

MrOS

Visit 4

**DXA Quality Assurance Manual
For Hologic Bone Densitometers**

SFCC DXA Quality Assurance Center

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REVISIONS

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Updated Excessive Bone Loss form; page 36

Updated Template for MrOS Excessive Bone Loss Alert Letter; page 38

Updated Template for MrOS Low Bone Alert Letter; page 39

1.0 Introduction

The purpose of this manual is to describe the DXA bone mineral density (BMD) and body composition quality assurance program for the clinical centers participating in the MrOS study. It provides information specific to the Hologic QDR 4500W and Discovery W with Windows based software 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 appropriate Hologic User's Manual. The study densitometry operators are required to have participated in a Hologic 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:

MrOS DXA Quality Assurance Center
SF Coordinating Center
185 Berry Street, Lobby 5, Suite 5700
San Francisco, CA 94107-1762
Telephone: (415) 514-8096
Fax: (415) 514-8150

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 **VISIT 4**. DXA scans will be made of the Hip and Whole Body. **Note: Spine scans will not be done at this visit.**

Table 1. DXA Scan Acquisition

DXA Scan	BL	Dental 24 Mo	Sleep 36 Mo	Visit 2 48Mo	Visit 3 72 Mo	Sleep V2	Visit 4 168 Mo
Hip	X	X	X	X	X	X	X
Spine	X	X	-	X	X	X	-
Whole Body	X	X	X	X	X	X	X

a. All clinics participated in Baseline, Sleep Visit, Visit 2, Visit 3, Sleep V2 and Visit 4

b. Only Portland and Birmingham participated in the Dental Visit

c. Sleep V2 not centrally reviewed; scans performed were clinic-specific

Table 2. Machine and Software at each Clinic

Clinic	Hologic Densitometer		Software		
	Model	ID #	Baseline	V3	V4
Birmingham	4500W	49454	8.26	9.8	Apex 3.3
Minneapolis	4500W	49487	8.26	9.8	Apex 3.3
Palo Alto	4500W	49430	10.0	11.2	Apex 3.2
Pittsburgh	4500W	48878	11.1	12.5	Apex 3.2
Portland	4500W	49415	8.26	12.3	12.6
San Diego	Discovery W	49450	8.26	12.6	12.6

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 local, state or national requirements for DXA operators, these must be met.
2. Identify a chief densitometry operator to train and supervise other operators. This person will be the primary contact person for any communications regarding technical issues from the UCSF DXA Quality Assurance Group.
3. Identify one, or preferably two, additional operators who will be available and trained to perform scans when the chief operator is not available.

4. Perform and review daily QC scans.
5. 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.
6. Upload participant scans and any reanalyze scans to the UCSF DXA Quality Assurance Center once a week as specified in Section 5.4.
7. Upload scanner QC data monthly to the UCSF DXA Quality Assurance Center as specified in Section 5.4.
8. Reanalyze centrally reviewed scans, as requested by the QA Center.
9. 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 scanner is being relocated
 - b. Record machine/software problems and service on the DXA Bone Densitometer Report. Provide copies of any service reports to the QA Center
 - c. Perform 10 QC phantom scans before (if possible) and after service
 - d. Perform 10 QC phantom scans before and after machine relocation
 - e. Regular preventive maintenance by Hologic

2.1.2 MrOS Quality Assurance Center responsibilities

The following are the responsibilities of the QA Center:

1. Write and maintain the DXA QA operations 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. Review random samples of scans from each clinical center.

6. Prepare quality control summary reports for MrOS Steering Committee review.
7. 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.**)

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

Caroline Navy
MrOS DXA Quality Assurance Center
SF Coordinating Center
185 Berry Street, Lobby 5, Suite 5700
San Francisco, CA 94107-1762
Telephone: (415) 514-8096
Fax: (415) 514-8150
cnavy@psg.ucsf.edu

2.2 Training and Certification of MrOS DXA Operators

To obtain consistent results, the densitometry operators must be aware of possible sources of error that may affect data collection and analysis. Only those operators who have been certified through Hologic training and the 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's user guide and this manual.
2. Successfully complete a Hologic training course.
3. Satisfactory review of each operator's initial scans by QA Center.

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. There may be a 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.

Recertification at Follow-up: In order for an individual operator to be certified to perform scans of a given skeletal site, 10 initial scans at both skeletal sites (hip and whole body) for each operator must be sent to the QA Center for review. These scans can be historical, but not more than 6 months old, and performed on the current scanner. Scans should have any private information removed or blackened out. If you do not have any initial scans to send, you can use the first participant scans for MrOS but we would like to review the scans as they are acquired. Printouts or digital images of the corresponding baseline scans must accompany the follow-up scans. The scans should be sent to Caroline Navy.

2.3 Review of DXA Scans

Scan analysis quality will be ensured by a central review of flagged whole body scans and hip scans. Whenever scans are to be reviewed centrally:

1. An electronic copy of the scan should be sent to the QA Center. Write the reason for the flagged scan on the Participant Scan Log.
2. It is the responsibility of the operator to reanalyze the scan according to QA Center comments and send an electronic copy to the QA Center for verification.

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

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 3.4, Scan Flagging Criteria.

Flagged scans should be uploaded weekly. Note the reason(s) for flagging on the MrOS Participant Scan Log (See Appendix B).

The scans 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 Review and Outlier Checks

Monthly, scans with outlying values will be reviewed. Additionally, a random sample will be conducted at regular intervals 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 DXA measurements are described in detail in the Hologic Users' Guide. 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.

Note: Please use the same scan mode (e.g. fast array or array) that was used at the baseline visit!

3.0.1 Analysis procedure with APEX software

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

1. Please do not reanalyze any baseline or follow-up scan at this visit! Please be sure to use the Compare feature when analyzing the Visit 4 scans.

