Sleep Diary

User Guide

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$C\mathepsilon$

The PRO-Diary is a Class I Medical Device (EU)

PRO-Diary Motion Regulatory Information

Medical Device Directive (European Union)

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

US FDA status

The PRO-Diary is FDA cleared for prescription use only with FDA 510(k) number K132764.

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Australian Sponsor:

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

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Applicable Standards:

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

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

IMPORTANT SAFETY INFORMATION

WARNINGS

- Not Defibrillation proof.

- Not indicated for use on areas of broken, damaged or irritated skin.

- Devices removed from subjects must be considered to be contaminated – see SECTION 9.

Safety Classification Information:

- PRO-Diary Motion is **INTERNALLY POWERED EQUIPMENT**.

- PRO-Diary Motion mode of operation is **CONTINUOUS OPERATION.**

- PRO-Diary Motion is for **PRESCRIPTION USE ONLY** (**R$_X$ only**) in the USA

Device and Packaging Symbols and Markings:

MEANING	SYMBOL	DESCRIPTION
General Warning		Potential hazard - refer to the warnings in the instructions for use (i.e. this user guide).
Consult Instructions for Use		This symbol indicates that important operational information is contained in the user instructions (i.e. this user guide).
Ingress Protection Rating	IP42	The PRO-Diary is not suitable for immersion in water (splash-proof – avoid contact with liquids if possible).
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 PRO-Diary is a **TYPE B APPLIED PART**. (Internally Powered – no mains connection)

FOR FURTHER HANDLING & ENVIRONMENTAL INFORMATION PLEASE REFER TO SECTION 12

Contents

1 Introduction to the Sleep Diary System

1.1 An Overview of the Sleep Diary

The Sleep Diary system uses a PRO-Diary worn on the wrist which prompts the wearer with standard questions for sleep and alertness monitoring. The results are collated and presented in a standard report by the included PC software. The overall system combines wrist-worn actigraphy with an electronic diary, presenting the subjective and objective data in a single easy to use report.

The PRO-Diary incorporates a tri-axial accelerometer to allow objective actigraphy data to be collected while the device is worn. The PRO-Diary has a direct USB connection for setting up, downloading and charging the battery. See Section 3 for details of battery charging and expected life.

The PRO-Diary has a clear, high contrast OLED. The front panel keys are touch sensitive and require no force to operate. There are three main controls: the function key which has multiple functions, the select key which is generally used to choose a selection and slider control which allows precise item selection by means of left or right swiping movements.
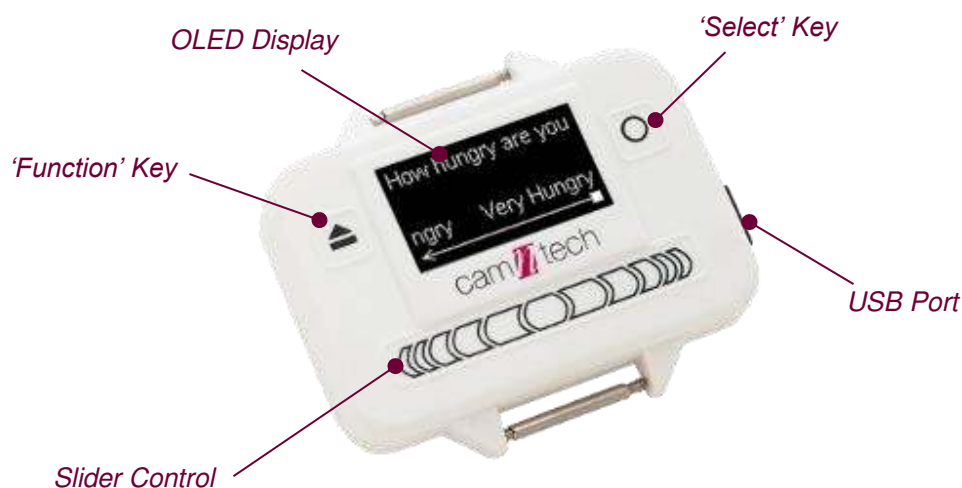
1.2   Indications For Use

The PRO-Diary 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 PRO-Diary can be used to assess activity in any instance where quantifiable analysis of physical motion is desired.

The PRO-Diary has a built-in score pad that allows the wearer to subjectively assign and enter responses to pre-programmed questions. The score pad can be used as a substitute or in addition to the traditional written patient diary in conjunction with activity monitoring.

1.3   Contraindications

The PRO-Diary Motion 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.

1.4   Required Skills, Training & Knowledge of Intended Users.

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

1.5   General Description of Use

The PRO-Diary Motion provides patient diary functionality by means of PC software based questionnaire configuration and upload to the device. The device will automatically prompt the subject for input at pre-defined intervals or, depending upon configuration, upon user request. The responses to the questions are recorded to internal non-volatile memory and the date may then be downloaded using the PC software. The resulting data may be exported for further analysis in third party software packages.

