MrOS Sleep Study – Visit 2

DXA Quality Assurance Manual
for
Hologic QDR-4500
Bone Densitometers

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Version 1.2
November 2009

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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 Visit 2 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 to have read and understood the entire Hologic QDR 4500 User's Manual. The study DXA 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.

2.0 STUDY LOGISTICS

The densitometry measurements performed at the Sleep Visit 2 will be clinic-specific. Instructions for acquisition of hip, spine and whole body scans are given in this manual. Please refer to the appropriate sections of the manual for information about the scans that will be acquired at your clinic.

Sleep Visit 2 scans will be compared to the MrOS Baseline scans for positioning, analysis, and assessing excessive bone loss (EBL) at the total hip and spine (if applicable at your clinic).

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;

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, file the following items in a MrOS Sleep V2 DXA study binder:
   a. Printouts of plots of the daily QC data
   b. Copies of scanner service reports (if service was performed during the month)
   c. Original printouts of flagged scans

6. Once a month, copy all scans (participant, WB phantom, and WB air QC scans) [UAB: please also copy your spine and hip phantom scans, as well]) to the MrOS Sleep V2 "traveling" optical disk

7. Assure proper functioning of hardware/software and request service from Hologic;
   a. Notify Hologic of any machine or software problems or if the QDR machine is being relocated
   b. Perform 10 QC phantom scans before (if possible) and after service / relocation

8. **FUNDING PENDING**, send all participant scans, appropriate paperwork and a QC archive to UCSF at the end of the visit once all participants have been scanned.

2.1.2 MrOS Quality Assurance Center responsibilities

The UCSF DXA QA Center will write and maintain this QA Manual, but it will not be doing monthly QA for MrOS Sleep V2. If funding is received, the DXA data will be forwarded to the QA Center at the end of the study for review.

2.2 Training and Certification of MrOS DXA Operators

The UCSF DXA QA Center will not be certifying DXA operators at Sleep V2. It is the responsibility of the clinical sites to ensure that all DXA operators are properly trained to acquire scans at this visit

Anyone performing scans for the MrOS study should:

1. Read and understand both the Hologic QDR4500 manual and this manual;
2. Successfully complete a Hologic QDR4500 training course;

2.3 Flagged Scans

Any scans that appear unusual or difficult to analyze should be marked as flagged. Guidelines for flagging scans are listed in Section 3.5.

Flagged scans should be printed out and filed with the study binder monthly. The reason(s) for flagging should be noted directly on the scan printout and on the Participant Scan Log. If the problem involves comparison to the Baseline scan, the Baseline scan should also be printed and filed in the binder.

3.0 DXA Scan Acquisition and Analysis

Standard scanning and analysis procedures for the hip, spine and whole body bone density measurements are described in detail in the Hologic QDR 4500 User's 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.

3.1 Participant data

This section describes in detail the specific procedures to be conducted for the MrOS Sleep Visit 2 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 should be filed 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 to be 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 Visit 2 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, Ethnicity, and Ref MD fields exactly.

At the Sleep Visit 2 the following biography fields should be updated as shown before scanning (see Figure 1):

Comment: Sleep V2

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

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

Height: [Measure the participant's height and enter into this field. 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 V2

Scan Code: B03 **Zip:**

DOB: 10/20/30 **Sex:** M **Weight:** 160 **Height:** 5' 9"

Ethnic: W **Ref MD:** MrOS

3.2 Hip Scans

The HOLOGIC Operator's Manual should be consulted for the proper hip scanning and analysis procedures. Clarifications and exceptions for the MrOS Sleep V2 Study are noted below.

3.2.1. Hip Acquisition

Follow-up – Please refer to the Baseline hip scan printout to aid in acquisition and analysis. Careful positioning and visual comparison of the current scan with Baseline are essential for producing precise measurements.

NOTE: The participant can participate in the Sleep Visit 2 study even if the hip can not be scanned.

