

# **DRCR.net Optical Coherence Tomography Procedure for OCT3 Systems (OCT-3)**

(adapted from University of Wisconsin–Madison/Department of Ophthalmology and Visual Sciences)

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## 1. Overview

Optical Coherence Tomography (OCT) is a diagnostic imaging technique using low-coherence interferometry to produce cross-sectional tomograms of the posterior segment eye structures. An 850 nm light source emits a probe beam of infrared light that is split between the eye and a reference mirror at a known spatial location. Both beams are reflected back to a photo detector, the time of flight delay of light back-scattered from different layers in the retina is determined, and thickness data are obtained. The OCT's internal computer acquires and processes the data to produce enhanced images by adjusting for movements of the eye and fluctuations in intraocular pressure. Retinal thickness is determined using many individual A-scans along each of six BScans.

A computer algorithm is used to determine the inner and outer retinal boundaries for each scan. This document contains information for sites using the Carl Zeiss Meditec Model 3000, OCT3 system with software version 4.0 or higher.

## 2. OCT Operator Certification

All operators performing OCT must be certified for the relevant procedure(s), *before submitting actual study scans*. (See Appendix A for a summary of certification requirements.) *Note that all sites MUST be using the OCT 3 machine with software version 4.0 or higher.* The requirement for submission of retinal thickness prints and/or digital files may be waived if the OCT operator has prior certification at a reading center approved by the DRCR Network Coordinating Center using the OCT3 system and has been actively performing OCT scans of good quality during the past year. Operators who have been previously certified for an identical procedure approved by the DRCR Network Coordinating Center, but have been inactive for more than one year, may be asked to submit an abbreviated certification set to become recertified. However, once an operator has been certified, he or she will remain certified for the life of the project.

**Certification** consists of:

1. Submission of a signed **Request for OCT Operator Certification form**.

Forms can be completed online at [www.drcr.net](http://www.drcr.net): *Clinical Sites < Certification < OCT Operator Certification Request Form*.

2. Demonstrated ability to perform the Fast Macular Thickness Map scan acquiring six 6mm scans of acceptable quality. This scan will be performed TWICE on two eyes to assess the operator's scan technique; one eye with the disorder to be studied (such as macular edema) and one eye with a normal macula. Note that each eye is referred to as a Case; Case 1 is the eye with pathology and Case 2 is the eye with a normal macula.
3. Demonstrated ability to perform the Cross Hair scan, centered on the macula, (using 512-resolution and the 6mm scan length) of acceptable quality for the eye with pathology. (See section 4.2 "Scan Parameters and Fixation Guidelines" on how to create a custom Cross Hair scan.)

4. Submission of **4 Retinal Map (Single Eye) Reports, 6 Retinal Thickness (Single Eye) Reports** and **2 Align Process Reports** for a total of 12 prints.
5. Data files exported to DVD or CD *as described in section 6.0.*

**Only DRCR Network certified OCT operators are allowed to take baseline/screening visit scans**, unless an exception 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/screen scans. Only under extraordinary circumstances may follow-up visit scans be performed by an uncertified operator. (See *section 3.0.*)

OCT operators who are not eligible for **certification** on the basis of previous certification by the DRCR Network must perform the following sequence of scans. The scans *may be performed on subjects in whom OCT is being carried out for clinical purposes or in volunteers.*

### **2.1. Required Prints and Data Files for Certification ONLY:**

The following guidelines should be met for certification scans to be considered of good quality:

- The center point standard deviation of each scan, located on the Retinal Map Report, should be within 10% of its center point value. (Refer to *section 4.3* for the standard deviation calculation.)
- The Retinal Map Reports from Session 1 and Session 2 should have center point values within 10% of each other (to assess the OCT Operator's scan reproducibility).
- The retina's inner limiting membrane (ILM) and the retinal pigment epithelium (RPE) should be correctly identified, as determined by the white boundary lines.

