ARIC Neurocognitive Study

Retinal Imaging Protocol

University of Wisconsin-Madison
Ocular Epidemiology Reading Center
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1. INTRODUCTION

The Atherosclerosis Risk in Communities Study (ARIC) recruited and examined 15,792 black and white men and women aged 45-64 in 1987-89, followed by periodic comprehensive examinations that included brief cognitive function tests. The ARIC Neurocognitive Study (ARIC-NCS) will include comprehensive measures of cognitive function for the survivors, aged 67-89, with cerebral imaging on a sample of participants, including a functional measure of cerebral blood flow. The overall goal is to demonstrate long-term prediction of poor cognitive function in the elderly based on modifiable vascular risk factors. The study will also identify persons with mild cognitive impairment (MCI) who may be amenable to the benefits of risk factor modification because of evidence that their impairment has a vascular basis. The ARIC-NCS is co-funded by three NIH institutes:
Lead sponsor; National Heart, Lung and Blood Institute (NHLBI); the National Institute of Neurological Disorders and Stroke (NINDS); and the National Eye Institute (NEI).

For the retinal examination section of the ARIC-NCS, approximately 2,600 subjects from the four ARIC communities in the U.S. will be examined. The four sites include Wake Forest University (WFU), University of Minnesota-Minneapolis (UMN), University of Mississippi-Jackson (UM), and Johns Hopkins University (JHU).

In both the ARIC 3-Eye and ARIC 5-Carotid Eye, retinopathy and vessel measurements (VM) were determined using 1 field of 1 randomly chosen eye using a nonmydriatic film camera. In the ARIC-NCS, two fundus photographs of two fields of both the right and left eyes of each participant will be taken using a Canon CR-1 Mark II digital fundus camera. These photographs will be graded at the Ocular Epidemiology Reading Center (OERC) at the University of Wisconsin-Madison for retinal microvascular characteristics, including focal arteriolar narrowing, arterio-venous nicking and retinopathy (e.g., microaneurysms, retinal hemorrhages). In addition, generalized arteriolar narrowing will be quantified using a computer-based measure of retinal vascular caliber. Other significant retinal conditions will also be noted, such as retinopathy or vascular occlusions in people with and without diabetes.

2. EQUIPMENT AND SUPPLIES

2.1 Equipment

A Canon CR-1 Mark II fundus camera equipped with a Canon EOS 50D (15.1 megapixels) camera back will utilize the Canon Retinal Image Control Software (RICS) for this project. The fundus camera will be mounted on a motorized instrument table to allow maximum subject and photographer comfort and optimum camera alignment. Both photographer and subjects will have pneumatically adjustable stools. Subject stools will have a backrest.

2.2 Supplies

An inventory of supplies for each of the 4 study sites follows:

(a)	1 box	Long-grain Red Cross sterile lens cotton batting, (4 oz/box) (such as Kendall CURTIY Lakeside cotton roll (p/n 6030). It is nonsurgical bleached cotton and comes in one pound rolls.)
(b)	1 bottle	Lens cleaning alcohol, (100% alcohol, 8 oz/bottle)

(c) 8 boxes Facial tissues, (200/box)
(d) 1 canister Compressed air with plastic delivery tip
(e) 1 box Chinrest paper, (500/box, p/n CO-AP)

The chinrest paper may be obtained from Synemed, Inc. 4562 E. Second Street, Benicia, CA 94510, 800/777-0650. CURTIY Lakeside long-grain sterile lens cotton batting can be purchased at a Walgreens or CVS type pharmacy or on-line. The 100% alcohol may be obtained in pint bottles from Fisher Scientific (www.fishersci.com or 800/766-7000) Catalog 04-355-450 Decon Laboratories No 2716TP.

3. EQUIPMENT SET-UP

The fundus camera, set on the motorized instrument table, should be placed in a room that can be completely darkened during the imaging procedure. This is because no dilating drops will be used and we rely on the natural dilation of the pupil that occurs in the dark to perform the fundus imaging. The camera should be placed in the room so that the subject has easy access to the examination stool (with backrest) and so the photographer has ready access to the room light switch. The computer screen and camera panel light provide enough illumination to allow the photographer to see and navigate and can be adjusted (not shining light into the subject's eyes) to minimize pupil constriction.

The EOS camera should not be turned off. Please confirm that the function dial on the EOS camera is set to "M" (for Manual), the display screen is illuminated and the camera on-off lever is in the "On" position before beginning photography. Please check that the camera is connected to the laptop and that the laptop is connected to the Internet, which will allow images to be transferred to the reading center (a wireless connection is acceptable).

3.1 Daily Set-up Procedures

The camera dust cover and lens cap should be removed at the beginning of the day and the lens inspected (see section 3.2) and cleaned, as necessary. Dust is the greatest enemy, producing the majority of artifacts on the images. When the camera is not in use, the lens cap should be in place and the special dust cover should be placed over the camera.

3.2 Camera Lens and Body Care

Before each subject is photographed, the camera lens will be inspected and if dusty, cleaned with an air bulb or canned air to remove loose debris. Should more extensive cleaning of the lens be required, the lens can be fogged with your breath or moistened with absolute alcohol. Cotton should then be used in a circular polishing motion until no dirt or oily film is visible on the lens when it is viewed from the front or when images are captured (see pages 30-31 in the Canon CR-1 Mark II Operation Manual). The body of the camera should be kept clean and free of dirt with a soft cloth and water or a common spray cleaner. The forehead rest should be cleaned between subjects with isopropyl alcohol pads. High humidity or temperatures must be avoided. Dusty conditions mean that the camera will need frequent cleaning.

3.3 Instrument Table and Stools

The instrument table and stools can be kept clean by wiping with a common spray cleaner and a soft cloth. Occasionally the castors on the table and stools might squeak, requiring a drop of light oil. The electric motor on the table requires no lubrication.

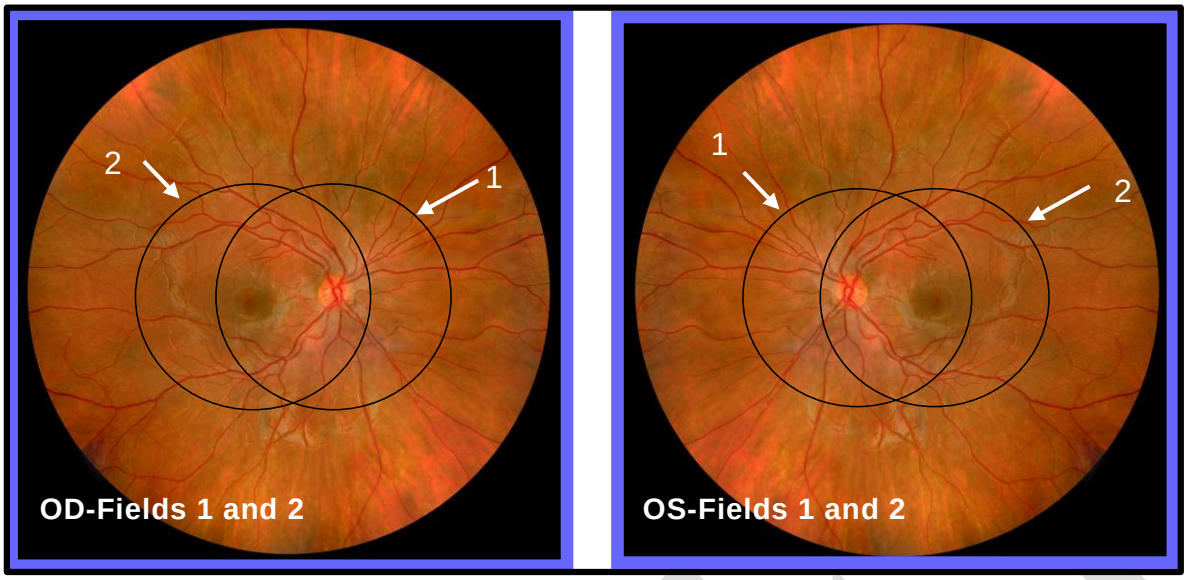
3.4 Camera Malfunctions or Errors

Since the camera requires virtually no other maintenance, any malfunction will need to be investigated first by the examiners at each center and when necessary, via telephone with the OERC staff. Trouble-shooting tests can be performed in consultation with the OERC staff to diagnose most malfunctions. Because the photographer can see the digital images immediately after they are taken, the photographer may be able to detect and correct problems by retaking the image(s). This includes problems with a dirty objective lens, improperly focused images or missed images caused by a subject's blink, or other software/hardware malfunctions.

Some camera malfunctions or photographer errors may not be evident to clinic staff during imaging and will not be discovered until the digital images are reviewed at the OERC. This includes unusual image artifacts or problems related to the camera or software. For this reason, the images will be transmitted directly to the OERC after each subject is photographed. Additionally, a telephone should be available in the camera room so that the site photographers and the OERC imaging consultants can communicate should a malfunction be discovered during imaging or if the photographers have a problem or question needing immediate attention. For imaging questions, contact Michael Neider at 608/410-0628. For computer questions or problems, contact Tony Fairbanks at 608/265-2625.

4. SUBJECT IMAGING OVERVIEW

All subjects will have two 45-degree images taken of each eye with the "study eye" (as determined at the ARIC Visit 3), being taken first. The first image, centered on the optic nerve, is referred to as Field 1. The second image, centered on the macula, is referred to as Field 2. On rare occasions, when it is only possible to obtain one image of an eye (e.g. when the subject cannot tolerate the procedure or refuses multiple images) the Field 2 image should be taken. A diagram of the location of the two fields can be seen below in Figure 1.



Images compliments of Richard Hackel

Figure 1

4.1 Subject Exclusion

The photographer will attempt to take images on all subjects, including some with poor visual acuity who may be unable to direct their gaze so that their optic nerve or macula is properly positioned on the camera monitor. This may be the case when the subject is blind in both eyes or when the subject is deaf and communication with them is too difficult. In these cases, the photographer should get the best field definition possible.

The photographer should attempt to take images on those subjects who are physically disabled, to the point that they can be comfortably positioned at the camera. To facilitate this, the subject can remain in a wheelchair positioned before the motorized camera table lowered to the appropriate height. Care should be taken when lowering the camera table to avoid pressing against the subject's legs.

If, in the photographer's judgment, no acceptable image can be taken of either eye, the subject will be excused from photography and the reason for not collecting retinal images should be documented in the comments section of the Retinal Examination Form (REX) (Attachment 12.1) accessed through the ARIC-NCS website.

4.2 Pre-examination Procedure

This ARIC-NCS Retinal Imaging Protocol uses terminology from the Canon CR-1 Mark II Operation Manual and it is recommended that both the protocol and the manual be reviewed by each photographer before attempting to take any images.

4.2.1 Subject/Guardian Explanation

Imaging begins with a complete explanation of the procedure to the study participant by the photographer. A color illustration may be useful to show what the retina looks like. It is important to reassure the subject that no retinal damage will result from this procedure. The subject should know to expect several flashes. The pictures will include one taken of the macula (area of central vision) and it is normal to experience a blue or red tint to vision immediately following the flash. This disappears within 5-7 minutes. No dilation drops will be used for this examination, and the eyes will not be touched. A sample script of a typical retinal imaging explanation (suitable for use as written material for deaf or interested subjects) follows:

We will be taking several images of the inside of the back of both of your eyes (the retina) so we can study the blood vessels and look for any unusual changes. We will not be touching your eyes or giving you any eye drops to take the pictures. Instead, you will be asked to sit in a darkened room before a special camera with your chin in a chin rest. We darken the room so that your pupils will dilate and we can align and focus the camera on your retina. During the aligning process you will only be aware of a green dot visible in the camera lens. We will ask you to follow the dot as we move it. Just before we take the images, we will ask you to blink your eyes and then open them really wide. The camera will flash a light from within the camera lens as each image is taken.