1. Use the DXA Worksheet (see Appendix B) to determine and document which side to scan. Store the DXA Worksheet in the participant's file. 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. 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 follow-up scan as at Baseline. **If it is impossible to reproduce the positioning from Baseline** (due to pain, worsening arthritis, etc.), produce the best possible scan. **Flag** the follow-up scan, write the problem directly on the scan printout and file it in the MrOS Sleep V2 DXA binder.

3. **Use the same scan mode (e.g., fast array or array) that was used on the Baseline scan.**

4. No metal or plastic object should be present 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.

5. Keep the participant's hands out of the scanning area by placing them well away from the hips.

6. 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.

7. After proper rotation, attach the leg to be scanned to the angled foot block supplied by the manufacturer.

8. 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, if needed. Maintain the participant at a comfortable body temperature for the duration of the scan.

9. 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.

3.2.2. Hip Analysis

Follow-up

Load the Baseline scan onto the hard disk. Display the Baseline evaluation using the COMPARE feature along with the current scan to be analyzed. It is important to realize that proper comparison of a follow-up 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.

1. *Global Region of Interest.*
   - The width and height of the global ROI must be the same s that used on the Baseline scan.
   - The dotted lines from the Baseline defining the bone region should overlay the follow-up as closely as possible.
   - The region surrounding the neck should have the best fit.

2. *Bone Edges.* Ensure that the follow-up scan's bone edges match the Baseline's.

3. *Femoral Midline.* Unevenness in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck. This will in turn cause the femoral neck box to twist. If the midline looks like it might be off or the box is twisted on either the Baseline or follow-up scan, it may be necessary to adjust the bone mask (e.g. filling in neck notches, or 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, flag the scan and file it in the MrOS Sleep V2 DXA binder.

4. *Femoral Neck Box.* It is most important to have the neck box location and size correspond as closely as possible to the Baseline scan.

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

   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.

   If the current location cannot be satisfactorily adjusted while maintaining the same sized neck box, reanalyze the Baseline scan.

5. *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.

6. *Printouts.* Make a printout for the participant's file.

3.3 Spine Scans

The HOLOGIC Operator's Manual should be consulted for the proper spine scanning and analysis procedures. Clarifications and exceptions for the MrOS Sleep V2 Study are noted below.

3.3.1. Spine Acquisition

Follow-up – Please refer to the Baseline spine scan printout to aid in acquisition and analysis. Careful positioning and visual comparison of the current scan with Baseline are essential for producing precise measurements.

NOTE: The participant can participate in the Sleep Visit 2 study even if the spine cannot be scanned.

1. Position the spine in exactly the same position as Baseline.

2. Use the same scan mode (e.g. fast array or array) that was used on the Baseline scan.

3. No removable metal or plastic object should be present in the scanning area. Check for jewelry, zippers, buttons, rivets, belts, underwire bras, hooks or any other clothing fasteners, as well as hip and back braces. Lower any heavy or tight clothing so that nothing obscures the scanning area.

4. Follow the instructions for participant positioning outlined in the Hologic Manual. Verify that the participant's spine is aligned with the center lines on the scanner table.

5. Use the Hologic positioning block under the participant's knees to reduce lordosis. Always use this same block and block position for all future scans.

6. Keep the participant's hands out of the scanning area by placing them over or behind the head or at the side but out of the scan field.

7. The participant should be made as comfortable as possible to reduce the chance of unwanted movements. Use a pillow for the head and elbows, if necessary.

8. Include 5 to 10 lines of the iliac crest. Terminate the scan if positioning is incorrect; reposition the participant and restart (F3) the scan. The spine should be well centered and part of the iliac crest should be clearly visible.

9. Scan from the middle of L5 up to the middle of T12, so that you will include all vertebrae from L1 to L4. Be sure to collect sufficient data for accurate identification of vertebral levels. If you are unsure of the levels, scan through T11.

3.3.2 Spine Analysis

Load the Baseline scan onto the hard disk. Display the Baseline evaluation using the COMPARE feature along with the current scan to be analyzed. It is important to realize that proper comparison of a follow-up spine 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.

