

# The Actiwatch Mini & Sleep Analysis Software *User Guide*

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### Actiwatch Mini Regulatory Information

The Actiwatch Mini is intended for use exclusively as a pre-clinical tool and is not indicated for use in humans.

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#### IMPORTANT SAFETY INFORMATION

#### **Device and Packaging Symbols and Markings:**

MEANING	SYMBOL	DESCRIPTION
Consult Instructions for Use	Í	This symbol indicates that important operational information is contained in the user instructions (i.e. this user guide).
Ingress Protection Rating	IP65	The Actiwatch Mini is suitable for temporary immersion in 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 <i>yyyy-mm</i> which indicates when the device was manufactured. The symbol is also accompanied by the address and contact details of the manufacturer

FOR FURTHER HANDLING & ENVIRONMENTAL INFORMATION PLEASE REFER TO APPENDIX B

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## Introduction to the Actiwatch Mini System

#### 1.1 An Overview of the Actiwatch Mini System

The Actiwatch Mini is a compact and lightweight electronic device that measures and records physical movement. Worn on the neck or by means of a pouch or harness, the Actiwatch Mini can be worn for long periods of time by animals of all sizes.

The Actiwatch Mini is designed to analyse physical activity and to measure sleep quality and circadian rhythm using the supplied analysis software.

The Actiwatch collects movement data which is stored in the non-volatile memory and is then transferred to the PC using CamNtech's proprietary telemetric reader/interface. The movement data can then be analysed using the relevant software package.

#### 1.1.1 Components required for a system

An Actiwatch Mini system consists of 3 elements:

- · One or more Actiwatch Mini devices.
- USB Reader interface.
- PC based Software providing set-up, download and analysis functions.

#### 1.1.2 The Actiwatch Mini & USB Reader



#### 1.2 Intended Use

The Actiwatch Mini is intended for use exclusively as a pre-clinical tool and is not indicated for use in humans.

## 2 Installing the Sleep Analysis Software

# 2.1 System Requirements

The Sleep Analysis 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 Sleep Analysis software:

- Windows<sup>®</sup> 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 thirdparty alternative) with automatic definitions updates enabled.

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

#### 2.2 Software Registration

To access the Sleep Analysis software download, it is necessary to first register the software with CamNtech. Please visit <a href="https://www.camntech.com/register">www.camntech.com/register</a> 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 <a href="section2.6">section 2.6</a> below)

The software will continue to be fully functional beyond the warranty period but updates will no longer be provided.

#### 2.3 Software Installation

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).

For USB driver installation see section 2.4 below.

## 2.4 Updating the software.

If you are updating or reinstalling the software a message will be displayed with options to repair or remove the Actiwatch Software. Select **remove** and wait for the process to complete. The installation has to then be restarted by double-clicking on the .msi file as detailed in section 2.3.

# 2.5 Installing the USB Reader Interface

The Actiwatch USB reader provides a telemetric connection to the Actiwatch Mini which allows the user to setup and download the Actiwatch using the software installed on the host PC. Note: Please install the Sleep/Activity Analysis software before connecting the reader – see section 2.3 of this guide.

The Actiwatch USB Reader is provided with a USB 'A' to 'Mini-B' cable. To connect the reader, connect the USB Mini-B plug into the rear of the USB reader and connect the USB 'A' plug into a spare USB socket on the PC. A message will then pop-up requesting USB drivers (see next section).

# 2.6 Installing the USB drivers

This section on installing drivers only applies to new installations.

Ensure the Software installation menu is displayed (see section 2.2) and that the Actiwatch reader/charger is connected (see section 2.4). Depending upon the operating system in use and the current driver status, the computer may display a message saying 'Found New Hardware' and will then load the drivers with no user intervention. No further action will be required.

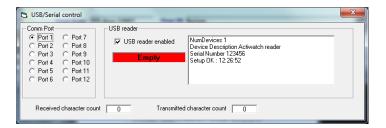
If the drivers loaded automatically, simply close this menu and the drivers should be ready to use.

If you have any problems installing the drivers, please read the help document and download the latest drivers from <a href="http://www.camntech.com/drivers">http://www.camntech.com/drivers</a>.

The driver installation is now complete.

# 2.7 Checking the USB Reader Operation

When using the Actiwatch USB reader, it is not necessary to manually set the communications port. Once the software has been installed and the USB reader plugged in, the correct communications port will be automatically set by the software. To check the USB communications manually, selecting 'Reader' and then 'Comms' brings up the following screen:



When an Actiwatch Mini is correctly placed on the USB reader, the message shown above in red will change to a green message stating that the Actiwatch has been detected and is ready. The red 'READY' LED should be lit on the front panel of the reader.

#### 2.8 Correct Placement of Actiwatch Mini on the USB Reader

It is very important to correctly position the Actiwatch Mini on the USB reader to ensure reliable communications:



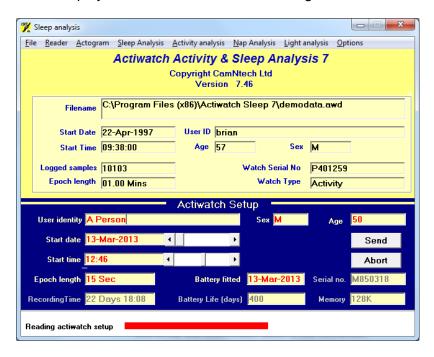
Correct Position of the Actiwatch Mini on the USB Reader.

## 3 Set-up for Recording

## 3.1 Set-up the Actiwatch Mini

Place the Actiwatch Mini onto the reader (as shown in section 2.7 above). The Actiwatch set-up begins by selecting 'Reader' and then 'Write' from the drop down menu.

This will display a screen similar to the following:



Note – if any of the controls are 'grayed' this means they are locked – see default set-up options in section 3.2 below.

The user may then enter/edit the following parameters:

#### 3.1.1 User ID

This is a free text field but must not include any of the following characters:

#### 3.1.2 Sex

Clicking on the 'Sex' field during the Actiwatch setup procedure scrolls between 'F' and 'M'.

#### 3.1.3 Age

The age field is a free text field allowing a 1 or 2 digit age to be input.

#### 3.1.4 Start date

It is possible to enter a delayed start date when setting up an Actiwatch. Any date up to 7 days in the future can be specified. This function is useful if several Actiwatches are to be fitted to subjects on the same date or if Actiwatches need to be shipped to a site following setup.

#### 3.1.5 Start time

A delayed start time can be selected if required. This can be up to 23.59 on the selected start date.

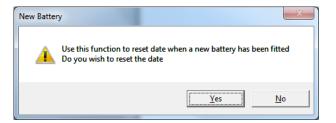
#### 3.1.6 Epoch length

The epoch length is user selectable by clicking on the epoch to scroll through the available options. The range of epochs available for the Actiwatch mini and approximate maximum recording lengths are as follows:

Epoch	Recording Length
2 Sec	3 Days
5 Sec	7 Days
10 Sec	15 Days
15 Sec	22 Days
30 Sec	45 Days
1 Min	90 Days
2 Min	182 Days

#### 3.1.7 Battery fitted date

The battery in the Actiwatch Mini is user replaceable. The battery life of the Actiwatch Mini is approximately 400 days. When a new battery is fitted, it is **essential** to reset the date of battery fitment. Clicking on the 'Battery Fitted' date in the software brings up the following screen:



Selecting 'Yes' will update the battery fitted date to the current PC date and the battery life in days will be updated for the Actiwatch Mini.

