

Fundus Photograph Reading Center

Autofluorescence Using Confocal Scanning Laser Ophthalmoscope (cSLO) Instruments (AF-D)

Effective Date: 27 Jun 2012

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1. Overview

This document details the Fundus Photograph Reading Center (FPRC) procedure for photographer certification, provides instruction to image autofluorescence using cSLO instruments, and offers pointers on imaging technique.

Digital systems must be certified for each study separately. See the *Digital System Certification* document for further details.

Further clarification regarding any information included in this document may be obtained by contacting the FPRC Imaging staff at (608) 410-0619 or by sending an email to Imaging_administrators@rc.ophth.wisc.edu.

2. Photographer Certification

2.1. Overview

Photographer certification is specific to each study, and photographers taking digital images for studies evaluated by the FPRC must be certified for the relevant procedure(s) before submitting actual subject images. The certification images may be taken on subjects being photographed for clinical purposes or of volunteers. Once a photographer is certified for a specific study, he/she is certified for the duration of that study, provided he/she meets the quality standards set by the FPRC. See section 6 Evaluation of Image Quality.

2.2. Certification Requirements

Certification consists of:

- Review of the study synopsis/protocol and imaging procedure(s)
- The ability to perform the imaging procedure(s), demonstrated by the submission of images of acceptable quality

2.2.1. Images Required if Previously Certified

The second certification requirement listed above will be waived if all of the following criteria are met:

- The photographer has prior certification at the FPRC using **an identical procedure**
- The photographer has been actively taking images during the past 12 months
- The images are judged to be of good quality by the FPRC

If a photographer feels that these criteria have been met or has been certified by the FPRC for a similar procedure, submit a certification request (see section 2.3 Submission for Certification) without sending images.

2.2.2. Images Required if Not Previously Certified

Submit a certification request (see section 2.3 Submission for Certification) and send autofluorescence and infrared images of four eyes (two right eyes and two left eyes)

taken using this procedure (AF-D). Two of the eyes should be normal, and two of the eyes should have autofluorescence changes.

2.3. Submission for Certification

Photographers are encouraged to send complete submissions for each procedure for which they are requesting certification (i.e., if four eyes are required for a certification submission, send image submissions for all four eyes together).

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 and unsuccessful certification submissions.

2.4. Uncertified Photographers

2.4.1. Baseline/Screening Visits

Only FPRC-certified photographers are allowed to take baseline (screening visit) photos, unless an exception to this rule is granted (on a case-by-case basis) by the study sponsor. The baseline images for a subject are critical since all follow-up measurements are compared to this point to determine the study outcome.

The sponsor may suspend subject enrollment if the site does not have a certified photographer available to take the baseline images.

2.4.2. Follow up Visits

On rare occasions during **follow-up** visits ONLY, 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 he/she understands the procedure and follows the study requirements. Include a comment with the submission or any official documentation indicating that the images were taken by an uncertified photographer and the reason why.

3. Equipment

Currently only Heidelberg HRA2[®] or Spectralis[®] systems can be used. Each system used must be FPRC certified for autofluorescence capture capability. For details about how to certify a system refer to the *Digital System Certification* document. Contact the FPRC if you have a cSLO system other than a HRA2 or Spectralis that you would like to use.

4. Acquiring Infrared and Autofluorescence Images

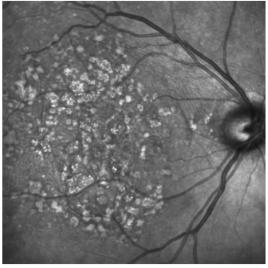
Color retinal images should always be taken before the autofluorescence images to increase retinal exposure to light and precipitate additional photoreceptor photopigment bleaching. When obtaining autofluorescence scans, it is important to have the patient's cooperation and steady fixation. The scanning takes approximately 4-5 seconds, so a stable head position is important to

maximize the quality of the autofluorescence image. It is also desirable to have pupil dilation of at least 4mm. The cornea should be undisturbed by prior examination with diagnostic contact lens.

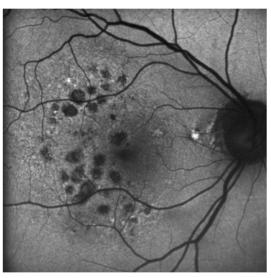
A total of four (4) thirty-degree (30°) images—two for each eye, one (1) infrared and one (1) autofluorescence—should be acquired, and submitted as .E2E files.

Images should be acquired in high speed (768x768 resolution) mode to reduce the effect of eye movement. The Heidelberg instruments allow for the capture of autofluorescence images at either high resolution (1536x1536 resolution) or low resolution (noted as high speed in the software).

Acquire infrared and autofluorescence images using the Automatic Real Time Mean (ART Mean) function set at approximately 25. In cases where poor fixation or media opacities results in a poor composite image, attempt to re-image until an acceptable result is attained. An acceptable infrared and autofluorescence image is taken at 30° and has clear focus with good contrast (Illustrated in the IR and AF images below).



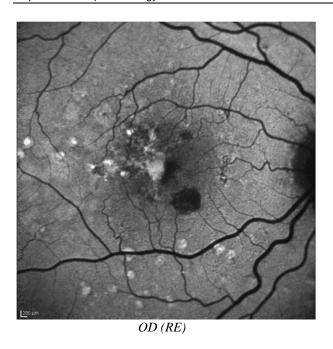


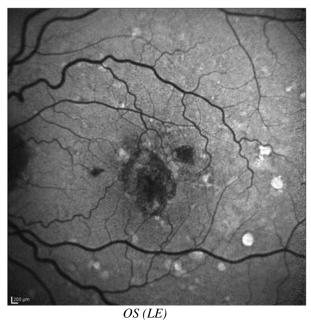


AF Image

4.1. Standard Fields

When capturing autofluorescence images, the HRA2 or Spectralis should be set at 30°, and the macula should be centered in the image as illustrated in the images below.





5. Format of Study Images Submitted to the FPRC

Images should be saved in the E2E format. For additional information on specific image-handling procedures, see the *Digital System Certification* document.

6. Evaluation of Image Quality

6.1. At the Study Site

The infrared and autofluorescence 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, 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.

6.2. At the FPRC

Autofluorescence 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.

7. Pointers on Imaging Technique

7.1. General

Photography of the photophobic subject can be challenging for the photographer and uncomfortable for the subject. Minimizing the length of time the eye is exposed to the

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scanning light can help make the photography procedure more comfortable. Additionally, keeping the room lights as low as possible can help make the photography procedure more tolerable. Patients should be asked to blink a few times immediately before the scans are acquired, trying not to blink during the scan.

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.

7.2. Focus/Clarity

The best image quality is obtained if corneas are not disturbed by prior examination with a diagnostic contact lens.

Focusing the image in red-free light *does not guarantee* crisp focus of changes appearing at the level of the RPE. Review the images on the computer monitor, adjusting focus as necessary, to obtain the best image sharpness.

7.3. Exposure

Very little light is emitted from autofluorescent structures. Imaging the weak autofluorescent light requires a careful balance between camera alignment and the sensitivity control to minimize electronic "noise" caused by a sensitivity level that is too high.

Position the cSLO carefully to obtain an even illumination of the scanned area. No stereo images are taken.

Autofluorescence images should be taken before fluorescein or indocynanine green angiography is performed since the presence of these dyes can interfere with image quality.

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