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|  | Title: | Bone Density by Dual- energy X-ray Absorption (DXA) - Hip Measurement | | |
| | Version Date: | 2017-AUG-09 | Document Number: | SOP_DCS_0015 |
| | Effective Date: | 2017-NOV-15 | | |
| Data Collection Site (DCS) | Version: | 3.1 | Number of Pages: | 11 |

1.0 Purpose:

The purpose of this document is to describe the standardized procedure for completing bone mineral density (BD) measurement of the hip on the *Hologic Discovery A* Dual Energy X-Ray Absorptiometry (DXA) machine.

2.0 Scope:

DCS staff must use this document when administering the BMD measurement of the hip on a participant.

3.0 Responsibilities:

DCS staff are responsible for performing the procedures as described in the current and approved version of the standard operating procedure.

4.0 Related Documents:

- **MAN_DCS_0014** – Additional training for the Dual-energy X-ray Absorptiometry
- **SOP_DCS_0014** – Bone Density Questionnaire
- **SOP_DCS_0043** – Dual - energy X-ray Absorption (DXA) SOP – Calibration (Quality Control) and Maintenance
- **SOP_DCS_0066** – DEXA Gold Standard Process

5.0 Definitions:

Anatomical Landmarkings;

- **Medial:** inner, toward the midline or centre of the body;
 - **Lateral:** outer, away from the midline or centre of the body;
 - **Proximal:** closer to the midline or center of the body;
 - **Distal:** farther from the midline or center of the body;
 - **Superior:** upper, nearer the head;
 - **Inferior:** lower, closer to the feet;
 - **Anterior:** in front, toward the front of the body;
 - **Posterior:** behind, toward the back of the body
- **Abducted:** To move a part of the body away from the central part of the body or away from another body part.

- **Adducted:** to move a part of the body towards the middle of the body or towards another body part.
- **Iliac Crest:** The superior and lateral border of the ilium, the largest of the bones within the greater pelvis.
- **Ilium:** The large broad bone forming the upper part of each half of the pelvis.
- **Ischium:** Forms the lower and back part of the hip bone.
- **Greater Trochanter:** A protrusion located at the proximal (near) and lateral (outside) part of the shaft of the femur.
- **Lesser Trochanter:** A pyramidal prominence that projects from the proximal (near) and medial (inside) part of the shaft of the femur.
- **Femoral neck:** A flattened pyramidal process of bone, connecting the femoral head with the femoral shaft.

6.0 Equipment:

- DXA machine (Hologic Discovery A);
- Hologic hip positioning fixture with Velcro straps;
- Head positioning cushion (optional).

7.0 Supplies:

- Radiation badges;
- Certainty wipes or equivalent.

8.0 Procedure Steps:

Contraindications:

- Weight over 450lbs (204kg);
- From the Contraindication Questionnaire;
 - Pregnancy;
 - Unable to stand unassisted;
 - Participated in any nuclear medicine studies within the last 2 days ;
 - Prosthetic hip on both hips;
 - Previous breaks or fractures on both hips.
- Please make a note of the following conditions from the Contraindications Questionnaire in the comments section of Onyx:
 - Polio;
 - Previous breaks or fractures of one hip;
 - Note the test type if participant was involved in nuclear medicine more than 48 hours ago but less than 7 days ago.

NOTE:

Sponges

Sponges can be used to provide participant comfort or support during DXA scans on an **as needed basis**. The sponge provides comfort to an **already existing** gap; it should not provide a further elevation or a further bend in the knee (i.e., if a participant is unable to place their head against the DXA table during a whole body scan or they already have a slight bend in their knee and require support as they are uncomfortable with holding the position). Sponges are not used to routinely position during bone density, but only in extreme cases where participants need some support from the positioning.

Performing the Hip Scan

The left hip is set as the Default for scanning in the CLSA. Scan the right hip when there is a contraindication or other reason for not scanning for the left hip.

Pay attention to which scan Onyx prompts you to choose and be sure to click on the correct scan.



All scans should be done in the same mode. All the hip scans should be done in array mode and never in express mode.

NOTE: In obese participants, adiposity can be a major source of error for DXA scans. With abdominal obesity, the fat pad of the belly can overlie the head of the femur, artificially increasing the BMD of the hip and invalidating results. However, obese participants should be asked to pull up on their abdominal fat pad during hip scanning to improve scan quality and validity, as indicated in **Step 8 of Performing the Hip Scan** section.

Step 1: Before this scan can be performed the Bone Density Questionnaire stage must be completed. Refer to *SOP_DCS_0014 - Bone Density Questionnaire* and complete the **Starting the BD Questionnaire** section.

