The MotionWatch User Guide

Applicable to MotionWatch 8,

MotionWatch R (Wrist),

MotionWatch R (Loop)

Document Reference: 30147
Version: 1.4.14
Date of current version: 12/06/2023

Covering the following product variants:

MotionWatch 8	04-111	A compact and light-weight wrist or body worn Actigraphy and light sensor.
MotionWatch R (Wrist)	04-121	Ruggedized wrist-worn version of the MotionWatch 8 primarily intended for use in harsh environments.
MotionWatch R (Loop)	04-125	Ruggedized version of the MotionWatch 8 primarily intended for veterinary applications.

All variants hereafter referred to as 'MotionWatch' for simplicity

$C\,\epsilon$

The MotionWatch is a Class I Medical Device (EU)

Please consult MotionWare Software User Guide ref 30238 for details of software installation, and data analysis.

IMPORTANT SAFETY INFORMATION
1.1 WARNINGS

- **Coin cell battery** – potential **swallowing hazard** for small children! See battery advice below.
- Not defibrillation proof.
- Not indicated for use on areas of broken or irritated skin. The MotionWatch Rugged metal casing contains nickel.
- Devices removed from subjects must be considered to be contaminated – see Appendix A.

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	ℹ	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 1 meter depth). Do NOT use in salt water.
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**.
Medical Device	MD	The MotionWatch is a Medical Device. Medical Device Regulation 2017/745.

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 Section 4**.**

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.**

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

Button Battery Warning

⚠ WARNING
THIS PRODUCT CONTAINS A BUTTON BATTERY

If swallowed, a lithium button battery can cause severe or fatal injuries within 2 hours.
Keep batteries out of reach of children.
If you think batteries may have been swallowed or placed inside any part of the body, seek immediate medical attention.

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 around young children and seek assistance from CamNtech.

FOR FURTHER HANDLING, ENVIRONMENTAL & REGULATORY INFORMATION PLEASE REFER TO THE APPENDICES

CONTENTS

1 Getting Started with the MotionWatch

1.1 Introduction to MotionWatch

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 B for technical and operational specifications.

Components Required for a System

A MotionWatch system consists of two elements:

- One or more MotionWatch devices.
- PC or Mac based MotionWare Software (See MotionWare User Guide).

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

The MotionWatch 8

Light sensor Event Marker Button

Status LED

Event Marker:	The MotionWatch 8 has a front-panel button that may be pressed by the subject to mark specific events. Typically 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 LED:	Provides visual feedback by flashing when the event marker is pressed. Also used to indicate USB connection and during the battery replacement process.

The MotionWatch 8 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 8 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 – no user intervention is required.

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.
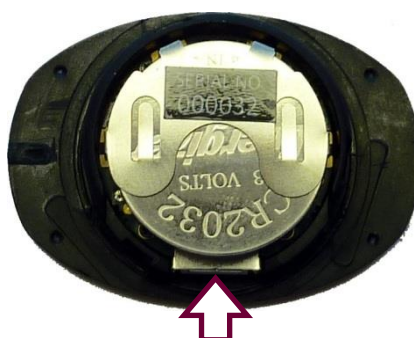
WARNING!
Do not attempt to force open/closed the MotionWatch 8 casing without twisting to unlock/lock. doing so will damage the casing and invalidate the warranty!

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.

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.
CamNtech recommends that ONLY the provided screwdriver (part number C92-0013) is used for this purpose:

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).

Electronics Module

O-ring seal
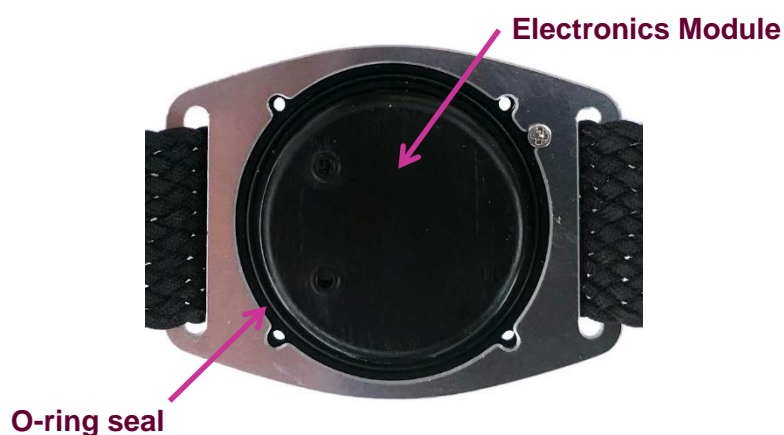
Now simply lift out the electronics module to reveal the USB connector and the battery:

USB Connector

When the MotionWatch is connected for the first time, the USB drivers will automatically be installed – no user intervention is required.

