



National Health and Nutrition Examination Survey (NHANES)

Dual Energy X-ray Absorptiometry (DXA) Procedures Manual



January 2007

TABLE OF CONTENTS

<u>Chapter</u>		<u>Page</u>
1	OVERVIEW OF DXA	1-1
	1.1 Overview of Dual Energy X-Ray Absorptiometry	1-1
	1.2 Personnel.....	1-2
	1.3 Flow of DXA Exam.....	1-2
2	EQUIPMENT/SUPPLIES/MATERIALS	2-1
	2.1 Description of Equipment for DXA.....	2-1
	2.1.1 Hologic QDR 4500A.....	2-1
	2.1.2 QDR System Operations	2-3
	2.1.3 Supplies.....	2-3
	2.1.4 Radiation Badges	2-3
	2.2 Maintenance/Repair of Equipment for DXA.....	2-4
	2.2.1 DXA Bone Densitometer Service Report	2-4
	2.3 Calibration of Equipment for DXA	2-5
3	PROTOCOL	3-1
	3.1 Introduction to the Examination	3-1
	3.2 Explanation of DXA	3-1
	3.3 QDR 4500A System Operation	3-3
	3.3.1 Startup Procedures for Hologic QDR (Start of Session).....	3-3
	3.3.2 End of Session Shutdown Procedures for QDR.....	3-4
	3.3.3 End of Day Shutdown Procedures for QDR	3-4
	3.4 Examinee Preparation for DXA.....	3-5
	3.4.1 Measurement of Weight.....	3-5
	3.5 AP Spine Scan	3-7
	3.5.1 Selecting an SP.....	3-8
	3.5.2 Selecting the Type of Scan.....	3-9
	3.5.3 Positioning the SP	3-10
	3.5.4 Positioning the C-Arm	3-11
	3.5.5 Scanning.....	3-12

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
3.6	Proximal Femur Scan.....	3-15
	3.6.1 Selecting the Type of Scan.....	3-15
	3.6.2 Positioning the SP.....	3-16
	3.6.3 Positioning the C-Arm.....	3-17
	3.6.4 Scanning.....	3-19
	3.6.5 Panniculus (Belly Fat Pad).....	3-21
3.7	DXA Scan Data.....	3-21
4	DATA ENTRY SCREENS.....	4-1
	4.1 Shared Exclusion Questions.....	4-1
	4.2 Weight Entry Screen.....	4-4
	4.3 Safety Exclusion Questions.....	4-6
	4.4 DXA AP Spine Scan Data Capture Screens.....	4-13
	4.5 DXA Proximal Femur Data Capture Screens.....	4-15
	4.6 DXA Component Status.....	4-17
	4.7 Close Exam.....	4-19
5	REFERRALS AND REPORT OF FINDINGS.....	5-1
	5.1 Observation Referrals.....	5-1
	5.2 Report of Findings for DXA.....	5-3
	5.2.1 Sample Preliminary Report of Findings.....	5-4
6	QUALITY CONTROL.....	6-1
	6.1 Equipment and Room Set-Up Checks.....	6-1
	6.1.1 Start of Stand.....	6-1
	6.1.2 Daily.....	6-2
	6.1.3 Weekly.....	6-2
	6.1.4 End of Stand.....	6-2
	6.2 Procedures for Completing QC Scans.....	6-2
	6.2.1 Hologic Anthropomorphic Spine Phantom (HASP).....	6-2
	6.2.2 Step Phantom.....	6-8
	6.2.3 Hologic Femur/Hip Phantom (Weekly Scan).....	6-11
	6.2.4 Circulating Hologic Spine Phantom (HSP Q-96).....	6-15

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
	6.2.5 Circulating Block Phantom (Hologic Block Phantom NH #1)	6-16
	6.2.6 Using Auto Scan at Start of Stand.....	6-17
6.3	QC Scan Checklists	6-19
	6.3.1 Instructions for Completing Weekly QC Scan Checklist....	6-19
	6.3.2 Instructions for Completing Start of Stand QC Scan Checklist.....	6-19
	6.3.3 Instructions for Accessing Blank QC Checklist Forms.....	6-20
6.4	Data Entry Screens for QC on Equipment.....	6-20
	6.4.1 Start of Stand QC Checks	6-22
	6.4.2 Daily QC Checks.....	6-23
	6.4.3 Weekly QC Checks	6-23
	6.4.4 End of Stand QC Checks.....	6-24
	6.4.5 Incomplete QC Checks	6-25

List of Appendixes

<u>Appendix</u>		
A	DXA Scripts.....	A-1
B	Set-up and Tear-down Procedures for DXA Room.....	B-1
C	DXA Bone Densitometer Report.....	C-1
D	DXA Scanner Reporting Procedures	D-1
E	Start of Stand QC Scan Checklist	E-1
F	Weekly QC Scan Checklist.....	F-1
G	Procedure for Securing the QDR 4500A for Travel	G-1
H	Procedure for Setting Up QDR 4500A for Operations	H-1
I	Power Failure Procedures for DXA.....	I-1

TABLE OF CONTENTS (continued)

List of Tables

<u>Table</u>		<u>Page</u>
1-1	Age groups and gender for DXA	1-2
1-2	Pregnancy status information for DXA by age and gender	1-2

List of Figures

<u>Figure</u>		
2-1	Hologic Densitometer QDR4500A.....	2-1
2-2	Instrument Control Panel on the QDR 4500A.....	2-2
2-3	Laser warning label.....	2-2
2-4	Laser locator label.....	2-3

List of Exhibits

<u>Exhibit</u>		
3-1	Hologic power module right side panel	3-3
3-2	Instrument control panel	3-6
3-3	Scan table mattress (top view)	3-7
3-4	Selecting “Perform Exam”.....	3-8
3-5	Patient selection screen	3-8
3-6	Operator field for initials	3-9
3-7	AP Lumbar Spine Scan selection screen	3-9
3-8	AP Lumbar Spine Scan Parameters screen.....	3-10
3-9	C-arm positioning for AP spine scan	3-11
3-10	Spine Scan window.....	3-12

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
3-11	Properly positioned AP spine.....	3-13
3-12	Exit Exam/New Scan window box	3-14
3-13	Left Hip Scan Selection screen.....	3-15
3-14	Scan Selection screen for proximal femur scan	3-16
3-15	SP positioning for femur scan.....	3-16
3-16	Foot placement against hip scan positioning fixture.....	3-17
3-17	Starting point and reposition mark for femur scan	3-18
3-18	Hip scan window	3-19
3-19	Repositioning the femur.....	3-20
3-20	Properly aligned and rotated femur scan	3-20
3-21	Data displayed after analysis	3-22
4-1	Shared Exclusion Questions	4-1
4-2	Exclusion from another component.....	4-2
4-3	Shared Exclusion Questions (pregnancy exclusion).....	4-3
4-4	Shared Exclusion Questions (No to pregnancy question).....	4-3
4-5	Exclusion due to weight.....	4-4
4-6	End of component status (weight limit).....	4-5
4-7	Weight data entry screen.....	4-5
4-8	Safety Exclusion Questions	4-6
4-9	Safety Exclusion Questions (contrast radiography).....	4-8

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-10	DXA Component Status (Data Effect)	4-9
4-11	Safety exclusion questions (nuclear medicine studies).....	4-10
4-12	Safety exclusion questions (femur scan questions).....	4-11
4-12a	Safety Exclusion Questions (right hip only).....	4-11
4-13	Safety Exclusion Questions (AP spine)	4-12
4-14	DXA data capture (AP spine scan) (1)	4-13
4-15	DXA data capture (AP spine scan) (2)	4-14
4-16	DXA data capture (AP spine scan) (3)	4-15
4-17	DXA data capture (femur scan) (1)	4-15
4-18	DXA data capture (femur scan) (2)	4-16
4-19	DXA data capture (femur scan) (3)	4-17
4-20	DXA component status (required comments).....	4-18
4-21	DXA component status	4-18
4-22	Close exam.....	4-20
5-1	Menu to select observation referral.....	5-1
5-2	Pick list of SPs in current session	5-2
5-3	Observation referral in DXA	5-2
5-4	Observation referral from another component in physician's referral review box.....	5-3
5-5	Sample Report of Findings for DXA.....	5-4
6-1	QDR main window	6-3

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
6-2	Daily QC Setup box.....	6-3
6-3	System self-test.....	6-4
6-4	System test passed	6-4
6-5	Spine Phantom QC image.....	6-5
6-6	Auto QC passed	6-5
6-7	Spine Phantom QC – plot for BMD.....	6-6
6-8	Spine Phantom QC – plot for BMC.....	6-7
6-9	Step Phantom Setup window	6-8
6-10	Step Phantom scan.....	6-9
6-11	Step Phantom Evaluation completed successfully.....	6-10
6-12	Step Phantom QC completed, press “Continue”.....	6-10
6-13	Selecting Hologic Femur/Hip Phantom from patient menu.....	6-11
6-14	Operator box for initials.....	6-12
6-15	Selecting Right Hip in the Scan Selection Screen	6-12
6-16	Hologic Femur/Hip Phantom Scan Parameters screen	6-13
6-17	Machine scanning Femur/Hip phantom.....	6-14
6-18	Exit exam/new scan window box	6-15
6-19	Selecting Auto Scan from QDR main menu.....	6-17
6-20	Number of times to run scan.....	6-18
6-21	Quality Control reminder message box	6-20

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
6-22	Utilities menu to select quality control	6-21
6-23	Quality Control log-on.....	6-21
6-24	Quality Control Start of Stand Checks (1).....	6-22
6-25	Quality Control Start of Stand Checks (2).....	6-22
6-26	Quality Control Daily Checks.....	6-23
6-27	Quality Control Weekly Checks	6-24
6-28	Quality Control End of Stand Checks.....	6-24
6-29	Quality Control Incomplete Checks entry	6-25

1. OVERVIEW OF DXA

Bone health will be evaluated in the current National Health and Nutrition Examination Survey (NHANES) by dual energy X-ray absorptiometry (DXA) scans of the femur and anterior-posterior (AP) spine. This method will be used to (1) monitor secular trends in overweight prevalence; (2) describe the prevalence of obesity; and (3) examine the relationship between overweight and obesity and other examination measures, including blood pressure, glucose intolerance, and a battery of indicators for cardiovascular disease.

1.1 Overview of Dual Energy X-Ray Absorptiometry

DXA will be used to assess overall skeletal changes that often occur with age by measuring bone mineral content (BMC) and bone mineral density (BMD). DXA measurements can also be used to provide information on early gender and ethnic changes in the rate of bone accretion and to determine the age when skeletal accretion ceases and when peak bone mass occurs. This information can be used to implement effective and timely measures with the objective of maximizing peak bone mass. Such measures may include calcium supplementation, dietary fortification, or programs promoting dairy products and other calcium and vitamin D rich foods. This information can also be used to assess the impact of factors such as diet or lifestyle on measures of bone status in various minority populations.

The femur and AP spine scans were added to the NHANES in 2005; the whole body scan was removed in 2006. Data obtained from both the femur and AP spine scans are considered gold standards for diagnosing osteoporosis. Collection of data from the DXA femur scan will be used to provide estimates of the prevalence of osteoporosis in the United States. Additionally, these data will be compared to the NHANES III femur data to track progress toward the Healthy People 2010 Objective 2.9, to reduce the overall numbers of people with osteoporosis. Collection of data from the AP spine scan will provide a more complete evaluation of skeletal health.

The DXA femur and AP scans will be completed on all individuals 8 years old and above (see Table 1-1). Pregnancy status will be assessed on all females aged 12 through 59 and menstruating 8- to 11-year-olds. If the result of the pregnancy test is positive, the sampled participant (SP) will be excluded from the entire exam. If a pregnancy test for an SP who is 8 through 17 years old comes back

positive, a second test will be done for confirmation. In addition, women aged 12 through 59 years will be asked to self-report their pregnancy status and will be excluded if they respond “Yes,” even if the pregnancy test was negative. Self-report on pregnancy status for 12- through 17-year-old females will be asked in the Physician’s Exam. Females aged 8 through 11 years will not be asked about pregnancy status (see Table 1-2).

Table 1-1. Age groups and gender for DXA

Component	Age	Gender
DXA (AP Spine)	8 and above	Males & Females
DXA (Femur)	8 and above	Males & Females

Table 1-2. Pregnancy status information for DXA by age and gender

Pregnancy Status	Age	Gender
Pregnancy Status – Urine Test	12-59 years	Females
Pregnancy Status – Urine Test	Menstruating 8-11 years	Females
Pregnancy Status – Self Report	12-59 years	Females
Pregnancy Status – Self Report (Asked in Physician’s Exam)	12-17 years Menstruating 8-11 years	Females
Pregnancy Status – Self Report (Asked in DXA Exam)	18-59 years	Females

1.2 Personnel

The health technologist who is a certified radiology technologist will conduct all DXA scans.

1.3 Flow of DXA Exam

The DXA exam will begin with the AP spine scan followed by the femur scan. Participants should receive no more than two total DXA scans. If a problem occurs during the scans, it should be documented in the ISIS Data Capture screen and/or an Unusual Field Occurrence (UFO) form, if necessary.

2. EQUIPMENT/SUPPLIES/MATERIALS

2.1 Description of Equipment for DXA

2.1.1 Hologic QDR 4500A

The Hologic QDR 4500A (Figure 2-1) is a fan beam X-ray bone densitometer, which uses two different energy levels produced by an energy tube to estimate bone mineral content (BMC) and bone mineral density (BMD). The QDR uses a low level of X-rays.

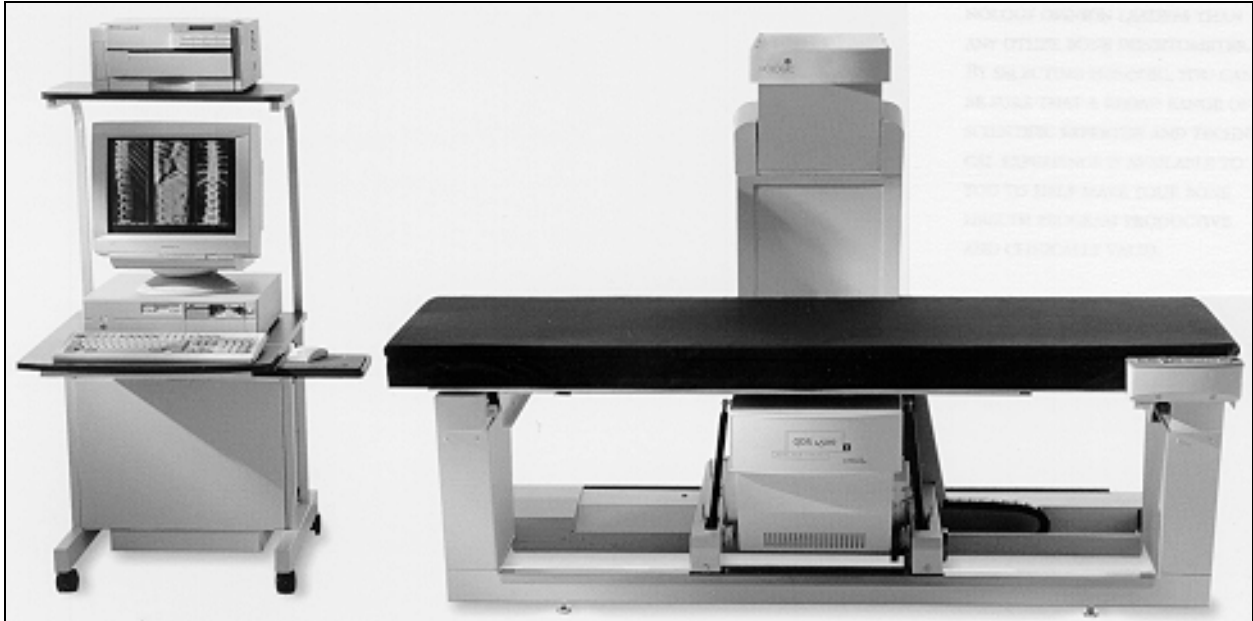


Figure 2-1. Hologic Densitometer QDR4500A

The densitometer produces ionizing radiation in the 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 of health technologists is required. The radiation from a DXA scan is less than one would receive during a round trip cross-country airplane flight or normal background radiation in a day.

The X-ray ON indicator is an amber light located in the lower right corner of the instrument control panel (see Figure 2-2). When the X-ray lamp is lit, X-rays are being produced.

The **Emergency Stop Button** is a round red button at the right end of the instrument control panel that is used for emergencies. When this button is pressed, the X-rays and the table are disabled and scanning stops immediately. Pulling on the button resumes normal operation.

- Press down on the button to stop the scan; and
- Pull up on the button to resume normal operation.

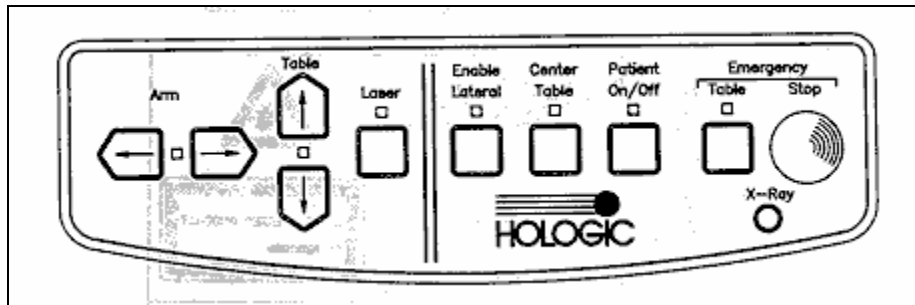


Figure 2-2. Instrument Control Panel on the QDR 4500A

Laser Positioning. The Laser-On Lamp is an amber light above the Laser switch on the Instrument Control Panel. It alerts the user that the laser position indicator is active. The laser position indicator unit produces 1 mW laser emission. The examinee and technologist should avoid looking directly into the beam, or placing reflective objects in the path of the beam.

The QDR 4500 Elite includes a laser safety feature that turns the laser off if the distance between the top (right side) of the table is less than approximately 15.5 inches from the laser light spot. This feature exists to help prevent shining the laser light in the examinee's eyes. Figure 2-3 shows the laser warning label located on the scanner arm.



Figure 2-3. Laser warning label

Arrows marked Laser Aperture mounted on the scanner arm note the location of the laser beam. Figure 2-4 shows the laser locator label.

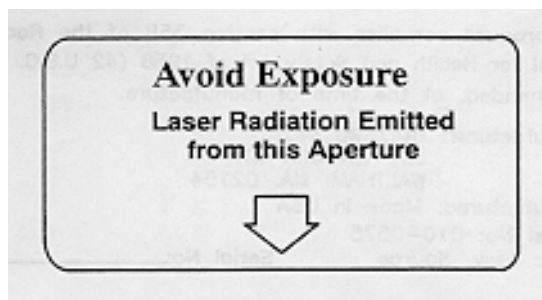


Figure 2-4. Laser locator label

2.1.2 QDR System Operations

See Section 3.3 in Chapter 3 for Start-up and Shut-down Procedures for the QDR System. See Appendix I for Power Failure Procedures.

2.1.3 Supplies

Completion of the AP spine and femur scans will require three pieces of accessory equipment. The large square cushion is used for positioning the SP for the AP spine scan. (See Section 3.5 for detailed procedures.) The radiolucent pillow is placed under the head before the AP spine scan. (See Section 3.5.3 for detailed procedures). The Hologic hip positioning device is used for positioning the SP for the femur scan. (See Section 3.6 for detailed procedures.)

2.1.4 Radiation Badges

Health technologists operating the densitometers are required to wear radiation badges for dosimetry processing. A control badge is placed in the room on the computer cart beside the densitometer.

2.2 Maintenance/Repair of Equipment for DXA

If the chief technologist needs to contact Hologic for repair, the contact number and other important information are listed below:

- Call Hologic customer support at 1-800-321-4659;
- You will need the model number and the serial number for your machine;
- Model number for all mobile examination centers (MECs) is QDR 4500;
- Serial number for MEC 1 is 45575;
- Serial number for MEC 2 is 45678; and
- Serial number for MEC 3 is 45700;

See Appendix D for detailed instructions of equipment repair notification.

2.2.1 DXA Bone Densitometer Service Report

When the Hologic densitometer is serviced or repaired:

- The chief technologist will complete a DXA Bone Densitometer Report (see Appendix C);
- Send/Scan copy of the report to the home office. See Appendix D for specific instructions about names and numbers. The home office will send this to the Quality Control Reading Laboratory;
- Send a copy of the service report completed by the service engineer to the home office when the repair or service is made;
- Put a copy of the service engineer's report and a copy of the DXA Bone Densitometer Report in the service report binder kept in the DXA room. This binder is used to store the Hologic Customer Service Reports and the DXA Bone Densitometer Service Report forms; and
- Blank DXA Bone Densitometer Service Report forms are stored electronically in the ISIS system. Open Word, select File/Open, look in the directory for Mecstaff/Blank forms/DXA_serv.doc.

2.3 Calibration of Equipment for DXA

Refer to Chapter 6 for complete instructions regarding calibration and quality control scanning procedures.

3. PROTOCOL

3.1 Introduction to the Examination

The technologist should briefly explain the examination when the SP is brought into the room. The exam should be explained in more detail as each scan is being completed. The objective is to inform the SP about the exam and to position the SP as quickly as possible. Below is a suggested introductory script, but the technologist should use his or her own words for this explanation. This is an explanation, not a standard script, so the technologist may adjust the explanation to the level of understanding of the examinee.

Suggested Introduction to Component (English Version):

In this room, I'm going to take two scans of your body with this machine. These scans can tell us how strong your bones are. I will explain each exam in more detail as I go along.

Suggested Introduction to Component (Spanish Version):

En este cuarto, voy a tomar dos escáneres de su cuerpo con esta máquina. Estos escáneres pueden decirnos qué tan fuertes están sus huesos. Explicaré cada examen con más detalles mientras los hago.

3.2 Explanation of DXA

The technologist is scanning the ID wrist band of the examinee during this explanation. This should be used as a guideline only and the technologist should adjust the explanation to the level of understanding of the SP. The script used for an 8-year-old will be different from the script used for a 60-year-old. The scripts below provide suggested explanations of the DXA exam, as well as each individual scan.

Suggested Explanation of DXA Scans (English Version):

It will take a few minutes to position you correctly for each scan and another few minutes to take the scans. The scan of your hip and spine will tell us how strong your bones are compared to other people like you. I will explain each scan in more detail as I position you for the scan. At this time, please remove all objects from your pockets

and place them in this container. I am going to ask you a few questions before I start the exam (SHARED AND safety exclusion questions are asked).

Suggested Explanation of DXA Scans (Spanish Version):

Tomará unos pocos minutos ponerle en la posición correcta para cada escáner y otros pocos minutos para tomar los escáneres. El escáner de su cadera y de su columna nos dirán qué tan fuertes están sus huesos comparados con los de otras personas como usted. Le explicaré cada escáner con más detalles mientras le posiciono para el escáner. En este momento, por favor saque todos los objetos que tiene en los bolsillos y póngalos en este recipiente. Le voy a hacer algunas preguntas antes de empezar el examen (SHARED AND safety exclusion questions are asked).

Suggested Explanation of AP Spine Scan (English Version):

For the spine scan, you will lie flat on the table. I'm going to place a pillow under your head. Then I am going to bend your legs at a 90-degree angle at the hip and knee by placing them on this large, soft, cube-shaped pillow. You will not feel anything during this scan. Please be as still as possible and do not talk during the scan.

Suggested Explanation of AP Spine Scan (Spanish Version):

Para el escáner de la columna vertebral, usted tendrá que acostarse extendido sobre la mesa. Le voy a poner una almohada debajo de la cabeza. Después, le voy a doblar las piernas en un ángulo de 90 grados en la cadera y las rodillas poniéndolas en esta almohada grande y suave en forma de cubo. Usted no sentirá nada durante este escáner. Por favor quédese lo más quieto(a) posible y no hable durante el escáner.

Suggested Explanation of Femur Scan (English Version):

The next scan will be of your hip. For this scan, please continue to lie still with your legs flat against the table. I will rotate your left leg inward slightly and then keep it in place using this foot brace. Please place your arms across your chest. You will not feel anything during the scan. Please be as still as possible and do not talk during the scan.

