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 5 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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US FDA status

The Actiheart is FDA cleared for prescription use only with FDA 510(k) number K052489. USA designated agent:

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IMPORTANT SAFETY INFORMATION

WARNINGS

- Contains Lithium Battery – DO NOT ATTEMPT TO DISSASEMBLE: 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.

- Remove ECG pads from skin if there is significant discomfort from skin irritation or reaction.

- 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	📖ℹ️	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 *yyyy-mm* 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 **TYPE B APPLIED PART**.

FOR FURTHER HANDLING & ENVIRONMENTAL INFORMATION PLEASE REFER TO APPENDIX 1

Contents

IMPORTANT BATTERY CARE INFORMATION!

The Actiheart device contains a miniature rechargeable battery which must be cared for correctly to maximise service life. Following any long recording, always ensure the battery is at least partly re-charged - do not leave it completely flat before storage. However, it need not be completely recharged.

If the device is to be stored for a period then it should ideally be part-charged rather than left either completely full or empty. For long term storage the device should be checked and re-charged to a medium level every six months. Leaving it to flatten for more than six months may cause long term damage to the battery.

1. Introduction to the Actiheart System

1.1 Overview

The Actiheart 5 and is a compact lightweight device that records the electrocardiogram (ECG) between two ECG pads on the chest, simultaneously with three-axis acceleration waveforms within the same unit.

Alternatively, the Actiheart 5 can record ECG peak information for continuous Inter-Beat-Interval (IBI) monitoring for up to two weeks, in addition to three-axis acceleration waveforms.

This allows detailed study of movement patterns on both a short and long term basis, in addition to heart rate variability and energy expenditure in everyday daily living and more intense sessions of exercise.

An Actiheart system consists of two components:

- The Actiheart device with detachable electrode connection
- Actiheart Analysis Software

Additionally, a standard micro-USB lead is used to connect the Actiheart to a PC for setup, download & charging of the device.

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 monitoring of physical movement and activities, measurement of Energy Expenditure and analysis of HRV in research applications.

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

The Actiheart has an LED indicator on the front which flashes to indicate ongoing recording.

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. The following are the minimum requirements of a host PC for installing the Actiheart software:

- Windows 8 or 10 operating system
- 1 GB hard disk space
- USB port
- A CD-ROM drive or equivalent
- Printer (if hard copy output is required)

In addition, if you wish to use the optional Live Display feature with an 'Actiheart 5 BT' which has the Bluetooth module fitted, your PC must also meet these requirements:

- Windows 10
- Bluetooth capable hardware

2.2 Software Installation Menu

Place the CD-ROM into the drive; the operating system should automatically offer to install the Actiheart 5 software. You will then see the installation wizard below:
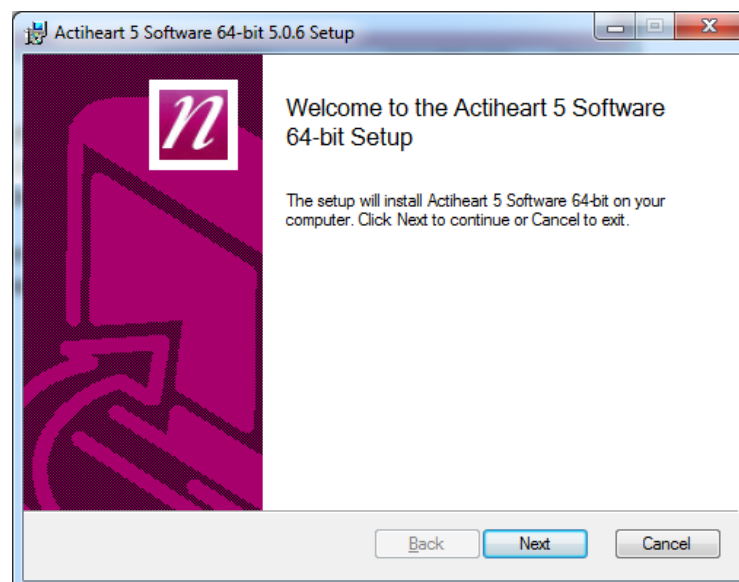
To install the software, click "Next" and follow the installation process prompts. If you are using a 32 bit version of Windows, you must install the 32 bit software instead, but we strongly recommend that you use a 64 bit machine instead with the appropriate software. The software may be limited in its ability to open large

recordings due to technical issues in the .NET 32 bit environment, which occur well before physical memory becomes a limitation.

If the above installer is not displayed, browse the CD and double-click the file named "Actiheart_5_Setup" or similar.

2.4 Installing the USB Drivers

Plug the Actiheart into a USB Port using the supplied micro-USB lead. Depending upon the operating system in use and the current driver status, the computer will display a message saying 'Found New Hardware' and will then load the drivers with no user intervention. This requires the computer to have a working internet connection, and for Windows to be configured to allow driver download from Windows Update.

If any problems are encountered, please see the web page below for latest guidance:

https://www.camntech.com/support/drivers

2.5 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:


When you register your Actiheart system with CamNtech, you will be supplied with an 8 digit serial number along with the software. 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 charged. This is performed simply by plugging the device into an available USB port of a PC which is running, or by connecting it to a mains powered USB supply such as a phone or tablet charger.

It is also possible to check the current battery level by beginning any setup process and connecting the Actiheart. A small graphic will indicate battery level and a specific warning will be given if the charge is considered low for the mode chosen. Care should still be taken to charge fully for any particularly long recording, but the automatic check will be sufficient for short ones.

