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A Comparison of Two Devices for Isometric Lingual Strengthening in Healthy Adults

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A COMPARISON OF TWO DEVICES FOR ISOMETRIC LINGUAL STRENGTHENING IN HEALTHY ADULTS

by

Daniel L. Gutierrez B.S.

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ABSTRACT

A COMPARISON OF TWO DEVICES FOR ISOMETRIC LINGUAL STRENGTHENING IN HEALTHY ADULTS

by

Daniel L. Gutierrez B.S.

The University of Wisconsin-Milwaukee, 2020
Under the Supervision of Professor Barbara Pauloski, Ph.D., CCC-SLP

The purpose of this study was to compare tongue pressure measurements recorded by an established device, the Iowa Oral Performance Instrument (IOPI) and a new device, the Tongueometer™.

Eight healthy adults ages 18 to 59 were participants. Independent variables included device type (IOPI & Tongueometer™) and bulb placement in oral cavity (anterior & posterior). The dependent variable was tongue pressure in kPa. Each participant attempted three trials of maximum tongue pressure at both the anterior and posterior bulb placement location for both devices. The order of device and bulb placement position was counterbalanced to reduce potential carryover effects. Participants were assessed at a single evaluation point.

There was a strong correlation in pressure measurements between the devices ($r = .91$). Paired t-tests revealed significant mean differences, with the Tongueometer™ consistently measuring 3-4 kPa lower than the IOPI. This study indicates that the Tongueometer™ provides reliable measurements of tongue pressure.

To

My beautiful child, Maximilian

"I recognize you. You are a boy – full of life, full of dreams, full of feeling."
Dan Kindlon

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taught me that procrastination is not a desired skillset. You have spent countless hours furthering my academic and clinical endeavors and have always made me feel like I could accomplish anything, even when I felt like I was accomplishing nothing. You are truly an incredible human being, instructor, and mentor. Thank you.

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CHAPTER 1

Introduction

The tongue has shown to have decreased strength and endurance in aging healthy adults (Namasivayam, Steele, & Keller, 2016), individuals with neurodegenerative disease (Mendes, Nascimento, Mansur, Callegaro, & Jacob Filho, 2015), stroke patients (Lee et al., 2016), and head and neck cancer patients (Lazarus, 2006). Reduced tongue strength may have a negative impact on nutrition, hydration, respiration (Namasivayam et al., 2016), and quality of life (McHorney et al., 2002).

Research has reported that increased lingual strength/endurance training reduces symptoms associated with dysphagia, including increased swallowing pressures (Oh, 2015; Namiki et al., 2019), decreased oral-transit times (Kim et al., 2017; Namiki et al., 2019), decreased oral and oral-pharyngeal residue (Kim et al., 2017; Robbins et al., 2007), increased pharyngeal response duration (Namiki et al., 2019), reduced diet modifications (Robbins et al.,2007), and decreased penetration and aspiration (Robbins et al., 2007; Namiki et al., 2019). Along with an overall reduction of dysphagia symptoms, evidence indicates that lingual strength training significantly impacts other musculature involved with efficient and effective deglutition. Using electromyography, Palmer et al. (2008) observed increased muscle activity in floor-of-mouth muscles, suprahyoid muscles, and jaw muscles during tongue-to-palate pressure tasks. More recently, Namiki et al. (2019) reported that "tongue pressure resistance training improved tongue strength, dexterity, both anterior and superior hyoid elevation, and swallowing function."

LINGUAL RESISTANCE TRAINING

Resistance training is defined as any movement which involves a muscle to move against a load (Saladin, 2014). Isometric resistance training occurs when the muscle being contracted is not lengthened (Saladin, 2014). This type of training relies on the tension created by the muscle contraction against the load. One method for isometric lingual strengthening takes place when the tongue is elevated and pressed up against the hard palate (typically at the alveolar ridge) for a specified number of repetitions and sets over a duration of time. Figure 1 illustrates tongue position at rest and during tongue pressure resistance training.

With lingual strengthening gaining traction in the world of deglutition and dysphagia, investigators continually propose new and innovative ideas to target these muscles with the consumer in mind. Clinicians also need to objectively measure lingual pressures to effectively and efficiently plan and modify interventions and track patient progress.

Currently, the Iowa Oral Performance Instrument (IOPI; Figure 2) is the standard for tongue pressure measurements and lingual strengthening interventions. While the IOPI is the industry leader, its $1000-$2000 (dependent on model, software, and accessories included) price

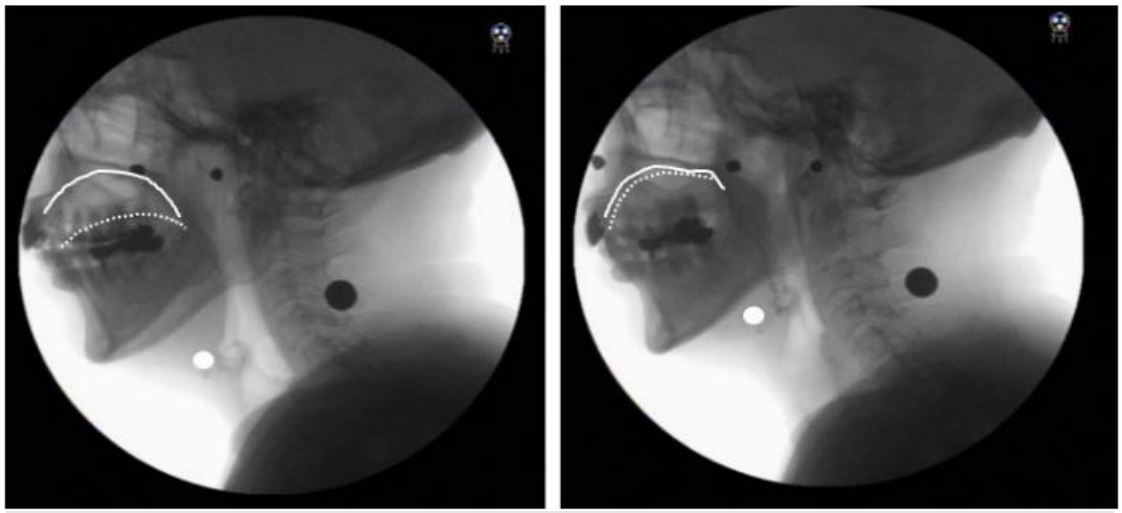


Figure 1 Tongue pressure resistance training (from Namiki et al., (2019).
Dotted line indicates tongue position and solid line indicates hard pallate. Left image shows the tongue at rest and the right image shows the tongue elevated against the hard pallate.

tag is prohibitive for many patients to use as part of a home program. In May 2019, E2 Scientific introduced the Tongueometer™ lingual strengthening device, developed with affordability in mind at a retail price of $149. The objective of this study was to evaluate E2 Scientific's lingual strength trainer's ability to provide objective and reliable lingual pressure measurements in clinical and home settings for the duration of a lingual strength training regimen using healthy adults in comparison to the IOPI over the course of an 8-week isometric lingual strengthening program.

RESEARCH QUESTIONS

The original intent of this study was to answer the following research questions:

(1) Is there a significant difference in measured tongue pressures (P_{Max}) in kPa between the IOPI and the Tongueometer™ at the same point in time?

(2) Is there a significant difference in P_{Max} measurements between devices over an 8-week lingual strengthening regimen?

(3) Does bulb placement (anterior & posterior) show a significant difference in P_{Max} measurements between the devices?

Because of the events surrounding the 2020 global pandemic and the suspension of in-person human participants research by the University of Wisconsin-Milwaukee, Research Question 2 could not be investigated. Therefore, the final research questions for this study were:

(1) Is there a significant difference in measured tongue pressures (P_{Max}) in kPa between the IOPI and the Tongueometer™ at the same point in time?

(2) Does bulb placement (anterior & posterior) show a significant difference in P_{Max} measurements between the devices?

CHAPTER 2

METHODS

RESEARCH STRATEGY AND DESIGN

This study was approved by the University of Wisconsin-Milwaukee Institutional Review Board. Appendix I includes recruitment materials and data collection instruments used for the study. The current study utilized quantitative data to describe the comparison of measurements obtained from two different lingual strengthening devices, IOPI & Tongueometer™. A group within-subjects design was used to analyze the effect of two independent variables (device type and bulb placement on the dependent variable of tongue strength in kPa (or P_{Max}). The levels of the independent variables were:

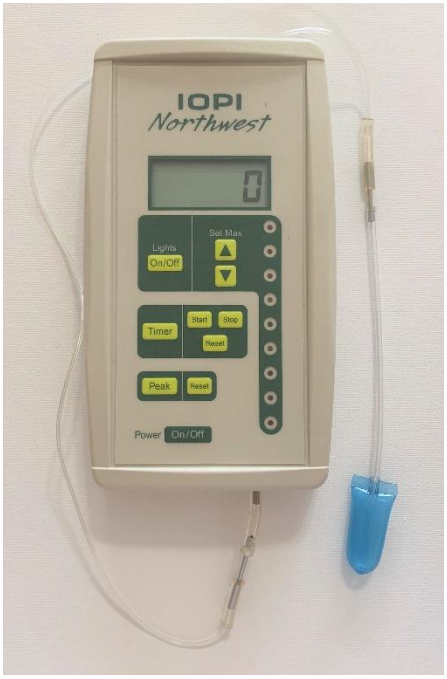
(1) device used (two levels: IOPI and Tongueometer™) and

(2) bulb placement (two levels: anterior and posterior).

DEVICES

The devices used in this study were the Iowa Oral Performance Instrument and the Tongueometer™. The Iowa Oral Performance Instrument by IOPI Medical LLC (Figure 2) is a standalone device used to measure maximum pressure exerted on an air-filled bulb. According to IOPI Medical LLC (2013), the IOPI can be used to accurately measure lingual strength to aid in the identification of lingual weakness and/or impairments. It may also be used as a therapy tool to increase lingual strength and endurance. The IOPI measures the pressures exerted in kilopascals (kPa) at a range of 0-100 kPa with a reported ±2 kPa. It can be used to obtain lingual peak strength measurements, measure lingual endurance, and measure lip strength (IOPI Medical LLC, 2013). The measurements obtained using the IOPI are then translated by a Speech

Figure 2 IOPI Model 2.0



Language Pathologist (or similar medical professional) and used to set therapy targets (Figure 3). The IOPI is powered by a standard 9-volt alkaline battery and features visual biofeedback via multicolored light emitting diodes which allow the user to remain within the therapy target area. The IOPI uses multiuse-replaceable bulbs which allow the same device to be used across multiple users. Current listing prices for the IOPI are $1,235-$2,140 depending on IOPI model, accessories, and software, and 2-year standard warranty (refer to IOPI Medical LLC for most current pricing and information). The IOPI used for this study was supplied by the University of Wisconsin-Milwaukee Swallow Physiology Laboratory and was an IOPI Model 2.0. The manual for the IOPI is included in Appendix II.

The Tongueometer™ by E2 Scientific Corporation (Figure 4) is marketed as "an affordable, at-home device designed to measure and increase tongue strength and endurance" (https://e2scientific.com/) that can be used as a multi-user device (Tongueometer™ User Manual, 2019; Appendix II). Current list price for the Tongueometer™ is $149 and can be purchased by anyone online, but per the Tongueometer™ User Manual (2019), "Setup of the Tongueometer™ should be completed under the guidance of a Speech-Language Pathologist or similar medical professional."

$$T = P_{max} \times \left(\frac{E}{100}\right)$$

T= Target value, P_{max} = Peak tongue pressure, E = Effort (%)

Figure 3 Target value formula IOPI User Manual (2013)

Unlike the IOPI, the Tongueometer™ is not a standalone device and requires the user to link the device, via cable, to a smart device (smartphone or tablet) equipped with the free Tongueometer™

software/application (Figure 5). At the time of this study, the Tongueometer™ was compatible with only the Android operating system; however, E2 Scientific has since released Bluetooth compatibility allowing its use with both iOS and Android devices. The Tongueometer™ application (Figure 5) allows the user to objectively measure tongue strength, complete strength and endurance exercises, identify therapy targets, track patient improvement, and evaluate therapy effectiveness. The application also allows the user to share data in the form of an excel spreadsheet with their medical professional (Figure 6). Like the IOPI, the Tongueometer™ utilizes an air-filled bulb to measure lingual pressure (strength) in kPa and is reported to accurately measure pressures between the range of 0-100 kPa (Tongueometer™ User Manual, 2019; Appendix II).

Figure 4 Tongueometer™ E2 Scientific Corp.

Figure 5 Tongueometer™ application E2 Scientific Corp.

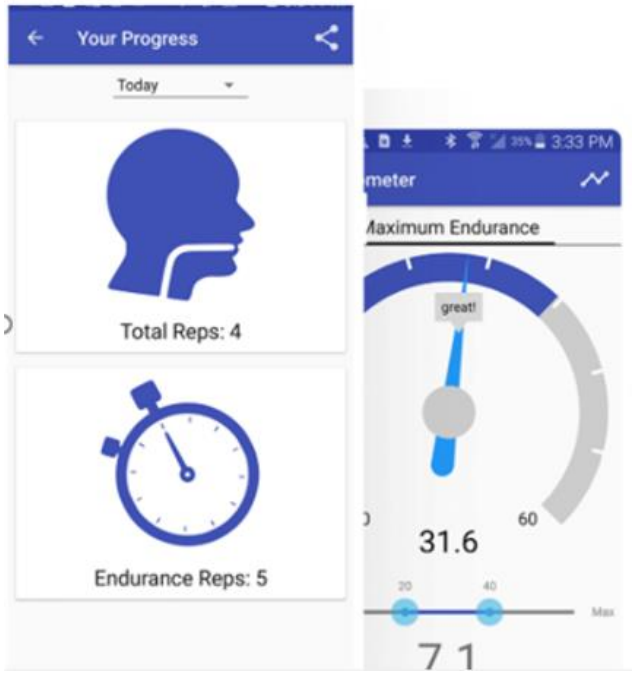


Figure 6 Tongueometer™ application therapy report example

	A	B	C	D	E	F	G	H	I	J	K	L
1	Date	Repetitive Strength Reps	Repetitive Strength Range - Minimum (kPa)	Repetitive Strength Range - Maximum (kPa)	Isometric Endurance Reps	Isometric Endurance Range - Minimum (kPa)	Isometric Endurance Range - Maximum (kPa)	Isometric Endurance Interval (sec.)	Maximum Strength (kPa)	Maximum Endurance (sec.)	Maximum Endurance Range - Minimum (kPa)	Maximum Endurance Range - Maximum (kPa)
2	20190810	30	20	40	30	20	40	3	68.15	35	20	40
3	20190812	30	20	40	30	20	40	3	68.53	40	20	40
4	20190813	30	20	40	30	20	40	3	68.18	38	20	40
5												

PARTICIPANTS

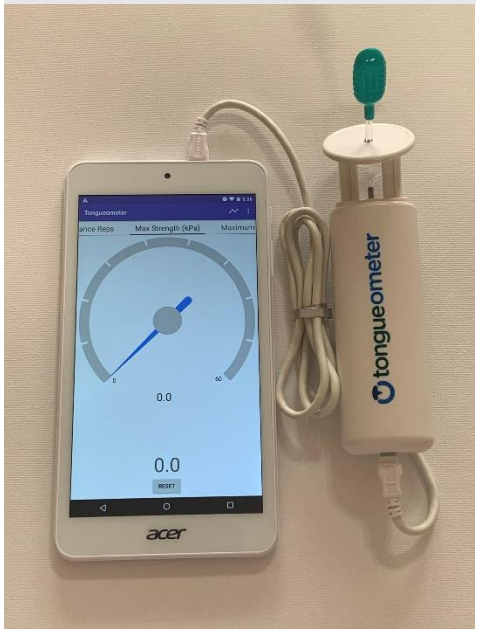
All individuals admitted into the study were considered healthy with no history of medical conditions that may have affected nerve function and/or musculature of the head and neck. Exclusionary factors were that no individual should have or have had tongue piercings (Lazarus, Logemann, Huang, & Rademaker, 2003) and no individual with a history of playing brass instruments, woodwind instruments, oration training, and/or dictation training within five years of the study initiation (Solomon & Munson, 2004) was admitted. According to Solomon and Munson (2004) individuals who play brass/woodwind instruments and/or have training in oration/dictation present with supranormal tongue endurance which may also have an impact on P_{Max} measurements.

