BIOCLINICA

DXA Quality Assurance Hologic / Lunar Training

Samumed SM04690-OA-06

Version 1.0

14-Aug-2018

SEE MORE CLEARLY

Agenda

Welcome

Bioclinica Team / Contact Information

Protocol Overview

DXA Facility Study Start-up

Instrument Quality Control (IQC)

Subject Data Submission

Good Clinical Practice and Archiving

DXA Scan Acquisition and Analysis

Welcome

- Welcome to the Bioclinica DXA training presentation.
- You and your imaging facility have been chosen to acquire DXA scans for this clinical study. A successful clinical study requires that all images are obtained, processed and evaluated in a similar fashion. As a participating facility, your role in providing accurate and reliable data is pivotal to the success of this study.
- Both GE Lunar and Hologic specific directions are mentioned in the this presentation. Please follow directions for your scanner type.

Bioclinica Team / Contact Information

Medical Imaging Operations - DXA
5841 Operations Team
Phone: 503.528.7800
Fax: 503.284.3357
Email: MI_DEP_MSK.Team.SM04690-OA-06@bioclinica.com

Medical Imaging Operations – IQC and Cross Calibration
Email: IQC@bioclinica.com

Submit data by SMART Submit portal when possible.

Ship DXA data by courier to:
5841 Study Team
7707 Gateway Boulevard
3rd Floor
Newark, CA 94560

Protocol Overview

A Phase 2, 52-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety, Tolerability, and Efficacy of Two Injections of SM04690 Injected in the Target Knee Joint of Moderately to Severely Symptomatic Osteoarthritis Subjects

Protocol Overview

- **DXA Visit Schedule**

Protocol Time Point	Screening (V2)	Week 24	Week 52 (EOS/ET)[1]
Lumbar Spine	X	X	X
Left Femur	X	X	X
Right Femur	X	X	X

- [1]All subjects who discontinue study drug early will be encouraged to complete study procedures thereafter for the duration of the study. If not done, early termination (EOS/ET) procedures should be performed at the time of discontinuation.

DXA Facility Study Start-up

DXA Facility Study Start-up

- **Study Start-up Requirements and Forms**
- Pre-Trial Questionnaire (PTQ) process
- Approved DXA Machines
- Supplies
- Supply Order Form
- DXA Technologist Training
- Baseline Instrument Quality Control (IQC)
- Authorization Letter

DXA Facility Study Start-up

- Pre-Trial Questionnaire
- The Pre-Trial Questionnaire (PTQ) is a study specific document and must include *ALL* DXA Technologists acquiring scans for each study.
- Changes in site personnel, contact information or DXA machines are to be documented on a new PTQ and submitted to Bioclinica.


BIOCLINICA

Samumed Protocol SM04690-OA-06
Pre-Trial Questionnaire for DXA

Principal Investigator Name: Enter Investigator Name
Site Number: Enter Site Number

To: Enter Investigator Name
Fax: Site Fax Number
Phone: Site Phone Number
Date: Enter Date

From: Samumed, SM04690-OA-06 (5841)
Fax: 503-284-3357
Phone: 503-828-7800
Email: M_DEP_GCK.Team.SM04690-OA-06@bioclinica.com

Dear Enter Investigator First Name

Your clinical site has been identified by Samumed as participating in the SM04690-OA-06 protocol. DXA scan(s) of the spine and bilateral femur will be acquired at protocol-defined time points during this study. These images will be submitted to Bioclinica for centralized assessment.

Please find the Pre-Trial Questionnaire on the following pages. The information you provide us in this questionnaire, will allow us to determine if your imaging facility is capable of acquiring the images required by the protocol. Please answer each question on this form completely and email or fax back to Bioclinica. Due to the start-up timeline of this study, please return this questionnaire as soon as possible.

Electronic data upload is the preferred method for all sites to send images and data to Bioclinica. Electronic uploading enables you to easily transmit images and data directly to Bioclinica using your broadband internet connection. The system is entirely web-based, if there are any issues with the portal, you can contact the helpdesk directly at helpdesk@bioclinica.com

Please let us know via email or fax if there will be a delay in sending the questionnaire to Bioclinica, so that we may notify Samumed of your site's status.

Please fax or email the completed Pre-Trial Questionnaire and a Phantom report to:

Attention: Samumed, SM04690-OA-06 (5841)

Fax Number: 503-284-3357
Phone Number: 503-828-7800
Study Team Email: M_DEP_GCK.Team.SM04690-OA-06@bioclinica.com

Thank you for your prompt attention to this matter. Please do not hesitate to contact us with any questions or concerns you may have.
Kind regards,

Samumed, SM04690-OA-06 (5841)

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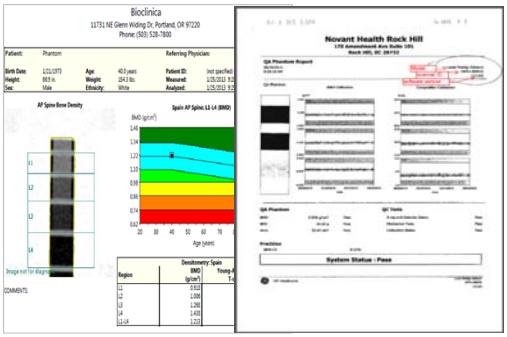
DXA Facility Study Start-up

- **Examples of acceptable phantom printouts**
- Send printout with DXA Pre-Trial Questionnaire

Hologic

Lunar



DXA Facility Study Start-up

- Approved DXA Machines list
- Both GE Lunar and Hologic specific directions are mentioned in this presentation.
- Your scanner specific directions are included in the DXA start up binder as reference.

Hologic	GE Lunar
Delphi series	Prodigy
Discovery series	iDXA
Horizon	

DXA Facility Study Start-up

- DXA Supplies and materials will be posted in Study Site portal in SMART Portal
- https://smart.bioclinica.com
- User access will be given once the PTQ is received using unique email addresses for site personnel.
- Once you have received the welcome email, you will be able to log into SMART Portal and change your default password and access the supplies in the Site Study Materials option.
- The SMART Portal Site Submission option is used for DXA and IQC Image Submission uploads. Upload details are covered in later sections.

DXA Facility Study Start-up

- **Supplies provided:**
- Start-up Checklist
- DXA Procedure Manual
- Quick Reference Guide
- Transmittal Forms
- DXA Supply Order Form
- Airway Bills- provided upon request

DXA Facility Study Start-up

- Supply Order Form
- The quickest and preferred method for Bioclinica to receive patient and IQC data is via electronic submission using Bioclinica's SMART Portal.
- If you are unable to submit data electronically and will be using courier to submit data, please submit the DXA Supply Order Form located in the SMART Portal Site Study Materials folder to receive paper copies and Airway bills.

DXA Facility Study Start-up

DXA Technologist Training

- If your site has previously worked with Bioclinica, some requirements *may* be waived per sponsor approval. Each site and DXA tech is assessed individually.
- At least one DXA technologist must attend a study-specific Bioclinica training. Bioclinica will schedule these trainings prior to the first subject visit.
- DXA training is remote (by phone).
- It may be acceptable for a DXA Technologist at the site who has completed the study-specific Bioclinica training to train other DXA Technologists.
  - Upon completion of remote (by phone) training, each technologist must send a completed DXA Training Sign-off form to Bioclinica.
  - For DXA Technologists trained by a previously trained DXA Technologist at the site, send a completed DXA Training Sign-Off form to Bioclinica.

