SCANLY®

HOME OCT Monitoring Program

Portal User Manual

REF 1.3.0

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

GENERAL

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Notal Vision Inc.

7717 Coppermine Drive

Manassas, VA 20109

USA

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PATENTS

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CONTACT US

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Customer satisfaction is a top priority at Notal Vision.

Please contact the Notal Vision Monitoring Center, provider of the SCANLY Home OCT, for comments, questions, or support: PracticeEngagement@notalvision.com or call 866-203-1188.

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1. INTRODUCTION

The SCANLY Portal is an interactive cloud-based interface that displays a patient's OCT testing information collected from the home-based device over time. Data includes patient information, volume scans (with image quality indicator scores), and hypo-reflective spaces estimation.

This User Manual contains information on the SCANLY Portal, part of the SCANLY Home OCT System. For best use of the SCANLY Portal, please adhere to the following:

- **Read the user manual carefully before using the SCANLY Portal.**
- **Retain the user manual for duration of use of the SCANLY Portal.**
- **The example patient data presented in this user manual are fictitious. Any similarities to a real person, living or dead, are completely coincidental.**

1.1. INTENDED AUDIENCE

This information is intended for use by authorized healthcare providers with provided consent to access patient data from the SCANLY Portal. The SCANLY Portal is intended to be used by eyecare providers who prescribe the SCANLY Home OCT to patients under their care.

1.2. INDICATIONS FOR USE

The Notal Vision Home Optical Coherence Tomography (OCT) System is an Artificial Intelligence (AI)-based Home Use device indicated for visualization of intraretinal and subretinal hypo-reflective spaces in a 10 by 10-degrees area centered on the point of fixation of eyes diagnosed with neovascular age-related macular degeneration (NV-AMD). In addition, it provides segmentation and an estimation of the volume of hypo-reflective spaces. The SCANLY Home OCT device is intended for imaging at home between regularly scheduled clinic assessments and not intended to be used to make treatment decisions or replace standard-of-care regularly scheduled examinations and clinical testing as needed, including in-office imaging and assessments for changes in vision, by an ophthalmologist.

1.3. ESSENTIAL PERFORMANCE

Capture and present retinal volume scans with acceptable image quality.

1.4. LIMITATIONS

The SCANLY Home OCT System and Portal results should not be used for diagnosis of any condition. Refer to the remainder of this user manual for information regarding system operation and capabilities.

2. WARNINGS AND PRECAUTIONS

2.1. SCANLY HOME OCT DEVICE WARNINGS FOR THE PATIENT

 **Warning: Indicates a situation in which the user may be in a potentially harmful situation.**

Ensure that your patient is aware of the following Warnings and Precautions while using the SCANLY Home OCT device.

	**Warning: The SCANLY Home OCT device is intended for personal use by a single prescribed patient only.**
	**Warning: Do not use the SCANLY Home OCT device if you have an open wound or an open sore.**
	**Warning: In the event your skin becomes irritated, while using the SCANLY Home OCT device, please discontinue usage and call the Notal Vision Monitoring Center.**
	**Warning: Use the SCANLY Home OCT device only with the dedicated power supply and cables supplied by manufacturer.**
	**Warning: Do not operate the SCANLY Home OCT device with a damaged power cord or plug. If case of a damaged cable or plug, call the Notal Vision Monitoring Center for service.**
	**Warning: Operate the SCANLY Home OCT device only if it is plugged into a standard outlet.**
	**Warning: The SCANLY Home OCT device contains NO user-serviceable components. Do not open the device's covers.**
	**Warning: To prevent fire or electric shock, do not open or expose the SCANLY Home OCT device to rain or excessive moisture.**
	**Warning: Changes or modifications to the SCANLY Home OCT device can affect the safety and effectiveness of the system.**

	**Warning: Do not use the SCANLY Home OCT device if the touchscreen is not working properly. Do not use the device if you cannot clearly see the instructions presented on screen.**
	**Warning: Do not use the system in case of speakers' fault that prevents you from hearing the instructions.**
	**Warning: Do not use the system if the volume level is too low. Adjust the speakers' volume before starting the scan.**
	**Warning: Do not spray SCANLY Home OCT device, immerse it in fluid, or allow fluid into any of its cavities.**
	**Warning: Portable Radio Frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SCANLY Home OCT, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
	**Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
	**Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
	**Warning: The SCANLY Home OCT device is intended to be used in an indoor home, and hence was not tested under the following special environment conditions:** • **Medical treatment areas with high powered medical equipment o (e.g., high-frequency surgical equipment, short-wave therapy equipment, inside the RF shielded room of an MRI system, diathermy, electrocautery)**

	• Military areas (e.g., submarines, radar installations, weapons control systems) • Heavy industrial areas (e.g., power plants, steel and paper mills, foundries, automotive and appliance manufacturing, smelting and mining operations, oil and gas refineries) • Aircraft environment (e.g., planes, helicopters) **Avoid operating the SCANLY Home OCT device in the above environments.**
	**Warning: In the intended indoor use environment, emitters such as base stations for radio (cellular/cordless) telephones and land mobile radio, 5G cellular network, wireless power transfer (WPT) and induction ovens may be found. If abnormal performance is observed, please contact the Notal Vision Monitoring Center.**
	**Warning: The NVHO device should not be used to delay in-office follow-up or to prolong the interim period between in-office follow-up visits.**
	**Warning: The NVHO device should not be used on patients with non-neovascular AMD (“dry” AMD) to detect conversion from “dry” to “wet” AMD.**
	**Warning: Patients should continue self-monitoring for visual changes (e.g., continue self-administration of Amsler grid testing) while using the NVHO device.**
	**Warning: The SCANLY Home OCT device shall not be used by patients with Visual Acuity of worse than 20/320.**

2.2. SCANLY HOME OCT DEVICE PRECAUTIONS FOR THE PATIENT

Upon receiving the SCANLY Home OCT, check the external package. Call the Notal Vision Monitoring Center if there is any damage to the package.
Verify that the device is placed on a stable surface, preventing it from falling, as described in this User Guide.
Verify that there are no wires or cables on the floor that you may trip over or that can cause any harm to you or the device.

Refer all service problems to qualified Notal Vision Monitoring Center staff only.
Do not wear glasses or contact lenses while performing a scan.
If you have physiological problems with the eye(s), do not use the system and contact your physician or Notal Vision service center for instructions.
The system contains NO user-serviceable components. Do not open the system covers.

2.3. SCANLY PORTAL WARNINGS FOR THE PHYSICIAN

	**Warning: Scans with poor image quality, e.g., below Manufacturer Signal quality Index (MSI) of <2, may be unreliable. MSI values with color indicator are presented under the Portal OCT B-scans. The following conditions may increase the likelihood of poor-quality scans:** • **Inability to maintain steady fixation** • **Unclear ocular media** • **Dementia**
	**Warning: The SCANLY Home OCT device shall not be used by patients with Visual Acuity of worse than 20/320.**
	**Warning: The SCANLY Home OCT device shall not be used to scan patients with pupil diameter of less than 2.5 mm.**
	**Warning: The SCANLY Home OCT device should not be used to delay in-office follow-up or to prolong the interim period between in-office follow-up visits**
	**Warning: The SCANLY Home OCT device should not be used on patients with non-neovascular AMD (“dry” AMD) to detect conversion from “dry” to “wet” AMD**
	**Warning: Patients should continue self-monitoring for visual changes (e.g., continue self-administration of Amsler grid testing) while using the NVHO device**

	**Warning: NOA estimations should be considered in the context of the variability observed across the range of estimations (i.e. larger percent variability for NOA quantification of smaller hypo-reflective spaces); lower notification thresholds in the presence of smaller hypo-reflective spaces will be inherently less reliable. A summary of the "006 Study" precision results is included in the Appendix.**

2.4. SCANLY PORTAL PRECAUTIONS FOR THE PHYSICIAN

Precaution: Data on the clinical performance of SCANLY Home OCT System was limited in the following populations: • **Patients with vision worse than 20/80** • **Patients of African and Asian decent and Hispanic/Latino patients** **Caution should be exercised when evaluating scans from these patient populations.** **In addition, the ability of patients with vision worse than 20/80 to successfully self-image and to generate consistently reliable images with the SCANLY Home OCT System is not well-characterized. Participants of the "006" clinical study comprised 21.5% of the safety cohort but 40.3% of those who failed to successfully self-calibrate.**
Always consider all the volume scan information available on the Portal. The presence of Hypo-Reflective Spaces on the edges of the scanned area may cause variability in the longitudinal estimation of the total space. Review of the Hypo-Reflective Spaces projection supports the identification of such cases. Refer to the Scan Quality Check section and to summary of the 006 study precision results in the Appendix. In addition, be aware that there may be hypo-reflective spaces outside of the 3×3-mm scan area. In the "001 Study," (see Section [fill in the blank]), 6.4% and 6.2% of sub-retinal and intra-retinal hypo-reflective spaces, respectively, were seen outside of the 3×3-mm scan area.
Regular and frequent review of all available B-scans, regardless of TRO level, is recommended to evaluate for appropriate scan centration and quality, for the presence of confounding pathologies, and for the presence of hypo-reflective spaces abutting or spanning the edge of the scan area*. Regular review of B-scans is also recommended to evaluate for hyper-reflective lesions such as hemorrhage.

Special care should be taken with interpretation of NOA estimations after an NVHO device exchange as the trajectory before and after the exchange may show a local discontinuity.

2.5. SCANLY PORTAL NOTES FOR THE PHYSICIAN

Upon receiving a notification, it is recommended to review all the individual SCANLY Home OCT B-scans from the most recent OCT volume scan. It is also recommended to review and consider the information available over several (at least three) scan timepoints in the trajectory. No single NOA estimation should be relied upon in making decisions about prompt patient follow-up.

2.6. SCANLY HOME OCT CLINICAL PERFORMANCE

Please refer to the Appendix.

2.7. GLOSSARY

Term	Definition
AI	Artificial Intelligence
AMD	Age-related Macular Degeneration
ETDRS	Early Treatment Diabetic Retinopathy Study
IRO	Intra-Retinal Hypo-reflective Spaces; IRO presence indicated by a hypo-reflective space located in the retina between the ILM and ISE layers
MSI	Manufacturer Signal quality Index
NOA	Notal OCT Analyzer
Notal PID	Notal Vision-designated Patient ID
NV-AMD	Neovascular Age-related Macular Degeneration
NVMC	Notal Vision Monitoring Center

Term	Definition
OCT	Optical Coherence Tomography
SRO	Sub-Retinal Hypo-reflective Spaces; SRO presence indicated by a hypo-reflective space located beneath the retina between the ISE and RPE layers
TRO	Total Retinal Hypo-reflective Spaces; The sum of IRO and SRO
VA	Visual Acuity

2.8. Adverse Events

No device-related adverse events were reported during the "001" and "006" studies performed for the SCANLY Home OCT. Report any adverse event to:

Notal Vision Inc.
7717 Coppermine Drive

Manassas, VA 20109

866-418-3387

casemanagement@notalvision.com

3. THE SCANLY HOME OCT SYSTEM OVERVIEW

The SCANLY Home OCT system allows Neovascular Age-related Macular Degeneration (NV-AMD) patients to self-scan their prescribed eyes at home, using a patient-operated home Optical Coherence Tomography (OCT) device, the SCANLY Home OCT device. The SCANLY Home OCT system, utilizing AI-based technologies, allows visualization and estimation of retinal hypo-reflective spaces in the central 10 degrees of the macula.

The SCANLY Home OCT System is comprised of two distinct components:

SCANLY Home OCT device, that allows patients to self-scan their eyes. At the end of each scanning session, the data is transmitted via a secured wireless communication to the Notal Health Cloud

Notal Health Cloud, a cluster of servers and analysis units that Notal Vision's proprietary algorithms run to analyze the scan data. Processed data is then presented on a dedicated interactive web-application, the SCANLY Portal.

3.1. SCANLY HOME OCT DEVICE

The SCANLY Home OCT device is a Spectral Domain (SD) OCT, designed for NV-AMD patients to self-install and then to self-image the central 10 degrees of the macula. The device is equipped with an external touch screen for viewing training materials and for administering the scanning flow. The device includes speakers for audio narration and auditory feedback. On first usage, the device runs a built-in tutorial that shows the user how to operate the device and self-scan. Subsequently, the device performs a calibration for each eye to account for the refractive error and eye length of the patient. Following the calibration, the user will be able to self-image. At the end of each scanning session, the OCT image data is automatically transmitted to the Notal Health Cloud.

Figure 3-1: The SCANLY Home OCT Device

3.2. NOTAL HEALTH CLOUD

Data from the SCANLY Home OCT device is transmitted to the Notal Health Cloud where it is stored in a secured database. The scanning data is processed through the following modules:

Volume Generator

In this module, the raw data is transformed into a sequence of B-scans that create the full volume scan of the macula. The Manufacturer Signal-quality Index (MSI) of the volume scan is calculated. The user can scroll through the B-scans using the SCANLY Portal (refer to sections below).

Notal OCT Analyzer

The Notal OCT Analyzer (NOA) is an AI-based software application within the Notal Health Cloud. It performs fully automated detection and segmentation of retinal hypo-reflective spaces including Intra-Retinal Hypo-reflective Spaces (IRO) and Subretinal Hypo-reflective Spaces (SRO) and estimation of Total Hypo-reflective Spaces (TRO) from SCANLY Home OCT macular cube scans. In addition, NOA generates (i) annotated B-scans, with areas of retinal hypo-reflective spaces shown color-coded according to hypo-reflective spaces type, (ii) en-face hypo-reflective

space projections (separately by IRO and SRO), and (iii) ranking of B-scans by order of largest to smallest hypo-reflective spaces (TRO) area.

SCANLY Portal

The eyecare provider and their designated staff have access to patient scan data through the cloud-based SCANLY Portal. After logging in, eyecare providers can select a patient's data to review by querying patient identifiers or by scrolling through the patient or notification list. After selecting a patient or notification, the eyecare provider can view data such as patient name, eye, and chronological SCANLY Home OCT scans.

The viewer tab utilizing NOA presents trajectories of total retinal hypo-reflective spaces (TRO) volume in volume units (VU) over the monitoring period. This information allows the user to identify the hypo-reflective spaces status and trends in volume estimation (TRO) between office visits. Eyecare providers can also scroll through the original B-scans with or without hypo-reflective spaces segmentation.

Additionally, hypo-reflective spaces projections of the B-scans are plotted onto an ETDRS grid. This guides the eyecare provider to the B-scans where hypo-reflective spaces are present and supports visualization of the morphology in a time-efficient manner.

The eyecare provider may use a simple interface to request a notification upon TRO reaching a certain volume threshold specific to that eye or to notify them that a certain number of days have passed since the last review. The notification criteria are defined by the eyecare provider based on their clinical judgement when a prompt review of the trajectory and related B-scan data is warranted to support their decision-making process.

4. PREPARING TO USE THE PORTAL

4.1. Obtaining User Profile Login

The NVMC creates a unique user profile for eyecare providers to access their patients' scan data through the cloud-based SCANLY Portal. User login information is shared directly from the NVMC via email.

4.2. Supported Browsers & System Configuration Requirements

For best results screens equal or larger than 24 inches are recommended.

Google Chrome is the supported web browser for the SCANLY Portal. Make sure to use its latest version. For optimal viewing, Google Chrome's zoom setting should be set at 100%.

4.3. Logging In

To log in to the SCANLY Portal, insert the following URL to the browser's address bar:

notalvision.info/OCTanalysis

Upon first login, users are asked to reset the initial temporary password.

For security reasons, when the system is idle for a long period of time it automatically logs out. To resume, log-in again.

4.4. Adjusting User Settings

Update settings as needed by clicking on the gear icon at the top right-hand side of the Portal.

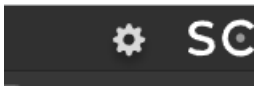


Figure 4-1 Settings Option

Notifications

Only prescribing physicians can update the notification default settings.

- **Initial Defaults – the default notification settings used for a newly prescribed eye**
    - **Initial state start: eye completes its first NOA eligible scan**
    - **Initial state end: first data review saved for this eye**
    - **By eye type, set Mute, TRO, and Time Interval settings as a default for all newly prescribed eyes. For example, initial default settings of TRO at 10 VUs and Time at 7 days will generate a notification when, after the patient completes their first scan, the TRO exceeds 10 VUs and/or the patient has been scanning for 7 days.**

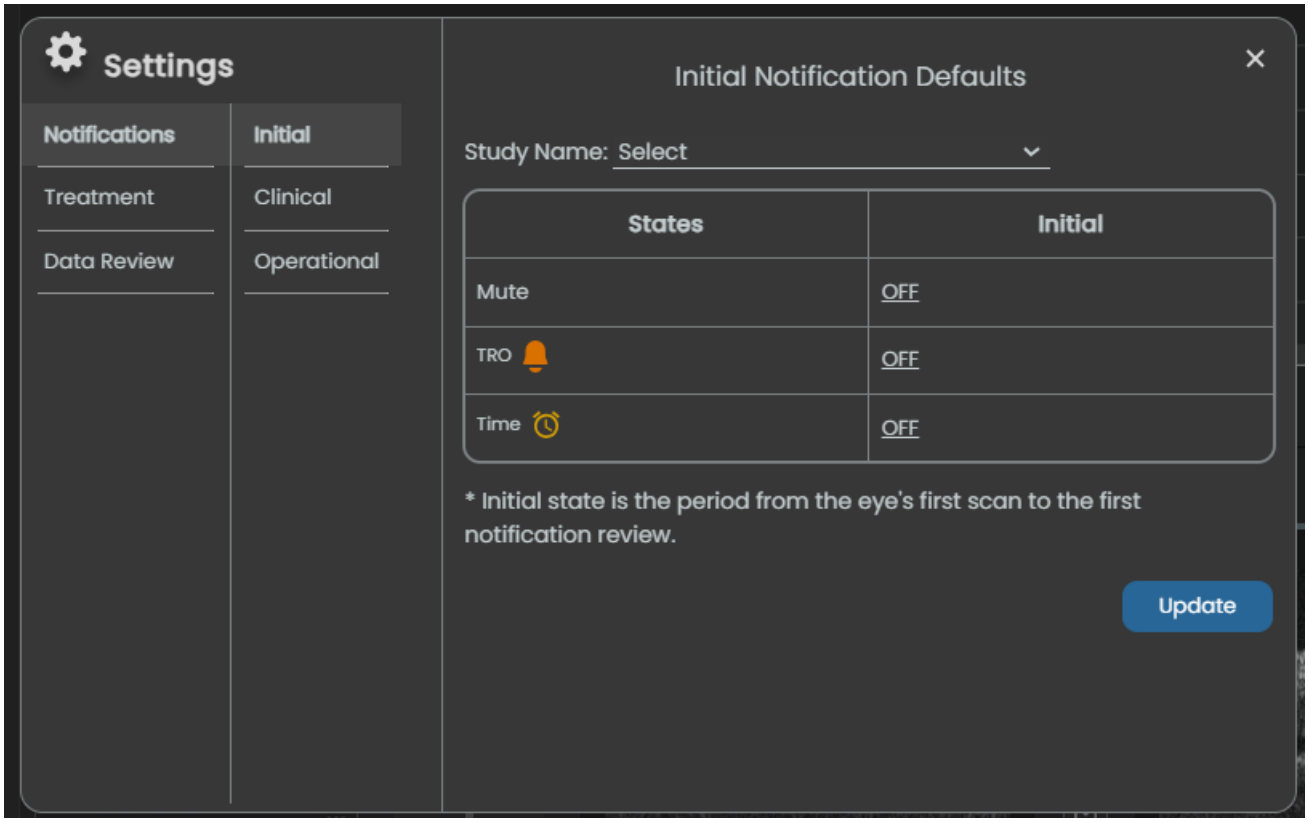


Figure 4-2 Initial Notification Default Settings

- **Clinical Defaults – the default settings used after the first data review. To assign settings more easily across the eye's journey, eyes can be categorized into the following states:**
    - **Monitoring State – the eye does not yet require a visit**

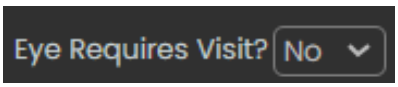


Figure 4-3 Eye Requires Visit set to No

        - **Monitoring State Start: saving that the eye does not require visit**

- **Monitoring State End: saving that the eye requires a visit or saving the notification settings following treatment entry**

- **Visit State – the eye requires a visit, but the visit information has not yet been entered (e.g. the patient is scheduled to come in for a future visit)**

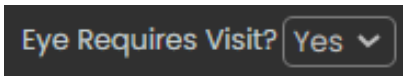


Figure 4-4 Eye Requires Visit set to Yes

- **Visit State Start: saving that the eye requires a visit**
- **Visit State End: visit information entered**

- **Treated State – the visit was completed, treatment entered, and updated notification settings saved**

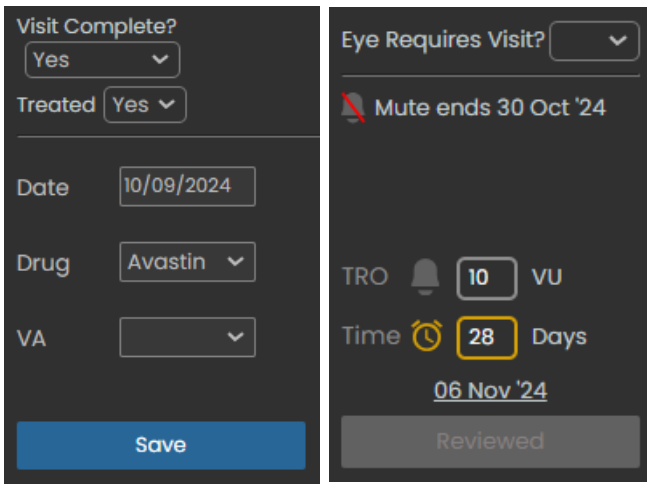


Figure 4-5 Treated State Settings

- **Treated State Start: saving the notification settings after treatment entry**
- **Treated State End: next "eye requires visit" decision made**

- **By eye state, set the mute, TRO, and Time Interval. For example, some providers may choose to keep TRO settings at a default level for eyes that don't require a visit. Additionally, they may choose to turn off or mute the notification settings while bringing patients into the office or while the TRO is resolving following treatment. Providers can also choose to store eye-specific settings. If they save a TRO value other**

than the default, the next time they review this eye, this setting will appear.