Suggested Explanation of Femur Scan (Spanish Version):

El siguiente escáner será para su cadera. Para este escáner, por favor continúe acostado/a sin moverse con las piernas extendidas sobre la mesa. Voy a moverle la pierna izquierda un poco hacia adentro y después la mantendré en esa posición usando estas bandas para los pies. Por favor cruce los brazos sobre el pecho. Usted no sentirá nada durante este escáner. Por favor quédese lo más quieto(a) posible y no hable durante el escáner.

3.3 QDR 4500A System Operation

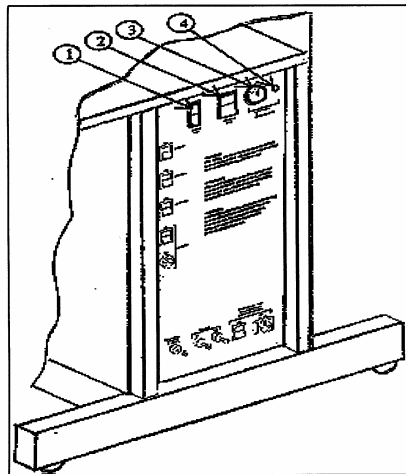
The QDR 4500 system should be turned on at the beginning of the day and off at the end of each session for that day. See Appendix H for setting up the QDR 4500 for operations. Routine startup procedures for the beginning of a session are outlined below in Section 3.3.1. See Appendix G for securing the QDR 4500 for travel. Routine shutdown procedures are outlined in Section 3.3.2. See Appendix I for power failure procedures for DXA.

3.3.1 Startup Procedures for Hologic QDR (Start of Session)

Confirm these settings first:

- Check that the POWER ON lamp on the Power Module is lit. (The switch and the lamp are located on the **bottom left of the back panel**. This light indicates that the system is in standby mode and power is maintained to the signal detector. This eliminates warming up the detector when the system is turned on. This should be left on at all times unless a power failure occurs. See Appendix I for power failure procedures.
- COMPUTER POWER switch (1) should be ON. This is left ON to allow network backup overnight (see Exhibit 3-1).
- Check that the INSTRUMENT POWER switch (2) on the Power Module **right side panel** is in the ON position.
- X-RAY ENABLE KEY (3) should be OFF (see Exhibit 3-1).

Exhibit 3-1. Hologic power module right side panel



Turning the Hologic QDR System ON (Start of Session Routine Procedure):

- **NOTE:** The X-RAY ENABLE KEY is already OFF.
- In the blue screen, select “Start” from the lower left. Select “Turn off computer” and select “Turn off.”
- The computer will shut down.

At this point, the X-ray table and the computer are both shut down.

Now both should be brought up to begin the session:

- Turn the X-RAY ENABLE KEY clockwise to enable production of X-rays.
- Push the Computer Power Button (on CPU). When the QDR login screen is displayed, double click on QDR (soccer ball icon).
- (If the QDR database has not been backed up, a tan Windows box will appear: “A backup of your QDR system’s database has not been performed in # days! ... Do you want to perform a system backup now?” Click “No.”)
- The X-ray table will turn on and the QDR Main Menu will be displayed.
- Log into the Integrated Survey Information System (ISIS).

3.3.2 End of Session Shutdown Procedures for QDR

- The screen should display the QDR Main Menu.
- Turn the X-RAY ENABLE KEY counterclockwise (OFF).
- Remove the key and put it in the designated spot.

3.3.3 End of Day Shutdown Procedures for QDR

- Click Exit (bottom right corner). Then select “Exit QDR **without** Shutdown” and click “OK.” Leave at blue screen.
- Turn the X-RAY ENABLE KEY counterclockwise (OFF).

- Remove the key and put it in the designated spot.
- Reboot ISIS.

3.4 Examinee Preparation for DXA

The SP should be logged into ISIS as soon as possible after he or she has entered the room.

3.4.1 Measurement of Weight

After answering the Shared Exclusion questions, the next screen displayed will be the weight data entry screen. See Exhibit 4-7 (Section 4). If the SP was in the anthropometry (BM) component or respiratory health (RX) component prior to this test, the weight will already be uploaded and displayed on the ISIS screen, along with the component from which it transferred (i.e., BM, RX). If the information is not displayed, you will need to measure the SP's weight using the floor scale in the room. The same precision to take the weight measurements in the anthropometry component must be used in this component.

3.4.1.1 Weight

Follow these steps to take the SP's weight:

1. Make sure the scale weighs in kilograms by checking the switch on the underside of the digital display.
2. Tap on the scale and 0.0 will appear on the digital display.
3. Have the SP remove any outer clothing such as sweaters, jackets, etc.
4. Have the SP step on the scale with his or her feet positioned in the center.
5. Ask the SP to stand straight and remain still.
6. Wait about 4 seconds for the weight to display on the digital readout.

7. Record the weight in kilograms in the weight field.
8. Ask the SP to step off the scale. The scale switches off automatically after 30 seconds.

If the SP's weight is more than 300 pounds, he or she will be excluded from the entire component due to weight limitation of the table. A message box will indicate that the SP is excluded from the exam. Click OK on the message and the Component Status Screen will appear, coded as "Not Done" with the comment "Weight limitation on equipment" (see Section 4.2).

3.4.1.2 Placing the SP on the Table

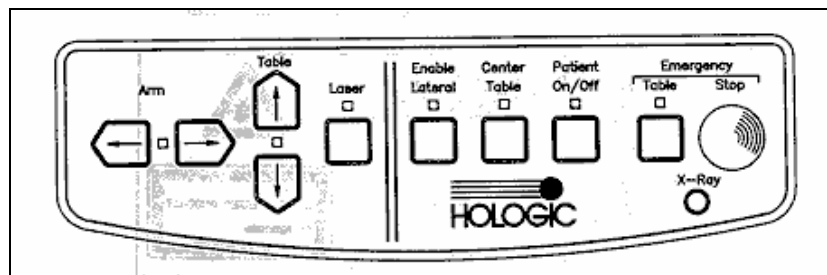
Have the SP remove all objects from his or her shirt and pants pockets (e.g., wallet, cell phones, underwire bras). False teeth, hearing aids, jewelry, and watches do not have to be removed.

Before moving the table or C-Arm:

- Confirm that the runner area of the table is clear of objects that might interfere with table movement; and
- Check that the table scan area is clear of articles that might interfere with table movement.

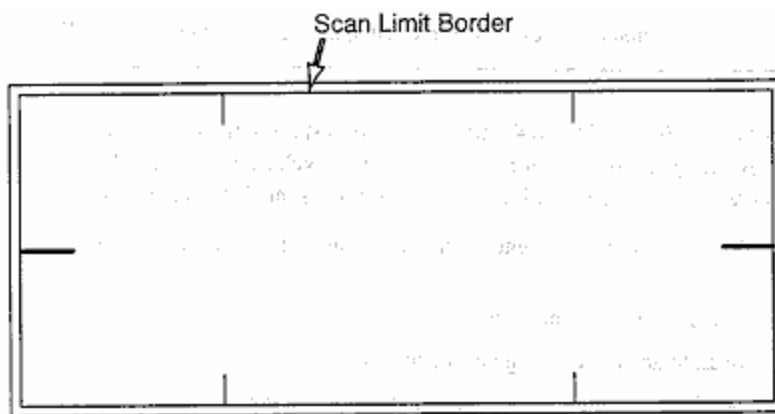
Press the Patient ON/OFF switch on the Control Panel of the Hologic densitometer to allow the C-arm to move to the far left and extend the table out from the base (see Exhibit 3-2). This will make it easier for the SP to get on (or off) the table.

Exhibit 3-2. Instrument control panel



- After the C-arm and table stop moving, assist the SP onto the table and have the SP lie down on his or her back with his or her head to your right as you face the table.
- Press the “Center” switch on the Control Panel, and wait for the C-arm to position itself to the center of the table.
- Make sure the SP is in the center of the table with respect to the center lines at the head and foot of the pad (Exhibit 3-3).
- Confirm that the SP is lying straight on the table. One method to check this is to position yourself at the foot of the table and look at the alignment of the body. Visualize a straight line from the nose, center of the body, and down through the knees and toes.
- If the SP continues to have difficulty lying flat or with the head slightly supported, exclude him or her from the exam.

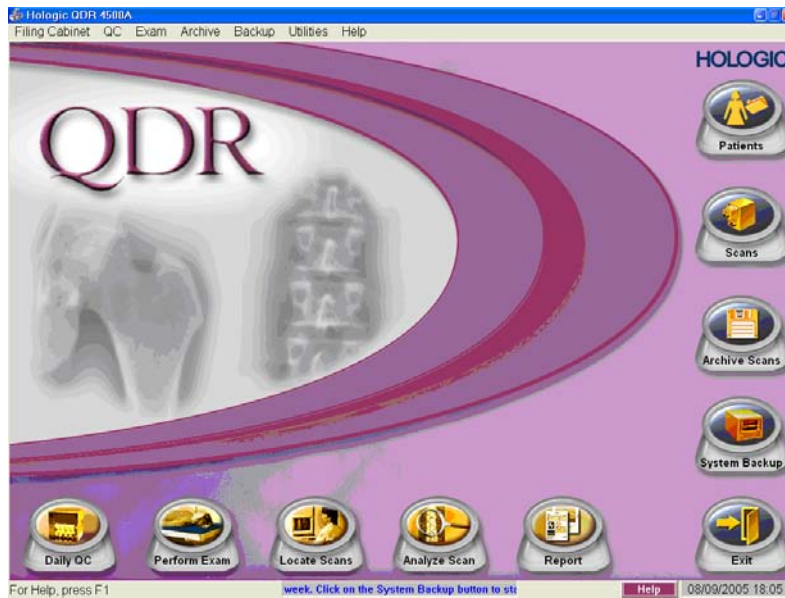
Exhibit 3-3. Scan table mattress (top view)



3.5 AP Spine Scan

- Read and answer all Safety Exclusion questions in ISIS. You must complete up to the Data Capture screen in ISIS before performing an exam.
- Click the “Perform Exam” icon in the QDR screen (see Exhibit 3-4).

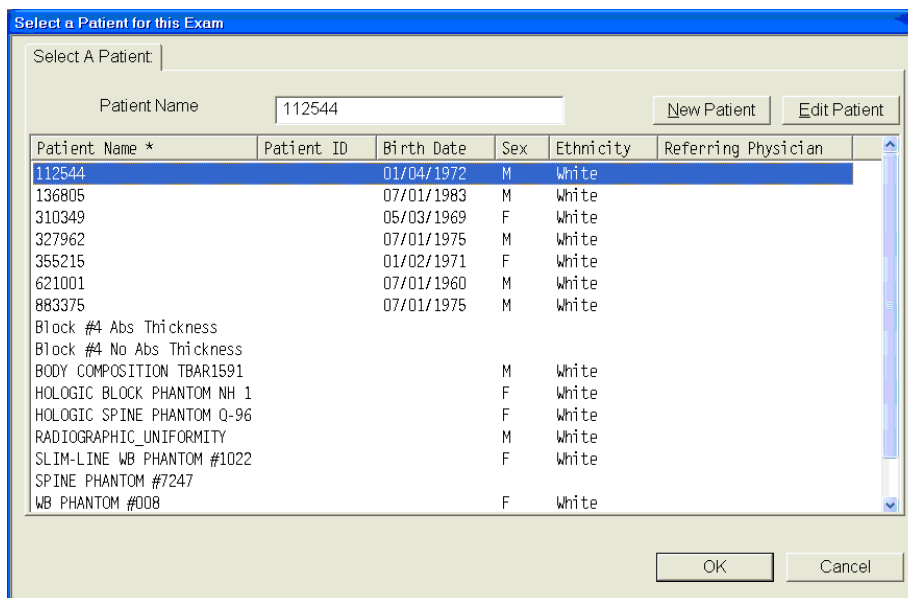
Exhibit 3-4. Selecting “Perform Exam”



3.5.1 Selecting an SP

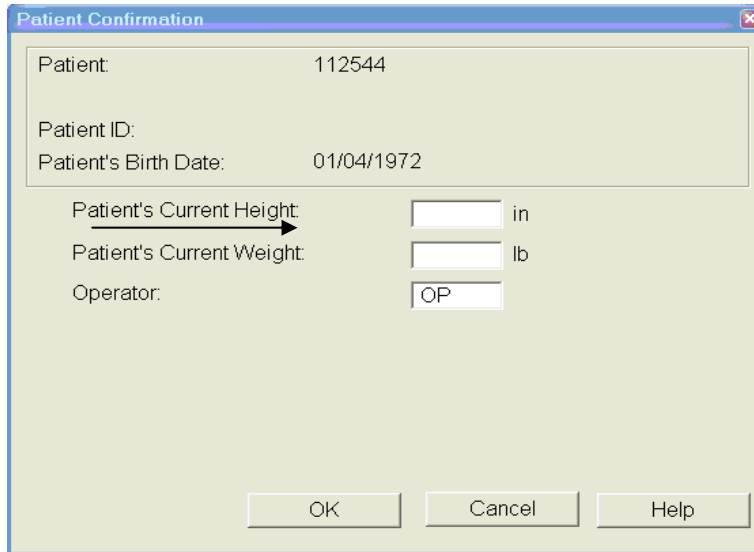
- In the “Patient Selections” screen, enter the SPID from the ISIS screen into the blank white field next to Patient Name. Double check that you entered the correct SPID by asking for the SP’s birthday. Press “OK” (see Exhibit 3-5).

Exhibit 3-5. Patient selection screen



- Enter your initials in the “Operator” field and click “OK” (see Exhibit 3-6).

Exhibit 3-6. Operator field for initials

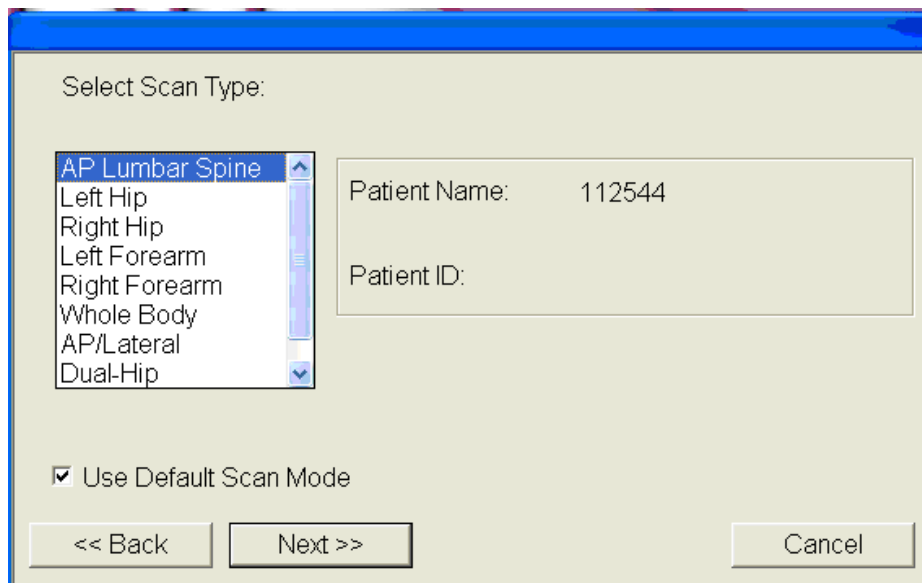


A screenshot of a 'Patient Confirmation' dialog box. The window title is 'Patient Confirmation'. It contains the following fields: 'Patient' with value '112544', 'Patient ID:' (empty), 'Patient's Birth Date:' with value '01/04/1972', 'Patient's Current Height:' with an empty input field and 'in' unit, 'Patient's Current Weight:' with an empty input field and 'lb' unit, and 'Operator:' with an input field containing 'OP'. At the bottom are three buttons: 'OK', 'Cancel', and 'Help'.

3.5.2 Selecting the Type of Scan

- In the “Scan Selection” screen, select the scan type by clicking on “AP Lumbar Spine” with the mouse. The scan type is highlighted (see Exhibit 3-7). Click the “Next>>” button.

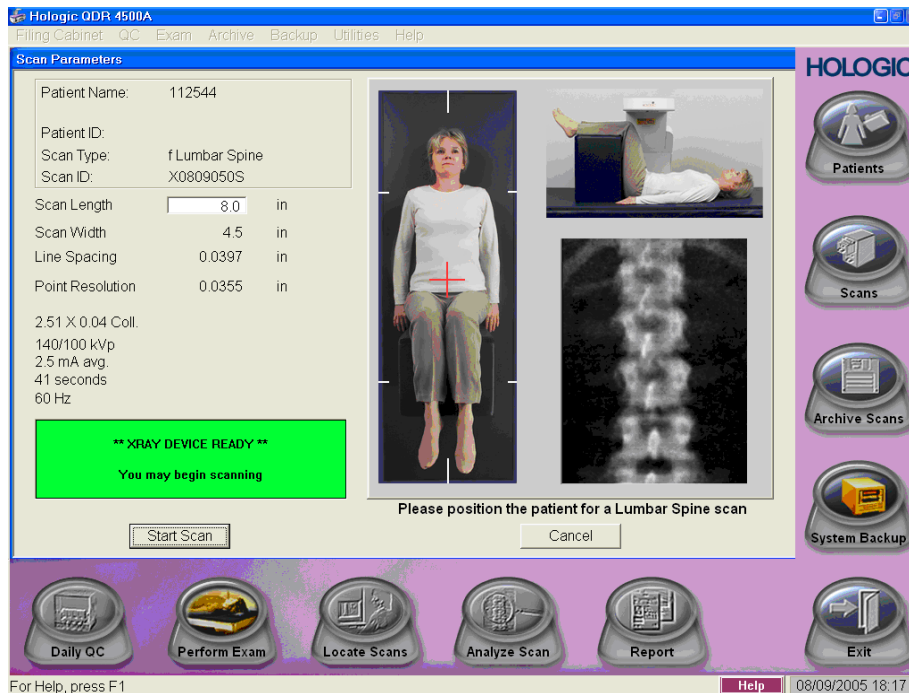
Exhibit 3-7. AP Lumbar Spine Scan selection screen



A screenshot of a 'Scan Selection' dialog box. The window title is 'Select Scan Type:'. It features a list box on the left with the following items: 'AP Lumbar Spine' (highlighted), 'Left Hip', 'Right Hip', 'Left Forearm', 'Right Forearm', 'Whole Body', 'AP/Lateral', and 'Dual-Hip'. To the right of the list box are two text fields: 'Patient Name:' with value '112544' and 'Patient ID:' (empty). At the bottom left is a checked checkbox labeled 'Use Default Scan Mode'. At the bottom are three buttons: '<< Back', 'Next >>', and 'Cancel'.

- The AP Lumbar Spine Scan Parameters screen will display (see Exhibit 3-8).

Exhibit 3-8. AP Lumbar Spine Scan Parameters screen



- Verify the scan type in the upper left corner. Stop here and position the patient and the C-arm.

3.5.3 Positioning the SP

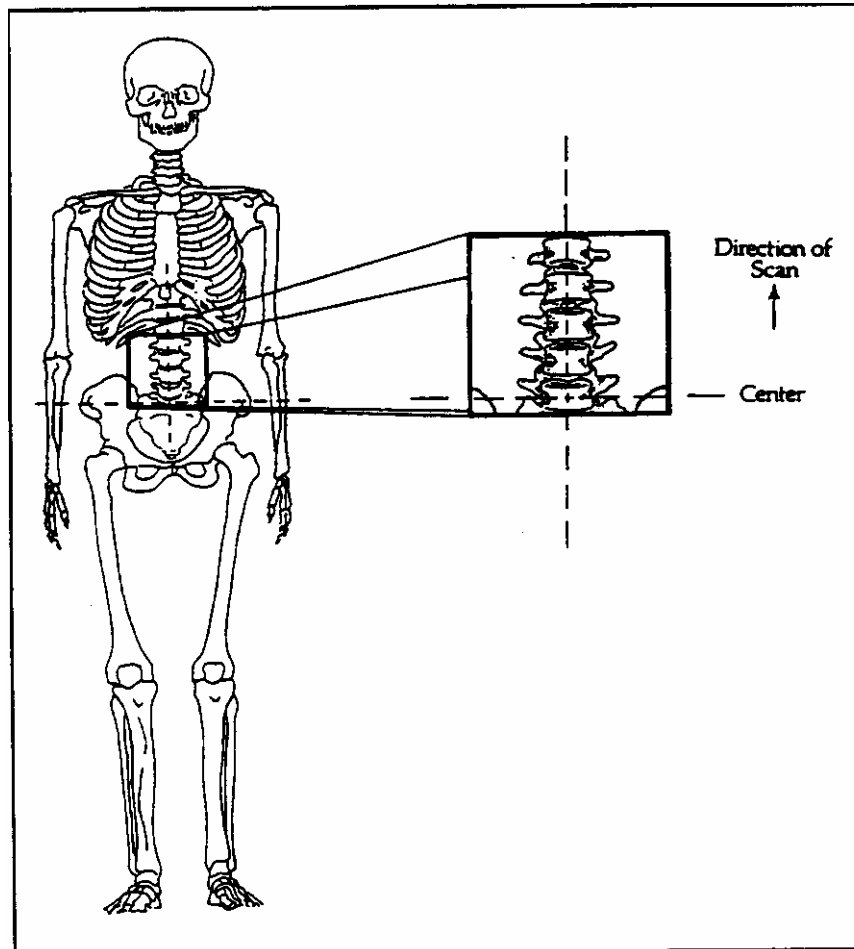
- The SP should be positioned with his or her head to your right as you face the table. Make sure that the SP is straight and centered on the table and that his or her shoulders are at the upper scan limit hash marks on the long edges of the table, to ensure the spine will be within the scan area.
- **NOTE:** Stand at the head end of the DXA table, reach under the SP's underarms, and gently pull toward you to straighten the spine.
- Place radiolucent pillow under SP's head and under the paper.
- On the control panel, press the center table switch to move the table and C-arm to the center position.

- Place the large square cushion under the SP's lower legs and under the paper with the thighs as close to a 90° angle to the body as possible.
- Have the SP rest his or her arms comfortably at his or her sides.

3.5.4 Positioning the C-Arm

- Locate the SP's iliac crest.
- Using the arm motion controls on the control panel, bring the laser indicator vertical line to approximately 2 inches below the iliac crest. The laser indicator horizontal line should coincide with the midline of the SP (see Exhibit 3-9). The laser indicator is projected when the motion control is activated.

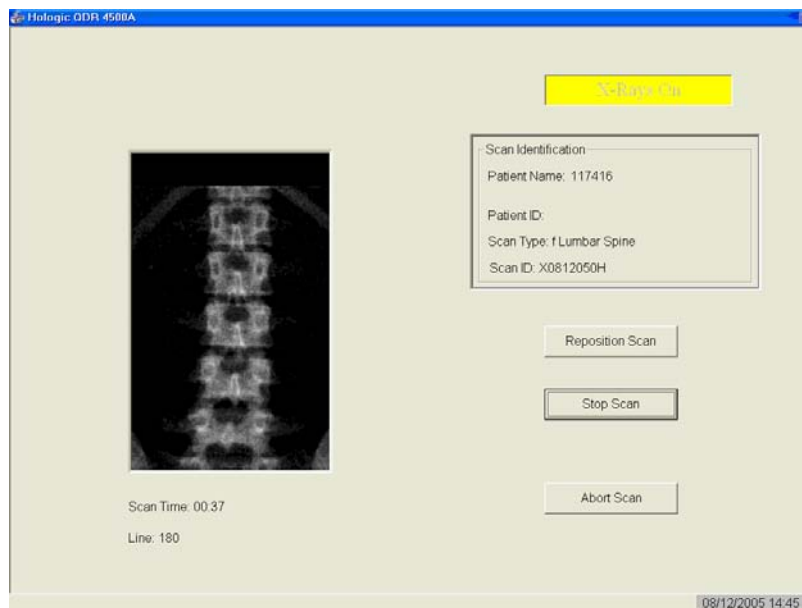
Exhibit 3-9. C-arm positioning for AP spine scan



3.5.5 Scanning

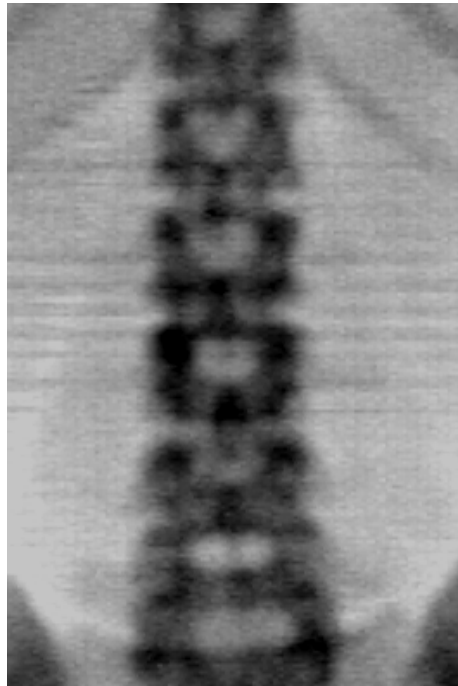
- Prior to beginning the scan, confirm that the SP's body is straight with respect to the laser, the table, and the lines on the table pad (see Exhibit 3-10).
- Press "Start Scan" to begin the scan.
- The Scan window displays with the image appearing on the left side. Flashing X-rays On indicator at the top of the window continues until the scan stops.