**Important Note:** It is essential to click on the battery fitted date as detailed above following the fitment of a new battery – the software cannot detect a new battery automatically.

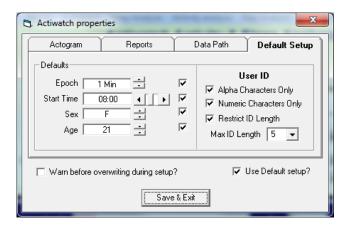
#### 3.1.8 Apply or Abort Set-up

Click the 'Send' Button to apply the new set-up to the Actiwatch Mini. Wait for the confirmation message and then immediately remove the Actiwatch from the reader.

Click the Abort button to exit without applying the new set-up.

# 3.2 Default Set-up Options

For studies where a large number of Actiwatch devices will be setup with the same settings, it is possible to set these items as default settings and 'lock' them to prevent editing in the normal set-up screen. From the file menu, select 'Properties' then in the properties window, ensure 'use default setup' is checked:

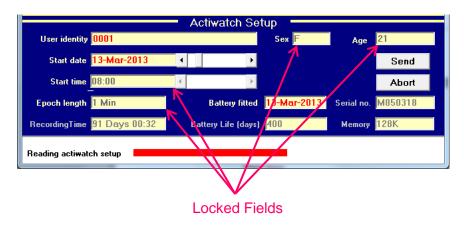


It is possible to lock the epoch, start time, sex and age by checking or unchecking the setting. Once checked, the default value may be set for each setting.

The User ID can have further filtering applied to restrict the input to alphanumeric characters only, Numeric characters only (or both). The number of characters can also be restricted.

Click on the 'Save & Exit' button to apply the changes.

Perform the set-up process as described in Section 3.1 above: the default items are now locked in the set-up screen which prevents accidental editing.



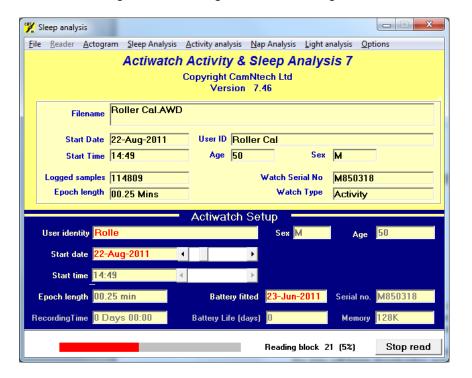
For details of other 'properties' window options see section 10.

## 4 Downloading data

#### 4.1 Actiwatch Download

To download Actiwatch data at the end of a recording, the Actiwatch should be correctly placed on the Actiwatch reader (see section 2.7). The user should then select 'Read' from the 'Reader' on the main screen.

Provided the Actiwatch is communicating correctly with the reader, the data will begin downloading and the following screen shown:

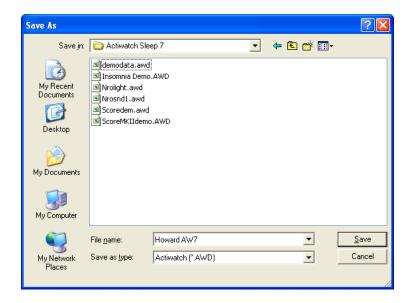


## 4.2 Saving Actiwatch Data

When the data has been successfully downloaded, the following message will automatically be shown:



Selecting 'Yes' allows the user to save the data and brings up the following screen:



As a default, all files are saved within the Actiwatch software in program files. This should only be changed if absolutely necessary.

#### 4.2.1 File Types

There are 3 different types of Actiwatch file:

**AWD Files:** Actiwatch data files are saved by default as Actiwatch (.AWD) files. This file type is used for data with epochs of 15 seconds or more.

**AWF Files:** When the Actiwatch has been set-up with a 2, 5 or 10 second epoch, the software will provide the option to save the file as an AWF file. AWF files are high resolution activity data files with the data stored with the original epoch length. It is possible to save this data in the AWD format; however the data will be processed into 30 second epochs automatically.

**AWC Files:** This file format organises the data into a tabular format which is useful for export to external packages such as Microsoft Excel.

The file type should not be manually edited otherwise the files may not be recognised by the Actiwatch software.

#### 4.3 After Download

#### 4.3.1 Sleep Mode

Following the download and save process, the software will prompt the user to place the watch into sleep mode. This is a battery saving mode and the data will not be lost, however, recording will be stopped.

#### 4.3.2 Lost Time

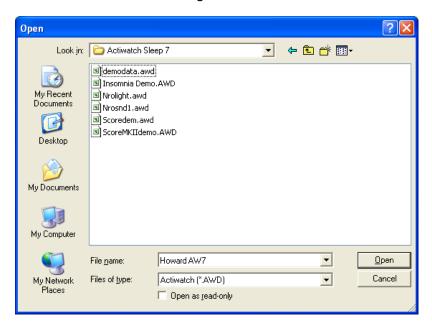
It is important to note that the download process will cause the Actiwatch to lose track of real time. For this reason the Actiwatch **must** be set-up again before commencing any further recording.

## 5 Preparing to Analyse Data

#### 5.1 Loading Saved Data

To load a previously saved file for viewing, select 'Load' from the 'File' menu on the main screen.

A screen similar to the following will be shown:



Choose the file type to load (see section 4.2 above). Double click on the required file to load it for viewing in the analysis software.

#### 5.2 Overview of Key Analysis Functions

#### 5.2.1 Sleep Analysis

This function allows the user to analyse Actiwatch files and produce an Actiwatch sleep summary. Full details on sleep analysis are given in **section 6** of this manual.

#### 5.2.2 Actogram Analysis

This function allows the user to view activity data from the 'Actogram' tab and perform various analyses using the in-built tools. Full details are given in **section 7** of this manual.

#### 5.2.3 Nap Analysis

This function allows the user to perform an analysis for shortduration daytime sleep periods (naps) activity data. Full details are given in **section 8** of this manual.

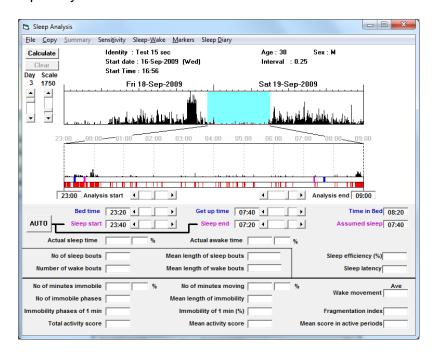
#### 5.2.4 Activity Analysis

This function allows the user to perform an analysis of activity before and after an event (i.e. administration of a drug). Full details are given in **section 9** of this manual.