Furthermore, full battery charge information can be checked using the Utilities -> Actiheart 5 -> Test Window function and then the "Battery" button. If charged, this will show a result similar to:
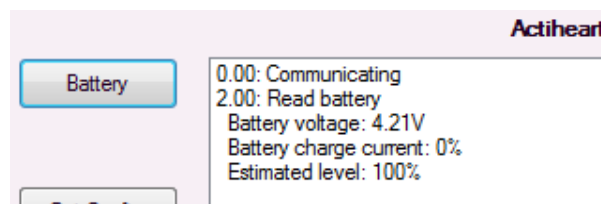
If you experiencing any battery charge issues, leave the Actiheart connected to a mains powered USB supply for at least three hours. Then connect to a PC and perform the check described above, noting the result values for CamNtech technical support.

It is very important that you DO NOT attempt to charge an Actiheart after setting up the device. You must charge before setup, or after the end of a recording. Attempting to charge after setting up a device will result in a shutdown of the device instead of a recording.

3.1 Charging the Actiheart using the Mains Power Supply

Where possible we recommend charging from a mains power supply rather than a PC USB port. This is only due to the risk of the computer switching off and saving power when left unattended, thereby interrupting the USB power and preventing charging. Full charging capability is available from either PC connection or mains power adaptor.

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 mains power supply into the wall outlet.
3. Connect the Actiheart 5 to the charger using the supplied cable.

4.0 Setting up a Database

All data used in the Actiheart system is stored in SQLite databases. For full details of the databases used by the system, please see the chapter in the main manual on databases. For now, note that when the software is first run, the window below will be displayed. Note the highlighted warning about a "demo database".
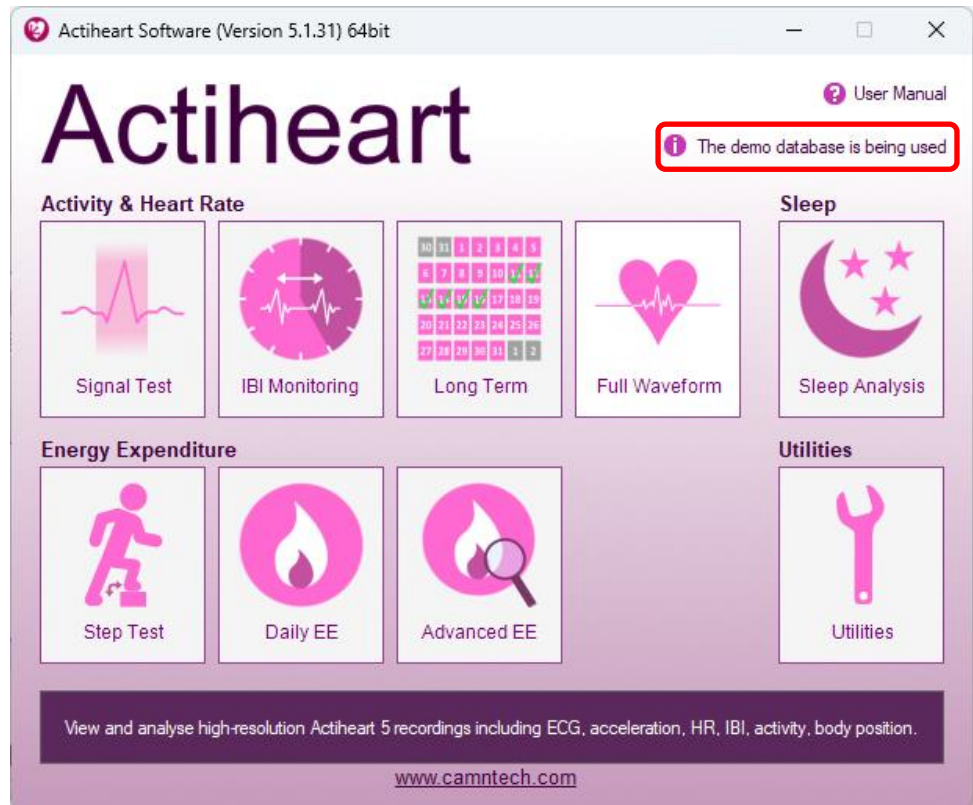
This highlighted warning indicates that the software has installed a database of demonstration data in your own Documents directory. This will allow you to quickly try out parts of the software to view data before needing to make a 'proper' recording. Note however that we strongly recommend creating a new (empty) database before beginning any significant data collection, as it will make it easier to organise the data and distinguish real results from test recordings.

When you wish to create a new recording database, use the Utilities button, and then the Database section and "New". This is not necessary for quick test purposes and trying out the software – you can continue with the demo database.

You are now is a position to begin using the Actiheart and software.

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. Users may experience some redness and itchiness from pads in normal use. However, if there is any significant discomfort from skin irritation or reaction then they must remove the ECG 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). We advise you to experiment with your local supplier and population group.

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.

- DORMO Solid Gel SP-50. These pads are usually supplied by CamNtech for initial testing, suitable for most purposes but we recommend testing yourself with the specific target group before committing to any pad.
- 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 CamNtech 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 Multi-Day Wear of ECG Pads

Although many of the ECG pads from manufacturers are labelled as "Long Term", this typically does not refer to use spanning a week from a single application. For recordings of this length, it is recommended to change pads regularly every few days. Note that it is particularly important to clean all residue off the skin after removing previous pads in order to avoid further irritation.

Subsequent applications of ECG pads may be applied in slightly varying location in order to avoid irritating exactly the same regions of skin. As described below, there is some latitude in positioning while still capturing good ECG data in order to facilitate this.

