Amblyopia Treatment Study (ATS)
Visual Acuity Testing Procedures Manual

29 June 2018

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Distance Visual Acuity Testing

Electronic Visual Acuity (EVA) Testing

It is essential to have standardized visual acuity measurements for each examination at each of the participating clinics to minimize the effects of acuity examiner and patient bias. Visual acuity testing is performed with the Electronic Visual Acuity Tester (EVA) using either the ATS-HOTV visual acuity testing protocol (for testing patients 3 to <7 years old) or the Electronic ETDRS (E-ETDRS) testing protocol (for testing patients >=7 years old).

A. Electronic Visual Acuity Tester

1. EVA System Description

The EVA utilizes a programmed handheld device that communicates with a personal computer. A full description of the system, its setup, and calibration appears in the EVA Users Manual which is included as an appendix to this document. The remainder of this manual will focus on procedures related to performance of visual acuity testing using the EVA tester.

2.   Initial Certification of the EVA

Each PC tester unit must be certified for use in PEDIG studies. Certification is obtained by performing an initial calibration on the EVA (see appendix for instructions) and completing the following information on the calibration form:

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1. PC Calibration Date: _____/_____/_____

2. Tower ID # _____
   from label

3. Testing distance _____ cm or inches
   from PC Tester to center of exam chair

4. Measurement of EVA square: horizontal: _____ mm   vertical: _____ mm

5. EVA Luminance: ☐ White screen is within marked black area

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3. General Instructions for Using the EVA

Before each patient study visit:

- Turn on EVA computer and handheld device and verify both are working properly and that the handheld device is sufficiently charged. Allow the monitor to warm up for at least 10 minutes for high- contrast testing and at least 45 minutes for low-contrast testing. PEDIG protocols utilize high-contrast testing unless otherwise specified in the protocol. Reattach the USB charging cable to the handheld device and plug into the EVA after each use. The PC must be powered on for the handheld device to charge.

- Calibrate the monitor for letter size (EVA Square)

- Check the monitor luminance

- Check the room lighting level (dim incandescent lighting is recommended; fluorescent lighting should not be used; no glare on screen; no spotlights)

Before Every Test

- Verify testing distance from EVA to center of exam chair is <u>3 meters</u> (118 inches)

PEDIG Patient Testing (must be used for study patients)

- On main iPod screen, select [either ATS-HOTV or E-ETDRS] icon

- Follow instructions on the iPod

Shut Down System

- Turn off the EVA tester by selecting either the [Shutdown] feature on the iPod or press and quickly release the power button on the EVA. Do NOT press and hold the EVA PC power button or the system may take longer to boot the next time. Alternatively, the EVA tester can be placed in sleep mode by selecting "Sleep" and can be activated again by choosing the "Wake up" icon on the iPod. The monitor does not need to be warmed up prior to testing if the EVA tester has been in sleep mode.

B. ATS-HOTV Visual Acuity Testing Protocol

The ATS-HOTV visual acuity testing protocol was developed to provide a reliable method for measuring visual acuity in 3- to <7-year olds. The test is based on presenting one of four optotypes (H or O or T or V) which can either be named or matched (using a matching card held on the patients lap). The development of the protocol has been described in detail and published elsewhere (*Holmes JM, Beck RW, Repka MX, et al. The amblyopia treatment study visual acuity testing protocol. Arch Ophthalmol 2001; 119:1345-53.)*

1. Overview of ATS-HOTV Testing Protocol

In brief, the ATS-HOTV testing protocol consists of an initial screening phase to obtain an approximation of the visual acuity threshold and then a testing phase to obtain the visual acuity score. The testing phase has a phase I and phase II which are separated by a Reinforcement Phase of larger targets to help keep the child's attention.

2. Pointers for Testing

For most children, the use of a matching card held on the patients lap facilitates testing. Children that are shy, or not willing or able to name the letters, should be directed to "Look at the TV", then instructed to point at the matching letter on the card. Even 5-7 year olds are more likely to match than name a letter when unsure, so the card should be used for all children.

Particularly with young children, the child may prefer to sit on the parent's lap for testing to encourage comfort. Rapid guessing without looking at the monitor, or intermittent effort, can give inaccurate results. One strategy that should be tried is to turn the matching card upside down (with no letters showing), and direct the child's attention to the monitor. After assuring they have looked at the letter on the monitor, turn the matching card over to show the letters and ask "which one was it?" This strategy may be needed for each letter.

3. Summary of Testing Algorithm

The testing protocol is summarized in the EVA Users Manual which is included as an appendix to this document. Steps for performing ATS-HOTV testing using an iPod are outlined on the next page.

ATS-HOTV Visual Acuity Testing
Steps for Using the iPod

Note: The HOTV matching card should be placed on the child's lap before starting testing. If the child has difficulty verbalizing the letters, he or she may point to the letters on the matching card.

1) On the iPod, select the [ATS-HOTV] icon on the home screen.

2) For a study patient, select the "PEDIG" from the dropdown menu and select [Continue]

3) The following screen will allow a new test to be performed or previous tests to be viewed. To perform a new test, select [New Test]

4) The next screen will show the current time and date. If the time or date is incorrect, select [Change Date and Time] to update. If the time and date are correct, select NEXT to proceed to test.

5) The following screen will give 3 choices
   - Selecting [Start Test] will start a new full test.
   - Selecting [Binocular Pretest] will start the binocular pretest (to determine whether a child is able to be tested.
   - Selecting [Quit] will exit testing.

6) Once you have selected "Start Test"
   - Verify the testing distance is 3 meters (118 inches) and the EVA calibration square is 114mm horizontal and vertical. Check the boxes to confirm and select NEXT to continue
   - On the next screen, select a protocol from the dropdown menu. If the specific study is not listed, select "Other Protocols". Once a testing protocol has been chosen, select NEXT to continue
   - Enter the participant's ID and VA tester ID and select NEXT to continue
   - Select which eye will be tested (right, left, or binocular) and select NEXT
   - Select optotype size (decision at tester's discretion) to begin testing by selecting [Start Test at 20/100] or by selecting [Start Test at 20/400]
   - Confirm the other eye is covered by checking the box and selecting NEXT

7) Testing will then begin. Select the participant's response on the iPod by select [Correct] or [Incorrect]

8) Confirm the participant's response.
   - If the recorded response is correct, select [Yes] and continue testing.
   - If the recorded response is incorrect, select [No] and then update the response.

9) When testing of an eye is complete, record the score, score code, date, and date code. Once recorded, select [Done]

10) When prompted, indicate whether you wish to test another eye. If testing is complete, select [No] and exit the application.

