



Bluetooth®

User Manual



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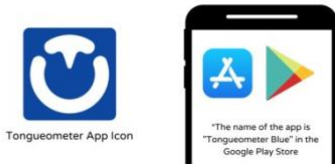


Quick Start

What's included:



1. Download the free Tongueometer app on your smartphone or tablet

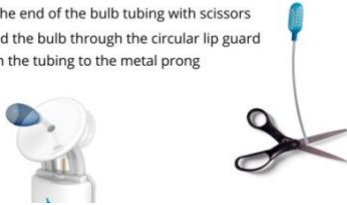


2. Connect the battery to the Tongueometer device using the BLACK cable



3. Attach the bulb to the Tongueometer device

- Snip the end of the bulb tubing with scissors
- Thread the bulb through the circular lip guard
- Attach the tubing to the metal prong



4. Open the Tongueometer app on your phone or tablet and click "Connect to Tongueometer."



Then click "Pair" on the pop-up box.

Important:

1. Bluetooth pairing is performed from **within** the Tongueometer app. If pairing is attempted within the host device's "settings" app, the connection may fail. After setup, if the app is not picking up pressure readings from the Tongueometer device when pressure is applied to the bulb, perform the one-minute troubleshooting steps on page 13.
2. Charge external battery fully prior to initial use (allow 4 hours for full charge).
3. On Android devices, "Location Services" must be turned on for Bluetooth to pair.



Bluetooth®

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A free, full-size, downloadable, color-copy of the Tongueometer User Manual is available at: www.tongueometer.com

Intended Use

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

Indications for Use

The Tongueometer is a multi-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) without consulting a physician.

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 other components are damaged.
- Do not lift, carry, hang or pull the device by the external battery, 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 surface of the device comes 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. Additional information can be found on the E2 Scientific FAQ webpage. **Consult with and defer to your facility's Infection Control department to determine protocol for disinfecting device between multiple users.**
- Assure that both your phone/tablet and the external battery has adequate charge (>50%) 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. Reverse engineering of the device is strictly prohibited.
- 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 for Tongueometer

The Tongueometer consists of six components:

- handheld device
- air-filled bulb
- bulb inflation tool
- external battery and connecting cable
- charging cable
- free, downloadable application



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

Downloading the App. Open the Google Play Store on your Android device or the App Store on your iOS device. Search for the Tongueometer app. The app is free to download. Once you locate the app, click "Install" or "Get." You can download the application on as many devices as you'd like.

Please note that the Google Play Store may have two Tongueometer apps; one black, one blue. Select the blue icon for the Bluetooth® Tongueometer. The icon will look like the image to the right.



Attaching the Bulb. Remove the air-filled bulb from the package. Snip the sealed end of the tubing with clean scissors at an angle. Discard small bit of plastic tubing that was cut off.



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.

Tip: if you experience difficulty threading tubing through the top of the device, try twisting the tubing as you thread it. You can increase or decrease the length of the tubing once it is attached to the top of the device.

Pairing the Device & App. Connect the Tongueometer device to the external battery using a standard USB cable with a mini-b connector (black cable included). External batteries or wall chargers must produce 5V of power. Battery should be sufficiently charged in order for device to work properly. Recommend charging battery between device use.



Once your Tongueometer device is connected to the external battery or wall charger, open the Tongueometer application on your phone/tablet. Press "Connect to Tongueometer." When connecting for the first time, you may receive a pop-up requesting permission to pair the Tongueometer device with your phone/tablet. Click "Pair."



Disconnecting Your Device. Please note that when you are finished exercising, disconnect your Tongueometer device:

- Click the Bluetooth® symbol in the upper right-hand corner.
- Disconnect the Tongueometer device from the external battery.

Troubleshooting Connection. If your device does not immediately pair to the app, you may need to reset your Bluetooth® pairing.

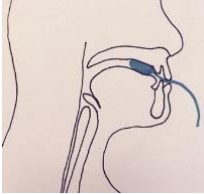
To Reset the Bluetooth® Pairing:

- Force close your Tongueometer app.
- Disconnect external battery or wall charger from the Tongueometer device.
- On your phone/tablet, go into "Settings" -> "Bluetooth" -> "Tongueometer" and then select "Unpair Device" (Android) or "Forget this Device" (iOS).
- Reconnect the external battery or wall charger.
- Re-open the Tongueometer app and click "Connect Tongueometer."