5.3 Electrode Positioning

The best ECG signals can usually be picked up by placing the large 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. This is illustrated on the chest in the diagram below. A position on the upper chest around 10cm higher than that shown in the diagram can also be used – this may be either more or less acceptable for female users depending on their breast size. According to
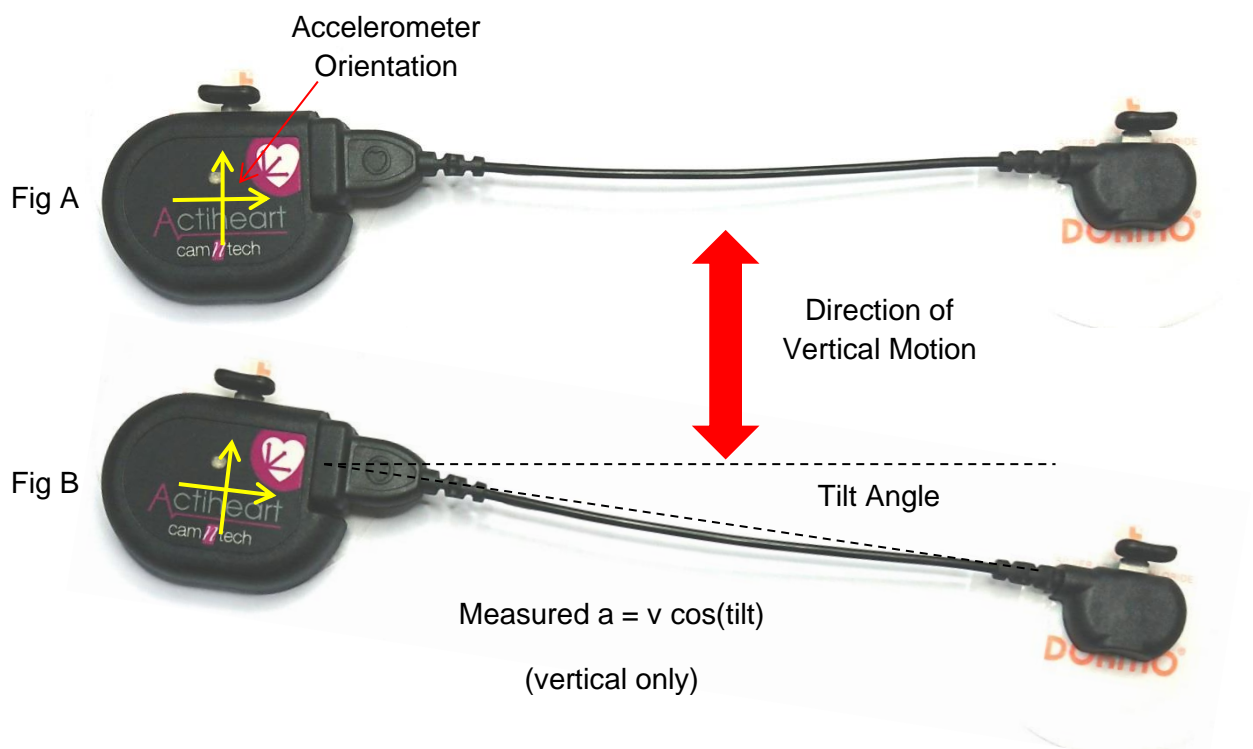
Rauharju et al.[1] breast tissue appears to have a practically negligible effect on ECG amplitudes, and in women, the placement of chest electrodes on the breast rather than under the breast is recommended in order to facilitate the precision of electrode placement at the correct horizontal level and 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 top edge of the device body as near to horizontal as possible. A 10 degree tilt (Fig. B) gives a theoretical activity reading error of 3% for vertical movement. However, a 45 degree tilt would mean that the detected magnitude is 30% less than the actual for vertical movement. The electrodes should be positioned so that the cable is nearly 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:

Accelerometer Orientation

Fig A

Direction of Vertical Motion

Fig B

Tilt Angle

Measured a = v cos(tilt)

(vertical only)

### 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.
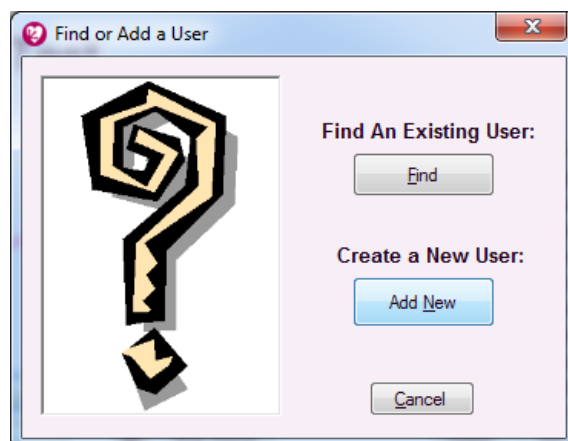
6.0 Setting up a User in the Database

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 any important 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.

After opening the main menu of the Actiheart software, click on the "Signal Test" button. This brings up the screen shown below:
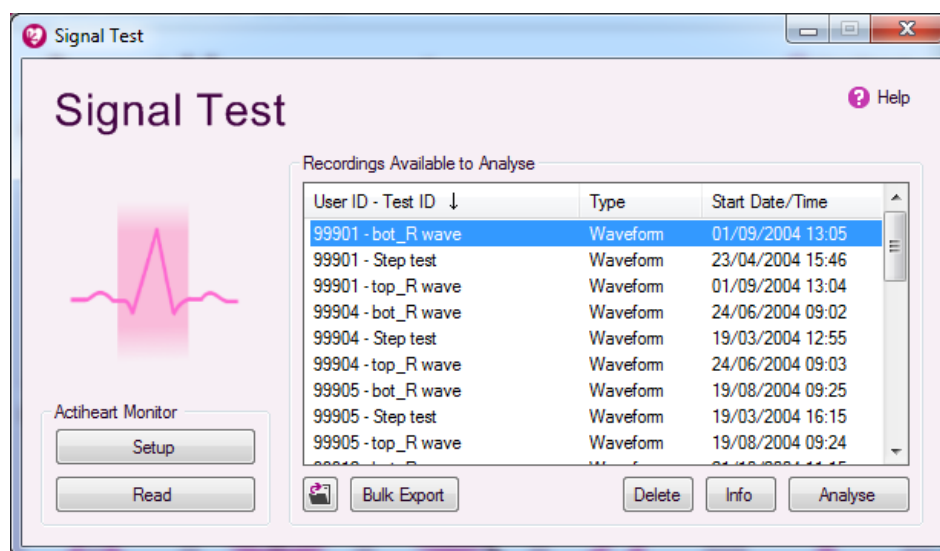
Clicking the "Setup" button then produces the following screen:

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**.
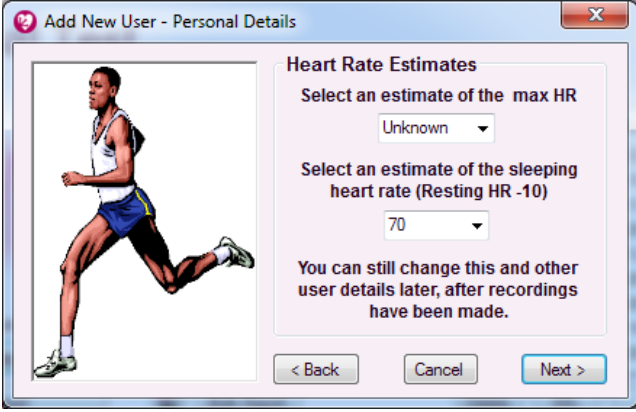
6.2 Setting up a new User

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 here. Selecting 'Next' produces the following:

The weight and height of the user are selected from here. It is possible to input the user details either in Metric or Imperial units. The increments are 1cm and 0.1 Kg. Accurate measurements are necessary for calculations of energy expenditure, but do not affect the recording process.

Once entered, selecting 'Next' produces the final user details window:

This screen allows an estimate of the maximum heart rate and sleeping heart rate to be entered. Neither of these are essential at this point. In general, all user details can be modified after initial entry in order to facilitate more accurate analysis at a later date.

The Maximum heart will only be used for an estimate of VO2Max to be made. It will not affect energy expenditure estimates, HRV, or any other measurements made using the software.

Sleeping heart rate is critical to accurate energy expenditure calculations during daily living. The easiest way to collect accurate sleeping data is to wear the Actiheart for at least one overnight recording, then use the "Set sleeping heart rate" function in the Long Term analysis window to extract the measure from the overnight Actiheart recording. However, it need not be set accurately in this window right now, and will not affect the recording process – only later analysis.

Once details are entered, clicking 'Next' shows the message "Do you want to save this user data?". Selecting 'Yes' produces a confirmation message that the new user has been saved correctly into the database.

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 each part of the recorded 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.

It is only necessary to record for a few minutes for this test – it is not designed to view longer recordings, and 10 minutes will be more than sufficient.
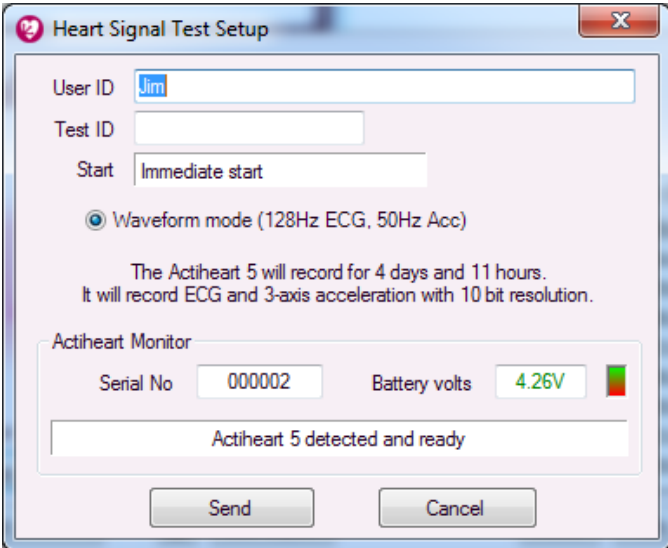
The method described below for making a recording and downloading the data to the PC for analysis applies equally to the various other recording modes described in the User Manual and summarised in **Section 8** of this guide.

7.1 How to set up a Signal Test

Connect the Actiheart to its micro-USB lead and to the PC. Look carefully before inserting the connector. The internal "D" orientation can be observed, or you can note that the USB connector icon should be visible upwards on the lead when connected to the Actiheart 5 with its label upwards.

From the main menu, click the 'Signal Test' button. Selecting 'Setup' then brings up a window 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'.

After the user is selected or created, the following screen will then be displayed:

You may enter an additional 'Test ID' (i.e. to identify this particular test for this user). Note that the exact modes displayed in this window will depend on the device connected. 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 PC. Failure to do so may lead to the Actiheart being unable to record in which case the setup procedure would need to be repeated. It must not be reconnected to charge until after the recording is complete.

Once the Actiheart is disconnected, it can be placed onto the user by clipping onto the previously attached pads. To do this, you will first need to attach the other electrode lead to the Actiheart main body's USB socket. The orientation for this can be seen by ensuring that the "heart" symbol on the connector is facing upwards when the Actiheart logo is also upwards.