Exhibit 3-10. Spine Scan window



- Make sure that the spine is centered and straight, there are even amounts of soft tissue on each side of the entire spine, and that a small amount of the iliac crest is visible in the lower corners of the screen (Exhibit 3-11). If not, click “Reposition Scan” to stop the scan.

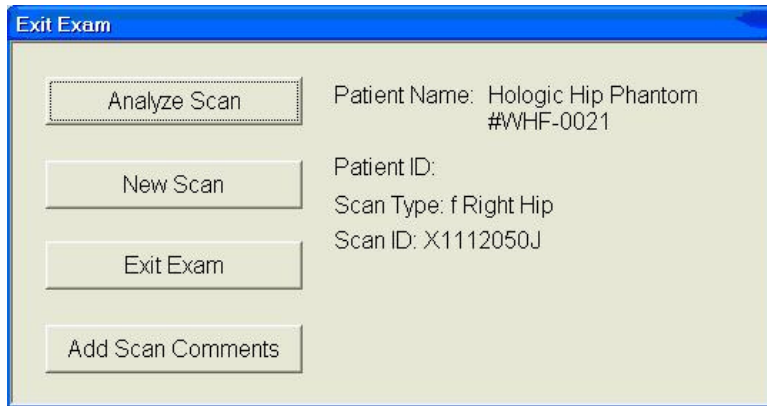
Exhibit 3-11. Properly positioned AP spine



- The image acquired so far displays with scroll bars on the right and bottom.
- Position the cursor over the spine image. The arrow cursor changes to a hand. Click and drag the image (or use the scroll bars) so that the iliac crest is at or below the blue horizontal positioning line and within the lower portion of the scan field. The center of the lumbar spine should be aligned with the blue vertical positioning line.
- If the spine is not straight, move the patient’s upper torso either left or right to straighten the spine. When the spine is repositioned correctly, click the “Restart Scan” button. The Scan Parameters window displays. Click the “Start Scan” button to start a new scan at the new position. The Scan window displays with a flashing X-rays On message. The image displays.

- When you see the ribs attaching at T-12 (see Exhibit 3-11), click the “Stop Scan” button. When the scan completes, the Exit Exam/New Scan window displays (see Exhibit 3-12).

Exhibit 3-12. Exit Exam/New Scan window box



- The analysis will be done later by the QC reading lab.
- Go to the ISIS screen and complete the DXA Data Entry screen.
- Remove the large square cushion from under the SP’s legs and place in designated spot in the DXA room.

3.5.5.1 Adjusting the Default Length of the AP Spine Scan

For the majority of SPs, the default length settings for the spine scan will be appropriate and will result in a spine scan that properly shows a small amount of iliac crest in the lower corners of the scan, L1 through L5, and the ribs attaching at T-12 at the top of the scan. However, it is possible that, for a tall SP, this length may not be adequate to include all necessary points of interest. If, during the scout scan, it becomes apparent that the default length of the scan will not be adequate, it will be necessary to adjust the default length of the scan. This should be done as follows:

- As soon as it is apparent that the length of the scan is not adequate, press “Reposition Scan” to stop the scan.
- Make any adjustments on the screen that may be necessary and press “Restart Scan” to accept the new starting position.

- The Scan Parameters screen (see Exhibit 3-8 shown earlier) will be displayed. To change the scan length, place the cursor in the Scan Length field and type the new length, number 10, and press “Start Scan.” The system may change the number entered to match the pre-programmed step size of the scanning mechanism.

3.6 Proximal Femur Scan

- Select “New Scan” from the Exit/New Scan window (see Exhibit 3-12).

3.6.1 Selecting the Type of Scan

- At the “Scan Selections” screen (Exhibit 3-13), choose left hip, unless answers to safety exclusion questions warrant using the right hip. Click “Next >>”.

Exhibit 3-13. Left Hip Scan Selection screen

Scan Selection

Select Scan Type:

- AP Lumbar Spine
- Left Hip
- Right Hip
- Left Forearm
- Right Forearm
- Whole Body
- AP/Lateral
- Dual-Hip

Patient Name: 112544

Patient ID:

Use Default Scan Mode

<< Back Next >> Cancel

- The Scan Parameters window appears (see Exhibit 3-14). Verify the patient name and scan type in the upper left corner.

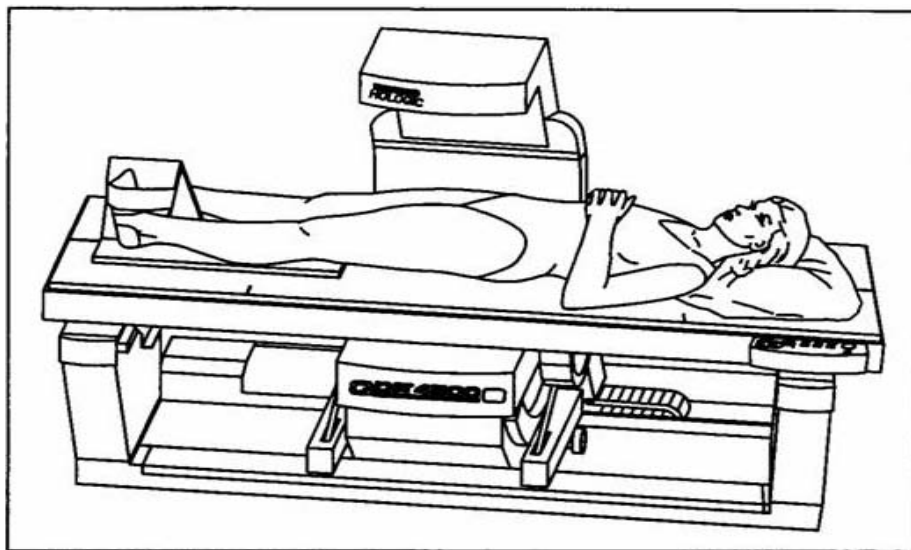
Exhibit 3-14. Scan Selection screen for proximal femur scan



3.6.2 Positioning the SP

- The SP should be positioned with his or her head to your right as you face the table. Make sure that the SP is straight and centered on the table. The hip region should be within the two sets of hash marks on either side of the long edge of the table (see Exhibit 3-15).

Exhibit 3-15. SP positioning for femur scan

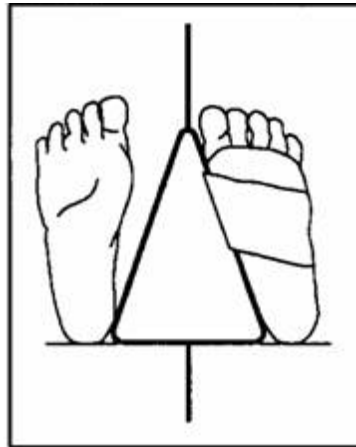


- On the control panel, press the Center Table switch to move the table and C-arm to the center position.
- Place the hip scan positioning device on the far left end of the table near the SP's feet. Align the center of the device with the patient's midline. The leg to be examined should be rotated inward so that the foot can be placed against the positioning device and secured with the strap (Exhibit 3-16). Adjust the abduction of the leg so that the shaft of the femur is parallel with the center of the table.

NOTE: In rotating the leg inward, place one hand above the knee and one hand below the knee and gently rotate the leg to ensure the whole leg is rotated, as opposed to just the lower portion of the leg.

- Make sure that the SP's arms are placed across his or her chest outside of the scanning area.

Exhibit 3-16. Foot placement against hip scan positioning fixture

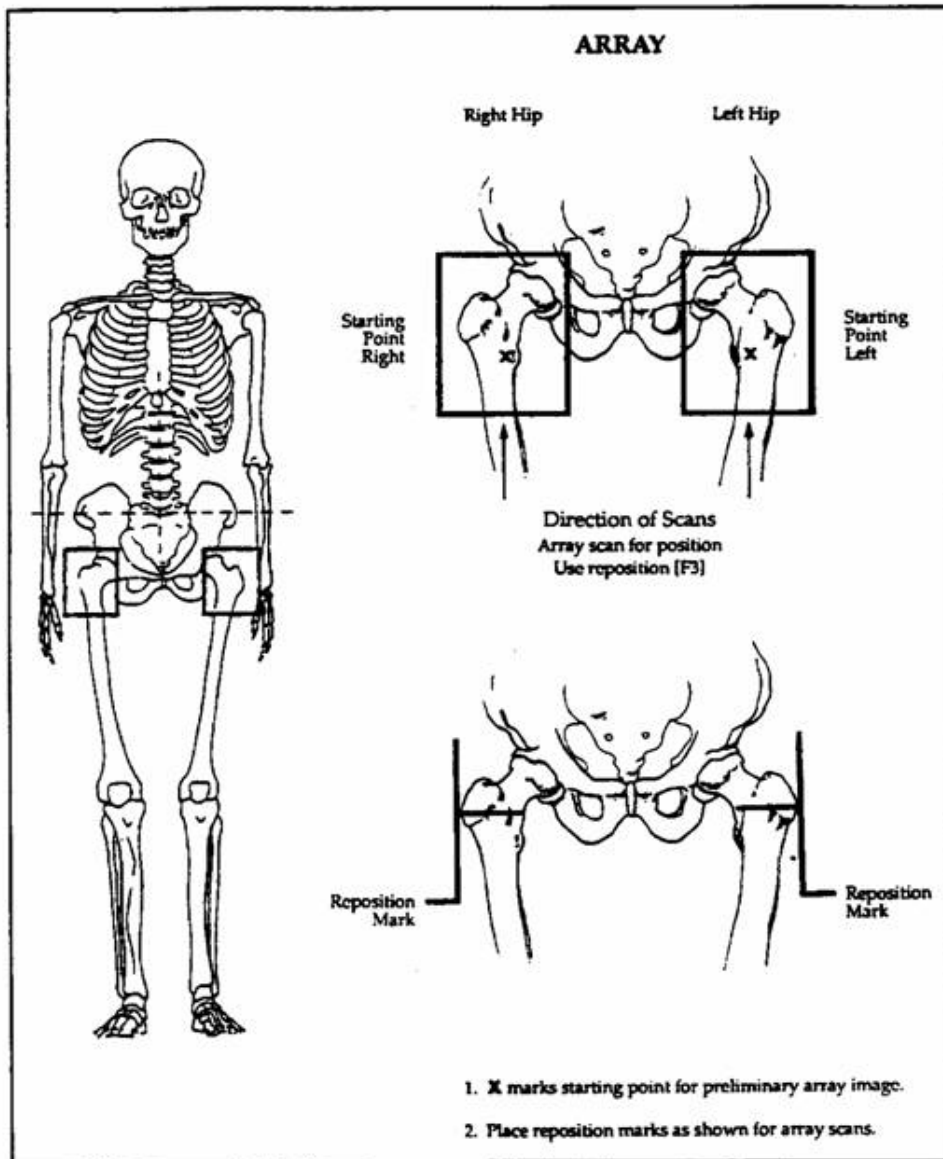


3.6.3 Positioning the C-Arm

- Locate the SP's greater trochanter. This can be done as described below:
 - Grasp the leg to be scanned near the ankle and gently rotate 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 fingertips.
 - If you are not able to feel the trochanter, have the SP bend the leg at the knee and lift (may be necessary to assist the SP). Locate the crease formed at the top of the leg and use this as an approximate location of the greater trochanter.
 - In both cases, these are approximate location(s) to begin the scan.

- Move the C-arm until the laser cross-hair is 2 inches below the level of the greater trochanter and is on the center shaft of the femur (Exhibit 3-17, see “Starting Point Left” and “Starting Point Right”).
- Align the femoral shaft so it is parallel to the horizontal line of the laser.

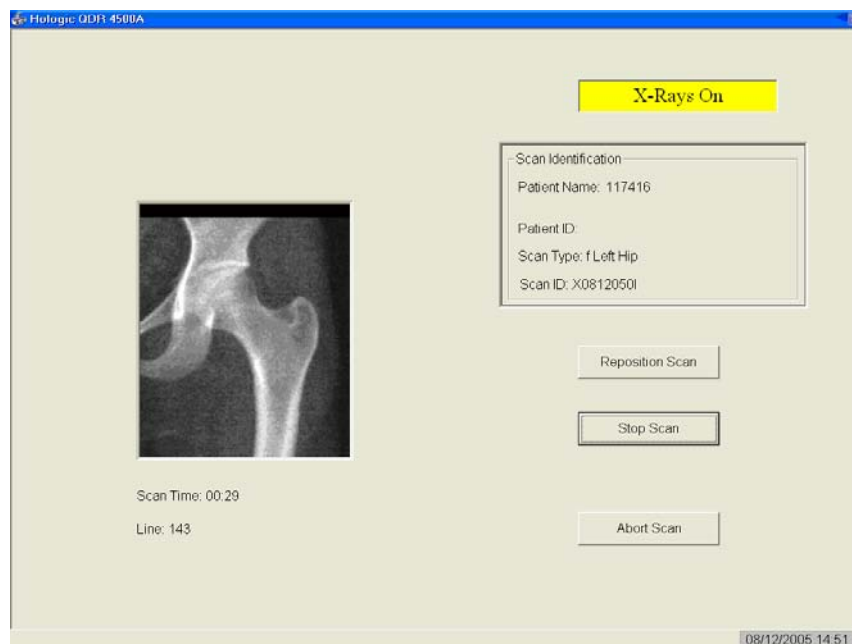
Exhibit 3-17. Starting point and reposition mark for femur scan



3.6.4 Scanning

- Reconfirm that the SP is properly positioned and press “Start Scan” to begin the scan.
- The Scan window displays with the image appearing on the left side. The flashing X-rays On indicator at the top of the window continues until the scan stops. The image will appear on the screen, one line at a time from the bottom up (Exhibit 3-18).

Exhibit 3-18. Hip scan window

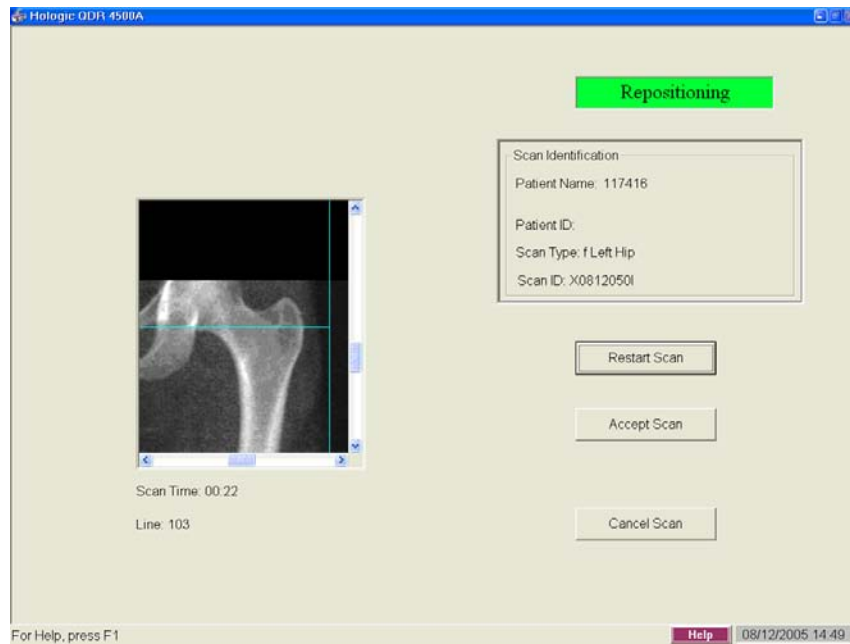


- Inspect the image as it is generated. If the hip is positioned correctly, allow the scan to complete. If the hip is not positioned correctly, click the “Reposition Scan” button to stop the scan.
- When the outer edge of the greater trochanter can be identified, press “Reposition Scan” to re-scan.

NOTE: If the scout scan reveals that the SP has a hip replacement or pin previously not reported, stop the scan and proceed with scan on the other hip, if possible. If this is not possible, discontinue the scan and complete the Femur Scan data entry scan to document the reason for the incomplete scan.

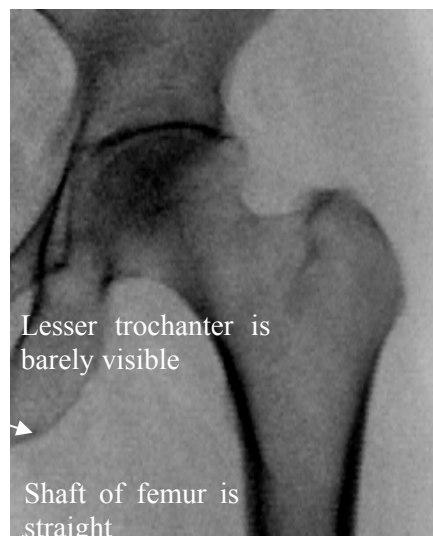
- Reposition the image up, down, left, or right using the scroll bars or cursor hand to include the entire femoral head, neck, and approximately 3 inches of the shaft (see Exhibit 3-19, “Reposition Mark”).
- The new starting point is automatically adjusted to have the correct amount of soft tissue lateral to the greater trochanter.

Exhibit 3-19. Repositioning the femur



- Press “Restart Scan” to return to the scan parameter screen.
- When the Scan Parameter screen re-appears, press “Start Scan” to repeat the scanning process.
- The scanning will start from the corrected starting point. Repeat the re-scan process until acceptable anatomy is shown, then allow the scan to finish. See Exhibit 3-20 for an example of a properly aligned and rotated femur scan.

Exhibit 3-20. Properly aligned and rotated femur scan



- The analysis will be done later by the QC Reading Lab.
- Go to the ISIS screen and complete the Femur Scan screen. Be sure to inspect the scan thoroughly to include any comments that may be necessary.
- Remove the SP's leg from the hip positioning device.

3.6.5 Panniculus (Belly Fat Pad)

- On very obese SPs, the fat pad of the belly can overlie the head of the femur, artificially increasing the BMD. This is a major source of error which will cause the analysis of the scan to be inaccurate.
- When presented with an obese SP, gently palpate the area to determine if there will be obesity noise. Ask the SP to hold the fat pad out of the way with their hands by pulling it up and away from the femoral area. If unsure from palpation, start scan, and if obesity noise is present, repeat scan with the panniculus retracted.
- Document this on the DXA Proximal Femur Data Capture Screen in the "Other" text box under "Comment on scan" by typing, for example, "Belly fat pad retracted."

3.7 DXA Scan Data

- Analysis of the scans will be done at the QC Reading Center.
- Exhibit 3-21 displays the bone mineral content (BMC) and bone mineral density (BMD) for the SP. In addition, the box below the graph gives the T-score and the Z-score for the BMD for this SP.

Exhibit 3-21. Data displayed after analysis

WESTAT CORPORATION

Hologic QDR-4500A (S/N 45575)
Whole Body V8.23a:3
oJun 11 16:42 1998

D0611980B Thu Jun 11 16:19 1998
Name: TROY, HELEN O.
Comment: baseline
I.D.: 199800 Sex: F
S.S.#: 999-99-999 Ethnic: F
ZIP Code: Height: 5' 6"
Operator: BDC Weight: 112
BirthDate: 08/17/62 Age: 35
Physician: BAER

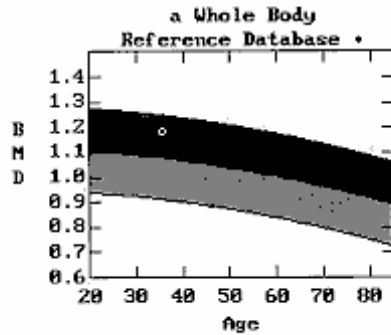
TBAR1459 - 1
F.S. 68.00% 0(10.00)%

Region	BMC (grams)	Fat (grams)	Lean (grams)	Lean+BMC (grams)	Total (grams)	% Fat (%)
L Arm	161.7	598.6	1939.6	2101.3	2699.9	22.2
R Arm	161.3	655.9	1888.2	2049.5	2705.4	24.2
Trunk	566.2	4118.8	10941.4	19507.6	23626.4	17.4
L Leg	422.1	3097.6	6839.1	6461.2	9558.8	32.4
R Leg	419.2	3135.8	6361.5	6780.7	9916.5	31.6
SubTot	1730.4	11606.7	35169.8	36900.2	48506.9	23.9
Head	585.2	838.9	2981.8	3487.0	4325.9	19.4
TOTAL	2315.6	12445.6	38871.5	40387.2	52832.8	23.6

*assumes 17.0% brain fat
LBM 73.2% water



WESTAT CORPORATION



D0611980B Thu Jun 11 16:19 1998
Name: TROY, HELEN O.
Comment: baseline
I.D.: 199800 Sex: F
S.S.#: 999-99-999 Ethnic: F
ZIP Code: Height: 5' 6"
Operator: BDC Weight: 112
BirthDate: 08/17/62 Age: 35
Physician: BAER

T(20.0)	Z
+0.88 107%	+1.19 118%

* Age and sex matched
T = peak BMD matched
Z = age matched

PS 10/25/91



4. DATA ENTRY SCREENS

The term “DXA” is used throughout this manual and is meant to refer collectively to both SP scans—spine and femur. In places where a specific answer to one of the shared exclusion or safety exclusion questions will exclude an SP from “DXA,” this term represents all SP scans. Other safety exclusion questions are specific to one of the scans (e.g., the question pertaining to a lumbar spine fusion pertains only to the spine scan) and the answer to that question may exclude the SP from that scan. In this case, the specific scan will be referenced by name.

4.1 Shared Exclusion Questions

The Shared Exclusion Questions in DXA consist of two questions. See Exhibit 4-1. These may be answered in several components in the MEC. If these questions have been answered in a previous component in the MEC, the questions and responses will be displayed in read-only format. If the SP is excluded from this exam based on his or her answers to the Shared Exclusion Questions in another component, the SP would be blocked from DXA by the Coordinator System and the SP would not be sent to this exam. The Component Status for DXA would be set to “Not done” with a comment specific to the reason for exclusion (safety exclusion, physical limitation, etc.).

Exhibit 4-1. Shared Exclusion Questions

DXA: Stand:410 Session:410580 10/15/2004 08:30 am - 12:30 pm
SP ID: 148004 Name: ROJAS, TINA Age: 27 years Gender: Female Date: 11/06/2006 Time: 03:02 PM

Shared Exclusion Questions

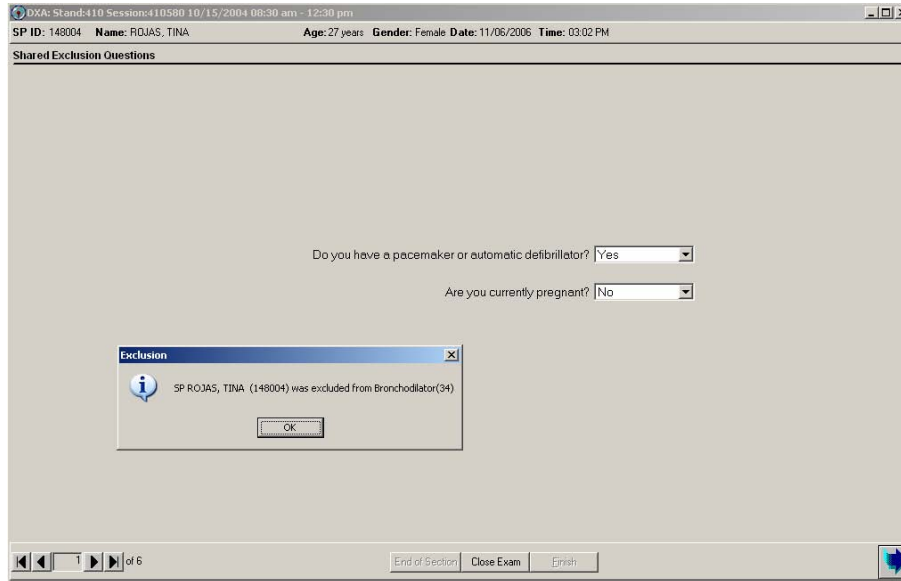
Do you have a pacemaker or automatic defibrillator?

