



National Health and Nutrition Examination Survey (NHANES)

Ophthalmology Procedures Manual



January 2008

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1. OVERVIEW OF OPHTHALMOLOGY

1.1 Background

The leading causes of visual impairment in the United States are primarily age-related eye diseases including cataracts, diabetic retinopathy, glaucoma, and age-related macular degeneration. More than 3.4 million Americans aged 40 years and older are either blind or are visually impaired. Although it is believed that half of all blindness can be prevented, the number of people with blindness continues to increase in the United States. Unfortunately, scant data exist for national estimates and trends, and current estimates are based on data that are 25 years old and not nationally representative.

Glaucoma is the leading cause of irreversible blindness and is a prevalent disease associated with aging. Although glaucoma can usually be controlled by early detection and treatment, half of the people with glaucoma are not diagnosed, and glaucoma is still the number one blinding disease among African Americans.

Diabetic retinopathy is the leading cause of new cases of blindness among adults aged 20-74 years. It can affect almost anyone with diabetes and contributes to both individual and societal burden. With the growing epidemic of diabetes and demographic changes in the American society, vision loss and eye diseases due to diabetes will be a growing major public health problem. Efficacious and cost-effective strategies to detect and timely treat diabetic retinopathy are available, but among people with diabetes, ocular eye examination is received by only about two-thirds of the persons for whom the exam is recommended and varies significantly across health care settings.

Age-related macular degeneration (AMD) is the leading cause of visual impairment and blindness in the U.S. among people aged 65 years or older. The frequency of AMD is expected to increase as the population lives longer. Population-based estimates of the prevalence and severity of AMD will help in allocating resources as treatment modalities become available.

1.2 General Overview of Procedures

Prior to the ophthalmology testing, the SP will complete the NHANES Vision examination component which includes visual acuity and objective refraction for SPs aged 8 years and older in addition to a near vision exam on SPs 50 years and older. The visual acuity and objective refraction tests in the current vision component must be completed prior to completing the examinations in the ophthalmology component because the flash from the retinal imaging may affect the visual acuity results. The coordinator will not assign SPs to the ophthalmology component until they have completed the vision component.

The ophthalmology exam will be completed on all SPs aged 40 years and older. SPs will be excluded if they have an eye infection, eye patches, or blindness.

Two eye examinations will be completed for the ophthalmology study. The first exam performed will be the visual field testing using Frequency Doubling Technology (FDT) perimetry. FDT perimetry tests for visual field loss from glaucoma. The second exam will be digital fundus photography using an ophthalmic digital imaging system to assess the presence of diabetic retinopathy, age-related macular degeneration, and other retinal diseases. The average time needed to complete both exams is 14 minutes.

1.3 Integrated Survey Information System (ISIS)

The Integrated Survey Information System (ISIS) is a computer-based infrastructure designed to support all survey operations including sample management, data collection, data editing, quality control, analysis, and delivery of NHANES data. Each component in NHANES such as Cardiovascular (CV) Fitness has a computer application for direct data entry. Data collected in the ophthalmology room of the mobile examination center are directly entered into the ISIS system computers. For more information about the NHANES and the ISIS system, see the ISIS Manuals and Presentations/ISIS Overview Presentation on the IntraWeb.

2. EQUIPMENT/SUPPLIES/MATERIALS

The ophthalmology component of the National Health and Nutrition Examination Survey (NHANES) uses two major instruments to complete the tests. The Humphrey Matrix Visual Field Instrument uses Frequency Doubling Technology (FDT) perimetry to test for visual field loss from glaucoma. The Canon CR6-45NM ophthalmic digital imaging system is used to assess the presence of diabetic retinopathy, age-related macular degeneration, and other retinal conditions. This chapter provides a description of the equipment and supplies as well as setup and calibration procedures for this component.

2.1 Ophthalmology Equipment and Supplies

A list of the equipment and supplies used in this component is provided below. The equipment is described in detail in Section 2.2. See Appendix C for diagrams of the equipment.

2.1.1 Nonconsumables (Instruments and Equipment)

- Humphrey Matrix Visual Field Instrument (with keyboard and SP response button);
- FDT chin rest;
- Canon CR6-45NM ophthalmic digital imaging system;
- Canon EOS 10D digital camera;
- Canon DCS Adaptor for Imaging System;
- Motorized instrument table;
- Pneumatically adjustable stools with backrest;
- Dust covers for the Visual Field Instrument and Canon digital imaging system;
- Small reading lamp with red bulb; and
- DYMO Label/Writer.

2.1.2 Supplies (Consumables)

- Canon camera fuses (125V, 4 amps);
- Lens cleaning alcohol;
- Absorbond lens wipes;
- Goo Gone;
- Lint-free Kimwipes;
- Cotton tipped applicators;
- Air bulb and brush;
- Penlight;
- Facial tissues;
- CD-Rs and jewel cases, CD labels;
- DVDs and jewel cases, labels;
- Preprinted shipping labels and envelopes; and
- Alcohol wipes.

2.2 Equipment Description, Setup, and Operating Procedures

The equipment used for the ophthalmology component is described below along with the procedures for initial setup, daily operation, and calibration.

2.2.1 Humphrey Matrix Visual Field Instrument

The Humphrey Matrix Visual Field Instrument is an automated visual field instrument that provides rapid, clinically validated and user-friendly visual field testing. A sliding SP visor aids in the selection of the eye to be tested and automatically occludes the opposite (untested) eye. A keyboard with an integrated track pad controls the operation of the instrument and the printer. The instrument has a

detachable SP response button. Figure 2-1 shows the instrument from the examiner's view and Figure 2-2 shows the instrument from the SP's perspective. Additional diagrams are found in Appendix C.



Figure 2-1. Humphrey Matrix Visual Field Instrument (examiner side)



Figure 2-2. Humphrey Matrix Visual Field Instrument (SP side)

2.2.1.1 Setup Procedures for the Humphrey Matrix

First, unpack the FDT chin rest from its designated box and place the chin rest on the FDT platform with the two horizontal metal bars facing the SP side. Next, open the storage box and carefully lift the instrument from the box and position it on the table.

Confirm Inventory

Check that all items listed below are present:

- Visual Field Instrument;
- Calibration cap covering the SP's eyepiece inside the SP visor;
- SP response button and response button holder;
- Instrument power cord;
- Keyboard; and
- Dust cover.

Preparation for Use

Lay the instrument on its side to prepare it for use and connect each component as outlined below:

- **SP Response Button:** Plug the SP response connector into the small round connector jack towards the SP end, underneath the base of the unit near the SP response symbol. See Figures 2.3 and 2.5.
- **Keyboard/Touchpad:** Plug the keypad and touchpad connectors into their jacks located underneath the base of the unit near the keyboard and mouse symbols, towards the operator's side. Match the symbols on the connectors with the labels on the jacks. See Figures 2.4 and 2.5.



Figure 2-3. SP Response Button



Figure 2-4. Keyboard/Touchpad

- **Power connector:** Plug the power cord into the appropriate power cord INPUT receptacle. (Don't confuse this with the OUTPUT receptacle for the printer). See Figure 2-5.



Figure 2-5. Power connector

Be sure all connections are fully seated. Once all the cables are connected, turn the instrument upright and place it on top of the metal base of the chin rest, being careful not to place the instrument feet on top of any of the cables. Ensure that the feet of the FDT machine rest completely in the indentations of the metal base of the chin rest so the machine rests on a flat surface.

2.2.1.2 General Operation

Turning the Instrument ON

- Locate the power switch on the left side of the instrument when facing the operator side and confirm that it is in the OFF (O) position **before** plugging the instrument into a power outlet;
- To turn the instrument ON, connect the instrument's power cord to a power outlet, then switch the power switch (O/I) to the ON (I) position; and
- The Main Menu will be displayed.

Turning the Instrument OFF

- Select Shut Down (lower right corner of the LCD) to turn OFF the instrument;
- Wait until the message "safe to shutdown" appears (~1 minute) before turning OFF the main power switch (left side of the instrument when facing the operator side); and
- NOTE: Turning the main power switch OFF with out selecting Shut Down will make it take longer to power up next time and could potentially corrupt the Matrix software and require service to restore normal operation.

Keyboard and Touch Pad Operations

- The keyboard function is similar to a normal computer keyboard;
- Pressing ALT and the underlined letter or number on the button selects the button;
- The touch pad controls the cursor like a mouse;
- The left button is used to select items or buttons. Double tapping the touchpad is the same as clicking the left button; and
- The right button is not active for the Matrix software.

2.2.1.3 Screens Overview

The functions of the Humphrey Matrix instrument are organized into various screens. The screen name is displayed at the top of every screen with the date and time at the bottom of the screen. The Shut Down button is also located at the bottom of the screen. The right side of the screen displays the main toolbar. The toolbar buttons may be selected with the mouse or the hot keys shown in the button icons (F1-F6 and Esc). The Esc button displays the screen that was viewed previously and the Enter key selects the default button on a screen.

2.2.1.4 Calibration

The calibration for the Humphrey Matrix Visual Field Instrument is automatically checked each time the instrument is powered ON and at the start of each test to be sure the unit is properly calibrated. If the instrument detects the need for calibration, the Operator LCD display will display a needs calibration warning. If not calibrated when the needs calibration warning is displayed, the unit will continue to operate normally until the unit reaches the calibration limits. Once the calibration limits are reached, the unit will not operate normally until a calibration is completed successfully. See below for directions on calibration.

Frequency of Calibration:

- **Daily:** The automatic calibration will be done at least once daily when the instrument is turned on; and
- **Start of Stand:** A calibration should be performed on the Humphrey Matrix Visual Field Instrument at the beginning of each stand and whenever a needs calibration warning is displayed.

Performing Calibration

- An automatic calibration is performed when the instrument is turned on; and
- To perform a manual calibration at the Start of Stand complete the following steps:
 - At the Main Menu screen on the FDT unit, select **F6**.

- Select 'Calibration';
- On the next screen, select "Calibrate";
- Select **OK** to message "Please attach calibration cap...";
- Calibration Progress Bar will be displayed; and
- Calibration will take approximately 5-10 minutes. Return to Main Menu Screen.

2.2.1.5 Backup of the FDT

Complete backup of the data is conducted by the ISIS. In addition, backup of the FDT data from the previous stand is completed on a CD which is subsequently sent to the Westat home office.

Frequency of backup:

- **Start of Stand:** A backup of the FDT data to a CD should be performed on the Humphrey Matrix Visual Field Instrument at the beginning of each stand. This backup is in addition to the complete backup of the data through the ISIS.

Performing backup:

- To perform a backup at the Start of Stand complete the following steps:
 - Label a CD with **Stand #** and **Date**;
 - **Insert a CD** in the CD Drive;
 - At the Main Menu screen on the FDT unit, select '**Backup**';
 - The process will take 2-3 minutes; and
 - Remove the CD and send to project staff at the home office.

2.2.1.6 Cleaning and Maintenance

The **housing surfaces** of the instrument should be cleaned with disposable alcohol-based wipes. The **SP eyepiece window** and **operator LCD display** should be cleaned with soft lint-free Kimwipes or lens cleaner if necessary. Do not use soap. The **SP contact surfaces** (forehead rest, chin rest, and SP response button) should be cleaned with alcohol swabs.

Frequency of Cleaning:

- **Daily:** The SP eyepiece window and operator LCD display should be **inspected daily** and cleaned only if necessary. The SP contact surfaces should be cleaned daily and prior to each SP exam;
- **Weekly:** The housing surfaces of the instrument should be cleaned; and
- **Start of Stand:** All daily and weekly cleaning procedures should be completed.

2.2.1.7 Repair of Equipment

Contact for Repair or Replacement of Parts:

Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, California 94568
Phone: 877-486-7473
Fax: 925-557-4101
Email: info@meditec.zeiss.com
www.meditec.zeiss.com

2.2.1.8 Equipment Manuals

The following equipment manual is kept in the Ophthalmology room on the MEC.

- *Humphrey Matrix Visual Field Instrument User's Guide.*

2.2.1.9 Troubleshooting

Table 2-1 outlines some problems that may occur and lists some things to check to try to trouble shoot the problem. If the problem is not resolved, contact the home office project staff person responsible for this component.

Table 2-1. Troubleshooting problems with the Humphrey Matrix Visual Field Instrument

Problem	Area to check
Matrix will not power up	Check the Matrix power cable connections. Replace power cord if defective. Ensure that the power cord is inserted firmly in the Matrix power input receptacle. The receptacle is located underneath the base of the instrument. Make sure the outlet being used is working. Connect instrument power cord to a working outlet.
The Matrix will turn on but will not boot up to the Main Menu screen.	Turn the Matrix OFF and let sit for 10 seconds. Turn unit back on and try again.
The Matrix will boot up to the Main Menu screen but will not perform a test.	Turn the Matrix OFF and let sit for 10 seconds. Turn unit back on and try again. Perform a calibration from the Help (F6) screen.
Receive message "Not enough space left on the disk" message.	Check to make sure the disk is not write-protected.

2.2.2 Canon CR6-45NM Ophthalmic Digital Imaging System and Canon EOS 10D Digital Camera

The Canon CR6-45NM digital imaging system is a non-mydratiatic retinal camera equipped with a Canon EOS 10D digital camera back. See Figures 2-6 and 2-7.



Figure 2-6. Canon CR6-45NM ophthalmic digital imaging system



Figure 2-7. Canon EOS 10D digital camera

2.2.2.1 Setup Procedures for the Canon CR6-45NM Ophthalmic Digital Imaging System

Open the storage box and carefully lift the instrument from the box and position on the table.

Confirm Inventory

Check that all items listed below are present:

- Canon CR6-45NM ophthalmic digital imaging system with lens cap;
- Canon EOS 10D digital camera;
- Instrument power cord; and
- Dust cover.

2.2.2.2 General Operation

Turning the Instrument ON

The Canon EOS 10D must be turned on first. This is done using the two small dials located on the back of the camera. See Figure 2-7. The EOS 10 D must be turned on first because the Canon CR6-45NM fundus camera looks for the other camera during startup.

The Canon CR6-45NM is turned on with the power switch located on the right side of the main unit. See Figure 2-6. The video display is activated once the power is on. If no photography or switch operations are performed for 10 minutes, a power saving mode is activated and the lamps and display are turned off to prevent unnecessary wear. During the power saving mode, a green “ready” light blinks on the monitor. Press any button to reactivate the system.

The flash power setting located at the right-hand corner of the monitor blinks when the main unit is switched on. This indicates that the system is charging up. Once it is fully charged, the blinking stops. Do not attempt to take pictures until the blinking stops.

The camera contains an internal clock and the date will automatically change each day. The technologist must manually change the date if the clock should fail or if the camera is left unplugged for a long period of time. The date is displayed on the fundus camera monitor and is changed through the menu in the “Set 3” screen.

The technologists must check the date and time on the retinal camera and the camera setting on the Canon EOS 10D camera on a daily basis. The settings and procedures for confirming and changing these settings are outlined in the Quality Control chapter, Section 4.3.4.

Turning the Instrument OFF

The camera is turned off at the end of each session. Turn the Canon CR6-45NM fundus camera off first and then turn off the Canon EOS camera.

2.2.2.3 Calibration

No calibration is required. If a problem occurs with the equipment, notify the chief technologist, who will contact the home office.

2.2.2.4 Cleaning and Maintenance

The **housing surfaces** of the instrument and the **SP contact surfaces** (forehead rest, chin rest, and SP response button) should be cleaned with disposable alcohol-based wipes.

If the sticky residue left by the tape cannot be removed from the base with alcohol wipes, Goo Gone can be used. The following guidelines must be followed when using Goo Gone on the MEC.

- Use the product sparingly at least 1 day before the MEC opens for study participants (i.e., set-up day);
- Dispose of the used paper towel OUTSIDE of the MEC; and
- Allow the MEC to air out after use. If possible, leave the back door open when using.

Reminder: Goo Gone should only be used on set-up day and only if it is necessary.

Frequency of Cleaning:

- **Daily:** The SP contact surfaces should be cleaned daily and prior to each SP exam. Inspect the camera lens with a penlight and if necessary clean camera lens by following daily cleaning instructions specified below.

Procedures for Inspection and Cleaning of the Camera Lens:

Wear a disposable glove for all cleaning and maintenance of the camera lens. The camera lens should be inspected daily with a penlight for dust, debris, streaks, and smudges. Point the penlight to the surface of the lens and view the lens at different angles. Use the air bulb to remove any debris detected on the surface. Hold the air bulb a few centimeters in front of the lens at a 45 degree angle and blow once. Inspect lens again with penlight. If debris is still detected, clean the lens from the center outward in a circular motion using Absorbond lens wipers wrapped around a cotton-tipped applicator sprayed or dabbed with lens cleaner or an alcohol swab to dampen it. Repeat a second time **only** if debris is still seen on the lens. It is very important to use a different part of the Absorbond lens wiper every time you wipe the lens. Clean lens only if necessary.

- **Weekly:** The housing surfaces of the instruments should be cleaned. Inspect the camera lens with a penlight and if necessary clean the camera lens by following weekly cleaning instructions specified above.
 - Wear a disposable glove for all cleaning and maintenance of the camera lens;
 - Turn the camera power on;
 - Turn the Illumination Lamp Knob (on right side of camera) to 10 (maximum);
 - While seated on the examiner side of the camera, turn the I.R. Filter Knob (on right side of camera) towards you;
 - Slide the Diopter Compensating Slider out until it stops;
 - Press the Alignment Switch; and
 - As specified above for the daily cleaning, inspect the lens with the penlight, use the air bulb to remove debris, and if necessary, clean the lens with the Absorbond lens wiper.

Once lens is clean, do the following:

- Set the Illumination Lamp Knob back to between 3 and 4;
 - Slide the Diopter Compensating Slider back in place;
 - While seated on the examiner side of the camera, turn the I.R. Filter Knob away from you;
 - Press the Alignment Switch; and
 - Turn off the camera.
-
- **Start of Stand:** Housing surfaces should be cleaned. Inspect the camera lens with a penlight and if necessary clean the camera lens by following the weekly cleaning instructions specified above.

