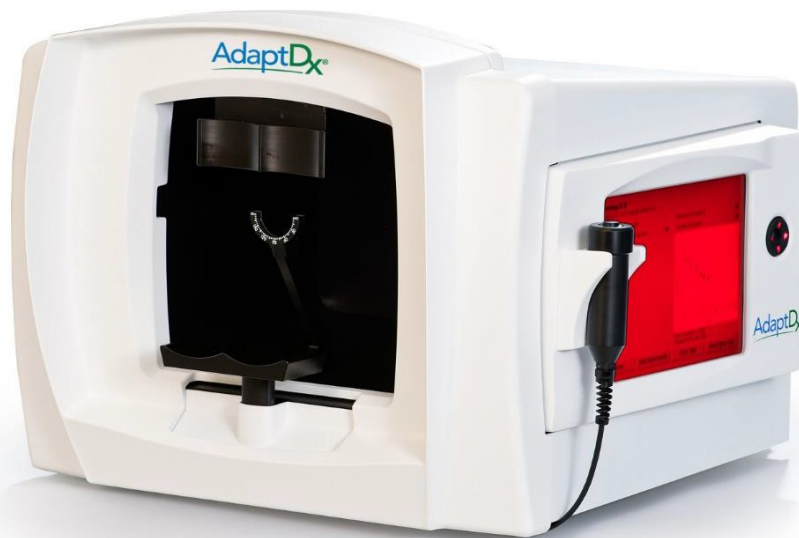




User Manual

United States Edition



Model Dx-04



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1 Introduction

1.1 Dark Adaptation

Dark adaptation is the process of the eyes adjusting to low levels of illumination. During dark adaptation the sensitivity of the eye to light is increased. The two major components of dark adaptation are dilation of the pupil and photochemical alterations of the retina.

For measurement of dark adaptation with the AdaptDx®, the patient is exposed to a bright flash followed by a dim adaptation stimulus. The intensity of the adaptation stimulus is gradually extinguished while the patient sits in complete darkness. The just-detectable stimulus intensity and the time at which it is detected are periodically recorded to generate a dark adaptation threshold curve, and the speed of dark adaptation recovery is characterized by a proprietary parameter called the Rod Intercept.

1.2 AdaptDx® Intended Use

The AdaptDx® is an AC powered, automated adaptometer (biophotometer) intended to measure the time for retinal adaptation after exposure to an adapting light.

1.3 AdaptDx® Limitations of Use

The AdaptDx® is not suitable for use with patients who are unable to follow simple instructions, operate a response button, or maintain attention for the anticipated duration of the test. The AdaptDx® is not suitable for use with patients who are unable to perform the AdaptDx® Practice Test (see Section 4.2).

1.4 Caution

Federal law restricts this device to sale by or on the order of a physician or other eye care professional.

1.5 Warning

The AdaptDx® is not intended to be used in the diagnosis or screening of any specific ocular disease.

1.6 AdaptDx® Specifications

Photobleaching Subsystem

| | |
|----------------------|---|
| Mechanism | flash |
| Bleaching Wavelength | 505 nm |
| Bleaching Range | 20% to 95% effective bleach (0.01 to 6,000 scot lx sec) |

Stimulus Subsystem

| | |
|---------------------|-----------------|
| Stimulus Wavelength | 505 nm |
| Stimulus Duration | 100 to 300 msec |
| Stimulus Size | 2° |

| | |
|----------------------------|--|
| Stimulus Location | 5°, 8.5° or 12° at eight azimuthal locations |
| Maximum Stimulus Intensity | 7.4 scot mlx |
| Dynamic Range of Stimulus | 10 ⁵ |

Patient Alignment

| | |
|---------------------|--------------|
| Fixation Wavelength | 635 nm |
| Fixation Intensity | 3.6 phot mlx |
| Viewing Distance | 30 cm |

Operation

| | |
|-----------------------|--------------|
| Maximum Test Duration | 1 to 100 min |
|-----------------------|--------------|

General
























| | |
|---------------------------|--|
| Dimensions | 43 cm (height) x 58 cm (width) x 56 cm (depth) |
| Weight | 21 kg |
| Electrical Specifications | 100-240VAC, 50-60Hz, 2.25A |
| Fuse Ratings | 250V, 2.25A, Slo-Blo 3AG |

Environmental Requirements

| | |
|-----------|---|
| Operating | +10° C to +35° C 20% to 80% RH (noncondensing) 700 hPa to 1,060 hPa |
|-----------|---|

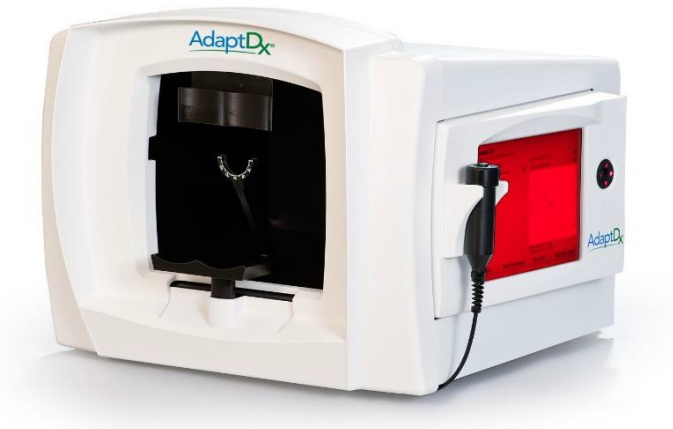
| | |
|-----------------------|--|
| Transport and Storage | -20° C to +65° C 20% RH to 80% RH (noncondensing) 500 hPa to 1,060 hPa |
|-----------------------|--|

1.7 Symbol Definitions

| | | | | | |
|---|----------------------------|---|--|---|-----------------------------|
|  | Power on |  | Power off |  | Alternating current |
|  | Non-ionizing radiation |  | Type B (degree of protection against electrical shock) |  | Follow instructions for use |
|  | Universal serial bus (USB) |  | Ethernet |  | Response button |
|  | Model number |  | Serial number |  | Manufacturer |
|  | Manufacture date |  | Temperature range |  | Humidity range |
|  | Atmospheric pressure range |  | This way up |  | Keep dry |
|  | Fragile |  | Do not stack |  | FCC Mark |
|  | ETL Listing |  | CE mark | | |

2 Installation & Setup

2.1 AdaptDx® System Components



The AdaptDx® system consists of the following three components:

- AdaptDx® Dark Adaptometer
- Response Button
- Power Cord

The following items are optional accessories:

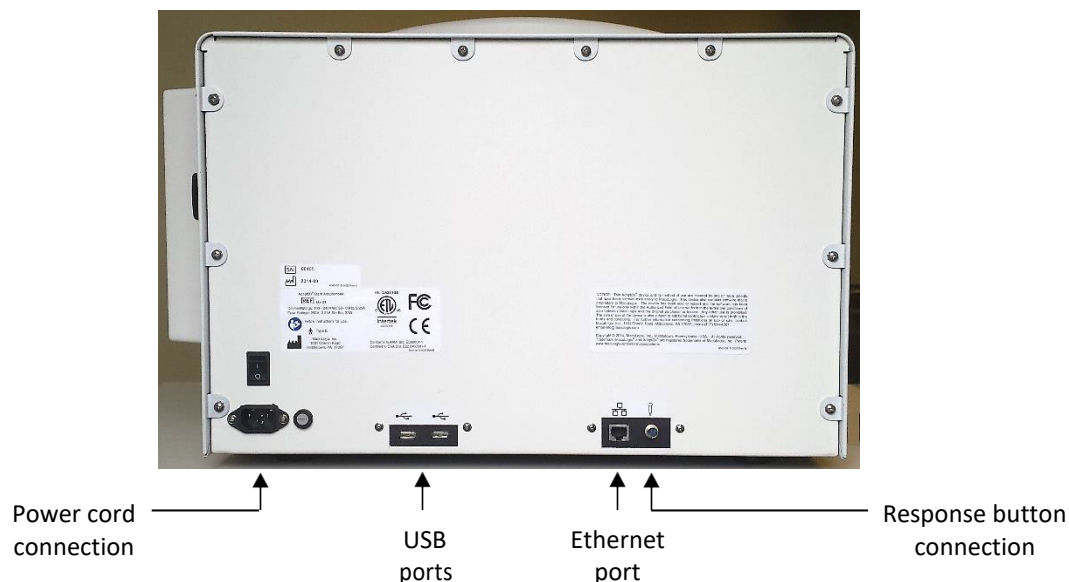
- Power Table
- Adjustable Patient Chair
- Operator Chair
- Keyboard
- Printer
- Wireless Network Adapter
- Ethernet Cable
- Full Aperture Trial Lens Set

The following item is a customer-supplied disposable:

- Eye Patches

2.2 AdaptDx® Setup

Back of AdaptDx®



There are two steps to setting up the AdaptDx®:

Step 1 – Plug the Response Button cord into the jack receptacle on the back of the AdaptDx® (labeled “response button connection” in the picture above).

Step 2 – Plug one end of the Power Cord into the power cord receptacle on the back of the AdaptDx® (labeled “power cord connection” in the picture above) and the other end into a standard, three-prong, grounded electrical outlet. The shape of the Power Cord plugs allows only one cord orientation.

The following additional steps are needed when connecting to optional accessories:

Optional Step 1 – If a Keyboard is being used, plug the Keyboard cord into either of the two USB ports on the back of the AdaptDx® (labeled “USB ports” in the picture above). This Keyboard may be used interchangeably with the on-screen keyboard and keypads. Only those keys which are present on the on-screen displays may be used.

Optional Step 2 – If the AdaptDx® is being connected to a dedicated Printer, plug one end of the Ethernet Cable into the Ethernet port on the back of the AdaptDx® (labeled “Ethernet port” in the picture above) and the other end directly into the Ethernet port on the dedicated Printer. See Section 5.5.4 for further step-by-step instructions required to complete the Printer connection and print a test page.

Optional Step 3 – If the AdaptDx® is being connected to a shared Printer on a local area network, plug one end of the Ethernet Cable into the Ethernet port on the back of the AdaptDx® (labeled “Ethernet port” in the picture above) and the other end into an Ethernet port on the local area network. Alternatively, the Wireless Network Adapter may be configured to allow the AdaptDx®

to connect to the local area network wirelessly. See Section 5.5.4 for further step-by-step instructions required to complete the Printer connection and print a test page.

No software installation or configuration is necessary. All software needed for operation of the AdaptDx® was preloaded and configured at the factory.

WARNING: To avoid damage or malfunction, do not power on the AdaptDx® before it reaches its specified operating temperature, humidity, and atmospheric pressure (see Section 1.7).

User Tips

- The AdaptDx® should be installed in a testing room that can be **completely** darkened. Ideally, the testing room walls should be painted a dark color and there should be no windows. If there are windows, they should be completely covered, with the covering sealed around the edges. Doors should be sealed around the edges and bottom (e.g., with weather stripping) to block any excessive light leakage into the room. Lighting on any other equipment in the testing room, such as display monitors, lit power on/off switches and status lights, should be turned off during dark adaptation testing or covered (e.g., with electrical tape or rubylith film).
- A red dark room lamp or a flashlight with a red filter may be used for operator convenience during testing without compromising the test results.
- It is recommended that the AdaptDx® be mounted on a Power Table and the patient be seated in an Adjustable Patient Chair (both are optional accessories not included with the basic AdaptDx® system) to facilitate patient alignment and comfort (see Section 4.2.4).
- When lifting or moving the AdaptDx®, place hands underneath the base plate. Do not use the front or display bezels as hand holds. It is recommended that the AdaptDx® be lifted by two people.

2.3 AdaptDx® Startup/Shutdown

Back of AdaptDx®



Startup – To start up the system, power on the AdaptDx® and the optional Printer (if connected). The AdaptDx® and Printer can be powered on in any order. The power switch for the AdaptDx® is located on the back panel (labeled “On/Off switch” in the picture above). Powering on these two devices will automatically result in the AdaptDx® reaching a fully operational state with the Home screen appearing on the Monitor, ready for use.

Shutdown – To shut down the system, power off the AdaptDx® and the optional Printer (if connected). The AdaptDx® and Printer can be powered off in any order. Powering off these two devices will automatically shut down the AdaptDx® software. The AdaptDx® can be shut down from any operator screen. There is no separate shut down for the software nor is there a need to first return to the Home screen.

User Tips

- If nothing appears on the Monitor after startup, adjust the brightness level by rotating the Brightness Adjustment Knob on the right side of the Monitor housing (see Section 4.2.5).
- It is not necessary to shut down the AdaptDx® at the end of a testing session. The AdaptDx® and Printer can be left powered on indefinitely without harm to the system or significant impact on its lifetime.

3 Overview of Operation

Measurement of dark adaptation with the AdaptDx® starts by exposing the test eye to a mild camera flash to pre-condition the retina to a standard, photobleached state. The patient is then asked to focus on a fixation light and indicate with a response button when a stimulus light appears in his peripheral vision. Stimulus lights are presented at a fixed location using a pattern of generally decreasing intensities to determine visual sensitivity recovery. Specifically, starting at a relatively bright intensity, stimulus lights are presented very briefly at intervals of 2 to 3 seconds. The intensity of the stimulus presentations remains unchanged until the patient responds. It is then decreased for each successive presentation until the patient stops responding. At that point, it is increased for each successive presentation until the patient once again responds. The final intensity in this sequence is defined as a sensitivity threshold, completing the cycle. After a short break, a new cycle begins at a stimulus light intensity slightly brighter than the previous threshold. Approximately one threshold is determined per minute for the duration of the test. After the test is completed, the AdaptDx® uses a plot of thresholds vs. time to calculate a proprietary parameter called the Rod Intercept. The Rod Intercept is the time in minutes at which the visual sensitivity recovery crosses three log units of recovery. This is a point when visual sensitivity recovery is completely rod-mediated. The Rod Intercept characterizes the visual sensitivity recovery rate, or dark adaptation speed. Testing is conducted in a darkened room on a single eye at a time.

The overall testing procedure consists of the following steps:

- Refract test eye (to determine appropriate trial lenses)
- Enter patient information in AdaptDx® (name, age, gender, etc.)
- Patch non-test eye
- Place appropriate trial lenses in AdaptDx® (if needed)
- Align patient to AdaptDx®
- Enter test information in AdaptDx® (protocol, test eye, pupil size, etc.)
- Conduct demonstration test with AdaptDx®*
- Conduct actual test with AdaptDx®†

*Typically less than two minutes.

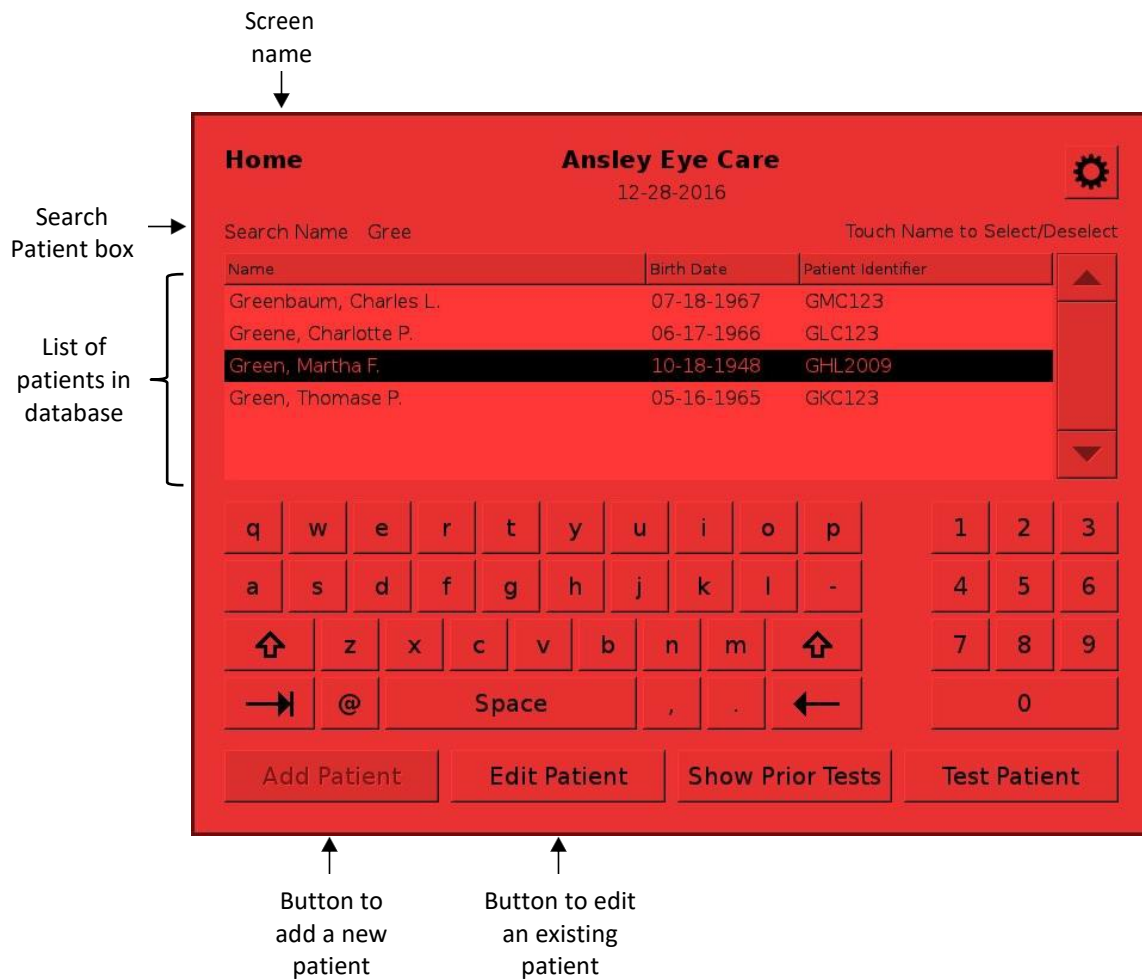
†From one to 100 minutes depending on the test protocol selected; typically five minutes for a Rapid Test and fifteen minutes for an Extended Test.

These procedures are described in detail in this User Manual.

4 Detailed Operating Instructions

4.1 Entering Patient Information

4.1.1 Overview



The AdaptDx® maintains a database of basic patient information such as name, date of birth and gender. Patient information can be entered separately from patient testing or as part of the testing procedure. For example, an eye care practice may want to enter information for all of its new patients at the start of the day, or it may want to enter information immediately prior to testing while the patient is present to confirm accuracy.

As illustrated above, the Home screen displays a scrollable list of all patients in the database. Typing all or part of a patient's name in the Search Patient box above the list narrows the display to matching entries. Touching a name in the list selects that patient for editing.

Patient information can be entered two ways:

Add Patient – Touch the Add Patient button at the bottom of the screen to add a new patient to the AdaptDx® database (see Section 4.1.2).

Edit Patient – Touch the Edit Patient button at the bottom of the screen to update information for an existing patient (see Section 4.1.3). The Edit Patient button will not become active until a patient is selected for editing by touching a name in the scrollable display.

User Tips

- The display of patient names lists only the most recent name associated with a Patient Identifier. If a patient's name is changed—for example to correct a misspelling or when the patient gets married—all information for that patient will be linked to the new name.

4.1.2 Add Patient

Screen name

↓

Patient information

Add Patient

Touch Item to Edit

Patient Identifier

Last Name, First Name, Middle Name (optional)

Date of Birth (MM-DD-YYYY) ▼ Age: Sex: ☐ Male ☐ Female

Q W E R T Y U I O P 1 2 3

A S D F G H J K L - 4 5 6

↑ Z X C V B N M ↑ 7 8 9

→ @ Space , . ← 0

Cancel & Home Save & Home Save & New Save & Test

Button to abandon entry without saving

Button to save entry and return to Home screen

Button to save entry and add another patient

Button to save entry and begin testing patient

The Add Patient screen is accessed from the Home screen (see Section 4.1.1). It is used to add a new patient to the AdaptDx® database.

Entering Patient Information – There are five required fields and one optional field:

- Patient Identifier (required) – sometimes called Medical Record Number
- Last Name (required)
- First Name (required)
- Middle Name (optional) – can be full middle name, middle initial or left blank
- Date of Birth (required) – must be entered in MM-DD-YYYY format
- Gender (required)

The Patient Identifier is unique to a single patient. Attempts to reuse or enter a duplicate Patient Identifier will not be allowed. Touching the triangle to the right of the Date of Birth field launches a date picker to facilitate entry. The patient's age is automatically calculated by the AdaptDx® and displayed next to the Date of Birth.

Four actions can be taken after entry of patient information:

Cancel & Home – Touch the Cancel & Home button at the bottom of the screen to abandon the entered patient information without saving it and return to the Home screen.

Save & Home – Touch the Save & Home button at the bottom of the screen to save the entered patient information and return to the Home screen.

Save & New – Touch the Save & New button at the bottom of the screen to save the entered patient information and clear all fields on the Add Patient screen for addition of another new patient.

Save & Test – Touch the Save & Test button at the bottom of the screen to save the entered patient information and proceed immediately to testing of the patient just added to the database (see Section 4.2).

User Tips

- Upon entering the Add Patient screen, the Patient Identifier field will initially be active. Touching the “tab” key at the lower left of the touch screen keyboard will advance to the next field. Alternately, a field can be made active by touching it.
- Entries can be corrected by touching on the field to be corrected and using the “backspace” key at the lower right of the touch screen keyboard to erase the entry.

4.1.3 Edit Patient

Screen name
↓

Edit Martha F. Green
DOB 10-18-1948; Patient ID GHL2009

Touch Item to Edit

Patient information

GHL2009
Patient Identifier

Green, Martha F.
Last Name First Name Middle Name (optional)

10-18-1948 ▼ Age: 68 Sex: ☐ Male ☒ Female
Date of Birth (MM-DD-YYYY)

q w e r t y u i o p 1 2 3
a s d f g h j k l - 4 5 6
⬆ z x c v b n m ⬆ 7 8 9
→ ⬆ @ Space , . ⬆ 0

Cancel & Home Save & Home Save & Test

Button to abandon edits without saving

Button to save edits and return to Home screen

Button to save edits and begin patient testing

The Edit Patient screen is accessed from the Home screen (see Section 4.1.1). It is used to update information for an existing patient. As illustrated above, the name of the patient selected for editing is displayed at the top of the screen, and the information fields are pre-populated with the current database information.

Editing Patient Information – There are six fields that can be edited:

- Patient Identifier (required) – sometimes called Medical Record Number
- Last Name (required)
- First Name (required)
- Middle Name (optional) – can be full middle name, middle initial or left blank
- Date of Birth (required) – must be entered in MM-DD-YYYY format
- Gender (required)

The Patient Identifier is unique to a single patient. Attempts to reuse or enter a duplicate Patient Identifier will not be allowed. Touching the triangle to the right of the Date of Birth field launches a date picker to facilitate entry. The patient's age is automatically calculated by the AdaptDx® and displayed next to the Date of Birth.

Three actions can be taken after editing patient information:

Cancel & Home – Touch the Cancel & Home button at the bottom of the screen to abandon the edits without saving them and return to the Home screen.

Save & Home – Touch the Save & Home button at the bottom of the screen to save the edits and return to the Home screen.

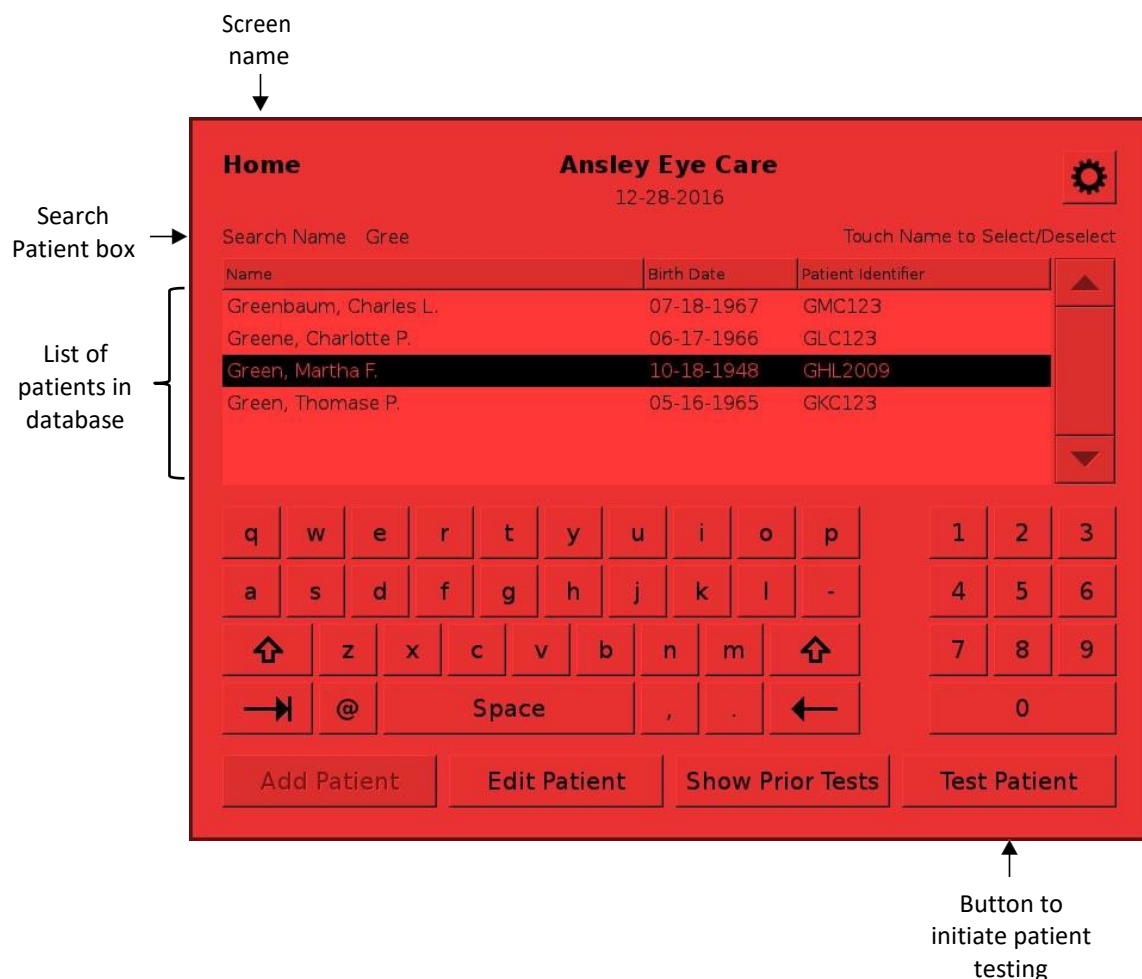
Save & Test – Touch the Save & Test button at the bottom of the screen to save the edits and proceed immediately to testing of the patient just edited (see Section 4.2).

User Tips

- Upon entering the Edit Patient screen, the Patient Identifier field will initially be active. Touching the “tab” key at the lower left of the touch screen keyboard will advance to the next field. Alternately, a field can be made active by touching it.
- Entries can be corrected by touching on the field to be corrected and using the “backspace” key at the lower right of the touch screen keyboard to erase the entry.

4.2 Preparation for Testing

4.2.1 Patient Selection



Testing is initiated from the Home screen (illustrated above) by selection of the patient to be tested.

Select Patient – As illustrated above, the Home screen displays a scrollable list of all patients in the AdaptDx® database. Typing all or part of a patient's name in the Search Patient box above the list narrows the display to matching entries. Touching a name in the list selects that patient. If the name of the patient to be tested does not appear in the scrollable display, it must be added to the AdaptDx® database before proceeding (see Section 4.1.2).

Proceed to Testing – Touch the Test Patient button at the bottom of the screen to proceed. The Test Patient button will not become active until a patient is selected from the scrollable display.

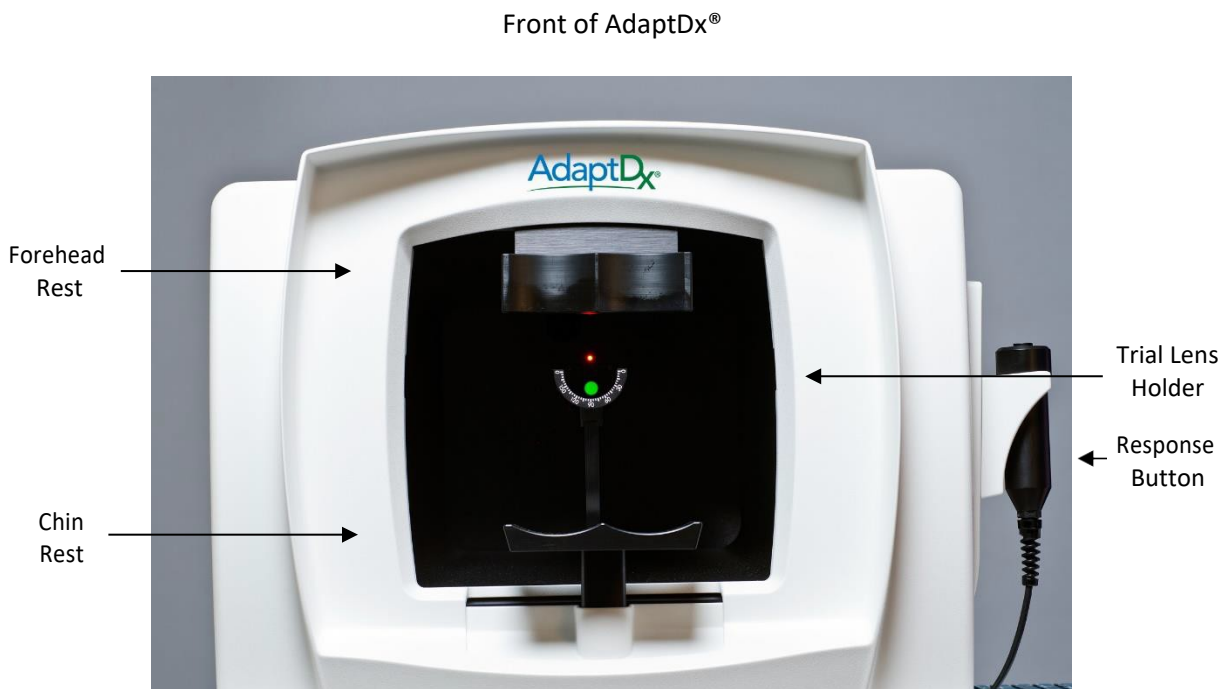
User Tips

- The display of patient names lists only the most recent name associated with a Patient Identifier. If a patient's name is changed—for example to correct a misspelling or when the patient gets married—all information for that patient will be linked to the new name.

4.2.2 Patient Preparation

Before bringing the patient to the AdaptDx®, there are two preliminary steps needed to prepare for dark adaptation testing:

Distance Refraction – Patients should be refracted for distance at six meters. This is needed to determine appropriate corrective trial lenses to be used during dark adaptation testing.



After bringing the patient to the AdaptDx® there are several additional steps needed to orient and position the patient:

Demonstrate Response Button – Demonstrate the operation of the Response Button to the patient. It can be held in whichever hand is most comfortable for the patient.

