



camnitech

The MotionWatch and MotionWare *User Guide*

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The MotionWatch is a Class I Medical Device (EU)

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MotionWatch Regulatory Information

Medical Device Directive (European Union)

The MotionWatch is a Class I Medical Device conforming to the essential safety & health requirements and provisions of EC Council Directives 93/42/EEC, Annex VII. An EC declaration of Conformity will be provided upon request.

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Health Canada

The MotionWatch is licensed for clinical use in Canada with HC license number 94219 until Dec 31st 2018.

Australian TGA

The MotionWatch has been cleared by the Australian TGA and is listed on the ARTG with ref no: 219452

Australian Sponsor: Please note that the sponsor **should** be contacted **ONLY** to report adverse events – all sales and support issues must be directed to CamNtech in the UK.

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IMPORTANT SAFETY INFORMATION

WARNINGS



- **Coin cell battery** – potential **swallowing hazard** for small children!
- Not Defibrillation proof.
- Not indicated for use on areas of broken or irritated skin.
- Devices removed from subjects must be considered to be contaminated – see APPENDIX C.

Safety Classification Information:

- MotionWatch is **INTERNALLY POWERED EQUIPMENT**.
- MotionWatch mode of operation is **CONTINUOUS OPERATION**.
- MotionWatch is for **PRESCRIPTION USE ONLY** (Rx Only) - USA.

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 MotionWatch 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 MotionWatch is a TYPE B APPLIED PART .

FOR FURTHER HANDLING & ENVIRONMENTAL INFORMATION PLEASE REFER TO APPENDIX C

IMPORTANT BATTERY ADVICE

Battery Replacement

The Motionwatch operates at very low power. When the battery is removed, the watch requires some time to fully reset.



It is essential that the battery replacement process is observed fully to ensure that any new battery is correctly registered in the watch.

Do not fit a new battery without observing the correct procedure as detailed in [appendix A4](#).

Always use a new, retail packaged battery – never re-use a part used battery.

Always choose a quality branded battery – budget brand batteries have much lower energy and can significantly reduce performance.

Failure to observe the correct procedure may result in **loss of data**.

Battery Storage

The Motionwatch uses a CR2032 coin cell battery:



NEVER Store loose batteries together – they will short and may generate heat.

Shorted batteries can no longer be used and should **NOT** be fitted to the MotionWatch.

Poor storage may result in **loss of data**

Choking/Swallowing Hazard



NEVER allow young children to have access to an **open** MotionWatch as the battery may be a choking or swallowing hazard.

In normal use the watch closure should be sufficient to prevent a child opening and accessing the battery.

If the case lid becomes loose, do not use the watch with young children and seek assistance from CamNtech.

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1 Introduction to the MotionWatch System

1.1 An Overview of the MotionWatch System

The MotionWatch is a compact, lightweight, body-worn activity monitoring device that may be used to document physical movement associated with applications in physiological monitoring. The device is intended to monitor limb or body movements during daily living and sleep. The MotionWatch can be used to assess activity in any instance where quantifiable analysis of physical motion is desired. MotionWare allows for the set-up, download and analysis of data captured with the MotionWatch. The MotionWatch also incorporates a light sensor to record luminous intensity (lux) of white light and an event marker button. Utilizing the latest low-power MEMs technology, the MotionWatch provides a convenient, flexible platform for Actigraphy studies of all sizes. See Appendix D – Technical Specifications for Technical and operational specifications.

Components Required for a System

A MotionWatch system consists of 2 elements:

- One or more MotionWatch devices.
- PC based MotionWare Software providing set-up, download and analysis functions.

Note that no reader or interface is required – the MotionWatch has a direct USB connection.

The MotionWatch



Event Marker: The MotionWatch has a front-panel button that may be pressed by the subject to mark specific events. Typically this will be used to mark when the subject goes to bed and when the subject gets up in the morning. The use of the marker will insert a date/time stamped mark within the data.

Light Sensor: The MotionWatch has a front-panel ambient light sensor which can optionally be enabled to collect indoor or outdoor light exposure. This function is also useful to observe the 'lights out' period during sleep.

Status Indicator: Provides visual feedback by flashing when the event marker is pressed. Also used to indicate USB connection and during the battery replacement process.

Opening the MotionWatch Casing

The MotionWatch utilises a 'twist-lock' casing which provides a waterproof seal for the electronics and USB connection while facilitating easy access to the battery. To open the casing, grasp the front of the watch by the two finger grips and **rotate anti-clockwise** by approximately 15 degrees to release.



WARNING!
DO NOT ATTEMPT TO FORCE OPEN/CLOSED THE MOTIONWATCH CASING WITHOUT TWISTING TO UNLOCK/LOCK. DOING SO WILL DAMAGE THE CASING AND INVALIDATE THE WARRANTY!

Now gently lift out the front section of the casing...



Then turn over to access the USB connection...



USB Connection

When the MotionWatch is connected for the first time, the USB drivers will automatically be installed (see Section 2.4 Installing the USB Drivers).

Closing the MotionWatch Casing

The casing must be closed with the parts correctly aligned. To aid with alignment, coloured indicators have been provided as shown in the figure below:



Alignment Indicators

With the indicators aligned, drop the top part of the casing into the lower part and then turn **clockwise by approximately 15 degrees** to close.

WARNING!

DO NOT ATTEMPT TO FORCE OPEN/CLOSED THE MOTIONWATCH CASING WITHOUT TWISTING TO UNLOCK/LOCK. DOING SO WILL DAMAGE THE CASING AND INVALIDATE THE WARRANTY!

1.2 MotionWatch Rugged Model



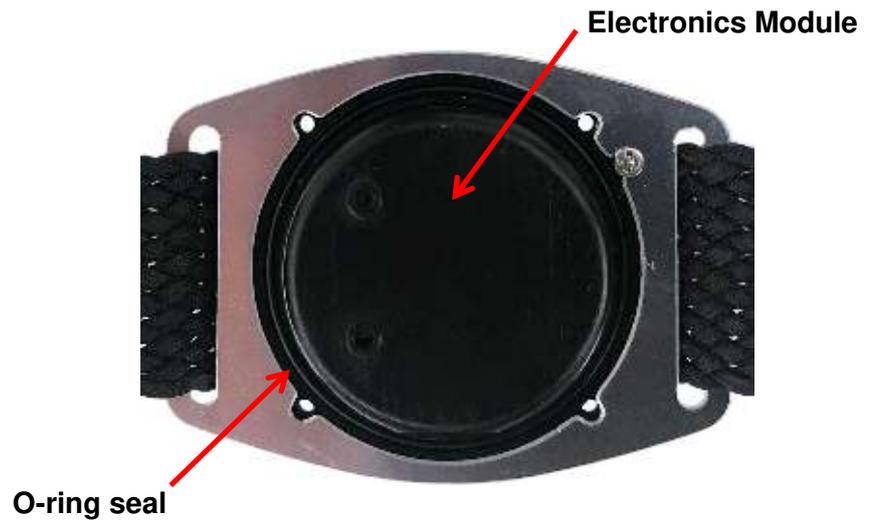
The MotionWatch R (Rugged) is a ruggedized version of the standard MotionWatch intended for use in harsh environments such as veterinary or military applications. The electronics are identical to the standard MotionWatch but the casing is all-metal to provide additional strength over the standard plastic casing. The Rugged case does **not** include the marker button or light sensor.

Opening the MW Rugged Casing

The MotionWatch R casing is secured with four Philips head screws. To open the casing, carefully remove the four screws using the micro screwdriver provided (See photo). Take care not to lose the screws:



Gently lift away the front cover taking care not to lose or damage the O-ring seal. The electronics module is enclosed within a plastic housing (see photo below).



Now simply lift-out the electronics module to reveal the USB connector and the Battery.



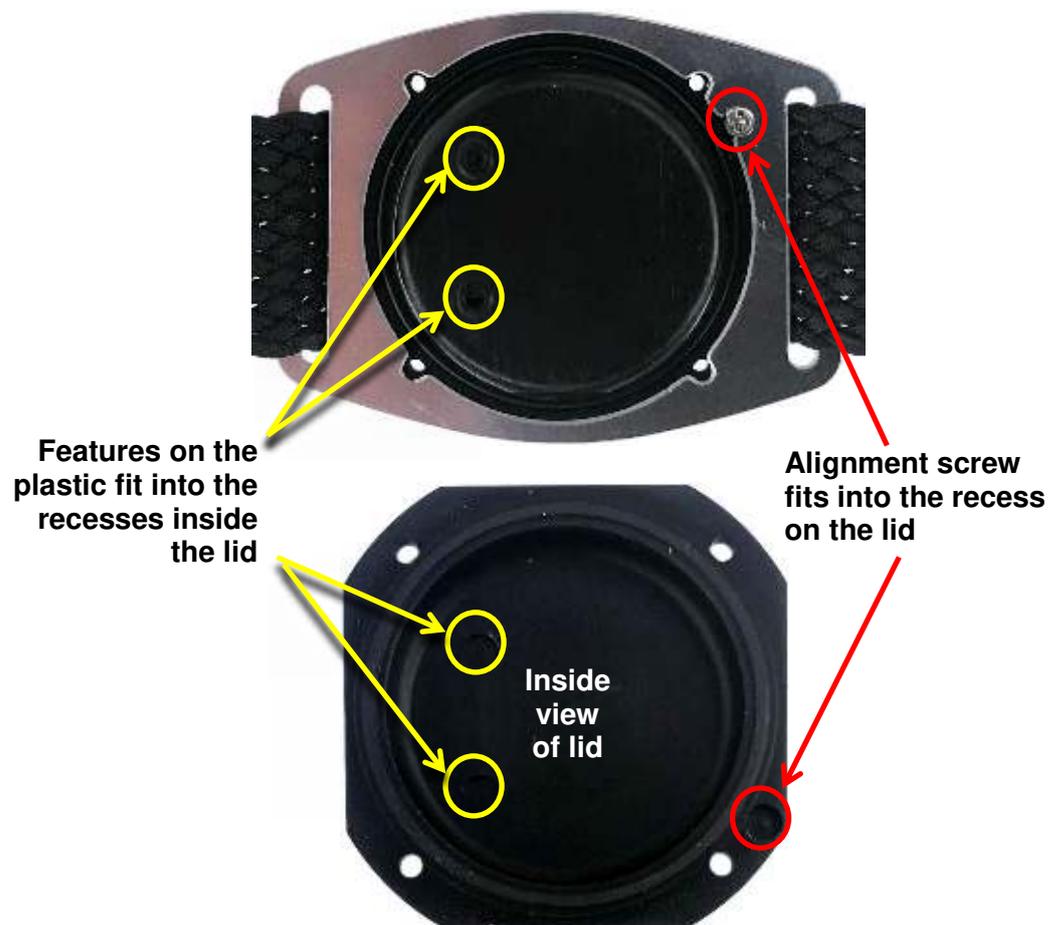
When the MotionWatch is connected for the first time, the USB drivers will automatically be installed (see Section 2.4 Installing the USB Drivers).

Closing the MW Rugged Casing

To ensure that the MotionWatch R maintains correct accelerometer orientation, the casing has two alignment features.

- Features on the plastic electronics module housing.
- Alignment screw on the casing lid.

Insert the electronics module into the lower casing and ensure that the features on the plastic part are aligned as shown with the yellow highlight below. Note also the position of the alignment screw highlighted in red below.



With the internal features correctly aligned, gently press the lid down; it will fit with a positive click and be aligned flush with the lower casing if the alignment is correct. Finally re-insert the four Philips head screws and tighten down gently – do not over-tighten as the thread may be stripped!

1.3 Indications For Use

The MotionWatch is a compact, lightweight, body-worn activity monitoring device that may be used to document physical movement associated with applications in physiological monitoring. The device is intended to monitor limb or body movements during daily living and sleep. The MotionWatch can be used to assess activity in any instance where quantifiable analysis of physical motion is desired.

1.4 Contraindications

The MotionWatch is indicated for use on healthy, undamaged areas of skin. Where the patient has a history of skin irritation, a device should be worn for a brief period to test for skin irritation prior to commencing any recording. Any device in close contact with the skin can trap sweat or moisture and cause redness or slight skin irritation. If this occurs, remove the watch and do not wear it for 2-3 days to allow the irritation to clear.

1.5 Required Skills, Training & Knowledge of Intended Users

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

1.6 General Description of Use

The MotionWatch contains a miniature accelerometer to allow measurement and recording of physical movement of the wrist which provides a close correlation to whole body movement. The data are sampled at 50Hz and processed into 'epochs' of user selectable length. These data are stored into an internal non-volatile memory and then downloaded for analysis at the end of the study period.

Data recorded by the MotionWatch may be downloaded and analysed off-line using the MotionWare Software Package.

2 MotionWare Software Installation & Settings

2.1 System Requirements

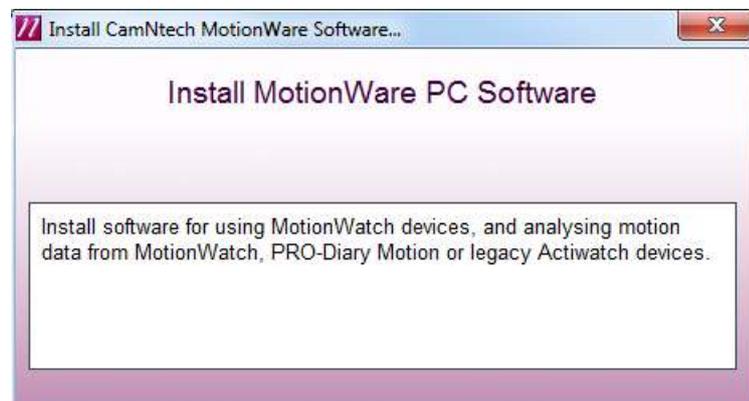
The MotionWare software is typically supplied on a CD-ROM or USB Memory Stick containing all of the components required to install the software package. The following are the minimum requirements of a host PC for installing the MotionWatch software:

- Windows 7, 8 or 10; 32 or 64bit operating systems
- IBM compatible 2GHz + processor speed recommended
- 100 MB hard disk space
- One free USB port
- A CD-ROM or DVD drive for software installation
- Graphics SVGA(1280 x 1024) recommended

The software has NOT been tested with any MAC OS.

2.2 Installing the Software

Place the CD ROM into the drive (or insert the USB stick into a free port); the MotionWare software installation menu should start automatically as shown below:



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

Click on the 'Install MotionWare PC Software' option. 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 MotionWare software requires the Microsoft .Net Framework to be installed; the

installation wizard will check and install this if required. This may result in a protracted installation procedure.

For USB driver installation see Section 2.4 Installing the USB Drivers below.

2.3 Updating the Software

For software versions 1.2.1 and higher, it will not be necessary to remove the old software before installing a new version. Note that any data and settings are not lost during re-installation.

2.4 Installing the USB Drivers

This section on installing drivers only applies to new installations.

- The MotionWatch utilises generic Windows USB drivers which are provided as part of the Windows operating system.
- To install the drivers, attach the supplied USB cable to a free USB port and connect to the MotionWatch.
- Depending upon the version of Windows, a sequence of messages similar to that shown below will be displayed at the bottom of the screen:



If prompted, you may be required to restart the PC.

The driver installation is now complete.

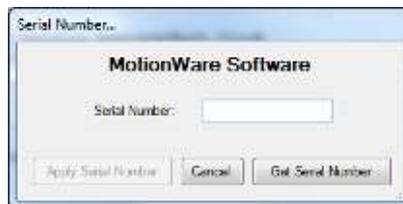
2.5 Software Serial Number

Double clicking on the MotionWare icon on the Windows desktop will start the software.

The software will run for a 30 day evaluation period and then the software serial number will be required.

If you do not already have a serial number you will need to register the software. To check or enter the software serial number, open the **Settings** window (☰→Settings), then click 'View or enter software serial number'. To initially register, please click the 'Get Serial Number' button to link to the CamNtech website (note: you will need the reference number supplied on the CD or media).

When you have received your serial number, enter the 8 digits and then click the 'Apply Serial Number' button.



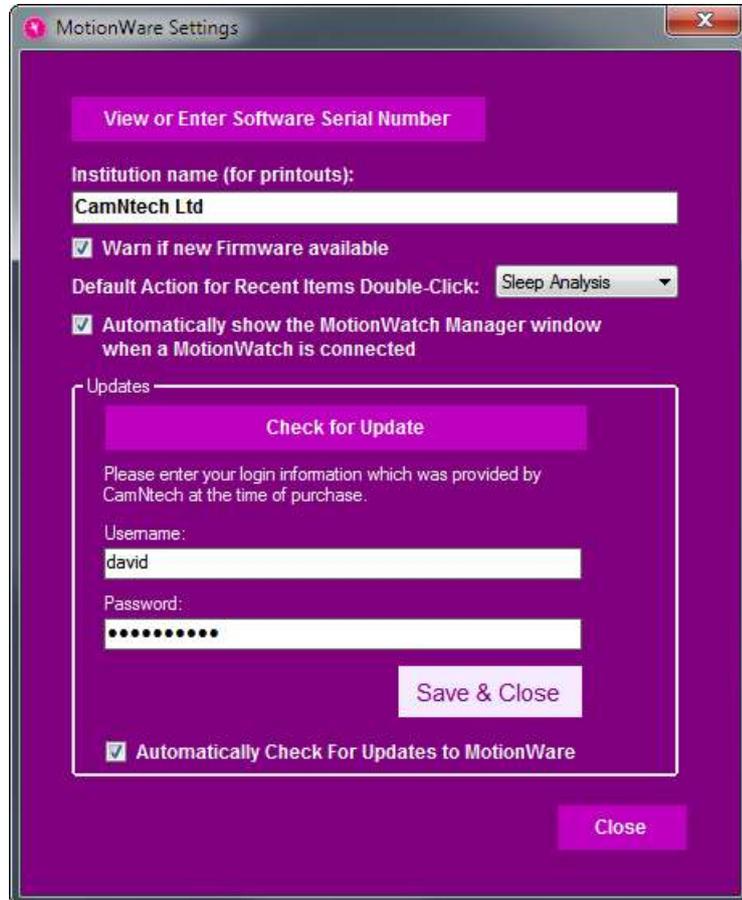
2.6 Running the Software – Main Screen

Double clicking on the MotionWare icon on the Windows desktop will start the software. If a MotionWatch is connected it will be automatically detected and the MotionWatch Manager screen will be displayed. The front screen of the software with no MotionWatch connected will be similar to that shown below:



2.7 MotionWare Settings

Click on the Settings button  on the start-up screen to open the MotionWare settings Window:



View or Enter Software Serial Number

Click this button to open the serial number entry window, see [section 2.5](#) above

Set Institution Name

You may also choose to enter an institution name in the settings window, which will then be included near the top of all printed reports. This may be desirable if you wish to hand the actogram or other reports directly to participants after use.