C. E-ETDRS Testing Protocol

The EVA runs a visual acuity testing program called E-ETDRS (which stands for Electronic Early Treatment of Diabetic Retinopathy). The program has been developed to provide a visual acuity letter score that is comparable to the ETDRS chart testing score.

As part of the development of the E-ETDRS protocol, a study was conducted in which high validity and test-retest reliability were demonstrated (*Beck R, Moke P, Turpin A, et al. A computerized method of visual acuity testing: adaptation of the early treatment of diabetic retinopathy study testing protocol. Am J Ophthalmol 2003; 135:194-205*).

1. Overview of E-ETDRS Testing Protocol

In brief, the E-ETDRS testing protocol consists of an initial screening phase to obtain an approximation of the visual acuity threshold and then a testing phase to obtain the visual acuity score.

The testing protocol is summarized in the EVA Users Manual which is included as an appendix to this document. Steps for performing E-ETDRS testing using an iPod are outlined on the next page.

Electronic ETDRS (E-ETDRS) Visual Acuity Testing
Steps for Using the iPod

1) On the iPod, select the [E-ETDRS] icon on the home screen.

2) For a study patient, select the "PEDIG" from the dropdown menu and select [Continue]

3) The following screen will allow a new test to be performed or previous tests to be viewed. To perform a new test, select [New Test]

4) The next screen will show the current time and date. If the time or date is incorrect, select CHANGE DATE AND TIME to update. If the time and date are correct, select NEXT

5) Once you have selected "Proceed to Test"

- Verify the testing distance is 3 meters (118 inches) and the EVA calibration square is 114mm horizontal and vertical. Check the boxes to confirm and select NEXT

- On the next screen, select a protocol from the dropdown menu. If the specific study is not listed, select "Other Protocols". Once a testing protocol has been chosen, select NEXT

- Enter the participant's ID and VA tester ID and select NEXT

- Select which eye will be tested (right, left, or binocular) and select NEXT

- Confirm the other eye is covered by checking the box and selecting NEXT

6) Testing will then begin. Select participant's response on the iPod by selecting [Correct] or [Incorrect]

7) Confirm the participant response.

- If the recorded response is correct, select [Yes] and continue testing.

- If the recorded response is incorrect, select [No] and then update the response.

8) When testing of an eye is complete, record the score, score code, date, and date code. Once recorded, select [Done]

9) When prompted, indicate whether you wish to test another eye. If testing is complete, select [No] and exit the application.

D. Viewing Previous Test

Previous results from tests can be reviewed the same date or from a previous date.

1) On the iPod, select the **HOTV or ETDRS** icon on the home screen.

2) For a study patient, select the "**PEDIG**" from the dropdown menu and select continue

3) The following screen will allow a new test to be performed or previous tests to be viewed. To view a previous test, select **VIEW PREVIOUS TEST**

4) Choose **VIEW BY PATIENT ID** or **VIEW BY TEST DATE**

5) Select **NEXT**

6) Choose the test you would like to review. Each eye and each test occurrence will be viewable.

E. Visual Acuity Testing Certification

All site personnel who will be performing visual acuity testing must be certified.

A single certification process is completed for both the ATS-HOTV and E-ETDRS testing protocols.

The certification process involves completion of an online test demonstrating general knowledge of the testing protocols. The test can be completed on the PEDIG website under the Certifications tab (https://studies.jaeb.org/pedig/ats/rdocs/Sites/Certifications/VATesting/VATesting.cgi).

1. Procedures for Initial VA Certification

Steps to complete before taking the online test:

a. Read the information about distance visual acuity testing in this document and in the separate EVA Users Manual on:

- Electronic Visual Acuity Tester and its calibration (page 4-5)
- ATS-HOTV Testing Protocol (page 6-7)
- E-ETDRS Testing Protocol (page 8-9)

b. Check the calibration of the EVA

c. Perform visual acuity testing using the ATS-HOTV testing protocol on both eyes of a child <5 years old

d. Perform visual acuity testing using the E-ETDRS testing protocol on both eyes of an individual (child or adult)

e. Proceed to the web and take the online test by answering questions on the EVA and the testing protocols.

2. **Maintaining Active Certification**

In order to maintain active certification, a visual acuity test on a study participant (masked or unmasked) must be performed at least once every six months on the EVA.

If acuity certification lapses, re-certification by repeating the online visual acuity certification test is required.
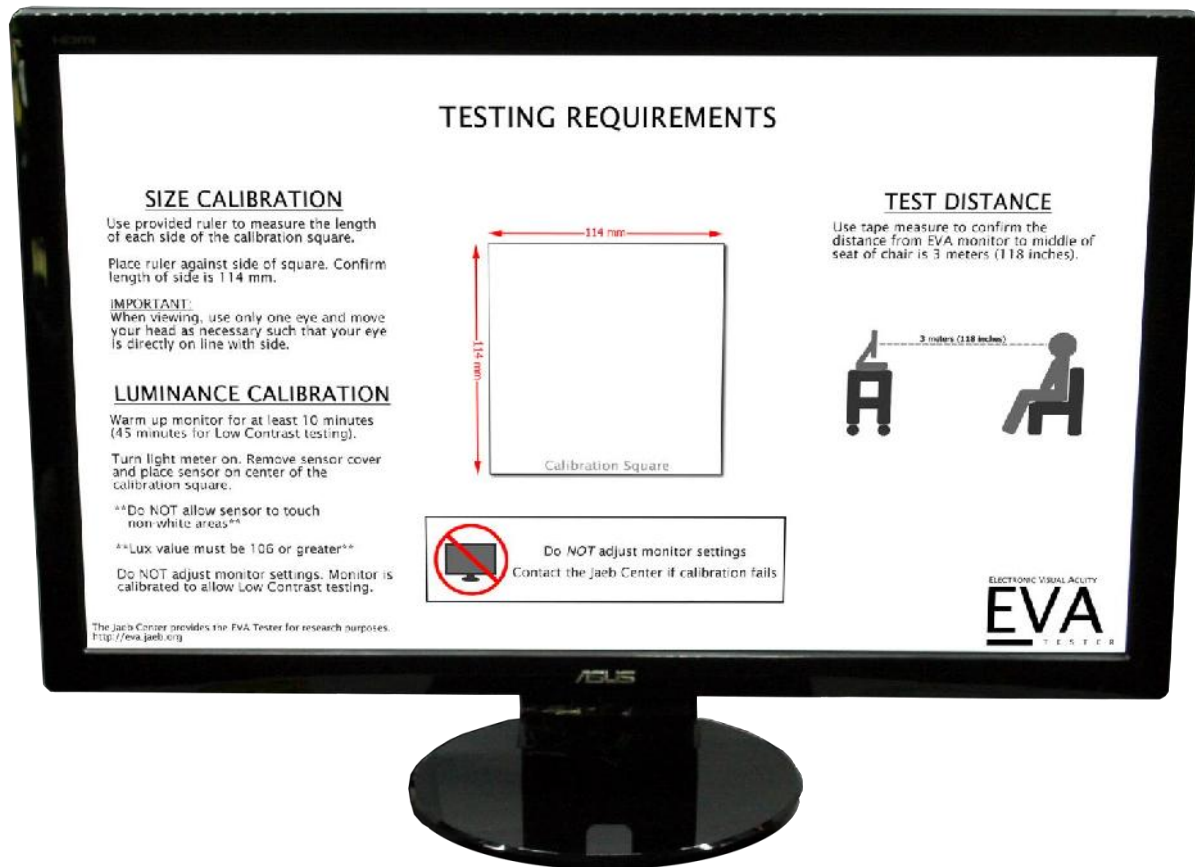
APPENDIX

