

Atherosclerosis Risk in Communities Study Protocol

Manual 14a

Retinal Photography

Visit 3

Version 1.0

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FOREWORD

This manual, entitled Retinal Photography is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manuals 2 and 3 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 11 and 13 through 15. Manual 12 on Quality Assurance contains a general description of the study's approach to quality assurance as well as the details for quality control for the different study procedures.

ARIC Study Protocols and Manuals of Operation

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Manual 14a: Retinal Photography

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1.0 INTRODUCTION

The Atherosclerosis Risk in Communities (ARIC) Study is an epidemiological research study of the major factors contributing to the occurrence and trend of cardiovascular disease in middle-aged (age 35-74) adults in the United States and has two main objectives: (1) to investigate factors associated with both atherosclerosis and incidence of clinical cardiovascular disease, and (2) to measure coronary heart disease (CHD) occurrence and trends and relate them to community levels of risk factors, medical care and atherosclerosis.

The study will examine 14,500 subjects including men, women, blacks and whites. Examinations will be conducted in four US communities located in Forsyth County, North Carolina, Jackson, Mississippi, suburbs of Minneapolis, Minnesota and Washington County, Maryland. Follow-up examinations will be performed on the subjects remaining from the 4,000 persons (aged 45-64 at first examination) originally selected to represent each community.

Fundus photographs will be used to evaluate changes in the retinal vasculature (presumed to be related to hypertension and/or arteriolar sclerosis) that may be prognostic for various cardiovascular outcomes. Generalized and focal narrowing of arterioles and changes in arterio-venous (A/V) crossings will be evaluated. Although rare, signs of "malignant" hypertension (hemorrhages and micronaneurysms, "cotton wool spots," and swelling of the optic nervehead) will also be assessed. Other significant retinal conditions will be noted, such as diabetic retinopathy or vascular occlusions.

One 45 degree non-mydratic (i.e., not requiring pharmacologic dilation of the pupil) retinal photograph will be taken of one eye of each of the 14,500 subjects. The photographs will be sent to the ARIC Retinal Reading Center for assessment of retinal status.

2.0 EQUIPMENT AND SUPPLIES

2.1 The Canon CR-45UAF Camera

A Canon non-mydratic, auto-focus fundus camera with 35mm camera back will be used for this project. (A Polaroid camera attachment will be used during the training session to provide instant photo quality feedback.) The camera is mounted on a motorized instrument table to allow optimum alignment. Both photographer and subjects have pneumatically adjustable stools, the latter with a back rest.

The Retinal Reading Center has made one modification to the camera, the attachment of an aligning mask to the viewing monitor. The transparent mask has two circles, labeled R and L, within which the photographer centers the optic disc of the right or left eye, respectively. The mask is taped to the monitor screen. It is easiest to attach the mask with the camera on and the external viewing function engaged. With the external viewing function engaged, the central viewing circles (used to align the pupil during photography) are visible and can be used to center the mask. The mask should be positioned with the right and left (R and L) circles equidistant from the viewing circles, and with the centers of the mask circles about 2 millimeters higher than the center of the concentric viewing circles. It is important to position the mask in relation to the viewing circles and NOT in relation to the edges of the monitor.

Additional transparent grids are available from Rose Brothers at the ARIC Retinal Reading Center, 610 North Walnut Street, Madison, WI 53705.

2.2 Supplies

Supplies can be divided into two categories: one-time purchases, and those bought on a repeat basis. One-time purchases include the Canon CR-45UAF fundus camera, adjustable table, two stools, and a camera cleaning kit containing a brush and air bulb for dust and lint removal.

A list of supplies that need to be reordered on a repeat basis follows:

- (a) Slide film Kodak Professional Ektachrome 100 EPN, 36 exposure, is required.
- (b) Photographic lens tissue
- (c) Lens cleaning fluid (supplied by the Canon representatives)
- (d) Kleenex tissues
- (e) Spare view, flash and split lamps
- (f) Bardes, side-loading, clear plastic slide mounting pages, #62022C, Bardes Products, Inc., 5245 West Clinton Avenue, Milwaukee, WI 53223
- (g) Film roll processing labels (1" X 2")

2.2.1 Inventory

An inventory of supplies for each of 4 study centers, assuming an average of 3,625 subjects per center, follows:

(a)	36 Exp.Prof. Ektachrome 100 film	101 rolls (minimum)
(b)	Lens tissue	500 sheet package
(c)	Lens fluid	1 8oz. bottle
(d)	Facial tissues	10 boxes (200 tissues/box)
(e)	Spare lamps	1 flash, view and split
(f)	Film roll labels	101 (minimum)
(g)	Bardes plastic slide pages	362 20-pocket pages

2.3 Equipment Set-up

2.3.1 Daily Set-up Procedure

The camera dust cover and lens cap should be removed at the beginning of the day and the lens inspected and cleaned (see section 2.4.1) as necessary. Dust is the greatest enemy, producing the majority of artifacts on the photographs. **When the camera is not in use, the lens cap should be in place and the special dust cover must remain on the camera.** The 35mm camera back should be checked for sufficient battery power (see page 26 of the Operations Manual) and the film counter should be checked to be certain that the camera is loaded with film before beginning photography.

