LSOCA

Fundus Photography Reading Center

Procedures for standard field color fundus images using film and digital imaging

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1.01 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 consultant, Dennis Thayer (608-263-9858) with any photography related questions. Pointers on photographic technique may be found in Section 13.

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.ophth.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 certified for LSOCA. 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 (preferably 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 (9-std-F) electing to perform this procedure digitally (9-std-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 9-standard fields are photographed using 35mm film (9std-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 pairs. 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 9-standard fields are imaged digitally (9-std-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 9-std-F or the 9-std-D procedure a **signed "UW-FPRC Photographer Certification Request Form" is always required (see the *FPRC Forms, Labeling, Study Conventions Information* document).** Copies of the photographer and digital system certification forms are available on the UW-FPRC website.

Photographers previously certified for this procedure on film (9std-F) electing to perform this procedure digitally (9std-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 to discuss a plan for additional photographer training.

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 Topcon TRC-50 series (50VT, 50X, 50EX, 50IA, and 50IX or similar models) as well as The Zeiss FF450-plus fundus cameras, all used at 50° are suitable cameras. Additionally, the Canon UVi (or similar models) used at the 60° setting, and the Kowa, Nikon and Olympus fundus camera models used at the 50° 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: Imaging 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 for Color Capture Capability

4.1 Overview

If your site is performing digital color photography for a given trial, the digital system must be certified for that trial before any patients may be enrolled. A "UW-FPRC Digital Color System Certification Request Form" is required for each digital system being certified.

For digital system(s) that have never been certified by the UW-FPRC see sections 4.0 for detailed certification instructions for color capture capability.

Some digital systems, (IMAGEnet® / MRP/ Escalon (using OphthaVision® software)/ Zeiss VISUPAC®) which have been previously certified for digital color capture capability with the UW-FPRC and no software or hardware changes have been made since the time of certification, require only a "UW-FPRC Digital Color System Certification Request Form" to complete system certification. Escalon (using Escalon software), OIS Winstation® and Digital Health Care systems which have been previously certified for digital color capture capability with the UW-FPRC, must submit one eye taken at both 35 degrees and 50 degrees to become certified

If hardware or software changes occur during the life of the trial a "Digital System Upgrade Form" should be completed and sent to the UW-FPRC. This form is located on the UW-FPRC website:
http://eyephoto.ophth.wisc.edu/Photography/System%20Upgrade%20Form.pdf
Depending on the upgrade, additional images may be necessary.

For digital systems which have been previously certified for FA capture capability an abbreviated set of images is typically required to certify for color capture capability. For Zeiss Visupac®, Topcon IMAGEnet® and MRP/Escalon (using OphthaVision® software) systems; one color image (centered on the posterior pole taken at the correct degree angle) is required to verify settings. For Escalon (using Escalon software), OIS Winstation® and Digital Health Care: one color and one red free image (centered on the posterior pole taken at the correct degree angle) of a common eye are required.

The system certification process is considered successful for color capture capability after the UW-FPRC staff ensures that image quality is acceptable and that the files can be successfully viewed and analyzed.

4.2 System Requirements

Color digital images must be taken using MRP OphthaVision®, OIS Winstation®, Escalon Medical Imaging (EMI), Topcon IMAGEnet®, Zeiss VISUPAC® or Digital Healthcare Classic digital systems using a 3 mega-pixel or larger image sensor. Each color digital system must be certified by the UW-FPRC. The color balance of images is also reviewed by UW-FPRC staff. If a system's color balance does not meet the UW-FPRC's requirements the system will not be certified until these issues are resolved.

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.

4.3 Certification Procedure

Each digital system with color capture capability used for the study must be certified by the UW-FPRC before beginning study participant photography. Certification begins with submission of a study specific "UW-FPRC Digital System Certification Request Form" (see the *UW-FPRC Forms, Labeling, Study Conventions Information* section of the study specific documents). For step-by-step exporting instructions by digital system; please visit our website at: http://eyephoto.ophth.wisc.edu/Photographers.html.