## 6 Sleep Analysis

#### 6.1 Introduction

The Sleep analysis function is designed to provide a number of objective sleep measures from overnight actigraphy data. It can be easily applied either to normal overnight periods, or used to examine any sleep period from an altered phase recording. From the main screen, click on the 'Sleep Analysis' menu to open the sleep analysis function:



In order to analyse a sleep file, it is necessary to perform the following actions:

- Ensure that the correct data file is currently loaded (file details are shown above the plot area). If another data file is to be analysed, use the 'Load File' option from the 'File' menu.
- It is important to remember that only data collected with epochs of 15 seconds (0.25 minute), 30 seconds (0.5 minute), 1 or 2 minutes can be analysed by this program.
   For accuracy it is recommended that epoch lengths of 1 minute or shorter are used.
- With the required data file loaded, select the day for which the analysis is to be performed (relative to the start day of the study data) by using the 'Day' slider control.
- The maximum value of the plotted data may be adjusted by using the 'Scale' control (minimum value is 50, maximum is equal to the maximum value of the data).

The upper plot provides an overall view of two days of activity with an analysis window (highlighted in blue) covering the period of data to be analysed. The lower plot provides an expanded view of the analysis window and will also show marker events (where used) as vertical blue lines.

The expanded analysis window plot has two further data bars just below the plot area. The upper bar shows the bed time/get up times (blue lines) and sleep start/sleep end times (pink lines). The lower bar represents periods of sleep as white areas and periods of wakefulness as red areas.

#### 6.1.1 Setting the Analysis Window period

Set the start time for the analysis by clicking on the upper activity plot with the LEFT mouse button until the blue highlighting starts at the required time. Set the end time for the analysis by clicking on the upper activity plot with the RIGHT mouse button until the blue highlighting ends at the required time.

Scroll bars are provided below the expanded activity plot to allow further adjustment of the analysis start/end times as required. The Analysis Window may be set to between 1 and 24 hours in length. The Analysis Window must be of sufficient duration to encompass the sleep periods of the subjects and this should be consistent for each day within the data file if possible.

#### 6.1.2 Setting Bed and Get Up Times

These times (or the equivalent such as lights on and lights off) have to be set by the operator and are indicated by the small dark blue lines underneath the Expanded Analysis Window. These can be moved by using a LEFT mouse click or by use of the slider bars for fine adjustment. They can also be set automatically by use of the Event Marker in the Sleep Diary routine (see section 5.1.8). The corresponding time in bed is shown in the box at the right of this information.

#### 6.1.3 Setting Sleep Start and Sleep End

These times have to be set by the operator and are indicated by the small pink lines underneath the Expanded Analysis Window. These can be moved by using a RIGHT mouse click or by use of the slider bars for fine adjustment (note these times must fall within the region encompassed by the blue bed and get up time lines).

Alternatively, the Sleep start/end times may be set automatically by clicking on the 'Auto' button thus allowing the sleep-wake scoring algorithm to calculate the times.

The bedtime and get up time must be set before selecting the 'Auto' option. The amount of assumed sleep will be shown in the box at the right of this information

#### 6.1.4 Performing the sleep analysis

When the correct periods have been selected, click on the 'Calculate' button to perform the analysis. The Actiwatch sleep-

wake scoring algorithm will calculate the Sleep-Wake and movement information for the period between sleep start and end times. The results will be displayed in the lower part of the screen. Please note that where actual times are involved they are expressed in terms of the 24-hour clock and calculated times, unless indicated, in terms of hours, minutes and seconds. This process will have to be repeated for each night.

# 6.2 Sleep analysis statistics

Once the desired sleep region is selected, the software will automatically perform a categorisation of each epoch of the period between "Fell Asleep" and "Woke Up" as either "Sleep" or "Wake", and also as either "Mobile" or "Immobile", and use these results to provide a number of measures from the period. These are described below:

- **Time in bed:** The total elapsed time between the "Bed Time" and "Get Up" times.
- **Assumed sleep:** The total elapsed time between the "Sleep Start" and "Sleep End" times.
- **Actual sleep time:** The total time spent in sleep according to the epoch-by-epoch wake/sleep categorisation.
- Actual sleep (%): Actual sleep time expressed as a percentage of the assumed sleep time.
- **Actual wake time:** The total time spent in wake according to the epoch-by-epoch wake/sleep categorisation.
- Actual wake (%): Actual wake time expressed as a percentage of the assumed sleep time.
- Sleep efficiency (%): Actual sleep time expressed as a percentage of time in bed.
- Sleep latency: The time between "Bed Time" and "Sleep Start".
- **Sleep bouts**: The number of contiguous sections categorised as sleep in the epoch-by-epoch wake/sleep categorisation.
- **Wake bouts:** The number of contiguous sections categorised as wake in the epoch-by-epoch wake/sleep categorisation.
- **Mean length of sleep bouts:** The average length of each of the sleep bouts.
- Mean length of wake bouts: The average length of each of the wake bouts.
- **No of minutes immobile:** The total time categorised as Immobile in the epoch-by-epoch mobile/immobile categorisation.
- Immobile minutes (%): The immobile time expressed as a percentage of the assumed sleep time.
- No of minutes mobile: The total time categorised as mobile in the epoch-by-epoch mobile/immobile categorisation.
- **Mobile minutes (%):** The mobile time expressed as a percentage of the assumed sleep time.

- No of immobile phases: The number of contiguous sections categorised as immobile in the epoch-by-epoch mobile/immobile categorisation.
- Mean length of immobility: The average length of each of the immobile bouts.
- **Immobility phases of 1 minute:** The number of immobile bouts which were less than or equal to one minute in length.
- Immobility of 1 minute (%): The number of immobile bouts less than or equal to one minute expressed as a percentage of the total number of immobile bouts.
- Total activity score: The total of all the activity counts during the assumed sleep period.
- Mean activity score: The total activity score divided by the number of epochs in the assumed sleep period. Note that this result will be expected to scale depending on the length of the epoch.
- Fragmentation Index: The sum of the "Mobile time (%)" and the "Immobile bouts <=1min (%)". This is an indication of the degree of fragmentation of the sleep period, and can be used as an indication of sleep quality (or the lack of it).

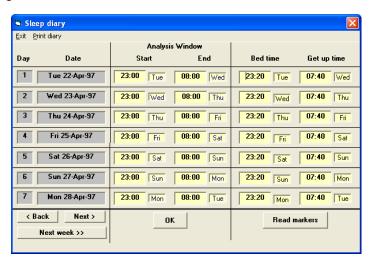
#### 6.3 Saving the analysis

From the 'File' menu of the sleep analysis window, select 'Save summary' to save the sleep statistics. The file will automatically default to the data folder location (see Properties) and will use the AWD file name with the extension 'AWS'.

When loading an AWD file that has a saved AWS summary file, a message will be displayed offering to load the saved statistics.