1. **Case 1** (eye with pathology): This case 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 (approximately **250 microns or greater**). Case 1 consists of two Fast Macular Thickness Map scans (the same eye scanned twice, approximately 5-10 minutes apart, referred to as Session 1 and Session 2), a 6.0mm Cross Hair Scan and exported data files (via CD or DVD). The following items need to be acquired and labeled as Case 1, Session 1 and Case 1, Session 2 (Refer to sections 2.2 and 2.3 for anonymization, printing, and labeling):

#### **Case 1, Session 1:**

- a. Fast Macular Thickness Map scan: This scan will acquire six 6.0mm radial line scans centered on the macula in 1.92 seconds, from which you will **print**:

**6 Retinal Thickness (Single Eye) Reports**  
**1 Retinal Map (Single Eye) Report**

- b. Cross Hair Scan: This scan will acquire the horizontal and vertical B-scans at the 512 resolution. You must remember to change the height and width scan length from 3.0mm to 6.0mm *prior to scanning* (see *section 4.2 "Scan Parameters and Fixation Guidelines"* on how to create a custom Cross Hair scan). From this scan you will **print**:

## 2 Align Process Reports (1 Horizontal and 1 Vertical)

- c. Exported Data Files (via DVD or CD): These data files should be labeled as “Case 1, Session 1.” See *section 6.0* for more details.

### Case 1, Session 2:

- a. Fast Macular Thickness Map scan: This scan will acquire six 6.0mm radial line scans centered on the macula in 1.92 seconds, from which you will **print**:

#### 1 Retinal Map (Single Eye) Report

2. **Case 2** (normal or near normal eye): This case should demonstrate a macula with a normal or near-normal foveal depression. Case 2 consists of two Fast Macular Thickness Map scans (the same eye scanned twice, approximately 5-10 minutes apart, referred to as Session 1 and Session 2). The following items need to be acquired and labeled as Case 2, Session 1 and Case 2, Session 2. (Refer to *sections 2.2 and 2.3* for anonymization, printing, and labeling.)

### Case 2, Session 1:

- a. Fast Macular Thickness Map scan: This scan will acquire six 6.0mm radial line scans centered on the macula in 1.92 seconds from which you will **print**:

#### 1 Retinal Map (Single Eye) Report

### Case 2, Session 2:

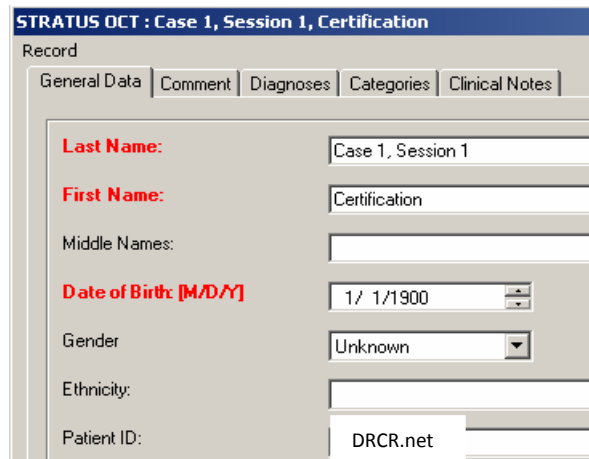
- a. Fast Macular Thickness Map scan: This scan will acquire six 6.0mm radial line scans centered on the macula in 1.92 seconds from which you will **print**:

#### 1 Retinal Map (Single Eye) Report

## 2.2. Identification of Certification Scans

The names of the subjects used for certification scans should be removed from the subject record. Manage the subject records using the “Edit” button located in the main patient database and anonymize in the following format:

Last Name:	<Case #>, <Session #> (e.g. Case 1, Session1)
First Name:	Certification
Middle Name:	<field left blank>
DOB:	1/1/1900
Gender:	Unknown
Patient ID:	DRCR.net



