

MrOS Sleep Study
DXA Quality Assurance Manual
for
Hologic QDR-4500
Bone Densitometers

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Departments of Epidemiology and Biostatistics, and Medicine
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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 clinical centers participating in the MrOS Sleep study. It provides information specific to the Hologic QDR 4500W 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 User's 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:

Russell Scott
MrOS Quality Assurance Center
University of California, San Francisco
74 New Montgomery St., Suite 600
San Francisco, CA 94105

Telephone: (415) 597-9312
Fax: (415) 597-9213

IMPORTANT: Unauthorized changes in scanner model, 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

Densitometry measurements will be acquired at the Sleep Visit. Bone mineral density scans will be performed at the Hip and Whole Body. **Note: PA Spine scans will not be done at this visit.** Sleep Visit scans will be compared to the MrOS Baseline visit for positioning, analysis, and Excessive Bone Loss at the Hip.

2.1 Division of Quality Assurance Responsibilities

2.1.1 Clinical center responsibilities

The clinical centers 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 operators are properly trained and certified. If there are State requirements for DXA operators, these must be met;
2. Identify a chief densitometry operator to train and supervise other operators;
3. Perform and review daily QC scans and scheduled cross-calibration scans of traveling phantoms;
4. Assure that proper archiving and back-up procedures for participant scans are performed and that archives are stored securely on appropriate archiving media until the end of the study;
5. Once a month, on or about the 15th, send the following materials to the QA 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. Traveling optical disk with all newly acquired scan files obtained since the last data transfer
6. Reanalyze centrally reviewed scans, as requested by the QA Center;
7. Assure proper functioning of hardware/software and request service from Hologic;

- a. Notify Hologic and the QA Center of any machine or software problems or if the QDR machine is being relocated
 - b. Record machine/software problems and service on the Hologic Repair/Service/Upgrade Log
 - c. Perform 10 QC phantom scans before (if possible) and after service
 - d. Perform 10 QC phantom scans before and after machine relocation
8. Contact the QA Center with any questions or problems that cannot be dealt with in the monthly batch mailings.
 9. Send a complete dBarchive at the end of each visit (ie., end of Sleep Visit after all participants have been scanned).

2.1.2 MrOS Quality Assurance Center responsibilities

The following are the responsibilities of the QA Center:

1. Write and maintain the quality assurance manual;
2. Promptly review the QC phantom scan data received from each 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 each clinical center;
5. Request and review random samples of scans from each clinical center;
6. Arrange for cross-calibration of all DXA instruments using traveling phantoms;
7. Prepare quality control summary reports for MrOS Steering Committee review;
8. Identify possible sources of error, and suggest possible solutions. (**However, the QA Center will not be responsible for the solution of a hardware or software problem; that will rest with the clinical center and Hologic.**)
9. Review and evaluate special purpose phantom scans;

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

Russell Scott

MrOS Quality Assurance Center

UCSF Prevention Sciences Group

74 New Montgomery, Suite 600

San Francisco, CA 94105

Phone: (415) 597-9312 FAX: (415) 597-9213

2.2 Training and Certification of MrOS DXA Operators

Note: All new operators will be certified for the MrOS Sleep study to ensure they are following proper follow-up scan procedures. If an operator has previously been certified for the MrOS baseline visit or the MrOS Dental study, recertification is not necessary.

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 QA Center review are allowed to perform the scanning and analysis for this study.

Anyone performing scans for the MrOS study must meet the following requirements:

1. Read and understand both the Hologic QDR4500 manual and this manual;
2. Successfully complete a Hologic QDR4500 training course ;
3. Satisfactory review of each operator's initial scans by the QA Center.

In order for an individual operator to be certified to perform scans of a given skeletal site, the first 10 followup scans done on study participants at each skeletal site for each operator must be sent to the QA Center for review. Printouts of the corresponding Baseline scans must accompany the followup scans. Printouts of the scans should be sent to the QA Center at the address listed above as soon as the first 10 followup scans have been completed.

It is the clinical center's responsibility to ensure that all of the above certification criteria are met as new operators are brought into the study. Since the Hologic central training sessions are held infrequently, there may be several months delay between when a new operator is hired and when certification is complete.

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

2.3 Review of DXA Scans

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

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

Procedures for compiling and forwarding scans to the QA Center are outlined in Section 5.

2.3.1 Flagged Scans

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

Flagged scans should be sent to the QA Center monthly. Note the reason(s) for flagging on the MrOS Participant Scan Log and on the original printout, for clarification of the problem. If the problem involves comparison to the Baseline scan, include a copy of the Baseline scan.

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

2.3.2 Random Sample and Outlier Checks

Periodically during the study, a random sample of scans and scans with exceptionally high or low BMD (outliers) will be reviewed by the QA Center. In the initial phases of the study, a relatively large number of scans will be checked to verify site performance. These checks may result in requests for reanalysis by the QA Center.

3.0 DXA Scan Acquisition and Analysis

Standard scanning and analysis procedures for the hip and whole body 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 manual for emphasis. Please note, however, that some of the scanning evaluation protocols for this study differ from those detailed by Hologic.

Use the same scan mode (eg., fast array or array) as was used on the Baseline scan.

3.1 Participant data

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

The MrOS DXA Worksheet (see Appendix B) should be completed before scanning the participant. The Worksheet is filed in the binder at the clinic. It is not sent or faxed to the MrOS Coordinating Center.