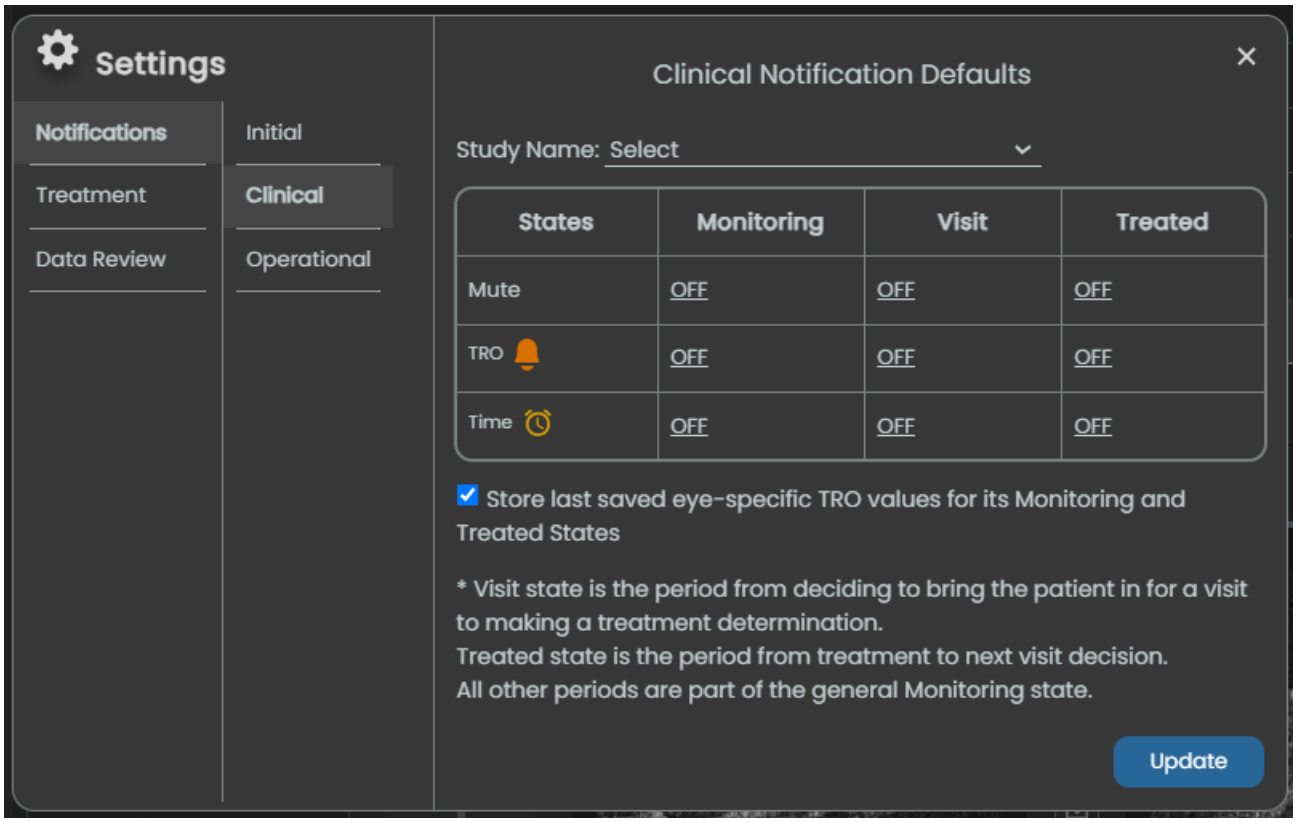


Figure 4-6 Clinical Notification Default Settings

- **Operational Defaults:**
  - **Adherence – notification if the patient has a gap of scans exceeding the adherence setting**
  - **Pause – notification if the patient sets a pause greater than the pause setting**
  - **Quality – notification if the eye has a gap of good scans exceeding the quality setting**
  - **Escalation – notification if a clinical (TRO or Time Interval) notification is open greater than the designated escalation period**
- **Operational defaults shall be set according to the doctor's discretion. The Notal Vision Monitoring Center is also responsible for supporting operational notifications, for example, for following up with patients after a gap of scans for 3 days in a row.**

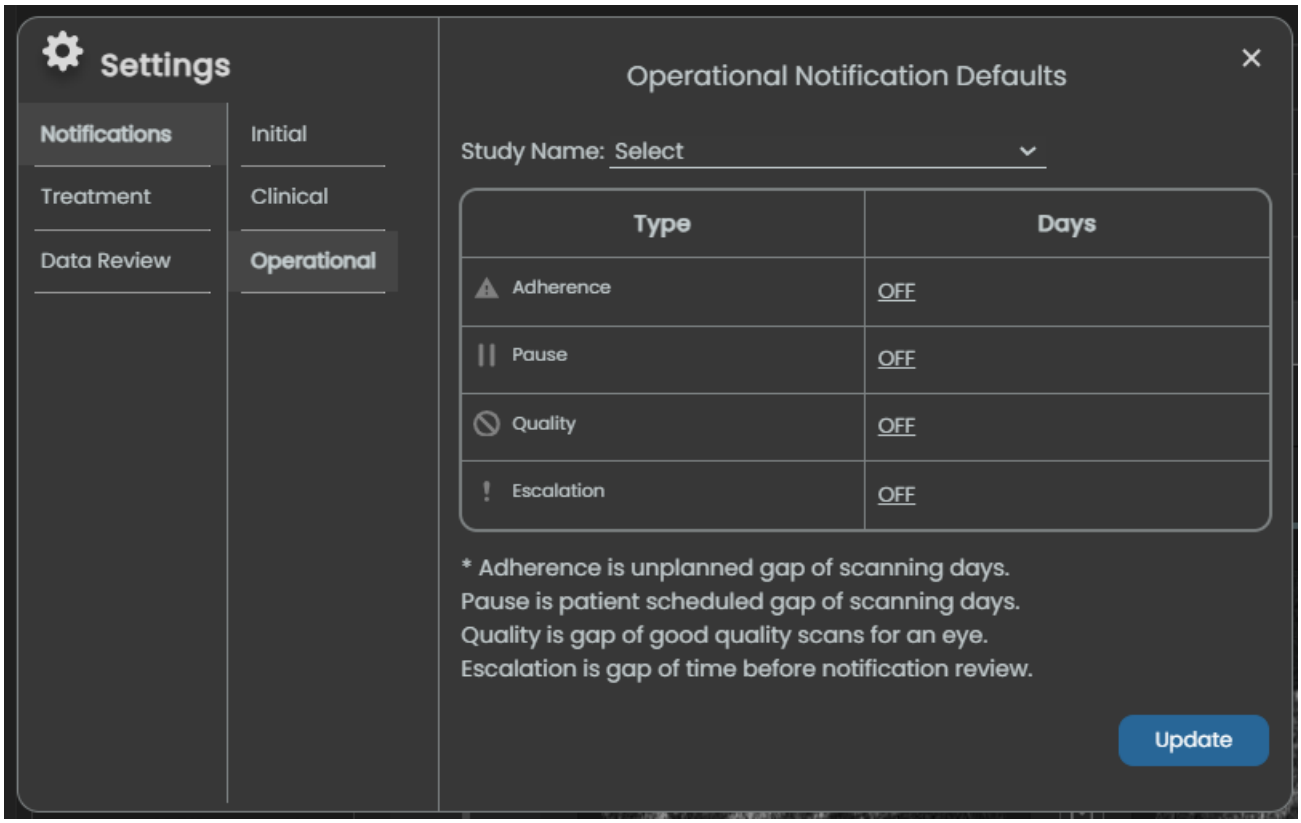


Figure 4-7 Operational Notification Default Settings

Treatment

Select default treatment settings:

- **Date – set default as today's date or blank**
- **Drug Type**
- **Treatment State Time Interval – set default from today or from the last treatment date**

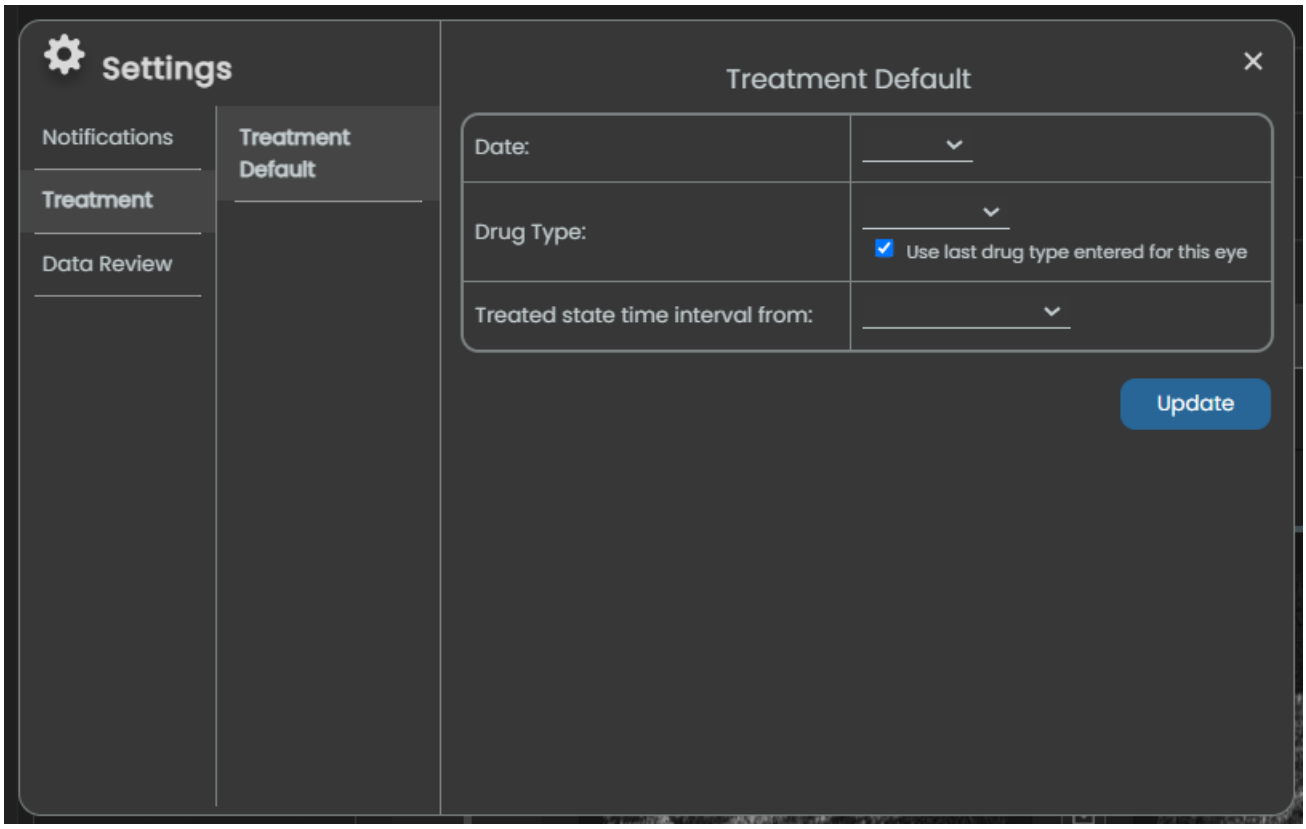


Figure 4-8 Treatment Default Settings

Data Review

- **Set Data Review defaults such as overlay, scroll speed, and scan locking.**

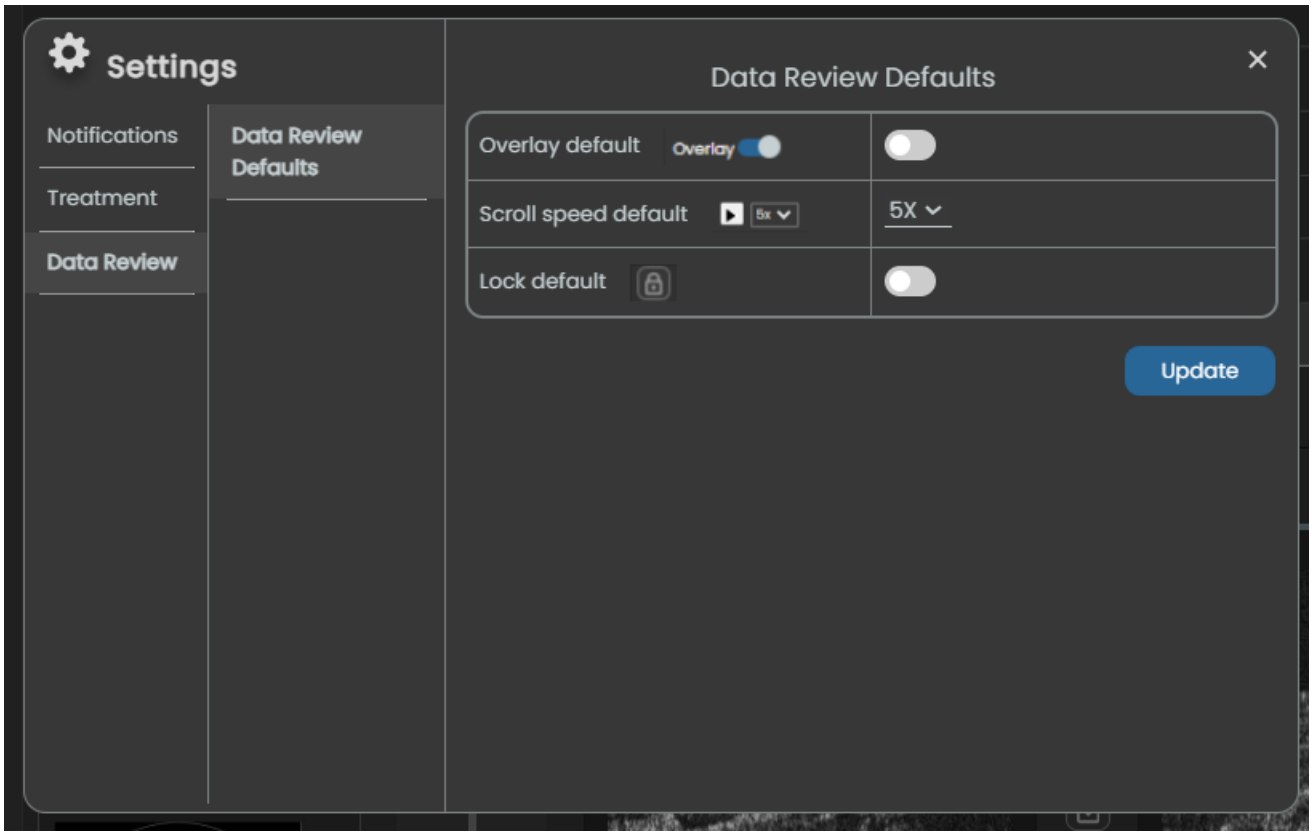


Figure 4-9 Data Review Default Settings

5. OVERVIEW OF THE SCANLY PORTAL INTERFACE

5.1. SCANLY PORTAL LAYOUT

There are three tabs at the top left of the Portal: Prescribe, View, and Info

The View tab is separated into three functional areas:

Patient/Notification Area – this section enables to toggle between "Patient list" mode in which you can select the patients you want their data to be reviewed and "Notifications" mode, which enables you to review notifications.

Data Review Area – this section presents the SCANLY Home OCT data. An interactive interface enables you to select the desired time-point(s) and B-scans to view.

Action Pane Area – in this section you can set, per patient and eye, hypo-reflective spaces quantities thresholds and time intervals. Once those thresholds are crossed and/or time intervals elapsed you'll get notifications in the Notification area.

The figure below shows the SCANLY Portal layout and main areas.

Figure 5-1: The SCANLY Portal main areas

5.2. Overview of Portal Symbols

The following information symbols appear in the SCANLY Portal.

Symbol	Description
	Complete Scan (Images tab)/Eligible Scan (NOA tab)
	Total Retinal Hypo-reflective Spaces - volume-based notification
	Incomplete Scan (Images tab)/Ineligible Scan (NOA tab)
	Lock function
	Multiple icons
	Acceptable MSI
	Poor MSI
	MSI not available
	Time-based notification
	Treatment

The following table describes the timeline's legend is Images and NOA tabs. For more details refer to "Selecting a date to review" section below.

Icon	Images Tab*	NOA Tab**
	Not reviewed completed volume scan	Not reviewed, eligible volume scan
	Not reviewed, incomplete volume scan	Not reviewed, ineligible volume scan
	Reviewed completed volume scan	Reviewed, eligible volume scan
	Reviewed, incomplete volume scan	Reviewed, ineligible volume scan

*** Completed scans are volume scans containing ≥ 80 B-scans**

**** Eligible scans are volume scans that meet the NOA criteria for estimation of the volume of hypo-reflective spaces. These include the spacing between B-scans that meet the image quality criteria of the individual B-scans.**

6. PRESCRIBING PATIENTS

6.1. CREATE NEW PRESCRIPTION

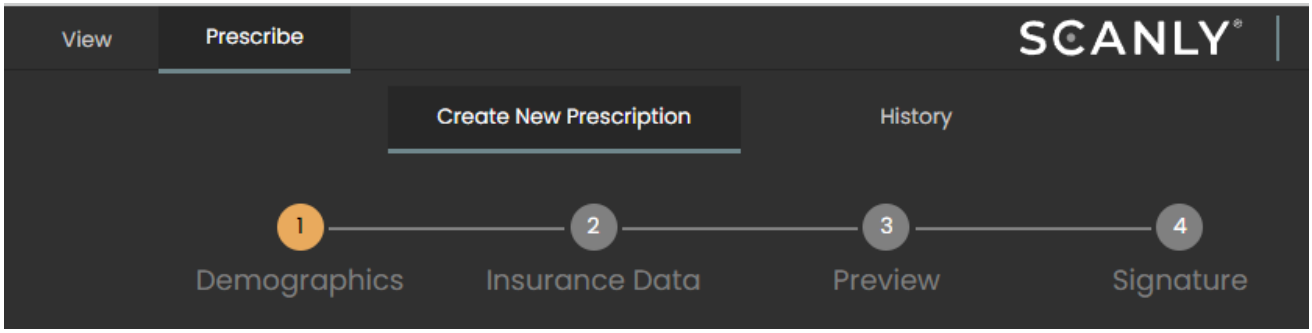


Figure 6-1 Create new prescription flow

Only doctors have access to the Prescribe tab in the Portal. To create a new prescription, enter the demographic and insurance data, preview, and sign. At least one eye must have a wet AMD diagnosis to save the prescription.

Your username and password must be entered to verify that you are the logged in user before signing.

After signing, there is an option to print, save, or send the prescription to an email address for reference.

6.2. PRESCRIPTION HISTORY

After signing the prescription, the patient's MRN, First Name, Last Name, Date of Birth, Prescribed date, and Prescriber are available in the History list.

7. SELECTING PATIENTS TO BE REVIEWED

7.1. PATIENT/NOTIFICATION AREA LAYOUT

Now, in the View Interface, the Patient/Notification Area allows users to select specific patients and eyes. The main components of the Patient/Notification Area are presented in the figure below.

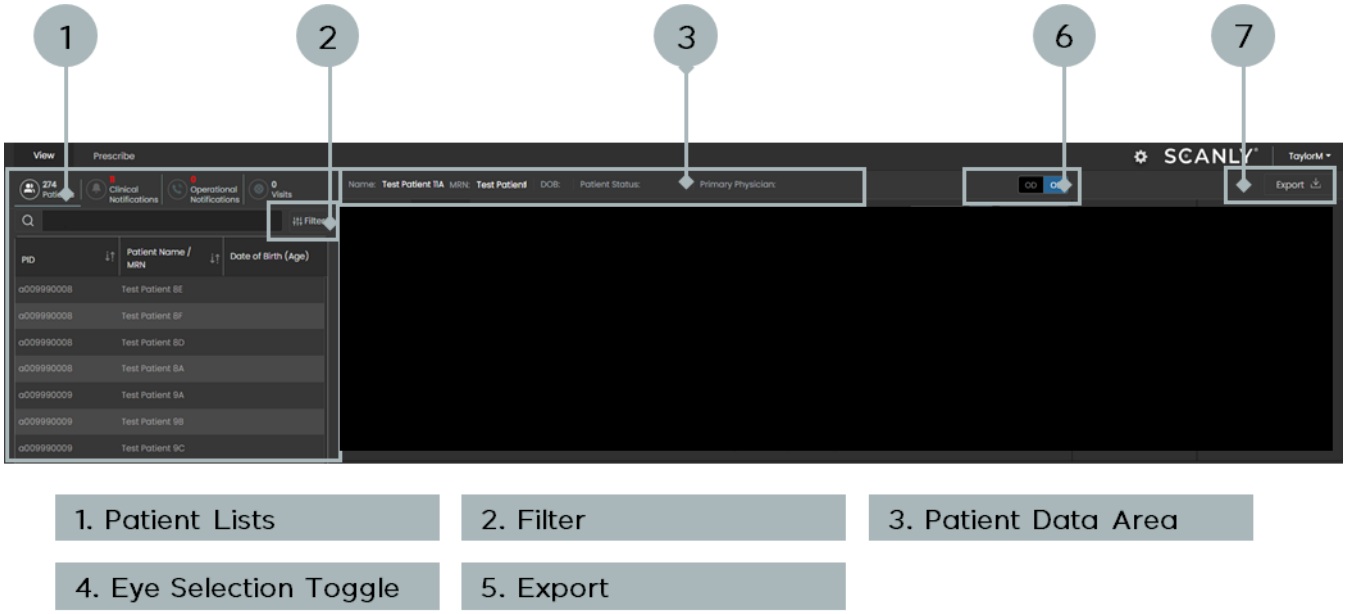


Figure 7-1: Patient/Notification Area - Components Layout

Note: The notification mechanism and interface are described below.

7.2. Select a Patient to Review

In the Patient/Notification Area, there are four different patient lists:

- **Patients List – select to view the full list of prescribed patients**
- **Clinical Notifications List – select to view the list of TRO and time interval notifications**
- **Operational Notifications List – select to view the list of adherence, lack of good quality, and pause notifications**
- **Visits List – select to view the eyes waiting for a visit entry**

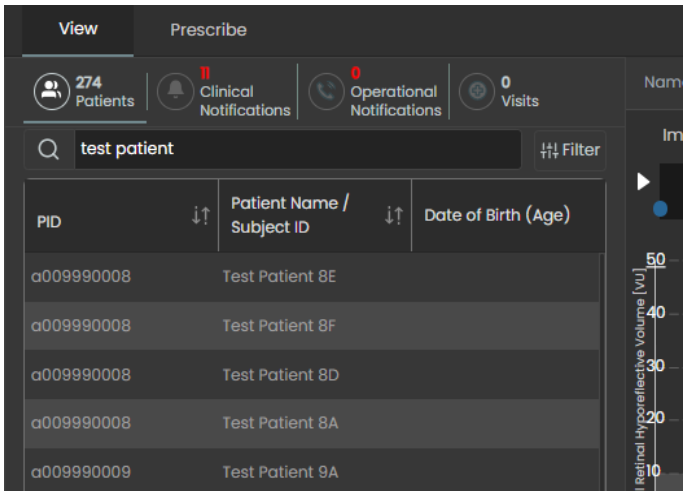


Figure 7-2: Patients List

Click on a list to display the associated patients. The selected patient's row will be highlighted. Select a different patient from the list by clicking on that patient's row. Scroll through the Patient List using the Scroll Bar located on the right side of the list.

Items in the list can be sorted using the Up/Down Arrows Icon located next to each column header (e.g. Patient Name, or MRN). Clicking that icon will toggle between descending and ascending sort, based on that column's information.

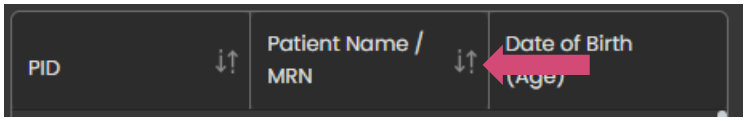


Figure 7-3: Patient List Headers

Search for a specific patient by entering key patient criteria (e.g., Patient Name, or MRN) into the Search Bar located above the Patient List.

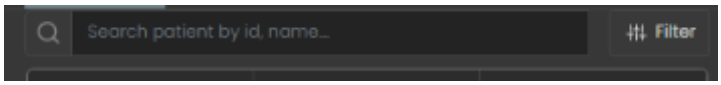


Figure 7-4: Search Bar

Use the Patient List Filter option to focus on patients of interest.

Figure 7-5: Filter Control

Clicking on the Patient List Filter icon opens a category filter: by Practice or by Physician. This is based on the practice(s) that the user is registered with.

A list of the corresponding data will be presented on the right side of that pane.

Select the data, e.g. physician names, when you want to view their associated patients in the Patient List.

The selected items are highlighted and check marked. Click Apply to run the filter or Reset to de-select and return to default Patient List.

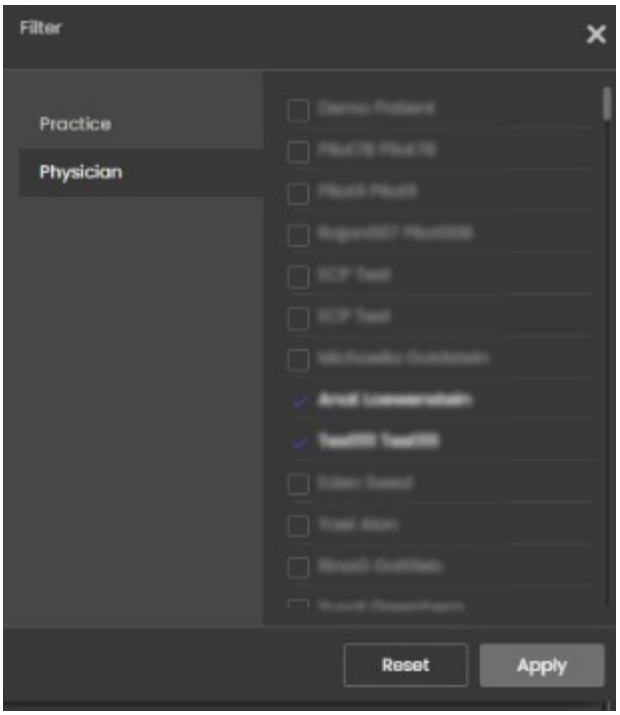


Figure 7-6: Filtered List

7.3. SELECTED PATIENT - DATA AND OPERATIONS

Once the patient is selected for review, the corresponding row in the Patient List is highlighted.