1. *Global Region of Interest.* Use the same ROI as used on the Baseline scan. **Never change the width of the global ROI on the follow-up scan**.

2. *Inter-vertebral Spaces.* It is most important that the inter-vertebral space markers of the follow-up scan correspond as closely as possible to those of the Baseline scan. The <COMPARE> feature will generate the Baseline vertebral spacing automatically. A slight manual adjustment may be necessary to place the line markers at the same level between the vertebrae.

3. *Labeling Vertebral Levels.* Match corresponding vertebral levels from Baseline to follow-up. Look carefully at the darker low density features at the inter-vertebral spaces and count up from the pelvic girdle to determine levels.

4. *Exclusion of Vertebrae.* Crush fractures and vertebral bodies with artifacts are to be excluded from the analysis. If the fracture/artifact was not present on the Baseline scan, reanalyze the Baseline to exclude the affected vertebral level, then reanalyze all follow-up scans, comparing to the new Baseline analysis.

5. *Bone Edges/Low Density Spine Software.* Do not alter the bone edges unless there are obvious gaps or holes. If low density spine software was used at Baseline, use this software at follow-up.

6. *Printouts.* Make a printout for the participant's file.

3.4 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 Sleep V2 Study are noted below.

3.3.1 Whole Body Acquisition

Follow-up – Please refer to the Baseline whole body scan printout to aid in acquisition and analysis. 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 file.

NOTE: The participant can participate in the Sleep Visit 2 study even if the whole body cannot be scanned.

The following points should be carefully followed, however, positioning 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, do not tuck the hands under the thighs. The hands may be placed in lateral position and taped, with paper tape, if necessary.

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 in order to reduce the chances of unwanted movements. In general, try to avoid the use any pillows or blankets. If the participant cannot lie flat at all without the aid of a pillow due to kyphosis, use a radio-lucent pillow.

6. Instruct the participant not to move until the end of the measurement.

3.3.2 Whole Body Analysis

<u>Follow-up</u>

Display the Baseline evaluation using the COMPARE feature along with the current scan to be analyzed. Match the location of the region markers as closely as possible to the Baseline measurement. The markers should be at the same position between the body regions as on the Baseline image.

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
  - Superimposed buttons, pins, zippers, pacemakers, vitamin pills, etc.
- ROI used on follow-up is different size than used at Baseline
- Bone edges have been altered in any way (bone additions or deletions)
- Follow-up analysis 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 this manual.
- The ischium is deleted
- Analysis program repeatedly fails to place regions appropriately - major operator interaction required for analysis

Spine

- Scans analyzed with low density spine software
- Analyses or reanalysis that exclude crushed vertebrae
- Baseline and follow-up scans with mismatched vertebral levels

Whole Body

- Participant motion without rescanning
- Positioning aids (i.e. pillows or blankets)
- Jewelry (rings, necklaces, bracelets, etc)
- Significant changes in positioning between Baseline and follow-up scan.
- Unable to fit arms, feet or head in scan field

3.6 Excessive Bone Loss Procedures

Excessive Bone Loss (EBL) is defined in Table 1. Use the Hologic ACTUAL Rate-of-Change plot to determine the percent loss between the Baseline and Sleep Visit 2.

For **DOS based software**: 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 only has actual rate-of change. Use the BMD Change vs. Baseline percent change.

Table 1. MrOS Sleep V2 EBL Criteria

Follow-up Time Point	Actual Rate of Change for Total Hip or Total Spine BMD
Baseline/Sleep V2	> 15% loss

If EBL is found, a second scan should be acquired. Reposition the participant (have the participant get off and back on the table) and perform another scan. Analyze the scan and check again for EBL. **This will necessitate analyzing the follow-up scans while the participant is still on the scan table.**

Average the actual rates-of-change of the two Sleep V2 scans; if the average is greater than 15% loss, EBL is confirmed. Complete the EBL form and notify the clinic coordinator.

