## NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY III

Fundus Photography for Health Technicians Manual

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# <u>Appendix</u>

# Operation Manual for the CR4-45NM Non-Mydriatic Retinal Camera

## List of Exhibits

## <u>Exhibit</u>

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#### NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY III

Fundus Photography Component

## **1. INTRODUCTION**

#### **1.1** Overview of Exam Component

Fundus photographs are used in the NHANES III to assess the presence of diabetic retinopathy, age-related maculopathy and other retinal diseases which are the leading causes of loss of vision in the United States. Grading of these photographs using standardized protocols provides data on the prevalence of these diseases which will be used by the National Institute of Diabetic and Digestive and Kidney Diseases (NIDDK), National Eye Institute (NEI), and the National Institute on Aging (NIA) for program planning, research and regulatory purposes.

As in previous NHANES studies, the survey's primary purpose is to produce descriptive statistics that can be used to measure and monitor the health of the civilian, noninstitutionalized U.S. population. One of the major components of the NHANES III is the study of glucose intolerance and diabetes. An integral component of this study is the assessment of retinal status through fundus photographs. Retinal abnormalities are among the first complications to develop in persons with glucose intolerance, and retinopathy is an extremely sensitive indicator of diabetes. To date, no nationally representative sample of persons has been studied using fundus photographs to detect retinopathy. Prevalence in persons with impaired glucose tolerance is unknown, as are the relative rates by race or sex. The assessment of retinal status through fundus photographs in the NHANES III is needed to provide the basis for a prospective study of the etiology and natural history of glucose intolerance in the U.S. population. In addition to the investigation of retinopathy, fundus photographs permit study of other eye diseases in the U.S. population. Of particular importance is macular degeneration which is a major cause of loss of vision in the elderly.

## **1.2 General Overview of Procedures**

Survey participants (SP's) 40 years of age and older receive one, non-stereoscopic, color 45° photograph of one eye centered between the optic nerve and the macula. It is estimated that a maximum of 164 SP's will be photographed during each of 44 stands, or 7,216 per three year cycle. The camera used is a Canon CR4-45NM non-mydriatic fundus camera, incorporating an infrared video camera to allow photographs to be taken in a darkened examination room without the use of dilating drops. In a darkened room, the sphincter muscle of the iris normally relaxes, allowing for dilation of the pupil, usually to 6 mm to 10 mm in diameter. The examiner observes the SP's natural dilation on a special video monitor and takes the color photograph with a single flash of white light. The SP usually experiences a temporary (< 5 minute) circular discoloration of his/her vision in the photographed eye. This typically appears as a bluish tint to the vision. There is no retinal damage. The entire procedure usually takes less than six minutes per SP.

#### 2. EQUIPMENT

### 2.1 Description of Exam Room in MEC

The Canon fundus camera shares a room with the X-ray equipment and is located in the third trailer of the Mobile Examination Center (MEC). The camera is mounted on a motorized table for easy height adjustment, and both the examiner and the SP have an adjustable stool to sit on. Once the SP and examiner are positioned at the camera, the room lights are dimmed so that only the lights of the camera and computer monitors remain on. The majority of the exam is performed in the dark.

Special care must be taken to shield the camera and all film from any X-rays. The loaded camera and spare rolls of film <u>will be damaged</u> by X-rays leading to loss of data. To prevent accidental exposure of film stock to X-rays, it should be stored in a different room or in a lead shielded container.

## 2.2 Description of Equipment and Supplies

Supplies can be divided into two categories, those which are one-time purchases, and those which are bought on a repeating basis. One-time purchases include the Canon CR4-45NM fundus camera with motorized table and two stools, and a camera cleaning kit containing brush, lens tissue, a Dust-off, canned air nozzle for dust and lint removal, iris color standards, and a pupil gauge card. A list of supplies that need to be reordered on a repeating basis follows:

- a) Slide film (Kodachrome 64, 24 exposure)
- b) Photographic lens tissue
- c) Chin rest covers
- g) Alcohol
- h) 2 x 2 gauze
- i) Facial tissues
- j) Spare view and flash lamps

- k) Film mailing envelopes/address labels
- l) Federal Express labels
- m) Cotton-tipped applicators

## 2.2.1 Inventory of Supplies and Equipment

An inventory of supplies for each stand, assuming a maximum of 164 SP's, follows:

a)	Kodachrome film	7 rolls
b)	Lens tissue	500 sheet package
c)	Chin covers	164
d)	Alcohol	12 oz. bottle
e)	2 x 2 gauze	Package of 100
f)	Facial tissues	1 box
g)	Spare lamps	1 flash and 1 view
h)	Film envelopes and labels	14 each
i)	Federal Express labels	14
j)	Cotton-tipped applicators (untreated)	250

k) Air bulb

## 2.3 Equipment Set-up Procedures

#### 2.3.1 Start of Stand Procedures

Once the MEC has been parked and is level, the camera is returned to the camera table. The base must be unlocked from the camera stage by releasing the stage lock knob. The cord from the table and camera is then plugged in, the camera back is loaded with film and the camera lens is inspected and cleaned as necessary. A MEC Setup Checklist, listing the procedures for testing camera operation after initial setup, should be completed by the health technician responsible for the fundus photography equipment.

## 2.3.2 Calibration Procedures

Following the interruption of power or whenever the camera is unplugged, the flash setting and automatic date must be checked and corrected, if necessary.

### 2.3.3 Daily Set-up Procedures

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. Replace the lens cap after each photograph is taken. The dust cover should be placed on the camera at the end of each day, or the end of each session if split sessions are held.

A checklist itemizing procedures for preparing the camera at the start of each day is posted on the wall near the fundus camera. Technicians responsible for the fundus equipment should carefully follow the daily procedures.

## 2.4 Care and Maintenance of Equipment

#### 2.4.1 Cleaning

It its extremely important that camera lens be inspected and cleaned, if dirty, before each photograph. The body of the camera is kept clean and free of dirt with a soft cloth and water. The headrest may be cleaned with alcohol. Each time the film is changed, the inside of the 35 mm camera back is inspected for dirt and film fragments. Compressed air is used to clean inside the camera back. The infrared 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. A spare 35 mm body and motor should be kept in the MEC, to be used in the event of a malfunction. It should be stored in a plastic bag to keep it clean.

#### **Cleaning the Lens**

The following procedures should be followed when cleaning the camera lens:

- 1) Remove IR filter to allow white light to exit the front of the camera lens. Sit opposite the lens so you can look directly onto the front surface.
- 2) Increase the view lamp intensity to setting "10". Dim the room lights to make dirt visualization easier. Inspect lens for any oily film, streaks, smudges or dirt.
  - a) Blow loose dust and dirt particles off of the front lens surface with the air bulb.
  - b) Wrap lens tissue around an untreated cotton-tipped applicator. Moisten the tissue with lens cleaning fluid and wipe the lens surface (this may leave a film on the lens) with small circular motions. Begin in the center of the lens and progress to the edges.
  - c) Remove any residual film by polishing the lens surface with a dry cotton-tipped applicator wrapped with a clean dry lens tissue. This is often easier if you fog the lens surface with your own breath and quickly wipe the moist surface clean. Pay special attention to the lens periphery. This lens is convex and the edges are further back. Sometimes breaking the applicator handle and wrapping the wooden stick end with a tissue will help get the very far edges. Sometimes buffing the surface with the cotton applicator tip alone will remove smudges and smears. Be diligent in cleaning until all the smears are gone. This requires about 15 minutes and a dozen applicators and tissues.

d) Please replace the lens cap on the camera whenever it is not in use.