Completely fill out the MrOS DXA Bone Density Form (teleform) (see Appendix B) after scanning the participant. This form is returned to the Study Coordinator for faxing to the MrOS Coordinating Center.

3.1.1 Patient Biography

Use the Patient Biography that was created for the MrOS Baseline scans. Do not create a new Biography for the Sleep study. In the rare case that the Baseline biography is not available, use the information on the Baseline scan printout to recreate the Name, Pat ID, DOB, Sex, Ethnic, and Ref MD fields exactly.

At the Sleep Visit the following Biography fields should be updated as shown before scanning (see Figure 1):

Comment: Sleep

Scan Code: [Enter the MrOS staff ID of the operator performing the scans.]

Weight: [Measure the participant's weight and enter. Do not presume the weight has not changed since Baseline.]

Height: [Measure the participant's height and enter. Do not presume the height has not changed since Baseline.]

Be sure to use the numbers zero (0) and one (1), not the letters "O" and "I" when entering numerical data into the Patient Biography fields and vice versa.

Figure 1. MrOS Sleep Study Patient Biography Screen

Patient Biography Information

Name: SMITH, JOHN

Soc Sec:

Pat ID:BI1301

Comment: Sleep

Scan Code: B03

Zip:

DOB: 10/20/30

Sex: M

Weight: 160

Height: 5' 9"

Ethnic: W

Ref MD: MrOS

3.2 Hip Scans

3.2.1. Hip Acquisition

Followup

1. Refer to the Baseline hip scan printout. Use the DXA Worksheet (see Appendix B) to determine and document which side to scan. The participant can be in the Sleep study even if the hip can not be scanned. Store the DXA Worksheet in the participant's clinic binder; do not send to the QA center. If the opposite hip from Baseline must be scanned, perform the acquisition and analysis according to the Baseline MrOS DXA operations manual, version 1.50.
2. Refer to the Baseline hip scan printout. Position the hip in exactly the same position as Baseline (even if the Baseline positioning was not optimal). In particular the hip rotation must be the same. The best way to check hip rotation is to be sure that the lesser trochanter has the same size, shape, and location on the followup scan as at Baseline.
3. **If it is impossible to reproduce the positioning from Baseline** (eg., pain, worsening arthritis), produce the best possible scan. **Flag** the followup scan, write the problem on the scan printout and send copies of both the Baseline and followup scan to the QA center.
4. Refer to the Baseline hip scan printout. **Use the same scan mode (eg., fast array or array) as was used on the Baseline scan.**
5. 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.
6. Keep the participant's hands out of the scanning area by placing them well away from the hips.
7. Ensure rotation of the hip by holding the knee and the ankle when positioning the leg. Optimum positioning of the leg is most important to achieve a consistent projection of the femur.

8. After proper rotation attach the leg to be scanned to the angled foot block supplied by the manufacturer.
9. 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 of the leg not being scanned. Maintain the participant at a comfortable body temperature for the duration of the scan.
10. 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.
11. Print out a hard copy of each scan and file in the participant's folder.

3.2.2. Hip Analysis

Followup

Load the Baseline scan onto the hard disk. Display this Baseline evaluation using the COMPARE feature along with the current scan to be analyzed. It is important to realize that proper comparison of a followup hip scan to its Baseline depends upon maintaining the identical size and relative position of the region markers. Vertical or horizontal shifts of these regions by one or more pixels can greatly alter the final values of the analysis.

Global Region of Interest

1. The width and height of the global ROI must be the same as that used on the Baseline.
2. The dotted lines from the Baseline defining the bone region should overlay the followup as closely as possible. Occasionally there are small changes in adduction and rotation of the leg that were not eliminated by rescanning. The region surrounding the neck should have the best fit.
3. If the global ROI cannot be moved to the appropriate position because it is too large, the Baseline scan will have to be reanalyzed with a properly reduced global ROI. Then the followup should be analyzed comparing it to the

reanalyzed version of the Baseline. **Flag** cases in which the Baseline had to be reanalyzed.

4. Use **<Control>** **<End>** to accept the global ROI and bone mask.

Bone Edges If the bone edges do not fill in properly on the followup analysis, first the Baseline will have to be reanalyzed with a larger ROI, and then proceed with the comparison scan analysis.

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 followup 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 you have made changes 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 QA Center.

Femoral Neck Box If the current location is optimally matched to the location of the neck box of the Baseline analysis, use it unchanged.

1. If the current location is not optimally matched to the location of the neck box on the Baseline, adjust the current region to achieve maximum correspondence. The size of the neck box must be the same on both Baseline and followup.
2. If the current location cannot be satisfactorily adjusted while maintaining the same sized neck box, reanalyze the Baseline within the constraints outlined above.
3. It is most important to have the neck box location and size correspond as closely as possible. If you cannot get the neck boxes to match, **flag** the scan for review by the QA Center.

Ward's Triangle If the Ward's triangle box appears on the followup scan in a significantly different position than on the Baseline, or if after reanalysis of the Baseline its location is different than that of the original Baseline placement, flag the scan for review by the QA Center.

Trochanteric Line The trochanteric line should intercept the bone edge at the same point on all scans. Matching is easily done during the compare analysis, especially since you will have the Baseline to consult during the compare.

3.3 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 MrOS Study are noted below.

3.3.1 Whole Body Acquisition

Followup

Before scanning the participant have a printout of the Baseline scan available. Refer to the Baseline printout for positioning of the participant; 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.

