

Health Aging and Body Composition Study

DXA Quality Assurance Manual
for
Hologic QDR-4500
Bone Densitometers operating with Apex software

DXA Quality Assurance Center
San Francisco Coordinating Center
University of California, San Francisco

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1.0 Introduction

The purpose of this manual is to describe the DXA bone mineral density (BMD) quality assurance program for the Memphis clinical center participating in the Health, Aging, and Body Composition study. It provides information specific to the Hologic QDR 4500 and is intended as a supplement to the Hologic Users' Manual.

To use this manual effectively, it is essential that to have read and understood the entire Hologic QDR 4500 Users' Manual. The study densitometry operators are required to have participated in a Hologic QDR 4500 training session and should be familiar with all instrument features and procedures discussed in the Hologic Users' Manual.

During the study, any questions regarding procedures that arise should be directed to:

Health ABC Help Desk
HABCHelp@psg.ucsf.edu

IMPORTANT: Unauthorized changes in scanner software or personnel can have a large impact on the integrity of study data. If, for any reason, changes in any of these areas are anticipated, please contact the DXA Quality Assurance Center in San Francisco in advance for further instructions.

2.0 Study logistics

During the sixteenth year (ninth DXA acquisition) of the study, DXA scans will be acquired at the Memphis clinic using the QDR 4500 as described below.

2.1 Overview of scans for Year 16

DXA scans will be obtained on the QDR 4500 scanner provided for use in the Health ABC study. No other scanner should be used.

Scans will be acquired as follows:

A hip and whole body scan should be obtained on the QDR 4500 for all participants in the study.

2.2 Division of quality assurance responsibilities

2.2.1 Clinical center responsibilities

The clinical center must ensure the overall quality and completeness of the DXA data and that all protocols and procedures are strictly followed. Specific responsibilities include the following:

1. require that technicians are properly trained and certified;
2. identify a chief densitometry operator to train and supervise other operators;
3. perform and review daily QC scans
4. assure that proper archiving and back-up procedures for participant scans are performed and that archives are stored securely on optical disk, CD, or network location until the end of the study;
5. at specified intervals, send the following materials to the Health ABC DXA Reading Center:
 - a. printouts of plots of the daily QC data
 - b. updated copies of participant scan and machine repair logs
 - c. original printouts of flagged scans
 - d. original printouts of other requested scans
 - e. CD with all newly acquired scan files obtained since the last data transfer
 - f. a copy of the current study database [DBARCHIVE] on a CD
6. reanalyze centrally reviewed scans, as requested by the Reading Center;

7. assure proper functioning of hardware and service from Hologic
 - a. notify Hologic and the Health ABC DXA Reading Center of any machine or software problems, or if the QDR machine is being relocated
 - b. record machine/software problems and service on the “service log”
 - c. perform 5 QC phantom scans before, (if possible) and after service
 - d. perform 5 QC phantom scans before and after a machine relocation

8. contact the densitometry specialists at the Reading Center with any questions or problems which cannot be dealt with in the monthly batch mailings.

2.2.2 Health ABC DXA Reading Center responsibilities

The following are the responsibilities of the Health ABC DXA Reading Center:

1. write and maintain the quality assurance manual;

2. promptly review the daily QC phantom scan data received from the clinical center in order to identify surges or drifts in machine performance;

3. incorporate new participant data into the study wide database;

4. review certification and flagged scans and return results to the clinical center;

5. review random samples of scans (from centralized database);

6. prepare quality control summary reports for Health ABC Steering Committee review;

7. identify possible sources of error, and suggest possible solutions. (**However, the Health ABC DXA Reading Center will not be responsible for the solution of a hardware or software problem; that will rest with the clinical center and Hologic.**)

Any questions or correspondence regarding the manual or the technical aspects of the DXA measurements should be directed to:

Health ABC Help Desk
HABCHelp@psg.ucsf.edu

2.3 Training and certification of Health ABC DXA operators

To obtain consistent results, the densitometry operators must be aware of possible sources of error that may affect data collection and analysis. Only those operators who have been certified through Hologic training and the Health ABC DXA Reading Center review are allowed to perform the scanning and analysis for this study.

Anyone performing scans for the Health ABC study must meet the following requirements:

1. read and understand both the Hologic QDR4500 manual and this manual;
2. satisfactory review of each operator's initial scans by the DXA Reading Center. In order for an individual technician to be certified to perform scans of a given skeletal site, the first 10 scans done on study participants at each skeletal site for each operator must be sent to the Reading Center for review. Original printouts of scans should be sent to the Reading Center at the address listed above as soon as the first 10 scans have been completed.

It is the clinical center's responsibility to ensure that as new operators are brought into the study, all of the above certification criteria are met.

Personnel not meeting these requirements may not scan participants without close supervision by a certified operator, unless specifically authorized by the Health ABC DXA Reading Center.

