PLMS Analysis Software

User Guide

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CE

The MotionWatch is a Class I Medical Device (EU)

Document revision history located at end of document

Please visit www.camntech.com/register to register your software.

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.

Manufacturer

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US FDA status

The MotionWatch is FDA cleared for prescription use only with FDA 510(k) number K132764. USA designated agent:

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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.

Emergo Australia
Level 20
Tower II, Darling Park
201 Sussex Street
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Australia

IMPORTANT SAFETY INFORMATION

WARNINGS

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

Safety Classification Information:

- MotionWatch is **INTERNALLY POWERED EQUIPMENT**.
- MotionWatch mode of operation is **CONTINUOUS OPERATION.**
- MotionWatch is for **PRESCRIPTION USE ONLY** (R_x 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. CamNtech recommends the battery is removed if the device is not used for a period of more than 30 days, in order to prevent potential damage from battery leakage. Observe the storage information below for the removed battery.

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.

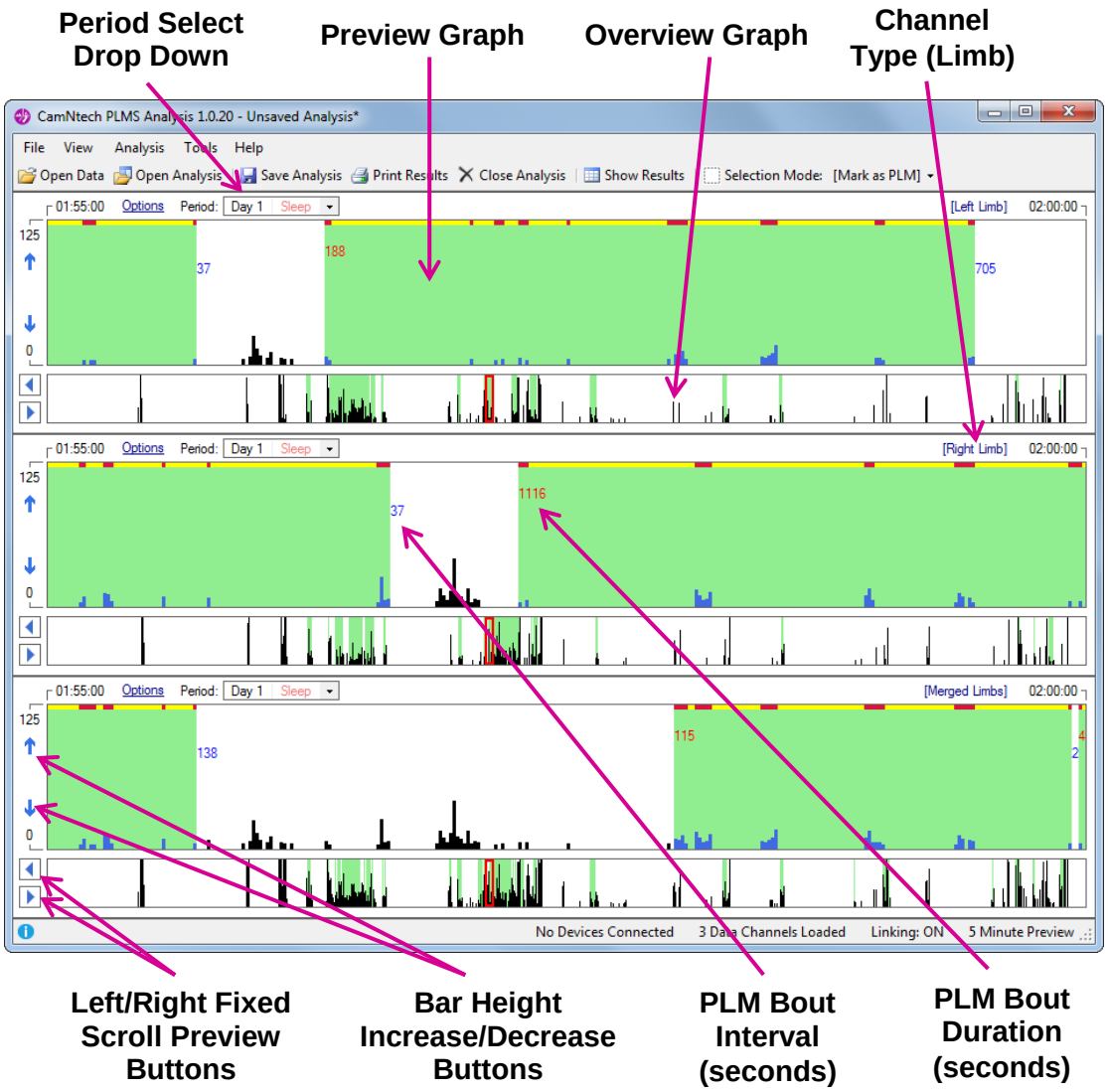
In normal use the watch closure should be sufficient to prevent a child opening and accessing the battery.

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

Contents

Main Window Overview

The following image identifies the main components referenced in this document.



1 Introduction to the MotionWatch for PLMS System

1.1 An Overview of the MotionWatch for PLMS System

The MotionWatch is a compact, lightweight, body-worn activity monitoring device that is used to document physical movement associated with applications in physiological monitoring. The device is built to monitor limb or body movements during daily living and sleep. The MotionWatch can be used to assess Periodic Limb Movement during Sleep using the PLMS Analysis software package. This allows for the set-up, download and analysis of data captured with the MotionWatch.

The MotionWatch itself also allows a variety of other physiological monitoring functions using other software – contact Camntech for further information.
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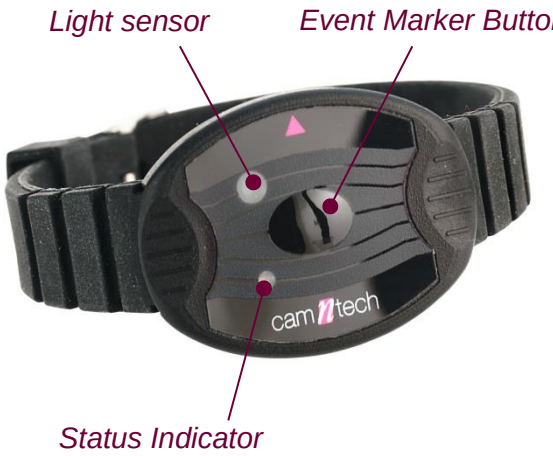
Components Required for a System

A MotionWatch for PLMS system consists of 2 elements:

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

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

1.2 The MotionWatch 8



Event Marker: The MotionWatch 8 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 8 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.

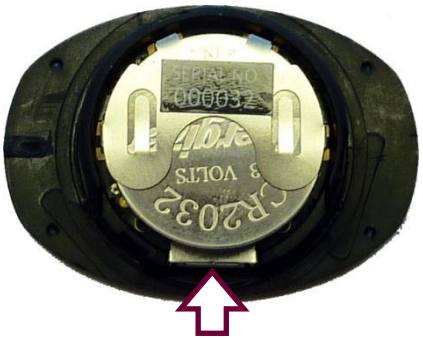
Opening the MotionWatch Casing

The MotionWatch utilises a novel '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 2.5 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!

1.3 Body Mounting Position

The MotionWatch should be mounted as far up the foot, and as close to the big toe as possible in order to maximise sensitivity for detecting PLM activity.

1.4 The PLMS Software

The software has been designed to analyse Periodic Leg Movements in Sleep (PLMS). Real world usage of this software includes the identification of Periodic Leg Movement Disorder (PLMD) in a person by analysing the movements which occur during sleep. This includes measuring the regularity and severity of the disorder.

The software is designed to use data recorded by MotionWatch 8 devices and you can therefore manage these devices directly from within the software.

A brief breakdown of the process is as follows:

- Set a MotionWatch for each limb to record movement activity
- Record data for a series of nights (or sleep periods)
- Download the data from each MotionWatch
- Load the data files into the PLMS Analysis software
- Set up the analysis by specifying start/end dates and times
- *Merge the independent data channels for each limb into a new channel
- *Assess the automatic identification of PLM assigned by the software and add or remove PLM where applicable
- *Create on-screen messages to highlight important areas
- Review scores and results
- *Print the analysis results to produce physical report
- *Export raw data to use in external applications
- *Save the analysis for future use

**Optional*

1.5 Intended 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.
NOTE: the device software should not be used directly for diagnostic or therapeutic decision making.

1.6 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.

1.7 Patient Population

There are no restrictions on the intended patient population for the MotionWatch devices.

1.8 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.

1.9 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 summarised every second for PLM analysis. 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 PLMS or MotionWare Software Package.

1.10 Inspection Before Use

The MotionWatch (including strap) shall be inspected for signs of damage or wear before each use. Do not use the device if the inspection reveals any damage.

Contact CamNtech UK or your local representative if you suspect your MotionWatch device(s) may have sustained damage.

1.11 Service Life

The recommended service life of the MotionWatch devices is **5 (five) years**.

1.12 Modifications

DO NOT ATTEMPT TO MODIFY THE MOTIONWATCH IN ANY WAY. Doing so may affect device safety and/or performance, and will nullify any remaining device warranty.

1.13 Adverse (Serious) Events

Any and all serious/adverse events which result in patient harm MUST be reported to CamNtech and your national Competent Authority. Refer to guidance provided by your local legal authority for information on reporting procedures and timescales.

2 Installing the PLMS Analysis Software

2.1 System Requirements

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

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

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

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

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

2.2 Software Registration

To access the PLMS software download, it is necessary to first register the software with CamNtech. Please visit www.camntech.com/register to register your software using the reference number provided with your equipment. You will then be provided with a username and password allowing log-in and download of the software at any time during the two year warranty period.
Note that CamNtech standard software licensing allows up to 3 users to register and use one copy of the software.
You will also be provided with a software serial number that will be required to activate the software following installation (see section 2.6 below)
The software will continue to be fully functional beyond the warranty period but updates will no longer be provided.

2.3 Installing the Software

Download the installer (.msi) from the CamNtech website: www.camntech.com/downloads
Double click on the downloaded .msi file to run the installer then follow the installation process.
A message warning that 'Publisher cannot be verified' may be displayed – click 'Run' to accept (this is a Windows security warning and is not a problem).
Note that the software requires the Microsoft .NET Framework 4 to operate – this will be automatically installed if not present.

2.4 Updating the Software

If you are updating or reinstalling the software you should first remove the old version. The installation has to then be restarted by double-clicking on the installation file as described in section 2.3 above. Note that any data and settings are not lost during re-installation.

2.5 Installing the USB Drivers

This section on installing drivers only applies to new installations.

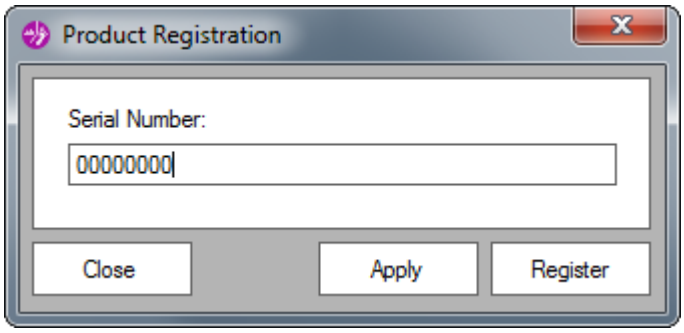
- The MotionWatch utilises generic Windows USB drivers which are provided as part of the Windows operating system.
- To install the drivers, attach the supplied USB cable to a free USB port and connect to the MotionWatch.
- Depending upon the version of Windows, a sequence of messages similar to that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

2.6 Software Serial Number

There is a 30 day evaluation period included with the software. After this time, a valid serial number will need to be applied. To apply a serial number, click on the **'Help'** menu and click the **'Serial Number'** menu item. Enter your 8-digit serial number into the serial textbox and click the **'Apply'** button.

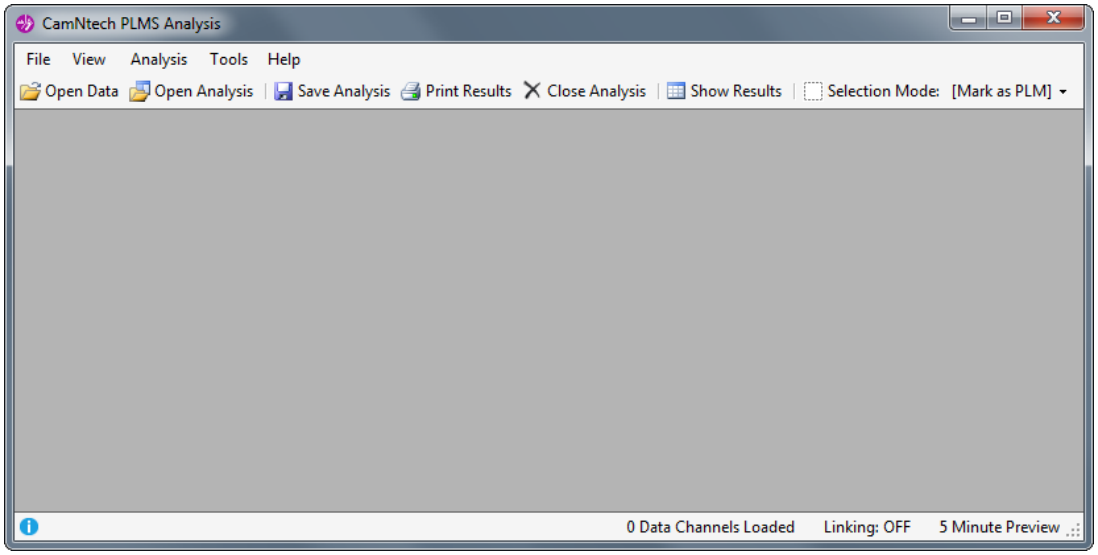


If you do not already have a serial number you will need to register the software. To do this, click the **'Help'** menu, and click the **'Serial Number'** menu item to load the serial dialogue box. Click the **'Register'** button to open a link to the CamNtech website (note: you will need the reference number supplied with the software). Fill out the registration form and click the **'Submit'** button to complete the registration. Your serial number will be delivered via email.

When you have received your serial number, enter the serial number into the serial textbox and then click the **'Apply'** button.