Warn of Firmware Updates

New firmware (software that is programmed into the MotionWatch) is sometimes provided within the software update. Check the 'Warn if new firmware available' selection to be automatically notified if new firmware is available.

It is recommended to check and update the MotionWatch firmware following a software update – see Appendix A2 - Firmware Update

Default Action for Recent items

Choose whether to open the data with either Sleep analysis or Daytime Activity Analysis upon double click in the recent items list.

Automatically show the MotionWatch Manager...

Controls whether or not to automatically show the MotionWatch Manager Window when a MotionWatch is connected to the computer.

Updates

See [section 2.9](#).

Save Settings and Exit

Click the 'Close' button to save the new settings – note that a check for updates will be immediately performed if the selection is checked. Click the close [x] icon at the top right to close the window without saving the settings.

2.8 Bulk Raw Data Export

This function allows you to export the raw data from every motion file in a directory into corresponding csv files. It may be useful if you wish to analyse the data yourself rather than using the MotionWare software. You may choose the directory to target using either the directory browser window, or the file browser to choose an example from that directory.

2.9 Bulk Result Export

The Bulk Result Export will export all of the analysed recordings in a folder, producing a single row of results per recording. Results where there are multiple periods will have their results averaged into a single set. This applies to the Sleep, Day, Nap and NPCRA (if applicable) functions.

Note: *It is recommended to analyse your recordings fully before using this function for maximum usefulness. Recordings which have not been analysed will produce empty results in the export for the particular set(s) of results.*

To open the Bulk Result Export window, click on the **Main Menu** button and then select the **Bulk Result Export** menu item (☰→Bulk Result Export).

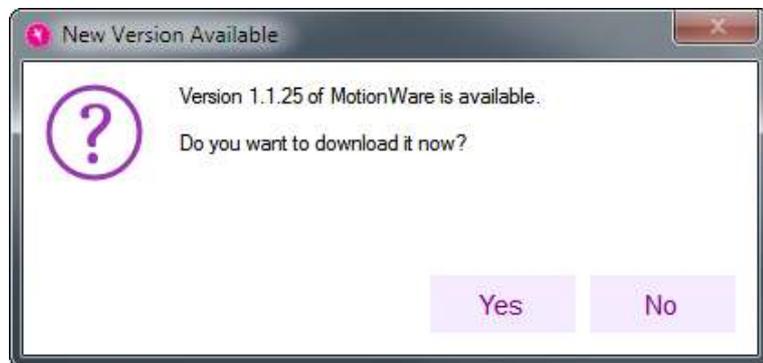
2.10 Updates

Checking for Updates

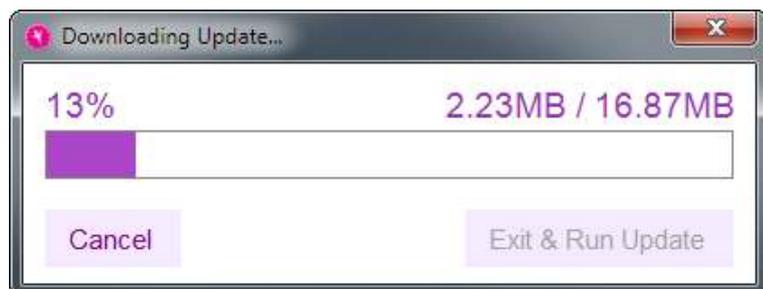
Your web login information is required before updates can be downloaded. To do enter this information, open the **Settings** window (☰→Settings), and enter your user name and password in the specified fields. Click the **Save & Close** button to save the information.

To check for updates, click on the menu ☰ button and select the **Check for Update** menu item, or alternatively click the **Check for Update** button on the **Settings** window.

If a new version is available following dialogue will be shown:



Click the **Yes** button to start the download. This will produce the following window:



When the download has completed, click the **Exit & Run Update** button to close the application and initiate the installer.

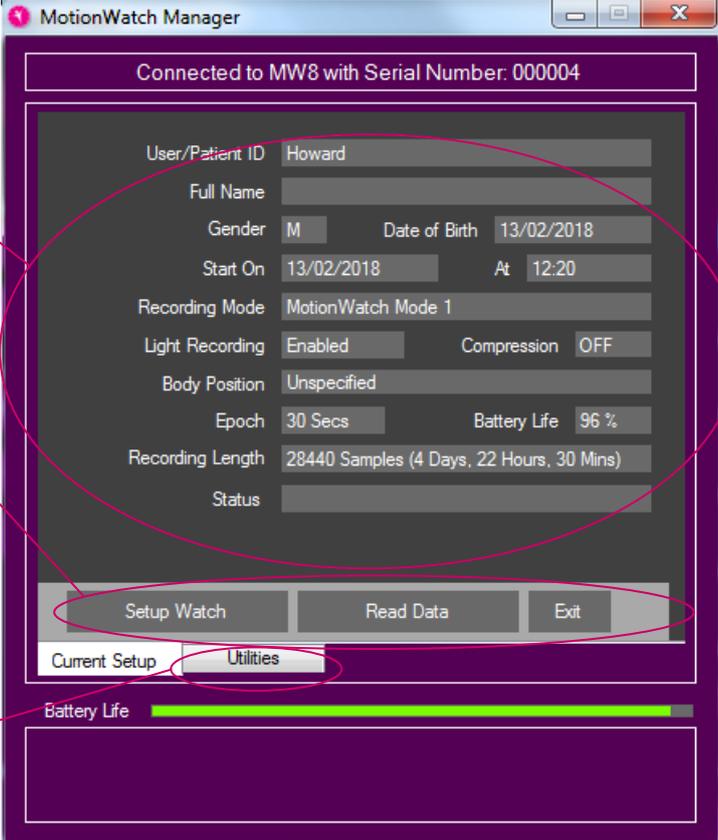
Automatically Check for Updates

Tick this checkbox if you would like the application to automatically check for new versions once a day.

3 The MotionWatch Manager

3.1 MotionWatch Current Set-up

With the MotionWare Software already started, connect a MotionWatch to the USB cable; the watch will automatically be detected and the 'MotionWatch Manager' screen will be displayed as shown below:



The screenshot shows the 'MotionWatch Manager' window. At the top, it says 'Connected to MW8 with Serial Number: 000004'. Below this, there is a form with the following fields: User/Patient ID (Howard), Full Name (empty), Gender (M), Date of Birth (13/02/2018), Start On (13/02/2018), At (12:20), Recording Mode (MotionWatch Mode 1), Light Recording (Enabled), Compression (OFF), Body Position (Unspecified), Epoch (30 Secs), Battery Life (96%), Recording Length (28440 Samples (4 Days, 22 Hours, 30 Mins)), and Status (empty). At the bottom of the form are three buttons: 'Setup Watch', 'Read Data', and 'Exit'. Below the buttons are two tabs: 'Current Setup' and 'Utilities'. At the very bottom, there is a 'Battery Life' indicator with a green progress bar.

CURRENT SETUP INFORMATION
Details of the current set-up stored in the MotionWatch.

3 MAIN OPTIONS:
Setup Watch: click to start a new MotionWatch setup (Section 3.2)
Read Data: click to download the data from the MotionWatch (Section 4.1)
Exit: Close the MotionWatch Manager window.

UTILITIES TAB
Click to view/edit advanced functions (Appendix A)

If a MotionWatch is connected but the above screen is not shown, click on the 'MotionWatch Manager' button on the front screen.

The MotionWatch Manager screen is automatically closed when the MotionWatch is disconnected.

The MotionWatch setup options will be explained in detail in the following section.

3.2 Applying a New Set-up

Click the 'Setup Watch' button, the *new setup* tab is activated and the settings may now be edited:

User ID: Enter characters to identify the subject/patient/study.

Full Name: [optional] Enter characters to identify the patient/study. Note that the maximum length is 64 characters shared between user ID and Full Name.

Gender: Use the dropdown to select M, F or X (if gender is to be undisclosed).

Date of Birth: Use the date control to enter the date of birth of the subject.

Start Date & Time: Select delayed start to begin a recording up to 30 days in the future. Immediate start will begin in 1-2 minutes after disconnection.

Recording Mode: Use the drop down control to select the recording mode.

Light Recording: Check the box to enable light recording (Not available on rugged model).

Compress Data: Check the box to compress the activity data (see below).

Body Position: Choose the mounting location of the MotionWatch.

Epoch: Use the drop down to select the required recording epoch.

Recording Length: Shows the expected maximum length of the recording based upon the chosen settings.

Battery Life: Indication of approximate battery life remaining in % and colour coded battery gauge. Hover over with the mouse for more information.

Disable Marker Button: Allows the event marker button to be disabled. (Not available on rugged model).

The screenshot shows the 'MotionWatch Manager' software interface. The window title is 'MotionWatch Manager' and it shows 'Connected to MW8 with Serial Number: 000004'. The form contains the following fields and controls:

- User/Patient ID: 9999-001234
- Full Name: A Subject
- Gender: M
- Date of Birth: 26/07/1990
- Start On: 19/02/2018 At 10:33
- Recording Mode: MotionWatch Mode 1
- Record Light:
- Compress Data:
- Body Position: Unspecified
- Epoch: 30 Sec
- Battery Life: 96%
- Recording Length: 45 Days and 12 Hours
- Disable Marker Button:

Buttons: Apply Setup, Cancel Setup

Bottom tabs: Current Setup, Utilities, New Setup

Battery Life gauge: 96% (green bar)

NOTE: The software will warn if data has not been downloaded when applying a new setup. If the data is NOT required, select 'Yes' to continue the setup. If the data is required, select 'No' and then download the data.

Apply Setup

Having entered your required setup information, click the 'Apply Setup' button to write the setup to the watch. Observe the message window for the confirmation message and then disconnect the watch. If any setup warnings are shown, consult the troubleshooting section in [Appendix B](#).

Immediate or Delayed Start

Select 'Immediate Start' to ensure that the MotionWatch begins recording straight away. The start date and time are taken from the PC clock so **please ensure that this is correct**. A delay of up to 2 minutes is added to the current time and the recording will start on a complete minute. If

for example the set-up is applied at 16:46:27, the delay will be one minute and 33 seconds and the recording will begin at 16:48:00.

Select '**Delayed Start**' to show the start date/time controls. This option allows the recording to be delayed for up to 30 days into the future. Use the date, hours and minutes controls to select the required start date and time.

Recording Mode

The MotionWatch offers the following recording modes:

- MotionWatch Mode 1 – This is an epoch based recording mode designed to produce similar behaviour to legacy Actiwatch and similar products, using a single axis algorithm and peak detection.
- Tri-Axial Mode 3 – This is an epoch based recording mode that uses all three of the accelerometer axes to produce a vector magnitude result per epoch. This mode is used for recording daytime activity when the watch can be mounted at other locations on the body (See body position below). Note that this mode will shorten the battery life as there is more data processing.

Body Position

For daytime activity analysis it is recommended to note the location upon the body where the MotionWatch is mounted. The physical mounting position will have an effect upon the data (e.g. data from the wrist will differ from that recorded at the waist). This is an optional field that does not affect the data processing.

Epoch

The epoch is the duration for which the MotionWatch will accumulate samples before storing the result in memory. For example, using a 1 minute epoch, one result will be stored in memory every one minute. The MotionWatch offers the following epoch length options:

1, 2, 5, 10, 30, 60 seconds.

Note: the algorithms used for sleep analysis are validated using a 30 second epoch.

Light Recording

The MotionWatch has a built in ambient light sensor. Light recording may be enabled or disabled by checking or unchecking the 'Record light' checkbox during setup. When enabled the MotionWatch will store light values in lux at the same epoch as the activity samples. The light sensor records white light with a response optimised to match the human eye. The light is sampled once per second and averaged over the epoch. The results are stored as lux values.

Light recording is not available on the MotionWatch R (Rugged) model.

Battery Life

The MotionWatch uses a standard non-rechargeable CR2032 coin cell which is easily replaced by the user (Appendix A4 - Changing the Battery). The MotionWatch incorporates smart battery monitoring to measure actual device usage and battery voltage to calculate an expected life remaining. Typically the expected battery life will be **4 months** (MotionWatch Mode), **60 Days** (Tri-axial Mode) and the battery life indication will provide a percentage of life remaining. Hovering over the battery life in either the current or new setup screens will show the expected battery life in days in the information pane of the MotionWatch Manager.

The MotionWatch monitors several parameters to automatically detect when a new battery is fitted. The watch will shut down when the battery is depleted – light recording will cease before activity recording.

Other factors such as operating temperature can significantly reduce the battery life.

The MotionWatch requires some time to shut down fully and restart when the battery is replaced. Always follow the steps for battery replacement in Appendix A4. **The correct battery replacement process is CRITICAL and data may be lost if not completed correctly.**

Compress Data

It is possible to compress the activity data to allow longer recordings at shorter epochs. The light data is not compressed. The function uses a logarithmic compression which provides lower accuracy with higher values (quantized data). At low levels, the accuracy is not affected hence for sleep analysis the compression function will have minimal effect upon data. Note that the validations were performed without data compression.

Disable Marker Button

Select to disable the marker button. Not available on the MotionWatch R (Rugged) model.

Recommended Setup for Sleep Recording

The recommended settings for sleep recording are:

- MotionWatch Mode 1
- 30 second epoch

These are the settings with which the validation studies were performed. It is possible to use other settings if required including tri-axial mode.

Recommended Setup for Daytime Activity Recording

The recommended settings for daytime activity recording are:

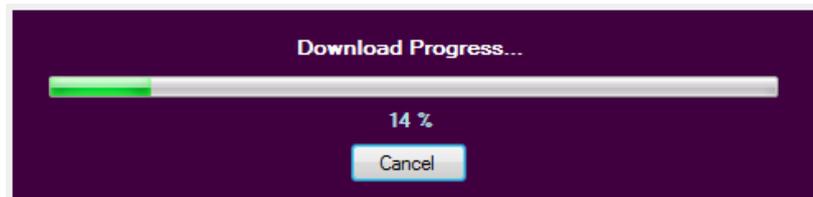
- Tri-Axial Mode 3
- Any epoch

Also set the body position during set-up so that this is noted within the data.

4 Downloading Data

4.1 MotionWatch Download

Connect the MotionWatch and then from the MotionWatch Manager Window click on the 'Read Data' button. The download will begin and the progress notification will be displayed...



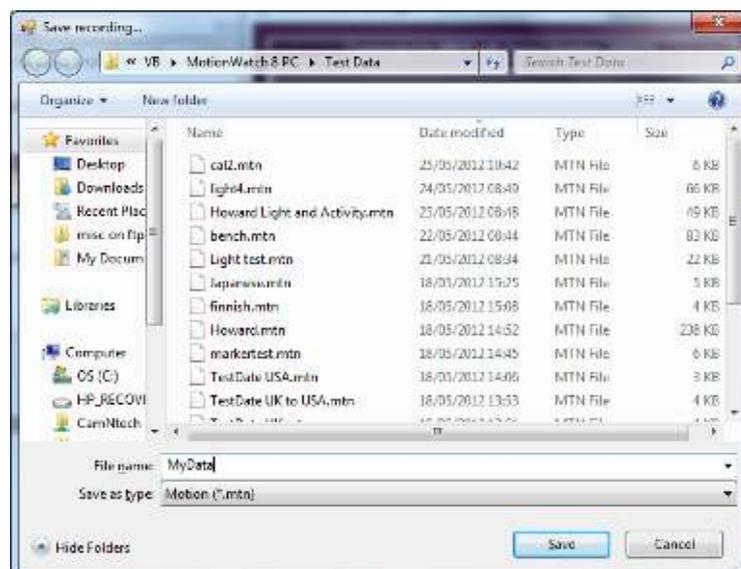
If the data download is not required, click the cancel button and the operation will be aborted.

When the all data has downloaded (full memory will take less than 1 minute) the 'Save Recording...' dialog will open to allow the data to be saved.

Note that the recorded data in the MotionWatch is **not erased** after download; It is only erased when the watch is set up again.

4.2 Saving MotionWatch Data

Upon completion of the download, the 'Save Recording...' dialog will open automatically to allow the data to be saved.



IMPORTANT! – ALWAYS MAKE REGULAR BACKUPS OF YOUR DATA

This window allows the destination for the file save to be specified. Type the name of the file as required and click the 'Save' button. The file will be saved in the default *.MTN format. If you do not wish to save the file, click the 'Cancel' button to return to the MotionWatch Manager.

Note that the MotionWatch Manager will **not** automatically close when the MotionWatch is disconnected if data has been downloaded and **not saved**. This serves as a reminder to save the data; you may manually close the window if the data is not required.

4.3 Shutdown after Download

The MotionWare software defaults to shut-down the MotionWatch into sleep mode to save the battery following download. Data will NOT BE LOST but the watch will cease recording. It is possible to disable this function such that the MotionWatch will continue to record following download and disconnection (see Appendix A3 - Shutdown Options).

NOTE! The MotionWatch cannot record movement data whilst connected to the PC. If a continuous recording is desired then the watch should be removed from the USB cable and returned to the subject as promptly as possible.

4.4 Join Files

It is possible to join (Concatenate) two MotionWatch recordings to create a single recording. The recordings must contain the same user details/setup and be concurrent.

1. Load the first data file for sleep analysis by selecting from the list of recent recordings or by browsing for Motion file.
2. From the 'file' menu select 'Join...'
3. In the file dialogue, browse and/or select the second motion file that is to be joined to the first.
4. A save dialogue will open to allow the file name and location for the joined file to be specified.
5. Click save to save the new file – both original files will be kept unless the joined file is given the same name (an overwrite warning will be given in this case).
6. The new joined file may now be loaded from the recent recordings list.
7. Any gap between the two recordings will show as 'missing data' and will be marked in grey.

5 Preparing to Analyse Data

5.1 Selecting Recent Recordings

When data is saved following download, the file automatically appears in the 'Recent Recordings' list on the front screen of the software. The recent recordings list provides a quick access method to the most recently opened or downloaded files.

It is possible to adjust the recording for **daylight saving** – see section [5.13](#) below for more information.

Click once on a file in the list to select it; more details of the file are displayed in the information pane below. The file can be opened after selection by clicking on the 'Open selected recording' button. Alternatively, double clicking on the file will open the file directly (choose which analysis type to open with double click in MotionWare Settings). Right click on the file for more options.

Recent Recordings: Click an item to view the file details in the information pane then open by clicking the *Open Selected Recording* button. Alternatively, double click an item to open directly. Where a file is a legacy file-type, this will be shown in the list entry.

Open in Sleep Analysis: Click to open the item selected in the *Recent Recordings* list with Sleep Analysis.

Open in Day Analysis: Click to open the item selected in the *Recent Recordings* list with Daytime Activity Analysis.