Insert Corrective Trial Lenses – If needed, insert appropriate full aperture trial lenses into the trial lens holder (see picture above). The trial lens calculator will be used to determine the trial lens(es) to be used during testing. The Trial Lens Calculator is described in Section 4.2.3. Test Set Up.

Patch Non-Test Eye – An Eye Patch should be placed over the non-test eye. The Eye Patch should be disposable and have foam around the edges of the patch to completely occlude the eye. Eye Patches that allow light to be visible to the occluded eye along the patient's nose can cause invalid measurements. Ensure that the Eye Patch string is not on the lid of the test eye as this can cause discomfort and affect the test results.

Position Patient – The patient should be seated comfortably in front of the AdaptDx® with chin resting on the chin rest and forehead firmly against the forehead rest (see picture above). Ensure that the height of the AdaptDx® is appropriate for the patient by adjusting the height of the Power

Table (if available) and/or by adjusting the height of the Adjustable Patient Chair (if available). The patient will need to remain in this position throughout the test so comfort is important. Instruct the patient to keep his forehead firmly against the forehead rest and keep his mouth closed (teeth together, but not clenched) and look at the red fixation light at the back of the viewing tunnel throughout the test.

Right Side of AdaptDx®



The final step before proceeding with testing is to align the test eye with the AdaptDx®.

Align Test Eye – Use the Chin Rest Adjustment Switch on the side of the AdaptDx® (see picture above) to move the test eye into gross alignment with the fixation light at the back of the viewing tunnel. After gross alignment, a close-up image of the patient's test eye should appear superimposed over an alignment cross hair on the left side of the Monitor (see picture above). Use the Chin Rest Adjustment Switch to fine tune the alignment by centering the test eye pupil over the alignment cross hair.

User Tips

- The Chin Rest Adjustment Switch has two speeds. Pressing the center button while also pressing a directional button (up/down/left/right) provides fast motion for gross adjustment. Pressing a directional button alone provides slow motion for fine adjustment.
- If the Monitor is too bright or too dim, adjust the brightness level by rotating the Brightness Adjustment Knob on the right side of the Monitor housing (see picture above).
- Full aperture or perimetry trial lenses should be used. Some older refractive lens sets have smaller apertures with a wide rim that can cause shadowing.

- All of the steps up until this point—AdaptDx® startup, patient selection, patient preparation, test parameter set up, and test eye alignment—can be done with the room lights on. It is not necessary to turn off the room lights until right before starting the Demonstration Test (see Section 4.3).

4.2.3 Test Set Up

Screen name
↓

Testing Martha F. Green
DOB 10-18-1948; Patient ID GHL2009

Protocol: ▼ Prescription: ▼

Test Eye: ▼ Pupil Size: ▼ Trial Lens:

Home Demonstration Test Quit

Button to return to Home screen Button to start Demonstration Test Button to start Actual Test

The Testing screen is accessed from the Home screen (see Section 4.2.1). As illustrated above, the name of the patient selected for testing is displayed at the top of the screen.

Entering Test Parameters – There are three required fields and two optional fields:

- Protocol (required) – defaults to last protocol used for patient being tested
- Test Eye (required) – defaults to right eye
- Pupil Size (required) – 2.0 mm to 10.0 mm
- Prescription (optional) – Sph: -19.0 to +13.0, Cyl: -5.0 to +5.0, Axis: 0° to 180°

Protocol defaults to the last protocol used for the patient being tested (or the Rapid Test protocol for new patients – see below). Test Eye defaults to the right eye. Touching the triangles to the right of these fields launches picker menus that allow the Protocol and Test Eye to be changed.

Pupil Size is initially blank. However, the diameter of the Test Eye pupil must be entered before proceeding to testing. Touching the triangle to the right of this field launches a utility for automatic or manual measurement of Pupil Size (see Section 4.2.4).

Prescription (and Trial Lens) default to blank. To preserve a record of the test conditions, it is recommended—but not required—that prescription cylinder, sphere, and axis values be entered. A valid prescription entry will automatically determine and display the correct Trial Lens(es) that should be used during the testing. Touching the triangle to the right of this field launches a popup menu to facilitate prescription entry.

Protocols – The AdaptDx® provides two types of protocols:

- Standard Test Protocols are intended for routine clinical use in the assessment and monitoring of dark adaptation. Two Standard Test Protocols are pre-loaded on the AdaptDx® before delivery. The first protocol, referred to as the “Rapid Test”, provides a rapid assessment of dark adaptation speed. The Rapid Test takes approximately 5 minutes to complete. The second protocol, referred to as the “Extended Test”, provides a detailed characterization of dark adaptation speed and a benchmark for monitoring changes over time. The Extended Test takes up to 20 minutes to complete.
- Custom Test Protocols are for custom user applications. Any number of Custom Test Protocols can be created to address specific user needs by varying the following parameters within the ranges indicated:

| <u>Parameter</u> | <u>Range</u> | <u>Default</u> |
|-----------------------|--|-------------------|
| Effective Bleach | 20% to 95% (0.01 to 6,000 scot lx sec) | 83% (673) |
| Starting Stimulus | 0.0 to 5.0 log units (0 to 7.4 scot mlx) | 1.0 (0.74) |
| Stimulus Duration | 100 to 300 msec | 200 |
| Stimulus Location | 5°, 8.5° or 12° at eight azimuths | 5° below fixation |
| Rest Break Interval | 0 to 60 sec | 15 |
| Maximum Test Duration | 1 to 100 min | 45 |

Custom Test Protocols can be added and edited using the Manage Protocol utilities (see Sections 5.3.2, 5.3.3 and 5.3.4).

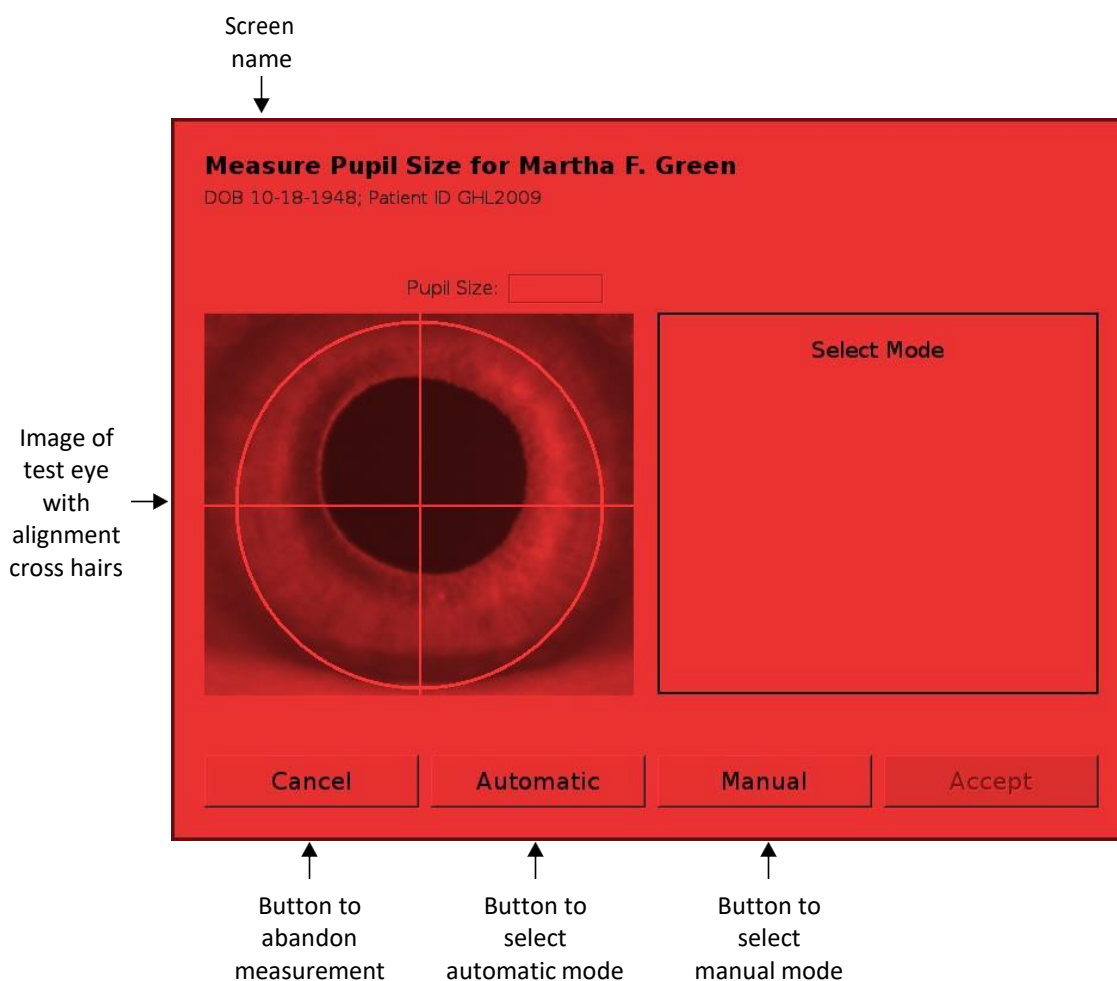
Three actions can be taken after completion of test parameter set up:

Home – Touch the Home button at the bottom of the screen to abandon testing and return to the Home screen.

Demonstration – Touch the Demonstration button at the bottom of the screen to proceed with a Demonstration Test (see Section 4.3).

Test – Touch the Test button at the bottom of the screen to proceed with an Actual Test (see Section 4.4).

4.2.4 Measurement Pupil Size - Select Mode



The Measure Pupil Size screen is accessed from the Testing screen (see Section 4.2.3). The operator is given the option of having the diameter of the test eye pupil measured automatically or entered manually.

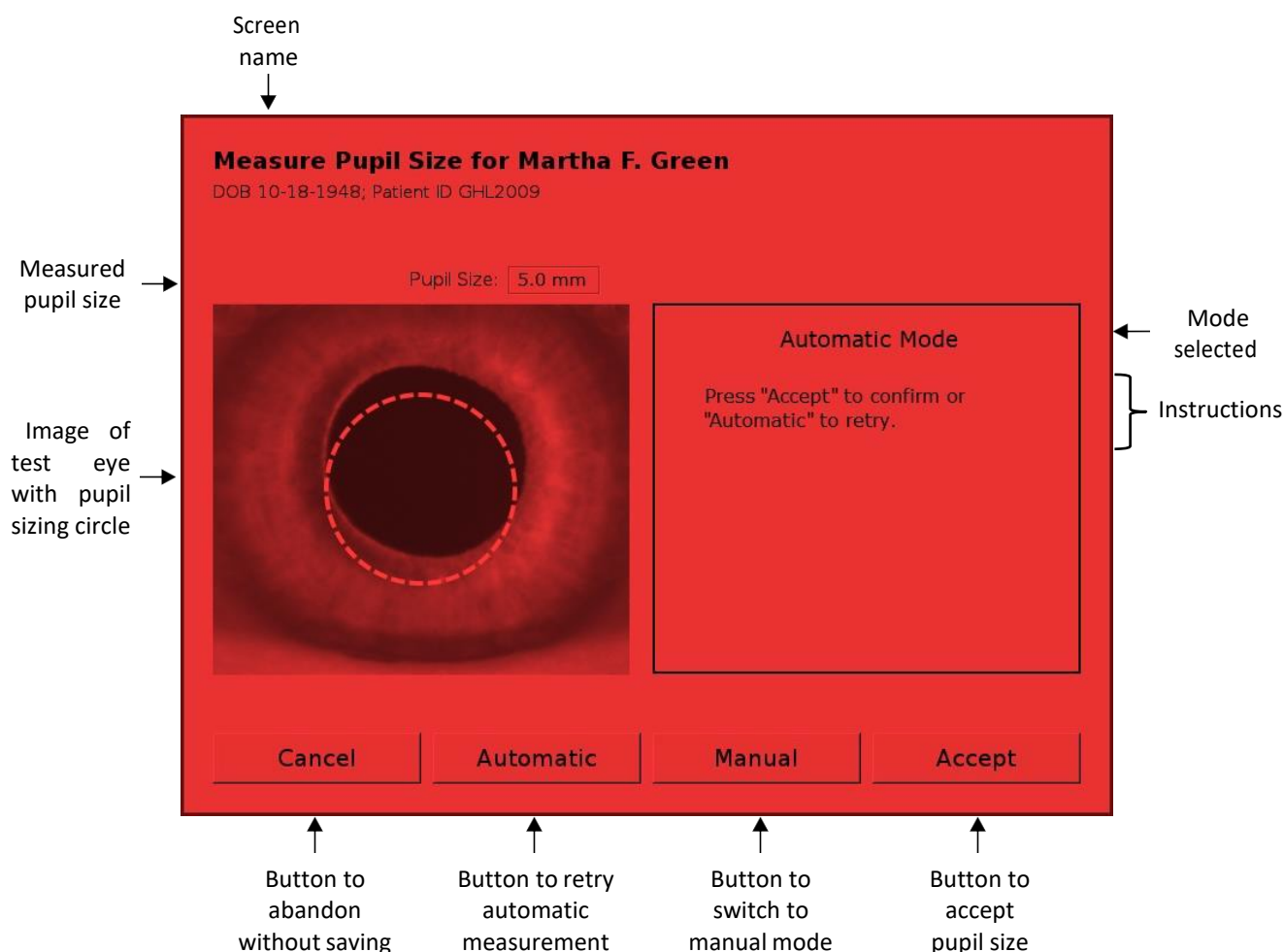
After centering the image of the test eye on the alignment cross hairs (see Section 4.2.2), three actions can be taken:

Cancel – Touch the Cancel button at the bottom of the screen to abandon Pupil Size measurement and return to the Testing screen.

Automatic – Touch the Automatic button at the bottom of the screen to select automatic measurement (see Section 4.2.5).

Manual – Touch the Manual button at the bottom of the screen to select manual entry (see Section 4.2.6).

4.2.5 Measure Pupil Size - Automatic Mode



When the automatic mode for Pupil Size measurement is selected (see Section 4.2.4), the AdaptDx® automatically adjusts the diameter of a pupil sizing circle overlaying the test eye image (see illustration above) to match the pupil diameter to the nearest 0.5 mm. The Pupil Size field is populated with that value. If the AdaptDx® is unable to determine the Pupil Size within three seconds, a dialog box will appear asking the operator to either re-align the patient and retry, or switch to manual mode (see Section 4.2.6).

Cancel – Touch the Cancel button at the bottom of the screen to abandon automatic mode without saving the measured Pupil Size and return to the Testing screen.

Automatic – Touch the Automatic button at the bottom of the screen to reject the automatically measured value and retry.

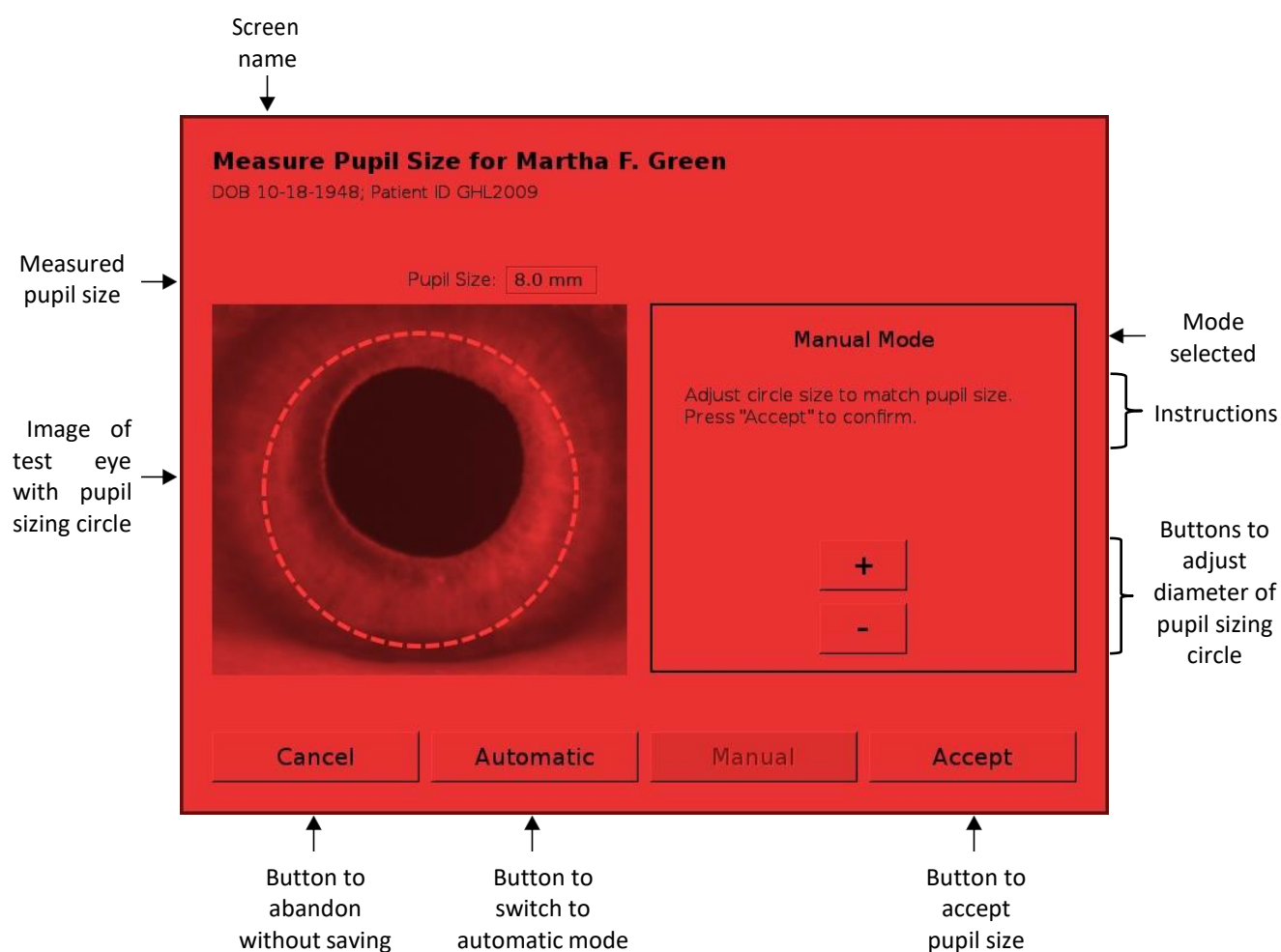
Manual – Touch the Manual button at the bottom of the screen to switch to manual mode (see Section 4.2.6).

Accept – Touch the Accept button at the bottom of the screen to save the measured Pupil Size and return to the Testing screen.

User Tips

- To allow an accurate Pupil Size measurement, stray hair and eye lashes should be brushed away from the test eye, and patients with ptosis may need to have a drooping eyelid taped open.
- If the diameter of the automatically generated pupil sizing circle does not appear to be a good match with the diameter of the pupil image, re-align the patient's eye and retry by touching the Automatic button at the bottom of the screen. If you continue to get a poor match, switch to manual mode.

4.2.6 Measure Pupil Size - Manual Mode



When the manual mode for Pupil Size measurement is selected (see Section 4.2.4), the operator can manually adjust the diameter of a pupil sizing circle overlaying the test eye image (see illustration above) to match the pupil diameter. “Plus” and “minus” buttons on the right half of the screen change the diameter in steps of 0.5 mm. The Pupil Size field is continuously populated with the diameter of the pupil sizing circle.

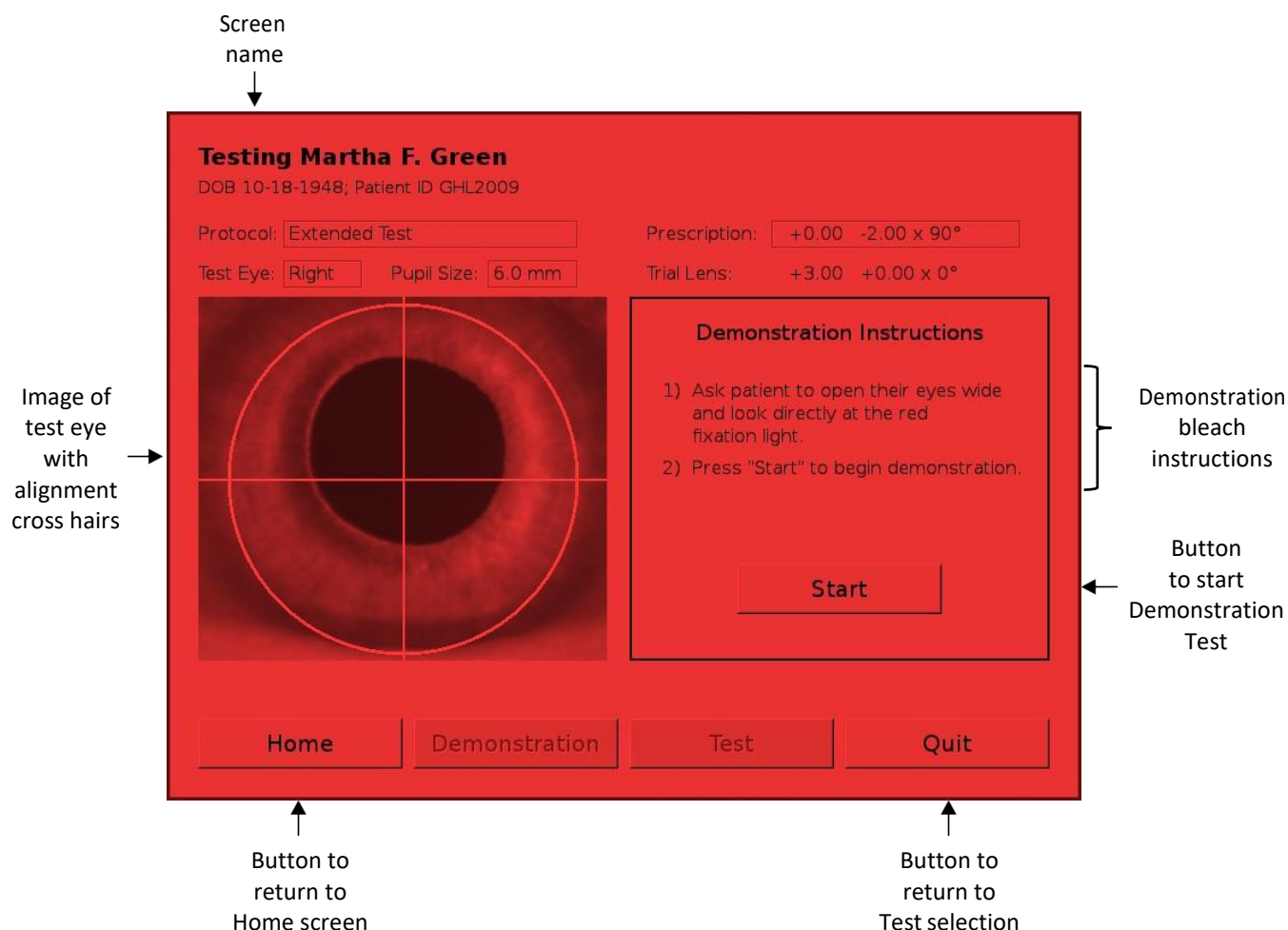
Cancel – Touch the Cancel button at the bottom of the screen to abandon manual mode without saving the measured Pupil Size and return to the Testing screen.

Automatic – Touch the Automatic button at the bottom of the screen to switch to automatic mode.

Accept – Touch the Accept button at the bottom of the screen to save the measured Pupil Size and return to the Testing screen.

4.3 Running a Demonstration Test

4.3.1 Start of Demonstration Test



The Demonstration testing screen is accessed from the Home screen (see Section 4.2.1). As illustrated above, the name of the patient selected for testing is displayed at the top of the screen.

Screen Layout – There are two major components to the Testing screen. The left half of the screen shows a close-up image of the patient’s test eye superimposed over an alignment cross hair. The right half of the screen initially shows patient instructions in preparation for the bleaching event. After the Start button is pressed, the demonstration bleaching flash is delivered and the screen reverts to a plot of visual sensitivity thresholds vs. time (see Section 3). The y-axis is log sensitivity, going from zero sensitivity at the top to five orders of magnitude of sensitivity recovery at the bottom. The x-axis is time from the start of the test in minutes.

A two-minute Demonstration Test is provided to familiarize the patient with the AdaptDx® test procedure before beginning an Actual Test. The Demonstration Test starts with a simulated (sub-ambient) bleaching flash that—unlike the bleaching flash in an Actual Test—is too weak to light adapt the patient’s retina. The patient is then asked to focus on the red fixation light and push

the Response Button whenever the stimulus light appears in his peripheral vision below the fixation light.

Demonstration Test Instructions – The recommended instructions to prepare the patient are:

“This is a short Demonstration Test so that you can become familiar with the test procedure. Your job is to look at the red light at the back of the viewing tunnel and use your peripheral vision to detect a spot of light that will appear at brief intervals. The Demonstration Test will start with a dim flash. After the flash, press the Response Button whenever you see the spot of light. The spot of light may appear brighter or dimmer and that is normal. The color of the light may change and that is normal. During the test, the best time to blink is right after you push the Response Button.”

Starting the Demonstration Test – Before starting the Demonstration Test, confirm that patient preparation (see Section 4.2.2) and test set up (see Section 4.2.3) have been properly completed, and the test eye is correctly aligned to the cross hairs. When everything is ready, recite the Demonstration Test instructions to the patient and turn off the room lights. Then ask the patient to open their eyes wide and look directly at the red fixation light. Touch the Start button, which will trigger the simulated flash and begin the Demonstration Test. The recommended instructions to the patient at the start of the Demonstration Test are:

“We are ready to start the demonstration. When I ask you to, please open your eyes wide and look directly at the red fixation light.

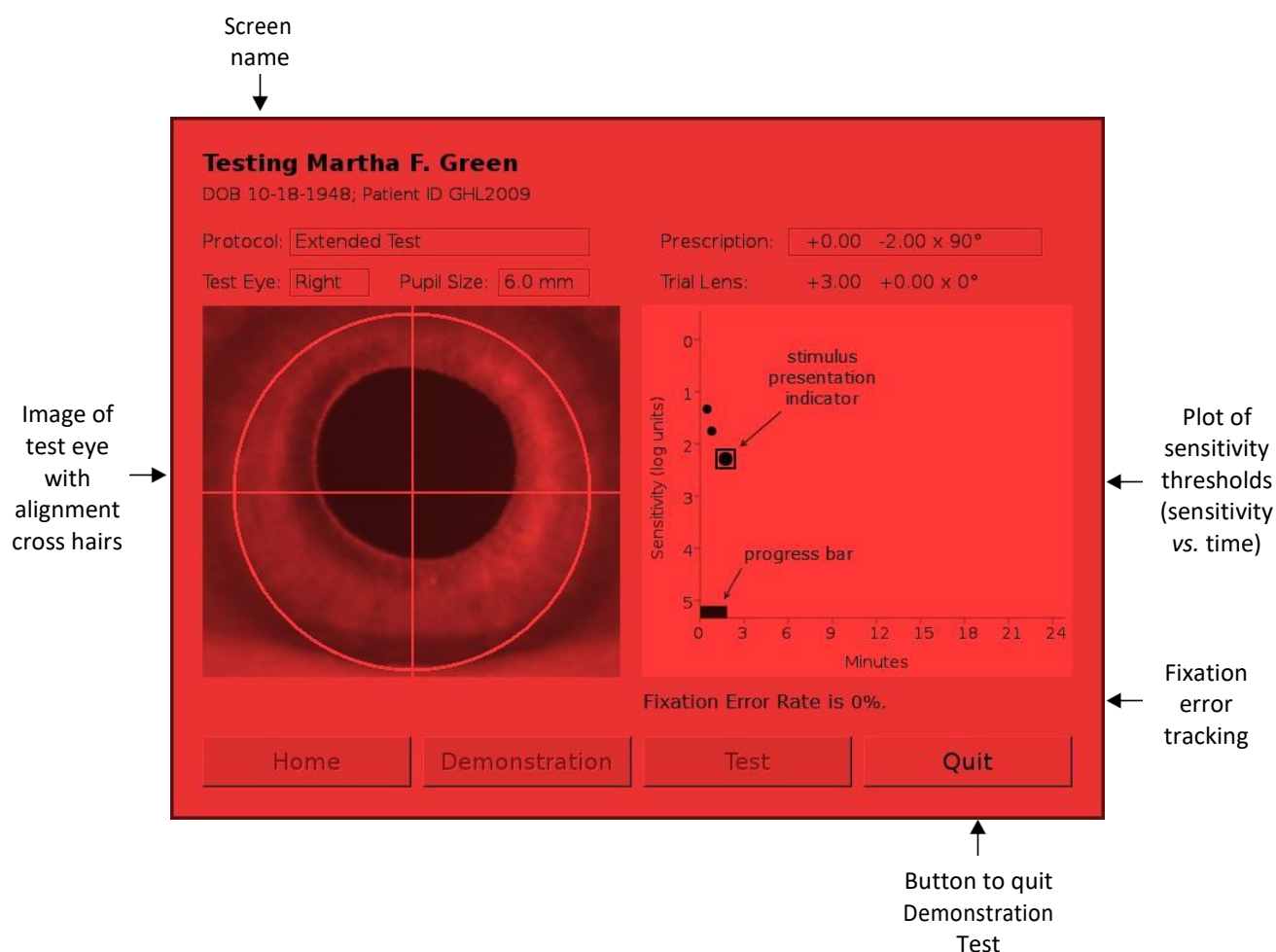
Here we go. Please open your eyes wide and look directly at the red fixation light.”

Immediately after the flash is triggered, the AdaptDx® will move from the bleaching aperture to the stimulus aperture, and begin presenting periodic stimulus lights below the red fixation light. Remind the patient to look at the red light and push the Response Button whenever he sees the stimulus light.

User Tips

- When starting the Demonstration Test, it is important that the patient is looking at the red fixation light. It is recommended that the operator touch the Start button after fixation is established.

