

Framingham Osteoporosis Study Generation 3 Musculoskeletal Exam

(May 2008- 2010)

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A. PRE-CLINIC PROCEDURES

Women who are pregnant or who think they might be pregnant will not be eligible to have a bone mineral density test. The following are the Framingham Study pre-clinic procedures used to determine who will need to be screened for pregnancy at the time of the clinic exam.

Pregnancy Determination

There is a minimal amount of radiation involved when having a bone scan. The radiation exposure could be a potential risk to a fetus. Thus, the following procedure is used for pregnancy screening:

Each female participant who is (a) 55 years or younger or (b) has not had a tubal ligation (tubes tied) or a hysterectomy (uterus removed) will be contacted by the phone 10 days prior to their clinic visit. Female participants will be asked to abstain from sex seven days prior to their clinic visit if they are not on some form of contraceptives because there is a slight chance that a positive pregnancy result would not show up on the day of clinic if the pregnancy occurred in that brief window of seven days prior to their clinic visit (explained in telephone call, see phone script below). If they are on a contraceptive make notation of method next to their name on the clinic schedule. Women who are over 55 years of age and older do not have to be contacted.

1. Telephone dialogue for pregnancy pre-clinic screening:

Hello Ms. _____

My name is _____ from the Framingham Heart Study and you are having a bone density scan as part of our clinic exam on (date). I need to ask you a few questions. Do you have a few minutes? (At this time mention about the minimal amount of radiation exposure while having the bone density scans [see reference above under **Pregnancy Determination**]).

- *Are you pregnant or trying to get pregnant?* NO (if trying to get pregnant, I tell them that they will not be able to have a bone density, but the rest of the exam is perfectly okay).
- *Have you had a tubal ligation?* NO (if they say yes, I say thank you I have no further questions, we will see you on the (date))
- *Have you had a hysterectomy?* NO (if they say yes, I say thanks you I have no further questions, we will see you on the (date))
- *Do you use any form of birth control?* (most will say yes) this will also include husband having a vasectomy—If NO, they must be told to abstain from sexual intercourse for 7 days prior to their exam, unless they use one of the following methods of birth control.

If they are on a contraceptive, make notation of method next to their name on the clinic schedule. The following are forms of birth control methods effective in preventing pregnancies:

- Oral contraceptives (the pill)
- Male condom
- Female condom
- Injection (Depo-Provera, Lunelle)
- Diaphragm with spermicide
- Cervical cap with spermicide
- Contraceptive patch
- Vaginal contraceptive ring
- Post-coital contraceptives, taken within 72 hrs of intercourse (Preven, PlanB)
- Implant (Norplant)
- IUD (Intrauterine Device)
- Male surgical sterilization

2. Completion of Pregnancy Determination Forms

At the end of every week the bone technician will fill out the Pregnancy Determination Forms for the upcoming week (**see Appendix A for form**). The bone technician will get the information from the written notation that the bone technician documented from the pregnancy screening telephone calls [referenced above]. The bone technician will put a label with participant's ID, name and date of exam on the form and fill in the appropriate pregnancy test information. These forms will be placed in the yellow folder labeled 'bone density' on the wall in the lab for the upcoming week pregnancy urine tests.

B. DAILY QUALITY ASSURANCE AND PHANTOM PROCEDURES

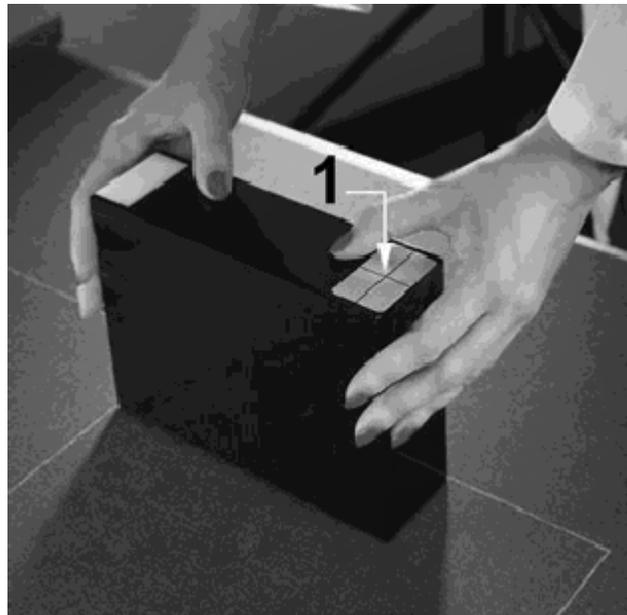
I. PRODIGY DAILY QUALITY ASSURANCE

A Quality Assurance (QA) test must be performed each morning before any participants are measured. This procedure assures quality measurements are obtained.

Use the black calibration block to complete a QA test (the calibration block consists of tissue-equivalent material with three bone-simulating chambers of known bone mineral content).

Leave the pad on the scanner table during the QA procedure.

1. Click Quality Assurance from the Main screen or from the Common tool bar. The Quality Assurance screen is shown.
2. Click the START icon . A message is shown instructing you to position the calibration block.
3. Put the calibration block on the pad so that the laser light shines in the center of the cross-hair label on the calibration block (1).



4. Click OK. Follow the screen prompts to complete the QA procedure.
5. Make sure the *Detector Status* and *System Status* have passed as shown on the Quality Assurance screen.

