Team Lead: Benjamin Diaz

Fiscal Lead: Rachel Lee

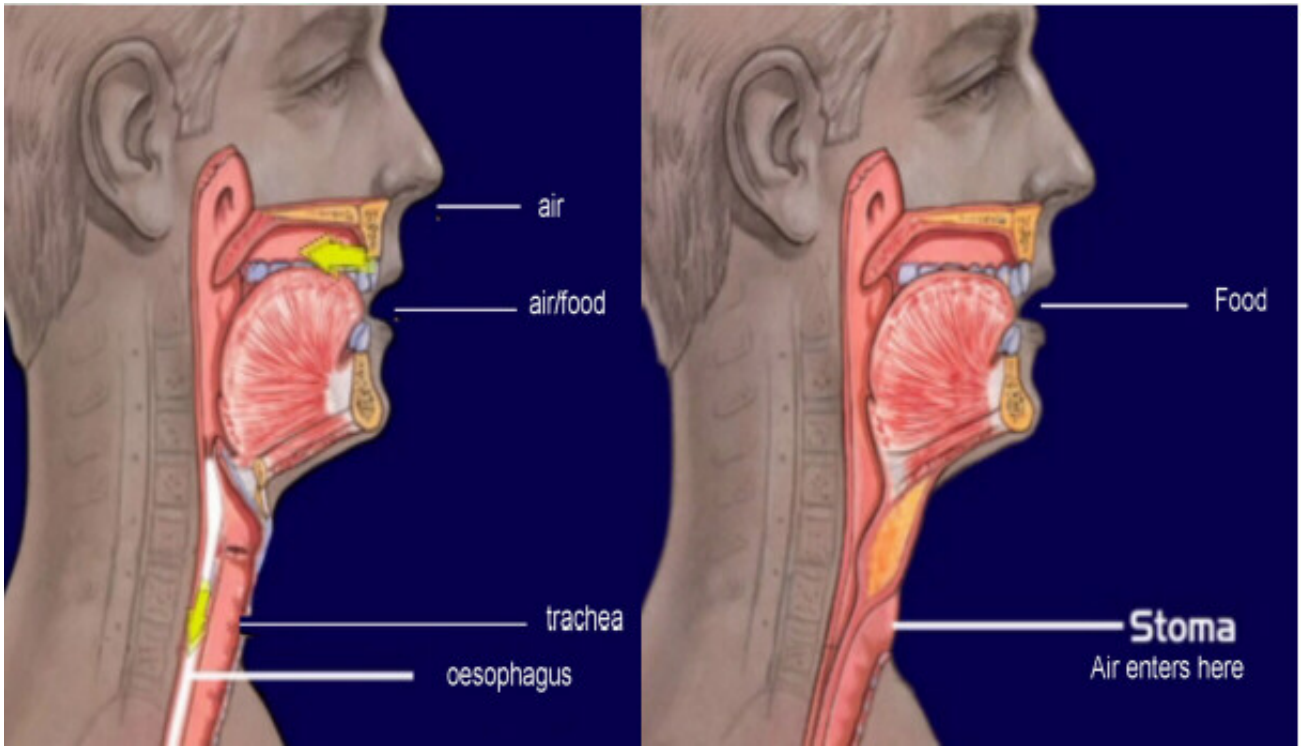
Team Members: Catherine Caicedo, Autumn Monsees, Luis Cuadros Lamas

Advisor: Dr. Venkat K. Chivukula

Background Info and Statistics

Laryngectomy

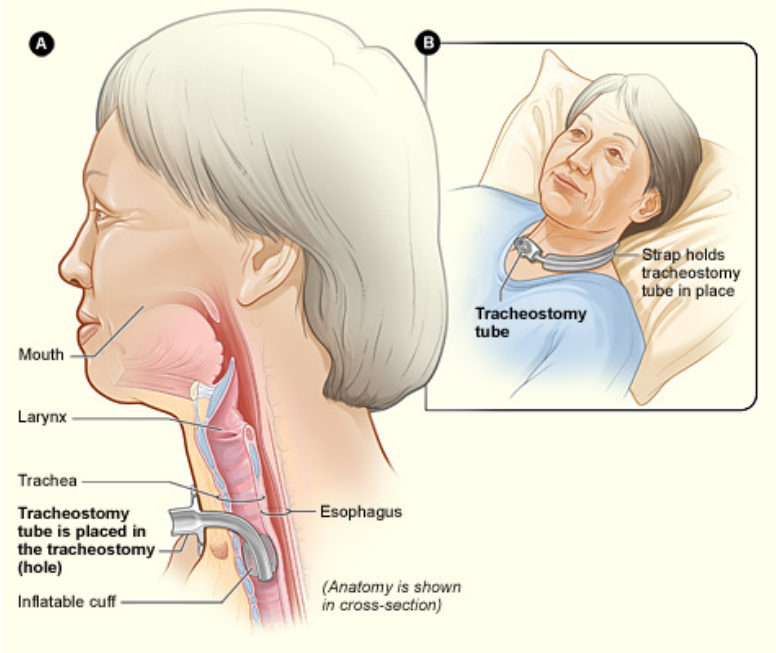
Figure 1. Laryngectomy Diagram



* 10,000 annually in the U.S
* Patients left permanently unable to speak
* Become reliant on speech aid devices like the electrolarynx

