UK Biobank

Breath Spirometry

Version 1.0

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

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This manual details the procedure for Breath Spirometry at an Assessment Centre of the UK Biobank

Contents

1. Introduction

1.1: This manual details the procedure for Breath Spirometry 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** • **Heel-bone ultrasound** • **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.

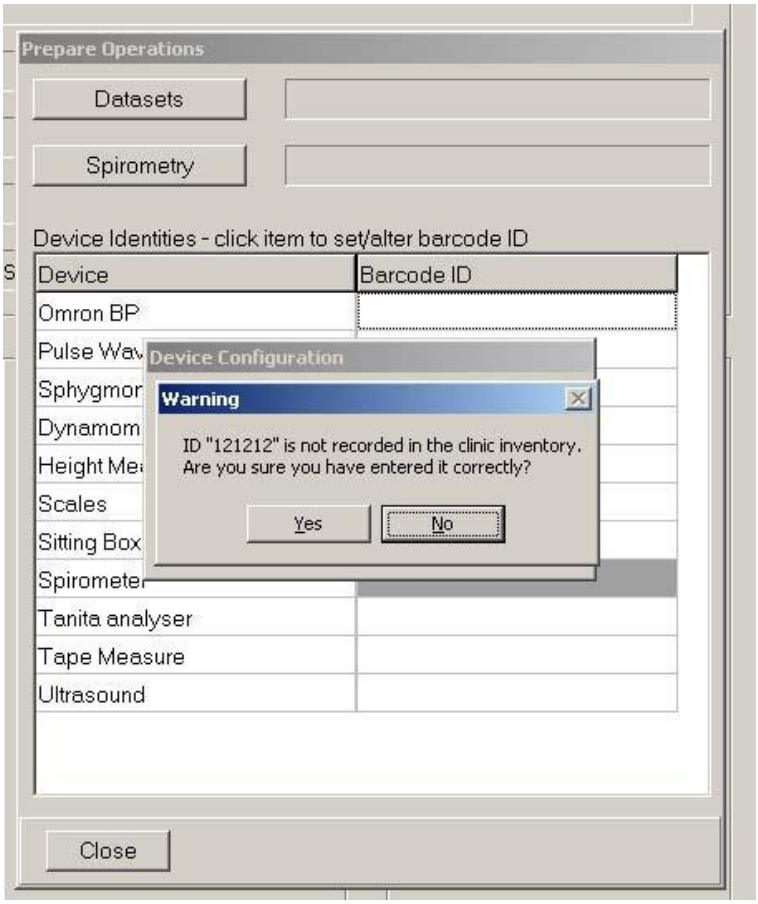
3. Order of physical measurements

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: The staff member 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. 2: 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. 3: The temperature of the physical measurement station is recorded twice daily (0800 and 1400). Spirometry is not undertaken if the room temperature is less than 16ºC or greater than 35ºC.

5. Calibration of measuring equipment

5.1: Breath spirometry is performed using a Vitalograph Pneumotrac 6800 (Vitalograph, UK; Figure 1; Appendix 1: Equipment list) operated via a PC for data capture and in order to visualise flow graphs from each test.

