



ADVISORY NOTICE

Abbott Medical Optics (AMO) STAR S4 IR Excimer Laser System Software Versions 5.00 – 5.22

July 18, 2011

Dear STAR S4 IR Customer:

Abbott Medical Optics Inc. (AMO) is providing this Advisory Notice to all customers who use the AMO **STAR S4 IR** Excimer Laser System to make you aware of a discrepancy with pupil centroid shift compensation in the STAR S4 IR software (Versions 5.00 through 5.22) and describe actions you should take.

Iris Registration (IR) is designed to compensate for pupil centroid shift and cyclorotation, to achieve optimal alignment of the **CUSTOMVUE** ablation. The compensation for right eye pupil centroid shift in Software Versions 5.00 through 5.22 is not functioning as intended. As a result, the center of the ablation pattern in the right eye may not be optimally aligned. Additionally, if IR capture in the right eye is not successful, the left eye ablation may also not be optimally aligned. Imperfect alignment may, in some cases, lead to visual disturbances or reduced best corrected visual acuity, although our investigation indicated no clinically significant effect on refractive outcomes from this software discrepancy.

Note that the compensation for cyclorotation is not affected by this discrepancy and functions as intended in both eyes. In addition, the **ACTIVETRAK** system continues to function as intended.

AMO is currently developing a STAR S4 IR software update to address this discrepancy. In the interim, AMO provides the following action to continue treatment on the STAR S4 IR Excimer Laser System.

Action to Take by the User:

Create a separate patient file for each eye on the WaveScan® WaveFront System.

This action achieves the full benefits of IR which includes compensation for pupil centroid shift and compensation for cyclorotation in both eyes. As always, caution must be exercised to ensure treatment is applied to the correct eye. See Appendix A for instructions.

To treat a patient who does not have a separate patient file created for each eye, do not engage the IR function in the STAR S4 IR Excimer Laser System before commencing treatment. Treatments without IR will not include compensation for pupil centroid shift and cyclorotation. As stated in the STAR S4 IR Excimer Laser System Operator's Manual (International version part number 0030-6738, Section 6.12), without IR engaged, "alter the ambient illumination (ring, oblique, and/or room)...[and] align the cornea using limbal landmarks noted at the slit lamp prior to the surgical procedure." See Appendix B for instructions.

For each CustomVue surgeon at your site, complete and return the attached facsimile to AMO via fax at +353 1675 4660 within the next 3 business days as an acknowledgement of:

- Receipt of this Advisory Letter, and
- Understanding of the information contained within this letter.

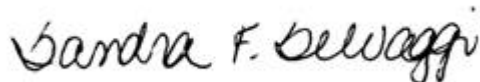
Your patients who have been previously treated with the AMO STAR S4 IR Excimer Laser System require no additional follow-up. Any adverse events or complaints experienced with use of this product should be reported to AMO by calling +353 1643 6272, or +1 949 862 3913, Press 1#, 2, 2.

Please share the information in this Advisory Notice with your staff. Please ensure that all personnel who operate your WaveScan(s) are aware of this Advisory Notice. If you or your facility has transferred your STAR S4 IR Excimer Laser System to other persons or facilities, please promptly forward the recipients a complete copy of this Advisory Notice, including the fax acknowledgement form.

AMO appreciates your attention to this issue and we apologize for any inconvenience this action may cause. AMO is committed to providing you with state-of-the-art technology that allows you to perform the safest and most effective laser vision correction treatments possible and as such, we are constantly improving our technology and ensuring it always meets our mutual high quality standards. We appreciate your cooperation in these efforts.

If you have any questions regarding the information or recommendations in this Advisory Notice, please contact your local distributor.

Very truly yours,

A handwritten signature in black ink that reads "Sandra F. Selvaggi". The signature is written in a cursive, flowing style.

Sandra Selvaggi
Senior Director, Quality and Compliance
Abbott Medical Optics Inc.

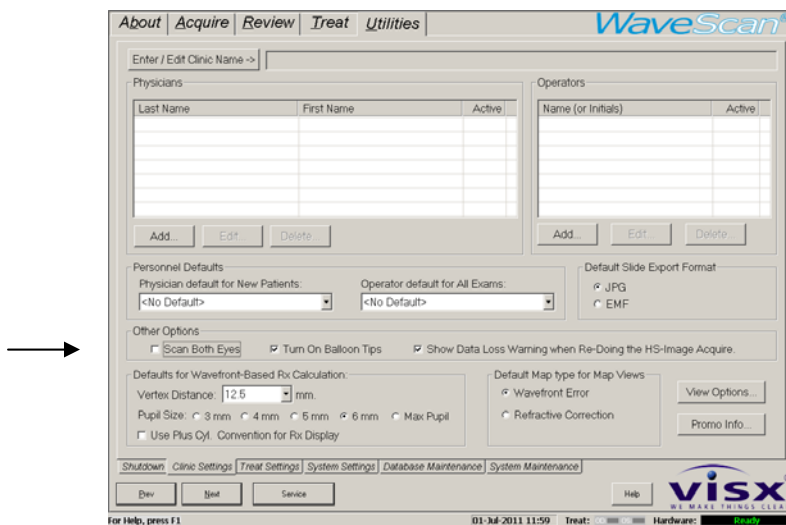
Appendix A: Naming of WaveScan Patient Acquisition Files

When using Iris Registration, it is necessary to Acquire, Design, Calculate and transfer the CustomVue treatment for the right eye and left eye separately. Please note that any patients in your WaveScan database that have been acquired but not treated will need to be recreated using these guidelines.