Step 2: To start the scan refer to *SOP_DCS_0014 - Bone Density Questionnaire* and complete the **Starting Each DXA Scan** section.

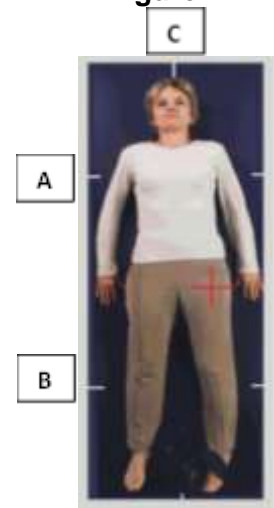
Step 3: Select **Left/Right Hip** from the list of scans and then select **Next**.

Step 4: Ensure that the participant's;

- Hips are centered and located between hashmarks A and B on the long edge of the table;
- Feet fully supported by the foot end of the table.
- Body is centered along the long axis of the bed.

Arms are by their side or across their chest and out of the scanning area.

Figure A.



If possible, the participant's shoulders can be just below hashmark A. This will have them close to or at the correct position on the table for IVA lateral spine scanning. However, this may not be possible during the hip scan for taller participants, where the feet must be fully supported by the scanner table.

- Step 5:** Press the **Center button on the scanner console** to move the table and C-arm to the center position.
- Step 6:** Ask the participant if you can palpate their hip area. Find the superior edge of the iliac crest. Once located, place the fifth fingertip of your right hand on the superior iliac crest, rest the palm of your hand on the participant and spread out your right fingers and thumb. Without moving your right hand, place fingers 2-5 (fingers closed/together) of your left hand beside the tip of your right thumb. The lateral border of your left 5th finger will be approximately at the starting level of the area of interest for the hip scan.
- Step 7:** Push the **Laser button** on the scanner and move the c-arm so that the laser crosshairs align with the lateral border of your left 5th finger.
- Step 8:** Keeping the laser crosshairs on, and without changing the level of the crosshairs on the hip, move the table away or toward you until the crosshairs are approximately 1cm lateral to the midline of the thigh. The scanner is now in position to start the hip scan.

NOTE: In very obese participants, the fat pad of the belly can overlie the head of the femur, artificially increasing the BMD. This is a major source of error, which will cause the analysis of the scan to be inaccurate.

When presented with an obese participant,

→ Gently palpate the area to determine if obesity will cause a problem with the scan.

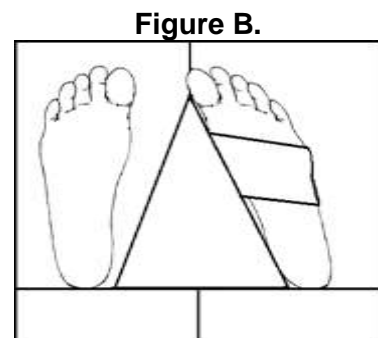
→ Ask the participant to hold the fat pad out of the way with their hands by pulling it up and away from the femoral area. If unsure from palpation, start the scan and, if obesity causes a problem, then repeat the scan with the fat pad retracted.

→ Document this at Step 30.

- Step 9:** Place the wedge-shaped hip positioning fixture between the participant's feet, aligning the centre of the fixture with the midline of the table, see **Figure B**.

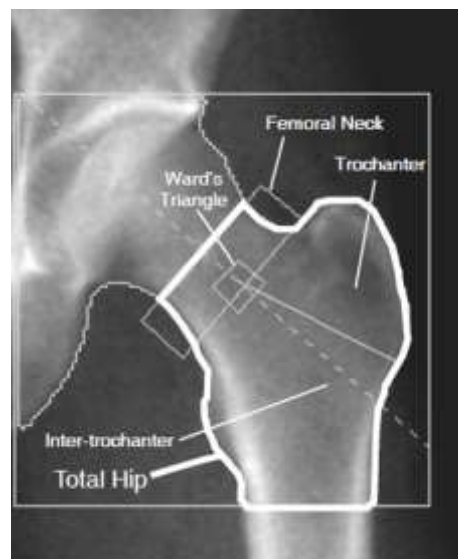
- The participant's heel should sit in the middle of the positioner. The leg to be examined should be rotated inward so that the foot can be placed against the positioning fixture and secured with the strap, see **Figure B**. The foot and leg should be internally rotated 25 degrees.

- Ask the participant to flex their toes and rotate their foot inward as far as they can toward the positioner. Guide their foot with your hands, but do not force the position. Secure the foot to the wedge with the Velcro strap provided.