DXA Facility Study Start-up

Training Sign-off Form

Any individual at each imaging site who will be performing DXA exams on study subjects needs to:

- Read the DXA Procedure Manual
- Participate in remote training or other approved training

Remote training:

- Return completed Training Sign-off form

Please remember to file a copy in the site binder.


BIOCLINICA TECHNOLOGIST TRAINING SIGN-OFF FORM

Sanofi Protocol SM04690-CA-06-DXA

Training Date		Bioclinica Study ID	5041

Check the appropriate box noting who performed training and how training was provided:

Performed by Bioclinica:	☐ Remote ☐ Centralized	☐ On-site
Performed by Bioclinica-trained registered technologist: (This option is not permitted for all studies)		☐ On-site
Other training format:	☐ Self-Directed	

Site	Print Participant Name(s)	*Role (T or O)	Signature
		T or O	
		T or O	
		T or O	
		T or O	
		T or O	
		T or O	
		T or O	
		T or O	
		T or O	
		T or O	

*Use abbreviations: Enter T for Technologist for anyone who will be acquiring images for the above-listed study, even if they also have other study responsibilities such as Study Coordinators or Principal Investigators. Enter O for Other for someone who is attending training for informational purposes, but will not be acquiring images.

*Trainer Printed Name	*Title/Role on Study
*Trainer Signature	Date (dd-mmm-yyyy)

Please send completed form to Bioclinica at MI_DEP_MSK.Team.SM04690-CA-06@bioclinica.com or fax: +1 503-284-3357

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Bioclinica Confidential Information

DXA Facility Study Start-up

Baseline IQC

- If your site has previously worked with Bioclinica, some requirements may be waived per sponsor approval. Each DXA facility and equipment is assessed individually.
  - You may be asked to submit current, up-to-date IQC data before Baseline IQC can be waived. Please ensure data is submitted as Baseline Submission Type

Baseline IQC procedures for Study Start-Up:

- Ensure that a separate database is set up for phantom scans. Instructions can be found in the IQC section of the DXA Manual.
- Ensure that you have at least 25 phantom or QA Block scans acquired within the last 30 days. If not, acquire 25 phantom or QA Block scans, with a maximum of 5 per day.
- Analyze all phantom scans, using compare function or auto-analysis, if available.
- Submit database file using the instructions listed in the Appendices section of the DXA Manual. Please do not submit scan image files or printouts for IQC data submissions.

DXA Facility Study Start-up

- **Baseline IQC Submission Requirements**
- Send via courier or through SMART Portal to Bioclinica:
  - SMART portal account will be listed as the scanner ID
  - Electronic phantom database copied to electronic media
    - Hologic machines: **QC Archive.mdb** file
    - Lunar machines: **lunar.mdb** file, **QA.mdb** file or **QC export** files
  - Select Baseline as Submission Type on IQC Submission Form

DXA Facility Study Start-up

- **Lunar** Baseline IQC Directions for copying Database file from DXA Manual APPENDIX Section-X, depending on type of phantom used and DXA scanner software version
- Using spine phantom:
  - Section 4.1 GE Lunar— Windows (software versions prior to 15.10, that export phantom database files as .mdb)
  - Section 4.2 GE Lunar—Windows version 15.10 and any future software versions that generate the phantom database files using SQL (not as an .mdb file).
  - Section 4.3 GE Lunar—Windows version 15.10 and any future software versions that generate the phantom database files using SQL (not as an .mdb file) –Alternate option if unable to export .txt file.
- Using QA Block:
  - Section 4.4 GE Lunar—Windows – (software versions 10.0 and above) Instructions for copying QA block
  - Section 4.5 GE Lunar—Windows – (software versions 10.0 and above) Instructions for copying QA block – Alternate option

DXA Facility Study Start-up

- **Hologic** Baseline IQC Directions for copying Database file from DXA Manual APPENDIX Section-X
- Using spine phantom:
  - Section 3.1 Hologic—Windows

DXA Facility Study Start-up

- **Authorization Letter**
- Prior to scanning study subjects, the site must receive an Authorization Letter indicating all start up requirements have been fulfilled.
- Each technologist that will acquire subject DXA scans must be listed on the Authorization Letter
- Authorization Requirements
  - Approved PTQ (per site)
  - Training (per technologist)
  - Baseline IQC (per scanner)
- Changes in Technologists or DXA Machines
  - Submit new PTQ
  - Training (may be required for new technologist or new machine)
  - Baseline IQC (if new machine)
  - Machine Equivalence (if new machine)

Instrument Quality Control (IQC)

Instrument Quality Control Overview

- The purpose of the IQC department is to ensure that DXA instruments (scanners) in a study are monitored in an efficient, controllable, and consistent manner in order to evaluate and document individual scanner performance.
- Scanner performance is used to calculate correction factors to be applied to DXA subject data.
- IQC is monitored using phantom data that is collected daily (or at least 3 times a week) by the site
- Phantom can be a Hologic spine phantom, aluminum bar (water bath) phantom or QA block
- Phantom data is collected by Bioclinica in the form of a database file (.mdb, or .txt files)
  - Database files are cumulative files that include results of all phantom data collected on the machine since machine installation

Instrument Quality Control

Phantom/QA Block Acquisition

- *Note: If scanning aluminum bar (water bath) phantom, ensure that a separate database and biography is set up for the phantom

For Baseline IQC:

- Ensure that at least 25 scans have been acquired over the last 2 months. Otherwise, scan your phantom/QA block 5 times a day for 5 days.

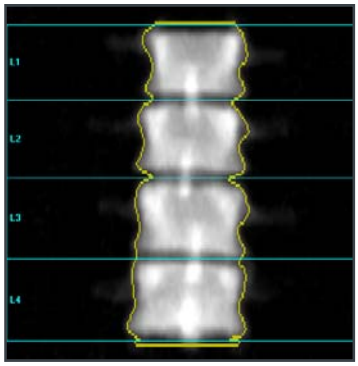
For Ongoing/Monthly IQC:

- Scan the phantom or QA Block (the one that was performed during Baseline IQC scans):
  - Always before scanning study subjects
  - At least three days a week
  - Consistently use same scan mode
  - Acquire and analyze L1-L4 consistently
- It is necessary to start scanning the phantom or QA Block immediately and consistently after completing the Baseline IQC to ensure that there are no gaps in calibration data. The calibration data is used to correct changes in BMD results that are related to changes in the calibration of the DXA machine used for this study.