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:

Features on the plastic fit into the recesses inside the lid

Alignment screw fits into the recess on the lid

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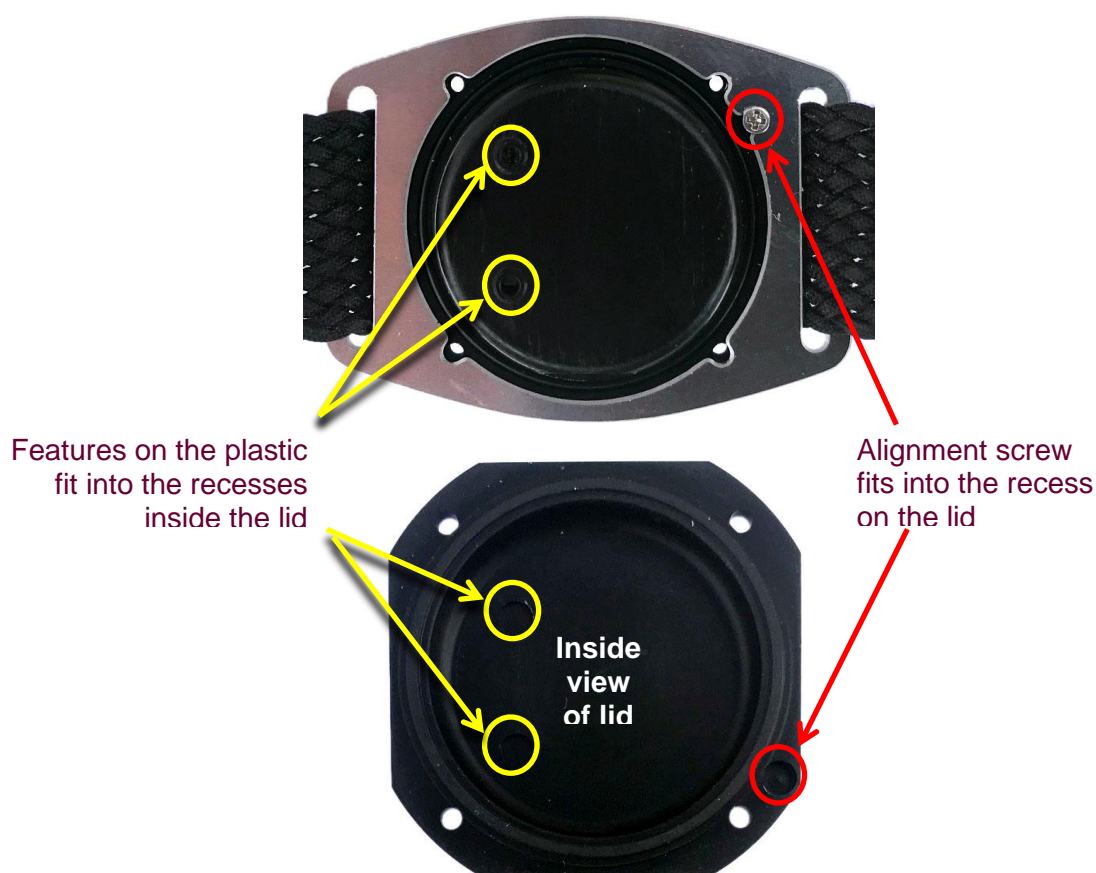
With the internal features correctly aligned, gently press the lid down; it will fit with a positive click and be aligned flush with the lower casing if the alignment is correct.
Finally re-insert the four Philips head screws and tighten down gently – use only the supplied screwdriver, and do not over-tighten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

1.3 Install MotionWare Software

The MotionWatch uses MotionWare software to configure, download, analyse and manage the devices. Please refer to the MotionWare Software User Guide for full details of MotionWare software installation and use.

---

2 Using The MotionWatch

2.1 MotionWatch Manager

Having installed the software (see MotionWare User Guide), open the MotionWare Software then connect a MotionWatch to the USB cable; 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 FUNCTIONS:

Setup Watch: click to start a new MotionWatch setup (Section 2.2)

Read Data: click to download the data from the MotionWatch (Section 3.1)

Exit: Close the MotionWatch Manager window.