2.4 Care and Maintenance of Equipment

2.4.1 Lens and Camera Body Care

Before each photograph, the camera lens must be inspected and, if dirty, cleaned with the brush and air bulb to remove debris. Should more extensive cleaning of the lens be required, the lens can be fogged with your breath or moistened with absolute alcohol and then tissue should 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 with the alignment lens removed and the view lamp on and turned up to its maximum intensity (see page 42 in the 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 like 409. The headrest may be cleaned with alcohol. The inside of the 35mm camera back is inspected for dirt and film fragments each time the film is changed. The air bulb or a puff of air is used to clean inside the camera back. The infra-red mirror relay lens assembly is cleaned as necessary to remove dirt or dust when seen on the display monitor. While these specks do not affect final photo quality, they are distracting and should be removed.

2.4.2 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 may squeak requiring a drop of light oil. The electric motor on the table requires no lubrication. The motor is protected by fuses that may need replacing should excessive current blow them out.

2.4.3 Flash, View and Split Lamp Concerns

It is anticipated that the flash, view and split lamps will fail at some point. Remember to keep all oil from your fingers off these lamps during replacement. The view and split lamp should last approximately one to two years and are easily replaced as needed. The flash lamp has a life of at least 5,000 flashes, enough to complete the study. Since the view and split lamps are relatively inexpensive bulbs, one spare for each should be ordered from Canon and kept at the field center. The flash lamp is expensive, and can be ordered from Canon when needed for overnight delivery.

As the flash lamp ages, the light output can diminish, producing progressively darker photographs. This can temporarily be over-ridden by an adjustment of the transformer output, though ultimately the lamp should be replaced. The decision to replace the lamp, due to dark photos, will be made with the Photography Consultant following routine review of processed photographs. The flash lamp requires careful handling during installation (the burnt out lamp may be hot, and the new lamp must be properly aligned), thus replacement should be attempted only by field center staff who have been trained to do this.

2.4.4 Film Concerns

The most consistent exposure will be obtained using a professional grade slide film such as Professional Ektachrome 100 (EPN). Professional grade films must be stored at a temperature of 55° F or lower. A conventional refrigerator is the perfect storage container for the Professional Ektachrome. Please remove the film from refrigerator at least 1 hour (but no more than 24 hours) to allow it to warm to room temperature before use. This warming is necessary to prevent condensation inside the camera or film tearing which can occur when the film is cold.

You may also freeze this film if refrigerator space is at a premium. In this case, please be sure to remove any rolls at least 3 hours before use to allow ample time for the film to reach room temperature. During this time it is best to leave the frozen film in its plastic storage container to prevent condensation.

It is not necessary to refrigerate the film after exposure. Film should be developed promptly after the last exposure is taken.

2.4.5 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 Retinal Reading Center Photography Consultant. Trouble-shooting tests can be performed in consultation with the consultant to diagnose any malfunction. Some camera malfunctions or photographer errors are not evident during photography and will only be discovered after examination of the processed films. This includes camera flash synchronization, transformer power settings, problems with a dirty objective lens or film loading problems. For this reason, prompt processing

of the film is important. A telephone link should be available between the photographers and the Photography Consultant at all times should a malfunction be discovered during the photography or following processing, or should the photographers have a problem or question needing immediate attention. The Photography Consultant, Michael Neider, can be reached at 608-263-9858 at the University of Wisconsin-Madison, Wisconsin. If he is not personally available, contact Ms. Rosemary Brothers (608-263-6976) instead. Service information can also be obtained directly from Canon USA in Itasca, Illinois or Lake Success, New York. Our contacts there are Tom Penkala, Canon USA, 100 Park Blvd., Itasca, IL 60143-2693, telephone number: 708-250-6230 or Ron Kaiser, Canon USA, 1 Canon Plaza, Lake Success, NY 11042-1113, telephone number: 516-328-4645.

3.0 EXAMINATION PROTOCOL

All subjects will have one 45-degree photograph taken of one eye. The eye to be photographed will be selected based on the subject's 6-digit ID number, excluding the check digit. When the ID number is even, the right eye will be photographed, and when it is odd, the left eye will be photographed. If the eye specified by this algorithm is considered too difficult to photograph with adequate photographic quality, the fellow eye should be photographed instead, and an explanatory note entered in the photography log. Conditions falling into this category are (based upon the technician's judgement): eye missing, inability to dilate at least 4 mm, inability to fixate adequately for proper photographic field definition, and opacities of the media preventing a reasonably clear view of the retinal vasculature.

3.1 Subject Exclusion

The photographer will attempt photography on subjects with poor visual acuity who may be unable to direct their gaze so that their nerve is properly positioned in the field alignment circle (as may be the case where both eyes are blind or when the subject is deaf and communication with them is impossible). In these cases, the photographer should get the best field definition possible remembering that it is better to have the nerve closer to the center of the picture than off too close to the edge. Additionally, the optic nerve can be displaced up or down by about 1/2 DD (disc diameter) and still provide useful information. If, in the photographer's judgement, no acceptable photograph can be taken, the subject will be excused from photography.

The photographer should attempt photography on those subjects who are physically disabled, provided that they can be comfortably positioned at the camera. To facilitate this, the subject may remain in a wheel chair 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 subjects legs. If, in the photographer's estimation, the subject can not be comfortably positioned, no photography will be performed.

3.2 Pre-examination Procedure

Before attempting photography, the photographer should become very familiar with the camera through a training session and by learning the terminology on pages 3 - 4 and 24 of the camera Operation Manual. The following protocol uses terminology from the Operation Manual and it is recommended that the entire manual be reviewed by each photographer performing photography.

