VITALITY Standard Operating Procedure

### pQCT

### SOP Development

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| --- | --- | --- | --- | --- |
|  | **Name** | **Title** | **Signature** | **Date** |
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| **Approver** |  |  |  |  |

### Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Version no.** | **Effective date** | **Change reference** | **Reason of change** |
| 1.0 | 1st Jan 2021 |  |  |
| 1.1 | Feb 2021 |  |  |

### Annual Review

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| --- | --- | --- | --- |
| **Due date** | **Review date** | **Reviewer name** | **Signature** |
| Jan 2022 |  |  |  |
|  |  |  |  |

### SOP User Knowledge

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

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# 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 pQCT scanning of children recruited into the VITALITY Trial in Zimbabwe. This SOP describes the procedures for scanning; checking and initial analysis of pQCT scans using the Stratec 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 pQCT scans for the VITALITY Trial 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:

***Radiography Lead***

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 to be working performing pQCT scans in this study

***All Radiographers***

To perform pQCT 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 pQCT Stratec machine or scan acquisition process.

All pQCT studies must have received ethical approval and no individual can be scanned outside the confines of a study. Only staff trained in pQCT can operate the scanner and perform initial analysis of scans. Other trained staff, students or visiting workers, who are not trained to scan participants, may perform QA’s and QC’s.

# 1.5 Health & safety

There is a small risk from ionising radiation to the participant and the operator when the x-rays are generated during scanning and calibration. The effective dose to the participant from a single slice (tibia, or the ‘scout scan’ is very low, about 0.1 μSv), and the total for a set of pQCT scans <1μSv. Although the radiation doses to the operator are much lower, the operator should try to remain at least one metre away from the edge of the scanning table.

# 2.1 Material required

* Stratec XCT 2000 scanner
* pQCT foot positioner
* pQCT quality control phantom
* pQCT Data Collection Form (Appendix 1)
* pQCT Scan Log (Appendix 2)
* pQCT Machine Function Report (Appendix 3)

# 2.2 General pQCT Machine Considerations

* Switch on computer, monitor and printer, check sufficient paper in printer.
* Log in s user, using the username and password set for the machine (password: user)
* One can also log in as manager for scan export or other administrative tasks such as changing data entries.
* The gantry and foot holders should be wiped clean after each participant with anti-bacterial wipes.

NB:

1. **The PC must not be connected to the internet, ever under any circumstances**
2. **Only nominated study hard drives can be connected to USB ports. No personal flash drives are allowed to be connected. This is because we cannot install virus scanner software on the pQCT computer as it interrupts the scan, and the PC must remain virus free.**
3. **Begin by checking and logging the room temperature in the scanning room prior to running quality assurance scans**

# 2.3 Quality Assurance Procedures

* Perform QA protocol before scanning participants on each working day (as detailed below). Print all QA and QC reports and keep them in a file named QA and QC in the scanning room.
* QC should be performed once a week with a cone phantom (report is 2 sheets of paper)
* QA is performed each day with a standard phantom (report is one sheet of paper). Printouts from both QC and QA must be stored in the pQCT study file named QA and QC in the pQCT room.
* Reference pictures of the phantoms and the densities can be found in the front of the QC folder.

**2.3.1 Performing a standard phantom scan**

* Use the following steps to perform standard phantom (Checks repeatability - to be performed on all working days)
1. Go to QA scans
2. ‘Select phantom’ and go to standard phantom: enter.
3. F4: save and proceed: If phantom holder installed press Yes, if holder needs to be changed press H. The machine will move so holder can be changed.
4. Press Enter to allow change of holder. Change holder once message “please change holder” appears on the screen. Place the phantom in the holder, ensure the phantom is positioned centrally. Enter.
5. Phantom is scanned automatically (about one minute) Yes to print 1 copy, enter
6. On printout check blue mark is in the light green area, if not check alignment of phantom and rerun. Make note (“green”) on QA printout to indicate this has been checked. The blue mark may drift into the dark green area; this isn’t a fail but should be monitored.
7. On printout check blue mark is in the light green area, if not check alignment of phantom and rerun. Make note (“green”) on QA printout to indicate this has been checked. The blue mark may drift into the dark green area; this isn’t a fail but should be monitored.
8. File printout and report any problems to the Radiography lead (Cynthia Kahari) who will then report to Professor Kate Ward and the manufacturer (Stratec). If the QA fails, document this on the pQCT Machine Function Report (Appendix 3) and report to the Radiography lead (Cynthia Kahari) who will then report to Stratec using the following contact details

<https://www.galileo-training.com/de-english/contact-form.html>

1. Log off (start button: select Log off Stratec) and turn off pQCT.
2. On Fridays and the day before holidays shut the computer down.
3. On Mondays, Tuesdays, Wednesdays and Thursdays leave the computer switched on

**2.3.2 Performing a cone phantom scan**

1. Cone Phantom (Checks calibration and standard- must be scanned once a week)
2. As for standard phantom, but select Cone phantom instead of standard phantom in step 2 above.
3. Start repeated measurement – R= reference line, M is the measurement line. Ensure the reference line is positioned correctly before beginning the scan.

NB

**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.**

**3.0 Scanning a participant**

# 3.1 Entering the biography of the participant

* Follow the following steps to enter the biography of the participant

1. Go to Measure in Main Menu

2. Select New Patient if participant is being scanned for the first time.

3. Select patient using ID or name if it is not the first time that the participant is having a pQCT scan on that machine.

4. If you have chosen, “New patient,” enter ‘VITALITY20’ in block letters on field “Name” and then enter the participant’s study number on the fields ‘first name’ and I.D as follows

Name: VITALITY20

First name: Participant’s unique study ID

I.D: Participant’s Unique study ID

5. Enter participant’s date of birth in the correct field and ignore ethnic field.

6. Select the Measurement mask: F2 to select correct mask.

7. A number of masks are available. For the purposes of the VITALITY Trial, select the tibial mask named Tibia with 4%, 38% and 66% slices

**NB**

**Correcting subject details: Details can only be modified if log in as Manager.**

**At main menu go to Measure then Edit Patient. ID numbers, height, weights etc can now be corrected.**

# 3.2 Before performing the pQCT scan

* Explain procedure to participant and emphasise the importance of them remaining still during the scan
* The participant must be made as comfortable as possible. Positioning must be modified to suit the individual (such as use of footrest, height of chair, height of gantry)
* They should be asked not to talk, and to keep perfectly still during the procedure.
* Correct (and comfortable) positioning of subject is vital for good results
* Find out from the participant which one is their non-dominant leg
* Ask the participant if they have had a fracture, injury or any metal inserted on any of their legs. If either of these is the non-dominant leg then scan the other leg
* Measure the tibial length with a metal ruler to the nearest 0.5mm and record on the pQCT data collection form

## 3.2.1 Measuring Tibial length

* The participant should be sitting down, with the leg to be measured positioned at 90 degrees and crossed over the thigh of the other leg.
* Locate tibial plateau from front of knee – run hand firmly down beneath kneecap till fingers bump against the ridge of bone. This is the tibial plateau (usually a finger’s breadth below kneecap).
* Follow tibial plateau round to inner side of leg, at a point directly above the medial malleolus (middle of the bony prominence at inner side of ankle).
* Measure distance of the straight line between tibial plateau and midpoint of medial malleolus to the nearest 0.5mm.

# 3.3 During the scan acquisition

* The operator must be present throughout the scanning process.
* Keep an eye on the participant and also on the screen
* During the measurement the patient must remain still. Do not talk to the patient or ask the patient any questions as this often causes movement artefacts that make analysis difficult or even impossible.
* The operator must keep the participant informed as to how scan is progressing during each scan
* To Abort scan at any point Press Esc (F4)

**3.4 Performing the tibial pQCT scan**

* After choosing the correct mask as explained on point 6 and 7 under section 3.1 above, press enter
* Enter the side of the tibia to be scanned by typing **L**eft or **R**ight and press enter.
* Enter the object length (mm), height (cm) and weight (kgs)
* No other modifications must be made to this menu
* Press F4 (save and proceed)
* Press **Y**es to continue with measurement, **H** to change **H**older, **N**o to abort measurement
* Change the holder if required and ensure holder is vertically positioned and secure.
* Continue with measurement
* A window will appear that shows the subject ID number- press OK to continue
* A positioning window will appear for the scout view measurement. Press ‘move to SV start position’- you will need to keep pressing this button until the scanner has moved to the correct position- the software will base this on the object length put in the measurement mask (the number is in grey and will be less than 230mm). When the scanner is in the correct position the top box will go green and say ‘please position patient now’.

# 3.5 Positioning the participant for the tibial pQCT scan

* Ensure the limb is straight and check limb will be centrally positioned for all scan slices. Make sure the foot is secured in the foot holder and that the holder ring is secured to prevent movement. This is most important but difficult for the leg.
* For very large participants ensure the leg at the 66% site fits into the holder and the scanner gantry.
* Ensure the laser light is distal to the medial malleolus (i.e., red line is below ankle).
* If the holder is prone to slippage (e.g. heavy person), request participant or assistant to hold lever of limb support in place while scanning.
* If the participant experiences any discomfort from the limb supports in the holder, a small towel can be placed across the supports.
* After positioning subject, press start SV button. Scout scan performed: ensure can clearly see end of tibial end plate and the tibiotalar joint. Press F4 to end scout view scan. If it fails to identify correct region, reposition the participant and repeat scout scan
* The computer normally selects the correct position.
* Ensure the line is in the middle of the flattest part of the endplate. (Refer to pictures showing examples of correct and incorrect scout views on the wall in the pQCT room.)
* If positioning of the line is obviously incorrect go to Position Menu (Pos Sel) and Use Up and Down arrows to reposition, Go to OK and start CT and enter.
* The sites defined by the mask will then automatically be scanned. Ensure participant keeps still during measurements.
* A ‘red’ section will appear during scanning if the limb touches the scanner. This is most likely to occur for 66% site of large subjects. If this occurs reposition subject carefully and repeat the scan if possible. If this is not possible, make a note on pQCT scan log under comment.
* When scan is completed, look at the images. If a lot of red streaking is present due to movement, data will be poor and maybe unusable. Consider repeating the scan if the participant is willing.
* When the machine completes scanning remove the limb.
* After completing the scan, manually enter the scan CT number and note any problems in the pQCT data collection form.
* If there is evidence of movement artefact, the scan should be repeated. Refer to the artefact grading system. If Grade 0-1, the scan is acceptable. If Grade 2-3 please repeat scan.

# 3.5 Instructions when performing a follow-up pQCT Scan

* If the participant has come for a follow-up scan, open the previous scan by clicking, ‘Analyse and then selecting id> and entering the participant ID, then press enter. This will open up the participant’s previous scan for you
* Check how participant details for initial scan compare to the pQCT data collection form for that day. Please note, the pQCT data collection forms are most likely to be correct as information for pQCT entry is usually copied from these sheets.
* Check study ID number, sex, date of birth, age etc are consistent for subject at all time-points. Check data have been entered in the correct order.
* Check heights, weights, forearm lengths are consistent for a subject. For the growing children in the Vitality study, expect height to increase (NOT decrease). Weight changes are more unpredictable but all large changes (>5kg) should be investigated.
* If any inconsistencies are noted, determine whether this is due to a) typing error, b) subject scanned under wrong ID, c) other problem or d) unidentifiable problem.
* Some measurements are difficult to measure accurately. Hence it is acceptable for height measurements for a subject to vary slightly from one time point to another.
* Large changes need to be investigated. The most common causes are typing errors (e.g., 156 on printout instead of 165 as written on the data collection form). If the source of error is obvious: change to the correct value. Note all changes made on the scan log and inform the research assistant/research nurse as well of the changes made or inconsistences noted.
* Subject identity may be incorrect. This occurs when a subject is scanned under the identity of the previous subject. Evidence for this is when 2 subjects are scanned under the same ID on the same day. Usually the first subject is correct, the second is wrong. Identity of subject can usually be verified from weight of subject determined from whole body DXA scan. Many subjects also have very distinctive shapes to their bones.
* Note any inconsistencies, and only change data when there is convincing evidence of an error.
* Data from subjects whose identity is uncertain must be excluded.

**3.6 Analysing pQCT Scans**

* Analysis of the pQCT scans shall be done by the radiographers. If time permits or if there are no other patients waiting to be scanned, scan analysis should be done immediately after scan acquisition, otherwise analyse scans by end of each working day.
* If analyzing the scan at a later date, log in as user, using username and password. To login If analyzing the scan just after acquiring it, then you are logged in already

***3.6.1 Analysing Tibia Scans***

* Select Analyse and select participant using Patient; ID
* Use Page Up/Down to Select Mask for tibia.

***Initial analysis of pQCT scans***

* Login to PC
* Go to, Analyse and select participant using ID, then press enter to proceed
* Check details against the scan log and when this is done tick the section on the scan log to ensure scan has been analysed
* Use Page Up/Down to Select Mask to check (in order tibia, muscle)
* A set of 6 images appears (for tibia masks)

***Checking of correct selection of Regions of Interest (ROIs)***

* ROI for 4% and 38% slices includes the tibia whereas for 66% slice, it includes muscle and bone.
* Check Regions of Interest (ROI) is correctly selected, according to table below. A solid green line is the active region; dashed white line defines inactive ROI, can use TAB to move between ROIs on the same slice.
* ROIs to be selected are:

|  |  |  |
| --- | --- | --- |
| **Slice** |  | **Lower limb** |
| 1 |  | TIBIA |
| 2 |  | TIBIA |
| 3 |  | TIBIA |
| Slices 4 to 6 ROIs are usually defined automatically. Visually inspect if they have been named correctly and make corrections if necessary |
| 4 (Automatically defined) |  | MUSCLE+BONE\_AR |
| 5 (Automatically defined) |  | BONE\_AREA |
| 6 (Automatically defined) |  | TOTAL\_AREA |

* For tibia scan, there should be a tibia ROI selected in slices 1,2,3 and NO ROIs selected in slices 4,5,6. Delete all unrequired ROIs.

***To define ROI***

* If region of interest is incorrectly defined, define it by first selecting slice of interest, using Page Up/Down keys to scroll between slices 1-6. Secondly select Menu\Analysis\Results\ROI\New and move the cursor to the bone of interest (using keyboard arrows) before pressing F to automatically create a border around the region of interest. Thirdly, press enter.
* To name the newly created ROI, use page up and select a previously used name. In the unlikely event that new ROIs need to be investigated, a new name can be created if you select Results\ROI\Name. This will be recorded and may be used as above in future ROIs.
* If bones are too close, or scan quality poor, the automatic drawing of an ROI round the bones may not work. First try drawing automatically again, using a new starting point. If this fails after several attempts, the ROI may then be drawn manually by selecting Menu\Analysis\Results\ROI\New and then enter changes cursor to a cross, then use keyboard arrows to draw line. Use B (to join two points)
* Rarely, it may be useful to create a ROI shaped like a right tibia (H is then used to flip the ROI horizontally for a left tibia) >K

***To delete unwanted or incorrect ROIs***

* To delete unwanted or incorrect ROIs select Results\ROI\Delete\Enter
* When ready, go back to the ‘front page’ with the 6 images, and check all altered ROIs are as expected.

***Printing out results***

* Run the Macros (e.g. Tibia4S; Muscle) and print
* To run Macros for Tibia: > Start Tibia4S; continue; Print Image (OK); Print Image (OK).
* After running Macros, go to CalcBD >Menu/Analysis/Results/CalcBD.
* For tibia >/Print (Enter); Ok. Tibia does not have reference values.

***Checking printouts***

* Tibia: Always check the object length is the same as the leg length on the data collection form and scan log, and TICK the scan log to show this is checked.

# 4.1 Documentation of the pQCT scanning session

* Each pQCT performed on a participant shall be recorded onto the pQCT data collection form and the pQCT scan and temperature log.
* The radiographer must cross check the data collection form before it leaves the pQCT unit to go to the data management people.
* The pQCT scan and temperature log shall remain in the pQCT unit for reference by radiographers.

# 4.2 Storing pQCT scan data

* Hard copy pQCT data collection forms will not be stored in the pQCT unit but will be immediately transported to the data management team by the following morning after the pQCT scan has been conducted.
* Hard copy forms of the pQCT scan and temperature log forms must be filed in lever arch files and stored in a lockable cabinet in the pQCT unit.
* pQCT scan data must be backed up on an encrypted hard drive for transportation to the data managers and also for backup in the event there is a problem with the pQCT computer.
* Follow the following steps to backup scans EVERY FRIDAY (or the last scanning day of the week)
1. Log in as manager
2. Go to Options
3. Go to Export
4. Ensure the pQCT backup hard drive is inserted correctly. **This backup external hard drive should never be taken out or unplugged.**
5. Select drive F
6. Select range of CT-numbers to back up
7. Enter CT-number to back up
* Follow the following steps to export data on the 30th OF EVERY MONTH (or last working day of the month)
1. Log in as manager
2. Go to Options
3. Go to Export
4. Insert memory stick/Menopause pQCT export hard drive
5. Select drive G
6. Select range of CT-numbers to export
7. Enter CT-number to export

**NB**

* **Data must be backed up onto a hard drive every Friday.**
* **Export and backup hard drives should have different colors and be clearly labelled.**
* **Remember that CT numbers are unique and merging with external scans needs extra software as some data may be lost.**

# 5.0 References

1. SOP\_0373\_Peripheral Quantitative Computer Tomography: basic procedures. MRC Cambridge/Gambia. Written by SdB, ES, AL, JT and KAW

2. Stratec Medizintechnik GmbH, XCT 2000 - User Manual, with software version 6.20, 2016.

# 6.0 Appendices

pQCT Data Collection Form (Appendix 1)

pQCT Scan Log (Appendix 2)

pQCT Machine Function Report (Appendix 3)

**Appendix 1**

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

**V17. PQCT FORM**

|  |  |  |  |
| --- | --- | --- | --- |
| PQ01 | *study* | Study number | V |
| PQ02 | *visit* | Study visit | 0 48 96  |
| PQ02a | *dob* | Date of birth | // |
| PQ03 | *ht* | Standing height | .cm |
| PQ04 | *wt* | Weight | .kg |
| PQ05 | *temp* | Room temperature prior to pQCT scan | .°C |
| PQCT measurements |
| PQ06 | *dpq* | Date of pQCT scan (dd/mm/yyyy) | // |
| PQ07 | *visrep* | Is this a repeat pQCT visit? (If no skip to PQ09) | Yes No  |
| PQ08 | *whyvr* | Why is the visit being repeated?Specify if other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | PA Previous visit unsuccessful Other  |
| PQ09 | *pid1* | pQCT operator ID 1 |  |
| PQ10 | *pid2* | pQCT operator ID 2 |  |
| PQ11 | *ttd* | Measured tibial length | mm |
| PQ12 | *tib4* | 4% left tibia scan performed (if no skip to PQ14) | Yes No  |
| PQ13 | *art1* | Artefact indicator grade | 0 1 2 3 4  |
| PQ14 | *tib38* | 38% left tibial scan performed (if no skip to PQ16) | Yes No  |
| PQ15 | *art2* | Artefact indicator grade | 0 1 2 3 4  |
| PQ16 | *tib66* | 66% left tibial scan performed (if no sip to PQ18) | Yes No  |
| PQ17 | *art3* | Artefact indicator grade | 0 1 2 3 4  |
| PQ18 | *rpt1* | Were any of the above scans performed more than once today?Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes No  |
| PQ19 | *ctt* | pQCT scan (CT) numbers | CTCTCTCT |

**Appendix 2**

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

**pQCT Scan Log**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **I.D** | **Scan Date** | **D.O.B** | **Sex****M/F** | **Side L/R** | **Tibial Length** | **Comment (If Any)** | **Radiographer Initials**  |
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**Appendix 3**

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

1. Did any QA test fail?

a). Standard Phantom Scan? 🞎Yes 🞎No b). Cone Phantom Scan? 🞎Yes 🞎No

***If yes***

Was support for the machine contacted?

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

2. Has there been any software change/re-installation 🞎Yes 🞎No

***If yes, explain***

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

………………………………………………………………………………..…………………… Date installed ……………………………

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

***If yes, explain***

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4. Additional Comment (Use reverse side if necessary)

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Radiographer : …………………………………………………………………………………. Date: …………………………………..