#### 6.4 Sleep Diary

It is possible to load information for each day of the study from the 'Sleep Diary' command. Clicking on 'Sleep Diary' brings up the following screen:



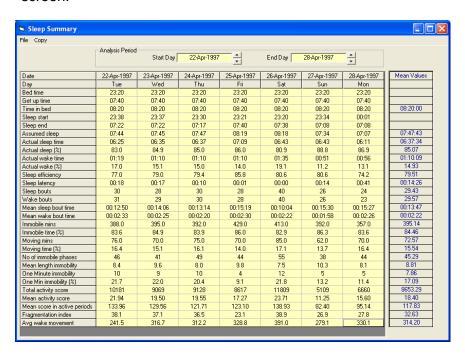
The following functions are available:

- The Analysis Window start and end times can be set for each day of the recording
- The bed time and get up time can be set for each day of the recording
- If the marker button has been used to demarcate bed time and get up time, then the 'Read markers' button can be used to automatically load the bed time and get up time for each day of the study. The AW Mini does not support markers.
- The option to print summary data from the sleep diary by selecting 'Print diary'

The sleep diary offers an efficient means of transferring information from a paper diary into the sleep analysis software. Click the 'OK' button to apply the diary times to each day of the sleep analysis.

#### 6.5 Sleep Summary Report

It is possible to display a summary of all parameters in the sleep analysis. Clicking on 'Display summary' produces the following screen:



The summary provides a tabular format report of the sleep statistics for each day and overall mean values.

#### 6.5.1 Producing summary reports

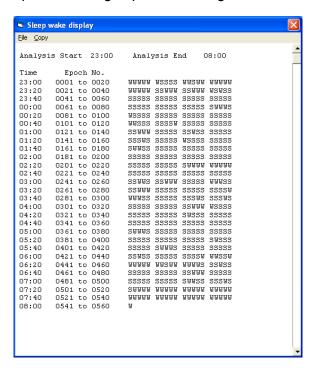
The 'File' menu allows the user to perform the following actions:

- Print 7 day report prints a complete summary for all parameters for 7 days
- Print 7 day report with graphs prints a complete summary for all parameters for 7 days complete with sleep graphs for each day.

It is possible to copy all days or displayed days of summary data to the clipboard for use in a third party program such as Excel.

#### 6.6 Sleep-Wake Display

Clicking on 'Sleep-Wake' brings up the following screen:



This enables the user to see which epochs during the night have been recorded as wake (w) and which have been recorded as sleep (s). For further details on how the software scores wake and sleep, please see the technical appendix.

#### 6.7 Sensitivity

The Actiwatch system can be set with one of 4 sensitivity values. These are:

- Low
- Medium
- High
- Auto

The default value is 'Medium' and this is the value which was used in the human validation study by Kushida et al.

# 6.8 Exporting Sleep Analysis Data

#### 6.8.1 Expanded raw data

Selecting 'Copy' and 'Expanded raw data' copies data from the analysis period epoch by epoch. The raw activity in counts is shown along with information as to whether the epoch has been scored as wake or sleep.

#### 6.8.2 Calculated data

Selecting 'Copy' and then 'Calculated data' copies all of the calculated data to the clipboard. This function only works when sleep data has been analysed. Each parameter for the selected day is reported.

# 6.9 Sleep Analysis File Menu Options

#### 6.9.1 Load file

Selecting 'File' and then 'Load file' allows the user to load an AWD file for analysis.

#### 6.9.2 Save summary

See section 6.3 above.

#### 6.9.3 Colours

If the file loaded contains secondary data (i.e. non-activity data), it is possible to change the colour in which the secondary data is displayed for clarity. **The AW Mini does not support secondary data.** 

#### 6.9.4 Print

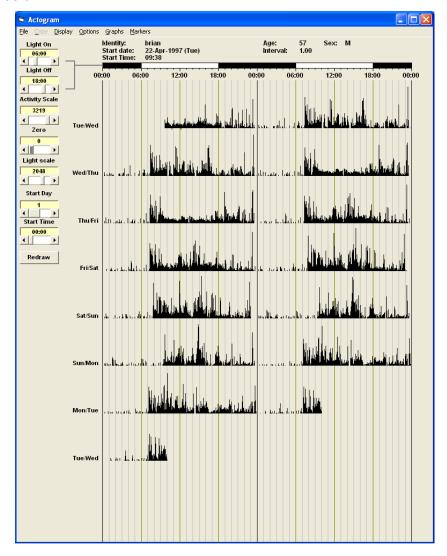
Selecting 'Print' prints the current screen including the Actogram plot for that day and the sleep statistics for the selected night.

## 7 Actogram Analysis

#### 7.1 Introduction

The Actogram function allows the user to observe a visual display of the activity-rest patterns over the entire length of an experiment. The identity, sex, age, start date, start time, age, gender and epoch are displayed at the top of the screen. The Actogram can either be shown as a single day or dual day plot. Which of these is shown by default can be selected from the properties menu.

The double day plot Actogram as shown in the example below is particularly useful for the visualisation of data collection over a long time period such as in chronobiological experiments. A typical double plotted actogram with 7 nights of data is shown below:



# 7.2 Actogram Display Options

#### 7.2.1 Display Menu: Redraw

Selecting 'Redraw' re-displays the Actogram for the file currently loaded. This function is duplicated by a button on the left hand side of the Actogram screen.

#### 7.2.2 Display Menu: Length

Selecting 'Display' and then 'Length' allows the user to select the number of days displayed in the Actogram. The options are:

- Auto (this is the factory default setting).
- 60 days allows up to 60 days to be displayed.
- 20 days allows up to 20 days to be displayed.

#### 7.2.3 Display Menu: Type

The 'Type' function allows the user to select either a single day display or a dual day display:

#### Single day display

The single day display plots each day on a single row from midnight to midnight. The single day display allows the user to look in more detail at specific parts of the data. The following information is available:

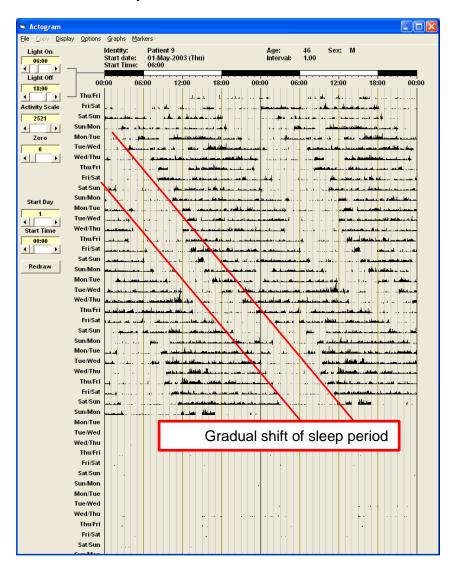
- Average activity value per epoch shown on the right of each day
- Peak activity for each day shown in the second column to the right of each day
- Activity at a given time each day can also be displayed by clicking on the required time. These are the figures shown in green on the far right hand side of the Actogram screen.
- It is also possible to mark a specific part of the single day plot for more detailed analysis. To do this click on the required start time and select 'Mark start'. Then click on the required end point and select 'Mark end'.

