

UK Biobank

Cardio Assessment

Version 1.0

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

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This manual details the procedure for Cardio Testing (physical fitness) at an Assessment Centre of the UK Biobank.

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1. Introduction

1.1: This manual details the procedure for cardio testing at an Assessment Centre of the UK Biobank. This is the 6th 'station' of the Assessment Centre visit, as listed in Table 1.

Table 1: sequence of assessment visit

	Visit station	Assessments undertaken
1	Reception	<ul style="list-style-type: none"> • Welcome & registration • Generating a USB key for Participants
2	Touch screen Section	<ul style="list-style-type: none"> • Consent • Touch screen questionnaire • Hearing Test • Cognitive function tests (Shape, Pairs, Fluid Intelligence, Snap)
3	Interview & blood pressure	<ul style="list-style-type: none"> • Interviewer questionnaire • Blood pressure measurement • Measurement of arterial stiffness (Pulse Wave Velocity)
4	Eye measurements	<ul style="list-style-type: none"> • Visual acuity • Auto-refraction • Intraocular pressure • Retinal image (OCT Scan)
5	Physical measurements	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • Exercise ECG (Cycling)

7	Sample collection & exit	<ul style="list-style-type: none"> • Blood samples collected • Urine sample sought • Saliva sample sought • Consent & result summary printed • Travel expense claim provided
8	Web-based diet questionnaire	<ul style="list-style-type: none"> • 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 Cardio (Physical Fitness) 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

All assessment centre staff certified to conduct assessments undertaken at this station may be operators responsible for carrying out this procedure. The Assessment Centre Duty Manager oversees that all Assessment Centre staff work in accordance with the protocol.

3. Cardio testing

3.1: The Cardio test uses a stationary bicycle in conjunction with a 4-lead electrocardiograph (ECG) device to record ECGs at pre-test (15 seconds); during activity (6 minutes) and in recovery (1 minute). The participant’s Risk Category is first calculated to determine whether they should perform the activity or have only a resting ECG (9.1: Appendix 1: Risk Categories). The percentage levels of effort during activity are then determined according to their risk category, and their maximum workload is calculated according to age, height, weight, resting heart rate and sex (9.2: Appendix 2: Power Calculation). This data is available on the participant’s USB key from previous stations at the Assessment.

3.2: The ECG device is a CAM-USB 6.5, which is operated using Cardiosoft v6.51. The stationary bike is an eBike, operated using Firmware v1.7.

4. Start of Session Preparation

The exercise bike and ECG devices are switched on before the PC base unit. Bike and ECG equipment ID numbers are recorded using the ‘Prepare’ function, by scanning rather than typing. The exercise booth is stocked with ECG electrodes, nursing wipes and tissues for the day ahead.

5. Participant Preparation

5.1: The next available participant is collected from the specified waiting area for this station, and seated in a curtained booth.

5.2: The participant's USB key is inserted into the computer and the technician logs in securely. From the Vox start-up screen, it is checked that the previous stations have been completed. If not, the participant is redirected to the correct station.

5.3: The staff member selects the 'Cardio' button and confirms their identity and that of the participant, then presses 'Next'.

Note: It is crucial that participants complete the Interview and Biometrics stations before the Cardio station, as measurement data is used to grade participants and allocate a Bike Test protocol.

The screenshot displays the 'UK Biobank : Vox' software interface. It is divided into several sections:

- Identities:** Fields for Centre Name (ctsu), Assessment ID (90999), Staff User (CARONP), PID code (900 300 101), and Visitor (Mr Fitz Fiddle). A yellow warning box states 'THIS IS A TEST CLINIC SYSTEM'.
- Status:** Shows a date/time stamp (08/10/2009 10:06:59) and a unique ID (2769.104-192.168.0.69).
- Control:** Buttons for Refresh, Change User, Prepare, Training, and Exit.
- Operation:** Buttons for Interview, Ocular, Biometrics, Cardio, Blood, and Conclude.
- Records:** A list of stations with progress indicators: Welcome, Consent, Touchscreen, Interview, Ocular, Biometrics, Cardio, Blood, and Conclusion.
- System:** Buttons for Information, Recovery, Archive, Synchronise, Administration, and Technical.

