

**THIRD NATIONAL HEALTH AND NUTRITION  
EXAMINATION SURVEY (NHANES III)**

**Bone Densitometry Manual**

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## **1. INTRODUCTION**

### **1.1 Overview of Bone Density Component**

Bone densitometry of the hip is a new component of the National Health and Nutrition Examination Survey III (NHANES III). The decision to include assessments of bone density in the survey was based on the recognition of the growing problem of osteoporosis, or decreased bone mass. The low bone mass that characterizes osteoporosis causes an increased susceptibility to spontaneous or a traumatic bone fracture. Primary osteoporosis, or osteoporosis of unknown cause, is the major interest of the NHANES III.

Several federal agencies collaborated with the National Center for Health Statistics (NCHS) in the design of the bone densitometry component: the National Institute of Diabetes, and Digestive and Kidney Diseases, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Aging, the Food and Drug Administration and the U.S. Department of Agriculture. The purpose of the bone density component is to obtain estimates of the prevalence of low bone density of the hip in the U.S. population over 20 years of age, and in various subpopulation groups.

Though valid estimates of national prevalence are not available, recent reports estimate that osteoporosis affects 15-20 million people in the United States. It is believed to be a common problem among postmenopausal white females and the elderly. Incidence rates for hip fractures begin to rise after age 50 years.

The significance of the problem also relates to the costs and mortality associated with fractures, particularly those of the hip. Costs from hip fractures due to osteoporosis are estimated to be \$3.5 billion per year in the U.S., and the mortality rates for persons with hip fractures is 12-20 percent greater than in age and sex matched controls. Since the proportion of persons over 65 years of age is projected to increase from 11 to 22 percent in the next 70 years, the extent of problems associated with hip fractures is not likely to decrease in the future.

Osteoporosis does not have a discrete onset, and assessment of the disease is complicated by several problems. Bone mass can decrease without symptoms for a significant period of time before fracture occurs, and since fracture is the main clinical sign of the disease, many clinicians and researchers limit the definitions of osteoporosis to the presence of an atraumatic fracture. However, not all osteoporotic individuals suffer atraumatic fractures, and the association between bone mass and fracture incidence has yet to be clearly defined. Also, because bone density values overlap between normal and osteoporotic individuals, clear criteria for definitions of abnormality have not been established. In addition, bone loss occurs at different rates in different types of bone, so it is possible for individuals to have bone loss in the spine, but normal bone density in the forearm.

Estimates of low bone density derived from NHANES III data will offer unique information regarding bone loss and osteoporosis. The osteoporosis component will also include assessment of risk factors for low bone mass and for falling, since both are related to the occurrence of osteoporotic hip fractures. The distribution of bone density at the hip that is collected in the survey will provide reference data for clinicians and researchers in assessing bone mass in individuals.

NHANES III will provide the first reference data on bone density from a nationally representative sample and will permit an examination of bone mineral density in black and Hispanic population subgroups, for whom prevalence of low bone mass is poorly defined.

## **1.2 Principles of Operation**

Bone density estimates will be obtained with the use of x-ray bone densitometers, scanners that use x-rays of two different energy levels to image and measure bone mineral content and bone density. NHANES III will use the QDR-1000 (Quantitative Digital Radiography) x-ray densitometers manufactured by Hologic, Inc. of Waltham, Massachusetts.

The bone area to be scanned, the proximal femur, is placed under the scanner arm and positioned with a narrow beam of laser radiation. The x-ray source and detector are scanned across the

bone and information from the detector is stored and calculated by the computer unit. The detector is mechanically connected to the source so it always remains directly above the beam as the source scans.

The soft tissues contained within the area of the scan are subtracted from the scan and only the bones are imaged and measured. Because soft tissue does not have a substantial effect on the bone mineral density calculations, the results are accurate for most sizes of sample persons. However, a measure of body thickness will be taken at the greater trochanter of sample persons to permit more accurate calculation of bone density.

A scan of the proximal femur (hip) will be obtained on adults over the age of 20 years. The SP will be positioned carefully and asked to hold the limb as motionless as possible while the scan is performed. Scans of the hip require about 10 minutes.

The unit produces ionizing radiation in form of x-rays and uses laser radiation to position scans; however the radiation exposure is so low that no shielding of the room or health technicians is required. No radioactive source is required and no license from the Nuclear Regulatory Commission is necessary. Radiation exposure to sample persons is less than 3 mRem, which is about 1/10 of the exposure from a standard chest x-ray. Though levels of ionizing radiation around the scanner are low, MEC health technicians operating the densitometers are required to wear film badges for dosimetry processing and to observe strict safety and quality control procedures.

This manual outlines the basic protocol procedures and use of the Hologic equipment. A more detailed description of the equipment and its operation is provided in the Hologic Operator's Manual. A copy of both the Hologic and NHANES III Bone Density Manual is issued to each health technician, and is present in all MECs.

## **2. EQUIPMENT**

### **2.1 Bone Density Area**

An examination room in each Mobile Examination Center is dedicated entirely to bone densitometry. No other tests or procedures will be performed in that room, which has been custom designed to accommodate the equipment. All equipment and supplies needed to perform bone densitometry exams are located in this room in the third trailer of the MEC, opposite the x-ray room.

No drinks, liquids or food should be taken into the bone density room. Access should be limited to examination staff and sample persons receiving scans. Visitors should be supervised.

### **2.2 Description of Equipment and Supplies**

The bone densitometry component includes a table scanner for the femur, and a dedicated computer system. The equipment and supplies required for this component are listed below:

#### **Equipment**

- Hologic QDR-1000 X-ray densitometer,
- PC/AT Compatible Computer including High Resolution Display, 5 1/4 inch floppy disk drive, 20 MByte Hard Disk Drive and Keyboard,
- Mitsubishi P-71U Video Copy Processor,
- Hologic X-Caliber DPA/QDR-1 Anthropomorphic spine phantom,
- Hologic X-Caliber WHF-1 Anthropomorphic femur phantom,
- 40 cm X-ray caliper,
- Foot brace,
- Table pad,
- Chair, adjustable height, and
- Cover for scanner arm and table.

## **Supplies**

- Exam table paper,
- Floppy disks - double sided,high density, soft-sectored 96 tracks per inch,
- Floppy disk storage box,
- Mitsubishi video copy processor printer paper,
- Radiation film badges (shared with X-ray and stored in X-ray cabinet),
- Phantom scan notebook,
- Bone Density Daily Log notebook (if needed),
- Anti-static spray, and
- Hologic Operator's Manual.

### **2.2.1 Description of Hologic QDR-1000 Bone Densitometer**

The QDR-1000 system is shown in Exhibit 2-1 being used to perform a spine scan. A self-contained x-ray source mounted beneath the sample person provides alternating pulses at 70 kVP and 140 kVP. The x-ray detector is mounted in the scanning arm above the sample person. Controlled by a computer, the source and detector move in tandem across the sample person, producing a longitudinal scan of the area of interest.

The x-ray beam is tightly collimated so that only a thin beam passes through the sample person, first passing through a calibration disk containing various x-ray absorbing materials. This process forms the basis of the Hologic Internal Reference System. The QDR-1000 contains a proprietary Automatic Internal Reference System which employs a calibration wheel to achieve drift-free measurement (Exhibit 2-2).

As the x-ray beam is detected, the information it contains about the x-ray absorbing characteristics of both the sample person and the calibration materials is digitized by the AC converter and sent to the computer for analysis.