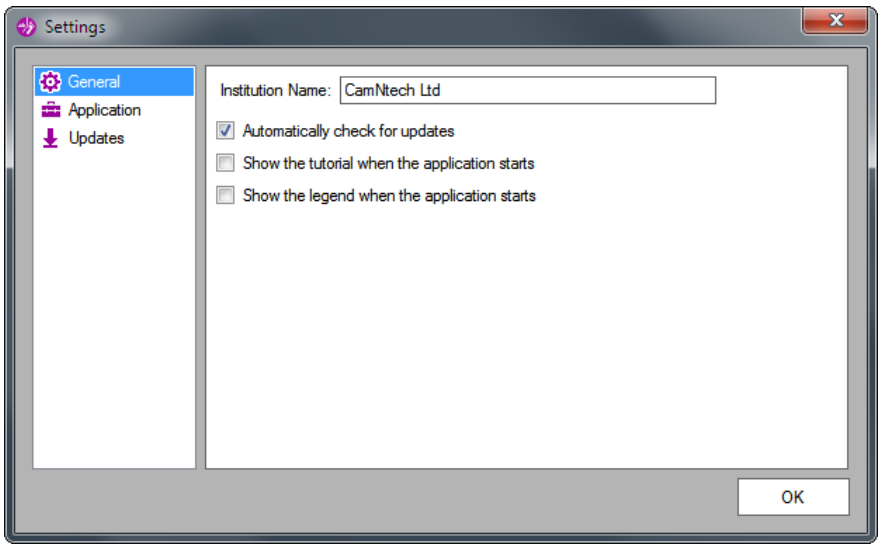
2.7 Running the Software

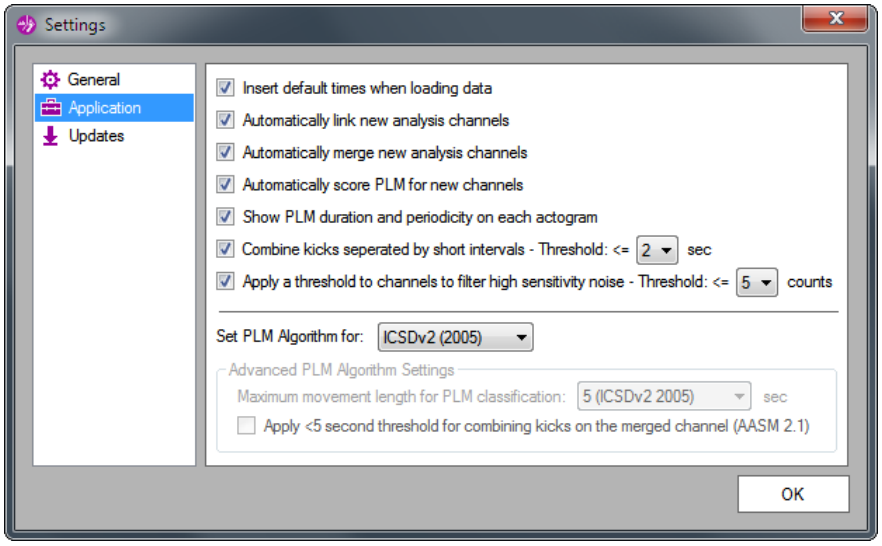
Double clicking on the PLMS Analysis icon on the desktop will start the software. If a MotionWatch is connected it will be automatically detected and the MotionWatch Manager screen will be displayed. The front screen of the software with no MotionWatch connected will be similar to that shown below:

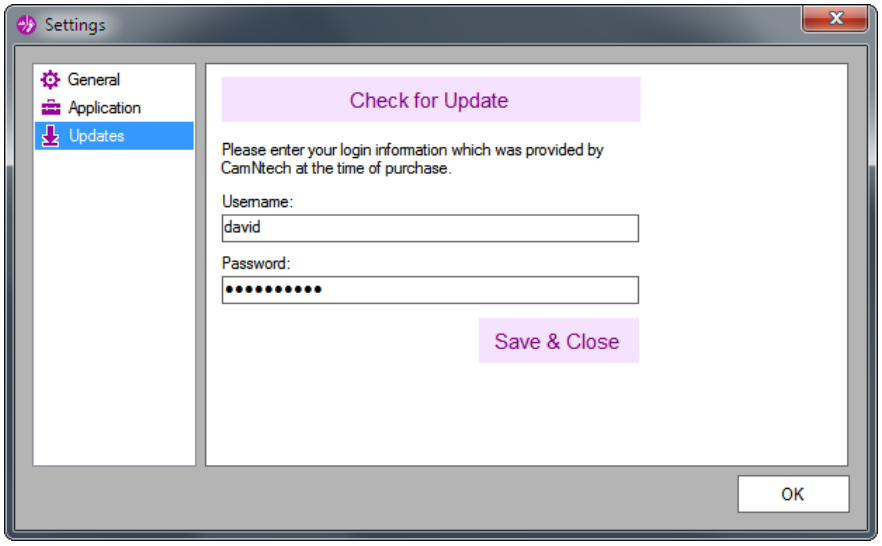


2.8 Software Settings

The operation of the PLMS Analysis software is affected by a number of global settings. These can be changed through the main window from the **'Tools'** menu and then **'Settings'** menu item.







Institution Name

Your institution name can be entered here. It will be used on printed reports, so that feedback to patients or volunteers can be linked with the organisation name.

Automatically Check for Updates

When this setting is checked, the application will check for a new version once per day.

Show Tutorial

Setting this option will show the tutorial help window every time the software is started. This is enabled by default to help you learn to use the software.

Show Legend

Setting this option will show the colour legend every time the software is started. This legend helps explain the different meaning of colours used in the PLM display, to assist in reading it and manually adjusting it.

Insert Default Times

When new recordings are loaded into the software, it is necessary to specify the sleep time periods before analysis. Selecting this option will auto-fill default times to speed up that process, but may not correctly fit all requirements.

Automatically Link

When two or more channels are loaded, they can be linked so that scrolling one graph will scroll the other to keep the scroll positions synchronised. Setting this option will cause this linking to happen automatically when recordings are set up, rather than manually through the Tools menu.

Automatically Merge

Once a recording from a left limb and a right limb are loaded, it is possible to create a merged recording using

the **'Analysis'** menu. Setting this option will instead automatically create the merged recording whenever two limb recordings are opened together.

Automatically Score

This setting determines whether or not the software will perform automatic PLM analysis and marking for a newly loaded recording.

Show PLM Duration and Periodicity

Enabling this setting will show the duration of PLM bouts, and periodicity between bouts on a channel's actogram. The duration will be marked in red and the periodicity will be marked in blue. The values are shown in second.

Combine Kicks

This setting controls how the automatic PLM analysis treats very close together movements with a short gap. The standard definition of PLM for diagnosis does not mention these but instead relies on sensible human interpretation of what a single movement is. We recommend a setting of ≤ 2 seconds.

Click **'OK'** to save the new settings. Click the close [x] icon at the top right to close the window without saving the settings.

Set Algorithm for

Allows you to switch between settings for abiding to **ICSDv2 (2005)** or **AASM 2.1 (2014)** specifications for handling PLM kicks. Selecting the **'Custom'** option will allow you to override these settings.

Maximum Movement Length

This setting allows you to override the maximum allowable length for classifiable PLM movements. The default of 10 is recommended as it abides to the current ICSDv3 in relation to PLM movement diagnostics.

Apply a Threshold

This setting controls how high sensitivity noise is filtered for recording. This is useful as the MotionWatches record in a high sensitivity mode to obtain the most accurate level of movement for PLM activity. As a result, recording can pick up low level noise which can mask genuine PLM activity. A threshold of 5 is recommended as it provides the best amount of filtering suitable for detecting PLM movements.

Check for Updates

Clicking this link will perform a manual check for updates to the application.

3 The MotionWatch Manager

3.1 MotionWatch Current Set-up

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

CURRENT SETUP INFORMATION

Details of the current set-up stored in the MotionWatch.

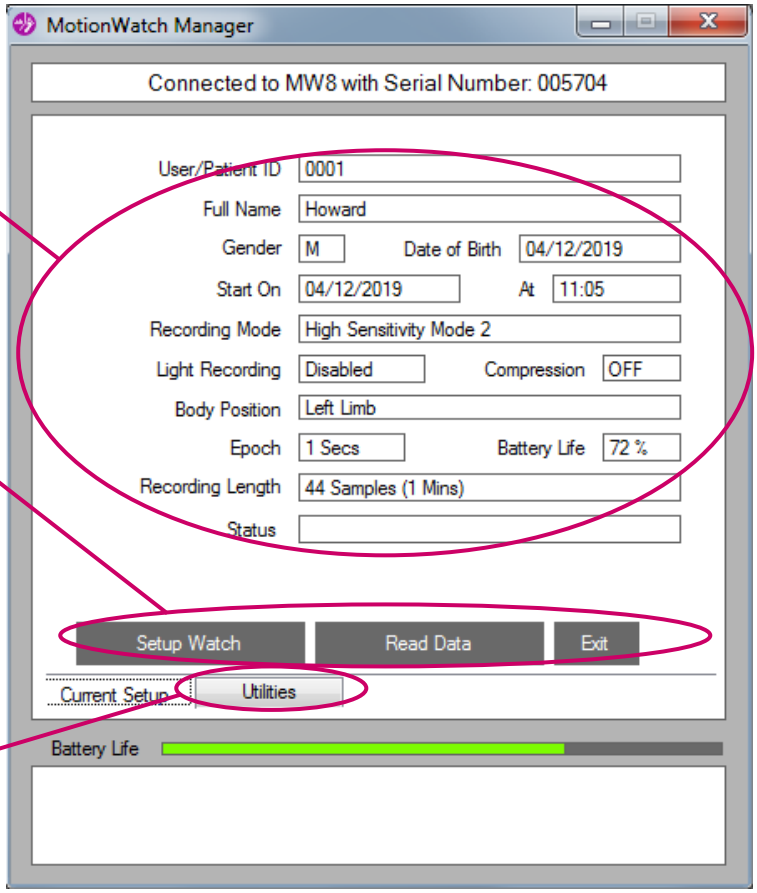
3 MAIN OPTIONS:

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)

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 **'Tools'** menu and **'MotionWatch'** item in the main window.

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.

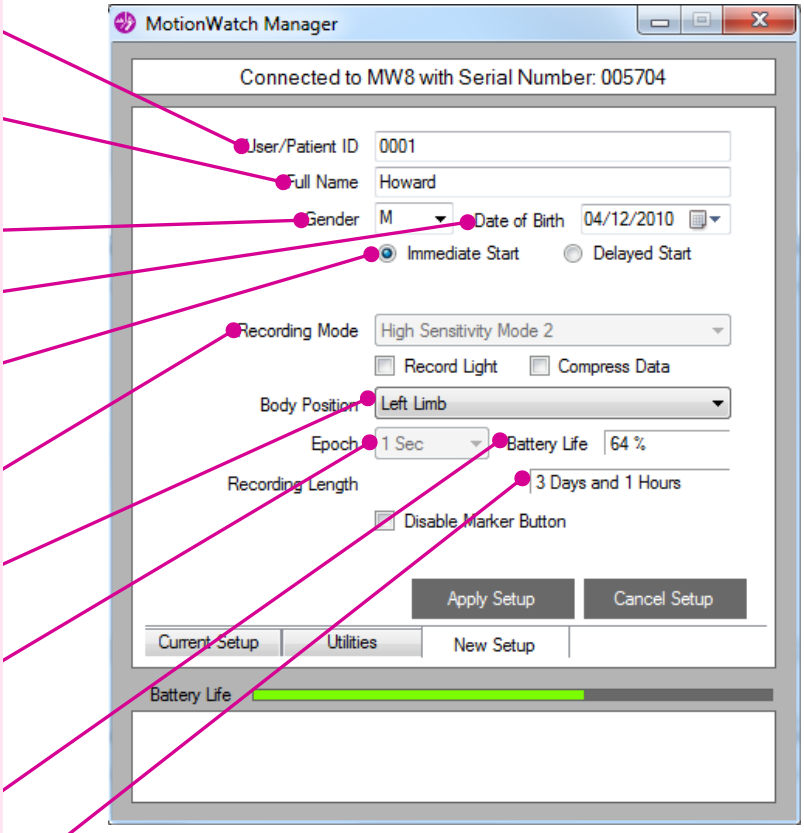
Recording Mode: The recording mode should be left in the preset choice for PLM detection.

Limb Type: Use the drop down control to select the left or right limb.

Epoch: An epoch of 1 second is used for PLM detection. Other epochs are only used for alternative uses with the MotionWare software.

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

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



***NOTE:** Applying a new set-up to the MotionWatch will result in the loss of any existing stored data or set-up information – please ensure that any required data has been downloaded first. Click the '**Cancel Setup**' button to return to the current setup tab without applying the new setup.*

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 several recording modes for other applications, but only the pre-selected high sensitivity mode should be used for PLM detection.

Body Position

For PLMS, select ‘Left limb’ or ‘Right Limb’ to ensure the monitored limb is identified in the analysis.

Epoch

The epoch is the duration for which the MotionWatch will accumulate samples before storing the result in memory. The MotionWatch offers a range of epochs for other purposes, but only the one second epoch is suitable for PLM detection.

Recording Length

The MotionWatch displays the expected maximum recording length, assuming the battery has sufficient capacity to fill the recording memory.

Battery Life Gauge

The MotionWatch Manager screen shows the battery life gauge to provide an indication of remaining battery life using a colour coded bar. The bar will change colour to provide a clear indication of battery status as the battery becomes depleted. The battery life gauge has the following indications:

Green – 60% to 100% (72 to 120 days approx.)

Yellow – 40% to 59% (48 to 71 days approx.)

Orange – 20% to 39% (24 to 47 days approx.)

Red – 0% to 19% (0 to 24 days approx.)

When the battery life falls below 15%, the gauge will flash and an additional message will be displayed in the status area (as shown above).
If set-up is attempted with a short battery life, an additional warning message will be displayed.

ALWAYS REPLACE THE BATTERY IF THE RECORDING IS LONGER THAN THE ANTICIPATED BATTERY LIFE.

Battery Life

The MotionWatch uses a standard non-rechargeable CR2032 coin cell which is easily replaced by the user (see Appendix A4). The MotionWatch incorporates smart battery monitoring to measure actual device usage and battery voltage to calculate an expected life remaining. The maximum expected battery life will be **4 months** (MotionWatch 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 function uses a logarithmic compression which provides lower accuracy at higher values (quantized data). At low levels, the accuracy is not affected at all. This option is enabled for PLM recording. It allows longer recording at the 1 second epoch, but means that some quantization will occur at higher movement values during the day. So caution should be used if the daytime movement data during a PLM recording is to be compared to other daytime recordings set up using the MotionWare software.