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

2. Please make sure the NHANES box is unchecked!

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

3.1 Participant data

This section describes in detail the specific procedures to be conducted for the MrOS 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.

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. Both pages must be completed before faxing.

3.1.1 Patient Biography - Follow-up

The Patient Biography was created in the Hologic database for the MrOS baseline scan. **Do not create a new biography for the follow-up visit.**

The participant's current weight and height must be updated at follow-up as well as the study visit code and operator scan code.

Figure 2. MrOS Patient Biography Screen for Windows Based Software

Patient Biography

Last Name: JSMI

First Name:

Middle Initial:

Sex: M

Ethnicity: White

DOB

Month:

Patient ID: BI0001

Day:

Identifier 2:

Year:

Referring Physician: MrOS

Menopause Age: Weight: lb 160 Height: 69 in

Patient Comment: Visit 4

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 Study are noted below.

Before scanning the participant, have a printout of the baseline available. Refer to the baseline printout as you go through the positioning of the participant for the follow-up scan; this is to ensure consistent scanning of the same area. Careful positioning and visual comparison of the current scan with baseline are essential for producing precise measurements.

3.2.1. Hip Acquisition at Follow-up

Consistent projection of the femur is more important than the actual angle of the foot rotation. Use the rescan feature as soon as any positioning errors are detected during the current scan.

1. Refer to the MrOS DXA Bone Density Form (Teleform- See Appendix B) to determine which hip to scan.
2. Position the hip in exactly the same position as baseline. 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.
3. **If it is impossible to reproduce the positioning from baseline** (e.g., pain, worsening arthritis), produce the best possible scan. **Flag** the follow-up scan, write the problem on the scan printout and send copies of both the baseline and follow-up scan to the QA center.
4. **Use the same scan mode (e.g., fast array or array) that 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. You may use a pillow for the head, if necessary for participant comfort. Please note that pillows should NOT be used in the scan field. The ONLY exception is if a pillow was used within the scan at baseline. In that case, use a pillow in the same position at the Visit 4 scan. 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 at Follow-up

NOTE: DO NOT REANALYZE THE BASELINE SCAN for **any** reason; if you believe a baseline scan needs reanalysis, please flag the scan for review by the QA Center.

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

Flag any scans that are difficult to analyze.

3.3 Whole Body Scans

The Hologic user's guide should be consulted for the proper whole body scanning and analysis procedures. Clarifications and exceptions for the MrOS Study are noted below.

Before scanning the participant, have a printout of the baseline available. Refer to the baseline printout as you go through the positioning of the participant for the follow-up scan; this is to ensure consistent scanning of the same area. Careful positioning and visual comparison of the current scan with baseline are essential for producing precise measurements.

3.3.1 Whole Body Acquisition at Follow-up

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

1. Have the participant remove all clothing, including shoes, and dress them in a hospital gown. Check that no metal or plastic objects remain in the scanning area. This includes hair clips and pins, 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. It is important that positioning of the hands remain the same as the baseline scan.
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 comfortable as possible since this reduces the chances of unwanted movements. Please note that pillows and blankets should NOT be used for the WB scan. The ONLY exception is if it was used for the baseline scan. In that case, use it in the same position for the Visit 4 scan.

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.
7. Instruct the participant not to move until the end of the measurement.
8. Print out a hard copy of each scan and file in the participant's folder.

3.3.2 Whole Body Analysis at Follow-up

NOTE: DO NOT REANALYZE THE BASELINE SCAN for **any** reason; if you believe a baseline scan needs reanalysis, please flag the scan for review by the QA Center.

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

Flag any scans that are difficult to analyze.

3.4 Scan Flagging Criteria

General

- Scan has unusual appearance or is difficult to analyze
- Any of the following in scan field (either in the bone or soft tissue)
 - Unusual anatomical variations
 - Surgical hardware
 - Participant motion during scan
 - Buttons, pins, zippers
 - Pacemakers, vitamin pills, etc. in scan ROI
 - Jewelry that could not be removed
- ROI used on follow-up is different size than used at baseline
- Bone edges have been altered in any way
- Follow-up scans cannot be reasonably matched to baseline analysis

Hips

- Femoral midline is not aligned and cannot be corrected by following the analysis procedures as outlined in the MrOS manual
- Neck box size needs altering in any way
- Ischium bone deleted; bone added to femoral head/neck
- Analysis program repeatedly fails to place regions appropriately - major operator interaction required for analysis

Whole Body

- Internal or external artifacts that cannot be removed (prostheses, implants, medical bracelets, etc.)
- Participant motion without rescanning (these scans are extremely susceptible to motion artifacts)
- Significant changes in positioning between baseline and follow - up scan
- Unable to fit both arms in scan field

3.5 Excessive Bone Loss Procedures

Excessive Bone Loss (EBL) is defined in Table 3. Use the Hologic Rate-of-Change plots to determine the **actual** (not annualized) percent loss between the baseline and Visit 4 visit.

Table 3. EBL Criteria

Time Points	<u>Actual</u> Rate of Change for Total Hip BMD
Baseline to Visit 4	≥ 16% bone loss since baseline.
Visit 3 to Visit 4	≥ 10% bone loss since Visit 3.

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 follow-up 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 forward to UCSF immediately. 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 for a template). 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.

3.6 QA Center Safety Review

It will be the QA Center's responsibility to identify participants with Low BMD, which is defined as a T-score at total hip or femoral neck of ≤ -2.5 . The T-score will be based on a FEMALE Caucasian reference database. Current Hologic software will not allow use of this reference database for men. Thus, the T-scores will need to be calculated at the QA Center. If the QA Center finds that a participant meets the criteria for low BMD, we will notify the Study coordinator and the lead DXA operator at the clinical site, using the Participant Safety: Low BMD form. Procedures for notification to the participant will be clinic-specific.

Procedures on what information to give to the participant at the time of the DXA scan will be clinic-specific.