2.4 Health ABC DXA Reading Center review of DXA scans

Scan analysis quality will be ensured by a central review of analyzed participant scans. Whenever scans are to be reviewed centrally:

1. An original printout of the scan should be sent to the Reading Center.
2. It is the responsibility of the Health ABC clinic operator to reanalyze the scan according to the Reading Center comments and return a printout of the reanalyzed scan with an electronic copy to the Reading Center for verification.

Procedures for compiling and forwarding scans to the Health ABC DXA Reading Center are outlined in Section 5.

2.4.1 Flagged scans

Any scans that appear unusual or difficult to analyze should be flagged for review by the Health ABC DXA Reading Center. Guidelines for flagging scans are listed in Section 3.5.

Flagged scans should be sent to the Reading Center monthly with the updated participant database. Note the reason(s) for flagging on the Health ABC DXA Scan Log and on the original printout, for clarification of the problem.

The printouts will be reviewed for standard positioning and analysis procedures and returned to the centers with instructions for reanalysis, if appropriate. Often, these problem scans have been analyzed correctly and will not require further action.

2.4.2 Random samples of scans

Periodically during the study, a random sample of scans will be reviewed by the Health ABC DXA Reading Center. These scans will be sampled from the centralized database at the DXA Reading Center. The number of scans sampled will vary according to the period in the study, the number and training of the technicians, and the results of previous samples.

3.0 DXA scan acquisition and analysis

Standard scanning and analysis procedures for the whole body and hip bone density measurements are described in detail in the Hologic QDR 4500 Users' manual.

Some of the information from the Hologic manual is repeated in this document for emphasis. Please note, however, that some of the scanning evaluation protocols for this study differ from those detailed by Hologic.

3.0.1 Analysis Procedures with Apex 2.7

Please follow these procedures carefully to ensure the data is consistent across all participant scans.

1. **Please do not reanalyze any baseline or follow-up scan at this visit! Please be sure to use the Compare feature when analyzing the Y16 scans**

If you use the COMPARE feature for analysis, the Apex software will analyze the scans using the analysis version of the BL scan. If you do not, the follow-up will be analyzed in 2.7 and the BMD will be calculated in a DIFFERENT way. **BE CAREFUL TO ONLY USE COMPARE AND TO NOT REANALYZE ANY BASELINE OR FOLLOW-UP SCANS.**

Please flag any baseline scan that you believe must be reanalyzed; the QA Center will review and reanalyze it at UCSF, if necessary. The scan will be sent back to the clinic for archiving.

2. Please make sure the NHANES box is unchecked!

To ensure the scans are all analyzed in the same algorithms across participants and visits, the NHANES box should be unchecked in the Hologic software. To check if this function is off, please go under Utilities→Systems Configuration→Analyze tab; there is a box that says “Enable NHANES BCA.” This box should be unchecked.

3.1 Participant data

This section describes in detail the specific procedures to be conducted for the Health ABC study with respect to entering the patient biography, scanning the participant, and analyzing the scans.

Prior to scanning each participant, a Health ABC DXA Scan (Hip and Whole Body) form should be completed for that participant.

NOTE: Please send a copy of the baseline hip and whole body scans to UCSF with the current scans.

3.1.1 Patient biography

Care should be taken **NOT** to create a new biography when the participant returns for repeat measurements

The following fields should be updated in the patient biography:

- Comment field – enter the number 9
- Operator scan code
- Weight

3.2 Whole body scans

The HOLOGIC Operator's Manual should be consulted for the proper whole body scanning and analysis procedures. Clarifications and exceptions for the Health ABC Study are noted below.

Please try to get the best possible positioning for the whole body scan, regardless of the positioning at baseline.

3.2.1 Participant set up

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

1. Have the participant remove all clothing, including shoes, 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 the participant remove any jewelry, earrings, bracelets, watches, and 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 dead center on the table. Match the positioning of the baseline scan as closely as possible, but it is more important to get the best possible positioning than to reproduce poor positioning. 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.
3. 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.
4. The participant should be positioned as comfortable as possible since this reduces the chances of unwanted movements. In general, try to avoid using any pillows or blankets. If the participant feels uncomfortable in this position, you may use pillows for the head only after the upper half of the scan is done. You may then carefully place a pillow under the head of the participant without causing motion artifacts. This procedure should be practiced with the participant before scanning. If the participant cannot lie flat at all without the aid of a pillow (due to kyphosis), use a radiolucent pillow.
5. If the participant is very tall, try to include their feet in the scan by placing their head near the very top of the table.
6. Instruct the participant not to move until the end of the measurement.

3.2.2 Whole body scan analysis

When positioning the participant for their follow-up scan, it is helpful to have a printout of their baseline scan on hand for reference (or view the baseline scan on the workstation).

