could withstand an average human's maximum bite force. To mitigate the risk of oral injury, all edges were rounded, and each team member independently assessed the device's comfort. To ensure compatibility with NIF testing equipment, the protruding tube's outer diameter was designed to match the inner diameter of the currently-in-use junction piece which connects the mouthpiece to the respiratory testing equipment.

XI. SUMMARY FEASIBILITY DISCUSSION

This device initially failed to create the necessary tight seal as the sidewalls were not tall enough to seal the airpath. In addition, the device caused discomfort during use because of the sharpness and length of the bite flanges. It also improperly fit users with smaller mouths. Design revisions were made to increase the height of the sidewall and to shorten the bite flanges, and these revisions were found to successfully resolve the issues. While testing the revised design, an active effort was made to not use facial muscles to augment the seal, and the seal was nonetheless created. Thus, the final design satisfies the need for a mouthpiece for NIF testing for patients with facial muscle weakness. The team has developed a 3D prototype as a proof-of-concept for larger scale manufacturing, but to meet cost and feasibility concerns, the product would be injection molded and made from biocompatible TPU or medical silicone.

XII. DISCUSSION, LESSONS LEARNED, AND CONCLUSIONS

Successful medical devices follow the design process detailed by the FDA – by first identifying user needs, translating these needs into engineering requirements, and then using these requirements to drive formation, verification, and validation of the device, the team was able to create a proof-of-concept for an adaptive mouthpiece for NIF testing for patients with NM disorders. There were several setbacks the team had to overcome – these primarily dealt with finding experts with time to lend for interviews and with sourcing NIF testing equipment to better augment the verification and validation processes. The biggest takeaway from this project is that the creation of medical devices truly is a team effort - forming relationships earlier with the respiratory departments at Summa and The University of Akron would have greatly improved the pace of this project and would have allowed for much easier access to interviews and testing equipment. Regardless, team members were able to rely on each other's strengths during the development of this project.

XIII. FUTURE WORK

Since NMDs afflict people of all ages, this device could be further developed with different sizing options to be more inclusive of pediatric and adolescent patients. The mouthpiece could also be altered to include an external set of sidewalls that allow seal formation for tests that monitor expiratory ability such as peak flow or vital capacity. This mouthpiece could also be adjusted to allow for more permanent implementation but would require that the bite flanges become thinner to reduce jaw discomfort and mitigate the formation of maladaptive bite habits in these patients.

XIV. INDIVIDUAL ROLES AND RESPONSIBILITIES

Through the process of developing an adapted mouthpiece, the team has integrated their skills and principles across disciplines. Combining the team's efforts, they applied their technical and professional skills to develop a promising proof-of-concept.

Andrew Pero acted as the design engineer for the team. He led the conceptualization of the design and focused his efforts on building the device in SolidWorks. He worked quickly to make revisions that incorporated lessons learned from verification testing. Also, he contributed to the creation of the FMEA and assisted in validation by demonstrating the working prototype.

Carissa Thompson acted as the quality manager and research and development expert. She was responsible for maintaining the Gantt Chart. Throughout the project, she organized the drive and instructed the lead on the project's timeline. She led the market analysis research. She co-authored the QFD. Also, she led the verification and validation plan.

Michael Dickens acted as the software engineer. He assisted in the conceptualization of the design and utilized Ansys modeling software to verify that the device could withstand the loads that would be applied to it during use. He additionally contributed to risk mitigation and the creation of FMEA.

Rebekah Starkey acted as the project manager for the team. Her primary contributions included leading weekly tasks and meetings and organizing interviews and testing with clinicians and departments. She was responsible for mentor updating and communication with professionals. She led verification testing by analyzing group members' NIF with both the current and proposed mouthpieces. She co-authored the QFD.

XV. PROFESSIONAL AND ETHICAL RESPONSIBILITIES

In each facet of the design process, the team considered global, economic, environmental, and societal implications. The ultimate goal of this adapted mouthpiece was to make NIF testing globally accessible for all populations who require respiratory monitoring or diagnostics. As this device is intended to improve upon and replace the existing solution, the team focused on minimizing the cost incurred by the patient and their insurance by prioritizing compatibility with current equipment and proposing efficient manufacturing (injection molding). Since the proposed design is for a standalone mouthpiece as opposed to current mouthpieces that come as a part of a kit, the environmental impact is reduced compared to existing devices. The device successfully allows all patients, including those afflicted with facial muscle weakness, to complete NIF testing – a significant metric for monitoring respiratory function and trends.

XVI. ACKNOWLEDGEMENTS

We would like to extend our sincerest gratitude to: our mentor Dr. Christopher Newey for voicing the need for this device; Senior Engineering Technician Steve Paterson for valuable design feedback and prompt 3D printing; BME Department Chair Dr. Hossein Tavana for his guidance throughout this process; Senior Design Professor Elijah Wreh for leading the course; respiratory therapists and clinicians at Summa Health for answering medical questions and providing valuable feedback; The University of Akron Applied Health RT Department for providing access to respiratory equipment and training; and all interviewees for their insight, advice, and passion. We are appreciative of everyone who supported and guided our team.

