

Visual Acuity Testing Procedures Manual

Version 1.2

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Table of Contents

CHAPTER 1: VISUAL ACUITY TESTING USING THE EVA SYSTEM.....	3
A. Electronic Visual Acuity Tester.....	3
1. EVA System Description.....	3
2. System Calibration.....	4
B. E-ETDRS Testing Protocol.....	4
1. Overview of E-ETDRS Visual Acuity Testing Protocol	4
2. Visual Acuity Testing Procedures	7
3. Safeguards to Avoid Bias.....	7
C. Poor Vision Testing (Testing Light Perception).....	8
CHAPTER 2: STANDARD ETDRS VISUAL ACUITY PROTOCOL.....	9
A. Visual Acuity Chart: Modified Bailey-Lovie	9
B. Illumination of Visual Acuity Charts and Room	9
C. Best-Corrected Visual Acuity Measurements.....	9
D. Poor Vision Testing	10
E. Calculating the Visual Acuity Score.....	10

CHAPTER 1: VISUAL ACUITY TESTING USING THE EVA SYSTEM

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 subject bias. Visual acuity testing is being performed with the Electronic Visual Acuity Tester (EVA) using a protocol called the Electronic ETDRS (E-ETDRS) Visual Acuity Testing Protocol. This protocol has been developed to provide a visual acuity score that is comparable to that using the manual testing protocol used in the Early Treatment Diabetic Retinopathy Study (ETDRS). The ETDRS chart testing is used as a back-up in case the EVA is not functioning if your site has ETDRS equipment and is ETDRS certified.

Visual acuity measurements for each eye are obtained by a certified visual acuity examiner after refraction and before the subject's pupils have been dilated.

A. Electronic Visual Acuity Tester

1. EVA System Description

The EVA (Figure 1) utilizes a programmed Palm™ handheld device that communicates with a personal computer running a Linux (or Windows XP) operating system.

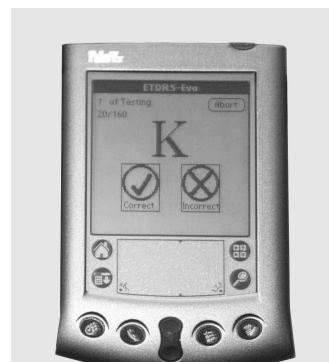
Stimuli are high-contrast, black-and-white letters with luminance of 85 to 105 candelas/meter² and contrast of 98%. The system can present single letters or lines of letters. Single letter testing is used in the Electronic ETDRS program whereas lines of letters can be used for refraction. Single letters are framed with crowding bars spaced one letter-width around the letter. For lines of letters, five letters are displayed for sizes smaller than 20/160 on models prior to July 2008 and smaller than 20/200 after July 2008; a decreasing number of letters is displayed as letter size increases. With a high-resolution (1600x1200) 17-inch monitor, the system is capable of displaying letters from 20/800 (1.6 logMAR) to 20/12.5 (-0.2 logMAR) at a test distance of 3 meters. With a 19" LCD monitor at 1280x800 (models since July 2007) the system displays a range from 20/800 (1.6 logMAR) to 20/10 (-.03 logMAR) at a test distance of 3 meters. Letter size is a close, but not exact, approximation of the logMAR progression of the ETDRS charts (within about 2% of the letter size at each logMAR level).

The Palm™ handheld device (Figure 2), communicating with the EVA through a connected cable or wirelessly with Bluetooth, provides instructions for the technician, allows entry of identification data, displays the letter that is being shown on the monitor, records the responses, and sends instructions to the EVA with regard to the sequence of letter presentations. The size of each letter presentation is determined by a computer program based on the subject's responses.

Figure 1: Electronic Visual Acuity Tester (EVA)



Figure 2: Palm Handheld



2. System Calibration

Two system calibrations are performed at regular intervals: (1) size calibration to confirm letters are displayed accurately and (2) luminance calibration to confirm the monitor screen is sufficiently bright for testing.

Size calibration must be performed at each study visit. For non-study use, size calibration is recommended at least quarterly. Luminance calibration must be performed at each study visit. Refer to the **EVA Users Manual** for instructions specific to your EVA Model, monitor and light meter.

