



The Actiwave Cardio and Cardio Viewer Software

User Guide

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Regulatory Information

European Union

The Actiwave Cardio is NOT a Medical Device as it does not provide any medical indications. The Actiwave Cardio is intended for research purposes only 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 Actiwave Cardio 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 Actiwave 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 DISASSEMBLE: 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 Actiwave is **INTERNALLY POWERED EQUIPMENT**.
- The Actiwave 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 Cardio is suitable for temporary immersion in water (up to 1 hour 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 Actiwave is a TYPE B APPLIED PART .

FOR FURTHER HANDLING & ENVIRONMENTAL INFORMATION PLEASE REFER TO APPENDIX 1

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1 Introduction to the Actiwave System

1.1 An Overview of the Actiwave Cardio

The Actiwave cardio is a miniature, wearable bioelectrical data logger which can record:

ECG (including inter-beat interval (IBI) and heart rate)
3 Axis body movement
Body position

The data from the Cardio may be stored in standard EDF format or as .CSV format.

Components required for a system

The Actiwave Cardio system consists of 4 components:

- One or more Actiwave Cardio recorders.
- USB Interface Dock (CardioDock).
- PC Software providing set-up, download and maintenance functions.
- Optional Cardio Viewer software to analyse and print out the data

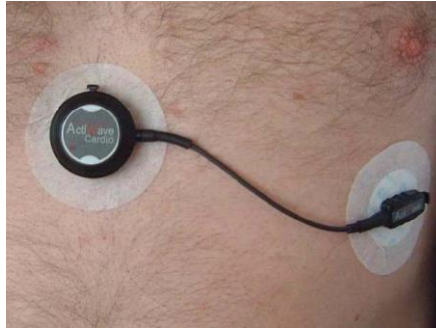


Actiwave Cardio

CardioDock

Actiwave Electrodes/Subject Connections

The Actiwave Cardio clips onto a standard ECG electrode with a short lead to another electrode that picks up the ECG signal. Alternatively, it can be mounted on a chest belt. This may be easier for intensive exercise, but is not as comfortable for extended wear during daily living as standard ECG electrodes. It is normally worn on the upper or lower chest. It is comfortable to wear continuously for long periods of time.



Actiwave Cardio mounted on ECG Electrodes

1.2 Contraindications

The Actiwave Cardio 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 or researchers.

1.4 General Principle of Operation

The Actiwave Cardio is NOT a Medical Device as it does not provide any medical indications. The Actiwave is intended for research purposes only and is NOT indicated for use in clinical applications. The Actiwave measures the small electrical activity of the heart (ECG) by means of miniature electrodes. The signals are measured by the Actiwave and are stored within an internal non-volatile memory.

The Actiwave is typically worn by the subject during their normal daily activities over a period of up to 36 hours thus providing a benefit over lab based systems which only provide a short 'snapshot' of signal activity.

Furthermore the Actiwave Cardio contains a miniature 3 axis accelerometer to allow measurement and recording of physical movement and relative position of the body. These data are recorded synchronously with the ECG waveform data thus providing a further insight into the physical condition of the subject.

2 Installing the Actiwave Setup Software

2.1 System Requirements

The Actiwave software is provided via download (A USB stick can optionally be provided at extra cost). The installer contains all of the components required to install the software package. The following are the minimum requirements of a host PC for installing the Actiwave software:

- Windows® 8 or 10, 32 or 64bit operating systems.
- IBM compatible 2GHz + processor speed recommended
- 500 MB hard disk space
- One free USB port
- SVGA graphics card (1280 x 1024) recommended.

CamNtech recommends the following minimum security requirements for the host PC:

- Use of strong user login passwords
- Enabling of automatic Windows updates
- If the host PC is networked, use of Windows Firewall (or third-part alternative) – ensuring updates applied
- Use of Windows Defender anti-malware (or third-party alternative) with automatic definitions updates enabled.

CamNtech recommends that the Actiwave is not connected to any PC other than a dedicated host PC which meets the above requirements and is running the Actiwave software.

2.2 Software Registration

To access the Actiwave software download, it is necessary to first register the software with CamNtech. Please visit www.camntech.com/register to register your software using the reference number provided with your equipment. You will then be provided with a username and password allowing log-in and download of the software at any time during the two year warranty period.

Note that CamNtech standard software licensing allows up to 3 users to register and use one copy of the software. The software will continue to be fully functional beyond the warranty period but updates will no longer be provided.

2.3 Installing the Software

Download the installer (.msi) from the CamNtech website:
www.camntech.com/downloads

Double click on the downloaded .msi file to run the installer then follow the installation process.

A message warning that 'Publisher cannot be verified' may be displayed – click 'Run' to accept (this is a Windows security warning and is not a problem).

The software should **not** be started until you have connected the reader and installed the drivers required by the USB reader charger (see Section 2.5).

Please note the copyright warning. By accepting this, the user is accepting the CamNtech terms and conditions of use of the Actiwave software

2.4 Updating the software.

If you are updating or reinstalling the software you should remove the old version first when prompted by the installation wizard. The installation has to then be restarted by removing and re-inserting the CD ROM or by double-clicking on the Actiwave.msi file.

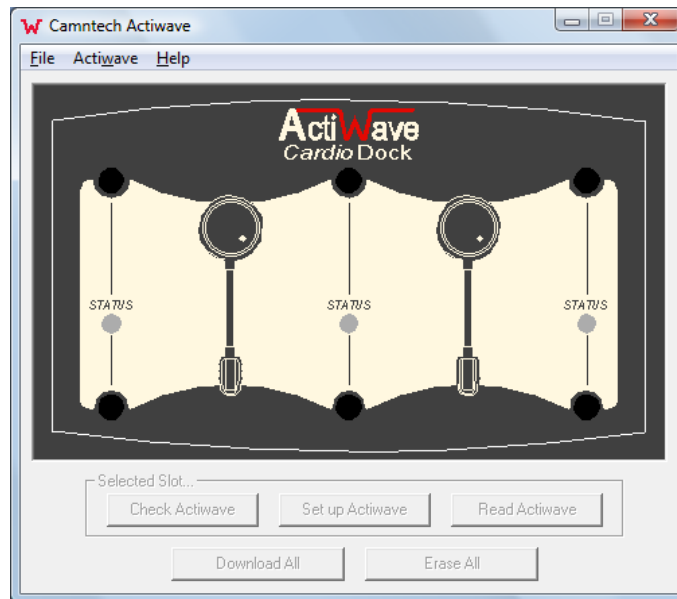
2.5 Installing the USB drivers for the CardioDock

For all CardioDocks shipped after September 2013, the USB driver installation will be automatic. Ensure that the PC has an internet connection and then connect the Interface Dock. The device will be detected and the drivers should load with no user intervention. Wait for the drivers to complete their installation before starting the Actiwave Software.

If there is no internet connection or if your CardioDock is older than SN020159 then please consult Appendix 2 for USB driver installation.

2.6 Running the Software for the first time

Double clicking on the 'Actiwave Signal Capture' icon on the desktop will start the software. If the dock is connected it should be detected and a view of it shown on screen:



2.7 Installing the Cardio Viewer Software (Optional)

Place the Cardio Viewer CD ROM into the drive then browse using Windows Explorer to view the CD ROM and double-click on the file 'CardioViewer.msi'.

Follow the installation wizard's onscreen prompts until the installation is complete. It is recommended that you install the software in the default location. The operation of this software on a remote server is not guaranteed as network settings vary considerably.

3 Connecting the Actiwave & Charging the Battery

3.1 Overview

Before the Actiwave is used for data collection, the user must ensure that it is fully charged. A depleted battery may result in an incomplete recording as the Actiwave may shut down before data collection is complete. If the battery is below 3.7V, a warning message will be displayed if set-up is attempted.

The Actiwave contains a lithium polymer rechargeable battery. The expected duration of the battery from fully charged is dependent on the recording mode but is always in excess of 2 days. The Actiwave may be recharged via the USB port of the Host PC or using a standard mains adaptor with a USB Type A connection (e.g. those used with MP3 players etc.).