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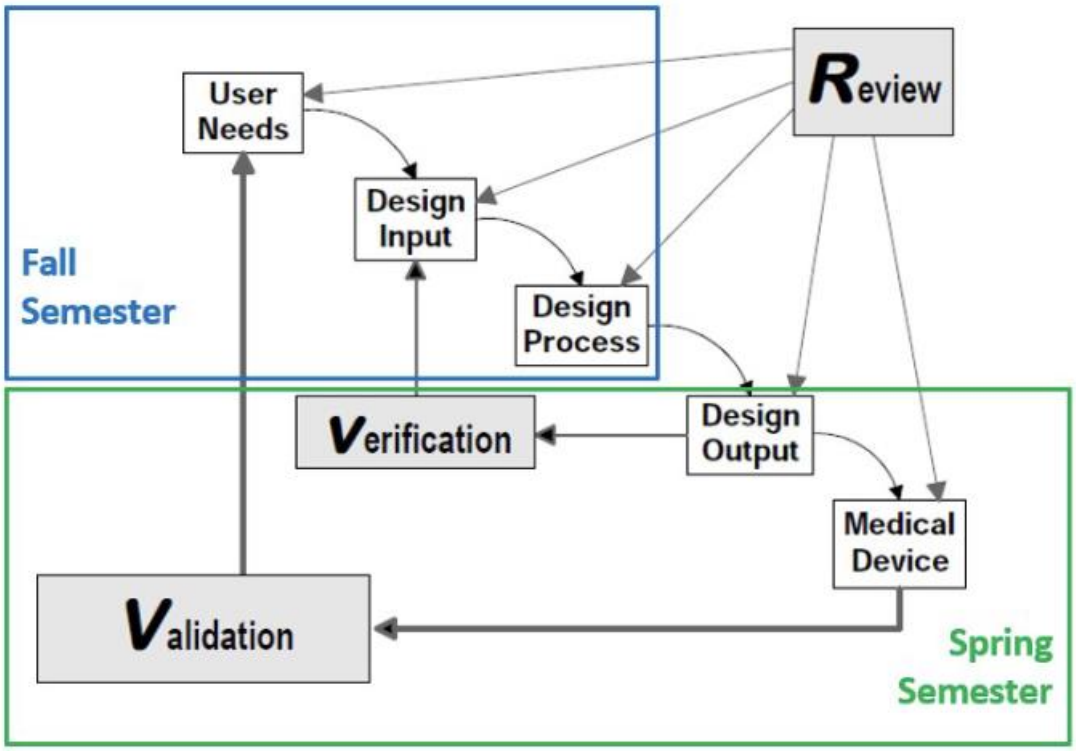
Appendix 1- FDA Waterfall Diagram

FDA Waterfall Diagram, with divisions indicating the focus of each semester's work



Appendix 2 - Gantt Chart

Facemasks for Patients with Neuromuscular Disorders

Company Name
Team Members

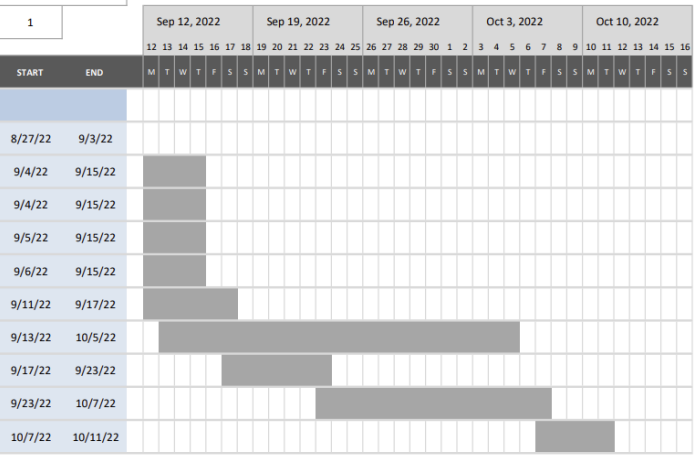
University of Akron, Biomedical Engineering

Project Start: Mon, 9/12/2022

Display Week: 1

: Andrew Pero, Michael Dickens, Carissa Thompson, Rebekah Starkey

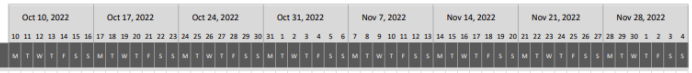
TASK	ASSIGNED TO	PROGRESS	START	END
User Needs Stage				
Team Formation	Elijah	100%	8/27/22	9/3/22
Background Research	All	100%	9/4/22	9/15/22
Patent Search	Carissa	100%	9/4/22	9/15/22
Competitive Product Search	Carissa	100%	9/5/22	9/15/22
Insurance / Regulations	All	100%	9/6/22	9/15/22
Problem Statement	All	100%	9/11/22	9/17/22
Customer Interviews	Bekah, All	100%	9/13/22	10/5/22
User / Customer Requirement	All	100%	9/17/22	9/23/22
Honors Project Proposal	All	100%	9/23/22	10/7/22
Gate 1 Review	All	100%	10/7/22	10/11/22



Display Week: 5

: Andrew Pero, Michael Dickens, Carissa Thompson, Rebekah Starkey

TASK	ASSIGNED TO	PROGRESS	START	END
Design Inputs Stage				
Engineering Requirements	All	100%	10/18/22	11/8/22
Phase 1 Quality Functional De	Bekah, Carissa	100%	10/25/22	11/15/22
Relationships	Bekah, Carissa	100%	10/31/22	11/8/22
Correlations	Bekah, Carissa	100%	10/31/22	11/8/22
Importance Rankings	Bekah, Carissa	100%	11/4/22	11/8/22
Competitve Analysis	Carissa	100%	11/4/22	11/15/22
Risk Management Plan	Michael, Andrew	100%	10/31/22	11/8/22
Gate 2 Review	Michael, Andrew	100%	11/15/22	11/22/22
Design Process Stage	(Waived)			
Phase 2 Quality Functional Deployment				
Desgin FMEA				
Gate Review				



