

FUNDUS PHOTOGRAPH READING CENTER

Modified 3-Standard Field Color Fundus Photography (3M-F) & Film Fluorescein Angiography (FA-F)

*(adapted from the Early Treatment Diabetic Retinopathy Study (ETDRS), Macular Photocoagulation Study (MPS) and the Age-Related Eye Disease Study (AREDS),
Manuals of Operations^{1, 2, 3})*

Generic

Effective Date: 30Jun2005, Supersede Date: 13Feb2005

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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*. For this study the photography procedures are for 1) color fundus photography and for 2) fluorescein angiography. The color fundus photography uses the UW-FRPC's modified 3-standard field procedure on film (3M-F). The fluorescein angiography is performed using the UW-FRPC's standard fluorescein angiography procedure, which can be imaged either on film (FA-F) or digitally (FA-D). An individual must have either (3M-F and FA-F) certification or (3M-F and FA-D) certification before they are certified for photography for this study.

Only UW-FRPC 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 2.0 below).*

Clinical sites are strongly encouraged to have a minimum of two, but no more than three, certified photographers. Photographers are encouraged to contact the UW-FRPC's photographic consultants, Hugh Wabers, Pamela Vargo, Dennis Thayer or Michael Neider (608-263-9858) with any photography related questions. Pointers on photographic technique may be found in Section 13.0.

Photographer certification is study specific and each photographer requesting certification must submit a signed "UW-FRPC Photographer Certification Request Form" to the UW-FRPC. Certification consists of (1) review of study synopsis or protocol and photography procedures and (2) demonstrating the 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-FRPC using **an identical procedure**, and has been active taking photographs, judged to be of good quality by the UW-FRPC, during the past year. Previously certified photographers who have been inactive for more than one year may be asked to submit sample photographs to become recertified. Photographers who are certified for **a similar procedure** may also be asked to submit sample photographs to become certified.

Photographers who are not eligible for certification on the basis of previous UW-FRPC certification should submit color photographs of 4 eyes (2 right eyes and 2 left eyes) and 2 fluorescein angiograms taken using the UW-FRPC's procedures for this study. The color photographs may be taken of patients in whom photography is being carried out for clinical purposes or in normal volunteers. 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 slides should be mounted as shown in Section 7.0. Pre-printed labels may be unavailable for labels certification photographs: if this is the case 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 negative strips of the fluorescein angiograms should be mounted as shown in Section 9.0. The slide pages containing the color photographs or the negative strip pages containing the fluorescein angiograms should be labeled with a page 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 Photographer Certification Request Form" is always required** (see the UW-FPRC Forms, Labels & Shipping Information document).

Photographers who meet certification criteria will receive 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. The sponsor will be notified after three complete unsuccessful attempts for certification.

2.0 Uncertified Photographers (Follow-up Visits 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 procedures may take the photos. The uncertified photographer should review the photography procedures before performing photography to be certain they understand and follow the procedures. The name of the uncertified photographer should be entered on the photo page labels.

3.0 Camera and Equipment

The 30° Zeiss FF4 (or similar models) and FF450-plus fundus cameras as well as 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.

4.0 Film and Processing

For color photography, the recommended films are Kodak Professional Ektachrome 100 Daylight films (EPN, EPP or E100G) or their equivalent. The film should be processed by a certified "Q-Lab" or other professional E-6 laboratory to ensure consistent quality. 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 black and white films are recommended for angiography. The film may be processed by the clinic staff or at a local processing laboratory. The use of Kodak D-19, HC-110, or similar developer, is recommended. Development times will vary with developer concentration, temperature and camera flash setting. Any processing procedure that 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 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.

6.0 Modified 3-standard Fields and Fundus Reflex Photographs

The modified 3-standard fields for color photography specified by this procedure differs from the fields presented in the ETDRS 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.