The patient's details appear in the Patient Data area.

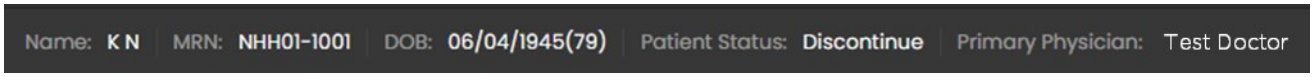


Figure 7-7: Patient Data

Patient Statuses include:

- **Pre-Activation – patient does not yet have a successful scan in a wet AMD eye**
- **Activated – patient is actively scanning on the program**
- **Decline – patient decided to dis-enroll before a successful scan in a wet AMD eye**
- **Discontinue – patient decided to dis-enroll after scanning on the program**

Use the Eye Selection Toggle to select between OD and OS eyes.

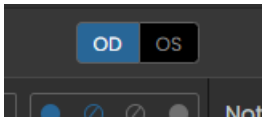


Figure 7-8: Eye Selection Toggle

Note: Selecting a date with no scan results in no scan information displayed. If one of the eyes was not prescribed for self-scanning, this eye (OD or OS) does not appear in the Eye Selection Toggle.

To review the scan history of the selected patient, click the + sign on the left side of the highlighted line.

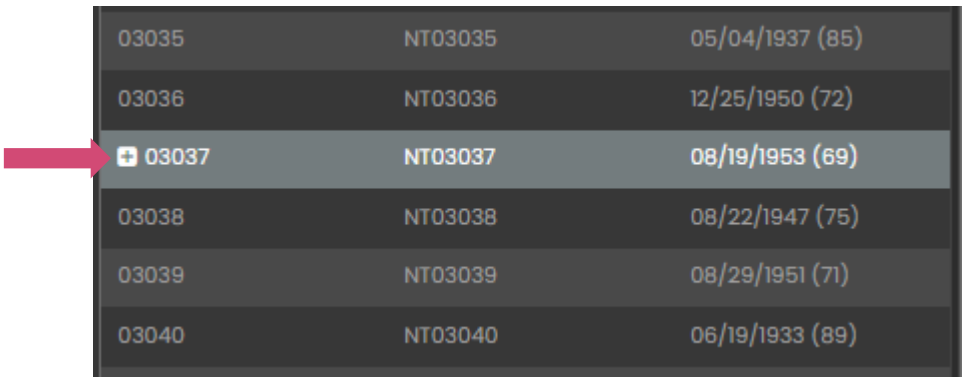


Figure 7-9: Scan History – Collapsed

A scan-history list will appear. To collapse back click the – sign.

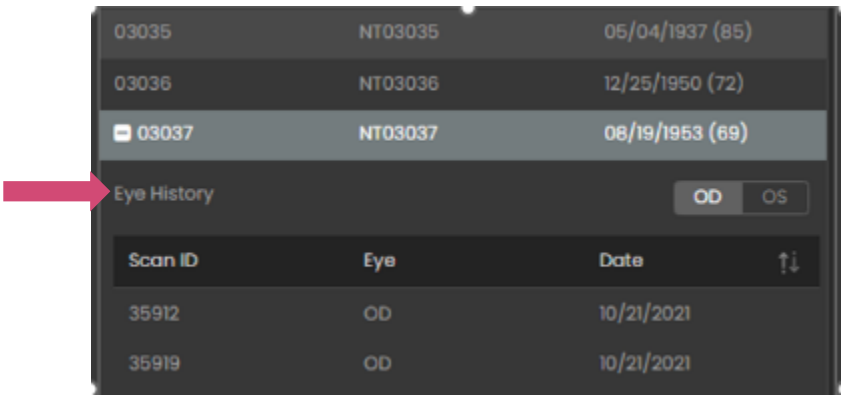
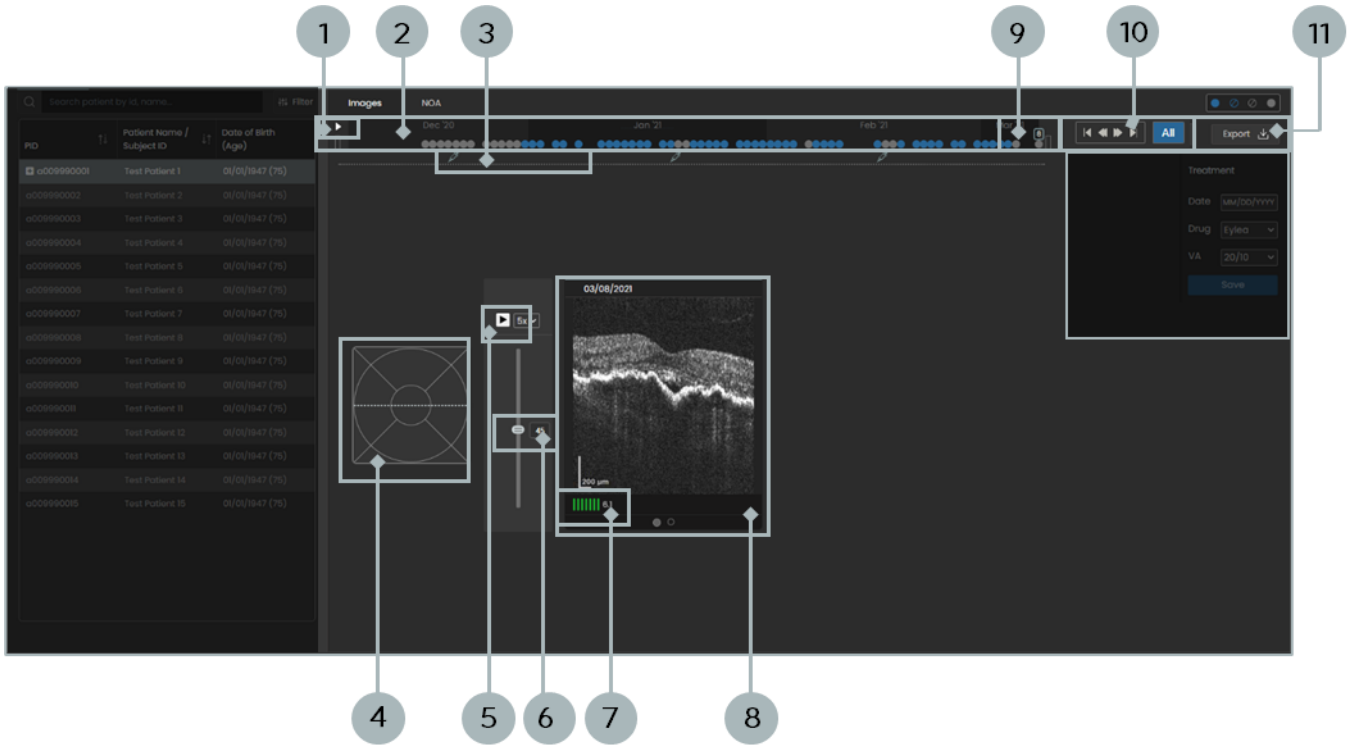


Figure 7-10: Scan History – Expanded

8. DATA REVIEW AREA – IMAGES TAB

8.1. IMAGES TAB LAYOUT

In the Images tab, you can review your patient's volume scan on a selected date by flipping over the reconstructed B-scans. The main components of the Images tab are presented in the figure below.



1. NOA Movies	2. Timeline	3. Treatment Icons
4. ETDRS Grid	5. Scan Player	6. Scroll Handle
7. Manufacturer Signal quality Index (MSI)	8. B-scan	9. Date Selector(s)
10. Time Range Display	11. Export Button	

Figure 8-1: Patient/Notification Area - components layout

8.2. Select Date to Review

The Timeline for the selected eye is displayed at the top of the Data Review Area. The months and years are shown along the timeline and the blue and gray circles indicate specific dates that the patient self-scanned that eye.

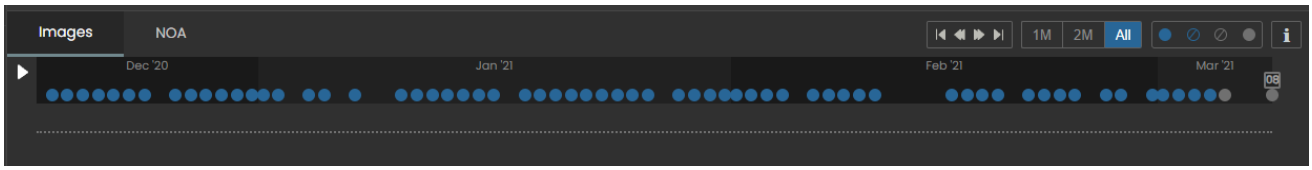


Figure 8-2: Timeline

The Date Selector indicates the date of the month that is selected. For example, the date selected below is March 8, 2021.

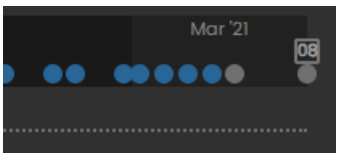


Figure 8-3: Date Selector

There are three methods to select a date to review:

1. **Click on the blue or gray scan indicators in the Timeline – the date selector jumps to the new date.**

2. **Click on the Date Selector and drag it to a new date while holding your left mouse button.**

Figure 8-4: Date Selector

3. **Click on the date above the currently presented B-scans and use the Calendar control to select a new date.**

Figure 8-5: Selecting Date to Review

Note: Days without scanning data appear disabled (black) in the calendar.

Once a date is selected, the corresponding data is presented below the timeline and the scan indicator turns gray to indicate that the data on that day was reviewed.

Note: Selecting a date with no scan results in no scan information displayed.

8.3. CHANGE TIMEFRAME

There are different tools available to navigate the timeline. To start, the system will predetermine the timeframe to select based on the data available. For example, if there are less than 30 days available, the system will display the first 30 days. If there are between 30 and 60 days available, the system will display 60 days. If there are over 60 days available, the system will display 90 days. The timeframe selected can be shown by the month buttons (1M, 2M, 3M, etc.), where "All" means that all data is currently displayed.

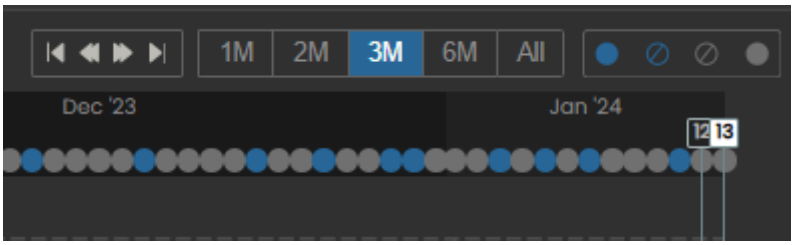


Figure 8-6 Timeframe Selector

Use these icons to navigate to the first and last two scans.

Figure 8-7 Timeframe Navigation - first and last scans

Use these icons to navigate by selected period.

Figure 8-8 Timeframe Navigation - next or past period

Zooming in and out

Click on the timeline and perform the following actions:

- **Scroll forward or backward with your mouse wheel**
- **Swipe up and down with your mousepad using two fingers**

Note: when zooming out past a 3-month period, scanning days will be sampled and some data WILL NOT be displayed!

Panning right and left

Click on the timeline and perform the following actions:

- **Click the left button on your mouse and drag the timeline left or right**
- **Press on the left side of your mousepad and drag the timeline left or right**

8.4. REVIEW B-SCANS

You can review the B-scans of the selected patient eye and date in the Data Review Area.

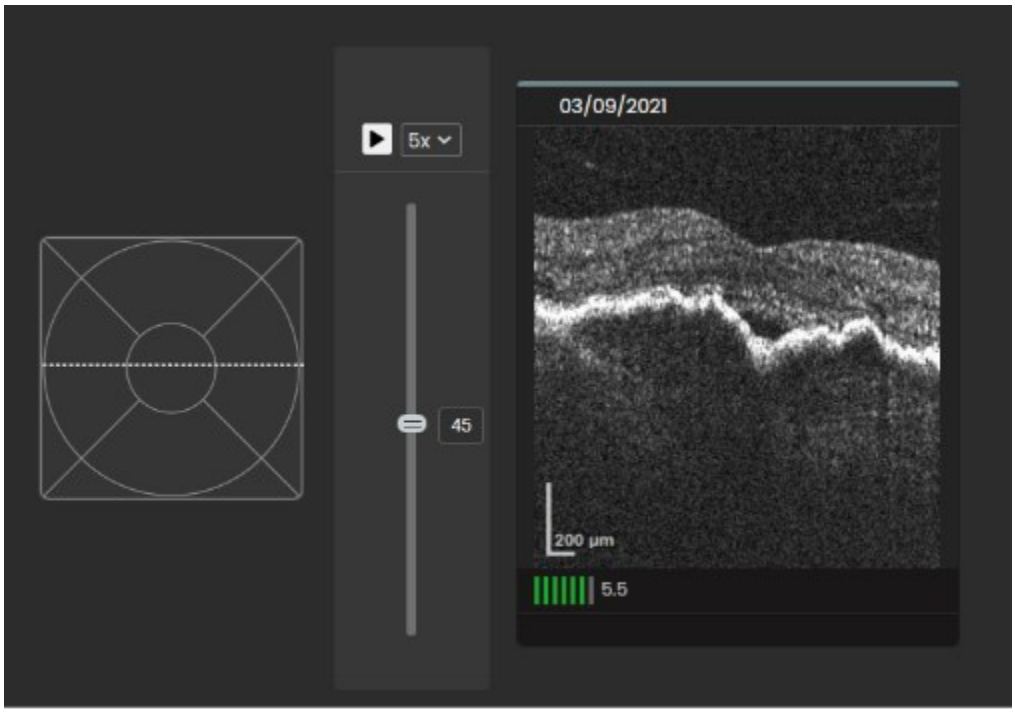


Figure 8-9: Images tab – B-scans review

The right panel presents the reconstructed selected B-scan. The date that volume scan was performed appears above the B-scan image. The Manufacturer Signal-quality Index (MSI) is displayed below the B-scan image (refer to Quality Check Tools below).

The middle panel contains the Scroll Handle that shows the order of the currently selected B-scan (45 in the example presented above). It also contains the Scan Player function to scroll through the scans.

The left panel shows the location of the selected B-scan on an ETDRS grid.

By default, the selected B-scan is the central macular section – see location in the example above. Select a different B-scan to review by clicking on the Scroll Handle and dragging it to a new location or by clicking on a location in the ETDRS Grid. Updating the selection using one method will update the presentation of the selected B-scan in the corresponding one.

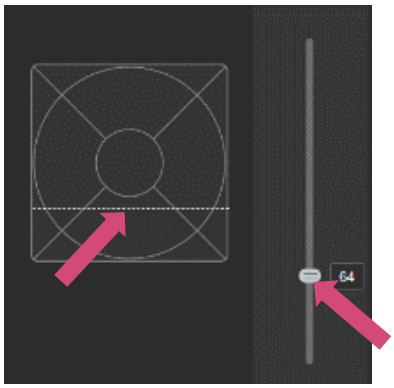


Figure 8-10: Images tab – Scan Scrolling Features

Use the Scroll Handle to flip through the entire volume scan, sequentially, B-scan by B-scan.

Open the drop-down menu located to the right of the Play icon and select the scroll speed – 1 is the slowest; 5 is the fastest.

Click on the Play icon. The B-scans are displayed sequentially according to their ordinal order.

The B-scan location on the EDTRS grid and on the B-scan Position Selector are updated accordingly.

During the animation, to pause the movie, click the Play icon. the Play icon then turns into Pause.

Figure 8-11: Images tab – Scan Scrolling Features

9. REVIEWING PATIENT DATA – NOA TAB

9.1. NOA TAB LAYOUT

This tab displays the NOA estimation of TRO over time. You can select two scans and review their corresponding Hypo-reflective Spaces Projections and scroll through their hypo-reflective spaces -segmented overlayed B-scans.

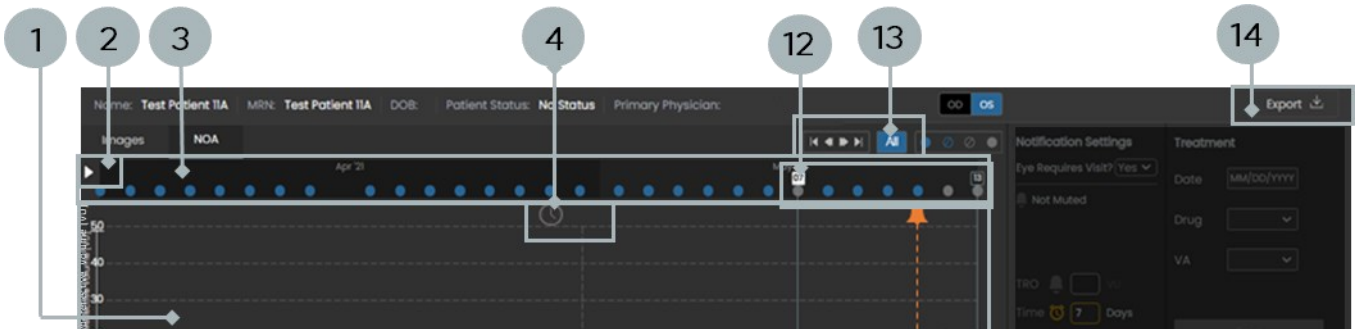
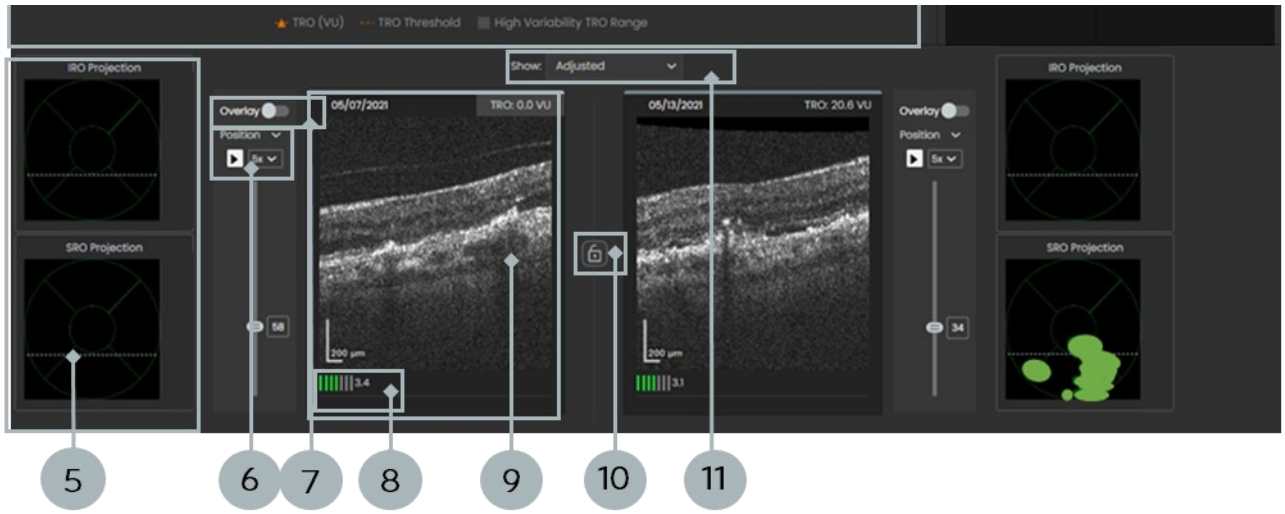


Figure 9-1 NOA Tab – Components Layout



1. Hypo-reflective Spaces Volume Trajectories	2. NOA Movies	3. Timeline	4. Event Indicators
5. Hypo-reflective Spaces Thickness Maps	6. Scan Player	7. AI Segmentation Overlay	8. Manufacturer Signal Quality Index (MSI)
9. B- Scan	10. Lock Images	11. Present Time Points	12. Date Selector(s)
13. Time Range Display	14. Export Button		

9.2. Selecting Scans to Compare in the NOA Tab

For a detailed description of the Timeline functionality and notations, review "Change Timeframe" in the Images tab section above. While in the Images tab, you are only able to select a single scan to review at a time. In the NOA tab, you can select and compare two scans of the examined eye.

In the NOA tab, one date selector is "active" at a given time, meaning if you select a date in between the two date selectors, only the active date selector will move. Click on the date selector, scan, or scan scroller, to select that date selector as active. This is shown with the gray fill at the top of the B-scan and date selector itself.

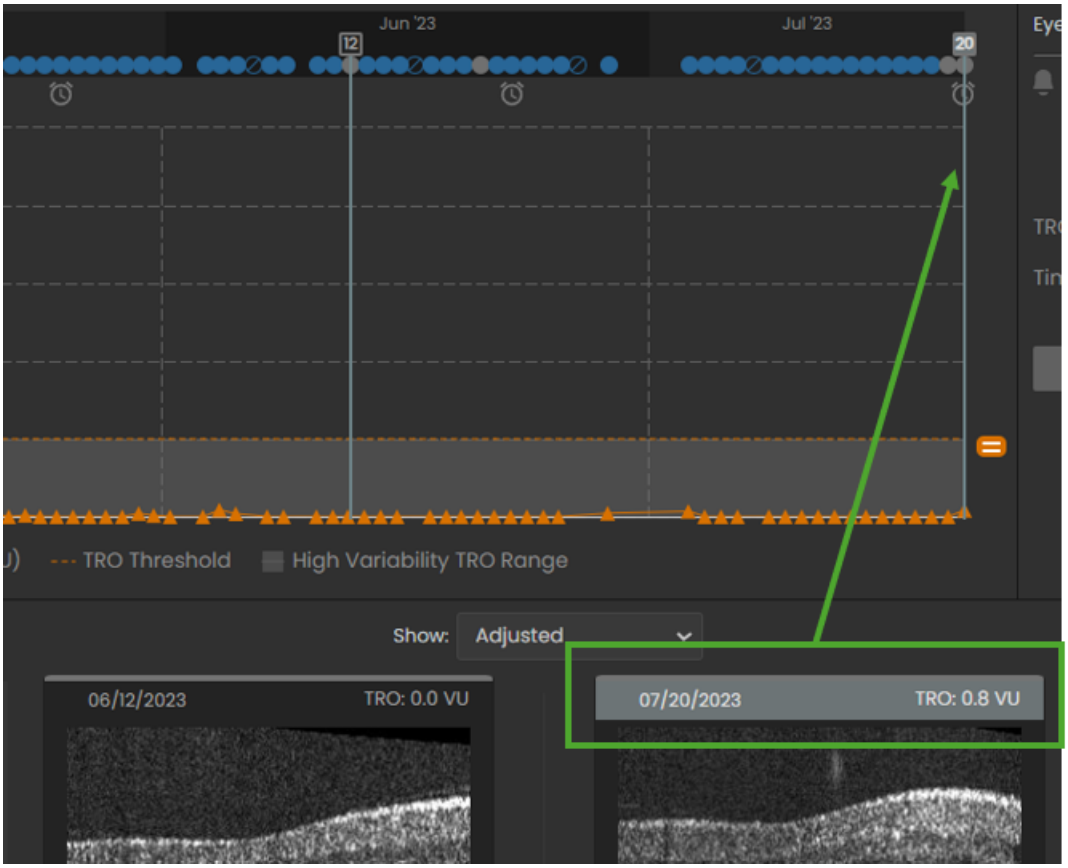


Figure 9-2 Active Date Selector

Clicking on a date to the right of the date selectors automatically moves and activates the right-hand date selector. Clicking on a date to the left of the date selectors automatically moves and activates the left-hand date selector.

The left-hand Date Selector is not able to be moved to the right-hand side of the right Date Selector. The right-hand date selector is not able to be moved to the right-hand side of the right Date Selector.

To select two dates to compare:

- **Click and drag the Date Selectors to a new date.**
  Click on a date in the graph to move the Date Selectors as mentioned above.

The data associated with those two scans, including B-scans and hypo-reflective spaces projections, are presented side-by-side at the bottom of the Viewer. In the example below, the data related to the first scan (blue arrow) is marked by an blue rectangle and the data related to the second scan (green arrow) is marked by a green rectangle.

