UK Biobank

Arterial Pulse-Wave Velocity

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1. Introduction

1.1: This manual details Pulse Wave Velocity measurement at an Assessment Centre of the UK Biobank. This takes place at the 3rd "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
		Refractometry
		Intraocular pressure
		 Optical Coherence Tomography (Retinal Imaging)
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	<u>Dietary assessment</u>

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.

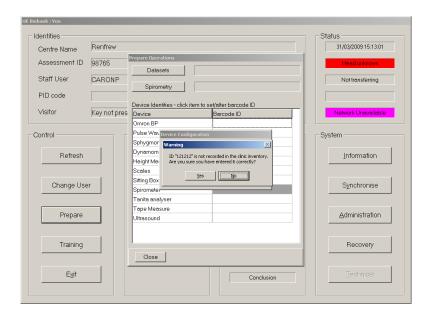
- **1.3:** The collection of data from assessment visits uses the direct data entry system of the Assessment Centre Environment (ACE). This has five components (Assessment Centre Environment), of which Vox operates the Interview, blood pressure and arterial pulse-wave velocity measurement station of 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

This procedure is carried out by registered nurses, trained and certified to conduct assessments undertaken at this station. The Assessment Centre Manager oversees that all staff work in accordance with the procedure.

3. Preparatory procedures at start of day

At the start of each day, the staff member logs on securely to Vox, then selects 'Prepare' to display the following screen:





4. Order of measurements at station

At the Interview/BP/Pulse Wave station, the following sequence is followed:

- 1. Interview: Part 1
- 2. First measurement of blood pressure
- 3. Interview: Part 2
- 4. Measurement of Pulse Wave Velocity
- 5. Second measurement of blood pressure

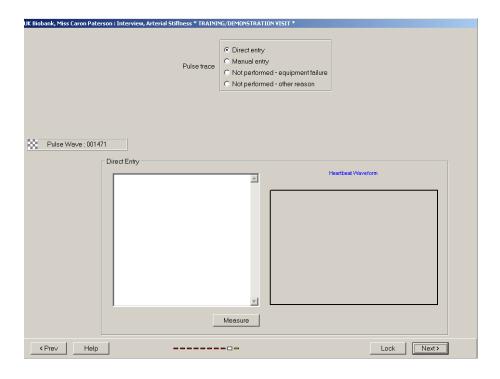
5. Measurement of Pulse Wave Velocity

5.1: Arterial stiffness is an independent predictor of cardiovascular risk, and can be measured non-invasively using the pulse waveform obtained at the finger with an infra-red sensor (Figure 1; PulseTrace PCA2, CareFusion, USA; Appendix 1: Equipment list). The shape of the volume waveform in the finger is directly related to the time it takes for the pulse waves to travel through the arterial tree in the lower body, and to be reflected back to the finger. The time between peaks of the waveform (the peak-to-peak time; PPT) is divided into the person's height to obtain the Stiffness Index (SI). Measurement is made by clipping the device to a finger; the reading is made over 10-15 seconds.

Figure 1: PulseTrace PCA2

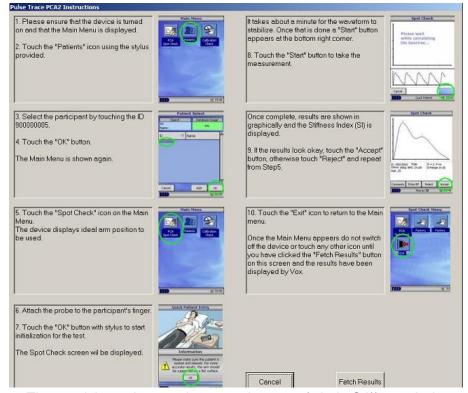


- **5.2:** The participant is asked to sit with feet parallel to each other, toes pointing forward and soles of feet flat on the floor. The left arm is placed on the desk top in supine position, fully supported.
- **5.3:** There should be no restrictive clothing to impede the circulation, and the participants hand should be warm. The probe is placed on any finger or thumb, but preferably the index finger of the non-dependant hand. The finger/thumb tip should be in contact with ledge inside the probe so that the cable is coming over the back of the hand. The probe can be placed transversally across the finger if dark nail varnish obstructs the accurate measurement of pulse wave velocity.
- **5.4:** The Pulse wave velocity is measured at rest. The participant is asked to breathe in and out slowly five times in a relaxed fashion.
- **5.5**: The Pulse Trace PCA2 device is switched on (0/I switch) and "direct entry" selected in Vox to connect the computer and pulse trace device.