Participants received an oral-motor examination to identify structural and/or functional deviations. The Harding University Speech Clinic Oral-facial Examination Form (Harding University Speech Clinic, 2016; Appendix I) was used to identify oral-facial differences that might have impacted study results. This examination form was chosen due to ease of access and familiarity of use within the study location, the University of Wisconsin-Milwaukee (UWM) Department of Communication Sciences and Disorders.

The recruitment goal for the study was two groups of 10 (n=20) to represent two age groups: young (18-29 years) and middle (30-59 years). The IOPI User Manual reports similar age groups in the Tongue Strength Normal Values section with a reported mean of 63 kPa for both young and middle age groups (IOPI Medical LLC, 2003, p.57, Appendix II). Although this study did not intend to examine the effect of age, the study replicated age groups specified in previous literature. Age was not used as an independent variable in this study a) because it is not the main objective of the study and b) according to studies published by Youmans, Youmans, & Stierwalt (2009) and Clark (2012), there is not a significant difference in P_{Max} scores between young and middle age groups.

A specific gender distribution was not targeted for this study because there is no gender category offered within the IOPI User Manual Tongue Strength Normal Values (IOPI Medical LLC, 2013). Instead, it is stated in the Tongue Strength Normal Values section of the IOPI User Manual that, "In some studies, males were somewhat stronger than females, by about 5-10 kPa, but only for young subjects" (IOPI Medical LLC, 2013, p.57, Appendix II). According to studies published by Clark & Solomon (2012) and Youmans, Youmans, & Stierwalt (2009), measurements obtained using the IOPI indicate that there is not a significant difference between men and women when measuring anterior tongue pressures. The current study therefore replicated only the young and middle age parameters reported by Clark & Solomon (2012).

Figure 7 Participant materials.
Android tablet was available to participants without access to a compatible Android device.



MATERIALS

Each participant received one Tongueometer™, one Tongueometer™ bulb, one Tongueometer™ User Manual, and one on-the-go cable. Participants who did not have an Android device received an Android device to be used for the duration of the study. Each Android device was equipped with the corresponding Tongueometer™ application (Figure 7). Each participant also had a designated IOPI bulb that was used to measure lingual strength for the duration of the study (Figure 8). The IOPI bulbs were stored in the Swallow Physiology Laboratory between assessments.

Participants were trained by the student principal investigator (PI) on proper use and maintenance of the Tongueometer™ device and associated software (Appendix II). Device setup was completed by the PI with the participant including preparation of the Tongueometer™ bulb, downloading the Tongueometer™ application from Google Play Store, and registration of the Tongueometer™ device.

MEASUREMENTS

Outcome measurements were taken by one of two qualified Communication Sciences and Disorders graduate clinicians (GC) who were trained in the use and function of both test devices and data collection protocol by the PI. Graduate clinicians demonstrated proficiency with the devices on two practice participants prior to collecting data from any research participant. Graduate clinicians were blinded to the study objectives.

Outcome measurements were completed using both the IOPI and Tongueometer™. The order of device measurement (IOPI vs. Tongueometer™) and placement (anterior vs. posterior)

was counterbalanced to reduce any potential carryover effects or potential biases from muscle fatigue across the testing conditions. Each participant was fitted with an IOPI bulb and Tongueometer™ bulb. Fitting took place during initial training and was conducted by the PI. Each bulb was marked with black and red permanent marker to reflect two bulb positions: anterior (black) and posterior (red) (Figure 9).

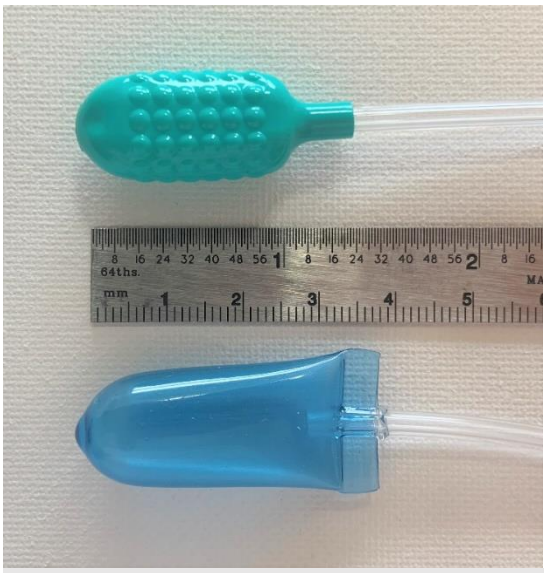
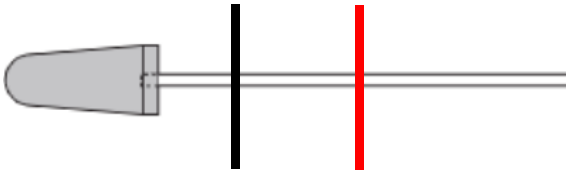


Figure 8 Pressure bulbs.
Although both bulbs are relatively similar in size, the Tongueometer™ (top) bulb has a textured exterior whereas the IOPI (bottom) bulb has a smooth exterior.

BULB POSITION

Bulb positions will follow the guidelines published by Clark and Solomon (2012) (Figure 10). For anterior placement, the bulb was "positioned longitudinally along the hard palate just posterior to the to the alveolar ridge" (Clark and Solomon, 2012). For posterior placement, the bulb was "positioned longitudinally along the hard palate, with the distal end of the bulb at the posterior border of the hard palate" (Clark and Solomon, 2012). During initial fitment, the PI ensured proper placement of the bulb within the participant's oral cavity and marked the tubing, with corresponding placement color, where the participant's lips contact the tubing. After fitment, each bulb tubing had two markings: red posterior marking and a more distal black anterior marking (Figure 9). Graduate clinicians checked to ensure markings were visible at each evaluation point and remark tubing if necessary. If the mark was completely removed, the PI was responsible for refitment and marking.

Figure 9 Bulb placement indication markers.
Black indicator mark corresponds with anterior placement and red indicator mark corresponds with posterior placement. Figure adapted from IOPI User Manual (2013)



PROCEDURES

According to the IOPI User Manual (IOPI Medical LLC, 2013, Appendix II), an accuracy check should be conducted monthly. The PI taught the GCs how to conduct accuracy checks. The GCs demonstrated proficiency of accuracy checks by completing the procedure side-by-side with the PI until accuracy checks completed by both were within ±2 kPa. The GCs were responsible for carrying out the monthly accuracy check (instructions included in the IOPI manual, Appendix II). This procedure was not conducted with the Tongueometer™ due to lack of calibration guidelines provided by the manufacturer.

Outcome measurements were recorded as maximum tongue strength measurements (P_{Max}) and taken following the guidelines published by Lazarus et. al., (2003). Participants were instructed to sit upright while measurements were being taken and were told to "Press up on the bulb with your tongue and squeeze the bulb against the roof of your mouth as hard as you can for 2-3 seconds." The GCs provided motivation in the form of "push, push, push!" or "squeeze, squeeze, squeeze!" during each trial. Participants performed four sets with each set containing three trials. During the set, the GCs timed a 30 second break between trials to allow for participant cooldown and documentation of each measurement on a data collection form. After each set that was completed, the participant rested for two minutes before beginning the next set. The highest P_{Max} value from each set was used as the participant's P_{Max} value. This value was used by the PI to set therapy goals. Figure 3 includes the formula for calculating target values.

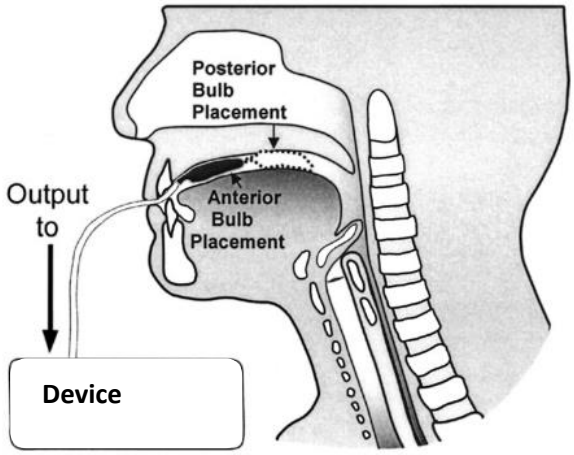


Figure 10 Bulb placement within oral cavity adapted from Robbins et al., 2007.

Figure 11 Tongueometer™ use with lip guard.
Bulb tubing passes through lip guard and is held firmly in place

EXERCISE REGIMEN

The original study design included a longitudinal exercise component. The exercise regimen followed a combination of the protocols outlined by Clark (2012), Lazarus et al. (2014), Oh (2015), and Robbins et al. (2007). Participant's completed three sets per day three times a week for an 8-week duration at home using the Tongueometer™ (Table 1). Each set consisted of 30 repetitions requiring the participant to create pressure on the bulb for 2-3 seconds at the target pressure. Targets were 60% P_{Max} the first week and 80% P_{Max} for the remainder of the regimen (Table 1). Targets were set using anterior P_{Max} measurements taken by the Tongueometer™ during the evaluation points. Therefore, P_{Max} values were to be used for two-week durations. Since participants were not seen by the PI at the beginning of the second week, the PI emailed each participant a reminder to increase targets from 60% P_{Max} to 80% P_{Max}. As part of the initial training with the PI, each participant learned how to adjust the target within the Tongueometer™ application.

Therapy adherence was to be monitored by the PI during the exercise program. As part of the initial training with the PI, each participant was taught how to forward therapy reports via email to the PI. Therapy reports (Figure 6) were sent directly to the UWM Swallow Physiology Laboratory's email address to be uploaded onto a data encrypted computer in the Swallow Physiology Laboratory by the PI. Only the PI received and documented Tongueometer™ therapy reports to ensure that the GCs remained blinded for the duration of the study. Therapy

reports were generated and sent by participants after each completed week. If therapy adherence was not being met, the PI contacted the participant directly to investigate the reason for lack of adherence.

Table 1 Exercise target value calculation schedule (Robbins et al., 2007)

Exercise target value calculation schedule	
Time point	Exercise target value
Beginning of week 1	60% of baseline max
Beginning of week 2	80% of baseline max
End of week 2	Recalculate max: 80% of new max
End of week 4	Recalculate max: 80% of new max
End of week 6	Recalculate max: 80% of new max
End of week 8	Final Max value

STATISTICAL ANALYSIS

Descriptive statistics included mean and standard deviation of tongue pressure measurements in kPa for each of the four testing conditions (IOPI at anterior and posterior bulb positions; and Tongueometer™ at anterior and posterior bulb positions). Inferential statistics included the Pearson correlation coefficient to determine the strength and direction of the relationship between IOPI and Tongueometer™ measurements at each bulb position and paired t-test to determine whether there was a significant difference between the devices at the anterior bulb placement and the posterior bulb placements. SPSS v. 22 was used for statistical analyses. Cohen's *d*, defined as the difference in means divided by the standard deviation, was used to estimate the magnitude of standardized mean effect. According to Schiavetti, Orlikoff & Metz, (2015), an effect size of 0.2 is considered small, 0.5 is considered medium, and 0.8 is considered large.

CHAPTER 3

Results

STUDY PURPOSE

The original objective of this study was to evaluate E2 Scientific's lingual strength trainer's ability to provide objective and reliable lingual pressure measurements in clinical and home settings for the duration of a lingual strength training regimen using healthy adults in comparison to the IOPI over the course of an 8-week isometric lingual strengthening program. The following research questions were proposed to meet this objective:

(1) Is there a significant difference in measured tongue pressures (P_{Max}) in kPa between the IOPI and the Tongueometer™ at the same point in time?

(2) Is there a significant difference in P_{Max} measurements between devices over an 8-week lingual strengthening regimen?

(3) Does bulb placement (anterior & posterior) show a significant difference in P_{Max} measurements between the devices?

However, because of the events surrounding the 2020 global pandemic and the suspension of in-person human-subjects research by the University of Wisconsin-Milwaukee in March 2020, Research Question 2 could not be investigated. Therefore, the final research questions had to be modified to reflect the temporary suspension of human-subjects research. The modified research questions for this study were:

(1) Is there a significant difference in measured tongue pressures (P_{Max}) in kPa between the IOPI and the Tongueometer™ at the same point in time?

(2) Does bulb placement (anterior & posterior) show a significant difference in P_{Max} measurements between the devices?

PARTICIPANTS

Three participants were admitted into the study prior to the UW-Milwaukee research laboratory shutdown that went into effect March 25th, 2020. Each participant was able to provide baseline data, complete device training, and receive required study materials. However, longitudinal data could not be collected as a result of the UW-Milwaukee research laboratory shutdown.

Additional data was generated during graduate clinician training. This provided data from five more participants that was utilized for device comparison. Table 2 summarizes the age and gender information for all participants.

Age Group	Age range	*n* value	Mean age	Gender	
				Male	Female
Young	18-29	4	27.75	1	3
Middle	30-59	4	39.5	2	2

Table 2 Participant demographics

Comparison of IOPI and Tongueometer™

The first aim of the study was to determine whether there was a significant difference in measured tongue pressures (P_{Max}) in kPa between the IOPI and the Tongueometer™ at the same point in time. The IOPI had n of 38 observations with a mean P_{Max} measurement of 59.05 kPa and a standard deviation of 13.36. The Tongueometer™ also had n of 38 observations with a mean P_{Max} measurement of 55.63 kPa and a standard deviation of 14.39. Refer to Table 3 for a summary of values used for device comparisons.

Inferential statistics included a Pearson correlation coefficient to evaluate the correlation and a paired t-test to analyze the mean difference between the two devices. The two devices had a Pearson correlation coefficient of .91 ($p = 0.000$; Table 3).

Device	n	Mean	Std. Deviation	Pearson correlation
IOPI	38	59.05	13.36	.91
Tongueometer™	38	55.63	14.39	

Table 3 Device descriptive statistics with Pearson correlation

There was a difference in means of 3.43 kPa between the IOPI and the Tongueometer™ at the same point in time. Paired t-test revealed a significant difference between the two devices at $p = 0.001$ (Table 4). Effect size estimate of observed differences using Cohen's *d* was 0.58 indicating a medium effect size.

	Paired Samples Test							
	Mean Difference	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
				Lower	Upper			
IOPI & Tongue-ometer™	3.43	5.91	.96	1.48	5.37	3.57	37	.001

Table 4 Results of paired t-test between IOPI and Tongueometer™

Comparison of IOPI and Tongueometer™ by location of bulb placement

The second aim of the study was to determine whether bulb placement (anterior & posterior) show a significant difference in P_{Max} measurements between the devices. The IOPI anterior measurements had an n of 19 observations with a mean Pmax measurement of 58.74 kPa and a standard deviation of 13.98. The Tongueometer™ anterior measurements also had an n of 19 observations with a mean P_{Max} measurement of 55.67 kPa and a standard deviation of 15.51. IOPI posterior measurements had an n of 19 observations with a mean Pmax measurement of 59.37 kPa and a standard deviation of 13.08. The Tongueometer™ also had an n of 19

observations for posterior measurements with a mean P_{Max} measurement of 55.58 kPa and a standard deviation of 13.59. Refer to Table 5 for a summary of values used for position comparisons.