STRATUS OCT : Case 1, Session 1, Certification

Record

General Data | Comment | Diagnoses | Categories | Clinical Notes

Last Name: Case 1, Session 1

First Name: Certification

Middle Names:

Date of Birth: [M/D/Y] 1/ 1/1900

Gender: Unknown

Ethnicity:

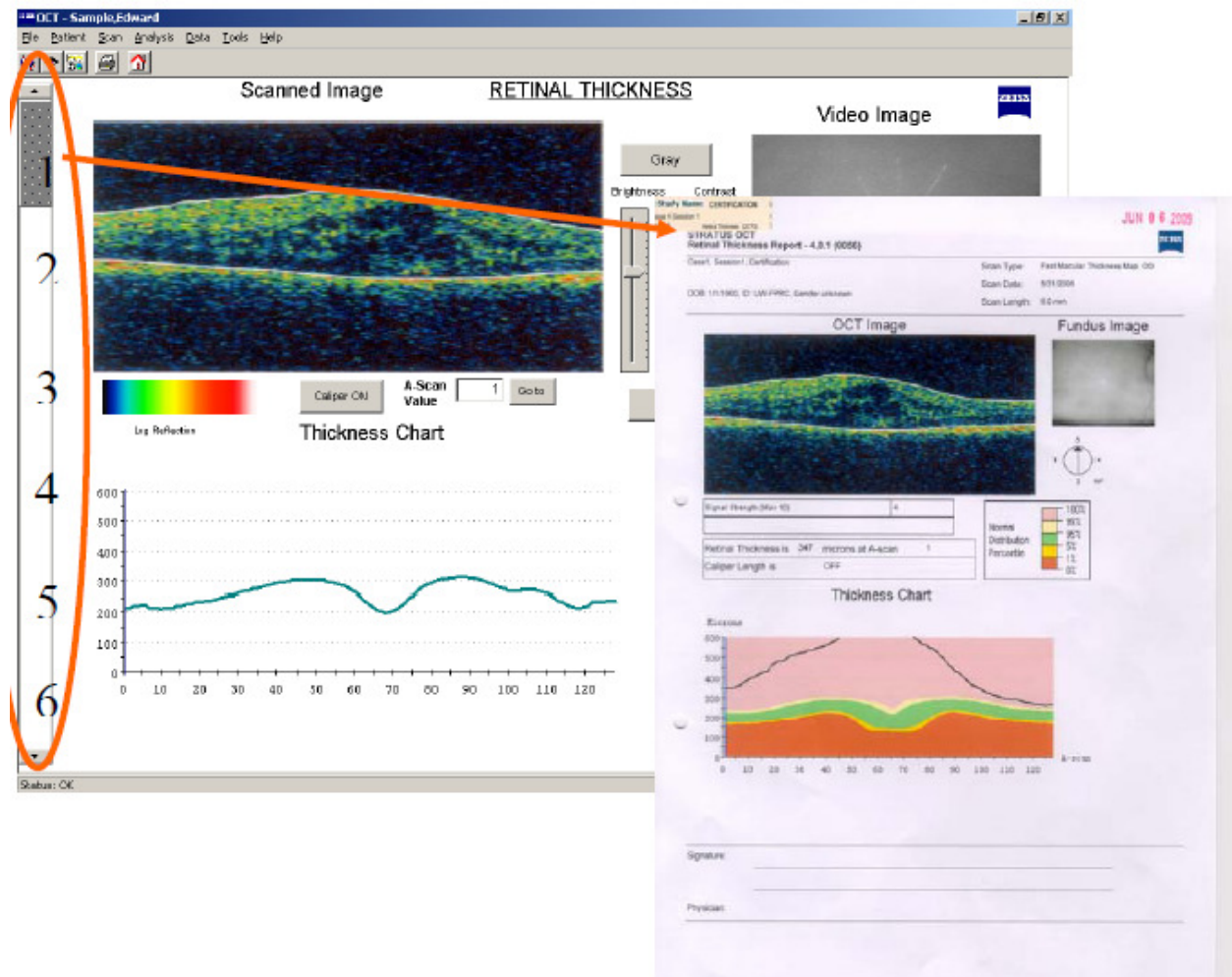
Patient ID: DRCR.net

## 2.3. Retinal Thickness (Single Eye), Retinal Map (Single Eye), and Align Analysis Printing and Labeling Instructions

In most cases pre-printed certification labels will be available for the twelve certification prints and the CD/DVD. If no labels are provided, hand