Browse for Motion File: Opens file manager dialog to select a file.

Information Pane: Provides more detail about the selected recording.



5.2 Managing Recent Recordings

If the recent recordings list becomes full or cluttered, it is possible to remove entries from the list or to fully delete the related file. To manage the recent recordings, right click on the required file name in the list to show a pop-up menu with the following options:

- Open in Sleep Analysis
- Open in Day Analysis

- Properties
- Remove From List
- Delete File
- Clear Recent Items List

Select 'Remove from list' to keep the file on the disk but remove it from the list; the file will not be deleted. Select 'Delete File' to remove from the list and delete the file from the disk. A warning message will be displayed before the file is permanently deleted.

Select 'Clear Recent Items List' to remove all files from the list – the files will not be deleted.

Clicking 'Properties' allows the recording details to be viewed.

5.3 Browse for Recordings

It is also possible to locate and load recordings that do not appear in the Recent Recordings list. From the main screen, click on the 'Browse for Motion File' button to open a standard Windows File dialogue. Use the folder controls to browse to the location of the required files. Note that the default file format is .MTN (depicting MoTioN) and this type of file will be displayed automatically. It is possible to change the file-type filter to browse for other file types (see below).

5.4 Import Legacy Recordings

As certain legacy products (such as CamNtech Actiwatch) used an open file format, it is possible to import existing .AWD format files. To import a legacy file, follow the instructions to browse for a file in Section 5.3 above and then change the file-type filter to 'Actiwatch (*.AWD)':



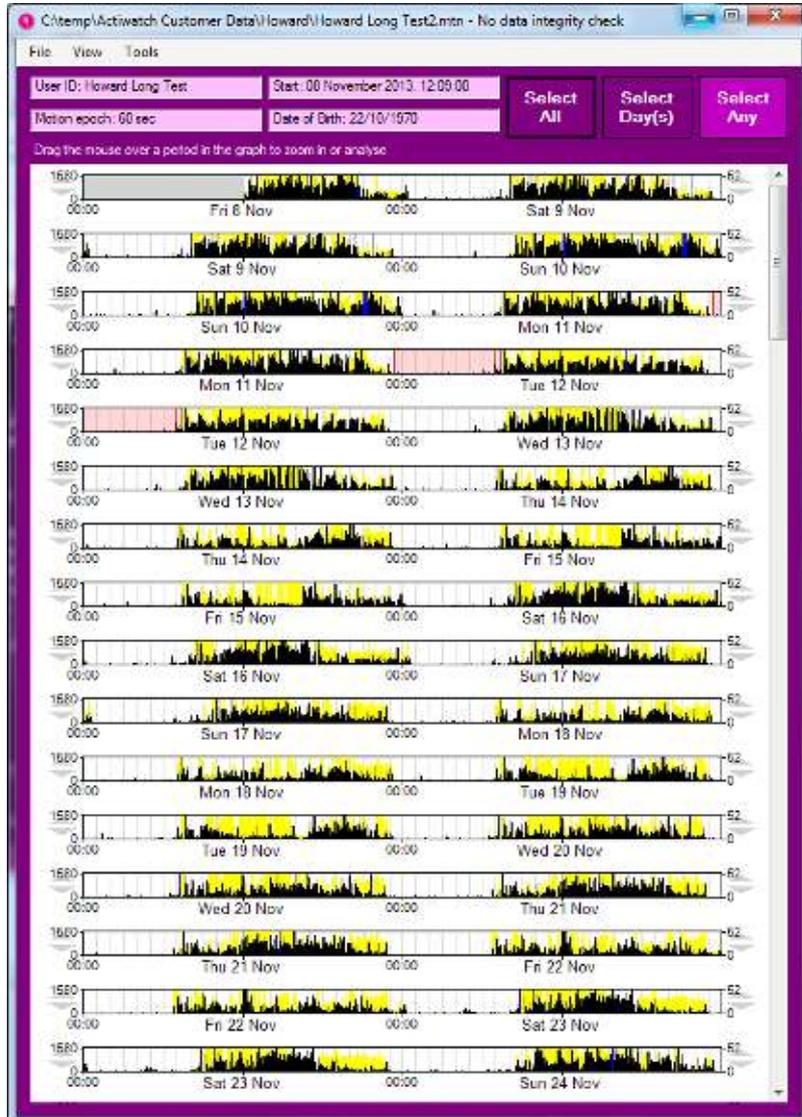
The table below lists the compatibility with various Actiwatch model data:

Actiwatch Model	Compatibility
Actiwatch 7	Y
Actiwatch 4	Y
Actiwatch Light Plus	Y
Actiwatch Mini	Y
Actiwatch Spectrum	Y ¹
Actiwatch 2	Y ¹

¹ It is not possible to directly open this type of file but it is possible to export data from the Actiware Software in .csv format and then use the csv import utility to re-save the data in compatible format (see Appendix E1 – CSV Import Utility).

5.5 The MotionWise Window

When a recording is opened the MotionWise window is displayed:

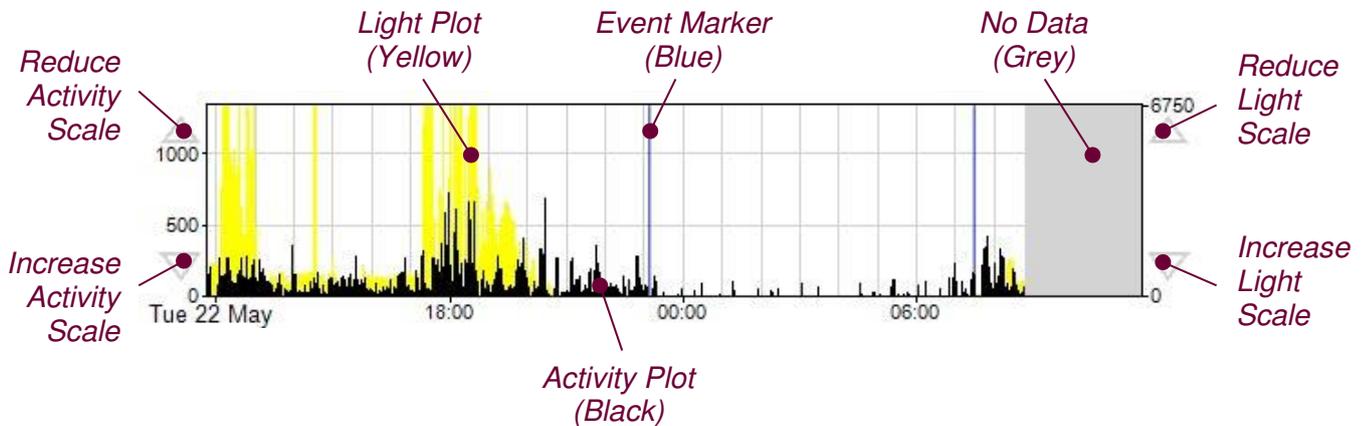


The MotionWise window provides a multiple-day, single or double plotted motion graph (actogram) within a flexible, scalable and scrollable window. The MotionWise window is the key tool for the selection of data for more detailed analysis. The top region of the window provides summary patient information. The entire window may be stretched and dragged by manipulating the corners of the window. The window can also be maximised to fill the full screen by using the window control.

Scroll through the days by using the slider control at the right hand side of the screen or by using the mouse scroll wheel.

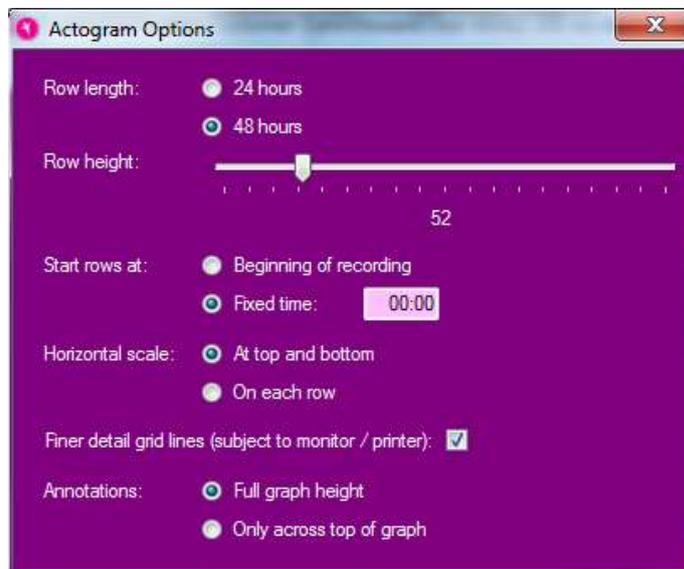
5.6 The MotionWise Graphs

For each day containing data, a graph similar to that shown below will be displayed.



5.7 MotionWise Graph View Options

The Actogram view can be adjusted for different purposes using the window below. This is found under the 'Options' item in the 'View' menu. The Actogram will adjust to give immediate feedback after you have changed any of the options.



Row Length

Select 24 or 48 hour graphs to show single day or double day plotted graph respectively. Each row of the graphs will then correspond to the length chosen, but the change forwards between rows will be 24 hours in both cases.

Row Height

Using this slider, you can adjust the heights of each row of the Actogram to show lots of detail on each graph, or very compressed rows to present a longer time period onscreen. Note that the range available here depends on the setting of the 'Horizontal scale' below.

Start Rows at

The MotionWise graphs default to a plot start time at the start of the recording. However, when comparing data between multiple users, it can be useful to have a fixed start time for the plots. So you can select either to always start from the beginning of the recording, or enter a fixed time in the text box.

Horizontal Scale

Using this option, you can choose to show self-contained graphs with a horizontal scale on each row, or close-fitted graphs with no horizontal axis on each. In the latter case, a time scale is added at the top and bottom of the actogram instead.

Finer Detail Grid Lines

Show or hide the light grey hourly grid lines on the graphs (these will also depend upon the resolution of the monitor or printer).

Annotations

The marker lines or highlighted periods on the graph can be shown at full graph height or just at the top of the graph. This can help to make the graph more clear when there are many marker events and selected periods.

5.8 Printing the MotionWise Graphs

You may produce a printed copy of the MotionWise graphs covering all days of data, by selecting the 'Print preview' option from the 'File' menu. This preview allows you to view and step through all of the report pages using the 'Prev' and 'Next' buttons.

The printed Actogram can be adjusted similarly to the on screen Actogram by clicking the 'Actogram Options' button. This includes an additional setting to include or exclude a list of the recording properties with the Actogram printout.

5.9 Selecting the Analysis Period

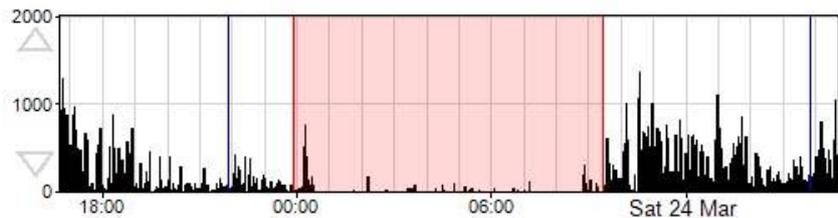
There are three main selection options which may be chosen by use of the control buttons in the MotionWise window:



Select Any

The 'Select Any' option provides a flexible means of selecting any analysis period between your chosen start and end points.

In the MotionWise window, choose the period of data for analysis by pointing at the start point, hold down the left mouse button and then drag to select the period required. The selected period is highlighted and the Analysis window is automatically displayed. The figure below shows a single overnight period selected:



It is possible to select a very short period (i.e. a few minutes) to several days using this method. By dragging off the bottom or top of the MotionWise graph area, the window will automatically scroll to allow selection of days that are not currently displayed.

Select Days

The 'Select Day(s)' option will select a period starting and ending at midnight on the chosen day(s). To make a selection, point anywhere within the graph on the day of interest, hold down the left mouse button and then drag to select the day(s) required. Drag across multiple graphs to select several days and drag off the bottom or top of the MotionWise graph area to automatically scroll while selecting.

Select All

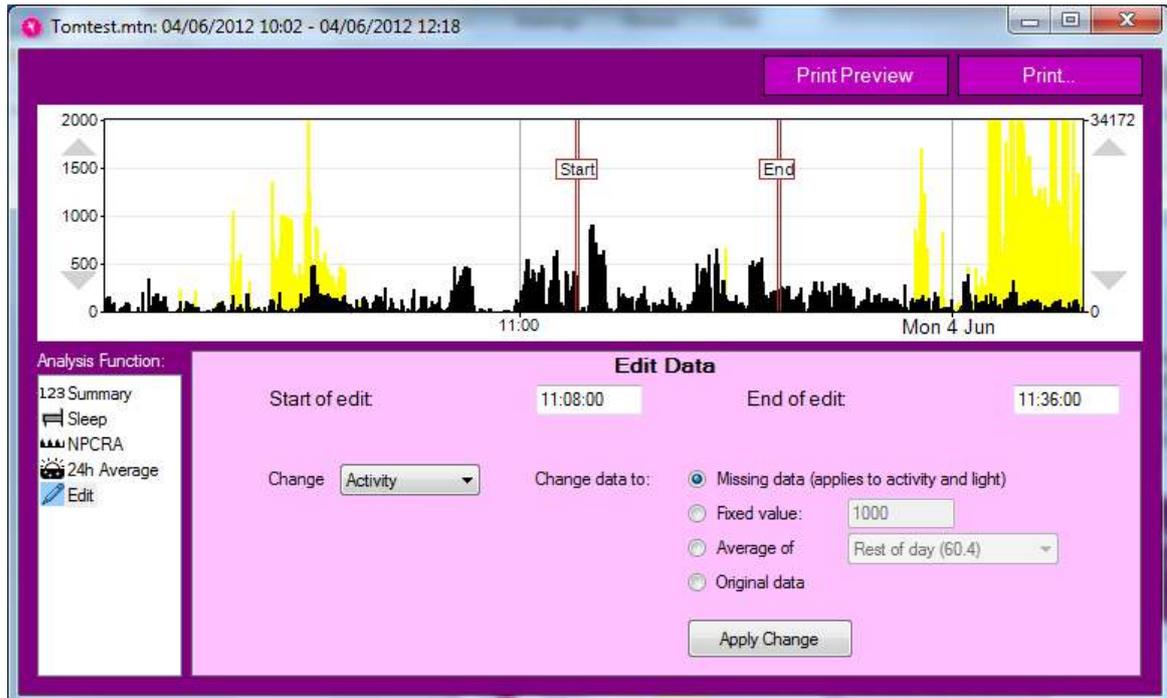
The 'Select All' option allows a one-click selection for all days of data ready for a multiple day analysis such as NPCRA.

5.10 Saved Periods and Longer Periods

The Analysis functions allow the selected periods to be saved. These periods will remain highlighted in the MotionWise Window and the analysis can be quickly re-opened by clicking anywhere in the highlighted region. If the saved period is longer than 24 hours (i.e. for an NPCRA analysis) then the highlight is not shown in the graph. These longer saved periods may be chosen from the 'Long periods' menu in the MotionWise Window.

5.11 Editing Data

It is possible to edit periods where there is believed to be some problem with the recorded data to change or remove the activity during that period. This may be necessary where for example the watch was not worn for a period, or where it is believed an activity gave particularly misleading activity counts for analysis purposes. The Edit function may be accessed by selecting a period for analysis in the manner described in Section 6 Sleep Analysis, then selecting the Edit analysis function from the list in the bottom-left of the window.



After selecting the Edit tool, it is possible to fine tune the time period for the edit either by dragging the 'Start' and 'End' bars on the graph, or by changing the text boxes containing times below the graph.

Next you must choose to change either the 'Activity' or 'Light' channel as appropriate. Note that marking missing data will cause both to be considered as missing.

The data samples within the selected period can be changed in four different ways:

- Missing data – this will set the data as missing, where the period is shown with a grey background, and analysis functions which take an average will ignore the missing samples.
- Fixed value – this will set the data samples (either activity or light) to the value entered in the box.
- Average of – this will set the data samples to either the average of the entire day (including the selected period), or the average of the day excluding the selected period. The day is taken as

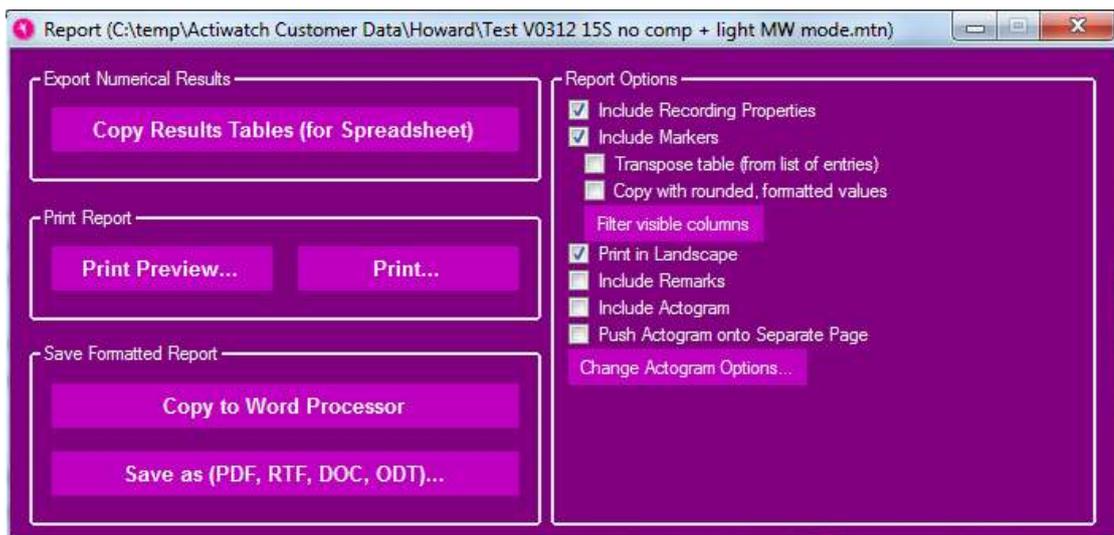
the 24-hour period between midnights which contains the start time of the edit.

- Original data – because all of the data and changes are contained as an audit log within the motion file, this option allows you to restore the original values first recorded before any edit took place.

If the last part of the recording is marked as “Missing data”, then this will also reduce the length of the printed Actogram to avoid printing unnecessary missing days. This is particularly useful if the watch has been left recording invalid data for some time after being worn, but before download. In this case, simply select all of the time after the valid recording and mark it as missing data. This can be restored at any point using the “Original data” option above.

5.12 Generating Reports

In the MotionWise window select ‘Tools -> Report’ to open the report generator window.



This tool provides a number of flexible reporting options which are discussed in more detail below.

Include Recording Properties

Select this option to include the User ID, Gender, DOB, Device information and start time within the report.