Are you currently pregnant?

1 of 6
End of Section Close Exam Finish

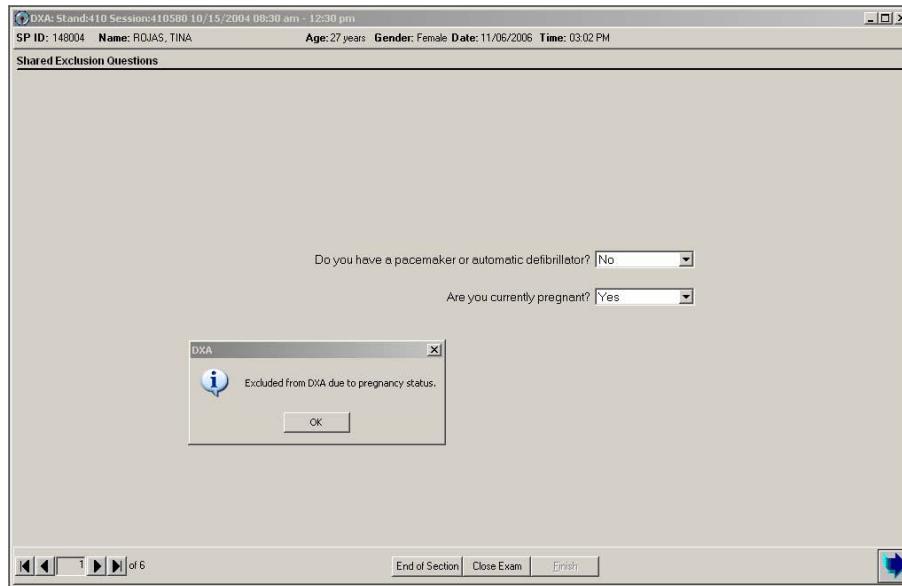
SPs are not to be excluded from the DXA exam based on the question “Do you have a pacemaker or automatic defibrillator?” from the Shared Exclusion Questions. If the answer is “Yes,” they will be excluded from another component and a message will be displayed. Click OK to the message to continue. See Exhibit 4-2.

Exhibit 4-2. Exclusion from another component



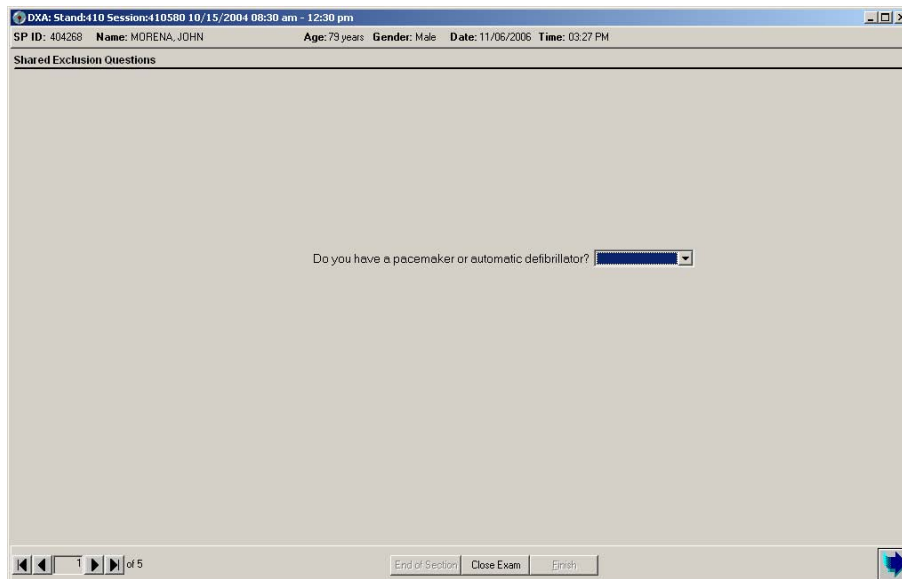
SPs who respond “Yes” to the question “Are you currently pregnant?” will be excluded from DXA due to pregnancy status. A message will be displayed: “Excluded from DXA due to pregnancy status” and a message about the other components that the SP will be excluded from will be displayed as well. Click “OK” to these messages. See Exhibit 4-3.

Exhibit 4-3. Shared Exclusion Questions (pregnancy exclusion)



The Component Status will be set to “Not done” with the comment “SP pregnant.” If the response to the question on pregnancy status is “No,” the system will continue to the next screen. If the SP is male, a female older than 60 years, or a female aged 8-17 years, the pregnancy questions will not be displayed. See Exhibit 4-4.

Exhibit 4-4. Shared Exclusion Questions (No to pregnancy question)



4.2 Weight Entry Screen

SPs weighing more than 300 pounds will be excluded from this component due to weight limitations of the DXA table. The DXA Component Status will be set to “Not Done” with the comment “Weight limitation on-equipment.” See Exhibits 4-5 and 4-6. After answering the Shared Exclusion Questions, the next screen displayed will be the weight data entry screen (Exhibit 4-7). If the SP was in the anthropometry (BM) component or respiratory health (RH) component prior to this test, the weight will already be uploaded and displayed on the ISIS screen, along with the component it transferred from (i.e., BM, RH). This information will be grayed out. If the information is not displayed, measure the SP’s weight using the floor scale in the room. Enter these numbers into the white entry field next to “Weight.” See Exhibit 4-7. For instructions on measuring weight, see Section 3.4.1.

Exhibit 4-5. Exclusion due to weight

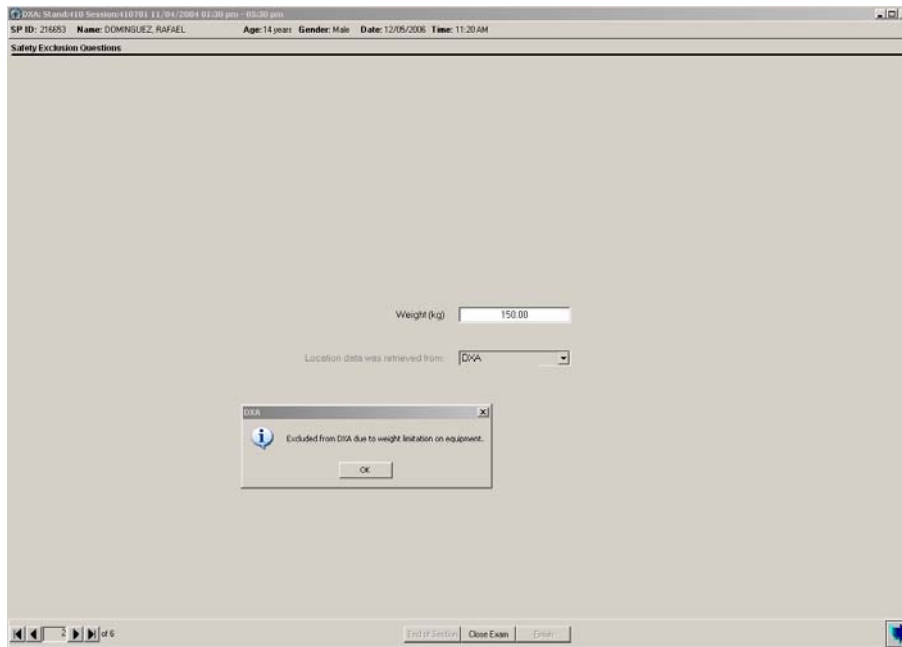


Exhibit 4-6. End of component status (weight limit)

DXA: Stand:410 Session:10580 10/15/2004 08:30 am - 12:30 pm
SP ID: 148004 Name: ROJAS, TINA Age: 27 years Gender: Female Date: 11/06/2006 Time: 03:02 PM

DXA Component Status

Status

- Complete
- Partial
- Not Done

Comments: Weight limitation on equipment

Other text:

6 of 6 End of Section Close Exam Finish

Exhibit 4-7. Weight data entry screen

DXA: Stand:410 Session:10791 11/04/2004 01:30 pm - 05:30 pm
SP ID: 216653 Name: DOMINGUEZ, RAFAEL Age: 14 years Gender: Male Date: 12/05/2006 Time: 11:20 AM

Safety Exclusion Questions

Weight (kg):

Location data was retrieved from: DXA

2 of 6 End of Section Close Exam Finish

4.3 Safety Exclusion Questions

The Safety Exclusion Questions should be read exactly as written. Read the entire question before accepting an answer. If the SP interrupts you before you have completed reading the question, say that you are required to read the entire question before accepting an answer (Exhibit 4-8). All Safety Exclusion Questions must be answered before the exclusion status will be displayed.

Exhibit 4-8. Safety Exclusion Questions

The screenshot shows a software window titled "DXA: Stand-410 Session:410781 11/04/2004 01:30 pm - 05:30 pm". The window contains a header with patient information: "SP ID: 216653 Name: DOMINGUEZ, RAFAEL Age: 14 years Gender: Male Date: 12/05/2006 Time: 11:20 AM". Below the header is a section titled "Shared Exclusion Questions: Observations 3". The main content area is a "Questions" box containing ten questions, each followed by a dropdown menu:

- Have you removed eyeglasses, wallet, keys, and other objects from all of your pockets?
- Do you have any artificial joints, pins, plates, shrapnel, or other types of metal objects in your body?
- Are you using an insulin pump or have insulin lines now?
- Do you have an ostomy, such as an ileostomy or colostomy?
- Have you had an X-ray with contrast material such as barium in the last 7 days?
- Have you had any nuclear medicine studies in the past 3 days?
- Have you ever fractured your hip, had a hip replacement, or do you have a pin in your hip?
- Is it your right hip, left hip, or both?
- Do you have a lumbar spine fusion?

At the bottom of the window, there is a navigation bar with a "3 of 6" indicator, "End of Section", "Close Exam", and "Finish" buttons, and a blue arrow icon.

The first question will not exclude SP's but it may invalidate the results or interpretation of the scan.

1. Have you removed eyeglasses, wallet, keys and other objects from all pockets?

The possible responses are listed below:

- Yes: The SP has removed objects that might interfere with the scan.
- No, OK to continue: The SP is unwilling or unable to remove all objects from pockets. Continue with the questions and make a comment about this in the DXA Data Capture screen.
- Don't Know: The technologist and/or the SP do not know if everything has been removed. This situation should not occur frequently.

The next three questions are asked as safety exclusion questions and will not flag an exclusion to this component but will be used in the analysis of data from this component.

2. Do you have any artificial joints, pins, plates, shrapnel, or other types of metal objects in your body?
3. Are you using an insulin pump or have insulin lines now?
4. Do you have an ostomy, such as an ileostomy or colostomy?

The next four questions may flag an exclusion to part or all of the DXA exam depending on the response.

5. Have you had an X-ray with contrast material such as barium in the last 7 days?
6. Have you had any nuclear medicine studies in the past 3 days?
7. Have you ever fractured your hip, had a hip replacement, or do you have a pin in your hip?
 - Is it your right hip, left hip, or both?
8. Do you have a lumbar spine fusion?

If the response to the question “Have you had an X-ray with contrast material such as barium in the last 7 days?” is “No,” continue with the next questions. If the response to the question is “Yes,” the SP will be excluded from DXA. Complete the remainder of the questions. When the Next button is pressed, a message will be displayed: “Excluded from DXA due to the effect contrast material may have on the data.” Click OK to this message. The DXA Component Status will be set to “Not Done” with the comment “data effect.” See Exhibits 4-9 and 4-10.

Exhibit 4-9. Safety Exclusion Questions (contrast radiography)

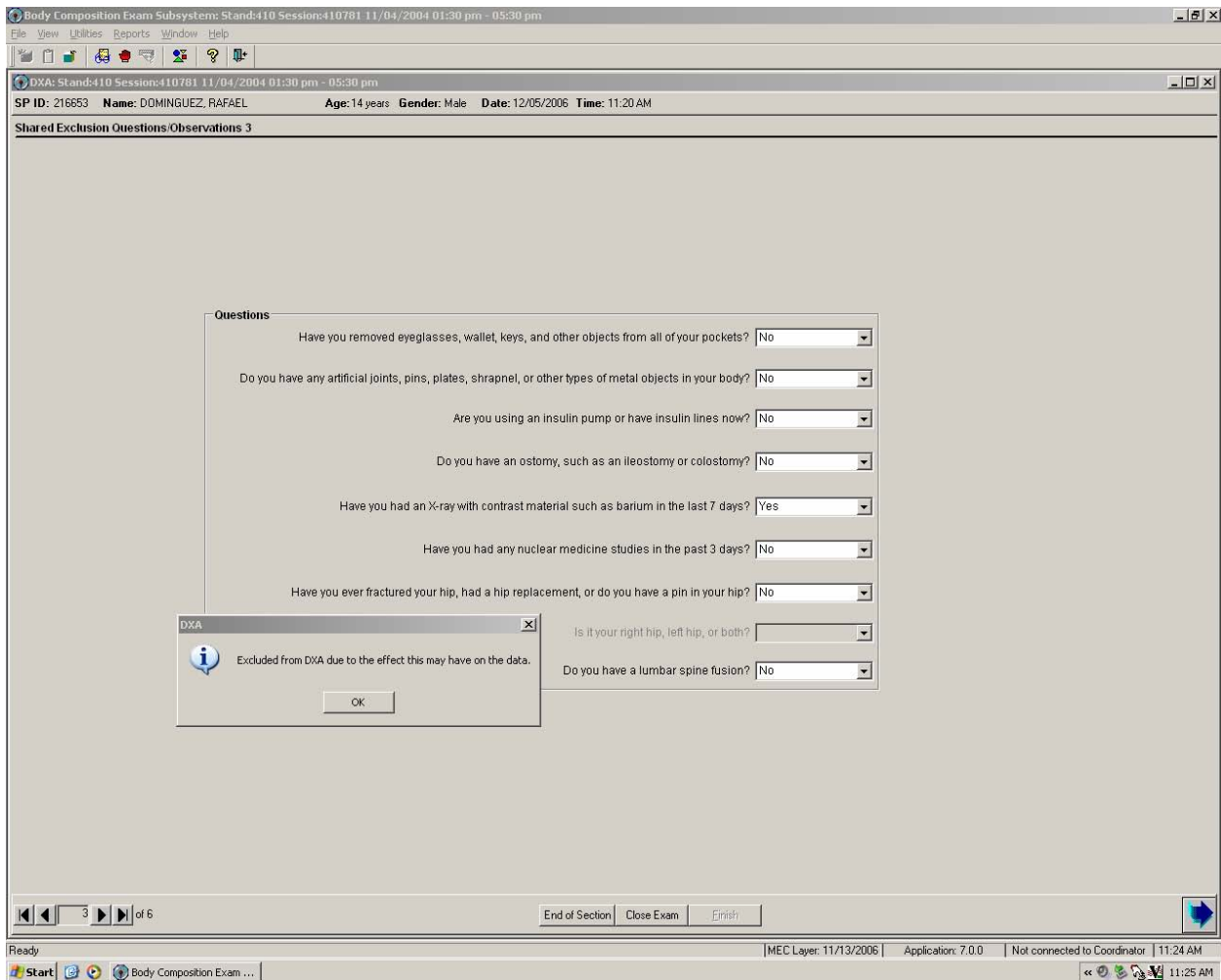


Exhibit 4-10. DXA Component Status (Data Effect)

Body Composition: Stand:410 Session:410910 11/17/2004 08:30 am - 12:30 pm

SP ID: 382803 Name: FRANCE 2, KAYLAH Age: 10 years Gender: Female Date: 12/19/2004 Time: 04:21 PM

DXA Component Status

Status

- Complete
- Partial
- Not Done

Comments

Other text

7 of 7

End of Section Close Exam Finish

If the response to the question “Have you had any nuclear medicine studies in the past 3 days?” is “No,” continue with the next questions. If the response to the question is “Yes,” the SP will be excluded from DXA. Complete the remainder of the questions. When the Next button is pressed, a message will be displayed: “Excluded from DXA due to the effect this may have on the data.” Click OK to this message. See Exhibit 4-11. The DXA Component Status will be set to “Not Done” with the comment “data effect.”

Exhibit 4-11. Safety exclusion questions (nuclear medicine studies)

The screenshot shows a software window titled "DXA: Stand-410 Session: 410781 11/04/2004 01:30 pm - 05:30 pm". The patient information at the top includes "SP ID: 216653", "Name: DOMINGUEZ, RAFAEL", "Age: 14 years", "Gender: Male", "Date: 12/05/2006", and "Time: 11:20 AM". The window title is "Shared Exclusion Questions/Observations 3". The main area contains a "Questions" section with several dropdown menus. The question "Have you had any nuclear medicine studies in the past 3 days?" is selected, and its dropdown menu shows "Yes". A dialog box is overlaid on the question, with the text "Excluded from DXA due to the effect this may have on the data." and an "OK" button. The dialog box title is "DXA". At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish".

If the response to the question “Have you ever fractured your hip, had a hip replacement, or do you have pins in your hip?” is “No,” continue with the next questions. If the response is “Yes,” the system will go to the next question to determine which hip the SP is referring to. See Exhibit 4-12.

Exhibit 4-12. Safety exclusion questions (femur scan questions)

DXA: Stand-410 Session:410781 11/04/2004 01:30 pm - 05:30 pm
SP ID: 216853 Name: DOMINGUEZ, RAFAEL Age: 14 years Gender: Male Date: 12/05/2006 Time: 11:20 AM
Shared Exclusion Questions/Observations 3

Questions

Have you removed eyeglasses, wallet, keys, and other objects from all of your pockets? No

Do you have any artificial joints, pins, plates, shrapnel, or other types of metal objects in your body? No

Are you using an Insulin pump or have insulin lines now? No

Do you have an ostomy, such as an ileostomy or colostomy? No

Have you had an X-ray with contrast material such as barium in the last 7 days? No

Have you had any nuclear medicine studies in the past 3 days? No

Have you ever fractured your hip, had a hip replacement, or do you have a pin in your hip? Yes

Is it your right hip, left hip, or both? Both

Do you have a lumbar spine fusion? No

DXA
SP is excluded from femur scan for safety reasons.
OK

3 of 6
End of Section Close Exam Finish

- If **Both** is chosen, the SP **will** be excluded from the femur scan for safety reasons. See Exhibit 4-12.
- If **Left Hip Only** is chosen, the SP **will not** be excluded from the femur scan. The femur scan will be conducted using the SP's right hip. See Exhibit 4-12a.
- If **Right Hip Only** is chosen, the SP **will not** be excluded from the femur scan. The femur scan will be conducted using the SP's left hip as per protocol.

Exhibit 4-12a. Safety Exclusion Questions (right hip only)

Have you ever fractured your hip, had a hip replacement, or do you have a pin in your hip? Yes

Is it your right hip, left hip, or both? Left

Do you have a lumbar spine fusion? No

Body Composition
Proceed with femur scan on right hip for safety reasons.
OK

If the response to the question “Do you have a lumbar spine fusion?” is “No,” continue with the next questions. If the response is “Yes,” the SP **will** be excluded from the AP spine scan. See Exhibit 4-13. If the response to the question is “No” or “Don’t Know,” the SP **will not be** excluded from the AP spine scan.

Exhibit 4-13. Safety Exclusion Questions (AP spine)

DXA: Stand-V10 Session:410781 11/04/2004 01:30 pm - 05:30 pm
SP ID: 216653 Name: DOMINGUEZ, RAFAEL Age: 14 years Gender: Male Date: 12/05/2006 Time: 11:20 AM
Shared Exclusion Questions/Observations 3

Questions

Have you removed eyeglasses, wallet, keys, and other objects from all of your pockets? No

Do you have any artificial joints, pins, plates, shrapnel, or other types of metal objects in your body? No

Are you using an insulin pump or have insulin lines now? No

Do you have an ostomy, such as an ileostomy or colostomy? No

Have you had an X-ray with contrast material such as barium in the last 7 days? No

Have you had any nuclear medicine studies in the past 3 days? No

Have you ever fractured your hip, had a hip replacement, or do you have a pin in your hip? No

Is it your right hip, left hip, or both?

Do you have a lumbar spine fusion? Yes

DXA
SP is excluded from spine scan for safety reasons.
OK

3 of 6
End of Section Close Exam Finish

4.4 DXA AP Spine Scan Data Capture Screens

- Exhibit 4-14 is the ISIS DXA data capture screen.
- This screen allows you to check whether or not the scan was completed.

Exhibit 4-14. DXA data capture (AP spine scan) (1)

Body Composition: Stand:410 Session:410910 11/17/2004 08:30 am - 12:30 pm

SP ID: 717506 Name: PALMER 4, ROSE Age: 53 years Gender: Female Date: 12/17/2004 Time: 04:15 PM

Spine Scan

AP Spine

Scan completed: Yes No

Comment on scan Check all that apply:

SP movement during exam

Positioning problem

Jewelry or other objects not removed

Equipment failure

Other:

Archive File name:

- There are no defaults on the screen when it is first displayed.
- This screen has check boxes to record any problems in getting a good quality AP spine scan. You can check one or more of the following problems.
 - SP movement during the exam;
 - Positioning problem;
 - Jewelry or other objects not removed;
 - Equipment failure; or
 - Other – open text.
- If the scan is completed, select “Yes.” See Exhibit 4-15
- The system will automatically enter the AP spine Archive file name.

Exhibit 4-15. DXA data capture (AP spine scan) (2)

AP Spine

Scan completed: Yes No

Comment on scan Check all that apply:

SP movement during exam

Positioning problem

Jewelry or other objects not removed

Equipment failure

Other:

Archive File name: **D11060600.ARC**

- The Archive number is D for DXA, 110606 for November 06, 2006, and 00 for the first file to be archived. The file extension is .ARC.
- During and immediately after the scan, check the scan for quality.
- If one or more of the Comments on the scan apply, check all that apply.
- If the scan cannot be completed, select “No.” See Exhibit 4-16.
- If the reason is equipment failure, check that comment.

Exhibit 4-16. DXA data capture (AP spine scan) (3)

AP Spine

Scan completed: Yes No

Comment on scan Check all that apply:

- SP movement during exam
- Positioning problem
- Jewelry or other objects not removed
- Equipment failure

Other:

Archive File name:

- If there is another reason, enter the reason in the free text box for Other.
- Press Enter to proceed to the Femur Scan Screen.

4.5 DXA Proximal Femur Data Capture Screens

- Exhibit 4-17 is the ISIS DXA data capture screen for the femur scan.
- This screen allows you to check whether or not the femur scan was completed.

Exhibit 4-17. DXA data capture (femur scan) (1)

Body Composition: Stand:410 Session:410910 11/17/2004 08:30 am - 12:30 pm

SP ID: 717506 Name: PALMER 4, ROSE Age: 53 years Gender: Female Date: 12/17/2004 Time: 04:15 PM

Femur Scan

Proximal Femur

Scan completed: Yes No

Comment on scan Check all that apply:

- SP movement during exam
- Positioning problem
- Jewelry or other objects not removed
- Equipment failure

Other:

Archive File name:

- There are no defaults on the screen when it is first displayed.
- This screen has check boxes to record any problems in getting a good quality femur scan. You can check one or more of the following problems.
 - SP movement during the exam;
 - Positioning problem;
 - Jewelry or other objects not removed;
 - Equipment failure; or
 - Other – open text.
- If the scan is completed, select “Yes.” See Exhibit 4-18.
- The system will automatically enter the Femur Archive file name.

Exhibit 4-18. DXA data capture (femur scan) (2)

Proximal Femur

Scan completed: Yes No

Comment on scan: Check all that apply:

SP movement during exam

Positioning problem

Jewelry or other objects not removed

Equipment failure

Other:

Archive File name: **D11060600.ARC**

- The Archive number is D for DXA, 110606 for November 06, 2006, and 00 for the first file to be archived. The file extension is .ARC.
- During and immediately after the scan, check the scan for quality.
- If one or more of the Comments on the scan apply, check all that apply.
- If the scan cannot be completed, select “No.” See Exhibit 4-19.
- If the reason is equipment failure, check that comment.