If the QA test did not pass, reposition the calibration block and repeat the procedure. If the procedure fails a second time, call GE Lunar Support for assistance. 1-888-281-4947

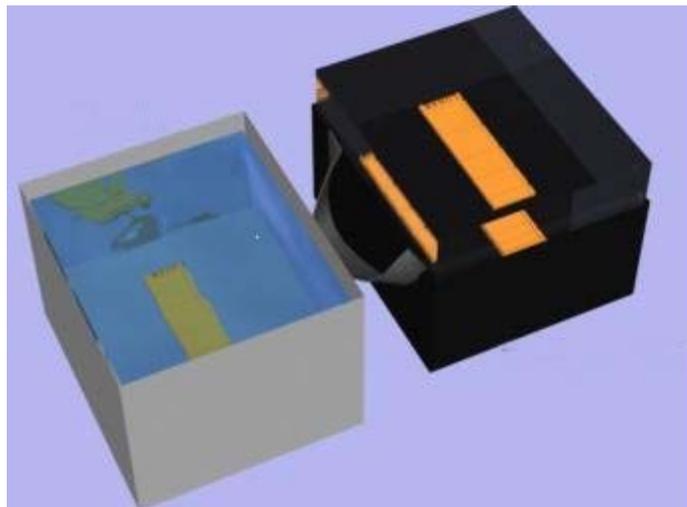
Give them our system # which is DF+12654

6. Click the REPORT icon  , if the auto print option is not set, to generate the QA results.
7. Save the report in the Daily QA binder and click the CLOSE icon  to exit the QA screen.

II. PRODIGY PHANTOM SCANNING PROCEDURES

An encapsulated spine phantom scan should be collected every day.

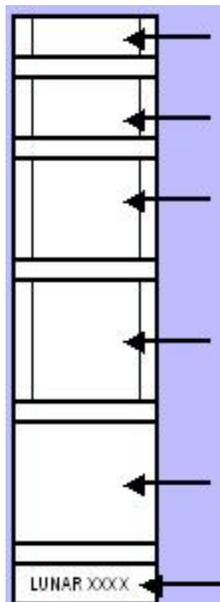
1. Go to Phantom Database
2. Click on Phantom 1.2652FHS/Spine
3. Click on “Measure”
4. Click on “AP Spine”
5. Click on “Position”
6. See Illustration below for Encapsulated Spine Phantom



Measure the Spine Phantom

1. Ensure the following primary information is in the dialogue box:
 - a. First Name

- b. Middle Initial
 - c. Last Name
 - d. Birth Date: record the current date minus 40 years. **DO NOT CHANGE THIS DATE FOR FUTURE SPINE PHANTOM**
 - e. Height: 67 inches
 - f. Weight: 154 pounds or 70 kilograms
 - g. Sex: Male
 - h. Ethnic Group: White
2. Select Secondary Tab and record the following information:
 - a. Facility ID: Record the Phantom number given on the L5 region of the spine phantom.
 - b. Department ID: Record your system ID number. This number is located in the User Options-System tab.
 3. Select "Position" from tool bar. A graph is shown which illustrates correct patient and laser position for the scan type.
 4. Position the laser cross-hair on the letter "R" in the word "LUNAR" on the L5 vertebral body of the phantom. Start the scan.



- | | |
|------------|---|
| T12 | Once, approximately B of T12 is imaged, select abort from the toolbar |
| L1 | |
| L2 | Choose Save Measurements from the Save Dialog box and select OK if the measurement was performed correctly |
| L3 | |
| L4 | |
| L5 | |

For spine phantom analysis it is necessary to verify and adjust accordingly for the following vertebral heights:

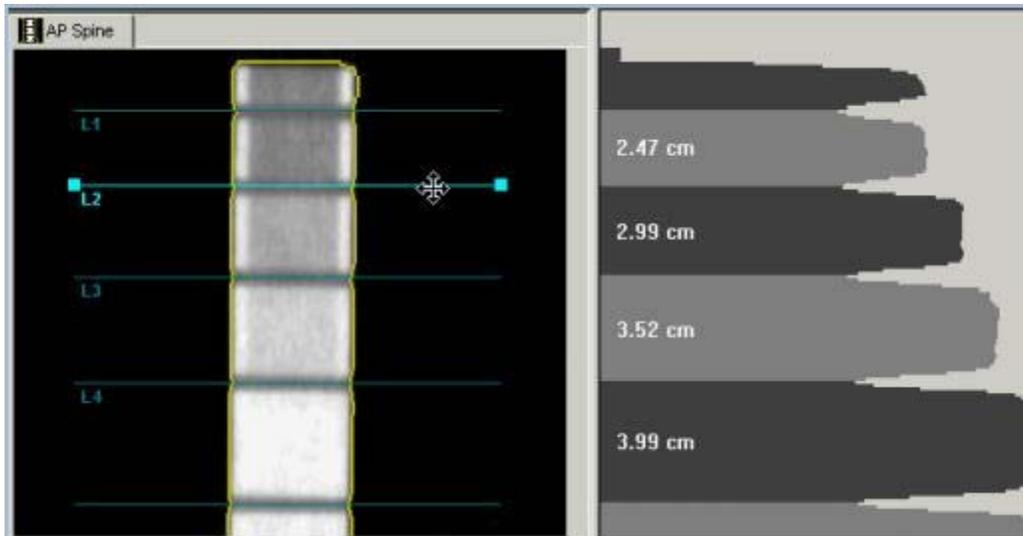
L1:

L2: 3.00 cm ± .02 cm

L3: 3.50 cm ± .02 cm

L4: 4.00 cm ± .02 cm

L2-L4 region height should be 10.5 cm



C. PARTICIPANTS ENTER MAIN CLINIC

- The lab technicians will collect a urine sample from those participants who need a pregnancy test (because of minimal radiation dosage received when having a bone density test that could possibly harm a fetus) on each female participant 55 years or younger who has not had a tubal ligation or a hysterectomy and will be having a bone density test or a CT. Once results of the urine pregnancy test are obtained in the lab, the lab technician will complete the Pregnancy Determination form (**see Appendix A for form**) and place the completed form in the folder outside the bone technician's door.

The lab technicians then place the results of the pregnancy tests outside the bone technician office door. The bone technician will then check the pregnancy results for each participant as they report to the bone density room for the Musculoskeletal exam.