In order to evaluate the follow-up measurements, display the baseline scan using the COMPARE feature and compare it to your current image on the screen. Match the location of the region markers as closely as possible to the baseline measurement. Optimally matched in this context means that the markers should be at the same position between the body regions as on the baseline image.

Scans that have metal or other artifacts should be flagged at follow-up (even if the artifact was present at baseline and hasn't changed). If the only metal in the scan is due to the presence of a wedding band, there is no need to flag these scans. However, if there is a significant change in the amount of jewelry a participant is wearing, these scans should be flagged.

Flag any scans that are difficult to analyze.

3.3 Hip scans

The Hologic Operator's Manual should be consulted for the proper hip scanning and analysis procedures. Clarifications and exceptions for the Health ABC Study are noted below.

3.3.1 Participant set-up

Before scanning the participant, load the baseline scan onto the hard disk and have a printout of the baseline available. Refer to the baseline printout as you go through the positioning of the participant for the follow-up scan; this is to ensure consistent scanning of the same area. Careful positioning and visual comparison of the current scan with baseline are essential for producing precise measurements. Consistent projection of the femur is more important than the actual angle of the foot rotation. Use the rescan feature as soon as any positioning errors are detected during the current scan.

NOTE: Please use the same scan mode that was used at the baseline visit!

1. Scan the same side that was scanned at baseline, unless there is fracture or hardware. UCSF will send a list of which hip side should be scanned at this visit. Please adhere to the list.
2. Use the Hologic hip positioning device. Keep the participant's hands out of the scanning area by placing them comfortably on the participant's chest.
3. Align the femoral shaft with the longitudinal axis of the table. Ensure rotation of the hip by holding the knee and the ankle when positioning the leg.
4. After proper rotation, firmly secure the foot using the hip positioner's Velcro strap.
5. The participant should be made as comfortable as possible to reduce the chance of unwanted movements.
6. Instruct the participant to remain quiet and still until the end of the measurement. You must rescan the participant if there is any movement during the scan.

3.3.2 Hip analysis procedures

In order to evaluate the follow-up measurements, display the baseline scan using the COMPARE feature and compare it to your current image on the screen. Match the location of the region markers as closely as possible to the baseline measurement.

Optimally matched in this context means that the markers should be at the same position between the body regions as on the baseline image.

Flag any scans that are difficult to analyze.

3.4 Excessive bone loss (EBL)

Excessive Bone Loss (EBL) is defined in Table 1 below. Use the Hologic Rate-of-Change plot to determine the percent loss between the Baseline and HABC Y16 visit.

Follow-up Time Point	Actual Rate of Change for Total Hip BMD
Baseline/HABC Y16	≥16% loss

1. If the rate-of-change meets the Y16 criteria listed above, reposition and rescan the participant; then analyze the repeat scan using "Compare" to the baseline scan and check for EBL again. **These procedures necessitate analyzing the follow-up scans while the participant is still on the scan table.**
2. Average the actual rates-of-change of the two Y16 scans; if the average is greater than or equal to 16% loss, complete the EBL form and send the scans to the Reading Center for review and confirmation.
3. If the average of the two scans does not meet the EBL criteria, complete the form and send the scans to the Reading Center for review.
4. See Appendices B and C for sample letters to participants and their primary care physicians regarding low BMD and confirmed cases of EBL.

3.5 Scan flagging criteria

General Scan has unusual appearance or is difficult to analyze
Any of the following in scan field (either in the bone or soft tissue)

- Unusual anatomical variations
- Surgical hardware
- Participant motion during scan
- Buttons, pins, zippers,
- pacemakers, vitamin pills, etc. in scan ROI.

ROI used on follow-up is different size than used at baseline
Bone edges have been altered in any way
Follow-up scans cannot be reasonably matched to baseline analysis

Hip

- Femoral midline misaligned and cannot be corrected by following the analysis procedures as outlined in the Health ABC manual
- Neck box width reduced from default
- Analysis program repeatedly fails to place regions appropriately - major operator interaction required for analysis
- Excessive bone loss

Whole body

- Participant motion without rescanning
- Significant changes in positioning between baseline and follow-up scan.
- Unable to fit both arms in scan field

3.6 Participant results

At Year 16 all participants will receive a "Result" letter informing them of their DXA results.

There will be two Result letters provided at Year 16 – one for the Hip BMD results and one for the Whole Body % Fat results.

3.6.1 Procedure for recording hip BMD results

After the hip scan has been analyzed and the BMD values checked for possible excessive bone loss, check the t – score of the Total Hip BMD.

Based on the participant’s Total hip BMD t-score, they will fall into one of the following three categories:

t - score < -2.5 = osteoporotic

t - score -2.5 to -2 = low

t - score > -2.0 = normal

Check the value given on the screen with the above t – score ranges and indicate the appropriate category on the Hip BMD Result letter.