** If the clinic decides to give the participant their DXA printouts at the time of the scan, they can set up their Hologic workstation to exclude the T-scores from the printouts. Please contact Caroline Navy for instructions **

Regularly, the MrOS Coordinating Center will provide a cumulative report of the t-scores calculated with the female Caucasian reference database to the clinics.

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.

Table 4. Quality Control Scanning Schedule

Phantom	Scanning frequency
Local Hologic Spine Phantom	Every day a subject is scanned but at least 3 times per week.
Local Hologic Hip Phantom	2 times/week
Local Hologic Whole Body Phantom	3 times/week
Step Phantom (not collected)	1 time/week
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 (See Appendix C for hip phantom protocol). **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. Archive all spine and hip phantom scans before deleting from the hard drive.

At the start of V4: Scan the hip phantom 10 times with repositioning. This will allow the setting of a consistent mean for monitoring performance and comparison purposes.

Whole body quality control consists of Hologic whole body phantom scans, and whole body air 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. Archive all whole body phantoms and air scans before deleting from the hard drive.

At the start of V4: Scan the whole body phantom 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.

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. 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 cannot 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. 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, contact both Hologic and the QA Center.
5. After the spine and hip phantom scans have been analyzed and added to the QC database, archive the scans, and then delete the scans from the hard drive.
6. If the CV of the BMD exceeds 0.60% please contact both the Reading Center and Hologic to initiate appropriate action.
7. Generate a printout of the daily phantom plots (BMD, BMC and AREA for 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.
8. Original printouts including the scan results of the most recent phantom QC plots (BMD, BMC and AREA for hip and spine) are to be uploaded for review monthly. The date range for the plots should cover the previous one year to the present.
9. Perform a System backup at least once a week and store at the clinical site.

Weekly, your scanner will automatically prompt you to scan the step phantom and then will perform the air scan (see below) immediately after. The scanner will let you choose to not perform the step phantom scan. This does not impact the hip scan, but if you make this choice and then perform a whole body scan, you will only get bone data. The step phantom results will not be collected for the MrOS study.

4.2 Whole Body Air Scans Instructions

After scanning the step phantom, it will automatically prompt you to scan the air scan. A Whole Body scan of "air" also known as the radiographic uniformity scan should be performed at least once a week. The "air" scan will assess the proper functionality of the scanner and indicate any potential problems with the x-ray beam or table top.

To prepare for the air scan, 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.

Once the air scan has been performed, check the Global SD values for the Hi and LoAir which is displayed right after the air scan is completed.

You will also need to send the electronic files of the air scan to the DXA QA Center once a month. Make sure to archive the scans before deleting scans from the hard drive.

IMPORTANT:

- In the event that the Global SD values exceed 3.0, immediately send the electronic scans to Caroline Navy at UCSF and call Hologic.
- If the Global SD values exceed 2.0, immediately send the electronic scans to Caroline Navy at UCSF. The DXA QA Center will review the data and decide if further action is needed.

4.3 Machine, Software, and Service Problems

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

1. Do a system backup before any work is done on your scanner.
2. Contact the 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. 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.

4.4 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.

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:

Proximal femur: Print the standard report.

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

5.2 Electronic Scan Archive

Scans should be archived to a primary and secondary archive disks (e.g. optical disk, CD, network) which will stay at the clinical site at all times. At the end of each day, the operator should archive all study data to the primary and secondary archive locations.

Participant and QC data (and study forms) should be transmitted electronically to the DXA QA Center, or sent as a "copy CD" if electronic transmission is not feasible.

5.3 Transfer of Data to the DXA Quality Assurance Center

Transfer of data will occur via the Coordinating Center's secure website. Secure remote access to the website is provided by the Juniper Networks Instant Virtual Extranet (IVE) appliance which sits behind our network firewall.

Clinics that are able to transfer scans electronically should do so. DXA operators should upload once a week. If uploading directly from the workstation is not possible, transfer should be worked out with the study coordinator. Please see Appendix B for the electronic transfer instructions.

5.4 Electronic Participant Scan Transmission

The following items are to be uploaded weekly:

1. PARTICIPANT SCANS. Send electronic copies of all participant scans acquired since the last data transfer. Archive scans using the COPY function.
2. PARTICIPANT SCAN LOG. Send a copy of the 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. REANALYZED SCANS. Send all scans from Visit 4 that has been reanalyzed according to the QA Center instructions since the last data transfer.

The following items are to be uploaded at the beginning of each month:

1. QC DATA. Send all spine and hip phantom scans, whole body phantom scans and aircans acquired since the last upload.
2. 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.
3. Copy of any manufacturer service reports for that time period, if appropriate.

5.4.1 Courier Service

If electronic transmission is not feasible, send the CD with scan images using a trackable courier (i.e. FedEx) service, within a week of acquisition.

The copy CD should be in a protective mailer or bubble wrap to avoid damage. Please ship these items to the following address:

Caroline Navy
MrOS DXA Quality Assurance Center
SF Coordinating Center
185 Berry Street, Lobby 5, Suite 5700
San Francisco, CA 94107-1762
Telephone: (415) 514-8096
Fax: (415) 514-8150
cnavy@psg.ucsf.edu

5.5 Sleep Visit 2 Archive

Each clinical center should have archived their study scans to the dedicated MrOS SleepV2 optical disk at the end of each day. Additionally, each clinic should have maintained a “traveling” disk and copied the study scans to it at the end of each day. While there is still no funding to centrally process the scans, we would like to archive the scans centrally so they are at the Coordinating Center and available for future use. Please send the scans to UCSF DXA QA Center.

The following items are to be uploaded around the same time as the first batch of MrOS V4 scans:

1. PARTICIPANT SCANS. Send electronic copies of all participant scans.
2. PARTICIPANT SCAN LOG. Send all participant scan logs.
3. REANALYZED SCANS. Send all scans that have been reanalyzed. Use the comment section on the scan log and note what scans were reanalyzed.