4.3.2 Demonstration Test Monitoring



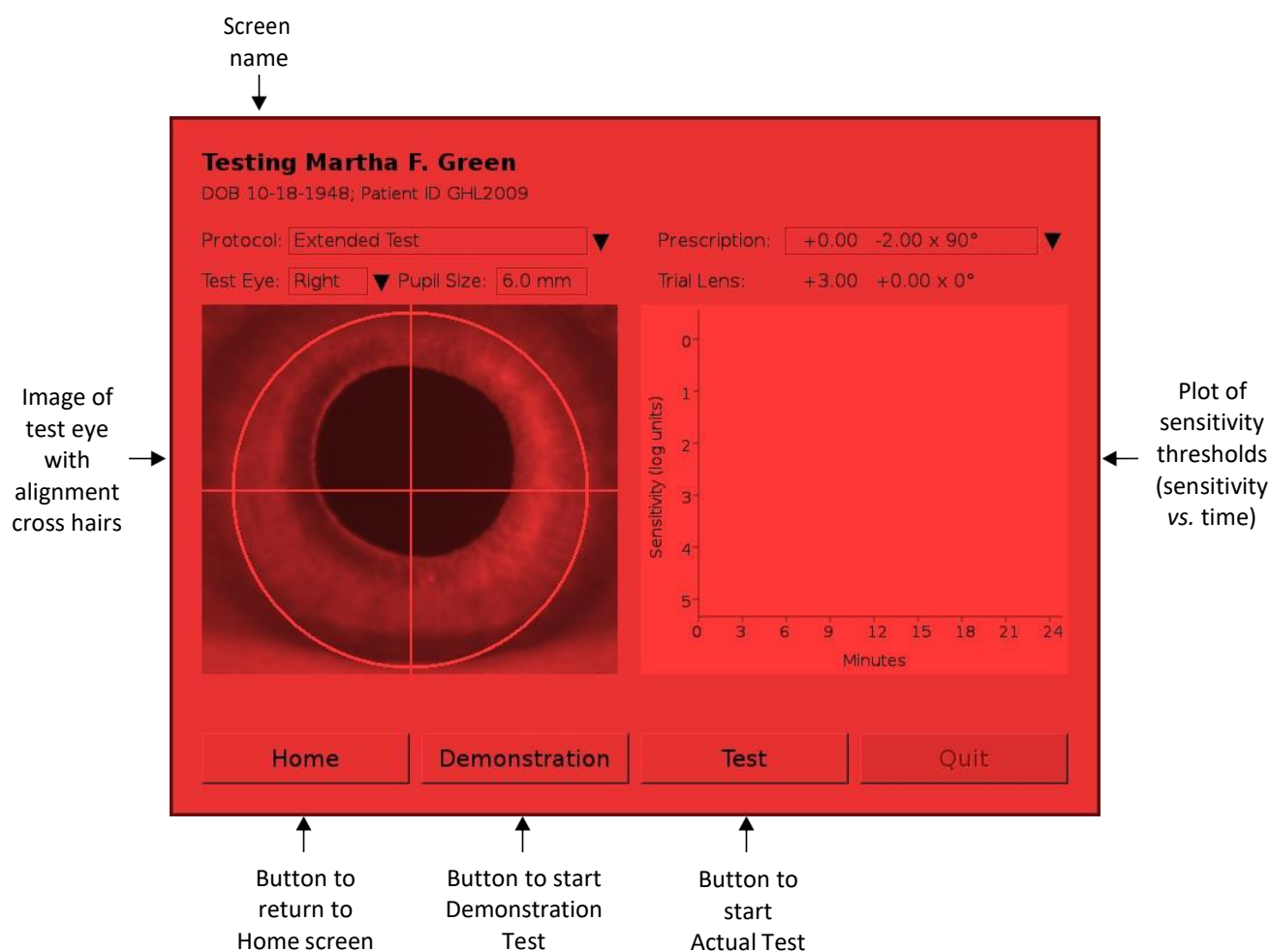
The AdaptDx® provides several progress indicators to help the operator monitor the patient's performance during testing. These progress indicators appear in the threshold plot on the right half of the Testing screen (see illustration above). In particular, a large closed circle blinks on and off every time a stimulus light is presented to the patient. It is located on the threshold plot at the sensitivity level (y-axis value) and time (x-axis value) of the stimulus then being presented to the patient, moving up and down as the sensitivity level changes and shifting to the right as time progresses. A square appears around this blinking circle every time the patient pushes the Response Button. When the patient has provided enough responses to generate a sensitivity threshold (see Section 3), the blinking circle is replaced by a smaller steady circle at the location of the threshold. A progress bar along the x-axis tracks the elapsed time since the beginning of the test. Finally, the fixation error rate (i.e., the percentage of times the patient generates invalid thresholds correlating to a loss of fixation) is continuously calculated and reported just below the threshold plot.

Operator Responsibilities – The operator is responsible for three things while monitoring a Demonstration Test:

- Tracking the patient's fixation via the image of the test eye on the screen and the reported fixation error rate. If the patient's eye is moving around or the fixation error rate increases, remind him to look at the red fixation light.
- Adjusting the test eye alignment as necessary. If the patient shifts position during testing, adjust the test eye alignment using the Chin Rest Adjustment Switch on the side of the AdaptDx® (see Section 4.2.2). It is important that alignment is maintained during testing.
- Providing positive feedback to the patient, such as saying "good job" when the patient pushes the Response Button in response to a stimulus light, thereby reinforcing that he is performing the test correctly.

A Demonstration Test can be terminated at any time by touching the Quit button at the bottom left of the screen. Otherwise a Demonstration Test will terminate automatically after two minutes.

4.3.3 End of Demonstration Test



At the conclusion of a Demonstration Test, the AdaptDx® provides three choices (see illustration above):

Home – Touch the Home button at the bottom of the screen to end testing and return to the Home screen.

Demonstration – Touch the Demonstration button at the bottom of the screen to repeat the Demonstration Test.

Test – Touch the Test button at the bottom of the screen to take the AdaptDx® out of the Demonstration Test mode and start an Actual Test (see Section 4.4).

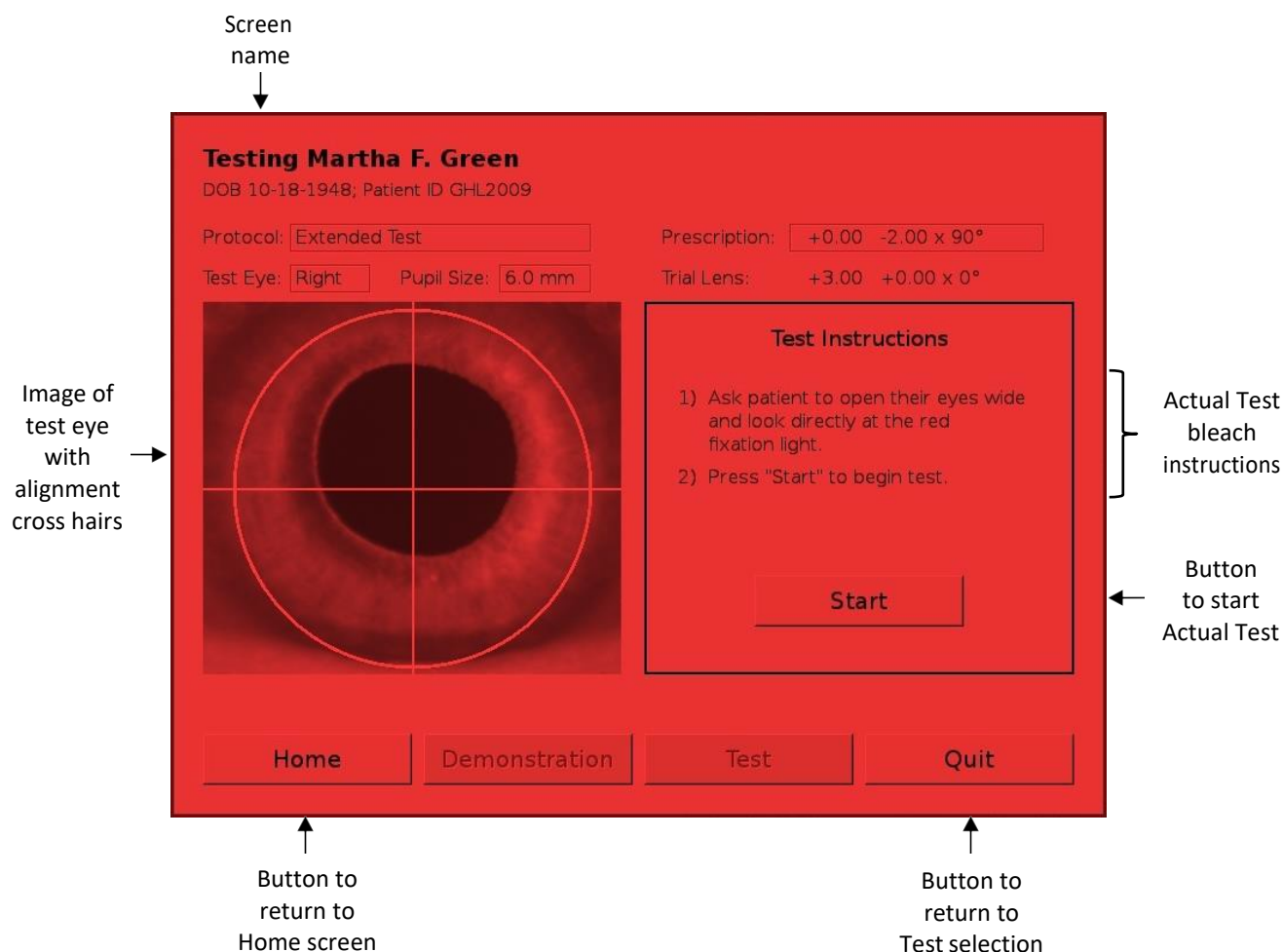
User Tips

- When the Demonstration Test is over, ask the patient if he has any questions about how to take the test. If the patient is clear on the task, proceed to the Actual Test. If the patient is unclear on the task, offer to rerun the Demonstration Test for additional reinforcement. If after a second Demonstration Test the patient is still unclear on the task, it is unlikely he will

be able to generate a meaningful dark adaptation curve and it may be best to abandon further testing.

4.4 Running an Actual Test

4.4.1 Start of Actual Test



The testing screen is accessed from the Home screen (see Section 4.2.1). As illustrated above, the name of the patient selected for testing is displayed at the top of the screen.

Screen Layout – There are two major components to the Testing screen. The left half of the screen shows a close-up image of the patient’s test eye superimposed over an alignment cross hair. The right half of the screen initially shows patient instructions in preparation for the bleaching event. After the Start button is pressed, the actual bleaching flash is delivered and the screen reverts to a plot of visual sensitivity thresholds vs. time (see Section 3). The y-axis is log sensitivity, going from zero sensitivity at the top to five orders of magnitude of sensitivity recovery at the bottom. The x-axis is time from the start of the test in minutes.

After the patient has shown proficiency with the Demonstration Test (see Section 4.3) testing can proceed to an Actual Test. The Actual Test starts with a bleaching flash to pre-condition the patient’s retina to a standard, unadapted state. The patient is then asked to focus on the red fixation light and push the Response Button when the stimulus light appears in his peripheral vision below the fixation light.

Actual Test Instructions – The recommended instructions to prepare the patient are:

“Now we are going to perform the Actual Test. The procedure is identical to the Demonstration Test. The most important thing for you to do is to look at the red fixation light. The initial flash will be much brighter—similar to a small camera flash when having your picture taken. After the flash, push the Response Button whenever you see the spot of light, just like in the Demonstration Test. Don’t worry if it takes more time to see the stimulus light than during the Demonstration Test; that is normal. You will be given periodic rest breaks. During a rest break, feel free to close your eyes. I will let you know when the rest break is over.”

Starting the Actual Test – Before starting the Actual Test, confirm that patient preparation (see Section 4.2.2) and test set up (see Section 4.2.3) have been properly completed, and the test eye is correctly aligned to the cross hairs. When everything is ready, recite the Actual Test instructions to the patient. Then ask the patient to open their eyes wide and look directly at the red fixation light. Touch the Start button, which will trigger the actual flash and begin the Actual Test. The recommended instructions to the patient at the start of the Actual Test are:

“We are ready to start the test. When I ask you to, please open your eyes wide and look directly at the red fixation light.

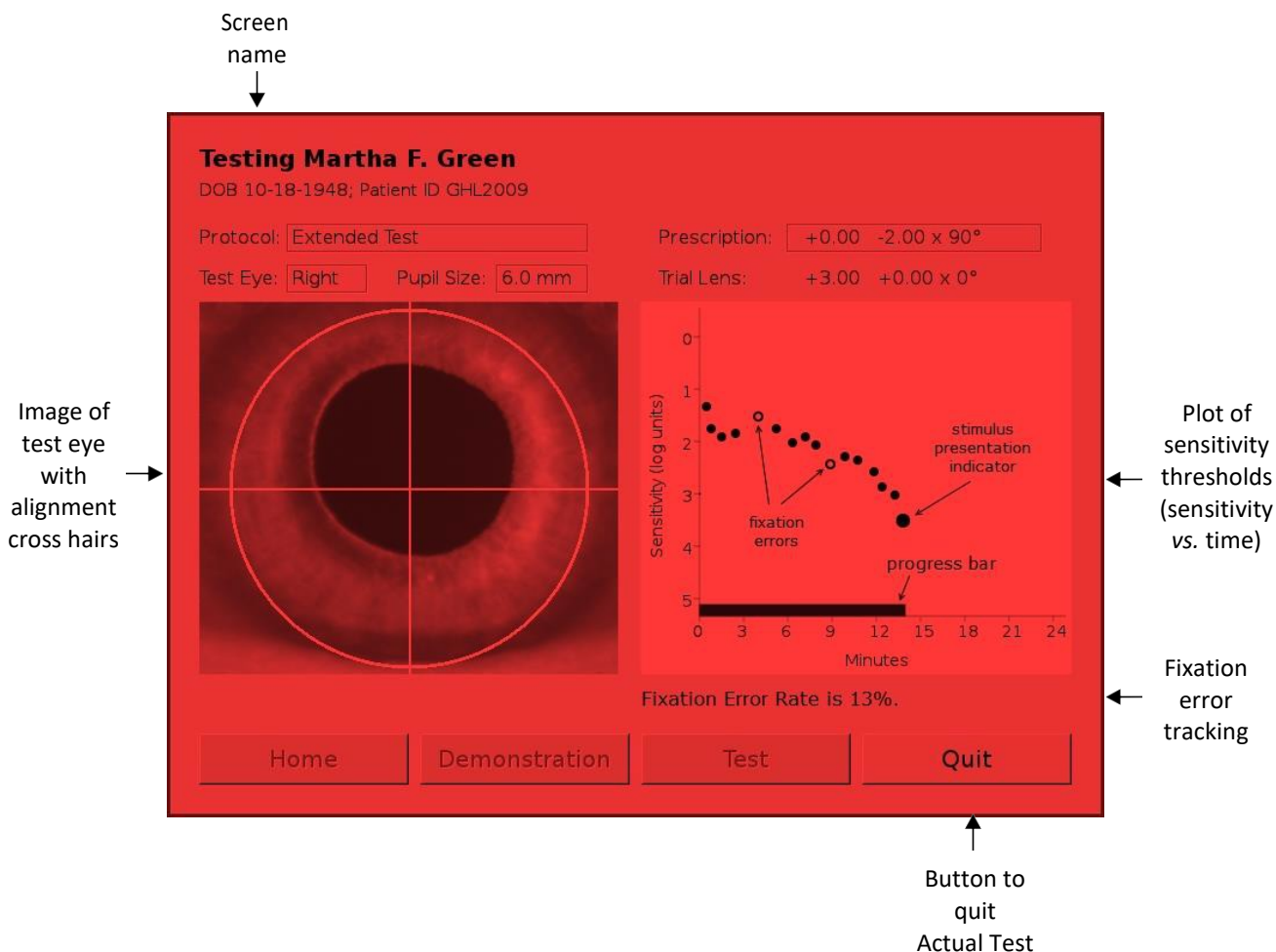
Here we go. Please open your eyes wide and look directly at the red fixation light.”

Immediately after the flash is triggered, the AdaptDx® will move from the bleaching aperture to the stimulus aperture, and begin presenting periodic stimulus lights below the red fixation light. Remind the patient to look at the red light and push the Response Button whenever they see the stimulus light.

User Tips

- The **room lights must remain off** during the transition from the Demonstration Test to the Actual Test and all the way through completion of the Actual Test.
- Starting the Actual Test when the patient’s eye is open and the patient is looking directly at the red fixation light is the most critical part of the operator’s job during the entire test.
- When starting the Actual Test, it is important that the patient is looking at the red fixation light. It is recommended that the operator touch the Start button after fixation is established.

4.4.2 Actual Test Monitoring



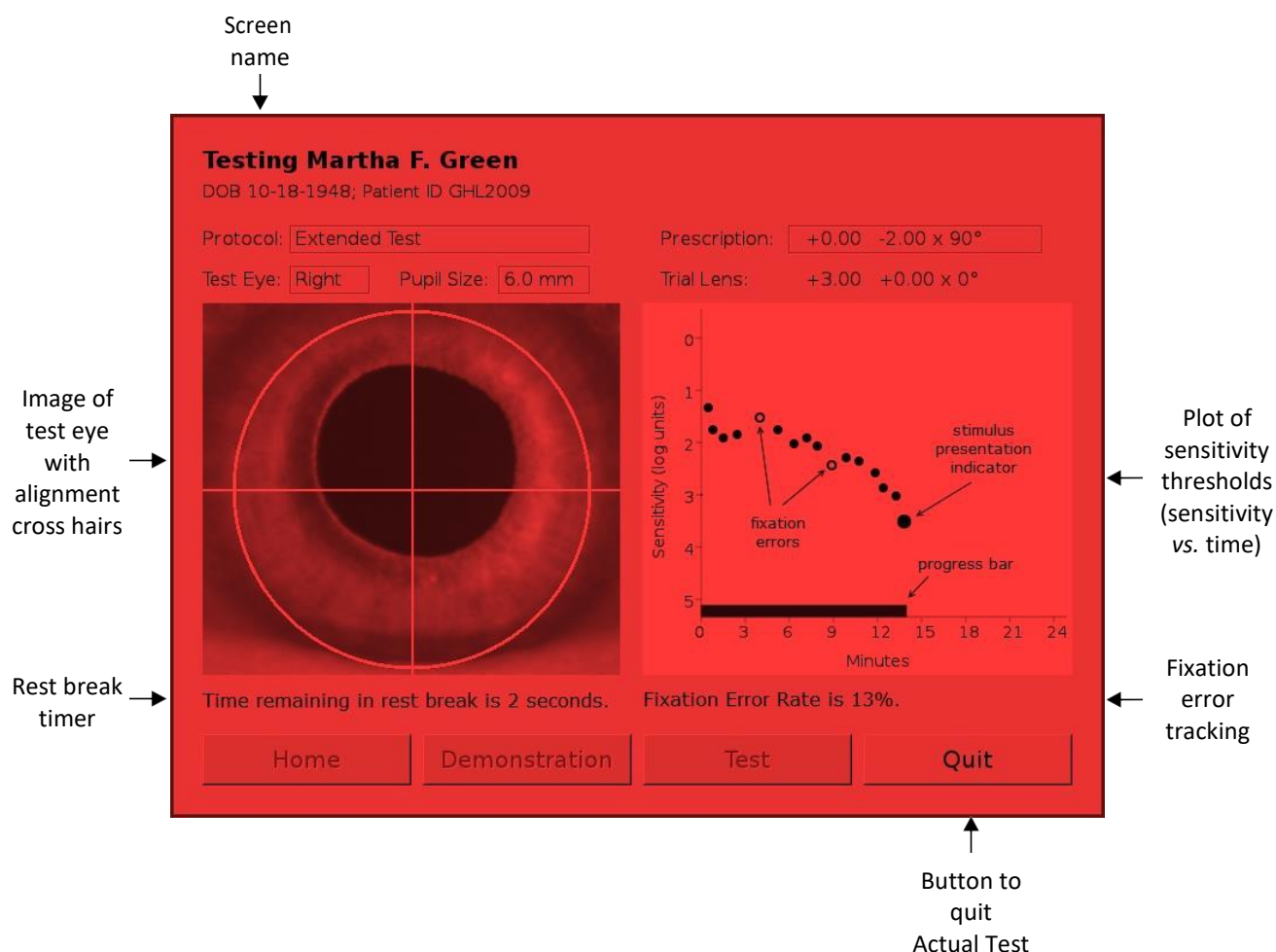
The AdaptDx® provides several progress indicators to help the operator monitor the patient's performance during testing. These progress indicators appear in the threshold plot on the right half of the Testing screen (see illustration above). In particular, a large closed circle blinks on and off every time a stimulus light is presented to the patient. It is located on the threshold plot at the sensitivity level (y-axis value) and time (x-axis value) of the stimulus then being presented to the patient, moving up and down as the sensitivity level changes and shifting to the right as time progresses. A square appears around this blinking circle every time the patient pushes the Response Button. When the patient has provided enough responses to generate a sensitivity threshold (see Section 3), the blinking circle is replaced by a smaller steady circle at the location of the threshold. A progress bar along the x-axis tracks the elapsed time since the beginning of the test. Finally, the fixation error rate (i.e., the percentage of times the patient generates invalid thresholds correlating to a loss of fixation) is continuously calculated and reported just below the threshold plot. Valid thresholds are plotted as closed circles. Invalid (or false) thresholds are plotted as open circles.

Operator Responsibilities – The operator is responsible for three things while monitoring an Actual Test:

- Tracking the patient's fixation via the image of the test eye on the screen and the reported fixation error rate. If the patient's eye is moving around or the fixation error rate increases, remind him to stare directly at the red fixation light.
- Adjusting the test eye alignment as necessary. If the patient shifts position during testing, adjust the test eye alignment using the Chin Rest Adjustment Switch on the side of the AdaptDx® (see Section 4.2.2). It is important that alignment is maintained during testing.
- Providing positive feedback to the patient, such as saying "good job" when the patient pushes the Response Button in response to a stimulus light, thereby reinforcing that he is performing the test correctly. Tell the patient not to worry if he misses a stimulus light, to just wait until he sees the next one and respond.

An Actual Test can be terminated at any time by touching the Quit button at the bottom left of the screen. The data collected up to the time the test is terminated will be saved just like any other test. Otherwise, an Actual Test will terminate automatically when it reaches one of several preset benchmarks (see Section 4.3.5). Unless there is an unusual circumstance, the operator should allow the Actual Test to run until it is automatically terminated.

4.4.3 Patient Rest Breaks



The AdaptDx® provides a short patient rest break (e.g., 15 sec) after determination of each sensitivity threshold. A short “beep” at the beginning of the rest break announces its start, and a second short “beep” three seconds before the end of the rest break announces its end. An additional progress indicator appears under the test eye image on the left half of the Testing screen (see illustration above). It counts down the number of seconds remaining in the rest break.

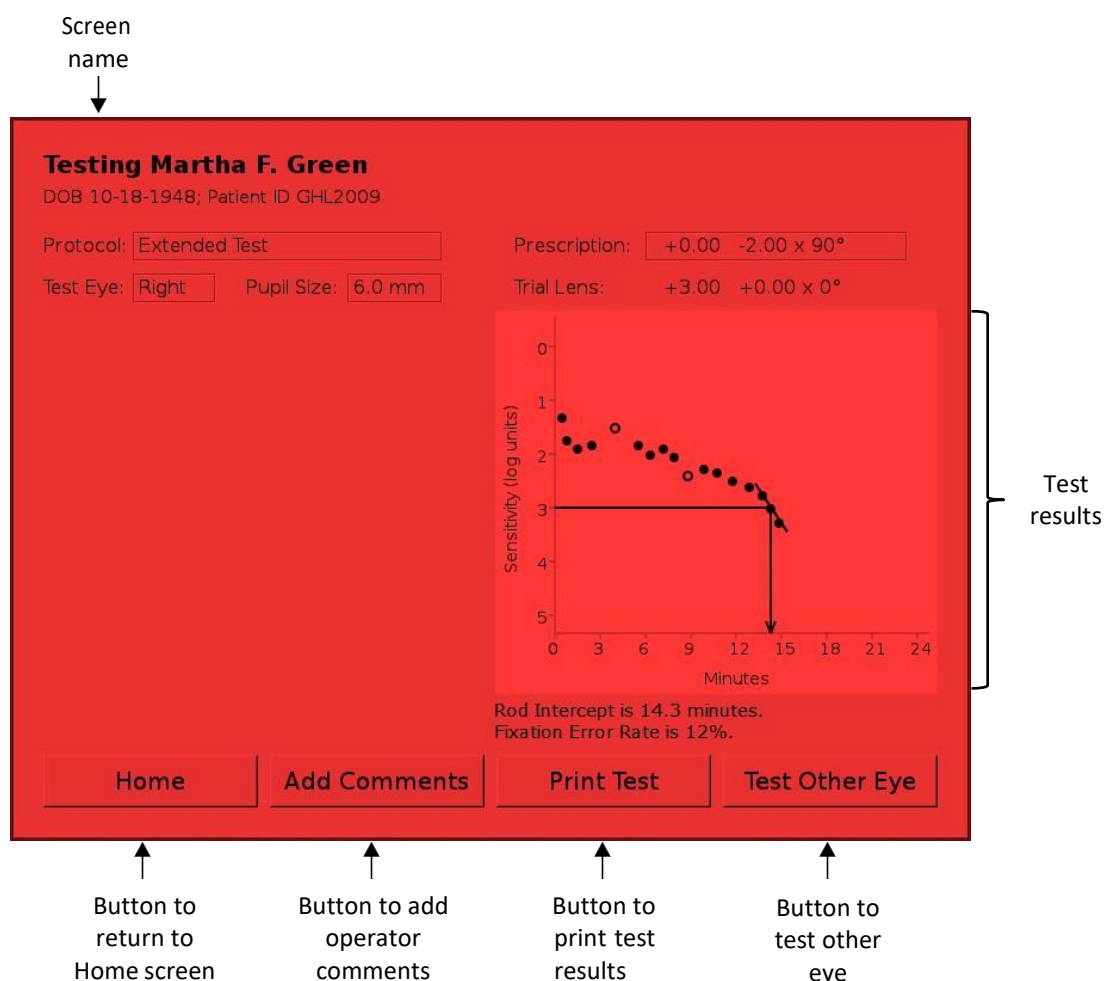
Operator Responsibilities – The operator is responsible for two things during a rest break:

- Alerting the patient that the rest break has begun, by saying for example, “Excellent, there will be a short rest break now.”
- Alerting the patient that the rest break is about to end, by saying for example, “The rest break is about to end, look straight at the red light and push the Response Button whenever you see a stimulus light.”

User Tips

- Tell the patient he can close and rest his eyes during the rest break, but encourage him to keep his chin on the chin rest and forehead against the forehead rest to prevent moving out of alignment.

4.4.4 End of Actual Test



At the conclusion of an Actual Test, the AdaptDx® calculates a proprietary parameter called the Rod Intercept to characterize the test results. The Rod Intercept is the time in minutes at which the visual sensitivity recovery crosses three log units of recovery. This is a point when visual sensitivity recovery is completely rod mediated. Test subjects with slower visual sensitivity recovery have longer Rod Intercept times. The Rod Intercept is displayed graphically on the threshold plot and reported in minutes just below the threshold plot (see illustration above).

The AdaptDx® includes two internal checks on the quality of the patient response data:

- Fixation Errors – Patient inattention during a test can cause loss of focus on the fixation light and inappropriate responses to the stimulus lights. These fixation errors produce a “noisy” dark adaptation curve, with individual sensitivity thresholds substantially out of line with normal sensitivity recovery. The AdaptDx® tracks fixation errors and displays the fixation error rate (i.e., the percentage of times the patient generates invalid thresholds correlating to a loss of fixation) with the test results. If the fixation error rate exceeds 30%, a warning message is displayed with the results.

- **Bleaching Errors** – If a patient blinks or averts his gaze during bleaching, he will show very rapid dark adaptation, faster than is typically seen in properly bleached patients. For the Rapid and Extended Tests only, when the AdaptDx® calculates an unusually fast Rod Intercept, a bleaching error is indicated graphically on the threshold plot and a warning message is displayed with the results.

The test results, including the Rod Intercept time, the diagnostic assessment and any error conditions, are all automatically saved.

There are four options for proceeding at the conclusion of an Actual Test:

Home – Touch the Home button at the bottom of the screen to end testing and return to the Home screen (see Section 4.2.1).

Add Comments – Touch the Add Comments button at the bottom of the screen to toggle to a screen where the operator can add comments to be saved with the test results (see Section 4.4.5).

Print Test – Touch the Print Test button at the bottom of the screen to print the test results, including any comments added by the operator (see Section 4.4.6). A system setting allows test results to be directed to a hard copy printer, a PDF file on an attached USB drive, or an XML file on an attached USB drive (see Section 5.2.3).

Test Other Eye – Touch the Test Other Eye button at the bottom of the screen to jump to an Actual Test of the fellow eye. A fresh Testing screen will appear, pre-populated with the patient information for the individual just tested. The test protocol just used will be selected as the Protocol, and the fellow eye will be selected as the Test Eye. Testing proceeds as before from that point (see Section 4.2.3).

User Tips

- A large number of fixation errors indicate that the test results are not reliable, and the patient may not be suitable for dark adaptation testing. If the fixation error rate exceeds 30%, a warning message is displayed with the test results.
- The Rapid Test takes approximately 5 minutes to complete. The Extended Test can take up to 20 minutes to complete.

4.4.5 Add Comments

Screen name
↓

Add Comments for Martha F. Green
DOB 10-18-1948; Patient ID GHL2009
Protocol: Extended Test
Tested: 01-03-2017 12:02 Test Eye: Right
Prescription: +0.00 -2.00 x 90° Age at Test: 68
Trial Lens: +3.00 +0.00 x 0° Pupil Size: 6.0 mm

Test by JGE. Attention wandered briefly about half way through the test. _

q w e r t y u i o p 1 2 3
a s d f g h j k l - 4 5 6
↑ z x c v b n m ↑ 7 8 9
→ @ Space , . ← 0

Home Return to Test Print Test Test Other Eye

Operator comments

↑ ↑ ↑ ↑
Button to return to Home screen Button to return to test results Button to print test results Button to test other eye

The Add Comments screen is accessed from the Testing screen at the end of an Actual Test (see Section 4.4.4). As illustrated above, the name of the patient tested and the test parameters are displayed at the top of the screen. A large text field is provided for the operator to add comments. These comments are automatically saved with the corresponding test results and are included on printouts of the test results (see Section 4.4.6).

There are four options for proceeding at the conclusion of adding comments:

Home – Touch the Home button at the bottom of the screen to end testing and return to the Home screen (see Section 4.2.1).

Return to Test – Touch the Return to Test button at the bottom of the screen to toggle to the associated test results (see Section 4.4.4).

Print Test – Touch the Print Test button at the bottom of the screen to print the test results, including any comments added by the operator (see Section 4.4.6). A system setting allows test results to be directed to a hard copy printer, a PDF file on an attached USB drive, or an XML file on an attached USB drive (see Section 5.2.3).