The Hip BMD Result letter can be found in Appendix B.

3.6.2 Procedure for recording whole body % fat results

Print the body composition report. Find the % Body Fat and record it on the Body Composition Result letter.

The Whole Body Result letter can be found in Appendix D.

4.0 Scanner quality control

Monitoring of machine performance throughout the study is the joint responsibility of the individual clinical centers and the Health ABC DXA Reading Center.

4.1 Daily phantom scans

Perform the daily QC phantom scans as outlined in the Hologic manual. The results of these scans should be reviewed locally for abrupt changes in machine performance and the results sent to the Reading Center once a month. Points of procedure to note:

1. Create only one patient biography per phantom. Avoid duplication of phantom biographies by using the patient menu to select the appropriate biography prior to scanning the phantom.
2. Scan the phantom on top of the pad. Ensure alignment with the scanner axis by using the laser cross-hairs.
3. Add the scan data to the QC database immediately after scanning and analysis are complete.

4. Use the plot feature daily to verify that the BMD, BMC, and AREA values of your scanner are within normal limits. If the most recent scan falls outside the limits, reposition the phantom and repeat the scan. If the second scan also falls outside the limits, contact both Hologic and the Health ABC DXA Reading Center.
5. After the phantom scan has been analyzed and added to the QC database, delete that day's scan from the hard disk. **Note: the Whole Body phantom scans should be electronically archived before being deleted from the hard drive.**
6. If the CV of the BMD exceeds 0.60% please contact both the Reading Center and Hologic to initiate appropriate action.
7. Generate a printout of the daily phantom plots (BMD, BMC and AREA) for the spine once a week on your designated "QC day." This will facilitate detection of long-term drifts as well as short-term inconsistencies.
8. Original printouts including the scan results of the most recent daily phantom QC plots (BMD, BMC, and AREA) are to be sent to the Reading Center for review monthly. The date range for the plots should cover the previous one year to the present.
9. Perform a System backup at least once a week.

In addition to the daily scanning of the Hologic spine phantom, a number of different phantoms will be used for Health ABC to monitor machine performance and for cross calibration purposes. The schedule for scanning these various phantoms can be found in the table below.

Phantom	Scanning frequency
Local Hologic Whole Body phantom	3 times/week
Whole body air scan	Once / week

4.2 Whole body air scan

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

The "air" scan will assess the proper functionality of the 4500A Whole Body 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. Locate the WB air scan biography.
3. Click on "Perform Exam". Click on the name WB AIR QC SCAN. Click "OK". Click "OK" again at the Patient Confirmation window. Select "Wholebody" scan type. Click on "Next" and then "Start Scan". Scan the entire length of the table. Perform a complete scan and do not interrupt it.
4. When the scan is complete, click on "Exit Exam" at the Exit Exam window. Then exit out of the Hologic software (without shutdown).
5. Open Windows Explorer from the start menu (start -> programs -> accessories -> windows explorer). Click on My computer\c:\QDR\Utilities. Click on Service.
6. The Hologic software will open in service mode. On the Utilities menu, go to Service Utilities, then Table Top Radiographic Uniformity.
7. Select the scan you just acquired, then click Next. Click on the HiBone tab and scroll down to the bottom of the page. Under Global Stats, record the StDev. This number should be < 2.0; if it is >2.0, this warrants a call to Hologic and the DXA QA Center.
8. Record the Global SD on the worksheet that follows; keep this with your QC materials for the study, and send a copy to the QA Center each month.
9. Archive the scan to your CD.

4.3 Machine, software and service problems

If your machine needs to be repaired or if any adjustment has to be made that possibly might affect your data:

1. Do a system backup before any work is done on your scanner.
2. Contact the Reading Center before the repairs or adjustments are made to find out whether additional measures are required.
3. Perform 5 scans of the Hologic daily QC spine phantom before (if possible) and after the repairs or adjustments are made.
4. After repairs or adjustments are completed, send the repair technician's notes and a copy of the completed study repair log to the Health ABC DXA Reading Center. The repair log should contain complete information on all repairs done on your machine. Please keep a repair log with your machine.

4.4 Software change control

Unauthorized software changes must be avoided. If for any reason you think you have to change the software, or your Hologic service representative recommends a software change, contact the Health ABC DXA Reading Center before any changes are made.

The system software installed on the Health ABC QDR 4500 densitometers should be Version Apex 2.7. Authorized upgrades must be cleared by the Health ABC DXA Reading Center before installation at the study sites.

5.0 Data management

5.1 Hard copies of scans

The study site is responsible for maintaining original hard copies of all scans performed during the study. Keep the original printouts in the participant's scan printout folder. The following printed report is needed for each scan:

Hip: print the standard report.