Pearson correlation coefficients between the IOPI and Tongueometer™ was .93 (p = 0.000) for the anterior bulb position and .90 (p = 0.000) for the posterior bulb position (Table 5).

Device	Position	n	Mean	Std. Deviation	Pearson correlation
IOPI	Anterior	19	58.74	13.98	.93
Tongueometer™	Anterior	19	55.67	15.51	
IOPI	Posterior	19	59.37	13.08	.90
Tongueometer™	Posterior	19	55.58	13.59	

Table 5 Position descriptive statistics with Pearson correlation

For the anterior bulb position, there was a difference in means of 3.07 kPa between the two devices with a standard deviation of 5.89 (*d*=.52) with a medium effect size. A paired t-test revealed a significant difference between the IOPI and the Tongueometer™ at the anterior bulb position. In the posterior bulb position, there was a difference in means of 3.79 kPa between the IOPI and the Tongueometer™ with a standard deviation of 6.07 (*d*=.62) with a medium effect size. The paired t-test was also significant between the two devices for the posterior bulb position. Table 6 summarizes the results of the paired t-tests for the anterior and posterior bulb positions.

	Paired Samples Test							
	Mean Difference	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
				Lower	Upper			
Anterior	3.07	5.89	1.35	.22	5.91	2.27	18	.036
Posterior	3.79	6.07	1.39	.86	6.71	2.72	18	.014

Table 6 Results of paired t-test between IOPI and Tongueometer™ by location of bulb placement

CHAPTER 4

Discussion

As of March 25, 2020, the University of Wisconsin-Milwaukee prohibited all in-person research activities which significantly impacted the ability to gather data from previously admitted participants and to recruit new participants. Because of these changes, conclusions about Tongueometer™ reliability and durability over the course of an eight-week training program cannot be made at this time. However, the baseline data collected from the three research participants and the data collected during the graduate clinician training portion of the study indicate a strong positive Pearson correlation of .91. This correlation indicates that there is a strong linear relationship between the measurements obtained from both devices at the anterior bulb position and posterior bulb position. However, despite having a strong positive correlation between the two devices, paired t-tests indicated that there was a significant difference between the two devices, with the Tongueometer™ consistently measuring 3-4 kPa lower than the IOPI. Cohen's *d* found a medium effect size for each significant difference observed.

According to the IOPI User Manual Technical Specifications (IOPI Medical LLC, 2013), the IOPI has a measuring range of 0-100 kPa with a pressure accuracy tolerance of ±2 kPa. Accuracy tolerance means that a calibrated IOPI which has completed and passed an accuracy check could potentially still be 2 kPa over or 2 kPa under the true pressure measurement. For example, if a known measurement of 50 kPa was to be taken using the IOPI, the IOPI would still meet calibration specifications and be within tolerance if the measurement provided was between 48-52 kPa. However, while the Tongueometer™ User Manual (2019) reports that the device has a similar measuring range of 0-100 kPa, it does not report pressure accuracy calibration

tolerance. Therefore, a similar tolerance cannot be assumed. Knowledge of the Tongueometer™ pressure accuracy tolerance would assist in the interpretation of the significant differences between mean measurements of the two devices. According to statistical analyses, the difference in means between the IOPI and Tongueometer™ was consistently between 3-4 kPa. Hypothetically, if E2 Scientific reported that the Tongueometer™ has similar pressure accuracy calibration tolerances as the IOPI (±2 kPa), the mean difference observed between the two devices could be explained as normal acceptable deviations in pressure accuracy calibration tolerances.

Another hypothesis involves bulb shape, texture, and size. The IOPI bulb is approximately 3.4 mm long and 1.5 mm wide with a height of 1 mm at its center. Its exterior is smooth and transparent (Figure 8). The Tongueometer™ bulb is approximately 2.6 mm long and 1.5 mm wide with a height of 0.7 mm at its center. The TongueometerTM bulb is opaque with a bumped texture around most of the bulb body (Figure 8). User feedback provided evidence of distinct differences in areas relevant to shape, texture, and size. Participants reported that the IOPI bulb, with its smooth surface, tended to have greater movement within the oral cavity when applying lingual pressure. Users also indicated that the IOPI bulb felt "larger" and "fuller" in comparison to the TongueometerTM bulb. It is possible that differences in bulb size, shape, and texture could impact recorded measurements For example, the IOPI has greater surface area; this surface area provides more contact with the tongue and the roof of their mouth. More surface area may allow users to produce greater pressure gradients which would be reflected as consistently higher P_{Max} measurements.

It is also important to compare the normative data reported in the IOPI User Manual (IOPI LLC, 2013, Appendix II) to the data measured in this study. The IOPI User Manual (IOPI

LLC, 2013) reports normal mean values for tongue strength at 63 kPa for young (n=276 SD=13.6) and middle (n=219 SD=12.5) age groups. A post-hoc t-test (SPSS Tutorials: Independent Samples t-test) was used to determine if there was a significant difference in means between collective study data and the published IOPI norms. Independent samples t-tests did not show a significant difference in means between observed data and IOPI reported data for either young or middle age group. Refer to Table 8 for a summary of values used for data comparisons.

	Age Group	Mean (kPa)	Standard Deviation	n
IOPI User Manual Data	Young	63	13.6	276
	Middle	63	12.5	219
Lab Data	Combined Groups	59.05	13.36	38

Table 7 Comparison of IOPI normative data by age group with study data.

Data Set	Age Group	n	Mean	t observed	t critical (df < 120)
IOPI	Young	276	63	1.70	1.98
Current Study	Combined	38	59.05		
IOPI	Middle	219	63	1.70	1.98
Current Study	Combined	38	59.05		

Table 8 Results of t-test between observed data and IOPI published data

Since the longitudinal portion of this study was not able to be carried out, comparisons to previous research using the IOPI as part of a tongue strengthening therapy program were not possible. This was only one of several limitations experienced over the duration of the study due to the 2020 global pandemic. The study design called for 20 participants who would participate for the duration of an eight-week isometric lingual strength training regimen with a total of five evaluation points. Since only three participants were admitted into the study and only baseline data were obtained, this study had limited participant data and measurements. Although the three admitted participants were encouraged to continue with the training regimen

while sheltering-in-place, none were able to do so. One participant reached the maximum limits of the device (100 kPa) after three weeks of the training regimen, one participant lost access to the device, and the final participant experienced application difficulties which could not be resolved due to the application software firm in Italy being shut down because of the 2020 global pandemic.

An assessment of long-term use of the Tongueometer™ was unable to be conducted due to limited participant admission, participant therapy breakdown that the PI could not resolve without in-person consultation, and prohibition of human-subjects research caused by the 2020 global pandemic. While no current comments and/or assumptions can be made about the durability of the Tongueometer™ at this time, the Tongueometer™ appears to provide reliable measurements at a given point in time despite recording consistently lower pressures (3-4 kPa) than the IOPI.

Clinically, the Tongueometer™ provides an affordable alternative to the current industry leader, the IOPI, which may increase availability to more diverse populations in terms of healthcare availability and/or socioeconomic status. With the recent release of Bluetooth compatibility that allows the Tongueometer™ to be used with both IOS and Android devices, this affordable option is accessible to even more patients. The Tongueometer™ provides clinicians the ability to assess and track tongue strength, monitor progression via application data reports, and even acquire information relevant to patient therapy adherence for multiple users. Whether the device is strictly used in the clinic or purchased for home therapy administration, the Tongueometer™ appears to be a practical clinical tool to improve lingual strength, which has shown to be effective in the reduction of dysphagia-related symptoms (Lazarus, 2006; Namasivayam et al., 2016; Park et al., 2015; Park & Kim, 2016; Robbins et al., 2007), help

strengthen floor-of-mouth muscles (Namiki et al., 2019), and increase patient quality of life (Davis, 2008; McHorney et al., 2002). However, it is still recommended that individuals privately purchasing this tool consult with a licensed speech language pathologist or similar medical professional prior to use.

The student principal investigator, graduate clinicians, and thesis mentor who all used the devices reported pros and cons for each device. These are summarized in Table 8. Overall, clinicians who used both devices reported a better experience with the Tongueometer™ over the IOPI. This preference had a large part to do with bulb texture and the incorporated lip guard. Participants also reported a similar preference, stating that the "bumpy" tongue bulb stayed in place better than the IOPI tongue bulb and that the lip guard ensured accurate placement of the bulb within the oral cavity.

IOPI	
Pros	• Reputation • More available research • Easy device navigation and use
Cons	• Untextured bulb produced unwanted movement during measurements • Unit had difficulty returning to zero after a measurement was taken • Price
Tongueometer™	
Pros	• Textured bulb stayed in place • Connectivity to phone/tablet • More precise measurement reports • Lip guard made it easier to accurately place bulb repeatedly • Affordability
Cons	• Limited research about the device itself • Mating device and phone/tablet can be difficult depending on device USB style

Table 9 Clinician device feedback

Additionally, research participants were asked to complete an exit survey (Appendix I) consisting of short answer responses and ratings using a five-point Likert scale (1 – Strongly

Disagree; 2 – Disagree; 3 – Neutral; 4 – Agree; 5 – Strongly Agree) to provide feedback about this study and the Tongueometer™. While only one participant provided a completed exit survey, the information provided is relevant and useful for the study purposes. Table 9 documents participant device feedback responses from the exit survey.

Short answer questions	**Participant response**
What were your initial impressions of the device?	"Despite the initial problems we experienced with connecting the device to my phone, I thought the device and application were neat. I did question the quality and consistency accuracy of the device based on the materials and new application"
What device features did you like the most?	"The ability to use my phone."
What device features did you like the least?	"I did not enjoy the experiences I had with lag between the device and my phone application." This was also reported by another user to be an issue.
Is there anything you would change about the device?	"Only if there was a way to help the device and application work together more seamlessly."
Is there anything you would change about the Android application?	Same as previous response and "I would have like to have a clearer understanding of the meaning of the categories of results."

Ratings questions	**Response rating**
The device is easy to use.	4 - Agree
The device application is user friendly.	4 - Agree
The device is of high quality.	4 - Agree
The device is sturdy.	4 - Agree
The device is easy to maintain.	5 – Strongly Agree
The lip guard is helpful to maintain bulb position.	5 - Strongly Agree
The textured bulb helped maintain bulb position.	4 - Agree
Changing the bulb was relatively simple.	4 - Agree
I would recommend this device to a friend.	5 - Strongly Agree
I liked the data sharing feature of the Android application.	3 - Neutral

Table 10 Participant device feedback responses from exit survey

Overall, clinician and participant feedback indicate that the Tongueometer™ provides a more user-friendly experience. This experience was significantly impacted by the device's built in lip guard, which holds the pressure bulb securely, and the textured pressure bulb, which moved less within the oral cavity when applying pressure. While one participant was unable to

continue the study because of application/software malfunctions, the 2020 global pandemic impacted E2 Scientifics Corp. ability to field application issues. It is likely that these issues would have been addressed in a timely manner prior to the 2020 global pandemic.

While this study was unable to complete the longitudinal aspect because of the 2020 global pandemic, it is recommended that future researchers investigate the use of the Tongueometer™ over the course of an eight-week therapy program to draw informed conclusions relevant to device durability and accuracy with prolonged use. Future research with larger sample size needs to be conducted to collect and evaluate more representative data. It is also suggested that device comparisons at the same point and at different bulb positions be completed with various patient populations to further investigate the relationships between the devices and how those relationships are affected by patient population. Diverse patient populations, specifically those with swallowing disorders will add to a growing body of literature showing the efficacy of isometric lingual strengthening in reducing dysphagia associated symptoms and increasing swallow function.

Recommended isometric training programs follows a combination of the protocols outlined by Clark (2012), Lazarus et al. (2014), Oh (2015), and Robbins et al. (2007). The protocol requires participants to complete three sets per day, three times a week for an 8-week duration using the Tongueometer™. Each set should consist of 30 repetitions that require the participant to create pressure on the bulb for 2-3 seconds at the target pressure. Prior to developing targets, participants P_{Max} must be recorded. Targets should be 60% P_{Max} the first week and increase to 80% P_{Max} for the remainder of the regimen (Table 1). It is recommended that P_{Max} scores be recorded at least every two weeks during the therapy protocol to monitor and

adjust therapy targets as the participant's strength will likely increase throughout the therapy protocol.

The results of this study suggest that the Tongueometer™ appears to be an affordable and practical alternative to the IOPI for practicing clinicians and patients alike. Despite consistently recording measurements 3-4 kPa below the IOPI, the measurements recorded had a strong correlation to the IOPI measurements. The differences observed could be addressed in the future with the reporting of pressure accuracy calibration tolerances by E2 Scientific Corp. Further investigation will need to be conducted to draw conclusions about comparisons over long-term use and how comparisons may be affected by population diversity and therapy program administration.

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APPENDICIES

APPENDIX I: RECRUITMENT MATERIALS AND DATA COLLECTION

UNIVERSITY of WISCONSIN
UWMILWAUKEE

College of Health Sciences
Department of Communication Sciences and Disorders

You are invited to participate in research to improve tongue strength

Study Title: A Comparison of Two Devices for Isometric Lingual Strengthening in Healthy Adults

Purpose of the Study: Compare tongue strength measured by two devices during an eight-week tongue strengthening exercise program.

Who is Eligible: Adults ages 18-59 whom are in generally good health without active tongue piercings.

Where: The Swallow Physiology Laboratory located in Enderis Hall, Rm B30

Do What: Participate in an eight-week home tongue strengthening program using a new device. Participants will visit the lab every other week (total of 5 visits) during the eight-week program to measure tongue strength. If you use your personal Android device for the study, you will download a free application from the GooglePlay Store. If you do not have an Android device, a loaner device will be available for the duration of the study.

If you are interested in participating or would like more information, please contact the lab at:

UWMSwallowLab@gmail.com

Use subject heading: Tongue strengthening

CONSENT FORM

Study title	A Comparison of Two Devices for Isometric Lingual Strengthening in Healthy Adults
Researchers	Daniel L. Gutierrez, B.S., Department of Communication Sciences and Disorders Barbara Pauloski, Ph.D., Faculty Advisor, Department of Communication Sciences and Disorders

We're inviting you to participate in a research study. Participation is completely voluntary. If you agree to participate now, you can always change your mind later. There are no negative consequences, whatever you decide.

What is the purpose of this study?

Reduced tongue strength can result in swallowing problems that may affect a person's health. Tongue strengthening exercise has shown to improve tongue strength and create a safer swallow. Two devices available for tongue strengthening programs include the Iowa Oral Performance Instrument (IOPI), a well-established instrument, and the Tongueometer™ a new, less expensive instrument. We want to understand whether the Tongueometer™ works as well as the IOPI.

What will I do?