Instrument Quality Control

Phantom Scanning - Analysis

- Use auto-analysis if available
- Top and bottom IV space-markers close to bone
- Use compare function for consistency
- Do not alter bone edges



Instrument Quality Control

- **Baseline and Monthly IQC Data - <u>Phantom Database Files required</u>**
- *Instructions are located in Appendices section of DXA Procedure Manual
- <u>Hologic</u>
  - QC Archive.mdb

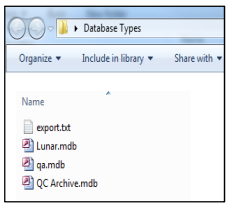
<u>Lunar</u>

Aluminum bar (water bath) phantom - lunar.mdb

- For versions 15 and higher – text file

OR

- QA Block - QA.mdb

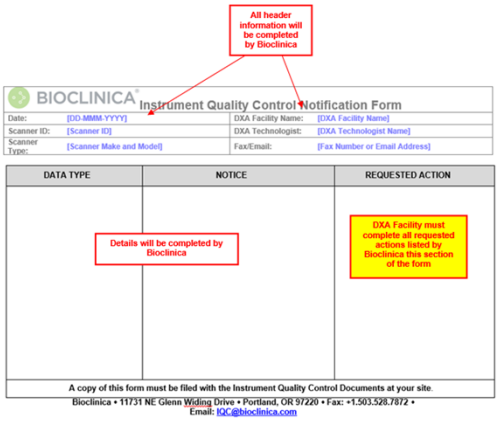


•For Monthly submissions, the phantom database file should be submitted to IQC at the end of each month.

•Please <u>do not submit scan files</u> for IQC (For example, Lunar .dfs or Hologic PA18412A.p04, PA18412A.r04 files are not allowed)

Instrument Quality Control

- **IQC Notification Form**
- Overdue IQC notifications from IQC team and study team will be sent if IQC data not submitted in a timely manner.
- Study Specific DCFs will be issued for overdue scanners and will remain open and reissued until acceptable IQC data is received.



Instrument Quality Control

Software or Hardware Upgrades, Major Service and Relocation of DXA Scanner

- Refer to the DXA manual for instructions
- Complete and submit a DXA Service Record form
  - Include Service Report, if available

Upgrades

- All upgrade requests must be made 30 days prior to the planned upgrade or as soon as possible.
- You must receive approval from Bioclinica *prior* to installing the software upgrades.

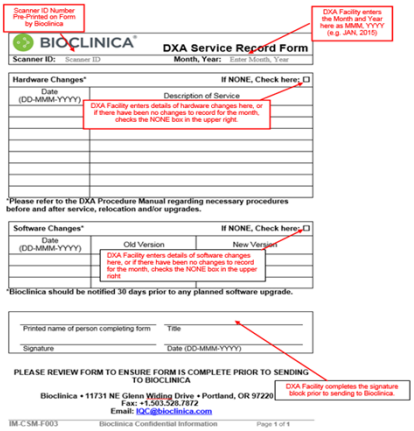
Major Service and/or Relocation

- Acquire 10 phantom or QA Block scans post-service and/or relocation if not completed by service technician
- For relocation only, complete a new DXA Pre-Trial Questionnaire noting the change in address

Instrument Quality Control

DXA Service Record Form

- Should be completed and submitted to Bioclinica when there is service, maintenance, relocation affecting the DXA scanner


Scanner ID Number Pre-Printed on Form by Bioclinica

DXA Facility enters the Month and Year here as MMM, YYYY (e.g. JAN, 2015)

BIOCLINICA

DXA Service Record Form

Scanner ID: Scanner ID Month, Year: Enter Month, Year

Hardware Changes* If NONE, Check here: ☐

Date (DD-MMM-YYYY)	Description of Service

DXA Facility enters details of hardware changes here, or if there have been no changes to record for the month, checks the NONE box in the upper right.

*Please refer to the DXA Procedure Manual regarding necessary procedures before and after service, relocation and/or upgrades.

Software Changes* If NONE, Check here: ☐

Date (DD-MMM-YYYY)	Old Version	New Version

DXA Facility enters details of software changes here, or if there have been no changes to record for the month, checks the NONE box in the upper right

*Bioclinica should be notified 30 days prior to any planned software upgrade.

Printed name of person completing form Title

Signature Date (DD-MMM-YYYY)

PLEASE REVIEW FORM TO ENSURE FORM IS COMPLETE PRIOR TO SENDING TO BIOCLINICA

Bioclinica • 11731 NE Glenn Widing Drive • Portland, OR 97220
Fax: +1.503.526.7872
Email: IQC@bioclinica.com

DXA Facility completes the signature block prior to sending to Bioclinica.

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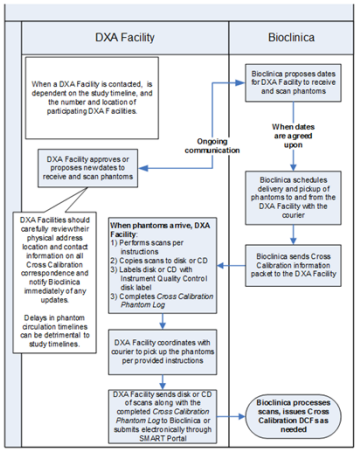
Instrument Quality Control

IQC Cross Calibration

- Completed once during the trial
- Agree on a date
  - Bioclinica office will contact you
  - Instructions will be sent after you have scheduled a time to receive the phantoms
- Hologic Spine, Block Phantom, BFP, or BBCP
  - Scan each phantom 10 times
  - Do *not* reposition phantom between scans
  - Verify correct acquisition
  - Complete Cross Calibration Log
  - Submit to Bioclinica via courier or SMART Portal



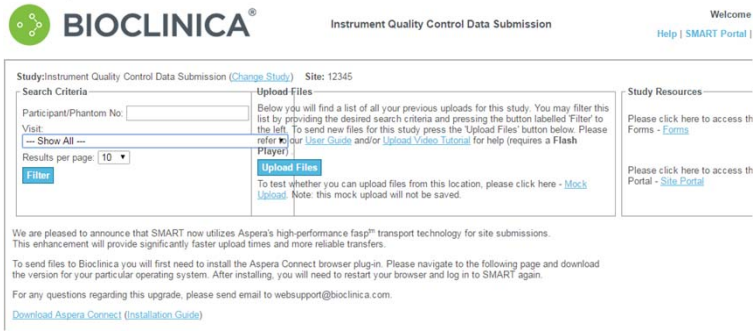
Instrument Quality Control

Machine Equivalence for change in DXA scanner

- Notify Bioclinica of proposed machine change
  - Minimum of 30 days notice required for all machine changes
  - Reason for change and action plan for any active subjects already scanned on old scanner
- Requirements
- Sponsor Notification
- Updated DXA Pre-Trial Questionnaire with scan analysis report from new scanner
- Baseline IQC on new scanner
- Machine Equivalence Data Collection
  - This process is separate from Baseline IQC
  - Typically, requires that the same phantom be scanned 10 times each on original and new machine – Phantom may be provided by Bioclinica
- Bioclinica will send an authorization letter once baseline IQC is approved
- DO NOT scan subjects until new scanner is authorized

