Fundus Photograph Reading Center

Stratus Optical Coherence Tomography
(OCT 3)

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1. Stratus Optical Coherence Tomography (OCT3) Overview

Technicians using the Stratus will perform two scan types: the Fast Macular Thickness Map scan and the Cross Hair scan. Sites must be using the Zeiss Stratus OCT3 machine, software version 4.0 or higher.

Note that the OCT machine used for the screening visit must be used on that subject throughout the study. If a study subject is screened using the Status OCT3, that machine will need to be maintained and kept at the study site until the last subject visit.

Further clarification regarding any information included in this document may be obtained by contacting the FPRC Imaging staff at (608) 410-0619.

2. OCT Technician Certification

2.1. Overview

All technicians performing OCT must be certified for the relevant procedure(s) before submitting actual subject scans.

The following scans may be performed on subjects for whom OCT is being carried out for clinical purposes or on volunteers.

2.2. Scans Required

Certification consists of performing the required scans on two eyes (one eye with pathology and one normal eye).

Case 1 – Eye with Pathology:

Session 1:
- One Fast Macular Thickness Map scan on an eye with central retinal thickening of at least 250 microns
- One 6.0mm Cross Hair

Session 2:
- One Fast Macular Thickness Map a few minutes later of the same eye as Case 1, Session 1

Case 2 - Normal or Near-Normal Eye:

Session 1:
- One Fast Macular Thickness Map scan on an eye with a normal or near normal macula.

Session 2:
- One Fast Macular Thickness Map a few minutes later of the same eye as Case 2, Session 1
2.3. Certification Scan Quality Guidelines

A Fast Macular Thickness scan is considered acceptable if:

- The scan is centered on the macula.
- The retinal boundaries indicated by white lines on the underlying scans (the internal limiting membrane and the retinal pigment epithelium) do not contain obvious major errors at the center of the macula.
- To assess the OCT technician’s scan reproducibility, the Retinal Map Reports from Session 1 and Session 2 should have center point values within 10% of each other.
- The standard deviation of the center point is not greater than 10%.

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\text{Standard deviation percentage} = \frac{\text{Standard Deviation}}{\text{Center Point Thickness}} \times 100
\]

2.4. Submitting Certification Scans to the FPRC

Certification submissions will be evaluated to determine if the scans are of acceptable quality and taken according to the specified parameters. Export scans as outlined in section 3 Exporting, and replace patient identifying information with certification information.

OCT technicians who meet certification criteria will receive written confirmation of certification via email. Technicians who do not meet these criteria will receive feedback from the FPRC Imaging consultants and will be required to submit additional scans.

2.4.1. Electronic Submission Using the FPRC Portal (Preferred)

To request certification apply online through the FPRC Portal and upload scans, if applicable. See https://fprcportal.ophth.wisc.edu/ for login and upload instructions.

2.4.2. CD/DVD Submission

In cases where the FPRC Portal cannot be used, the scans should be sent with the completed Certification Request Form. See the CD/DVD Submission document for details about labeling and sending scans to the FPRC. Burning Stratus export files to CD requires specific file format settings. If you are not familiar with these settings, refer to the Stratus procedures on the FPRC website http://eyephoto.ophth.wisc.edu/.

2.5. Uncertified Technicians

2.5.1. Baseline/Screening Visits

Only FPRC-certified OCT technicians are allowed to take baseline (screening visit) scans, unless an exception to this rule is granted (on a case-by-case basis) by the study sponsor. The baseline measurements for a subject are critical since all follow-up measurements are compared to this point to determine the study outcome.
The sponsor may suspend subject enrollment if the site does not have a certified technician available to take the baseline scans.

2.5.2. Follow-up Visits

On rare occasions during follow-up visits ONLY, when a certified technician is not available to perform the scans, an uncertified technician familiar with the procedure may perform the scans. The uncertified technician should review the OCT procedure before performing scans to be certain he/she understands the procedure and follows the study requirements. Include a comment on the Transmittal Log or any official documentation indicating that the scans were performed by an uncertified technician and the reason why.

2.6. Acquiring the Scans

Standard clinic procedures should be followed to obtain optimal quality scans for analysis. A good quality scan should have a signal strength of at least 5. If media opacities or other factors prevent good scan quality, note this in the Comments section of your submission. The eye(s) to be scanned is determined by the visit schedule in the study protocol. The following scans are required for each study visit:

- One Fast Macular Thickness Map
- One 6.0mm Cross Hair scan

3. Exporting

3.1. Renaming Subjects Prior to Export

1. Highlight the patient and go to Patient >Edit Patient
2. Enter anonymized information using the following format and select Apply.
   - Last Name: Study Name
   - First Name: Site#-Subject#
   - Date of Birth: 1/1/1900
   - Gender: Unknown
   - Patient ID: Subject#

3.2. Exporting Data Files

1. Export files should be saved to a folder on the desktop or jump drive. The folder should be named with the Site#-Subject# (or as Certification for certification submissions).
2. Select **Data > Export**.

3. Select the Subject, Visit and Exam set (i.e., Fast Macular Thickness Map scan and the Cross Hair scan sets) from the database.

4. Click **File > Database Export**.

5. When the **Export Options** box displays browse to the location of the folder to save files. Be sure that the **Obscure Patient** box is not checked.

6. Select **OK** to export the data. A notification will appear stating the export process is complete.
The following files should be in the folder.

- dataFiles
- export.ini
- Transfer.jpg

4. Submitting Study Scans to the FPRC

4.1. Electronic Submission Using the FPRC Portal (Preferred)

Digital scans may be transferred to the FPRC by uploading them through the FPRC Portal. See https://fprcportal.ophth.wisc.edu/ for login and upload instructions.

4.2. CD/DVD Submission

In cases where the FPRC Portal cannot be used, the study scans should be sent with the completed Transmittal Log. See the CD/DVD Submission document for details about labeling and sending scans to the FPRC. Burning Stratus export files to CD requires specific file format settings. If you are not familiar with these settings, refer to the Stratus procedure on the FPRC website http://eyephoto.ophth.wisc.edu/.