



# **The Actiheart Guide to Getting Started**

**Covering Actiheart & Actiheart Software**

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This equipment must be configured and operated in accordance with these instructions and in conjunction with:

***'The Actiheart User Manual'***

# Regulatory Information

## European Union

The Actiheart is NOT a Medical Device and is intended for the measurement of Energy Expenditure only. The Actiheart may be used for applications relating to Energy Expenditure and research related to HRV and is NOT indicated for use in clinical applications. Please contact CamNtech UK for advice on application if further clarification is required.

The CE mark is applied to the Actiheart to indicate conformity with the following Directives:



Electromagnetic Compatibility Directive 2014/30/EU.

RoHS2 Directive 2011/65/EU.

WEEE Directive 2012/19/EU.

## Manufacturer:

For assistance with set-up, use or maintenance of the Actiheart or to report any unexpected operation or events, please contact CamNtech using the details below or contact your local representative.

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# IMPORTANT SAFETY INFORMATION

## WARNINGS



- Contains Lithium Battery – DO NOT ATTEMPT TO DISSASSEMBLE: No user serviceable parts, danger of chemical hazard if battery is damaged.
- Not Defibrillation proof.
- Not indicated for use on areas of broken, damaged or irritated skin.
- Devices removed from subjects must be considered to be contaminated – see Appendix 1.

## Safety Classification Information:

- The Actiheart is **INTERNALLY POWERED EQUIPMENT**.
- The Actiheart mode of operation is **CONTINUOUS OPERATION**.

## Device and Packaging Symbols and Markings:

MEANING	SYMBOL	DESCRIPTION
General Warning		Potential hazard -refer to the warnings in the instructions for use (i.e. this user guide).
Consult Instructions for Use		This symbol indicates that important operational information is contained in the user instructions (i.e. this user guide).
Ingress Protection Rating	IPX7	The Actiheart is suitable for temporary immersion in water (up to 30 minutes at 1m).
Serial Number	SN	This number provides a unique identification for a particular device. Always quote this number when seeking technical assistance.
Catalogue Number	REF	This number identifies this particular variant of the product range.
Manufacturer and Date of Manufacture		This symbol is accompanied by a date in the format <b>yyyy-mm</b> which indicates when the device was manufactured. The symbol is also accompanied by the address and contact details of the manufacturer
Electrical Safety Classification		The Actiheart is a <b>TYPE B APPLIED PART</b> .

FOR FURTHER HANDLING & ENVIRONMENTAL INFORMATION PLEASE REFER TO APPENDIX 1

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## IMPORTANT BATTERY CARE INFORMATION!

The Actiheart device contains a miniature rechargeable battery which must be cared for correctly to maximise service life. Observing the following points will ensure maximum service life of the battery:

- Following download of data, always fully re-charge the Actiheart.
  - Following a full re-charge, ensure the device is 'powered down' (this will delete any data).
-

# 1. Introduction to the Actiheart System

## 1.1 Overview

The Actiheart is a compact lightweight device that:

a. Records:

- Heart Rate
- Physical activity
- Variability of R-R Inter-beat Interval (IBI) if a relevant recording mode is selected

b. Calculates energy expenditure based on the activity and heart rate data.

An Actiheart system consists of 3 components:

- The Actiheart device
- Actiheart Reader/Charger (USB connection for configuration & charging)
- Actiheart Analysis Software

## 1.2 Contraindications

The Actiheart is indicated for use on healthy, undamaged areas of skin. Where the subject has a history of skin irritation, a sample ECG electrode should be tested for skin irritation prior to commencing any recording.

## 1.3 Required Skills, Training & Knowledge of Intended Users.

It is intended that the device be administered only by duly qualified health care professionals, researchers and or trained nursing staff.

## 1.4 General Description of Use

The Actiheart is intended for the measurement of Energy Expenditure and for analysis of HRV in research applications.

The Actiheart measures the small electrical activity of the heart by means of two self-adhesive electrodes (not supplied by CNT) placed upon the chest of the subject. This Electrocardiogram (ECG) signal is processed within the Actiheart and, dependent upon storage mode selected, a full waveform, heart rate, Inter-Beat Interval (IBI) or a combination thereof are stored within an internal non-volatile memory.

The Actiheart is typically worn by the subject during their normal daily activities over a period of up to 21 days thus providing a benefit over lab based ECG tests which only provide a short 'snapshot' of heart activity.

Furthermore the Actiheart contains a miniature accelerometer which records the physical movement of the body. These data are recorded synchronously with the ECG derived data thus providing an ideal solution for deriving Energy Expenditure.

The Actiheart has an LED indicator on the front which flashes with a frequency that depends on the recording mode selected - see table below (for further details on the recording modes please see Section 8.1 on recording modes).

Epoch	Flashing Frequency				
	Short Term	Long Term	Advanced EE	Daily Living	Step Test
15 sec with IBI	Every beat	-----	Every beat		
15 sec	-----	Every 15 sec	Every 15 sec	-----	-----
30 sec	-----	Every 30 sec	Every 30 sec	-----	-----
60 sec	-----	Every 30 sec	Every 30 sec	Every 30 sec	-----

## 2. Installing the Actiheart Software

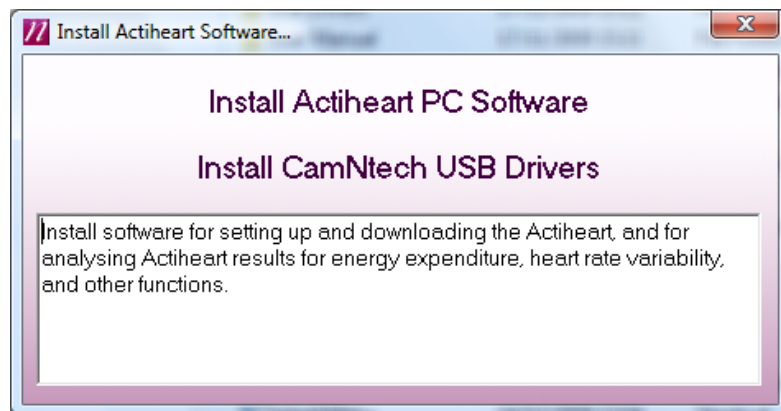
### 2.1 System Requirements

The Actiheart system is supplied with a CD ROM containing all of the components of the software package ordered and the drivers to support the hardware required by the system. The following are the minimum requirements of a host PC for installing the Actiheart software:

- Windows XP, Vista, 7 or 8 operating system
- 100 MB hard disk space
- USB port
- A CD-ROM drive or equivalent
- Graphics (1024 x 768 pixels minimum)
- Printer (if hard copy output is required)

### 2.2 Software Installation Menu

Place the CD-ROM into the drive; the software should start automatically and display the following installation menu:



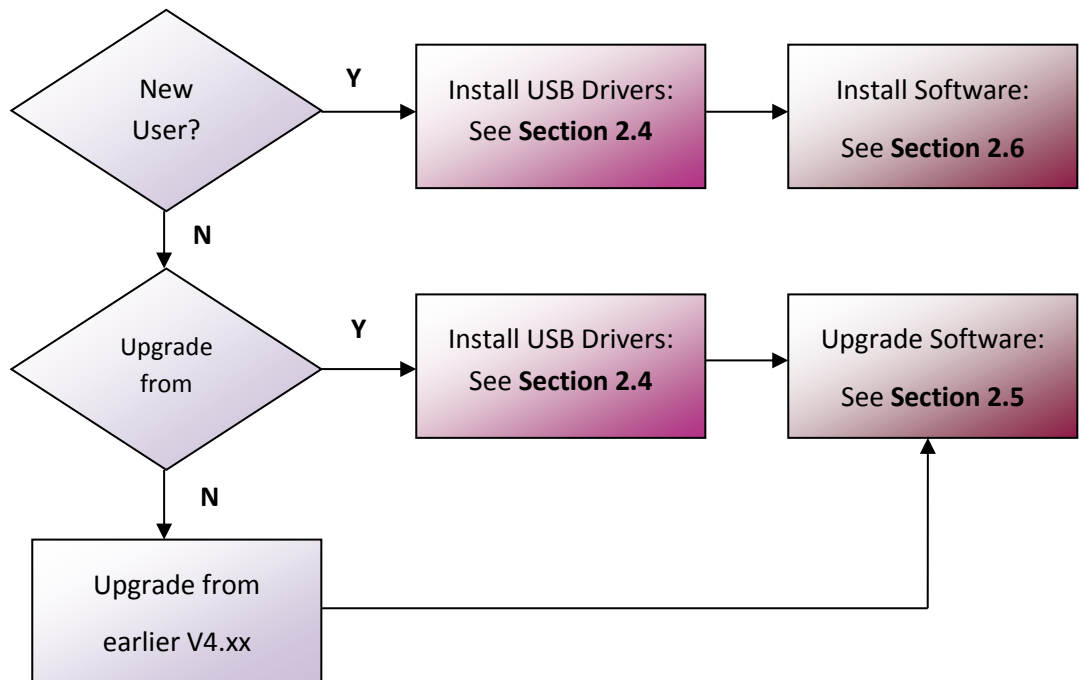
To install the software, click on 'Install Actiheart PC Software' and follow the installation process. Note that the installation will differ for new users and existing users as described in **Section 2.3** below.

If the above menu is not displayed, browse the CD and run the file 'SplashMenu.exe'.



## 2.3 Software & Driver Installation

The software and driver installation requirements will differ for **new users**, **existing V2.xx users** and **existing V4.xx users**. Use the decision tree below to select the appropriate installation route.

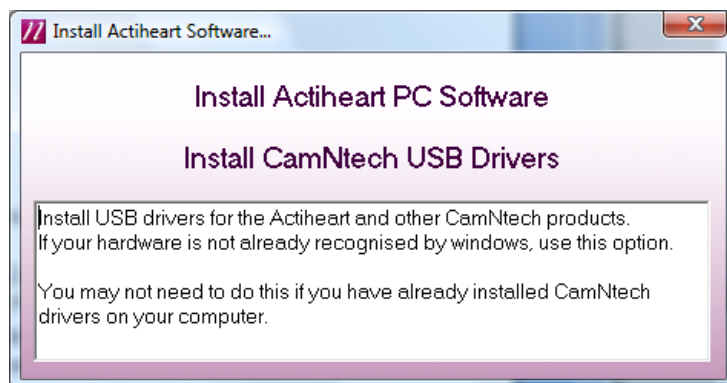


## 2.4 Installing the USB Drivers

This section applies to new installations and upgrades from V2.xx of the Actiheart Software.