This screen shows the following information:

- Start and end times of the analysis period
- Total time in the analysis period
- Total activity in counts during the analysis period
- Average activity per epoch during the analysis period
- Peak activity (in any epoch) during the analysis period
- RMS (a measure of deviation)

#### **Dual day display**

The dual day plot is useful for visually representing longer periods of recording. The example below is a dual day Actogram showing a clear circadian rhythm shift:



#### 7.2.4 Display Menu: Day

This menu entry may be used to toggle between day of the week or date for the x axis of the Actogram.

#### 7.2.5 Display Menu: Activity / Light

These menu entries may be used to show/hide the activity and/or light data in the Actogram (**The Actiwatch Mini does not record light**).

#### 7.2.6 Display Menu: Change Epoch

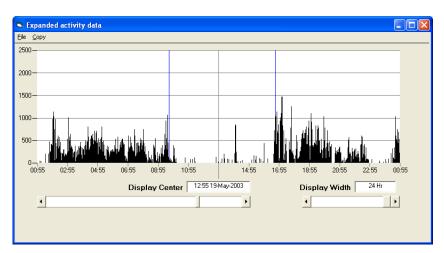
See 'Advanced functions' in Section 10.

## 7.3 Actogram on screen controls

- **Light on** used in the calculation of light and dark average activity (average graph).
- **Light off** used in the calculation of light and dark average activity (average graph).
- Activity scale automatically set by the software to best display the activity data. This may be used to clip the upper end of the data by reducing the value.
- Zero sets the minimum activity value may be used to clip the lower end of the data.
- **Start day** may be used to plot the Actogram starting at any day during the recording.
- **Start time** may be used to plot the Actogram starting at any time during the recording.
- **Redraw** refreshes the Actogram (also found in the display menu).

# 7.4 Expanded activity display

Double click on the Actogram to 'zoom' in on the data and show the expanded activity data:



It is possible to alter the following parameters and perform the following functions:

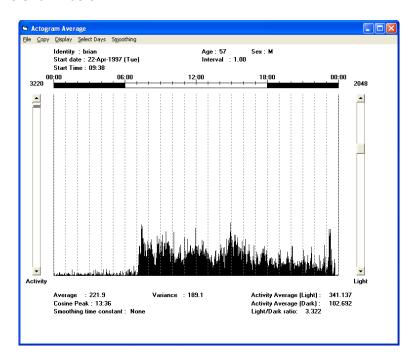
- Display centre (marked by the central line above)
- Display width (defaults to 24 hours but adjustable between 24 hours and 5 minutes)
- Selecting 'File' and then 'Print' allows the user to print the expanded data
- Selecting 'Copy' copies the data from the expanded display window to the clipboard for use in a third party program such as Excel.

# 7.5 Actogram Graphs Menu

It is possible to graphically represent and analyse the activity data in a number of different ways.

#### 7.5.1 Average

Selecting the 'Average' option produces a screen similar to the one shown below:



This is a graphical representation of the average activity in each epoch over all or selected days of the recording. The graph has the following controls:

- Select Days: allows the days for inclusion to be selected.
   A pop-up menu will appear; Click and drag to select a range of days or hold the <Control> key and click to select individual days. Click away from the pop-up to apply the selection.
- Smoothing: It is possible to smooth the data to better delineate trends. The smoothing factor applied can be between 2 minutes and 1 hour.
- Display: Choose to show/hide activity and/or light data in the plot. (AW Mini does not record light).
- **Copy**: The 'Copy' function allows the user to copy the data in one of three ways:
  - Raw average data copies the raw average data for the selected days of the recording
  - Smoothed data copies the processed data if smoothing has been applied to the raw data
  - Statistics copies a summary of the statistics shown at the bottom of the screen

• **Print:** From the file menu, select print to print a copy of the average graph report.

The average graph provides additional analysis parameters as follows:

Activity Average (light & dark): The data per epoch for each day are day totalized and averaged over the number of days in the analysis. The average activity in the daytime and nighttime periods are then calculated and displayed.

**Light/Dark Ratio:** This is the daytime activity average / nighttime activity average.

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

**Variance:** Calculated using the RMSD method (Root Mean Square Deviation) and is calculated as follows:

Variance 
$$=\sqrt{rac{\sum_{i=1}^n(x_{1,i}-x_{2,i})^2}{n}}$$

Where:

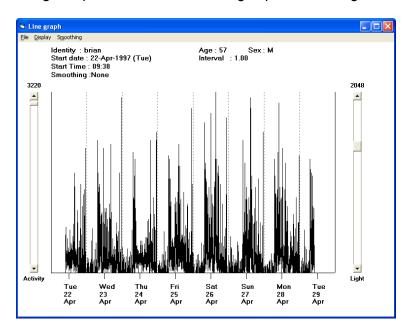
 $x_1$  = sample value (average over all days selected)

 $x_2$  = overall average over all days selected

n = number of samples per day

#### 7.5.2 Line

Selecting 'Graphs' and then 'Line' brings up the following screen:



This shows each or selected days of data drawn end to end. It is possible to manipulate the data in the same way as described in the section on average data. Please see section 7.5.1 for details.

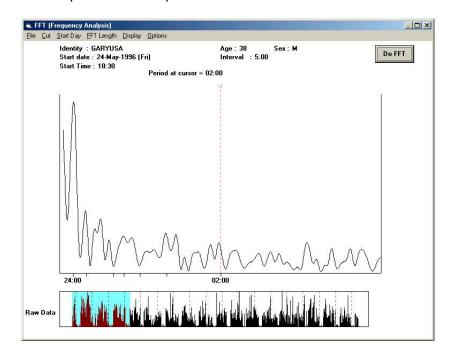
This option provides a plot of the frequency distribution of events for selected data. Select the 'Start Day' for the analysis, (this defaults to the first day of the study). Select the 'FFT Length' from the options displayed and the time base from the 'Display' menu (1 minute to 12hrs). A longer FFT length will provide a more accurate plot. A representation of the data to be analysed is displayed across the bottom of the screen. Click on the 'Do FFT' button to perform the analysis; the plot will be re-drawn.

The peaks on the plot show a correlation of the rhythmicity of activity. For example, a 24-hour circadian rhythm will show a strong peak on the FFT plot at 24 hrs.

A cursor line may be placed at any point on the plot by use of the left mouse button. The right mouse button moves the cursor at fixed intervals across the screen. The period at the cursor is displayed above the plot.

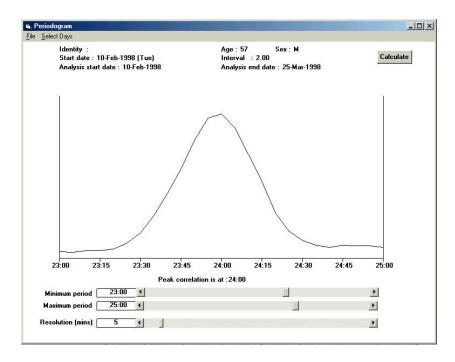
The 'Options' menu allow a Cosine window or cubic spline filtering to be applied to the date to minimise end effects.

