CISA ÉICV Canadian Longitudinal Study on Aging Etude longitudinale canadienne sur le vieillitsement	Title:	Bone Mineral Density by Dual- energy X-ray Absorption (DXA) - IVA Lateral Spine Measurement		
	Version Date:	2014-JUL-10	Document	
	Effective Date:	2014-OCT-15	Number:	SOP_DCS_0010
Data Collection Site (DCS)	Version:	3.0	Number of Pages:	6

#### 1.0 Purpose:

The purpose of this document is to describe the standardized procedure for completing bone mineral density (BMD) and intervertebral assessment (IVA) of the lateral spine on the Hologic Discovery A Dual Energy X-Ray Absorptiometry (DXA) machine.

#### 2.0 Scope:

This document is to be used by the DCS staff when administering the BMD measurement of the spine on a participant.

#### 3.0 Responsibilities:

It is the responsibility of the DCS staff to perform the procedures as described in the current and approved version of the standard operating procedure.

#### 4.0 Related Documents:

#### MAN\_DCS\_0014 – Additional training manual for the Dual X-ray Absorptiometry (DXA)

#### 5.0 Definitions:

• **Sacrum:** a large, triangular bone at the base of the spine and at the upper and back part of the pelvic cavity, where it is inserted like a wedge between the two hip bones

#### 6.0 Equipment:

• DXA machine (Hologic Discovery A)

#### 7.0 Supplies:

- Square cushion for positioning;
- Head positioner;
- Radiation badges; and,
- 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:
  - $\rightarrow$  Pacemaker or defibrillator (Contraindications Questionnaire);
  - $\rightarrow$  Cochlear implant or hearing aid (Contraindications Questionnaire);
  - $\rightarrow$  Any metal implants in the body (e.g., plates or screws);
  - $\rightarrow$  Previous breaks or fractures (Contraindications Questionnaire); or
  - $\rightarrow$  Prosthetic limbs or joints (e.g., hip replacement) (Contraindications Questionnaire).

### **IVA Lateral Spine Scan**

- Step 1: Double click on APEX inc. icon on the desktop to launch the Hologic software. **NOTE:** Before proceeding you need to have the **participant's ID**, **date of** birth, gender, height and weight (if this is the first scan).
- Step 2: If the participant did not complete the hip body scan, have him/her 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. Ensure that 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 being positioned for the scans.

Step 3: To position the participant correctly, make sure that the participant is straight and centred on the table and that his/her shoulders are just within the hatched marks on the table. If the patient is shorter, i.e., 5'2 or less, their shoulders can be below the marks for shoulders (see picture). **NOTE:** it may be helpful to stand at the head of the table, reach under the participant's underarms, and gently pull the participant toward you to straighten the spine. You may also stand at the foot of the table and pull the feet. Centre the table and move the participant so they are centred on the table.



Step 4: Place the large square cushion under the participant's lower legs with the thighs as close to a 90 degree angle as possible. Use the tallest cushion side possible, without making the participant's feet stick

up in the air. Place a cushion under the participant's head (if not already done) and ask the participant to place their arms above their head (see picture).

#### Step 5: On the screen, select Perform Exam. The default scan length is 39.3cm and can be found on the left hand side of the DXA IVA imaging screen (the one with the showing the patient on the table in position). **NOTE:** The scan length needs to be changed from 39.3cm to 45.2cm.

Step 6: If this is the first scan - click on the New Patient button. Enter participant's ID, gender, date of birth, height and weight and then press OK.

If this is not the first scan, then in the "Patient ID" column, select the participant ID, press OK. Verify that their information (height and weight) is entered, press OK.

Step 7: Place the laser to the left of the tape, which is to the left on the side of the bed. Adjust your participant upward or downward, so that the laser is 2 inches below the participant's belly button. If the laser is not in this position, then shift the participant accordingly. This is to avoid error messages about positioning. Taller participants may also need the scan length increased on the 'start scan' page.
If you do get an error message, click OK. Then go to the main screen of Helegic. On tap of the menu.

go to the main screen of Hologic. On top of the menu bar under 'utilities', click AP reposition. Move the participant down the table; reselect 'patient' from perform exam and then select IVA imaging

- Step 8: Select the type of exam: IVA Imaging and then select Next. Continuously press Enable Lateral on the Control Panel until the C-arm has rotated fully to the lateral scan position.
- **Step 9:** If the participant is positioned correctly for the scan, press **Start Scan** to begin. Ask the participant to take a small breath and hold during the exam. The participant should remain still until the scan is complete.

Step 10: Inspect the image as the scan starts. Make sure only a small part of the sacrum is showing at the bottom of the scan. If more is showing, allow the scan to finish, reposition the participant, and start the scan again.
→ Move the scan in the screen to match the picture on the right.



 $\rightarrow$  When you see L5 through T4 on the image, click **Stop Scan** and tell the participant to breathe normally.

- Step 11: On the 'Exit Exam' window, press Analyze Scan.
- Step 12: On the 'Analyze Setup" window click Next.
- Step 13: Click on Sun/Moon symbol on the bottom left of the screen.
  → Move the circle within the triangle to change the lightness or darkness of the scan.
  - $\rightarrow$  Press the zoom button twice.

→ Press Marker. With cursor over the scan, right click and select Add Marker. The L4 marking will appear. You need to place the marker on L4 (two vertebrae up from the sacrum or above L5) before clicking on **Close**. Note: If scoliosis is present and L4 is tilted, put the centre marker in the centre of the superior or inferior surface aspect. (see picture)

- $\rightarrow$  Place each marker on the outer edge of the vertebrae.
- $\rightarrow$  Click out of the area to turn the marker from yellow to red.