Exhibit 2-1. QDR-1000 System (spine scan)

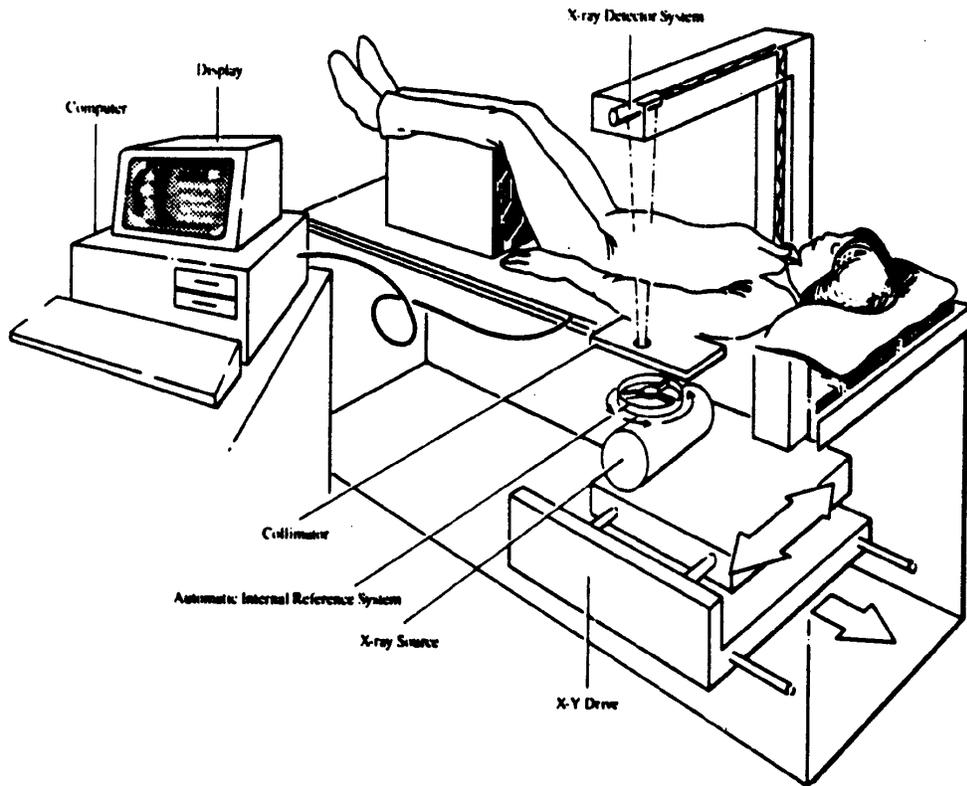
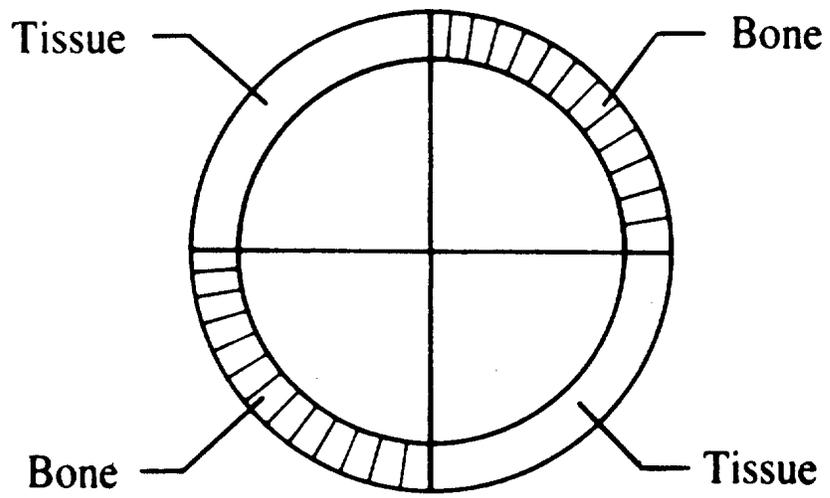


Exhibit 2-2. Calibration wheel



## **2.2.2 The AT Computer and Keyboard**

The Hologic bone densitometry software is run on a PC/AT compatible computer and driven by a main menu from which all other functions are accessed. The system has a 20 Mbyte hard disk drive which means that a limited amount of data, or approximately 100 analyzed sample person scans, can be stored on the hard disk. An NEC Multisync monitor is provided for this system, and is linked to a Mitsubishi video copy processor to print copies of analyzed sample person and anthropomorphic scans, and quality control plots.

### **2.2.2.1 Keyboard Controls**

There are several ways to move through the software menus:

- Move the highlight to the desired function shown on the main menu and press <Enter>. The highlight is moved by the arrow keys on the keypad or by pressing the spacebar.
- Press the key that corresponds to the first uppercase letter, as shown on the monitor, of the function to be selected. For example, press <r> to select archive.
- At any point in the program press a function key, (F1-F6, and F-9), and the function will be immediately performed. The function keys are located at the top of the keyboard, and do not require that <Enter> be pressed to operate.

### **2.2.2.2 Function Keys**

The operator of the QDR-1000 should be familiar with the function keys in order to move through daily operations smoothly. The Hologic Operator's Manual provides a more detailed description of the use of the function keys, but in brief, health technicians should be familiar with the following keys:

|      |                                      |
|------|--------------------------------------|
| <F1> | Enter or retrieve patient scan       |
| <F2> | Select patient scan                  |
| <F3> | Perform bone mineral scan            |
| <F4> | Perform analysis of scan             |
| <F5> | Save selected scans to diskette      |
| <F6> | Delete selected scans from hard disk |
| <F9> | Help for highlighted item            |

The <F9> key may be pressed at any time to obtain help information on the highlighted selection. Pressing <Esc> will exit the help text and return to operation of the scanner program. Also, pressing <Esc> will terminate the current menu selection and return to the main menu.

### **2.2.2.3 Additional Important Keys**

Health technicians should also be familiar with the following keys:

- <Enter>  
Press <Enter> when the highlight is on the desired function or entry to select that item.
- Arrow keys  
Use the arrow keys on the keypad to move the highlight up, down, left or right.
- <Spacebar>  
Press <Spacebar> at the main menu to move highlight to the right. Continued pressing will cycle the highlight through all of the main menu selection.
- <CapsLock>  
When this key is pressed, all typed entries will appear in capital letters. A light on the keyboard will be lit to indicate that the key is activated. Press the key again to de-activate the function.

### **2.2.3 NEC Multisync Monitor Settings**

Detailed information regarding the settings for the NEC monitor are included in the NEC Multisync users manual which will be present in the bone density room. The correct switch settings for the monitor should be set as follows (refer to Exhibit 2-3):

1. Back Panel
  - O Power Switch: ON for operation of monitor
  - Text Color Switches
    - Switches 2-5: ON
    - Switch 6: OFF
  - Manual Switch: OFF
  - TTL/Analog Switch: Set to ANALOG
- 2 Top Panel
  - Text switch: OFF
  - H. Width: ON
  - Bright, V. Hold, Cont., H. Position: Set at installation. DO NOT ALTER SETTINGS.

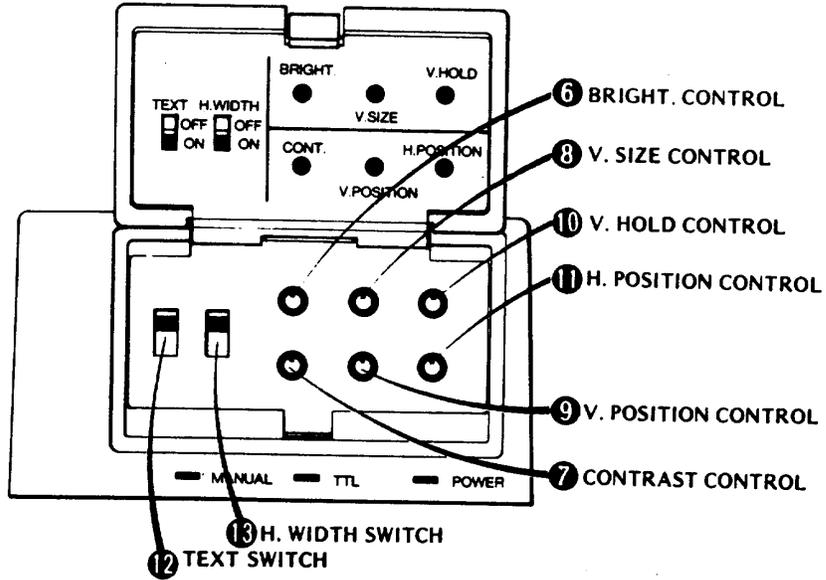
### **2.2.4 Mitsubishi P-71U Video Copy Processor**

A Mitsubishi video copy processor is provided to print copies of analyzed scans and quality control plots. Instructions for setting the switches, and illustrations of the control panels, are provided in the Hologic Operators Manual.

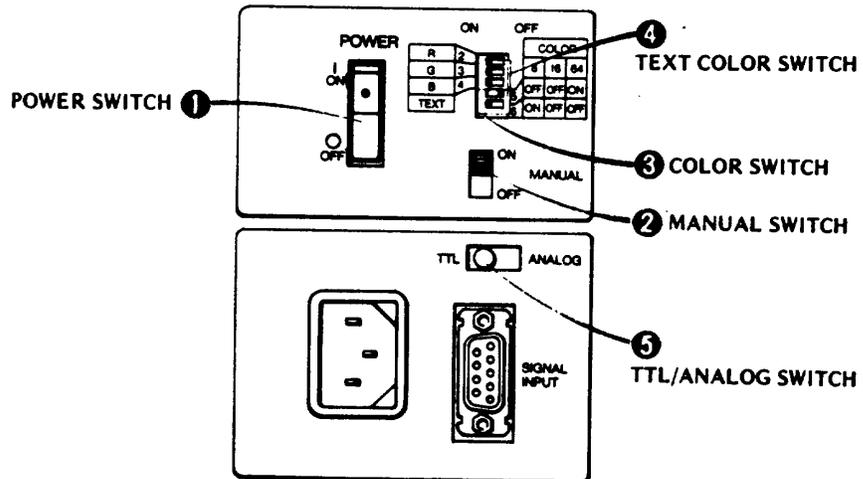
The Power Switch on the front panel should be set to ON for use of the printer, and shut off at the end of the day.

