2.1

Introduction

PROCEDURES FOR OCULAR EXAMINATIONS

2.1 INTRODUCTION

The purpose of the eye examination of SOF subjects is to determine whether there is evidence of senile cataract, glaucoma, age-related macular disease or uncorrected refractive error. During the examination, the examiner will perform visual acuity testing, an automated refraction, automated perimetry, intraocular pressure measurement, and photography after dilation. Three types of photographs will be taken, two of the lens (slit-lamp and retroillumination) and one of the fundus or back of the eye.

In a large study such as this, there is great opportunity for potential errors to become manifest. This is particularly true when more than one examiner participates in the study. As you are all well aware from previous examinations in SOF, a patient examination performed as part of a study must be conducted in a different fashion and different frame of mind than a clinical office examination.

A study patient must be examined according to a set procedure that cannot vary from patient to patient or with time. The technique of examination and criteria for filling out the examination forms must be identical for all examiners participating in the study. The protocol must be strictly adhered to and extreme care must be taken in examining the patient. It is recommended that the protocol be reviewed periodically to keep these points fresh in your memory. The protocol is necessarily long in order to maintain consistency and reduce the examiner variability, and to provide a reference guide as you begin to collect data back at your home institutions.

When filling out the forms, please use ink, and specifically do not use either pencil or red ink. In most instances, data recording involves writing the appropriate code for each item being assessed in the proper box. When errors in the recording are made, do not write over the initial entry, but cross it out and write the new entry above or the side. If an entry becomes to confusing for the coder to understand, make a comment to the side describing the correct entry.

2.1.1 Introduction for Participants

Participants should be told to wear the eyeglasses they usually wear for driving or watching TV (distance activities). If they wear contact lenses and their distance glasses have not been recently changed, they should wear their contact lenses. Participants who have had recent eye surgery should be encouraged to participate in SOF-ES at least 30 days after their surgery. **Please remind all participants to bring their glasses.**

2.1.2 Backup Examiners

Backup examiners should do the complete exam on at least one subject a week so that he/she maintains his/her skills.

2.2

Patient Identification & History

SOF-ES MEMO

Re: Ocular History

a. uveitis vs conjunctivitis.

b. retinal hemorrhage vs subconjunctival hemorrhage.

If you are taking the ocular history information from the participant, it is important that you differentiate between uveitis and conjunctivitis. Uveitis is specifically asked about in the disease section of the eye survey. Uveitis is a serious inflammation inside the eye. Conjunctivitis is a mild infection that affects the outer surface of the eye.

Another item that may cause some confusion is the question about retinal hemorrhages. A retinal hemorrhage is bleeding inside the eye from the retina or the back of the eye. Patients may confuse this with a subconjunctival hemorrhage, which is on the outside of the eye under the clear membrane that covers the sclera (white part of the eye). The subconjunctival hemorrhage is very visible and clears up on it's own over time, like a bruise on the skin. It is not a serious condition in itself. A subconjunctival hemorrhage does not affect vision or require special treatment.

A retinal hemorrhage is much more serious, may affect vision, and requires immediate treatment or observation by a physician. It is not visible from the outside of the eye.

Be sure to find out which type of hemorrhage the patient is talking about. We are most interested in the retinal hemorrhages since a retinal hemorrhage may indicate other diseases, such as diabetes.

2.2 PATIENT IDENTIFICATION

The examinee's SOF record number, date of birth, date of examination and place of examination will be filled in when the patient is first registered for the eye examination. Under the place of examination; 1 = "clinic" refers to the SOF-ES examining rooms, 2 = "local" refers to any exam done by the SOF-ES staff outside the "clinic", e.g., in the examinee's home, nursing home, hospital, etc.

In all exams, the right eye will be evaluated first. Prior to beginning the exam, the examiner will determine the status of both eyes by asking the following questions:

1) Have you ever had an eye removed? If the patient indicates that she has had an eye removed, determine which eye and record on the form. This question includes enucleation and phthisis bulbi (a blind eye which is obviously smaller than normal).
2) Do you have any of the following: glaucoma, macular degeneration, cataracts, uveitis (inflammation of the eyes), a history of a stroke or hemorrhage in the eyes, diabetes in the eyes, or a corneal graft or transplant?
3) Have you ever had cataract surgery? If so, which eye and when?
4) Did you have intraocular lens implants? If so, which eye and when?
5) Have you ever been hit in the eye? If so, which eye and when? Participants will also be asked about other eye surgeries and about the use of systemic and topical eye medications. Finally, each participant will be asked five questions about their current visual functioning.

2.3

Visual Acuity Testing

2.3 BAILEY-LOVIE VISUAL ACUITY TESTING

a) Illumination: It is important that all of the vision tests be performed in areas of UNIFORM illumination, e.g., no abrupt changes in illumination or shadows when moving a few feet or changing orientation. Diffuse natural light, fluorescent light or a combination of the two is best. The chart luminance should be between 50 and 70 foot Lamberts for each of the two tests. The light meter from the vision contrast sensitivity test (or similar one) should be used to standardize chart luminance. If natural light levels vary considerably from day to day you should check luminance levels daily. The spatial relation of the targets to the subject should be positioned in such a way as to minimize glare on target surfaces. Determine the optimal positioning through trial and error under a range of naturally varying light conditions.

b) Distance: The test is administered with the participant seated at 10 feet from the target. This distance should be marked on the floor with tape. Measure from the target to the middle of the chair.

c) Glasses: Acuity is tested with habitual correction for distance vision and a second time for each eye using pinhole acuity.

Before testing vision, ask the subject if she normally wears glasses all the time, wears them for distance vision only, wears glasses for reading only, wears bifocals, or if she does not wear glasses. (probes: "Do you wear glasses to see things far away, like when you go to a movie theater or when you drive a car?") If she answers that she has glasses for distance but sees better without them, distance tests should be performed with glasses on. When scheduling participants for visits, remind them to bring or wear the glasses that they use most often for distance vision.

2.3.1 Focal Acuity

Introduction:

The Bailey-Lovie visual acuity letter charts incorporate the following features:
a) geometric progression of letter size;
b) near equal legibility of all letters in the chart;
c) each row has the same number of letters (5);
d) between row spacing is equal to the height of the letters in the smaller row;
e) letter spacing is equal to one letter width.

These features ensure that the visual acuity task is essentially the same for all letter sizes so that the angular size of the letters is the only parameter which determines the visual acuity score. This combined with letter size progression on a uniform logarithmic scale, allows for acuity testing at optional non-standard distances determined by the progression

of letter sizes. We are assessing acuity at the optional distance of 10 feet. The size of the chart is reduced to produce standard scores at this critical viewing distance. (See Bailey IL, Lovie JE. New design principles for visual acuity letter charts. Am J Optom Physiol Optics 53(11): 740-745, 1976.)

2.3.2 Equipment

a) Bailey-Lovie Letter Charts

b) Pinhole occluder

c) Light meter. Ideally the VISTECH VCTS 6500 light meter used with the contrast sensitivity will be used to test illumination.

Light meter instructions:

1. With the dial facing up, hold the light meter two inches from and perpendicular to the upper right corner of the chart. Be sure you are not casting a shadow on the chart as you measure luminance.

2. Note the position of the pointer. It should be in the upper 50% of the green area (between 14 and 20 degrees).

3. Repeat the measurement holding the meter two inches from the lower left corner of the chart.

4. For consistent repeated measurements, the readings from one area of the chart to another or from one test to the next should be within five degrees of pointer movement.

5. If your test area has significant natural light, evaluate chart illuminance under a variety of naturally varying conditions to determine if additional artificial light will sometimes be needed, especially at different times of day.

Illumination: Since we will be working with an older population we will restrict the chart luminance range to 50-70 ft-Lamberts. For consistent measurement of contrast sensitivity and visual acuity, luminance must be kept constant from one area of the chart to another, and from one test to the next.

d) A Pointer

2.3.3 Measurement Procedures

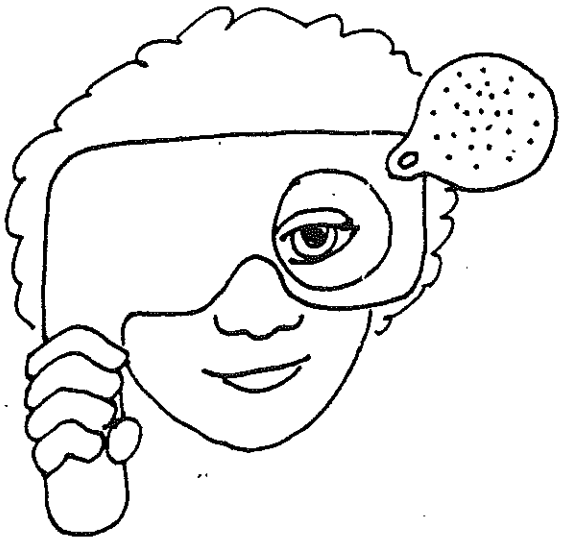
a) The target should be placed at approximately the eye level of seated subjects. Seat subject on straight-backed chair, 10 feet from the midline of the body to the target.