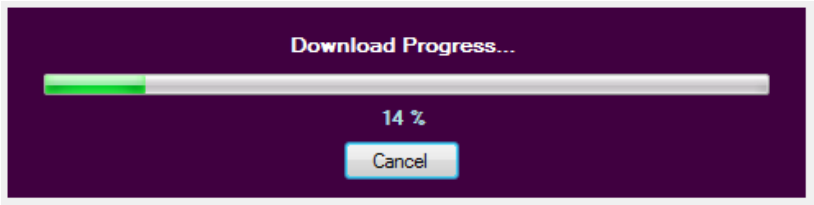
Disable Marker Button

Select to disable the marker button.

4 Downloading Data

4.1 MotionWatch Download

From the MotionWatch Manager Window click on the **'Read Data'** button. The download will begin and the progress notification will be displayed…



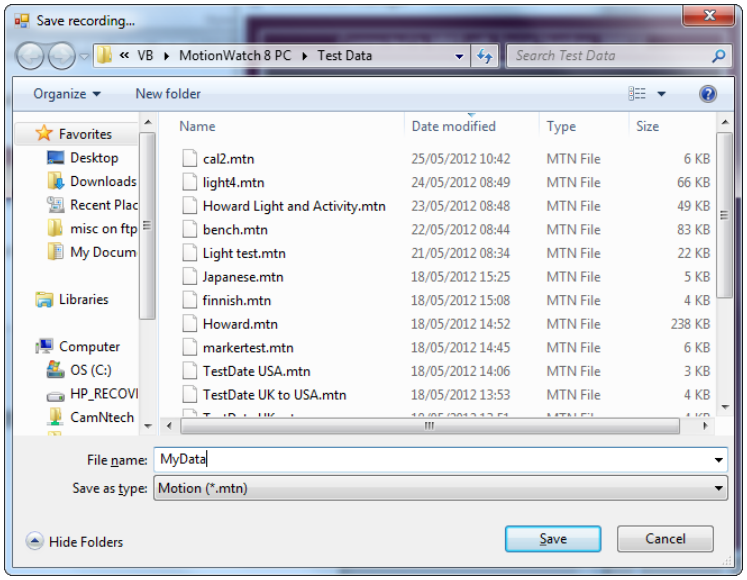
If the data download is not required, click the **'Cancel'** button and the operation will be aborted.

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.



This window allows the save file to be specified for the downloaded recording. 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 PLMS Analysis software defaults to shut-down the MotionWatch into sleep mode to save battery power following download. Data will NOT BE LOST but the watch will cease recording.

5 Preparing to Analyse Data

5.1 The PLM Analysis Window

The PLM analysis window is the centre for displaying and analysing PLM data. When initially opened, the menus for opening data files and changing settings are available. The main display is shown when one or more recordings have been loaded for analysis, or if a saved analysis (.pax) file has been opened.

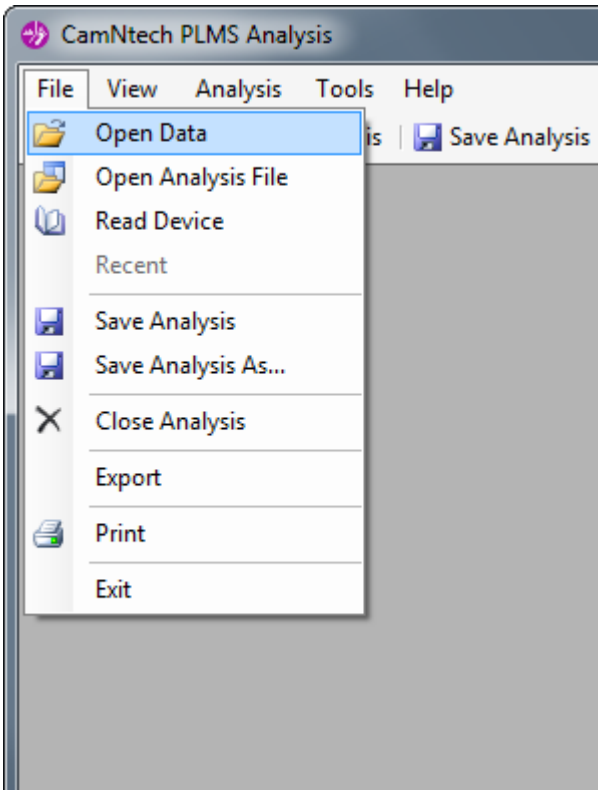
5.2 Loading Recordings

The application comes with two demonstration files which are installed by default. These can be found in the following directory (replace [Username] with your username):

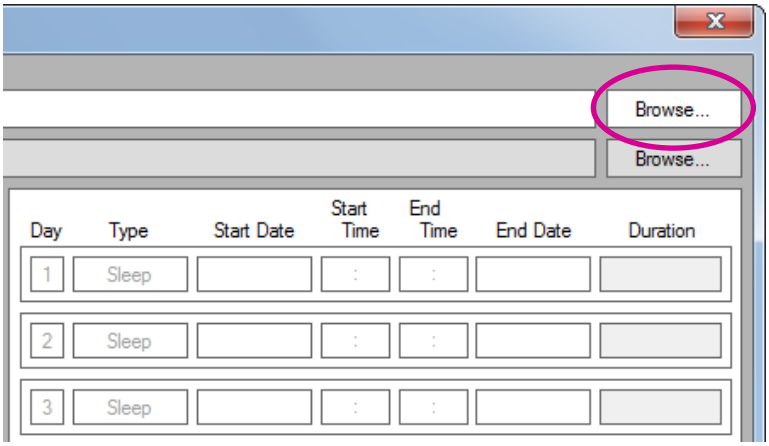
C:\Users\[Username]\Documents\PLMS Analysis Data

After downloading data, you must choose which recordings to open for analysis. This may be one or more left or right limb recordings, loaded alongside one another. To load your recordings, follow the procedure below:

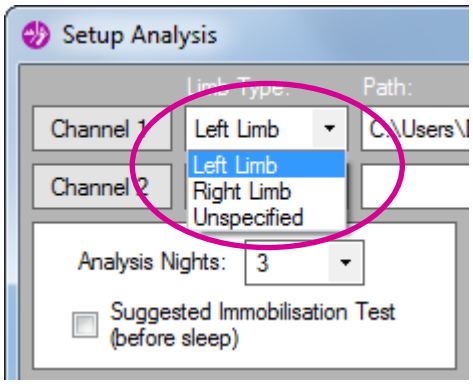
1) When the application has loaded, click on the **'File'** menu, and then click on the **'Open Data'** menu item.



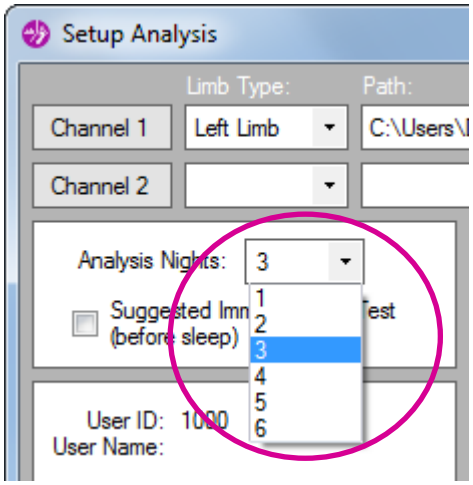
2) From the Setup Analysis window, click on the **'Browse'** button for Channel 1 located in the top right corner of the window.



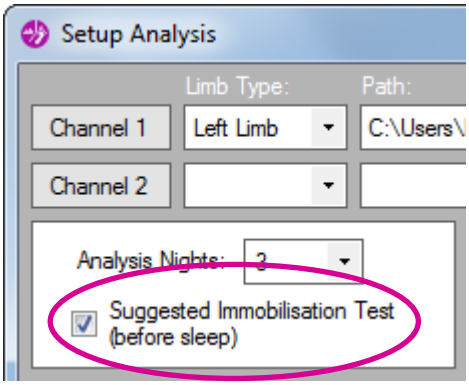
3) The application may automatically try to guess the correct amount of sleep periods and dates/times for the recording, depending on the current setting. Default values will be applied if it cannot determine them.
4) If applicable, select the correct limb type from the drop down box.



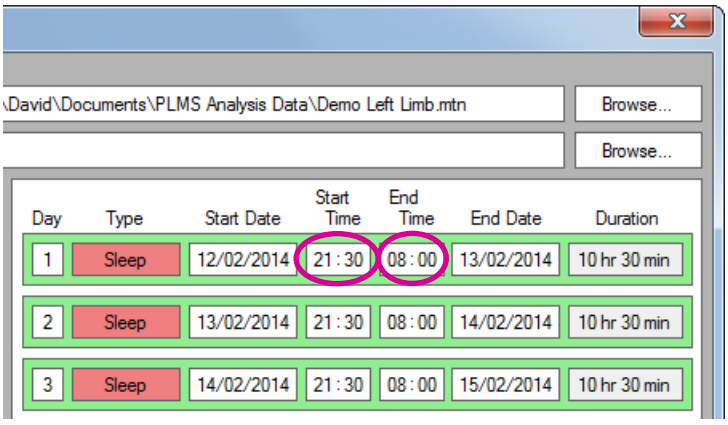
5) Enter the correct number of sleep periods contained within the recording from the drop down box.



6) If your test includes a Suggested Immobilisation Test (SIT), or your test is for PLM in Wakefulness (PLMW), then click the **Suggested Immobilisation Test** checkbox.

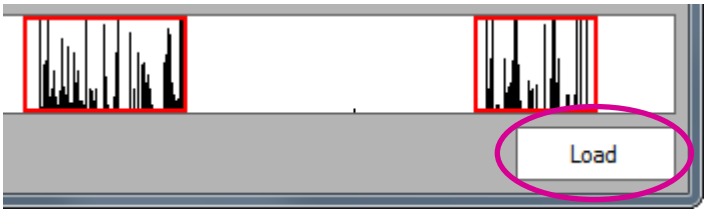


7) Enter the correct start and end date/times for each day in the recording. Dates can be changed by clicking the left mouse button on the individual date element (e.g. dd/mm/yyyy). Times can be changed by typing in the hours and minutes in the time fields. The time ranges will be highlighted as a red rectangle in the recording overview at the bottom of the window.



You can quickly switch between time fields by pressing the **tab** key on the keyboard.

8) Confirm that all fields are correct and left-click the **'Load'** button.



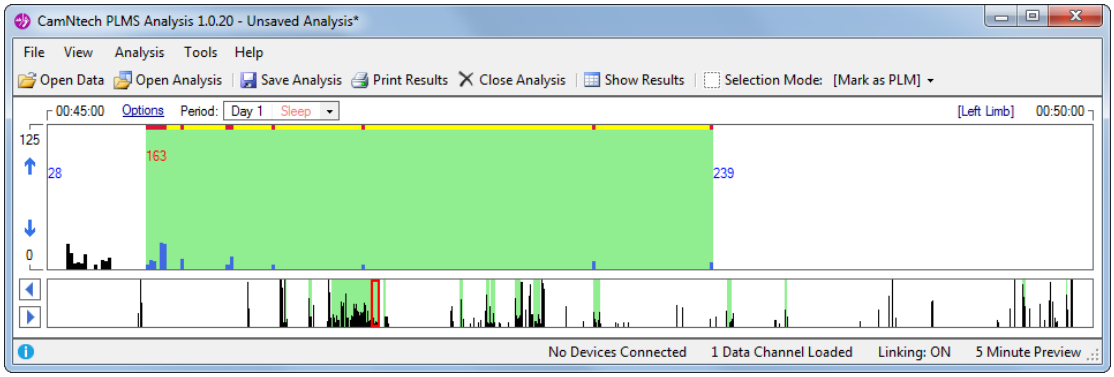
9) You load two limb recordings simultaneously by clicking on the **'Browse'** button for both channel 1 and then channel 2. The start and end dates/times will be applied to both channels and both will be loaded.

5.3 The Movement Display

For each recording channel, a graph similar to that shown below will be displayed. This shows a single period of movements. Two graphs can be loaded in one analysis session, and an optional third merged channel can also be created.

The large upper graph shows a zoomed-in period of the recording - in this instance showing 5 minutes of the movement period starting at 00:45:28 and ending at 00:48:11. Each vertical black block represents the amount of movement during a single second of the recording. Solid blocks of black are produced by consecutive seconds of movement.

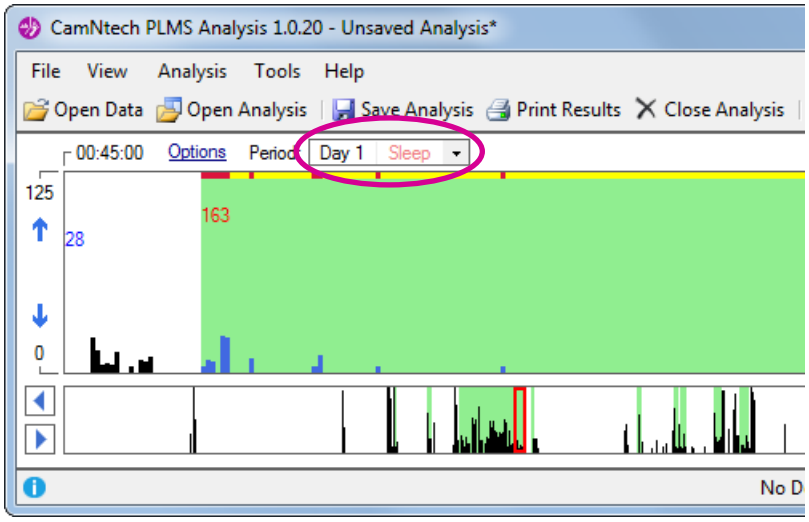
The shorter lower graph shows the movement over the entire movement period. It is not as clear as the zoomed graph, but displays an overview of the entire night. It is overlaid with a red rectangle illustrating the current location of the zoomed-in period.



A legend explaining the meaning of the various colours on the graph can be shown (if not already open) by clicking the **'Help'** menu and then the **'Colour Legend'** menu item.

5.4 Switching Days

When recordings are broken down into multiple days, each day will be listed in the **Period** drop down for that recording. Periods (Sleep or Wake) can be switched at any time by clicking on the relevant item from the drop down menu.