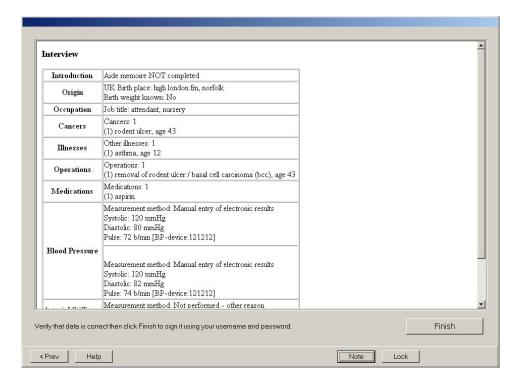
5.6: The instructions shown in the dialog box on the PC monitor are followed:

- 1. Please ensure that the device is turned on and that the Main Menu is displayed.
- 2. Touch the "Patients" icon using the stylus provided.
- 3. Select the participants by touching the ID 900000005 (NOTE: the last number displayed may vary)
- 4. Touch the "OK" button. The main menu is shown again.
- 5. Touch the "Spot Check" icon on the main menu. The device displays ideal arm position to be used.
- 6. Attach the probe to the participant's finger.
- 7. Touch the "OK" button with stylus to start initialization for the test. The Spot Check screen will be displayed. It takes about a minute for the wave form to stabilize. Once that's done a "Start" button appears at the bottom right corner. **NOTE:** If the waveform does not fill 2/3 or more on display, or does not stabilize, the probe is moved to a larger finger or thumb to maximise the blood volume
- 8. Touch the "Start" button to take the measurement. Once complete results are shown in graphically and the Stiffness Index (SI) is displayed.
- 9. If the results are recorded, touch the "accept" button
- 10. Touch the "Exit" icon to return to Main menu.
- 11. The auto save function will save the data on the Pulse Trace device (If this is not enabled then Click "yes" in response to question on saving data displayed on PulseTrace device). Once the main menu appears do not switch off the device or touch any other icon. Click on the "Fetch Results" button displayed on Vox monitor.



Note. The participant is not given a print out of their Stiffness Index, since this requires height data to correctly assess.

5.7: To conclude this station of the Assessment Centre Visit, interview, blood pressure and Pulse Wave Velocity data are checked on screen (see below) and any incorrect data corrected using the 'Prev' button to return to the relevant page, then 'Finish' is selected.



5.8: Any incidental findings are noted and recorded by clicking on the 'Note' button. Supplementary notes on the management of any incidental findings are included in Appendix 2: Procedures for dealing with potentially serious results and incidental findings.

5.9: The staff member logs off, removes the USB key from computer and hands it to the participant, who is directed to the designated waiting area for the Physical Measurements station, or the Eye Measurements station in more recent versions of UK Biobank (see Assessment Centre Environment for history).

6. Appendices

6.1. Appendix 1: Equipment list

Furniture	1 desk
	2 chairs
	Modular partition dividers with curtains across entrance
Computing	1 desktop personal computer
	1 monitor
Other Equipment	Omron 705 IT electronic blood pressure monitor (OMRON Healthcare
	Europe B.V. Kruisweg 577 2132 NA Hoofddorp)
	(with 4x AA rechargeable batteries)
	1 small BP cuff
	1 regular BP cuff
	1 large BP cuff
	1 tape measure
	1x manual blood pressure monitor (backup if required)
	AA batteries (spares: non-rechargeable)
	PulseTrace PCA2 (CareFusion, San Diego, USA)

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

6.2.1: Background

- **6.2.1.1**: 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 <u>not</u> receive any feedback of their individual results. (The overall findings from research based on UK Biobank will, however, be made available to participants.)
- **6.2.1.2:** 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.
- **6.2.1.3:** Assessment centre staff are trained <u>not</u> 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).

6.2.2: Dealing with potentially serious results

6.2.2.1: 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).

- **6.2.2.2:** 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).
- **6.2.2.3:** 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.
- **6.2.3:** Dealing with potentially serious incidental findings
- **6.2.3.1:** 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.
- **6.2.3.2:** 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).
- **6.2.3.3:** 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.
- **6.2.3.4:** 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.]
- **6.2.3.5:** 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.