

Treatment Visit Scan Acquisition – Hologic Scanner

Overview

Prior to treatment visit scan acquisition, please ensure that you have submitted a **Pre-Qualification Phantom Scan** from your facility and have received a *Pre-Qualification Approval Certificate*.

A complete Treatment Visit Scan includes:

- DXA Scan Analysis Report in acceptable image file format
- DXA Scan Images in acceptable image file format, if applicable

Subject Preparation

- ✓ Ensure that the subject has removed all objects from their pockets and is not wearing clothing with metal such as jewelry, belts, snaps, underwire bras, zippers, etc.
- ✓ Ensure the subject is explained the exam procedures and instructions for positioning.
- ✓ Ensure the same machine and scan modes are adhered to for all treatment visits. Refer to the Subject Scan Card (**Figure 1**).
- ✓ At Day 1 Visit, ensure Subject Biography Form is readily available (**Figure 2**).

Figure 1

This scan is for Primrose Clinical Study 16-OBE2109-008

Please follow Canfield's DXA image acquisition guideline for Hologic

- Obtain scan of Lumbar Spine and Left Hip
 - If contraindicated due to prosthetic or inability to position correctly, then the right hip should be scanned. Be sure to scan the same hip for all visits within a subject during the trial.
- Please use the ARRAY scan mode (Explorer machines use "e" mode)
 - **Fast scan modes** (i.e., Fast Array, Turbo, "X", Quick Mode, etc.) **are not acceptable, and will require a repeat scan** in Array or Performance
- Please be certain the scan mode is consistent throughout all imaging time points
- Please follow instructions for entering Subject Biography as outlined in IAG
- Copy all the scans onto the labeled media **BEFORE** analyzing or archiving the data
- Scans will be acquired at Study Day1, Week 24, week 52 and Week 76

Subject Number: _____

For any questions regarding study parameters please contact:

Requesting Physician: _____ OR

Study Coordinator: _____

16-OBE2109-008_Scan Card Hologic_V1_02Feb2017

Figure 2

Canfield Scientific, Inc. – Quality Management System (QMS)
CANFIELD Scientific, Inc.
16-OBE2109-008

OBSEVA
obstetrics & beyond
Subject Biography Form

Site Code: 2276 Site Number:
To: CRIMT Study Site:
From: HQ 912 887 1240

DESCRIPTION	IDENTIFIER	FORMAT	SUBJECT INFORMATION
Waist	Waist L	RAW	01 Jul
Waist	Waist R	RAW	
Left Hip	Left Hip L	RAW	
Left Hip	Left Hip R	RAW	
Right Hip	Right Hip L	RAW	
Right Hip	Right Hip R	RAW	

DATE: _____

NOTE: PLEASE FOLD OVER ENDS TO ENROLL SUBJECT IN THE STUDY AND TO OBTAIN A COPY OF THIS DOCUMENT. THIS COPY IS NOT VALID UNLESS SIGNED BY THE STUDY COORDINATOR AND THE FORMS OFFICER AND ACTUAL BY THE APPROPRIATE AUTHORIZED PERSONNEL.

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Subject Biography

At Day 1 Visit, reference the Subject Biography Form provided by the Treating Investigative Facility to create the subject biography in the DXA scanner database. Ensure all information is transcribed as written in the correct format.

At **Follow-up visits**, do not create a new subject biography. Locate the subject and update the subject weight and height, if applicable.

Treatment Visit Scan Subject Biography		
<u>Descriptor</u>	<u>Identifier</u>	<u>Format</u>
Acquisition Date	Date of Scan	DD/MMM/YYYY
Patient Identification (ID)	ID Number	NNNNN (where N = 5 digit number, 1 digit country code + 2 digit site ID + 2 digit subject number)
Date of Birth (or Born On)	Subject year of birth <u>only</u>	01/JUL/YYYY (where Y = subject actual year of birth)
Sex	F	F
Weight (update as needed)	Subject Weight	NNN.N
Height (update as needed)	Subject Height	NN. N
Exam Type	Exam Type	Example: AP Lumbar Spine or Total Left Hip
Comment	Identify non-removable artifacts, if any	Example: Pacemaker leads, bone fractures, previous surgeries, radioactive seeds, bone implants, surgical staples, foreign bodies, heavy metal poisoning, kidney stones, etc.)
Scan Code (or Attendant)	DXA Technologist's Name	(Last Name, First Name)

NOTE: All images should be blinded with respect to subject name and additional identifiable PHI not included in the Subject Biography Form provided. If PHI is received, Canfield may request a Repeat Scan.