If the average actual rate-of-change is less than 15% loss, EBL is not confirmed.

See Appendix B for sample letters to participants and their primary care physicians regarding confirmed cases of EBL.

4.0 Scanner Quality Control

Monitoring of machine performance is the responsibility of the clinical center. The following table lists the quality control procedures and schedules.

NOTE: If your clinic is not acquiring hip scans at Sleep V2, you do not need to scan the hip QC phantom; if your clinic is not acquiring whole body scans at Sleep V2, you do not need to scan the tissue bar, the whole body QC phantom, or whole body air scan.

Table 2. Quality Control Scanning Schedule

If you acquire these scans for Sleep V2	Then scan these Phantoms	This often
Hip, spine, WB	Hologic Spine Phantom	Daily (at least 3 times/week and always on a day a participant is scanned)
Hip	Hologic Hip Phantom	2 times/week
WB	Hologic Tissue Bar	1 time/week
WB	Hologic Whole Body Phantom	3 times/week
WB	Whole Body Air Scan	1 time/week

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.

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

Points of procedure to note:

1. Use the same phantom biography you have used for other MrOS visits.

2. Scan each phantom on top of the pad. Ensure alignment with the scanner axis by using the laser cross-hairs.

3. 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.**

4. Use the plot feature to verify that the spine and hip phantom BMD, BMC and AREA values of your scanner are within normal limits. You should 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 or BMC exceeds 0.60%, contact Hologic .

5. 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 disks before being deleted from the hard drive.**

6. For DOS workstations: 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.

7. 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. Monthly, place a copy of these plots in the MrOS Sleep V2 DXA binder.

8. Perform a dbArchive / System Backup at least once a week and store at the clinical site. Disks may be rotated monthly.

4.2 Whole Body Air Scan for the QDR 4500

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 scanner and indicate any potential problems with the x-ray beam, if present.

4.2.1 DOS Based Software

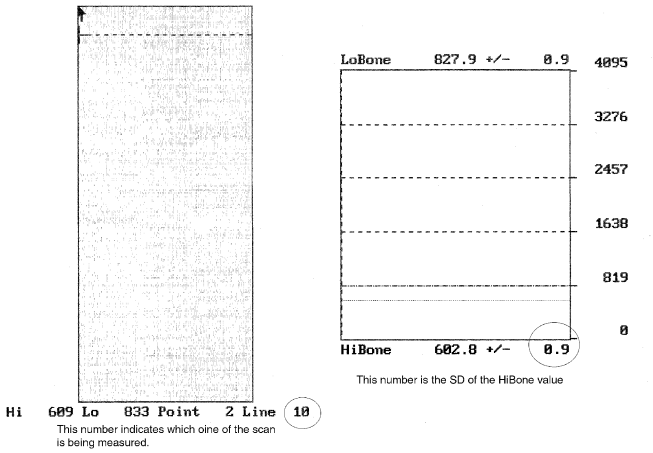
1. Clear the entire tabletop of any objects and clean the pad of any debris. Only the table pad should remain on the table. This is critical since the test can detect items as thin as a single piece of Scotch tape.

2. Use the existing biography for the **WB AIR QC SCAN.**

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.

5. 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 contact Hologic.

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:

4.2.2 Windows Based Software

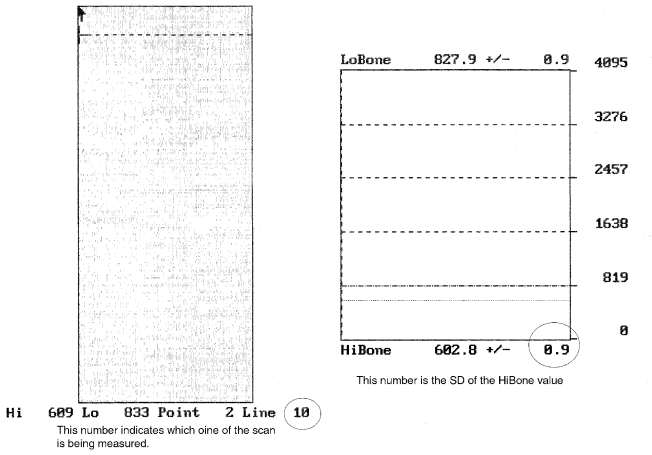
1. Clear the entire tabletop of any objects and clean the pad of any debris. Only the table pad should remain on the table.

