

University of Wisconsin-Madison
Fundus Photograph Reading Center
(UW-FPRC)

Modified 3-Standard Field Color Fundus Photography
and
Fluorescein Angiography Procedure

*(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})*

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Attachment A: Pointers on Photographic Technique

Attachment B: Study Forms and Labels for Photography

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*. 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, Michael Neider (608-263-9858) or Hugh Wabers (608-263-0740) with any photography related questions. Pointers on photographic technique may be found in Attachment A.

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-FRPC 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 accompanying 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-FRPC certification request form is also required. (See Attachment B: *Study Forms and Labels (Study Specific)*)

Photographers who meet certification criteria will receive written confirmation of certification. Photographers who do not meet these criteria will receive feedback from the UW-FRPC 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

On rare occasions when a certified photographer is not available, an uncertified photographer, familiar with the procedure, may take study photographs. The name of the uncertified photographer should be entered on the photo page labels.

3.0 Camera and Equipment

The Zeiss FF4 series and the Topcon TRC-50EX (used at the 35° setting) or similar model 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, 610 N. Walnut Street, Room 438, Madison, WI 53705, 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 Kodachrome 25 or 64 Daylight film, processed by any authorized Kodalux Laboratory, or Professional Ektachrome 100 Daylight film, or its equivalent, preferably processed by a certified "Q-Lab" to ensure consistent quality. 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 film are recommended for angiography. The film may be processed by the clinic staff or at a local processing laboratory. The use of Kodak D-11 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 Attachment A.

6.0 Modified 3-standard Fields and Fundus Reflex Photographs [Figure 1]

The modified 3-standard fields for color photography specified by this procedure differs from the ETDRS standard fields 1-3 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.

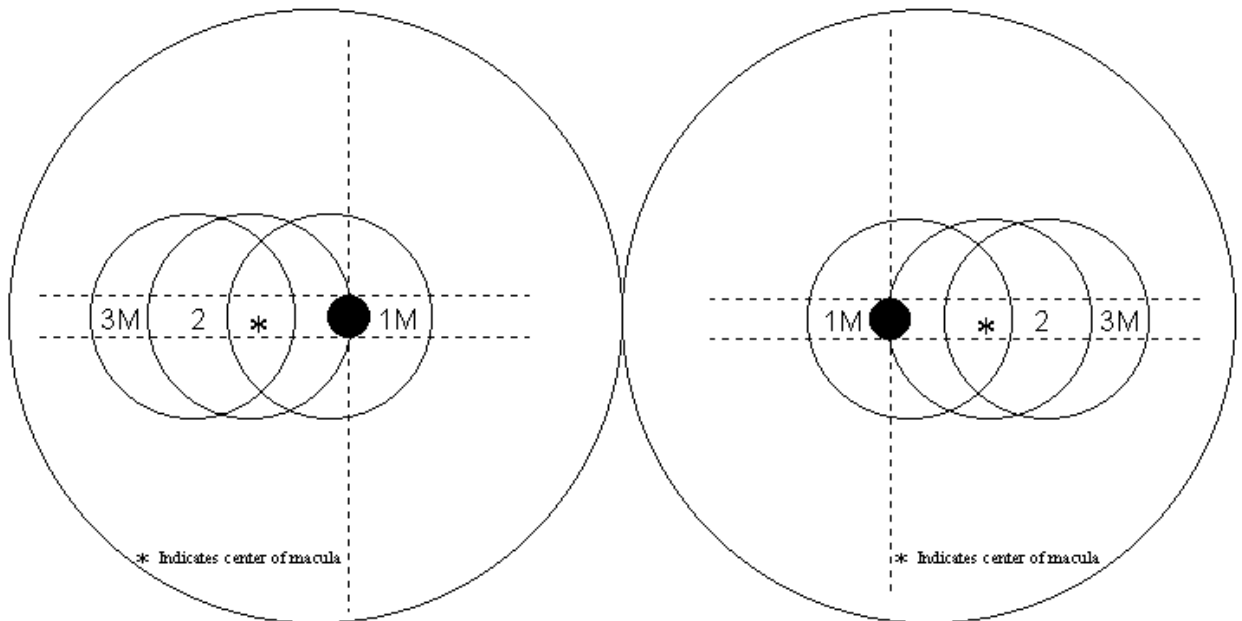


Figure 1

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.

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.

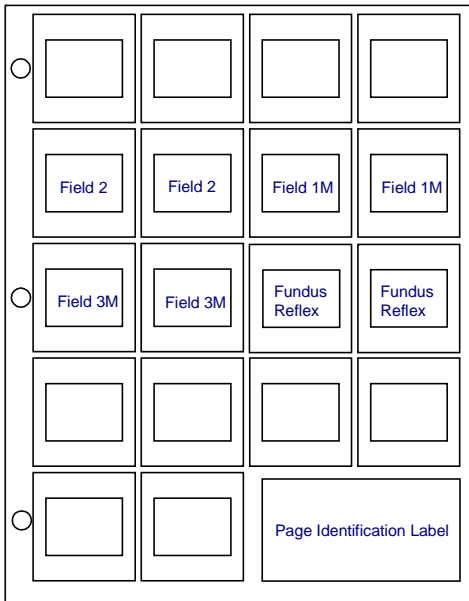
7.0 Mounting and Labeling Color Photographs [Figure 2]

The transparencies returned from the processing lab are mounted in standard 2X2 inch mounts. The mounted transparencies are labeled with individual labels (see Attachment B (study specific)).

