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# IRIS USER MANUAL

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<b>Manual Information</b>		
Date of release:	June 28, 2014	
Revision number:	1.0	
Reference software version:	1.0	
Service provider:	Intelligent Retinal Imaging Systems, LLC Pensacola, FL 32501 Tel. +1 888-535-2574	

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# 1. Introduction

Caution: Federal law restricts this device to sale by or on the order of a physician.

## 1.1 Indications for Use

The IRIS Intelligent Retinal Imaging Systems is a comprehensive web-based software system application intended for use in storing, managing, and displaying patient data, diagnostic data and images from computerized diagnostic instruments or systems. Original and enhanced images can be viewed by trained healthcare professionals for use in analysis of images and data.

## 1.2 About Iris Intelligent Retinal Imaging Solutions

**Imaging** Iris operates by using images exported from a fully automated non-mydriatic fundus camera. The intention is to allow endocrinologists, hospitalists, general practitioners, community health clinics and others to directly serve a growing population of diabetics in need of regular screenings.

**Enhancement Technology** The Iris service automatically enhances the contrast of the image without changing its geometry with better visualization of small objects resulting in higher sensitivity.

**Tele-Medicine Grading & Reporting** Iris uses a simple and powerful web-based platform that requires only an Internet connection and no software expertise. The Iris integrated grading module follows the American Academy of Ophthalmology (AAO) classification criteria, allowing real-time reading and classification of the image. The functions include: ability to add comments, ability to remotely interact with a specialist, production and printing of reports, interfacing with Electronic Medical Record (EMR) systems, secure access management, multiple accounts and multi-user-graders.

The platform also allows any healthcare professional to generate a detailed patient report that can then be printed or e-mailed for easy referral to a specialist. This report includes:

- Client information
- Normal image vs. Enhanced image
- Iris findings & conclusions
- Grader findings & conclusions

**Compliance** Iris is HIPPA compliant.

**Please Note:** The clinical interpretation of images enhanced by Iris software is restricted to licensed eye care practitioners. The process of making a diagnosis using enhanced images is the responsibility of the eye care practitioner. Only a licensed ophthalmologist can provide feedback based on their interpretation of the image.

## 2 System Requirements

### 2.1 Camera Compatibility

Iris software is compatible with any FDA cleared non-mydratic fundus camera.

### 2.2 Internet Browser Compatibility

Iris software is compatible with modern versions of browsers that support CSS/JavaScript and HTML5. It is best viewed with the following Internet browsers:

- Google Chrome (versions 5 - latest )
- Google Chrome for Mac (latest version)
- Google Chrome for iPad
- Microsoft Internet Explorer (versions 6 – 11; 9 is excluded)
- Mozilla Firefox (versions 2 - latest )
- Safari
- Safari for Mac version
- Safari for iPad
- Opera (versions 10 - recent)

## 3 Importing Images to Iris

Iris software automatically imports Digital Imaging and Communications in Medicine (DICOM) images from a network shared folder. The method used to initially export these images from your fundus camera to the network shared folder will vary depending on the model of camera. Please consult your camera's user manual for instructions regarding the exportation of DICOM images from your automated fundus camera to a network shared folder.

## 4 Definitions

**Interface or Dashboard** - The visible portion of the web-based software (terms used interchangeably)

**Grader** – The licensed retina specialist or ophthalmologist who analyzes the fundus photos

**Technician** – The individual working in the physician's office who takes the fundus photo of the patient's retina

**OD** – Oculus Dexter or right eye

**OS** – Oculus Sinister or left eye

**OU** - Oculus Uterque or both eyes

**Patient Order** – The eye images received for one patient

## 5 User Classification

There are two classifications of software users:

### 5.1 Technicians

Technicians are responsible for taking fundus photos. These users have access only to the client dashboard.

### 5.2 Graders

Graders are the physicians who read and grade the images exported to the Iris dashboard each day. These individuals are licensed retina specialists or ophthalmologists. Graders have access to both the client dashboard and the grading.

## 6 Accessing the Iris Interface

The only prerequisites for accessing the Iris software are a user account and access to a client record. Images and orders stored within the IRIS interface can be viewed on the Internet anywhere a browser can be connected to the Internet.

Please note: Order reconciliation and grading should be performed in a quiet environment, free of distraction.

- Open the internet browser on the desktop or laptop computer<sup>1</sup> (Google Chrome is the preferred browser).
- Enter <https://app.retinalscreenings.com> into the address bar of the browser.
- Enter your Iris username in the Username field on the Iris Login screen (see Figure 1).
- Enter the password provided to you by Iris in the Password field.
- Click **Login**.
- If an invalid username or password is entered, an error message will be displayed directing the user to reenter their login credentials.

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<sup>1</sup> Not provided by Iris

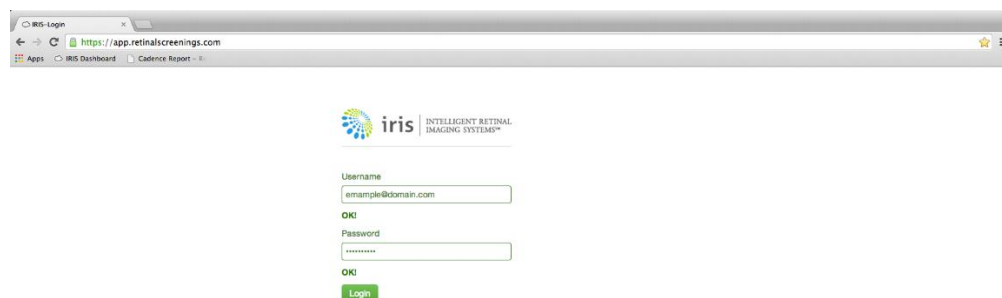


Figure 1 - View of Login Prompt

## 7 Using the Iris Web Based Interface

### 7.1 Diabetic Retinopathy Analysis

#### 7.1.1 Technicians

Once you have logged into the interface you will have access to the Iris dashboard (see Figure 2). This is a central location on the interface that allows users to reconcile the number of visiting patients, review images, and communicate notes to graders.



Figure 2 – Technician's Interface Home Page

## 7.1.2 View Orders

On the dashboard, orders that are ungraded and unsigned can be viewed in the following way:

- Select a location/clinic from the dropdown menu.
- Upon selecting the location/clinic, orders may be viewed using two populating methods:
  - Click the **Get All Orders** button to populate all orders that are ungraded and unsigned.
  - Click the **Get Today's Orders** button to populate only ungraded and unsigned orders for that calendar day.
  - Orders will be displayed accordingly as shown in Figure 3.
- Click on the View Images button next to a patient name to view the retinal images associated with that patient.

	Patient	Order Date/Time	Images
<a href="#">View Images</a> <a href="#">Add Note</a>	TEST, EPREScribing MRN: 016001946 DOB: 05-15-1955 Gender: M	Friday, February 21, 2014 3:09 PM	Laterality Right Eye ✓ Left Eye ✓ Left Eye Enhanced ✓ Right Eye Enhanced ✓
<a href="#">View Images</a> <a href="#">Add Note</a>	TEST, EPREScribing MRN: 016001946 DOB: 05-15-1955 Gender: M	Friday, February 21, 2014 3:09 PM	Laterality Right Eye ✓ Left Eye ✓ Left Eye Enhanced ✓ Right Eye Enhanced ✓
<a href="#">View Images</a> <a href="#">Add Note</a>	TEST, EPREScribing MRN: 016001946 DOB: 05-15-1955 Gender: M	Friday, February 21, 2014 3:09 PM	Laterality Right Eye ✓ Left Eye ✓ Left Eye Enhanced ✓ Right Eye ✓

Figure 3 – Technician home page showing all ungraded and unsigned orders on the Iris web interface

### 7.1.2.1 View the Images

To view a patient's fundus photos on the interface:

- On the client/location home page, click **View Images** on the respective patient order.
- Click the photo that needs to be reviewed. The window defaults to displaying right eye photo and enhanced image. The left eye photo and enhanced image can be displayed by clicking the **Left Eye** link below the right eye photo set (see Figure 4).
- To see the enlarged image click on the respective photo (see Figure 5).
- To zoom in on the image, move your cursor onto the image. The zoom feature is automatic (see Figure 6).
- To close the windows, click the X in the top right corner of the window or press the ESC key on the keyboard.