Use the DXA Worksheet (see Appendix B) to determine and document artifacts. Store the DXA Worksheet in the participant's clinic binder; do not send to the QA center.

The participant can be in the Sleep Study even if the whole body cannot be scanned.

The following points should be followed when possible. However, repositioning the same as Baseline always takes precedence:

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, snaps, zippers and buttons. Have participant 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. If the hands do not fit in the scan field, tuck the hands under the thighs.
3. Place a loop of tape around the top of the feet so that the feet are slightly inverted - this will help to prevent motion during the scan and create a separation between the tibia and fibula. If the feet do not fit in the scan field, keep the legs straight and cut the feet from the scan field.

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 feels uncomfortable in that 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 radio-lucent pillow.
 6. 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.
1. Instruct the participant not to move until the end of the measurement.
 2. Print out a hard copy of each scan and file in the participant's folder.

3.3.2 Whole Body Analysis

Followup

Display the Baseline evaluation 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.

If adjustment cannot be done satisfactorily, it will be necessary to reanalyze the Baseline scan. If it is necessary to reanalyze the Baseline measurement, all subsequent followup measurements should be reanalyzed using COMPARE.

3.4 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
 - Superimposed buttons, pins, zippers, pacemakers, vitamin pills, etc.
- ROI used on followup is different size than used at Baseline
- Bone edges have been altered in any way
- Followup scans cannot be reasonably matched to Baseline analysis

Hips

- Femoral midline is not aligned and cannot be corrected by following the analysis procedures as outlined in the MrOS manual
- Neck box width reduced from default
- Ward's triangle persistently located outside of Ward's region - difficulties in redefining search region
- Analysis program repeatedly fails to place regions appropriately - major operator interaction required for analysis

Whole Body

- Participant motion without rescanning (these scans are extremely susceptible to motion artifacts)
- Significant changes in positioning between Baseline and followup scan.

- Unable to fit both arms in scan field

3.5 Excessive Bone Loss Procedures

Excessive Bone Loss (EBL) is defined in Table 1. Use the Hologic Rate-of-Change plots to determine the **actual** (not annualized) percent loss between the Baseline and Sleep Visit.

For **DOS based software** (this software is in use at the beginning of the Sleep Visit): Do **NOT** use the first Rate-of-Change plot that appears; this is annualized. Instead hit Home key to get the actual Rate-of-Change.

For **Windows based software**: This software does not have annualized rate of change. Use the BMD Change vs. Baseline percent change; this will be the actual rate of change.

Table 1. EBL Criteria

Followup Time Point	<u>Actual</u> Rate of Change for Total Hip BMD Compared to Baseline
Sleep Visit	See the MrOS Sleep EBL Schedule since cut-off value depends on actual follow-up length since baseline

If EBL is found, rescan by having the participant get off and on the table, repeat the positioning and scanning / analysis, and check again for EBL. **This will necessitate analyzing the followup scans while the participant is still on the scan table.**

Whether or not the second scan confirms EBL, fill out the “Excessive Bone Loss Form” (see Appendix B) and follow the directions for sending documentation to the QA Center. The QA Center will confirm EBL and return the form to the clinical center. At that time the clinical center staff can provide the participant and his physician with the appropriate MrOS Sample Excessive Bone Loss letter (see Appendix B). These letters can be altered by the Principal Investigator as desired.

Do not discuss the presence or implication of EBL with a participant until the QA Center has confirmed that the bone loss is real. Do not inform the clinic coordinator that EBL is suspected until the QA Center has confirmed it.

4.0 Scanner Quality Control

Monitoring of machine performance throughout the study is the joint responsibility of the clinical centers and the QA Center. The following table lists the quality control procedures and schedule. Although spine scans will not be done at the Sleep visit, for quality control purposes, please continue to follow the spine phantom QC procedures explained below.

Table 2. Quality Control Scanning Schedule

Phantom	Scanning frequency
Local Hologic Tissue Bar	1 time/week
Local Hologic Spine Phantom	Daily (at least 3 times/week and always on a day a participant is scanned.)
Local Hologic Hip Phantom	2 times/week
Local Hologic Whole Body Phantom	3 times/week
Whole Body Air Scan	1 time/week
Hologic “Gold Standard” Hip, Spine and Block phantoms	To Be Determined

4.1 Phantom Scans

Perform the spine and hip QC phantom scans as outlined in the Hologic manual, Quality Control Chapter. **Be sure to scan the hip phantom in Array mode, not the default Fast Array mode** (Fast Array hip scans cannot be added to the QC database). The results of these scans should be reviewed locally for abrupt changes in machine performance and the results sent to QA Center once a month.

Whole body quality control consists of Hologic whole body phantom scans, whole body air scans, and tissue bar scans. The Hologic whole body phantom comes with instructions from Hologic and there are supplemental instructions in Appendix A. The instructions for the whole body air scans are in section 4.2 of this manual. The tissue bar comes with instructions from Hologic.

Points of procedure to note:

1. Create only one patient biography per phantom. There should be a biography for the Spine, Hip and Whole Body phantoms. Avoid duplication of phantom biographies by using the patient menu to select the appropriate biography prior to scanning the phantom.
2. Use the following instructions to create the phantom biographies. The phantom serial number is on the phantom label. It may have letters in front of the numbers. If this is a new biography, put in both letters and numbers. If you are checking an existing biography that only contains the numbers, that is acceptable. If an existing biography contains a site identifier, that is acceptable, but new biographies will not have a site identifier.