Figure 1: Vitalograph Pneumotrac 6800

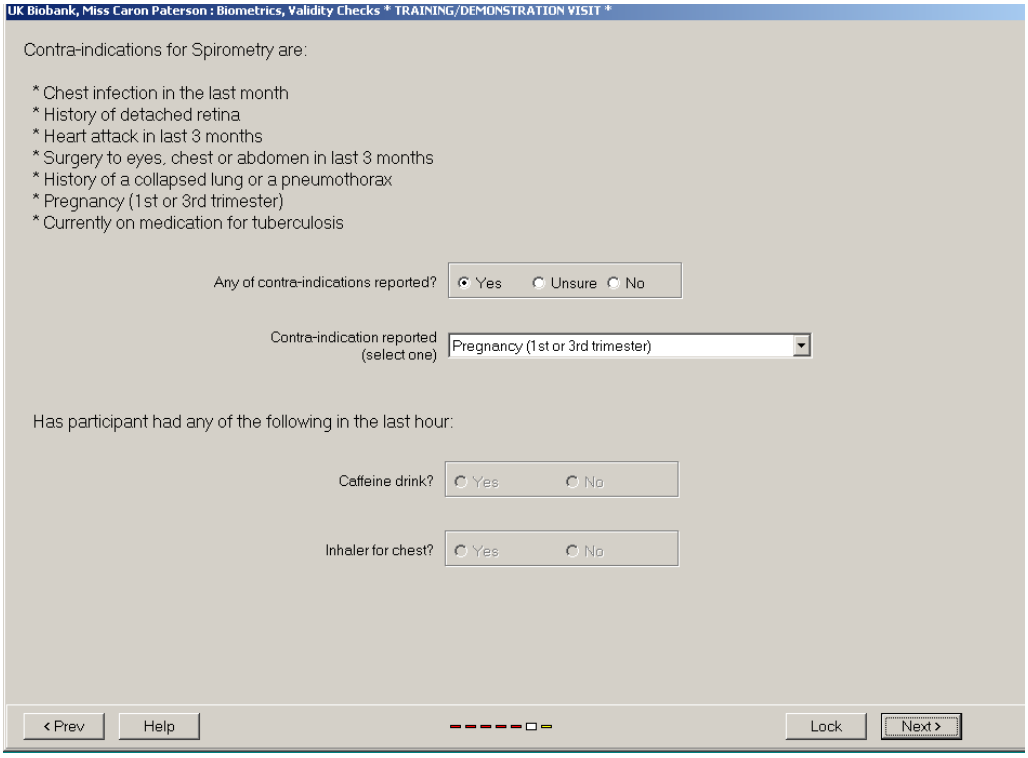
5.2: The spirometer is calibrated at the start of each day using the Spirotrac software supplied with the Pneumotrac 6800. A 3L calibration syringe is attached to the spirometer flow head and 'spirometry' in Vox is selected. The serial number of the calibration syringe is entered in a pop-up window and on-screen instructions are then followed. A calibration record is maintained.

6. Participant assessment

6.1: Spirometry is the last of the physical measurements taken at this station. The participant remains in the assessment area and is asked if they have any of the contra-indications listed. Answers are recorded onto the computer.

- Chest infection in the last month (ie, influenza, bronchitis, severe cold, pneumonia)
- History of detached retina
- Heart attack or surgery to eyes, chest or abdomen in last 3 months
- History of a collapsed lung
- Pregnancy (1st or 3rd trimester)
- Currently on medication for tuberculosis

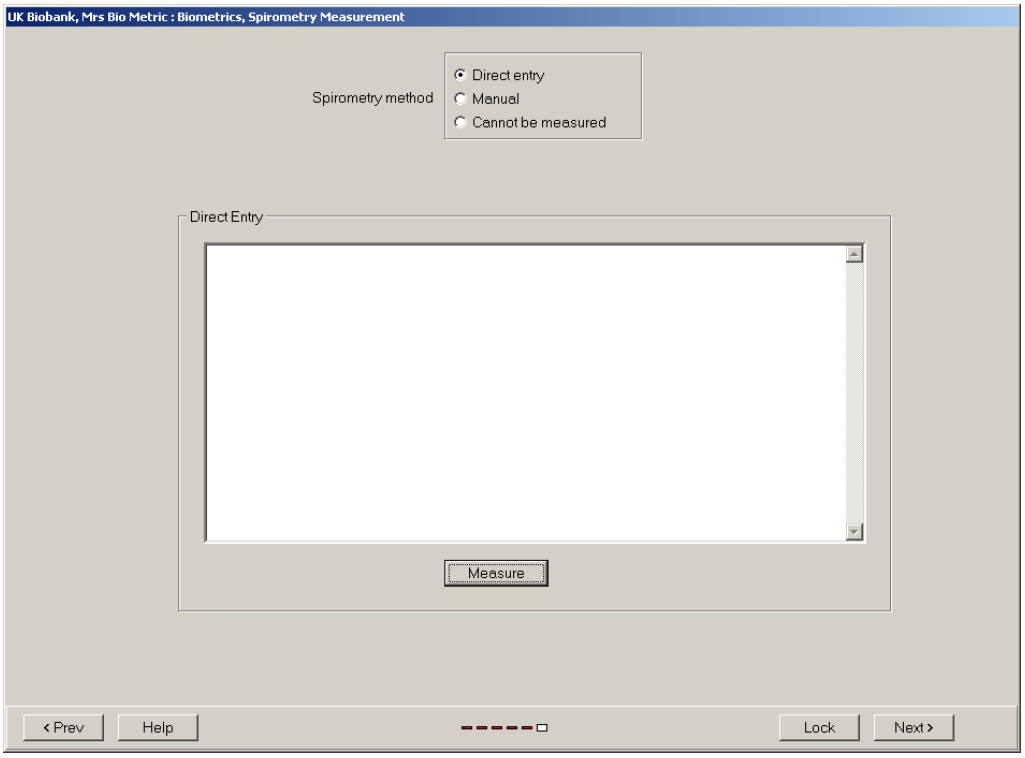
6.2: If they answer "Yes" or "Unsure" to any of the above then the lung function test is not undertaken. Reasons for non-completion of spirometry are recorded using the Contra-indication pull-down menu.