B. E-ETDRS Testing Protocol

The EVA runs a visual acuity testing program called E-ETDRS (which stands for Electronic Early Treatment Diabetic Retinopathy Study). 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 (*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.*)

1. Overview of E-ETDRS Visual Acuity Testing Protocol

In brief, 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.

Electronic ETDRS (E-ETDRS) Visual Acuity Testing Protocol Overview

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.

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

Example:

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 will 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

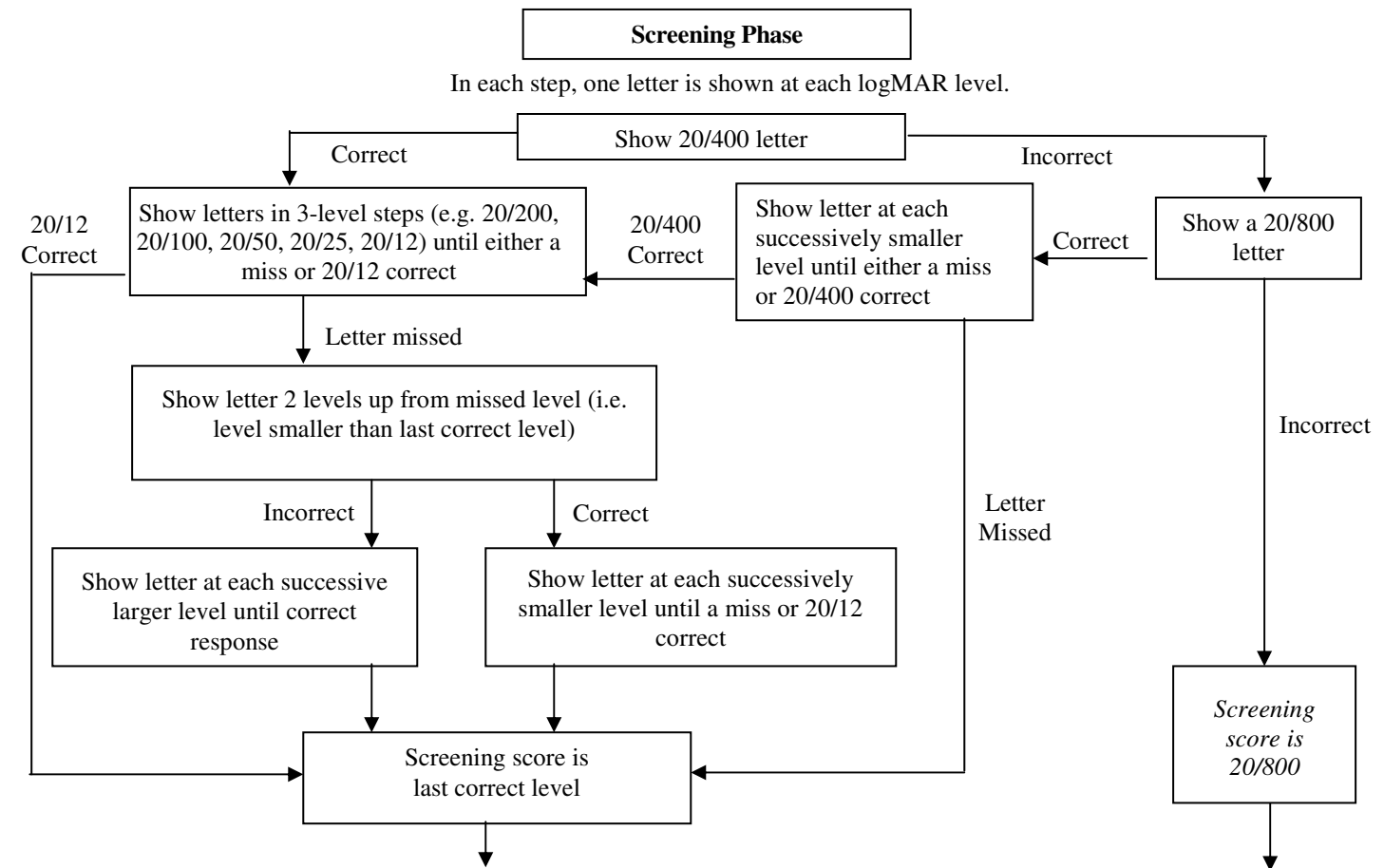
Test summary

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 Notation (logMAR to Snellen conversion for 65 letters): 20/50