After switching to the ECG connector lead, connect both clips to the ECG pads attached to the chest. This is performed for each connector separately. First, depress the small "button" to release the connector. While holding this depressed, move it onto the ECG pad metal nipple. Once onto the nipple, release the "button" and the Actiheart will grip the ECG pad. Note that no physical "push" is required to connect the ECG pad – simply depress the button first, then move it over the pad and release afterwards.

To remove the Actiheart from ECG pads, simply squeeze the small "button" above the clip again. While holding it squeezed, lift the device clear of the ECG pad. Then release the button. You can perform this for the main body of the device and the lead connector one by one.

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.

Disconnect the Actiheart from the ECG pads as described above by depressing the button and gently lifting it off. Then reconnect the Actiheart to the PC using the micro-USB lead with connector logo facing upwards as for the main Actiheart logo.

After connecting the Actiheart back to the PC 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 using the "Read" button, or from the general Read function which can be selected after clicking the 'Utilities' button from the main screen.
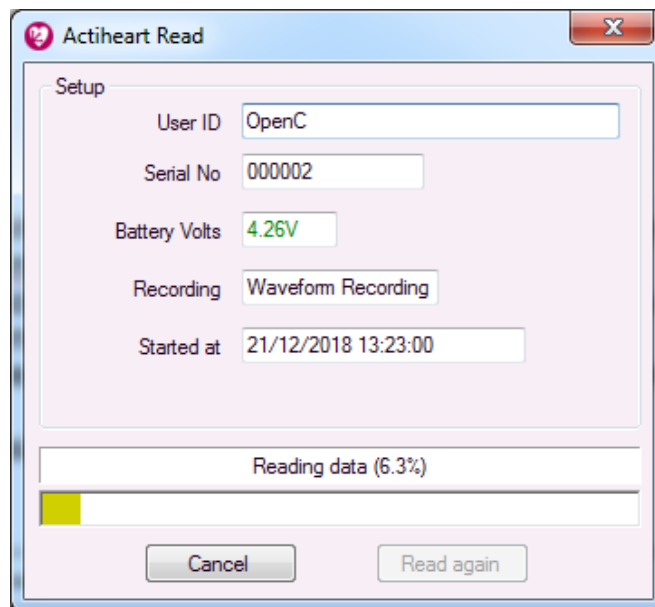
The data recorded on the Actiheart is then downloaded to the PC via the Reader/USB interface. Download progress is indicated by means of the yellow progress bar. Once this is finished, the following screen is shown:

7.3 Storing Comments with the Data
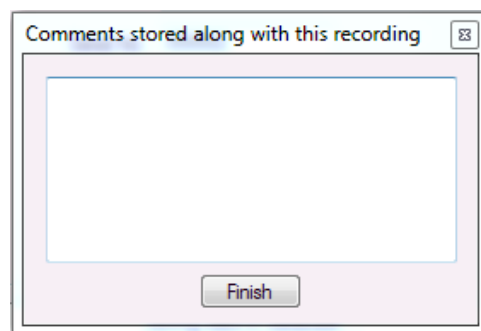
This allows the user to add comments on the recording which will be stored along with the data. This could be, for example, that the wearer has described when they did or did not wear the Actiheart during the period, or the type of ECG pads that were used for the recording. Once any comment required is entered into this screen, "Finish" saves the data into the selected database.

7.5 Analysing the Signal Quality

Once the recording has been downloaded into the current 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:
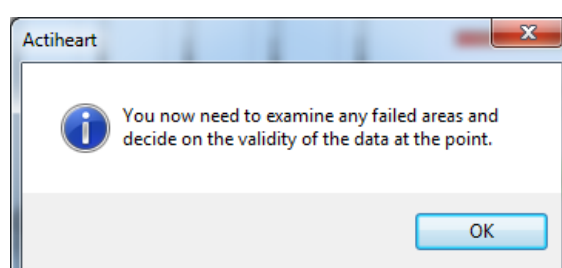
Any areas of the recording that have failed the test are displayed in red on the scan as shown in the screen below. You may click on the scroll bar just above the red / green bar to move the main data display to that point. This will allow you to examine each 10 second region which may have been problematic.

Scan results
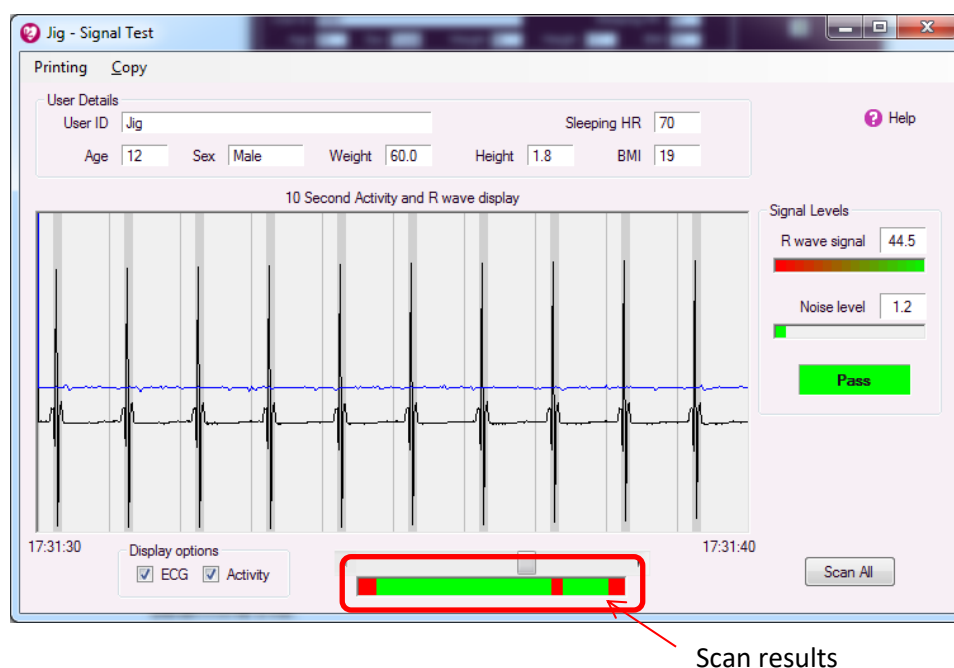
It should normally be obvious from the recording why an area of the recording has failed, for example due to movement artefacts. If it is not obvious, ensure that the "Activity" box is selected to show the activity trace recorded with the R wave. This may help the user identify if the problems have been caused by movement. If a recording has failed for the 10 second period currently displayed, as indicated by the graphics to the right of the window, 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-[signal/noise x 2] <7
- signal /noise > 4.75
- 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.