The retinal camera should remain covered when not in use. High humidity or temperatures must be avoided. Dusty conditions mean that the camera will need frequent cleaning. The objective lens should be checked and cleaned with the air bulb if necessary before each subject is photographed. A more extensive cleaning is required to remove grease, smudges or stubborn spots from the lens. This cleaning requires removal of the lens "boot" and external

alignment lamp ring and should be referred to the chief photographer at each field center.

3.2.1 Subject Explanation and Informed Consent

Photography begins with a complete explanation of the procedure by the photographer. A Polaroid print may be useful to show what the optic nerve and retina looks like. It is important to reassure the subject that no retinal damage is caused by this procedure. The camera flash is bright and the subject should know when to expect a flash. The pictures will include 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 five to seven minutes. No dilation drops will be used for this examination, and the eyes will not be touched. A sample script of a typical retinal photography explanation (suitable for use as written material for deaf or interested subjects) follows:

We will be taking a photograph of the inside of the back of one 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 be giving you any eye drops to take the picture. 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. While your pupils are dilating, we may ask you some questions about your vision and the health of your eyes. During the aligning process you will only be aware of some small red lights and a blinking green light visible in the camera lens. We will ask you to follow the blinking green as we move it. Just before we take the picture, we will ask you to blink your eyes and then open them real wide. The camera will flash a bright flash from within the camera lens as the picture is taken.

Just after the picture is taken, you may see a blue or red circular spot before the eye photographed. This will disappear within 5-7 minutes and causes no permanent damage to the eye. Please remember that we are taking only one picture (not an x-ray) of a small portion of one of your eyes and that this picture 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.

3.2.2 Completing the Retinal Artery Examination Form

Before photographing the subject, the photographer completes the first part of the ARIC Retinal Artery Examination Form (Example 5), which concerns the subject's ophthalmic history. The second part of the form records the circumstances of the photographic session, and can only be completed as the session begins. Part of the form can be completed while the subject becomes sufficiently dilated to be photographed. This will depend upon adequacy of ambient light for the photographer (to be able to read questions and record answers) and upon the time required to answer the questions.) In particular, if the assigned eye cannot be photographed for a reason gathered during the

ophthalmic history (e.g., that eye has been enucleated) or for a reason that emerges during the first part of the session (the assigned eye does not dilate sufficiently well to be photographed), the photographer indicates that the other eye has been selected and the reason for departing from the assignment. For logistical reasons, this form will be completed as a paper form, and later entered into the computer system.

3.2.3 Preparing the Camera

The video display is activated when the power switch on the side of the main unit is turned on. If no photography or switch operations are performed for 10 minutes, a power saving mode is activated, turning the lamps and display off to prevent unnecessary wear. During this power saving mode a "ready" lamp blinks on the monitor. Pressing any button below the arrows under the monitor, the joystick trigger, or the alignment button will reactivate the system.

Notice that three vertical arrows blink on the monitor when the main unit is switched on. This indicates the system is charging up. **Do not take photographs until the blinking stops, indicating a fully charged flash.** Pictures taken before the flash is fully charged will be severely underexposed.

The current date and subject ID number are displayed in the upper left-hand corner of the monitor. The camera contains an internal clock and the date will automatically change each day. The photographer must manually change the date if this clock should fail or if the camera is left unplugged for a long period of time. The date and time display is changed through Menu 3. The date format will read Month-Day-Year. The "Time Set" screen is used to adjust the current date and correct time. The camera is capable of recording a six-digit subject ID number (the ARIC ID with the field center number truncated), accessed through Menu 3, which **must be reset for each subject photographed.** Once properly entered into the camera, the number will appear below the date on the monitor. **This number must be checked and adjusted before each subject is photographed because this information is recorded on each slide and will become a permanent part of the data slides and will become the primary identifier for each picture.**

The 35mm camera body should be attached to the main unit and loaded with a fresh roll of Professional Ektachrome 100 EPN color slide film (36 exposures). The photographer needs to check that film is indeed loaded in the camera at the beginning of each photography session. The frame counter on the top of the camera will indicate the number of exposures taken. After 36 pictures are taken, the camera automatically rewinds the film. If the film needs to be removed before 36 exposures have been taken, a manual rewind button on the 35mm camera back (page 30 of the Operations Manual) needs to be depressed.

To load the camera, open the camera by sliding the camera latch down while pressing in on the cover lock button. Insert the new film cartridge in the left side and thread the film across the shutter to the right side, making sure that the film leader is aligned with the orange index mark. Be careful not to poke the shutter blades with a finger because damage to the blades can

easily occur. Take up any slack in the film by sliding excess film back into the cartridge. Close the back; the camera automatically threads the film and advances the film and counter to the number one exposure position. A blinking "check film back" warning on the monitor or blinking film marks on the camera back LCD display indicates the film is not loaded properly. In this case, reload the film. When the film is properly loaded, the camera back "reads" the film speed and automatically adjusts the flash output. At this point the photographer must press the "DSP" (for "display") button below the monitor to confirm that the following settings are correct:

BACK : RE 100 45	(35mm EOS body, 100 ASA, 45-degree field)
AF : ON	(autofocus on)
AE : ON	(autoexposure on)
BLINK: OFF	(blink detector off)
SPLIT : IN	(split focus detector in)
NO : H 000001	(6-digit ARIC subject ID ¹)
DATE : MM-DD-YY 12:00	

The photographer will keep a manual film log on the ARIC Retinal Photography Log Form (example 1) kept in the camera room. This log file will include: film roll number, date, photographer ID number, subject name, subject ID number, eye photographed, and a comments section. Each roll of film will be assigned a unique roll number and will contain photographs of 36 subjects. Once a roll is completely exposed, it is removed from the camera and identified with a film roll number label for identification during processing and mounting.