- **GETTING HEIGHT & WEIGHT INFORMATION**-The daily schedule with the participants' information (id, weight, and height) will be posted at the main desk in clinic. The participants' measurements are taken shortly after the participants are first registered, and the data is recorded on the daily clinic staff's schedule. The bone technician has a copy of the daily schedule in the bone density room and will copy the clinic staff's recorded measurements onto the bone technician's schedule. On the rare occasion that the clinic staff does not take these measurements and a clinic room with a scale is available; the bone technician will take the height and weight measurements and record the height and weight in the bone technicians schedule book. If all clinic rooms are being used and the participant is ready to see the bone technician for a scan and has no

weight and height recorded, the bone technician will ask the participant his/her/ weight and height and use these measurements and proceed with the bone density scanning.

- At the foot of the Prodigy table there is a roll of paper to cover the table for sanitary reasons. For each new participant, the bone technician shall discard the previous paper covering and recover the examination table paper from the paper roll at the foot of the table.
- The bone technician will have in place the already printed out consent form with label of participant's ID, name and date on the first and last page of consent form, along with the urine pregnancy test results from lab (also with ID, name and date) and a copy of the Supplement to Pregnancy Determination form if required. **See Appendix B for form.**

D. PARTICIPANTS ENTER BONE ROOM

a. Consent participant/review pregnancy issues

[PLEASE NOTE, FOR ALL PARTICIPANTS, PRIOR TO ANY OTHER STEPS, THE BONE TECHNICIAN SHALL EXPLAIN THERE SHALL BE A SMALL EXPOSURE TO RADIATION]

First Step: Determination of Pregnancy Status.

- For those male participants and/or female participants who are either (1) over 55 years of age, (2) had a hysterectomy or (3) tubal ligation then the bone density technician should
 - Explain that the consent form gives the technician permission to ask some questions about falls, fractures, osteoporosis medications and recreational activities during the past 7 days;
 - Once the DXA technician has answered any of the participant's questions about the exam and he/she signs the consent form, continue with the Musculoskeletal Exam Components Procedures outlined in Section E.
- If Participant is a female and under 55, determine if they had pregnancy test in clinic immediately prior to entering bone density room.
- For those female participants with a **positive** test result, the bone technician will not perform any DXA scans. The bone technician should offer to do their DXA scan at a later date, if she would be willing to reschedule. If the female participant says yes, the bone technician

would give her a Framingham Heart Study business card with the telephone number to call when ready to reschedule.

- For those female participants with a **negative** test result, the bone technician will query the participant as to whether they had intercourse in the past week and if they used any contraceptive and explain the potential risks to a fetus due to radiation from a DXA scan. (see Appendix B) . At that time have the participant sign and date the pregnancy determination form. Then explain that the consent form gives the technician permission to scan the hip, lower lumbar, and total body. Again mention that the bone scanning does involved slight radiation, less than a chest x-ray. Also, state that the consent form gives the technician permission to ask some questions about fall and fractures and recreational activities over the past 7 days and a quadriceps strength test (knee extension strength test);
- Should the participant indicate there is a **possibility of being pregnant** and is not willing to undergo the DXA scan the bone technician would acknowledge her concern and ask if she would be willing to reschedule and have a bone scan at a time when she is not trying to get pregnant. If, she says yes, the bone technician would give her a Framingham Heart Study business card with the telephone number to call when ready to reschedule.
- If there is **no possible pregnancy and/or** participant understands and accepts the potential risk, the bone technician will complete the consent process and begin bone density exam (go to Hip and AP DXA Scan Procedures).

Second Step: Participant preparation

- Every participant comes in the bone density room with their locker key on the wrist or in their bathrobe pocket.
 - Ask that they put the key in the blue bowl that is on the countertop.
 - If you notice that they have metal rings or piercings, watches or metal hair clips ask them to remove these items and place them in the blue bowl along with their key.
 - Impress upon them that in order to get the most accurate bone density reading it is imperative to remove as much metal artifacts as possible.
 - Query about any implants or fixation devices such as pins or screws (e.g. hip replacement, spine implants, belly button rings, finger/toe rings that they can't or won't remove). (If so, make note on the daily sheet and in the patient directory tab labeled ADDITIONAL comments). Put a check next to the appropriate item. If not on the list, check **other** and write the item in the comments.

E. Hip and AP DXA Scan Procedures

DXA scan acquisition

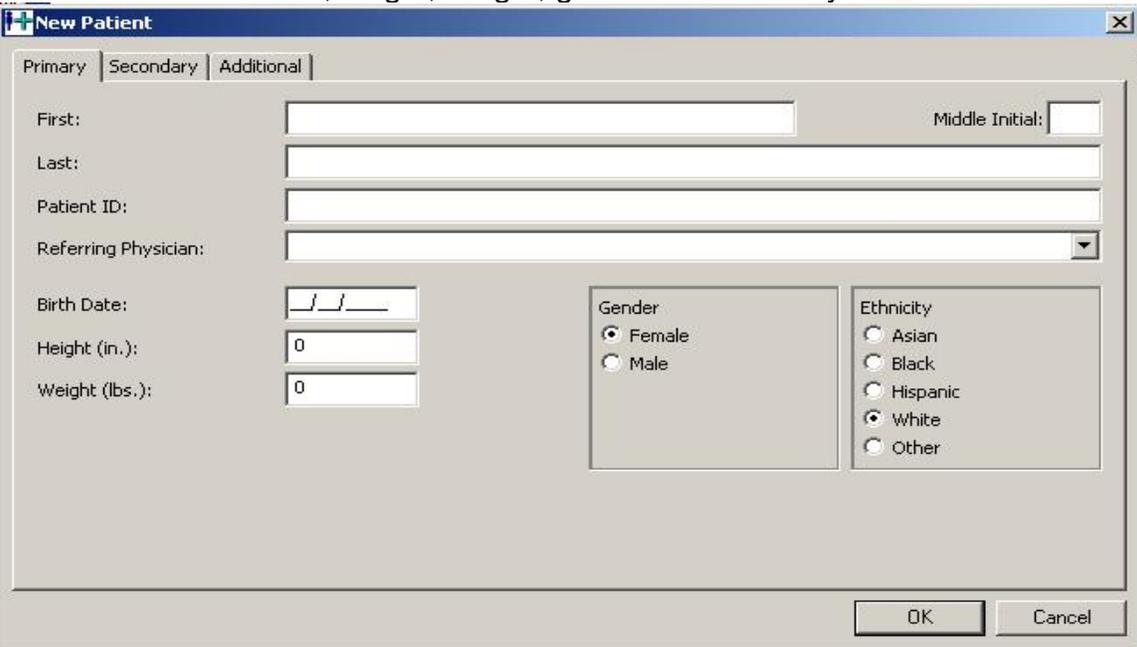
- If participant indicates they have a right hip implant/replacement, perform a scan of the left hip
- If participant indicates they have bilateral hip replacements, do not perform a hip scan
- If participant indicates spine implants, perform spine scan and during analysis, determine whether the implants interfere with any of the L2-L4 vertebrae
- Total body scan should be completed regardless of any implants
 - Place Participant on the Prodigy Table with fresh paper liner as noted above.