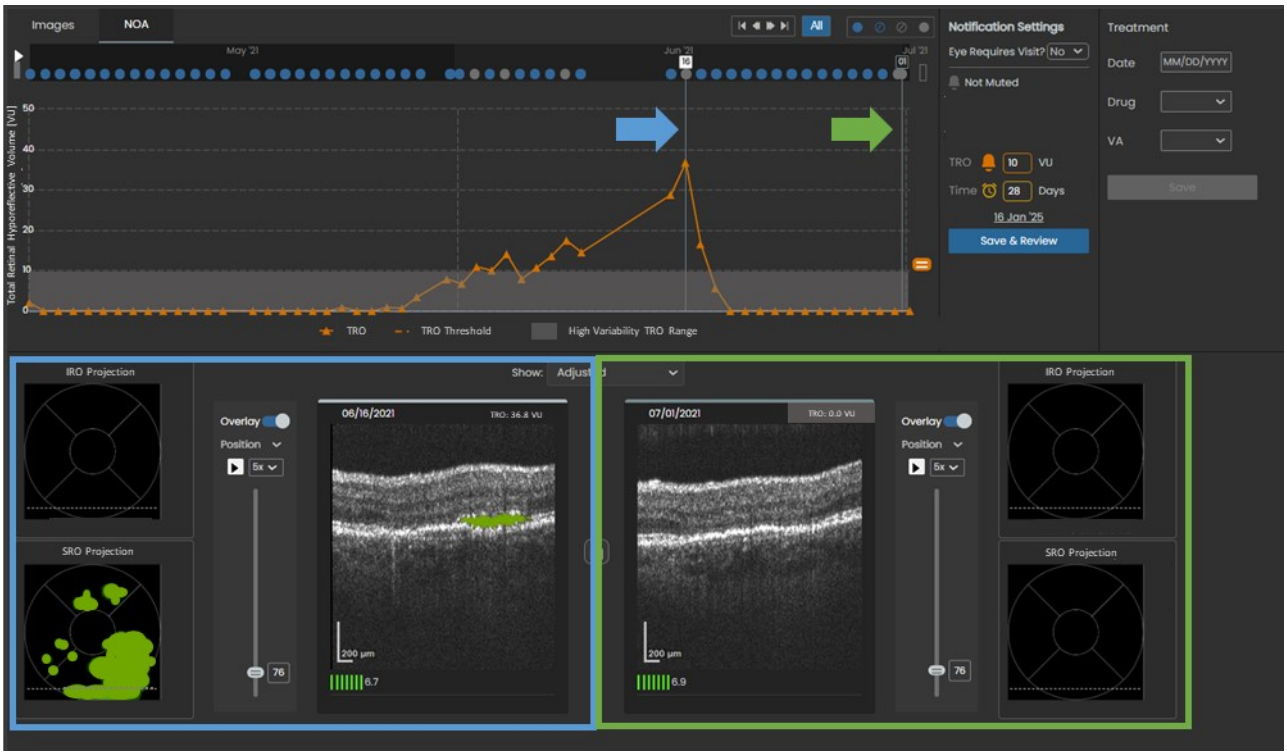


Figure 9-3: NOA tab – Selected test points and their corresponding data

9.3. Display Preset Time Points

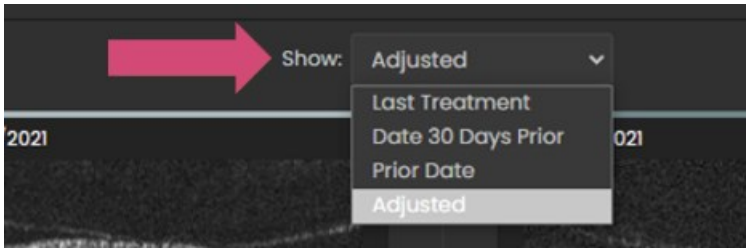


Figure 94: The Show Control

In the NOA tab, use the Show function to select preset time points. Click the "Show" drop-down list located above the B-scans pane and select the associated setting.

9-

NOTE: The preset time points only adjust the earlier (left) scan, while the right scan is set to the last scan performed by the reviewed eye.

Show options:

Option	Left-hand Date Selector	Right-hand Date Selector
Last treatment	Last treatment date	Last scan date
30 days prior	Last scan closest to 30 days prior to last scan date	Last scan date
Prior Date	Date prior to last scan	Last scan date
Adjusted	Will be displayed when you manually select the dates	

9.4. Reviewing Hypo-reflective Spaces Trajectories

NOA identifies, localizes, and estimates the size of hypo-reflective spaces in the 3x3 mm area centered on the point of fixation. NOA calculates the hypo-reflective spaces volume based on segmentation of the hypo-reflective spaces area on each B-scan and the spacing between neighboring B-scans.

NOTE: Additional hypo-reflective spaces **may be present outside of the scan area.**

NOTE: It is recommended to review and consider the information available over several (at least three) days in the trajectory. No single NOA estimation should be relied upon in making decisions about prompt patient follow-up.

TRO trajectory is plotted in a chronological manner to show a graphical representation of the TRO trend over time and assist in monitoring your NV-AMD patient.

The following figure shows an example of TRO trajectory of hypo-reflective spaces (in VU) over time.

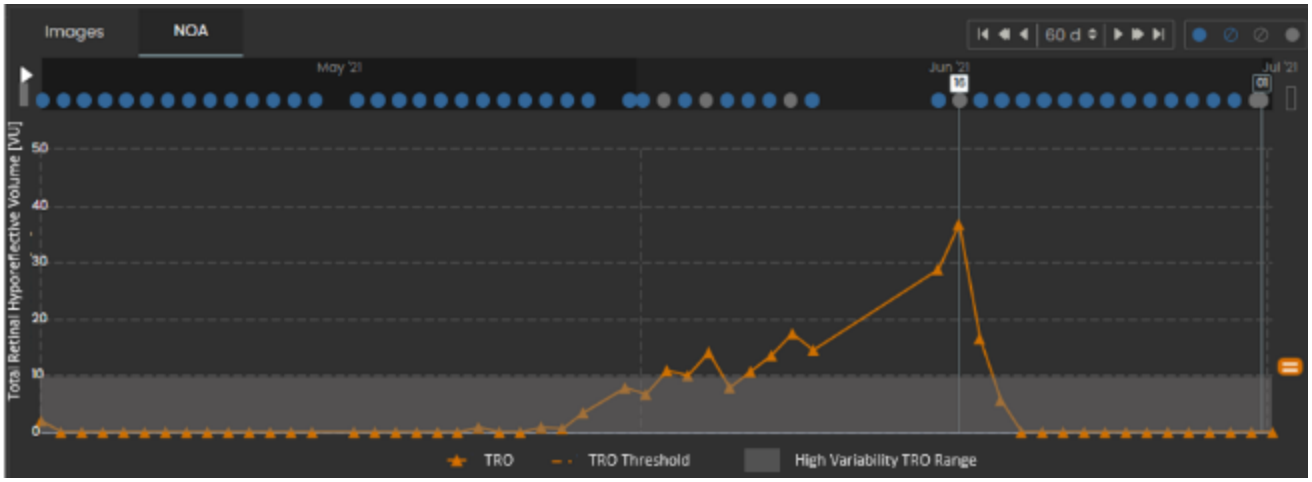


Figure 9-5: TRO trajectory

NOTE: The TRO Trajectory **presents the** Hypo-reflective Spaces **dynamics of the selected eye.**

NOTE: TRO data from ineligible scans are not displayed in the hypo-reflective spaces trajectory of the NOA **tab and will not trigger a TRO notification**.

9.5. Reviewing Hypo-reflective Spaces Projections

NOA segments SRO and IRO on each B-scan and then plot the SRO and IRO Hypo-reflective Spaces projections over ETDRS grids. SRO projection is colored in Green and IRO projection is colored in Blue. The horizontal dashed line across the hypo-reflective spaces thickness maps represents the position of the B-scan that appears next to it. This feature allows visualization and selection of areas with high amounts of hypo-reflective spaces. Selecting a new position on the Hypo-reflective Spaces Projection changes the displayed B-scan.

Use the hypo-reflective spaces projections to review the spatial distribution of the retinal hypo-reflective spaces and to select B-scans of interest.

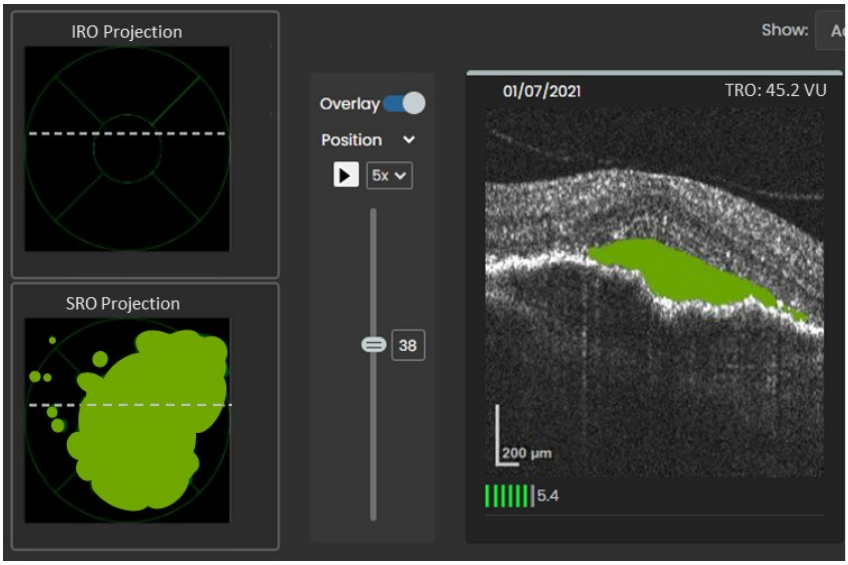


Figure 9-6: Hypo-reflective Spaces Projections next to a selected B-scan

9.6. Reviewing B-scans in the NOA Tab

For a detailed description on how to review and select B-scans, "Reviewing B-scans" in the Images tab section above.

NOTE: While in the Images **tab you select a single test point to review, in the** NOA **tab you can select and compare two test points of the examined eye**.

The following features are exclusive to the NOA tab:

9.7. Toggle Switch for NOA Segmentation Overlay

To present the reconstructed raw B-scans or B-scans with NOA segmentation overlay, use the Overlay toggle.

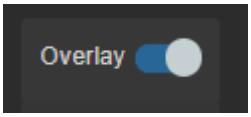


Figure 9-7: Overlay Toggle Control

When the Overlay toggle is ON, IRO segmentation overlay is displayed in blue and SRO segmentation overlay is displayed in green. Note that there is a separate Overlay toggle for the left and right scans.

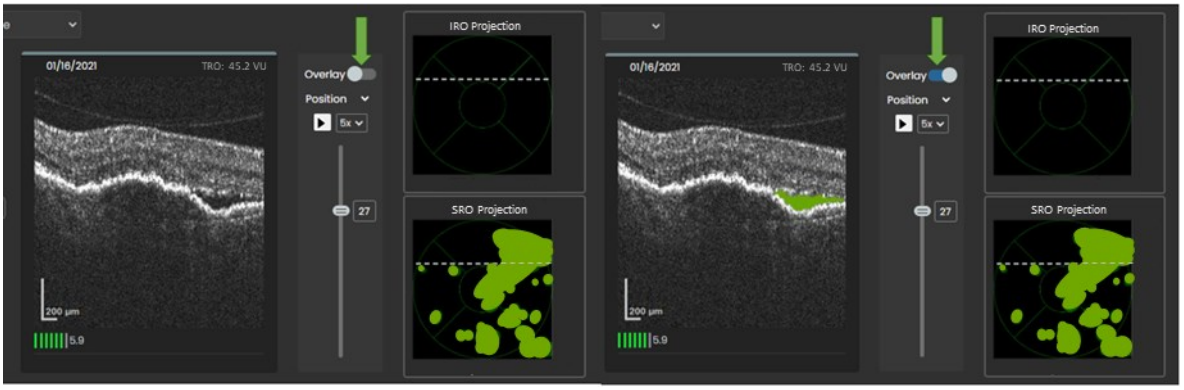


Figure 9-8: B-scans without (left) and with (right) IRO and SRO segmentation overlay

NOTE: It is recommended to review the raw B-scans.

9.8. B-SCAN SCROLLING OPTIONS

For a detailed description on how to review and select B-scans, "Reviewing B-scans" in the Images tab section above.

In the NOA tab, you can scroll through the scans based on additional criteria.

Note that there is a separate B-scan Position Selector to the left and right test points.

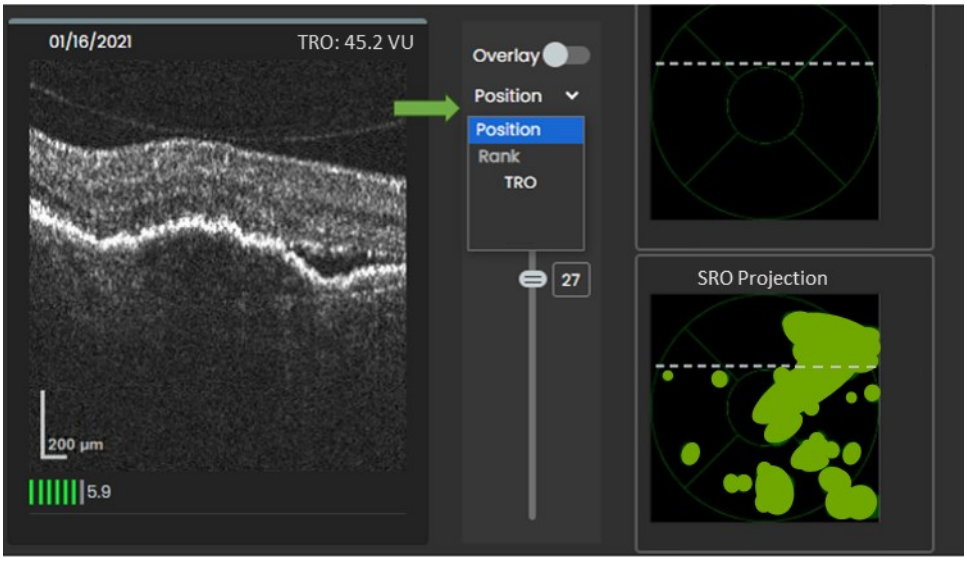


Figure 9-9: B-scan Scrolling Options

The scrolling options are:

Scrolling Option	Scrolling Order
Position	B-scan position in the volume scan (mid position is the fixation point)
Rank->TRO	TRO area, where rank 1 is the B-scan with the largest TRO area

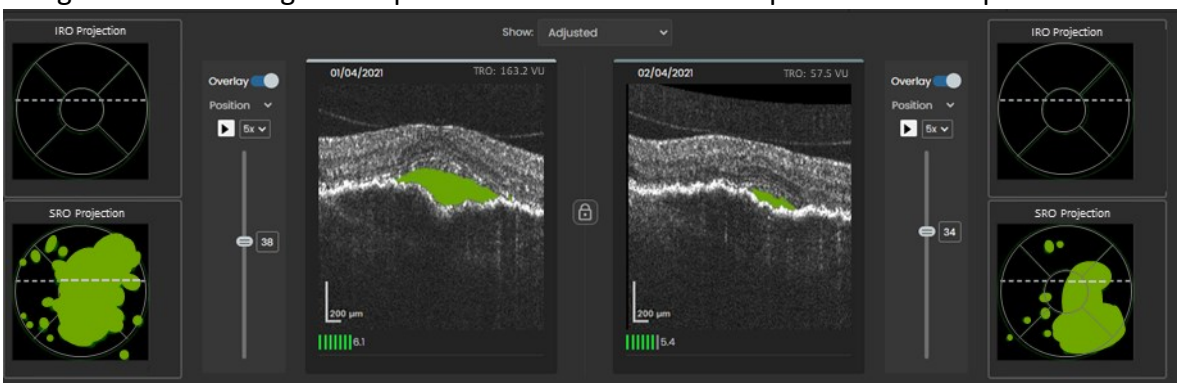
9.9. Locking Images

Click the Lock icon to toggle between Locked and Unlocked scans.

In the Unlock state, the scans can be scrolled through separately.

In the Lock state, when the B-scan position changes on one scan, the NOA algorithm selects the matching B-scan position on the other scan. In the example below, the first selected (left) scan is before this eye was treated and the second selected (right) scan is 3 weeks later. By using the Lock state, you can see the reduction in SRO area following the treatment in B-scans approximately on the same position.

Figure 9-10: Locking to compare between similar B-scan positions in test points.



Note: when Lock **is selected, the Scroll Option for both scans resets to** Position

9.10. NOA Movies

The NOA Movies function allows you to quickly view hypo-reflective spaces projection changes over time. To run the NOA Movie, click on the Play button located above the right side of the Timeline. When running, the date indicator will start from the first timepoint and will jump to the next timepoint, while resting at each timepoint.

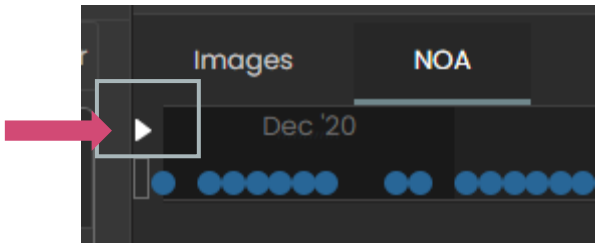


Figure 9-11: NOA Movies

When the lock function is on, this feature will display B-scans with a similar location with respect to the patient's fixation point. When the lock function is off, this feature will display B-scans with the highest total retinal hypo-reflective spaces.

When pressed, the Play button is changed to Pause. Click on the Pause button when you want to stop the movie for further review.

10. SCAN QUALITY CHECK

10.1. QUALITY CHECK TOOLS

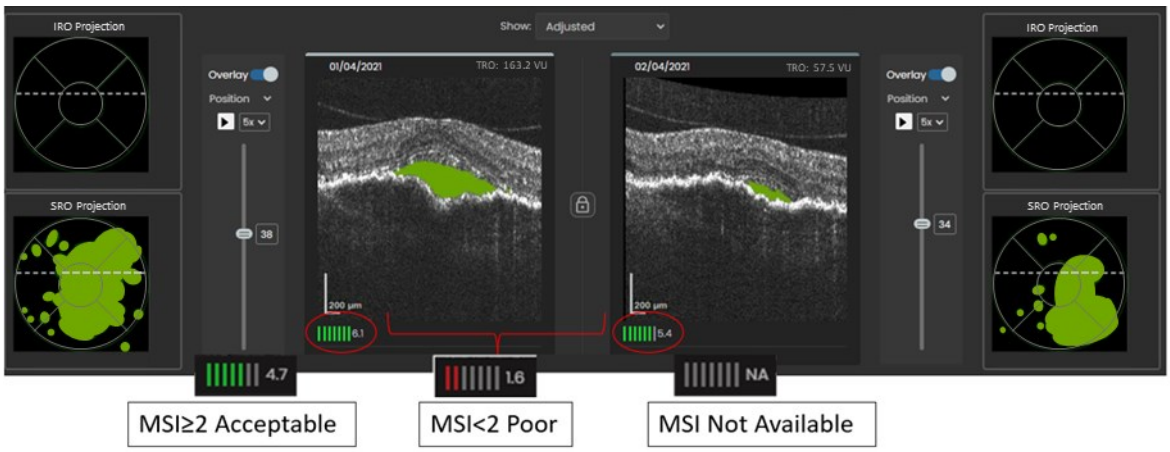
Manufacturer Signal-quality Index (MSI)

The volume-scan MSI is displayed at the lower left corner on the selected B-scan(s).

Note: in the Images tab, one test point with a corresponding volume scan is presented, while in the NOA tab there are two selected test points.

The scale of the MSI is between 0 to 7. Volume scans with MSI values below 2 are poor and is indicated by a red color. Acceptable volume with MSI >=2 is indicated by a green color. The eyecare provider is advised to look for scans with better quality in the adjacent time points if available.

Figure 10-1: Display of the MSI in the Portal– NOA tab



10.2. CRITERIA FOR IMAGE ACCEPTANCE

In addition to the MSI, the operator should qualitatively assess the scan quality for major image artifacts and segmentation errors in the image(s).

This review should include visualization of the B-scans, the TRO trajectory, the hypo-reflective spaces projections, and the segmentation overlay of the hypo-reflective spaces on B-scans.

Upon identification of an imaging or NOA artifacts, it is recommended to review other time points. Examples of artifacts are shown below:

Differentiation of hypo-reflective spaces type in individual or multiple B-scans

To evaluate how well NOA differentiated between hypo-reflective space types (IRO versus SRO), the eyecare provider should review B-scans for accuracy of hypo-reflective spaces segmentation at locations where horizontal streaks or sharp discontinuities of hypo-reflective spaces appear on the projections.

The figure below shows retinal hypo-reflective spaces estimation from two consecutive dates. An artifact caused the SRO to be mistakenly identified as IRO by the NOA. Such artifact is characterized by horizontal streaks or sharp discontinuities of hypo-reflective spaces as seen in the left upper IRO projection (see arrow).

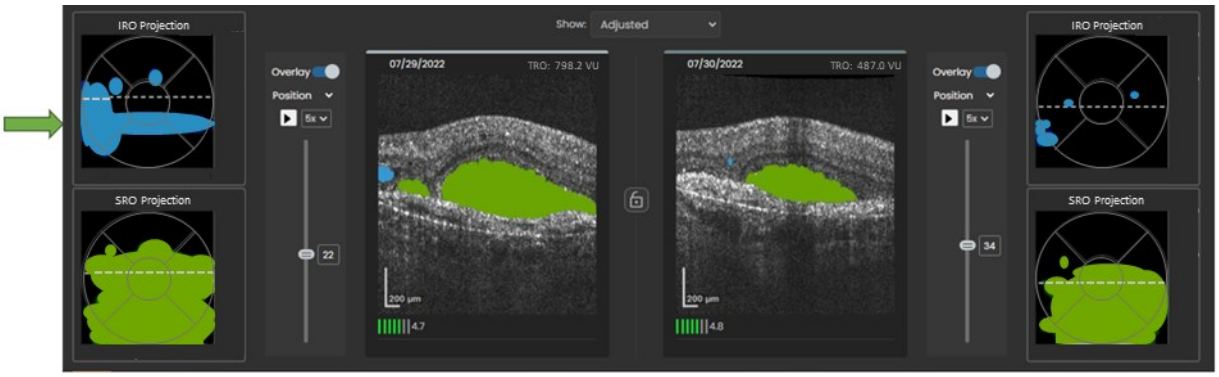


Figure 10-2: Hypo-reflective spaces type differentiation artifact

Incorrect segmentation of hypo-reflective spaces

Whenever the report indicates the presence of a sharp discontinuity of the IRO or SRO presented in the hypo-reflective spaces projection, the eyecare provider is advised to scroll through the B-scans with and without the Segmentation Overlay within a session and to also review scans in the adjacent time points (if available) which may not include such artifact. The figure below shows a case with incorrect segmentation of SRO (image on the right correctly showing no hypo-reflective spaces and image on the left showing erroneous segmentation).

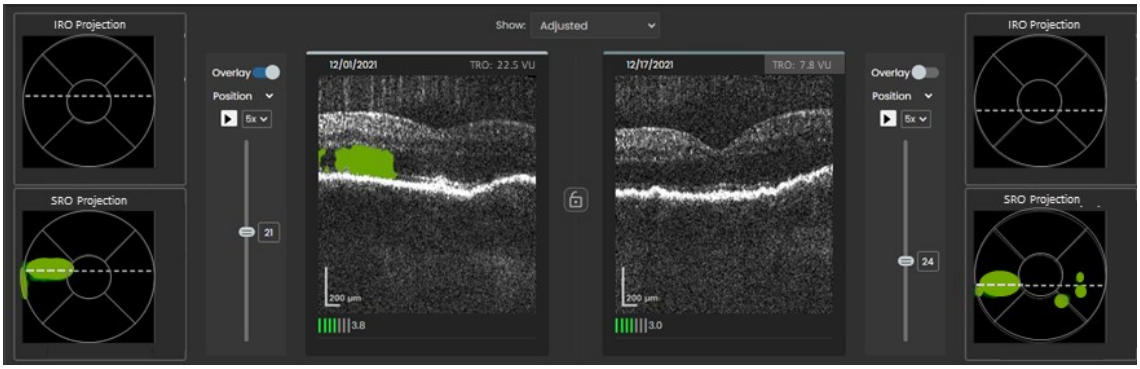


Figure 10-3: Incorrect SRO segmentation

10.3. Inconsistency due to Hypo-reflective Spaces at Scan Edges

Review the hypo-reflective spaces location in the Hypo-reflective Spaces Projections. Note that hypo-reflective spaces located at the volume scan edges may be an underestimation of the true hypo-reflective spaces of the 3 mm x 3 mm centered on the point of fixation. In addition, review the hypo-reflective spaces trajectory to identify any general trend and separate it from fluctuations due to large hypo-reflective spaces around the edges of the scan area.

