

T.O.V.A. 9 International User's Guide

Software version 9.1-339

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Important Information

Description

The Test of Variables of Attention (T.O.V.A.) is an accurate and objective continuous performance test (CPT) that measures the key components of attention and inhibitory control. The T.O.V.A. is used by qualified healthcare professionals in the assessment of attention deficits, including attention-deficit/hyperactivity disorder (ADHD), in children and adults. In addition, the visual T.O.V.A. is used to evaluate treatment for attention deficits, including ADHD.

The T.O.V.A. is a culture- and language-free, sufficiently long computerized test that requires no left/right discrimination or sequencing. Responses to visual or auditory stimuli are recorded with a specially designed, highly accurate (±1 ms) microswitch. The T.O.V.A. calculates response time variability (consistency), response time (speed), commissions (impulsivity), and omissions (focus and vigilance). These calculations are then compared to a large age- and gender-matched normative sample (over 1,700 individuals for the visual test, and over 2,600 individuals for the auditory test), as well as to a sample population of individuals independently diagnosed with ADHD. These comparison results are used to create an immediately available, easy-to-read report.

The T.O.V.A. is a stand-alone software application that is installed on Windows or Mac computers, and requires USB-based hardware be attached while operating. The T.O.V.A. does not require internet access to operate, although access to the internet will enable many features, including software updates and direct access to technical support.

The T.O.V.A. kit includes:

- USB flash drive with software installer for Mac and Windows PCs
- T.O.V.A. USB device
- T.O.V.A. microswitch
- International User's Guide
- User's Manual (English only, may be in electronic format)
- Clinical Manual (English only, may be in electronic format)
- Accessory cables (USB, VGA, and audio cables)

Indications

The Test of Variables of Attention (T.O.V.A.) provides healthcare professionals with objective measurements of attention and inhibitory control. The visual T.O.V.A. aids in the assessment of, and evaluation of treatment for, attention deficits, including attention-deficit/hyperactivity disorder (ADHD). The auditory T.O.V.A. aids in the assessment of attention deficits, including ADHD. T.O.V.A. results should only be interpreted by qualified professionals.

Contraindications

The T.O.V.A. microswitch and USB device should not be used in conjunction with magnetic resonance imaging (MRI) equipment.

Warnings and Precautions

The T.O.V.A. provides objective measures of attention and inhibitory control. The T.O.V.A. does not diagnose any disease or disorder or make a recommendation of treatment. T.O.V.A. performance should always be considered in the context of all available clinical information and should only be interpreted by a qualified professional.

T.O.V.A. results should be interpreted only by qualified professionals.

WARNING: Repetitive flashing of display may cause eye strain, headaches, or seizures. Please seek medical help if you experience any eye strain or headache.

Warning: The surface of the T.O.V.A. microswitch may become hot (41 °C / 106 °F) during use. Discontinue use if holding the switch becomes uncomfortable.

The T.O.V.A. microswitch is a Type B Applied Part, i.e., a part of the system meant to be handled by the subject. The T.O.V.A. USB device and associated cables are not applied parts, and are not meant to be handled by the subject.

The T.O.V.A. can only be connected via the USB connector: Only connect the USB input to equipment that is certified to UL 60950-1 and IEC 60950-1.

The T.O.V.A. microswitch should be cleaned in between subjects. See the <u>Cleaning instructions</u> section below.

The T.O.V.A. is designed to be stored, operated and transported in a standard indoor environment: a temperature of 10 to 40 °C (50 to 104 °F), 0 to 100% relative humidity, and an atmospheric pressure of 64.4 to 106.6 kPa.

Do not interrupt the T.O.V.A. test while it's being administered. Pressing the **Esc** key will result in the test being Interrupted.

Do not open the T.O.V.A. hardware enclosures; there are no user serviceable parts inside the T.O.V.A. hardware.

Do not unplug the T.O.V.A. hardware when in use (during a test). This will result in lost session data.

Always make sure that your PC is plugged into a power outlet during testing. A low battery during a test session may cause the test data to be lost.

Caution: If a new display or new PC is used, the display must be recalibrated prior to administration of

the T.O.V.A. test.

The T.O.V.A. Precision Test Environment does not support the use of multiple monitors/screens.

The T.O.V.A. does not support network share databases. Storing data on a server or network share will most likely result in lost data. Please only use the T.O.V.A. with the database on a local drive.

We always recommend that you back up your T.O.V.A. database before installing or uninstalling the T.O.V.A. Automatic local database backups are built into the T.O.V.A. application and enabled by default, but we recommend that you also regularly back up your database (and the rest of your PC) to a secure location.

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

Information Security for T.O.V.A. Computers

The T.O.V.A. database may contain private or personal Protected Health Information (PHI). The T.O.V.A. application does not secure or encrypt the database itself. Instead, you should secure access to the T.O.V.A. database and backup folders within your computer's operating system (Windows or macOS). For example, you should use full disk encryption on your local drive that runs the T.O.V.A. Please be sure that all authorized users of the T.O.V.A. have full permissions on the system to the database folder and its subfolders.

We also expect users will follow information security best practices on the host PC, among which are:

- Use separate user and admin accounts.
- Use strong passwords.
- Lock the computer after a few minutes of inactivity.
- Control physical access to your T.O.V.A. PC.
- Keep T.O.V.A. software up to date.
- Back up your PC regularly and store your backups securely.
- If your T.O.V.A. system is online, keep your OS up to date. Use internet security software to prevent malware infections.

The T.O.V.A. does not require internet access to operate. When access is available, the T.O.V.A. uses SSL to secure any communication with our servers, and no PHI is transmitted without your consent. Any information on our servers is securely maintained.

Compliance Information

Canada

The Test of Variables of Attention (T.O.V.A.) is licensed by Health Canada as a Class I medical device manufactured under Medical Device Establishment License (MDEL) Number 9655.

European Union

The Test of Variables of Attention (T.O.V.A.) is a Class I medical device manufactured in accordance with the European Union's Medical Device Directive (MDD 93/42/EEC).



European Authorized Representative:



For vigilance inquiries, use EmergoVigilance@ul.com

Quality Standards

The TOVA Company is a medical device manufacturer that is certified under ISO 13485:2016 and the Medical Device Single Audit Program (MDSAP). Please see https://www.tovatest.com/iso for our certificate.



Symbols

SN	Serial number			
•••	Manufacturer address			
[OBJ	Production date			
Ţ i	Consult instructions for use			
\triangle	Caution, consult accompanying documents			
Ť	Keep dry			
	Do not used if damaged			
	Not for general waste			
CE	European Union (EU) CE Mark			
Æ	Federal Communication Commission (FCC) compliance			
†	Type B applied part			
EC REP	Authorized representative in the European Union (EU)			

Cleaning instructions

The T.O.V.A. microswitch

Because the T.O.V.A. microswitch comes in direct contact with a patient, it should be cleaned after every use.