5.4: The Bike Test procedure is now explained. The participant is informed that the Bike Test consists of three stages, a Pre- Test Stage, where a 15 second resting ECG is recorded. An Activity Stage, where the participant pedals for a set period for of time (6 minutes) either with or without an increase in cycling resistance, and finally a Recovery Stage, where the participant has stopped pedalling and an ECG is recorded for 1 minute. It is explained that for some participants only a resting ECG will be recorded.

5.5: After checking that the participant is happy to proceed, the operator reads the following questions (exactly as worded on the screen) to the participant and inserts the answers as directed, then clicks 'Next'.

1. Has a doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor (Select from 'Yes', 'Unsure' or 'No')

2. Do you feel pain in your chest when you do physical activity (Select from 'Yes', 'Unsure' or 'No')
3. In the past month, have you had chest pain when you were NOT doing physical activity (Select from 'Yes', 'Unsure' or 'No')
4. Are you able to walk or cycle unaided for 10 minutes (Select from 'Yes', 'Unsure' or 'No')

Note: Participants fitted with a pacemaker do not complete the Bike Test or resting ECG. A pop up message informs the operator if the presence of a pacemaker was recorded during the Biometrics module.

UK Biobank, Miss Caron Paterson : Cardio, Screening Checks

Please read questions to participants using exact wording

Has a doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor Yes Unsure No

Do you feel pain in your chest when you do physical activity Yes Unsure No

In the past month, have you had chest pain when you were NOT doing physical activity Yes Unsure No

Are you able to walk or cycle unaided for 10 minutes Yes Unsure No

Recommended Protocol

Protocol will be determined once all the screening questions have been answered

Male, age 43, systolic=120, diastolic=78, bpm=70, height=1.75m, weight=80.0Kg, safe HRT=132bpm

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5.6: It is explained to the participant that they will follow a recommended protocol which has been calculated based on these screening questions and their earlier measurements. They are informed that during the test if their heart rate increases to a certain level, a beep will sound, and the operator will stop the test. It is explained that this is nothing to worry about, but that they have reached the stopping criteria for this test and this safety factor has been added to ensure their safety and well being during the bike test.

5.7: On completion of the screening questions the Bike Test Protocol is displayed on the Vox screen. The participant is informed about the test or resting protocol they will follow.

5.8: Participants allocated to a Bike Test either cycle at a constant workload for 6 minutes, or cycle for the first 2 minutes at a constant workload, with the pedalling resistance increasing over the last 4 minutes.

5.9: For participants allocated to a Resting ECG only, the participant has a tracing of their heart rhythm taken for a 2 minute period.

5.10: On Vox, the ECG Method is recorded by selecting either 'Bicycle' or 'Resting Only'. If the Bike Test cannot be performed the reason why is selected (Equipment Failure or Other Reason. Other Reason can be either a reason from the drop down menu or free text entered in the blank window space).

UK Biobank, Miss Caron Paterson : Cardio, ECG

Recommended protocol: M130/89 : cycle 2 mins at 40W, 4 mins ramp to 130W (50% of 261W), 1 min rest

ECG method

Bicycle
 Resting only
 Not performed - equipment failure
 Not performed - other reason

ECG : 001641
Bicycle : 001642

Direct Entry

Measure

Test completed

Fully completed
 Participant wanted to stop early
 Participant reported chest-pain and/or other discomfort
 Heart rate reached safety level
 Incomplete - other reason

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5.11: For those participants allocated a Bike Test Protocol, the participant is asked to remove any items from pockets and place in a tray on the desk. They may also remove jacket and loosen clothing, if required.

5.12: The participant is asked to sit on the bike; the seat height is adjusted to their comfort by using the ↑up and ↓down buttons on the bike keypad. The participant is asked to place their feet in the foot straps on the pedals (with assistance if necessary) the knees should not connect with handle bars. When one pedal is at the bottom of the stroke the leg should be almost fully extended.