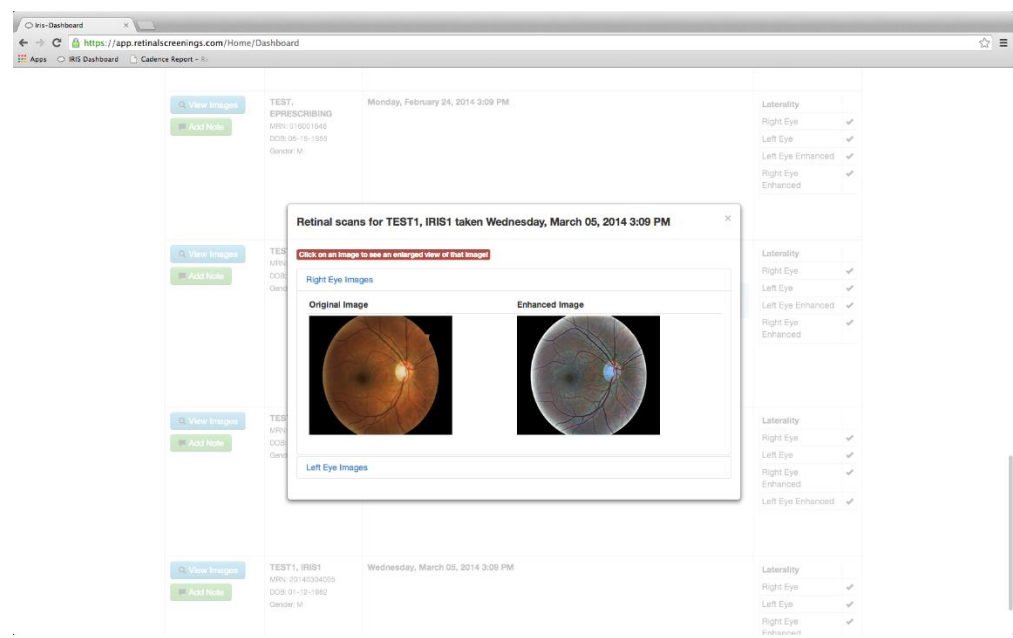


Figure 4 - Viewing right eye photos

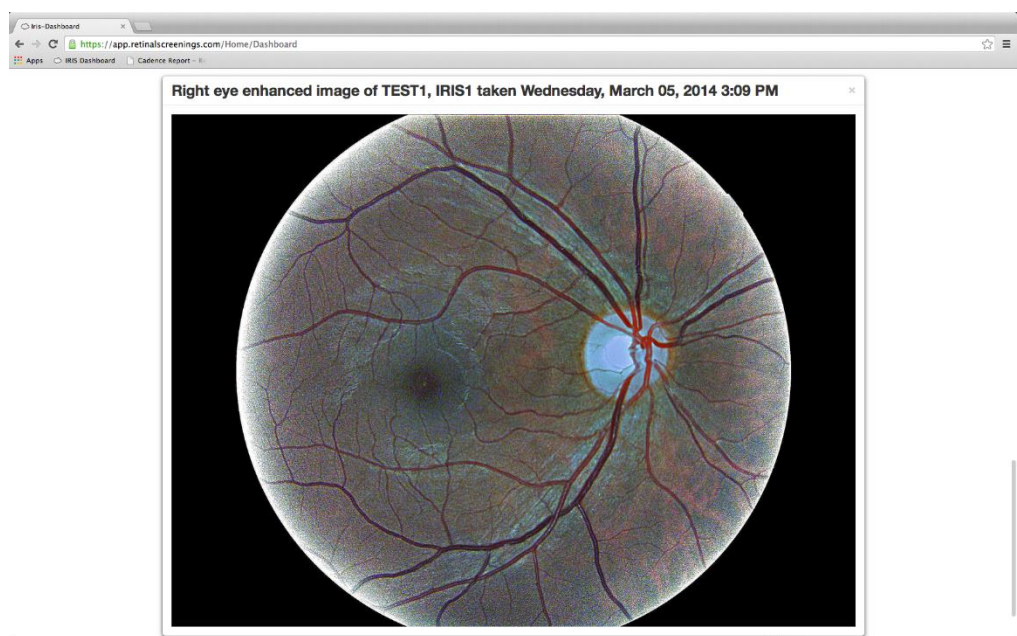


Figure 5 - Viewing enlarged enhanced image of right eye



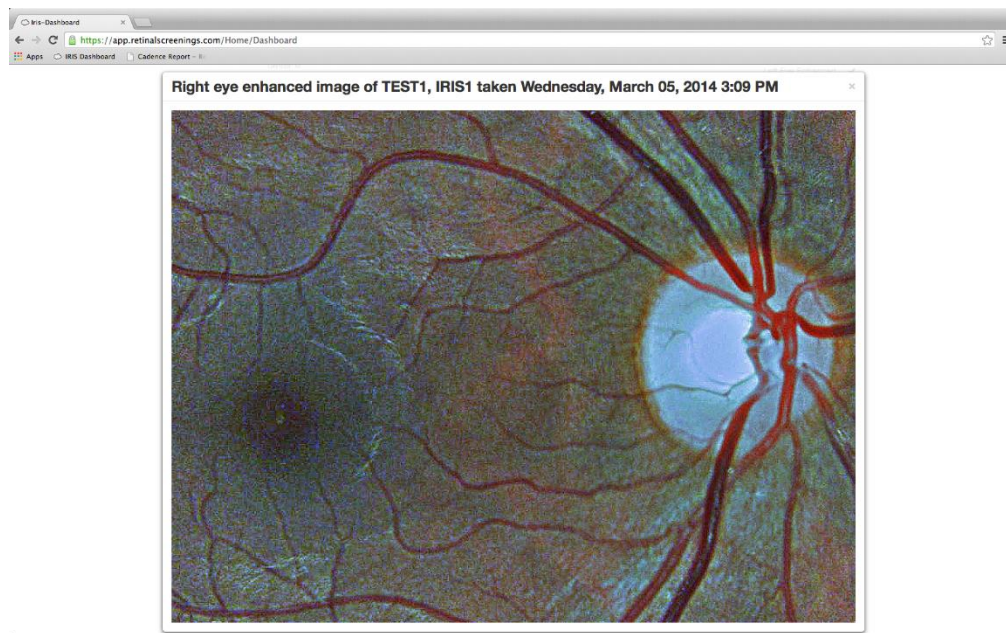


Figure 6 - Zoomed in view of enhanced right eye image

### 7.1.2.2 *Communicate Notes for Graders*

On occasion, circumstances prevent a perfect fundus photo from being captured. For example, a photo of the retina is not possible with a patient who has a glass eye. In cases such as this, the grader would not want to count that photo as un-gradable and refer the patient for a full eye exam.

To assist the grader in making the appropriate recommendation, a note can be added to the record by following the steps below:

- Log into the Iris Interface.
- View the desired orders as described above.
- Click the **green Add Note** button next to the appropriate patient name.
- Enter the pertinent note in the Note box. A note for the above-proposed scenario might be "OD is prosthetic. OK to grade" (see Figure 7).
- Click **Save** to attach the note to the order (see Figure 8).
  - Clicking **Cancel** will close the window and any comment will be deleted.

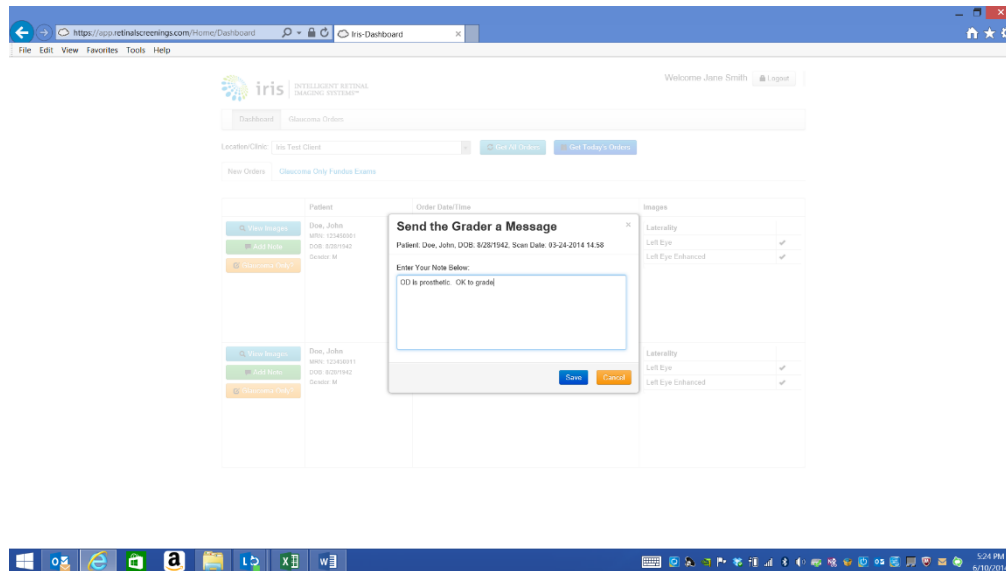


Figure 7 - 'Send the Grader a Message' Window

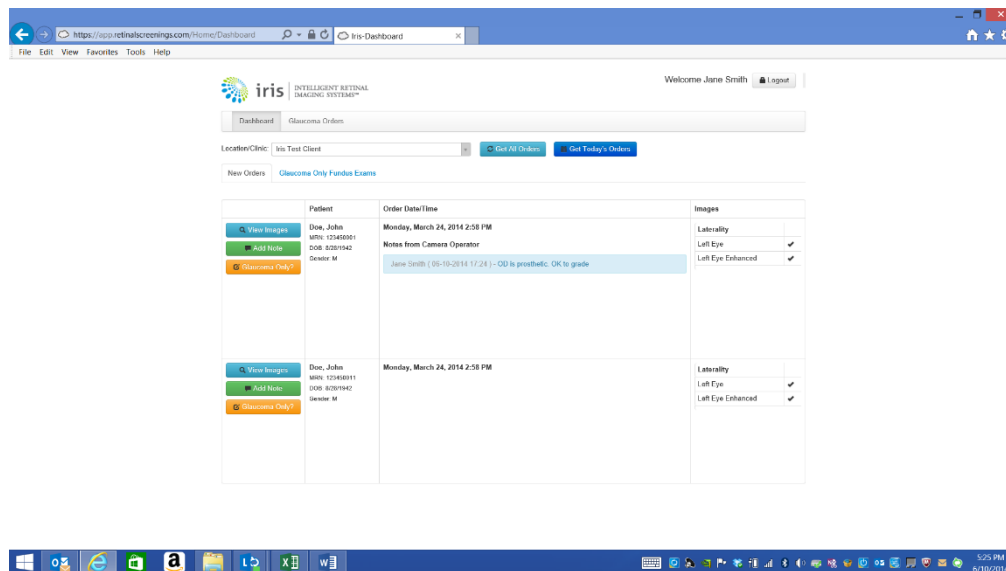


Figure 8 - Ungraded orders home page showing user's note for grader

## 7.1.3 Graders

Similar to the home page provided to Technicians, once a Grader has logged into the interface, the Iris dashboard will be displayed, but with an additional tab for grading orders (see Figure 9). This is a central location on the interface that allows Graders to review images, grade, and sign results.

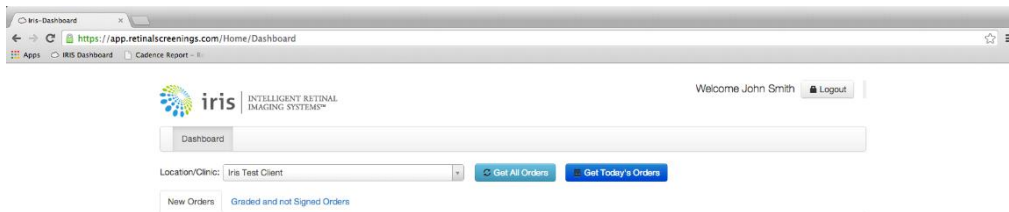


Figure 9 - Grader's Interface Home Page Viewing Orders

### 7.1.3.1 View Orders

On the dashboard, orders that are ungraded and unsigned can be viewed:

- Select a location/clinic from the dropdown menu.
- Upon selecting the location/clinic, orders may be viewed using two populating methods:
  - Click the **teal Get All Orders** button to populate all orders that are ungraded and unsigned.
  - Click the **blue Get Today's Orders** button to populate only ungraded and unsigned orders for that calendar day.
  - Orders will be displayed accordingly as shown in Figure 10.
- Click on the View Images button next to a patient name to view the retinal images associated with that patient and follow the directions as described in Section 7.1.1.1.2.

