DIAMONDS- BCdVA and Refraction Guideline

Guideline for measuring visual acuity to the standard procedure developed for the Early Treatment Diabetic Retinopathy Study (ETDRS)

Visual Acuity Equipment and Facilities:

The procedure described in this section utilizes the following equipment:

- a set of three ETDRS Distance Visual Acuity Test charts which are modified ETDRS Charts 1, 2 and R for testing visual acuity at 4 meters
- retro-illuminated box providing standardized chart illumination

Visual acuity testing is required at a distance of 4 meters and, for subjects with sufficiently reduced vision, at 1 meter. The 4-meter distance should be marked clearly and permanently. The 1-meter distance must be measured with a 1-meter stick when the subject is seated (see below).

Visual Acuity Charts

Charts 1 and 2 are used for testing the right and left eye, respectively, and Chart R is used for entering acuity measurements and refraction for each eye. The features of the charts are high-contrast Sloan Letters in each of 14 lines, lines of equal difficulty, and a geometric progression of letter size (and, thus, an arithmetic progression of the logarithm of minimum angle of resolution) from line to line. Charts 1, 2, and R have different letter sequences. Subjects should be prevented from seeing charts 1 and 2 until refraction has been completed and the visual acuity test begins.

Visual Acuity Box

The dimensions of the light box are 24 ¾ inches by 7 inches. The box can be mounted on a wall or on a cylindrical stand. The stand is mounted on a five-pronged wheelbase, with each prong about 14 inches long; two of the five wheels are lockable. When the box is mounted on the stand, its height can be varied.

The light box should be mounted at a height such that the top of the third row of letters (0.8 log MAR) is 49 (2 inches +/-) from the floor. The rear of the box provides storage space for the two charts not being used.

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 results. Additional light can have an adverse effect. With the light box off, the light box should appear uniformly dark with no specular reflections visible to the subject sitting in the examination chair.

The visual acuity light box is equipped with two General Electric Cool Daylight 20-watt fluorescent tubes and a ballast. Because the illumination of fluorescent tubes diminishes by 5% during the first 100 hours and by another 5% during the next 2,000 hours:

- New Tubes should be kept “on” for about 4 days (96 hours, does not have to be continuous). A note should be kept on the back of the light box, indicating the date and time when new tubes were replaced.
- NO testing will be done with the light box during the initial 4 day period
- All tubes should be replaced once a year.

Each tube is partly covered by a 14-inch fenestrated sleeve, open in the back, which serves as a baffle to reduce illumination. Each sleeve should be centered on the tube such that an equal length of tube (4 3/16 inches) is left uncovered to the right and left of the sleeve. The openings in the backs of the sleeves should be oriented to point directly toward the back of the box (i.e., the sleeves should not be tilted up or down). Also, the lower sleeve has a cutout that should point toward the ballast.

4- and 1- Meter Visual Acuity Lanes

A distance of exactly 4 meters (13 feet and 1 1/2 inches, or 157.5 inches) is required between the subject's eyes and the visual acuity chart for the 4-meter test, and a distance of exactly 1 meter (39 and 3/8 inches) is required for the 1 meter test.

The room for visual acuity testing must have, in addition to the 4-meter lane, space for the visual acuity box (and possibly a stand) and space for the seated subject. Minimum room-length requirements vary according to how the box is mounted:

- Wall-mounted box: In addition to the 4-meter lane, 7 inches must be allowed for the depth of the box plus space for the seated subject.
- Stand-mounted box: In addition to the 4-meter 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 seated subject.

Marking the Distance

4 meters

If the chair and visual acuity box are permanently affixed, distance measurements need to be made only once and no floor marks are needed to ensure the correct distance.

If the box is mounted on the wall but the subjects chair is not permanently affixed, the 4 meter distance of the subject's eye from the chart must be marked clearly and permanently.
The room lights should be reduced to a maximum of 15 foot-candles during the visual acuity test. The box itself provides sufficient illumination for the examiner to record the test results. Additional light can have an adverse effect. With the light box off, the light box should appear uniformly dark with no specular reflections visible to the subject sitting in the examination chair.