Whole body: print the BMD and body composition reports (2 pages).

5.2 Electronic scan archive

Scans should be archived to a primary and secondary location, which will stay at the clinical site at all times. Scans sent to the Reading Center should be copied to the traveling media. The clinical centers are responsible for following the archive schedule and for keeping the CD and any other electronic archives safe until the end of the study.

5.3 Transfer of data to the Health ABC DXA Reading Center

The following items are to be sent to the Reading Center at the end of each month:

1. QC PRINTOUT. Send printouts of the most recent plots of the QC database, (BMD, BMC, and AREA) for the hip, spine, and ESP phantoms . The plots are reviewed at the Reading Center, and problems are reported back to the clinic.
2. PARTICIPANT SCAN LOG. Send a copy of the written participant scan log sheet covering participants scanned since the last data transfer. Use the log sheets to “flag” individual scans for review at the Reading Center.
3. SCANS FOR REVIEW. Send original printouts of certification scans, “flagged” scans, and any scans requested for review by the Reading Center. Please write the reason the scan was flagged, requested, or is being sent directly on the printout. These scans will be triaged visually based on the original printouts and analyzed on the Hologic workstation if necessary.
4. CDs. Send electronic copies of all scans acquired and reanalyzed since the last data transfer. Archive scans using the COPY feature.

NOTE: Please remember to send a copy of the baseline scans (hip and whole body) on the CD to UCSF

5. REANALYZED SCANS. Send original printouts of all scans which have been reanalyzed according to the DXA Reading Center instructions since the last data transfer. Attach the annotated printouts sent by the coordinating center which indicated the problems requiring reanalysis. You MUST also copy the reanalyzed scan images on the traveling optical.
6. Copy of the Maintenance/Repair Log (with a copy of the Hologic service report), if service was done.

Ship these items monthly using a trackable courier to the following address:

Health ABC DXA Reading Center
Caroline Navy
185 Berry Street, Lobby 5, Suite 5700
San Francisco, CA 94107

5.4 Return materials sent by the Reading Center

The Health ABC DXA Reading Center will return the following items to the study site after review:

1. Annotated printouts of scans requiring reanalysis
2. Traveling media.
3. Any recommendations for service, additional phantom scans, etc., as necessary based on the quality control database.

Appendix A. STUDY FORMS

The following forms are included in this Appendix:

BMD Batch Record Form

Bone Density (DXA) Scan Form

HABC DXA Hologic Repair/Service/Upgrade Log

DXA Scan Log

Excessive Bone Loss Form

Master copies of the forms will be mailed directly to your site. Always keep a copy of any form you send to the HABC DXA Reading Center.

BMD Batch Record Form



Batch Number: _____ Date Batch Mailed: _____
Month / Day / Year

Clinic Name: _____ Staff ID #: _____

Contents

QC Plots No Yes→ Date Printed: _____
Month / Day / Year

Scan Log Sheet No Yes

Flagged Scans No Yes→ Number: _____

Reanalyzed Scans No Yes→ Number: _____

Other Scans No Yes→ Number: _____
 (Specify: _____)

Did you have any service event since last DXA shipment? No Yes→ Date of service: _____
Month / Day / Year
Please include Hologic service report

Traveling Optical No Yes

DB Archive Disk No Yes→ Date Archived: _____
Month / Day / Year

Certification Scans: No Yes

Staff ID	Number of Scans	Scan Type
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Bone Density (DXA) Scan Form
(page 2 of 3)



HABC Enrollment ID #	Acrostic	Visit Year
H [] [] [] [] [] []	[] [] [] [] [] []	● 16

DXA SCAN (HIP and WHOLE BODY)

3. Have you had any of the following tests within the past ten days?
- | | Yes | No | Don't know | Refused |
|--|-------------------------|-----------------------|-----------------------|-----------------------|
| a. Barium enema | <input type="radio"/> * | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b. Upper GI X-ray series | <input type="radio"/> * | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c. Lower GI X-ray series | <input type="radio"/> * | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| d. Nuclear medicine scan | <input type="radio"/> * | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| e. Other tests using contrast ("dye") or radioactive materials | <input type="radio"/> * | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

(Examiner Note: If "Yes" to any, reschedule bone density measurement so that at least 10 days will have passed since the tests were performed.)

4. Have you ever had hip replacement surgery where all or part of your joint was replaced?
- Yes No Don't know Refused

On which side did you have hip replacement surgery?

Right Left Both

Do NOT scan right hip.	Do NOT scan left hip.	Do NOT scan either hip. Go to Question #6 on the next page.
------------------------	-----------------------	--

5. Which hip was scanned at the Baseline (Year 1) Clinic Visit?
(Examiner Note: Refer to Data from Prior Visits Report to see which hip was scanned at Baseline.)