Tracheostomy

Figure 2. Tracheostomy Diagram



* Over 100,000 annually performed in the U.S.
* Patients left temporarily unable to speak but electrolarynxs have shown favorable results for them
* Current handheld electrolarynxs have a low functional compatibility with these patients

Project Impact

Social Impact

- Greatly improve the lives and communication skills of over a total of 110,000 people annually
- The handsfree design has strong potential implementations in hospital settings to improve patient to doctor communication in Tracheostomy patients which is currently an open spot in healthcare

Echo Lynx Design Specifications

Heading	Examples
1. Geometry	2-4 cm x 2-4 cm x 42 cm
2. Kinematics	Produce ~120 Hz for vibrations
3. Forces	Vibrational outward force toward the user's neck
4. Materials	Exterior casing: Pitch, Volume, and Power Controls TPU, PLA, Flexible and Hard Resin
5. Signals	On/Off Switch, Dynamic volume, and pitch control
6. Safety	Electrical insulation, heat insulation, and biocompatible materials for the neckband
7. Ergonomics	Sit comfortably on the neck of the user, easily manipulated dynamic controls of volume, pitch, and power.
8. Production	3D printed casing
9. Quality control	Abide by material standards and FDA specifications
10. Operation	~120 Hz
11. Maintenance	Regular cleaning of the device casing and around the stoma
12. Costs	~$250
13. Schedules	Spring 2023

Components list

3D print Material Heat Resistance (Celcius):

PLA= 60-110C, Resin= 200-300C.

Motor Design: Pot magnet, Magnet Holder (PLA), Coil Piston (PLA), Flex Damper (Elastic 50A Resin), Supporting Ring, Motor Lid (PLA), contact disk (PLA).

Hardware Design: Digital Potentiometer, Bluetooth Chip, 9V Battery, Waveform Generator, Arduino Nano.

Casing Design: Soft Resin (Elastic 50A Resin) for the casing components, PLA for the Lid design, and cable runner.

Component (Motor Design)	Description
Pot Magnet	Ensures magnetic polarity in one direction
Magnet Holder	Keep the pot magnet in place
Coil Piston	Coil inductor to produce magnetic field
Flex Damper	Support for the piston, contact disk, and ring
Supporting Ring	Protect motor components from damaging
Motor Lid	Holds component to avoid unnecessary motion
Contact Disk	Coil inductor repels towards this component

Component (Hardware Design)	Description
Bluetooth Chip	Establishes wireless connection
Arduino Nano	Provides vibration controls
Digital Potentiometer	Digital interference with waveform generator
Waveform Generator	Controls amplitude and pitch
9V Battery	Power Supply with heating range from 20 to 60C