UTILITIES TAB

Click to view/edit maintenance functions (Section 4)

MotionWatch Manager — Connected to MW8 with Serial Number: 000004

User/Patient ID	Howard
Full Name	
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)
Status	

Setup Watch   Read Data   Exit

Current Setup   Utilities

Battery Life

The MotionWatch Manager window has two main functions for normal use:

Setup Watch	This allows you to reconfigure the device for a new recording, choosing recording mode, epoch, light recording, and other settings.
Read Data	This will download the data collected by the device, along with the option to save that data for analysis.

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.

2.2 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).

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

Immediate or Delayed Start

Select 'Immediate Start' to ensure that the MotionWatch begins recording straight away. The start date and time are taken from your computer 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 recording and processing, only post-recording physical activity analysis. It can be changed after a recording is changed if necessary, using the physical activity analysis function, but is better noted at the time of setting up

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 and 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.

Recording Lengths

The MotionWatch calculates and displays the expected recording length as the settings are changed. The recording mode, epoch, light settings and compression will all affect the maximum recording length. The following table provides the recording lengths for MotionWatch Mode 1 recording:

Epoch (Seconds)	Activity Only (days)	Activity & Light (days)	Activity Compressed*
1	3	1.5	6
2	6	3	12
5	15	8	30
15	45	23	90
30	91	46	91
60	91	91	91

*see below for details of data compression

Note that the maximum recording time is limited to 91 days (MW Mode) and 60 days (Tri-axial mode) due to battery life.

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% 54 to 91 days (MW Mode)
36 to 60 days (Tri Mode)

Yellow 40% to 59% 36 to 53 days (MW Mode)
24 to 35 days (Tri Mode)

Orange 20% to 39% 18 to 35 days (MW Mode)
12 to 23 days (Tri Mode)

Red 0% to 19% 0 to 17 days (MW Mode)
0 to 11 days (Tri Mode)

WARNING! - Battery life is below 15%

When the battery life falls below 15%, the software will warn the user to try and avoid potential loss of data.

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

If set-up is attempted with a short battery life, an additional warning message will be displayed.

Battery Life

The MotionWatch uses a standard, non-rechargeable CR2032 coin cell which is easily replaced by the user (see Section 4). 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 90 Days (MotionWatch Mode) or 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 Section 4.

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 are 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, where there is no marker button available.

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 Physical Activity Recording

The recommended settings for physical activity / 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. This may be modified after data download (within the physical activity analysis function).

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 Section 5.

---

3 Downloading Data

3.1 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…
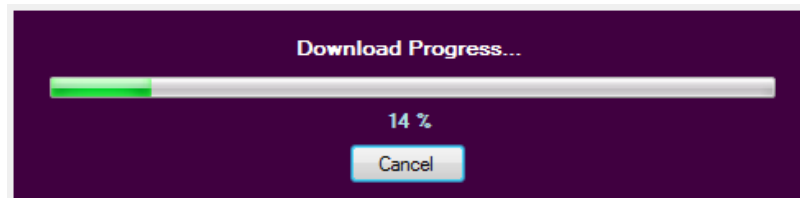

If the data download is not required, click the cancel button and the operation will be aborted.

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.

3.2 Saving MotionWatch Data

Upon completion of the download, the 'Save Recording…' dialog will open automatically to allow the data to be saved.
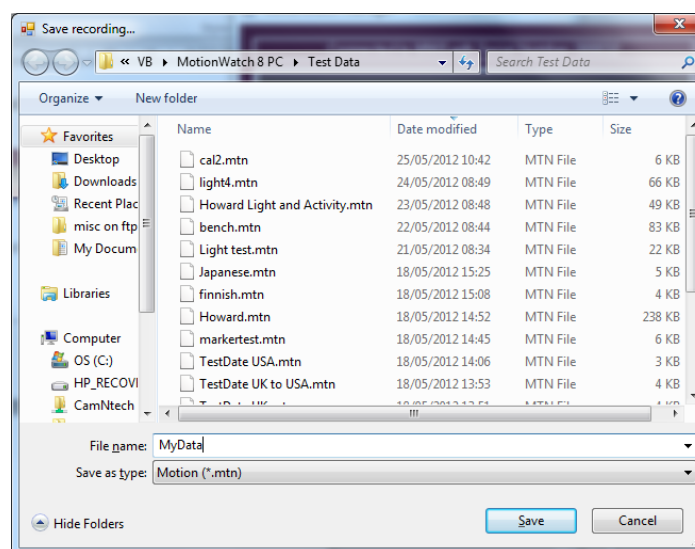
IMPORTANT! – ALWAYS MAKE REGULAR BACKUPS OF YOUR DATA

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 are not required.