Include Markers

Select this option to include a date/time stamped listing of marker events within the report.

Include Sleep Analysis

Select this option to include full Sleep Analysis results for all saved analysis periods within the report (see Section 6 Sleep Analysis).

Transpose Table

Select this sub-option to swap the row/column layout of the report.

Copy with Rounded, Formatted Values

This sub-option applies to data exported via the clipboard only. When selected, the results will contain rounded values with periods formatted as hours and minutes. When un-selected, the results will be exported as un-rounded values and periods will be formatted in seconds. The latter option is useful when importing data into external packages for further analysis.

Print in Landscape

This option swaps the default (portrait) report format to landscape orientation. This can be useful to best 'fit' the report to the page. This option only applies to printed reports.

Copy Results Tables (for spreadsheet)

Having selected the required report options, click the 'Copy Results Tables' button to export the data. The data may now be imported into external software (e.g. a spreadsheet) for further analysis or formatting.

Copy to Word Processor

Places the selected results and actograms for all days onto the clipboard formatted to paste directly into a word processor. This facilitates rapid production of custom reports.

Save as (PDF, RTF, DOC, ODT)...

The selected results and actograms for all days are saved into your selected file format. Choose the document type in the 'Save as type...' dropdown, choose from the following options:

- RTF – Rich Text Format – open in most word processors.
- PDF – Portable Document Format – open in Adobe Acrobat Reader.
- DOC – Microsoft Word Document.
- ODT – Open Document – use with Open Office.

Enter a file name/location to save the file. These options facilitate rapid production of custom reports.

Print Preview

Having selected the required report options, click the 'Print Preview' button to view the report on screen before printing.

The print preview window has a number of formatting and zoom options. There is also a 'Print' button in the menu to allow printing without the need to close the window.

Print

Having selected the required report options, click the 'Print' button to send the report to the printer. A standard printer dialogue will be displayed allowing the target printer options to be selected.

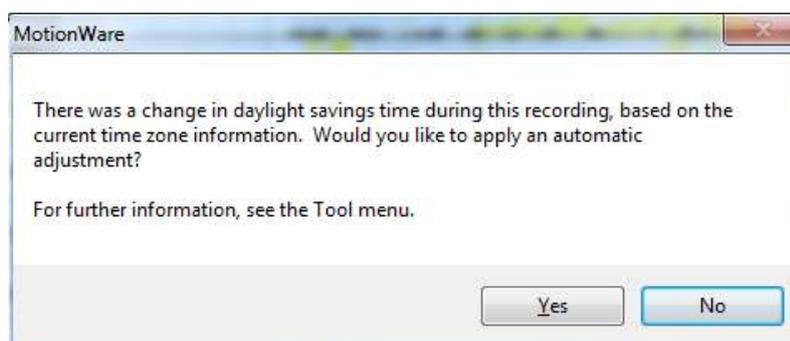
Filter Visible Columns

It is possible to further customise the parameters that will be included in the report. Click on the 'filter visible columns' button for either the marker or sleep analysis data. A window containing a checklist of parameters will be displayed (sleep parameters are shown in this example). Ensure that the required parameters are checked for inclusion in the report.



5.13 Daylight Saving Adjust

If a clock change is detected (daylight saving) during a recording, a message will be displayed upon first opening of the recording:

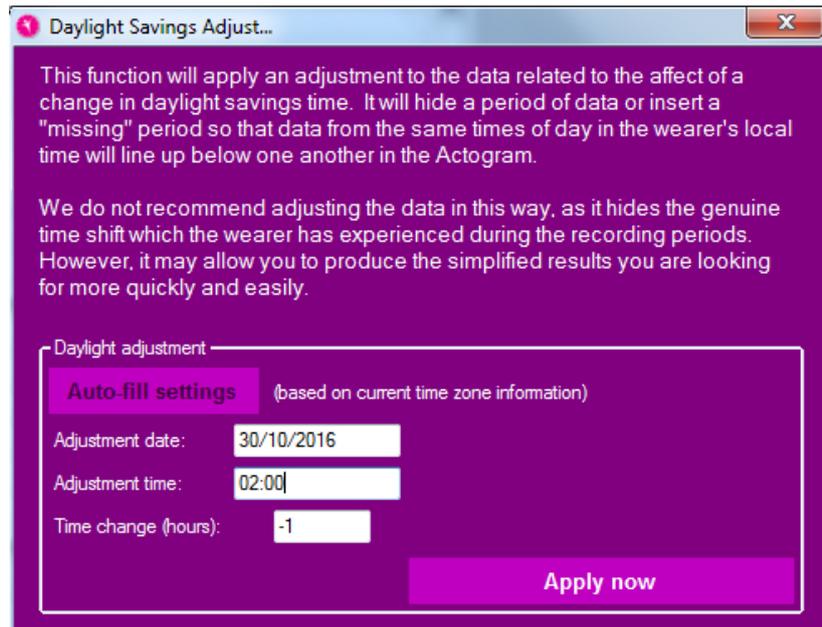


- Select 'Yes' to apply a daylight saving adjustment to the data. This will default to the local regional

settings of the computer (typically add or remove 1 hour of data at 2am.) This can be undone – see 5.14 below.

- Select 'No' to ignore the daylight saving adjustment (Adjustment can be applied later if required)

It is possible to apply the daylight saving adjustment by clicking on the 'Tools' menu then selecting 'Daylight Savings Adjust'. The following window will be displayed:



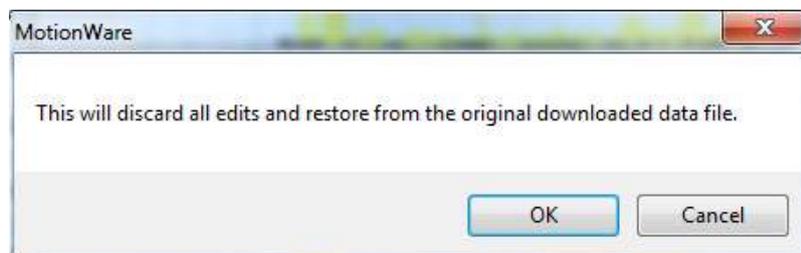
The adjustment values can be changed here if required and then be applied to the data by clicking 'Apply now'.

5.14 Restore original download

To reverse (undo) any daylight saving adjustment or any other edits or any saved analysis, first close the recording and then re-open it.

Next select 'Restore original download' from the 'Tools' menu.

A warning will be displayed as follows:



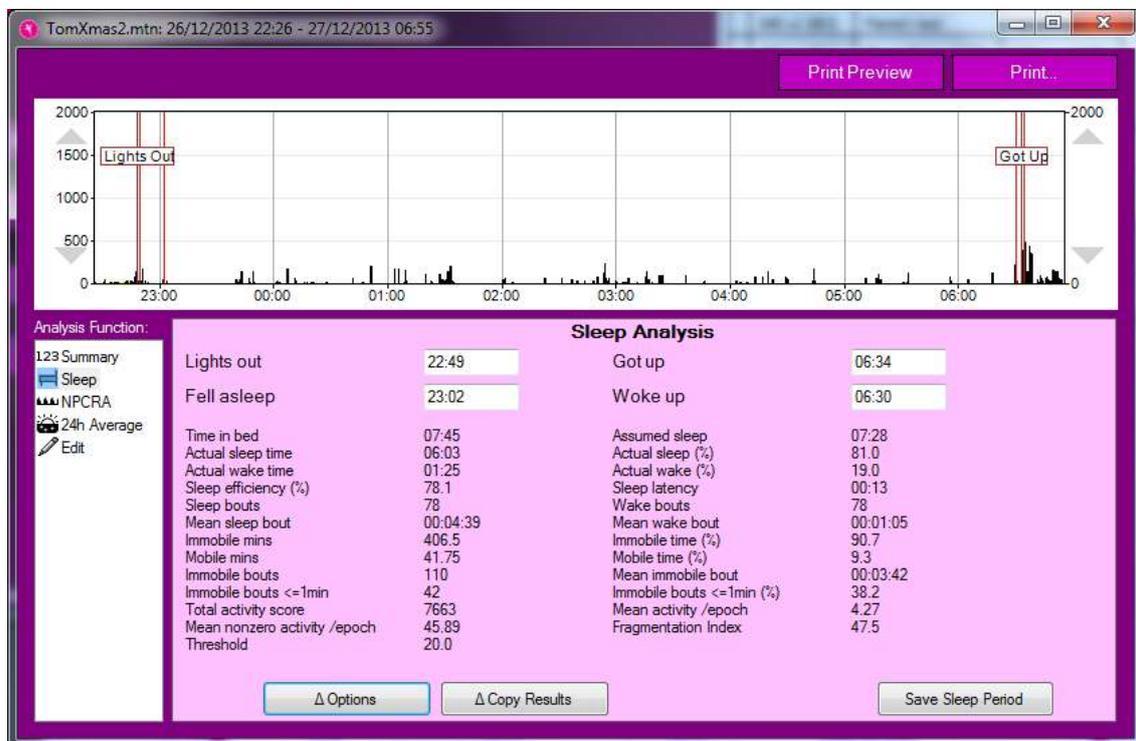
Click 'Ok' to restore the original download or cancel to keep the adjusted data. Note that all edits have been made to the data, will be lost (including any saved sleep periods or analysis).

6 Sleep Analysis

6.1 Introduction

The Sleep analysis function is designed to provide a number of objective sleep measures from overnight actigraphy data. It can be easily applied either to normal overnight periods, or used to examine any sleep period from an altered phase recording such as a shift worker.

First select a region using the MotionWise window (see Section 5.9 Selecting the Analysis Period above) which includes a short period of daytime activity at the start and end. The detailed analysis window will be displayed and may initially default to the summary function. To select Sleep Analysis, choose 'Sleep' from the Analysis Function options at the left of the screen. The detailed Sleep Analysis window will be displayed:



It is now possible to drag the 'Lights Out' and 'Got Up' markers to the appropriate positions in the data, and the thinner red markers inside which denote 'Fell Asleep' and 'Woke Up' will be automatically adjusted from the combination of your markings and the activity data. All of these four times are also displayed in the information box below the graph.

6.2 Sleep Analysis Statistics

Once the desired sleep region is selected, the software will automatically perform a categorisation of each epoch of the period between 'Fell Asleep' and 'Woke Up' as either 'Sleep' or 'Wake', and also as either 'Mobile' or 'Immobile',

and use these results to provide a number of measures from the period. These are described below:

- **Time in bed:** The total elapsed time between the 'Lights Out' and 'Got Up' times.
- **Assumed sleep:** The total elapsed time between the 'Fell Asleep' and 'Woke Up' times.
- **Actual sleep time:** The total time spent in sleep according to the epoch-by-epoch wake/sleep categorisation.
- **Actual sleep (%):** Actual sleep time expressed as a percentage of the assumed sleep time.
- **Actual wake time:** The total time spent in wake according to the epoch-by-epoch wake/sleep categorisation.
- **Actual wake (%):** Actual wake time expressed as a percentage of the assumed sleep time.
- **Sleep efficiency (%):** Actual sleep time expressed as a percentage of time in bed.
- **Sleep latency:** The time between 'Lights Out' and 'Fell Asleep'.
- **Sleep bouts:** The number of contiguous sections categorised as sleep in the epoch-by-epoch wake/sleep categorisation.
- **Wake bouts:** The number of contiguous sections categorised as wake in the epoch-by-epoch wake/sleep categorisation.
- **Mean sleep bout:** The average length of each of the sleep bouts.
- **Mean wake bout:** The average length of each of the wake bouts.
- **Immobile mins:** The total time categorised as Immobile in the epoch-by-epoch mobile/immobile categorisation.
- **Immobile time (%):** The immobile time expressed as a percentage of the assumed sleep time.
- **Mobile mins:** The total time categorised as mobile in the epoch-by-epoch mobile/immobile categorisation.
- **Mobile time (%):** The mobile time expressed as a percentage of the assumed sleep time.
- **Immobile bouts:** The number of contiguous sections categorised as immobile in the epoch-by-epoch mobile/immobile categorisation.
- **Mean immobile bout:** The average length of each of the immobile bouts.
- **Immobile bouts <=1min:** The number of immobile bouts which were less than or equal to one minute in length.
- **Immobile bouts <=1min (%):** The number of immobile bouts less than or equal to one minute expressed as a percentage of the total number of immobile bouts.

- **Total activity score:** The total of all the activity counts during the assumed sleep period.
- **Mean activity /epoch:** The total activity score divided by the number of epochs in the assumed sleep period. Note that this result will be expected to scale depending on the length of the epoch.
- **Mean nonzero activity per epoch:** The total activity score divided by the number of epochs with greater than zero activity in the assumed sleep period. Note that this result will be expected to scale depending on the length of the epoch.
- **Fragmentation Index:** The sum of the 'Mobile time (%)' and the 'Immobile bouts <=1min (%)'. This is an indication of the degree of fragmentation of the sleep period, and can be used as an indication of sleep quality (or the lack of it).
- **Threshold:** The threshold used for analysing movement data. The MotionWatch was validated with a threshold of 20, but this may be chosen differently depending on the population.
- **Rest per 24h (%):** The percentage of epochs in a 24 hour period which would be counted as sleep if the whole period were analysed as night time. The period runs for 24 hours from midday to midday around the "To Bed" time of the analysis.
- **Average light (lux):** This measure is only present if light was recorded. It is the average light level over the period between falling asleep and waking up.
- **Central Phase Measure (mins):** This is the midpoint between "Fell asleep" and "Wake up", expressed as the number of minutes past midnight. For ease of normal use, it will be negative for phase times prior to midnight but after midday.

6.3 Saving or Removing Analysis Statistics

With the analysis for the period complete, the analysis may be saved by clicking on the 'Save Sleep Period' button. The detailed analysis window will close automatically and the analysis period will remain highlighted in the MotionWise window. To re-open the saved analysis, simply click anywhere on the highlighted region in the MotionWise window.

If the saved analysis is no longer required, click on the 'Delete Sleep Period' button in the sleep analysis screen to remove it.

6.4 Adjusting Analysis Threshold

The threshold used for sleep analysis can be adjusted under the 'Options' button. Note that the MotionWatch system has been validated with a threshold of 20, so this should normally be the default choice.

6.5 Exporting Sleep Analysis Results

The 'Copy Results' button and 'Epoch Results' or 'Statistics' options will allow you to transfer either the detailed epoch-by-epoch results or the overall statistics easily into a spreadsheet program or similar. Simply click the button, transfer to a spreadsheet window on your computer, and use the normal Windows paste function to create a table of your results.

6.6 Printing Sleep Analysis Results

Click on the 'Print Preview' button to preview the report and click on the 'Print' button to send the report to the printer.

6.7 Sleep Summary Table

From the MotionWise window, select 'Sleep Summary Table' from the 'Tools' menu. This window provides a summary of the saved Sleep analysis periods. Furthermore, it is possible to edit the 'lights out' and 'got up' times within this window using patient provided information (i.e. a sleep diary).

Lights Out:	Got Up:	End Day:
22:10	06:07	30/05/2012
21:51	06:44	31/05/2012
23:16	06:34	31/05/2012
23:34	06:30	01/06/2012
00:08	06:31	02/06/2012
none	none	03/06/2012
23:46	06:29	04/06/2012
22:37	06:35	05/06/2012
23:30	06:35	06/06/2012

Adding or changing times in this table will not re-analyse the sleep. You must also review each sleep period by clicking it from the Actogram and save the results from there.

Save Changes Cancel

To enter data, highlight the required time and then type in the data in HH:MM format.

Click on 'Save Changes' when complete and the analysis periods will be automatically highlighted in the MotionWise window. Click on any highlighted period to open Sleep Analysis. This will perform the analysis on the visible data. After checking the data and results for any anomalies, you must then re-save the sleep period to capture the night's results for the report output.

7 NPCRA Analysis

7.1 Introduction

Traditional analysis of circadian rhythms has attempted to fit physiological indicators to a Cosine waveform shape (Cosinor analysis). Activity-rest data do not typically fit well with this type of analysis, hence the MotionWare software provides the function of Non-Parametric Circadian Rhythm Analysis (NPCRA). With this approach, we do not assume that the data fit any pre-defined distribution. The method used is to analyse full-days of data over several days to determine some useful variables which are explained in more detail below. Studies have shown that the non-parametric variables are a valuable indicator of rhythm disturbances caused by disease or aging and their associated treatments.

7.2 Reference

The NPCRA analysis is based upon the work of Dr. Eus Van Someren at the Netherlands Institute for Brain Research e.van.someren@nin.knaw.nl
The original paper published by Dr. Van Someren is:

Van Someren, E J W, DF Swaab, C C Colenda, W Cohen, W V McCall, and P B Rosenquist. *Bright Light Therapy: Improved sensitivity to its effects on rest-activity rhythms in Alzheimer patients by application of nonparametric methods.* Chronobiology Int. (1999) **16** (4) 505-518.

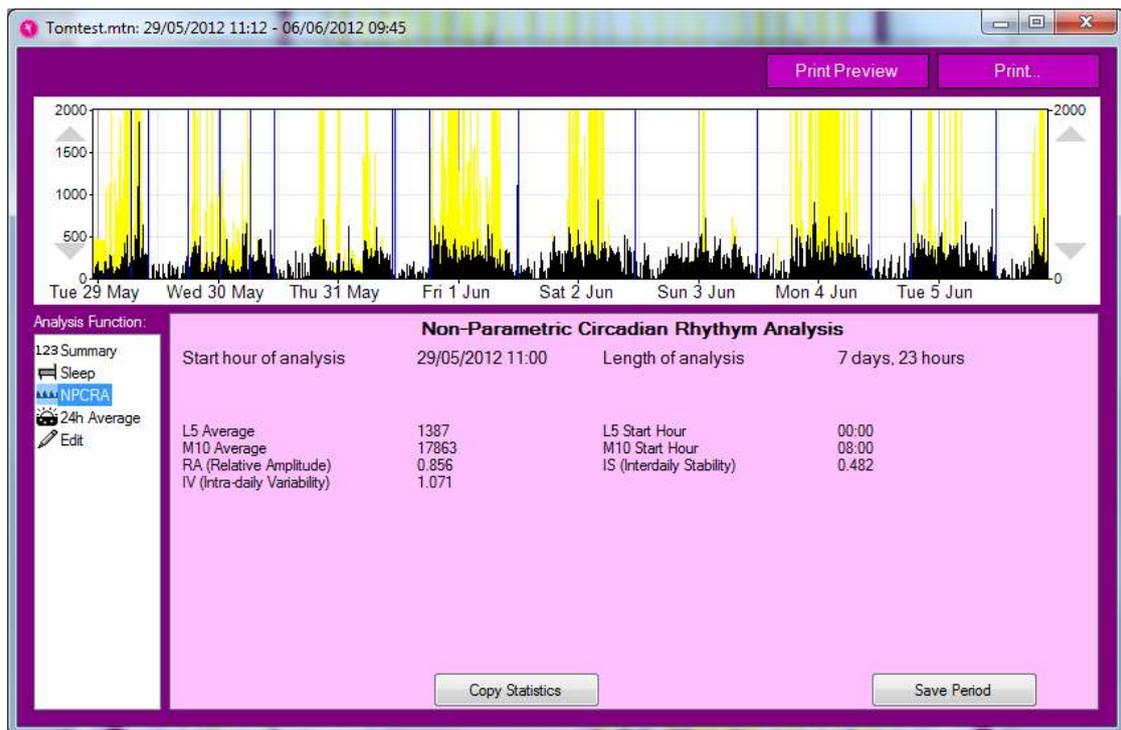
7.3 Analysis

NPCRA analysis requires complete data from as many full days as possible. It is not recommended to attempt analysis with less than 7 days of data and best results are obtained with 14 or more days.