If the box is mounted on a moveable stand, 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. When the stand touches the rear wall of the room, two of the five casters should touch the wall.

1 meter

The 1 meter distance is measured from the eye of the subject, seated comfortably in a chair with his or her back firmly placed against the back of the chair, to the center of the second or fourth letter on the third line of the chart. A non-flexible measuring device should be used for this measurement such as a yardstick, a dowel or a rod purchased at a local hardware store.

Refraction Technique

The technique described below is recommended for all study subjects whenever a manifest refraction and best-corrected visual acuity measurement is indicated by the study protocol. Refraction Chart R must be used for determining the best lens correction in each eye. Charts 1 and 2 are not used for refraction, only for visual acuity testing. The right eye is refracted first and then the left eye. For the purpose of DIAMONDS, the Chart 1 will be used to test visual acuity in the right eye,

the Chart 2 to test visual acuity in the left eye, and the Chart 1 will be also used to test binocular vision.

Beginning Approximate Refraction

Patients who arrive for examination wearing contact lenses should remove lenses and the refraction performed no less than 30 minutes later. The lens correction recorded should be the final correction in the trial frame at the end of refraction and spherical refinement in the visual acuity lane. Corrected aphakic patients, including those with intraocular lenses, should undergo subjective refraction as specified below. For uncorrected aphakic patients, a +10.00 diopter sphere should be added to the trial frame as the beginning approximate refraction.

The beginning approximate refraction is the result of the subjective refraction on the previous visit.

At the screening visit, if the visual acuity is 20/100 (2/10) or better, and the subject does not wear glasses for distance, the beginning approximate refraction is plano.

If he or she does wear glasses for distance, the beginning approximate refraction is the measured power of those glasses (using a lensometer).

Before the subjective refraction, visual acuity is measured using the beginning approximate refraction and Chart R.

If the subject's visual acuity is <20/200 (2/20) in either eye with the subject's present distance glasses (or without correction, if the subject does not have glasses), retinoscopy should be performed by an examiner proficient in this procedure.

An acceptable alternative is to use an automated refractor. The refraction steps below are recommended for visual acuities of 20/20 through 20/80 with the beginning approximate refraction. For visual acuities worse than 20/80, refer to the refraction table for the appropriate sphere and cylinder powers and testing distance (see Table 1) and follow a similar procedure using steps in power that are equal to the power of the lens being presented. *NOTE: Whenever the visual acuity improves to a higher range by improved correction, for example, from the 20/80 to 20/160 range to the 20/20 to 20/80 range, refinement should be performed with the smaller sphere and cylinder powers given for the better visual acuity.*

TABLE 1 : REFRACTION PROTOCOL SUMMARY

Vision with Best Correction (Refraction distance)	Sphere		Cylinder			Sphere Refinement	
	Power	Increment	Axis	Power	Increment	Power	Increment
20/10 – 20/100 (4 meters)	+0.50 -0.37 +0.50	+0.50 -0.25 +0.50	0.50 JCC	0.25 JCC	+0.25 -0.25	+0.25 -0.37 +0.25	+0.25 -0.25 +0.25
<20/125 – 20/200 (4 meters)	+1.00 -0.75 +1.00	+1.00 -0.75 +1.00	1.00 JCC	1.00 JCC	+1.00 -1.00	+0.50 -0.37 +0.50	+0.50 -0.25 +0.50
20/250 – 20/400 (4 meters)	+1.50 -1.00 +1.50	+1.50 -1.00 +1.50	1.00 JCC	1.00 JCC	+1.00 -1.00	+0.75 -0.50 +0.75	+0.75 -0.50 +0.75
<20/400 (1 meter)	+2.00 -1.50 -2.00	+2.00 -1.50 +2.00	No cylinder test			No refinement	

AXIS STEP SIZES FOR REFINEMENT OF CYLINDER

Cylinder Power	Axis Step Sizes
<1.00 D	**10°**
1.00 - <2.00 D	**5°**
2.00 - <3.00 D	**3°**
3.00-<5.00 D	**2°**
5.00-<8.00 D	**1°**

Subjective Refraction

The trial frame is placed and adjusted on the subject's face so that the lens cells are level and parallel to the anterior plane of the orbits and centered in front of the pupils. The left eye is occluded (by lightly patching with an eye pad or folded tissue with tape) and the beginning approximate refraction, as determined above, is placed in the right lens cells with the cylindrical correction anterior. Chart R should be read at a distance of 4 meters.

