

## ACCELEROMETRY

## TABLE OF CONTENTS

1.	Background and rationale .....	2
2.	Training.....	2
2.1	Certification of accelerometry technicians.....	3
3.	Participant safety and exclusions .....	3
4.	Pre-examination procedures.....	3
4.1	Prescreen participants.....	3
4.2	Initial setup of accelerometers.....	3
4.3	Actigraph setup.....	4
4.3.1	Epoch period.....	6
4.3.2	Start/stop time.....	6
4.3.3	Subject name (Health ABC Participant ID#).....	6
4.4	Actiheart set-up 1 – Enter participant details.....	7
4.5	Actiheart set-up 2 – Initialize Actiheart for data collection .....	9
5.	Placement of Actigraph and Actiheart .....	12
5.1	Actigraph.....	12
5.2	Actiheart.....	13
6.	Recording during clinic examination including the 20 meter and ldc walk.....	13
6.1	Setting-up Actigraph for walk tests (short epoch).....	13
6.2	Setting-up Actiheart for walk tests .....	14
6.3	Download the Actiheart and Actigraph monitors upon completion of the walk tests. ....	17
7.	Prepping the participant for monitoring free-living activity.....	18
7.1	Free-living set-up of Actigraph .....	18
7.2	Free-living set-up of Actiheart .....	18
8.	Return visit (14 to 16 days).....	20
8.1	Download the data using the following methods .....	20
9.	Equipment support and troubleshooting .....	24
10.	Description of equipment.....	26
10.1	Actigraph technical specification .....	26
10.2	Actiheart technical specification .....	29
11.	Data backup and transfer .....	30
12.	Quality assurance .....	30
12.1	Training and certification.....	30
12.2	Certification requirements .....	30
12.3	Quality assurance checklist .....	30
	Appendix 1 Participant waist monitor instructions .....	32
	Appendix 2 Participant chest monitor instructions.....	33
	Appendix 3 Year 10 Energy Expenditure Telephone Follow-up Form.....	34
	Appendix 4 Data Backup and Transfer.....	36

## ACCELEROMETRY

### 1. Background and rationale

Accurate and reliable assessment of physical activity remains an important measurement for epidemiologists, exercise scientists, clinicians, and behavioral researchers. However, a cost-effective and objective assessment of physical activity has until recently been unavailable. Recent advances in accelerometers, which quantify body movements in terms of acceleration, offer a cost-effective way to objectively record physical activity. The accelerometers capture accelerations in one to three orthogonal axes (anteroposterior, mediolateral, and longitudinal) that can be used to estimate the intensity of physical activity over time. The data is held in internal memory (usually about 7 to 18 days worth) and later downloaded through a computer port (i.e., USB). The Actigraph is an accurate and widely used device for physical activity assessment and will be used for this substudy.

The follow-up of participants in the first doubly-labeled water substudy provides a rare opportunity to validate and quantify physical activity in very old adults (>80 years of age). The physical activity measurement obtained from doubly-labeled water (DLW) is often defined as free-living activity as it quantifies total energy expenditure, which when subtracted from resting energy expenditure provides a concise measure of all free-living activity. Although the DLW method is accurate and precise, the measurement cannot discriminate gross activities such as walking and very fine movements such as fidgeting, nor can one determine the intensity of the activity. The addition of accelerometry to this substudy will determine the gross physical activity (i.e., walking and exercise) components of free-living activity energy expenditure. Therefore, we will be able to better characterize physical activity into non-exercise activities and exercise activities.

A weakness of the monitoring accelerations is the inability to account for external work performed (walking up an incline or climbing stairs). A solution to this problem is to combine heart rate (HR) and accelerometry data. This technology has been successfully developed and has been marketed as a device called Actiheart. However, no validity data on this monitor exists in very old adults. The inclusion of this monitor will help to determine both physiological and biomechanical aspects of the intensity of exercise activities during normal daily living in this age group.

Overall, the combination of accelerometry, heart rate, and the criterion measure of free-living activity energy expenditure by doubly-labeled water will provide an unprecedented opportunity to understand physical activity in older adults.

### 2. Training

A representative from the Medical Research Council Epidemiology Unit (MRC Epid), Cambridge, UK will travel to the field centers to conduct the initial training session. The MRC Epid initially developed the Actiheart and performed much of validation work. Additionally, the Unit has extensive experience performing studies using accelerometers.

Training for the Actigraph and Actiheart will be done simultaneously. After completion of training, technicians will be certified as described below. New personnel will be trained by certified accelerometry technicians. The Health ABC staff ID number will provide tracking information so the reading center (MRC Epid) can perform technician-specific quality control.

## 2.1 Certification of accelerometry technicians

Accelerometry technicians must be certified before they can administer the measurement. The certification procedure is as follows.

1. Initial set-up of monitors
2. Proper placement of *Actigraph* and *Actiheart* on a test participant
3. Download *Actigraph* and *Actiheart* data using respective software programs

## 3. Participant safety and exclusions

Participants in the energy expenditure substudy will be excluded under four general criteria (below).

1. Insulin using (dependent) diabetes mellitus
2. A requirement for supplemental oxygen
3. Blood transfusions, administration of blood products, or administration of intravenous fluids in excess of 500 mL in the week previous to the first energy expenditure visit or an expectation of same during the period between the first and second energy expenditure visit
4. Travel in excess of 200 miles away from home during week prior to energy expenditure visit 1 or an expectation of same during the period between visits 1 and 2

No extra exclusion criteria are needed for wearing the accelerometers.

## 4. Pre-examination procedures

### 4.1 Prescreen participants

The Prescreener for Energy Expenditure will be administered before the participant comes into the clinic for their Year 10 clinic visit. The participant will have already been told about the monitors during the prescreening.

### 4.2 Initial setup of accelerometers

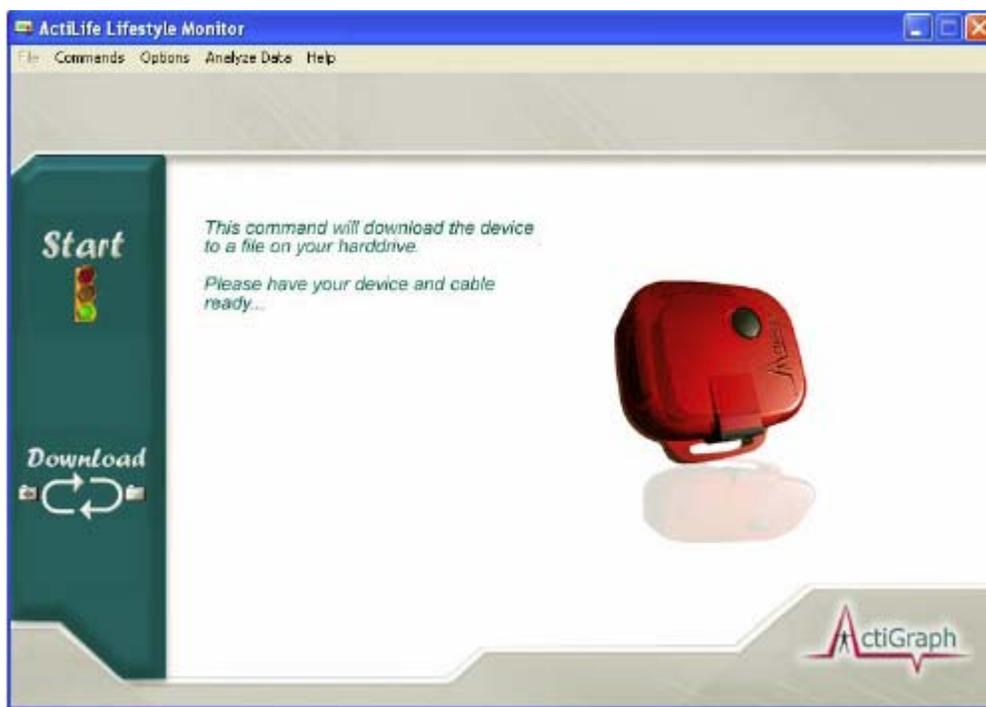
The monitors will be set up differently in the clinic and in free-living conditions. We want to collect data in short epochs during the walk tests (20 meter, 2 minute, and long-distance corridor walk) (e.g., 1 second) and long epochs during free-living conditions (e.g., 10 seconds). The initial setup of each monitor will allow you to change these epoch settings.

### 4.3 Actigraph setup

Set up the ActiGraph to start collection data.

*NOTE: The ActiGraph must be plugged into the USB Port before clicking this button.*

Press the Start button.



If your ActiGraph is not connected to the USB Cable, you will get the following message.





The ActiGraph GT1M connected to the USB cable.

When the ActiGraph GT1M is connected to the USB port, you will get the following message.



Click "OK" to continue.

The following screen will appear:

**For details of specific set-up for walk tests and free-living, read sections 6.1 and 7.1.**



### 4.3.1 Epoch period

The ActiGraph collects and reports physical activity in “counts” and then can be used to estimate time spent at different intensity levels. Counts are simply the summation of the accelerations measured during the epoch period. The GT1M ActiGraph measures changes in acceleration 30 times each second. When one-minute cycles are used, 1,800 measurements are summed and that value is written to memory at the end of the selected epoch period.