label the prints, indicating the Case and Session number. Label the top left corner of each print.

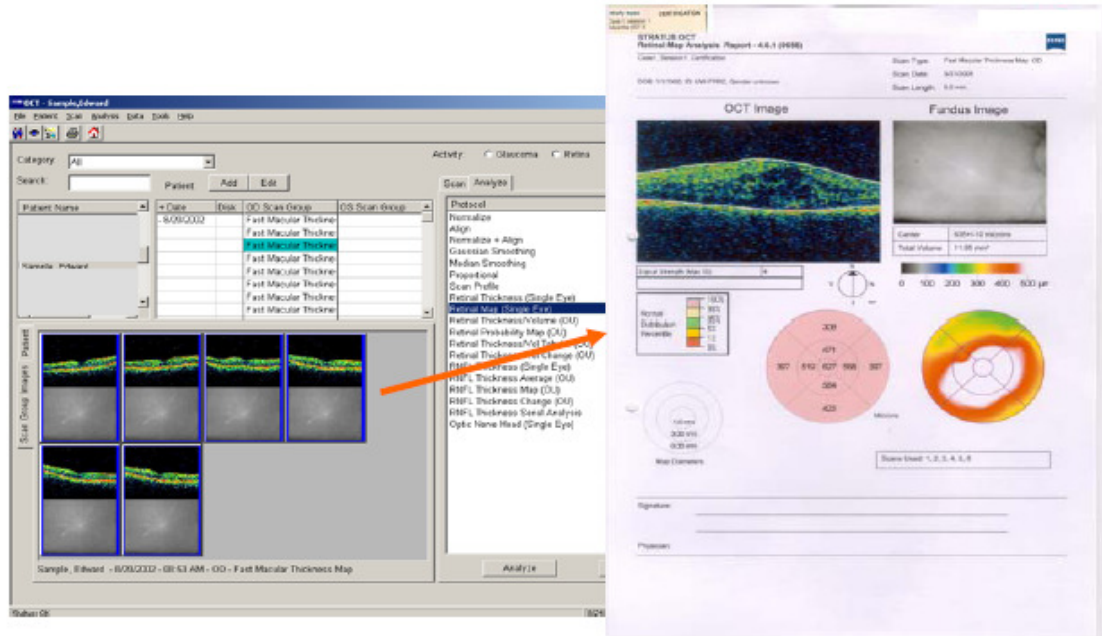
### 2.3.1. Retinal Thickness (Single Eye) Printing and Labeling

The Fast Macular Thickness Map scan should be analyzed using the **Retinal Thickness (Single Eye)** report. Use the scroll bar on the left of the display screen to select and print each of the six scans. The relative position of the scroll bar for scans 1-6 is shown below. (These numbers do not appear on the display screen but are added here for illustration purposes.)