4.3.1 MRP/Escalon (using OphthaVision® Software)

System Certification is handled through MRP/Escalon and is a two step process. Those wishing to certify a camera should **submit on film and digital** 2 red free images, of the same patient, with the optic nerve head centered in the photograph. If a variable degree fundus camera is used, images should be taken at all magnifications. Send the processed film and a CD containing the digital images to:

Escalon Digital Solutions
49 Blanchard Street
Lawrence MA. 01843
Attn: Matt Carnevale

Once the images are analyzed by Escalon Digital Solutions, the scale factor for that fundus camera will be sent to the study site. These factors will need to be entered into the preference files within the OphthaVision software. (Please contact Escalon Digital Solutions (800-676-0043) when you have received the scale factors to assure they are entered correctly.) After entering the scale factor the values are verified within the OphthaVision software and written to a floppy disk. This floppy disk should then be sent to Escalon Digital Solutions at the above address for final certification.

Once the system has been approved, images will be requested from the UW-FPRC to verify image settings. CD/DVDs sent to the UW-FPRC must include a

.dbf and a .tif file.

4.3.2 OIS Winstation® System, Escalon (using Escalon Software) 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® 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 4.19 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.

4.3.3 Topcon IMAGEnet® System

Run the Digital System Evaluation Software (DSES), which can be found on the web at http://eyephoto.ophth.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 via courier; to Choices for Service in Imaging, Inc., 233 Rock Road #249, Glen Rock, NJ 07452, or to the company's email address, tony@cfsimaging.com. If you have any questions during the process please contact Tony Pugliese at 800-499-2291, tony@cfsimaging.com.

Once Tony Pugliese has verified that the system settings are correct he will issue a document to the UW-FPRC. Upon receipt of this document the UW-FPRC will need to verify the system settings by reviewing recent images (taken after Tony's documentation has been issued).

4.3.4 Zeiss Visupac® System

Receipt of the "UW-FPRC Digital System Certification Request Form" will initiate contact between the UW-FPRC and Carl Zeiss Meditec Inc. Make sure the serial # of the Visupac system and a phone # to access the system are included. A representative from Carl Zeiss Meditec Inc. will in turn contact the site to arrange a time to go through the certification process. CD/DVDs sent to the UW-FPRC must include .dcm files.

5.0 Film and Processing

For color photography, the recommended films are Kodak Professional Ektachrome 100 Daylight films (EPN, EPP or E100G), Fuji (Provia and Velvia) or their equivalent at 100 ISO. 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. If sites are finding it difficult to process the color film a lab located in Madison Wisconsin processes E-6 on a daily basis. The company is Burne Photo Imaging, Inc., (608) 277-0802, barry@burne.com. They are a "Q-Lab" and have been processing film for clients throughout the country for years.

6.0 Obtaining Good Image Quality and Adequate Stereoscopic Effect

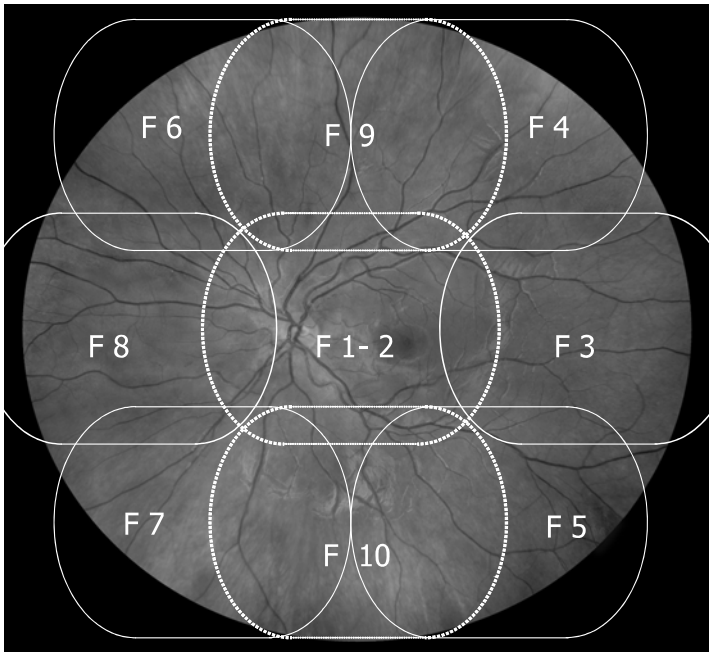
When obtaining stereo pairs, care should be taken that at least one member of the pair is of good technical quality with crisp focus. In many cases, it will be possible to obtain good quality in both members of the pair, but if this is not the case, *the aim should be to obtain good quality in one member 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 9-Std Fields and Fundus Reflex Photographs