Electronic ETDRS (E-ETDRS) Visual Acuity Testing Protocol Algorithm



Threshold Phase

1. To start, letter pool consists of letters from 2 levels*: level of screening phase score and one level smaller.
2. Each letter presentation is randomly selected from active pool of letters with the stipulation that every third letter must be from the largest level in active letter pool.
3. A level remains in active pool until 5 letters are tested at the level.
4. A new level is added to active letter pool when:
 - a. A letter from largest level in the pool is missed: one level larger is added to letter pool†
 - b. A letter from smallest level in the pool is correct: one level smaller is added to letter pool‡
5. Testing continues until an upper logMAR level with 5 of 5 letters correct and a lower logMAR level with 0 of 5 letters correct are determined and 5 letters are tested on all levels in between upper and lower logMAR levels.§
6. Visual acuity score is the number of letters correctly identified during threshold testing, plus 5 letters for each logMAR line above the upper logMAR level through 20/800.

NOTE: EVA Models released after July 2008 (6-WRH and above) include a 20/10 letter size. The smallest size on models prior to July 2008 is 20/12.5.

The screening phase uses the letters V, R, K and D. The threshold phase uses the same 5 letters from the Sloan letter set that appear on the original ETDRS charts for right and left eyes.

*Unless screening score was 20/12.5, in which case letter pool consists of only 20/12.5 level letters (Models with 20/10 include both 20/12.5 and 20/10 in letter pool)

†Unless 20/800 letter is missed.

‡Unless 20/12.5 is correct (20/10 on newer models.).

§If 20/12.5 (20/10 on newer models) becomes part of the active letter pool, it will be the lower logMAR level.

Testing Procedures Using the EVA

Before each subject study visit:

- Calibrate monitor for letter size
- Check monitor luminance
- Check 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 3 meters (118 inches)
- Turn on Palm™ and remove stylus

Study Subject Testing

- Turn on Palm™ and remove stylus
- On main menu, tap [E-ETDRS] icon
OR
Tap upper right corner of screen, select 'EVA-Application'; select [E-ETDRS] icon
- Follow instructions on Palm™

Shut Down System

- Turn off the PC tester by selecting [Shutdown] icon on main menu
OR
Briefly press and release the power button on the EVA tower.

2. Visual Acuity Testing Procedures

- a. Trial frames are to be used for refractive correction. In addition to the occluder in the trial frame, for testing the right eye, left eye is occluded with an eye patch or pad placed beneath the trial frames and vice versa.
- b. If the protocol specifies that both eyes are to be tested, the right eye is always tested first.
- c. Visual acuity testing is to be done without cycloplegia and without pupil dilation.

3. Safeguards to Avoid Bias

The examiner will be masked to prior visual acuity scores when feasible for a study. Due to the automated nature of the computerized EVA testing, the potential for induction of bias on the part of the technician is minimized.

Technician instructions to the subject are to be minimal:

- a. The subject should be told that there are only letters and no numbers and that each letter is “bracketed” by lines on all four sides.
- b. For subjects with poor central vision, it may be suggested that the subject fixate eccentrically or turn or move his/her head from side to side if this improves visual acuity. If the subject employs these maneuvers, care must be taken to ensure that the fellow eye remains covered.
- c. When the subject cannot read a letter, he/she is told to guess. If the subject states that a letter is one of two letters, then he/she is asked to choose only one letter and, if necessary, to guess.
- d. When the subject gives one response but then gives a second response before the first response has been finalized (i.e., before the technician has verified the response as correct or incorrect and before the letter presentation on the EVA screen changes), the subject should be asked if that is his/her final answer; if the subject equivocates, ask the subject to choose one letter. Once the technician has verified the response and the letter presentation has changed on the EVA, no changes can be made in the subject’s response.
- e. If the subject provides a number or any other response other than one of the 26 letters of the alphabet, the subject should be told again that there are only letters on the chart and to respond with a letter.

C. Poor Vision Testing (Testing Light Perception)

If the subject cannot identify any letters on visual acuity testing of an eye (i.e., letter score = 0), the eye is tested for light perception with the indirect ophthalmoscope as the light source. The testing procedure can be performed according to the investigator’s usual routine. The following procedure is suggested:

- Room lighting should remain at the level of normal visual acuity testing. The trial frame should be removed, and the subject should close the opposite eye and occlude it by making a tight seal with the palm around the orbit and the bridge of the nose. The indirect ophthalmoscope light should be in focus at three feet, and the rheostat set at six volts. From a distance of three feet the beam should be directed in and out of the eye at least four times; the subject should be asked to respond when he/she sees the light. If the examiner is convinced that the subject perceives the light, vision should be recorded as light perception, otherwise as no light perception.

