Diabetic Retinopathy Clinical Research Network

Photography and OCT Testing Procedures Manual

Version 3.0

April 8, 2005

Table of Contents

Optical Coherence Tomography (OCT) for OCT3 Systems

CHAPTER 1

FUNDUS PHOTOGRAPH **READING CENTER**

Modified 7-Standard Field/Modified 3-Standard Field

Color Fundus Photography

&

Film Fluorescein Angiography

University of Wisconsin – Madison / Department of Ophthalmology and Visual Sciences
Park West One – Suite 400 / 406 Science Drive / Madison, WI 53711-1068
PHONE: (608) 263-4538 FAX: (608) 263-0525 Business Hours: 8:00 to 4:00 CST

1.0 Photographer Certification

Photographers taking photographs for studies read by the UW-FRPC must be certified for the relevant procedure(s), *before submitting actual patient photographs.* Certification for the modified 7 & 3-field color procedure and the fluorescein angiography procedure are separate, but both are required. **Only UW-FPRC certified photographers are allowed to take the baseline (Screening Visit) photographs** unless an exception to this rule is granted (on a case-by-case basis) by the study sponsor. The sponsor may suspend patient enrollment if the site does not have a certified photographer available to take the baseline photographs. Clinical sites are strongly encouraged to have a minimum of two, but no more than three, certified photographers. Photographers are encouraged to contact the Reading Center's photographic consultants, Hugh Wabers (608-263-0740), Pam Vargo (608-263-6468) or Michael Neider (608-263-9858) or with any photography related questions. Pointers on photographic technique may be found in section 13.0.

Certification consists of (1) review of study synopsis and photography procedures and (2) demonstrated ability to perform the photographic procedure by submission of photographs of acceptable quality. The second requirement may be waived if the photographer has prior certification at the UW-FPRC using a similar procedure. Photographs must have been taken within the past year.

Photographers who are not eligible for certification on the basis of previous certification in another study should submit color photographs and fluorescein angiograms *of two patients taken using this procedure. The angiograms may be taken of patients with any retinal or choroidal disorder in whom angiography is being carried out for clinical purposes. The color photographs may be taken of patients in whom photography is being carried out for clinical purposes or in normal volunteers.* The color slides and fluorescein angiograms should be mounted as shown in Sections 7 & 9. Pre-printed labels may be unavailable for labeling certification photographs, please hand label the color slides indicating the field and the eye photographed and the right side (RS) or left side (LS) of the stereo pair. The slide pages containing the color photographs and the fluorescein angiograms should be labeled with a slide identification label indicating the patient initials or patient identifier, photographer's name, date of photography and that the photographs are certification sets. A signed UW-FPRC certification request form is also required (see *Project Management Study Specific Information* section).

Photographers who meet certification criteria will receive written confirmation of certification. Photographers who do not meet these criteria will receive feedback from the UW-FPRC photographic consultants, and will be required to submit additional sets of photographs and/or angiograms. After three unsuccessful attempts for certification, no additional photographic submissions will be accepted until a plan for improving photographic quality has been developed in collaboration with the sponsor and principal investigator.

2.0 Uncertified Photographers (Follow-up visit only)

On rare occasions during follow-up visits, when a certified photographer is not available to take the photographs, an uncertified photographer familiar with the procedure may take the photos. The name of the uncertified photographer should be entered on the photo page labels.

3.0 Camera and Equipment

The 30° Zeiss FF4 series and the Topcon TRC-50 series (50VT, 50IA, 50EX, and 50X, used at the 35° setting) or similar models are suitable cameras for the study. Cameras other than these may be substituted upon approval of the UW-FPRC. Approval may be obtained by submitting two sets of color photographs and accompanying fluorescein angiograms, taken according to procedure, together with a letter requesting camera substitution, to the Fundus Photograph Reading Center, Park West One, 406 Science Dr., Suite 400, Madison, WI 53711-1068, Attention: Michael Neider. Photographer certification photographs may also be used for camera approval.

4.0 Film and Processing

For color photography, the recommended films are Kodak Professional Ektachrome 100 Daylight films or their equivalent. Ektachrome EPN, EPP or E100G, preferably processed by a certified "Q-Lab" to ensure consistent quality, are preferred. Kodak Kodachrome 64 Daylight film, processed by any authorized Kodalux Laboratory is also acceptable. It is important that the processor correctly number the slide mounts to make slide sorting more accurate and easier.

Kodak T-Max or Ilford 400 speed films are recommended for fluorescein angiography. The film may be processed by the clinic staff or at a local processing laboratory. The use of Kodak D-11, or similar formulation developer is recommended. Development times will vary with developer concentration, temperature and camera flash setting. Any processing procedure, which yields good quality negatives, may be used. Proper care should be taken to adequately fix the film to insure archival image stability.

5.0 Obtaining Both Good Image Quality and Adequate Stereoscopic Effect

When obtaining stereo pairs, care should be taken that at least one member of the pair is of good technical quality with crisp focus. In many cases, it will be possible to obtain good quality in both members of the pair, but if this is not the case, *the aim should be to obtain good quality in one member and **some** stereo separation between the members, accepting **somewhat** poorer quality in the second member of the pair, if necessary.*

Dilation of the pupil to at least 6mm is important to permit good quality stereo photography. *If the pupils cannot be dilated to at least 4mm for the screening visit, the subject should not be entered into the study.* The cornea should be undisturbed by prior examination with diagnostic contact lens.

If the subject has great difficulty tolerating the screening visit photography procedure and the photographer thinks this will lead to a problem at follow-up visits, the situation should be discussed with the principle investigator and/or coordinator and consideration should be given to not enrolling the subject in the study.

For more suggestions regarding photographic technique, see section 13.0 *Pointers on Photographic Technique*.

6.0 Modified 7-standard Fields and Fundus Reflex Photographs [Figure 1]

The modified 7-standard fields for color photography specified by this procedure differs from the ETDRS 7-standard field protocol in the position of two fields: Field 1M and Field 3M are both modified to include the center of the macula, in Field 1M near the edge of the field and in Field 3M midway between the edge and center of the field.

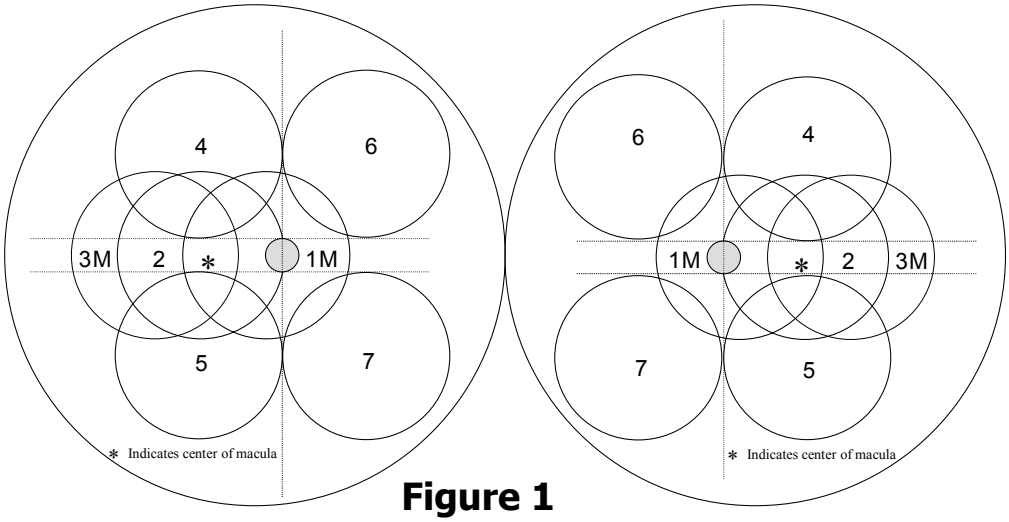


Figure 1

The following descriptions of the standard fields assume that there are two cross hairs in the camera ocular, one vertical and the other horizontal intersecting in the center of the ocular.

Field 1M - Disc: Center the temporal edge of the optic disc at the intersection of the cross hairs in the ocular.

Field 2 - Macula: Center the macula near the intersection of the cross hairs in the ocular. To keep the central gray artifact created by some cameras from obscuring the center of the macula, the intersection of the cross hairs should be placed about 1/8 – 1/4 DD above the center of the macula. A suitable position can often be obtained by rotating the camera temporally from the Field 1M position, without vertical adjustment.

Field 3M - Temporal to Macula: Position the intersection of the cross hairs in the ocular 1.0-1.5DD temporal to the center of the macula. If Field 2 was centered above the center of the macula, as suggested above, Field 3M may be centered 1.0-1.5 DD temporal to Field 2, a position easily achieved by rotating the camera without making any vertical adjustment or movement of the fixation device.

Field 4 - Superior Temporal: The lower edge of the field is tangent to a horizontal line passing through the upper edge of the optic disc and the nasal edge of the field is tangent to a vertical line passing through the center of the disc.

It is convenient to take Field 6 immediately after Field 4 by rotating the camera nasally.

Field 6 - Superior Nasal: The lower edge of the field is tangent to a horizontal line passing through the upper edge of optic disc and the temporal edge of the field is tangent to a vertical line passing through the center of the disc.

Field 5 - Inferior Temporal: The upper edge of the field is tangent to a horizontal line passing through the lower edge of the optic disc and the nasal edge of the field is tangent to a vertical line passing through the center of the disc.

Field 7 - Inferior Nasal: The upper edge of the field is tangent to a horizontal line passing through the lower edge of the optic disc and the temporal edge of the field is tangent to a vertical line passing through the center of the disc.

Field 8 - An optional field outside the modified 7-standard fields should be taken to document new vessels and/or pre-retinal or vitreous hemorrhage when these features are not well documented in the standard fields. The label should reflect the area photographed.

If two or more photographs outside the modified 7-standard fields are needed to document new vessels, they should be labeled "Field 8a," "Field 8b," and so on sequentially. ***If one or more Field 8's are taken at screening, their location should be noted and these fields should be taken at each follow-up visit.***

At all visits, a stereoscopic fundus reflex photograph should be taken to document media opacities. The photographer is asked to use his/her discretion to achieve a limbal diameter of approximately 13mm on the finished slide. The best stereo effect is obtained by moving the camera laterally about 3mm between exposures. The lateral shift can be obtained by moving the joystick, sliding the camera, or using the Allen stereo separator. A fixation target should be positioned to direct the subject's gaze in the primary (straight ahead) position, so that the optic nerve *does not appear* directly behind the lens.

7.0 Mounting and Labeling Color Photographs [Figures 2a-b]

The transparencies returned from the processing lab are mounted in standard 2X2 inch mounts. The mounted transparencies are labeled with individual labels (Figure 2a).

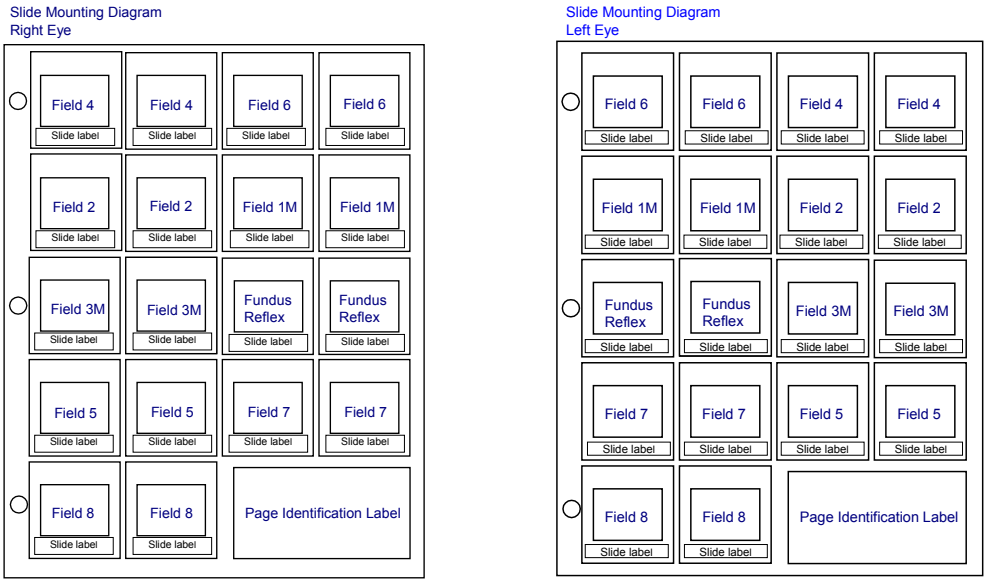


Figure 2a

Photographs taken of the modified -standard fields (and stereo fundus reflex) of each eye should be mounted in an individual plastic sheet (Figure 2a, above). At selected visits, photographs will be taken of the modified 3 standard fields (and stereo fundus reflex) and should be mounted in an individual plastic sheet (Figure 2b). See visit schedule (*Project Management Study Specific Information* section) to determine which photographs should be taken at any given visit.

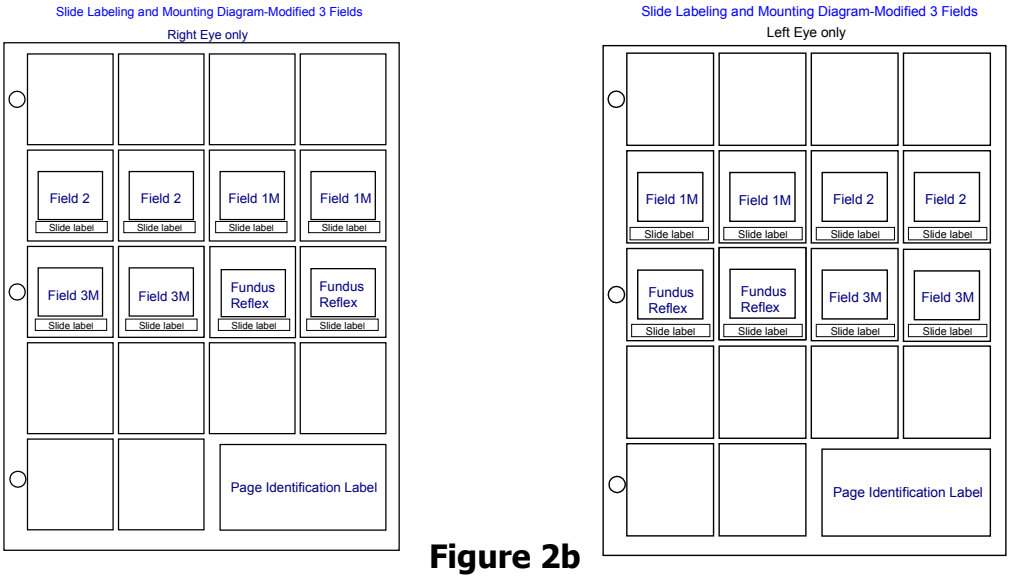


Figure 2b

The plastic sheets should be constructed so that the pockets open at the side rather than at the top; that is, the *open* side of the left pocket should face the *open* side of the right pocket.[†] A sheet identification label is completed and attached to the front of each plastic sheet (see Figure 2a or 2b).

Photographs submitted in frosted plastic pages or thin "archival" plastics may be returned to the site for remounting.

It is suggested, but not required, that duplicates of the color photographs be retained at the clinical center for patient management.

8.0 Fluorescein Angiography

The fluorescein angiogram contains stereoscopic views of 2 fields at specified times after injection. These fields include the macula (Field 2) of both eyes and the disc field (Field 1M) of the study eye. In order to obtain stereopairs that are correctly oriented in the filmstrip for stereoscopic viewing (i.e., do not have reversed stereoscopic effect), **the right member of each pair must be taken first, followed by the left member.** Stereoscopic red-free photographs are taken of Field 2 in each eye prior to the injection of the fluorescein dye.

8.1 Fluorescein Injection

After the red-free photographs of both eyes have been taken, the camera is positioned for Field 2 of the study eye. Fluorescein is injected rapidly (less than 5 seconds if possible) into the anticubital or other convenient vein according to usual clinic procedures.

[†] The Reading Center recommends Bardes 20-pocket pages, product #62022C available from Bardes Products, Inc., 5245 West Clinton Avenue, Milwaukee, WI 53223-9839, phone 800-223-1357, website www.bardes.com

8.2 Timing

8.2.1 Early Phase

The first photograph of the early phase is taken at time "0"; that is, at the moment injection of the fluorescein dye begins. The second photograph is taken at the moment the injection is complete. These photographs constitute a stereo pair and are referred to as the "control" photographs. They serve to document the integrity of the interference filters. The time shown on the second frame documents the rate of injection.

Ideally, the control photographs are followed by a series of 10 to 16 exposures taken at 1 to 2 second intervals, beginning about 15 seconds after the start of fluorescein injection (sooner if fluorescein appears sooner or delaying the initial exposures until fluorescence begins when a slow circulation time is expected). The usual result is 5 to 8 stereo pairs following the control pair, typically culminating about 40-45 seconds after the start of injection.

8.2.2 Mid-Phase

After the early photographs are completed the photographer takes stereo pairs of Field 2 and then of Field 1M of the study eye at approximately 60 to 90 seconds. At this point the camera is positioned in front of the fellow eye and a stereo pair is taken of Field 2 at approximately 2 minutes. At this point, the camera is repositioned back to the study eye and a stereo pair of Field 2 is taken between 2 and 3 minutes.

8.2.3 Late-Phase

A stereo pair of Field 2 in the study eye is taken at 5 minutes. Two final stereo pairs are taken of Field 2 in both eyes at 10 minutes.