9 Standard Field Diagram Left Eye

The nine standard photographic fields of the fundus are defined below for both right and left eyes. These fields are modified from those used in the Diabetic Retinopathy Study (DRS) and are designed for documentation of the observable area which may be involved in CMV retinitis, i.e., most of the post-equatorial fundus. Stereoscopic photography is required for Field 1-2 only.

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 1-2 (F1-2) Disc/Macula - Center the camera on the papillomacular bundle midway between temporal margin of the optic disc and the center of the macula. A stereoscopic photograph is obtained by taking one picture through the left portion of the pupil, moving the joystick laterally, and then taking a second picture through the right portion of the pupil. This field should include both the disc and macula, and outline the posterior pole.

Field 3 (F-3) Temporal to macula - Move the camera temporal from F1-2 along the same horizontal meridian (i.e., straight temporally). The nasal edge of F3 should be located one disc diameter temporal to the center of the macula; typically just beyond the temporal margin of the hyperpigmented area (thus the center of the macula will not appear in F3). There will be an overlap of about three disc diameters between F3 and F1-2.

Field 8 (F-8) - Nasal to the optic disc - Move the camera nasal to F1-2 along the same horizontal meridian (i.e., straight nasally). The temporal edge of F8 should be located adjacent to the nasal margin of the disc (thus the disc will not appear in F8). There will be an overlap of about three disc diameters between F8 and F1-2.

Field 9 (F-9) Superior - Move the camera directly superior to F1-2. The inferior edge of F9 should overlap the superior edge of F1-2 by 1 to 1½ disc diameters (be careful to retain at least 1 DD overlap). Selecting a retinal landmark (such as a vessel crossing) located one disc diameter below the center of the superior edge of F1-2 prior to shifting the camera will facilitate placement of F9.

Field 4 (F-4) Superior temporal - From F9, move the camera temporally along the same horizontal meridian. The nasal edge of F4 should be located at the center of F9, resulting in an overlap of about five disc diameters between F4 and F9. (The inferior edge of F4 will overlap the superior margin of F3 by 1 to 1½ disc diameter, although F4 is not as far temporal as F3). Selecting a retinal landmark located at or near the center of F9 prior to shifting the camera will facilitate placement of F4.

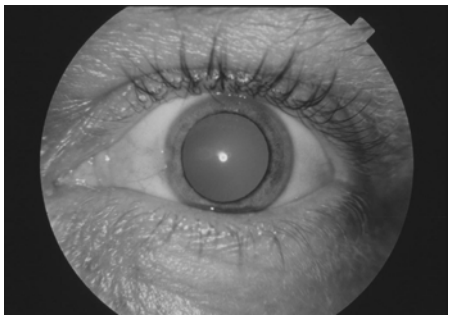
Field 6 (F-6) **Superior nasal - From F9, move the camera nasally along the same horizontal meridian. The temporal edge of F6 should be located at the center of F9, resulting in an overlap of about five disc diameters between F6 and F9. (The inferior edge of F6 will overlap the superior margin of F8 by 1 to** 1½ disc diameter, although F6 is not as far nasal as F8). Selecting a retinal landmark at or near the center of F9 prior to shifting the camera will facilitate placement of F6.

Field 10 (F-10) Inferior - Move the camera directly inferior to F1-2. The superior edge of F10 should overlap the inferior edge of F1-2 by 1 to 1½ disc diameters. (Be careful to retain at least 1 DD overlap). Selecting a retinal landmark located one disc diameter above the center of the inferior edge of F1-2 prior to shifting the camera will facilitate placement of F10.