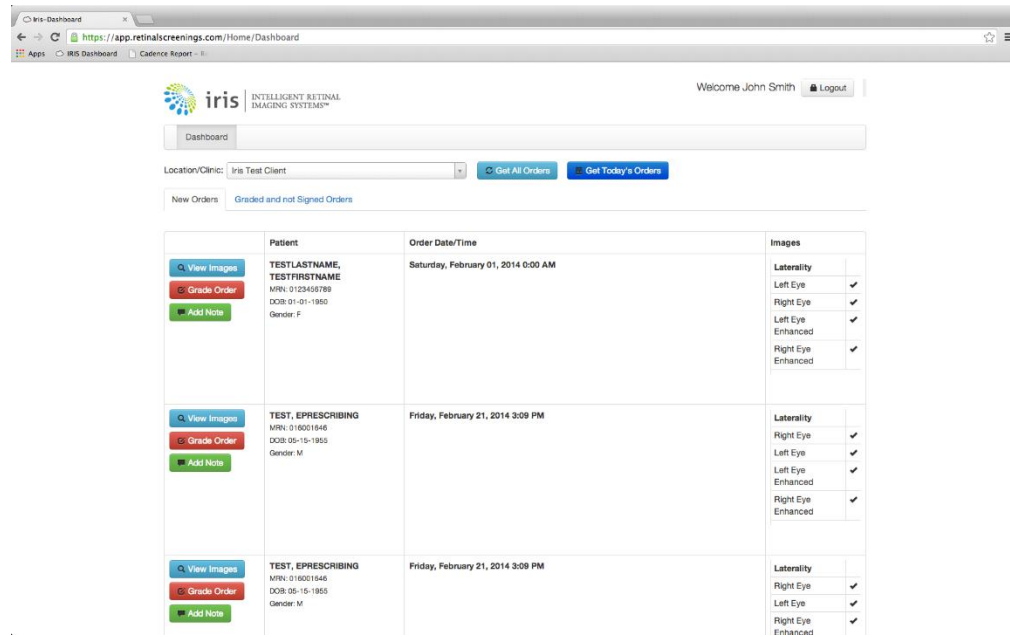


Figure 10 – Grader’s populated Iris interface home page

## 7.1.3.2 Grade the Orders

Only a certified, licensed practitioner is allowed to grade physician orders. Therefore, access to this level of the Iris interface is restricted to those users with a role of Grader.

- Log into the Iris dashboard.
- Select the Location/Clinic.
- Click the teal **Get All Orders** button or the blue **Get Today's Orders** to populate the ungraded orders.
- Click the red **Grade Order** button next to the desired patient record to open the grading window.

### 7.1.3.2.1 Right Eye Grading

When the grading window is opened, the default shows both the original and enhanced right eye images first. Grade the right eye first using the buttons on the left-hand side.

- Click on the image to enlarge it.
- If no pathology is detected, click the green **Normal OD** button.
- If the image is not gradable, click the red **Ungradable** button.
- If pathology is detected, select the type of pathology by following the steps below. The severity level buttons will turn blue to indicate what has been selected.

#### 7.1.3.2.1.1 Diabetic Retinopathy

If diabetic retinopathy is found:

- Click **Right Eye Diabetic Retinopathy**.
- Click the observed severity of the pathology using the dropdown buttons (see Figure 11):
  - None
  - Mild
  - Moderate
  - Severe
  - Proliferative

### 7.1.3.2.1.2 Macular Edema

If macular edema is found:

- Click **Right Eye Macular Edema**.
- Click the observed level of pathology using the dropdown buttons (see Figure 12):
  - None
  - Mild
  - Moderate
  - Severe

### 7.1.3.2.1.3 Other Pathology

If another pathology is detected in the right eye:

- Click Other OD.
- Select the suspected other pathology from the buttons (see Figure 13):
  - Glaucoma
  - Dry MD
  - Wet MD
  - Vein Occlusion
  - HTN Retinopathy
  - Epiretinal Membrane
  - Macular Hole
  - Cataract
  - Other

The screenshot displays the Iris Dashboard interface for grading the right eye (OD). The top navigation bar shows the user is logged in as John Smith. The main content area is divided into several sections:

- Patient Information:** A table with fields for Name, Birth Date, Gender, and Mm. The values are TESTLASTNAME, TESTFIRSTNAME, 01-01-1950, F, and 0123456789.
- Right Eye Diabetic Retinopathy:** A dropdown menu with options: None, Mild, Moderate, Severe, Proliferative.
- Right Eye Macular Edema:** A dropdown menu with options: None, Mild, Moderate, Severe, Proliferative.
- Other OD:** A dropdown menu with options: Glaucoma, Dry MD, Wet MD, Vein Occlusion, HTN Retinopathy, Epiretinal Membrane, Macular Hole, Cataract, Other.
- Image Viewer:** Two circular fundus images of the right eye are displayed side-by-side.
- Test Details:** A section at the bottom left showing the test name (TEST, EPRESORBING), date (Friday, February 21, 2014 3:09 PM), and other metadata.
- Laterality Summary:** A table at the bottom right summarizing the laterality of the findings.

Laterality	Right Eye	Left Eye
Right Eye	✓	
Left Eye		✓
Right Eye	✓	
Enhanced	✓	

Figure 4 - Grading window for OD showing severity levels of pathology for Diabetic Retinopathy

The screenshot shows the Iris grading interface for a patient named TEST1, IRIS1. The patient's birth date is 01-12-1982, gender is M, and Mm is 20140304004. The right eye (OD) is graded as 'Normal OD' (green button) and 'Ungradable' (red button). The left eye (OS) is also graded as 'Normal OS' (green button) and 'Ungradable' (red button). The right eye's diabetic retinopathy is graded as 'None', 'Mild', 'Moderate' (selected), 'Severe', or 'Proliferative'. The left eye's diabetic retinopathy is graded as 'None', 'Mild', 'Moderate', 'Severe', or 'Proliferative'. The right eye's macular edema is graded as 'None', 'Mild', 'Moderate' (selected), 'Severe', or 'Proliferative'. The left eye's macular edema is graded as 'None', 'Mild', 'Moderate', 'Severe', or 'Proliferative'. The right eye's other OD is graded as 'Glaucoma', 'Dry MD', 'Wet MD', 'Vein Occlusion', 'HTN Retinopathy', 'Epiretinal Membrane', 'Macular Hole', 'Cataract', or 'Other'. The left eye's other OS is graded as 'Glaucoma', 'Dry MD', 'Wet MD', 'Vein Occlusion', 'HTN Retinopathy', 'Epiretinal Membrane', 'Macular Hole', 'Cataract', or 'Other'. The right eye's image is shown in the center, and the left eye's image is shown to the right. The right eye's image is selected for grading.

Figure 5 - Grading window showing moderate macular edema selected for OD

The screenshot shows the Iris grading interface for a patient named TEST1, IRIS1. The patient's birth date is 01-12-1982, gender is M, and Mm is 20140304004. The right eye (OD) is graded as 'Normal OD' (green button) and 'Ungradable' (red button). The left eye (OS) is also graded as 'Normal OS' (green button) and 'Ungradable' (red button). The right eye's diabetic retinopathy is graded as 'None', 'Mild', 'Moderate', 'Severe', or 'Proliferative'. The left eye's diabetic retinopathy is graded as 'None', 'Mild', 'Moderate', 'Severe', or 'Proliferative'. The right eye's macular edema is graded as 'None', 'Mild', 'Moderate', 'Severe', or 'Proliferative'. The left eye's macular edema is graded as 'None', 'Mild', 'Moderate', 'Severe', or 'Proliferative'. The right eye's other OD is graded as 'Glaucoma', 'Dry MD', 'Wet MD', 'Vein Occlusion', 'HTN Retinopathy', 'Epiretinal Membrane', 'Macular Hole', 'Cataract', or 'Other'. The left eye's other OS is graded as 'Glaucoma', 'Dry MD', 'Wet MD', 'Vein Occlusion', 'HTN Retinopathy', 'Epiretinal Membrane', 'Macular Hole', 'Cataract', or 'Other'. The right eye's image is shown in the center, and the left eye's image is shown to the right. The right eye's image is selected for grading.

Figure 6 - Other suspected pathologies for OD

### 7.1.3.2.2 Left Eye Grading

When the right eye has been graded, click the 'Left Eye' link in the grading window below the images for the right eye. This will show the original image and the enhanced image for the left eye. Click on the image to enlarge.

- If no pathology is detected, click the **green Normal OS** button.

- If the image is not gradable, click the **red Ungradable** button.
- If pathology is detected, select the type of pathology by following the steps below. The severity level buttons will turn **blue** to indicate what has been selected.