Just after the image is taken, you may see a blue or red circular spot before the eye that was just photographed. This will disappear within 5-7 minutes and causes no damage to the eye. Please remember that we are only taking images (not an x-ray) of a small portion of the back of your eyes and that this image will not substitute as an eye examination. You will certainly be notified should we notice anything requiring immediate attention. Please continue to see your eye doctor on a regular basis for your complete eye examinations.

5. EXAMINATION PROCEDURE

5.1 Subject Positioning and ID Entry

Before the first subject of the day is imaged, the photographer prepares the camera by turning on the power switchs on the camera unit and laptop computer. The Canon retinal software can be opened by double-clicking on the “Canon CR-1 Mark II” icon (Figure 2).

Figure 2

The User ID and Password (both are ARIC) must be entered into the laptop (see Figure 3).

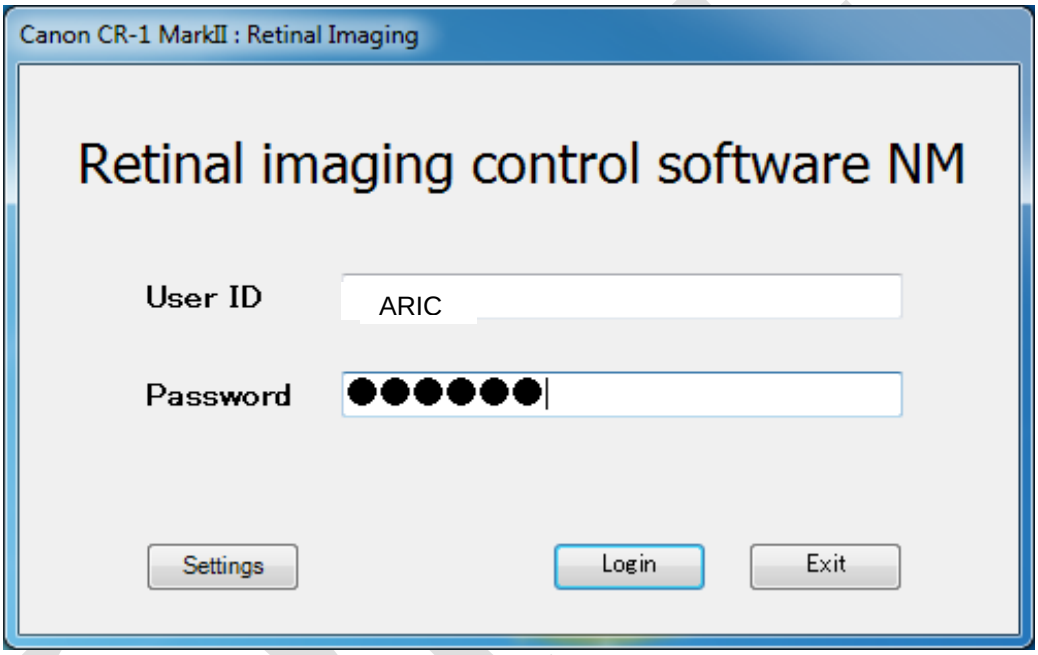


Figure 3

Prior to turning off the room light, the subject and photographer are seated on the appropriate sides of the retinal camera. The camera should be pulled fully back, away from the subject, so they don’t bump the lens when they sit forward into the chin rest. The subject is positioned so that he/she is comfortable with their chin and forehead in the headrest (Figure 4). The table may be adjusted by raising or lowering the table with the button under the table. Adjustments to the camera height can be made by rotating the joystick clockwise or counterclockwise. Adjustments to the patient’s eye height can be made by using the motorized chinrest button (up/down, Figure 5). Chin height should be adjusted so that the eyes are approximately level with the height adjustment mark located on the headrest post. Next, turn off the room light. The only light in the room should come from the laptop and the illumination light located on the back of the camera. After positioning, have the subject sit back and relax while their eyes dilate in the darkened room.

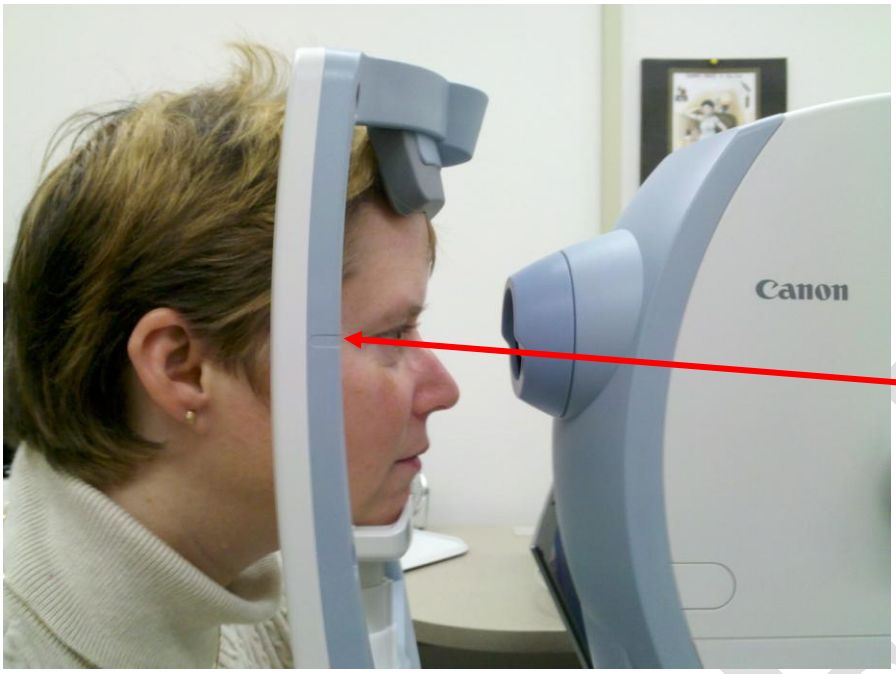


Figure 4

Figure 5

While the subject's eyes begin to dilate, the photographer begins the image capture procedure. The laptop screen should have the main camera software screen displayed on it (Figure 6).

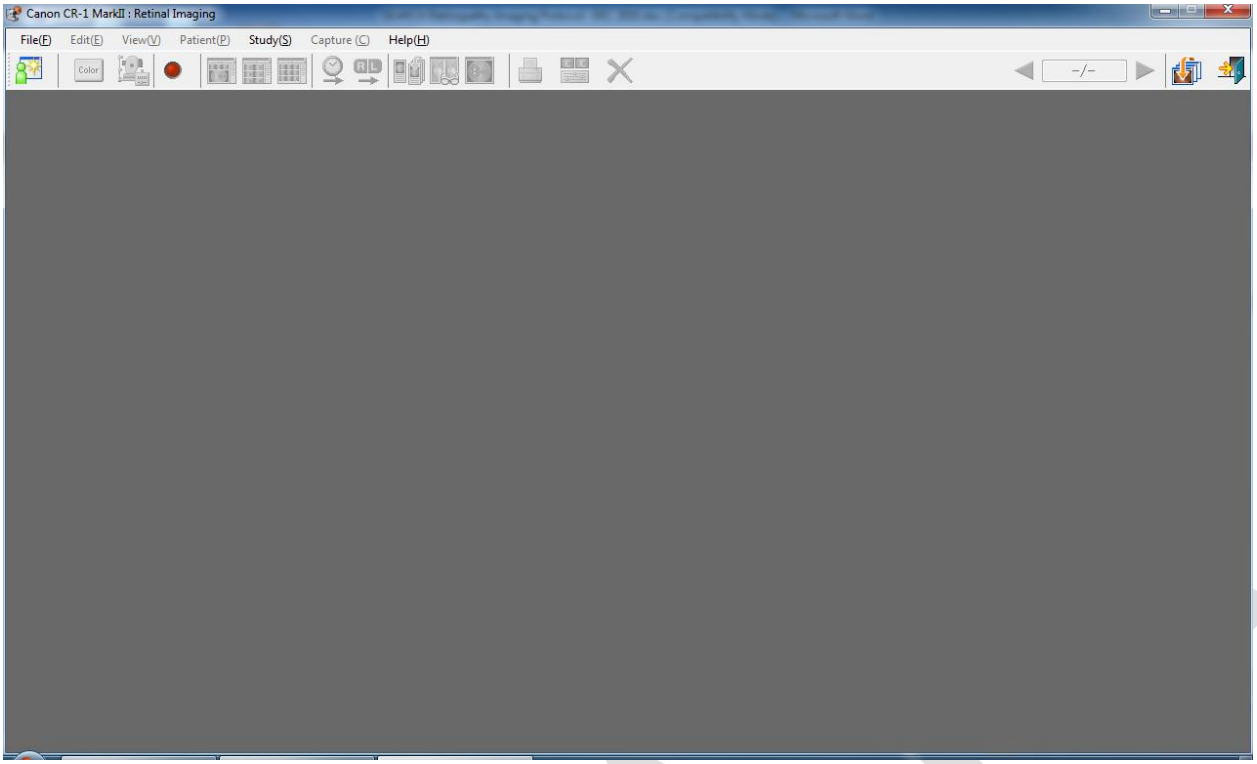


Figure 6

The photographer clicks on the “New” button (Figure 7):

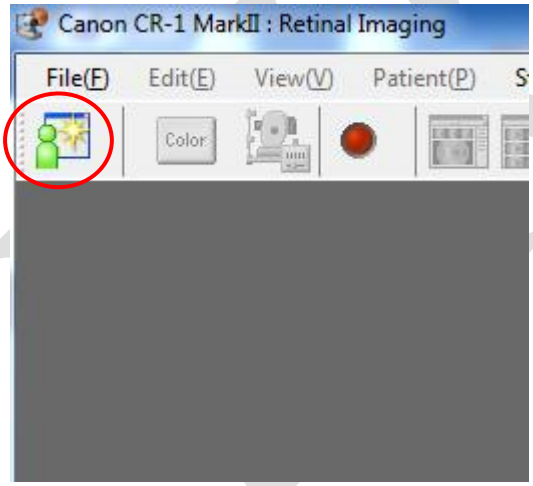


Figure 7

Next, the photographer enters the subject's unique 7-digit subject ID number in the Patient ID text field (Figure 8).

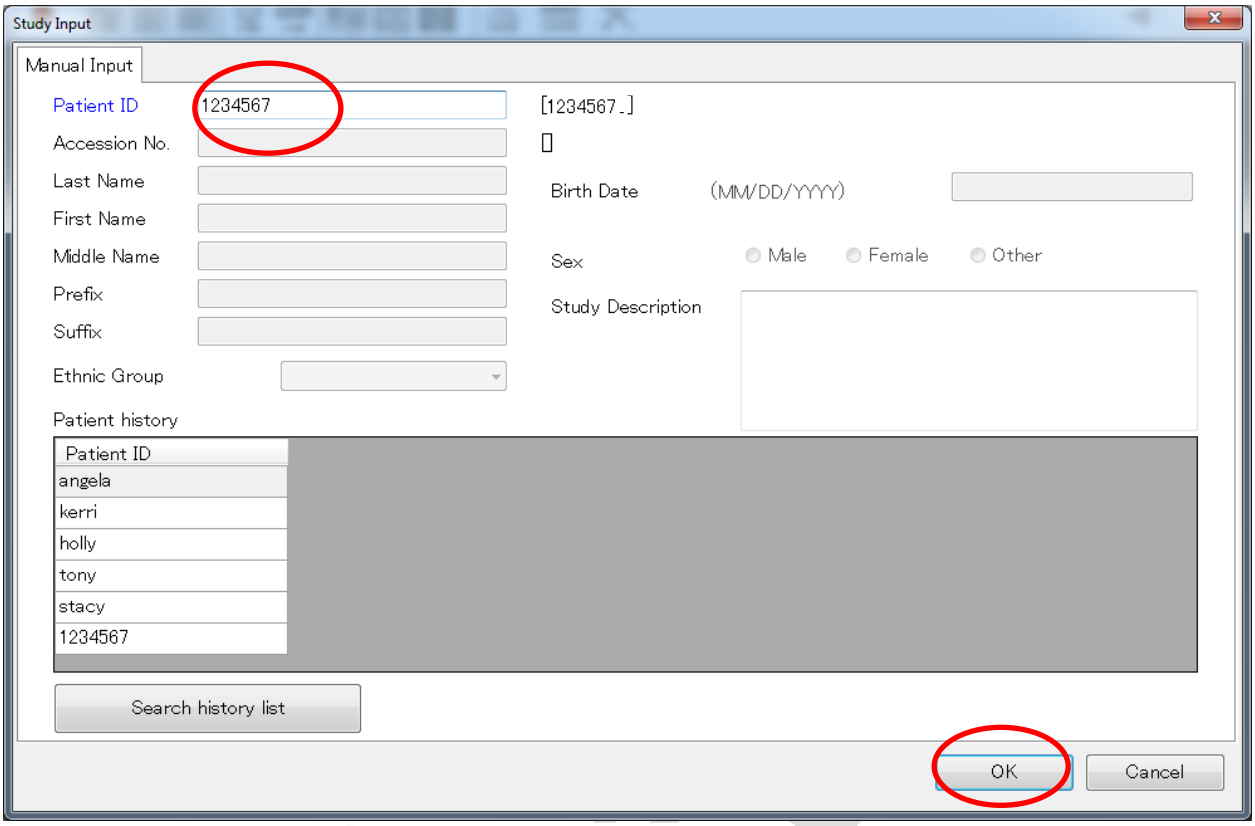


Figure 8

The OK button is clicked after the subject's Patient ID is entered, and the software proceeds to the photography screen.