Exhibit 2-3. NEC monitor panels

Top Panel



Back Panel



## **2.3 Equipment Setup Procedures**

### **2.3.1 Beginning of Stand Procedures**

1. Complete a beginning of the stand inventory of equipment and supplies for the bone density room.
2. Check with the MEC Manager to be sure that the allocation of power to the trailers is sufficient to operate the unit before applying power. The NCHS engineer will also be present to assist with any problems during setup day, when power is applied to the Hologic QDR-1000.
3. Remove equipment cover.
4. Apply power to the system.
  - Plug the power cord into the AC outlet in the bone densitometry room.
  - Turn on the CB 1 switch on the rear panel of the QDR-1000. This switch keeps the signal detector on and is necessary for accuracy. It should be left on at all times for the duration of the stand. A standby light will come on, indicating the CB 1 is on.
  - Turn on the Power Switch. Turn the X-ray Enable Key clockwise to enable the X-ray system (key cannot be removed when system is enabled. Power will be supplied to the computer and monitor, and the main menu will appear after a few minutes.
  - Allow the signal detector to warm up for 60 minutes before using the system. This will only be required when the system is brought up after being shutdown for transport, or after a power failure during a stand.
  - Turn on the video copy processor.
  - After 60 minutes, move the scanner arm to the extreme left, right, front and back using the position controls to make sure the mechanical scanner device is sufficiently lubricated.
5. Perform a scan on the anthropomorphic spine phantom.
6. Print the results of the scan and store in the Phantom Scan notebook file, the stand number and phantom name.

7. Archive the scan to a floppy diskette. Label the diskette with the NCHS box label (BB) sticker. Archive the scan to the Quality Control (plot) file.
8. Perform a scan of the anthropomorphic femur phantom.
9. Print the results of the scan and store in the Phantom Scan notebook file.
10. Archive the scan to the quality control diskette and the Quality Control (plot) file. Make sure the diskette has an NCHS box label sticker, and that the stand number and phantom name are clearly marked.
11. The QDR-1000 is now ready for sample person examinations.

### **2.3.2 Calibration Procedures**

The QDR-1000 X-ray employs an Automatic Internal Reference System to correct for changes in tube voltage and current. Initial calibration of the equipment will be performed by a qualified Hologic Service Representative. No daily calibration of the system is necessary.

To assist in monitoring equipment performance over time, health technicians will perform scans of anthropomorphic phantoms on a daily and weekly basis. These procedures are explained in Section 5.0, Quality Control.

### **2.3.3 Daily Procedures**

1. Make sure the CB 1 switch on the densitometry unit is on. If not, turn the switch on and warm up signal detector for 60 minutes. Inform the Coordinator and MEC manager of the delay in preparing for exams.
2. Make sure the densitometer Power Switch is on. Turn X-ray Enable key to the on position.
3. Turn up the brightness on the monitor.
4. Turn the Power Switch on the video copy processor to ON.
5. Check hard disk files and make sure all files have been copied to diskette. Copy any

files that have not yet been copied to the diskette.

6. If it is the first work day of a new week, perform a scan of the anthropomorphic femur phantom.
7. Analyze and print the result. Save the hard copy in the Phantom Scan notebook provided in the room. Follow procedures outlined in Section 2.3.1.
8. Perform and analyze a scan of the anthropomorphic spine phantom. Store the hard copy in the Phantom Scan notebook. Follow procedures outlined in Section 2.3.1.
9. The QDR-1000 is now ready for performing sample person exams.
10. At the end of each session, health technicians will:
  - Insure that all analyzed SP scans and phantom scans from that session have been copied onto floppy diskettes for NCHS and for consultant reviewers.
  - Make sure room log is completed or print a copy of the log for each examination session from the MEC automated system.
  - Turn off the X-ray Enable key. Leave the power switch and the CB 1 switch on.
  - Turn down the brightness on the terminal monitor, but leave the unit on.
  - Turn off the video copy processor.
11. Checking Backup Files and Cleaning the Hard Disk
  - At the end of the second session of the day, the health technician responsible for the bone density room will check to be sure all scan files on the hard disk have been backed up to floppy diskettes, which have been carefully labeled for Quality Control operations, NCHS SP Scans and Reviewer SP scans. All diskettes should be labeled with NCHS box label numbers, SP ID numbers (if SP scans are on disk) and stand numbers.
  - If any files have not been copied, the health technician will copy the files to a labeled disk.
  - After verifying the backup files and preparing the disks for the review center, the health technician will ask the MEC manager to review the files and confirm the preparation. After the MEC manager approves the copy procedures, the health technician will delete all files except the original file for each phantom scan from the hard disk.
  - The hard disk is now prepared for the next exam day.

### **2.3.4 Weekly Procedures**

1. Femur Phantom Quality Control Scan
  - On the first session of the first work day of the week, perform a scan of the anthropomorphic femur phantom.
  - Print a report of the scan.
  - Archive the scan to the Femur Phantom Quality Control disk.
  - Place the scan report in the file provided.
2. Preparing and Shipping Quality Control Disks
  - The Quality Control floppy disks including phantom scans and SP files should be prepared for mailing to the review center and delivered to the MEC manager. A Transmittal Form and a copy of the Daily Log for each session of the week (automated printout or xerox of hard copy room log) must accompany the disks. Copies of the phantom scan reports and SP scan reports should also be sent to the review center. A Transmittal Form must be completed for these items.

### **2.3.5 End of Stand Procedures**

1. Complete an inventory of all equipment and supplies in the bone density room.
2. Make sure all SP and phantom scans have been copied to diskette and that diskettes are clearly and correctly labeled. Copy all SP files not previously sent to the review center and prepare diskettes to be shipped for review.
3. After insuring that all files have been copied to original diskettes and diskettes for the review center, delete all SP scans from the hard disk.
4. Make sure there are no diskettes in the disk drive.
5. Shut down the system and prepare for transport.
  - At the main menu, exit to the Disk Operating System, (DOS) and type RETRACT. The scan arm will then lock in place.

- At the main menu, turn off the X-ray enable switch by turning the key counter clockwise.
  - Turn off the Power Switch.
  - Turn off the CB 1 switch.
6. Make sure a complete set of all session logs has been printed from the MEC automated system.
  7. Prepare all disks, logs and scan reports for shipping and give to the MEC manager.
  8. Clean the densitometry examination table and pad.
  9. Place cover over the scanner arm and table.

## **2.4 Care and Maintenance of Equipment**

### **2.4.1 Cleaning Equipment**

#### **2.4.1.1 The Examination Table**

The examination table should be dusted as needed. Since housekeepers will be instructed not to clean this room, health technicians should check the unit and keep it free of dust.

The table pad may need to be wiped with a mild detergent or occasionally with isopropyl alcohol, but as examination table paper will be provided, this should be done only if the pad shows dirt or smudge marks. Never use abrasive cleansers or substances.

The table and scanner arm should be covered at the end of each exam session and at the end of the stand.

No other regular cleaning is need for the densitometer.

#### **2.4.1.2 NEC Monitor**

The NEC monitor should be kept free of dust by the health technicians. If the screen becomes smudged, clean the screen with a soft cloth and glass cleaner or a product designed specifically for computer monitors (like Screenclean).

The monitor case and keyboard can be cleaned with a mild detergent and soft cloth. Be sure not to drip or spill excess liquid into the equipment.

#### **2.4.1.3 Mitsubishi Video Copy Processor**

Unplug and clean the cabinet as needed with a soft cloth slightly moistened with a mild soap and water solution. Allow to dry completely before operating. Never use petroleum based solutions or abrasive cleaners.

The rubber printer roller should be kept free of dust and dirt. If dust accumulates on the roller for an extended period of time, the prints may become uneven or appear to have lines running through the print. Should this occur, clean the roller with a soft brush.

To access the roller, follow the directions for clearing a paper jam as described in Section 2.4.2.1.

### **2.4.2 Maintenance**

#### **2.4.2.1 QDR-1000 Densitometer and NEC Monitor**

Examination staff members will not perform any maintenance procedures for this equipment. However, problems should be reported to the MEC Manager as soon as they are noted.

Software updates will periodically be issued from the manufacturer. If, after reviewing the updates, the NCHS planning personnel and engineer decide to load the new software, either the MEC managers or the NCHS engineer will load the software and discuss any new features with the health technicians.

