



Brain Gauge Pro

User Manual

Revised June 2018

***Please read the entire User Manual
before using your Brain Gauge***

Introduction

The Brain Gauge is a handheld device that delivers a series of cognitive tests and uses an individual's score(s) on these tests to provide a quantitative summary of cognitive function. Users rest one hand on top of the device to receive stimuli, and use their other hand to respond to a variety of tasks through the ProTools web application. For each test, vibrational tips 'buzz' the ends of the user's fingers in a specific manner. Users respond to test questions according to instructions provided with respect to their perceptions of the tip vibrations.

- The Brain Gauge is not a stand-alone diagnostic.
- The Brain Gauge does not identify or confirm the presence or absence of a clinical diagnosis.
- The Brain Gauge does not prevent or treat any disease or condition.
- The Brain Gauge does not contain any user-serviceable components. Do not attempt to open or modify the Brain Gauge.
- Do not use the Brain Gauge if the package or any part of the device is damaged. Contact our Customer Support team: support@corticalmetrics.com.
- The Brain Gauge is not compatible with any third-party accessories (with the exception of the required testing computer).
- To avoid electrical shock, always unplug your Brain Gauge from the computer before cleaning the device. Do not drop or place the Brain Gauge in any fluids or allow any fluids to enter the device.
- Not for use in an oxygen-rich or flammable anesthetic environment.
- The Brain Gauge is designed for indoor use only.

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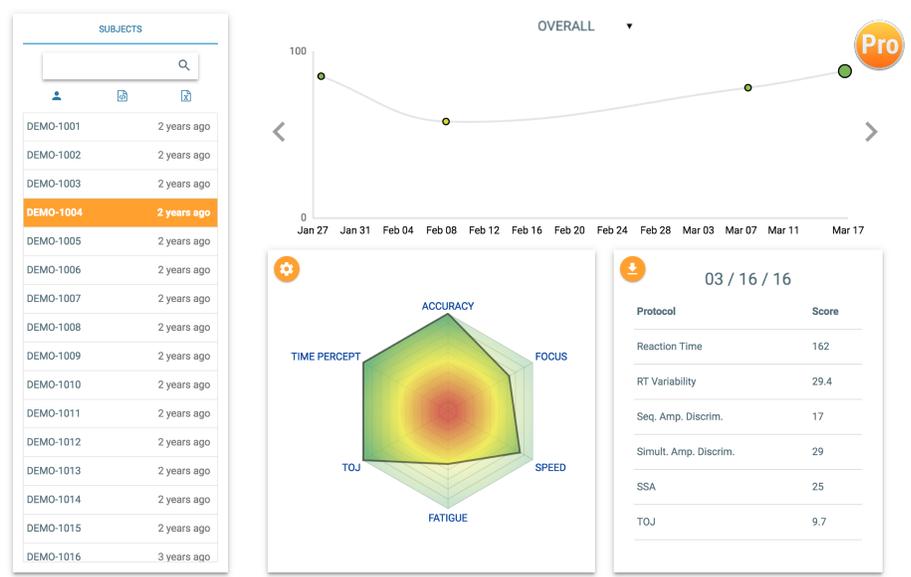
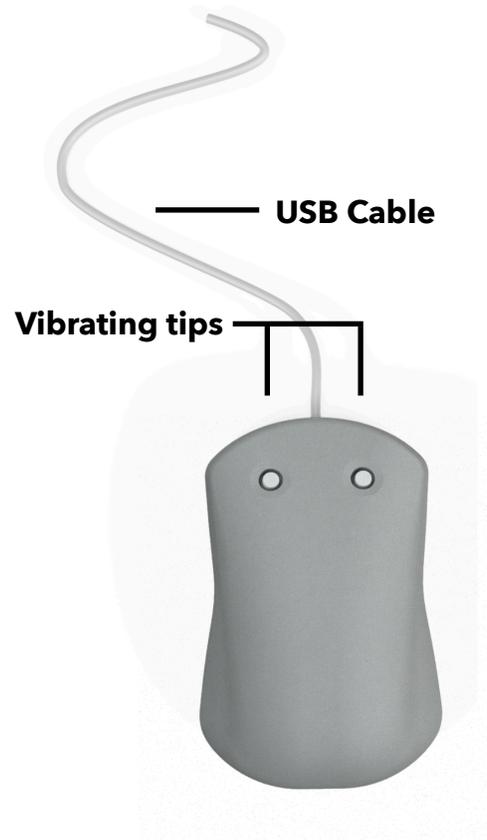
Brain Gauge at a glance

Brain Gauge

The Brain Gauge is a two-point vibrotactile stimulator that can be used as a computerized cognitive assessment aid. The device connects to your computer and interacts with the Brain Gauge app - **ProTools** - to take users through a series of cognitive tasks in which the vibrating tips deliver various tactile stimuli.

ProTools

The Brain Gauge is designed to integrate seamlessly with the ProTools app. This app is available for download at www.corticalmetrics.com. ProTools handles user data at every step of the cognitive assessment process: collection, analysis, and storage. Users have access to both the raw testing data (such as reaction time and amplitude discrimination threshold) as well as our own algorithmically-determined metrics that provide comprehensive summaries of essential cognitive functions. ProTools displays results through intuitive, easy-to-read charts that allow you to monitor a user's entire testing history on one screen. There are also fields to add any pertinent health-related information and events.



Science of the Brain Gauge

Background

The technology behind the Brain Gauge was first conceived by two members of the medical school faculty at the University of North Carolina - Robert Dennis and Mark Tommerdahl. It is our goal to continue to develop this technology in a way that gives clinicians and users an affordable, accurate, and reliable way to investigate brain function.

Why is the Brain Gauge based on the sense of touch?

In the somatosensory nervous system, sensory receptors in adjacent regions of the skin project to adjacent regions of the cerebral cortex. This corresponding neurological map - known as the *cortical homunculus* - makes the somatosensory system well suited for assessing the central nervous system. Tactile stimuli are transmitted by the somatosensory system and can be delivered to trigger very specific regions of the brain without the risk confounding of distractions - a common issue with visual and auditory stimuli.

Over the past 50 years, neuroscientists have steadily advanced our understanding of the interactions both within and between the adjacent cortical regions in response to tactile stimuli. Our founders alone have over 30 years of research experience, which has helped build a strong foundation for understanding particular aspects of brain function.

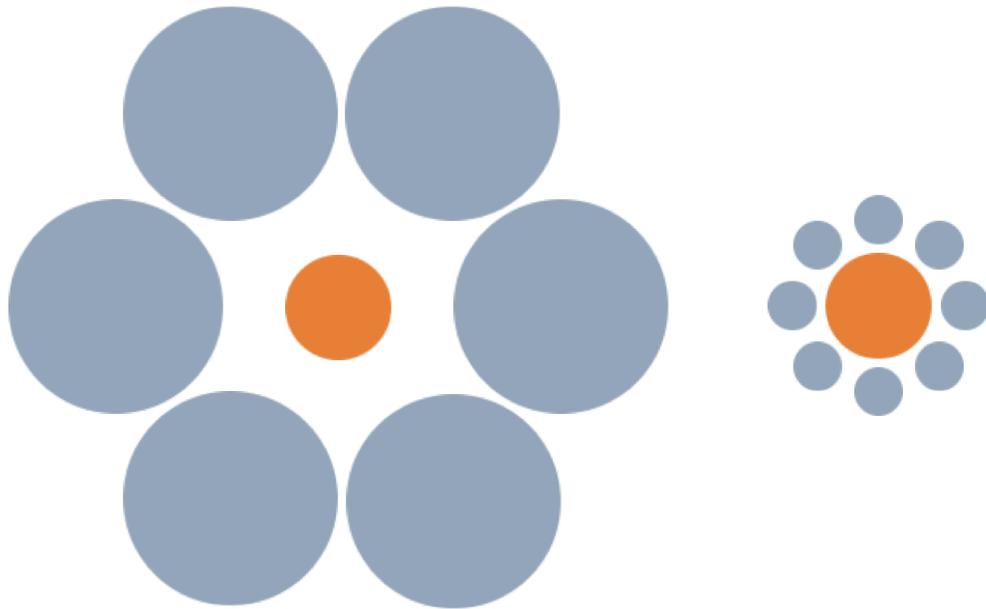
While medical imaging (such as MRI or CT scans) can be a useful tool for identifying widespread injuries to the brain, our testing protocols are much better at identifying more subtle changes to brain function. For example, midazolam - an anxiolytic commonly delivered to users prior to an MRI - has been shown to significantly alter our metrics but would not affect the resulting medical image.

How does the Brain Gauge work?

The Brain Gauge delivers gentle vibrations to your fingertips, activating sensory receptors and their corresponding regions in the brain. When adjacent regions are activated, they interact with each other in highly predictable patterns. The integrity of these interactions determines your perception of how the vibrations feel. By changing the vibrations in specific ways, and then asking questions about what you feel, we can assess the soundness of vital cognitive functions.

You may be familiar with tasks that are similar to Brain Gauge tests, but which are based on sight or hearing rather than the sense of touch. Using a Brain Gauge is similar to reading an eye chart: as you answer the questions correctly, the successive questions become more difficult as we approach your limits of sensory detection. Some of the tests even involve illusions - sensory discrimination tasks which are the tactile equivalent of the figure below. Some of the tests even involve illusions - sensory discrimination tasks which are the tactile equivalent of the figure below.

Some of the tests even involve illusions – sensory discrimination tasks which are the tactile equivalent of the figure below.



In this illusion, the center circles of each cluster appear to be of different sizes. However, a quick measurement will show that the circles are in fact the same exact size. The efficacy of this illusion relies on unimpaired neural mechanisms; a CNS-impaired individual (such as a user who has sustained a concussion or traumatic brain injury) would **not** be fooled by the illusion. This phenomenon is embedded in the protocols of the Brain Gauge system to assess an individual's CNS impairment.