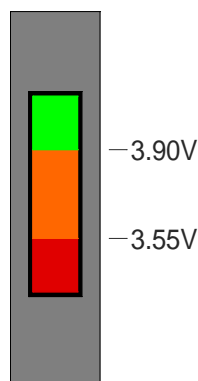
3.2 Charging the Actiwave from the PC

There are two modes of operation when the dock is connected to the PC (and the PC is switched on):

1. **Stand-alone mode:** The Actiwave software is not running; the Actiwave devices are charged and their charge status is indicated by the LEDs on the dock. While the Actiwave is charging, the LED will be RED. When the Actiwave is charged, the LED will stay GREEN. Note that the status will alternate between charged/charging as the charge level rises, and occasionally show red in order to maintain full battery charge.

2. **Managed Mode:** In this mode, the Actiwave software is running on the PC. The main display will show a bar graph of the approximate battery level on the respective channel.

Approximate
Voltage
indicated by
charge gauge



An Actiwave which has been used should be left charging on the reader for a period of several hours (i.e. overnight) if you require it to be fully charged. The estimated battery level shown may not be fully accurate during charging itself, so it is advisable to leave the unit connected and charging for some time if the indication has reached green after only a short period.

3.3 Charging using the Mains Power Supply

The Actiwave Dock 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.



To charge the Actiwave Cardio using the mains adaptor the USB cable provided should be plugged into the mating socket on the mains adaptor.

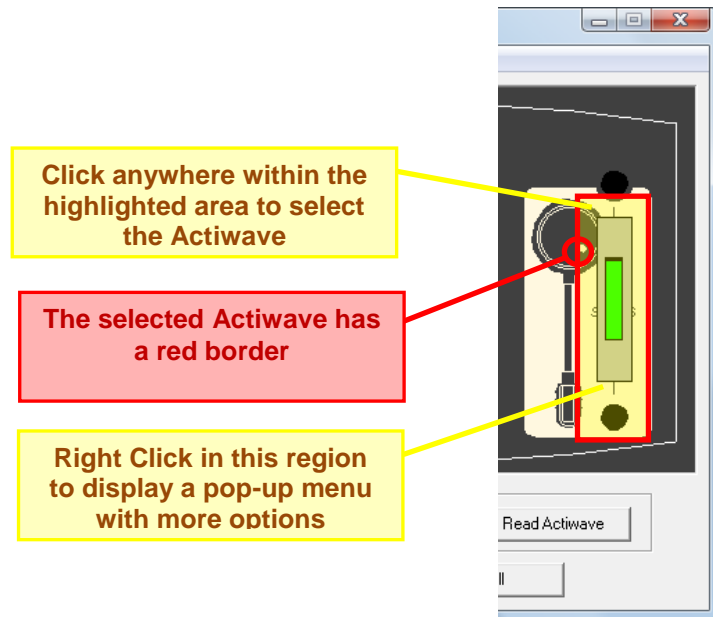
The dock will operate in 'stand alone mode' with Actiwave charge status indicated by means of the front panel LED's (see 'Stand alone mode' above).

IMPORTANT! If battery charging is attempted AFTER setup the recording will be stopped and will not re-start. The setup will need to be performed again to continue the recording.

4 Selecting an Actiwave and Viewing Status.

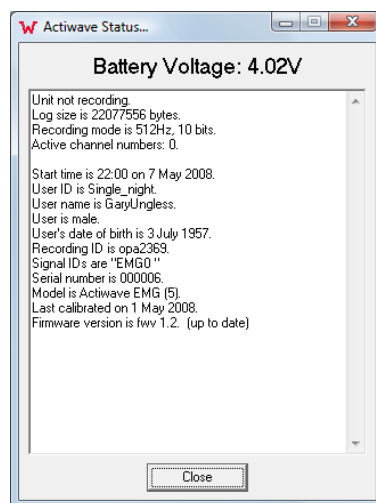
4.1 Selecting an Actiwave

To select a docked Actiwave, click on the image of the required device (see figure below). The selected Actiwave will be outlined in red and the corresponding LED on the dock will flash amber. The user may then either use the options in the top menu bar, the buttons at the bottom of the screen or right click to display a pop-up menu.



4.2 Viewing Actiwave Status

Having selected the required Actiwave, click the 'Check status' button (or right-click on the required Actiwave image and select 'Check status' from the pop-up menu) will display the window below.



This window provides information about the battery voltage, details of the current device settings, details of the previous recording and technical information about the Actiwave.

5 Setting up an Actiwave for a Recording

5.1 Actiwave Set-up

Select the required Actiwave from the main screen and then click 'Set up Actiwave'. Note that the previous recording will then be erased. Note that there is a limit of approximately 50 characters shared across the User ID, Full name, DOB, recording ID and channel names. A warning message will be displayed if the limit is exceeded and the set-up will not be written to the device.

The screenshot shows the 'Set up Actiwave Cardio 000740' window. It has a title bar with a red 'X' button. The form is organized into sections. The top section contains fields for 'User/Patient ID', 'Full Name', 'Sex' (a dropdown menu), 'Date of Birth', 'Weight' (with a unit dropdown), and 'Height' (with a unit dropdown). Below these is a 'Recording ID' field. The next section has 'Start On' (date and time) and 'Sample at' (frequency) and 'Resolution' (bits) dropdowns. The 'Channel 1' section has an 'Enable' checkbox, a radio button for 'ECG', and a text field for the channel name 'ECG0' with a help button '?'. The 'Accelerometer' section has three checkboxes for 'X Axis', 'Y Axis', and 'Z Axis', and a 'Sample at' dropdown. At the bottom, it says 'Recording time will be 1 day, 0 hrs.' and has 'OK' and 'Cancel' buttons.

Required – enter user or subject identification information.

Optional – When using an ID, the full subject name can be entered here.

Optional – Select the subject gender

Optional – Enter subject DOB

Optional – Enter subject weight & height

Optional – Enter information to uniquely identify this recording

Required – Start date and time must be entered. Start can be delayed for up to 1 month.

Required – Select the sample rate and resolution:

8 bit = 1 in 256 resolution

9 bit = 1 in 512 resolution

10 bit = 1 in 1024 resolution

Required – Enable or **Disable*** ECG recording and enter a channel name. Note that the EDF format has a recommended naming convention (click the [?] button for information)

Required – Enable or **Disable*** the accelerometer axes and select the accelerometer sample rate.

Total recording time will be displayed as the settings are changed.

*** IMPORTANT NOTE:** To use the Cardio Viewer software, the ECG and all three axes of acceleration must be **ENABLED**.

5.2 Cardio Recording Times

The table below shows the recording time for the different setup options for the Cardio.

Sample Rate (Hz)		Recording Time @ Resolution		
ECG	ACC	8 bits	9 bits	10 bits
32	Off	2d 0h	2d 0h	2d 0h
32	32	2d 0h	2d 0h	1d 19h
50	Off	2d 0h	2d 0h	2d 0h
50	25	2d 0h	2d 0h	1 d 20h
50	50	1d 10h	1d 7h	1d 3h
64	Off	2d 0h	2d 0h	2d 0h
64	32	1d 19h	1d 14h	1d 10h
64	64	1d 3h	1d 0h	21h 50m
100	Off	2d 0h	2d 0h	2d 0h
100	25	1d 15h	1d 11h	1d 7h
100	50	1d 3h	1d 0h	22h 22m
100	100	17h 28m	15h 32m	13h 58m
128	Off	2d 0h	2d 0h	1d 19h
128	32	1d 7h	1d 3h	1d 0h
128	64	21h 50m	19h 25m	17h 28m
128	128	13h 39m	12h 8m	10h 55m
200	Off	1d 10h	1d 7h	1d 3h
200	25	1d 1h	22h 35m	20h 20m
200	50	19h 58m	17h 45m	15h 58m
200	100	13h 58m	12h 25m	11h 11m
200	200	8h 44m	7h 46m	6h 59m
256	Off	1d 3h	1d 0h	21h 50m
256	32	19h 51m	17h 39m	15h 53m
256	64	15h 36m	13h 52m	12h 28m
256	128	10h 55m	9h 42m	8h 44m
256	256	6h 49m	6h 4m	5h 27m
500	Off	13h 58m	12h 25m	11h 11m
500	125	7h 59m	7h 6m	6h 23m
500	250	5h 35m	4h 58m	4h 28m
500	500	3h 29m	3h 6m	2h 47m
512	Off	13h 39m	12h 8m	10h 55m
512	32	11h 29m	10h 13m	9h 11m
512	64	9h 55m	8h 49m	7h 56m
512	128	7h 48m	6h 56m	6h 14m
512	256	5h 27m	4h 51m	4h 22m
512	512	3h 24m	3h 2m	2h 43m
1024	Off	6h 49m	6h 4m	5h 27m
1024	32	6h 14m	5h 32m	4h 59m
1024	64	5h 44m	5h 6m	4h 35m
1024	128	4h 57m	4h 24m	3h 58m
1024	256	3h 54m	3h 28m	3h 7m
1024	512	2h 43m	n/a	n/a
1024	1024	n/a	n/a	n/a

Assumes all three accelerometer axes are either all enabled or all off.