2.2.2.5 Repair of Equipment

Contact for Repair or Replacement of Parts:

Canon U.S.A., INC
1-800-OK-CANON (1-800-652-2666)

2.2.2.6 Equipment Manuals

The following equipment manual(s) are kept in the ophthalmology room on the MEC:

- Canon Non-Mydriatic Retinal Camera CR6-45NM Operation Manual;
- Canon EOS 10D Digital Instruction Manual;

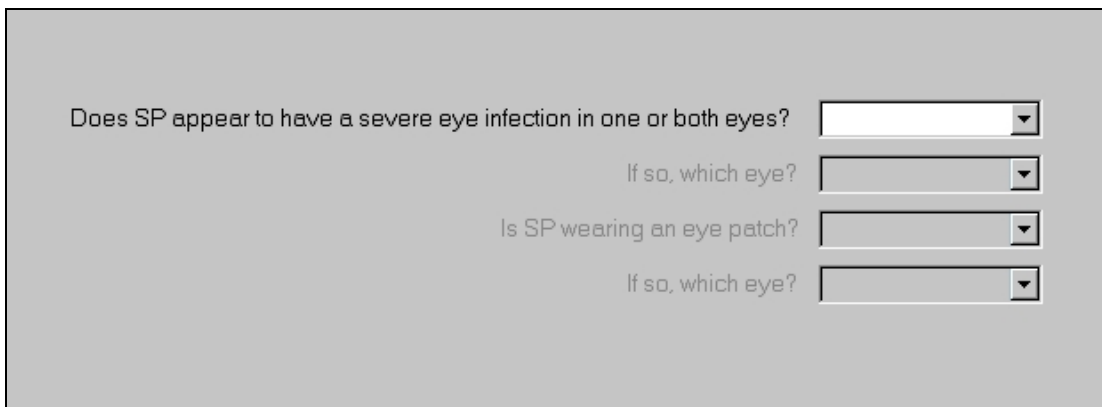
3. PROTOCOL

3.1 Eligibility Criteria

All SPs 40 years and older will be eligible for the ophthalmology study. SPs may be excluded from the ophthalmology component due to blindness, eye infections, or eye patches on both eyes. Although some SPs may not be able to complete the examination due to physical limitation or an eye-specific limitation, all attempts will be made to facilitate the examination and test as many people as possible. The room is designed to accommodate SPs in wheelchairs.

SPs can be excluded from several sources. The first place where an SP can be excluded is based on responses to questions in the Household Interview to determine if the SP meets the criteria for blindness. If the SP is unable to see light with both eyes open, he or she will be excluded from the ophthalmology component. The second source for excluding the SP from ophthalmology is the safety/exclusion observations in the vision component. If the SP responded “Yes” to eye infection or has an eye patch covering both eyes, the SP will be excluded from ophthalmology and will not be assigned to this room. For SPs who are not excluded, the responses to the safety/exclusion questions asked in the vision component will be pulled from the database and displayed on the screen in the ophthalmology component in a read only format. See Exhibit 3-1.

Exhibit 3-1. Safety exclusion observations from vision component



Does SP appear to have a severe eye infection in one or both eyes?

If so, which eye?

Is SP wearing an eye patch?

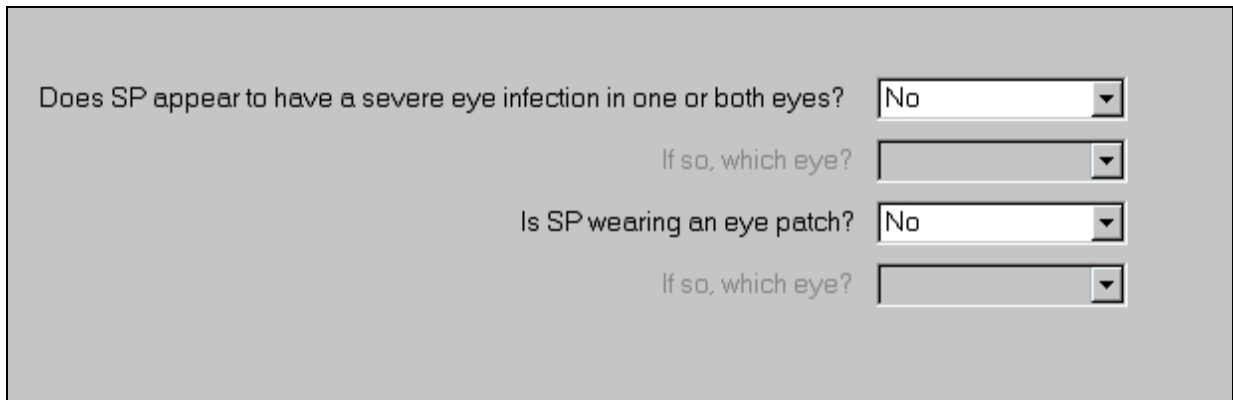
If so, which eye?

The visual acuity and objective refraction tests in the current vision component must be completed prior to completing the examinations in the ophthalmology component because the flash from the light may have a temporary effect on the SPs visual acuity. The coordinator will not assign SPs to the ophthalmology component until they have completed the vision component. The only exception to this is a situation where the SP cannot or does not want to do the vision exam but can or will do the ophthalmology exam. The vision component for that SP must be opened and coded “No Time” or other appropriate reason. The SP will then be assigned to ophthalmology and the exclusion questions can be answered.

3.1.1 Safety Exclusion Questions Completed in Ophthalmology

If the safety exclusion questions are completed in the ophthalmology component, the Safety/Exclusion questions in ophthalmology will be enabled. See Exhibit 3-2. The technologist should attempt to complete the examinations on SPs who are physically disabled, to the point that they can be comfortably positioned at the camera. If necessary, the SP may remain in the wheelchair instead of the adjustable stool.

Exhibit 3-2. Safety exclusion questions completed in ophthalmology

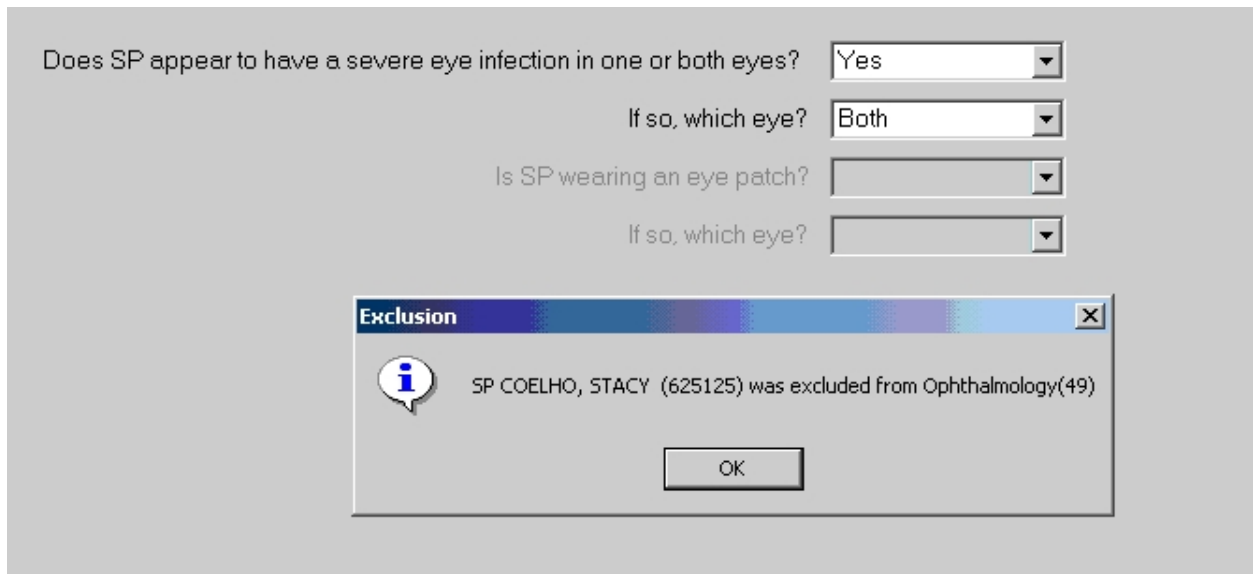


The screenshot shows a form with four questions and their corresponding dropdown menus. The first question is "Does SP appear to have a severe eye infection in one or both eyes?" with a dropdown menu showing "No". The second question is "If so, which eye?" with an empty dropdown menu. The third question is "Is SP wearing an eye patch?" with a dropdown menu showing "No". The fourth question is "If so, which eye?" with an empty dropdown menu.

Does SP appear to have a severe eye infection in one or both eyes?	No
If so, which eye?	
Is SP wearing an eye patch?	No
If so, which eye?	

The health technologist observes the SP's eyes and determines if an eye infection or eye patch is present. SPs with severe eye infection in one or both eyes will be excluded for medical safety reasons. See Exhibit 3-3.

Exhibit 3-3. Exclusion due to eye infection




The screenshot shows a form with four questions and dropdown menus:

- Does SP appear to have a severe eye infection in one or both eyes?
- If so, which eye?
- Is SP wearing an eye patch?
- If so, which eye?

An information dialog box titled "Exclusion" is overlaid on the form. It contains the text: "SP COELHO, STACY (625125) was excluded from Ophthalmology(49)" and an "OK" button.

If the SP is excluded based on an eye infection, the component status screen will be displayed and the status will be set to "Not Done" with a comment of "safety exclusion." See Exhibit 3-4.

Exhibit 3-4. Component Status due to eye infection exclusion



The screenshot shows a "Status" section with three radio buttons:

- Complete
- Partial
- Not Done

Below the radio buttons is a "Comments" field with a dropdown menu containing the text "safety exclusion". Below that is an "Other text" field with an empty text input box.

An eye patch covering one eye only is not a reason for exclusion but obviously, if both eyes are covered for some reason, the examination will not be done. See Exhibit 3-5.

Exhibit 3-5. Exclusion due to eye patch-both eyes

Does SP appear to have a severe eye infection in one or both eyes?

If so, which eye?

Is SP wearing an eye patch?

If so, which eye?

Exclusion [X]

SP COELHO, STACY (625125) was excluded from Ophthalmology(49)

OK

If the SP is excluded based on an eye infection, the component status screen will be displayed and the status will be set to “Not Done” with a comment of “eye specific limitation.” See Exhibit 3-6.

Exhibit 3-6. Component Status due to eye patch exclusion

Status

Complete

Partial

Not Done

Comments

Other text

3.2 Pre-examination Procedures

The Humphrey Matrix visual field instrument and the Canon CR6-45NM ophthalmic digital imaging system are positioned on a motorized instrument table in the ophthalmology room. The SP will sit on one side of the table and the technologist will sit on the opposite side. Both the height of the table and the SP's chair are pneumatically adjustable to provide optimum comfort for the SP and facilitate optimum camera alignment. A small reading lamp will be placed near the camera to help the technologist navigate during the procedure when the room lights are turned off.

Each day, the technologist completes the appropriate setup, calibration, and cleaning procedures for the equipment and the ophthalmology room as outlined in Chapter 2 prior to the beginning of the session. Supplies are checked, equipment is turned on as appropriate, and the room is prepared for the first exam. The dust covers are removed from the instruments and are replaced at the end of each session. The lens cover for the camera lens should remain in place until just prior to each exam. It should be put on the equipment as soon as the examination is completed to protect the instruments from damage due to dust.

Throughout the procedures, suggested scripts are given as guidelines for the technologist. Although the scripts are not standard scripts and do not have to be read word for word, most information included in the suggested scripts should be given to the SP to facilitate his or her understanding of the procedures. This will maximize the chances of obtaining good data from these exams. See Appendix A for Step-by-Step Procedures with suggested scripts and Appendix B for the Spanish translation version.

The visual field exam will be completed first, followed by the retinal imaging. As the SP enters the room, briefly explain what procedures will be performed in this room, log the SP into the system, and clean the chin rests and forehead support areas on the equipment. At this point, give a brief overview only and leave the more detailed information until you are ready to do each individual procedure. Let the SP know that you will explain each step of the procedure and answer any questions he or she may have.

Suggested Script: “Please come in and have a seat in the chair while I enter some information in the computer and get ready for the exam. {Log SP into the ISIS system. Clean chin rest and support areas while explaining the tests.} In this room I am going to do two examinations of your eyes. These exams are to look for conditions resulting from aging or diseases like diabetes that affect people’s vision. The first examination will be a test to determine how well you

can see objects out to the side. For the second test, I will take two pictures of the back of the lining of each of your eyes. I will not be touching your eyes or giving you any eye drops. I'll turn off the lights because a darker room will help your pupils or the black part of your eyes get larger so that we can get better pictures. I will explain each test in more detail as we are doing it.”

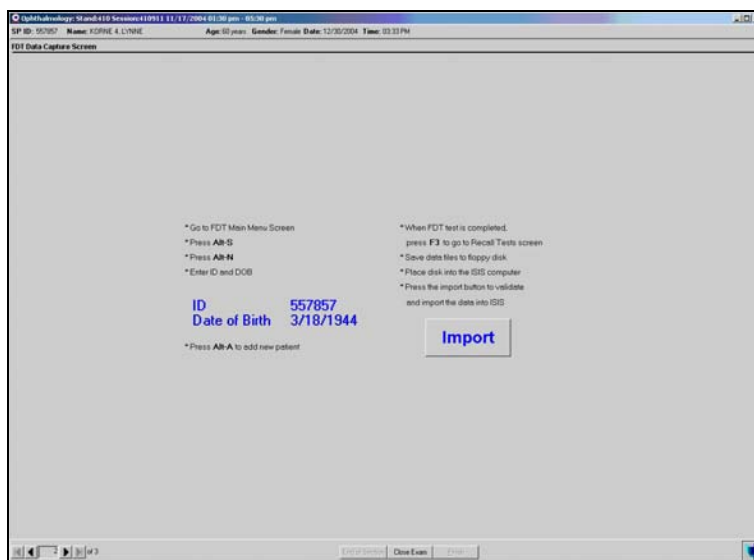
3.3 Visual Field Test (Frequency Doubling Technology Perimetry)

FDT perimetry uses the Humphrey Matrix Visual Field Instrument that specifically tests for visual field loss from glaucoma. SPs are asked to fixate on a central target and to press a thumb switch when they detect the appearance of the target. Each target is 10 degrees square, shown on a dim, colorless screen within the instrument. The instrument automatically varies the contrast between dark and light portions of the target to determine the contrast at which the target could be detected.

3.3.1 Setting Up ISIS and FDT Screens

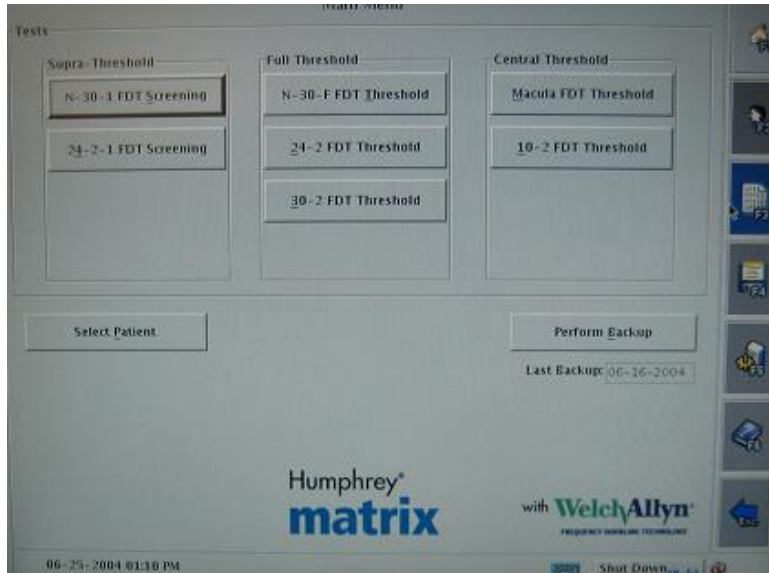
Once you have logged the SP into the ISIS system, the safety and exclusion questions from the vision exam are displayed. As noted above, these questions will most likely be grayed out and displayed for your information only. (See Exhibit 3-1.) When you move to the next screen, the FDT Data Capture Screen is displayed. See Exhibit 3-7. This screen provides information you will need to enter in the FDT software (identification number and date of birth).

Exhibit 3-7. FDT Data Capture Screen



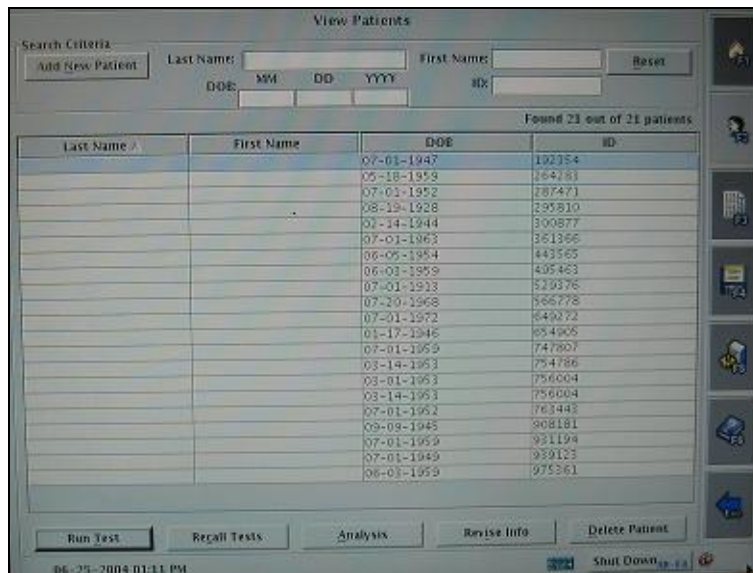
The FDT machine should be turned on prior to each session and the Main Menu screen should be displayed. See Exhibit 3-8. Press **Alt-S** or select N-30-5 Screening Test on the FDT keyboard to go to the View Patients Screen.

Exhibit 3-8. FDT Main Menu Screen



When the FDT View Patient Screen is displayed (See Exhibit 3-9), press **Alt-N** or select “Add New Patient” on the FDT keyboard to go to the “Select New Patient” screen.

Exhibit 3-9. FDT View Patient Screen



When the “Enter New Patient” screen is displayed (See Exhibit 3-10), enter the SP’s identification number (SPID) and the SP’s date of birth for this SP in the designated fields using the data listed on the ISIS “FDT Data Capture” screen. Then press **Alt-A** or select “Add Patient” to add the SP to the FDT database.

Exhibit 3-10. FDT Enter New Patient Screen

Enter New Patient

Personal Information * Need to enter ID or Last and First Name along with DOB.

Last Name: _____ DOB: MM DD YYYY
First Name: _____ Gender: Male Female
Middle Name: _____ Race: _____
ID: _____

Contact Information

Phone Number: _____
Address 1: _____
Address 2: _____
Address 3: _____

General Patient Notes

Reset Cancel Add Patient

06-25-2004 03:13 PM Shot Down

A message will be displayed on the FDT screen to indicate that the SP information has been added to the database. See Exhibit 3-11.

Exhibit 3-11. FDT View Patient Screen

Enter New Patient

Personal Information * Need to enter ID or Last and First Name along with DOB.

Last Name: _____ DOB: 01 01 1940
First Name: _____ Gender: Male Female
Middle Name: _____ Race: _____
ID: 121450

Contact Information

Phone Number: _____
Address 1: _____
Address 2: _____
Address 3: _____

General Patient Notes

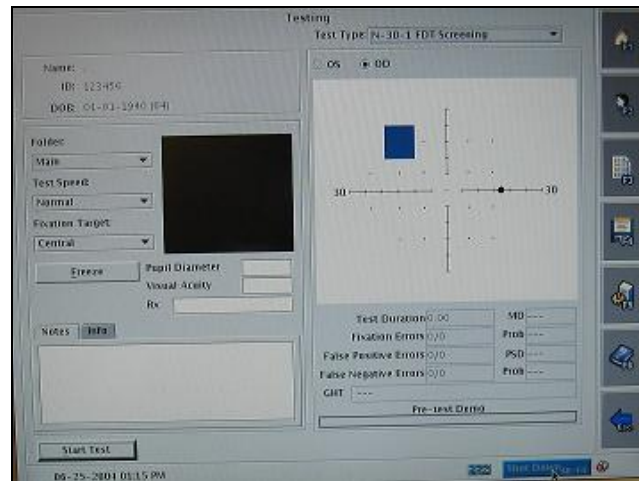
Reset Cancel Add Patient

06-25-2004 03:15 PM Shot Down

Information! @163
Patient information added.
OK

Click OK to “Patient Information added” message. The “Testing” screen will be displayed. See Exhibit 3-12. This is the screen used to collect the visual field test data.