The camera is now ready to begin taking images.

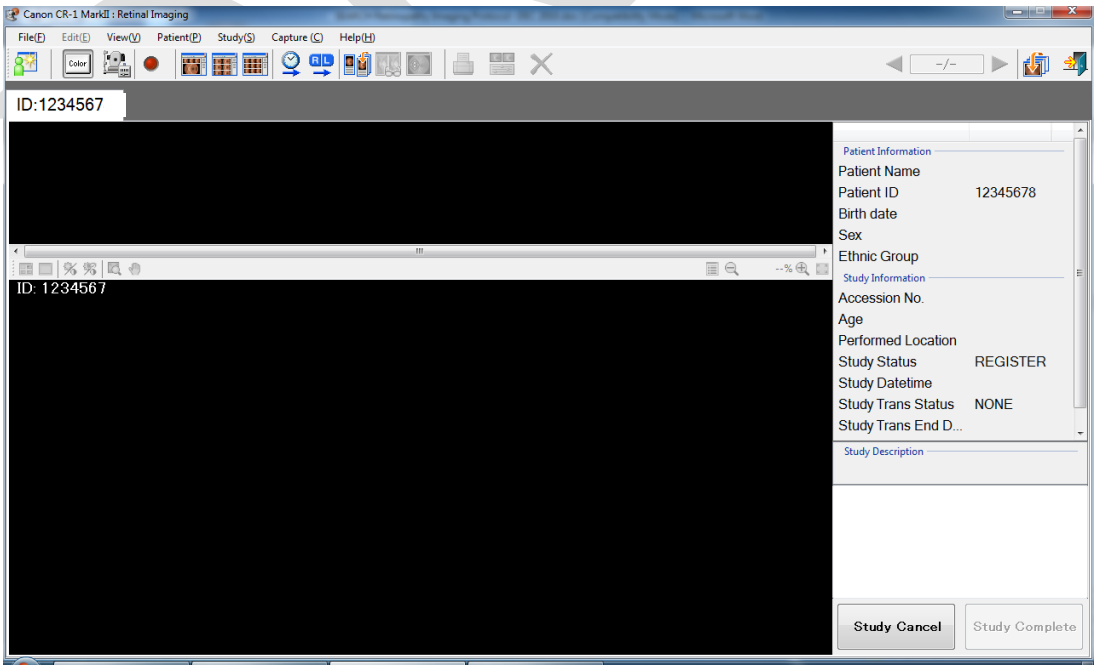
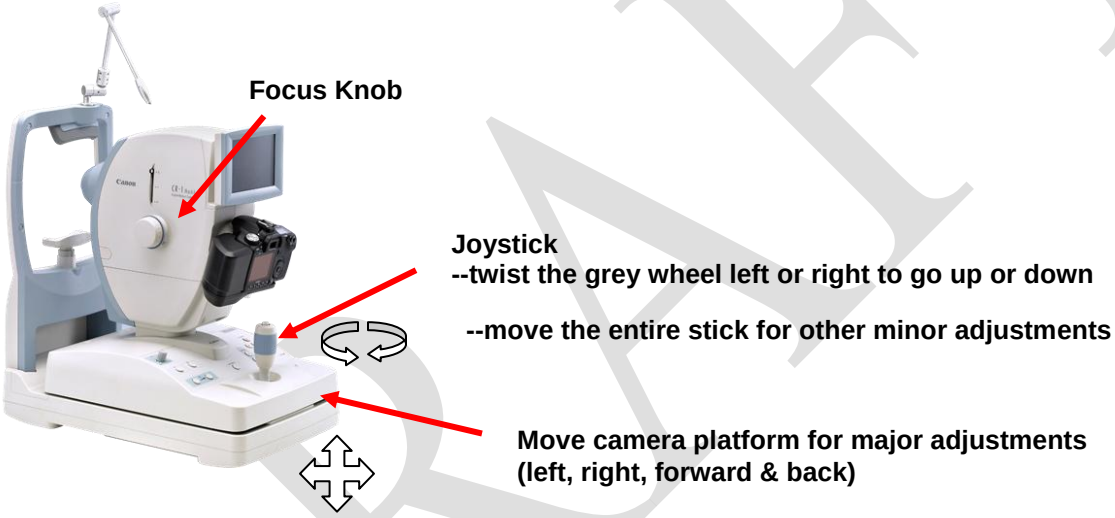
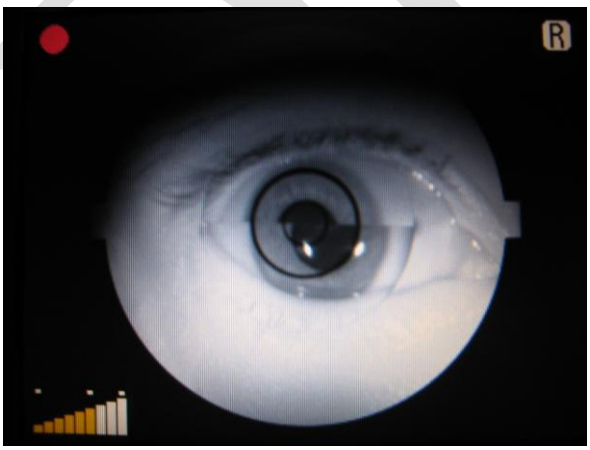


Figure 9

5.2 Pupil Size and External Camera Alignment

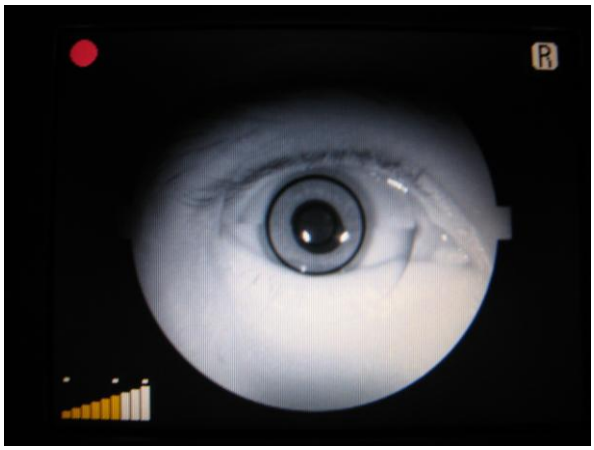
The first step to taking fundus images is to align the camera with the pupil. Once the subject is in the correct position behind the camera, move the camera platform in front of the eye being photographed. The pupil should appear on the camera monitor coincident with the central 4mm diameter circle. Adjust the vertical height if necessary to position the pupil in the circle by turning the joystick. The pupil will appear split and will become round as the camera base is moved forward. Advance the base by sliding it with the left hand while holding the joystick back with the right hand. As the pupil becomes more round, adjust the focus knob to sharpen the image and make fine movements with the joystick until the image of the pupil is no longer split (it should appear as a perfect circle as seen in Figure 11). At this point, proper external alignment has been achieved. A pupil at least the size of the central 4mm circle on the monitor is required for adequate imaging (see Figure 11). If the eye does not dilate to at least 4mm after a 5-minute waiting period, the small pupil aperture (section 6.1) should be activated, and imaging attempted again***. The small pupil feature needs to be un-selected before imaging of the next eye begins, since the pupil size in the other eye may be adequate.***





Unaligned Pupil

Figure10



Proper Pupil Alignment

Figure 11

5.3 Internal Eye Alignment

Once proper external positioning is complete, press the alignment button located in front of the joystick on the camera base to move into the posterior segment of the eye (Figure 12). The Photography Status Display dot will switch from red to green, the retina will become visible, and the photographer will see central white horizontal focus bars; a green fixation dot, working distance dots, and the Photography Status Display dot on the camera monitor (see Figure 13). If no working distance dots are seen, the joystick should be adjusted forward or backwards until they appear. The camera joystick is rotated to raise or lower the camera or is moved left or right to position the eye in the center of the viewing screen. The fixation target may be moved by adjusting the Fix Target buttons on the camera base (see Figure 12). The photographer will manually adjust the focus knob and should confirm good focus by checking that the horizontal focus bars are aligned and look like the image in Figure 13.

Alignment and fixation buttons

Figure 12

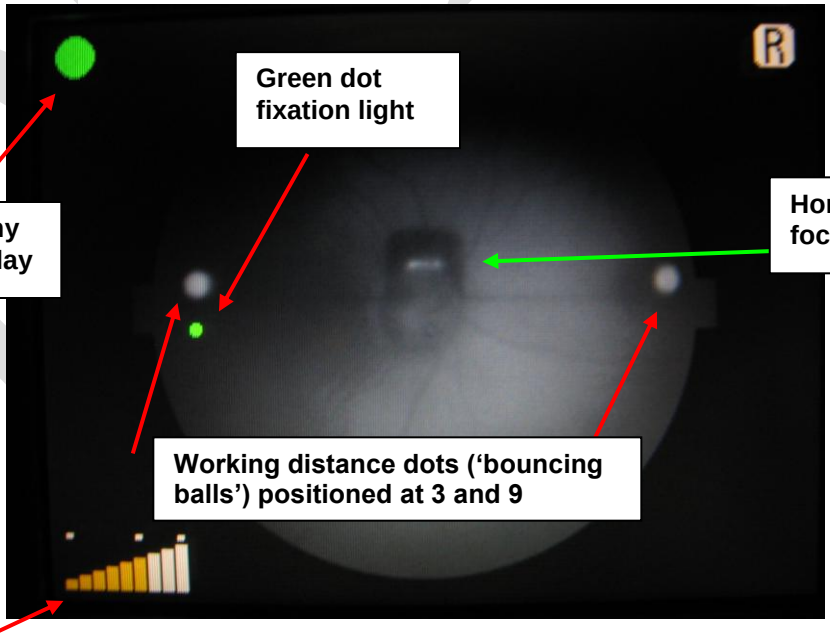


Figure 13

The focus bars are only visible when the diopter compensation lever is in the “0” position. This position is used for almost all subjects and allows imaging of eyes with a refractive error between -10 to +15 diopters. In subjects with extreme myopia or hyperopia (near or far sightedness) the diopter compensation lever will need to be set to either the “-” or “+” position and focus achieved by dialing the focus knob until the retinal vessels appear sharp on the video display monitor since no focus bars will be present. Obtaining a brighter retinal image by increasing the view light intensity can make it easier to see the vessels and obtain sharp focus.