3.3 Subject Photography

3.3.1 Subject Positioning and ID Entry

The subject and photographer are seated on the appropriate sides of the retinal camera. The subject is positioned so that he/she is comfortable with chin and forehead in the headrest. Chin height should be adjusted so that the eyes are approximately level with the height adjustment mark on the face rest pole. The room is darkened to the level where a newspaper can barely be read (equal to about 5 lux) and the camera room door is closed. The only light in the room should come from the display monitor. If a red lamp is used to aid the examiner during administration of the questionnaire, it must be turned off when photography is performed. While the subject begins to dilate, the photographer enters the last six digits of the subject ID (minus the prefix identifying the field center) into the camera via the number pad on the control panel, so that this can be imprinted at the edge of the photographic frame along with the date when the photograph is taken. After the number is entered, the photographer pushes the "DSP" button (explained above) to

¹The "H" before the subject ID number stands for "Hold," i.e., the camera holds the number until it is changed to another (rather than "C" for counting up automatically after each exposure). This letter is not available to be set to the code for the ARIC field center.

display the current camera values on the monitor, so that accuracy of subject ID entry can be checked.

3.3.2 Pupil Size and Alignment

The camera stage holding knob is unlocked, the alignment switch is turned on and the stage is moved to center the eye to be photographed horizontally and the height adjustment ring is used to position the eye vertically. The pupil should appear on the TV screen coincident with the central circle on the monitor. The camera joystick is moved forward or back until the pupil appears perfectly round. At this point, proper external alignment has been achieved. A pupil larger than the central 4mm circle on the monitor is required for adequate photography. If the eye assigned for photography does not dilate to at least 4mm after a 5-minute waiting period, the fellow eye should be examined for pupillary dilation as well. If dilation of the fellow eye is larger, the photographer will photograph it instead of the selected eye.

3.3.3 Fellow Eye Selection

For methodological reasons (approximately random and equal inclusion of right and left eyes) photography should be performed in the assigned eye whenever possible. The fellow eye should be selected only if characteristics of the assigned eye prevent a reasonably clear view of the retina. Such factors include poor pupillary dilation, as specified above, and substantial media opacities, including lens cataract, corneal irregularities, and opacities in the vitreous (e.g., vitreous hemorrhage). Assymetry of any other type (e.g., the fellow eye has more or less retinal pathology than the assigned eye) should be ignored when selecting the eye to be photographed. If the fellow eye is selected, an explanatory note must be written in the Photography Log Form.

3.3.4 Photography Through Small Pupils

The photographer will experience much more difficulty attempting photography through small (less than 4mm) pupils because all of the camera light doesn't enter thru 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 as possible.

A small percentage of participants' eyes don't dilate the minimum 4mm required for adequate photography. Certain medication may prevent any dilation and the pupil size observed on the monitor may be 1-2mm, inadequate for the photographer to appreciate any retinal landmarks on the viewing monitor.

If no landmarks are visible, the photographer should adjust the camera slightly to position the corneal reflection dots slightly above or below their optimum position. 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, a picture should be taken. However, if no retinal landmarks are visible, which is often the case

when dilation is less than 1.5mm, no picture is taken and the fellow eye is examined for dilation instead.

3.3.5 Exposure Compensations for Dark or Light Retinas

Photography of darkly pigmented retinas (black or Asian) will require increased flash output to avoid underexposed pictures. The photographer will press the "RE N" button under the main screen until a "+" appears in place of the "N" thus indicating a 1/3 f-stop increase in exposure. Photography of lightly pigmented retinas (blond, albino or Scandinavian) will require decreased flash output to avoid overexposed pictures. The photographer will press the "RE N" button on the main screen until a "-" appears in place of the "N" indicating a 1/3 f-stop decrease in exposure.

3.3.6 Internal Eye Alignment

Once proper external pupil alignment is achieved, the alignment switch is pressed to provide a view of the fundus, split focusing lines, corneal reflection dots, and the fixation light. If no split lines are seen, the height or left/right adjustment is improper, the "SPLT" (split lines) setting is set to "Out" (Menu 1), or the diopter compensating slider is pulled out. The split lines may fade in and out if the pupil is too small, the alignment of the camera is not centered on the pupil, or if the eyelashes or lids eclipse the light. If no corneal reflection dots are seen, the forward/backward adjustment is improper. The best photographs are obtained when the eye is well dilated, fixation is on the target; and lids and lashes are held wide open.

3.3.7 Focus with High Myopia or Hyperopia

The diopter compensation slide should be set to the "0" position for most eyes. This is the only setting in which the auto-focus mechanism works and allows photography of eyes with refractions between -12 and +15 diopters. In the event that the eye photographed falls outside this range and auto-focus cannot be achieved, as in the case of aphakia or high myopia, the diopter compensation slider must be adjusted for the clearest focus to the "+" or "-" position and the focusing knob is then turned manually to provide the sharpest image on the monitor. This can be facilitated by obtaining a brighter retinal image on the monitor by increasing the view light intensity. The normal setting for the view light intensity adjustment is approximately 4.