3.3 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 Section 4).

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.
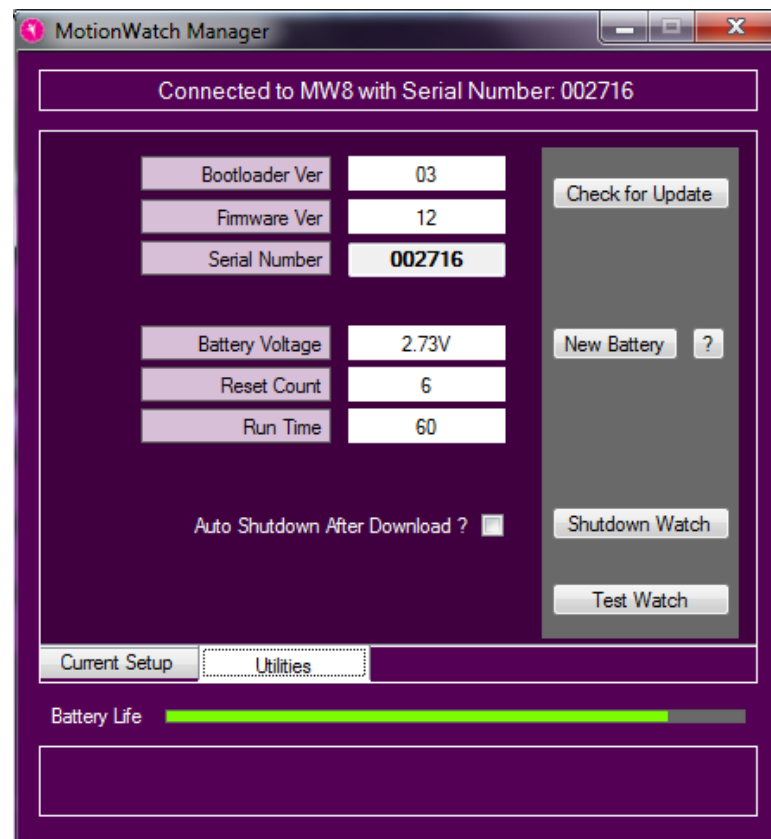
3.4 Analysing Data

Full details of the various data analysis functions and tools are provided in the MotionWare Software User Guide ref 30238.

4 Maintenance and Utilities

4.1 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.

4.2 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.
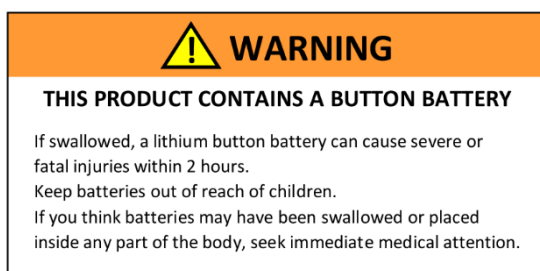
4.3 Shutdown Options

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.

4.4 Changing the Battery

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

⚠ **WARNING**

THIS PRODUCT CONTAINS A BUTTON BATTERY

If swallowed, a lithium button battery can cause severe or fatal injuries within 2 hours.
Keep batteries out of reach of children.
If you think batteries may have been swallowed or placed inside any part of the body, seek immediate medical attention.

- The 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.
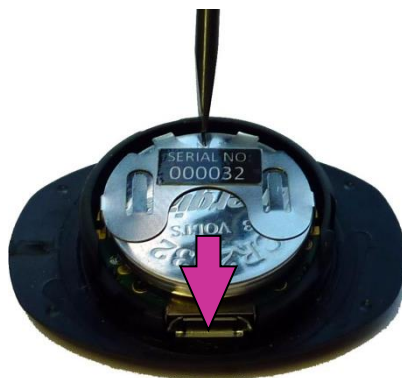
- Grasp the battery and withdraw it completely from the holder.
- Wait at least 1 minute or press the marker button 4 times then place a fresh CR2032 battery into the holder (ensuring correct orientation!) and push back until fully home.