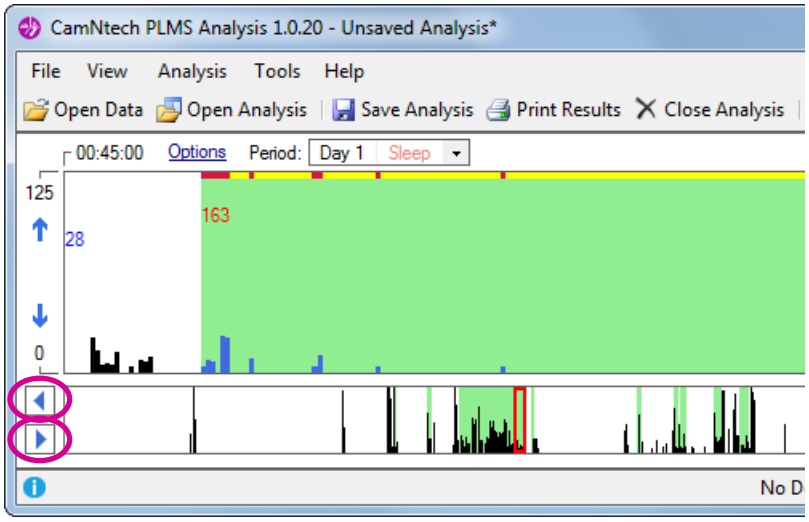


If the channels are linked, then all other channels (including merged channels) will change to the day specified.

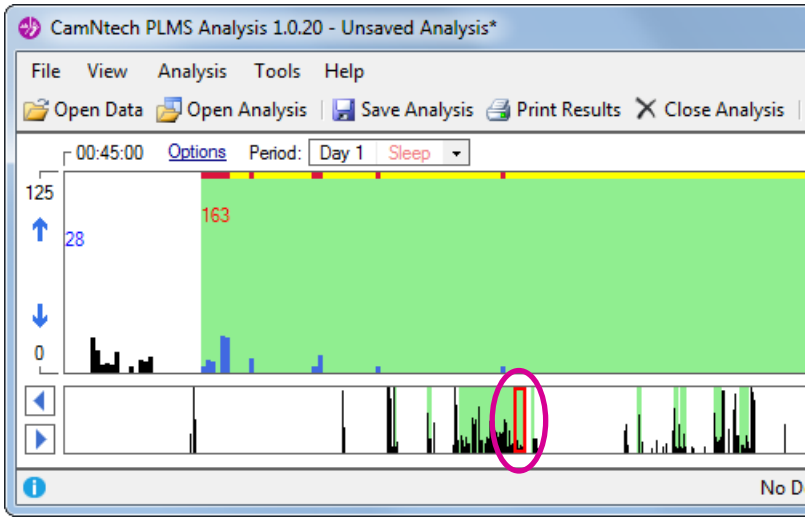
5.5 Scrolling Graphs

The application is designed so that the user sees a window of data (default 5 minutes) at any given time. This provides an efficient way to browse through large sleep periods. Scrolling through the data can be achieved in the following ways:

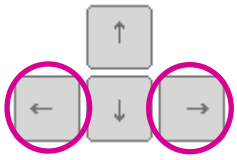
1) By clicking on the previous/next buttons on each panel to scroll in fixed values (default 5 minutes).
2)



3) By dragging the red preview rectangle with the mouse (hold left click) to scroll freely.



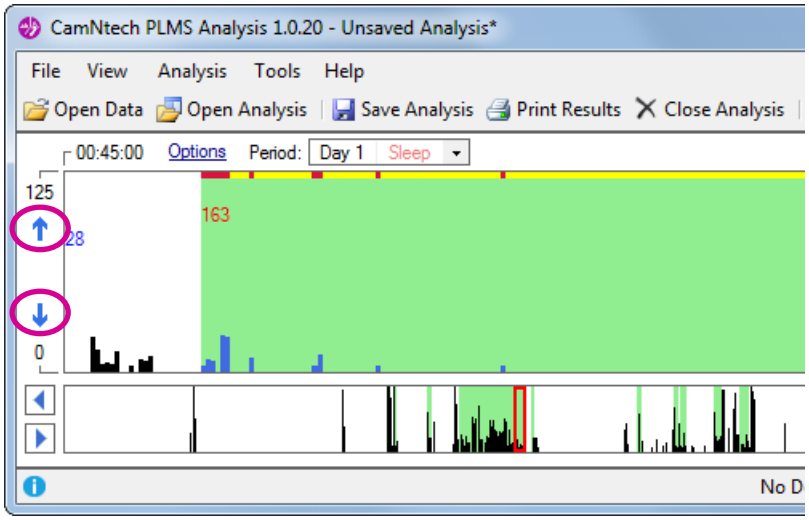
4) By pressing the **left** and **right** keys on the keyboard to scroll freely.



5.6 Changing the Graph Scale

Data shown on the graphs can become difficult to view, especially with a large variation between maximum and minimum data values. To address this, the magnitude for each data channel can be changed to increase low values or decrease high values.

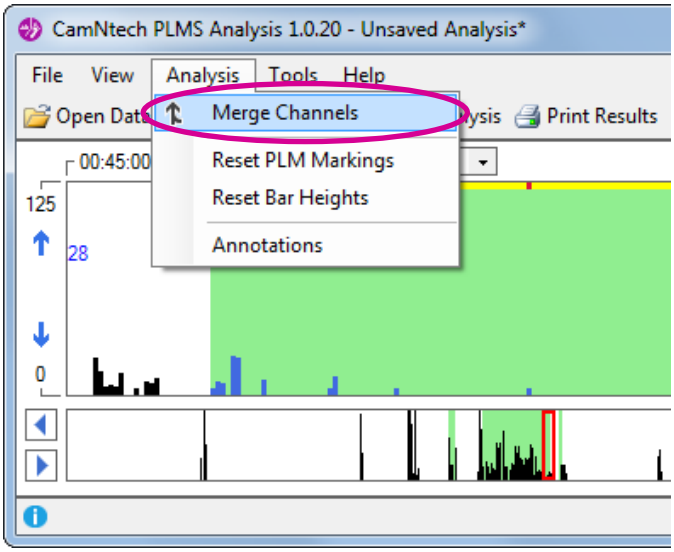
The factor of magnitude for data values is increased or decreased by clicking on the arrows at the left side of a channel's activity graph.



5.7 Merging Channels

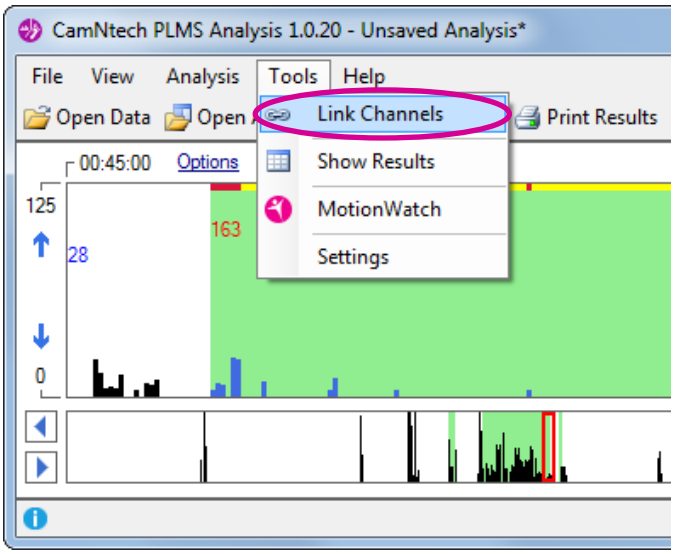
Multiple channels can be merged into a separate channel in order to create a unified view of a recording when more than one limb is monitored.

With two channels loaded, click on the **'Analysis'** menu, and click on the **'Merge Channels'** menu item. The application will automatically combine the data from both channels by comparing the data samples for each second and obtaining the value with the higher magnitude value. The application will then analyse this new channel to identify PLM bouts and will produce a new set of results. A new graph will appear at the bottom of the window to view the combined data.

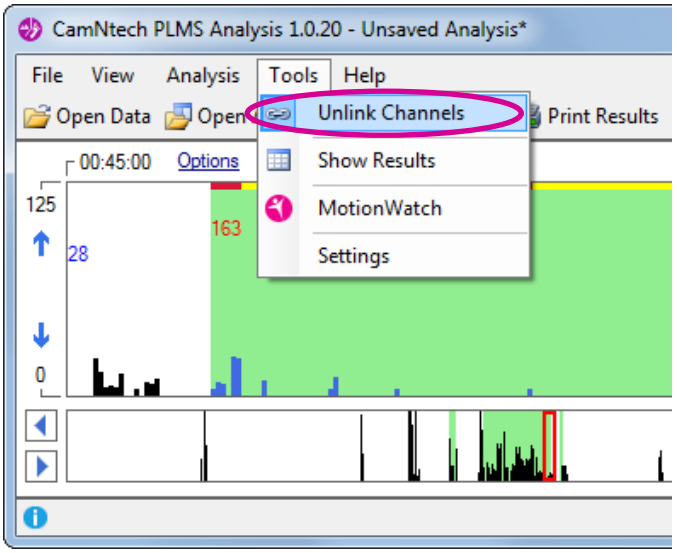


5.8 Linking Graphs

To synchronise channel scrolling, click on the **'Tools'** menu, and click on the **'Link Channels'** menu item.



To desynchronise channel scrolling, click on the **'Tools'** menu, and click on the **'Unlink Channels'** option.

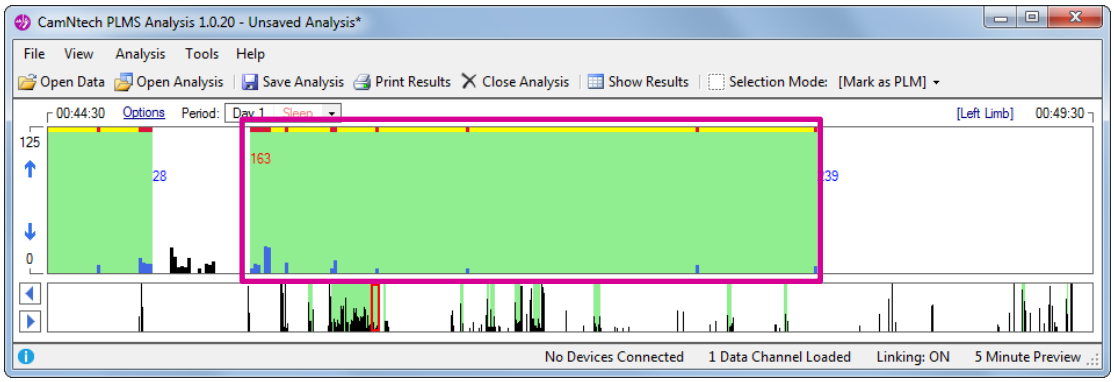


6 Analysing for PLM during Sleep

6.1 Automatic Analysis

The software will automatically analyse all recordings loaded, attempting to mark relevant sequences of limb movements in line with the common definitions for periodic limb movement.

The window below shows how this is illustrated when a short sequence of six movements has been marked as a PLM bout.



In this example, the bout is shown by the central shaded green region. It contains six movements, each of which are also highlighted by the short red burst at the top of the green shading. The movements before the bout were not marked as part of the bout as they were considered to be too continuous. The gap after the end of the bout was not marked as it was too large to be classified as PLM. A previous, not related, bout is also shown on the left of the displayed period.

Automatic Analysis Rules

Automatic analysis is carried out for movements which satisfy the criteria for diagnosis of Periodic Limb Movement Disorder in the International Classification of Sleep Disorders Diagnostic and Coding Manual, 3rd Edition (2014). These are applied to the movement data by the software, but results must then be considered alongside other observations by a practitioner before any diagnosis can be made.

In line with the ICSD Manual, but applied to actigraphy, parts of the recording are searched for which demonstrate repetitive, highly stereotyped, limb movements that are:

a. **0.5** to **10** seconds in duration*
b. In a sequence of **4** or more movements
c. Separated by an interval of more than **5** seconds (from limb-movement onset to limb-movement onset) and less than **90** seconds

(typically there is an interval of **20** to **40** seconds)

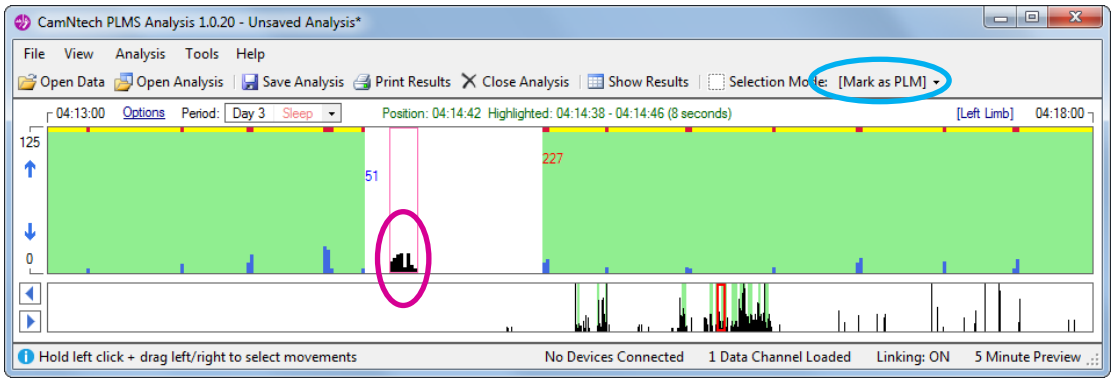
**The ICSDv2 threshold (0.5 to 5 seconds) can be optionally set in the program settings*

Combining Kicks

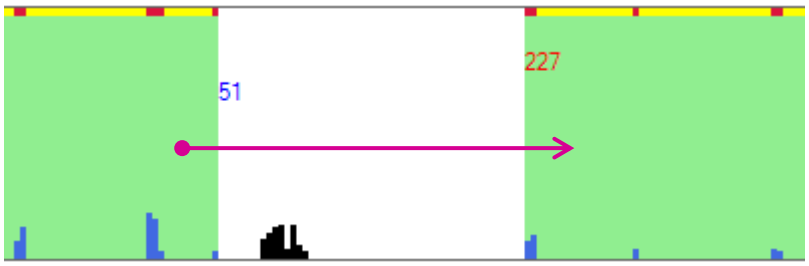
In addition to the PLM criteria above, movements which are separated by only a few seconds may be joined before consideration. A human performing analysis would normally make such an adjustment automatically where for example there are large gaps both before and after movements but a short movement on each limb separated by only a second. This setting may be changed in the software through the **'Tools'** menu, then **'Settings'** menu item and the **'Combine kicks…'** setting.