Field 5 (F-5) Inferior temporal - From F10, move the camera temporally along the same horizontal meridian. The nasal edge of F5 should be located at the center of F10, resulting in an overlap of about five disc diameters between F5 and F10. (The superior edge of F5 will overlap the inferior margin of F3 by 1 to 1½ disc diameter, although F5 is not as far temporal as F3). Selecting a retinal landmark located at or near the center of F10 prior to shifting the camera will facilitate placement of F5.

Field 7 (F-7) Inferior nasal - From F10, move the camera nasally along the same horizontal meridian. The temporal edge of F7 should be located at the center of F10, resulting in an overlap of about five disc diameters between F7 and F10. (The superior edge of F7 will overlap the inferior margin of F8 by 1 to 1½ disc diameter, although F7 is not as far nasal as F8). Selecting a retinal landmark located at or near the center of F10

Fundus Reflex photograph - At all visits, a single frame 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:



Fundus Reflex Photo

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

All of the peripheral fields specified above are obtained through a combination of shifting the camera and directing the gaze of the subject in the appropriate direction. For example, the following sequence of actions works well to locate Field 9 (superior). Starting from Field 1-2 (centered midway between the temporal margin of the disc and the center of the macula), first tilt the camera up to the limit of its travel (this maneuver achieves about half of the vertical elevation required for Field 9). Then move the fixation target up carefully, being sure not to drift nasally or temporally, until the location described in the protocol is reached.

Some of the peripheral field definitions specify offsets of one disc diameter (DD). For example, Field 3 (the temporal field) is located so that its nasal edge is one disc diameter temporal from the center of the macula. In most Canon cameras, the cross-hairs in the ocular are spaced 1 DD from the center of the frame, and thus can be used to gauge this offset.

The typical locations of the four ampullae of the vortex veins provide an approximate means for checking the proper placement of some of the peripheral fields. The usual relationship is illustrated in Figures 1 and 2. Note that at its proper elevation Field 9 (the superior field) tends to be centered between the two superior ampullae, so that they appear at the middle of both horizontal ends of the frame. When the camera is shifted nasally to obtain Field 6, the supernasal ampulla tends to be centered in the middle of the frame. When the camera is shifted temporally, the supertemporal ampulla tends to be centered in the middle of the frame. Similar relationships exist between the inferior photographic fields (Fields 10, 5, and 7) and the inferior ampullae. It is expected that if at all possible photographers will use retinal landmarks rather than the ampullae to determine proper locations of the peripheral fields. However, in a patient with typical placement of the ampullae they can be used as an approximate check on the definition of these fields, particularly when difficulties with patient cooperation is interfering with the use of retinal landmarks.

Because of the extent of the periphery photographed, it is not always possible to move the fixation target to the ideal location. It may collide with the nose in some instances, or with the camera lens barrel in others. It may be necessary to instruct the patient to look further to the side than the fixation target for proper alignment of the field. In the case of F4 (superior temporal), the lens barrel may contact the subject's nose, which necessarily restricts the temporal placement of that field.