For participants allocated a Resting Only protocol, they are asked to remain seated on the chair, removing jacket and loosening clothing if required.

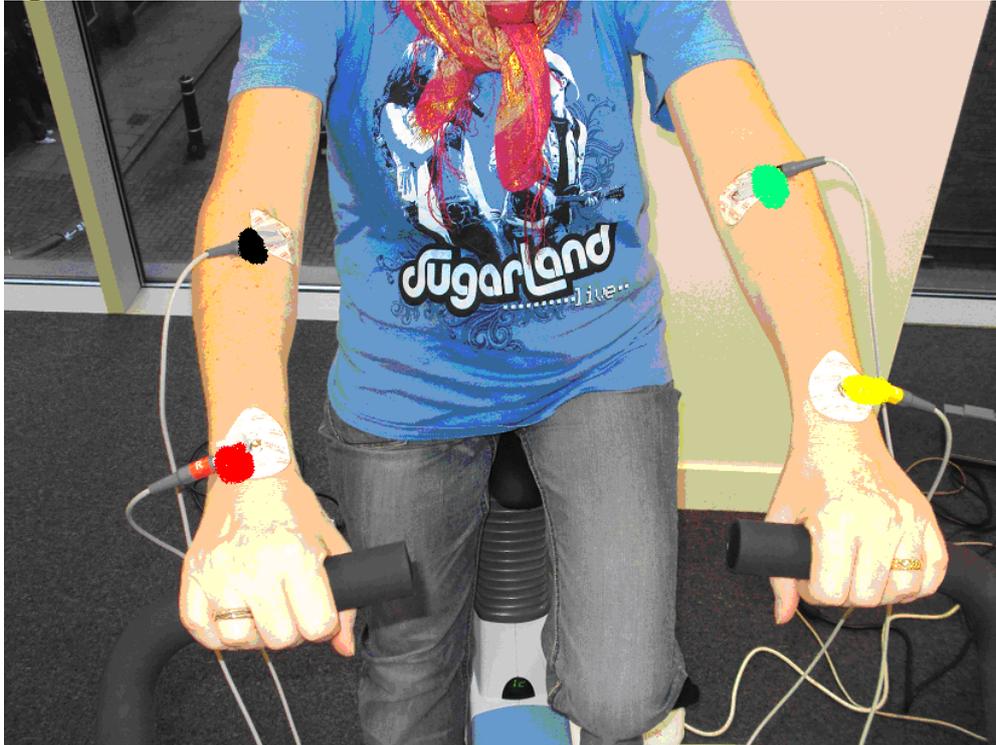
5.13: ECG electrodes and leads are placed according to figure 1, in the following locations:

Right antecubital fossa = Black

Left antecubital fossa = Green

Right wrist = Red

Left Wrist = Yellow

Figure 1: Placement of ECG electrodes and leads

For those participants undertaking the Bike test, the ECG device is hung on the centre of the handlebars. It is checked that the leads are trailing up and away from the electrodes so as they will not be knocked by the participant's legs during pedalling.

Where the participant is undergoing ECG only, the ECG device is placed on the table beside the participant.

5.14: All lead connections are made secure and a good contact is made between skin and electrodes. The participant is reassured that they will be observed by the test operator at all times during the test.

5.15: The participant is asked to let the operator know immediately if they experience any discomfort during the test and to stop at any time should they experience chest pain, feel faint or otherwise ill. It is explained that talking must be kept to a minimum during the test period.

5.15: On the Vox page 'Measure' is selected. After approximately 1 minute the CardioSoft page shows a picture of the lead connections. Good connections are shown as Green; poor connections are shown in Red.

5.16: If poor connections are shown, it is checked that the ECG lead connections are secure and that electrodes are in firm contact with skin. If poor connections persist the electrodes are replaced. When all 4 connections are shown as green and the waveform is sharp the test is ready to start.