Exhibit 4-19. DXA data capture (femur scan) (3)

Proximal Femur

Scan completed: Yes No

Comment on scan Check all that apply:

- SP movement during exam
- Positioning problem
- Jewelry or other objects not removed
- Equipment failure

Other:

Archive File name:

- If there is another reason, enter the reason in the free text box for Other.
- Press “ENTER” to proceed to the Component Status screen.

4.6 DXA Component Status

The completion status for the DXA component is.

- **Complete** 8 years old and above—Spine and femur scans completed
- **Partial** 8 years old and above—At least one scan not completed
- **Not Done** 8 years old and above—None of the protocol scans completed
- If a comment is not selected when the status is “Partial” or “Not Done,” a message will be displayed: “Please select comments.” See Exhibit 4-20.
- Click OK to this message and select the appropriate comment.
- Press the Finish button to end the exam.

Exhibit 4-20. DXA component status (required comments)

DXA Component Status

Status

Complete

Partial

Not Done

Comments

Other text

Body Composition

Please, select comments

OK

- If the component status is “Partial” or “Not Done,” the system will require a comment to be selected from the drop-down menu. See Exhibit 4-20.

Exhibit 4-21. DXA component status

Status

Complete

Partial

Not Done

Comments

Other text

safety exclusion

SP refusal

no time

physical limitation

communication problem

equipment failure

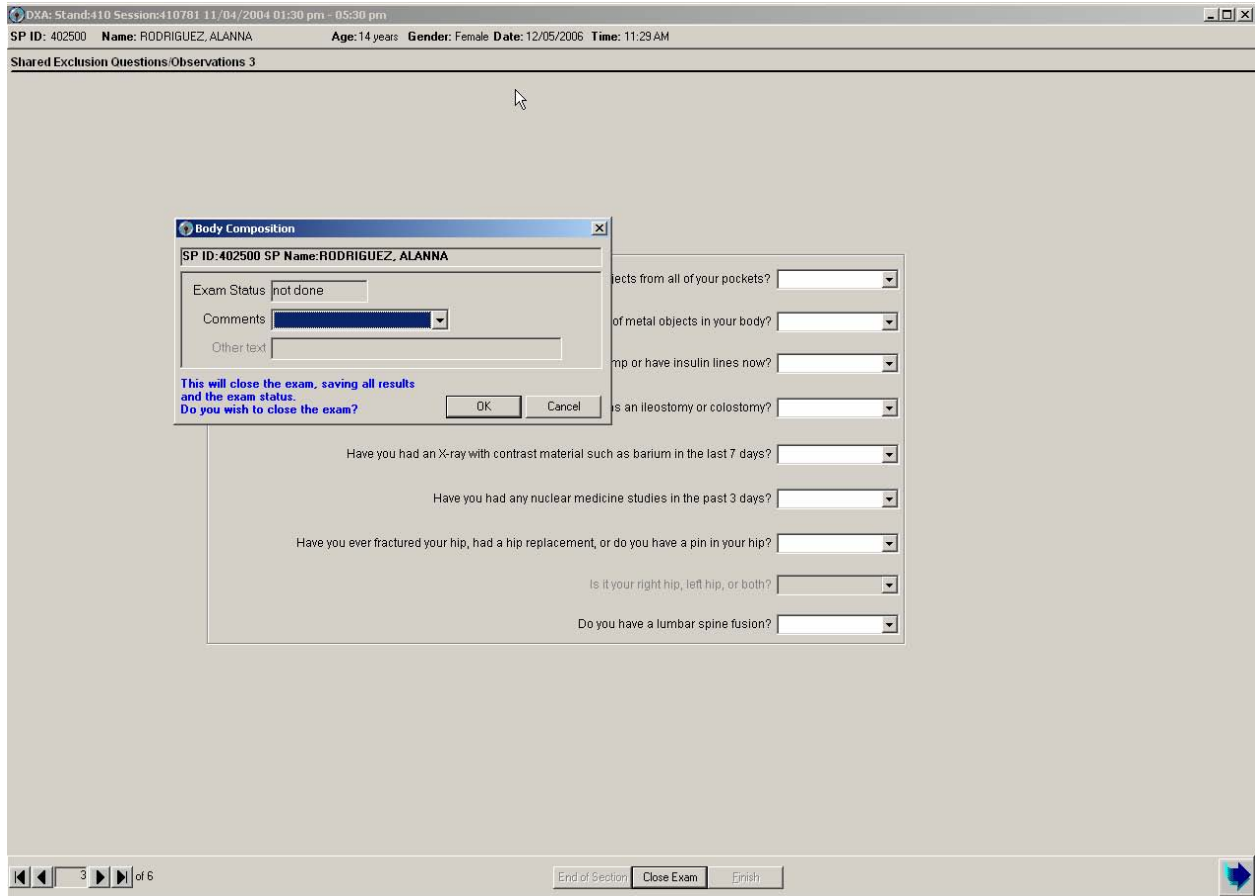
- The comments in the drop-down box are:
 - Safety exclusion;
 - SP refusal;
 - No time;

- Physical limitation;
 - Communication problem; and
 - Equipment failure.
- Other comments in the drop-down box that are not shown in Exhibit 4-21 are:
- SP ill/emergency;
 - Data effect;
 - Inability to lie still;
 - Awaiting pregnancy results
 - Interrupted;
 - Pain or discomfort;
 - Proxy, no information;
 - SP moved during the procedure;
 - SP pregnant;
 - Weight limitation on equipment;
 - Urine not collected;
 - SP unable to comply;
 - Error (technician/software/supplies); and
 - Other, specify.

4.7 Close Exam

Any exam may be terminated at any point during the exam (SP becomes ill, changes his or her mind about completing the test). The “Close Exam” button is used to end the exam abruptly without going through the remaining screens. Choose a comment and click on Close to end the exam. The use of this feature is strongly discouraged; it should be used only when necessary.

Exhibit 4-22. Close exam



5. REFERRALS AND REPORT OF FINDINGS

5.1 Observation Referrals

Observation referrals are nonemergency situations that may arise in any of the examination rooms in the MEC. Technologists may send an observation referral to the MEC physician if they notice any condition that may be abnormal or that may warrant further assessment. This type of referral may be sent at any time from any of the exam rooms. The referral may or may not have anything to do with the current exam being performed.

Once a technologist sends a referral to the physician, the ISIS system will flag the referral for the SP in the Physician Referral Review box. The SP will not be checked out of the MEC until the physician has reviewed this referral. The physician will make a decision whether further action is warranted and a physician referral to the SP's health care provider may be given to the SP.

- Observation referrals may be sent during the exam or after the exam has been closed;
- Under 'Utilities,' select 'Observations.' If an exam is already opened, the Observation referral box for that SP will be displayed (see Exhibit 5-1); and
- If the exam has been closed, select 'Observation' from the 'Utilities' menu. A pick list with the names of the SPs in the current session will be displayed. This list is only displayed if 'Utilities/Observations' is selected when an exam is not open (see Exhibit 5-2).

Exhibit 5-1. Menu to select observation referral

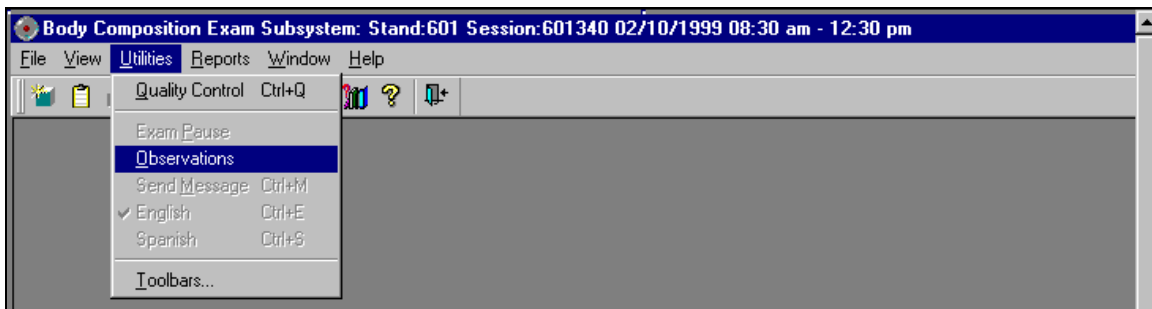
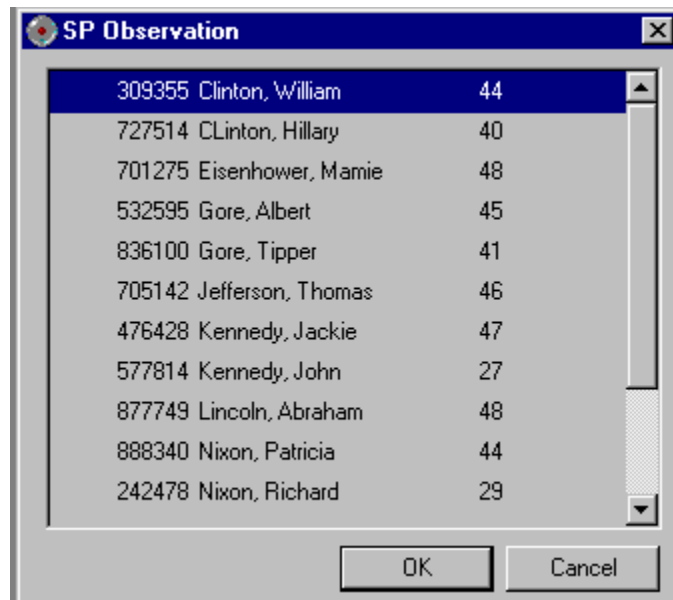
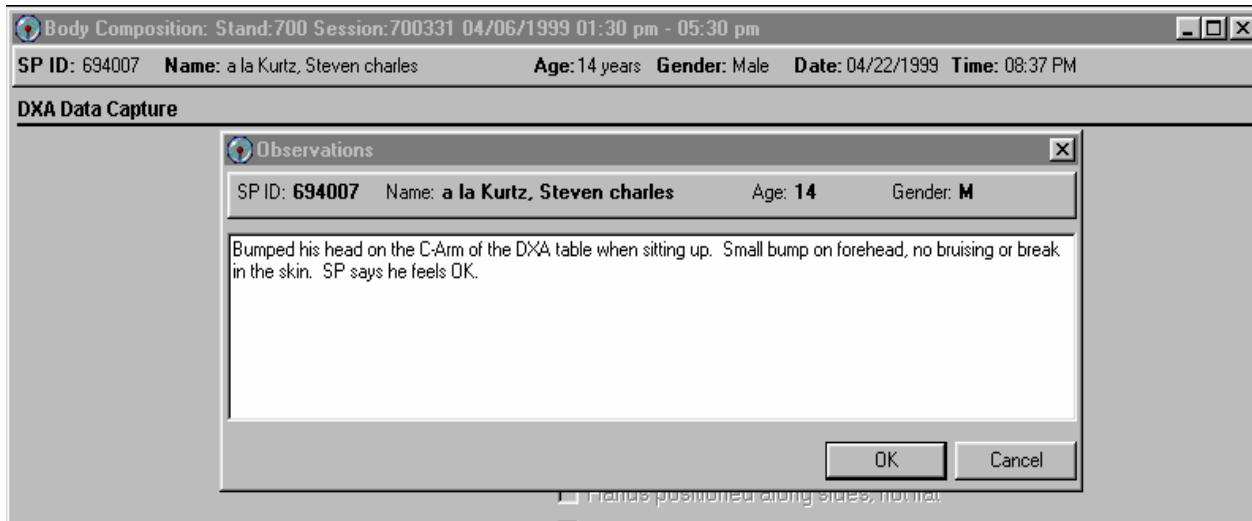


Exhibit 5-2. Pick list of SPs in current session



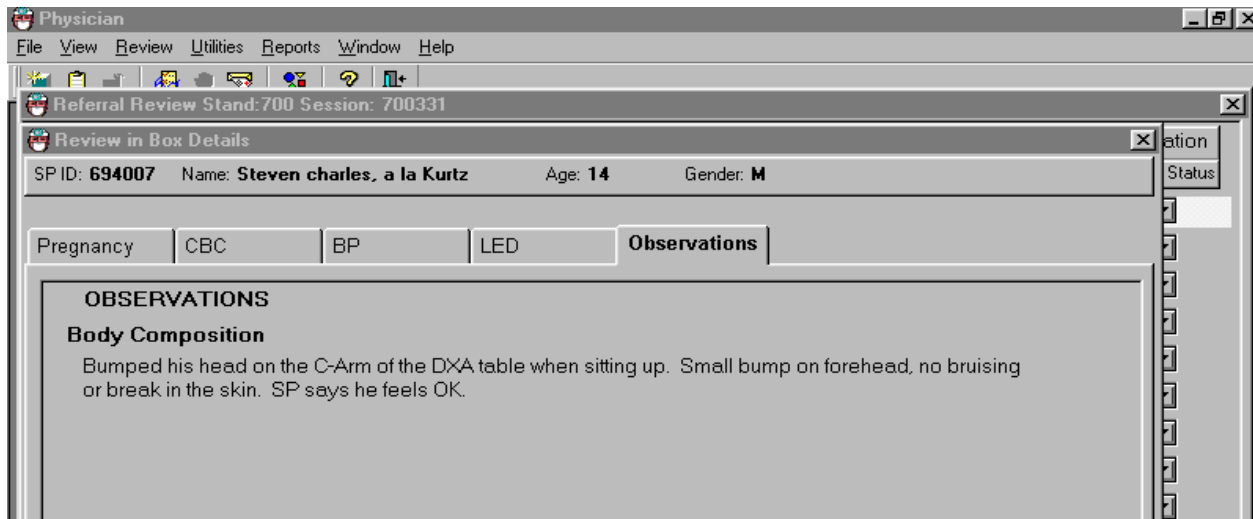
- Select the name of the SP for whom an observation referral should be sent. Click OK.
- Type in the message you would like to send to the physician. When you are finished, click OK (see Exhibit 5-3).

Exhibit 5-3. Observation referral in DXA



- Exhibit 5-4 shows the referral as it appears in the Physician’s Referral Review box. The message typed in the Observation Referral box in (Exhibit 5-3) appears in this box in the Physician Referral Review;
- The physician will review this referral and make a decision about further action if warranted; and
- The SP cannot be checked out of the MEC until the physician has reviewed this referral.

Exhibit 5-4. Observation referral from another component in physician’s referral review box



5.2 Report of Findings for DXA

Each SP will be given a report of the results or findings for the exams performed. The heading for the report will be ‘Bone Density.’

Results will be included in the final report of findings sent from NCHS. Participants who are 20 through 69 years of age will receive a report of findings on their AP spine scan and hip/femur scan. The variables reported from the AP spine and hip/femur scans include the bone density and Z- or T-score. Participants are told how these results compare with people of their age and gender.

Participants less than 20 years of age will not receive the results from their scans because the reference group used for analyzing the BMD does not include persons under 20 years. These participants will be told that their participation will let us determine what a normal result is for their age.

5.2.1 Sample Preliminary Report of Findings

Refer to Exhibit 5-5 for a sample of preliminary reports of findings.

Exhibit 5-5. Sample Report of Findings for DXA

National Health and Nutrition Examination Survey Report of Findings

Body Scan and Bone Density

AP Spine and Hip/Femur Scans:

SP is \geq 20 years of age: *The Hologic QDR 4500A was used to measure your bone density.* The bone density measurement can help spot persons who may be at greater risk for fracture because they have weaker bones. In general, a lower bone density means that the bone is weaker. Yet, not all men or women with low bone density will have fractures.

SP is < 20 years of age: This is the first time that bone density in young people is being studied in a national survey. We are using this information to learn about bone formation in your age group. We will not be able to give you results about your bone density until we know what a normal result is. Your participation is helping us determine this.

Bone Density Result (only participants aged 20 years and older).

If SP Male aged 20-64 do A

If SP Male aged 65 and older do B

If SP Female aged 20-49 do C

If SP Female aged 50 and older do D

A:

The results from your **hip** (*left or right*) scan show:

Hip bone density _____g/cm²

Z-score ____.

Compared with men your age, your hip bone density is *<insert statement>*.

The results from your **spine** scan show:

Lumbar spine (L1-L4) bone density _____g/cm²

Z-score ____.

Compared with men your age, your spine bone density is *<insert statement>*.

B:

The results from your **hip** (*left or right*) scan show:

Hip bone density _____g/cm²

T-score ____.

Compared with young male adults, your hip bone density is *<insert statement>*.

Exhibit 5-5. Sample Report of Findings for DXA (continued)

The results from your **spine** scan show:

Lumbar spine (L1-L4) bone density _____g/cm²

T-score ____.

Compared with young male adults, your spine bone density is <insert statement>.

C:

The results from your **hip** (*left or right*) scan show:

Hip bone density _____g/cm²

Z-score ____.

Compared with women your age, your hip bone density is <insert statement>.

The results from your **spine** scan show:

Lumbar spine (L1-L4) bone density _____g/cm²

Z-score ____.

Compared with women your age, your spine bone density is <insert statement>.

D:

The results from your **hip** (*left or right*) scan show:

Hip bone density _____g/cm².

T-score ____.

Compared with young female adults, your hip bone density is <insert statement>.

The results from your **spine** scan show:

Lumbar spine (L1-L4) bone density _____g/cm².

T-score ____.

Compared with young female adults, your spine bone density is <insert statement>.

Statement Choices:

*If examinees Z-score is ≥ -2.0 insert **normal***

*If examinees Z-score is < -2.0 insert **low***

*If examinees T-score is ≥ -1.0 insert **normal***

*If examinees T-score is less than -1.0 but greater than -2.5 insert **low**.*

*If examinees T-score is ≤ -2.5 insert **very low***

Summary Paragraph:

<If T-score is ≤ -2.5 for either hip or spine print the following:> Most people develop low bone density over many years. We recommend you discuss these results with your doctor as soon as possible, since fractures due to osteoporosis often occur at sites with very low bone density. Your doctor can review your diet and lifestyle and tell you what you can do to prevent more bone loss.

<If (T-score is > -2.5 and less than -1.0 for either hip or spine and neither is ≤ -2.5) OR (If Z-score is < -2.0), print the following:> Most people develop low bone density over many years. We recommend you discuss these results with your doctor. Your doctor can review your diet and lifestyle and tell you what you can do to prevent more bone loss.

If hip and spine T-scores are greater than or equal to -1.0 , or Z-scores are greater than or equal to -2.0 , then no summary paragraph.

6. QUALITY CONTROL

6.1 Equipment and Room Set-Up Checks

The equipment, room supplies, and room set-up need to be checked on a regular basis. Some checks are completed daily and others need only be completed on a weekly basis or at the beginning of each stand. These checks include calibration checks, maintenance inspection of equipment and supplies, and preparation of the room and equipment for the session exams.

Each time you log onto the application, the system will remind you to do quality control (QC) checks if the checks have not been completed for that time period. The checks are to be completed at Start of Stand, Daily, Weekly, and End of Stand. If you do not have time to do the checks when you log on, you can bypass this message and complete the checks at a later time. However, this message will be displayed each time you log on until you have completed the checks for that time period. Once you have completed the checks and entered this in the system, the message box with the reminder will not be displayed again until the appropriate time period has passed.

An exception to the above is the QC check for the Hologic Anthropomorphic Spine Phantom (HASP). The spine phantom must be calibrated daily before the densitometer will allow scans to be completed. If an attempt is made to perform a scan before the daily QC is completed, an error message will be displayed. Press “Enter” at this message and complete the spine phantom calibration.

The Start of Stand, Daily, Weekly, and End of Stand checks are listed in the following sections.

6.1.1 Start of Stand

- Check that the locking pins have been removed before attempting to complete any scans.
- Complete the following checks:
 - 1 Spine Phantom (HASP);
 - 1 Step Phantom;

- 5 Hologic Femur Phantom scans;
- 10 scans of the Circulating Spine Phantom (HSP-Q-96); and
- 10 scans of the Circulating Block Phantom (NH #1).

6.1.2 Daily

- Check that the table scan area is clear of articles that might interfere with table movement;
- Check runner area of table to confirm that the area is clear of articles that might interfere with table movement; and
- Complete 1 Spine Phantom (HASP).

6.1.3 Weekly

- Perform the daily checks;
- Complete 1 Step Phantom; and
- Complete 1 Femur Phantom.

6.1.4 End of Stand

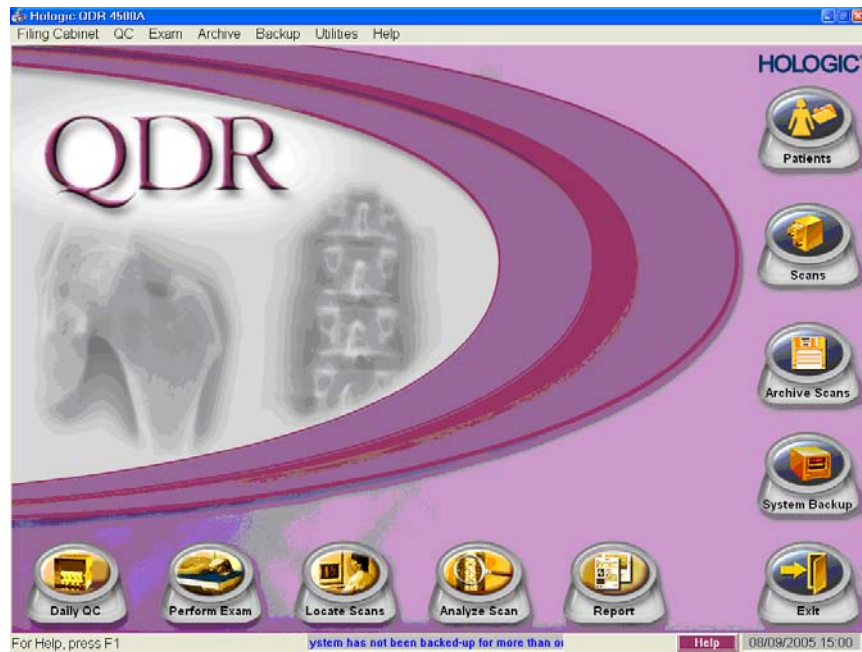
- Clean DXA table.

6.2 Procedures for Completing QC Scans

6.2.1 Hologic Anthropomorphic Spine Phantom (HASP)

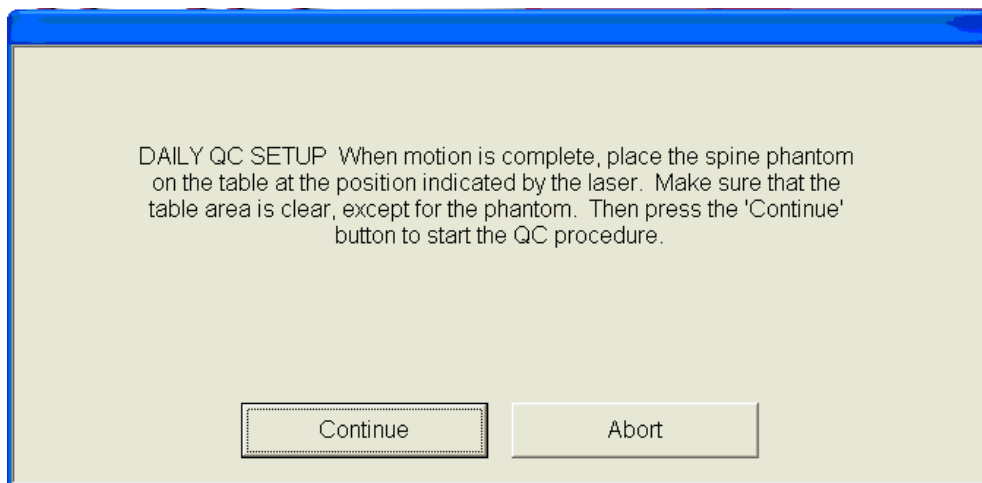
- In the QDR main menu (Exhibit 6-1), click on the Daily QC button; and
- Alternatively, “Daily QC” can be selected from the QC pull-down menu in the main window to start the daily QC procedure.