Additional Diagrams and Design Features

Circuit Diagrams

Figure 3. Echolynx Body Circuit Diagram

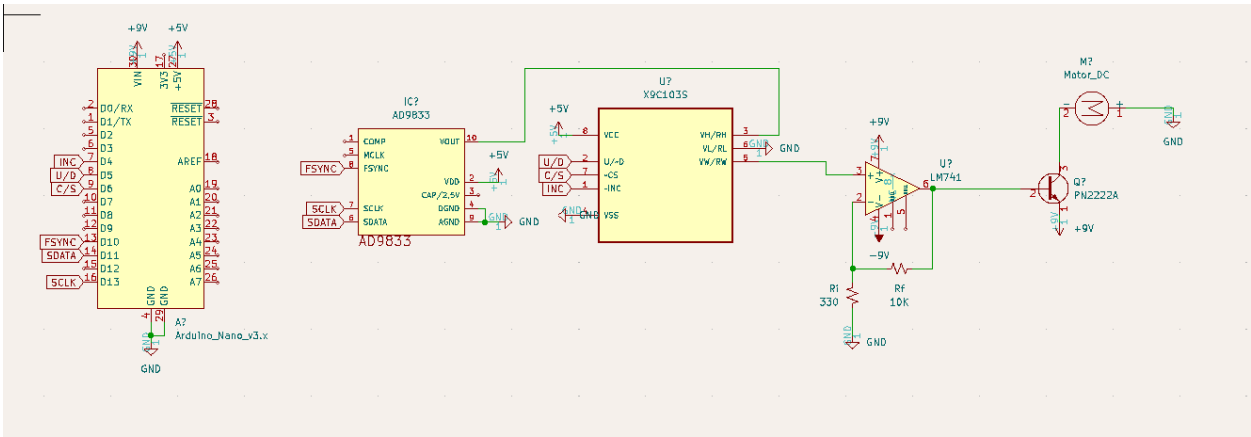
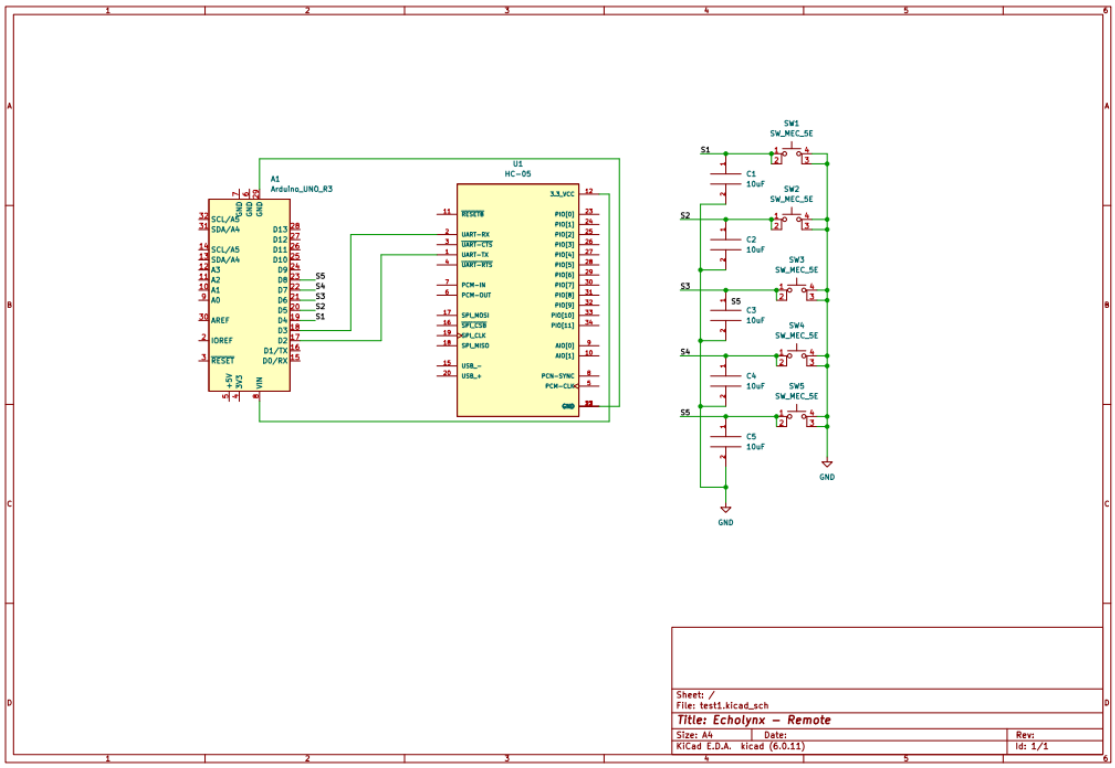