5.3 *Completing the setup*

Click on the 'OK' button to store the setup to the Actiwave unit. The software will confirm when it is configured and show the programmed start time.

The Actiwave can now be removed and attached to the subject. If a long start delay has been set the Actiwave will enter a low power sleep mode until it needs to start logging.

IMPORTANT! Do NOT place the Cardio back onto the dock after setup: the recording will be stopped and will not re-start. The setup will need to be performed again to continue the recording.

5.4 *Erasing the Actiwave Memory*

Before set-up, the Actiwave memory must be erased - this can take a few minutes to complete depending on the device and the amount of memory used in the previous recording.

When preparing to set-up several Actiwave devices, a faster option is to use the 'Erase All' button. This will begin erasing the memory in all connected Actiwave devices simultaneously. The Actiwave devices can now be individually set-up as above, and there will be no delay for the erase step.

NOTE: Beginning a new set-up or erasing the Actiwave will result in loss of any existing stored data or set-up information – please ensure that any required data has been downloaded first.

The recording times will vary depending upon the Actiwave sampling settings. Please consult section 11 'FAQ and Troubleshooting' for details of allowed sampling options.

6 Preparing for an Actiwave Cardio ECG Recording

6.1 Electrode pad selection

There is huge variety of electrode pads available to suit various applications. Signal quality is more dependent on skin preparation than pad type. Wear ability and adhesion are the main variables between pad types. We recommend using your existing suppliers or searching the web to obtain the type of pads you require. The only criterion is that a standard 4mm stud is required on the pad. **Some electrodes can cause skin irritation on certain subjects – always be vigilant!**

6.2 Skin Preparation

In all cases, adequate skin preparation is vital to the success of any recording. The ECG signal that the Actiwave Cardio acquires is usually low and adequate skin preparation is required to ensure noise levels are low enough for a good quality recording. The main sources of noise are skin resistance and pad movement. Both these are improved by good skin preparation. The recommended skin preparation procedure is as follows:

Procedure for Skin Preparation

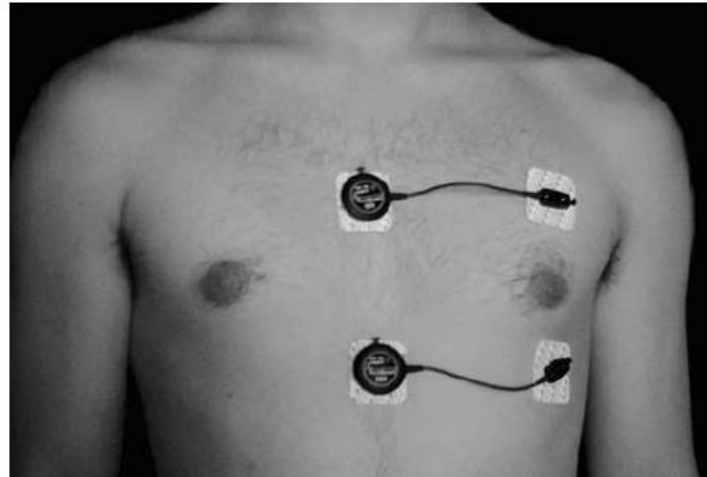
Clean the skin to ensure that it is clean, oil free and preferable hairless. This can easily be achieved by using warm water and soap. Alcohol should not be used as this can potentially cause skin irritation. Shaving is also not ideal and should if possible be done several days before application.

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. (eg. Unomedical, stock code 2121M.) 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; 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 Cardio on it. Attach the second pad to the other clip on the Cardio and use the wire to position the second electrode. Further details on positioning of the Cardio are shown below:

6.3 Electrode Positioning

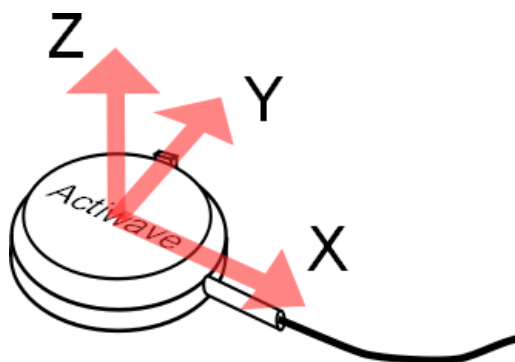
The best ECG signals can usually be picked up by placing the round end of the Actiwave Cardio unit in a position midway between and below V1 and V2. The other electrode can be placed at V4 or V5. A position on the upper chest shown in the diagram below can also be used. This may be either more or less acceptable for female users depending on their breast size.



6.4 Positioning of the Actiwave cardio

For good accurate measurement of activity and body position the cable needs to be placed with the cable exit as **near the horizontal as possible**. If necessary use a small piece of tape {Micropore or similar} to hold the cable horizontal. This will avoid unnecessary rotation of the sensor in situ. The main body of the device should be located close to the centre line of the chest (see photo).

The acceleration output of the Actiwave cardio is labeled in X, Y and Z axes, with meanings as described and illustrated following. Note that the software can also be made to produce text annotations of the body orientation during steady non-moving periods. This may be easier to interpret than the three acceleration numbers.



- The direction of positive X acceleration is outward from the body of the unit along the wire.
- The direction of positive Y acceleration is outward from the unit in the direction of the plastic button for releasing the clip.
- The direction of positive Z acceleration is outward from the unit in the direction of the lid. For example this would be directly upwards if the device is resting normally on a table with the label upwards.

6.5 Use of the Actiwave Cardio in water

Although the Actiwave **cardio** is waterproof, use in the water will result in attenuated and noisy ECG signals. The acceleration signals will not be affected. This can be reduced by covering the device in a swimsuit to reduce movement over the area, or avoided by covering the unit completely with a large waterproof plaster or equivalent.

Important! In the European Union the Actiwave is **not** a medical device and is intended for **research only**. Please contact CamNtech UK for further clarification on suitability of application.

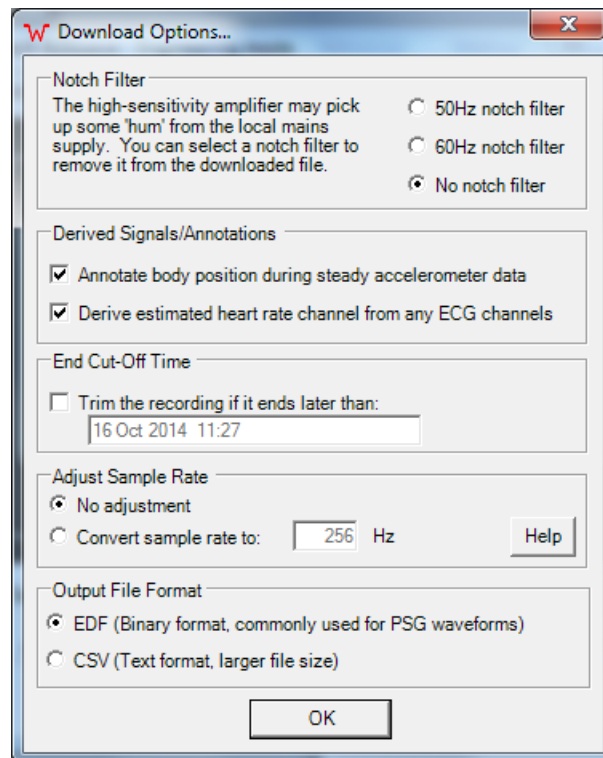
WARNING!

Care should be taken when electrodes are applied to the subject to ensure that unconnected leads or parts are not accidentally shorted to other conductive paths or to earth (ground).

7 Downloading data

7.1 Download options

Select the appropriate channel and then click on the 'Read Actiwave' button. The following window will appear:



Notch Filter

Mains pickup is not usually a problem with the Actiwave devices. They are connected only to the body and will not normally pick up signal from mains supplies. However, any mains pickup that does occur can be removed by selecting the appropriate filter for your local mains frequency.