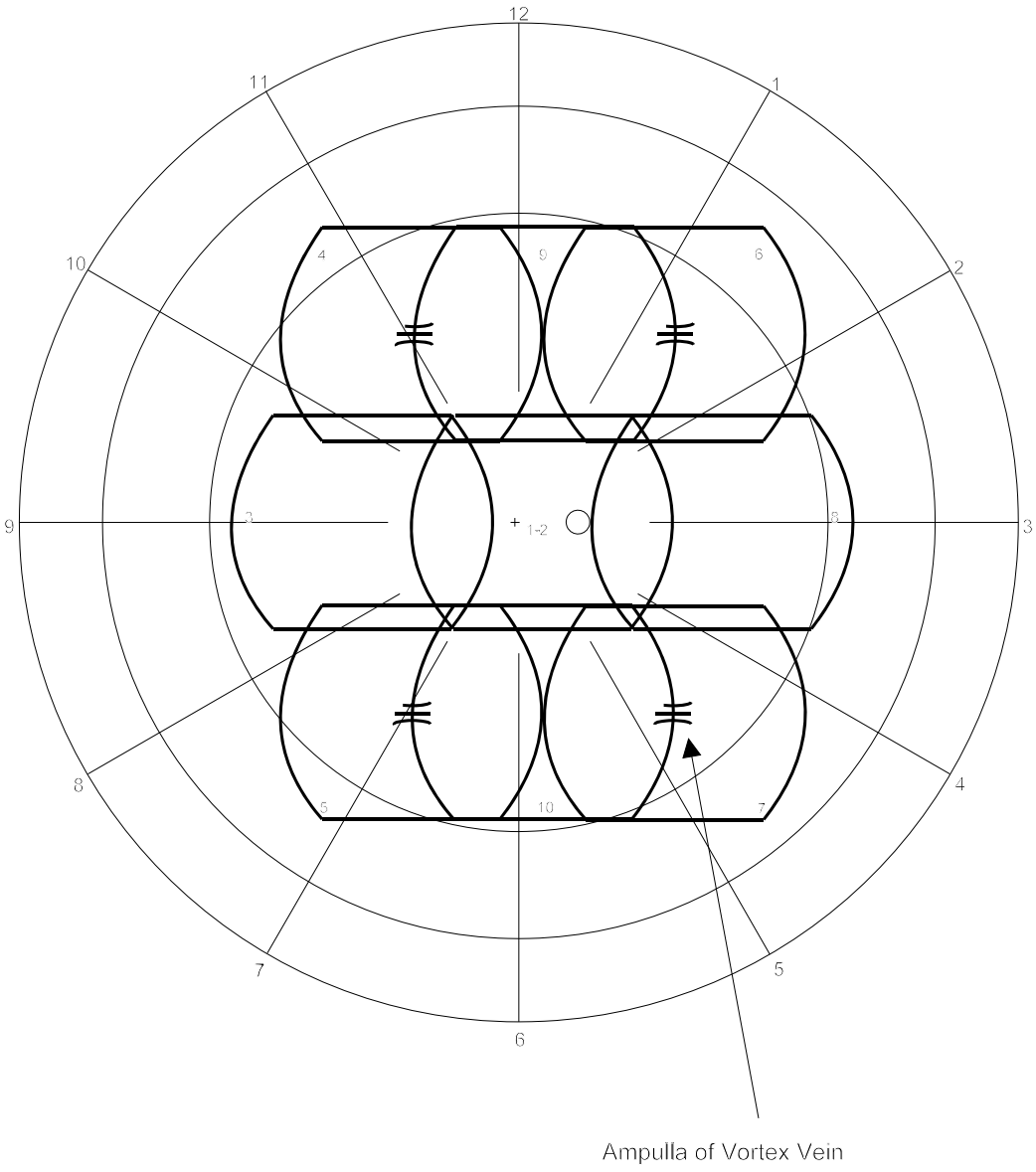
It will likely be necessary to refocus the camera from field to field, concentrating upon the sharpness of retinal landmarks near the center of each field. Given the curvature of the retina encountered in the peripheral fields, it is not always possible to get all of the retinal features in crisp focus across the entire field. Only if the sole pathology observed in the field is located near the edge should the picture should be focused there rather than on retinal detail near the center.

Since changing the focus has an appreciable effect on the area of retina included in the photographic field (changing the boundary by as much as one disc diameter), it is advisable to focus the camera at least approximately after moving to the desired position of each field and before finalizing its location.