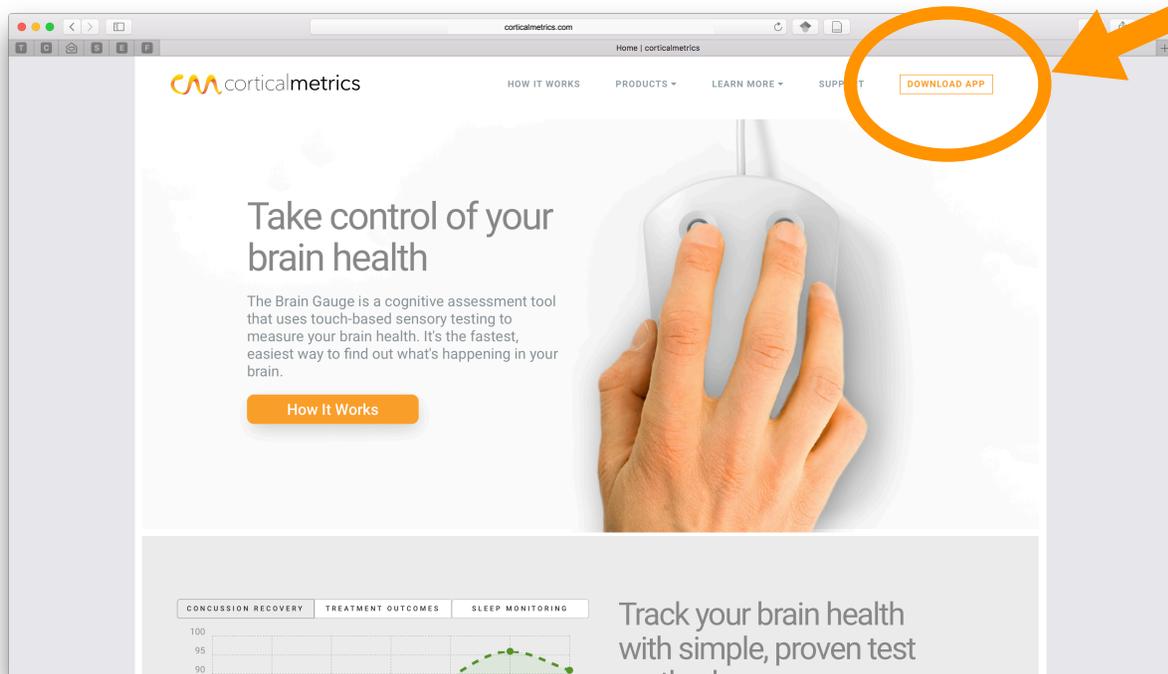
Getting Started

Required Materials

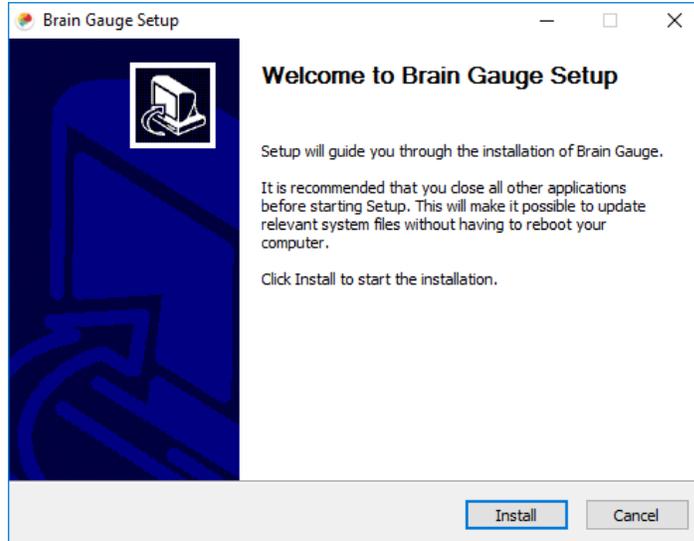
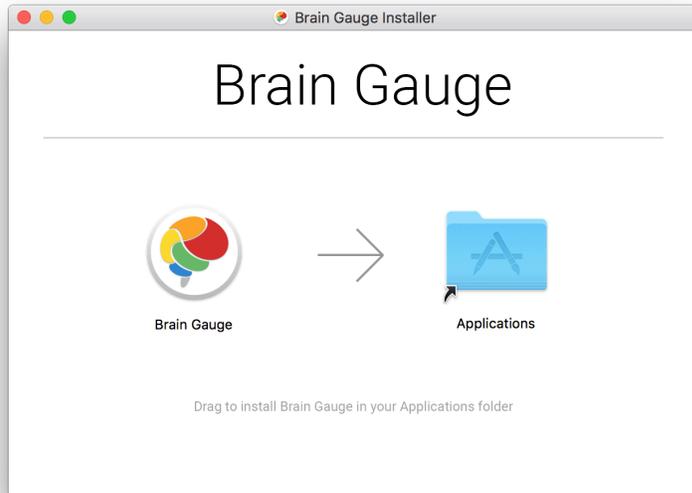
- Brain Gauge
- PC (Windows 8 or later) or Mac (MacOS 10.10 or later) or Chromebook
- USB 2.0 port
- Stable internet connection
- Computer mouse (**optional**)
- Flat, smooth tabletop or surface

Software Installation

To set up your Brain Gauge, visit <http://corticalmetrics.com> on the computer you will be using with the Brain Gauge. Click on the **DOWNLOAD APP** button in the upper right-hand corner. This will automatically begin downloading the Brain Gauge app installer.



Locate and open the Brain Gauge Installer (brain_gauge.dmg on Mac, brain_gauge_setup.exe on Windows) in your downloads folder. Follow the on-screen instructions to install the Brain Gauge app. When the installation is complete, click on the Brain Gauge icon in your applications folder or desktop to launch the app.

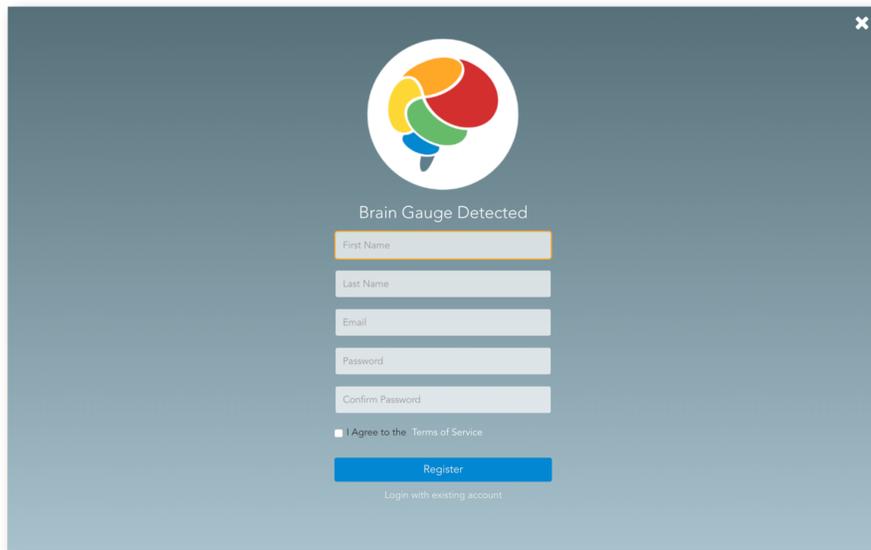


If you receive an error, visit <https://corticalmetrics.com/support> for troubleshooting.

New Users

If this is your first time using the ProTools software, you will need to register for a new account. Plug the Brain Gauge into an available USB 2.0 port on your computer. The registration page will appear once your computer recognizes the device.

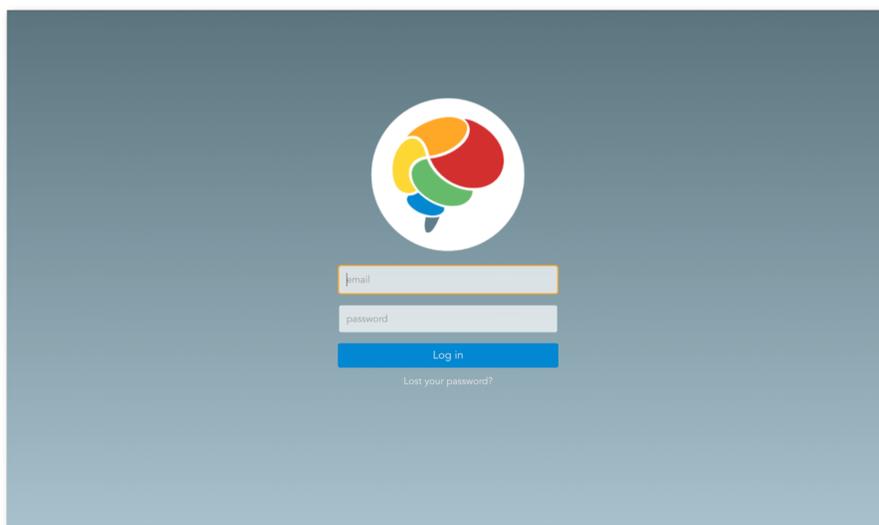
Enter the first and last name, email address, and a password for the clinician or administrator that will be operating the device (**not** the user who will be testing). Agree to the Terms of Service by checking the corresponding box, then click **Register**.