Third Step: Create new record in DXA database

1. If the PRODIGY software has not been started, double click on the PRODIGY icon on the Windows desktop. (As of April 11, 2008 this exam uses software version 11.40.044.) Make sure that a Quality Assurance (QA) has been performed that day. If not, perform a QA scan before scanning.
2. Have the participant lie in the middle of the scanning table with his/her head on at the head (opposite of computer) of the table. **From PRODIGY operator's manual: for total body scans, make sure approximately 3cm below the horizontal line (head) on the table pad.**
3. Ask the subject to point to their belly button. Open up the calipers, slide the fixed bottom arm underneath the participant and carefully lower the top of the instrument to the belly button area. Lightly tap the top arm of the calipers to make sure it has settled properly over the participant's clothes and record the number showing underneath the top arm on the daily sheet. Measure the hip thickness at inferior iliac spine by opening up the calipers, slide the fixed bottom arm underneath the participant again and carefully lower the top of the instrument to the inferior iliac spine. Lightly tap the top arm of the calipers to make sure it has settled properly over the participant's clothes and record the number showing underneath the top arm also on the daily sheet.
5. At the main screen, click the DIRECTORY icon (or press F4).

6. In the left column of the DIRECTORY screen, look for the list of PRODIGY databases. If they are not displayed, click the MORE>> bar. The list of databases will drop down.
7. Under ALL DATABASES, click the “Gen3” database.
8. To scan a new participant, click the NEW icon  in the Directory toolbar to add the participant to the database.
9. The Participant Information dialog box will appear. The box contains three tabs labeled Primary, Secondary, and Additional. Enter the following information in the corresponding tabs:

Primary enter the participant's name, ID number (e.g. 10123), birth date, height, weight, gender and ethnicity.



Secondary *Address:* enter participant's hip thickness
 City: enter participant's exact height
 Postal: enter body thickness (from daily sched)
 Country: enter ID number a second time
 Attendant: enter bone density technician initials

Additional Indicate any conditions that may potentially affect DXA scan results. Click On the “Additional” tab and under the Fracture drop down menu, highlight one or more of the following comments:

Comment categories:

1. Amputee
2. Brace
3. Bracelet
4. Breast implants
5. Buttons
6. Cast
7. Hair (thick, dense)
8. Hand position (movement or fist)
9. Hearing aid (external battery)
10. Hearing aid (internal ear)
11. Hip replacement (total/partial)
12. Implantable defibrillator
13. Incomplete scan
14. Knee replacement (total/partial)
15. Movement
16. Outside region of interest
17. Pacemaker
18. Pager (deleted from comments)
19. Pelvis reconstruction
20. Penile implant
21. Piercings

22. Pillow used
23. Rings
24. Scoliosis
25. Shoulder reconstruction
26. Spine/neck internal fixation
27. Surgical staples
28. Thick (poor beam penetration)
29. Vascular stent
30. Wallet (deleted from comments)
31. Watch
32. Zipper
33. Other
34. Braces on teeth
35. Plate/pins in extremities

Click OK when finished and the name and ID will appear highlighted in the participant box.

Begin collecting DXA scans in this order: 1) hip, 2) AP spine, 3) total body.

Femur Scan

1. Click the MEASURE icon  to get to the New Measurement screen.
2. At the New Measurement screen, click on the skeleton's right femur to scan the hip. **REMEMBER: DO NOT CHANGE THE SCAN MODE!**
3. Click the POSITION icon  to move the scanner to the approximate start position.
4. Position the participant for a right femur scan (if for some reason the right hip cannot be scanned-e.g. hip replacement-then the left hip may be scanned. Follow the procedures using the left hip instead.
 - Stand at the foot of the table and make sure the participant's body is in the center of the scanner table—use the centerline on the table as a reference to align the participant. Make sure the participant's pelvis is flat on the table and give the ankles a slight tug to straighten out the spine.
 - Place the foot brace between the participant's feet. Position the foot brace with the perpendicular division on the center line of the table pad. The left leg should be perpendicular and tightly strapped to the leg brace. Place tissue equivalent (TE) bag (#1) around the subject's left foot to provide stabilization. Place TE bag (#2) under right knee.

Please note that we are using the foot brace from the original LUNAR DPX-L system, which rotates only one hip, not both as with the PRODIGY foot brace.