Activity counts represent a quantitative measurement of activity over time. Think of epochs as the resolution of the recorded data. The lower the epoch the greater resolution of data you will get.

### ActiGraph, LLC Users Manual GT1M and ActiWeb

The following epoch lengths are available: Raw, 1, 2, 5, 10, 15, 30, 60, 120, 180, 240, 300 seconds.

The following formulas can be used to determine the number of days of data collection the ActiGraph GT1M, based on selected Epoch Period, will support.

Days = (512,000 x Epoch Period in seconds) / 86,400

Note: Divide the resulting number by 2 if Step Count Data is collected.

**Use 1 second epochs for walk tests and 10 second epochs for free-living conditions.**

### 4.3.2 Start/stop time

The GT1M supports user configurable start and stop times. This allows the user to program the monitor to start recording at a specific time. This should be used to check the monitor will begin recording at the correct time.

### 4.3.3 Subject name (Health ABC Participant ID#)

Enter the Health ABC Participant ID (4 numbers and 4 letters) at the Subject Name prompt.

When setting up the monitor for walk tests identify file by **H\*\*\*\*\*\_W**.

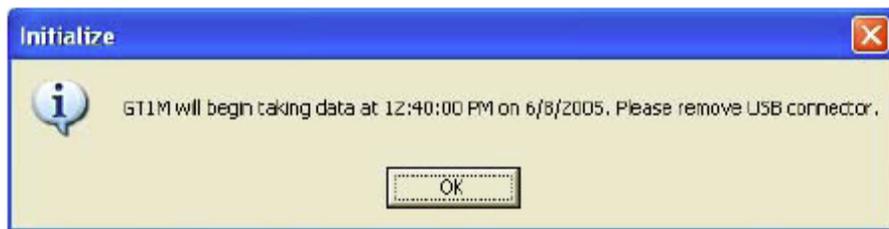
When setting up the monitor for free-living identify file by **H\*\*\*\*\*\_F**.

It is important to identify the file names with these identifiers to decrease the potential that the files are overwritten resulting in lost data.

Once you have entered the appropriate information, click OK.



Please be patient while the computer sends the commands to the ActiGraph unit.

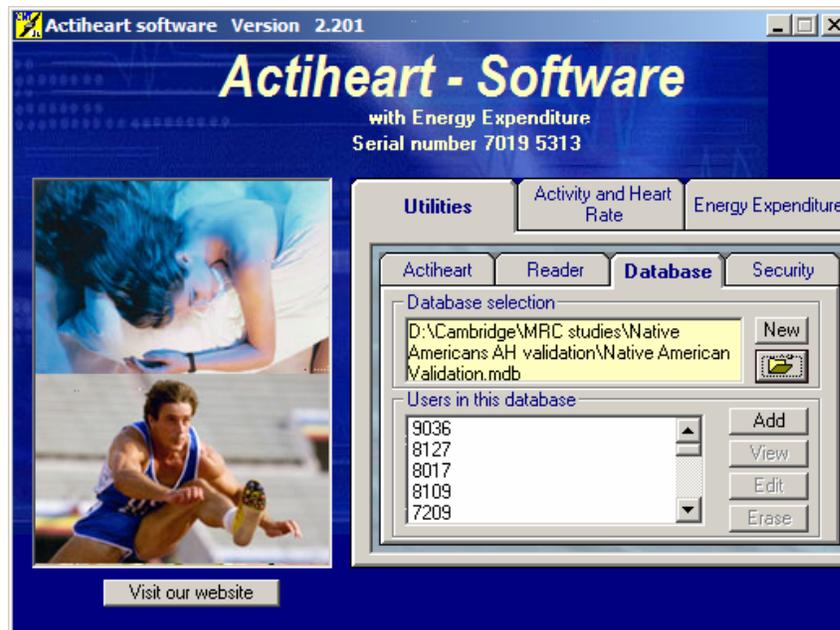


Once the ActiGraph has been successfully started, it will report when the ActiGraph will start collecting data. Disconnect the ActiGraph immediately from the USB Cable and click OK. (The monitor will flash intermittently until the monitor starts recording data, then the light will cease to flash).

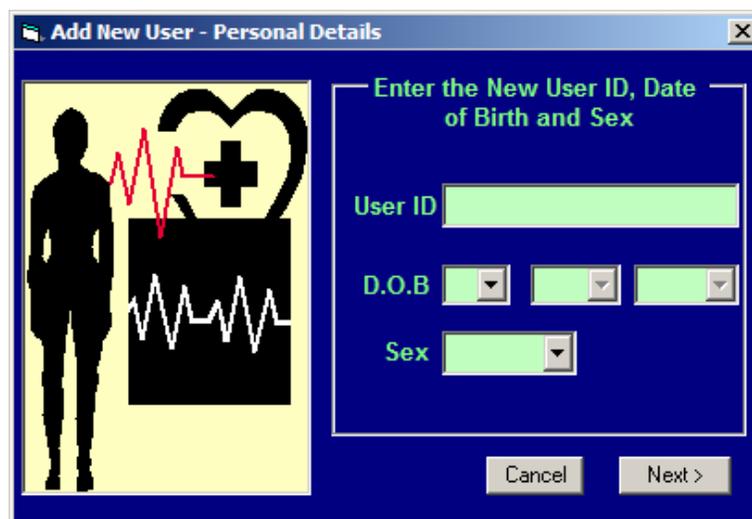
Congratulations! You are now ready to place the ActiGraph on the participant and collect activity data!

#### 4.4 Actiheart set-up 1 – Enter participant details

1. Ensure the USB cable with the reader is plugged in. Run the Actiheart software.
2. Click on “Utilities” tab from main menu, then “Database” tab.
3. Make sure, you are using the right database (\*.mdb) – the file path is displayed in the yellow window.
4. First time users require you to specify a “new” database. Create a database called HABC on the C: drive (C:\HABC\_site name).



5. Click “Add” - this opens the following window



6. Enter Health ABC ID (4 numbers and 4 letters) in the ‘User ID’ field
7. Select Date of Birth (D.O.B.)
8. Select gender
9. Click Next

10. Enter weight
11. Enter height
12. Click “Next” leaving this screen as default, “Next” and ”Yes” when asked whether user details need to be saved.

#### 4.5 Actiheart set-up 2 – initialize Actiheart for data collection

To initialize the Actiheart, place on the reader interface. Make sure the USB cable is plugged in:

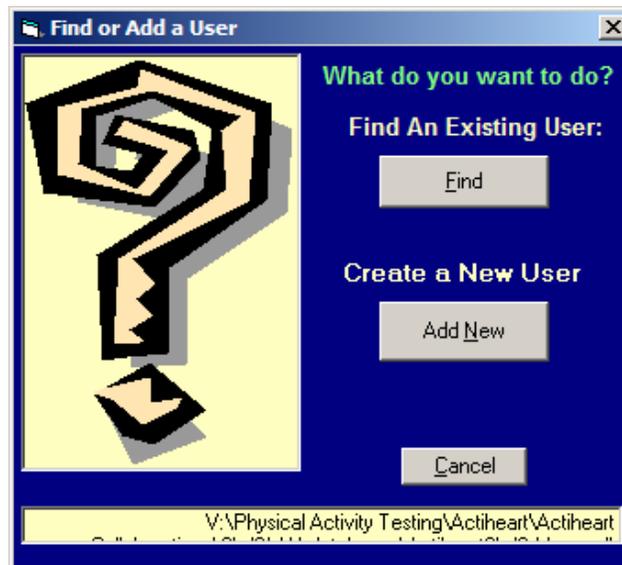
1. Run the Actiheart software. Again, ensure the USB cable is plugged in.
2. Click on “Utilities” tab from main menu, then the “Actiheart” sub-tab.
3. Open the “Verify Set-up” screen.
4. If setting up for walk test, click “Step Test” under “Energy Expenditure” tab.  
If setting up for free-living, click “Long Term” under the “Activity and Heart Rate” tab.



