



INSTRUCTIONS FOR EYEDOC VISION SCREENING FORM (EVS)



I. General Instructions

The vision screening reporting form is designed to collect a participant's basic vision exam data and intraocular pressure. It should be completed at the time of testing but BEFORE any dilation.

II. Detailed Instructions for Each Item

- 0a. Enter the date on which this form was last updated. Enter the date using either the calendar function or by keying the date with MM/DD/YYYY format. Leading zeroes are not necessary in CDART, but are acceptable.
- 0b. The person who initially started the EVS form enters his/her code number in the boxes provided.

A. Distance Presenting Vision (ETDRS Chart)

For the EyeDOC study, we are only measuring habitual visual acuity, i.e. acuity with currently worn glasses or contacts, or with no glasses if the subject doesn't wear distance correction or forgot them at home. If the participant has glasses but doesn't wear them or if their glasses are lost and broken, then testing should proceed without correction. We are measuring visual acuity separately in the right and left eyes.

If the subject forgot to bring their eyeglasses for distance, the protocol should continue, and it should be noted that distance acuity was not measured with correction in question 2a and 2b.

Illumination:

Most of the room lights should be turned off during the visual acuity test. The box itself provides sufficient illumination for the examiner to record the test result. Since additional light can have an adverse effect, a baseline lux meter reading should be taken in the room with all lights turned off, door closed, and light box turned off. This baseline reading with the light box off should be less than 20 lux. Then, another lux meter reading should be used to check the illumination under testing conditions (door closed, lights off, only light box switched on). The lux meter should be held at the middle letter of light box to measure illumination. Under testing conditions, the acceptable range is 807- 1345 lux. Since the baseline and testing conditions are unlikely to change much between participants, these lux meter readings should be taken once per week and recorded in the lux meter reading log book.

4-meter Lanes:

A distance of exactly 4 meters is required between the participant's eyes and the visual acuity chart for the 4-meters tests.

The room for visual acuity testing must have, in addition to the 4-meters lane, space for the visual acuity box and stand, and space for the participant. In addition to the 4-meters lane, 13 inches must be allowed for two of the stand's casters to touch the rear wall (or a line marked on the floor when there is no wall) plus space for the participant to sit or stand.

If the visual acuity box and the chair are permanently affixed, distance measurements generally do not need to be made for every subject to ensure the correct distance. However, measurements may need to be made if the subject sits forward in the chair due to obesity or a physical condition

that keeps the subject leaning forward.

The 4-meter distance must be marked clearly and permanently on the floor. The location and orientation of the box must be rechecked each time a new chart is put in place or the box is touched. When the stand touches the rear wall of the room, two of the five casters should touch the wall. A mark should exist at 4 m from the subject chair, on which to put the ETDRS chart and light box.

4-meter Distance Visual Acuity Test:

Testing of all eyes begins at 4 meters. **Testing is completed with right eye using Chart 1 and left eye using Chart 2. The charts should remain hidden from view until testing is ready to begin.**

The distance from the participant's eyes to the visual acuity chart must be exactly 4 meters. The participant may stand or sit for the 4-meter visual acuity test. If the participant is seated, his or her back should be firmly touching the back of the chair. The examiner should ensure that the participant is sitting comfortably, that the head does not move forward or backward during the test, and that the participant's eyes remain at the 4-meter distance. We are testing for habitual visual acuity, so ensure that subjects are wearing the glasses or contacts that he/she normally uses for distance vision. The eye that is not being tested should be occluded completely with an occluder or adhesive patch.

The testing procedure for visual acuity is based on the principle that the objective is to test visual acuity and not intelligence or the ability to concentrate or follow or remember instructions (although all of these factors are involved). The participant should be told that the chart has letters only and no numbers. If the participant forgets this instruction and reads a number, he or she should be reminded that the chart contains no numbers and the examiner should request a letter in lieu of the number. The participant may start with a row he/she can read comfortably. The examiner should establish one row in which the participant achieves 100% accuracy.

The participant should be asked to read slowly (at a rate not faster than about one letter per second) in order to achieve the best identification of each letter and to not proceed until the participant has given a definite response. It may be useful for the examiner to demonstrate the letter-a-second pace by reciting "A, B, C, ..." If, at any point, the participant reads quickly, he or she should be asked to stop and read slowly. If the participant loses his or her place in reading or the examiner loses his or her place, the examiner should ask the participant to go back to where the place was lost. Examiners should never point to the chart or to specific letters on the chart or read any of the letters during the test.

Each letter is scored as right or wrong. Once a participant has identified a letter with a definite single-letter response and has read the next letter, a correct of the previous letter cannot be accepted. If the participant changes a response aloud (e.g., "That was a 'C,' not an 'O'") before he or she has read aloud the next letter, then the change should be accepted. If the participant changes the response after beginning to read the next letter, the change is not accepted.