4. QC DATA. If hip and spine phantom scans, whole body phantom scans, and whole body airscans were scanned during this visit, please send electronic copies of all scans.
5. HOLOGIC SERVICE REPORTS. Send any service reports done during Sleep V2.

5.6 Feedback by the DXA 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 instructions for reanalysis, as necessary. Paperwork will be sent electronically.
2. Any recommendations for service, additional phantom scans, etc., as necessary based on the quality control data.

Appendix A. WHOLE BODY PHANTOM PROTOCOL

WHOLE BODY PHANTOM PROTOCOL

I. Phantom Assembly

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

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

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

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

II. Phantom Positioning

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

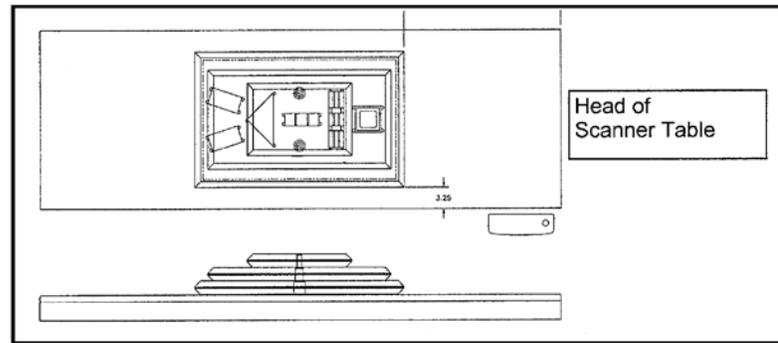


Figure 1. Layout of Whole Body Phantom positioned on the scanner table. Also shown, the fully assembled phantom viewed from the side. (Note that the amount of empty space between the side of the phantom and the sides of the table will vary depending upon scanner model). This is assuming your table pad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

III. Data acquisition - Scanning the whole body phantom

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

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

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

IV. Analysis

A. General Comments

The goal of the analysis is to carefully delineate the various body regions in a standard and reproducible fashion, so that measured results will reflect instrument performance, not variations in analysis techniques. Of particular importance are the placement of the head ROI 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 baseline scan.

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

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

V. Interpretation of measured values

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

Example Whole Body Phantom Scan.

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

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

Referring Physician:

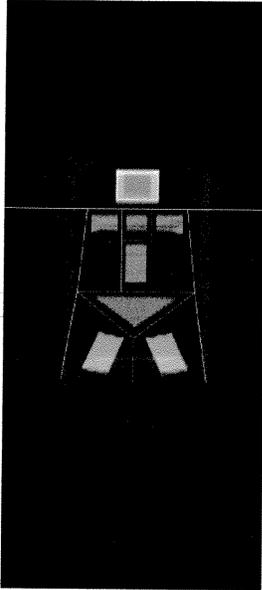


Image not for diagnostic use
327 x 150

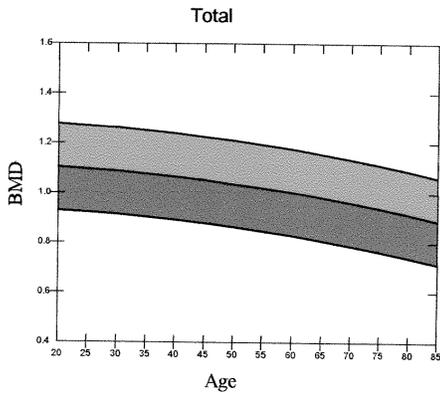
Scan Information:

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

DXA Results Summary:

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

Total BMD CV 1.0%



Physician's Comment:

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

HOLOGIC[®]

APPENDIX B. STUDY FORMS

The following forms are included in this Appendix:

Example of Hologic DXA printout

MrOS DXA Worksheet (to be completed by the DXA site)

MrOS DXA Bone Density Form - Teleform (to be completed by the DXA site)

Hologic Repair/Service/Upgrade Log (to be completed by the DXA site)

Excessive Bone Loss Form (to be completed by the DXA site)

Participant Safety: Low BMD form (to be completed by DXA QA Center)

Template for the Excessive Bone Loss Alert Letter

Template for the Low BMD Alert Letter

Instructions to copy scans from your Hologic workstation

Instructions to upload scans to MrOS IVE secure website

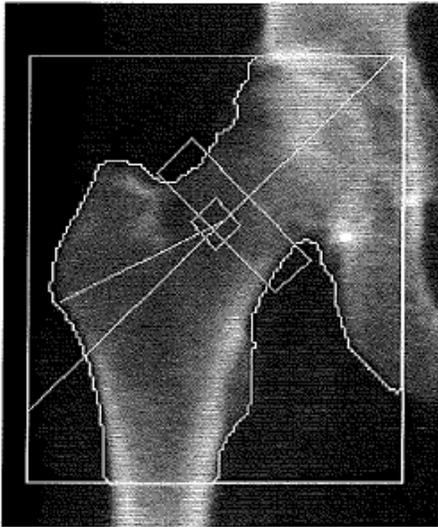
Participant Scan Log (to be completed by the DXA site)

Master copies of the forms will be sent directly to your clinical center. Always keep a copy of any form you send to the QA Center.