This opens one of the following two windows:



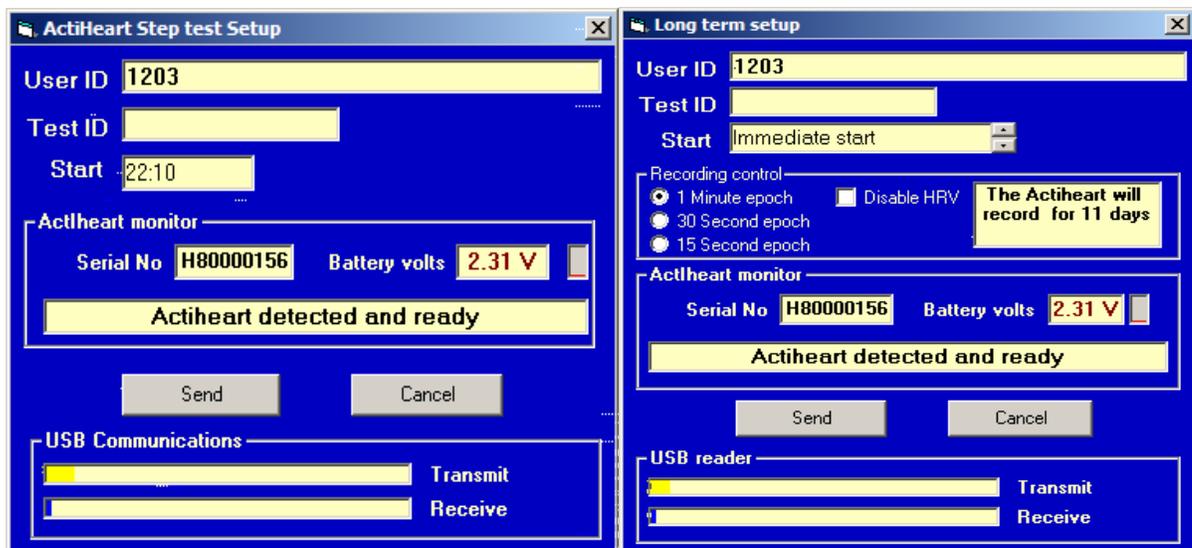
5. Click "Setup" on the relevant screen - this takes you through the usual setup procedure



6. Click "Find" (unless the person has not been entered, in which case you click "Add New" and follow the procedures described under 4.5 Actiheart Setup 1, points 5-11 and go to point 9 in this section.)
7. Select the right HABCID from the list

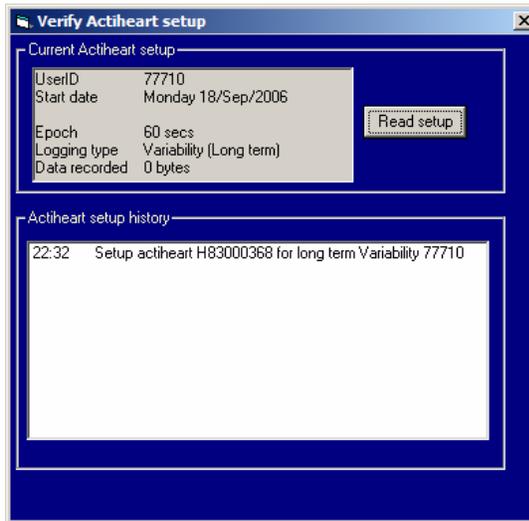


8. Click “Next”
9. Once serial number and battery volts are displayed in the respective screens, clicking “Send” will initialize the monitor. Be sure to use 1-minute epoch and with HRV enabled (Do NOT tick the box that says “Disable HRV”) for free-living.



*More detail about specific walk test and free-living set-up is provided below in sections 6.2 and 7.2.*

Confirm on the verify set-up screen that the monitor will be recording in the correct mode for the correct participant ID.



## 5. Placement of Actigraph and Actiheart

### 5.1 Actigraph

The Actigraph comes with a waistband that will be worn around the hip. It should be worn on the hip (as close as possible to the iliac crest). It is important that the accelerometer is fastened tightly to the belt or measurements will be inaccurate.



ActiGraph GT1M with Belt Clip attached.



ActiGraph GT1M attached to Elastic Belt.



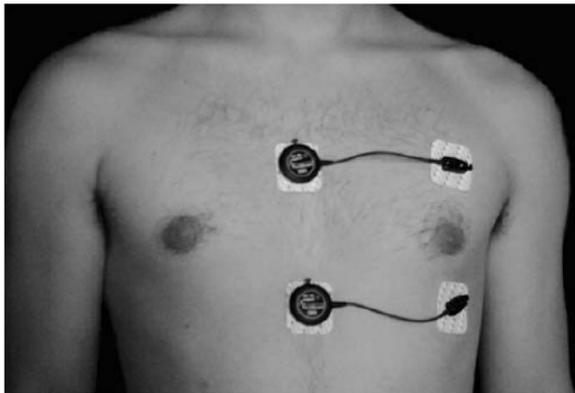
## 5.2 Actiheart

### Skin preparation

Ask the participant to rub the surface of the skin with a paper towel or tissue before electrode placement (where the electrodes will be placed). This preparation is **VITAL** to ensure a good quality recording.

### Electrode placement

Place the medial electrode below the sternum. Place the lateral electrode between V4 and V5 positions so the wire lies in a horizontal position but is not stretched. You may need to shave small sections of hair where the electrodes are to be placed.



Use upper position only for women who are uncomfortable with the lower position

Use lower position for everyone else  
**MAKE SURE THE BRA DOES NOT INTERFERE WITH ACTIHEART**

**Fig. 1** Upper and lower positions for Actiheart attachment. The accelerometer is placed in the larger round clip orthogonally to the wire axis, thus here orientated to measure accelerations along the longitudinal axis of the body

## 6. Recording during clinic examination including the 20 meter and long-distance corridor walks

It is vital that both activity monitors be worn during the usual and rapid 20-meter walk tests, the 2-minute walk test, and the long-distance corridor walk test. The walk tests will need to be done in a specific order to correctly match activity accelerations. Following the 20-meter and 2-minute walk test, the Actiheart monitor will be downloaded and set up again for the long-distance corridor walk test. Once that is completed, this data will be downloaded. The Actigraph monitor can be left on for all three walk tests but the data will be downloaded immediately following the walk tests. Both monitors will then be set-up for the participant to wear in free-living.

*The initial set-up for each monitor will require a short term recording.*

### 6.1 Setting-up Actigraph for walk tests (short epoch)

1. Plug in the Actigraph USB cable, start the ActiLife software, and go under

“Commands” and click on “initialize GT1M”. This command is used to initialize the ActiGraph GT1M for data collection, it provides the same functionality as the “Start” button on the main screen of the ActiLife Lifestyle software.

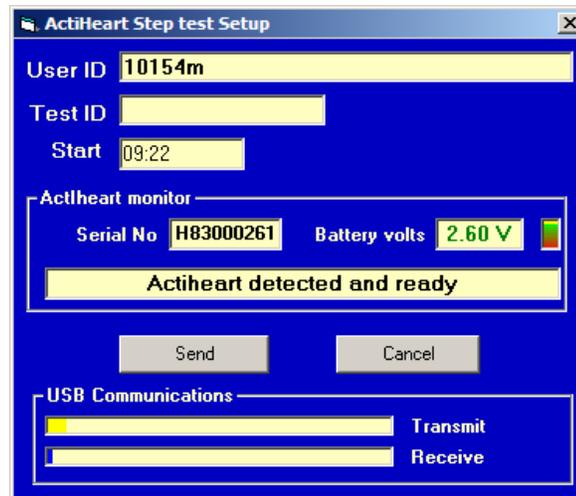
2. Tick the box in order to record Step Count. (Activity will be collected also but this is as default).
3. Enter the epoch of 1 second for the walk tests. Check start time against computer time, make sure the monitor start time is 2 minutes ahead. Click OK.

## 6.2 Setting-up Actiheart for walk tests

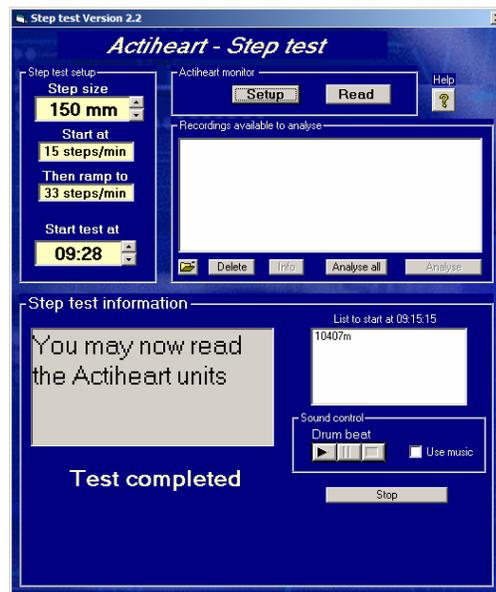
The Actiheart collects “raw” waveform data in “step-test” mode. This mode should be used during the walk tests to collect detailed heart rate and accelerometry data.

Ensure the participant skin has been prepared and the electrodes are placed as described in 5.2 prior to setting up the monitor.

1. In the Actiheart software, click the “Energy expenditure” tab, and then “step-test” – this opens the step test window.
2. If necessary, adjust the start time of the test by clicking on the arrows if so desired.
3. Click “setup” – this takes you through the usual setup procedure as described previously in section 4.5.
4. Click on “find” and select the person from the list. Click “Next”.
5. Add Test ID for walk tests only (“Walk” for short walks and “400m” for the long-distance corridor walk).
6. Once the serial number and battery voltage is displayed, click ”Send”. Remove monitor from reader and attach on to participant.



