



University of Wisconsin
**SCHOOL OF MEDICINE
AND PUBLIC HEALTH**

Fundus Photograph Reading Center

Non-study Specific 7-Standard Field Digital Color Fundus Photography (7STD-D)

Effective Date: *TBD*

Supersedes Date: *New*

Revision History

Effective Date: **Supersedes Date:** **Revised by:** **Description:**

New

N/A

New

Informational Only

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1. Overview

The study will be using the University of Wisconsin Fundus Photograph Reading Center (FPRC) 7 Standard Digital Color Fundus Photography procedure (7STD-D). Please refer to documents specific to a study to determine if additional UW-FPRC procedures apply to a given trial. Each clinical center participating in this study will use the information from this Imaging Procedure document and the *FPRC Forms, Labeling, and Shipping Information* section of the FPRC's study-specific document to request certification, collect images from each study patient, appropriately label each piece of data, and ship the data to the FPRC for subsequent analysis. Further clarification regarding any information included in this document may be obtained by contacting the FPRC at the telephone numbers or email addresses provided in Section 2.

2. 7-Standard Field Digital Procedure (7STD-D)

The following is the FPRC's 7STD-D procedure. All clinical sites using this procedure must take images using a digital system that is FPRC certified for color capture capability. This typically requires a minimum 3 mega pixel resolution or higher with a preferred 5 or 6 mega pixel resolution color image capture system. For details about how to certify a digital system refer to the *Digital System Certification* section of the FPRC's *Imaging Procedures* document.

Only 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 4.)

Clinical sites are strongly encouraged to have a minimum of two, but no more than three, certified photographers. Photographers are encouraged to contact the 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 9.

3. Photographer Certification

Photographers taking photographs (or digital images: the terms will be used interchangeably in this procedure) for studies evaluated by the 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 *FPRC Photographer Certification Request Form* for each study. This form can be found in the *FPRC Forms, Labeling, and Shipping Information* section of the FPRC's study-specific document. A copy of the form may also be available on the FPRC website: <http://eyephoto.ophth.wisc.edu>, which may require a username and password. One form will be used for all photography procedures associated with a given study. Digital photography system certification requires a separate study-specific form for **each** system being used.

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 FPRC using **an identical procedure**, and has been actively taking images, judged to be of good quality by the FPRC, during the past 12 months. Photographers who are certified for **a similar procedure** also may be asked to submit sample photographs to become certified.

Photographers who are not eligible for certification on the basis of previous FPRC certification should **submit color images of four (4) eyes (two right eyes and two left eyes)** taken using this procedure. The color images may be taken of patients with whom photography is being carried out for clinical purposes or of normal volunteers. Photographers previously certified for this procedure on film (7STD-F) electing to perform this procedure digitally (7STD-D) must submit stereo color photographs of two (2) eyes (one right eye and one left eye). This allows us to check image quality (stereo effect, color quality and image resolution) and to determine whether we can open the CD/DVD and archive the images.

Photographers are encouraged to send complete submissions for each procedure for which he/she is requesting certification (i.e., if four eyes are required for certification, send all four 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 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, he or she is certified for the duration of that specific study, even if inactive for more than 12 months. However, if a certified photographer consistently fails to meet study standards, certification may be suspended.

4. 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 identified on the CD/DVD, as well as any other study documentation requiring the photographer's name. A brief description should be entered on the transmittal log explaining the reason an uncertified photographer took the images.

5. Fundus Cameras

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

Cameras other than these may be substituted upon approval of the 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.

6. 7-Standard Stereoscopic Fields and Fundus Reflex Images

The 7-standard fields specified by this procedure, illustrated in Figure 1, are identical to the fields used in the Early Treatment of Diabetic Retinopathy Study (ETDRS).

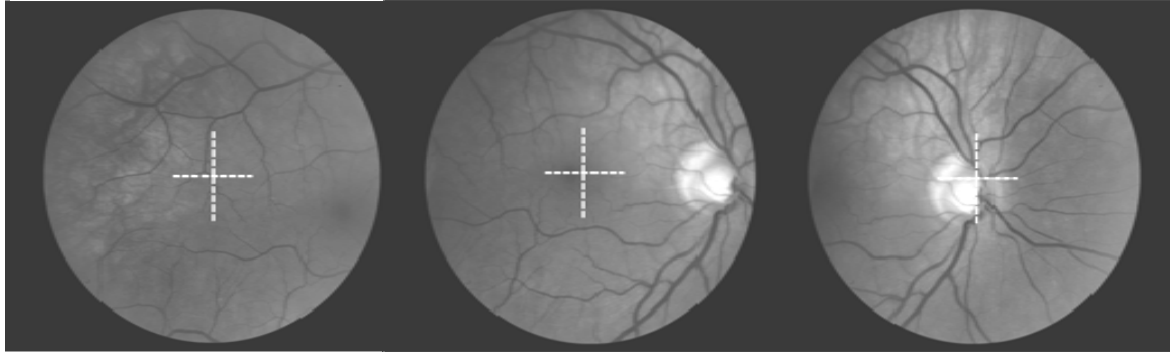


Figure 1: Right Eye fields 1, 2, and 3



Figure 2: Left Eye fields 1, 2 and 3

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 fields in a quick and easy manner, *keep in mind that fields 1 and 3 will have a different field definition than what is in the tutorial*. 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. Fields 1, 2, and 3 of the right and left eyes are illustrated in Figures 1 and 2.