6.2 Manually Adjusting Movements / Bouts

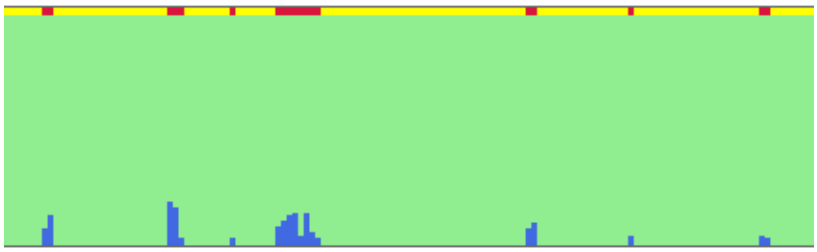
After automated analysis, all of the detailed classifications can be examined and if desired, manually adjusted to suit the opinion of the practitioner. All such adjustments will be taken into account in results statistics subsequently viewed. The example below illustrates how to make manual adjustments.



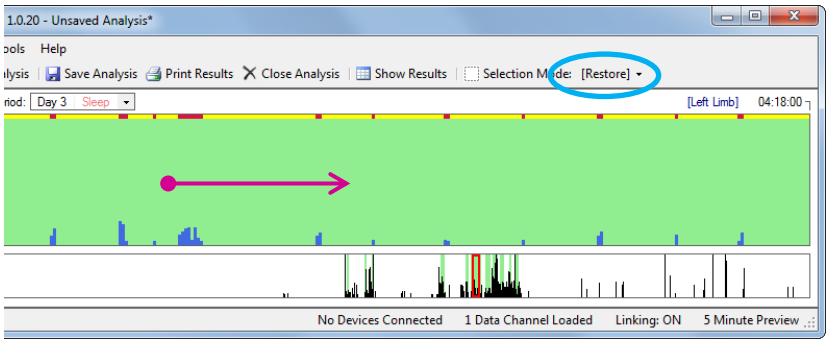
In this data, the movement circled in purple has been excluded from the following PLM bout because it is 8 seconds long, and thus doesn't follow the ICSD criteria above. But it can be added manually if desired. First, you must check in the blue circle above and use the drop-down menu to ensure that **[Mark as PLM]** is the selected tool. Then, use the mouse to drag across the time period as shown in the next image.



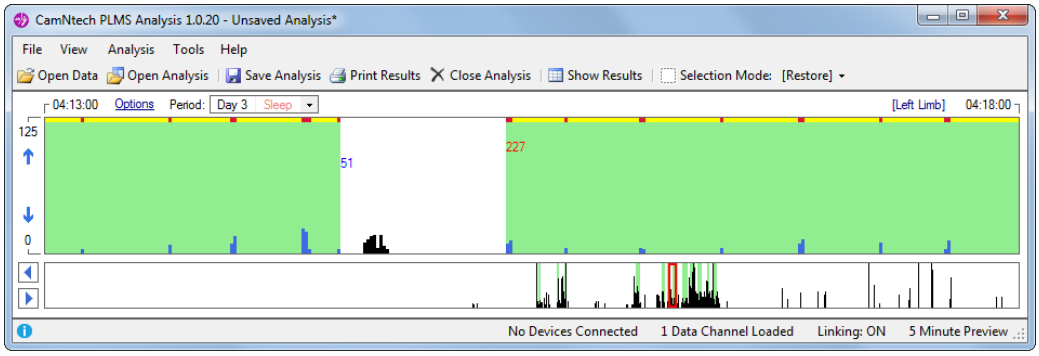
After dragging the mouse across this with the **[Mark as PLM]** tool selected, the new marked classification will look as below, showing the extra movement added into the following bout.

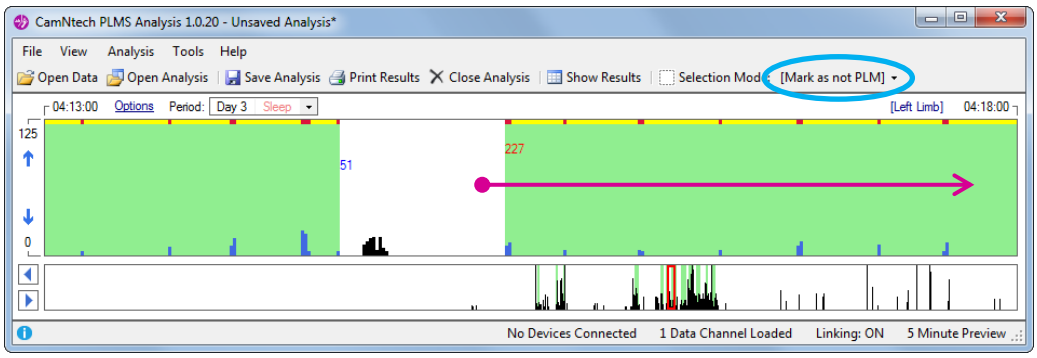


If subsequently you decide this was a mistake, return to the blue circle below and select the **[Restore]** function, before dragging across the pink arrowed period again. This will restore all of the original classification to that time period.

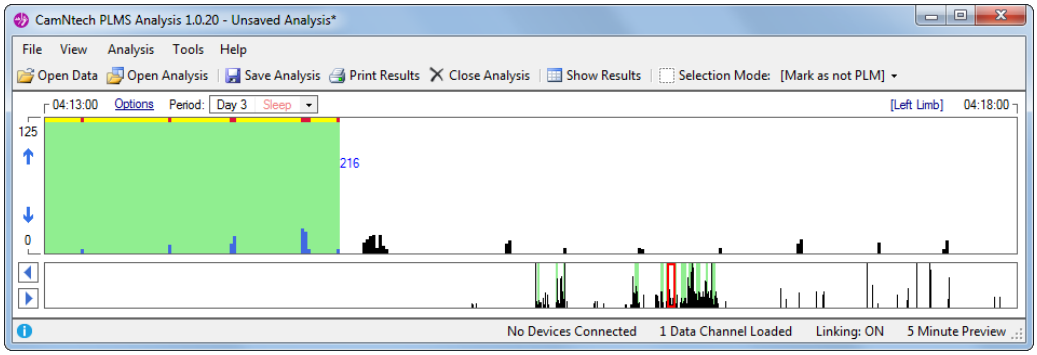


Finally, it is also possible to manually remove movements which have been labelled as PLM. Returning to the original classification period, the last movement of the prior bout was both longer and later than previous movements, so we wish to remove it. This time follow the blue circle to select the **[Mark as not PLM]** tool.





After selecting, drag the mouse across the movement for removal, as shown by the pink arrow. This will cause the green background of the previous PLM bout to recede to cover only up to the prior movement.

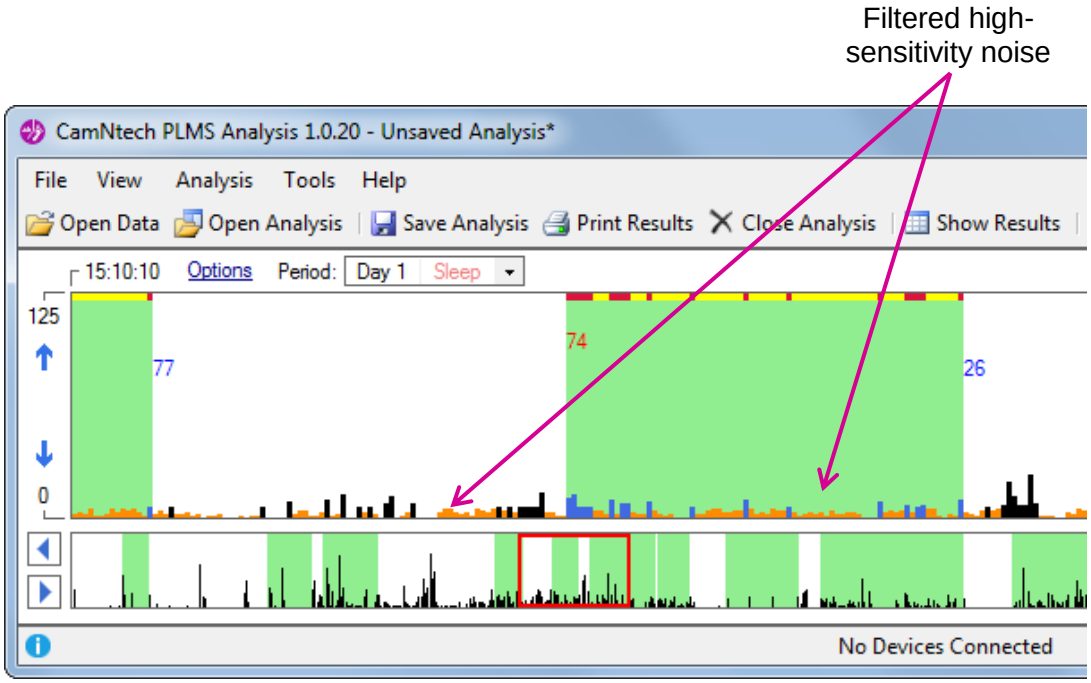


You can also restore the original classification here using the **[Restore]** tool as before. In addition to dragging across the movements, each of the tools can be used in a single-click mode, where the effect will be isolated to the clicked item.

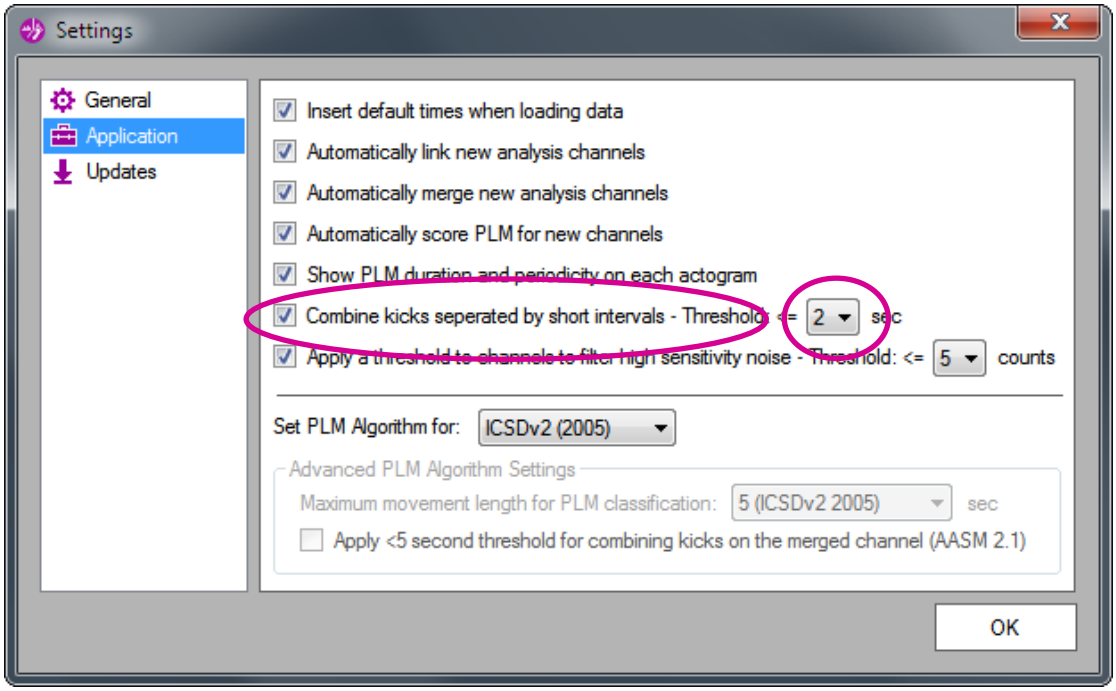
6.3 High Sensitivity Data

The software applies a high sensitivity setting when setting up a MotionWatch which provides greater accuracy for detecting PLM. This can introduce additional low-level noise, and so it is necessary to apply a filter to recording data to remove unwanted noise.

By default, the software will filter any samples below 5 counts, and thus will be ignored by the data analysis function. The filtered samples will be drawn in orange as a reference.



This setting can be overridden* either by disabling the function entirely, or by setting the filter count threshold. To change these settings, open the program settings by clicking on the '**Tools'** menu, followed by the **'Settings'** menu item. To disable the noise filter, click on the **'Apply a threshold to channels to filter high sensitivity noise'** option/checkbox to disable the option. The noise threshold can be set by clicking on the dropdown box for **'Threshold: <='**.

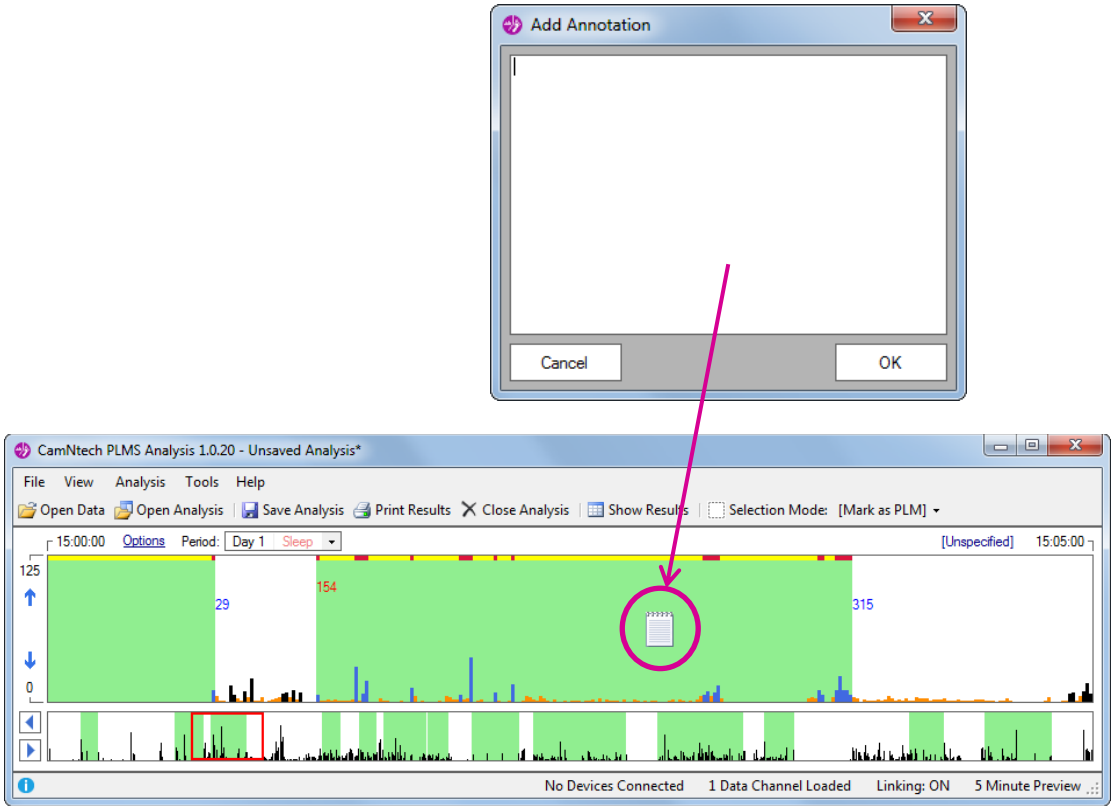


** PLM markings may be reset*

6.4 Adding User Annotations

The application allows annotations to be placed anywhere on a graph. These annotations are saved when the analysis is saved which allows them to be viewed by other users at a later date.

