VITALITY Standard Operating Procedure

### GE Lunar iDXA

**SOP Development**

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| --- | --- | --- | --- | --- |
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**Revision History**

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**Annual Review**

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| **Due date** | **Review date** | **Reviewer name** | **Signature** |
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**SOP User Knowledge**

I acknowledge that I have read, understood and agree to follow this SOP

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# 1.1 Background

The VITamin D for AdoLescents with HIV to reduce musculoskeletal morbidity and ImmunopaThologY (VITALITY) study aims to to investigate the impact of weekly high-dose (20,000IU) vitamin D3 (cholecalciferol) plus daily 500mg calcium carbonate supplementation for 48 weeks on musculoskeletal health and immune-regulation in CWH aged 11-19 years in Zambia and Zimbabwe. VITALITY is a dual-site trial. This SOP applies to the Zimbabwean site in Harare.

**1.2 Purpose**

To describe procedures for DXA scanning of children recruited into the VITALITY Trial in Zimbabwe. This SOP describes the procedures for scanning; checking and initial analysis of DXA scans using the GE Lunar iDXA machine.

**1.3 Applicability**

The policies and procedures described in this SOP are applicable to all radiography personnel involved in the planning and conducting of DXA scans for the Vitality study for the Zimbabwean Site. All radiography personnel are responsible for ensuring the implementation of this procedure

# 

**1.4 Responsibilities**

Certain duties and responsibilities have been assigned to specific personnel as follows:

***Lead Radiographer***

To ensure that all radiography personnel adhere to the policies and procedures outlined in this SOP.

To ensure appropriate training and qualifications of all radiography personnel performing DXA scans in this study.

***All Radiographers***

To perform DXA scans according to the procedures described in this SOP.

To perform quality assurance procedures as described in this SOP.

To promptly report and document any problems with the DXA machine or scan acquisition processes.

**2.0 Health & Safety**

There is a small risk from ionising radiation to the participant and the operator when the X-rays are generated during scanning. The effective dose to the participant for a complete set of 3 scans (whole body, spine, hip) is estimated to be about 4μSv. Although the radiation doses to the operator are much lower, during scanning, the operator should try to remain at least one metre away from the edge of the scanning table.

Only those persons whose presence is essential shall remain in the DXA room when the machine is actively producing X-rays. Research staff should stay away as far as is reasonably possible and occupy the areas of the room where the radiation levels are lowest. The radiographer should ensure that participants and research staff are properly instructed in their respective roles before DXA examinations begin. The aim during any procedure using X-rays is to minimize unnecessary exposure to radiation. Follow the positioning guidelines in this SOP carefully to ensure no unnecessary exposure to the gonads occurs. The radiographer should always have a clear view of the participant throughout the procedure. There is an emergency stop button (red) on the control panel that is on the side of the scanner table which can be used to stop the machine in the case of an emergency.

***NB: In case of a medical emergency****, participants shall be taken to the accident and emergency unit.*

**3.0 Procedures**

**3.1 Materials Needed**

1. DXA data collection form (Appendix 1)
2. DXA Scan Log (Appendix 2)
3. DXA Machine Function Report (Appendix 3)
4. GE Lunar iDXA scan machine
5. GE Lunar iDXA positioning aids

**3.2 General Procedures and considerations**

* Switch on the iDXA computer, monitor and printer and check sufficient paper is in printer
* The iDXA scanner bed and positioning devices should be cleaned with anti-bacterial wipes after each participant

**3.3 Quality Control Procedures**

* Check that the DXA QA has been performed that day
* Perform daily quality assurance test scan of the spine phantom

**3.3.1 Quality Assurance Procedures**

* Quality assurance procedures should be completed daily before scanning participants. Select quality assurance from the main screen and click start
* Position the quality assurance calibration block on the bed such that the laser light rests in the centre of the cross hair on the calibration block and the brass is on the bottom.
* Print the results of the QA procedure and put them on file to be save for one year. In the event that QA procedure does not pass the test, check position of the calibration block and restart the quality assurance procedure again.
* If the Quality Assurance procedure does not pass again contact support for the iDXA machine
* If there are no participants booked for that whole week and the scanner is not being used, ensure the quality assurance procedure is performed at least once a week.
* Record the room temperature before the first scan of the day and record it in the DXA Temperature Log.
* In the event that room temperature changes more than 5°C during the day, then perform another daily quality assurance procedure to calibrate and verify functionality as well as the accuracy and precision of the densitometer.

**3.3.2 DXA Cross-Calibration using the European Spine Phantom (ESP)**

* This must be performed at the beginning of the study before scanning any of the study participants and at regular 6 month intervals throughout the period of the study (the same phantom will also be scanned on the Hologic DXA machine in Lusaka) and after any maintenance/ repair is performed on the iDXA.
* This DXA cross calibration will be performed using the EUROPEAN SPINE PHANTOM (ESP)
* Please scan the ESP using the protocol below for patient spine scanning:
* Enter the ESP as a new patient, with last name “ESP”, weight 60kg, height 1.60m and date of birth 01/01/1960.
* Centre the scan arm and table to the location where scanning will proceed. Place the ESP on the table in the location indicated by the laser. Position the phantom so that the picture of the spine faces upwards. Adjust the phantom so that the sides are parallel to the sides of the table, and the top of the phantom is nearest the head end of the table. Make small adjustments to the phantom position to align the horizontal line in the bottom most vertebral body with the laser cross-hair.
* Choose AP lumbar spine analysis with the default scan mode. Enter scan length as 10cm. Start the scan.
* Verify that the phantom has been correctly positioned and scanned. Repeat the procedure if the scan is not completely satisfactory.
* Perform analysis of the scan. Ensure the bone map includes all of L1 to L3. Allow automatic analysis of the bone edges. If necessary, adjust the intervertebral lines so that they are between the vertebral bodies.
* Save and print a copy of the scan report.
* Remove the ESP from the table.
* Repeat the scan of the phantom, in the same way as described above, until you have 10 phantom scans acquired on the same day.
* Store securely in the ESP Box.

**3.4 Before performing a study participant DXA scan**

The following must be ensured:

* If the participant is female, confirm that she is not pregnant.
* The participant is able to lie flat on their back for about 10 minutes.
* The participant has not had any contrast enhanced imaging procedure within the past two weeks. If the participant has had such a procedure their DXA scan should be rescheduled to a week later.
* The participant has changed into a comfortable loose-fitting gown and has removed their shoes.
* The participant has removed all radiopaque objects or any clothing with metal fasteners and any metal jewellery, from within the scan area e.g. glasses, belts, underwire bras, zippers, buttons etc.
* Whether the participant has had a prior fracture. If they have had a prior fracture, record information on the previous fracture on the additional tab as described under section 3.5 below

**3.5 Entering the biography of the participant**

* A separate database has been set up for the VITALITY study.
* To select VITALITY as the active database, you can select Composer menu > Database, then click open and select, ‘VITALITY.’
* Select measure from the main screen to open the participant information dialogue box which has primary, secondary and additional tabs.
* Enter the participant name in the primary tab. For every participant in the VITALITY study, the participant’s last name must be “VITALITY”. The participant’s first name must be the participant’s unique study ID. The participant’s unique study I.D must be entered again in the Participant ID tab on the participant information dialogue box
* Record all other necessary information for the participant information dialogue box which includes sex, date of birth, height and weight on the appropriate sections in the primary tab.
* Use default scan mode to allow optimised operation as the programme defaults to the appropriate mode based on the participant’s height and weight.
* Weight limit for the iDXA machine is 204kg. It is rare to have participants exceeding 204kgs; however, ensure the participant weight is under the limit.
* If the radiographer has any other comment on the participant e.g. having an orthopaedic device, record that on the secondary tab.
* For information on prior fractures, which you will have checked with the participant before examination begins, select appropriate comment on the additional tab.
* For selection of measurement site, the screen shows a skeletal image of the sites you can select to measure. It is better to stick to the exam protocol created for the VITALITY study.
* Do not use Quickview for any spine or femur scans in this study.

# 3.6 During the scan acquisition

* Keep an eye on the participant and also on the screen.
* If the image is not correct or if you determine that an insufficient area of the measurement has been obtained, select, ‘Abort,’ from the New Measurement toolbar or press F5. The measurement will stop and give you a choice to either resume measurement, save measurement, reposition measurement or setup a new measurement without saving the aborted one.

# 3.7 Regions of the body for which DXA scans will be performed in this study.

* The DXA scans to be performed for the VITALITY study are:
  1. Whole body
  2. Left femur
  3. Lumbar Spine
  4. Hand
* This series of measurements has been set up as a sequence of exams so they proceed through one to another without going back to the main database screen each time.

- **Do not delete, rename, edit or change the sequence for this protocol for the VITALITY study.**

**3.8 Performing the DXA scans**

**3.8.1 Performing the whole body scan**

* Before positioning the participant, select, “Position” from the New Measurement Bar on the screen to allow the scanner arm to move to an appropriate position for a correct measurement start position.
* Do not use thick blankets, padding or pillows for whole body scans as these may interfere with the scan and distort results.
* With participant shoes removed, assist the participant onto the scanner table, with the head near the scan arm.
* Ensure the participant’s body is in the centre of the scanner table using the centre line on the table as a reference to align the participant. Look from the top of the head to the feet to ensure the participant is central and straight.
* It is rare to have a child/adolescent who will be wider than the scan area but if a participant is wider than the scan area, position the participant for a half body scan to include all of the right side of the body, the entire head and spine
* Ensure arms are alongside the participant’s body **without touching the legs** and with at least a 1cm air gap between the hands and the torso, whilst ensuring the participant’s arms remain within the scan area lines on the table pad.
* Ensure the participant’s head is approximately 3 cm below the horizontal line on the table pad.
* Use the Velcro straps to secure the participant’s knees and feet to prevent movement during the measurement. Make sure the feet aren’t outside the bottom line on the table pad and that the shoulders are relaxed.
* After starting the measurement, monitor the image to make sure there isn’t movement and that it is correctly aligned, showing the participant’s entire body as shown in the image below.

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| **Correct whole body scan image** |
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***Image courtesy of GE Healthcare Lunar, X-ray Bone Densitometer with enCORE v17 software - User Manual, 2016.***

* If the whole body scan is affected by an external artefact, repeat scan. If repeating scan is not possible or not the best option, please state presence of an artefact by selecting yes on section DX12 of the DXA data collection form and also specify type of artefact on the same section

**3.8.2 Performing the left femur scan**

* With the participant still on the DXA scanner table, click next to move to the next examination on the VITALITY protocol which will be the left femur.
* Ensure the participant is still positioned in the centre of the scan table, using the centre line on the table as a reference.
* The participant’s arms should now be crossed over the chest, away from the side of each hip.
* Position the foot brace between the feet, ensuring it is centred, using the centreline on the scanner table as a reference, as well and making sure the centreline is aligned with the guide on the base of the foot brace.
* The participant’s legs should be internally rotated and secured to the foot brace using velcro straps.
* Select the appropriate scan mode based on the thickness of the femur area. There are 3 basic scan modes for the femur based on the patient’s thickness i.e thick; >25cm, standard; 13 – 25cm and thin; <13cm. Patient thickness determines the appropriate measurement scan mode. The program defaults to the appropriate mode based on the patient's height and weight. Use the default scan mode selected by the machine.
* Select Position from the New Measurement toolbar to move the scanner arm to the approximate start position. The laser light must be positioned approximately 7-8 cm below the greater trochanter where the transverse (Pubic Symphysis) and midline of the femoral shaft intersect.
* After selecting start from the New Measurement toolbar, monitor the image to make sure it is in the correct starting position, with a minimum of 3cm visible below the pelvic ischium. The final image shows the greater trochanter (1), a small part of the lesser trochanter, a femoral shaft parallel to the edge of the DXA table, the femoral neck (2), and pelvic ischium (3) as shown in the image below.

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| **Correct Femur scan image** |
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***Image courtesy of GE Healthcare Lunar, X-ray Bone Densitometer with enCORE v17 software - User Manual, 2016.***

* A minimum of 3cms of tissue should be seen below the ischium and above the greater trochanter.
* After the left femur scan is complete, the DXA scan arm will move to the approximate start position for the next scan which is the lumbar spine scan.
* If the femur scan is affected by an external artefact, repeat scan. If repeating scan is not possible or not the best possible option, please state presence of an artefact by selecting yes on section DX10 of the DXA data collection form and also specify type of artefact on the same section

**3.8.3 Performing the lumbar spine scan (AP)**

* Always use the foam cube leg block positioner
* With the participant already on the scanner table, ensure they are still positioned in the centre of the scan table, using the centre line on the table as a reference to align the participant.
* Ensure the participant’s arms are back on the scanner table, alongside the participant’s body.
* Ensure the legs are positioned at 90 degrees on top of the cube. This makes sure the lumbar lordosis is reduced and the spine is flat against the scan bed.
* Select the appropriate scan mode based on the thickness of the AP Spine area. There are 3 basic scan modes for the lumbar spine, based on the patient’s thickness i.e thick; >25cm, standard; 13 – 25cm and thin; <13cm. Patient thickness determines the appropriate measurement scan mode. The program defaults to the appropriate mode based on the patient's height and weight. However, the iDXA operator makes the final decision based on patient thickness before starting the exam. The scan mode for the lumbar spine may be different from the scan mode used for the total femur or whole body, because it depends on the participant’s weight distribution. The program defaults to the appropriate mode based on the patient's height and weight. Use the default scan mode selected by the machine. Select Position from the New Measurement toolbar to move the scanner arm to the approximate start position. The laser light should be approximately 5 cm below the participant’s navel and in the same longitudinal plane as the participant’s midline.
* Start the measurement and monitor the image to make sure the spine is in the centre of the image, and the image includes all of L4 (1), the top of the ischium (to make sure you can define L5 easily), at least half of L5 (2) in the first 1 to 2 sweeps and about half of T12 (3) as shown in the image below.

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| **Correct lumbar spine scan image** |
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***Image courtesy of GE Healthcare Lunar, X-ray Bone Densitometer with enCORE v17 software - User Manual, 2016.***

* The start position can be readjusted by stopping the scan and repositioning the region of interest (ROI) box.
* If the lumbar spine scan is affected by an external artefact, repeat scan. If repeating scan is not possible or not the best possible option, please state presence of an artefact by selecting yes on section DX14 of the DXA data collection form and also specify type of artefact on the same section

**3.8.4 Performing the hand x-ray**

* Assist the patient from the scanner table
* Place a chair without arms or wheels onto the side of the bed and have the participant seated on the chair with the median sagittal plane parallel to the side of the table. Use the same chair for all hand measurements to get optimal precision.
* Have the patient place the hand flat on the table, 2 cm from the line on the table pad, with the thumb and fingers together
* Be sure the fingers and thumb are flat and together.
* Select position from the measurement tool and the scanner arm will move to the approximate start position. A graphic is shown that gives the correct patient position and measurement start position. Be careful that the scanner arm does not bump the patient's head.
* Use the graphic shown on the measurement screen to adjust the position of the laser light. Position the laser light in the center of the wrist, adjacent to the ulna styloid. Be sure all of the ulna styloid is visible.
* To start the measurement, select Start from the measurement toolbar.
* Monitor the image to make sure it is correct with the scan proceeding past all fingertips and all of the ulna styloid is visible

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| **Correct Hand X-ray image** |
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***Images courtesy of GE Healthcare Lunar, X-ray Bone Densitometer with enCORE v17 software - User Manual, 2016.***

* If the image is not correct, select Abort and reposition the patient.
* To complete another measurement for the patient, select Set Up from the New Measurement toolbar.
* If you have completed measurements for the patient, select Home to move the scanner arm to the Home position.
* Select Analyze to proceed to Analysis, or Close to exit the Measurement screen

**4.0 Analysis of iDXA Scans**

* Analysis of DXA scans must be performed by the lead radiographer who will be the central reader, in order to reduce inter-operator variability on the DXA results.

**NB- During scan analysis, the scanner software will automatically place region of interest lines and point typing. In the majority of circumstances this will be OK. Do not make adjustments to the region of interest lines or the point typing automatically placed by the scanner software unless only if there are major errors. More errors and inaccuracy will be induced if every operator starts to make changes.**

**4.1 How to analyse an iDXA scan**

* From the Main screen, click Analyze, select the image to analyze, and click OK.
* Select, ‘Imaging,’ and select the imaging tool to adjust the image. Use these to adjust the brightness, contrast or to zoom the image as described below
* Brightness: To adjust the brightness for the image, click and drag the brightness scroll bar right or left.
* Contrast: To adjust the contrast for the image, click and drag the contrast scroll bar right or left.
* Zoom: To zoom the image, use the bar to scroll through the percentage values. Use the Pan tool if the image is larger than the window area on the Analyze screen
* Adjust the image before moving any ROIs or point typing (see below)
* Check the position of the ROIs automatically placed on each image and adjust if necessary. Do not make adjustments to the analysis unless there is an obvious adjustment needed.
* Follow the instructions below to adjust region of interest
* 1. Select Add ROI to add an ROI during AP Spine/ Femur analysis. When you add a new ROI, it is inserted below the ROI that is selected on the image. Select Label ROI to label the ROIs accordingly.

2. Select Delete ROI to remove an ROI during AP Spine/Femur analysis. Click the ROI, then select Delete ROI. Select Label ROI to label the ROIs if necessary.

3. Select Move ROI to move ROIs.

4. Select Rotate ROI to rotate an ROI.

5. Select Label ROIs to relabel ROIs after you have added or deleted an ROI from an image.

6. Select Exclude ROI, and then select the ROIs you want to exclude from analysis. Parentheses appear around the ROI labels of excluded ROIs. 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 vertebra

* Point typing determines the placement of bone edges. Check point typing for each image but do not adjust the point typing unless the program has made an obvious error. Adjusting the point typing unnecessarily affects the accuracy and reproducibility of the images.
* Follow the instructions below to adjust the point typing.

1. Select Points from the Analyze toolbar. The Point Type window is shown. The program automatically determines if a sample is bone, tissue, neutral, air, or artifact:

* + Bone: Verify that the bone is typed as Bone.
  + Artifact: Foreign material to be excluded in analysis.
  + Tissue: Tissue point typing is specific to each measurement site.
  + Neutral: Select the Neutral brush type and verify that a thin border of neutral samples is shown around the bone. Neutral point typing is not available on Total Body scans.

2. To adjust point typing, select a brush type (Bone or Neutral) and a brush size.

3. Click on the image to make your changes.

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

* + To return the image to its original state, select Reset.

To correct errors, you make while adjusting the point typing, select Undo.

Examples of correct bone typing are shown in the images below

|  |  |
| --- | --- |
| Lumbar spine | Femur |
|  |  |

***Images courtesy of GE Healthcare Lunar, X-ray Bone Densitometer with enCORE v17 software - User Manual, 2016.***

**4.1.1 Analysis Considerations specific to the Whole Body Scan**

* Both the bone and soft tissue images are shown when you open a total body image for analysis. Changes you make to the cut positions (margins) on one image are also made on the other image.
* Ensure that:

1. The head cut is located immediately below the chin,
2. Both arm cuts pass through the arm sockets
3. Both arm cuts as close to the body as possible separating the hands and arms from the body,
4. An additional cut may be available to separate the upper and lower arm
5. Both spine cuts are as close to the spine as possible without including the rib cage,
6. Both pelvis cuts pass through the femoral necks and do not touch the pelvis,
7. The pelvis top cut is immediately superior to the iliac crests,
8. Both leg cuts separate the hands and forearms from the legs
9. An additional cut may be available to separate the upper and lower leg
10. The center leg cut separates the right and left leg.

* For participants wide enough not to fit within the scan boundaries analyse only half of the body
* Image below shows where to place the cut lines during analysis

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| **Correctly placing the cut lines during whole body scan analysis** |
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***Image courtesy of GE Healthcare Lunar, X-ray Bone Densitometer with enCORE v17 software - User Manual, 2016.***

**4.1.2 Analysis Considerations specific to the Femur Scan**

* Ensure the neck of femur ROI includes no part of the greater trochanter, includes soft tissue on either side of the neck, is perpendicular to the femoral neck, and contains little or no ischium. If ischium is included, paint it out and reanalyze.
* If the neck of femur is too short to ensure the neck of femur box excludes the greater trochanter, select the neck of femur box and adjust size. Record this under scan comment to allow the same size box to be used on follow up scan
* Use the following instructions to adjust the neck of femur box size
  + Select the ROI tool from the Analyze toolbar to complete these procedures:
  + Select the Search tool to position the neck ROI correctly. Search locates the region of the lowest BMD and narrowest area of the neck.
  + Use the cursor to select and move the Neck ROI and the Neck Axis.
  + Use the cursor to select and rotate the Neck ROI and the Neck Axis.
  + Select the Size tool. Use the cursor to include tissue on either side of the neck if none is present. Never edit the Neck ROI width.

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| **Adjusting the neck of femur size** |
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***Image courtesy of GE Healthcare Lunar, X-ray Bone Densitometer with enCORE v17 software - User Manual, 2016.***

**4.1.3 Analysis Considerations specific to the AP Lumbar Spine Scan**

* Ensure the vertebrae are correctly identified and intervertebral markers are between the vertebral bodies and located at the lowest point of bone density as indicated on the bone profile as shown in the image below.

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| **Image to show intervertebral (IV) markers between the vertebral bodies (1) and located at the lowest point of bone density as indicated on the bone profile (2).** |
|  |
| ***Image courtesy of GE Healthcare Lunar, X-ray Bone Densitometer with enCORE v17 software - User Manual, 2016.*** |

**4.1.3 Analysis considerations specific to the hand x-ray**

Ensure the hand ROIs are positioned correctly as follows:

* The enclosed area includes the entire hand to the tips of the fingertips and ends at the ulna styloid process
* The ROI includes the carpal bones, but not the ulna or radius

**5.0 Documentation of the DXA scanning session**

* A DXA data collection record form (CRF) will be provided in tablet form; please fill in a CRF for each participant who is scanned. Appendix 1 shows an example of this form. This form will also be available in paper form, if needed.
* For each DXA performed the participant initials and/or ID number, and the performing radiographer must also be recorded into a DXA scan tracking log (Appendix 2) to confirm the scan has been performed and to ensure every stage has been completed properly.
* The radiographer should cross-check the scan tracking log with the DXA CRF to ensure both have been completed properly and the information on the log agrees with information on the data CRF **before** the participant leaves the DXA unit.

**6.1 iDXA participant scan data export**

* Participant scan data in the VITALITY database will be exported as tab-delimited text files (which can then be imported into a Microsoft Excel spreadsheet).
* This data export will be done on the 30th of every month or the closest working day
* Before exporting a database, create a folder in documents named, ‘Vitality10.’
* To export the results for VITALITY participants, follow the following step, select, ‘VITALITY,’ from the Database sidebar
* Then select Directory menu > Database Utilities > Export
* Follow the steps on screen to customize the output
* Select where to save the exported files by choosing the file folder, ‘Vitality10’ under documents.
* Name the file name as VitalityDayMonthYear’ *e.g*. Vitality30Nov20. This filename will be used as a prefix for the output files to be generated.
* Click OK.
* Results of all the patients and exams in the database are exported to tab-delimited text files, saved at the path you specified.

**6.2 Storing DXA scan data**

**6.2.1. GE Lunar Archiving iDXA scan data**

* Archiving DXA scans will copy image files from your computer hard drive to an archive. Do this at the end of every working day when scans have been collected. To archive iDXA scans, select, ‘Archive,’
* Select, ‘Archive all exams for all patients,’ from the options available
* Then select, ‘Copy,’ (and not to, ‘Move,’) to copy the image files to archive location. This ensures the original image file remains in the database directory. The ‘Move,’ file option will move the image files to the archive location, and delete it from the local drive, please don’t do this.

**6.2.2 External Storage and backup**

* Electronic data, which includes the archived DXA data, must be uploaded onto an external hard drive (which must ***only*** be used for storing DXA data [this is to avoid computer viruses corrupting the hard drive]) for both storage and back-up at the end of every day when scans have been collected, in the event there is a problem with the DXA computer. This external hard drive shall stay in the DXA room and shall always be connected to the DXA computer to facilitate easy daily backup of data. These files will be copied onto a second external hard drive once every week and this second backup hard drive must not be stored in the same room as the DXA computer. The external hard drive needs to be stored securely and separately in a cabinet in the VITALITY room used by the research nurse (because it is in a separate building), otherwise in the event of both the external hard drive and the DXA computer being stolen/destroyed *e.g*. by fire, then we will lose all data archived on the computer’s local hard drive as well as its backup on the external hard drive.

**7.0 Precision Assessment (PA) Scans**

* To assess reproducibility of the DXA data being collected throughout the study, an in vivo precision assessment (PA) will be performed.
* 60 participants will be scanned twice on two separate days. The two visits must be scheduled within 2 weeks of each other.
* The average precision error combining data from the DXA radiographers will be used to determine precision error for the DXA unit and also the least significant change in BMD over time.
* DXA scanning procedures for precision assessment will follow exactly the same DXA scanning procedures as described in section 3.8.1 (whole body), 3.8.2 (left femur) and 3.8.3 (lumbar spine) above.
* Participants included in the precision assessment will need to be identified by

1. Answering the part of the DXA data collection form (appendix 1) that asks about whether or not this is a repeat scan and then select ‘PA scan’ on the reason for repeat

**8.0 References**

1. GE Healthcare Lunar, X-ray Bone Densitometer with enCORE v17 software - User Manual, 2016.
2. SOP\_0435 Lunar iDXA - Dual-energy X-ray Absorptiometry: scans and analysis. MRC Unit the Gambia @ London School of Hygiene and Tropical Medicine
3. Cynthia Kahari, Ruramayi Rukuni, Celia Gregson. IMVASK DXA Standard Operating Procedures, (IMV\_S11\_DXA SOP\_08/20, version 2), Aug 20
4. Cynthia Mukwasi, The Bone-Mukwasi (BM) study research proposal Standard Operating Procedure (S.O.P)

**9.0 Appendices**

**Appendix 1**

**VITALITY: VITamin D for AdoLescents to reduce musculoskeletal morbidITY**

**V16. DXA FORM**

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| --- | --- | --- | --- | --- |
| DX01 | | *STUDYNO* | Study number | V |
| DX02 | | *VISIT* | Visit week | 0 48 96 |
| DX02b | | *DOB* | Date of Birth | // |
| DX03 | | *HT* | Standing height | .cm |
| DX04 | | *WT* | Weight | .kg |
| DXA measurements | | | | |
| DX05 | *DDATE* | | Date of DXA (dd/mm/yyyy) | // |
| DX06 | *VISREP* | | Is this a repeat DXA visit?  If no, skip to DX08 | Yes No |
| DX07 | *WHYVREP* | | Why is the visit being repeated?  Specify if other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | PA scan  Previous visit unsuccessful  Other |
| DX08 | *DXOP* | | DXA operator ID |  |
| DX09 | *LHP* | | Femur scan performed  If neither, skip to DX11 | Left Right  Both Neither |
| DX10 | *HART* | | Was the femur scan affected by external artefact?  Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes No |
| DX11 | *TBS* | | Total body scan performed  If no, skip to DX13 | Yes No |
| DX12 | *TART* | | Was the whole body scan affected by external artefact?  Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes No |
| DX13 | *LSP* | | Lumbar spine scan performed  If no, skip to DX15 | Yes No |
| DX14 | *LART* | | Was the lumbar spine scan affected by external artefact?  Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes No |
| DX15 | *SCANREP* | | Were any of the scans above performed more than once today? (tick all that apply)  Specify reason for repeat \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Femur  Whole body  Lumbar spine  No repeats |
| DX16 | *LHD* | | Hand x-ray performed (If neither, skip to DX17) | Left Right Neither |
| DX17 | *HandART* | | Was the hand x-ray affected by external artefact?  Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes No |
| DX18 | *HandRep* | | Was the hand x-ray performed more than once today?  Specify reason for repeat \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes No |

**Appendix 2**

**VITALITY: VITamin D for AdoLescents to reduce musculoskeletal morbidITY**

**DXA Scan Log**

|  |  |  |  |
| --- | --- | --- | --- |
| **Participant Study I.D** | **Date of DXA Scan** | **Radiographer Initials** | **Comment (If Any)** |
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**Appendix 3**

Scanner Serial Number: ………………………………………………………….

1. Did any QA test fail?

a). Daily QA? 🞎Yes 🞎No

***If yes***

Was support for the machine contacted?

………………………………………………………………………………………………………………………………………………………..

2. Has there been any software change 🞎Yes 🞎No

***If yes, indicate***

Old software version: …………………………………………………………

New Software Version: ……………………………………………………… Date installed ……………………………

3. Were there any maintenance/recalibration/repair problems? 🞎Yes 🞎No

***If yes, indicate***

Service Performed and Date of service

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***Please attach a copy of the service report if available***

4. Additional Comment (Use reverse side if necessary)

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DXA Operator: …………………………………………………………………………………. Date: …………………………………..