Display Week: 19

: Andrew Pero, Michael Dickens, Carissa Thompson, Rebekah Starkey

TASK	ASSIGNED TO	PROGRESS	START	END
Design Outputs Stage				
Brainstorming	All	100%	1/9/23	1/9/23
Design Concepts	Andrew, Michael	100%	1/17/23	1/24/23
First 3D Model	Andrew, Michael	100%	1/20/23	1/24/23
First Prototype Print	Andrew, Steve	100%	1/31/23	2/5/23
Verification Testing of Prototy	All	100%	2/5/23	2/7/23
Update to Design	Andrew	100%	2/7/23	2/14/23
Measurements of Teeth	All	100%	2/7/23	2/10/23
3D Model 2	Andrew	100%	2/10/23	2/25/22
Risk Mitigation	Michael	100%	2/5/23	2/20/23
Major Components List	All	100%	2/16/23	2/25/23
Device Specifications	All	100%	2/20/23	2/25/23
Bill of Materials	Bekah	100%	2/25/23	2/27/23
Material Research	All	100%	2/15/23	2/25/23
Purchase Order	Bekah	100%	2/24/23	2/27/23
Assembly Plan / Instruction	All	100%	2/20/23	2/27/23
Verfication Plan	Carissa	100%	2/14/23	2/27/23
Verfication Procedure	Carissa	100%	2/14/23	2/27/23
Verfification Report	Carissa	50%	2/14/23	
Design Report Draft	All	75%	2/14/23	3/7/23
Gate Review	All	100%	2/7/23	2/28/23

Please open attached link below to view full Gantt Chart:

BME Design Gantt Chart.xlsx

Appendix 3 - Interview Questions

Questions:

1. What type of respiratory testing will our device be used for?
    a) Diagnostic/Therapeutic?
2. How is this testing typically performed in the general population?
    a) How does this change when evaluating patients with neuromuscular disorders?
3. Specific age range/specific disorders? Population size?
4. Are there current solutions that help assist patients with NMDs?
    a) If so, do you find them sufficient? What needs to change?
    b) Do you have a model name/number? Pictures/videos?
5. What is your vision for this device? How will our device be used? What are some of the most critical aspects?
6. Will our mask/mouthpiece be single-use?
7. What are some features/functions you would like us to include?
8. How can we best support the needs of your patients?
9. Do you have any contacts to refer us to for more information/insight?
    a) Pulmonologists, technicians, RNs, etc?

Appendix 4 - User Needs

User Needs:

1. Single-use/disposable
2. Creates an air-tight seal within the patient's mouth
3. Is comfortable for most adult patients
4. Does not inhibit normal breathing capabilities
5. Compatible with current NIF/VC equipment
6. Compatible with current NIF/VC procedure
7. Biocompatible material
8. Affordable price

Appendix 5 - Engineering Requirements

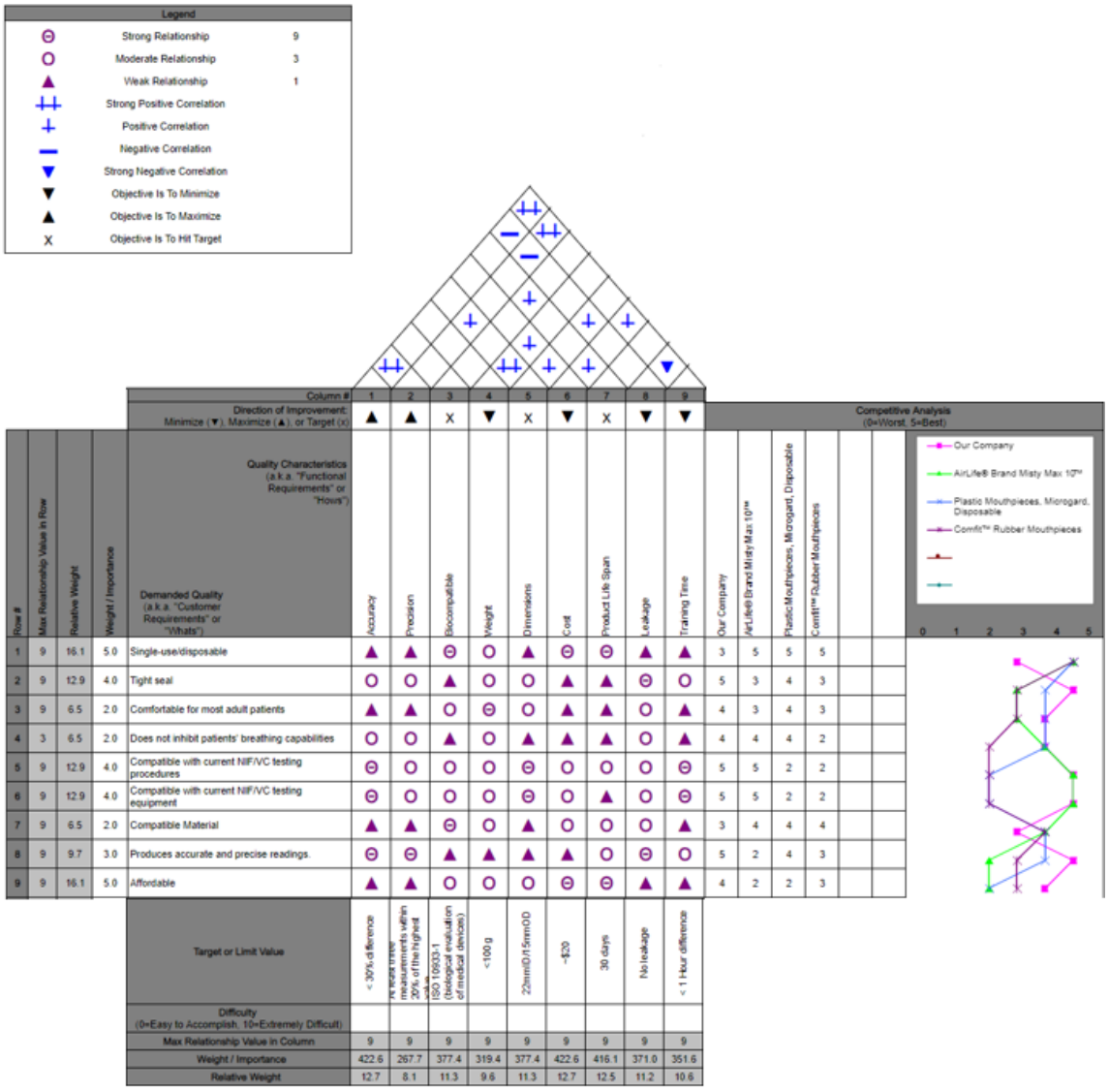
I. Engineering Requirements:

1. Total life span of the product must be comparable to existing products
2. The device will have no air leakage
3. Total weight of the device is under 20 grams
4. The dimensions must fit with the current testing equipment
5. Training time for the device is comparable to the current system
6. Device must be biocompatible
7. Device will be compatible with most patients' facial structure
8. Device must have comparable or more accuracy than the current mouthpiece
9. Device must have comparable or more precision than the current mouthpiece
10. Device must be affordable

II. User Needs Translated to Engineering Requirements

Product Lifespan	30 days
Leakage	No leakage at the joints or mouth
Weight	< 20 grams
Dimensions	22mmID/15mmOD
Training Time	< 1 Hour
Biocompatibility	ISO 10933-1 (biological evaluation of medical devices) 1-134 ISO 18562-1.2,3,4 First Edition 2017-03 (Biocompatibility)
Accuracy	NIF Measurement Range ± 2cm H2O
Precision	At least three measurements within 20% of the highest value
Cost	~ $20 for 50 units

Appendix 6 – Quality Function Deployment (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")	Accuracy	Precision	Biocompatible	Weight	Dimensions	Cost	Product Life Span	Leakage	Training Time	Our Company	AirLife® Brand Misty Max 10™	Plastic Mouthpieces, Microgard, Disposable	Comfit™ Rubber Mouthpieces
				Column #	1	2	3	4	5	6	7	8	9				
				Direction of Improvement: Minimize (▼), Maximize (▲), or Target (x)	▲	▲	x	▼	x	▼	x	▼	▼				
				Quality Characteristics (a.k.a. "Functional Requirements" or "Hows")										Competitive Analysis (0=Worst, 5=Best)			
1	9	16.1	5.0	Single-use/disposable	▲	▲	⊖	O	▲	⊖	⊖	▲	▲	3	5	5	5
2	9	12.9	4.0	Tight seal	O	O	▲	O	O	▲	▲	⊖	O	5	3	4	3
3	9	6.5	2.0	Comfortable for most adult patients	▲	▲	O	⊖	O	▲	▲	O	▲	4	3	4	3
4	3	6.5	2.0	Does not inhibit patients' breathing capabilities	O	O	▲	O	▲	▲	▲	O	▲	4	4	4	2
5	9	12.9	4.0	Compatible with current NIF/VC testing procedures	⊖	O	O	O	⊖	O	O	O	⊖	5	5	2	2
6	9	12.9	4.0	Compatible with current NIF/VC testing equipment	⊖	O	O	O	⊖	O	▲	O	⊖	5	5	2	2
7	9	6.5	2.0	Compatible Material	▲	▲	⊖	O	▲	O	O	O	▲	3	4	4	4
8	9	9.7	3.0	Produces accurate and precise readings.	⊖	⊖	▲	▲	▲	▲	O	⊖	O	5	2	4	3
9	9	16.1	5.0	Affordable	▲	▲	O	O	O	⊖	⊖	▲	▲	4	2	2	3
				Target or Limit Value	< 30% difference	Repeat trials: measurements within 20% of the highest	ISO 10993-1 (biological evaluation of medical devices)	<100 g	22mmID/15mmOD	~$20	30 days	No leakage	< 1 Hour difference				
				Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)													
				Max Relationship Value in Column	9	9	9	9	9	9	9	9	9				
				Weight / Importance	422.6	267.7	377.4	319.4	377.4	422.6	416.1	371.0	351.6				
				Relative Weight	12.7	8.1	11.3	9.6	11.3	12.7	12.5	11.2	10.6				

Please open attached file below to view full QFD:

QFD (2).xlsx

Appendix 7 - Failure Modes Effect Analysis (FMEA)

Process Function	Potential Failure Mode(s)	Potential Effect(s) of Failure	Severity	Occurence	Detection	RPN
What is the process step and input under investigation?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements?)				
NIF Testing	The material used is not biocompatible with the patient	Discomfort, allergic reaction	3	1	5	15
NIF Testing	Device breaks off in the patients mouth	Choking hazard, inability for patient to perform test	4	1	4	16
NIF Testing	Size is incompatible with patient's mouthshape/teeth position	Discomfort, inability to receive accurate results	2	4	4	32
NIF Testing	Edges on mouthpiece are too sharp	Injure patient's mouth	2	1	1	2
NIF Testing	Patient is unable to bite down to form a seal	Inability to perform test	3	2	3	18
Implementation with Equipment During Testing	Improper seal in junction between device and machine	Inability to receive accurate results	3	2	1	6