### 2.3.2. Retinal Map (Single Eye) Printing and Labeling

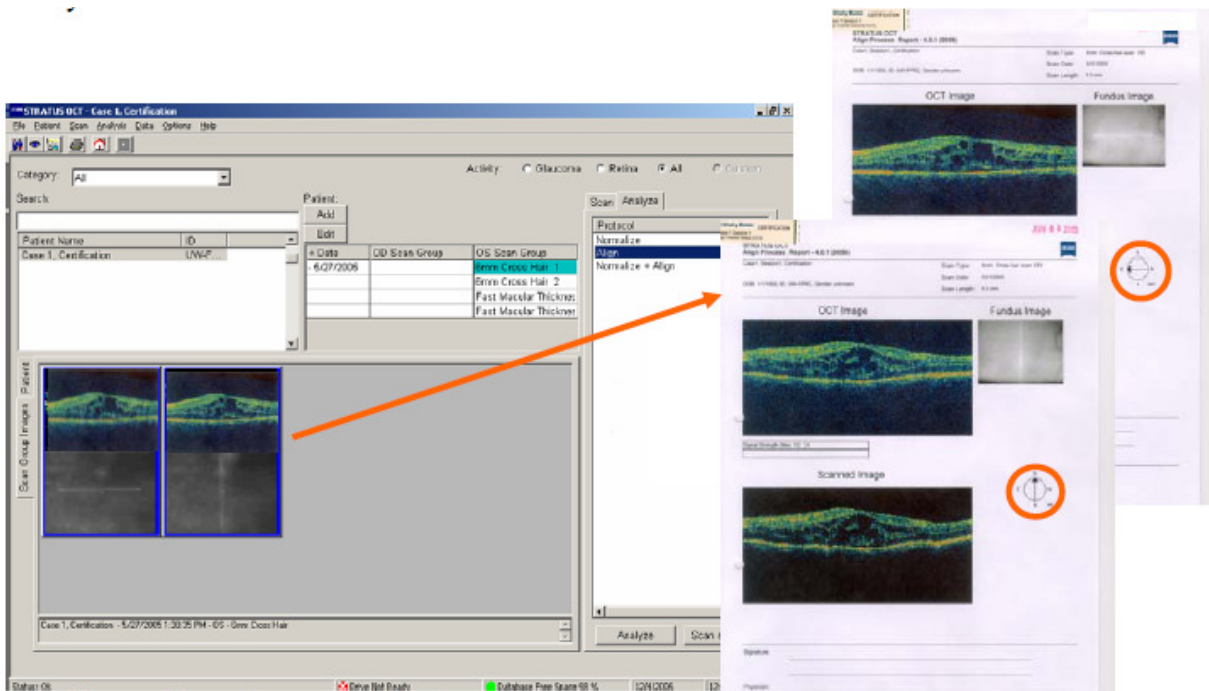
The **Retinal Map (Single Eye)** report is obtained by selecting the appropriate Fast Macular Thickness Map scan and the Retinal Map (Single Eye) analysis. It combines the six Fast Macular Thickness scans into one analysis that obtains the average retinal thickness values for the 9 ETDRS subfields.



*Retinal Map (Single Eye) Printing and Labeling Illustration*

### 2.3.3. Align Process Report Printing and Labeling

The **Align** process report is obtained by selecting the Cross Hair scan and the Align analysis. You will use the scroll bar to move to the vertical and horizontal scans.



*Align Process Report Printing and Labeling Illustration*

## **2.4. Review of Certification Materials**

OCT operators who meet certification criteria will receive written (via fax or email) or verbal (via phone) confirmation of certification from the DRCR Network Coordinating Center.

Operators who do not meet these criteria will receive feedback from the imaging staff providing certification for the Network and will be required to submit additional materials. After three unsuccessful attempts for certification, no additional submissions will be accepted until a plan for improving scan quality or data file preparation has been developed in collaboration with the Coordinating Center and principal investigator for the OCT operator.

## **THE FOLLOWING INFORMATION REFERS TO ACTUAL STUDY PATIENT SUBMISSIONS—READ CAREFULLY:**

### **3. 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 he or she understands and follows the procedure. The name of the uncertified operator should be entered on the OCT page labels, and a comment should be made on the transmittal log.