#### 2.4.2 Maintenance

The camera should require **no routine** maintenance. It is anticipated that the view lamp and flash will fail at some point. The view lamp should last approximately one year and is easily replaced as needed. The flash lamp has a life of at least 5,000 flashes, enough to almost complete a three-year cycle. However, as the lamp ages, the output can diminish, producing progressively darker photographs. This can temporarily be over-ridden by an adjustment of the transformer output controlled through the camera monitor switch operations, though ultimately the lamp should be replaced. Once a lamp is replaced, another one should be ordered immediately so that a spare is always available. The decision of when to replace a lamp, short of a complete failure of the lamp, will be made with the Photography Consultant following routine review of processed photographs.

Spare view and flash lamp should be located where health technicians can easily find and install them.

## 2.4.3 Malfunctions

Since the camera requires virtually no maintenance, any malfunction will need to be investigated first by the examiners in the MEC and then via telephone with the Photography Consultant. Together, trouble-shooting tests can be performed to diagnose any malfunction. Should parts be necessary to perform a repair, they can be ordered from Canon USA through NCHS by phone.

Some camera malfunctions or photographer errors are not evident during photography and will be discovered only after examination of the processed films. This includes camera flash synchronization, transformer power settings, or film loading problems. For this reason, prompt processing of the film is important. A telephone communication link must be available between the MEC and the Photography Consultant at all times should a malfunction be discovered during the data recording or processing or should the photographers have a problem or question needing immediate attention. The Photography Consultant can be reached at (608) 263-9858 at the University of Wisconsin-Madison. The Canon camera representative, Mr. Tom Penkala, will also be available to help should an emergency require calling Canon directly. He is available at (312) 250-6642.

## 2.5 End of Stand Procedures

#### 2.5.1 Equipment Breakdowns

The camera base should be locked to the stage before transport and removed from the table to a padded location to eliminate road vibration. It should be covered and secured to prevent movement. The lens cap **must** be in place. Care must be taken to prevent impact from any objects in the room such as chairs, tables, etc. Ideally, a padded protective case would safeguard against accidental damage. The table and stools should be secured to prevent rolling during transport.

## 2.5.2 Packing Supplies and Equipment

All other fundus photography supplies should be consolidated and packed in one location to facilitate quick and easy start-up at each new stand.

#### 3. EXAMINATION PROTOCOL

#### 3.1 Eligibility Criteria

All SP's aged 40 and over are eligible for fundus photography of one eye. The eye to be photographed is selected by computer and displayed on the data screen at the beginning of the examination. If the check digit (the last digit of the SP ID number) is even, the right eye is photographed. If it is odd, then the left eye is photographed. If for any reason the designated eye is unavailable, for example, due to an extremely small pupil, severe cornea or lens opacity, or complete retinal detachment, the other eye should be photographed. If both eyes are unavailable, no photography is performed. Photography can be performed directly through contact lenses.

## **3.2 Pre-examination Procedures**

Before attempting photography, the examiner must become very familiar with the camera through a training session and by learning the terminology on pages 3, 6 and 23 of the camera operation manual (Exhibit 3-1). The following protocol uses terminology from the operation manual, which is attached as Appendix A to this manual.

The retinal camera should remain covered when not in use and the lens should be capped after each photograph. High humidity or temperatures must be avoided. Dusty conditions mean that the camera will need frequent cleaning. Before each SP is photographed, the objective lens should be checked and cleaned if necessary.

Photography begins with a complete explanation of the procedure to the SP by the examiner. It is important to reassure the SP that no retinal damage is caused by this procedure. The camera flash is bright and the SP should know when to expect a flash. Since pictures will include the macula (area of central vision), it is normal for the SP to experience a blue or red tint to vision immediately following the flash. This totally disappears within two to five minutes. No dilation drops are used for this examination, and the eyes will not be touched.





Exhibit 3-1. Description of the CR4-45NM camera (continued)

#### DESCRIPTION OF MAIN UNIT

CR4-45NM Main Unit



Exhibit 3-1. Description of the CR4-45NM camera (continued)

#### 35mm PHOTOGRAPHY



Prior to performing photography, the examiner is to inform the SP about the nature of the exam using something like the following phrase:

"A single fundus photograph of one eye is not an eye examination. You should continue to have routine eye care or to see an eye doctor if you are concerned about the health of your eyes."

With the normal room lights on, the iris color and the prephotography pupil diameter of the study eye are determined and entered into the appropriate data screens by the examiner. Normal room lights include all overhead fluorescent lighting and the incandescent table lamp, which should not be directed toward the SP's eyes. There are two example prints for iris color which will be used for comparison. The iris will be graded as being brown, blue or other. There is also a pupil gauge card available to help in estimating pupil size.

The camera, table height, and chin rest are adjusted so that the SP 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.

#### **Preparing the Camera**

When the power switch on the main unit is turned on, the following screen is displayed:



If no photography or switch operations are performed for five minutes, a power saving "sleep" mode is activated. Pressing **any** button below the arrows will reactivate the system.

The number above the word "menu" should be 64, the same as the speed of the film: ISO 64. If this number is not 64, it must be changed to 64 by pressing the "menu" button, followed by the "35 mm" button and "ISO" button. Continue to press the "ISO" button until 64 appears; then press the "set" button. Notice that the ISO number may blink when the main unit is switched on or the ISO is changed. A blinking ISO indicates the system is charging. <u>Do not</u> take photographs until the blinking stops, indicating a fully charged flash.

There are two narrow vertical slots above the number 64 visible on the display screen. The correct date must appear in the left hand slot. The camera contains an internal clock and this date should automatically change each day. The examiner must manually change the date if this clock should fail or if the camera is left unplugged for a long period of time. The right hand slot contains the SP ID number. The camera is incapable of recording seven digits automatically, **so only the rightmost digits of the SP ID number, including the check digit, will be entered, deleting the leftmost digit. Enter the ID correctly and double check it.** Once properly entered into the camera, the number will appear in the right hand slot. This must be done before any photographs are taken because this information is recorded on each slide and will become a permanent part of the data slides and be the primary identifier for each picture.

The 35 mm camera body should be attached to the main unit and loaded with a fresh roll of Kodachrome 64, 24 exposure color slide film. If the camera already contains film from the previous day's photography, the examiner must simply confirm that the camera is loaded by applying slight clockwise pressure to the film rewind crank and feeling for resistance and confirming that the film counter on the camera indicates the number of exposed frames already taken. A second frame counter which counts backwards, is also visible on the motor drive.

If the camera needs to be loaded, open the camera by pressing the lid release button while lifting up on the rewind knob. 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 is engaging both upper and lower sprocket wheels. Be careful not to poke the shutter blades with a finger because damage to the blades can occur easily. Take up the

slack in the cartridge by winding the rewind knob slowly clockwise. Close the back and advance the camera to the number one exposure position by firing the camera shutter release button. <u>Do not</u> do this by firing the main unit joystick button. Watch to be sure that the rewind knob <u>unwinds</u> (counter-clockwise) while advancing the film during loading and photography. This indicates that the film is advancing properly. If the rewind knob does not unwind, the film must be reloaded.

Once the film is properly loaded, set the frame counter wheel to 24, (the maximum number of exposures on the roll of film). This is an important safeguard! The motor drive is powerful enough to damage the film and may pull it out of the cartridge if the film counter wheel is not properly preset. Remember that this counter counts backwards displaying the number of exposures left on a given roll of film. Once a roll of film has been completely exposed, the winder frame counter displays 0 and the alarm lamp lights.

