The Actiwave User Guide

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The Actiwave is a Class IIa Medical Device

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

Actiwave - Medical Device Information

The Actiwave system is certified as a **Class 2a** Medical device and complies with the applicable requirements of the Medical Devices Directive **93/42/EEC**.

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Applicable Standards:

Standard	Description
EN60601-1:1990	**Medical electrical equipment – Part 1: General requirements for safety.**
EN60601-1-2:2002	**Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.** **Group 1 equipment / Class B – (emissions only)**
EN60601-1-2:2002	**Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.** **Non life supporting equipment (immunity section only)**
EN60601-1-4:1997	**Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: General requirements for programmable electrical medical systems.**

Safety Classification Information:

The Actiwave is INTERNALLY POWERED EQUIPMENT.

The Actiwave is a TYPE B APPLIED PART.

The Actiwave mode of operation is CONTINUOUS OPERATION.

Note: For further safety and maintenance advice please refer to Section 11

Contents

1 Introduction to the Actiwave System

1.1 An Overview of the Actiwave System

The Actiwave system is designed to offer maximum flexibility for the recording of physiological waveforms. Instead of one bulky multi channel recorder, the Actiwave devices are available in 1, 2 or 4 channels and are physically small enough to be located close to the measuring electrodes.

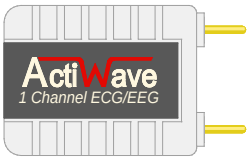
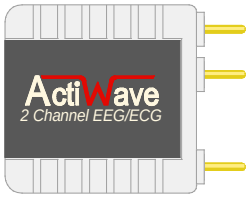
1.1.1 Components required for a system

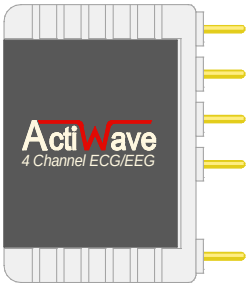
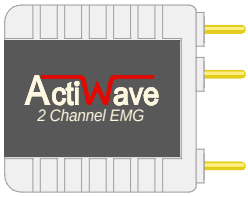
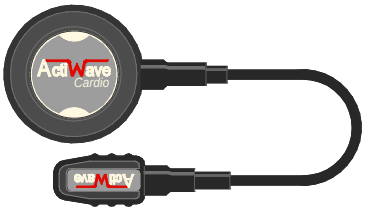
The Actiwave system consists of 3 main components:

- One or more Actiwave recorders with appropriate electrodes.
- USB Interface Dock.
- PC Software providing set-up, download and maintenance functions.

1.1.2 The Actiwave Recorders

There are five variants of the Actiwave recorder; the basic functionality of each variant is summarized in the table below:

	Actiwave Model	Functionality	Memory	Recording Time *
	EEG/ECG **1** [08-514]	Single channel recorder for EEG or ECG waveforms.	16Mb	36 hours
	EEG/ECG **2** [08-521]	Dual channel recorder for 2 x EEG or 2 x ECG or 1 of each type of waveform.	24Mb	27 hours

	EEG/ECG **4** [08-557]	Four channel recorder for EEG or ECG waveforms in any combination.	24Mb	13 hours
	**EMG 2** [08-536]	Dual channel recorder with range and frequency response optimized for EMG recording.	24Mb	27 hours
	**Cardio** [08-603]	Single channel recorder for ECG waveforms with synchronized three axis accelerometer providing activity and body position.	24Mb	31 hours**

* Example recording times are based on 128Hz sampling with 8 bit resolution.

** Assuming 3 axes acceleration sampled at 32Hz.

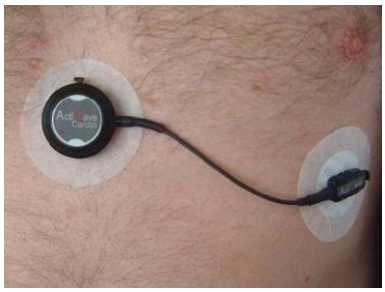
1.1.3 Actiwave Electrodes/Patient Connections

The Actiwave recorders (with the exception of the Cardio) have 1mm male contact pins to mate with 1mm female sockets attached to the electrode cables. The use of 1mm pins/sockets helps to reduce the physical size of the Actiwave in use.

There is a vast range of third party electrodes available to suit specific applications. Typically third party electrodes will be fitted with 1.5mm female sockets which are not directly compatible with the Actiwave. To counter this, CamNtech offer the following solutions:

Solution	Catalogue Ref	Description
EEG/EMG electrode pack 450mm	08-450	Pack of 6 gold plated 'disc' electrodes (11mm dia) with 450mm leads and 1mm connector. Includes Abrasive skin prep paste, Conductive Adhesive paste and gauze.
EEG/EMG electrode pack 100mm	08-100	As above but with 100mm leads.
ECG/EMG 4mm stud to 1mm socket assembly	08-788	Available in cable lengths of 50mm to 600mm.
Self assembly cable accessory kit	08-791	Pack of ten 1mm cable sockets with 5m of 1.6mm black cable to allow self assembled leads.
1mm socket to 1.5mm plug adaptor	#	Pack of 10 adaptors to allow connection of standard 1.5mm leads to the Actiwave.
Lead Customization Service	*	Modification of customer supplied leads to attach 1mm sockets.