Determination of Spherical Refraction

The visual acuity of the right eye is assessed and noted. A +0.50 sphere is then held in front of the right eye and the subject is asked if the vision is "better", "worse", or "no different" while he or she is looking at the smallest line read well.

1. If vision is improved, the subject is requested to read the chart and if at least one more letter is read, the sphere in the trial frame is replaced by a sphere that is 0.25 diopter less plus. If vision is improved or there is no change, the sphere in the frame is replaced with one that is one-half diopter more plus. The +0.50 sphere is held in front of the right eye again and the subject is asked again if the vision is "better", "worse" or "no different". This process of increasing the plus sphere in the trial frame is repeated until the subject says that the +0.50 sphere held in front of the trial frame makes the vision worse. When the subject responds that the vision is made "worse", the lens should be left in place for 10 to 15 seconds in an attempt to evaluate whether the subject is accommodating (an unlikely situation in a population over age 60). If the vision clears during this period, the +0.50 sphere may be added again and succeeding attempts to evaluate additional plus lenses should be accompanied with a 10 to 15 second delay. If there is no evidence of unrelaxed accommodation, the delay period while assessing plus lenses is not necessary at any time further in the examination.

2. Whenever the subject says that the vision is "worse" and remains worse, the +0.50 sphere is removed from in front of the trail frame.

   By this process, the highest-plus or least-minus sphere that is tolerated without blurring the subject's vision is determined. After determining this highest-plus or least–minus sphere, the subject is asked to read the smallest line possible.

   Next, a –0.37 sphere is held in front of the trial frame and the subject is asked if the vision is "better", "worse", or "no different".

1. If vision is improved, the subject is requested to read the chart and if at least one more letter is read, the sphere in the trial frame is replaced by a sphere that is 0.25 diopter less plus.

2. In certain situations, the subject may be unable to read more letters, but is convinced that the vision is actually improved. If the examiner believes this is the case, the additional minus lens can be added. At any stage in the examination, no more than 0.25 diopters of minus should be added without an increase in the number of letters read correctly. The additional minus lens should not be added if the subject reads fewer letters but states that the acuity is better. There is a general attempt in this refraction protocol to avoid "over-minusing" the subjects. However, when plus cylinders are in the refraction, one must be careful not to unnecessarily withhold minus which may be necessary for the subject to accept the needed plus cylinders later in the refraction. Minus spherical power is added in –0.25 diopter increments until the subject shows no further improvement in vision. If minus power is added, a +0.50 sphere is tried again to determine if more plus will be accepted.

3. If the subject says the vision is "no different" or "worse", no minus power should be added and the spherical determinations are completed.

Determination of Cylindrical Refraction

For purposes of this discussion <u>only plus cylinder techniques</u> are presented.

1. <u>Cylinder axis determination</u>: If the approximate refraction contains a cylinder correction, changes in cylindrical axis are tested by adding a 0.25, 0.37, or 0.50 diopter cross-cylinder, first with the positive axis 45 degrees to one side of the cylinder axis, and then with positive axis 45 degrees to the

opposite side of the cylinder axis. Since neither position may produce a clear image, the subject is encouraged to select the position producing "less blur" while fixating on a single round letter on the line above the lowest line on the chart he or she is able to read when the cross-cylinder is not held up before the trial frame. If the subject cannot choose between the two positions of the cross-cylinder at the beginning of this test, the axis of the cylinder is moved 5 to 15 degrees, first in one direction and then in the other, with the cross-cylinder being checked in each position to confirm that the original axis was indeed correct. If the subject prefers one position of the cross-cylinder to the other and the cylinder in the trial frame is plus the axis of the cylinder is moved 5 to 15 degrees toward the positive axis of the cross-cylinder when it is in the position found to be less.