EVA USER'S MANUAL

EVA
USER'S MANUAL

MODEL 14-WIN

Indications for Use Statement: The Emmes EVA Tester is intended to assess visual acuity performance.

Manual Revised January 2018

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1.   MODEL HIGHLIGHTS

- Model 14-WIN is a desktop EVA Tester configured to display Low Contrast letters.

- System controlled remotely via Apple iPod Touch.

- Able to display letters down to 20/10.

- E-ETDRS algorithm available in 5% and 2.5% low contrast levels.

- Sleep option to make the Display dark without turning it off.

- System is ~8.50" deep and ~16" to top of Display with PC mounted on the back of the Display (Display is ~22.25" wide).

- Test results are stored as encrypted files per HIPAA requirements.

- Site can configure the EVA to store test results on their network

> ⚠ Model 14-WIN EVA Tester is configured and calibrated for low contrast testing. DO NOT adjust the Display settings. If the Display does not fall within range (greater than 106 lux on the provided light meter) contact EVA Support.

2.   SYSTEM DESCRIPTION

The Electronic Visual Acuity (EVA) Tester uses an Apple iPod Touch to communicate with a Windows-based computer.

For normal (high contrast) testing, stimuli are high-contrast, black letters with luminance of 95 cd/m² or higher and contrast of 98%. The system can present single letters or lines of letters. Single letters are framed with crowding bars around the letter. For low contrast testing, stimuli are gray letters with a contrast of either 2.5% or 5% compared to the white background. Letters are framed with crowding bars of the same contrast.

For lines of letters in the Chart application, five (5) letters are displayed for sizes smaller than 20/100; a decreasing number of letters is displayed as letter size increases. With a 23.6-inch LCD/LED Display at 1920 x 1080 pixels, the system is capable of displaying letters from 20/800 (1.6 logMAR) to 20/6 (-0.5 logMAR), at a test distance of 3 meters. Letter size corresponds to the logMAR progression of the ETDRS charts.

The iPod, communicating with the PC wirelessly via Wi-Fi, provides instructions to the technician and displays the letter that is being shown on the Display. For the automated tests (ATS-HOTV, E-ETDRS) the size and sequence of letter presentations is determined from a computer algorithm based on the subject's responses.

Model 14-WIN automatically saves test results as encrypted records in a database on the EVA hard drive and can be configured to also save results to an XML file on the local site network.

Definitions

EVA PC
The personal computer (PC) sent with the EVA Tester. Also referred to as the "Tower."

EVA Tester
All components of the EVA Tester including Display, PC, iPod, programs on the PC, and communication between the iPod and PC.

iPod
The Apple iPod Touch that is used as the controller for the EVA Tester.

PIN
Study specific four digit value required to retrieve study test results from the database.

Light Meter
Used to ensure EVA Display is able to attain sufficient luminance prior to running a test.

Program Flash Drive
Portable memory device used to store printable test results (optional) and retrieved data. The flash drive must be inserted in a USB port to run a visual acuity test.

Retrieval Flash Drive
Used to retrieve study data from the EVA database. The flash drive must be inserted before the data can be retrieved.

Splash Screen
The initial screen when EVA starts up. EVA Testing Requirements are displayed with a white square outlined in black in the middle of the screen. The square is used for Display calibration.

Tower ID
Unique identifier used to configure wireless connection between the iPod and EVA PC. Printed on a label attached to the EVA PC; example "T000123".

Validation Codes
Coded values representing test date, identifier (e.g., patient ID), eye, and test result that can be used during data entry to confirm test results are correctly entered on the case report forms.

System Components

The shipment should include the components listed below:

- EVA PC (*Tower ID label*)
- EVA PC power adaptor
- 23.6" LED/LCD Display (*Tower ID label*)
- Display power adaptor
- HDMI cable
- Surge Protector (Power Strip)

- Apple iPod Touch (*TowerID label*)
- iPod USB charging cable
- EVA Program Flash Drive
- Light Meter
- Plastic Ruler
- Tape Measure

Note: ***PC items may vary slightly from photos depending on hardware availability***

*A keyboard and mouse are **not used** with the EVA Tester and are not included*

3.   TIPS FOR SUCCESSFUL USE

- Keep the iPod battery charged by reattaching to the USB charging cable plugged into the EVA after each use. The EVA PC must be *powered on* for the iPod to charge.

- Do not tamper with or change the iPOD network settings (i.e. Bluetooth or WiFi). This will render the EVA inoperable.

- The EVA Program Flash Drive is required to run a test.

- To shut down the EVA PC, use either the Shutdown feature on the iPod or press and quickly release the power button on the EVA. Do NOT press and hold the EVA PC power button or the system may take longer to boot the next time.

- Do not turn the sound off. The beep heard during testing is a signal to the subject that the displayed letter has changed.
- If you experience any issues, please contact The EVA Team at Emmes for support.
    - Web: eva.emmes.com
    - Email: eva@emmes.com
    - Phone: 301-251-1161 (ask for EVA support)

4.   SYSTEM SETUP

Follow these instructions to set up the 14-WIN EVA Tester.

1. Ensure the display and/or participant chair are such that the line of site from the center of the display to the participant's eyes, is parallel with the ground. Then, this line-of-site distance should be 3m in length. This can be achieved in many ways if using a height adjustable resting place for the EVA and a height adjustable participant chair.