The registration form is displayed on a dark blue background. At the top center is the Brain Gauge logo, a circular icon with four colored segments (yellow, red, green, blue) and a white brain silhouette. Below the logo, the text "Brain Gauge Detected" is centered. The form consists of several input fields: "First Name", "Last Name", "Email", "Password", and "Confirm Password". Below these fields is a checkbox labeled "I Agree to the Terms of Service". A blue "Register" button is positioned below the checkbox. At the bottom of the form, there is a link that says "Login with existing account".

Returning Users

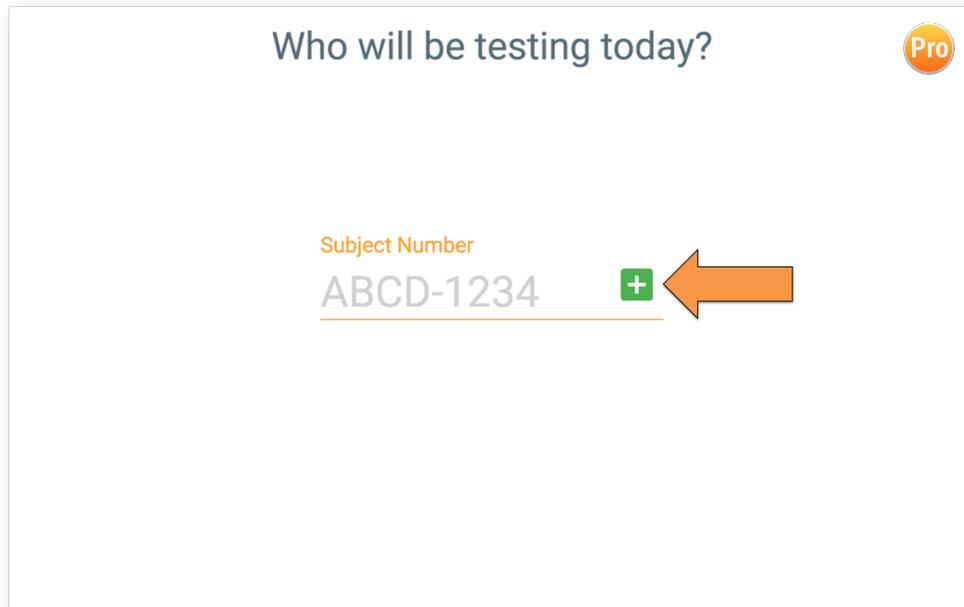
If you have previously used a Brain Gauge, you may already have an account. In this case, open the app and select **Already have an account?** Enter your email and password and click **Log in**.



The login form is displayed on a dark blue background. At the top center is the Brain Gauge logo, a circular icon with four colored segments (yellow, red, green, blue) and a white brain silhouette. Below the logo, there are two input fields: "Email" and "password". A blue "Log in" button is positioned below the password field. At the bottom of the form, there is a link that says "Lost your password?".

Creating a new user

Once you have successfully logged in, the home screen will appear. You should assign each user a unique **Subject Number**. Enter a new Subject Number for the user and click on the '+'.

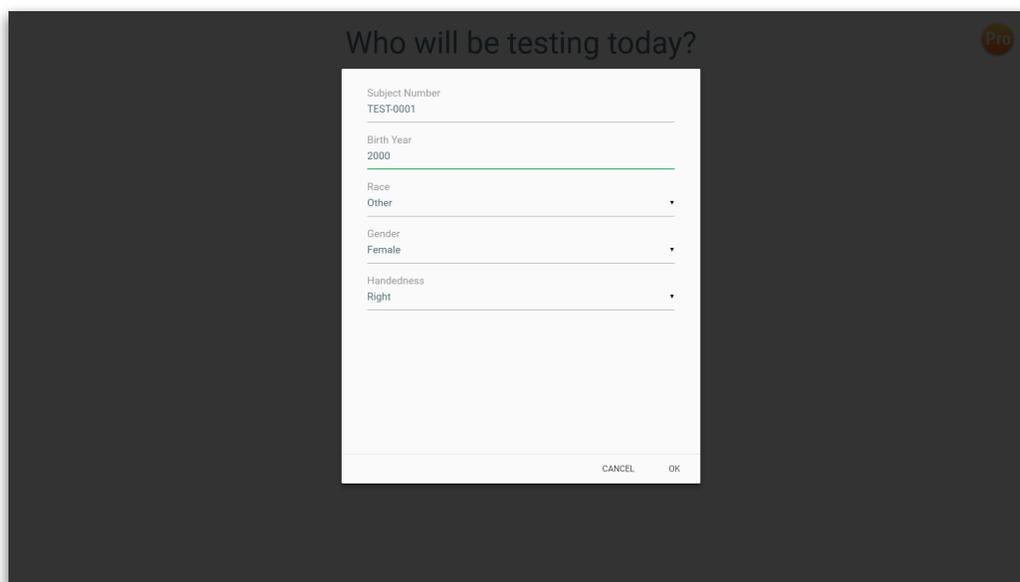


Who will be testing today? Pro

Subject Number
ABCD-1234 +

An orange arrow points to the green '+' button.

A form will appear where you can enter identifying information about the user. Enter your user's information and click **OK**.



Who will be testing today? Pro

Subject Number
TEST-0001

Birth Year
2000

Race
Other

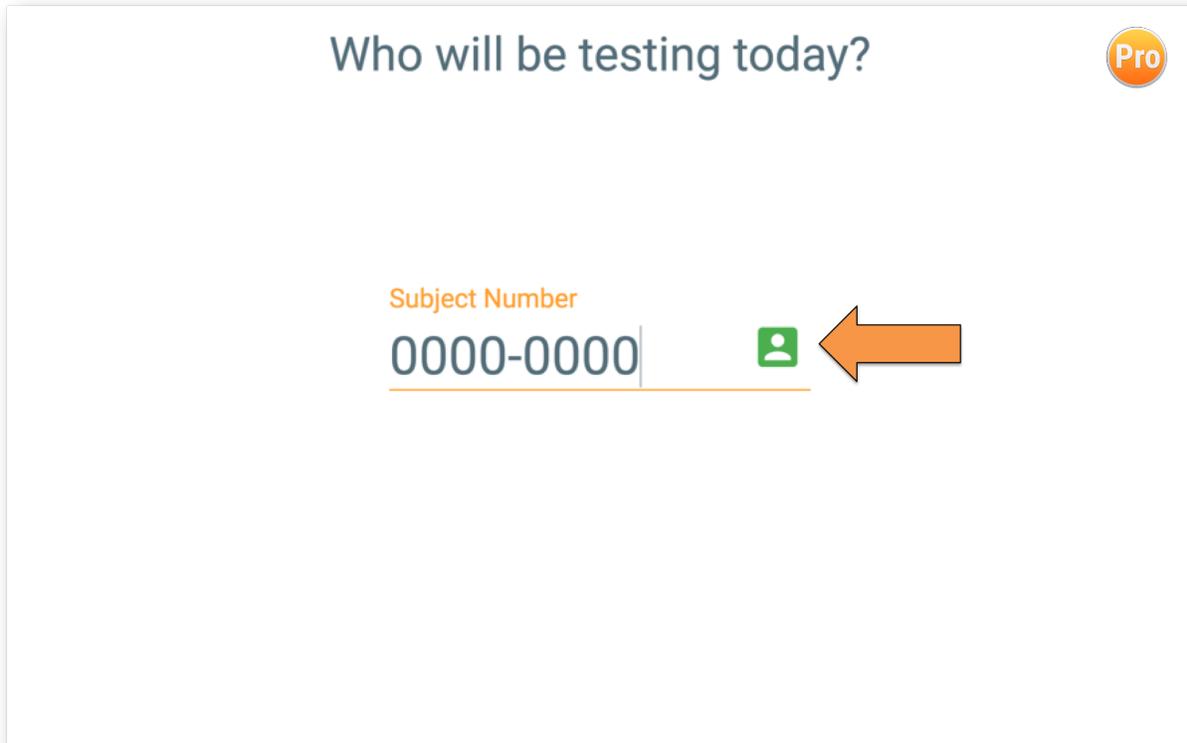
Gender
Female

Handedness
Right

CANCEL OK

Loading a previous user

On the Home Screen, enter the Subject Number for the user, and click on the green user icon.



Testing

Test should be conducted in quiet environment with minimal distractions.

Before each test, you can add notes about a user's current prognosis.

Condition Classifications

Who will be testing today?

TEST-0001

'00 Birth Year F Gender R Handedness

Condition: Healthy Treatment: No-treatment

Subject Notes
Add Note

CANCEL OK

- Healthy
- Migraine
- Degenerative
- Developmental
- Stroke
- Traumatic Brain Injury (TBI)

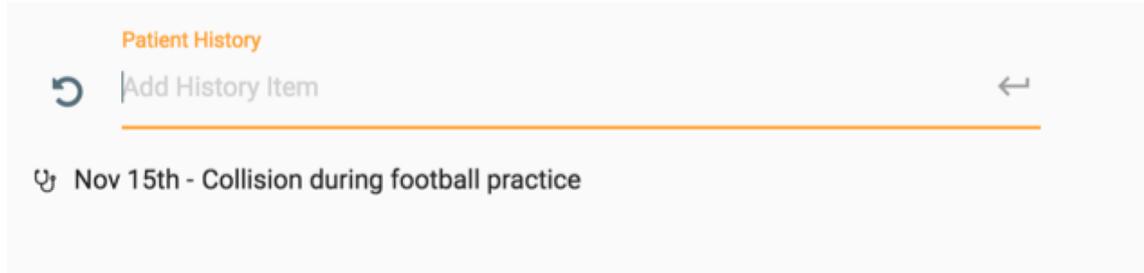
Treatment Classifications

- No-treatment
- Pre-treatment
- Post-treatment

User History

You can also add custom notes for each user before they begin the testing session*. These notes may include information about a user's symptoms, medications, traumatic events, or other factors that may impact cognitive function.