In the event that the examiner attempts to take a photograph in this position, no photograph will be taken and the words "check film back" will be displayed on the monitor. This is a reminder that the film needs to be rewound and a new film loaded into the camera before continuing.

Four computer screens display SP information, including age, sex, ID number and eye to be photographed (see 3.3.2). A log file for each roll of film is created (see Section 4) so that detailed information about each roll of film can be printed and mailed along **with every roll** (see Section 4) of film sent to the Reading Center. Data for the log file include: date, examiner ID, SP ID number, film roll number, eye photographed, and a comments section. Each roll of film is assigned a unique roll number and will contain photographs of up to 24 eyes. At the end of each week, a roll of film and a film transmittal form will be generated and forwarded by 2 day express mail to the Reading Center for processing. At the same time the log will also be sent to the Reading Center under separate cover via 2 day express mail.

Upon receipt of the packages, if any discrepancies are discovered, the Fundus Photography Coordinator will attempt to resolve them by phoning the MEC Manager. Written notification of unresolved discrepancies will also be sent to the MEC Manager, the Director of MEC Operations and NCHS. If a transmittal form arrives with no matching film or log file within a reasonable period of time, the MEC Manager will be notified of a missing or partial shipment.

### **3.3 Examination Procedures**

#### 3.3.1 Survey Participant Photography

The SP and the examiner are seated on the appropriate sides of the retinal camera. It is helpful if the examiner wears dark upper body clothing to minimize light scatter in the room from the display monitor. The room is darkened so that the only light is that of the monitor. The camera is positioned before the appropriate eye and the alignment switch is pressed to provide an anterior segment view of the pupil. The camera stage is moved to center the eye 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. See diagram below.



A pupil larger than the central 4 mm circle on the monitor is required for adequate photography. On the average, pupils dilate almost immediately. Eyes of older people may require 2-3 minutes to achieve acceptable dilation. Eyes that do not dilate to >4 mm after 5 minutes are photographed through the suboptimal pupil. The pupil size of all eyes at the moment of photography is estimated and recorded on the log form.

Once proper external pupil alignment is achieved, the alignment switch is pressed again to provide a view of the fundus, split focusing lines, corneal reflection dots, and a fixation light. If no split lines are seen, the height or left/right adjustment is improper. 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, the diopter compensation slide is in the plus or minus setting, 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.

The diopter compensation slide should be set to the "0" position for most eyes. This will allow photography of eyes with refractions between -12 and +15 diopters. In the event that the eye photographed falls outside this range, i.e., focus cannot be achieved by aligning the split line and the view on the monitor remains out of focus, as in the case of aphakia or high myopia, the split line focus system does not operate. In these cases, the diopter compensation slider must be adjusted for the clearest focus to the "+" or "-" position and focusing knob is then turned 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.

Use the least amount of light necessary to see the fundus to focus. This will improve pupillary dilation because the room will remain darker. The normal setting for the light intensity adjustment is approximately 4.

Standard TV monitored functions can be adjusted for the photographer's viewing comfort 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.

While viewing the fundus image on the screen, the examiner carefully adjusts the internal fixation target lever to position the fundus correctly on the screen. In the correctly positioned photograph, a horizontal line bisecting the center of the screen will bisect the optic nerve. The optic nerve should be positioned one to one and a half disc diameters from the edge of the field. This will produce a slide containing all of the optic nerve, the macula, and temporal retina clearly visible. See diagram below for both right and left eyes.



The final adjustment of SP 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.

Once the fixation is confirmed, the focus is fine tuned and final alignment is done with the joystick and the height adjustment ring. At this time the photographer must <u>constantly</u> 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, clearly in focus 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 confirmed and the shutter release, located in the tip of the joystick, is depressed.

## 3.3.2 Recording Results Using the Automated System Examination Form

NCHS has designed a series of screens for use in recording the results of the fundus photography examination. In this section each of the screens you use is discussed in detail. Procedures for logging on to the system entering your ID entering the SP's ID are discussed elsewhere.

The first screen is the Introductory Screen (Exhibit 3-2). This screen displays a menu listing procedures. Use the arrow keys to move the curser to "Fundus Photography and press <SELECT>. This will call up the Fundus Photography Screen (Exhibit 3-3).

On the Fundus Photography Screen the curser will automatically appear in the film number field at the upper left of the screen. The film number is assigned automatically, but if it does not correspond to the next available film number ID label, you can enter the film number manually by typing over the number which is there. Press <RETURN> to move to the next field.

The automated system should display which eye to photograph, i.e., left or right, in the upper right corner of the screen. Note that you can change this designation if necessary by typing over it and pressing <RETURN>.

Exhibit 3-2.	Introductory	screen
--------------	--------------	--------

\_\_\_\_\_

In :roduction

Technician

~ h# <u>1234</u>

me Linda Elias

Examinee Sample# <u>5151515</u> Name NURSE

> Age <u>42</u> Years/Months <u>Y</u> Sex <u>F</u>

Procedures

Ecg Fundus Photography

Char Mode: Replace Page 1

Count: \*2

Exhibit 3-3. Fundus photography screen

Fundus Photography

Name NURSE Sample# 5151515 Film Number <u>AA11111</u> Sequence Number <u>12</u> Photograph \_\_\_\_\_ eye Right eye <u>1</u> 1. Blue 2.\_Other 3. Brown Eye Color: Left eye <u>1</u> 1. Blue 2. Other 3. Brown  $\frac{8}{6}$  (mm) Pupil size before dilation in normal room light  $\frac{6}{6}$  (mm) Pupil size during photography as measured on camera monitor 5 (min) Elapsed time between darkening room and taking photograph:  $\overline{25}$  (sec) Photograph taken?  $\frac{1}{2}$  1. Yes 2. No Number of <u>1</u> Which eye? <u>1</u> 1. Right Photographs 2. Left Char Mode: Replace Page 1

Count: 1

The next two fields ask you to record the color of the SP's eyes. First enter the code which corresponds to the color of the SP's right eye. Enter a 1 for blue, 2 for other, or a 3 for brown. Press <RETURN>. Repeat for the left eye.

Record the SP's pupil size in mm in normal room light. Press <RETURN>.

Record the SP's pupil size in mm during photography, as measured on the camera monitor. Press <RETURN>.

Record the number of minutes between darkening the room and taking the photograph. Press <RETURN>.

Record a code to indicate whether or not a photo was taken. Record a 1 for "Yes" or a 2 for "NO." Press <RETURN>.

Record how many photographs were taken. Press <RETURN>.

Record a code to indicate which eye you photographed: 1 for right or 2 for left. Press <RETURN>.

Press <NEXT SCREEN> to enter the data into the data base and to continue to the Results Screen. Press <PREV> to return to the Introductory Screen without entering the data.

Note that the software requires that all fields have data in them if a fundus photograph was taken. If a field has no data, then the cursor will automatically go to that field and will not allow the examiner to continue until data are entered.

If a fundus photograph is not taken, the software will enter blanks into the fields for film number, sequence number, number of photographs and which eye.

When the Results Screen (Exhibit 3-4) appears, use the arrow keys to move the cursor to the appropriate choice. Select "Satisfactory Test" and press <SELECT> if the test was completed.