- Rotate the participant's right ankle and at the same time, feel for movement of the trochanter. Next, with your left hand under the subject's knee and your right hand over the leg at the knee area, rotate the leg inward toward you and tightly strap the participant's foot in the brace. Place large white rice bag (#3) around the area of the right hip. Pack it closely to the hip. Make sure the right leg is maximally rotated by placing your hands on the right thigh and twisting it toward the inside of the body. Additionally, make sure the participant's pelvis is flat on the table, not rotated upwards, to avoid a shortened femoral neck in the analysis image.
5. Position the laser light. Use the graphic shown on the New Measurement screen and the basic techniques that follow to adjust the position of the laser light. Position the laser light approximately 2 inches below the greater trochanter where the transverse (pubic symphysis) and midline of the femur intersect. To find the midline of the femur, place your left hand on top of the knee cap and point your index finger up the middle of the thigh. Your finger should point right up the midline of the femur.
 6. **DO NOT PLACE THE BAGS ON TOP OF PARTICIPANT'S FEMUR.** The PRODIGY system does **NOT** require additional tissue surrounding the femur, which the DPX-L did.
 7. Click the START icon  on the New Measurement toolbar to begin the scan.
 8. Watch the scan image very carefully to ensure proper positioning. The ischium should be seen within the first 3-4 sweeps of the scanner. If it shows in the 1st sweep, the start position is too high. If it shows in the 4th sweep, the start position is too low. Also, the shaft of the femur should be to the left of the center of the scan region so that the neck of the femur falls in the middle of the scan region.

If you feel the positioning is wrong, click the ABORT icon  from the New Measurement toolbar to stop the scan for repositioning. A dialog box will appear. Select the "Do not save measurement. Reposition this measurement." option and click OK. This will allow you to change the start position on the computer without manually moving the scanner.

The partial image will appear on the screen with a blue line bordering the scan image. Left click and hold inside the blue border and use the mouse to drag the border so that:

- A. The bottom line of the border is placed so that the ischium will be picked up in the 3rd or 4th sweep. To ensure the proper number of sweeps, place the bottom border of the blue box so that it is just touching the bottom of the ischium. Hold down the shift key and then press the down arrow key 3 or 4 times. For each shift+arrow, the box will move down the equivalent of one sweep of the scanner arm.
- B. The blue box in the middle of the bottom line of the border falls below the center of neck of the femur.

When the scan region box is placed properly, click the START icon  in the New Measurement toolbar to restart the scan. Watch the scan carefully to make sure the positioning is correct. If not, click the ABORT icon  and reposition. If the positioning is correct, allow the scanner to finish the scan. A correct femur image will show 1) the greater trochanter, 2) the femoral neck and 3) the ischium:



When the scanner stops, the PRODIGY will save the scan for analysis.

Spine Scan

Unstrap the participant's feet from the foot brace and remove the brace from the table. Remove the pillow from under the participant's head. Position the participant for a spine scan by using the graphic displayed on the computer as a guide for proper positioning. Stand at the foot of the table and make sure the participant's body is in the center of the scanner table—use the centerline on the table as a reference to align the participant. Give the ankles a slight tug to straighten out the spine. Use the support block to elevate the participant's legs. Make sure the participant's thighs form a 60°–90° angle with the table top. This step helps separate the vertebrae and flatten the lower back. If you can slide your hand under his/her back, they are not supported properly. Place his/her hands so that they are flat with the palms down on the scanner table and their arms are alongside the body.

Next, using the graphic as a guide, position the laser light approximately 1 inch below the participant's navel and in the same longitudinal plane as the participant's midline.

When the laser light is positioned properly, click the START  icon from the New Measurement toolbar to begin the scan.

Watch the scan image very carefully to ensure proper positioning. The top of the iliac crests should be seen within the first 1 or 2 sweeps of the scanner. If it does not show in the 2nd sweep, the start position is too low. If you cannot see the iliac at all in the first sweep, the start position is too high and you must restart the scan lower. Also, the vertebrae of the spine should fall in the middle of the scan region.

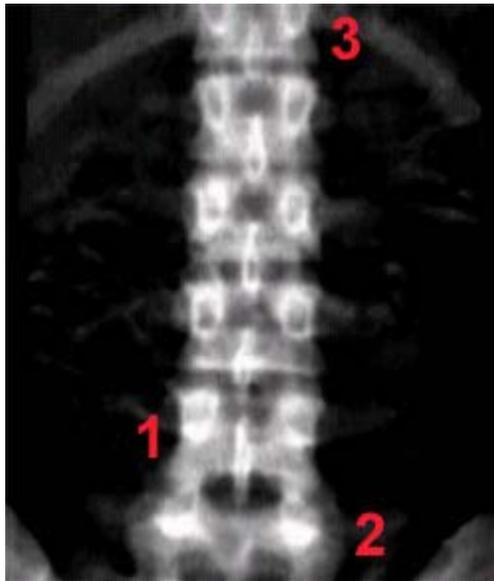
If you feel the positioning is wrong, click the ABORT  icon from the New Measurement toolbar to stop the scan for repositioning. A dialog box will appear. Select the “Do not save measurement, reposition this measurement” option. This will allow you to change the start position on the computer without manually moving the scanner.

The partial image will appear on the screen with a blue line bordering the scan image. Left click and hold inside the blue border and use the mouse to drag the border so that:

- A. The top of L5 and all of L4 can be seen above the bottom line of the border. To ensure the proper number of sweeps before the top of the iliac crests, place the bottom border of the blue box so that it is just touching the top of the iliac crests. Hold down the shift key and then press the down arrow key 2 or 3 times. For each shift+arrow, the box will move down the equivalent of one sweep of the scanner arm.

B. The vertebrae are in the center of the scan image.

When the scan region box is placed properly, click the START icon  in the New Measurement toolbar to restart the scan. Watch the scan carefully to make sure the positioning is correct. If not, click the ABORT icon  and reposition. If the positioning is correct, allow the scanner to finish the scan. A correct AP spine image will have the spine in the center of the image, all of L4 (1) shown, the top of L5 (2) shown in the first 1-2 sweeps of the detector, and (3) approximately ½ of T12 shown:



When the scanner stops, the PRODIGY will save the scan for analysis.

Click the HOME icon  to return the scanner to the home position.

Click the CLOSE icon  to close the New Measurement screen and return to the directory screen.