#### *7.1.3.2.2.1 Diabetic Retinopathy*

If diabetic retinopathy is found:

- Click **Left Eye Diabetic Retinopathy**.
- Click the observed severity of the pathology using the dropdown buttons (see Figure 14):
  - None
  - Mild
  - Moderate
  - Severe
  - Proliferative

#### *7.1.3.2.2.2 Macular Edema*

If macular edema is found:

- Click **Left Eye Macular Edema**.
- Click the observed level of pathology using the dropdown buttons (see Figure 15):
  - None
  - Mild
  - Moderate
  - Severe

#### *7.1.3.2.2.3 Other Pathology*

If another pathology is detected in the left eye:

- Click Other OS.
- Select the suspected other pathology from the buttons (see Figure 16):
  - Glaucoma
  - Dry MD
  - Wet MD
  - Vein Occlusion
  - HTN Retinopathy
  - Epiretinal Membrane
  - Macular Hole
  - Cataract
  - Other

The screenshot shows the Iris Dashboard interface. At the top, there's a browser address bar with the URL <http://app.retinalscreenings.com/Home/Dashboard>. Below the address bar, there's a navigation bar with "Apps", "Iris Dashboard", and "Cadence Report". The main content area is divided into several sections. On the left, there's a "Patient" section with a "Save" button, a "Save and Sign" button, and a "Cancel" button. Below this, there's a table with patient information: Name (TEST1, IRIS1), Birth Date (01-12-1982), Gender (M), and Mm (20140304005). To the right of the patient information, there's a "Right Eye" section with a "Normal OD" button and an "Ungradable" button. Below this, there's a "Right Eye Diabetic Retinopathy" section with buttons for "None", "Mild", "Moderate", "Severe", and "Proliferative". To the right of the retinopathy section, there's a "Right Eye Macular Edema" section with an "Other OD" button. In the center, there's a "Click on an image to see an enlarged view of that image!" prompt. Below this, there are two retinal images: "Right Eye" and "Left Eye". The "Left Eye" image is selected, and its corresponding "Mild" button in the "Left Eye Diabetic Retinopathy" section is highlighted. To the right of the "Left Eye" image, there's a "Left Eye" section with a "Normal OS" button and an "Ungradable" button. Below this, there's a "Left Eye Diabetic Retinopathy" section with buttons for "None", "Mild", "Moderate", "Severe", and "Proliferative". To the right of the retinopathy section, there's a "Left Eye Macular Edema" section with an "Other OS" button. At the bottom, there's an "Assessment" section.

Figure 7 – Grading left eye with mild Diabetic Retinopathy selected

The screenshot shows the Iris Dashboard interface. At the top, there's a browser address bar with the URL <http://app.retinalscreenings.com/Home/Dashboard>. Below the address bar, there's a navigation bar with "Apps", "Iris Dashboard", and "Cadence Report". The main content area is divided into several sections. On the left, there's a "Patient" section with a "Save" button, a "Save and Sign" button, and a "Cancel" button. Below this, there's a table with patient information: Name (TEST1, IRIS1), Birth Date (01-12-1982), Gender (M), and Mm (20140304005). To the right of the patient information, there's a "Right Eye" section with a "Normal OD" button and an "Ungradable" button. Below this, there's a "Right Eye Diabetic Retinopathy" section with buttons for "None", "Mild", "Moderate", "Severe", and "Proliferative". To the right of the retinopathy section, there's a "Right Eye Macular Edema" section with an "Other OD" button. In the center, there's a "Click on an image to see an enlarged view of that image!" prompt. Below this, there are two retinal images: "Right Eye" and "Left Eye". The "Left Eye" image is selected, and its corresponding "Moderate" button in the "Left Eye Diabetic Retinopathy" section is highlighted. To the right of the "Left Eye" image, there's a "Left Eye" section with a "Normal OS" button and an "Ungradable" button. Below this, there's a "Left Eye Diabetic Retinopathy" section with buttons for "None", "Mild", "Moderate", "Severe", and "Proliferative". To the right of the retinopathy section, there's a "Left Eye Macular Edema" section with an "Other OS" button. At the bottom, there's an "Assessment" section.

Figure 8 - Grading left eye with moderate Macular Edema selected



The screenshot shows the Iris Dashboard web application. The browser address bar displays <https://app.retnalscreenings.com/Home/Dashboard>. The main interface is a grading window for the left eye. At the top, there are buttons for 'Save', 'Save and Sign', and 'Cancel'. Below these are input fields for 'Name' (TEST1, IRIS1), 'Birth Date' (01-12-1982), 'Gender' (M), and 'Mm' (20140304005). The central part of the window displays two fundus images, one for the 'Right Eye' and one for the 'Left Eye'. To the left of the images are buttons for 'Right Eye Diabetic Retinopathy' (None, Mild, Moderate, Severe, Proliferative), 'Right Eye Macular Edema', and 'Other OD'. To the right are buttons for 'Left Eye Diabetic Retinopathy', 'Left Eye Macular Edema', and 'Other OS'. Below the 'Other OS' section is a 'Glaucoma' section with buttons for 'Dry MD', 'Wet MD', 'Vein Occlusion', 'HTN Retinopathy', 'Epiretinal Membrane', 'Macular Hole', 'Cataract', and 'Other'. At the bottom of the window is an 'Assessment' box.

Figure 16 - Grading left eye with suspected Glaucoma selected

### 7.1.3.3 Assess and Sign

After the eyes have been graded, the grader must enter his/her assessment.

- In the grading window, click in the **Assessment** box at the bottom of the window.
- Indicate the best course of action for the patient's care with respect to the pathology and severity detected (see Figure 17).
- If **Other** was indicated for the Pathology with either eye, include the pathology that was detected
- Additional information and/or instruction to the patient or provider may be included in the assessment box
- Click the gray **Save and Sign** button to save the grade and assessment and sign the order. This action will automatically send the Final Results report to the shared folder associated with the clinic/location.
- To sign, the grader's or default ordering physician's password must be entered (see Figure 18).
- Click OK after the password has been entered

The screenshot shows the 'Patient' assessment form in the Iris Dashboard. The patient information is TEST1, IRIS1, born 01-12-1982, male, with ID 20140304005. The assessment for the Right Eye shows 'Refer: Urgent' for both Diabetic Retinopathy and Macular Edema. The Left Eye assessment is also 'Refer: Urgent'. The form includes buttons for 'Save', 'Save and Sign', and 'Cancel'.

Figure 17 - Assessment of Refer: Urgent for the suspected pathologies detected

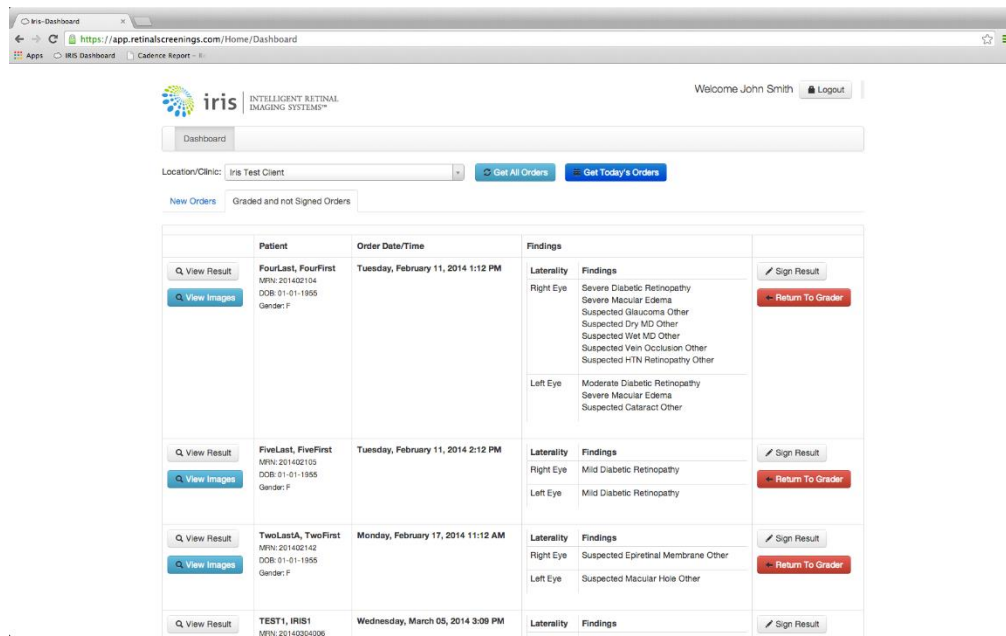
The screenshot shows the 'Patient' assessment form in the Iris Dashboard. A 'Please Authenticate Your Signature' dialog box is displayed over the form, prompting the user to enter a password and sign off on the order's grade and assessment. The patient information and assessment details are the same as in Figure 17.

Figure 18 - Password entered to sign off on the order's grade and assessment

### 7.1.3.4 View and Sign Results

The **Graded and not Signed Orders** tab populates all orders that have been graded by a licensed practitioner but have not yet been signed off by the final/signing authority. To populate these orders, click the **Graded and not Signed Orders** button (see Figure 19).

## Iris User Manual



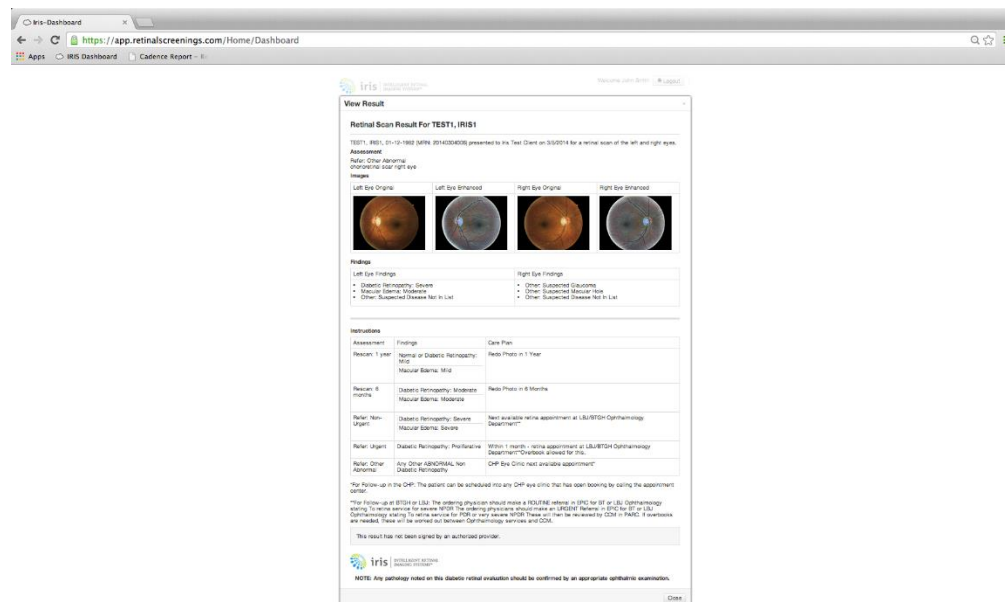
	Patient	Order Date/Time	Findings	
<a href="#">View Result</a> <a href="#">View Images</a>	<b>FourLast, FourFirst</b> MRN: 201402104 DOB: 01-01-1955 Gender: F	Tuesday, February 11, 2014 1:12 PM	<b>Laterality Findings</b> Right Eye: Severe Diabetic Retinopathy, Severe Macular Edema, Suspected Glaucoma Other, Suspected Dry MD Other, Suspected Wet MD Other, Suspected Vein Occlusion Other, Suspected HTN Retinopathy Other Left Eye: Moderate Diabetic Retinopathy, Severe Macular Edema, Suspected Cataract Other	<a href="#">Sign Result</a> <a href="#">Return To Grader</a>
<a href="#">View Result</a> <a href="#">View Images</a>	<b>FiveLast, FiveFirst</b> MRN: 201402105 DOB: 01-01-1955 Gender: F	Tuesday, February 11, 2014 2:12 PM	<b>Laterality Findings</b> Right Eye: Mild Diabetic Retinopathy Left Eye: Mild Diabetic Retinopathy	<a href="#">Sign Result</a> <a href="#">Return To Grader</a>
<a href="#">View Result</a> <a href="#">View Images</a>	<b>TwoLastA, TwoFirst</b> MRN: 201402142 DOB: 01-01-1955 Gender: F	Monday, February 17, 2014 11:12 AM	<b>Laterality Findings</b> Right Eye: Suspected Epiretinal Membrane Other Left Eye: Suspected Macular Hole Other	<a href="#">Sign Result</a> <a href="#">Return To Grader</a>
<a href="#">View Result</a>	<b>TEST1, IRIS1</b> MRN: 20140304006	Wednesday, March 05, 2014 3:09 PM	<b>Laterality Findings</b>	<a href="#">Sign Result</a>