5.17: For those participants undergoing the Bike Test protocol, they are informed that once instructed to pedal they should aim for approximately 60 revolutions per minute (rpm). If the participant slows down too much, or speeds up above a certain level, a red arrow will appear, to indicate the need to readjust the pedalling speed.

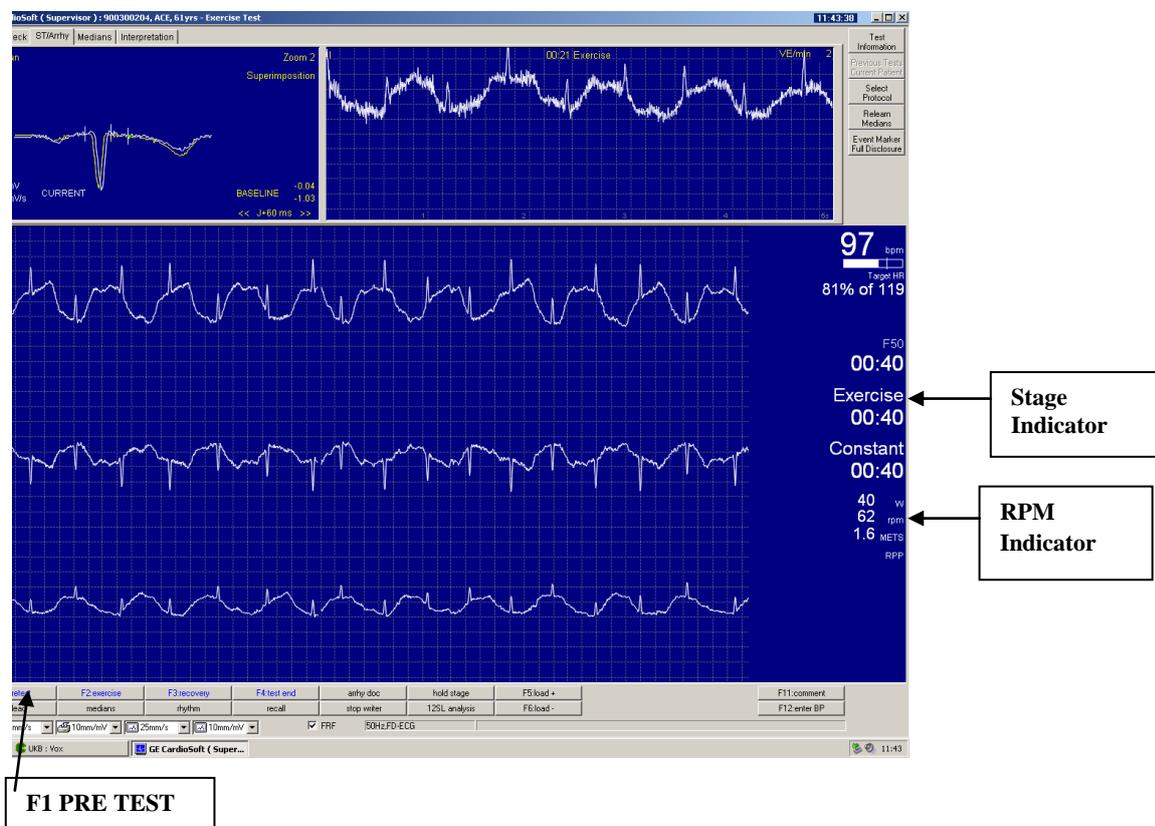
5.18: For participants Allocated to Resting ECG Protocol Only

The participant is asked to sit still, relaxed and quiet for this stage. On the CardioSoft page, the 'F1 Pre Test' button is clicked to start the test.

5.19: Throughout the test period the participant and CardioSoft screen are observed. It is checked that the ECG lead and electrode connections are good, and that the participant is fine. After 2 minutes the CardioSoft screen shows 'Test End' Data is saved and CardioSoft program is Exited as per instructions in Section 6.7: Test Completion.