Example of Hologic DXA Printout

Name: JDOE	Sex: Male	Height: 168.9 cm
Patient ID: EXAMPLE	Ethnicity: Black	Weight: 84.3 kg
DOB: March 25, 1930		Age: 77

Referring Physician: MROS



Scan Information:

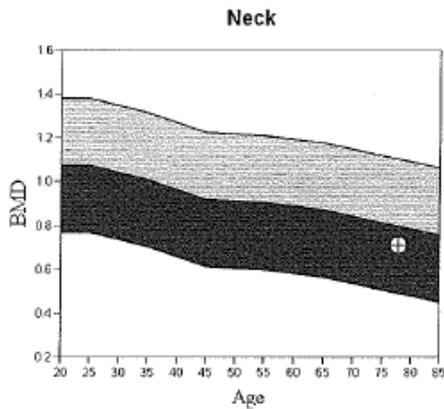
Scan Date: February 13, 2008 ID: A02130808
 Scan Type: f Right Hip
 Analysis: February 13, 2008 09:51 Version 12.6.1:5
 Right Hip
 Operator: O13
 Model: QDR 4500W (S/N 49415)
 Comment: VISIT 3

DXA Results Summary:

Region	Area (cm ²)	BMC (g)	BMD (g/cm ³)	T - score	Z - score
Neck	5.54	3.93	0.709	-1.6	-0.5
Total	44.37	44.08	0.993	-0.3	0.2

Image not for diagnostic use
 k = 1.116, d0 = 48.8
 109 x 123
 NECK: 49 x 15

Total BMD CV 1.0%, ACF = 1.033, BCF = 1.003, TH = 6.547
 WHO Classification: Osteopenia



Comment:

T-score vs. White Male; Z-score vs. Black Male. Source:BMDCS/NHANES

HOLOGIC®

DXA Worksheet

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	<input type="radio"/>	<input type="radio"/>
ii. Left arm	<input type="radio"/>	<input type="radio"/>
iii. Right arm	<input type="radio"/>	<input type="radio"/>
iv. Left ribs	<input type="radio"/>	<input type="radio"/>
v. Right ribs	<input type="radio"/>	<input type="radio"/>
vi. Thoracic spine	<input type="radio"/>	<input type="radio"/>
vii. Lumbar spine	<input type="radio"/>	<input type="radio"/>
viii. Pelvis	<input type="radio"/>	<input type="radio"/>
ix. Left Leg	<input type="radio"/>	<input type="radio"/>
x. Right leg	<input type="radio"/>	<input type="radio"/>

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

	Yes	No
a. Barium enema	<input type="radio"/> *	<input type="radio"/>
b. Upper GI X-ray series	<input type="radio"/> *	<input type="radio"/>
c. Lower GI X-ray series	<input type="radio"/> *	<input type="radio"/>
d. Nuclear medicine scan	<input type="radio"/> *	<input type="radio"/>
e. Other tests using contrast ('dye') or radioactive materials	<input type="radio"/> *	<input type="radio"/>

*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.

Visit 4

DXA Bone Density Form (Page 1 of 2)

 Draft	DXA Bone Density Form	Office Use Only-		
		MrOS ID#	Acrostic	Staff ID#
		<input type="text"/>	<input type="text"/>	<input type="text"/>

① Was a bone density measurement obtained for the whole body?
 Yes No, unable No, refused

↓

Last 2 characters of scan ID #:

② Which hip was scanned at the MrOS baseline visit?
 Right Left

③ Which hip was scanned at this visit?
 Right Left Hip Not Scanned

④ Was the same hip scanned at the baseline visit and this visit?
 Yes No, other hip scanned Scan not completed

Record reason:
 Fracture
 Hip replacement
 Other _____

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

↓

Last 2 characters of scan ID #:

⑤ Date of scan(s): / /

⑥ Temperature of room during scan: degrees Celsius

DXA Bone Density Form (Page 2 of 2)

 Draft	EBL and Osteoporosis Alerts	Office Use Only--		
		MrOS ID#	Acrostic	Staff ID#
		<input type="text"/>	<input type="text"/>	<input type="text"/>

3 Was excessive bone loss confirmed by the Coordinating Center? Yes No

a. Was study physician notified? Yes No →

Other action taken _____

How was study physician notified?

Phone MD name _____

Letter Date _____

b. Was participant notified? Yes No →

Other action taken _____

How was participant notified?

Phone Date _____

Letter _____

4 Was a T-score of -2.5 or lower noted? Yes No

a. Was study physician notified? Yes No →

Other action taken _____

How was study physician notified?

Phone MD name _____

Letter Date _____

b. Was participant notified? Yes No →

Other action taken _____

How was participant notified?

Phone Date _____

Letter _____

MrOS DXA Service Log

MrOS DXA Service Log

Instructions: Please complete this log thoroughly and attach a copy of the Hologic service report. Keep a copy with your scanner in your repair log.

Clinic: _____	
Date problem(s) encountered: ____/____/____ System Serial #: _____ <small>Month Day Year</small>	
Describe problem: _____ _____	
Were there hardware/software changes or upgrades? <input type="checkbox"/> Yes, please describe: _____ <input type="checkbox"/> No	
Was the scanner operational during the problem period? <input type="checkbox"/> Yes <input type="checkbox"/> No	
<div style="border: 1px solid black; padding: 5px;">Did problem affect scans? <input type="checkbox"/> Yes <input type="checkbox"/> No Please describe, including time period: _____ _____</div>	<div style="border: 1px solid black; padding: 5px;">How long was the scanner out of service? ____ days</div>
Describe the action taken: _____ _____	
Was the problem resolved? <input type="checkbox"/> Yes <input type="checkbox"/> No → Explain: _____	
<div style="border: 1px solid black; padding: 5px;">Date problem resolved: ____/____/____ Please describe how problem was resolved: _____ _____</div>	
Was a recalibration of the scanner necessary? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Were phantom scans performed after the repair or the recalibration? <input type="checkbox"/> Yes <input type="checkbox"/> No	
<div style="border: 1px solid black; padding: 5px;">Did you notice a change in the phantom values? <input type="checkbox"/> Yes <input type="checkbox"/> No</div>	

MrOS DXA Form Version 1.0 01/29/14

MrOS Excessive Bone Loss Form

MrOS

Date	MrOS ID#	Acrostic	Staff ID #

MrOS Excessive Bone Loss (EBL) Form

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.

- Electronic copies of the baseline and **all** follow-up hip scans

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 accurate.
- The scans were not analyzed properly. Please reanalyze the scan(s) following our instructions and send the scans to the QA Center for further review.