(When the power of the cylinder is low or if the subject's discrimination is poor; larger shifts will produce more clear-cut answers.) The cross-cylinder is tried again with the positive axis 45 degrees first to one side and then to the opposite side of the new cylinder axis to determine which position is producing less blur.

If the subject finds one position less blurry, the axis of the plus cylinder is moved toward the positive axis of the cross-cylinder. Testing for change of axis is repeated until the subject finds neither position definitely better than the other.

2. Cylinder Power determination: Change in cylinder power is tested by adding the cross-cylinder, first with the positive axis and then with the negative axis coincident with the cylinder axis. For this test, the subject is requested to focus attention on a round letter on the lowest line on the chart he or she is able to read. If the subject prefers the position axis coincident with the cylinder axis, the power of the correcting plus cylinder is increased by an additional +0.25 diopter. If the subject prefers the negative axis coincident with the cylinder axis, the total power of the correcting plus cylinder is reduced by 0.25 diopter. The process is repeated until the subject finds neither position definitely better than the other. As plus cylinders are added, the examiner should recognize that the spherical equivalent of the refraction is being changed. More minus spheres may be needed as plus cylinders are added. When using plus cylinders for every 0.50 diopter of cylinder power added, the sphere should be changed by –0.25 diopter. If, at any time, the preference with the cross-cylinder indicates that cylinder power should be removed entirely, the 0.25 cylinder should be rotated 90 degrees from its original position. The axis should be refined and the power should be tested again. If the beginning refraction is a "pure" sphere , the presence of astigmatism is tested by arbitrarily placing a +0.25 cylinder at 180 degrees in the trial frame, after having determined the highest-plus or least-minus sphere producing minimal blurring of vision, as described above. The refraction is then continued by using the cross-cylinder to test for cylinder axis and then cylinder power using the cross-cylinder technique outlined above. If, at any time, the preference with the cross-cylinder indicates that cylinder power should be removed entirely, the 0.25 cylinder should be rotated 90 degrees from its original position and the power should be tested again. At this point, if the subject prefers additional power, it should be added. If, on the other hand the subject prefers to remove the +0.25, it should be removed and the final refraction is then purely spherical. An example of this procedure follows:

Beginning refraction: -2.50 + 0.25 axis 37 degrees. Use of the cross-cylinder to check cylinder axis indicates that the subject prefers the 37-degree axis. If, upon using the cross-cylinder to check cylinder power, the subject wants the 0.25 cylinder removed, rotate the cylinder to 127 degrees and test for cylinder power again. If additional power is preferred, add it.

If the preference with the cylinder at 127 degrees is to remove the 0.25 cylinder, this should be done and the resulting refraction is 2.50.

Minus cylinders may be used instead of plus cylinders to determine the best correction for the cylinder power and axis. If minus cylinders are used, the above procedure must be revised to reflect the change in sign (+ or -).

When using minus cylinder correcting lenses, the preferred orientation of the cross cylinder is determined in the same way as when using plus cylinder lenses. When determining cylinder axis however, the correcting minus cylinder axis is rotated toward the minus cylinder axis of the cross cylinder (not the cylinder axis as it is when a plus cylinder correcting lens is used.) When determining cylinder power, the correcting minus cylinder power is increased when, in the preferred orientation, the minus axis of the cross cylinder coincides with the minus cylinder axis of the correcting lens.

Refining Final of Spherical Power

When neither the power nor the axis of the cylinder can be improved, the power of the sphere is refined by testing with +0.25 sphere and –0.37 sphere and changing the spherical power (see below). If the sphere is changed at this point, the cylinder should be rechecked. This process is repeated until no further significant lens changes are made.