Figure 19 - Graded and not Signed Orders tab

The default ordering physician is urged to inspect the grader's suggestions prior to signing off on the order.

To view the grader's results:

- Click the **View Result** button to the left of the respective patient's order.
- Review the results (see Figure 20).
- Click the **Close** button or press the **ESC** key to close the results window.



**Retinal Scan Result For TEST1, IRIS1**

TEST1, IRIS1, 01-19-1982 (MRN: 20140304006) presented to the Test Client on 3/5/2014 for a retinal scan of the left and right eyes.

**Assessment:**  
 Refractive Error: Normal  
 Refractive Error: Normal

**Images:**  
 Left Eye Original, Left Eye Enhanced, Right Eye Original, Right Eye Enhanced

**Findings:**  
 Left Eye Findings:  
 • Suspected Diabetic Retinopathy  
 • Suspected Macular Edema  
 • Other: Suspected Diabetic Retinopathy Not in L&L  
 Right Eye Findings:  
 • Suspected Diabetic Retinopathy  
 • Suspected Macular Edema  
 • Other: Suspected Diabetic Retinopathy Not in R&R

**Recommendations:**

Assessment	Findings	Care Plan
Refractive Error: Normal	Normal or Diabetic Retinopathy: Mild	Retina Photo in 1 Year
Refractive Error: Normal	Macular Edema: Mild	
Refractive Error: Normal	Diabetic Retinopathy: Moderate	Retina Photo in 6 Months
Refractive Error: Normal	Macular Edema: Moderate	
Refractive Error: Normal	Diabetic Retinopathy: Severe	Next available retinal appointment at L&R/STON Ophthalmology Department
Refractive Error: Normal	Macular Edema: Severe	
Refractive Error: Normal	Diabetic Retinopathy: Proliferative	Within 1 month - retinal appointment at L&R/STON Ophthalmology Department
Refractive Error: Normal	Any Other ABNORMAL Non-Diabetic Retinopathy	CHP Eye Clinic next available appointment

\*For Follow-up in the OPH: The patient can be scheduled into any OPH eye clinic that has open booking by calling the appointment center.

\*For Follow-up at STON or L&R: The ordering physician should make a ROUTINE referral to OPH for ST or L&R. Ophthalmology testing is done at the OPH. The ordering physician should make a ROUTINE referral to OPH for ST or L&R. Ophthalmology testing is done at the OPH. The ordering physician should make a ROUTINE referral to OPH for ST or L&R. Ophthalmology testing is done at the OPH.

\*This result has not been signed by an authorized provider.

NOTE: Any pathology noted on this diabetic retinal evaluation should be confirmed by an appropriate ophthalmic examination.

**Close**

Figure 20 - Grader results for a patient order

All graded and unsigned orders remain on the dashboard until they are signed by the licensed practitioner with signature authority. Once an order is signed by the licensed practitioner with signature authority, the

image is automatically exported off of the Iris interface and deposited into the Iris shared folder or the client's EMR.

To sign off on the grader's suggested presence and severity of pathology (if any), the default ordering physician must click the **Sign Result** button to the right of the patient order. The physician must then enter his/her password for the order signature to be accepted and exported onto the location's shared folder (see Figure 21).

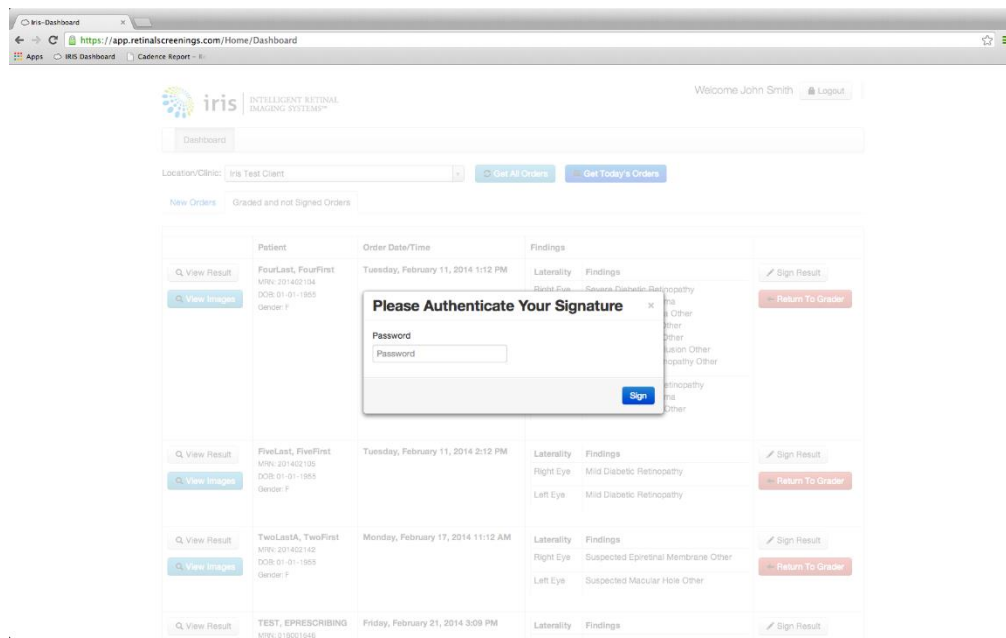


Figure 21 - Prompt for physician to enter password to sign off on an order

If the physician is not comfortable or disagrees with the retina specialist's suspected diagnosis, the physician may request that the order be re-graded by completing the following steps:

- While in the **Graded and not Signed Orders** tab, click the **Return to Grader** button.
- Select the images that should be re-graded. The prompt's default has both right and left eyes selected (see Figure 22).
- Click the link for the respective eyes that should be re-graded.
- Select the reason for the re-grade request or submit your own words (see Figure 23).
- Click the **blue Send for Re-grading** button.
- If a mistake is made in requesting a re-grade, click the **red Start Over** button.
- To exit the request, press the ESC on your keyboard or click the X on the top right corner of the window. All data that has been entered in the prompt will not be saved if you do this.