Available Q3 2009 * Contact CamNtech for details

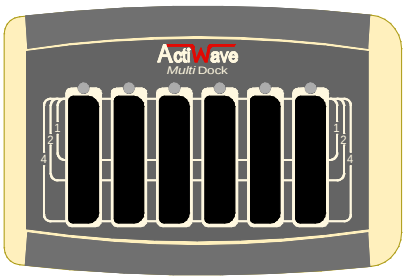
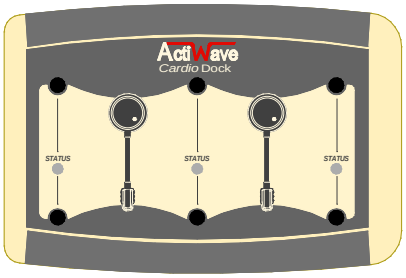


The Actiwave Cardio is designed to be worn on the upper or lower chest (see photo). The Cardio is equipped with spring loaded contacts to allow direct connection to the standard 4mm studs found on ECG electrode pads.
The choice of electrode pad will depend upon the application. The Actiwave Cardio can be comfortably worn for several days.

For further information regarding electrode types and electrode placement, see section 6 of this manual.

1.1.4 The Actiwave Interface Docks

To provide flexibility for users of multiple Actiwave devices, CamNtech offer 3 models of interface dock as summarized in the table below:

	Model [catalog ref]	Description
	*Multi*Dock [08-715]	Allows set-up, reading and charging of up to six Actiwave 1, 2 or 4 devices (Not Cardio). USB interface for connection to PC (Cable supplied)
	*Cardio*Dock [08-733]	Allows set-up, reading and charging of up to three Actiwave Cardio devices only. USB interface for connection to PC (Cable supplied)
	*Combi*Dock [08-727]	Allows set-up, reading and charging of up to four Actiwave 1, 2 or 4 devices plus one Actiwave Cardio. USB interface for connection to PC (Cable supplied)

2 Installing the Actiwave Software

2.1 System Requirements

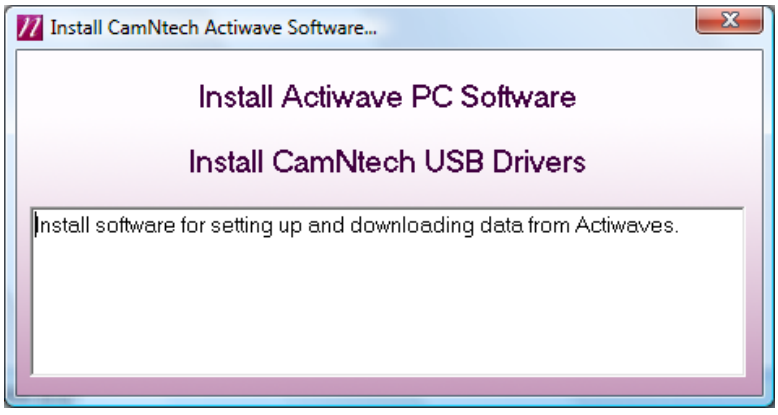
The Actiwave software is supplied on a CD ROM containing all of the components of the software package including the USB drivers for the Interface Dock. The following are the minimum requirements of a host PC for installing the Actiwave software:

- IBM compatible 1000MHz +
- Windows XP, Vista or Windows 7 operating system
- 100 MB hard disk space
- USB port
- A CD-ROM drive or equivalent
- Graphics (1024 x 768 pixels minimum)

In general, a faster processor will provide superior performance.

2.2 Installing the Software

Place the CD ROM into the drive; the Actiwave software installation menu should start automatically as shown below:



If it does not start automatically (this functionality is sometimes disabled for security reasons) you will need to browse with Windows Explorer to view the CD ROM then double-click on the file 'SplashScreen.exe'.

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.

The software should not be started until you have connected the reader and installed the drivers required by the USB reader charger (see Section 2.4).

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

2.3 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.

2.4 Installing the USB drivers for the Interface Dock

This section on installing drivers only applies to new installations.

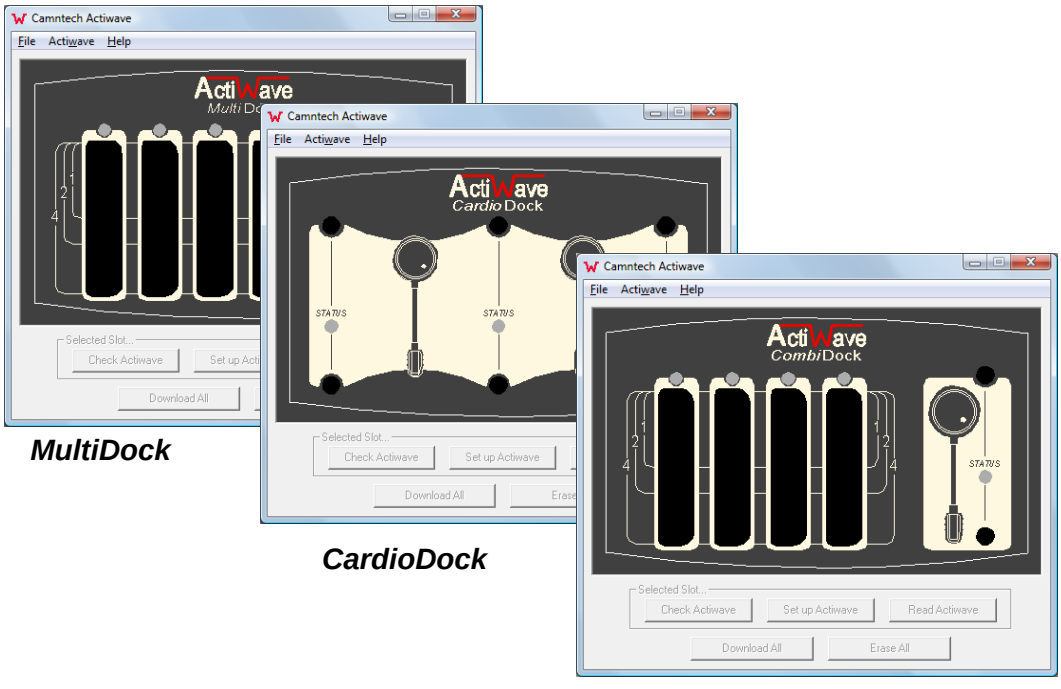
- Insert the supplied CD ROM into the CD/DVD drive on the host PC and plug the Actiwave reader/charger into a free USB Port.
- The installation menu will automatically be displayed (see Section 2.2).
- Depending upon the operating system and current driver status, the computer may display a message saying '*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, consult the procedure; 'Installing USB Drivers Manually', which is included in Appendix A of this manual.