Derived Signals / Annotations

The derived parameters are body position and heart rate. The body position can only be calculated when there is no movement and is applied as an annotation in the EDF file. The heart rate is found using a simple R wave detector. If you require a more sophisticated algorithm and measurements then there are specialist programs available that will carry out this work.

End Cut-Off Time

The data can be trimmed so that large amounts of unwanted data need not be downloaded and stored. For example, An overnight recording may be needed until 7am but not actually read until 10am. If the data is not trimmed then 3 hours of unwanted recording will be downloaded and stored.

Adjust Sample Rate

This function will resample the downloaded data to a different frequency using a natural cubic spline. This allows you to use the Actiwave with software which expects input samples using a different frequency. Most analysis packages will not have this limitation, so you will not need to use this function. You can enter any whole number sampling frequency of at least 100Hz.

Output File Format

After the data is downloaded, it can be saved in two different standard file formats.

The EDF format is a standard format used for EEG files and similar, and can be loaded in many software packages. The details of this format are available at: <http://www.edfplus.info/>.

The CSV format is a text file listing all of the data samples separated by commas, which can be loaded directly into a spreadsheet. However, it is significantly larger and may be slower to handle as a consequence.

7.2 Completing the Download

Having selected the appropriate options, click on the 'OK' button to download the Actiwave. Data is downloaded at 2Mbit per second from the Actiwave device. Even at this speed the data download may take a few minutes for a full memory. After downloading, the data is processed if required to apply any of the filters/annotations described above. The data is then saved using a default filename which is made up from the setup information and the download date. The user may change this filename before storing.

The recorded data in the Actiwave device is **not erased** after download. It is only erased if the unit is set up again or erased using the erase all option.

7.3 The 'Download All' Option

This function downloads data from all the Actiwave devices in the interface dock and stores them in different sequentially numbered files. The download options need only be selected once and then no further user intervention is required.

7.4 Viewing the Saved Data

Cardio Viewer Software

This is a purpose designed software package intended to be used with the combined ECG and accelerometer data from the Actiwave Cardio. This software is optional and may be purchased in addition to the standard set-up software. Please see section 8 for details of how to use the Cardio Viewer software.

Selecting a file to view with a third-party viewer

When a file has been downloaded the user may view the data by using the file menu. The last 4 files downloaded are available on this menu. When a relevant file viewer is installed it should automatically link the EDF or CSV extension to itself. This allows you to open your files using the viewer of your choice.

Detailed Analysis of EDF files

EDF compatible analysis packages available include:

- VivoSense
 - <http://vivonoetics.com/products/vivosense/>
- Polyman
 - www.edfplus.info
- Biopac
 - www.biopac.com
- Kubios
 - <https://www.kubios.com/>
- Sciworks from Datawave
 - www.dwavetech.com
- Labscribe from iWorx
 - www.iworx.com/research/software/

Free EDF file viewers

A number of free EDF viewers are available including Polyman, EDFbrowser, jEDF, OpenXDF Viewer, etc. CamNtech recommends Polyman, which is available in a free version from:

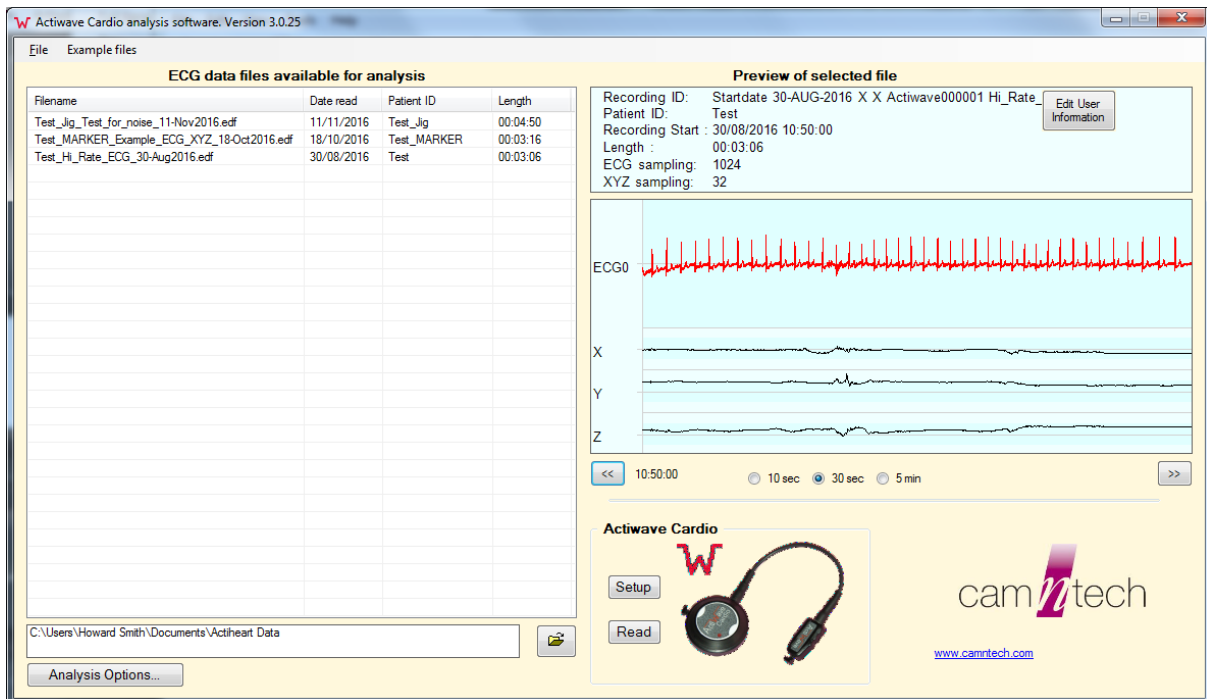
<http://www.edfplus.info/downloads/downloads.html>. Many more advanced commercial packages are available for loading and analysing EDF files

8 Cardio Viewer Software (Optional)

8.1 Starting the software

Double click on the desktop icon to run the Cardio Viewer software and the software will open with the list of files from the default data directory. The directory is that which was used most recently for saving EDF files from the Actiwave set-up software. Only files that are compatible with the Cardio Analysis software will be shown. **This means the recording must contain both ECG and xyz acceleration data.**

Selecting a recording from the list provides a preview of the raw ECG and acceleration data in the file with the user and setup information. You can scroll through the data using the left and right arrow keys and select a 10s, 30s or 5m preview window width.



The software is supplied with some example files. These file are accessed from the top menu bar.

- **24Hr_cardio_example.edf**
A single channel 24 hour Holter test.
- **Overnight_cardio_example.edf**
An overnight recording for sleep analysis
- **Short_cardio_example.edf**
A short recording for quick demonstration

8.2 *Setting up an Actiwave Cardio*

It is not necessary to separately run the Actiwave setup software to set-up the Actiwave Cardio. The Cardio Viewer software has a 'Setup' button on the main screen which opens the set-up as detailed in [Section 5](#) above.

8.3 *Reading an Actiwave Cardio*

It is not necessary to separately run the Actiwave setup software to download the Actiwave Cardio. The Cardio Viewer software has a 'Read' button on the main screen which opens the read window as detailed in [Section 7](#) above.

