WARNINGS AND PRECAUTIONS

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 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 SCANLY Home OCT device.
	**Warning**: The SCANLY Home OCT device shall not be used by patients with Visual Acuity of worse than 20/320.

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.

SCANLY Home OCT Web Viewer 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 Web Viewer 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 SCANLY device
	**Warning:** Notal OCT Analyzer (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.

SCANLY Home OCT Web Viewer 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 Web Viewer. 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 SCANLY device exchange as the trajectory before and after the exchange may show a local discontinuity.

SCANLY Home OCT Web Viewer 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.

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

1-888-910-2020

casemanagement@notalvision.com