- 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.

2.5 Running the Software for the first time

The USB drivers must be installed before using the software for the first time.

Double clicking on the Actiwave icon on the desktop will start the software. If a dock is plugged in it should be detected and a view of it shown on screen. The three types of interface dock are shown in the figures below:



MultiDock

CardioDock

CombiDock

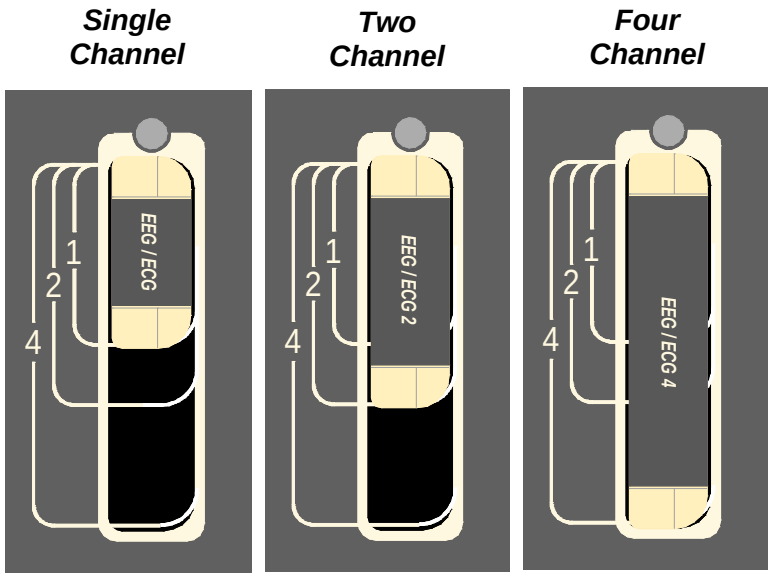
3 Connecting the Actiwave & Charging the Battery

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 type of Actiwave and 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 Correct orientation and position in the dock

The Actiwave devices must be correctly oriented and located in the correct position within the slots of the interface dock. The Actiwave devices (not Cardio) have a profiled case to ensure correct orientation. Furthermore, the Actiwave should always be fitted into the topmost position within the slot (see figures below). Always take care to align the pins with the holes inside the slot and do not use excessive force or the pins may be damaged.

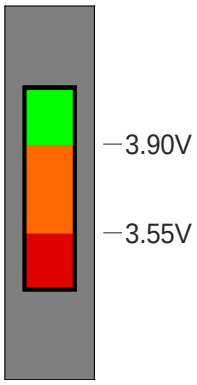


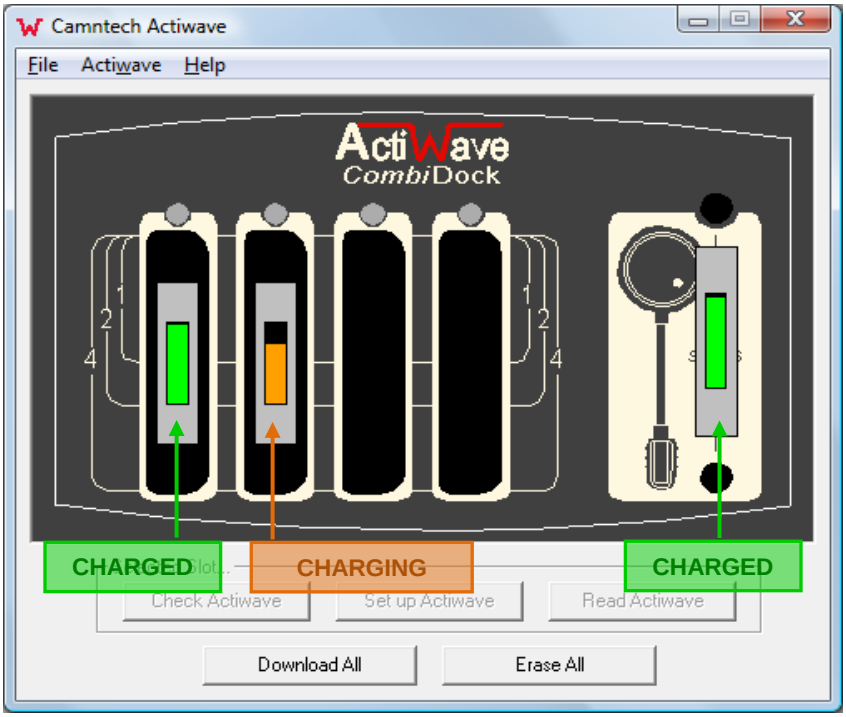
3.3 Charging the Actiwave from the PC

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 be GREEN. Note that the status may alternate between charged/charging 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, if you require it 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.