Note that you will always expect that the beginning and end of the signal test will be marked as red since these regions will not show a stable ECG pad connection. This is not a concern – only those periods of recording where you know a good signal should have been present.

8.0 Viewing Live Actiheart 5 Data

The Actiheart 5 can be ordered with an optional Bluetooth module, for live display of ECG and accelerometry data during an activity. This will allow monitoring of the wearer's ECG, heart rate and movement during a step test or other physical activity. Data is displayed "Live" on the PC via the link, but can also be downloaded in full via the USB connection after the end of a recording for further analysis.

The 'Actiheart 5 BT' model is fitted with the Bluetooth module; the front label design of the device will indicate this. In addition, when you try to set up the device for the Step Test or Waveform functionality, a "Live Display" option will appear in the available mode list as shown below.

Note that the Actiheart 5 is not designed to provide alarms or warning of any kind against high heart rate, arrhythmia, or any other heart condition. It is presenting live data and estimated heart rate as additional information for the researcher or clinician, not diagnostic purposes or as a preventative alarm for a life-threatening condition.

8.1 Set up for Live Display

To view live data from an Actiheart 5 BT, you must choose the Live Display mode when setting up the device. This can be done from the Waveform or Step Test setup window. As an example, the Step Test Setup is shown below.

Note that the choice of two modes will only appear here if your Actiheart 5 is fitted with the optional Bluetooth Module. You may still use it with or without the module enabled by choosing either one of the two modes. Begin the recording as described in previous sections.

8.2 Pairing (for first use)

The first time you use each Actiheart with your Windows PC, you must ensure that you enable Bluetooth and then pair with the device (after it is recording and broadcasting data).

First, use the Windows start menu to open the settings window, and then select the "Devices" section, and specifically "Bluetooth & other devices".

Next, ensure that the Bluetooth function is set to "On".
Then, click "Add Bluetooth or other device", and choose to add a "Bluetooth" device.

The computer will then display any nearby devices. Your Actiheart 5 must be broadcasting in order to appear in this list. If you have set it up as described previously, you will still need to wait for it to begin recording before it will appear in the list as shown below:
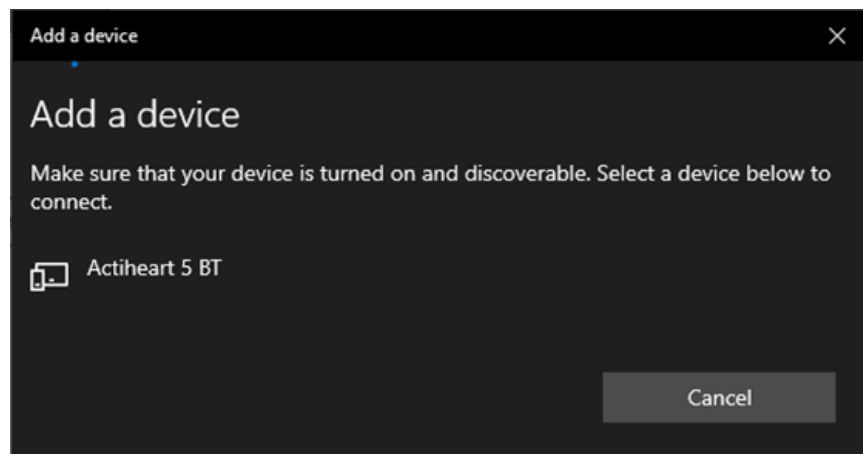
Click on the Actiheart 5 BT in order to pair with it, and close the window.