Exhibit 3-12. FDT Testing Screen

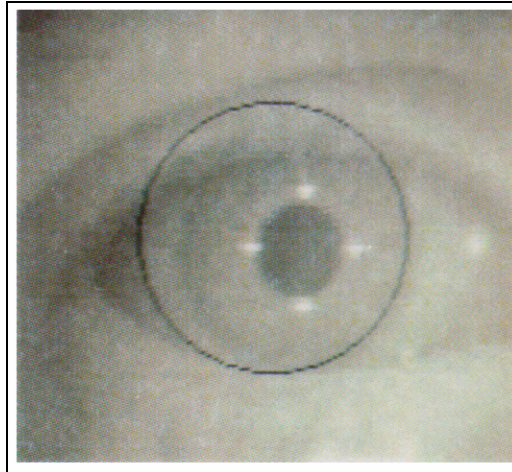


3.3.2 SP Positioning for the Visual Field Test

The SP should be positioned in the chair in front of the FDT equipment. Move the headpiece on the FDT machine to test position for the SP's right eye. The table and/or chair can be moved up or down as necessary to position the SP as comfortable as possible. Ask the SP to move the chair in toward the FDT machine. SPs should lean forward slightly to position their forehead against the forehead rest. SPs should move their head straight toward the headpiece (as opposed to leaning in sideways to the right or left). Tell the SP that the lens cap is on and will feel awkward against his or her nose but right now you are just checking the height of the table. While sitting comfortably in the chair, the SP should be able to lean forward slightly into the headpiece without slumping down or stretching up. After you have the table position correct, explain the procedures. Remove the lens cap and have the SP lean into the machine and adjust the eye position. After the SP positions their forehead against the forehead rest of the FDT machine and they are positioned such that their pupil is inside the circle, move the chin rest up by twisting the black knob located on the tech's right side. The chin rest should be raised until it touches the SP's chin. (Slight adjustments of the SP's head up or down can be made by adjusting the chin rest.) Confirm that the chin rest is touching the SP's chin by asking the SP if the chin rest is in a comfortable position. The lights in the room should be turned off at the beginning of the exam to allow the SP's pupils optimal dilation for the retinal imaging.

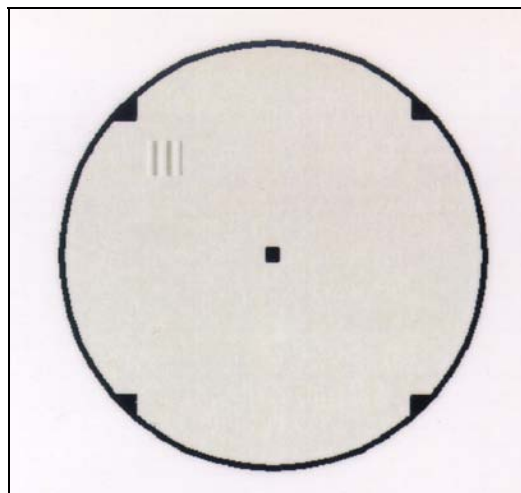
The testing screen will default to OD to test the right eye. When eye monitoring is turned on, an image of the SP's eye will be displayed on the testing screen. The SP's pupil should be kept inside the circle on the video image throughout the test. See Exhibit 3-13. The pupil does not have to be perfectly centered for proper alignment but it should stay within the circle. Adjust the position of the patient to obtain proper alignment. The SP should be able to see all four self-alignment points at the same time while fixating on the black square target in the center. See Exhibit 3-14. The fixation target may appear fuzzy to the SP. Give the SP the Patient Response Button.

Exhibit 3-13. FDT Eye Positioning



Some SPs may have problems fixating properly on the black square while doing the test. In an effort to improve the quality of the data, put a special emphasis on the importance of focusing on the black square. Explain the procedure with repetitive statements regarding fixation on the black square throughout the exam. Use the following statements to emphasize this point: “Focus on the black square.” “While looking at the black square, you should see patterns that flicker, shimmer, or are striped.” “Keep looking at the black square and press the button each time you see a pattern.” “Don’t look at the pattern; keep looking at the black square.”

Exhibit 3-14. FDT SP Video Screen Pattern



Once you start the test, continuously remind the SP to keep looking at the black square. Reinforce the SP if they are doing it correctly – let them know when they are doing it correctly so they understand what is expected. If the SP was unable to fixate on the black square continuously, enter XXX in the ‘Notes’ field on the FDT screen for each test where this was a problem.

3.3.3 Starting the Visual Field Test

The sequence for testing the visual field test always starts with the right eye, followed by the left eye, and then the test is repeated for each eye. Explain this part of the exam to the SP using the suggested script below:

Suggested Script: “I’ll turn off the room lights because a darker room will help your pupils or the black part of your eyes dilate or get larger so that we can get better pictures of your eyes in the next test.”

“This examination will determine how well you can see things at the outer areas of your vision field. The instrument is going to show you some patterns that flicker, or shimmer, or are striped. Each time you see one of these patterns, press (and release) the button you have in your hand. You don’t have to hold it down, just press and release. Please place and keep your forehead on the instrument forehead rest.”

“Are you comfortable?”

“Can you see the black spot in the center of the screen? You must keep looking at the black spot in the center at all times during the test.”

“While looking at the black spot in the center, can you see all four triangles at the edge of the screen?”

“We are now running a practice test. Please press the button whenever you see a pattern that flickers, or shimmers, or is striped. You may blink your eyes whenever you want. A good time to blink is whenever you press the button. Do you understand what you are to do?”

“We’ll start the test now. There will be a brief flash just before the actual test begins.” Please remember to keep looking at the black spot in the center of the screen at all times during the test.”

When you are ready to start the test, press Alt-S or select “Start Test” on the testing screen. The test will take approximately 30-45 seconds. Throughout the test, give the SP encouragement as needed with reminders to concentrate on the black spot in the center.

If you need to reposition the SP, press Alt-P or select Pause to pause the test. After repositioning the SP, press Alt-R or select Resume to continue the test. When the test is finished, there will be a beep.

Have the SP sit back, move the headpiece to test the SP's left eye. Position the SP again. When repositioning the SP to test the opposite eye, the chin rest may need readjusting. Adjust the chin rest as necessary. Inform the SP that you are going to test the left eye. Remind him or her to focus on the black spot in the center. When the SP is ready to resume, press "Enter" on the testing screen. OS will be selected for the left eye test.

Repeat the above sequence for the right and left eyes. Press Alt N or select New Test to begin the second set of tests. Press Alt-S or select Start to start the second test. When you have completed a total of two tests on each eye, press F3 to save the files to a floppy disk, put the lens cover back on the lens, move the chin rest down to its lowest position, and return the headpiece to the right side.

3.3.4 Saving Files to the ISIS Database

Once the screening test is completed, save the data in tab delimited files onto a floppy disk. The naming convention will be SN20031111305_TestResults_datetimestamp.csv. SN20031111305 is the serial number of the FDT machine. Datetimestamp is in the format 01-28-2004_10.52.43 with 01-28-2004 indicating the date the file was saved and 10.52.43 indicating the time (HH.MM.SS) the file was saved.

This file contains the patient information (ID and DOB) along with the test results. Because the protocol calls for conducting two sets of screening tests, there will be two "TestResults" files on the floppy. The application will perform validation of the files to ensure that the SPID and DOB were entered correctly. If any of these are not true, the appropriate error message will be displayed to the technologist and the data will not be imported. If the files are validated, the relevant data will be taken from the files and stored in the database. Once all of the data are retrieved from the files, the application will delete all files from the floppy to ensure that only one set of exported data will be on the floppy at any given time.

At the FDT Main Menu, use the following steps to save the files to the ISIS database.

Exhibit 3-15. Recall Test Screen-Saving files

1. Press F3 to go to the Recall Test screen. See Exhibit 3-15.
2. Put a floppy in the FDT A drive.
3. Select the first test file for the current SP.
4. Select Alt-S or “Save As.”

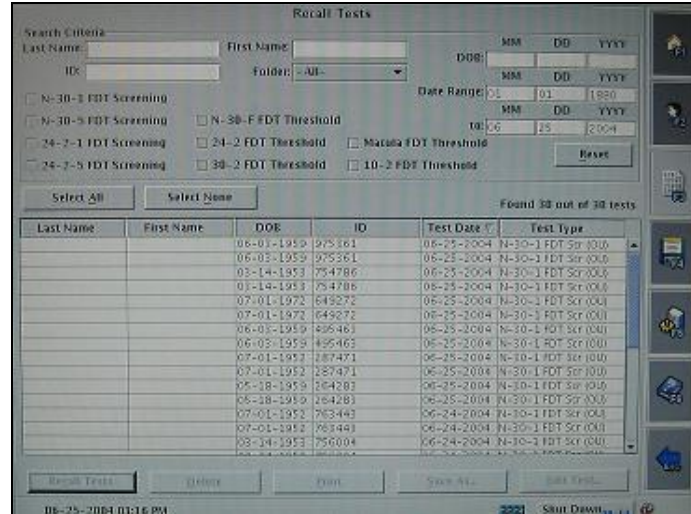


Exhibit 3-16. Recall Test Screen – Selecting format

5. Change “Database Backup Format” to “CSV” by selecting from the drop-down menu. See Exhibit 3-16.
6. For “Location,” select “Floppy.”
7. Click OK to save the file to the floppy.

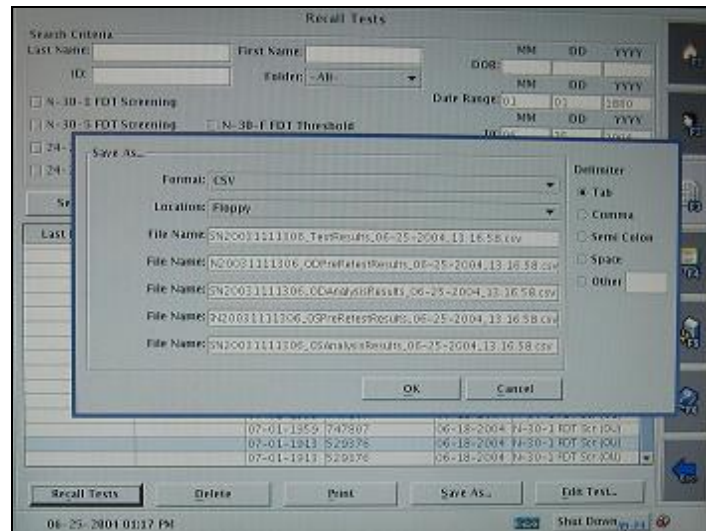


Exhibit 3-17. Recall Test Screen Files saved successfully

8. Click OK to the “Files saved successfully” message. See Exhibit 3-17.
9. Select 2nd file for this SP.
10. Select “Save As” Format needs to be set only once after turning on the FDT machine. Repeat steps 7 & 8.
11. Take the floppy from the drive on the FDT machine and put it in the ISIS CPU drive.

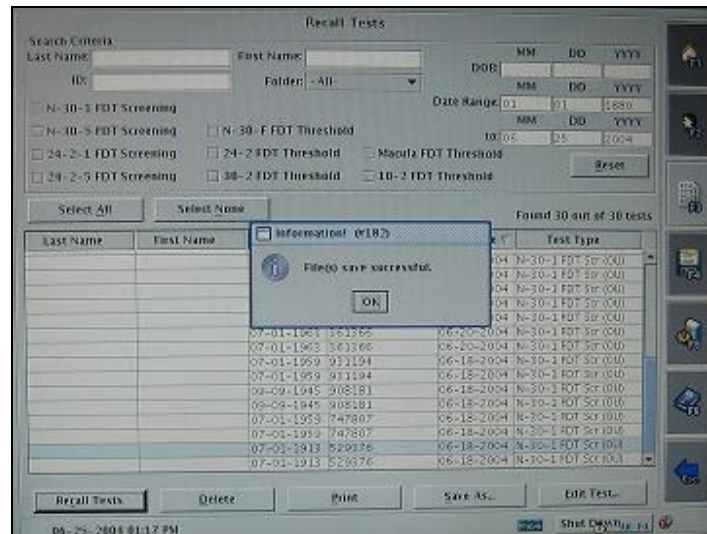
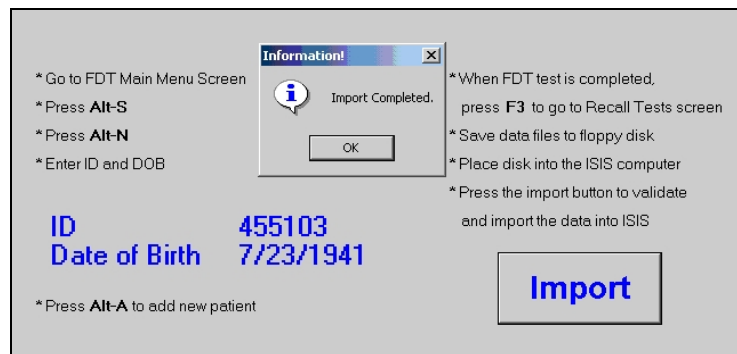


Exhibit 3-18. ISIS Data Capture Screen

12. Click on “Import” on the ISIS Data Capture screen. See Exhibit 3-18.
13. The files are imported to the ISIS database and files are deleted from the floppy disk.
14. When the files are saved to the ISIS database, a message is displayed to indicate the import is complete.

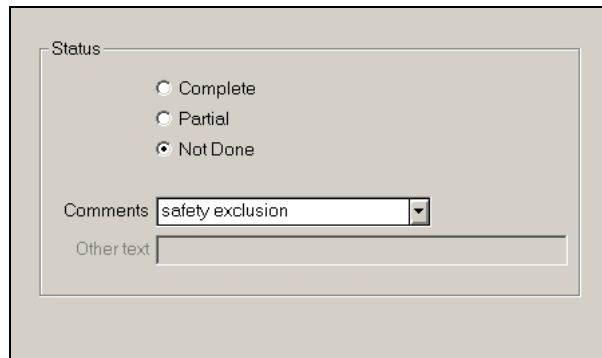


3.3.5 FDT Section Status

The FDT section status screen displays the status for the FDT section (See Exhibit 3-19). If the technologist answers “Yes” to either of the exclusion questions, the status will be Not Done and the comment code will default to safety exclusion. If the technologist conducted both screening tests, the status will be listed as Complete. If the technologist captured one of the screening tests, the status will be

Partial, allowing the technologist to provide a reason. If the technologist performed no screening tests, the status will be Not Done, allowing the technologist to provide a reason.

Exhibit 3-19. FDT Section Status Screen



The screenshot shows a window titled "Status" with a light gray background. Inside the window, there are three radio buttons: "Complete", "Partial", and "Not Done". The "Not Done" radio button is selected. Below the radio buttons, there is a "Comments" label followed by a dropdown menu that currently displays "safety exclusion". At the bottom of the window, there is an "Other text" label followed by a text input field.

3.3.6 Procedure for Testing One Eye Only

If the SP has an eye patch, glass eye, or a problem that prevents testing in that eye, the FDT test should be done on the other eye. The procedures for testing the right eye or left eye only are outlined below:

Testing Right Eye Only:

1. Move visor to position for **right eye test**.
2. **OD** is selected as the default position for testing the right eye.
3. Press **Alt S** or select Start Test to start the test.
4. When the first test on the right eye is completed, select **Alt-N** or New Test.
5. Press **Alt S** or Start Test to begin the second test of the right eye. (OD is still selected).
6. When the second test of the right eye is completed, press **Alt D** or Done Testing.
7. Press **F3** to go to the Recall Test screen where the test files are saved.
8. This creates two test files with OD files only. (The files are labeled OU when both tests are completed and OS when the left eye test only is completed.)

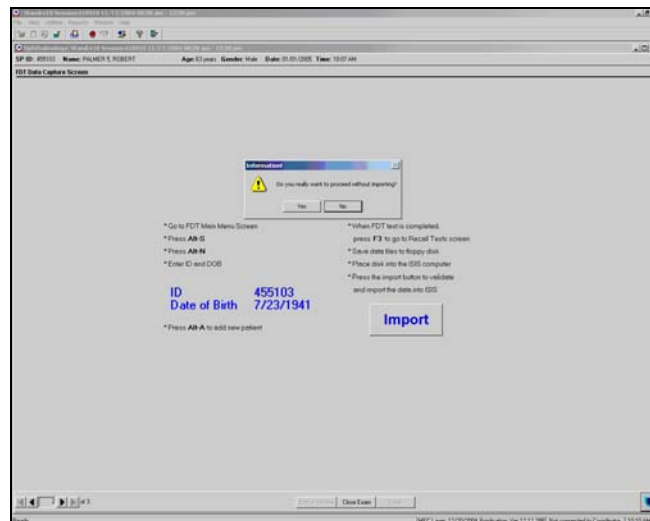
Testing Left Eye Only:

1. Move visor to position for **left eye test**.
2. Select **OS** at the top of the screen.
3. Select **Alt-S** or Start Test to start the test.
4. When first test on left eye is finished, press **Alt-N** for New Test.
5. Press **Alt-S** or Start Test to begin the second test on the left eye. (OS is still selected.)
6. When the second test of the left eye is completed, press **Alt D** or Done Testing.
7. Press **F3** to go to the Recall Test screen where the test files are saved.
8. This creates two test files with OS files only. (The files are labeled OU when both tests are completed and OD when the right eye test only is completed.)

3.3.7 Problems with Importing Files

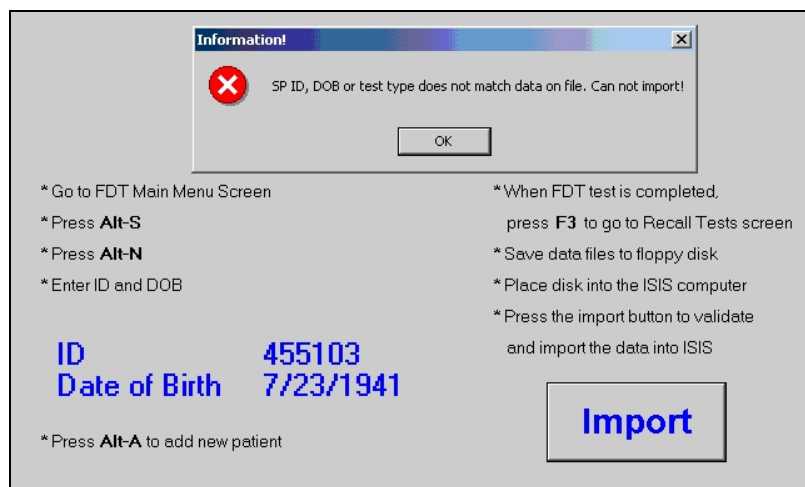
If the technologist is unable to complete the FDT test but is able to do the retinal imaging, the FDT import screen can be bypassed. Then you go forward to the next screen, a message will be displayed asking if you really want to proceed without importing. See Exhibit 3-20. If you select Yes to this message, the section status will be displayed with the status set to “Not Done.” You must select a reason from the drop-down menu in the comment box.