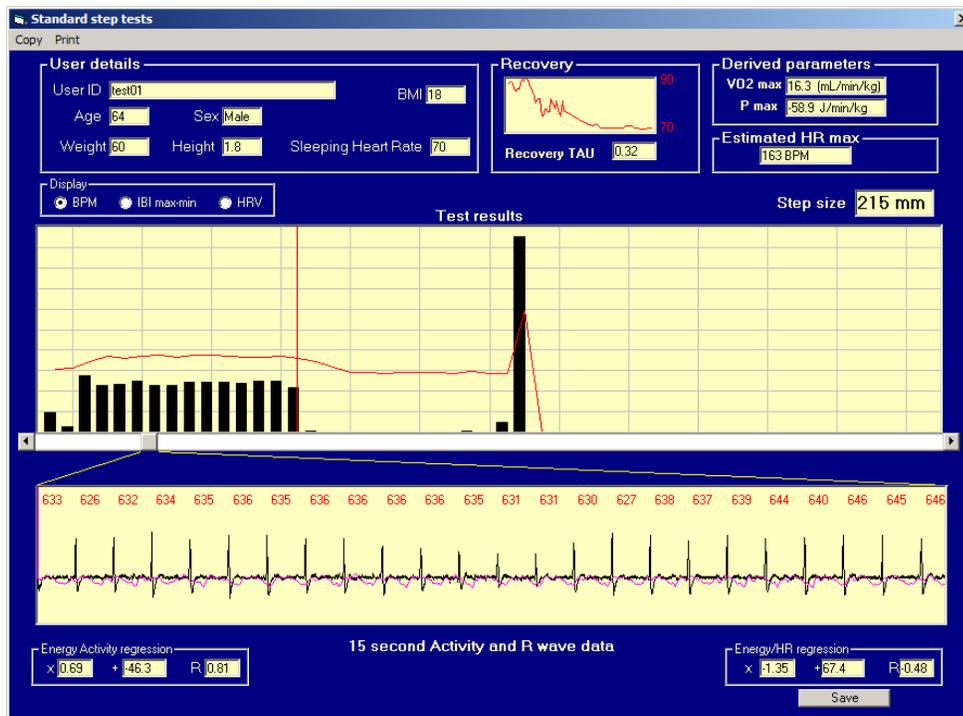
7. Once set up, touch one electrode (earthing/grounding), and place the Actiheart on the participant.
8. The software will count down and the participant should be standing on the start line before the countdown reaches 30.
9. The 20-meter “Usual pace” walk should start when the countdown reaches 0. (See 20-meter and long distance corridor walk test operations manuals for walking instructions for the walk tests). After the standard explanation (approximately 15 seconds), the participant should complete the “as fast as possible” walk back to the start line.
10. When the participant has reached the end of the walk they **MUST** stand still and relax quietly as much as possible for two minutes, in order for the HR recovery index to be measured. Minute 1: **NO TALKING!** (this also applies to the investigator) Minute 2: Investigator to explain 2 minute walk test while participant is still resting.
11. The 2 minute walk test should commence on  $\frac{1}{4}$  of a minute on the Actiheart Software timer. (mm:00, mm:15, mm:30, mm:45).
12. On completion of the 2 minute test, again, participant must stand still and relax for 2 minutes (**NO TALKING**). Use stop watch to track time. (If second 2 minute walk test is required, repeat point 11 and 12).
13. When the recovery period has finished, remove the monitor from the participant and download the Actiheart via the USB reader by clicking “Read” (click “Stop” on the step test screen once or twice until the ‘Read’ button is not greyed out anymore, allowing the monitor to be read).



The following message will appear:



14. Click Exit. View your recording by double-clicking on the file in the list or by highlighting the file and clicking "Analyse" (do NOT click "Analyse all"). The file should appear in the top of the displayed list.



15. A message is likely to appear with “User stopped before end of test”, click OK.
16. Click through the test by clicking in the large middle window and review the ECG waveform in the lower window (zoomed 15-sec epochs). If the data looks very noisy, you may try downloading the Actiheart again.
17. The monitor should now be set up for the long-distance corridor walk test in the same way following points 1 to 8 above with the Test ID “400m”. Start the walk test as the countdown reaches 0.
18. On completion of the long-distance corridor walk test, again, participant must stand still and relax for 2 minutes (NO TALKING). During minute 2, the standard questions can be asked regarding symptoms during the walk test with participant still remaining rested.
19. Download the monitor again, following points 13 to 16.

### 6.3 Download the Actiheart and Actigraph monitors upon completion of the walk tests.

#### **IMPORTANT!!**

**DOWNLOAD DATA FROM BOTH ACTIVITY MONITORS WHEN THE WALK TESTS ARE COMPLETED. THEN INITIALIZE MONITORS FOR FREE-LIVING CONDITIONS.**

Please follow data downloading instructions above for Actiheart and in section 8.1 for Actigraph.

## **7. Prepping the participant for monitoring free-living activity**

Be sure to set up both the Actiheart and Actigraph for free-living monitoring. See instructions in section 4.3 (Actigraph) and 4.4 (Actiheart).

### **7.1 Free-living set-up of Actigraph**

*Be sure to download the data from short-epoch (section 6.2) before setting up for free-living monitoring.*

Once the monitor has been downloaded and data checked, set up monitor for free-living.

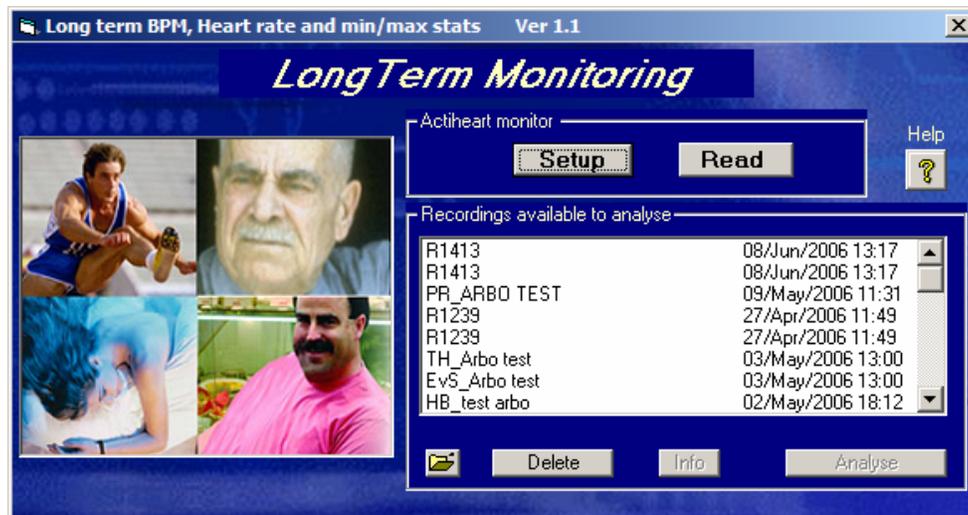
1. Start the Actigraph software, and go under “Commands” and click on “initialize GT1M”. This command is used to initialize the ActiGraph GT1M for data collection, it provides the same functionality as the Start button on the main screen of the ActiLife Lifestyle software.
2. Enter the epoch of 10 seconds for free-living conditions

### **7.2 Free-living set-up of Actiheart**

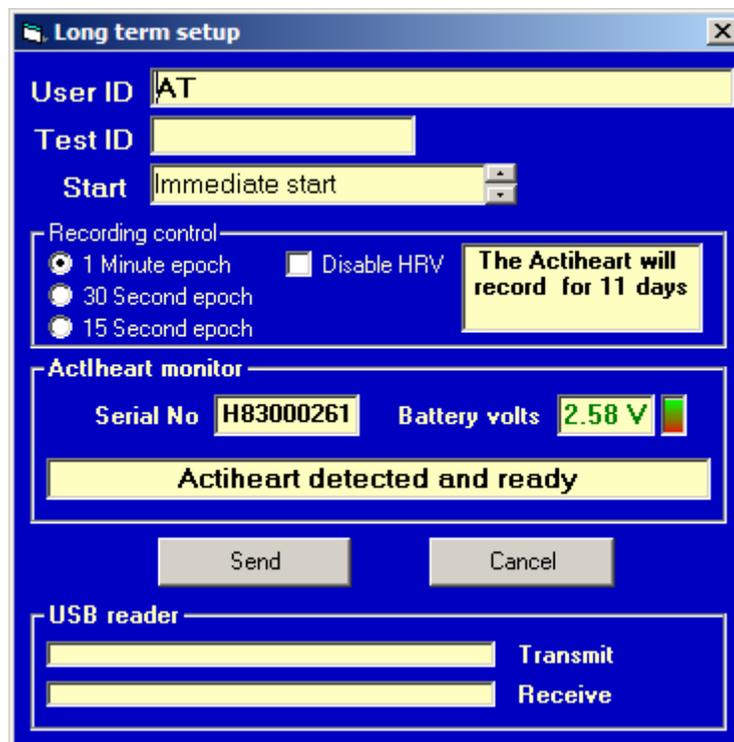
*Be sure to download the data from walk test (section 6.2) before setting up for free-living monitoring.*

Once the monitor has been downloaded and data checked, set-up monitor for free-living.