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 Attachment B (study specific)).

[†] 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.

Slide Mounting Diagram
Right Eye



Slide Mounting Diagram
Left Eye

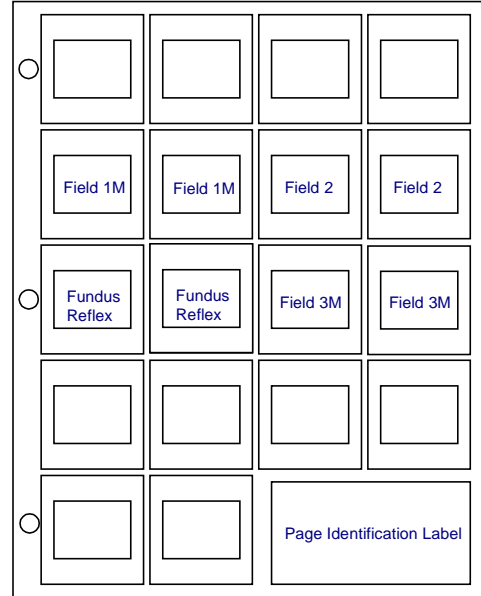


Figure 2

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 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 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.

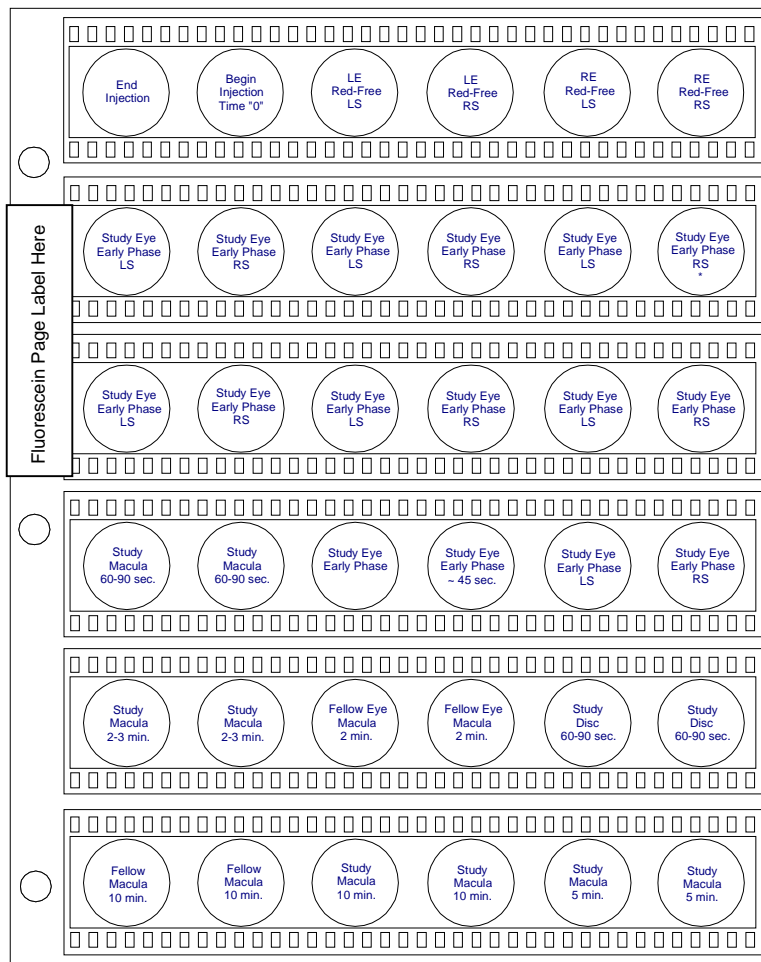
8.2.3 Late-Phase

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 heavy gauge transparent plastic sheet containing six pockets per sheet.[‡] A page identification label (Attachment B (study specific)) 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 Bardes Sheet #62122



*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).

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 Attachment B (study specific)) 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-FRPC. 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 irremedial 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-FRPC (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-FRPC may issue a Retake Request Form (See Attachment B (study specific)).

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-FRPC 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 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.

Attachment A

Pointers on Photographic Technique Prepared by the UW-FPRC

Field Definition

When the modified three standard stereo fields are taken, the following sequence is recommended: disc (Field 1M), macula (Field 2), and temporal to macula (Field 3M).

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.

Stereoscopic Effect

The technique described by Allen¹ 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, Michael Neider (608/263-9858; neider@rc.ophth.wisc.edu) or Hugh Wabers (608/263-0740; wabers@rc.ophth.wisc.edu).

Reference

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