Exhibit 3-4. Results screen A

Name NURSE

\_ Sample# <u>5151515</u>

Examination results

Select one

Satisfactory test Test complete, but unsatisfactory Not done

Comments:

Char Mode: Replace Page 1

Count: \*3

If the test was complete but unsatisfactory, select that field and press <RETURN>. The next screen (Exhibit 3-5) will list 10 possible result codes and a field for comments. Use the arrow keys to move the cursor to the appropriate result. Press <SELECT>. Comments are optional. If you would like to make any comments, type them in and then press <NEXT> to return to the Introductory Screen.

The third result on the Results Screen is "Not done." Press <SELECT> to choose this result category. You will automatically move to a screen (Exhibit 3-6) listing nine possible result codes and a field for comments. Use the arrow keys to move the cursor to the appropriate result category. Press <SELECT> to record the result and move to the Comments field. Comments are optional. If you would like to make any comments, type these in and then press <NEXT> to return to the Introductory Screen.

## 3.3.3 Recording Results Using the Hard Copy Exam Form

There may be times when the automated system is not functioning and it is necessary to use a hard copy examination form (Exhibit 3-7) to record the results of the fundus photography screen. Follow the steps below to complete the form:

- Record your ID number in the upper left corner;
- Record the seven digit film number in the next box. Also record the two digit sequence number.
- Place an SP ID number label in the upper right box.
- Q1. Check the box to indicate the color of the SP's right eye and left eye. Note that it is possible to record a different color for each eye.
- CHECK BOX: This instruction tells you to photograph the right eye if the rightmost digit of the NCHS number is even and the left eye if the rightmost digit of the NCHS number is odd.
- Q2. Record pupil size in mm in normal room light.
- Q3. Record pupil size in mm as measured on camera monitor.
- Q4. Record the number of minutes and seconds which elapsed between darkening the room and taking the photograph.

Name NURSE Sample# 5151515

Examination results
Select one

Equipment failure
Refused or uncooperative
No Fixation
Corneal change
Pupil not dilated
Severe lens opacity
Vit Hem or opacity
Insufficient time available
Other

Comments:

Char Mode: Replace Page 1

Count: 10

Exhibit 3-6. Results code C

N > NURSE \_\_\_\_\_ Sample# 5151515

imination results

Select one

Equipment failure	
Refused or uncooperative	x
Eye removed	
No fixation	
Corneal change	
Pupil not dilated	
Insufficient time available	
Examinee medically excluded by staff for safety	
Other	

Comments:

Char Mode: Replace Page 1

Count: \*9

		Cime nd. 0320-021
	FUNDUS PHO Ages 40 An	TOGRAPHY D OLDER
·	FILM NO	
STAFF NO	SEQ. NO	SAMPLE NO
1. Eye Color:	A. Right eye 1 blue 2 dther 3 brown	B. Left eye 1 ⊡ blue 2 ⊡ other 3 ⊡ brown
NOTE: Photograph number is o	right eye if sample number dd.	is even and left eye if sample
2. Pupil size before dilation	n in permal room light:	
<ol> <li>Pupil size during photog as measured on camera r</li> </ol>	jraphy monitor: mm	
Elapsed time between da	arkening room and taking photogra 1 Right eye done 2 Right eye done bu 3 Left eye done but 5 Neither eye done	sh:
i. REASONS TEST INCOMPL	ETE OR NOT DONE: 1 2 2 3 2 4 0 4 0 4 0 4 0 4 0 4 0 4 0 4 0 4 0 4	Equipment problem or lack of supplies Refused or uncooperative Eye removed Movement

Exhibit 3-7. Fundus photography hard copy examination form

- Q5. Record the results of the exam. Note that these codes are different from those used on the automated Result Screen. Choose one code.
- Q6. If the test was not done, that is if box 5 (Neither eye done) was checked for Item 5, complete Q6. Again, you will notice that these codes do not match those used in the automated screens. Specifically, the screens provide a code for "other" while the paper form does not. If using the paper form, one would check the box for comments and record the other response on the line provided.

## 3.4 Physician Referrals

If the technician sees a significant vision - threatening abnormality (e.g., tumor, hemorrhage or detached retina), the MEC physician should be consulted. If the physician thinks there may be a problem, the SP should be advised to see an ophthalmologist. Also, a Polaroid print should be taken of the eye and shipped with the other study materials at the end of the week. Finally, a comment should be added to the log for the SP who was referred.

#### 4. LOGS AND RECORDS

## 4.1 Fundus Photography Daily Log Sheet

A Fundus Photography Daily Log Sheet (Exhibit 4-1) will be maintained for each roll of film to provide an accurate listing of each SP photographed. The complete log for each film roll will contain stand number, location, date, session number. One line of the log is completed for each SP. Each line includes a space for a preprinted label with the SP's ID, the disk label (film roll) number, time in, time out, exam status, and comments. The examiner 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 as well as helping the Photography Consultant give accurate feedback during the initial learning period. SP's may volunteer information about their eyes, for example, saying that they have a corneal scar or cataracts that prevent photographing a clear image of the retina. Such information should be included in the comments section.

### 4.1.1 Automated System

The daily film logs will be kept on the computer and updated by the examiners at the terminal located in the ECG room. Computer logs will be available to the Reading Center via a call-up link directly with the Coordinating Center and hard copy of the logs for each roll of film will be produced to accompany each mailing.

### 4.1.2 Hard Copy Daily Log

If the automated system is not available, use the hard copy version of the Fundus Photography Daily Log Sheet (Exhibit 4-1).



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Exhibit 4-1. Fundus photography daily log sheet

#### 4.2 Calibration Logs

Not applicable.

#### 4.3 Shipment of Forms and Logs

Every week, the film, a transmittal form confirming rolls sent, and the log information for each roll of film will be sent from the two stands. The first roll of film initiating a new stand and the last roll of film concluding a stand **must be clearly marked as such on the transmittal form**.

The weekly mailing of the fundus photography film and the accompanying transmittals will be done via 48 hour Federal Express, using preaddressed Federal Express envelopes. At the same time, a separate Federal Express mailing of the room log will be made to the same address. Check each envelope to make sure that it is correctly addressed to the following:

> NHANES III Coordinator WARF Office Building 610 North Walnut Street, Room 465B Madison, WI 53705 (608) 263-0277

Ship the exposed films on Friday afternoon or Saturday morning each week. If a stand ends on a Saturday or Sunday, the final roll of film should be mailed immediately after exams are completed.

When shipping photography logs staple together all of the logs which correspond to a given roll of film. Each film roll should be labeled with a box label. The number on the box label should be written on the log sheets that pertain to the roll of film. The box label number should be recorded on the transmittal form.

Mail the original (white) copy of the transmittal form to the NHANES III coordinator with the roll(s) of film. A copy of the transmittal should also be sent by regular mail to Receipt and Control at NCHS on the same day the film is shipped. Keep one copy of the transmittal form in the MEC and send it to the Director of MEC Operations at Westat at the end of the stand.

#### 5. QUALITY CONTROL

Photographic quality will be monitored continuously throughout the survey. Initially all photographs will be reviewed by the Photography Consultant and feedback will be provided to the examiners using a Polaroid photograph and a standard letter detailing problems and suggesting improvements. Once the study is well underway and the examiners are sufficiently trained, a percentage of the photographs will be reviewed for photographic quality, and written feedback will be provided to the photographers by the Photography Consultant. Additionally, as part of the grading process, specially trained photograders will also judge every photograph. Periodically, summary reports from this will be sent to the MEC Manager and to NCHS.

As part of the quality control procedures for this component, it is extremely important that the examiner document any condition that would affect the quality of the photograph. The examiner's comments should be as succinct and as precise, as possible.