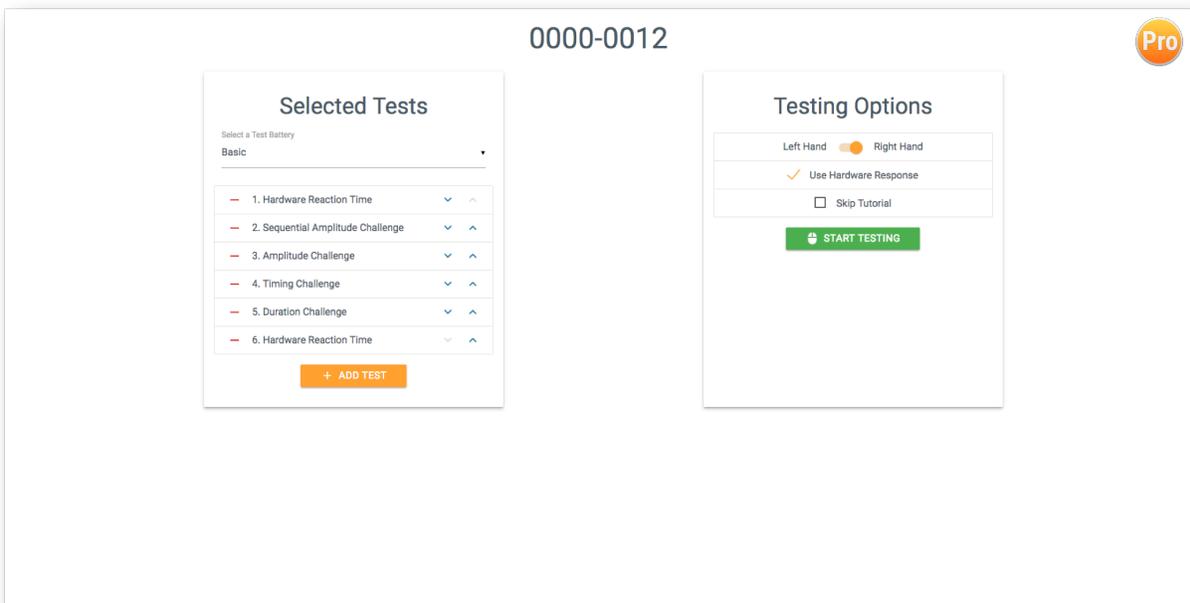
To add a History Item, type any notes into the dialog box and hit **Enter** on your keyboard.



***Note:** History items will not impact the user's test scores.

Testing Sessions

For a comprehensive analysis of cognitive function, we recommend that all subjects complete the **Basic** series of tests. Depending on time constraints or user conditions, you may wish to add or remove tests, or select one of the other predefined testing sessions. To request modifications to the software or additional tests, please contact info@corticalmetrics.com.



The table below shows which tests are required to calculate a given score.

Score	Tests
Speed	Simple Reaction Time
Focus	Simple Reaction Time
Accuracy	Sequential Amplitude Challenge Amplitude Challenge
Sequencing	Timing Challenge
Time Percept	Duration Challenge
Fatigue	Simple Reaction Time*
Plasticity	Sequential Amplitude Challenge Amplitude Challenge Single Site Adaptation (SSA)^ Duration Challenge^ Duration Confound Challenge^
Connectivity	Timing Challenge TOJ with confound Challenge
Overall	All tests

*To receive a **Fatigue** score, you must take the Simple Reaction Time test at both the beginning and end of your testing session.

^Optional tests

Hand Selection

After choosing the user's tests, select the hand that will be placed on the Brain Gauge. We recommend that users place their **dominant** hand on the device. This is especially important for the tests that are dependent upon response time (Simple Reaction Time, Choice Reaction Time, Dynamic Threshold). Depending on user condition, it may be more practical to test with the non-dominant hand.

Hardware response

Instead of a computer mouse, users can respond to test questions by using only the Brain Gauge hardware. For tests that ask you to compare two stimuli, simply press down on the corresponding probe tip to select that side. You should feel a "click" on that finger, which indicates a recorded response. For Simple Reaction Time tests, after feeling the stimulus on one finger, click using the **opposite** tip. Hardware reaction time is recommended for all Reaction Time tests.

Hand Placement

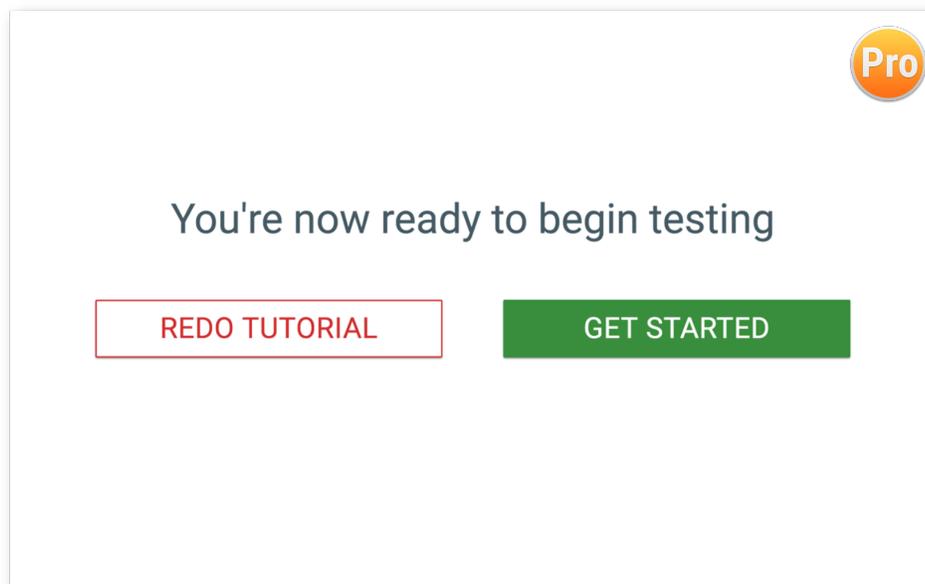
The user does not need to press down on the Brain Gauge. However, ensure that there is contact between the fingertips and the probe tips. Pressing down too hard during testing will generate a notice that the user should loosen their grip.



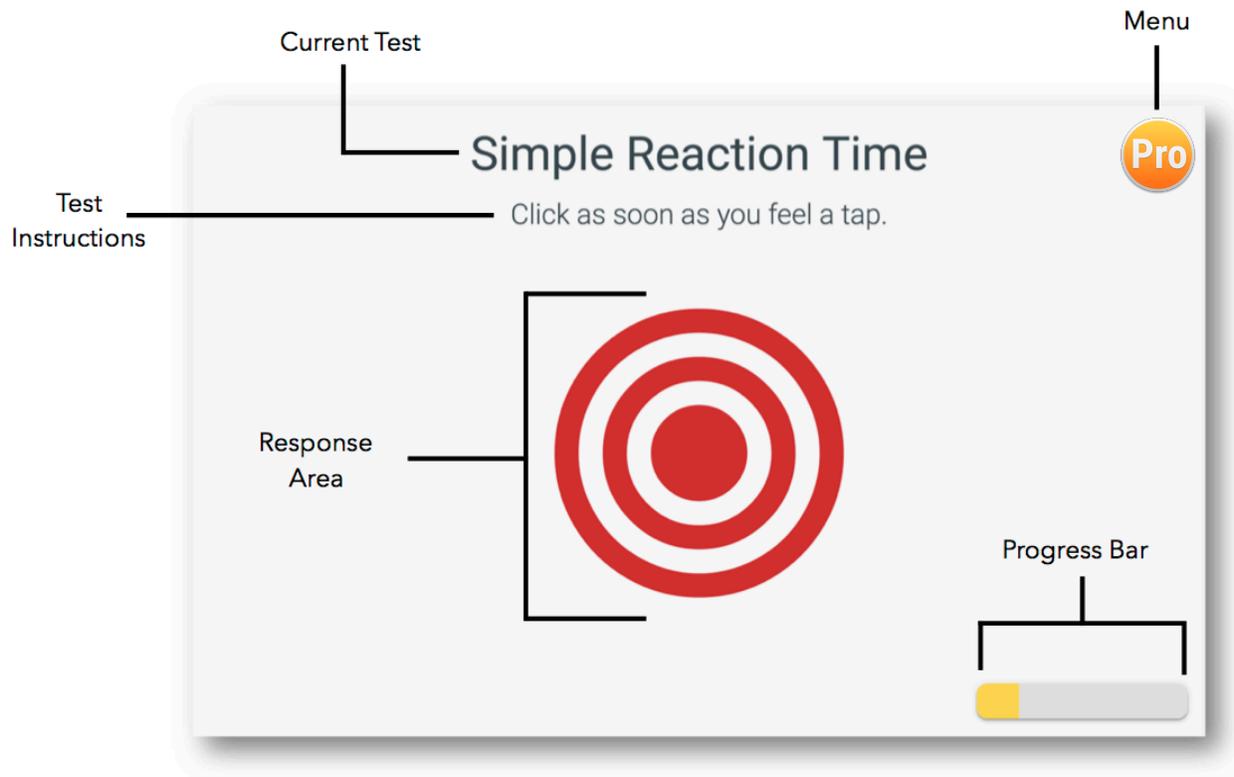
Testing Environment

The user should sit in front of the computer with their hand on the Brain Gauge. When they are ready to begin testing, instruct the user to click **OK**. This will initiate a short demonstration of what the vibrations will feel like on each finger.

If the user cannot feel the demo vibrations, or if the vibrations feel 'uneven', check their finger placement and select **Redo Tutorial**. Otherwise, select **Get Started**.



Below is an example of the ProTools testing environment.