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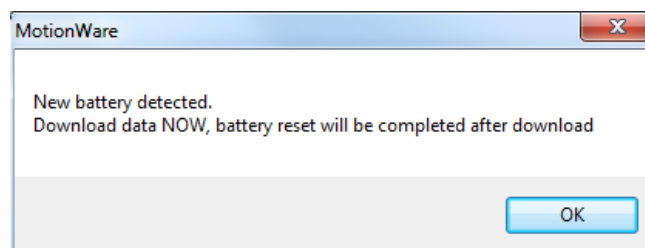
Click 'OK' and then download the data from the watch.

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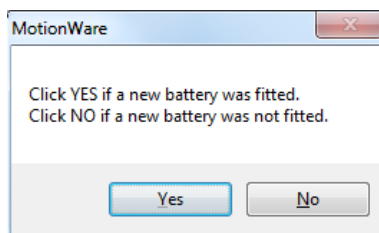
Select 'Yes' and the software should display 100% in the battery life indication. If the new battery is not detected remove the battery and repeat the steps above taking time to observe each step. If the battery is not replaced correctly the watch may stop prematurely with no warning and the battery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

4.5   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). Note the seal will NOT withstand salt water.
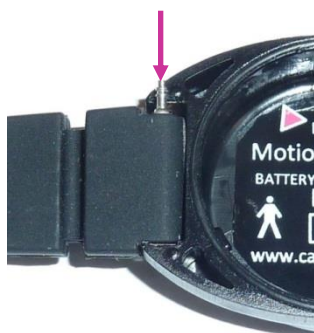
4.6   MotionWatch Strap

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. Please see our web store for details of alternative straps and accessories:

https://www.camntech.com/product-category/wrist-straps/

4.7   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

Please see our web store for details of mounting straps and accessories:

https://www.camntech.com/product-category/mounting-straps/

5 FAQ & Troubleshooting

What does 'No data integrity check' mean?	The data are protected by a security key which is generated when the data are 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 MotionWare 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 firmware update process).
What are the potential effects of Electromagnetic Interference (EMI)?	The MotionWatch is designed and manufactured 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 A5). 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 Section 4 for further information.

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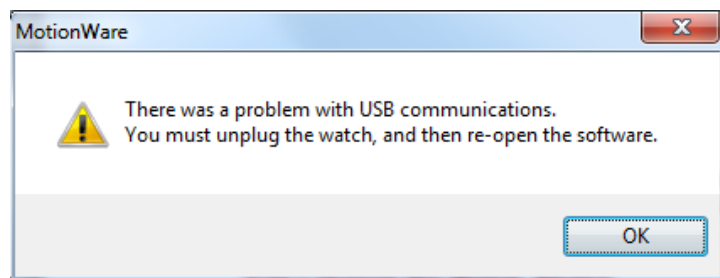
In this case, click 'OK' then disconnect the MotionWatch from the USB. Re-run the software, re-connect the watch and re-apply the set-up.

Appendix A – Safety & Environmental Information

A1 - 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.

- The above prohibited cleaning products may also cause skin irritation.

- 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!

- Rinse with clean water following de-contamination.

- Ensure that the casing and strap have been allowed to thoroughly dry prior to attaching to a subject.

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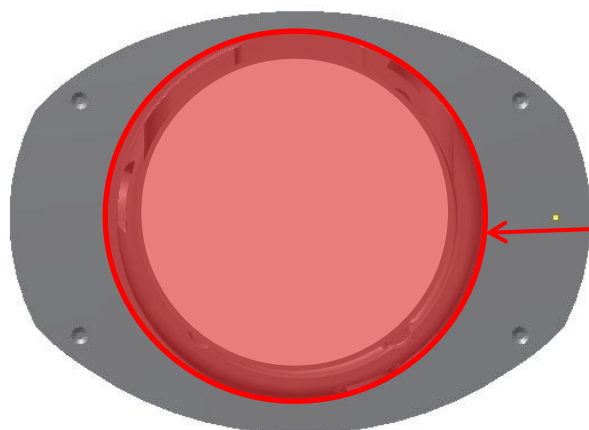
Clean only OUTSIDE of the red bounded area – do not clean the vertical side walls and ensure no cleaning agent enters the electronics.

A2 - 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 Section 4 for further information).

