	<b>Title:</b>	<b>Bone Mineral Density by Dual- energy X-ray Absorption (DXA) - Dual Hip Measurement</b>		
	<b>Version Date:</b>	2015-OCT-29	<b>Document Number:</b>	SOP_DCS_0015
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<b>Data Collection Site (DCS)</b>	<b>Version:</b>	2.2	<b>Number of Pages:</b>	10

**1.0 Purpose:**

The purpose of this document is to describe the standardized procedure for completing bone mineral density (BMD) measurement of both hips 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(s) 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

**5.0 Definitions:**

- **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

**7.0 Supplies:**

- Radiation badges
- Straps for positioning
- Disinfectant spray

## 8.0 Procedure Steps:

### Contraindications:

- Weight over 450lbs (204kg);
- Pregnancy (Contraindications Questionnaire);
- Had an x-ray with contrast material such as barium in the last 7 days (Contraindications Questionnaire);
- Participated in any nuclear medicine studies in the past 7 days (Contraindications Questionnaire); or,
- Please make a note of the following in the comments section of Onyx:
  - Pacemaker or defibrillator (Contraindications Questionnaire);
  - Cochlear implant or hearing aid (Contraindications Questionnaire);
  - Any metal implants in the body (e.g., plates or screws);
  - Previous breaks or fractures (Contraindications Questionnaire); or
  - Prosthetic limbs or joints (e.g., hip replacement) (Contraindications Questionnaire).

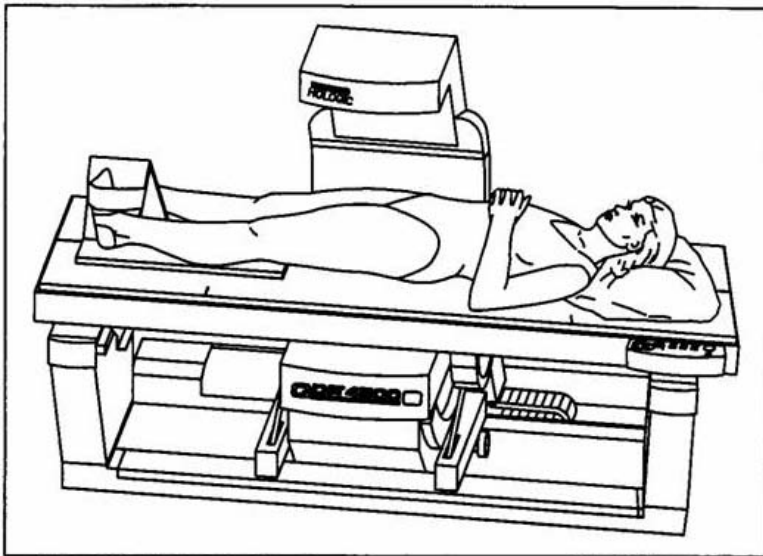
A dual hip scan will be done unless there is a contraindication for one of the hips. Pay attention to which scan Onyx prompts you to choose and be sure to click on the correct scan.

**Step 1:** Double click on APEX icon on the desktop to launch the Hologic software. **Before proceeding you need to have the participant's ID, date of birth, sex, height, weight, and ethnicity (Caucasian, African, Asian, or Hispanic).**

**Step 2:** Have the participant lie on the table. If necessary, press the **Patient ON/OFF** switch on the Control Panel to move the C-arm to the side to enable the participant to reposition her/himself. Ensure the participant does not have any metal on their clothing or jewelry. If there are small pieces of jewelry that cannot be removed, the scan can still be done, but a note needs to be made about this. False teeth or hearing aids need NOT be removed. Because these scans may cause some anxiety in the participants, be sure to explain what you are doing as you go along. Make sure the participant is comfortable with having you position them for the scans.

**Step 3:** In the Hologic Discovery A screen, select **Perform Exam**.

**Step 4:** In the Patient screen, click on the **New Patient** button. **Enter participant's ID, date of birth, sex, height, weight, and ethnicity (Caucasian, African, Asian, or Hispanic)** and then press **OK**.