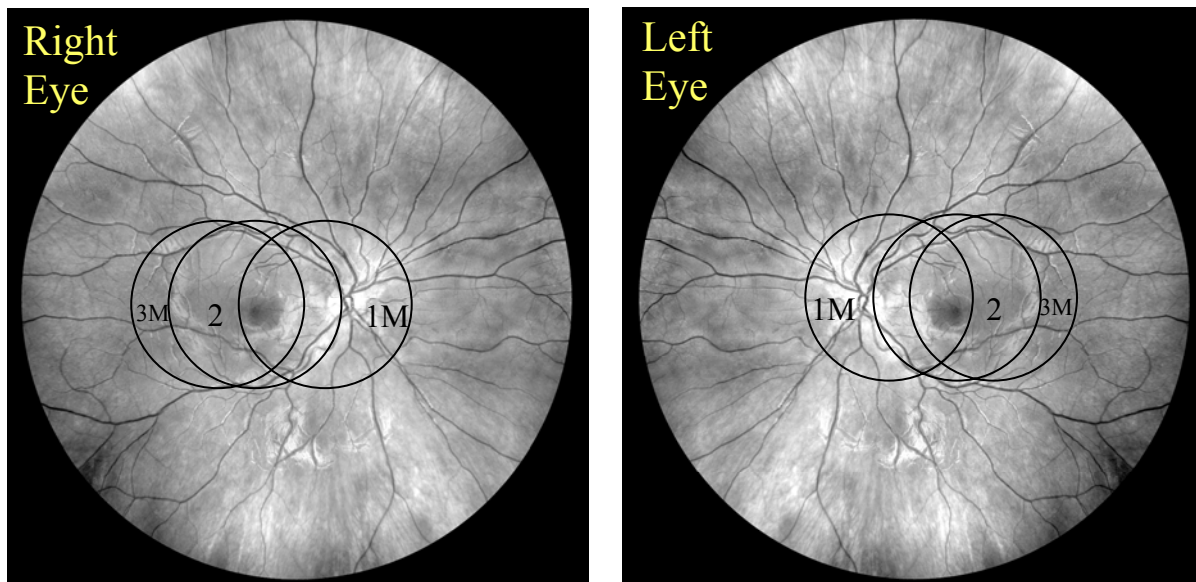


Figure 1

Visit our website <http://eyephoto.opth.wisc.edu/Photographers.html>. Click on the [Modified 7-Standard Field Photography Tutorial](#) to view a color fundus photography tutorial on acquiring the 7 modified fields in a quick and easy manner. Remember you only need to be concerned with the central 3 fields, F1M, F2 and F3M, for this procedure.

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.

Fundus Reflex photograph [Figure 2] - 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. 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. The ideal magnification is displayed below:

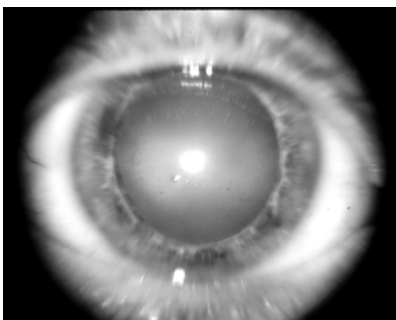


Figure 2

The ideal limbal diameter is approximately 13mm on film or the field of view is canthus to canthus.

7.0 Mounting and Labels of Color Photographs

The transparencies returned from the processing lab are mounted in standard 2X2 inch mounts. Do not use mounts with glass slides. The mounted transparencies are labeled with individual labels (see the UW-FPRC Forms, Labels & Shipping Information document).

Photographs of each eye should be mounted in an individual plastic sheet.[†] 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 3, below).

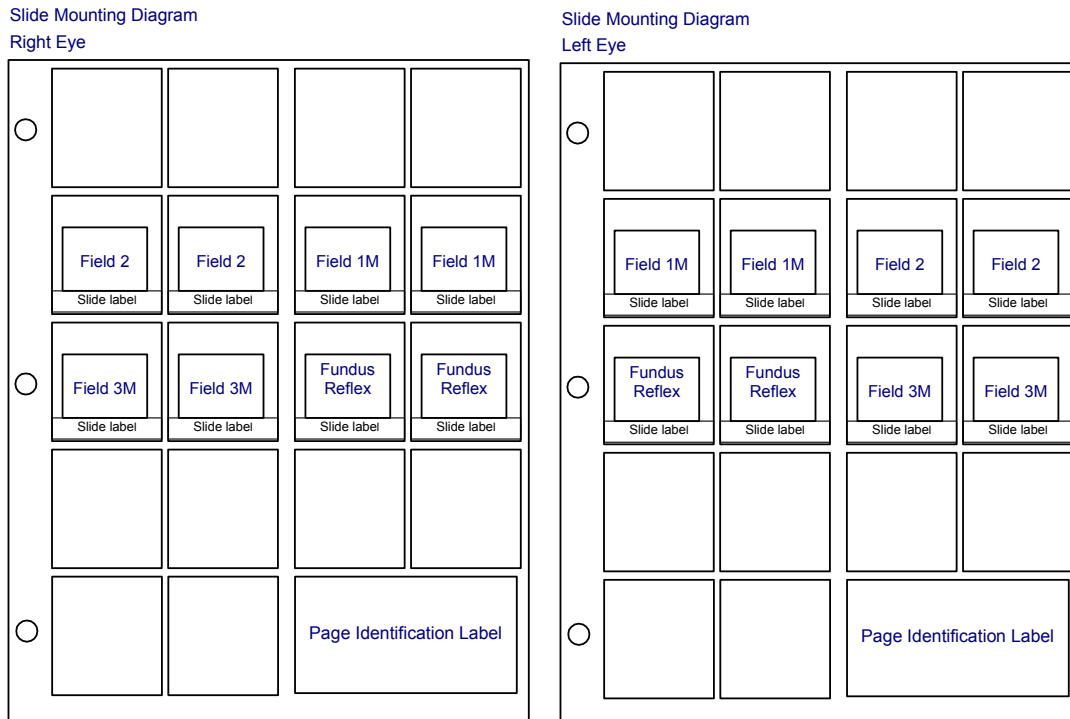


Figure 3

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 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. If necessary, in trials investigating choroidal new vessels (CNV) Field 2 can be shifted by 1 disc diameter to include as much of the lesion as possible. In order to obtain stereo pairs 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**

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

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 antecubital or other convenient vein according to usual clinic procedures.