8.4 *Analysing a File*

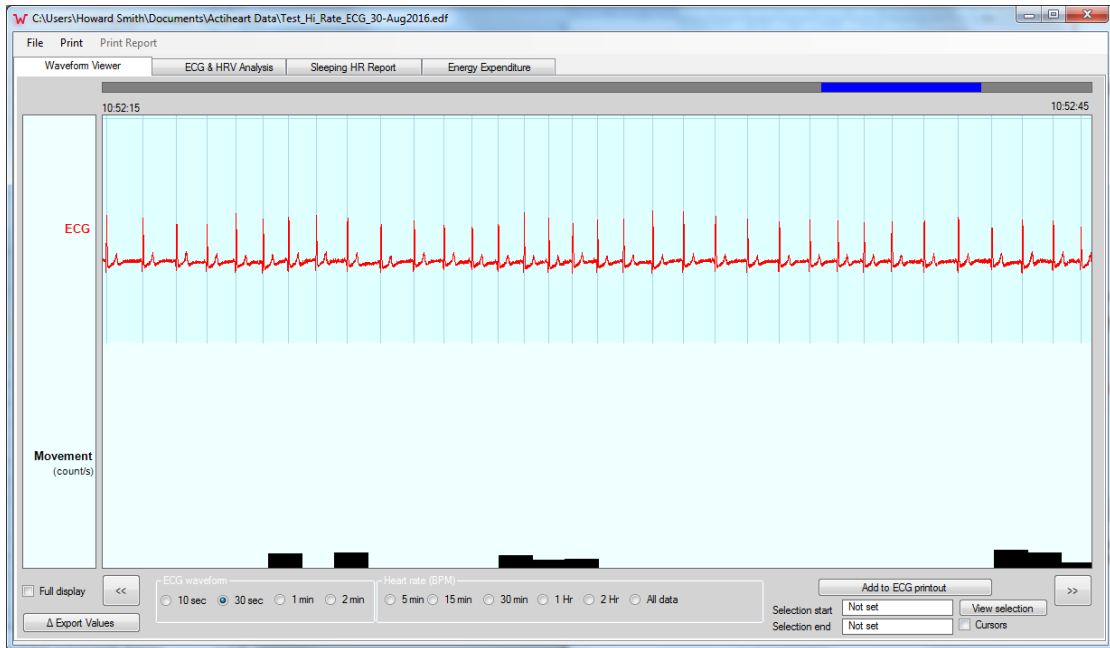
Double click on a file in the list. The full analysis screen will be displayed and the data file loaded after a few moments.

The ECG is always re-sampled to 512Hz – a cubic spline is carried out to interpolate and smooth the data for original sample rates below 512Hz. The resulting ECG is analysed to find all the R waves, and the IBI (Inter Beat Interval or RR interval) data is then calculated.

The acceleration waveforms are also filtered and analysed. The orientation of the sensor with respect to gravity is derived from the steady 3 axis acceleration data. This can only be calculated when the wearer is not moving, as any movement renders the calculation ambiguous. The Y axis of the sensor (up-down when standing) is rectified and summed to determine the overall Activity level. Such movement is normally associated with work against gravity and hence energy expenditure. This integrated value is referred to as 'Actimetry Y'. These mathematical operations can take up to a minute to load the whole of a large EDF file.

8.5 Data Analysis Window

Data Overview



Multiple data analysis windows may be opened, but long files will use large amounts of RAM (300/400 MB for a 24 hour recording). This means that the user should be careful when opening multiple long files.

There are several tabs at the top of the screen:

- **Waveform Viewer** gives a simple overview of the raw data.
- **ECG & HRV Analysis** gives a view of the averaged ECG and Heart Rate Variability statistics.
- **Sleeping HR Report** provides sleep statistics. Heart rate statistics during sleep periods are also shown.
- **Energy Expenditure** gives the energy expenditure, calculated from a standard model based on the validation of the CamNtech Actiheart system.

Heart Rate / ECG

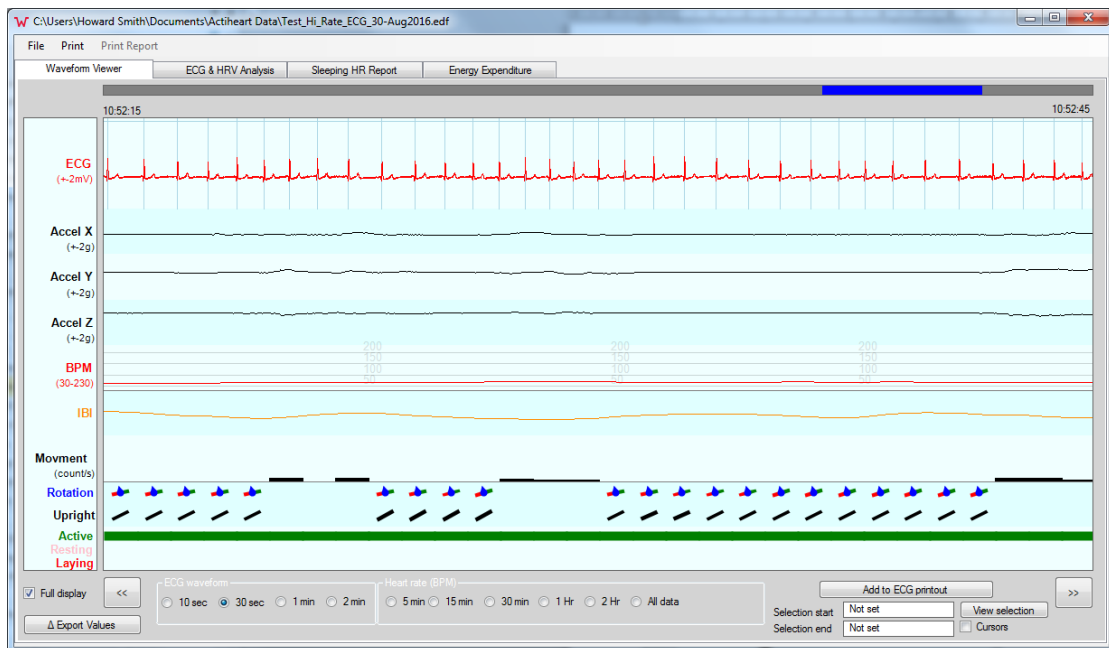
The full ECG is shown if possible. If the time-base is 5 minutes or greater, then the derived 1 second Beats Per Minute (BPM) graph is shown as the display would otherwise become unreadable.

Movement (Accelerometry)

This is a measure of the amount of up/down (Y axis) movement in each second. It is calculated by summing the rectified movement signal with the steady level removed.

8.6 Full Data Overview

By clicking on the 'Full display' checkbox the display is changed:



All the original data is shown along with all the derived signals. The acceleration is shown for all 3 measured axes. The X-axis is left-right on the body, Y is up-down, and Z is back-front.

BPM and IBI Data

The heart rate (Beats Per Minute) data is derived once per second regardless of the heart rate and is displayed in red. The Inter-Beat-Interval (IBI) data is displayed in orange.

This shows the time interval between every single beat, rather than simply the overall rate of heart beats.

Orientation Data

The orientation of the user is shown with a black bar representing the standing / laying down position. The rotation of the body is shown using a red/green bar, where red denotes the left should and green the right. This allows you to see clearly which side the wearer was lying on, particularly when asleep.

Status Data

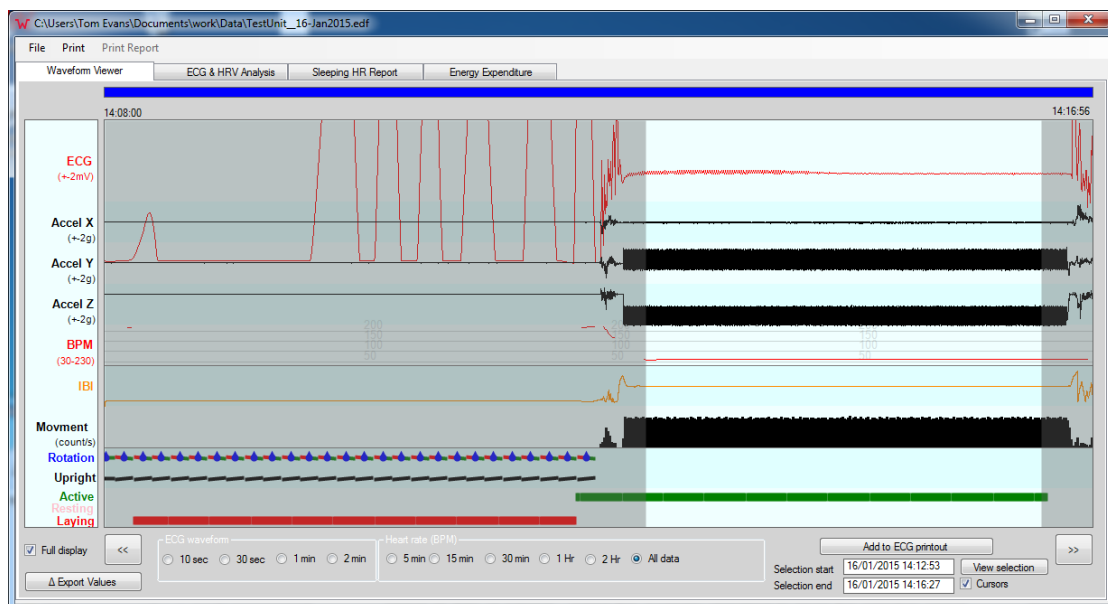
Using the Actimetry Y and the orientation data, the user's status is set as Active, resting or laying down. This status is used later for HRV analysis.