The NAME field contains the type of phantom and the phantom serial number (indicated by XXXX):

Spine Phantom #XXXX

Hip Phantom #XXXX

Whole Body Phantom #XXXX

The PAT ID field contains the phantom serial number (indicated by XXXX):
#XXXX

3. Scan each phantom on top of the pad. Ensure alignment with the scanner axis by using the laser cross - hairs.
4. Add the spine and hip phantom scan data to the QC database immediately after completing scanning and analysis. See the Hologic manual, Quality Control Chapter, section "Adding Data to QC Database". Note: the Whole Body phantom and Whole Body Air scan data can not be added to the QC database.
5. To start using the hip phantom, scan the phantom four times a day for five days (20 scans). **Be sure to scan the hip phantom in Array mode, not the default Fast Array mode** (Fast Array hip scans cannot be added to the QC database). See the Hologic manual, Quality Control Chapter, section "Setting Up a New QC Plot (Graphs)". Follow the directions to set up the mean and limit lines for the hip QC plot. After the set up is done, scan the hip phantom two times a week.

6. Use the plot feature to verify that the spine and hip phantom BMD, BMC and AREA values of your scanner are within normal limits. It is best to plot at least one year of data. 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 and/or the CV of the BMD exceeds 0.60%, contact both Hologic and the QA Center.
7. After the spine and hip phantom scans have been analyzed and added to the QC database, delete the scans from the hard drive. Note: the Whole Body phantom scans should be archived to the clinic optical and copied to the traveling optical disks before being deleted from the hard drive.
8. Check the system drift weekly by pressing <R> while viewing the plot. 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 QA Center.
9. Generate a printout of the daily phantom plots (BMD, BMC and AREA for hip and spine) once a week on your designated "QC day." This will facilitate detection of long-term drifts as well as short-term inconsistencies. Store these plots in a QC log book.
10. Original printouts including the scan results of the most recent phantom QC plots (BMD, BMC and AREA for hip and spine) are to be sent to the QA Center for review monthly. The date range for the plots should cover the previous 12 months to the present.
11. Perform a dBarchive at least once a week and store at the clinical site. Disks may be rotated monthly.
12. Follow these procedures for the Whole Body phantom:

Scan and analyze the phantom three times a week according to the instructions provided by Hologic and Appendix A of this manual.

COPY the whole body phantom scans to the traveling optical disk, then ARCHIVE to the clinic optical before deleting scans from the hard drive.

The QA Center will retrieve the scans from the traveling optical, plot the desired variables, and notify the clinical centers of any problems.

4.2 Whole Body Air Scan for the QDR 4500

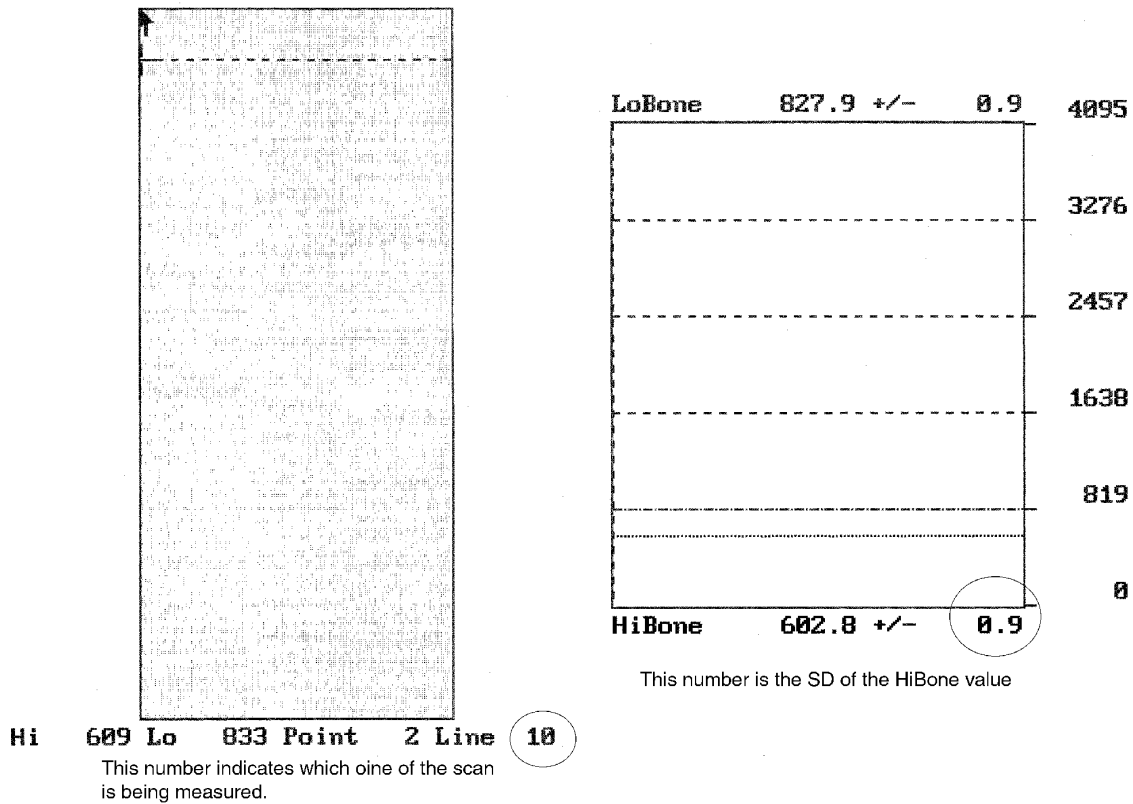
DOS Based Software

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 with **WB AIR QC SCAN** in the Name field. Enter the **system** serial number in the Pat ID field. Leave the remaining fields blank. Press <F10> when completed. Please be certain to use this biography for all future WB air scans.
3. Perform a scan by choosing “whole body” from the Scan menu. Scan the entire length of the table. Do not interrupt the scan; perform a complete scan.
4. 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.