Figure 4. Echolynx Controller Circuit Diagram



Sectional Breakdown

Figure 5. Breakdown of Motor Design

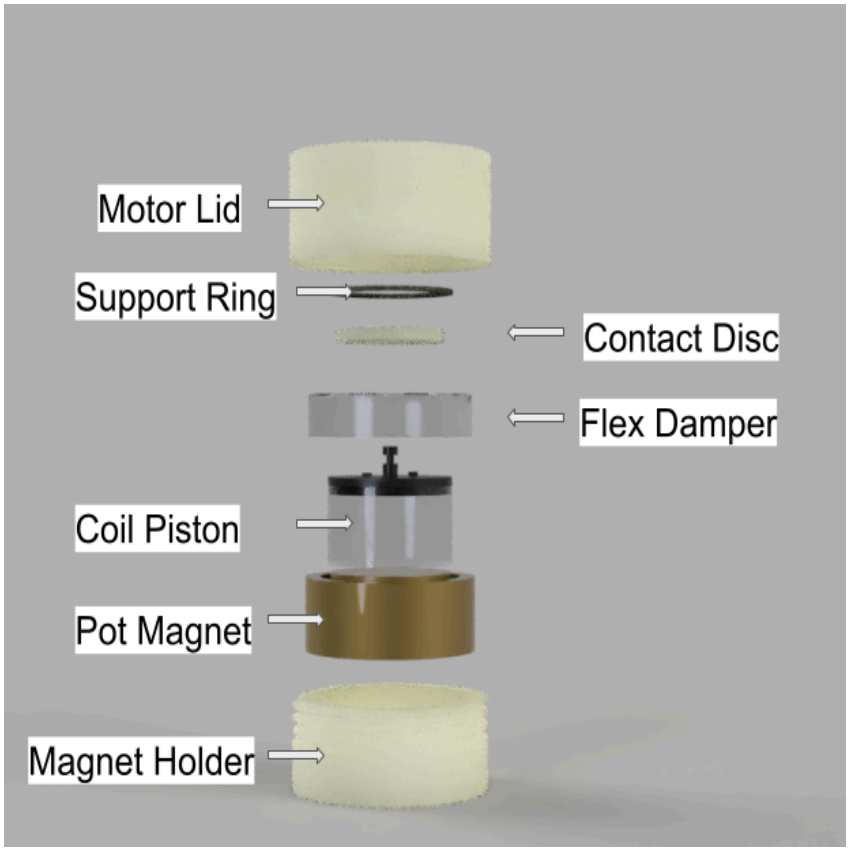


Figure 6. Breakdown of Components in Casing

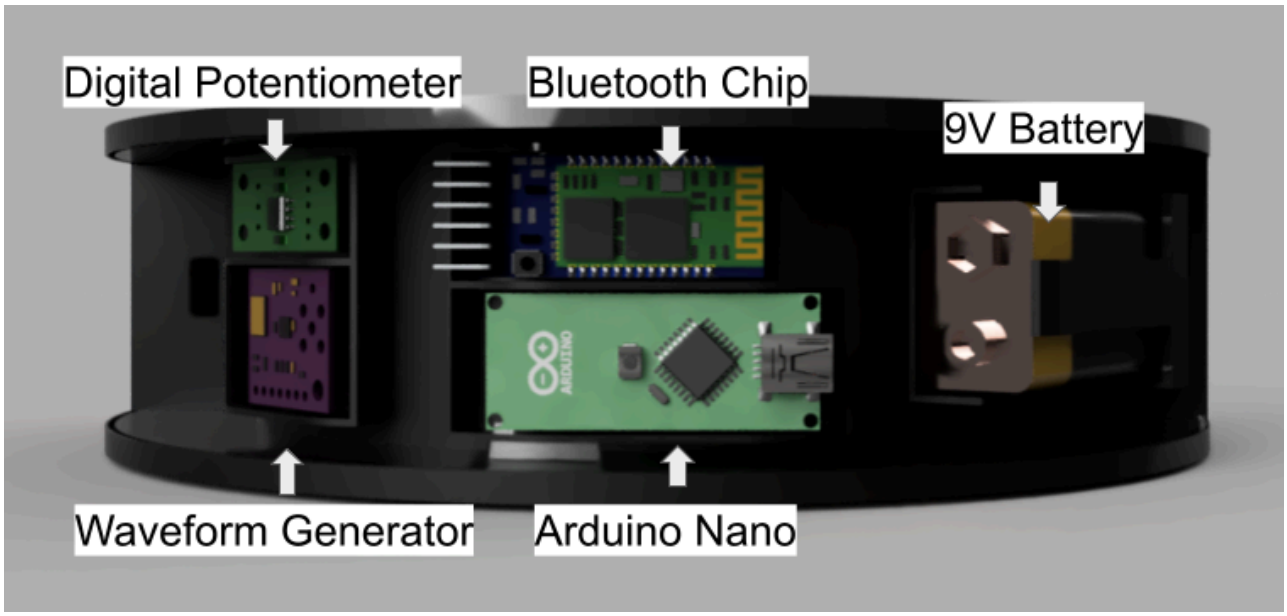
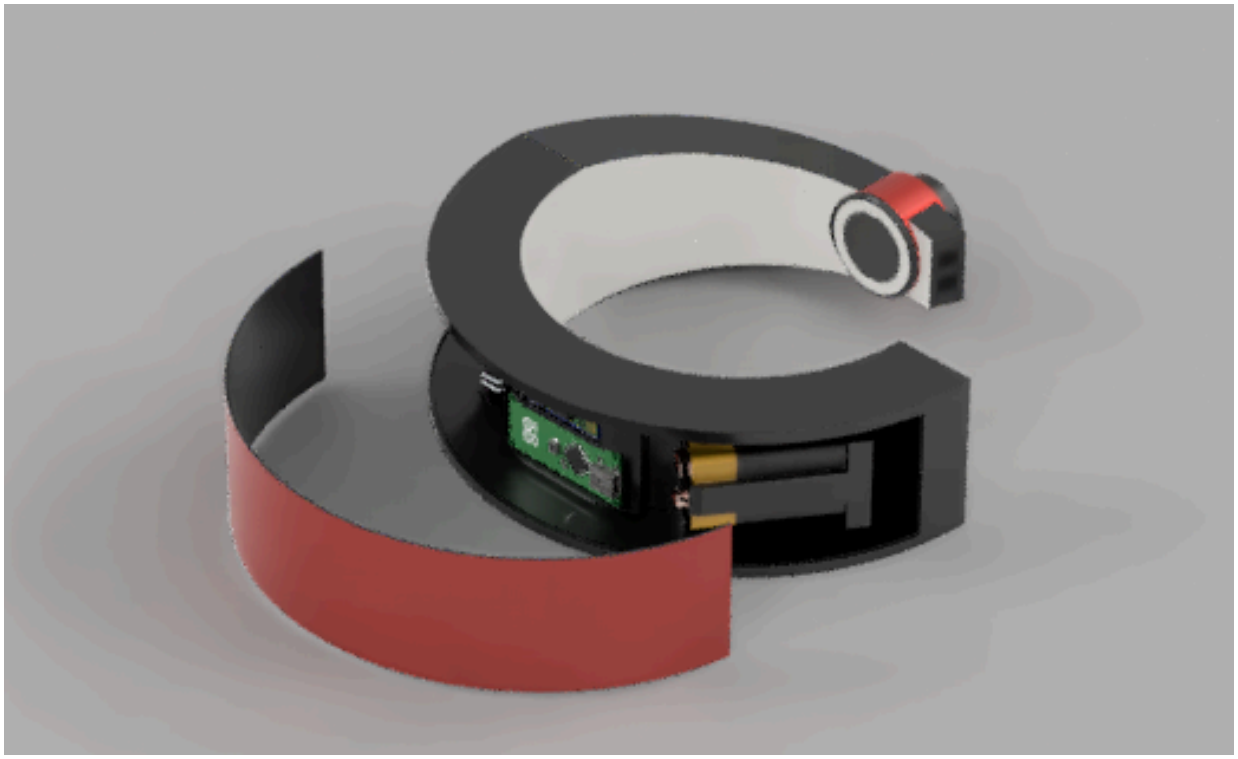