Standard TV monitor functions can be adjusted for the photographer's viewing comfort (including contrast and brightness) by opening the access door below the TV monitor. These are standard controls similar to those found on a home TV set and only effect viewing; they do not effect final photo quality.

3.3.8 Alignment, Focus and Proper Fixation

While viewing the fundus image on the screen, the photographer carefully adjusts the internal fixation target lever to position the optic nervehead (also called the optic disc) correctly on the screen. To facilitate consistent position of the optic disc, an aligning mask with two circles has

been added to the monitor. When the right eye is correctly positioned on the monitor, the disc falls into the right-hand circle. When the left eye is correctly positioned on the monitor, the disc falls into the left-hand circle. These aligning masks are provided by the Retinal Reading Center and, when properly attached to the monitor, they position the optic nerve centered from top to bottom and the nasal edge of the optic nerve falls between 1.50-2.00DD from the nasal edge of the photograph. If the photographer experiences difficulty placing the optic disc within the proper circle, it is preferable to have the disc shifted towards the center of the photographic field. Final confirmation of proper mask position is made at the Reading Center by measuring the optic nerve position on processed slides (not on the monitor).

Any fine adjustment of subject fixation is made by moving the fixation lever and instructing him/her to look into the lens of the camera at the green target light. In the event that the subject sees no fixation light with the eye being photographed, the photographer must carefully instruct the subject to make micro movements (fine movements up, down, left or right) until the disc falls into the appropriate circle.

Once the fixation is confirmed, the photographer must constantly adjust and position the camera to maintain the correct position of the corneal reflection dots. It is important that these dots be properly positioned at the three and nine o'clock positions before the picture is taken. This will ensure the correct distance from the eye and will allow a sharp image to be produced on the film. Focus is done automatically but should be confirmed by the photographer by assessing image sharpness and by checking the auto focus confirmation indicator (see page 18 of the Operation Manual) on the monitor.

3.3.9 Focusing Manually When The Auto-Focus Mechanism Doesn't Lock

When the auto-focus mechanism focuses the camera on the retina, a motor adjusts the focus knob until the auto-focus "locks" and a clear image is identified. This "lock" is confirmed in two ways. Two vertically stacked equal signs appear in the lower left-hand corner of the screen. Also, two rectangular boxes appear, stacked one on top of the other, in the center of the monitor.

If the operator notices that the auto-focus mechanism can't "lock" (obvious when the motor keeps running for several seconds and then shuts off) no vertically stacked equal signs appear and the auto-focus mechanism turns off. At this point you can manually focus the camera by turning the focus knob until the two rectangular boxes in the middle of the monitor appear stacked.

The photographer will instruct the subject to blink once or twice just before the picture is taken. This blinking will insure a moist (and subsequently clearer) cornea and will safeguard against unwanted blinks at the moment of exposure. Once alignment is satisfactory, the shutter release, located in the tip of the joystick, is depressed and the exposure is made. Only one eye on each subject is photographed.

3.3.10 Retake Policy

Should the photographer suspect that an inadequate photograph was taken (due to a possible blink, shadow, excessive movement or mis-alignment) or should the subject comment that they blinked or did not see the flash, the size of the pupil should be checked (a larger pupil indicates that no light reached the eye) and a second picture should be taken. In this situation, the best picture is sent to the Retinal Reading Center.

4.0 LOGS AND RECORDS

4.1 Photography Log Form

A daily Photography Log Form (see Example 1) will be maintained for each roll of film to provide an accurate listing of each subject photographed. The complete log for each film roll will contain the film roll number, date, photographer ID number, subject name, subject ID number, eye photographed, and a comments section. The photographer is encouraged to comment on anything unusual such as strange artifacts, small pupil size, pathology or other problems. This information will be helpful in identifying specific photographs, and in understanding any artifacts that may appear on the processed slides. Since comments from the log accompany the photographs to the Retinal Reading Center, staff there can take this information into account when providing feedback.

5.0 FILM HANDLING

5.1 Film processing

The film will be removed from the camera after automatically rewinding as each roll is fully exposed. Film will be processed at least weekly. Partially exposed rolls of film may be removed after rewinding the film automatically by depressing the Manual Rewind Button (see page 30 of the Operation Manual). The photographer will attach a numbered film roll label to each exposed roll of film before sending it for processing. The film roll label appears as follows:

The film roll number must correspond with the sequential number appearing on the corresponding Photography Film Log page.

The undeveloped rolls of film will be sent to a reputable Ektachrome processing laboratory², preferably three times per week. A record of film sent will be kept and films will be logged out and in so any lost films can be easily recognized and traced. A Film Processing Log (example 2) will be completed whenever film is sent out or received back from processing. Special attention must be paid to the slide cutting and mounting (framing into either cardboard or plastic mounts) to be certain that the date and ID information is located on the left side of the retinal image on the slide with the registration "notch" on the right-hand side.

Film is processed locally so that photographers can review their results as soon as possible for possible camera malfunction. Also, the opportunity for photographers to critique their work is critical to the maintenance of satisfactory photographic quality.