#### **2.4.2.2 Mitsubishi Video Copy Processor**

Health technicians should insure that paper is kept in the video copy processor, and that paper jams are avoided. Procedures for loading paper, clearing jams and misfeeds are summarized in this section.

Do not operate the unit if condensation is present. The "Stand-By" indicator will not illuminate if condensation is present. Report condensation to the MEC Manager and review instructions provided in the Hologic Operator's Manual.

Condensation is likely to occur when:

1. The unit is moved from one extreme temperature to another, such as from a cold environment to a warm environment. This condition may occur during transport between stands.
2. A cold room is heated quickly.
3. The humidity is very high.

Do not place any objects on top of the video copy processor, and never insert any object into the set.

Also, the paper used in the processor requires careful handling, which is summarized in Section 2.4.2.3.

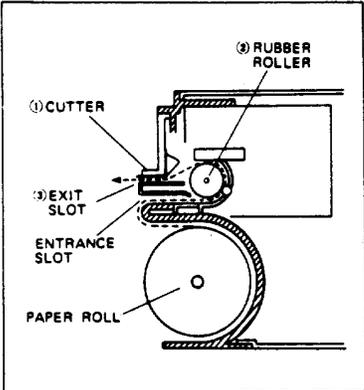
### **Loading Paper (see Exhibit 2-4)**

1. Open the door by pulling down on the top left corner.
2. If old paper remains in the unit, press "Feed" to remove the paper. (Note: "Feed" does not work when the "Parallel" button is pushed in).
3. Push the paper holder (black lever to the right of the end of the roll #3) to the right and install a new paper roll. The paper should come off the bottom and to the rear of the roll.
4. Lift the tension lever (small black lever to the right of the exit slot, #2).
5. Insert the paper end into the entrance slot, #4, until the "Stand-by" light comes on. Be sure that the paper is straight and that there is no slack.
6. Lower the tension lever and press "Feed" until the paper comes out the exit slot, #5. Tear off the excess paper and close the door.
7. Push in the "Parallel" button.

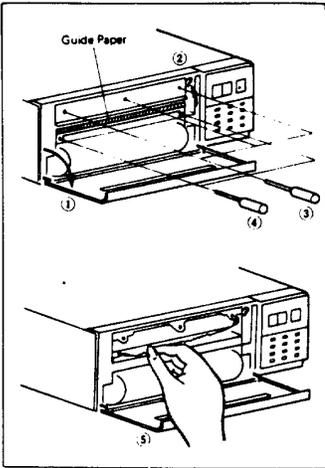
Note: Instructions and a diagram are also inside the Video Copy Processor door.

Exhibit 2-4. Video copy processor

Printer Paper Path



Clearing a Paper Jam



### **Clearing a Misfeed**

If the paper does not feed from the exit slot when the copy or print buttons are operated and with the Stand-By indicator lit, the paper may be jammed. NOTE: If condensation is present inside of the set or it is out of paper, the stand-by indicator will not light.

A paper misfeed may occur:

1. At the cutter if the paper is badly wrinkled when torn off at the cutter.
2. At the rubber roller if the set is continuously operated in a high humidity location. Moist paper may stick to the rubber roller.
3. At the exit slot if the paper is installed improperly, either misaligned or wrinkled at the entrance slot. It may jam at the exit slot.

### **Removing a Paper Jam**

1. Open the door.
2. Lift the tension lever to the upward position.
3. Remove the cutter by unscrewing with a screwdriver.
4. Remove the paper guide by unscrewing with a screwdriver.
5. Remove the jammed paper.
6. Reassemble and reload the paper.

**DO NOT SCRATCH THE ROLLER OR ALLOW DIRT AND DUST TO CONTACT THE ROLLER**

NOTE:

1. If the paper is slightly wrinkled in printing, print the picture repeatedly (about 5 times) or until normal printing is resumed.

2. If the prints are still wrinkled after applying step 1, the paper may be misaligned. Adjust the paper to the normal position by lifting the tension lever and realigning. When paper is realigned, return lever to downward position.
3. If there is only a little paper remaining (red warning appears), the print may become uneven. Install a new roll of paper.
4. When powder from the paper accumulates on the cutter, clean with a soft brush.

#### **2.4.2.3 Printer Paper Precautions**

1. Use K-70S paper for print. This is Super paper for high-grade prints.
2. One roll will yield approximately 90 prints.
3. The paper is provided with a red-edge warning section which indicates paper for approximately 2 prints remain. Print quality may decrease after the red warning section.
4. Do not touch prints with wet hands as fading may occur.
5. If paper runs out during operation, printing stops and the "Stand-By" indicator goes off. Install a new paper roll.
6. Store prints in a low humidity location away from direct sunlight to avoid discoloration or deterioration of the image.
7. When the paper absorbs non-volatile organic solvents such as alcohol, ether and ketone, the image will be discolored or faded. Cellophane tapes and soft vinyl chlorides also may cause discoloration or fading.
8. Dirt or dust on the paper can result in poor quality prints. Advance or "Feed" the paper until clean paper is visible. The Video copy processor will now print correctly.

#### **2.4.2.4 Floppy Diskette Precautions**

1. Do not touch the exposed disk surface.
2. Do not expose the disk to any magnetic sources (e.g., magnetized scissors or screwdrivers).

3. Do not write on the envelope with pencil or pen; use a felt tip pen. This pencil lead will cause problems with the disk drive heads and using a pen can emboss the disk material.
4. Do not use paper clips or other fasteners on the disk. The material will be embossed or bent.
5. Keep the disks away from water or sunlight.

The best way to store the disks is to keep them in their original paper envelopes and place them in a disk storage container. Do not forget to label them.

### **2.4.3 Malfunctions**

Only authorized Hologic Representatives should attempt to repair or service the equipment included in the QDR-1000 system. Any problems or unusual occurrences should be reported to the MEC Manager immediately.

The Mec Manager will consult with the NCHS engineer regarding the problem and, if necessary, a Hologic representative will be requested.

### **3. EXAMINATION PROTOCOL**

#### **3.1 Eligibility Criteria**

Sample persons under the age of 20 years and female SP's between the ages of 20 and 59 who are pregnant, or may possibly be pregnant, are excluded from the examination. Sample persons under the age of 20 years are excluded for reasons related to issues of bone development.

Femur scans should also not be performed on examinees who have broken both hips, or who have had both hips surgically pinned or replaced with implants. The bone content in these areas will not be normal and should not be included in data collection.

When hard copy forms are in use during the exam session, the examinee's chart will indicate whether or not a pregnancy test has been performed. When the MEC automated system is in use, the pregnancy test will be recorded in the system and will be reported to the health technicians when the bone density program is accessed.

Do not perform either bone scan on female examinees until the results of their pregnancy test performed in the MEC are available. If the results are positive, or if in response to the question about possible pregnancy, female examinee responds "yes" or "don't know," do not scan that SP, regardless of the test result.

#### **3.2 Pre-Examination Procedures**

1. Pull a clean sheet of table paper over the length of the QDR-1000 exam table.
2. Verify the SP's name and NCHS identification number on the Daily Appointment schedule on the automated system, or, if the system is not available, on the hard copy from the field office.
3. Enter SP NCHS identification number, and your examiner identification number into the MEC automated system. Use the Bone Density Log sheet if the automated system is not available. Specifications for completion are provided in Section 4.1.2.

4. From the introductory screen on the automated system, select the bone density program. Enter the disk label number (NCHS "BB" label number) as requested on the screen.
5. Confirm that the pregnancy test has been obtained and is negative, if applicable to the SP. If no results are recorded in the automated system (or, if in use, on hard copy forms) consult the coordinator. Do not perform the scan if pregnancy status cannot be confirmed. Do not discuss results of the pregnancy test with SP's. The MEC physician will report positive tests to SP's.
6. Ask the SP the screening questions on the automated system (or on the hard copy form, if needed) before beginning the examination, and record the results. Exclude any sample persons who are under 20 years of age, pregnant or possibly pregnant, have broken both hips or who have pins or implants in both hips. The automated system will provide a message prompt if the SP is ineligible. See Section 3.3.2 for questionnaire specifications.
7. If the SP is ineligible, complete the screens on the automated system (or complete the hard copy forms), explain to the SP the reason for exclusion, and return the SP to the Coordinator. Data entry should be completed on all SP's to record the exclusion. Do not fail to complete data entry on ineligible SP's.
8. If the SP is eligible, proceed to examination procedures.