Exhibit 3-20. Proceed without importing



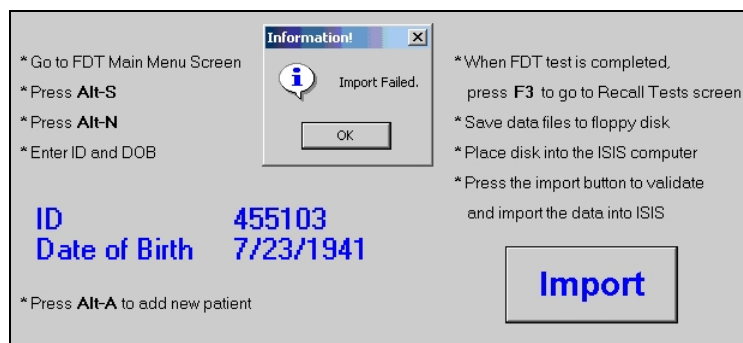
When the test files are imported, the program validates the SP identification number and the date of birth. If these do not match, a message is displayed “SP ID, DOB or test type does not match data on file. “Cannot import.” See Exhibit 3-21. When you select OK to this message, a message will be displayed that “Import Failed” and the files will be deleted from the floppy. You should remove the floppy from the ISIS computer and insert it in the FDT drive and save the correct files to the floppy. You can then repeat the import process.

Exhibit 3-21. DOB and ID do not match



If the import process failed for any reason, a message will be displayed to indicate this. See Exhibit 3-22. All files will be deleted from the floppy. Put the cleaned file from the ISIS computer and put it in the FDT disk drive. Go to the FDT screen and revise the SPID and/or DOB.

Exhibit 3-22. Import failed

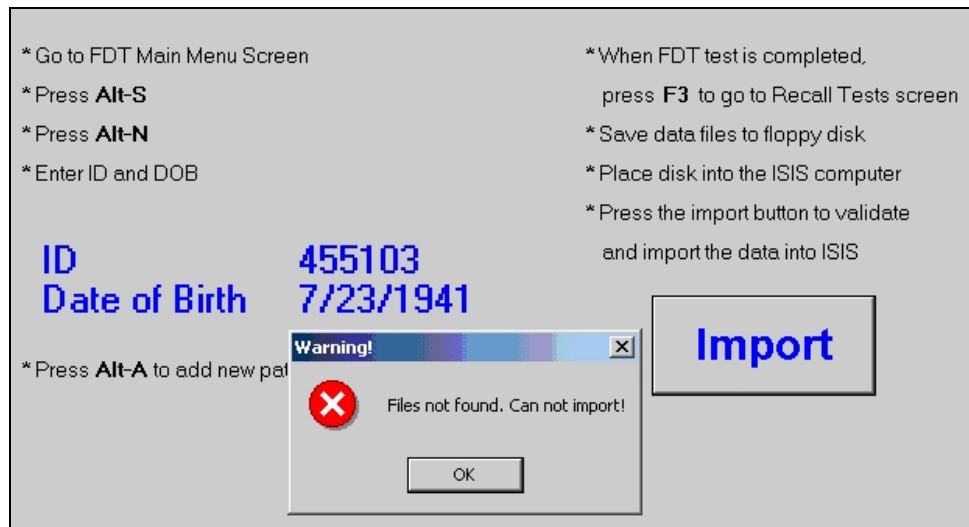


Revising SP ID and/or DOB

- Select F2 on the FDT machine to display SP Biography Information.
- Highlight SPID (or DOB).
- Select “Revise Info” or Press “Alt I.”
- Edit SPID or Date of Birth as necessary.
- Select “Update” or Press “Alt U.”
- Press ‘OK.’ All files associated with that SPID will now have the revised SPID and DOB.
- Save these files in the usual manner and import them into ISIS. See Section 3.3.4.

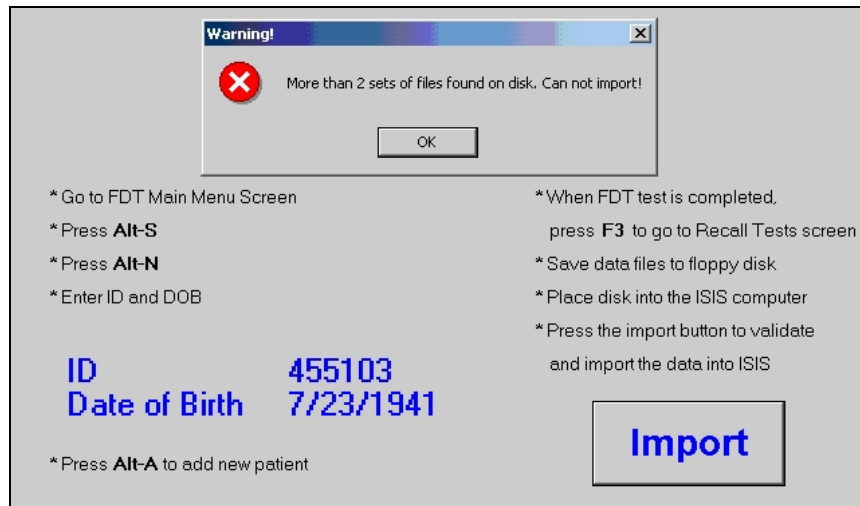
If you try to import using a disk with no files, a message will be displayed to indicate the source of the problem. See Exhibit 3-23.

Exhibit 3-23. Files not found



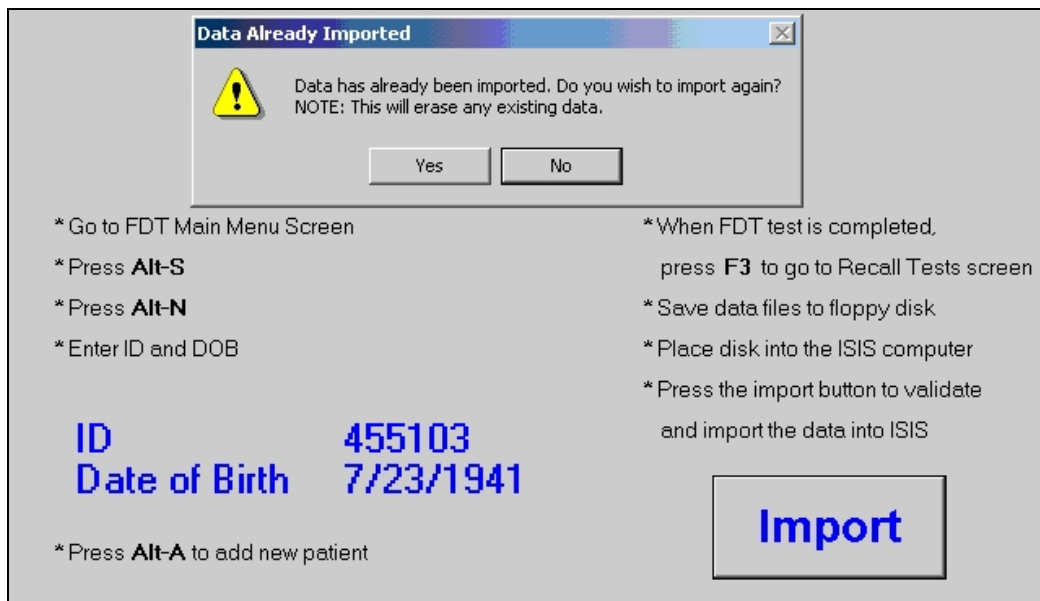
If more than two sets of files are found on the disk, a message will be displayed “More than 2 sets of files found on this disk. Cannot import.” See Exhibit 3-24. All files on the disk will be deleted. You must go to the FDT Recall Screen and save the appropriate files again and repeat the import process.

Exhibit 3-24. More than two sets of files



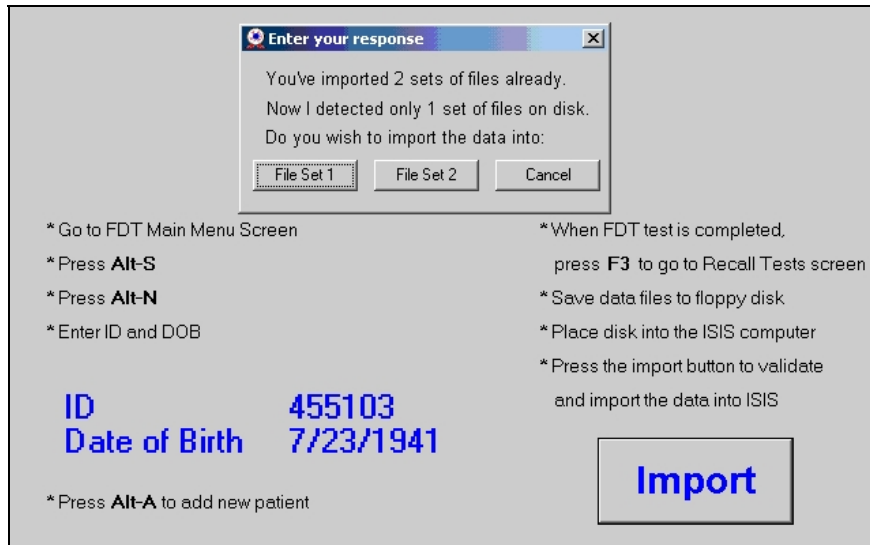
If you have already imported data for this SP but for some reason you want to import again, a message will be displayed: "Data already imported. Do you want to import again? NOTE: This will erase existing files. See Exhibit 3-25. If you select Yes, all existing files for this SPID will be deleted from the database and the new files will be saved.

Exhibit 3-25. Data already imported



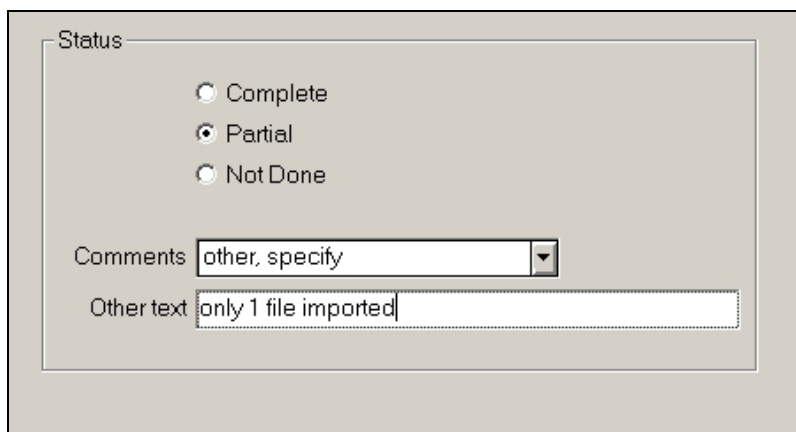
If two tests were already imported and for some reason you try to import only one file, a message will be displayed to indicate the source of the problem. If you want to overwrite one file, you must indicate which file you want to overwrite. See Exhibit 3-26.

Exhibit 3-26. Imported two sets of data already



If you import only one test file, the section status will be set to Partial with a comment of Other, Specify, "only 1 file imported." See Exhibit 3-27.

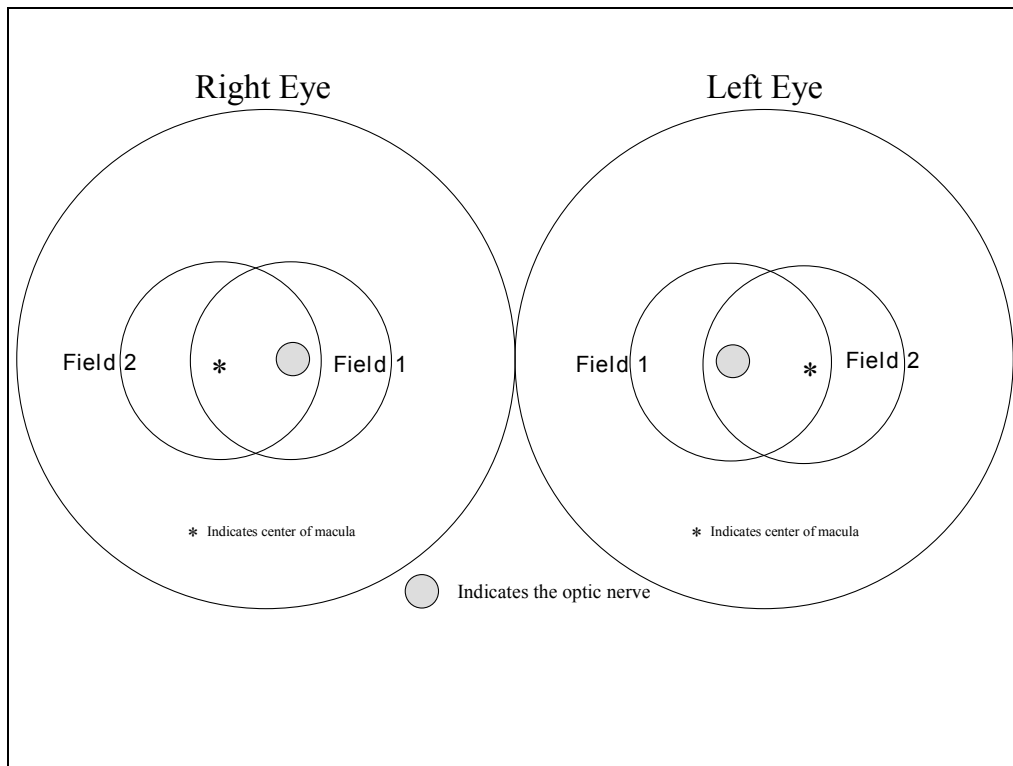
Exhibit 3-27. FDT Section Status for one file imported



3.4 Digital Fundus Photography

Non-mydriatic digital images of the retina will be captured on all SPs aged 40 years and older by a technologist trained in the use of the digital imaging system. The room will be darkened while these images are captured to allow the pupils to dilate naturally. No pharmacologic dilation will be used. Each SP will have two digital images per eye (total of 4 images). The first image will be centered on the macula (field 2) and the second on the optic nerve (field 1). See Exhibit 3-28 for a diagrammatic representation of the fields that will be imaged in each eye. The first eye to be imaged will be determined by ISIS (right eye imaged first if even number; left eye imaged first if odd number). The digital images will be copied to DVDs and shipped to a remote reading center for grading using standardized methods used for other populations.

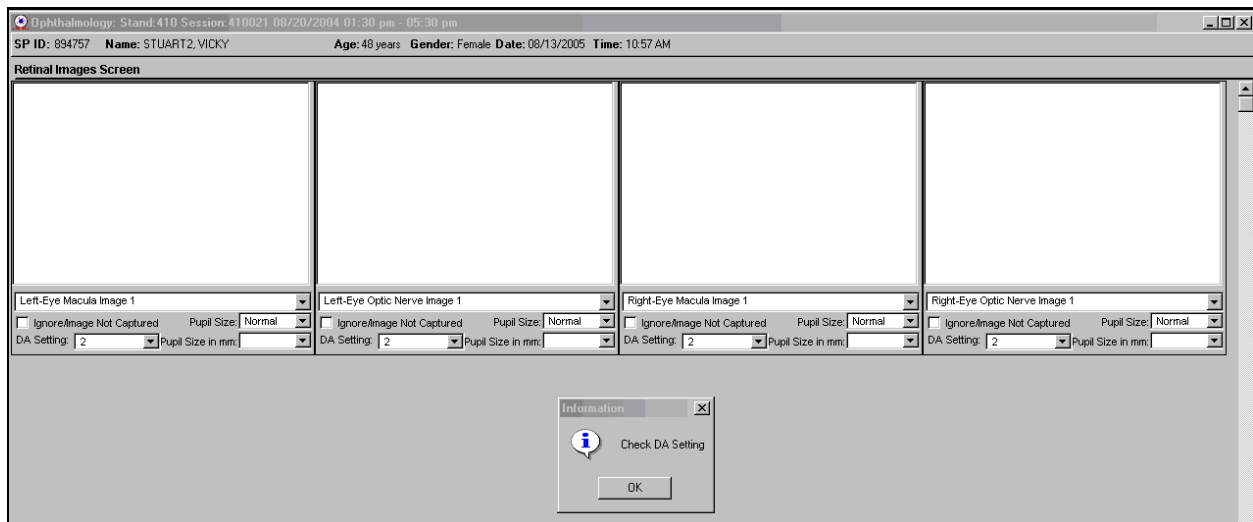
Exhibit 3-28. Diagram of optic fields for imaging



3.4.1 ISIS Screen for Retinal Images

After the FDT test is completed, move to the retinal imaging screen in ISIS. See Exhibit 3-29. The Retinal Images Screen provides a method to record the capturing of retinal images and to label the images accurately. When the technologist takes an image, the ISIS application will get the entire RAW image from the camera, convert the image to an 8 bit/pixel TIFF file, displaying the resulting image in the next available image display area, and deleting the image from the CF card in the camera.

Exhibit 3-29. Retinal Images Screen



A small message box will be displayed to remind the technologist to check the DA or flash setting and adjust it as necessary. The default for the flash setting is 2. The technologist will confirm that the DA setting is set correctly for the SP. These criteria are outlined in more detail in Section 3.4.12.2.

The ISIS application will also provide the ability to view a larger version of the thumbnail. If you double click on the image display area, the ISIS application will open up a window that shows the thumbnail as a 640 x 480 image.

The application will verify that you have either captured an image or have given a reason for the image not being captured for each of the four retinal shots required by the protocol and that there is only one of each type of image. When you advance to the next screen, the application will move the images from the import directory to the output directory and rename the image files with the following naming convention: *spid image type.tif*. An example of this is 123456 OD Optic Nerve 1.TIF.

3.4.2 Positioning for Retinal Imaging

Ask the SP to move the chair to the retinal imaging system. The SP should be positioned so that he or she is comfortable with the chin and forehead in the headrest. Chin height should be adjusted so that the eyes are approximately level with the height adjustment mark on the face rest pole and the SP can comfortably lean his or her forehead on the forehead rest. The camera lens should be in place at this time. The room should be darkened and the table lamp should be turned off when the photography is being performed.

3.4.3 Achieving Maximum Pupil Dilation

To obtain optimal retinal images, you need to achieve maximum pupil dilation. As noted in Section 3.3.3, turn off room lights at the beginning of the exam. After you have finished importing the FDT files, place the black cover over the FDT screen and turn off the ISIS computer monitor. You should turn on the monitor briefly in the middle of the retinal imaging test to confirm that the images are downloading correctly. After the FDT test, have the SP slide the chair in front of the retinal image camera and close his or her eyes while you are importing the FDT data. You may have to get them to open their eyes briefly when you position them for the imaging test but try to have them keep their eyes closed as much as possible to allow for maximum dilation prior to the test.