User Guide

Bulb Placement: Once the bulb 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: Between use, gently clean the bulb with a damp cloth and store in a clean, dry area (See Caring for the Tongueometer section for more details). Bulbs are designed for use by a single individual. 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 or the tubing in liquid. To replace the bulb, gently pull on the tubing connected to the metal prong until it detaches. Dispose of the used bulb in the trash. Then, rethread a new bulb and tubing (see **Attaching the Bulb** above).

The Tongueometer application offers four modules:

- Repetitive Strength: to exercise tongue strength
- Isometric Endurance: to exercise tongue endurance
- Maximum Strength: to assess maximum tongue strength
- Maximum Endurance: to assess maximum tongue endurance

To access the modules, open the Tongueometer app from your phone or tablet. 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.



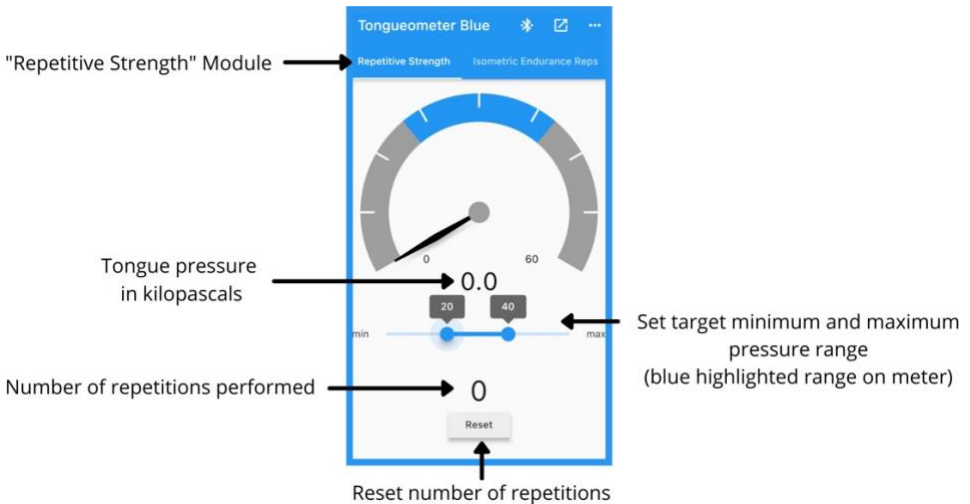
The following four pages describe the purpose and instructions for each of the four modules.

Repetitive Strength Module. This module records the number of times that a user achieves tongue pressure within a specified target range. Target ranges should be determined by your SLP.

To perform the exercise:

1. Swipe to 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.
 - a. If you swipe to another module or close and reopen the application, the pressure range on the Repetitive Strength module will not change.
3. Place the bulb in your mouth and, using your tongue, press the bulb 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 pressing the bulb against the roof of your mouth. The bulb may remain in the mouth between repetitions, however be sure that the needle returns to “0” before completing the next repetition.
 - a. 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 you press RESET.