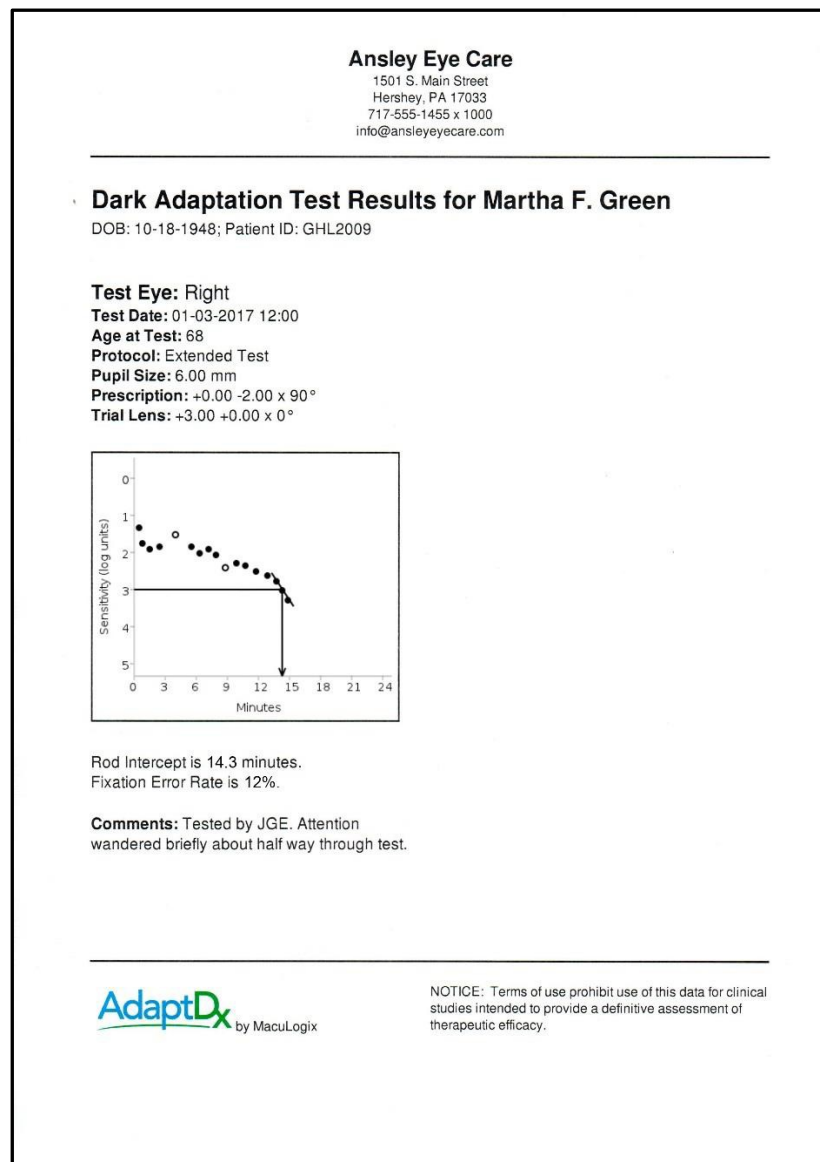
Test Other Eye – Touch the Test Other Eye button at the bottom of the screen to jump to an Actual Test of the fellow eye. A fresh Testing screen will appear, pre-populated with the patient information for the individual just tested. The test protocol just used will be selected as the Protocol, and the fellow eye will be selected as the Test Eye. Testing proceeds as before from that point (see Section 4.2.3).

User Tips

- Comments can be corrected during entry by using the “backspace” key at the lower right of the touch screen keyboard to erase the entry.

4.4.6 Print Test Results

Printing the results of a just completed test can be initiated from the Testing screen (see Section 4.4.4) or from the corresponding Add Comments screen (see Section 4.4.5). Following is an example test result printout.

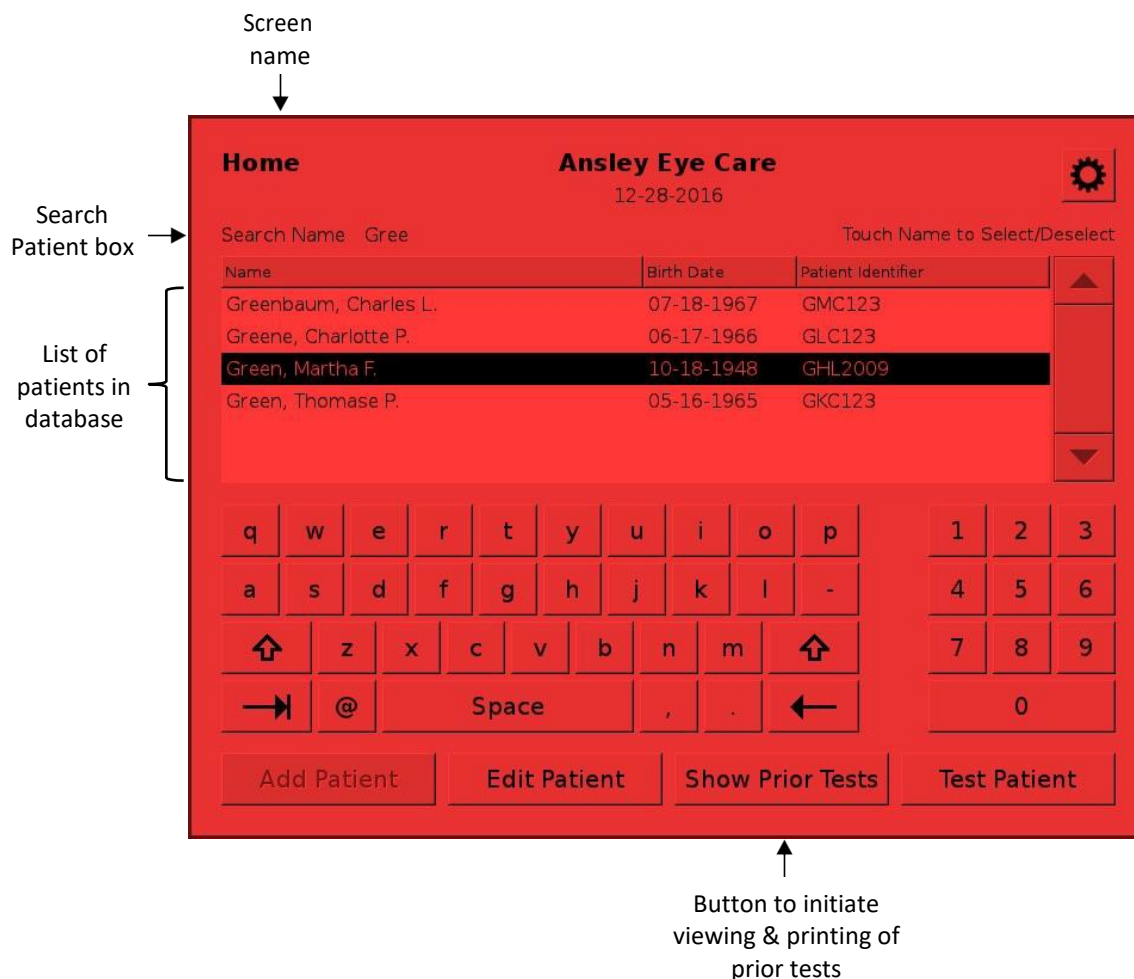


User Tips

- If Touching the Print Test button fails to produce a printout of the test results, check the following items: whether the Printer is properly connected to the AdaptDx® (see Section 5.5.4), whether the Printer is plugged into a power outlet, whether the Printer is turned on (see separate Printer manual), and whether paper is loaded in the Printer (see separate Printer manual).

4.5 Viewing & Printing Prior Test Results

4.5.1 Patient Selection



Viewing and printing of prior test results is initiated from the Home screen (illustrated above) by selecting the patient for whom prior results are sought.

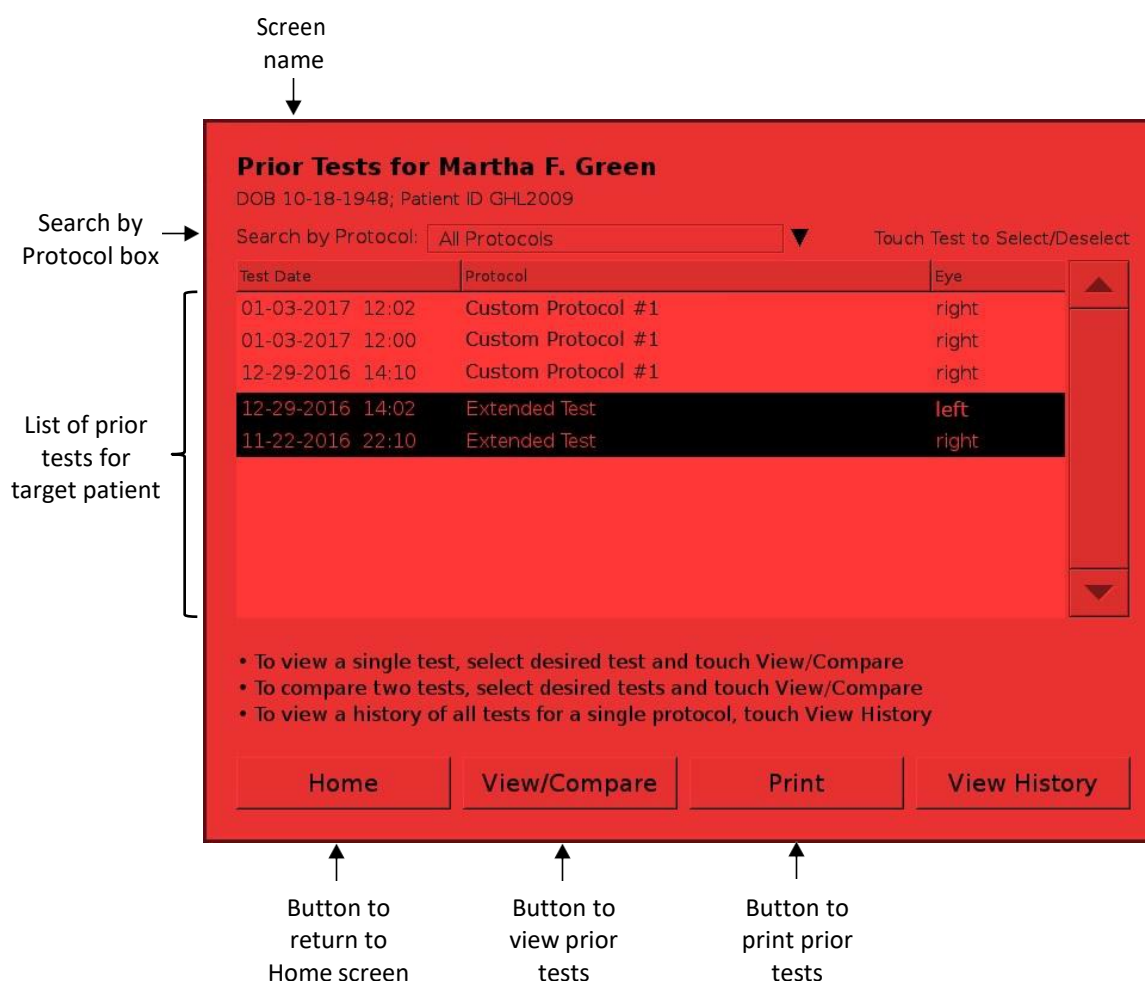
Select Patient – As illustrated above, the Home screen displays a scrollable list of all patients in the AdaptDx® database. Typing all or part of a patient's name in the Search Patient box above the list narrows the display to matching entries. Touching a name in the list selects that patient.

Proceed to Selection of Prior Tests – Touch the Show Prior Tests button at the bottom of the screen to proceed. The Show Prior Tests button will not become active until a patient is selected from the scrollable display.

User Tips

- The display of patient names lists only the most recent name associated with a Patient Identifier. If a patient's name is changed—for example to correct a misspelling or when the patient gets married—all information for that patient will be linked to the new name.

4.5.2 Prior Test Selection



The Prior Tests screen is accessed from the Home screen (see Section 4.5.1). It is used to select prior test results for viewing or printing. As illustrated above, the name of the target patient for whom prior results are being sought is displayed at the top of the screen, and all prior tests for that patient are listed in a scrollable window.

Narrow Choices – The Search by Protocol box above the scrollable display can be used to narrow the choices. The pre-populated default option is All Protocols, which displays all prior tests for the target patient in reverse chronological order. Touching the triangle beside the Search by Protocol box launches a protocol picker that narrows the display to those matching a particular test protocol.

Select Specific Tests – Touching a test in the list selects that test for viewing (see Sections 4.5.3 and 4.5.4) or printing (see Section 4.5.5). As indicated in the on-screen instructions, either one or two tests can be selected at a time.

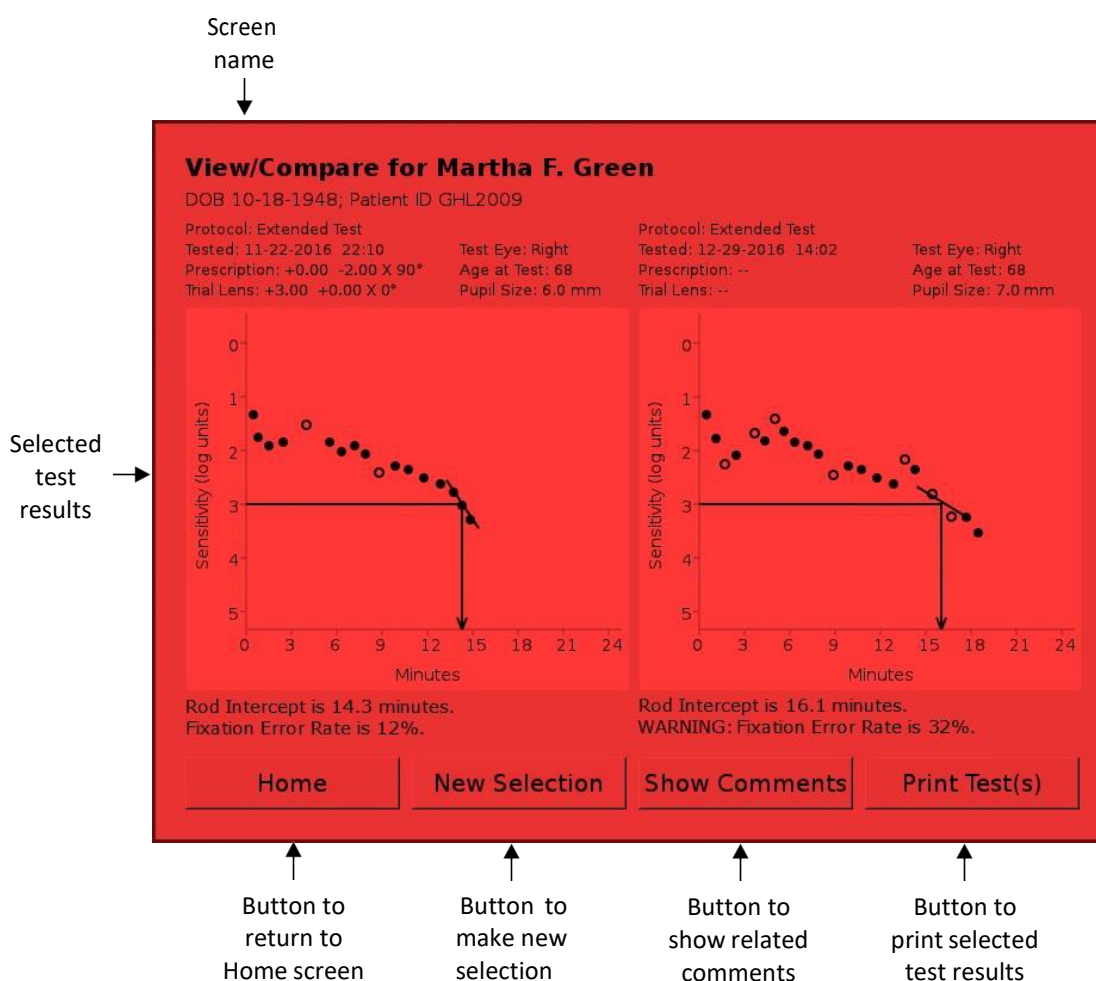
Three options are available for proceeding from this screen:

Home – Touch the Home button at the bottom of the screen to abandon viewing and printing of prior test results and return to the Home screen.

View/Compare – Touch the View/Compare button at the bottom of the screen to view the selected prior test result(s) (see Sections 4.5.3 and 4.5.4).

Print – Touch the Print button at the bottom of the screen to print the selected prior test result(s). A system setting allows test results to be directed to a hard copy printer, a PDF file on an attached USB drive, or an XML file on an attached USB drive (see Section 5.2.3).

4.5.3 View/Compare Prior Test Results



The View/Compare Prior Test Results screen is accessed from the Prior Tests screen (see Section 4.5.2). It is used to view selected prior test results for a patient of interest. As illustrated above, the name of the patient whose tests are being viewed is displayed at the top of the screen, and one or two prior test results are shown. If tests for both a right eye and a left eye were selected, the test for the right eye appears on the left half of screen. If two tests for the same eye were selected, the earlier test appears on the left half of the screen.

Four options are available for proceeding from this screen:

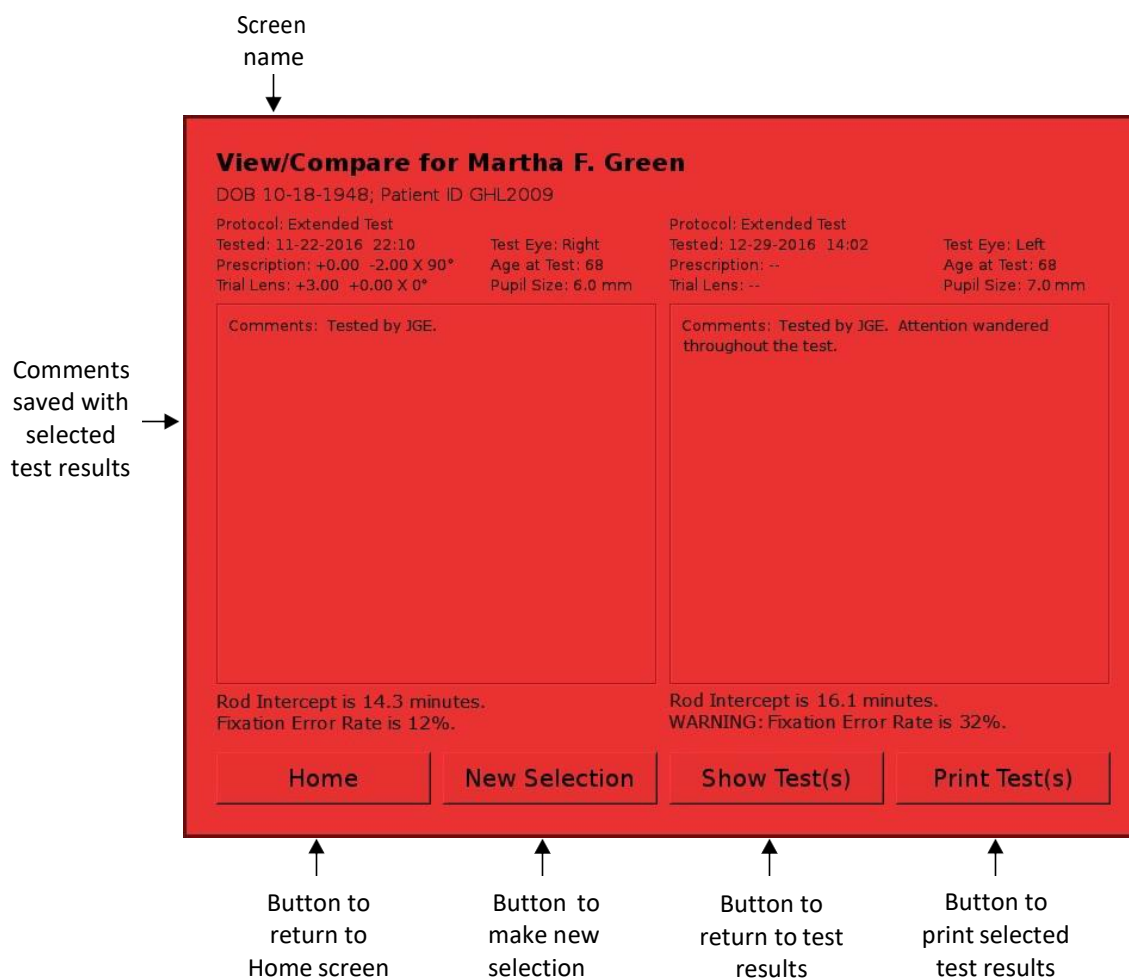
Home – Touch the Home button at the bottom of the screen to abandon viewing and printing of prior test results and return to the Home screen.

New Selection – Touch the New Selection button at the bottom of the screen to return to the Prior Tests screen and make a new selection of prior test results (see Section 4.5.2).

Show Comments – Touch the Show Comments button at the bottom of the screen to toggle to a screen showing operator comments saved with the selected prior test result(s) (see Section 4.5.4).

Print Test(s) – Touch the Print Test(s) button at the bottom of the screen to print the selected prior test result(s) (see Section 4.5.5). A system setting allows test results to be directed to a hard copy printer, a PDF file on an attached USB drive, or an XML file on an attached USB drive (see Section 5.2.3).

4.5.4 View/Compare Prior Test Comments



The View/Compare Prior Test Comments screen is accessed from the View Compare Prior Test Results screen (see Section 4.5.3). As illustrated above, the patient name and other identifying information for the selected prior tests are displayed at the top of the screen, together with operator comments that were saved with those tests.

Four options are available for proceeding from this screen:

Home – Touch the Home button at the bottom of the screen to abandon viewing and printing of prior test results and return to the Home screen.

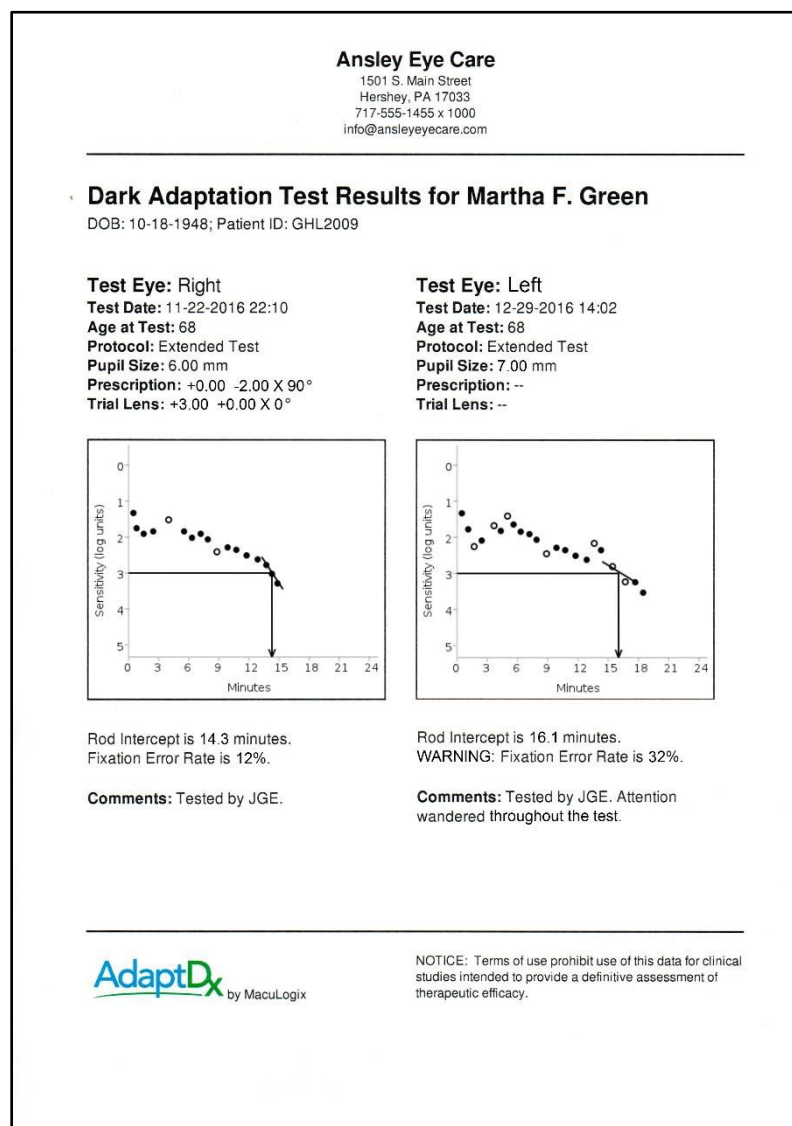
New Selection – Touch the New Selection button at the bottom of the screen to return to the Prior Tests screen and make a new selection of prior test results (see Section 4.5.2).

Show Test(s) – Touch the Show Test(s) button at the bottom of the screen to toggle to the associated prior test result(s) (see Section 4.5.3).

Print Test(s) – Touch the Print Test(s) button at the bottom of the screen to print the selected prior test result(s) (see Section 4.5.5). A system setting allows test results to be directed to a hard copy printer, a PDF file on an attached USB drive, or an XML file on an attached USB drive (see Section 5.2.3).

4.5.5 Print Prior Test Results

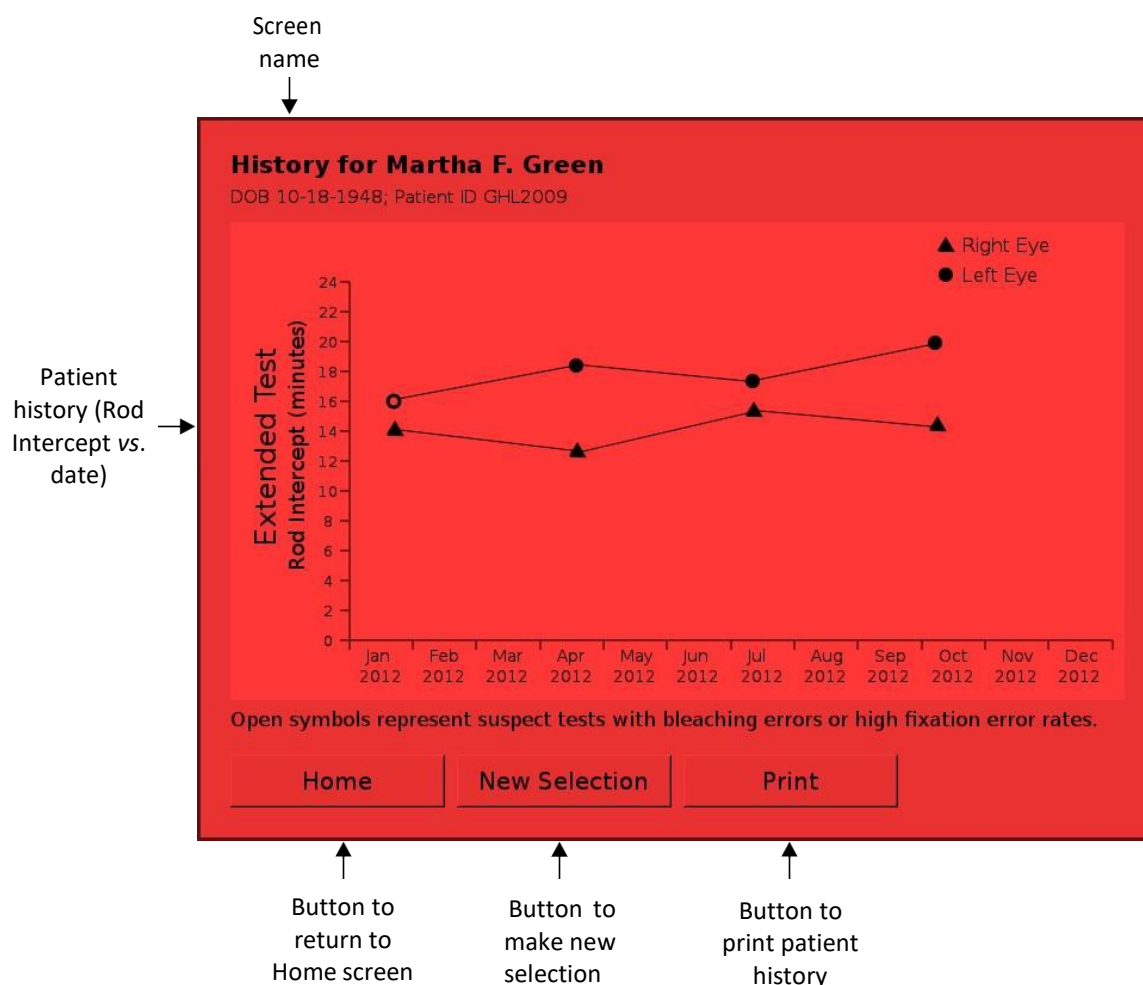
Printing of prior test results can be initiated from the Prior Test Selection screen (see Section 4.5.2), from the View/Compare Prior Test Results screen (see Section 4.5.3) or from the corresponding View/Compare Prior Test Comments screen (see Section 4.5.4). Following is an example of a prior test results printout.



User Tips

- If Touching the Print Test(s) button fails to produce a printout of the test results, check the following items: whether the Printer is properly connected to the AdaptDx® (see Section 5.5.4), whether the Printer is plugged into a power outlet, whether the Printer is turned on (see separate Printer manual), and whether paper is loaded in the Printer (see separate Printer manual)

4.5.6 View Patient History



The History screen is accessed from the Prior Tests screen (see Section 4.5.2). It is used to show a summary of all test results collected for a patient using a particular protocol. As illustrated above, the name of the patient is displayed at the top of the screen and two graphs of Rod Intercept vs. date are displayed—one for the right eye and one for the left eye.

Three options are available for proceeding from this screen:

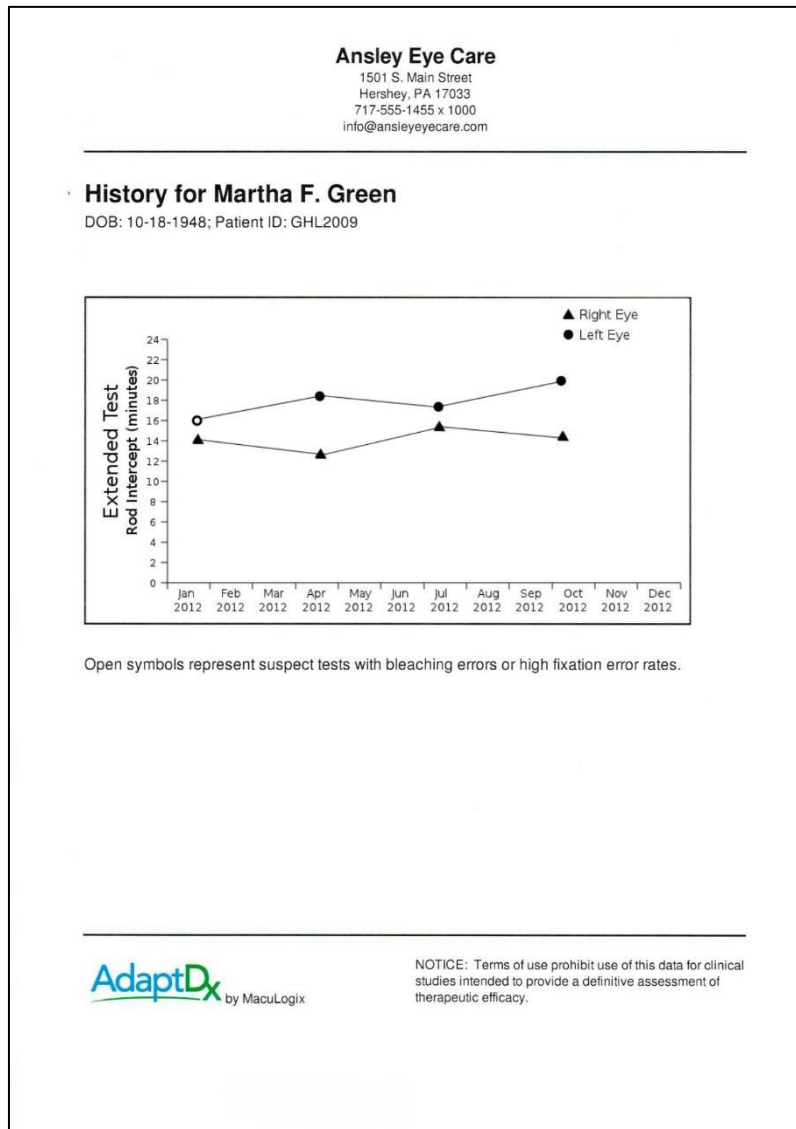
Home – Touch the Home button at the bottom of the screen to abandon viewing and printing of prior test results and return to the Home screen.

