IRIS USER MANUAL
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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-mydriatic 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\(^1\) (Google Chrome is the preferred browser).
- Enter [https://app.retinalscreenings.com](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.

\(^1\) Not provided by Iris
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.
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 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 3.
- Click on the View Images button next to a patient name to view the retinal images associated with that patient.

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**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
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 ungradable 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.
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.
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.
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

Figure 4 - Grading window for OD showing severity levels of pathology for Diabetic Retinopathy
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
**Figure 7** – Grading left eye with mild Diabetic Retinopathy selected

**Figure 8** – Grading left eye with moderate Macular Edema 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
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).
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.

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](image)

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.
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](image)

- 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.
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).

![Dashboard showing glaucoma orders requiring grading](http://www.docstoc.com/docs/74164107/PROGRESSION-OF-OPTIC-NERVE-CUPPING-GLAUCOMA-CENTER-OF-MICHIGAN)

- 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).

![Enlarged image with cup to disk ratios](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).

![Add New Screening for Glaucoma](image)

**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.

![Grader’s Interface Home Page with Glaucoma](image)

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).
- 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

Figure 35 – Final Scan Result

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.

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