An example of the FFT plot is shown below:



#### 7.5.4 Periodogram

This plot allows the user to view the best correlated time period for the data sets loaded. Three scroll bars are provided below the plot that allow the user to set the maximum period, minimum period and the resolution (in minutes). Choose the data to be included in the analysis from the 'Select Days' menu (4 or more consecutive days are required). The Periodogram will be plotted showing a peak and the correlated best fit for the time period displayed. An example is shown below:



#### 7.5.5 NPCRA Analysis

#### Introduction

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

#### Reference

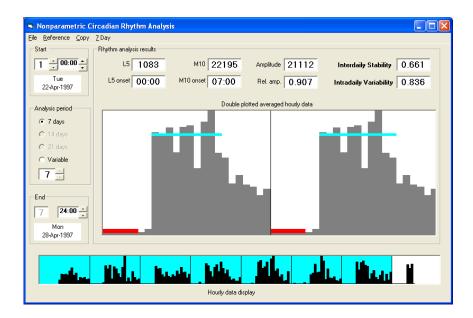
The NPCRA analysis is based upon the work of Dr. Eus Van Someren at the Netherlands Institute for Brain Research <a href="mailto:e.van.someren@nih.knaw.nl">e.van.someren@nih.knaw.nl</a>. The original paper published by Dr. Van Someren is:

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

#### **Analysis**

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

To select the analysis days, use the 'analysis period' control at the left of the display to select 7, 14 21 or variable number of days. Note also that the analysis is sensitive to periods of inactivity when the Actiwatch has not been worn.



#### **Non-Parametric Variables**

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

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

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

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

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

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

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

## 7.6 Actogram Options Menu

**Time bars:** The 'Time bars' function on the 'Options' menu allows the user to select to either view or hide the time bars shown at the top of the Actogram screen.

**Tau Line:** This option allows a free running rhythm (Tau) value to be calculated from the data loaded, if it is suitable. Select 'Tau Line' then click and drag with the left mouse key to mark the start and end of the Tau line where required (usually activity onset or offset). A value for Tau, which will automatically be updated as the line is moved, will be displayed at the top of the screen. Selecting the 'Redraw' option at the bottom left of the screen will refresh the Actogram and remove the line and the Tau value from the display. **Graticule:** By selecting 'Options' and then 'Graticule' the graticule lines on the Actogram can be switched on and off.

#### 7.7 Actogram File Menu

#### 7.7.1 Load

Selecting 'File' and then 'Load' allows a new AWD file to be opened for analysis without leaving the Actogram window.

#### 7.7.2 Edit Data

This function allows periods of data to be edited (replaced). See section 10.2 for details.

#### 7.7.3 Colours

If the file loaded contains secondary data (i.e. non-activity data), it is possible to change the colour in which the secondary data is displayed for clarity. **The AW Mini does not support secondary data.** 

#### 7.7.4 Print Actogram

Selecting 'Print' from the file menu brings up the following screen:



This allows the user to specify the parameters to be printed. Correctly setting these parameters and then selecting 'Confirm' will print the selected parameters.

#### 7.7.5 Printer setup

Selecting 'Printer setup' displays a standard Windows printer dialog. This allows the user to select which printer is used for printing and to alter the page setup when printing.

#### 7.7.6 Load setup

This function loads previously saved settings for controls and menu options if they have been saved by the user. For a full list of these settings please see section 7.7.7.

#### 7.7.7 Save setup

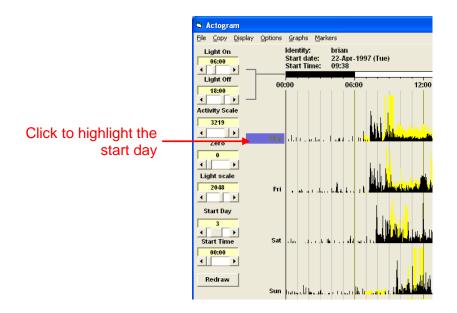
This Function saves the current control settings defined by the user. The parameters that will be saved are as follows:

- Light on
- Light off
- Activity scale
- Zero
- Start day
- Start time
- Time bars (on/off)
- Graticule (on/off)
- Length (20 days/60 days/auto)
- Single day/dual day plot as default
- Day/date displayed as default

## 7.8 Exporting Actogram Data

#### 7.8.1 Copy Menu

It is possible to copy parts of the Actogram either a day at a time or in a block of 7 or 14 days. To do this, click on the Actogram to the left of the required day as shown below:



The required day is highlighted in blue. It is then possible to access the 'Copy' menu. Selecting 'Copy' brings up the following options:

- Single day copies activity data for the selected day to the clipboard
- 7 days copies activity for the selected day and the following 6 days
- 14 days copies activity for the selected day and the following 13 days

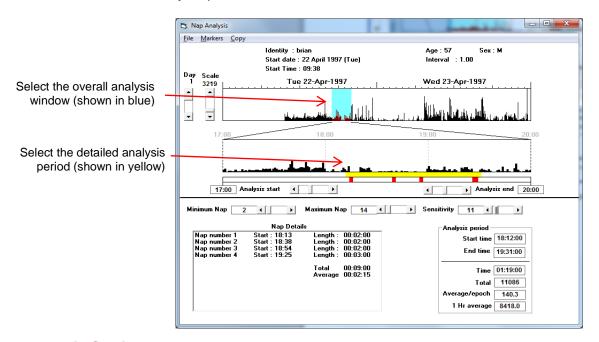
## 8 Nap Analysis

The Nap Analysis section of the Actiwatch sleep and activity software is designed to allow the user to look for periods of activity below a user definable threshold. This is useful for analysis periods of daytime drowsiness or micro-sleep events.

#### 8.1 Selecting the Analysis Period

From the front screen, select the 'Nap Analysis' menu to open the nap analysis window. First select the required day for analysis using the 'day' slider control. Next select the general period of interest by using the left and right mouse buttons to select the start and end of the analysis window in the **upper** graph.

Now repeat the process in the **lower** graph to select the detailed analysis period:



#### 8.2 Analysis Settings

#### 8.2.1 Minimum Nap

The user can define the minimum period of inactivity required to be scored as a nap. This can be set to a value of between 1 minute and 20 minutes.

#### 8.2.2 Maximum Nap

It is also possible to define the maximum amount of time to be scored as a nap. This value can be set to between 6 minutes and 3 hours but must be >5 minutes higher than the minimum nap figure.

#### 8.2.3 Sensitivity

The sensitivity value can be set between 0 and 100. This is the threshold below which inactivity is scored as a nap. It is equivalent to the number of counts in the epoch. For example if the sensitivity value is set to 5 then if an epoch has fewer than 5 counts in it then that epoch is scored as napping. Please note that in order to avoid periods of low activity such as television viewing being scored as napping, it is recommended that the threshold is set to 0.

#### 8.3 Nap Analysis Results

The 'Nap Details' screen shows the following information:

- Nap number
- Start time
- Nap length
- Total nap length
- Average nap length

Please note that if no period of time fulfils the criteria set then this screen will be blank.

#### 8.4 Exporting Nap Data

#### 8.4.1 Copy Menu

Nap Details: this function copies the information displayed in the 'Nap Details' box as shown in the screen shot above to the clipboard for use in a third party program such as Excel.