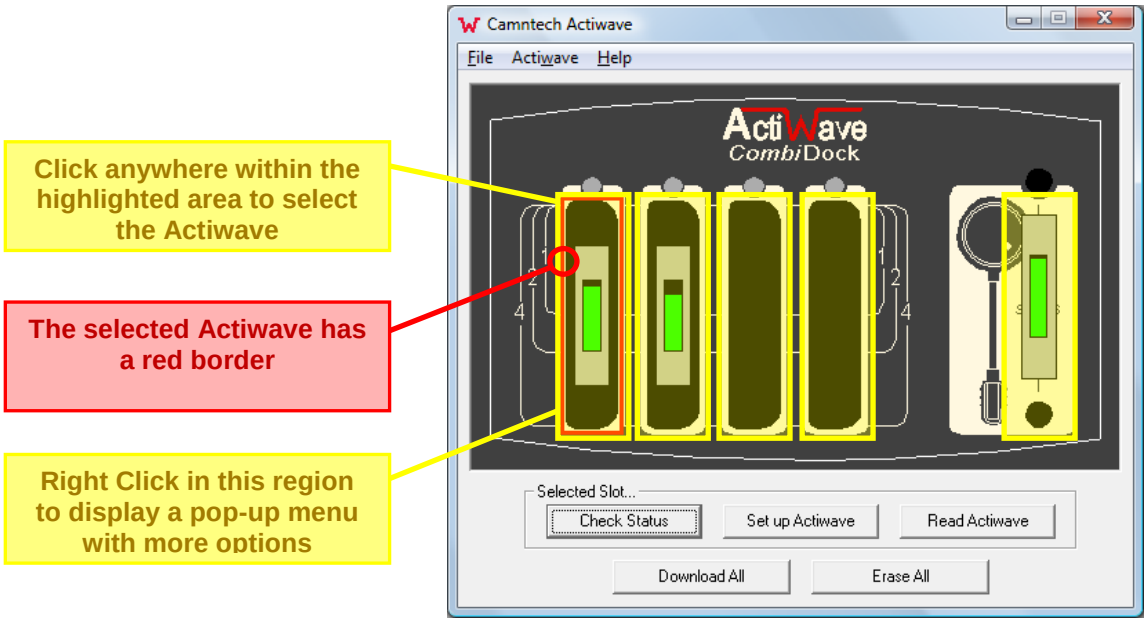
3.4 Charging with a USB mains adaptor

The Interface Dock may be connected to a suitable USB mains adaptor (as supplied). In this case, the USB cable provided should be plugged into the mating socket on the mains adaptor. The mains adaptor must provide 5V DC and at least 100mA.
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).

4 Selecting an Actiwave and Viewing Status.

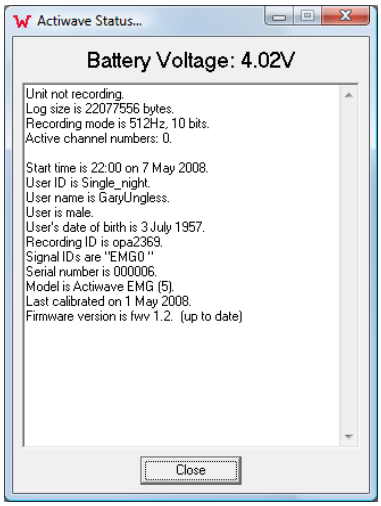
4.1 Selecting an Actiwave

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 bring up a small 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.

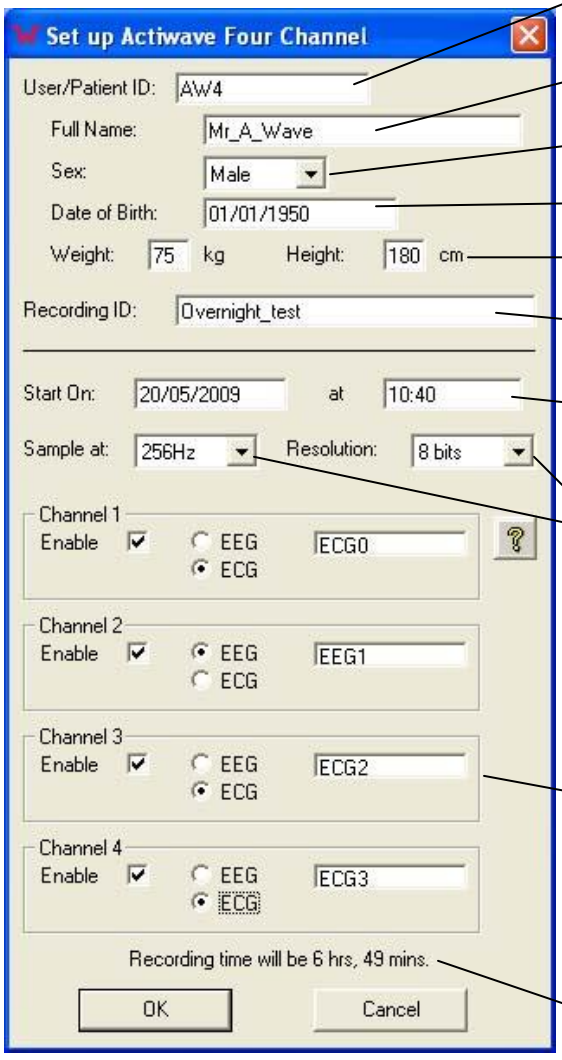


This window provides information about the battery voltage, details of the current device settings, details of the previous recording and technical information about the Actiwave.