Figure 7. Full Body Rendering



Testing

Response time testing

- Performed to confirm and adequate response time for setting inputs
- Theoretical response time based on hardware assessment is 1 ms/input
- Inputs from the controller initiate a timer on the arduino as the information relays to the secondary bluetooth unit which sends a response to stop the timer.
- These times are then halved to match a one way response and analyzed to confirm data

Current theoretical value- 1 ms/input, based on a 9600 baud rate (bytes/sec) and an approximate 10 bytes per input. (10 bytes)/(9600 bytes/sec) = 0.00104 sec = 1.04ms

Operating time and safety testing

- Performed to ensure the device operates for expected period of time in a safe manner
- Device is left operating for an extended period of time with 30 min intervals where the system is checked for signs of overheating
- If the device overheats, the time is recorded and the device is turned off until it cools down
- Once cooled, the device is turned on again until it overheats or ceases to function
- The time periods will be used to assess safe extended functioning time and total functioning time

Convenience Rating

- Test participants will be drawn from individuals who currently use electrolarynx devices or any other similar speech aid device
- These individuals will record lines from the grandfather passage to record every potential phonetic sound in the english language
- Participants will then fill a survey comparing their experience with a standard electrolarynx with the echolynx
- Survey data will then be analyzed to ensure statistical significance
- The recordings will then be used in an audibility test to ensure listeners can adequatelys hear the participant’s voice to further evaluate the functionality of the device