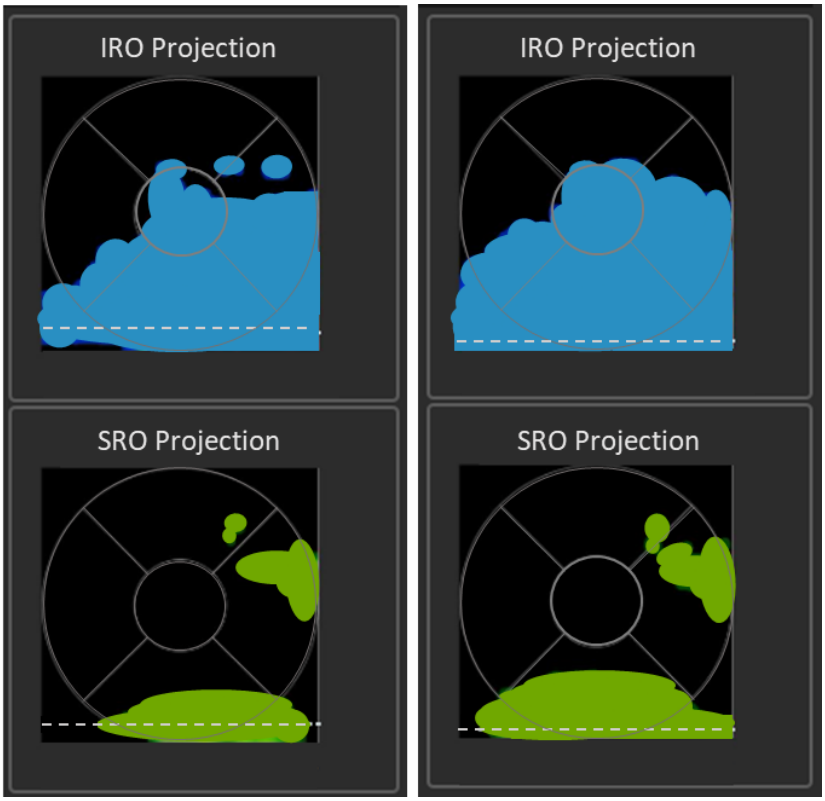


Figure 10-4: An example of changes in hypo-reflective spaces on the edge of the scan area

11. NOTIFICATIONS

NOA estimates the size of TRO on each scan. Review the TRO Trajectory trend graph and enter Notification Settings. For example, you can set a TRO Threshold for a specific eye to be notified if TRO reaches 50 VU. For eyes without a history of TROs, you may set a lower threshold for notifications. On the other hand, for eyes with fluctuating TRO values, you might set a notification threshold that is above the fluctuations.

Warning: Setting a notification at a threshold of below 10 VU is not recommended. Values at 10 VU or below has high measurement variability. This is shown in Figure 10-2.

The following section describes how to adjust Notification Settings and review Notifications.

11.1. HOME OCT PHASE

Eyes can be categorized into four different Home OCT Phases (see User Settings Section for more detail):

- **Initial – period from the eye's first scan to the first notification review**
- **Monitoring – Provider saves that the eye does not require a visit**
- **Visit – period from deciding to bring the patient in for a visit to making a treatment determination**
- **Treated – period from treatment to next visit decision**

11.2. NOTIFICATION PANE LAYOUT

The Notification Settings Pane only appears in the NOA tab. It enables you to set Notifications.

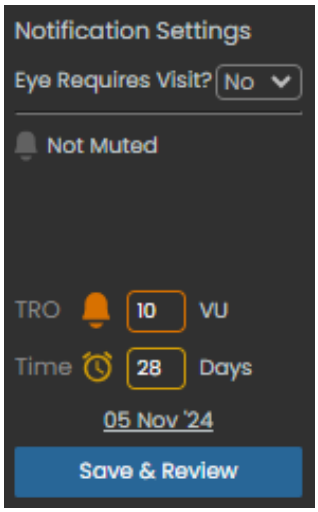


Figure 11-1: Notification Pane - Components Layout

11.3. Overview of Clinical Notifications

There are two notification categories (multi-selection is allowed):

1. **TRO – if TRO (VU) reaches the threshold, a notification will be generated.**
2. **Time – if the selected number of days elapsed, a notification will be generated.**

11.4. Review Clinical Notifications

Select Clinical Notification to Review

In the Patient/Notification Area, select the Clinical Notifications tab.

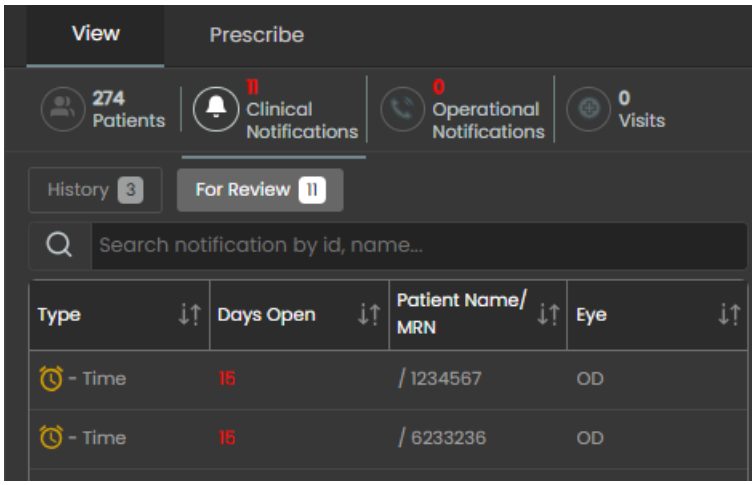


Figure 11-2: Notification Tab

The Notifications are sorted in two separate categories:

1. **For Review – new notifications that have not yet been reviewed.**
2. **History – notifications that were already reviewed.**

Select the category you want to review (e.g. For review).

For a specific search, enter key patient criteria (e.g., Notal PID, MRN, or Name) into the Search Bar located above the Notification List.

Select the Sort Icon next to each column header to sort Notifications by Days Open, Patient Name/MRN or by Eye.

Scroll through the Notification List using the Scroll Bar.

Review selected notification

The Timeline presents the date that the notifications were generated- see Bell icon in the example below. A vertical dashed line marks the corresponding date. Hover over the TRO Notification icons to view the Thresholds and actual values related to the TRO notification.

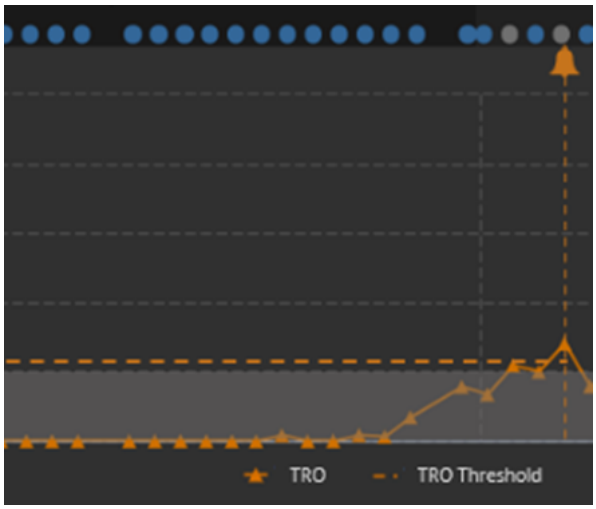


Figure 11-3: TRO Notifications Display on the TRO Trajectory Graph

Additionally, exceeded settings are colored in red in the notification settings pane.

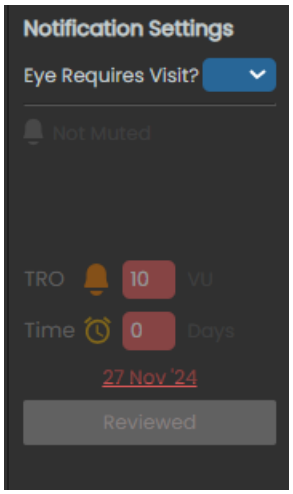


Figure 11-4: TRO and Time Interval Notifications Display in the Notification Settings Pane

After the Eye Requires Visit field is selected and the notification settings Reviewed button is pressed, the open notification(s) move from the For Review tab to the History tab, and the colored notification icons (bell and/or clock icon) above the TRO Trajectory graph turn gray.

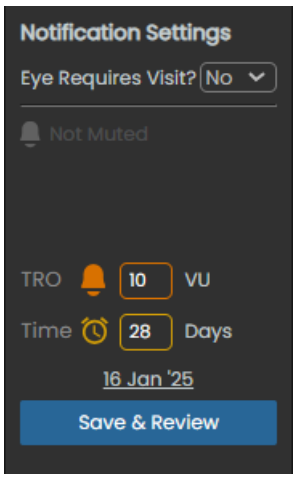


Figure 11-5: Notification Settings without Thresholds set or Open Notifications

Note: Whenever new scanning data is added, the Review button turns active and colored in blue, indicating to review the results and confirm your review. Whenever a new notification is triggered, e.g. TRO spaces exceeds the pre-set threshold, the Eye Requires Visit **field turns active indicating that you should make a new decision.**

11.5. SET NOTIFICATIONS

Tip – Follow the blue buttons indicating an action is needed!

Eye Requires Visit Entry

After a notification is received, the “Eye Requires Visit?” field turns blue. Select this field and choose “Yes” or “No”. The notification settings (Mute, TRO, and Time Interval) will update based on your user settings. Adjust the settings as needed and press save.

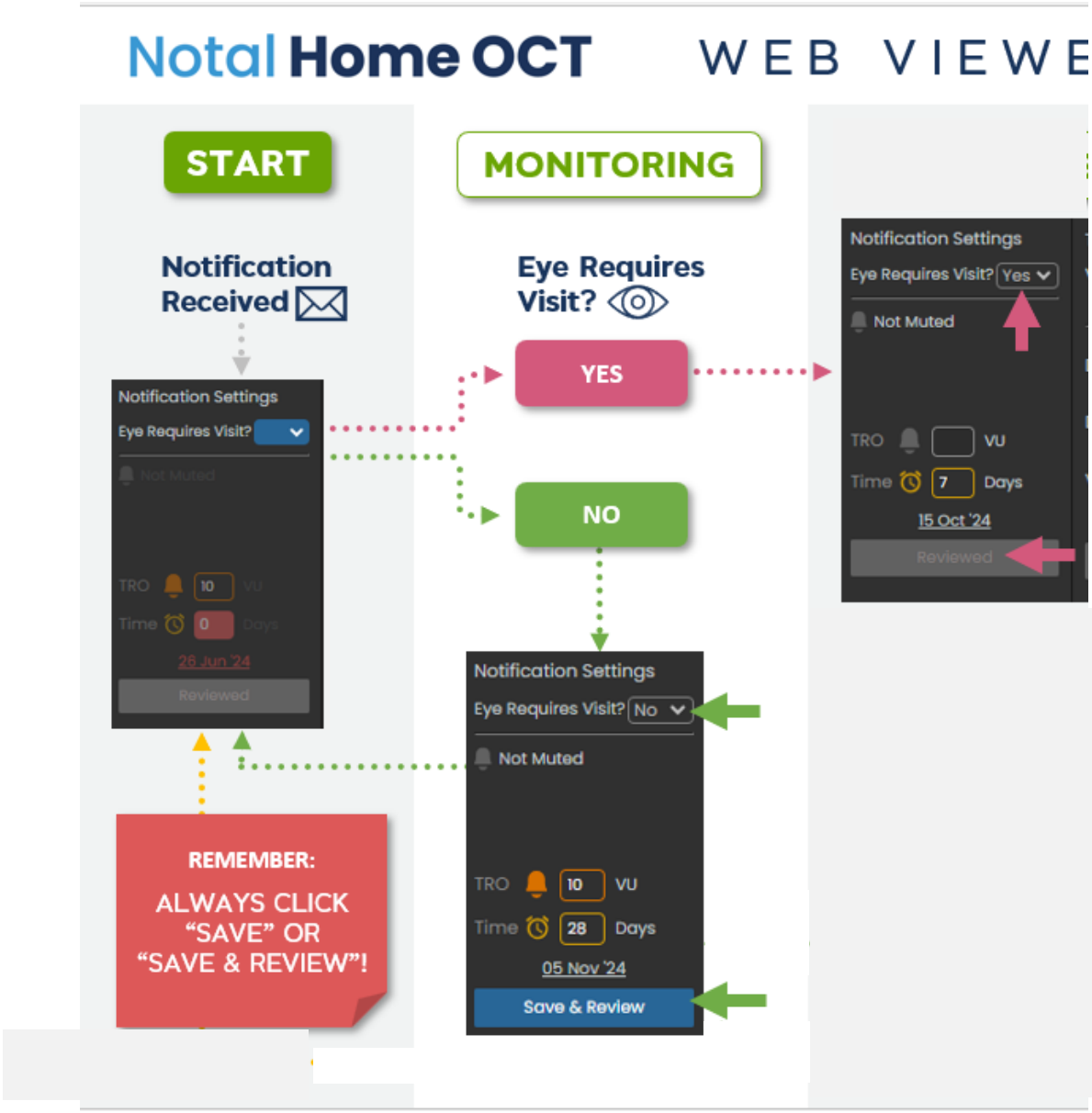


Figure 11-6 Eye Requires Visit Decision

Note: selected TRO and Time interval settings are illustrative.

Adjusting Notification Settings

Turn Thresholds on by clicking on the bell or clock icons or by directly inserting a value into the Threshold field – the field and its icon becomes colored.

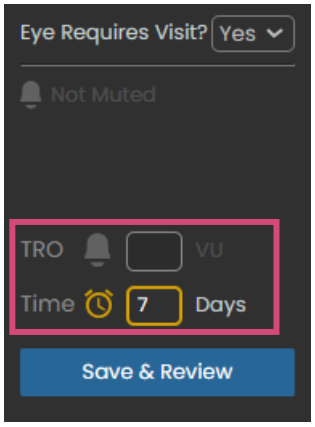


Figure 11-7 Threshold Entry

For TRO thresholds, an orange horizontal handle appears on the right side of the TRO Trajectory graph.

Click and drag the handle on the right side of the TRO Trajectory graph to adjust the Threshold. The TRO Threshold updates accordingly.

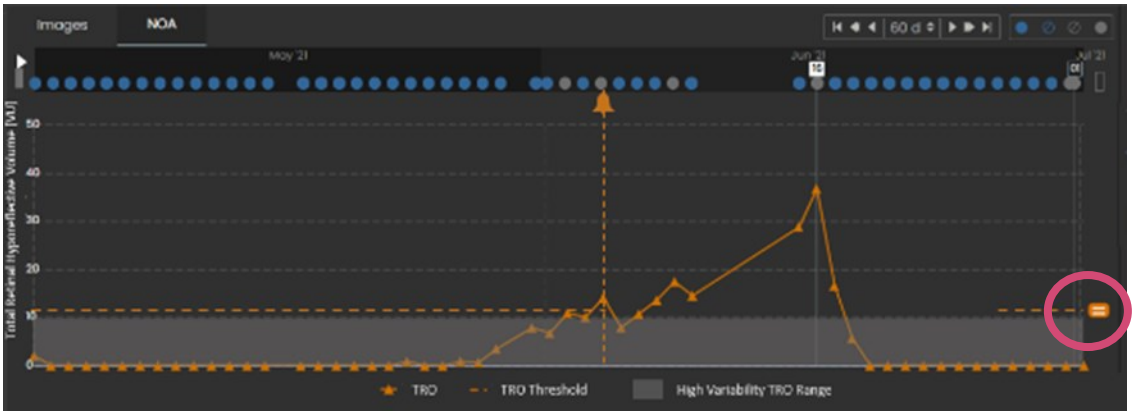


Figure 11-8: TRO Trajectory and Notification Setting

Saving Notification Settings

Click the Save and Reviewed button to save and confirm the selected Thresholds. The text on the button will be changed to Reviewed.

Note: Notifications can only be generated when the associated threshold is set, and its value is exceeded. Time-based threshold values continue to decrease each day until 0 days is reached, then the notification is triggered.

Entering Visit Complete or Cancelled

If the eye does require a visit, schedule the patient for an office visit. If the visit is cancelled, or the visit decision was made by accident, select "Cancelled" in the "Visit Complete?" field.

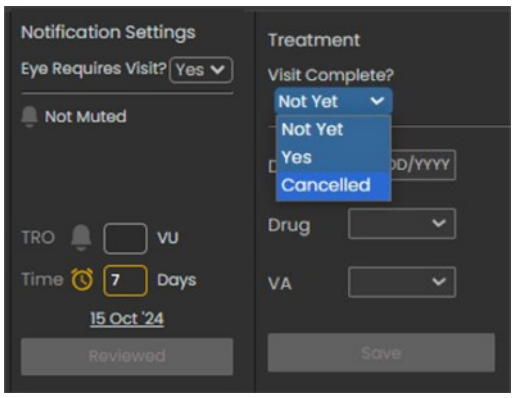


Figure 11-9 Visit Complete Entry

Entering Treatment Information

After the patient comes in for an office visit, mark "Visit Complete" and whether the eye was treated.

Treatment information should be added to better understand the TRO Trajectory for a given eye.

To add treatment information, use the Treatment Pane located on the right side of the screen:

1. **Date - Insert the treatment date by typing in the data (MM/DD/YYYY) or click on the date field and use the Calendar control to set the treatment date.**
2. **Drug - Use the drop-down list to select the drug used.**
3. **VA - Use the drop-down list to select the VA of the eye during the treatment visit.**
4. **Click Save.**

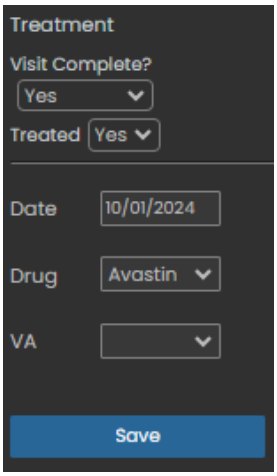


Figure 11-10: Treatment Pane

Once the treatment data is saved, an Injection icon displays in the Timeline and the Treatment Pane goes back to the default (empty) setting so that more treatment information can be added.

To see the treatment details, hover over the Injection icon:

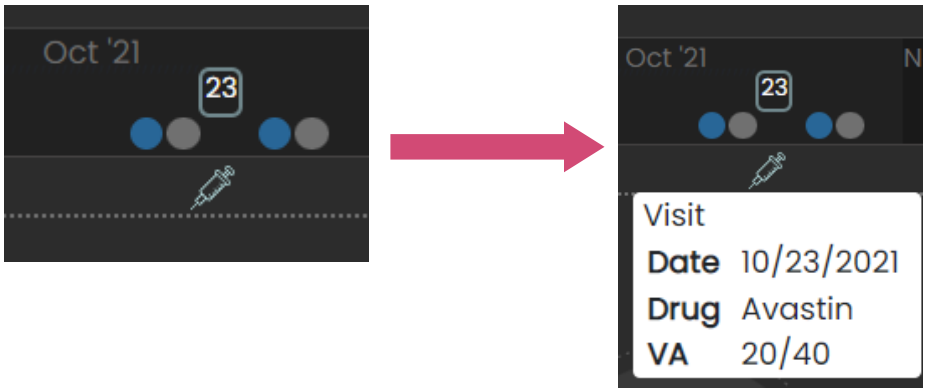


Figure 11-11: View Treatment Details

Adding, Modifying, and Deleting Treatment Information

Select the Treatment Date, the Drug, and the Visual Acuity (VA) score at the time of treatment.

Modify treatment information by right clicking on the Treatment Icon to open the Treatment Pane to edit the data.

Delete treatment information by right-clicking on the Treatment Icon to open the Treatment Pane. Click the trash bin icon to delete the treatment.

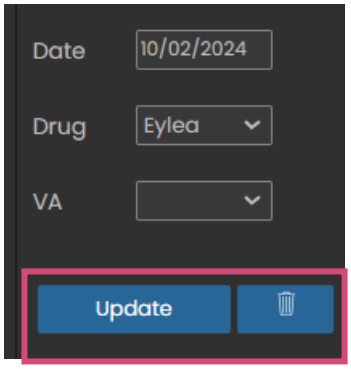


Figure 11-12 Update Treatment Data

Save the treatment form and updated notification settings.

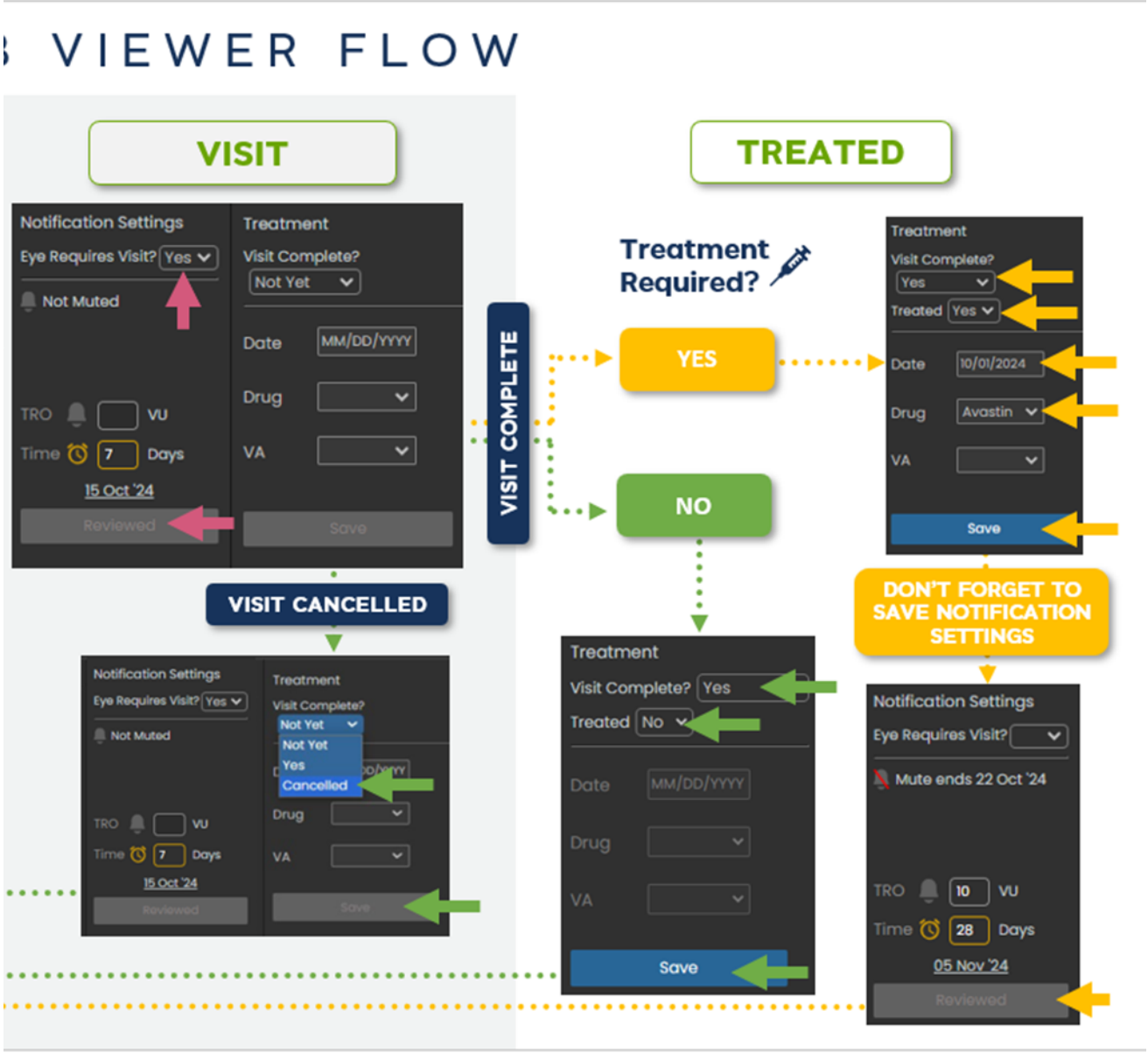


Figure 11-13 Visit Completion and Treated State Flow

Get ready for your next notification!

11.6. Review Operational Notifications

Operational notifications appear in the Operational Notifications List until the patient is out of that state.