2. Attach the Tower to the mounting bracket on back of Display.

3. Plug the Display Power Adaptor and HDMI cable into the back of the Display (Figure 2).

4. Plug the other end of the HDMI Cable into the side of the Tower.

5. Plug the Tower Power Adaptor into the back of the Tower.

6. Insert the iPod Charging Cable into the USB ports on the side of the Tower as shown in Figure 1.

7. Connect the iPod to the (white) USB charging cable.

8. Plug the Display and PC power cords into the power strip and then plug the power strip into a wall outlet.

9. Turn the Display on by pressing power button.

10. Insert the **EVA Program Flash Drive** in USB port as shown in Figure 1.

11. Turn the PC on by pressing the power button on the top of the PC as shown in Figure 3. The computer will go through start up (boot) sequence.

12. When start up is complete, the Display will display the splash screen with the calibration square in the center.

13. Select the studies that will be displayed for visual acuity tests. (MUST be configured before initial use).

       a. On the iPod, tap **Settings** on the Home page, then tap **Manage Studies**.
       b. Under Current Studies, tap the switch to activate the study
       c. When finished activating studies for your site, tap Save.

14. Confirm testing distance is 3 meters (118 inches) from the patient to the Display screen.

The EVA Tester is ready to use. Refer to Section 6 for patient testing procedures.

IMPORTANT

⚠️ An <u>EVA Program Flash Drive</u> is required to perform Visual Acuity Tests or retrieve data on this EVA Tester.

⚠️ You should never need to adjust the iPod's wireless network connection. Do NOT connect iPod to any network other than the TowerID network (e.g., the iPod for TowerID T000123 is connected to the wifi network named T000123.

iPOD TIP
Use the YELLOW USB port on the EVA for a convenient way to quickly charge the iPOD!

Figure 1
View of the back of the EVA PC

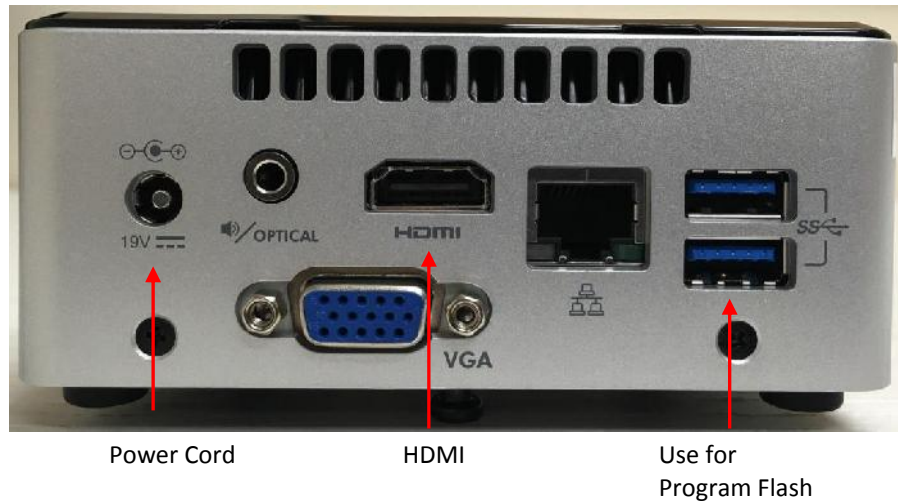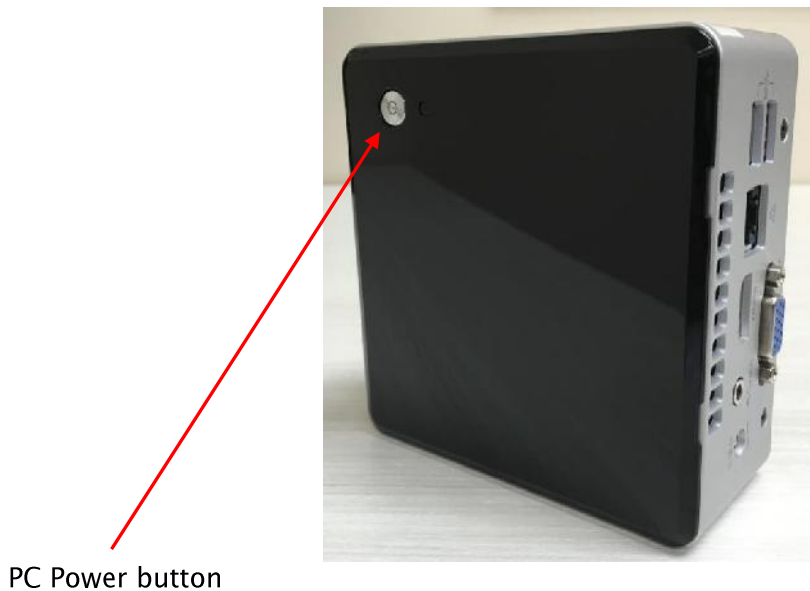
Power Cord   HDMI   Use for
                                      Program Flash

Figure 2
View of the back of the Asus Display

Power Cord   HDMI

Figure 3
View of Top of EVA PC

PC Power button

5. DISPLAY CALIBRATION

The EVA Display must be correctly calibrated for valid testing. The calibration square is the image displayed on the EVA splash screen. Two Display calibration checks are performed at regular intervals: (1) size calibration check to confirm letters are accurately displayed and (2) luminance calibration check to confirm the Display screen is sufficiently bright for testing. Procedures to check calibration on your Display are as follows:

Size Calibration

1. Display the EVA splash screen. The outlined square in the middle of the screen is used for size calibration. Each side of the square should be 114 mm in length.

2. Complete the following steps on the top and left side of square:

    a. Place a ruler with millimeter scale against side of the square. Confirm the length of the side is 114 mm.

> ⚠️ **When viewing, use only one eye and adjust your head as necessary so your eye is directly on line with side.**

3. If the either side is not 114 mm, contact support for assistance.

Luminance Calibration

For correct testing, the white area of the calibration square should be 95 cd/m^2 or greater (106 lux or higher on the provided light meter). See Appendix A for instructions and photos.

1. Allow Display to warm up.
   a. For regular testing, the Display should be on for ***at least 10 minutes.***
   b. For Low Contrast testing, the Display should be on for ***at least 45 minutes.***
2. Turn room lights OFF and follow instructions in Appendix A for your light meter.

> Use **Sleep** to darken the screen but keep the Display warmed up so you do **not** have to repeat the warm up. You should still perform calibration checks before testing.

6.   USING THE EVA TESTER

Perform Visual Acuity Test

Follow these instructions to perform visual acuity testing with the EVA Tester.