#### **COMMUNICATION CHANNELS**

It is vital that proper and frequently used channels of communication be established for the effective exchange of questions and information among all staff members. Following is a listing of names, addresses, and telephone numbers:

Sarah Baumgart NHANES III Coordinator WARF Office Building, Room 465B 610 North Walnut Street Madison, WI 53705 (608) 263-0277

Photography Consultant Michael Neider University Hospital and Clinics Department of Ophthalmology 600 Highland Avenue Madison, WI 53792 (608) 263-9858 Ophthalmologist Ronald Klein, M.D., M.P.H. University Hospital and Clinics Department of Ophthalmology 600 Highland Avenue Madison, WI 53792 (608) 263-6641

Director of MEC Operations Catherine Novak 1650 Research Boulevard Rockville, MD 20850-3129 (301) 251-4318

NCHS Project Officer Michael Rowland, Statistician Nutrition Statistics Branch Division of Health Examination Statistics Room 2-58 Federal Center Building 3700 East-West Highway Hyattsville, MD 20782 (301) 436-7073

Systems Analyst Anik Ganguly WARF Office Building 610 North Walnut Street Madison, WI 53705 (608) 263-4603

Photograders Stacy Meuer and Carol Hoyer WARF Office Building 610 North Walnut Street Madison, WI 53705 (608) 263-8835

## 6. SAFETY PROCEDURES

This procedure poses no risks to the SP or to the photographer. Therefore, there are no specific safety procedures for this component.
# APPENDIX

Operation Manual for the CR4-45NM Non-Mydriatic Retinal Camera Thank you very much for your purchase of our product. Please read this operation manual thoroughly to fully understand the functions of this product for ensuring proper use.

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The CR4-45NM is capable of performing non-mydriatric retinal photography when the main unit is combined with the Polaroid back unit or camera back unit and in addition, is capable of performing the retinal observation through visible light when combined with the viewfinder unit.



#### How to Read Operation Manual

This manual is divided into three sections: (1) Photography by Polaroid back unit, (2) Photography by camera back unit, and (3) Retinal observation by viewfinder unit.

Please refer to the description applicable to the combination of products you have purchased.

Precautions for Use

- Since a strong shock might cause preadjustment disorder, please handle the unit carefully.
- Be sure to check that there are no stains or scratches on the objective lens before photography, since they may appear on the print as white dots. After photography, place the cap over the lens.
- 3. This unit is a precision instrument. Avoid high humidity or temperature, and dusty conditions.
- 4. Be sure not to handle this unit in other manners than those described in this manual.

Installation

- Install the instrument where it is possible to control the brightness to the degree a newspaper can be barely read (about 5 luxes).
- 2. Place the instrument on a table.
- 3. Insert one end of the power cable into the instrument.
- After confirming that the cables are connected properly, insert the power plug for the main unit into the power source.

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Attachment/Detachment to/from Main Unit

Follow the procedure below to attach the Polaroid back unit to or detach it from the main unit.

- 1. Turn off the power.
- 2. Insert the Polaroid back unit plug into the back unit receptacle on the main unit, and tighten the clamping screw by fully turning it clockwise.



3. With the mount groove of the Polaroid back unit aligned to the positioning pin of the main unit, push the Polaroid back unit against the main unit and push the lever down.



4. Detach the Polaroid back unit in the reverse order of the attachment.

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#### Precautions after Detachment

Dust may enter into the Polaroid back unit and the main unit if the Polaroid back unit is left as it is after detached. Place the supplied caps over both mounts.

### Film Loading

The usable film is Polaroid High Speed Land Film 600 or Type 779. Each film pack includes 10 films. Since the Polaroid back unit does not operate if detached from the main unit, a film pack should be loaded in the state with the Polaroid back unit attached to the main unit. Refer to the previous item to attach/detach the Polaroid back unit.

1. Turn on the power.

- 2. Open the film pack insertion slot.
  - Push the film take-out lever in the direction of the arrow.
  - The lever returns to the original position naturally when the finger is released.



- 3. Insert the film pack into the Polaroid back unit.
  - The film cover (dark slide) should face upwards.
  - The film tab should face the operator.
  - Insert the film pack fully until the narrow strip portion opens.

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4. Close the film insertion slot cover. • Push the cover upward from the lower side. 5. Press the film cover take-out button (green) to remove the film cover. Chin Rest Paper Attachment When attaching the chin rest paper, follow the procedure below: 1. Pull up 2 retaining pins. 2. Insert the retaining pins into the left and right holes on the chin rest papers. 3. Push the retaining pins with chin rest papers down into 2 holes on the chin rest. Photography Procedure Be careful so that the examinee's pupil does not become small because of the influence caused by the examiner's clothes, the sitting position, and the direction of the monitor. 1. Set the shutter knob to 0. 2. Determine light intensity for observation. • Set the light intensity adjusting knob to 4. (Standard intensity)

3. Turn on the power. • The following screen is displayed on the monitor. • If no photography or switch operations are performed for more than 5 min., the power saving system will work. P600 MENU 0 Display of ISO sensitivity Note 1: When the monitor does not display the screen normally, turn off the power once and after about 5 sec., turn on the power again. 2: If the Polaroid back unit is detached from the main unit during the operation and attached again, the following screen will be displayed. Press the button below POLA. POLA 35MM C - 11 -

4. Confirm the flash intensity. • See the screen when the power is first turned on (Step 3, above) to confirm that P600 is displayed at the lower left. [To compensate flash intensity] (1) Press the button below MENU. • The following screen is displayed on the monitor. 1.50 DATA SPLT P/35 (2) Press the button below ISO. • The following screen is displayed on the monitor and "P600" blinks. POLA ISO PECO + ) SET [ -• Press the button below "-" to decrease the intensity and the button below "+" to increase the intensity. • In the respective cases "P600" or "P600" blinks. - 12 -

	3 After setting the flash intensity, press the button below "SET".				
	<ul> <li>The monitor displays the screen, which appears when the power is turned on, and "P600", "P600" or "P600" blinks at the lower left.</li> <li>While the display blinks, the power is being charged. When it lights continuously, then it becomes possible to perform photography.</li> </ul>				
	[In the case P600 is not displayed on monitor although power is turned on]				
	Follow the procedure below:				
	1 Press the button below MENU.				
	2 Press the button below P/35.				
	3 Press the button below POLA.				
5.	Darken the room to a level where a newspaper can be read anyhow (about 5 luxes) or darker.				
6.	Have an examinee sit.				
	<ul> <li>When the examinee is in a dark room, the examinee's pupils dilate naturally.</li> </ul>				
	Note: If the examinee puts on spectacles or contact lenses, have him take them off.				
7.	Adjust height of the chin rest.				
	<ul> <li>Adjust height of the chin rest by rotating the chin rest height adjusting ring so that the eye to be examined is aligned with the height adjusting mark.</li> </ul>				
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8.	Release the lock of the stage.					
	<ul> <li>Rotate the stage lock knob counterclockwise.</li> </ul>					
9.	Move the main unit to the eye to be photographed.					
	<ul> <li>Grasping the joy stick, move it to the left or right.</li> </ul>					
10.	. By pressing the ALIGNMENT switch, display the external eye image on the monitor.					
	<ul> <li>Instruct the examinee to look straight ahead.</li> <li>The external eye image and pupil alignment mark ( mark) is displayed on the monitor.</li> <li>Whenever pressing the switch, the external eye image and the retinal image are displayed alternately.</li> </ul>					
11.	Observe the external eye image on the TV monitor, focus the pupil alignment mark, and align the split images with the mark.					
	• Left/right and height adjustment.					
	Left/right adjustment Adjust the left/right					
	position by tilting the joy					
	stick to the left/right.					
	Height adjustment Adjust the height by rotating					
	the height adjusting ring. If					
	not adjustable sufficiently,					
	rotate the chin rest height					
	adjusting ring.					
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(4) Split lines are OFF: Turn on the split lines by displaying the above screen for step 4 and by pressing the button below SPLIT. Push the diopter compensating slider if it is out. If the split lines cannot be aligned even when the focusing knob is fully rotated and the split function is on, pull out the diopter compensating slider. (The diopter of the eye to be tested is outside the measurement range of -12 to +15D) • The split lines disappear. • In this case, adjust the focusing by rotating the focusing knob so that the retinal image is clearly seen on the monitor. Х When the left line is up: 2 steps When the right line is up: 111151111 1 step Х 15. Determine the area to be photographed. Have the examine look at the fixation target, move the fixation target lever and determine the retinal image area to be photographed on the TV monitor. • If flares are seen or the corneal reflection dots at. the left and right are not seen, adjust the height, forward/backward and left/right positions of the main unit once more.