- In our lab, the Swallow Physiology Laboratory, Department of Communication Sciences and Disorders, University of Wisconsin-Milwaukee (UWM)
    - Visit 1 (60 minutes)
        - We will examine your mouth and throat, and ask you to perform some speech movements (5 minutes)
        - We will customize two pressure-sensing bulbs to fit your mouth (5 minutes)
        - We will measure how much pressure you can apply to the pressure-sensing bulbs with your tongue. We will measure this pressure in two locations on your tongue and with two different devices (IOPI and Tongueometer™). (20 minutes)
        - If you want to use your personal Android device for this study, you will download the free Tongueometer™ application from the Google Play Store to your personal device. (5 minutes)
        - If you do not own an Android device with operating system 4.4 or later, a loaner device will be available.
        - We will teach you some exercises using the Tongueometer™ that may increase your tongue strength. (15 minutes)
        - We will teach you how to take care of the Tongueometer™ and change the device settings as needed. (10 minutes)
    - Visits 2-4 (30 minutes)
        - We will measure how much pressure you can apply to the pressure-sensing bulbs with your tongue. We will measure this pressure in two locations on your tongue and with two different devices (IOPI and Tongueometer™). (20 minutes)
        - We will reset the training levels on your Tongueometer™ based upon the new tongue-pressure measurements from this visit. (5 minutes)
        - We will review your exercises and answer any questions you have. (5 minutes)
    - Visit 5 (30 minutes)
        - We will measure how much pressure you can apply to the pressure-sensing bulbs with your tongue. We will measure this pressure in two locations on your tongue and with two different devices (IOPI and Tongueometer™). (20 minutes)
        - You will complete a survey about your experience with the Tongueometer™. (10 minutes)
- At home
    - Week 1 (20 minutes)

- You will push your tongue against the bulb on the Tongueometer™ until the unit indicates you reached the target pressure set by us.
- You will repeat this 30 times, 3 times a day for 3 days this week.
- You will keep track of your completed exercises and send an email to the Swallow Physiology Laboratory with your completion record at the end of the week.

- Week 2 (25 minutes)
  - You will adjust the target pressure on your Tongueometer™ as we demonstrated at the beginning of this week.
  - You will push your tongue against the bulb on the Tongueometer™ until the unit indicates you reached the target pressure set by us.
  - You will repeat this 30 times, 3 times a day for 3 days this week.
  - You will keep track of your completed exercises and send an email to the Swallow Physiology Laboratory with your completion record at the end of the week.
- Weeks 3-8 (20 minutes)
  - You will push your tongue against the bulb on the Tongueometer™ until the unit indicates you reached the target pressure set by us.
  - You will repeat this 30 times, 3 times a day for 3 days each week.
  - You will keep track of your completed exercises and send an email to the Swallow Physiology Laboratory with your completion record at the end of each week.

Risks

Possible risks	**How we're minimizing these risks**
Breach of confidentiality (your data being seen by someone who shouldn't have access to it)	• All identifying information is removed and replaced with a study ID. • We'll store all electronic data on a password-protected, encrypted computer. • We'll store all paper data in a locked filing cabinet in a locked office. • We'll keep your identifying information separate from your research data, but we'll be able to link it to you by using a study ID. We will destroy this link after we finish collecting and analyzing the data.
Online data being hacked or intercepted	• This is a risk you experience any time you provide information online. We're using a secure system to collect this data, but we can't completely eliminate this risk. • In addition, your online data will be identified only with your study ID number.
Use of the IOPI and Tongueometer™	• These devices are small pressure-measuring units. There are no known risks associated with their use.

There may be risks we don't know about yet. Throughout the study, we'll tell you if we learn anything that might affect your decision to participate.

Other Study Information

Possible benefits	• The results of this study may potentially benefit persons with swallowing problems if the study shows that the new strengthening device is as good as the established device. • The study may provide data to support a cheaper option to increase tongue strength at home.
Estimated number of participants	20 adults ages 18-59

How long will it take?	Eight weeks from initiation date
Costs	There is a $2/hr parking fee if you use UWM parking structures or lots. Free street parking is available in some locations; however, it is your responsibility to follow posted parking guidelines (e.g. parking time limits).
Compensation	Prepaid Visa gift card for $20 Due to UWM policy and IRS regulations, we may have to collect your name, address, social security / tax ID number, and signature to give you this compensation. No payments will be awarded for partial completion of the study.
Future research	De-identified (all identifying information removed) data may be shared with other researchers. You won't be told specific details about these future research studies.
Removal from the study	During Visit 1, if you have any major physical differences in your mouth such as an overbite, underbite, or tongue tie, we will need to remove you from the study. During Visit 1, if your tongue is extra strong (measured above 80 kPa), we will need to remove you from the study. In order for our data to be useful, it is important that you attend every laboratory visit. If you miss a session and can't reschedule, we'll have to take you out of the study. It is important that you follow the home strengthening program. The Tongueometer™ application has a built-in feature that tracks your exercises and makes it easy to share this information with the investigators. The investigators will contact you if you miss more than two home practice sessions to help with any issues you may have. If you miss four sessions, you may be removed from the study if you cannot make up the practice.
Equipment Agreement Equipment being lent, check all that apply. [ ] Tongueometer™ [ ] Android Tablet	**Equipment Agreement Policies** Android and Tongueometer™ devices are the property of the UWM Swallow Physiology Laboratory and must be returned at the end of your study participation. Please handle devices with the same care you would use for your personal electronics. Devices will be inspected upon return to make sure they are working correctly. Report any loss or damage to loaner equipment to the Student PI as soon as possible. You will be asked to replace any lost or damaged equipment at the current market value. **Android Only** Please do not personalize the Android device loaned to you. The Android device is for purposes of this study only and should not be used for personal communication or entertainment.

	The loaner device will undergo a factory reset upon return to the Swallow Physiology Laboratory so be sure to back up any data or files you put on the loaner device before your final study visit.

Confidentiality and Data Security

We'll collect the following identifying information for the research: your name, email address, phone number, and social security number. This information is necessary to contact you for future correspondence and to provide compensation for your participation.

Where will data be stored?	Data will be stored securely on a BitLocker-protected computer in the Swallow Physiology Laboratory, Enderis Hall, Room B30, UWM
How long will it be kept?	De-identified data (no identifying information) will be stored securely for fifteen years after completion of the study

Who can see my data?	**Why?**	**Type of data**
The researchers	To conduct the study and analyze the data	Data will be coded (names removed and labeled with study ID)
The IRB (Institutional Review Board) at UWM The Office for Human Research Protections (OHRP) or other federal agencies	To ensure we're following laws and ethical guidelines	Data will be coded (names removed and labeled with study ID)
Anyone (public)	If we share our findings in publications or presentations	• Aggregate (grouped) data • De-identified (no names, birthdate, address, etc.)

Contact information:

For questions about the research	Daniel L. Gutierrez, B.S. Barbara Pauloski, Ph.D.	gutier78@uwm.edu pauloski@uwm.edu
For questions about your rights as a research participant	IRB (Institutional Review Board; provides ethics oversight)	414-229-3173 / irbinfo@uwm.edu
For complaints or problems	Daniel L. Gutierrez, B.S. Barbara Pauloski, Ph.D.	gutier78@uwm.edu pauloski@uwm.edu
	IRB	414-229-3173 / irbinfo@uwm.edu

Signatures

If you have had all your questions answered and would like to participate in this study, sign on the lines below. Remember, your participation is completely voluntary, and you're free to withdraw from the study at any time.

_____

Name of Participant (print)

Signature of Participant _____ Date _____

Name of Researcher obtaining consent (print) _____

Signature of Researcher obtaining consent _____ Date _____

SCREENING FORM

Ask the potential subject the following screening questions. Circle response.

1. Are you between 18 and 59 years of age?
    a. If YES, continue to Q2.
    b. If NO, please thank the person and excuse them from further questioning.

2. Do you consider yourself in general good health?
    a. If YES, continue to Q3.
    b. If NO, describe:_____

    _____

    _____

    (If reporting any of the exclusion criteria or reporting other long-term illness or unremitting problem, potential subject is not eligible. Please thank the person and excuse them from further questioning.)

3. Have you had any surgery to your mouth, throat or neck?
    a. If NO, continue to Q4.
    b. If YES, describe:_____

    _____

    _____

    (If tonsil or adenoid removal, tooth extractions including wisdom teeth removal, or rhinoplasty ("nose job"), continue to Q4)

    (If other surgery, potential subject is not eligible. Please thank the person and excuse them from further questioning.)

4. Have you been treated for cancer of the head and neck?
    a. If NO, continue to Q5.
    b. If YES, potential subject is not eligible. Please thank the person and excuse them from further questioning.

5. Do you have now or do you have a history of neurologic disease? (examples include multiple sclerosis, muscular dystrophy, myasthenia gravis, Parkinson's disease, ALS, cerebral palsy)
    a. If NO, continue to Q6.
    b. If YES, potential subject is not eligible. Please thank the person and excuse them from further questioning.

6. Do you have a history of stroke?

a. If NO, continue to Q7.

b. If YES, potential subject is not eligible. Please thank the person and excuse them from further questioning.

7. Do you have any previous or current tongue piercings?

a. If NO, continue to Q8.

b. If YES, potential subject is not eligible. Please thank the person and excuse them from further questioning.

8. Do you currently play or have a history of playing brass or woodwind instruments?

a. If NO, continue to Q9.

b. If YES, potential subject is not eligible. Please thank the person and excuse them from further questioning.

9. Do you have training in oration or dictation?

a. If NO, tell potential subject that he/she is eligible and ask to schedule a visit to discuss the study, obtain informed consent, and conduct baseline evaluation.

b. If YES, potential subject is not eligible. Please thank the person and excuse them from further questioning.

Check One: Eligible ☐ Not Eligible ☐

If eligible, record name and preferred method of contact.

Name: _____ Contact at: _____

Initial Visit Scheduled? Yes ☐ No ☐

SUBJECT DEMOGRAPHICS FORM

A Comparison of Two Devices for Isometric Lingual Strengthening in Healthy Adults

Demographics Form

Subject Name: _____ Study ID #: _____

Email address: _____

Preferred Phone Number: _____

Mailing Address: _____

_____

SSN (needed for compensation): _____

Preferred method of contact (circle): email phone text

Birthdate: (__ __/ __ __ /__ __ __ __) Gender: _____

(MM/DD/YYYY)

Ethnicity (circle): 1 = Hispanic or Latino 2=Not Hispanic or Latino

Race (circle all that apply):

1=American Indian or Alaska Native

2=Asian

3=Native Hawaiian or Other Pacific Islander

4=Black or African American

5=White

6=other (specify) _____

ORAL EXAMINATION FORM

Harding University Speech Clinic
Oral-Peripheral Examination Form

Name: _____ Age: _____ Date: _____

Examiner's Name: _____

Instructions: Check and circle each item noted. Include descriptive comments in the right-hand margin.

Evaluation of Face

_____ Symmetry: normal/droops on right/droops on left _____

_____ Abnormal movements: none/grimaces/spasms _____

_____ Mouth breathing: yes/no _____

_____ Other _____

Evaluation of Jaw and Teeth

Tell client to open and close mouth.

_____ Range of motion: normal/reduced _____

_____ Symmetry: normal/deviates to right/deviates to left _____

_____ Movement: normal/jerky/groping/slow/asymmetrical _____

_____ TMJ noises: absent/grinding/popping _____

_____ Other _____

Observe dentition.

_____ Occlusion (molar relationship): normal/neutroclusion (Class I)/ distoclusion (Class II)/mesioclusion (Class III) _____

_____ Occlusion (incisor relationship): normal/overbite/underbite/crossbite _____

_____ Teeth: all present/dentures/teeth missing (specify) _____

_____ Arrangement of teeth: normal/jumbled/spaces/misaligned _____

_____ Hygiene _____

_____ Other _____

August 1, 2016

Evaluation of Lips

Tell client to pucker.

_____ Range of motion: normal/reduced _____

_____ Symmetry: normal/droops bilaterally/droops right/droops left _____

_____ Strength (press tongue depressor against lips): normal/weak _____

_____ Other _____

Tell client to smile.

_____ Range of motion: normal/reduced _____

_____ Symmetry: normal/droops bilaterally/droops right/droops left _____

_____ Other _____

Tell client to puff cheeks and hold air.

_____ Lip strength: normal/reduced _____

_____ Nasal emission: absent/present _____

_____ Other _____

Evaluation of Tongue

_____ Surface color: normal/abnormal (specify) _____

_____ Abnormal movements: absent/jerky/spasms/writhing/fasciculations _____

_____ Size: normal/small/large _____

_____ Frenum: normal/short _____

_____ Other _____

Tell client to protrude the tongue.

_____ Excursion: normal/deviates to right/deviates to left _____

_____ Range of motion: normal/reduced _____

_____ Speed of motion: normal/reduced _____

_____ Strength (apply opposing pressure with tongue depressor): normal/reduced _____

_____ Other _____

Tell client to retract the tongue.

_____ Excursion: normal/deviates to right/deviates to left _____

_____ Range of motion: normal/reduced _____

_____ Speed of motion: normal/reduced _____

_____ Other _____

Tell client to move tongue tip to the right.

_____ Excursion: normal/incomplete/groping _____

_____ Range of motion: normal/reduced _____

_____ Strength (apply opposing pressure with tongue depressor): normal/reduced _____

_____ Other _____

Tell client to move the tongue tip to the left.

_____ Excursion: normal/incomplete/groping _____

_____ Range of motion: normal/reduced _____

_____ Strength (apply opposing pressure with tongue depressor): normal/reduced _____

_____ Other _____

Tell client to move the tongue tip up.

_____ Movement: normal/groping _____

_____ Range of motion: normal/reduced _____

_____ Other _____

Tell client to move the tongue tip down.

_____ Movement: normal/groping _____

_____ Range of motion: normal/reduced _____

_____ Other _____

Observe rapid side-to-side movements.

_____ Rate: normal/reduced/slows down progressively _____

_____ Range of motion: normal/reduced on left/reduced on right _____

_____ Other _____

Evaluation of Pharynx

_____ Color: normal/abnormal _____

_____ Tonsils: absent/normal/enlarged _____

_____ Other _____

Evaluation of Hard and Soft Palates

_____ Color: normal/abnormal _____

_____ Rugae: normal/very prominent _____

_____ Arch height: normal/high/low _____

_____ Arch width: normal/narrow/wide _____

_____ Growths: absent/present (describe) _____

_____ Fistula: absent/present (describe) _____

_____ Clefting: absent/present (describe) _____

_____ Symmetry at rest: normal/lower on right/lower on left _____

_____ Gag reflex: normal/absent/hyperactive/hypoactive _____

_____ Other _____

Tell client to phonate using /ɑ/.