Measure chart luminance to insure lighting conditions are within desirable limits (50-70 ft-Lamberts). Use a pointer to indicate rows on the chart.

b) If the participant wears glasses (bifocals or regular glasses) for distance viewing, such as driving, walking or at a theater, test with her glasses on. If she only wears glasses (bifocals or regular) when she reads, test distance vision at 10 feet without glasses. Test contact lens wearers with lenses in. If a participant says that she wears glasses but sees better without them, test WITH THEM (her "normal" state).

c) Ask the subject to hold the occluder so that her left eye's vision is blocked and only the right eye can be tested. Then ask the subject to start reading the letters on the chart starting with the row with the double bar, proceeding down the chart toward the smaller letters. Say:

"I would you to read aloud the letters on this chart." (Read from left to right)



"Don't squint and don't lean forward. Start at the row with the double bar and read down as far as you can and then say 'That's all'."

"Now, can you easily read the row with the double bar?"

If she says yes or reads the row without error then say:

"OK (begin/continue)."

If she says no or reads it with one or more errors, then say:

"How about the top row? Can you read that one?"

If she says no or reads it with error, then test at 5 feet (low vision distance) using the same procedure. Be sure to record that you are testing at 5 feet.

d) As the subject reads, keep a running tally of the total number of letters missed by drawing a line over those read correctly and drawing a line through the incorrect ones.

e) When it is apparent that the subject is struggling (e.g. misses 3 or 4 letters on a row or goes very slowly) then point to the next row and say:

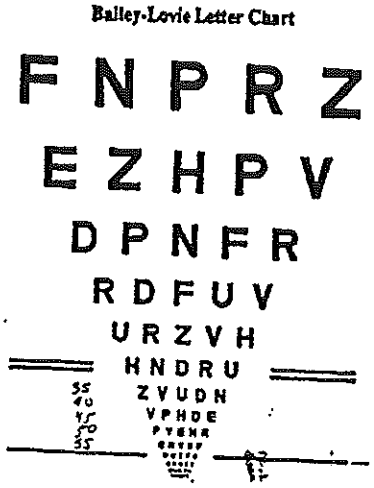
"I want you to try reading the next row even if you just have to guess"?

Note the errors on that row, then stop. If she misses all 5 letters on a row, add those to your tally and then stop. If she says "That's all," in the middle of a row, have her guess at the rest of the row and then stop. Draw a line through the first row not attempted.

f) REMEMBER TO RECORD THE NUMBER OF LETTERS READ CORRECTLY. The number next to each line on the score sheet is the number of all the letters from the top row to that row. So, if a subject attempted to read up to the line marked 40, she read a total of 40 letters. Compute the number of letters she read correctly by subtracting the number of letters crossed off from the number on the last line read e.g. 40 -5 crossed off = 35 correct.

g) If the subject reads 50 letters correctly at 10 feet, they do not need to use the pinhole occluder for that eye. Now have the subject hold the occluder so that the vision is still blocked in the left eye. Put the pinhole occluder in front of the right eye (with glasses on) and ask if they can read any more letters on the last row that they read. If they can, record the additional number of letters that can be read on the form. If they cannot read any more letters, please mark the form with the same score as without the pinhole.

For your information: with the Reduced Bailey-Lovie chart, the logarithm of minutes of arc (Log MAR) is computed according to the formula Log MAR = 1.1 - [(55n).02], where n = total letters missed. Snellen fraction equivalents can be obtained from the Log MAR scale. They can also be obtained directly from the number of errors and the testing distance. These conversions are printed on page 13a so you can tell the participants their acuity score in a form they will understand.



Rationale for using a non-standard testing distance. Acuity is usually measured at 16 inches for near and 20 feet for distance. However, for this study we are interested in acuity at viewing distances representative of all situations, or mid-distances. Acuity at near may not be representative of acuity at 10 feet, especially in the elderly. Elderly with glasses may be out of focus at near distances. Very restricted pupils could affect acuity differently at different distances, as could light scatter due to cataracts. Reduced focusing flexibility in the elderly could also cause focus error across different distances. These problems are not likely to contribute to any significant differences in the result at 10 feet versus 20 feet. So we could test at 20 feet, but a larger room would be required. So we chose 10 feet.

(h) For subjects that cannot see the chart at 5 feet, you need to test their vision with your fingers. Finger counting is tested by holding two or three fingers two feet from the patient and should be recorded as CF@____feet. Hand motion is tested by moving a hand back and forth in front of the patient with the other eye occluded. This recorded as HM@___feet. Light perception should be tested by carefully occluding the fellow eye and directing the light of the penlight at the examinee's eye from about a one-foot distance. This is recorded as LP@___1 foot. No light perception is recorded as NLP.

(i) The subject now holds the occluder so that the vision from the right eye is blocked. Steps c-h are then repeated.

Bailey - Lovie Visual Acuity Conversion to Snellen Equivalent

Reduced Bailey - Lovie Chart at 10 ft Number of letters correct	Snellen Acuity at 20 ft
5	20 / 200
10	20 / 150
20	20 / 100
35	20 / 50
40	20 / 40
50	20 / 25
55	20 / 20
60	20 / 15
65	20 / 12.5
70	20 / 10

Enter the Snellen Visual Acuity in the Humphrey Automated Perimeter.

2.4

Contrast Sensitivity

2.4 Contrast Sensitivity

2.4.1 Equipment

VISTECH VCTS 6500 wall chart and light meter. Mark the right and left hand sides of chart with a large R and L, clearly visible to the participant.

2.4.1 Description

Vision is generally measured by acuity tests that determine the smallest detail, such as black letters on a white background, that can be seen. However, our everyday visual world contains objects that have varying levels of contrast (the level of black and white parts of an object and background) and a range of sizes. Those objects must often be seen under visually degraded conditions such as nighttime, fog, or rain. Contrast sensitivity measurements are needed to determine an observer's ability to see a wide range of everyday objects under normal and visually degraded conditions. Because any object can be decomposed into a combination of simple patterns, called sine waves, contrast sensitivity to sine waves provides a generalized measure of visual sensitivity to everyday objects.

The VISTECH contrast sensitivity test system, Model 6500, uses highly controlled photographic and printing techniques to present a series of sine wave gratings at calibrated levels of contrast. In a manner similar to reading the typical acuity chart, the observer simply reports whether or not a grating is visible; and if visible, at what orientation of all grating sizes. At the 10 foot distance, this spatial frequencies tested can be made higher or lower by simply changing viewing distance.

2.4.3 Illumination

The VCTS is designed so that it can accurately measure contrast sensitivity under normal room illumination corresponding to a chart luminance of 30-70 ft-Lamberts. However, since we are working with an older population we will restrict the chart luminance range to 50-70 ft-Lamberts. For consistent measurement of contrast sensitivity, luminance must be kept constant from one area of the chart to another, and from one test to the next.

2.4.4 Light Meter Instructions

1. With the dial facing up, hold the light meter two inches from and perpendicular to the upper right corner of the chart. Be sure you are not casting a shadow on the chart as you measure luminance.

2. Note the position of the pointer. It should be in the upper 50% of the green area (between about 14 and 20 degrees).

3. Repeat the measurements holding the meter tow inches from the lower left corner of the chart.

4. For consistent repeated measurements, the readings from one area of the chart to another or from one test to the next should be within five degrees of pointer movement.

5. If your test area has significant natural light, evaluate chart luminance under a variety of naturally varying conditions to determine if additional artificial light will sometimes be needed.

Administration

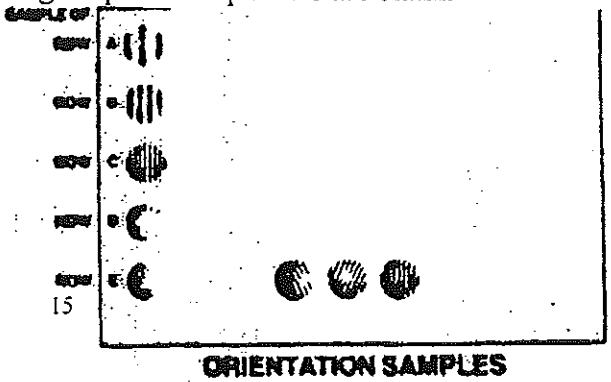
a. Place chart system in an area where it receives uniform lighting. Shadows or glare on the chart can affect contrast sensitivity measurement. To minimize glare, the chart should not be facing a window or have a window directly behind it. Measure chart luminance to insure lighting conditions are within desirable limits (see Light Meter Instructions). HAVE A POINTER HANDY.

b. The subject should be seated 10 feet from the chart, with the middle of the chart around eye level. TEST WITH GLASSES ON IF SHE WEARS GLASSES FOR DISTANCE.

c. Tell the subject: "This test measures your contrast sensitivity, or how well you are able to see differences in shades of dark and light. (We test this by seeing how well you are able to see the fuzzy bars on this chart at different levels of contrast between dark and light. Your ability to see these bars relates to how well you see everyday objects.)"

Continue, pointing to the upper left hand patch (A1). "Each of the circular patches on the chart contain bars that vary in contrast. Can you see the light and dark bars on this patch?" (If "no", point to c1 and ask again. If unable to see the bars on c1, then follow instructions for low vision.) Then point up and down the first column (1). "Each row contains a different size bar pattern. The patches on the far left of each row are high contrast sample patches which show the size bars you will be looking for to the right of that sample patch on the same row."

"The four patches on the bottom of the chart show the three ways the bars may be oriented and a blank. The bars will be slanted slightly up to the left, slanted slightly up to the right, and straight up. Some patches are blank."