Appendix 8 – Risk Priority Number (RPN) Scale

	Risk Priority Number					
Severity	1	5	10	15	20	25
	2	10	20	30	40	50
	3	15	30	45	60	75
	4	20	40	60	80	100
	5	25	50	75	100	125
		5	10	15	20	25
	Occurence x Detection					

Rating	Value Assigned
Acceptable	1-30
Investigate	31-60
Unacceptable	61-125

Appendix 9 - Risk Assessment

SEVERITY

Rating	Value Assigned	Level Description
Acceptable	1	Results in an inconvenience to patient or user Results in slight discomfort to the patient
Acceptable	2	Results in no measurement and requires alternative measurement device Results in temporary injury or impairment not requiring professional medical intervention
Investigate	3	Results in incorrect measurement that requires another measurement recording or alternative measurement device Results in injury or impairment to the patient or user requiring professional medical intervention
Unacceptable	4	Results in permanent impairment, life-threatening impairment, or life-threatening injury
Unacceptable	5	Results in patient death

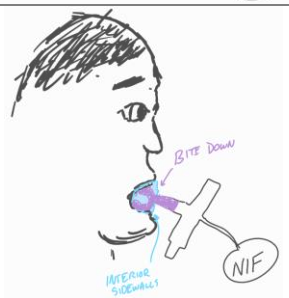
OCCURENCE

Rating	Value Assigned	Level Description
Acceptable	1	Rare/Never
Acceptable	2	Not very likely to occur
Investigate	3	Sometimes likely to occur
Unacceptable	4	Very likely to occur
Unacceptable	5	Almost certain to occur

DETECTION

Rating	Value Assigned	Level Description
Acceptable	1	Design control will almost certainly detect cause mechanism and subsequent failure
Acceptable	2	High likelihood the design control will detect cause mechanism and subsequent failure
Acceptable	3	Moderate likelihood the design control will detect cause mechanism and subsequent failure
Investigate	4	Low likelihood the design control will detect cause mechanism and subsequent failure
Unacceptable	5	Design control will not detect cause mechanism and subsequent failure

Appendix 10 – Preliminary Design Concept Sketches

Concept	Design	Preliminary Sketch
Concept 1	External Facemask, held by straps	
Concept 2	Intraoral Mouthpiece, internal sidewall seal	
Concept 3	Intraoral Mouthpiece, external sidewall seal	

Appendix 11 – Design Concept Down Selection Matrix

	User Needs/Customer Requirements															
Concept	*cost, affordability*	*produces accurate and precise readings*	*biocompatible material*	*compatibility with NIF equipment*	*minimizes training time for clinicians*	*does not inhibit breathing capabilities*	*comfortable for most adult patients*	*tight seal, no leakage*	*single-use, disposable*	**Weighted Score**	**Final Rank**	*complete in time?*	*meet budget?*	*prototype fabrication method*	*mass manufacturing method*
Requirement Weight/100	*16.1*	*9.7*	*6.5*	*12.9*	*12.9*	*6.5*	*6.5*	*12.9*	*16.1*	*Score/10*					
External Facemask, held by straps	7	7	-	10	4	9	4	7	7	6.49	3	Yes	Yes	3D Resin Printing	Injection Molding
Intraoral Mouthpiece, internal sidewall seal	**9**	**9**	**-**	**10**	**9**	**8**	**8**	**9**	**10**	**8.58**	**1**	**Yes**	**Yes**	**3D Resin Printing**	**Injection Molding**
Intraoral Mouthpiece, external sidewall seal	9	7	-	10	8	8	6	8	10	8.00	2	Yes	Yes	3D Resin Printing	Injection Molding

Appendix 12 – Material Decision Matrix

	`	Requirements							
Material	*Manufacturing Method*	*meets ISO 10933-1*	*affordability*	*pace of mass manufacturing*	*able to be sterilized*	*resistant to critical damage upon bite*	*flexibility for insertion*	**Weighted Score**	**Final Rank**
Weight/100	-	*25*	*17.5*	*17.5*	*10*	*15*	*15*	*Score/10*	
50A Resin	3D Printing	0	4	4	10	5	9	4.50	4
80A Resin	3D Printing	0	5	4	10	9	8	5.13	3
TPU	**Injection Molding**	**10**	**8**	**8**	**10**	**8**	**9**	**8.85**	**1**
Medical Silicone	Injection Molding	10	6	8	10	9	9	8.65	2

Appendix 13 – Project Expenses

I. Bill of Materials

Bill of Materials					
Item	**Part #**	**Description**	**Qty**	**Unit Price**	**Total**
Resin Tank	RT-F3-02-01	Form 3 Resin Tank V2.1	2	$149.00	$298.00
50A	RS-F2-ELCL-01	Elastic 50A Resin 1 L	1	$199.00	X
80A	RS-F2-FL80-01	Flexible 80A Resin 1 L	1	$199.00	X

II. Purchase Request Form

PURCHASE REQUEST FORM

Try to provide as much of the information below as possible.
Try to consolidate orders with one vendor. Amazon or McMaster Carr are preferred vendors. *Use ASIN numbers not Amazon Links*
NOTE: All purchases need *justification* as to what part is used for, did you do a comparitive evaluation, and are you at the stage that buying parts is reasonable, that is, did you do your design? ! Explain this in the box below:

These resin tanks will be used to replace the current resin tanks. The current tanks need replaced due normal wear and tear.