CHAPTER 2: STANDARD ETDRS VISUAL ACUITY PROTOCOL

The Standard ETDRS Visual Acuity Protocol should only be used as a back-up in the event the Electronic Visual Acuity Tester (EVA) is not functioning (if your site has ETDRS equipment and is ETDRS certified).

A. Visual Acuity Chart: Modified Bailey-Lovie

The ETDRS visual acuity charts 1 and 2 are used for standardized measurement of visual acuity. Acuity testing of all subjects, regardless of visual acuity, begins at four meters. Two ETDRS Visual Acuity Charts are used for the measurement of visual acuity, each with a different letter sequence. The right eye will always be tested with Chart 1 and the left eye with Chart 2.

B. Illumination of Visual Acuity Charts and Room

Each clinic must have/use an ETDRS light box for the ETDRS visual acuity charts during any study acuity testing if the EVA is non-functional. The light box should be hung on the wall or placed on a stand (that can be purchased from the Lighthouse for the Blind in New York) at a height such that the top of the 3rd row of letters (0.8 LogMAR) is 49 ± 2 inches (124.5 ± 5.1 cm) from the floor. Room lighting should be approximately 50 foot-candles and should be uniform between the subject and the light box. The distance from the center of the exam chair to the Visual Acuity Chart should be 4.0 meters.

C. Best-Corrected Visual Acuity Measurements

The right eye is tested first and then the left eye. The subject is seated such that the distance from the center of the exam chair to the ETDRS Visual Acuity Chart is 4.0 meters. This testing distance is always used first even if the subject could not be refracted at four meters. In addition to the occluder in the trial frame, the left eye is occluded with an eye patch or pad placed beneath the trial frames. With the lens correction obtained by subjective refraction in the trial frame, the subject is asked to read ETDRS Visual Acuity Chart 1 from the top with the right eye. It is emphasized to the subject that each answer will be scored so adequate time should be allowed for each letter in order to achieve the best identification. The subject is instructed that all of the figures to be read are letters and that there are no numbers.

The examiner records each letter identified correctly by the subject as he/she reads the chart by circling the corresponding letter on the ETDRS score sheet (or study form). Letters read incorrectly, or for which no guesses are made, are not marked on this form. Each letter read correctly is scored as one point. The score for each line (including zero if no letters were read correctly on that line) and the total score for the eye are recorded on the form, as soon as the four meter testing has been completed.

If the number of letters read correctly at four meters is less than twenty, the test should be repeated at one meter and both the four-meter and one-meter totals should be recorded on the ETDRS score sheet (or study form). Both eyes should be tested at four meters before the subject is moved up to the one-meter test distance. It is strongly advised that the total number of letters correctly read at four meters be calculated as soon as the four meter testing has been concluded in order to identify subjects who require 1 meter testing. Prior to actual testing at one-meter, + 0.75 D sphere should be

added to the correction already in the trial frame to compensate for the new distance. The subject must sit for testing at the one-meter distance.

The same procedure for obtaining visual acuity for the right eye is used for the left eye, except that ETDRS Visual Acuity Chart 2 is used. Chart 1 should never be exposed to the left eye and chart 2 should never be exposed to the right eye, even when switching charts and occlusion.

D. Poor Vision Testing

Follow the procedures described in Chapter 1, Visual Acuity Testing using the EVA System.

E. Calculating the Visual Acuity Score

After each measurement of visual acuity, the visual acuity score for the visit is calculated. The visual acuity score is defined as follows:

- If twenty or more letters are read correctly at the four-meter test distance, the visual acuity score is equal to the number of letters (N) read correctly at four meters +30. If one or more but less than twenty letters are read correctly at four-meter distance, the visual acuity score is equal to the number of letters read correctly at four meters plus the number of letters read correctly at one meter in the first six lines.
- If no letters are read correctly at either the four-meter distance or the one-meter distance, the visual acuity score is 0, and testing for light perception should be performed as described in Section C. Poor Vision Testing (Testing for Light Perception), page 8.