

FUNDUS PHOTOGRAPH READING CENTER

Non-study Specific

Modified 7-Standard Field 35mm Film Color Fundus Photography (7M-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})*

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1.0 Overview

The following is the University of Wisconsin-Fundus Photograph Reading Center's (UW-FPRC's) Modified 7-Standard Field 35mm Film Color Fundus Photography procedure (7M-F). Please refer the documents specific to a study to determine if additional UW-FPRC procedures apply to a given trial.

Only UW-FPRC certified photographers are allowed to take Qualifying Visit (baseline) images 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 a site does not have a certified photographer available to take the qualifying images. Only under extraordinary circumstances may follow-up visit images be taken by an uncertified photographer (see section 3.0 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-FPRC's imaging consultants, Dennis Thayer thayer@rc.ophth.wisc.edu, Pamela Vargo vargo@rc.ophth.wisc.edu or Hugh Wabers wabers@rc.ophth.wisc.edu (608-263-9858) with any photography related questions. Pointers on imaging technique may be found in Section 10.0.

2.0 Photographer Certification

Photographers taking photographs (or images: the terms will be used interchangeably in this procedure) for studies evaluated by the UW-FPRC must be certified for the relevant procedure(s), *before submitting actual patient images.*

Photographer certification is specific for each study and each photographer requesting certification must submit a signed "UW-FPRC Photographer Certification Request Form" for each study. This form can be found in the *UW-FPRC Forms, Labeling, Study Conventions Information* section of the study specific documents. A copy of the form may also be available on the UW-FPRC website: <http://eyephoto.ophth.wisc.edu>, which may require a username and password. One form will be used for all imaging procedures associated with a given study.

Certification consists of (1) review of study synopsis/protocol and imaging procedures and (2) demonstrating the ability to perform the imaging procedure(s) by submission of images of acceptable quality. The second requirement may be waived if the photographer has prior certification at the UW-FPRC using **an identical procedure**, and has been active taking images, judged to be of good quality by the UW-FPRC, during the past 12 months. 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-FPRC certification should submit color images of 4 eyes (2 right eyes and 2 left eyes) taken using this procedure. The color images may be taken of patients in whom photography is being carried out for clinical purposes or in normal volunteers. Photographers previously certified for this procedure digitally (7M-D) electing to perform this procedure on film (7M-F) must submit stereo color photographs of two eyes (one right and one left). This allows us to check image quality (stereo effect, exposure, film quality, film processing and correct labeling/mounting of 2X2 slides).

Photographers are encouraged to send complete submissions for each procedure that they are requesting certification (i.e. if 4 eyes are required for certification please send all 4 eyes in one submission).

Photographers who meet certification criteria will receive confirmation of certification. Those who do not meet these criteria will receive feedback from the UW-FPRC imaging consultants, and may be required to submit additional sets of images. A plan for improving image quality may be necessary after three complete unsuccessful certification submissions.

Once a photographer is certified for a specific study they are certified for the duration of that specific study, even if they are inactive for more than one year.

3.0 Uncertified Photographers (Follow-up Visits Only)

On rare occasions during **follow-up** visits, when a certified photographer is not available, an uncertified photographer familiar with the procedure(s) may take the images. The uncertified photographer should review the imaging procedure(s) before performing photography to be certain they understand and follow the procedure(s). The name of the uncertified photographer should be entered on the slide page label, as well as any other study documentation requiring photographer name. A brief description should be entered on the transmittal log explaining the reason an uncertified photographer took the images.

4.0 Fundus Cameras

The Zeiss FF4 (or similar models), Zeiss FF450-plus, Topcon TRC-50 series (50VT, 50X, 50EX, 50IA, 50IX and 50DX) and the Kowa and Nikon camera models used at the 30° or 35° settings are suitable cameras. Additionally, Canon cameras (UVi or similar models) used at the 40° setting are also suitable.

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 this procedure, to the Fundus Photograph Reading Center, Attention: Imaging Services, 406 Science Dr., Suite 400, Madison, WI 53711-1068.

5.0 Film and Processing

For color photography, the recommended films are Kodak Professional Ektachrome 100 Daylight films (EPN, EPP, E100S or E100G), Fuji 100 ISO films (Provia or Velvia) or their equivalent. The film should be processed by a certified "Q-Lab" or other professional E-6 laboratory to ensure consistent quality. It is important that the processor correctly number the slide mounts to make slide sorting easier and more accurate.