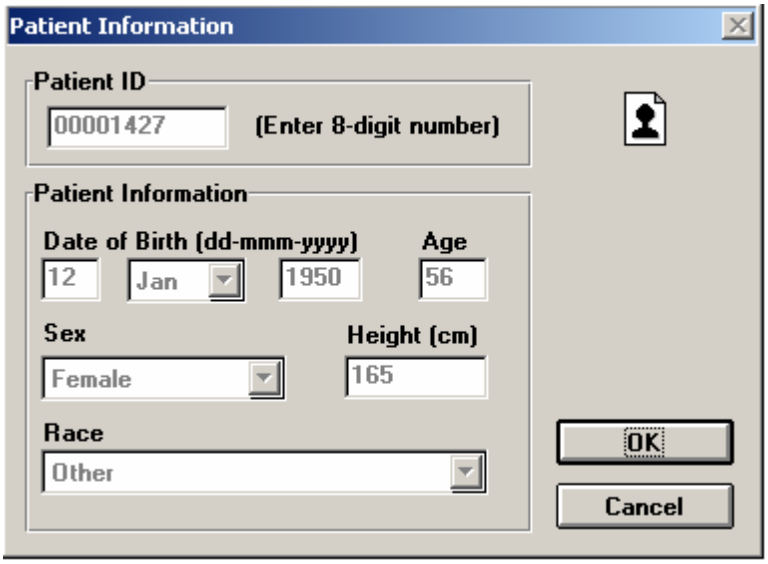
6.3: It is recorded whether in the last hour the participant has had a drink containing caffeine, used an inhaler or smoked.

6.4: When the message is displayed: “Please show the spirometry training video”, ‘OK’ is selected and the video is played by double clicking on the spirometry video icon (Measurement of lung function) on the computer desktop.

6.5: When the video is complete, the participant is reminded of the following:
• To fill lungs as much as possible;
• To seal lips around mouthpiece (without blocking by teeth or tongue)
• To blow air out as hard and fast as possible
• To continue blowing until no more air will come out of lungs.
On the next screen, ‘Direct entry’ is selected, and Spirometry loads automatically:



6.6: The participant information is confirmed by selecting 'OK'