This refraction protocol can be summarized as follows: First, having eliminated any possible accommodation with plus spheres, the best spherical equivalent power is found, which places the circle of least confusion on the retina. Then the cylinder power and cylinder axis are assessed. This process of checking sphere, cylinder axis, and cylinder power is repeated until there are no changes that result in an increased number of letters being read. Ideally, at the end of the refraction, the sphere is checked and the subject neither tolerates increased plus nor improves with increased minus spheres. Then the axis is checked and no change in axis is indicated. Finally, the cylindrical power is checked and no change in this is indicated. At this point, the refraction is completed. Sometimes this endpoint cannot be reached because there is an unending number of small corrections at each repetition of the process. When it becomes clear that these small changes are not resulting in an increased number of letters read correctly, the examiner may terminate the refraction.

The lens corrections obtained in this way for the right eye are recorded on the BCdVA Assessment Form as the corrections obtained by subjective refraction for the right eye. The entire process is repeated for the left eye, and these lens corrections are recorded on the BCdVA Assessment Form as the corrections obtained by subjective refraction for the left eye.

Refraction for Subjects with Poor Visual Acuity

If it is not possible to perform a subjective refraction at 4 meters because visual acuity is too poor and the patient reads less than 20 letters correct on the refraction chart at this distance, the refraction should be attempted at 1 meter. If the subjective refraction can be performed successfully at 1 meter, a +0.75 sphere should be subtracted from the results of the 1- meter refraction to make the correction appropriate for the 4-meter distance. This correction should be entered on the BCdVA Assessment Form in the space provided for distance subjective refraction. (NOTE: Visual acuity will be tested first at the 4-meter distance even if the subject cannot be refracted at this distance. If the patient reads less than 20 letters correctly at 4 meters, visual acuity must also be tested at 1 meter, in which case the +0.75 sphere should be added to the 4-meter refraction.)

Testing Best Corrected Visual Acuity

4- Meter Test

Testing of all eyes begins at 4 meters. First, the right eye is tested with Chart 1 and then the left eye is tested with Chart 2. Each Chart should remain hidden from view until the eye in question is ready for testing. For the binocular BCdVA testing the Chart 1 should be used.

The distance from the subject's eyes to the visual acuity chart must be exactly 4 meters (13 feet and 1 ½ inches, or 157.5 inches). The subject must sit for the 4-meter visual acuity test. As indicated previously, the subject should be seated comfortably with his or her back firmly placed against the back of the chair. The examiner should ensure that the subject is seated comfortably, that the head does not move forward or backward during the test, and that the subject's eyes remain at the 4-meter distance.

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 subject should be told that the chart has five letters in each line, and has letters only and no numbers. If the subject 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 subject 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 they have 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 subject reads too quickly, he or she should be asked to stop and read slowly. If the subject loses his or her place in reading or the examiner loses his or her place (possibly because the letters are read too quickly), the examiner should ask the subject 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; instead a sheet of white paper may be used to guide the subject to the proper location on the chart. Each letter is scored as right or wrong (see below). Once a subject has identified a letter with a definite single-letter response and has read the next letter, a correction of the previous letter cannot be accepted. If the subject 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 subject changes a response after beginning to read the next letter, the change is not accepted.

When the subject says he or she cannot read a letter, he or she should be encouraged to guess. If the subject 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 subject turn his or her head or eye in any manner if this improves visual acuity. If the subject does this, care must be taken to ensure that the fellow eye remains covered. If testing the right eye, the left eye must be occluded by lightly patching with an eye pad or a folded tissue with tape. The subject should be encouraged to read as many letters as possible.

There are several reasons for encouraging subjects to guess:

- Subject's statements that they cannot identify a letter are often unreliable
- Encouraging them to guess helps to maximize the subject's effort
- It helps to assure uniformity among procedures performed in different clinics;
- It may help to prevent subject bias (malingering).