Right Left Neither Don't know

Scan <u>right</u> hip unless contraindicated.	Scan <u>left</u> hip unless contraindicated.	Scan <u>right</u> hip unless contraindicated.
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Bone Density (DXA) Scan Form
(page 3 of 3)



HABC Enrollment ID #	Acrostic	Year of Visit
H [] [] [] [] [] []	[] [] [] []	● 16

DXA SCAN (HIP and WHOLE BODY)

6. Was a bone density measurement obtained for...?

a. Whole body

Yes No

Last 2 characters of scan ID #: [] []

Date of scan: [] [] / [] [] / 2 0 1 [] []

Month Day Year

b. Hip

Yes No

Last 2 characters of scan ID #: [] []

Date of scan: [] [] / [] [] / 2 0 1 [] []

Month Day Year

Health ABC Year 16 DXA Scan Log

Clinic:

Date	Ppt ID#	Acrostic	Scan Type	Scan #	Flagging Comments
			Whole Body (Y16)		
			Whole Body (Y1)		
			Hip (Y16)		
			Hip (Y1)		
			Whole Body (Y16)		
			Whole Body (Y1)		
			Hip (Y16)		
			Hip (Y1)		
			Whole Body (Y16)		
			Whole Body (Y1)		
			Hip (Y16)		
			Hip (Y1)		
			Whole Body (Y16)		
			Whole Body (Y1)		
			Hip (Y16)		
			Hip (Y1)		
			Whole Body (Y16)		
			Whole Body (Y1)		
			Hip (Y16)		
			Hip (Y1)		
			Whole Body (Y16)		
			Whole Body (Y1)		
			Hip (Y16)		
			Hip (Y1)		
			Whole Body (Y16)		
			Whole Body (Y1)		
			Hip (Y16)		
			Hip (Y1)		

Appendix B. Health ABC BMD Results**BONE MINERAL DENSITY**

Thank you for your continued participation in the Health ABC study. Attached are the results from your bone density test from your Year 16 clinic visit. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this report is to help you and your doctor understand your bone density measurement.

What is a bone density measurement?

A bone density test measures how much calcium is contained in certain bones, such as the hip. In general, lower bone density and lower calcium means that the bone is weaker.

What do bone density measurements mean?

We all lose bone as we get older, but some people lose bone faster than others. Certain factors can reduce bone density, such as smoking, low calcium intake, lack of exercise, high alcohol intake, use of some medications, and some medical conditions.

Individuals with low bone density have weaker bones, and weaker bones are more likely to fracture during an accident (even a minor accident such as a fall). However, not all women and men with low bone density will have fractures and, occasionally, even those with high bone density will suffer a fracture.

What are my bone density results?

Your hip bone density value was compared to that of young men / women and is at the level checked below:

_____ Normal
_____ Low
_____ Osteoporosis

If your bone density is checked as "low" or "osteoporosis," we suggest that you discuss these results with your personal doctor, and we would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a local doctor who specializes in treating osteoporosis.

If you have questions regarding these results, please contact _____
_____ at _____.

Appendix C. Excessive bone loss alert letter

August 13, 2013

Jane Doe
1234 Market Street
Pittsburgh, PA 15213

Dear Ms. Doe:

During your last clinic visit for the Health ABC study, we repeated measurements of your hip bone density. Analysis of the results indicated that you have lost bone in the hip at a rate greater than or equal to 16% since your baseline measurement was made.

This loss is greater than average for a person your age and may indicate an increased risk of fracture. This bone loss may also be related to other health conditions, or could result from use of certain medications.

We have enclosed both copies of your hip scan, your baseline measurement and your last measurement. We suggest that you consult with your personal doctor to find out why this is occurring, and we would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a doctor who specializes in treating osteoporosis in Pittsburgh.

Thank you for your time and interest in the Health ABC study. Please do not hesitate to call us if you have questions at () _____ and ask for _____.

Sincerely,

Anne Newman, M.D., M.P.H.
Health ABC Principal Investigator

/sa

August 13, 2013

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

Your patient, _____, who has been a participant in the Health ABC study for the past 16 years, was here on ____/____/____ for his/her annual visit. We have measured bone mineral density of the hip with state-of-the-art densitometry machines at baseline, Year 3, Year 5, Year 8, Year 10, and now at Year 16. The BMD scans of his/her total hip showed 16% bone loss since the start of the study. Our study experts have reviewed these scans and believe the bone loss to be real. This is considered to be a significant amount and is referred to as “excessive bone loss” by our study. Significant declines in hip BMD may indicate the presence of an important medical condition, such as vitamin D deficiency or multiple myeloma, but we cannot rule out the possibility of positioning or other measurement errors.

We are enclosing a copy of the participant’s hip scan and reference plots that show the bone loss to be _____ %.