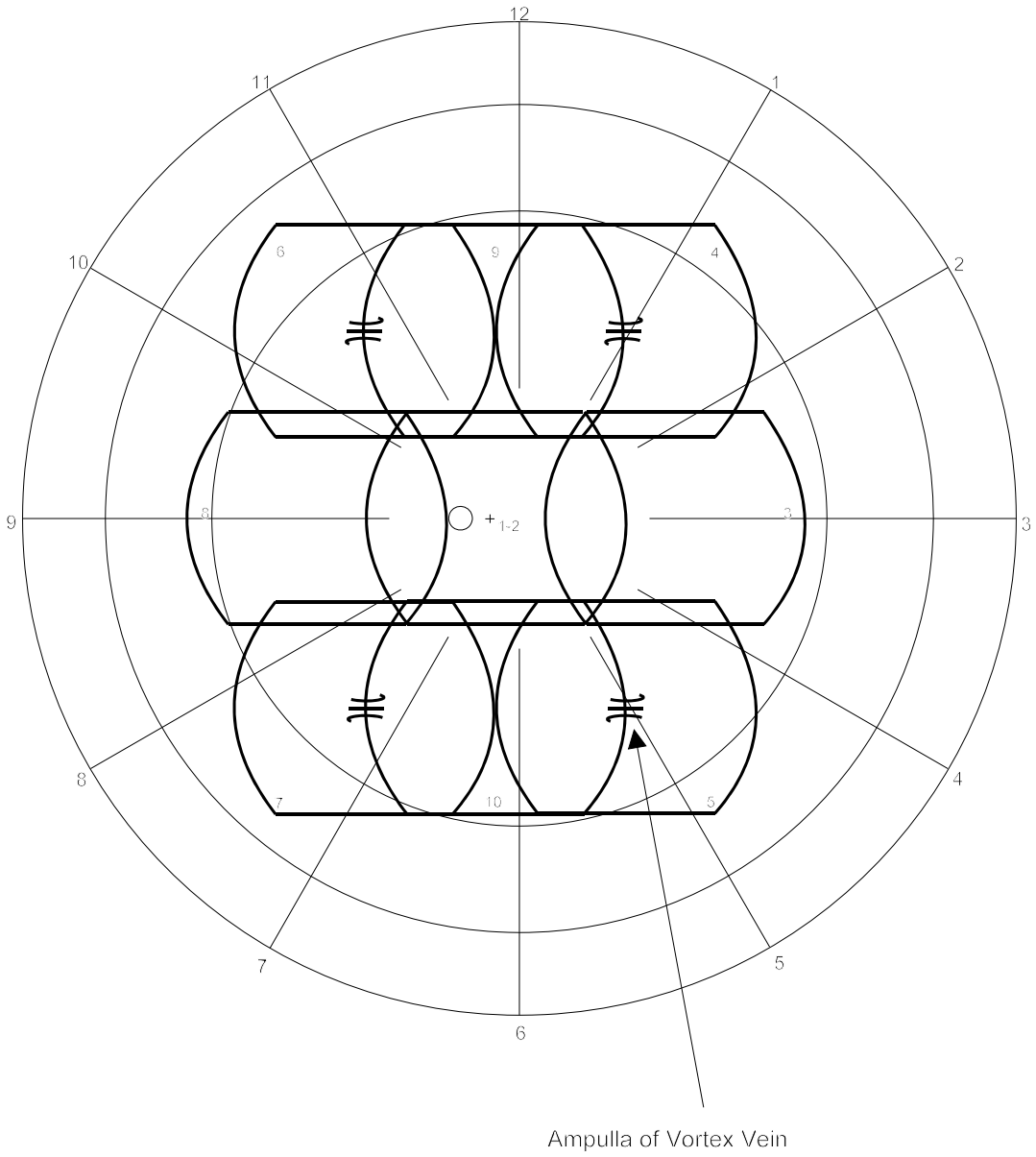
Sometimes it is not possible to obtain even illumination across the entire photographic field, especially in the periphery. This problem is more likely to occur in patients who do not dilate well. If it is not possible to equalize the illumination across the field, it is preferable to restrict the darker area to the more anterior portion of the field.