To select the analysis days, use the 'Select All' button in the MotionWare screen to automatically select all available days. Alternatively, use the 'Select Days' or 'Select any' tools to specify the analysis period (see Section 5.9 Selecting the Analysis Period).

Note also that the analysis is sensitive to periods of inactivity when the MotionWatch has not been worn.

Having selected the analysis period, the analysis window will be displayed. Select 'NPCRA' from the sidebar functions.



7.4 Non-Parametric Variables

The NPCRA window provides a table of resulting Non-Parametric variables with the following meanings:

IS (Interdaily Stability): quantifies the degree of regularity in the Activity-Rest pattern with a range of 0 to 1 where a value of 0 indicates a total lack of rhythm and a value of 1 indicates a perfectly stable rhythm.

IV (Intra-Daily Variability): quantifies the degree of fragmentation of activity-rest periods. Typical healthy subjects will show a single prolonged activity period and a single prolonged rest period per 24 hour cycle. Certain physiological conditions may lead to multiple short-length periods of activity-rest within any 24 hour period. The variable has a theoretical range of 0 to 2 with higher values indicating higher fragmentation. Typical values for healthy subjects will be below 1.

L5 (Least 5) Average: all days of data are overlaid and averaged in 24-hour periods. The L5 average provides the average activity level for the sequence of the least five active hours. This value provides an indication of how restful (inactive) and regular the sleep periods are.

L5 Start Hour: Indicates the onset of the L5 sequence and provides an indication of the phase of the most restful hours.

M10 (Most 10) Average: all days of data are overlaid and averaged in 24-hour periods. The M10 average provides the average activity level for the sequence of the highest (most) ten active hours. This value provides an indication of how active and regular the wake periods are.

M10 Start Hour: Indicates the onset of the M10 sequence and provides an indication of the phase of the most active hours.

RA (Relative Amplitude): First we calculate the Amplitude (AMP) which is the difference between the average activity level in the M10 and that in the L5 periods. To remove sensitivity to overall activity level, we then calculate the RA by dividing the AMP by the sum of the L5 and M10. The variable has a theoretical range of 0 to 1 with higher values indicating a rhythm with higher amplitude.

7.5 Exporting NPCRA Analysis Results

The 'Copy Statistics' button will allow you to transfer the overall statistics easily into a spreadsheet program or similar. Simply click the button, transfer to a spreadsheet window on your computer, and use the normal Windows paste function to create a table of your results.

7.6 Printing NPCRA Analysis Results

Click on the 'Print Preview' button to preview the report and click on the 'Print' button to send the report to the printer.

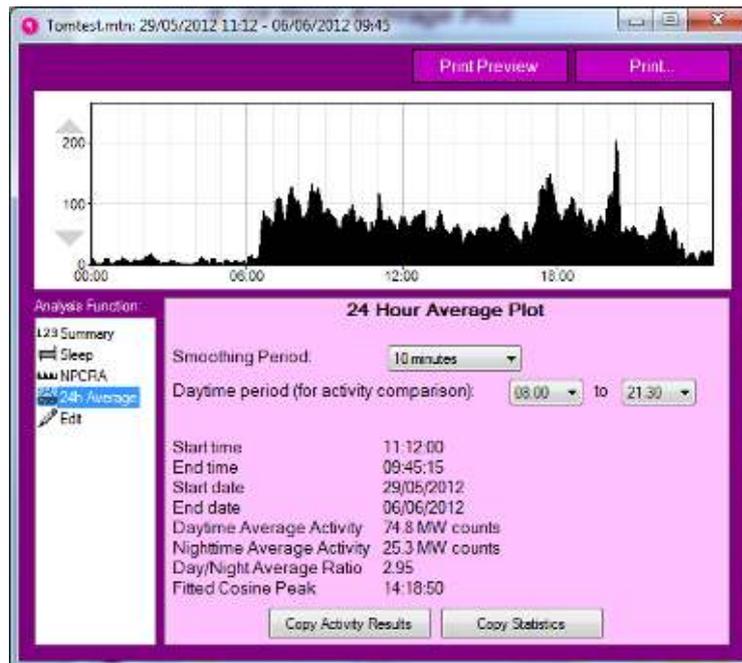
7.7 Save NPCRA Analysis Period

Click on the 'Save Period' button to save the selected analysis. Long periods are not highlighted in the MotionWise window as they would hide shorter periods and become confusing. Instead use the 'Longer periods' menu from the MotionWise window to select any saved periods greater than 24 hours.

8 24 Hour Average Plot

8.1 Select Data for Analysis

From the MotionWise window, use the 'select days' option to choose a range of days or use the 'select all' option to analyze all days. The analysis window will open automatically; if not already selected, select '24h Average' from the analysis functions side bar. A screen similar to that shown below will be displayed.



Smoothing Period

The smoothing period allows a time constant to be applied to the plotted data which is useful when analyzing for trends. The period may be selected between no smoothing and 60 minutes.

Daytime Period

It is possible to specify the start and end of the daytime period to be used for the analysis. This will affect the daytime and nighttime average values accordingly.

Activity Average

The data per epoch for each day are day totalized and averaged over the number of days in the analysis. The average activity in the daytime and nighttime periods are then calculated and displayed. Note MW counts are MotionWatch counts.

Day/Night Average Ratio

This is the daytime activity average / nighttime activity average.

Fitted Cosine Peak

A cosine is fitted to the averaged data and the time of day where the cosine peak occurs is displayed.

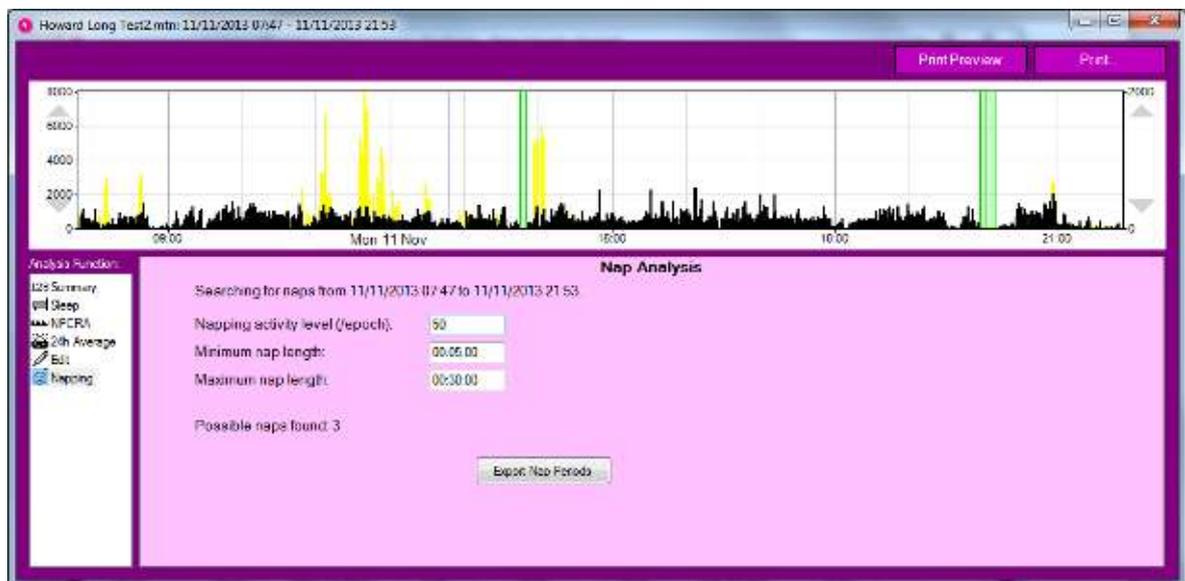
9 Nap Analysis

9.1 Overview

The Nap analysis function allows detection of periods of inactivity that could be attributed to daytime napping or micro-sleeps. The function provides user adjustable parameters for duration and threshold to detect the potential naps.

9.2 Select Data for Analysis

From the MotionWise window, use the 'select any' option to a period of data to analyze – this will typically be during the normal active daytime period. The analysis window will open automatically; if not already selected, select 'Napping' from the analysis functions side bar. A screen similar to that shown below will be displayed.



9.3 Select Nap Activity Threshold

The 'Napping activity level (/epoch)' is used to set the activity threshold for nap detection. The activity level in every epoch within the specified period must be less than or equal to the entered value for the period to be scored as a nap. For example, if the threshold is set to 10, the period will be scored as a nap if every epoch ≤ 10 counts. Change the threshold value by typing the number of counts.

9.4 Select Min Nap Length

Set the minimum period of inactivity required to be scored as a nap. The value should be typed in the format hh:mm:ss. Periods shorter than the selected value will not be scored as a nap period.

9.5 *Select Max Nap Length*

Set the maximum period of inactivity required to be scored as a nap. The value should be typed in the format hh:mm:ss. Periods longer than the selected value will not be scored as a nap period.

9.6 *Analysis Results*

The analysis window will show the number of potential naps detected. The analysis graph will display the potential nap periods as green highlighted areas.

9.7 *Export Nap Periods*

To export the nap analysis details, click on the 'Export Nap periods' button. The nap analysis details will be copied to the clipboard which may then be pasted into Excel or similar for further analysis.

10 Day Activity Analysis

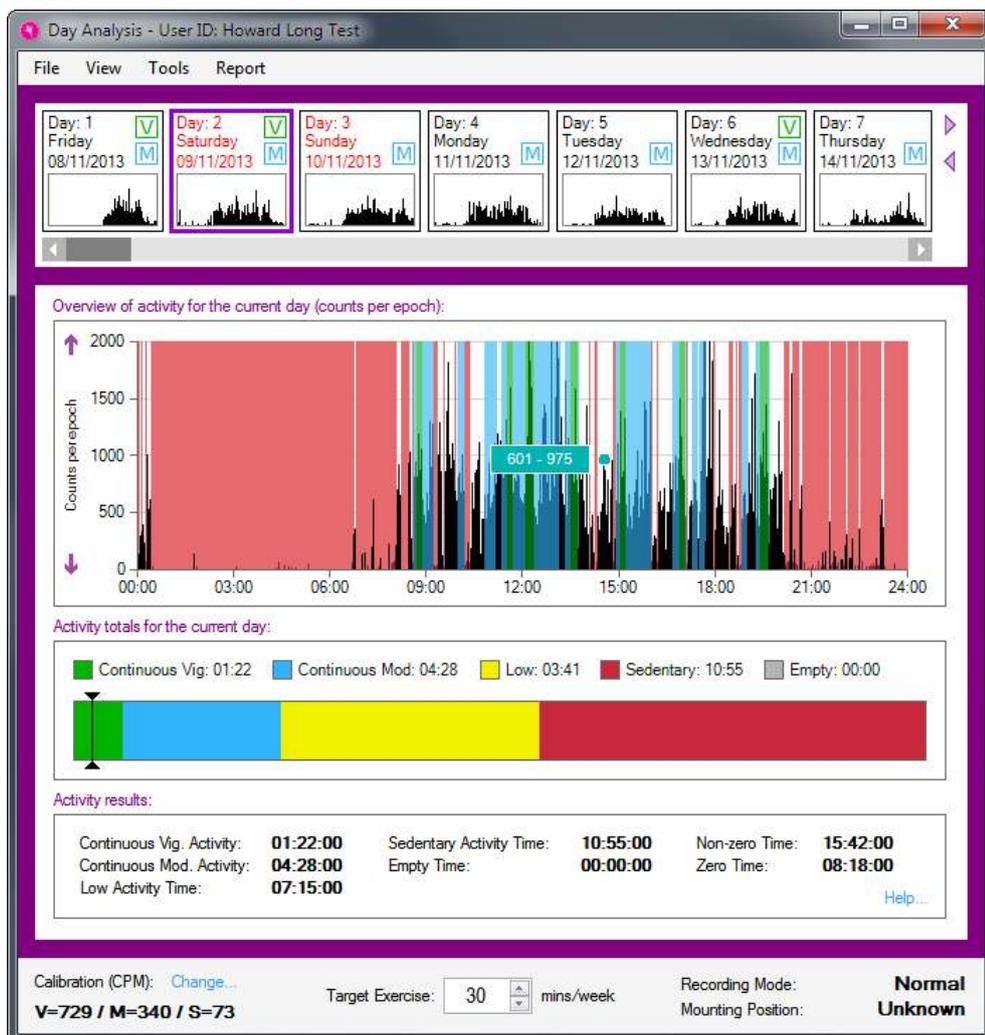
10.1 Overview

The day activity analysis function provides an overview and summary of the activity levels of the wearer during the daytime. It is intended to assist in monitoring of the amount of time spent active on a daily or weekly basis, and the approximate intensity of that activity.

To use the Day Analysis function, single click to select a recording from the recent files list and then click the “Day Activity Analysis” button.

10.2 Day Analysis

Once the recording has been opened with the daytime analysis function, the Day Analysis window will show as below. It allows you to step through every day of the recording and see the highlighted activity periods and daily summary data.



Selecting Days

To select which day of the recording to view, note the sequence of small day graphs across the top of the Day Analysis window. You can click on any of these to view that day in more detail below. You can also scroll this selection to view more days later in the recording. Days which contain some moderate or vigorous activity are highlighted with the “M” or “V” stamp respectively on the quick selection view.

In addition, the **left** and **right** arrows to the right of the day calendar, as well as the **directional keys** on the keyboard can be used to step through all days of the recording.

Highlighted Activity Graph

The main activity graph in the Day Analysis window highlights periods of constant activity – those where higher levels of movement are maintained for 10 minutes or more. You can control whether moderate and vigorous periods are highlighted in this way using the View menu of this window.

Summary Activity

Below the main activity graph, a bar chart summarises the amount of time spent in constant activities of vigorous, moderate or low intensity alongside sedentary time. The table of results below this includes both the constant totals drawn in the bar chart and highlighted on the activity graph (where only 10 minute or greater periods are counted), and the total times in each category (where every epoch is counted).

Definition of Results

The following tables describe the criteria used when categorising time expenditure:

Vigorous Activity Time	The total amount of time when the activity count exceeds the ‘Vigorous’ calibration threshold.
Moderate Activity Time	The total amount of time when the activity count is greater than or equal to the ‘Moderate’ calibration threshold and is less than ‘Vigorous’ threshold.
Low Activity Time	The total amount of time when the activity count is greater than or equal to the ‘Sedentary’ calibration threshold and is less than ‘Moderate’ threshold.
Sedentary Activity Time	The total amount of time when the activity count is greater than zero and is less than the ‘Sedentary’ threshold.

Empty Time	The total amount of time when the recording did not take place – such as at the start or end of the recording (for example the difference between 00:00 and the start time or the end time and 24:00).
Non-zero Time	Any data within the recording with a count value above zero.
Zero Time	Any data within the recording with a count value of zero.

If the '**Show Only Continuous Activity**' option is checked under the '**View**' menu, '**Vigorous Activity Time**' and '**Moderate Activity Time**' are replaced with:

Continuous Vig. Activity	As ' Vigorous Activity Time ', but only when the amount of time is 10 minutes or more.
Continuous Mod. Activity	As ' Moderate Activity Time ', but only when the amount of time is 10 minutes or more.

10.3 Set Calibration

It is possible to set the calibration for the intensity of activity used in classification. This can be done by clicking the Tools menu on the Day Summary and selecting the "Set Calibration" function.

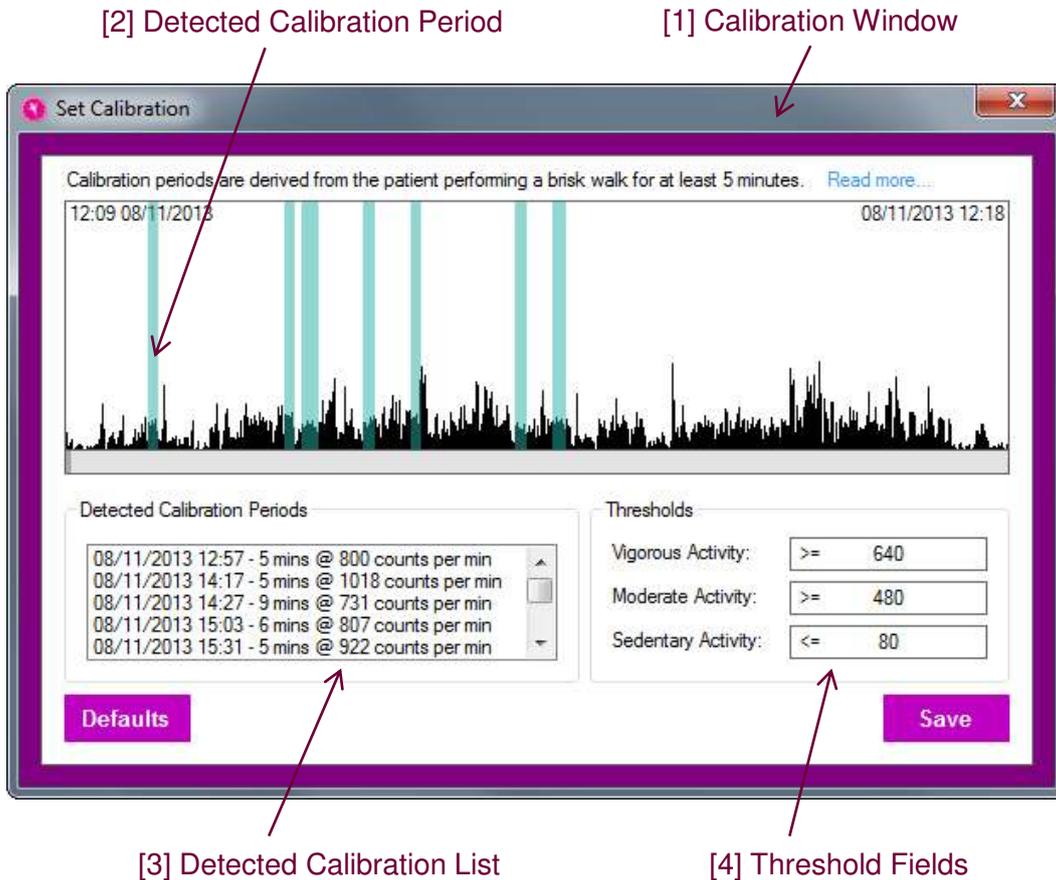
The analysis function uses a calibration to derive reference thresholds for vigorous, moderate, low and sedentary activity types. These values differ from patient-to-patient depending on their capabilities, so it is desirable to perform a calibration for each patient or recording (where applicable).