2. Use the existing biography for the **WB AIR QC SCAN.**

3. Click on "Perform Exam". Click on the name WB AIR QC SCAN. Click "OK". Click "OK" again at the Patient Confirmation window. Select "Whole body" 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. Click on "Utilities" which is found on the top tool bar. Click on "Scan File Plot". Click on the WB AIR QC scan that was just acquired. Click "OK". A blank image will appear. Press the <Page Down> key once to move to line 10.

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



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.

5. 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 contact Hologic.

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:

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. Perform a dbArchive / System Backup before any work is done on your scanner.

2. Perform 10 scans of the Hologic daily QC spine and hip phantom before (if possible) and after the repairs or adjustments are made.

3. Keep the Hologic report to document any service done to your scanner. File a copy of the service report in the MrOS Sleep Visit 2 DXA binder.

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 file. The following printed reports are needed for each scan:

Hip: Print the standard report.
Spine: Print the standard report.
Whole body: Print the BMD and body composition reports (2 pages).

5.2 Electronic Scan Archive

Each clinical center should archive their study scans to the dedicated MrOS Sleep V2 optical disk at the end of each day. Additionally, each clinic should maintain a "traveling" disk and copy the study scans to it at the end of each day. If funding is received, the "traveling" disk will be sent to UCSF DXA QA Center for data management and review at the end of the visit.

Please be sure to re-archive to your clinic disk and re-copy to your "traveling" disk any scans that you reanalyze after you have completed the reanalysis.

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: If a scan needs to be restored and reanalyzed for any reason, it will need to be re-archived.

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 Monthly "Batches" to be Organized and Kept at the Clinical Site

The following items are organized and maintained monthly, but kept at the clinical site, pending further instruction:

1. QC PRINTOUT. Print the most recent plots of the QC database (spine and hip phantom- BMD, BMC and AREA) and place them in the MrOS Sleep V2 DXA binder.

2. PARTICIPANT SCAN LOG. Place a copy of the written participant scan log with all participants scanned during the month in the MrOS Sleep V2 DXA binder. . Use the Comment Section on the log sheets to "flag" individual scans.

3. "TRAVELING" OPTICAL DISK. Copy all scans done during the month, along with any reanalyzed Baseline scans, to the "traveling" optical disk and keep at the clinical site.

4. HOLOGIC SERVICE REPORT. Place a copy of the Hologic service report, if service was done during the month, in the MrOS Sleep V2 DXA binder.

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

Center the table. 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. 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.)

