

STUDY OF OSTEOPOROTIC FRACTURES
Visit 9

DXA Quality Assurance Manual
for
Hologic QDR-4500 and QDR for Windows

University of California San Francisco
San Francisco Coordinating Center

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I. INTRODUCTION

The purpose of this manual is to standardize the scanning and evaluation procedures among the clinical centers participating in the Study of Osteoporotic Fractures (SOF). It provides information specific to the Hologic QDR 4500 to ensure consistent data collection and analysis. It is intended as a supplement to the Hologic User's Manual.

Prior to reading this document, it is essential that the Hologic User's Manual for the QDR 4500 be read and understood. The DXA operators for SOF are all experienced Hologic users and are expected to be familiar with all of the instrument features and procedures discussed in the Hologic User's Manual. Some of the information from each of the Hologic manuals is repeated in this document for emphasis; note, however, that some of the scanning evaluation protocols for this study differ from those detailed by Hologic. In these cases, the protocol changes are clearly explained below.

NOTE: Unauthorized software changes must be avoided. Contact the DXA QA Center regarding any recommendation concerning a change in software.

II. DUAL ENERGY X-RAY ABSORPTIOMETRY (DXA)

High quality bone mineral densitometry requires competent and consistent quality assurance (QA). This manual contains information that will help to obtain accurate and reproducible results. Procedures for three major areas are covered:

- Scanning the participant
- Analysis of participant data
- Quality control (QC) measures

Each of these procedures is of equal importance. To obtain consistent results, the operator in charge of the densitometry has to be aware of possible sources of error that may affect data collection and analysis.

Bone density measurements for SOF V9 will be obtained at two clinical centers. The hip and whole body will be scanned. Care should be taken to ensure that both participating clinical centers obtain results of comparable precision. The DXA QA Center will be reviewing the data and will notify the clinical centers if inconsistencies are detected. Possible sources of error and solutions will be suggested. The DXA QA Center will not be responsible for the solution of hardware or software problems; that will rest with the clinical center and the scanner manufacturer.

During the study, any questions regarding procedures that arise should be directed to the DXA QA Center. Instances in which the operator is unsure of the analysis should be identified on the Participant Scan Log (Appendix B). These cases should be compiled and forwarded to the DXA QA Center for review. Often these problem cases have been analyzed correctly and will require no further action; however, in some instances, the DXA QA Center may request re-analysis of a scan.

Data for the study will be sent monthly to the DXA QA Center using the Batch Record Form (see Appendix B). Additionally, any questions or correspondence regarding the DXA manual, technical aspects of the DXA measurements or other DXA QC issues should be directed to:

Michaela Rahorst
UCSF San Francisco Coordinating Center
185 Berry Street, Lobby 4, Suite 5700
San Francisco, CA 94107
Tel (415) 514-8095
Fax (415) 514-8150
Email: mrahorst@psg.ucsf.edu

III. PATIENT BIOGRAPHY

Since V9 scans will be acquired on the QDR4500, it is imperative that care be taken to recreate the patient biography EXACTLY as it appears on the QDR1000 (for hip) or QDR2000 (for whole body). A copy of the baseline scans should be available for biography information. In the patient biography, the following fields should be entered:

- NAME
- PAT ID
- SCAN CODE
- DOB
- SEX
- WEIGHT
- HEIGHT

All other fields may be left blank.

Important: Enter the SOF staff ID number of the person performing the scan in the SCAN CODE field. Also update the patient height and weight in the biography with the Visit 9 values.

IV. HIP MEASUREMENTS

Hip DXA scans will be acquired on the QDR 4500. Use the Array mode for all participant scan acquisition. Do NOT use the Fast Array mode. If the image generated in Array mode is too grainy or has a "moth eaten" look, the technologist may use High Definition, if available. An extremely grainy image indicates that the tissue thickness or quality of the tissue is too great for the x-rays to penetrate in enough quantity to render a good image for analysis.

A. HIP SCANNING PROCEDURES

In general, scan on the same side as the baseline scan. It is not necessary to reproduce poor baseline positioning or analyses. Try to get the best positioning as possible on the Visit 9 scans. If the participant has hardware in the hip that was scanned at baseline, scan the other hip and make a note on the scan log.