### **3.3 Examination Procedures**

#### **3.3.1 Protocol Procedures**

1. Select the hip to be examined, based on the SP's responses to the screening questions. If both hips are eligible, use the left hip for the scan.
2. Select F1 for 'new patient' and enter the required demographic sample person data into the blank Patient Biography screen on the bone density computer. The date and time of the scan are recorded automatically by the program. The required information and program fields into which the information should be entered are as follows:

| <u>Information</u>            | <u>Field of Entry</u> |
|-------------------------------|-----------------------|
| SP initials                   | Name                  |
| SP NCHS identification number | I.D.                  |
| Sex                           | Sex                   |
| Ethnicity                     | Ethnic                |
| Height (feet/inches)          | Height                |
| Weight (lbs)                  | Weight                |
| SP date of birth              | Birthdate             |
| SP age                        | Age                   |
| Examiner I.D.                 | Scan code             |
| Thigh thickness               | Physician             |

The height and weight of the SP must be estimated by the SP.

3. Explain the procedure to the SP and instruct him or her to lie flat and motionless during the procedure.
4. Make sure that there are no removable objects in the scan field, such as snaps or jewelry.
5. Ask the SP to lie in a supine position on the table with his or her head at the right of the scanner (as the technician faces the scanner) as close to the top as possible.
6. Use the xray calipers to measure the thickness of the hip to be scanned, at the level of the greater trochanter. Enter this measurement on the Patient Biography screen in the Physician field.
7. Check that the data in the Patient Biography screen are accurate. After the scan is run, there will be no way to correct errors. Press <F10> to save the data. <Esc> will not save the data.
8. Place the foot of the leg selected for the scan (i.e., the right foot if the right hip is selected) in the positioning foot brace and make sure the foot is fitted snugly. The foot should be inclined slightly towards the midline of the body.
9. Locate the SP's greater trochanter by grasping the leg to be scanned near the ankle and gently rotating the leg inward and outward several times. Press firmly on the outside of the thigh while rotating the leg. You should feel the greater trochanter roll under your finger tips. (For heavy examinees, you may not be able to feel the trochanter, so instead, locate the anterior iliac crest and measure 8 1/2 inches from the top of the crest for a female and 9 inches from the top for a male). This is the approximate location to begin the scan.

10. Move the scanner arm just lateral to the greater trochanter of the side to be examined. This will be about 2 inches below the level of the femoral head. The starting point should be within the SP's body, not on the table. The entire femoral head, greater and lesser trochanter should be included in the scan field.
11. As soon as the scanner arm is moved, the positioning laser will automatically illuminate to mark the center point of the first line of the scan. The scan will start at that point.
12. Press 'S' to begin the scan. Select the hip to be scanned, and carefully follow instructions for scans provided in the Hologic Operator's Manual.
13. After the hip has been selected, a screen will be displayed with scan parameters. The size of the scan should generally be 8 inches. There should be no need to change any other entries. Make sure the SP is ready before you press <Enter>.
14. As soon you press <Enter>, the parameters are selected and the scan arm will begin the scan.
15. The image of the scan will be displayed on the monitor line by line. Check the position of the SP as the scan proceeds and halt it as soon as possible if the position is incorrect. Press any key to halt the scan.
16. Reposition the scan from the keyboard by pressing <F3> and moving the blue arrow. Press <Enter> to restart the scan.
17. The scan arm will automatically move to the new position and the scan parameters screen will appear. Select the parameters as before and press <Enter > to restart the scan. The previously started scan will not be saved. You should be able to detect incorrect positions within 30-45 seconds after a scan begins.
18. When the desired anatomy has been acquired, press <any key>, except <F3> to stop scan and save it for analysis. A tone from the unit will signal that x-rays have ended and the scan has halted. The Analysis screen will automatically appear.
19. Reminders:
  - When positioning the scanner arm, a beeping tone indicates the laser positioning light is illuminated. Do not stare into the beam. Caution SP's not to stare into the beam.
  - The start of x-ray will be signalled by a tone from the unit, flashing red light on the scanner arm and flashing red indicator on the monitor screen.
20. Return SP to coordinator. Proceed to post-examination procedures.

### **3.3.2 Bone Density Examination Form**

#### **3.3.2.1 Automated System**

The Bone Density Examination Form on the automated system is accessed from the room menu on the VT320 monitor by selecting the bone density option (see Exhibit 3-1). The automated program is patterned after the hard copy form discussed in Section 3.3.2.2.

After selecting the bone density form, the technician will confirm the SP name, NCHS identification number, age and sex. Next, the screen will prompt the health technician for English or Spanish versions of the screening questions. If the SP requires the questions to be asked in Spanish, select the Spanish option and administer the questions in Spanish. The program will then prompt the health technician to confirm the age and sex of the sample person. The screening questions will then appear individually on the monitor screen as shown in Exhibit 3-2. Each question must be read to the SP exactly as it appears on the screen, and an answer must be recorded. A message will appear for SP's who are ineligible. Upon completion of the screening questions, the Results of Examination screen will appear.

After the scan has ended, record the results of the examination on the automated system. Select Test Done, Test Incomplete or Test Not Done. If Test Incomplete or Test Not Done is selected, the program will move to a Reasons screen (Exhibit 3-3) and the technician must explain the reason why the test was not completed.

Before exiting the Reasons screen, the cursor will move to the Comments section, and the technician should record any pertinent observations regarding the exam. Such observations as the SP was extremely obese are helpful during data analysis.

Exhibit 3-1. Bone Density Examination Form

---

Introduction

| Technician              |  | Examinee               |                       |
|-------------------------|--|------------------------|-----------------------|
| Tech# <u>1002</u>       |  | Sample# <u>2525252</u> |                       |
| Name <u>Bill Hadden</u> |  | Name <u>sp25</u>       |                       |
|                         |  | Age <u>25</u>          | Years/Months <u>Y</u> |
|                         |  | Sex <u>F</u>           |                       |

Procedures

Bone Density

Char Mode: Replace Page 1

Count: \*1

---

Exhibit 3-2. Screening questions

---

Name sp25 NCHS# 2525252

bone density

Is there any possibility that you might be pregnant?

1 No

2 Yes

3 Don't know

1

---

---

Name sp25 NCHS# 2525252

bone density

Have you ever fractured or broken your left hip?

1 Yes

2 No

3 Don't know

1

---

Exhibit 3-3. Reasons screen

---

Name sp25 Sample# 2525252

Examination results

Select one

- Equipment malfunction or lack of supplies
- Insufficient time available or room not available
- Examinee refused or uncooperative
- Examinee medically excluded (example-pregnant)
- Examinee has pre-existing condition affecting test
- Examinee unable physically to cooperate
- Other

Comments:

Char Mode: Replace Page 1

Count: \*7

---

### 3.3.2.2 Hard Copy Form

In the event the automated system is not available for data collection, the hard copy version of the bone density form should be used to administer the screening questions and record the results of the examination. These forms will be available on the MEC as needed.

The hard copy version of the form is shown in Exhibit 3-4. The form should be completed as follows:

- a. Staff No  
Enter your examiner ID number
- b. Disk No  
Enter the box label number of the diskettes being used to record the SP scan.
- c. Scan No  
Enter the number assigned to the SP scan by the Hologic system.

#### Exclusion Criteria

##### A. Pregnancy Status

1. Any possibility of currently pregnant pregnant  
Mark the box to indicate whether answer is "YES," "NO," or "DK" (don't know).
2. Record of pregnancy test results  
Mark the box indicating whether results of pregnancy test were positive or negative.

##### B. Hip Scan

For questions B1-B4, record the SP's response to each question by marking the box corresponding to the SP's answers. Do not leave blank boxes. Follow skip patterns.

##### C. Results of Examination

Record the outcome of the scan. If the scan was not completed or performed, complete Section D., Reasons Test Incomplete or Not Done.

Exhibit 3-4. Hard Copy Form

**BONE DENSITOMETRY**  
AGES 20 AND OVER

|                      |                     |                     |                        |
|----------------------|---------------------|---------------------|------------------------|
| a. Staff No<br>_____ | b. Disk No<br>_____ | b. Scan No<br>_____ | c. NCHS ID No<br>_____ |
|----------------------|---------------------|---------------------|------------------------|

**A. Pregnancy Status**

1. If female <60 years old, ask:

Is there any possibility that you might be pregnant?

- 1  No
- 2  Yes - No Bone Scan
- 3  DK - No Bone Scan

2. Results of pregnancy test

- 1  No
- 2  Pregnant - No Bone Scan
- 3  DK - No Bone Scan

**B. Hip Scan**

Ask examinee:

1. Have you ever fractured or broken your left hip?

- 1  Yes - go to B3
- 2  No - go to B2

2. Do you have a pin or artificial hip replacement joint in your left hip?

- 1  Yes - go to B3
- 2  No - Scan Left Hip

3. Have you ever fractured or broken your right hip?

- 1  Yes - No bone Scan
- 2  No - go to B4

4. Do you have a pin or artificial hip replacement joint in your right hip?

- 1  Yes - No Bone Scan
- 2  No - Scan Right Hip

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D. Reasons Test Incomplete or Not Done

Complete this section to explain why a scan was not completed or obtained. Select the reason that best applies to the situation. Additional explanation should be provided in the Comments section.