"Your task is to read across each row, starting at row A. Patch 1. and call out weather the patch is pointing to the left, right, straight up and down or blank. I will record your responses. (Some of the patches are very low in contrast and you may not see any bars in these patches). If this is the case, simply answer 'blank'. However, if you do see something in a patch but you are not sure which direction the bars are pointing, you are allowed to guess."

d. Scoring: Record the subject's response for each patch in the appropriate place on the scoring sheet by drawing a line through those called out incorrectly. Circle the patch number just before the first incorrect one on each line. This is the score for that line.

Point at each circle. Ask about every circle don't stop. Cross out the first one missed then circle the one just before that. Score each now before going on to the next.

e. Low Vision: If the subject cannot see the bars in patch C1, mark the box for low vision on the scoring sheet and test at 5 feet.

For low vision, a quantitative measure of the subject's visual capability in terms of contrast sensitivity is accurately obtained. The low vision subjects can be tested by simply moving her closer to the chart. The spatial frequencies change in direct proportion to distance. (for example, at a 5ft. viewing distance, the spatial frequencies become .75, 1.5,3,6, and 9 cycles per degree).

2.5

Humphrey Autorefraction

2.5 PROCEDURE FOR OBJECTIVE REFRACTION USING THE HUMPHREY AUTOREFRACTOR

Overview:

The Humphrey Automatic Refractor is an automatic instrument that provides a fast, accurate objective refraction in seconds. The Automatic Refractor is easy to use. The operator takes only a few simple steps to align the patient, and then the instrument's auto-tracking mechanism takes over. a single push of the READ button initiates the refraction cycle, and a single push of the PRINT button prints the patient's prescription.

2.5.1 Visual Acuity with the Humphrey Autorefractor

An initial visual acuity is obtained using the autorefractor by following these steps:

a) Turn on the autorefractor.
b) Select the "R" right eye.
c) The autorefractor automatically calibrates to "Plano", or no prescription.
d) Have the patient sit forward and place her face in the chin rest while wearing her current eyeglasses or contact lenses.
e) The technician aligns the autorefractor with the patient's eye.
f) Using the arrow keys, move the line to be read to 20/30.
g) Ask the patient to read left to right.
h) If successful at 20/30, move the cursor down (arrow keys) to 20/25 and ask the patient to read it. Proceed to 20/20, if possible.
i) Record the results. The print out will list this correction as "unaided", but keep in mind that it was done with the patient's current correction or contact lenses.
j) Proceed to the refraction instructions (2.5.2) for the right eye after removing the patient's eyeglasses or contact lenses.
k) Repeat for the left eye.

2.5.2 Objective Refraction

An objective refraction is a measurement of refractive error that requires no response from the patient. The equipment makes an objective measurement.

An objective refraction may be performed using the READ sequence. READ permits the taking of initial and final acuities or the measurement of a single eye.

a) Set up the refractor.

    1. If this is the first refraction of the day, remove the dust cover and the lens cover. Turn the refractor on.

2. If this is not the first refraction of the day, press CLEAR before beginning to refract a new patient.
3. For every patient, clean the chin and forehead rest areas with an alcohol swab. Remove the top chin paper to expose a fresh one.

b) Position the subject.

1. Make sure the subject is seated comfortably with his or her chin and forehead resting firmly in the subject support system. The subject's glasses should be on for the first part of the test.
2. Use the chin rest knob to raise or lower the chin rest until the subject's eyes are lined up with the silver marker on the forehead rest.

c) Align the Refractor.

1. Since you are using READ, press Right Eye (R. EYE), to indicate that the right eye is to be tested first.
2. Ask the patient to look at the acuity chart while you look at the subject's eye through the viewing window.
3. Use the control ball to position the blinking green alignment light in the middle of the pupil and let go. The Refractor will then make an automatic vertex adjustment for the patient. You should observe that the instrument has positioned the green light between the two yellow lights.
4. Perform an Objective Refraction with READ.
5. Once you have the refraction, then measure visual acuity and enter on form ___. Participants can only miss one letter in a given row to get credit for that row.
6. When the Refractor has completed its measurement cycle, press PRINT. The print out will show both "unaided" and "objective" visual acuities. Remember that the "unaided" visual acuity was done with the patient's current eyeglasses or contact lenses in place.

7. Record the refraction on form ____.

To initiate the refraction for the left eye select the left eye, (L. EYE).

Repeat the same procedures, c and d, for the left eye.

Print the information, add the participant's study number and the date, and staple the printout to the clinical center's data collection form.

Addendum to Section 2.5 in SOF-ES MOP
Re: Autorefraction Script

(Place this page at the end of Section 2.5, Humphrey Autorefraction of your SOF-ES MOP)

SCENE #1:
"Mrs. _____, please have a seat here. We will start the exam with your glasses **on**. Please place your chin in the chin rest and move your forehead forward. You will see an eye chart with letters. Please read the row of letters from left to right. The letters may appear to move a little, but try to read them without moving your head."

If the patient was successful at the 20/30 line, move down to the 20/25 and then to the 20/20 line. Record the results for the right eye.

SCENE #2:
"Mrs. _____, I would like you to remove your eyeglasses and place your chin in the chin rest again. You will be reading the letters again, but this time the machine will correct your vision instead of your eyeglasses."

If the patient was successful at the 20/30 line, move down to the 20/25 and then to the 20/20 line. Record the results for the right eye.

SCENE #3:
"Mrs. _____, please place your glasses back on your face, place your chin in the chin rest, and your forehead forward again. You will see the eye chart once again, but this time with your left eye. Please read the letters again from left to right. If the letters appear to move a little, try to read them without moving your head."

If the patient was successful at the 20/30 line, move down to the 20/25 and then to the 20/20 line. Record the results for the left eye.

SCENE #4:
'Mrs. _____, I would like you to remove your eyeglasses and place your chin in the chin rest again. You will be reading the letters again, but this time the machine will correct your vision instead of your eyeglasses."

If the patient was successful at the 20/30 line, move down to the 20/25 and then to the 20/20 line. Record the results for the left eye.

2.6

Humphrey Autolensometry

SOF-ES MEMO

Re: Autolensometer

On the vision forms 6, page 16, question number one asks you to check *"all that apply"*. It then lists four choices, distance, bifocals, trifocals or reading only. You should check all that apply to the pair of glasses in which the participant walks around wearing. Therefore, if the pair of glasses that the participant wears to walk around in is a bifocal, you would check only the bifocal box. If the participant wears only distance glasses to walk around in, then you would check the box for "Distance". If a subject wears bifocals more often than distance glasses only (more than 50% of the time) then check the bifocal box.

2.6 AUTOLENSOMETRY USING THE HUMPHREY LENS ANALYZER

Overview:

A lensometer is used to measure the optical power of a pair of eyeglass lenses. In this study, this is used so that the correct reading prescription can be placed in front of subject's for the automated perimetry test. The instrument used in this study is a Humphrey Instruments Lens Analyzer.

2.6.1 To Neutralize a Pair of Eyeglasses

a) Power on.

If necessary adjust modes from Mode Selector setting.

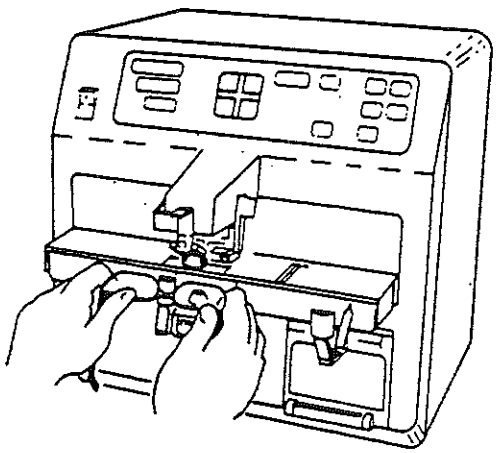
The mode selector is explained in the appendix for The Humphrey Lens Analyzer. The mode selector is located on the back of the instrument. #1 needs to be set to "+ cyl". #2 needs to be set to ".25 RND". The rest need to be "OFF".

To change modes, turn off the power, change the appropriate mode selector switch and power on again.

b) Position spectacles.

Position spectacles with temples down (earpieces pointing toward the floor) and the bottom edge of the eyeglasses against the machine, with lens to be read over the read head and the bridge of the glasses against the nose piece.

It is best to hold glasses with thumb against the top edge of the frame and the fore finger along the side as pictured below.



The instrument will automatically detect the lens and begin a continuous read of sphere, cylinder, axis and pupillary distance (PD).

c) Read the lens for the right eye first.

When the lens to be read is in the desired position (see figure above), hold spectacles firmly on lower measuring head with frames pressed against the lens table. Be sure to press the lens not being measured against the table until you see the right/left indicator on the screen.

Press STORE or the foot switch. It is necessary to store the lens values if they are to be printed.

Note: It is the pressure of the frame of the lens NOT being measured against the table that triggers the table switch, indicating to the instrument which lens has been measured; right or left.

d) Skip. Go to page 21.

e) Next read the left lens following the same procedure..
Position spectacles for second lens. Do Not move the table between the right and left reading.

f) Print RX.
Press PRINT. The printout will include sphere, cylinder, axis, and adds, if measured. Label the print-out with the patient's SOF ID Number, the date, which eye, and enter this information on the form ___ to be sent to the reading center.
Keep print out in patient's chart.

g) The SOF-ES will need only the distance reading entered in the Humphrey visual field analyzer. The add is not needed for the Humphrey Visual Field Analyzer because the instruments calculate the correct add and combine it with the distance correction for the most accurate lens correction.