1. Open the ‘Activity and Heart Rate’ menu
2. Click “Long Term Recording”



3. Set up for free-living by following normal set-up procedure: Click Setup
4. Click on “Find” and select user from the list. Click “next”.



5. Confirm that the serial number is read. Ensure the monitor will record on a 1 minute epoch (AH will record for 11 days). Ensure that the Disable HRV remains UNTICKED.
6. IMPORTANT: Use the verify set-up screen to ensure the monitor is set up in the correct mode for the correct participant ID.

The participant will be responsible for wearing and removing the monitor.

Show the participant how to use the waist and chest monitors (directions in section 5. “Placement of Actigraph and Actiheart”).

Provide the necessary instructions and contact information to the participant (Appendices 1 and 2). You may want to color-code the instructions. For example, you can print the Actiheart instructions on pink paper and the Actigraph instructions on white paper.

Review the instructions with the participant and specifically point out that they can wear the chest monitor to bed and during showering. You may want to have the participant practice removing and replacing the Actiheart in clinic to make sure they can do it. Let the participant know that if they have difficulty reattaching the Actiheart that it helps to stand in front of a mirror as they reattach it. They can also ask someone to help them. Another option is to also let participants know that unless they are uncomfortable, they should not remove the Actiheart at all during the free living period. Finally, in the event of the monitor being removed for some reason and reattachment being difficult, advise the participant to remove the electrodes also, attach new electrodes to the monitor before sticking the electrodes onto the skin in the same place they were originally.

Remind participants that they will receive a follow-up call (about 5 to 7 days from the clinic visit) to address any issues, and remind them of the upcoming visit.

Provide the participant with replacement electrodes for the Actiheart and information sheets.

Log out the monitors to the participant on the log sheet to keep track on the location of monitors.

## **8. Return visit (14 to 16 days)**

### **8.1 Download the data using the following methods**

#### *Actigraph*

Follow these steps to download your collected data from the ActiGraph:



Click on the Download Button on the ActiWeb Client Software. If your ActiGraph is not connected to the USB Cable, you will get the following message.



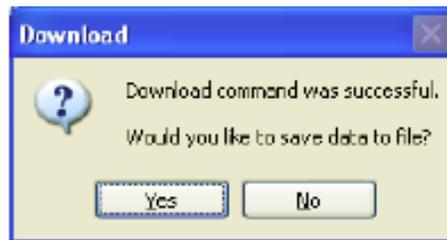
Make sure your ActiGraph is properly connected to the USB Cable and attached to your computer.



This message is displayed to indicate the ActiLife Lifestyle Software has located the ActiGraph GT1M. Click OK to continue.



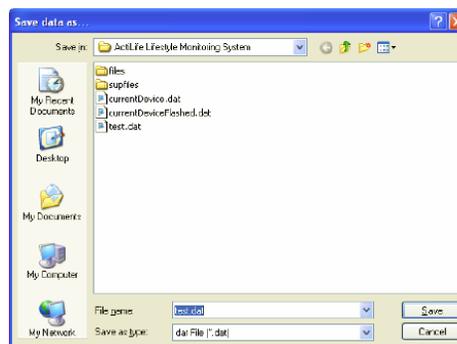
This message is displayed to indicate the status of the execution of the Download command. The ActiLife Lifestyle Software will begin to download the data from the ActiGraph GT1M.



Once the data is downloaded it must be saved on the computer for analysis. Please save using HABCID and the file extension \*.dat. The walk test data and free-living data will be identified with by H\*\*\*\*\*\_W for the walk tests and H\*\*\*\*\*\_F for the free-living data.

Note: If you get an error message with “File already exists. Do you want to replace it?” Click “No”. This means that the file extension was not correct for free-living set-up. Change file name to what you wish to save it as, then click save. Otherwise data will be overwritten.

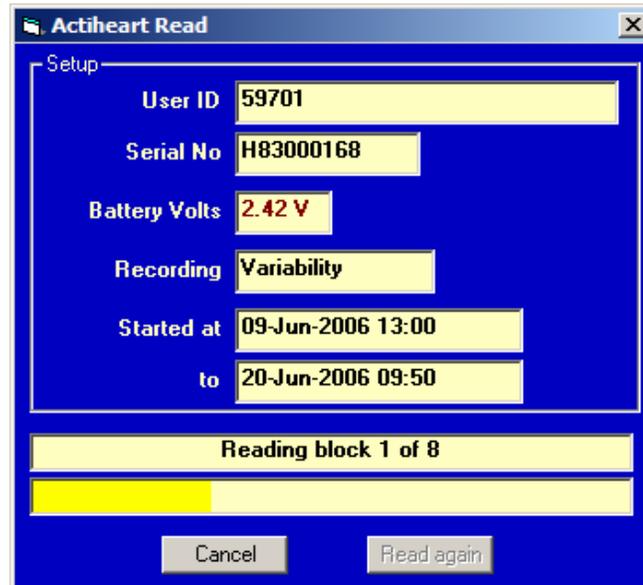
Now that the data has been successfully downloaded, it can be imported into your own statistical analysis programs or you can choose any of the Analysis functions available within the ActiLife Lifestyle Software.



### *Actiheart*

Once the Actiheart is returned, download the data by placing the Actiheart on the reader and click "Read" (in “Long Term Recording” under the “Activity and Heart Rate” menu or in

“Advanced Energy Expenditure” or “Daily Energy Expenditure” under the “Energy Expenditure” menu).



Actiheart Read

Setup

User ID 59701

Serial No H83000168

Battery Volts 2.42 V

Recording Variability

Started at 09-Jun-2006 13:00

to 20-Jun-2006 09:50

Reading block 1 of 8

Cancel Read again

Enter any relevant information in the comments box if necessary. Otherwise click finish.

The following message will appear:



Power Down Actiheart

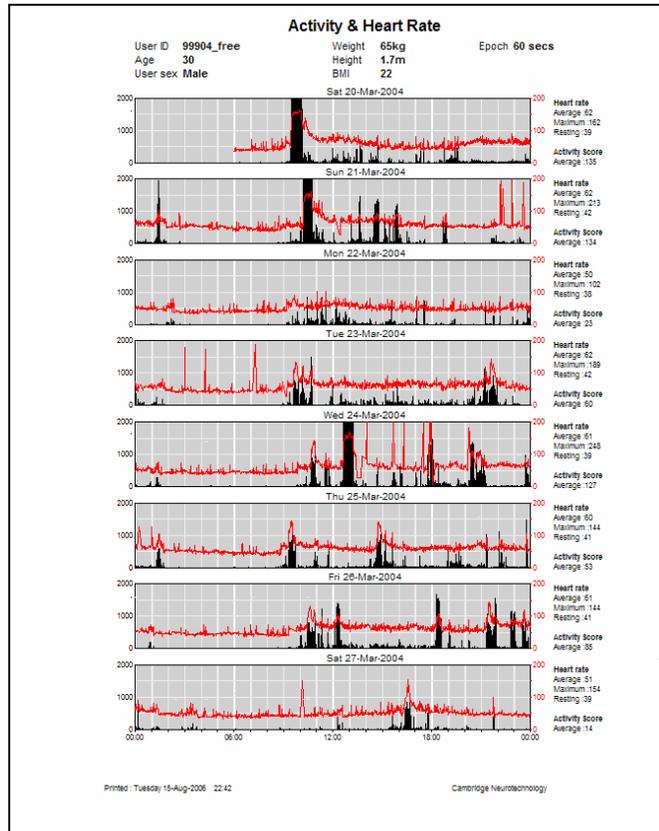
If you want to stop making recordings, the Actiheart unit should be powered down and recharged. Storage of the Actiheart without powering down and recharging will shorten battery life.

(Powering down will make the data unreadable. We recommend that you quickly view your recording before clicking on the button below to power down)

Power down Actiheart Exit

To view your recording before this message is actioned, click on the relevant file that has just been downloaded and follow the instructions below. If the data looks ok, click on “Power down Actiheart” to conserve battery life. If there has been a problem downloading for instance or the data you may try downloading the Actiheart again.