Data Display Width

Using the available options you may select the display window period. Note that this will affect the display of ECG or heart rate data depending on the period, as described above.

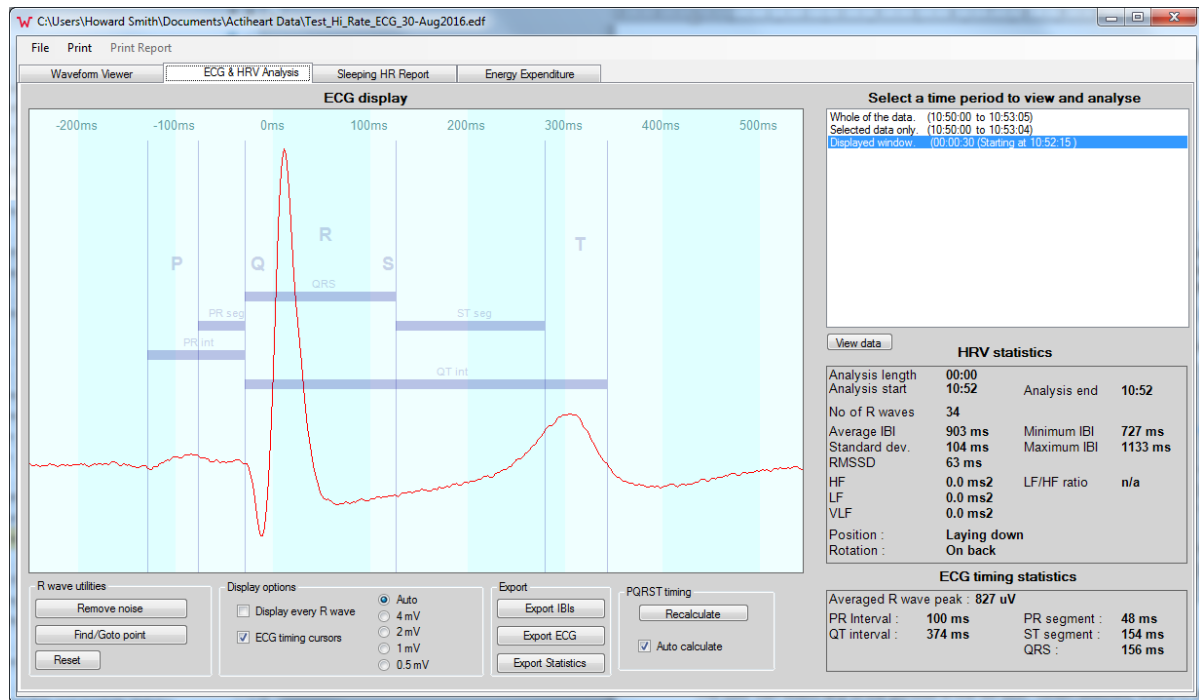
Data Analysis Start and End

The user can set the start and stop time of analysis of the data display, to include only the period of data of interest. Select the "Cursors" checkbox to show the selection period graphically. You can then drag the start and end of the selected (brighter) period to fine-tune your time selection.



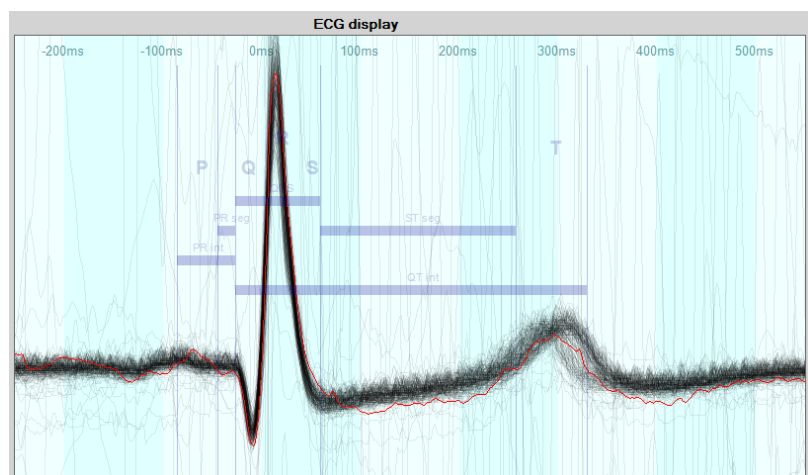
8.7 ECG and HRV Analysis

The ECG and HRV analysis allows the user to view the averaged ECG from a particular section of data. The HRV statistics are displayed and an algorithm will automatically attempt to find the PQRST points on the averaged trace.



Selecting a Data Period

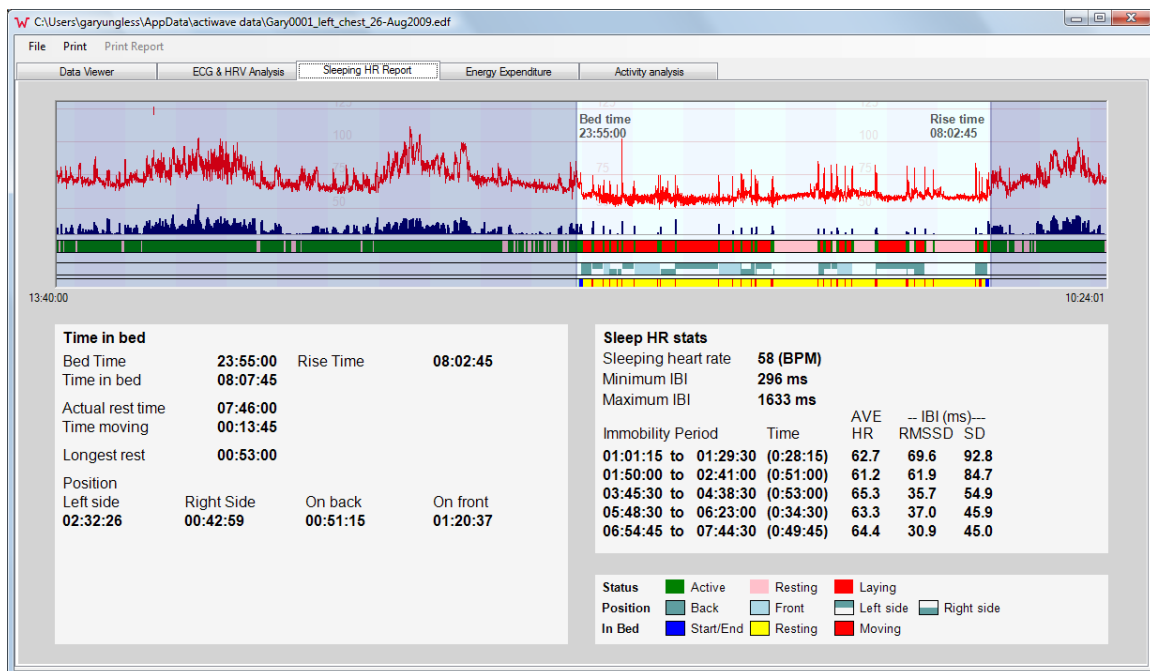
The user can select any of the periods in the list box. When selected, every R wave in the period is added to create an average. This average is shown in red on the display. If the 'Display every R wave' check box is ticked then each ECG is plotted onto the display in black, but each one only faintly. This then builds up to display the 'ECG signal window'. The main use of this feature is to very quickly see any noise or arrhythmia on the ECG trace.



PQRTS Timing Statistics

The average ECG is analysed to get the PQRTS timings, although the algorithm may be upset by noise and irregular waveforms. The ECG may not always contain all the classic ECG elements so the user must always check and adjust the PQRTS cursors if necessary. This is done simply by clicking and dragging the relevant line on the display.

8.8 Sleeping Heart Rate Report



Sleeping HR is carried out on the basis of body position, movement and heart rate. The movement data is accumulated into 15 second epochs. This data along with the body orientation calculated from the 3 axis accelerometer is used to determine the sleep parameters.

Studies that have looked at heart rate and heart rate variability have not shown a reliable correlation to sleep staging. Heart rate variability (HRV) does show promise, but underlying HRV reduces considerably with age and fitness, and varies greatly between individuals. Sleep problems such as sleep apnoea also cause variations in the heart rate.