Insert the supplied CD ROM into the CD/DVD drive on the host PC and plug the Actiheart reader/charger into a free USB Port. Depending upon the operating system in use and the current driver status, the computer may display a message saying 'Found New Hardware' and will then load the drivers with no user intervention. No further action will be required.

The Installation menu should be automatically displayed as shown below:



If the drivers loaded automatically, simply close this menu and the drivers should be ready to use.

If the drivers do not load automatically, or if you wish to make sure they install correctly, you should select 'Install CamNtech USB Drivers' and carefully follow the on-screen instructions. If you still experience problems with the USB drivers, follow the procedure 'Installing USB Drivers Manually', which is included in Appendix 3 of this manual.

Windows should automatically search the CD drive for the driver, but if it does not do so you will be required to 'Search manually' and then 'Browse' to point to the CD drive.

A screen may appear that tells the user that the driver is not digitally signed by Microsoft.

Select 'Continue Anyway' (Please note that this is NOT a problem and just means that the Actiheart version of the driver software has not been assessed by Microsoft. In fact the actual drivers are Microsoft approved). The drivers will be installed and the computer will then tell the user that the new hardware is ready to use. If you change the USB port that the reader is plugged into then the driver may be automatically re-installed by Windows. This is an automatic process and the user need take no action.

If you have any problems installing the drivers, please read the help document and download the latest drivers from <http://www.camntech.com/drivers>.

## 2.5 Users upgrading from an earlier version of Actiheart Software

Upon following the procedure described in **Section 2.6**, users upgrading older versions of software may be asked if they wish to repair or remove the existing version of the software when the new software installation is run for the first time. The option to **remove** should be selected and then the software installation run for a second time to install the new version as described in **Section 2.6**.

The following message may be displayed – click 'Run' to accept.



## 2.6 Installing the Software

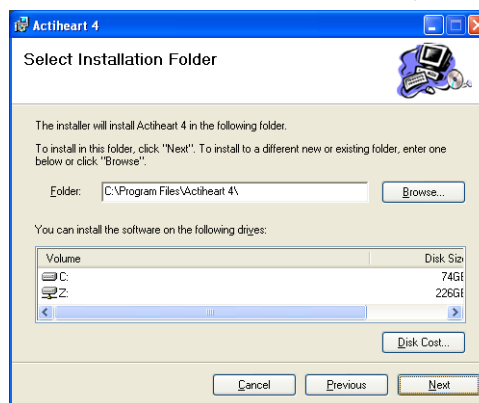
Insert the Actiheart CD which should automatically run the installation menu (see **Section 2.2**). Select 'Install Actiheart PC Software' from the menu and follow the on-

screen instructions as shown below. If the installation menu is not shown, use Windows explorer to browse to the CD and then double click on the file called 'Actiheart4.msi'.

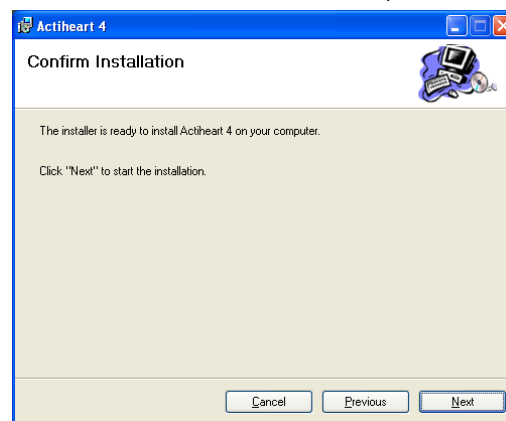
Follow the on-screen instructions to complete the installation.



You are required to accept the Licensing agreement for use of the Actiheart software



Select the destination folder or accept default (recommended).

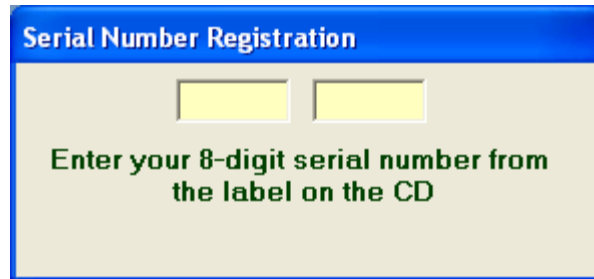


### **IMPORTANT !**

The Actiheart V4 software will be installed in a folder labelled Actiheart 4 in C:\Program Files. Any existing installation of V 2.x software will not be affected.

## **2.7 Using the Software for the first time**

Double clicking on the Actiheart icon on the desktop will produce the following screen asking the user to input a serial number for the software:



The image shows a Windows-style dialog box titled "Serial Number Registration" in a blue header bar. The main area has a light beige background. At the top, there are two empty yellow rectangular input fields. Below them, the text "Enter your 8-digit serial number from the label on the CD" is displayed in a green, bold font.

Into this screen, enter the 8 digit serial number that will have been supplied with the software on the front of the CD case. This serial number is unique to the user and will enable the user to obtain software support from CamNtech. Once this is done, the software is ready to use.

## 3.0 Charging the Actiheart

Before the Actiheart can be used, the user must ensure that it is fully charged. The charging function is accessed in the Utilities tab in the software. The Actiheart system is supplied with a combined reader/charger that allows an Actiheart to be set-up and read on one port and up to 3 Actihearts to be re-charged.

During charging, the reader/charger unit may be powered from the host PC USB port or from the supplied mains adaptor.

### **IMPORTANT**

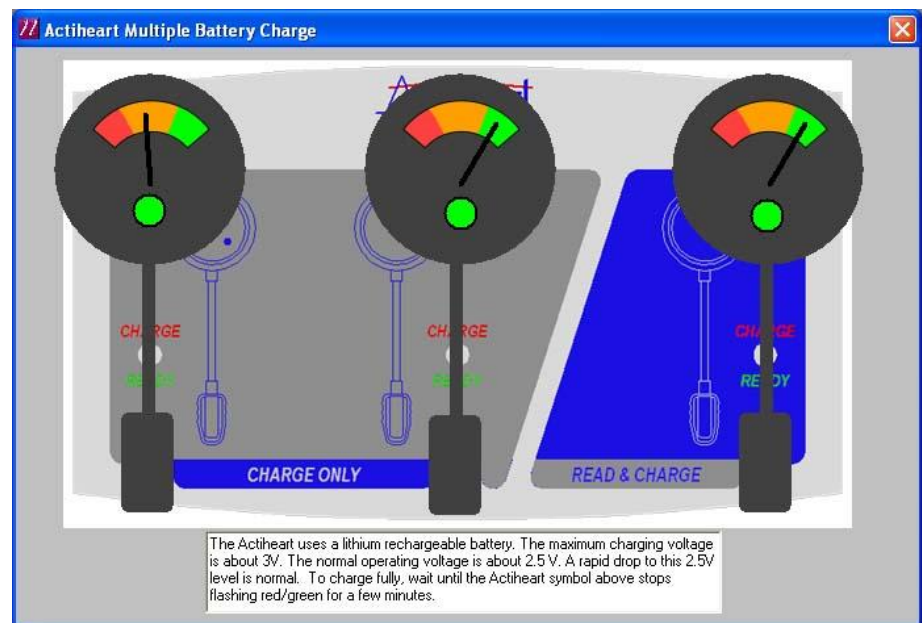
**After an Actiheart is read it should be powered down and then recharged as soon as possible either for storage or for making a new recording. Storage of the Actiheart with little or no charge will shorten battery life.**

### **WARNING**

**Charging an Actiheart will disable recording. Recorded data will not be lost. However any further recording will require a new setup to be initiated.**

### 3.1 Charging Actihearts from the PC

When Actihearts are to be charged from the PC, select 'Utilities' from the main screen then select the 'Recharge Actiheart' button. A screen similar to that shown below will be displayed:



If no Actihearts are placed on the Reader/charger the display will show – 'Searching for Actihearts'. As an Actiheart is placed in each location, it will be detected and the battery status will be displayed. The battery gauge provides an estimated indication of battery charge level/remaining charge time with the following interpretation:

The coloured bands in the gauge represent the voltage level in the Actiheart and correspond to the very approximate voltages and estimated charging times as follows:

Voltage	Colour	Expected charging time
<2.3	None (No Actiheart detected)	12 hours
2.3-2.4	Red	4 to 8 hours
2.4-2.6	Orange	2 to 4 hours
2.6-2.75	Green	1 to 2 hours
2.75-2.9V	Upper Green	Charged

The Actiheart uses a lithium rechargeable battery. The maximum voltage is 3.0V. However a rapid drop to 2.75 volts is normal. When fully charged the battery will last about 21 days when doing a long term recording. The battery life in the short term recording mode is only 4 days due to the LED flashing with every heart beat.

### **IMPORTANT NOTES ABOUT USB CHARGING:**

- Many Computers have power saving functions which shut down all or part of the PC after a period of time – this will stop the charging of the Actiheart.
- Un-powered USB hubs can have an output voltage below that required for Actiheart charging.
- For reliable charging of the Actiheart, CamNtech recommend using the supplied mains power supply (see 3.3 below).

### **3.2 Testing the Actiheart Battery**

It is possible to test the capacity of the Actiheart battery to determine the maximum length of recording. As with all rechargeable batteries, the Actiheart battery capacity will reduce with age/usage. To test the battery, first fully charge the Actiheart overnight using the mains power supply (see section 3.3 below). Place the Actiheart onto the reader and click 'utilities' then 'test & maintenance'. Click on the battery test tab and then click the 'run full battery test' button. Note that this will take several hours to complete and that the Actiheart software cannot be used during this period. At the end of the test the following message will be shown:

"Estimated battery level was nnn% of nominal capacity."

Where 'nnn' is a number from 0 to 100% and 21 days is the nominal capacity. The Actiheart should be fully recharged overnight using the mains adaptor following the battery test (see section 3.3 below).

### **3.3 Charging the Actiheart using the Mains Power Supply**

The Actiheart Reader/Charger is supplied with a 5V USB mains power adaptor which is safety approved to EN60950-1 and EMI standard EN55022 (also FCC part 15, Class B). This adaptor is supplied with appropriate adaptors to suit mains outlets in most world regions.