To add an annotation, point the mouse cursor anywhere over a graph, then hold down the **Ctrl** key on the keyboard and click the left mouse button. In the dialog box which appears, enter any text remarks and press the **'OK'** button to save the annotation. A notepad icon will be placed onto the graph where the mouse cursor was pointing.



To open a previously created annotation, point the mouse cursor over the notepad icon, hold down the **Ctrl** key on the keyboard and click the left mouse button. The annotation can be updated by making any changes to the text field and clicking the **'OK'** button.

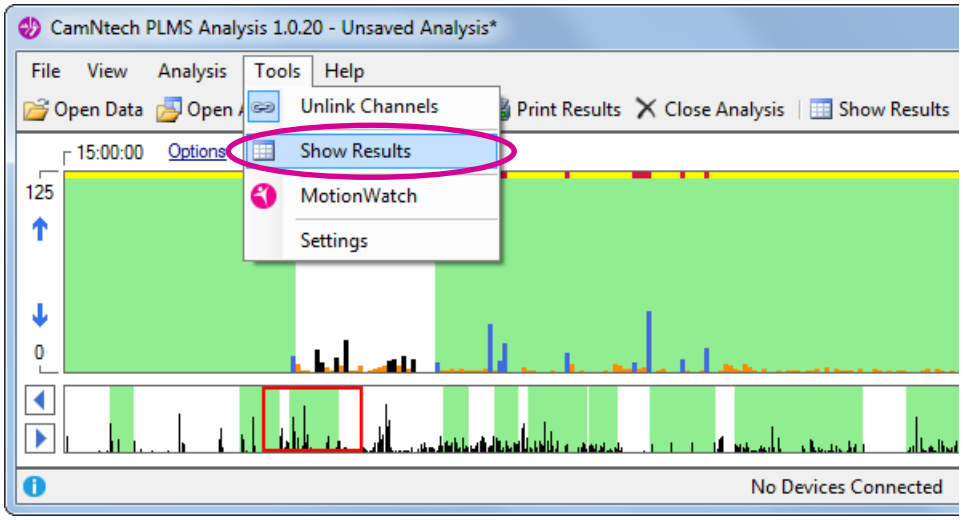
To delete an annotation, point the mouse cursor over it, hold down the **Ctrl** key and click the left mouse button. Click on the **'Delete'** button to remove it. The notepad icon will disappear.

7 Using Your Results

7.1 Viewing Summarised Results

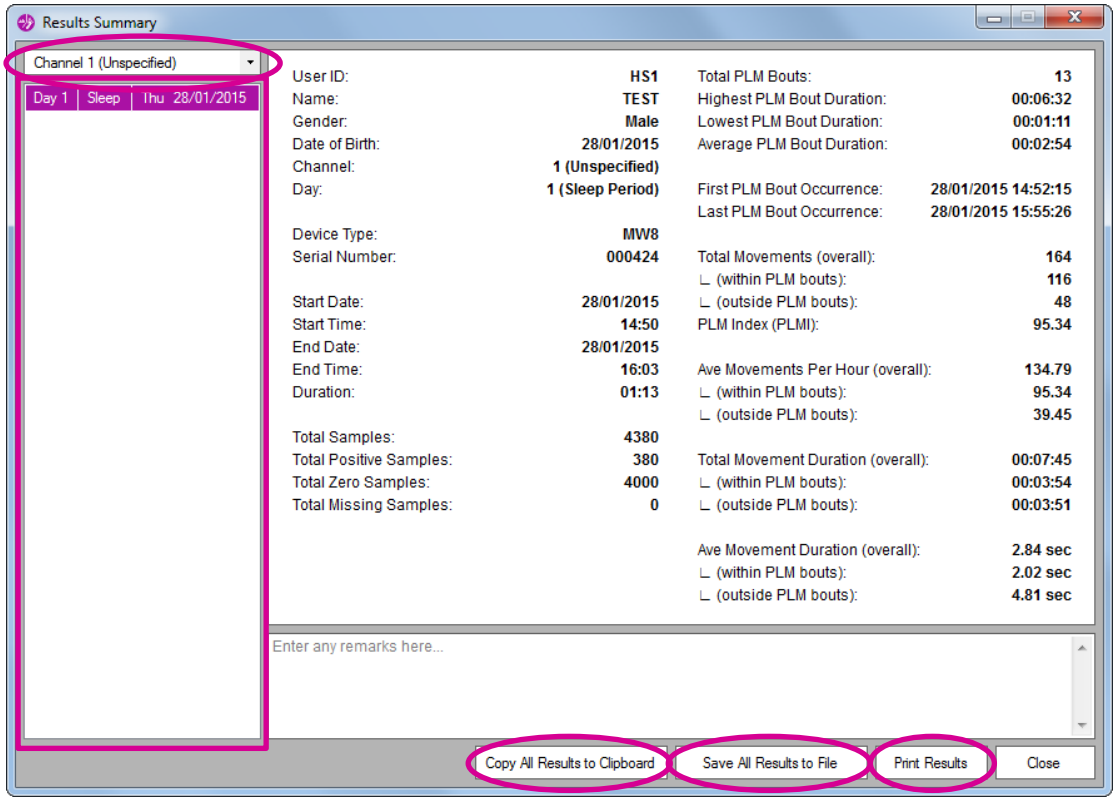
The application automatically produces an on-screen summary report which contains scores, results and statistics for each day in a channel, across each channel in an analysis (including a merged channel).

The summary can be viewed by clicking on the **'Tools'** menu and clicking on the **'Show Results'** menu item.



The summary for the first available channel and day will be shown automatically. Each channel can be selected by selecting the appropriate entry in the drop-down box located at the top-left of the summary window.

Periods (Sleep/Wake) can then be selected from the list below the channel select drop down.



The results summary window allows users to enter custom text into the text box at the bottom of the form. Any text which is entered is saved when the window is closed.

Result Measures

The table of summary results includes a large number of summary measures; these are defined in the list below.

Channel: Left or Right limb
Day: Day number in the recording
Device Type: MW8, the recording device used
Serial No.: The serial number of the recording device, in case any fault must be traced
Start Date: Of the selected night
Start Time: Of the selected night
End Date: Of the selected night data
End Time: Of the selected night data
Duration: Of the selected night
Total Samples: Number of 1-second epochs in the night period
Total Positive Samples: Number of epochs with activity data ≥1
Total Zero Samples: Number of epochs with zero activity
Total Missing Samples: Number of epochs marked as missing data in recording
Total PLM Bouts: The number of contiguous periods classified as PLM during the night
Highest PLM Bout Duration: The length, in hours, minutes and seconds, of the longest continuous PLM bout

Lowest PLM Bout Duration: The length, in hours, minutes and seconds of the shortest PLM bout
Average PLM Bout Duration: The total of all PLM bout lengths divided by the number; again in hours, minutes and seconds
First PLM Bout Occurrence: Date and time of the start of the first PLM bout
Last PLM Bout Occurrence: Date and time of the start of the last PLMS bout
Total Movements (overall): The number of isolated periods of activity, subject to the current setting for combining kicks with a short gap
∟ **(within PLM bouts):** The number of isolated movements which occurred within time classified as a PLM bout
∟ **(outside PLM bouts):** The number of isolated movements which occurred outside time classified as a PLM bout
PLM Index (PLMI): The number of movements within PLM divided by the length of the night period in hours
Ave Movements Per Hour (overall): Total movement count divided by the length of the night period in hours
∟ **(within PLM bouts):** Total movements within PLM divided by the length of the night period
∟ **(outside PLM bouts):** Total movements outside PLM divided by the length of the night period
Total Movement Duration (overall): Total time of all isolated movements, in hours, minutes and seconds
∟ **(within PLM bouts):** Total time of isolated movements, within periods classified as PLM bouts
∟ **(outside PLM bouts):** Total time of isolated movements, outside periods classified as PLM bouts
Ave Movement Duration (overall): Average length of all movements (PLM or non-PLM), in seconds
∟ **(within PLM bouts):** Average length of all movements within time classified as PLM, in seconds
∟ **(outside PLM bouts):** Average length of all movements not within time classified as PLM, in seconds

Copy All Results to Clipboard

Clicking this button will copy the results for all days in all channels to the clipboard. These can then be pasted into an external application such as a word processor.

Save All Results to File

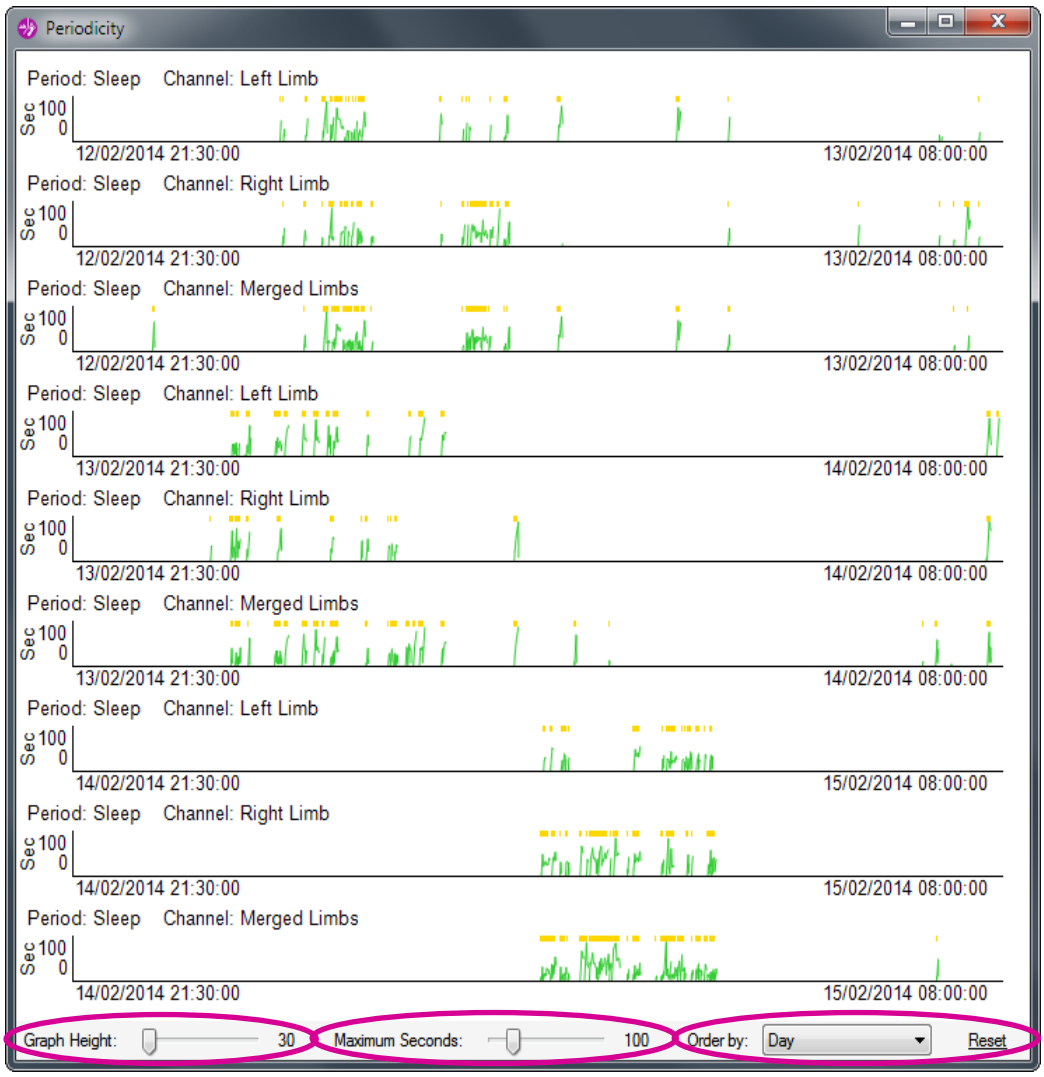
Clicking this button will allow you to save the results for all days across all channels to a text file for external use or storage.

Print Results

Clicking this button will open the report preview for the analysis which can be used to preview and print a physical copy of the analysis (detailed in the next section).

7.2 Viewing Periodicity

The periodicity window allows you to compare the duration and frequency of periodic leg movements in a recording. This window can be opened by clicking the **'Tools'** menu, followed by the **'Periodicity'** menu item.



The green elements represent the duration in seconds of PLMs and the yellow elements show the duration of PLMs laterally. A graph is shown for each day in each channel.

There are two ordering modes: **Day** and **Channel**. The **Day** mode displays each channel in order of date. The **Channel** mode will display each day within each channel in channel order. The display order can be changed by clicking the '**Order by:'** drop down and the clicking either the **Day** or **Channel** options.