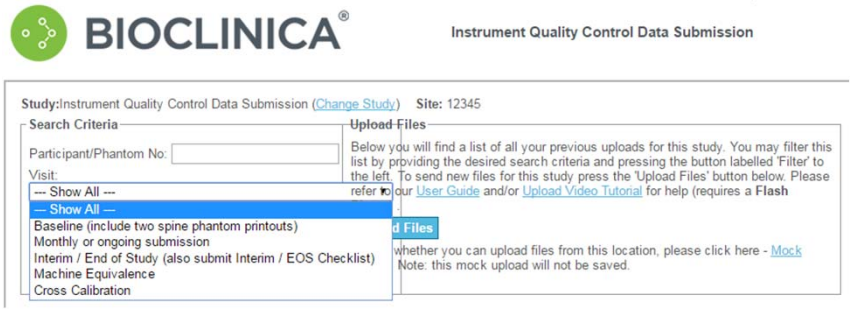
IQC Data Submission

- IQC Data Submission via SMART Portal - Initial screen



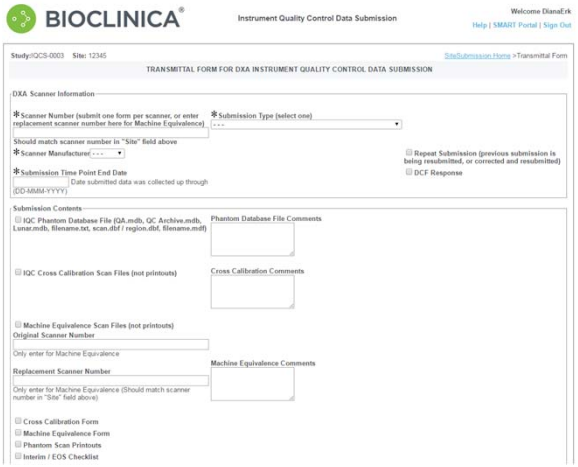
IQC Data Submission

- IQC Data Submission via SMART Portal - Visit dropdown



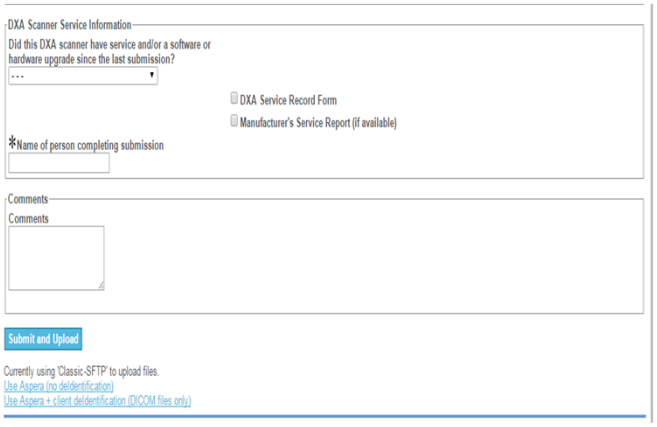
IQC Data Submission

- IQC Data Submission via SMART Portal - Uploading IQC data



IQC Data Submission

- IQC Data Submission via SMART Portal - Uploading IQC data (Part 2)



Subject Data Submission

Subject Data Submission

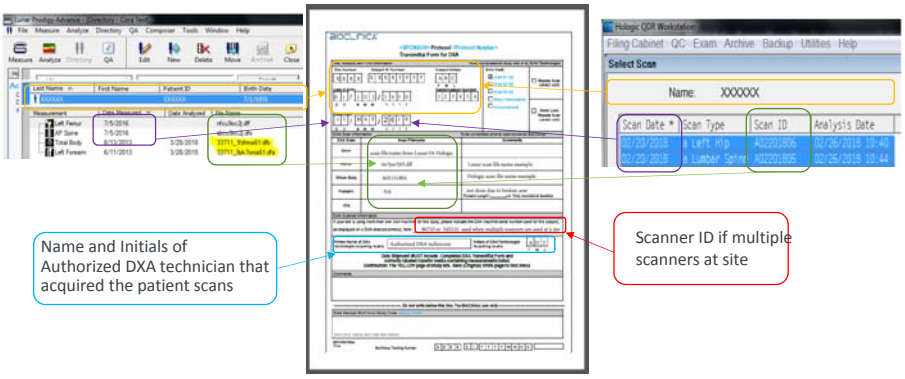
Forms

- DXA Transmittal Form
- Submission of Data:
- Hologic and Lunar information is included in this presentation, please follow the appropriate directions for your scanner type. Consult the DXA Procedure Manual for additional scanner specific directions.
- Data Clarification Form
- Interim Analysis / End of Study Checklist

Subject Data Submission
How to complete the TF

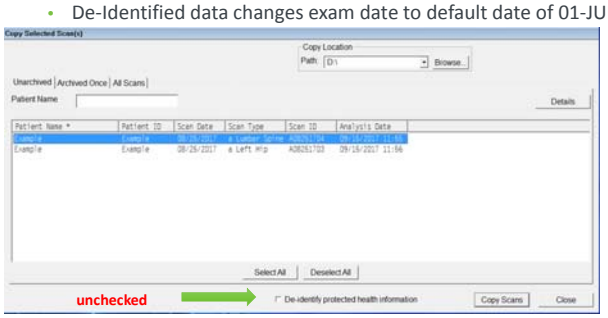
Lunar Scans

Hologic Scans



Hologic Subject Data Submission – Copy DXA Scans

- **Do not de-identify when copying the scans**
  - De-Identified data removes subject ID from biography
  - De-Identified data changes exam date to default date of 01-JUL



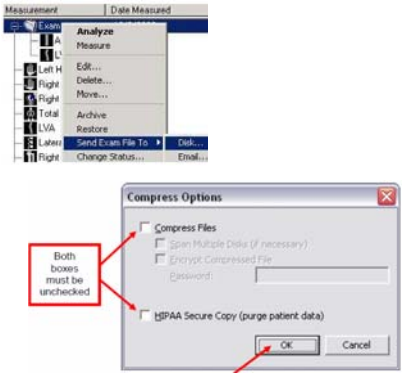
Example Hologic scan file:

PA17825A.p04	9/18/2017 3:38 PM	P04 File	213 KB
PA17825A.r04	9/14/2017 1:58 PM	R04 File	770 KB

Directions for copying Hologic DXA Scan Image file Located in DXA Manual APPENDIX B

Lunar Subject Data Submission – Copy DXA Scans

- Uncheck the "HIPAA Secure Copy" option
- HIPAA Secure removes the Subject ID



Example Prodigy scan file:

0auy1n6ih6.dff	3/7/2014 2:37 PM	DFF File

Directions for copying Lunar DXA Scan Image file Located in DXA Manual APPENDIX C

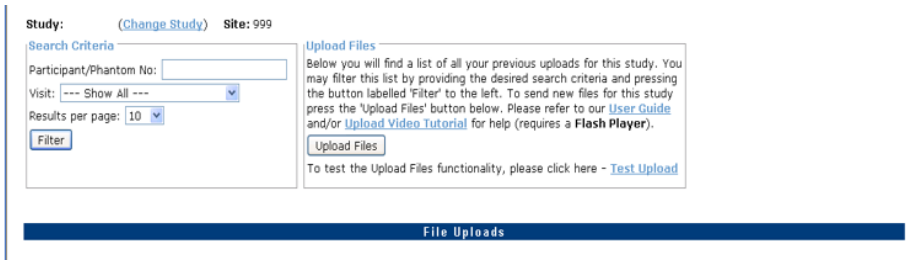
Subject Data Submission

SMART portal - electronic upload

- Electronic Transmittal Form contains same fields as Paper Transmittal Form
- Documentation Storage
  - Protocol and other documents stored on the web
- Reports
  - Standard reports now available via the web instead of email and fax
- Web Based Image Capture
  - Send images to Bioclinica via the web
  - Includes online Transmittal Form data entry
  - Save money by avoiding shipping costs
- Request SMART Portal access on PTQ
- Consult User guide or Video Tutorial for more information