If you have any questions, please feel free to contact us at ()_____.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

/sa

Appendix D. Health ABC Body Composition Results**BODY COMPOSITION**

One of the goals of Health ABC is to determine how weight and body composition (fat and lean muscle mass) affect health as we get older. With age, our weight changes and this is often the result of an increase in body fat along with a decrease in lean mass. These changes in body fat and lean mass may lead to an increased risk for health problems and disability. For example, obesity (high percent body fat) may reduce life expectancy by increasing the risk of developing coronary artery disease, high blood pressure, Type II diabetes, certain types of cancer, and several other diseases including arthritis. Although less common, a person may have too little body fat. Since we need a certain amount of body fat (called essential fat) to maintain normal body functions, older men and women with too little fat may also be at risk for health problems.

The bone density test you had during your most recent Health ABC visit also allowed us to measure your percentage of body fat. It is important to measure percent fat in addition to weight alone since *it is the composition of the weight that may be important and not weight alone*. Your body fat percentage is marked below. There is no exact level of percent body fat that is definitely associated with risk of health problems or disability among all older adults. As a participant in Health ABC, you are helping us to determine what percentage of body fat either maintains or improves health as we age or increases the risk for poor health or disability as we age.

Your Percent Body Fat: _____ %

Appendix E. Whole Body Phantom Protocol

WHOLE BODY PHANTOM PROTOCOL

I. Phantom Assembly

Before lifting or transporting the phantom, break it down into its individual components. Use care, the impact force of a phantom component dropped from table height can cause severe injury, particularly if the impact is delivered through one of the phantom's beveled edges. Having another person help move the phantom components is strongly recommended.

A thin, gray PVC sheet is attached to the large white plastic piece that contains the two plastic locating pins. This HDPE/PVC combination is the bottom layer (base) of the phantom. Position it on the scanner table such that the PVC is on the bottom (i.e. the gray PVC is in contact with the table pad and the two plastic locating pins project out of the plane of the table towards the ceiling).

Place the second large white plastic piece on top of the phantom base, using the locating pins as a guide. The second piece should be placed such that the beveled edge forms a "V" with the base.

Next, place the medium size white plastic pieces on the phantom, again forming a "V" with the two beveled edges of the middle pieces. Then place the small white plastic pieces on top, forming another "V" with the small pieces. The final assembly will form a pyramid (see Figure 1, side view). This is the only valid configuration for the phantom measurement. All other configurations including adding materials to the phantom, removing pieces of the phantom, scanning the phantom upside down, etc. violate the intended use of the phantom and may produce invalid results.

II. Phantom Positioning

Make sure your table pad is centered to the table. There is a screw at the top and bottom of the table that indicates the middle of the table top. The center line of your table pad should line up with this screw at both ends of the table. Tighten the table pad down using the Velcro strips on the table pad. **Center the table.** Position the whole body phantom in the center of the scanner table using the laser light. The head of the phantom should be oriented towards the head of the table. Carefully position the phantom parallel with the long axis of the table, using the table pad markings as a guide. You can check your alignment by running the laser light along one of the sides of the phantom. When properly centered, there will be an equal amount of space on either side of the phantom. (See Figure 1.)

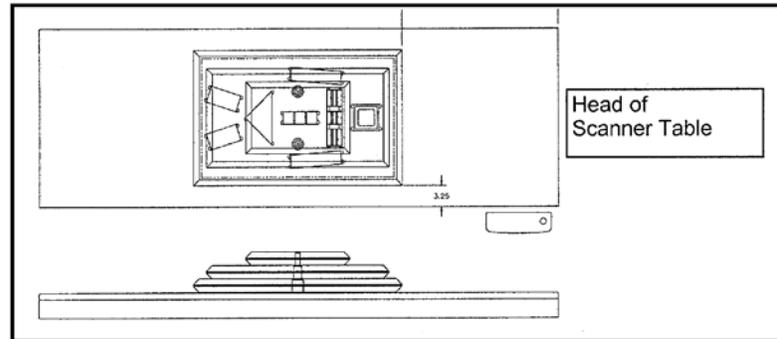


Figure 1. Layout of Whole Body Phantom positioned on the scanner table. Also shown, the fully assembled phantom viewed from the side. (Note that the amount of empty space between the side of the phantom and the sides of the table will vary depending upon scanner model). This is assuming your table pad is mounted and centered properly.