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.



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 following page. Please make photocopies of the blank worksheet for your use.

**WHOLE BODY AIR QC SCAN
WORKSHEET**

Clinical Center:

Serial Number:

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:

5. Press the <ALT><PRINTSCREEN> keys to obtain a hard copy of the plotted data. If this does not work on your scanner, do not print the data. COPY the WB AIR QC SCAN to your traveling optical and archive to the clinic opticals. Delete the air scan from your hard disk.

6. **IMPORTANT:** In the event that the SD exceeds the limit of 2.0 units, immediately fax the worksheet to Lisa Jones at Hologic (FAX 781/ 280 – 0614) and to Bonnie Blunt at UCSF (FAX 415/ 597 – 9213).

4.3 Cross-Calibration of Scanners

In order to assess accurately the absolute variations in scanner performance between clinical centers, periodically throughout the study phantoms will be either mailed or brought to each of the field centers and scanned. The Hologic hip, spine and block phantoms will be used. A detailed protocol will accompany the phantoms.

4.4 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 dBarchive before any work is done on your QDR.
2. If possible, contact the QA Center before the repairs or adjustments are made to find out whether additional measures are required.
3. Perform 10 scans of the Hologic daily QC spine phantom before (if possible) and after the repairs or adjustments are made.
4. Perform 10 scans of the Hologic daily QC hip phantom before (if possible) and after the repairs or adjustments are made.
5. Send the repair technician's notes and a copy of the completed Hologic Repair/Service/Upgrade Log to the QA Center with the monthly data transfer. The log should contain complete information on all repairs and upgrades done on your machine. Please keep a repair log with your machine.

4.5 Hardware/Software Change Control

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

Future hardware/software upgrades will be checked by the QA Center in conjunction with Hologic technical support personnel to assure that the upgrade will not

adversely affect the study. Authorized upgrades must be cleared by the QA Center before installation at the clinical centers.

Record hardware/software upgrades on the Hologic Repair/Service/Upgrade Log.

5.0 Data Management

5.1 Hard Copies of Scans

The clinical center 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 reports are needed for each scan:

Hip: Print the standard report.

PA Spine: Print the standard report.

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

5.2 Electronic Scan Archive

Each clinical center works on a four optical disk system, two clinic opticals and two traveling opticals. Both clinic optical disks and one traveling optical are updated at the end of each day. The other traveling optical may be in transit between the QA Center and clinical center. Please be sure to re-archive any scans that you reanalyze after you have completed the reanalysis. In order to use the optical disks efficiently, do not save or archive scans individually. Saving scans in batches (e.g. at the end of a day) will ensure the longevity and efficient usage of the optical disk space. The QDR software will give a warning message when optical capacity has been reached. Fill side A of the disk first, then fill side B. (See the Hologic User's Manual for detailed instructions.). One clinic optical should be a dedicated MrOS optical, used only for archiving scans acquired for MrOS.

Scans to be archived **each day** to the clinic opticals and traveling optical disks include:

1. All new participant scans acquired since the last archive was performed;
2. All scans that have been reanalyzed since the last archive. Note that if a scan needs to be restored and reanalyzed for any reason, it will need to be re-archived.

Clinic opticals will remain at the clinical center at all times. The traveling opticals will be sent back and forth between the clinical center and the QA Center.

The clinical centers are responsible for following the archive schedule and for keeping the optical disk archives safe until the end of the study.

5.3 Transfer of Data to the MrOS Quality Assurance Center

The following items are to be sent to QA Center by the 15th of each month:

1. QC PRINTOUT. Send a printout of the most recent plots of the QC database (spine and hip - BMD, BMC and AREA). The plots are reviewed at the QA Center and problems are reported back to the clinic.
2. PARTICIPANT SCAN LOG. Send a copy of the written participant scan log covering participants scanned since the last data transfer. Use the log sheets to “flag” individual scans for review at the QA Center.
3. SCANS FOR REVIEW. Send original printouts of certification scans, “flagged” scans, random sample scans, and any scans requested for review by the QA Center. Please write directly on the printout the reason the scan was flagged, requested or being sent. These scans will be triaged visually based on the original printouts and analyzed on the Hologic workstation if necessary.
4. TRAVELING OPTICAL DISK. Send electronic copies of all scans acquired and reanalyzed since the last data transfer. Archive scans using the <COPY> feature. Do not archive the scans individually, as this will use up the disk space rapidly.
5. REANALYZED SCANS. Send original printouts of all scans that have been reanalyzed according to the QA Center instructions since the last data transfer. Attach the annotated printouts sent by the QA Center that indicated the problems requiring reanalysis. You MUST also send back the reanalyzed scan images on the traveling optical.
6. Copy of the Hologic Repair/Service/Upgrade Log (with a copy of the Hologic service report), if service has been done.