Exhibit 6-1. QDR main window



- The system displays the “Daily QC Setup” window, prompting the placement of the Spine Phantom on the table (Exhibit 6-2).

Exhibit 6-2. Daily QC Setup box



- When the table motion is complete, place the Spine Phantom on the table at the position indicated by the laser cross;
- The positioning star should be placed toward the foot of the table (your left as you face the table);

- The laser cross should be centered on the positioning star;
- The upper two-thirds of the table should be clear except for the phantom;
- Press “Continue” to start the automatic scan/analyze QC procedure; and
- Before scanning the phantom, the system will perform a self-test. The test will take approximately 30 seconds. When finished, a “Pass System Test” message will flash on the screen (Exhibits 6-3 and 6-4).

Exhibit 6-3. System self-test

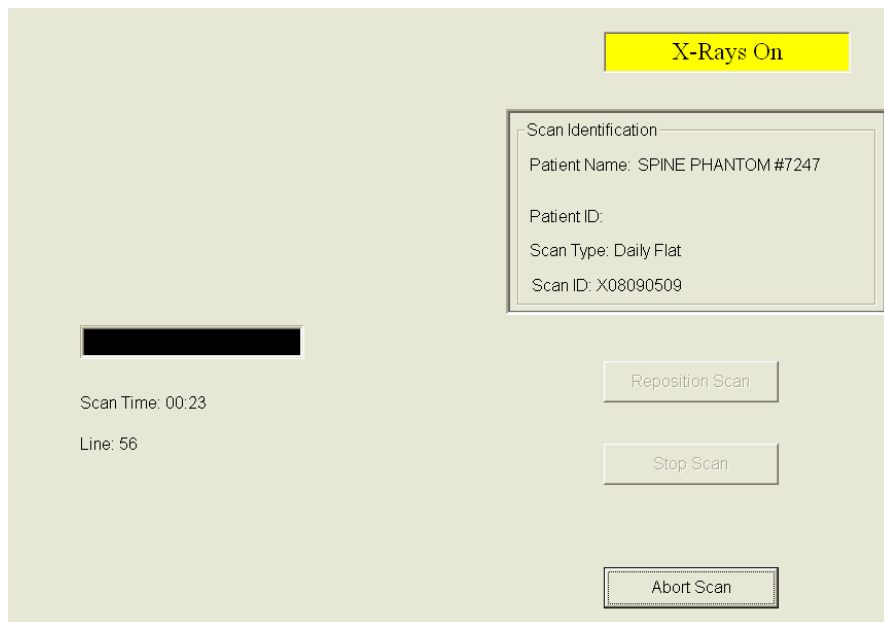
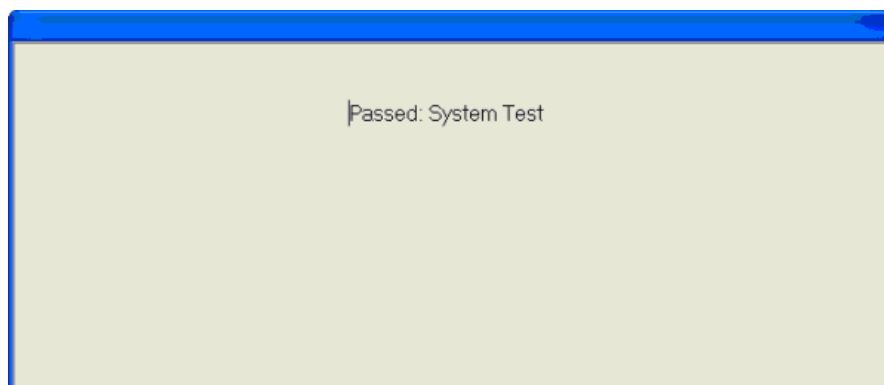


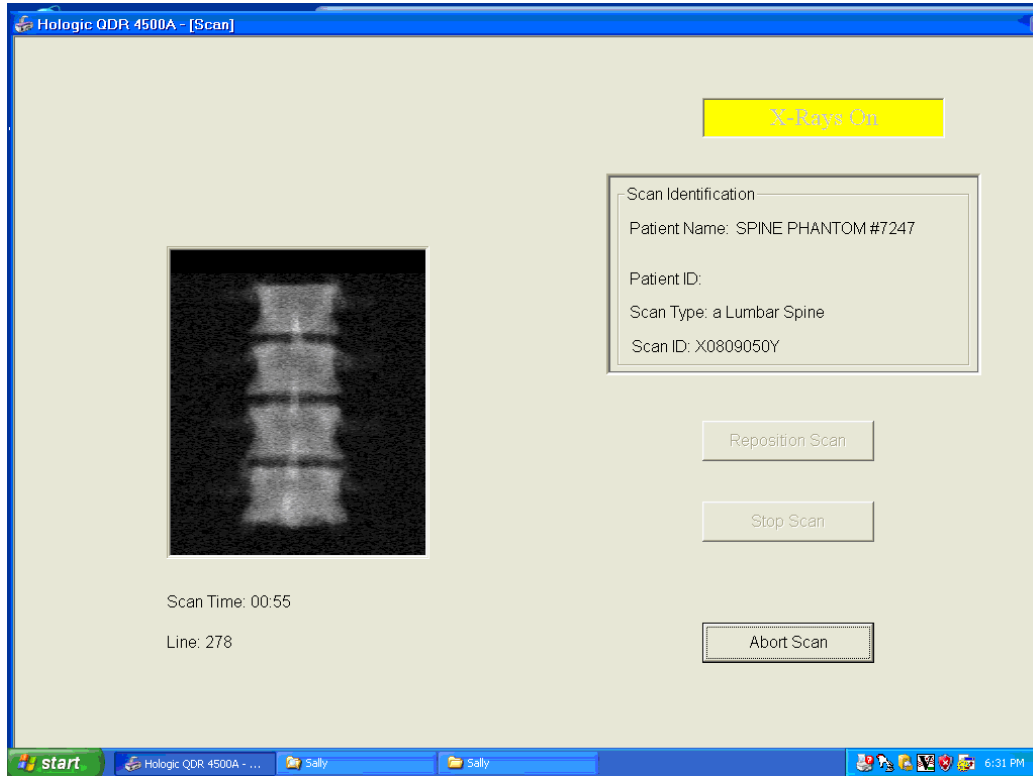
Exhibit 6-4. System test passed



- If the automatic system test fails, the system displays a message stating that the test failed and information on how to correct the error; and

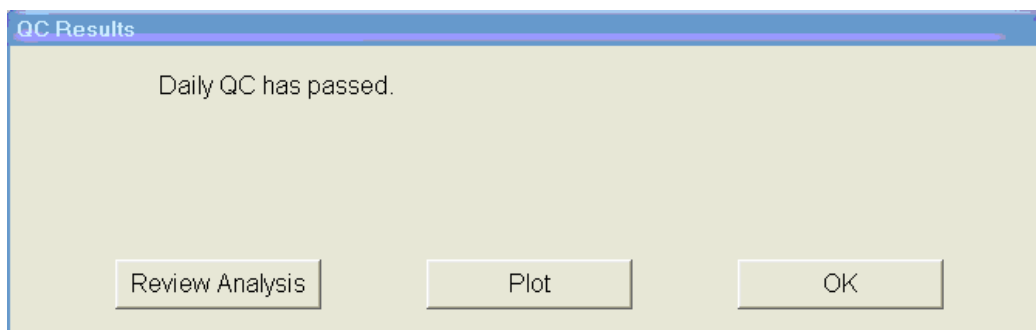
- Upon successful completion of the system test, the system runs Auto QC (Exhibit 6-5). The spine will display in the black box in the left center of the screen.

Exhibit 6-5. Spine Phantom QC image



- When Auto QC has been completed, a window appears giving either a passed or failed message. See Exhibit 6-6.

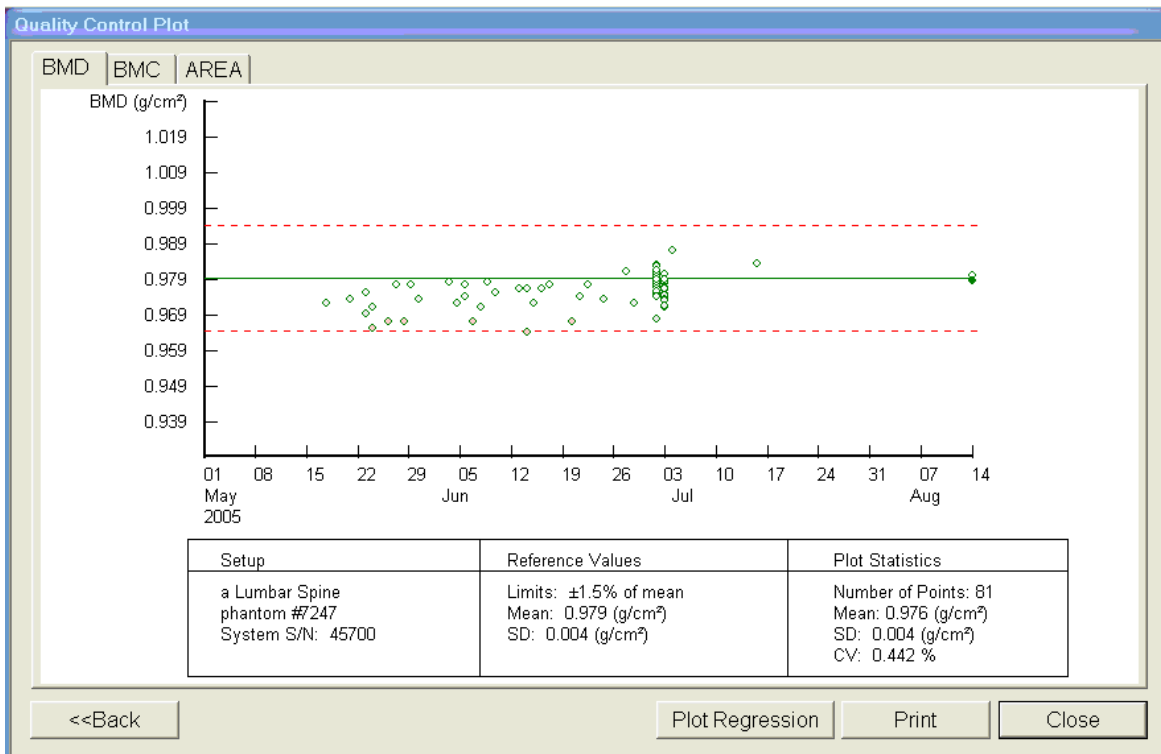
Exhibit 6-6. Auto QC passed



6.2.1.1 Checking BMD and BMC

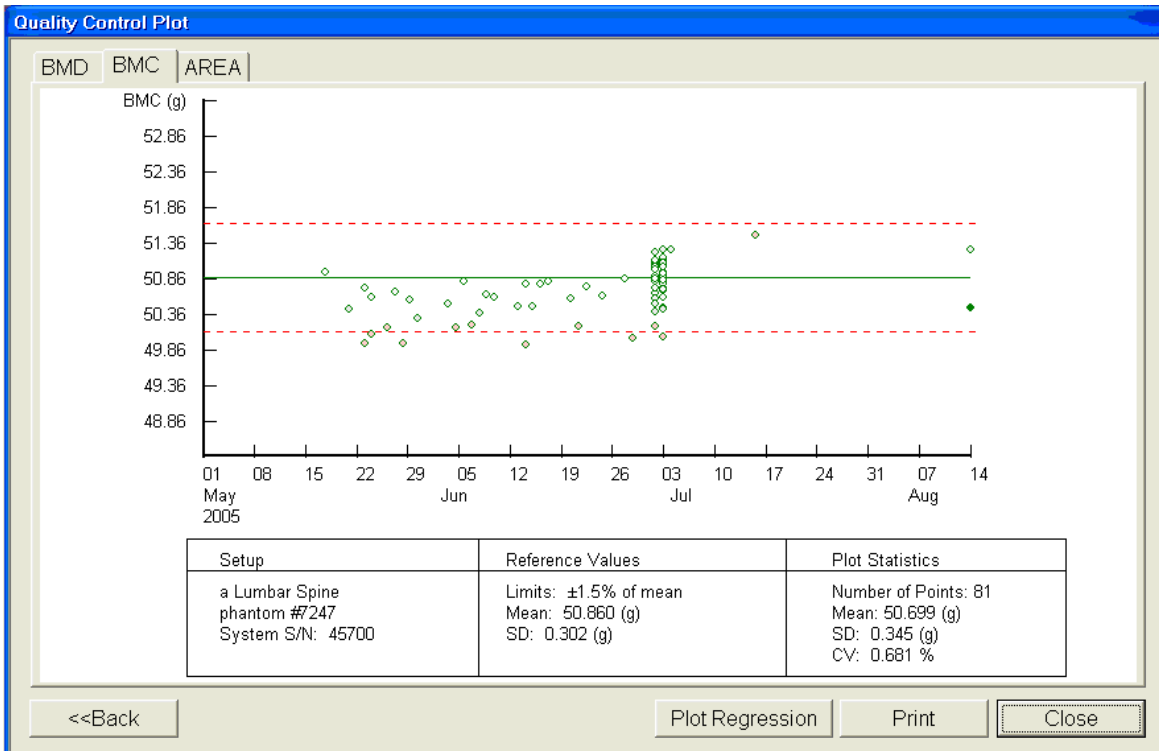
- To review the QC plot, click on the PLOT button from the QC Results window for a passed Auto QC (Exhibit 6-6). The QC Plot window appears;
- Check the BMD graph for the circle for today's scan (at far right side of graph). See Exhibit 6-7;
- **The circle should be within the two dotted lines; and**
- **The CV for BMD should be at or below 0.60 percent.**

Exhibit 6-7. Spine Phantom QC – plot for BMD



- If the circle is not within the dotted lines or the CV is greater than 0.60 percent, see directions in Section 6.2.1.2;
- To check the BMC select the BMC tab at the top of the screen by clicking on it; and
- Check the BMC graph for the circle for today's scan (at the far right side of the graph) (Exhibit 6-8).

Exhibit 6-8. Spine Phantom QC – plot for BMC



- **The circle should be within the two dotted lines;**
- **The CV for BMC should be at or below 0.80 percent;**
- If the circle is not within the dotted lines or the CV for BMC is greater than 0.80 percent, see directions in Section 6.2.1.2;
- If the circle is within the dotted lines and the CV for BMC is at or below 0.80 percent, press BACK to return to the Auto QC passed window or CLOSE to return to the system main window; and
- Read the messages on the Hologic computer screen. (If the Step Phantom hasn't been scanned in the past week, a message will be displayed stating that it should be scanned following the Spine Phantom scan.) See Exhibit 6-9.

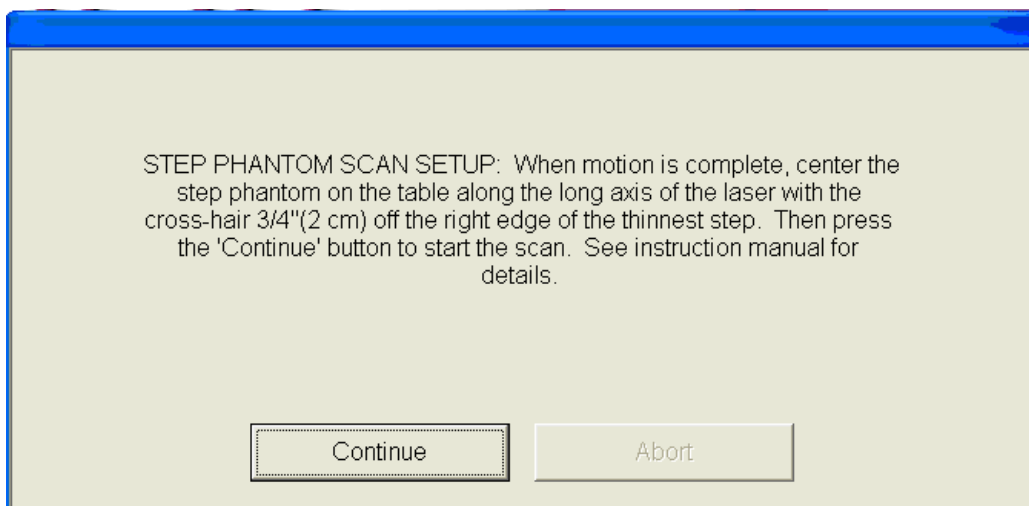
6.2.1.2 Auto QC Failure

- If Auto QC fails, the message is “Daily QC failed” and a series of steps is provided. The QC Results Window contains four buttons: Details, Review Analysis, Plot, and OK. Clicking “Details” provides additional information about the QC failure;
- Click “OK” to return to the system main window so Daily QC can be re-run. If the “Daily QC Failed” message appears again, repeat the process one more time;
- If after three attempts, the Daily QC continues to fail, report this to the chief technologist **AND** the MEC manager. This information is reported to Hologic;
- The MEC manager is responsible for all calls, but may delegate this responsibility to the chief technologist at his or her discretion; and
- Record this call on the “Hologic Customer Service Call Log.”

6.2.2 Step Phantom

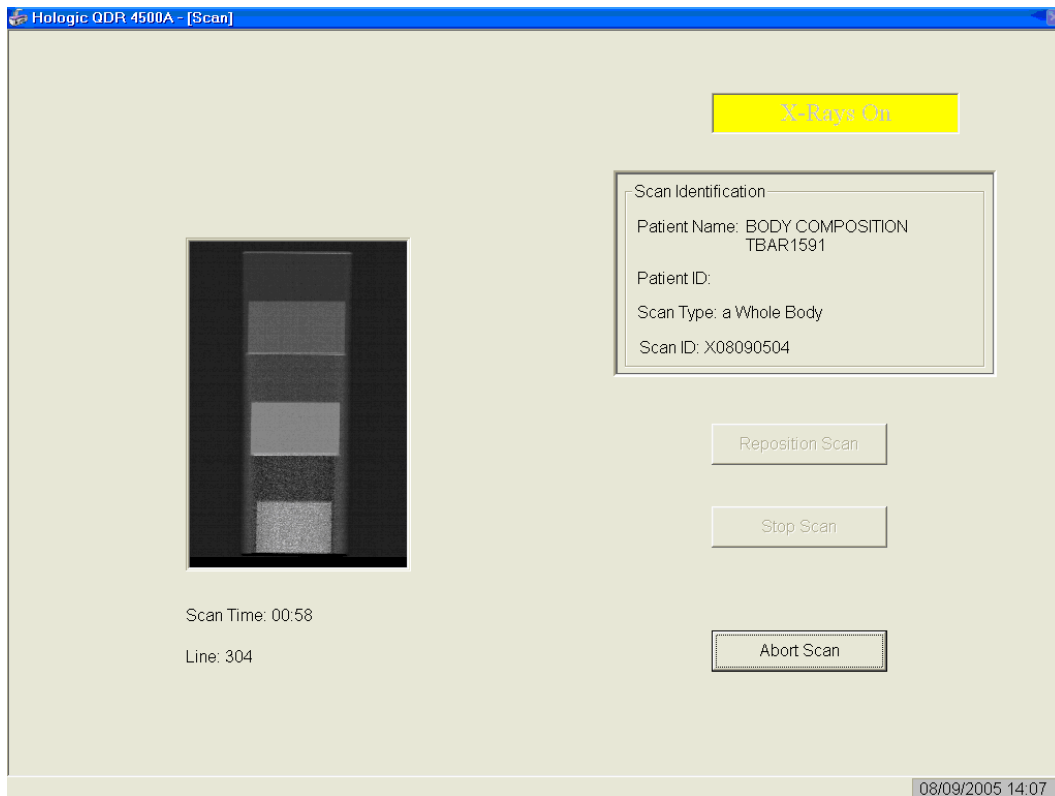
- Select QC from the top menu bar in the QDR Main Menu (See Exhibit 6-1.) and select Step Phantom from the drop-down menu. A message box will prompt the setup of the Step Phantom QC (Exhibit 6-9).

Exhibit 6-9. Step Phantom Setup window



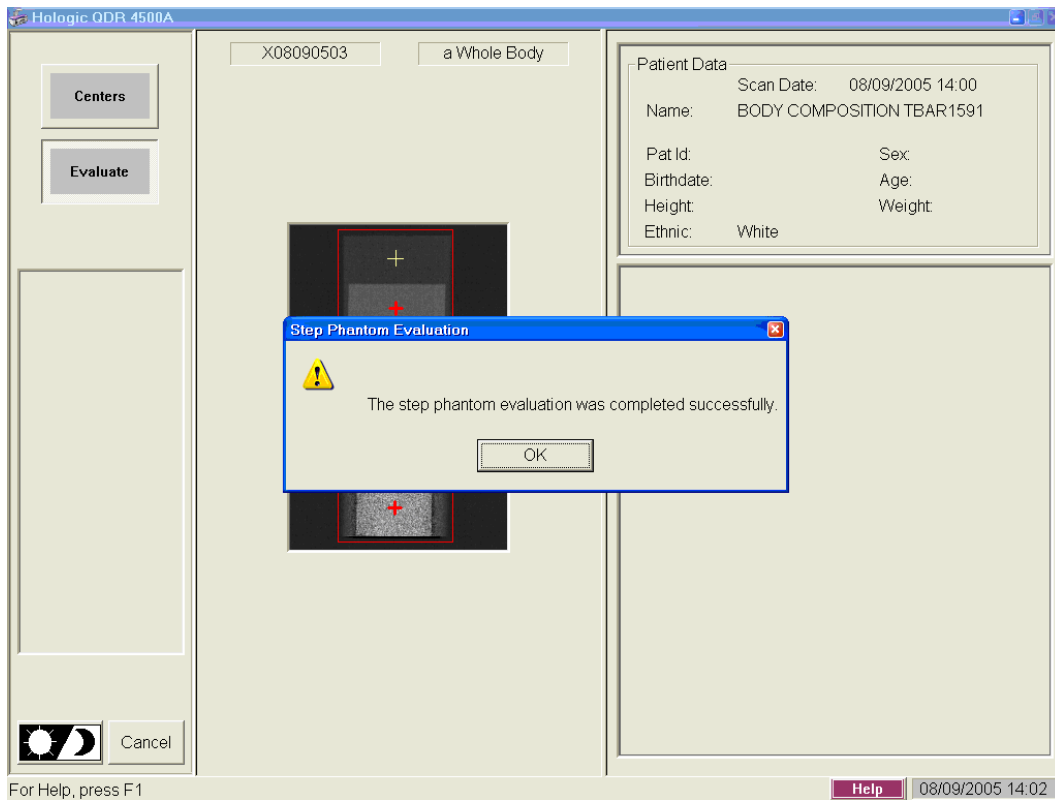
- When the table motion is complete, place the body composition phantom lengthwise on the table with the thinnest step to your right as you face the table;
- Center the long axis of the phantom to the long axis of the laser light;
- Center the middle of the crosshair 3/4 of an inch from the right side of the thinnest step;
- Press “Continue” to start the scan; and
- The Step Phantom will display in the black box in the left center of the screen (Exhibit 6-10).

Exhibit 6-10. Step Phantom scan



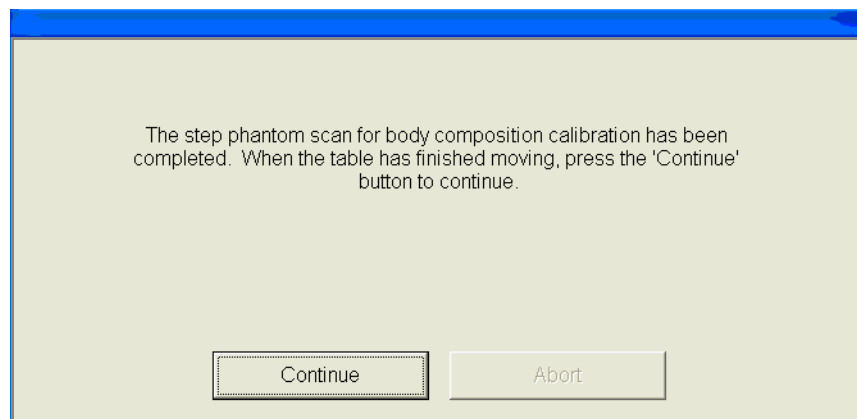
- At the conclusion of the scan, the Step Phantom is automatically analyzed and the data are stored in a separate file in the system; and
- The system will display a message “The step phantom evaluation was completed successfully” (Exhibit 6-11).