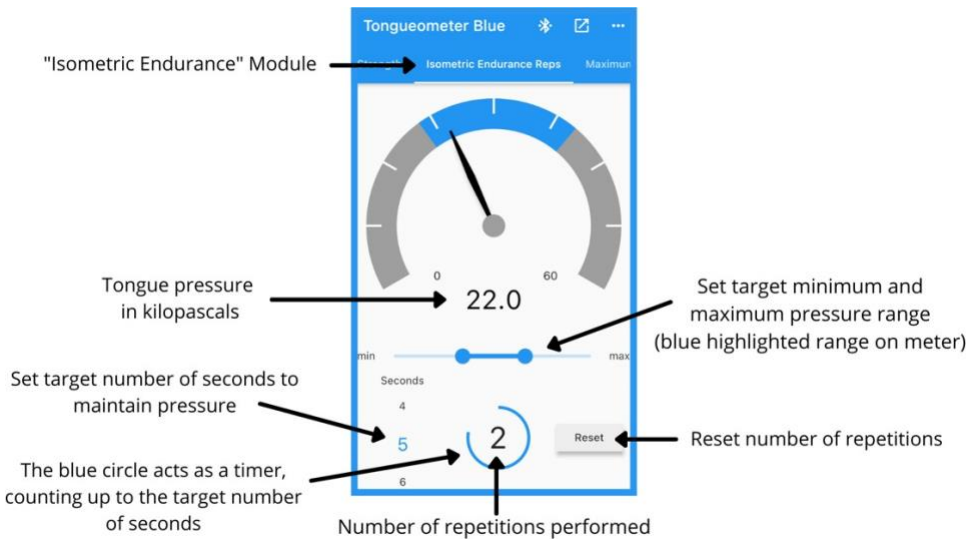


Isometric Endurance Module. This module records the number of times that a user maintains tongue pressure in a specified range for a specified period of time.

To perform the exercise:

1. Swipe to 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.
 - a. You will need to set the target range for this module, even if you have already set it for the Repetitive Strength.
 - b. If you swipe to another module or close and reopen the application, the pressure range on the Isometric Endurance module will not change.
3. Set the target duration, measured in seconds, on the bottom left panel. This is the amount of time you will attempt to maintain the tongue pressure within the specified range.
4. Place the bulb in your mouth and, using your tongue, press the bulb against the roof of your mouth until the meter's needle moves into the specified range highlighted in blue. 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.
 - a. You will see the number of successful repetitions completed inside of the progress circle. 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.

The RESET button resets the counter to zero. The Data Report will store practice information even if you press RESET.



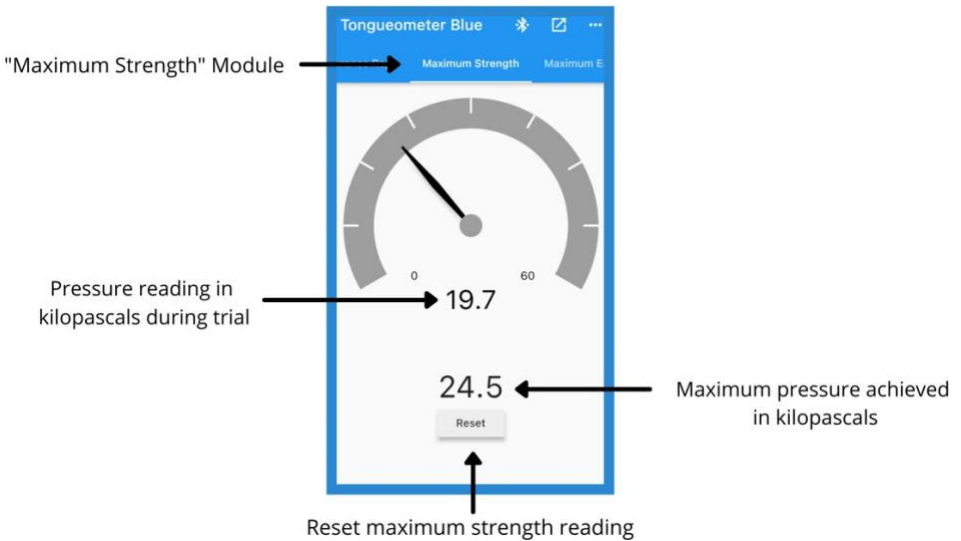
Maximum Strength Module. This module measures the highest pressure achieved when applying pressure to the bulb.

To perform the exercise:

1. Swipe to the Maximum Strength module.
2. Place the bulb in your mouth and, using your tongue, press the bulb against the roof of your mouth as hard as you can.
3. The meter's needle indicates the pressure generated.
4. The numerical reading at the bottom of the screen displays the maximum pressure reached.

The RESET button resets the reading to zero. The Data Report will store the maximum reading even if you press 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.