- The battery must be replaced observing the correct procedure to prevent possible data loss (see Section 4 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 <u>swallowing hazard</u> 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.**

⚠ **WARNING**

THIS PRODUCT CONTAINS A BUTTON BATTERY

If swallowed, a lithium button battery can cause severe or fatal injuries within 2 hours.
Keep batteries out of reach of children.
If you think batteries may have been swallowed or placed inside any part of the body, seek immediate medical attention.

A3 - Warnings – General

- The MotionWatch is NOT defibrillation proof.

A4 - 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 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.

A5 - 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.
Harmonic Emissions EN61000-3-2	Not Applicable	The MotionWatch has not been tested for use in the following special environments: Military areas.
Voltage Fluctuations / flicker emissions EN61000-3-3	Not Applicable	Heavy Industrial Areas. Medical treatment areas with high powered ME equipment. Inside the shielded room of an MRI system.

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.

You may also need to use an adaptor if your Mac or PC laptop only has USB-C ports, and not rectangular USB-A. In this case you should still connect the cable supplied by CamNtech between the output end of the adaptor and the MotionWatch.

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 B – Technical Specifications

<u>B1 - Specifications</u>

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)
Accelerometer:		Tri-axial, MEMs technology. 0.01g to 8g range, 3 – 11Hz
Battery:		CR2032 Lithium Coin Cell
Battery Life:		3 Months run time*; simple user change
Memory:		4Mbits non-volatile (91 days recording @ 1min epoch – activity and light, uncompressed)
Waterproof:		IPX7 - up to 1 hour at 1m (suitable for swimming)
Marker button:		**MW 8:** 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 a maximum of around one minute.
Strap:		Bespoke XL 12mm silicone (245mm overall length) or 12mm nylon. **MotionWatch R** has various mounting options
Light Sensor Specifications (not fitted to MotionWatch 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. Battery performance can be significantly reduced during low temperature operation.

<u>B2 - Operating & Storage Conditions</u>

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

B3 - 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.
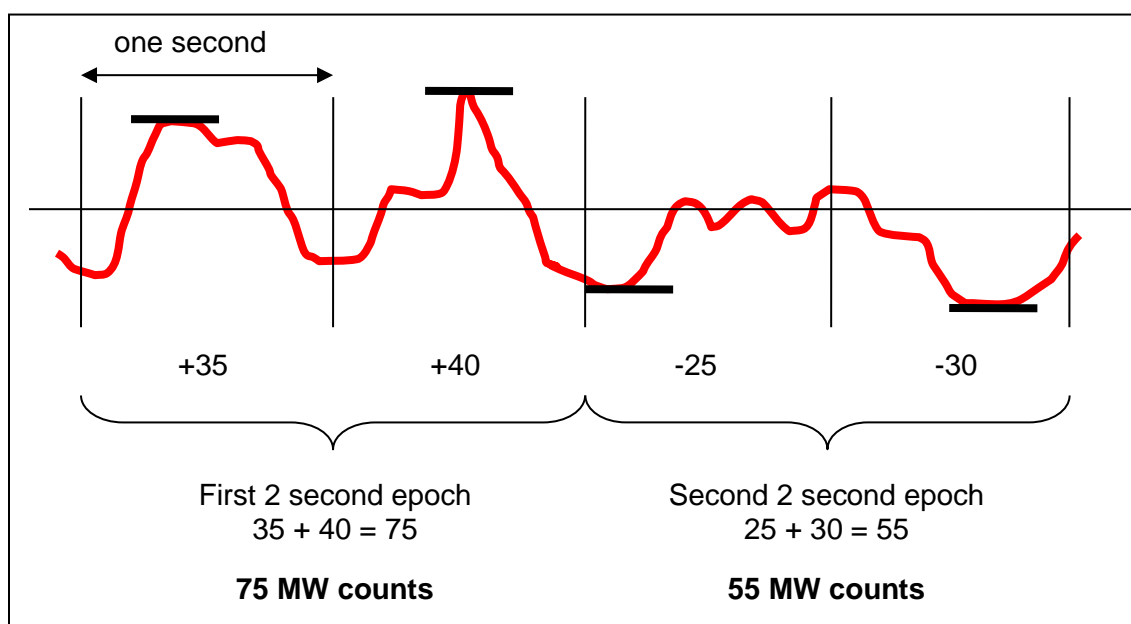
B4 - Tri-Axial Mode Data Processing

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 tracked.
3. At the end of each second, the square root of the peak value from that second is calculated.
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 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 'Tri-Axial count' for the epoch.