**Comments**

Enter any pertinent remarks concerning the scan or the examinee. Comments are extremely helpful during analysis of the data for the survey.

**3.3.2.3 Questionnaire Specifications**

The questions and responses on the Bone Density Examination Form are the same for the automated system and the hard copy form. The identification information has already been explained in Sections 3.3.2.1. and 3.3.2.2. Specific screening questions, exclusion criteria and results of examination responses are explained in this section. Refer to Exhibit 3-4 Bone Density Examination Form for exact questions and response.

**Exclusion Criteria**

A. Pregnancy Status

1. Any possibility of current pregnancy  
Pregnant SP's must not receive the bone density scan. Record answer of SP to question regarding current pregnancy. Exclude SP's who are currently pregnant or unsure of pregnancy status, regardless of pregnancy test results.
2. Record of pregnancy test results  
Mark the box indicating whether results of pregnancy test were positive or negative. SP's with positive results must be excluded from the scan.

B. Hip Scan

Read the four screening questions exactly as they are written. Record answers in the appropriate boxes.

- B1. If examinee responds "NO" to question regarding hip fracture of the left hip, proceed to Question B2. Ask about left hip. Record result in appropriate box. If SP responds "YES," skip to Question B3.

- B2. If SP responds "YES" to a pin or artificial hip replacement in the left hip, record response in appropriate box and proceed to question B3. If SP responds "NO," proceed to scan the left hip.
- B3. If the SP responded "YES" to a fractured left hip in question B1, and the SP responds "YES" to question B3, exclude the examinee from the scan. If "NO," proceed to question B4.
- B4. If the SP responded "YES" to a pin or artificial hip for the left hip and responds "YES" to B4, exclude the examinee from the scan. If "NO", scan the right hip.

C. Results of Examination

Record the outcome of the scan. If satisfactory, record "Test Done". If test was completed, mark "Test Done." If the test was not completed, mark "Test Incomplete." If the test was not obtained, mark "Test Not Done." If the scan was not completed or performed, complete Section D, Reasons Test Incomplete or Not Done.

D. Reasons Test Incomplete or Not Done

Complete this section to explain why a scan was not completed or obtained. Select reasons based on definitions as follows:

1. Equipment malfunction or lack of supplies  
Choose this option when the bone densitometry equipment did not function properly. Scans should still be obtained if supplies are lacking, as there are no critical supplies for this exam. Be sure equipment malfunctions are described in the Comments section.
2. Insufficient time available  
Choose this option if there was not sufficient time left in the examination session to obtain the scan, or the room could not be accessed.
3. Examinee refused or uncooperative  
This response should be selected if the examinee refused to be scanned, or was too uncooperative to be positioned correctly and lie still for the exam.
4. Examinee medically excluded  
If the examinee is excluded for a medical reasons such as pregnancy, this response should be selected.
5. Examinee has pre-existing condition  
If the examinee has a pre-existing condition, such as fractured hips, pins or artificial implants, this response should be selected.

6. Examinee unable to physically cooperate  
Select this response for examinees who are physically unable to receive a scan, such as extremely obese or wheelchair-bound examinees.

Additional explanations for all response should be provided in the Comments section.

#### Comments

Enter any pertinent remarks concerning the scan or the examinee. For example, if equipment malfunctioned or if the examinee could not be positioned properly a brief description of the problem should be entered. Comments are extremely helpful during analysis of the data for the survey, and for field consultants or Hologic personnel when trying to repair instrument malfunctions.

### 3.4 Post-examination Procedures

1. Complete the Bone Density Examination Form.
2. Return the SP to the Coordinator for assignment to another component.
3. If hard copy logs are in use, complete the Bone Density Log sheet.
4. Analyze the SP scan:
  - The Analysis screen will appear after the scan ends. Press <a> to analyze the scan. The image of the scan is displayed with a double line; the area outside the line will be shown in green and the area inside the line will be shown in yellow. The yellow box is the region of interest to be analyzed.
  - Adjust the image contrast if desired. **DO NOT TOUCH THE MONITOR CONTROLS.** <Enter> and follow the directions in the Hologic Operator's Manual to adjust contrast.
  - Select the region of interest. Refer to the Hologic Manual and follow the instructions for this procedure exactly as provided in the manual. The region of interest (ROI) must be adjusted to outline the area to be analyzed. The entire femoral head, the greater trochanter and the femoral shaft extending to just below the lesser trochanter should be included in the area outlined. Best results are achieved if the entire box is kept within the sample person.
  - After adjusting the box, fix the box and center over the image.
  - When satisfactory placement is achieved, press <End>.

- Remember to check the top of the screen for the parameter being analyzed.
  - If the image appears unacceptable, press <Ctrl Home> to restore the original image and restart the process.
  - Erase any soft tissue artifacts.
  - DO NOT MANUALLY CHANGE THE EDGES OF THE IMAGE.
  - Confirm the midline of the femoral neck. Under most conditions, this will not need to be adjusted.
  - Confirm the location of the femoral neck. Usually, this will be the only adjustment to the image.
  - If necessary, position Ward's triangle. Usually this will be satisfactorily adjusted by the system. If adjustment is required, use the automatic adjustment.
  - Adjust the trochanter region if necessary.
  - Print the report.
5. After printing the scan report, archive the scan onto the floppy diskette. The NCHS SP identification number should be written onto the floppy disk label. Also, number the disks starting with #1 so they can be filed properly and archived scans easily located and restored.
  6. If there is not sufficient time to analyze the scan, make sure the scan is saved to the hard disk and analyze the scan later in the session. All scans should be analyzed and archived at the end of each session to the backup files for NCHS and for the review center.
  7. Place the copy of the scan report in the notebook provided in the room.
  8. Change the exam table paper and prepare both computer systems for the next SP.

## **4. LOGS AND RECORDS**

### **4.1 Bone Density Daily Log**

#### **4.1.1 Automated Daily Log**

An automated log of daily activities for each examination component will be generated by the automated system. Therefore, under usual circumstances, health technicians will not be required to enter data for daily logs.

The automated system contains a clock that will record the beginning and end of each examination record, and can record examiner I.D. numbers, SP I.D. numbers and comments from the examination records to construct a record of the sequence of examinations for each component.

Health technicians should remember that the clock for the timing of the examination begins at the moment the bone density examination form appears on the screen, and continues to run until the Comment section is exited and the screen is returned to the introductory room menu.

#### **4.1.2 Hard Copy Daily Log Sheet**

A hard copy Bone Density Daily Log Sheet will need to be maintained whenever the automated system is not available. A copy of this form is shown in Exhibit 4-1.

The purpose of the Bone Density Daily Log Sheet is to document what has occurred in the examination room, and in particular to note unusual circumstances and reasons for examination exclusions or terminations.

For each new examination session, the technician should begin a new page by entering the examination date at the top of the form on the lines provided. S/he should enter his/her examiner number on the line next to the quality control scans and file backups performed that day.

Exhibit 4-1. Bone density daily log sheet

Femur Phantom Scan Tech ID # \_\_\_\_\_  
 Spine Phantom Scan Tech ID # \_\_\_\_\_

National Health and Nutrition Examination Survey III

Stand No. \_\_\_\_\_  
 Location \_\_\_\_\_  
 Date \_\_\_\_/\_\_\_\_/\_\_\_\_  
 Session: AM PM EVE

**BONE DENSITY DAILY LOG SHEET**

| SP ID # | Disk Label Number | Examiner ID # | Time In/Time Out | Femur Side Analyzed | Status Code | Comments |
|---------|-------------------|---------------|------------------|---------------------|-------------|----------|
| 1.      |                   |               | ____/____        |                     |             |          |
| 2.      |                   |               | ____/____        |                     |             |          |
| 3.      |                   |               | ____/____        |                     |             |          |
| 4.      |                   |               | ____/____        |                     |             |          |
| 5.      |                   |               | ____/____        |                     |             |          |
| 6.      |                   |               | ____/____        |                     |             |          |
| 7.      |                   |               | ____/____        |                     |             |          |
| 8.      |                   |               | ____/____        |                     |             |          |
| 9.      |                   |               | ____/____        |                     |             |          |
| 10.     |                   |               | ____/____        |                     |             |          |

STATUS CODES: C - Complete, PC - Partially Complete (must include comments), NE - No Exam (must include comments)

The rest of the page should be used to record the information requested about each examinee. That information includes the following:

|                   |  |
|-------------------|--|
| Examinee #        | Enter examinee hard copy label with NCHS identification number.  |
| Disk Label Number | Enter the NCHS Box Label (BB) Number assigned to the diskette for the bone density scan.   |
| Examiner #        | Enter ID number of technician who performed the scans and analyses.  |
| Time In/Out       | Record the exact time (hrs/mins) the examination procedures began with the SP, and the exact time the SP left the exam room.                                       |
| Femur             | Enter R for right and L for left side scanned. Place a check mark in the space provided after analyzing the scan. Note all problems in the comments section.       |
| Status Code       | Enter one of the codes displayed at the bottom of the form that best describes the outcome of the exam (C for complete, P for Partially complete, NE for No Exam). |
| Comments          | Enter all pertinent comments regarding reasons scans were not performed/completed, and any problems or irregularities.   |

#### **4.2 Calibration Logs**

The QDR-1000 bone densitometer has an internal referencing system that calibrates the machine automatically. No calibrations are performed by health technicians and no log is required.