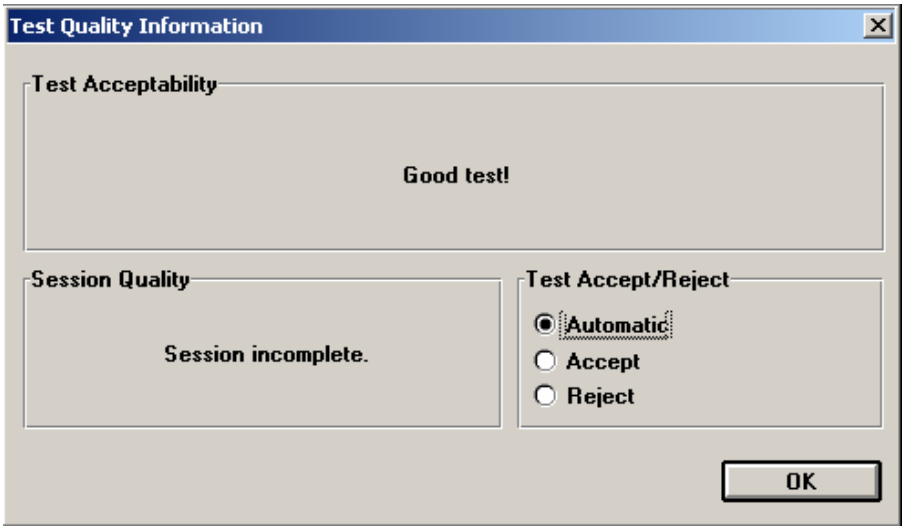
6.7: When the participant is ready, a new disposable spirette is inserted securely in the flowhead of the spirometer. A viral filter is used if the person has a visible active cough. It is explained that the participant should record two to three blows within a period of about 6 minutes. The computer will compare the reproducibility of the first two blows and, if acceptable, defined as a ≤5% difference in forced volume vital capacity (FVC) & Forced Expiratory Volume in 1 second (FEV1), will indicate that the third blow is not required.

6.8: When the 'Exhale to begin' message is displayed, the participant is asked to take their deepest breath in as deep as possible, to place the spirette into their mouth making a good

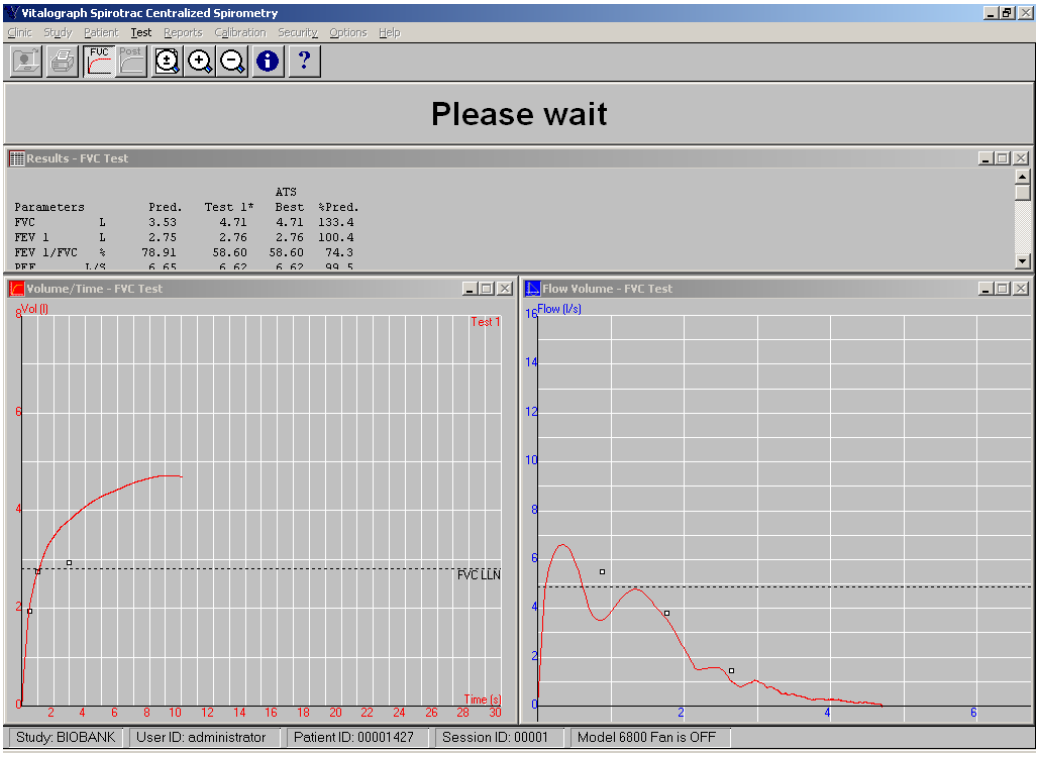
seal around the tube, and then to blow out as hard and fast as possible and for as long as possible.