### **4. Study Patient Examination Procedure**

To determine which eye(s) need to be scanned, refer to the visit schedule listed on the DRCR.net website: *Main Menu < Manuals < OCT Visit Schedule by Protocol*. The eyes should be maximally dilated to help ensure optimal quality scans. The operator should be familiar with the archive and back-up routines for the computer system and should take all necessary precautions to prevent loss of subject data.

#### **4.1. Adding subjects to the database**

*The subject's name should NOT be entered into the database.* The operator should register the subject prior to printing and/or exporting the scans using the following format:

<b>Last Name:</b>	<study abbrev>-<protocol letter> (e.g. DRCR-B)
<b>First Name:</b>	DRCRnet patient namecode (e.g. LOWSM)
<b>Middle Name:</b>	<field is left blank>
<b>DOB:</b>	1/1/1900
<b>Gender:</b>	Unknown
<b>Patient ID:</b>	DRCRnet patient ID (e.g. B039-17LS)

## 4.2. Scan Parameters and Fixation Guidelines

### 4.2.1. Scan Parameters

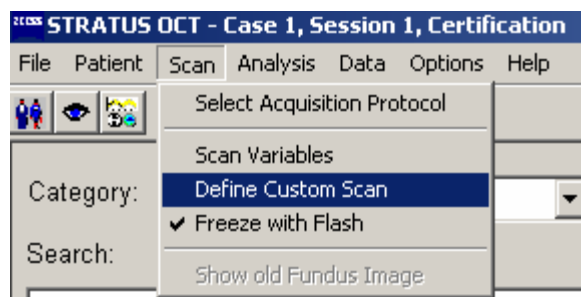
Two scan types are used for the OCT 3 procedure:

1. **The Fast Macular Thickness Map** scan is used to acquire six 6mm radial line scans in 1.92 seconds of scanning.
2. The **6mm Cross Hair** scan is used to acquire two 6mm scans using the 512 resolution setting, one horizontal B-scan and one vertical B-scan, centered on the macula.

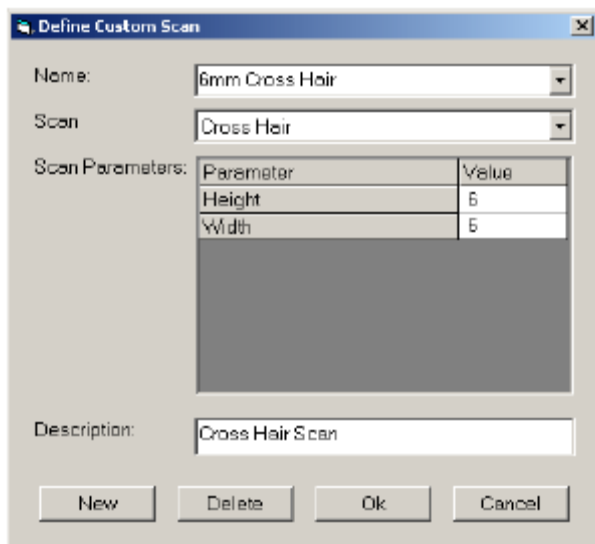
**NOTE:** Be certain to change both the height and width values to 6.0mm. (The default scan length is 3.0mm.)

**To set up a custom Cross Hair scan:**

- a. Click Scan > Define Custom Scan:



The *Define Custom Scan* dialog box displays.



- b. In the *Name* section, type *6mm Cross Hair*.
- c. From the *Scan* drop-down list, select *Cross Hair*.
- d. In the *Scan Parameters* section, change the height and width values to 6.
- e. Select *OK* to save your custom scan.