5.1.2 Film sorting and labeling

The processed films will be sorted and labeled using the Photography Log Form as a guide. Extreme care is necessary no avoid incorrect identification and labeling. The pictures will be labeled with pre-printed slide identification labels. To make them easy to locate, labels will be printed in batches by the field center computer in date and subject ID order. The labels appear as follows:

<p>ID: F999999 CY: 07 ARIC</p>

²A professional film processing laboratory (i.e., not supermarket or drugstore service) offering consistent and timely E-6 processing for Ektachrome film must be selected. Professional photographers in your area can advise you about the identity of such a laboratory, or the Retinal Reading Center will help you find one.

5.1.3 Slide mounting

The sorted and labeled slides are loaded into Bardes plastic slide pages so that each row contains two photographs, thus only columns 1 and 3 are used. The mounting pattern is diagrammed in Example 3. Slides are mounted in the order taken and developed. The proper order is confirmed by comparing the slides with the corresponding Photography Log Form for each roll of developed slides. A roll of film of 36 exposures would result in 4 sheets of photos, specified as sheets 1,2,3 and 4 with only 6 slides in the final sheet.

5.1.4 Photo Shipping

Packages of processed, mounted slides and the relevant Photography Log Forms are sent weekly to Rose Brothers at the ARIC Retinal Reading Center, under cover of the shipping list (Example 4).

The Reading Center recommends the use of plastic lined air bubble mailers similar to the Avery "Post-Lite" or the Jiffy "Jiffylite". These are available in a variety of sizes and do not contain the recycled fiber padding prone to shed dust and dirt on the slides. Please be sure to put the plastic slide pages in a manila folder to prevent the sharp edges from cutting through the mailing envelope. The standard Federal Express or UPS envelopes, reinforced with a manila folder around the photos, are also acceptable.

5.1.5 Shipping Couriers

When using couriers such as Federal Express or UPS, please use the Retinal Reading Center's complete street address. When sending slides by US Mail, please use the same Retinal Reading Center address. (The Retinal Reading Center no longer has a post office box.) Address information can be found under section 8. on page 14 of this protocol.

6.0 QUALITY CONTROL

Photographic quality will be continuously monitored throughout the study. Initially all photographs will be reviewed by the Photography Consultant and feedback will be provided to the photographers in cases that warrant critique. A telephone call or letter will be used detailing problems and suggesting improvements. Once the study is well underway and the photographers sufficiently trained, data on quality will be generated from the photograph readers' evaluations of all photographs. A small percentage of the photographs will be reviewed by the Photography Consultant, and feedback will be provided to the photographers in cases that warrant critique.

7.0 PHOTOGRAPHER CERTIFICATION

Each examiner taking fundus photographs will need to become certified before taking photographs for the study. The initial group of photographers received didactic and hands-on training during the January 23-25, 1993, training session in Charleston, South Carolina. Following this training they returned to their respective centers and assembled their cameras. A photographer is fully certified after submitting satisfactory quality photographs of 10 eyes. These photographs must show proper field definition, exposure, alignment and focus. The photographs must be completely labeled and mounted according to protocol.

As additional personnel need training to become certified, a certified photographer at that center will provide complete instruction and copies of the protocol and Operation Manual. The trainee photographer will practice on volunteers and, when ready, prepare and submit photographs of 10 eyes for consideration for full certification.

8.0 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. Following is a listing of names, addresses, and telephone numbers:

ARIC Retinal Reading Center

610 North Walnut Street
Madison, WI 53705

Rosemary Brothers (608) 263-6976
Senior Grader

Michael Neider (608) 263-9858
Photography Consultant

Matthew Davis, M.D. (608) 263-6071
Consulting Ophthalmologist

Larry Hubbard (608) 263-2245
Associate Director

Canon USA, Inc.

Thomas Penkala (708) 250-6200
Canon USA, Inc.
100 Park Boulevard
Itasca, IL 60143

Ron Kaiser (516) 328-4645
Canon USA
1 Canon Plaza
Lake Success, NY 11042-1113

ARIC Study Photography Log Form Film Roll Number _____

	Date	Ph/ID	Subject ID #	Eye	Comments
1					
2					
3					
4					
5					
6					
7					
8					
9					
1					
1					
1					
1					
1					
1					
1					
1					
1					
1					

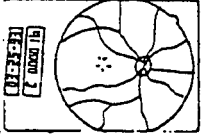
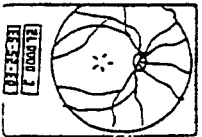
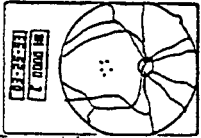
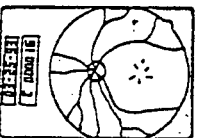

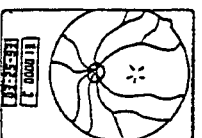
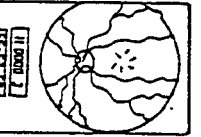
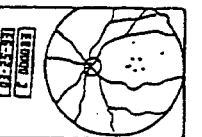
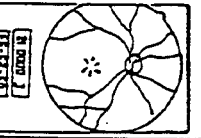
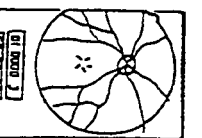
Example 1

ARIC Study Photography Log Form Film Roll Number _____

	Date	Ph/ID	Subject ID #	Eye	Comments
1					
2					
2					
2					
2					
2					
2					
2					
2					
2					
2					
2					
2					
3					
3					
3					
3					
3					
3					
3					

