Fundus Photograph Reading Center

Spectral Domain Optical Coherence Tomography (SD-OCT)
Heidelberg Spectralis

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## Table of Contents

1. Heidelberg Spectralis OCT Overview

2. OCT Technician Certification
   - 2.1. Overview
   - 2.2. Scans Required
     - 2.2.1. Volume Scan
     - 2.2.2. Cross-Scan
   - 2.3. Submitting Certification Scans to the FPRC
   - 2.4. uncertified Technicians
     - 2.4.1. Baseline/Screening Visits
     - 2.4.2. Follow-up Visits

3. Acquiring the Scans
   - 3.1. Volume Scan
   - 3.2. Cross Scan
   - 3.3. Exporting E2E Files
1. Heidelberg Spectralis OCT Overview

Technicians using the Heidelberg Spectralis will capture one 20° x 20° Volume Scan at high speed with a 5/frame rate and 97 B-scans. Additionally, a 20° x 20° high-resolution cross-hair scan is performed at a 10/frame rate.

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

2. OCT Technician Certification

2.1. Overview

All technicians performing OCT must be certified for the relevant study procedure(s) before submitting actual study 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 will consist of performing the required scans on one eye. Scans should demonstrate the disorder to be studied, such as macular edema or exudative age-related macular degeneration, involving retinal thickening at the center of the macula (center point should be 250 microns or greater).

2.2.1. Volume Scan

This scan will acquire the volume scan at 20° x 20° at High Speed with a 5/frame rate and 97 B-scans.

2.2.2. Cross-Scan

This scan will acquire the horizontal and vertical B-scans at 20° x 20° at High Resolution with a 10/frame rate.

2.3. 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 3.3 Exporting E2E Files of this document, 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 Digital Imaging Specialists and will be required to submit additional scans.
2.4. Uncertified Technicians

2.4.1. 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.

2.4.2. 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 with the submission or any official documentation indicating that the images were taken by an uncertified technician and the reason why.

3. Acquiring the Scans

To obtain scans of good quality (high signal, low noise) be sure that the scan image is in the top third of the scan window. A good quality scan should have a quality score of at least 20. If media opacities or other factors prevent good scan quality, note this in the comments section of your submission.

3.1. Volume Scan

A custom volume scan can be created and saved so that each time you take an FPRC volume scan, it will capture with the correct settings.

1. Click on the Volume Scan icon.

2. Roll the mouse wheel forward to 97 B-Scans.

3. Select the High Speed (HS) button.

4. Move the ART slider to 5 frames.

5. Click and hold a Custom button for 3 seconds.
6. Name the file *FPRC Volume*.
7. Click *OK*.

### 3.2. Cross Scan

A custom cross scan can be created and saved so that each time you need to take an FPRC cross scan it will capture with the correct settings.

1. Click on the Radial Scan icon.
2. Roll the mouse wheel back until 2 lines are visible.
3. Select the High Resolution (*HR*) button.
4. Move the *ART* slider bar to 10.
5. Click and hold a *Custom* button for 3 seconds.
6. Name the file *FPRC XHair*.
7. Click *OK*.

### 3.3. Exporting E2E Files

1. Choose the study subject’s scans to export using the *No split screen* display.
2. Highlight all scans to be exported (images turn blue).
3. Right mouse click on one of the highlighted scans and select *Export > as E2E*.
4. Click the check box *Anonymize data*. Type in the Site#-Subject#.

5. Select *Browse* to select the export path. A window will then display to allow you to create a new folder to save the images to. Rename the folder with the format *Site#-Subject#*. 