Field 1 - Disc: Center 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. A suitable position can often be obtained by rotating the camera temporally from the Field 1 position, without vertical adjustment.

Field 3 - Temporal to Macula: Position the macula so it is bisected at the nasal edge of the field. If Field 2 was centered above the center of the macula, as suggested above, Field 3 may be easily achieved by rotating the camera without making any vertical adjustment or movement of the fixation device.

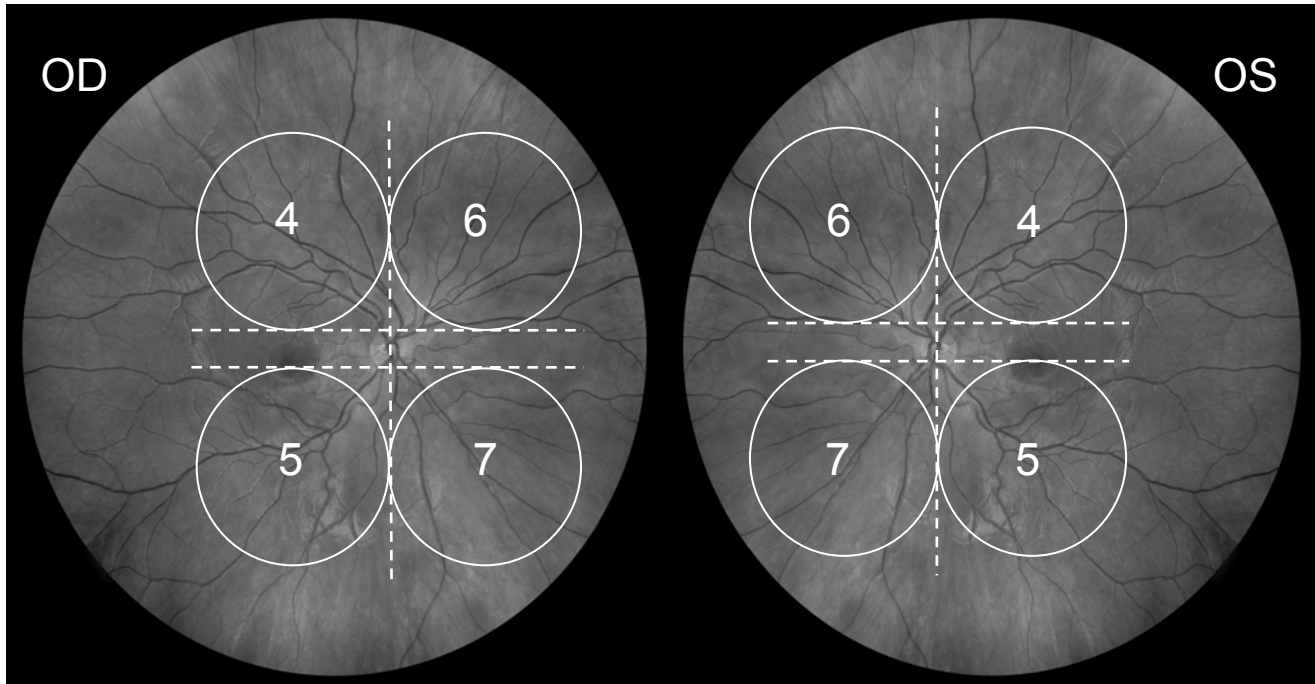


Figure 3: Photograph provided by: Richard Hackel, CRA

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. Fields 4, 5, 6, and 7 of the right and left eyes are illustrated in Figure 3.

Tips on field definition: The peripheral fields are only 1 DD away from the optic nerve. Fields 4 and 6 abut without an overlap or gap between these two fields. This is true for Fields 5 and 7 also.

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.

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

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

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

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

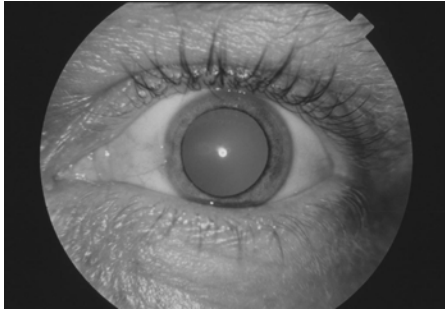


Figure 4: Fundus Reflex

At all visits, stereoscopic fundus reflex images should be taken to document media opacities. If no opacities are present, focus on the pupillary margin of the iris; if opacities are present, focus deeper on the lens opacities. The magnification of these images should match that of the image in Figure 4. 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 the optic nerve *does not appear* directly behind the lens.

7. Exporting and Labeling Digital Images

Digital images should be saved to CD/DVD at full resolution, using no compression or lossless compression. Lossy compressed (standard .jpg) images may be accepted but will be evaluated by the FPRC on a case-by-case basis.