9.0 Mounting, Labeling and Duplication of Fluorescein Angiograms [Figure 3]

The original negatives are cut into strips of six images per strip, and are placed in a 10½ x 9-inch thin gauge transparent plastic sheet containing six pockets per sheet.[‡] A page identification label (see Figure 3) is attached to each page of negatives. **When cutting the film into strips, the photographer should take care not to separate the members of a stereo pair (i.e., not to leave one member of the pair at the end of one strip and the second member of the pair at the beginning of the next strip).** Clinical Centers should retain a copy of the angiogram.

[‡] The Reading Center recommends Print File Archival Preservers Style #35-6HB, available from Print File, PO Box 607638, Orlando, FL 32860-7638, phone 407-886-0008, website www.printfile.com

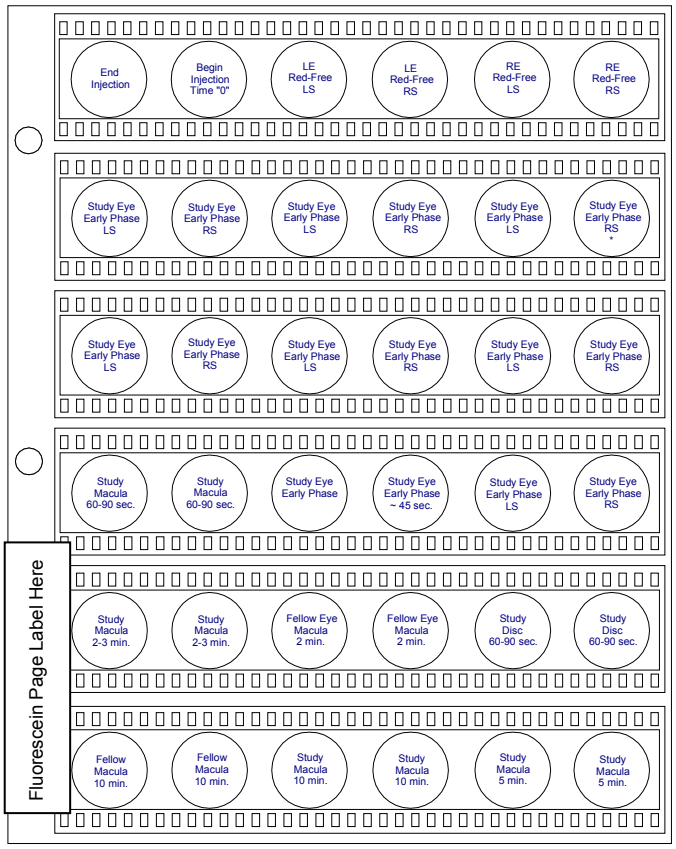


Figure 3

10.0 Transmission of Color Photographs and Angiograms to the UW-FPRC

The original color transparencies and angiographic negatives should be processed, assembled and labeled as described above within 10 working days (sooner if possible) after being taken. Sets should be sent together with the completed **Transmittal Log** (see *Project Management Study Specific Information* section) to the UW-FRPC.

11.0 Retakes

Color photos and fluorescein angiograms should be evaluated for quality by the *principal investigator and/or photographer* before submission to the UW-FPRC. If quality is not adequate for assessment of key features of the study eye, such as extent of macular edema, and extent of fluorescein leakage, and if no irremediable cause of inadequate quality is present (such as lens opacities or a pupil that will not dilate adequately), the photos and/or angiograms should be retaken before submission to the UW-FPRC (waiting, ideally, at least until the next day to allow fluorescein to clear from the eye). When color photos and/or fluorescein angiograms are considered ungradable because of poor quality, the UW-FPRC may issue a **Retake Request Form** (see *Project Management Study Specific Information* section).

12.0 Evaluation of Photographic Quality

Color photographs of each eye are reviewed and assigned a grade for overall quality. Additionally, an overall quality grade is assigned for each fluorescein angiogram. For both types of photographs the grades include three indicating that a set can be evaluated with no problem (excellent, good, fair), two signifying that a set can be assessed although quality interferes somewhat (borderline-explained, borderline-unexplained), and two indicating that a set cannot be completely evaluated (inadequate-explained; inadequate-unexplained). The "explained" variant of borderline or ungradable is selected if the UW-FPRC grader sees media opacities in the fundus reflex (anterior segment) photograph explaining the reduced quality, or if the photographer records that the patient had difficulty cooperating.

Feedback will be provided to the photographers as needed to help with resolution of any problems. Special attention will be given to photographers having difficulty meeting study photo quality standards. If a certified photographer consistently fails to meet study standards, certification may be suspended.

13.0 Pointers on Photographic Technique

13.1 Field Definition

When the modified seven standard stereo fields are taken, the following sequence is recommended: disc (Field 1M), macula (Field 2), temporal to macula (Field 3M), superior temporal (Field 4), superior nasal (Field 6), inferior temporal (Field 5), inferior nasal (Field 7). Stereo Fields 1M, 2 and 3M may be taken on the same horizontal plane.

The following technique may be used for attaining proper definition of Field 4: (1) move the camera from the center of the disc upwards until the upper edge of the disc meets the bottom of the photographic field, (2) take note of some landmark at the intersection of the cross hairs (e.g., a small vessel or microaneurysms), (3) swing the camera temporally until this landmark is at the nasal border of the photographic field (at this point, the lower edge of the field will fall on the same plane as the upper edge of the disc) -- this is the proper position for Field 4. To locate Field 6, rotate the camera nasally until the landmark is at the temporal edge of the field. A similar approach can be used to obtain Fields 5 and 7.

13.2 Focus/Clarity

Constant attention must be paid to keeping the cross hairs in the camera ocular in focus, otherwise the photos will be out of focus.

Proper camera-to-eye distance should be maintained to avoid haziness and artifacts.

If it is not possible to get the entire photographic field in crisp focus, the photographer should concentrate on getting the center of the field in focus, sacrificing a bit on the periphery if necessary. This is especially important in Fields 1M and 2.

When the photographer moves to Field 2, having just taken Field 1M, **he/she should refocus on retinal vessels near the center of the field.** *Failure to do so results in photographs that show the foveal area to be slightly out of focus while the periphery is in focus*.

A common problem is focusing too deep. Photographs which include the disc (Fields 1M and often Field 2) sometimes show clear focus on the bottom of the cup, while the retina is slightly out of focus. It appears that some photographers use the lamina cribrosa (at the bottom of the cup), the disc margin, or the granular pattern of the pigment epithelium for focusing. Instead, it is desirable to focus on fine retinal vessels. Since the depth of focus is greater posterior to the plane of absolute focus than anterior to it, it makes sense to err on the side of focusing slightly up into the vitreous rather than too deep. This should keep both the anterior surface of the retina and the pigment epithelial background in focus. Such a strategy is of special importance when macular edema is present.

13.3 Stereoscopic Effect

The technique described by Allen[4] is used for taking stereo fundus photographs. An Allen stereo separator or manual lateral movement of the camera may be used to obtain the required, non-simultaneous stereo pairs. If the manual method is used, the camera should not be rotated; instead, it should be moved from left to right with the joystick (or by sliding the camera base on its table, if preferred). It is customary to take the left member of the pair first, but this is optional (**for angiograms to be viewed in strips, the right member is taken first**). The first member of the pair is taken as far to one side of the pupil as possible, while maintaining good illumination and a clear image. If the separator is used, it is then flipped to the other side and the second photograph is taken if its quality is good. If the quality is not good, refocusing with spherical or astigmatic correction and/or slight vertical movement of the camera (to avoid lens opacity) may be needed. Such vertical movement will not impair the stereoscopic effect. **Somewhat less than optimal focus and clarity is acceptable, if necessary, in the second member of the pair in order to maintain the stereoscopic effect.** The same principles apply when the manual technique is used. If the stereo separator is used, it should be set between 2.25 and 2.75mm. About 2mm is the minimum separation between members of the stereo pair to be aimed for when moving the joystick or sliding the camera.

Photographers should monitor their own work

A 4X or 5X magnification stereoscopic viewer for examining stereo fundus photographs is required, so that the photographer can critically examine his/her work and make appropriate corrections in technique. Examples of good stereoscopic photos can be found at the UW-FPRC website, http://eyephoto.ophth.wisc.edu.

What to do if the subject finds the photography procedure unusually difficult

Photography of the photophobic subject can be very challenging for the photographer and uncomfortable for the subject. Minimizing the number of flashes and the length of time the eye is exposed to a bright viewing lamp are two things that can help make the photography procedure more comfortable. We recommend shooting only one set of fundus photographs, copying those fields that you want to retain in your clinic files, to minimize the number of flashes. Additionally, keeping the view lamp as low as possible (maybe even dimming the room lights) can help make the photography procedure more tolerable. For additional help managing difficult photography situations, please contact Michael Neider or Hugh Wabers.

Questions or Comments

For questions or comments concerning this photography procedure, please contact the UW-FPRC photographic consultants, Hugh Wabers (608/263-0740; wabers@rc.ophth.wisc.edu, Pam Vargo; (608/263-6468; vargo@rc.ophth.wisc.edu or Michael Neider (608/263-9858; neider@rc.ophth.wisc.edu).

14. Reference

1. Early Treatment Diabetic Retinopathy Study Research Group, Manual of Operations. Chapter 13. Baltimore: ETDRS Coordinating Center, University of Maryland. Available from: National Technical Information Service, 52285 Port Royal Road, Springfield, VA 22161; Accession No. PB85 223006/AS Chapter 13.

2. Macular Photocoagulation Study Group, Macular Photocoagulation Study: Manual of Procedures. MPS Coordinating Center, Baltimore, MD. Available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; Accession No. PB90-207903.

3. Age Related Eye Diseases Research Group, Manual of Operations. Chapter 8. Potomac, MD: AREDS Coordinating Center, EMMES Corporation, 11325 Seven Locks Road, Suite 214, Potomac, MD 20854.

4. Allen L. Ocular fundus photography. *Am J Ophthalmol* 1964;57:13-28.

CHAPTER 2

FUNDUS PHOTOGRAPH **READING CENTER**

Digital Fluorescein Angiography

University of Wisconsin – Madison / Department of Ophthalmology and Visual Sciences
406 Science Drive, Suite 400 / Madison, WI 53711 /USA
PHONE: 608-263-4538 FAX: 608-263-0525 Business Hours: 8:00 to 4:00 CT

1.0 Overview

This module is prepared to supplement the University of Wisconsin-Madison, Fundus Photograph Reading Center's procedures, titled: 1) Modified 7-Standard Field Color Fundus Photography and Film Fluorescein Angiography Procedure, 2) Modified 3-Standard Field Color Fundus Photography and Film Fluorescein Angiography Procedure, and 3) Modified 7-Standard Field/Modified 3-Standard Field Color Fundus Photography and Film Fluorescein Angiography Procedure, and is designed for clinics electing to use a digital capture system instead of film for the fluorescein angiograms. Please remember that color photographs that accompany the fluorescein angiogram must still be taken using 35mm color slide film.

Clinical sites using digital fluorescein angiography systems instead of the 35mm black and white film must obtain both photographer and digital camera system certification from the UW-FPRC *before initiating study photography*. Digital system software and hardware components will be evaluated and recorded as part of the system certification process. Submission of a completed **Digital Fluorescein Angiography System Certification Request Form** (see the FPRC Forms, Labeling & Shipping Information document) is required for each system used for this study. UW-FPRC digital system evaluation software may be run on the digital system as part of the certification process, *and periodically throughout the study,* to monitor system elements critical to accurate assessment of digital images.

The UW-FPRC may require modifications to the system, for example, the addition of a CD writer, before completing certification. Additionally, it is strongly recommended that the digital system support "dial-in" access to allow system vendors and UW-FPRC technical staff access to the system throughout the study, to monitor settings or facilitate system maintenance. Any changes in the digital system that occur after the system is certified (including software or hardware changes) must be reported immediately after they are made to the UW-FPRC photography staff (Hugh Wabers, Pam Vargo, Dennis Thayer or Michael Neider at 608-263-9858) and may require system re-certification.

2.0 Photographer Certification

Photographers taking digital angiograms must be certified for the relevant procedure(s), *before submitting actual patient photographs*. ***Only UW-FPRC certified photographers are allowed to take baseline (Screening Visit) photographs*** *unless an exception to this rule is granted (on a case-by-case basis) by the study sponsor.* The sponsor may suspend patient enrollment if the site does not have a certified photographer available to take the baseline photographs. *Only under extraordinary circumstances, may follow-up visit photographs be taken by an uncertified photographer (see Section 2.1 below).* Photographers electing digital angiography are still required to demonstrate the ability to perform color fundus photography on 35mm film. Certification for film-based angiograms does not qualify a photographer for digital angiography certification.

Photographer certification is study specific and each photographer requesting certification must submit a signed UW-FPRC certification request form to the UW-FPRC. Certification consists of (1) review of the study synopsis or study protocol and photography procedures and (2) demonstrated ability to perform the angiographic procedure by submission of digital images of acceptable quality. Digital angiograms must have been taken within the last 2 months. The second requirement may be waived if the photographer has prior certification at the UW-FPRC using a similar procedure, and has been active taking photographs, judged to be

of good quality by the UW-FPRC, during the past year. Previously certified photographers who have been inactive for more that one-year may be asked to submit current sample photographs (often an abbreviated set) to become re-certified.

Photographers who are not eligible for certification on the basis of previous certification in another study should submit digital fluorescein angiograms *of two patients taken using this procedure. The angiograms may be taken of patients with any retinal or choroidal disorder in whom angiography is being carried out for clinical purposes.* The digital files should be written to CD and the CD labeled as shown in Figure 3 (Section 7.0). Pre-printed labels may be unavailable for labeling the CD; please hand label the CD using a permanent felt-tip marker. The CD should be labeled indicating the patient initials, photographer's name, date of photography and that the photographs are certification sets. **A signed UW-FPRC Request for Photographer Certification form is also required** (see the FPRC Forms, Labeling & Shipping Information document).

Photographers who meet certification criteria will receive written confirmation of certification. Photographers who do not meet these criteria will receive feedback from the UW-FPRC photographic consultants, and will be required to submit additional angiograms. After three unsuccessful attempts for certification, no additional photographic submissions will be accepted until a plan for improving photographic quality has been developed in collaboration with the sponsor and principal investigator.

2.1 Uncertified Photographers (Follow-up visits only)

On rare occasions during follow-up visits, when a certified photographer is not available to take the angiograms, an uncertified photographer familiar with the procedure may perform the procedure. The uncertified photographer should review the procedure before performing angiography to be certain they understand and follow the procedures. The name of the uncertified photographer should be entered on the CD label.

3.0 Camera System Certification

System Requirements - Digital images must be taken using either the Heidelberg HRA System, MRP OphthaVision®, Ophthalmic Imaging Systems (OIS) WinStation®, Topcon IMAGEnet®, Zeiss Visupac® digital systems. Systems must use a Microsoft Windows operating system (no DOS or Macintosh systems, please) and must have CD writing capability. OIS systems may need to be upgraded to Windows NT before certification can be obtained. Digital images should be approximately 1MB (uncompressed) or larger. Heidelberg HRA images must be taken at 512 X 512 or higher resolution. Very high-resolution systems (producing greater than 6MB images) may be suitable but only with prior Reading Center approval. Please contact Hugh Wabers, Pam Vargo, Dennis Thayer or Michael Neider if you have a question about the suitability of your imaging system.

It is preferred that the digital system contains software and hardware that allows remote access and operation. The Reading Center or their representative may inspect the digital camera system to assure that all capture settings are correct for accurate image analysis. This inspection may be performed via "dial-in" access or as part of a site visit. Inspection software may be used to verify and record system settings.

Certification Procedure - **Each digital system used for the study must be certified by the UW-FPRC before beginning study participant photography.** Certification begins with submission of the UW-FPRC Digital Angiography System Certification Request Form (see the FPRC Forms, Labeling & Shipping Information document). If the digital system is new to the UW-FPRC, or if the system is certified with the UW-FPRC but hardware or software changes have been made since the system was certified with the UW-FPRC, the system specific procedure, outlined below, should be followed. If the system is certified with the UW-FPRC but images have not been sent to the UW-FPRC within the previous 2 months new images should be sent to the UW-FPRC to verify that they still match the certification settings.

Heidelberg HRA System - The HRA Classic or HRA 2 systems used at the 30-degree setting are suitable. Eye Explorer® software, version 1.4.1.0 or higher, must be used and the system must have CD writing capability. Submit one angiogram saved using the .E2E file format (not as a movie image series).

MRP OphthaVision - System certification must be handled through MRP. Contact Peter Dirsa at (978) 687-7979.

OIS System - Capture 10 redfree images, of 10 different eyes, at the acceptable image angle (determined by camera type). The redfrees should be centered between the disc and macula; both the entire disc and macula must be in view. All files must be uncompressed. Send the images along with the System Certification Request Form.

At any time, if there are any changes made to the OIS system, 10 more redfrees are required to recalibrate the system. On the same note, it is a good idea to photograph a patient that will be available in the future and then to save those photographs. This way if the system changes, the patient could be re-photographed and the old and new photos may be sent to the FPRC for recertification. This avoids the need for 10 additional redfrees.

Topcon IMAGEnet System - Run the Digital System Evaluation Software (DSES), which can be found on the web at http://eyephoto.ophth.wisc.edu/DSES.html or it can be mailed to you by contacting the FPRC. Follow the directions included with the software and send the results to: Choices For Service in Imaging, Inc., 233 Rock Road #249, Glen Rock, NJ 07452. If you have any questions during the process please contact Tony Pugliese at 1-800-499-2291.

Zeiss Visupac System - System certification must be handled through Carl Zeiss Meditec. Contact Lon Dowell, C.R.A. at (877) 486-7473 ext. 4204.

