

# FUNDUS PHOTOGRAPH READING CENTER

## **Modified 3-Standard Field Color Fundus Imaging Using Film (3M-F) or Digital Imaging (3M-D)**

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

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## 1.0 Photographer Certification

Photographers taking photographs (or digital images: the terms will be used interchangeably in this procedure) for studies read by the University of Wisconsin-Fundus Photograph Reading Center (UW-FPRC) must be certified for the relevant procedure(s), *before submitting actual patient photographs*. **Only UW-FPRC certified photographers are allowed to take Qualifying Visit (baseline) 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 qualifying 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-FPRC's photographic consultants, Hugh Wabers 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-FPRC Photographer Certification Request Form" found on the UW-FPRC website: <http://eyephoto.opth.wisc.edu>, to the UW-FPRC. 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-FPRC using **an identical 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 than one year may be asked to submit sample photographs to become for the AREDS 2. 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 photographs of 4 eyes (2 right eyes and 2 left eyes) taken using this procedure. The color photographs 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 on film (3M-F) electing to perform this procedure digitally (3M-D) must submit stereo color photographs of two eyes. This allows us to check image quality (stereo effect, color quality and image resolution) and to determine whether we can open the CD and archive the images.

If the modified 3-standard fields are photographed using 35mm film (3M-F) the slides should be mounted as shown in Section 8.0. Pre-printed labels may be unavailable for labeling certification photographs: if this is the case please hand label the color slides indicating the field and the eye photographed as well as the right side (RS) or left side (LS) of the stereo pair. The slide pages containing the color photographs 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.

Clinical sites using digital color systems instead of 35mm film must obtain UW-FPRC certification for both photographer(s) and digital camera system(s) *before initiating study photography*.

If the modified 3-standard fields are imaged digitally (3M-D) the digital images should be saved to CD at full-resolution using no or lossless compression. Lossy compressed (standard .jpg) images may be accepted but will be evaluated by the UW-FPRC on a case-by-case basis. Images of the right eye should be separated from images of the left eye and should be taken so that stereo pairs have the proper stereo orientation when viewed in proof sheets. Image handling procedures will be unique to the digital capture system used and photographers are encouraged to contact the UW-FPRC photographers to answer additional questions. Because pre-printed labels may be unavailable for labeling the CD, please hand-label the certification CD using a permanent felt-tip marker. The CD should be labeled indicating the fundus camera head serial #, the patient initials or patient identifier, photographer's name, date of photography and that the photographs are certification sets.

Whether using the 3M-F or the 3M-D procedure a **signed "UW-FPRC Photographer Certification Request Form" is always required** (see the *FPRC Forms, Labeling, Study Conventions Information* document).

Photographers previously certified for this procedure on film (3M-F) electing to perform this procedure digitally (3M-D) must submit stereo color photographs of two eyes. This allows us to check image quality (stereo effect, color quality and image resolution) and to determine whether we can open the CD and archive the images.

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 or CD.

## **3.0 Fundus Cameras**

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, Attention: Photography Services, 406 Science Dr., Suite 400,

Madison, WI 53711-1068. 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 Digital System Certification**

System Requirements - Digital color images must be taken using either MRP OphthaVision<sup>®</sup>, OIS Winstation<sup>®</sup>, Escalon Medical Imaging (EMI), Topcon IMAGEnet<sup>®</sup>, Zeiss VISUPAC<sup>®</sup> or Digital Healthcare Classic digital systems using a three mega-pixel or larger image sensor. Each digital angiogram system must be certified by the UW-FPRC. This is accomplished by submitting the "**UW-FPRC Digital Color System Certification Request Form**" (see the *FPRC Forms, Labeling, Study Conventions Information* document). Copies of the digital system certification form are available on the UW-FPRC website.

It is preferred that the digital system contains software and hardware that allows remote access and operation. The UW-FPRC or a manufacturer 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 Color System Certification Request Form" (see the *FPRC Forms, Labeling, Study Conventions Information* document). Each system you plan to use requires a separate form and certification. For digital systems not 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 3 months, new images should be sent to the UW-FPRC to verify that they still match the certification settings. If the system was certified with the UW-FPRC but hardware or software changes have occurred since certification, a "Digital System Upgrade Form" should be completed and sent to the UW-FPRC. This form is located on the UW-FPRC website (<http://eyphoto.ophth.wisc.edu>). Depending on the upgrade, additional images may need to be sent with the form.