For those with confirmed EBL (Total Hip BMD):

- Visit 4 BMD (first scan) _____ Baseline BMD _____
 Visit 4 BMD (second scan) _____

 Actual % Change _____ (average of 2 scans)
- Visit 4 BMD (first scan) _____ Visit 3 BMD _____
 Visit 4 BMD (second scan) _____

 Actual % Change _____ (average of 2 scans)

- After scan review we cannot confirm an excessive bone loss.
- Comments: _____
- Signature of QA Center Reviewer _____ Date _____

MrOS Participant Safety: Low BMD form

Participant Safety: Low BMD

To be filled out by the QA Center

Date Form Completed	MrOS ID #	Acrostics
_ _ / _ _ / _ _	_ _ _ _ _	_ _ _ _ _

UCSF has identified a T-Score ≤ -2.5 using a female reference database at the:

TOTAL HIP / FEMORAL NECK

Total Hip T-score: _____ Femoral Neck T-score: _____

Both T-scores are displayed for reference

Comments: _____

Signature of QA Center Reviewer _____ Date _____

Template for MrOS Excessive Bone Loss Alert Letter

Template for excessive bone loss alert letter

DATE

John Doe
ADDRESS

Dear Mr. Doe:

Thank you for your continued participation in the MrOS study. During your last study clinic visit, we measured your hip bone mineral density using the dual x-ray absorptiometry (DXA) scanner. We are writing to inform you that in examining your recent and past MrOS bone density tests, your loss of bone at the hip is greater than average hip bone loss in men aged 65 years and older.

A bone mineral density (BMD) test is the best way to determine your bone health. The test can identify osteoporosis (brittle bones) and determine your risk for fractures (broken bones). In general, lower bone density means that the bone is weaker.

How much bone have I lost?

___ You have lost ___ % of hip bone since your baseline measurement was made about 14 years ago. Average hip bone loss over 14 years for men 65 years and older is 5.5%.

___ You have lost ___ % of hip bone since your Visit 3 measurement was made, about 7 years ago. Average hip bone loss over 7 years for men 65 years and older is 2.7%.

Your hip bone loss is greater than average for men your age and may indicate an increased risk of fracture. In addition, this bone loss may be related to your other health conditions, or could result from use of certain medications.

We have enclosed copies of your hip scans from baseline, Visit 3 and your last measurement. We suggest that you consult with your health care provider to find out why this greater than average bone loss is occurring. With your permission, we would be happy to communicate this information to your provider.

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,

XXXXXXXXXXXXX
MrOS XXXXX Principal Investigator

Template for MrOS Low BMD Alert Letter

Template for Low BMD alert letter

DATE

John Doe
ADDRESS

Dear Mr. Doe:

Thank you for your continued participation in the MrOS study. During your recent clinic visit for the MrOS study, we measured your hip bone density. We are writing this letter to inform you that your hip bone density is low and indicates that you have osteoporosis (brittle bones).

Your hip bone density was measured with a dual x-ray absorptiometry (DXA) scanner. This DXA test measures your hip bone mineral density and compares it to that of an established standard to calculate a bone density T-score. T-scores can be calculated in comparison to young adult men or young adult women. However, it is more useful in predicting fracture risk to compare your bone density to young adult women.

Although no one bone density test is 100-percent accurate, the DXA test is an important predictor of your risk of a future fracture (broken bone). A bone density T-score of -2.5 or lower indicates that you have osteoporosis. In general, lower bone density (i.e. lower T-scores) means that the bone is weaker. Weaker bones are more likely to fracture during an accident (even a minor accident such as a fall). However, not all men with low bone density will have fractures and, occasionally, even those with high bone density will suffer a fracture.

What are my bone density results?

Your T-scores in comparison to young adult women are:

Total hip _____ Femoral neck _____

We have enclosed a copy of your hip bone density scan that includes your results at two hip sites, the total hip and femoral neck. We suggest that you discuss these results with your health care provider. With your permission, we would be happy to communicate this information to your provider.

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,

XXXXXXXXXXXXX
MrOS XXXXX Principal Investigator

Instructions to copy scans from your Hologic workstation (Page 1 of 1)

Instruction to copy scans from your Hologic workstation

Part 1

A. Hologic DXA workstation:

1. Create a folder on the desktop—name the folder the date of the transfer
2. On Hologic screen, click Archive at the top; then click on Copy Scans
3. Click on All Scans Tab
4. Select scans that you want to copy
5. Click on the Browse button (at top next to path)—select the folder that you created on the desktop
6. Click on Copy scans
7. Click on OK when scans have copied successfully
8. Go to the desktop and right click on the folder; click on Send to; then select Compressed (zipped) folder to create the zip folder.

For those who have internet access on their DXA computer, please see attached “Instructions for the MrOS IVE secure website.”

For those who do not have internet access on their DXA computer, please see Part 2 “PC upload” instructions.

Part 2

PC upload using flash drive:

1. Put flash drive in your DXA computer
2. Open up the flash drive
3. Drag the zip folder to the flash drive
4. Eject flash drive and take it to a PC that has internet access where you will upload the scans from the flash drive to the secure website
5. Please see attached “Instructions for the MrOS IVE secure website.”

You can also copy the zip folder to a CD; then take to your PC to upload

Instructions to upload scans to MrOS IVE secure website (Page 1 of 7)

Instructions for uploading scans to the MrOS IVE secure website

- A. In any browser, go to the IVE secure interface at <http://ive2.sfcc-cpmc.net/MrOs> and enter your username and password.

Prevention Sciences Group

Username Please sign in to begin your secure IVE session.

Password

- B. After clicking “sign in,” you will see a screen that lists all of the active MrOS sites. Select your site.



Instructions to upload scans to MrOS IVE secure website (Page 2 of 7)

- C. On the next screen, you will see a list of folders. Please click on the DXA folder.