When the participant says he or she cannot read a letter, he or she should be encouraged to guess. If the participant identifies a letter as one of two or more letters, he or she should be asked to choose one letter and, if necessary, to guess even if the next letter has already been read. The examiner may suggest that the participant turn or shake his or her head in any manner if this improves visual acuity. If the participant does this, care must be taken to ensure that the fellow eye remains covered. When it becomes evident that no further meaningful readings can be made (usually with the participant being unable to guess at a letter), despite urgings to read or guess, the examiner should stop the test for that eye. If the participant guesses a letter that is incorrect, tell them to try again. If the guess incorrectly a second time, record this as an incorrect letter.

There are several reasons for encouraging participants to guess: (1) Participants' statements that they cannot identify a letter are often unreliable; (2) encouraging them to guess helps to maximize the participant's effort; (3) it helps to assure uniformity among procedures performed in different clinics; and (4) it may help to prevent participant bias (malingering). The study technician must take a standardized approach to giving encouragement to participants; it is very important that the examiner does not encourage some participants more than others as this may lead to inconsistent results for each participant.

The examiner records each letter identified correctly by circling the corresponding letter on the data collection form. Letters read incorrectly are marked with an "X" and letters for which no guesses are made are not marked on the form. Each letter read correctly is scored as one point. The examiner should be looking at the participant while they are reading the letters to ensure they are not "cheating" or inadvertently looking with their other eye. The examiner should also make sure the participant is not squinting or leaning forward. If the examiner sees the participant doing any of these things, they should correct the participant right away by asking them not to squint/lean forward or look with their other eye as well. If participants guess a number or symbol instead of a letter, tell them that there are only letters on the chart and allow another guess.

Make sure they are covering their left eye completely. Start at the top line corresponding to 20/200 visual acuity and tell the participant:

"Please read across the entire top line and tell me out loud what each letter is. Continue reading down from there."

1a. Add up all of the line totals and put the number in the space beside "Total Correct". Enter 0 if no letters are read correctly.

2a. Mark whether or not the participant wore glasses or contacts during the testing.

Repeat this procedure for the left eye, while keeping the right eye covered.

1b. Add up all of the line totals and put the number in the space beside "Total Correct". Enter 0 if no letters are read correctly.

2b. Mark whether or not the participant wore glasses or contacts during the testing.

3. Mark whether or not matching cards were used, in the case of an illiterate participant. This should only be marked "Yes" if the participant is not able to recognize and read the letters on the standard chart.

B. Near Vision (MN Read)

4. Reading acuity will be tested using the MN Read card, designed to test near vision. Ask the participant:

"Do you currently use glasses or contact lenses to see when you read or do other tasks that require you to see things close?"

If the participant responds YES, then choose option 1 and ask the participant to put on their reading glasses or confirm that they are currently wearing their contacts. If the participant normally does not use glasses or contacts to read, then choose option 2. If the participant uses over the counter reading glasses but did not bring their reading glasses with them, then provide the participant with a pair of reading glasses provided by EyeDOC and check option 3. Allow the participant to choose the strength that they find most comfortable for reading some provided text at the distance where reading will be tested (40 cm).

Testing should occur with all lights on. A lux meter reading should be taken under

testing conditions once per week, and this should be recorded on the log. The optimal illumination is 200-400 lux.

4a. If option 3 is selected for item 4, then indicate the strength of the eyeglasses chosen by the participant here.

5-21. Explain the MNRead test to the participant by telling them:

“We will now test how quickly you read text of different sizes. There are several sentences on the chart, each in a smaller size than the previous one. When I say ‘begin’, please uncover only the first sentence and read it out loud. Try to read as fast and accurately as possible. Please don’t go to the next sentence until I tell you to.”

Cover the chart with a non-transparent board. Measure 40 cm from the center of the chart to the point between the participant’s eyes, and place the chart in a comfortable position where it can be held for a few minutes.

Starting at the first sentence, have the participants read the sentence as quickly and accurate as they can. Start your timer as soon as the sentence is uncovered, even if this occurs before any words are said. Stop timing when the last word of the sentence is read, or until 60 seconds pass. Encourage participants to continue attempting further reading for the entire 60 seconds, even if they feel like they cannot see additional words. Circle the words that are misidentified or skipped during the first attempts and put down the number in the errors blank. Record the time as 60 (sec) if a sentence is started but not completed within 60 seconds, and record words not yet read as skipped. If the participant starts the sentence but insists on stopping before 60 seconds, indicate that 60 seconds have passed, and record words not yet read as skipped (contributing to total number of errors). Continue having the participant read through additional lines until no letters were read for a given sentence, or if a sentence could not be completely read within 60 seconds. The rest of the chart should be skipped after a record of 60 seconds, and the items afterwards for MNRead should be left blank (i.e. If a subject reads 7/12 words out of the Log 0.0 line in 60 seconds, record “60.00” for EVS item 16a, “05” for EVS item 16b, and leave items 17a~21b blank).