Diagrams of photographic field positioning in the right and left eye are seen in the two following diagrams

Right Eye Photographic Field Positioning



Left Eye Photographic Field Positioning



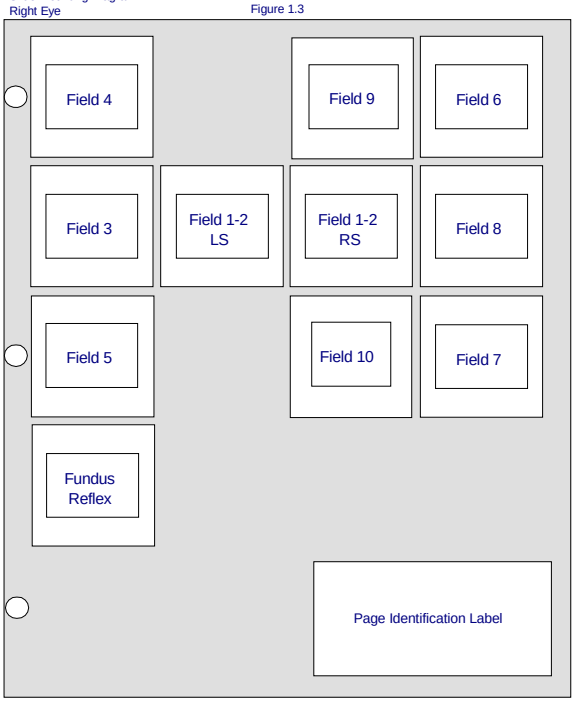
8.0 Mounting and Labeling of Color Film Photographs

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 *SOCA General Handbook &. Fundus photography protocol* document) for slide labeling instructions**.

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 Illustration below).

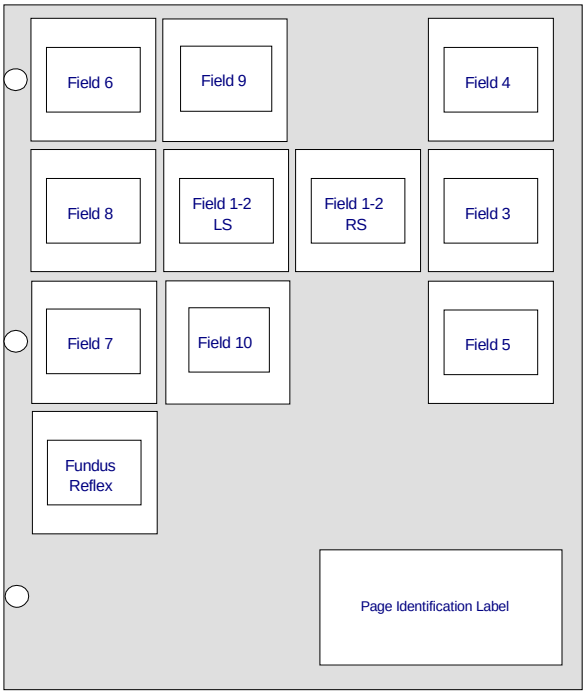
Slide Mounting Diagram
Right Eye

Figure 1.3



Slide Mounting Diagram
Left Eye

Figure 1.4



Slide Mounting Diagram

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 Exporting and Labeling of 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 UW-FPRC on a case-by-case basis.

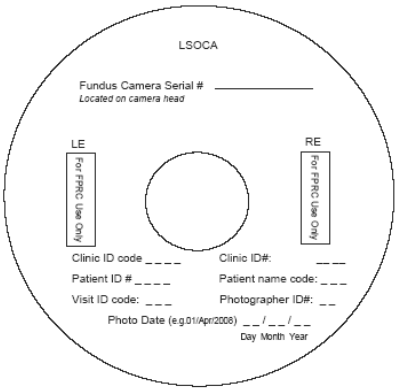
†The UW-FPRC recommends Bardes 20-pocket pages, product #62022C available from Bardes Products, Inc., 5245 West Clinton Avenue, Milwaukee, WI 53223-9839, phone 800-223-1357.

Only the standard methods existing in the software of the imaging system should be used to isolate images for submission. Specific image handling procedures are outlined on the UW-FPRC's website. Digital images should be "burned" to CD/DVD before being archived on the computer system (a process that often compresses the images for storage).

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

For *submissions of study participants* please comply with HIPPA regulations by replacing the subject's ID number, last name, and first name with study specific information, as outlined in **the *UW-FPRC Forms, Labeling, Study Conventions Information* section of the study specific documents** (for OIS systems editing is only possible with specific versions of Winstation®).