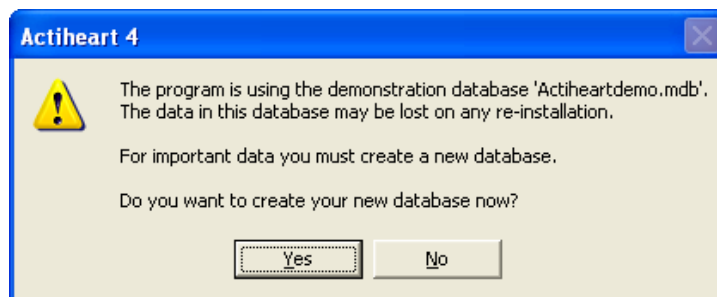


1. Select and fit appropriate ac input socket adaptor for country of use.
2. Plug the USB cable from the reader/charger directly into the USB type A socket on the mains power supply.
3. Plug the mains power supply into the wall outlet.
4. Place Actiheart onto Reader/charger.
5. The status LED will remain red while the Actiheart is charging.
6. The status LED will turn green when charging is completed.
7. Note that it is normal for the LED to alternate between red/green towards the end of the charging period; this ensures that the Actiheart battery is kept fully charged.

## 4.0 Setting up a Database

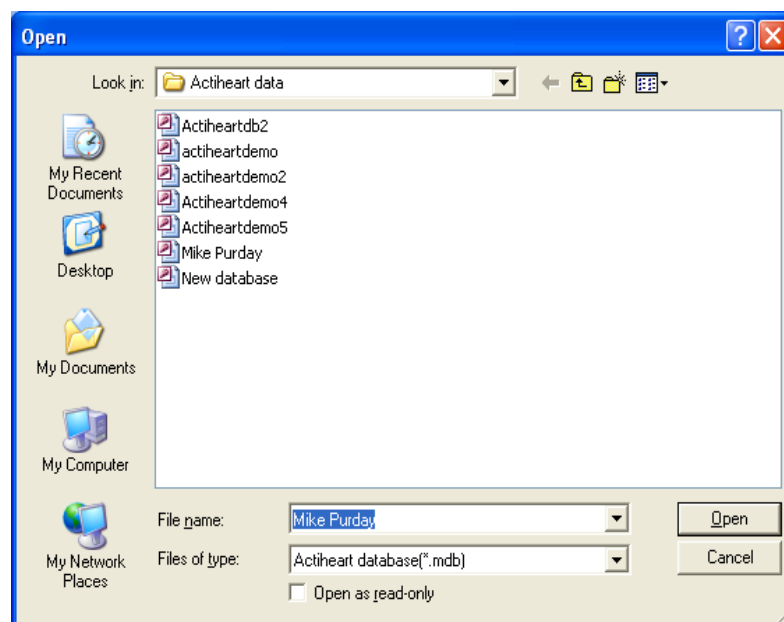
All data used in the Actiheart system is stored in Microsoft Access databases. For full details of the databases used by the system, please see the chapter in the main manual on databases.

Once the software and drivers for the USB Reader have been installed, the Actiheart software will be installed by default in the following folder: C:\Program Files\Actiheart. A shortcut icon will also have been created on the desktop. If this is double clicked the message below appears and a database called ActiheartDemo containing a selection of short term and long term recordings is installed in C:\Documents and Settings\Username\Actiheart Data\.



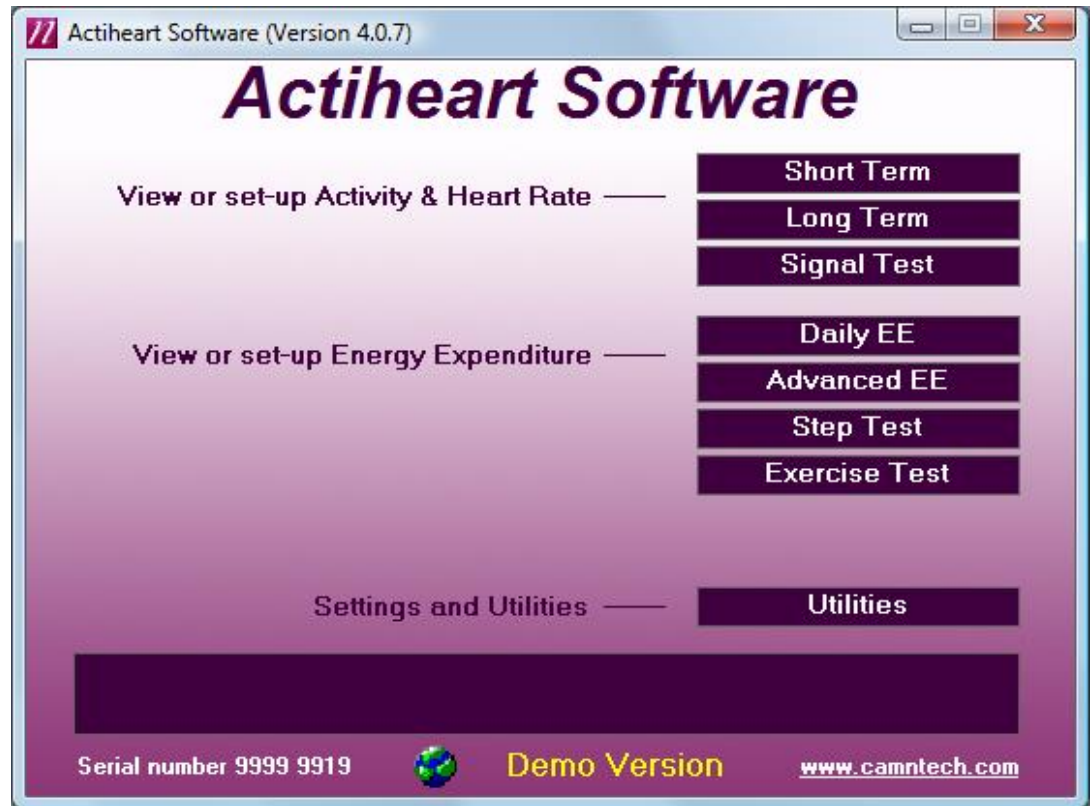
### 4.1 Reason for the Creation of a new Database

The reason why the software recommends that a new database is created is that, if in the future a new version or update of the software is installed, this may overwrite any data stored in the demo database. If 'Yes' is selected at this point then the following screen is shown:





This new database will then be stored in the following folder: *C:\Documents and Settings\Username\Actiheart Data\database name'.mdb*. When 'OK' is selected, the following screen is produced:



The user is now in a position to begin using the Actiheart and software.

### ***IMPORTANT***

**The Actiheart Demo database first installed will not be overwritten when a later version of the software is installed.**

## 5.0 Preparing for a Recording

### 5.1 Selection of appropriate ECG Pads and Preparation of the Skin

#### Range of Pads

Before the Actiheart can be used, the subject has to be fitted with ECG pads to clip the Actiheart to. Selection of appropriate pads is difficult because there are many different types of skin and different skin types react differently to different pads.

There are a huge variety of electrode pads available. CamNtech has tried many but suggest as a starting point the following (**NOTE:** information is intended for general guidance only and does not constitute clinical advice or endorsement of any particular product – the user is responsible for the suitability of the electrodes)

#### Short Term Recording Pads

These tend to be foam backed pads with high adhesion.

- 3M Red Dot 2560. These are extremely adhesive pads that provide very good adhesion for short term use. The downside of this is that on removal, CamNtech has noticed some gel residue left on the skin. They are not really suitable for long term use.

#### Long Term Recording Pads

These tend to be micro porous cloth backed pads which allow the skin to breathe during longer term recordings.

- Unomedical Unilect Long Term 4620M. These are cloth backed pads and are small in size. These pads would be the most suitable type for paediatric use.
- Unomedical Unilect Long Term 4060M. These are similar to the 4620M but larger in size. They have a raised section of the backing plastic that is designed for use in skin preparation.
- Bio Protech ECG electrode E5 Tele815. These are very similar in construction to the Unilect Long Term 4060M pads. They also appear to be good value financially.

### 5.2 Skin Preparation

In all cases, adequate skin preparation is vital to the success of any recording. The R wave signal that the Actiheart requires is usually low and adequate skin preparation is required to ensure that the levels captured by the device are high enough and consequently that noise levels are low enough for a good quality recording.

The purpose of skin preparation is to remove the top layer of the skin, the Stratum Corneum and to scratch the surface of the next layer of skin down, the Stratum Granulosum. The recommended skin preparation procedure is as follows:

## Procedure for Skin Preparation

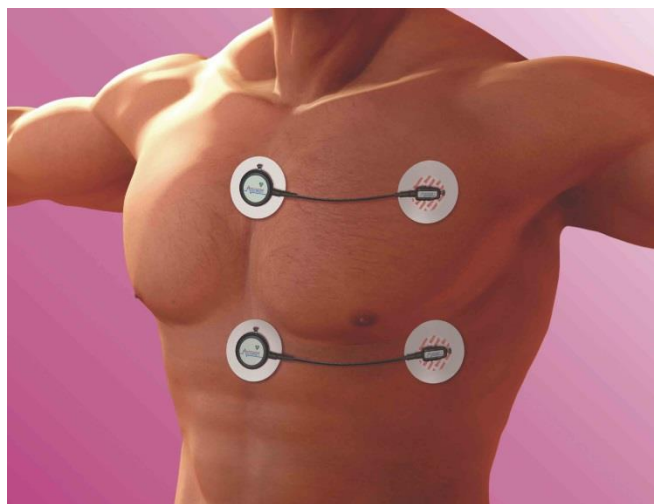
Clean the skin to ensure that it is clean and oil free. This can easily be achieved by using warm water and soap or other detergent. Alcohol should not be used as this can potentially cause skin irritation which needs to be avoided.

Use an abrasive material to remove the top layer of skin. The ideal preparation material is a Cardio prep which is similar to very fine emery paper. One that CNT has tried with success is the Cardio Prep from Unomedical, stock code 2121M. These are low cost adhesive backed skin preparation pads which are supplied in packs of 50. In the absence of an abrasive material a suitable alternative is to rub the skin with a towel or other cloth. If this is done it should be vigorous enough to remove the top layer of skin. Some redness will be seen and this is normal and should not be cause for concern.