Note: Enthusiasm is essential: during procedure the participant is actively encouraged to keep blowing until their lungs are completely empty and no more air will come out. This should be for at least 6 seconds.

6.9: A message is displayed as to whether test was acceptable or not. The “Automatic” option should be selected each time, and then ‘OK’ button selected.

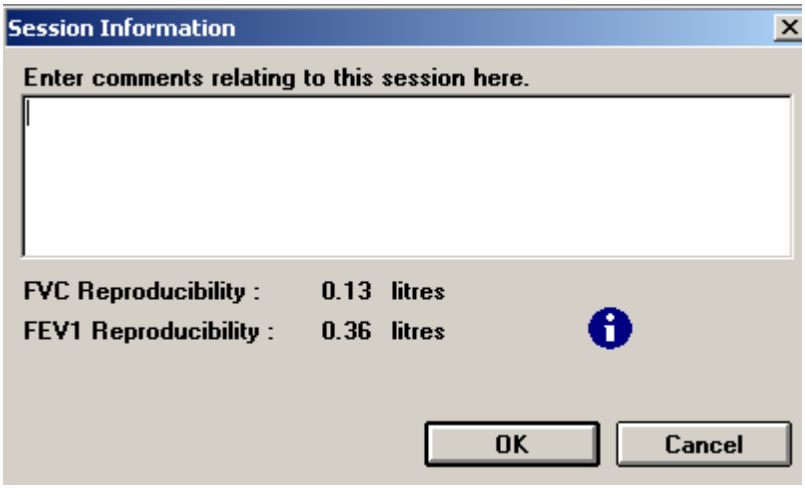


6.10: If the screen message indicates that measurement was not acceptable then the likely reason is determined by reviewing the flow curve (as displayed on the screen below), and the problem is explained to the participant:

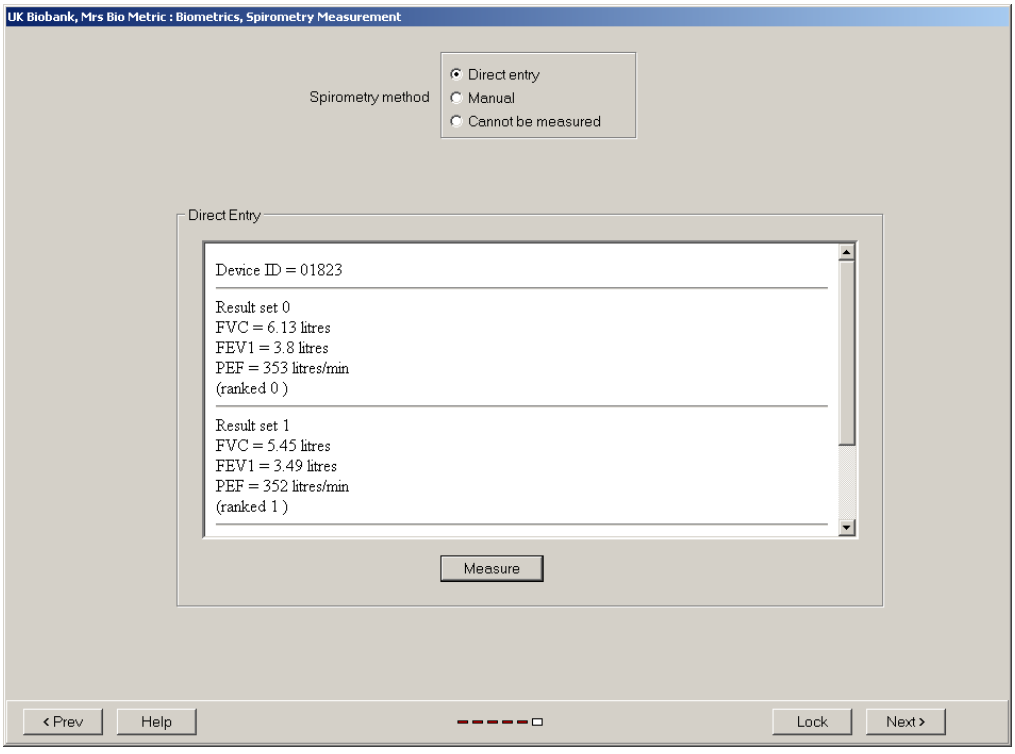


6.11: When participant has had an opportunity to recover, they are asked to repeat the procedure. Participants are not left unattended during/between measurements in case it has made them fatigued or faint.