If you notice an artifact on the scan during scan acquisition, stop the scan (abort ) and check whether the participant has metal on their clothing or in their pockets. If there is metal have the participant remove it and re-start the scan. If there is no metal, ask the participant if they have recently taken any calcium pills or ingested any contrast material, such as those administered for some diagnostic imaging procedures ie: Gadolinium. If so, re-start the scan and note in the schedule book that there is an artifact in the scan and reason for its presence. If there is no obvious explanation for the presence of an artifact, note in the schedule book that there is an artifact on the scan.

DXA scan analysis - when all scans (hip and AP spine) have been completed.

Femur Scan

1. If the PRODIGY software has not been started, double click on the PRODIGY icon on the Windows desktop.
2. At the main screen, click the DIRECTORY icon (or press F4).
3. In the left column of the DIRECTORY screen, look for the list of PRODIGY databases. If they are not displayed, click the MORE>> bar. The list of databases will drop down.
4. Under ALL DATABASES, click the “Gen3” database.
5. Locate the participant you wish to analyze in the participant list window. You can use the Search window or simply scroll up or down the list of participants.
6. In the Image list of the participant, highlight the femur image you want to analyze and then click the ANALYZE  icon (or simply double-click the image). The Analyze screen is shown.
7. Adjust Image

If you feel the image needs adjusting, click the IMAGING  icon from the Analyze tool bar. The Image Tools window is shown. You can use this window to change the gray levels of the image and magnify the image. Placement of ROIs and verifying point typing is made easier if you can see the bone edges clearly.

The Image Tools window shows a bone profile and gives the options that follow:

- **Contrast**-To adjust the contrast for the image, select contrast and enter a value in the Black and White fields, or select and move the vertical lines that are shown on the bone profile. Click **OK**.
- **Range**-Use the Range option to adjust the levels of white and black that is used to adjust the contrast of the image. Select Range and enter a value in the Black and White fields, or select and move the vertical lines that are shown on the bone profile. Click **OK**.
- **Magnification**-To magnify the image, enter a value in the Magnification % field or use the arrows next to the field to scroll

through the percentage values. Click **OK**. (You can also use the Zoom tool to magnify an image.) Use the pan tool if the image is larger than the window area on the Analyze screen.

8. Zoom and Pan an image

Use the tools given in the following table to magnify an image during analysis. These tools are always shown on the left side of the Analyze screen.

Icon	Tool	Description
	Reset Mode	Select to deactivate the Zoom and Pan Image tools.
	Zoom Image	Select the Zoom Image tool and move the cursor over the image. Click the left mouse button to zoom in on the image. To zoom out, select the Ctrl key and click the left mouse button at the same time.
	Pan Image	If you magnify the image larger than the viewable area on the screen, use the Pan Image tool to view hidden areas of the image. Select the Pan Image tool, then drag the cursor to move the image.

9. Point typing

If it appears that the auto-analysis has mistyped bone or tissue on the scan image, you can alter the typing manually. To view the point typing click the POINTS icon  on the Analyze tool bar and the Point Type window will show. The program automatically determines if a sample is bone, tissue, neutral, air, or artifact:

Bone: Verify that the bone is typed as Bone.

Tissue: Select the Tissue brush type and verify that one strip of tissue is shown on both sides of the bone.

DO NOT adjust the point typing unless the program made obvious errors. Use only the 5x5 brush size to change the point typing.

To adjust point typing, select a brush type (Bone or Tissue) and 5x5 brush size. Click on the image to make your changes.

If necessary, select the Artifact brush to point type an artifact in the image.

If necessary, click the RESET  icon to correct errors you make while adjusting the point typing. Click CANCEL  to return the point typing to the program's original settings (as if the file had never been analyzed).

The following is an example of correct point typing for a femur scan:



To apply the changes you make to the point typing, click the RESULTS  icon.

10. Region of interest (ROI) box

Make sure the Neck ROI is positioned correctly as follows:

- 1) The Neck ROI does not include any portion of the greater trochanter.
- 2) Soft tissue is contained in both ends of the Neck ROI.
- 3) The Neck ROI is perpendicular to the femoral neck.
- 4) The Neck ROI, ideally, does not contain any portion of the ischium. If the ischium is included in the Neck ROI, the program automatically types the bone as Neutral.

An example of a proper femur analysis:



If you feel that the ROI box is placed incorrectly, you can adjust it by clicking on the ROIs  icon. Use the tools given in the following table to adjust the ROI; however, you should not change the SIZE of the ROI without consulting Principle Investigators.

Icon	Tool	Description
	Move/Size ROI	Select to move or size the Neck Axis and Neck ROI. DO NOT move or size the Neck Axis or Neck ROI unless they are obviously incorrect.
	Rotate ROI	Select to rotate the Neck ROI. DO NOT rotate the Neck ROI unless it is obviously incorrect.

Click CANCEL  to return the ROI position to the program's original settings (as if the file had never been analyzed). To apply the changes you make to the ROI, click the RESULTS  icon.

If there is still a portion of the ischium in the Neck ROI after moving it, you can go back and change the point typing of the ischium from bone to tissue using the point typing as described in part 9 of this protocol.

When you are satisfied with the femur analysis, click the SAVE  icon to save the analysis (or click CLOSE  then **no** if you do not want to save your changes).

If you have any questions about the analysis, make a note in the daily schedule book and have Field Coordinator or Principal Investigator review the scan at a later date.

Spine Scan

1. If the PRODIGY software has not been started, double click on the PRODIGY icon on the Windows desktop.
2. At the main screen, click the DIRECTORY icon (or press F4).
3. In the left column of the DIRECTORY screen, look for the list of PRODIGY databases. If they are not displayed, click the MORE>> bar. The list of databases will drop down.
4. Under ALL DATABASES, click the “Gen3” database.
5. Locate the participant you wish to analyze in the participant list window. You can use the Search window or simply scroll up or down the list of participants.
6. In the Image list of the participant, highlight the AP spine image you want to analyze and then click the ANALYZE icon  (or simply double-click the image). The Analyze screen is shown.
7. Adjust Image

If you feel the image needs adjusting, click the IMAGING  icon from the Analyze tool bar. The Image Tools window is shown. You can use this window to change the gray levels of the image and magnify the image. Placement of ROIs and verifying point typing is made easier if you can see the bone edges clearly.