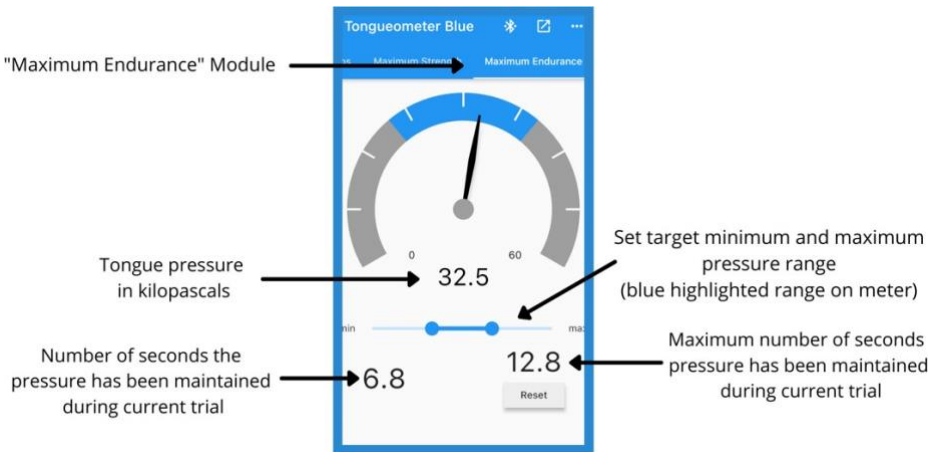


Maximum Endurance Module. This module measures the length of time a person can maintain pressure within the highlighted target pressure range.

To perform the exercise:

1. Swipe to 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.
 - a. 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.
 - b. If you swipe to another module or close and reopen the application, the pressure range on the Maximum Endurance module will not change.
3. Place the bulb in your mouth and, using your tongue, press the bulb against the roof of your mouth until the meter’s needle moves into the target range.
4. Maintain tongue pressure in the highlighted range for as long as you can.
 - a. The numerical display on the bottom right records the maximum length of time, in seconds, the pressure was maintained in or above the minimum of the set range.
 - b. If the pressure drops below the minimum target range, the stopwatch will stop.
 - c. 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 you press RESET.



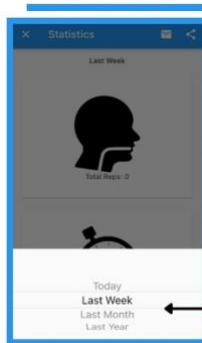
Enhanced Biofeedback Options. The Tongueometer application allows users to turn on/off tactile and auditory feedback (in host phones and tablets that support this capability) for the Repetitive Strength and Isometric Endurance Modules. Tactile (vibratory) feedback is only available on smartphones. Auditory feedback is available on smartphones and tablets. To turn these features on/off, press the three dots [...] in the upper right-hand corner of the app and select "Settings." Then Tactile and/or Auditory Feedback on or off.



Reports. The Tongueometer application has a built-in reporting feature that captures user data in the "Statistics Report."

On the "Statistics Report" page, users can view progress over the course of the day, week, month, and year. To review data, click on the "Statistics Report" icon in the top right corner. Users can reset data at any time by scrolling to the bottom of the Reports page and click "Reset." Data **cannot** be restored once users have clicked "Yes, reset stats."

Tap here to change the "Statistics Report" to show progress for the day, week, month, or year



Scroll here to highlight your preferred view for the "Statistics Report"

To reset the data, click "Reset." Once you reset this, you will **not** be able to retrieve this information



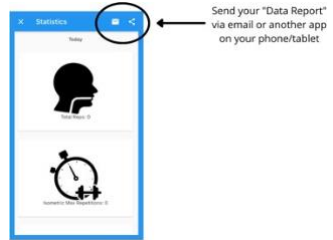
A prompt will appear when you click "Reset" to assure you want to clear all data. Once you reset this, you will **not** be able to retrieve this information.



Sending Data. The Tongueometer application allows users to send collected data through the application. A user's 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:

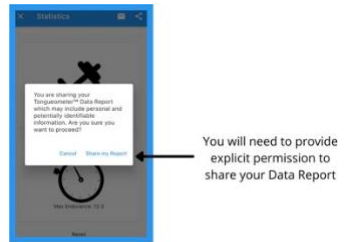
- Open Data Report (see "Reports" above)

- There are two primary options for sharing your report: "Email" & "Share." "Share" options include messaging apps on the phone/tablet such as iMessage, WhatsApp, DropBox™.



- Once you click the "Email" or "Share" icon, a pop-up message will prompt a user to provide explicit permission to share 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."