- Do
- Clean the microswitch casing after every use.
- Use a low-level disinfectant on a soft, lint-free cloth. Examples of low-level disinfectants include 70% or greater isopropyl alcohol, 10% bleach solution, or various commercial disinfectant wipes.
- Do NOT
 - Do not immerse in or spray the microswitch with a liquid.
 - Do not use abrasive cleaners.

The T.O.V.A. USB device

The T.O.V.A. USB device and all associated cabling do not require cleaning. If you wish to clean it, please follow these instructions:

- Do
- Use a mild cleaning solution on a soft, lint-free cloth
- Do NOT
 - o Do not immerse in or spray the T.O.V.A. USB device with a liquid.
 - Do not use abrasive cleaners.

Installing the T.O.V.A.

If you need help installing the T.O.V.A. on your computer, please don't hesitate to contact us at support@tovatest.com or call us at 562.594.7700. From within the T.O.V.A. software, you can also contact us by choosing Help and then Technical Support.

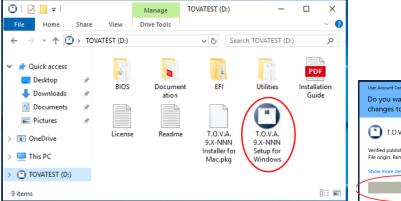
Step 1: Install the software

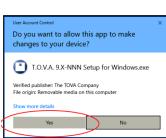
Note: You will need to have administrator privileges.

Note: Please close all other open programs before installing.

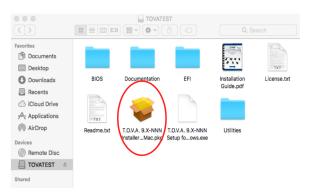
- Insert the T.O.V.A. flash drive into your computer.
 - You can also download the latest software installer from our website: Go to tovatest.com/download and enter the T.O.V.A. serial number found on the bottom of your T.O.V.A. USB device.

Windows: Double-click on T.O.V.A. 9.X-XXX Setup for Windows and confirm it can make changes to your device.





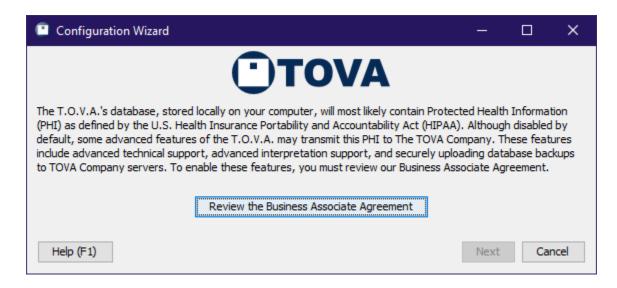




Step 2: Configure the T.O.V.A. software

Note: You can change these preferences later.

1. The T.O.V.A. has a Business Associate Agreement, as required by the U.S. Health Insurance Portability and Accountability Act (HIPAA). Some features will be disabled until the agreement is accepted (or marked as not applicable).



- 2. Choose if you want to back up your T.O.V.A. data to The TOVA Company's secure servers.
- 3. Choose if we can send information to help with technical support.
- 4. Choose which of the two hardware setups work best for your computer. (You can change your hardware setup later.)

5. Click Finish and go to Step 3 below.

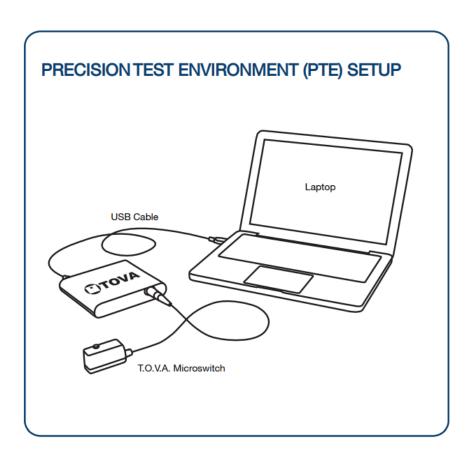
Step 3: Set up the hardware

The T.O.V.A. has two hardware setups:

- The **Precision Test Environment (PTE)** setup will reboot your computer into a T.O.V.A. testing environment and then boot back to your regular operating system after testing.
- The **External Audio/Video (EAV)** setup lets the T.O.V.A. USB device take over an external VGA-compatible monitor and speakers.

For helpful videos on setting up your T.O.V.A. hardware, please see https://www.tovatest.com/videos.

Please choose a hardware setup:

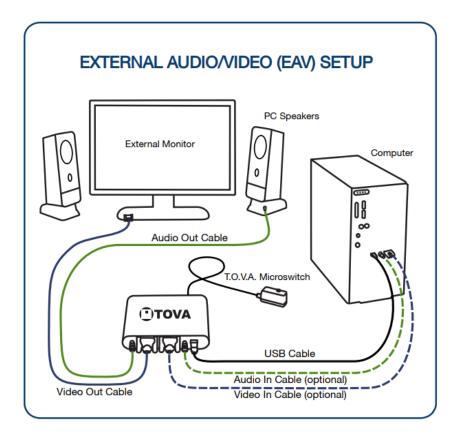


Use the **PTE setup** if you:

- Have a laptop and you don't want to use an external monitor
- Don't mind rebooting to administer a test

Features:

- Works with laptops
- Minimal hardware setup



Use the EAV setup if you:

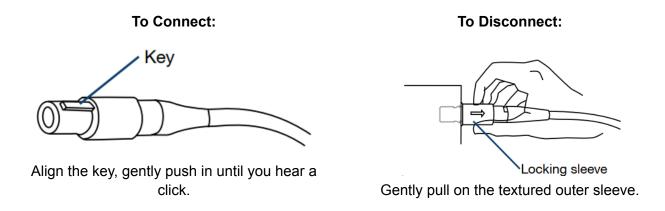
- Have a standard desktop computer with a VGA-capable monitor.
- Have a laptop with an external VGA monitor available.
- Don't want to reboot to give a test.

Features:

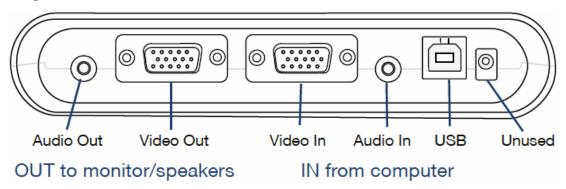
- No rebooting!

Connecting the T.O.V.A. microswitch

Use care when connecting and disconnecting.



Connecting other hardware



Step 4: Test the hardware

Once connected, follow the instructions to test your T.O.V.A. hardware. If you've chosen the PTE setup, you can try out the PTE.

Preparing to Administer the T.O.V.A.