6. Bike Test Measurement

6.1: Pre-Test Stage: The participant is asked to sit still, relaxed and quiet for this stage. On the CardioSoft page, the 'F1 Pre Test' button is clicked to start the test. This records a resting ECG for 15 seconds. The ECG is recorded while the participant is sat on the bike but they are not to pedal during this time.



6.2: Activity Stage: As soon as the Stage Indicator on the CardioSoft display changes from Pre Test to Exercise the participant is instructed to start pedalling.

6.3: the operator observes the RPM indicator or bike display panel and reminds if necessary, to keep pedalling at approximately 60 rpm. The operator frequently checks this either by reviewing the display panel on the bike or the CardioSoft display on pc monitor.

6.4: The participant is reminded that after 2 minutes they may feel a slight increase in pedalling resistance (they should still aim to keep to around 60 rpm).

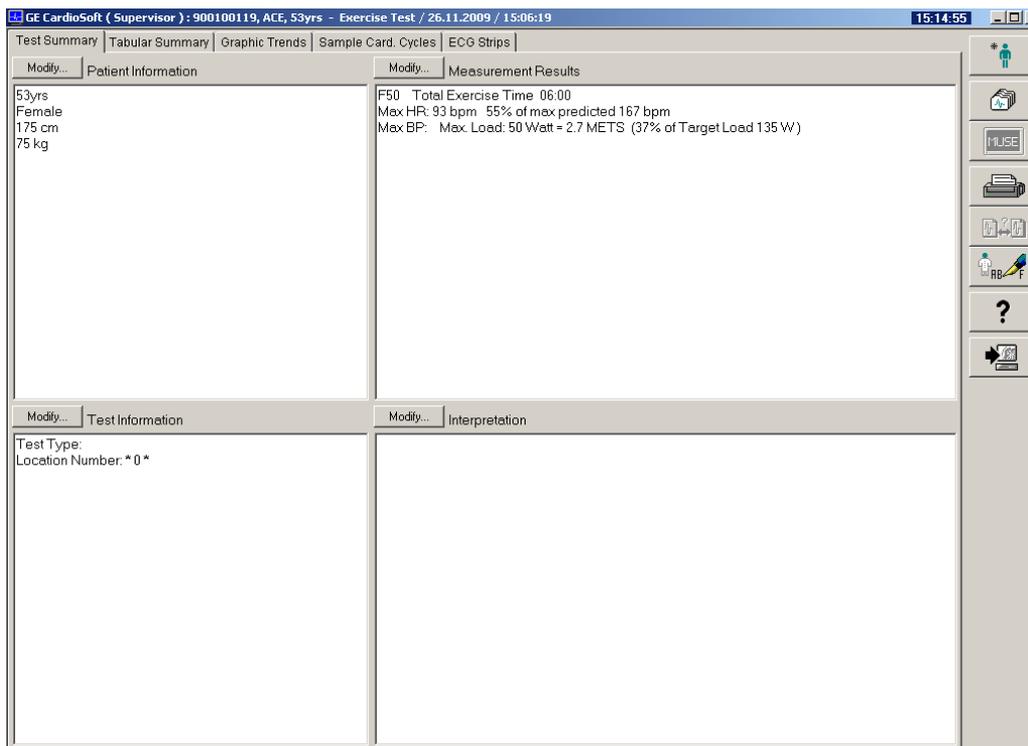
6.5: Throughout the test the participant is observed and ensured they are not unduly uncomfortable. If necessary, they are reminded to avoid talking (unless necessary) during the test. The output is checked to ensure that leads are not displaced.

6.6: Recovery Stage: When the stage indicator shows 'Recovery' stage (after 6 minutes of exercise) the participant is asked to stop pedalling immediately (this is an instant stop not a gradual slow down), then rest for 1 minute on the bike, with their hands remaining on the handlebars whilst remaining still and silent. The ECG is recorded for this period. After 1 minute the CardioSoft screen shows 'Test End'.