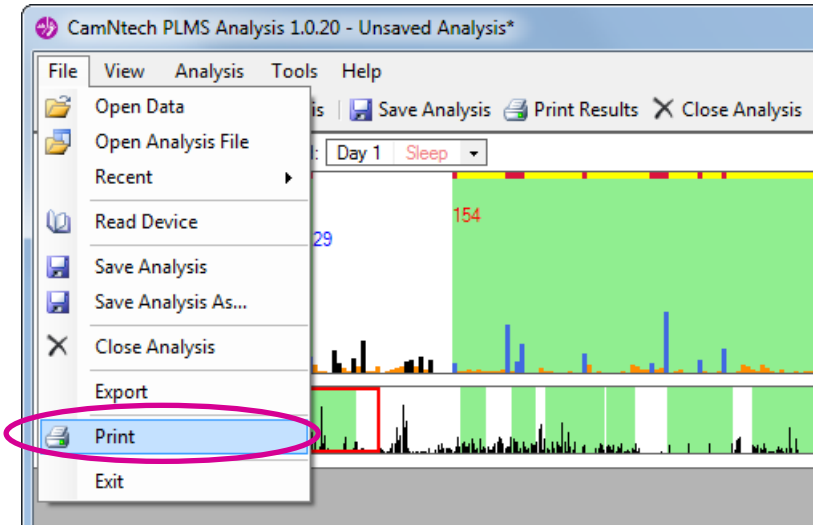
The height of the graphs can be changed by dragging the **'Graph Height:'** slider left or right. The amount of vertical seconds to display can be changed by dragging the **'Maximum Seconds:'** slider left or right.

The periodicity settings can be reset by clicking the **'Reset'** button.

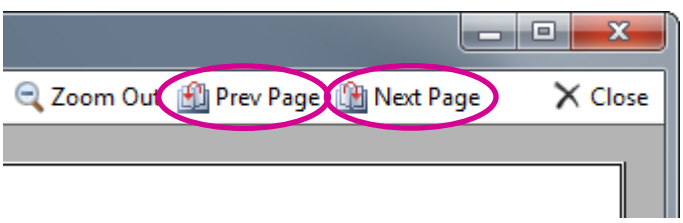
7.3 Printing the Analysis

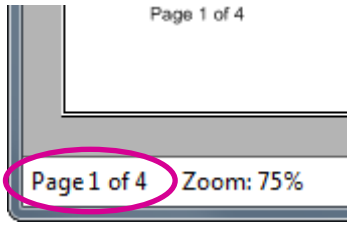
The application provides printing functions to produce physical copies of the analysis graphs and results. The analysis can be previewed and customised prior to being sent to the printer.

To preview a printed report, ensure at least one channel is set up and click the **'File'** menu, then click the **'Print'** menu item. The report preview window will then be displayed as shown below:

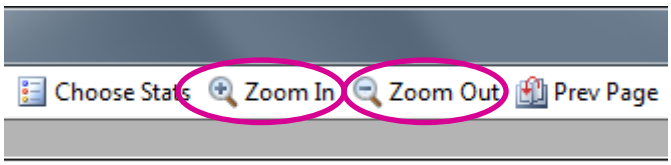


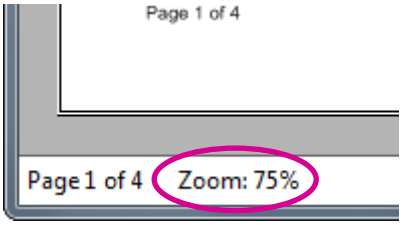
Reports can be browsed by clicking the **'Prev Page'** and **'Next Page'** buttons located on the top toolbar. This will move to the previous or next pages in the report. The current page number is shown in the bottom status strip.



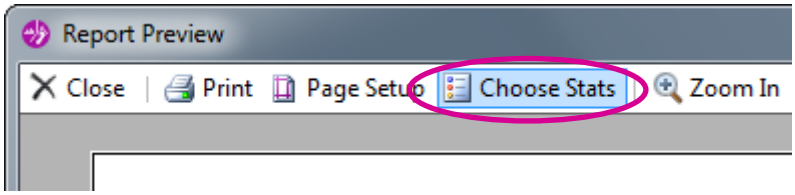


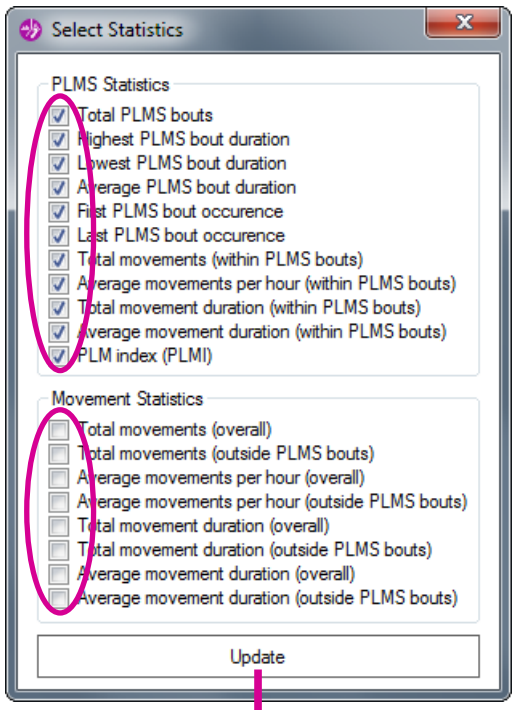
The preview can be zoomed to provide better readability of the report contents. This can be done by clicking the **'Zoom In'** and **'Zoom Out'** buttons located on the top toolbar. The current zoom level is also shown in the bottom status strip.

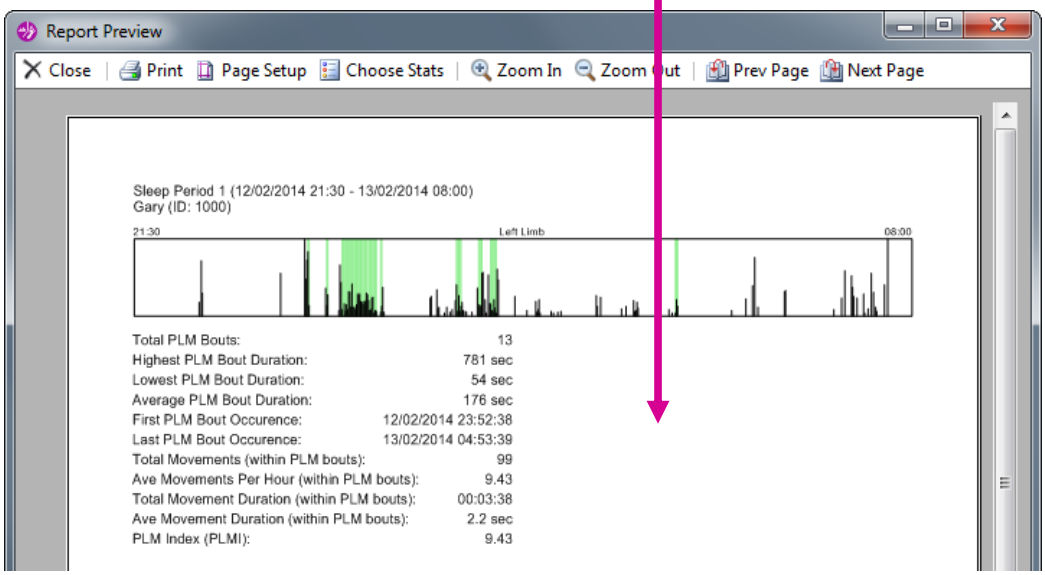

Choose Stats
Zoom In
Zoom Out
Prev Page


Page 1 of 4
Page 1 of 4
Zoom: 75%

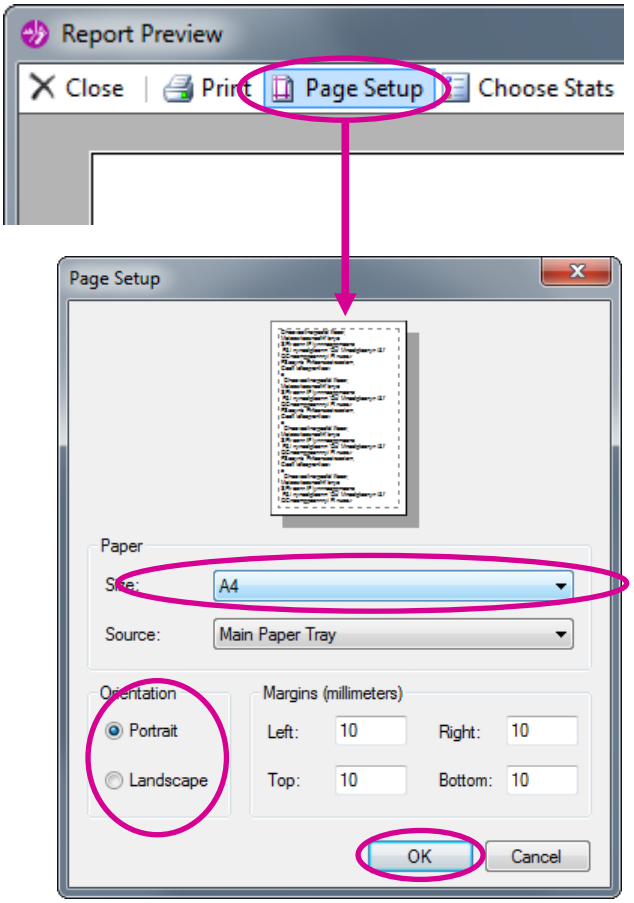
To customise which results/statistics are shown on the printed report, click on the **'Choose Stats'** button located on the top toolbar to open the 'Select Statistics' dialog. Options which are checked will be shown on the report, whereas options which are unchecked will be absent from the report. Click on an option to enable or disable it and then click the **'Update'** button at the bottom of the window. This will cause the report to be recreated.



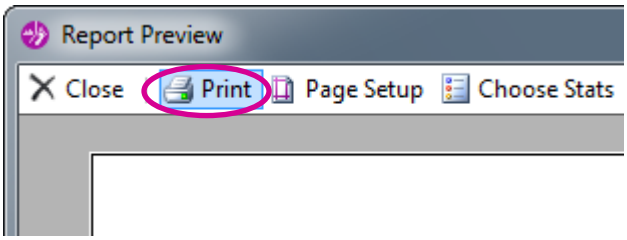


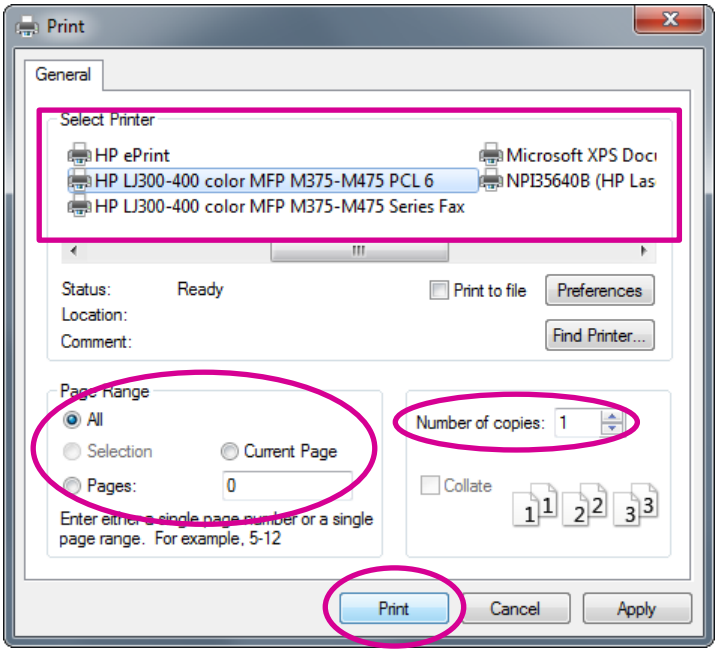


To change the page size for the report, click on the **'Page Setup'** button located on the top toolbar. Paper size can be changed by clicking on the **'Size'** drop down menu and selecting a new size. Printing orientation can be changed by clicking the **'Portrait'** or **'Landscape'** options. Click on the **'OK'** button to save the changes.



To print the report, click on the **'Print'** button located on the top toolbar. To select a printer, click on one of the printer entries in the **'Select Printer'** box. To customise which pages are printed, click on the **'Current Page'** option, or enter specific page numbers into the **'Pages'** text box. The number of copies to print can be set by entering a number in the **'Number of Copies'** box. Click on the **'Print'** button to send the report to the printer.





7.4 Saving the Analysis

After one or more recordings have been analysed, the analysis can be saved to a single file for later use. This allows the recordings to be quickly restored without having to set them up again. Manual PLM adjustments and user notes and remarks are also saved.

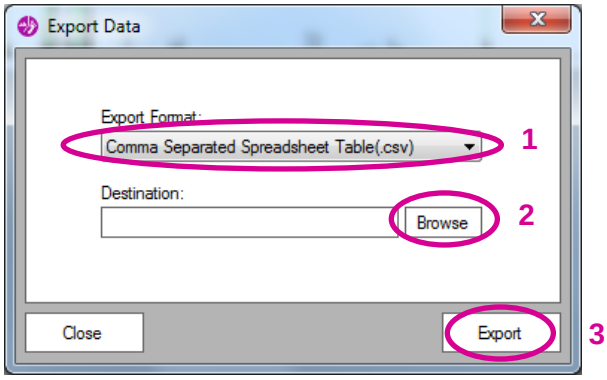
To save, click on the **'File'** menu and then click on the **'Save Analysis'** menu item. The application will prompt you to save a file with the extension '.pax' which captures all of the details above.

To reload a saved analysis file, click on the **'File'** menu, followed by the **'Open Analysis File'** menu item. Note that all loaded recordings and analysis results will be discarded to reload a previous analysis.

7.5 Exporting Results Data

Raw Classification Results

The detailed epoch-by-epoch analysis results can be exported from the software through the **'File'** menu followed by then **'Export'** menu item. The 'Export Data' window below will be produced:

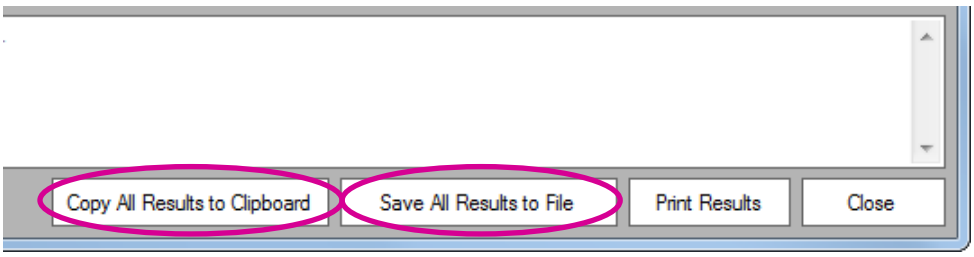


Firstly, select the intended output format. Both options create a plain text format file, but with slightly different formatting:

- **Plain Text Document** creates a text format file which can be opened and viewed directly in a text editor. The output is spaced such that the table content will appear correctly.
- **Comma Separated Spreadsheet** creates a text format file which can be opened directly by most spreadsheet programs, such as Excel. The values will be placed into the cells of the spreadsheet.