At the beginning of every test, instruct the user to read the **Test Instructions** very carefully.

The **Progress Bar** gives an indication of the number of questions left in the **Current Test**. There are several variations of the **Progress Bar** and **Response Area**, depending on the current testing protocol.

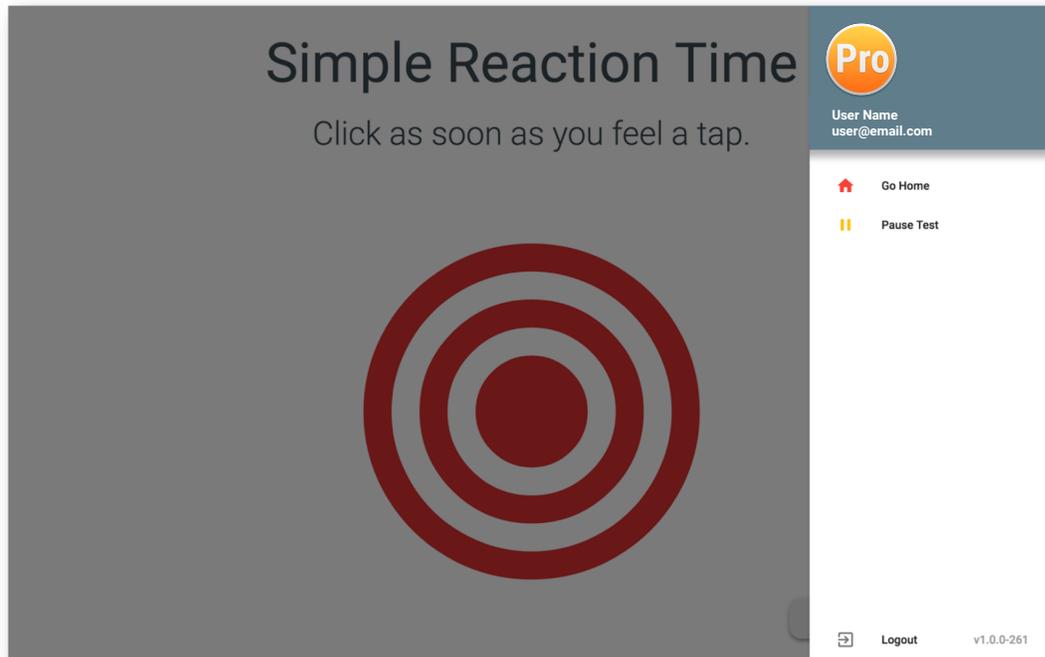
Testing Procedure

The software will lead the user through a series of tests that take between 1 and 3 minutes each. Once all tests are complete, the software will return to the Home screen. Instruct the user to focus but stay relaxed, and answer each question to the best of their ability.

Most tests offer three practice trials to familiarize the user with the testing procedure. Users must answer all three trial questions correctly before proceeding. If a user is unable to successfully complete the training trials after several attempts, consider navigating to the next test before they become too discouraged (see below).

Navigating

Use the **Menu** to pause or exit the testing session at any time.



The **Pause Test** button will allow you to freeze the session and manually navigate between tests in the scheduled session*. You can also use this button to skip a test, or access a particular test, if you don't want to complete the entire session. Just begin the testing process as usual, then navigate to the Pause menu at the end of the Tutorial.

When skipping a test or quitting early, results from all completed tests will be stored. However, if you leave in the middle of a test, a score for this uncompleted test will **not** be recorded.

***Note:** pausing for longer than 10 minutes between tests will cause results to be stored as separate testing sessions.

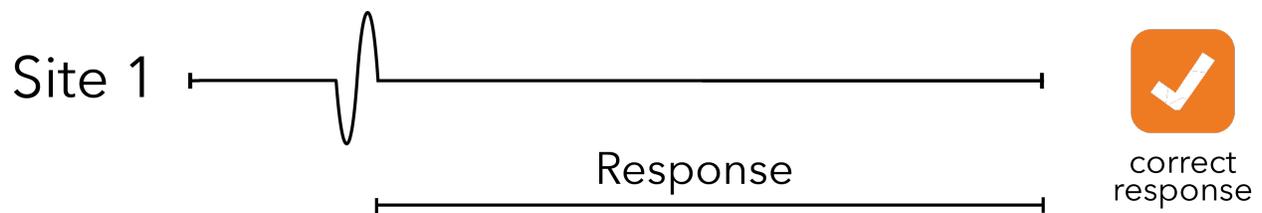
Testing Protocols

There are several types of testing protocols available for the Brain Gauge, each designed to assess a different aspect of cognitive function.

Reaction Time

These protocols quantify processing speed and response timing. The results from reaction time tests contribute to the **Speed** score.

Simple Reaction Time



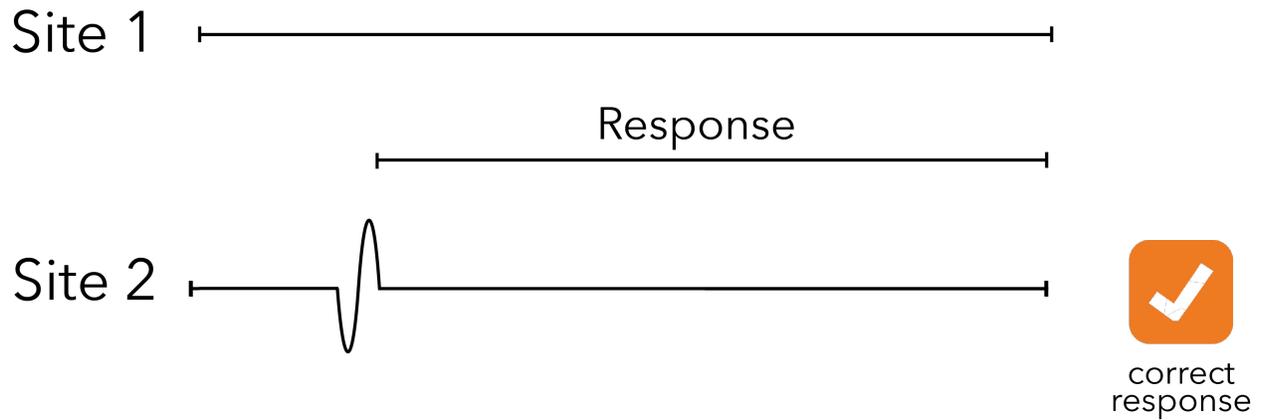
Directions

The subject will receive a single pulse to the right finger, starting a timer. As soon as the pulse is detected, click the **left** probe tip. Once the subject has clicked, the timer will stop and the software will record and display the result.

Testing Notes

This test is a direct measure of reaction time, and it is essential that the user responds as quickly as possible to the stimulus. If the user does not feel the pulse (either because they weren't prepared, or because they removed their finger from the probe tip), you may instruct them to simply click and move on to the next trial.

Choice Reaction Time



Directions

The user will receive a single pulse to one of their fingers, starting a timer. As soon as the pulse is detected, click on the **left** or **right** where it occurred. Once the user has clicked, the timer will stop and the software will record and display the result.

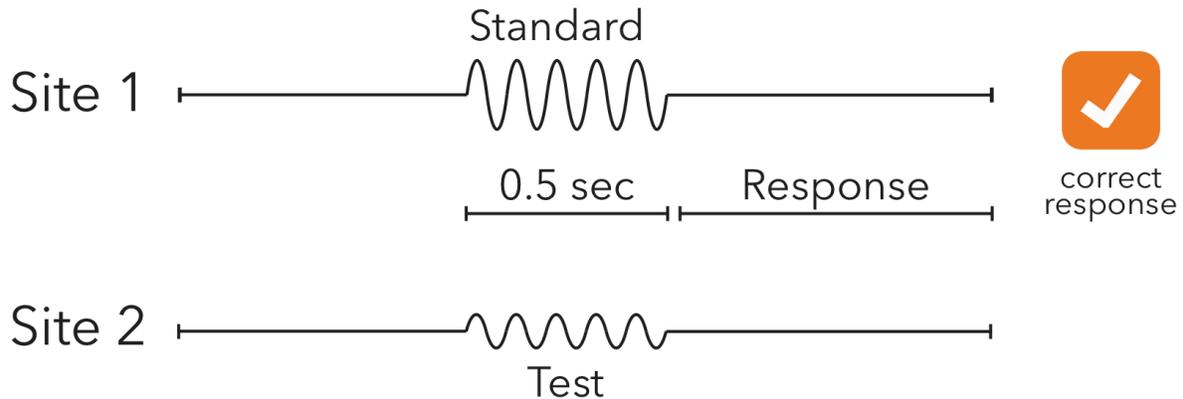
Testing Notes

Response time and accuracy are of equal importance in this test. If the user does not feel the pulse, either because they were not prepared or took their finger off the stimulator, you may instruct them to just click and move on.

Amplitude

These protocols assess the ability to distinguish between two stimuli with or without the pretense of a conditioning stimulus. Amplitude tests contribute to the **Accuracy** score.

Amplitude Discrimination



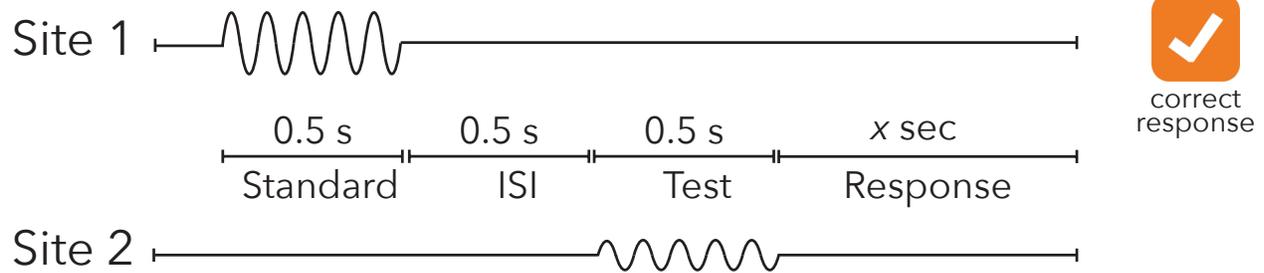
Directions

The user will be asked to compare the intensity of two vibrations. The stimuli will be delivered simultaneously to their index and middle fingers. Click the probe tip corresponding to the **larger / stronger / more intense** vibration.