_____ Symmetry of movement: normal/deviates right/deviates left _____

_____ Posterior movement: present/absent/reduced _____

_____ Lateral movement: present/absent/reduced _____

_____ Uvula: normal/bifid/deviates right/deviates left _____

_____ Nasality: absent/hypernasal _____

_____ Other _____

Comments:

Summary of Findings:

TONGUE STRENGTH DATA COLLECTION FORM

A Comparison of Two Devices for Isometric Lingual Strengthening in Healthy Adults

Tongue Strength Data Collection Form

Subject ID #: _____ **Date:** _____

Baseline _____ **End Week 2** _____ **End Week 4** _____

End Week 6 _____ **End Week 8 (Study Completion)** _____

Randomization Sequence (refer to schema for correct sequence number): _____

First Device (circle)	**IOPI**	**Tongueometer**
First bulb position (circle)	**Anterior**	**Posterior**
Trial 1 (kPA)		
Trial 2 (kPA)		
Trial 3 (kPA)		
Second bulb position (circle)	**Anterior**	**Posterior**
Trial 1 (kPA)		
Trial 2 (kPA)		
Trial 3 (kPA)		

Second Device (circle)	**IOPI**	**Tongueometer**
First bulb position (circle)	**Anterior**	**Posterior**
Trial 1 (kPA)		
Trial 2 (kPA)		
Trial 3 (kPA)		
Second bulb position (circle)	**Anterior**	**Posterior**
Trial 1 (kPA)		
Trial 2 (kPA)		
Trial 3 (kPA)		

STRENGTHENING PROGRAM DOCUMENTAION FORM

A Comparison of Two Devices for Isometric Lingual Strengthening in Healthy Adults
Strengthening Program Documentation Form

Subject ID #: _____

Anterior Marking (mm from bulb): _____ **Posterior Marking (mm from bulb):** _____

BASELINE Evaluation date: _____	**Values**
Anterior Tongue Pressure Maximum (kPa)	
Week 1 Training Level (60% max)	
Week 1 % prescribed training sessions completed	
Week 2 Training Level (80% max)	
Week 2 % prescribed training sessions completed	

Week 2 Evaluation date: _____	**Values**
Anterior Tongue Pressure Maximum (kPa)	
Week 3-4 Training Level (80% max)	
Week 3 % prescribed training sessions completed	
Week 4 % prescribed training sessions completed	

Week 4 Evaluation date: _____	**Values**
Anterior Tongue Pressure Maximum (kPa)	
Week 5-6 Training Level (80% max)	
Week 5 % prescribed training sessions completed	
Week 6 % prescribed training sessions completed	

Week 6 Evaluation date: _____	**Values**
Anterior Tongue Pressure Maximum (kPa)	
Week 7-8 Training Level (80% max)	
Week 7 % prescribed training sessions completed	
Week 8 % prescribed training sessions completed	

STUDY EXIT SURVEY

A Comparison of Two Devices for Isometric Lingual Strengthening in Healthy Adults

Exit Survey

The following questions are regarding study requirements and participation

1. What made you want to participate in this study?

_____

_____

_____

2. In your own words, what did you like most about participating in this study?

_____

_____

_____

3. In your own words, what could have been different to make this study more enjoyable?

_____

_____

_____

4. Did you feel this study requirements and participation was (circle one) what you expected; slightly more than you expected; or significantly more than you expected?
Briefly describe why if you chose slightly or significantly more than you expected:

_____

_____

_____

5. In your own words describe how you felt about the study's level of involvement:

_____

_____

_____

The following questions and ratings are regarding the Tongueometer™

6. What were your initial impressions of the device?

_____

_____

_____

7. What device features did you like the most?

_____

_____

_____

8. What device features did you like the least?

_____

_____

_____

Circle the rating the most closely describes your feelings about the Tongueometer™

1 – Strongly Disagree 2 – Disagree 3 – Neutral 4 – Agree 5 – Strongly Agree

9.	The device is easy to use.	1 2 3 4 5
10.	The device application is user friendly.	1 2 3 4 5
11.	The device is of high quality.	1 2 3 4 5
12.	The device is sturdy	1 2 3 4 5
13.	The device is easy to maintain.	1 2 3 4 5
14.	The lip guard is helpful to maintain bulb position.	1 2 3 4 5
15.	The textured bulb helped maintain bulb position.	1 2 3 4 5

16. Changing the bulb is relatively simple. 1 2 3 4 5

17. I would recommend this device to a friend. 1 2 3 4 5

18. I liked the data sharing feature of the android Application. 1 2 3 4 5

19. Is there anything you would change about the device?

_____

_____

_____

20. Is there anything you would change about the Android application?

_____

_____

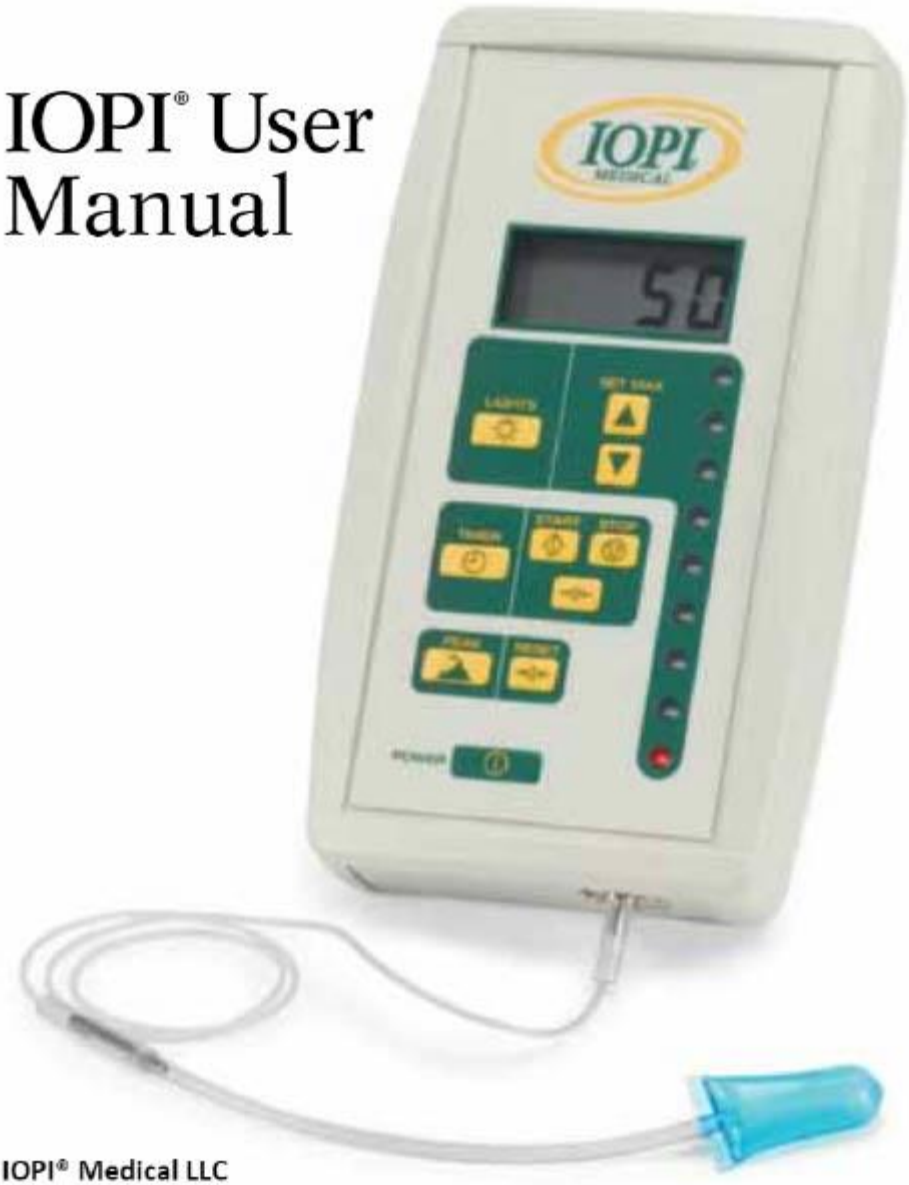
_____

APPENDIX II: DEVICE USER MANUALS

IOPI MEDICAL

Iowa Oral Performance Instrument
MODEL 2.3

IOPI® User Manual



IOPI® Medical LLC
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Redmond, WA 98053
PHONE: +1 (425) 549-0139
FAX: +1 (425) 558-4596

www.IOPImedical.com

IOPI® Icons

Symbol	Identity
REF	Catalogue Number
SN	Serial Number
	Manufacturing Date
	Consult Instructions Before Use
	Caution
	Type B patient applied part according to IEC 60601-1
 4mA 9V alkaline	9 Volt Alkaline Battery
	Do Not Dispose of in Household Refuse
EC REP	EU Authorized Representative
	Manufactured By
CE	Conformity European

Notes:

IOPI Medical LLC is certified to ISO 13485:2003 under the Canadian Medical Device Regulation

Table of Contents

Indications for Use

Tongue and lip strength and endurance measurement in patients with oral motor problems, including dysphagia and dysarthria.

Contraindications:

- **Do not** use with children under the age of 3.
- **Do not** put the Tongue Bulb in a patient's mouth if there is a risk of the patient having a seizure.
- **Do not** use the Tongue Bulb with a patient who has any current or past problem with pain disorders involving the jaw muscles or joint of the mandible ("TMJ Disorder," "Myofacial Pain Disorder").

⚠ WARNINGS

- The medical professional should ensure the patient is healthy enough to perform a maximal motor task, recognizing that it may produce a generalized effort response.
- The medical professional should **hold on to the Tongue Bulb tube** any time it is in a patient's mouth.
- The Tongue Bulbs, as supplied by IOPI Medical LLC, are **not sterile and are not intended for sterilization**.
- The Tongue Bulbs, as supplied by IOPI Medical LLC, are intended for **single patient use only**. Please read the IOPI Tongue Bulb Directions for Use for cleaning instructions between uses with the same patient.
- Keep Tongue Bulbs out of the reach of children.
- The medical professional should inform any patient who is to perform the tongue endurance measurement at 50% or more of the Peak pressure that they may experience the sensation of "throat" soreness following the measurement. This condition may persist for as long as 24 hours.

IOPI® Components

Included in The IOPI System (PN 1-2300):

Component	Item	PN	Description
A	Iowa Oral Performance Instrument (IOPI) Model 2.3	8-2301	Device measures and displays pressure from an air-filled bulb. Pressure In port is a short stainless steel tube to which the Connecting Tube is attached (C).
B	Box of Tongue Bulbs	5-6010	Squeezed by the tongue to measure tongue strength and endurance.
C	Connecting Tube	5-0001	Connects the Tongue Bulb to the Pressure In port.
D	Carrying Case	5-0002	Padded case for storing and transporting the IOPI device.
E	Accuracy Check Syringe	5-0101	Syringe used in the Accuracy Check procedure.

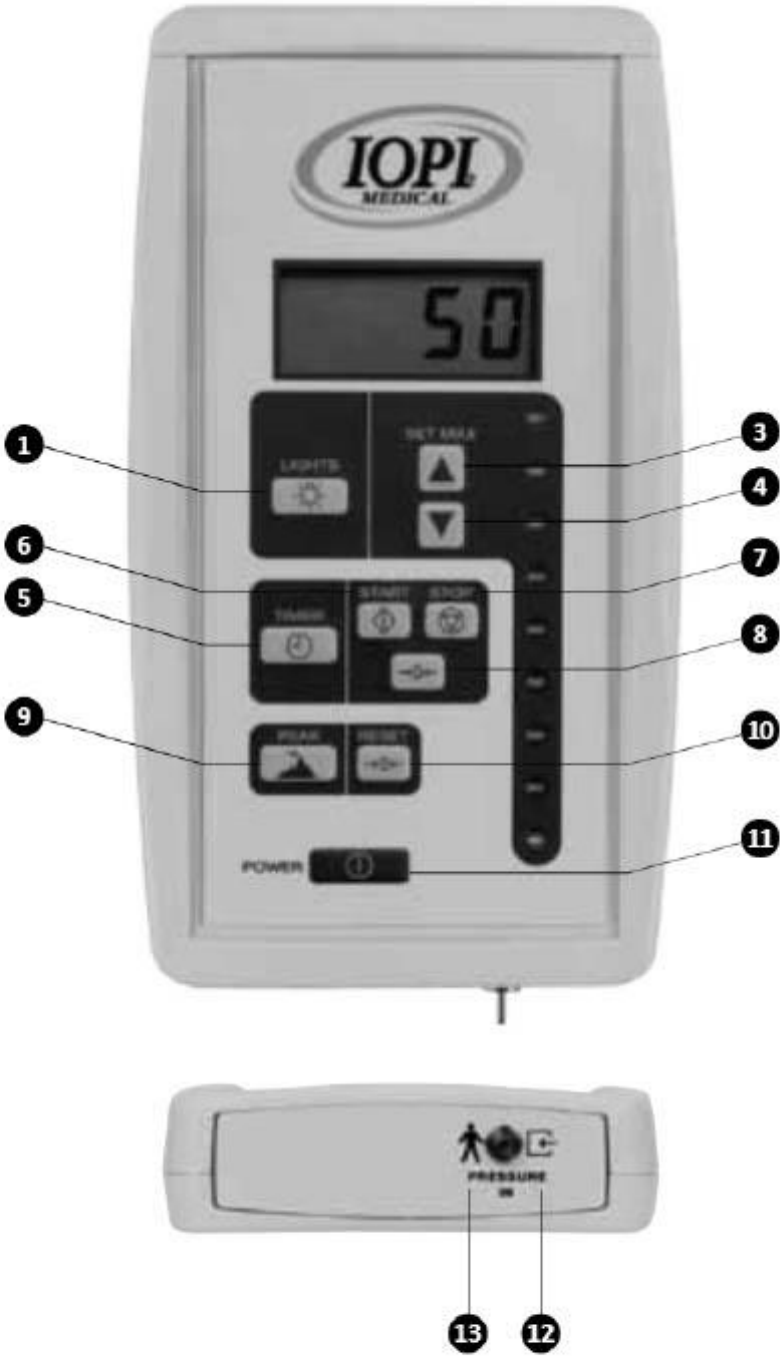
IOPI® Medical LLC approved accessories:

5-6010 Box of Tongue Bulbs
5-0001 Connecting Tube
5-0101 Accuracy Check Syringe

NOTE: Only use IOPI® Medical LLC approved accessories with The IOPI System.

IOPI® Control Buttons

#	Symbol	Identity	Description
1		Lights Mode	Toggles the column of lights On and Off. The LCD display shows the target pressure required to illuminate the top (green) light of the light array. When entering Lights Mode, the LCD displays the default target pressure of fifty (50) and one light will be illuminated.
2	SET MAX	Set Maximum Pressure	Identifies the buttons for adjusting the target pressure that corresponds to the top (green) light of the light array in Lights Mode.
3		Adjust Maximum Up	Increases the target pressure corresponding to the top (green) light of the light array in Lights Mode.
4		Adjust Maximum Down	Decreases the target pressure corresponding to the top (green) light of the light array in Lights Mode.
5		Timer Mode	When pressed, the LCD display shows the elapsed time, in seconds, between pressing the Start Timer [◇] and Stop Timer [▽] buttons.
6		Start Timer	This button will start the Timer.
7		Stop Timer	This button will stop the Timer.
8	→0←	Timer Reset	This button will reset the Timer to zero (0).
9		Peak Mode	Activates a peak-finding function. Displays the maximum pressure achieved when an attached bulb is compressed.
10	→0←	Peak Reset	This button will reset the peak-finding function to zero (0).
11		Power	Toggles the battery power between On and Off. The IOPI will turn itself off after 15 minutes without a button push or pressure response.
12		Pressure In	Short stainless steel tube that connects to female end of Connecting Tube.
13		Type B	Patient Isolation: Type B patient applied part according to IEC 60601-1.



Safety & Care Instructions

Safety precautions

Please observe the following safety precautions when setting up and using your IOPI:

- This device is only intended for measuring oral motor structures.
- This device is sold only to medical professionals assisting patients with oral motor problems, including dysphagia and dysarthria. The medical professional is in charge of supervising a patient's use of the IOPI in order to ensure that it is only used as intended.
- To avoid measurement errors, carefully read this manual before using the IOPI.
- Prior to using IOPI accessories (such as the IOPI Tongue Bulb) with the IOPI device, carefully read the Directions for Use for the accessory.

Caring for your IOPI

To ensure that you receive the maximum benefit from using this device, please abide by the following care guidelines:

- When not in use, store the IOPI device in the carrying case provided with the device.
- Do not immerse the IOPI device in water. If the surface of the device comes into contact with water, dry it immediately with a soft cloth.
- To clean the exterior of the IOPI device, wipe it with a soft slightly moistened cloth. Use of mild soaps or disinfectants is suitable. Do not use abrasive or corrosive cleaning agents, as these may damage the unit.
- Remove the 9V battery whenever you plan to store the IOPI device for a long period of time.
- When replacing the battery, only use a new 9V alkaline battery. Do not use a rechargeable battery.
- Do not expose the IOPI device to strong electromagnetic fields, excessive force, shock, dust, temperature changes, or humidity. These environmental conditions may result in malfunction, a shorter electronic life span, or damage to the device.
- Do not open up the IOPI and tamper with the internal components; doing so will terminate the product warranty and may cause damage.
- At the end of its useful life, dispose of the IOPI device and its accessories in accordance with local or national disposal or recycling laws.

How Does the IOPI Work?

How does the IOPI measure strength?