- Carefully adjust the position of the fixture and secured foot so that the shaft of the femur of the hip under investigation is parallel to the long axis of the table. **Ask the participant to relax the muscles in the entire leg**, place your hands above and below the knee (one on the calf, the other on the thigh above the knee) and gently rotate the leg inward again to ensure optimal internal rotation for hip scanning.

NOTE: For participant's who are able to tolerate the placing of straps on both feet, repeat foot positioning against the wedge for the opposite leg, but without aligning the femur to the table long axis. However, older arthritic participants may not be able to tolerate more than one foot rotated and immobilized at a time.



Step 10: Reconfirm that the participant is properly positioned, that they can tolerate the position.

Step 11: Remind the participant to remain still throughout the scan, but to breathe normally.

Step 12: Press **Start Scan**. The Hologic screen will indicate that the X-ray is active on the top right of the screen in bold text highlighted in yellow, and a scanning preview window will appear. Inspect the image as it is generated for the following optimal features:

- The shaft of the femur should be straight (neither abducted or adducted);
- Approximately 3 cm of the femoral shaft should be visible in the image below the greater trochanter;
- The greater trochanter should appear halfway up in the image, with approximately 1cm of soft tissue to its right (for the right hip, to the left).

If the hip is:

- **Positioned correctly**, allow the scan to complete and skip to **Step 14**.
- **Not positioned correctly**;
 - Select **Reposition Scan** to stop the scan.
 - Click on the partially acquired image (the cursor arrow turns into a hand), and drag the image in the preview box to change the starting point of the scan where you think that features a. to c. are likely to be achieved.
 - Select **Restart Scan**.
 - You will be returned to the *Start Scan* screen once more, and the scanner will adjust to a new starting position, based on movement of the image in the scan preview window.
 - Select **Start Scan** to begin a new scan.

! Hip Replacement or Pins found but NOT Reported

If the scan reveals that the participant has a hip replacement or pin previously not reported,

- 1 Stop the scan and;
 - a. If possible, proceed with the scan on the other hip, if possible.
 - b. If not possible, discontinue the scan.
- 2 Correct the BD Questionnaire stage in Onyx.

! Updating the BD Questionnaire Stage

If for any reason it is impossible to complete the hip that was first indicated, the BD Questionnaire will need to be updated before attempting to transfer the scan to Onyx.

- In Onyx click on bone density questionnaire.
- Click through, using the **next** button until you reach the hip you are not completing/did not complete and switch the radio button to “no”.
- Click **Next** button.
- Click **Finish** button.

! Scan Fails to Transfer

If the scan fails to transfer to Onyx, check that the hip scan chosen in the BD Questionnaire corresponds with the hip scan completed (i.e.: both are the right side or both are the left side). If they do not,

- Abort the attempt to transfer the scan in Onyx by cancelling the “Single or Dual Hip Bone Density” stage.
- Complete the **Updating the BD Questionnaire Stage** section above.
- Continue to **Step 23** in the **Data Transfer** section.

Step 13: When the scan is finished and the X-ray turned off, remove the hip positioning fixture and strap from the participant’s feet. If the participant is set to do a

- **Forearm scan**, they will be able to get off the table.
- **IVA lateral spine scan**, they will need to remain on the table. The participant should remain in position on the table until it stops moving and they are instructed to move

Step 14: Clean the hip positioning fixture with disinfectant spray and put it away.

Analyzing the Scan(s)

Step 15: In Hologic on the ‘Exit Exam’ select **Analyze Scan**.

Step 16: An ‘Analyze Setup’ window will open, click **Next**.

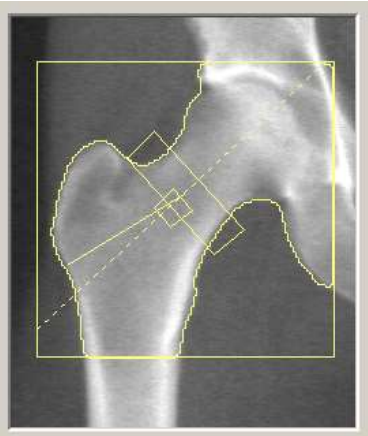
Hologic software Auto analysis of hip scans is done automatically, but you must check to verify that the analyses are correct. Examples of correct analyses of both Left and Right hips are shown in **Figure C**.