- D. Once you click on the DXA folder, it will take you to the following screen where you can upload your scans by clicking on the Upload Files. Before you click on Upload Files, please click on New Folder and name it the day of the upload formatted this way: MMDDYY



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Once the folder is created, click on the folder you just created to upload files in that folder.

Instructions to upload scans to MrOS IVE secure website (Page 3 of 7)

- E. Click on the Choose file button to find the folder/drive where the zip folders are.

Windows Files >
Upload Files...

Use the Browse buttons below to select the files, then click Upload. You can opt to u cannot upload files larger than 500 MB.

Files to Upload |||

Upload to: \MROSAccel_SFCC\BIRM\DXA

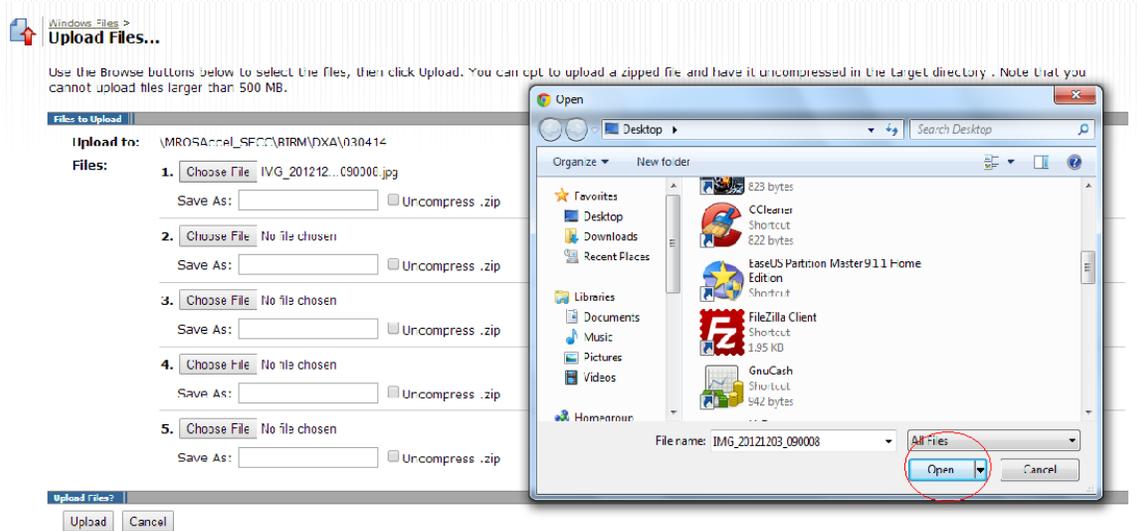
Files:

- No file chosen
Save As: Uncompress .zip

Upload Files? |||

Instructions to upload scans to MrOS IVE secure website (Page 4 of 7)

F. Once you've select your zip folder, click on Open.



Instructions to upload scans to MrOS IVE secure website (Page 5 of 7)

G. The path will now show up on the browse bar.

Windows Files >
Upload Files...

Use the Browse buttons below to select the files, then click Upload. You can opt to upload a zipped file cannot upload files larger than 500 MB.

Files to Upload

Upload to: \MROSAccel_SFCC\BIRM\DXA

Files:

1. IMG_201212...090008.jpg
Save As: Uncompress .zip
2. No file chosen
Save As: Uncompress .zip
3. No file chosen
Save As: Uncompress .zip
4. No file chosen
Save As: Uncompress .zip
5. No file chosen
Save As: Uncompress .zip

Upload Files?

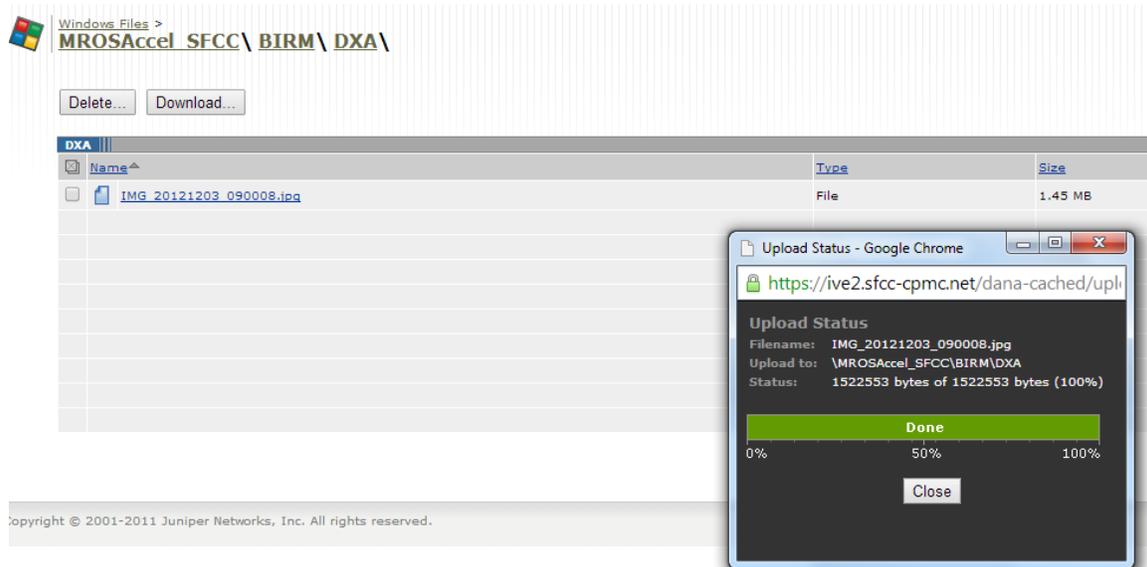
To note, if you select a file by mistake, click on the Choose File button again; choose the correct file and click on “Open.