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’. The setup options are dependent on the unit type (Example shows an EEG/ECG 4). 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.



Required – enter user or patient identification information.

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

Optional – Select the patient gender

Optional – Enter patient DOB

Optional – Enter patient 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

Note that these settings apply to all enabled channels.

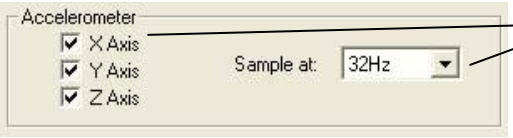
Required – Enable the required number of channels, choose the signal type and enter a channel name. Note that the EDF format has a recommended naming convention (click the [?] button for information)

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

5.2 Additional Actiwave Cardio Options

5.2.1

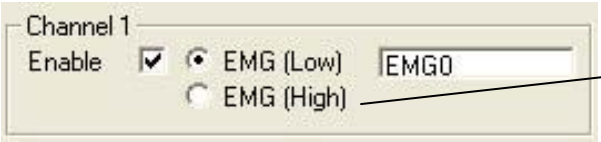
The Actiwave Cardio has additional settings related to the in-built 3-axis accelerometer:



Required – Enable the axes of orientation and select the accelerometer sample rate.

5.3 Additional Actiwave EMG Options

The EMG setup offers the option of setting a low or high range as EMG signals can vary considerably depending upon electrode type and positioning.



Required – Select EMG Range:
'Low' (500uV p-p)
'High' (8mV p-p)

Refer to section 8 for additional information regarding EMG recordings.

5.4 Completing the setup

Click on the 'OK' button to store the setup to the Actiwave unit. Before a new recording can be made, the internal flash memory of the Actiwave will be erased. This will be done automatically when the device is set-up unless the memory has already been erased (see 'Erasing the Actiwave Memory' below).

Erasing the memory will take a few minutes – please be patient!

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

5.5 Erasing the Actiwave Memory

During set-up, the Actiwave memory will be erased for the individual device (see above)-this can take a few minutes to complete.
When preparing to set-up several Actiwave devices, a faster option is to us the ‘Erase All’ button. This will erase the memory in all connected Actiwave devices simultaneously.

The Actiwave devices can now be individually set-up as per 5.4 above and the erase step will be skipped.

NOTE: Applying 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.

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.

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:

6.2.1 Procedure for Skin Preparation

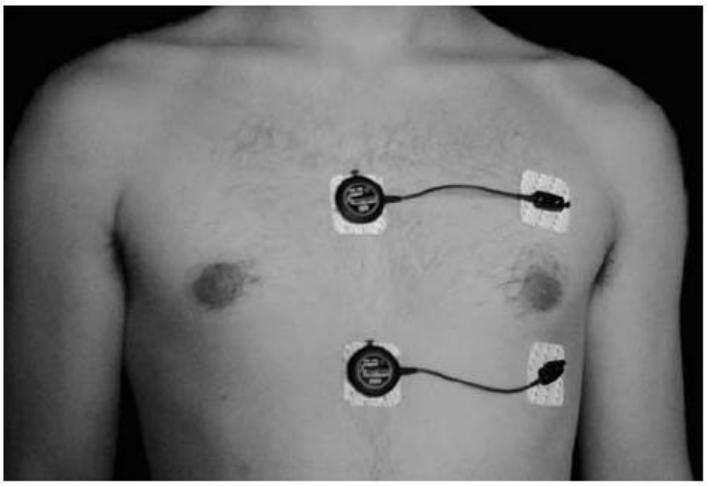
Clean the skin to ensure that it is clean, oil free and preferable hairless. This can easily be achieved by using warm water and soap. Alcohol should not be used as this can potentially cause skin irritation. Shaving is also not ideal and should if possible be done several days before application.

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).

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.

WARNING!

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

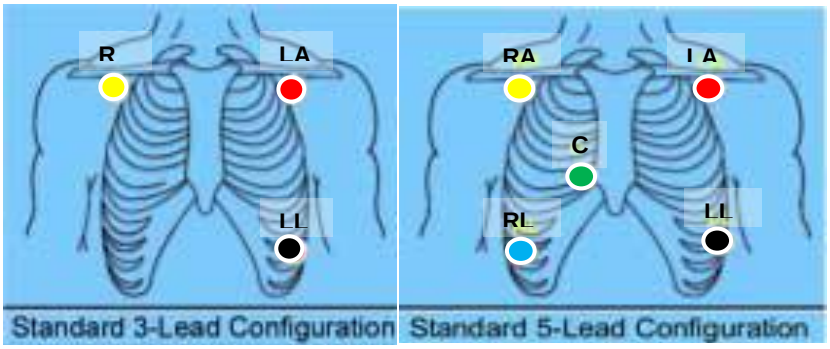
7 Preparing for a 3 or 5 Channel ECG Recording

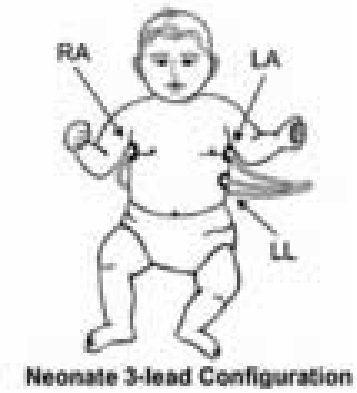
7.1 Electrode pad Selection and Skin Preparation

See **6.1** and **6.2** above.