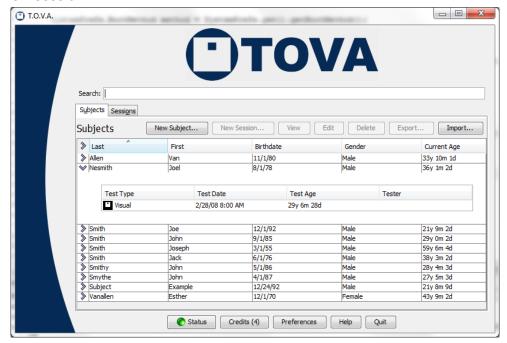
Preparing the subject is crucial, because it assures that the test is administered properly and replicates the same conditions as the T.O.V.A. normative study.

- Prior to testing, explain to the subject (or to caregivers) that no caffeinated beverages (e.g., coffee, tea, cocoa, or soft drinks) should be ingested on the day of a test. Nor should the subject have smoked within 3-4 hours. Please note: a baseline test assumes no stimulants have been taken prior to test administration (stimulant medication, coffee, nicotine). To evaluate treatment effects on T.O.V.A. performance administer the test during peak effect of stimulants.
- Setting: Testing should be done in a quiet, softly lit room with a glare-free monitor. Clocks should not be visible or audible. It is best if the subject faces a neutral colored wall without distracting pictures. If possible, the keyboard should not be visible during the test.
- If using the auditory T.O.V.A., use adequate speakers on either side of the computer screen.
 The screen will display the focus point, which the subject should visually focus on during the test.
- At test time:
 - Introduce yourself to the subject.
 - Ask if the subject needs to use the bathroom.
 - Determine whether they have glasses or hearing aid if needed.
 - Have the subject remove his or her watch; mute all potential sources of noise including cell phones and place them out of line of vision.
 - Determine from subject or caregiver any and all medications taken in the last 24 hours, with dosage and interval since administered, and record them in the New Test Session window.
 - Determine whether the Auditory or Visual test is to be administered based on history and any previous test results. Consider giving both practice tests if the subject is between the ages 6 and 29 to see which is the more challenging to the subject.
 - o Position the subject and chair so he or she may sit with feet on the floor.
 - Position the monitor so the screen is at or near eye level.

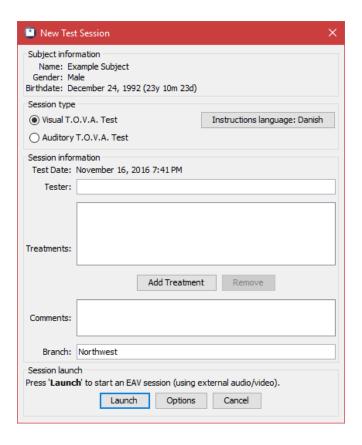
The <u>T.O.V.A.</u> Observation Form (Appendix A) can be used by the test administrator to gather information before, during, and after the test. Behaviors that affect test performance can be noted to help determine the reason for test results. These observations are often critical to understanding test performance. If the test is administered by a psychometrist or other staff member, the Observation Form should be given to the clinician along with the T.O.V.A. report.

Administering a T.O.V.A. Test

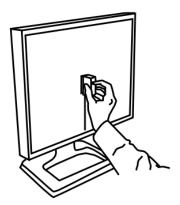
- 1. Run the T.O.V.A.
 - Windows: Double-click the **T.O.V.A.** icon on your desktop.
 - Mac: In the applications folder, open the TOVA folder and double-click the T.O.V.A. application.
- 2. Create a new session.



- Click New Subject... to create a new subject, and fill in the subject information, and click Save and start new session.
- o **OR** select an existing subject and click **New Session...** to start a new session.
- 3. Enter the session information.
 - Make sure that the name, birth date, gender, and age are correct.
 - Choose Visual or Auditory for a visual or auditory test.
 - Select a test instruction language.
 - Add any relevant treatments to the Treatments section.



- 4. Click Launch.
 - a. PTE setup: Your computer will restart.
 - b. The T.O.V.A. session screen will appear.
- 5. If this is your first visual test session, select **Calibrate display** to calibrate your monitor. Follow the on-screen instructions that explain how to hold the microswitch against your monitor and press the button.



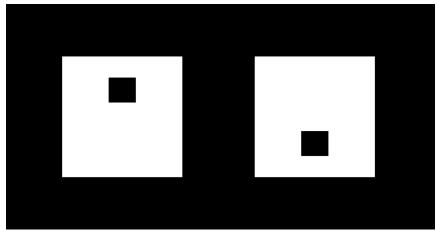
- 6. Position the subject near eye level to the screen. The test administrator can sit behind and to the side of the subject, but not so close as to be in the subject's field of vision.
- 7. Click **Test instructions**. This tells your subject how to take the test.
- 8. Click Practice test.

- a. Listen for the end-of-test tones to let you know the two-minute practice test is over.
- b. Review the results and repeat the practice if the subject needs further explanation.
- 9. Click **T.O.V.A. test**. After some final instructions, the subject will click the microswitch to begin the T.O.V.A. test.
 - o For subjects 5.5 years or older, the test is 22 minutes long.
 - o For subjects under 5.5 years old, the test is only 11 minutes.
 - o Listen for the end-of-test tones to let you know the test is finished.
- 10. PTE Setup: Click **Done**, and your system will restart back to the T.O.V.A. application.
- 11. Review the test summary.
- 12. Click **Save test results**. This will spend a test credit to move your T.O.V.A. test data from the T.O.V.A. USB device to a database on your computer.
- 13. Click View report.
- 14. Click Quit in the main window to exit the T.O.V.A.
 - Note: You don't need to "power down" the T.O.V.A. USB device or disconnect the T.O.V.A. hardware when not using it.

Understanding the T.O.V.A.

The T.O.V.A. test was designed from the ground up to accurately and reliably measure attention and inhibitory control. Some of its features are:

- Non-language-based stimuli
 - The T.O.V.A. uses non-language-based stimuli to minimize the potential confounding of the test results by language, culture, and/or a learning disability. In the figure below, the target stimulus is on the left, the non-target stimulus is on the right.



- The Auditory T.O.V.A. uses two single tones: the target is G above middle C (392.0 Hz), and the non-target is "middle C" (261.6 Hz).
- Visual and auditory modes
 - Both visual and auditory modalities may need to be evaluated since there can be problems with auditory and/or visual information processing. Most individuals process visual and auditory information similarly. That is, without a visual or auditory disorder, they process visual and auditory information similarly in terms of speed, variability, and accuracy.
 - O However, some individuals process one type of sensory input differently than the other. Thus, the Visual T.O.V.A. performance may be within normal limits, but the Auditory T.O.V.A. may not be normal and vice versa. The T.O.V.A. intentionally separates the auditory and visual tests to minimize distractions and/or stimulation so that specific auditory and visual processing strengths and difficulties can be identified.
- Task Length
 - The longer the test, the harder it is to attend and inhibit. This is important when measuring vigilance, a key factor in attention disorders. The T.O.V.A. is a 21.6-minute test with two 10.8-minute subtests. For children ages 4 and 5, the T.O.V.A. is 10.8 minutes in length, and the two subtests are each 5.4 minutes each.
- Infrequent and frequent target "Subtests"