When performing hip scans, the following guidelines must be adhered to:

- No metal or plastic object should remain in the scanning area. Check for jewelry, coins or other objects in the hip pockets, zippers, buttons, rivets, belts or any other clothing fasteners, as well as hip and back braces.
- Lower any thick clothing that might obscure the scanning area.
- Keep the participant's hands out of the scanning area by placing them well away from the hips.
- Ensure rotation of the hip by holding the knee and the ankle when positioning the leg. Optimum positioning of the legs is most important.
- Attach the measured leg to the angled foot block supplied by the manufacturer.
- The participant should be made as comfortable as possible to reduce the chance of unwanted movements. Use a pillow for the head and a small pillow under the knee opposite to the scanned hip. Maintain the participant at a comfortable body temperature for the duration of the scan.
- Instruct the participant to remain still until the end of the measurement. Make sure that the leg is not moved during the scan. Flag any scans in which the participant has moved and has not been rescanned. Movement during a hip scan appears as either a discontinuity or as a smear.
- If the scan shows a "short" neck with little space between itself and the ischium, this could be due to poor rotation of the leg. If the positioning is not consistent with the baseline, then reposition the participant and rescan.

- In order to improve the positioning for the measurement, the rescan option (F3 key) should be used freely. Start the hip scan and keep scanning until the lateral contour of the greater trochanter becomes clearly visible. Initiate rescan (F3) and position the blue arrow that appears in a way that it points to the most lateral aspect of the greater trochanter. Allow for approximately 5 scan lines between the arrow and the trochanter. Restart the scan.
- Interrupt scanning about 1.5cm (15 lines) beyond the medial extent of the acetabulum if scan width limit has not yet been reached.

B. HIP ANALYSIS PROCEDURE

Analysis Procedures

Global Region of Interest (ROI): The procedures outlined in the Hologic User's Manual are to be followed. The points listed below are for emphasis.

To provide sufficient soft tissue for analysis, the global ROI should be at least 5 lines beyond the lateral edge of the greater trochanter; the medial side and the top of the global ROI should be 5 lines beyond the femoral head. The bottom edge of the global ROI should be at least 10 lines below the lesser trochanter.

Bone Edges: If the bone edges are not properly determined by the analysis program, increase the size of the global ROI by first moving the top border up 10 lines further from the femoral head, then by moving the medial border 10 lines further out, if possible, to include more soft tissue in the analysis. Repeat as needed. Do not move the bottom or lateral border. Do not fill in bone edges manually unless absolutely necessary. The software will automatically fill any "holes" within the bone. Occasionally, the bursa or tendons surrounding the greater trochanter can be calcified. This will produce "knobs" that can merge with the trochanter and throw off the automatic placement of the four regions. Expanding the global ROI will not always separate these from the trochanter and they will have to be manually excluded. Flag for review by the DXA QA Center any cases in which the bone edge is manually altered.

Femoral Midline: Unevenness (notches) in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck. This will in turn cause the femoral neck box to twist. If the midline looks like it might be off or the box is twisted on either the baseline or follow-up scan, it may be necessary to adjust the bone mask (e.g. filling in neck notches, deleting the ischium) in order to obtain appropriate positioning of the midline. **The position of the midline itself should not be altered.** If changes have been made to the scan such as filling in bone in order to alter the midline, or if the midline is still off, flag these cases for review by the DXA QA Center.

Femoral Neck Box: If the default neck box provided by the Hologic program looks reasonably placed, leave it unchanged.

If the default neck box partially extends into the trochanter, ischium, or femoral head and acetabulum, adjust its location or size while maintaining the maximum possible area. If necessary, use the procedures given in the Hologic User's Manual for deleting the bone of the ischium. Flag these cases for review by the DXA QA Center.

Ward's Triangle: The Hologic software should place the square marking Ward's triangle in or adjacent to the femoral neck box. In participants with low BMD or short femoral neck projections, the Ward's Triangle box may be misplaced considerably. If this happens, follow the instructions in the Hologic manual to modify the search region. Flag extreme cases for review by the DXA QA Center.

Trochanteric Line: The trochanteric line should intercept the bone edge just below the lateral aspect of the greater trochanter. There is no need to correct minor.

V. WHOLE BODY SCANNING

Whole body DXA scans will be acquired on the QDR 4500.

A. WHOLE BODY SCANNING PROCEDURES

When performing whole body scans, attention has to be paid to the following points:

1. Have the participant remove all clothing and dress them in a hospital gown. Check that no metal or plastic objects remain in the scanning area. This includes hair clips and pins, underwire bras, snaps, zippers and buttons. Have patient remove any jewelry, earrings, bracelets, watches, or rings.
2. Position the participant in the center of the scanning table with their head just below the head of the table. It is extremely important that the participant is correctly positioned on the exact center of the table. The arms should be separated from the sides of the body with the hands placed palm down, within a few centimeters of the table edge.
3. Place a loop of tape around the top of the feet so that the feet are straight (or slightly inverted) - this will help to prevent motion during the scan and bring the femoral necks into better position for scan analysis.
4. Verify that the participant is aligned with the scanner axis (solid line on the table). If during scanning it is apparent that part of the participant's body lies outside the scan field, restart the scan.
5. The participant should be positioned as comfortably as possible since this reduces the chances of unwanted movements. In general, try to avoid the use any pillows or blankets. If the participant cannot lie flat at all without the aid of a pillow (due to kyphosis), use a radio-lucent pillow.
6. Instruct the participant not to move until the end of the measurement.

