



University of Wisconsin
**SCHOOL OF MEDICINE
AND PUBLIC HEALTH**

Fundus Photograph Reading Center

Spectral Domain Optical Coherence Tomography (SD-OCT) Imaging Procedures

Topcon 3D OCT 1000 Mark II

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1. OCT Operator Certification

1.1. Overview

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

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

1.2. Scans Required

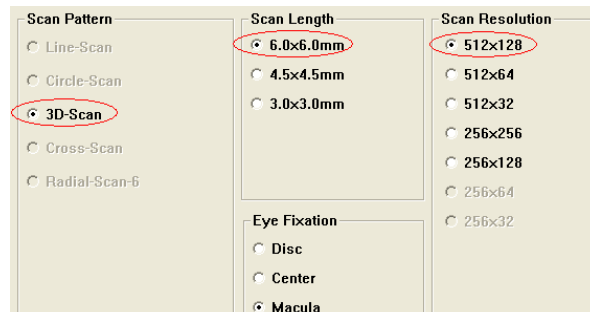
Scans should demonstrate the disorder to be studied involving retinal thickening at the center of the macula (approximately 250 microns or greater).

1.2.1. 3D Scan

This scan will acquire the cube scans at 6.0 x 6.0mm scan length and a resolution of 512x128 with the fixation on the macula.



- Select 3D-Scan
- Make sure settings are set at the following parameters:
 - Scan length : 6.0 x 6.0mm
 - Scan Resolution: 512 x 128



1.2.2. Cross-Scan

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

- Select Cross Scan
- Make sure settings are set to the following parameters:
 - Scan length : 6.0mm
 - Scan Resolution: 1024
 - Averaging Count: 1

The image shows a software interface for configuring an OCT scan. It is divided into several sections: 'Scan Pattern' with radio buttons for Line-Scan, Circle-Scan, 3D-Scan, Cross-Scan (selected), and Radial-Scan-6; 'Scan Length' with radio buttons for 6.0mm (selected), 4.5mm, and 3.0mm; 'Scan Resolution' with radio buttons for 2048 and 1024 (selected); 'Eye Fixation' with radio buttons for Disc, Center, and Macula (selected); and 'Averaging' with a dropdown menu for Count set to 1 and a checkbox for 'Check before averaging' which is unchecked.

1.3. Submission

A complete certification submission consists of the following:

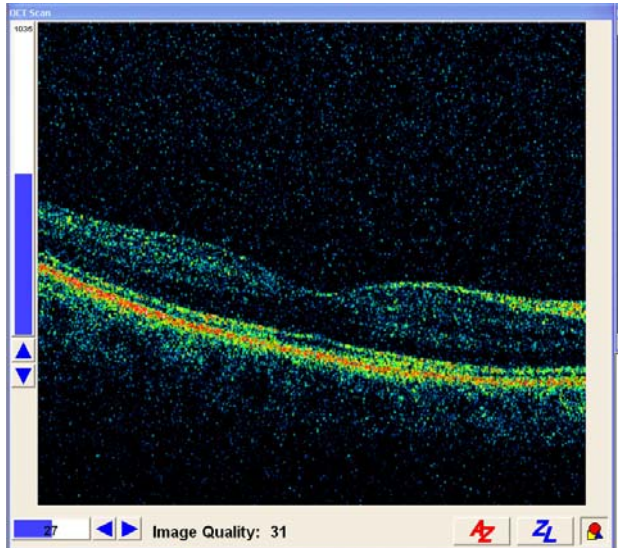
- Signed **Request for OCT Operator Certification** form
- Demonstrated ability to perform required scans of acceptable quality
- Submission of exported files on DVD or CD

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

Only FPRC-certified OCT operators 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 sponsor may suspend subject enrollment if the site does not have a certified operator available to take the baseline scans. Only under extraordinary circumstances may follow-up visit scans be performed by an uncertified operator.

2. OCT Scan Quality Guidelines

Standard clinic procedures should be followed to obtain optimal quality scans for analysis. Care should be taken to select scans that identify the retina's inner limiting membrane (ILM) and the retinal pigment epithelium (RPE).