The IOPI measures the Peak pressure a patient can produce in an IOPI Tongue Bulb by pressing the bulb against the roof of the mouth with the tongue. Peak pressure is a measure of strength, expressed in units of pressure, the kiloPascal (kPa).

How does the IOPI measure endurance?

For patients with dysphagia or dysarthria, oral motor fatigability may be of interest. The IOPI can be used to assess tongue fatigability by measuring its endurance, which is inversely proportional to fatigability. Low endurance values are an indicator of a high fatigability.

Endurance is measured with the IOPI by quantifying the length of time that a patient can maintain 50% of his or her Peak pressure. This procedure is conducted by setting the maximum pressure in the Lights Mode to 50% of the patient's Peak pressure and timing how long the patient can hold the top (green) light on.

How is the IOPI used for exercise therapy?

In Lights Mode, the pressure required to illuminate the green light at the top of the light array can be adjusted using the Set Max arrow buttons. This green light is used as a target for the patient. The medical professional determines what target value is appropriate for exercise therapy purposes and provides specific instructions to the patient for a particular exercise protocol. A protocol should include the number of times to illuminate the green light and, for each repetition, how long the green light should be illuminated before releasing pressure on the bulb.

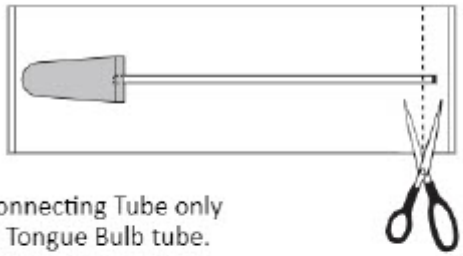
Please visit our website (***www.IOPImedical.com***) for a list of articles providing information about exercise therapy for oral motor structures.

$$T = P_{max} \times \left(\frac{E}{100}\right)$$

T= Target value, P_{max} = Peak tongue pressure, E = Effort (%)

Set Up

1. Remove the IOPI device from the carrying case and place on a flat surface.
2. Remove the Connecting Tube from the package and notice that it has two ends: a female end (plastic tubing) and a male end (metal).
3. Connect the female end (plastic tubing) to the Pressure Port [ ] on the IOPI® device by sliding the tubing over the metal port as far as it will go.
4. Look at the Tongue Bulb and notice that one end is a blue bulb and the other end is tubing.
5. Use scissors to cut the seal off the end of the tubing by cutting across the package while the Tongue Bulb is still in its package. *(See image to the right).*



6. Insert the metal (male) end of the Connecting Tube only 2–3 mm into the opened end of the Tongue Bulb tube.
7. Remove the Tongue Bulb from its package to use it with a patient, taking care not to touch the parts of the Tongue Bulb that go into the patient's mouth.
8. Turn the IOPI device on by pressing the Power button [ ]. The display will show 0 (+/- 1 kPa).

Tongue

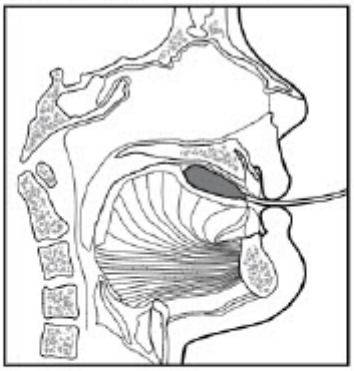
Measuring Tongue Strength

1. With the IOPI® turned on, push the Peak Mode button [ ]. In this mode, the LCD displays the highest pressure applied to the IOPI.

NOTE: When the IOPI is first turned on, the LCD display shows pressure in a continuous mode.

2. Press the Peak Reset button [→0←]. The LCD display will read "0".
3. Position the Tongue Bulb against the patient's hard palate *(see image to the below).*

WARNING: Hold onto the stem of the Tongue Bulb.



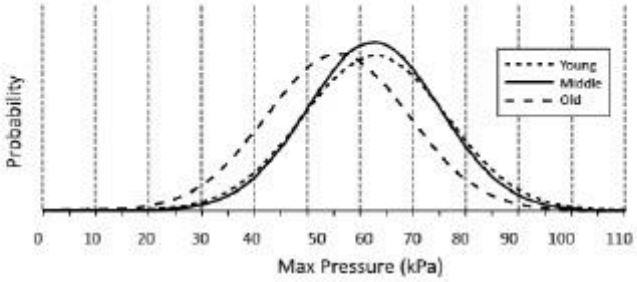
4. Tell the patient: **"Press the Tongue Bulb with your tongue as hard as you can for about 2 seconds."**
   - *Visual and verbal encouragement during the test is acceptable, and helps some people.*
   - *The 2 second hold time is not important; it just avoids the question "How long should I hold it?" when you tell them to squeeze the bulb.*

5. After the patient has made his or her maximum response and relaxed, record the value you see on the IOPI LCD display, and then push the Peak Reset button [→0←].
6. Let the patient rest for 30–60 seconds, and then repeat Steps 3–5 two more times.
7. The Peak tongue strength is the highest of the three recorded values. If the values consistently decrease over the three trials, the rest period may not be long enough.

Tongue Strength Normal Values

These normal values are derived from 10 studies conducted on the US population. New research indicates there may be national variation in these normal values, perhaps dependent on the language spoken by the subjects/patients. For the latest studies that IOPI Medical is aware of, please visit our website.

Estimated normal probability distributions of maximum tongue pressure of three age groups of normal U.S. subjects are shown to the right:



These data were derived from the weighted average of the means and standard deviations of tongue strength of normal subjects reported in 10 publications. Consult "Normal Values" in ***www.IOPImedical.com*** for references and details of the numerical procedures.

Group	Mean	SD	Age (years)	Number of Subjects
Young	63	13.6	20–39	276
Middle	63	12.5	40–60	219
Old	56	13.5	>60	198

Most groups contained approximately equal numbers of males and females. In some studies, males were somewhat stronger than females, by about 5-10 kPa, but only for young subjects. For middle-aged and old subjects, there was no consistent gender difference.

Peak tongue strength values corresponding to various percentiles from the estimated normal distributions are shown below. It is common to consider values below the 5th percentile to be "abnormal" (shaded table cells).

Group	Tongue Strength (kPa)					
	1%	5%	10%	20%	25%	50%
Young	**31**	**41**	**46**	**52**	**54**	**63**
Middle	**34**	**43**	**47**	**53**	**55**	**63**
Old	**25**	**34**	**39**	**44**	**48**	**56**

Measuring Tongue Endurance

1. Measure and record the patient's Peak pressure as described on page 11.
2. Press the Lights Mode button [☼] and note that the bottom light of the light array will turn on and the LCD will display the value 50 (kPa).
3. Use the SET MAX arrows [▲▼] to adjust the value in the LCD display to 50% of the patient's Peak pressure.

NOTE: The top (green) light of the light array will now illuminate when the patient compresses the Tongue Bulb to 50% of their Peak pressure.

4. Place the IOPI so that the light array can be seen easily by the patient.
5. Prepare to use the Timer Mode on the IOPI to measure the length of time that the patient can illuminate the top (green) light.

NOTE: A stopwatch may be used in place of the IOPI's timer feature.

6. To use the Timer Mode, press the Timer Mode button [◴] and notice that the LCD display will show "0" seconds. If the display does not show "0", press the Timer Reset button [→0←].
7. Position the Tongue Bulb in the patient's mouth as described for tongue strength measurement.
8. Instruct the patient to "Squeeze the Tongue Bulb until the top (green) light comes on, and keep it on for as long as possible."
9. When the top (green) light comes on, press the Start Timer button [◈].
10. If if a red light turns on for more than a second, remind the patient to squeeze hard enough to keep the green light on. It is acceptable to encourage the patient "to keep going as long as possible".
11. If the patient cannot illuminate the green light within about 2 seconds, press the Stop Timer button [▽] and tell the patient to relax.
12. Record the time shown in the LCD display.

NOTE: Usually this test is done only once per session with each patient.

Tongue Endurance Normal Values

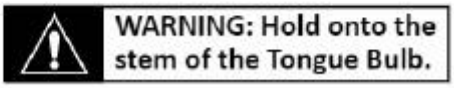
The data is as yet insufficient to assume the statistical normality of the endurance distributions in the normal population, so an estimate of a normal probability function is not yet warranted. However, the U.S. studies published so far suggest an average endurance of about 30–35 seconds for the tongue. Endurance times of 10 seconds or less would be an indication that a patient probably has low endurance; it may be useful to consider that fatigability is a contributing factor to this patient's oral motor problems.

Lip

Measuring Lip Strength

> ***NOTE:*** ***In the following method of measuring lip strength, the bulb is not placed directly between the lips. The described method is valid, however, because the pressure developed in the bulb depends upon the strength of the circumferential muscle complex that surrounds the mouth. It is tension in these muscles that allows the lips to be compressed against one another.***

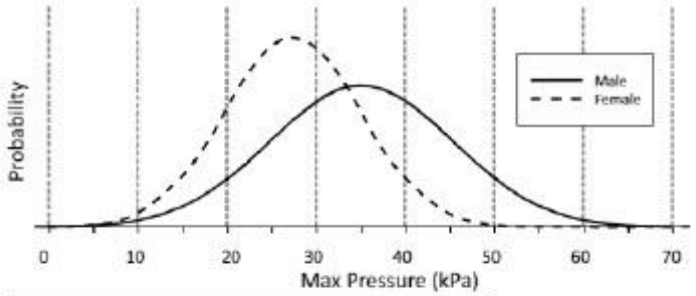
1. With the IOPI on, push the Peak Mode button []. In this mode, the LCD will display the highest pressure applied to the IOPI.
2. Press the Peak Reset button [→0←]. The LCD display will read "0".
3. Position an IOPI Tongue Bulb inside the patient's cheek just lateral to the corner of the mouth.



4. Tell the patient: "Press the Tongue Bulb against your teeth by pursing your lips as hard as you can for about 2 seconds."
   - *Visual and verbal encouragement during the test is acceptable, and helps some people.*
   - *The 2 second hold time is not important; it just avoids the question "How long should I hold it?" when you tell them to squeeze the bulb.*
5. After the patient has made his or her maximum response and relaxed, record the value you see on the IOPI LCD display, and then push the Peak Reset button [→0←].
6. Let the patient rest for 30–60 seconds, and then repeat Steps 3–5 two more times.
7. The Peak lip strength is the highest of the three recorded values. If the values consistently decrease over the three trials, the rest period may not be long enough.

Lip Strength Normal Values

An estimated normal probability distribution of a group of 171 normal U.S. persons, aged 18–89, is shown below. Although there were no consistent age differences there was a pronounced gender difference.



Gender	Mean	SD	Number of Subjects
Male	35	10.3	88
Female	28	7.7	83

Data are taken from Clark et al., 2012. No significant differences were found when comparing the right and left lip strengths, so these data have been pooled. See ***www.IOPImedical.com*** for the complete reference of this study, and details of numerical procedures.

References

Please refer to ***www.IOPImedical.com*** for a list of up-to-date references that may be useful for understanding normal values, applications of the IOPI, and protocols that have been published by researchers.

IOPI® Maintenance

Replacing the Battery

1. Replace the battery if the display shows a low battery icon [LO BAT], the display is dim, or if the display does not illuminate when the Power button has been pressed.
2. To replace the battery, slide the battery cover on the back of the IOPI to its fully open position.
3. Install a new 9V alkaline non-rechargeable block battery and connect it to the battery connector, being sure to correctly match the polarity.
4. Slide the battery cover to its fully closed position.

NOTE: Contact your local waste disposal authority for instructions on how to dispose of used alkaline batteries. In Europe, used batteries should be recycled in accordance with council directive 2006/66/EC as transposed into national laws. Do not dispose of in clinic trash.

Accuracy Check

Perform the following accuracy check monthly. Note that this procedure is a check only. If you would like IOPI Medical or an authorized electronics shop to check the calibration rigorously, contact IOPI Medical or your local distributor for instructions.

NOTE: Practice this process a few times until the timing is smooth before you record your readings. The exact starting and ending positions are important.

1. Connect the Connecting Tube to the Pressure Port on the IOPI.
2. Turn on the IOPI and press the Peak button.
3. Set the front edge of the plunger of the syringe just touching the back edge of the 30 ml mark *(see Figure 1)*.
4. Leave the plunger in this position and connect the syringe tubing to the metal end of the Connecting Tube.
5. Over a period of about 5 seconds, depress the plunger so that its front edge ends up just touching the back edge of the 15 ml mark *(see Figure 2)*.
6. Note the peak pressure reading on the IOPI.
7. Disconnect the syringe tubing from the Connecting Tube and push the Reset button on the Peak function.
8. ***Repeat Steps 3–7 several times***. Discard readings if you know you pushed the plunger past the ideal position, or if the depression time was too slow or too fast. If there is variability in the readings, this is due to variability in your method. Repeat until your reading stabilizes (±1 kPa).
9. Using the altitude at your location, compare this pressure reading to Figure 3 (for altitude in meters) or Figure 4 (for altitude in feet).
10. If the pressure reading does not fall within the shaded region of Figure 3 or 4, contact IOPI Medical or your local distributor.

Figure 1.

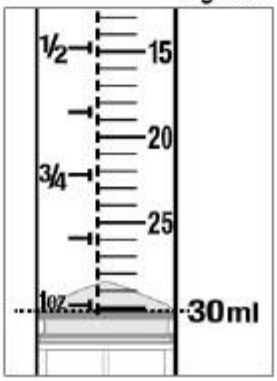


Figure 2.

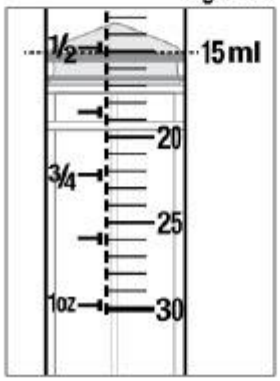


Figure 3.