The best way to calibrate a recording is to arrange for the patient to perform a brisk walk (3-4 mph) for at least 5 minutes. This should take place at the start, or at the end of a recording to ensure that it is easily identifiable when selecting it in the calibration window [1].

The calibration period can be selected by either clicking the highlighted period in the activity graph [2], or by selecting a reported period in the detected periods list [3]. The selected period will use an average of the activity counts found within the period to produce the moderate threshold. This value will also be used to derive the vigorous and sedentary thresholds. The low threshold accounts for any values found between the sedentary and moderate thresholds.

The entire recording will be analysed to detect any bouts of activity which are longer than 5 minutes and who's activity

counts are within an acceptable range. These can be selected as alternative calibration values but they may not reflect the values of a brisk walk and should be used with caution. Calibration periods can also be selected manually by dragging the mouse cursor over a period on the activity graph, or by entering fixed values in the thresholds fields [4].



Definition

Physical activity includes everyday activity such as walking and cycling to get from A to B, work-related activity, housework, DIY and gardening. It also includes recreational activities such as working out in a gym, dancing, or playing active games, as well as organised and competitive sport. (See the Chief Medical Officers' [CMOs'] report.)

National recommendations

The CMOs' current recommendations for physical activity (see UK physical activity guidelines) state that:

- All adults aged 19 years and over should aim to be active daily.
- Over a week, this should add up to at least 150 minutes (2.5 hours) of moderate intensity¹ physical activity in bouts of 10 minutes or more.
- Alternatively, comparable benefits can be achieved through 75 minutes of vigorous intensity² activity spread across the week or combinations of moderate and vigorous intensity activity.
- All adults should also undertake physical activity to improve muscle strength on at least 2 days a week.
- They should minimise the amount of time spent being sedentary (sitting) for extended periods.
- Older adults (65 years and over) who are at risk of falls should incorporate physical activity to improve balance and coordination on at least 2 days a week.
- Individual physical and mental capabilities should be considered when interpreting the guidelines, but the key issue is that some activity is better than no activity.

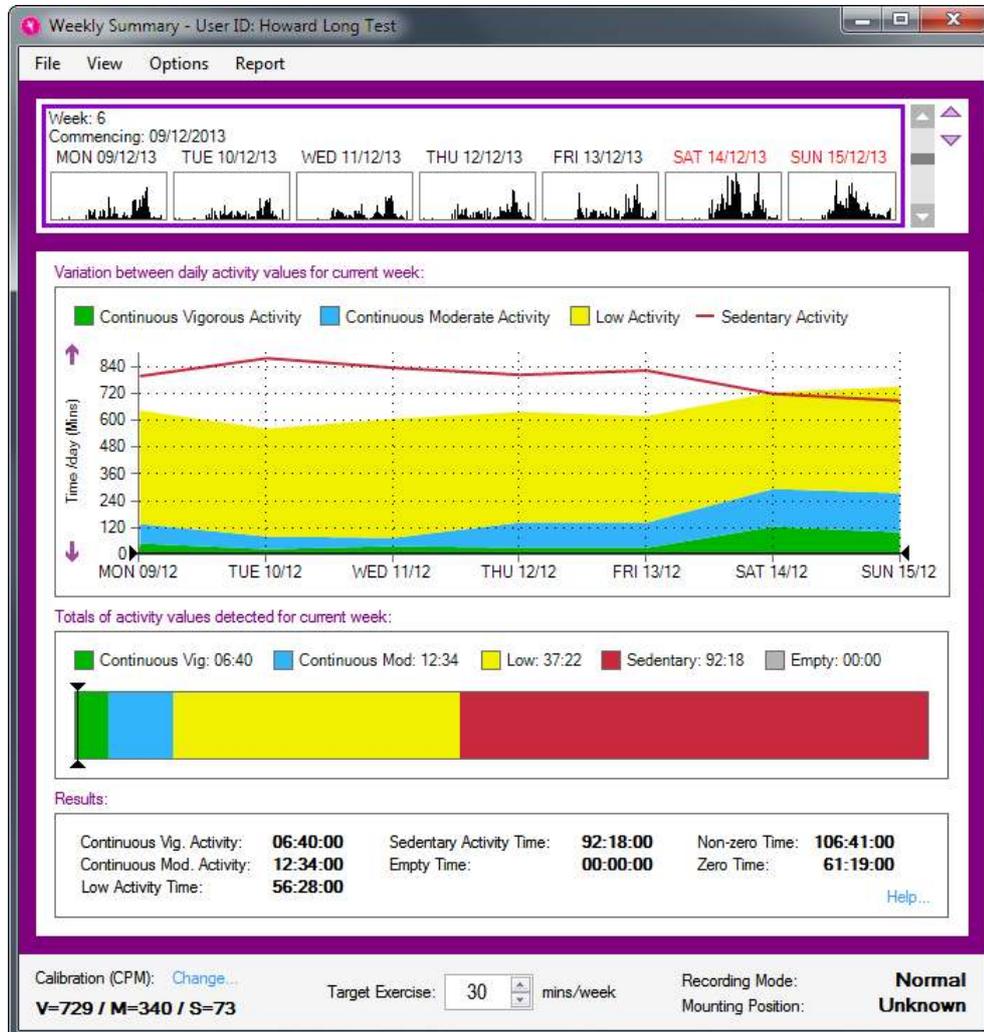
¹ Moderate-intensity physical activity leads to faster breathing, increased heart rate and feeling warmer. Moderate-intensity physical activity could include walking at 3–4 mph, and household tasks such as vacuum cleaning or mowing the lawn.

² Vigorous-intensity physical activity leads to very hard breathing, shortness of breath, rapid heartbeat and should leave a person unable to maintain a conversation comfortably. Vigorous-intensity activity could include running at 6–8 mph, cycling at 12–14 mph or swimming slow crawl (50 yards per minute).

NICE Public Health Guidance 44, 2013

10.4 Weekly Summary

The Weekly Summary window can be opened through the Tools menu of the Day Analysis window. It shows a graph of the wearer's activity levels over a single week at once:



Selecting a Week

The available weeks can be scrolled through in the first graphic of the Weekly Summary window. Use the scroll bar at the right to move through the weeks and click on the one of interest. Alternatively, you can scroll through the weeks using the **up** and **down** arrows to the right of the week calendar, or by using the **directional keys** on the keyboard.

Note that using the Options menu, the weeks can be chosen to begin either on Monday (Calendar Week), or on the first day of the recording (Consecutive Week).

Weekly Summary Graph

The main graph in the Weekly Summary window shows the time spent in different constant intensity levels on each

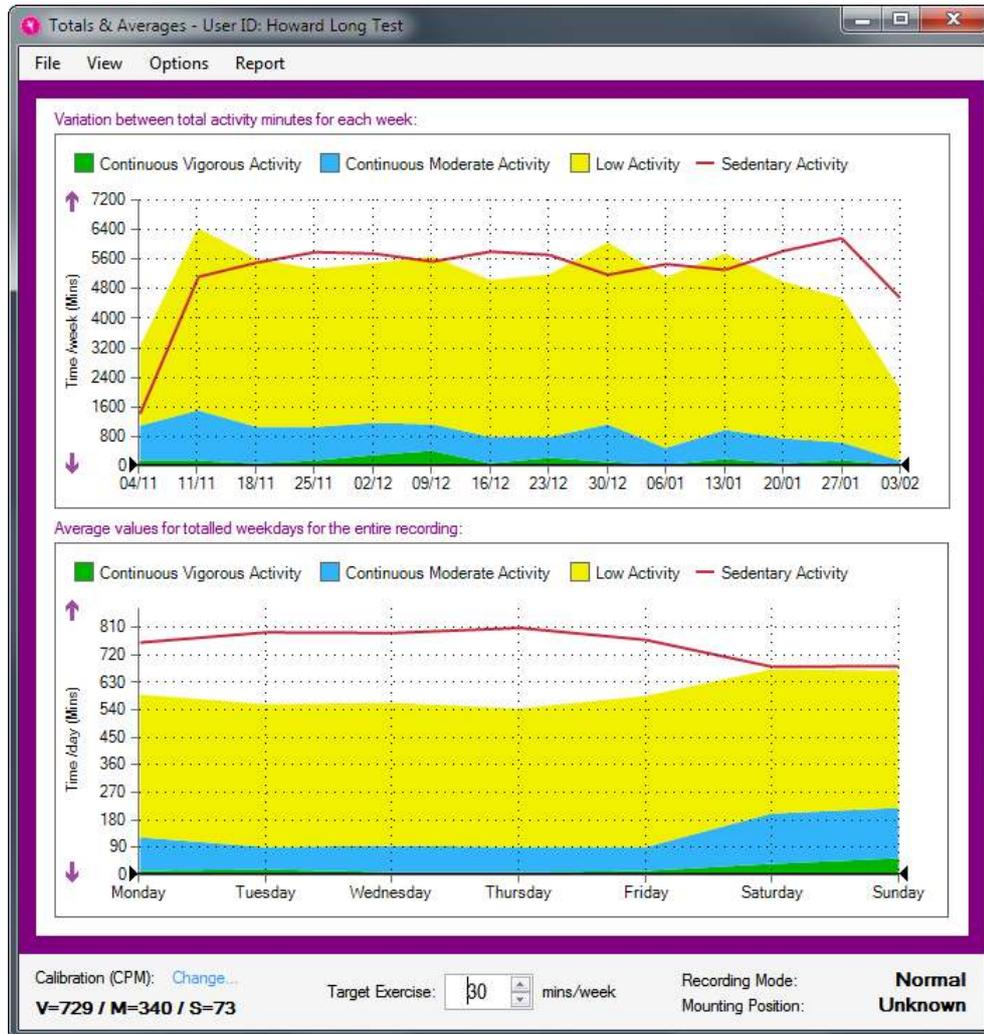
day of the selected week. You can see both how the time each day compares to the target time illustrated by the black line, and how it varies across the week. For instance, the graphic above clearly shows that whilst the target for moderate activity was missed during most of the week, the wearer was then very active on Saturday. The View menu can be used to turn on and off the highlighting of Low, Medium and Vigorous levels.

Weekly Summary Totals

Below the summary graph, a bar chart illustrates the total amounts of time spent in each of Vigorous, Moderate and Low activity, and Sedentary time. Along with the graph above, this will be updated as the weeks of the recording are stepped through. The bar graph also shows the target black line, controlled by the weekly exercise target figure below it.

10.5 Totals & Averages

The Totals & Averages window can be opened through the Tools menu of the Day Analysis window. This window is designed to illustrate the variation of activity over the full length of the recording. The upper graph shows the changes between weeks, and the lower graph shows the average variation within weeks.



Weekly Totals

The upper graph of the Totals & Averages window shows the total time spent in different activity bands over the weeks of the recording. In the example shown, the recording spanned over 6 weeks and showed relatively steady levels apart from an increase in week 4 and a lower total in week 6. It is easy to see both the absolute level versus the target black line (set at the bottom of the window), and the variation between weeks.

Day of Week Averages

The lower graph of the Totals & Averages window is produced by averaging each weekday across all weeks of

the recording. This shows up any variation caused by weekly patterns of behaviour. In the example shown the wearer is clearly far more active on Saturday than on an average weekday, but there is more variation within those also.

Note that both graphs can be affected by the View and Options menus. The View menu controls whether highlights are shown for each of the intensity levels. The Options menu controls whether the discrete weeks are considered to always start on a Monday (Calendar Week), or on the first day of the recording (Consecutive Week).

11 Cloud Data Management (CDM)

11.1 Overview

Our CDM system allows you to securely manage recordings from multiple sites. It is available as an additional service which you may add to your account at any time. Please contact us to find out more information.

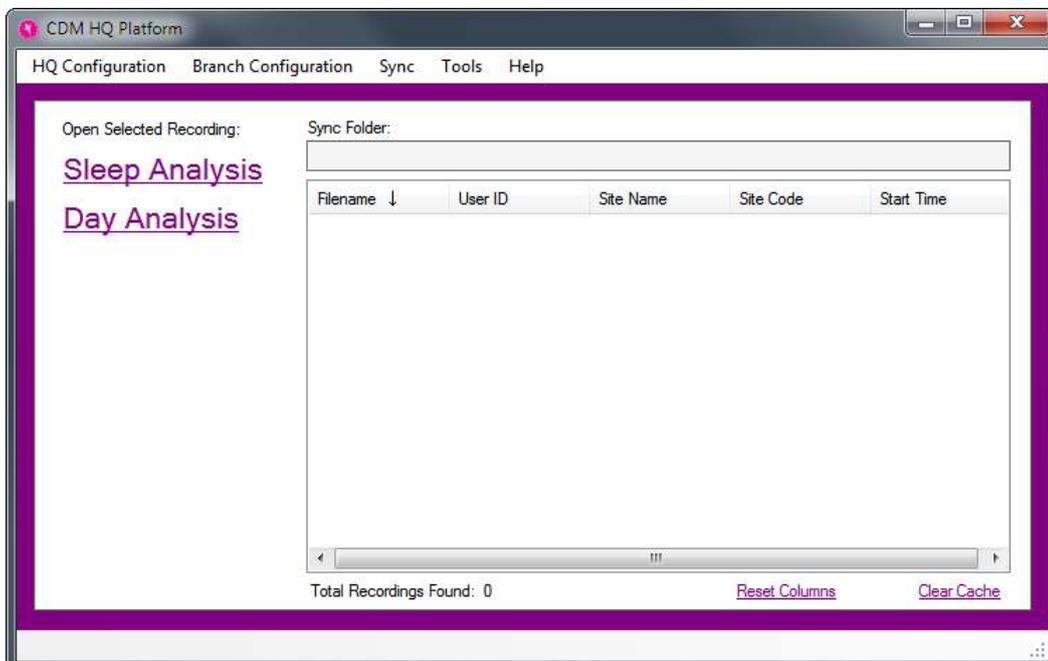
The system uses a HQ and Branch model, where the Branch site(s) will upload their data to our cloud server, and the HQ site(s) will download the data from our cloud server.

All data is encrypted using the encryption keys created at your HQ management site, and is completely secure when distributed from Branch to Cloud to HQ.

Note: CamNtech has no access to your raw data or encryption keys at any time.

11.2 HQ / Management Site Computer Configuration

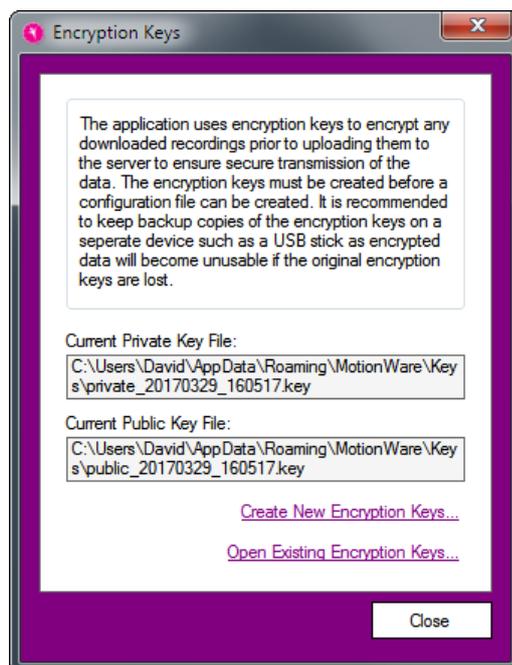
To set up your software as a HQ site, click the **HQ Manager** button on the main window to open the HQ window as shown below.



Create Encryption Keys

Before any data is transferred over the internet, it must be encrypted with keys specific to your project. This function will allow you to create and store those keys. Click on the

HQ **Configuration** menu and click the **Manage Encryption Keys** menu item.



Before any branch can be configured, you must click on the link to Create New Encryption Keys. Do this now.

When prompted, you should create backup copies of the encryption keys to keep in order to prevent loss of data. If you lose the encryption keys, you will lose access to all of your data encrypted with them. CamNtech will not be able to help you read your encrypted data – we do not have copies of your keys.

Close the Encryption Keys window after creating your new keys.

Enter Login Information

You will have been provided with your HQ login information by CamNtech as part of your purchase. To use this, first click on **HQ Configuration → Login Information**.

Server Login Information

Enter your login information for accessing the server here.

Login ID:
camntech

Password:
XXXXXXXX

Project Name:
test

Close Save

Enter all of the fields and click on the **Save** button. This will allow the software to connect to the data server as necessary.

Sync Folder

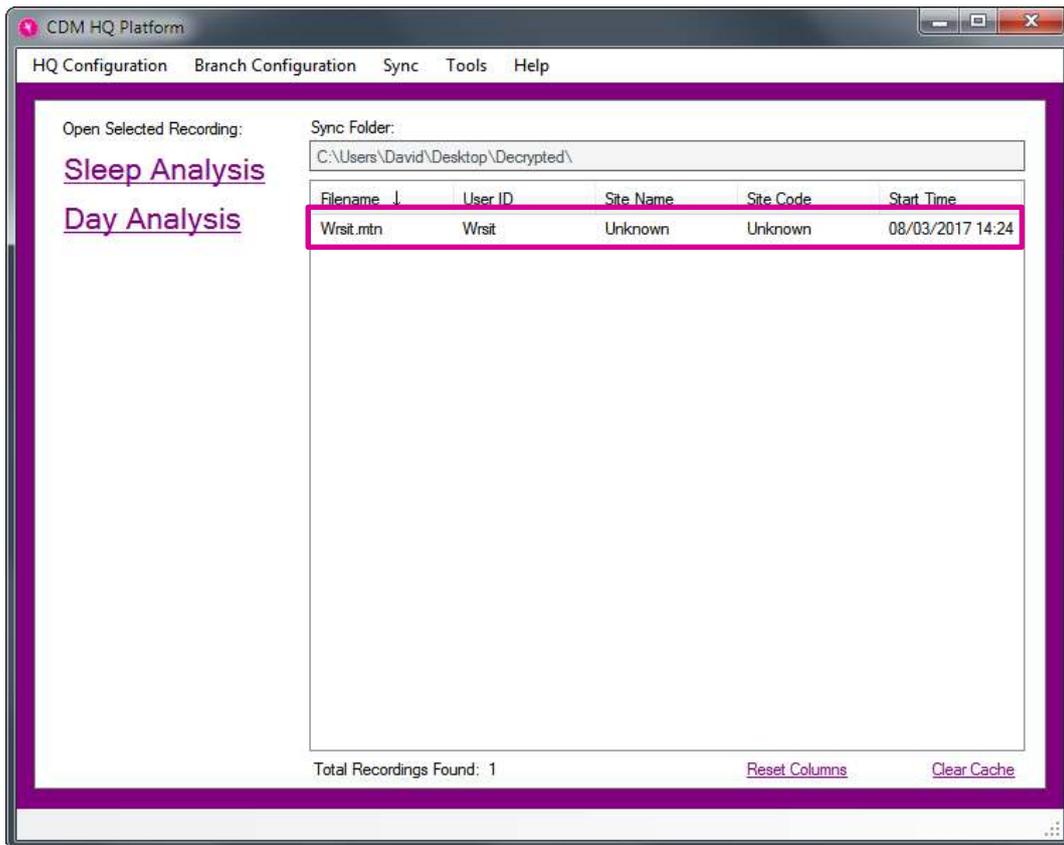
You must also select a folder for the software to store data on the HQ computer. Click on **HQ Configuration → Set Local Sync Folder** in the menu to do so. This folder will contain all data transferred from the branch sites.