Data

Response Time Test

Figure 8: Response Time Vol Up

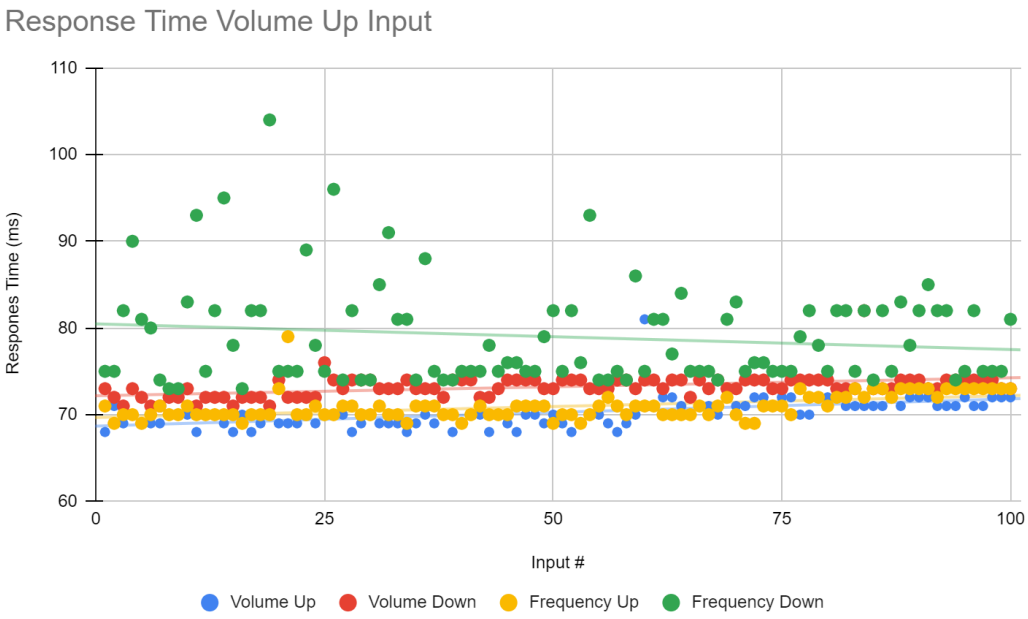


Figure 9: Average Response Time

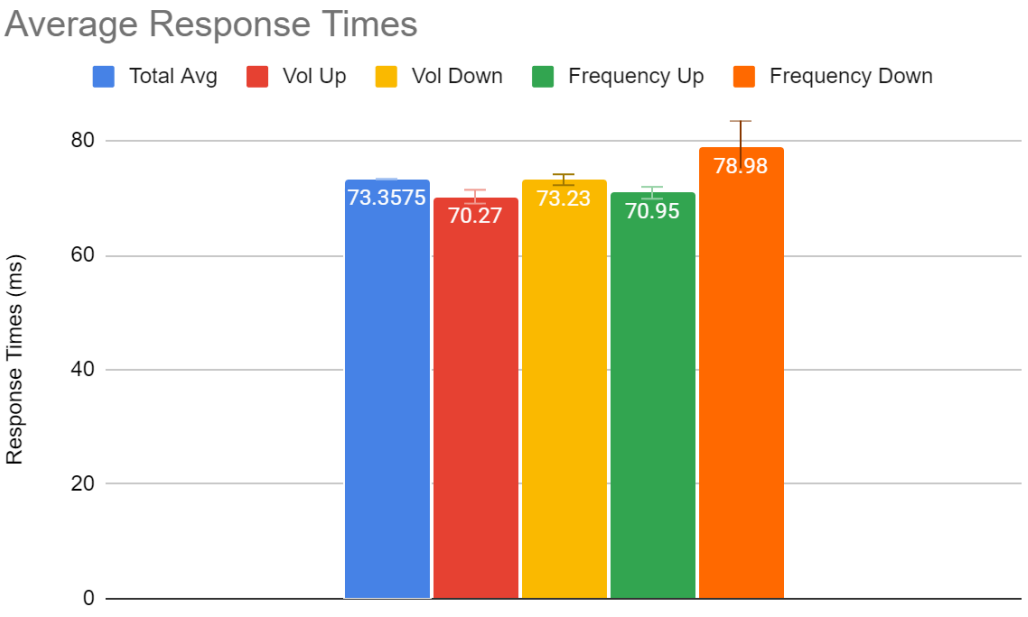


Table 1: Response Accuracy

Command	Count	# Correct	% Correct
Total	400	400	100.00%
<VOL_UP>	100	100	100.00%
<VOL_DOWN>	100	100	100.00%
<FREQ_UP>	100	100	100.00%
<FREQ_DOWN>	100	100	100.00%

Table 2: Response Time Statistics

Mean RT	Median RT	Standard Dev	25th Percentile	75th Percentile	IQR	# Outliers
73.3575	72	4.67700542	70	74	4	0
70.27	70	1.716556337	69	71	2	0
73.23	73	1.301553074	73	74	1	0
70.95	71	1.47281768	70	72	2	0
78.98	76	5.823983849	75	82	7	0