2.7

Humphrey Visual Field Testing

SOF-ES MEMO

Re: Visual Fields

There are two visual fields attached to this memo from a patient with age-related macular degeneration. Note the similarities of the visual fields with visual acuity of 20/300 or 20/40 and macular degeneration. As you can see, even with a Visual Acuity of 20/300 we can get useful information about an individual's peripheral vision.

Secondly, please remember to bring the corrective lens as close as possible to the patient's eye during testing. This prevents the lens holder blocking the patient's. This type of error results in an artifact that appears to be a ring of vision loss in the periphery.

Finally, I have attached a Visual Field Testing-Information for Patients sheet with this memo. It is for your use to help you guide your participants through this test and achieve the best results possible.

Visual Field Testing-Information for Patients

A visual field examination determines the sensitivity of your peripheral vision, that is, how well you see "out of the corner of your eye." The examination will be performed by a computerized machine known as the Humphrey Field Analyzer. The examination is not difficult, but there are some aspects of it with which you should be familiar. Please read this material prior to your examination.

Since this test is an examination of your "side" vision, it is most important that you hold your eye still and look straight ahead at all times. Inside the machine there is a steady yellow light for you to look at. Unless instructed otherwise, you should stare at this light at all times. The test light will flash on and off randomly at different places within the machine. You will be given a response button to hold, and you should press the button whenever you think you have seen a light flash. The best time to blink is right after you have pushed the button. Some lights will be bright and some will be dim; some lights will be too dim to be seen and there will be periods of time when you will not see anything. You should not be alarmed by this variation-- the machine purposely makes some of the lights too dim as it tries to measure the sensitivity of your eye at various points.

During the examination, you will hear various noises as the light projector moves and the shutter opens and closes. Try to ignore these noises and respond only to the lights-- the machine periodically tests your responses by either not projecting any lights (to see if you are responding to the noises) or by projecting very bright lights (to see if you are paying attention).

This examination can be quite long and tiring, and can take up to 10 minutes per eye. It is most important that you be seated comfortably with your forehead pushed forward into the machine as far as possible. You should feel relaxed with no tension in your shoulders or neck. The fixation light should be clearly in focus. If you are not comfortable or if the light is not in focus, tell the technician immediately.

It is hoped that this information will make visual field testing easier for you. Please do not hesitate to ask the technician to explain anything that is not clear to you.

(Adapted from: Choplin, NT, Edwars RP. Visual Field Testing with the Humphrey Field Analyzer. Thorofare, New Jersey: Slack, Inc.; 1995).

CENTRAL 24 - 2 THRESHOLD TEST

NAME

BIRTHDATE 12-23-19 DATE 01-30-97

STIMULUS III, WHITE, BCKGND 31.5 ASB BLIND SPOT CHECK SIZE III

FIXATION TARGET CENTRAL ID 128-85-67 TIME 01:55:57 PM

STRATEGY FULL THRESHOLD

RX USED +4.25 DS DCX DEG PUPIL DIAMETER 3.8 MM VA

Macular degeneration 20/300

LOW PATIENT RELIABILITY

LEFT

AGE 78

FIXATION LOSSES 5/10 xx

FALSE POS ERRORS 2/15

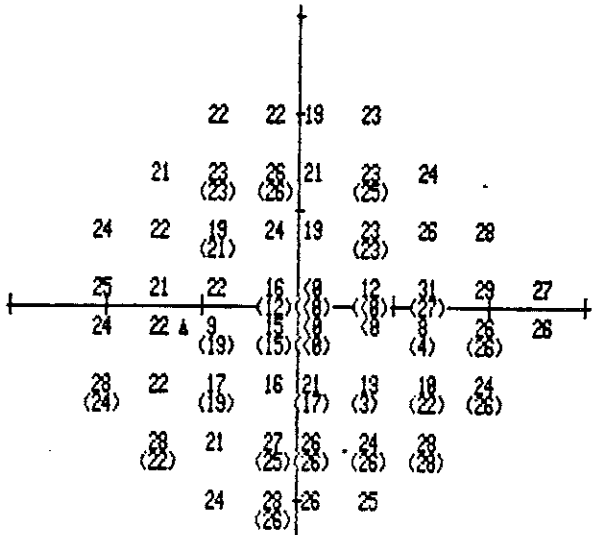
FALSE NEG ERRORS 2/13

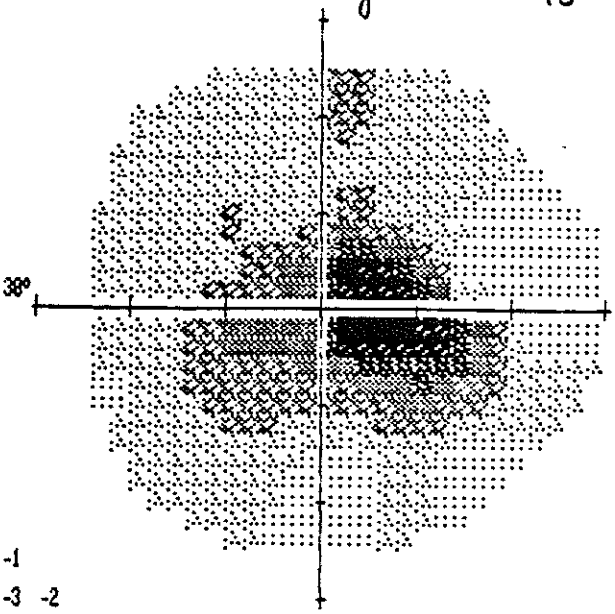
QUESTIONS ASKED 489

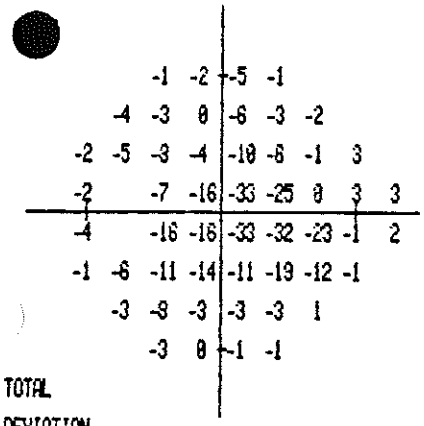
FOVEA: 8 DB

TEST TIME 15:33

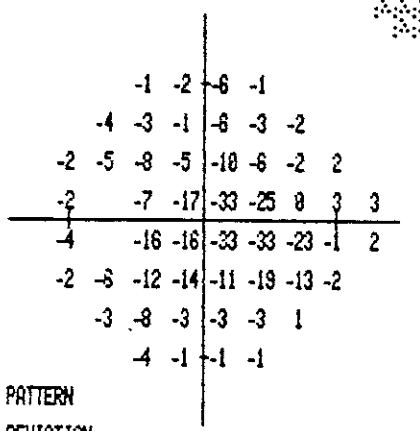
HFA S/N 648-2174







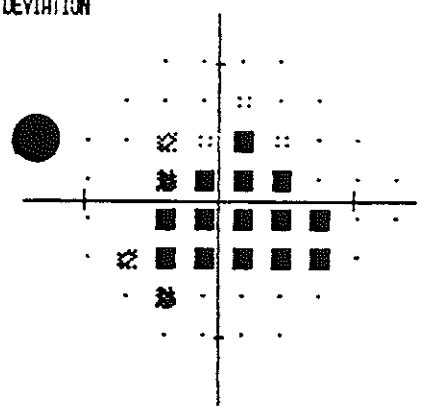
TOTAL DEVIATION



PATTERN DEVIATION

GLAUCOMA HEMIFIELD TEST (GHT)

OUTSIDE NORMAL LIMITS



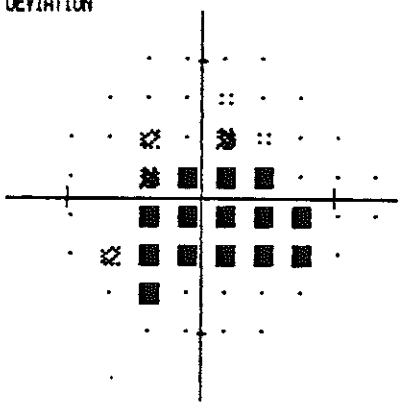
PROBABILITY SYMBOLS

:: P < 5%

※ P < 2%

▒ P < 1%

■ P < 0.5%



MD	-9.51 DB P < 0.5%
PSD	11.29 DB P < 0.5%
SF	4.81 DB P < 1%
CPSD	10.45 DB P < 0.5%

GRAYTONE SYMBOLS REV 8.2 X2

SYM										
ASB	.8 - .1	2.5 - 1	8 - 3.2	25 - 10	79 - 32	251 - 100	794 - 316	2512 - 1000	7943 - 3162	≥ 10000
dB	41 - 50	36 - 40	31 - 35	26 - 30	21 - 25	16 - 20	11 - 15	6 - 10	1 - 5	≤0