1. Power on the EVA PC.

2. Perform size and luminance calibration checks on the Display.

3. Confirm test distance is 3 meters (118 inches) from the Display screen to the position of the patient's face.

4. Allow Display to warm up as directed in Section 5.

5. Confirm florescent lighting is not used in the exam room. Dim incandescent lighting is recommended.

6. Insert the **EVA Program Flash Drive** into a USB port (see Figure 1 on Page 9).

7. Turn iPod on, tap a test icon (E-ETDRS, ATS-HOTV, Low-Contrast E-ETDRS, Low-Contrast ATS-HOTV) to start a test.

8. High-Contrast E-ETDRS and ATS-HOTV

    a. For a <u>study patient</u>, select protocol (e.g., DRCRnet, PEDIG, etc.). For non-study patient select Non-Study. Tap **Next**.

    b. Confirm Date and Time are correct. If not, tap **Change Date & Time**, enter the correct date and time and tap **Save Changes**.

    c. Tap **Next**, verify testing distance and calibration, tap **Next**.

    d. Enter data for study patient, tap Next. Non-study tests will skip this step.

    e. Follow directions on iPod screen to perform test.

9. Low Contrast E-ETDRS and ATS-HOTV

    a. Confirm Display has been on for 45 minutes prior to test. Tap **Yes**.

    b. For a <u>study patient</u>, select protocol (e.g., DRCRnet, ROCS, etc.). For non-study patient select Non-Study. Tap **Next**.

    c. Confirm Date and Time are correct. If not, tap **Change Date & Time**, enter the correct date and time and tap **Save Changes**.

    d. Tap **Next**, verify testing distance and calibration, tap **Next**.

    e. Verify that all ten (10) 'Light' boxes are visible. Tap **Next**. Verify that all ten (10) 'Dark' boxes are visible. Tap **Next**.

    f. Enter data for study patient. (Non-Study tests will skip this step.)

    g. Choose the eye to be tested and the contrast level (scroll down to select contrast level), tap Next.

    h. Follow directions on the iPod screen to perform test.

Validation Codes

EVA vision test results include coded values that represent the test score and eye tested, and optionally for other identifiers such as patient ID and test date. These codes are displayed on

the iPod with the test result and can be used by the coordinating center to confirm results are entered correctly into case report forms.

View Previous Test Results

You can view the results of a previous study patient test. The most common use for this is to confirm the validation codes displayed with the test results.

1. Select **Test Results** on the iPod Home page then select the study.
2. Tap either **View by Date** or **View by Patient ID**.
3. Select the test you want to view and the test results will be displayed.

Print Test Results

If the study coordinating center chose to enable print functionality a printable copy of a test result can be created. (Some coordinating centers may choose to disable printing in order to avoid creating documents with unencrypted study test results.)

If the study has authorized print functionality, do the following to print a file:
1. If **Automatic Printing** is enabled a printable file is automatically placed on the Program Flash Drive at the end of each test.
2. If **Manual Printing** is enabled:
    a. Select **Test Results** on the iPod Home page then select the study.
    b. Tap either **View by Date** or **View by Patient ID.**
    c. Select the test you want and test results will be displayed.
    d. At the bottom of the screen tap **Print** and a printable file is placed on the Program Flash Drive.
3. Remove the Program Flash Drive and insert in a PC with printer access
4. On the flash drive Navigate to \\Eva\AutoPrint\TestResults\<Name of Study>.
5. Identify the file you want to print. Format is <patientID and date time>.txt
6. Open the file in Notepad or similar and print.
7. Return the Program Flash Drive to the EVA Tester.

7.   MANAGE STUDIES

Enable a Study for Patient Testing

The EVA ships with a base package of studies that have data entry programs for patient testing. Before using the EVA you **must** enable the studies in which your clinical site is participating. The enabled studies will be displayed when an E-ETDRS or ATS-HOTV test is performed. For example, if a site is participating in the DRCRnet and PEDIG studies, those studies would be enabled and and displayed when E-ETDRS or ATS-HOTV is used.The package also includes a non-study version (no data entry) that is always enabled.

1.   Select **Settings** on the iPod Home page then tap **Manage Studies**.
2.   Tap the switch control to enable the studies at your site.
3.   Tap Settings to return to Settings menu or Home to return to Home page.

8.   RETRIEVE STUDY DATA

Periodically your coordinating center may want you to download stored test data from the PC hard drive. The EVA will retrieve the data, decrypt it, and save it to your flash drive.

> ⚠️ You will need the **study PIN** and a **Retrieval Flash Drive** from your coordinating center to retrieve the data.

1.   Confirm the Retrieval Flash Drive is inserted.
2.   Select **Settings** on the Home page, then select **Retrieve Study Data**.
3.   Select the study to retrieve and enter the study PIN. The data will be retrieved and placed on the Retrieval Flash Drive as an XML file.

> ⚠️ The XML file placed on the Retrieval Flash Drive is *not encrypted.* Take care to protect the drive from unauthorized access.

9.   SLEEP/WAKEUP THE EVA TESTER

The **Sleep/Wakeup** feature allows you to darken the Display but leave the Display powered on to keep it warmed up. If you turn off the Display the screen will cool down and you must repeat the warmup process (10 minutes for high-contrast, 45 minutes for low-contrast) before performing patient tests.

1. Tap **Sleep** on the iPod Home page to darken the Display without turning it off.

2. Tap **Wakeup** on the home page to awaken the Display.

10.   SHUT DOWN THE EVA TESTER

To shut down the EVA Tester, tap **Shutdown** on iPod Home page. You can also press and quickly release the PC power button and the PC will safely shut itself down. (Do **NOT** press and hold the power button or system will crash and require several minutes to restart.)

11.   NETWORK CONNECTION OVERVIEW

The 14-WIN EVA Tester can be configured to save test results directly to an XML file on your network in addition to storing as encrypted records in the EVA database. See the **Network Configuration Guide** for setup instructions. It is recommended that configuration be handled by someone with computer networking experience.

⚠️ **KEY POINTS ABOUT EVA NETWORKING**

- Tests are saved in study-specific XML files on your network *in addition to* encrypted storage in the EVA database.

- If EVA cannot connect to your network, tests are still saved in the database.

- At the start of each test EVA displays a notice if the network file needs to be updated with records from the database.

- Updating the network XML file will save the existing file with today's date then recreate the file with all records from the database.

- The update feature is a *one-way* process. The EVA can update network XML files but the XML files cannot be used to update the EVA database.

Test results for each study stored on the network are placed in a separate folder dedicated to the specified study. This allows permissions to be configured separately for each study. For example, staff with permission to access test results in study A's folder can be different than staff given access to study B's folder.