7.2 Pad placement.

There are standard placements for a 3 and 5 lead ECG. A three lead ECG recording can be made using an Actiwave EEG/ECG 2 device and a 5 lead ECG recording using an Actiwave EEG/ECG 4 device.





The Actiwave ECG devices do not need a ground reference. In all these configurations the LL lead (Plain Black) should be connected to the common (C) of the Actiwave. The other channels can be derived in your EDF file viewer by subtracting relevant channels. If the two channels were measured as RA-LL and LA-LL, your EDF software can then calculate RA-LA from them.

The electrode cables are marked with colour coded sleeves to allow identification of channels with respect to electrode

position. A suggested colour coding scheme is shown in the table below:

Cable Marker Colour	Actiwave Channel	3-Lead Position	5-lead Position
Black (none)	Common (C)	LL	LL
Red	1	LA	LA
Yellow	2	RA	RA
Green	3	-	C
Blue	4	-	RL

Note: The Actiwave is not intended for use with infants of below 10kg in weight.

WARNING!

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

8 Preparing for an EMG recording

8.1 Electrodes

There are two main types of electrode for measuring EMG: surface and needle. The needle electrodes give a small very local signal from within the muscle. Surface electrodes are the more common type and give a larger 'averaged' signal. For measuring surface EMG the electrodes tend to be smaller than the ECG types although some pads are dual use.

8.2 Pad placement

Generally the EMG is measured along the muscle and the signal level will vary according to distance between the pads. There are many different sites and placements for the electrodes and there is a huge amount of information available on this subject. For measuring impulse response along fibre we recommend that the common be used for the central point. The signals are measured synchronously so they can be summed or differenced in your PC software. This also allows the measurement of transit time.

8.3 Signal level & Sampling

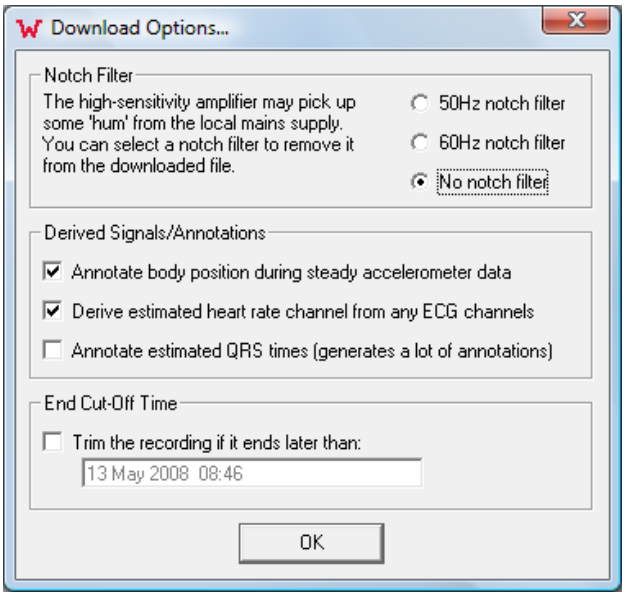
The level of EMG varies and the Actiwave unit has a high signal mode (8mV) and a low signal mode (500uV). The user selects which range to use when setting up. The expected signal level depends on the placement of the EMG electrodes. If in doubt try a short recording on the low range; if the signal is too large then switch to the high range.
It has also been found that a sampling rate of below 256Hz for EMG recording may provide poor results (again depending upon the location from which the signal is being recorded). It is suggested that a short test recording is performed to verify the suitability of the sampling frequency before engaging in a full test.

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

9 Downloading data

9.1 Download options

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



9.1.1 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.

9.1.2 Derived Signals / Annotations

The derived parameters are body position, heart rate and inter beat interval. 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 and IBI are 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.

9.1.3 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.

9.2 Completing the Download

Having selected the appropriate options, click on the 'OK' button to download the Actiwave. Data is downloaded at 1Mbit per second from the Actiwave device. Even at this high 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.

The data is stored in standard EDF+ format (which is backwards compatible with EDF). The details of this format are available at: http://www.edfplus.info

9.3 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.

9.4 Viewing the Saved Data

9.4.1 Selecting a file to view

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. The files are always stored in standard EDF with a filename extension of '.edf'. When an EDF file viewer is installed it should automatically link the EDF extension to itself. This allows you to open your files using the viewer of your choice.

9.4.2 Detailed Analysis of EDF files

CamNtech are able to supply the comprehensive Biopac AcqKnowledge analysis package. Contact CamNtech for current pricing and information.
Acq*Knowledge* is an interactive, intuitive program that lets you instantly view, measure, analyze, and transform data. Perform complex data acquisition, stimulation, triggering and analyses using simple pull-down menus and dialogs. Online analysis settings, filters, and transformations provide real-time feedback, or you can choose from a wide variety of off-line analysis tools. The software also includes quality presentation capabilities.

Contact CamNtech for current pricing and information.

9.4.3 Other 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

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

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

See Appendix B: 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 9.1.1 for details of filtering this noise.