B. WHOLE BODY ANALYSIS PROCEDURES

Operators will analyze V9 whole body scans as baseline scans (i.e. there is no need to visually compare with whole body scans done at previous SOF visits).

1. Locate the horizontal shoulder line just below participant's chin.
2. The vertical shoulder lines should bisect the shoulder joints and separate the arms from the trunk. Avoid including any body soft tissue in the arm ROI.
3. Align the spine ROI with the curvature of the spine, if possible. Divide the spine at the T12-L1 disc space.
4. The horizontal line above the pelvis should be just above the iliac crest. The angled lines define the pelvic triangle so that they bisect the femoral neck.
5. The vertical line between the legs should run between the participant's feet and evenly divide the legs. The lateral leg lines should be moved to include as much of the thigh soft tissue as possible without crossing the hands.
6. Sub-region cut line placement should be such that left/right symmetry is maintained (i.e. placement of lines on the left side of the body should match those on the right).

VI. ARCHIVING DATA

All Visit 9 scans should be archived to the clinic disk on a daily basis for the safety of the data.

The scans should be copied to the traveling optical disk to be sent with the monthly batches. The scans on the traveling optical disk will be loaded to the DXA QA Center database and the disk will be returned to the clinic.

Optimal use of the both the clinic and traveling optical disks can be achieved by archiving/copying larger batches of scans at a time (instead of one scan at a time).

VII. REPEAT DXA MEASUREMENTS

In rare circumstances, DXA scans may need to be repeated. If this occurs, the DXA QA Center will contact the clinic about the repeat scan. The clinic should then follow the steps below:

1. Contact participant to come back into the clinic. Schedule repeat scan as soon as possible.
2. Repeat scan, paying particular attention to problem described by the DXA QA Center.
3. On the original TELEform form for the scan, change necessary information on the form (the date of the scan, for example). DO NOT REFAX the form. Make changes to the data system (by posting a query to the website), as needed.
4. Send the repeat scan and a hard copy of the TELEform form to the DXA QA Center at the DXA QA Center.

VIII. SOF VISIT 9 DXA PARTICIPANT SCAN LOGS

The Participant Scan Log is a paper record of SOF Visit 9 scans (Appendix B). It has evolved into a useful crosscheck and reference for the BMD data, and should always accompany the monthly batches. It is important that the Participant Scan Logs be filled out carefully and accurately.

IX. TOTAL HIP *OR* FEMORAL NECK BMD T-SCORE < -2.5

Participants will be given their BMD T-scores following their clinic visit. Participants with a total hip *OR* femoral neck BMD T-score of less than -2.5 will be identified and appropriately counseled.

On a monthly basis, the DXA QA Center will send the clinics a list of participants who have total hip or femoral neck T-scores less than -2.5 to verify that they were counseled about low BMD.

X. CERTIFICATION

Only those operators who have been certified through Hologic training and the DXA QA Center are allowed to perform the scanning and analysis for SOF. It is the clinical center's responsibility to ensure that as new operators are brought into the study, all of the certification criteria are met.

If an operator has previously been certified by the DXA QA Center to scan on a QDR 4500, there is no need to repeat the certification procedures. The names, SOF staff ID numbers, and certification information of such operators should be sent to the DXA QA Center.

Operators who have not been certified by the DXA QA Center to scan on a QDR 4500 should send their first ten SOF hip scans for review along with printouts of the baseline scans. Write "Certification" on the top of the page and include the operator's SOF staff ID number and name. If it will take more than two months to scan 10 SOF participants, non-SOF hips on the QDR 4500 can be sent for review. Please cross out any identifying patient information. Write "Certification" on the top of the page and include the operator's SOF staff ID number and name.

After successful review of ten hip and whole body scans, an operator will be considered certified and the appropriate documentation will be sent to the clinical center.

XI. QC MEASURES

QC measures are the responsibility of the individual clinical centers and must be performed to monitor scanner performance throughout the period of the study.

The following table lists the quality control procedures and schedule.