### 4.2.2. Fixation—Central

The subject is asked to look into the objective lens and is asked to determine (if their visual acuity allows it) if the point of intersection of the red scan lines is coincident with the center of the green fixation target. If it is, the subject fixates on the center of the green target, and no further fixation adjustment is needed. If the subject cannot see the point of intersection of the red scan lines, he or she is asked to fixate at the center of the green fixation target, and the operator attempts to adjust the point of intersection to be coincident with the green fixation dot. The purpose of this alignment is to place the point of intersection as close as possible to the center of fixation. On the rare occasion when the subject cannot see the green fixation target at all, he or she is asked to use whatever visual clues they have to estimate the center. In these situations, the operator will most certainly need to adjust the position of the scan lines to best coincide with the location of the center of the macula and may also elect to use the external fixation target to obtain the best scans.

### 4.3. OCT Scan Quality Guidelines

Follow standard clinic procedures to obtain optimal quality scans for analysis. Take care to select scans that correctly identify the retina's ILM and the RPE and have a center point standard deviation of < 10% (see calculation below). The OCT operator is encouraged to repeat the Fast Macular Thickness scan in cases where these quality guidelines are not met (and the operator believes that another attempt may produce a more suitable scan for analysis). The baseline measurements for a patient are critical since follow-up measurements are compared to this point to determine the study outcome.

Standard deviation percentage = (Standard Deviation/Center Point Thickness) X 100

## 5.0 Submission of Images

The DRCCR.net OCT image upload procedure is located at [www.drccr.net](http://www.drccr.net): *Study Documents > Manuals and Installers > Imaging Manuals “Electronic OCT Upload Procedures”* (versions for 4.0, 5.0, and 6.0 are available). This document should be followed when submitting OCT images to the DRCCR.net Coordinating Center

## 6.0 Retakes

The OCT scans should be evaluated for quality by the *principal investigator and/or OCT operator* before submission to the DRCCR.net Coordinating Center. **Scans should be retaken before submission** if quality is not adequate (e.g., if the ILM or RPE surfaces are not accurately depicted by the white boundary lines on the 6 **Retinal Thickness (Single Eye) Reports**). If no adequate quality scan(s) can be acquired (due to lens opacities or a pupil that will not dilate), record the discrepancy on the transmittal log.

## 7. Appendix A: Certification Requirements

### CASE 1:

- *9 Prints needed for Case 1, Session 1 (Eye with Pathology)*
  - **1 Retinal Map (Single Eye)** analysis print prepared from the Fast Macular Thickness Map Scan
  - **6 Retinal Thickness (Single Eye)** analysis prints (one displaying each of the six individual radial line Bscans) prepared from the Fast Macular Thickness Map scan.  
  
*Prints are made using the 6.00mm display option.*
  - **1 DVD or CD** containing the export files. (CASE 1, SESSION 1 ONLY)
  - **2 Align** analysis prints (one displaying each of the horizontal and vertical scans) prepared from the Cross Hair scan at the 512 resolution and at the 6.0mm scan length.
  - **9 Total prints (single eye) + 1 DVD or CD** containing the 6 export files
- *1 Print needed for Case 1, Session 2*
  - **1 Retinal Map (Single Eye)** analysis print prepared from the Fast Macular Thickness Map Scan. This is a repeat scan of the eye used in Case 1, Session 1, performed a few minutes after Session 1 is completed, and is used to assess the operator's scan technique.
  - **1 Total prints (single eye)**

### Case 2:

- *1 Print needed for Case 2, Session 1 (Normal Eye)*
  - **1 Retinal Map (Single Eye)** analysis print prepared from the Fast Macular Thickness Map Scan
  - **1 Total prints (single eye)**
- *1 Print needed for Case 2, Session 2 (Normal Eye)*
  - **1 Retinal Map (Single Eye)** analysis print prepared from the Fast Macular Thickness Map Scan. This is a repeat scan of the eye used in Case 1, Session 1, performed a few minutes after Session 1 is completed, and is used to assess the operator's scan technique.
  - **1 Total prints (single eye)**

\* A **Request for OCT Operator Certification** form, signed and dated by the OCT operator, is also required in order for certification to be complete.

# 8. Appendix B: Labeling Instructions for the Retinal Thickness Reports