New Selection – Touch the New Selection button at the bottom of the screen to return to the Prior Tests screen and make a new selection of prior test results (see Section 4.5.2).

Print – Touch the Print button at the bottom of the screen to print the selected patient history (see Section 4.5.5). A system setting allows test results to be directed to a hard copy printer, a PDF file on an attached USB drive, or an XML file on an attached USB drive (see Section 5.2.3).

4.5.7 Print Patient History

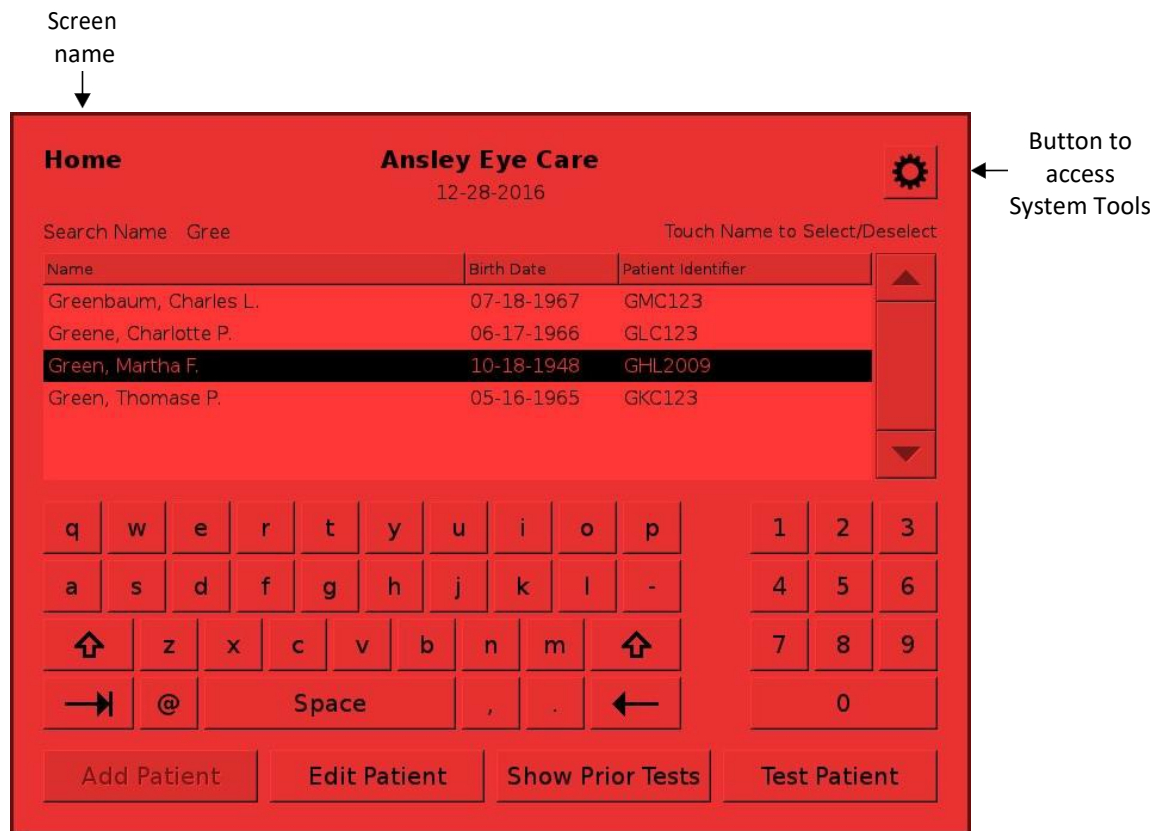
Printing of patient histories is initiated from the Show Patient History screen (see Section 4.5.6).
Following is an example patient history printout.



5 System Tools

5.1 Overview

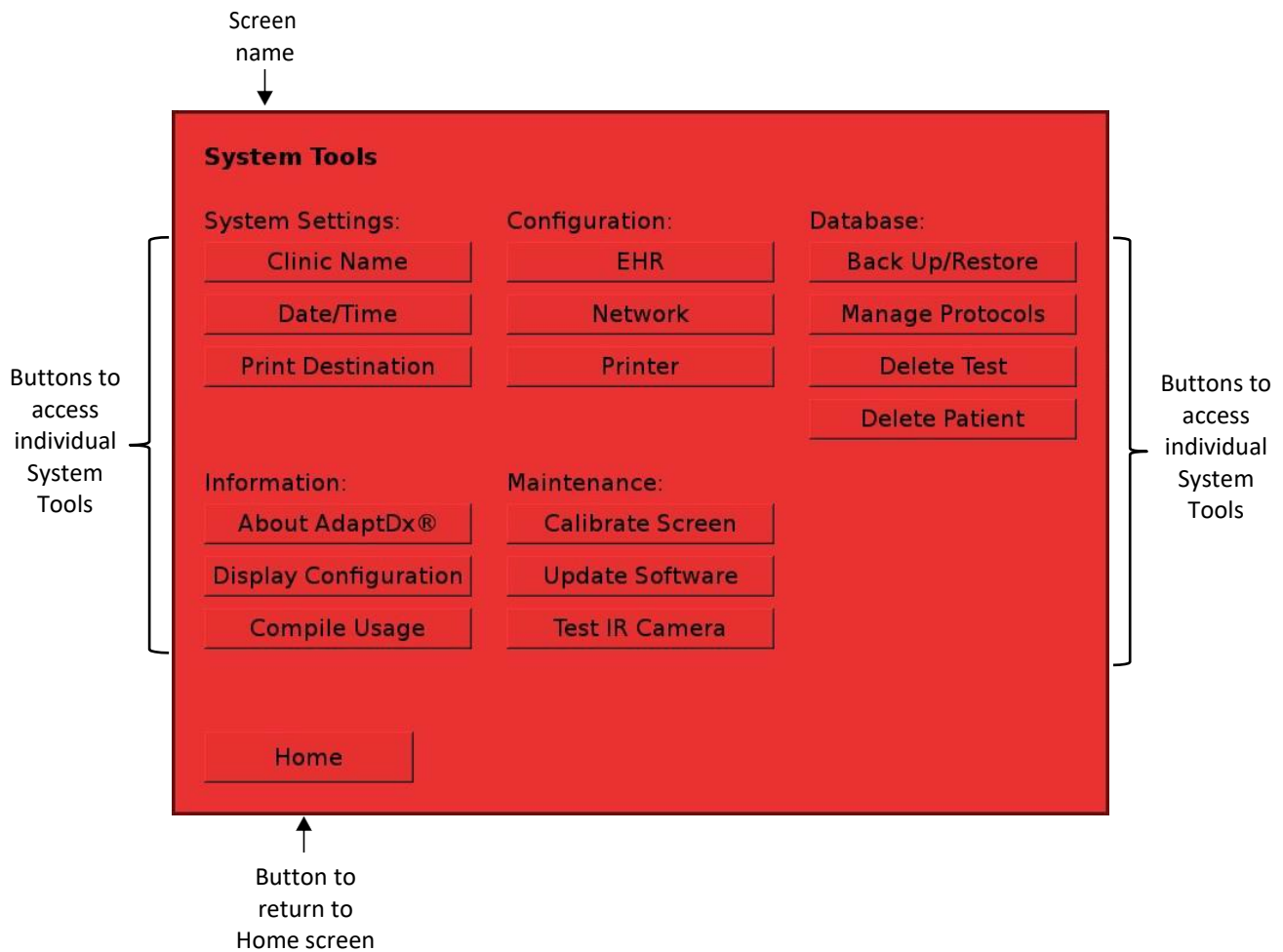
5.1.1 Accessing System Tools



The AdaptDx® provides a set of System Tools for system settings, database management, system information and configuration, and maintenance.

System Tools are accessed from the Home Screen. As illustrated above, touch the “Gear” icon to display an actionable directory of available tools (see Section 5.1.2).

5.1.2 System Tools Directory



Individual system tools are accessed from the System Tools screen (illustrated above). The tools fall into the following categories:

System Settings

- Clinic Name (see Section 5.2.1)
- Date/Time (see Section 5.2.2)
- Print Destination (see Section 5.2.3)

Configuration

- EHR (see Section 5.5.7)
- Network (see Sections 5.5.2 and 5.5.3)
- Printer (see Section 5.5.4)

Database

- Back Up/Restore (see Section 5.3.1)
- Manage Protocols (see Sections 5.3.2, 5.2.3 and 5.2.4)
- Delete Test (see Sections 5.3.5 and 5.3.6)
- Delete Patient (see Section 5.3.7)

Information

- About AdaptDx® (see Section 5.4.1)
- Display Configuration (see Section 5.4.2)
- Compile Usage (see Section 5.4.3)

Maintenance

- Calibrate Screen (see Section 5.5.1)
- Update Software (see Section 5.5.6)
- Test IR Camera (see Section 5.5.5)

Touch the appropriate System Tool button to access the desired tool. Touch the Home button at the bottom of the screen to return to the Home screen.

5.2 System Settings

5.2.1 Set Clinic Name

Screen name

↓

Set Clinic Name

Touch Field to Edit

Clinic name & contact information

Clinic Name: Ansley Eye Care

Address 1: 1501 S. Main Street

Address 2:

City: Hershey State: PA Zip Code: 17033

Phone: 717-243-1455 x1000

Email: info@ansleyeyecare.com

Q W E R T Y U I O P 1 2 3

A S D F G H J K L - 4 5 6

↑ Z X C V B N M ↑ 7 8 9

→ @ Space , . ← 0

Cancel & Done Save & Done

Button to abandon entry without saving

Button to save entry

The Set Clinic Name screen is accessed from the System Tools screen (see Section 5.1.2). It allows customization of the AdaptDx® with a clinic name and contact information. As illustrated above, the information fields are pre-populated with any previously stored information.

Entering Clinic Name & Contact Information – There are seven fields, all optional:

- Clinic Name
- Address Line 1
- Address Line 2
- City
- State
- Zip Code
- Phone Number
- Email Address

Two actions can be taken after entry of the clinic information:

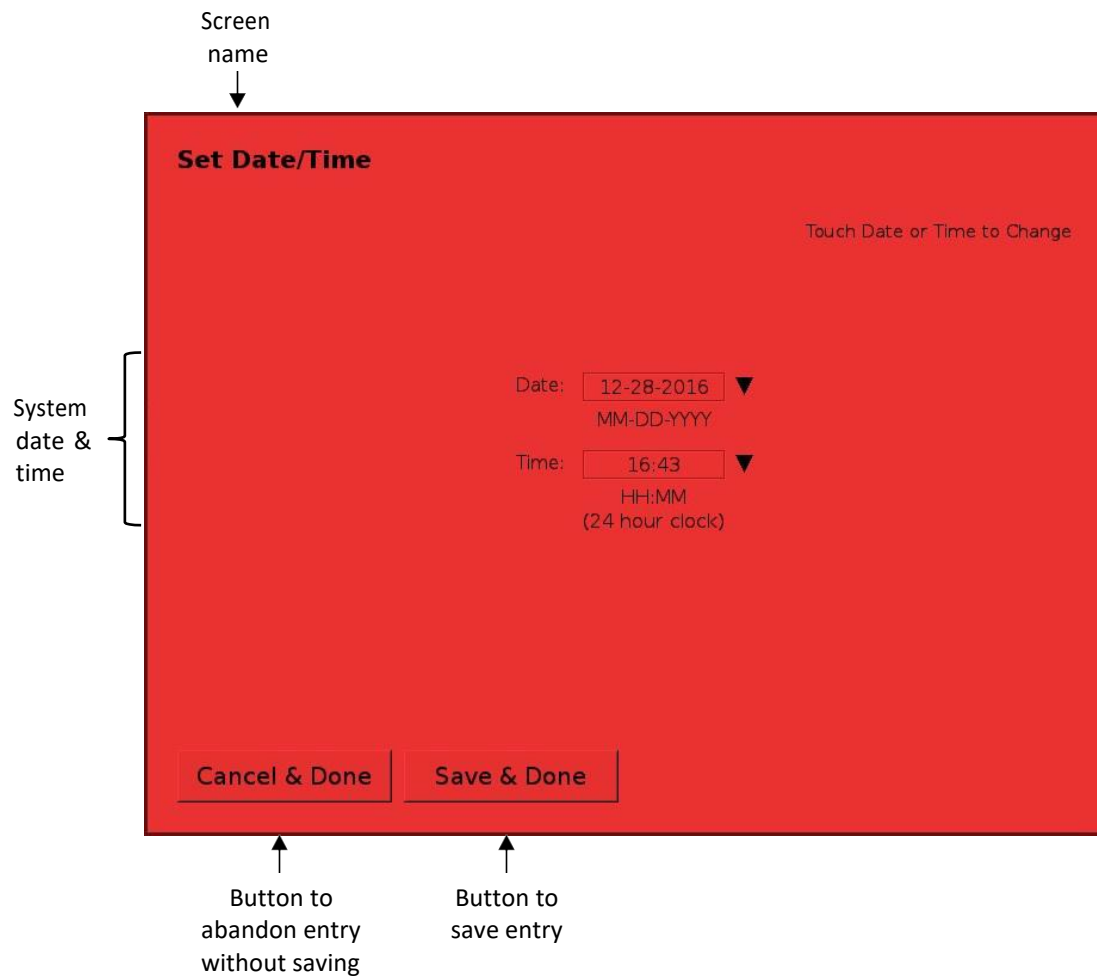
Cancel & Done – Touch the Cancel & Done button at the bottom of the screen to abandon the entered clinic information without saving it and return to the System Tools screen.

Save & Done – Touch the Save & Done button at the bottom of the screen to save the entered clinic information and return to the System Tools screen.

User Tips

- Upon entering the Set Clinic Name screen, the Clinic Name field will initially be active. Touching the “tab” key at the lower left of the touch screen keyboard will advance to the next field. Alternately, a field can be made active by touching it.
- Entries can be corrected by touching on the field to be corrected and using the “backspace” key at the lower right of the touch screen keyboard to erase the entry.
- The Clinic Name will appear at the top of the Home screen (see Section 4.1.1).
- The Clinic Name and Contact Information will appear at the top of test result printouts (see Sections 4.4.6 and 4.5.5).

5.2.2 Set Date/Time



The Set Date/Time screen is accessed from the System Tools screen (see Section 5.1.2). It allows the system date and time to be changed to the local date and time.

Setting Date & Time – The date and time are entered separately:

- Date – must be entered in MM-DD-YYYY format
- Time – must be entered in HH:MM format using a 24 hour clock (e.g., enter 3:21 PM as 15:21)

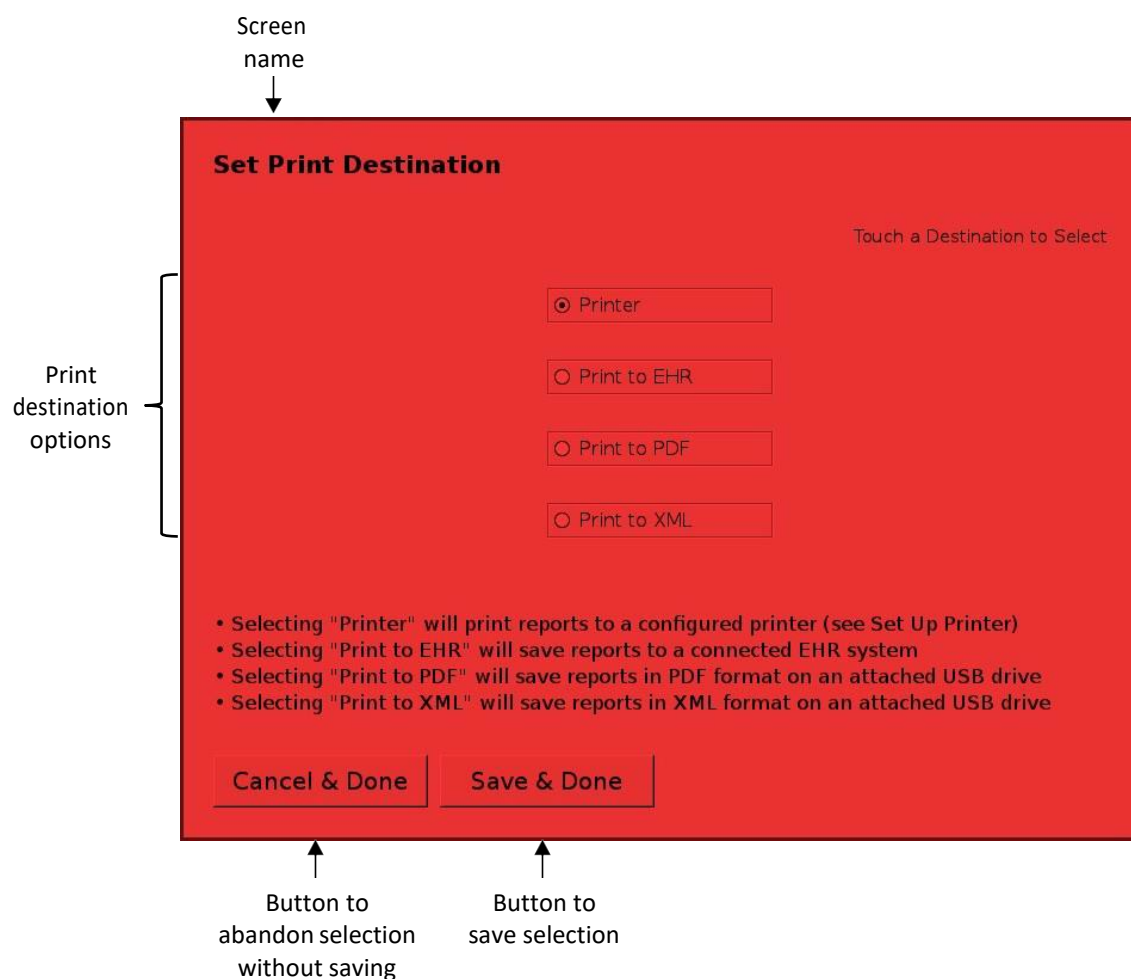
Touching the triangles to the right of these fields launches picker menus to facilitate entry.

Two actions can be taken after adjustment of the Date and Time:

Cancel & Done – Touch the Cancel & Done button at the bottom of the screen to abandon the changes without saving them and return to the System Tools screen.

Save & Done – Touch the Save & Done button at the bottom of the screen to save the changes and return to the System Tools screen.

5.2.3 Set Print Destination



The Set Print Destination screen is accessed from the System Tools screen (see Section 5.1.2). It determines which of the following three options will be used for outputting test reports.

- Printer – When this option is selected, “Print” buttons will cause test results to be printed as hardcopies on an attached printer. This is the default setting.
- Print to EHR – When this option is selected, “Print” buttons will cause test results to be saved in JPEG and (optionally) XML on a shared-network disk drive device.
- Print to PDF – When this option is selected, “Print” buttons will cause test results to be saved in PDF format on a USB thumb drive or other USB storage device.
- Print to XML – When this option is selected, “Print” buttons will cause test reports to be saved in XML format on a USB thumb drive or other USB storage device.

Two actions can be taken after selecting the print destination:

Cancel & Done – Touch the Cancel & Done button at the bottom of the screen to abandon a change in print destination without saving and return to the System Tools screen.

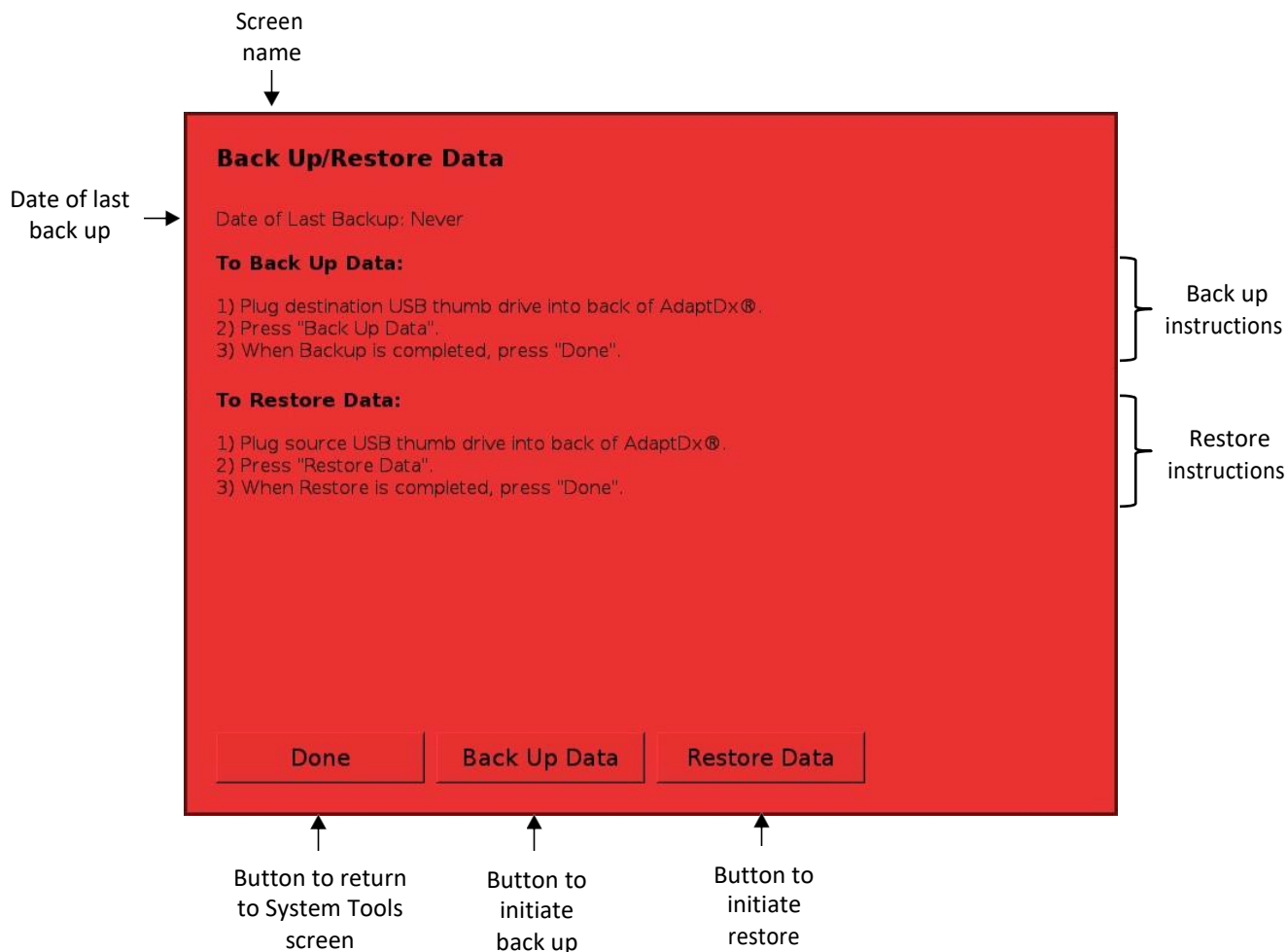
Save & Done – Touch the Save & Done button at the bottom of the screen to save a change in print destination and return to the System Tools screen.

User Tips

- “Print to EHR” is useful for creating reports that can easily be uploaded to an electronic health record (EHR) system. Depending on the sophistication of the on-site EHR system, these files may be automatically incorporated, or may require an operator to manually import the JPEG and/or XML files into the EHR. For test reports, the JPEG file is named “AdaptDx <Last Name>,<First Name><MM-DD-YYYY><hhmm>.jpg”, where “<MM-DD-YYYY><hhmm>” is the date and time of the test. If two test reports are selected, both are placed in the same JPEG file and the time stamp used in the file name is the date and time of the most recent referenced test. For history reports, the JPEG file is named “AdaptDx <Last Name>,<First Name><MM-DD-YYYY><hhmm> History.jpg”, and the time stamp corresponds to the date and time of the most recent test referenced in the report
- “Print to PDF” is useful for creating reports that can be readily uploaded to an electronic health record (EHR) system via USB thumb drive. For test reports, the PDF file is named AdaptDx <Last Name>,<First Name><MM-DD-YYYY><hhmm>.pdf”, where “<MM-DD-YYYY><hhmm>” is the date and time of the test. If two test reports are selected, both are placed in the same PDF file and the time stamp used in the file name is the date and time of the most recent referenced test. For history reports, the PDF file is named “AdaptDx <Last Name>,<First Name><MM-DD-YYYY><hhmm> History.pdf”, and the time stamp corresponds to the date and time of the most recent test referenced in the report.
- “Print to XML” is useful for creating an electronic database for subsequent analysis and for generating manuscript quality data plots. For test reports, the PDF file is named AdaptDx <Last Name>,<First Name><MM-DD-YYYY><hhmm>.xml”, where “<MM-DD-YYYY><hhmm>” is the date and time of the test. If two test reports are selected, both are placed in the same PDF file and the time stamp used in the file name is the date and time of the most recent referenced test. For history reports, the PDF file is named “AdaptDx <Last Name>,<First Name><MM-DD-YYYY><hhmm>History.xml”, and the time stamp corresponds to the date and time of the most recent test referenced in the history report. See Appendix A for a detailed description of XML file formats.

5.3 Database Management

5.3.1 Back Up/Restore Data



The Back Up/Restore Data screen is accessed from the System Tools screen (see Section 5.1.2). It allows a complete back up and restoration of all patient, protocol and test data stored on the AdaptDx® using a USB thumb drive or other USB storage device plugged into either of the USB ports on the back of the AdaptDx® (see Section 2.2). As illustrated above, the date of the last backup is displayed near the top of the screen, and step-by-step on-screen instructions are provided for backup and restore operations.

Back Up Data – Each backup operation will create a single, encrypted file on the USB storage device named “YYYYMMDD_HHMMSS-adaptDx_backup_4_3.tgz”, where “YYYYMMDD” is the date of the backup and “HHMMSS” is the time of day of the backup.

Restore Data – Each restore operation searches the USB storage device for the backup file having the most recent date and time. The restore operation adds to the instrument database any records found in the backup file that are not already in the instrument database, leaving intact records already in the instrument database. This allows recovery from accidental deletions by adding records found on the backup medium that are no longer in the instrument database. It

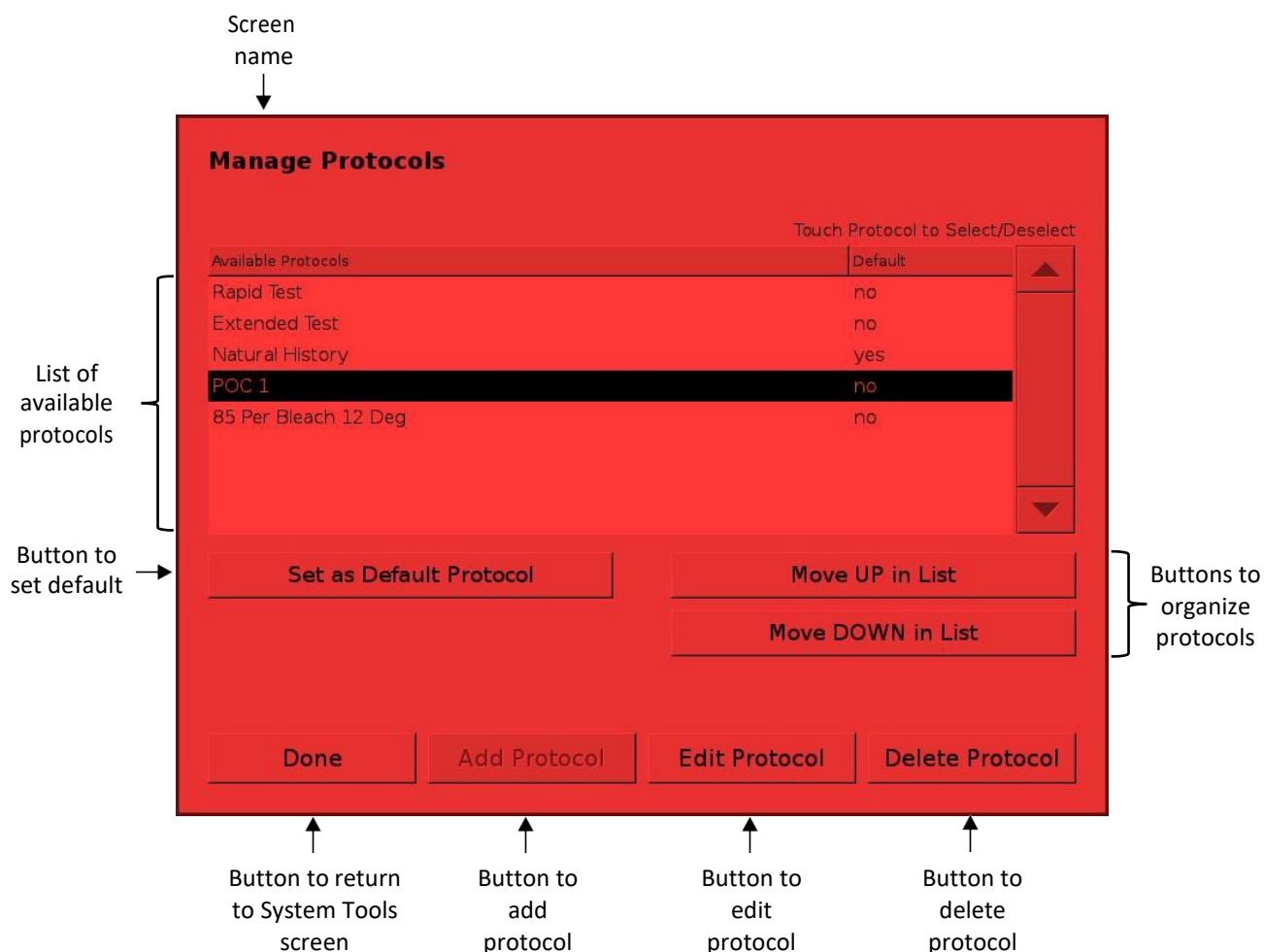
also allows disaster recovery by making an empty AdaptDx® database (on a repaired or replacement instrument) into an exact copy of the backup database.

Done – After the backup or restore operation is completed, remove the USB storage device and touch the Done button at the bottom of the screen to return to the System Tools screen.

User Tips

- Frequent backups are recommended. Data that has not been backed up cannot be restored.
- A progress screen will appear during backup and restore operations and disappear after the operation is completed, signifying that the USB storage device can be disconnected and the AdaptDx® can be returned to normal operation.
- Backup files are encrypted using 256-bit AES encryption in a HIPAA-compliant fashion.
- Because each backup file is assigned a unique filename, multiple backups can be stored on the same USB device without fear of overwriting a previous backup.