For *study submissions* the CD/DVD should be labeled using a circular CD/DVD label (as shown below). These labels are provided by the LSOCA Coordinating Center and include the study name, site information, 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 of each submission should be retained at the site.



Example of CD Label

When shooting the fields digitally, it is preferable to shoot the right eye images first, followed by left eye images and begin photography of each eye by shooting Field 1-2. This procedure will help us separate images from the right eye and left eye when we view the proof sheets. Images of field 1-2 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 optimize 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. Color balance should be reviewed frequently to insure correct evaluation of pigmentary and vascular changes. Images which have over expressed red channels will not accurately reflect changes of these structures.

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, image sharpness and color balance 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 10 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.

1.11 Minimum Protocol When Patients Cannot Adequately Cooperate

Although photographers are strongly encouraged to obtain all of the photographs specified by the protocol at each visit, there may be instances during follow-up in which patients are not able to tolerate the complete procedure. (The full photographic protocol must be carried out at baseline.) In such cases, the following abbreviated procedure (which allows omission of up to four fields if CMV lesions are not present in them) should be substituted:

(1) Take a stereoscopic pair of Field 1-2.

(2) Move nasally to Field 8, and take a photograph.

(3) Move temporally to Field 3, and take a photograph.

(4) Move superiorly to Field 9, and take a photograph.

(5) Move nasally to Field 6 from Field 9, and if any CMV lesions are visible take a photograph (otherwise omit).

(6) Move temporally to Field 4 from Field 9, and if any CMV lesions are visible take a photograph (otherwise omit).

(7) Move inferiorly to Field 10, and take a photograph.

(8) Move nasally to Field 7 from Field 10, and if any CMV lesions are visible take a photograph (otherwise omit).

(9) Move temporally to Field 5 from Field 10, and if any CMV lesions are visible take a photograph (otherwise omit).

(10) Take the red reflex photograph.

If the patient is unable to cooperate sufficiently even to carry out the truncated procedure described above, the photographer should make every effort to obtain the stereoscopic photograph of Field 1-2. If opacities of the ocular media are so great that no red retinal reflex is observed, the photographer should obtain only the "red reflex" photograph to document the opacities.

12.0 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 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 SOCA General Handbook &. Fundus photography protocol document)**.

13.0 Evaluation of Photographic Quality

Color photograph/images of each eye are reviewed and assigned a grade for overall quality. A Confidence Score of 1 indicates that a set can be evaluated with no problem. A Confidence Score of 2 signifies that a set can be assessed, although the image quality compromises the evaluation somewhat. A Confidence Score of 3 indicates that a set cannot be completely evaluated.

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.

14.0 Pointers on Photographic Technique

14.1 General

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 1-2. This procedure will help us separate images from the right eye and left eye when we view the proof sheets. 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, un-needed images.

14.2 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.

14.3 Field Photographic Sequence

When the modified 9-std fields are taken, the following sequence is recommended: disc (Field 1-2), temporal to macula (Field 3), nasal to optic nerve (Field 8), superior to macula (Field 9), temporal (Field 4), superior nasal (Field 6),inferior to macula (Field 10), inferior temporal (Field 5), inferior nasal (Field 7). Fields 1-2, 3 and 8 should be taken on the same horizontal plane. Field 1-2 is taken as a stereo pair.

14.4 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 Field 1- 2.

When the photographer moves to Field 3, 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 (Field 1-2) 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.

14.5 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 Allen[4] 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.

Stereo pairs of field 1-2 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.*

14.6 Exposure, Gain and Flash

It is very important that photographers utilize flash, gain and gamma changes to avoid overexposure or grainy effects in the images. To safeguard against this, we recommend that photographers use the camera controls available to insure good exposure and image quality throughout the angiogram.

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.

Questions or Comments

For questions or comments concerning this photography procedure, please contact the UW-FPRC photographic consultants, Dennis Thayer; thayer@rc.ophth.wisc.edu

15.0 Reference

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