#### **4.3 Quality Control Records**

A notebook is provided to store the printed records of the quality control scans performed on a daily and weekly basis.

#### **4.4 Bone Density Inventory Form**

The technician assigned to the bone density examination area will be responsible for completing an inventory of equipment and supplies in the examination room at the beginning and end of each stand. Inventories are recorded on an inventory form provided by the MEC manager and returned to the MEC manager promptly upon completion of the inventory.

#### **4.5 Shipment of Forms and Logs**

Each week a copy of the bone density Daily Log (automated version or xeroxed hard copy) should be sent to the review center with a floppy disk containing all scans performed during the week. These procedures are explained in Section 5.2.2.1. Copies of all phantom scan and SP scan reports should be sent to the review center, accompanied by a Transmittal Form.

At the end of the stand, all hard copy forms and logs should be shipped to the National Center for Health Statistics as described in Part I, Section 2.0, Standardized Procedures.

A hard copy of the daily log should be printed after each session for reference during the stand. A complete set of daily logs will be printed out on a weekly basis in Rockville from the automated system data tape.

Transmittal forms for hard copy forms will be generated by the automated system if needed. A copy of the transmittal form should accompany all material shipped to NCHS.

## **5. QUALITY CONTROL**

A variety of quality control procedures have been chosen to ensure the accurate collection and documentation of reliable data. Quality control procedures for bone density technicians and consultants are described in this section.

### **5.1 Examination Forms**

#### **5.1.1 Automated System Records**

Examination data recorded on the automated system will be backed up daily and sent to NCHS for review on a weekly basis by the MEC manager. In the event the automated system is not available, hard copy versions of the forms will be on each MEC, and will be used to record examination data.

#### **5.1.2 Hard Copy Forms**

As mentioned in Section 3.3, a Bone Density Examination Form will be available in the bone densitometry examination room when the automated system is not available. When the automated system is again operational, examination data that was collected on hard copy forms will be entered into the automated system. The hard copy versions will be marked as entered into the system and returned to NCHS at the end of the stand as previously described.

### **5.2 Examination Data Items**

#### **5.2.1 Preparation of Floppy Disks**

Two sets of floppy disks for sample person scans will be maintained, a set of original backup

disks and a set of disks for copies of analyzed scans to be sent for review by outside consultants. One floppy diskette will hold only about 6 scan files.

At the end of each work day the hard disk will be cleared of all scan files after backup procedures for original backup and review center disks are completed.

The hard disk can hold only about 100 scan files, which is not enough files to complete an average stand. Therefore, all scan files will need to be transferred to floppy disks to make space on the hard disk for new scan files. Remember, all scans are automatically saved to the hard disk.

It will be much easier to account for the files on a session by session basis, rather than waiting until the hard disk is full to transfer files. Consequently, it is important to copy the scan files to the floppy disks at the end of each session as previously described in Section 3.

#### **5.2.1.1 Original Backups**

At the end of each examination session, the technician responsible for the bone density room will check to make sure that all scans performed during the sessions are analyzed and archived to a properly labeled floppy diskette for NCHS and for the review center. The NCHS series of disks will serve as the original backups for scans saved on the hard disk.

Also, hard disks occasionally "crash", resulting in the loss of information, and are also known to experience other problems which can cause data to be lost. Therefore, a floppy disk backup system is standard operating procedure when original data are saved to hard disks.

#### **5.2.2.1 Floppy Disks for Consultant Review**

A second floppy disk system will be maintained to allow weekly review of bone density scan files by our consultants at the review center.

At the end of each work day in the Mobile Exam Center, before the hard disk is cleared of files, the health technician responsible for the bone density room will copy all scan files recorded that day onto separate disks. At the end of each week these disks will be shipped to consultants at the review center. A copy of the daily log (automated or Xerox copies of hard copy log) for each exam session that week must accompany disks sent.

Scan files of quality control phantom scans will also be included in the files sent to the review center each week. Copies of the phantom scan reports should also be sent to the review center, accompanied by a Transmittal Form.

### **5.2.2 Tracking Floppy Disks**

The health technicians performing scans in the bone density room will each be responsible for the maintenance and filing of the floppy disks for backup and review. The health technician assigned to the room will supervise the preparation and filing of backup and review copies, and monitor the number of scan files on the hard disk.

When the hard disk is ready to be cleared by deletion of all scan files, the health technician assigned to the room will make sure that all sample person and quality control scans are copied, and then inform the MEC manager that the disk is ready to be cleared. The MEC manager will double check the health technician's files, and after insuring that all hard disk files are backed up, will supervise the deletion of all files from the hard disk.

### **5.2.3 Shipping Floppy Disks**

The health technician assigned to the bone density room will prepare a Transmittal Form, as described in the Standardized Procedures Section, to accompany the disks and logs. One copy of the Transmittal Form will be sent to the review center, one copy will be sent to NCHS as a record of the transaction and the health technician will keep one copy until the end of the stand. At end of the stand,

the health technician's copies of the Transmittal Form will be sent to the Director of MEC Operations at Westat.

Floppy disks and accompanying forms must be packed properly in floppy disk mailers, and labeled with the address of the review center and stand location. The health technician responsible for the bone density room will prepare, pack and label these items, and deliver them to the MEC manager for shipment. The packages will be shipped standard air via Federal Express on the next first available MEC work day, which will be either Tuesday or Wednesday, depending on the schedule.

### **5.3 Quality Control Anthropomorphic Scans**

Anthropomorphic phantoms of the lumbar spine and femur will be present on each MEC to permit weekly and daily quality control scans. In addition, a spine phantom will be circulated among all Mobile Exam Centers and scanned by each of the three densitometers on a rotating basis. The "circulating" spine phantom will be scanned once per stand by each densitometer. The health technician assigned to the bone density room will be responsible for performing all quality control scans.

#### **5.3.1 Weekly Anthropomorphic Femur Scan**

A weekly scan of the Hologic anthropomorphic femur phantom will be conducted at the beginning of the examination session on the first day of the MEC work week by the technician assigned to the bone density area.

The weekly scan of the femur phantom will assist the supervision of health technician performance and aspects of software performance unique to the femur scan.

Procedures for scanning the femur phantom are explained in detail in the Hologic Operator's Manual, and should be followed as written to perform the scans.

In summary, procedures for scanning femur phantom are:

1. At the start of the first exam session of the week, after the equipment is ready, place the anthropomorphic femur on the QDR-1000 examination table.
2. Select either right or left hip.
3. Check the name (phantom identification) and hip selection.
4. Perform the scan.
5. Analyze the scan. No adjustments to the image are necessary for phantoms.
  - Fix box to the standard size, 110x128.
  - Erase any artifacts if present.
6. After analysis, locate Ward's triangle. Adjust box if necessary.
7. Print a report of the scan.
8. Archive the scan to the Quality Control disk.
9. Place the printer report in the notebook provided.
10. Record on the automated system or the hard copy log that the scan was performed.
11. Place the phantom back into the case and prepare for SP exams.

### **5.3.2 Daily Anthropomorphic Spine Scans**

At the start of the first session of the work day, the health technician responsible for the bone density room will perform a scan of the anthropomorphic spine phantom. The scans will be performed daily to monitor intra-machine performance and calibration.

The procedures for performing the scan of the anthropomorphic spine phantom are explained in detail in the Hologic Operator's Manual.

In summary, the procedures for performing the scan of the anthropomorphic spine phantom are:

1. At the start of the first session of each work day, after the equipment is ready, place the spine phantom on the densitometry examination table.
2. Select the spine scan.
3. Check the name (phantom identification) and spine selection. Use the default settings.
4. Perform the scan.
5. Analyze the scan. No adjustments should be needed.
6. Print a report of the scan.
7. Archive the scan file.
8. Place the printer record of the scan in the notebook provided.
9. Place the phantom back in the case.
10. Record in the automated system log (or on the hard copy daily log) that the scan was performed.
11. Prepare to examine sample persons.

