RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	EMG Voice Restoration

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: EMG Voice Restoration

PROTOCOL NO.: R44DC017097
IRB Protocol #20182089

SPONSOR: Altec Inc.

INVESTIGATOR: Gianluca De Luca, MSc
23 Strathmore Rd
Natick, Massachusetts 01760
United States

SITE(S): Altec Inc.
23 Strathmore Rd
Natick, Massachusetts 01760
United States

STUDY-RELATED PHONE NUMBER(S): **Principal Investigator:** Gianluca De Luca, MSc
508-545-8202 (Office Hours)

Study Coordinators:
Serge H. Roy, Sc.D., P.T.
508-545-8235 (Office Hours)

Jennifer M. Vojtech, Ph.D.
508-545-8208 (Office Hours)

SUB-INVESTIGATOR: Jennifer M. Vojtech, Ph.D.

Subject Name: _____

This consent form may contain words that you do not understand. Please ask the study investigator or study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE: The purpose of this research is to develop a device that can be used for non-verbal communication based on the electrical signals that emanate from the speech muscles of the face and neck. The study device is intended to non-invasively record and process the electrical signals

from these muscles during non-auditory speech (silently mouthing a word or phrase). Such a device may be useful for persons with speech disorders that result from a laryngectomy. The study device records electrical signals, referred to as EMG (electromyographic) signals, which come from the muscles of the face and neck. The signals are similar to those recorded by an electrocardiogram (ECG or EKG; i.e., tracing of the electrical activity of the heart). EMG signals are collected using an EMG sensor, which is a small recording device taped to the skin directly over the muscle of interest. The study device is investigational, which means it has not been approved by the U.S. Food and Drug Administration (FDA).

The test procedures that you are being asked to participate in are designed to help the researchers attain a capability for a device that is not currently available. This capability would enable the device to recognize when you are emphasizing words in a sentence—as, for instance, when you want to convey a question or make a statement of fact—and then translate this directly to a synthesized (artificial) voice.

PROCEDURES: Approximately 32 volunteers will be involved in this study, including 12 volunteers with laryngectomy (surgery to larynx or voice box) for the *EMG Sensor Recording Study* and another 20 volunteers with healthy voices for the *Listening Study*. All experiments will be conducted at Altec, Inc., located at 23 Strathmore Rd. Natick, Massachusetts, 01760. In special circumstances where travelling is a hardship for you, the study may be conducted in your home with your permission.

EMG Recording Study: Volunteers for this study will have as few as one, or as many as five sessions, wherein each session may require up to 5 hours to complete. As many as 8 sensors may be placed to record different muscles near your mouth, face, chin, and neck. This study will begin by preparing an approximate 1-inch area of the skin where the sensors will be placed. The skin preparation begins by wiping the skin with rubbing alcohol and shaving an area, approximately 1×1 inch for each sensor location, using a disposable safety razor if there is facial hair or stubble. After the skin dries from the alcohol, a hypoallergenic tape may be applied and immediately removed from your skin several times to remove dead skin and oils from the sensor site. Small sensors about 0.5×1.0 inch will then be placed on your skin using a double-sided medical grade adhesive.

During the experiment, these sensors may be removed and re-attached to immediately adjacent sites to test the effect of sensor position on signal quality. Video recordings, audio recordings, and photographs will be taken of you to help analyze the data.

After the sensors are in place, you will be asked to produce speech. You will produce vowels by themselves, read text that we provide you on a computer screen, and answer questions we may ask to elicit spontaneous speech. In some instances, you will be asked to silently mouth these words or phrases and, if you are able, to say them out loud. For those who are experienced in communicating via an electrolaryngeal speech aid or by means of a tracheoesophageal voice prosthesis (TEP), you may be asked to recite some of the text using this method of speech production. You will be seated and asked to remain still during most of these experiments; however, in some experiments we may ask you to turn your head, raise your arms, stand up, or even walk in place. You will be provided with rest periods as needed between these tasks to

avoid fatigue. For sessions scheduled for 4–5 hours, we will provide a rest period of 30–40 minutes halfway into the study for nourishment and a beverage, as well as 5-minute rests every 30 minutes (or sooner if requested). We may also schedule the experiment over three to four sessions if you are easily tired. Bathroom breaks can be requested at any time.

Following each test session, all sensors and related equipment will be removed and the skin cleansed with soap and water after the test session. Your skin will be inspected for possible irritation and an over-the-counter skin moisturizer will be available to apply to the skin area if it feels dry or irritated.