- "Email" Option: Enter the email address to whom you wish to send your data and click the "Send" icon. The email is sent from the phone/tablet email account.



- "Share" Option: "Share" options are dependent on apps downloaded on the phone/tablet. Not all apps have the capability to share the Data Report.

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



A free, downloadable Tongueometer Performance Dashboard and instructions for use are available on the E2 Scientific Corp website. The dashboard graphically displays a user's assessment and exercise data over time online to view progress and adherence. This can be found on our website's FAQs webpage under the "Tongueometer Performance Dashboard" heading.

Troubleshooting.

Bluetooth® Connectivity: If you have difficulty connecting the Tongueometer to your phone or tablet, follow these steps. For additional assistance, please visit the FAQ webpage at e2scientific.com for detailed tutorials. As technology is continuously changing, we will continue to update the online manual to provide simple directions for connecting your device.

1. Assure you have downloaded the correct app; particularly if using an Android device. The first Tongueometer model, only compatible with Android, required an OTG cable connecting the phone/tablet. This app icon is black. The app icon for the Bluetooth® model is blue. If you are uncertain, contact E2 Scientific Corp at info@e2scientific.com.
2. For the Bluetooth® model, make sure that your phone/tablet has Bluetooth® capabilities turned on. To check, go into your phone/tablet “Settings” -> “Bluetooth” -> “On.” (Note, for Android devices, Location services may have to be turned on as well.)
3. Assure that your external battery device is sufficiently charged.
4. Assure that your iOS and/or Android operating systems are updated.
5. **To Reset the Bluetooth® Pairing:**
 - a. Force close your Tongueometer app.
 - b. Disconnect external battery or wall charger from the Tongueometer device.
 - c. Go into phone/tablet “Settings” -> “Bluetooth” -> “Tongueometer” and then select “Unpair Device” (Android) or “Forget this Device” (iOS).
 - d. Reconnect the external battery or wall charger.
 - e. Re-open the Tongueometer app and click “Connect Tongueometer.”

Sensor Tolerance.

The tolerance of the sensor used in the Tongueometer device is +/- 2.5 kPa, per the sensor manufacturer’s data sheet.

Warranty & Return Policy.

It is important to us that our products meet the highest standards. If the Tongueometer device and/or bulb(s) is received in a damaged condition, or if it is found to be defective in any way, we will immediately send a replacement upon return of the damaged products. **Please note: Due to the personal nature of this product we cannot offer refunds for any reason.** If you believe your Tongueometer arrived damaged or becomes defective within the first year of purchase, please contact us as soon as possible. You can reach us by sending an email explaining the nature of the problem to info@e2scientific.com. We will work to troubleshoot the issue and provide detailed return instructions at that time.

All merchandise must be returned in its original condition, including the original packaging, manuals, and all accessories. We are unable to accept returns if the packaging is not in its original condition. Be sure to send it in a box that will protect the original package from being damaged by the shipping carrier.

Changes or modifications not approved by E2 Scientific Corp could void the user’s authority to operate the Tongueometer. Note: This equipment has been tested and found to comply with the limits for Class B digital device, pursuant to part 15 of the FCC Rules.

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.

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

Example: John's SLP evaluated his tongue strength and endurance. John's results were as follows:

Maximum Tongue Strength: 14 kPa

Maximum Tongue Endurance: 10 seconds

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

Repetitive Strength Settings:

Minimum Strength Setting: 8 kPa ($14 \text{ kPa} \times 60\% = 8$)

Maximum Strength Setting: 11 kPa* ($14 \text{ kPa} \times 80\% = 11$)

John's SLP 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 ($10 \text{ seconds} \times 50\%$)

John's SLP 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

Appendix C: Bulb Inflation Tool

This tool can be used to inflate bulbs that have become depressed/uninflated. A new bulb should not need this tool. A bulb that has been used, then removed from the device, and stored for later use by the same user might benefit from this tool.

Bulb inflation tool instructions:

1. Pull syringe plunger to 5ml.
2. Attach bulb tube to the syringe post (about 1/8th of an inch).
3. Push plunger about 4 ml until bulb fully inflates and hold for 10 seconds (allows for bulb material memory).
4. Release plunger and detach the bulb tube from the syringe.
5. Attach bulb tube to the Tonguometer device.