- **Pause - if the patient's pause ends, the pause notification moves to history**
- **Quality - if the patient starts scanning successfully in an eye after a quality notification, the quality notification moves to history**
- **Adherence – if the patient starts scanning after a gap of scans, the adherence notification moves to history**

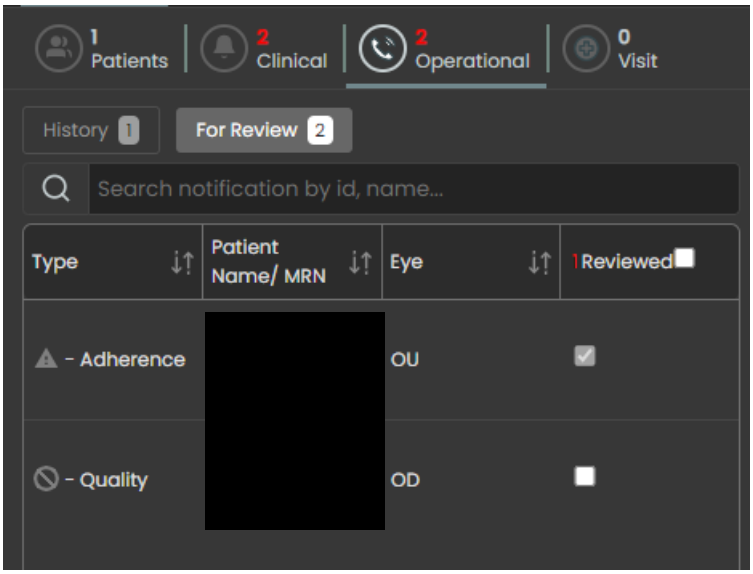


Figure 11-14 Operational Notification List

Choose to review the notification by checking the Reviewed box. This doesn't move the notification to history but shows that it has been reviewed and appropriate actions taken.

11.7. Multiple Scans Performed on the Same Date

If a patient performs multiple scans in one eye on the same day, the scans appear as a single scan in the Timeline. There will be multiple gray circles that appear below the B-scan. Each circle represents a separate scan. Click on a circle to view that scan.

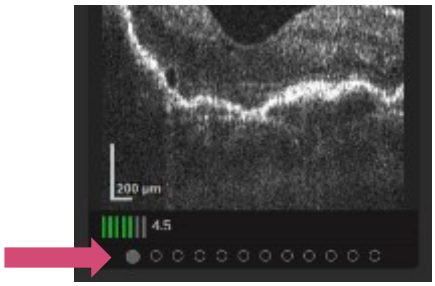


Figure 11-15: Multiple Scans Performed in One Day

Note: In case of multiple scans on the same day, the default displayed scan is

Images tab: the first scan performed chronologically.

NOA tab: the volume scan with the largest total retinal hypo-reflective spaces.

11.8. INACTIVE EYES

After patients disenroll from the program, or an eye is closed on the device, the TRO and Time Interval settings turn gray and an inactive eye message appears, indicating that you cannot rely on SCANLY Home OCT to monitoring that eye.

11.9. PRIMARY EYES

A dot on the eye toggle indicates eyes with nAMD from the SCANLY Home OCT prescription.

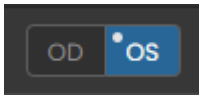


Figure 11-16 Primary Eyes Indicator

11.10. NON-COMPLIANT PATIENTS

An indication will appear on the timeline to clearly identify when the last scan date displayed is far from today (greater than the adherence period selected in your user settings).

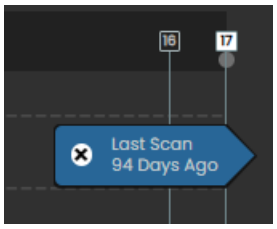


Figure 11-17 Non-compliant Patient Indicator

11.11. Device Exchange Indication

In certain scenarios, a patient might undergo a device exchange, potentially leading to a trajectory adjustment. To ensure that this exchange is noticeable to the physician, a "Device Exchange" icon (triangle) will be affixed to the timeline bar at the timepoint of the exchange. This indication allows the physician to make clinical judgments with access to all relevant data. An example of a "Device Exchange" indication is shown below.

Precaution: There may be measurement variability between different devices.

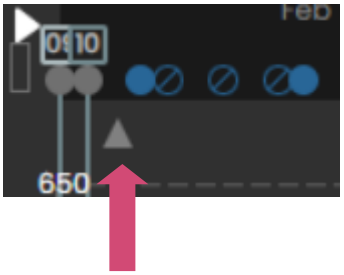


Figure 11-18 Device Exchange Indication

11.12. Exporting Reports

Select the Export button to export a report of patient data.

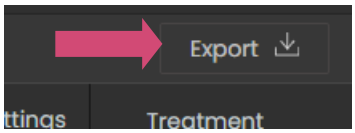


Figure 11-19: The Export Button

Enter the date that you'd like to pull the last 30-days of data from and select the report format.

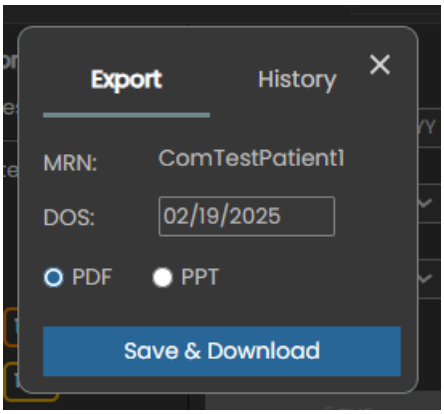


Figure 11-20 Export Interface

Click Save & Download to download the report.

In the History tab, you can find previously saved reports. Select the relevant row and select download.

11.13. LOGOUT

To logout, click on the arrow next to your username, located on the upper-right side of the webpage. Click on the Logout option to logout of the system.

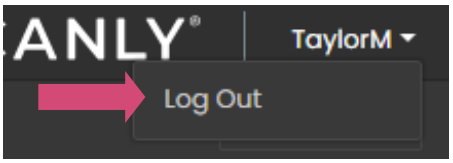


Figure 11-21: Logout Control

12. REVIEW CUMMULATIVE PATIENT DATA

12.1. INFO TAB

Select the Info tab at the top left corner of the Portal to review interactive lists, reports, and dashboards.

13. SAFETY INSTRUCTIONS AND DATA SECURITY

13.1. POTENTIAL SERIOUS INCIDENTS OF DEVICE ON HEALTH

There are no known serious safety or health risks caused by or related to the use of SCANLY Portal, which is a software-only module. Proper use of the information generated by the SCANLY Portal device is explained in this manual. The SCANLY Portal output is intended to be used in conjunction with other patient information and based on professional judgment by qualified and trained personnel who are fully aware of the software functionality and limitations.

13.2. SAFETY MEASURES — DATA PROTECTION AND INFORMATION

The SCANLY Home OCT device uses wireless communication to send the OCT scans to a protected and secure cloud-based portal for eyecare provider access. Patient data is protected by encryption provided by using the platform-approved data storage service and in accordance with the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA).

13.3. USER RESPONSIBILITY

Authorized users should ensure that the host computer is not left unlocked, or otherwise unsecured when not in use and should ensure that unauthorized individuals are not exposed to, or gain access to, system files or Protected Health Information (PHI).

Users are reminded that usernames and passwords for systems, which provide access to SCANLY Portal results or files, should not be shared with others, even if they are permitted by law and site policy to view the same type of information.

Select a unique password, do not share the password with others and store the password in a safe place.

13.4. REPORTING SECURITY OR PRIVACY BREACHES

Users should inform their local IT department, and the Notal Vision Monitoring Center, of any suspected or confirmed compromised user accounts and any other

privacy or security breaches, including but not limited to those that may provide access to SCANLY Portal results or files.

14. CYBERSECURITY

The SCANLY Home OCT System is a "Cyber Device". The SCANLY Home OCT device uses wireless communication to send OCT scans to a protected and secured Notal Health Cloud. Accessing the SCANLY Portal is granted to pre-defined users only and requires authentication. Registered eye-care providers are limited to review information regarding patients of their clinic(s) only. Notal Vision understands the importance of protecting personal health care information. All necessary precautions to ensure that personal health care information is secure are taken. Stored data is fully encrypted in accordance with the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA). In case you have noticed any activity that might be related to Cybersecurity attack, e.g. inability to log into the SCANLY Home OCT portal, please contact the Notal Vision Monitoring Center:

Phone Number: 855-691-8600
Email: privacy@notalvision.com

15. REGULATORY COMPLIANCE

15.1. MANUFACTURER

	**Notal Vision Ltd.** **5 Druyanov St.** **Tel Aviv, Israel, 6314305** **+972-3-6293763**

15.2. INTERNATIONAL STANDARDS

- **ISO 13485:2106 Medical devices – Quality Management Systems – Requirements for regulatory purposes.**
- **ISO 9001:2015 Quality Management Systems – Requirements.**
- **IEC 62304:2006+AMD1:2015 Medical device Software life cycle processes**
- **FDA Guidance (2016), Applying Human Factors and Usability Engineering to Medical Devices**
- **ISO 14971:2019 Medical Devices – Application of risk management to medical devices.**
- **ISO 24971:2020 Medical devices — Guidance on the application of ISO 14971.**
- **ISO 15223-1:2021 Symbol to be used with medical device labels, labeling and information to be supplied.**
- **CFR Part 820 Quality System Regulation.**
- **IEC 62304:2016, Medical Device Software – Software Life-Cycle Processes.**
- **ISO 13485:2016, ISO 9001:2015 certified manufacturer.**

16. LABELS AND SYMBOLS

Symbol	Description	Location
	Unique Device Identification	Shipping Package and Device
	Manufacturer	Shipping Package and Device
	Country of Manufacturer	Shipping Package and Device
	Catalogue Number	Shipping Package and Device
RX Only	Available by prescription only	Device
	User manual must be read before operating the SCANLY Portal	Hard copy supplied to eyecare provider
	Indicates that the device is a medical device	Shipping Package and Device

17. APPENDIX: SCANLY HOME OCT CLINICAL PERFORMANCE

17.1. NOTAL VISION HOME OCT (NVHO)/NOA PERFORMANCE DATA

Clinical performance data were collected from two pivotal clinical studies: 1) the C2021.001 study ("001 Study"): A 5-Week "Home OCT Fluid Visualization Agreement Study"; 2) the C2012.006 study ("006 Study"): A cross-sectional in-office study for "The Evaluation of the Agreement and Precision of the Notal Vision Home OCT in the Automatic Fluid Quantification in Patients with NV-AMD."

Note: The protocols for these studies used the term "retinal fluid" (e.g., total, sub-retinal and intra-retinal fluid [TRF, SRF, IRF]) to refer to hypo-reflective spaces (HRS; or TRO, SRO, and IRO). However, not all hypo-reflective spaces on macular OCT imaging are retinal fluid, and not all exudative fluids will necessarily be hypo-reflective; therefore, the terms TRF, SRF, and IRF are not synonymous or interchangeable with the terms TRO, SRO, and IRO.

17.2. SUMMARY OF 001 CLINICAL STUDY

Overview:

The "001 Study" was a prospective, longitudinal study conducted at seven sites in the United States. Adults age 55 or older with diagnosed NV-AMD in at least one eligible eye and best-corrected visual acuity of 20/320 or better were enrolled 1 week prior to a previously scheduled, routine clinic visit. Those who required anti-VEGF treatment for NV-AMD in the study eye at the screening visit, those who had any other retinal disease requiring steroidal or anti-VEGF treatment, or those with prior NVHO device use experience were excluded. One NV-AMD eye was determined to be the study eye.

The purpose of the study was the following: 1) to evaluate the agreement between in-office OCT macular scans versus the NVHO scans in the visualization of retinal fluid in the central 10 degrees of the macula, as determined by expert graders at a third-party

reading center (RC); and 2) to evaluate the ability of participants to successfully self-image with the NVHO device. RC graders were masked to each other's determinations, to the source device, and to the participant ID number. Ordering of the scans was randomized. Disagreements between graders were adjudicated. IRF and SRF were graded as present when definite hypo-reflective space is observed in OCT B-scan images. IRF is anterior to the photoreceptor layer and SRF is posterior to the photoreceptor layer and anterior to the retinal pigment epithelium (RPE). The presence of confounding lesions (epiretinal membrane [ERM], macular hole, pseudocysts, outer retinal tubulations, hemorrhage, pigment epithelial detachments, subretinal hyper-reflective material [SHRM], geographic atrophy [GA], and hyper-reflective retinal spots or foci) was also assessed by the RC. Refer to Figures 16.1, 16.2 and 16.3 for examples of some confounding lesions.

During the enrollment visit, participants underwent imaging with a clinic-based, spectral-domain OCT imaging system (CIRRUS HD-OCT) to establish a "baseline" status of the macula. After verification of eligibility during screening, participants were assigned an NVHO device. The assigned NVHO device was delivered to participants' homes. Participants set up the NVHO device using the onscreen tutorial. To continue in the study, participants must be able to achieve successful initial NVHO calibration. Continuing participants were instructed to self-image at home with the NVHO every day for five consecutive weeks, including on the days of scheduled office visits. Remote telephone technical support ("Notal Vision Diagnostic Clinic," NVDC) was available to participants. In-clinic visits were scheduled at Week 1 and Week 5. At these scheduled visits, CIRRUS HD-OCT imaging was performed and best-corrected visual acuity (BCVA), subjective symptoms, and adverse events were assessed. The daily NVHO scans of participants designated as without retinal fluid at baseline were reviewed by the reading center (RC). The RC triggered an alert for an interim clinic visit if fluid was identified on two consecutive NVHO scans from two consecutive days. CIRRUS HD-OCT images, BCVA, and any symptoms or adverse event information were also collected at these interim visits.

The primary effectiveness endpoints were positive and negative percent agreements (PPA, NPA) of central macular (central 3x3-mm area) fluid status between NVHO and RC-graded CIRRUS HD-OCT scans, success rate of initial NVHO setup, and success rate

for NVHO self-imaging attempts. The primary analysis of the PPA and NPA of visualizing Total Retinal Fluid (TRF) on NVHO volume scans was based on repeated measurements of the primary eyes using the optimal weighting method (Jung et al.) to test H_0: $p \leq 0.8$ vs. H_a: $p > 0.8$ with normal approximation and a two-sided significance level of 0.05. The secondary endpoints were the success rates of total (completed plus incomplete) and completed self-imaging transmission to the Notal Health Cloud. The safety outcomes of interest were any adverse events occurring during the conduct of the study.

Results:

198 participants were enrolled. Of these, seven (3.5%) were screen failures, eight withdrew consent prior to initiating participation (4.0%), two (1.0%) were exited due to inability to scan, and one (0.51%) was exited because of inability to return for follow-up. Therefore, 180 participants (90.9%) comprise the safety cohort. From the safety cohort, an additional 12 participants were excluded (10 due to device-use, inadequate image quality, self-calibration, and/or self-imaging problems and two who withdrew consent) to form the 168 participants (84.8%) in the "Visualization Analysis Population" (VAP) cohort (those who underwent clinic-based and NVHO imaging at Week-1, interim, or Week-5 visits). From the VAP cohort, another eight participants were excluded (seven due to not having NVHO scans with MSI score ≥2 and clinic-based OCT scans paired within 24 hours at Week-1, interim and Week-5 visits; one exited early due to difficulty with self-imaging) to form 160 participants (80.8%) in the "Modified Visualization Analysis Population" (mVAP) cohort. Primary analyses were based on the mVAP cohort.

Racial distribution, demographics, and relevant baseline clinical characteristics are shown in Tables 16.1 and 16.2.

Demographics		Safety Population N = 180	Modified Visualization Analysis Population N = 160
Age	N	180	160
	Mean ± SD	77.1 ± 7.2	76.8 ± 7.2
	Median	77.5	77.0
	Min, Max	55, 92	55, 92
Gender	Male	78 (43.3%)	70 (43.8%)
	Female	102 (56.7%)	90 (56.3%)
Race	Asian	1 (0.6%)	1 (0.6%)
	Black or African American	4 (2.2%)	3 (1.9%)
	White	174 (96.7%)	155 (96.9%)
	Not Reported	1 (0.6%)	1 (0.6%)
Ethnicity	Not Hispanic or Latino	178 (98.9%)	158 (98.8%)
	Not Reported	2 (1.1%)	2 (1.3%)
Education	Less than High School Degree	8 (4.4%)	7 (4.4%)
	High School Degree	43 (23.9%)	38 (23.8%)
	Some college (no degree)	47 (26.1%)	44 (27.5%)
	College Degree (Associate or Bachelor's Degree)	51 (28.3%)	45 (28.1%)
	Graduate Degree	25 (13.9%)	21 (13.1%)
	Other[1]	6 (3.3%)	5 (3.1%)
Study Eye	OD	93 (51.7%)	82 (51.3%)
	OS	87 (48.3%)	78 (48.8%)

% = n / N × 100%.

[1] Including some graduate school, trade school, and tech school

Table 17-1: Demographics of Safety Population and mVAP – 001 Study

Baseline Characteristics		Safety Population		Modified Visualization Analysis Population	
		Primary Eye[1] N = 180	Secondary Eye[1] N = 137	Primary Eye N = 160	Secondary Eye N = 123
AMD diagnostic[2]	AMD - Early AMD	0 (0.0%)	10 (7.3%)	0 (0.0%)	9 (7.3%)
	NV-AMD - non active (no fluid present)	92 (51.1%)	35 (25.5%)	84 (52.5%)	27 (22.0%)
	AMD - Intermediate AMD	0 (0.0%)	61 (44.5%)	0 (0.0%)	58 (47.2%)
	NV-AMD - active (fluid present)	88 (48.9%)	31 (22.6%)	76 (47.5%)	29 (23.6%)
Lens status	Phakia (cataract present)	65 (36.1%)	47 (34.3%)	61 (38.1%)	46 (37.4%)
	Pseudophakia	115 (63.9%)	90 (65.7%)	99 (61.9%)	77 (62.6%)
Ocular Media Assessment	Main vessels and the small vessels are clearly seen	179 (99.4%)	136 (99.3%)	159 (99.4%)	122 (99.2%)
	Both main and small vessels cannot be seen	1 (0.6%)	1 (0.7%)	1 (0.6%)	1 (0.8%)
Visual Distortions	Present	17 (9.4%)	7 (5.1%)	15 (9.4%)	7 (5.7%)
	Absent	163 (90.6%)	130 (94.9%)	145 (90.6%)	116 (94.3%)
Blurry Vision	Present	57 (31.7%)	28 (20.4%)	54 (33.8%)	26 (21.1%)
	Absent	123 (68.3%)	109 (79.6%)	106 (66.3%)	97 (78.9%)
Scotoma	Present	57 (31.7%)	28 (20.4%)	54 (33.8%)	26 (21.1%)
	Absent	123 (68.3%)	109 (79.6%)	106 (66.3%)	97 (78.9%)
Prior total # of Injections	N	180	137	160	123
	Mean ± SD	26.4 ± 26.5	12.1 ± 21.4	25.3 ± 26.6	12.0 ± 21.9
	Median	17.0	0.0	16.0	0.0
	Min, Max	0, 128	0, 125	0, 128	0, 125
Manifest Refraction Spherical Equivalent	N	151	113	137	104
	Mean ± SD	0.066 ± 1.924	0.044 ± 1.810	0.109 ± 1.881	0.135 ± 1.672
	Median	0.000	0.000	0.000	0.000
	Min, Max	-8.000, 5.000	-8.000, 5.000	-7.000, 5.000	-7.000, 5.000
Best Corrected Visual Acuity	N	180	137	160	123
	Mean logMAR (Snellen)	0.301 (20/40.0)	0.234 (20/34.3)	0.281 (20/38.2)	0.211 (20/32.5)
	SD logMAR	0.251	0.324	0.226	0.309
	Median logMAR (Snellen)	0.220 (20/33.2)	0.120 (20/26.4)	0.220 (20/33.2)	0.120 (20/26.4)
	Min logMAR (Snellen)	-0.10 (20/16.0)	-0.10 (20/16.0)	-0.10 (20/16.0)	-0.10 (20/16.0)
	Max logMAR (Snellen)	1.20 (20/320.0)	1.90 (CF)	1.04 (20/219.3)	1.90 (CF)
Best Corrected Visual Acuity category	20/40 or Better	110 (61.1%)	106 (77.4%)	102 (63.8%)	100 (81.3%)
	20/41 to 20/80	50 (27.8%)	20 (14.6%)	44 (27.5%)	16 (13.0%)
	20/81 to 20/200	14 (7.8%)	9 (6.6%)	12 (7.5%)	6 (4.9%)

	20/201 to 20/320	6 (3.3%)	1 (0.7%)	2 (1.3%)	1 (0.8%)
	Worse than 20/320	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Principal Investigator's retinal fluid assessment based on commercial OCT[2]	Both IRF and SRF	10 (5.6%)	3 (2.2%)	8 (5.0%)	3 (2.4%)
	SRF only	40 (22.2%)	13 (9.5%)	36 (22.5%)	13 (10.6%)
	IRF only	25 (13.9%)	14 (10.2%)	20 (12.5%)	11 (8.9%)
	No IRF nor SRF	105 (58.3%)	107 (78.1%)	96 (60.0%)	96 (78.0%)

% = n / N × 100%. Manifest refraction was not recorded at the initial phase of the study.

[1] Primary Eye = study eye. Secondary Eye = the AMD or NV-AMD fellow eye of the study eye

[2] AMD diagnostic findings were collected from participants' medical record. OCT fluid status is based upon review by PI of the OCT taken during the enrollment visit.

Table 17-2: Baseline Characteristics of Safety Population and mVAP – 001 Study

Concomitant pathologies identified by the RC on CIRRUS scans for the mVAP cohort are summarized in Table 16.3.

Pathology	Week 1 n (%)	Interim n (%)	Week 5 n (%)
N (Graded)	**124**	**47**	**138**
Any pathology	122 (98.4%)	47 (100%)	134 (97.1%)
Epiretinal membrane (ERM)	48 (38.7%)	15 (31.9%)	47 (34.1%)
Macular hole	0 (0.0%)	1 (2.1%)	1 (0.7%)
Pseudocysts	30 (24.2%)	12 (25.5%)	30 (21.7%)
Outer retinal tubulations	6 (4.8%)	2 (4.3%)	1 (0.7%)
Hemorrhage	0 (0.0%)	1 (2.1%)	0 (0.0%)
Pigment epithelial detachments	104 (83.9%)	42 (89.4%)	112 (81.2%)
Subretinal hyper-reflective material (SHRM)	19 (15.3%)	3 (6.4%)	18 (13.0%)
Sub-retinal pigment epithelium (RPE) hypo-reflective areas	26 (21.0%)	17 (36.2%)	28 (20.3%)
Geographic atrophy (GA)	25 (20.2%)	15 (31.9%)	33 (23.9%)
Hyperreflective retinal spots (Foci)	97 (78.2%)	41 (87.2%)	120 (87.0%)
Not Graded - Poor Image Quality	1	0	0

The Cirrus scans without paired NVHO scans taken within 24 hours were excluded from the analysis.
Only the scans of Primary Eye were graded.
N = number of eyes with available data. Not reported = number of eyes returned for the Visit but without the corresponding data. Total = total number of eyes returned for the Visit.
% = n/N × 100%.

Table 17-3: Concomitant Pathologies Identified by the Reading Center on Cirrus Scans mVAP

For the safety cohort (N=180), the success rate of initial NVHO setup with completion of the non-qualifying tutorial was 86.7% (95% CI 80.8% – 91.3%; 156/180). 24 participants (13.3%) who still performed NVHO self-imaging did not successfully complete tutorials for either the primary or secondary eyes. The success rate of NVHO self-imaging (i.e., completing the self-imaging regardless of completing imaging data transmission to Notal Health Cloud) was 96.1% (95% CI 92.2% – 98.4%). Seven participants (3.9%) did not self-scan successfully. The rate of successful transmission of any self-imaging being transmitted to the Notal Health Cloud was 97.2% (95% CI, 93.6% – 99.1%) in study eyes and 94.9% (95% CI, 89.8% – 97.9%) in fellow eyes. The rate of successful transmission of completed self-imaging to the Notal Health Cloud was 96.7% (95% CI, 92.9% – 98.8%) in study eyes and 94.2% (95% CI, 88.8% – 97.4%) in fellow eyes. 31 of 180 participants (17.2%) encountered device errors and/or malfunctions that precluded self-imaging and necessitated a device exchange. 120 of 180 participants (66.7%) contacted the NVDC for technical

support. The NVDC contacted 47 of 180 participants (26.1%) with low adherence to device use to remind them to perform self-imaging and 84 of 180 (46.7%) for technical support. The NVDC also contacted 173 of 180 participants (96.1%) to remind participants of an upcoming scheduled in-clinic study visit.