5. Record if the first sentence could be read by the participant

6a-21a. Record the time in seconds that the participant took to read the sentence. Record the time as 60 (sec) if a sentence is not completed within 60 seconds. If the participant attempts the sentence but insists on stopping before 60 seconds, indicate that 60 seconds have passed (even if no words were read). Participants should continue to attempt sentences until the previous sentence had no words read correctly and/or could not be completed within 60 seconds. Subsequent sentences should be left blank for the time variable, indicating that they were not attempted.

6b-21b. Record the total number of words that are circled (misidentified or skipped) for each sentence. If a sentence was attempted but no words were read, then all words should be marked as skipped. The space should be blank only if the sentence was not attempted (see instructions above).

C. MARS Letter Contrast Sensitivity

Contrast sensitivity is tested using the MARS chart.

Illumination:

The chart should be illuminated uniformly, with luminance of 189 to 377 lux, optimally 267 lux. EyeDOC will provide a light meter and the measurements should be recorded on the log provided. Testing should not be conducted through any coatings, laminations, or coverings on the chart, even if these are transparent or translucent.

Viewing Distance and Correction:

The participant's viewing distance to the chart is by design 50cm (20 inches), but may range from the standard near refraction distance of 40 cm (15.75 inches) to 59 cm (23 inches). Participants should wear their appropriate near vision correction, or their distance correction. Care must be taken not to allow the participant's head to occlude the light source illuminating the chart.

Clean an occluder with an alcohol swab and then pass it to the participant. Alternatively, use an adhesive patch to occlude the eye not being tested. Ask the participant:

“Could you please cover your left eye completely with this?”

Tell the participant:

**“Please read the letters from left to right across each line of the chart.
Only the letters C, D, H, K, N, O, R, S, V, or Z will appear”**

If the participant responds with a letter other than C, D, H, K, N, O, R, S, V, or Z, or with a numeral, do not score the response as incorrect and remind them of the restricted letter set. Encourage the participant to guess even when they report that the letters appear too faint.

NOTE: If participant is illiterate, they may use the matching sheet provided if feasible. Otherwise, contrast sensitivity and near vision testing may be skipped for these participants.

On the worksheet sheet, circle each letter the participant identifies correctly, put an “x” or line through each letter incorrectly identified or omitted and write the total correct for that row in column at right. Enter 0 if no letters are read correctly. Terminate testing only when the participant makes three consecutive errors or reaches the end of the chart.

Do not terminate the test because the participant has given up and has stopped responding. If this happens, encourage the participant to guess, and score the guesses as ordinary responses. This will help to ensure that the score is based on what the participant can see and not on what the participant believes he or she can see.

EVS 22. Record if correction (habitual or provided reading glasses) was used in the Right eye

EVS 23. Add up all of the line totals and put the number in the space beside “TOTAL”.

Repeat this procedure for the left eye, while keeping the right eye covered.

EVS 24. Record if correction (habitual or provided reading glasses) was used in the LEFT eye

EVS 25. Add up all of the line totals and put the number in the space beside "TOTAL".

D. Refractive Error (Autorefractor)

Use the autorefractor to measure the refractive error in both eyes without any correction. The participant will need to remove any glasses or contacts for this procedure.

Tell the participant:

"We are now going to get measurements that will tell us whether you might see better with a good pair of glasses."

If the participant is wearing glasses or contacts ask:

"Can you please remove your [glasses/contacts] now?"

Show the participant where contacts can be safely and cleanly removed. The EyeDOC study will provide solution and contact cases for participants to use during this test.

Start with the right eye and run the autorefraction algorithm.

26a. Record the Sphere measurement and circle on the form "+" or "-". This will need to be specified in CDART when the data are recorded. If a measurement could not be taken then mark "N/A".

27a. Record the Cylinder measurement. If a measurement could not be taken then mark "N/A".

28a. Record the Axis measurement. If a measurement could not be taken then mark "N/A".

29a. Record the Visual Acuity measurement by starting at the largest line. Consider a line read, and then proceed to the next line of testing, if greater than 50% of the presented letters are read correctly. Continue until a line is missed (less than 50% of the letters stated correctly), or until the smallest line of text is read. If a measurement could not be taken then mark "N/A". Please refer to the guidelines above for distance testing with regard to participants who change their mind concerning the letter they see.