8.3 Live Display on the PC

Immediately after you have started an Actiheart with the Live Display mode, a corresponding data window will appear showing when data is expected:
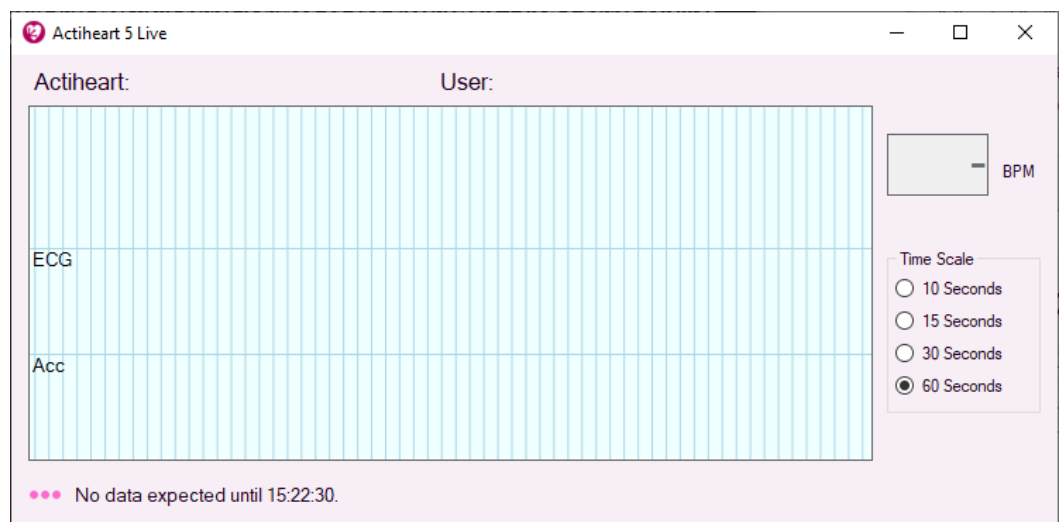
Once the start time of the set up is reached, the Actiheart will begin recording, broadcasting its data, and flashing the red light on its front at the same time. The Live Display window should then recognise incoming data within a few seconds.
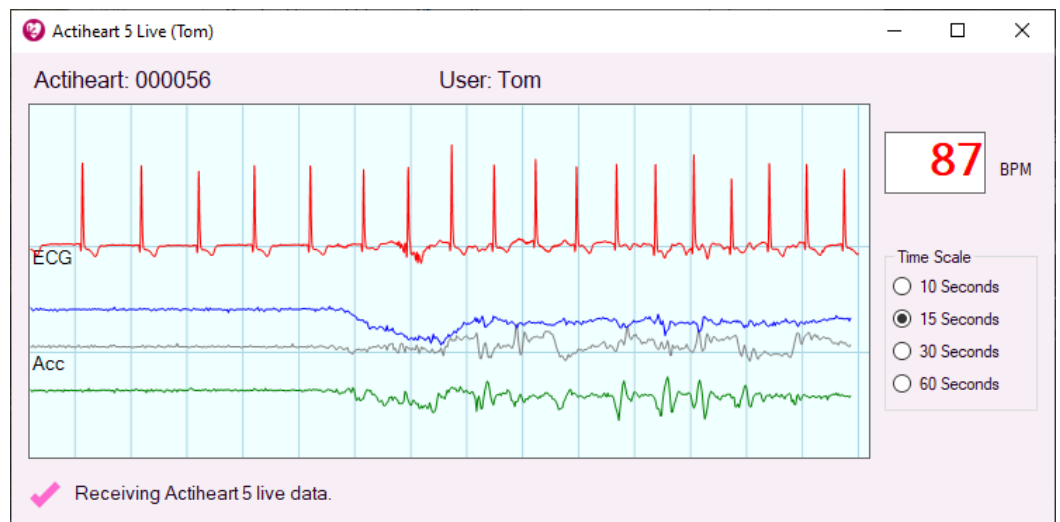
Note that you must have paired your Windows computer with the device on first use, as described in the previous section.

The data shown includes ECG as a red trace, and three axes of acceleration data. The horizontal scale may be varied from 10 seconds up to one minute using the Time Scale options in the window. A shorter scale will allow more detailed view of the ECG and acceleration waveforms, while the longer options make it easier to observe changes during an ongoing activity. Once a steady heart rate has been detected, it will be shown in the BPM box and will update continuously.

If you need to open the Live Display window without first setting up an Actiheart, for example if it was set up on another computer, you can do so from the main menu via Utilities -> Actiheart 5.

Several Actiheart 5 BT live streams can be shown simultaneously. The windows may be opened automatically as each is set up, or through the Utilities window as described above.

8.4 Capabilities & Requirements

The Live Display feature requires Windows 10 and Bluetooth functionality in your PC in order to function.

Range of the live data is at least 5m in normal use, but may vary greatly depending on other nearby electronics and signal obstructions. If you are experiencing difficulties then try to arrange a clear line-of-sight between your computer and the Actiheart 5 unit and minimise the distance.

In typical use, the battery of the Actiheart will last for around 24 hours of live data. However, this will vary with range and the presence of signal obstructions.

If you have followed the instructions above (including pairing for first use) and are still experiencing difficulties with your data link, please test with at least one additional computer to confirm the Bluetooth functionality, and then contact CamNtech support with details of your devices and exactly what steps you have attempted.

9.0 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 what the data will be used for, both immediately and for any potential future analysis. This section summarises both the physical recording capabilities of the Actiheart 5, and the focus of the main operating modes of the software both for configuration and analysis.

9.1 Actiheart 5 Recording Modes

The Actiheart 5 offers two internal recording modes:

Full Waveform: This mode records the ECG waveform between the two ECG pads on the chest, simultaneously with three-axis acceleration waveforms. Recordings made with this mode are marked as "Ah5 Wave" in the list of recordings.

IBI Mode: This mode records the amplitudes and timings of each peak captured in the ECG waveform, along with three-axis acceleration waveforms. The ECG peak recording allows a visual representation of the ECG waveform to be given and also produces more robust IBI results than simple device-beat-detection algorithms. Recordings made with this mode are marked as "Ah5 IBI" in the list of recordings.

In both of these cases, the acceleration waveforms will consist of X, Y & Z axes and may be recorded with sample rates of 25Hz, 50Hz or 100Hz. Note that the exact acceleration sampling frequency will vary internally, but it is timestamped alongside the ECG signal capture and interpolated as necessary for each analysis window. The raw data exported as text from the Recording Details window will show the timing for each raw sample rather than any interpolated results.

For the Full Waveform mode, the ECG may be captured at 128Hz, 256Hz, 512Hz or 1024Hz. In all cases, the analogue bandwidth is limited to ~55Hz, and the analysis software will interpolate each IBI to 1ms resolution. For this reason, we do not recommend the highest rate modes (particularly 1024Hz), unless you have a specific need to interface to legacy software which cannot interpolate waveforms.