3.4.4 Explanation of Retinal Imaging

Explain the digital imaging process to the SP as you are preparing for the imaging. Below is a suggested script that includes the information that should be given to the SP.

Suggested Script: “This is the part of the exam where I will take several pictures of the lining on the back of your eyes. I will not be touching your eyes or giving you any eye drops. As I mentioned before, I turned off the lights because a darker room will help your pupils or the black part of your eyes dilate or get larger so that we can get better pictures of your eyes. While I am focusing the camera on your eyes I will ask you to focus on certain objects. You will see a bright flash as each picture is taken. Just after the picture is taken, you may see a blue or red circular spot before the eye that was photographed. This will disappear and causes no damage to your eye. I will explain the procedures in more detail as we go through each step. First, I want to get you positioned correctly. Please place your chin on the chin rest and press your forehead on the forehead rest.”

Once the SP is positioned correctly and the camera is ready, use the following scripts to guide the SP through the exam step by step.

Suggested Script: “You should be able to see an orange dot. Can you see it? Good. Please look at that dot.”

“When I change the screen, please keep looking straight ahead. If possible, please do not talk or move until the picture is taken.”

Keep reminding the SP what you need him or her to do and let them know they are following instructions correctly.

Suggested Script: “Keep looking straight ahead. You’re doing a good job. Keep looking straight ahead.”

“You should be able to see the orange dot again. Can you see it? Good. Please look at that dot.”

“This time when I change the screen, you should be able to see red bars and a green square. Do you see them? Good. Please look at the green square and follow it as it moves. If possible, please do not talk or move until the picture is taken.”

As you are taking each image, repeat the instructions as necessary and appropriate and continue to give feedback to the SP and reinforce your directions with comments such as: You’re doing a great job,” “Keep looking at the green square,” “We’re almost finished.”

3.4.5 Camera Alignment and Imaging Procedures

General alignment, focus, and proper fixation of fundus photographs: While viewing the fundus image on the screen, carefully adjust the fixation target control button to locate Fields 1 and 2 correctly on the screen. Field 2 (macula) is always photographed first.

Any fine adjustment of fixation is made by moving the joystick and instructing the SP to look into the lens of the camera at the green target box. If the subject sees no fixation target with the eye being photographed, press the fixation target button to enlarge the green box. The green target box will flash and enlarge as the fixation target button is pressed and will return to original size when button is

released. If SP still cannot locate the green box, carefully instruct the SP to make micromovements (fine movements up, down, left, or right) until the protocol fields are located.

Once the fixation is confirmed, constantly adjust and position the camera to maintain the correct position of the corneal reflection dots. It is important that these dots be properly positioned at 3 and 9 o'clock before the picture is taken. This will ensure the correct distance from the eye and will allow capture of a sharp digital image. Focus is done manually by dialing either of the focus knobs located on the side of the fundus camera. Proper focus is obtained by aligning the two horizontal focus bars visible on the fundus camera monitor. Good focus is critical for grading photographs.

Instruct the SP to blink once or twice just before the picture is taken. This blinking will ensure a moist (and subsequently clearer) cornea and will safeguard against unwanted blinks at the moment of exposure. Once alignment is satisfactory, depress the shutter release, located in the tip of the joystick, and the exposure is made.

3.4.6 Pupil Size and External Camera Alignment

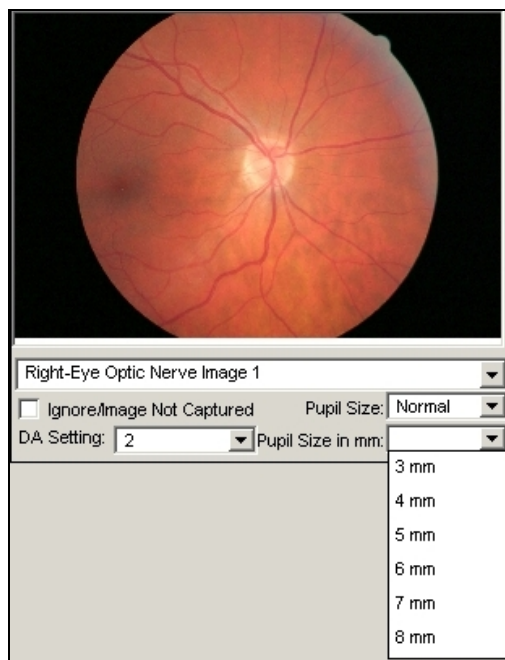
Once table and chair height is adjusted, ask the SP to sit back. Remove the camera lens, unlock the camera stage holding knob and move the base back (away from SP) before the SP is repositioned on the chin rest to prevent the SP from accidentally touching the lens. Move the base to center the eye to be photographed horizontally and the height adjustment ring to position the eye vertically. The pupil should appear on the screen with the central circle on the monitor. Move the camera joystick forward or backward until the pupil appears perfectly round. Position the pupil within the small circle with the three white dots inside the pupil. At this point, proper external alignment has been achieved.

Estimate the size of the pupil during the external alignment of the pupil, once for each eye, prior to taking the first image for that eye. Once you have estimated the size, record the number and take the macula and optic nerve image for that eye. Prior to taking the images for the second eye, estimate and record the size of that eye. The black circular rings on the monitor should be used as a reference. The small ring is 4 mm and the large ring is 8 mm. Use the criteria listed below for the estimate and select the number from the drop-down box. See Exhibit 3-30.

Criteria for estimating pupil size:

- 3 mm = pupil slightly smaller than small ring
- 4 mm = pupil is same size as small ring
- 5 mm = pupil is slightly larger than the small ring
- 6 mm = pupil size is between the small and large ring
- 7 mm = pupil size is close to the large ring
- 8 mm = pupil size is same size as the large ring

Exhibit 3-30. Drop-down menu for estimating pupil size in mm



3.4.7 Internal Eye Alignment – Macula Image

Once proper external pupil alignment is achieved, press the alignment button to provide a view of the fundus, split focusing lines, corneal reflection dots, and the fixation target. If no split lines are seen, the height or left/right adjustment is improper, the “Split” (split lines) setting is set to “off” (Set 1, Split/FCD), or the diopter compensating slider is pulled out. The split lines may fade in and out if the

pupil is too small, the alignment of the camera is not centered on the pupil, or the eyelashes or lids eclipse the light. If no corneal reflection dots are seen, the forward/backward adjustment is improper. The best photographs are obtained when the eye is well dilated, fixation is on the target; and lids and lashes are held wide open. Move the joystick slowly forward or backward until reflection dots are in view.

When the external alignment is correct, tell the SP to keep looking ahead when the screen changes. Press the square alignment button to complete the internal alignment. As soon as you press the alignment button, remind the SP to keep looking straight ahead. Look for the white dots and get them in approximate alignment at the 3 and 9 o'clock positions (in the notches). Align the red bars with the round black focus bar to the right or left on the upper part of the camera. Confirm that the macula is in the center of the image.

As you are taking each image, repeat the instructions as necessary and continue to give feedback to the SP. When the dots are aligned and crisp, snap the image using the white button at the top of the joystick. Immediately ask the SP to close his or her eyes and relax. Wait approximately 30 seconds for the macula image to download.

3.4.8 Internal Eye Alignment – Optic Nerve Image

Repeat the external alignment procedures and when the external alignment is correct, tell the SP that you are going to change the screen and ask him or her to look for the green square. Get the white dots in proper alignment at the 3 and 9 o'clock position and align the red bars. Move the green square so that the optic nerve is positioned just below the red bars. Make further adjustments as necessary to get the dots positioned in the notches and crisp. Repeat the instructions as necessary and continue to give feedback to the SP. Snap the image when the dots are aligned and crisp. Wait approximately 30 seconds for the optic nerve image to download.

3.4.9 Labeling the Images

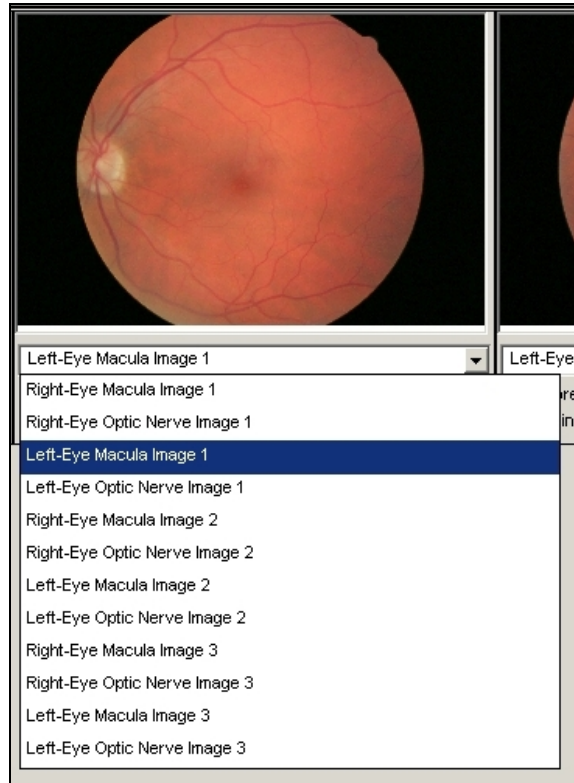
Each SP will have two digital images per eye (total of 4 images per eye). The first image will be centered on the macula and the second on the optic nerve. If the SPID is an even number the images should be captured in the following order: right eye macula 1, right eye optic nerve 1, left eye macula 1,

and left eye optic nerve 1. If the SPID is an odd number, images should be displayed in this order: left eye macula 1, left eye optic nerve 1, right eye macula 1, and right eye optic nerve 1.

The retinal images screen will have four empty image display objects with a drop-down menu to label the images. Currently, the appropriate label for each display object will need to be changed by the technologist to identify which image is displayed in the display box. See Exhibit 3-31. There will be 12 different types of images listed in the drop-down menu.

- Right Eye Macula Image 1
- Right Eye Optic Nerve Image 1
- Left Eye Macula Image 1
- Left Eye Optic Nerve Image 1
- Right Eye Macula Image 2
- Right Eye Optic Nerve Image 2
- Left Eye Macula Image 2
- Left Eye Optic Nerve Image 2
- Right Eye Macula Image 3
- Right Eye Optic Nerve Image 3
- Left Eye Macula Image 3
- Left Eye Optic Nerve Image 3

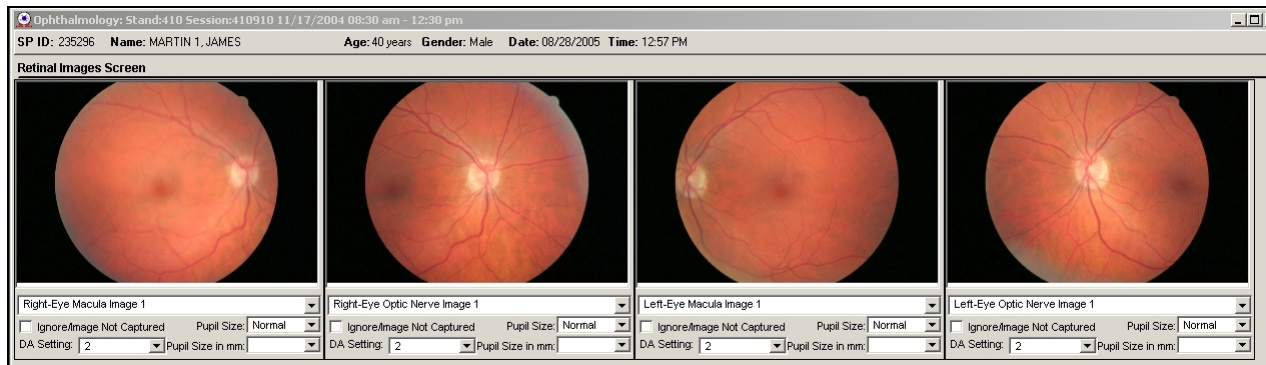
Exhibit 3-31. Retinal Images Screen with drop-down menu



3.4.10 Criteria for Taking Repeat Images

Each digital image will be initially evaluated as it appears on the back of the digital camera, while the SP is resting his or her eyes. At this time the technologist may determine that the quality of the image is ungradeable but will wait for all four required images to be captured before taking any repeat images. When all four images are displayed on the ISIS Retinal Images Screen, the technologist will make a final evaluation regarding the need for repeat images. See Exhibit 3-32.

Exhibit 3-32. Images required by protocol



When an image is obviously not acceptable, the image capture is repeated. Examples of unacceptable images are:

- Image is overexposed (too light)
- Image is underexposed (too dark)
- Flash setting was adjusted (take repeat image with new flash setting)
- Field 1- there is an obvious shadow on the optic nerve
- Field 2 – there is an obvious shadow on the macula
- Shadows cover over 40 percent of image
- Image is out of focus or blurry
- Specific area out of focus (Field 1 – optic nerve; Field 2 – macula)
- Field definition is incorrect (Field 1 – optic nerve is not centered; Field 2 – macula is not centered; deviates more than 1 disc diameter)
- Image captured during blink (image is white and yellow with no obvious view of optic nerve or macula)
- Halo – a green/white halo or partial halo are present
- Arc – a crescent shaped arc appearing on the image when SP has a small pupil or with incorrect patient to camera distance; arc range in color from yellow to orange to blue and in size from a small slice to an arc that obscures more than half of the field
- Halo appears in image

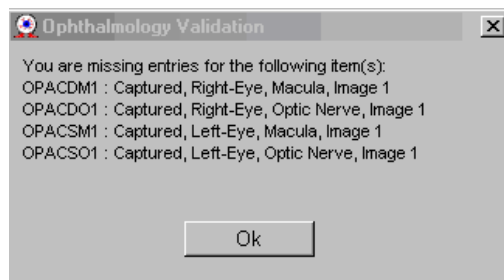
If one or more images need to be repeated, additional image display objects will be created as the images are downloaded and place it at the end of the list of currently displayed image objects. See Exhibit 3-33. The fifth image display object will not be defaulted to any image type. The technologist will determine which image type is in the image display area and select the appropriate label. The maximum number of images that can be taken is 12.

Exhibit 3-33. Image display for additional images



If the images are not properly labeled, the program will validate that all images are labeled and there are no duplicate labeled images. If a problem is detected, a message will be displayed indicating the problem. See Exhibit 3-34.

Exhibit 3-34. Missing entries message



3.4.11 Ignore/Image Not Captured

Each image display object has a checkbox for ignore/image not captured. This checkbox has two functions: (1) Inform the system to ignore selected images and (2) Flag a display box if the image cannot be captured. Specific details for each of these two functions are described below.

Ignore Image

The 'ignore/image not captured' checkbox has two functions. The first is to tell the software to ignore the image that is being displayed and not to send it to the graders. The system will, however, count this image in the total number of images taken for that eye. The ignore checkbox is selected if the image is clearly classified as upgradeable in the following cases ONLY:

- Image is completely black
- Image was taken when SP blinked

If one of the above situations occurred, check the Ignore box. See Exhibit 3-35. If you are able to get a replacement image, and all other protocol images were obtained, the component status will be complete. The Data Acquisition screen will count this image in the total images taken for that eye but the ignored image will not be sent to the grader.

Exhibit 3-35. Ignore image

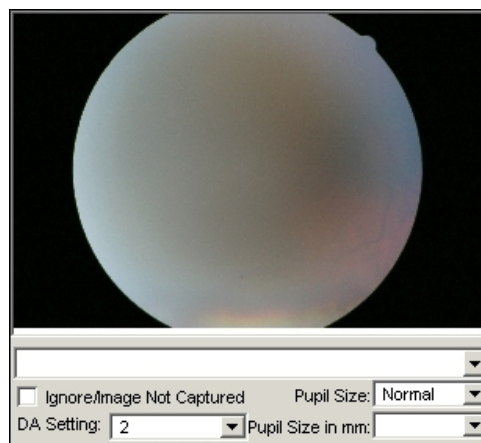
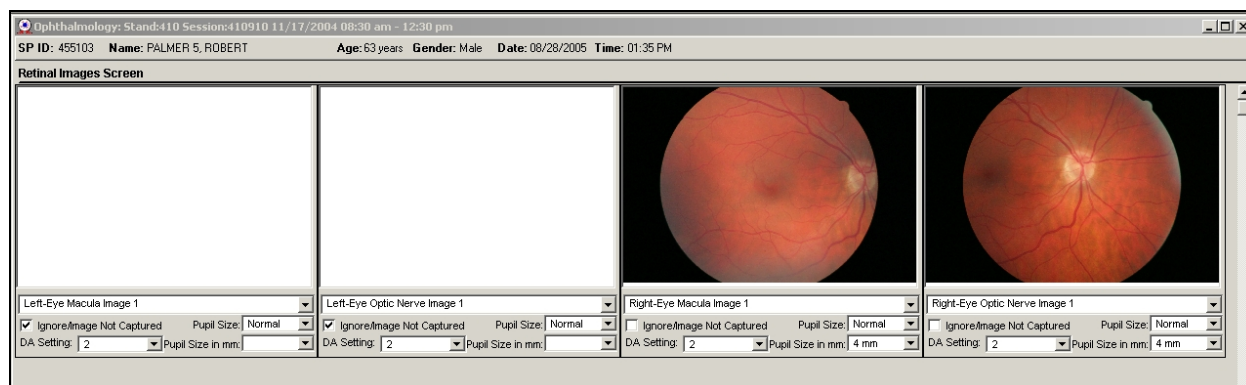


Image Not Captured

The 'ignore/image not captured' checkbox is also used to indicate that this particular image type has not been captured. Reasons for this include eye specific limitation, SP refusal, and no time. The reason for this can be checked on the Data Acquisition screen or on the Component Status screen depending on the reason. See Exhibit 3-36.

Exhibit 3-36. Image not captured



3.4.12 Imaging Procedures for Challenging Circumstances

3.4.12.1 Photography Through Small Pupils

Photography through small (less than 4mm) pupils will be difficult because some of the camera light doesn't enter through the smaller pupil. This usually results in uneven illumination (seen as dark shadows) on the monitor. In this situation, make careful camera adjustments to position the shadows as far away as possible from the optic nerve in the Field 1 photo and away from the macula in the photo of Field 2.

A small percentage of SP's eyes will not dilate to the minimum 4mm required for adequate photography. Certain medication may prevent any dilation and the pupil size observed on the monitor may be 2-3mm, inadequate for the photographer to appreciate all retinal landmarks on the viewing monitor.