1- Meter Test

At 4 meters, if less than 20 letters on the chart are read correctly then visual acuity must also be tested at 1 meter. If the trial frame is to be removed when changing the test distance from 4 meters

to 1 meter, the testing chart (Chart 1 and 2) should first be removed from view to prevent the subject from reading the chart with the fellow eye.

Before testing at 1 meter, a +0.75 sphere should be added to the 4-meter correction already in the trial frame to compensate for the closer testing distance. (As previously indicated, the subject should be seated comfortably with his or her back firmly placed against the back of the chair.) The distance of 1 meter should be confirmed with a rigid measuring device. The avoidance of any head movement forward or backward is particularly important during the 1-meter test. The subject should be asked to read only the first six lines at 1 meter, making 30 the maximum score attainable at that distance.

After the test of the right eye is completed, switch the occlusion from the left to the right eye and replace Chart 1 by Chart 2. The test is repeated for the left eye, starting at 4 meters. When testing of the left eye is completed Chart 2 should be removed from view. Once each eye, right eye and left eye, have been tested, then Chart 1 should be mounted again and, after giving a patient a rest of few minutes, then binocular vision with this Chart 1 should be undertaken.

Scoring Best-Corrected Visual Acuity

On the BCdVA Assessment Form, the total number of letters read correctly in each row of letters should be written down. Visual acuity will be measured once for each eye, using Chart 1 for the right eye, Chart 2 for the left eye, and Chart 1 for binocular vision testing. After each measurement of visual acuity, the visual score for the visit is calculated. The visual acuity score is defined as follows:

a. If 20 or more letters are read correctly at the 4-meter test distance, the visual acuity score is equal to the numbers of letters read correctly at 4 meters, plus 30; or
b. If less than 20 letters are read correctly at the 4-meter test distance, the visual acuity score is equal to the number of letters read correctly at 1 meter plus the number at 4 meters; or
c. If no letters are read correctly at either the 4 meter distance or the 1-meter distance, the visual acuity score is 0.

Count Fingers Visual Acuity

If visual acuity is so poor that the subject cannot read any of the largest letters at 1 meter (i.e. number of letters read correctly at 1 meter is zero), count fingers vision (CF), the examiner's hand holding 1, 2, or 5 fingers is held steady at a distance of two feet directly in front of the eye being examined. If testing the right eye, the left eye must be occluded by lightly patching with an eye pad or a folded tissue with tape. A light should be shone directly on the hand from behind the patient. The examiner's fingers should be presented in random order and repeated 5 times. Eccentric fixation, if present, should be encouraged. If the subject correctly identifies three of the five presentations, then count fingers (CF) is noted as "yes." If not, the subject should be tested for hand motion vision.

Hand Motion Visual Acuity

The examiner's hand with all fingers spread out should be extended two feet directly in front of the eye being examined. The fellow eye should be occluded. If testing the right eye, the left eye must be occluded by lightly patching with an eye pad or a folded tissue with tape. A light should be shone directly on the hand from behind the subject. The examiner's hand should be moved in an up and down direction (vertically) or in a side to side direction (horizontally) at a constant speed of approximately one back and forth presentation per second. The subject is instructed that the examiner's hand will be presented and they will have to respond to the question: "What am I doing with my hand?" This should be repeated five times. Four out of five correct responses indicate that hand motion vision is present. If the subject does not correctly identify four of five, then light perception must be tested.

Light Perception and No Light Perception

Light perception should be tested with an indirect ophthalmoscope in a darkened room. The fellow eye should be well occluded, ideally with a taped tissue behind the trial frame as well as the occlude lens in the trial frame. The indirect ophthalmoscope light should be in focus at 3 feet with the rheostat set at maximum voltage. From a distance of 3 feet, the beam should be directed in and out of the eye being examined at least four times, and the subject should be asked to respond when he or she sees the light. If the examiner is convinced that the subject perceives the light, vision should be recorded as “light perception”; if not, vision should be recorded as “no light perception.”

When examiners conclude that the final visual acuity score is totally unreliable because of the subject’s decreased mental ability, the visual acuity score must still be entered on the appropriate form.