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• If the split lines become misaligned, align them again.



16. Press the shutter release button.

- The flash lamp lights and an exposed picture will come out automatically.
- As neither data nor counter number is printed, describe necessary information onto the available space on the Polaroid picture.

Note 1: While "P600" blinks, the power is being charged and no photography can be made.

2: Be careful not to take the film out forcefully or to block film movement during film advancement.

17. When the photography is completed, turn off the power.

• Place the cap over the objective lens.

#### Film Pack Replacement

When the film is used up, the film counter indicates 0, "CHECK FILM BACK" is displayed on the monitor, and the warning lamp blinks if the ALIGNMENT switch is set for the retinal image. Take out the empty film pack by following the procedure below.

- Push the film take-out lever fully in the direction of the arrow.
- 2. Pull the tab and take out the empty film pack.
- 3. Load a new film pack by following the procedure for film loading.

Various Display Function

Alarm Display

In the following conditions, "CHECK FILM BACK" is displayed on the monitor, and the warning lamp blinks if the ALIGNMENT switch is set for the retinal image. In these cases, the flash lamp does not light and no picture will come out.

- When the Polaroid film is used up: Exchange the film pack with a new one.
- (2) When a film pack is loaded and the film cover (dark slide) is not removed: Press the film cover take-out button (green).

```
3 When the shutter knob is set to "C":
Set it to "O".
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When the shutter release button is pressed without the camera plug (Polaroid back unit, camera back unit) being connected to the receptacle on the main unit. Connect the plug to the receptacle.

Note: If the alarm is still displayed on the monitor although the above problems are solved, contact a Canon representative or distributor.

Normally, when the above problems are solved, the monitor will display the screen when the power is turned on or the previous screen before "CHECK FILM BACK" is displayed.



### Power Saving System

If photography and switch operation are suspended for more than 5 minutes, the power saving system will work. The monitor turns to the screen below, and "SLEEP" blinks.

- To restore the power, press one of the buttons indicated by the arrow.
- After the buzzer sounds, the monitor displays the screen, which appears when the power is first turned on.



# Selection of Photography Camera

When the Polaroid back unit is detached and replaced with the camera back unit during photography, the following screen is displayed on the monitor. In this case, press the button below either name of back units to be used.



# Blink Detection Function

This function is to prevent photography error by suspending photography if an examinee blinks at the moment the shutter release button is pressed. When this function works, the following performance will ensue.

1 The flash lamp does not light.

- 2 The "BLINK" is displayed at the lower left on the monitor and it blinks for about 3 seconds. At the same time, the buzzer sounds.
- 3 The film counter does not advance and no exposed pictures come out.

To switch on or off this function, display the following screen on the monitor and press the button below "BLNK".

• The "ON" and "OFF" are displayed alternately every time when the button is pressed.

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Note: Parts which are not described in the above do not function as the components of the retinal camera and it is therefore not required to operate them. Further, normally the parts numbered from 1 to 3 below should be set as shown when used.

1	Shutter release button	Set to A	L The shutter release button is locked.
			S Self-timer
2	Mode selector	Set to S	OFF The winder does not operate.
			C When the winder shutter release button is pressed, the film advances continuously.
3	Release lock dial	Set to L	A Controlled by the mode selector set- ting, this button functions as shutter release button.

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# Camera Back Attachment/Detachment

Follow the procedure below to attach the camera back to the main unit.

- 1. Turn off the power.
- 2. Insert the plug of the camera back into the receptacle on the main unit and turn the clamping screw fully clockwise.
- 3. Align the main unit positioning pin with the mount groove of the camera back, push the camera back against the main unit and lower the mounting lever.
- 4. To detach the camera back, reverse the procedure above.

## Cautions after Detachment

- If the detached camera back is left uncovered, dust and dirt may get inside the camera back as well as the main unit. Be sure to place the supplied dust cover over both mounts.
- 2. The mirror inside the camera back is longer than that of an ordinary camera. If a lens is attached to the camera back and the shutter release button is pressed, the mirror installed in the camera back will break. Do not try so.

### Film Loading

The usable film is the 35mm film with ISO sensitivity (ASA) 64 - 400. Since the camera back does not work if detached from the main unit, load a film with the camera back attached to the main unit. For the film loading method, refer to the previous item.

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- 1. Turn on the power.
- 2. Open the back lid of the camera back.
  - While pressing the back lid releasing button, pull up the rewind knob.
  - Pull up the rewind crank to make operation easy.
- 3. Insert a film cartridge into the cartridge chamber.
  - Press down the rewind knob so that its spindle is inserted into the cartridge.
  - If the rewind knob cannot be pressed down, lightly rotate the rewind knob clockwise or counterclockwise.
- 4. Put the film around the film take-up spool.
  - Insert the film end into the film insertion slot securely.
  - Press the shutter release button to wind the film one around.
  - Check that the film performations are engaged on the sprocket and spool tooth.
- 5. Remove the film slack.
  - Slowly turn the rewind crank clockwise.
  - Lay down the rewind crank.



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- Note 1: Do not press the aperture mask as it is easily deformed.
  - 2: When the mode selector is set to off, the film can be wound by the winding lever.
  - 3: If the film tries to be wound by pressing the shutter release button on the main unit the flash lamp will light. Do not press it during the film loading.
- Press the shutter release button on the camera back to confirm that the film is properly wound up, and close the back lid.

• The back lid is automatically shut locked.

Note 1: When the film is advanced properly, the rewind knob turns counterclockwise. If not, load the film again from the beginning.

- 2: If film tries to be reloaded, take care that film leader is not rolled in. If this happens, the film cannot be loaded again.
- 7. Press the shutter release button on the camera back until "1" is shown on the frame counter.
- 8. When "1" is shown, set the frame counter to "S".
  - Press the frame counter reset button.
- 9. Set the frame counter to number of frames (12, 24 or 36) of the film to be used.
  - Turn the frame counter set gear in the direction of the arrow while pushing it.

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- Note 1: If the frame counter is set to a larger number than the number of film frames actually used, the film may be severed. Therefore, the counter should be set accurately.
  - 2: If the counter number is set wrongly, first, set the counter to "S". Then, set it to a correct number.
  - 3: The number of the counter on the camera back increases and that on the winder decreases.
- Photography Procedure

Since the basic operation for 35mm photography is the same as that for Polaroid photography, refer to the "Polaroid Photography" procedure.

- Follow the procedure for "Polaroid photography", steps 2 and 3.
  - Set the light intensity adjusting knob to 4. (Standard intensity)

• When the power is turned on, the screen at the left is displayed on the monitor.



Note: When the Polaroid back unit is replaced with the camera back unit while in use, the screen at the right is displayed on the monitor. In this case, press the button below "35mm".

- 2. Confirm flash intensity.
  - Looking at the screen which appears when the power is first turned on, confirm that the number above "MENU" is the same as ISO sensitivity of the loaded film.
  - [If ISO sensitivity is different]