Criteria for Using the Small Pupil Function:

The following criteria are used to determine if the small pupil function should be used to take the images:

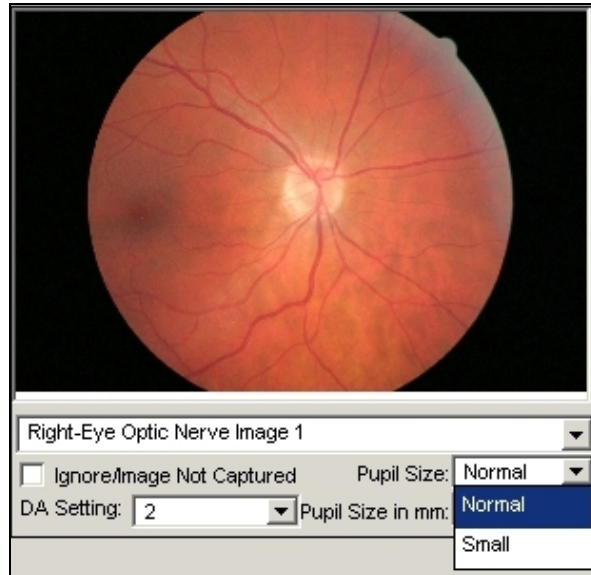
- If the three small dots are positioned within the pupil, use the normal size pupil function.
- If the three small dots are positioned just on the rim of the pupil, you may want to try the first image with the normal pupil function. Subsequent images may have to be taken with the small pupil function.
- If the three small dots are positioned outside the pupil, use the small pupil function.

The small pupil aperture is located on the left side of the fundus camera body. This function adjusts the illumination to concentrate more of the retinal illumination into a smaller area, providing more even illumination to the center of the field while sacrificing illumination at the field perimeter. If after introducing the small pupil function only one focus line is visible, it might be necessary to adjust the camera position, either vertically or horizontally, to bring the second line into view so that accurate focus can be set. However, there may be circumstances that prevent the second line from appearing, even when the camera adjustments are made. In these cases it may be helpful to remove the small pupil function momentarily while searching for the second line and adjusting focus, reintroducing the small pupil function before taking the photograph.

If no retinal landmarks are visible, often the case with <2mm diameter pupils, adjust the camera slightly to position the corneal reflection dots slightly above or below their optimum position. This technique allows a portion of the illumination light (which falls on the iris when the pupil is small) to enter the eye. If any retinal landmarks become visible with this technique, a picture should be taken. However, if no retinal landmarks are visible, no picture is taken.

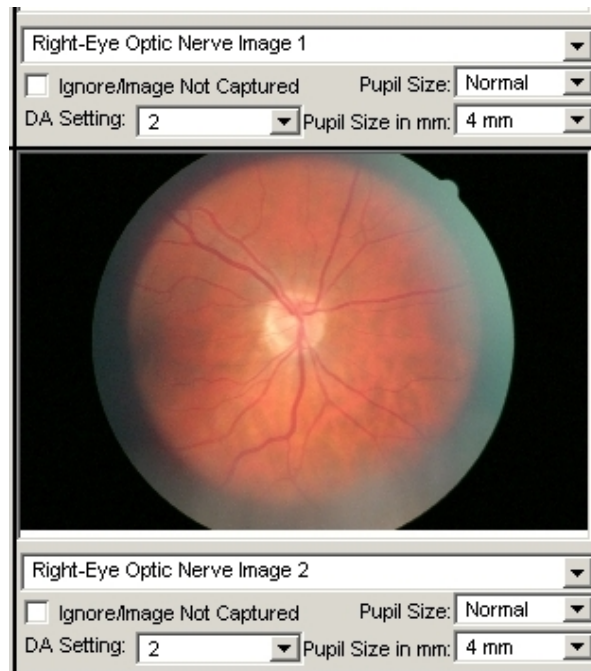
If the small pupil function is used for an image, select 'small' from the drop-down menu. The default is normal. See Exhibit 3-37.

Exhibit 3-37. Drop-down menu for pupil size setting



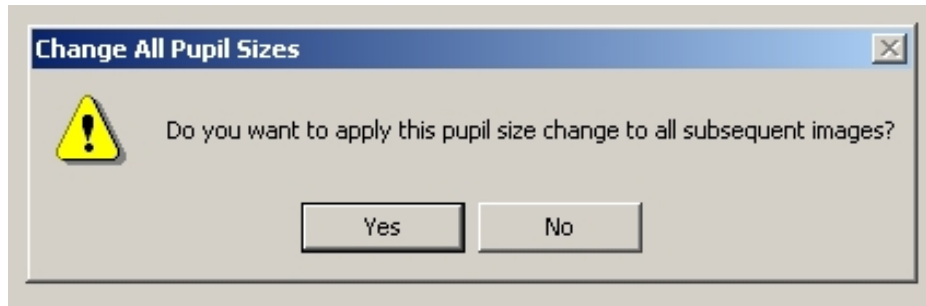
The image in Exhibit 3-38 was taken with small pupil function. ‘Small’ should be selected from the drop-down menu.

Exhibit 3-38. ISIS screen for changing pupil setting



If you change the pupil size setting, a message will be displayed asking if you want to apply this to all subsequent images. Click the appropriate response. See Exhibit 3-39.

Exhibit 3-39. Apply pupil size setting to all subsequent images



3.4.12.2 Exposure Compensations for Dark or Light Retinas

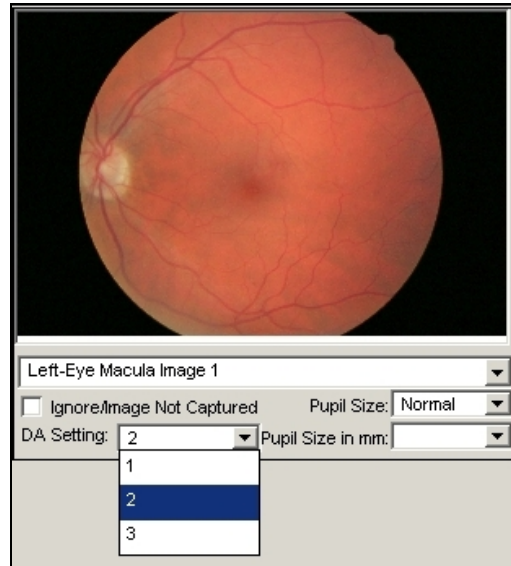
The normal flash output used in this study will be flash number 2. The flash output can be increased or decreased by first pressing the “DA” button followed by the +/- buttons located under the main video display screen of the fundus camera monitor. Higher numbers increase flash output and produce brighter images while lower numbers decrease flash output and produce darker images. A one number increase or decrease in flash intensity is usually all that is needed.

Criteria for Changing the DA Setting

- If the SP is African American or Asian, change the DA setting to 3.
- For all other SPs, check the color saturation of the first image taken of each participant, and adjust the flash if necessary before proceeding.

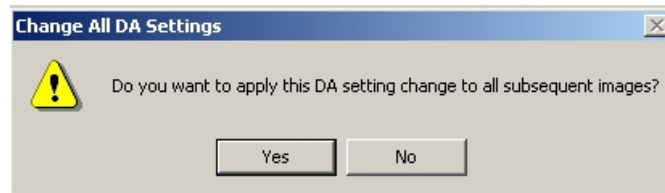
If the DA setting is changed from 2 for an image, select this from the drop-down box on the ISIS screen. The default is 2. See Exhibit 3-40.

Exhibit 3-40. ISIS screen for changing DA setting



If you change the DA setting, a message will be displayed asking if you want to apply this to all subsequent images. Click the appropriate response. See Exhibit 3-41.

Exhibit 3-41. Apply DA setting to all subsequent images



3.4.13 Completing the Exam

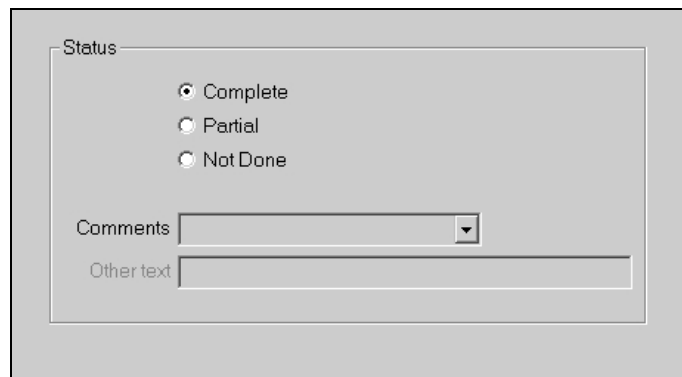
When both exams are completed, remind the SP that this examination does not take the place of the complete clinical eye examination.

Suggested Script: “Please remember that this is NOT a complete clinical eye examination. Only a small portion of your retina was photographed. The exam is done for research purposes and does not take the place of a thorough eye examination done by an eye doctor. The photographs will be carefully examined by trained professionals, without any information about your vision, or general health status. You will certainly be notified should we notice anything requiring immediate attention. Please continue to see your eye doctor on a regular basis for your complete eye examinations.”

3.4.14 Retinal Imaging Section Status

The Retinal Imaging Section Status screen displays the status for the imaging section. See Exhibit 3-42. If the technologist answers Yes to either of the exclusion questions, the status will be not done and the comment code will default to safety exclusion. If the technologist captured all four images, the status will be listed as complete. If the technologist captured at least one of the four required retinal images, the status will be partial, allowing the technologist to provide a reason. If the technologist captured no retinal images, the status will be Not Done, allowing the technologist to provide a reason.

Exhibit 3-42. Retinal Images Section Status Screen



The screenshot shows a form titled "Status" with three radio button options: "Complete" (selected), "Partial", and "Not Done". Below the radio buttons is a "Comments" field with a drop-down menu, and an "Other text" field.

The comments that can be selected from the drop-down menu when the status is partial or not done are as follows:

1. Safety Exclusion;
2. SP Refusal;
3. No Time;

4. Physical limitation;
5. Communication problem;
6. Equipment failure;
7. SP ill/emergency;
8. Eye specific limitation;
9. Other, specify; and
10. Unable to capture one or more images.

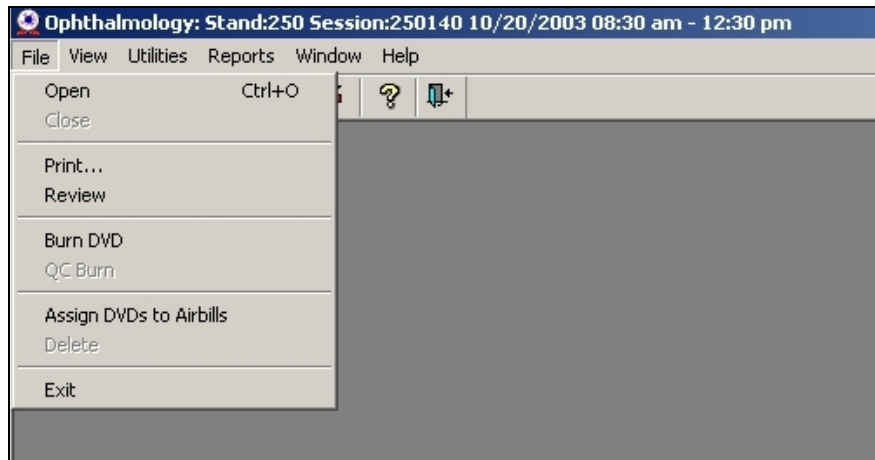
3.5 Storing and Shipping Images

Digital retinal images will be burned to a DVD and shipped to the graders on a weekly basis. The technologist will select 'Burn DVD' from the drop-down file menu in the ophthalmology application. See Exhibit 3-46. The application will then complete the process of burning the DVD.

The application will first get the user name of the technologist doing the burning. Then the application will get a unique batch number for the DVD and create a record in the database for that batch. This number will be used for tracking purposes. The ISIS application will eject the DVD tray and prompt the technologist to put in a DVD. The technologist will acknowledge that a DVD was inserted and the application will verify that a DVD was inserted. The application will retrieve from the database the list of all retinal images that need to be burned onto the DVD and locates the images stored on the hard drive that match the images retrieved. These images are moved to a holding directory. The application creates an XML file that contains the image data necessary for processing at the reading center. Once all of the images are collected into the temporary holding directory and the XML is created, the XML file and the images will be burned onto the DVD.

As the DVDs are burned, the software displays a status bar with a series of messages (testing speed, writing tracks, writing lead-out). See Exhibit 3-43. When the process is completed, a message will be displayed "Burn process completed successfully."

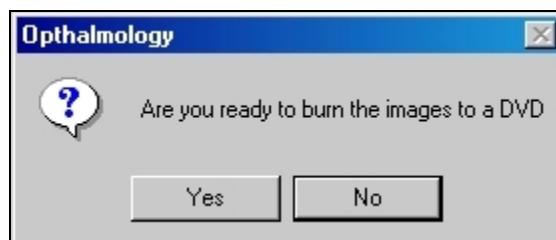
Exhibit 3-43. Burn DVD menu



The steps for burning DVDs are listed below:

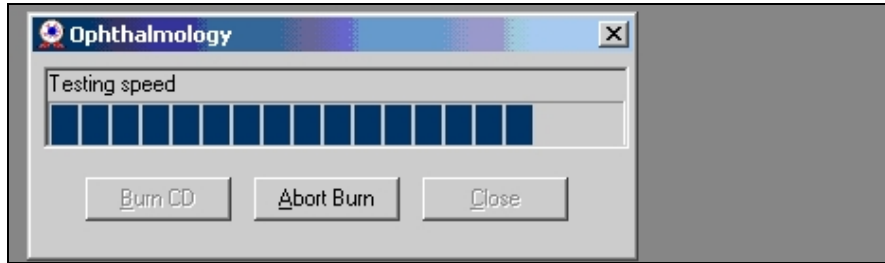
- Get labels from lab staff;
- Put DVD in drive and close drive;
- Select File from menu and select Burn DVD; and
- A message will be displayed asking if you are ready to burn the DVD. (See Exhibit 3-44).

Exhibit 3-44. Burn DVD message



- It may take 1-2 minutes for the hourglass to change to the next screen.
- Progress screens are displayed: (Testing speed, Writing Lead out, Writing tracks) (See Exhibit 3-45.)

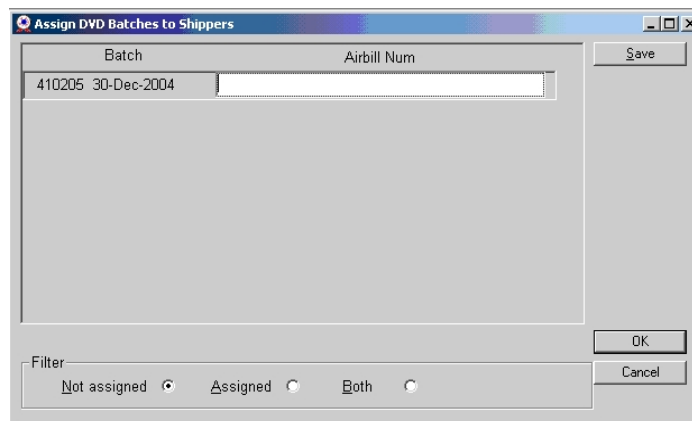
Exhibit 3-45. DVD burn status bar



- It will take 30-60 minutes to burn the DVD.
- When DVD has burned, it will pop out; “Assign DVDs to airbills screen” will be displayed.
- Enter FedEx Tracking Number (do not include spaces) for the airbill to the grader.
- Get DVD label from the Dymo printer and attach to the DVD.
- Put DVD in Fed Ex pack and send to grader.

The label given to the DVD will be the batch number that was generated at the beginning of the process. Once the DVD is done, the ISIS application will eject the DVD and print a label with the batch number. Once the technologist is done burning DVDs, the ISIS application will move the XML file and the images from the temporary holding directory to the archive directory. The technologist will put the label on the DVD. The application will display a message to assign air bills. See Exhibit 3-46. The technologist will enter the air bill number in the field and click OK. The DVD will then be shipped to the graders.

Exhibit 3-46. Assign air bills –assigned list



A list of all assigned air bills can be viewed by clicking on the “assigned” button. See Exhibit 3-47.

Exhibit 3-47. Assigned air bills- not assigned

Batch	Airbill Num
410204 29-Dec-2004	123456456465465465
410205 30-Dec-2004	

Filter
 Not assigned Assigned Both

Buttons: Save, OK, Cancel

4. QUALITY CONTROL

4.1 Overview

Quality control procedures ensure the accurate and reliable collection and documentation of data. Quality assurance/quality control procedures for the ophthalmology component include development of standard procedures for the collection of data for the visual field test and retinal imaging, and intensive training and evaluation of health technologists. Technologist adherence to procedures is monitored regularly through observational visits and specific data analysis for evaluation of performance. The validity and reliability of specific data are also monitored routinely in addition to regular equipment calibration and maintenance procedures.

4.2 Training

Prior to data collection for the main study, a multistage training period was conducted to train eight technologists. The objective of this extensive training was to have all technologists ready to collect quality data as soon as the data collection started. Each technologist was required to image a minimum of 25 volunteers (50 eyes).

4.2.1 Initial Training

The initial training was conducted onsite over a 2-day period. The objective of this training was to familiarize technologists with the protocol, equipment, step-by-step procedures, and data entry. The next step of training was on-site practice and monitoring. The ophthalmology equipment was set up on each of the MECs to allow the technologists to practice procedures on volunteers. The technologists were asked to take images on three volunteers per week between the initial training and start of the main study. This time period allowed technologists to image 25 volunteers. Images were sent to Westat for evaluation and Westat project staff conducted frequent on site monitoring to provide additional training and feedback. At the end of this period, images from six volunteers (12 eyes) for each technologist were sent to graders for evaluation.

4.2.2 Followup Training Prior to Main Study

A 2-day followup training period was conducted prior to the start of the main study data collection. An ophthalmologist consultant conducted didactic training to include an overview of relevant diseases of the eyes and to observe imaging procedures, provide relevant feedback, and review grader evaluation comments.

4.2.3 Training of New Technologists

New health technologists will be trained in a similar manner to the original training. They will receive an initial training over a 2-3 day period to become familiar with the equipment and procedures. This will be followed by a period of imaging volunteers to achieve a minimum of 25 volunteers (50 eyes). Images for 12 eyes (6 volunteers) will be sent to the graders for evaluation.

4.3 Equipment and Room Setup Checks

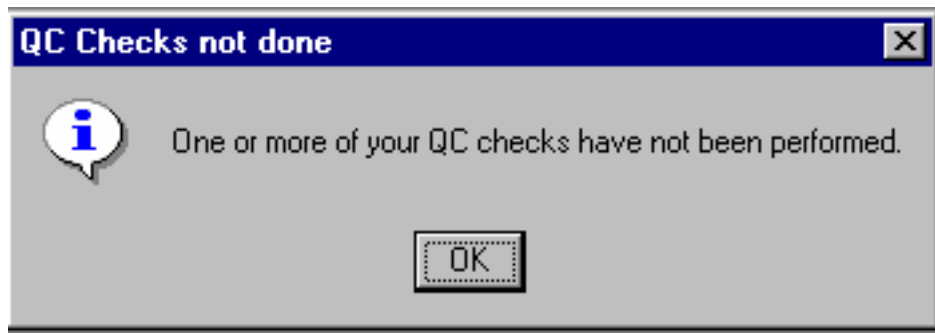
The equipment, room supplies, and room setup need to be checked on a regular basis. Some checks are completed daily and others need only be completed on a weekly basis or at the beginning of each stand. These checks include calibration checks, maintenance inspection of equipment and supplies, and preparation of the room and equipment for the session exams.