Testing Notes

Response time is not important for this test. If the user cannot detect a difference between the two stimuli, instruct them to make their best guess.

Sequential Amplitude Discrimination



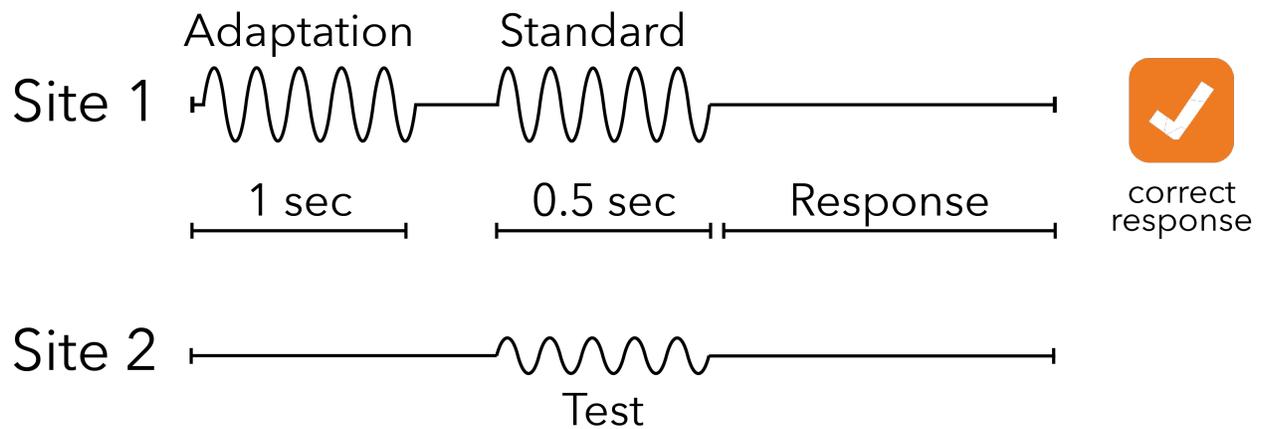
Directions

The user will be asked to compare two vibrations. The stimuli will be delivered sequentially to the index and then middle finger. Determine which stimulus was **larger / stronger / more intense** and click on the corresponding probe tip.

Testing Notes

Response time is not important for this test. If the user cannot detect a difference between the two stimuli, instruct them to make their best guess.

Single Site Adaptation



Directions

The user will feel a single conditioning stimulus (which should be ignored), followed by a pair of vibrations that they will need to compare. Click on the probe tip corresponding to the **larger / stronger / more intense** of the **simultaneous** stimuli.

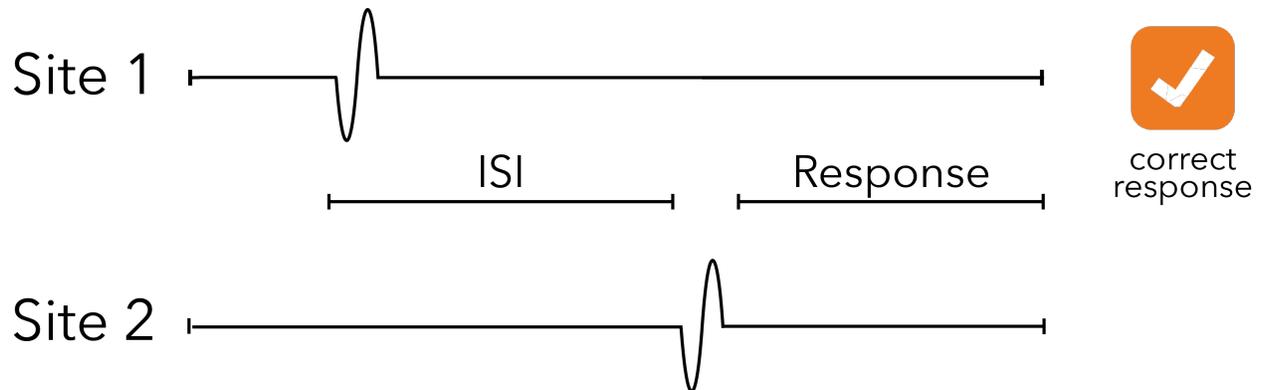
Testing Notes

Response time is not important for this test. If the user cannot tell a difference between the two stimuli, instruct them to make their best guess. If the user seems confused, frustrated, or they repeatedly miss the training trials, remind them to "read the directions on the screen carefully."

Temporal Order Judgment (TOJ)

These protocols assess the ability to distinguish the correct order of two stimuli that occur in rapid succession. TOJ tests contribute to the **Sequencing** score.

Temporal Order Judgement



Directions

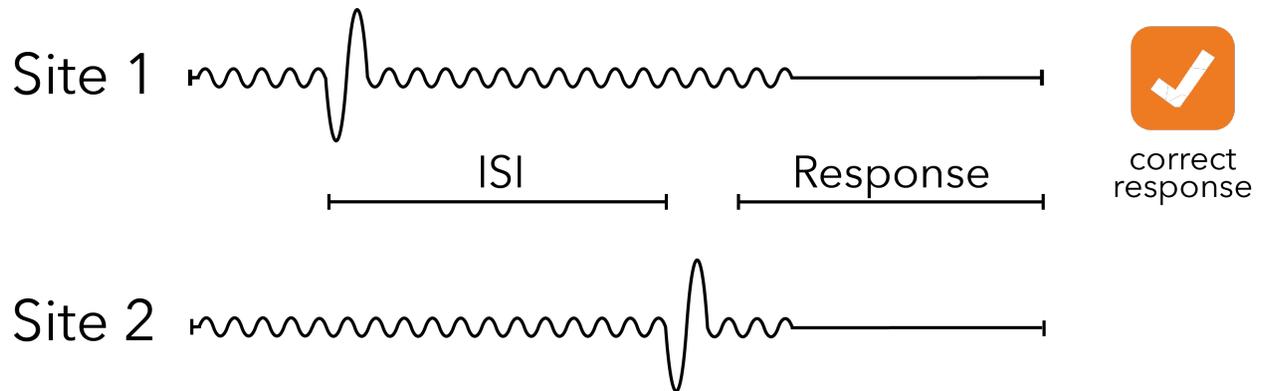
The user will receive two asynchronous stimuli in rapid succession. They should click on the probe tip corresponding to the **first** stimulus that they felt.

Testing Notes

Response time is not important for this test. Encourage the user to make the best choice possible. If they cannot detect the location of the first stimulus, instruct them to make their best guess. Most users enjoy this test and find it easy.

Some users find it easiest to remember the last stimulus they felt, and then click the opposite probe tip. User strategy has no impact on the test results.

Temporal Order Judgement With Carrier



Directions

The user will receive two asynchronous stimuli in rapid succession. The stimuli will be accompanied by a confounding "carrier". They should click on the probe tip corresponding to the **first** stimulus that they felt.

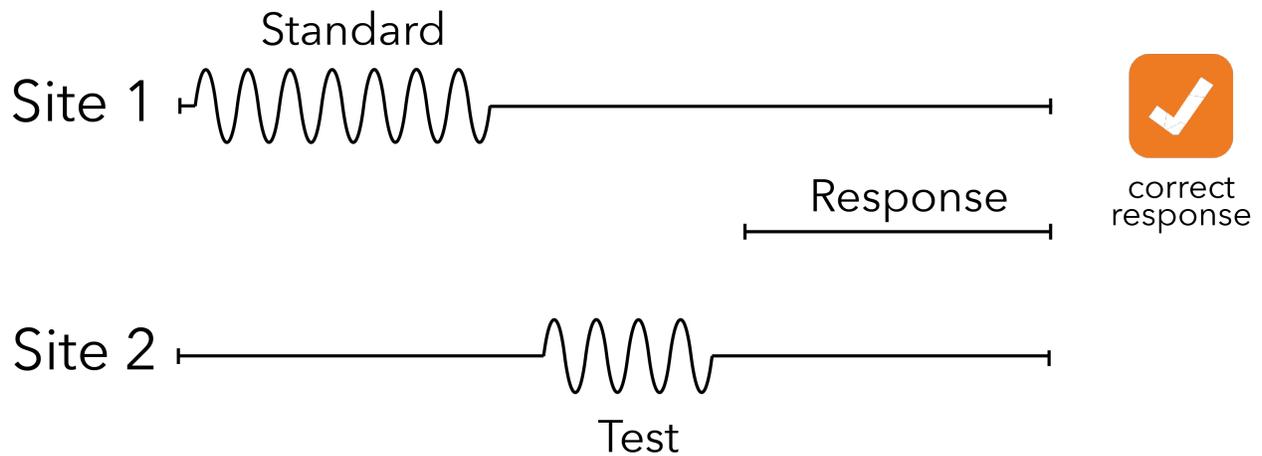
Testing Notes

Response time is not important for this test. Encourage the user to make the best choice possible. If they cannot detect the location of the first stimulus, instruct them to make their best guess. Most users enjoy this test and find it easy. The background vibration is so insignificant that most users easily ignore it without being given specific directions to do so.