Quality Control Scanning Schedule

Phantom	Scanning frequency
Local Hologic Tissue Bar	1 time/week
Local Hologic Spine Phantom	Daily (at least 3 times/week)
Local Hologic Whole Body Phantom	3 times/week
Whole Body Air Scan	1 time/week
Cross-calibration Phantoms (hip, spine, block)	To be determined

A. PHANTOM SCANS

Perform the spine QC phantom scans as outlined in the Hologic manual, Quality Control Chapter. The results of these scans should be reviewed locally for abrupt changes in machine performance and the results sent to the DXA QA Center once a month.

Whole body quality control consists of Hologic whole body phantom scans, whole body air scans, and tissue bar scans.

Create only one patient biography per phantom. * **IMPORTANT: Enter the phantom serial number (i.e. Q-135) as PATIENT ID.** Avoid duplication of patient biographies by using the patient menu to select the appropriate biography prior to scanning the phantom.

Scan the spine phantom on top of the pad. Ensure alignment with the scanner axis by running the laser light up and down the edge of the phantom or by using the phantom case as a spacer between the ledge on the back of the scanner table and the phantom block.

Evaluate the QC scans using the compare feature. Update the QC database daily; back up to diskette once a week. **Keep the original that you use as “baseline” for the compare permanently stored on the hard disk.** Additional copies of this baseline phantom scan should be stored on diskette. Phantom scans themselves are not archived: only the phantom database needs be archived for subsequent analysis of machine performance.

Add the scan to the QC database immediately after scanning and analysis, following the procedure outlined in the Hologic manual.

Use the plot feature daily to verify that the BMD of the scanner is within normal limits. If the most recent scan falls outside the limits, repeat the scan. If the second scan also falls outside the limits, contact both Hologic and the DXA QA Center.

The CV should be less than 0.5%; if it is greater than 0.5%, contact both Hologic and the DXA QA Center.

Periodically check the system drift. The slope of the calculated regression line should be within the range of the standard deviation shown. If the drift is greater than the standard deviation, contact both Hologic and the DXA QA Center.

Generate a printout of the QC spine phantom BMD plot once a week on the designated "QC day." This will facilitate detection of long term drifts, as well as short-term inconsistencies.

The QC database is archived using the archive option from the QC menu. Follow the instructions in the Hologic manual.

B. WHOLE BODY AIR SCANS

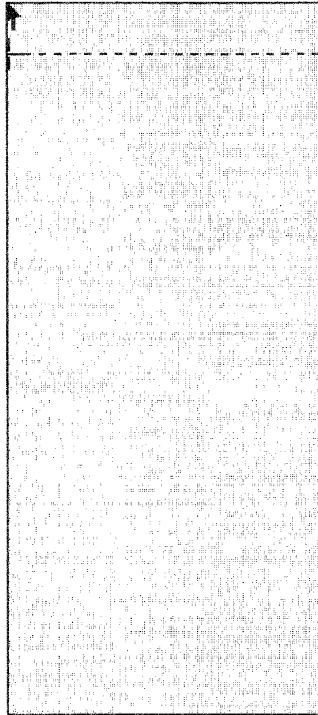
A Whole Body scan of "air" (i.e. nothing on the table but a clean pad) should be performed once a week.

The "air" scan will assess the proper functionality of the QDR 4500 scanner and indicate any potential problems with the x-ray beam, if present.

1. Clear the entire tabletop of any objects and clean the pad of any debris. Only the table pad should remain on the table. This is critical since the test can detect items as thin as a single piece of Scotch tape.
2. Enter a Patient Biography as **WB AIR QC SCAN**. Enter the system serial number in the Pat ID field.
3. Perform a scan. Scan the entire length of the table. Do not interrupt the scan.
4. In DOS software: with the air scan selected, <ESC> to the Main Menu. Choose the UTILITY option and press <ENTER>. Then choose SERVICE and then PLOT. A blank image will appear. Press the <PgDn> key once to move to line 10.

In Windows software: Click on "Utilities" and then click on "Scan File Plot". Choose the WB AIR QC scan that was just acquired. Click "OK". A blank image will appear. Press the <Page Down> key once to move to line 10.

The image will appear along with a graph. At the bottom of the graph an indicator of the reference wheel segment that produced the data will appear along with an attenuation value +/- a SD(Standard Deviation). See diagram below.



LoBone	827.9 +/-	0.9	4095
			3276
			2457
			1638
			819
			0
HiBone	602.8 +/-	0.9	

This number is the SD of the HiBone value

Hi 609 Lo 833 Point 2 Line 10
 This number indicates which one of the scan is being measured.