- The T.O.V.A. is made up of 648 stimuli presentations. These presentations are divided into two 10.8-minute halves, and each half is divided into two 5.4-minute quarters. The T.O.V.A. has two "subtests", one per half:
 - The infrequent half (or "low response demand mode" subtest) in the first half has only one target per 3.5 nontargets, and thus is the more boring task and is the traditional form for measuring vigilance. Individuals with "low CNS arousal" tend to do poorly on this form.
 - The frequent half (or "high response demand mode/high inhibition demand mode" subtest) in the second half has 3.5 targets to every one nontarget, and thus is a more stimulating task during which individuals with "high CNS arousal" can become overstimulated. In this half, individuals with "low CNS arousal" tend to "wake up".
 - The T.O.V.A. for children 4 to 5.5 is a shorter test and consists of only quarter 1 (infrequent target mode subtest) and quarter 3 (frequent target mode subtest) to more appropriately match a normal attention span for their age. On the T.O.V.A. report these are shown as Half 1 and Half 2.
- Test/Retest Reliability (Practice vs. Novelty Effects)
 - The T.O.V.A. has excellent test-retest reliability (see the T.O.V.A. Professional Manual), and thus T.O.V.A. results can be compared over days, weeks, and even years. The T.O.V.A. can also be repeated even in the same day which is useful for off (baseline) off and on (challenge dose) medication testing. Note that we recommend at least 90 minutes between T.O.V.A. sessions.

The T.O.V.A. Variables

The T.O.V.A. accurately and precisely measures all of the significant variables of both auditory and visual information processing, including response time, response time variability, omissions and commissions, allowing the clinician to see the full picture of the subject's performance on the test.

The primary T.O.V.A. variables are the variables scored compared to the T.O.V.A. normative study, called the **Comparison to the Normative Sample**. The following variables are included:

Response Time Variability

Response Time Variability ("RTV") is a measure of variability (consistency) of response time. RTV is the standard deviation of correct response times, and thus directly measures the spread of the subject's response times. Individuals with ADHD tend to have inconsistent response times on the 10 - 100 millisecond time scale, and thus have a wider RTV. RTV is the most sensitive measure of the T.O.V.A. Because changes in RTV are on the 10 - 100 millisecond time scales, timing measurements must be very accurate; hence, the need for accurate timing (the T.O.V.A. USB device), an accurate and repeatable subject input device (the T.O.V.A. microswitch), and the need to calibrate out delays and variability in the computer screen (the T.O.V.A. microswitch's calibration photodiode).

Correct Response Time

 Correct Response Time is the processing time (in milliseconds) taken to respond correctly to a target. Persons with ADHD may respond slower than the normative sample, especially in the infrequent (boring) first half of the test.

Errors of Commission

Errors of Commission are a measure of impulsivity and/or disinhibition and occur when the subject incorrectly responds to the nontarget; that is, the subject pushes the button when they should have refrained. In the T.O.V.A., commission errors are far more frequent in the second half (high response demand). Generally, excessive commission errors decrease omission errors, shorten response times, and increase variability. Impulsivity is a hallmark of ADHD, predominantly hyperactive/impulsive presentation, and combined presentation.

• Errors of Omission

- Errors of Omission are a measure of focus and vigilance and occur when the subject does not respond to a target stimulus; that is, the subject omits pressing the button when a target appears or is played. This may be due to inattention, distractibility, or hyperactivity (looking away from the computer). Omission errors are rare in adults, and long strings of omission errors should be investigated. Use the I.O.V.A. Observation Form (Appendix A) to record behaviors during the test to determine and record the reason(s) for Omission errors.
- When evaluating omissions, always look at the absolute or raw numbers of omission errors on the Summary page and/or the Tabulated Data page. In some cases one or two

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errors reach statistical significance because of the lack of omission errors in older ages of the T.O.V.A. normative study, yet there may be little or no clinical significance to one or two errors. As an example, a single error early in quarter 1 may signify that the subject was surprised when the test began even though the practice session preceded the test. Always interpret standard score data alongside actual raw data to determine clinical significance of the results.

The T.O.V.A. Report

This section contains T.O.V.A. reports and a discussion of the forms and findings. There are four types of reports:

- Visual Preschool Report (ages 4 to 5.5)
- Visual School-Age Report (ages 5.5 to 17)
- Visual Adult Report (ages 18 to 80+)
- Auditory Report (ages 6 to 29).

Reports are identified by the age and gender of the subject and the type of test administered. The following example report is a School-Age report. When printing out a report, you may select which pages you want printed.

Introduction Page

This page provides basic information about the T.O.V.A. and its uses. It can be given to persons unfamiliar with the T.O.V.A. as an overview of the test.



Introduction

The Test Of Variables of Attention (T.O.V.A.®)

The **Test of Variables of Attention (T.O.V.A.)** is an FDA-cleared, state-of-the-art continuous performance test that provides healthcare professionals with objective measurements of attention and inhibitory control. The T.O.V.A. aids in the assessment of, and evaluation of treatment for, attention deficits, including attention-deficit/hyperactivity disorder (ADHD). T.O.V.A. results are available for children and adults (ages 4 - 80+) and should only be interpreted by qualified professionals.



The T.O.V.A. continuously measures performance during a 10.8-minute task or a 21.6-minute task, depending on age. It records speed, accuracy, and consistency of responses to a series of squares (in the visual T.O.V.A. test) or tones (in the auditory T.O.V.A. test) that are presented in two-second intervals. These measurements (accurate to ±1 ms) are then compared by age and gender to a normative sample (a sample of people without attention problems). This comparison determines whether the test results are "within normal limits" or not. The T.O.V.A. also compares results to a group of people independently diagnosed with ADHD. The T.O.V.A. report is based on these two comparisons, as well as performance, session, and response validity measures.



If you have questions about this report, please contact the person who provided it to you. For more information about attention and the T.O.V.A., please visit our website at https://www.tovatest.com/. To contact us please email info@tovatest.com or call 800.PAY.ATTN (562.594.7700).

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Summary Page

The Summary page contains the overall results of the T.O.V.A. Report.

Demographic Information

Session, Response and Performance Validity

This section summarizes whether there were any validity issues that might affect the test results, such as user interruptions, excessive errors, or unusual test results (regardless of ADHD diagnosis). If Session, Response, or Performance Validity is noted, the description will be on the Interpretation Notes page. All validity issues should be taken into account when looking at the test results.

T.O.V.A. Interpretation

The T.O.V.A. Interpretation summarizes the results of two different performance comparisons:

- The subject's performance compared to the T.O.V.A. normative sample by age and gender, called the Comparison to the Normative Sample (CNS). The CNS compares the subject's performance with individuals who do not have an attention problem.
- The Attention Comparison Score (ACS), which compares the subject's performance with individuals who have been independently diagnosed with ADHD. (See the Attention Comparison Score Page.)