Example 1

ARIC Study
Mounting of Retinal Photographs

1  ARIC CY: 07 F000016		6  ARIC CY: 07 F000072	
2  ARIC CY: 07 F000018		7  ARIC CY: 07 F000015	
3  ARIC CY: 07 F000073		8  ARIC CY: 07 F000013	
4  ARIC CY: 07 F000011		9  ARIC CY: 07 F000033	
5  ARIC CY: 07 F000012		10  ARIC CY: 07 F000010	ARIC Study Visit 3 Batch ARFR3 <u>001</u> Sheet <u>1</u>

Example 3

ARIC Study
Retinal Photography Shipping List

Clinical Center: Forsyth

Shipping Batch: ARFR3 ___ ___ ___

Number of Mounting Sheets ___ Number of Retinal Photographs _____

Date Shipped ___ ___ / ___ ___ / ___ ___ Person Shipping _____

Retinal Reading Center use only.

Date Received ___ ___ / ___ ___ / ___ ___ Person Receiving _____

Comments _____

Example 4

ARIC

Atherosclerosis Risk in Communities

RETINAL EXAMINATION FORM

ID NUMBER: CONTACT YEAR: FORM CODE: R E X VERSION: A 03-09-93

LAST NAME: INITIALS:

Public reporting burden for this collection of information is estimated to average 7 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information including suggestions for reducing this burden to Reports Clearance Officer, PHS, 721-H Hubert H. Humphrey Bldg., 200 Independence Ave. SW, Washington, D.C. 20201, Attn. PRA; and to the Office of Management and Budget, Paperwork Reduction Project (OMB 0925-0281), Washington, D.C. 20503.

INSTRUCTIONS: This form should be completed on paper during the participant's visit. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

RETINAL EXAMINATION FORM (REXA screen 1 of 8)

<p>1. When was the last time you saw a doctor, optometrist, or eye specialist concerning your vision?</p> <p>Less than 1 year A</p> <p>At least 1 year but less than 2 years B</p> <p>At least 2 years but less than 3 years C</p> <p>3-10 years D</p> <p>Greater than 10 years E</p> <p>Never F</p> <p>2.a. Has a doctor ever told you that you had sugar diabetes? Yes Y</p> <p><input type="checkbox"/> No N</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin-left: 20px;">Go to Item 3a, Screen 2</div>	<p>2.b. Has a doctor ever told you that you have eye problems as a result of diabetes? Yes Y</p> <p><input type="checkbox"/> No N</p> <p><input type="checkbox"/> Unknown U</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin-left: 20px;">Go to Item 3a, Screen 2</div> <p>c. Which eye or eyes were affected? Right R</p> <p>Left L</p> <p>Both B</p> <p>Unknown U</p> <p>d. Have you ever had laser treatments on your eyes for diabetes? Yes Y</p> <p><input type="checkbox"/> No N</p> <p><input type="checkbox"/> Unknown U</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin-left: 20px;">Go to Item 3a, Screen 2</div>
---	---

Example 5

RETINAL EXAMINATION FORM (REXA screen 2 of 8)

<p>2.e. On which eye or eyes? Right R</p> <p style="padding-left: 150px;">Left L</p> <p style="padding-left: 150px;">Both B</p> <p style="padding-left: 150px;">Unknown U</p>	<p>3.a. Has a doctor ever told you that you have eye problems as a result of glaucoma, or increased pressure inside one or both of your eyes? Yes Y</p> <p style="padding-left: 150px;">No N</p> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-left: 100px;">Go to Item 4a, Screen 3</div> <p style="padding-left: 150px;">Unknown U</p> <p>b. Which eye or eyes were affected? Right R</p> <p style="padding-left: 150px;">Left L</p> <p style="padding-left: 150px;">Both B</p> <p style="padding-left: 150px;">Unknown U</p>
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RETINAL EXAMINATION FORM (REXA screen 3 of 8)

<p>4.a. Has a doctor ever told you that you have eye problems as a result of age-related macular degeneration? Yes Y</p> <p style="padding-left: 150px;">No N</p> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-left: 100px;">Go to Item 5a, Screen 4</div> <p style="padding-left: 150px;">Unknown U</p> <p>b. Which eye or eyes were affected? Right R</p> <p style="padding-left: 150px;">Left L</p> <p style="padding-left: 150px;">Both B</p> <p style="padding-left: 150px;">Unknown U</p>	<p>4.c. Have you ever had laser treatments on your eyes for macular degeneration? Yes Y</p> <p style="padding-left: 150px;">No N</p> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-left: 100px;">Go to Item 5a, Screen 4</div> <p style="padding-left: 150px;">Unknown U</p> <p>d. On which eye or eyes? Right R</p> <p style="padding-left: 150px;">Left L</p> <p style="padding-left: 150px;">Both B</p> <p style="padding-left: 150px;">Unknown U</p>
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RETINAL EXAMINATION FORM (REXA screen 4 of 8)

<p>5.a. Has a doctor ever told you that you have eye problems as a result of cataracts, or cloudiness of the lens, in one or both of your eyes? Yes Y</p> <p style="text-align: right;">No N</p> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-right: 10px;">Go to Item 6a, Screen 5</div> <p style="text-align: right;">Unknown U</p> <p>b. Which eye or eyes were affected? Right R</p> <p style="text-align: right;">Left L</p> <p style="text-align: right;">Both B</p> <p style="text-align: right;">Unknown U</p>	<p>5.c. Have you ever had eye surgery because of cataracts? Yes Y</p> <p style="text-align: right;">No N</p> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-right: 10px;">Go to Item 6a, Screen 5</div> <p style="text-align: right;">Unknown U</p> <p>d. On which eye or eyes? Right R</p> <p style="text-align: right;">Left L</p> <p style="text-align: right;">Both B</p> <p style="text-align: right;">Unknown U</p>
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RETINAL EXAMINATION FORM (REXA screen 5 of 8)