## Iris User Manual

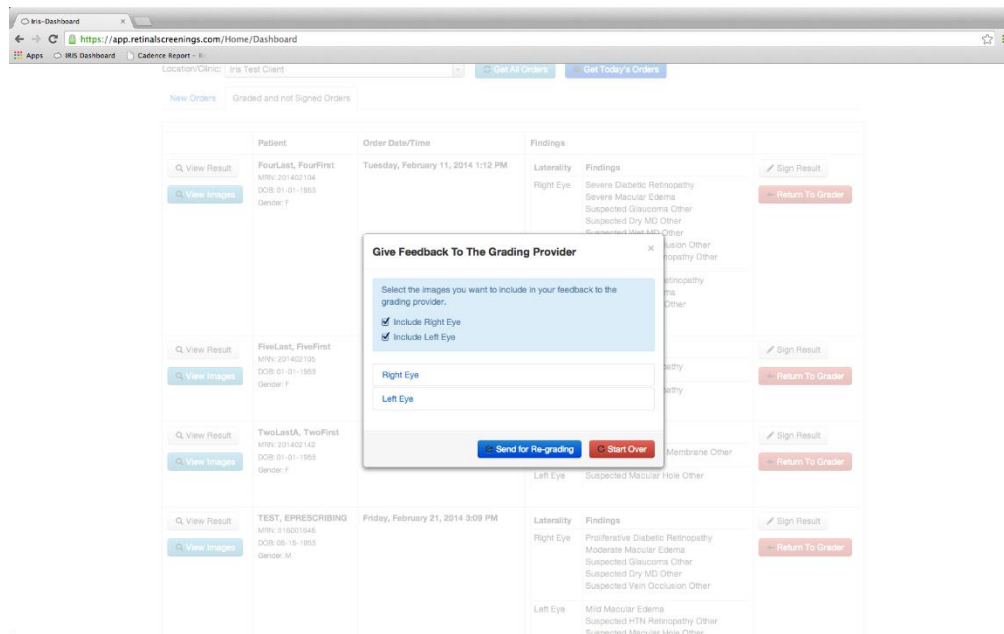


Figure 22 - Prompt for reasons the order is being returned to grader

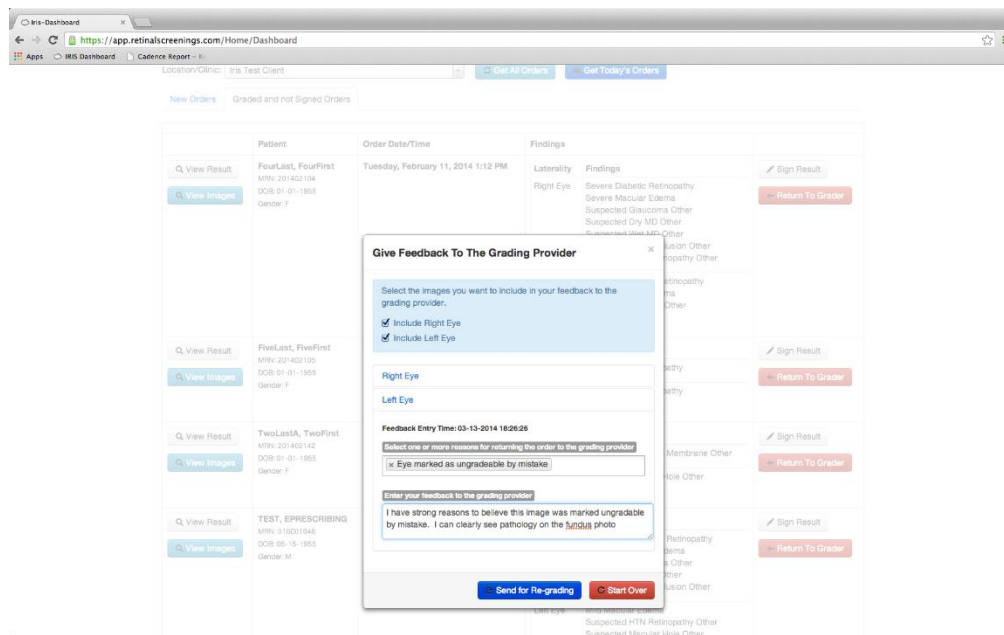


Figure 23 - Select a reason or enter your own words for requesting a re-grade

## 7.2 Glaucoma Analysis

### 7.2.1 Technician

#### 7.2.1.1 Access the Glaucoma Service

For organizations with the glaucoma service feature enabled, an additional **Glaucoma Screenings** dashboard is presented in the application (see Figure 24) once the user logs in as described in Section 6.

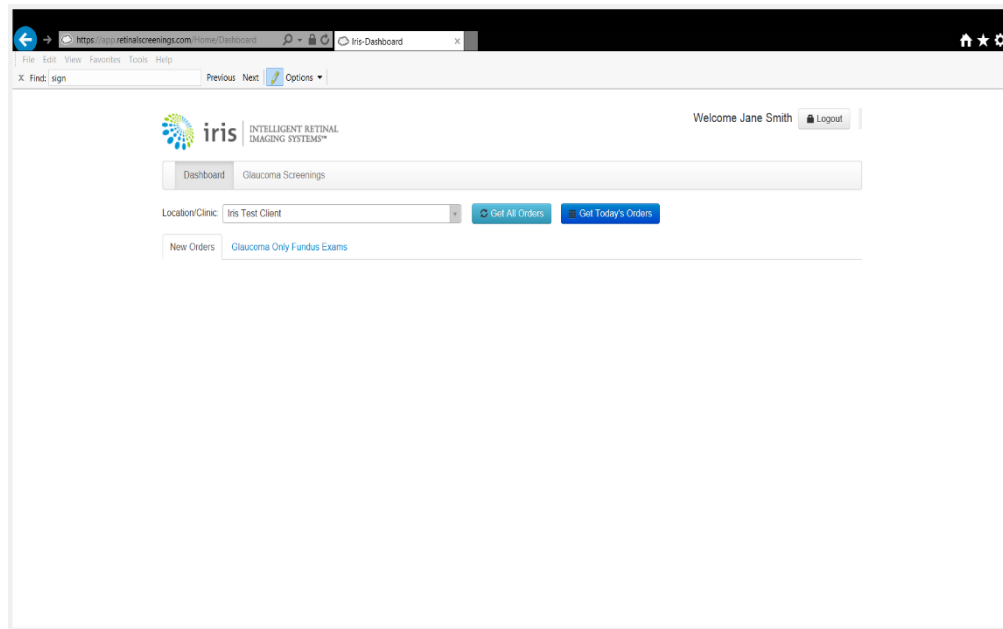


Figure 24 - Technician's Interface Home Page with Glaucoma

- To utilize the glaucoma feature, the patient's fundus images must first be exported to the dashboard as described previously for diabetic retinopathy analysis. Iris does not require a separate image export for glaucoma analysis as it is capable of utilizing a patient's fundus photos for both diabetic retinopathy analysis and glaucoma analysis.
- Orders can be displayed for the appropriate location/clinic as outlined in Section 7.1.1.1:
  - If the patient is diabetic, the diabetic retinopathy analysis should be completed as described in Section 7.1.1.
  - If the patient is not a diabetic, click on the **orange Glaucoma Only** button (see Figure 25). This will remove the fundus photos from the diabetic retinopathy analysis queue so that they are only evaluated for glaucoma. A message will be displayed to indicate that the record was set as a Glaucoma Only Fundus Exams (see Figure 26).
  - Click on the **blue** OK button to close the popup.

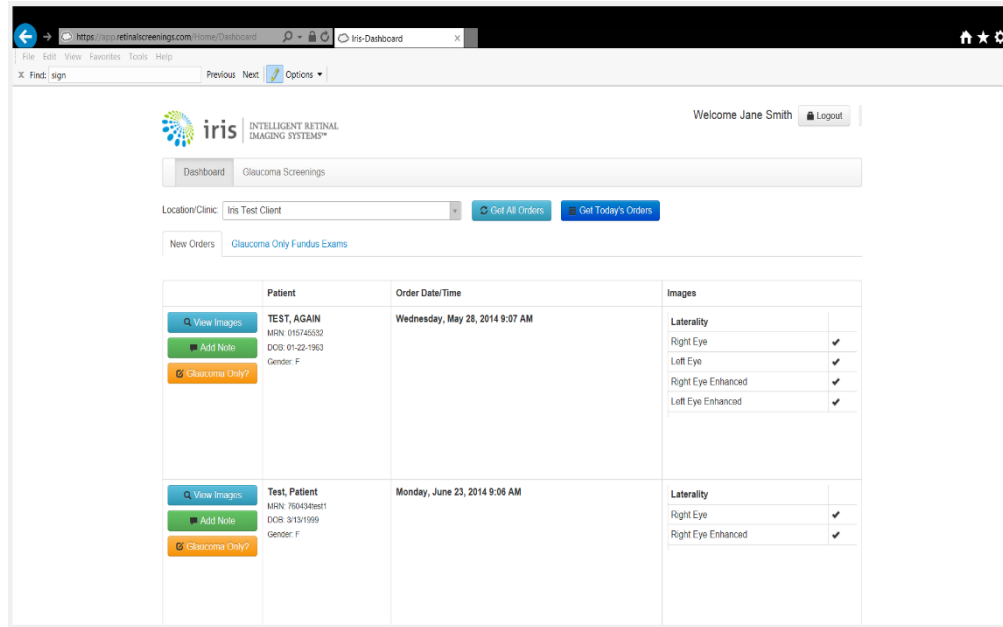


Figure 9. Dashboard showing orders in queue for diabetic retinopathy assessment along with orange Glaucoma Only? button

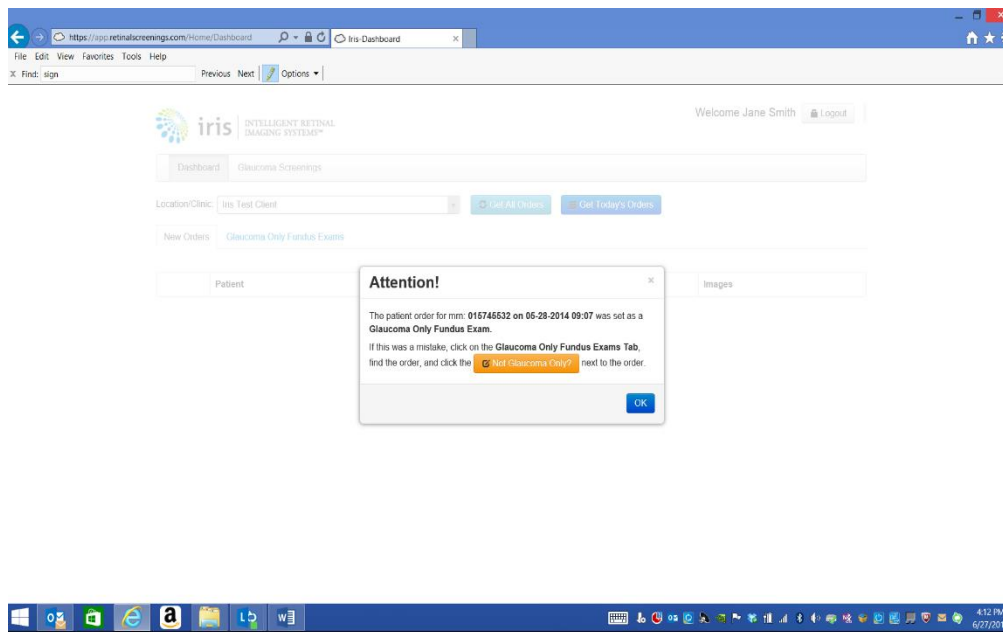


Figure 24 - Technician's View Setting Glaucoma Only

- If the patient record is inadvertently set as a Glaucoma Only Fundus Exam but needs the diabetic retinopathy analysis, it can be reclassified:
  - Click on the **Glaucoma Only Fundus Exams** tab to display the glaucoma only queue.
  - Enter the date range for which you want to search for a patient record (if no date is entered, the system will default to the current calendar year) and click the **blue Get Orders** button (see Figure 27).
  - Click on the **orange Not Glaucoma Only?** button which will move the fundus photos from the glaucoma only analysis queue back to the diabetic retinopathy analysis queue

so that they be evaluated for both. A message will be displayed to indicate that the record was moved (see Figure 28).

- Click on the **blue** OK button to close the popup.