  - While displaying the above screen, press the button below "MENU".
    - The following screen is displayed on the monitor.



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(2) Press the button below "ISO".



- 3 Press the button below "ISO".
  - o The ISO sensitivity changes to 100, 200, 400 and 64 on the monitor every time the button is pressed. Set the ISO sensitivity to that of the film to be loaded.

[Flash intensity compensating procedure]

- (1) Display the screen shown for step 2 in the previous item.
- (2) Press the button below "-" to decrease the intensity and the button below "+" to increase the intensity. In case of ISO 400, the flash intensity cannot be compensated.

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- (4) After setting the flash intensity, press the button below "SET".
  - The acreen which appears when the power is first turned on is displayed and the set flash intensity (ISO sensitivity) blinks at the lower left.
  - While the set flash intensity blinks, the power is being charged. When the display lights continuously, then it becomes possible to perform photography. (In the case P600 is displayed on monitor when power is turned on). Follow the procedure below.
    - 1. Press the button below "MENU".
    - 2. Press the button below "P/35".
    - 3. Press the button below "35mm".
- 3. Follow the steps from 6 to 16 for "Polaroid Photography".
  - Chin rest height adjustment, external eye image/retinal image selection, height, forward/backward, left/right adjustment of the main unit, etc.
- 4. Press the shutter release button.
  - The flash lamp lights, 1 frame is exposed, the film is wound up automatically and stops.
  - The counter number and the data written on the data card are printed simultaneously.
  - On every photography, the number on the counter decreases.

Note: When the shutter release button on the camera back is pressed, the flash lamp does not light and the film is wound up.

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#### Film Rewinding

When the set number of film frames are exposed, the winder frame counter becomes zero and the alarm lamp lights. Although the shutter release button is pressed under this condition, photography is not taken and "CHECK FILM BACK" is displayed on the monitor. In this case, rewind the film by following the procedure below.

- 1. Press the frame counter reset button.
- 2. While rotating the rewind set lever in the direction of the arrow, push it in.



• The lever is locked in the state of being pushed.

Note: When the lever is pushed in by mistake, lightly press the shutter release button on the camera back. The lever will return.

- 3. Pull up the rewind crank and turn it in-the direction of the arrow.
  - Rewinding sound is heard while the film is being rewound. Turn the rewind crank until the rewinding sound is no longer heard.

- The frame counters (on both the camera back and the winder) are not affected by the film rewinding.
- At the same time when the film is taken up by the take-up spool, the winder makes one wind-up operation and the alarm lamp goes out.

Note: The rewinding can be made without pressing the frame counter. In this case, however, after completing the rewinding, the alarm lamp does not go out. To put the alarm lamp out, (1) set the mode selector to OFF, (2) return the winder counter to S, and (3) return the mode selector to S.

- 4. Open the back lid of the camera back and take out the exposed film.
  - After confirming that the alarm lamp was out, open the back lid.
  - If not performing photography continuously, close the back lid.
     For the opening/closing procedure of the back lid, refer to the steps for the film loading.

Data Card Handling

Describe data within the data card frame with thick pencil. Insert the data card into the data card insertion slot with the described side of a card facing the left. The described data is displayed on the left side of the monitor.

• Two of the following data; counter number, description on data card and auto-calendar record are displayed simultaneously on monitor. They are printed on film when the shutter release button is pressed.

When the data card is inserted, the data card description is displayed on the left data area. Further, to select either the counter number or the auto calendar record, display the screen shown for step 3.

 Whenever the button below "DISP CHANGE" is pressed, either data is displayed alternately on the right data area.



Note: Data on left area is hidden by the data card.

Setting of Counter Number

To change the counter number, follow the procedure below.

- Display the screen, which appears when the power is first turned on.
- 2. Press the button below "MENU".
  - The following screen is displayed on the monitor.



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- 3. Press the button below "DATA".
  - The following screen is displayed on the monitor.



- 4. Press the button below "NO. SET".
  - The following screen is displayed on the monitor.



- Press either of the buttons below "HOLD" and "COUNT".
- The display for the button pressed blinks.

- 5. When completing the setting, press the button below "SET".
  - The following picture is displayed on the monitor:



- The number is to be set in every two digit from the left.
- When the first upper two digits blink, set the desired number for them and press the button below "SET".
- When the number for the first 2 digits is finished setting, the next 2 digits will blink. Set the number in the same manner as the above successively.
- When the button below "?" is pressed, the number will increase and when the button below "FAST" is pressed simultaneously, the pace will become fast.
- When the button below "4" is pressed, the number will decrease.
- The counter figures flash in 2 digits simultaneously and they can be changed.
- After setting all 6 digits, press the button below "SET". The monitor shows the screen, which appears when the power is first turned on.

Confirmation of Auto Calendar

To check the auto calendar display, follow the procedure below.

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- Display the screen for the step 3 in the item, "Setting of Counter Number", and press the button below "TIME CHECK".
- The following screen is displayed on the monitor. (To make a change, refer to "Setting of Auto Calendar".)
  - Confirm the auto calendar display.



• After about 5 seconds, the screen returns automatically to the one which appears when the power is turned on.



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To change the date and time, follow the procedure below.

- 1. While pressing the shutter release button, turn on the power.
  - Continuously press the shutter release button until the following screen is displayed on the monitor.



• While the first two digits for the year blink, determine the number and press the button below "SET".

• Set the month, day, hour and minute in the same manner.

- If no changes are to be made, simply press the button below "SET".
- When the button below "+" is pressed, the number will increase.
- When the button below "+" is pressed, the number will decrease.
- When the buttons below "+" and below "FAST" are pressed simultaneously, the pace will become fast.
- When the buttons below "+" and below "FAST" are pressed simultaneously, the pace will become fast.
- \* Time is displayed in 24-hour system.
- 2. When the setting is completed, press the SET button.
  - The buzzer sounds, and the screen on the monitor returns to the one, which appears when the power is turned on and photography becomes ready.

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## 5. RETINAL OBSERVATION THROUGH VISIBLE LIGHT

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Retinal observation through visible light can be made on either the Polaroid back unit or camera back unit. For the retinal observation it is necessary to attach the viewfinder (replace with the fixation target box) and the external fixation target after dilation of the pupil to be tested.

Viewfinder Attachment/Detachment

- 1. Turn off the power.
- 2. Detach the plug of the fixation target box from the Polaroid back unit or camera back unit.
  - o In case of the camera back unit, detach the camera back from the main unit first to perform the operation above.



3. While pressing the detachment buttons at both sides, pull the entire fixation target box.

4. Insert the tip of finger nail into the Polaroid or camera back unit hollow and raise the field lens.

Note: In removing the field lens, be careful not to give finger prints or scratches.

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- 5. Insert one side of the field lens B under the retainer of the Polaroid back unit or camera back unit and press it down.