## **5.4 Review, Observation and Replication**

### **5.4.1 Review of Scan Files.**

Floppy disk copies of bone density data will be received regularly by outside consultants at the review center. Data will be assessed for instrument performance as well as for technician performance. Quality control data from instruments will be used to assess stability of the densitometers over time, identify time trends and develop correction factors.

Reports regarding the scan files reviewed and any equipment or technician problems noted will be directed to the NCHS personnel responsible for the component. NCHS will provide reports of the

review to the Director of MEC Operations to monitor technician performance and arrange retraining as needed.

#### **5.4.2 Observations and Replication**

At regular intervals, consultants from the review center will observe a sample of bone density exams performed by technicians. Consultants will observe whether the appropriate procedures and techniques are followed and deviations from the standard procedures will be noted.

Review of quality control data will provide assessments of instrument performance, while review of SP scans will provide assessments of both equipment and technician performance.

Replications of bone densitometry exams will be included in the quality control protocol. A small percentage of sample persons in each stand will be asked to volunteer for complete replications of the entire MEC examination, in which case the bone density exam would also be repeated. However, these individuals will have an entirely new SP identification (NCHS) number.

Preparations are also in progress to designate approximately ten sample person files as "blind replicates" so that files sent to the review center may be sent again under another set of identifiers (like sample person numbers) to receive another review. The two reviews of the same file will then be compared for consistency by NCHS personnel.

#### **5.5 Refresher Sessions**

Periodically, refresher sessions will be scheduled for all technicians to provide an opportunity for review of procedures as well as to confirm the consistency of procedures performed in the field.

## **6. SAFETY**

### **6.1 Equipment Precautions**

#### **6.1.1. Precautions Against Radiation Exposure**

Several safety precautions have been included in the Mobile Exam Center procedures to minimize the risk of unnecessary exposure to radiation. These precautions are observed by NCHS and examination staff at all times, and include:

- Exclusion from the exam of persons at greater risk of radiation exposure, such as pregnant SP's, or SP's under the age of 20 years,
- Radiologic certification of health technicians operating the bone densitometer,
- Restriction of the bone density examination room to MEC staff, sample persons and authorized visitors,
- Exclusion of food and beverages from the exam room,
- Monitoring of radiation emissions from bone densitometry equipment, and
- Monitoring of health technicians with film badges.

##### **6.1.1.1. Monitoring Equipment**

The QDR-1000 densitometer will be monitored by the NCHS engineer in cooperation with Hologic, Inc. to assure that radiation emissions are within the limits specified by the manufacturer.

##### **6.1.1.2 Monitoring Technicians**

Health technicians performing the bone densitometry exam and NCHS, Westat and consultant personnel will wear film badges when observing examination procedures.

The film badge will be the radiation measuring device used in NHANES III. Photographic film has been successfully used for nearly half a century as a personnel radiation monitor. The design of the film badge has undergone many refinements and enables it to measure not only the quantity of radiation but also the type of radiation, the approximate energy, and the direction. Consequently it is very important that such a monitor be properly handled and worn.

Each shipment of personnel monitors will be accompanied by a control badge. The control badge will be stored in a location distant from any radiation source. Individual radiation monitors will not leave the MEC. The badge will be worn unshielded, at the collar region. New badges will be required every three months. When the new ones are received, the used badges will be returned to Westat and sent for reading.

Film badge readings are distributed to Westat, NCHS and Mobile Exam Center staff. The MEC manager will be responsible for posting the readings in the bone densitometry room.

### **Pregnant Technicians**

Should a health technician become pregnant during the field period of study, it will be her responsibility to inform her supervisors when she suspects or confirms that she is pregnant. The pregnant technician will be provided with a second radiation badge with instructions to wear it at waist level. The radiation monitoring report associated with this badge will reflect that it is a fetal dose monitor.

## **6.2 SP Movement and Positioning**

Sample persons who are unable to maintain a motionless, supine position on the bone densitometry table should be excluded from the densitometry procedure. Sample persons in wheelchairs who cannot support their weight on one leg without assistance should not be physically removed from their wheelchairs to receive this exam, and should be excluded from the procedure.

Before excluding an SP from a procedure for reasons other than protocol exclusions, health technicians should consult with the MEC manager to review the problem.

Health technicians must exercise caution in assisting sample persons to sit on the exam table and avoid bumping the scanner arm. A foot stool is present in the bone density exam room to help SP's step up to the scanner table. Also, sample persons will be instructed to lie quietly on the table, and to keep their arms at their sides while the scanner is in motion.

If the examinee is too obese to fit under the scanner arm, or if the examinee is unable to lie supine and motionless for the length of the scan, health technicians may find it necessary to exclude these examinees from the scan.

### **6.3 Emergency Procedures**

Sample persons who report feeling too ill to complete the bone density exam should be reported to the MEC physician as soon as possible. Examinees who appear ill or confused should also be discussed with the physician to determine whether the SP should be medically excluded from the exam. Health technicians should not make independent assessments about the health of an SP but discuss any questions with the MEC physician.

The MEC physician should be notified immediately in the event of a medical emergency and in all cases, the emergency procedures established for the MEC should be followed. The emergency procedures are discussed in detail in Part I, Section 3.

Appendix  
Block Phantom Quality Control Procedure

In October, 1992, an additional quality control procedure was included in the NHANES III bone density protocol by adding a circulating block phantom. The block phantom consists of three hydroxyapatite blocks of equal projected area but of different height. The block phantom was included in the second phase of NHANES III to monitor BMD at low, intermediate, and high levels.

The block phantom was circulated along with the circulating spine (or gold standard spine) phantom among all Mobile Exam Centers and scanned by each of the three densitometers on a rotating basis. The block phantom was scanned six times at the beginning of each stand. The scan protocol for the block phantom is given on the next page.

For more details about the NHANES III bone density quality control procedures and for results from phase 1, see the following reference:

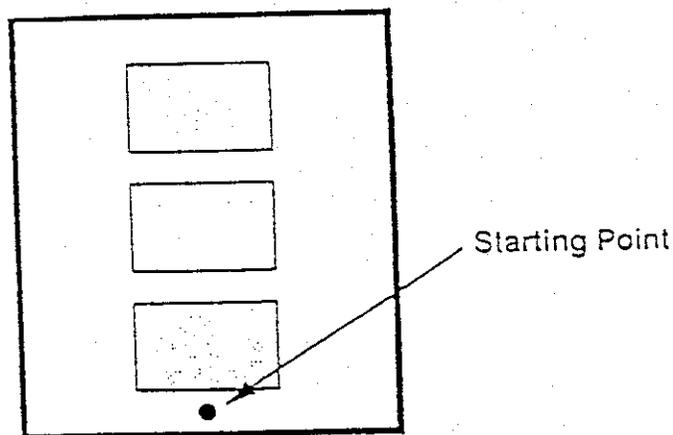
Wahner HW, Looker AC, Dunn WL, Walters LC, Hauser MF, Novak C. Quality control of bone densitometry in a National Health Survey (NHANES III) using three mobile examination centers. J Bone Mineral Research 1994;9:951-60.

**BLOCK PHANTOM SCANNING PROTOCOL**  
(To be scanned 6 times prior to the beginning of  
each stand along with the gold Standard Spine)

**SCANNING:**

1. Create a Patient Biography for the block phantom if one does not already exist. Be sure to include the phantom number in the Name entry. For example, BLOCK PHANTOM #1. The patient ID field should read 1. Enter your technologist # in the scan code field as done for other phantoms. Place in comment box NHANES BLOCK PHANTOM.
2. Place the block phantom box cover against the back edge of the table.
3. Place the block phantom against the box cover. Insure the block is within the mechanical limits of the scan arm. Align the block on the scanning table with the largest bone region nearest the foot of the table.
4. Move the scanner arm so that the laser positioning light is 1 cm to the left of, and centered on, the largest bone region as the operator is facing the machine.
5. Place a black indelible mark at this spot if one does not already exist to simplify subsequent scans of the block. See Figure 1 below.

FIG. 1.



6. Scan.
  - A) As a Lumbar Spine.
  - B) Use the default length and width.
  - C) Use F3 (rescan) if you are not centered.
  - D) Let the scan complete itself. Insure all 3 blocks are scanned.
  - E) Scan block 6 times.
  - F) Do not analyze scans nor add to the QC database. Archive unanalyzed scans onto floppy disk and send to Mayo Center for analysis.