Only the standard methods existing in the capture software of the imaging system should be used to isolate images for submission. Specific image handling procedures are outlined in the FPRC's *Digital System Certification* section of the FPRC's *Imaging Procedures* document or the FPRC website, <http://eyephoto.opth.wisc.edu/>. Digital images should be "burned" to CD/DVD before being archived on the computer system (a process that often compresses the images for storage). We recommend confirming that the images were successfully burned to CD/DVD by checking the CD/DVD on another computer.

For *certification images* comply with HIPAA regulations by masking patient identifiers on the digital files. If pre-printed labels are not available for labeling the CD/DVD, hand-label using a permanent felt-tip marker. The CD/DVD label must indicate the fundus camera head serial number, patient identifier, photographer's name, date of photography and that the images are certification sets.

For *submissions of study participants* comply with HIPAA regulations by replacing the subject's ID number, last name, and first name with study specific information (as shown in the following table). For OIS systems editing is only possible with specific versions of Winstation[®].

Replace	With	Study Specific
Patient's ID#	Site#, Subject#	Study specific info here
Patient's Last Name	Study Name	Study specific info here
Patient's First Name	Site#, Subject#, Name code	Study specific info here

Patient's Date of Birth	01/01/1900	Study specific info here
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For *study submissions* the CD/DVD should be labeled using a circular CD/DVD label (as shown in Figure 5). These labels are typically provided by the FPRC and include the study name, site ID, patient ID and visit information (sites may need to manually enter information for initial visits). The CD/DVD label also includes a space for date of photography, the photographer's name(s) and the serial number of the fundus camera used (located on the head of the fundus camera). A full resolution (uncompressed) duplicate set of images of each submission should be retained at the site.

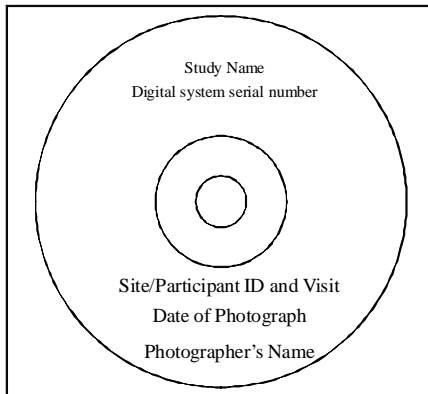


Figure 5

The CD/DVDs should be prepared and labeled as described above. The sets of images should be sent together with the completed Transmittal Log (see the *FPRC Forms, Labeling, and Shipping Information* section of the FPRC's study-specific document) to the FPRC as soon as possible after being taken.

8. 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 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 FPRC. When color images are considered ungradable because of poor quality, the FPRC may issue a retake request.

9. Evaluation of Image Quality

Color images of each eye are reviewed and assigned a grade for overall quality. 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. Pointers on Imaging Technique

10.1. General

When shooting the fields digitally, shoot the study eye images first, followed by fellow eye. Stereo pairs should be taken shooting the left member of the pair first, followed by the right member of the pair. 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, unnecessary images.

10.2. Patient Cooperation

Photography of the photophobic subject can be 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 principal investigator and/or coordinator, and consideration should be given to not enrolling the subject in the study.

10.3. Field Definition

When the 7-standard stereo fields are taken, the following sequence is recommended: disc (Field 1), macula (Field 2), temporal to macula (Field 3), superior temporal (Field 4), superior nasal (Field 6), inferior temporal (Field 5), inferior nasal (Field 7). Fields 1, 2, and 3 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.

In a properly aligned digital system, the cross hairs and the retina are in focus at the same time. In these instances, constant attention must be paid to keeping the cross hairs in the camera ocular in focus when focusing on the retinal vessels. However,

some digital systems are not par focal with the eyepiece; in these cases, it is important to confirm that image on the monitor is as sharp as possible. 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 1 and 2.

When the photographer moves to Field 2, having just taken Field 1, **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 that include the optic nerve (Fields 1 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 Allen¹ is used for taking non-simultaneous stereo fundus images. The camera **should not be rotated or pivoted**; 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.

Stereo pairs should be taken shooting the left member of the pair first, followed by the right member of the pair. 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.*

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

10.6. Exposure, Gain and Flash

It is important that photographers use flash, gain, and gamma changes to obtain optimal exposure, as well as to avoid severe over or under exposure to avoid loss of image detail. We recommend that photographers become familiar with using the camera and software controls available to ensure optimal exposure and good color balance. The FPRC Imaging staff is available to assist in recommending acceptable settings.

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. Pay careful attention to obtaining optimum exposure and image sharpness so that enhancements are not necessary. For more information on color balance for retinal images, refer to the Color Balance Paper on our website <http://eyephoto.opth.wisc.edu/Photographers.html>.

11. References

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.

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.

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.

12. Approvals

The following signatures indicate approval of this document.

12.1. Document Control

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Manager, Document Control

Date

12.2. Author

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Photographic Consultant

Date

12.3. Review

Hugh Wabers
Senior Imaging Consultant

Date

Dennis Thayer
Ophthalmic Imaging Specialist

Date

12.4. Approval

Michael Neider
Associate Director, Imaging

Date