<p>6.a. Has a doctor ever told you that you have eye problems as a result of blockage of an artery or vein in one or both of your eyes? Yes Y</p> <p style="text-align: right;">No N</p> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-right: 10px;">Go to Item 7a, Screen 6</div> <p style="text-align: right;">Unknown U</p> <p>b. Which eye or eyes were affected? Right R</p> <p style="text-align: right;">Left L</p> <p style="text-align: right;">Both B</p> <p style="text-align: right;">Unknown U</p>	<p>6.c. Have you ever had laser treatments on your eyes for this blockage? Yes Y</p> <p style="text-align: right;">No N</p> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-right: 10px;">Go to Item 7a, Screen 6</div> <p style="text-align: right;">Unknown U</p> <p>d. On which eye or eyes? Right R</p> <p style="text-align: right;">Left L</p> <p style="text-align: right;">Both B</p> <p style="text-align: right;">Unknown U</p>
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RETINAL EXAMINATION FORM (REXA screen 6 of 8)

<p>7.a. Have you ever had eye surgery for another condition? Yes Y</p> <p style="padding-left: 100px;">No N</p> <p style="padding-left: 100px;">Unknown U</p> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin: 5px 0;">Go to Item 8a.</div> <p>b. What was the condition?</p> <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"> <tr> <td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td> </tr> </table> <p>c. On which eye or eyes? Right R</p> <p style="padding-left: 100px;">Left L</p> <p style="padding-left: 100px;">Both B</p> <p style="padding-left: 100px;">Unknown U</p>																						<p>8.a. Have you ever had laser treatments on your eyes for another condition? Yes Y</p> <p style="padding-left: 100px;">No N</p> <p style="padding-left: 100px;">Unknown U</p> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin: 5px 0;">Go to Item 9a, Screen 7</div> <p>b. What was the condition?</p> <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"> <tr> <td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td><td style="width: 10%;"></td> </tr> </table> <p>c. On which eye or eyes? Right R</p> <p style="padding-left: 100px;">Left L</p> <p style="padding-left: 100px;">Both B</p> <p style="padding-left: 100px;">Unknown U</p>																					

RETINAL EXAMINATION FORM (REXA screen 7 of 8)

<p>9.a. Are you completely blind in one or both eyes? Yes Y</p> <p style="padding-left: 100px;">No N</p> <p style="padding-left: 100px;">Unknown U</p> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin: 5px 0;">Go to Item 10a.</div> <p>b. In which eye? Right R</p> <p style="padding-left: 100px;">Left L</p> <p style="padding-left: 100px;">Both B</p>	<p>10.a. Have you ever had an eye removed? Yes Y</p> <p style="padding-left: 100px;">No N</p> <p style="padding-left: 100px;">Unknown U</p> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin: 5px 0;">Go to Item 11, Screen 8</div> <p>b. Which eye was removed? Right R</p> <p style="padding-left: 100px;">Left L</p> <p style="padding-left: 100px;">Both B</p>
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RETINAL EXAMINATION FORM (REXA screen 8 of 8)

<p>11. Type of eye selection? Assigned A Selected S</p> <p>If selected, explain: _____</p> <p>12. Which eye was photographed? ..</p> <table style="margin-left: 20px;"> <tr> <td style="border: 1px solid black; padding: 2px;">Go to Item 14.</td> <td style="padding: 2px;">—</td> <td style="padding: 2px;">Right</td> <td style="padding: 2px;">R</td> </tr> <tr> <td></td> <td style="padding: 2px;">—</td> <td style="padding: 2px;">Left</td> <td style="padding: 2px;">L</td> </tr> <tr> <td></td> <td style="padding: 2px;">—</td> <td style="padding: 2px;">Both</td> <td style="padding: 2px;">B</td> </tr> <tr> <td></td> <td style="padding: 2px;">—</td> <td style="padding: 2px;">None</td> <td style="padding: 2px;">N</td> </tr> </table>	Go to Item 14.	—	Right	R		—	Left	L		—	Both	B		—	None	N	<p>13. Reason for not photographing?</p> <table style="margin-left: 20px;"> <tr> <td>Equipment failure</td> <td style="text-align: right;">A</td> </tr> <tr> <td>Participant refusal</td> <td style="text-align: right;">B</td> </tr> <tr> <td>Biologically not feasible</td> <td style="text-align: right;">C</td> </tr> <tr> <td>Other</td> <td style="text-align: right;">D</td> </tr> </table> <p>14. Interviewer ID: <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/></p> <p>15. Photographer ID: <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/></p> <p>16. Date of data collection: <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> / <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> / <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/></p>	Equipment failure	A	Participant refusal	B	Biologically not feasible	C	Other	D
Go to Item 14.	—	Right	R																						
	—	Left	L																						
	—	Both	B																						
	—	None	N																						
Equipment failure	A																								
Participant refusal	B																								
Biologically not feasible	C																								
Other	D																								