4.3.1 Quality Control Log-on Box

Each time you log on to the application, the system will remind you to do Quality Control (QC) checks if the checks have not been completed for that time period. The checks are to be completed daily, weekly, and/or at every stand. If you do not have time to do the checks when you log on, you can bypass this message and complete the checks at a later time. However, this message will be displayed each time you log on until you have completed the checks for that time period. Once you have completed the checks and entered this in the system, the message box with the reminder will not be displayed again until the appropriate time period has passed.

When you log on to the application before the quality control checks are performed, the system displays a message telling you that one or more of the QC checks have not been performed. See Exhibit 4-1. Click 'OK' to this message.

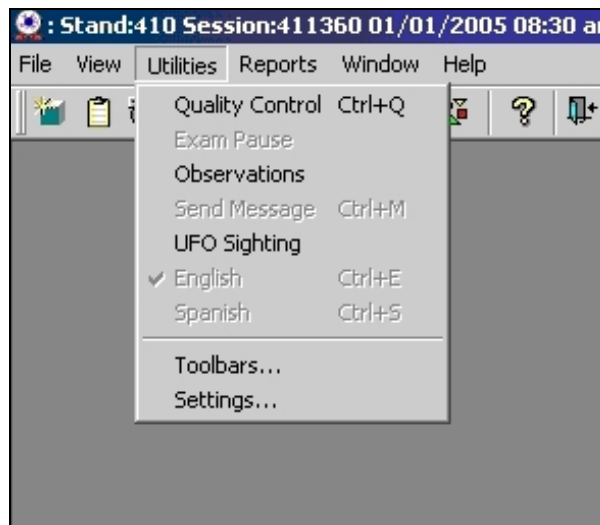
Exhibit 4-1. Quality control reminder message box



4.3.2 Utilities Menu to Select Quality Control

When you want to complete the QC checks, select "Utilities." Then select "Quality Control" from the menu. See Exhibit 4-2. Clicking on the QC icon from the Toolbar can also access the QC screens.

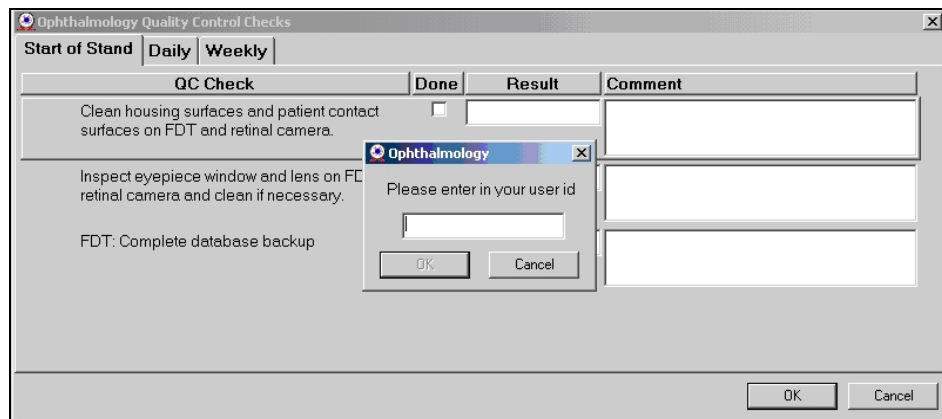
Exhibit 4-2. Utilities menu to select quality control



4.3.3 Quality Control Log-on Box

When QC is selected from the Utilities menu, the User ID entry box will be displayed. See Exhibit 4-3. Each technologist will have a personal ID. This ID will be used to identify the person who completed the QC checks for this time period. Enter your User ID and click “OK.” If you do not want to do the QC checks at this time, click “Cancel.”

Exhibit 4-3. Quality control log-on



4.3.4 Daily Quality Control Checks

The checks and setup procedures that are required on a daily basis in the ophthalmology component are listed below:

- FDT: Clean housing surfaces and patient contact area;
- FDT: Turn power button for machine to perform self-calibration;
- FDT: Check lens for dust, smudges and clean only if necessary;
- FDT: Confirm lens cover is on lens at beginning and end of session;
- FDT: Confirm plastic cover is over the instrument at end of each session;
- Canon: Clean housing surfaces and patient contact area;
- Canon: Confirm pupil size button is in the ‘off’ position;
- Canon: Confirm the DA setting is set to 2;

- Canon: Confirm lamp setting is at 2.5;
- Canon: Confirm IR filter setting is set to IN;
- Canon: Confirm base is in the locked position;
- Canon: Check lens for dust, smudges and clean only if necessary;
- Canon: Confirm lens cover is on lens at beginning and end of session;
- Canon: Confirm plastic cover is over the instrument at end of each session; and
- Check camera settings per protocol.

On the QC screens, check “Done” for the listed items when that item has been completed. See Exhibit 4-4. You are not required to enter anything in the “Result” or “Comment” fields unless there is a problem. The “Result” field is used to enter values for selected QC items if required. The “Comment” field is used to enter information about problems encountered with the QC item check. This field is also used to indicate if something has been reported or confirmed with another staff member (chief technologist, MEC manager). The daily QC screens are displayed below in Exhibits 4.4a-d.

Exhibit 4-4a. Daily QC checks

QC Check	Done	Result	Comment
FDT: Clean housing surfaces and patient contact area	<input type="checkbox"/>		
FDT: Turn power button for machine to perform self-calibration.	<input type="checkbox"/>		
FDT: Check lens for dust, smudges and clean only if necessary	<input type="checkbox"/>		
FDT: Confirm lens cover is on lens at beginning and end of session	<input type="checkbox"/>		

Exhibit 4-4b. Daily QC checks

QC Check	Done	Result	Comment
FDT: Confirm plastic cover is over the instrument at end of each session	<input type="checkbox"/>		
Canon: Clean housing surfaces and patient contact area	<input type="checkbox"/>		
Canon: Confirm pupil size button is in the 'off' position	<input type="checkbox"/>		
Canon: Confirm the DA setting is set to 2.	<input type="checkbox"/>		

Exhibit 4-4c. Daily QC checks

QC Check	Done	Result	Comment
Canon: Confirm Lamp setting is at 2.5.	<input type="checkbox"/>		
Canon: Confirm IR filter setting is set to IN.	<input type="checkbox"/>		
Canon: Confirm base is in the locked position.	<input type="checkbox"/>		
Canon: Check lens for dust, smudges and clean only if necessary	<input type="checkbox"/>		

Exhibit 4-4d. Daily QC checks

QC Check	Done	Result	Comment
Canon: Check lens for dust, smudges and clean only if necessary	<input type="checkbox"/>		
Canon: Confirm lens cover is on lens at beginning and end of session	<input type="checkbox"/>		
Canon: Confirm plastic cover is over the instrument at end of each session	<input type="checkbox"/>		
Check camera settings per protocol	<input type="checkbox"/>		

The procedures for confirming and changing the date on the retinal camera and the settings on the Canon EOS 10D camera are outlined below. These settings should be checked very carefully using the procedures to make any changes if necessary. Do not press buttons without knowing the function of the button.

4.3.4.1 Changing the Date on the Retinal Camera

- Press the 'Set' button and then press the 'Down' button to select 'Set 3';
- Press 'Select' button and then press the 'Date' button;
- Press the 'Target Fixation' button to the right or left to move to the date or time number(s) that need to be changed. When you are on the number that needs to be changed, press the 'Target Fixation' button up or down to move to the correct number; and
- Press 'RTN' button to save the changes and return to the main screen.

4.3.4.2 Checking the Settings on the Canon EOS 10D Camera

- The Canon EOS 10 D camera body should be set with the settings listed in Table 4-1 on page 4-9;
- With the camera turned on, press the 'Menu' button at the top left hand corner of the back of the camera;
- The items and corresponding settings will be displayed in the LED screen of the camera;
- Turn the click wheel right or left to move up or down through the menu;
- Press the black button in the center of the wheel to select a setting;
- The options for that setting will be displayed. Move the click wheel through the options and press the black button in the center to select the appropriate setting;
- Date and time: Press the black button in the center of the click wheel to increase or decrease the numbers. Use the black button in the center of the click wheel to move across the screen from month, day, year, etc. Keep moving the click wheel clockwise to get back to the menu or press the menu button;

- When all the settings have been confirmed, press the 'Menu' button again to exit.
Note: The 'Menu' button must be turned off to check the following settings;
- Shooting Mode: Confirm the setting is "Manual." The mode dial is used to modify this setting. It is located on the top left hand side of the camera. The setting should be at 'M' for manual;
- Shutter speed is the length of time the camera's shutter opens to expose the sensor to the light coming through the lens. It should be set to 60. Shutter speed can be changed by turning the dial on the top of the camera on the right hand side;
- Metering Mode: Confirm setting is "Evaluative." To change this mode if needed, press the button on the top of the camera to the right of the "Drive-ISO" button. While looking at the LCD panel, turn the dial on the top of the camera on the right hand side. The options are Evaluative, Partial, Center-weighted average. Choose "Evaluative." This is the icon with the two half circles with a black dot in the center; and
- ISO Speed: Confirm setting is 400. 'Drive-ISO' button at the top surface of the Canon EOS 10D. The current ISO setting will be displayed. Change this setting by moving the click wheel right or left. When the setting is confirmed, press the ISO button again to exit.

Table 4-1. Settings for the Canon EOS 10D camera body

Setting name	Value
Quality	RAW
Red Eye On/Off	OFF
AEB	0 (Option 1)
WB-BKT	Middle or 0 (Option 1)
BEEP	ON
CUSTOM WB	Not Set
Color Temp	5400k
Parameters	STANDARD
ISO Expansion	OFF
Protect	Not Set
Rotate	Not Set
Print Order	Not Set
Auto Play	Not Set
Auto Power Off	OFF
Review	ON
Review Time	8 Sec.
Auto Rotate	ON
LCD Brightness	3 Bars (Option 3)
Date / Time	Current Date and Time
File Numbering	Continuous
Language	English
Video System	NTSC
Communication	Normal
Below properties obtained	From captured images
Shooting Mode	Manual
TV (Shutter Speed)	1/60
Metering Mode	Evaluative
ISO Speed	400

4.3.5 Weekly Quality Control Checks

The checks and setup procedures that are required on a weekly basis in the ophthalmology component are listed below. (See Exhibits 4-5 and 4-6.)

- Burn DVD and send to grader;
- Clean FDT and Retinal Image camera lenses as per protocol;

- Canon: Inspect the camera lens using the weekly inspection procedures; AND
- Canon: After inspection and cleaning, confirm all settings are set to default settings.

Exhibit 4-5. Weekly QC checks

QC Check	Done	Result	Comment
Complete all daily checks	<input type="checkbox"/>		
Burn DVD and send to Grader	<input type="checkbox"/>		
Clean FDT and Retinal Image camera lenses as per protocol	<input type="checkbox"/>		
Canon: Inspect the camera lens using the weekly inspection procedures.	<input type="checkbox"/>		

Exhibit 4-6. Weekly QC checks

QC Check	Done	Result	Comment
Burn DVD and send to Grader	<input type="checkbox"/>		
Clean FDT and Retinal Image camera lenses as per protocol	<input type="checkbox"/>		
Canon: Inspect the camera lens using the weekly inspection procedures.	<input type="checkbox"/>		
Canon: After inspection and cleaning, confirm all settings are returned to default settings outlined in the weekly procedures.	<input type="checkbox"/>		

4.3.6 Start of Stand

The checks and setup procedures that are required at the start of stand in the ophthalmology component are listed below.

- Complete all daily and weekly checks;
- Perform backup of FDT – send CD to Westat. (See Section 2.2.1.4 for procedures); AND
- Complete manual calibration. (See Section 2.2.1.5 for procedures.)

Exhibit 4-7. Start of stand QC checks

QC Check	Done	Result	Comment
Complete all daily and weekly checks	<input type="checkbox"/>		
Perform backup of FDT - send CD to Westat	<input type="checkbox"/>		
Perform System Calibration	<input type="checkbox"/>		

4.4 Review of Images by Graders

Digital images of the retina and visual field information will be sent to graders under contract (Principal Investigators Dr. Ronald Klein and Dr. Barbara Klein, Department of Ophthalmology and Visual Sciences, University of Wisconsin, Madison) for reading. Dr. Ronald Klein, the Principal Investigator for the NHLBI Multi-Ethnic Study of Atherosclerosis (MESA-EYE) study, has developed the grading protocol for assessing retinopathy, macular degeneration, and other retinal lesions that was successfully performed in NHANES III. In addition to the Drs. Klein, the grading team includes nine experienced graders (a preliminary grading coordinator, two preliminary graders, and six detail graders).

The digital retinal images will be loaded onto DVDs and shipped to a remote reading center for grading using standardized methods.

The images will be evaluated in semi-quantitative fashion by two independent graders using EyeQ Lite software for storage, retrieval, and manipulation of digital images. The standard MESA-EYE protocols will be used for grading the digital images. There are three distinct steps involved—early review for pathology, preliminary grading, and detail grading. A preliminary grading coordinator reviews images for significant pathology and generates pathology notification within 3 days of receiving the images. All images are further graded by at least two graders (a preliminary grader and a detail grader). The preliminary grader or detail grader may see a pathology that was missed in early pathology review. It is extremely rare in early review to miss a serious pathology that requires early notification. Upon systematic grading, if the first two graders do not agree on pathology, a third grader grades the eye. If two of the three graders disagree, Dr. Ron Klein will do adjudication for retinal pathology and Dr. Barbara Klein will do adjudication for optic nerve abnormalities to make the final decision. Among the conditions evaluated are retinopathy severity levels and its supporting lesions, age-related maculopathy, and other vascular and retinal changes.

4.5 Observational Visits

At regular intervals, NCHS personnel and Westat component staff will observe the ophthalmology examinations conducted in the mobile examination center. These observations will serve to verify that the protocol is being implemented correctly and consistently and that standard procedures and techniques are being followed. Problems and feedback will be noted and feedback will be provided to the technologists as necessary.

4.5.1 Site Visit Report Form

The Site Visit Report form (Exhibit 4-8) is an online method to identify, document, and followup on issues or problems noted during observational field visits. This form is completed by consultants and development staff following each field visit and is posted to the project intranet site. This form is used to give an overall assessment of the status of the component and team performance.

Exhibit 4-8. Site Visit Report form

Date(s) of Visit:		Stand #	
Name of Observer:		Visit # (this year to this team)	
Component:	Ophthalmology	# of SP exams observed:	
ID number of examiners/recorders observed			
<p>1. Outstanding issues from last visit or QC meeting (if any):</p> <p>2. Observations/issues:</p> <p>3. Issues that need to be addressed at the next visit:</p> <p>4. Comments:</p>			

5. REFERRALS AND REPORT OF FINDINGS

5.1 Report of Findings

Each SP will be given a report of the results or findings for the ophthalmology. There are three distinct steps involved in the report of findings process for this component: early review for pathology, preliminary grading, and detail grading.

5.1.1 Early Reporting of Pathology

The early pathology review and notification is a separate process from the systematic grading of the digital images. If the grading contractors detect eye pathology requiring further evaluation, they will notify the DHANES Operations Branch Medical Officer by fax within 3 days of receiving the images. No identifying information other than the participant's sample number will be provided on the fax. The medical officer will send a letter to the participant within 24 hours of receiving the fax with recommendations for followup.

Pathology reported early with immediate followup recommended:

- Active Proliferative Retinopathy;
- Clinically Significant Macular Edema (CSME);
- Treatable Age-Related Macular Degeneration (signs of neovascularization);
- Hollenhorst Plaque;
- Irregular Nevus;
- Branch Vein or Central Vein Occlusion; or
- Other (describe).

Pathology reported early with followup in the next 2 months recommended:

- Suspicious Cup/Disc Ratio;
- Preproliferative Diabetic Retinopathy;

- Macular Edema (not CSME);
- Macular Hole;
- Surface Wrinkling Retinopathy/Epiretinal Membrane;
- Branch Vein or Central Vein Occlusion;
- Abnormal Visual Field; and
- Other (describe).

5.1.2 Preliminary Grading

A preliminary grading coordinator reviews images for significant pathology and generates pathology notification within 3 days of receiving the images. All images are further graded by at least two graders (a preliminary grader and a detail grader). The preliminary grader or detail grader may see a pathology that was missed in early pathology review. However, it is extremely rare in early review to miss a serious pathology that requires early notification. Upon systematic grading, if the first two graders do not agree on pathology, a third grader grades the eye. If two of the three graders disagree, Dr. Ron Klein will do adjudication for retinal pathology and Dr. Barbara Klein will do adjudication for optic nerve abnormalities to make the final decision. Among the conditions evaluated are retinopathy severity levels and its supporting lesions, age-related maculopathy, and other vascular and retinal changes.

5.1.3 Detailed Grading

A detailed grading protocol written by the contract graders is available.

5.1.4 Final Report of Findings

Findings from the NHANES Ophthalmology component will be provided in the Final Report of Findings sent to participants 12-16 weeks after the examination. Abnormal findings will be reported to participants as early as possible.

Findings reported will be reported in two categories: (a) visual field testing results (eye-specific), and (b) retinal image findings.

NOTE: Reporting is automated and will be based on the grading following a standard protocol.

- (1) **Visual field testing:** Visual field test results will be reported for each eye. The definition of a visual field abnormality (eye-specific) is any two fields on an FDT below 1 percent threshold level in first test, AND at least two fields below 1 percent threshold level in second test, AND at least one of which is the SAME field as in first test.

“We did a visual field test to find out how well you can see things peripherally or out to the side.”

“Your visual field test was <normal> or <outside normal limits> in your right eye, and <normal> or <outside normal limits> in your left eye. *If either eye abnormal, add:* This may suggest an eye problem, which should be evaluated by an eye doctor within the next two months.”

- (2) **Retinal image findings:** In some cases, the participant may have received a pathology notification earlier. Reported findings may be the same as the previous pathology notification or may contain additional information about other less severe conditions.

- a. No Significant Abnormalities. If all of these variables are coded None or Questionable (ARM Feedback code 0, Diabetic Retinopathy Level coded 10/13/14/15, all other variables coded 0/1/8), then the feedback text will state:

“No significant abnormalities were found in the back of your (right/left) eye(s).”

- b. Ungradable Images. If ARM Feedback and Retinopathy Level are both coded as ungradable (ARM Feedback coded 8 **and** Retinopathy Level coded 88) then the feedback statements should state:

“Unfortunately, we were unable to evaluate the photographs of the back (the retina) of (your right/your left/either) eye.”

- c. Abnormalities Present.

APPENDIX A
OPHTHALMOLOGY SCRIPTS
(ENGLISH)

Ophthalmology Scripts

English

Suggested Script (Introduction, Setup, and Visual Field Test)

“Hi {...Name of SP...}. My name is {...Your name...}. Please come in and have a seat in this chair. (CLEAN MACHINES WHILE ON THAT SIDE OF THE TABLE) I am going to turn off the lights in order to do a couple of examinations on your eyes.”

“These exams are to look for conditions resulting from aging or diseases like Diabetes that affect people’s vision. I will tell you about these exams in more detail before I do them. For now, just relax for a minute while I enter some information into the computer.”