UCLA/JSEI
VISUAL FIELD LAB
100 STEIN PLAZA
L.A., CA. 90024
310-825-5897

HUMPHREY INSTRUMENTS
A CARL ZEISS COMPANY

CENTRAL 24 - 2 THRESHOLD TEST

NAME

BIRTHDATE 12-23-19 DATE 01-30-97

STIMULUS III, WHITE, BCKGND 31.5 ASB BLIND SPOT CHECK SIZE III

FIXATION TARGET CENTRAL ID 128-65-67 TIME 01:33:27 PM

STRATEGY FULL THRESHOLD

RX USED +4.75 DS DCX DEG PUPIL DIAMETER 3.0 MM VA 20/40

macular degeneration

RIGHT

AGE 78

FIXATION LOSSES 2/7

FALSE POS ERRORS 0/9

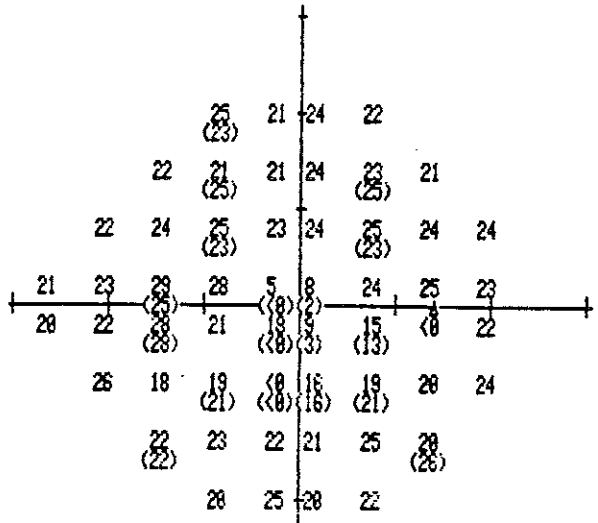
FALSE NEG ERRORS 3/11

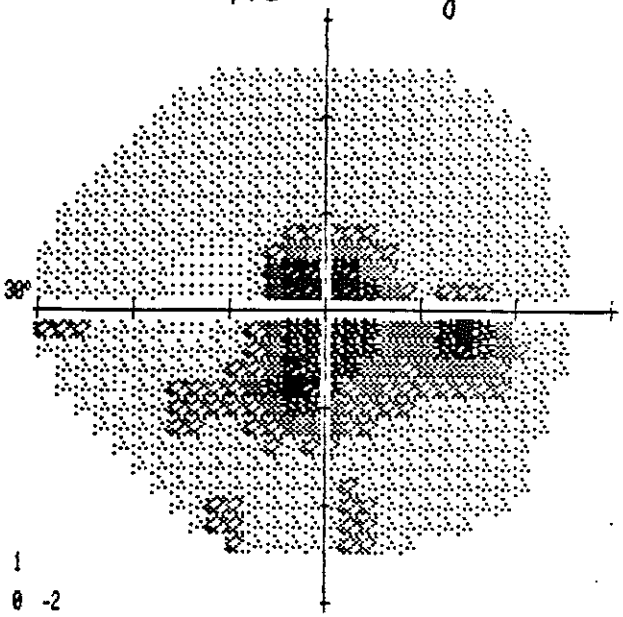
QUESTIONS ASKED 40

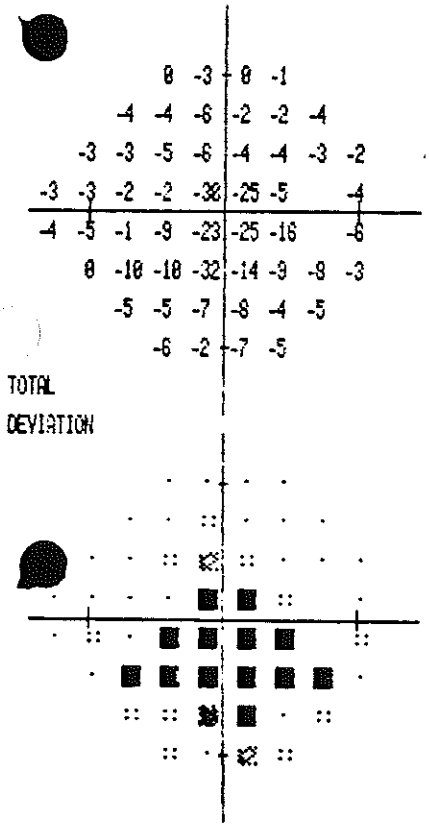
FOVEA: 18 DB

TEST TIME 12:57

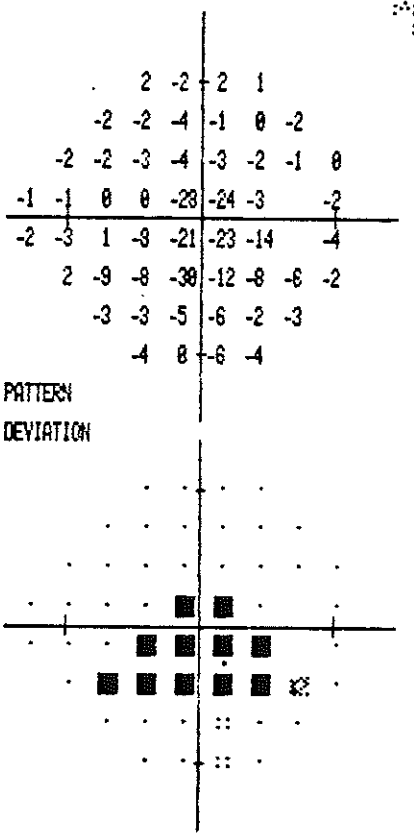
HFA S/N 640-2174







TOTAL DEVIATION



PATTERN DEVIATION

GLAUCOMA HEMIFIELD TEST (GHT)

OUTSIDE NORMAL LIMITS

PROBABILITY SYMBOLS

:: P < 5%

P < 2%

P < 1%

P < 0.5%

MD	-8.70 DB	P < 0.5%
PSD	9.39 DB	P < 0.5%
SF	2.48 DB	P < 5%
CPSD	9.01 DB	P < 0.5%

GRAYTONE SYMBOLS REV 8.2 X2

SYM										
ASB	.8 .1	2.5 1	8 3.2	25 10	79 32	251 100	794 316	2512 1000	7943 3162	≥ 10000
P	41 5%	36 4%	31 3%	26 2%	21 2%	16 1%	11 1%	6 1%	1 <1%	≤0

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HUMPHREY INSTRUMENTS
A CARL ZEISS COMPANY

2.7 PROCEDURE FOR THE MEASUREMENT OF VISUAL FIELDS USING THE HUMPHREY VISUAL FIELD ANALYZER

Overview:

The Humphrey Automated Visual Field Analyzer is an instrument designed to conduct static, visual field examinations in a standardized manner. There are three major advantages to using an automated approach.

1. A technician with limited training can use the instrument effectively

2. It conducts visual field measurements in a standardized manner.

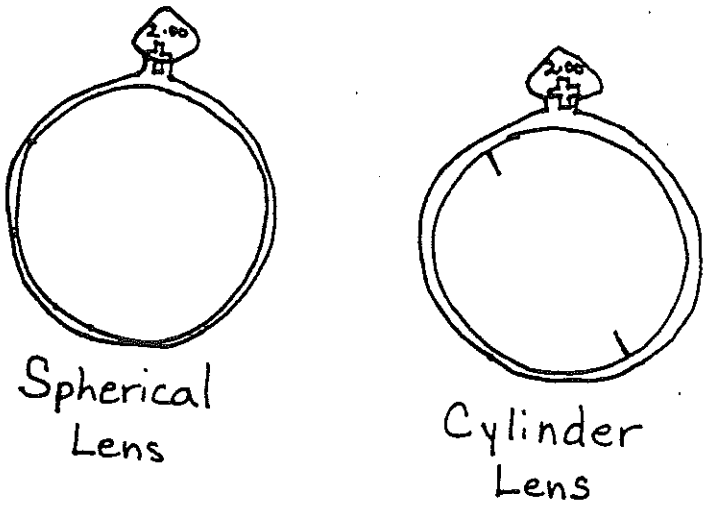
3. It reports data from only those areas tested and does not infer result to untested locations in the visual field.

   The visual field testing is done with the subject's current eyeglass correction which is obtained from the lensometer. In subjects who do not wear glasses, the correction to be entered is + 0.00, A correction may consist of several components and may be written in this manner:

   +2.00 +1.25 × 180° add: + 3.25

   This refers to +sphere +cylinder at an axis of 180 degrees add: additional correction for near vision. Remember numeric transparitions will make the visual field measurement inaccurate.

   Spheres correct for near and far by using plus or minus lenses. The cylinder portion corrects for astigmatism and must be at a specific rotation in front of the eye, and is therefore, an axis measurement. An add is the portion of the lens that is added to the distance correction to bring near objects into focus.