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

MotionWatch X-Y-Z axes using Tri-Axial mode.
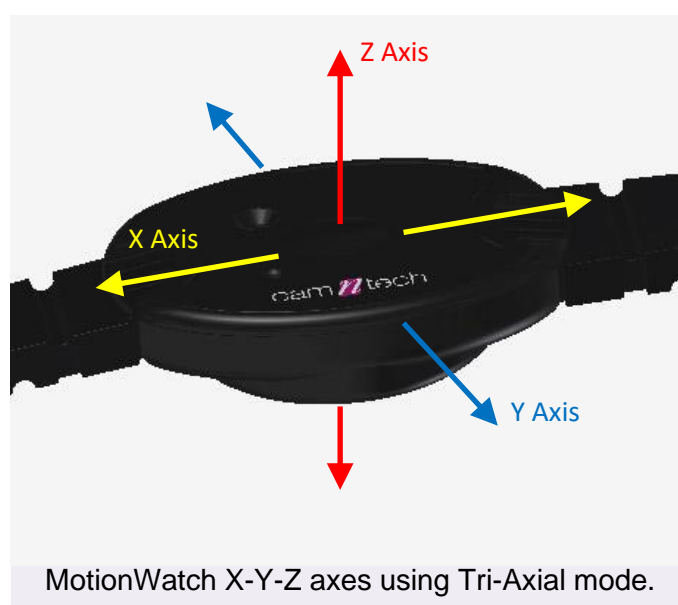
Appendix C – Regulatory Information

C1 - Medical Device Information

Medical Device Regulation (European Union)

The MotionWatch is a Class I Medical Device conforming to the requirements of Regulation (EU) 2017/745 (MDR). An EC Declaration of Conformity will be provided upon request.

Authorised Representative (European Union)

EC	REP	Qarad EC-REP BV Pas 257 2440 Geel Belgium

Authorised Representative (Switzerland)

CH	REP	Qarad Suisse SA World Trade Center Avenue Gratta-Paille 2 1018 Lausanne Switzerland

Manufacturer:

CamNtech Ltd
Manor Farm
Fenstanton
Cambridgeshire
PE28 9HU, UK

Tel: 01480 831223
Fax: 01480 831733
Email: admin@camntech.co.uk
Web: www.camntech.com

US FDA status

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

CamNtech Inc.
630 Boerne Stage Airfield,
Boerne,
Texas 78006,
USA

Phone: +1 830-755-8036
Fax: +1 830-755-8085
Email: inquiry@camntech.com

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
Sydney, NSW 2000
Australia

C2 - 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.

C3 - 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. Observe the correct de-contamination procedure (Appendix A1) to avoid cleaning agents causing skin irritation.

C4 - Patient Population

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

C5 - 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.

C6 - 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.

C7 - 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.

C8 - Service Life

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

C9 - 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.

C10 - Adverse (Serious) Events

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.

Document Revision History

Issue From	Issue To	Date	Description	By
1.2.36a	1.2.42	01/03/20	Added section 5.16 for Temperature data import	TE
1.2.42	1.2.44	29/05/20	Clarified description of tri-axial counts to the same wording as uniaxial for latter stages	TE
1.2.44	1.2.46	03/06/20	Updated battery life indications and battery gauge to match software	HS
1.2.46	1.2.47	11/06/20	Added NPCRA edit instructions to section 7.	HS
1.2.47	1.3.12	11/09/20	Added specific notes for Mac version installation and where appropriate elsewhere. Updated main menu and other screenshots with significant changes.	TE
1.3.12	1.3.16	24/11/20	Update user manual to include EU Authorised Representative details.	HS
1.3.16	1.3.17	06/01/21	Minor updates following EC Rep review	HS
1.3.17	1.3.17a	25/06/21	Updated contraindications and decontamination sections to minimise risk of skin irritation due to residual cleaning agents.	HS
1.3.17a	1.3.17b	07/12/21	Corrected menu selection in 'excluding sleep periods' for daytime activity.	HS
1.3.17b	1.3.33	30/06/22	Added CH-REP details, bump version no. to match software release.	HS
1.3.33	1.3.33a	16/11/22	Updated and extended coin cell battery warning throughout	HS
1.3.33a	1.4.14	12/06/23	Separated into Hardware and software manuals, revised all sections	HS