26b.-29b. Repeat for the left eye

E. Intraocular Pressure (Icare)

The Icare TA01i tonometer should be used to measure eye pressure. Start by loading a fresh probe into the machine, and press the big grey button to magnetize the probe- this will ensure the probe does not fall out on to the participant. If you do drop the probe, open a new one and load it. Do not reuse probes that have fallen on the ground or have been used on another participant.

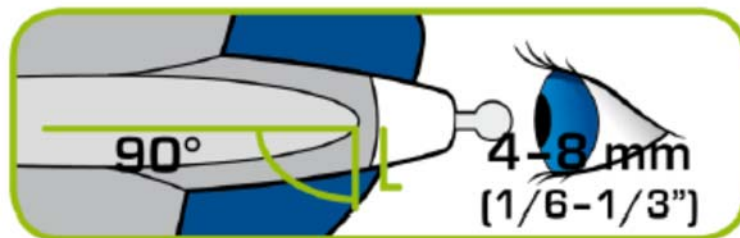
Tell the participant:

"I will now be checking your eye pressure and you may feel something lightly

fluttering against their eyelashes. However it will not last more than a few seconds. You may also hear some beeps as the machine takes its measurements.”

Since local anesthetic may lower the tonometer reading, topical anesthetic should NOT be used when performing measurements.

Ask the participant to relax and look straight ahead at a specific point. Their chin should be held straight (parallel with the floor). Bring the tonometer near the participant's eye. The central groove should be in a horizontal position, and the distance from the eye to the front part of the collar should be the length of the collar. In other words, the distance from the tip of the probe to the participant's cornea (see picture below) should be 4-8 mm (1/6-1/3 inch).



If necessary, adjust the distance by turning the forehead support adjusting wheel. Press the measurement button lightly to perform the measurement, taking care not to shake the tonometer. The tip of the probe should make contact with the central cornea six consecutive times to obtain one IOP measurement.

After each time the probe makes contact with the cornea, you will hear a short beep. Once the six beeps have been heard, the IOP measurement will be shown on the display after the 'P'.

Error Messages:

If the P is blinking, it means that the standard deviation of the measurements is greater than normal and a new measurement should be taken.

P_(line down) The standard deviation of the different measurements has a slightly greater value than normally, but the effect on the result is unlikely to be relevant. The reading should be included.

P-(line in the middle) The standard deviation of the different measurements is clearly greater than normal, but the effect on the result is probably irrelevant. A new measurement should be taken if the IOP is over 19 mmHg; otherwise the reading should be included.

P-(line up) The standard deviation of the different measurements is great and a new measurement should be taken.

Repeat the measurement up to a total of 6 times for each eye, or until 2 acceptable readings are obtained. Alternate right and left eye measurements (switching eyes after an acceptable reading is obtained).

EVS 30a-31a. Record the two acceptable intraocular pressure measurements obtained for the right eye

EVS 30b-31b. Record the two acceptable intraocular pressure measurements obtained for the left eye.

If the first or second measurement are unreliable, a third measurement can be taken and recorded on the paper form under measurement #3. **Only the two most reliable measurements should be entered in CDART.**

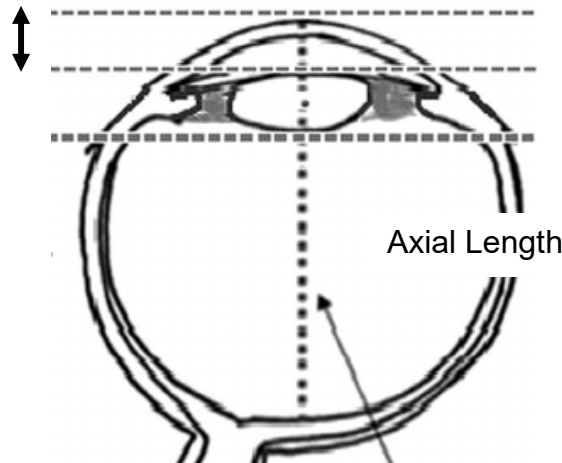
Note that an eye with an intraocular pressure of 30 or higher is at risk for further pressure elevation from dilation and should NOT be dilated.

F. Ascan (IOL Master)

The axial
anterior
the iris) will

Anterior
Chamber
Depth

length (length of the eye from surface to retina) and
chamber depth (ACD, length of the eye from surface to
be measured with the IOL Master.



Use the IOL master to measure axial length in both eyes, then use the machine to measure anterior chamber depth. If the machine requires a K value, use 45.

EVS 32a & b. Record the axial length measurements for the right eye (32a) and left eye (32b).

EVS 33a & b. Record the anterior chamber depth for the right eye (33a) and left eye (33b).

Note that an eye with an anterior chamber depth ≤ 2.50 mm is at risk for reaction to dilation and should NOT be dilated.

Print the IOL master results. This page will need to be scanned and sent to COOL & JHU along with the OCT images.