12. SAVE A STUDY ON YOUR NETWORK

You must select each study that you want to store on your network. This allows each study coordinating center to decide whether or not test results for their study subjects will be saved on the network.

1. Select **Settings** from the Home page then select **Save Study Tests to Network**
2. Select the studies you want to store on the network and tap Save.

NOTE: *Uncheck* a study to *stop* saving to the network. If all studies are unchecked no data will be stored although the network is still configured.

13. UPDATE A STUDY ON YOUR NETWORK

If tests are performed when the network connection is unavailable, the test results are saved only to the EVA database which causes the database to have more test results than the network XML file. When the network connection is restored, the XML files can be updated with tests that were performed while the network was not available.

The update procedure archives the current network XML file by appending the current date to the filename then recreates the XML file with all records in the EVA database.

1. Select **Settings** from the Home page then select **Update Study Tests on Network**
2. Select study to update (one study at a time) then tap **Update**.

14. EVA VISUAL ACUITY TESTING APPLICATIONS

E-ETDRS Visual Acuity Test

The Electronic Early Treatment of Diabetic Retinopathy (E-ETDRS) is a visual acuity testing program for subjects 7 years of age or older.   It was developed to provide a visual acuity letter score comparable to the ETDRS chart testing score.

The E-ETDRS Visual Acuity Testing protocol consists of an initial screening phase to obtain an approximation of the visual acuity threshold followed by a testing phase to obtain the visual acuity score. Details of the E-ETDRS algorithm and an example are included in Appendix D.

The E-ETDRS application displays the test result as a letter score (number of letters correctly identified) and as a Snellen approximation. Also displayed are validation codes for the test result, patient identifier, and test date. These codes can be used to validate correct entry when the data are entered into a case report form.

The **E-ETDRS** application includes study versions for use in specified clinical studies. ***These study versions MUST be used for study patients and patients being screened for the study***. Data entry of the study-specific information is required; results are identified by the patient identifier and stored on both the Program Flash Drive and on the hard drive.

ATS-HOTV Visual Acuity Test

The ATS-HOTV is the electronic version of the Amblyopia Treatment Study Visual Acuity Testing protocol that was developed to facilitate the standardization of visual acuity testing in clinical trials of pediatric eye disease involving children in the three to less than 7 years old range.

In brief, the ATS-HOTV consists of the presentation of single-surrounded optotypes (letters H, O, T, and V) in 4 steps: a screening phase, a first threshold determination (Phase I), reinforcement phase, and a second threshold determination (Phase II). Details of the ATS-HOTV algorithm are included in Appendix C.

The ATS-HOTV application displays the test result as a Snellen value. Also displayed are validation codes for the test result, patient ID, and test date. These codes can be used to validate correct entry when the data are entered into a case report form.

The **ATS-HOTV** application includes study versions for use in specified clinical studies. ***These study versions MUST be used for study patients and patients being screened for the study***. Data entry of the study-specific information is required; results are identified by the patient identifier and stored on both the Program Flash Drive and on the hard drive.

Low-Contrast E-ETDRS Visual Acuity Test

The Low-Contrast E-ETDRS uses the same algorithm as the E-ETDRS Visual Acuity Test. The Low-Contrast version of the test allows the user to select from two different low contrast levels: 2.5% and 5%. The contrast levels represent the percentage of difference in luminance between the foreground (letter image) and background.

Two Low Contrast Calibration screens are used to check Display calibration before low contrast testing. The first screen displays a white background with squares that progress from light gray to white. The second screen displays a black background with squares that progress from gray to black. If the Display's calibration changes, one or more of the squares will not be visible. If that occurs, technicians are advised to contact support at the Emmes Corporation and to not perform any low contrast testing with the system.

Low-Contrast ATS-HOTV Visual Acuity Test

The Low-Contrast ATS-HOTV uses the same algorithm as the ATS-HOTV Visual Acuity Test. The Low-Contrast version allows the user to select from two different low contrast levels: 2.5% and

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Chart

An application that can be used for manual vision testing. Chart displays individual letters or lines of letters using HOTV or Sloan letters sets.

15.   FREQUENTLY ASKED QUESTIONS

System Questions

1.   How much space do I need to properly operate the EVA Tester?

The system is calibrated for a 3 meter (118 inches) testing distance from the patient to the front of the Display screen. Since the base of the Display has a depth of about 6 inches, you will need approximately 11 feet from the patient to the back of the Display.

2.   Why does the testing distance need to be 3 meters?

For standardized testing of visual acuity in a clinical trial it is best to have the same testing distance at all clinical sites since visual acuity can vary with testing distance. It was therefore decided to have a fixed test distance of 3 meters even if this means that the EVA Tester must be wheeled into position when it is used to test a study patient.

3.   What is the proper height of the EVA for testing?

The EVA Display must be placed at eye level which is typically when the middle of the screen is 47"-51" from the floor.

4.   I have an LCD Display that didn't come with the EVA Tester; can I use it?

No. EVA Testers are carefully calibrated and validated with specific hardware. Any variation of this hardware could cause the testing to be invalid.

5.   Can I use any Display for Low Contrast testing?

No. Only the Display that came with your model 14-WIN EVA Tester can be used for Low Contrast testing. The Display is part of the system as a whole. The system is carefully calibrated to display the gray levels needed for testing. Using a different Display would

result in different gray levels being displayed and invalidate results obtained with that system.

6.   **Does it matter if the EVA PC and Display are stacked or separate?**

The system will work either way. Choose the setup that is easiest and most comfortable for you. Be sure that you adjust the cart as needed for the correct testing height.

7.   **Where are the keyboard and mouse?**

The EVA Tester does not require a keyboard or a mouse to operate so this equipment is not included. The only equipment required is the PC, the Display, and the iPod.

8.   **How do I find out which program version my EVA Tester is running?**

The program version for your EVA Tester is located on the bottom of the splash screen.

9.   **Why do I have to let the Display warm up? When do I do it?**

All EVA Tester Displays need to warm up to achieve display stability. For high contrast testing, this can be achieved in 10 minutes. For low contrast testing, this requires 45 minutes. After the warm up period the Display's luminance is stable and all optotypes displayed will be consistent.

The warm-up period should be followed any time the Display is off for longer than a reboot. If you need to turn the Display off to make the lane dark for other use, consider using the **Sleep/Wakeup** function on the iPod Home page. You do not need to wait for the warm-up period if the Display has already warmed up and you use the **Sleep/Wakeup** function.