Summary Result Measures

In addition to the raw classification data above, the summary statistics can also be exported from the results table described previously. To do so, re-open the results window as shown below, and select one of the export options highlighted.



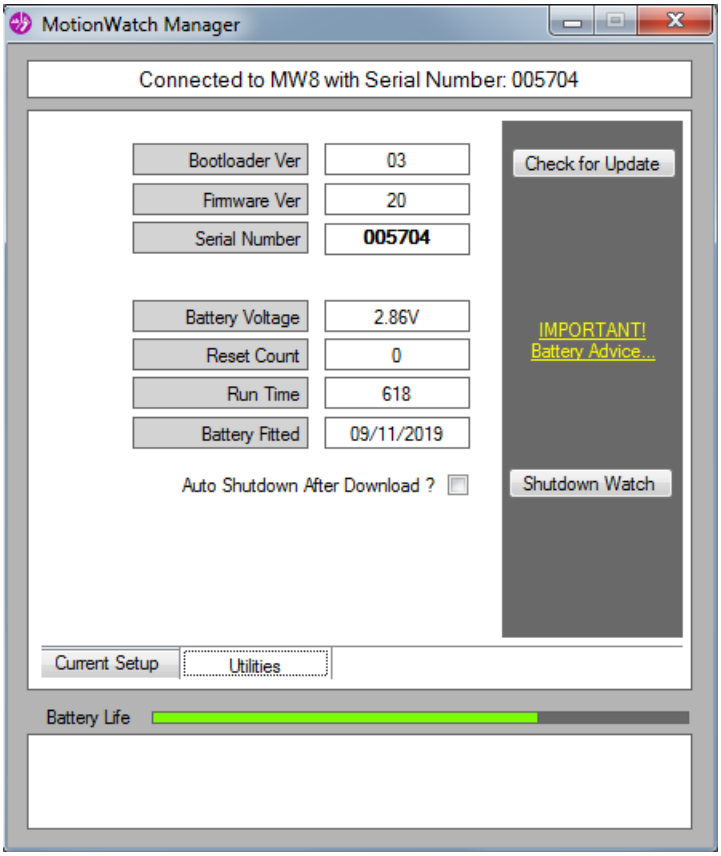
After clicking on **'Copy All Results to Clipboard'**, you should open a spreadsheet program and use the **paste** function to place the result measures there. Note that you may need to scroll down to see the table of results from each night of the recording.

The **'Save All Results to File'** option exports in the same format but directly to a text file, allowing it to be opened in a text editor or directly processed by scripts as needed.

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:** hours of run time since last battery change – should reset to zero when a new battery is fitted.
- **Battery Fitted:** 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

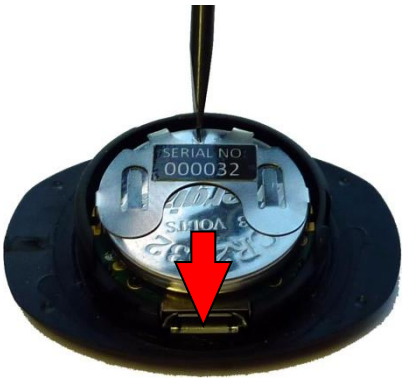
The MotionWatch has a low power shutdown function which will help maximise the life of the battery. In the utilities windows, there are two options as follows:

- **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.

- The change the battery, open the MW8 casing as described in Section 1.1 An Overview of the MotionWatch for PLMS System 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** then place a fresh CR2032 battery into the holder (ensuring correct orientation!) and push back until fully home.

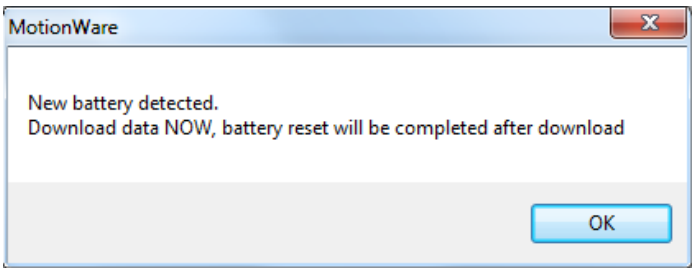
Note: Data will NOT be lost by removal of the battery.

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.

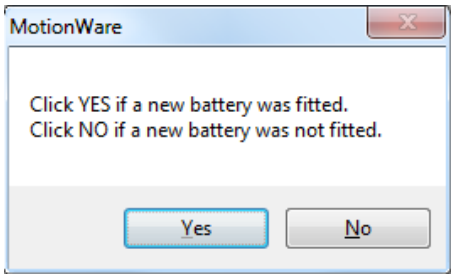
This sequence is **critical** to the correct watch operation – if the LED does not flash, remove the battery and repeat the process.

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).

A6 - MotionWatch Strap

The PLMS foot mounting strap is supplied with a spare lower watch casing to facilitate use of the MotionWatch without the need to remove the wrist strap. Note that the MotionWatch will not be waterproof when fitted the the PLMS 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.

Appendix B – FAQ & Troubleshooting

What limits the memory size?

Availability of the correct type of memory chips is the main limitation. The technology used is reliable, low power and does not require protracted erase cycles. The MotionWatch uses the maximum amount of this type of memory that will physically fit within the device.

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.

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.**

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.

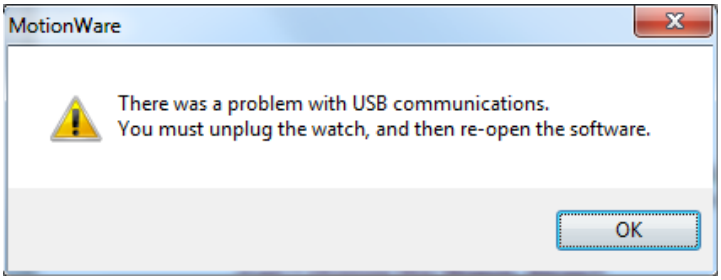
Can I change the Watch Strap?

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:



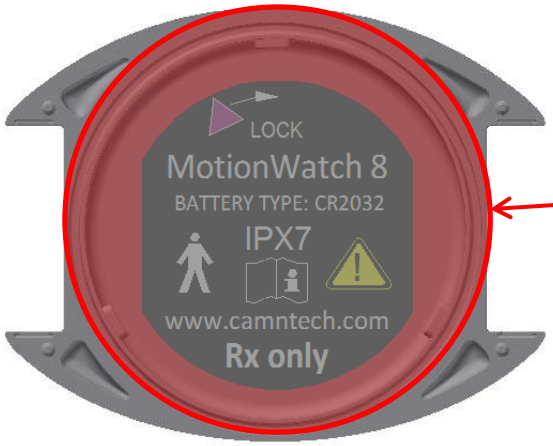
In this case, click ‘OK’ then disconnect the MotionWatch from the USB. Re-run the software, re-connect the watch and re-apply the set-up.

Appendix C – Safety & Environmental Information

C1 - Decontamination

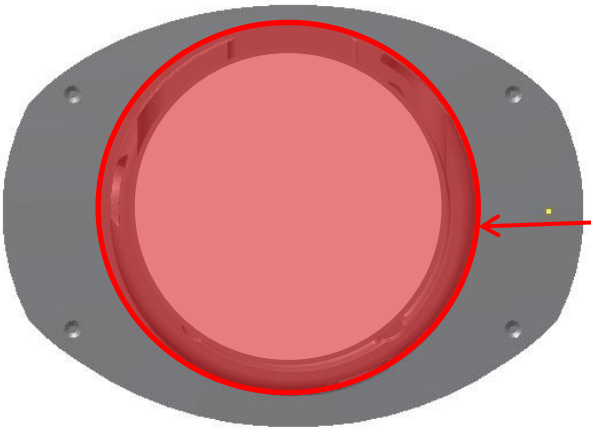
- All used devices must be considered to be contaminated with surface borne bacteria and must hence be de-contaminated before re-use using a suitable disinfection and cleaning procedure.
- Care must be taken to use the correct de-contamination procedure and cleaning materials because long term exposure 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).

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 (see Appendix A4 for further information).
- The battery must be replaced observing the correct procedure to prevent possible data loss (see Appendix A4 for further information).
- 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 2012/19/EU that manufacturers and/or distributors of Electronic and/or Electrical Equipment manage and pay for the collection and further handling of WEEE products, as well as provide WEEE-related information to their customers. CamNtech has taken the following approach to complying with this Directive:

- CamNtech has registered with an approved producer compliance scheme (PCS) in accordance with the requirements of the WEEE Directive.
- CamNtech will provide free recycling for all of its WEEE products when returned to CamNtech.
- 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 (EM) compatibility of the MotionWatch devices.

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 professional healthcare and home healthcare environments. The MotionWatch has not been tested for use in the following special environments: Military areas. Heavy Industrial Areas. Medical treatment areas with high powered ME equipment. Inside the shielded room of an MRI system.
Harmonic Emissions EN61000-3-2	Not Applicable	
Voltage Fluctuations / flicker emissions EN61000-3-3	Not Applicable	

Essential Performance

In severe cases of EM disturbance, the MotionWatch may be reset and may require intervention within the software to restart. Recorded data will not be affected. Patient safety is not affected.

Adjacent Equipment

The MotionWatch normal mode of operation is typically well spaced from other devices or equipment. The device should not be operated close to potential sources of EM disturbance (e.g. a mobile phone).

Connecting Cables

The MotionWatch is supplied with a Micro USB cable of length 1.8m. Cables exceeding 1.8m are not recommended and cables exceeding 3m are prohibited. WARNING: Use of cables and/or accessories other than those specified by CamNtech may result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.

Use adjacent to Portable RF Communications equipment

WARNING: Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations and walkie-talkies should be used no closer than 30 cm (12 inches) to any part of the MotionWatch, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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**
Radiated Field Immunity	IEC61000-4-3 IEC61000-4-3	10 V/m 80-2700 MHz 1 kHz 80% am 9-28 V/m 385-6000 MH pulse mode	The MotionWatch is suitable for use in professional healthcare and home healthcare environments.
Electrostatic Discharge (ESD) IEC 61000-4-2	IEC 61000-4-2 IEC 61000-4-2	+/-8kV Contact +/-15kV Air	

The MotionWatch is not mains powered hence no ac power line tests are applicable.

Appendix D – Technical Specifications

Specifications

Functional Specifications	
Size mm:	36(l) x 28.2(w) x 9.4(d) excluding strap
Weight:	9.1 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:	Yes – with visual feedback
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
Light Sensor	
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

Operating & Storage Conditions

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

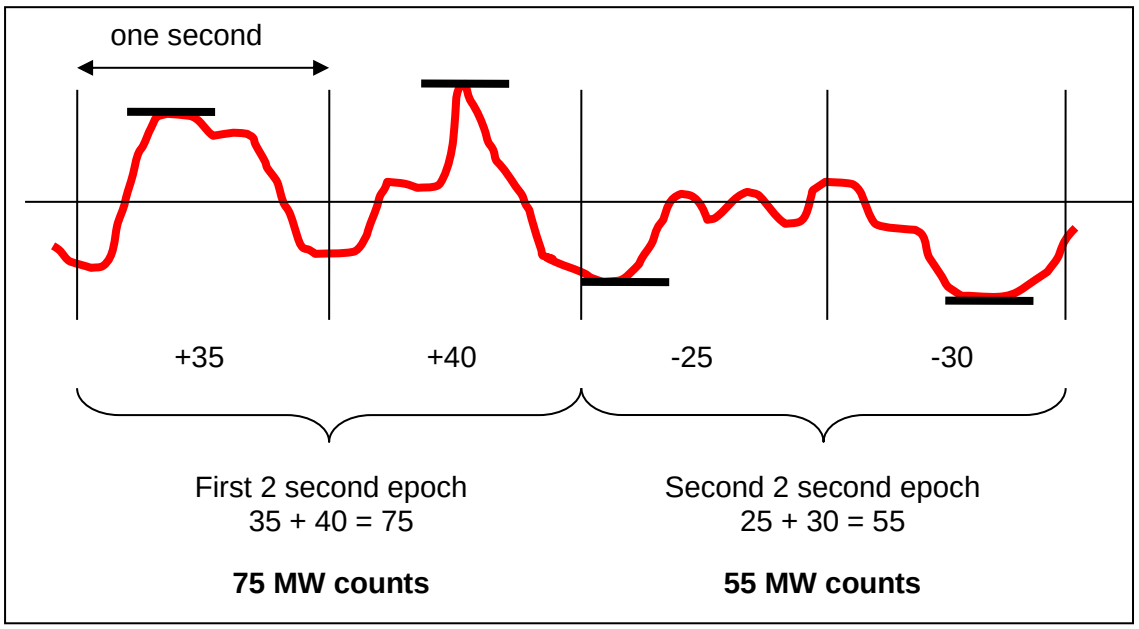
	Operating	Storage
Temperature	+5°C to + 40°C	-25°C to +70°C
Relative Humidity	0 to 93%	0 to 93%
Atmospheric Pressure	70kPa to 106kPa	70kPa to 106kPa

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. 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.



Document Revision History

Issue From	Issue To	Date	Description	Initiator
0.0	0.9	28/04/14	First draft	DW
0.9	1.0	10/11/14	Updated ready for release	TE
1.0	1.0.1	21/11/14	Updated screenshots, additional context	DW
1.0.1	1.0.2	05/06/15	Updated references of ICSD to version 3 (2014) Added body mounting context	DW
1.0.2	1.0.3	29/06/15	Added updated settings screenshots and context for ICSDv2/AASM 2.1 configurations	DW
1.0.3	1.0.4	11/07/16	Added main window overview page	DW
1.0.4	1.0.5	12/07/16	Updated document with screenshots from a recent build.	DW
1.0.5	1.0.21	03/04/17	New settings layout. Changed version to match software version.	DW
1.0.21	1.0.22	19/06/17	Added periodicity information.	DW
1.0.22	1.0.23	31/12/19	Updated Device Manager screen shots, updated for MDR, new CamNtech address, EMC guidance, software installation, Win 7	HS