**Step 5:** Select the type of exam: **Dual Hip**, and then select **Next**.

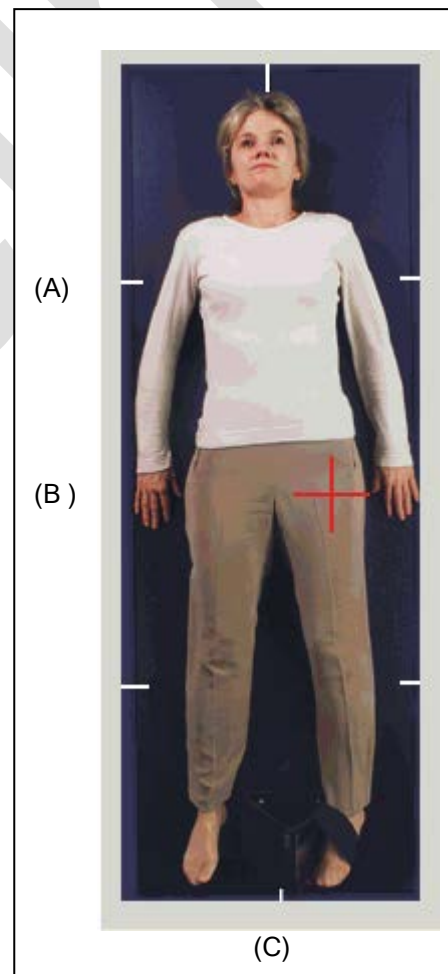
**Step 6\*:** The head positioner should be placed on the table at the first hash markers (A). This may need to be adjusted to down for tall participants. Make sure the participant is straight and centred on the table. The hip region should be within the two sets of hash marks (93 and 99 cm) on the long edge of the table (B).

Arms can be by their side or across their chest.

\*This step helps to position the participant better for the IVA scan and is not critical for the hip scan.

**Step 7:** Press the **Center** switch to move the table and C-arm to the center position. Make sure the participant is also centred. **Always start with the left hip.**

**Step 8:** Locate the participant's hip, ask to touch their side. When you feel the top of their hip, spread your right hand out to the left. Place the left hand beside it. Then switch on the **Laser**, move the table until the laser is in line with the left side of your left hand. Move the table towards or away from you until the crossing line is one cm off the centre of the thigh.



**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,

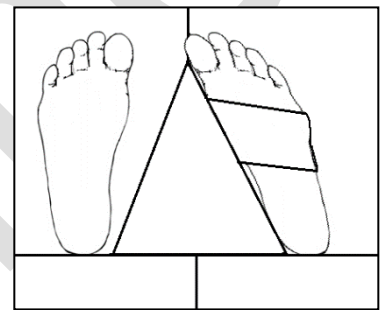
→ Gently palpate the area to determine if obesity will cause a problem with the scan.

→ 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 26.

**Step 9:** Make sure the participant's arms are outside of the scanning area.

**Step 10:** Place the hip scan positioning fixture between the participant's feet, aligning the centre of the fixture with the table's midline (figure above (C)).