To review data, Double-click on the participant’s file. Click on ‘Preview days’ from the ‘Preview’ menu to view the trace (this is not cleaned):



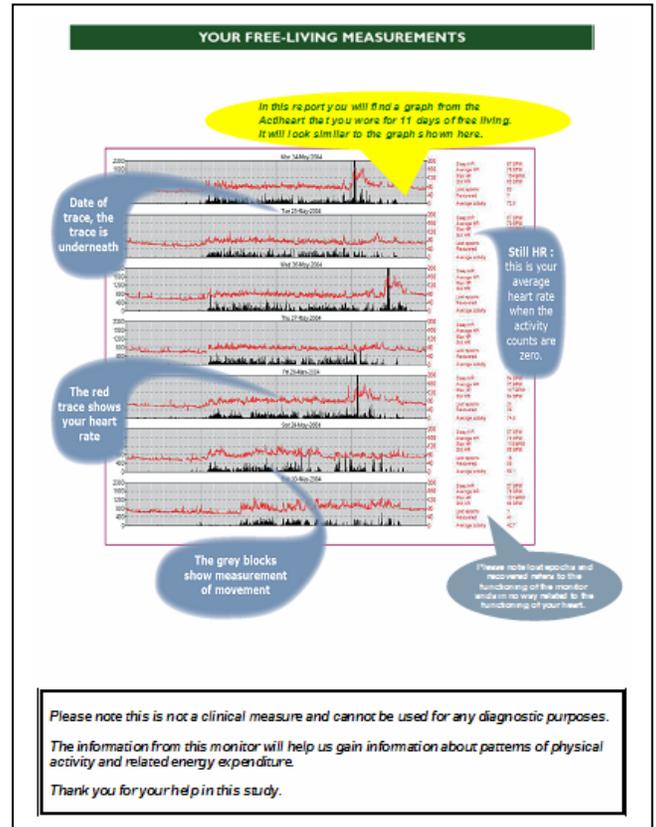
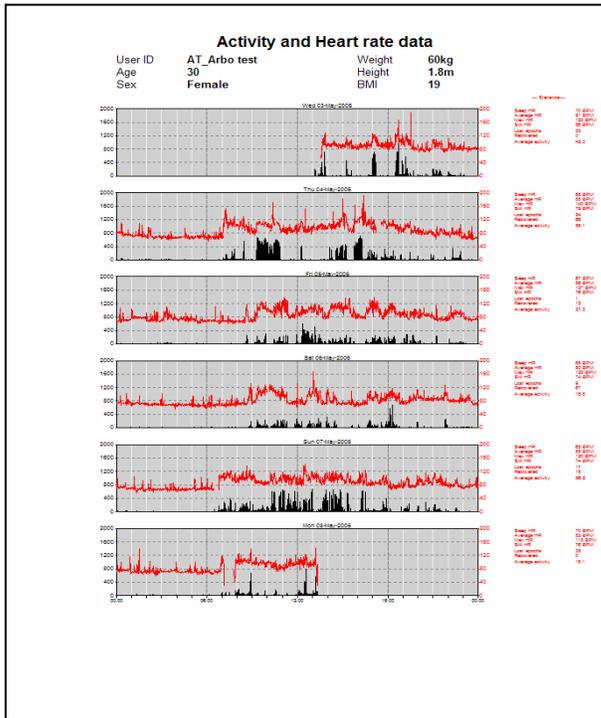
**Print a physical activity summary (from the Actiheart) for each participant.**

This stage can be done after the clinic visit. (The software must be on a computer connected to a color printer in order to print off the documents).

- Click on “Daily Energy Expenditure”.
- Click on the file of interest. When prompted “Would you like to autofill?” click “Yes”.
- To print a report click Print, Activity and HR.



A report that looks like this will be appear:  
Send this with the sample cover sheet which explains the trace to the participant.



## 9. Equipment support and troubleshooting

*How do I tell if the ActiGraph is collecting data?*

After the monitor has been initialized, no flashing when the GT1M is not connected to the computer via a USB indicates that the monitor is collecting data.

*Communication with Actiheart unit and USB reader fails:*

1. Go to 'Utilities' menu and 'Reader'. Click "Test" with NO monitor on the reader. Both sets of characters should increase.
2. If it does not, click "Change settings" and then "Search". The USB reader will be found automatically. Click ok. Try the test sequence again.
3. If it does not, unplug and re-plug the USB reader cable and repeat the "Search" routine.
4. If it does not, try restarting the program and PC and repeating the "Search" routine.
5. If it does not, replace the USB reader and/or the USB cable and repeat the "Search" routine. If this solves the problem, the original USB reader and/or cable could be faulty.

*Communication with Actiheart unit fails:*

1. If the USB reader is flashing but there is no communication with the Actiheart unit (and there is good communication with other units), try pressing lightly the unit onto the reader as it is trying to read. If this fails charge the Actiheart for a couple of hours and try again.
2. If communication still fails, the unit should be returned to MRC with a note describing the problem AND IF THE DATA NEED TO BE RECOVERED.

If you need technical advice after following the above instructions for the *Actigraph* or the *Actiheart*, please contact:

Kate Westgate  
Telephone: +44 1223 748180  
E-mail: [kate.westgate@mrc-epid.cam.ac.uk](mailto:kate.westgate@mrc-epid.cam.ac.uk)

Or

Soren Brage  
Telephone: +44 1223 741275  
E-mail: [soren.brage@mrc-epid.cam.ac.uk](mailto:soren.brage@mrc-epid.cam.ac.uk)

## 10. Description of equipment

### 10.1 Actigraph technical specification

The Actigraph (model GT1M) is a solid-state accelerometer which collects and records physical activity data. It weighs 27 grams and its dimensions are 1.5" x 1.44" x 0.70" (3.8 x 3.7 x 1.8 cm). It can store the number of times it moves x the rate of movement change (acceleration) on a continuous basis for a period of up to 14 days in the "pedometer mode". [ActiGraph, [www.theactigraph.com](http://www.theactigraph.com)]. The ActiGraph is housed in a tamper proof water resistant case. The ActiGraph collects and records this information in its memory where it is then transferred from the GT1M and a Microsoft Compatible PC via a standard USB 2.0 interface. This connection also serves as the battery charger.

The GT1M activity monitor accurately and consistently measures and records time varying accelerations ranging in magnitude from approximately 0.05 to 2 G's. The acceleration signal, represented by an analog voltage, is sampled and digitized by a twelve-bit (12) Analog to Digital Converter (ADC) at a rate of thirty times per second (30 Hertz). Once digitized, the signal passes through a digital filter that band-limits the accelerometer to the frequency range of 0.25 to 2.5 Hz. This frequency range has been carefully chosen to detect normal human motion and to reject motion from other sources. The digital filter yields an output signal that responds linearly to changing accelerations within the pass band. Each sample is summed over a user specified interval of time called an 'epoch'.

The primary hardware components of the GT1M include a 16-bit microcontroller with on chip 12 bit ADC, 1 Megabyte (MEG) of NON VOLATILE FLASH memory, a solid-state accelerometer, voltage regulator, and a battery charger. A rechargeable 3.7V single prismatic cell Lithium Ion/Lithium Polymer battery supplies power. Battery life, defined as the time between battery charges, is in excess of fourteen days.

### Battery

The GT1M's rechargeable Lithium Ion battery is capable of providing power for fourteen (14) days without a recharge. Recharging is automatic and is accomplished by connecting the GT1M to any standard USB port. Charging time will depend on the battery life, but will typically not exceed three hours for a fully depleted battery. Once the battery is completely charged, the red LED light inside the ActiGraph will remain lit.

Note: If a PC is not available or if multiple ActiGraph's need to be recharged, a self-powered USB hub can be used. By using this method, it is possible to daisy chain hubs such that 127 GT1Ms can be recharged at once.

**\*If charging multiple GT1Ms by way of a USB hub, it is recommended that the hub not be connected to the computer. If connected to the computer, each GT1M connected will attempt to communicate with the computer and could potentially cause instability issues with the computer.**

### Data Storage

The ActiGraph GT1M contains 1 MB (one megabyte) of non-volatile FLASH memory for data storage, providing 512,000 memory slots for data storage. This will support 345 days of Activity Data or 172 days of Activity Data and Step Count Data to be recorded when the standard one-minute Epoch Period is used.

The following formulas can be used to determine the number of minutes, hours or days of data collection the ActiGraph GT1M, based on selected Epoch Period, will support.

Minutes = (512,000 x Epoch Period in seconds)/ 60

Hours = (512,000 x Epoch Period in seconds)/ 3600

Days = (512,000 x Epoch Period in seconds)/ 86,400

Note: Divide the resulting number by 2 if Step Count Data is collected.

The storage capacity of the ActiGraph GT1M exceeds the battery life (single charge). In most cases, data will be downloaded from the ActiGraph GT1M during each battery charging. However, the user has the option to wait until a later date to download the data.

### USB connection

The GT1M utilizes an industry standard USB 2.0 interface for both data transfer and battery charging. Data transfer rate is set to 115,200 bps with no parity, one (1) stop bit, eight (8) data bits and no handshaking.

**MINIMUM SYSTEM REQUIREMENTS**

Operating System: Windows 2000 Professional with SP4 / XP Home or Professional Edition  
Internet Access

FULL ADMINISTRATOR RIGHTS (see your IT Department)

Microsoft Office with Excel 2000/XP in English US or English UK in order to analyze data

Graphics: at least 256 colors; Small Fonts

Screen Resolution: 800x600 or 1024x768

Serial Port or USB Connection (Adapter Required)

Processor Speed: 300MHz Pentium

Memory: at least 32MegaBytes

Hard Drive: at least 32Mb available

The GT1M has five distinct operational modes. They consist of Active, Low Battery, Halt, Recovery, and USB/Charging.