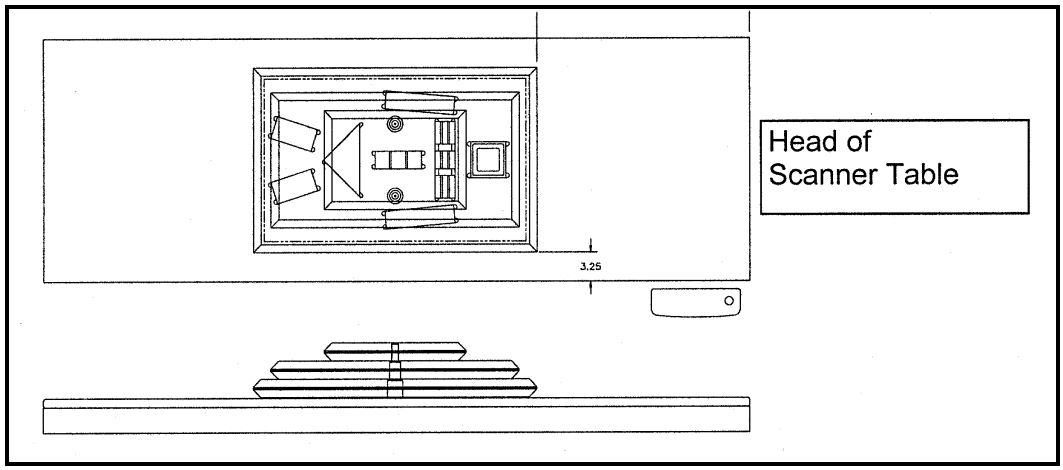


Figure 1. Layout of Whole Body Phantom positioned on the scanner table. Also shown, the fully assembled phantom viewed from the side. (Note that the amount of empty space between the side of the phantom and the sides of the table will vary depending upon scanner model).

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. The pad is secured to the table by Velcro strips. The pad can loosen up over time and should be adjusted. 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.
3. Use the 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 #xxxx** . **Patient ID: this should be the phantom ID number xxxx.**
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. You should be scanning 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 analysis is performed by direct comparison to the Baseline scan.

B. Specific Instructions - Hologic QDR systems

Use the Compare feature to register the ROI cutlines 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 Whole Body Phantom scans to both the clinic and traveling opticals, 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 optical and notify the clinic center of any problems.

Please refer to the example given of the analysis. There should be no arm values. If you notice that there are values for the arms, you have probably not positioned the phantom on the table well and should readjust the positioning and rescan the phantom. The mask provided for the comparison should fit the newly acquired scan.

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)

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)

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.

DXA WORKSHEET

Do not fax **Keep with participant's file**

MrOS ID	Acrostic	Staff ID

1 **Determine which hip will be scanned. If possible you should always scan the same hip that was scanned during the baseline visit!**

IF RIGHT HIP SCANNED AT BASELINE

Has the participant fractured their right hip or had a right hip replacement since baseline visit?

○ Yes ○ No → **Scan right hip**

Has the participant ever fractured their left hip or had a left hip replacement?

○ Yes ○ No → **Scan left hip**

Do not scan either hip

IF LEFT HIP SCANNED AT BASELINE

Has the participant fractured their left hip or had a left hip replacement since baseline visit?

○ Yes ○ No → **Scan left hip**

Has the participant ever fractured their right hip or had a left hip replacement?

○ Yes ○ No → **Scan right hip**

Do not scan either hip

2 **Does the participant have any metal objects in their body, such as a pacemaker, staples, screws, plates, etc.?**

○ Yes ○ No ○ Don't Know ○ Refused

a. Flag scan for review by DXA Reading Center.

b. Indicate the location of the joint replacement, hardware or other artifacts. (Sub regions are those defined by the whole body scan analysis.)

Sub	Hardware?	Other Artifacts?
i. Head	○	○
ii. Left arm	○	○
iii. Right arm	○	○
iv. Left ribs	○	○
v. Right ribs	○	○
vi. Thoracic spine	○	○
vii. Lumbar spine	○	○
viii. Pelvis	○	○
ix. Left Leg	○	○
x. Right leg	○	○

3 **Has the participant had any of the following in the past ten days?**

	Yes	No
a. Barium enema	○ *	○
b. Upper GI X-ray series	○ *	○
c. Lower GI X-ray series	○ *	○
d. Nuclear medicine scan	○ *	○
e. Other tests using contrast ('dye') or radioactive materials	○ *	○

***Examiner note: If 'Yes' to any responses above, reschedule bone density measurement so that at least 10 days will have passed since the tests were performed.**

Mr. OS Sleep

Instructions for Completing the DXA Bone Density TELEForm:

*NOTE: This form is to be completed only at clinical sites that are acquiring DXA scans as part of MrOS Sleep Visit 2. (Sites that are **not** scanning as part of their protocol are not required to submit the TELEform into the data system.)*

SPINE

If your site is not acquiring spine scans, mark the "spine" bubble. Go on to the second section.