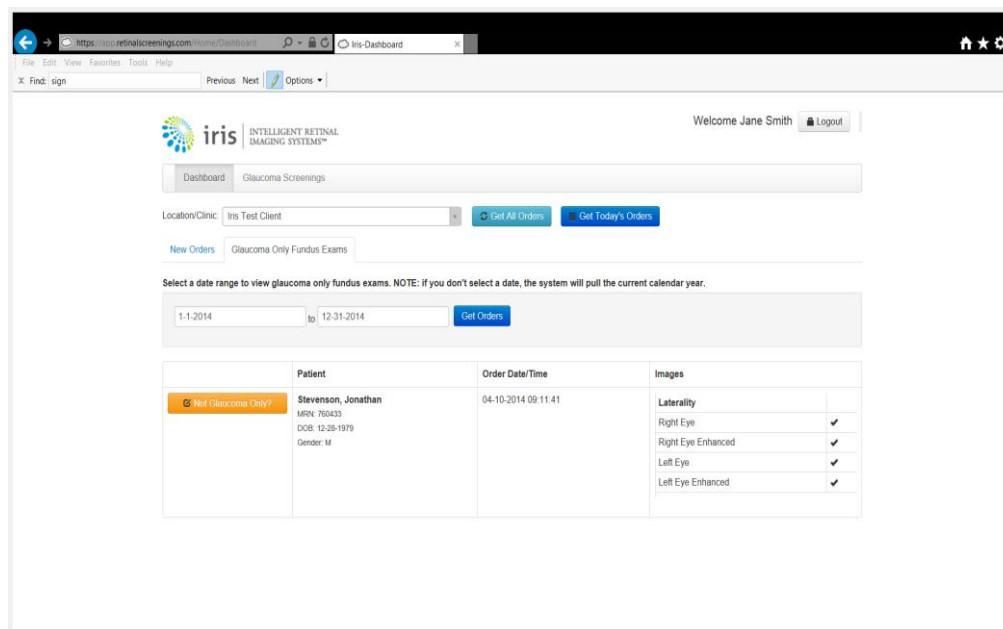


Figure 27 – Glaucoma-only Queue

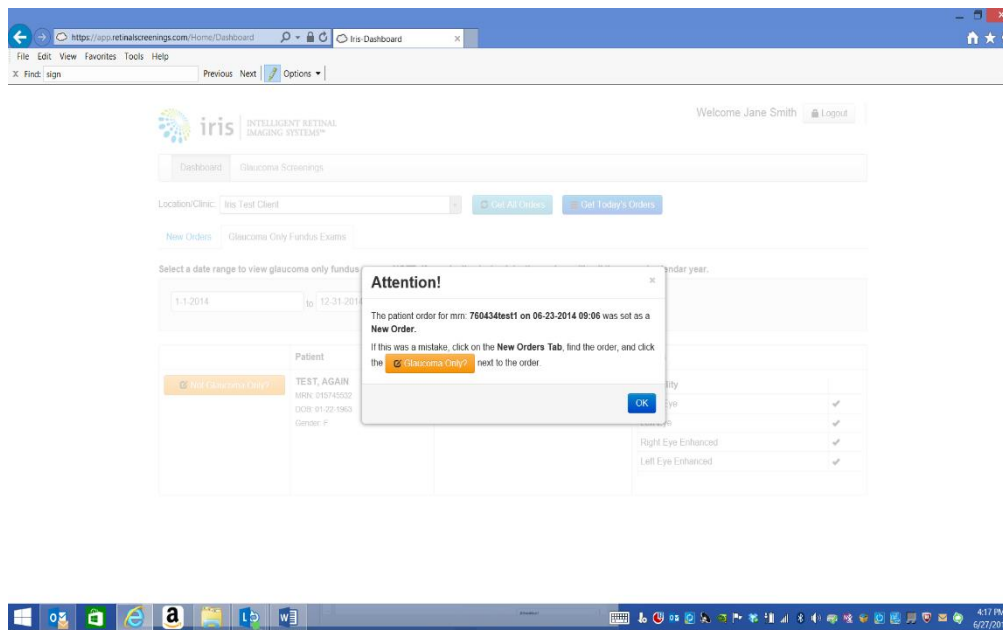


Figure 28 – Patient reset from Glaucoma Only to New Order message



### 7.2.1.2 View Glaucoma Screenings

- Click on the **Glaucoma Screenings** tab located to the right of the **Dashboard** tab on the control ribbon at the top of the home page to display the Glaucoma Screening page.
- Ensure the correct location/clinic is selected from the drop down box and click **Select Client** to display all glaucoma orders requiring grading (see Figure 29).

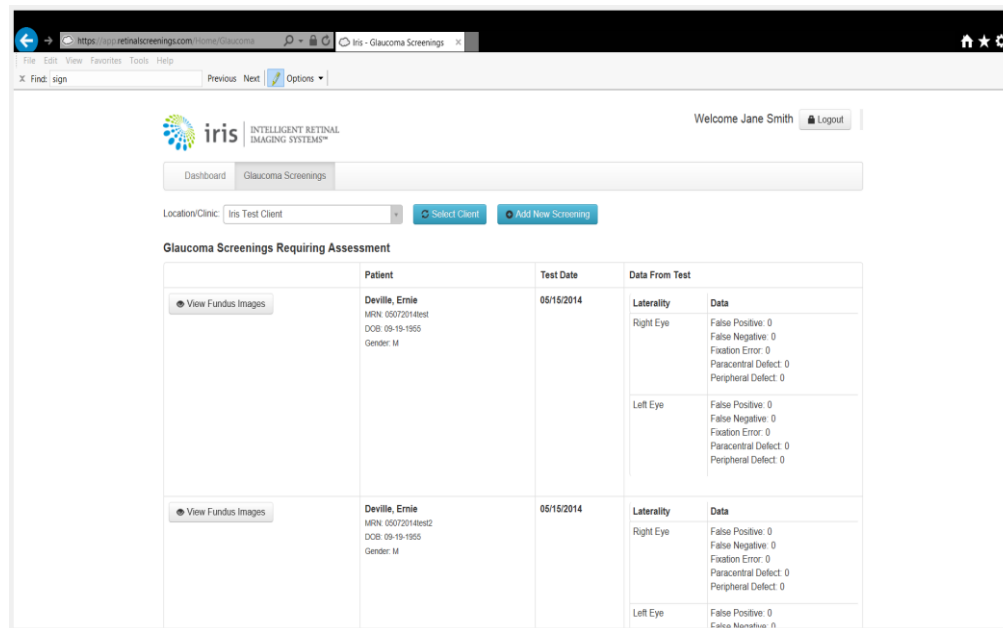


Figure 29. Dashboard showing glaucoma orders requiring grading

- Click on the View Fundus Images button to view the enlarged images of the eye and the ranges of the cup to disc ratio (see Figure 30).<sup>2</sup>

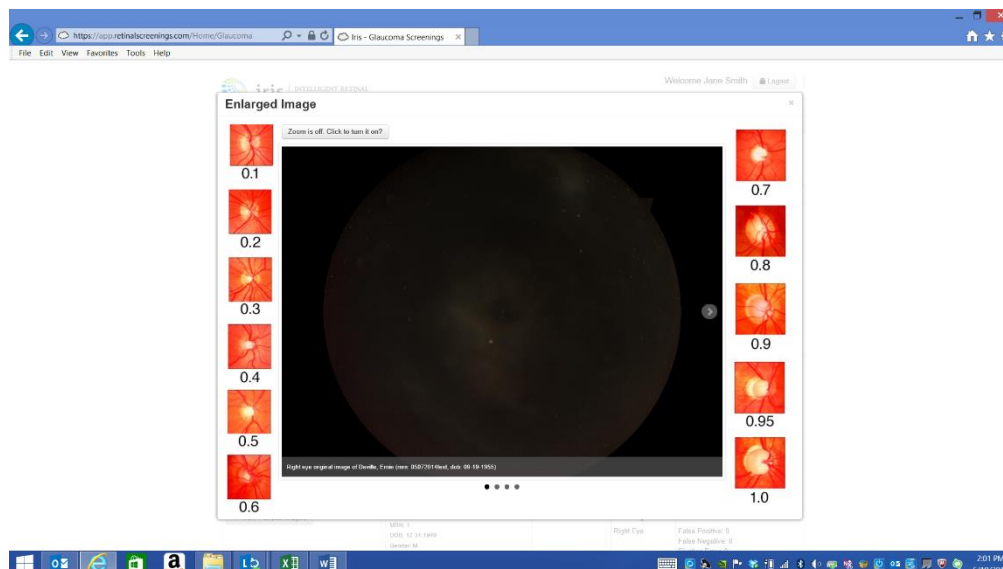


Figure 30 – Enlarged image with cup to disk ratios

<sup>2</sup> <http://www.docstoc.com/docs/74164107/PROGRESSION-OF-OPTIC-NERVE-CUPPING-GLAUCOMA-CENTER-OF-MICHIGAN>

- Click the arrows on the image to scroll either to the right or the left to view both original and enhanced images available of the right and left eyes.
- Click on the **Zoom** button above the image to zoom in on an image and again to turn the zoom function off.

### 7.2.1.3 Add New Glaucoma Screening

- To add a new glaucoma order for grading, Click **Add New Screening** and the glaucoma screening popup where the patient's visual field results will be entered will be displayed (see Figure 31).

The screenshot shows a web browser window with the URL <http://app.retinalscreenings.com/Home/Glaucoma>. The application is titled "Iris - Glaucoma Screenings". The "Add New Screening" popup is open, displaying a search bar for patient MRN, a "Search for Patient" button, and a "Glaucoma Screening Date" field set to 05/05/2014. Below this is a table for "Grading" with columns for "Laterality", "Finding Type", "Result", and "Remove Grading". The table contains 10 rows of data, each with a "Left Eye" and "Right Eye" button, a "Finding Type" dropdown menu, a "Result" input field, and a "Remove Grading" button. The "Add Grading" button is green and located at the top left of the table. The "Save Screening" and "Close" buttons are at the bottom right of the popup.

Figure 31 – Add New Screening for Glaucoma

1. Type the patient's MRN in the search box and click **Search for Patient**.
2. Enter the date the glaucoma screening was conducted in the **Glaucoma Screening Date** field or select it from the calendar popup.
3. Select either Left Eye or Right Eye in the **Laterality** column (the system defaults to Left Eye for the first set of results).
4. Select the Finding Type to be recorded. The system defaults to False Positive for the first result set; however, the complete list includes:
  - False Positive
  - False Negative
  - Fixation Error
  - Paracentral Defect
  - Peripheral Defect
  - Abnormal
  - Normal
  - Cup to Disc Ratio
5. Enter the result of the visual fields test in the corresponding **Result** box.
6. Repeat steps 3-6 for subsequent glaucoma tests.
7. If additional results need to be recorded, click the green **Add Grading** button at the top of the results area.