→ Results should appear on the lower right window.
 NOTE: Aortic Calcification is assessed by looking at vertebrae L5 to L1.

- Step 14: The Dose Area Product (DAP) will come up, click OK.
- **Step 15:** Minimize the APEX program and go back to Onyx.
- **Step 16:** At the *Interview Tab* in Onyx, look for Bone density – IVA Imaging in the list of stages. Then select Start in that row.
- Step 17: The 'Bone density IVA Imaging: Start' window will pop up



- **Step 18:** Scan the Interview ID barcode, click on Continue.
- **Step 19:** Press **Start** in the Instrument application launch to open the Hologic software. A Hologic Apex Receiver box will pop up.
- Step 20: 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 21:** One or Two messages will pop up. Click on **OK** (after each message), until you are back to the 'DICOM/IVA' page. Go back to Onyx.
- Step 22: 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, check which one should have transferred and delete the other one.
- Step 23: Click on Next. The 'Bone density IVA Imaging: Finish' screen will pop up.
- **Step 24:** 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 25:** Click **Continue** to return to the *Interview Tab* page.

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- **Step 26:** Return to the Apex program- Report and click on **Cancel**.
- **Step 27:** Continuously press **Enable Lateral** on the Control Panel until the C-arm has rotated to its original position.
- Step 28: Click on the Patient on/off button.
- **Step 29:** Remove the cushion from underneath the participant's legs, clean with disinfectant spray, and put away.
- Step 30: You will now move on to the next scan, as prompted by Onyx. Depending on the scan, refer to that SOP.If the participant is unable or unwilling to do this scan, or no further scan is prompted, refer to the Final Steps below to see how to end the procedure.

### **Final Steps**

- **Step 31:** Once the machine has stopped moving, help the participant off of the table.
- **Step 32:** 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 33:** Click on **Exit** in the bottom right corner. The 'Exit Analysis' window will open; select the **Exit without shutdown** option.
- Step 34: Wipe down the DXA tabletop.

#### 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.
- DEXA Calibration and Maintenance SOP (SOP\_DCS\_0043).

#### **Baseline** Revision History:

New Version #	<b>Revision Date</b>	Revision Author	Content Approval
3.0	2014-JUL-10	Lorraine Moss	Mark Oremus
Summary of Revisions			
<b>NOTE for Step 5 edited:</b> If the patient is taller than 5'6" the default The scan length			
needs to be changed from 39.3cm to 45.2cm.			
Clarified directions of Step 7: Place the laser to the left of the tape, which is to the left on			
the side of the bed. Adjust your participant upward or downward, so that the laser is 2			
inches below the participant's belly button.			
Sentence in Step 13 edited: You need to place the marker on L4 (two one-vertebrae up from			
the sacrum <u>or above L5</u> ) before clicking on Close.			

**Added Note:** If scoliosis is present and L4 is tilted, put the centre marker in the centre of the superior or inferior surface aspect. Added picture.

Step 20, added "Make sure the report type selected is 'Interpreting' with one copy'
SOP formatting updated. Grammar and spelling edits.

Scope, Purpose, Responsibilities sections reviewed and updated.

New Version #	<b>Revision Date</b>	Revision Author	Content Approval
2.1	2013-May-28	Lorraine Moss	Mark Oremus

# Summary of Revisions

Changed wording of Step 13, last point to:

NOTE: Aortic Calcification is assessed by looking at vertebrae L5 to L1.

Step 20, added "Make sure the report type selected is 'Interpreting' with one copy" Spelling and grammar changes

New Version #	<b>Revision Date</b>	Revision Author	Content Approval
2.0	2013-Jan-07	Lorraine Moss	Mark Oremus

#### Summary of Revisions

Added Training manual to section 7.0

Various formatting throughout document.

Step 3 – in Section 6.0 Procedures updated to read "To position the participant correctly, make sure that the participant is straight and centered on the table and that his/her shoulders are just within the hatched marks on the table. If the patient is shorter, ie. 5'2 or less their shoulders can be below the marks for shoulders (see picture)."

Step 7 in section 6.0 Procedures should read "Move the **Laser** so that it is 2 inches below the participant's belly button. Ensure that the laser to the left of the tape to the left on the side of the bed. If the participant doesn't meet this criterion, shift the participant accordingly. This is to avoid error messages about positioning. Taller participants may also need the scan length increased on the 'start scan' page."

Added: "The default scan length is 39.3cm and can be found on the left hand side of the dexa IVA imaging screen (the one with the showing the patient on the table in position). **NOTE:** If the patient is taller than 5'6" the default scan length needs to be changed from 39.3cm to 45cm." under step 5 in section 6.0

Added steps 11 & 12 in section 6.0

Removed Step 16 in section 6.0

Changed step 14 to step 13 and renumbered the remainder of section 6.0

Added Calibration SOP to section 9.0

Added "**If you do get an error message, click ok.** Then go to main screen of Hologic. On top of menu bar under utilities, click AP reposition. Move participant down the table; reselect patient from perform exam and then select IVA imaging" under step 7.

Added the sun/moon symbol to step 13

Second paragraph of step 10 re-worded to read "If more is showing allow the scan to finish, reposition the participant and start the scan again.

Step 22 reworded to read "**Step 22** – 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, check which one should have transferred and delete the other one.

Added definition for sacrum in section 8.0