- Remove the viewfinder cap and place it over the CCP camera lens of the main unit.



7. Align the rails (at both sides) of the viewfinder with the rail supports of the Polaroid back unit or camera back unit and press in the viewfinder until a click sound is heard.



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#### Reattachiment of Fixation Target Box

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The attachment method of the fixation target box is the same as that for the viewfinder. However, the fixation target cord should be connected with the either back unit.

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### Cautions after Detachment

If the fixation target box, the viewfinder, or the field lens, is left uncovered, dust and dirt may get inside the fixation target box, the viewfinder, as well as the back unit. Be sure to place supplied caps over the openings and put the field lens into a vinyl bag or the like.

#### External Fixation Target Attachment/Detachment

- 1. Turn off the power.
- 2. Fit the fixation target fixture to the upper side of the pole.
- 3. Tighten the fixture by rotating the clamping screws clockwise.
- 4. Insert the eye fixation target plug into the receptacle.
- 5. To detach the lamp, turn off the power and reverse the procedure above.

#### Retinal Observation Procedure

Except for the following operations, the procedure for retinal observation is the same as that for the Polaroid and 35mm photography. For the basic operation of the main unit, refer to the procedure for the Polaroid photography.

- 1. Turn the infrared filter knob counterclockwise.
  - The infrared filter gets out of the optical path.
- 2. Turn off the split function as necessary.
- 3. Adjust the viewfinder diopter.
  - Turn the diopter compensating ring from the ⊕ side and stop at a position where the cross hairs are clearly seen. (Diopter compensating range: +2 to -4D) If the viewfinder diopter is not adjusted to the examiner's vision, focusing may become incorrect.)
- 4. Have the examinee sit after making his pupil dilated with mydriatic drugs.
  - Ensure that the examinee's pupil has been sufficiently dilated.
  - Place the examinee's chin and forehead securely on the respective rests.
- 5. Focus the retinal image.
  - Turn the focusing knob while looking through the viewfinder.

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 Adjust focusing so that the retinal image and cross hairs in the view are simultaneously seen clearly.



- 6. Determine the light intensity for observation.
- When it is desired to perform photography consecutively, follow the procedure for the Polaroid or 35mm photography.

6. OTHERS

Handling in Cold Climates

Sudden heating of the room in cold areas will cause condensation to form on the lenses and internal optical system. In this case, leave the CR4-45NM for at least 40 minutes after heating is turned on. Perform photography after condensation disappears.

Objective Lens & Field Lens Cleaning

Use a piece of clean gauze (washed and dried), commercial lens cleaning paper, or a blower-brush.

1. When covered with dust or dirt:

Wipe the lens surface lightly with a blower-brush.

Note: Do not touch the brush to avoid smearing the lens with hand grease.

2. When smeared by fingerprints or grease:

Brush off the dust or dirt on the lens surface, and wipe the surface lightly with a clean gauze or lens cleaning paper soaked in a mixed solution of 2 parts of absolute alcohol to 8 of ether. Other than the above solution, effective and easy-to-use commercial solutions can be recommended. Contact a Canon representative or distributor.

Note 1: If the lens is wiped when covered with dust or rubbed too strongly, it may be scratched. In addition, if soaked excessively, the surface may be unevenly cleaned.

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- 2: Disifecting alcohol contains water. If the lens is wiped with it, the surface will be damaged and therefore, never use it.
- If the infrared filter is out of the optical path when cleaning the objective lens, dust or dirt on the surface of the objective lens can be seen. Clean the objective lens by following the procedure below.
  - 1. Turn on the power.
  - Turn the infrared filter knob counterclockwise.
    (The infrared filter gets out of the optical path.)
  - 3. When completing the cleaning, turn the infrared filter knob clockwise.
- 7. SERVICE INFORMATION

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For information on overhaul or other services, contact a Canon representative or distributor.

## 8. SPECIFICATIONS

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Type: Picture angle: Image size:

Required pupil diameter: Examinee's diopter compensating range for photography:

Positioning of a pupil:

Focusing:

Working distance adjustment: Blink detection system:

Light source:

Fixation target:

Non-mydriatic type 45° (at 0 diopter) ø72mm on a Polaroid film ø22mm on a 35mm film frame 4.0mm or more

-12 to +15D.: without compensating lenses (Applicable range of split line focusing) -7 to -33D.: with negative compensating lens +11 to +35D.:" with positive compensating lens \$50mm area of the external eye can be observed on TV monitor. Split image system is applied to the \$20mm area of the pupil, and working distance preadjustment is possible by aligning split images. By aligning the split lines on the retinal image (-12D to +15D.); (Split lines can be set off.) By using flickering corneal reflection dots Function to prevent flash when the examine blinks. (This system can be switched off.) For observation: 12V 75W Halogen lamp (through infrared filter) For photography: 300V300Ws rated Xenon flash lamp Incorporated through the optical system and can be observed on the TV monitor. - 47 -

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Data printing:	Two of the following data can be printed on 35mm film: Description on exclusive plastic card, 6-digit ID. number, auto-calendar
TV camera and	CCD camera; 5 in. black & white
monitor:	TV monitor built-in
Film used:	Polaroid High Speed Land Film
	600 or Type 779; 35mm film ISO
	(ASA) 64 to 400
Power supply:	Designed according to the area
	used.
	120V, 60Hz, 240VA
Dimensions & weight:	With a Polaroid back unit
	324 (W) x 545 (L) x 590 (H) mm
	27.0 kg approx.
	(13" x 21" x 23" approx.
	60 lbs. approx.)
	With a 35mm camera back unit
	324 (W) x 510 (L) x 590 (H) mm
	27.0 kg approx.
	(13" x 20" x 23" approx.
	60 lbs. approx.)

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# 9. COMPONENTS

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Main unit 1
Power cord 1
Data card
Cap (for objective lens, camera mount) 1 each
Dust cover 1
Chin rest paper 100
Blower brush 1
Spare lamp (for observation illumination) 1

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- 1. Polaroid color back unit CR4-PC
- 2. 35mm camera back unit CR4-FR
- Viewfinder unit CR4-DF (For retinal observation through visible light)
- 4. External fixation target CR4-FL
- 5. Chin paper CR4-AP
- 6. Motorized table
- 7. Motorized chair
- 8. Main unit case CR4-MC
- 9. Data card CR4-DC (A set of plastic cards, 100 pcs.)
- 10. Slide viewer CR-SV

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- 11. Slide viewer stand CR-VS
- The viewfinder unit CR4-DF includes an external fixation target.

Polaroid is a trademark of Polaroid Corporation.

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#### Information

This equipment generates and uses radio frequency energy and if not installed and used properly, that is, in strict accordance with the manufacturer's instructions, may cause interference to radio and television reception. It has been type tested and found to comply with the limits of ISM equipment in accordance with the specifications in Part 18 of FCC Rules, which are designed to provide reasonable protection against such interference in hospitals or health-care facilities. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures.

\* Reorient the receiving antenna.

\* Relocate the equipment with respect to the receiver.

\* Move the equipment away from the receiver.

• Plug the equipment into a different outlet so that equipment and receiver are on different branch circuits.

If necessary, the user should consult the dealer or an experienced radio/television technician for additional suggestions. The user may find the following booklet prepared by the Federal Communications Commission helpful: "How to Identify and Resolve Radio-TV Interference Problems".

This booklet is available from the U.S. Government Printing Office, Washington, DC 20402, Stock NO.004-000-00345-4.