In IBI mode, the ECG will be sampled at 256Hz. Peaks are detected in this data and both their timing and amplitude recorded for processing later in the PC software. Again, the timing of each IBI is interpolated to 1ms resolution.

9.2 Setup and Analysis Functions Summary

From the main menu of the Actiheart software, specialist windows are available for recording and analysing for a specific purpose. Note that there is not a separate hardware recording mode specific to each one, more that the purpose is to offer one or more appropriate recording modes together with the right visualisation and measurement tools for that purpose.

Signal Test: Designed for a simple short recording in order to check ECG pads before a longer test. Requires waveform ECG and at least a single axis of acceleration recording. Using an Actiheart 5, Full Waveform Mode.

IBI Monitoring: Designed for capturing and measuring heart rate variability for up to two weeks. Requires IBI recording, and activity data quantifying the amount of movement each 15 seconds. Using an Actiheart 5, IBI Mode.

Long Term: Designed for robustly capturing heart rate and movement data for up to two weeks, without emphasis on individual IBIs. Requires heart rate recording and activity data quantifying movement each 15 seconds. Using an Actiheart 5, IBI Mode.

Full Waveform: Designed for recording and visualising detailed movement waveforms with three-axis acceleration, alongside ECG waveform view. With fast zooming and scrolling from full recording length down to seconds of display at once. Also supports display of Ah5 IBI mode data with reduced ECG functionality. Requires three axes of acceleration recording. Using an Actiheart 5, Full Waveform Mode.

Sleep Analysis: Alternative focus of the IBI Monitoring window, with specific functions intended for sleep analysis. Note that these are published algorithms, but we do not consider them sensitive or specific enough for any diagnostic use. Using an Actiheart 5, IBI Mode.

Step Test: Designed for individual calibration of Energy Expenditure using any Actiheart, by leading the Actiheart wearer through an 8 minute step test of steadily increasing intensity while capturing movement and heart rate. Using an Actiheart 5, Full Waveform Mode.

Daily EE: Designed for a simple measurement of Energy Expenditure during daily living without too many complex options. Makes use of heart rate and activity data. Using an Actiheart 5, IBI Mode.

Advanced EE: Designed for more flexible measurement of Energy Expenditure and including many more options for individual calibration adjustment and

breakdown of the branched model. Makes use of heart rate and activity data. Using an Actiheart 5, IBI Mode.

Appendix 1 - Handling & Environmental Information

A1.1
Decontamination

- All used devices must be considered to be contaminated with surface borne bacteria and must hence be de-contaminated before re-use using a suitable disinfection and cleaning procedure.
- The operator must use gloves to handle such devices before and during de-contamination.
- Care must be taken to use the correct de-contamination procedure and cleaning materials because long term exposure to certain cleaning materials is known to attack plastics which can lead to premature failure of the mechanical integrity of the device casing or labelling.
- CamNtech recommend the use of aqua based disinfection products and our recommended products are Clinell® Universal Wipes or Spray. These products do not contain chemicals known to cause deterioration of plastics.
- Do not use products containing Glutaraldehyde, Glucoprotamin, Isopropyl, ethyl, or methyl alcohols, hydrogen peroxide, or bleach products. Do not use plasma sterilization or ethylene oxide sterilization procedures, Do not autoclave.
- Do not apply self-adhesive labels or tapes to the casing.
- **Begin by spraying and/or wiping all visible surfaces** of the Actiheart body, clips, and cable with the cleaning agent. Ensure that all surfaces are dried before proceeding.
- Take care not to place excessive stress on the cable assembly during cleaning.
- **Do not** clean the metal plug or socket where the cable attaches to the body.

A1.2 Battery Care

- The device is INTERNALLY POWERED and operates at voltages below 5VDC; 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, ensure it is not left for long periods completely flat or completely charged. It is recommended to charge after use, and only avoid fully recharging if the device will be left stored for a long period, when it should be left part-charged.
- For long term storage the device should be checked and re-charged to a medium level every six months. Leaving it to flatten for more than six months may cause long term damage to the battery.

A1.3 Disposal

Waste Electrical & Electronic Equipment (WEEE) The EU requires, under the Waste Electrical and Electronic Equipment Directive 2012/19/EU, 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 EMC Guidance & Declaration

Please consult the Actiheart User Manual for details of Electromagnetic environment and compliance.

Appendix 2 – Troubleshooting

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

The Actiheart recorded nothing – After set-up, the Actiheart must be removed from the USB lead immediately. Furthermore, it must not be reconnected to USB for charging until after the recording is complete. Charging should be done before set-up.

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 PC – 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, then try to download again.

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.

Document Revision History

From iss.	To iss.	Date	Description	Rev By
0.0.0	5.0.6	21/12/2018	First Issue: Pre-production	TE
5.0.6	5.0.6a	01/02/2019	Corrected doc ref, corrected page no. position, minor layout corrections.	HS
5.0.6a	5.0.28	01/12/2019	Inclusion of live Actiheart 5 data display	TE
5.0.28	5.0.29	31/12/2019	Updated CamNtech address details	HS
5.0.29	5.1.11	24/02/2020	Updated for longer IBI recordings up to two weeks	TE
5.1.11	5.1.11a	29/01/2021	Updated de-contamination section A1.1	HS
5.1.11a	5.1.24	02/11/2021	Removed mentions of Actiheart 4 and Cardio, to simplify documentation and because the products are outside of support.	TE
5.1.24	5.1.30	30/6/2022	Removed exercise test.	TE
5.1.30	5.1.31a	03/01/2024	Updated screenshot on page 11 to remove exercise test icon	HS