7. **DBARCHIVE. An archive of the participant database (dBarchive) will be sent at the end of each visit (ie. after the last participant has been scanned at the Sleep Visit).**

Please include the following on the disk label:

“MrOS Sleep DB ARCHIVE”

Batch #

Clinic name

Date of Archive

If more than 1 disk, label each disk as above and 1 of 3, 2 of 3, etc.

Diskette Label for DB Archive

MrOS
DB Archive
Date _____
Clinic _____
Batch # _____
Diskette No. ____ of ____

Please note: The QA Center will use the most recent scan data for participants whenever there are multiple analyzed scans from the same date in the data base. Please notify us if there are exceptions to this.

Pack the materials carefully. The optical disk should be placed in a plastic bag and then wrapped in plastic bubble wrap to avoid damage. Batches containing the optical disk should be send via FedEx/UPS.

Assign a number to each batch of BMD data, beginning with the first batch of BMD materials sent. Start with batch number 001. The batch number should be the clinic identifier followed by this 3-digit number. Thus the batch number should be a 5-digit field: e.g. for the Portland clinic, batch number 1, the number should be PO001.

Complete a BMD Batch Checklist, indicating the number and which materials are included in the batch, and send it along with the batch materials.

The materials in the batch should be bundled separately by type.

Ship these items monthly to the following address (be sure to include a person's name in the address):

Russell Scott
MrOS Quality Assurance Center
UCSF Prevention Sciences
74 New Montgomery, Suite 600
San Francisco, CA 94105
Phone: 415-597-9312

5.4 Return Materials Sent by the MrOS Quality Assurance Center

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

1. Annotated printouts of flagged scans, random sample scans, and any other requested scans are returned to the clinical center with explicit instructions for reanalysis, as necessary. The clinic then reanalyzes the problem scans according to the QA Center's recommendations. The reanalyzed scan is then saved and re-archived and the database at the clinical center is automatically updated. An original printout of the reanalyzed scan is sent to the QA Center with the next data transfer to verify compliance.
2. Traveling optical.
3. Any recommendations for service, additional phantom scans, etc., as necessary based on the quality control data.

Appendix A.

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

Carefully position the whole body phantom in the center of the scanner table with the head of the phantom at the head of the table. Allow 24" (61cm) of empty air space at 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. When properly centered, there will be a constant 3.5" (8.9 cm) gap between the side of the phantom and the front and back limits of the QDR 4500 scanner table (see Figure 1).

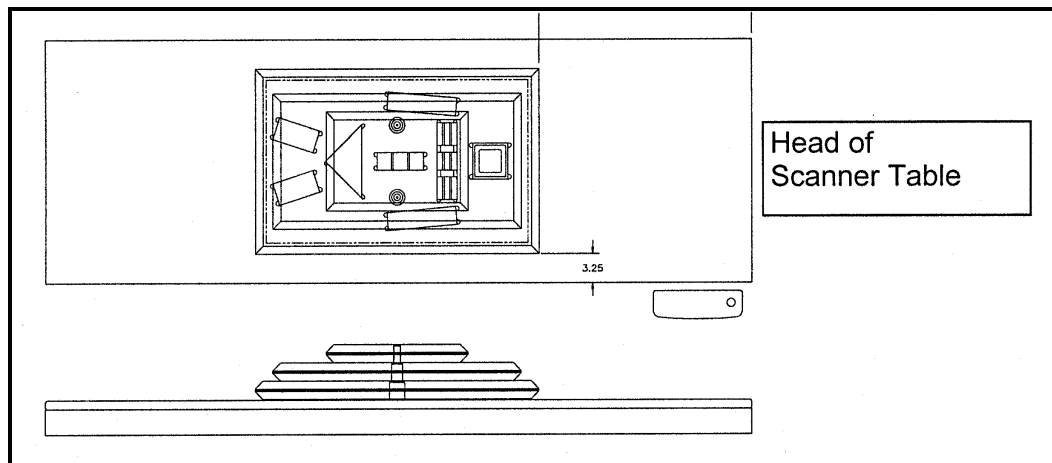


Figure 1. Layout of Whole Body Phantom positioned on the QDR 4500 scanner table. Also shown, the fully assembled phantom viewed from the side. (Note that the amount of empty space between the side of the phantom and the sides of the table will vary depending upon scanner model).

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. Enter **Whole Body Phantom #xxxx** in the Name field of the Patient Biography (where **xxxx** is the phantom serial number, including any letters, found on the phantom label). Enter **#xxxx** in the Pat ID field of the Patient Biography (where **xxxx** is the phantom serial number, including any letters, found on the phantom label).
3. Remove all artifacts from the table surface. Extraneous objects in the scan field will interfere with the measured results in an unpredictable fashion.
4. Select the standard Adult Whole Body scan mode commonly employed at your facility. Accept the default scan length and scan width. Perform a complete scan of the entire table surface including the phantom. Do not interrupt the scanner during the measurement.
5. Carefully inspect the scan image to ensure that the phantom was (i) centered, (ii) parallel to the long axis of the scanner table and (iii) the phantom's head appears at the top of the image. If the scan image appears satisfactory, proceed to the analysis section. If not, carefully reposition the phantom according to the instructions in Section II and repeat the scan.
6. After receipt of the whole body phantom, 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.

7. 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 outline and the outlines 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 sample analysis on the Hologic diskette labeled: "SAMPLE ANALYSES: WB PHANTOM" or "Whole Body Phantom Analysis Template". Use the sample scan for your model of scanner (see Table 1).