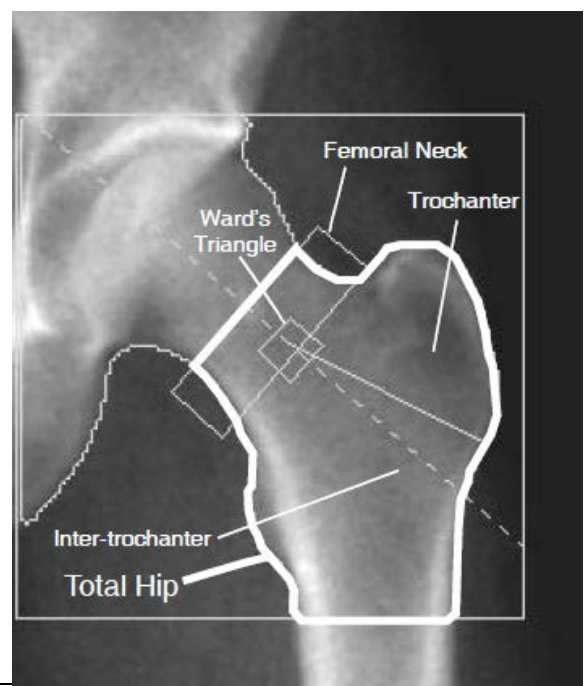


- The participant's heel should sit in the middle of the positioner. The leg to be examined should be rotated inward so that the foot can be placed against the positioning fixture and secured with the strap (see picture). The foot should be internally rotated 25 degrees.
- Before securing the foot, ask the participant to flex their toes and then move the foot toward the positioner. Adjust the abduction of the leg so that the shaft of the femur is parallel with the centre of the table. In rotating the leg inward, place one hand above the knee and one hand below the knee and gently rotate the leg to ensure the whole leg is rotated.
  - The complete rotation of the leg will place the femoral neck in profile and elongate the femoral neck for a better scan

**Note:** For participants who are able to tolerate the placing of straps on both feet, please secure both feet using the straps. However, older patients may not be able to tolerate more than one foot strapped in at a time.

**Step 11:** Reconfirm that the participant is properly positioned and press **Start Scan** to begin the scan.

**Step 12:** The Scan window display will show the image appearing. Inspect the image as it is generated.



**The femur should be straight. Greater Trochanter should be 1 cm in and midway up.**

**Approximately 3 cm of the shaft should be visible.**

If the hip is positioned correctly, allow the scan to complete. If the hip is not positioned correctly, click **Reposition Scan** to stop the scan.

Move the scan in the screen to match the picture on the left.

**NOTE:** if the scan reveals that the participant has a hip replacement or pin previously not reported, stop the scan and proceed with the scan on the other hip, if possible. If this is not possible, discontinue the scan and complete the Data Entry screen to document the reason for the incomplete scan.

**Step 13:** When the outer edge of the greater trochanter is identified, press **Restart Scan**. The new starting point is automatically adjusted to have the correct amount of soft tissue lateral to the greater trochanter. Press **Start Scan** to repeat the scanning process.

**Once the left side is complete the program will reposition for the right hip - steps 10 to 13.**

**Step 14:** 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. If the participant is set to do an IVA lateral spine scan, they will need to remain on the table. Center the table before proceeding.

**Step 15:** Clean the hip positioning fixture with disinfectant spray and put it away.

**Step 16:** When the exam completes, an 'Exit Exam' window box displays. Press **Analyze Scan**.

**Step 17:** An 'Analyze Setup' window will open. Click **Next**.

**Step 18:** Auto analysis would have already occurred, but check to see if the analysis is correct. **Additional information is provided in section 7.**

→ The blue line should touch the head of the femur on both sides.

→ The red diagonal line should intersect the midline of the femur, but not necessarily the corner of the box.

→ The diagonal box (femoral neck area) should touch bone (anchored) on only one corner. All other corners should be in soft tissue.

→ The bottom line should be where the lesser trochanter starts.

**To make adjustments**

→ Click on **Sun/Moon** symbol  on the bottom left of the screen.

**NOTE:** In obese participants if the picture is snowy looking, click on the SE/DE button to obtain a clearer picture.

→ Move the circle within the triangle to change the lightness or darkness of the scan.



→ Press the zoom button twice.

→ Use **Line Mode** to adjust the box.

→ If the diagonal box is not correct (femoral neck too short), bone may need to be deleted. Click on **Bone Map**, click **Delete Bone**. Place the cursor where you need to start and drag in the smooth line. Then press **Sink Island**. **Click on Neck, then press Auto Position**, now the diagonal box should be in the correct place.

→ When adjustments are complete press **Results** (not Auto Analysis).

**NOTE:** For more details on manual analysis or corrections see Section 7.0, below.

**Step 19:** Close Analyze page, and then select **Analyze Another Scan**. When complete, close. The Dose Area Product (DAP) will come up, click **Okay**.

**Step 20:** When the analysis of both hips is complete, then both scans can be sent to Onyx. Select **Report** and the 'Select Patient' window will pop up. Click on both of the participant's left and the right hip scans to select (press the ctrl button for the second one), then click on **Next**.