The Actiwave won't communicate and I get a message about 'A device which may be an Actiheart 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 page 2). In cases where strong EMI does affect the Actiwave, the device will recover with no user intervention.

11 Safety and Maintenance Information

11.1 Symbols used for marking devices & packaging

Medical devices carry symbols to provide universally recognised warnings and information. The Actiwave products use the following markings on the device and/or packaging.

11.1.1 Serial Number

This number indicates a unique identification for a particular device. Always quote this number when seeking technical assistance.

11.1.2 Catalogue Number

This number identifies this particular variant of the product range.

11.1.3 Manufacturer & 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.

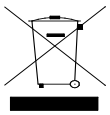
11.1.4 Consult instructions for use

This symbol indicates that important operational information is contained in the user instructions (i.e. this user guide).

11.1.5 Keep Dry

The device is not resistant to moisture and must be kept dry.

11.1.6 Wheelie bin symbol



This symbol indicates that the device must not be disposed of in the normal waste stream. See 11.6 ‘Disposal’ below.

11.2 Decontamination

- Devices used in the field must be considered to be contaminated.
- Returned devices must be cleaned with alcohol wipes to minimise any potential contamination. The operator should use gloves to handle such devices before and during de-contamination.
- The devices are not sealed – do not attempt to autoclave and do not submerse in any liquid.

11.3 Battery

- The device is battery operated and operates at voltages below 5V DC; there is hence no risk from electric shock.
- The battery is **NOT** user replaceable and no attempt should be made to open the device.

11.4 Water Ingress

- The Actiwave Cardio device is tested to 2 Bar and is considered to be suitable for exposure to moisture in normal daily living and swimming for short durations.
- The other Actiwave units are not waterproof.

11.5 Warnings – general

- None of the Actiwave devices is defibrillation proof.
- Always refer to the instructions for use accompanying any electrodes used.
- Do not attempt to open the device – no user serviceable parts are contained therein.
- Not for use in the presence of pacemakers.
- The Actiwave is **not** intended for use with infants of below 10kg in weight.

11.6 Disposal at end of life

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 CNT.
- 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

Appendix A – Installing USB Drivers Manually

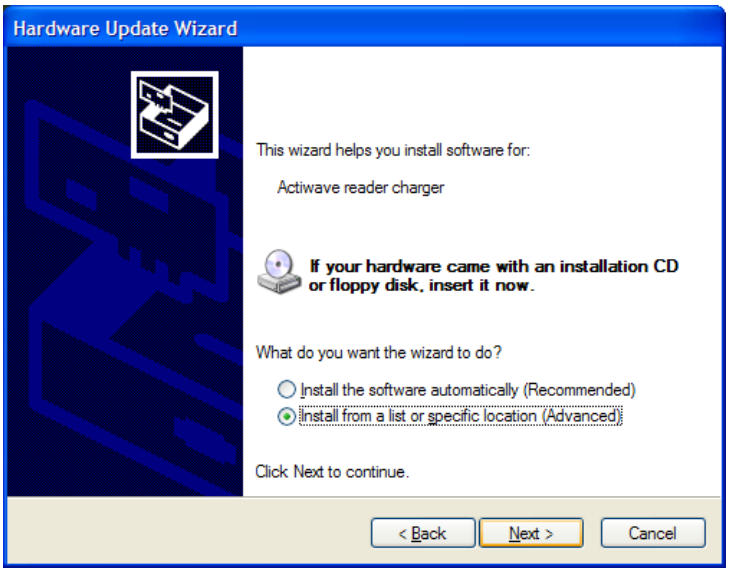
Sometimes the automatic installation of drivers will not work, often because your computer has previously had similar, but different, drivers installed on it before and sometimes because of flaws in the Windows installation process. To install drivers manually, follow the procedure below.

To begin installing drivers:

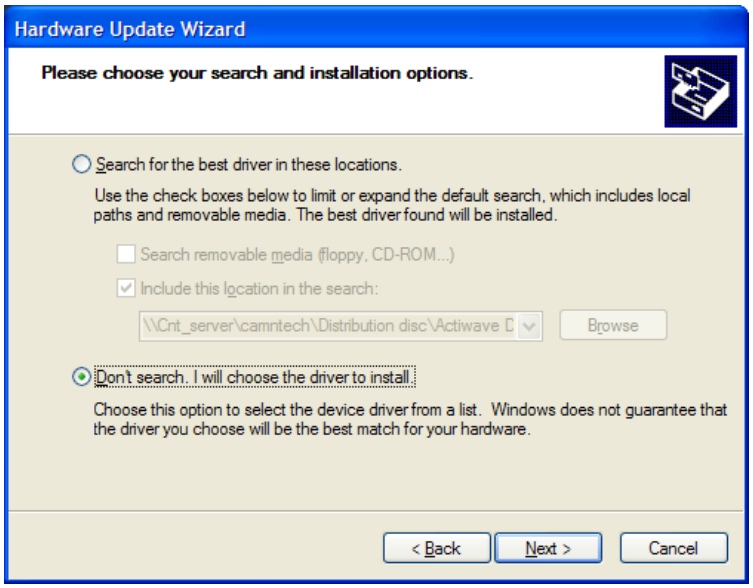
Plug the device into a USB port. Something similar to the window shown below should appear. If it does not, then open it manually like this:

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

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

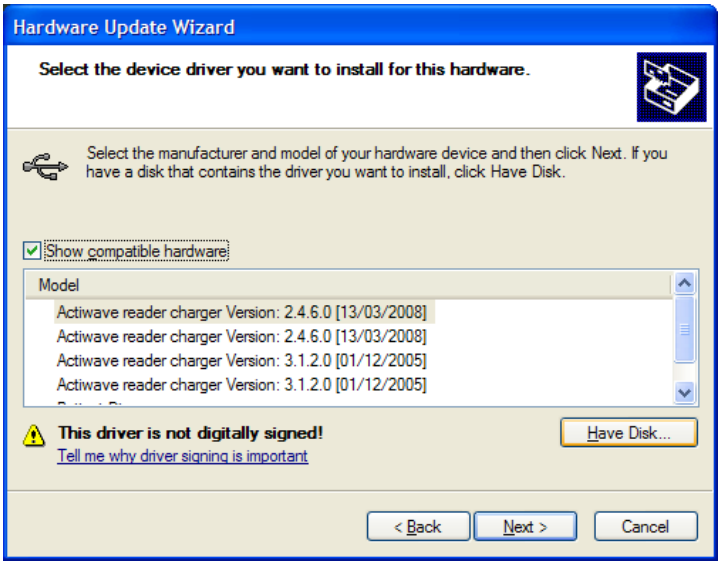


Select ‘Install from a list or specific location (Advanced)’ and click ‘Next’.

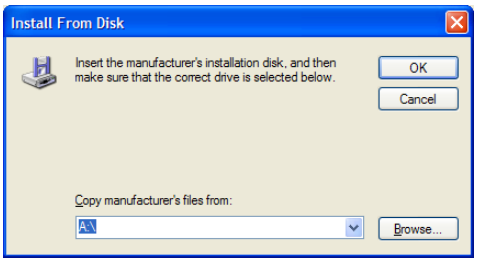


Select ‘Don’t search. I will choose the driver to install.’ and click ‘Next’.

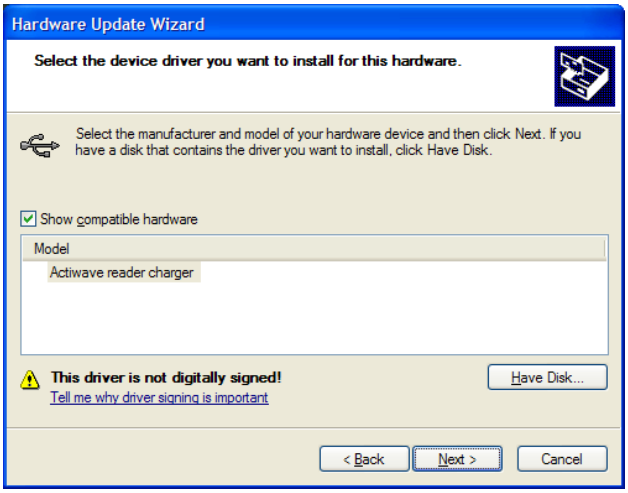
The window on the next page should appear. Sometimes, windows will decide to display some other windows first, possibly appearing to lock up for a minute or two at one point. If it does this, you may be forced to choose a device category. Choose any, and look out for the ‘Have Disk..’ button next, which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



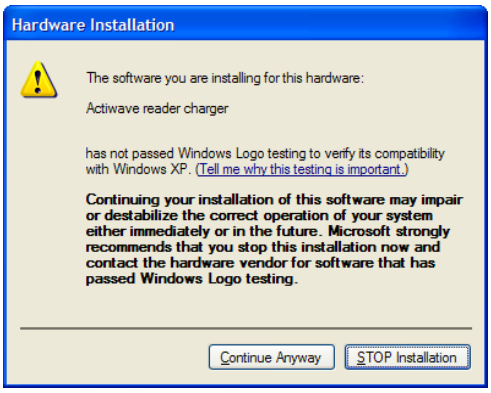
Ignore the items in the list, and click 'Have Disk…' instead.



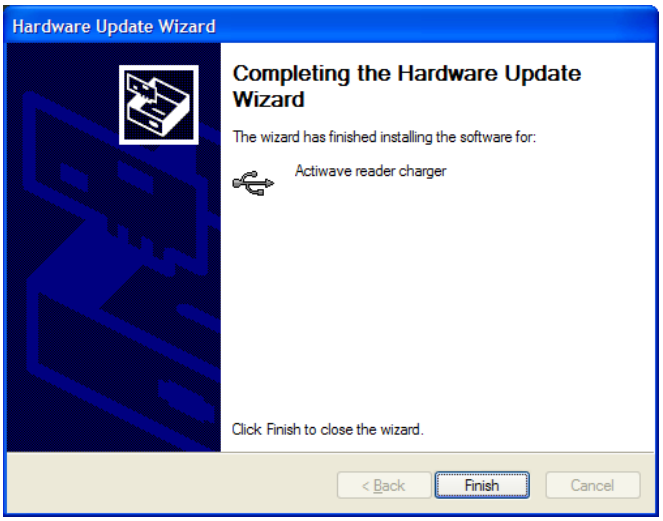
Click on 'Browse…' and then use the standard file window to find the 'USB drivers' folder on the CD. Select 'ftdibus.inf' from this folder and click on 'Open'. The window above will re-appear with a filename at the bottom. Then click 'OK'.



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



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



When this window appears your drivers are installed.

If you still have issues installing the USB drivers then please check our website for up to date information, at the link below: http://www.camntech.com/drivers.htm

Appendix B – 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.