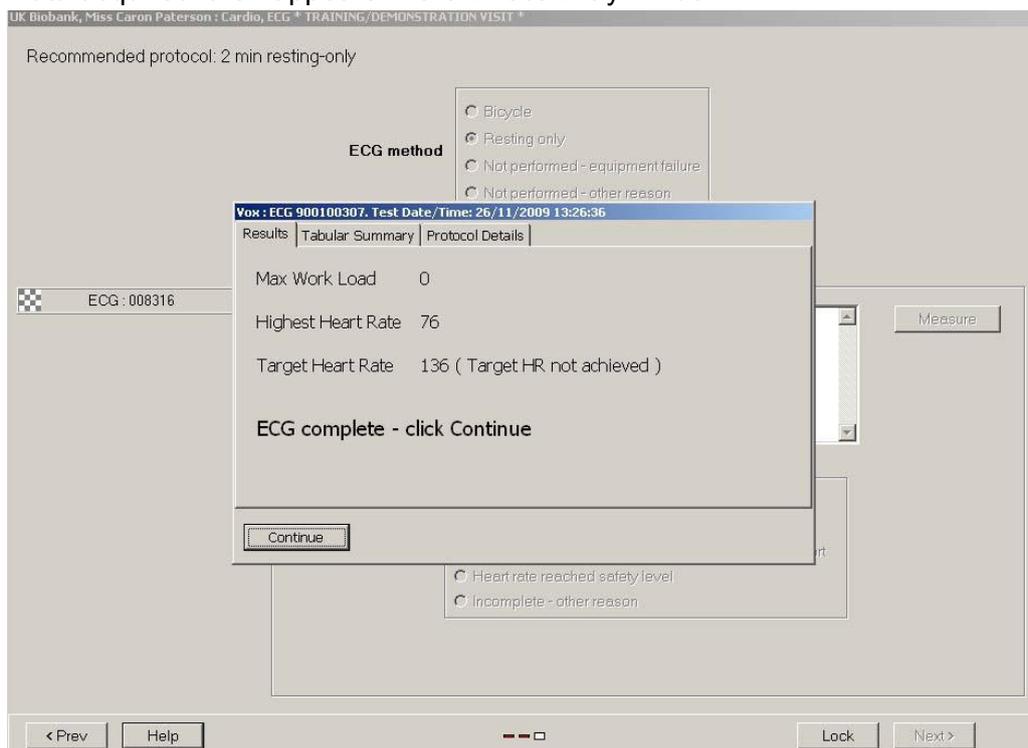
6.7: Test Completion: At 'Test End' a pop up box appears on the screen. The 'OK' option is selected then the Open Folder Icon (Post Test Review) is clicked to view and save the test.

The screenshot shows the GE CardioSoft software interface. The main display area shows a 12-lead ECG waveform. A 'Test End' dialog box is displayed in the center, asking 'Save Full Disclosure ECG?' with 'Yes' and 'No' buttons. On the right side, a vertical panel displays test parameters: 82 bpm (61% of 133 Target HR), F50, 06:00 TEST END, 01:00 Noload, 00:59, 1.9 METS, and RPP. At the bottom, there are navigation buttons for 'F1 pretest', 'F2 exercise', 'F3 recovery', 'F4 test end', 'F5 load +', and 'F12 enter BP'. A callout box labeled 'Post test review' points to an icon in the top right corner of the software window.

6.8: A test summary page is displayed showing participant information and test results. This page is exited by clicking on the X (Close button on the top right of the screen).



6.9: The Vox page (below) displays ECG Complete: 'Continue' is selected. The message 'Data acquired' then appears in the Direct Entry window.



6.10: In the Test Completed section, if the participant successfully completes the Bike Test, 'Fully Completed' is selected. If 'Incomplete – other reason' is selected, a text box opens up and the reason for an incomplete test is entered in here by the operator.

6.11: The ECG leads are disconnected from the electrodes and the participant allowed to dismount the bike and sit on a chair to recover. Electrodes are removed from the arm;

tissues are offered to remove gel and nursing wipes should the participant need to wipe face /hands. The participant's valuables and jacket are returned.