Apply the chosen pads to the chest. This is best achieved by placing the pad in the centre of the chest and locating the Actiheart on it. Attach the second pad to the other clip on the Actiheart and use the wire to position the second electrode. Further details on positioning of the Actiheart are shown below:

## 5.3 Electrode Positioning

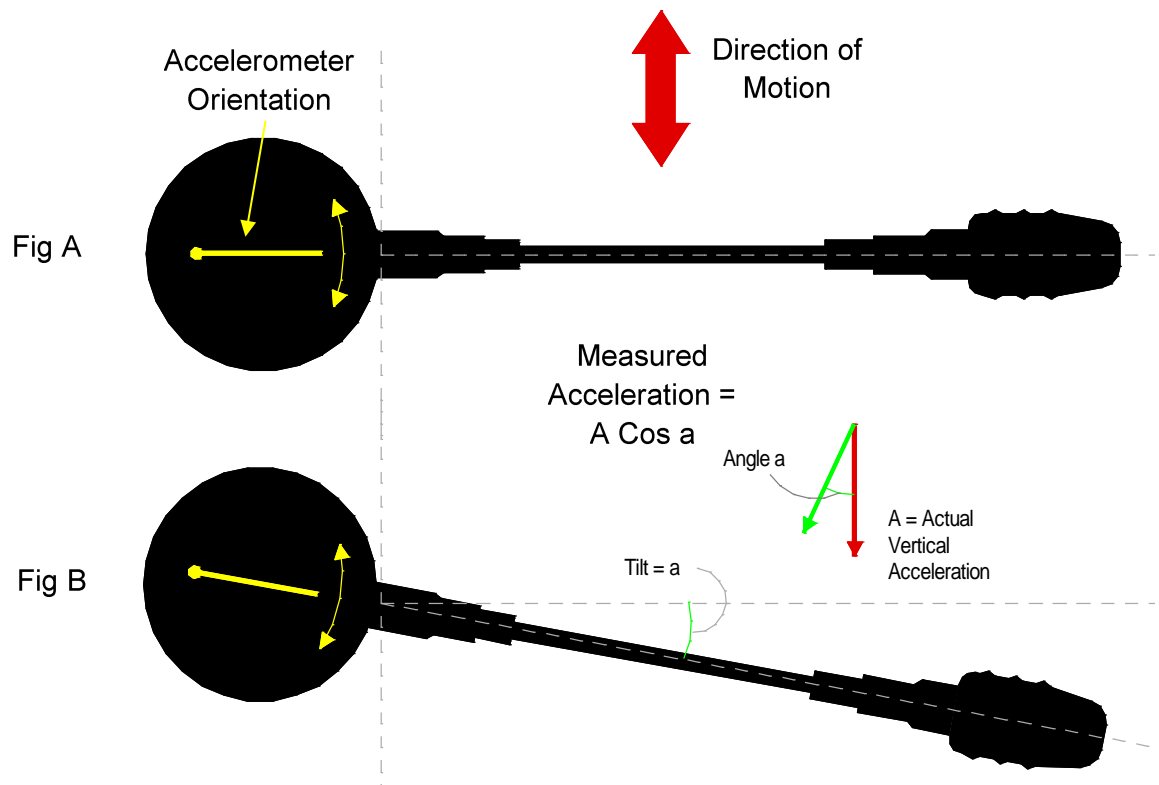
The best ECG signals can usually be picked up by placing the round end of the Actiheart unit in a position midway between and below V1 and V2. The other electrode can be placed at V4 or V5. A position on the upper chest shown in the diagram below can also be used. This may be either more or less acceptable for female users depending on their breast size. According to Rautaharju et al.<sup>1</sup> breast tissue appears to have a practically negligible effect on ECG amplitudes, and in women, the placement of chest electrodes on the breast rather than under the breast is recommended in order to facilitate the precision of electrode placement at the correct horizontal level and at the correct lateral positions.



**1. Rautaharju PM, Park L, Rautaharju FS, Crow R.** A standardized procedure for locating and documenting ECG chest electrode positions: consideration of the effect of breast tissue on ECG amplitudes in women. J Electrocardiol. 1998 Jan; 31(1):17-29.

## 5.4 Positioning of the Actiheart

For good accurate measurement of activity the Actiheart needs to be placed with the cable exit as near the horizontal as possible. A 10 degree tilt (Fig. B) gives a theoretical activity reading error of 3%. A 45 degree tilt would mean that the detected magnitude is 30% less than the actual. The electrodes should be positioned so that the cable is stretched to its full length (Fig. A). This will avoid unnecessary rotation of the sensor in situ. The diagram below shows an illustration of this:



For more information about the implications of electrode placement on physical activity estimates please refer to:

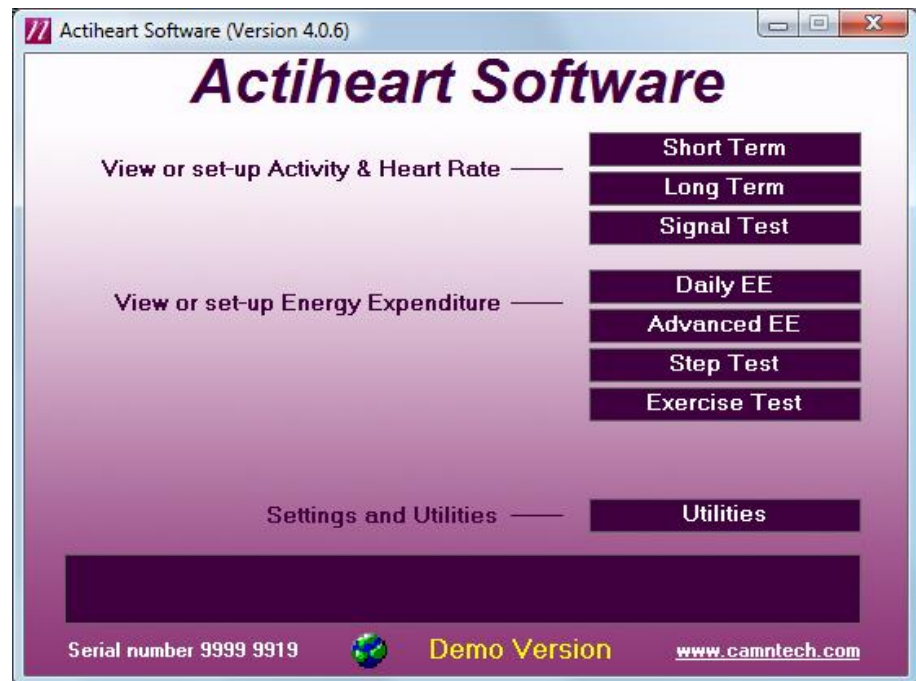
**Søren Brage, Niels Brage, Ulf Ekelund, Jian'an Luan, Paul W. Franks, Karsten Froberg, Nicholas J. Wareh,** *Effect of combined movement and heart rate monitor placement on physical activity estimates during treadmill locomotion and free-living.* Eur J Appl Physiol (2005), DOI 10.1007/s00421-005-0112-6.

## 5.5 Use of the Actiheart in Water

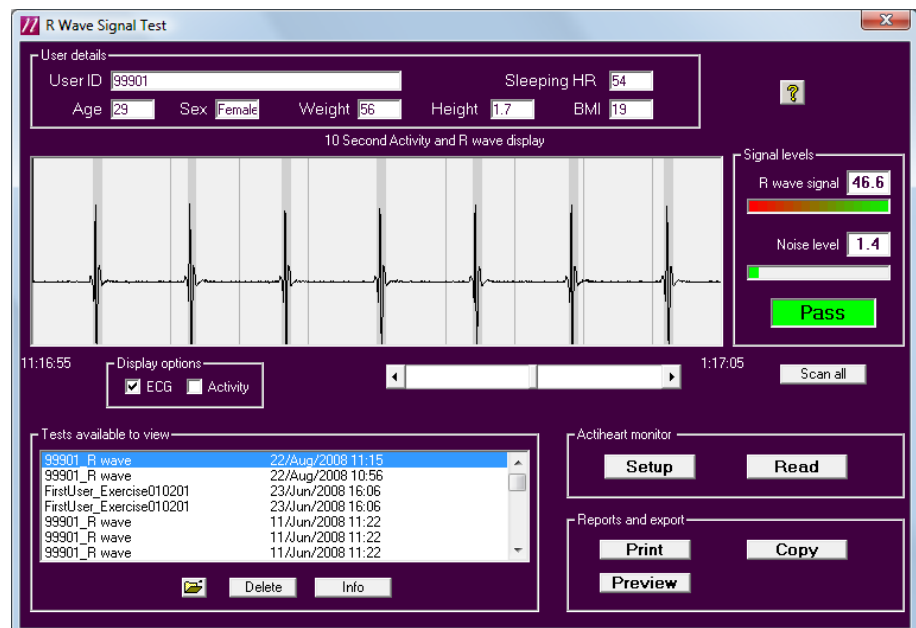
Although the Actiheart is waterproof, use in the water, for example when swimming, can result in movement of water and the Actiheart, which will result in noise on the ECG signal. This can be avoided by covering the Actiheart unit completely with a swimsuit which will isolate movement over that area, or large waterproof plaster or equivalent whilst swimming.

## 6.0 Setting up a User in the Database

Once the subject has been fitted with ECG pads and before a recording is started it is necessary to set up the user in the selected database. A user can be set up in any of the recording modes but prior to commencing a long term or short term recording it is recommended that the level of signal being picked up by the unit is checked by recording a short signal test so this is usually the most appropriate place to set up a new user.



Click on the 'Signal Test' button. This brings up the screen shown below:



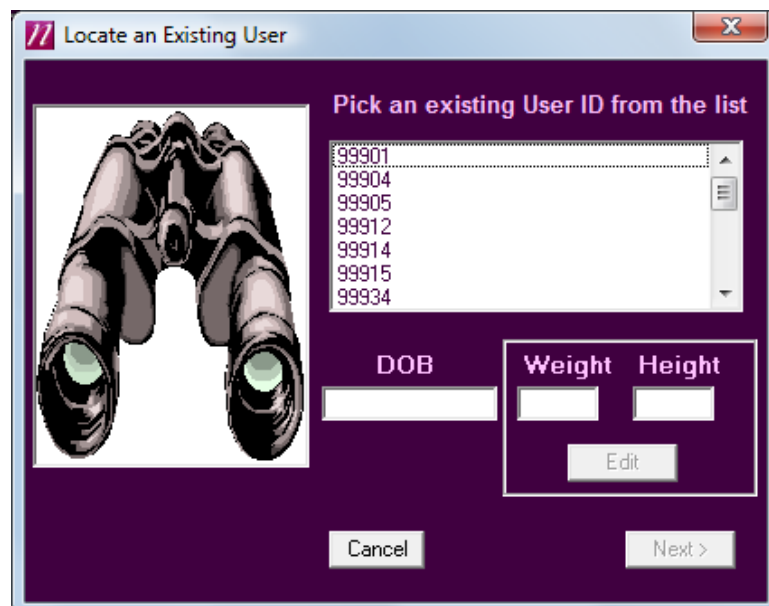
Clicking the 'Setup' button produces the following screen:



Clicking 'Find' allows the settings for an existing user to be retrieved. Clicking 'Add New' allows the details for a new user to be added.