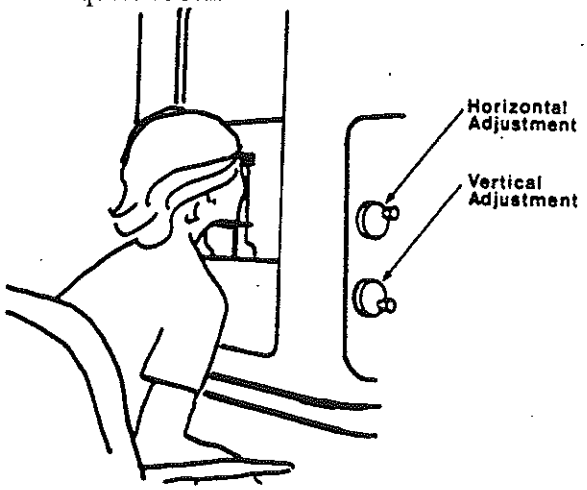
2.7.1 Preparation For Visual Field Testing Using The Humphrey Automated Visual Field Analyzer

a) Calibration

The Humphrey Automated Visual Field Analyzer autocalibrates itself when first turned on in the morning. If there is a problem, an error message will appear on the screen. The error message will also instruct you as to what steps need to be taken to correct the problem.

b) Preparing the Patient

1. The patient should be seated at the instrument and aligned using the power table controls, as well as, the controls on the instrument itself to adjust the chin rest and center the eye to be tested in the screen. One knob moves the patients chin rest up and down and the other moves the chin rest left and right. Remember this test takes concentration and should be performed in a dimly lit and quiet room.



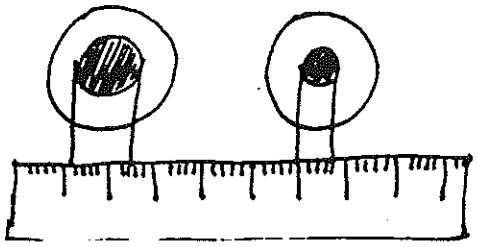
2. Record the following data on the screen of the instrument:
a. Enter the distance correction from the lensometer for the right and left eyes into the instrument. Select "calculate trial lens." The correction to be used will appear in the column headed "trial lens." Record this on Form ____.

b. Examiner's SOF ID number

c. Birthdate: (entered as month, day and year. The Humphrey Visual Field Analyzer assumes that patients are between the ages of 7 years and 104

years. If you have anyone older than 104 years you will need to adjust the year of birth to be no older than 104 years.

d. Pupil diameter in millimeters
Right _____ Left _____



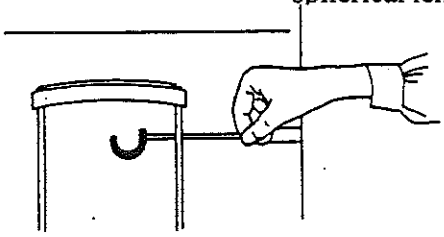
Measuring pupil diameter

e. Name: Subject's SOF ID number here

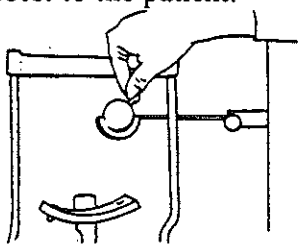
f. Converted B-L Visual Acuity (see page 13a for the converison table):
Right _____ Left _____

g. Refractive correction used for this examination

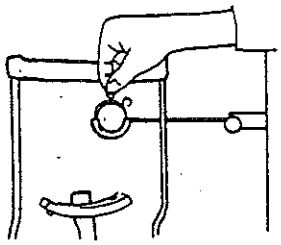
3. Place the appropriate corrective lenses in the trial lens holder. Put the spherical lens closest to the patient.



1. *Move the trial lens holder into the bowl.*



2. *Place the cylinder lens in the slot farthest away from the patient and align axis.*



3. *Place sphere lens in the slot closest to the patient.*

The patient's refraction will be modified for testing as follows:

a) For cylinders of +0.25 diopters or less, do not put in a cylinder correction.

b) For cylinders between +0.50 and +0.75, add +0.25 diopters to the sphere to generate the spherical equivalent. Do not put in a cylinder correction.

c) For cylinders of +1.00 or greater, the full cylindrical correction should be given. Do not forget to enter the axis.

d) All subjects should have a +3.25 Sphere add.

4. Select the 76 point screening, supra threshold related, test from the menu on the screen of the instrument.

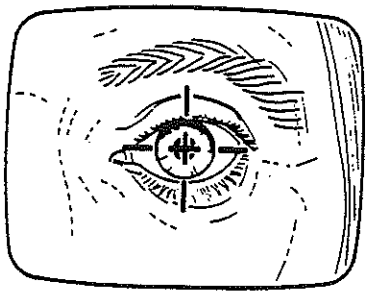
5. Check the test parameters on the instrument screen. All test parameters should be set to standard test parameters, as follows:

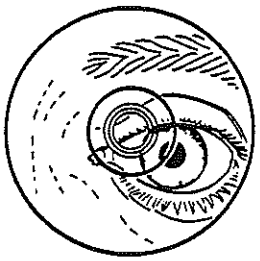
   Threshold strategy - **supra threshold**
   Fixation target - central
   Blind spot check - III
   Stimulus size - III
   Stimulus color - while
   Foveal threshold - off
   Fluctuation test - off

6. A the start of every week, a blank formatted diskette is inserted in both the upper and lower drives for storage of the examination results.

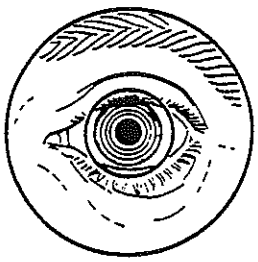
2.7.2 Procedures

The subject should be seated at the instrument with the left eye occluded using the plastic eye patch listed in the supply list. Have the subject's chin resting on the chin cup and their forehead firmly placed against the forehead rest. The subject may hold the response button in their right or left hand. The operator should explain the test procedure by reading the test procedure description on the screen of the instrument. After the description, the subject's eye should be aligned by looking at the screen and centering the subject's eye in the mires using the horizontal and vertical alignment wheels. The trial lens combination should then be placed close to the subject's eye, making sure that the lashes do not touch the lenses.





Realignment required



Correct alignment

a) Testing

1. First demonstrate the test procedure by invoking the demonstration by touching the box on the screen with the stylus that corresponds to the demonstration program.
2. After the demonstration, start the test by touching "start" with the light pen.
3. Alignment should be checked continually by watching the subject's eye on the screen and adjusting the horizontal and vertical knobs, if needed.

4. If the subject has 3 or more errors, then stop the test and reposition subject and reinforce instructions. Then restart the test from the beginning. The test should be completed regardless of the number of errors the second time. Please note that this was done on the Form ____. After the procedure is completed in the right eye, allow the subject to rest while you reset the test procedure, change the lenses, then repeat for the left eye.

b) Printing and storing results

After each eye is tested, the results are printed using the numeric format. The printed results for each eye should be stored in the subjects folder along with all other forms generated during the examination process. Once printing is completed, the examination results are stored by touching the "save on disk" command with the light pen. This will save the results on both the upper and lower drives. The files stored on these drives should be identical and one will serve as the back-up for the other.

At the end of each week, both diskettes are removed from the machine and labeled with the following information:

- SOF-ES Center Number
- Diskette number
- Date
- Study numbers of persons who have data on the disk

One diskette should be stored at the study center and the other diskette should be Fed-Exed to:

Dr. Anne Coleman
Attn: Jackie Sanguinet, COT
JSEI Room 2-118
100 Stein Plaza
Los Angeles, CA 90095-7004

2.8

Intraocular Pressure Measurements

2.8 PROCEDURE FOR MEASUREMENT OF INTRAOCULAR PRESSURES USING THE MENTOR TONOPEN XL

Overview:

The Mentor Tonopen XL unit is a precision electronic tonometer which measures intraocular eye pressures (IOP). The Tonopen is easy to use and can measure IOP reliably with minimal training. It is easily portable and versatile. The accuracy of the Tonopen is equal to that of other electronic applanation tonometers. It is highly correlated with Goldmann applanation tonometry and other measurements of intraocular pressure.

Intraocular pressure is measured in both eyes using the Tonopen before the pupils are dilated.

2.8.1 Calibration check

a) The Tonopen is internally calibrated, thus the instrument calibration should be checked only before the first use each day, after changing batteries, or after depressing the RESET button.

b) If the previous calibration was good, the LCD (the small window on the Tonopen that displays messages) will briefly display "----" followed by "====" and a beep.

c) If the previous calibration was bad, then a long beep sounds, followed by "CAL" and a short beep. The display will then change to "----" and another short beep will sound.

d) Hold the Tonometer vertically with the probe tip pointing straight down.

e) Press and release the activation switch twice in rapid succession. Two beeps will sound and "CAL" will appear on the LCD.

f) Wait until a beep sounds and "UP" appears.

g) Quickly turn the Tonopen XL unit so that the probe tip is pointing straight up.

h) Wait a few seconds. A second beep will sound indicating the end of the calibration check.

i) Read the output on the LCD. If it says "Good" it was successful, if it says "bAd" it was not and you need to repeat the process.

2.8.2 Patient Preparation

a) Instill one drop of the Ophthetic (topical anesthetic) into the lower fornix of the eye to be examined. Avoid contact with lashes or lid margins.

b) Position the patient in front of a fixation target (any item at eye level at least 3 ft away that the patient can look at with the eye not being tested) to minimize eye movement.

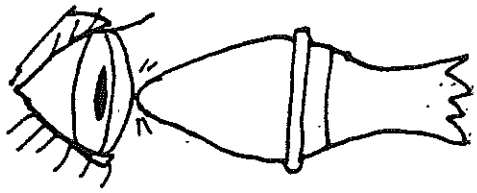
c) Place a fresh latex Ocufilm cover over the tono-tip for each patient. It is not necessary to change it between testing the eyes of the same patient, unless a patient has had eye surgery within the past month.