Subject Data Submission

- **SMART Portal - Initial screen**

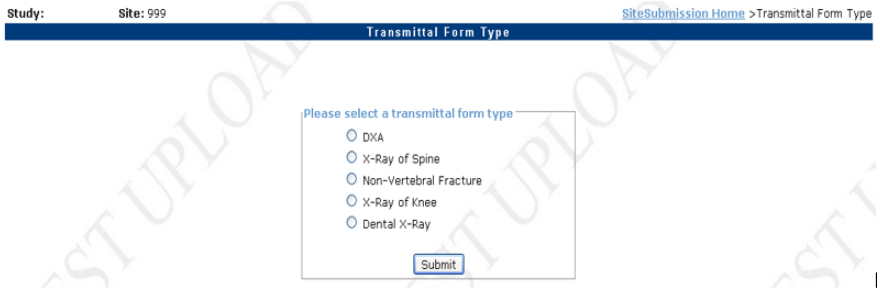


Subject Data Submission

- **SMART Portal - Visit dropdown**

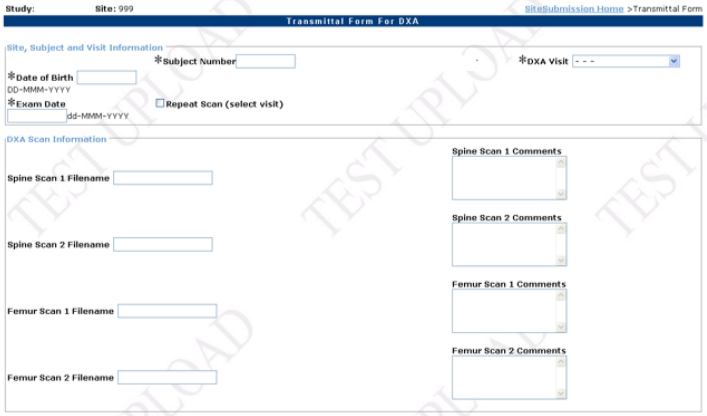
Subject Data Submission

- **SMART Portal - Uploading data**



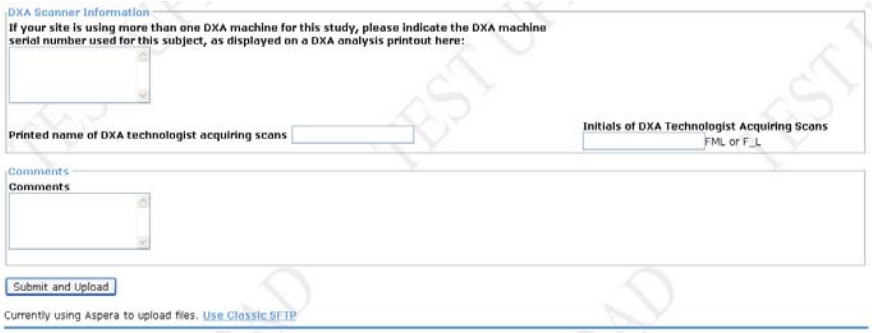
Subject Data Submission

- **SMART Portal**
- DXA TF Screen – part 1



Subject Data Submission

- **SMART Portal**
- DXA TF Screen – part 2



Courier Data Submission

If it is not possible to use the Electronic upload Portal, you may submit data by courier.
Courier submissions must include the following:
Completed DXA or IQC Transmittal form(White copy). Keep yellow copy in site records.
Electronica media containing DXA Scan Image Files or IQC database file.
Label media with a permanent marker.

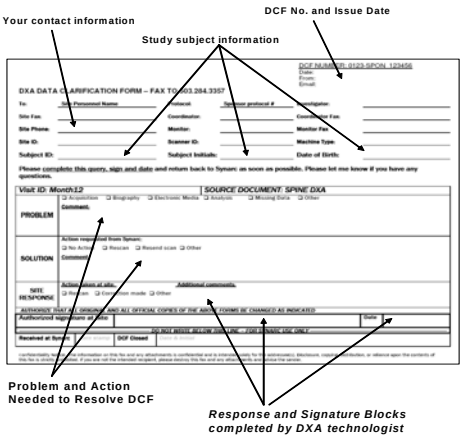
Subject Information:
- Sponsor / Protocol
- Site ID
- Subject ID
- Exam Date (DD-MMM-YYYY)
- DOB (01-Jul-YYYY)
- Time Point (TP)

IQC Information:
- Scanner number
- Scanner Type
- Timepoint

Subject Data Submission

Data Clarification Form (DCF)

- The Data Clarification Form is sent to the sites to clarify any discrepancy found in data submitted to Bioclinica, for example:
  - Incorrect Transmittal Form completion
  - Date of Birth or Subject ID questions
  - DXA images missing from the transfer media
  - Repeat examination requests
  - Visit date/designation questions
  - Visit date questions



Subject Data Submission

Data Clarification Form

- If you receive this form you will need to write an answer in the "Solution" section, sign and date the form and return it to Bioclinica:
  - Via fax or email to study team if the solution does not require resending a package
  - Submit signed copy with submission if the solution requires resubmission of subject data
- *It is important to respond to all DCFs immediately*.
- All DCFs should be signed, dated and returned.
- If the DCF is requesting something to be resubmitted, the completed DCF should be included in that package.
- All repeats should be performed within 60 days of the original visit date.
- If you are not sure what the DCF is asking, please contact us at MI_DEP_MSK.Team.SM04690-OA-06@bioclinica.com and be sure to reference your study and site.

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Subject Data Submission

Data Receipt at Bioclinica

- Scan Acknowledgements are issued after data is processed summarizing the data received
- The Data Clarification Form (DCF) is sent to the sites to clarify any discrepancy found in data submitted to Bioclinica
  - DCF Examples:
    - Incorrect Transmittal Form completion
    - Date of Birth or Subject ID questions
    - DXA images missing from the transfer media
    - Repeat image requests
    - Visit date/visit designation questions
- If you receive a DCF you will need to write an answer in the "Solution" section, sign and date the form and return it to Bioclinica with any additional requested materials
- DCFs are reissued to the site until the issue detailed in the DCF is solved. Contact Bioclinica if you need clarification to solve a DCF.

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Subject Data Submission

Subject Data Acknowledgement Fax

- Bioclinica will fax/email an Acknowledgement of Scans Report to the site
  within 3 days after receipt.
- Please remember to file these in your site binder.
- Confirmation reply from Smart Portal is NOT the same as the DXA Scan Acknowledgment

Subject Data Submission

Interim Analysis or End of Study Procedures

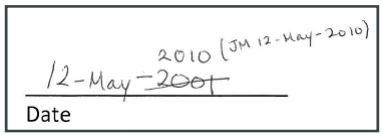
- The Bioclinica study team will send an Interim Analysis (IA) or End of Study (EOS) packet to the site as is approaching the IA or EOS time point
- Package Contents
  - IA or EOS Study Checklist – to be completed by the site
  - Request for QC Archive or QC Export file that includes phantom scan acquisition on the day the last subject has a DXA image acquired for the IA or EOS time point
- Steps to take when the IA or EOS packet is received at the site
  - Complete the IA or EOS Study Checklist
  - Document the date that your last subject was scanned
  - Submit the checklist with an electronic copy of your QC Archive or QC Export
  - Contact the Bioclinica study team if you have any questions

Good Clinical Practice and Archiving

Good Clinical Practice and Archiving

Good Clinical Practice

- Maintain subject and clinical protocol confidentiality
- Use black or blue ink
- Write clearly and legibly
- Fill out forms completely
- Include proper signatures
- Use diskette labels provided
- Correct mistakes properly (line through the error, initial and date)
  - do not use white-out



- Contact Bioclinica with questions

Good Clinical Practice and Archiving

Archiving

- At any time throughout a study, or after a study has closed, Bioclinica may identify missing data or discrepancies in the provided data that require clarification.
- To ensure that the data are retrievable, please follow these guidelines:
  - Keep copies of all study related forms and correspondence in an organized binder.
  - Copy all subject scans to secure electronic media for long term storage at the DXA Facility. Secure media is defined as a CD, optical disk or network directory backed up on tape.
  - Maintain study related materials in compliance with Sponsor requirements and in an environment that is safe, secure and accessible.