Note: "May be suggestive of an attention problem" does not mean the subject has an attention disorder, including ADHD, only that the session results were not within normal limits.

In the sample protocol shown below, the CNS and the ACS were not within normal limits and the Interpretation is "The results of this T.O.V.A. are not within normal limits and may be suggestive of an attention problem, including ADHD."

Treatment

Any current treatments, including any prescribed medications (with dosages and medication-test interval), neurofeedback sessions, or other forms of treatment are printed here.

Note: The clinician will need to determine what effects the treatment may have on the T.O.V.A. performance.

In the sample protocol shown below, treatment shows "None was entered."

Comparison to the Normative Sample

The subject's comparison to the T.O.V.A. normative study is shown as quarter-by-quarter standard scores illustrated by bar graphs. **RT Variability** and **Response Time** show percentile rank below the standard score, while **Commissions** and **Omissions** show the number of errors in that quarter below the standard score.

- Standard scores above 85 are within normal limits.
- Standard scores 80-85 are borderline.
- Standard scores below 80 are not within normal limits.

In the sample protocol shown below, the subject had results that were not within normal limits compared to the T.O.V.A. normative study for Response Time Variability (Quarters 2-4), Response Time (Quarters 1-2), and Omission Errors (Q3).

The next table shows T.O.V.A. performance in standard scores by Quarters, Halves and Totals. Each of these is an independent calculation. They are not averages. Any quarter, half or total that is Not Within Normal Limits or Borderline causes the Interpretation to be Not Within Normal Limits or Borderline.

- Scores with a dotted line around them means that the quarter may not be valid and must be
 interpreted cautiously; see the Session Validity information on the Interpretation Notes page
 for more information.
- Shaded scores mean that the results are not within normal limits, and may be suggestive of an attention disorder.
- Outlined ("boxed") scores means that the results are borderline.



Summary

ID: 0 12y Male with ADHD DX Example Subject (Jan 1, 2006) Male - 12y 0m 0d Visual T.O.V.A. (v9.0-89 sn30000) Jan 1, 2018 at 9:00 AM

Session, Response, and Performance Validity

This session meets session, response and performance validity criteria.

T.O.V.A. Interpretation

The results of this T.O.V.A. are not within normal limits, and may be suggestive of a possible attention deficit, including ADHD. Please see the Interpretation Notes page for additional information.

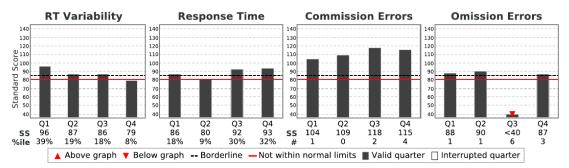
Treatment

No treatments entered.

Comparison to the Normative Sample

These scores compare this subject's performance to the performance of individuals of the same gender and age in the T.O.V.A. Normative Sample, a study of individuals who did not have attention problems.

Results are reported as standard scores (average standard = 100; standard deviation = 15). Standard scores above 85 are considered to be in the normal range, scores between 80 and 85 are considered borderline, and scores below 80 are considered not within normal limits. Scores less than 70 are considered significantly below normal range. Standard scores less than 40 are more than 4 standard deviations from normal, and are denoted as "<40".



Quarters, Halves and the Total are independently calculated and are not averages. Any Quarter, Half or Total that is Borderline or Not Within Normal Limits causes the Interpretation to be Borderline or Not Within Normal Limits. See the Interpretation Notes page for more information on these variables and on the subject's performance.

	Quarter				Half		Total
	1	2	3	4	1	2	
RT Variability	96	87	86	79	90	81	81
Response Time	86	80	92	93	82	92	90
Commission Errors	104	109	118	115	106	118	116
Omission Errors	88	90	<40	87	79	65	65
	Infrequent			quent			

Key: Borderline , Not within normal limits , Invalid

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Interpretation Notes Page

Session, Response and Performance Validity

Validity issues are described here. Session Validity refers to user interruptions or hardware errors. Response Validity indicates greater than 9.9% Anticipatory Errors in a quarter or less than 25% correct responses in a quarter.

Performance Validity (PV) is embedded in the test for persons 17 and older. Performance Validity flags a performance that does not match the Normative Sample or the majority of the ADHD sample. The reasons for PV flags should be understood before completing a clinical evaluation.

Notes on the Comparison to the Normative Sample

Definitions of each variable with summaries of "not within normal limit" and "borderline" scores.



Interpretation Notes

0 12y Male with ADHD DX Example Subject (Jan 1, 2006) Male - 12y 0m 0d **Visual T.O.V.A.** (v9.0-89 sn30000) Jan 1, 2018 at 9:00 AM

Session comments

12-year-old male independently diagnosed with ADHD.

Session, Response, and Performance Validity

Performance Validity

Performance Validity is applicable only to ages 17 or above.

Notes on the Comparison to the Normative Sample

Variability is a precise measure of variations in correct response times, and measures the consistency of response times. Variability was borderline in Half 2 and Total, and not within normal limits in Quarter 4.

Response Time is the average speed of correct responses to targets, and is a measure of information processing speed. **Response Time was borderline in Quarter 2 and Half 1.**

Commission Errors occur when the subject incorrectly responds to a nontarget, and are a measure of inhibitory control. **Commission Errors were within normal limits.**

Omission Errors occur when the subject does not respond to a target, and are a measure of sustained attention. Omission Errors were not within normal limits in Quarter 3, Half 1 and 2, and Total.

Response Patterns

Only Quarter 1 is within normal limits. This may represent a limited span of attention (i.e., about 5 minutes).

Other Notes

Consider administering an Auditory T.O.V.A. to this subject for a more comprehensive assessment of attention. This is important because an individual can have markedly different results on one test versus the other.

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Attention Comparison Score Page

A brief description of the Attention Comparison Score (ACS) is followed by the ACS score and formula. The ACS compares the subject's performance to a group of individuals that were independently diagnosed with ADHD. Scores below zero suggest a performance more like the ADHD sample. A simple line graph is shown with the ACS score. A right or left facing triangle indicates ACS values that are past the limits of the graph.

Note the ACS does not include important parts of the Comparison Score. The ACS should always be used with the full Comparison to the Normative Sample on the Summary page. When the Comparison to the Normative Sample is not within normal limits or borderline and the ACS is at or about zero, the results should be considered not within normal limits or borderline.



Attention Comparison Score

0 12y Male with ADHD DX Example Subject (Jan 1, 2006) Male - 12y 0m 0d **Visual T.O.V.A.** (v9.0-89 sn30000) Jan 1, 2018 at 9:00 AM

Treatment

No treatments entered.

Attention Comparison Score

The Attention Comparison Score (ACS) is a subset of T.O.V.A. variables used to compare the subject's performance to a sample of individuals independently diagnosed with ADHD. Scores below 0 suggest a performance more similar to that of individuals with ADHD.