Of those in the safety cohort who did not discontinue after completion of the initial tutorial and device calibration and performed self-imaging (N=165), the mean MSI score of the first-completed, study-eye self-images ranged from 4.388 to 4.557 during the first week (study days 1 to 7), 4.47 to 4.57 during the second week (study days 8 to 14), 4.28 to 4.49 during the third week (study days 15 to 21), 4.32 to 4.45 during the fourth week (study days 22 to 28), and 3.64 to 4.35 during the fifth week (days 29 to 35). The proportion of participants who obtained a first-completed NVHO study-eye scan with MSI <2 ranged from 0.6% to 4.3% during the first week (study days 1 to 7), zero to 3.7% during the second week (study days 8 to 14), zero to 6.4% during the third week (study days 15 to 21), 0.8% to 4.0% during the fourth week (study days 22 to 28), and 2.1% to 6.5% during the fifth week (days 29 to 35).

The following table shows the primary analysis of NVHO Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for Retinal Hypo-reflective Spaces Visualization based on Retinal Hypo-reflective Spaces Visualized on the Cirrus 3mm×3mm Area Modified Visualization Analysis Population (including subjects with NVHO and Cirrus scans within 24 Hours apart).

The PPA was 0.864 (95% CI 0.802, 0.926; p=0.043) and NPA was 0.849 (95% CI 0.792, 0.907 p=0.094).

Total Retinal Hypo-reflective spaces (TRO)	Positive Percent Agreement (PPA)		Negative Percent Agreement (NPA)	
	Rate (95% CI)	**Two-sided p-value for H0: P_P £ 0.8 vs. Ha: P_P > 0.8**	**Rate (95% CI)**	**Two-sided p-value for H0: P_N £ 0.8 vs. Ha: P_N > 0.8**
# pairs of scans of # subjects	163 pairs of scans of 105 eyes with Cirrus = TRO		146 pairs of scans of 95 eyes with Cirrus = no TRO	
# NVHO scans with TRO	143		20	
# NVHO scans without TRO	19		124	
# NVHO scans not gradable	1		2	
Pragmatic estimation per repeated measurements using optimal weighting method, Pw[1,2]	0.864 (0.802, 0.926)	0.043	0.849 (0.792, 0.907)	0.094
Point estimates and 95% CIs per 2000 Cluster Bootstrap re-sampling* for PPA and NPA	0.877 [143/163] (95% CI, 0.819 – 0.929)		0.849 [124/146] (0.791, 0.903)	

The NVHO and Cirrus scan pairs with a scan time difference of > 24 hours were excluded from the analysis.

* The mean and (2.5^{th}, 97.5^{th}) percentiles of 2000 Cluster Bootstrap samples with re-sampling of participants.

1 Article, Sin-Ho Jung, Seung-Ho Kang and Chul Ahn (2001), Sample size calculations for clustered binary data, Statist. Med. 2001; 20:1971–1982

2 Pragmatic estimation: PPA is based on all pairs of Cirrus and NVHO scans with Cirrus graded as with fluid (i.e., + or present) regardless of whether NVHO cannot be graded; NPA is based on all pairs of Cirrus and NVHO with Cirrus graded as without fluid (i.e., - or absent) regardless of whether NVHO cannot be graded. Colin B. Begg, Robert A. Greenest, and Boris Iglewicz (1986), The Influence of Uninterpretability on the Assessment of Diagnostic Tests, J Chron Dis Vol. 39, No. 8, pp. 575-584.

Table 17-4: Primary Analysis of NVHO PPA and NPA for Retinal Hypo-reflective Spaces Visualization

51 interim visits for 51 of 180 participants (28.3%) were conducted in response to the daily RC review. An NV-AMD treatment was administered at 26 of the 51 interim visits (51.0%). (Note: The "001 Study" was not designed to demonstrate the ability of the NVHO device to serve as an "early detection tool.")

10 adverse events (AEs) were reported for six participants. Of these 10, four were considered serious (SAEs). All SAEs were non-ocular in nature (myocardial infarction, pulmonary edema, fall, COVID-19 infection). Two AEs in two participants were ocular in nature (ocular pain and redness at the site of an intravitreal injection; eyelid stye). No ocular AEs involving vision loss were reported. None of the AEs were considered related to the NVHO device, and all AEs resolved prior to study termination.
As noted above, the presence of confounding lesions was assessed by the RC and the figures below provide sample images of some confounding lesions.

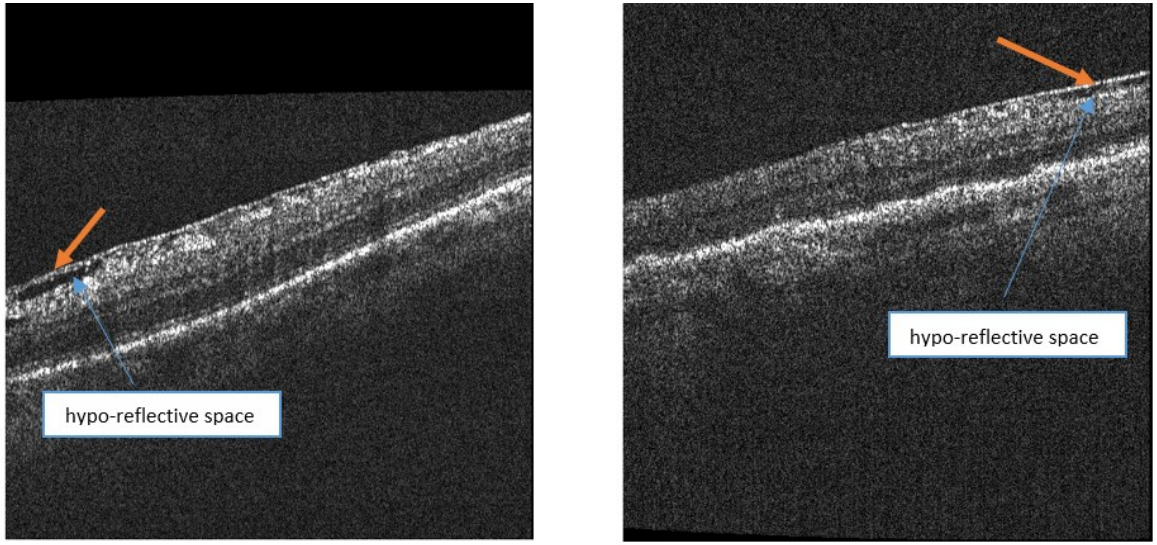


Figure 17-1: Hypo-reflective space from epiretinal membrane (ERM)

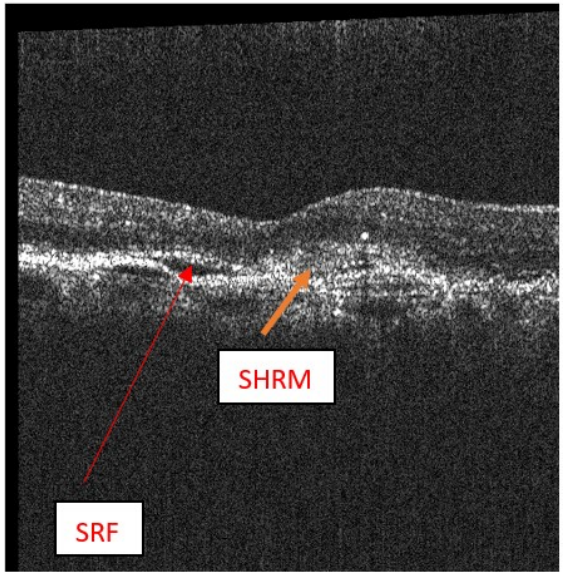


Figure 17-2: Subretinal hyper-reflective material [SHRM]

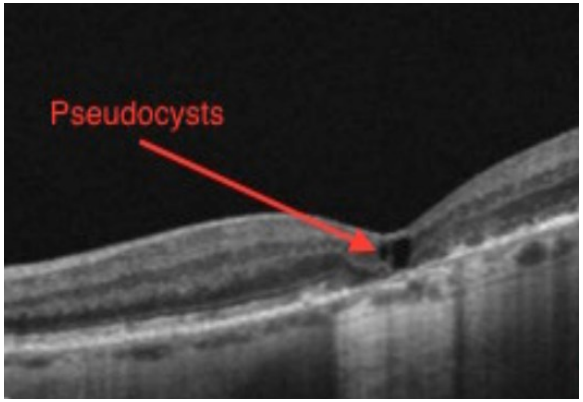


Figure 17-3: Pseudocyst

17.3. SUMMARY OF 006 CLINICAL STUDY

The "006 Study" was a prospective, cross-sectional, observational, single-visit study conducted at six sites in the United States. Participants with diagnosed NV-AMD in at least one eligible eye and best-corrected visual acuity of 20/320 or better in the study eye were enrolled. There was no minimum or maximum age requirement for eligibility. Those who had any other retinal disease requiring steroidal or anti-VEGF treatment, CIRRUS HD-OCT scan on screening visit with a signal strength <6, or those with non-neovascular (i.e., "dry") AMD in the study eye were excluded. The presence of confounding lesions (epiretinal membrane [ERM], macular hole, pseudocysts, outer retinal tubulations, hemorrhage, pigment epithelial detachments, subretinal hyper-reflective material [SHRM], geographic atrophy [GA], and hyper-reflective retinal spots or foci) was not exclusionary. One NV-AMD eye was determined to be the study eye. The purpose of the study was the following: 1) to evaluate the agreement in estimated retinal fluid volume between manually segmented CIRRUS HD-OCT macular scans versus the Notal OCT Analyzer (NOA) algorithm analyzing NVHO scans; 2) to estimate the repeatability and reproducibility of the TRO parameter; 3) to evaluate the amount of overlap in segmentation of IRF and SRF between NOA and manual graders.

Demographic information and medical history were collected from enrolled participants. Manifest refraction, best-corrected Snellen visual acuity (BCVA) assessment, and assessment of media opacity were performed. Initial macular scanning with the CIRRUS HD-OCT was performed. One study eye per participant was selected. Participants then received a general overview on how to self-operate the NVHO device. Imaging without pharmacologic pupil dilation using CIRRUS HD-OCT and two NVHO devices was performed. The order of CIRRUS vs. NVHO imaging for each participant and the order of NVHO device use were randomized. Independent, masked graders from a third-party reading center (RC) performed manual segmentation of hypo-reflective spaces on the central 3×3-mm area of acceptable CIRRUS macular scans. Graders were masked to each others' determinations and to the participant ID number. Ordering of the scans was randomized. SRF was defined as a hypo-reflective space located beneath the retina between the ISE (integrity of the inner segment ellipsoid band, or inner segment/outer segment [IS/OS] border) and RPE

layers and IRF was defined as a hypo-reflective space located in the retina between the internal limiting membrane (ILM) and ISE layers.

The measurement variability of NOA-based volume estimates under repeatability conditions (i.e., within the same person using/operating the same NVHO device repeatedly) and reproducibility conditions (i.e., the same person using/operating different NVHO devices repeatedly) were determined using a random-effects analysis of variance (ANOVA) model. The agreement between NOA-based and CIRRUS-based volume estimates was calculated using Bland-Altman 95% limits of agreement (LOAs) and Deming regression analyses. The segmentation overlap analysis included calculation of the device-grader Dice coefficient for each grader averaged over cases and the calculation of the grader-grader Dice coefficient for each pair of graders averaged over cases. Since the Dice coefficient is undefined when both methods in the comparison do not provide a segmentation, those cases were excluded from the calculation of the average of Dice coefficients. To account for these excluded cases, the device-grader negative percent agreement (NPA) was calculated for each expert. Uncertainty of results was characterized by 95% confidence intervals representing case variability.

398 participants were enrolled. 11 (2.8%) were screen failures; therefore, the safety cohort (all eligible participants who underwent CIRRUS or NVHO scanning) is comprised of 387 participants. 78 (19.6%) exited from the study early (due mainly to inability to successfully calibrate the NVHO [N=57]). Participants who could not successfully complete either NVHO or CIRRUS imaging (or both) or whose scans did not have eligible fluid measurements were excluded from precision, agreement, and Dice coefficient analysis cohorts. The "Fluid Precision Analysis Population" and "Fluid Agreement Analysis Population" cohorts were comprised of 331 participants and the "Dice Analysis Population" was comprised of 336 participants.

Racial distribution, demographics, and relevant baseline clinical characteristics are shown in Tables 16.5 and 16.6.

Demographics		Safety Population N = 387	Fluid Marking (DICE) Analysis Population N = 336	Fluid Agreement Analysis Population[1] N = 331
Age	N	387	336	331
	Mean ± SD	76.2 ± 7.5	75.4 ± 7.4	75.5 ± 7.3
	Median	77.0	76.0	76.0
	Min, Max	53, 91	53, 91	53, 91
Gender	Male	158 (40.8%)	140 (41.7%)	137 (41.4%)
	Female	229 (59.2%)	196 (58.3%)	194 (58.6%)
Race	American Indian or Alaska Native	2 (0.5%)	1 (0.3%)	1 (0.3%)
	Asian	2 (0.5%)	1 (0.3%)	1 (0.3%)
	Black or African American	6 (1.6%)	5 (1.5%)	5 (1.5%)
	Native Hawaiian or Other Pacific Islander	1 (0.3%)	1 (0.3%)	1 (0.3%)
	White	370 (95.6%)	322 (95.8%)	317 (95.8%)
	Not Reported	6 (1.6%)	6 (1.8%)	6 (1.8%)
Ethnicity	Hispanic or Latino	9 (2.3%)	9 (2.7%)	9 (2.7%)
	Not Hispanic or Latino	375 (96.9%)	324 (96.4%)	319 (96.4%)
	Not Reported	3 (0.8%)	3 (0.9%)	3 (0.9%)
Education	Less than High School Degree	13 (3.4%)	11 (3.3%)	11 (3.3%)
	High School Degree	109 (28.2%)	87 (25.9%)	85 (25.7%)
	Some college (no degree)	80 (20.7%)	71 (21.1%)	70 (21.1%)
	College Degree (Associate or Bachelor's Degree)	125 (32.3%)	112 (33.3%)	111 (33.5%)
	Graduate Degree	52 (13.4%)	49 (14.6%)	48 (14.5%)
	Trade School	6 (1.6%)	5 (1.5%)	5 (1.5%)
	Other[2]	2 (0.5%)	1 (0.3%)	1 (0.3%)
Study Eye	OD	181 (46.8%)	160 (47.6%)	157 (47.4%)
	OS	206 (53.2%)	176 (52.4%)	174 (52.6%)

% = n / N × 100%.

[1] Fluid Agreement Analysis Population = Fluid Precision Analysis Population for this study

[2] Including some graduate school, trade school, and tech school

Table 17-5: Demographics of Safety Population and mVAP – 006 Study

Baseline Characteristics		Safety Population N = 387	Fluid Marking (DICE) Analysis Population N = 336	Fluid Agreement Analysis Population[1] N = 331
AMD Diagnosis Based on Participants' Medical Record	AMD - Early AMD	1 (0.3%)	1 (0.3%)	1 (0.3%)
	AMD - Intermediate AMD	6 (1.6%)	4 (1.2%)	4 (1.2%)
	NV-AMD - active (fluid present)	372 (96.1%)	323 (96.1%)	319 (96.4%)
	NV-AMD - non active (no fluid present)	8 (2.1%)	8 (2.4%)	7 (2.1%)
Lens Status	Phakia (cataract absent)	6 (1.6%)	5 (1.5%)	5 (1.5%)
	Phakia (cataract present)	123 (31.8%)	119 (35.4%)	116 (35.0%)
	Pseudophakia	258 (66.7%)	212 (63.1%)	210 (63.4%)
Ocular Media Assessment	Main vessels and the small vessels are clearly seen.	357 (92.2%)	307 (91.4%)	305 (92.1%)
	Small vessels are invisible while main vessels can be seen.	30 (7.8%)	29 (8.6%)	26 (7.9%)
Prior Total # of Injections	N	359	313	310
	Mean ± SD	25.9 ± 25.6	25.7 ± 25.2	26.0 ± 25.2
	Median	17.0	18.0	18.0
	Min, Max	1, 142	1, 134	1, 134
	N (Unavailable)	28	23	21
Medication Most Recently Administered	Aflibercept (Eylea)	190 (49.1%)	167 (49.7%)	166 (50.2%)
	Bevacizumab (Avastin)	97 (25.1%)	85 (25.3%)	84 (25.4%)
	Brolucizumab (Beovu)	5 (1.3%)	4 (1.2%)	4 (1.2%)
	Other Investigational Drug	13 (3.4%)	12 (3.6%)	11 (3.3%)
	Ranibizumab (Lucentis)	47 (12.1%)	39 (11.6%)	39 (11.8%)
	Vabysmo (Faricimab-svoa)	7 (1.8%)	6 (1.8%)	6 (1.8%)
	Unavailable	28 (7.2%)	23 (6.8%)	21 (6.3%)
Spherical Equivalent	N	387	336	331
	Mean ± SD	-0.131 ± 1.686	-0.166 ± 1.745	-0.172 ± 1.749
	Median	0.000	0.000	0.000
	Min, Max	-7.500, 4.750	-7.500, 4.750	-7.500, 4.750
Best Corrected Visual Activity	N	387	336	331
	Mean logMAR (Snellen)	0.370 (20/46.9)	0.350 (20/44.8)	0.344 (20/44.2)
	SD logMAR	0.293	0.283	0.277
	Median logMAR (Snellen)	0.300 (20/39.9)	0.300 (20/39.9)	0.300 (20/39.9)
	Min logMAR (Snellen)	-0.10 (20/16.0)	-0.10 (20/16.0)	-0.10 (20/16.0)
	Max logMAR (Snellen)	1.20 (20/320.0)	1.20 (20/320.0)	1.20 (20/320.0)

Best Corrected Visual Activity	20/40 or Better	194 (50.1%)	178 (53.0%)	177 (53.5%)
	20/41 to 20/80	110 (28.4%)	92 (27.4%)	92 (27.8%)
	20/81 to 20/200	68 (17.6%)	55 (16.4%)	52 (15.7%)
	20/201 to 20/320	15 (3.9%)	11 (3.3%)	10 (3.0%)
Principal Investigator's Retinal Fluid Assessment Based on Commercial OCT	Both IRF and SRF	82 (21.2%)	73 (21.7%)	73 (22.1%)
	SRF only	123 (31.8%)	108 (32.1%)	109 (32.9%)
	IRF only	142 (36.7%)	121 (36.0%)	120 (36.3%)
	No IRF nor SRF	35 (9.0%)	29 (8.6%)	28 (8.5%)
	Unavailable	5 (1.3%)	5 (1.5%)	1 (0.3%)

% = n / N × 100%.

[1] Fluid Agreement Analysis Population = Fluid Precision Analysis Population for this study

Table 17-6: Baseline Characteristics Safety, Fluid Marking and Fluid Agreement Analysis Populations

The repeatability and reproducibility percent coefficient of variation (%CV) ranged from 24.6% to 436.4% and from 26.2% to 475.2%, respectively, for TRO <10 VU. For TRO >10 VU, repeatability %CVs ranged from 5.9% to 25.0%, and reproducibility %CVs ranged from 11.4% to 33.4%.

The following Table 16.7 and Figures 16.4, 16.5 and 16.6 show the device-grader Dice coefficient and NPA for each grader acting as the “reference standard”.

Statistics	NOA vs. Grader 1	NOA vs. Grader 2	NOA vs. Grader 3	Grader 1 vs. Grader 2	Grader 1 vs. Grader 3	Grader 2 vs. Grader 3
Comparing NOA-Grader TRO DICE to Grader-Grader TRO DICE						
N*	278	289	299	279	297	298
Dice Mean ± SD	0.5819 ± 0.2958	0.5655 ± 0.3203	0.5196 ± 0.3182	0.6222 ± 0.2754	0.5453 ± 0.3018	0.6000 ± 0.2918
95% CI of DICE Mean	0.5470, 0.6168	0.5284, 0.6026	0.4834, 0.5558	0.5897, 0.6546	0.5108, 0.5797	0.5668, 0.6333
Dice Median	0.6802	0.6844	0.6123	0.7221	0.6274	0.6964
NPA	0.734 (58/79)	0.746 (47/63)	0.787 (37/47)	0.722 (57/79)	0.494 (39/79)	0.603 (38/63)
95% CI of NPA[1]	0.623, 0.827	0.621, 0.847	0.643, 0.893	0.609, 0.817	0.379, 0.609	0.472, 0.724
Comparing NOA-Grader SRO DICE to Grader-Grader SRO DICE						
N*	213	223	241	205	232	235
Dice Mean ± SD	0.5379 ± 0.3495	0.5394 ± 0.3550	0.4951 ± 0.3612	0.5670 ± 0.3283	0.4934 ± 0.3530	0.5558 ± 0.3403
95% CI of DICE Mean	0.4907, 0.5852	0.4925, 0.5862	0.4492, 0.5409	0.5218, 0.6122	0.4477, 0.5390	0.5120, 0.5995
Dice Median	0.6811	0.6799	0.6536	0.7161	0.6129	0.6956
NPA	0.764 (123/161)	0.801 (113/141)	0.856 (95/111)	0.814 (131/161)	0.646 (104/161)	0.716 (101/141)
95% CI of NPA[1]	0.691, 0.827	0.726, 0.864	0.776, 0.915	0.745, 0.871	0.567, 0.720	0.634, 0.789
Comparing NOA-Grader IRO DICE to Grader-Grader IRO DICE						
N*	160	172	224	180	231	229
Dice Mean ± SD	0.4594 ± 0.3139	0.4316 ± 0.3263	0.2972 ± 0.3107	0.5100 ± 0.3312	0.3631 ± 0.3358	0.4227 ± 0.3444
95% CI of DICE Mean	0.4104, 0.5084	0.3825, 0.4807	0.2563, 0.3381	0.4613, 0.5587	0.3196, 0.4067	0.3779, 0.4676
Dice Median	0.5429	0.5133	0.1970	0.6519	0.4059	0.5467
NPA	0.946 (176/186)	0.965 (164/170)	0.966 (112/116)	0.839 (156/186)	0.565 (105/186)	0.629 (107/170)
95% CI of NPA[1]	0.903, 0.974	0.925, 0.987	0.914, 0.991	0.778, 0.888	0.490, 0.637	0.552, 0.702

N* is the number of cases that have a segmentation from NOA or the Grader

[1] Exact CI per binomial distribution

Table 17-7: Descriptive Statistics of Eye-Level DICE Between NOA versus Graders and Graders versus Graders