DXA Scan Acquisition and Analysis

DXA Scan Acquisition

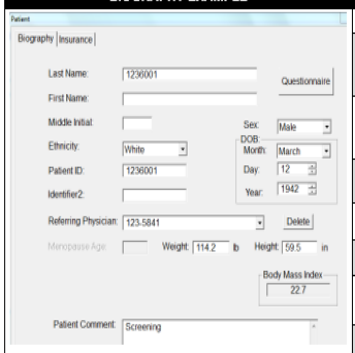
Screening/Baseline Scan Submission

- DXA scans acquired at your center will be used to ensure subjects are enrolled properly in the trial and to compare bone mineral density changes during the trial. Correct subject positioning, scan acquisition, analysis, and consistency at follow-up are key to obtaining reliable bone density data.
- The BMD results obtained from the screening/baseline DXA acquired in this study serve as the reference point from which BMD change over time is measured
- It is critical that the screening/baseline images be of the best possible quality to be used as comparison for follow up exams
- The screening/baseline images must be submitted to Bioclinica within 24-48 hours of acquisition unless otherwise specified in your study specific materials so that a repeat (if necessary) can be requested quickly. Each DXA visit needs to be submitted on a separate DXA TF.
- Please refer to your study-specific materials for:
  - On-site screening/baseline scan analysis

Hologic DXA Scan Biography

Subject Biography, Hologic Windows

BIOGRAPHY EXAMPLE



SUBJECT BIOGRAPHY ENTRY

Update Attendant Initials, Visit ID, Height and Weight at follow-up visits.

Last Name:	XXX6XXX	Enter 7-digit Subject ID number (3-digit site number-6 follow by 3-digit subject number)
Patient ID:	XXX6XXX	Enter 7-digit Subject ID number (3-digit site number-6 follow by 3-digit subject number)
Operator:	SCM	Enter initials of the technologist acquiring the scans
DOB:	MM-DD-YYYY	Enter the date of birth
Height:	165	Enter to the nearest inch/ cm
Weight:	59	Enter to the nearest pound/kg
Sex:	F	Enter F for female or M for male
Ethnicity:	Asian	Enter Hologic code for ethnic group

Hologic DXA Scan Acquisition

- **Hologic Scan Modes**
- Hologic Windows

QDR-4500, Delphi, Discovery and Horizon Series

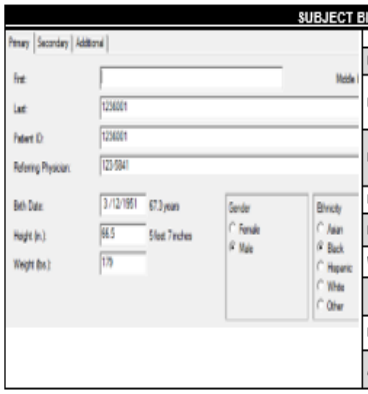
Site	Scan Mode
Lumbar Spine	Array
Femur	Array
Forearm	Left (Right*) Forearm
Whole Body	Whole Body (default)

* Scan forearm indicated in study-specific materials.

- Do NOT use the Express, Quick View, Turbo, Fast and Survey modes.

Lunar DXA Scan Biography

Subject Biography, Lunar Prodigy



Update Attendant Initials, Visit ID, Height and Weight at follow-up visits.		
First Name:		LEAVE BLANK
Last Name:	XXX6XXX	Enter 7-digit Subject ID number (3-digit site number-6 follow by 3-digit subject number)
Patient ID:	XXX6XXX	Enter 7-digit Subject ID number (3-digit site number-6 follow by 3-digit subject number)
DOB:	MM-DD-YYYY	Enter the date of birth
Height:	165	Enter to the nearest inch/ cm
Weight:	59	Enter to the nearest pound/kg
Sex:	F	Enter F for female or M for male
Ethnicity:	Asian	Select appropriate ethnicity from list
Attendant:	LMJ	Enter initials of the technologist acquiring the scans

Lunar DXA Scan Acquisition

Lunar Scan Modes

Prodigy, Prodigy Advance, iDXA Series

Site	Subject Thickness	Mode	Current (mA)
Lumbar Spine	> 25 cm	Thick	3.000
	13 – 25 cm	Standard	3.000
	< 13 cm	Thin	0.750
Femur	> 25 cm	Thick	3.000
	13 – 25 cm	Standard	3.000
	< 13 cm	Thin	0.750

DPX-NT Series

Site	Subject Thickness	Mode	Current (mA)
Lumbar Spine	> 25 cm	Thick	3.000
	15 – 25 cm	Standard	3.000
	< 15 cm	Thin	0.750
Femur	> 25 cm	Thick	3.000
	15 – 25 cm	Standard	3.000
	< 15 cm	Thin	0.750

DXA Scan Acquisition

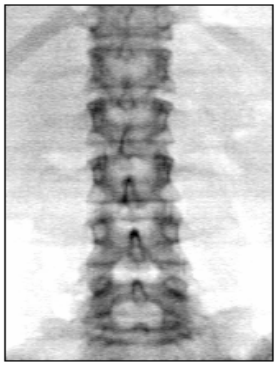
Important scan mode comments

- It is important to ensure that the proper scan mode is used for each subject.
- Quick or Scout modes are acceptable to ensure that the subject is properly positioned. Please refer to the DXA procedure manual for densitometer specific parameters.
- The same scan mode used at baseline should be used for all subsequent visits regardless of which scan mode suggested by the DXA software.
- The DXA image should be examined to ensure that all anatomy and bone edges are properly visualized.