**MRP OphthaVision<sup>®</sup> System**- System certification must be handled through MRP. Contact MRP's Matt Carnevale at 978-687-7979.

**OIS Winstation<sup>®</sup> System or Escalon Medical Imaging (EMI) or Digital Healthcare (DHC)** - Each system requires a calibration for certification. The calibration uses 10 color images, of 10 different eyes, at the acceptable image angle (determined by camera type). The color images should be centered on the posterior pole so that both the disc and macula are in view. If the center of the macula and the center of the disc are not clearly defined they can not be used for calibration. The UW-FPRC would prefer that OIS Winstation<sup>®</sup> systems have software version 10.0 or higher. EMI systems must have RCPrep software version 1.4 or higher. DHC Classic systems must have software version 4.22.06 or higher.

If there are any hardware or software changes made to the system 10 more color images may be required to recalibrate the system. This requirement can be abbreviated if one of the 10 eyes used in the initial calibration is from someone who can be photographed in the future (i.e.

the same staff member's eye photographed under 2 different system perimeters). This way if the system changes, the patient can be re-photographed and the old and new photos can be sent to the UW-FPRC for calibration and recertification.

**Topcon IMAGEnet<sup>®</sup> System** - Run the Digital System Evaluation Software (DSES), which can be found on the web at <http://eyephoto.opth.wisc.edu/DSES.html> or it can be mailed to you by contacting the UW-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 800-499-2291, [tony@cfsimaging.com](mailto:tony@cfsimaging.com).

**Zeiss Visupac<sup>®</sup> System** – Send a completed "UW-FPRC Digital Color System Certification Request Form" to the UW-FPRC. Make sure the serial# of the Visupac<sup>®</sup> system and a phone number to access the system are included. Receipt of this form will initiate contact between the UW-FPRC and Carl Zeiss Meditec Inc. A representative from Carl Zeiss Meditec Inc. will in turn contact the site to arrange a time to go through the certification process.

The system certification process is considered successful, and sites are notified, after the UW-FPRC staff ensures that the color balance is correct and that image files can be successfully viewed and analyzed.

## 5.0 Film and Processing

For color photography, the recommended films are Kodak Professional Ektachrome 100 Daylight films (EPN, EPP or E100G) or their equivalent. If possible 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.

## 6.0 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.*

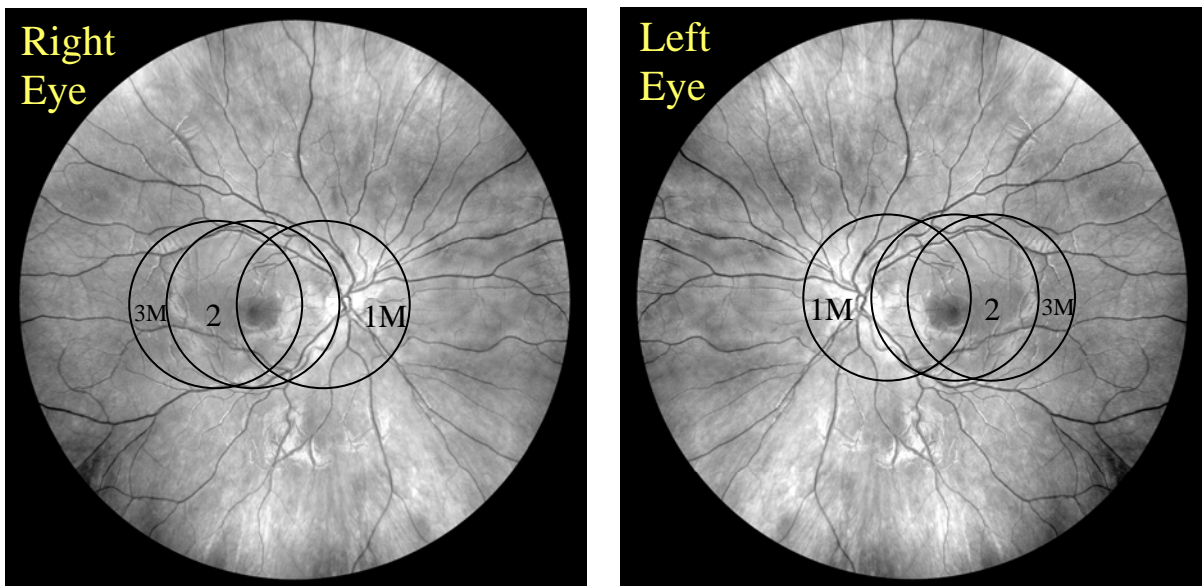
**Dilation of the pupil to at least 6mm is important to permit good quality stereo photography.** *If the pupils cannot be dilated to at least 4mm for the qualifying visit, the subject should not be entered into the study.* The cornea should be undisturbed by prior examination with diagnostic contact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