Note that the ACS does not include important variables from the Comparison to the Normative Sample. In order to understand the overall test results, the ACS should always be used with the Comparison to the Normative Sample, found on the Summary page. In particular, when the ACS is above zero and the Comparison to the Normative Sample is not within normal limits, the results should be considered not within normal limits.

The ACS is calculated by summing the following Z scores:

Response Time (Half 1)	-1.21
D Prime (Half 2)	-0.73
Variability (Total)	-1.24
Calibration constant	1.80
Attention Comparison Score	-1.38



-10 ADHD Sample	0	Normative Sample	10
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Tabulated Data Page

The Tabulated Data page provides tabulated statistics on the subject's test results. The T.O.V.A. session parameters used for the test are also documented on this page. Tabulated data are listed by quarters, halves, and total.



Tabulated Data

12y Male with ADHD DX Example Subject (Jan 1, 2006) Male - 12y 0m 0d

Visual T.O.V.A. (v9.0-89 sn30000) Jan 1, 2018 at 9:00 AM

This page contains tabulated raw data and documents T.O.V.A. session parameters.

			Qua	rter		Half		Total
		1	2	3	4	1	2	
RT Variability	ms	115	154	155	188	139	172	171
Response Time	ms	492	551	427	409	521	418	441
Post-commission respons	ses #	0	0	2	2	0	4	4
Response Time	ms	0	0	480	428	0	454	454
Variability	ms	0	0	7	73	0	58	58
Commission Errors	#	1/126	0/126	2/36	4/36	1/252	6/72	7/324
Percentage	%	0.8	0	5.6	11.1	0.4	8.3	2.2
Response Time	ms	644	0	252	327	644	302	351
Omission Errors	#	1/36	1/36	6/126	3/126	2/72	9/252	11/324
Percentage	%	2.8	2.8	4.8	2.4	2.8	3.6	3.4
D Prime		4.33	6.18	3.26	3.2	4.57	3.19	3.85
Standard Score		72	93	89	89	79	89	85
Beta		2.93	1425.08	0.88	0.3	5.43	0.51	1.46
Anticipatory	%	0	0	0	0.6	0	0.3	0.2
To Nontargets	#	0	0	0	1	0	1	1
To Targets	#	0	0	0	0	0	0	0
Multiple Responses	#	0	1	0	0	1	0	1
Total Correct	#	160/162	161/162	154/162	154/162	321/324	308/324	629/648
Percentage	%	98.8	99.4	95.1	95.1	99.1	95.1	97.1
Skew	ms	-14	115	78	51	88	59	83
User Interrupts	#	0	0	0	0	0	0	0
Hardware errors	#	0	0	0	0	0	0	0
		Infre	quent	Freq	uent			

Session parameters

Session information

Format: 1 (standard) Tester:

ISI: 2000 ms Import Filename: example-subjects.tova (1 / 7) Stimulus On Time: Import Date: Aug 15, 2022 2:56:34 PM 200 ms

Stimulus Off Time: 300 ms Errors/Warnings:

Anticipatory Cutoff 150 ms

Hardware information

PTE Session mode:

USB device: HW 5, BD 0, FW 1.1-219-gd36f0e2

Microswitch: HW 3, BD 0, FW 9

15000, 150000, 15000, 15000, 15000, 15000, 15000, 15000, 15000, 15000, 150000Monitor calibration:

15000, 15000, 15000

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Raw Data Graphs

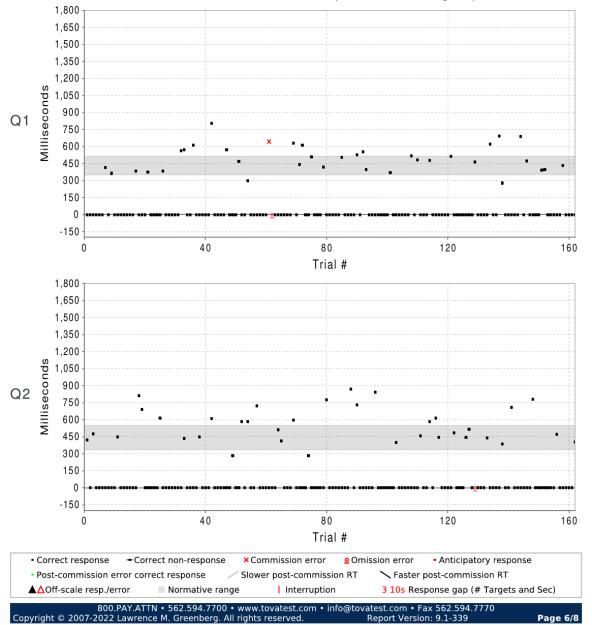
The Raw Data Graphs are the stimuli-by-stimuli responses of the subject for each Quarter. These graphs provide a detailed picture of the subject's performance throughout the test. Quarters 1 and 2 are on the Raw Data Graphs page and Quarters 3 and 4 are on the Raw Data Graphs (continued).

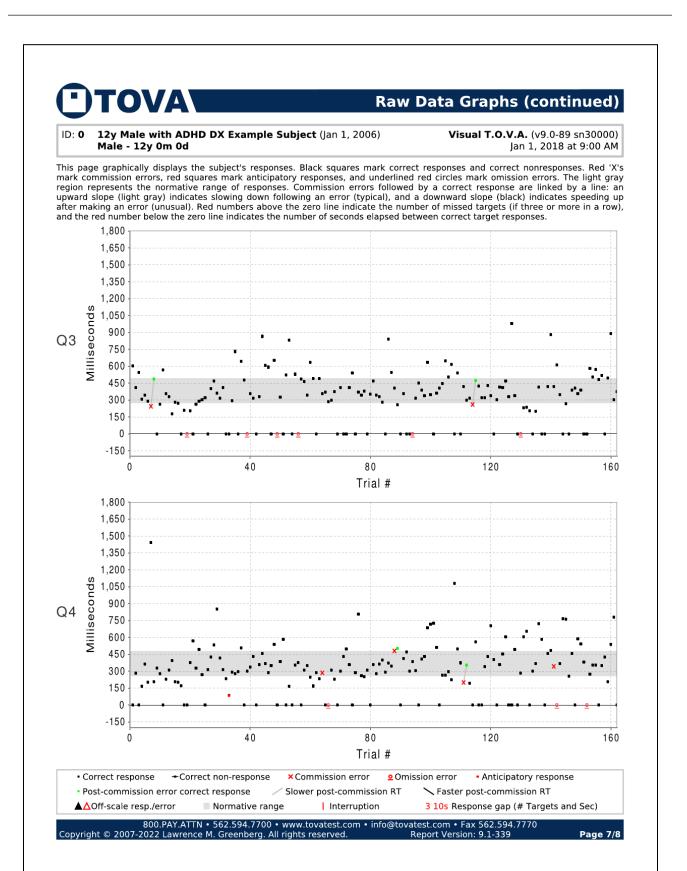


Raw Data Graphs

ID: 0 12y Male with ADHD DX Example Subject (Jan 1, 2006) Male - 12y 0m 0d **Visual T.O.V.A.** (v9.0-89 sn30000) Jan 1, 2018 at 9:00 AM

This page graphically displays the subject's responses. Black squares mark correct responses and correct nonresponses. Red 'X's mark commission errors, red squares mark anticipatory responses, and underlined red circles mark omission errors. The light gray region represents the normative range of responses. Commission errors followed by a correct response are linked by a line: an upward slope (light gray) indicates slowing down following an error (typical), and a downward slope (black) indicates speeding up after making an error (unusual). Red numbers above the zero line indicate the number of missed targets (if three or more in a row), and the red number below the zero line indicates the number of seconds elapsed between correct target responses.