5.3.2 Manage Protocols



The Manage Protocols screen is accessed from the System Tools screen (see Section 5.1.2). As illustrated above, it displays a scrollable list of all test protocols in the AdaptDx® database and provides a number of options for organizing and modifying these protocols.

There are three options for organizing the list of test protocols:

Set Default Protocol – To set the system default protocol, touch the name of a protocol in the scrollable list to select it and then touch the Set as Default Protocol button. In the absence of specific directions to the contrary, the AdaptDx® will use the system default protocol for patient testing (see Section 4.2.3).

Move UP in List — To move a protocol to a higher position in the scrollable list, touch the name of the protocol to select it, and then touch the Move UP in List button.

Move DOWN in List — To move a protocol to a lower position in the scrollable list, touch the name of the protocol to select it, and then touch the Move DOWN in List button.

There are also three options for modifying the test protocols:

Add Protocol – Touch the Add Protocol button at the bottom of the screen to add a new protocol to the list available for patient testing (see Section 5.3.3).

Edit Protocol – Touch the Edit Protocol button at the bottom of the screen to edit an existing protocol (see Section 5.3.4). The Edit Protocol button will not become active until a protocol is selected for editing by touching the protocol name in the scrollable list.

Delete Protocol — Touch the Delete Protocol button at the bottom of the screen to delete an existing protocol. The Delete Protocol button will not become active until a protocol is selected for deletion by touching the protocol name in the scrollable list.

User Tips

- The Rapid Test and Extended Test protocols cannot be moved from the top two positions in the scrollable list.

5.3.3 Add Protocols

Screen name
↓

Protocol parameters

Add Protocol

Protocol Name:

Effective Bleach: 20% to 95% (2.82E+02 scot lx sec)

Starting Stimulus: 0.0 to 5.0 log units (7.40E-01 scot mlx)

Stimulus Duration: 100 to 300 msec

Rest Break: 0 to 60 sec

Max Test Duration: 1.0 to 100.0 min

Terminate test at Rod Intercept? ☒ Yes ☐ No

Touch Test Location

| | | | | | | | | | | | | |
|---|---|-------|---|---|---|---|---|---|---|---|---|---|
| q | w | e | r | t | y | u | i | o | p | 1 | 2 | 3 |
| a | s | d | f | g | h | j | k | l | - | 4 | 5 | 6 |
| ↶ | z | x | c | v | b | n | m | ↷ | | 7 | 8 | 9 |
| → | @ | Space | | | | | | | , | . | ← | 0 |

↑ Button to abandon without saving
 ↑ Button to save and return to System Tools screen
 ↑ Button to save and add another protocol

The Add Protocol screen is accessed from the System Tools screen (see Sections 5.1.2 and 5.3.2). It is used to add new test protocols to the list available for patient testing.

Entering Protocol Parameters – Any number of additional protocols can be created to address specific user needs by varying the following parameters within the ranges indicated:

| <u>Parameter</u> | <u>Range</u> | <u>Default</u> |
|-----------------------|--|-------------------|
| Effective Bleach | 20% to 95% (0.01 to 6,000 scot lx sec) | 83% (673) |
| Starting Stimulus | 0.0 to 5.0 log units (0 to 7.4 scot mlx) | 1.0 (0.74) |
| Stimulus Duration | 100 to 300 msec | 200 |
| Stimulus Location | 5°, 8.5° or 12° at eight azimuths | 5° below fixation |
| Rest Break | 0 to 60 sec | 15 |
| Maximum Test Duration | 1 to 100 min | 40 |

The Protocol Name can be any desired alphanumeric descriptor up to 20 characters. As illustrated above, retinal illuminance values corresponding to the Effective Bleach percentage and the Starting Stimulus log units are automatically calculated by the AdaptDx® and displayed. These calculations assume an 8 mm diameter pupil. The test location is selected by touching on the

desired location. In addition, the protocol can be set to automatically terminate testing after sufficient data has been collected to determine the Rod Intercept (see Section 3 for a description of the Rod Intercept), or it can be set to continue until the Maximum Test Duration has been reached. The default option is termination at the Rod Intercept.

Three actions can be taken after entry of parameters for a new protocol:

Cancel & Done – Touch the Cancel & Done button at the bottom of the screen to abandon the entered parameters without saving the new protocol and return to the System Tools screen.

Save & Done – Touch the Save & Done button at the bottom of the screen to save the entered parameters as a new protocol and return to the System Tools screen.

Save & New – Touch the Save & New button at the bottom of the screen to save the entered parameters as a new protocol and remain on the Add Protocol screen for addition of another new protocol.

User Tips

- Note that the test location is specified as a field view, not a physical location. For example, a location 5° inferior on the vertical meridian in the field view is physically located 5° superior on the vertical meridian.
- Upon entering the Add Protocol screen, the Protocol Name field will initially be active. Touching the “tab” key at the lower left of the touch screen keyboard will advance to the next field. Alternately, a field can be made active by touching it.
- Entries can be corrected by touching on the field to be corrected and using the “backspace” key at the lower right of the touch screen keyboard to erase the entry.
- To measure a complete dark adaptation curve, create a custom test protocol with a Maximum Test Duration of at least 90 minutes and elect NOT to terminate the test at the Rod Intercept.

5.3.4 Edit Protocols

Screen name
↓

Protocol parameters

Edit POC 1

Protocol Name:

Effective Bleach: 20% to 95% (6.92E+02 six sec)

Starting Stimulus: 0.0 to 5.0 log units (2.34E+00 smlx)

Stimulus Duration: 100 to 300 msec

Rest Break: 0 to 60 sec

Max Test Duration: 1.0 to 100.0 min

Terminate test at Rod Intercept? ☒ Yes ☐ No

Touch Test Location

| | | | | | | | | | | | | |
|---|---|-------|---|---|---|---|---|---|---|---|---|---|
| q | w | e | r | t | y | u | i | o | p | 1 | 2 | 3 |
| a | s | d | f | g | h | j | k | l | - | 4 | 5 | 6 |
| ↶ | z | x | c | v | b | n | m | ↷ | | 7 | 8 | 9 |
| → | @ | Space | | | | | | , | . | ← | 0 | |

Cancel & Done Save & Done

Button to abandon without saving Button to save and return to System Tools screen

The Edit Protocol screen is accessed from the System Tools screen (see Sections 5.1.2 and 5.3.2). It is used to edit existing test protocols. As illustrated above, the name of the protocol selected for editing is displayed at the top of the screen, and the parameter fields are pre-populated with the existing parameters.

Editing Protocol Parameters – Any of the following protocol parameters can be modified within the ranges indicated:

| <u>Parameter</u> | <u>Range</u> |
|-----------------------|--|
| Effective Bleach | 20% to 95% (0.01 to 6,000 scot lx sec) |
| Starting Stimulus | 0.0 to 5.0 log units (0 to 7.4 scot mlx) |
| Stimulus Duration | 100 to 300 msec |
| Stimulus Location | 5°, 8.5° or 12° at eight azimuths |
| Rest Break | 0 to 60 sec |
| Maximum Test Duration | 1 to 100 min |

The Protocol Name can be left the same or changed to any desired alphanumeric descriptor up to 20 characters. As illustrated above, retinal illuminance values corresponding to the Effective

Bleach percentage and the Starting Stimulus log units are automatically calculated by the AdaptDx® and displayed. These calculations assume an 8 mm diameter pupil. The test location is selected by touching on the desired location. In addition, the protocol can be set to automatically terminate testing after sufficient data has been collected to determine the Rod Intercept (see Section 3 for a description of the Rod Intercept), or it can be set to continue until the Maximum Test Duration has been reached.

Two actions can be taken after editing the protocol parameters for an existing protocol:

Cancel & Done – Touch the Cancel & Done button at the bottom of the screen to abandon the edits without saving them, retaining the original protocol unchanged, and return to the System Tools screen.

Save & Done – Touch the Save & Done button at the bottom of the screen to save the edits as a revised protocol and return to the System Tools screen.

User Tips

- Note that the test location is specified as a field view, not a physical location. For example, a location 5° inferior on the vertical meridian in the field view is physically located 5° superior on the vertical meridian.
- Upon entering the Add Protocol screen, the Protocol Name field will initially be active. Touching the “tab” key at the lower left of the touch screen keyboard will advance to the next field. Alternately, a field can be made active by touching it.
- Entries can be corrected by touching on the field to be corrected and using the “backspace” key at the lower right of the touch screen keyboard to erase the entry.

5.3.5 Delete Test Selection

Screen name

Search Patient box

List of patients in database

Delete Test

Search Name Gree_

Select patient for test you want to delete.

| Name | Birth Date | Patient Identifier |
|-----------------------|------------|--------------------|
| Greenbaum, Charles L. | 07-18-1967 | GMC123 |
| Greene, Charlotte P. | 06-17-1966 | GLC123 |
| Green, Martha F. | 10-18-1948 | GHL2009 |
| Green, Thomase P. | 05-16-1965 | GKC123 |

q w e r t y u i o p 1 2 3

a s d f g h j k l - 4 5 6

↑ z x c v b n m ↑ 7 8 9

→ @ Space , . ← 0

Done Show Tests

Button to return to System Tools screen

Button to initiate deletion of a test record

The Delete Test screen is accessed from the System Tools screen (see Section 5.1.2). Deletion of test records is initiated by identifying the patient for whom test records are to be deleted.

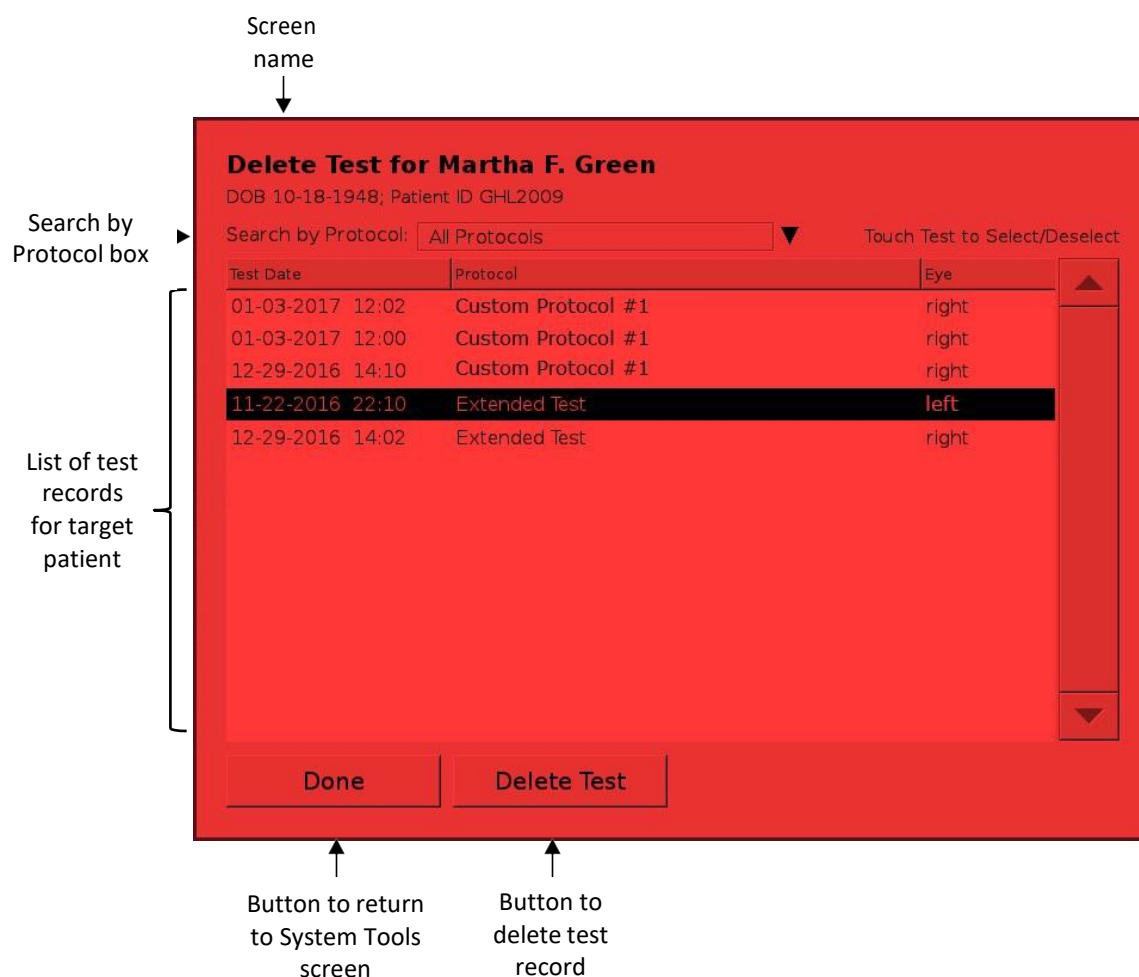
Select Patient – As illustrated above, the Delete Test screen initially displays a scrollable list of all patients in the AdaptDx® database. Typing all or part of a patient's name in the Search Patient box above the list narrows the display to matching entries. Touching a name in the list selects that patient.

Proceed to Selection of Tests for Deletion – Touch the Show Tests button at the bottom of the screen to proceed. The Show Tests button will not become active until a patient is selected from the scrollable list.

User Tips

- The display of patient names lists only the most recent name associated with a Patient Identifier. If a patient's name is changed—for example to correct a misspelling or when the patient gets married—all information for that patient will be linked to the new name.

5.3.6 Delete Test



After identification of the patient for whom test records are to be deleted (see Section 5.3.5), the Delete Test screen converts to a display of all test records for that patient. As illustrated above, the name of the target patient is displayed at the top of the screen, and the test records appear in a scrollable window. Specific test records can be selected and deleted.

Narrow Choices – The Search by Protocol box above the scrollable display can be used to narrow the choices. The pre-populated default option is All Protocols, which displays all prior tests for the target patient in reverse chronological order. Touching the triangle beside the Search by Protocol box launches a protocol picker that narrows the display to those matching a particular test protocol.

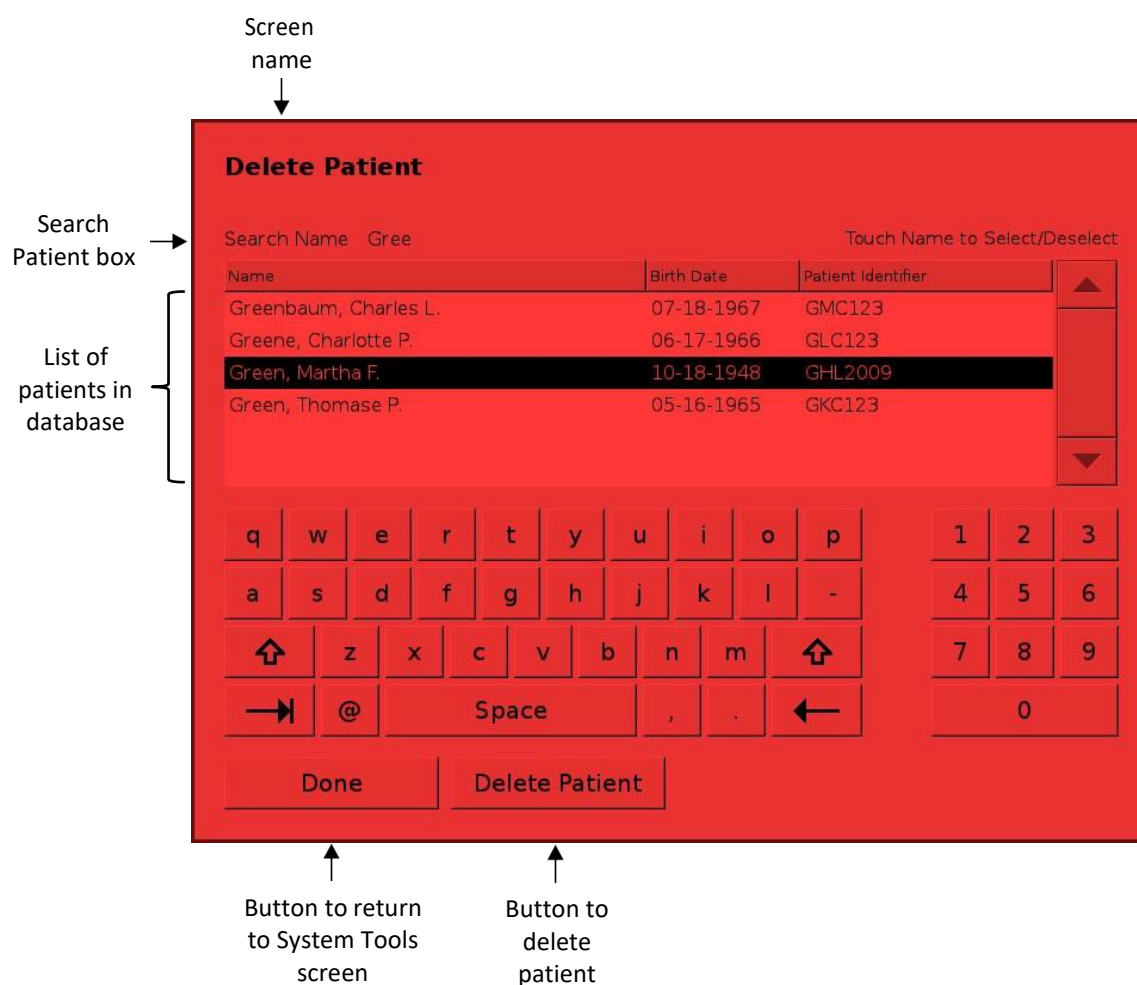
Delete Test – To delete a test record, touch the appropriate test date/protocol/eye combination in the scrollable list to select it and then touch the Delete Test button at the bottom of the screen. The Delete Test button will not become active until a test record is selected from the scrollable list.

When all desired deletions have been made, touch the Done button at the bottom of the screen to return to the System Tools screen.

User Tips

- If a test record is inadvertently deleted, it may be possible to restore the record to the AdaptDx® database using the Back Up/Restore Data tool (see Section 5.3.1).

5.3.7 Delete Patient



The Delete Patient screen is accessed from the System Tools screen (see Section 5.1.2).

Select Patient – As illustrated above, the Delete Patient screen displays a scrollable list of all patients in the AdaptDx® database. Typing all or part of a patient's name in the Search Patient box above the list narrows the display to matching entries. Touching a name in the list selects that patient for deletion.

Delete Patient – Touch the Delete Patient button at the bottom of the screen to delete the selected patient. The Delete Patient button will not become active until a patient name is selected from the scrollable list.

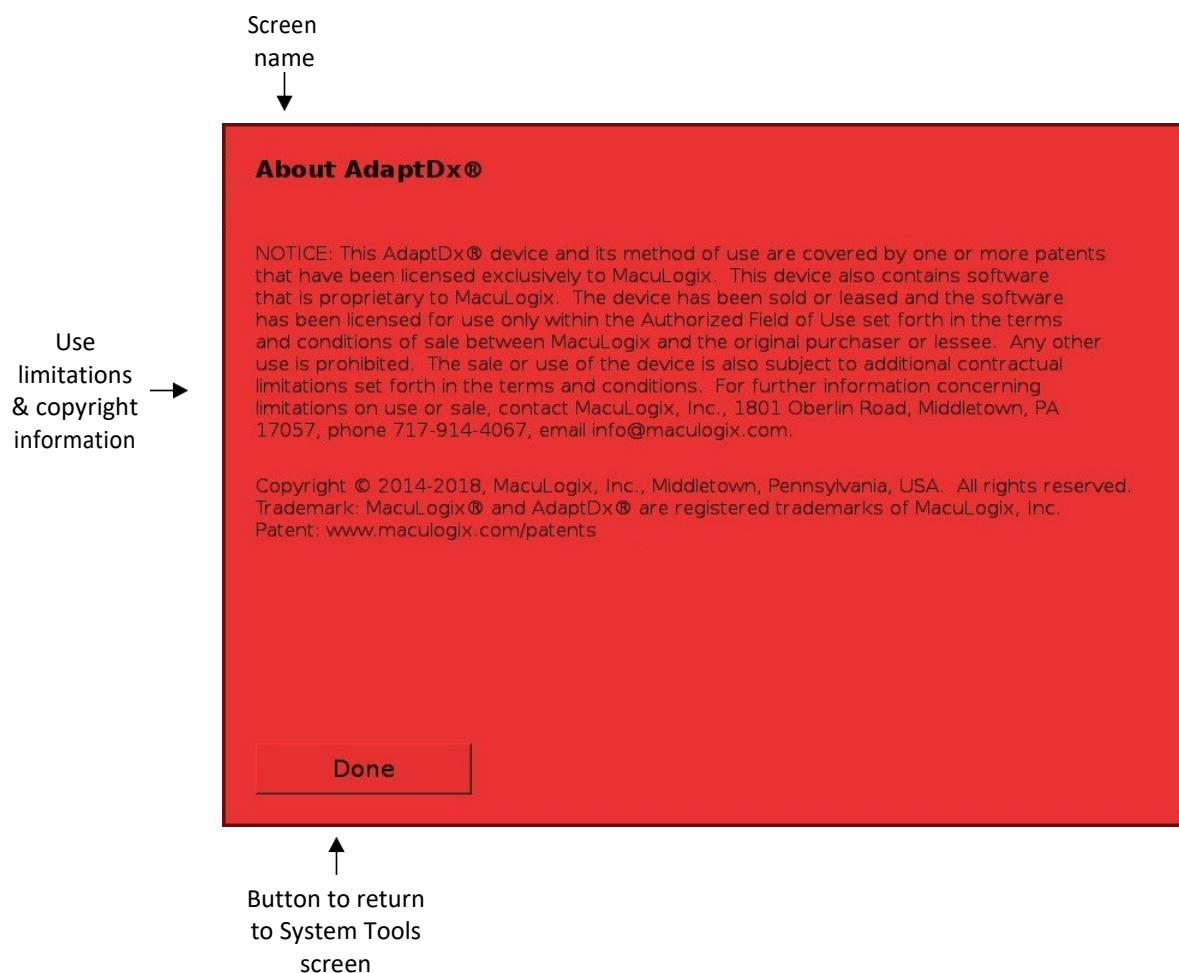
When all desired deletions have been made, touch the Done button at the bottom of the screen to return to the System Tools screen.

User Tips

- If a patient record is inadvertently deleted, it may be possible to restore the record to the AdaptDx® database using the Back Up/Restore Data tool (see Section 5.3.1).
- The display of patient names lists only the most recent name associated with a Patient Identifier. If a patient's name is changed—for example to correct a misspelling or when the patient gets married—all information for that patient will be linked to the new name.

5.4 Information

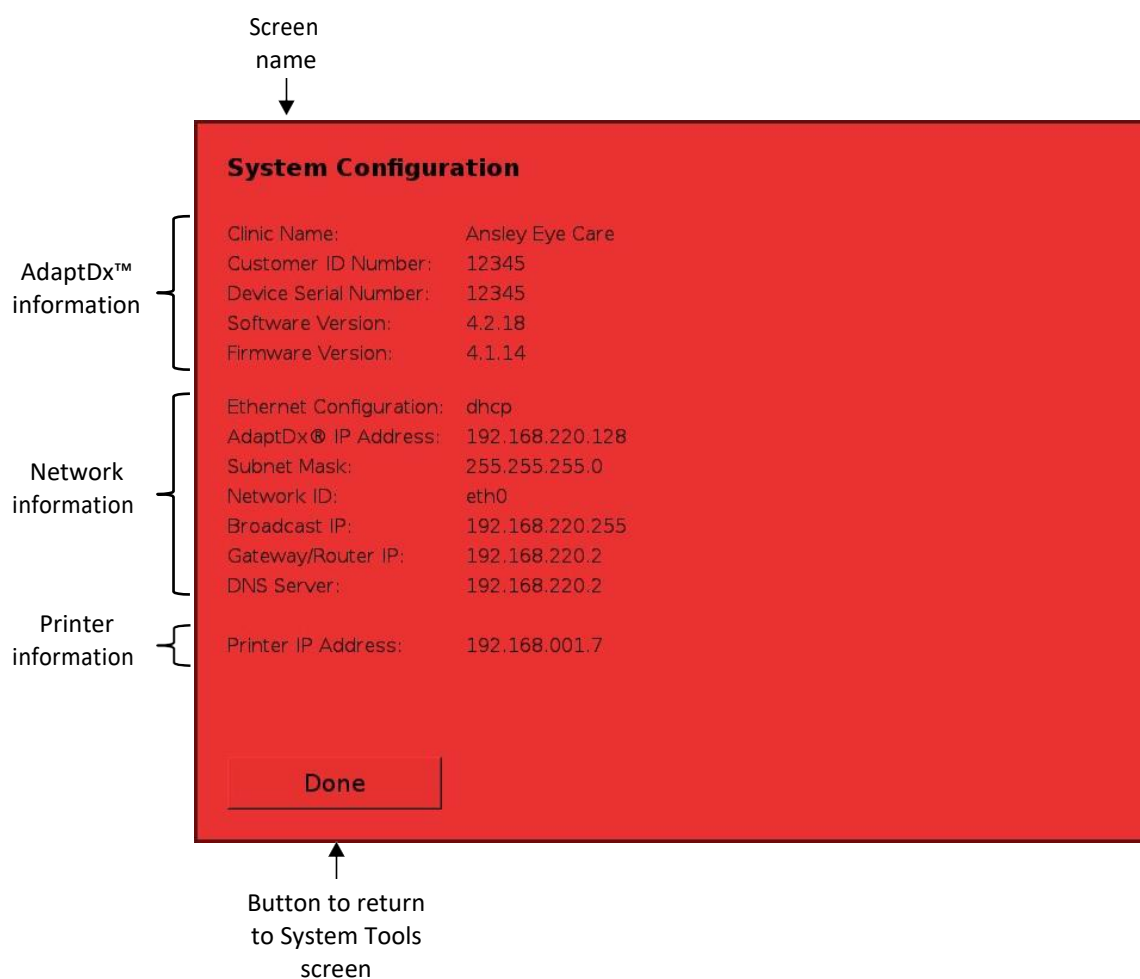
5.4.1 About AdaptDx®



The About AdaptDx® screen is accessed from the System Tools screen (see Section 5.1.2). It provides use limitations and copyright information.

Done – Touch the Done button at the bottom of the screen to return to the System Tools screen.

5.4.2 Display System Configuration

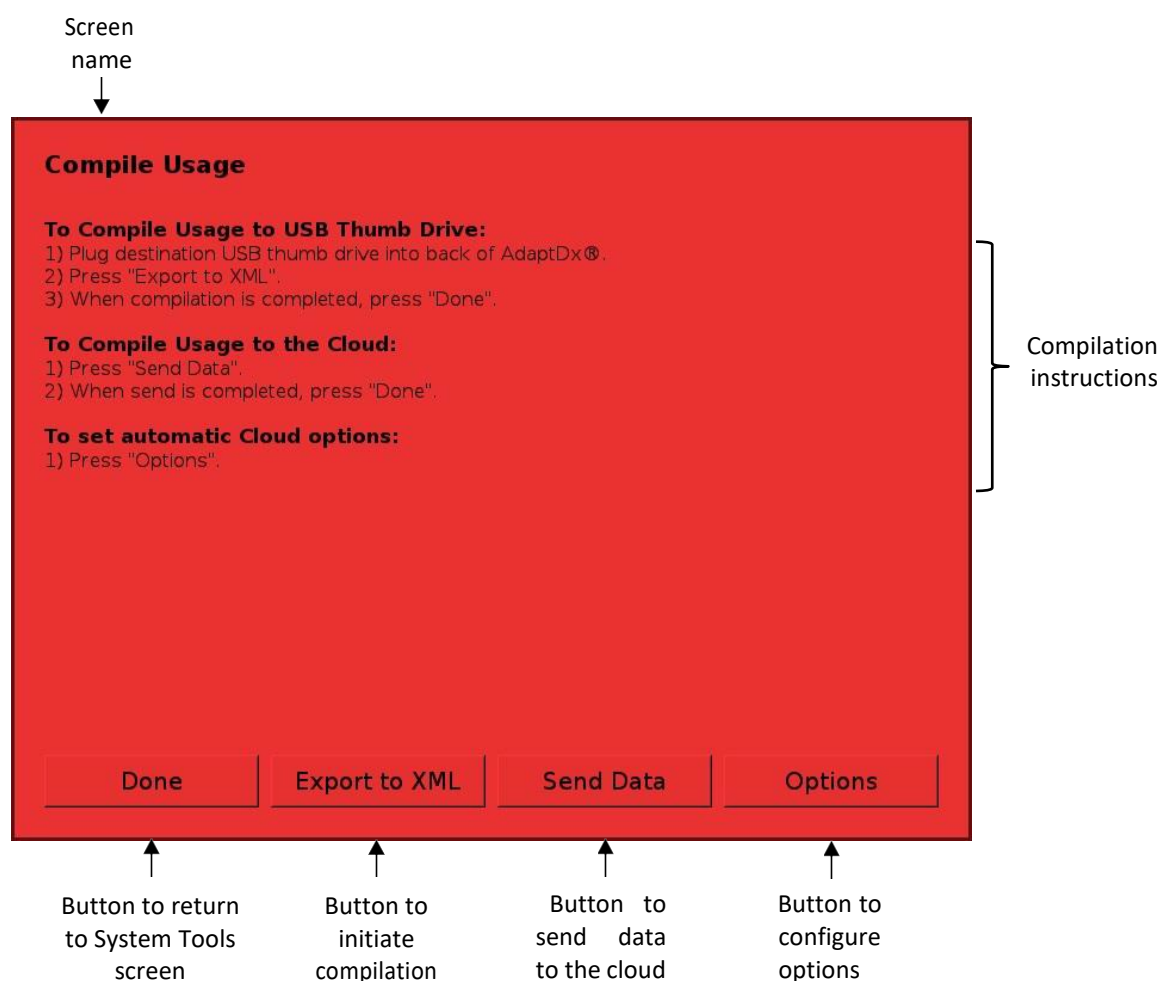


The System Configuration screen is accessed from the System Tools screen (see Section 5.1.2). It provides basic information about the AdaptDx®, the network to which it is connected (if applicable), and the printer to which it is connected (if applicable). Touch the Done button to return to the System Tools screen.

User Tips

- When contacting MacuLogix for service or other support (see Section 7), the System Information screen provides valuable information to help orient the technician.

5.4.3 Compile Usage



The Compile Usage screen is accessed from the System Tools screen (see Section 5.1.2). Utilization statistics can be saved to a local flash drive (via “Export to XML”) or transmitted to MacuLogix over the internet (via “Send Data”). With the first option, the utilization statistics are exported to a USB thumb drive or other USB storage device plugged into either of the USB ports on the back of the AdaptDx® (see Section 2.2). With the second option, utilization data will be sent to the secure MacuLogix server provided a network connection has been configured (see Section 5.5.2 or 5.5.3). As illustrated above, step-by-step on-screen instructions are provided.

Options – The “Options” screen allows the operator to select the frequency of utilization data transmission to MacuLogix. Available options include Never, Daily, Weekly, or Monthly. Automatic sends are always checked and performed (if necessary) upon AdaptDx® boot.