(COME AROUND THE TABLE, LOG IN TO EXAM, LOG IN SP, AND ENTER THE SP INFORMATION. SEE WALL CARD FOR PROCEDURES IF NECESSARY. TAKE OFF THE LENS AND POSITION THE SP. TELL THE SP ONE TIME WHAT IS NEEDED FOR POSITIONING AND THEN RE-POSITION WITH HANDS IF NECESSARY.)

“The first exam will determine how well you can see objects at the outer area of your vision field. Please hold this button that you will use and place your forehead on the forehead rest.”

“Are you comfortable?”

“Can you see the black spot in the center of the screen? You must keep looking at the black spot in the center at all times during the test.”

“While looking at the black spot in the center, can you see all four triangles at the edge of the screen?”

The instrument is showing you patterns that flicker, or shimmer, or are striped. We are now running a practice test. Each time you see one of these patterns, press (and release) the button you have in your hand. You don’t need to hold it down - you just press and release. You may blink your eyes whenever you want. A good time to blink is whenever you press the button. Do you understand what you are to do?”

“We’ll start the test now. There will be a brief flash just before the actual test begins. Please remember to keep looking at the black spot in the center of the screen at all times during the test.”

(DURING EXAM REMIND SP TO LOOK AT THE BLACK SPOT IN THE CENTER; REMIND THEM TO BLINK IF THEY NEED TO.)

Ophthalmology Scripts

English

Standard Script (Retinal Imaging)

(AFTER FDT EXAM IS COMPLETED):

“In the second part of the exam I will take a few pictures of the lining on the back of your eyes. While I save the information from this first exam, please close your eyes and keep them closed to help your pupils or the black part of your eyes dilate or get larger so that we can get better pictures.”

(EXPLAIN WHILE FDT DATA IS IMPORTING)

“Mr./Ms. _____, please keep your eyes closed while I explain the next part of the exam. The lights were turned off because a darker room will help your pupils or the black part of your eyes dilate or get larger so we can get better pictures of your eyes. In this part, I will not be touching your eyes or giving you any eye drops.”

“While I am focusing the camera on your eyes I will ask you to focus on certain objects. You will see a bright flash as each picture is taken. After each picture, you may see a blue or red circular spot. This will disappear and will not damage to your eye. I will explain the procedures in more detail and answer any questions you may have as we go through each step. First, I want to get you positioned correctly. Please open your eyes and place your chin on the chin rest and press your forehead on the forehead rest. Make sure your forehead is pressed on the forehead rest throughout the exam”.

“You should be able to see an orange circle. Can you see it? Good. Please look at that circle and don’t look anywhere else so I can align your eye.” In a moment, I will change the screen and the circle will disappear. When it disappears, please continue looking straight ahead where the circle was.”

(SECOND IMAGE):

“Again, please look at the yellow circle.” (PRESS ALIGNMENT BUTTON)

“Now you should be able to see red bars and a green square. Do you see them? Good. Please look at the green square and follow it as it moves. If possible, please do not talk or move until after I take the picture. “

“You’re doing a great job”, “Keep looking on the green square”, “We’re almost finished”

(EXPLAIN WHILE LAST IMAGES ARE TRANSFERRING)

“Please remember that this is NOT a complete clinical eye examination. Please continue to see your eye doctor on a regular basis for your complete eye examinations.”

APPENDIX B
OPHTHALMOLOGY SCRIPTS
(SPANISH)

Ophthalmology Scripts

Spanish

Suggested Script (Introduction, Setup, and Visual Field Test)

“Buenos(as) (días/tardes) {NAME OF SP}. Mi nombre es {YOUR NAME}. Por favor venga y siéntese en esta silla (CLEAN MACHINES WHILE ON THAT SIDE OF THE TABLE). Voy a apagar las luces para hacerle un par de exámenes en los ojos.

Estos exámenes son para ver si tiene condiciones que resultan del envejecimiento o de enfermedades tales como la diabetes que afectan la visión de las personas. Le hablaré acerca de estos exámenes con más detalle antes de hacerlos. Por ahora, relájese por un minuto mientras anoto alguna información en la computadora.”

(COME AROUND THE TABLE, LOG IN TO EXAM, LOG IN SP, AND ENTER THE SP INFORMATION. SEE WALL CARD FOR PROCEDURES IF NECESSARY. TAKE OFF THE LENS AND POSITION THE SP. TELL THE SP ONE TIME WHAT IS NEEDED FOR POSITIONING AND THEN RE-POSITION WITH HANDS IF NECESSARY.)

“Este primer examen determinará qué tan bien puede ver usted los objetos que están fuera del área de su campo visual. Por favor tome este botón el cual usará luego y ponga la frente en la parte para apoyar la frente.”

“¿Está cómodo(a)?”

“¿Puede ver el punto negro en el centro de la pantalla? Debe seguir mirando el punto negro en el centro en todo momento durante la prueba.”

Mientras está mirando el punto negro en el centro, ¿puede ver los cuatro triángulos en el borde de la pantalla?

El instrumento está mostrándole formas que resplandecen o brillan o que son rayadas. Ahora haremos una prueba para practicar. Cada vez que usted vea una de estas formas, presione (y suelte) el botón que tiene en la mano. No necesita mantenerlo presionado – solamente presione y suelte.”

Usted puede parpadear cuando quiera. Un buen momento para parpadear es cuando presiona el botón. ¿Comprende lo que tiene que hacer?”

“Empezaremos la prueba ahora. Habrá un pequeño destello justo antes de que empiece la prueba verdadera. Por favor recuerde mantenerse mirando el punto negro en el centro de la pantalla todo el tiempo durante la prueba.”

(DURING EXAM REMIND SP TO LOOK AT THE BLACK SPOT IN THE CENTER; REMIND THEM TO BLINK IF THEY NEED TO.)

Ophthalmology Scripts

Spanish

Standard Script (Retinal Imaging)

(AFTER FDT EXAM IS COMPLETED):

“En la segunda parte del examen, tomaré unas pocas fotos del revestimiento de la parte posterior de los ojos. Mientras proceso la información del primer examen, por favor cierre los ojos y manténgalos cerrados para ayudar a las pupilas o la parte negra de sus ojos a que se dilate o se haga más grande para que yo pueda tomar mejores fotos.

(EXPLAIN WHILE FDT DATA IS IMPORTING)

Sr./Sra./Srta. _____, por favor mantenga los ojos cerrados mientras yo le explico la siguiente parte del examen. Apagamos las luces porque un cuarto más oscuro ayudará a que la pupila o parte negra de los ojos se dilate o se haga más grande para que yo pueda tomar mejores fotos de los ojos. En esta parte, no le tocaré los ojos ni le pondré gotas para los ojos.

Mientras enfoco la cámara sobre los ojos le pediré que fije la vista en ciertos objetos. Verá un destello brillante cada vez que se tome una foto.

Después de cada foto, es posible que usted vea un punto circular azul o rojo. Esto desaparecerá y no le causará daño a los ojos.

Le explicaré los procedimientos con más detalle y le contestaré las preguntas que usted tenga mientras vamos por cada paso.

Primero, quiero colocarlo/la correctamente. Por favor abra los ojos y ponga la barbilla en la parte para poner la barbilla y presione la frente sobre la parte para poner la frente. Asegúrese de mantener la frente presionada sobre la parte para poner la frente durante todo el examen.”

“Usted debe poder ver un círculo de color naranja. ¿Lo puede ver? Bien. Por favor mire ese círculo, y no mire a ningún otro lado para que así yo pueda alinear sus ojos.” En un momento, cambiaré la pantalla y el círculo desaparecerá. Cuando desaparezca, por favor continúe mirando derecho hacia delante donde estaba el círculo.”

(SECOND IMAGE):

Nuevamente, por favor mire el círculo amarillo. (PRESS ALIGNMENT BUTTON)

“Ahora usted debe poder ver barras rojas y un cuadrado verde. ¿Los ve? Bien. Por favor mire el cuadrado verde y sígalo cuando se mueve. Si es posible, por favor no hable ni se mueva hasta después de que yo tome la foto.”

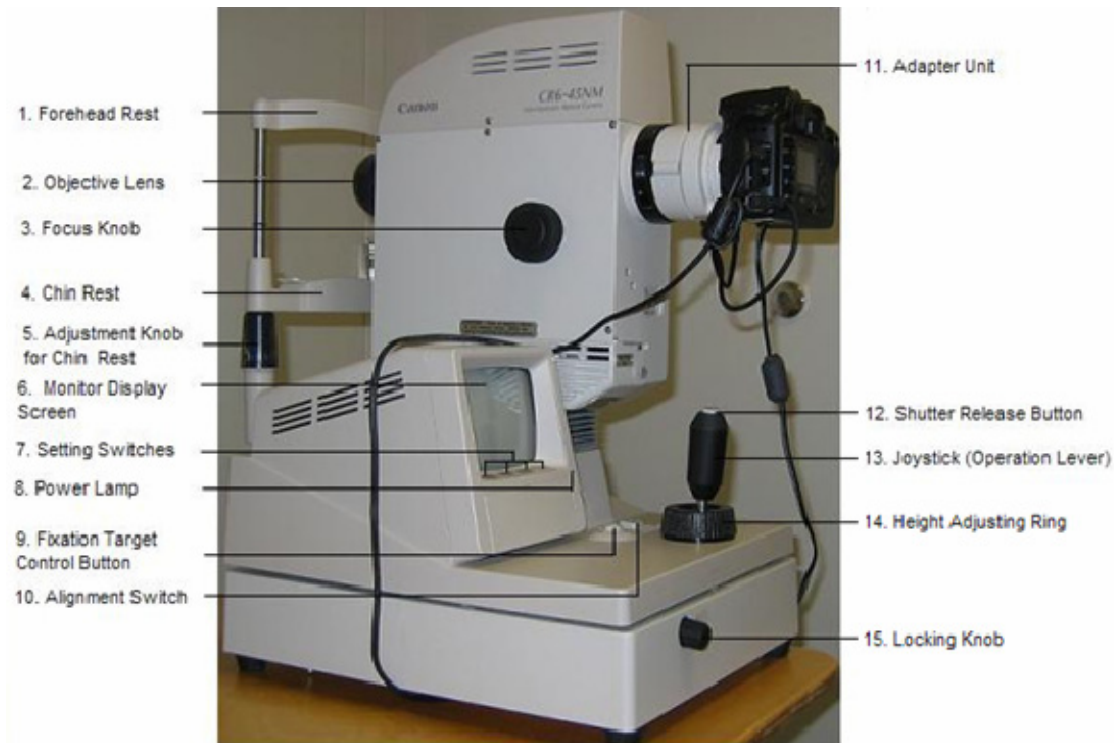
“Lo está haciendo muy bien”, “Siga mirando el cuadrado verde”, “Ya casi terminamos”

(EXPLAIN WHILE LAST IMAGES ARE TRANSFERRING)

“Por favor recuerde que éste NO es un examen clínico completo de la vista. Por favor, siga consultando a su médico de la vista en forma regular para su examen completo de la vista.”

APPENDIX C

OPHTHALMOLOGY
Equipment Diagrams



Canon CR6 45NM Retinal Camera (Left Side View)

1. Forehead Rest – SP’s forehead is positioned against this rest.
2. Objective Lens – The main lens for photography.
3. Focus Knob – Used for focusing on examinee’s eye.
4. Chin Rest – SP’s chin is positioned on this rest.
5. Adjustment Knob for Chin Rest – Used for adjusting the height of the chin rest.
6. Monitor Display Screen – Display for external eye image, retinal image, & setting,
7. Setting Switches – Used for selecting functions (DA) or setting data (time, date, etc.).
8. Power Lamp – Lights when power is turned on and blinks while power saving system is working.
9. Fixation Target Control Button – Moves the eye fixation target during observation of the retina.
10. Alignment Switch – Changes the display on the monitor from external eye image to retinal image.
11. Adapter Unit – Unit for attaching the Canon EOS10 to the retinal camera.
12. Shutter Release Button – Press this button to take a picture.
13. Joystick (Operation Lever) – Used for positioning the retinal camera in relation to the SP’s eye.
14. Height Adjusting Ring – Used for adjusting the height of the retinal camera.
15. Locking Knob – Used for locking the base.



Canon CR6 45NM Retinal Camera (Right Side View)

1. Diopter Compensating Slider – A diopter is a unit of measurement that helps determine how much a lens should be altered to bend or refract light rays to achieve correct focus. In some settings the slider can be pulled out when the diopter of the eye exceeds -12D to +15 D. This is not used as part of our protocol.
2. IR Filter Knob – Must be set to ‘IN’ for imaging and out when cleaning the objective lens.
3. Lamp Knob – Used for adjusting brightness for observation. The lamp is set to 2.5 for this protocol.
4. Fuse Holders – There are two holders and each contains a 125V 4A fuse.
5. Power Switch – Used for turning power on and off.
6. Objective Lens – The main lens for imaging.
7. Forehead Rest – Place the SP’s forehead against this rest.
8. Height Adjustment Mark – Align the height of the SP with this mark by adjusting the chin rest.
9. Chin Rest – Place the SP’s chin on this rest.
10. Small Pupil Knob – The is turned to “ON” when imaging an eye with pupil size smaller than 4.0 mm.
11. AC (IN) Power Connector – Connector for the power cable.



Canon EOS10 Digital Camera

1. Menu Button – Controls on-screen menus for setting camera settings.
2. Digital Terminal – Connects to computer or printer.
3. LCD Monitor – Screen for viewing images.
4. Remote Control Terminal – Connects to remote or to adaptor.
5. Erase Button – Erases images.
6. Main Switch – Button to turn on the camera.
7. ISO Speed Button – Used for changing ISO settings (a numeric indication of the sensitivity to light. Higher ISO indicates a higher sensitivity to light).
8. Quick Control Dial Switch – Switch to turn on the click-wheel or dial.
9. Quick Control Dial – Click-wheel or dial to modify settings.
10. Setting Button – Sets the settings once a setting is selected.



Canon EOS10 Digital Camera Accessories

1. Power Cord – Connects to the AC adaptor and DC Coupler plug to power the battery pack.
2. AC Adapter (ACK-E2) – Adaptor for the battery pack.
3. Battery Pack – Power for the camera can be from a fully charged battery or using an AC adaptor.
4. Canon EOS 1-D Digital Camera
5. USB Cable to Computer – Cable to connect to the computer.
6. Digital Cable to Camera- Cable from computer is connected to this port on the camera.
7. Cables from Adapter to Camera – Cables from the adaptor are connected to the PC terminal and Remote Control terminal.
8. Adapter for Retinal Image Camera – Used to connect the Retinal Image camera to the digital camera.



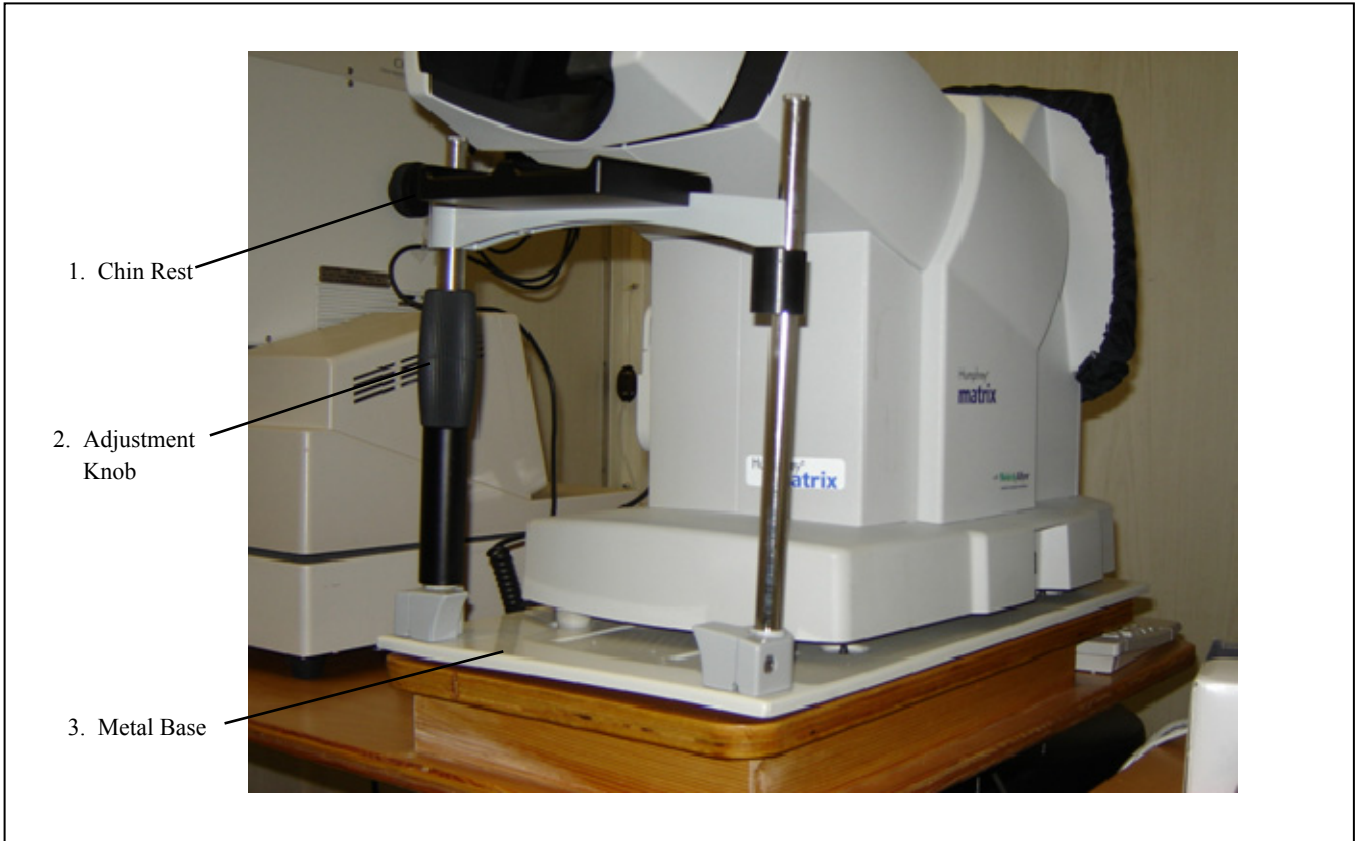
**Humphrey Matrix Visual Field Instrument (FDT Instrument)
SP Side**

1. SP Response Button – SP presses button when a pattern is seen.
2. Forehead Rest – SP should position his or her forehead on this rest.
3. Calibration Cap Covering Eyepiece – Cap used to protect the lens when equipment not in operation.
4. SP Visor – Moves right and left to test each of the SP's eyes.



**Humphrey Matrix Visual Field Instrument (FDT Instrument)
Technician Side**

1. Power Button –Turns the unit on and off.
2. Monitor Screen – Displays data entry and testing screens.
3. CD Drive
4. Floppy Drive
5. Keyboard
6. Touchpad



**Humphrey Matrix Visual Field Instrument (FDT Instrument)
Chin Rest**

1. Chin Rest
2. Adjustment Knob
3. Metal Base