For example: **HiBone 602.8 +/- 0.9**

The last value, 0.9, is the value we want to record. It represents the SD of the air values across a scan line. The value should not exceed 2.0 units. Use the <DOWNARROW> key to view (9) additional lines to obtain a better estimate of the SD. Record all 10 SD values for HiBone for lines 10 through 19 on the worksheet on the next page. Please make photocopies of the worksheet for your use.

WHOLE BODY AIR QC SCAN WORKSHEET

Clinical Center:	Serial Number:
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LINE	SEGMENT	SD
10	HiBone	
11	HiBone	
12	HiBone	
13	HiBone	
14	HiBone	
15	HiBone	
16	HiBone	
17	HiBone	
18	HiBone	
19	HiBone	

Date:	Signature:
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5. Press the <PRINTSCREEN> key to obtain a paper copy of the plotted data. Archive the WB AIR QC SCAN to the clinic optical and COPY the scan to the traveling optical.

IMPORTANT: In the event that the SD exceeds the limit of 2.0 units, fax the worksheet to Michaela Rahorst at the DXA QA Center (415-514-8150).

C. FLAGGED SCANS

Original printouts of any scans flagged for review should be sent to the DXA QA Center every month on the traveling optical disk. **Note any reasons for flagging on the original printout.** The printouts will be reviewed and returned to the centers if reanalysis is necessary. It will be up to the operator to reanalyze the scan according to the DXA QA Center comments. Reanalyzed scans must be re-archived to the traveling optical and re-copied to the clinic optical. Return a printout of the reanalyzed scan to the DXA QA Center for verification with the monthly batch. Please refer to Appendix A for specific guidelines regarding when to flag a scan.

D. OTHER QC MEASURES

If the QDR needs to be repaired or if any adjustment has to be made that possibly might affect the data: Perform 5 scans of the Hologic spine phantom before and after the change. In addition, contact the DXA QA Center before the repairs or adjustments are made to find out whether additional measures have to be taken. A SOF DXA Hologic Repair/Service/ Upgrade Log (Appendix B) should be filled out and returned to the DXA QA Center along with a copy of the Hologic Customer Service Report.

Unauthorized software changes must be avoided. If for any reason you think you have to change the software, contact the DXA QA Center before any changes are made.

XII. DATA MANAGEMENT

A dbArchive/System Backup of the patient database should be sent to the DXA QA Center at the end of Visit 9.

Each clinical center should have optical disks to use for storing scans at the clinic and another optical disk for transferring scans to the DXA QA Center. In each monthly transfer, all Visit 9 scans should be copied to a traveling optical using the copy function. The traveling optical should be sent to the DXA QA Center with each monthly batch. It will be returned to the clinic before it is needed for the next monthly batch.

Data transfer to the DXA QA Center occurs monthly. Each monthly batch should include:

1. Completed Batch Record Form – Appendix B
2. QC printouts (spine phantom – BMD, BMC & Area)
3. Participant Scan Log – Appendix B
4. Printouts of flagged scans for review (See Appendix A for flagging criteria)
5. Printouts of reanalyzed scans from previous transfer
6. Electronic copies of all SOF scans since last transfer on the traveling optical disk
7. DXA Hologic Repair/Service/Upgrade Logs (as necessary) – Appendix B
8. dbArchive/System Backup of patient database at the end of Visit 9.

Ship the batch contents via **FedEx or UPS** monthly to the following address:

Michaela Rahorst
San Francisco Coordinating Center/DXA QA
185 Berry Street, Lobby 4, Suite 5700
San Francisco, CA 94107
Tel (415) 514-8095

The DXA QA Center will return the following items to the clinical center after review:

1. Annotated printouts of flagged scans that require reanalysis with explicit instructions, as necessary.
2. Any recommendations for service, additional phantom scans, etc., as necessary based on the QC database.
3. The traveling optical disk

APPENDIX A - Flagging Instructions

WHEN TO FLAG SCANS FOR REVIEW BY THE DXA QA Center FOR VISIT 9

General

- Scan has unusual appearance or is difficult to analyze.
- Participant has moved and scan cannot be repeated without movement.
- Unusual anatomical variations, surgical hardware, superimposed buttons, pins, zippers, vitamin pills, or anything else that might affect scan results.

Hip Scans

- Midline looks misplaced.
- Bone deletion or addition
- Neck box width reduced or extended from default.

Whole Body

- Difficulty positioning due to participant mobility
- Unable to fit both arms in scan field

APPENDIX B - Forms

1. Batch Record Form – Photocopy as needed
2. Participant Scan Log – Photocopy as needed
3. DXA Hologic Repair/Service/Upgrade Logs – Photocopy as needed
4. DXA Bone Density Form (TELEform) – Do NOT photocopy