The Image Tools window shows a bone profile and gives the options that follow:

- **Contrast**-To adjust the contrast for the image, select contrast and enter a value in the Black and White fields, or select and move the vertical lines that are shown on the bone profile. Click **OK**.
- **Range**-Use the Range option to adjust the levels of white and black that is used to adjust the contrast of the image. Select Range and enter a value in the Black and White fields, or select and move the vertical lines that are shown on the bone profile. Click **OK**.
- **Magnification**-To magnify the image, enter a value in the Magnification % field or use the arrows next to the field to scroll through the percentage values. Click **OK**. (You can also use the Zoom tool to magnify an image.) Use the pan tool if the image is larger than the window area on the Analyze screen.

8. Zoom and Pan an image

Use the tools given in the following table to magnify an image during analysis. These tools are always shown on the left side of the Analyze screen.

Icon	Tool	Description
	Reset Mode	Select to deactivate the Zoom and Pan Image tools.
	Zoom Image	Select the Zoom Image tool and move the cursor over the image. Click the left mouse button to zoom in on the image. To zoom out, select the Ctrl key and click the left mouse button at the same time.
	Pan Image	If you magnify the image larger than the viewable area on the screen, use the Pan Image tool to view hidden areas of the image. Select the Pan Image tool, then drag the cursor to move the image.

9. Point typing

If it appears that the auto-analysis has mistyped bone or tissue on the scan image, you can alter the typing manually. To view the point typing click the POINTS icon  on the Analyze tool bar and the Point Type

window will show. The program automatically determines if a sample is bone, tissue, neutral, air, or artifact:

Bone: Verify that the bone is typed as Bone.

Tissue: Select the Tissue brush type and verify that one strip of tissue is shown on both sides of the bone.

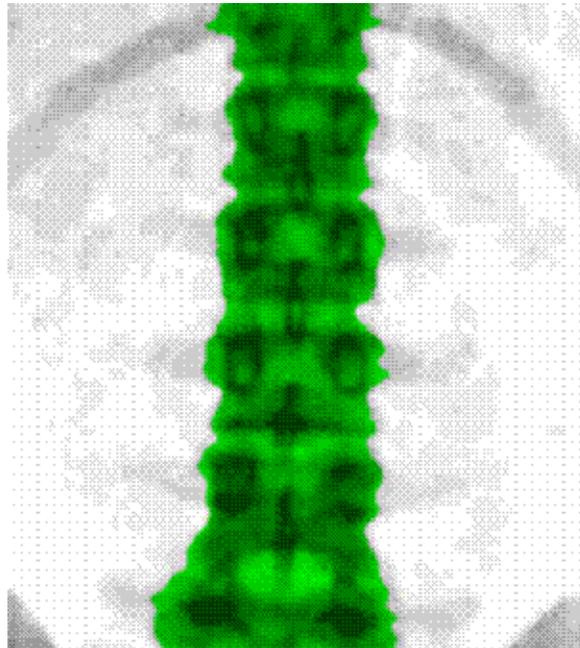
DO NOT adjust the point typing unless the program made obvious errors. Use only the 5x5 brush size to change the point typing.

To adjust point typing, select a brush type (Bone or Tissue) and 5x5 brush size. Click on the image to make your changes.

If necessary, select the Artifact brush to point type an artifact in the image.

If necessary, click the RESET  icon to correct errors you make while adjusting the point typing. Click CANCEL  to return the point typing to the program's original settings (as if the file had never been analyzed).

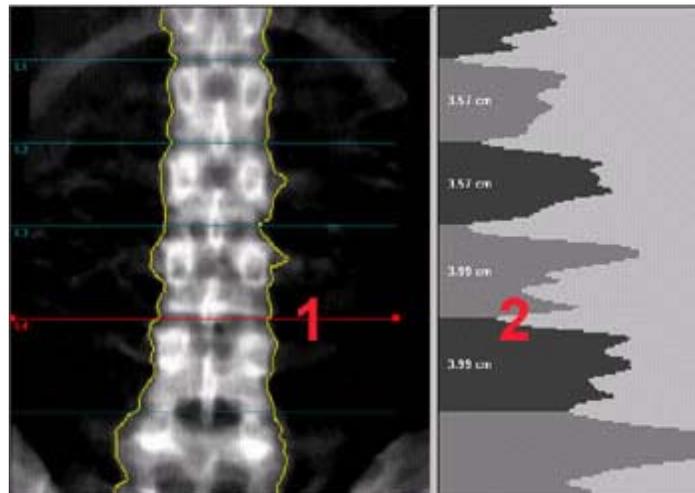
The following is an example of correct point typing for an AP spine scan:



To apply the changes you make to the point typing, click the RESULTS icon.

10. Vertebral Body Region of Interest (ROI)

Click the ROIs icon  from the Analyze tool bar. Make sure intervertebral (IV) markers are between the vertebral bodies (1) and located at the lowest point of bone density as indicated on the bone profile (2). In up to 13% of humans, there are no ribs on T12, which means there may be one additional lumbar appearing vertebral body than usual. In such cases you should start from L4 and work upward until you reach L1. DO NOT START AT THE L1 vertebral body because it may be T12 with no ribs.



If you feel that the IV markers are placed incorrectly, you can adjust them by clicking on the ROIs icon . Use the tools given in the following table to adjust the IV markers:

Icon	Tool	Description
	Add ROI	This tool is shown when you select ROIs . Select the Add ROI tool to add an ROI during AP Spine analysis. When you add a new ROI, it is inserted below the ROI that is selected on the image. Select the Label ROIs tool to label the ROIs accordingly.
	Delete ROI	This tool is shown when you select ROIs . Select the Delete ROI tool to remove an ROI during AP Spine analysis: use the left mouse button to click on the ROI, then select the Delete ROI tool. Select the Label ROIs tool to relabel the ROIs if necessary.
	Label ROIs	This tool is shown when you select ROIs . Select the Label ROIs tool to relabel ROIs after you have added or deleted an ROI from an image.

	Move/Size ROI	This tool is shown when you select ROIs . Select the Move/Size ROI tool to move ROIs.
	Rotate ROI	This tool is shown when you select ROIs . Select the Rotate ROI tool to rotate an ROI.
	Exclude ROIs	<p>The Exclude ROI tool lets you remove ROIs from AP spine results.</p> <p>Select the Exclude ROI tool, and then select the ROIs you want to exclude from analysis. Parentheses appear around the ROI labels of excluded ROIs.</p> <p>Results for individual ROIs are shown even if the ROIs are excluded from analysis. Excluded ROIs are not included in the results for combinations of vertebrae.</p>

Intervertebral Marker Labels

If you need to re-label the ROIs, use the left mouse button to click on the label you want to change.

Click the LABEL ROIs icon . The Relabel ROI list is shown.

Select an ROI label from the list and click OK. The label you select replaces the label on the image and all remaining vertebrae are labeled appropriately.

Intervertebral Markers

If the IV markers are not correct, click the Move/Size ROI icon , or ROTATE ROI icon , then use the left mouse button to click and drag a marker. You can also use the arrow keys to adjust the marker.

Start at either the top or the bottom of the lumbar vertebra and try to identify and label the vertebra, L1 to L5. Use the spine image to place the vertebral marker grossly approximate to where it should separate one vertebra from the next vertebra. Then use the bone profile to fine-tune the vertebral separation. Use the bone profile to line up the marker with the shortest line on graph, making sure this is the correct space separating the vertebrae. Usually the area of vertebral separation is the smallest bar in the histogram, **but be careful, sometimes it is not**, especially if there is a **crush fracture**. It is typical to start with the marker between L1 and

T12. If it is difficult to differentiate the spacing at the top of the lumbar vertebra, then start at L5.

Click CANCEL  to return the ROI position to the program's original settings (as if the file had never been analyzed). To apply the changes you make to the ROI, click the RESULTS icon .

When you are satisfied with the spine analysis, click the SAVE icon  to save the analysis (or click CLOSE  then **no** if you do not want to save your changes).

If you have any questions about the analysis, make a note in the daily schedule book and have Principle Investigators review the scan at a later date.

In the interest of saving paper and file cabinet space, both the hip and spine scans may be printed together on a single sheet of paper. To do this:

- While in the enCORE software, open one of the participant's scan files by double clicking the file or highlighting the file and clicking the analyze icon .
- Click the analyze icon  and the participant database will appear. Open the participant's other scan
- Click the Reports icon .
- In the Report Center window, make sure that only Exam Reports and All Sites are checked.
- Click OK.

Appendix A

Pregnancy Determination Form

The Framingham Heart Study

Pregnancy Determination Form

[Required for all Women]

FHS I.D. Number: □-□□□□ Initials: □□

1. Are you Pregnant? Yes → Participant is disqualified from the study
 No
 Don't Know

2. For women < 55 years old:

2.a Have you had a hysterectomy [removal of the uterus] or tubal ligation [tubes tied]?

- Yes → Pregnancy test NOT required
 NO → Pregnancy test REQUIRED

3. For women > 55 years old:

3.a Have you had a hysterectomy?

- Yes → Pregnancy test NOT required
 NO
↓

3.b When was your last menstrual period?

- > 6 months ago → Pregnancy test NOT required
 Within 6 months → Pregnancy test REQUIRED

4. Pregnancy Test Required? Yes → Result Positive Negative
 NO

5. Date of pregnancy interview and pregnancy test [if required]:

□□/□□/□□□□
m m d d y y y

6. ID number of the person completing this form □□□□

Appendix B

SUPPLEMENT TO PREGNANCY DETERMINATION FORM SELF-ADMINISTERED PREGNANCY QUESTIONNAIRE

*Introduction: The Framingham Osteoporosis Study will provide important information about Musculoskeletal health. However, women should not have a bone scan **if** they are pregnant or even **if** they could possibly be pregnant, to avoid any potential risk to the fetus. Because the urine pregnancy test cannot detect pregnancies of less than one week, we must ask about your sexual activity in the past seven days. Identifying the chances of a possible pregnancy is done for your safety. If there is a possibility that you are now pregnant, please tell us so that we may re-schedule your bone scan.*

1. Have you had sexual intercourse in the past seven days?

- Yes **If** Yes, proceed to #2.

- No **If** No, proceed to #3.

2. Did you use one of the following forms of birth control each time you had sexual intercourse in the past seven days? (Birth control methods not found on this list are not considered effective in preventing pregnancies by our study physicians.)

Oral contraceptives (the pill) Male condom Female condom Injection (Depo-Provera, Lunelle) Diaphragm with spermicide Cervical cap with spermicide Contraceptive Patch Vaginal contraceptive ring Post-coital contraceptives, taken within 72 hours of intercourse (Preven, Plan B) Implant (Norplant) IUD (Intrauterine Device) Male surgical sterilization

- Yes **If** Yes, proceed to #3.

- No **If** No, stop here. YOU WILL BE RESCHEDULED FOR A PREGNANCY TEST AND A BONE SCAN AT A TIME AFTER ONE WEEK FROM TODAY.

3. PLEASE READ: When you report for your bone scan, the Framingham Heart Study coordinator will repeat questions 1 and 2 above regarding whether there is any reason to believe you are pregnant. **If** you have sexual intercourse between now and the bone scan, and you do not use one of these forms of birth control, you should tell the technician, "Yes, I may be pregnant". In this case, you will not be permitted to have a bone scan due to the radiation risk to a possible fetus, and we will work with you to reschedule your bone scan.