Duration

This protocol assesses the perception of passing time without the presence of a clock or watch. Duration testing contributes to the **Timing Perception** score.

Duration Discrimination



Directions

The user will receive two sequential vibrations - one to each finger - of unequal duration. They should click on the probe tip corresponding to the stimulus that lasted **longer**.

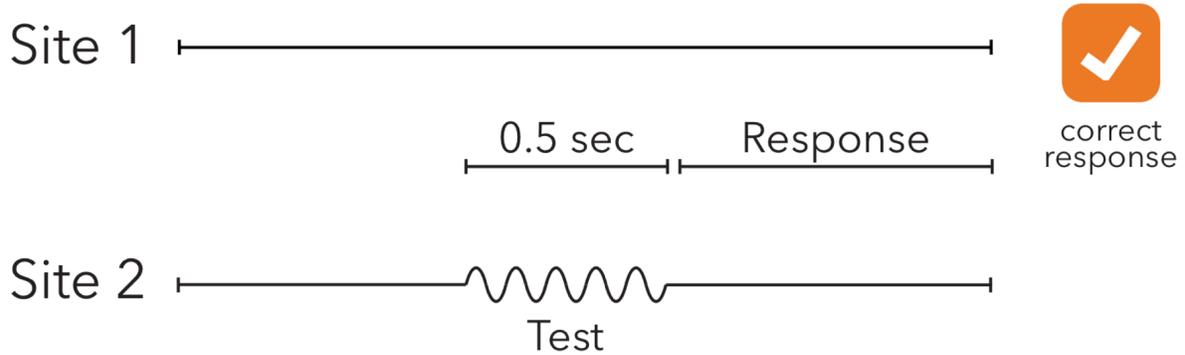
Testing Notes

Response time is not important for this test. The user may feel as though the two vibrations are of equal duration. If they cannot detect a difference in duration, instruct them to make the best guess.

Threshold

These protocols determine the smallest vibration that a user is able to detect. Threshold test results contribute to the **Sensitivity** score.

Static Threshold



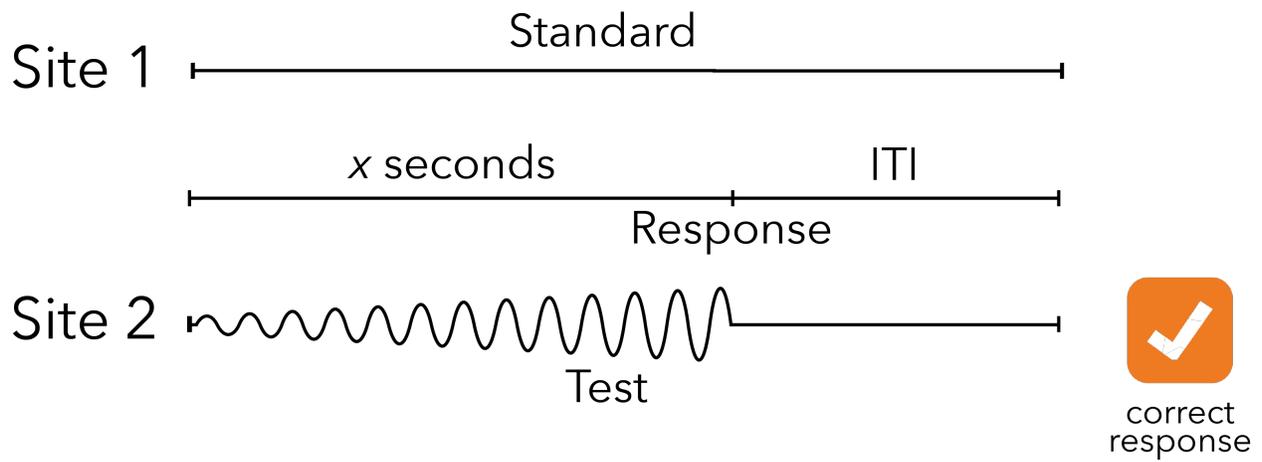
Directions

The user will receive a faint vibration to one of their fingers. If they are able to detect the vibration, they should click on the probe tip where it occurred.

Testing Notes

Make sure that the subject responds as soon as they detect the vibration. Response time is important for this test.

Dynamic Threshold



Directions

The user will receive a single, barely noticeable vibration to one of their fingers. They should click on the probe tip that delivered the stimulus.

Testing Notes

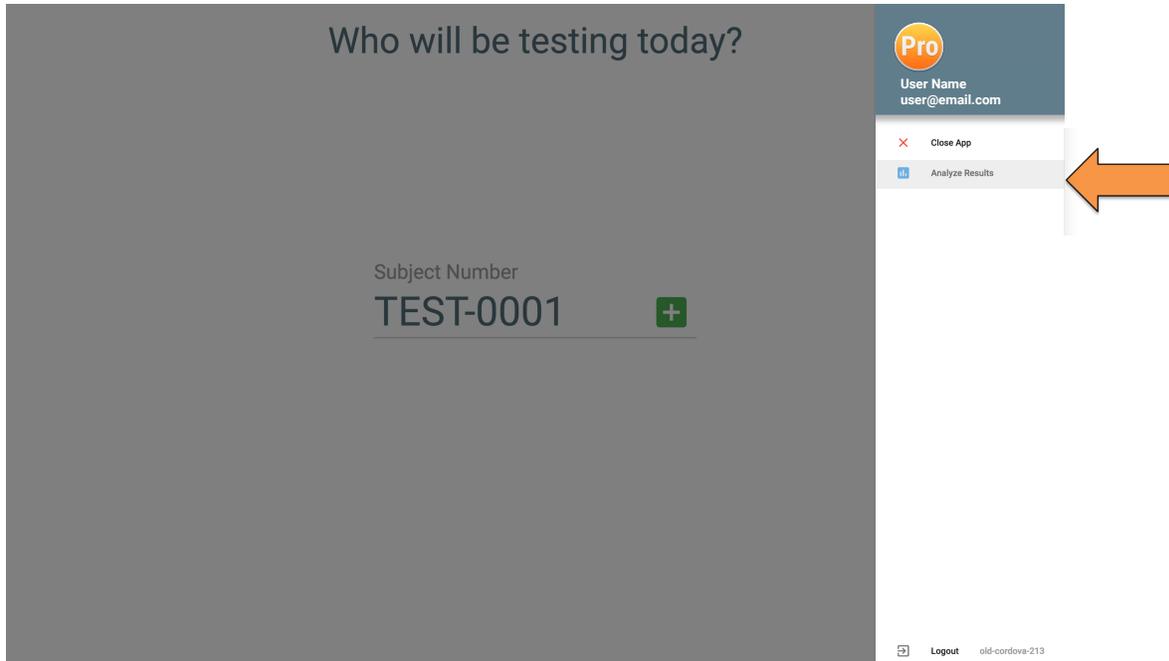
Make sure the user responds as soon as they can detect the vibration. Response time is important for this test.

Results

Viewing Subject Results

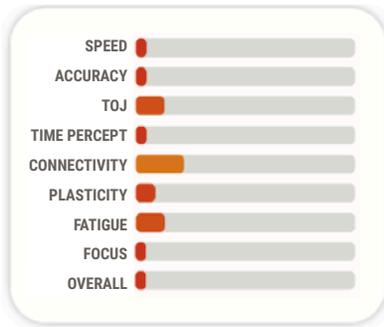
From the Home screen, use the Menu button (in the upper right-hand corner) to navigate to results.

You can also view results at <https://app.corticalmetrics.com>



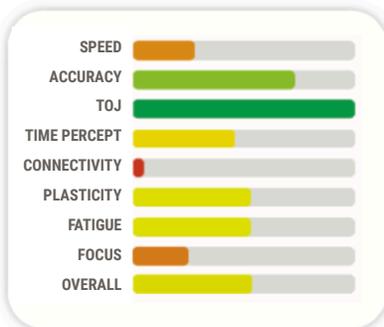
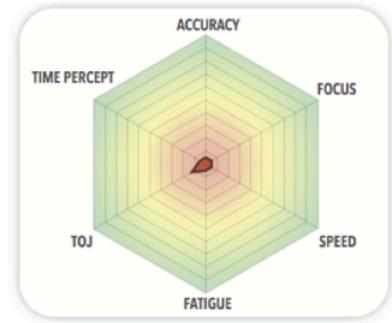
Reading Results

Once a user has completed a testing session, you will receive a report that includes the raw scores for each test completed, along with a chart of calculated metrics. Long, green bars indicate strong performance while short, red bars indicate poor performance.



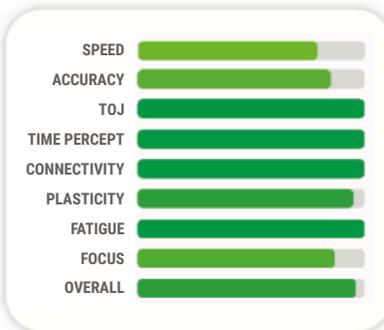
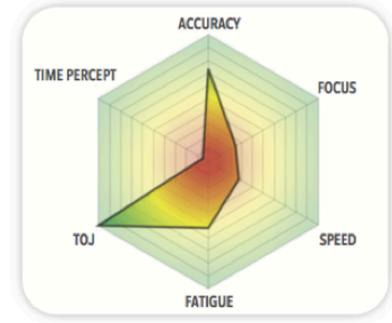
Poor

Note that most of the bars are very short and red. This means that the patient did not perform well on any of the tests. In this example, the patient was suffering from severe cognitive impairment.