If the auto analysis of the hip scan is:

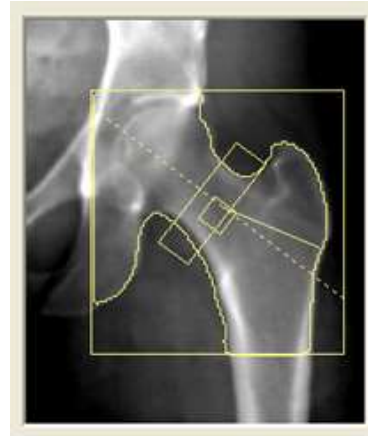
- **Correct** and requires **no adjustments** continue to **Step 18**.

- **Correct** and requires **adjustment** of the image contrast refer to the **Adjusting Image Quality** section below.
- **Requires re-analysis** refer to the **Manual Analysis of Hip Scan** section below.

Figure C.



Proper Analysis Right Hip Scan

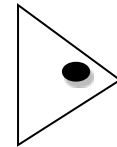


Proper Analysis Left Hip Scan

Adjusting Image Quality:



Image contrast can be adjusted by selecting the **Sun/Moon** symbol on the bottom left of the screen, then move the circle within the triangle to change the lightness or darkness of the image.



Once contrast is optimal, select the Sun/Moon again to set the contrast.

Use the zoom in/out buttons as needed to enhance detail.

Step 17: Select **Close**.

Step 18: Select **Analyze Another Scan** or **Close**, if all scans have been analyzed. The Dose Area Product (DAP) will come up, click **Okay**.

Data Transfer:

Step 19: Analyzed scans must be sent to Onyx. In the Hologic software at the home screen, select **Report**, the 'Select Patient' window appear.

Step 20: Select the participant's visit ID number and select **Next**. A list of analyzed scans performed on the participant during the exam will appear, including the hip scan.

Step 21: Keep Hologic software running at this screen, but minimize the window and return to the participant's Onyx interview home page.

Step 22: Find the 'Single or Dual Hip Bone Density' Stage in Onyx, and select **Start**. The 'Bone Density – Hip: Start' window will appear.

Step 23: Scan the Interview ID barcode, select **Continue**.

- Step 24:** Select **Start** in the Instrument application launch window to open the Hologic Apex Receiver window with a Capture function. Do NOT select **Capture**, rather return to the report window minimized in the Hologic software.
- Step 25:** Select from the list the Hip Scan, and the report type selected is Interpreting' with one copy. Select **DICOM/IVA**. Next the 'DICOM/IVA' page will come up, click on **Send**.
- Step 26:** Select **OK** for each of the next 2 pop-up windows that appear, then return to Onyx and the Hologic Apex Receiver window.
- Step 27:** In Onyx press the **Capture** button in the Hologic Apex Receiver window. Wait until the 2 rows below go green, then select **OK**.
- Step 28:** Press **Refresh** to show the scans that transferred to Onyx. If there is more than the required amount of scans, delete the appropriate ones.
- Step 29:** Click on **Next**. The 'Bone density – Hip: Finish' screen will appear.
- Step 30:** Click **Finish** and indicate in the comments field if there was anything that may have affected the measurement. Ensure that comments do not contain any personal identifying information.
- Step 31:** Click **Continue** to return to the Onyx *Interview Tab* page.
- Step 32:** Return to the 'APEX program – Report' and click on **Cancel**.
- You will now move on to the next scan. If the participant is unable or unwilling to do this scan, or no further scan is prompted, then refer to the **Final Steps** section of *SOP_DCS_0014 - Bone Density Questionnaire*.

Fracture Risk Assessment Tool

- Step 1:** At the 'Interview Tab' in Onyx in the list of stages, select **Start** in the 'Fracture Risk Assessment Tool' row.
- Step 2:** The 'Fracture Risk Assessment Tool' window will appear. Scan or enter the Interview ID barcode, then click on **Continue**.
- Step 3:** Press **Start**. Wait for the Java window to disappear, and then click on **Next**.
NOTE: If you click on **Next** too soon, an error message will appear.
- Step 4:** Click **Finish**. The 'Fracture Risk Assessment Tool' window will appear.
- Step 5:** Indicate in the comment field in Onyx if there was anything that may have affected or influenced the measurement. Ensure that comments do not contain any personally identifying information.
- Step 6:** Click **Continue** to return to the status page.

Manual Analysis of Hip Scan

The following directions are for a left hip scan.

If one of the following conditions is seen, manual analysis may be required:

- Regions are positioned incorrectly.
- Poor bone mapping.

Step 1: Select **Global ROI**. This identifies the outer boundaries of the region of interest (ROI), within which analyses are done.