2.8.3 Patient Examination

a) In order to measure the eye pressure of the right eye, you need to instruct the patient to look at the fixation target with the left eye.

b) Hold the Tonopen XL as you would a pencil.

c) Position yourself to facilitate viewing of the probe tip and patient's cornea (the very front of the eye). Central corneal contact is recommended.



d) Before making contact with the cornea, activate the Tonopen XL unit by depressing the activation switch momentarily, then release.

e) The LCD will change to "═══" and a beep will sound when the Tonopen XL is ready to take a measurement.

f) Once activated, touch the tip to the cornea lightly and briefly, then withdraw. Repeat several times. The corneal surface needs to be momentarily contacted; indentation is not required and may lead to inaccurate readings.

g) A click will sound and a digital IOP measurement will be displayed each time a valid reading is obtained.

h) After four (4) valid readings are obtained, a final beep will sound and the averaged measurement will appear on the LCD along with the single bar denoting the amount of statistical error (reliability). 5% or less reliability is required for accurate measurement to be recorded.

i) If there was 5% or less statistical error, then only two additional average eye pressures should be obtained so that on form ___ there will be a total of 3 average eye pressure measurements with a statistical error of 5% or less.

If there was greater than 5% statistical error, then take a fourth reading. Record each of the average eye pressures (a total of 4) and its statistical error (a total of 4).

j) To take another measurement, reactivate the Tonopen XL unit by pressing the activation switch as described previously.

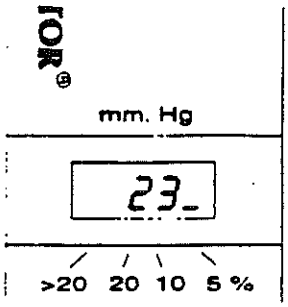
k) Now, measure the eye pressure for the left eye.

l) Replace the Ocufilm tono-tip cover before using the Tonopen XL on another patient and before storage.

m) Do not clean the Tonopen tip. See the instructions for cleaning the Tonopen in the Tonopen Appendix.

n) If the eye pressure is equal to or greater than 30 mmHg, the subject should not be dilated. The subject should have one non-dilated Canon Fundus photograph per eye. If the pressure is greater than 35 mmHg, the subject should be referred to an ophthalmologist within 8 hours.

o) If the eye pressure is between 24 and 30 mmHg, the subject can be dilated if there are no other exclusions. The subject should be referred to an ophthalmologist within one week.

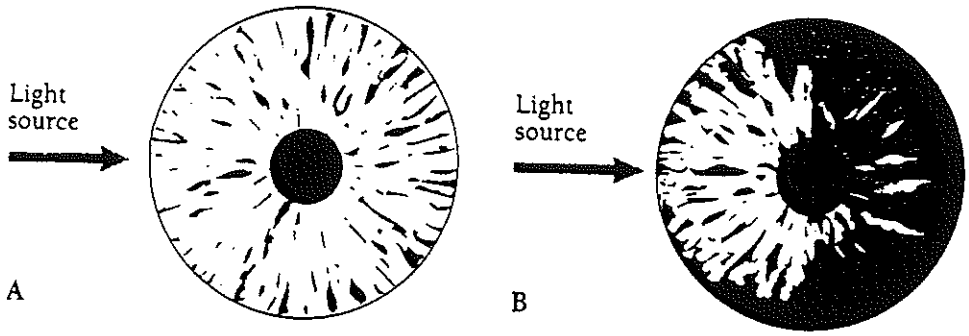


2.9

Pupil Dilation

2.9 PUPIL DILATION

Angle depth should be estimated with penlight. The penlight is held several inches from the temporal limbus of the cornea with its light beam traversing horizontally across the anterior chamber of the eye. In patients with wide open angles, the light will be seen from the temporal limbus to the nasal limbus. If the chamber is shallow, a shadow will be cast onto the nasal iris due to the bowling forward of the lens-iris diaphragm in patients with shallow anterior chamber (van Herick W, Shaffer RN: Estimation of width of angle of anterior chamber; Incidence and significance of the narrow angle. AM J Ophthalmol 68:624-629, 1969).



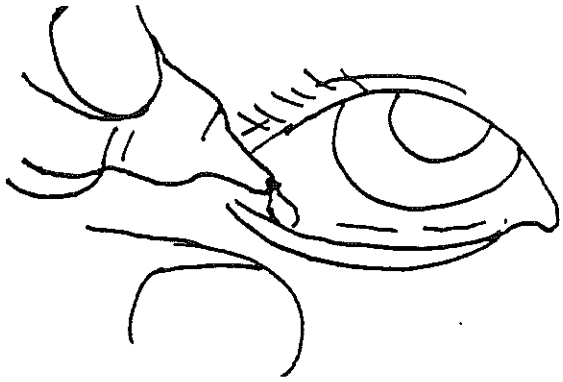
Whether or not the subject is to be dilated, record the pupil size of both pupils on Form ____. If it is okay for the subject to be dilated, dilate both eyes with one drop of 1% tropicamide. Make sure the subject closes their eyes after you instill the drop and practices nasolacrimal occlusion. While the eyes are dilating, the patient may go back to the central waiting area or continue to the next station in the SOF exam . After a period of 30 minutes, the examinee will be brought back by the examiner for the remainder of the examination.

Persons not to dilate:

1. Subject's eye doctor told patient to not be dilated
2. Subject is allergic to dilating drops
3. Subject refuses dilation
4. Anterior chamber appears to be narrow by penlight exam
5. Subjects with eye pressures of 30 mmHg.

For patients, who can not or are not dilated, place the subject in a dark room,(with the canon fundus camera) or patch both eyes for 10 minutes. One non-dilated canon fundus photograph should then be taken of the right eye. Repeat this procedure for the left eye. These subjects will not be eligible for lens photographs with the Topcon or Marcher cameras.

Adequate dilation of the pupil is important to permit good quality photography. Sufficient time should be allowed for dilation to at least 6mm, if necessary, to achieve and maintain a pupil of at least this size during photography. You may use a millimeter ruler held up near the patient's eye to determine the size of the pupil. Remember to check pupil dilation with a bright light. If the pupil is not 6mm in diameter, another set of drops may be instilled. If after another 30 minutes the pupil is not 6mm, the subjects should still be prepared for the next part of the exam.



Proper placement of eyedrops in a patient's eye. Note that the patient is looking up and away from the bottle tip, that the tip does NOT touch the patient's eyelid or eye, and that the lower lid is gently held down to form a "pocket" for the drop.

2.10

Home Examination

SOF-ES MEMO

Re: Home Visit Visual Acuity

A question came up about measuring visual acuity with the Good-lite box during the home visits. The score sheet asks for visual acuity in the form of a Snellen Fraction at ten feet (20/20, 20/30, etc.). The scores on the chart are written as if they were at 20 feet, such as 20/20, 20/30, etc, but they have been converted to reflect the ten foot distance by the manufacturer.

The question arises if you need to move the participant to **5 feet.** When using Snellen fractions to record visual acuity at five feet during the home visit, all you need to do is double the denominator from the ten-foot chart. See the example below:

EXAMPLE:

At 5 feet the participant reads the ***20/100*** line on our 10-foot Good-lite box. You would record it as ***20/200*** and mark the five foot box for distance on the form.

SOF-ES MEMO

Re: Home visit participants that switch to clinic visits

If a participant starts out as a "Home Visit" participant and then switches and comes to your clinic for a portion of the SOF-ES exam, please do as much as possible of the vision exam in the clinic, including photographs, as long as the participant is willing. Also, repeat the visual acuity using the Bailey-Lovie chart and do contrast sensitivity.

2.10 HOME EXAMINATION

2.10.1 Patient Identification

The examinee's SOF record number, date of birth, date of examination and place of examination will be filled in when the patient is first registered for the eye examination. Under the place of examination; 1 = "clinic" refers to the SOF-ES examining rooms, 2 = "local" refers to any exam done by the SOF-ES staff outside the "clinic", e.g., in the examinee's home, nursing home, hospital, etc.

In all exams, the right eye will be evaluated first. Prior to beginning the exam, the examiner will determine the status of both eyes by asking the following questions;

1) "Have you ever had an eye removed?" If the patient indicates that she has had an eye removed, determine which eye and record on the form ____. This question includes enucleation and phthisis bulbi (a blind eye which is obviously smaller than normal).

2) Do you have any of the following: glaucoma, macular degeneration, cataracts, uveitis (Inflammation of the eyes), a history of a stroke or hemorrhage in the eyes, diabetes in the eyes, or a corneal graft or transplant? Record on Form ____.

3) Have you ever had cataract surgery? If so, which eye and when? Record on Form ____.

4) Did you have intraocular lens implants? If so, which eye and when? Record on Form____.

5) Have you ever been hit in the eye? If so, which eye and when? Participants will also be asked about other eye surgeries and about the use of systemic and topical eye medications. Record all answers on Form ____.

Finally, each participant will be asked five questions about their current visual functioning.