5.4 Alignment, Focus and Proper Fixation of Fundus Images

The study eye is always imaged first beginning with Field 1 with the optic disc positioned centrally, followed by Field 2 with the macula positioned centrally.

Once alignment and focus are confirmed, the photographer will instruct the subject to blink once or twice just before the images are taken to ensure a moist (and subsequently clearer) cornea. This will also safeguard against unwanted blinks at the moment of exposure. The photographer takes the image by pressing the shutter button located on the top of the camera joystick. Once the saving process is complete, the new image will appear in the lower part of the split screen on the laptop. The photographer will review the image for quality and may take another image if he/she believes a better quality image can be obtained or they may accept the image by simply taking the next image when the subject is ready and the pupil is adequately dilated. As additional images are taken, small thumbnail images will appear in the top part of the split screen above the most recent image taken. Once an acceptable image is taken of Field 1, the photographer moves the fixation target to focus on Field 2 and repeats the above process.

After images of the study eye have been taken, the photographer will repeat the same process for the opposite eye; first capturing Field 1, followed by Field 2.

The position of the fixation target is controlled using the arrows (Figure 12) located on the right-hand side of the camera control panel. A summary of fixation target movement for each image is described below.

Right Eye disc image (Field 1): Using the fixation button, move the fixation dot 2 positions (press the arrow twice) to the left. The disc should be near the center of the camera monitor screen.

Right Eye macula image (Field 2): The fixation dot returns to the default position after each image. To take the macula image, move the fixation dot from the default position 1 position to the right. The disc will be at the extreme right of the view of the camera monitor screen.

Left Eye disc image (Field 1): Using the fixation button, move the fixation dot 2 positions to the right. The disc should be near the center of the camera monitor screen.

Left Eye macula image (Field 2): The fixation dot returns to the default position after each image. To take the macula image, move the fixation dot from the default position 1 position to the left. The disc will be at the extreme left of the view of the camera monitor screen.

5.5 Finishing an Imaging Session

When the photographer has completed the subject's imaging session; he/she will review all of the images in the contact strip and may reject any unwanted images at this time. This can be done by selecting the image to be rejected with the mouse and clicking on the "X" button at the top right corner of the screen (Figure 14).

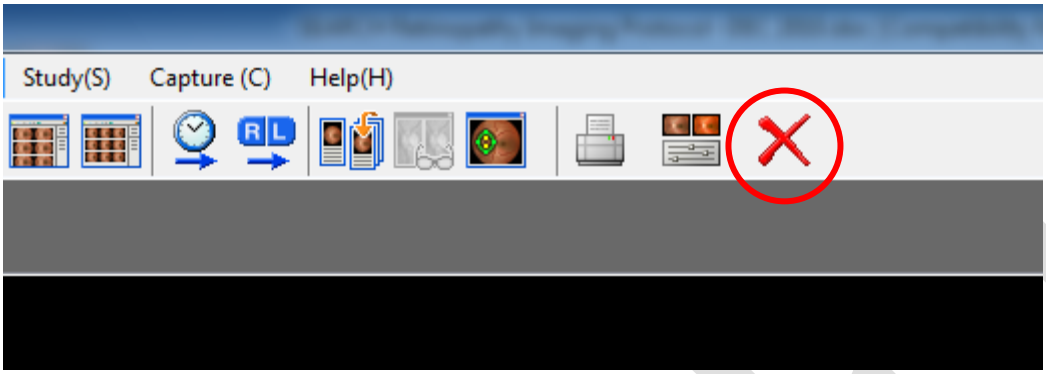


Figure 14

Clicking the red "X" button will mark the image as rejected. This can be seen by the presence of a red X in the lower right of the image in the contact strip (Figure 15).

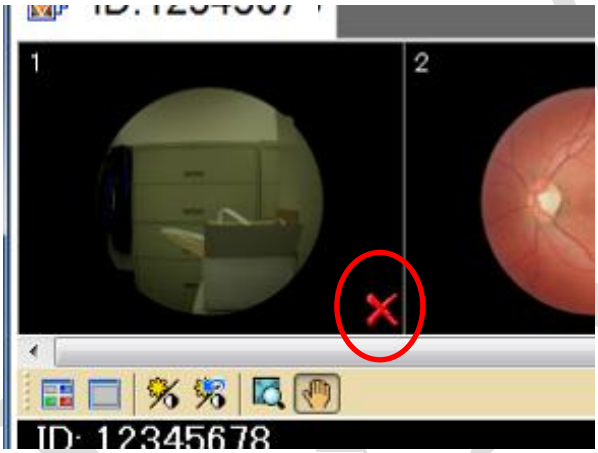


Figure 15

Once the photographer has determined that all images have been taken and is ready to transmit the images, they select the "Study Complete" button (Figure 16).

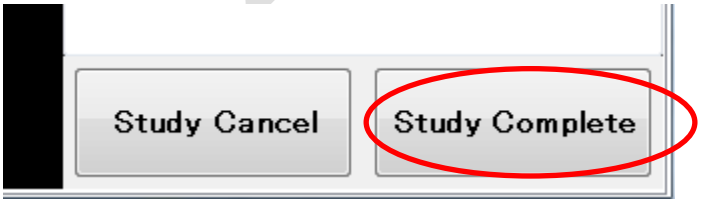


Figure 16

After confirming that imaging session is finished, select 'OK' and the laptop will transmit the images directly to the OERC. The images marked for rejection will not be transmitted.

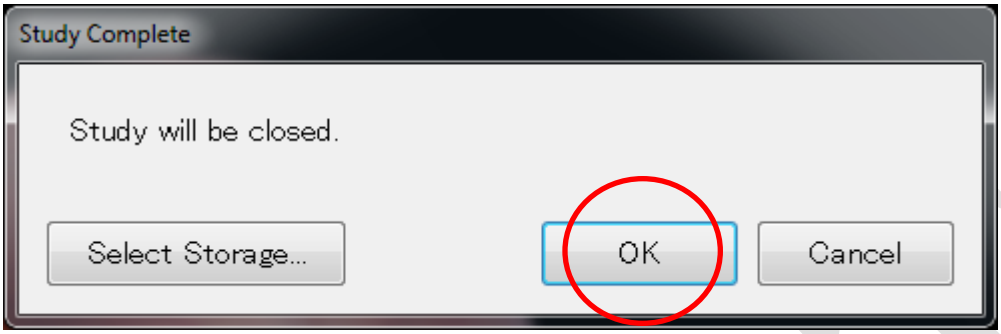


Figure 17

A spinning blue icon will appear in the upper right side of the camera software indicating that a image upload is in progress (Figure 18).

Transmitting photos

Figure 18

Note: If the images are test or training images, see Attachment 12.3 for instructions on how to change the image storage location to the laptop's export folder. This will prevent transmission of the test images to the OERC in Madison.

At this point, the photographer may start a new subject's imaging session by repeating the steps above. Note: If the camera stays on and is inactive for >10 minutes awaiting the next subject, it will go into an energy saving "sleep" mode where the power lamp begins to blink. Using the software or sliding the camera base "awakens" the camera controls. If no other subjects will be seen, the photographer can turn the camera and laptop off.

5.6 Turning Off the Laptop and Camera

Once the imaging session is completed for the day, the laptop and camera should be shut down.

To shut down the laptop, the photographer first clicks the "Logout" button (Figure 19):

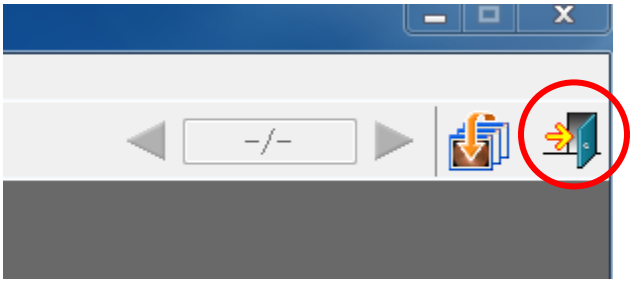


Figure 19

The laptop then returns to the camera software login screen. If there are any images still transferring to the OERC, the Exit button will be disabled and a progress indicator will display until it is finished (Figure 20).

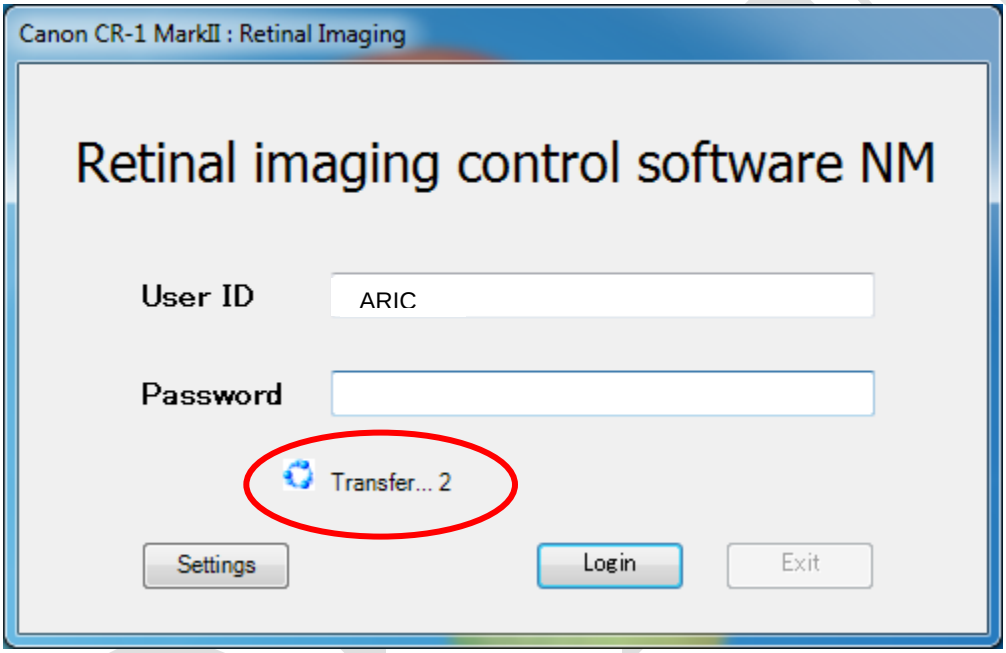


Figure 20

Once transfer is complete, press Exit and shut down the laptop by clicking the Start button in the lower left of the screen, and then selecting “Shut Down.”

Once the laptop is off, the fundus camera can be powered down by pressing the power switch located on the right-hand side. Replace the lens cap and dust cover.

5.7 Image Transfer Problems

If there is ever an issue related to image transmission to the OERC in Madison, the camera software will display an alert in the upper-right corner:

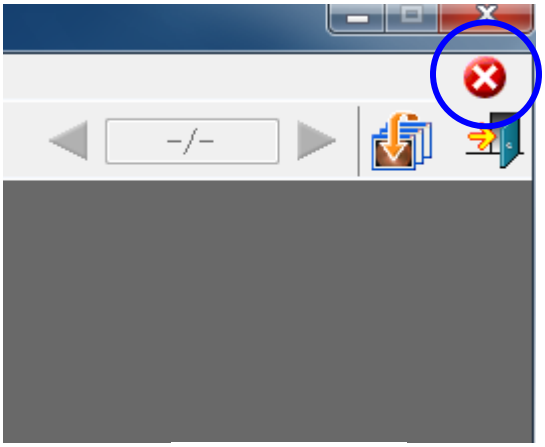


Figure 21

To attempt to resend the images, the photographer can click the “Log out” button. The following screen will be displayed:

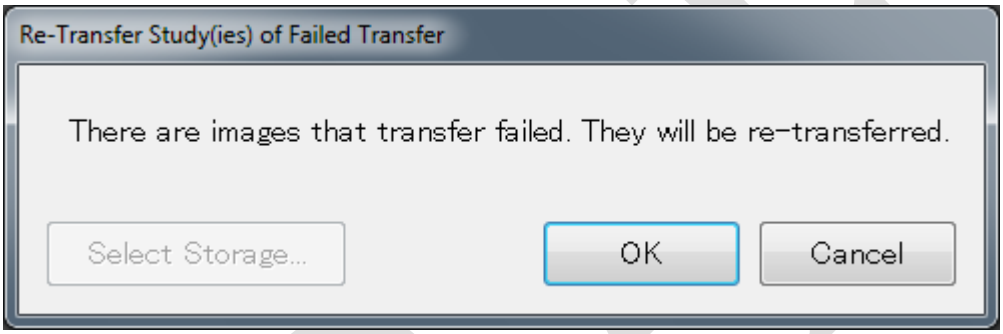


Figure 22

If the images still do not send successfully, the next time the camera software is opened it will again try to re-transmit the images.