III. Data acquisition - Scanning the whole body phantom

1. Make sure that the phantom is centered, is parallel to the long axis of the table and is correctly oriented with respect to the head of the table.
2. Check the table pad. Moving the phantom onto the table may have shifted the table pad since it is secured only by the Velcro strips on each side. There is a screw at the top and bottom of the table that indicates the middle of the table top. Make sure the center line of your table pad lines up with this screw at both ends of the table. Tighten the table pad down using the Velcro strips on the table pad if needed.
3. If you have an existing Hologic biography for this particular phantom, please do not create another biography. The following information should be in the biography:
Last Name: Whole Body Phantom #1041. Patient ID: Enter 1041. Referring Physician: Study Name. Sex: Female. Ethnicity: White.
4. Remove all artifacts from the table surface. Extraneous objects in the scan field will interfere with the measured results in an unpredictable fashion.
5. Select Whole Body scan mode. Accept the default scan length.
6. Enter your initials as the operator performing the scans.
7. Carefully inspect the scan image to ensure that the phantom was centered, parallel to the long axis of the scanner table and the phantom's head appears at the top of the image. If not, carefully reposition the phantom according to the instructions in Section II and repeat the scan.
8. Scan the phantom four (4) times a day for the first week (20 scans). This will allow the setting of a consistent mean for monitoring performance and comparison purposes. Note that the whole body phantom scans can NOT be added to the QC

database. The QA Center will plot and check the data and notify the clinical centers of any problems.

9. After the first 20 scans are performed, scan the phantom three times a week.

IV. Analysis

A. General Comments

The goal of the analysis is to carefully delineate the various body regions in a standard and reproducible fashion, so that measured results will reflect instrument performance, not variations in analysis techniques. Of particular importance are the placement of the head ROI cutline and the cutlines that delineate the ribs, since these two regions affect global body composition and BMD. It is essential that the baseline measurement is technically adequate and that the analysis is performed by direct comparison to the baseline scan.

IMPORTANT NOTES: Please reference the example scan given. There should be zero values for the arms. If there are values in these fields after you have analyzed your follow up scan using the Compare Feature, the phantom may not be positioned correctly. The phantom is probably crooked on the table. You should rescan the phantom after repositioning. If the problem persists, you may adjust the cutlines to render the desired results and flag the scan to our attention.

All future whole body phantom measurements will be compared to the initial baseline measurement. Archive Whole Body Phantom scans to both the clinic and traveling archive media, then delete the scans from the hard drive.

V. Interpretation of measured values

The phantom measurements should be printed out, placed in a logbook/file and kept at the clinic center. The QA Center will plot selected variables periodically from the scans sent on the traveling archive media and notify the clinic center of any problems.

Example Whole Body Phantom Scan.

Note that all cut lines are within the boundaries of the phantom plastic.

Name: WB phantom #1111	Sex: Female	Height:
Patient ID: 1111	Ethnicity: White	Weight:
DOB:		Age:

Referring Physician:

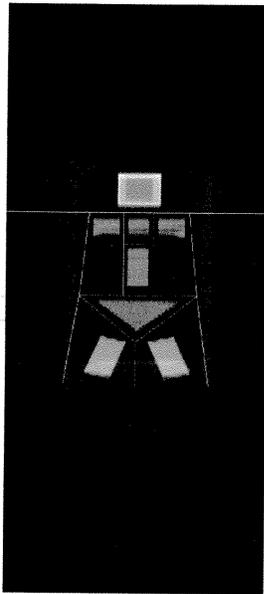


Image not for diagnostic use
327 x 150

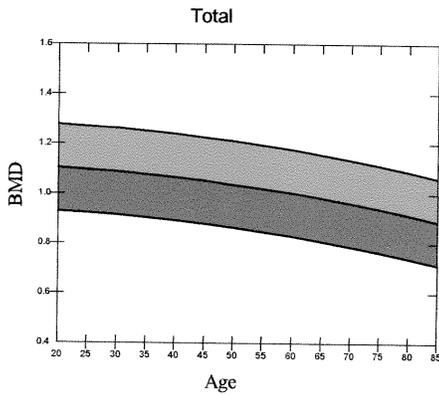
Scan Information:

Scan Date: November 05, 2004 ID: A11050409
 Scan Type: a Whole Body
 Analysis: November 05, 2004 15:12 Version 11.2
 Whole Body Fan Beam
 Operator:
 Model: Delphi A (S/N 70461)
 Comment:

DXA Results Summary:

Region	Area (cm ²)	BMC (g)	BMD (g/cm ²)	T - score	PR (%)	Z - score	AM (%)
L Arm	0.00	0.00	0.000				
R Arm	0.00	0.00	0.000				
L Ribs	43.98	38.14	0.867				
R Ribs	47.15	39.75	0.843				
T Spine	32.09	29.61	0.923				
L Spine	71.32	77.93	1.093				
Pelvis	129.17	97.19	0.752				
L Leg	91.93	124.16	1.351				
R Leg	91.53	121.45	1.327				
Subtotal	507.18	528.23	1.042				
Head	132.34	202.66	1.531				
Total	639.52	730.89	1.143			104	

Total BMD CV 1.0%



T-score vs. White Female; Z-score vs. White Female. Source:Hologic

Physician's Comment:

HOLOGIC®