Raw Data Tables

These tables present the sequence of targets and nontargets with the subject's response to each one in a tabular format. Errors are shown in red, and response times are in ms. A negative response time indicates a response that was made before the stimulus was displayed.



Raw Data Tables

ID: 0 12y Male with ADHD DX Example Subject (Jan 1, 2006) Male - 12y 0m 0d

Visual T.O.V.A. (v9.0-89 sn30000) Jan 1, 2018 at 9:00 AM

This page shows a trial-by-trial view of T.O.V.A. test data. Each entry in the table indicates the stimulus type (target or nontarget) and the subject's response to that stimulus. Error responses are shown in red, and response times are in milliseconds. A negative response time indicates a response that was made before the stimulus was presented.

1-2	7	28-	-54	55-	81	82-	108	109	9-135	130	6-162
N		N		N		N		N		N	
N		N		N		Ν		Т	483	Т	691
N		N		Ν		Ν		N		Т	278
N		N		N		Т	506	N		Ν	
N		Т	565	N		N		N		N	
N		Т	572	N		Ν		Т	479	Ν	
Т	415	N		C	643	Ν		N		Ν	
N		N		0		N		N		N	
Т	363	Т	614	N		Т	529	N		Т	689
N		N		N		N		N		N	
N		N		N		Т	554	N		Т	472
N		N		N		Т	396	N		N	
N		N		N		N		Т	515	N	
N		N		N		N		N		N	
N		Т	804	Т	631	Ν		N		Ν	
N		N		N		N		N		Т	391
Т	385	N		Т	441	N		N		Т	398
N		N		Т	610	N		N		N	
N		N		N		N		N		Ν	
N		Т	569	N		Т	371	N		Ν	
Т	375	N		Т	508	N		Т	463	N	
N		N		N		Ν		N		Ν	
N		Ν		Ν		Ν		N		Т	434
N		Т	469	N		Ν		N		Ν	
N		N		Т	418	N		N		Ν	
Т	384	Ν		Ν		Ν		Т	621	Ν	
Ν		Т	300	Ν		Т	518	Ν		Ν	

16	3-189	19	0-216	21	7-243	24	1-270	27	1-297	29	8-324
T	421	N		N		N		N		N	
N		Ν		Ν		Ν		N		Ν	
т	474	Ν		Т	723	Ν		Т	456	Т	387
N		N		N		Ν		N		Ν	
N		N		N		N		N		N	
N		Т	433	Ν		Ν		Т	583	Т	707
N		Ν		Ν		Т	868	Ν		Ν	
N		N		N		Ν		Т	613	N	
N		N		N		Т	728	Т	444	N	
N		N		Т	509	Ν		N		Ν	
T	448	Т	446	Т	414	Ν		N		Ν	
N		N		Ν		Ν		N		N	
N		N		N		N		N		Т	778
N		N		N		N		Т	485	N	
N		Т	609	Т	596	Т	841	Ν		Ν	
N		N		Ν		N		N		N	
N		N		N		N		N		N	
T	812	Ν		N		N		Т	444	N	
T	688	Ν		Ν		Ν		Т	515	Ν	
N		N		Т	284	Ν		N		Ν	
N		N		N		N		0		Т	469
N		Т	281	N		Т	399	N		N	
N		N		N		N		N		N	
N		N		N		N		N		N	
I T	615	Т	583M	N		N		Т	438	N	
N		N		T	774	N		N		N	
N		Т	584	N		N		N		Т	401

32	5-351	352	2-378	379	9-405	400	6-432	43	3-459	460	0-486
T	602	Т	470	Т		Т	345	Т	541		415
т	411	Т	359	0		Т	330	N		Ν	
Т	546	Т	314	Т	487	Т	280	Т	420	N	
Т	307	Т	412	Т	464	Ν		Т	297	Т	418
Т.	342	N		Т	345	Т	841	Т	315	Т	881
Т	291	N		Т	635	Т	545	C	260	Т	420
С	244	Т	294	Т	490	Т	408	Т	473	Т	610
Т	486	Т	730	N		Т	256	Т	422	Т	348
N		N		Т	489	Ν		Т	320	N	
Т	263	Т	644	Т	356	Т	359	Т	322	Т	269
Т.	566	Т	478	Т	368	N		Т	430	N	
T	356	0		Т	284	Ν		Т	337	Т	388
ΙΤ.	329	Т	355	Т	296	0		N		Т	404
T	178	Т	316	Т	373	Т	315	Т	301	Т	355
T	282	N		N		Т	450	Т	416	Т	388
T	270	Т	332	Т	409	Т	387	Т	412	N	
N		Т	865	Ν		Т	337	Т	470	Ν	
T	208	Т	606	N		Т	636	Т	330	Т	581
0		Т	592	Т	412	Т	348	Т	980	Т	505
Т	205	N		Т	541	Ν		Т	340	Т	569
N		Т	653	Ν		Т	361	Ν		Т	480
T	265	0		Т	370	Т	405	0		Т	520
T	291	Т	326	Т	342	Т	446	Т	232	Ν	
Τ.	301	Ν		Т	377	Т	647	Т	236	Т	496
Τ.	322	Т	524	Ν		Т	505	Т	204	Т	891
N		Т	831	Т	352	Т	615	Ν		Т	301
Т	400	N		Т	470	Ν		Т	199	Т	373

487-513	514-540	541-567	568-594	595-621	622-648
N	T 531	T 355	T 279	T 498	T 724
T 281	T 853	T 375	T 363	T 374	T 583
N	T 417	N	T 400	C 200	N
T 166	T 315	T 311	T 292	T 355	T 457
T 362	T 234	T 350	T 374	T 192	T 485
T 201	NA 87	T 249	T 345	N	C 343
T 1441	T 290	T 168	C 480	T 561	0
T 207	T 278	T 289	T 501	N	T 367
T 329	T 296	T 231	N	N	T 764
T 276	T 509	C 285	T 413	T 342	T 760
N	N	N	T 473	T 430	T 254
T 230	T 301	0	T 299	T 704	T 459
T 311	T 338	T 308	T 387	T 405	N
T 395	T 430	T 229	T 304	N	T 589
T 206	N	N	N	T 360	T 540
T 200	T 357	T 301	T 409	T 454	T 382
T 172	T 457	T 432	T 429	T 604	0
N	T 369	T 496	T 684	N	T 273
N	T 289	T 357	T 719	N	T 354
T 377	T 351	N	T 724	T 493	T 356
T 570	T 539	T 287	T 509	N	N
T 327	N	T 807	N	T 285	T 349
T 492	T 387	T 260	T 267	T 605	T 424
T 270	T 583	T 253	T 263	T 654	T 205
N	N	T 310	T 296	N	T 538
T 315	T 167	N	T 222	T 300	T 778
T 427	N	T 360	T 1078	T 366	N