2.10.2 Visual Acuity Testing Using A Portable Eyetest Case

a) Illumination: It is important that all of the vision tests be performed in areas of UNIFORM illumination, e.g., no abrupt changes in illumination or shadows when moving a few feet or changing orientation. The portable eye test case is illuminated, so abrupt changes in illumination should not be a problem.

b) Distance: The test is administered with the participant seated at 10 feet from the eyetest case. Measure from the eyetest case to the middle of the chair.

c) Glasses: Acuity is tested with habitual correction for distance vision and a second time for each eye using pinhole acuity.

Before testing vision, ask the subject if she normally wears glasses all the time, wears them for distance vision only, wears glasses for reading only, wears bifocals, or if she does not wear glasses. (probes: "Do you wear glasses to see things far away, like when you go to a movie theater or when you drive a car?") If she answers that she has glasses for distance but sees better without them, distance tests should be performed with glasses on.

2.10.3 Equipment

a) Illuminated eye chart

b) Pinhole occluder

c) A pointer

2.10.4 Measurement Procedures

a) The portable eye test case should be placed at approximately the eye level of seated subjects. Seat subject on straight-backed chair, 10 feet from the midline of the body to the chart. Use a pointer to indicate rows on the chart.

b) If the participant wears glasses (bifocals or regular glasses) for distance viewing, such as driving, walking or at a theater, test with her glasses on. If she only wears glasses (bifocals or regular) when she reads, test distance vision at 10 feet without glasses. Test contact lens wearers with lenses in. If a participant says that she wears glasses but sees better without them, test WITH THEM (her "normal" state).

c) Ask the subject to hold the occluder so that her left eye's vision is blocked and only the right eye can be tested. Then ask the subject to start reading the letters on the chart starting with the row with the double bar, proceeding down the chart toward the smaller letters. Say:

"Id like you to read aloud the letters on this chart. (Read from left to right)

Don't squint and don't lean forward. Start at the row with the double bar and read down as far as you can and then say 'That's all'.

Now, can you easily read the row with the double bar?"

If she says yes or reads the row without error then say:

"OK (begin/continue)."

If she says no or reads it with one or more errors, then say:

"How about the top row? Can you read that one?"

If she says no or reads it with error, then test at 5 feet (low vision distance) using the same procedure. Be sure to record that you are testing at 5 feet.

d) As the subject reads, keep a running tally of the total number of letters missed by drawing a line over those read correctly and drawing a line through the incorrect ones.

e) When it is apparent that the subject is struggling (e.g. misses 3 or 4 letters on a row or goes very slowly) then point to the next row and say:

"I want you to try reading the next row even if y ou just have to guess"?

Note the errors on that row, then stop. If she misses all 5 letters on a row, add those to your tally and then stop. If she says "That's all," in the middle of a row, have her guess at the rest of the row and then stop. Draw a line through the first row not attempted.

f) REMEMBER TO RECORD THE NUMBER OF LETTERS READ CORRECTLY. The number next to each line on the score sheet is the number of all the letters from the top row to that row. So, if a subject attempted to read up to the line marked 40, she read a total of 40 letters. Compute the number of letters she read correctly by subtracting the number of letters crossed off from the number on the last line read e.g. 40 - 5 crossed off = 35 correct.

g) Now have the subject hold the occluder so that the vision is still blocked in the left eye. Put the pinhole occluder in front of the right eye (with glasses on) and ask if they can read any more letters on the last row that they read. If they can, record the additional number of letters that can be read on Form ____. If they cannot read any more letters, please mark the form with "0".

h) For subjects that cannot see the chart at 5 feet, you need to test their vision with your fingers. Finger counting is tested by holding two or three fingers two feet from the patient and should be recorded as CF@____feet. Hand motion is tested by moving a hand back and forth in front of the patient with the other eye occluded. This recorded as HM@___feet. Light perception should be tested by carefully occluding the fellow eye and directing the light of the penlight at the examinee's eye from about a one- foot distance. This is recorded as LP@___1 foot. No light perception is recorded as NLP

i) The subject now holds the occluder so that the vision from the right eye is blocked. Steps c-h are then repeated.

2.10.5 Procedure For Measurement Of Intraocular Pressures Using The Mentor Tonopen

Overview:

The Mentor Tonopen XL unit is a precision electronic tonometer which measures intraocular eye pressures (IOP). The Tonopen is easy to use and can measure IOP reliably with minimal training. It is easily portable and versatile. The accuracy of the Tonopen is equal to that of other electronic applanation tonometers. It is highly correlated with Goldmann applanation tonometry and other measurements of intraocular pressure.

Intraocular pressure is measured in both eyes using the Tonopen before the pupils are dilated.

2.10.5.1 Calibration check

a) The Tonopen is internally calibrated, thus the instrument calibration should be checked only before the first use each day, after changing batteries, or after depressing the RESET button.

b) If the previous calibration was good, the LCD (the small window on the Tonopen that displays messages) will briefly display "----" followed by "====" and a beep.

c) If the previous calibration was bad, then a long beep sounds, followed by "CAL" and a short beep. The display will then change to "----" and another short beep will sound.

d) Hold the Tonometer vertically with the probe tip pointing straight down.

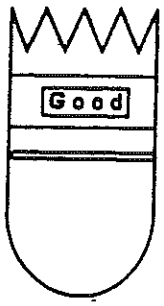
e) Press and release the activation switch twice in rapid succession. Two beeps will sound and "CAL" will appear on the LCD.

f) Wait until a beep sounds and "UP" appears.

g) Quickly turn the Tonopen XL unit so that the probe tip is pointing straight up.

h) Wait a few seconds. A second beep will sound indicating the end of the calibration check.

i) Read the output on the LCD. If it says "Good" it was successful, if it says "bAd" it was not and you need to repeat the process.



2.10.5.2 Patient Preparation

a) Instill one drop of the Ophthetic (topical anesthetic) into the lower fornix of the eye to be examined. Avoid contact with lashes or lid margins.

b) Position the patient in front of a fixation target (any item at eye level at least 3 ft away that the patient can look at with the eye not being tested) to minimize eye movement.

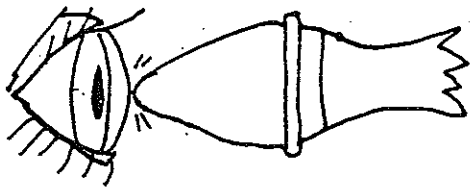
c) Place a fresh latex Ocufilm cover over the tono-tip for each patient. It is not necessary to change it between testing the eyes of the same patient, unless a patient has had eye surgery within the past month.

2.10.5.3 Patient Examination

a) In order to measure the eye pressure of the right eye, you need to instruct the patient to look at the fixation target with the left eye.

b) Hold the Tonopen XL as you would a pencil.

c) Position yourself to facilitate viewing of the probe tip and patient's cornea (the very front of the eye). Central corneal contact is recommended.



d) Before making contact with the cornea, activate the Tonopen XL unit by depressing the activation switch momentarily, then release.

e) The LCD will change to "====" and a beep will sound when the Tonopen XL is ready to take a measurement.

f) Once activated, touch the tip to the cornea lightly and briefly, then withdraw. Repeat several times. The corneal surface needs to be momentarily contacted; indentation is not required and may lead to inaccurate readings.

g) A click will sound and a digital IOP measurement will be displayed each time a valid reading is obtained.

h) After four (4) valid readings are obtained, a final beep will sound and the averaged measurement will appear on the LCD along with the single bar denoting the amount of statistical error (reliability). 5% or less reliability is required for accurate measurement to be recorded.

i) If there was 5% or less statistical error; then only two additional average eye pressures should be obtained so that on form ___ there will be a total of 3 average eye pressure measurements with a statistical error of 5% or less. Record each average eye pressure measurement and each statistical error on the form.

If there was greater than 5% statistical error; take a fourth reading. Record all 4 average eye pressure measurement and each statistical error (a total of 4) on Form ____.

j) To take another measurement, reactivate the Tonopen XL unit by pressing the activation switch as described previously.

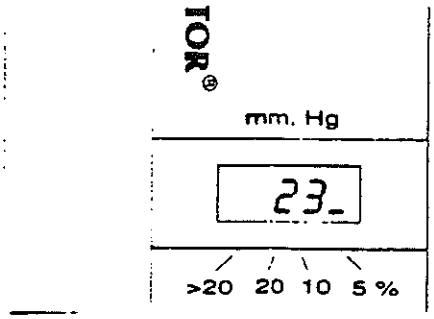
k) Now, measure the eye pressure for the left eye.

l) Replace the Ocufilm tono-tip cover before using the Tonopen XL on another patient and before storage.

m) Do not clean the Tonopen tip. See the instructions for cleaning the Tonopen in the Tonopen Appendix.

n) If the eye pressure is equal to or greater than 30 mmHg, the subject should not be dilated. However, if the pressure is greater than 35 mmHg, the subject should be referred to an ophthalmologist within 8 hours.

o) If eye pressure is between 24 and 30 mmHg, the subject should be referred to an ophthalmologist within one week.



2.11

Adverse Event(s)

SOF-ES MEMO

Re: Adverse Events

Just a reminder that we are available at Jules Stein Eye Institute to offer back-up and advice when you encounter an adverse event. Please page Jackie at 1-800-233-7231, ID#94381, if you need advice or have a question.

Please notify Jackie Sanguinet at the above number as soon as possible of an adverse event so that she can relay that information to the Primary and Co-Investigators and follow-up with you concerning the participant.