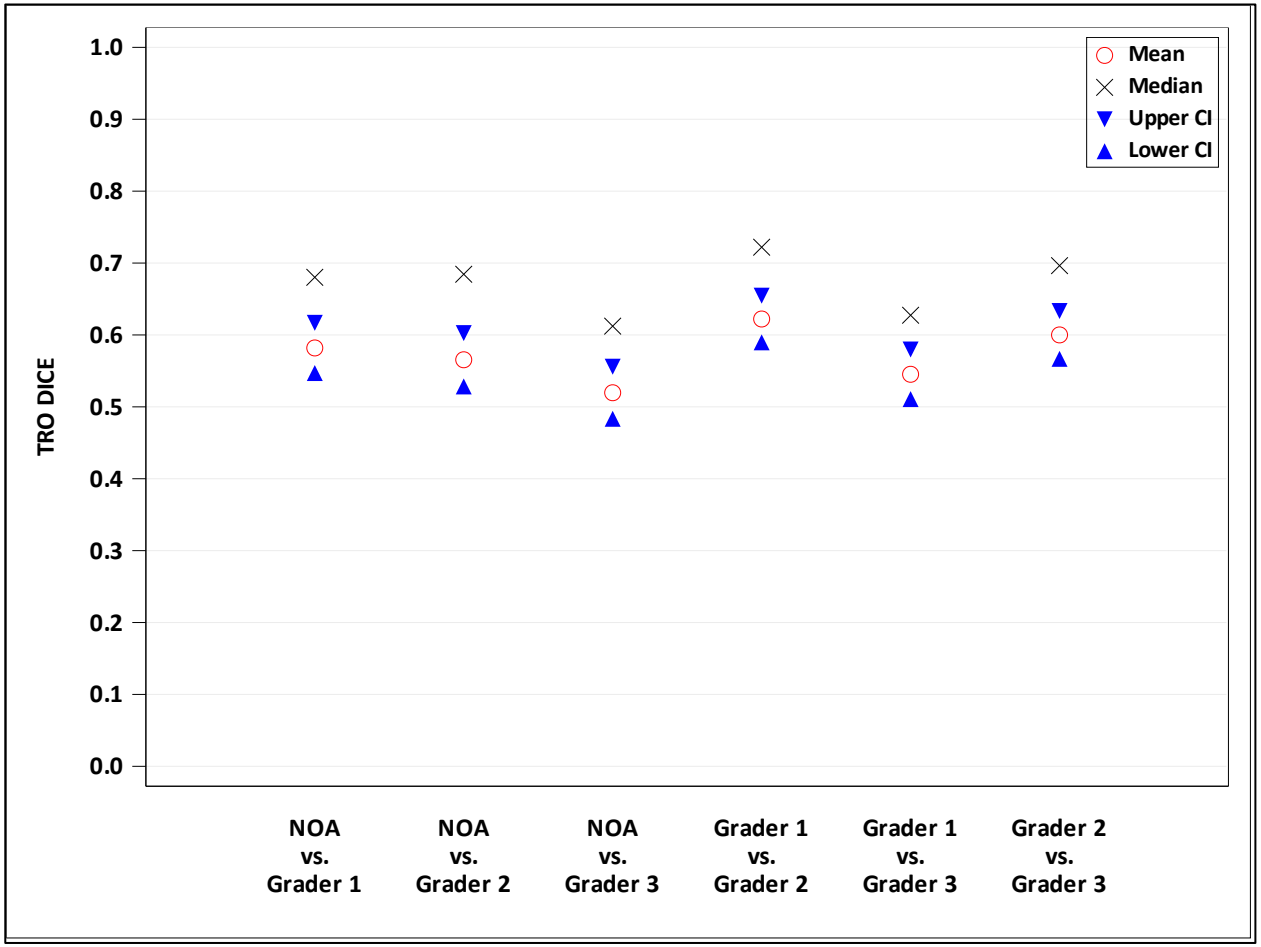


Figure 17-4: Comparing NOA-Grader TRO DICE to Grader-Grader TRO DICE on NVHO Scan

(Without Imputation of 1 for No Segmentations from Both Method)

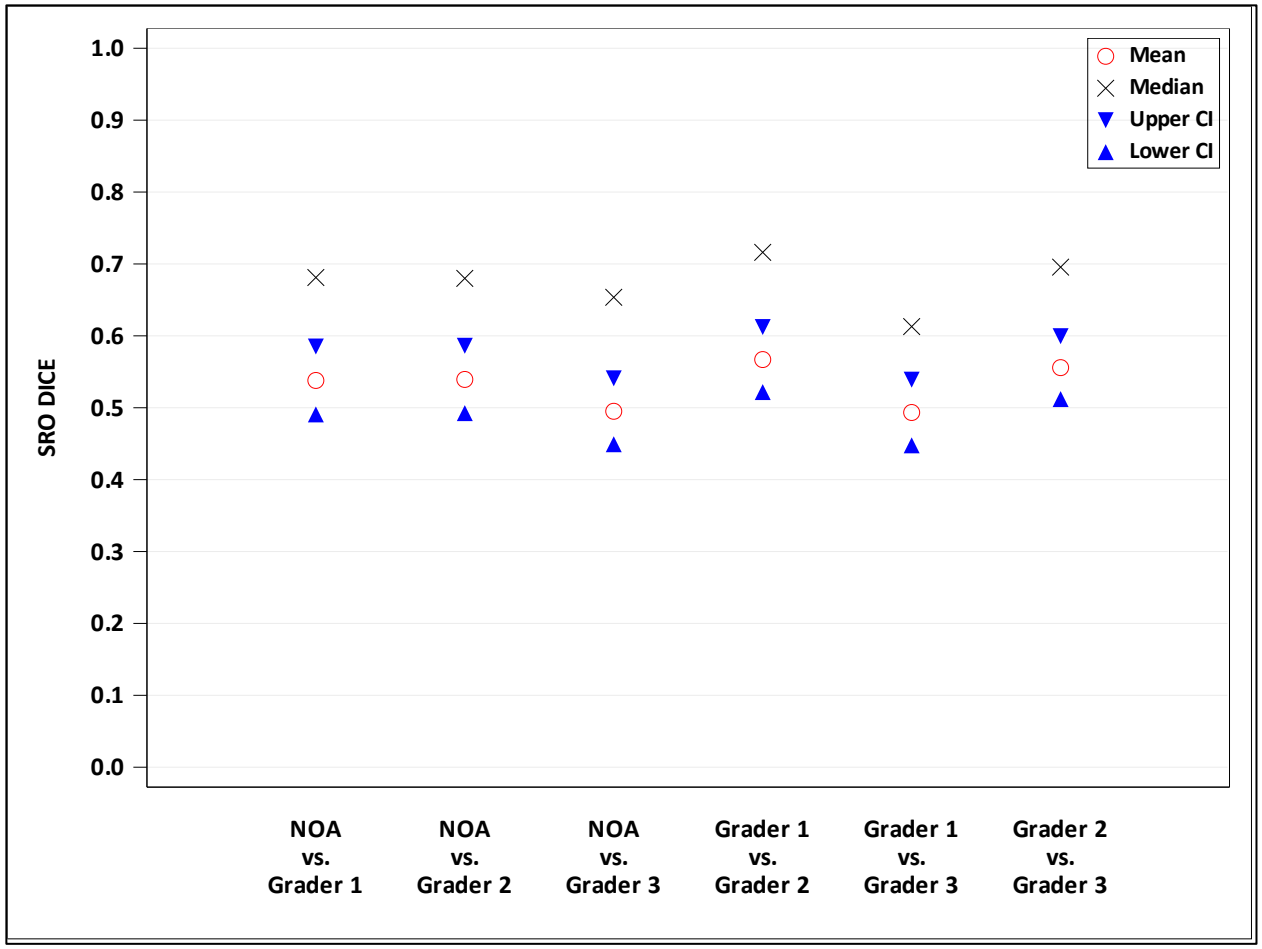


Figure 17-5: Comparing NOA-Grader SRO DICE to Grader-Grader SRO DICE on NVHO Scan

(Without Imputation of 1 for No Segmentations from Both Method)

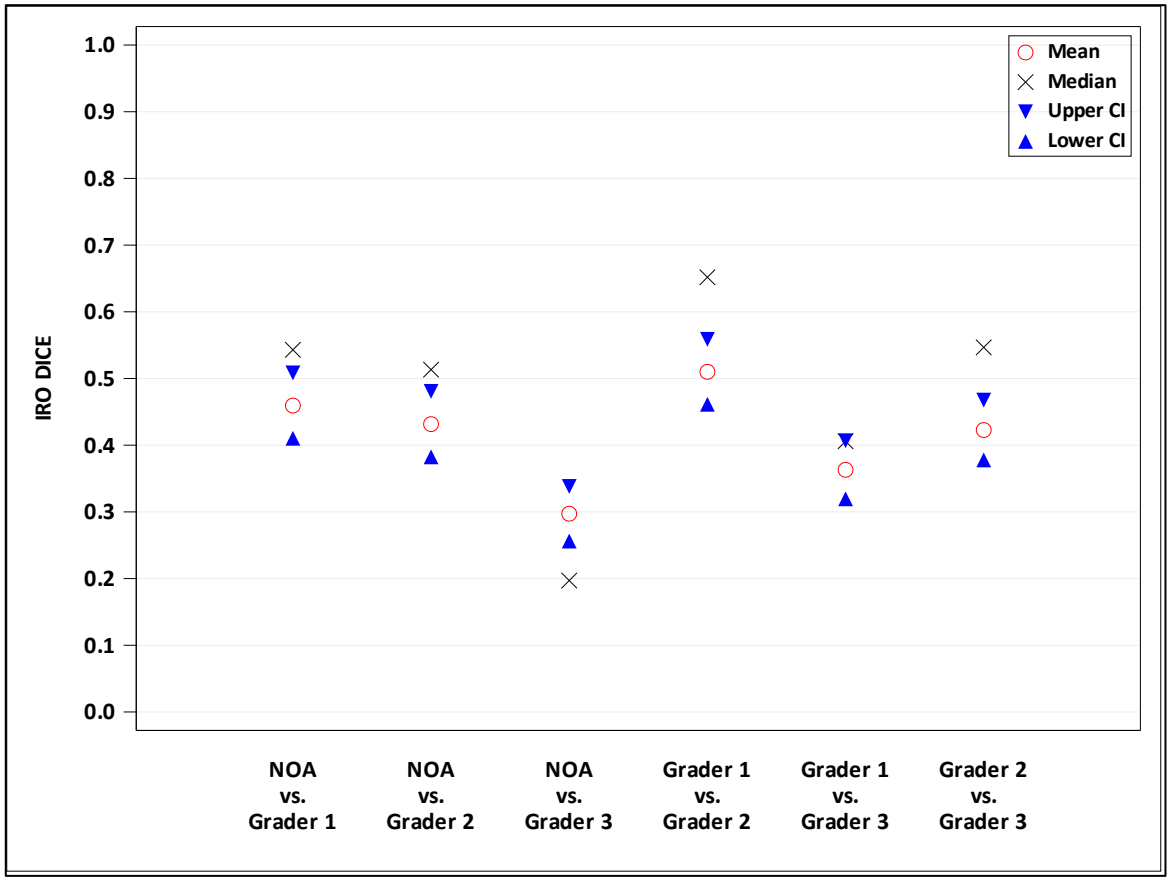


Figure 17-6: Comparing NOA-Grader IRO DICE to Grader-Grader IRO DICE on NVHO Scan

(Without Imputation of 1 for No Segmentations from Both Method)

The following Table 16.8 and Figures 16.7, 16.8 and 16.9 show the device-grader and grader-grader PPA for each grader acting as the "reference standard."

	"True"	Grader 1			Grader 2			Grader 3		
	"Test"	NOA	Grader 2	Grader 3	NOA	Grader 1	Grader 3	NOA	Grader 1	Grader 2
TRO	N[1]	273	273	273	257	257	257	289	289	289
	Mean ± SD	0.5315 ± 0.2958	0.6147 ± 0.2676	0.7007 ± 0.2346	0.5919 ± 0.2686	0.7511 ± 0.2197	0.7262 ± 0.2140	0.4832 ± 0.3162	0.6278 ± 0.2989	0.5356 ± 0.3054
	95% CI of Mean	0.4963, 0.5668	0.5828, 0.6466	0.6727, 0.7286	0.5589, 0.6249	0.7241, 0.7781	0.6999, 0.7525	0.4466, 0.5198	0.5932, 0.6624	0.5002, 0.5709
	Median	0.6011	0.7049	0.7793	0.6600	0.8158	0.7926	0.5143	0.7207	0.6262
SRO	N[1]	195	195	195	175	175	175	225	225	225
	Mean ± SD	0.5584 ± 0.3147	0.5640 ± 0.3066	0.6727 ± 0.2478	0.6462 ± 0.2853	0.7580 ± 0.2502	0.7133 ± 0.2287	0.5011 ± 0.3615	0.6277 ± 0.3544	0.5019 ± 0.3567
	95% CI of Mean	0.5139, 0.6028	0.5207, 0.6073	0.6377, 0.7077	0.6036, 0.6887	0.7207, 0.7954	0.6792, 0.7474	0.4536, 0.5486	0.5811, 0.6742	0.4551, 0.5488
	Median	0.6667	0.6849	0.7639	0.7311	0.8478	0.7944	0.5875	0.7802	0.6400
IRO	N[1]	166	166	166	150	150	150	220	220	220
	Mean ± SD	0.3789 ± 0.2931	0.5606 ± 0.3186	0.7010 ± 0.2694	0.4209 ± 0.2812	0.6510 ± 0.2911	0.6799 ± 0.2694	0.2466 ± 0.2710	0.4187 ± 0.3408	0.3555 ± 0.3271
	95% CI of Mean	0.3340, 0.4239	0.5117, 0.6094	0.6597, 0.7422	0.3755, 0.4663	0.6040, 0.6979	0.6365, 0.7234	0.2106, 0.2826	0.3735, 0.4640	0.3120, 0.3989
	Median	0.4054	0.6793	0.8168	0.4616	0.7601	0.7533	0.1429	0.4770	0.3483

[1] Excluding eyes with 0 "True" segmentations

Table 17-8: Descriptive Statistics of Pixel-level Positive Percent Agreement of Study Eyes on NVHO Scan

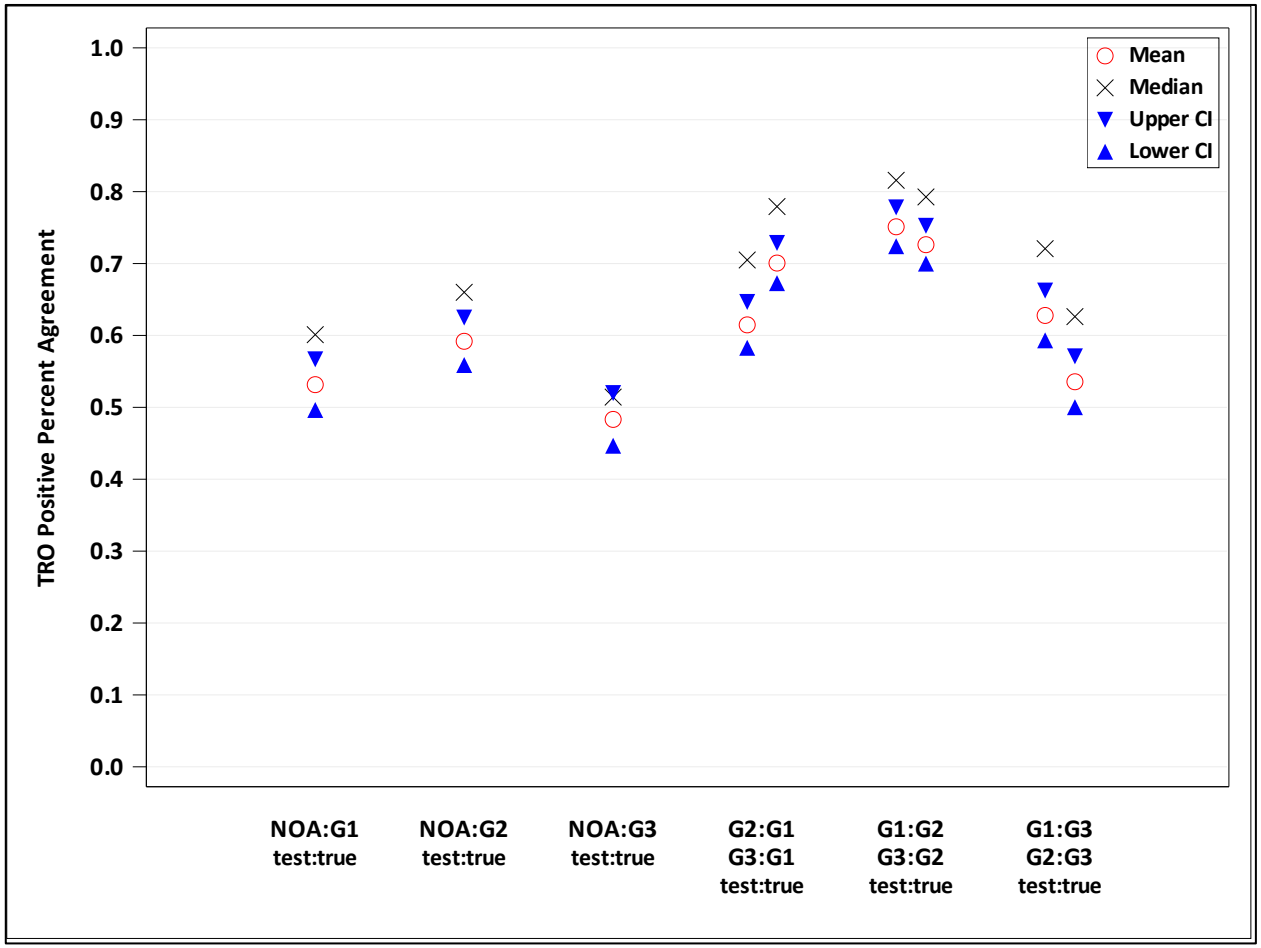


Figure 17-7: Comparing Device-Grader Positive Percent Agreement to Grader-Grader Positive Percent Agreement of TRO on NVHO scan

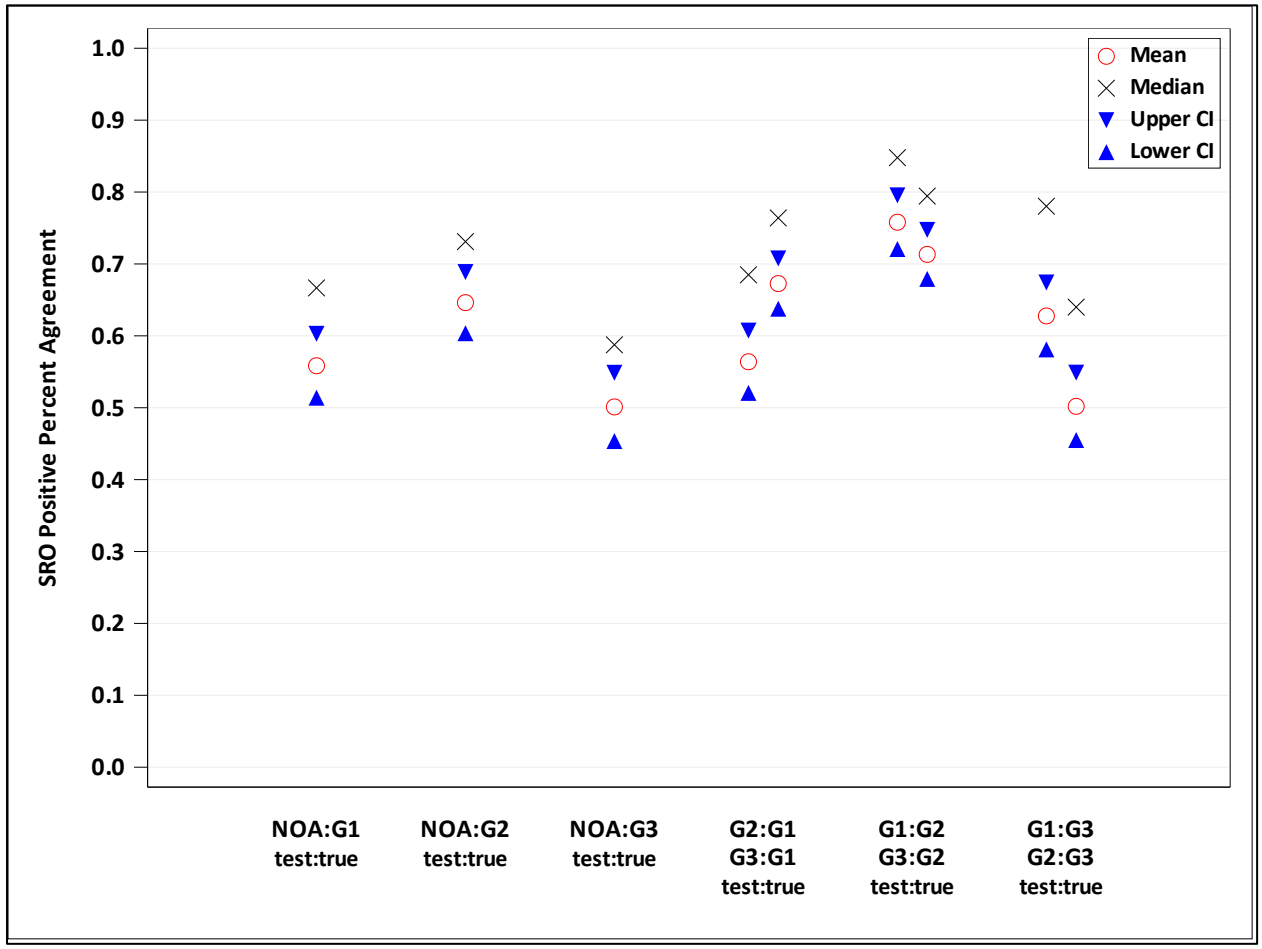


Figure 17-8: Comparing Device-Grader Positive Percent Agreement to Grader-Grader Positive Percent Agreement of SRO on NVHO scan

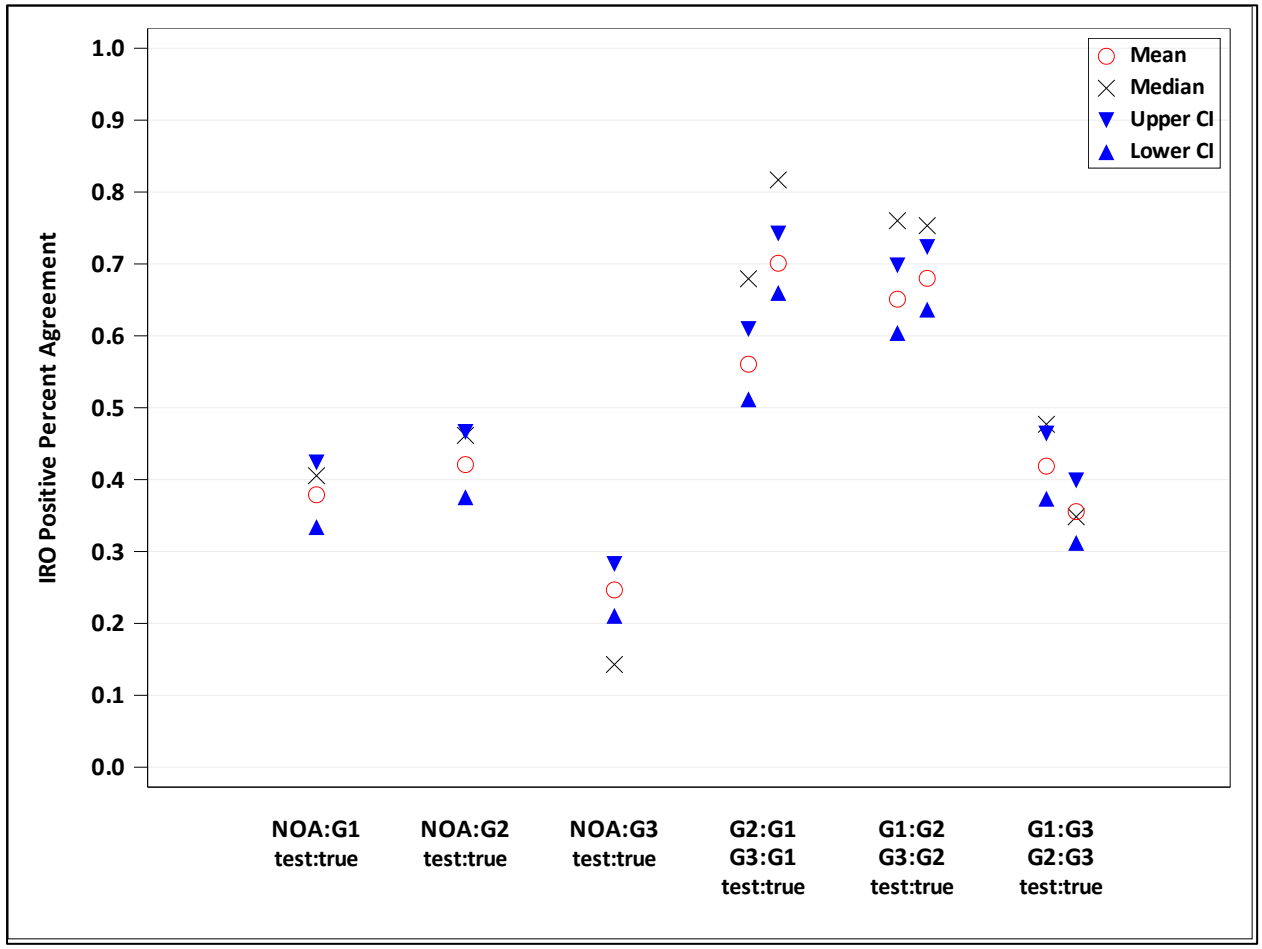


Figure 17-9: Comparing Device-Grader Positive Percent Agreement to Grader-Grader Positive Percent Agreement of IRO on NVHO scan