The PRO-Diary Motion 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. Activity data recorded by the PRO-Diary may be analysed off-line using the MotionWare Software Package.

2 Installing the Sleep Diary Software

2.1 System Requirements

The Sleep Diary software is supplied on a CD-ROM containing all of the components required to install the software package. The following are the minimum requirements of a host PC for installing the PRO-Diary software:

- Windows Vista, 7, 8 or 10 operating systems.
- One free USB port
- A CD-ROM or DVD drive for software installation

In general, a faster processor will provide superior performance.

2.2 Software Installation Menu

Place the CD-ROM into the drive; Windows will offer to run the installation program and you should select this. Note that the installation will differ for new users and existing users as described in **Section 2.3** below.

A message warning that 'Publisher cannot be verified' may be displayed at some point – click 'Run' to accept. (this is a Windows security warning and is not a problem).

Note that the software requires the Microsoft .NET Framework 4 to operate – this will be automatically installed if not present, but may require an internet connection to do so.

2.3 Users upgrading from an earlier version of the Software

Upon following the procedure described in **Section 2.2**, users upgrading older versions of software may be asked if they wish to repair or remove the existing version of the software when the new software installation is run for the first time. The option to **remove** should be selected and then the software installation run for a second time to install the new version as described in **Section 2.2**.

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).
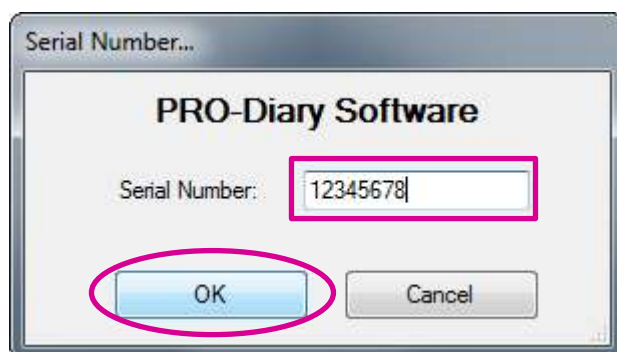
2.4 Installing the USB Drivers

When the first PRO-Diary is connected to your computer, Windows will attempt to detect and automatically install drivers to communicate with it. These can be tested by attempting to use the Sleep Diary PC software.

If the correct drivers cannot be installed automatically, then proceed to the CamNtech website to check for the latest available driver instructions in the support section.
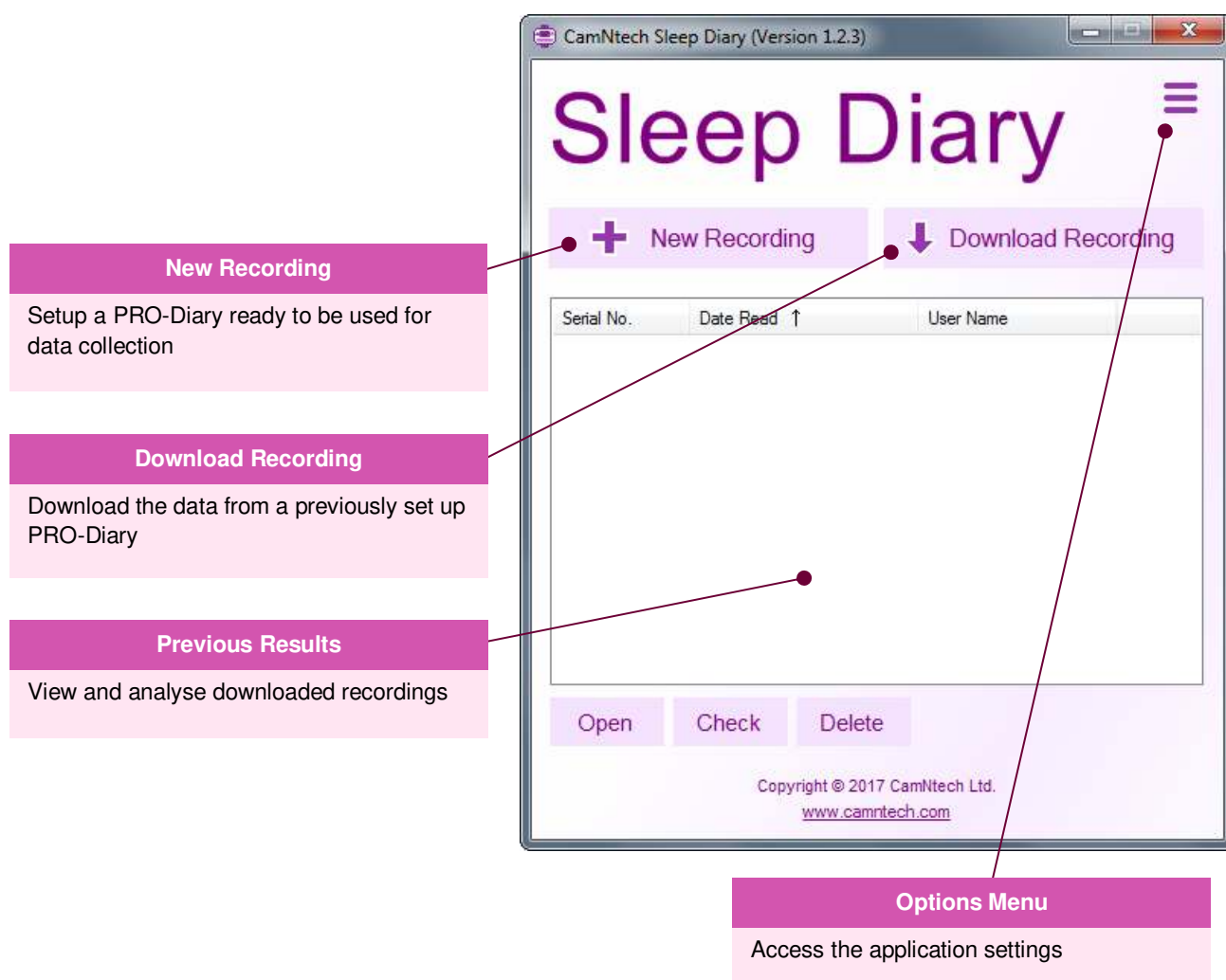
2.5   Using the software for the first time