Required Scan Acquisition Sites

1. AP Lumbar Spine (From L1 to L4)
2. Total Left Hip (Including Femoral Neck)

Image Acquisition Guidelines

Follow all standard procedures for scan acquisition and scan analysis. The points below are only for emphasis.

1. **AP Lumbar Spine Scan**

a. **Scan Selection** – Refer to subject scan card provided

b. **Subject Positioning**

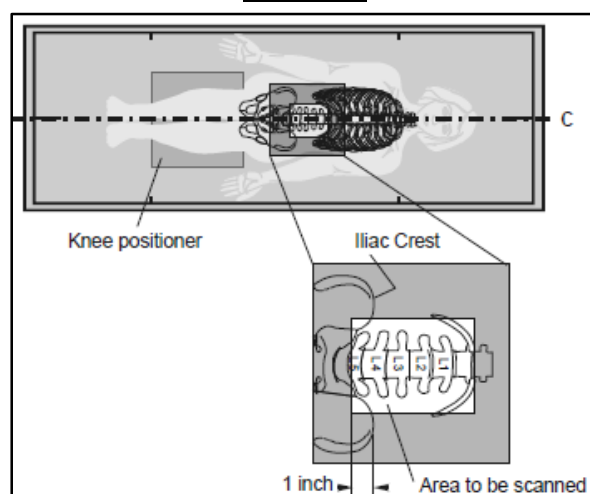
i. Instruct subject to:

- Lie on the scan table with arms comfortably at sides
- Position themselves so that spine, shoulder and pelvis are aligned straight
- Remain quiet and still until scan acquisition is complete

ii. Assist subject:

- Place large cube cushion under the subject's legs
- When comfortable with subject and scanner positioning, perform scan.
See sample subject positioning and area to be scanned (**Figure 2**).

Figure 2



c. **Quality Review** – Review completed scan to ensure quality. Reference the Quality Control Examples QRG provided in this section for good and bad examples.

- i. Optimal quality scan requirements:
 - ✓ Spine is straight and centered in the middle of the scan window
 - ✓ Even amounts of soft tissue on each side of the spine
 - ✓ Top of the scan includes all of T12 (usually includes bottom of rib cage)
 - ✓ Bottom of the scan includes half of L5 (usually includes some of iliac crest)
- ii. Scan should be repeated if any of the following occur:
 - ✓ Subject moved during scan acquisition
 - ✓ Unusual anatomical variations
 - ✓ Artifacts visible in scan
 - ✓ Less than four (4) vertebral bodies are included for spine density
 - ✓ Scan has an unusual appearance or is difficult to analyze

d. **Scan Analysis** – Review completed scans analysis report to ensure quality

- i. Acceptable Lumbar Spine Scan Region of Interest (ROI) includes the following:
 - ✓ Correct vertebral labeling for L1-L4
 - ✓ Intervertebral markers dissect disc space
 - ✓ Edges appropriately separate bone and soft tissue
 - ✓ At **Follow-up visits**, compare the current scan vs. the Day 1 scan and ensure the width and the height of the global ROI is the same.
NOTE: Vertical or horizontal shifts of these regions can greatly alter the final values of analysis.
- ii. Scans should be repeated if at **Follow-up visits** the ROI is different than at Day 1 or follow-up scans cannot be reasonably matched to Day 1 analysis

2. **Total Left Hip Scan** (including Femoral Neck)

a. **Scan Selection** – Refer to subject scan card

b. **Subject Positioning**

- i. Instruct subject to:
 - Lie on the scan table with arms across chest
 - Position themselves so that spine, shoulder and pelvis are aligned straight
 - Remain quiet and still until scan acquisition is complete
- ii. Assist subject:

- Place foot brace under the subject's feet
- Rotate the left leg inward about 25° and keep in place by using the velcro strap on the foot brace (**Figure 3**)
- Ensure that the foot is flexed toward the ceiling and the femur is straight and parallel with the center of the table (**Figure 4**)
- Abduct the leg from the midline of the body in order to straighten femur and align femur parallel to the table edge
- When comfortable with subject and scanner positioning, perform scan

Figure 3

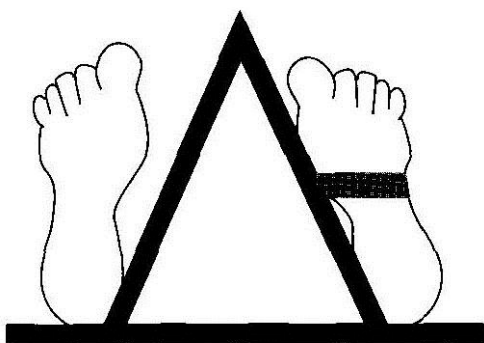
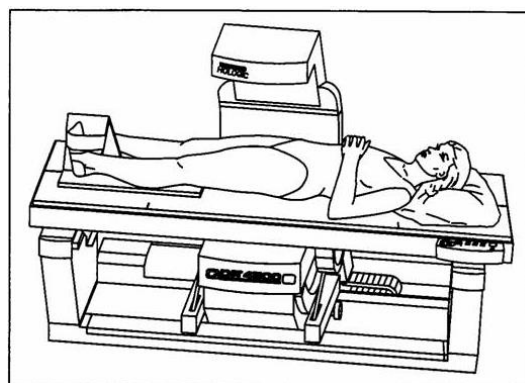


Figure 4



c. **Quality Review** – Review completed scan to ensure quality. Reference the Quality Control Examples QRG provided in this section for good and bad examples.

i. Optimal quality scan requirements:

- ✓ Femoral shaft is straight and parallel to the edge of the scan image
- ✓ Greater trochanter is centered vertically in the scan window
- ✓ The entire femoral head, neck and approximately three (3) inches of shaft is visible
- ✓ A 25-degree internal hip rotation of the hip showing minimal or lesser trochanter on the scan image

ii. Scans should be repeated if any of the following occur:

- ✓ Subject moved during scan acquisition
- ✓ Unusual anatomical variations
- ✓ Artifacts visible in scan

- ✓ Scan has an unusual appearance or is difficult to analyze

d. **Scan Analysis** – Review completed scans analysis report to ensure quality

i. An acceptable Left Hip Scan ROI includes the following:

- ✓ Total femur box should be aligned around femoral neck, just below the lesser trochanter and just outside the greater trochanter. Corner of box is anchored on greater trochanter and other 3 corners should be in non-bone tissue.
- ✓ The lateral side of the global ROI should be at least 5mm beyond the outer edge of the greater trochanter to provide sufficient soft tissue for analysis, although it should not extend outside the participant's body
- ✓ The bottom edge of the global ROI should be at least 1cm below the lesser trochanter to provide sufficient soft tissue for analysis.
- ✓ Edges appropriately separate bone and soft tissue
- ✓ At **Follow-up visits**, compare the current scan vs. the baseline scan and ensure the width and the height of the global ROI is the same.

NOTE: Vertical or horizontal shifts of these regions can greatly alter the final values of analysis.

- ii. Scans should be repeated if at **Follow-up visits** the ROI is a different size than used at baseline or follow-up scans cannot be reasonably matched to baseline analysis

Image Acquisition Save & Submission

Save the images to a secure labeled folder on an internet-compliant computer or on a labeled, hard copy media* before archiving to your system. Must include:

- AP Lumbar Spine (L1-L4) Analysis Report
- Total Hip (including Femoral Neck) Analysis Report

Once saved, please upload to Canfield within 24 hours of acquisition. For upload instructions, reference the **Image Upload Quick Reference Guide** of this Canfield IAG.

*Note: For Hard Copy Media, one disc or USB should be used per Pre-Qualification Scan. Discs or USB should be retained at your site for the duration of the study.