**Analysis:** this function places the information from the 'Analysis period' box onto the clipboard for use in a third party program such as Excel. Please note that in order to be able to copy analysis data, an analysis period must previously have been selected. Please see section 8.1 for details.

#### 8.5 Printing Nap Data

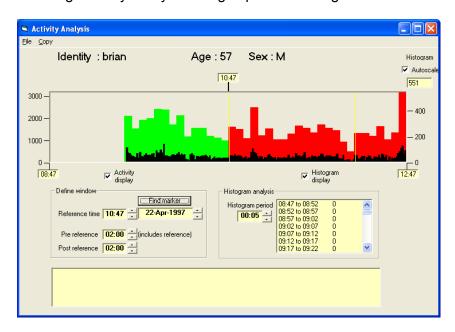
Select 'Print' from The 'File' menu to provide a printed report which shows the analysis information including the graphs, user info and results for the current analysis.

# 9 Activity Analysis

The activity analysis section of the software is designed to allow the user to analyse a period of activity in more detail. It is ideal for examining activity pre and post administration of a drug or therapy. Up to 24 hours prior to and following a reference time can be analysed.

# 9.1 Analysing a file using Activity Analysis

Selecting 'Activity Analysis' brings up the following screen:



# 9.2 Activity Analysis Controls

### 9.2.1 Reference time

This is set to demarcate the pre and post reference times and is shown on the top of the screen shot above.

#### 9.2.2 Pre reference

This is set to define the pre reference analysis period. It can be set up to 24 hours before the reference time.

#### 9.2.3 Post reference

This is set to define the post reference analysis period. It can be set up to 24 hours after the reference time.

### 9.2.4 Histogram period

The histogram period is user selectable and a value greater than 1 min can be selected. The activity data is averaged for the epochs in the histogram period.

#### 9.2.5 Activity display

When the 'Activity display' box is ticked, the activity data is displayed in black as shown on the screen shot above. If this is un-ticked then the activity data is not displayed.

# 9.2.6 Histogram display

When the 'Histogram display' box is ticked, the histogram data is displayed in red and green as shown on the screen shot above. If this is un-ticked then the histogram data is not displayed.

#### 9.2.7 Autoscale

Leaving the 'Autoscale' box ticked allows the software to best display the data loaded. It is recommended that this box is left ticked.

Once the above parameters have been set, the average activity per epoch within each histogram period is shown in the box on the lower right hand side of the screen.

# 9.3 Exporting Activity Analysis Data

# 9.3.1 The Copy Menu

**Histogram data:** This option copies only the histogram data in counts. No time data is displayed. An example of copied data is shown in column A below.

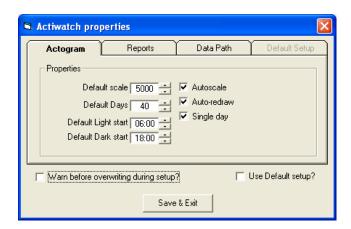
**Times and data:** Selecting 'Copy' and then 'Times and data' copies both the histogram data in counts and the time covered by the histogram period. An example is shown in column B below Activity data: Selecting 'Activity data' copies the activity data for each epoch along with the time of the epoch. An example is shown column C below.

**Daily activity data**: Selecting 'Copy' and 'Daily activity data' copies the time stamped activity data for each epoch for each day. An example is shown in Column D below.

# 10 Advanced Functions

# 10.1 Properties

From the front screen, selecting 'File' and then 'Properties' brings up the following screen:



This screen allows a number of preferences, properties and default settings to be applied to the software. The settings are saved and automatically re-loaded each time the software is run.

#### 10.1.1 Warn before overwriting during setup checkbox

It is possible to activate a warning which is shown before an Actiwatch is set-up. By ticking the box 'Warn before overwriting during setup' the following warning message is displayed when an Actiwatch is being set-up:



Selecting 'Yes' allows the user to proceed with the setup. Selecting 'No' aborts the setup procedure. The aim is to remind the user to download the data before setting-up for a new recording.

## 10.1.2 Use Default setup checkbox

It is possible to specify a default setup for certain parameters by ticking the 'Use default setup' tick box. See section 3.2 for details.

#### 10.1.3 Actogram tab

The Actogram tab allows the user to alter the following parameters:

**Default scale:** This is the default scale used when an Actogram is displayed. The software default value is 5000 which is the maximum allowable value.

**Default Days:** This is the number of days shown when an Actogram is displayed. The software default is 40 days and the maximum allowable value is 60.

**Default Light start:** This is the default for the 'lights on' value shown on the left hand side of the Actogram screen. The software default value is 06.00

**Default Dark Start:** This is the default for the 'lights off' value shown on the left hand side of the Actogram screen. The software default value is 18.00

## 10.1.4 Actogram tab

The reports tab allows the user to select what information is included on printed reports. This includes the option to include:

- User name free text field
- Date/Time selected by tick box
- Watch serial number selected by tick box
- User name selected by tick box
- Actiwatch read date selected by tick box

#### 10.1.5 Data Path tab

The Actiwatch data path tab allows a default data path to be selected for saving Actiwatch files to. The software default path is C:\program files\actiwatch sleep 7

This may be changed to a local or network drive folder as required.

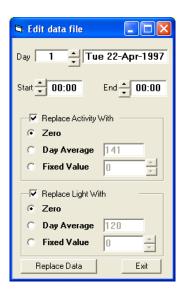
#### 10.2 Edit Data

Selecting 'Edit file' brings up the following screen:

This allows the user to edit AWD files to replace specific periods with aero, day average or fixed activity values.

The procedure for editing is as follows:

- Select the day/date of the file to be edited.
- Enter the start and end times required (all times are in 24 hour format).



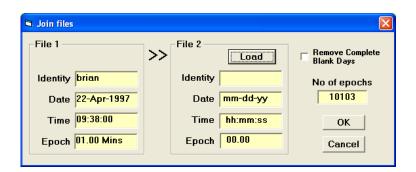
- Select the format to replace the activity data with. This can be one of three things:
  - o Zero
  - Day average for the selected day
  - User enterable fixed value
- Click on 'Replace' to replace the value.
- Edited files are saved as 'filename (edited).awd' to differentiate them from the original files.
- The Actogram for the edited file can now be displayed.

## 10.3 Join Data

It is possible to join two Actiwatch AWD files together. It is important to note that when joining files, the epoch lengths of the 2 files joined must be the same. Ideally the files should also be from the same Actiwatch.

To join two files it is necessary to follow the following steps:

- Firstly load the earlier of the 2 files to be joined (this must be the file with the earlier date).
- Selecting 'File' and then 'Join files brings up the following screen:



- Clicking on 'Load' then lists the files available for joining to the previously loaded file.
- Selecting the tick-box 'Remove Complete Blank Days' brings up the following message. When this option is selected, complete blank days are removed and part days are filled with zeros to maintain timing. If this option is selected then the 2 files will be displayed sequentially ignoring the start date of the second file:



• If compatible, the two files will be joined and the following message displayed:



The new file has been created and is automatically named joined.awd

It is important to note that each time a new joined file is created, it is named 'joined.awd' and the previous joined file is overwritten. To avoid this it is important to re-name joined files as soon as they are created.