Please follow the instruction below:

Setting Default on Clinic Settings Sub Tab of Utilities Tab

1. On the Clinic Settings Sub Tab of the Utilities Tab, uncheck the Scan Both Eyes Checkbox. Use this setting for acquiring patient data for all patients.



Acquiring Patient Data for OD at the WaveScan® WaveFront System

1. On the Patient sub-tab of the Acquire tab, click on **New Patient**.
2. Enter the patient's demographic information in the **Add Patient** window.
3. For the Patient's Right Eye, enter the last name of the patient with the capitalized eye (OD) added to the last name. (Example: PatientOD, Joe)

A screenshot of the 'Add Patient' dialog box. The 'Demographics' tab is active. The 'Last Name' field contains 'PatientOD', 'First Name' contains 'Joe', and 'ID' contains '01'. The 'Date of Birth' is set to MM/DD/YYYY format. The 'Sex' is set to Male. The 'Address' and 'Referral' fields are empty. The 'OK', 'Cancel', and 'Help' buttons are at the bottom.

Example of programming for Right (OD) eye

4. On the Acquire Tab, ensure the “Scan Both Eyes” checkbox is unchecked.

WaveScan®

About Acquire Review Treat Utilities

Patient Search: Last Name: PatientOD First Name: Joe ID: 01

Last Name	First Name	ID
PatientOD	Joe	01
PatientOS	Joe	01

Selected Patient: <No Patient Selected>

Patient Notes:

Physician: Doctor, Test Operator: 1

Scan Both Eyes: ☐ Eye to Scan 1st: OD Vertex: 12.5 mm Exams to Acquire: 3

Default OD Exam Notes: Default OS Exam Notes:

Patient: New Patient... Edit Patient... Clear Search Fields

visx® WE MAKE THINGS CLEAR

Please select patient, eye. 21-Jun-2011 16:45 Treat: Hardware: ready

5. Eye to Scan 1st: Select OD
6. Exams to Acquire: Select 3.
7. Acquire exams for OD.

Acquiring Patient Data for OS

1. On the Patient sub-tab of the Acquire tab, click on **New Patient**.
2. Enter the patient’s demographic information in the **Add Patient** window.
3. For the Patient’s Left Eye, enter the last name of the patient with the capitalized eye (OS) added to the last name (Example: PatientOS, Joe)

Add Patient

Demographics Notes

Last Name: PatientOS First Name: Joe ID: 01

Date of Birth - MM: DD: YYYY:

Sex: M

Address:

Referral:

OK Cancel Help

Example of programming for Left (OS) eye

4. On the Acquire Tab, verify the “Scan Both Eyes” checkbox is not selected
5. Eye to Scan 1st: Select OS
6. Exams to Acquire: Select 3.
7. Acquire exams for OS.

Programming Treatments

Program and calculate treatments utilizing your current process. Save each treatment on a USB drive and transfer the desired treatment(s) to the STAR S4 IR Excimer Laser System hard drive.

Performing Treatments on the STAR S4 IR Excimer Laser System

Confirm each named patient with the individual eye treatment is saved to the STAR S4 IR Excimer Laser System hard drive. When opening the patient file confirm that it contains the correct treatment for the correct eye. After completing the treatment for the Right eye, the Left eye treatment must be opened and a fluence check will be required before proceeding.

NOTE: It is critically important that the correct patient file for the Right Eye be selected when Acquiring, Designing and Calculating a WaveScan on the Right eye, and the correct patient file for the Left Eye be selected when Acquiring, Designing and Calculating a WaveScan on the Left eye.

It is the responsibility of the operating surgeon to confirm the correct treatment is loaded on the STAR S4 IR Excimer Laser System for the correct eye of the correct patient.

Appendix B: Treatment without Iris Registration

When treating with CustomVue in the absence of Iris Registration, the following is recommended:

- To minimize the pupil centroid shift, adjust the operative illumination to keep operative pupil diameter as close as possible to WaveScan pupil diameter (between 4 mm and 7 mm)

NOTE: The operative pupil diameter must be maintained between 1.5 mm and 6mm for the **ACTIVETRAK** system to operate.

- To compensate for cyclorotation that occurs when the patient is measured in the upright position at the WaveScan and treated in the supine position under the STAR S4 IR Excimer Laser System, note any limbal landmarks at the slit lamp that will allow alignment with the reticle under the laser or follow the steps below to mark the eye pre-operatively:
 1. With patient at the slit lamp and the eyes anesthetized, ask the patient to fixate with both eyes on a distant target
 2. Use a sterile marking pen to mark the limbus at either 6 and 12 o'clock or 3 and 9 o'clock.
 3. Position patient in the laser chair
 4. Deflate head fixation pillow with patient under the laser
 5. Occlude contralateral eye
 6. Elevate the flap
 7. Align limbal marks with appropriate reticle hash marks

These recommendations are in our training/certification materials.



STAR S4 IR SOFTWARE ACKNOWLEDGEMENT

Versions 5.00 – 5.22

RETURN FAX TO: +353 1675 4660

Please read this acknowledgment and complete all information below.

I certify that I have been informed of the Advisory Notice related to the STAR S4 IR Software Versions 5.00 – 5.22

STAR S4 IR

Laser Serial

Number: _____

WaveScan

System Serial

Number: _____

Account Name: _____

Physician Name: _____

Street Address: _____

City: _____

Postal Code: _____

Country: _____

Signature: _____

Date: _____

Please return this fax acknowledgement to AMO within 3 business days.