Vendor: Form Labs
Date Submitted: 2/24/2023
Address 1: Attn: Steve Paterson, University of Akron, 185 E Mill St, ASEC West 275, Akron, Ohio 44325
Requestor's Name: Rebekah Starkey
Project Name: Facemasks for NMD
Phone: Stephen Paterson: 330-972-6677
Requestor email address: rks48@uakron.edu
Fax:
Should this order be faxed?
Requestor Phone No.: 330-877-0821
Special ordering instructions:
Placed order with:
Invoice Terms:
Date
Shipping Instructions:
Budget/Center # to be charged:
Staff

Catalog No.	Description and why this part is needed. Did you do shop around? Use more than one line or separate page if needed.	Unit Price	Qty.	Discount	Total
RT-F3-02-01	Form 3 Resin Tank V2.1 https://formlabs.com/store/form-3-resin-tank/	$149.00	2		$298.00
					$0.00

III. Material Cost Breakdown

3D printed part: 20,021.6 mm^3
1 mm^3 = 1.0E-6 L
1 L Flexible 80A Resin is $199.00
Calculations:

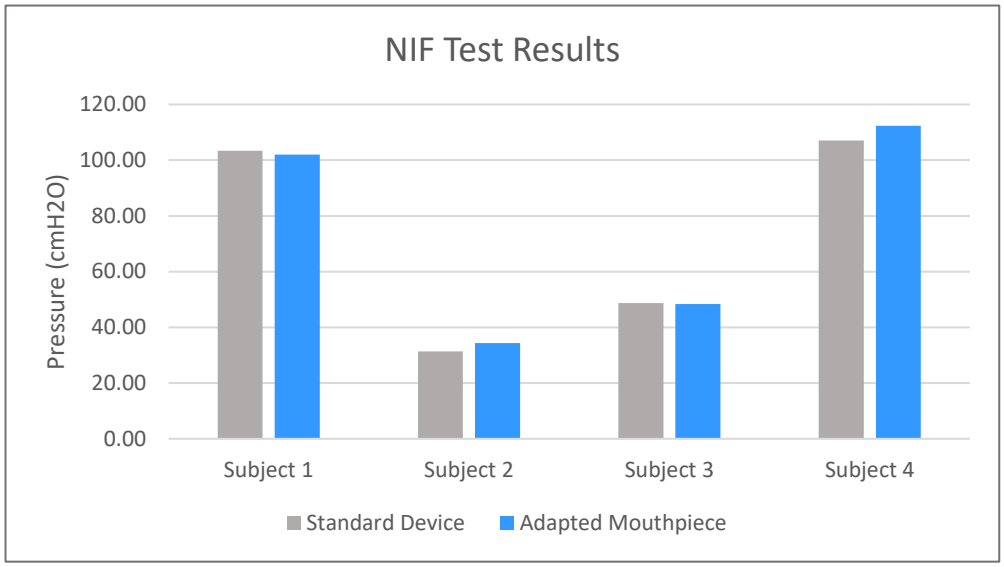
(20,021.6 mm^3) / (1.0E^ (-6) L)/(1 mm^3) = 0.02 L
(1 L) / (0.02 L) = 50 parts for $199.00
$3.98 per print

Appendix 14 - Verification Report

I. Report

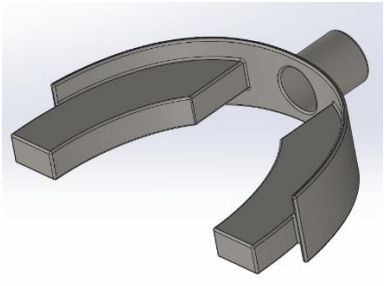
Rev D.								
Verification Procedure Number	**Test Name**	**Test Method**	**Acceptance Criteria**	**Prototype #**	**Test Date**	**Tester**	**Pass/ Fail**	**Comments**
1.1	Accuracy	Test	Within ±3.0% for accuracy, linearity, and repeatability ISO 26782, Section 7, Annex C	Alpha	4/11/23	CT, AP, RS, MD	Pass	NIF Test Results Below – were within tolerance
1.2	Precision	Test	At least three measurements within 20% of the highest value	Alpha	4/11/23	CT, AP, RS, MD	Pass	NIF Test Results below – within 20% of the highest value
1.3	Seal / Leakage	Test	No leakage at the joints	Alpha	4/14/23	CT	Pass	No leakage around the mouthpiece
1.4	Dimensions	Inspect	22mmID/ 15mmOD	Alpha	4/11/23	AP	Pass	Dimensions were within the allowed tolerance
1.4	Weight	Inspect	20 (+2/-7) g	Alpha	4/11/23	AP	Pass	
1.5	Biocompatibility	Analysis	Material Selection biocompatible	Alpha	4/13/23	RS, AP	Fail	80A Resin used for the prototyping is not biocompatible. A different material would be used for large-scale production.
1.6	Strength	Analysis	Withstand at least 120-160 PSI	Alpha	4/3/23	MD	Pass	ANSYS simulation run
1.7	Material Hardness	Analysis	Material Selection 75-85 durometer	Alpha	4/3/23	CT, RS	Pass	Literature research shows a hardness of 80
1.7	Fit / Compatibility	Inspect/ Demonstration	Survey: The majority find it as comfortable or more comfortable than the competing mouthpiece	Alpha	4/13/23	CT, AP, RS, MD	Pass	Team members completed the NIF test and found the mouthpiece to be more comfortable than the current solution
1.8	Training Time	Analysis	< 1-hour difference	Alpha	4/11/23	AP	Pass	The mouthpiece can directly replace the current mouthpiece – no additional training is required
1.9	Cost	Analysis	~ $20 for 50 units	Alpha	4/3/23	RS	Fail	80A Resin used for prototyping is not a cost-effective material for large-scale production. A different material would be selected for production.