6.0 Modified 7-standard Fields and Fundus Reflex Images

The modified 7-standard fields 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 (see Figure 1).

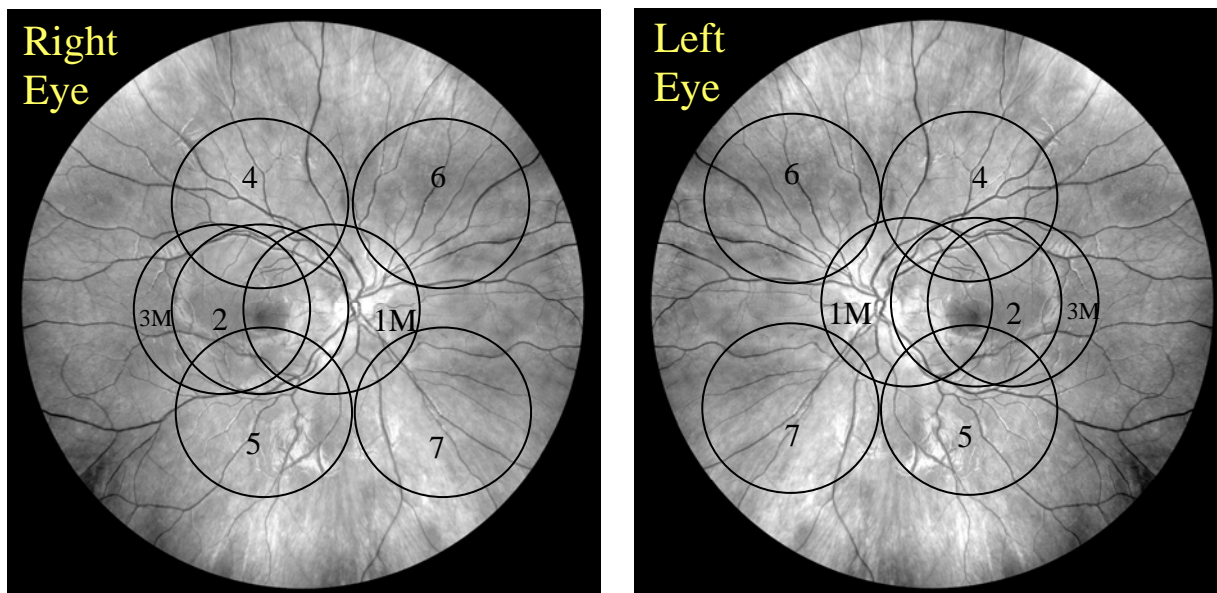


Figure 1 (photos courtesy Richard Hackel)

Visit our website <http://eyephoto.ophth.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.

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 in the center of the cross hairs in the ocular.

Field 2 - Macula: Center the macula near the intersection of the cross hairs in the ocular. A suitable position can often be obtained by rotating the camera temporally from the Field 1M position, without vertical adjustment. If your camera has a central "gray dot" artifact near the intersection of the cross hairs center about 1/8 – 1/4 DD above the macula to keep from obscuring the center of the macula

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 pivoting 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.

It is convenient to take Field 7 immediately after Field 5 by rotating the camera nasally.

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.***

Fundus Reflex image [Figure 2] - At all visits, stereoscopic fundus reflex images should be taken to document media opacities. The magnification of these images should match that of the image in Figure 2. 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.

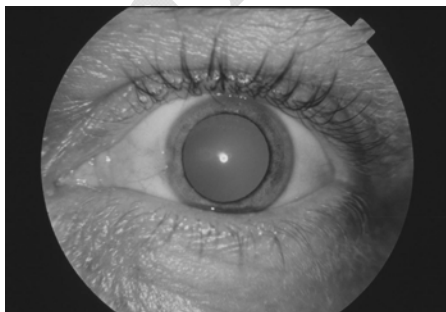


Figure 2

7.0 Mounting and Labeling of 35mm Color Images

The transparencies returned from the processing lab are mounted in standard 2X2 inch mounts. Do not use mounts with glass slides. Each slide should be individually labeled on the slide mount (see the *UW-FPRC Forms, Labeling, Study Conventions Information* section of this document).

Photographs of each eye should be placed 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 page identification label is completed and attached to the front of each plastic sheet. See Figure 3 below.