If you need to cancel the upload all together, please click the “Cancel” button. Once you click on “Cancel,” it will not ask you if you want to confirm the cancel; it will automatically cancel your upload. You will have to upload the scans again.

If you need to upload more than 5 files, finish the first set of upload. Then click on “Upload file” again and go through the same process.

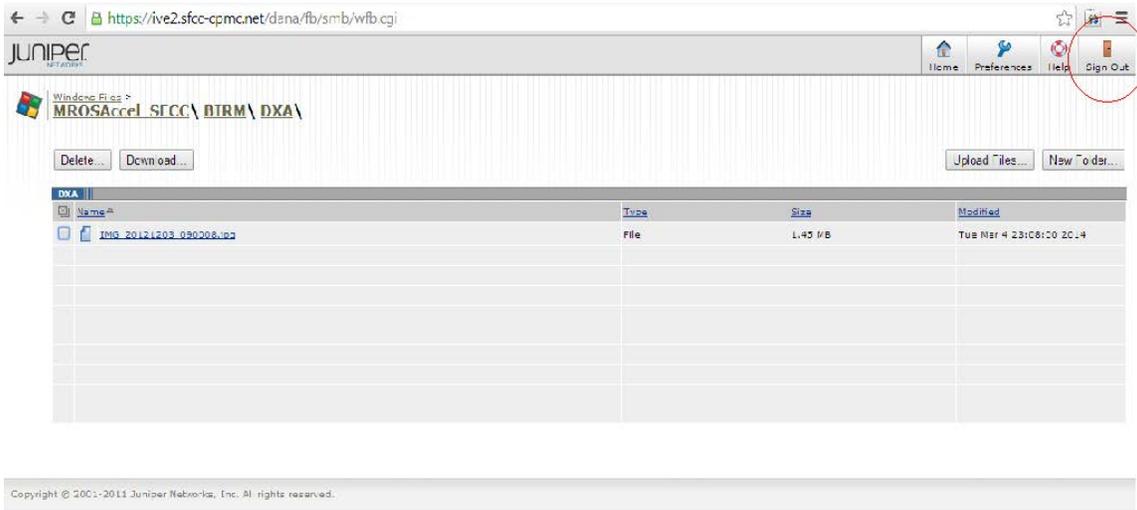
Instructions to upload scans to MrOS IVE secure website (Page 6 of 7)

- H. Once you're done choosing your files, click on the "Upload" button. The upload status will appear when the upload is successful. Click on "Close." You should now see the files you uploaded in the Name column.



Instructions to upload scans to MrOS IVE secure website (Page 7 of 7)

- I. Once you are finish, click “Sign Out” (at the top right of the window) and close your browser.



MrOS DXA Scan Log

MrOS Study Participant Scan Log						
VISIT: _____					CLINIC NAME: _____	
Date	Participant ID	Acroscopic	Scan Type	Scan ID	Flag 4	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			

Appendix C. HIP PHANTOM PROTOCOL

Hologic Hip Phantom Scanning

1. Create a new phantom biography phantom.
2. Press the "Center Table" button on the scanner.
3. Place the Hip Phantom on the mat with the black star at the foot end of the table. Make sure it is parallel to the back of the table. Use the edge of the phantom to align the phantom by moving the cross hairs from head to foot along the edge of the phantom to check the alignment. Align the phantom as shown in Figure 2 below:

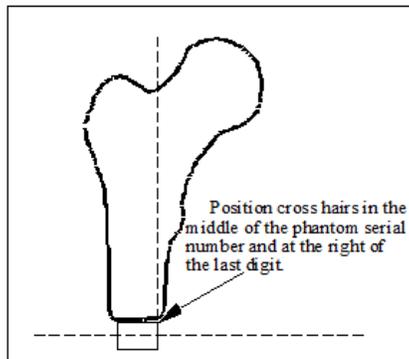


Figure 2: Placement of cross hairs on hip phantom

4. Click on the **Perform Exam** icon, which will display the Select a Patient dialog box. Choose the hip phantom you just added. Click **OK**. This will display the Patient Confirmation window. Click **OK** again. (You do not need to enter your operator ID number.)
5. The Select Scan Type window will appear. Choose **Right hip**. Unclick the Use Default Scan Mode box. The scan will be performed using array mode—not the fast array default. Click **Next**. Choose **Array** mode. Again, click **Next**. Leave the default at 15 cm (6 inches). Click on **Start Scan**.
6. Click on **Reposition Scan** if you do not have all the shaft of the femur included.
7. There should be at least 4 scan lines below the end of the phantom's femoral shaft.
8. Let the scan complete itself. Do not include air in the scan field.

Hologic Hip Phantom Compare

1. Once a baseline Hologic hip phantom scan has been established, use that scan as the reference scan to which to compare all subsequent scans.
2. After a subsequent scan has been performed, click on the **Analyze Scan** icon. Select the scan you want to analyze. Click **Next**. At the Analyze Setup window, check the box indicating you want to compare to a previously analyzed scan. At this point, a window will open up displaying patient scans. Choose the baseline hip phantom. Click **Next**.
3. The Analysis window will appear with two images. The baseline hip phantom image will appear on the right; the unanalyzed scan will be on the left. Click the **Global ROI** tab if it is not already selected. Click on **Whole Mode**. Using the arrow keys, move the entire ROI so it matches as best as possible over the image.
4. Click **Bone Map**. DO NOT INSERT OR DELETE ANY POINTS.
5. Click **Neck**. Ensure that the neck box is positioned right up against the greater trochanter. If adjustment is necessary, click **Whole Mode** and use the arrow keys for proper placement. Remember if you adjust the position of the neck box on the subsequent scans, you will also have to reposition Ward's Triangle box. Click **Other Regions**, then click **Ward's Triangle**. Select **Manual**. Align the box as in Figure 4 (against the femoral midline and 2 pixels down from the edge of the neck box).
6. Click **Results** and then **Close** to exit out of the Analysis window.