***Active***

Active mode is the normal operating mode of the GT1M. During this mode, the device is on, collecting data.

***Low Battery***

The GT1M enters the Low Battery mode automatically when the battery voltage drops below a factory programmed threshold. It is identical in behavior and action to the Active mode, except the LED flashes two times every three seconds<sup>1</sup>. Once the device has entered this mode, a battery charging sequence must be initiated within three and a half (3 ½) hours or the GT1M will enter the Halt mode.

***Halt***

In this mode, the GT1M will preserve the previously collected data, quit taking subsequent data, flash the LED three times every three seconds, and will enter a very low power state. The GT1M will enter Halt mode 3 ½ hours after Low Battery mode is entered if a battery recharge is not initiated. The device must be either re-initialized or restarted after Halt mode is entered if the user wishes to continue use of the GT1M. Note that if a recharge is not initialized in a timely manner, the battery will completely discharge. In this scenario, the device is rendered unusable until the battery is recharged.

***USB/Charging***

The USB/Charging mode is entered each time the GT1M is connected to a PC by way of the USB port. When in this mode, the GT1M will automatically stop taking data, and the battery will automatically begin charging (if needed). Assuming the ActiGraph drivers for the GT1M have been installed on the PC the user may communicate with the device via the application. If the GT1M is placed in Halt mode by the user (see “pushbutton” section) it will remain in Halt mode even after it is disconnected from the PC.

*LED Reference Chart*

<b>GT1M LED Flashing Reference</b>	
<b>GT1M Connected to PC</b>	
1 Flash	LiOn Battery is Charging
2 Flashes	LiOn Battery is Faulty
Steady On	Battery Charged
<b>GT1M Not Connected to PC</b>	
No Flashes (LED Off)	Actively Taking Data ("Flash Mode" Disabled)/User Turned Off/Battery Dead
1 Flash	Actively taking data ("Flash Mode" Enabled)
2 Flashes	Delay Mode/Battery is Low (check application for remaining battery life)
3 Flashes	Recovery Mode (Must be re-initialized)
<i>Note: The LED will ALWAYS flash to indicate LOW BATTERY (2 or 3 flashes as indicated in the table above) regardless of whether "Flash Mode" is enabled.</i>	

**Installing Actigraph software:** Exit all programs and restart your computer. Log into your computer as normal. After your computer has started again, insert the CD into your CD-ROM drive. The installation screen opens automatically if you have Autorun enabled on your system. If you have Autorun disabled or the installation menu does not start automatically, go to your Desktop on your computer and double click on "My Computer" Icon. Click on your CD Drive and then double click on the file "actiloader.exe".

1. Click on the Install Drivers Button. Follow the onscreen instructions for installing the necessary drivers for the ActiGraph.
2. Once the drivers have been successfully installed, click on the Install Software button and follow the onscreen directions.
3. Click on the Exit Button to close the Installation program.

## 10.2 Actiheart technical specification

The main component of the Actiheart is 7 mm thick with a diameter of 33 mm and houses a movement sensor, a rechargeable battery, a memory chip, and other electronics (**Figure 1**). A wire of approximately 100 mm length runs to a smaller (5 x 11 x 22 mm) clip. The total weight is 8 g. The Actiheart is capable of measuring acceleration, HR, HR variability, and ECG amplitude for a set time resolution. Available epoch settings are 15 s, 30 s, or 1 min. The memory capacity of 128 kb allows the user to store data for more than 11 days with an epoch setting of 1 min. Another recording mode stores acceleration (15 s epoch) and all inter-beat-intervals (IBI), i.e., the time-intervals between 'R' spikes of the QRS complex for approximately 24 hrs, and finally the non-integrated waveforms of acceleration (sampled at 32 Hz) and HR (sampled at 128 Hz) can be recorded for 13 min 38 s.

*Movement measurement:* Acceleration is measured by a piezo-electric element contained in the Actiheart with a frequency range of 1 Hz to 7 Hz (3 dB). This movement sensor generates a transient charge, when exposed to time-varying acceleration and thus produces a voltage signal, which is then converted into a binary signal by an 8-bit A/D converter. This results in 256 distinctive levels of acceleration (128 positive and 128 negative levels). The accelerometer has a dynamic range of  $\pm 25 \text{ m}\cdot\text{s}^{-2}$  ( $\pm 2.5 \text{ G}$ ) and its sensitivity per bit is  $0.2 \text{ m}\cdot\text{s}^{-2}$  (0.02 G). The instantaneous acceleration is quantified as numerical difference from zero acceleration in binary units, thus leaving a 2 bit ( $\sim 0.4 \text{ m}\cdot\text{s}^{-2}$ ) wide deadband. The binary signal is stored in a cache 32 times a second and summed up over the epoch. At the end of the epoch, the sum is divided by 16 and then again by 2,  $N$  number of times until the number is below 32. The resulting integer and  $N$  are then stored in a single byte (5 bits for integer, 3 bits for  $N$ ) in the non-volatile memory and the cache is reset to zero. The movement sums are then divided by the calibration factor for the particular Actiheart unit during download by the software. Actiheart units are calibrated by the manufacturer with sinusoid accelerations of  $\pm 1 \text{ G}$  (average  $\sim 0.7 \text{ G}$ ), obtained with a calibration frequency of 3 Hz.

*Heart rate measurement:* The Actiheart has a sensitivity of 0.250 mV. The ECG signal is electronically amplified by a factor of 900 (amplifier frequency response: 10 - 35 Hz). The resulting ECG signal is sampled at 128 Hz and each R-wave decaying edge is identified by using the average difference of ECG samples  $n_i$  and  $n_{i+1}$  and ECG samples  $n_i$  and  $n_{i+2}$ . The threshold detection sensitivity changes with the amount of movement detected. At the end of the epoch, the trimmed mean of the last 16 R-R intervals is calculated by ignoring values outside  $\pm 25\%$  of the initial mean. This is converted to beats-per-minute (bpm) and written to the memory at the end of each epoch. When the Actiheart is set up to record HR variability over the epoch, the two fastest and the two slowest inter-beat intervals occurring in that epoch are also stored. The measurable range of HR in the manufacturer specification is 31-250 bpm.

## 11. Data backup and transfer

Data should be backed up every day onto a CD. Also, the data should be transferred to an ftp site every month. Review Appendix 4 to see instructions for backing up and transferring the files to the ftp site. The files should be named using the following convention:

For Memphis: MEMAH $mmddyy$ .zip, (for the Actiheart data);  
and MEMAG $mmddyy$ .zip for the Actigraph data, where  $mmddyy$  is the date transmitted.  
For Pittsburgh: PITAH $mmddyy$ .zip, (for the Actiheart data);  
and PITAG $mmddyy$ .zip for the Actigraph data, where  $mmddyy$  is the date transmitted.

## 12. Quality assurance

### 12.1 Training and certification

The examiner requires no special qualifications or experience to perform this assessment. Training should include:

- Read and study manual
- Attend Health ABC training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

### 12.2 Certification requirements

- Complete training requirements
- Conduct exam on two volunteers while being observed by QC officer:
  - According to protocol, as demonstrated by completed QC checklist

### 12.3 Quality assurance checklist

- Actigraph computer set up done correctly for walk tests
- Actigraph placed on participant properly
- Actiheart computer set up done correctly for walks tests
- Actiheart electrodes placed horizontal in correct position on participant's chest
- Actigraph data from walk tests downloaded
- Actigraph correctly set up for free-living conditions
- Actiheart data from walk tests downloaded properly
- Actiheart correctly set up for free-living conditions

## Appendix 1 Participant waist monitor instructions



## Waist Monitor Instructions

1. Clip the Actigraph activity monitor to the belt provided and place it around your waist. Position the monitor so that it rests over your hipbone directly underneath your **RIGHT** armpit. If worn correctly, you should be able to see the sticker that says "top". Refer to picture for proper placement.
2. Keep the monitor on all day, including when you may take a nap.
3. You may remove the monitor when you go to bed at night, but remember to place it back on in the morning.
4. The waist monitor **MUST** be removed when bathing (either bath or shower) or when going swimming. **DO NOT GET THE WAIST MONITOR WET!**



If you have any questions  
please call:

---

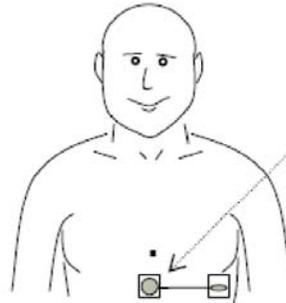
7/11/06

## Appendix 2 Participant chest monitor instructions



## Chest Monitor Instructions

The chest monitor will measure your heart rate and you will wear it to bed.



Main piece clips on the inner electrode.

Wire should be straight (horizontal) but not stretched.