Digital angiograms must be submitted on CD using only the standard methods existing in the software of the imaging system to isolate images for submission (do not use Windows Explorer to copy images to the CD). Images must not be compressed. The participant's name must be removed from the file so it is not displayed during image evaluation. When the participant's name is edited out of the file, the last name should be replaced with the words "System-Certification." The participant's first name should be replaced with the serial number of the fundus camera. Photographer certification photos may also be used for camera system certification.

The system certification process is considered successful after the UW-FPRC staff ensures that image files can be successfully viewed and analyzed and that each angiographic image (the red-free images are just sequentially numbered) contains a timing number (displayed in

seconds). Additionally, the patient names should be removed from the images and replaced with information as described above. Currently, the masking of patient information may not be possible with OIS systems.

4.0 Fundus Camera Requirements

The same model fundus camera used to take the stereo color fundus photographs should be used to perform the digital angiogram whenever possible. We realize that this is not possible when using the Heidelberg system and that a separate fundus camera will be needed to perform the stereo color photography. The 30° Zeiss FF4 and FF450-plus fundus cameras and the Topcon TRC-50 series (50VT, 50X, 50EX, 50IA, and 50IX or similar models) used at the 35° setting are suitable cameras. Additionally, the Canon UVi (or similar models) used at the 40° setting, and the Kowa, Nikon and Olympus camera models used at the 30° or 35° settings are suitable cameras for the study.

Cameras other than these may be substituted upon approval of the UW-FPRC. Approval may be obtained by submitting sample photographic sets, taken according to procedure, to the Fundus Photograph Reading Center, 406 Science Dr., Suite 400, Madison, WI 53711-1068, Attention: Photography Services. Photographer certification photographs may be used for camera approval. Cameras used to submit satisfactory certification photographs are considered suitable cameras for the study.

Digital Image Exposures: All images acquired during angiography should be saved and sent to the UW-FPRC. Please do not delete any images taken during the sequence to obtain only the recommended number of exposures or to remove images thought to contain objectionable artifacts. It is very important that photographers minimize flash/gain changes and avoid digital image overexposure, which can cause the areas of hyperfluorescence to appear artificially bright and possibly larger than they really are. A gain above 12db should not be used, to avoid grainy effects in the images.

Many digital cameras have a wider range of flash/gain settings available to control image exposure. Some photographers may frequently adjust the flash or gain settings during the angiogram to improve image quality. While this is often a useful adjustment, we do not want areas of hyper fluorescence to become overexposed. To safeguard against this, we recommend that photographers start the angiogram series using a flash setting that avoids overexposure, increasing the flash setting *only if several underexposed frames are observed*. This technique is preferred over starting the series with a flash setting that may be too bright and reducing it only if overexposure is observed. For the Heidelberg systems, we recommend that photographers start the angiogram series using a sensitivity setting set at a 1 o'clock setting, decreasing the setting carefully throughout the transit phase to avoid overexposure. This technique should capture the early transit-filling phase. Monitoring the sensitivity setting will ensure that the images will not be overexposed.

Heidleberg HRA Scanning Laser Considerations: The laser intensity must be set to full power (setting 7). The mode selector is set to the "Red-Free" setting to take the stereo red-free photos and the sensitivity should be adjusted to provide a properly exposed image. When setting the sensitivity for the fluorescein images, it is recommended that the setting be approximately 10% higher than the setting typically used for acquiring IR images (IR images are optional and not required by this procedure). This will insure that the laser will be more sensitive at the time the fluorescein dye first appears, making capture of the transit phase more

likely. Once the dye appears, the sensitivity may need further adjustment to maintain good contrast without image overexposure. The scan depth should be set to "0.0". The focus setting should be adjusted on the fine retinal vessels.

When using the HRA for stereo images, the "stereo" button in the acquisition software should not be pushed activated. We prefer that the stereo pairs are not "locked" as a single image icon.

5.0 Standard Fields (Figure 1)

The following descriptions of the standard fields assume that there are two cross hairs in the camera ocular (with the exception of the HRA system which does not contain a cross hair in the ocular), one vertical and the other horizontal intersecting in the center of the ocular.

Field 1M - Disc: Center the temporal edge of the optic disc at the intersection of the cross hairs in the ocular. When a cross hair is not available, as is the case with the HRA system, center the temporal edge of the optic disc in the center of the screen.

Field 2 - Macula: Centered up to 1DD from the center of the macula, including all or most of the CNV lesion, if possible. A suitable position can often be obtained by rotating the camera temporally from the Field 1M position, without vertical adjustment. When a cross hair is not available, as is the case with the HRA system, center the macula in the center of the screen.

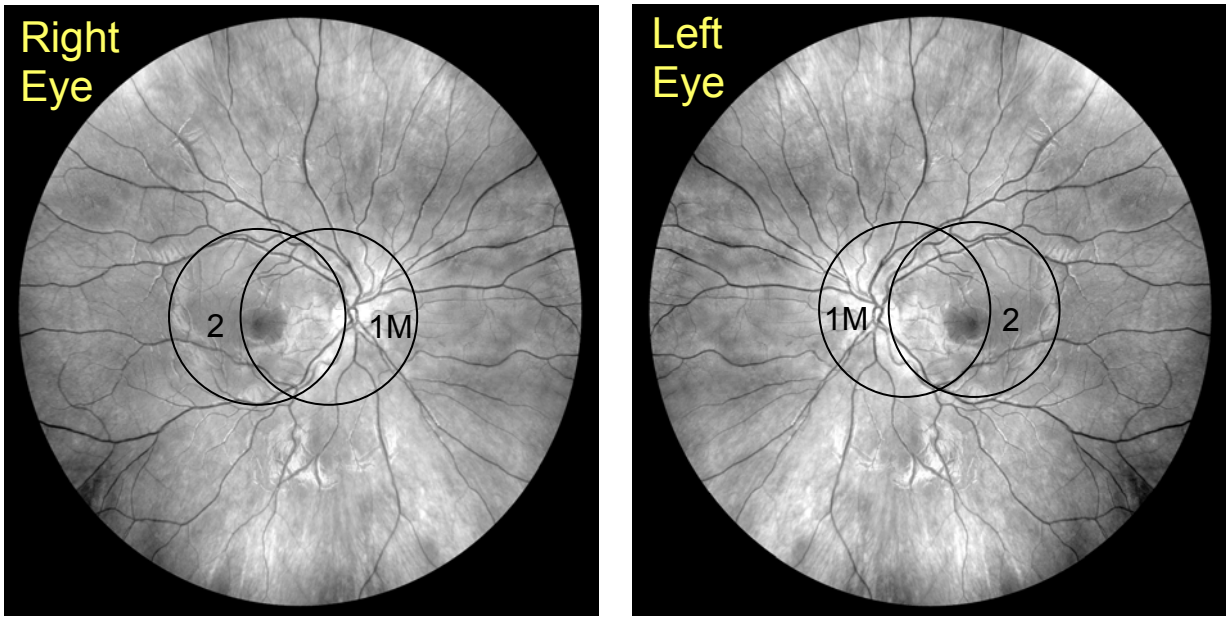


Figure 1

6.0 Fluorescein Angiography

Overview

The fluorescein angiogram contains stereoscopic views of 2 fields at specified times after injection. These fields include the macula (Field 2) of both eyes and the disc field (Field 1M) of the study eye. For Field 2, the camera should be centered near the center of the macula but not exactly on it, so that the artifact that is present in some fundus photographs will not obscure the center. If necessary, in eyes with choroidal new vessel (CNV) lesions, in order to include all or most of the CNV lesion, the camera may be centered up to 2 DD from the center of the macula. In order to obtain stereo pairs that are correctly oriented on the computer monitor for stereoscopic viewing (i.e., do not have reversed stereoscopic effect), the photographer must be careful to shoot the members of each stereo pair in the proper sequence. For example, OIS systems may arrange the images on the monitor in rows, starting in the upper right-hand corner and therefore it is best that the right member of each pair be taken first, followed by the left member, as you would if you were preparing a film-based fluorescein angiogram. However, IMAGEnet® and Heidelberg systems arrange the images on the monitor in rows, starting in the upper left-hand corner and therefore it is best that the left member of each pair be taken first, followed by the right member.

Stereoscopic red-free photographs are taken of Field 2 in each eye prior to the injection of the fluorescein dye.

6.1 Fluorescein Injection

After the red-free photographs of both eyes have been taken, the camera is positioned for Field 2 of the study eye. Fluorescein is injected rapidly (less than 5 seconds if possible) into the anticubital or other convenient vein according to usual clinic procedures.

6.2 Timing

6.2.1 Early Phase

The first photograph of the early phase is taken at time "0"; that is, at the moment injection of the fluorescein dye begins. The second photograph is taken at the moment the injection is complete. These photographs constitute a stereo pair and are referred to as the "control" photographs. They serve to document the integrity of the interference filters. The time shown on the second frame documents the rate of injection.

Ideally, the control photographs are followed by a series of 10 to 16 exposures taken at 1 to 2 second intervals, beginning about 15 seconds after the start of fluorescein injection (sooner if fluorescein appears sooner or delaying the initial exposures until fluorescence begins when a slow circulation time is expected). The usual result is 5 to 8 stereo pairs following the control pair, typically culminating about 40-45 seconds after the start of injection.

6.2.2 Mid-Phase

After the early photographs are completed the photographer takes stereo pairs of Field 2 and then of Field 1M of the study eye at approximately 60 to 90 seconds. At this point the camera is positioned in front of the fellow eye and a stereo pair is taken of Field 2 at approximately 2 minutes. At this point, the camera is repositioned back to the study eye and a stereo pair of Field 2 is taken between 2 and 3 minutes.

6.2.3 Late-Phase

A stereo pair of Field 2 in the study eye is taken at 5 minutes. Two final stereo pairs are taken of Field 2 in both eyes at 10 minutes.

7.0 CD Preparation and Labeling and Fluorescein Angiogram Duplication

The entire angiogram should be written to CD using only the standard methods existing in the software of the imaging system to isolate images for submission to the UW-FPRC. *Do not use Windows Explorer® to copy images to the CD*. Before writing the CD, please replace the subject's ID number, last name and first name with study specific information, as outlined in the FPRC Forms, Labeling & Shipping Information document. Remember that the editing of patient information may not be possible with current OIS systems.

During the export of image files, a dialog box may appear allowing the operator to edit patient data. An example of the Patient Data Export dialog box from the Heidelberg system (Figure 2) as shown below:

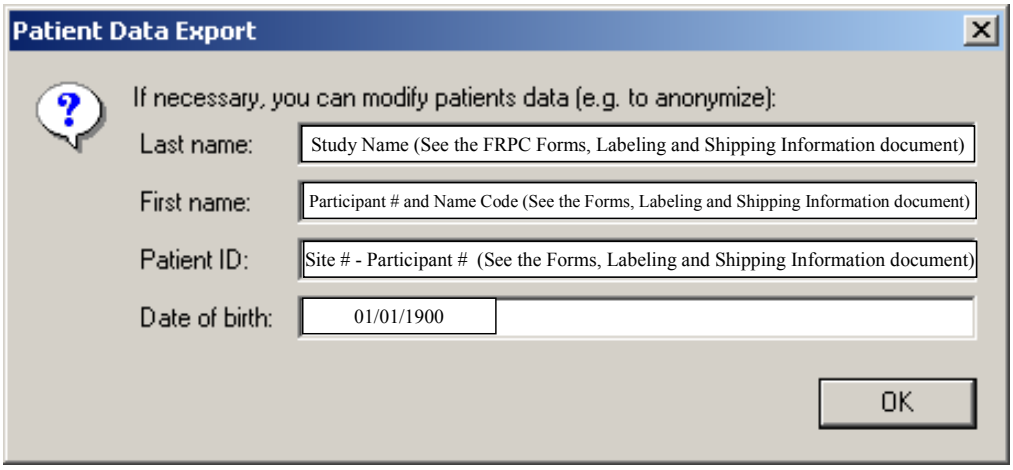


Figure 2

Please no not compress the images and don't use re-writable CDs (CD-RWs). The images from only one participant should be written to each CD. Multiple visits from the same participant can be written to the same CD. Images should be sent promptly to the Reading Center. The CD should be labeled using a circular CD label. These labels are provided by the UW-FPRC and include the study name, name of the institution/investigator submitting the photographs, patient ID information, visit, date(s) of photography and photographer's name(s) and the serial number of the digital system used to perform the angiogram. A full resolution (not compressed) duplicate of the entire angiogram should be retained at the site. The circular CD label is shown in Figure 3.

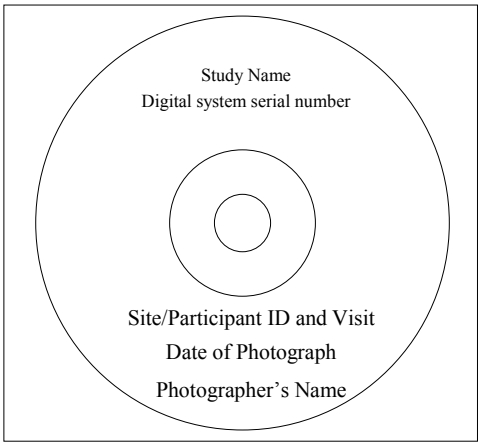


Figure 3

8.0 Transmission of Angiograms to the UW-FPRC

The digital angiographic file on CD and the original color transparencies should be sent together to the UW-FPRC within 10 working days (sooner if possible) after being taken.* The labeled CD should be placed inside a protective jewel case and the case placed inside a "bubble-wrap" or similar cushioned envelope to protect the media from damage. The completed **Transmittal Log** (see the FPRC Forms, Labeling & Shipping Information document) must accompany the shipment.

*If UW-FPRC review of angiograms only is required prior to the entry of the patient into the study, the CD alone should be sent to the UW-FPRC as soon as possible. The color photographs should be sent separately as soon as they have been processed. Each shipment must be accompanied by a properly completed Transmittal Log, per the FPRC Forms, Labeling & Shipping Information document.

CHAPTER 3

FUNDUS PHOTOGRAPH READING CENTER

Optical Coherence Tomography (OCT)
for OCT3 Systems

DRCRnet
Diabetic Retinopathy Clinical Research Network

OCT-3, Effective Date: 04Apr2005, Supersedes Date: 08Feb2005

University of Wisconsin – Madison / Department of Ophthalmology and Visual Sciences
Park West One – Suite 400 / 406 Science Drive / Madison, WI 53711-1068
PHONE: (608) 263-4538 FAX: (608) 263-0525

1.0 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, which 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 B-Scans. 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 A1.1 or newer.

2.0 OCT Operator Certification

All operators performing OCT must be certified for the relevant procedure(s), *before submitting actual subject scans.* ***Only UW-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 (see section 4.0 below).*

Certification consists of:

1. Submission of a signed **Request for OCT Operator Certification form.** Forms can be completed online at www.drcr.net (Click on *DRCRnet Study Website*, enter your User ID and password, select *Clinical Sites > Certification > OCT Operator Certification Request Form* (located under "Photography and OCT").
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; 1 eye with the disorder to be studied (such as macular edema) and 1 eye with a normal macula. Please 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 *"5.2 Scan Parameters and Fixation Guidelines"* on how to create a custom cross-hair scan).
4. Submission of **Retinal Map (Single Eye)**, **Retinal Thickness (Single Eye)** and **Align** analysis prints.
5. The exported data file sets *as described below in Section 7.0*. The data files are exported to DVD-RAM cartridge (or CD if available).

The requirement for submission of retinal map prints and/or digital files may be waived if the OCT operator has prior certification at the UW-FPRC using the OCT3 system, and has been actively performing OCT scans of good quality during the past year. Previously certified operators who have been inactive for more than one-year may be asked to submit current sample scans (often an abbreviated set) to become recertified.

OCT operators who are not eligible for **certification** on the basis of previous UW-FPRC certification 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:

A. **Case 1, Session 1:** (Eye with Pathology) This case should demonstrate the disorder to be studied, such as macular edema or exudative age-related macular degeneration, involving the center of the macula. The following items need to be acquired and labeled as Case 1, Session 1:

1. Fast Macular Thickness Map scan: This scan will acquire six, 6mm scans, from which you will print:
    a. **6 Retinal Thickness (Single Eye)** Analyses:
    This analysis is used to obtain graphs of retinal thickness for each of the six radial B scans. Refer to *section 2.2 & 2.3* for printing & labeling instructions.
    b. **1 Retinal Map (Single Eye)** Analysis:
    This analysis is used to obtain center point thickness, standard deviation and average retinal thickness (in microns) in nine subfields. Refer to *section 2.2 & 2.3* for printing & labeling instructions.

2. Cross-Hair Scan: This scan will acquire the horizontal and vertical B-scans at the 512 resolution and at the 6.0mm scan length. You must remember to change the height and width scan length from 3.0mm to 6.0mm (see *section "5.2 Scan Parameters and Fixation Guidelines"* on how to create a custom cross-hair scan). From this scan you will print:
    a. **2 Align** Process Reports (Horizontal B-scan and Vertical B-scan):
    This analysis is used to identify retinal morphology (i.e., cystoid changes). Refer to *section 2.2 & 2.3* for printing & labeling instructions.

3. Exported Data Files (via DVD or CD): Depending on what software version you are using (i.e. 1.0 – 4.0), there are two different ways to export data files. These data files should be labeled as "Case 1, Session 1." See *Section 7.0* for more details.