**NOTE:** If for any reason it is impossible to complete both hip scans, the DXA Questionnaire will need to be updated before attempting to transfer the scans 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

**Step 21:** Minimize the APEX program and go back to Onyx.

**Step 22:** At the *Interview Tab* in Onyx, look for Bone density – hip scan in the list of stages. Then select **Start** in that row.

**Step 23:** The 'Bone density - Hip: Start' window will pop up.

**Step 24:** Scan the Interview ID barcode, click on **Continue**.

**Step 25:** Press **Start** in the Instrument application launch to open the Hologic software. A 'Hologic Apex Receiver' box will pop up.

**Step 26:** Go back to the APEX program. Make sure the report type selected is 'Interpreting' with one copy. Select **DICOM/IVA**. Next the 'DICOM/IVA' page will come up, click on **Send**.

**Step 27:** Two messages will pop up click on **OK** (for each message), until you are back to the 'DICOM/IVA' page. Go back to Onyx.

**Step 28:** In Onyx press the **Capture** button. Wait until the 2 rows below go green, click on **OK**. Press **Refresh** so that the scans will appear on this page. If there is more than the required amount of scans, delete the appropriate ones.

**Step 29:** Click on **Next**. The 'Bone density – Dual Hip: Finish' screen will pop up.

**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 *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 below to see how to end the procedure.

### **Final Steps**

**Step 33:** Press the **Patient ON/OFF** switch on the control panel and wait for the C-arm to move to the far left and extend the table out from the base.

**Step 34:** Once the machine has stopped moving, help the participant off of the table.

**Step 35:** If the participant needs to change clothes, follow the steps in the Participant Changing SOP to ensure that they are provided with privacy and assistance, as required.

**Step 36:** Click on **Exit** in the bottom right corner. The 'Exit Analysis' window will open. Select the **Exit without shutdown** option.

**Step 37:** Wipe down the DXA tabletop.

### **MANUAL ANALYSIS OF HIP SCAN (following directions are for a left hip scan)**

**Step 1:** Click **Global ROI**;

→ Place the top blue dotted line on the head of the femur (*use yellow line to move blue line*);

**NOTE:** Click on the top line of the red box if it doesn't have yellow and blue dotted lines visible.

→ Click on the medial line of the red box (it will change to yellow and blue dotted lines). Place the inside (*medial*) line on the head of the femur (*use yellow line to move blue line*);

→ Click on the bottom line of the red box. Place the bottom line at the base of the lesser trochanter (*use yellow line to move blue line*);

→ Click on the lateral line of the red box .Place the outside (*lateral*) line at the outer edge of the greater trochanter (*use yellow line to move blue line*)

**Step 2:** Click **Bone Map**;

**Step 3:** Verify that all bone has been filled in

→ If all bone has been filled in continue to **Step 4**

→ If editing is required skip **Steps 4 - 8** and proceed to the “Problem Hips / Non Standard Hips – Placement of Neck box” instructions

**Step 4:** Click **Neck**;

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

**Step 6:** Verify that placement of the neck box is correct;

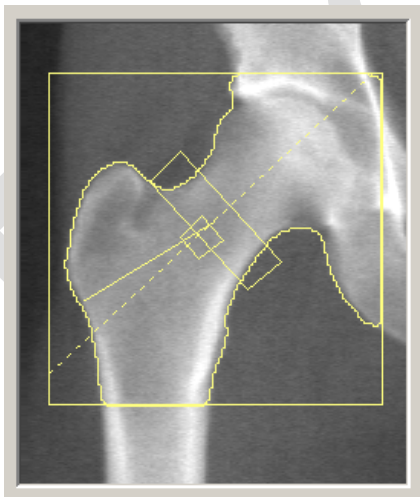
→ The lower outer corner of the neck box is placed in the trochanteric notch;

→ The other three corners of the neck box are in soft tissue;