1. From the main piece, a wire runs to a little button. These two pieces clip on to electrodes (stickers on your skin). **The chest monitor is waterproof and you may wear it during showering or swimming.**
2. The chest monitor is held to the skin by two stickers (electrodes), which are safe to wear. These will be placed on the lower left side of your chest during your visit, but should they for any reason become detached, please place new electrodes in the same place, as shown in the diagram below.
3. Before application, the skin must be prepared in the following manner: Clean the skin and dry thoroughly with a clean towel or paper towel. Please do not use skin lotion where the electrodes are placed. Attach the main round piece of the monitor and the small piece of the monitor to the stickers (electrodes), you will need to press the little tabs on the edges of the pieces towards the center of the monitor to allow you to clip it onto the electrodes.
4. You may replace electrodes as often as you like with the electrodes provided by the clinic. Follow the skin cleaning procedure described above before you apply a new set of electrodes.

7/11/06

Appendix 3 Year 10 Energy Expenditure Telephone Follow-up Form

	HABC Enrollment ID #	Acrostic	Date Form Completed			Staff ID #
	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
			Month	Day	Year	

**YEAR 10 ENERGY EXPENDITURE  
TELEPHONE FOLLOW-UP**

Hello. My name is <insert interviewer's name>. May I please speak to <insert participant's name>? I am calling from the <insert name of institution> to thank you for participating in the Health ABC energy expenditure substudy and to see how you are doing with the activity monitors that we gave you during your last clinic visit. The call will take about 5 minutes. Is this a good time to talk?

*If this is not a good time to talk, reschedule the interview. If participant agrees to interview, thank them for agreeing to participate in the Health ABC energy expenditure substudy and complete the interview.*

Thank you for agreeing to participate in the Health ABC energy expenditure substudy.

1. Have you had any problems with the activity monitors that we gave you during your visit to the Health ABC clinic?

Yes                       No                       Don't know

↓

2. Have you been wearing the waist monitor?

Yes                                       No

↓

↓

3. Have you been wearing the chest monitor?

Yes                                       No

↓



HABC Enrollment ID #	Acrostic
<input type="text"/>	<input type="text"/>

**YEAR 10 ENERGY EXPENDITURE  
TELEPHONE FOLLOW-UP**

4. Have you been wearing the chest monitor to bed at night?

Yes



Thank you. We just want to make sure that it is comfortable.

No



Could you wear it to bed? We would like to measure your sleeping heart rate.

5. Thank you again for agreeing to participate in this important Health ABC substudy.

Your next visit to the clinic will be on

/  /

Month

Day

Year

Please remember to bring both activity monitors with you to the clinic. Of course, if you have any questions, please feel free to contact the Health ABC clinic at <insert telephone number>.

**Appendix 4 Data Backup and Transfer**

Data should be backed-up onto a CD at the end of every day.

**Actiheart:**

Actiheart data is stored in an Access database located in C:\documents and settings\[user]\Actiheart data\HABC\_(site). The database should be copied onto a CD. Rename the file by adding a date stamp, eg., Actiheart data\HABC\_(site)03Oct06.mdb.

**Actigraph:**

Actigraph data is stored in individual .dat files for each participant. There will be two files for each participant (one with \_W extension, one with \_F extension). These are stored in C:\Program Files\ActiLife GT1M\Files. These must be copied individually onto a CD.

Once a month transfer the data on the secure web gateway. See instructions on next page.

## Data Transfer Using the Secure Web Gateway

The following instructions explain the process for transferring data securely to the SF Coordinating Center.

In your initial connection, you may be requested to download an ActiveX control. This takes only a few seconds and is required for access to the secure site.

### To Start:

In any browser go to site <https://ive.psg-ucsf.org/> and enter your username and password.

Prevention Sciences Group

Username:  Password:

Please sign in to begin your secure IVF session.

You will see a page similar to the page below. Most of you will only have a single role listed, although you may have more as does the user below. Select the appropriate project/task based on the data you wish to transfer.

### For the HABC/ Accelerometry data transfer: Choose HABC Accelerometry

Prevention Sciences Group

You have access to the following roles through the secure gateway:

- [FileUploadUsers](#)
- [EPREC Data Admin](#)
- [HABC\\_DFT](#)
- [CitrusUsers\\_NEWSE2](#)
- [CHIMES Data Transport](#)

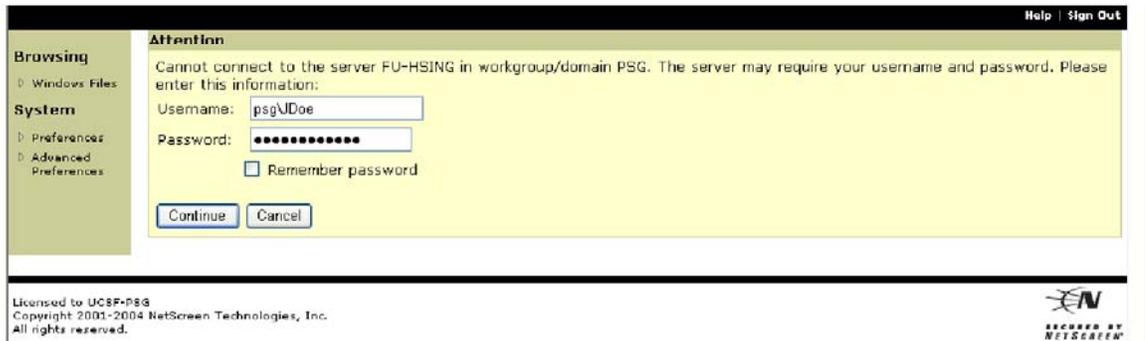
Each role allows you to access certain resources. Click on the role you want to join for this session. Please contact your administrator if you need help choosing a role.

This will take you to a screen similar to the one below. Choose the appropriate folder.

**For the HABC/ Accelerometry data transfer: Choose HABC Accelerometry**



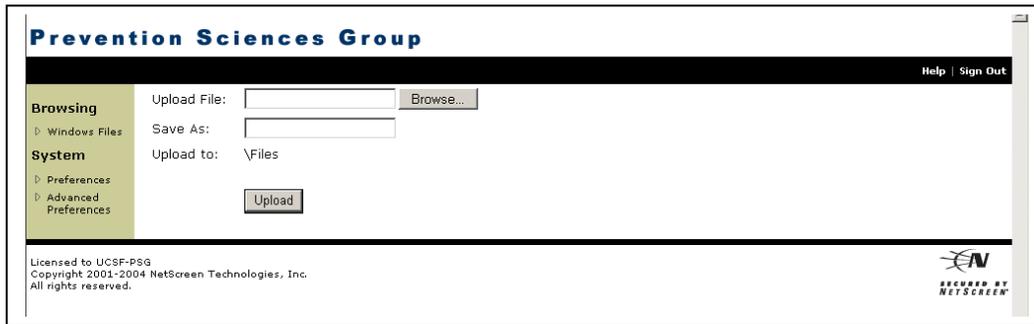
Some users may receive a request to type their username and password in again. Please do so, using the "psg\" prefix as shown below.



To upload data:

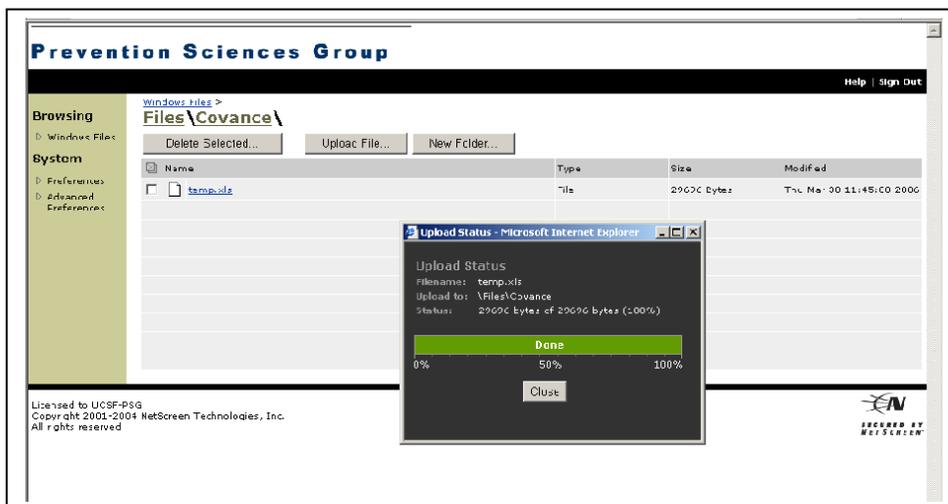
Select "Upload File"

Select "Browse" to locate the files for uploading. If you wish to rename the file, use "Save As" to enter the new name (otherwise this field can be left blank). Select "Upload".



Once the file has been transferred, the upload status should reflect "Done". Click "Close". You should now see the file you uploaded in the Name column. To upload additional files, click "Upload File" and repeat the above process.

Once you are finished, click "Sign Out" and close your browser.



Save as:

For Memphis: MEMAHmmddy.zip, (for the Actiheart data);  
and MEMAGmmddy.zip for the Actigraph data, where mmddy is the date transmitted.  
For Pittsburgh: PITAHmmddy.zip, (for the Actiheart data);  
and PITAGmmddy.zip for the Actigraph data, where mmddy is the date transmitted.