B. **Case 1, Session 2:** (Eye with Pathology) In this session, the Fast Macular Thickness Map scan is repeated on the same eye used in Case 1, Session 1 approximately 5-10 minutes after the Session 1 scanning is complete. The objective of repeating the scan is to review the operator's scan technique and reproducibility of retinal thickness values. To be considered of good quality, the Retinal Map Reports from Session 1 and Session 2 should have center point values within 10% of each other (*see section 5.3 for more details on scan quality*). The following scan is needed for Case 1, Session 2:

1. Fast Macular Thickness Map Scan: From this scan you will print:
    a. **1 Retinal Map (Single Eye)** Analysis. Refer to *section 2.3* for print instructions. This Print should be labeled as "Case 1, Session 2"

C. **Case 2, Session 1:** (Normal or near normal Eye) This case should demonstrate a normal or near normal macula (i.e. the center of the macula should not be thickened). Please perform the following scan for Case 2, Session 1:

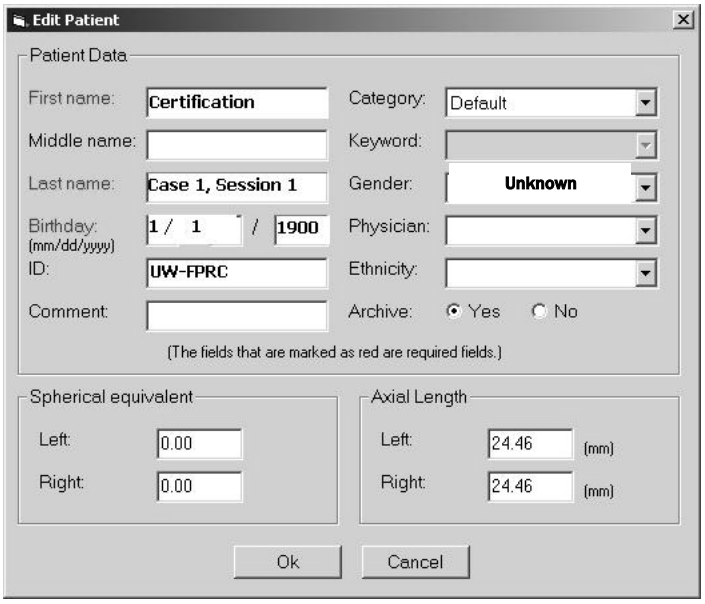
1. Fast Macular Thickness Map Scan: From this scan you will print:
    a. **1 Retinal Map (Single Eye)** Analysis. Refer to *section 2.3* for print instructions. This Print should be labeled as "Case 2, Session 1."

D. **Case 2, Session 2:** (Normal or near normal Eye) In this session, the Fast Macular Thickness Map scan is repeated on the same eye used in Case 2, Session 1 approximately 5-10 minutes after the Session 1 scanning is complete. The objective of repeating the scan is to review the operator's scan technique and reproducibility of retinal thickness values. To be considered of good quality, the Retinal Map Reports from Session 1 and Session 2 should have center point values within 10% of each other (*see section 5.3 for more details on scan quality)*. The following scan is needed for Case 2, Session 2:

1. Fast Macular Thickness Map Scan: From this scan please print:
    a. **1 Retinal Map (Single Eye)** Analysis. Refer to *section 2.3* for print instructions. This Print should be labeled as "Case 2, Session 2."

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 Patient" dialog box seen below:



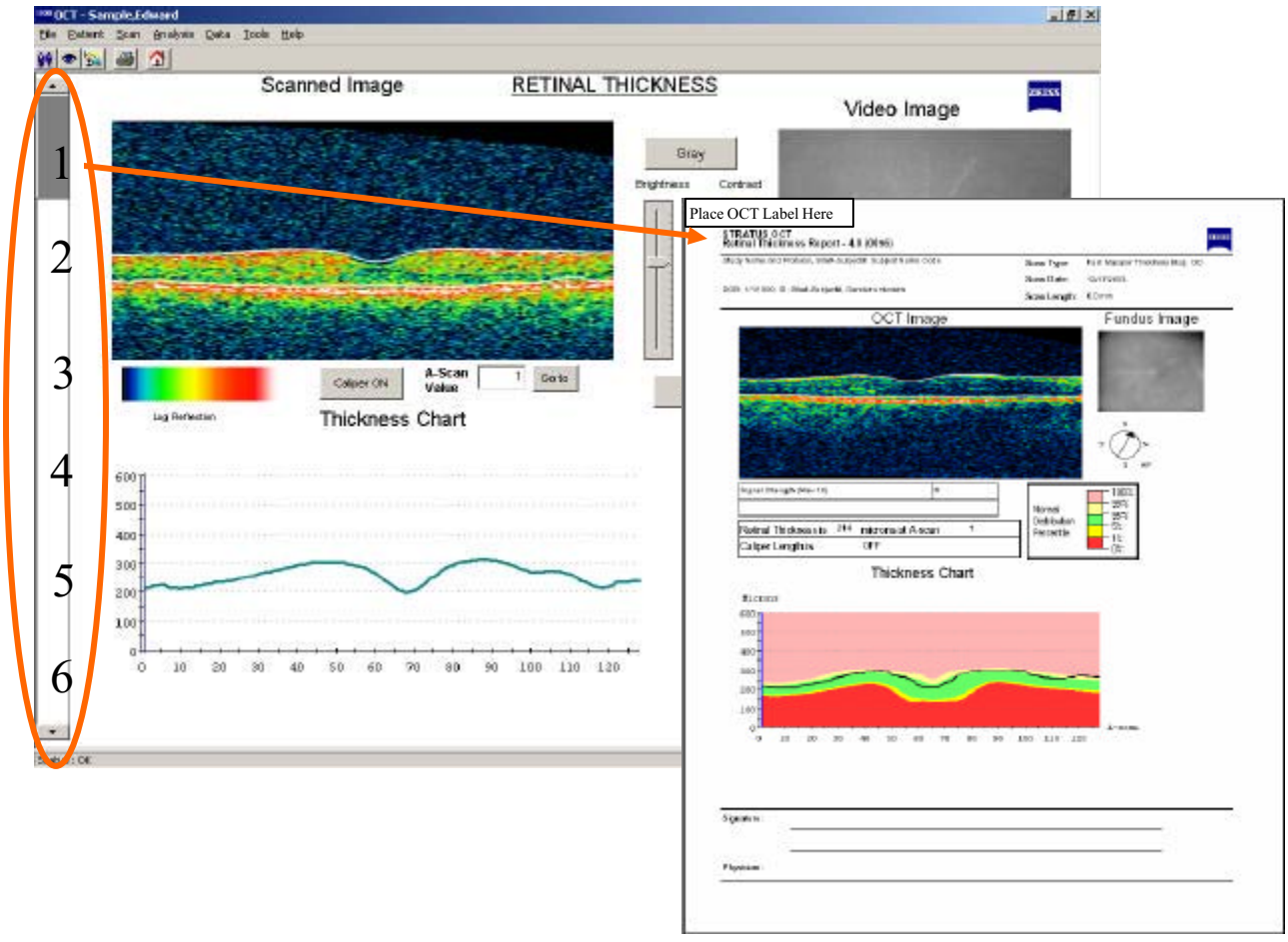
The **First name** field should contain the word "Certification", the **Middle name** field should remain blank and the **Last name** field should contain the case and session number, assigned sequentially, for each of the 4 sets of scans, i.e., "Case 1, Session 1", "Case 1, Session 2", "Case 2, Session 1" and "Case 2, Session 2". Please anonymize the patient's date of birth as "01/01/1900." The patient **ID** field should read "UW-FPRC" and the patient **Gender** should be "Unknown."

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

2.3.1 Retinal Thickness (Single Eye) Printing and Labeling

The 6 **Retinal Thickness (Single Eye)** report prints are selected using the scroll bar located on the left edge of the Retinal Thickness display. Moving this scroll bar allows the operator to scroll through all six scans. When the scroll bar is in the top-most position, the vertical scan (Scan 1) is displayed. As the scroll bar is moved incrementally down the display screen, Scans 2-6 can be displayed, printed and/or exported. 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 only). The 6 Retinal Thickness Reports should be labeled as Case 1, Session 1: Scan 1, Scan 2, Scan 3, Scan 4, Scan 5 or Scan 6. Please note that Case 1, Session 1 is the only session that requires the 6 Retinal Thickness Report prints.

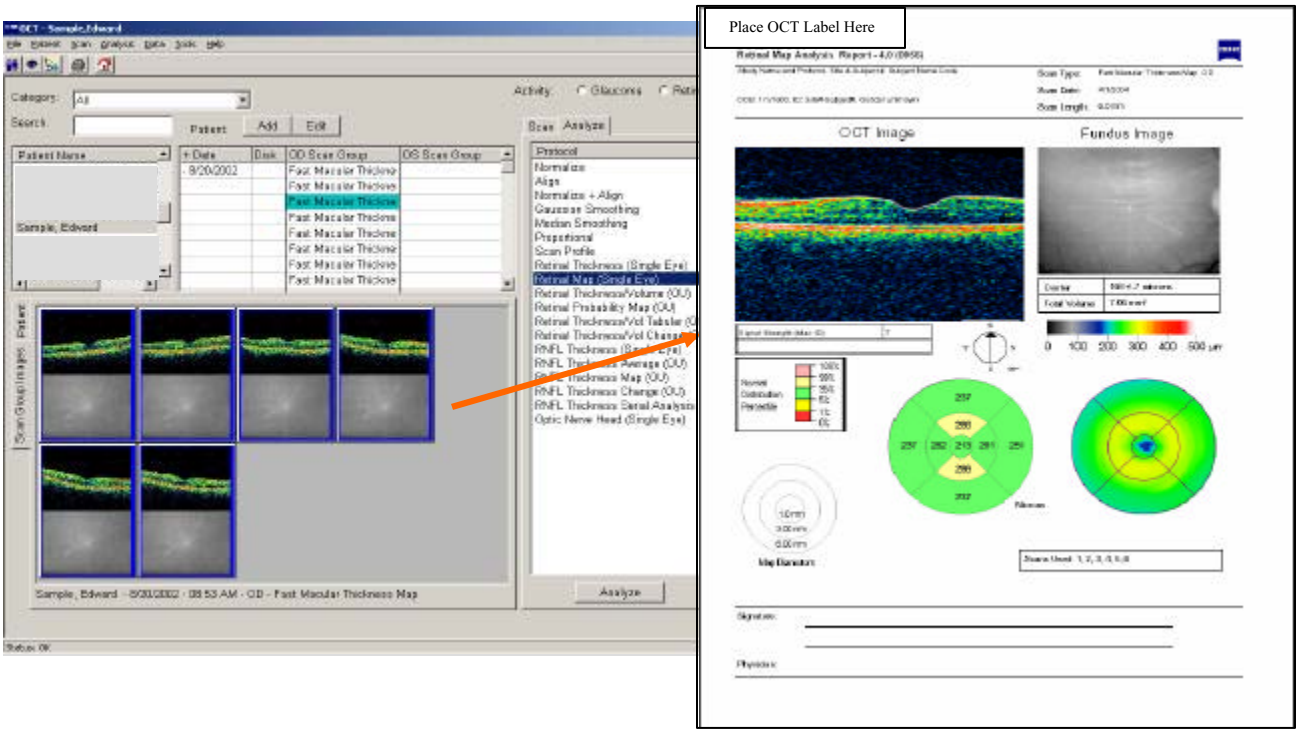
Retinal Thickness Report Printing & Labeling Illustration



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 (see illustration below). The label will be placed on the top left hand corner (shown below) and will be labeled with the appropriate Case and Session number. For certification, you will have a total 4 Retinal Map Reports: Case 1, Session 1; Case 1, Session 2; Case 2, Session 1; Case 2, Session 2.

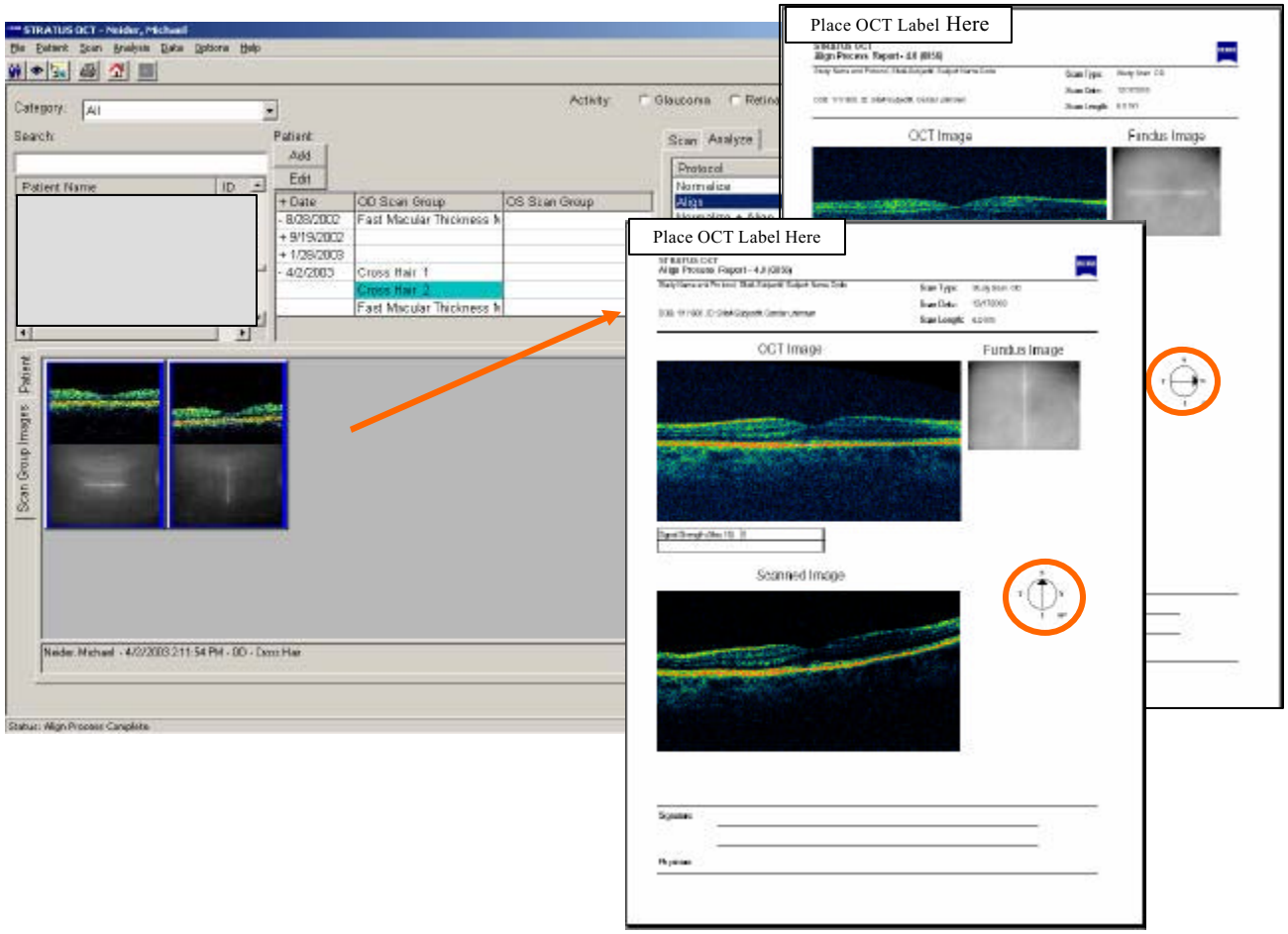
Retinal Map Report Printing & Labeling Illustration



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 (see illustration below). You will use the scroll bar to move to the vertical and horizontal scans. When the scroll bar is in the top-most position, the vertical scan is displayed and when the scroll bar is moved down, the horizontal scan is displayed. Again, the labels will be placed on the top left hand corner (shown below) and will be labeled Case 1, Session 1: Horizontal Cross-Hair and Case 1, Session 1: Vertical Cross-Hair. The Cross-Hair scan is only performed for Case 1, Session 1.

Align Process Report Printing & Labeling Illustration



In most cases, pre-printed certification labels will be available for labeling the twelve certification prints and the DVD cartridge; if not, please hand label them using standard page labels and a permanent felt-tip marker. They should be labeled indicating the case and session numbers, the photographer's name, date of the scans and that the scans are for certification.

2.4 Review of Certification Materials

The final certification submission will consist of a total of 12 OCT prints, 1 DVD or CD containing the export files (from Case 1, Session 1) and the "Request for OCT Operator Certification Form." For a review of the certification requirements, please refer to **Appendix A**.

Certification will be considered complete if the UW-FPRC determines the scans are of good quality and the correct data files can be successfully exported to DVD or CD and sent to the UW-FPRC for analysis. OCT operators who meet certification criteria will receive written (via fax or email) or verbal (via phone) confirmation of certification. Operators who do not meet these criteria will receive feedback from the UW-FPRC imaging consultants, and will be required to submit additional scans, prints and/or data files. 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 sponsor and principal investigator.