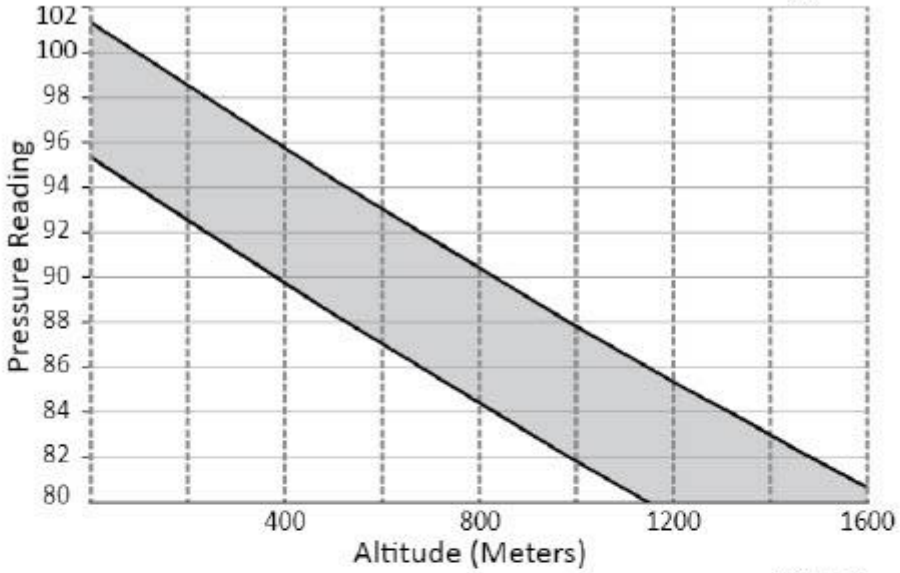
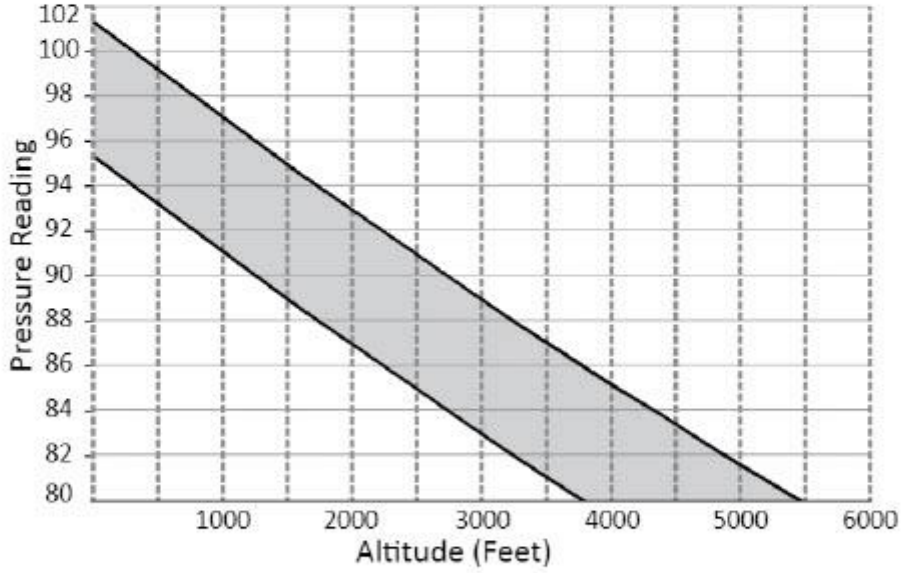
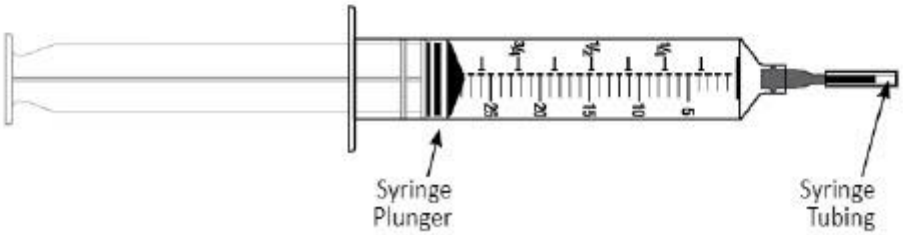


Figure 4.





Troubleshooting

Symptom	Possible Cause	Actions
Tongue Bulb stays flattened or dimpled after compression	An air leak can occur anywhere in the system (Tongue Bulb, Connecting Tube, or inside in the IOPI device itself.)	*1. Determine if the Tongue bulb leaks by trying another Tongue Bulb.* *2. Determine if there is a leak where the Connecting Tube connects to the Pressure Port. Put some soap bubbles around the seam between the Pressure Port and the end of the attached Connecting Tube. Apply a squeeze to a Tongue Bulb and look for soap bubbles that get larger or move around.* *3. While leaks inside the IOPI device are unlikely, if steps 1 and 2 have been tried and the cause of the leak has not been detected, then please contact IOPI Medical LLC or your local distributor as soon as possible.*
Abnormally short endurance values.	A small air leak	*See steps above to determine the source of the air leak.*
The LCD display reads >2 kPa when there is no bulb attached to the IOPI device.	A change in accuracy	*Contact IOPI Medical LLC or your local distributor as soon as possible.*
Peak pressure measurements that seem too high or too low based on experience with the IOPI device and the patient.	A change of accuracy	*Perform an Accuracy Check (see page 16). If the pressure reading is not within specifications, contact IOPI Medical LLC or your local distributor as soon as possible.*
The IOPI device will not turn on.	Battery is dead	*Follow the Replace Battery procedure in the Maintenance section as described on page 15. If the device still does not turn on, contact IOPI Medical LLC or your local distributor as soon as possible.*

Technical Specifications

APPLICATION				
Measuring method	Pressure in an air-filled bulb (in kPa).			
Indications for use	Tongue and lip strength and endurance measurement in patients with oral motor problems, including dysphagia and dysarthria.			
APPLIED STANDARDS				
EN 60601-1, 2nd Ed.				
EN 60601-1-2:2007				
EN 60601-1-6:2007				
ISO 14971:2012				
DIMENSIONS OF IOPI DEVICE				
Height x Width x Depth	18 cm x 10 cm x 2.5 cm			
Weight	258 g			
MEASURING RANGE				
Pressure	0 to 100 kPa			
ACCURACY				
Pressure	±2 kPa			
POWER				
Power supply	9V alkaline battery			
CLASSIFICATIONS				
Protection against electric shock	According to IEC 60601-1: Type B			
Protection against ingress of water	None			
Mode of operation	Continuous duty			
Device Classification	FDA/US	HC/Canada	EC - MDD	TGA/Australia
	I	II	I	I
OPERATING ENVIRONMENT				
Temperature	16°C to 27°C (60°F to 80°F)			
Humidity	10% to 83% relative humidity			
STORAGE/TRANSPORT ENVIRONMENT				
Temperature	-20°C to 49°C (-4°F to 120°F)			
Humidity	10% to 83% relative humidity			
MANUFACTURER				
	**IOPI® Medical LLC** 11920 198th Ave NE Redmond, WA 98053 U.S.A. Tel: +1 (425) 549-0139 FAX: +1 (425) 558-4596			
EU AUTHORIZED REPRESENTATIVE				
EC REP	**EMERGO EUROPE** Molenstraat 15, 2513 BH, The Hague, The Netherlands			
AUSTRALIAN SPONSOR				
	EMERGO AUSTRALIA Level 20 Tower II, Darling Park, 201 Sussex Street Sydney, NSW 2000 Australia			

Limited Warranty

WARRANTY

IOPI Medical LLC warrants your product to be free from defects in material and workmanship for a period of two years from the original date of purchase. If you discover a defect in a product covered by this warranty, we will repair it using new or refurbished components, or if repair is not possible, replace the item.

EXCLUSIONS

This warranty covers defects in manufacturing discovered while using the product as recommended by the manufacturer. The warranty does not cover loss or theft, nor does coverage extend to damage caused by misuse, abuse, unauthorized modification, improper storage conditions, and other failures to use or maintain in accord with the manufacturer's instructions. The warranty does not cover parts that are subject to normal wear and tear.

LIMITS OF LIABILITY

Should the product(s) fail, your sole recourse shall be repair or replacement, as described in the preceding paragraphs. IOPI Medical LLC will not be held liable to you or any other party for any damages that result from the failure of this product. Damages excluded include, but are not limited to, the following: lost profits, lost savings, loss of or injury to data, damage to person or property, and incidental or consequential damages arising from the use, or inability to use, this product. In no event will IOPI Medical LLC be liable for more than the amount of your purchase price, not to exceed the current list price of the product, and excluding tax, shipping, and handling charges.

IOPI Medical LLC disclaims any and all other warranties, express or implied. By using the product, the user accepts all terms described herein.

HOW TO OBTAIN SERVICE UNDER THIS WARRANTY

Before sending the unit for repair, contact IOPI Medical LLC:

+1 (425) 549-0139
sales@iopimedical.com

REQUIREMENTS

The cost of shipping to the manufacturer and payment of any customs clearance fees or duties are the responsibility of the user. These costs may be credited to the user's account if the product is determined to be under warranty. Return shipping costs for products repaired or replaced under this warranty will be paid for by IOPI Medical LLC.

tongueometer

User Manual

E2 Scientific Corp
340 S. Lemon Ave. #8049
Walnut, CA 91789
Phone: (608) 709-8804
Email: info@e2scientific.com

e2 scientific

Quick Start

To set up and begin using your Tongueometer, follow these 4 steps.

1. Remove contents from packaging.	
2. Attach bulb to the device.	
3. Download and open the "Tongueometer" app from the Google Play Store.	
4. Connect the Tongueometer to your phone or tablet using the OTG cable.	
Begin Exercising	

tongueometer

Table of Contents

Intended Use

The Tongueometer is a non-prescription medical device designed to measure and increase tongue strength and endurance. The Tongueometer measures maximum tongue strength and endurance, enables users to perform repetitive and isometric exercise activities, and provides objective biofeedback via custom software installed on a user's mobile phone or tablet device. The device is safe for use in home and clinical environments.

Indications for Use

The Tongueometer is a single-user device designed to measure and exercise tongue strength and endurance in patients with oral motor problems, including dysphagia and dysarthria.

CONTRAINDICATIONS:

- Do not use with children under the age of 3.
- Do not place the Tongueometer bulb in the mouth of someone who is at risk of having a seizure.
- Do not use if you have past or present pain disorders involving the jaw or mandible (e.g., TMJ disorder, myofascial pain disorder).

WARNINGS

- Setup of the Tongueometer should be completed under the guidance of a Speech-Language Pathologist ("SLP") or similar medical professional.
- The Tongueometer bulbs supplied by E2 Scientific Corp are not sterile and are not intended for sterilization.
- Only the Tongueometer bulbs supplied by E2 Scientific Corp should be used with the Tongueometer. Do not use the Tongueometer bulbs with any other device.
- The Tongueometer bulbs are intended for individual use only. Please refer to the manual for cleaning instructions between same-patient uses.
- Keep the Tongueometer device and bulbs out of reach of children.
- Discontinue use immediately if use results in mouth or throat pain and contact your SLP or medical professional.

Safety Precautions

Please observe the following safety precautions when setting up and using your Tongueometer device.

- This device is only intended to measure and exercise tongue strength and endurance.
- While the device may be sold directly to patients with oral motor problems, it is intended to be set up and used under the guidance of a medical professional caring for patients with oral motor problems, such as an SLP.
- To avoid measurement errors, carefully read and refer back to the user manual when using the Tongueometer.
- Do not use the device in or near water.
- Discontinue use of the Tongueometer immediately if the bulb, device, or On-the-Go ("OTG") cable is damaged.
- Do not lift, carry, hang or pull the device by the OTG cable, bulb or bulb tube.
- Discontinue use immediately if use results in pain in the mouth or throat and contact your SLP or medical professional.

Caring for the Tongueometer

To receive the maximum benefit from the Tongueometer device, please adhere to the following care guidelines:

- When not using the Tongueometer device, store the device in a dry, cool location.
- Do not immerse the Tongueometer device or bulb in water. If the surfaces come in contact with water, dry immediately with a cloth.
- To clean the hand-held unit of the Tongueometer device, wipe it gently with a moistened cloth with a mild soap or disinfectant. Do not use abrasive or corrosive cleaning agents as these may damage the surface and functionality of the device.
- Assure that your Android device has adequate charge before use with the Tongueometer for most accurate readings.
- Do not expose the Tongueometer to excessive force, humidity, temperature changes, shock, dust, or strong electromagnetic fields. Changes to environmental conditions may damage or destroy the device or cause malfunction.
- Do not open the Tongueometer device or tamper with the internal components. This could result in injury and result in device damage, destruction, or malfunction. E2 Scientific Corp is not responsible for any injury or damage caused by opening the device and tampering with the internal components.
- To dispose of the Tongueometer device and its components, follow local and national disposal and recycling laws.
- The device is not intended for use on an airplane. If the Tongueometer is taken on a plane, disconnect and reconnect bulb before use as the bulb may have depressurized and result in inaccurate results.

Device Setup

The Tongueometer consists of four components:

- handheld device
- air-filled bulb
- connecting OTG (on-the-go) cable specific to your Android device
- free, downloadable application for your Android tablet or smartphone

The Tongueometer application requires an Android smartphone or tablet that can download an app from the Google Play Store. Device setup only needs to be done once per Android device. You may download the Tongueometer application on as many Android devices as desired.

1. Remove the Tongueometer components from the packaging and place on a clean, flat surface.
2. Remove the air-filled bulb from the package.
3. Thread the clear tubing extending from the air-filled bulb through the circular unit at the top of the device and connect tightly onto the metal prong.
    a. Tip: if you experience difficulty threading tubing through the top of the device, try twisting the tubing as you thread it.

b. You can increase or decrease the length of the tubing once it is attached to the top of the device.

4. Set the Tongueometer device aside while you download the application on your Android device.

5. Open the Google Play Store on your Android device and search for the Tongueometer app. You can download the application on as many Android devices as you'd like. The icon will look like this:

6. The app is free to download. Download, install and open it. The app should prompt you to connect your Tongueometer device.

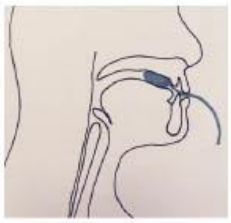
7. Connect the Tongueometer device to your Android device using the OTG cable. **Please note that the OTG cable is specific to your Android device.** When you purchased the Tongueometer, you were prompted to provide the make/model of your Android device so that you would receive the correct OTG cable. The OTG cable has a mini-USB connector on one end and a mini-connector on the other. Insert the mini-USB connector into the bottom of the hand-held unit and insert the mini-connector into the Android device. Assure your Android device is fully charged prior to set-up.

8. Once the Tongueometer is attached to the Android device, the Tongueometer app should automatically recognize the device. It will provide written prompts while it is connecting and provide an alert when it is ready to use. To test if the app is ready for use, you can squeeze the Tongueometer device bulb to move the needle in the app gauge. If it does not move, see Troubleshooting below.

   a. Note: each time you use the device, you will see a pop-up box (see below). You can either select "Use by default for this USB device" or click "OK" to connect. If you click "Cancel," the application will not recognize that the device is attached and will not work.

User Guide

Bulb Placement: Once the bub is securely attached to the device, place the bulb in the mouth so that it rests on the tongue just behind the front teeth. Your SLP can advise alternative placements of the bulb in your mouth.



The circular unit at the top of the Tongueometer device is designed to be a lip guard to prevent the bulb from slipping into the back of the mouth. Users can adjust the length of the tubing for optimal placement. Adjust the length of the tubing so that the mouth guard is flush with your lips. **Never bite down on the bulb or tubing as this may impose a choking hazard to the user or result in damage, causing the device to work inaccurately.**

Bulb Care and Replacement: Gently clean the bulb with a damp cloth following each use and store in a clean, dry area (See *Caring for the Tongueometer* section for more details). Bulbs are designed for an individual's use. If a bulb becomes damaged, discontinue use immediately and replace. It is recommended that you replace the bulb every 8 weeks. Never submerge a bulb in liquid. To replace the bulb, gently pull on the tubing connected to the top of the device until it detaches. Dispose the used bulb in the trash. Then, rethread a new bulb and tubing (see Setup above).

The Tongueometer application offers four modules:

1. Repetitive Strength: to exercise tongue strength
2. Isometric Endurance: to exercise tongue endurance
3. Maximum Strength: to assess maximum tongue strength
4. Maximum Endurance: to assess maximum tongue endurance

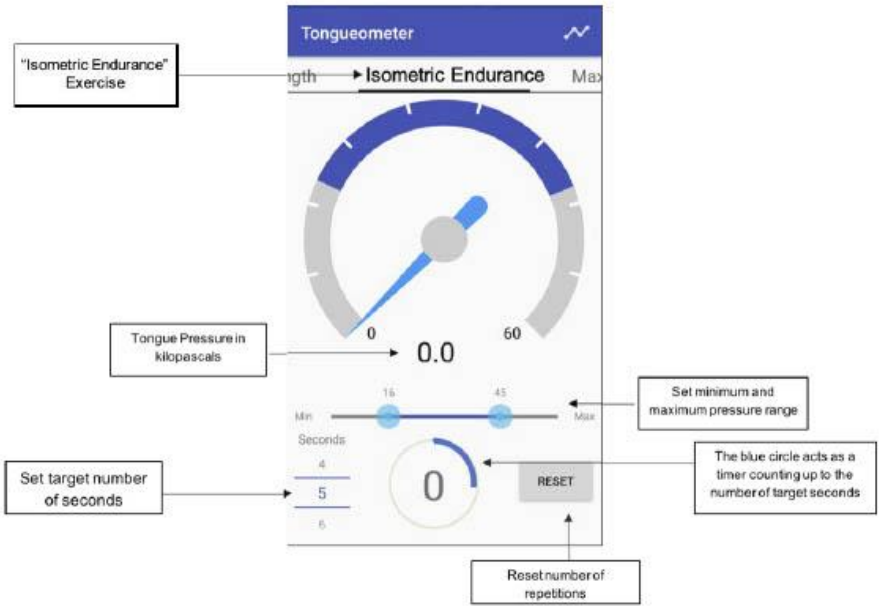
To access the modules, open the Tongueometer app from your Android device. You may switch between modules at any time by swiping left or right on the screen. The instructions for each module are on the following pages.