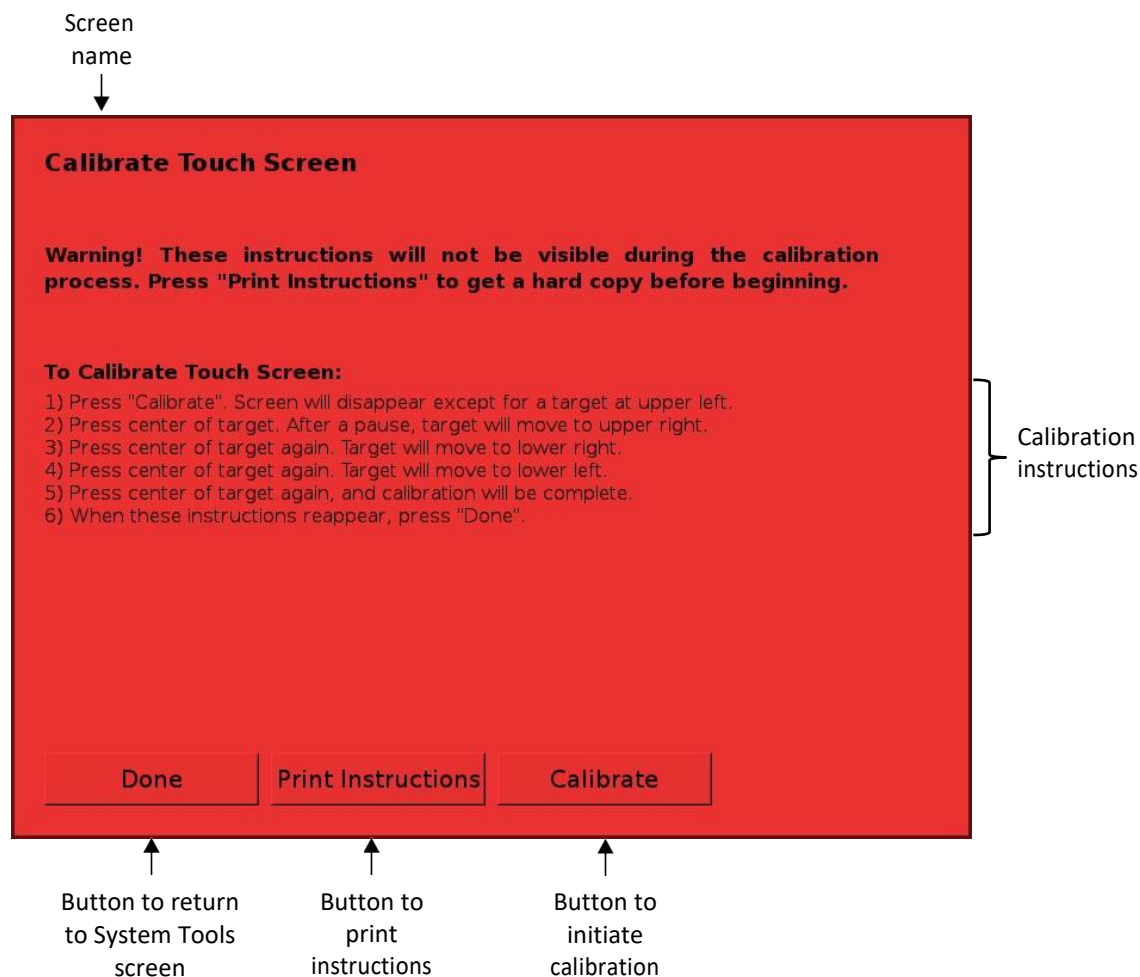
Done – After the compilation is completed, remove any USB storage device and touch the Done button at the bottom of the screen to return to the System Tools screen.

User Tips

- This utility is principally intended to support maintenance.

5.5 Configuration & Maintenance

5.5.1 Calibrate Touch Screen



The Calibrate Touch Screen utility is accessed from the System Tools screen (see Section 5.1.2). It ensures proper alignment of the touch screen sensing region with the underlying monitor image. As illustrated above, step-by-step instructions are provided for the calibration procedure.

Print Instructions – Touch the Print Instructions button at the bottom of the screen to print a copy of the calibration instructions. **The instruction should be printed or copied before initiating calibration as they will not be visible during the calibration process.**

Calibrate – Touch the Calibrate button at the bottom of the screen to initiate calibration, then follow the step-by-step calibration instructions.

Done – Touch the Done button at the bottom of the screen to return to the System Tools screen.

User Tips

- The AdaptDx® touch screen was factory calibrated. It should not be recalibrated unless problems are experienced with the touch screen operation. It is recommended that you contact MacuLogix for support before attempting to recalibrate the touch screen (see Section 7).

5.5.2 Set Up Network - Static Mode

Screen name

Network parameters

Set Up Network

Current Ethernet Configuration Mode: Static IP Address

Network ID: eth0

AdaptDx® IP Address: 192.168.220.128

Subnet Mask: 255.255.255.0

Broadcast IP: 192.168.220.255

Gateway/Router IP: 192.168.220.2

DNS Server: 192.168.220.2

q w e r t y u i o p 1 2 3

a s d f g h j k l - 4 5 6

↑ z x c v b n m ↑ 7 8 9

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Cancel & Done Save & Done Make Automatic Make Static

Button to exit without connecting Button to connect Button to switch to DHCP mode

The Set Up Network screen is accessed from the System Tools screen (see Section 5.1.2). It establishes a connection between the AdaptDx® and a local area network to support remote printing. Both static connection and automatic Dynamic Host Configuration Protocol (DHCP) connection are supported. The default mode is static. As illustrated above, in static mode the network parameters are entered manually. The AdaptDx® IP Address is 192.168.2.104. Ask your office information technology (IT) group for the local area network parameters.

Before establishing a network connection, the AdaptDx® must be physically wired to the network by plugging an Ethernet cable from the network into the Ethernet port on the back of the instrument (see Section 2.2). The AdaptDx® does not support a wireless connection.

Make Automatic – Touch the Make Automatic button at the bottom of the screen to switch to DHCP mode (see Section 5.5.3).

Make Static – The Make Static button at the bottom of the screen is not active when the network connection is already in static mode.

Cancel & Done – Touch the Cancel & Done button at the bottom of the screen to exit without completing the network connection and return to the System Tools screen.

Save & Done – Touch the Save & Done button at the bottom of the screen to complete the network connection and return to the System Tools screen.

User Tips

- Before establishing a network connection to the AdaptDx®, ask your office information technology (IT) group if there are any special requirements related to your local area network.

5.5.3 Set Up Network - DHCP Mode

Screen name
↓

Network parameters {

Set Up Network
Current Ethernet Configuration Mode: Automatic with DHCP
Network ID: eth0
AdaptDx® IP Address: 192.168.220.128
Subnet Mask: 255.255.255.0
Broadcast IP: 192.168.220.255
Gateway/Router IP: 192.168.220.2
DNS Server: 192.168.220.2

Cancel & Done Save & Done Make Automatic Make Static

↑ ↑ ↑
Button to exit without connecting Button to connect Button to switch to static mode

The Set Up Network screen is accessed from the System Tools screen (see Section 5.1.2). It establishes a connection between the AdaptDx® and a local area network to support remote printing. Both automatic Dynamic Host Configuration Protocol (DHCP) connection and static connection are supported. As illustrated above, in DHCP mode the AdaptDx® will automatically establish a network connection and display the network parameters.

Before establishing a network connection, the AdaptDx® must be physically wired to the network by plugging an Ethernet cable from the network into the Ethernet port on the back of the instrument (see Section 2.2). The AdaptDx® does not support a wireless connection.

Make Automatic – The Make Automatic button at the bottom of the screen is not active when the network is already in DHCP mode.

Make Static – Touch the Make Static button at the bottom of the screen to switch to static mode (see Section 5.5.2).

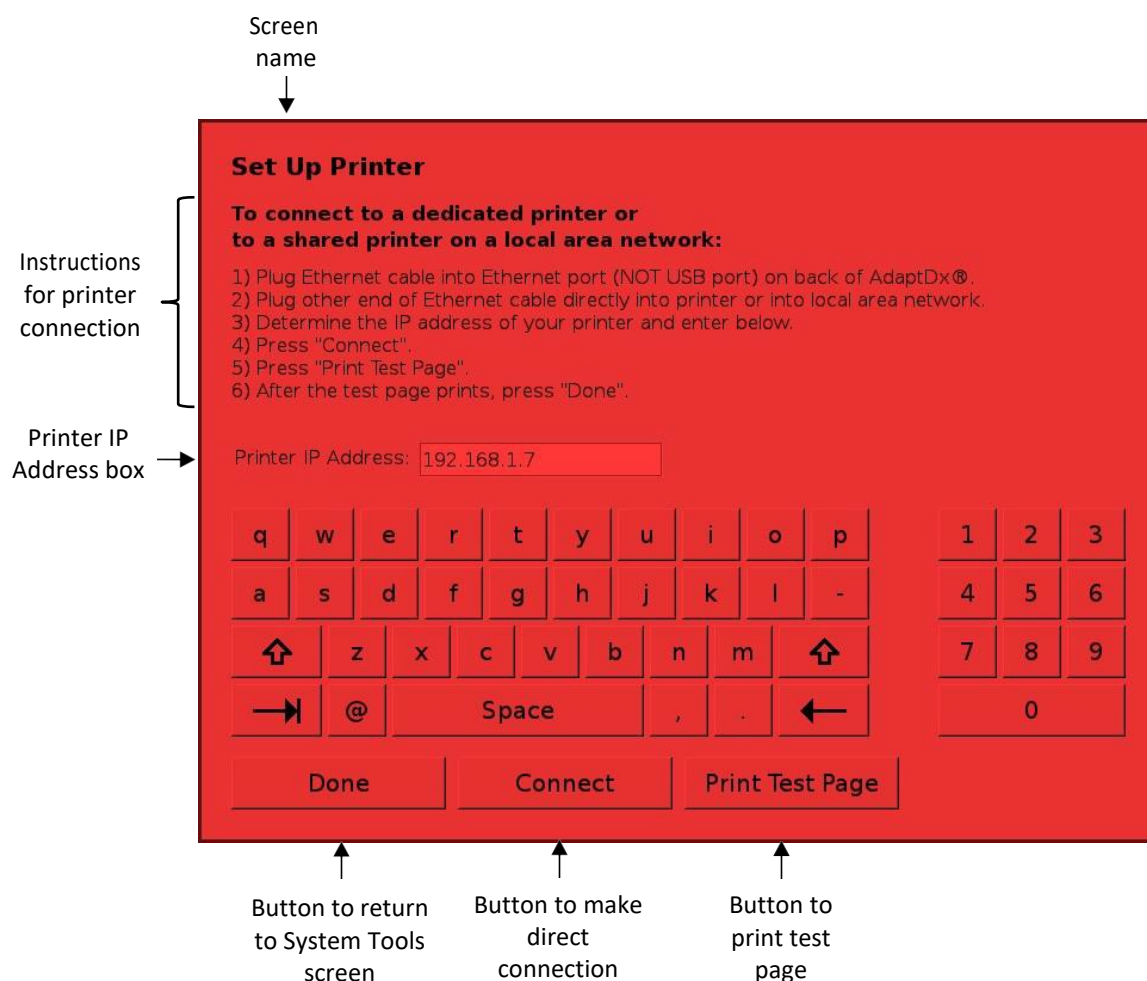
Cancel & Done – Touch the Cancel & Done button at the bottom of the screen to exit without completing the network connection and return to the System Tools screen.

Save & Done – Touch the Save & Done button at the bottom of the screen to complete the network connection and return to the System Tools screen.

User Tips

- Before establishing a network connection to the AdaptDx®, ask your office information technology (IT) group if there are any special requirements related to your local area network.

5.5.4 Set Up Printer



The Set Up Printer screen is accessed from the System Tools screen (see Section 5.1.2). It enables connection to a dedicated AdaptDx® printer or to a local area network with a shared office printer. As illustrated above, step-by-step instructions are provided.

To establishing a printer connection, the AdaptDx® must first be physically wired to the printer by plugging one end of an Ethernet cable into the Ethernet port (NOT the USB port) on the back of the AdaptDx® and plugging the other end of the cable directly into a dedicated printer or into a local area network with a shared printer (see Section 2.2).

Connect – Enter the printer IP address into the Printer IP Address box in the middle of the screen and touch the Connect button at the bottom of the screen to complete printer set up. For a dedicated printer, see the separate printer manual for instruction on how to find the printer IP address. For a shared printer on a local area network, ask your office information technology (IT) group for the printer IP address.

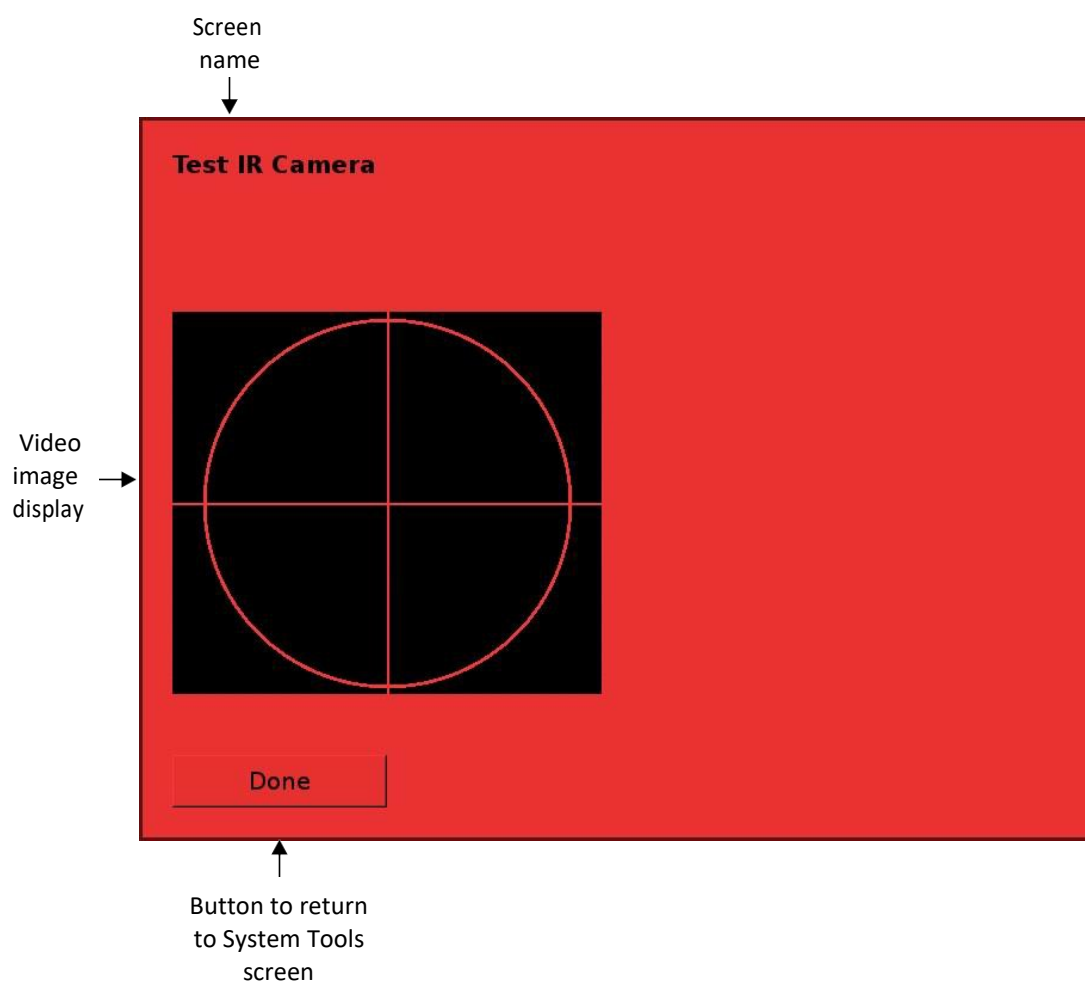
Print Test Page – Touch the Print Test Page button at the bottom of the screen to confirm successful printer set up.

Done – Touch the Done button at the bottom of the screen to return to the System Tools screen. Leaving the Set Up Printer screen before fully completing the instructions will result in the printer not being connected.

User Tips

- For a list of printers that are supported by the AdaptDx®, contact MacuLogix at 717-914-4067 Monday through Friday between 9:00 AM and 5:00 PM US Eastern time.

5.5.5 Test IR Camera



The Test IR Camera screen is accessed from the System Tools screen (see Section 5.1.2). It provides confirmation that the IR camera is functioning properly. As illustrated above, a video image is displayed on the left half of the Monitor screen.

Test IR Camera – To check for proper operation, position a picture or page of text in front of the trial lens holder facing the back of the viewing tunnel (see Section 4.2.2). The picture or text should be clearly visible in the video image display.

Done – Touch the Done button at the bottom of the screen to return to the System Tools screen.

User Tips

- If the IR camera is not functioning properly or is badly out of focus, contact MacuLogix for support (see Section 7).

5.5.6 Update Software



The Update Software screen is accessed from the System Tools screen (see Section 5.1.2). It updates the AdaptDx® software from a USB thumb drive, or from a secure MacuLogix server, provided a network connection has been configured (see Section 5.5.2 or 5.5.3). As illustrated above, step-by-step on-screen instructions are provided for performing a software update.

USB Update – After removing any existing thumb drives from the back of the AdaptDx®, plug a MacuLogix provided USB thumb drive containing a software update into either of the USB ports on the back of the AdaptDx® (see Section 2.2). Touch the Update Software button at the bottom of the screen to initiate the update. When the software update is successful, the system will automatically initiate a system reboot. During this reboot you should remove the MacuLogix supplied thumb drive containing the software update and reinsert any previously removed thumb drives.

Cloud Update – Pressing the Cloud Update button will check the secure MacuLogix server to determine if this unit has any software updates available. If so, it will install the update and automatically initiate a system reboot upon success.

Done – If the software update was unsuccessful, or the USB Update or Cloud Update button was untouched, touch the Done button at the bottom of the screen to return to the System Tools screen. You may then reinsert any previously removed thumb drives.

Options – The “Options” screen allows the operator to select the frequency of automatically checking and installing updates from the secure MacuLogix server. Available options include Never, Daily, Weekly, or Monthly. Automatic updates are always checked and performed (if necessary) upon AdaptDx® boot.

User Tips

- This utility is principally intended to support maintenance.
- A progress screen will appear during the software update operation and disappear after the operation is completed, signifying that the USB thumb device can be removed and the AdaptDx® can be returned to normal operation (after the system has rebooted).

5.5.7 Set Up EHR

Screen name

Instructions for EHR connection

Connection information

Connection status

Connection options

Set Up EHR

To connect to a shared-network disk drive on a local area network:

- 1) Plug Ethernet cable into Ethernet port (NOT USB port) on back of AdaptDx®.
- 2) Plug other end of Ethernet cable directly into local area network.
- 3) Determine the Machine Name, Share Name, Login, and Password and enter below.
- 4) Press "Connect".

Machine Name: Login:

Share Name: Password:

Current Status: Not connected to EHR.

Resolution (dpi): ☐ 72 ☒ 300 ☐ 600

Export XML? ☐ Yes ☒ No

| | | | | | | | | | | | | |
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| ↶ | z | x | c | v | b | n | m | ↷ | | 7 | 8 | 9 |
| → | @ | Space | | , | . | ← | | | | 0 | | |

Done Connect Disconnect

Button to return to System Tools screen

Button to connect EHR

Button to disconnect EHR

The Set Up EHR screen is accessed from the System Tools screen (see Section 5.1.2). It enables connection to an EHR shared-network disk drive connected to the same local area network as the AdaptDx®.

To establish an EHR connection, the AdaptDx® must first be connected to a local area network (see Sections 5.5.2 and 5.5.3) with a shared-network disk drive which the EHR uses to import data. The Machine Name, Share Name, Login, and Password information appropriate for this shared-network disk drive will be required.

Connect – Enter the Machine Name, Share Name, Login, and Password in the appropriate text fields on the screen. Note that the Machine Name may be an IP Address or the alpha-numeric text name of the computer. The password entered will not be displayed as typed. An asterisk character (*) will appear instead for each character entered. After successfully entering all 4 values, touch Connect. If the connection is successful, the Current Status field will change to "Connected to EHR". This connection will be maintained as long as the AdaptDx is powered up, and if the machine is restarted, the connection will be automatically restored.

Disconnect – Touch the Disconnect button to disconnect from the current EHR shared-network disk drive. All connection information will be saved, but no connection will be attempted until Connect is touched again.

Done – Touch the Done button at the bottom of the screen to return to the System Tools screen. Leaving the Set Up EHR screen before fully completing the instructions will result in the EHR not being connected.

User Tips

- The Resolution radio buttons on this screen control the resolution of the JPEG files uploaded to the EHR system. 300 dpi is the default and should work for most EHR systems. Higher resolution images will be uploaded if 600 dpi is selected, and lower resolution images will be uploaded when 75 dpi is selected.
- The “Export XML?” radio buttons control whether or not XML patient data is uploaded to the EHR system. Some EHR system support this feature. The default is not to upload this data.

6 Clinical Performance Data

6.1 Summary

The results of two studies are provided to characterize the clinical performance of the AdaptDx®.

AdaptDx® vs. Goldmann-Weekers Agreement Study – This study compared the AdaptDx® to the Goldmann-Weekers Adaptometer. Both devices were used to test 12 adults having a range of eye health status and physiological responses. Dark adaptation speed as characterized by both the rod-cone break and the Rod Intercept parameters was found to be highly correlated between the two instruments. Details are provided in Section 6.2.

AdaptDx® Precision Study – This study assessed the measurement error (precision) of the AdaptDx®. The study population consisted of 14 adults with normal retinal health and 8 patients with age-related macular degeneration (AMD) having a broad range of dark adaptation speeds. Each participant was tested twice with the AdaptDx®, separated by two weeks. Dark adaptation speed was characterized using both the rod-cone break and the Rod Intercept parameters. For comparison, similar measurements were made on a separate group of 6 normal adults using the Goldmann-Weekers Adaptometer. The measurement errors for both devices are summarized in the following table. Dark adaptation speeds for the AdaptDx® were highly correlated between the first and second visits for both parameters. Furthermore, the rod-cone break and Rod Intercept parameters were highly correlated with each other. Details are provided in Section 6.3.

| Comparison of Measurement Errors (minutes) for AdaptDx® and Goldmann-Weekers Adaptometer | | | | |
|---|----------------|------------------|-----------------|----------|
| | | Normal Adults | AMD Patients | Combined |
| AdaptDx® | Rod-Cone Break | 1.2 | 1.0 | 1.1 |
| | Rod Intercept | 1.2 | 0.9 | 1.1 |
| Goldmann- Weekers | Rod-Cone Break | 1.2 | NA | NA |
| | Rod Intercept | 1.7 | NA | NA |

6.2 AdaptDx® vs. Goldmann-Weekers Agreement Study

The purpose of this study was to compare the AdaptDx® to the Goldmann-Weekers Adaptometer. Because dark adaptometers do not provide standardized measurements or have standardized interpretations, the criterion for comparison was the correlation of dark adaptation speed.

The study sample consisted of 12 participants with a range of eye health status, including 8 healthy volunteers (normal), 2 participants with age-related macular degeneration (AMD) and 1 participant with diabetic retinopathy (DR), providing a broad range of physiological responses. In particular, normal adults are known to exhibit relatively rapid dark adaptation, whereas AMD patients are known to exhibit relatively slow dark adaptation [1].

Each participant's dark adaptation was measured with both the AdaptDx® and the Goldmann-Weekers. The AdaptDx® measurements were made using the default device settings listed in Section 4.2.3. The order of testing was counter balanced between the participants. The speed of dark adaptation was estimated using two parameters: the rod-cone break and the Rod Intercept. The rod-cone break is the time at which rods become more sensitive than cones and is characterized by the classic inflection point in the dark adaptation function. The Rod Intercept is the time at which visual sensitivity recovers to a criterion level (0.0074 scot mlx). For the AdaptDx®, the device automatically reports the Rod Intercept parameter, and the rod-cone break was estimated by hand. For the Goldmann-Weekers, both the rod-cone break and Rod Intercept parameters were estimated by hand.

Estimated rod-cone break and Rod Intercept values for each participant are listed in Table 6.2-1. The relationship between dark adaptation speeds as measured on both devices was tested by the Pearson correlation coefficient for each parameter.

- Rod-cone break parameters are significantly correlated between the AdaptDx® and Goldmann-Weekers adaptometer ($r = 0.71$, $p = 0.0132$). The relationship between the rod cone-break parameters measured by each machine is shown in Figure 6.2-1A.
- Rod intercept parameters are significantly correlated between the AdaptDx® and Goldmann-Weekers adaptometer ($r = 0.75$, $p = 0.008$). The relationship between the Rod Intercept parameters measured by each machine is shown in Figure 6.2-1B.

Thus, dark adaptation speed as measured by the AdaptDx® and Goldmann-Weekers Adaptometer is highly correlated. That is to say, those individuals with faster dark adaptation as measured on the AdaptDx® exhibit faster dark adaptation as measured on the Goldmann-Weekers, and conversely, patients with slower dark adaptation as measured on the AdaptDx® exhibit slower dark adaptation on the Goldmann-Weekers.

References

- 1 Jackson GR, Owsley C, Curcio CA. Photoreceptor degeneration and dysfunction in aging and age-related maculopathy. *Aging Res Rev* 2002;1(3):381-86

Table 6.2-1. Dark Adaptation Parameter Values

| Participant | Eye Health | AdaptDx® | | Goldmann-Weekers | |
|-------------|------------|--------------------------|-------------------------|--------------------------|-------------------------|
| | | Rod-Cone Break (minutes) | Rod Intercept (minutes) | Rod-Cone Break (minutes) | Rod Intercept (minutes) |
| 1 | normal | 5.8 | 8 | 8.4 | 12 |
| 2 | normal | 5.5 | 8.1 | 4.7 | 7.4 |
| 3 | normal | 4.5 | 6.9 | 9.5 | 15.7 |
| 4 | normal | 6.2 | 10.8 | 10.4 | 14.4 |
| 5 | normal | 6.8 | 9.5 | 12 | 14 |
| 6 | AMD | 11.2 | 15.6 | 17.5 | 20.6 |
| 7 | normal | 6.9 | 9.1 | 10.3 | 13.3 |
| 8 | AMD | none ¹ | none ¹ | none ¹ | none ¹ |
| 9 | normal | 5 | 8.1 | 10.5 | 12.6 |
| 10 | normal | 5.5 | 8.3 | 12.5 | 14.1 |
| 11 | AMD | 7.5 | 13.2 | 14.4 | 19.9 |
| 12 | DR | 5.2 | 7.8 | 12 | 14.5 |

¹Participant with late AMD exhibited minimal sensitivity recovery during dark adaptation measurements and had no identifiable rod cone break or Rod Intercept on the AdaptDx® or Goldmann-Weekers.

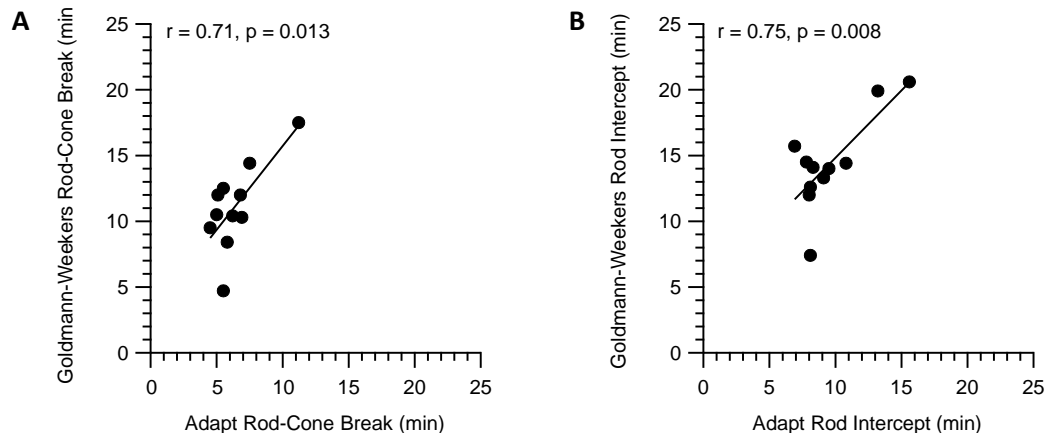


Figure 6.2-1. Dark adaptation speed measured on the AdaptDx® and the Goldmann-Weekers Adaptometer is highly correlated, whether estimated using the rod-cone break (A) or the Rod Intercept (B).

6.3 AdaptDx® Precision Study

The purpose of this study was to assess the measurement error (precision) of the AdaptDx® in participants with a broad range of dark adaptation speeds. The study sample consisted of 14 adults with normal retinal health (mean age = 47 years, range = 28 to 75 years) and 8 patients with age-related macular degeneration (mean age = 74 years, range 63 to 87 years). Normal adults are known to exhibit relatively rapid dark adaptation, whereas AMD patients are known to exhibit relatively slow dark adaptation [1].

Each participant's dark adaptation was measured twice with the AdaptDx®. The measurements were made using the default device settings listed in Section 4.2.3. The second dark adaptation measurement was made two weeks after the first measurement. The speed of each dark adaptation function was characterized by two parameters: the rod-cone break and the Rod Intercept. The rod-cone break is the time at which rods become more sensitive than cones and is characterized by the classic inflection point in the dark adaptation function. The Rod Intercept is the time at which visual sensitivity recovers to a criterion level (0.0074 scot mlx). The rod-cone break and the Rod Intercept were estimated using an unbiased modeling method [2]. Measurement error was calculated using a method based on within standard deviation, as described by Bland & Altman [3].

Representative dark adaptation curves for a participant with normal retinal health and a participant with AMD are shown in Figure 6.3-1. Estimated rod-cone break values and Rod Intercept values for each participant are listed in Table 6.3-1.

- Using the rod-cone break parameter, the measurement errors for the normal group, the AMD group and the combined study population were 1.2, 1.0 and 1.1 minutes, respectively. Overall, there was no relationship between the variability of the measurement as a function of the magnitude of the rod-cone break (Pearson $r = 0.02$, $p = 0.91$; Figure 6.3-2A), and the two rod-cone break estimates were highly correlated (Pearson $r = 0.83$, $p < 0.0001$; Figure 6.3-3A).
- Using the Rod Intercept parameter, the measurement errors for the normal group, the AMD group and the combined study population were 1.2, 0.9 and 1.1 minutes, respectively. Overall, the Rod Intercept measurement variability did not increase with the magnitude of the Rod Intercept (Pearson $r = 0.28$, $p = 0.21$; Figure 6.3-2B), and the two Rod Intercept estimates were highly correlated (Pearson $r = 0.89$, $p < 0.0001$; Figure 6.3-3B).