HRV is affected by both movement and to a lesser extent by body position. This software analyses HRV only during periods of no movement. This gives much more reliable HRV statistics during the longest sleep periods.

The bed time and rise time are manually edited by dragging the marker showing the edge of the sleep period.

The sleep and heart rate statistics are recalculated when the marker is released. When the sleep report screen is first accessed, a search is made for the most likely bed and rise times. These should be checked and edited if necessary.

Status

The subject's status is marked as either Active, Resting or Laying down. Active/Inactive is determined by the amount of movement. Laying down is determined by the angle of the body being less than 40 degrees from horizontal with no movement. This means someone who is propped up in bed will not be considered to be laying down. They will still be considered as asleep if they meet the movement criteria.

Sleeping Position

The subject's sleeping position is determined by using the 3 axis accelerometer readings. This can only be done when the subject is not moving so that the angle with respect to gravity can be calculated using simple vector maths. For simplicity the position is broken down into four body positions. Anything from -40 to + 45 degrees is considered as on the back. The limits for being on the front are +120 to -120 degrees. The angles in between are taken as left and right sides.

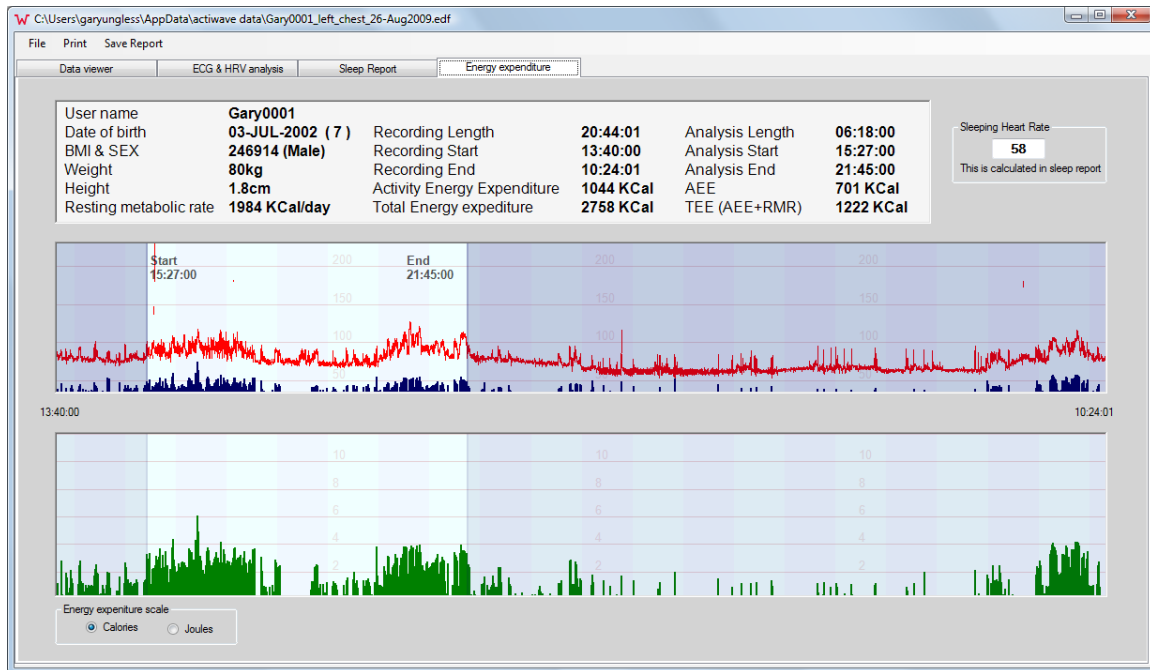
Sleeping Heart Rate and Variability Statistics

The measurement of heart rate during sleeping is not affected by as many outside factors as being during the day. Movement, exercise, stimulants etc. can all lead to inaccuracies in resting heart rate measurement. This means that measurements taken during sleep are both more accurate and more repeatable. Some conditions, such as apnoea, do affect the sleeping heart rate and its variability. But this is relatively clear when looking at the heart rate trace.

The sleeping heart rate is calculated as the rate in beats per minute which the subject has been below for a total of 30 minutes during the night. This gives a good robust measure of the sleeping heart rate. It is not affected by periods of waking or movement during the night.

Heart rate variability statistics are calculated for the five longest periods of sleep during the night. All HRV statistics are susceptible to noise on the ECG waveform causing problems with inter-beat interval (IBI) measurements. The IBI measurements made during periods of no movement are likely to more faithfully reflect the underlying variability.

8.9 Energy Expenditure



Energy Expenditure Algorithm

The energy expenditure algorithm is based on a published model (see ref . JAP2007) that uses the activity and heart rate from each epoch. We use a group model that is based on the subject's age, sex, body mass index and sleeping heart rate. This algorithm depends on the accurate sleeping heart rate based on the lowest 30 minutes of heart rate during sleep, which is calculated automatically during the sleep report. The user may input the sleeping heart rate manually but the accuracy of the energy expenditure calculation may be compromised.

Resting Metabolic Rate (RMR)

This is the energy expenditure that the subject needs for their normal metabolic functions without any activity. It is sometimes referred to as basal metabolic rate (BMR). This number is not measured, but derived from the standard Schofield equations that take into account age, sex and weight.

Activity Energy Expenditure

The lower graphical display shows the energy expenditure during activity in metabolic equivalents (METs). One MET unit is equal to the RMR. For example walking expends between two and three METs. There are tables available for most activities giving approximate energy expenditure or intensity in METs.

9 FAQ & Troubleshooting

What limits the memory size?

Large flash memories are very power hungry. Erasing and writing a large memory array would severely affect the battery life. Writing to the memories is the main source of battery drain even with the low power serial flash we use.

What limits the download speed?

In order to keep the power consumption to a minimum a low power low speed processor is required. It cannot send data any faster than this. The download and saving of the data to disc also takes considerable time even on a fast PC.

Is data compression used?

No. Data compression takes a lot of processing power and no algorithm is able to guarantee 100% true reproduction of the waveform whilst compressing. This means that depending on the choice of algorithm, either the waveform could be altered in an unpredictable manner, or the device may not record for as long as the user is expecting. We do not know the users application so we do not wish to lower the integrity of the data. Data compression algorithms always need to be applied with care taking into account the intended analysis methods.

Why do the first few seconds sometimes show a DC offset

To conserve power the Actiwave unit powers down during the start delay. When it powers up to start storing data the amplifiers need a few seconds to settle.

How synchronous are the channels?

The waveforms on one unit are all recorded within a hundred microseconds. The variation between units is less than 0.5 seconds when set up, although larger drift may occur over a long recording.

The Actiwave Dock is not recognised or will not communicate:

The most likely cause of problems will be due to the USB drivers. Windows will sometimes automatically try to choose the wrong driver during installation or may in some other way fail to install the drivers correctly. See Appendix 2 for advice on installing the USB drivers manually.

The software offers to update the Actiwave firmware – what does this mean?

The Actiwave Software is shipped with the latest device operating firmware. If the software detects that any Actiwave has older firmware, it will inform you that an update is available. It is recommended that firmware updates are applied to ensure that you benefit any improvements to the device. Follow the on-

I have two or more EDF files that I wish to join together – how do I do this?

screen instructions to update the firmware and do not remove the device or interrupt the process.

See Appendix 3: Joining EDF files.

The Recordings are very noisy:

The typical causes of noisy data are due to pad selection and poor skin preparation. See sections 6.1 and 6.2 for advice. Mains noise may in rare cases cause a problem; see section 7.1 for details of filtering this noise.

The Actiwave won't communicate and I get a message about 'A device which may be an Actiwave has been detected':

The battery in the Actiwave is below the level required to communicate. This message is a safety warning to prevent users of other CamNtech products attempting to use the wrong interface. Leave the Actiwave in the dock to charge and check again later.

What are the potential effects of Electromagnetic interference?

The Actiwave system was designed to minimise the effects of external EMI upon the device and to minimise the effect upon the environment from the device. The system conforms to the appropriate standards with respect to EMI performance (see section 11.7). In cases where strong EMI does affect the Actiwave, the device will recover with no user intervention.