THE FOLLOWING INFORMATION REFERS TO ACTUAL STUDY PATIENT SUBMISSIONS, PLEASE READ CAREFULLY:

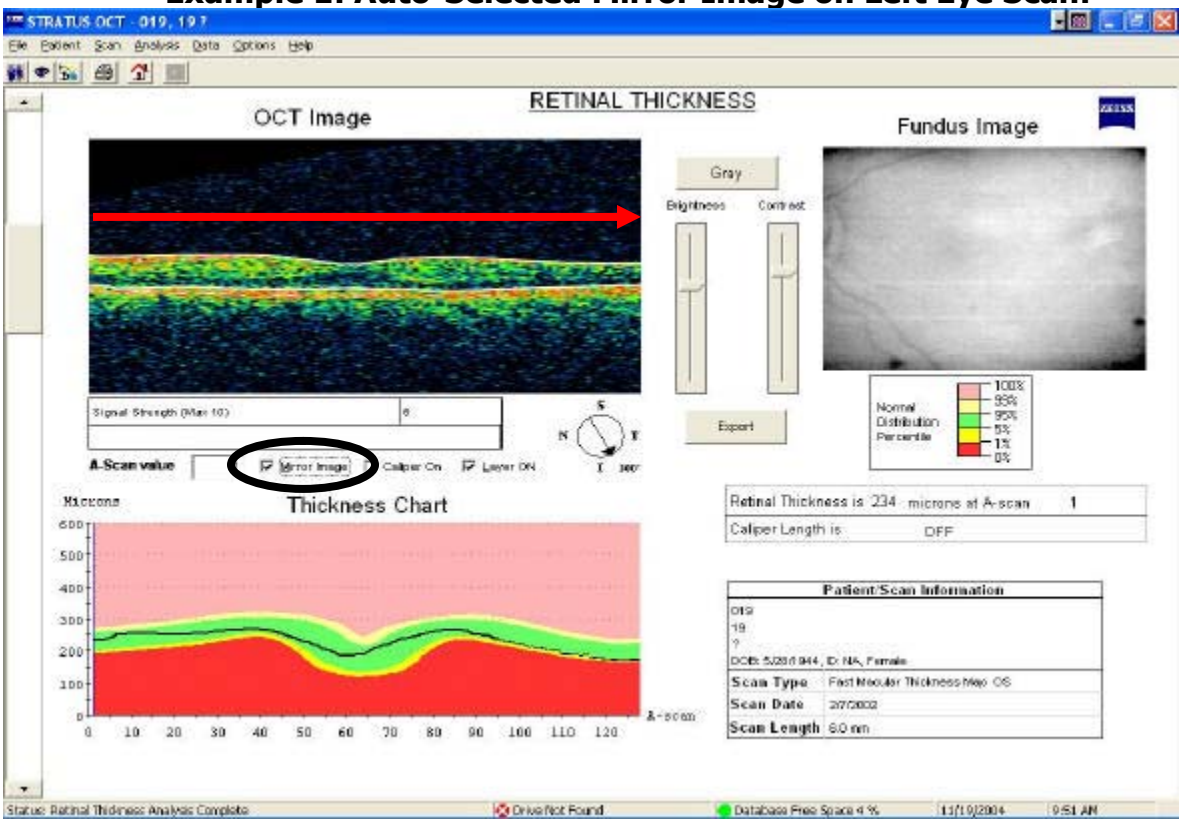
3.0 Software Version Upgrade from 3.0 to 4.0

Please note that Carl Zeiss Meditec is offering an upgrade from version 3.0 to version 4.0 on the Optical Coherence Tomography 3 (OCT 3) machine. This upgrade is an installation of new software **only** and is **NOT** a new generation of the OCT machine (i.e. OCT 4 machine). To upgrade, simply follow the manufacturer installation instructions that are included with the upgrade CD. Please note that you do NOT need to re-certify your OCT machine with the Fundus Photograph Reading Center (FPRC) when upgrading to version 4.0. Re-certification is only required when transitioning to a different OCT machine (i.e. OCT2 to an OCT 3). If you have any questions in regards to this procedure, please contact a member of the photography department at the FPRC at 1-608-263-9858.

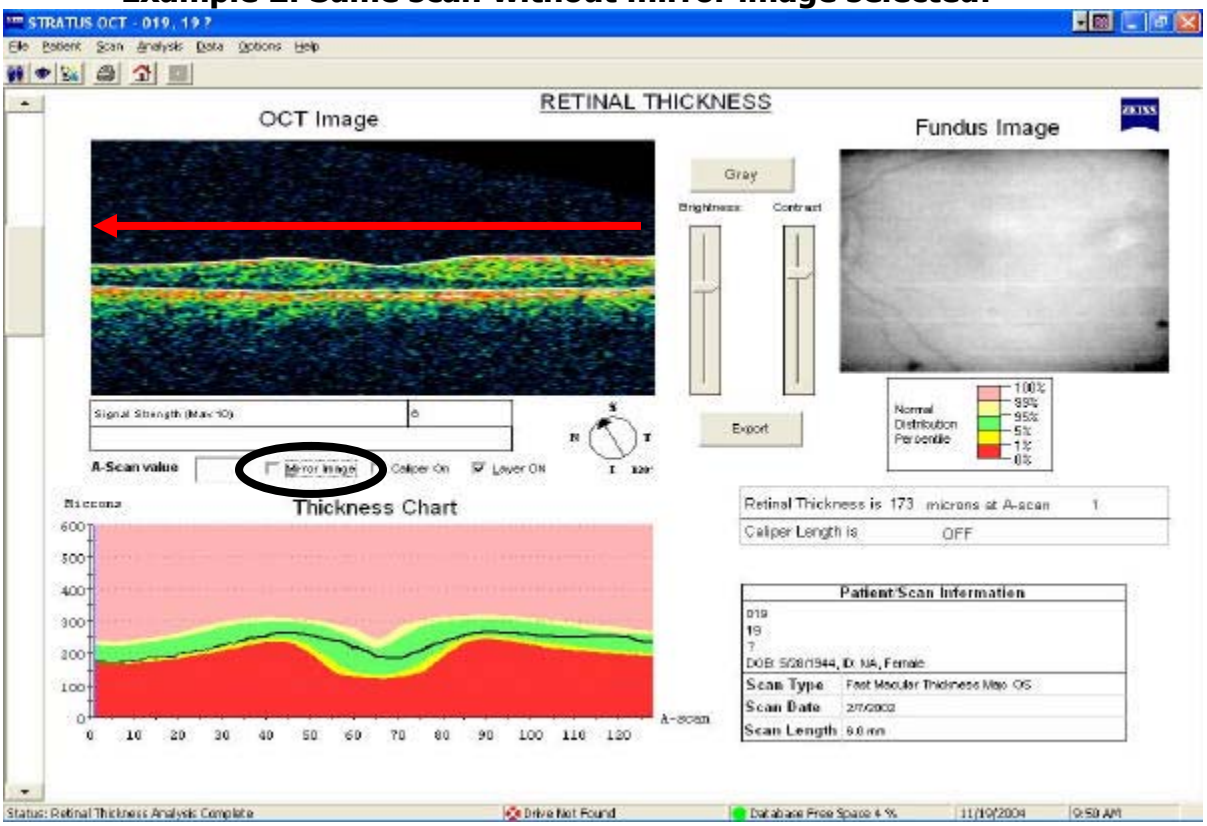
3.1 New Feature of the version 4.0 software - Mirror Image Default Setting for Left Eye Scans

Please note that if you are upgrading to the version 4.0 software, the "Mirror Image" setting is automatically selected as the default for all ***left eye*** scans, see the illustrations below to compare auto-selected "Mirror Image" [Example 1] versus unchecked "Mirror Image" [Example 2]. The retinal analyses affected by the "Mirror Image" default are the *Retinal Thickness Report* (Scans 2-6) and the *Align Process Report* (horizontal scan only). The FPRC asks that you do NOT adjust the default setting, as it is an important tool in analyzing OCT images.

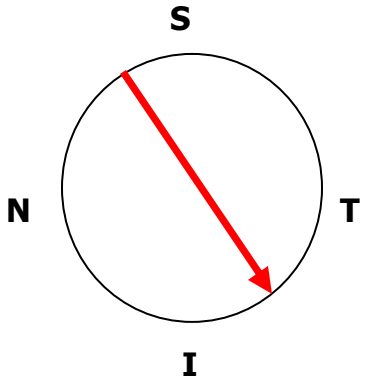
Example 1: Auto-Selected Mirror Image on Left Eye Scan:



Example 2: Same scan without mirror image selected:



The "Mirror Image" feature changes the direction of the left eye scans to read nasal to temporal, or left to right if viewing the OCT image on the Retinal Thickness Report (see Example 1 above). The direction of the scan is illustrated by the clock arrow seen below:



This Scan represents the second scan (300 degrees) taken nasal to temporal; left to right

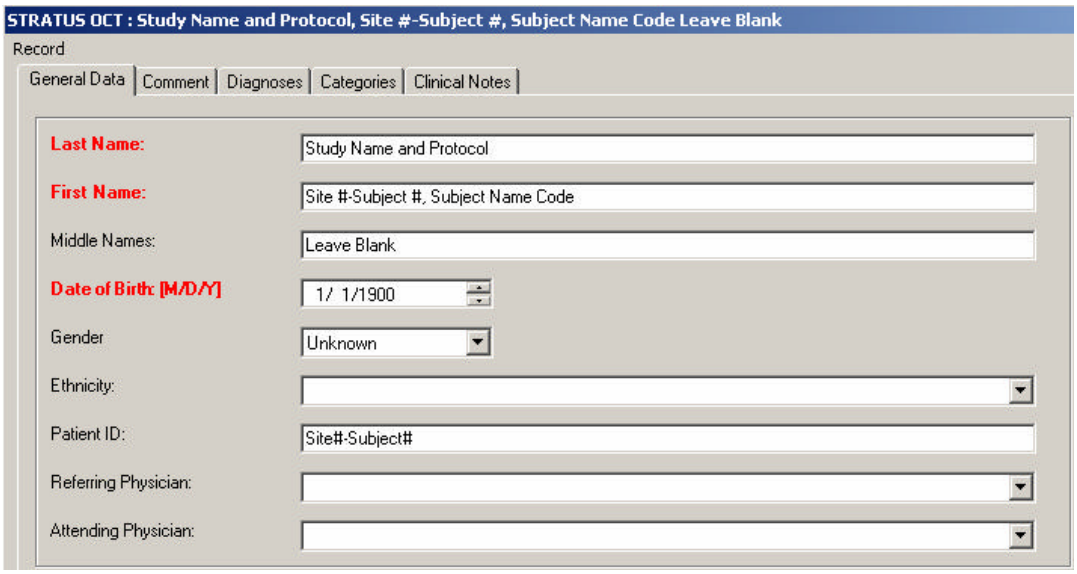
4.0 Uncertified Operators (Follow-up visit only)

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 they understand and follow the procedure. The name of the uncertified operator should be entered on the OCT page labels.

5.0 Study Patient Examination Procedure

The Schedule of OCT's will specify by visit whether to scan both eyes or the study eye, usually the latter, and will list scanning and printing requirements (this document is available on the DRCRnet website, listed as "*DRCRnet OCT Visit Schedule by Protocol"*). The eye(s) should be maximally dilated to help insure 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.

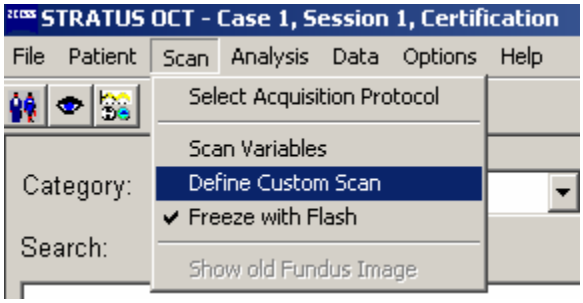
5.1 Adding subjects to the database - *The subject's name should not be entered into the database.* The operator should register the subject prior to printing the scans using the following format: Please enter the site number and subject's unique study ID number and the subject's namecode in the **First name** field and leave the **Middle name** field blank. The **Last name** field should contain the Study name and protocol. The **Date of Birth** field must be filled in using 1/1/1900 on each subject. Please do not use the subject's actual birth date. The **Gender** should be masked as "unknown." Please record the clinic number and subject's unique study ID number in the subject **ID** field. (See the illustration listed below) For specific examples, please refer to Appendix B.



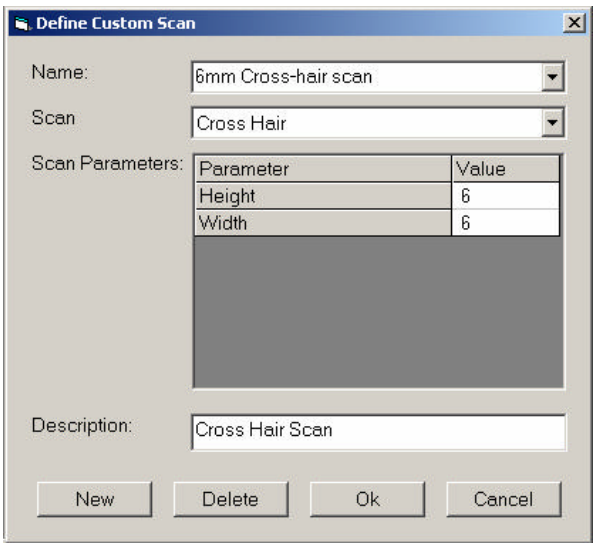
5.2 Scan Parameters and Fixation Guidelines

5.2.1 Scan Parameters - Two scan types are used for the OCT 3 procedure:

1. **The Fast Macular Thickness Map** scan - used to acquire six 6mm radial line scans in 1.92 seconds of scanning.
2. The **Cross-Hair** scan - used to acquire two 6mm scans using the 512 resolution setting, one horizontal B-scan and one vertical B-scan, centered on the macula. *Please be certain to change both the height and width values to 6.0mm*; the default scan length is 3.0mm.
   a. To set up a custom cross-hair scan, follow the instructions below:
      i. Click Scan > Define Custom Scan (as displayed below):



ii. A "Define Custom Scan" dialog box will appear:



1. In the "Name" section, type "6mm Cross-hair.
2. From the "Scan" drop-down list, select "Cross-hair."
3. In the "Scan Parameters" section, change the height and width values to "6."
4. Select "OK" to save your custom scan.

5.2.2 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, they are 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. In the rare occasion when the subject cannot see the green fixation target at all, they are 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.

5.3 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). The operator is encouraged to repeat the Fast Macular Thickness scan in cases where any one of the analysis prints display an inaccurately identified ILM or RPE boundary (and the operator believes that a second attempt may produce a more suitable scan for analysis). Because changes in macular thickness as determined by optical coherence tomography (OCT) scans are a primary outcome in DRCRnet, it is imperative that these OCT scans be of reliable quality. For that reason, the study protocol requires that clinics submit the Fast Macular Thickness scans with the standard deviation of the center point measurement within 10% of the magnitude of that measurement. Specifically, a Fast Macular Thickness scan is acceptable if (a) the standard deviation of the center point does not exceed 10% of the magnitude of that measurement, and (b) 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.

In order to obtain the Standard Deviation percentage, follow these guidelines:

1. Standard deviation percentage = $\frac{\text{Standard Deviation}}{\text{Center Point Thickness}} \times 100$
2. If the standard deviation percentage of mean value is:
    a. $\leq$ 10%, the scan is Acceptable and the center point is deemed gradable
    b. $>$ 10%, the scan is NOT acceptable because it suggests extreme variability of the scan at the center point

The baseline measurements for a patient are critical, since all of the follow-up measurements are compared to this point to determine the study outcome. Thus, we ask that clinics check their OCT scans carefully to make sure that at least one of the scans has acceptable internal quality - standard deviation not more than 10% of the center point, and that no obvious boundary errors are present on the underlying scans.

6.0 Printing, Labeling and Assembly of OCT's for Study Patient Submissions

6.1 Printing (Single Eye)

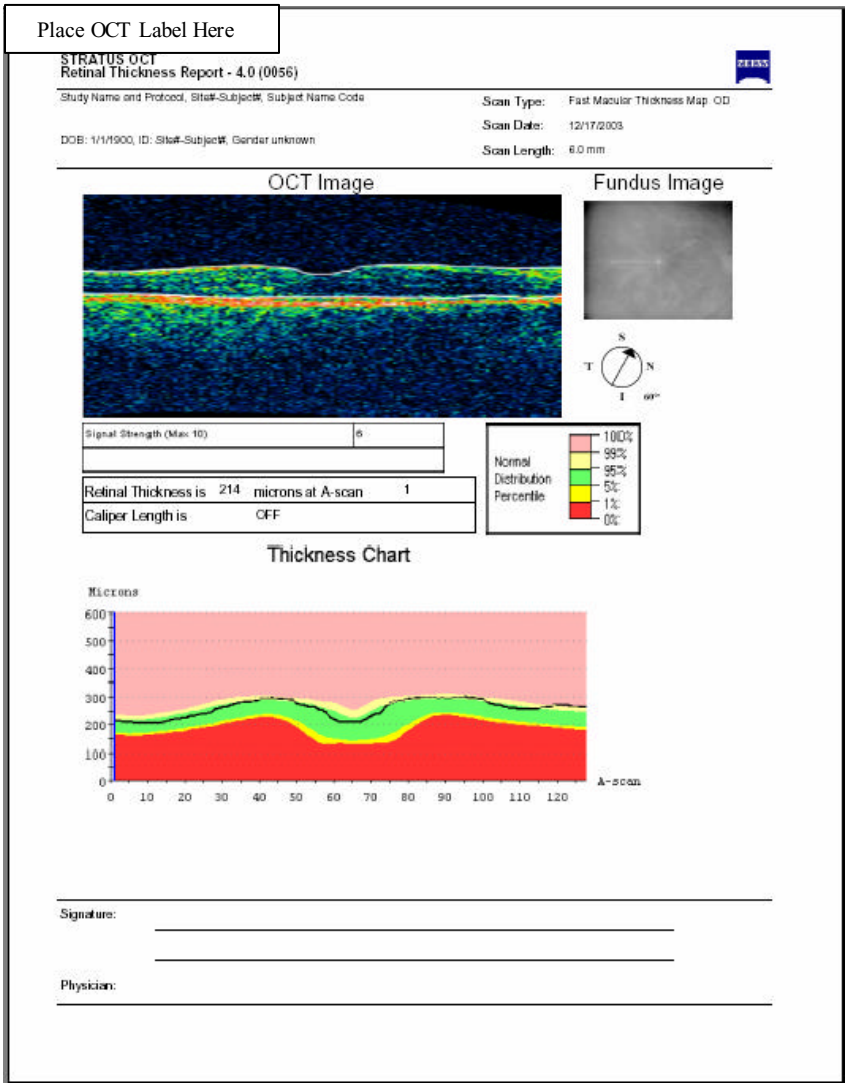
Nine prints,[1] using the 6.00mm display option, are required for each eye. Six **Retinal Thickness (Single Eye)** analysis prints (one displaying each of the six radial line B-scans), one **Retinal Map (Single Eye)** analysis print, and two **Align** analysis prints (from the 512-resolution, 6mm Cross-Hair scan, one displaying the vertical B-scan and the other the horizontal B-scan) are required.