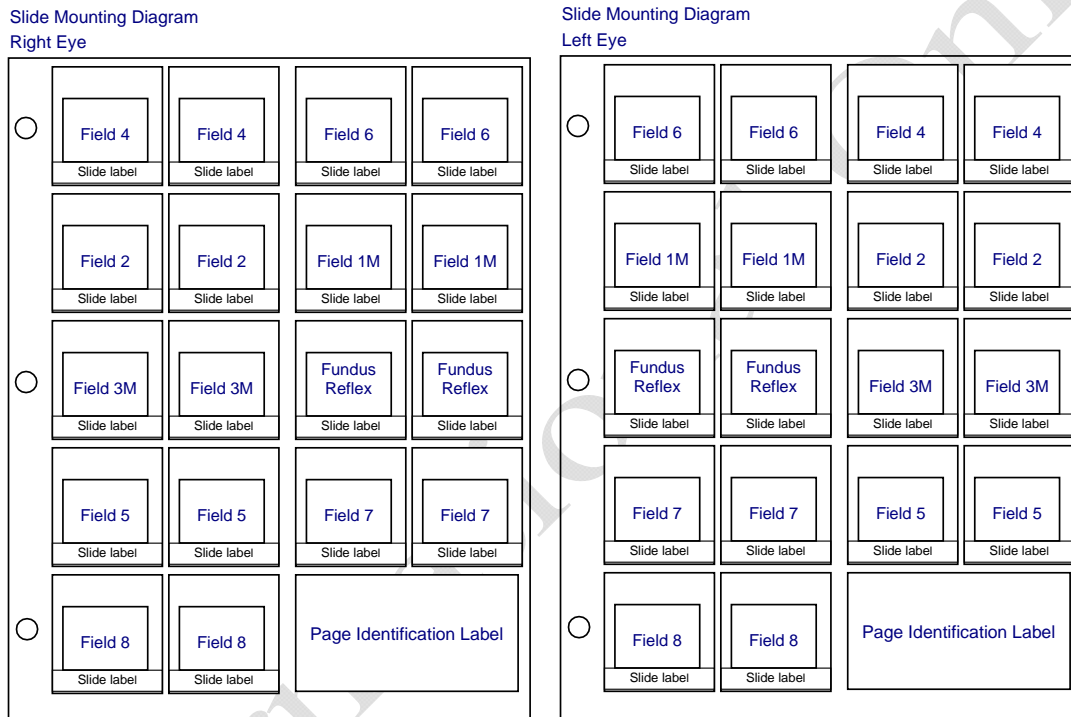


Figure 3

For *certification images* if pre-printed labels are not available please hand-label using a permanent felt-tip marker. The individual slide labels must indicate which eye, the field location and which member of the stereo pair (e.g. RE-F1M-LS). The plastic sheet page labels should indicate a patient identifier, photographer's name, date of photography and that the images are certification sets. Certification images will be returned upon clinic's request; otherwise they will be disposed of by the UW-FPRC.

For labeling of *study participant submissions* please refer to the information outlined in the *UW-FPRC Forms, Labeling, Study Conventions Information* section.

[†] 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.

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 Retakes

The color images 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 if no irremediable cause of inadequate quality is present (such as lens opacities or a pupil that will not dilate adequately), the images should be retaken before submission to the UW-FPRC. When color images are considered ungradable because of poor quality, the UW-FPRC may issue a retake request.

9.0 Evaluation of Image Quality

Color images of each eye are reviewed and assigned a grade for overall quality. 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) image 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.

10.0 Pointers on Imaging Technique

10.1 General

A 4X or 5 X magnification stereoscopic viewers 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.

10.2 Patient Cooperation

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. Additionally, keeping the view lamp as low as possible (maybe even dimming the room lights) can help make the

photography procedure more tolerable. Patients should be asked to blink to help keep the cornea clear.

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.

10.3 Field Definition

When the modified 7-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.

10.4 Focus/Clarity

Remember that the best image quality can be acquired if corneas are not disturbed by prior examination with a diagnostic contact lens.

Constant attention must be paid to keeping the cross hairs in the camera ocular in focus; otherwise the images 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 images 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. Images 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. 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 preferable 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.

10.5 Stereoscopic Effect

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 technique described by Allen⁴ is used for taking non-simultaneous stereo fundus images. The camera **should not be rotated or pivoted for stereo images**; instead, it should be moved laterally from left to right with the joystick (or by sliding the camera base on its table, if preferred). About 2mm is the minimum separation between members of the stereo pair to be aimed for when moving the joystick or sliding the camera.

It is customary to take the left member of the pair first, followed by the right member of the pair, but this is optional. 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.*

11.0 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.