DXA Scan Acquisition

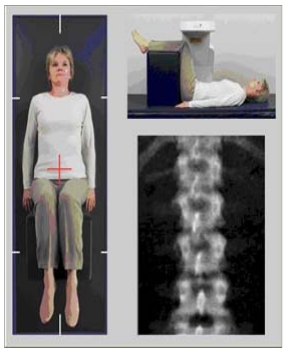
- **Subject Positioning**
- Describe the procedure to the subject.
- Remove all external artifacts present within the scan field.
  - buttons, snaps, rivets
  - bras, belts, zippers
  - jewelry
  - thick elastic, metallic paint
- Use positioning devices in a correct and consistent manner if necessary.
- Align the subject to midline of scanning table.
- Make sure the subject is comfortable.
- Caution the subject to remain still.
- Avoid unnecessary conversation with the subject.
- Poor subject positioning or improper scan acquisition will result in a repeat request DCF
- Excessive Repeat Rate may result in required re-training for DXA technicians

DXA Scan Acquisition



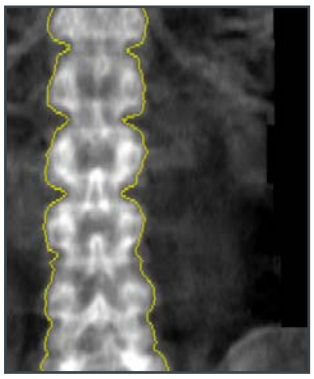
Spine, Good Acquisition

- Correctly use block positioner
- Subject straight, centered, spine within limits
- Entire L1-L4 region visible
- Pelvis and ribs visible as landmarks
- Spine as straight as possible
- Spine centered in scan field
- Reposition and rescan if necessary
- Analyze screening scan



DXA Scan Acquisition

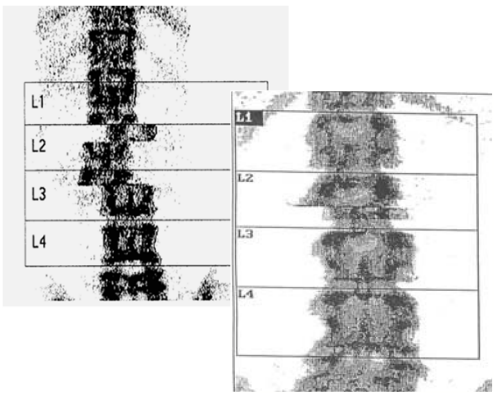
- **Spine, Poor Centering and Poor Start**
- Poor centering and starting too low affects:
  - Reproducibility
  - Tissue calculations
- Corrective Actions:
  - Reposition subject using the repositioning tool and block positioner to reduce lordosis, and ensure spine is straight and centered within the scan field.
  - Ensure there is equal tissue on either side and that the complete L1-L4 region is acquired.



DXA Scan Acquisition

Spine, Subject Movement

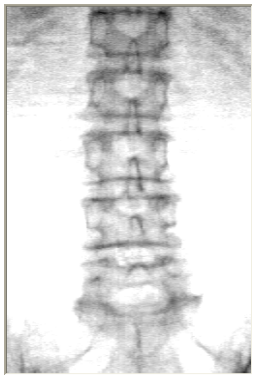
- Motion affects:
  - Reproducibility
  - Bone Mapping
- Corrective Actions:
  - Rescan subject; ask subject to remain still during scanning procedures.



DXA Scan Acquisition

Spine, Incomplete Acquisition

- Incomplete acquisition affects:
  - Correct Analysis
- Corrective Actions:
  - Rescan subject using the repositioning tool.
  - Begin the scan at the level of mid L5 and end it at mid T12 to ensure entire region has been acquired.



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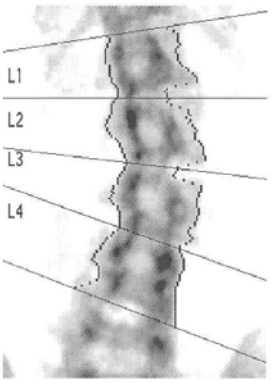
DXA Scan Acquisition

Spine, Scoliosis

- Ensure optimal centering of the L1-L4 region with in the scan field
- This may require starting the scan a little off center to ensure that there are equal (as much as possible) amounts of soft tissue on either side of the L1-L4 region
- Include all vertebrae and anatomical landmarks
- Allow room for proper placement of the entire L1-L4 region of interest box
- Note the presence of scoliosis on the DXA Transmittal Form



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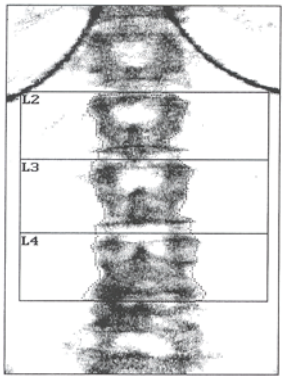
DXA Scan Acquisition

Spine, Artifact

- Remove all external artifacts
- Repeat scan
- Flag non-removable artifacts on the DXA Transmittal Form
- If the artifact is still present, make a note about the artifact on the DXA Transmittal Form as well as the fact that you tried to determine if it could be removed.



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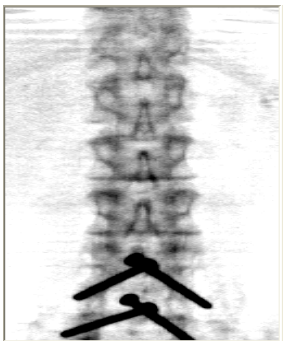
DXA Scan Acquisition

Spine, Artifacts

- External or internal artifact?
- Internal artifacts should be documented on the Transmittal Form
- External artifacts should be removed if possible before scanning subjects- repeat as needed



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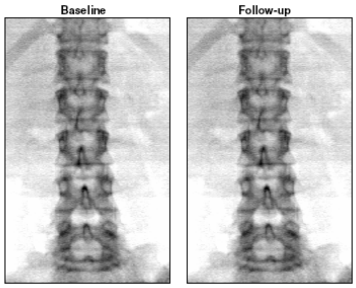
DXA Scan Acquisition

Common Reasons for Repeat Spine Requests

- Poor subject positioning
  - Spine not straight
  - Spine rotated
  - The positioning block was not used
  - Poor centering of the subject's anatomy within the scan field
- Scan mode discrepancies
  - Use of the incorrect scan mode for a given subject size
  - Use of a different scan mode compared to what was used at the screening/baseline visit
- Incomplete acquisition of required lumbar spine anatomy
- Inclusion of external (removable) artifacts
- Subject motion during acquisition
- Please consult your manual for more details

DXA Scan Acquisition

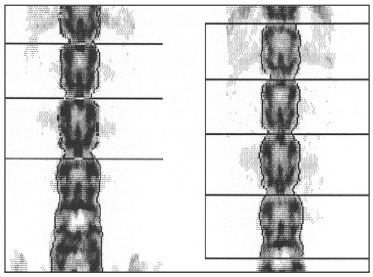
- **Spine – Good Follow-Up Acquisition**
- Use hard-copy image of Baseline scan as reference for follow-up.

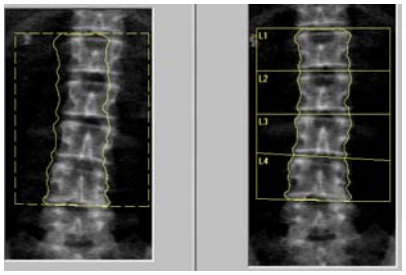


- DO NOT ANALYZE FOLLOW-UP SCANS

DXA Scan Acquisition

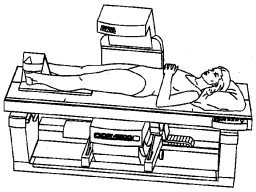
- **Spine, Follow-Up Acquisition**
- L1-L4 region should be comparable on follow-up
- Scan image must be reproduced in order to consistently monitor any changes in BMD over time

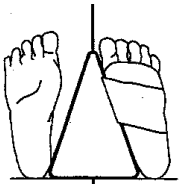




DXA Scan Acquisition

- **Femur, Good Acquisition**
- Scan left and right femur
- Subject straight and centered
- Femur within limits
- Correct use of foot positioner
- Entire edge of foot rests on positioner
- Optimally rotate entire leg
- Abduct leg if necessary for straight femoral shaft
- Poor subject positioning or improper scan acquisition will result in a repeat request DCF