### 6.1 Selecting an existing User from the Database

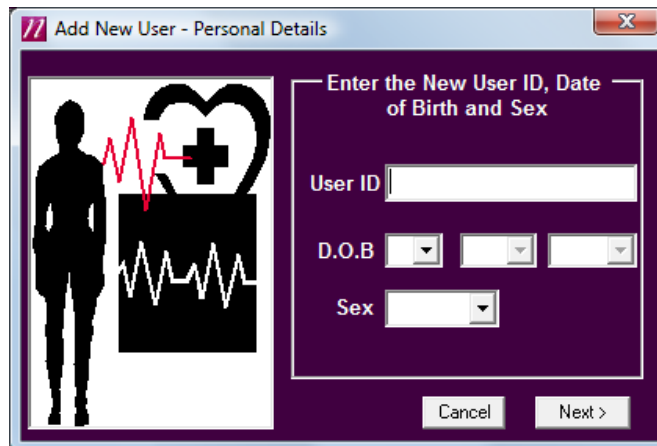
If the user is already present in the selected database, selecting 'Find' will produce the following screen:



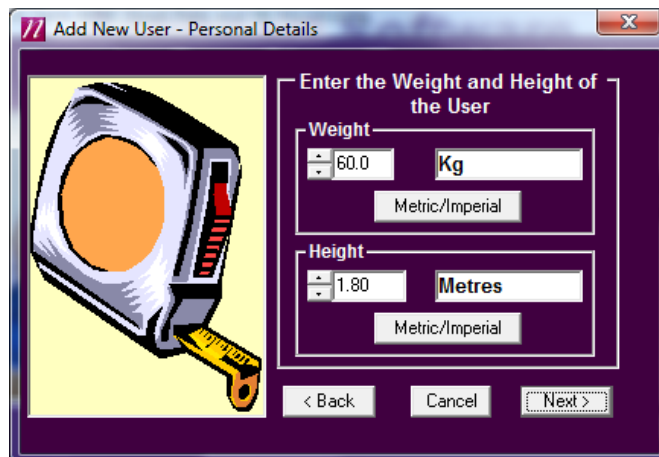
The required user can now be selected from the list and the recording can be set up as detailed in **Section 7**.

## 6.2 Setting up a new User

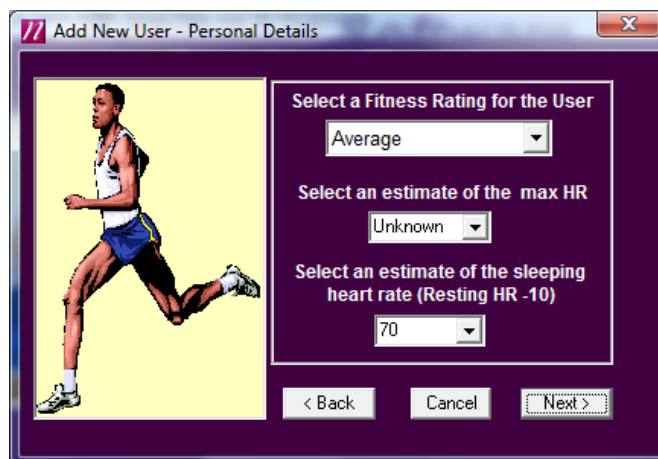
If a new user is being set up, selecting 'Add New' produces the following screen:



The user ID, date of birth and sex are entered in this screen. Selecting 'Next' produces the following screen:



The weight and height of the user are selected from this screen. It is possible to input the user details either in Metric or Imperial units. The increments are 1cm and 0.1 Kg. Once entered, selecting 'Next' produces the following screen:



This screen allows selection of a fitness rating and an estimate of the maximum heart rate and sleeping heart rate to be entered. Once this is done, clicking 'Next' shows the message "Do you want to save this user data?".

Selecting 'Yes' produces a conformation message that the new user has been saved correctly into the database.

Click 'OK' to finish and exit.



## 7.0 Checking Signal Integrity and Performing a Test Recording

Before starting any multi-day recording it is recommended that a short signal test be carried out. This is to check that the level of R wave signal being picked up by the Actiheart is adequate and helps to avoid serious recordings being marred by artefacts due to either high noise or a low R wave signal.

The test involves making a short recording and analysing the signal using a built in utility called **Signal Test** which provides a Pass/Fail indication of whether the signal is acceptable. For full details on analysing a signal test recording please see the main **Actiheart User Manual**.

Since artefacts are often aggravated by poor adhesion of the pads with the skin and movement of the pads relative to the skin during exercise **it is important that:**

- a. The pads are worn for at least 30 minutes before conducting the test.
- b. The subject moves around and even jogs on the spot for a few minutes during the test.

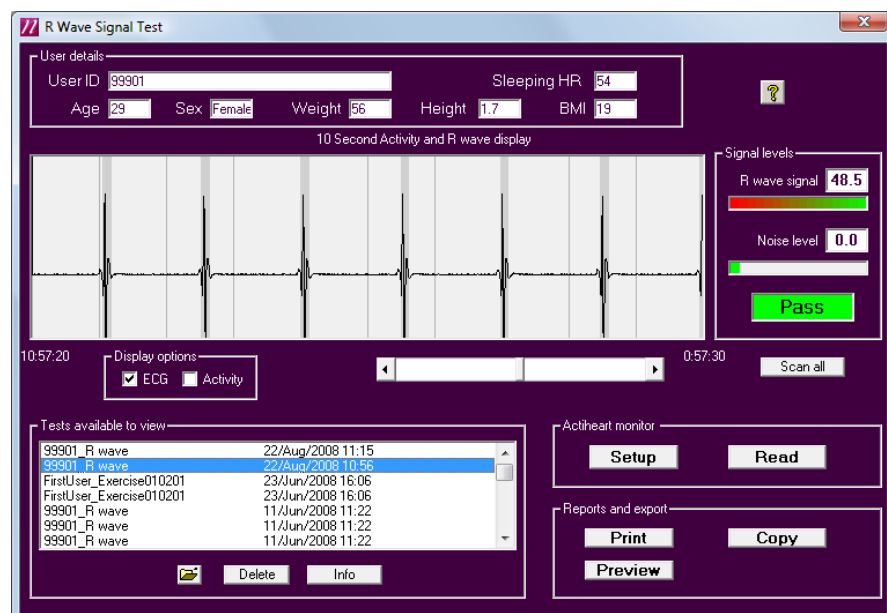
The user has the ability to record for up to 53 minutes in this mode although four or five minutes will be sufficient.

The method described below for making a recording and downloading the data to the PC for analysis applies equally to the various recording modes described in the User Manual and summarised in **Section 8** of this guide.

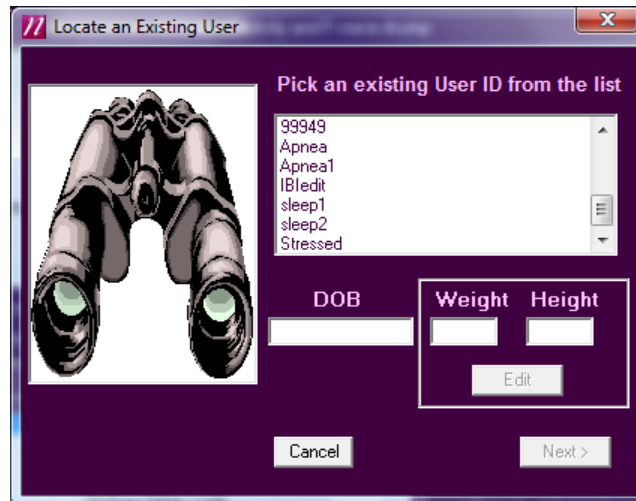
### 7.1 How to set up a Signal Test

Place the Actiheart onto the Reader. The face of the Reader indicates which way round the Actiheart should be placed.

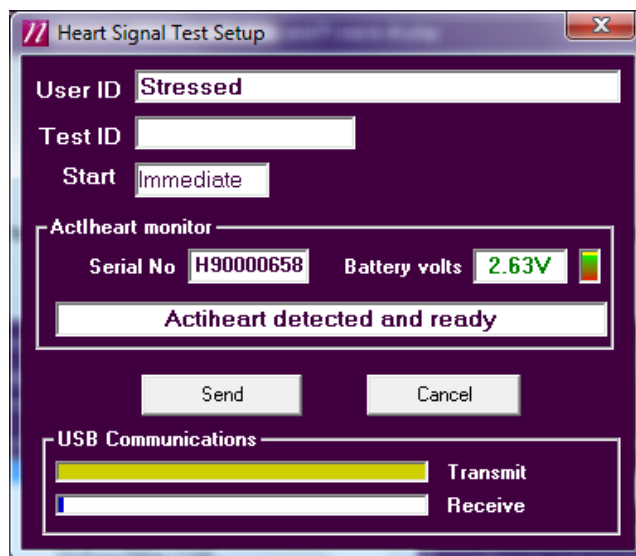
From the 'Utilities' tab, select the 'Actiheart' tab then click the 'Signal Test' button to show the screen shown below:



Selecting 'Setup' brings up a screen allowing where you may add a new user by clicking 'Add New' (see section 6.2 for details) or find an existing user by clicking 'Find'; the following screen will then be displayed:



To select the required user, simply click on the user ID in the list. The user details will be displayed in the DOB, weight and height boxes. Click 'Next' to proceed to the setup screen as shown below:



You may enter an additional 'Test ID' (i.e. to identify this particular test for this user). Click the 'Send' button to write the setup information into the Actiheart. You will see a confirmation message when this is complete.

### WARNING

**The Actiheart MUST be removed IMMEDIATELY from the Reader. Failure to do so may lead to the Actiheart being unable to record in which case the setup procedure would need to be repeated.**

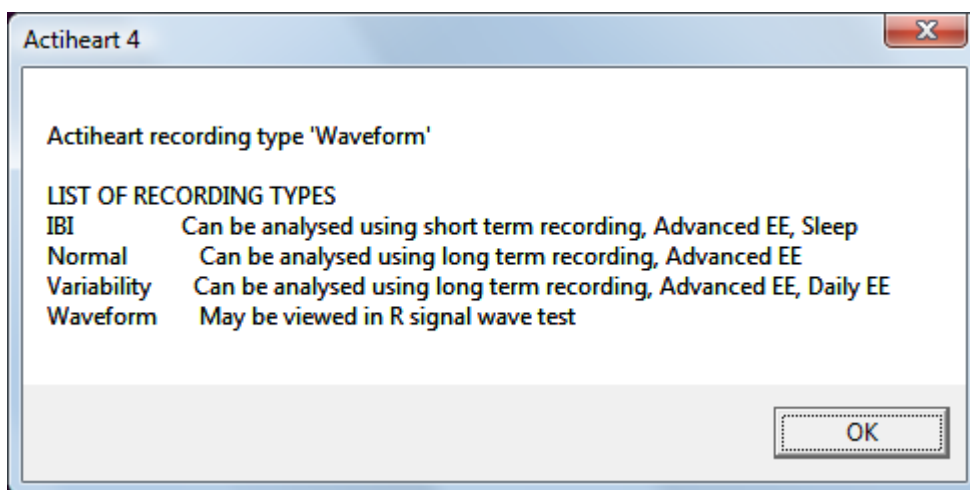
Once the Actiheart is removed from the Reader, it can be placed onto the user by clipping onto the previously attached pads.