Repetitive Strength. This module records the number of times that a user achieves tongue pressure within a desired range. Target ranges should be determined by your SLP. To perform the exercise:

1. Open the Repetitive Strength module within the Tongueometer application.
2. Adjust the target range by sliding the blue dots on the "Min-Max Bar" to set the desired minimum and maximum pressure range.
   - If you swipe to another module or close and reopen the application, the pressure range on the Repetitive Strength module will not change.
   - The application requires there to be at least a 5 kPa difference between the minimum and maximum setting.
3. Place the bulb on your tongue and squeeze it against the roof of your mouth until the meter's needle moves into the desired range highlighted in blue.
4. Once the needle moves into the highlighted range, stop applying pressure to the bulb. The bulb may remain in the mouth between repetitions.
   - The needle must return to 0 before another repetition will be counted.
   - The counter at the bottom of the screen keeps track of each successful repetition during which the pressure applied to the bulb enters the highlighted range.
   - The RESET button resets the counter to zero. The Data Report will store practice information even if a user presses RESET.

Isometric Endurance. This module records the number of times that a user maintains desired tongue pressure for a set period of time. To perform the exercise:

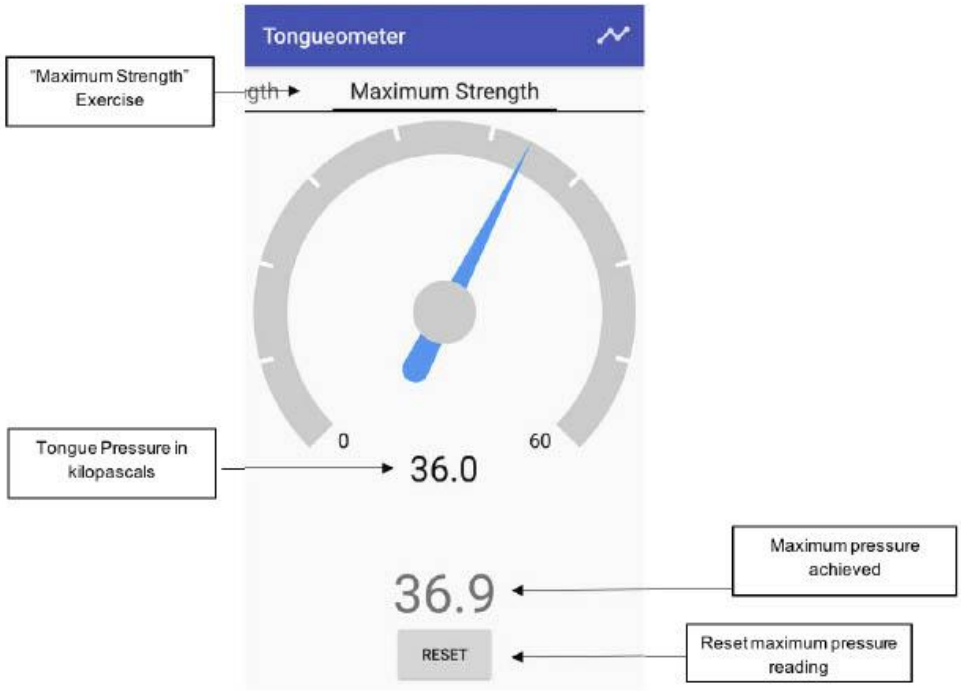
1. Open the Isometric Endurance module within the Tongueometer application.
2. Adjust the target range by sliding the blue dots on the "Min-Max Bar" to set the desired minimum and maximum pressure range.
   - You will need to set the target range for this module, even if you have already set it for the Repetitive Strength.
   - If you swipe to another module or close and reopen the application, the pressure range on the Isometric endurance module will not change.
   - The application requires there to be at least a 5 kPa difference between the minimum and maximum setting.
3. Set the target duration measured in seconds on the bottom left panel. This is the amount of time you are challenged to hold the tongue pressure within the target range.
4. Place the bulb on your tongue and squeeze it against the roof of your mouth until the meter's needle moves into the target range and maintain that pressure. A counter displays a moving 'progress circle' and when the target seconds are met or exceeded, the module records a successful repetition.
5. Once you successfully complete a repetition, stop applying pressure to the bulb.
   - The counter at the bottom of the screen keeps track of each successful repetition during which the pressure applied to the bulb remained in the highlighted range for the set duration of time.
   - If the target duration (seconds) is changed mid-session, the repetitions reset to 0.
   - The RESET button resets the counter to zero. The Data Report will store practice information even if a user presses RESET.



Maximum Strength. This exercise measures the highest pressure achieved when applying pressure to the bulb. To perform the exercise:

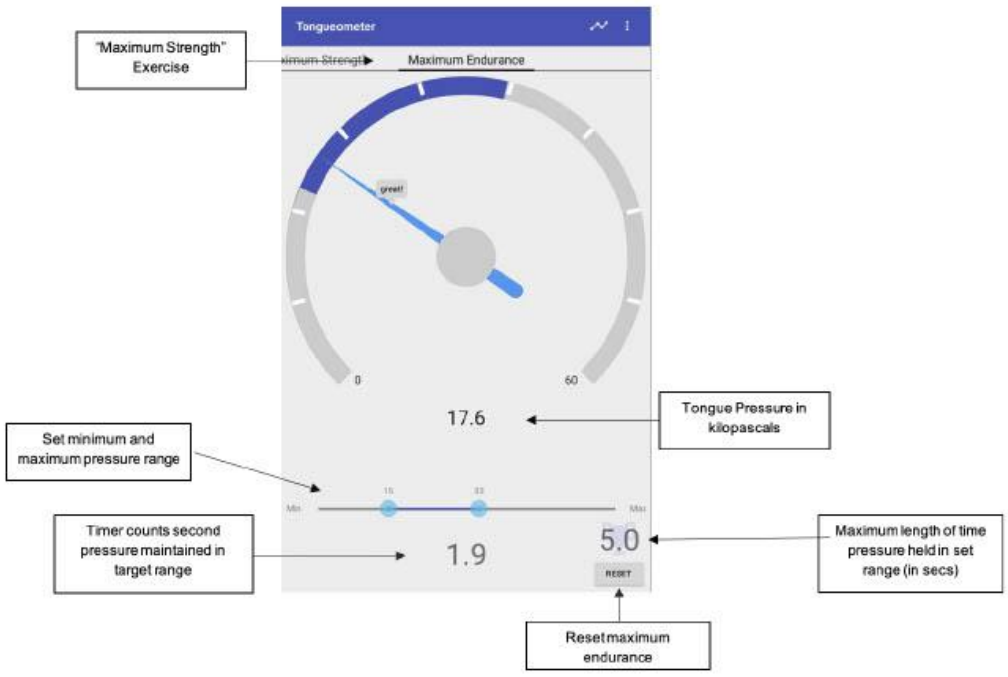
1. Open the Maximum Strength module.
2. Place the bulb on your tongue and squeeze it against the top of your mouth as hard as you can.
3. The meter's needle indicates the pressure reached.
4. The numerical reading at the bottom of the screen displays the maximum pressure reached.
   - The reset button resets the counter to zero.
   - The Data Report will store the maximum reading even if a user presses RESET.

Warning: never bite down on the tube or the bulb as this may result in a choking hazard or cause the device to malfunction.

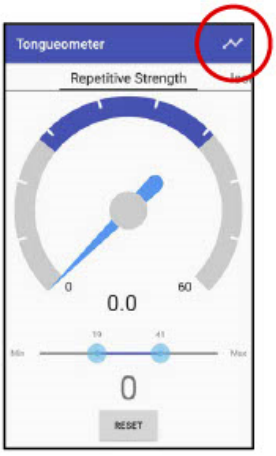


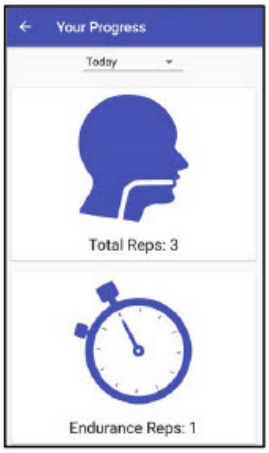
Maximum Endurance. This exercise measures the highest pressure achieved when applying pressure to the bulb. To perform the exercise:

1. Open the Maximum Endurance module.
2. Adjust the target range by sliding the blue dots on the "Min-Max Bar" to set the desired minimum and maximum pressure range.
   - You will need to set the target range for this module, even if you have already set it for the Repetitive Strength and/or Isometric Endurance modules.
   - If you swipe to another module or close and reopen the application, the pressure range on the Maximum Endurance module will not change.
   - The application requires there to be at least a 5 kPa difference between the minimum and maximum setting.
3. Place the bulb on your tongue and squeeze it against the roof of your mouth until the meter's needle moves into the target range; maintain that pressure for as long as you can.
   - The numerical display on the bottom right records the maximum length of time the pressure was maintained in or above the minimum of the set range.
   - If the pressure drops below the minimum target range, the stopwatch will stop.
   - Changing the target range will not reset the stopwatch.
   - The reset button resets the stopwatch to zero.
   - The Data Report will store the maximum length of time even if a user presses RESET.



Reports: The Tongueometer application has a built-in reporting feature that captures user data. Users can track progress over the course of the day, week, month, and year. To review data, click on the data icon in the top right corner (see below). Users can reset data at any time by scrolling to the bottom of the Reports page and click "Reset All." Data cannot be restored once users have clicked "Reset All."

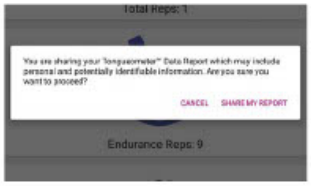




ending Data: The Tongueometer application allows you to send collected data through the application. To send data, users must have an email account set up on their smartphone or tablet. Users' tablet or smartphone must be connected to Wi-Fi or Data in order to send the Data Report. Data will never be sent without the user's explicit permission. Explicit permission is required for each transmission of data. To send data:

- Open Data Report (see "Reports" above)
- Click the "Share" icon in the upper right-hand corner

- Once you click the "Share" icon, a pop-up message will prompt you to provide explicit permission to share your data, recognizing that it may include personal and potentially identifiable information. If you want to proceed, click "SHARE MY REPORT." If you do not want to proceed, click "CANCEL."



- Once you click "SHARE MY REPORT," a screen will appear with a drafted email that includes your Tongueometer Data Report. Enter the email address to whom you wish to send your data and click the "Send" icon.

- The Data Report will be sent as a .csv file

Troubleshooting
If you have difficulty connecting the Tongueometer to your Android device, follow these steps:

1. Assure you have the correct OTG cable for your Android device. If you are uncertain, contact E2 Scientific Corp at info@e2scientific.com.
2. Make sure that the OTG cable is properly inserted into the Android device and into the Tongueometer device.
3. Assure that your Android device is sufficiently charged.
4. Each time you connect the Tongueometer to your smartphone or tablet, you will be prompted with a pop-up screen allowing the device to access the application**. If you click "Cancel," your device will not connect.** If this happens, disconnect the USB from your Android device and reconnect, selecting "OK" or "Use by default for this USB device."
5. Assure that your Android operating system is updated.

Sleep Mode: Please note that if your Android enters "sleep mode" (where the screen turns off or enters "power saving mode"), the application may no longer receive input from the Tongueometer device. Solutions to this problem:

1. Unplug the Tongueometer device from the Android device. Then, plug it back in. You do not need to exit the application.
2. Completely close the application by pressing the "SQUARE" icon on the Android device home screen. Then swipe the Tongueometer application screen to the left. Then, reopen the application by pressing the application icon.
3. Modify your "Power Saving Mode" in your Android device settings so that the Android device does not enter power saving mode as quickly.

Support
If you require assistance with the Tongueometer, please contact E2 Scientific Corp at info@e2scientific.com.

Warranty
E2 Scientific Corp products are warranted to the original purchaser to be free from defects in materials and workmanship for 90 days from date of purchase as verified by official proof of purchase. Warranty is invalidated if the user has opened or tampered with the handheld Tongueometer device.

Appendix A: Determining Appropriate Exercise Settings

It is advised that users work together with their SLP or medical professional to determine the appropriate settings for exercising with the Tongueometer. **E2 Scientific Corp does not provide patient-specific advice.**

It is advised that the SLP or medical professional perform an evaluation with the user to first determine whether exercise with use of the Tongueometer is appropriate and beneficial. If the Tongueometer is an appropriate treatment tool, the SLP can determine appropriate goals and exercise settings, monitor progress over time, and adjust the exercise settings as appropriate.

Your SLP can help determine the appropriate effort level for each exercise. For example, he/she may advise setting the Repetitive Strength exercise parameters between 60% - 80% of the users maximum strength. He/she may advise setting the endurance parameter (measured in seconds) be set at 50% of the user's maximum endurance.

Example: John's speech-language pathologist evaluated his tongue strength and endurance. John's results were as follows:

Maximum Tongue Strength: 14 kPa
Maximum Tongue Endurance: 10 seconds

John's speech-language pathologist recommended he perform the Repetitive Strength exercise at 60% - 80% of his maximum strength. She recommended John perform 10 repetitions, 3 times a day, every other day.

Repetitive Strength Settings:
Minimum Strength Setting: 8 kPa (14 kPa x 60% = 8)
Maximum Strength Setting: 11 kPa* (14 kPa x 80% = 11)

**Please note that the Tongueometer settings require at least a 5 kPa range between the minimum and maximum settings. In this case, setting the maximum at 13 kPa would be advised.*

John's speech-language pathologist recommended he perform the Isometric Endurance exercise at 50% of his maximum endurance, measured in seconds, and use the same pressure settings as the Repetitive Strength exercise. She recommended John perform 10 repetitions, 3 times a day, every other day.

Isometric Endurance Settings:
Minimum Strength Setting: 8 kPa
Maximum Strength Setting: 11 kPa*
Endurance Setting: 5 seconds (10 seconds x 50%)

**Please note that the Tongueometer settings require at least a 5 kPa range between the minimum and maximum settings. In this case, setting the maximum at 13 kPa would be advised.*

John's speech-language pathologist requested that he repeat the Maximum Strength and Maximum Endurance assessment modules and send his Data Report to her every two weeks to determine the need for adjustments to the exercise settings.

Appendix B: Quick Reference

Exercise Setting Values (kPa) Determined by Maximum Strength (kPa) x Effort Level (%)					
Max Strength (kPa)	**Effort Level (%)**				
	60%	**65%**	**70%**	**75%**	**80%**
10	6	7	7	8	8
12	7	8	8	9	10
14	8	9	10	11	11
16	10	10	11	12	13
18	11	12	13	14	14
20	12	13	14	15	16
22	13	14	15	17	18
24	14	16	17	18	19
26	16	17	18	20	21
28	17	18	20	21	22
30	18	20	21	23	24
32	19	21	22	24	26
34	20	22	24	26	27
36	22	23	25	27	29
38	23	25	27	29	30
40	24	26	28	30	32

**Please note that the Tongueometer settings require at least a 5 kPa range between the minimum and maximum settings.*