1 Please note that the total number of prints required is different for each protocol. For specific print requirements, please refer to the "*DRCRnet OCT Visit Schedule by Protocol*" (located on the DRCRnet website).

6.2 Labeling

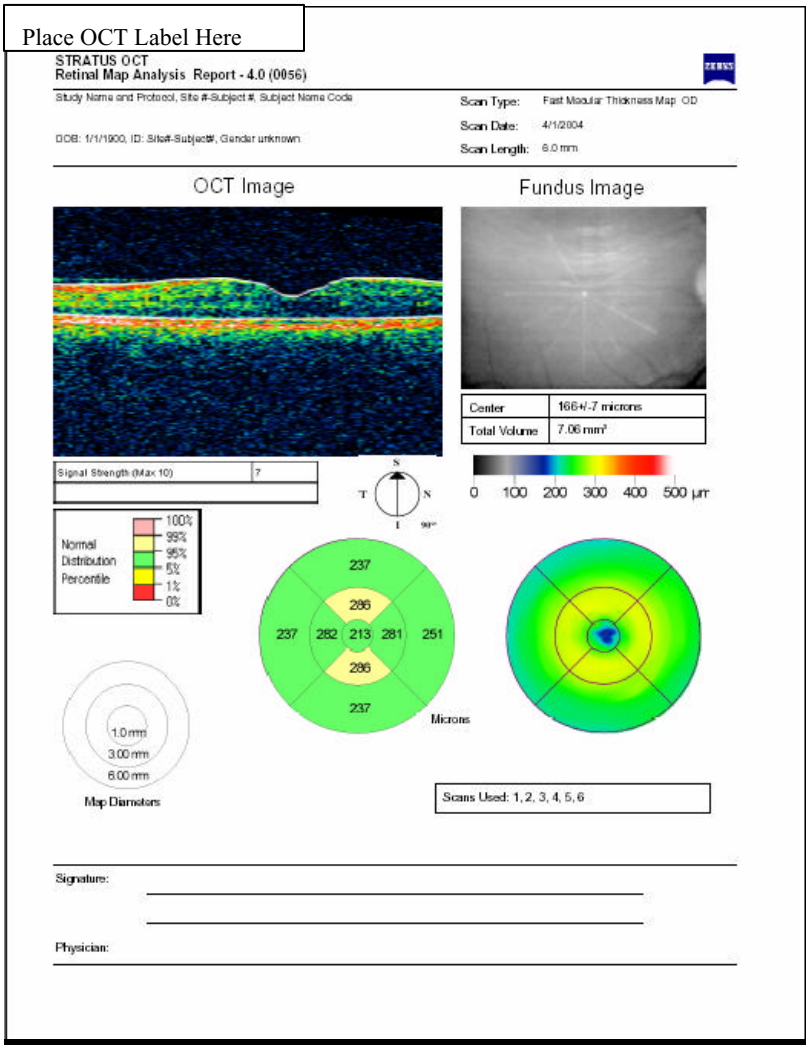
Pre-printed labels will be provided (online) for all of the prints for study patient submissions. Extra attention must be paid when labeling the 6 **Retinal Thickness (Single Eye)** analysis prints, applying the appropriate labels: Scan 1, Scan 2, Scan 3, Scan 4, Scan 5, and Scan 6 (corresponding to the relative position of the scroll bar which indicates the scan number as shown in Section 2.3, above). Please see **Appendix D** for more information on how to label the Retinal Thickness Reports (for both eyes) according to the OCT software version. Examples of the required prints with correct labeling are shown below. Please note that if you are using versions 2.0 – 4.0, all scans will print in the portrait orientation only, not landscape.

Example 1: Retinal Thickness Report (Single Eye)



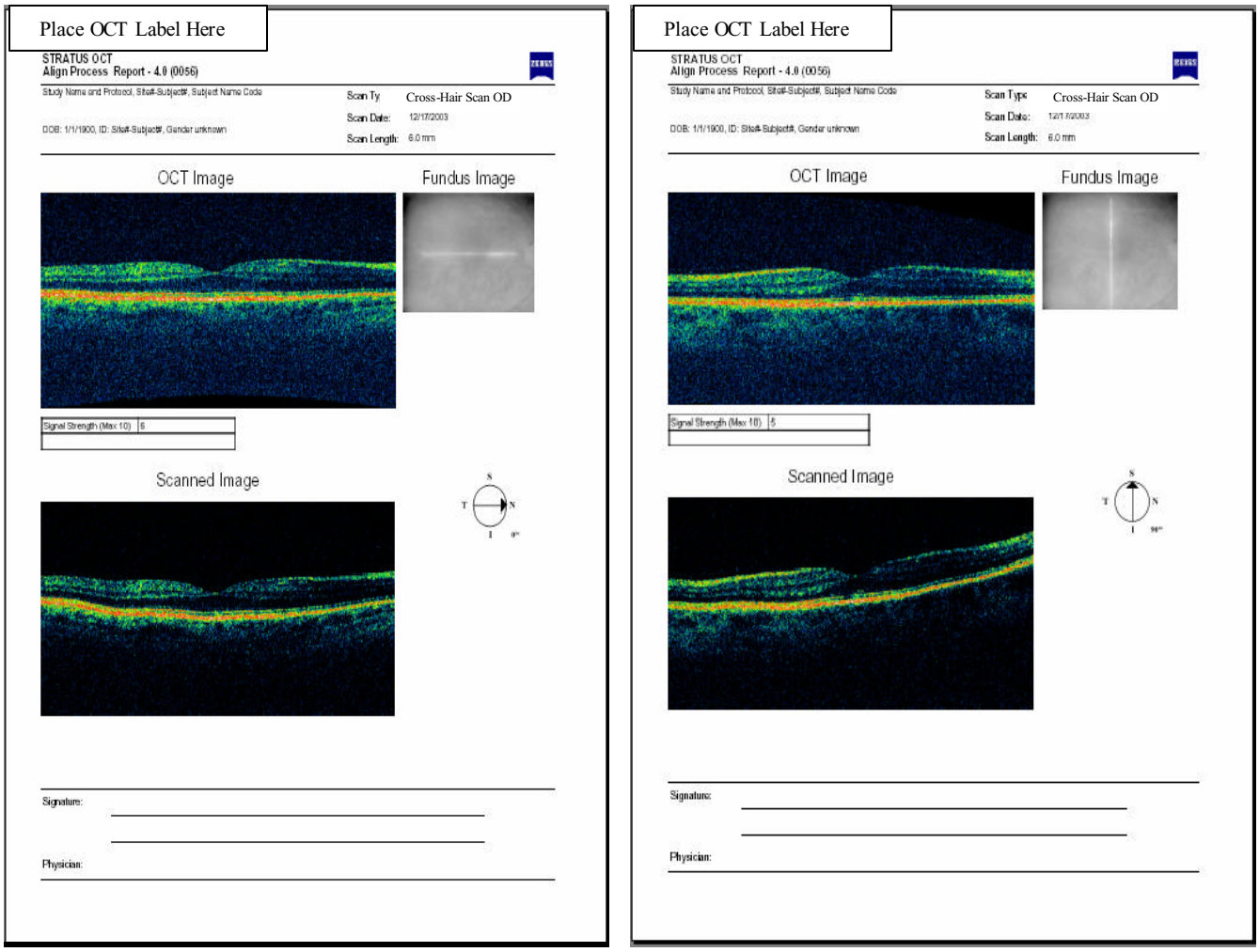
6 Retinal Thickness (single eye) prints, one corresponding to each of the six radial scan lines, are produced by adjusting the scroll bar located along the left edge for the computer display.

One Retinal Map (Single Eye) analysis print



Combines the six Fast Macular Thickness scans into one analysis that obtains the average retinal thickness values for the 9 ETDRS subfields.

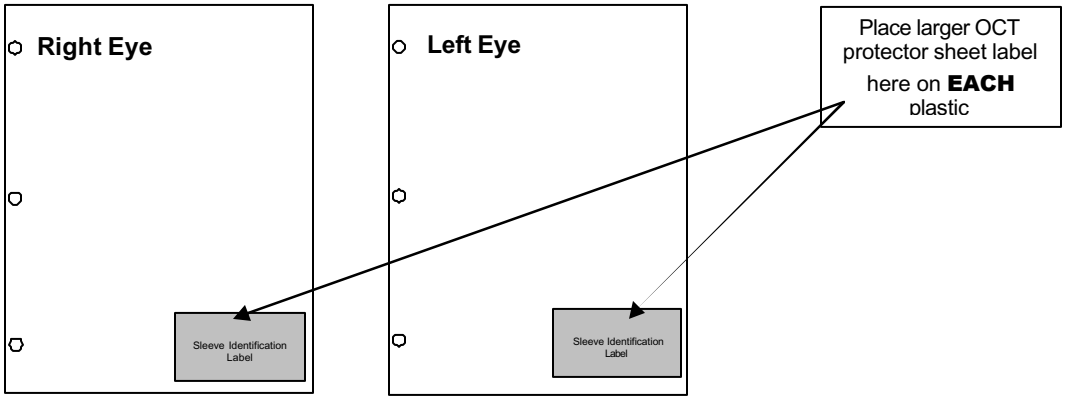
Align analysis prints



One displaying the vertical B-scan and the other the horizontal B-scan obtained using the 512-resolution Cross-Hair scan at 6.0mm.

6.3 Assembly of Prints

All **RE prints** should be placed into one protective plastic sleeve, all **LE prints** into a second plastic sleeve, and a sleeve identification label should be affixed to each plastic protective sleeve. All subject information should be filled in, as well as the OCT operator name.



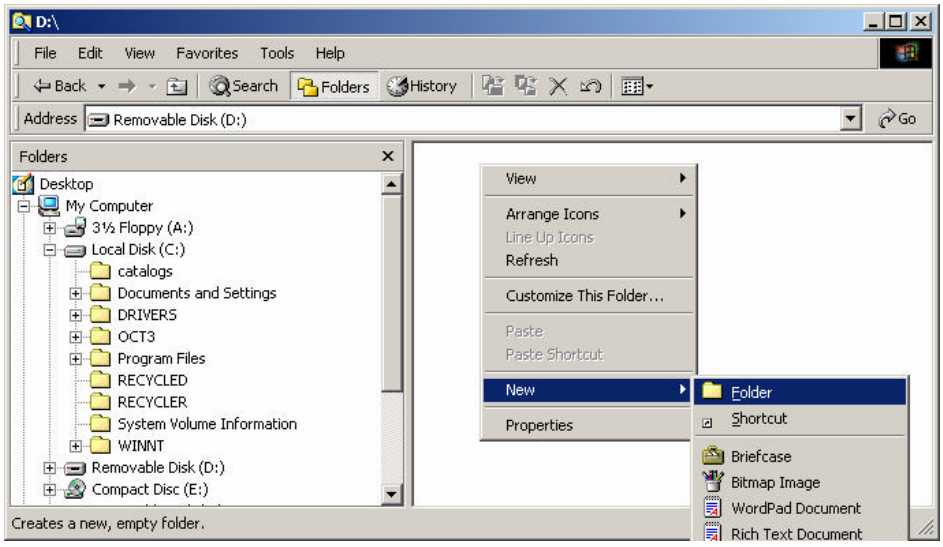
7.0 Exporting Data Files

Data Files – ***The data files will NOT be sent routinely to the FPRC for study patient submissions***, but they may be requested on a case-by case basis, whenever the FPRC determines that they are needed. **However, for certification purposes you MUST submit the data files in order to demonstrate your technical competence of the export procedure.** If you are using an OCT 3 machine with a software version of 1.0 – 3.0 please refer to section 7.1 below. If you are using an OCT 3 machine with a software version of 3.1 or above please refer to section 7.2.

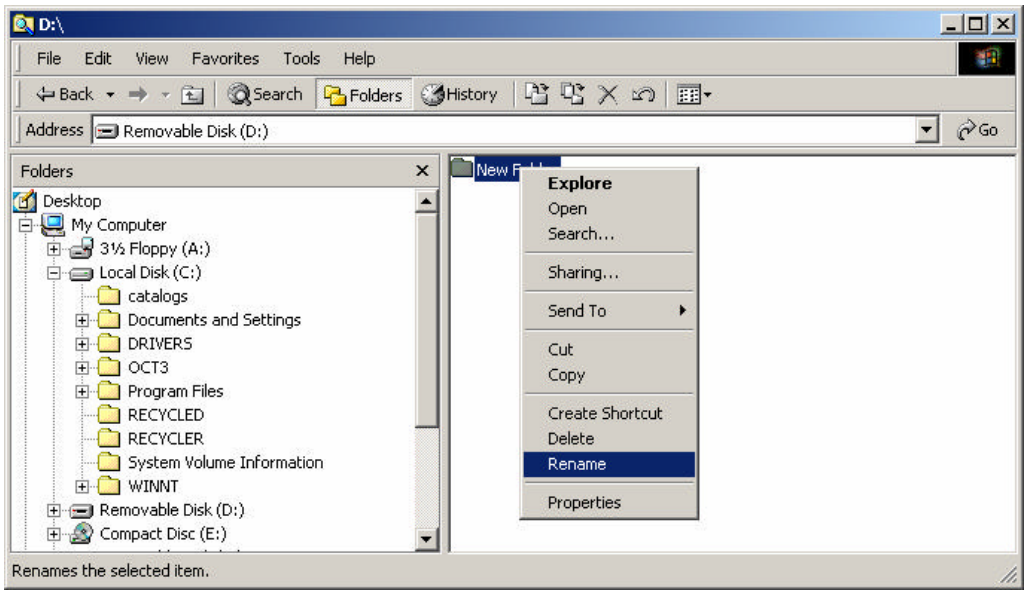
7.1 Exporting Data Files for Software Versions 1.0 – 3.0

When requested by the FPRC, the data files corresponding to each of the six radial scans from the Fast Macular Thickness scan, are exported to DVD (or CD if available) using the "Export" button located on the **Retinal Thickness (Single Eye)** analysis screen. Please do not attempt to export the data files from the OCT3 system to floppy diskettes because the cumulative file size exceeds the 1.44MB floppy disk capacity. Please export the files to another form of removable media. Acceptable options include CDs (by using a removable USB jump drive) or use of the existing DVD writer located in the OCT3's CPU. You may elect either of these options for collecting the exported data files. Please follow the directions below:

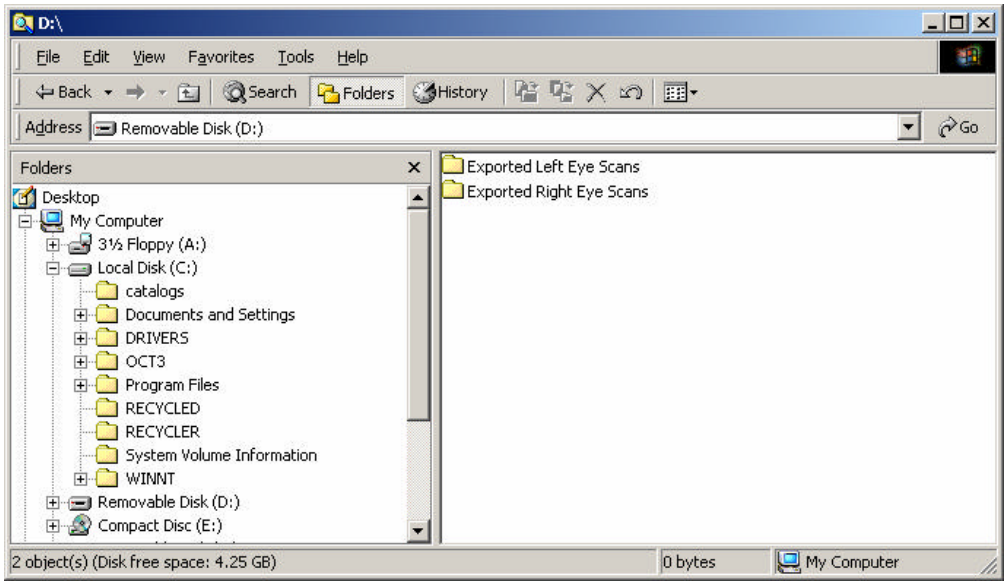
1) First, you MUST format the DVD-RAM cartridge in the "FAT32" format.
    a. Install the DVD cartridge into the DVD drive.
    b. Click Windows **Start > Programs > DVD-RAM > DVDForm.**
    c. Click on the down-arrow next to **Format Type** and select **FAT32.**
    d. Click **Start.** A DVDFORM window will appear.
    e. Click **Yes** to begin the formatting. When the formatting is complete, you may click the "X" to exit the program.
2) Create Export folders on the DVD drive.
    a. Right Click on Windows **Start >** left click on **Explore >** left click on **DVD Drive (D:/).**
    b. To create the folders, right click on the blank panel on the right hand side of the screen > left click on **New** > left click on **Folder:**