If the subject has great difficulty tolerating the qualifying visit photography procedure and the photographer thinks this will lead to a problem at follow-up visits, the situation should be discussed with the principal 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.

## 7.0 Modified 3-standard Fields and Fundus Reflex Photographs

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

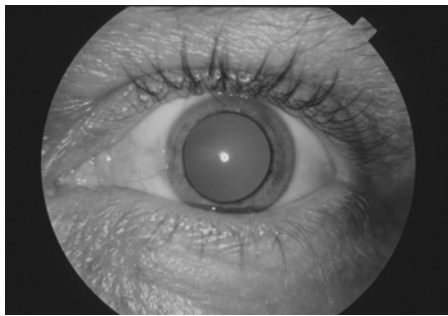
**Field 1M** - Disc: Center the temporal edge of the optic disc at the intersection of the cross hairs in the ocular.

**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 9mm 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 and focus should be on the pupillary margin. The ideal magnification is displayed below:



**Figure 2**

(The ideal limbal diameter is approximately 9 mm on film)

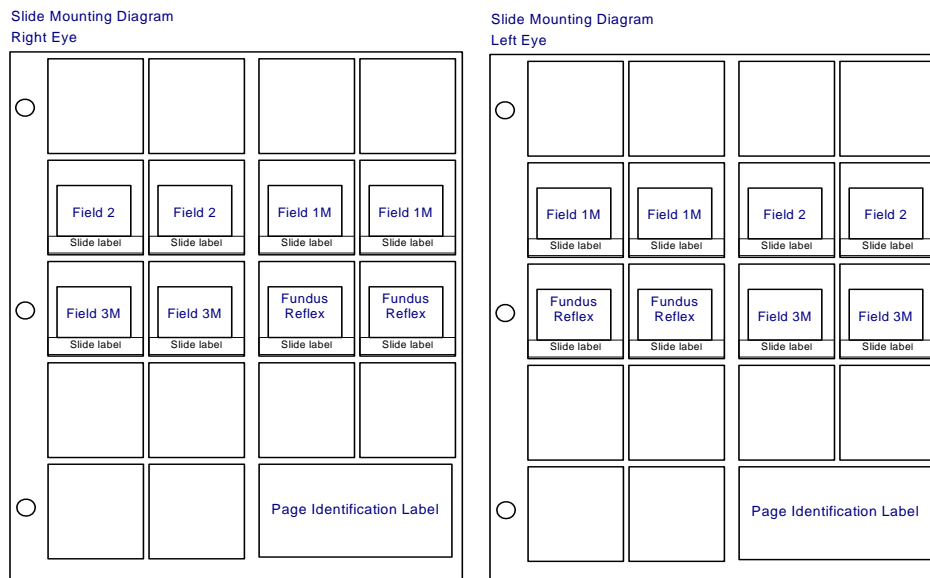
## 8.0 Mounting and Labeling of Color Film Photographs

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 *FPRC Forms, Labeling, Study Conventions Information* document).

Photographs of each eye should be mounted in an individual plastic sheet.<sup>†</sup> 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).

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<sup>†</sup> 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.