10.   **I need to look up a previous score for a patient. How do I do that?**

There are two ways to view previous patient test results; by patient and by date. On the iPod, select **Test Results** from the Home page, then tap the appropriate study for the patient and tap **Next**. Tap **View by Date** or **View by Patient ID**. Select the appropriate date or Patient ID to view previous tests.

iPod Questions

1.   **Can I use a Palm PDA from a previous EVA model?**

No. The 14-WIN model EVA Tester requires the Apple iPod Touch to access the Wi-Fi signal. PDAs from previous EVA models used Bluetooth to communicate with the PC.

2.   **I am locked out of my iPod. How can I fix this?**

The iPODs are not configured with a passcode as new. If your model was configured with a passcode, the passcode to unlock the iPod is the last four digits of your EVA TowerID. The TowerID can be found on the PC on the label with the barcode in the format

"T000123". (Be sure you are using the iPod that came with the EVA. Each iPod is configured for a specific tower and will not work with a different EVA tower.)

IMPORTANT: If the iPod cannot be unlocked with the above instructions <u>after a couple attempts</u>, contact support.

3. **My iPod won't communicate with the EVA PC. What do I do?**

Make sure all cords are plugged in firmly. It may be best to unplug and plug back in all of the cords to ensure a good connection. After checking all cords, reboot the EVA PC by pressing the power button on the front. The PC connection will be restored and the EVA program restarted. When the Splash Screen is displayed the EVA is ready to use.

Also make sure your iPod is connected to the EVA Tester's network. See the answer below for details.

4. **Someone connected my iPod to another Wi-Fi network. How do I get it to work with the EVA Tester again?**

Press the Home button, tap **Settings** and tap **Wi-Fi**. There should be a checkmark next to the network named with your EVA Tester's Tower ID (e.g. T000123). If you have connected the iPod to another network, you will need to tap ⓘ at the right side of the screen, and tap **Forget this network.** Once you have done that, go to the previous screen and find your Tower ID in the list of networks. Tap on it and the iPod will join the EVA network. Press the Home button and tap the EVA icon to begin using the EVA Tester.

16.   COMMON PROBLEMS

Many problems with the EVA tester can be solved by applying one of the following solutions.

1. **iPod cannot connect to EVA. (See Figure 1)**
    If the EVA Tester cannot connect after 3 minutes, check the following:
    - Confirm the iPod is connected to the TowerID network. Press the iPod home button, tap Settings, then Wi-Fi. The top section should show a network with a check mark (✓) next to it.
    - <u>Only</u> if this is <u>NOT</u> your TowerID proceed with the following:
        o Tap **Forget This Network**. When prompted, tap **Forget**.
        o Now in the "Choose a Network" list, select the network that matches your TowerID (label on front of PC), tap the name of the correct network (TowerID) and it should automatically connect.
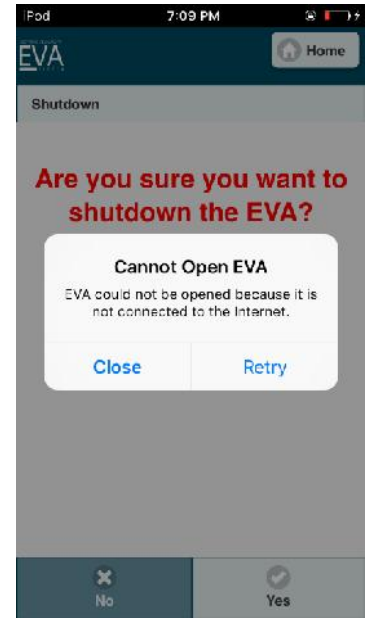   - If Wi-Fi connection is unable to be established with the iPOD, contact the EVA support team.

Figure 1

2. **EVA will not turn on.**
    - Confirm the powerstrip (if applicable) is turned on. The light on the powerstrip should be illuminated.
    - Confirm the EVA is NOT in sleep mode:
        o Tap **Sleep/Wakeup** on the iPod EVA home screen.
        o Close the EVA app on the iPod and restart the app if the above does not resolve the issue.

3. **Display is distorted (overscan) or not functioning**
    - HDMI cable is securely connected. Turn off EVA, unplug and re-insert HDMI cable. Turn EVA on.
    - Input source on Display is set to HDMI. On Display, press the button to the left of the Power button (icon is a square with an arrow in it) to see what the Input is currently set to. Press that button successive times to change the Input until it is on HDMI.

17. APPENDIX A

Light Meter Instructions

The light meter is used to calibrate the computer Display on your EVA Tester. See below for photographs and instructions to identify and correctly use your light meter.

⚠ YOU MUST USE THE CORRECT PROCEDURE FOR VALID TEST RESULTS

- Your EVA Tester MUST display the calibration image with a white square inside a black frame as shown at right. If you do not have this image, contact your coordinating center. Do NOT continue with calibration.

- Allow Display to warm up:

   o For High Contrast testing AT LEAST 10 MINUTES.

   o For Low Contrast testing AT LEAST 45 MINUTES.

- Be sure other room lights are off when you take light meter readings.
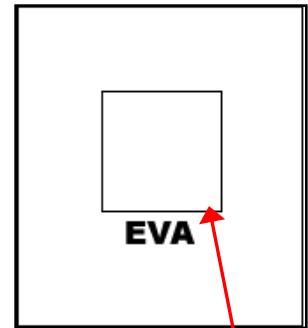
Calibration Square on Splash Screen

Dr. Meter LX1010B Model

Photo Sensor   Power slider

LCD Screen

Confirm that all other lights are off in the room.

1. **Confirm Display has been warming up for at least 10 minutes.**

2. Display the EVA splash screen.

3. Make sure range is set to 2000 (slider closest to the LCD screen).

4. Turn the light meter on by moving the top slider from the off position

5. (left) to the on position (middle). If the battery icon is displayed on the LCD screen, replace the 9V battery.

6. Confirm the light meter screen displays "x1" and "Lux" (on the bottom right).

7. Remove the sensor protective cover and place the side with the white circle (see image above) on the white area in the center of the EVA calibration square. Do NOT allow the sensor to touch non-white areas.

8. The will return the lux value of the Display screen. Confirm that the displayed value is above the minimum lux value specified.

   a. If the value is below specified minimum lux, contact EVA Support.

9. When finished with light meter calibration, replace protective cover to avoid damage when not in use and turn the light meter off by moving the top slider to the off position.