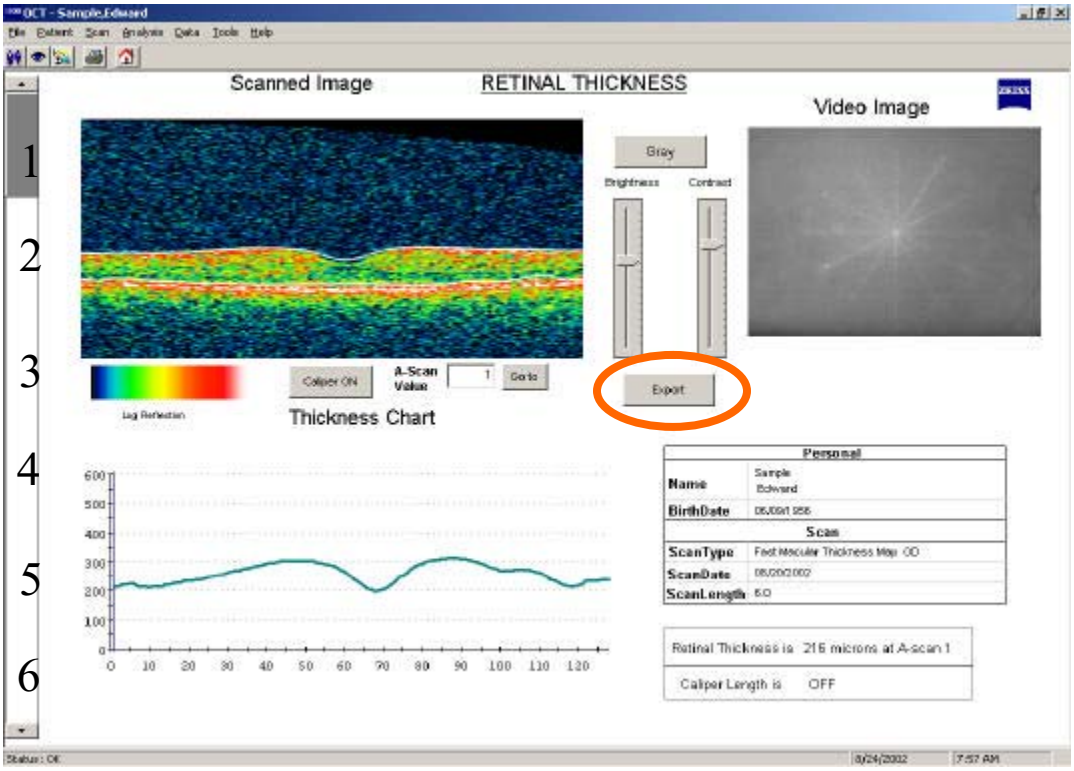
c. To rename the folders, right click on **New Folder >** left click on **Rename:**



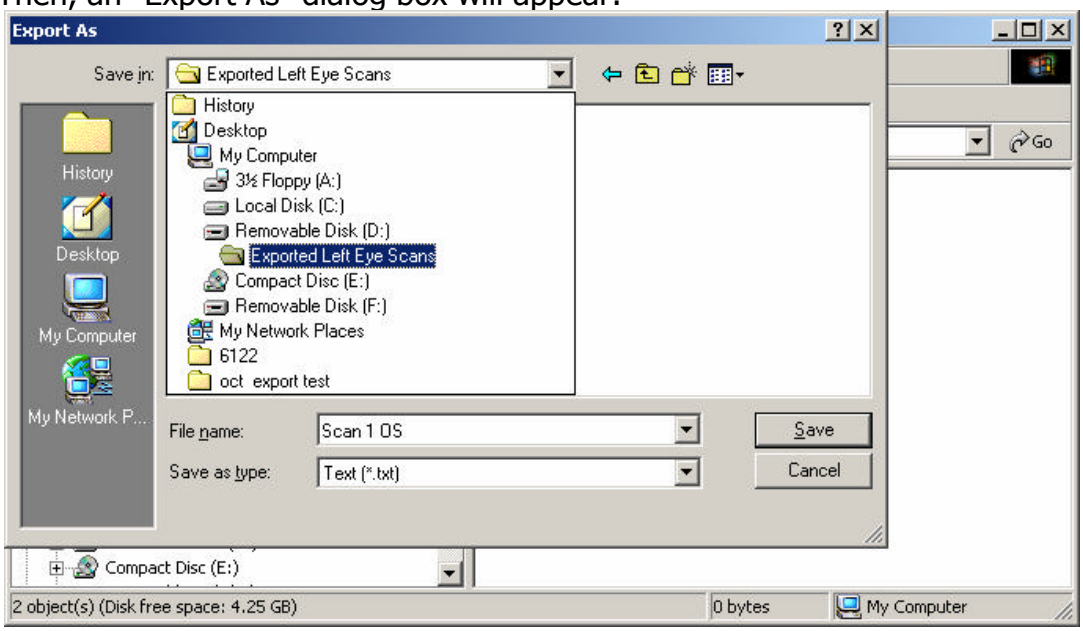
d. Label the folder as "Exported Right Eye Scans" or "Exported Left Eye Scans" (see below). Follow steps b and c to create a second folder. **Please note, if you are exporting for certification, you only need to create 1 folder and it should be labeled "Case 1, Session 1"**:



3) To export, open the "Retinal Thickness (Single Eye)" analysis, select the "Export" button (located to the right of the OCT image):

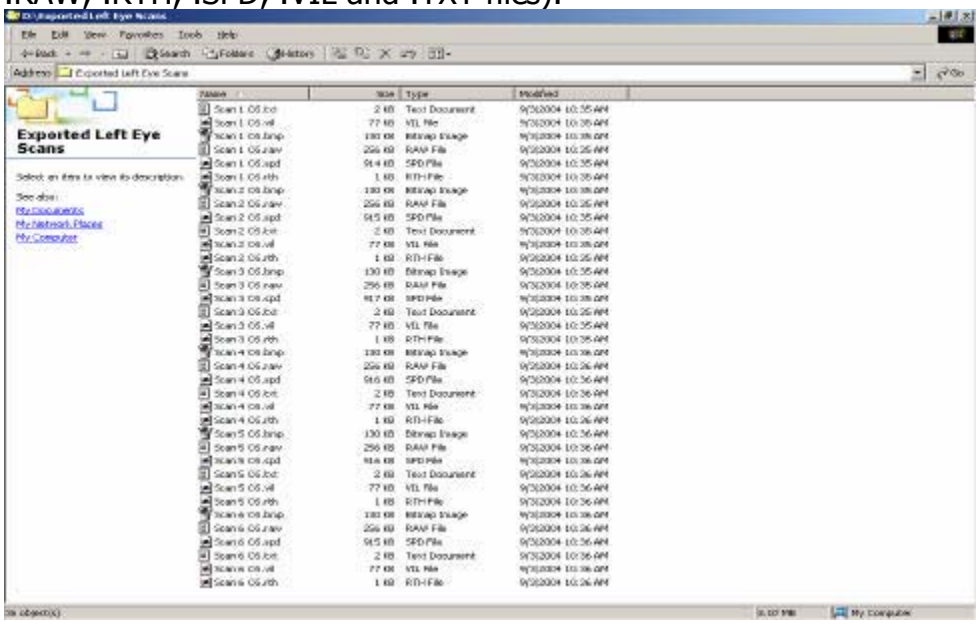


4) Then, an "Export As" dialog box will appear:



a. From the **Save In** box, left click on the **D Drive** > left click on **Exported Right/Left Eye Scans**. **If this is for certification you will select the folder titled "Case 1, Session 1."** (see diagram above)
b. Now, you need to reassign the **File Name** (according to the scan orientation) to Scan 1 OD, Scan 2 OD, Scan 3 OD, Scan 4 OD, Scan 5 OD or Scan 6 OD, for scans of the right eye and Scan 1 OS, Scan 2 OS, Scan 3 OS, Scan 4 OS, Scan 5 OS or Scan 6 OS, for scans of the left eye. (see **File name** box in above diagram)

c. The export process takes a few seconds per scan and the successful export writes six files for each of the six B-scans (one each of .BMP, .RAW, .RTH, .SPD, .VIL and .TXT files):

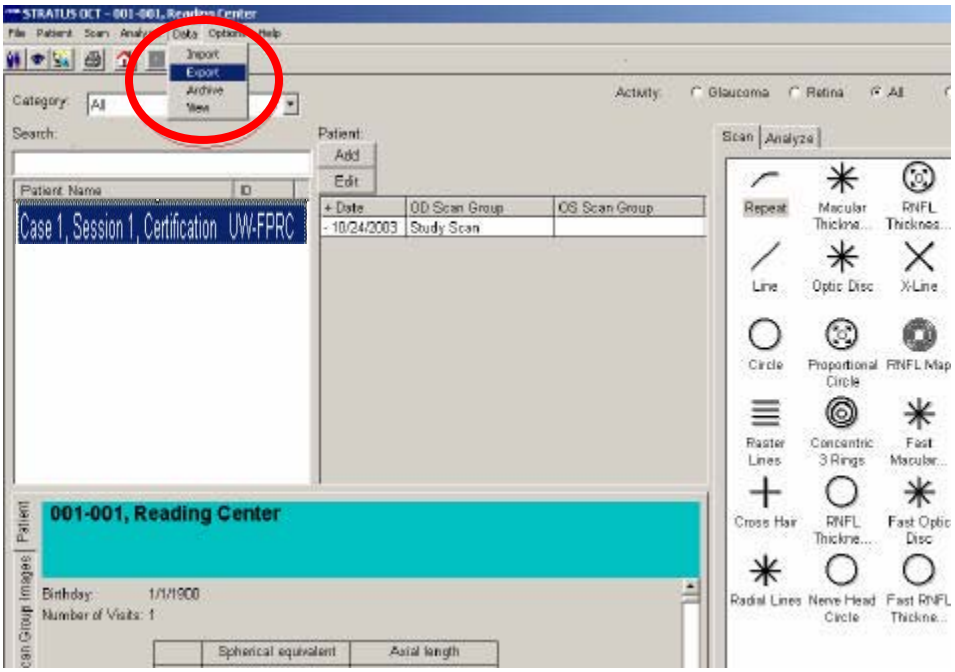


5) Please see section *8.0* for information on how to label the DVD or CD.

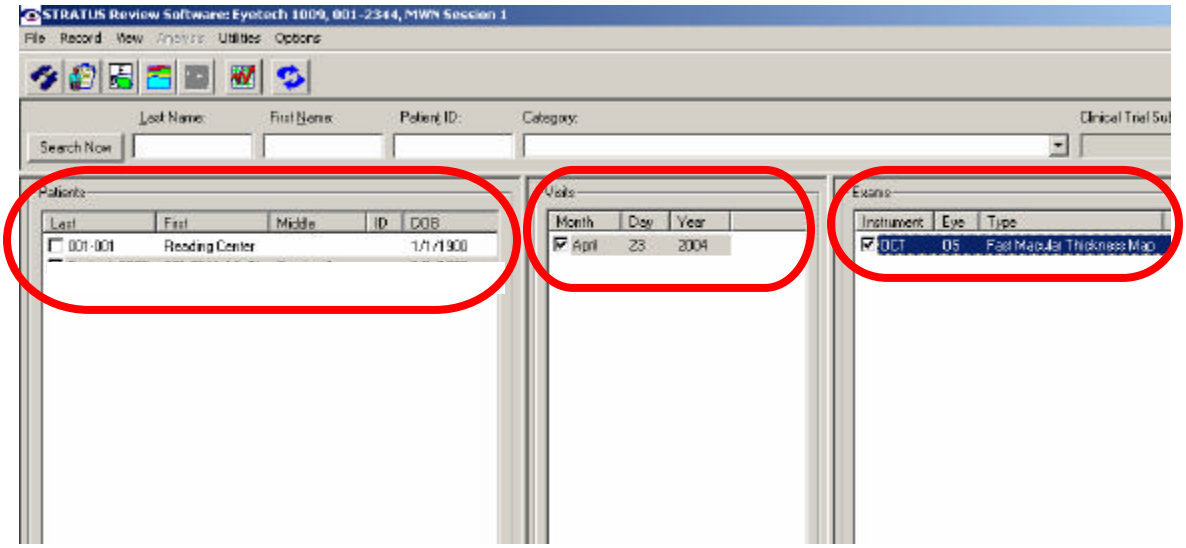
7.2 Exporting Data Files for Software Versions 3.1 & Above

When requested by the FPRC, the data files corresponding to <u>each of the scan patterns performed (i.e. Fast Macular Thickness Map scan, Cross-Hair scan, etc.)</u>, are exported to DVD (or CD if available). Please do not attempt to export the data files from the OCT3 system to floppy diskettes because the cumulative file size exceeds the 1.44MB floppy disk capacity. Please export the files to another form of removable media. Acceptable options include CDs (by using a removable USB jump drive) or use of the existing DVD writer located in the OCT3's CPU. You may elect either of these options for collecting the exported data files. Please follow the directions below:

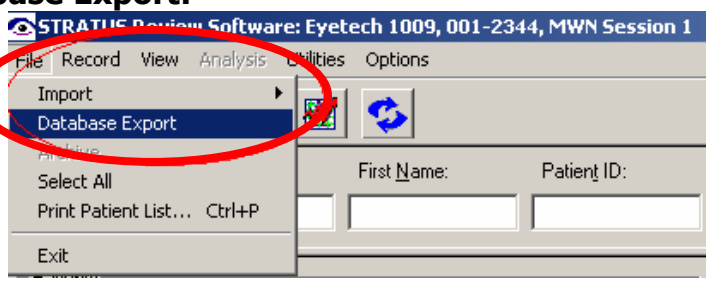
1) First, you MUST format the DVD-RAM cartridge in the "FAT32" format.
   a. Install the DVD cartridge into the DVD drive.
   b. Click Windows **Start > Programs > DVD-RAM > DVDForm.**
   c. Click on the down-arrow next to **Format Type** and select **FAT32.**
   d. Click **Start.** A DVDFORM window will appear.
   e. Click **Yes** to begin the formatting. When the formatting is complete, you may click the "X" to exit the program.
2) To export, click on **Data** from the toolbar, then select **Export** (see illustration below):



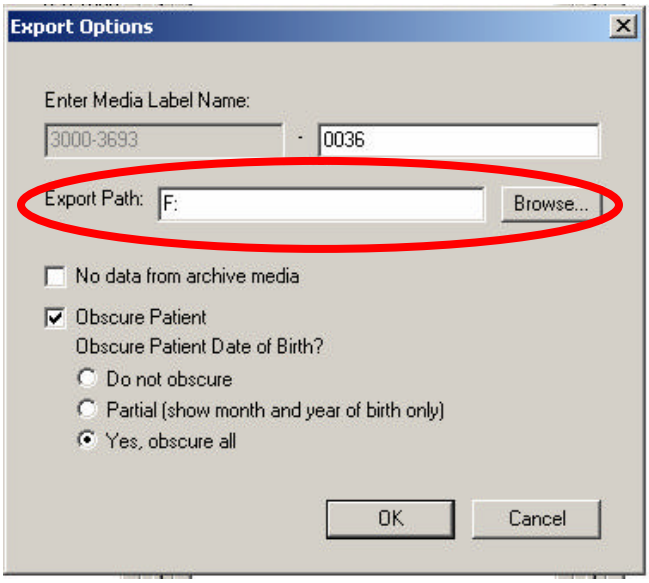
3) Select the Patient, Visit and Exam set (i.e. Fast Macular Thickness Map scan and the Cross-Hair scan sets) from the database. You must remember to anonymize the patient information in the "*Edit*" patient information screen PRIOR to exporting the patient's exams to DVD or CD. Please refer to section *5.1* for more details on how to properly anonymize study patient visits.



4) After the patient ID, visit date and scan set have been selected, click **File > Database Export:**



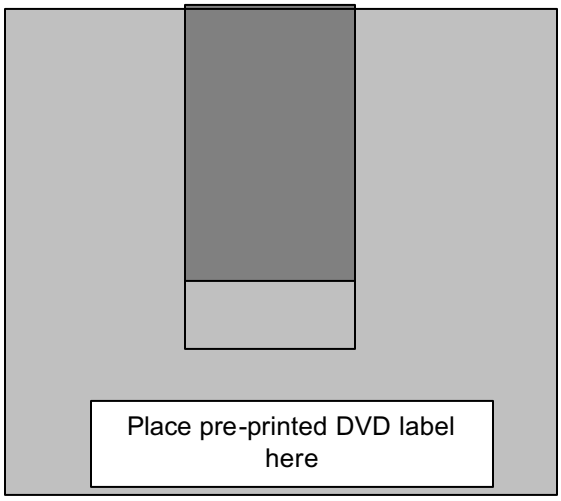
5) When the "Export Options" box appears, select the appropriate export path. For example, you will export the scan set to a DVD (i.e. "D" drive), jump drive (i.e. "F" drive) or network drive:



6) After you have identified the appropriate export path, select **Obscure Patient** and **Yes, obscure all** (shown above) options. Then, select **OK** to export the data.
7) Once the files have been exported successfully, a notification will appear stating the export process is complete: select **OK** to complete the export process.
8) See section *7.3* for information on how to label the DVD or CD.

7.3 DVD or CD Labeling Instructions

The CD or DVD containing the exported OCT scan files are labeled as indicated below. **If this is for certification**, please include the following information on the label: "Case 1, Session 1 Certification Set," Operator's name and date the scans performed.



8.0 Shipment Information

The 9 prints (per eye)[2] and the **Transmittal Log** form (found online at www.drcr.net > *Clinical Sites Menu > Fundus Photograph Reading Center > Create New Shipment*) should be assembled into a protective shipping envelope and sent via trackable courier to the FPRC. When requested to send the data files on DVD or CD, please include a **Transmittal Log** form and wrap the labeled cartridge in protective bubble-wrap before sending it via trackable carrier to the FPRC.