B. Specific Instructions - Hologic QDR systems

Follow the instructions in Sections II and III of Appendix A to acquire a technically adequate scan of the Whole Body phantom. Restore the appropriate scan from the Hologic diskette labeled "SAMPLE ANALYSES: WB PHANTOM" or "Whole Body Phantom Analysis Template" to the analysis workstation (see Table 1 for the correct scan to restore for your QDR model). Select the newly acquired WB Phantom scan. Then use the Compare feature to register the ROI outlines of the sample scan to the newly acquired scan of the WB Phantom. Once the ROI's have been matched as nearly as possible, complete the analysis and print the first and last pages of the report.

Archive the baseline measurement for safekeeping but do not delete it from the analysis workstation. All future whole body phantom measurements will be compared to the initial baseline measurement. After the initial measurement, the sample scan restored from the sample diskette should be deleted. Archive Whole Body Phantom scans to both the clinic and traveling opticals, then delete the scans from the hard drive.

QDR MODEL NUMBER	WB PHANTOM SCAN (RESTORE FROM SAMPLE DISK)
1000W, 1500, 2000 Pencil beam	1000/1500/2000 Pencil WB Phantom
2000 Fan Beam	2000 Fan WB Phantom

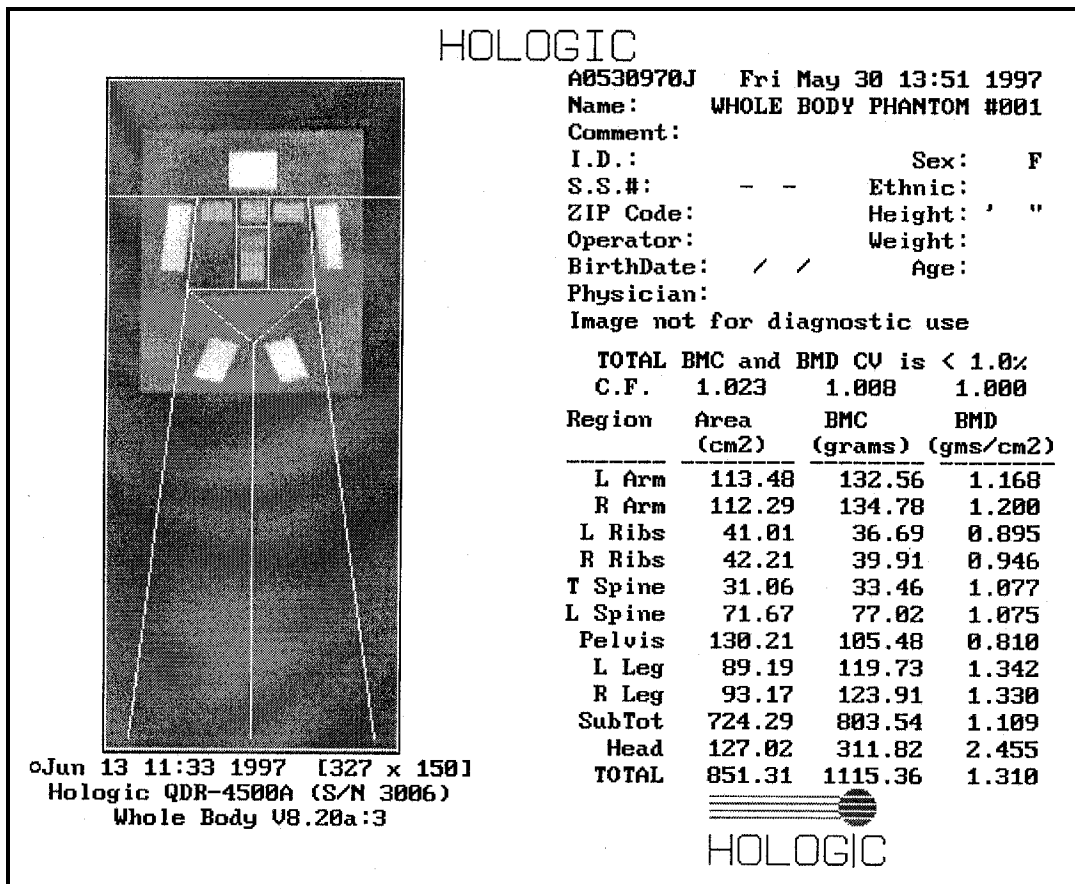
4500W	4500W WB Phantom
4500A	4500A WB Phantom

Table 1. Scans to restore for a given QDR model number.

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 optical and notify the clinic center of any problems.

Please note a correction to the Biography in the following printout. The phantom serial number should be in the ID field: I.D.: #001



**APPENDIX B.
STUDY FORMS**

The following forms are included in this Appendix:

MrOS DXA Worksheet (Download form from the MrOS website.)

MrOS Sleep DXA Bone Density Form (Do NOT photocopy. Download form from the MrOS website.)

DXA Participant Scan Log (Photocopy as needed)

DXA Batch Record Form (Photocopy as needed)

Hologic DXA Repair/Service/Upgrade Log (Photocopy as needed)

Whole Body Air QC Scan Worksheet (Photocopy as needed)

Excessive Bone Loss Form (Photocopy as needed)

Sample Excessive Bone Loss Letters for participant and MD (may be edited at the PI's discretion)

Confirmation of DXA Tech Certification (For QA Center use only)

Master copies of the forms are provided in this manual. Photocopy these forms at your clinical center as needed (except the MrOS Sleep DXA Bone Density Form). Always keep a copy of any form you send to the QA Center.

