Fundus Photograph Reading Center

Spectral Domain Optical Coherence Tomography (SD-OCT)
Topcon 3D OCT

Effective Date: 29 Jun 2012
# Table of Contents

1. Topcon 3D OCT Overview .................................................................................................................. 2  

2. OCT Technician Certification ........................................................................................................ 2  
2.1. Overview .......................................................................................................................................... 2  
2.2. Scans Required ................................................................................................................................. 2  
2.2.1. Macular Cube Scan .................................................................................................................. 2  
2.2.2. Cross Scan .............................................................................................................................. 2  
2.3. Submitting Certification Scans to the FPRC ............................................................................. 2  
2.4. Uncertified Technicians ............................................................................................................... 2  
2.4.1. Baseline/Screening Visits ....................................................................................................... 2  
2.4.2. Follow up Visits ...................................................................................................................... 3  

3. Acquiring the Scans .............................................................................................................................. 3  
3.1. OCT 1000 ...................................................................................................................................... 3  
3.1.1. 3D Scan ..................................................................................................................................... 3  
3.1.2. Cross Scan .................................................................................................................................. 4  
3.2. OCT 2000 ..................................................................................................................................... 4  
3.2.1. 3D Scan ..................................................................................................................................... 5  
3.2.2. Cross Scan .................................................................................................................................. 6  

4. Exporting .......................................................................................................................................... 7  
4.1. Renaming Subjects Prior to Export ............................................................................................ 7  
4.2. Export of Data files ....................................................................................................................... 7
1. Topcon 3D OCT Overview

Technicians using the Topcon 3D OCT will capture one Macular Cube Scan of 512 A-scans and 128 B-scans and a Cross Scan at 6.0mm with 1024 A-scan resolution.

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. Macular Cube Scan

This scan will acquire one cube scan at 512 x 128.

2.2.2. Cross Scan

This scan will acquire the horizontal and vertical B-scans at the 6.0 mm scan length and 1024 resolution.

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 4 Exporting 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 Imaging consultants 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 on the Transmittal Log or any official documentation indicating that the scans were performed by an uncertified technician and the reason why.

3. Acquiring the Scans

3.1. OCT 1000

To obtain scans of good quality (high signal, low noise) be sure that the scan image is in the top half of the scan window. A good quality scan should have an Image Quality value of approximately 30-50. Retake the scan if there are blink artifacts (black lines) or movement artifacts (vessels will not line up on the fundus images). If media opacities or other factors prevent good scan quality, note this in the comments section of the submission.

3.1.1. 3D Scan

1. Select *Macula Mode*.

2. Select *3D Scan*.

3. Use the following scan parameters:
   a. Scan length: 6.0 x 6.0mm
   b. Scan Resolution: 512 x 128
3.1.2. Cross Scan

1. Select Cross Scan.

2. Use the following scan parameters:
   a. Scan length: 6.0mm
   b. Scan Resolution: 1024
   c. Averaging Count: 4

3.2. OCT 2000

To obtain scans of good quality (high signal, low noise) be sure that the scan image is in the top half of the scan window and has been optimized. A good quality scan should have an Image Quality value of above 45 (quality meter should reach green). Retake the scan if there are blink artifacts (black lines) or movement artifacts (vessels won’t line up on the fundus images). If media opacities or other factors prevent good scan quality, note this in the comments section of your submission.
3.2.1. 3D Scan

1. Select *Macula Mode*.

2. Select 3D 6.0 x 6.0.
3. Use the following scan parameters:
   a. Scan size: 6.0 x 6.0mm
   b. Scan Resolution: 512 x 128
3.2.2. Cross Scan

1. Select *Cross Scan*.

2. Use the following scan parameters:
   a. Scan length: 6.0mm
   b. Scan Resolution: 1024
   c. Averaging Count: 4
4. Exporting

4.1. Renaming Subjects Prior to Export

Identifying subject information must be anonymized before sending to the FPRC.

1. Go to the Main System and select Edit Patient Information.
2. Enter anonymized information using the following format and select Update.
   - Last Name: Study Name
   - First Name: Site #-Subject #
   - Date of Birth: 1/1/1900
   - Gender: Other
   - ID: Subject #

4.2. Export of 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#.

2. From the opening screen select

3. Select both 3D-Scan and Cross-Scan for subject and choose Copy to: Study Drive.
4. Copy files from *Study Drive* to the folder created in step 1.