9.0 Retakes

The OCT scans should be evaluated for quality by the *principal investigator and/or OCT operator* before submission to the FPRC. If quality is not adequate for assessment of key features of the study eye, such as presence of macular edema or if the Inner Limiting Membrane (ILM) or Retinal Pigment Epithelium (RPE) surfaces are not accurately located on the 6 **Retinal Thickness (Single Eye)** maps, and if no irremediable cause of inadequate quality is present (such as lens opacities or a pupil that will not dilate adequately), **the scans should be retaken before submission to the FPRC**. When OCT scans are considered ungradable because of poor quality, the FPRC may issue a Retake Request Form (see Appendix C for an example of the Retake Request form).

2 Please note that the total number of prints required is different for each protocol. For specific print requirements, please refer to the "*DRCRnet OCT Visit Schedule by Protocol*" (located on the DRCRnet website).

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 B-scans) 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 (Eye with Pathology)

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)**

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 2, 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**

Appendix B: Form Convention and OCT Naming Convention for DRCRnet

Conventions for completing UW-FPRC Forms for DRCRnet:

Description	Convention	Example
Site #:	3 DIGITS	090
Participant #:	Protocol: 1 Letter Site#: 3 Digits Patient#: 1-4 Digits Patient Initials: 2 Letters	B090-1AC
Name Code:	5 LETTERS	ABXCD
Visit:	Baseline, Month #, etc.	Baseline, Month 4, etc.
Date:	DAY: 2 DIGITS MONTH: 3 LETTERS YEAR: 4 DIGITS	01 / JAN / 2003

OCT File Naming Conventions for DRCRnet:

Replace	With	Example
Participant's ID#	Participant # (see above)	B090-1AC
Participant's Last Name	Study Name and Protocol Letter	DRCRnet Protocol B
Participant's First Name	Participant #, (space) Name Code	B090-1AC, ABXCD
Patient's Date of Birth	01/01/1900	01/01/1900
Patient's Gender	"Unknown"	"Unknown"

Appendix C: DRCRnet OCT Retake Request Form

OCT RETAKE REQUEST

DRCRnet

Protocol _____ (e.g., A, B, C, etc.)

Site Contact Person: _____

Site# __ __ __ __ (e.g., B001) Subject# __ __ __ __ - __ __ __ __ __ __ (e.g., B001-1AC)

Namecode __ __ __ __ __ (e.g., ABXCD) Visit _____

Date of Original OCT __ __ / __ __ __ / __ __ __ __
Day Month Year
(e.g., 13/JAN/2005)

[ ] Please include the following in the retake OCT for the Right Eye:

Fast Macular Thickness Map Scan
[ ] 1 Retinal Map Analysis (using the Fast Macular Thickness Map Scan)
[ ] 6 Retinal Thickness Reports (using the Fast Macular Thickness Map Scan)

Cross-Hair Scan
[ ] 2 Align Process Reports (horizontal and vertical b-scans using the Cross Hair Scan)

[ ] Please include the following in the retake OCT for the Left Eye:

Fast Macular Thickness Map Scan
[ ] 1 Retinal Map Analysis (using the Fast Macular Thickness Map Scan)
[ ] 6 Retinal Thickness Reports (using the Fast Macular Thickness Map Scan)

Cross-Hair Scan
[ ] 2 Align Process Reports (horizontal and vertical b-scans using the Cross Hair Scan)

==========

FPRC Comments ONLY:

_____
_____
_____

FPRC Reviewer: _____

Date __ __ / __ __ __ / __ __ __ __
Day Month Year

[ ] Faxed form to the Jaeb Center
[ ] Faxed form to the clinic

==========

CLINIC RESPONSE: **PLEASE SEND OR FAX THIS FORM TO THE PROJECT MANAGER AT THE FPRC (Fax = 1-608-263-0525) & TO THE JAEB CENTER (Fax = 1-800-816-7601)**

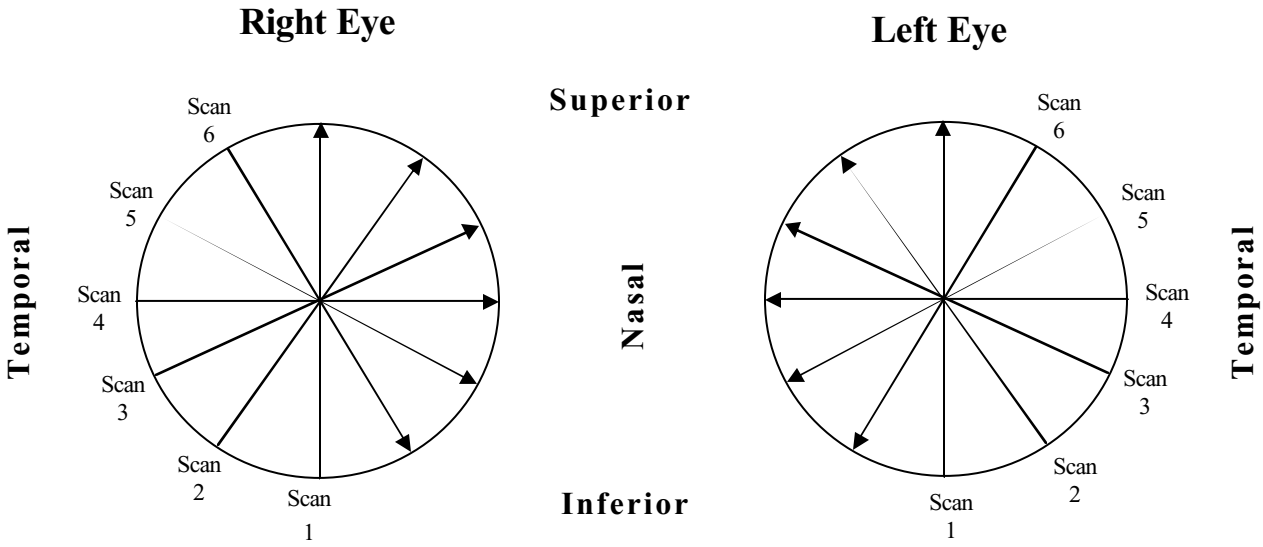
[ ] Yes, we are sending Retakes
[ ] No, we are unable to send retakes (If no, please explain below)
Explanation:

_____
_____
_____

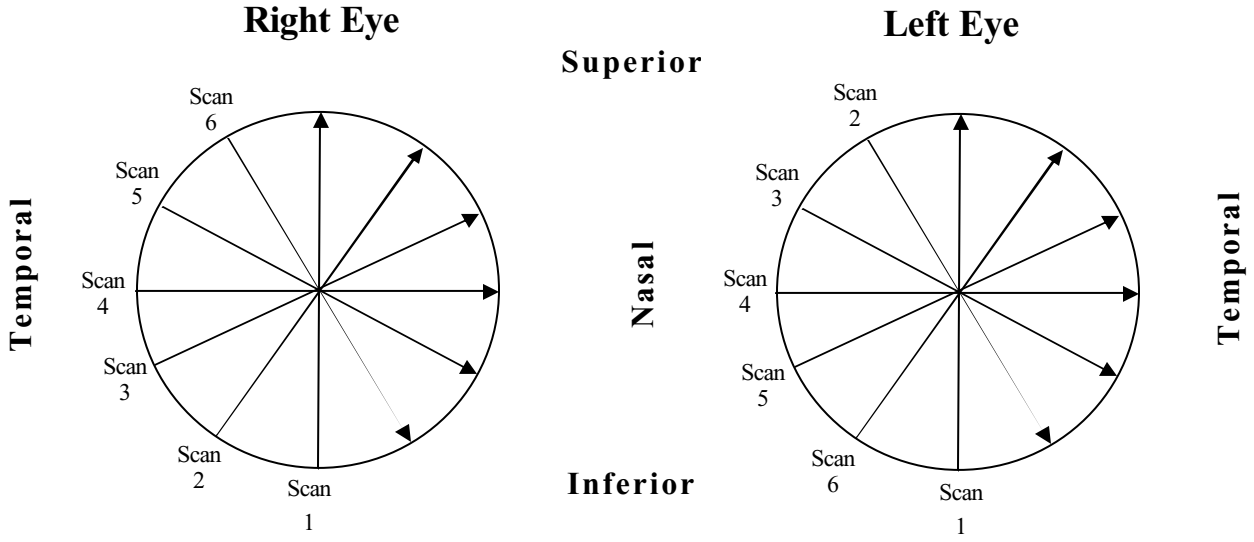
Date: __ __/ __ __ __ / __ __ __ __ Initials: _____
Day Month Year

Appendix D: Labeling Instructions for the Retinal Thickness Reports

Example 1: How to label OD & OS for OCT 3 Software versions 1.0 - 3.0



Example 2: How to label OD & OS for OCT 3 Software version 4.0



FPRC OCT 3 Procedure for DRCRnet Protocol A

DRCRnet Protocol #1A: A Pilot Study of Laser Photocoagulation for Diabetic Macular Edema

For this protocol, the Fundus Photograph Reading Center (FPRC) asks that the following scan sets be performed on each eye:

1) One Fast Macular Thickness Map Scan (6mm). From this scan you must print:
   a. 1 Retinal Map Report
   b. 6 Retinal Thickness Reports

2) One Cross-Hair Scan (at 6.0mm and at 512 resolution). From this scan you must print:
   a. 2 Align Process Reports (single eye)
      i. 1 Horizontal B-Scan
      ii. 1 Vertical B-Scan

Please see the visit schedule (listed below) for more details:

Visit	Fast Macular Thickness Map Scan (6mm)		Cross-Hair Scan at 6.0mm & 512 resolution	Total # of Prints
	1 Retinal Map	6 Retinal Thickness Reports	2 Align Process Prints (Horizontal & Vertical)	
Baseline	Both Eyes	Both Eyes	Both Eyes	18
Month 3.5	Both Eyes	Both Eyes	Both Eyes	18
Month 8	Both Eyes	Both Eyes	Both Eyes	18
Month 12	Both Eyes	Both Eyes	Both Eyes	18
Month 24	Both Eyes	Both Eyes	Both Eyes	18
Month 36	Both Eyes	Both Eyes	Both Eyes	18

- Please note that for study patient submissions, it is only necessary to send data files when requested by the Fundus Photograph Reading Center

FPRC OCT 3 Procedure for DRCRnet Protocol B

DRCRnet Protocol B: A Randomized Trial Comparing Intravitreal Triamcinolone Acetonide and Laser Photocoagulation for Diabetic Macular Edema

For this protocol, the Fundus Photograph Reading Center (FPRC) asks that the following scan sets be performed on each eye (when applicable):

1) **One** Fast Macular Thickness Map Scan (6mm). From this scan you must print:
    b. 1 Retinal Map Report
    c. 6 Retinal Thickness Reports

2) **One** Cross-Hair Scan (at 6.0mm and at 512 resolution). From this scan you must print:
    a. 2 Align Process Reports
        i. 1 Horizontal B-Scan
        ii. 1 Vertical B-Scan

3) At the Baseline visit ONLY, you will need to perform the following scans on EACH EYE:
    a. **Two** Fast Macular Thickness Map Scans. From this scan you must print:
        i. 2 Retinal Map Reports (1 Map from each scan)
        ii. 12 Retinal Thickness Reports (6 Retinal Thickness Reports from each scan)
    b. **One** Cross-Hair Scan (at 6.0mm and at 512 resolution). From this scan you must print:
        i. 2 Align Process Reports
            1. 1 Horizontal B-Scan
            2. 1 Vertical B-Scan

Please see the visit schedule (listed below) for more details:

DRCRnet Protocol B STUDY PATIENT SUBMISSION REQUIREMENTS

Visit	Fast Macular Thickness Map Scan (6mm)		6.0mm Cross-Hair Scan at 512 resolution	Total # of Prints
	1 Retinal Map	6 Retinal Thickness Reports	2 Align Process Prints (Horizontal & Vertical)	
Baseline	Both Eyes*	Both Eyes*	Both Eyes	32
Month 4	Both Eyes	Both Eyes	Both Eyes	18
Month 8	Study Eye	Study Eye	Study Eye	9
Month 12	Both Eyes	Both Eyes	Both Eyes	18
Month 16	Study Eye	Study Eye	Study Eye	9
Month 20	Study Eye	Study Eye	Study Eye	9
Month 24	Both Eyes	Both Eyes	Both Eyes	18
Month 28	Study Eye	Study Eye	Study Eye	9
Month 32	Study Eye	Study Eye	Study Eye	9
Month 36	Both Eyes	Both Eyes	Both Eyes	18

- ***** Indicates that the Fast Macular Thickness Map Scan needs to be performed *TWICE* on both eyes at the baseline visit.
- Please note that for study patient submissions, it is only necessary to send data files when requested by the Fundus Photograph Reading Center

FPRC OCT 3 Procedure for DRCRnet Protocol C

DRCRnet Protocol C: Temporal Variation in Optical Coherence Tomography Measurements of Retinal Thickening in Diabetic Macular Edema

For this protocol, OCT will be performed on first the right eye and then the left eye at 8 am, 9 am, 10 am, 12 noon, 2 pm, and 4 pm. The Fundus Photograph Reading Center (FPRC) asks that the following scan set be performed on each eye at each time point mentioned above:

1) **Two** Fast Macular Thickness Map Scans (6mm). From these scans you must print:
   a. 2 Retinal Map Reports (1 Map from each scan)
   b. 12 Retinal Thickness Reports (6 Retinal Thickness Reports from each scan)

2) **One** Cross-Hair Scan (at 6.0mm and at 512 resolution). From this scan you must print:
   a. 2 Align Process Reports
      i. 1 Horizontal B-Scan
      ii. 1 Vertical B-Scan

Please see the visit schedule (listed below) for more details:

Time Interval	**2** Fast Macular Thickness Map Scans (6mm)				**1** 6.0mm Cross-Hair Scan at 512 resolution		Total # of Prints
	2 Retinal Maps		12 Retinal Thickness Reports		2 Align Prints		
	1 print from scan #1	1 print from scan #2	6 prints from scan #1	6 prints from scan #2	1 Vertical B-Scan	1 Horizontal B-Scan	
8:00 am	Both Eyes		Both Eyes		Both Eyes		32
9:00 am	Both Eyes		Both Eyes		Both Eyes		32
10:00 am	Both Eyes		Both Eyes		Both Eyes		32
12:00 pm	Both Eyes		Both Eyes		Both Eyes		32
2:00 pm	Both Eyes		Both Eyes		Both Eyes		32
4:00 pm	Both Eyes		Both Eyes		Both Eyes		32
					TOTAL NUMBER OF PRINTS		**192**

FPRC OCT 3 Procedure for DRCRnet Protocol D

DRCRnet Protocol D: Evaluation of Vitrectomy for Diabetic Macular Edema Study

For this protocol, OCT will be performed on the study eye only for Baseline, Month 3, Month 6, Month 12, Month 24 and Month 36. The Fundus Photograph Reading Center (FPRC) asks that the following scan sets be performed for the above mentioned visits:

3) **One** Fast Macular Thickness Map Scan (6mm). From this scan you must print:
   a. 1 Retinal Map Report
   b. 6 Retinal Thickness Reports

4) **One** Cross-Hair Scan (at 6.0mm and 512 resolution). From this scan you must print:
   a. 2 Align Process Reports
      i. 1 Horizontal B-Scan
      ii. 1 Vertical B-Scan

Please see the visit schedule (listed below) for more details:

Visit	Fast Macular Thickness Map Scan (6mm)		Cross-Hair Scan at 6.0mm & 512 resolution	Total # of Prints
	1 Retinal Map	6 Retinal Thickness Reports	2 Align Process Prints (Horizontal & Vertical)	
Baseline	Study Eye	Study Eye	Study Eye	9
Month 3	Study Eye	Study Eye	Study Eye	9
Month 6	Study Eye	Study Eye	Study Eye	9
Month 12	Study Eye	Study Eye	Study Eye	9
Month 24	Study Eye	Study Eye	Study Eye	9
Month 36	Study Eye	Study Eye	Study Eye	9

- Please note that for study patient submissions, it is only necessary to send data files when requested by the Fundus Photograph Reading Center

FPRC OCT 3 Procedure for DRCRnet Protocol E

DRCRnet Protocol E: A Pilot Study of Peribulbar Triamcinolone Acetonide for Diabetic Macular Edema

For this protocol, OCT will be performed on both eyes for Baseline, Month 1, Month 2, Month 4, Month 8, Month 12, Month 24 and Month 36. The Fundus Photograph Reading Center (FPRC) asks that the following scan sets be performed on each eye for the above mentioned visits:

5) **One** Fast Macular Thickness Map Scan (6mm). From this scan you must print:
   a. 1 Retinal Map Report
   b. 6 Retinal Thickness Reports

6) **One** Cross-Hair Scan (at 6.0mm and 512 resolution). From this scan you must print:
   a. 2 Align Process Reports
      i. 1 Horizontal B-Scan
      iii. 1 Vertical B-Scan

Please see the visit schedule (listed below) for more details:

Visit	Fast Macular Thickness Map Scan (6mm)		Cross-Hair Scan at 6.0mm & 512 resolution	Total # of Prints
	1 Retinal Map	6 Retinal Thickness Reports	2 Align Process Prints (Horizontal & Vertical)	
Baseline	Both Eyes	Both Eyes	Both Eyes	18
Month 1	Both Eyes	Both Eyes	Both Eyes	18
Month 2	Both Eyes	Both Eyes	Both Eyes	18
Month 4	Both Eyes	Both Eyes	Both Eyes	18
Month 8	Both Eyes	Both Eyes	Both Eyes	18
Month 12	Both Eyes	Both Eyes	Both Eyes	18
Month 24	Both Eyes	Both Eyes	Both Eyes	18
Month 36	Both Eyes	Both Eyes	Both Eyes	18

- Please note that for study patient submissions, it is only necessary to send data files when requested by the Fundus Photograph Reading Center