T = Correct response to target

O = Omission error

A = Anticipatory response

 ${f N}={\sf Correct}$ nonresponse to nontarget Green = Post-Commission-error correct respons∈ U = User interrupt

C = Commission error

M = Multiple responseH = Hardware interrupt

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Evaluation of Treatment

Note: Only the visual T.O.V.A. has been FDA cleared as an aid in evaluating treatments for attention deficits, including ADHD. The auditory T.O.V.A. has only been cleared for assessing attention disorders and is not cleared to evaluate treatments. References in this section to the "T.O.V.A." refer only to the visual T.O.V.A. test and reports.

It is recommended that multiple measures be used in the evaluation of treatment for attention deficits, including ADHD. Determining whether treatment needs to be increased, decreased, maintained, discontinued, or changed requires a thorough review of all available measures and the person's daily experience. The section below speaks to the role of the visual T.O.V.A. in the assessment process.

It is possible to measure the effects of treatment on T.O.V.A. performance. To do this most effectively, administer a visual T.O.V.A. without the treatment. This establishes a baseline of performance (baseline T.O.V.A.). To assess change in performance, the test is then repeated with the treatment. For short-acting stimulant medication, administer the visual T.O.V.A. 90 minutes after taking the medication (longer for extended release medications). Consult the drug manufacturer for peak effect of prescribed medication. For non-pharmaceutical treatment, establish a baseline prior to the beginning of the treatment if possible. Visual T.O.V.A. sessions can be administered throughout the duration of the treatment to monitor progress or identify the need to modify the treatment protocol.

When comparing a baseline to a treatment interpretation, use a comparison graph to see the results side by side. If the baseline interpretation was "not within normal limits" and the treatment interpretation is "within normal limits", the treatment has been successful overall. However, it is always good to compare the results side by side to see if the scores are stable or improved in all measures of the T.O.V.A.

To generate a comparison graph, choose two or more sessions on the main screen using the **Shift** or **Ctrl** key, and then choose **Compare**.

If a baseline cannot be established prior to treatment, administer the visual T.O.V.A. and review the Interpretation, the Comparison to the Normative Sample, and the Attention Comparison Score (ACS). If all standard scores are "within normal limits" and the ACS is above zero, use the other elements of the assessment to confirm optimal response to treatment. If any standard score is "not within normal limits" or "borderline" and/or the ACS is below zero, establish the reason for the "not within normal limits/borderline" performance. This could indicate a need for a modification of, or a change in, the treatment protocol. It may also mean that more time is needed to see an improvement in performance. When a subject has significant losses and gains in performance when comparing a baseline T.O.V.A. to her/his T.O.V.A. during or after treatment, this is called a mixed result. Optimal T.O.V.A. performance will mean a rise in standard scores to "within normal limits" without any drop in standard score more than 8 points in any quarter when compared to the baseline T.O.V.A. If a mixed result occurs, determine the cause of the mixed result and adjust treatment if needed.

Ordering Test Credits

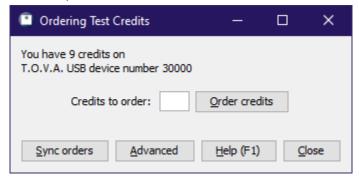
You need test credits to administer the T.O.V.A. test. Test credits are stored on your T.O.V.A. USB device. When you save results after a test, you spend one test credit.

A new T.O.V.A. USB device comes with five free test credits, so you can administer five tests before you need to order more credits. You can order more anytime.

To enable ordering test credits with the T.O.V.A., please make sure your T.O.V.A. is registered with The TOVA Company: https://www.tovatest.com/forms/TOVA Customer Registration Form.pdf

Online

- 1. From the main window, click **Credits**. It will show your remaining credits.
- 2. Enter the number of credits you want to order and click Order credits.
- 3. Click Order to confirm the purchase.



Your organization will be billed as previously authorized. Contact T.O.V.A. customer service if your device is disabled for ordering.

Offline

If your computer is not on the internet, you can exchange ordering codes by email or phone.

Getting Help

Click **Help** from the main T.O.V.A. window to get help:

- Tech Support Get help with errors or technical problems
- Interpretation Support Send us test sessions you have questions about. Subject names are removed automatically.
- Customer Service Sales, billing, or credit ordering problems



Or contact us by phone (1.800.PAY.ATTN or 562.594.7700), email (<u>info@tovatest.com</u>), or fax (800.452.6919 or 562.594.7770) instead.

Appendix A: The T.O.V.A. Observation Form



Completed by:	

The T.O.V.A. Observation Form is designed to provide information about factors that may influence T.O.V.A. results. **Pre-test** information can help the clinician understand some of the conditions that may influence T.O.V.A. performance. **During test** information provides behavioral clues and other information not collected by the T.O.V.A. **Post-test** information can provide insight into the subject's approach to, and experience of, the test.

Section 1: Pre-test

Name:		DC	DB:	Age:	Gender:
Test Date:	Test Time:	AM/PM	Test type:	_VisualAuditory	
Hours of sleep last night:	_				
	Туре	Amount	Last Dose (Hrs)	Duration of use (da	ys/Wks/Mths/Yrs)
Challenge Medication					
Caffeine Intake					
Nicotine Intake					
Medications/Other					
Medications/Other					

Other pre-test observations or comments:

Section 2: During test

Practice Test Results:	RTV:	ms	RT:	ms	Omissions:	Commissions:

Please rate all observed behaviors quarter by quarter. Note any behaviors not listed below under 'Other' or 'External Distractions'. Circle the part of the quarter where the behavior occurred. Each number (1-5) corresponds with the minutes during each quarter. For short form test sessions (e.g., 4-5 year old sessions), only quarters 1 and 2 should be used.

Quarter		1	2	3	4
Time at start of quarter (each quarter is 5 min 12 sec)					
Talks, makes sounds	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Fidgets/taps feet and or fingers	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Moves in chair (leaning, spinning, etc)	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Looks away from the computer	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Stops Responding	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Falls asleep	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Covers screen with hand	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Complains	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Prompting needed	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
External distractions (list):	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Other (list):	Minute #	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Unsolicited comments made by the subject during the test:

Section 3: Post-test

Unsolicited comments made by the subject at the end of the test:

Answer to "How did it go?" and/or "How did you do?":

Other observations/comments: