UK Biobank

Ultrasound Bone Densitometry

Version 1.0

http://www.ukbiobank.ac.uk/

15th April 2011

This manual details the procedure for Ultrasound Bone Densitometry at an Assessment Centre of the UK Biobank

Contents

1. Introduction

1.1: This manual details the procedure for Ultrasound Bone Densitometry at an Assessment Centre of the UK Biobank. This takes place at the 5th "station" of the Assessment Centre visit, as listed in Table 1.

Table 1: Sequence of assessment visit

	Visit station	**Assessments undertaken**
1	Reception	• **Welcome & registration** • Generating a USB key for Participants
2	Touch screen Section	• **Consent** • **Touch screen questionnaire** • **Hearing Test** • Cognitive function tests (**Shape, Pairs, Fluid Intelligence, Snap**)
3	Interview & blood pressure	• **Interviewer questionnaire** • **Blood pressure measurement** • **Measurement of arterial stiffness (Pulse Wave Velocity)**
4	Eye measurements	• **Visual acuity** • **Auto-refraction** • **Intraocular pressure** • **Retinal image (OCT Scan)**
5	Physical measurements	• **Height (Standing and Sitting)** • **Hip & waist measurement** • **Weight and Bio-impedance (Body Composition) measurement** • **Hand-grip strength** • **Ultrasound bone densitometry** • **Spirometry (Lung function Test)**
6	Cardio (Physical fitness)	• **Exercise ECG (Cycling)**
7	Sample collection & exit	• **Blood samples collected** • **Urine sample sought** • **Saliva sample sought** • Consent & result summary printed • Travel expense claim provided

8	Web-based diet questionnaire	• **Dietary assessment**

1.2: Throughout this document, the term “Participant” signifies a study participant who is taking part in the Assessment Centre process, regardless of whether they eventually give or withhold consent to take part in the UK Biobank study.

1.3: The collection of data from assessment visits uses the direct data entry system of the Assessment Centre Environment (ACE). This has five components **(Assessment Centre Environment**), of which Vox operates the Physical Measurement test station of the assessment visit.

1.4: At the start of their visit, each participant is issued with a USB Key at the Reception station. This USB Key acts as a participant identifier (it contains Participant ID, name, date of birth and gender) and as a temporary storage device for the recorded data. As the participant progresses between stations, the USB key acts as an identifying token and also as a data transfer mechanism. At the Reception & Exit module, all data on the USB key is removed, after it has been backed up to the Assessment Centre head PC.

2. Staff

Healthcare technicians or nurses certified to conduct assessments undertaken at this station are responsible for carrying out this procedure. The Assessment Centre Manager oversees that all Assessment Centre staff work in accordance with the protocol.

3. Order of physical measurements

After completing the Interview and Blood Pressure procedures, the participant arrives at the Physical Measurements station, which follows the order:

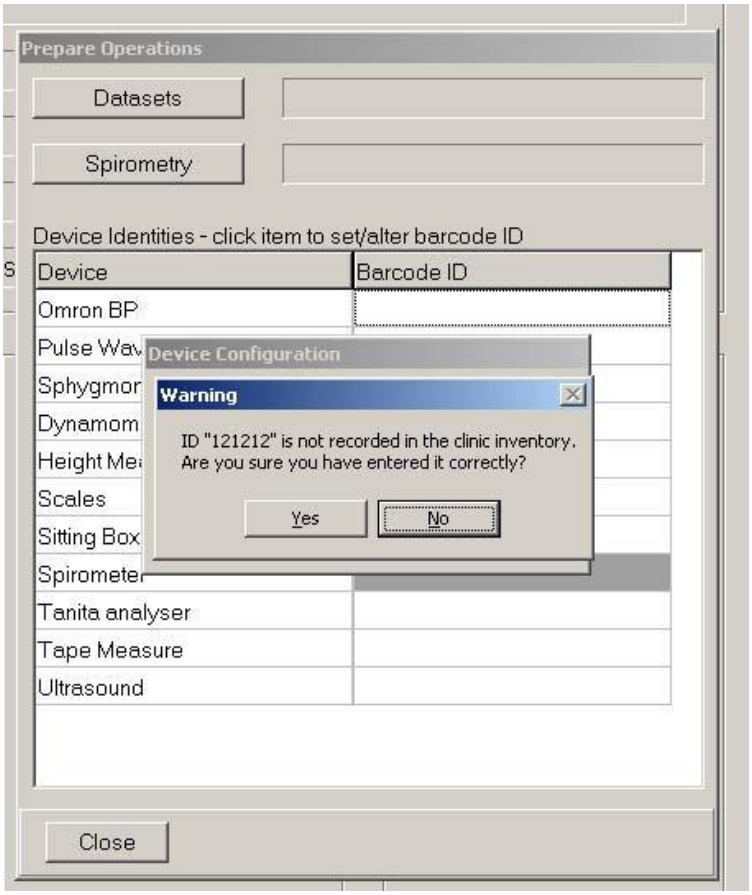
1. Measurement of grip strength
2. Measurement of waist and hip circumference
3. Measurement of standing height
4. Measurement of sitting height
5. Measurement of weight & bioimpedance
6. Left and Right Heel ultrasound measurement
7. Spirometry

4. Preparations at the start of the day

4.1: Before switching on the computer base unit the Sahara heel ultrasound device is switched on.

4. 2: Before opening Vox, the technician undertakes quality control measurement of the Sahara heel ultrasound device (Section 5).

4. 3: The technician then opens the Vox component of the Assessment centre environment, entering their username and password. From the Vox start-up screen ‘Prepare’ is selected to display the following screen:



4. 4: The barcode scanner is used to enter the unique identifier for each device listed. If the equipment ID number is not recognised by the Assessment Centre inventory the coordinating centre is notified of the equipment identifier discrepancy.

4. 5: The temperature of the physical measurement station is recorded twice daily (0800 and 1400). A temperature of between 16ºC and 35ºC is maintained for the heel ultrasound Sahara device. A document is maintained daily to facilitate monitoring procedures.

5. Quality Control of Sahara heel ultrasound device

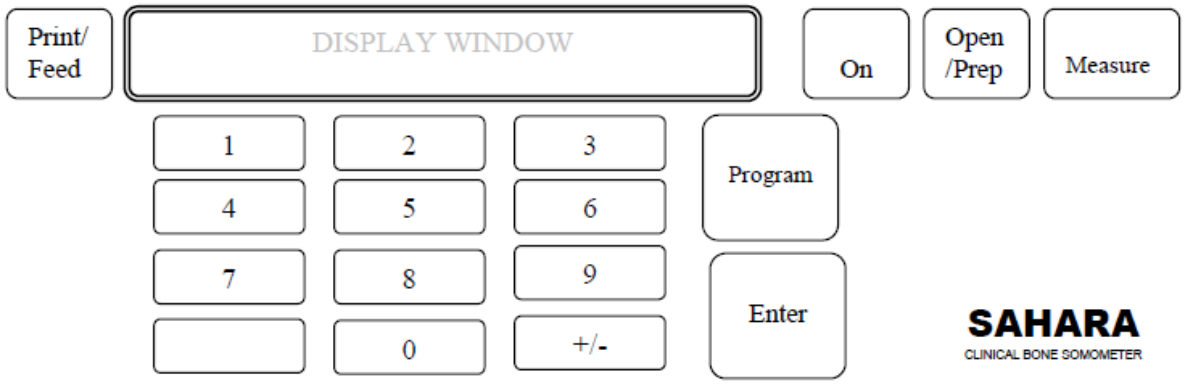
5.1: The Sahara Clinical Bone Sonometer (Figure 1; Appendix 1: Equipment list), estimates bone mineral density (BMD) based on an ultrasound measurement of the calcaneus. It does not actually measure bone mineral density, but speed of sound (SOS, in metres/second) and broadband ultrasound attenuation (BUA, in decibels/megahertz). These results are combined to give the Quantitative Ultrasound Index (QUI), or 'Stiffness'. From this an estimate is made of bone mineral density (BDM, in grams/cm^2), and a T-score, which is a person's bone density compared with what is normally expected in a healthy young adult of their sex. The units of the T-score are the number of standard deviations (SD) that the bone density is above or below the standard. The Z-score is the number of standard deviations above or below what is normally expected for a person of the same age, sex, weight, and ethnic or racial origin.

Figure 1: Sahara bone sonometer

5.2: The Sahara heel ultrasound device is turned on 1 hour to "warm up" before the first participant enters the station for measurement. During this hour the quality control (QC) phantom is placed in the heel cup so that the rounded end lies snugly in the positioning contour and that the flat side of the phantom is lying against the bottom of the foot plate with the label facing up. The phantom serial number is checked to be the same as the Sahara device.

5. 3: The heel ultrasound requires daily quality control (QC) check at the start of the day. The phantom is removed from Sahara unit and from the keyboard of the device (Figure 2), 'On' is selected to initialise Sahara (display screen shows 'apply gel to pads') Then 'Program' is selected, followed by '1' and 'Enter' to enter the QC mode (display screen shows 'Apply gel for QC').

Figure 2: Sahara keyboard



5. 4: Using a finger (not gloves) a pea sized amount of coupling gel is applied to each transducer pad, making sure that the leading edge of each transducer is fully covered. 'Open/Prep' is pressed to retract the transducer pads.

5. 5: The display shows 'Insert Phantom'. The QC phantom is positioned correctly in the heel cup (rounded edge snugly in positioning contour – label on top) and then 'Measure' is pressed.

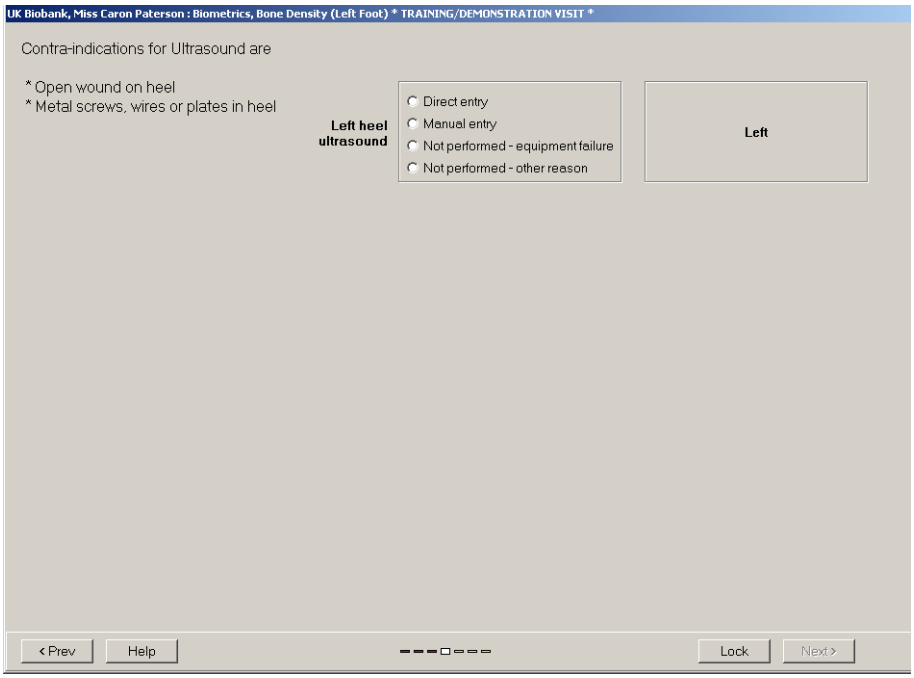
5. 6: The phantom is removed when prompted; ‘Open/Prep’ is pressed to return transducers to ready position for cleaning. Transducers and phantom are thoroughly cleaned with Azowipes (Synergy Health, UK).

5.7: When the measurement is complete, and Sahara displays ‘QC Passed’, the +/-button is pressed to display results, which are then recorded on the Quality Control record log daily.

6. Left and Right Heel ultrasound measurement

6.1: Following weight measurement the participant remains seated in an assessment area.

6.2: First it is checked with the participant if they can undertake both left and right heel ultrasound measurement. Those with open wounds, breaks or sores around the heel, or metal work (such as pins) in the heel should not undertake measurement of that heel. If the participant cannot undertake heel measurement this is recorded by clicking on the ‘Not Performed – other reason’ button, and recording the reason why the measurement was not performed. The left heel is measured first. If no contraindications are present, ‘Direct entry’ is selected.



6.3: Heel measurement is managed throughout using Vox rather than the Sahara unit. ‘Initialise’ is selected on the Vox display to begin preparation. If the participant is happy to continue, a pea sized amount of gel is applied to both transducer pads and ‘Gel Applied’ is selected on the computer. The sides of the heel to be measured are cleaned using a disposable wipe and dried using dry wipes.

6.4: The participant is asked to sit with their back straight, and their foot is positioned in the footwell with heel snug against the positioning contour and the positioning line located between the 2nd and 3rd toe. The foot is secured using the positioning aid with the Velcro strap.

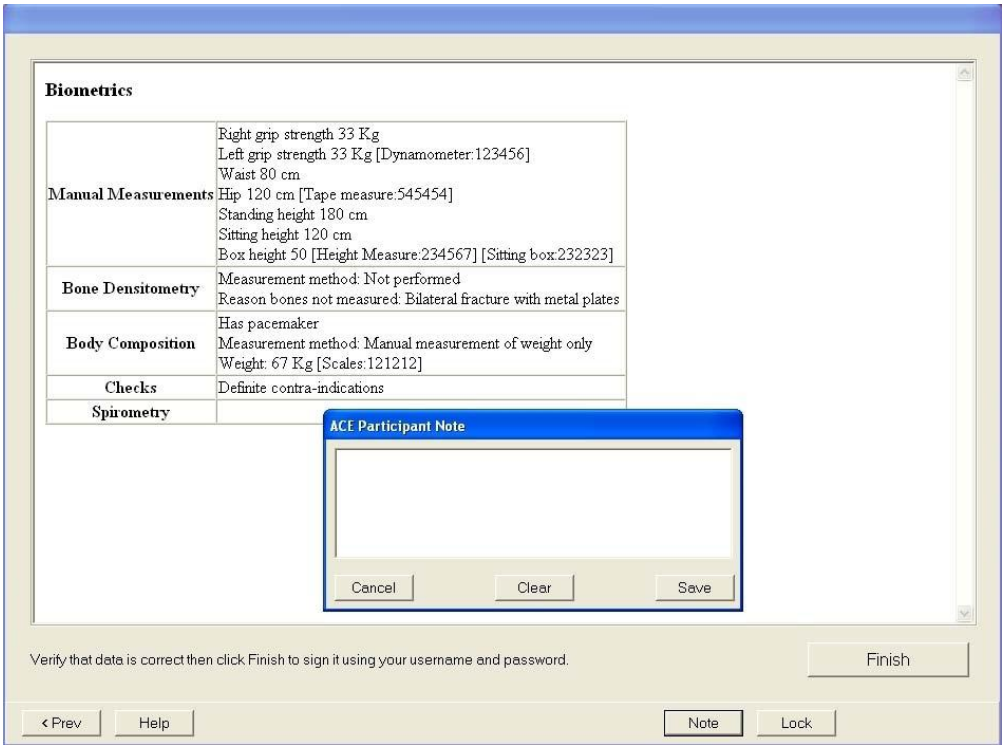
6.5: The participant is asked to sit still, and 'Measure Now' is pressed on the Vox display. The participant is advised that the transducer pads will close to fit snugly against the heel and that the measurement should be complete in around 10 seconds.

6.6: When the measurement is complete the transducer pads automatically retract. The participant is asked to remove their foot when prompted and 'Foot Lifted' is selected on the Vox display. Selecting 'OK' then displays the results on the measurement display window, then 'OK' stores the results. The participant is offered a tissue to wipe gel from their heel.
6.7: Sound waves can produce bubbles in the gel, so on completion of left foot measurement the gel is removed from the transducer pads and fresh gel applied. The right foot is then measured as for the left foot.

Note: Overnight, the phantom is stored in the footwell with the label facing up and the T-bar portion of the phantom resting just above the transducer pads. The phantom is never stored touching the transducer pads.

6.8: The participant is again offered tissues to wipe gel from their heel, is invited to put on their shoes and socks, and proceeds to the **Breath Spirometry test.** The Sahara bone sonometer is cleaned with Azowipes after each participant.

6.9: On the "Data Check and signoff" screen (following Spirometry) it is checked that all results are entered and, if not, the reason for measurement not being undertaken is recorded. Any incidental or disclosed findings are noted and recorded at the end of the measurements by selecting 'Note'. Supplementary notes on the management of any incidental findings are included in Appendix 2: Procedures for dealing with potentially serious results and incidental findings



7. Appendices

7.1 Appendix 1: Equipment list

Equipment for Physical Measurement station	
2 chairs (1 participant chair with armrests –no wheels on participant chairs.)	Modular partition dividers with curtains across entrance
1 desktop personal computer	1 monitor Other Equipment 1 Jamar J00105 hydraulic hand dynamometer (Lafayette Instrument USA) 1 Marsden Seca 200 measuring tape (Seca GMBH, Germany) 1 Seca Height measure (Seca GMBH, Germany) 1 Wooden sitting height box 1 Tanita BC418ma (Tanita Europe, NL) 1 Sahara Heel Ultrasound device (Hologic, USA) 1 Vitalograph spirometer (Vitalograph Ltd, UK)
1 Barcode scanner	Tray to hold valuables (during body composition measurement) Consumables Sahara Ultrasound Coupling Gel Sahara printer paper

7.2 Appendix 2: Procedures for dealing with potentially serious results and incidental findings

7.2.1: Background

7.2.1.1: The Information Leaflet advises participants that the baseline assessment visit is not a health check. With the exception of the feedback of a limited range of measures (e.g. blood pressure, weight, lung function and bone density) at the end of the assessment visit, participants will not receive any feedback of their individual results. (The overall findings from research based on UK Biobank will, however, be made available to participants.)

7.2.1.2: Staff do not have the same duty of care that they would have in a clinical setting. Rather, their legal duty of care is determined by the research context, and relates to safe and competent collection of consent, questionnaire data, physical measurements, and blood and urine samples.

7.2.1.3: Assessment centre staff are trained not to provide interpretation of results. There may, however, be occasions when it is appropriate to draw attention to results (e.g. very high blood pressure) or incidental findings (e.g. suspected melanoma) that may be potentially serious (i.e. life-threatening).

7.2.2 Dealing with potentially serious results

7.2.2.1: At the end of the assessment visit, participants receive a printed summary of the results of a limited number of physical measurements made during the visit. This summary

indicates whether any of these results fall outside defined desirable ranges depending on age, sex and weight (as relevant).

7.2.2.2: Staff may draw these findings to the attention of the participant, but should not attempt to interpret them. Instead, the person should be directed for relevant advice (e.g. stopping smoking; reducing dietary fat and salt) to leaflets available in the Assessment Centre and to NHS Direct (telephone 0845-4647 or www.nhsdirect.nhs.uk).

7.2.2.3: Participants found to have high blood pressure levels at the assessment visit are to be asked whether this is already being managed by their own doctor. If not, the person should be advised to discuss the result with their GP at the earliest opportunity.

7.2.3 Dealing with potentially serious incidental findings

7.2.3.1: An incidental finding is defined as an unexpected finding which is not part of the research assessment and may have clinical significance. Incidental findings may be identified at any stage of the assessment visit.

7.2.3.2: Incidental findings can be divided into two main types:

- Observational findings: Staff may identify observational findings that range from physical evidence (e.g. skin discolouration suggestive of melanoma) through to comments made by participants (e.g. threatened suicide); and
- Disclosed findings: Participants may voluntarily raise health concerns with staff during the course of the assessment visit (e.g. severe chest pain on exercise).

7.2.3.2: Potentially serious incidental findings identified during the Assessment Centre visit by any member of staff should be reported immediately to the Assessment Centre manager or their deputy. This senior member of staff should use their professional judgement to decide what action to take.

7.2.3.3: This may involve discussing the finding with the participant in a neutral manner (e.g. “Are you aware of changes in this mole?”) and, if it remains a serious concern, enquiring about any action already taken (e.g. “Have you asked your GP to look at this mole?”). Where no action has been taken regarding a potentially serous incidental finding, the participant should be advised to discuss it with their GP at the earliest opportunity. [Note: In an emergency, it would be appropriate to call for an ambulance or other appropriate assistance.]

7.2.3.4: A record is to be made in the comments section of the ACE IT system of actions taken for potentially serious incidental findings that are identified. These records will be monitored by the Coordinating Centre on a regular basis.