**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.

## **9.0 Guidelines for Acquiring and Handling of Stereo Digital Images**

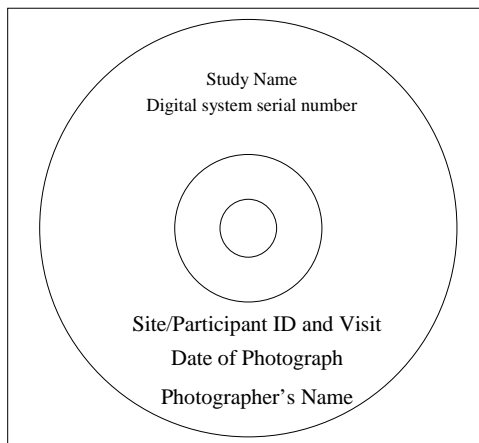
Digital images must be submitted on CD using only the standard methods existing in the software of the imaging system to isolate images for submission (do not use Windows Explorer to copy images to the CD). Digital images should be “burned” to CD before being archived on the computer system. The digital images should be saved to CD at full-resolution using no or lossless compression. Lossy compressed (standard .jpg) images may be accepted but will be evaluated by the UW-FPRC on a case-by-case basis. Images from only one participant and only 1 visit should be written to each CD. The participant’s name and birth date must be removed from the file so it is not displayed during image evaluation (for OIS systems this is only possible for systems with Winstation<sup>®</sup> version 10.0 or higher).

For certification submissions the participant’s name should be edited out of the file: the last name should be replaced with the words “System-Certification” and the participant’s first name should be replaced with the serial number (the one located on the head of the fundus camera). Photographer certification photos may also be used for camera system certification.

For submissions of study participants please replace the subject's ID number, last name, and first name with study specific information, as outlined in Figure 4 and the *FPRC Forms, Labeling, Study Conventions Information* document (for OIS systems editing is only possible with Winstation® version 10.0 or higher). Images should be sent promptly, within 5 business days, to the UW-FPRC.

**Figure 4**

The CD should be labeled using a circular CD label (as shown in Figure 5 below). These labels are provided by the UW-FPRC and include the study name, name of the institution submitting the photographs, participant's study information (sites may need to manually enter this for the initial visits) and visit. The CD label also includes a space for the photographer to document the date of photography, the photographer's name(s) and the serial number of the fundus camera used (the one located on the head of the fundus camera). A full resolution (or lossless compressed) duplicate of each submission should be retained at the site.



**Figure 5**

When shooting the fields digitally, please shoot the right eye images first, followed by left eye images and begin photography of each eye by shooting Field 1M. This procedure will help us separate images from the right eye and left eye when we view the proof sheets. Images should be taken so that stereo pairs have the proper stereo orientation when viewed in proof sheets. All digital images should be reviewed for quality at the time of photography and the photographer should select the best stereo pairs for each field, deleting extra, unwanted images.

It is very important that photographers minimize flash/gain changes to avoid overexposure or 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 photography session to improve image quality. While this is often a useful adjustment, we do not want a wide variety of exposure across fields of the same eye. To safeguard against this, we recommend that photographers determine the best gain and flash combination at the beginning of the photography session, taking one or two test frames to confirm proper exposure/gain settings and then stay with one setting for the photography session.

Most digital systems have a wide variety of image enhancement tools to adjust image contrast, brightness or sharpness after image capture. Enhancement tools should not be used at the clinical site to adjust image quality. Careful attention must be paid to obtaining optimum exposure and image sharpness so that enhancements are not necessary.

## **10.0 Transmission of Color Photographs/Images to the UW-FPRC**

The original color transparencies or CDs should be prepared and labeled as described above within 5 working days (sooner if possible) after being taken. The sets of photos/images should be sent together with the completed Transmittal Log to the UW-FPRC.

## **11.0 Retakes**

The color photos 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 photos should be retaken before submission to the UW-FPRC. When color photos are considered ungradable because of poor quality, the UW-FPRC may issue a Retake Request Form (see the *FPRC Forms, Labeling, Study Conventions Information* document). For qualifying visits, retakes must be received at the UW-FPRC at least 1 week prior to randomization.

## **12.0 Evaluation of Photographic Quality**

Color photograph/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 signify that a set can be assessed, although the quality compromises the grading somewhat. Grades of ungradable-explained and ungradable-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/image 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 image pairs of 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 Allen<sup>4</sup> 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. Some type of viewer may be necessary to review stereoscopic images displayed on a monitor. 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 Hugh Wabers or Michael Neider.

#### Questions or Comments

For questions or comments concerning this photography procedure, please contact the UW-FPRC photographic consultants, Hugh Wabers; [wabers@rc.opth.wisc.edu](mailto:wabers@rc.opth.wisc.edu) or Michael Neider; [neider@rc.opth.wisc.edu](mailto:neider@rc.opth.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 Disease 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.