## 7.2 Downloading recorded Data from the Actiheart

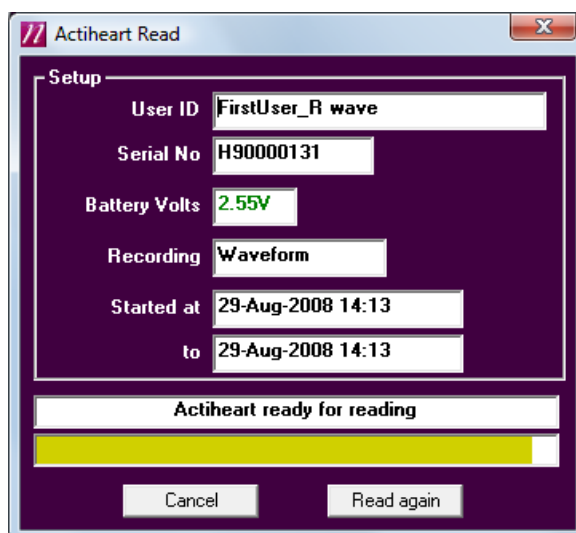
Once the subject has worn the Actiheart for the required length of time (making sure that the subject has moved around to fully test pad contact), the data can then be downloaded to the PC.

After placing the Actiheart on the Reader there are two options for reading the data. The data can either be read from the recording mode/ application that the unit was set up in e.g. the Signal Test in this instance or alternatively the general Read function can be selected after clicking the 'Utilities' button from the main screen.

Selecting the general read function produces the following screen detailing the different recorded file formats and where in the software they can be analysed. This message does not appear if the Actiheart has been set up and read from within a particular application or using one of the specific recoding modes detailed in **Section 8 of this guide**.

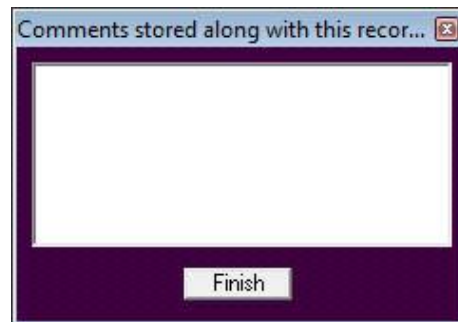


Clicking 'OK' then commences the download of the data and the screen below is shown:



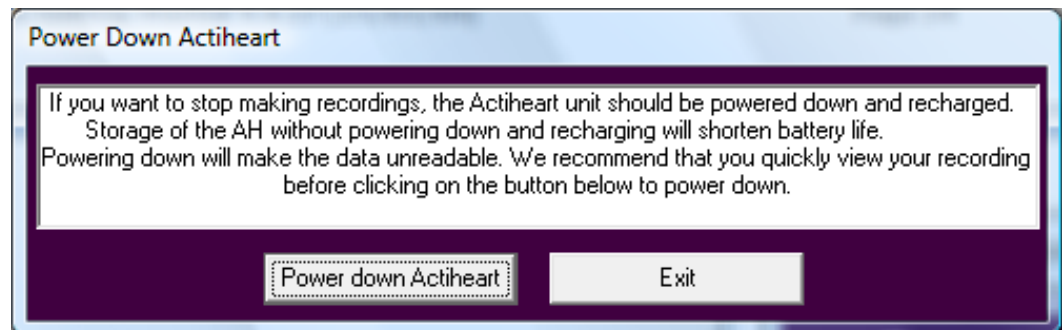
The data recorded on the Actiheart is then downloaded to the PC via the Reader/USB interface. Download progress is indicated by means of the yellow progress bar. Once this is finished, the following screen is shown:

### 7.3 Storing Comments with the Data



This allows the user to add comments on the recording which will be stored along with the data. This could be, for example, the type of ECG pads that were used for the recording etc. Once any comment required is entered into this screen, pressing finish saves the data into the selected database and produces the following message:

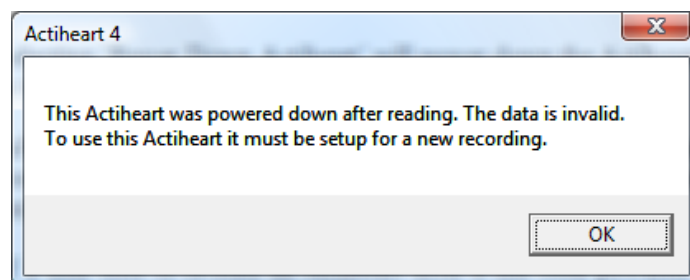
### 7.4 Powering down the Actiheart



Selecting 'Power Down Actiheart' will power down the Actiheart and the data stored in the unit will then become unreadable.

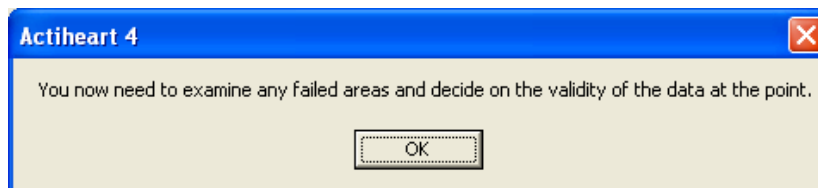
**After an Actiheart is read it should be powered down and then recharged as soon as soon as possible either for storage or for making a new recording. Storage of the AH with little or no charge will shorten battery life.**

If a user tries to re-read an Actiheart after it has been powered down the following message will be displayed



## 7.5 Analysing the Signal Quality

Once the recording has been downloaded with the correct user ID and in the correct database, it can be analysed for the quality of the signal. Select the recording requiring analysis from the list of available recordings and click 'Scan all'. This will examine the recording in detail and the message shown below will then be displayed:



Any areas of the recording that have failed the test are displayed in red on the scan as shown in the screen below:



It should normally be obvious from the recording why an area of the recording has failed, for example due to movement artefacts. If it is not obvious, selecting the 'Display Activity' box will show the activity trace recorded with the R wave and this may help the user identify if the problems have been caused by movement. If a recording has failed overall, this usually means that either the noise level is too high or the R wave is too low. The following tests are applied to determine this:

- $16 - [\text{signal/noise} \times 2] < 7$
- $\text{signal / noise} > 4.75$
- $\text{signal} > 9.6$  but this is normally true anyway.

In either case, it is necessary to check the position and impedance of the ECG pads. For further details on the selection of ECG pads and skin preparation, please see **Section 5** of the Guide to Getting Started.

## 8.0 Summary of Recording, Reading and Analysis Options

Once a **Signal Test** has been successfully completed the collection of data can then commence. It is important to choose the recording mode taking into account:

- a. Type of data required. Activity and average heart rate are always recorded but the Interbeat Interval (IBI) is not.
- b. The recording resolution (epoch), which is fixed in some modes and selectable in others.
- c. The duration of the recording, which is dependent on both a) and b) (see table below).
- d. The type of analysis required.

### 8.1 Set-up Activity and Heart Rate Options

Recording can be set up for one of two main objectives namely Activity/Heart rate and Energy Expenditure.

#### 8.1.1 Short Term Recording

- a. Maximum 440,000 beats. Maximum 96hrs\* at an average of 76 BPM.
- b. Fixed 15 sec epoch.
- c. Activity and Heart Rate recorded.
- d. Every Interbeat Interval (IBI) is logged for HRV analysis if required.

#### **WARNING**

**The recording time is dependent on the signal quality. A poor signal with many artifacts will result in a shorter recording time.**

#### 8.1.2 Long Term Recording

- a. Maximum 21 days recording.
- b. Choice of 15sec, 30 sec or 1 minute epoch.
- c. Activity and Heart Rate recorded.
- d. *Optionally* limited IBI logging, i.e. min–max interval per epoch.

#### 8.1.3 Signal Test

See section 7 of this manual.

## 8.2 Set-up Energy Expenditure Options

### 8.2.1 Daily Energy Expenditure

- a. Fixed 1 minute epoch for daily living studies.
- b. Limited IBI logging as standard.
- c. Maximum recording time 21 days.

### 8.2.2 Advanced Energy Expenditure

- a. Maximum recording time 21 days.
- b. Choice of 15 sec with every IBI and 15 sec, 30 sec or 1 minute epoch with limited IBI logging as standard.

The table below summarises the recording durations (refers to Actiheart 4):

Epoch	15 sec	30 sec	1 min
Recording time HR + Activity	21 days	21 days	21 days
Recording time HR + Activity + IBI Max-Min	10 days	20 days	21 days
Recording IBI 440,000 beats maximum	Maximum 96 hrs at 76 BPM depending on signal quality		

### 8.2.3 Step Test

Activity and R wave waveform recording for 53 minutes of standardised step test and can be used for individual calibration.

### 8.2.4 Exercise Test

Activity and R wave waveform recording for 53 minutes and can be analysed for other exercise tests such as walking, running, rowing etc.

## 8.3 Reading the Data

Data can be downloaded from the Actiheart using the 'read' button from any of the above set-up screens or from the utilities menu. Note however that the mode of set-up determines which analysis can be performed upon the data.