II. NIF Results Comparison Using Standard and Adapted Mouthpiece

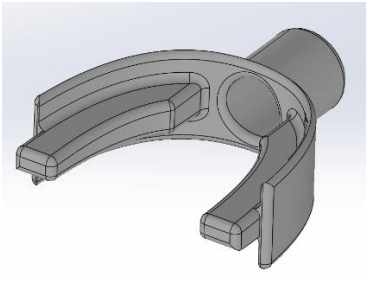


Appendix 15 - SolidWorks Designs

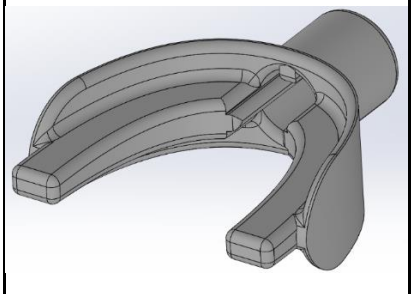
Revision 1



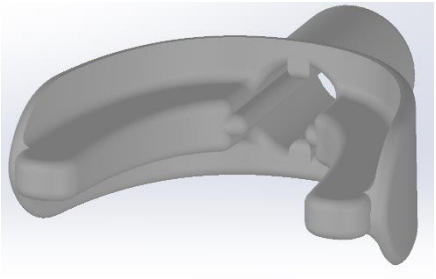
Revision 2

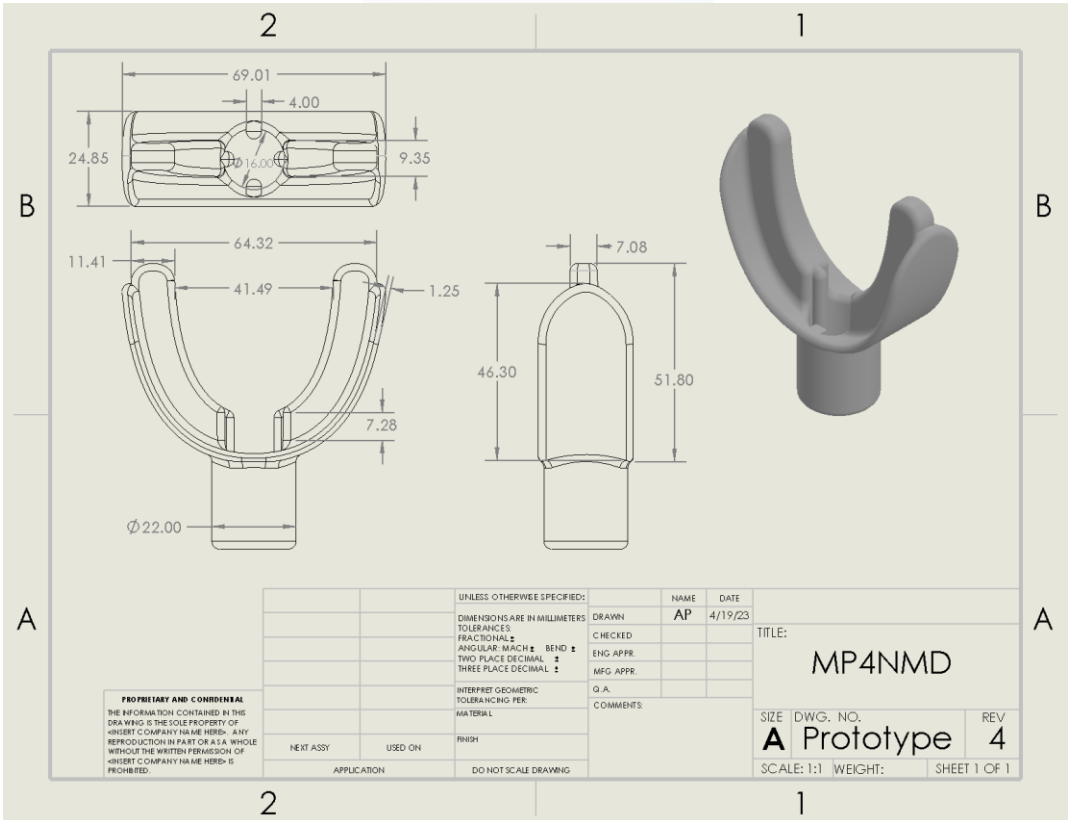


Revision 3



Revision 4

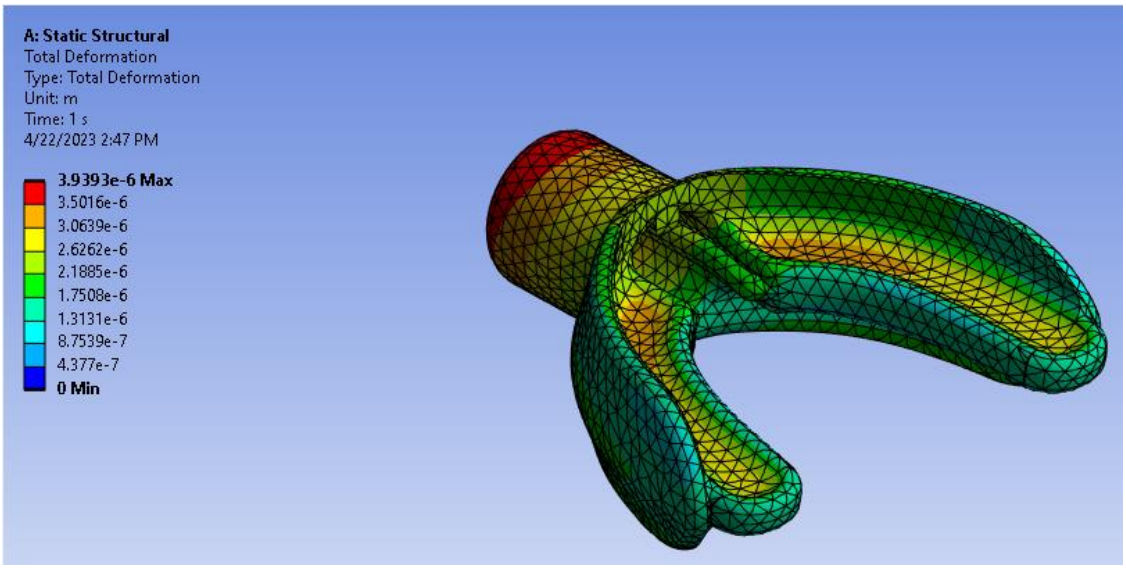




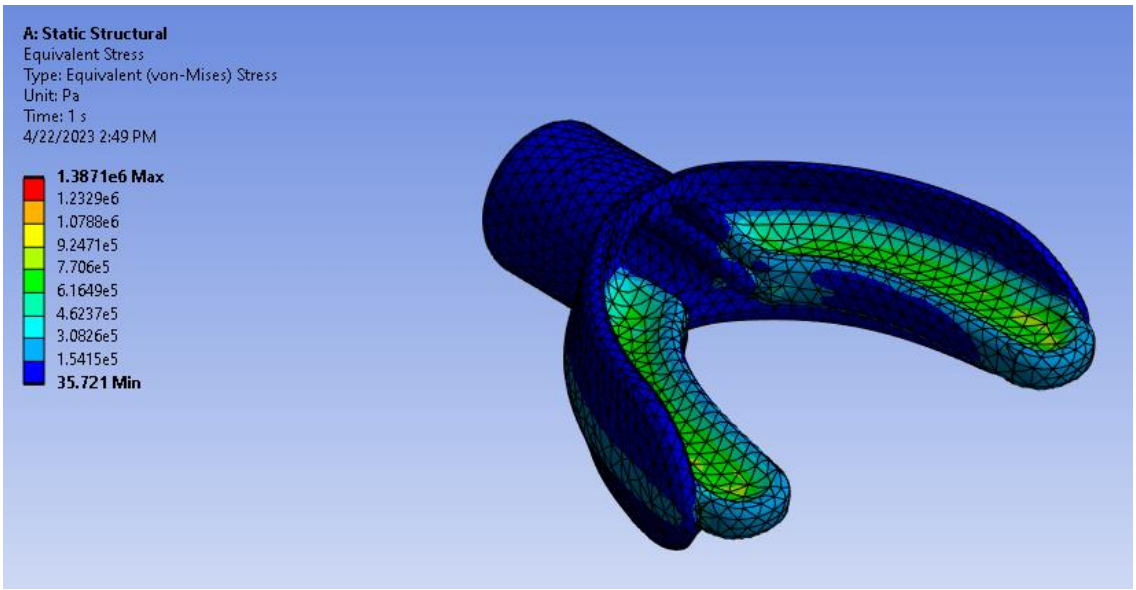
Appendix 16 - Ansys Simulations using mechanical properties of Thermoplastic Polyurethane (TPU)

Final Prototype – Ansys Simulations

Total Deformation



Equivalent Stress



Appendix 17 – Validation Report

Rev. B							
Test Method	**Test Name**	**Acceptance Criteria**	**Prototype**	**Test Date**	**Tester**	**Pass/Fail**	**Comments**
Analysis	Single Use / Disposable	Material Analysis demonstrates the ability to be produced as sterile and is comparably easy to dispose of	Alpha	4/20/23	CT	Fail	80A is not the final material for production and an acceptable material will be chosen
Test	Tight Seal	Passes Leakage testing from verification and 3/4 can make a seal	Alpha	4/11/23	CT, AP, MD, RS	Pass	Passed verification and 100% of the small sample of subjects were able to make a seal
Test	Comfortable	Survey: 75% found it comfortable	Alpha	4/11/23	CT, AP, MD, RS	Pass	A small sample of subjects found it comfortable; Future considerations for a bigger/more diverse sample