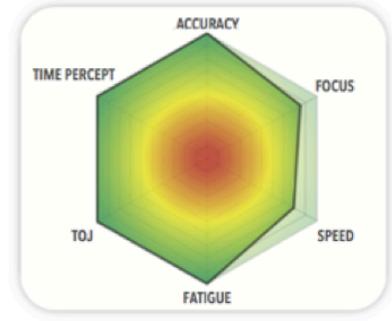
Mixed

This chart shows a combination of red and green bars, suggesting that the patient performed well on some tests and poorly on others. The individual in this example sustained a concussion, but only certain scores were affected due to



Normal results

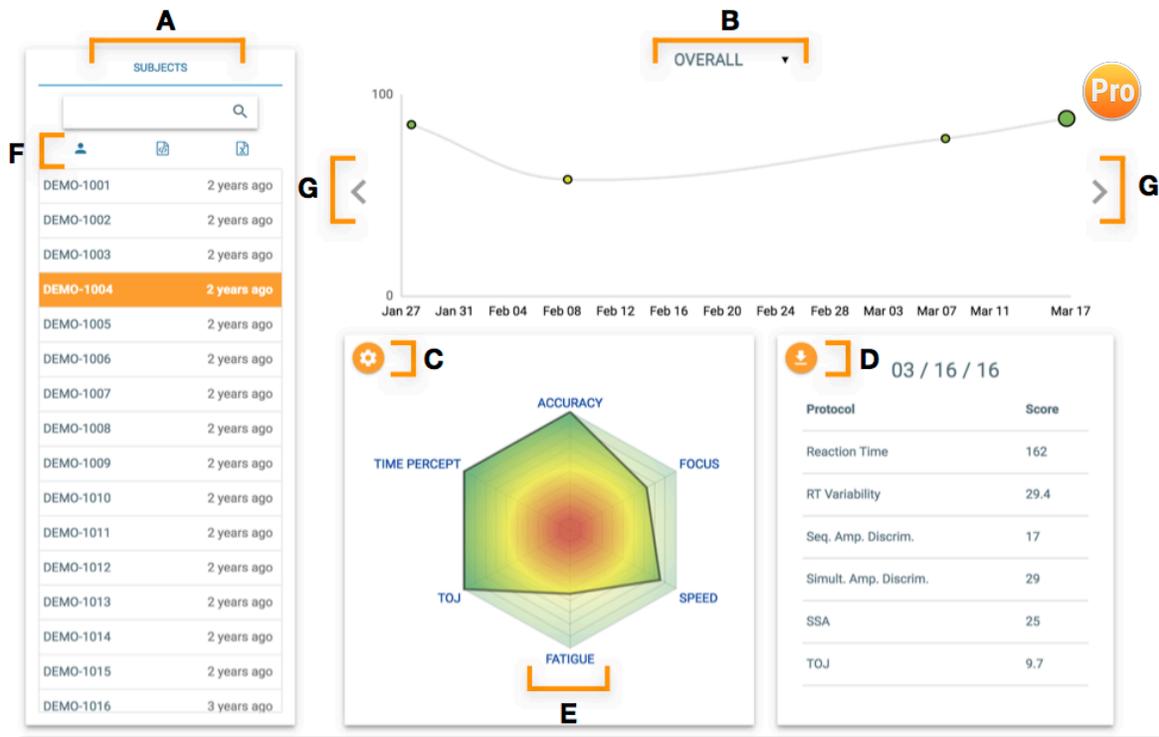
All bars in this chart indicate strong performance. When an individual exhibits cognitive function in the normative range for all tests, results should look like this.



A simple way to track overall performance is to count the number of green bars for each session. Comparing this number between sessions can help quantitatively assess your progress over time. For example, if the results from your first test appear to be **Poor**, you might improve to **Mixed** results after a successful period of treatment.

Navigating the Results Screen

From the results screen, there are several options to view and analyze each user's data.



- A** - search by subject name
- B** - select a metric to display on the timeline
- C** - toggle between a radar chart (shown) and a bar chart
- D** - download testing session report (.pdf format)
- E** - click on each metric to learn more about what they represent
- F** - view subject profile
- G** - scroll through testing sessions on the timeline

To exit the app, click on the **Menu** button in the upper right-hand corner from the testing or results screen. Select **Go Home** and then **Close App**.

Metrics

Once testing is complete, individual metrics can be evaluated in order to assist with user diagnosis and symptom tracking.

SPEED is computed directly from the reaction time tests. This metric reflects the time required to respond to a tactile stimulus. Speed is correlated with white matter integrity and the integrity of frontal-parietal pathways. Damage to cortical white matter occurs with a number of conditions, including traumatic brain injury (TBI), multiple sclerosis (MS), and some neurodegenerative disorders.

ACCURACY is computed by averaging scores from the simultaneous and sequential amplitude discrimination tests. This metric reflects the smallest detectable amplitude difference between two stimuli. Accuracy has been found to correlate strongly with structural integrity of the parietal lobe.

SEQUENCING is computed from the Simple Temporal Order Judgment test. This metric reflects the smallest time difference between two stimuli such that a user can still identify which stimulus came first. Higher than normal values for Sequencing are consistent with autism, migraine, non-headache chronic pain, some neurodegenerative disorders, and TBI (particularly to the frontal-striatal area).

TIMING PERCEPTION is computed from the duration discrimination tasks. This metric reflects the smallest duration difference between two stimuli that a user can perceive. Damage to the cerebellar lobe or cerebellar pathways is associated with a decline in timing perception performance (increase in time). Higher than normal values for timing perception are consistent with migraine, non-headache pain, and TBI (particularly to the cerebellum).

CONNECTIVITY is a measure of how well groups of brain cells are communicating with each other. This metric is determined by comparing the scores of two temporal order judgment tasks (TOJ and TOJc). TOJc delivers the same stimuli as the TOJ task but with a concurrent conditioning stimulus in order to create an illusion. In the presence of this illusion (or confound), temporal order judgment should be ~30% worse. If the TOJc score is not greater (worse) than TOJ, the connectivity score will be low.

PLASTICITY Plasticity is a computed metric based on comparisons between several scores, and is a measure of how well your brain is integrating, processing, and adapting to information from its external environment. States of hyper-excitation, which can be caused by low GABA levels, lead to poor plasticity scores.

FATIGUE is computed from the variability between the first and second reaction time tests. High variability in speed measurements has been linked to micro-lesions in the cortical white matter. When reaction time performance degrades significantly, this score will be low.

FOCUS is computed from the variability on the reaction time tasks. It measures the ability to attend to a task.

Normal Scores

Cognitive function can vary between individuals. Results for an individual may also vary between testing sessions, and can be affected by alertness, medication, and overall health.

ProTools Metric	Neurocognitive Equivalent
Speed	Reaction Time
Accuracy	Amplitude Discrimination
Sequencing	Temporal Order Judgment
Timing Perception	Duration Discrimination
Connectivity	Systemic function
Plasticity	Neuroplasticity
Fatigue	Reaction Time Variability
Focus	Attention

Context

All ProTools metrics should be considered in the context of a user's entire medical history, which may include surgical events, treatments, and previous Brain Gauge testing sessions. Clinicians should discuss all results, as well as the limits and interpretations of these results, with users, families of users, and any other associated individuals as guided by their professional judgment regarding the particular circumstances.

Repeat Testing

In the case of an erroneous testing session, or one in which extraneous events may have interfered with a testing session, a repeated testing session may be warranted. Such events may include but are not limited to: head trauma, other injury, stroke, cardiovascular event, metabolic crises (hypo/hyperglycemia, renal failure), toxic exposure, disruptive testing environment, intoxication, and medicinal side effects.

Proper care and maintenance

Cleaning Materials

- Isopropyl alcohol
- Microfiber cloth
- Sanitary work environment

Cleaning your device

To properly clean your Brain Gauge, lightly moisten a microfiber cloth with isopropyl alcohol. Wipe down all device surfaces and dispose of cloth in a waste receptacle. Wait until unit is fully dry before resuming use.

The Brain Gauge should be fully sanitized before initial use and after each individual testing session. Failure to properly sanitize the Brain Gauge between testing sessions may result in transmission of pathogens between users.

Environmental restrictions

The Brain Gauge is for indoor use only in a clinical setting. This device is operable at air temperatures between -25 and 70 C and relative humidity levels up to 93%.

Storage

When not in use, the Brain Gauge should be unplugged and stored indoors in a cool, dry environment. Improper storage of the device may result in inaccurate test results or electrical damage to the device.

The Brain Gauge contains sensitive magnetic and electronic equipment. Do not ship or store your device near strong electrostatic, electromagnetic, magnetic, or radioactive fields.

Disposal

To properly dispose of your Brain Gauge, please pack the device securely in a cardboard box and ship to:

Cortical Metrics, LLC
209 Lloyd St.
Suite #360
Carrboro, NC 27510

Technical Description

Specification	
Interface	USB 2.0
Ambient Temperature	+5 C to +24 C (57 F to 75 F)
Humidity	15% to 95% Relative, non-condensing
Dimensions	113mm x 73mm x 40mm (4.5" x 2.9" x 1.6")
Weight	117g (4.1 oz)
Warranty	One Year Limited
Applied Parts	Probe tips and device shell

Troubleshooting

Problem / Error message	Solution(s)
"Please connect your device"	Ensure that the USB cord is fully inserted If using a Windows PC, update your USB drivers
Tips not vibrating during test	Device malfunction. Contact support@corticalmetrics.com

Contact and Technical Support

For questions, comments, or concerns regarding proper use of your Brain Gauge device or the ProTools web application, please contact:

Cortical Metrics, LLC
209 Lloyd St.
Suite #360
Carrboro, NC 27510

Tel: +1 (919) 903-9943

Product Questions: info@corticalmetrics.com

Technical Support: support@corticalmetrics.com

For 24/7 Technical Support, check out:

<https://www.corticalmetrics.com/support>