8. To delete any of the results lines, click on the **red Remove Grading** button next to the appropriate results line.
9. Save the results by clicking **Save Screening**.
10. Click the **red Close** button or the **X** at the top right corner to close the glaucoma screening page.

## 7.2.2 Grader

### 7.2.2.1 Grader Access to Glaucoma Screens

Graders access glaucoma screens in a similar way as technicians but through a slightly different view that includes the Graded and Not Signed Orders tab (see Figure 32). Otherwise, the steps outlined in Section 7.1.1.1 (Access the Glaucoma Service), 7.1.1.2 (View Glaucoma Screenings), and 7.1.1.3 (Add New Glaucoma Screening) and can be followed.

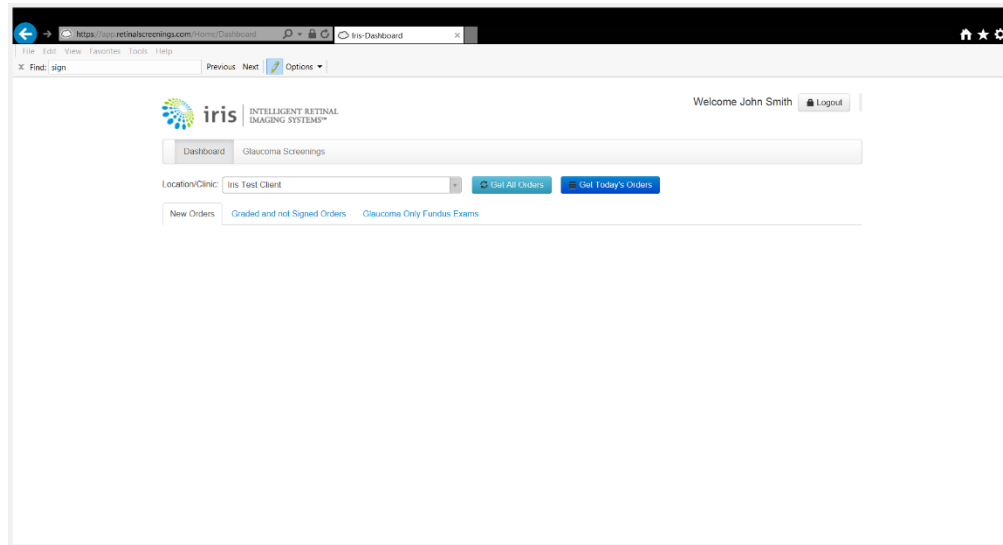


Figure 32 - Grader's Interface Home Page with Glaucoma

### 7.2.2.2 Grade Glaucoma Screens

As with diabetic retinopathy grading, only a certified, licensed practitioner is allowed to grade glaucoma orders. Therefore, access to this level of the Iris interface is restricted to those users with a role of Grader.

- Log into the Iris dashboard.
- Click on the **Glaucoma Screenings** tab located to the right of the **Dashboard** tab on the control ribbon at the top of the home page to display the Glaucoma Screening page.
- Ensure the correct location/clinic is selected from the drop down box and click **Select Client** to display all glaucoma orders requiring grading (see Figure 33).

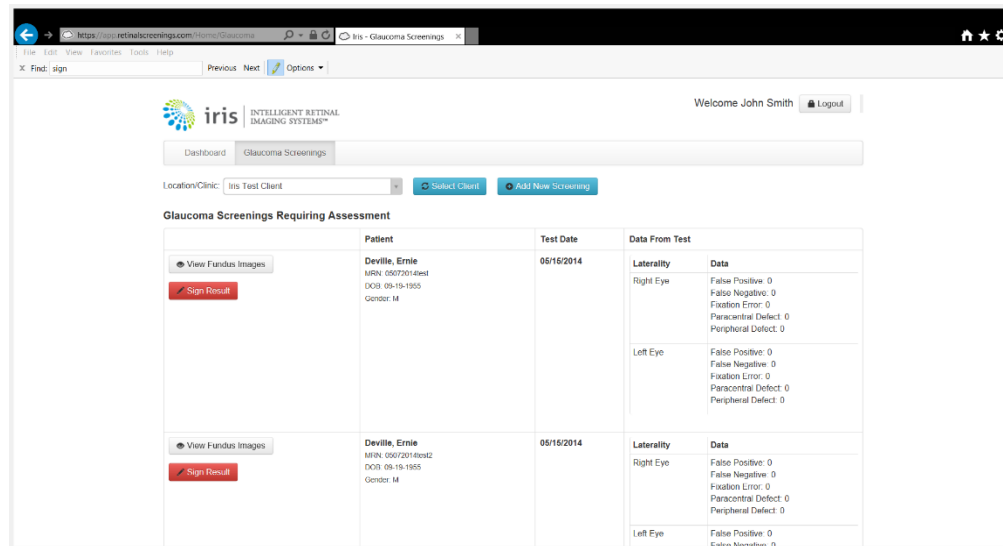


Figure 33 - Glaucoma screenings requiring assessment

- Click the **red Sign Result** button.
- In the pop up window (see Figure 34) click **View Fundus Images** to view the fundus images and measure the cup to disc ratios as described in Section 7.2.1.2.
- Click the **X** at the top right of the image screen to close it.
- Click the button corresponding to the patient's observed cup to disc ratio for the right eye
- Click the button corresponding to the patient's observed cup to disc ratio for the left eye
- Click the **blue Was Test Abnormal?** button to indicate that something about the image is abnormal that is not otherwise noted.
- This button will automatically be selected with a care plan that reflects the need to schedule an appointment for further evaluation when:
  - The cup to disc ratio for either eye is greater than or equal to .5
  - One or more peripheral or paracentral defects are noted
- If additional assessment information is available, enter the date in the Additional Assessment text box.
- To sign the result, enter your password in the bottom text box and click the **blue Sign Result** button.

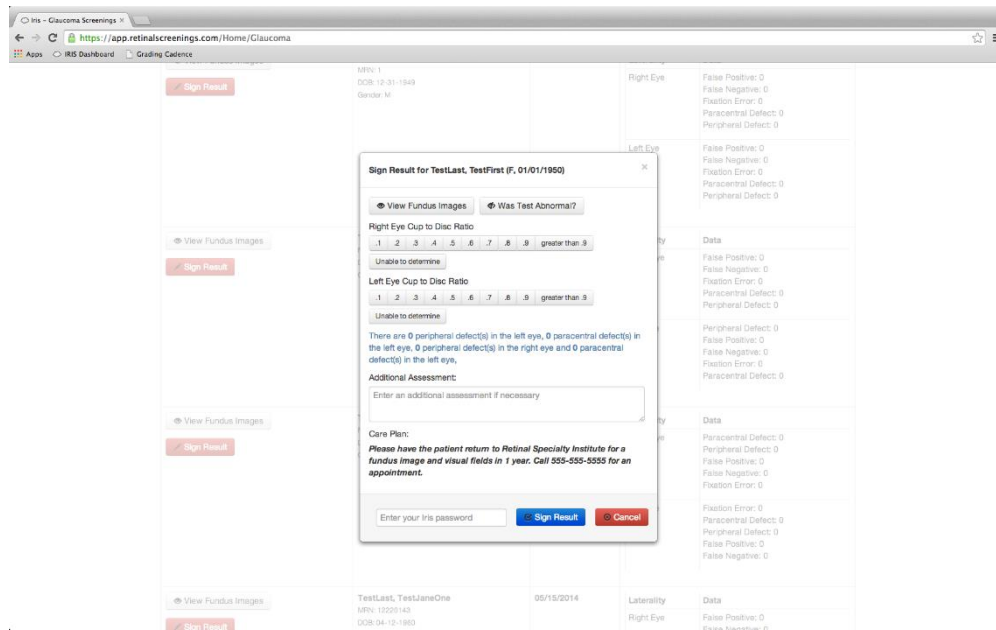


Figure 34 –Glaucoma Assessment and Sign Results<sup>3</sup>

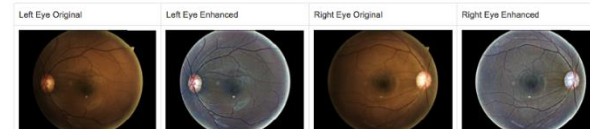
#### Retinal Scan Result For Smith, John

Smith, John, 01151970 (MRN: 000100887) presented to North Mississippi Tupelo IMO on 1/9/2014 for a retinal scan of the left and right eyes.

##### Assessment

Plan: mild nonproliferative diabetic retinopathy right eye, no retinopathy left eye  
Rescan in 1 year

##### Images



##### Findings

Left Eye Findings	Right Eye Findings
Normal Result	• Diabetic Retinopathy: Mild

##### Instructions

Assessment	Findings	Care Plan
Rescan: 1 year	Normal or Diabetic Retinopathy: Mild Macular Edema: Mild	Redo Photo in 1 Year
	All other nonnormal findings	Referral to Ophthalmology for further evaluation

This result was electronically signed by Baranano, Anne, on 1/10/2014 9:13:03 PM UTC time.



NOTE: Any pathology noted on this diabetic retinal evaluation should be confirmed by an appropriate ophthalmic examination.

Figure 35 – Final Scan Result

<sup>3</sup> <http://www.docstoc.com/docs/74164107/PROGRESSION-OF-OPTIC-NERVE-CUPPING-GLAUCOMA-CENTER-OF-MICHIGAN>

## 8 Exiting the Iris Dashboard

To log out of Iris, click the gray **Logout** button with the lock icon at the top right corner of the page.

As a safety feature, if a user is inactive for 5 minutes, the dashboard will prompt the user to click a button to remain logged in. After 30 seconds, the user will automatically be logged out of the system.

## 9 Automatic Software Update

When updates are made to the Iris system, an email identifying the improvements or added features/functionality will be sent to the Super User. Additionally, when a user logs into the system following an update, an alert will be presented to them denoting any new updates to the system that Iris may have put into place.

## 10 Troubleshooting

Below are some basic troubleshooting guidelines for common issues that may be encountered. For any other issues please call Iris support at +1 888 535-2574.

Issue	Solution
Patient Order not visible on dashboard	Check Final Results folder for report. The patient order may have already been graded.
Order was graded and saved but final result is not in folder	Check Saved but Not Signed Tab. If present, sign the graded order.
Final Results Report not in shared folder	Check patient record.
Image clarity issues	Refer to your fundus camera user manual.