Test	Normal Breathing	Survey: 75% found it natural to breathe with	Alpha	4/11/23	CT, AP, MD, RS	Pass	A small sample of subjects found it easy to breathe with; Future considerations for a bigger/more diverse sample
Test	Compatibility with equipment	Fit Testing: mouthpiece fits into the current device set-up without additional materials needed and does not fall out during the procedure	Alpha	4/15/23	AP	Pass	Mouthpiece directly attached to existing equipment without extra materials being needed
Test	Compatibility with procedure	Fit Testing: mouthpiece can be used as a direct replacement for the current mouthpiece used	Alpha	4/15/23	AP	Pass	Mouthpiece required little to no extra steps in the procedure of the current NIF test methods
Analysis	Material	Material Analysis demonstrates biocompatibility and ability to withstand bite force	Alpha	4/3/23	MD	Fail	80A Resin is not final material; replacement material to be selected
Test	Accurate and Precise	Within ±3.0% for accuracy, linearity, and repeatability ISO 26782, Section 7, Annex C and At least three measurements within 20% of the highest value should be obtained	Alpha	4/11/23	AP	Pass	Passed verification testing for both accuracy and precision; Used by RT staff to complete testing with AP
Analysis	Affordable	Lower cost or no significant difference between the new mouthpiece and the current solution	Alpha	4/15/23	CT, RS	Fail	Prototype: $199 for 50 units vs Competitor: $20 for 50 units