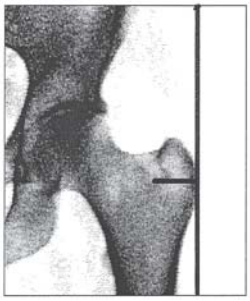




DXA Scan Acquisition

Femur, Good Positioning

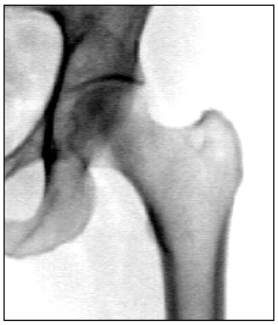
- Always use repositioning tool (F3)
- Ensure consistent projection of bone, centering



DXA Scan Acquisition

Femur, Good Acquisition

- Greater trochanter fully acquired
- Femoral head fully acquired
- Enough femoral shaft acquired
- Use repositioning tool
- Femoral shaft as straight as possible
- Femur optimally rotated
  - Rotation occurs at hip, not the foot
  - Very little lesser trochanter should be showing
- Reposition and rescan if necessary



DXA Scan Acquisition

Femur, Poor Shaft Angle

- Poor Shaft Angle affects:
  - Reproducibility
  - Proper Neck box placement
- Corrective Actions:
  - Reposition the subject so the femoral shaft is straight as possible
    - Left image (abducted)- bringing the femoral shaft in towards the body so that it is as straight as possible.
    - Right image (adducted)- bringing the femoral shaft in away from the body so that it is as straight as possible

DXA Scan Acquisition

Femur, Poor Rotation

- Poor Rotation results in:
  - Analysis difficulties
  - Poor reproducibility
  - Decreased available neck box region
- Corrective Actions:
  - Reposition the subject by rotating the entire femur from the hip, not the foot. When the femur is properly rotated the lesser trochanter will be much less prominent.

DXA Scan Acquisition

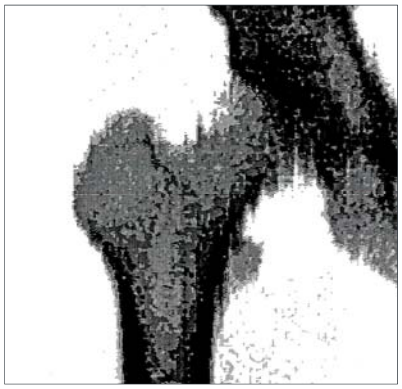
Femur, Poor Pelvic Separation

- Poor Separation affects:
  - Reproducibility
  - Difficult analysis
  - Bone Mapping
  - Decreased available neck box region
- Corrective Actions:
  - Reposition the subject by adjusting the rotation and abduction to increase tissue space above and below the femoral neck region.

DXA Scan Acquisition

Femur, Movement

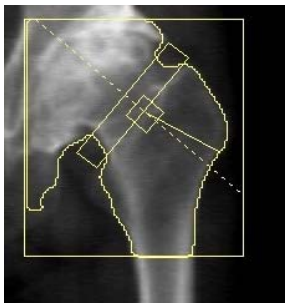
- Motion affects:
  - Reproducibility
  - Bone Mapping
- Corrective Actions:
  - Rescan subject; ask subject to remain still during scanning procedures.



DXA Scan Acquisition

Femur, Internal Artifact

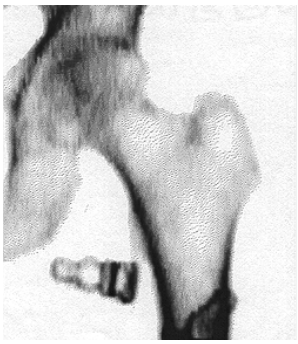
- Flag any internal, non-removable artifact on the Comments section of the DXA Transmittal Form
  - e.g. subject reports history of sclerotic lesion
- Scan right femur



DXA Scan Acquisition

Femur, External Artifact

- Do not send scans with artifacts that are external and removable
- Remove artifacts and rescan, send only the good scan



DXA Scan Acquisition

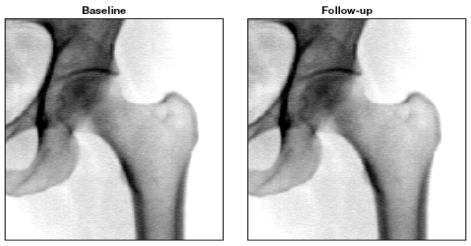
Common Reasons for Repeat Femur Requests

- Poor subject positioning
  - Femoral shaft not straight; over/under abducted
  - Femoral shaft not properly rotated
- Poor centering of the subject's anatomy within the scan field
- Scan mode discrepancies
  - Use of the incorrect scan mode for a given subject size
  - Use of a different scan mode compared to what was used at the screening/baseline visit
- Incomplete acquisition of required femur anatomy
- Inclusion of external (removable) artifacts
- Subject motion during acquisition
- Consult your manual for more details

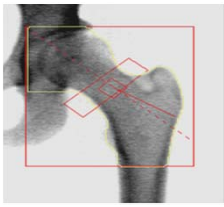
DXA Scan Acquisition

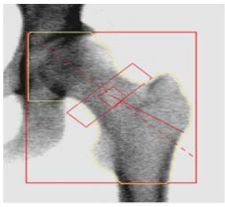
Femur – Good Follow-Up Acquisition

- Reproducibility (comparability) is essential at follow-up
  - Good match of rotation and femoral shaft angle
  - Ensure optimal match



DXA Scan Acquisition





Inconsistent Femur Rotation

- Change affects Area and BMD
- Reposition and rescan to match rotation

Screening 2

Region	Area(cm²)	BMC(g)	BMD(g/cm²)
Neck	4.36	4.61	1.058
Troch	8.31	7.94	0.955
Inter	16.06	21.11	1.315
TOTAL	28.73	33.66	1.172

Screening 1

Region	Area(cm²)	BMC(g)	BMD(g/cm²)
Neck	4.97	4.77	0.960
Troch	9.78	8.53	0.872
Inter	18.29	21.07	1.152
TOTAL	33.05	34.37	1.040

DXA Scan Acquisition

Follow-Up Scan Acquisition - Review

- Consistency is *very* important
  - Scan under same biography
  - Same scan mode
  - Optimally match positioning to baseline
    - refer to printout of first scan
- Reposition subject or detector if necessary
- Ensure changes in BMD values are due to subject actual anatomy changes and not due to inconsistent positioning.

Summary

- **Study Start-up steps**
- Pre-Trial Questionnaire needed for site contact and DXA scanner changes
- Participate in training and complete the DXA Training documentation – training may be waived in certain situations
- DXA QA Manual - read and understand the manual
- Baseline IQC requirements - send data via courier to Bioclinica or upload thru SMART Submit
  - Electronic phantom database copied to electronic media

Note - Submission of baseline IQC is not required if your DXA machine is currently being monitored by Bioclinica *and up to date.*

- Indicate protocol and site number on all correspondence.
- Please use the DXA Procedure Manual as a detailed reference to this training presentation.
- Contact Bioclinica study team with any questions.

MI_DEP_MSK.Team.SM04690-OA-06@bioclinica.com

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Thank you