Functionality Time

Figure 10: Supply voltage drop of Echolynx

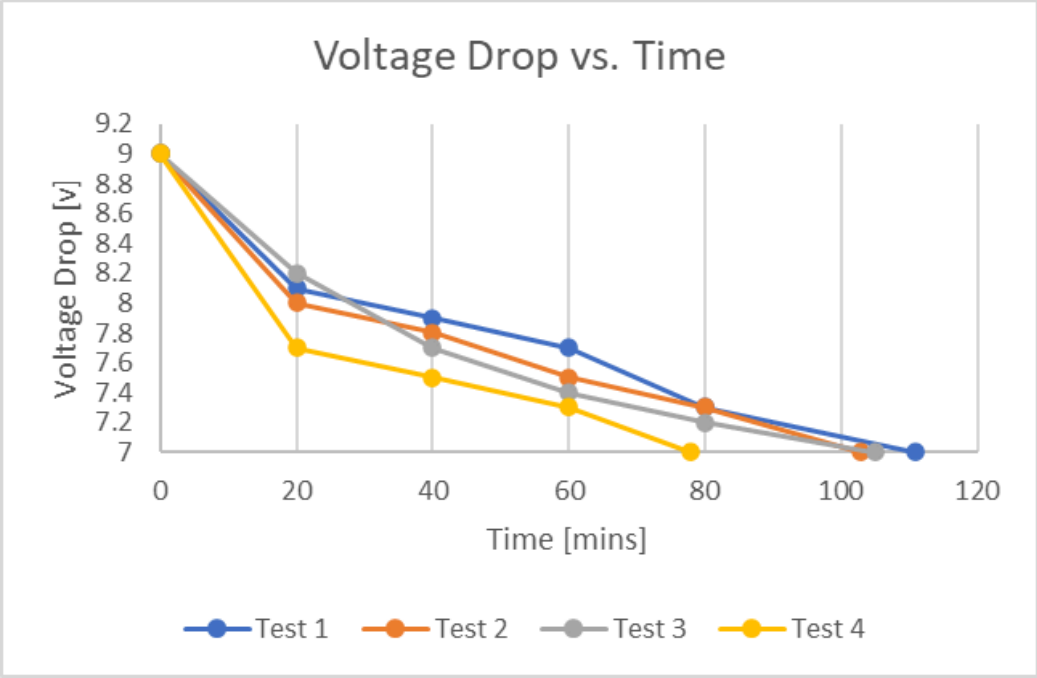


Figure 11: Supply voltage drop in current market electrolarynx devices

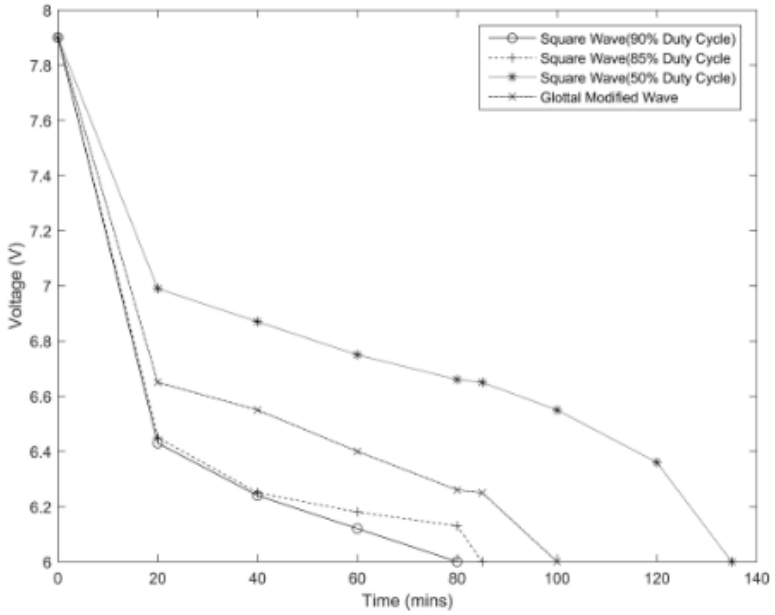
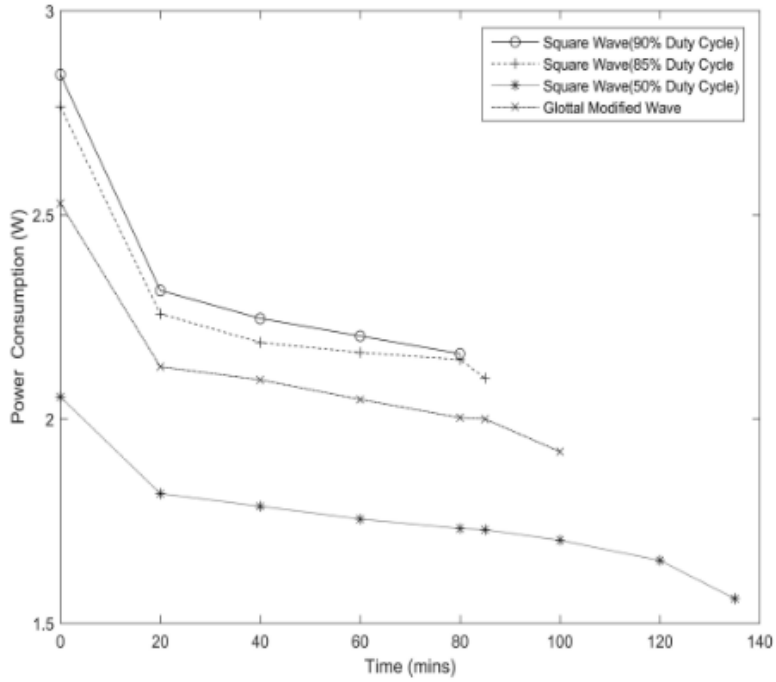


Figure 12: Power consumption of standard market electrolarynx



Cost Breakdown

Component	Price
Arduino Nano (2x)	$49
Bluetooth HC-05 (Transmitter and Receiver)	$12.99
Copper Wire	$0.95
Wire Jumpers	$6.89
Neodymium Pot Magnet	$44.69
Silicone Sealant	$6.58
AD9833 Waveform Generator	$12.99
X9C103s Digital Potentiometer	$10.99
9V Battery clips	$2
9V Battery	$5
FDM	$21.99
PLA	$19.59
Flexible Resin	$24.64
Total	$218.30

Market Impact

- Electrolarynx market is valued at $409.5 million in 2021 and is projected to reach $703.0 million in 2031
- High costs greatly hinder the growth of the electrolarynx market
- The Echolynx would hold a unique position in the market due to its handsfree design which should offer substantial opportunities for growth

Aspects	Details
Market Size By 2031	USD 703 million
Growth Rate	CAGR of 5.5%
Forecast period	2021 - 2031
Report Pages	190
Type	• Built-in Battery • External Battery
Application	• Laryngeal Cancer • Speech Rehabilitation
End user	• Hospitals • Ambulatory Surgical Centers • others
By Region	• **North America** (U.S., Canada, Mexico) • **Europe** (Germany, France, UK, Italy, Spain, Rest of Europe) • **Asia-Pacific** (Japan, China, Australia, India, South Korea, Rest of Asia-Pacific) • **LAMEA** (Brazil, Saudi Arabia, South Africa, Rest of LAMEA)
Key Market Players	Ultravoice Limited, Inhealth Technologies, Griffin Labs, Servona GmbH, Labex Trade, AMPLICORD DI GABRIELLA SALVATORE, Romet Limted, Nu-Vois, LLC, Andreas Fahl Medizintechnik - Vertrieb GmbH, Atos Medical AB

Echo lynx

December 4, 2022
U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-00002
RE:

To Whom It May Concern,

Echolynx, submits this Notification of Intent to market a modification to the NU-VOIS BATTERY POWERED ARTIFICIAL LARYNX by MOUTAIN PRECISION MFG. LTD. CO. as described within this Traditional 510(k) Device Modification Premarket Notification (21 CFR 807.95(e)). The device currently marketed was cleared by the FDA under K934483 on 3/16/1994.