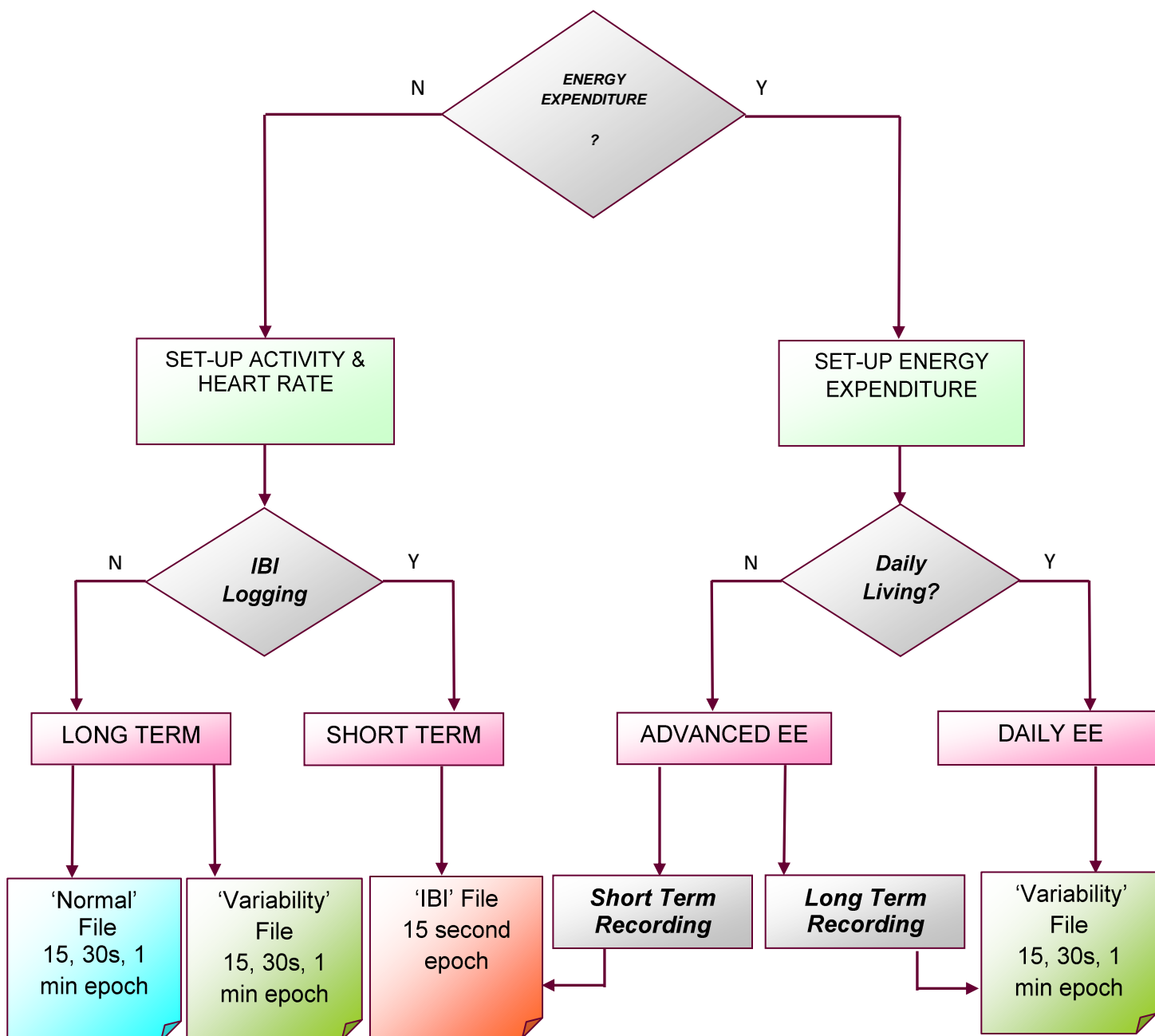
## 8.4 Analyzing the data

'IBI' files can be analysed using Short Term Recording or Advanced Energy Expenditure.

'Normal' files can be analysed using Long Term Recording or Advanced Energy Expenditure.

'Variability' files can be analysed using Long Term Recording or Advanced Energy Expenditure or Daily Energy Expenditure.

The following flow chart and tables summarise the various recording and analysis capabilities mentioned:





### 8.5 Recording Options for Activity and Heart Rate

	SHORT TERM	LONG TERM	
Epoch	With IBI ( IBI)	With HRV ( Variability)	Without HRV (Normal)
15 sec	✓	✓	✓
30 sec	×	✓	✓
1 min	×	✓	✓

### 8.6 Recording Capability for ADVANCED Energy Expenditure

ADVANCED ENERGY EXPENDITURE			
Epoch	Short Term ( IBI)	Long Term ( Variability)	Daily Living Compatible
15 sec	✓	✓	×
30 sec	×	✓	×
1 min	×	✓	✓

**8.7 Recording**  
**Capability for DAILY**  
**Energy Expenditure**

DAILY ENERGY EXPENDITURE		
Epoch	With HRV ( Variability)	Without HRV ( Normal)
15 sec	×	×
30 sec	×	×
1 min	√	×

# Appendix 1 - Handling & Environmental Information

## A1.1 Decontamination

- Devices removed from subjects must be considered to be contaminated.
- The operator must use gloves to handle such devices before and during decontamination.
- The Actiheart casing, cable and clip must be carefully cleaned with alcohol wipes to minimise any potential contamination.
- Take care not to place excessive stress on the cable assembly during cleaning.

## A1.2 Battery Care

- The device is INTERNALLY POWERED and operates at voltages below 3VDC; there is hence no risk from electric shock (equipment Type B).
- The battery is **NOT** user replaceable – **no attempt should be made to open the device casing.**
- The battery is re-chargeable; to maximise the service life of the battery:-
  - Following download of data, always fully re-charge the Actiheart.
  - Following a full re-charge, ensure the device is 'powered down' (this will delete any data).
  - As with all rechargeable batteries the capacity of the Actiheart battery will deteriorate with time/usage. It is possible to test the battery capacity – see section 3 of this manual.

## A1.3 Disposal



Waste Electrical & Electronic Equipment (WEEE) The EU requires, under the Waste Electrical and Electronic Equipment Directive 2002/96/EC, that manufacturers and/or distributors of Electronic and/or Electrical Equipment manage and pay for the collection and further handling of WEEE products, as well as provide WEEE-related information to their customers.

CamNtech has taken the following approach to complying with this Directive:

- CamNtech has registered with an approved producer compliance scheme (PCS) in accordance with the requirements of the WEEE Directive.
- CamNtech will provide free recycling for all of its WEEE products when returned to them.
- CamNtech WEEE products will be designed with recycling, reuse and waste management as a consideration.
- CamNtech WEEE products will be labelled or stamped with the WEEE marking in accordance with European Standard EN 50419

## A1.4 ENVIRONMENTAL

The Actiheart must be used and stored in accordance with the following environmental conditions:

	Operating	Storage & Transport*
<b>Temperature</b>	+5°C to +40°C 41°F to 104°F	-25°C to +70°C -13°F to 158°F
<b>Relative Humidity</b>	15% to 93% Non-condensing	15% to 93% Non-condensing
<b>Atmospheric pressure</b>	700hPa to 1060hPa	

\*Applies while packaged within manufacturer supplied packaging and after having been removed from packaging and subsequently between uses.

## A1.5 EMC Guidance & Declaration

The following tables provide a declaration of compliance and user guidance regarding Electromagnetic compatibility of the Actiheart system.

### A1.5.1 Electromagnetic Emissions


Guidance and Manufacturers Declaration – Electromagnetic emissions		
The Actiheart is intended for use in the electromagnetic environment specified below. The customer or the user of the Actiheart should assure that it is used in such an environment.		
Emissions Tests	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The Actiheart uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  The Actiheart is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR 11	Class B	
Harmonic Emissions EN61000-3-2	Not Applicable	
Voltage Fluctuations / flicker emissions EN61000-3-3	Not Applicable	

## A1.5.2 Electromagnetic Immunity

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
The Actiheart is intended for use in the electromagnetic environment specified below. The customer or the user of the Actiheart should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/-6kV Contact  +/-8kV Air	+/-6kV Contact  N/A (#1)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material. The relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	+/-2kV for power supply lines  +/-1kV for input/output lines	+/-2kV for power supply lines  +/-1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1kV differential mode  +/-1kV common mode	N/T (#2)  N/T (#2)	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle.  40% $U_T$ (60% dip in $U_T$ ) for 5 cycles.  70% $U_T$ (30% dip in $U_T$ ) for 25 cycles.  5% $U_T$ (95% dip in $U_T$ ) for 5 seconds.	N/T (#2)  N/T (#2)  N/T (#2)  N/T (#2)	
Power frequency 50/60Hz magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE - $U_T$ is the a.c. mains voltage prior to application of the test level.			

#1: Test not applied because contact discharge could be applied to all points.

#2: Not tested because the 2 operating modes where essential operation is important do not have a mains connection.

Guidance and manufacturer's declaration—electromagnetic immunity			
The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	$[V_1]$ V	Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ V/m	$d = \left[ \frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$  where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  
NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [EQUIPMENT or SYSTEM].			
<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

**Example:** For a typical mobile phone, the radiated RF will be in the 80MHz to 2.5GHz band and if the transmission power were 1W, the separation distance should be at least 2.33 meters.

## Appendix 2 – Troubleshooting

**Software will not start up** – The Actiheart software must be installed and run from an account with administrator permissions. Limited accounts will prevent the software installation/operation.

**USB Reader is not recognised** – The USB drivers are the most common cause of problems with the reader. Follow the advice provided in Appendix 3 as a first step. Close the Actiheart software before attempting to install USB drivers.

Check that Windows recognises the reader: in Windows 7 or above, select 'Devices and printers' from the start menu and ensure that there is an entry for 'Actiheart reader charger'. In older versions of Windows, you will need to go to control panel – system – device manager and then expand the USB devices list to check for this entry.

If the Reader appears in the device list – re-start the Actiheart software and check if the reader is recognised.

From the Utilities window in the Actiheart software – select 'communications settings'. Click the 'diagnose/repair USB connection button'. Select YES to search for a multi-channel reader charger.

If the reader is not recognised at all, there may be a fault – contact CamNtech or your local agent for support.

**The Actiheart did not start recording** – Following set-up, the Actiheart must be removed from the reader immediately. If the Actiheart is left on the reader, the set-up will be cancelled and the device will not start recording.

**The Actiheart stopped recording early** – Ensure that the Actiheart battery is fully charged. It is recommended that prior to any long term recording that the Actiheart is fully charged overnight. It is advisable to use the mains power adaptor to supply the charger as the PC may shut-down or sleep hence interrupting the charging.

**My data is very noisy** – The Actiheart requires a good, low impedance connection to the skin of the subject. Carefully follow the advice provided in section 5 and allow the ECG electrodes time to 'settle' (at least 30 minutes) before attempting a recording. Perform a signal test to determine the quality of the ECG. If the signal quality is poor, try moving the position of the ECG electrodes slightly, or try the alternative mounting location (see section 5).

**The Actiheart is not recognised by the reader** – Ensure the Actiheart battery is fully charged. If the Actiheart is not detected at all, contact CamNtech or your local agent for support.

**I received read errors during download** – Ensure that the Actiheart battery is fully charged; a low battery can affect communications and result in errors during download. The device can be re-charged following a recording without loss of data.

**I get a warning message with my data** – The Actiheart software attempts to verify that the data is correct with respect to the set-up. Inspect the data to ensure that the required period is valid. It may also be advisable to charge the Actiheart and re-download to remove the possibility of read errors.