> If value being displayed on the LX1010B Model is incorrect, before contacting the Emmes Corporation please first check:
>
> 1. That the hold position "**H**" is not selected (shown by an "**H**" in the bottom left corner of the light meter LCD screen). If it is, move the switch from the "**H**" to "ON".
>
> 2. If the value displayed is an unreasonably low number (50 or less) be sure that the range is not set to 20000 or 100000 (shown by either "x10" or "x100" in the bottom center of the LCD screen). If it is, move the switch to the "2000" position.

18. APPENDIX B

Apple iPod Touch 6G 16GB Diagram

Sleep/wake

Home Button

19. APPENDIX C

ATS-HOTV© Visual Acuity Test Protocol

Single letters with surround bars ½ letter width from the letter are presented in four phases: screening, phase I (first threshold determination), reinforcement, and phase II (second threshold determination).

- In phase I and phase II, up to four single letters are sequentially presented at each logMAR level* that is tested.
- A level is considered to be 'passed' if 3 of 3 or 3 of 4 letters are correct and 'failed' if 2 letters at a level are missed.
- Testing of a level stops as soon as criteria are met for either 'pass' or 'fail'.

Screening Phase
Starting from either 20/100 or 20/400, single letters, in sequential descending logMAR sizes, are shown until one is missed.
1. Tester selects 20/100 or 20/400 size letter to present as starting point (depending on the expectation of visual acuity level based on previous testing or a pretest).
2. If response is correct, letter at next smallest logMAR level is presented and testing continues sequentially with one letter per logMAR level through 20/20 until there is an incorrect response.
3. If starting point was 20/100 and response is incorrect at either 20/100 or 20/80, screening is restarted at 20/400.
4. If starting point is 20/400 and response is incorrect at either 20/400 or 20/320, screening is restarted at 20/800.
   - If 20/800 is missed, 20/800 becomes the starting level for phase I.

Phase I
Starting 2 logMAR levels above the missed level in Screening, the smallest logMAR level at which 3 of 3 or 3 of 4 letters are correctly identified is determined.
1. Up to 4 single letters are sequentially presented 2 logMAR levels above the level missed in screening
   - Exception: if 20/20 was correct in Screening, phase I starts at 20/30.
   - Exception: if 20/800 or 20/640 was missed in Screening, phase I starts at 20/800
2. If first tested level is failed, testing continues at sequentially larger logMAR levels until a level is passed.
   - If 20/800 is failed, phase I ends, the Reinforcement phase is omitted, and 20/800 is retested in phase II
3. If first tested level is passed, testing continues at sequentially smaller logMAR levels until a level is failed.

Reinforcement Phase
In order to get the child whose attention is drifting back on track, 3 letters larger than the phase I threshold are sequentially presented.
1. Starting 3 levels larger than the level missed in phase I, 3 successively smaller single letters are presented.
   - Exception: if the level failed in phase I is 20/500 or 20/640, 3 20/800 letters are shown for reinforcement
   - Note: the reinforcement phase responses do not contribute to the visual acuity score and even if the responses are incorrect, the test proceeds to phase II.

Phase II
The last level missed in Phase I is retested and if 'passed', testing continues until a level is 'failed'
1. Up to 4 single letters are sequentially presented at the last level missed in phase I
2. If the level is failed, testing stops.
3. If the level is passed, testing continues at sequentially smaller logMAR levels until a level is failed.

Final Visual Acuity Score
The visual acuity score is the smallest logMAR level passed in Phase I or Phase II.

*logMAR levels (Snellen equivalents): 20/800, 20/640, 20/500, 20/400, 20/320, 20/250, 20/200, 20/160, 20/125, 20/100, 20/80, 20/63, 20/50, 20/40, 20/32, 20/25, 20/20, 20/16, 20/12APPENDIX D

E-ETDRS© Test Protocol

The EVA runs a visual acuity testing program called E-ETDRS© (Electronic Early Treatment of Diabetic Retinopathy). The program has been developed to provide a visual acuity letter score that is comparable to the ETDRS chart testing score.

During development of the E-ETDRS protocol, a study was conducted in which high validity and test-retest reliability were demonstrated *(Moke PS, Turpin AH, Beck RW et al. A computerized method of visual acuity testing: adaptation of the amblyopia treatment study visual acuity testing protocol. Am J Ophthalmol 2001; 132:903-14).*

Overview

The E-ETDRS Visual Acuity Testing Protocol consists of an initial screening phase to obtain an approximation of the visual acuity threshold and then a testing phase to obtain the visual acuity score. The protocol is summarized below. The complete algorithm is depicted in the figure that follows. Letters are displayed with surround bars one full letter width from the letter.

The E-ETDRS testing protocol:	
Screening phase:	With single letter presentations, determines smallest logMAR level at which a letter is correctly identified.
Testing phase:	Starts testing letters by intermixing letter sizes of screening phase score and one level smaller.
Test progress:	If a letter is missed at a level, one level larger is added to the testing mix; if a letter is correct at a level, one level smaller is added to the testing mix.
Acuity determination:	Tests 5 letters at each level until smallest level with 5/5 correct and the smallest level with 0/5 correct are determined.

Example:

IN THE FOLLOWING EXAMPLE, C = CORRECT AND M = MISSED

Screening: 20/400c, 20/200c, 20/100c, 20/50c, 20/25m, 20/40m   Score = 20/50

Test progress
1. Start by intermixing 20/50 and 20/40 letters: 20/50c, 20/40m, 20/50c, 20/40m, 20/50m
2. Because a 20/50 letter was missed, add 20/63 to the letter mix (so now have letters of 20/40, 20/50, and 20/63 intermixed): 20/63c, 20/50c, 20/40c
3. Because 20/40 was correct, add 20/32 to the letter mix (mix is now 20/32, 20/40, 20/50, and 20/63): 20/32m, 20/63c, 20/63c, 20/50m
4. Five letters at 20/50 have been tested, so it drops out of the mix (mix is now 20/32, 20/40, and 20/63): 20/63c, 20/40c, 20/32m, 20/40m
5. Five letters at 20/40 have been tested, so it drops out of the mix (mix is now 20/32 and 20/63): 20/32m,   20/32m, 20/63c
6. Five letters at 20/63 have been tested, so it drops out of the mix (mix is now 20/32 only): 20/32m
7. Five letters at 20/32 have been tested; there are no letters left in the mix so test is over

Test summary
20/63   5/5 correct
20/50   3/5 correct
20/40   2/5 correct
20/32   0/5 correct

Letter Score: 10 (number of letters correctly identified)
                   + 55 (5 times the number of lines above (larger than) 20/63 and through 20/800)
                   = 65

Snellen Approximation (logMar to Snellen conversion for 65 letters): 20/50