Exhibit 6-11. Step Phantom Evaluation completed successfully



- Press “OK”; and
- The system will display a message “The Step Phantom scan for body composition calibration has been completed.” When the table has finished moving, press the “Continue” button to continue. See Exhibit 6-12. (If this window message continues to appear, after pressing continue, press “abort” to return to the Main QDR window.)

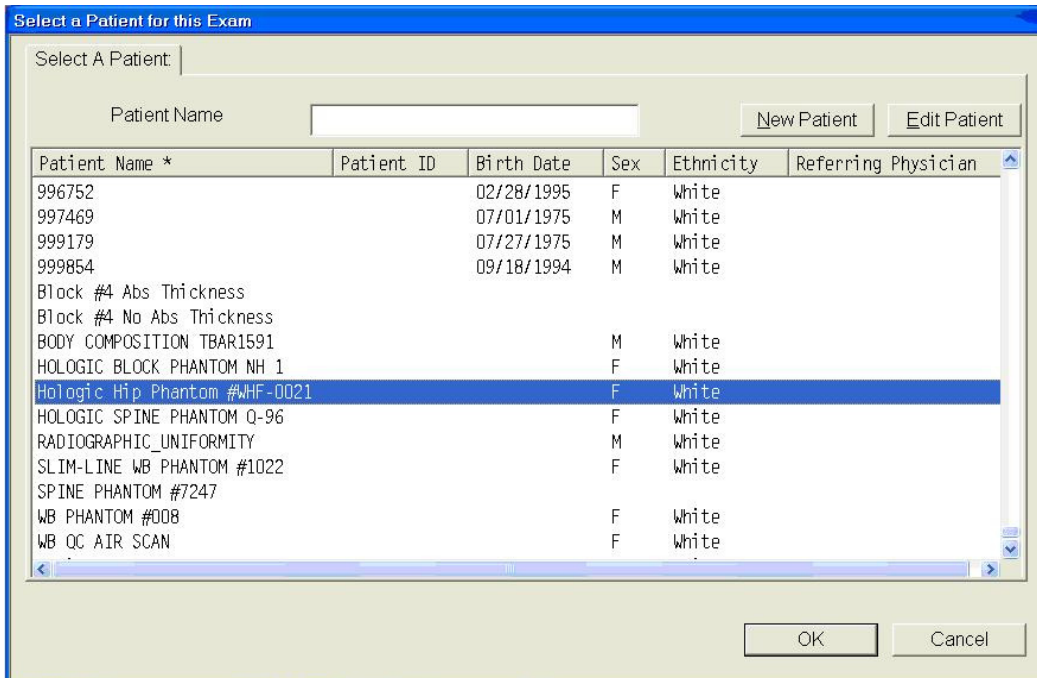
Exhibit 6-12. Step Phantom QC completed, press “Continue”



6.2.3 Hologic Femur/Hip Phantom (Weekly Scan)

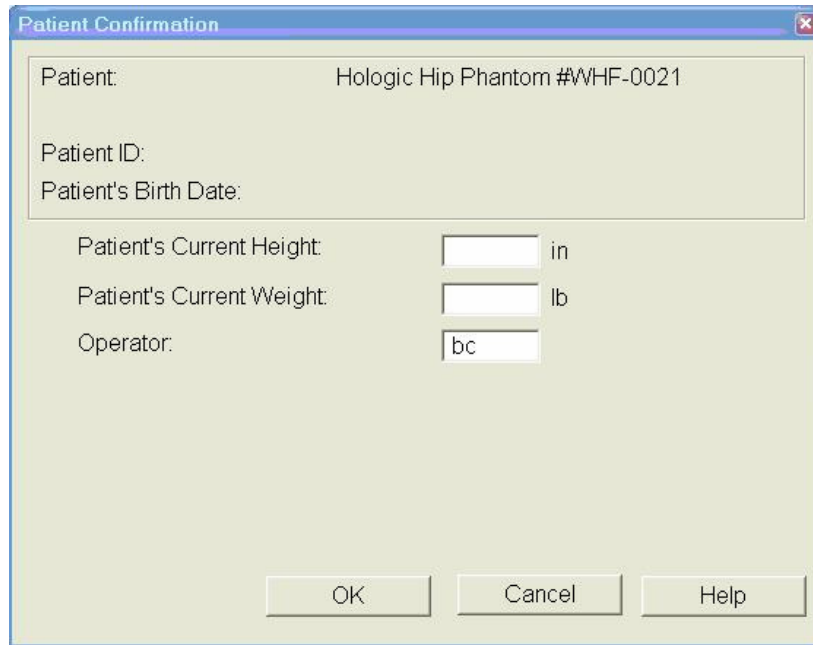
- Center the table. When the table motion is complete, position the Hologic Femur/Hip Phantom on the table and align laser cross with mark on phantom;
- Select “Perform Exam” from the QDR Main Menu. See Exhibit 6-1 shown earlier; and
- Choose/highlight “Hologic Femur/Hip Phantom #WHF-XXXX” (XXXX is 0013 on MEC 1, 0021 on MEC 2, or 0018 on MEC 3) from the list. See Exhibit 6-13. Click “OK.”

Exhibit 6-13. Selecting Hologic Femur/Hip Phantom from patient menu



- Type in initials in the white text box next to the word Operator (Exhibit 6-14) and Click “OK.”

Exhibit 6-14. Operator box for initials



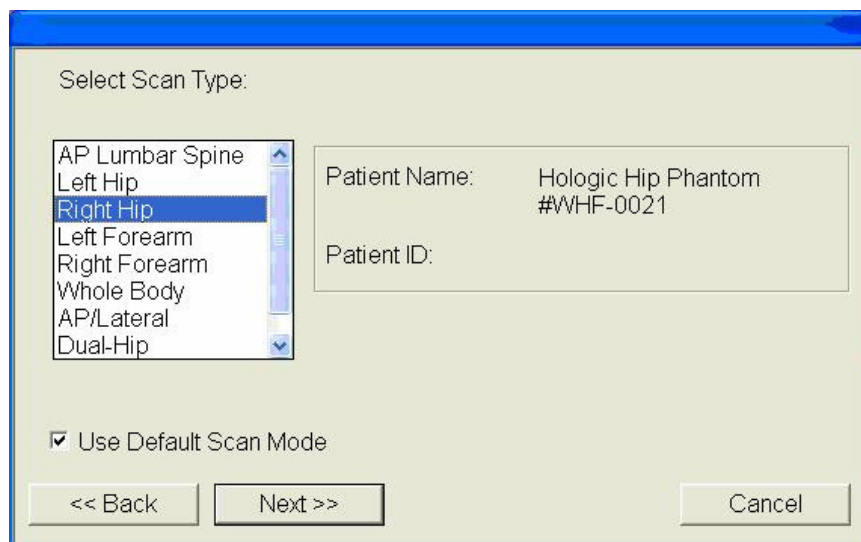
The image shows a 'Patient Confirmation' dialog box. It contains the following fields and values:

- Patient: Hologic Hip Phantom #WHF-0021
- Patient ID:
- Patient's Birth Date:
- Patient's Current Height: [] in
- Patient's Current Weight: [] lb
- Operator: bc

At the bottom, there are three buttons: OK, Cancel, and Help.

- CONFIRM that “Hologic Femur/Hip Phantom #WHF- XXXX” is in the Patient Field.
- Select “**Right Hip**” in the Scan Selection Screen (Exhibit 6-15).

Exhibit 6-15. Selecting Right Hip in the Scan Selection Screen



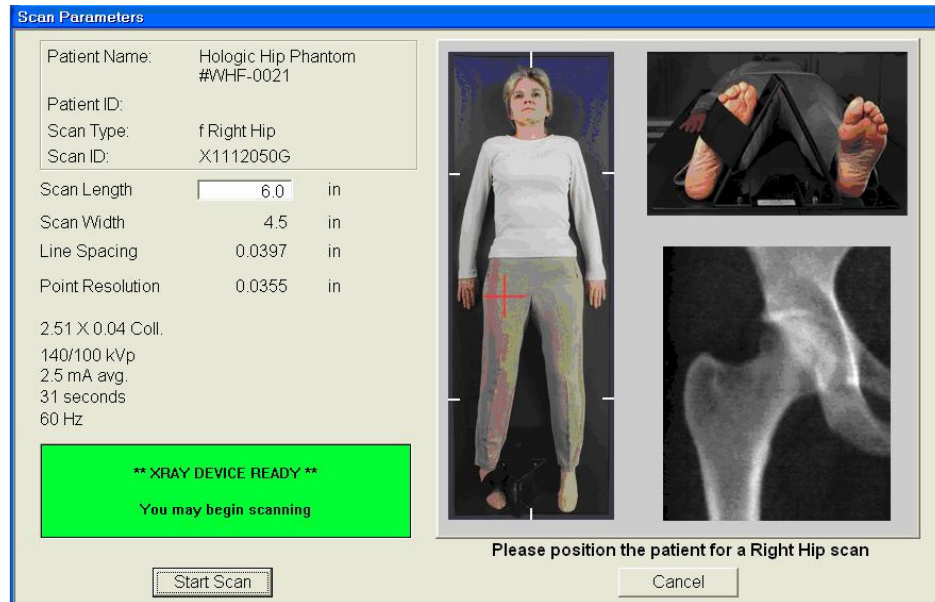
The image shows a 'Select Scan Type' dialog box. It contains the following elements:

- Select Scan Type:
- A list box with the following items: AP Lumbar Spine, Left Hip, **Right Hip** (highlighted), Left Forearm, Right Forearm, Whole Body, AP/Lateral, Dual-Hip.
- Patient Name: Hologic Hip Phantom #WHF-0021
- Patient ID:
- Use Default Scan Mode
- Buttons: << Back, Next >>, Cancel

Confirm “Use Default Scan Mode” is checked. Click “Next>>”; and

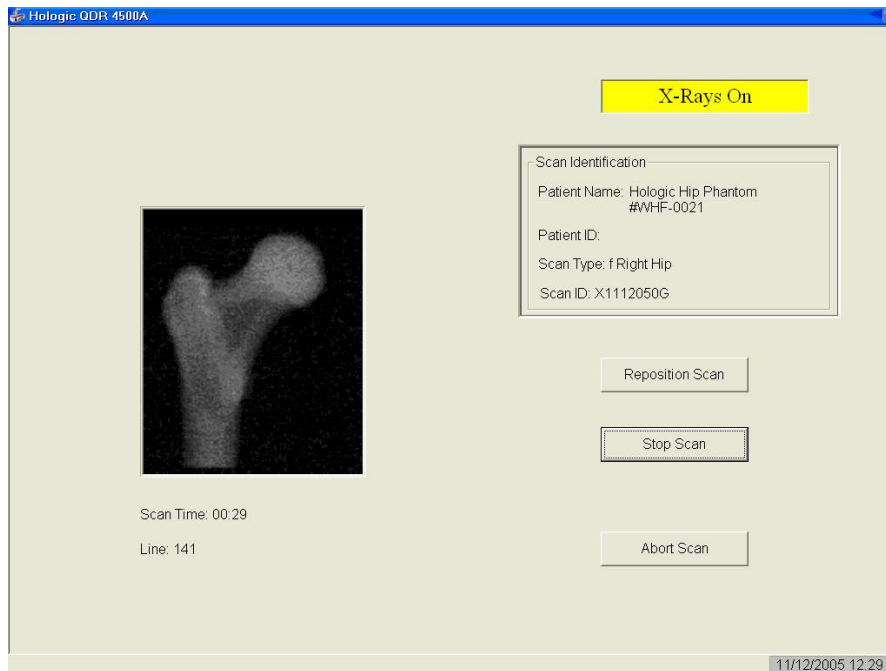
- The Scan Parameters screen is displayed (Exhibit 6-16).

Exhibit 6-16. Hologic Femur/Hip Phantom Scan Parameters screen



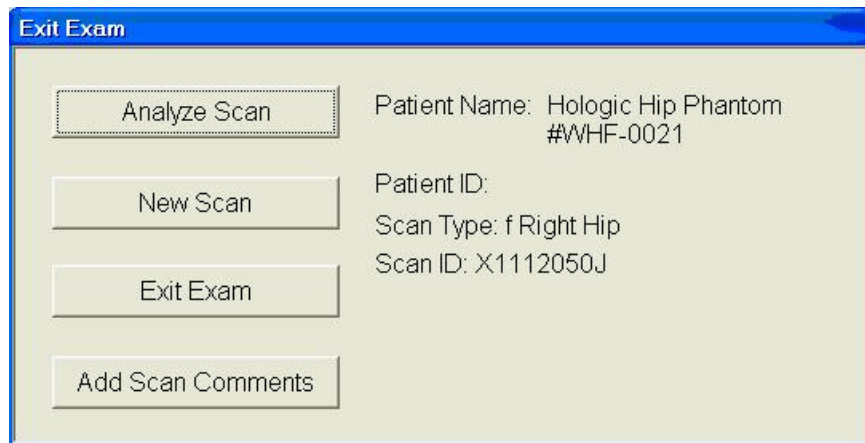
- If phantom is positioned correctly, click “Start Scan”; and
- The machine will scan the phantom (Exhibit 6-17).

Exhibit 6-17. Machine scanning Femur/Hip phantom



- As the scan is completing, carefully inspect the image to ensure that the phantom was correctly positioned;
- If the scan is not satisfactory, click “Reposition Scan,” use the scrollbars or mouse to position the phantom correctly in the black box, and click “Restart Scan”; and
- Upon successful completion of the scan, select “Exit Exam” to return to the QDR Main menu, or to perform a different scan. Select “New Scan” if performing another Femur/Hip Phantom scan. See Exhibit 6-18.

Exhibit 6-18. Exit exam/new scan window box



6.2.3.1 Hologic Femur/Hip Phantom Start of Stand using Auto Scan

- Follow procedures from Section 6.2.3 for positioning and scanning the Hologic Femur/Hip Phantom #WHF- XXXX;
- A total of five scans should be completed for start of stand; and
- To use the Auto Scan feature, follow procedures in Section 6.2.6.

6.2.4 Circulating Hologic Spine Phantom (HSP Q-96)

- **NOTE:** This phantom is a different phantom from the one used for daily scans. Do not use the regular spine phantom that is used for daily QC scans;
- Center the table. When the table motion is complete, position the Circulating Hologic Spine Phantom on the table at the position indicated by the laser cross;
- The positioning star should be pointing to the foot of the table (your left as you face the table);
- The laser cross should be centered on the positioning star;
- The laser line should be centered on the line between the numbers 9 and 6;
- On the QDR main menu screen, click “Utilities” at the top of the screen;
- From the drop-down menu, select “Service Utilities” and then “Auto Scan” from the second drop-down menu. See Exhibit 6-19;

- Choose Hologic Spine Phantom Q-96 from the list or begin typing Hologic Spine... in the white text box next to Patient Name and the name will highlight in the list. Click “OK”;
- Type in initials in the white text box next to the word Operator. Click “OK”;
- CONFIRM that “Hologic Spine Phantom Q-96” is in the patient field;
- Select “AP Lumbar Spine” in the Scan Selection screen (Exhibit 6-20);
- In white text box to the left of “Number of times to run scan,” type the number 10 (Exhibit 6-20);
- Click “Next >>”;
- The Scan Parameters Screen is displayed. Click “Start Scan”;
- The machine will scan the phantom; and
- A total of 10 scans should have been completed.

6.2.5 Circulating Block Phantom (Hologic Block Phantom NH #1)

- Center the table. When the table motion is complete, position the Circulating Hologic Spine Phantom on the table at the position indicated by the laser cross;
- The positioning star should be pointing to the foot of the table;
- The laser cross should be centered on the positioning star;
- The laser line should be positioned between the numbers 1 and 2;
- On the QDR main menu screen, click “Utilities” at the top of the screen;
- From the drop-down menu, select “Service Utilities” and then “Auto Scan” from the second drop-down menu. See Exhibit 6-19;
- Choose Hologic Block Phantom NH #1 from the list or begin typing Hologic Block... in the white text box next to Patient Name and the name will highlight in the list. Click “OK”;
- Type in initials in the white text box next to the word Operator. Click “OK”;
- CONFIRM that “Hologic Block Phantom NH #1” is in the Patient Field;
- Select “AP Lumbar Spine” in the Scan Selection Screen (Exhibit 6-20);
- In white text box to the left of “Number of times to run scan,” type the number 10 (Exhibit 6-20);

- Click “Next >>”;
- The Scan Parameters Screen is displayed. Click “Start Scan”;
- The machine will scan the phantom; and
- A total of 10 scans should have been completed.

6.2.6 Using Auto Scan at Start of Stand

- The feature Auto Scan may be used for scanning multiple phantom scans at the start of stand. It can be used for:
 - Hologic Femur Phantom #WHF – XXXX – 5 scans;
 - Circulating Spine Phantom (HSP Q96) – 10 scans; and
 - Circulating Block Phantom (NHANES Block #1) – 10 scans.
- To use the Auto Scan feature, click “Utilities” at the top of the screen in the QDR Main Menu. See Exhibit 6-19; and
- From the drop-down menu, select “Service Utilities” and then “Auto Scan” from the second drop-down menu (Exhibit 6-19).

Exhibit 6-19. Selecting Auto Scan from QDR main menu



- Select or highlight the appropriate phantom from list. Click “OK”;
- Type in initials in the white text box next to the word Operator and Click “OK”;
- CONFIRM that the correct phantom is in the patient field;
- Select the appropriate Scan Type (AP Lumbar Spine, or Right Hip) in the Scan Selection Screen (Exhibit 6-20); and
- In white text box to the left of “Number of times to run scan,” type the number of scans needed (i.e., 5 or 10). See Exhibit 6-20.

Exhibit 6-20. Number of times to run scan

- Click “Next >>”;
- The Scan Parameters screen is displayed. Click “Start Scan”;
- The machine will continue to scan the phantom the number of times indicated;
- As the scan is completing, carefully inspect the image is satisfactory; and
- If the scan is not satisfactory, stop the Auto Scan, reposition the phantom again, carefully following the instructions above.

6.3 QC Scan Checklists

The QC Scan checklists were developed to ensure that all QC Scans are completed as outlined in the protocol. There are two forms: one is used for all daily and weekly QC scans; the other is used for all Start of Stand QC scans. See Appendixes E and F for sample forms.

6.3.1 Instructions for Completing Weekly QC Scan Checklist

- The checklist should be filled out on each day of the workweek by the health technologist who is responsible for completing the QC scans that week;
- As scans are completed each day, check the appropriate boxes; and
- During the week, keep the checklist in the DXA Procedures manual. At the end of each week, file the completed form in the “Weekly QC Scans Checklist” section in the back of the manual, behind the previous week’s form.

6.3.2 Instructions for Completing Start of Stand QC Scan Checklist

- The checklist should be filled out at the start of the stand by the health technologist who is responsible for completing the start of stand scans;
- As each scan is completed, check the appropriate box; and
- File the completed form in the “Start of Stand QC Scans Checklist” section in the back of the manual, behind the form from the previous stand.

6.3.3 Instructions for Accessing Blank QC Checklist Forms

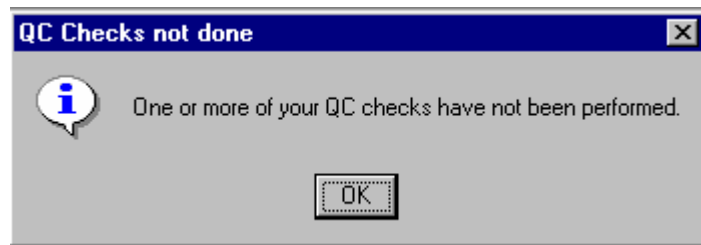
Blank QC Checklists for all DXA scans are stored electronically in the “Blank Forms” folder on the ISIS computer in the MEC. Use the following steps to access the forms.

- Open Microsoft Word. (Click on the icon on the desktop);
- From the “File” menu, select “Open”;
- Select the “MECStaff” directory;
- Select “Blank Forms”;
- Select the appropriate form:
 - DXA_QC1 Daily, 3x/Week, and Weekly QC checklist; and
 - DXA_QC2 Start of stand checklist.
- Open the document by double clicking on it or by selecting it and clicking “Open”;
- From the “File” menu, select “Print.”

6.4 Data Entry Screens for QC on Equipment

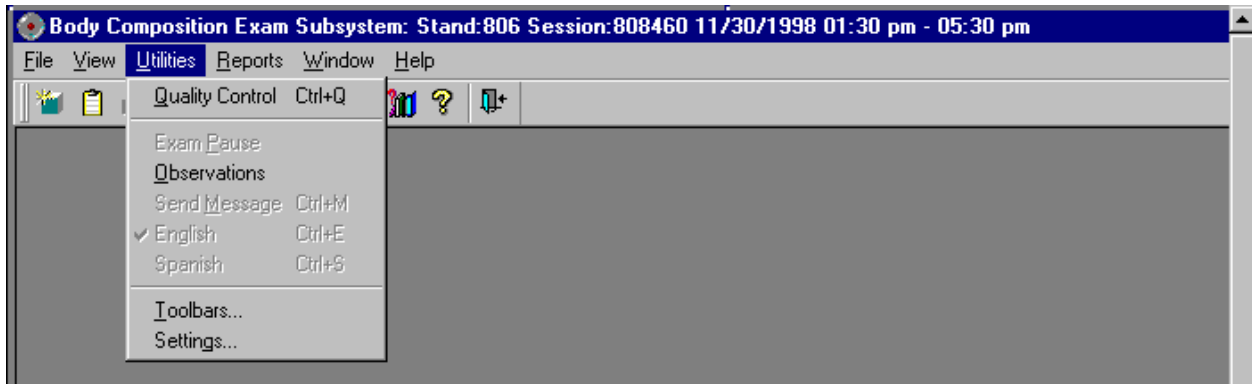
- When you log onto the application before the quality control checks are performed, the system displays a message: “One or more of your QC checks have not been performed.” See Exhibit 6-21; and
- Click OK to this message.

Exhibit 6-21. Quality Control reminder message box



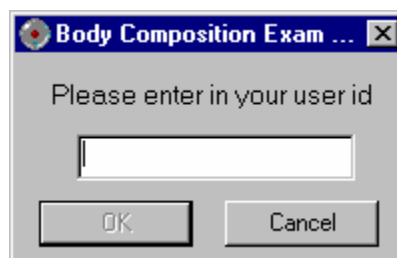
- When you want to complete the QC checks, select “Utilities.” Then select “Quality Control” from the menu (Exhibit 6-22).

Exhibit 6-22. Utilities menu to select quality control



- Clicking on the QC icon from the Toolbar can also access the QC screens; and
- When QC is selected from the Utilities menu, the User ID entry box will be displayed (Exhibit 6-23).

Exhibit 6-23. Quality Control log-on



- Each technologist will have a personal ID. This ID will be used to identify the person who completed the QC checks for this time period;
- Enter your User ID and click OK; and
- If you do not want to do the QC checks at this time, click Cancel.

6.4.1 Start of Stand QC Checks

- The Quality Control Start of Stand Checks data entry screen is shown in Exhibits 6-24 and 6-25.

Exhibit 6-24. Quality Control Start of Stand Checks (1)

QC Check	Done	Result	Comment
Complete all daily checks.	<input type="checkbox"/>		
Complete all weekly checks.	<input type="checkbox"/>		
DXA - Check that locking pins have been removed before attempting to complete any scans.	<input type="checkbox"/>		
DXA - Complete 10 Hologic Circulating Spine Phantom scans (HSP Q-96).	<input type="checkbox"/>		

Exhibit 6-25. Quality Control Start of Stand Checks (2)

QC Check	Done	Result	Comment
DXA - Check that locking pins have been removed before attempting to complete any scans.	<input type="checkbox"/>		
DXA - Complete 10 Hologic Circulating Spine Phantom scans (HSP Q-96).	<input type="checkbox"/>		
DXA - Complete 10 Hologic Circulating Block Phantom scans (NH #1).	<input type="checkbox"/>		
DXA - Complete 5 Hologic Femur Phantom scans.	<input type="checkbox"/>		

- Complete all “Start of Stand” checks;
- “Start of Stand” checks include all daily and weekly checks;
- When the “Start of Stand” checks are complete, click “OK” to close the QC checks;
- Complete the remaining “Start of Stand” checks; and
- When you have completed all checks, click “OK” to close the QC box.