6. IMAGING CHALLENGES

Length of an Imaging Session

A difficult imaging session is as frustrating and exhausting for the subject as it is for the photographer. Try to get the best images you can, but be aware of how the subject is tolerating the procedure. An imaging session shouldn’t take more than twenty minutes. Get the distance dots in focus and snap the image as quickly as possible. It is better to take a few images (deleting those of poor quality) than to draw out the process of capturing any one image. Time is of the essence for difficult sessions, so have the most experienced photographer available to work with the more challenging subjects.

6.1 Small Pupils

The photographer will experience much more difficulty in attempting imaging through small (less than 4mm) pupils because all of the light from the camera does not enter through the smaller pupil. This usually results in uneven illumination (seen as dark shadows) on the monitor. In this situation, the photographer must make careful camera adjustments to position

the shadows as far away from the optic nerve in the Field 1 image and away from the macula on the image of Field 2.

A small percentage of subjects' eyes will not dilate to the minimum 4mm required for adequate imaging. Certain medication may prevent any dilation and the pupil size observed on the monitor may be 2-3mm which is inadequate for the photographer to appreciate all retinal landmarks on the viewing monitor. In this case, it is recommended that the photographer activate the small pupil button and decrease the flash level 3 bars (Figure 23). This function adjusts the illumination to concentrate more of the retinal illumination into a smaller area providing more even illumination to the center of the field while sacrificing illumination at the field perimeter (Figures 24-25). If after introducing the small pupil function only one focus line is visible, it may be necessary to adjust the camera position either vertically or horizontally to bring the second line into view or to allow visualization of each line segment individually. In these cases, the photographer may need to adjust focus by estimating when the 2 lines would be aligned so that accurate focus can be set. However, there may be circumstances that prevent the second line from appearing, even when these camera adjustments are made. In these cases, the photographer should increase the viewing light briefly to better illuminate the retinal vessels and focus on the vessels. Sharp focus is confirmed by reviewing the captured retinal image on the computer, adjusting focus and retaking the image as necessary to achieve a sharp image.

Ask subjects with small pupils to try to look through the target and not directly at it, focusing the eyes on the near target light may constrict the pupils.

Small Pupil & Flash Intensity Buttons

Figure 23

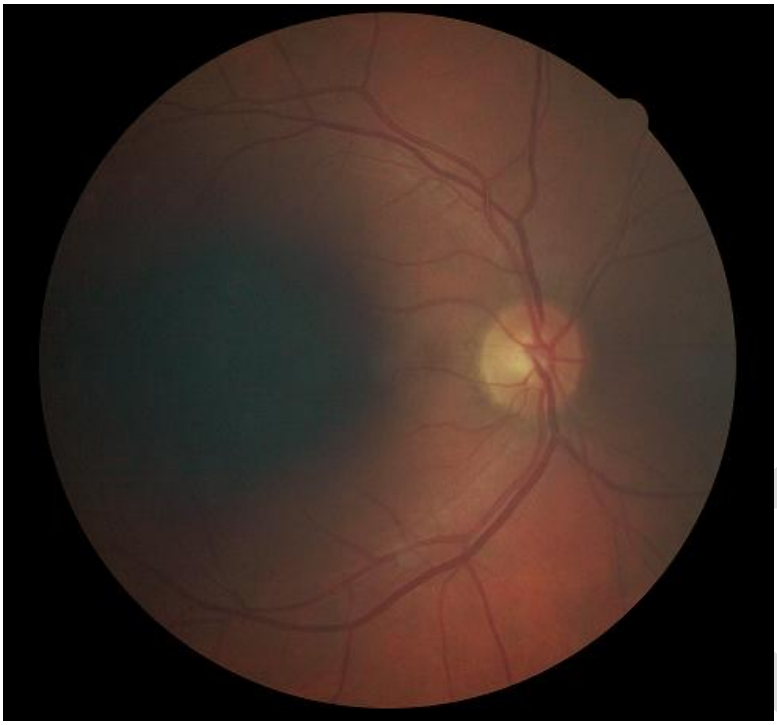


Image taken <u>without the small pupil button selected</u> on an eye with <4mm dilation

Figure 24

Image <u>taken with small pupil button selected</u> on an eye with <4mm dilation.

Figure 25

If no retinal landmarks are visible and the camera is in small pupil mode, (often the case with <2mm diameter pupils), the photographer should adjust the camera slightly to position the corneal reflection dots <u>slightly above or below their optimum position</u>. This technique allows a portion of the illumination light, which falls on the iris when the pupil is small, to enter the eye. If any retinal landmarks become visible with this technique, photography should be attempted.

However, if no retinal landmarks are visible, no image should be taken. This information is then documented in the Comments section of the Retinal Examination Form (see Attachment 12.1).

6.2 Exposure Compensations for Dark or Light Retinas

The flash setting should be adjusted as needed to produce images with good exposure. The recommended standard value is 6 bars on the flash meter. Flash output can be increased or decreased by pressing the flash intensity buttons located on the camera base. More bars increase flash output and produce brighter images while fewer bars decrease flash output and produce darker images. More than a one bar increase or decrease in flash intensity may be needed. Retinal imaging through media opacities or of darkly pigmented retinas (African American or Asian) will require increased flash output to avoid under-exposed images. Imaging of lightly pigmented retinas (blonde, albino or Scandinavian) may require decreased flash output to avoid over-exposed pictures. The photographer should check the color saturation of the first image taken of each subject, and adjust the flash if necessary before proceeding. An example of under and over exposed images is shown below in Figure 26. Note that whenever the flash setting is changed or if the camera is turned off, the camera does NOT go back to the default setting of 6 bars. The flash must be manually reset to avoid over or underexposure of subsequent images.

Over-exposed image
(decrease the flash setting)

Under-exposed image
(increase the flash setting)

Figure 26

6.3 Common Problems Seen

Many of the arcs and other issues seen in imaging are due to poor subject positioning—the subject is too far away or not centered. The subject should always be positioned before the camera base is moved.

a. Poor subject positioning (Figure 27)

Camera is too far away from the subject. Notice the arcs and general haze around the images.

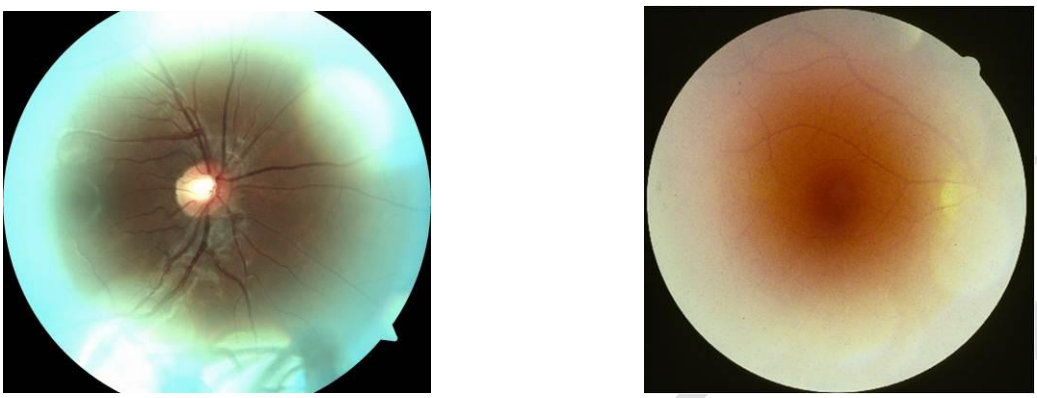


Figure 27

b. Poor <u>camera</u> positioning (Figure 28)

Camera is too far right or left. In this example, move the camera away from the crescent (to the left) to remove the crescent.

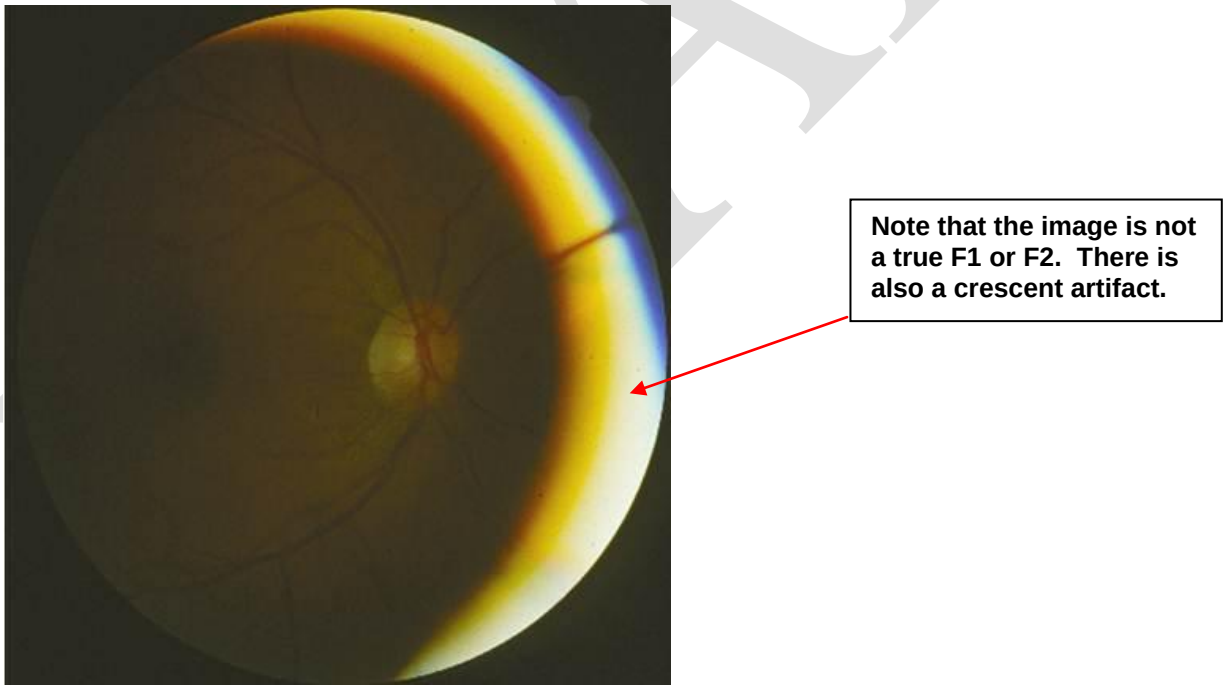


Figure 28

c. Eye lashes and excessive blinking (Figures 29-30)

Eyelashes are commonly seen in images due to the subject anticipating the image, they are photophobic, or the subject can have particularly long lashes. It is important to let the subject know that they can blink. In some cases, subjects may have to hold their own lids open with

their fingers or have another person do it for them. Be aware that this is not comfortable for the subject and that the cornea will dry out very quickly. Obtain proper focus before having the subject holding their lids open, and then take the picture as quickly as possible.