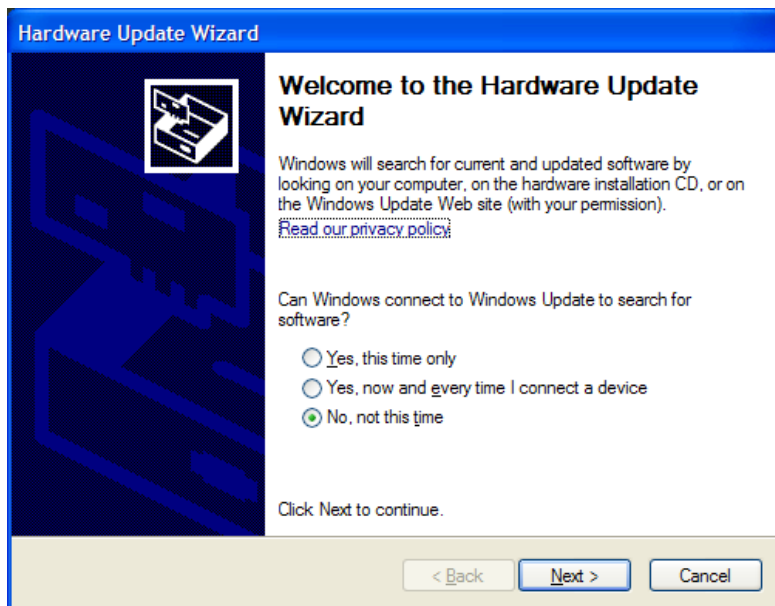
## Appendix 3 – Installing USB Drivers Manually

Sometimes the automatic installation of drivers will not work, often because your computer has previously had similar, but different, drivers installed on it before and sometimes because of flaws in the Windows installation process. To install drivers manually, follow the procedure below.

### *To begin installing drivers:*

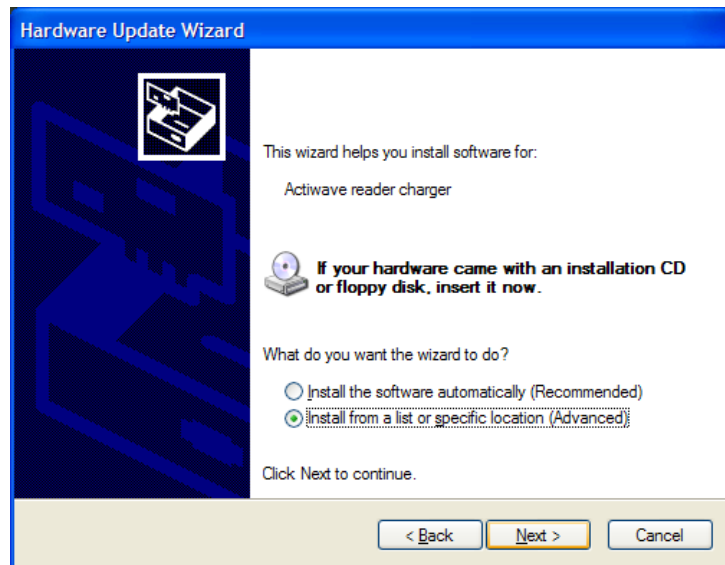
Plug the device into a USB port. Something similar to the window shown below should appear. If it does not, then open it manually like this:

- Click on the Start menu, and open the Control Panel.
- Open 'System'. If you can't see this, choose 'Performance and Maintenance', then 'System'.
- Select the 'Hardware' tab, and click the 'Device Manager' button.
- Scroll down and open up the section called 'Universal Serial Bus controllers'. The device you are trying to install should be listed here. It may have a yellow question mark next to it.
- Right-click on the device name and select 'Update Driver...'. The window below should then appear.

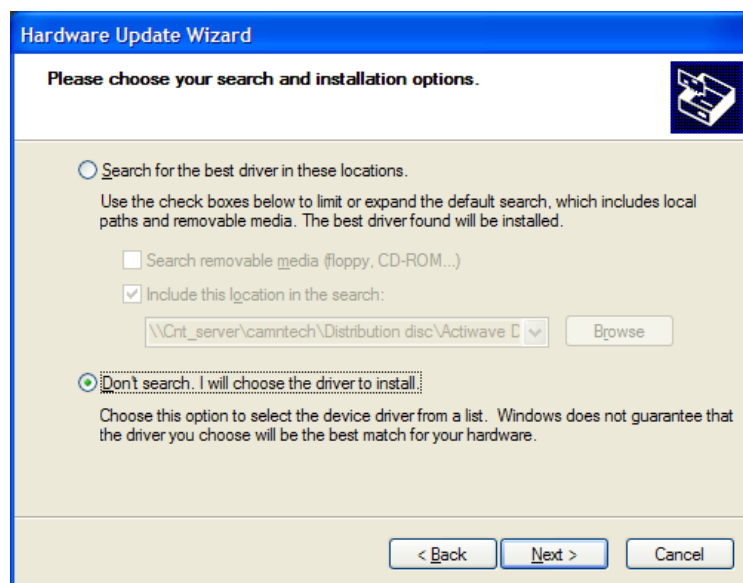


Select 'No, not this time' and click 'Next'.



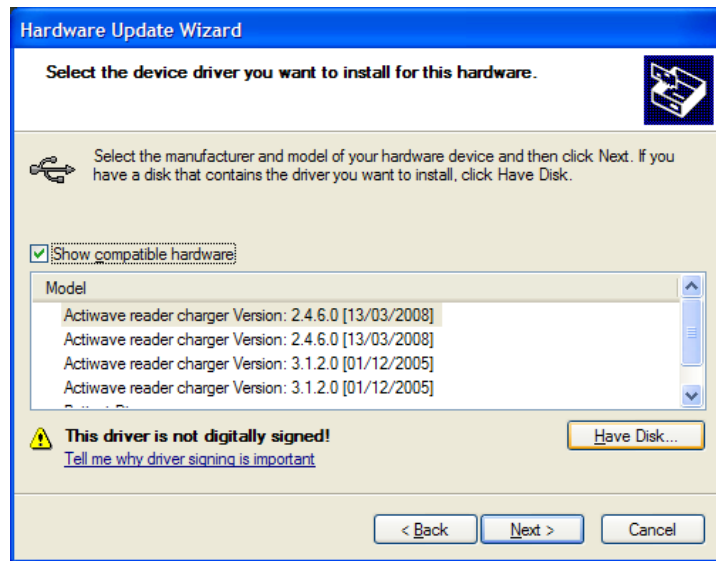


Select 'Install from a list or specific location (Advanced)' and click 'Next'.

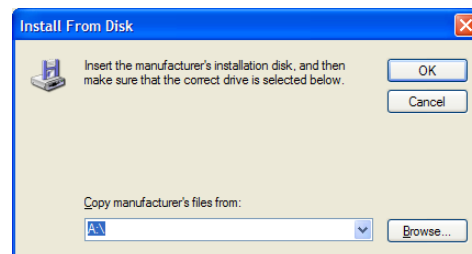


Select 'Don't search. I will choose the driver to install.' and click 'Next'.

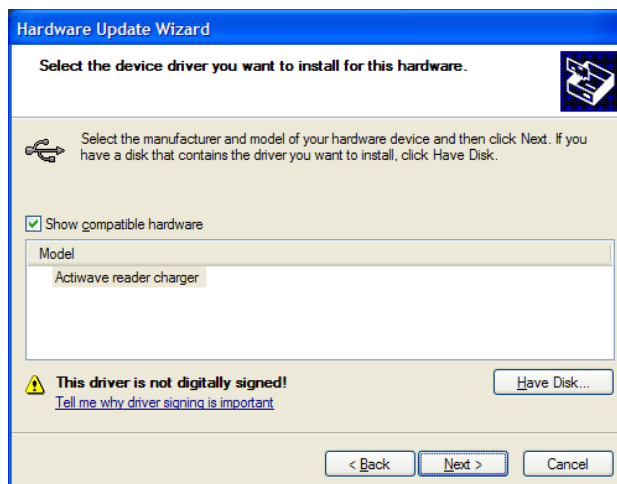
The window on the next page should appear. Sometimes, windows will decide to display some other windows first, possibly appearing to lock up for a minute or two at one point. If it does this, you may be forced to choose a device category. Choose any, and look out for the 'Have Disk..' button next, which you must find in order to proceed.



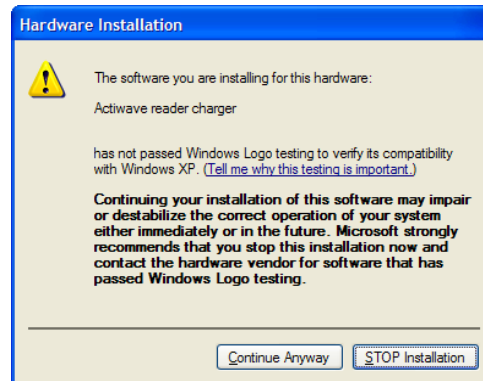
Ignore the items in the list, and click 'Have Disk...' instead.



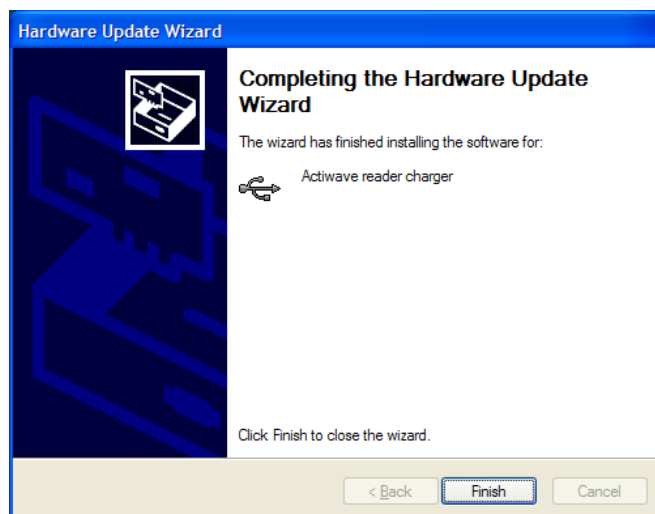
Click on 'Browse...' and then use the standard file window to find the 'USB drivers' folder on the CD. Select 'ftdibus.inf' from this folder and click on 'Open'. The window above will re-appear with a filename at the bottom. Then click 'OK'.



You can now select the correct driver in the list and click 'Next'. Depending on your system settings, the window below may appear.



If this window appears, click 'Continue Anyway'. The underlying drivers are in fact tested and approved by Microsoft, but the certification is invalidated when they are configured to match our reader devices.



When this window appears your drivers are installed.

If you still have issues installing the USB drivers then please check our website for up to date information, at the link below:

<http://www.camntech.com/drivers>