6.4.2 Daily QC Checks

The Daily Quality Control Checks data entry screen is shown in Exhibit 6-26.

Exhibit 6-26. Quality Control Daily Checks

QC Check	Done	Result	Comment
DXA - check table scan area is clear of articles that might interfere with table movement.	<input type="checkbox"/>		
DXA - check runner area of table is clear of articles that might interfere with table movement.	<input type="checkbox"/>		
DXA - complete spine phantom check.	<input type="checkbox"/>		

- On the QC screens, check “Done” for the listed items when that item has been completed;
- You are not required to enter anything in the “Result” or “Comment” fields unless there is a problem;
- The “Result” field is used to enter values for selected QC items if required;
- The “Comment” field is used to enter information about problems encountered with the QC item check;
- Use the scroll bar to move to the remaining items; and
- When you are finished with the daily item checks, click “OK” to close the QC box.

6.4.3 Weekly QC Checks

- The Weekly Quality Control Checks data entry screen is shown in Exhibit 6-27.
- Complete all the daily checks.

Exhibit 6-27. Quality Control Weekly Checks

QC Check	Done	Result	Comment
Complete all daily checks.	<input type="checkbox"/>		
DXA - Complete 1 Step Phantom scan.	<input type="checkbox"/>		
DXA - Complete 1 Hologic Femur Phantom scan.	<input type="checkbox"/>		

- Check “Done” for each item on the weekly checks when complete;
- Use the Scroll down bar on the right of the screen to get to the remaining items; and
- If you notice a problem with any of the items on the check list, make a note of this in the comment box and report it to the MEC manager.

6.4.4 End of Stand QC Checks

- Clean the DXA table by wiping it down with a clean damp cloth and liquid Ivory™ soap. Do not complete this item until all exams for the stand have been completed to ensure that no scans are done on a damp table. See Exhibit 6-28.

Exhibit 6-28. Quality Control End of Stand Checks

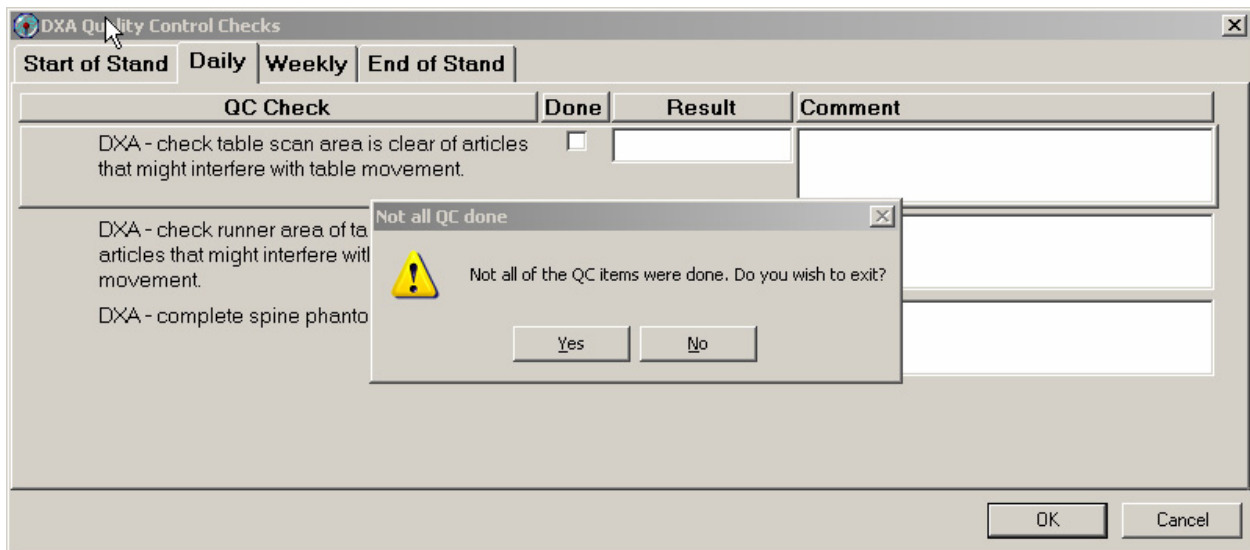
QC Check	Done	Result	Comment
Clean DXA table - wipe down with damp clean cloth and liquid Ivory Soap after all exams for the stand have been completed.	<input type="checkbox"/>		

- If the table needs to be cleaned more often, follow the procedures for end of stand cleaning at the end of the examination week. This will allow the table to dry prior to the beginning of the next week.

6.4.5 Incomplete QC Checks

- If you do not check that all items are complete, the system will display this message: “Not all the QC items were done. Do you wish to exit?” See Exhibit 6-29.

Exhibit 6-29. Quality Control Incomplete Checks entry



- If you want to complete the items before exiting, click “No” to this message and complete the items;
- If you wish to exit without completing all the QC checks, click “Yes” to this message; and
- If all QC items were not complete, the system will remind you each time you log on that the QC checks are not complete.

APPENDIX A

DXA SCRIPTS

APPENDIX A

DXA SCRIPTS

Introduction to Component (Suggested Script)	
English	Spanish
In this room, I'm going to take two scans of your body with this machine. These scans can tell us how strong your bones are. I will explain each exam in more detail as I go along.	En este cuarto, voy a tomar dos escáneres de su cuerpo con esta máquina. Estos escáneres pueden decirnos qué tan fuertes están sus huesos. Explicaré cada examen con más detalles mientras los hago.
General Explanation of DXA Scans	
English	Spanish
It will take a few minutes to position you correctly for each scan and another few minutes to take the scans. The scan of your hip and spine will tell us how strong your bones are compared to other people like you. I will explain each scan in more detail as I position you for the scan. At this time, please remove all objects from your pockets and place them in this container. I am going to ask you a few questions before I start the exam (shared/safety exclusion questions are asked).	Tomará unos pocos minutos ponerle en la posición correcta para cada escáner y otros pocos minutos para tomar los escáneres. El escáner de su cadera y de su columna nos dirán qué tan fuertes están sus huesos comparados con los de otras personas como usted. Le explicaré cada escáner con más detalles mientras le posiciono para el escáner. En este momento, por favor saque todos los objetos que tiene en los bolsillos y póngalos en este recipiente. Le voy a hacer algunas preguntas antes de empezar el examen (shared/safety exclusion questions are asked).

(Revised December 2006)

General Explanation of AP Spine Scan	
English	Spanish
<p>For the spine scan, you will lie flat on the table. I'm going to place a pillow under your head. Then I am going to bend your legs at a 90 degree angle at the hip and knee by placing them on this large soft cube-shaped pillow. You will not feel anything during this scan. Please be as still as possible and do not talk during the scan.</p>	<p>Para el escáner de la columna vertebral, usted tendrá que acostarse extendido sobre la mesa. Le voy a poner una almohada debajo de la cabeza. Después, le voy a doblar las piernas en un ángulo de 90 grados en la cadera y las rodillas poniéndolas en esta almohada grande y suave en forma de cubo. Usted no sentirá nada durante este escáner. Por favor quédese lo más quieto(a) posible y no hable durante el escáner.</p>
General Explanation of Femur Scan	
English	Spanish
<p>The next scan will be of your hip. For this scan, please continue to lie still with your legs flat against the table. I will rotate your left leg inward slightly and then keep it in place using this foot brace. Please place your arms across your chest. You will not feel anything during the scan. Please be as still as possible and do not talk during the scan.</p>	<p>El siguiente escáner será para su cadera. Para este escáner, por favor continúe acostado/a sin moverse con las piernas extendidas sobre la mesa. Voy a moverle la pierna izquierda un poco hacia adentro y después la mantendré en esa posición usando estas bandas para los pies. Por favor cruce los brazos sobre el pecho. Usted no sentirá nada durante este escáner. Por favor quédese lo más quieto(a) posible y no hable durante el escáner.</p>

(Revised December 2006)

APPENDIX B

**SET-UP AND TEAR-DOWN PROCEDURES
FOR DXA ROOM**

APPENDIX B

SET-UP AND TEAR-DOWN PROCEDURES FOR DXA ROOM

Set-up Procedures

DXA set-up:

- Remove locking pin from base of C-arm.
- Remove Velcro straps from pillar under C-arm.
- Remove pillar from bed of DXA and store pillar in Body Composition box in MEC belly.
- Remove signs from C-arm and Hologic monitor indicating C-arm is locked. Put signs in Set-up/Tear-down binder.
- C-arm must be unbolted from locking pins before any attempt is made to move C-arm.

CPU cart set-up and tie-down material removal:

- Remove tie-down strap from CPU cart and from wall anchors.
- Remove wall anchors (2) from walls.
- Store tie-down strap and wall anchors in their container and store container in DXA supply box.
- Check that ISIS CPU, ISIS keyboard, Hologic CPU, and Hologic monitor are still secured to CPU cart.
- Check that DXA UPS, phantom boxes, and DXA machine are still secured to the floor.

Supply set-up:

- Remove rubber bands from telephone handset.
- Unpack binders for DXA room and place in basket on wall grid.
- Restock containers in grid baskets where needed.
- Place new Velcro foot strap in grid basket; discard used strap.

- Restore trash can and chair to upright positions.
- Store DXA supply box in MEC belly during the stand.

Chief Technologist:

- Make a final check on room set-up.

Tear-down Procedures

Technologist:

- Center C-Arm and bed of DXA Machine.
- Remove wall anchors and tie-down straps from supply box stored in MEC belly.
- Attach all wall anchors to the walls.
- Attach the long end of the strap to the wall anchor on the telephone wall, and attach the ratchet strap to the opposite corner wall anchor.
- Pack manuals into DXA supply box.
- Consolidate supplies into DXA supply box.
- Empty grid baskets may be left on the grid.
- Place extra paper roll in supply box.
- Use two rubber bands to hold handset onto telephone.
- Store packed DXA supply box on floor. Nothing should be stored on the table.
- Center C-arm and DXA table.
- *** Bolt C-arm with locking pins at the base of the C-arm (**Chief Tech or Advance Arrangements Staff should assist with this step**).
- *** Position pillar under outside edge of C-arm. Use caution when doing this. The C-arm should not be forced out of position. (**Chief Tech or Advance Arrangements Staff should assist with this step**).
- Secure pillar to C-arm with Velcro straps.
- Post sign on Hologic monitor and C-arm: **“Locking pins are in position. Do not attempt to turn on DXA machine until the locking pin is removed.”**
- Anchor computer cart with nylon strap around cart legs and tighten ratchet.
- Check that the ISIS CPU, the ISIS keyboard, the Hologic CPU and the Hologic monitor are all secured to the computer cart.
- Check that the UPS, the phantom boxes, and the DXA are secured to the floor.
- Turn room chair upside down.

- Turn trash can on its side.

Chief Technologist:

- Make final check on pack-up of the room with the technologist.

Advance Arrangements Staff / FES:

- Disconnect ISIS mouse and keyboard.
- Pack the computer mouse and the Hologic keyboard into a box with packing material.
- Place all packed boxes on the floor. Nothing should be stored on the bed of the DXA.
- Bolt sliding shelf for Hologic keyboard with sliding pin.

APPENDIX C

DXA BONE DENSITOMETER REPORT

APPENDIX C

USE ONE FORM FOR EACH SCANNER IN THIS STUDY

THIS FORM ONLY PERTAINS TO STUDIES IN WHICH DXA DATA ARE SENT TO UCSF. HOLOGIC SCANNER OPERATORS SHOULD SEND THIS FORM ALONG WITH QC ARCHIVE OR dBARCHEIVE DISKETTE(S) AND BMD, BMC, AND AREA PLOTS FOR THE MOST RECENT SIX MONTHS.

DXA Bone Densitometer Report ♦ NHANES IV

MEC number (1, 2, or 3) _____

Scanner Serial Number _____ Hologic Spine Phantom Number _____

1) Has a new/different scanner been used for any study patients? Yes No If Yes, circle.

Was scanner change approved in advance by UCSF? Yes No By Whom? _____

2) Has there been any software changes? Yes No If Yes, indicate: _____

Old software version: _____ New software version: _____ Date installed: _____

Was software change approved in advance by UCSF? Yes No By Whom? _____.

3) Were there any technologist changes? Yes No If Yes:

Technologist	Added / Departed	Date of Change	Date of Manufacturer's Training
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

4) Were there any maintenance/recalibration/repair problems? Yes No If Yes, indicate:

Service Performed	Date of Service
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

5) Additional comments (Use reverse side if necessary):

Main Technologist: _____ Date: _____ Telephone: _____

Please make copies of this blank form. Complete this form each reporting period and send the original to the UCSF Quality Assurance Center and keep a copy for your records.

DXA Bone Densitometer Service Report

When the Hologic densitometer is serviced or repaired:

- The chief technologist will complete a DXA Bone Densitometer Report.
- Fax a copy of the report to the home office. See laminated cards in the DXA room for names and fax numbers. The home office will send this to the Quality Control Reading Laboratory.
- Fax a copy of the service report completed by the service engineer when the repair or service was made to the home office and to the reading laboratory.
- Put a copy of the service engineer's report and a copy of the DXA Bone Densitometer in the service report binder kept in the DXA room.

APPENDIX D

DXA SCANNER REPORTING PROCEDURES

DXA SCANNER REPORTING PROCEDURES

MEC

1. If the scanner problem occurs Monday-Friday and cannot be resolved by MEC staff, the chief health tech or MEC manager will contact Hologic dispatch at 1-800-321-4659 (press 3) to set up a service visit. If there is no answer, Hologic's after-hours number should be called. Normal Hologic coverage and emergency service are provided 8:00 a.m. to 9:00 p.m. local time, Monday-Friday (exclusive of Hologic holidays), if the call is placed by 2:00 p.m.

If the scanner is down after Hologic's regular office hours or on a weekend, Hologic's after-hours telephone number should be called at 330-995-0582 and a message left specifying the location of the MEC in order to dispatch the local representative, the problem with the scanner, and a contact name and number. Specify that an immediate response is needed. Calls received after 3:00 p.m. on Sunday will not be dispatched until Monday at 8:00 a.m.

When calling Hologic, remind them that we have platinum coverage.

2. The MEC manager will send an email to Deborah Kim, Catherine Novak, Barbara Lindstrom, Vera Osidach, Dave Larson, George Zipf, Lori Borrud, the MEC FES, Taylor Cooper, Stephen Bernas, and Terri Jones. The study manager, field manager, and office manager for the site and the MEC manager for the other team will be sent a Cc copy.

The email should be sent as soon as possible, preferably within 2 hours of scan interruption. In addition, if the problem occurs on a weekend or Federal holiday, the MEC manager should notify Vera Osidach via cell phone at 301-717-8077.

The email should include the following information: 1) when the scanner went down; 2) a brief description of the problem and resolution by MEC staff; 3) the date and time Hologic was called (if problem not resolved by MEC staff); 4) the name of the Hologic contact person and telephone number; 5) a call/service number; and 6) the result of the call to Hologic.

The MEC manager will send a followup email to the Westat home office and NCHS staff describing the result of the Hologic service visit and the total number of DXA exams missed (if any). Additional followup emails will be sent if additional service visits are needed to resolve the problem.

3. The Hologic representative should prepare a report at the time of service with a copy to be left at the MEC. The representative can print the customer service report to the label shipping printer in the lab. The MEC manager should ensure that the Hologic representative leaves a copy of the report. If the representative is unable to provide a service report prior to his departure, either the MEC manager or chief health tech can contact Hologic and request a copy of the service report. If after two attempts, the service report is not available, contact the Westat home office for assistance. Provide information about date of repair, name of representative, and MEC location.

4. As soon as possible after each repair has been completed, the chief health tech will fill out a DXA Service/Repair Report Form and email the form, together with a copy of the Hologic representative's customer service report to the Westat home office. Copies of the DXA Service/Repair Report and the Hologic representative's service report will be put in the service report binder kept in the DXA room.

Home Office

1. The home office will notify the reading laboratory at the University of California, San Francisco (UCSF) by email of any major service/repair issue as soon as possible. A major service/repair is anything that affects the operation of the scanner, such as replacement of parts, hardware or software changes, or recalibration. A copy of the DXA Service/Repair Report and the Hologic representative's service report should be emailed or faxed to UCSF when received by the home office. Preventive maintenance and reports of error messages resolved by the MEC staff can be sent to UCSF at the end of a stand.
2. If exams were missed and rescheduling was attempted, the home office will notify Lori Borrud and George Zipf of the number of exams that were able to be rescheduled.
3. In cases where service reports are difficult to retrieve, the home office will contact Hologic to get a copy of the service report. A copy of the report will be emailed to the MEC manager or chief health technologist to keep it in the service report binder in the DXA room.
4. The home office will send copies of all reports to Vera Osidach at the end of each stand.

DXA SERVICE/REPAIR REPORT FORM

Use one form for each Hologic service or repair visit. The form is to be filled out by the chief health technologist and emailed to the Westat home office together with a copy of the Hologic technician's report.

MEC number (1, 2 or 3): _____

Scanner serial number: _____

MEC 1 = 45575

MEC 2 = 45678

MEC 3 = 45700

Hologic Spine Phantom number: _____

MEC 1 = 5560

MEC 2 = 7026

MEC 3 = 7247

Service Performed:

Name of Hologic Technician: _____

Date of Service: _____

Chief Health Technologist: _____

Date: _____

APPENDIX E

START OF STAND QC SCAN CHECKLIST



APPENDIX E
Start of Stand QC Scan Checklist

Stand#: _____ **Tech ID#:** _____ Scale Check [(your wt + dumbbell) – your wt]: _____

Type of Scan	Scan 1									
Spine Phantom	<input type="checkbox"/>									
Step Phantom	<input type="checkbox"/>									
		Scan 2	Scan 3	Scan 4	Scan 5					
Hologic Femur / Hip Phantom (#WHF- XXXX)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
						Scan 6	Scan 7	Scan 8	Scan 9	Scan 10
Circulating Spine Phantom (HSP Q96)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Circulating Block Phantom (NHANES Block #1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

E-1

APPENDIX F
WEEKLY QC SCAN CHECKLIST



APPENDIX F

WEEKLY QC SCAN CHECKLIST

Week of: _____

Tech ID#: _____

Please note: For Day 1 of the first week of each stand, it is not necessary to repeat scans that were done as part of the Start of Stand QC.

Daily:

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6 (if applicable)
Type of Scan	Scan 1	Scan 1	Scan 1	Scan 1	Scan 1	Scan 1
Spine Phantom (HASP)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hologic Femur/Hip Phantom	<input type="checkbox"/>					
Step Phantom (HASP)	<input type="checkbox"/>					

APPENDIX G

PROCEDURE FOR SECURING
THE QDR 4500A FOR TRAVEL

APPENDIX G

PROCEDURE FOR SECURING THE QDR 4500A FOR TRAVEL

POSITION TABLE & NORMAL SHUTDOWN

CHIEF TECHNOLOGIST

- Press “Center Table” switch on the Control Panel to position the C-arm and table in the middle of its range.
- Press and hold “Table In” switch on the Control Panel until the table is all the way back.
- Complete the normal shutdown procedures.
- Press “Shutdown.”
- When prompted, turn the X-ray Enable key off and put the key in the Spine Phantom box.
- Turn the Computer Power switch off (the small button on the right side of the CPU). Do not press the button on the front of the CPU.
- Turn the Instrument Power switch to the OFF position (O).
- Switch off the QDR 4500A Main Power switch (located on back panel at the bottom of panel).

TURN OFF UPS

ADVANCE TEAM

- Switch the UPS STOP/RUN switch to STOP.
- Switch off the UPS main breaker.

INSTALL C-ARM STABILIZER

CHIEF TECHNOLOGIST/ADVANCE TEAM

Carefully complete the following steps:

- The stabilizer fits snugly between the C-arm and the table but it should not be forced.
- Place the notched end of the Stabilizer on the bottom of the C-arm (tank end) and pivot the top toward the top of the C-arm.
- Position the Stabilizer so that the top and bottom foam pads are wedged between the top of the tank cover and the bottom of the C-arm.

- The C-arm must be vertical.
- Secure Stabilizer by clamping the Velcro strap tightly around the top of the C-arm and fasten it to the Stabilizer pad.

SECURE C-ARM ROTATION LOCK

CHIEF TECHNOLOGIST/ADVANCE TEAM

- The C-arm Rotation Lock is located on the bottom left side of the C-arm (facing the scanner), behind the black shock absorber.
- Turn the handle of the lock until the plunger releases and locks into place.
- The Carriage Lock is located on the lower left side of the carriage.
- Turn the handle until the plunger releases and locks into place.
- Put pink neon signs on the C-arm and over the Hologic computer screens that indicate that the locking pins are in position.

APPENDIX H

PROCEDURE FOR SETTING UP
QDR 4500A FOR OPERATIONS

APPENDIX H

PROCEDURE FOR SETTING UP QDR 4500A FOR OPERATIONS

UNLOCK CARRIAGE & ROTATION LOCKS:

ADVANCE TEAM /CHIEF TECH

- Unlock the Carriage Lock.
- Unlock the C- arm rotation Lock.
- Remove the pink neon signs from the C-Arm and Hologic computer screen and store in supply box.

REMOVE C- ARM STABILIZER

CHIEF TECHNOLOGIST/ADVANCE TEAM

- Remove the Velcro strap from the Stabilizer.
- **Gently** remove the Stabilizer from its position.
- The Stabilizer is stored in the black belly box during the stand.

POWER UP THE QDR 4500 SYSTEM

ADVANCE TEAM

Note: The QDR 4500 X-ray Bone Densitometer System should only be shut down when necessary, primarily during road travel. Other than during road travel, the system should remain powered whenever possible, to avoid warm-up delays. Failure to follow this procedure may cause the UPS batteries to discharge and require significant recharge time.

- Verify that the QDR 4500 main breaker is OFF, the UPS main breaker is OFF and the UPS Stop/RUN Switch is in the STOP position.
- Plug in the QDR 4500 Power Module into one of the UPS outlets.
- Plug in the UPS into a live power outlet (shore power or motor generator).
- If running on motor generator and generator is off, start the motor generator. If running on shore power, verify that the shore power link is ON.
- Switch on the UPS main breaker and wait 30 seconds. Verify that the AC line light on the UPS is lit.

- Switch the UPS STOP/RUN switch to RUN and wait for the end of the second long beep. Verify that the INVERTER light on the UPS is lit.
- If the UPS batteries are discharged, wait until the batteries are charged. (If you switch on the QDR 4500 without waiting for the batteries to charge, you will lose power outage protection).
- Turn on the QDR 4500 Power Switch (located on the BACK PANEL AT THE BOTTOM LEFT OF THE PANEL if you are facing the panel.)

POSITION TABLE AND POWER ON

TECHNOLOGIST

Carefully follow the Startup Procedures (step by step) for Hologic QDR (beginning of session).

- Check that the Power On lamp on the Power Switch is on.
- Turn the Instrument Power Switch to the ON position.
- Allow 30 minutes warm-up time.
- Turn the X-ray Enable key to the ON position.
- Turn the Computer Power switch to the ON position. (Do not use the button on the front of the CPU.)

APPENDIX I

POWER FAILURE PROCEDURES FOR DXA

APPENDIX I

POWER FAILURE PROCEDURES FOR DXA

Use the following procedures when power fails during a session or when staff members are present in the MEC.

1. During a power failure, the Uninterruptible Power System (UPS) will maintain power for a sufficient period of time to allow for proper shutdown of the system.
2. Turn the X-ray Enable key to the OFF position (counterclockwise). Turn the Instrument Power and Computer Power switches to the OFF (O) position.
3. Turn the Main Power switch on the Power Module back panel to the OFF position. This protects the system from power surges when power is restored.
4. After power is restored, bring the Main Power switch, and then the Instrument Power switch, back to the ON position. (See Section 3.3.1 of the *DXA Procedures Manual*.) Allow the system to warm up for 30 to 60 minutes.
5. Verify system performance after a power failure by performing the daily QC procedure.

If power has failed and was restored during the night or when the MEC was unattended:

1. Follow the procedures described in *Section 3.3.2 of the DXA Procedures Manual* to properly shut the system down.
2. Turn the system on as described in *Section 3.3.1 of the DXA Procedures Manual*, allow it to warm up, and verify system performance by completing the daily QC procedure.