6.12: The measurement is stopped when either two acceptable, or a total of three flow curves have been recorded. Any comments are entered in the session information box on Vox, and 'OK' selected.

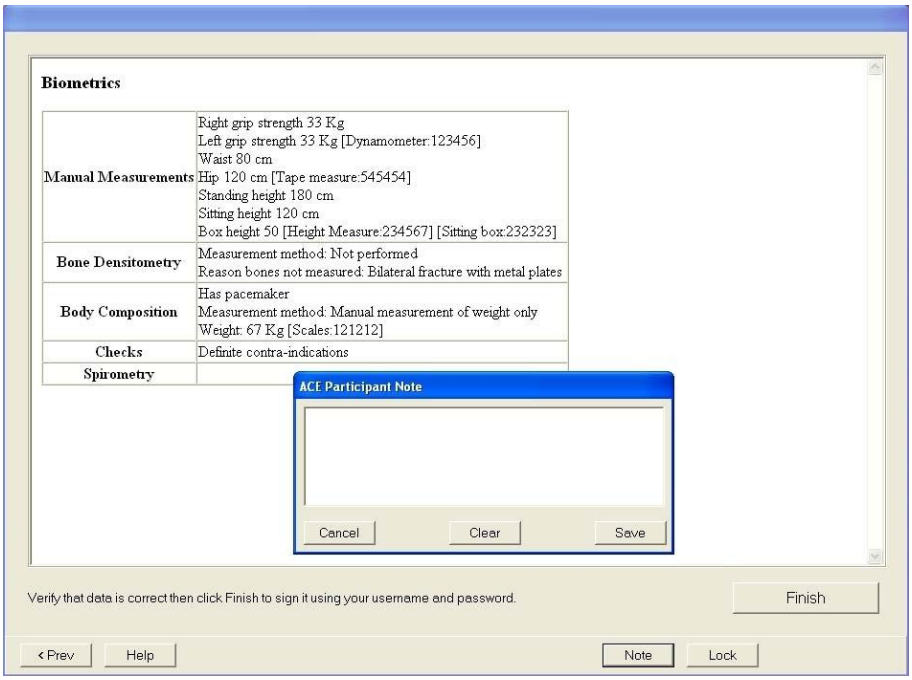


6.13: A summary of results is shown on screen. 'Next' is selected.



6.14: On the "Data Check and signoff" screen (see below), it is checked that all results are entered and, if not, the reason for measurement not being undertaken is recorded and then 'Finish' selected. 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.



6.15: The participant is thanked and asked to put on their shoes and socks if they haven't already, and retrieve their valuables. The staff member logs out of Vox and the USB key is removed from the computer and handed to the participant. The participant is taken to the next station (**Blood Collection,** or in later versions of UK Biobank, **Cardio.** See **Assessment Centre Environment** for history of changes).

6.16: If **Blood Collection** is next, the participant is reminded that they will provide a Saliva sample after their blood collection and is offered some water before entering the Blood Collection area. They are instructed that this is solely for consuming and cannot be used as rinse for Saliva sample collection (in later versions of UK Biobank, this is done after the **Cardio** station).

6.17: The Vitalogragh Spirometer is cleaned with Azowipes after each participant. Weekly cleaning and disinfection of the spirometer are performed, and monthly checks are made by the duty manager. These include checking of the cleaning and disinfection record and checking that the interior of the spirometer has no visible signs of damage, rust, liquid or debris. Both flowhead meshes are replaced, and an accuracy check is performed on the re-assembled device.

Appendices

7.1 Appendix 1: Equipment list

Equipment list for Physical Measurements station	
2 chairs (1participant 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 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.