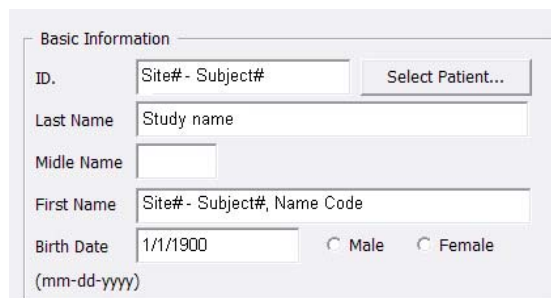
- Scan should appear in upper 1/2 of the display screen
- Image Quality value approximately 30-50
- No Black lines (black lines may appear if subject blinks)
- Vessels should line up on fundus image (if subject moves vessels will not line up)

The baseline measurements for a patient are critical since all follow-up measurements are compared to this point to determine the study outcome.

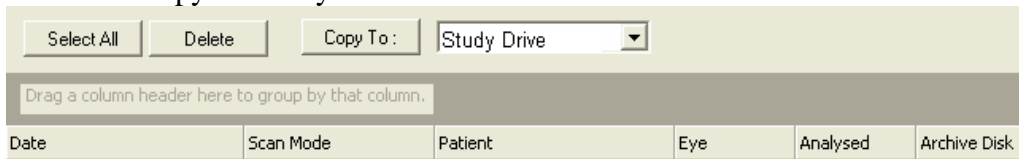
3. Renaming Subjects prior to export

Identifying subject information needs to be anonymized before sending to FPRC

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

A screenshot of a software form titled "Basic Information". The form has several input fields and a button. The "ID" field contains "Site# - Subject#" and has a "Select Patient..." button next to it. The "Last Name" field contains "Study name". The "Middle Name" field is empty. The "First Name" field contains "Site# - Subject#, Name Code". The "Birth Date" field contains "1/1/1900" and has radio buttons for "Male" and "Female". Below the "Birth Date" field is the text "(mm-dd-yyyy)".

3. Copy to: Study Drive



4. Go back to the OCTDB and rename the subject back to how it was as per medical records and select 'Update'
5. Continue to section Export images from study drive to CD/DVD.

4. Exporting Certification and Study scans

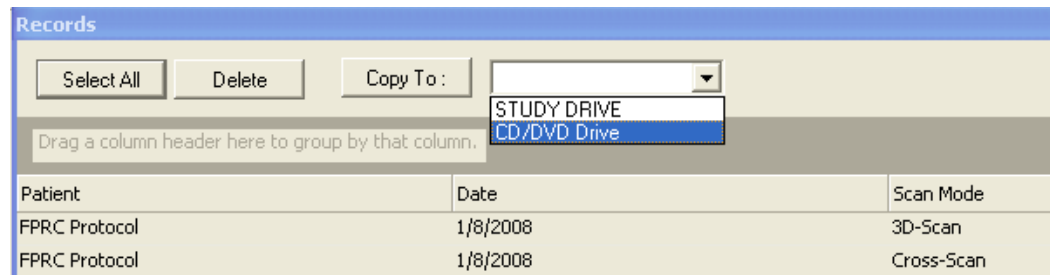
Export files should be saved to a separate folder on the desktop. The folder should be named with the Site#-Subject#, Name Code.

4.1. Exporting Raw and Analyzed data

Export selected files containing the unanalyzed raw data file and the analyzed data. The reading center needs to be able to reanalyze the images in the manufacturer specific review software if necessary.



1. From the opening screen select
2. Prior to Export the CD/DVD needs to be formatted
3. Select both 3D-Scan and Cross-Scan for subject and Choose Copy to: CD/DVD Drive



4.2. Contents of CD/DVD

The final CD/DVD should contain the following files:

- Datafiles
 - fda
 - fds
 - FILELIST

Send using the Labeling Instructions listed below.

5. Uncertified Operators (Follow-up Visit Only)

On rare occasions during follow-up visits ONLY, when a certified operator is not available to perform the scans, an uncertified operator familiar with the procedure may perform the scans. The uncertified operator should review the OCT procedure before performing scans to be certain s/he understands and follows the procedure. The name of the uncertified operator should be recorded on the DVD/CD labels. Include a comment on the transmittal log to indicate that the scans were performed by an uncertified operator.

6. Labeling Instructions

The DVD or CD containing the exported OCT scan files are to be labeled using the FPRC pre-printed labels. **If this is for certification and you do not have pre-printed certification labels, include the following information on the label:**

- Certification Set
- Study and Site information
- Operator's name
- Date the scans were performed



CD/DVD Labeling

7. Shipment Information

Send all study and certification scans via trackable carrier to the FPRC. Include a **Transmittal Log** form with all study (not certification) scans.