If your site is acquiring spine scans, answer Question 1.

WHOLE BODY

If your site is not acquiring whole body scans, mark the "whole body" bubble. Go on to the third section.

If your site is acquiring whole body scans, answer Question 2.

HIP

If your site is not acquiring hip scans, mark the "hip" bubble. Go on to the final section.

If your site is acquiring hip scans, answer Questions 3-5.

DATE OF SCAN(S) / TEMPERATURE OF ROOM

Fill in the date of the scan(s) (Question 6) and the temperature of the scanning room in degrees C (Question 7).

64070

DXA

Bone Density Form

Office Use Only--
MrOS ID# | **Acrostic** | **Staff ID#**

Pittsburgh Only: ○ Marrow Cohort

Please mark if spine scans are NOT BEING OBTAINED as part of your clinic protocol: ○ Spine

1 **Was a bone density measurement obtained for the spine?**

○ Yes ○ No, unable ○ No, refused

Last 2 characters of scan ID #: ☐☐

Please mark if whole body scans are NOT BEING OBTAINED as part of your clinic protocol: ○ Whole body

2 **Was a bone density measurement obtained for the whole body?**

○ Yes ○ No, unable ○ No, refused

Last 2 characters of scan ID #: ☐☐

Please mark if hip scans are NOT BEING OBTAINED as part of your clinic protocol: ○ Hip

3 **Which hip was scanned at the MrOS baseline visit?**

○ Right ○ Left

4 **Which hip was scanned at this visit?**

○ Right ○ Left ○ Hip Not Scanned

5 **Was the same hip scanned at the baseline visit and this visit?**

○ Yes

○ No, other hip scanned

Record reason:
- ○ Fracture
- ○ Hip replacement
- ○ Other _____

○ Scan not completed

Record reason:
- ○ Refused radiation
- ○ Unable to lie on table
- ○ Bilateral hip replacement
- ○ Other _____

Last 2 characters of scan ID #: ☐☐

6 **Date of scan(s):** ☐☐ / ☐☐ / ☐☐☐☐

7 **Temperature of room during scan:** ☐☐ degrees Celsius

MrOS Sleep V2 Study Participant Scan Log

Clinic Name: ____

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

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 Excessive Bone Loss (EBL) Form

Date	MrOS ID#	Acrostic	Staff ID #

MrOS Sleep Visit 2 EBL Criterion is defined as:

Follow-up Time Point	Actual Rate of Change for Total Hip or Total Spine BMD
BL/Sleep V2	> 15% loss

Total Hip BMD:

BL BMD: _____ Sleep V2 BMD (first scan): _____
Sleep V2 BMD (second scan): _____

From Hologic Report: % loss since BL (first scan): _____
% loss since BL (second scan): _____

Average % loss since BL: _____

Is EBL confirmed? Yes No

If EBL is confirmed, notify the Study Coordinator.

Total Spine BMD:

BL BMD: _____ Sleep V2 BMD(first scan): _____
Sleep V2 BMD (second scan): _____

From Hologic Report: % loss since BL (first scan): _____
% loss since BL (second scan): _____

Average % loss since BL: _____

Is EBL confirmed? Yes No

If EBL is confirmed, notify the Study Coordinator.

Sample excessive bone loss alert letter for participant

[date]

[participant
address]

Dear Mr. Doe:

During your last clinic visit for the MrOS study, we repeated measurements of your [hip and/or spine] bone density. Analysis of the results indicated that you have lost a significant amount of bone in the [hip and/or spine] since your Baseline measurement was taken.

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 MrOS 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 MrOS study was here on _____/_____/_____. We have measured the bone mineral density of the [hip and/or spine]at Baseline and approximately 10 years later. The BMD scans of his total [hip and/or spine]showed _____% bone loss. This is considered to be a significant amount and is referred to as "excessive bone loss" by our study.

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,