Actiwave Cardio Sample Rates Table:

ECG Sample Rate	Available Accelerometer Sample Rates
32Hz	32Hz
50Hz	25Hz, 50Hz
64Hz	32Hz, 64Hz
100Hz	25Hz, 50Hz, 100Hz
128Hz	32Hz, 64Hz, 128Hz
200Hz	25Hz, 50Hz, 100Hz, 200Hz
256Hz	32Hz, 64Hz, 128Hz, 256Hz
500Hz	125Hz, 250Hz, 500Hz
512Hz	32Hz, 64Hz, 128Hz, 256Hz, 512Hz
1024Hz	32Hz, 64Hz, 128Hz, 256Hz, 512Hz, 1024Hz*

*Note that 1024Hz acceleration is blocked by the software

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 de-contamination.
- The Actiwave 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 4VDC; 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 Actiwave.

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

	Operating	Storage & Transport*
Temperature	+5°C to +40°C 41°F to 104°F	-25°C to +70°C -13°F to 158°F
Relative Humidity	15% to 93% Non-condensing	15% to 93% Non-condensing
Atmospheric pressure	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 provides compliance and user guidance regarding Electromagnetic compatibility of the Actiwave system.

A1.5.1 Electromagnetic Emissions


Guidance and Manufacturers Declaration – Electromagnetic emissions		
The Actiwave is intended for use in the electromagnetic environment specified below. The customer or the user of the Actiwave should assure that it is used in such an environment.		
Emissions Tests	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The Actiwave 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.
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 Actiwave is intended for use in the electromagnetic environment specified below. The customer or the user of the Actiwave 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	<p>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.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ V/m	

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.

^a 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].

^b 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 – Installing USB Drivers Manually

***If you have no internet connection
on the PC where the software is
installed***

The Drivers normally automatically download from Microsoft update, however this requires an active internet connection.

Use a different PC to visit our website at <https://www.camntech.com/support/drivers> and download the drivers package or download from the link below:

https://www.camntech.com/images/downloads/Driver/CDM20830_Setup.exe

***If you have an older CardioDock
and need to use a new version of
Windows***

When Microsoft launched Windows 8, they decided to automatically block certain USB drivers as a security precaution. This has led to many legitimate USB drivers being incorrectly and silently blocked. This problem affects certain versions of Windows 7 (with updates), Windows 8 and 10.

Our devices were modified in response to this issue in August 2013. Any CardioDock with serial number higher than 020159 will automatically download and install the correct driver when the CardioDock is connected. This requires an internet connection (see above).

For any CardioDock that has serial number lower than 020159, it will be necessary to return the dock to CamNtech for an update. This will be performed free of charge and will ensure that the device will operate with any current version of Windows.

***If you have an older CardioDock
and need to use an old version of
Windows***

- Insert the supplied CD ROM into the CD/DVD drive on the host PC and plug the Actiwave reader/charger into a free USB Port.
- The installation menu will automatically be displayed (see Section 2.2).
- Depending upon the operating system and current driver status, the computer may display a message saying 'Found New Hardware' and should then load the drivers with no user intervention. The installation menu can be cancelled in this case.

- If the drivers do not load automatically, or if you wish to make sure they install correctly, you may choose 'Install CamNtech USB Drivers' from the installation menu and then carefully follow the instructions on-screen.
- If you have difficulty, visit our website at <https://www.camntech.com/support/drivers> and follow the instructions.
- 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 Actiwave 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.

Appendix 3 – Joining EDF Files

Introduction

The Actiwave software installation contains a utility to allow the joining of EDF files produced by Actiwave devices. In the Start menu of the PC, locate the program 'EDFjoin' (this should be grouped within the Actiwave folder). If there is no Start menu entry or shortcut to this program, locate and run the file EDFjoin.exe in the Actiwave installation folder.

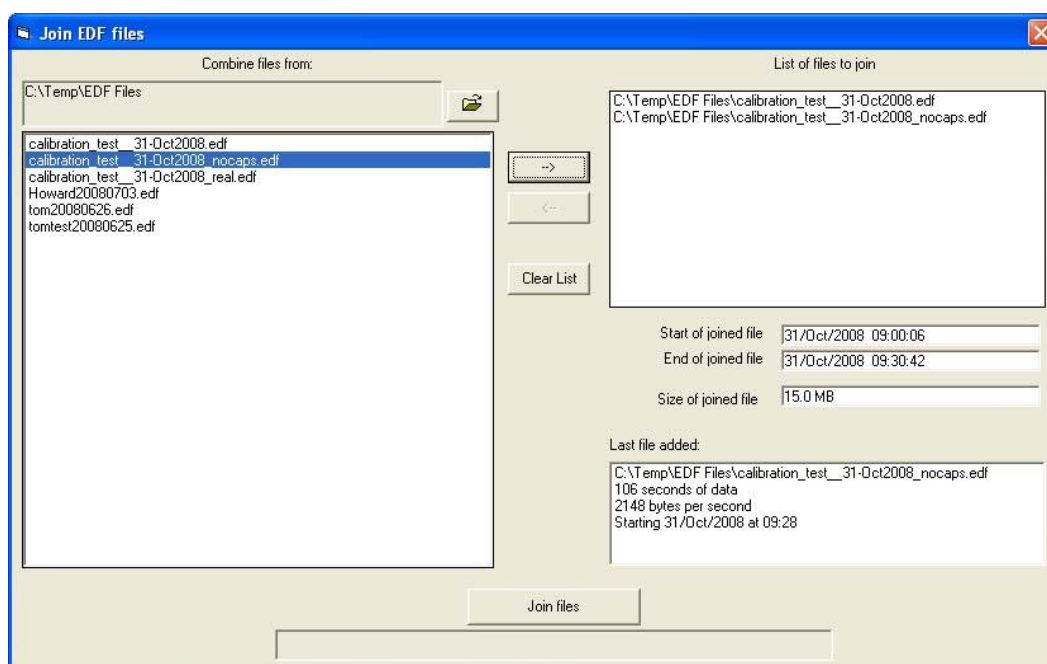
Using EDFjoin

The folder defaults to the one where you have been storing files in the Actiwave software. To select an alternative folder, click on the browse (folder icon) button. A list of EDF files is displayed in the left hand list. Click on a file in the left hand list then click the add button [->] to add it to the 'list of files to join'. To remove a file from the right hand list, select it then click the remove button [<-]. The start date/time and end date/time of the joined file is displayed along with the file size. Selecting files that do not overlap will create a very large file; check the length of the joined file before you start the joining process.

The output file name will be that of the first file in the 'join' list with '_joined' appended.

To complete the process click on the 'Join files' button.

The process can take a few seconds and progress of the operation is shown by a progress bar at the bottom of the screen.



Document Revision History

Issue From	Issue To	Date	Description	Initiator
0.0	1.0	16/05/08	First Issue	GSU
1.0	1.1	26/09/08	Updated to reflect current software modifications	GSU
1.1	1.2	20/05/09	Revisions to add appendices, improved formatting, additional safety and regulatory information added.	HS
1.2	1.3	24/06/09	Further safety information added.	HS
1.3	1.4	25/06/09	Further safety information added.	HS
1.4	1.5	08/07/09	CE mark with NB number added to page 1	HS
1.5	1.6	27/09/09	Formatting changed to corporate style	HS
1.6	1.7	11/01/10	Corrected minor formatting errors, added installation splash screen	HS
1.7	1.8	27/04/10	Added EMC declaration and guidance tables (section 11.7)	HS
1.8	1.9	25/05/12	Revisions for 3 rd edition EN60601-1 and related collateral standards	HS
1.9	1.10	15/01/13	Added EC Declaration of conformity to Appendix 1	HS
1.10	1.11	12/02/13	Corrected some formatting and TOC errors, moved rev history to end of manual	HS
1.11	1.12	20/2/14	Removed EU DoFC, revised Motion section	HS
1.12	2.0.2	1/10/14	Changed memory erasing instructions. Added motion orientation. Added CSV format output.	TE
2.0.2	2.0.3	29/03/16	Added table of sample rate options for Cardio to section 11	HS
2.0.3	2.0.4	12/01/17	EU device classification changed – not a medical device in the EU or EEA.	HS
2.0.4	2.0.14	07/08/18	Removed legacy devices and Motion, added recording time table, combined with CardioViewer software manual using the SW manual document ref 30161	HS
2.01.14	2.014a	24/01/19	Added warnings to not re-connect to dock after setup	HS
2.0.14a	2.1.2	31/12/19	Updated CamNtech address and software installation section	HS