6.12: The participant is offered a drink of water (this helps moisten the mouth – it is explained that at next station they will be asked to give a saliva sample). They are thanked and directed to the next station.

7. Early Termination of Test

7.1: If the heart rate reaches the pre-set maximum heart rate level (75% of age-predicted maximum heart rate), a small beep will be heard, the heart rate display turns red and the operator will stop the test. The participant may also terminate the test early should they report chest pain, feel faint, dizzy or for any other reason.

7.2: To stop the test, the operator asks the participant to stop pedalling, keep their hands on the handlebars and remain still and quiet for the 1 minute recovery period. At this point the 'F3 Recovery' button is clicked so that a 1 minute ECG is recorded in Recovery Mode.

7.3: If the participant reports a non-serious complaint, such as muscle fatigue or mild joint pain and wishes to stop the test, they are asked if they would allow a 1 minute resting ECG to be recorded. If so, 'F3 Recovery' is clicked. If they decline this the 'F4 Test End' button is selected.

7.4: If the participant reports chest pain, feels faint, dizzy or otherwise unwell the test is terminated immediately.

7.5: The 'F4 Test End' button is clicked. The ECG leads are disconnected from electrodes and the participant is helped to dismount the bike as soon as they feel able to do so safely.

7.6: The Open Door Icon is clicked on to Exit the CardioSoft page. The Vox page now displays the message 'Data acquired' in the Direct Entry window.

7.7: In the Test Completed section, the operator records why the test was terminated early by selecting one of the 5 listed options. If 'Incomplete – other Reason' is selected a blank text box appears and a concise explanation is entered in the space provided.

7.8: All reports of chest pain, dizziness or fainting are escalated to the Duty Manager, who records them the Incidents and Near Misses Log. The 'Note' function is used to record any observed or incidental findings.

Cardio

Screening	Doctor recommended activity only: No Chest pain due to physical activity: No Chest pain at rest in past month: No Able to walk/cycle for 10 mins: Yes
ECG	Method: Bicycle Protocol: M130/88 : cycle 2 mins at 50W, 4 mins ramp to 130W (55% of 247W), 1 min rest [ECG-device:001641] [Bicycle-device:001642] Data acquired: 2830K Completion: Fully completed

ACE Participant Note

You can insert a note here

Cancel Clear Save

Verify that data is correct then click Finish to sign it using your username and password. Finish

< Prev Help Note Lock

8. Daily Download of Bike Test Data

After the last participant has left the Bike Test station, the 'Archive' button on the VOX program is pressed to download the data onto the USB key, which is inserted into the ACE computer. The following morning when all the data has been downloaded the USB key is securely couriered to the UK Biobank data processing centre.

9. APPENDICES

9.1: Appendix 1: Risk Categories

9.1.1: Participants are divided into 5 'risk' Categories, which influence the protocol assigned as follows:

1. Minimal risk, cycle at 50% level
2. Small risk, cycle at 35% level
3. Medium risk, cycle at constant level
4. High risk, take measurement at rest-only
5. ECG to be avoided, either unsafe or pointless

9.1.2: A participant with no risk factors is in Category 1. A participant with one or more risk factors is in the highest Category corresponding to those risk factors. The following table shows risk factors and their corresponding Categories.

Risk Factor	Risk Category
heart condition	2
chest pain during physical activity	3
chest pain at rest	4
unable to walk/cycle	4
pregnant	4
height unknown	3
weight unknown	4
heart rate unknown	3
bp unknown	4
bp very high	4
bp high	2
Weight high	4
pacemaker unknown	4
pacemaker	5

9.1.2: Risk factors are defined as follows.