Eyelashes

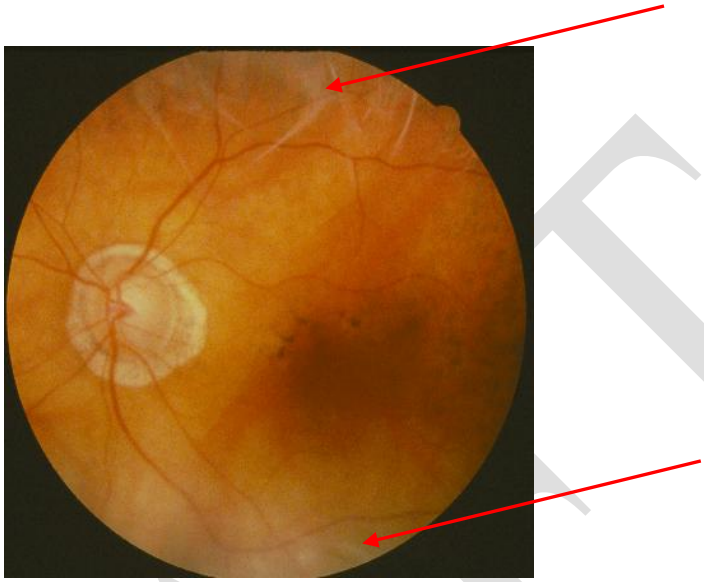


Figure 29

Blinks

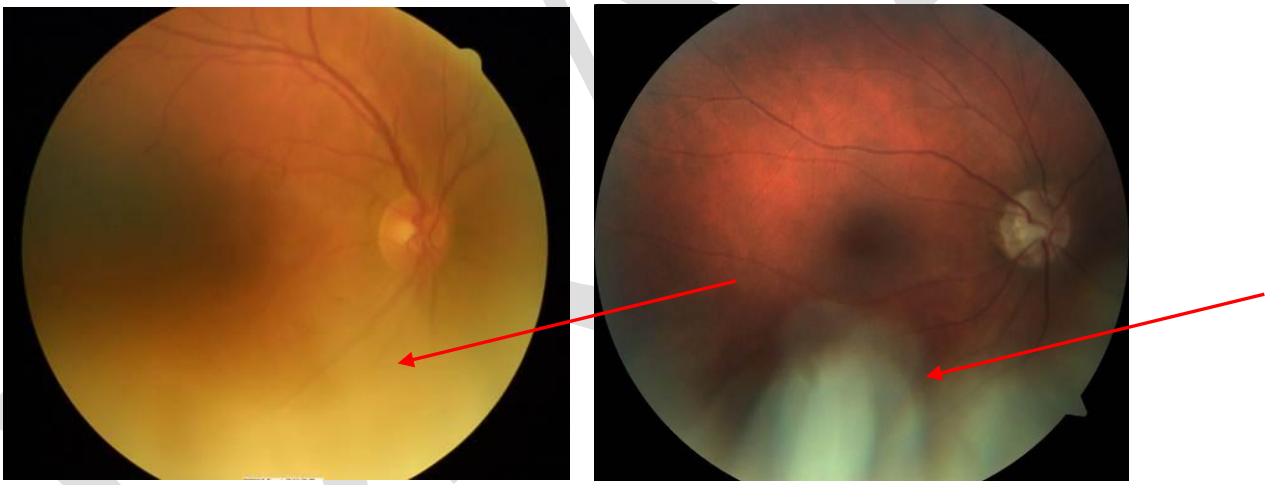


Figure 30

d. Dust & Smudges on the camera lens (Figures 31-32)

At times, the photographer will notice the same artifact in the same place on all the images taken. This is usually dust or a smudge and can be immediately remedied by cleaning the lens with the appropriate lens cleaning supplies. ***Please refer to section 3.2 for details on cleaning the lens.***

Dust

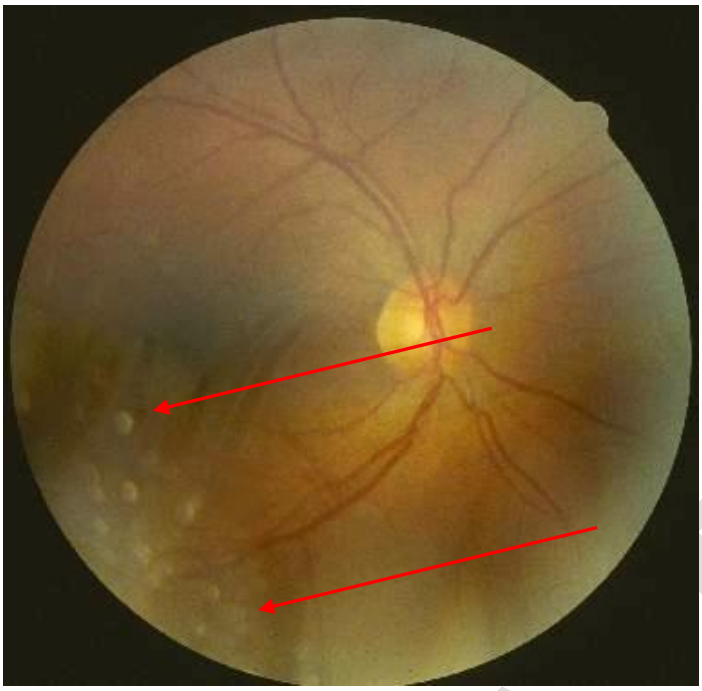
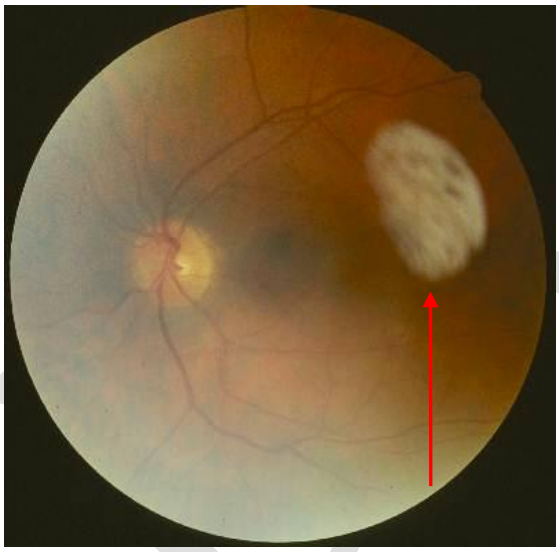


Figure 31

Smudges



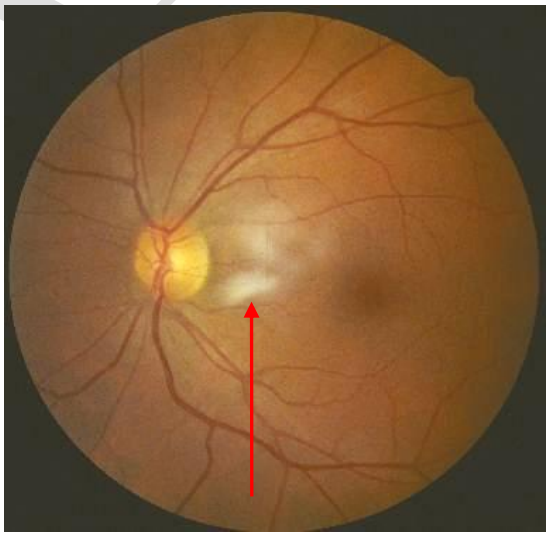


Figure 32

7. RETINAL EXAMINATION FORM

At all sites, the photographer will complete the Retinal Examination Form (REX) for each participant. This can be completed while the subject becomes sufficiently dilated to be photographed. Section A of the form includes questions about the subject's ophthalmic history and Section B has questions specific to the subject's photography session (see Attachment 12.1). The form will be used by the OERC to confirm that the information entered on the REX matches the images transmitted from the camera. Comments or problems with the images or other deviations from protocol should be recorded in the "Comments" box on the REX.

Each photographer will be responsible for filling out the Retinal Examination Form (REX) for each subject. Section B, at the end of the form, includes questions about the photograph session and The OERC study coordinator will confirm to the site coordinator that the images were received and that they match the information on the exam form via e-mail.

8. DIGITAL FILE HANDLING

Each subject's images are transmitted automatically after their imaging session (see section 5.5 for details). The images are uploaded (transmitted) directly to the OERC automatically.

9. PHOTOGRAPHER CERTIFICATION

9.1 Obtaining Certification

Each photographer taking fundus images will need to become certified using this new camera before taking images for the study. Central training will occur on April 11, 2011, at the Coordinating Center site at Chapel Hill, NC. Photographers will receive didactic and hands-on training conducted by the OERC team. Following the central training, each site's camera will be shipped to them. Once the cameras arrive back at the sites, photographers may practice taking images and prepare image sets for submission to the OERC for certification.

Certification begins with the completion of the Photographer Certification Request Form (Attachment 12.2). This form will be used for certification purposes only and should be faxed back to the OERC Study Coordinator, Tiffany Jan, as soon as certification images of 10 eyes (5 right eyes and 5 left eyes, Field 1 and Field 2 of each) have been taken and transmitted to the OERC according to study protocol. A photographer is fully certified after submitting satisfactory quality images of 10 eyes taken on non-study volunteers and the form is signed and faxed to the Coordinating Center at the OERC. These images must show proper field definition (Fields 1 and 2 of each eye, 20 images total), proper exposure, alignment and focus. Photography certification subjects will be given a unique 7-digit subject ID number. It will begin with CERT and the next number will be a number 1 through 5. The last 3 digits will be the photographer's 3 character initials (i.e., CERT1ABC is the first person imaged for this photographer and CERT2ABC is the second person etc). The OERC will confirm certification by sending a signed certification form back to each site's coordinator who will notify the photographers. In cases where compromised image quality prevents certification, the OERC staff will contact the photographers directly providing helpful feedback and requesting the submission of additional images to resolve a problem and complete certification.

Please select subjects for certification who dilate well, so that the small pupil setting will not be needed for certification images.

9.2 Sending Certification Images

Photographers should be familiar with the standard imaging protocol as documented above. Images taken for certification purposes should only be transferred to the OERC once the photographer has taken images of all 10 eyes. Therefore when taking certification images, the photographer should store images from each certification subject in the local export folder until the complete, 10 eye set is obtained (see Attachment 12.3 for details).

When ready to transmit finalized certification images, follow the instructions in Attachment 12.3 to recall the existing images. However, instead of changing the storage to the local folder, the photographer shall just press “OK” to automatically send the images to the OERC.

The certification images will automatically be transmitted to the OERC (see Section 5.5 for procedure) for review.

9.3 Certification of New Photographers

As additional personnel need training to become certified, a certified photographer at that center will provide complete instruction. Copies of all training materials and manuals will be available on the ARIC-NCS website. The trainee photographer will practice on volunteers and when ready, prepare and submit images of 10 eyes (5 subjects, Field 1 and Field 2 for both eyes) for consideration for certification.

10. QUALITY CONTROL

10.1 Image Quality

A big advantage to digital imaging is that photographers are able to provide the first assessment of image quality. This “on the spot” review of images allows for the immediate assessment of photo quality and the opportunity to retake any images before the subject leaves the camera area. Additionally, reading center staff will continuously monitor image quality throughout the study. Initially, all images will be reviewed by OERC staff and feedback will be provided to the photographers in cases that warrant critique. A telephone call or e-mail will be used, detailing problems and suggesting improvements. Once the study is underway, photo quality reports will be generated from the OERC photograph readers' evaluations of all images and sent to the ARIC-NCS Coordinating Center as well as to each site coordinator for distribution. The OERC Imaging Consultant will review a small percentage of the images, and feedback will be provided to the photographers in cases that warrant critique. In cases where problems with image quality persist, additional training by webinar or in the form of a site visit may be recommended.