## 10.4 Change Epoch

From the Actogram – display menu, it is possible to change the post hoc analysis epoch to one greater than that with which the recording was made. For example, it is possible to load a recording made with 1 minute epochs with a 1 hour epoch and in this case 60 one minute epochs would be combined to produce a 1 hour epoch.

Please note that this action should only be performed once as it is not possible to, for example, go from 1 minute to 1 hour and then back to 1 minute. Should this be required, it is necessary to reload the original file. Changing the analysis epoch does not alter the original data.

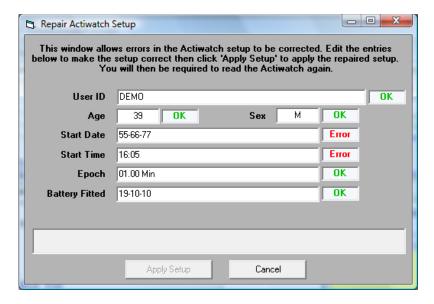
# Appendix A – Troubleshooting & Maintenance

#### A1 - Test Actiwatch

This function will test various functions of the Actiwatch Mini. Note that **all data will be lost** during this process hence ensure the Actiwatch is downloaded before commencing. If any stage of the test fails, please contact CamNtech.

# A2 - Repair Actiwatch Setup:

The Actiwatch software attempts to automatically detect errors in the settings during both the set-up and download phases. If an Actiwatch is downloaded and errors are detected in the settings, a warning will be displayed and the user will be offered the option to attempt to repair the settings. The following 'repair setup' screen will be displayed:



Each item in the setup is checked and will be flagged as 'error' if there is a problem. In the above example the start date is corrupted, note that the start time is correct but both date and time are checked and flagged as one error in the software. To correct this error, the user may enter the correct start date in the format DD-MM-YY (ONLY!) then click on 'apply setup'. The watch settings will be repaired and it should be possible to then download the watch normally.

Note also that the User ID, age and sex are treated as one error hence all three may be flagged when only one item is incorrect. If all of the settings show as corrupted, there may be a read error. In this case, select 'cancel', and then try re-positioning the Actiwatch and re-downloading.

# A3 - Things to try before contacting CamNtech

CamNtech is confident that the user should have a trouble-free time when using the Actiwatch system. However, some easily solvable problems may occur examples of which are given below.

- Reader red light does not come on when the Actiwatch is placed on it and/or the PC will not communicate with the Actiwatch:
  - Check the Communication links is the USB reader recognised, are the USB drivers correctly installed (see Appendix C)?
  - Is the Actiwatch on the Reader in the correct orientation the arrow should point upwards indicating correct orientation (see section 2.7).
  - Try adjusting the position of the Actiwatch slightly on the reader.
  - Does the battery in the Actiwatch need changing?
  - Is the Actiwatch placed Plastic Lid side down i.e. is the ID number visible?
- 2. The PC will not let the user access the Software:
  - The software must be installed and RUN with administrator permissions.

If there are any other problems with the Actiwatch system or for any technical queries please contact technical support. Please try to have the serial number from your Actiwatch and details of your software version when making contact.

## A4 - Changing the Battery

The Actiwatch Mini has been designed to facilitate user battery changing (Data will not be lost).

Battery is a standard coin cell type **CR1220**:

- The change the battery, remove the three screws from the rear of the Actiwatch Mini Casing.
- Remove the metal rear cover this may be stuck slightly with sealant.
- Remove the old battery.
- Place a new battery ensuring correct orientation. (i.e. positive (+) side outwards).
- Carefully align the rear cover and press down while tightly securing the fixing screws.
- Download or set-up the Actiwatch as required.

# Appendix B – Safety & Environmental Information

#### **B1** - Decontamination

- Devices used in the field must be considered to be contaminated.
- Returned devices must be cleaned with alcohol wipes to minimise any potential contamination. The operator should use gloves to handle such devices before and during decontamination.

### B2 - Battery

- The device is battery operated and operates at voltages below 5V DC; there is hence no risk from electric shock.
- The battery is user replaceable (refer to Appendix A).
- The battery is a standard Coin Cell type CR1220.

# B3 - Warnings - general

- The Actiwatch Mini is not defibrillation proof.
- The Actiwatch Mini is not indicated for use on humans.

# B4 - 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

# Appendix C - Manually Installing USB Drivers

For older USB Readers, a firmware update may be required for use with Windows 8 or 10 – please contact us for advice. Sometimes the automatic installation of drivers will not work, often because your computer has previously had similar, but different, drivers installed on it before and sometimes because of flaws in the Windows installation process. Also, new versions of Windows may require updates to the USB drivers.

To download the latest USB drivers please visit our website at the link below:

### http://www.camntech.com/drivers

To install drivers manually, follow the procedure below.

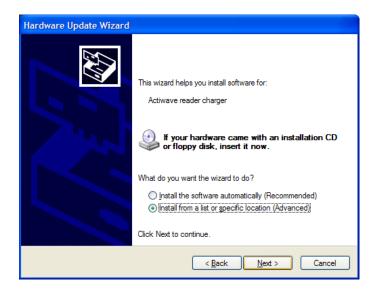
## To begin installing drivers:

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

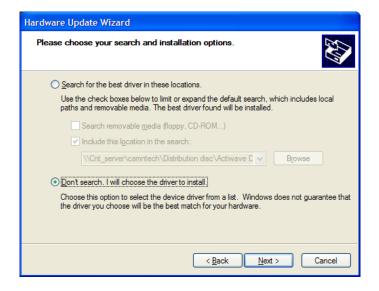
- Click on the Start menu, and open the Control Panel.
- Open 'System'. If you can't see this, choose 'Performance and Maintenance', then 'System'.
- Select the 'Hardware' tab, and click the 'Device Manager' button
- Scroll down and open up the section called 'Universal Serial Bus controllers'. The device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



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

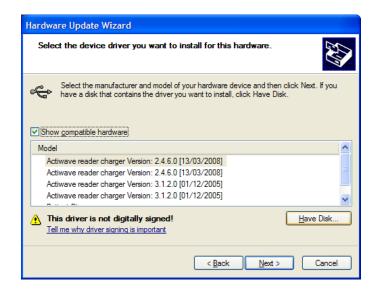


 Select 'Install from a list or specific location (Advanced)' and click 'Next'.



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

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



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



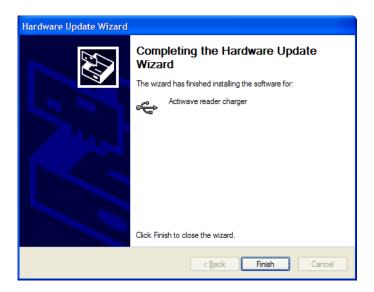
Click on 'Browse...' and then use the standard file window to find the 'USB drivers' folder on the CD. Select 'ftdibus.inf' from this folder and click on 'Open'. The window above will re-appear with a filename at the bottom. Then click 'OK'.



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



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



When this window appears your drivers are installed.

If you still have issues installing the USB drivers then please check our website for up to date information, at the link below:

http://www.camntech.com/drivers