Risk Factor	Definition
heart condition	answer to: "Has a doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor" is 'yes' or 'unsure'
chest pain during physical activity	answer to "Do you feel pain in your chest when you do physical activity" is 'yes' or 'unsure'
chest pain at rest	answer to "In the past month, have you had chest pain when you were NOT doing physical activity" is 'yes' or 'unsure'
unable to walk/cycle	answer to "Are you able to walk or cycle unaided for 10 minutes" is 'no' or 'unsure'
pregnant	participant is female and has not been declared as definitely not pregnant
height unknown	participant's height is unknown
weight unknown	participant's weight is unknown
heart rate unknown	participant's resting heart rate is unknown
bp unknown	systolic or diastolic bp is unknown
bp very high	lowest systolic bp \geq 180 or lowest diastolic bp \geq 110
bp high	lowest systolic bp \geq 160 or lowest diastolic bp \geq 95
Weight high	Weight \geq 150 kg
pacemaker unknown	participant has not declared as not having pacemaker
pacemaker	participant has pacemaker

9.1.3: Values of resting heart-rate and blood pressure are the lowest recorded during the blood-pressure section of the Interview stage. Values of height, weight, pregnancy and pacemaker are those recorded during the Biometrics stage. Note that if the Interview has not been completed then many of these variables will be unknown, moving the participant

into Category 4. If the Biometrics have not been completed then the pacemaker variables will be unknown, moving the participant into Category 5.

9.2: Appendix 2: Power Calculation

9.2.1: For participants in Categories 1 and 2, their predicted absolute maximum workload is calculated using the formula:

ABSOLUTE MAXIMUM WORKLOAD =

$$\begin{aligned}
 &105.2749 + (-0.0935 \times \text{AGE}) + (-0.0280973 \times \text{AGE} \times \text{AGE}) \\
 &+ (2.809493 \times \text{SEX}) + (119.0087 \times \text{HEIGHT}) + (0.309456 \times \text{WEIGHT}) \\
 &+ (-2.698067 \times \text{RHR}) + (0.0090985 \times \text{RHR} \times \text{RHR}) + (-0.3783405 \times \text{AGE} \times \text{SEX}) \\
 &+ (60.72548 \times \text{HEIGHT} \times \text{SEX}) + (-0.15016 \times \text{WEIGHT} \times \text{SEX}) \\
 &+ (-0.3730664 \times \text{RHR} \times \text{SEX}) + (0.0180811 \times \text{RHR} \times \text{AGE})
 \end{aligned}$$

Variable	Meaning	Unit
AGE	age, calculated from DOB	years
SEX	sex factor, 0 for females, 1 for males	none
HEIGHT	height, taken from Biometric stage	metres
WEIGHT	weight, taken from Biometric stage	Kg
RHR	resting heart-rate, taken as lowest value from BP measurement in Interview	beats per minute (bpm)

For participants in Category 1, the target-power is 50% of the absolute-max-workload.

For participants in Category 2, the target-power is 35% of the absolute-max-workload.

9.2.2: After the target power has been calculated the participant is assigned to one of the following protocols – chosen to be the ‘hardest’ protocol for which the peak power does not exceed the participants target power.

All bicycle protocols consist, in order, of

- Initial 15 seconds rest (pretest resting ECG)
- 2 minute phase at constant power
- Linear increase over 4 minutes from Start to Peak power level
- Concluded by a 1 minute recovery period.

The ECG measurement is taken throughout the 7 minutes 15 seconds period.

Female Protocols

Number	Name	Start Power (W)	Peak Power (W)
60	F30	30	30
61	F40	30	40
62	F50	30	50
63	F60	30	60
64	F70	30	70
65	F80	30	80
66	F90	30	90
67	F100	30	100
68	F110	30	110
69	F120	30	120
70	F130	30	130

Male Protocols

Number	Name	Initial Power (W)	Peak Power (W)
80	M40	40	40
81	M50	40	50
82	M60	40	60
83	M70	40	70
84	M80	40	80
85	M90	40	90
86	M100	40	100
87	M110	40	110
88	M120	40	120
89	M130	40	130
90	M140	40	140

9.2.3: The resting-protocol is unisex, number -1, name "R", consisting of a 2 minute ECG performed seated on a standard chair with no connection to the bicycle.