After configuring all of the items above, you may click on **Sync → Sync Now**. This should produce no new data in the list, but no error messages either. This is because there is no data available yet on the server. Your HQ system is now configured.

11.3 Syncing with Cloud

To sync with the Cloud, click the **Sync Now** menu item in the **Sync** menu.

New recordings will be downloaded and decrypted, with a corresponding entry added to the recordings list as shown below:



These recordings can be opened by selecting them in the recordings list and clicking the **Sleep Analysis / Day Analysis** options.

11.4 Branch Configuration File

A configuration file is used to automatically configure your branch computer(s) to sync recordings with the cloud. The configuration file is created by your HQ site computer and contains information such as login details and public encryption key.

Note: a single configuration file can be used on more than one computer per site but we would recommend using one configuration file per geographical location.

To create a new configuration file, click the **Branch Configuration** menu found on the **HQ Manager** window, and then click the **Create New Configuration File** menu item. The following window will be shown:

Overview of fields:

Site Name: provide a name for the site which the configuration file will be used on.

Site Code: provide a site code used to identify the site's recordings when data is synchronised with the HQ site.

Recordings Folder Location: this is location of the *Recordings Folder Name* (see below) on the branch computer where the encrypted recordings will be stored after they have been downloaded from a MotionWatch.

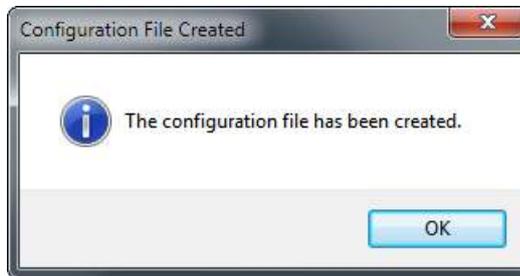
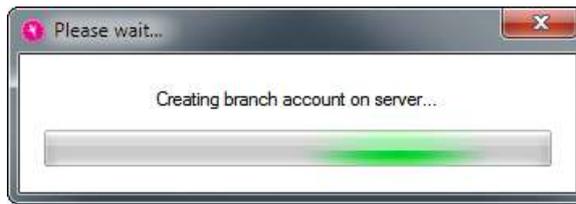
Recordings Folder Name: this is the name of the folder inside the *Recordings Folder Location* where the encrypted recordings will be stored after they have been downloaded from a MotionWatch.

Destination File Preview: shows the combined *Recordings Folder Location* and *Recordings Folder Name* and the folder structure within it.

Configuration File Name (without extension): provide a file name for the configuration file without an extension.

Configuration File Save Folder: click the **Browse...** link to specify a folder to save the configuration file to.

After providing the necessary information, click the **Save** button to save the configuration file and create the branch account on the cloud server.



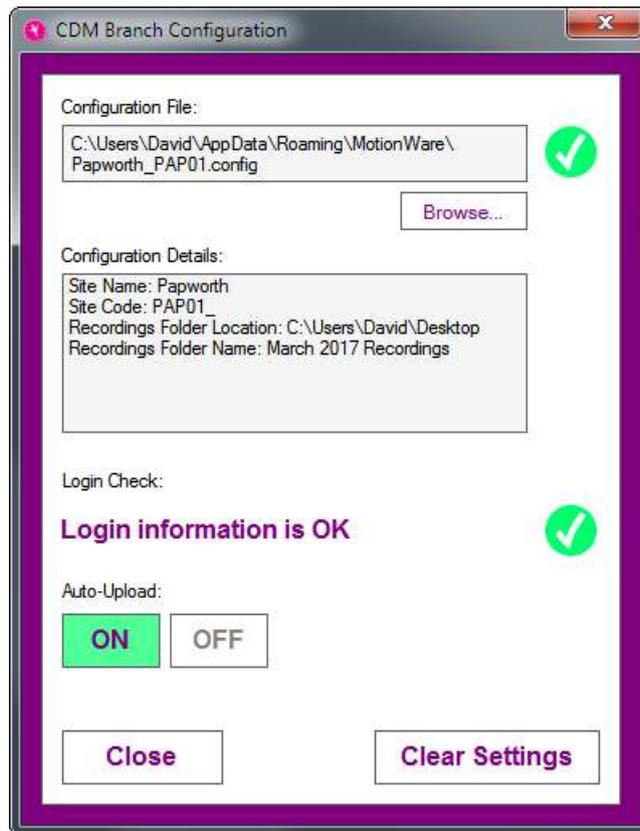
At this stage, you should transfer the configuration file to your branch site(s) using your own delivery method (such as secure email).

11.5 Branch Site Computer Configuration

Ensure you have created a configuration file as discussed in [section 11.4](#).

Loading a Configuration File

Open the **Cloud Data Configuration** window from the main window (**Menu**  **→ Cloud Data Configuration**).



To load a configuration file, click the **Browse...** button and select your configuration file using the file selection dialogue.

The configuration information will be loaded and a configuration file and login check will be performed. A green tick will be shown next to the **Configuration File** field and one will be shown next to the **Login Check** field if these checks succeed.

Auto-Upload

The **Auto-Upload** feature automatically uploads new recordings to the cloud immediately after they have been downloaded from a MotionWatch.

To turn the feature on or off, click the **On/Off** buttons.

Clear Settings

To clear the currently loaded configuration information, click the **Clear Settings** button at the bottom of the window.

11.6 Synchronising Recordings with the Cloud

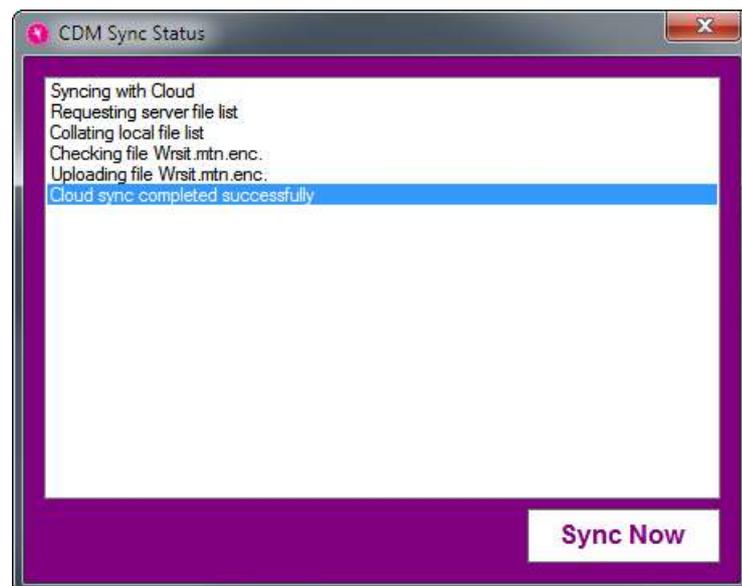
If you are using the **Auto-Upload** feature, recordings will automatically be uploaded to the cloud after they have been downloaded from a MotionWatch.

If previously downloaded recordings were not uploaded (such as loss of Internet connection), you can manually sync them by clicking the **Sync Now** button on the **Settings** menu (**Main Window** → **Menu** ≡ → **Sync Now**).

The sync indicator will show on the Main Menu:



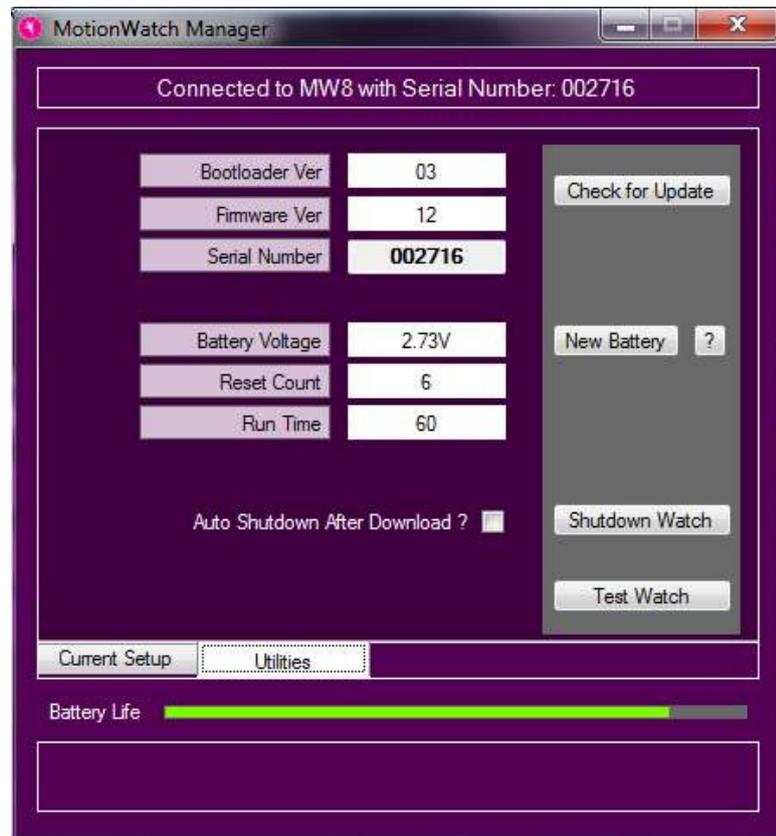
Clicking this indicator will open the **Sync Status** window:



Appendix A - Maintenance and Utilities

A1 - The Utilities Tab

The MotionWatch manager has an additional tab called 'Utilities', click on this tab to display a window similar to the following:



This screen shows some technical information about the MotionWatch:

- **Bootloader Ver:** This is the version number of part of the embedded operating software that allows the MW8 to be updated remotely.
- **Firmware Ver:** This is the version number of the main operating software for the MW8.
- **Serial Number:** The watch serial number
- **Battery voltage:** Typically this will show a value above 3.0V for a **new** battery and will decline gradually over the usage period.
- **Reset Count:** Used as debug information – the number of unexpected reset events.
- **Run Time:** amount of run time since last battery change – should reset to zero when a new battery is fitted.
- **Battery Fitted Date:** the date that the watch battery was fitted.

A2 - Firmware Update

The MotionWatch has the ability to be re-programmed when new features become available. It is always recommended that the most up-to-date firmware and PC software are used to avoid possible conflicts and data loss. To check for an update, select the 'Utilities' tab then click on the 'Check for Update' button. The software will provide a confirmation if an update is available for the MotionWatch.

To update the firmware, ensure that the MotionWatch is connected and then click on the 'Update Firmware' Button. Take note of the warning message and click OK if you wish to proceed.

IMPORTANT: All data and settings will be destroyed by the firmware update process. Please ensure that any data has been downloaded before commencing.

WARNING! Do not interrupt the firmware update process – doing so may damage the MotionWatch which will then require factory re-programming.

A progress bar will indicate the update progress (this will take a few seconds).

The MotionWatch will then automatically disconnect, apply the firmware, then re-connect. The MotionWatch Manager window will be temporarily closed during this period and will automatically re-load and show a verification message upon completion.

Depending upon the type of update, it may be necessary to **manually re-set** the MotionWatch. If the MotionWatch Manager does not re-load automatically, disconnect the Watch, remove the battery for at least 1 minute, re-fit and re-connect the USB. The verification message should then be shown.

A3 - Shutdown Options

The MotionWatch has a low power shutdown function which will help maximise the life of the battery. In the utilities windows, there are two options as follows:

- **Auto Shutdown After Download:** this option allows the MotionWatch to shutdown automatically following download. Data in the watch will NOT be lost but the watch will stop recording. When not selected, the MotionWatch will continue to record until its memory is full and then shutdown.
- **Shutdown Watch:** Allows the watch to be shutdown manually. Click this button to ensure the watch will be shut down when disconnected from the USB cable.

A4 - Changing the Battery

The MotionWatch has been designed to facilitate quick and simple battery changing.

- To change the battery, open the MotionWatch casing as described in Section 1.1 or 1.2 to expose the USB connection and battery.
- **Do not connect the USB cable!**
- Using a suitable tool, carefully push the battery out from the holder towards the USB connector.



- Grasp the battery and withdraw it completely from the holder.
- **Wait at least 1 minute** or **press the marker button 3 times** then place a fresh CR2032 battery into the holder (ensuring correct orientation!) and push back until fully home.



Note: Data will NOT be lost by removal of the battery.

Observe the LED on the front of the MotionWatch, the correct start sequence is indicated as follows:

- LED stays on for 4 seconds.
- LED goes off for 8 to 12 seconds.
- LED flashes once.

This sequence is **critical** to the correct watch operation – if the LED does not flash, remove the battery and repeat the process.

The MotionWare software will automatically detect that a new battery has been fitted. If the watch contains data that

has not been downloaded the following message will be displayed:



Click 'OK' and then download the data from the watch.

To complete the battery replacement process a confirmation message will be displayed.



Select 'Yes' and the software should display 100% in the battery life indication. If the new battery is not detected remove the battery and repeat the steps above taking time to observe each step. If the battery is not replaced correctly the watch may stop prematurely with no warning and the battery life indicator will be incorrect.

A5 - Waterproof Seal

The MotionWatch relies upon a rubber O-ring seal around the top face of the lower part of the casing. The seal should be periodically checked to ensure that it is correctly seated, clean and not damaged. (note that some silicone grease residue will be apparent – do not remove this). Periodically apply a small amount of silicone grease to ensure the seal remains supple.

A6 - MotionWatch Strap

The MotionWatch is supplied as standard with an extra-long moulded silicone watch strap. The strap is fitted with two standard 12-14mm watch spring bars. These bars are spring loaded to allow fitting and removal from the watch casing (see photo).



To remove the Strap: Use a flat bladed tool to gently depress one end of the spring bar by levering against the side of the casing. Take care not to damage the MotionWatch casing.

To Fit a Strap: Push the spring bar into the hole through the strap then place one end of the spring bar into one hole in the watch casing. Gently depress the exposed end of the spring bar and then slide into the hole in the casing; a positive 'click' will be heard.



Replacement straps and alternative straps are available from CamNtech.

It is possible to use any standard watch strap with a 12 to 14mm shoulder with the MotionWatch.

A7 – Alternative Mountings

The MotionWatch may be worn at locations on the body other than the wrist. A range of elasticated straps is available to allow location on the waist, ankle, thigh or upper arm. There are also special straps for mounting on the feet for use with PLMS analysis. These mountings

require the removal of the watch strap and the use of special Velcro mounting tabs. These attach using the same spring bars as the watch straps (see photos).

Velcro Mounting Tabs Fitted



Fitted to Waist Strap with Adaptor



A8 – Data Export Options

The MotionWatch data may be exported from for analysis in third party applications such as MS Excel. To export all of the Activity and light data as time stamped epoch by epoch format, first use the 'Select All' button from the MotionWise window and then choose the 'Summary' option from the 'Analysis Function' side bar. Click on the 'Copy raw data' button to copy the data to the clipboard. Now in your external package, select 'paste' to paste the data from the clipboard.

It is possible to use this mechanism with all data (as explained above) or with any part of the data that is selected. Use the 'Select Any' or 'Select Days' buttons to select the data for export and then follow the same steps as above.

It is also possible to 'bulk export' data directly into .csv text files (see section 2.8). In this way, one folder containing multiple data files can be exported directly to multiple text format files with a few clicks.

Appendix B – FAQ & Troubleshooting

What does 'No data integrity check' mean?

The data is protected by a security key which is generated when the data is originally downloaded. Any changes to the data after the download (e.g. data corruption, tampering, editing, daylight saving adjustment) will result in the data integrity check failure. If a deliberate change has been made, the warning can be safely ignored. The original data can be restored if required following any deliberate edit.

Will I lose my data if I fit a new battery?

The MotionWatch uses non-volatile memory so any data stored will not be lost if the battery is removed or replaced. Note that the MotionWatch will automatically shut down when the battery voltage is low to prevent erroneous data. Always try to download data BEFORE fitting a new battery. If this fails, fit a new battery and then download immediately to prevent data loss.

The MotionWatch is not recognised or will not communicate:

Ensure that the battery has sufficient charge. If the battery has run down, the watch will not be recognised when attached to the USB port. Disconnect from the USB and remove then refit/replace the battery (see maintenance section for details of battery changing). **Wait at least 1 minute before re-fitting the battery and observe the correct start-up sequence.**

- Some types of Micro USB cable will not make a positive connection – please use the cable supplied.
- Occasionally the cable connector may become damaged or worn – try a new USB cable.

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

The MotionWatch Software is shipped with the latest device operating firmware. If the software detects that any MotionWatch 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 (see maintenance section for details of battery changing).

What are the potential effects of Electromagnetic interference?

The MotionWatch 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 Appendix

C5 - EMC Declaration and Guidance). In cases where strong EMI does affect the MotionWatch, the device will recover with no user intervention.

Can I change the Watch Strap?

Yes – see Appendix A6 - MotionWatch Strap above

I see 'Device setup re-write' message when I apply a new set-up

The MotionWare software will read back the watch set-up and verify that it is correct. If the verification fails, the following message will be displayed:



This indicates that the software is re-trying to write the setup to the watch. In most cases the re-try will solve the problem and the message will change to the normal setup confirmation message. If the setup problem persists then the software will display the following warning:



In this case, click 'OK' then disconnect the MotionWatch from the USB. Re-run the software, re-connect the watch and re-apply the set-up.