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 earlier or later if poor circulation or a slow injection delays the presence of fluorescein). 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 in front of 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.

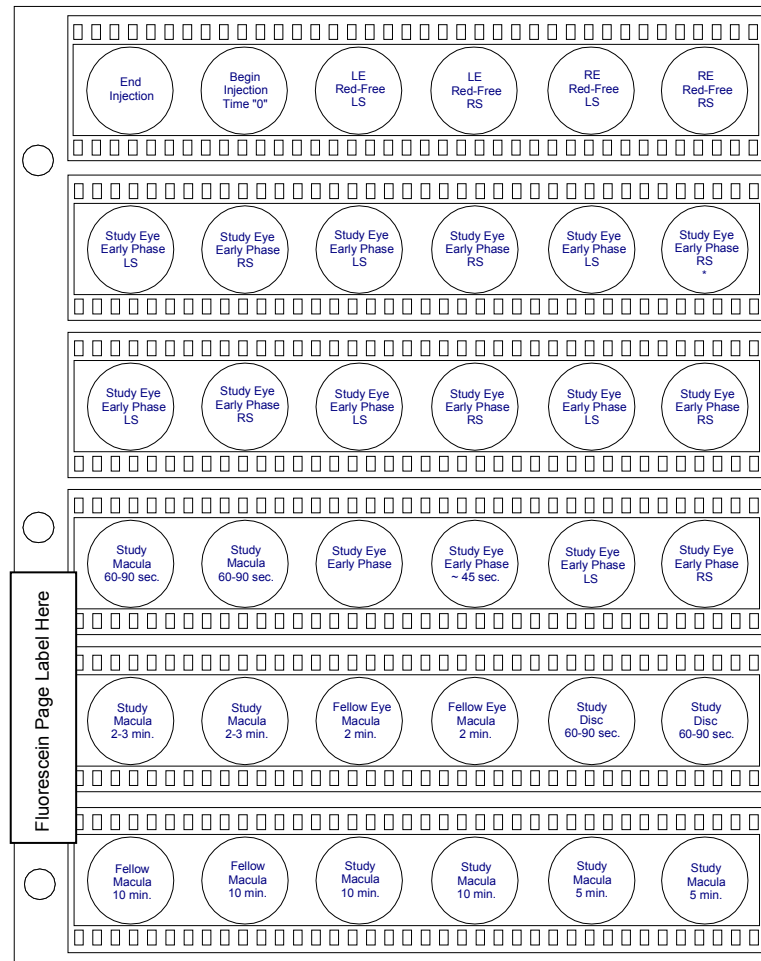
9.0 Mounting, Labels and Duplication of Fluorescein Angiograms

The original negatives are cut into strips of six images per strip, and are placed in a 10½ x 9-inch transparent plastic sheet containing six pockets per sheet.[‡] A page identification label

[‡] The UW-FPRC 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 4) 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).** It is recommended that the Clinical Centers retain a copy of the angiogram.

Figure 4



*5-8 stereo pairs taken beginning about 15 seconds after the start of fluorescein injection (or at first appearance of fluorescein, if sooner than 15 seconds or if a delay due to slow circulation time is expected).

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. The color photographs and fluorescein angiograms should be sent together with the completed Transmittal Log (see the *UW-FPRC Forms, Labels & Shipping Information document*) to the UW-FPRC.

11.0 Retakes

Color photos and fluorescein angiograms should be evaluated for quality by the *principal investigator and/or photographer* (unless prohibited by Study Protocol) 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 the *UW-FPRC Forms, Labels & Shipping Information document*).

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 color photographs and angiograms grades of excellent, good and fair indicate that a set can be evaluated with no problem. Grades of borderline-explained and borderline-unexplained signifying that a set can be assessed, although the quality compromises the grading somewhat. Grades of inadequate-explained and inadequate-unexplained indicate that a set cannot be completely evaluated. 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 3-standard stereo fields are taken, the following sequence is recommended: disc (Field 1M), macula (Field 2), temporal to macula (Field 3M). Stereo Fields 1M, 2 and 3M may be taken on the same horizontal plane.

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 below the surface of the retina. 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 above the retina 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 Allen⁴ is used for taking stereo fundus photographs. A lateral movement of the camera is used to obtain the required, non-simultaneous stereo pairs. 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 film-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. The camera is then moved laterally to the other side of the pupil and the second photograph is taken. If the image 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.** 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, as well as correctly label the right side and left side of stereo pairs. Examples of good stereoscopic photos can be found at the UW-FPRC website, <http://eyephoto.opth.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 Pamela Vargo, Dennis Thayer, Hugh Wabers or Michael Neider.

Questions or Comments

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

14.0 References

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.