11. COMMUNICATION CHANNELS

It is vital that proper and frequently used channels of communication be established for the effective exchange of questions and information between all staff members. The following is a listing of names, addresses, and telephone numbers to facilitate this exchange:

Ocular Epidemiology Reading Center
610 North Walnut Street, 4th Floor WARF
Madison, WI 53726-2336

Tiffany Jan Study Coordinator	(608) 262-6266 jan@epi.ophth.wisc.edu
Stacy Meuer Senior Grader	(608) 263-8835 meuers@epi.ophth.wisc.edu
Michael Neider Imaging Consultant	(608) 410-0628 neider@rc.ophth.wisc.edu
Tony Fairbanks IT Coordinator	(608) 265-2625 fairbanks@epi.ophth.wisc.edu
Ronald Klein, MD, MPH Co-Director OERC	(608) 263-7758 kleinr@epi.ophth.wisc.edu
Barbara EK Klein, MD, MPH Co-Director OERC	(608) 263-0276 kleinb@epi.ophth.wisc.edu
Synemed, Inc. Josh or Jayson/ Service Dept	(800) 777-0650 Order parts and installation direct

12. ATTACHMENTS

12.1 Retinal Examination Form (Section B. Photographic Section only)

B. Photographic Section

12. Which eyes were photographed? ☐

Right.....R
Left.....L→ **Go to Item 13e**
Both.....B
None .....N→ **Go to Item 13i**

13a. Right eye flash setting (1, 2, or 3) ☐

13b. Right eye pupil measurement (mm) ☐☐

13c. Right eye field 1 taken: ☐

Yes.....Y
No .....N

13d. Right eye field 2 taken: ☐

Yes.....Y
No .....N

13e. Left eye flash setting (1, 2, or 3) ☐

13f. Left eye pupil measurement (mm) ☐☐

13g. Left eye field 1 taken: ☐

Yes.....Y
No .....N

13h. Left eye field 2 taken: ☐

Yes.....Y
No .....N

13i. If neither eye was photographed, specify reason. ☐

Equipment failure .....A
Participant refusal .....B
Biologically not feasible.....C
Other.....D

13j. Comments:

14. Comments

Photographer ID: ☐☐☐

12.2 Photographer Certification Request Form

Photographer Certification Request Form
ARIC Neurocognitive Study

Institution Name:	**Site:** **Coordinator:**
Photographer's Name/Address:	**Phone:** **Fax:** **E-Mail:**

Quality Assurance Statement

I have read the protocols listed below, and I understand and agree to abide by the design and procedures of the study. *Study Protocol: ARIC-NCS Protocol*

Color Ophthalmic Photography Protocol: *ARIC-Neurocognitive Study Retinal Imaging Protocol (digital, non-stereo, standard Fields 1 and 2)*

_____ _____
Signature Date

☐ I request certification based on prior certification for Study

_____
Name of Study

The following photographs are being submitted for consideration of my certification as a fundus photographer for:

The ARIC-NCS Study

Patient ID Number	Photo Date	Eye	Photograph (*circle fields present*) Fields
	__ __/__ __/__ __ MM DD YY	OD OS	Digital Image: 1 2 Digital Image: 1 2
	__ __/__ __/__ __ MM DD YY	OD OS	Digital Image: 1 2 Digital Image: 1 2
	__ __/__ __/__ __ MM DD YY	OD OS	Digital Image: 1 2 Digital Image: 1 2
	__ __/__ __/__ __ MM DD YY	OD OS	Digital Image: 1 2 Digital Image: 1 2
	__ __/__ __/__ __ MM DD YY	OD OS	Digital Image: 1 2 Digital Image: 1 2

Fax completed form to: 608-265-8129

Questions may be directed to Tiffany Jan: phone 608-262-6266
e-mail: jan@epi.ophth.wisc.edu

Export the images electronically to the secure FTP Site

Michael Neider: phone 608-410-0628
e-mail: neider@rc.ophth.wisc.edu

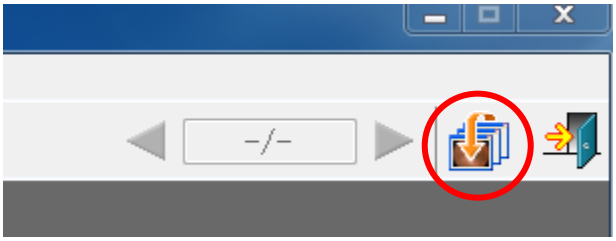
For Reading Center use only Certification Approved: __ __/ __ __ / __ __

Reviewer's Signature_____

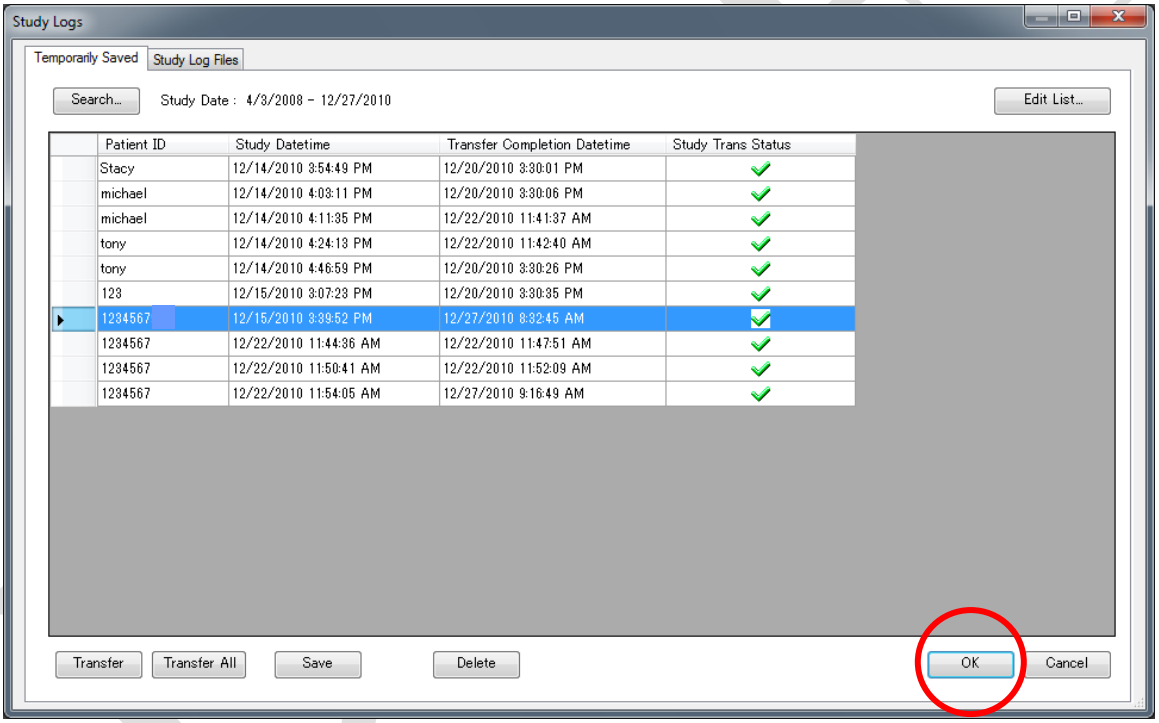
12.3 How to Save Images to the Local Export Folder

If a participant wants to have a copy of their images, they can be recalled using the software on the laptop and then copied to a CD or flash drive.

The photographer selects the “Study Logs” button from the main screen:

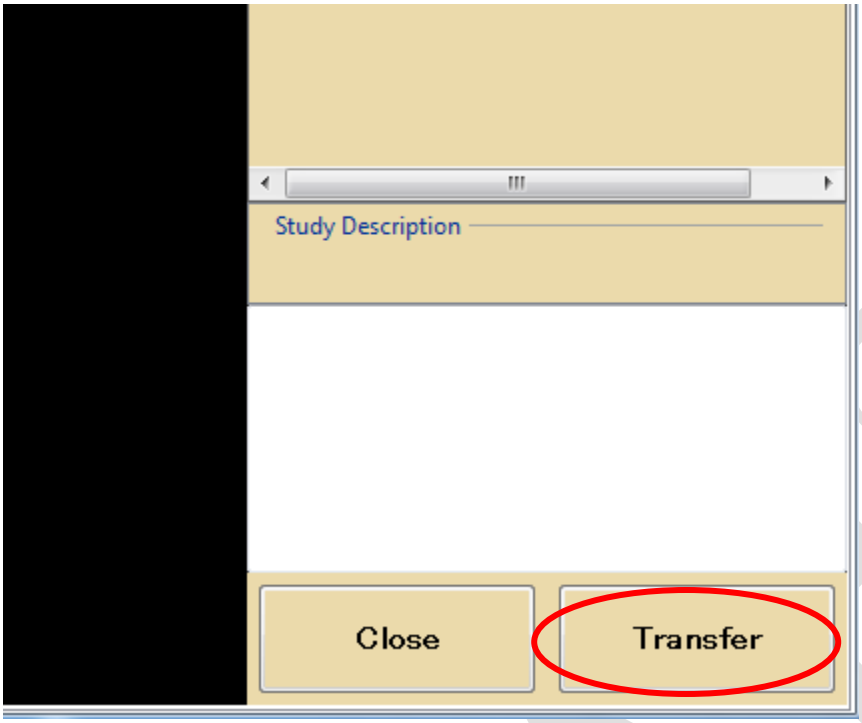


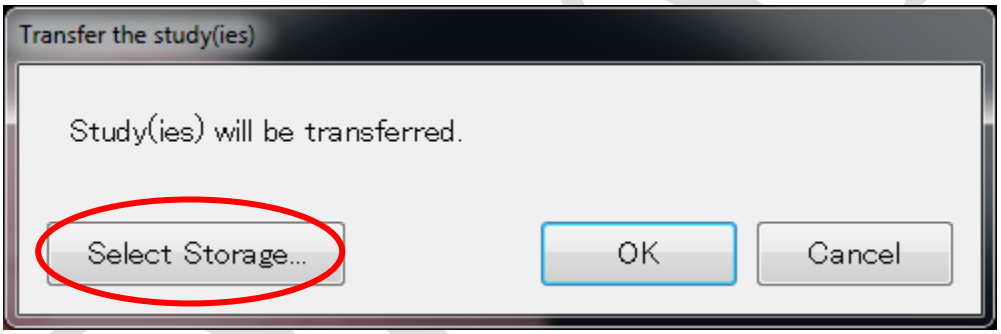
And then chooses the existing visits that they wish to export:



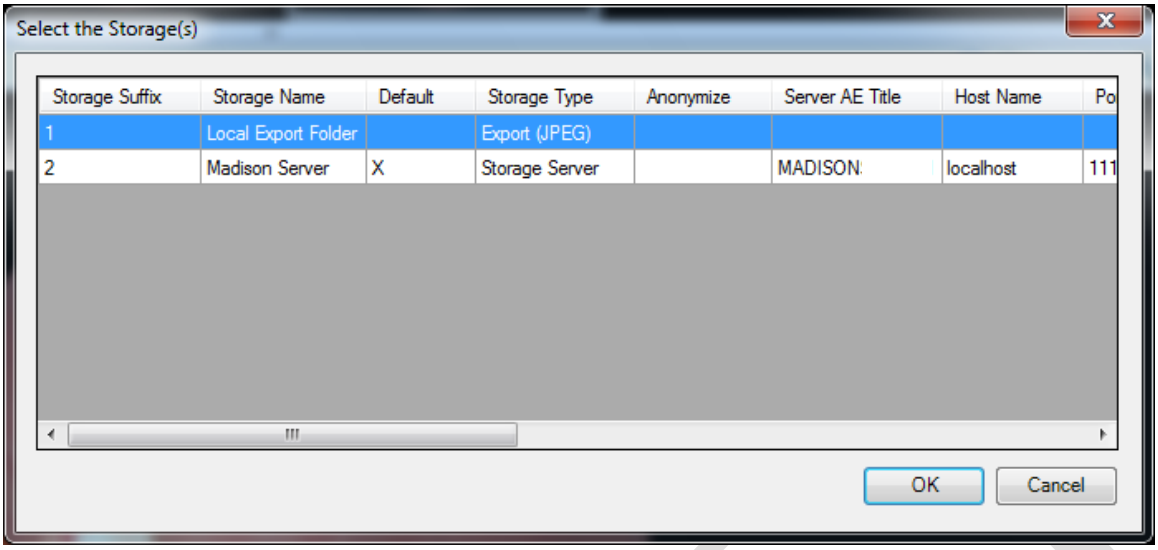
Selecting “OK” will bring up a review of the existing images.