Step 2: Select **Line Mode** to check and adjust placement of the box:

- Click on the red line forming the top of the ROI box. The line should change to a solid outer yellow line with an inner pale blue dashed line. Adjust the position of this pair of lines so the blue dashed line is positioned just along the SUPERIOR surface of the head of the femur.
- Click on the red line forming the medial side of the ROI box. The line should change to a solid outer yellow line with an inner pale blue dashed line. Adjust the position of this pair of lines so the blue dashed line is positioned just along the MEDIAL surface of the head of the femur.
- Click on the red line forming the bottom of the ROI box. The line should change to a solid outer yellow line with an inner pale blue dashed line. Adjust the position of this pair of lines so the blue dashed line is positioned just at the base of the lesser trochanter.
- Click on the red line forming the lateral side of the ROI box. The line should change to a solid outer yellow line with an inner pale blue dashed line. Adjust the position of this pair of lines so the blue dashed line is positioned just next to the most lateral aspect of the greater trochanter.

Step 3: Select **Bone Map**. Verify that all bone has been filled in.

Acceptable Bone Map – all the bone inside the global region of interest (ROI) has been mapped (covered by yellow).

Unacceptable Bone Map – look for any bone that was not mapped (covered by yellow) from the bone map.

If:

- **All bone has been filled in** continue to **Step 4**.
- **Editing is required** complete the steps identified in the **Edit the Bone Map** section below.

Step 4: Select **Neck**. Verify that placement of the neck box is correct;

- The right upper corner of the neck box should be anchored in the trochanteric notch;
- The other three corners of the neck box should be located in soft tissue. If it is necessary to lengthen the neck box so that the lower, medial border of the box is in soft tissue, select Line Mode, and extend the medial border of the neck box so that it sits in soft tissue between the ischium and the femoral neck.

Step 5: Select **Auto Position** if Global ROI and/or bone map have been changed. This will recalculate the locations of all the hip regions.

Step 6: Select **Results**.

Step 7: Return to **Step 18** in the **Analysis Steps** section.

Edit the Bone Map:

Step 1: Complete the correction selecting one or all of the techniques described in the sections below:

Correct Missing Bone in the Femur:

- Missing bone in the femur may be correctly identified by increasing the height of the top of the ROI box.
- Select **Global ROI**.
- Select the top line forming the ROI box, and move it up 10-20 lines toward the top of the image.
- Select Bone Map, verify that all femoral bone is correctly identified

To Add Bone:

No more than 5% of bone mapped in a given region of the ROI should be manually added.

- **Add Bone** – place the cursor in the yellow of the bone map, click **Add Bone**, trace the outline of the bone, ending in the yellow of the bone map
- Click **Fill Holes**; or,
- Click **Sink Islands**.

To Delete Bone:

If the femoral shaft is too close to the ischium, it may be necessary to delete the ischium from the ROI.

- Place the cursor in the dark area (soft tissue) outside the bone map between the femoral neck and ischium.
- Select **Delete Bone**, cut straight across and through the ischium (all the way through the bone).
- Select **Sink Islands**.

Step 2: Return to **Step 4** of the **Manual Analysis of Hip Scan** section.

9.0 Documentation and Forms:

- CRF_DCS_0014_1 - DXA Case Report Form

10.0 References:

- Body Composition Procedures Manual. NHANES; 2006.
- Discovery QDR Series: Operator's Manual. Document No. MAN-01794 Revision 002. Hologic, Inc.; 2010.

F1 Revision History:

| New Version # | Revision Date | Revision Author | Content Approval |
|--|---------------|-----------------|------------------|
| 3.1 | 2017-AUG-09 | Lorraine Moss | Harriet Sauve |
| Summary of Revisions | | | |
| Removed information for starting a scan and ending a scan. | | | |
| Added Fracture Risk Assessment Tool section | | | |
| Added section on sponges. | | | |

| Section 8.0 rewritten to adhere to training provided at the Super User training session. | | | |
|--|---------------|-----------------|------------------|
| Removed information regarding starting and ending scans | | | |
| SOP edited to correct the Contraindications and to be noted sections for this measurement. | | | |
| New Version # | Revision Date | Revision Author | Content Approval |
| 3.0 | 2016-APR-14 | Lorraine Moss | Mark Oremus |
| Summary of Revisions | | | |
| SOP edited to reflect that only one hip scan will be required. | | | |
| New Version # | Revision Date | Revision Author | Content Approval |
| 2.2 | 2015-OCT-29 | Lorraine Moss | Mark Oremus |
| Summary of Revisions | | | |
| Added ethnicity to the list of participant information in Step 1 and Step 4 | | | |
| Step 10 added: the foot should be internally rotated 25 degrees. | | | |

FOLLOW-UP