[Insert the *MrOS DXA Worksheet* (found on the MrOS web site)]

[Insert the *MrOS Sleep DXA Bone Density Form* (found on the MrOS web site)]

MrOS Sleep Study

Participant Scan Log

VISIT: SLEEP

CLINIC NAME: _____

Date	Participant ID	Acrostic	Scan Type	Scan ID	Flag ✓	Comments/Reason for Flag
			Whole Body Hip			
			Whole Body Hip			
			Whole Body Hip			
			Whole Body Hip			
			Whole Body Hip			
			Whole Body Hip			
			Whole Body Hip			
			Whole Body Hip			
			Whole Body Hip			
			Whole Body Hip			

MrOS Sleep Study DXA Batch Record Form

Batch Number: _____

Date Batch Mailed: _____

Clinic name: _____

Contents: (Check yes or no)

QC Plot Printouts Yes No
(hip and spine: BMD, BMC, Area)

Date
Printed: ____/____/____

Scan Log Sheet Yes No

Flagged Scans Yes No

Number: _____

Reanalyzed Scans Yes No

Number: _____

Other scans Yes No
(Please specify: _____)

Number: _____

Hologic Repair/Service/ Upgrade Log (include copy of
any paperwork from Hologic) Yes No

Traveling Optical Yes No

Certification Scans: Yes No

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

DB Archive Disk(s) Yes No Date archived: ____/____/____
(Send once at end of Sleep Visit after last participant is scanned or as requested)

Staff ID # _____ Initials _____

MrOS Sleep DXA Hologic Repair/Service/Upgrade Log

Date problem(s) encountered: ____/____/____

Clinic name: _____ Scanner serial #: _____

Describe problem: _____

Were there hardware/software changes or upgrades?

Yes, please describe: _____

Was the Hologic operational during the problem period?

Yes

No

Did the problem affect scans?

Yes

Please describe, including time period: _____

How long was the Hologic out of service?

_____ days

Describe the action taken: _____

Was the problem resolved?

Yes

—————> Explain: _____

Date problem resolved: ____/____/____

Please describe how the problem was resolved: _____

Was a recalibration of the Hologic necessary? **Yes**

Were phantom scans performed after the repair or recalibration?

Yes

Did you notice a change in the phantom values? **Yes**

**WHOLE BODY AIR QC SCAN
WORKSHEET**

Clinical Center:	Serial Number:
------------------	----------------

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:
-------	------------

MrOS

<u>Date</u>	<u>MrOS ID#</u>	<u>Acrostic</u>	<u>Staff ID #</u>

MrOS Excessive Bone Loss (EBL) Form

Be sure to follow all procedures for participants with suspected excessive bone loss.

Suspected Excessive Bone Loss checklist

Please make sure that this form is accompanied by all the items listed below for the hip with suspected excessive bone loss.

- Printouts of the screening (baseline) and **all** follow-up scans
- Printouts of the "rate of change" report(s)
- Copies of the screening (baseline) and **all** follow-up scans on floppy disk

Your Comments: _____

To be filled out by the QA Center

- Yes, we can confirm an excessive bone loss. The scans are technically correct and the analyses are performed appropriately.
- Yes, we can confirm an excessive bone loss. However, the scans were not analyzed properly. Please reanalyze the scan(s) following our instructions and inform the participant of the correct bone loss %.

For those with confirmed excessive bone loss:

TOTAL HIP BMD: Follow-up scan _____ Baseline _____
Actual % Change _____

- After scan review we cannot confirm an excessive bone loss.

Comments: _____

Signature of QA Center Reviewer _____ Date _____

Sample excessive bone loss alert letter for participant

[date]

[participant
address]

Dear Mr. Doe:

During your last clinic visit for the Mr.OS study, we repeated measurements of your hip bone density. Analysis of the results indicated that you have lost a significant amount of bone in the hip 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 copies of 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.

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

Sincerely,

Sample excessive bone loss alert letter for participant's MD

[date]

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

Dear Dr. Friedman:

Your patient, _____, who has been a participant in the Mr. OS study was here on ____/____/____. We have measured the bone mineral density of the hip with state-of-the-art densitometry machines at baseline and approximately 3 years later. The BMD scans of his total hip showed _____% bone loss. 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 and is adjusted for the actual length of time between the baseline and follow-up visit.

We are enclosing copies of the participant's scans and reference plots that show the bone loss to be _____ %.

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

Sincerely,

MrOS Sleep Study

CONFIRMATION OF DXA TECH CERTIFICATION

To be filled out by the Coordinating Center	
Clinic Site:	
Certification of technologist _____ # _____ confirmed after review by MrOS Coordinating Center.	
Date	Signature
Certification of technologist _____ # _____ confirmed after review by MrOS Coordinating Center.	
Date	Signature
Certification of technologist _____ # _____ confirmed after review by MrOS Coordinating Center.	
Date	Signature
Certification of technologist _____ # _____ confirmed after review by MrOS Coordinating Center.	
Date	Signature
Certification of technologist _____ # _____ confirmed after review by MrOS Coordinating Center.	
Date	Signature
Certification of technologist _____ # _____ confirmed after review by MrOS Coordinating Center.	
Date	Signature