The photographer then presses the “Transfer” button, which will bring up the transfer window.

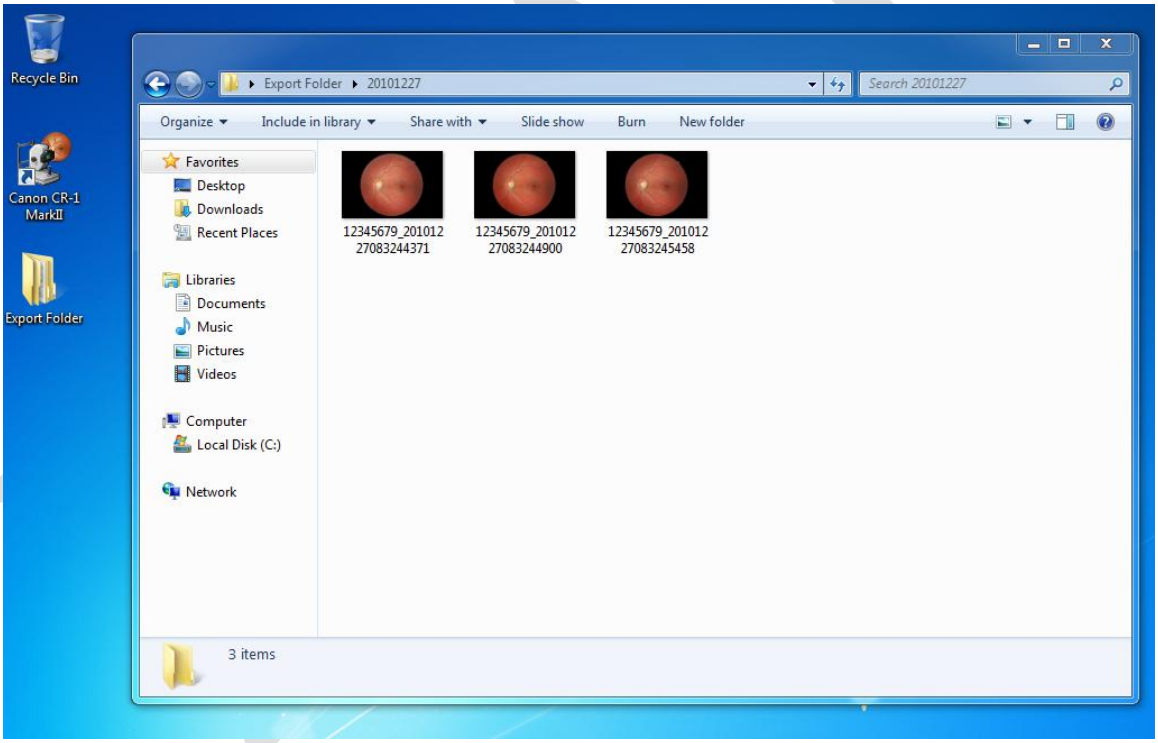




The photographer then clicks the “Select Storage…” button and changes the selection from “Madison Server” to “Local Export Folder”, and presses OK.



This will send a copy of the images to the folder located on the Desktop screen of the laptop called “Export Folder”, organized by export date. At this point, the photographer may copy the files to a CD or flash drive as needed. The photographer should then delete the exported files from the Export Folder.



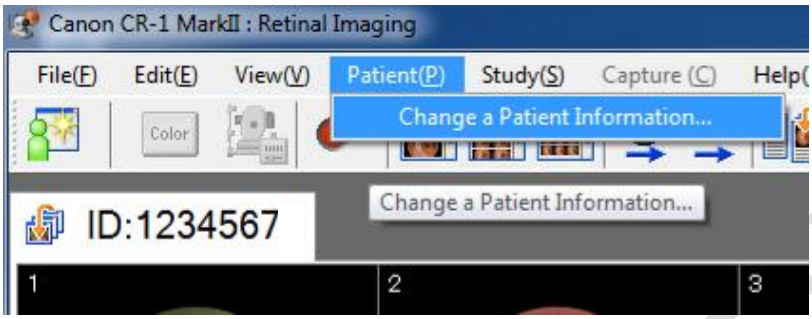
12.4 How to Save Certification Images to the Local Export Folder

Certification images can be recalled from the export folder using the same procedure as above. Remember that the patient ID for the certification sets should read as indicated in section 9.1. The patient ID for each certification set can be edited to indicate that the sets are for certification by double-clicking on the patient record on the study log screen and following the steps in Attachment 12.5.

To send the certification images to the OERC (all 10 eyes at once), the photographer chooses the ten eyes he/she wants to submit and selects “Transfer” and then “OK” from the Transfer Study(ies) window.

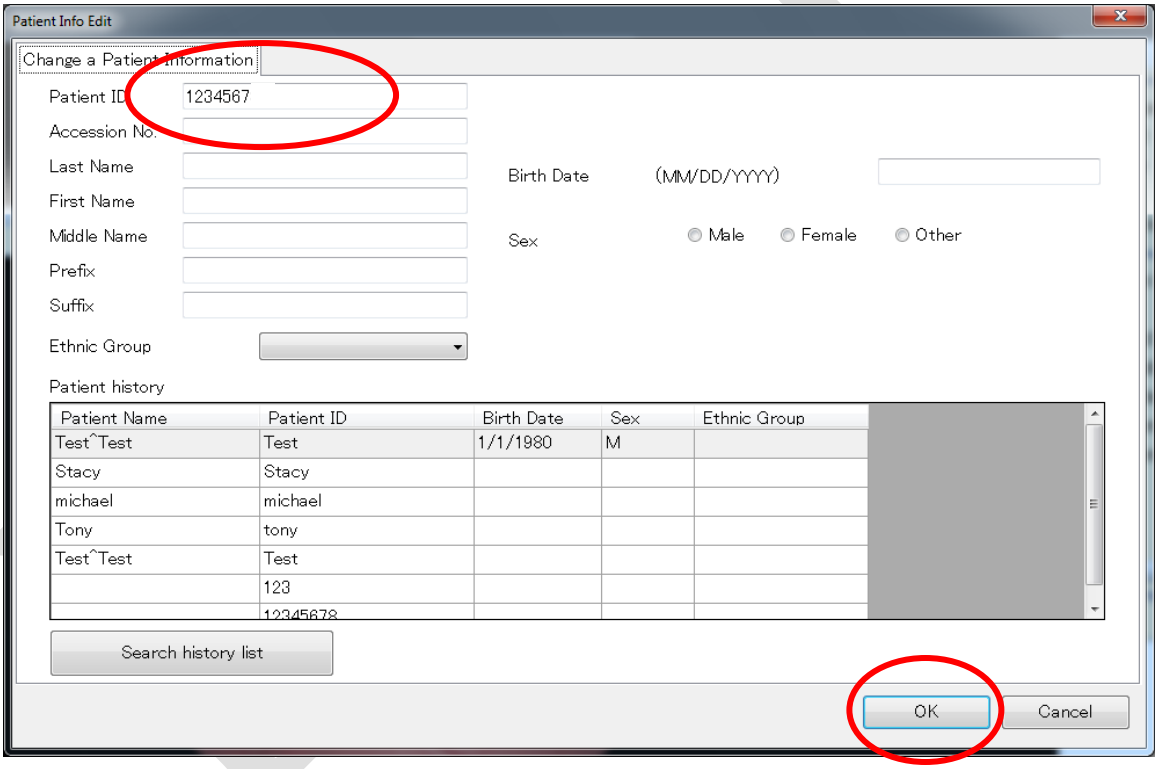
12.5 How to Edit a Subject

The photographer may edit the subject's 7-digit ID during photography by selecting the "Patient" menu and the selecting "Change a Patient Information"



It brings up this screen.

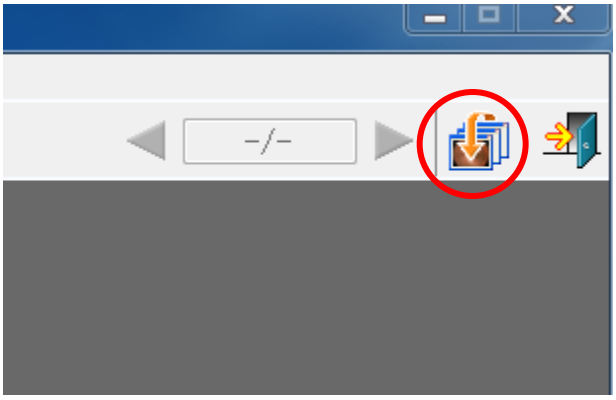
Enter the subject's ID that you want to change and then enter the correct ID. Select "OK".



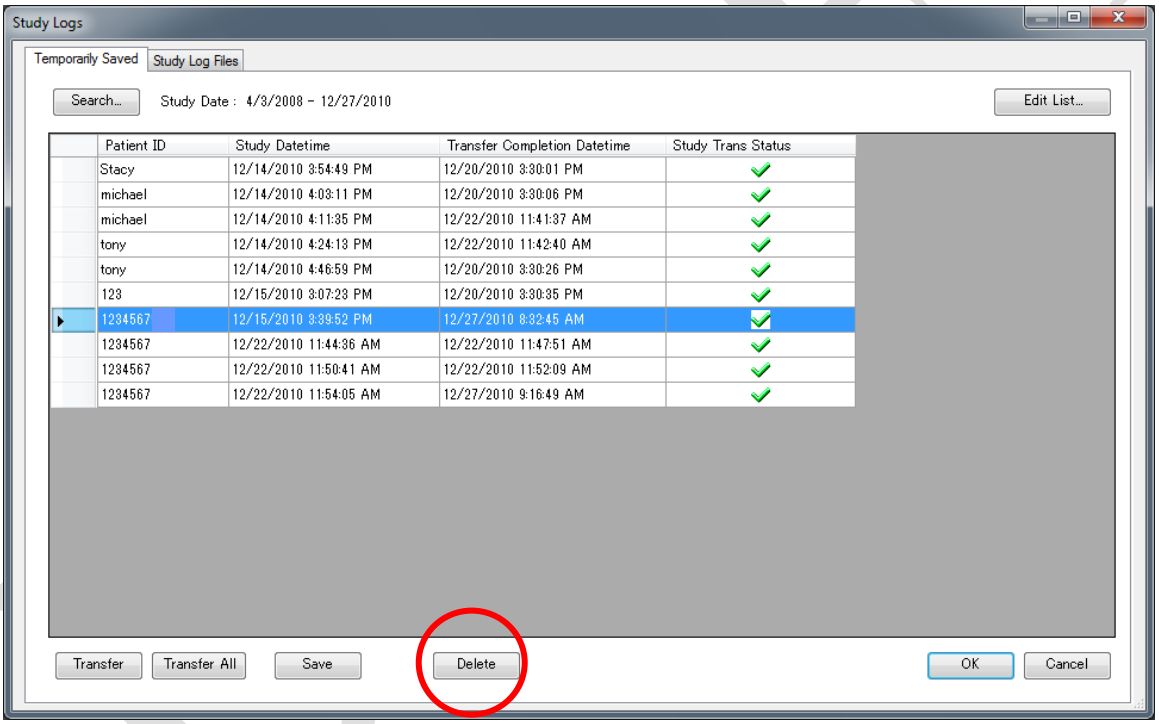
The subject ID has been successfully changed.

12.6 How to Delete an Imaging Session

The photographer selects the “Study Logs” button from the main screen:



And then chooses the existing visit that they wish to delete, and presses the “Delete” button:



Confirm deletion by selecting “OK”.