→ Soft tissue is any area outside the yellow bone map outline

**Step 7:** Click **Results**.

**Step 8:** Return to **Section 6.0 - Step 19** to complete the analysis or send report



Proper Analysis Right Hip Scan



Proper Analysis Left Hip Scan

#### **PROBLEM HIPs / NON STANDARD HIPs – Placement of Neck Box**

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

→ Regions are positioned incorrectly

→ Poor bone mapping



## To complete manual analysis:

### Step 1: Click **Global ROI**

- Place the top dotted blue line just above the femoral head
- Place the outside dotted blue line just touching the outer edge of the greater trochanter
- Place the bottom dotted blue line is at the base of the lesser trochanter
- Place the inside dotted blue line just touching the femoral head

### Step 2: Click **Bone Map**. Verify whether the bone map is acceptable or needs to be edited

- **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

#### **Edit the Bone Map:**

- If significant portions of the bone in the femur were not identified, increase the global ROI height by clicking on the "Global ROI" button and moving the upper global ROI up 10-20 lines toward the top of the image
- If necessary, no more than 5% of the bone in a given region should be filled in manually
- In some cases, if the femoral shaft is too close to the ischium it may be necessary to delete the ischium

#### **To edit the bone map:**

- **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
- **Delete Bone** – place the cursor in the dark area (soft tissue) outside the bone map between the neck and ischium, click **Delete Bone**, cut through the ischium (all the way through the bone),
- Click **Sink Islands**

### Step 3: Click **Neck**. **NOTE:** If it is necessary to lengthen the neck box, click **Line Mode**, pull the yellow dotted line down to make the neck box longer

### Step 4: Click **Auto Position** (in the Neck Toolbox)

### Step 5: Click **Results**

### Step 6: Return to **Section 8.0 - Step 19** to complete the analysis or send report

## 9.0 Documentation and Forms:

- CRF\_DCS\_0014\_1 - DXA Case Report Form

## 10.0 References:

- Body Composition Procedures Manual. NHANES; 2006.
- DEXA Calibration and Maintenance SOP (SOP\_DCS\_0043)
- DEXA Gold Standard Process (SOP\_DCS\_0066)

### Baseline Revision History:

New Version #	Revision Date	Revision Author	Content Approval
2.2	2014-AUG-20	Lorraine Moss	Mark Oremus
<b>Summary of Revisions</b>			
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.			
New Version #	Revision Date	Revision Author	Content Approval
2.1	2014-AUG-20	Lorraine Moss	Mark Oremus
<b>Summary of Revisions</b>			
Added definitions for Greater and Lesser Trochanter and Femoral Neck.			
The amount of the Lesser Trochanter that is visible is dictated by proper positioning.			
Removed sentence in <b>Step 12</b> : <del>If too much of the Little Trochanter shows in the scan, rotate the thigh inwards before starting the scan again.</del>			
Added point to <b>Step 10</b> : The complete rotation of the leg will place the femoral neck in profile and elongate the femoral neck for a better scan.			
Added note to <b>Step 10</b> : For participants who are able to tolerate the placing of straps on both feet, please secure both feet using the straps.			
Re-added the left hip scan image under <b>Step 12</b> .			
Under <b>Step 26</b> added "Make sure the report type selected is 'Interpreting' with one copy"			
Updated SOP formatting. Grammar and spelling changes			
<i>"Added ethnicity to step 1 and the note under step 1"</i> – This information was not implemented in the last update <b>as it isn't required</b> and was added to the revision history in error.			
New Version #	Revision Date	Revision Author	Content Approval
2.0	2012-Dec-17	Lorraine Moss	Mark Oremus
<b>Summary of Revisions</b>			
Added definitions for Greater and Lesser Trochanter and Femoral Neck.			
Added Note in section 6.0 – under steps 20 and 8			
Various formatting corrections throughout document			
Added training manual in section 7.0 & document numbers			
Added Calibration SOP to section 9.0			
Changed bone to box in the last sentence of point 5 of to make changes beside the word diagonal			
Added the sun/moon symbol in the "To Make Adjustments" section under step 18.			
Various grammatical corrections throughout document.			
Added calibration SOP names to 2.0			
Added Gold Standard SOP to section 9.0			

Added definition for Ischium in section 8.0

Added ethnicity to step 1 and the note under step 1

Baseline