User Manual
# Quick Start

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.</td>
<td>Remove contents from packaging.</td>
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<tr>
<td>2.</td>
<td>Use scissors to cut off the sealed end of the tubing. Attach bulb to the device.</td>
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<tr>
<td>3.</td>
<td>Download &amp; open the “Tongueometer” app on your phone or tablet. <strong>For Android Users: There are two Tongueometer apps in the Google Play Store</strong></td>
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<td>4.</td>
<td>Connect the Tongueometer to your phone or tablet via OTG cable or Bluetooth®.</td>
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Begin Exercising
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A free, downloadable 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 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 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).

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. 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 four components:

- handheld device
- air-filled bulb
- external battery (Bluetooth® Tongueometer) OR OTG (on-the-go) cable (Android-only Tongueometer)
- free, downloadable application for your tablet or smartphone

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.

1. Remove the Tongueometer components from the packaging and place on a clean, flat surface.

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

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. 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. The icon will look like this:

CONNECTING YOUR DEVICE

A. Bluetooth® Tongueometer Model (for OTG model, see part B)

1. Connect the Tongueometer device to the external battery using a standard USB cable with a mini-b connector. 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.**

2. Once your Tongueometer device is connected to the external battery or wall charger, open the Tongueometer application. The app should prompt you to connect your Tongueometer device. 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.”

3. **Disconnecting Your Device.** Please note that when you are finished exercising, it is important to disconnect your Tongueometer device in this order:
   a. Click the Bluetooth® symbol in the upper right-hand corner.
   b. Disconnect the Tongueometer device from the external battery.

4. **Troubleshooting Connection**
   a. If you do not disconnect your device properly, you may experience difficulty with reconnecting and may need to reset the Bluetooth® pairing.
   b. **To Reset the Bluetooth® Pairing:**
      i. Force close your Tongueometer app
      ii. Disconnect external battery or wall charger from the Tongueometer device.
      iii. Go into “Settings” -> “Bluetooth” -> “Tongueometer” and then select “Unpair Device” (Android) or “Forget this Device” (iOS).
      iv. Reconnect the external battery or wall charger.
      v. Re-open the Tongueometer app and click “Connect Tongueometer.”
B. OTG Tongueometer

1. 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.

![Insert Image]

2. 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. 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.

![Insert Image]
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: 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 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 in liquid. To replace the bulb, gently pull on the tubing connected to the top of the device until it detaches. Dispose of 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 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.
**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.” **Data cannot be restored once users have clicked “Reset.”**

Sending 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. 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)
- 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**

**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 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.”
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:**
   1. Force close your Tongueometer app
   2. Disconnect external battery or wall charger from the Tongueometer device.
   3. Go into “Settings” -> “Bluetooth” -> “Tongueometer” and then select “Unpair Device” (Android) or “Forget this Device” (iOS).
   4. Reconnect the external battery or wall charger.
   5. Re-open the Tongueometer app and click “Connect Tongueometer”

**Sleep Mode for OTG Model:** 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. Force stop the application. 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.

**Warranty & Return Policy**

It is important to us that our products meet the highest standards. If Tongueometer device, bulbs, and/or tablet 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 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.

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 user’s 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.
### Exercise Setting Values* (kPa)
Determined by Maximum Strength (kPa) x Effort Level (%)

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<thead>
<tr>
<th>Max Strength (kPa)</th>
<th>Effort Level (%)</th>
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*Please note that the Tongueometer settings require at least a 5 kPa range between the minimum and maximum settings.*