Appendix C – Safety & Environmental Information

C1 - Decontamination

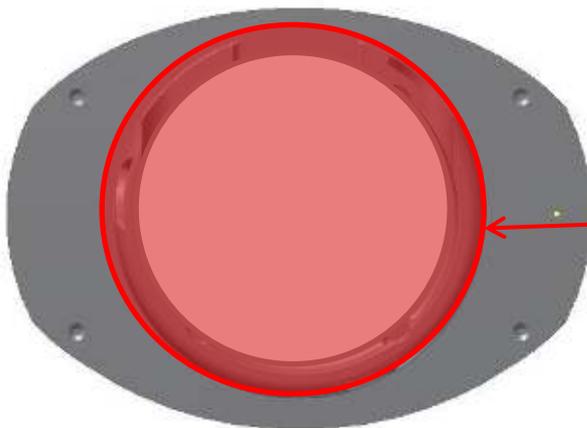
- All used devices must be considered to be contaminated with surface borne bacteria and must hence be de-contaminated using a suitable disinfection and cleaning procedure.
- Care must be taken to use the correct de-contamination procedure and cleaning materials because long term exposure to certain cleaning materials is known to attack plastics which can lead to premature failure of the mechanical integrity of the medical device casing.
- The MotionWatch casing relies upon maintaining the lubrication of the seals and mating surfaces to ensure water resistance and to aid opening/closing of the casing.
- CamNtech recommend the use of aqua based disinfection products and our recommended products are Clinell® Universal Wipes or Spray. These products do not contain chemicals known to cause deterioration of plastics.
- Do not use products containing Glutaraldehyde, Glucoprotamin, Isopropyl, ethyl, or methyl alcohols, hydrogen peroxide, or bleach products. Do not use plasma sterilization or ethylene oxide sterilization procedures, **Do not autoclave**.
- Do not apply self-adhesive labels or tapes to the casing.
- **Begin by spraying and/or wiping all visible surfaces** of the closed MotionWatch body and strap with the cleaning agent. Ensure that all surfaces are dried before proceeding. Open the casing to clean only the areas outside of the waterproof seal (see diagrams below). NOTE - it is essential not to allow cleaning solutions to enter the electronics!
- Important! – do not clean the O-ring seal as this removes the lubricant which can make the casing difficult to open and may reduce the water resistance. There is no requirement to clean inside the waterproof area of the casing (see diagrams below).
- It is advisable to periodically apply a very small amount of silicone lubricant to the seal to aid with water resistance and to assist opening/closing the casing. Contact CamNtech for details of a suitable lubricant.

Cleaning the lower casing (strap not shown)



Clean only OUTSIDE of the red bounded area – do NOT remove the lubrication from the O-ring seal.

Cleaning the upper casing



Clean only OUTSIDE of the red bounded area – do not clean the vertical side walls and ensure no cleaning agent enters the electronics.

C2 - Battery

- The device is battery operated and operates at voltages below 5V DC; there is hence no risk from electric shock.
- The battery is user replaceable (refer to Appendix A4 - Changing the Battery).
- The battery must be replaced observing the correct procedure to prevent possible data loss. (refer to Appendix A4 - Changing the Battery).
- The battery is a standard Coin Cell type CR2032. Always ensure that the battery used conforms to the safety standard EN60086-4:2007.
- **Battery is a swallowing hazard for small children – do not leave small children unattended when the device casing is open. Take care when handling and disposing of coin cell battery.**

C3 - Warnings – General

- The MotionWatch is NOT defibrillation proof.

C4 - 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

**C5 - EMC
Declaration and
Guidance**

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

Electromagnetic Emissions

Guidance and Manufacturers Declaration – Electromagnetic emissions		
The MotionWatch is intended for use in the electromagnetic environment specified below. The customer or the user of the MotionWatch should assure that it is used in such an environment.		
Emissions Tests	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The MotionWatch 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	The MotionWatch is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions EN61000-3-2	Not Applicable	
Voltage Fluctuations / flicker emissions EN61000-3-3	Not Applicable	

Electromagnetic Immunity

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
The MotionWatch is intended for use in the electromagnetic environment specified below. The customer or the user of the MotionWatch 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	+/-8kV Contact +/-8kV Air	+/-8kV 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_1 (>95% dip in U_1) for 0.5 cycle. 40% U_1 (60% dip in U_1) for 5 cycles. 70% U_1 (30% dip in U_1) for 25 cycles. 5% U_1 (95% dip in U_1) for 5 seconds.	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_1 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.

C6 - Applicable Standards:

The appropriate clauses of the following standards have been used as a means of demonstrating compliance.

Standard	Description
EN60601-1:2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN60601-1-2:2007	Medical electrical equipment – Part 1-2: Collateral standard: Electromagnetic compatibility – Requirements and tests. <i>See Appendix C for declaration and guidance</i>
EN60601-1-11:2010	Medical electrical equipment – Part 1-11: Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN60601-1-6:2010	Medical electrical equipment – Part 1-11: Collateral standard: Usability
EN62304:2006	Medical device software – Software life-cycle processes

Appendix D – Technical Specifications

Specifications

Functional Specifications	
Size mm:	MW 8 36(l) x 28.2(w) x 9.4(d) excluding strap
	MW-R 42.7(l) x 32.8(w) x 11.5(d) excluding strap
Weight:	MW 8 9.1 grams (including battery, excluding strap)
	MW-R 19.5 grams (including battery, excluding strap)
Sensor:	Tri-axial, MEMs technology. 0.01g to 8g range, 3 – 11Hz
Battery:	CR2032 Lithium Coin Cell
Battery Life:	4 Months run time*; simple user change
Memory:	4Mbits non-volatile (120 days recording @ 1min epoch - uncompressed)
Waterproof:	IPX7 - up to 1 hour at 1m (suitable for swimming)
Marker button:	MW8: Yes – with visual feedback. MW-R: No
Epoch:	1, 2, 5, 15, 30, 60 seconds
Comms:	Direct USB, Plug & Play drivers, Micro USB cable.
Download:	All data in 50 seconds approx.
Strap:	Bespoke XL 12mm silicone (245mm overall length) or 12mm nylon. MW-R has various mounting options
Light Sensor (not fitted to MW-R)	
Type:	Digital – human eye response optimized.
Range:	Automatic ranging; 0 to 64000lux
Resolution:	0.25lux (0-1000 lux range) 1.00lux (1000-4000 lux range) 4.00lux (4000-16000 lux range) 16.0lux (16000 – 64000 lux range)
Sampling:	1 sample per second – averaged over epoch

*Applies to MotionWatch Mode, Tri-Axial Mode is 60 days.

Operating & Storage Conditions

Complies with the requirements of EN60601-1-11:2010

	Operating	Storage
Temperature	+5°C to + 40°C	-25°C to +70°C
Relative Humidity	0 to 93%	0 to 93%
Atmospheric Pressure	70kPa to 106kPa	70kPa to 106kPa

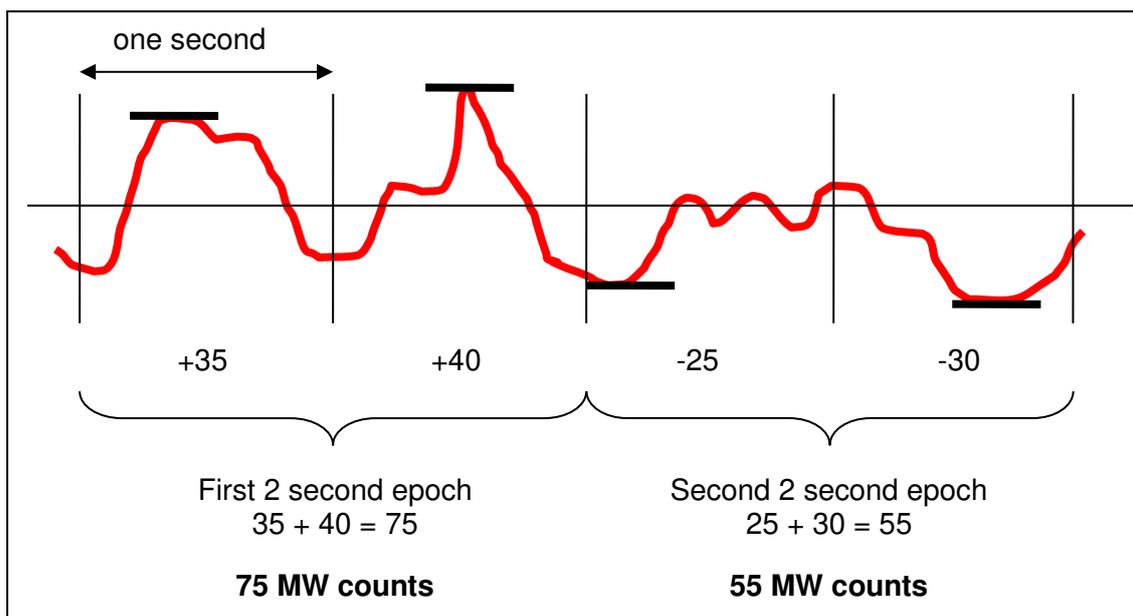
Accelerometer Processing

Raw acceleration measurements are processed by the on-board software of the MotionWatch to produce a quantitative measure of the activity during each epoch. This is a four stage process which is applied to the accelerometer data:

1. The channel perpendicular to the watch is separated and subjected to the bandwidth filtering specified above (3-11Hz).
2. The peak acceleration (either positive or negative) during each second is recorded.
3. This is compared to a minimum “not moving” threshold of approximately 0.1g. Values below this threshold are ignored to simplify the final activity graph.
4. The result from each second is summed over the epoch and scaled to produce a standard result in controlled jig testing. This value is then recorded as the MotionWatch count for the epoch.



This process is illustrated in the diagram below, showing the acceleration waveform over two epochs, each containing two seconds of data.

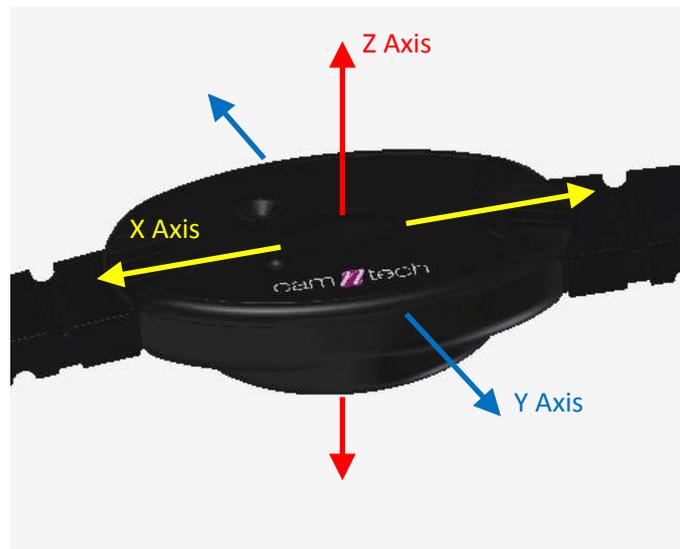


Tri-Axial Mode Data Processing

This is similar to above except all three axes are utilized to form counts based upon a peak vector magnitude.

1. The X, Y and Z axes are sampled with filtering at 3-11Hz.
2. The peak $X^2 + Y^2 + Z^2$ value is found per second.
3. The square root of the sum of squares is calculated and added to the epoch sum.
4. This is compared to a minimum “not moving” threshold of approximately 0.1g. Values below this threshold are ignored to simplify the final activity graph.
5. The values are scaled to produce a ‘Tri-Axial count’ for the epoch.

The diagram below shows the X, Y, Z orientation relative to the watch casing:



MotionWatch XYZ axes: Tri-Axial mode

Appendix E – Utilities

E1 – CSV Import Utility

To allow import of data recorded with the Actiwatch Spectrum or Actiwatch 2, a CSV import utility is provided. Three steps are required to import the data:

1. Export the data in CSV format from the Actiware Software.
2. Load the CSV into the utility and perform the conversion.
3. Load the resulting AWD file into MotionWare.

Step 1 – Export the CSV

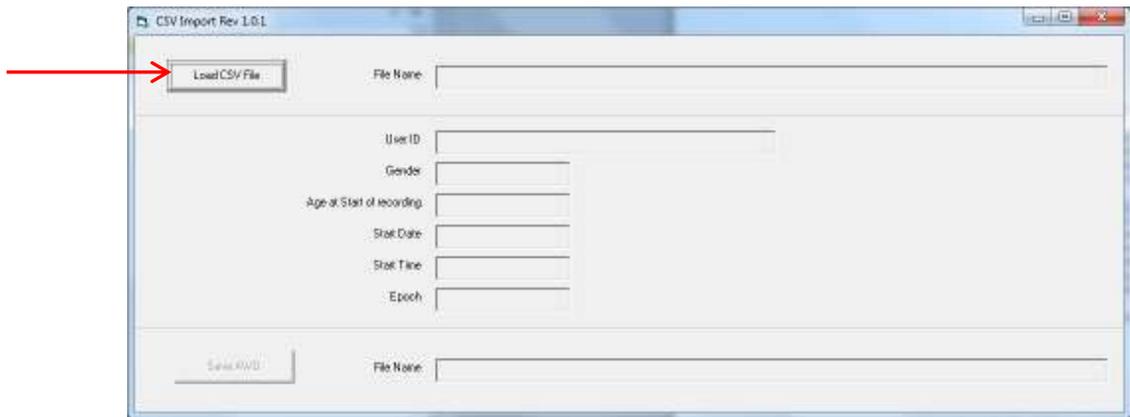
- In the Actiware Software, select new analysis and then click the Actogram button to show the graph of the required data.
- Next set up the Actiware report generation (you should only need to do this once).
- From the tools menu, select 'options' and then click on the export tab. Ensure that the 'full header' and 'epoch-by-epoch list' options are checked.
- Now click the 'data list' tab and ensure that the 'activity' option is checked.
- Click OK to save and close the options window.
- From the main file menu, select the 'export...' option – ignore the 'reminder' pop-up.
- You can now choose the file name and location and then save the export data as a csv file.

Step 2 – Convert the CSV Data

- Run the CSV_Import utility from the MotionWare start menu:



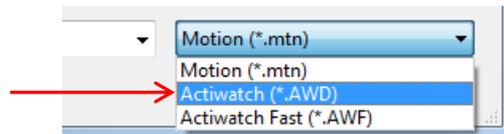
- Click on the 'Load CSV file' button.



- Browse to locate the CSV file saved in step 1 and click 'Open'
- The user ID, Gender etc. from the exported CSV file should be displayed.
- Confirm that the recording details are correct in the display.
- If the details are not correct, the export may not be in the correct format – please ensure the correct settings were applied in Actiware for CSV export.
- Click 'Save AWD' to generate the output file.

Step 3 – Load the AWD File

- Use the MotionWare software to browse for the AWD file created in step 2. (Note you will need to change the 'file type' to .AWD to see the files):



- Load the AWD file
- The data may now be analysed and re-saved as required.

Document Revision History

Issue From	Issue To	Date	Description	Initiator
0.0	1.0	28/05/12	First draft Issue	HS
1.0	1.1	30/05/12	First Issue	HS
1.1	1.2	01/06/12	Added Utilities Tab information to section 8	HS
1.2	1.3	24/08/12	Added MotionWise view menu options + minor tweaks & additions	HS
1.3	1.4	10/10/12	Corrected MotionWatch counts mode	TE
1.4	1.5	07/01/13	Removed warning regarding use with pacemakers (section 10.5)	HS
1.5	1.0.12	06/03/13	Added 24 hour average graph, recent file management, csv import, moved safety info to front, moved rev history to back, changed issue no to match software.	HS
1.0.12	1.0.13	12/03/13	Added description of accelerometer processing, added details of auto-check for updates, added details of strap fitting.	TE/HS
1.0.13	1.0.13a	19/04/13	Changed FW update details	HS
1.0.13a	1.0.13b	30/05/13	Added details of 'Longer periods' menu and saved period functionality	HS
1.0.13b	1.0.14	22/06/13	Added battery gauge details.	HS
1.0.14	1.0.19	23/09/13	Added battery life update button details and details for minor revs.	HS
1.0.19	1.0.20	22/11/13	Updated software registration section	HS
1.0.20	1.0.20a	04/12/13	Added Australian Sponsor Details	HS
1.0.20a	1.0.20b	10/12/13	Updated indications for use to align with FDA submission	HS
1.0.20b	1.0.22	14/01/14	Updated screenshots and added instructions for new View options and Editing Data	TE
1.0.22	1.0.22a	31/01/14	Updated battery replacement procedure in section A5	HS
1.0.22a	1.0.27	24/04/14	Changed Battery Life, added section for nap analysis	HS
1.0.27	1.0.27a	25/06/14	Corrected battery gauge info, corrected sleep epoch recommendation	HS
1.0.27a	1.1.2	30/09/14	Added new reporting options and data compression details.	HS
1.1.2	1.1.5	22/10/14	Added Daytime Analysis section	TE
1.1.5	1.1.9	11/03/2015	Tweaked Day Analysis section, added updated screenshots and calibration info	DW
1.1.9	1.1.15	28/05/15	Added Tri-mode, mounting locations + straps and misc. software revisions	HS
1.1.15	1.1.15a	07/07/15	Corrected email contact for E Van Someren in NPCRA section	HS
1.1.15a	1.1.20	17/11/15	Updated battery life info and battery fitted date to coincide with V1.1.20 SW	HS
1.1.20	1.1.21	13/01/16	Added 'Definition of Result' sub section which describes each day analysis result in detail.	DW
1.1.21	1.1.25	29/06/16	Updated for V1.1.25 software and V03.20 firmware release	HS
1.1.25	1.1.25a	22/09/16	Added coin cell warning, updated accelerometer processing and CSV export sections.	HS
1.1.25a	1.1.25b	01/11/16	Added join files, daylight saving and restore data instructions	HS
1.1.25b	1.1.39	07/02/17	Updated descriptions of Zero/Non-zero data.	DW
1.1.39	1.2.1	30/03/17	Updated Day Analysis section, added CDM section	DW
1.2.1	1.2.5	02/05/17	Updated de-contamination advice	HS
1.2.5	1.2.6	06/07/17	Added sub-section for Bulk Result Export	DW
1.2.6	1.2.14	01/12/17	Added Average light level measurement	TE
1.2.14	1.2.22	26/02/18	Added battery advice page (p4), improved battery replacement advice throughout, revised cleaning advice, updated misc screen shots and minor detail changes.	HS
1.2.22	1.2.22a	05/03/18	Added export options to appendix A8. Clarified installer information	HS
1.2.22a	1.2.23	23/3/18	Added Central Phase Measure to sleep statistics	TE
1.2.23	1.2.25	23/07/18	Updated for V1.2.25 release, updated battery life in tri-mode, added rugged model.	HS
1.2.25	1.1.26	23/08/18	Updated HC information.	HS