Thus, the AdaptDx® provides highly repeatable estimates of dark adaptation speed using either parameter. Furthermore, the rod cone break and Rod Intercept parameters are highly correlated with each other (Pearson $r = 0.89$, $p < 0.0001$ for first visit; Pearson $r = 0.82$, $p < 0.0001$ for second visit; Figure 6.3-4).

To put the AdaptDx® precision in perspective, we collected test-retest data on 6 normal adults with the Goldmann-Weekers Adaptometer. Rod-cone break and Rod Intercept values for each participant are listed in Table 6.3-2. Measurement error for the rod-cone break time was calculated to be 1.2 minutes. Measurement error for the Rod Intercept parameter was calculated to be 1.7 minutes. A summary comparison of the measurement errors for the two devices is shown in Table 6.3-3.

References

- 1 Jackson GR, Owsley C, Curcio CA. Photoreceptor degeneration and dysfunction in aging and age-related maculopathy. *Aging Res Rev* 2002;1(3):381-86
- 2 Jackson GR, Edwards JG. A short-duration dark adaptation protocol for the assessment of age-related maculopathy. *J Ocul Biol Dis Infor* 2008;1:7-11
- 3 Bland JM, Altman DG. Statistics Notes: Measurement error. *BMJ* 1996;313(7059):744

Table 6.3-1: Test-Retest Values for AdaptDx®

| Participant | Eye Health | Rod-Cone Break (minutes) | | Rod Intercept (minutes) | |
|-------------|------------|-----------------------------|--------|----------------------------|--------|
| | | Test 1 | Test 2 | Test 1 | Test 2 |
| 1 | normal | 5.31 | 5.86 | 8.65 | 9.28 |
| 2 | normal | 4.53 | 4.67 | 8.89 | 8.87 |
| 3 | normal | 4.23 | 4.51 | 9.78 | 9.63 |
| 4 | normal | 4.52 | 4.53 | 9.72 | 9.80 |
| 5 | normal | 5.48 | 4.52 | 6.27 | 6.39 |
| 6 | normal | 4.84 | 3.00 | 7.00 | 9.47 |
| 7 | normal | 4.32 | 6.20 | 8.62 | 9.18 |
| 8 | normal | 4.64 | 4.55 | 8.61 | 8.29 |
| 9 | normal | 5.95 | 6.05 | 12.76 | 11.29 |
| 10 | normal | 4.51 | 2.75 | 9.12 | 6.09 |
| 11 | normal | 3.43 | 3.13 | 8.22 | 6.72 |
| 12 | normal | 13.80 | 8.50 | 18.23 | 13.75 |
| 13 | AMD | 4.72 | 4.37 | 9.12 | 8.68 |
| 14 | normal | 7.51 | 7.00 | 11.48 | 11.15 |
| 15 | normal | 5.02 | 4.20 | 8.21 | 6.72 |
| 16 | AMD | 3.44 | 3.14 | 9.25 | 9.30 |
| 17 | AMD | 6.72 | 5.84 | 12.52 | 11.26 |
| 18 | AMD | 8.73 | 6.99 | 13.43 | 12.44 |
| 19 | AMD | 5.01 | 3.95 | 10.70 | 10.90 |
| 20 | AMD | 6.86 | 4.79 | 12.45 | 10.72 |
| 21 | AMD | 7.53 | 5.08 | 13.83 | 11.34 |
| 22 | AMD | 10.44 | 9.68 | 17.51 | 17.13 |

Table 6.3-2: Test-Retest Values for Goldmann-Weekers Adaptometer

| Participant | Eye Health | Rod-Cone Break (minutes) | | Rod Intercept (minutes) | |
|-------------|------------|-----------------------------|--------|----------------------------|--------|
| | | Test 1 | Test 2 | Test 1 | Test 2 |
| 1 | normal | 12.1 | 14.2 | 14.2 | 15.9 |
| 2 | normal | 9.5 | 11.1 | 12.5 | 13.5 |
| 3 | normal | 11.0 | 11.4 | 14.0 | 14.8 |
| 4 | normal | 8.5 | 9.0 | 12.0 | 12.5 |
| 5 | normal | 5.0 | 8.2 | 8.0 | 13.2 |
| 6 | normal | 9.7 | 9.5 | 16.0 | 14.2 |

Table 6.3-3: Comparison of AdaptDx® and Goldmann-Weekers Precision

| Device | Parameter | Measurement Error (minutes) | | |
|------------------|----------------|-----------------------------|--------------|----------|
| | | Normal Adults | AMD Patients | Combined |
| Adapt™ | Rod-Cone Break | 1.2 | 1.0 | 1.1 |
| | Rod Intercept | 1.2 | 0.9 | 1.1 |
| Goldmann-Weekers | Rod-Cone Break | 1.2 | NA | NA |
| | Rod Intercept | 1.7 | NA | NA |

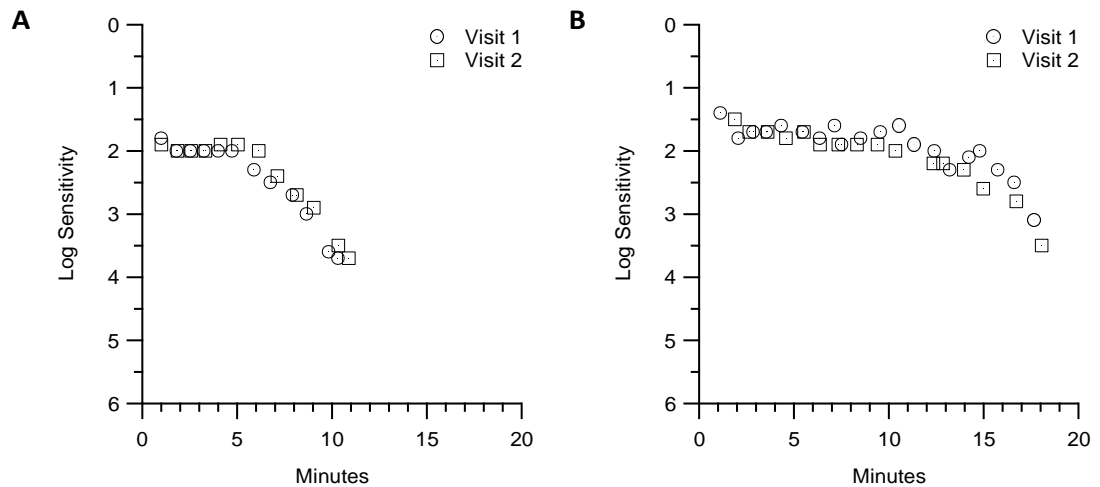


Figure 6.3-1: Dark adaptation curves for a participant with normal retinal health (A) and a participant with AMD (B) measured on the AdaptDx®. Visit 1 and Visit 2 occurred on separate days.

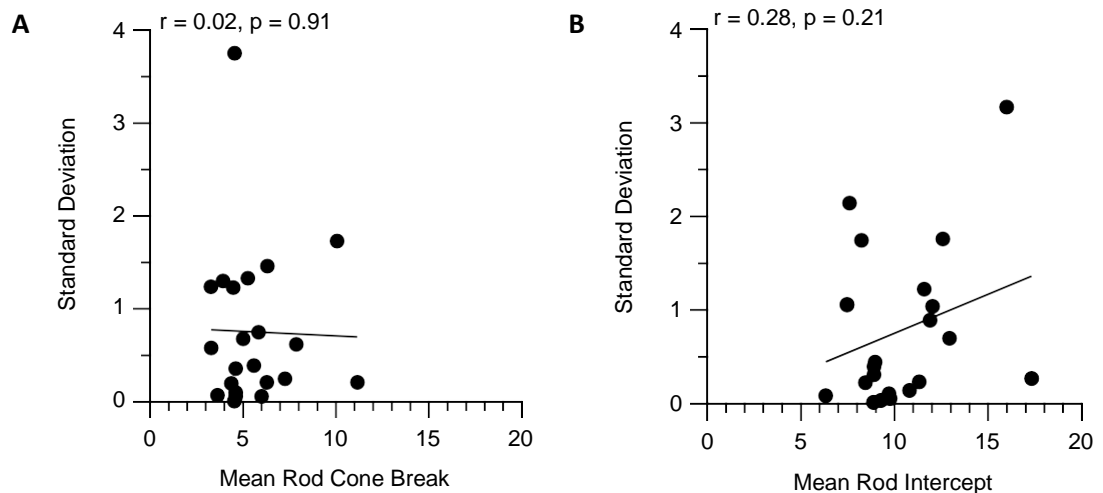


Figure 6.3-2: Plots of within standard deviation as a function of rod-cone break estimates (A) and Rod Intercept estimates (B) measured on the AdaptDx®. There was no relationship between the magnitude and the variability of the measurements.

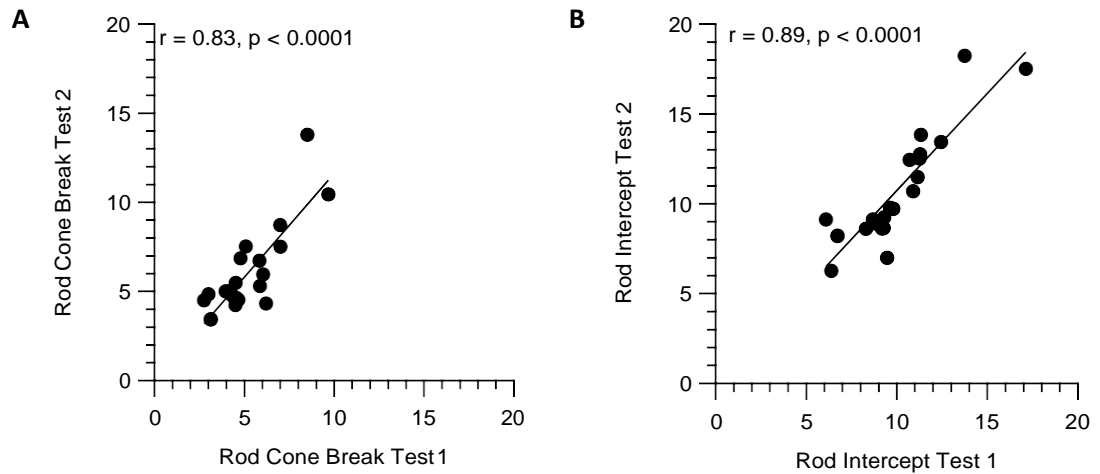


Figure 6.3-3: Scatter plots of dark adaptation parameters measured on the AdaptDx®. Rod-cone break estimates (A) and Rod Intercept estimates (B) were highly correlated between the first and second visits.

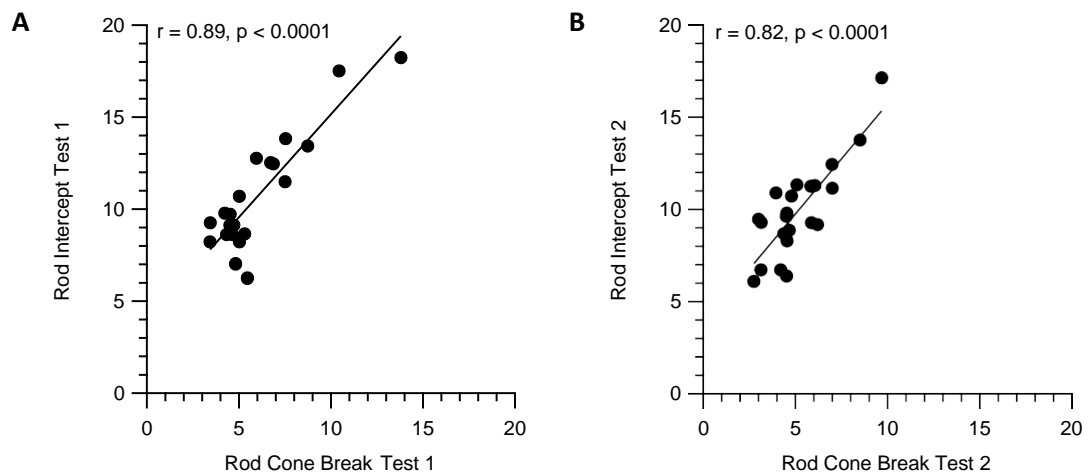


Figure 6.3-4: Rod-cone break and Rod Intercept estimates measured on the AdaptDx® are highly correlated within the first visit (A) and second visit (B).

7 Maintenance, Cleaning & Disposal

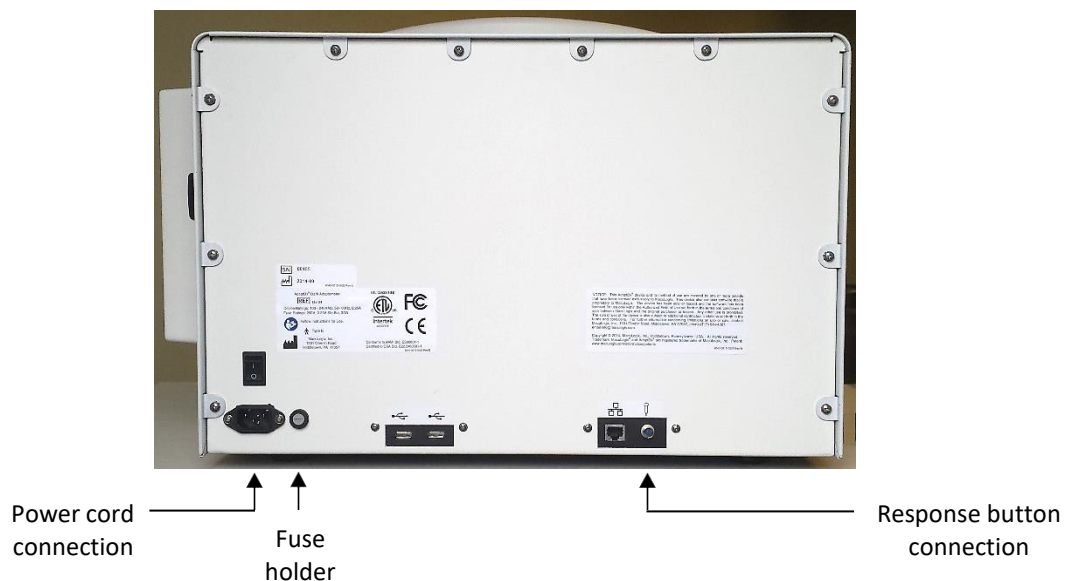
7.1 Maintenance

MacuLogix provides return-to-factory service for the AdaptDx®. Contact MacuLogix at 717-914-4067 Monday through Friday between 9:00 AM and 5:00 PM US Eastern time if you encounter any problems requiring maintenance.

IMPORTANT: Before returning the AdaptDx® to the factory, back up the database using the Back Up/Restore Data tool (see Section 5.3.1).

The only maintenance activities that should be performed by the operator are replacement, if necessary, of the Response Button, Power Cord, or Fuse.

Back of AdaptDx®



- To replace the Response Button, plug the new Response Button cord into the jack receptacle on the back of the AdaptDx® (labeled “response button connection” in the picture above). Use only a Response Button supplied by MacuLogix.
- To replace the Power Cord, plug one end of the new Power Cord into the power cord receptacle on the back of the AdaptDx® (labeled “power cord connection” in the picture above) and the other end into a standard, three-prong, grounded electrical outlet. The shape of the Power Cord plugs allows only one cord orientation. Use only a medical grade Power Cord.
- To replace the Fuse, unscrew the Fuse holder on the back of the AdaptDx® (labeled “fuse holder” in the picture above), place a new Fuse in the holder, and screw the holder back into the AdaptDx®. Use only a Fuse rated 250V, 2.25A, Slo-Blo 3AG. If frequent replacement of the Fuse is necessary, contact MacuLogix at 717-914-4067 Monday through Friday between 9:00 AM and 5:00 PM US Eastern time.

7.2 Cleaning

The only routine cleaning required is regular swabbing of the patient contact points and periodic cleaning of the touch screen.

- The patient contact points (chin rest, forehead rest, and response button) should be swabbed between each patient. Any conventional cleaner can be used, such as alcohol wipes, disinfectant, or soap and water. However, the response button should not be immersed in a cleaning solution.
- The touch screen should be cleaned as necessary using a soft cloth or tissue about four layers thick folded into a cleaning pad approximately 10 cm x 10 cm. Moisten the cleaning pad with isopropyl alcohol and wipe slowly from the center of the touch screen to the edge. Do not apply the isopropyl alcohol or any other solvent directly to the touch screen. Do not wipe a dry cleaning pad or other cloth across the touch screen. These actions can damage the surface.

7.3 Disposal

The AdaptDx® includes electronics, display screens and other components that may release toxic materials into the environment with improper disposal. Disposal of the AdaptDx® should be in accordance with applicable state and local law for disposal of electronic equipment. See the separate printer manual, if applicable, for additional information on disposal.

8 Electrical Safety & Electromagnetic Compatibility

8.1 AdaptDx® IEC 60601-1 Classifications

- Class I (type of protection against electrical shock)
- Type B (degree of protection against electrical shock)
- Ordinary IPX0 (degree of protection against ingress of water)
- Not sterile
- Not suitable for use in the presence of a flammable anesthetics mixture with air or with oxygen or with nitrous oxide
- Continuous mode of operation

8.2 Electrical Safety

The AdaptDx® and all of its accessories are suitable for use in a patient environment. The chin rest, forehead rest, and response button are applied parts that contact the patient.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: No modification of this equipment is allowed.

WARNING: Do not attempt to remove any of the AdaptDx® covers or modify the system in any way. Only an authorized AdaptDx® service technician should perform repairs or make modifications to the system. Removing covers or modifying the system could result in electrical shock or other safety hazards.

WARNING: Do not simultaneously touch the patient and any part of the AdaptDx® while a cover is removed or a cable is unplugged. This could result in electrical shock.

The AdaptDx® should be located such that the Power Cord connection to the supply mains remains accessible at all times.

Do not place any container holding liquid near the AdaptDx®.

8.3 Electromagnetic Compatibility (EMC)

The AdaptDx® needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided herein.


Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING: The use of accessories, transducers or cables with the AdaptDx® other than those specified may result in increased emissions or decreased immunity of the AdaptDx®.

WARNING: The AdaptDx® should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|------------|--|
| The AdaptDx® is intended for use in the electromagnetic environment specified below. The customer or the user of the AdaptDx® should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF Emissions CISPR 11 | Group 1 | The AdaptDx® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR 11 | Class A | |
| Harmonic Emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | The AdaptDx® is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|--|
| The AdaptDx® is intended for use in the electromagnetic environment specified below. The customer or the user of the AdaptDx® should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±6 kV contact ±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines ±1 kV for input/output lines | ±2 kV for power supply lines ±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | ±1 kV differential mode ±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% U_T dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec | <5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% U_T dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the AdaptDx® requires continued operation during power mains interruptions, it is recommended that the AdaptDx® be powered from an uninterruptible power supply or battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE U_T is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|--|--|-------------------------|--|
| The AdaptDx® is intended for use in the electromagnetic environment specified below. The customer or the user of the AdaptDx® should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p> | <p>3 V</p> <p>3 V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the AdaptDx®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.33\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p> |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. | | | |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| <p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AdaptDx® is used exceeds the applicable RF compliance level above, the AdaptDx® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AdaptDx®.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> | | | |

| Recommended separation distances between portable and mobile RF communication equipment and the AdaptDx® | | | |
|--|--|--------------------|--------------------|
| The AdaptDx® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AdaptDx® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AdaptDx® as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
| | 150 kHz to 80 MHz | 150 kHz to 80 MHz | 150 kHz to 80 MHz |
| | $d = 1.17\sqrt{P}$ | $d = 1.17\sqrt{P}$ | $d = 2.33\sqrt{P}$ |
| 0,01 | 0.12 | 0.12 | 0.23 |
| 0,1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.33 |
| 10 | 3.70 | 3.70 | 7.37 |
| 100 | 11.70 | 11.70 | 23.30 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. | | | |
| NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. | | | |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people. | | | |

Appendix A: XML File Formats

A.1 XML Test Report

When “Print to XML” is selected as the print destination (see Section 5.2.3) and the Print to XML button is touched on a screen displaying a test report, an XML file containing the test report data elements is copied onto an attached USB drive. The XML file is named “AdaptDx <Last Name>,<First Name> <MM-DD-YYYY><hhmm>.xml”, where <MM-DD-YYYY><hhmm>” is the date and time of the test included in the report. If two test reports are selected, the data elements for both are placed in the same XML file and the time stamp is the date and time of the most recent test referenced in the report.

A.1.1 XML Test Report File Example

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- MacuLogix Test Report(s) Export -->
<MacuLogixTestReport>
  <LimitedLicenseWarning>
    Terms of use prohibit use of this data for clinical studies intended to provide a definitive assessment of therapeutic efficacy.
  </LimitedLicenseWarning>
  <ClinicInfo>
    <clinic_name>Demo System</clinic_name>
    <clinic_address1>1801 Oberlin Road</clinic_address1>
    <clinic_address2>Suite 301</clinic_address2>
    <clinic_city>Middletown</clinic_city>
    <clinic_state>PA</clinic_state>
    <clinic_zip>17057</clinic_zip>
    <clinic_phone>717-914-4067</clinic_phone>
    <clinic_email>info@maculogix.com</clinic_email>
  </ClinicInfo>
  <Patient>
    <last_name>Doe</last_name>
    <first_name>Jane</first_name>
    <middle_name>X.</middle_name>
    <sex>F</sex>
    <date_of_birth>01-01-1948</date_of_birth>
    <age_at_test>64</age_at_test>
    <patient_identifier>GHL2009</patient_identifier>
  <Test>
    <test_eye>left</test_eye>
    <test_date>12-15-2012</test_date>
    <test_time>11:30</test_time>
    <protocol_name>Rapid Test</protocol_name>
    <pupil_size_mm>6.5</pupil_size_mm>
    <prescription_spherical>+1.0</prescription_spherical>
    <prescription_cylindrical>+3.0</prescription_cylindrical>
    <prescription_axis>45</prescription_axis>
    <trial_lens_spherical>+4.0</trial_lens_spherical>
    <trial_lens_cylindrical>+3.0</trial_lens_cylindrical>
    <trial_lens_axis>45</trial_lens_axis>
  <Threshold>
    <threshold_time_minutes>0.56</threshold_time_minutes>
    <threshold_value>2.3</threshold_value>
    <threshold_validity>true</threshold_validity>
  </Threshold>
```

```

<Threshold>
  <threshold_time_minutes>1.29</threshold_time_minutes>
  <threshold_value>2.3</threshold_value>
  <threshold_validity>true</threshold_validity>
</Threshold>
<Threshold>
  <threshold_time_minutes>1.90</threshold_time_minutes>
  <threshold_value>2.4</threshold_value>
  <threshold_validity>true</threshold_validity>
</Threshold>
<Threshold>
  <threshold_time_minutes>2.61</threshold_time_minutes>
  <threshold_value>2.7</threshold_value>
  <threshold_validity>true</threshold_validity>
</Threshold>
<Threshold>
  <threshold_time_minutes>5.35</threshold_time_minutes>
  <threshold_value>3.6</threshold_value>
  <threshold_validity>true</threshold_validity>
</Threshold>
<rod_intercept_minutes>3.45</rod_intercept_minutes>
<fixation_error_rate>0.0000</fixation_error_rate>
<rod_intercept_message>Rod Intercept is 3.45.</rod_intercept_message>
<fixation_error_message>Fixation Error Rate is 0%.</fixation_error_message>
<bleach_error_message></bleach_error_message>
<main_graph_diagnostic_message></main_graph_diagnostic_message>
<operator_comment>Took test well </operator_comment>
</Test>
</Patient>
</MacuLogixTestReport>

```

A.1.2 XML Test Report Data Element Descriptions

| Element/Tag Name | Description |
|---------------------------------|--|
| <MacuLogixTestReport> | Beginning of test report |
| <LimitedLicenseWarning> | Contains the limited license warning message |
| <ClinicInfo> | Clinic information section |
| <clinic_name> | Clinic name |
| <clinic_address1> | Line 1 of the clinic address |
| <clinic_address2> | Line 2 of the clinic address |
| <clinic_city> | Clinic city |
| <clinic_state> | Clinic state |
| <clinic_zip> | Clinic zip code |
| <clinic_phone> | Clinic phone number |
| <clinic_email> | Clinic contact email |
| <Patient> | Patient information section |
| <last_name> | Patient last name |
| <first_name> | Patient first name |
| <middle_name> | Patient middle name |
| <Sex> | Patient sex (M = male, F = female) |
| <date_of_birth> | Patient date of birth (MM-DD-YYYY) |
| <age_at_test> | Patient age at test date in years |
| <patient_identifier> | Patient medical identifier |
| <Test> | Test information section (will be repeated for multiple tests) |
| <test_eye> | Test eye (right or left) |
| <test_date> | Test date (MM-DD-YYYY) |
| <test_time> | Test time (HH:MM, 24-hour format) |
| <protocol_name> | Test protocol name |
| <pupil_size_mm> | Pupil size in millimeters (2.0 to 10.0, required) |
| <prescription_spherical> | Prescription spherical correction (-19.0 to +13.0, optional) |
| <prescription_cylindrical> | Prescription cylindrical correction (-5.0 to +5.0, optional) |
| <prescription_axis> | Prescription axis correction (0° to 180°, optional) |
| <trial_lens_spherical> | Trial lens spherical correction (-16.0 to +16.0, optional) |
| <trial_lens_cylindrical> | Trial lens cylindrical correction (+1.5 to +5.0, optional) |
| <trial_lens_axis> | Trial lens axis correction (0° to 180°, optional) |
| <Threshold> | Threshold information section (will be repeated for multiple thresholds, or absent for no thresholds) |
| <threshold_time_minutes> | Threshold time in minutes |
| <threshold_value> | Threshold value in log-units |
| <threshold_validity> | Threshold validity (true or false) |
| <rod_intercept_minutes> | Rod Intercept time in minutes |
| <fixation_error_rate> | Fixation Error Rate percentage (0 – 100) |
| <rod_intercept_message> | Rod Intercept message |
| <fixation_error_message> | Fixation Error Rate message |
| <bleach_error_message> | Bleaching Error message if present |
| <main_graph_diagnostic_message> | Operator termination message if present |
| <operator_comment> | Operator comment (optional) |

A.2 XML History Report

When “Print to XML” is selected as the print destination (see Section 5.2.3) and the Print to XML button is touched on the View Patient History screen, an XML file containing the history report data elements is copied onto an attached USB drive. The XML file is named “AdaptDx <Last Name>,<First Name><MM-DD-YYYY><hhmm> History.xml”, where <MM-DD-YYYY><hhmm>” is the date and time of the most recent test included in the history report.

A.2.1 XML History Report File Example

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- MacuLogix History Report Export -->
<MacuLogixHistoryReport>
  <LimitedLicenseWarning>
    Terms of use prohibit use of this data for clinical studies intended to provide a definitive assessment of therapeutic efficacy.
  </LimitedLicenseWarning>
  <ClinicInfo>
    <clinic_name>Demo System</clinic_name>
    <clinic_address1>1801 Oberlin Road</clinic_address1>
    <clinic_address2>Suite 301</clinic_address2>
    <clinic_city>Middletown</clinic_city>
    <clinic_state>PA</clinic_state>
    <clinic_zip>17057</clinic_zip>
    <clinic_phone>717-914-4067</clinic_phone>
    <clinic_email>info@maculogix.com</clinic_email>
  </ClinicInfo>
  <Patient>
    <last_name>Doe</last_name>
    <first_name>Jane</first_name>
    <middle_name>X</middle_name>
    <sex>M</sex>
    <date_of_birth>01-01-1948</date_of_birth>
    <patient_identifier> GHL2009</patient_identifier>
    <TestHistory>
      <protocol_name>Rapid Test</protocol_name>
      <RightEye>
        <Test>
          <test_date>05-01-2012</test_date>
          <test_time>15:40</test_time>
          <test_duration_minutes>6.00</test_duration_minutes>
          <test_validity>>false</test_validity>
          <rod_intercept_minutes>5.50</rod_intercept_minutes>
        </Test>
        <Test>
          <test_date>05-01-2013</test_date>
          <test_time>15:47</test_time>
          <test_duration_minutes>6.10</test_duration_minutes>
          <test_validity>>true</test_validity>
          <rod_intercept_minutes>5.55</rod_intercept_minutes>
        </Test>
        <Test>
          <test_date>05-01-2014</test_date>
          <test_time>15:57</test_time>
          <test_duration_minutes>6.00</test_duration_minutes>
          <test_validity>>true</test_validity>
        </Test>
      </RightEye>
    </TestHistory>
  </Patient>
</MacuLogixHistoryReport>
```

```
<rod_intercept_minutes>5.10</rod_intercept_minutes>
</Test>
</RightEye>
<LeftEye>
<Test>
<test_date>05-01-2012</test_date>
<test_time>15:42</test_time>
<test_duration_minutes>5.00</test_duration_minutes>
<test_validity>false</test_validity>
<rod_intercept_minutes>4.50</rod_intercept_minutes>
</Test>
<Test>
<test_date>05-01-2013</test_date>
<test_time>15:52</test_time>
<test_duration_minutes>5.20</test_duration_minutes>
<test_validity>true</test_validity>
<rod_intercept_minutes>4.25</rod_intercept_minutes>
</Test>
</LeftEye>
</TestHistory>
</Patient>
</MacuLogixHistoryReport>
```


A.2.2 XML History Report Data Element Descriptions

| Element/Tag Name | Description |
|------------------------------|--|
| <MacuLogixHistoryReport> | Beginning of history report |
| <LimitedLicenseWarning> | Contains the limited license warning message |
| <ClinicInfo> | Clinic information section |
| <clinic_name> | Clinic name |
| <clinic_address1> | Line 1 of the clinic address |
| <clinic_address2> | Line 2 of the clinic address |
| <clinic_city> | Clinic city |
| <clinic_state> | Clinic state |
| <clinic_zip> | Clinic zip code |
| <clinic_phone> | Clinic phone number |
| <clinic_email> | Clinic contact email |
| <Patient> | Patient information section |
| <last_name> | Patient last name |
| <first_name> | Patient first name |
| <middle_name> | Patient middle name |
| <sex> | Patient sex (M = male, F = female) |
| <date_of_birth> | Patient date of birth (MM-DD-YYYY) |
| <patient_identifier> | Patient medical identifier |
| <TestHistory> | History information section |
| <protocol_name> | Test protocol name |
| <RightEye> | Right eye test(s) section |
| <Test> | Test(s) information (will be repeated for multiple tests, or absent for no tests) |
| <test_date> | Test date (MM-DD-YYYY) |
| <test_time> | Test time (HH:MM, 24-hour format) |
| <threshold_duration_minutes> | Test duration in minutes |
| <test_validity> | Test validity (true or false) |
| <rod_intercept_minutes> | Rod Intercept time in minutes |
| <LeftEye> | Left eye test(s) section |
| <Test> | Test(s) information (will be repeated for multiple tests, or absent for no tests) |
| <test_date> | Test date (MM-DD-YYYY) |
| <test_time> | Test time (HH:MM, 24-hour format) |
| <threshold_duration_minutes> | Test duration in minutes |
| <test_validity> | Test validity (true or false) |
| <rod_intercept_minutes> | Rod Intercept time in minutes |