Listening Study: For those volunteers recruited without laryngectomy, you may be asked to participate in a separate Listening Study, also at Altec, Inc. You may be asked to complete a hearing screening using standard audiological procedures. You may be asked to listen to speech samples and make judgments about certain characteristics of the speech, such as what the speaker is saying or how well you can distinguish one voice from another. If so, we will train you on how to make these judgments and you will be asked to complete tasks such as rating or transcribing these samples using a computer program while listening to the samples through headphones. The duration of this portion of the study is expected to require 1–2 hours of your time and you may take short breaks whenever you like.

RISKS AND DISCOMFORTS: The risks of injury to you during the test procedures are minimal. Whenever a recording device is placed on the skin, as in the EMG Recording Study, the sensor can irritate the skin by mild electric currents if the sensor were to malfunction, which could lead to a mild skin irritation. This risk is extremely small as we safeguard you from this possibility by using wireless battery-powered sensors (isolated from electrical sources such as wall sockets) and designing the sensors so that they comply with FDA and other stringent safety standards. You may also experience a mild reddening or irritation of the skin due to the application and removal of the adhesive tape that holds the sensors to the skin. This reaction is similar to taking a Band-Aid off the skin. Medical-grade adhesives that are approved by the FDA will be used and are designed to produce minimal irritation to the skin. The reddening of the skin, if it occurs, typically goes away in several minutes.

For both sets of studies you may also feel some tiredness and boredom from the repeated task and duration of the study. You will be provided frequent rest periods if you feel tired, and if the study exceeds 2–3 hours we can provide snacks or a break for lunch which we provide at no additional cost. Bathroom breaks will be accommodated at any time, and you are free to discontinue participation at any time.

By coming into Altec, Inc. and interacting with other people, you increase your risk of exposure to COVID-19. COVID-19 is an infectious disease that is easy to get and can pose a serious health threat to some people.

NEW FINDINGS: You will be told about any new information that might change your decision to be in this study.

BENEFITS: There are no expected benefits to you for your participation in this study. This device may be helpful in the future to those people that have speech disorders.

PAYMENT FOR PARTICIPATION: Payment of $25.00 per hour will be provided to pay you for your travel time and study participation time. Additional costs of transportation such as public transportation will be reimbursed upon arrival. Taxi transportation, when pre-arranged and approved by us, will be billed directly to Altec Inc. If you decide not to continue your participation in the study, or do not qualify for the study, you will be paid at the rate of $25.00 per hour for the time completed. All payments for participation will be made immediately at the end of the study.

ALTERNATIVES: Your alternative is to not be in this study.

CONFIDENTIALITY: All information regarding your participation in this study will be assigned a code number rather than referring to you by name. Mr. Gianluca De Luca, the principal researcher in this study, will keep the code associated with your name in a locked cabinet in his office.

Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies which are contracted by the sponsor to have access to the research information during and after the study. It may also be given to the U.S. Food and Drug Administration (FDA). The consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor;

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA;
- Department of Health and Human Services (DHHS) agencies; and
- The WCG Institutional Review Board (WCG IRB).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. All publications or presentation of the research will be of summary results of all subjects tested and no personal identifiers such as your name will be used.

SOURCE OF FUNDING: Funding for this research study will be provided by National Institutes of Health (NIH).

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your doctor or healthcare provider (such as a speech therapist or specialist) may also be an investigator of this research study. As an investigator, these persons are interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor or speech specialist who is not an investigator in this study. You do not have to participate in any

research study offered by your doctor or speech specialist. Your refusal to participate will in no way affect your status as a patient or receipt of medical care.

Your participation in this study may be stopped at any time by the study investigator or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

QUESTIONS: If you have any further questions, concerns or complaints regarding this study or about a possible research-related injury, contact the Principal Investigator, Mr. Gianluca De Luca, at 508-545-8202 or sub-investigator Dr. Jennifer Vojtech at 508-545-8208.

If you have questions regarding your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

WCG IRB
1019 39th Avenue SE Suite 120
Puyallup, Washington, 98374-2115
Telephone: 855-818-2289

WCG IRB is a group of people who perform independent review of research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all your questions.

If you agree to participate in this study, you will be given a signed and dated copy of this consent form.

CONSENT: I have read this consent form (or it has been read to me). All of the procedures have been explained to me and my questions have been answered.

I agree to participate as a research subject in this research study.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

_____
Printed Name of Subject

CONSENT SIGNATURE:

_____ _____
Signature of Subject Date

---------- Use this witness section only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

_____ _____
Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered their questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

Printed Name of Person Conducting the Informed Consent Discussion	Position
Signature of Person Conducting the Informed Consent Discussion	Date
Investigator's Signature (if different from above)	Date