Trade/Device Name: *NU-VOIS BATTERY POWERED ARTIFICIAL LARYNX*
Regulation Number: 874.3375
Device Classification Name: Larynx, Artificial (Battery-Powered)
Device Classification: Class 1
Product Code: ESE
Panel: Ear Nose & Throat

This 510(k) submission has been formatted in accordance with the following Guidance Document: "Format for Traditional and Abbreviated 510(k)s" issued on September 13, 2019.
The modifications to the existing device are as follows"

- The fundamental functions and characteristics of the *Echolynx* device are similar to those in the NU-VOIS BATTERY POWERED ARTIFICIAL LARYNX. Both devices use similar mechanics to produce vibrations applied to the user's neck. However, the components and design of the device are different.

The intended uses of the device are as follows:

- The *Echolynx* uses vibrations produced by a motor system in the device which are directed toward the user's neck to replicate the user's voice. The device uses a wireless design to allow for hands-free communication.

Regards,
Rachel Lee
Group Member, Echo Lynx
E-mail: rlee2019@my.fit.edu

Date Prepared: 12/04/2022

Name of Device:	*Echolynx*
Classification Name:	Larynx, Artificial (Battery-Powered)
Regulatory Class:	Class 1
Product Code:	ECH
Contact Person:	Rachel Lee 150 W. University Blvd, Melbourne, FL 32901 Phone: (856) 375 3687 Email: rlee2019@my.fit.edu
Trade/Device Name:	*NU-VOIS BATTERY POWERED ARTIFICIAL LARYNX* K934483
Reason for 510(k) Submission	New medical device intended for US commercial market.

I. DEVICE DESCRIPTION

Similar to the predicate device, NU-VOIS BATTERY POWERED ARTIFICAL LARYNX, the *Echolynx* device uses mechanisms to produce a vibrational surface applied to the user's neck allowing for the passage of vibrations and the production of sound. *Echolynx* is composed of a vibrational unit attached to a neckband and a wireless control unit situated on the user's wrist. Since the devices are located close to the user's body, both the vibrational neck unit and wireless control unit include heat and electrical insulation to maintain the user's safety. The wireless control unit includes an adjustable wrist strap and can be worn on whichever wrist is most comfortable for the wearer. The hardware components of the *Echolynx* are listed as following:

1. Microcontroller Unit (Arduino Nano)
2. Digital Potentiometers
3. AD9833 Signal Generator
4. Neodymium Magnet

IRB Approval

Florida Institute of Technology
Institutional Review Board

Notice of Expedited Review Status
Certificate of Clearance for Human Participants Research

Principal Investigator:	Benjamin Diaz
Date:	March 22, 2023
IRB Number:	23-043
Study Title:	Echolynx

Your research protocol was reviewed and **approved** by the IRB Chairperson. Per federal regulations, 45 CFR 46.110, your study has been determined to involve no more than minimal risk for human subjects. Federal regulations define minimal risk to mean that the probability and magnitude of harm are no more than would be expected in the daily life of a normal, healthy person.

Unless you have requested a waiver of consent, participants must sign a consent form, and the IRB requires you give each participant a copy of the consent form for their records. For online surveys, please advise participants to print out the consent screen for their files.

All data, which may include signed consent form documents, must be retained in a locked file cabinet for a minimum of three years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained on a password-protected computer if electronic information is used. Access to data is limited to authorized individuals listed as key study personnel.

Prompt reporting to the IRB is required in the following conditions:

- Procedural changes increasing the risk to participants or significantly affecting the conduct of the study
- All adverse or unanticipated experiences or events that may have real or potential unfavorable implications for participants
- New information that may adversely affect the safety of participants or the conduct of the study.

This study is approved for one year from the above date. If data collection continues past this date, a Protocol Renewal Form must be submitted.

References

1) Throat Cancer Statistics: Cases of Throat Cancer per Year." *Throat Cancer Statistics | Cases of Throat Cancer Per Year*, https://www.cancer.org/cancer/laryngeal-and-hypopharyngeal-cancer/about/key-statistics.html.
2) "What Is a Tracheostomy?" *Sierra Care*, 3 May 2021, https://www.sierracare.com/what-is-a-tracheostomy/#:~:text=It%20is%20actually%20a%20common,the%20United%20States%20every%20year.
3) *The Use of the Electrolarynx in Patients with Temporary Tracheostomies ...* https://pubs.asha.org/doi/abs/10.1044/jshd.3803.335.
4) "Electrolarynx Market Size, Share: Statistics Report - 2031." *Allied Market Research*, https://www.alliedmarketresearch.com/electrolarynx-market-A15637.
5) Madhushankara, M., et al. "A Design of Low Power Electrolarynx with Glottal Modified Source." *Journal of Engineering Science and Technology Review*, vol. 11, no. 6, 2018, pp. 77–84., https://doi.org/10.25103/jestr.112.11.
6) What's The right resin for sla? 3D printing materials compared. Hubs. (n.d.). Retrieved December 13, 2022, from https://www.hubs.com/knowledge-base/sla-3d-printing-materials-compared/
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