Double clicking on the Sleep Diary icon on the desktop will start the software.

You will be prompted to enter a serial number when you first run the application. Enter your serial number and click the **OK** button to apply it.

The main menu will be shown as below.

New Recording

Setup a PRO-Diary ready to be used for data collection

Download Recording

Download the data from a previously set up PRO-Diary

Previous Results

View and analyse downloaded recordings

Options Menu

Access the application settings

3 Charging the PRO-Diary Battery

The PRO-Diary contains a lithium polymer rechargeable battery. The life of the battery is very dependent on usage of the unit – more frequent and longer interactions will be more demanding. However it should be at least 14 days in normal Sleep Diary use.

Before the Diary can be used, the user must ensure that it is fully charged. You may charge it directly from the PC, from a mains power supply or from a separate USB hub. It will typically take around **3-4 hours** for the PRO-Diary to be fully charged.

3.1   Charging the Diary from the PC

Connect the Diary to a free USB port of the PC and it will be automatically charged from the PC. If you connect multiple Diaries to the same PC at the same time, windows will attempt to find extra drivers. This will generate windows/warnings which can be safely cancelled. You may only communicate with a single Diary but as long as your PC is capable of it, several should charge together.

Note that many PC's have power saving functions which may shut down the USB ports after a period of time; this will stop the diary charging until normal operation is resumed. If you any issues related to charging or battery life, we recommend using a mains power supply for charging to avoid this issue.

3.2   Charging the Diary using the Mains Power Supply

The PRO-Diary may be recharged using a mains adaptor with a standard USB power output (the type often used for charging MP3 players or phones). Please ensure any such adaptor is safety approved to EN60950-1 and EMI standard EN55022 (also FCC part 15, Class B for the USA).

1. Select and fit appropriate *ac input* socket adaptor for country of use.
2. Plug the USB cable from the Diary directly into the USB socket on the mains power supply adaptor.
3. The Diary will be automatically charged.

CamNtech can supply a suitable mains power supply if required – please contact your local distributor.

3.3   Charging Several Diaries from a USB Hub

A USB extension hub may be more convenient to charge several PRO-Diary devices at once without requiring a PC to be connected. This hub must be powered by a separate mains adapter itself. CamNtech have tested the PRO-Diary with a Belkin 4-Port Hub; other hubs with a separate mains adapter are also likely to work, but CamNtech have not tested against them.

CamNtech can supply a suitable powered USB Hub if required – please contact your local distributor.

4 PRO-Diary Setup/Download

4.1 Introduction

A Sleep Diary recording consists of questionnaires and motion logging. The questionnaires have been carefully designed and tested by an independent party and cover sleep, alertness and mood. The questionnaires are completed at various times of the day. The scheduling of the questionnaires is as follows:

Questionnaire	Type	Time
Bed Time	On user request	Every evening (18:00-04:00)
Woke Up	On user request	Every morning (04:30-15:00)
Mood, Alertness & Sleepiness	Automatic	All Day

4.2 Creating a Results Database

A results database has to be created to store your downloaded recordings. Click the **Options Menu** to open it and the click the **Settings** menu item to open the settings window.
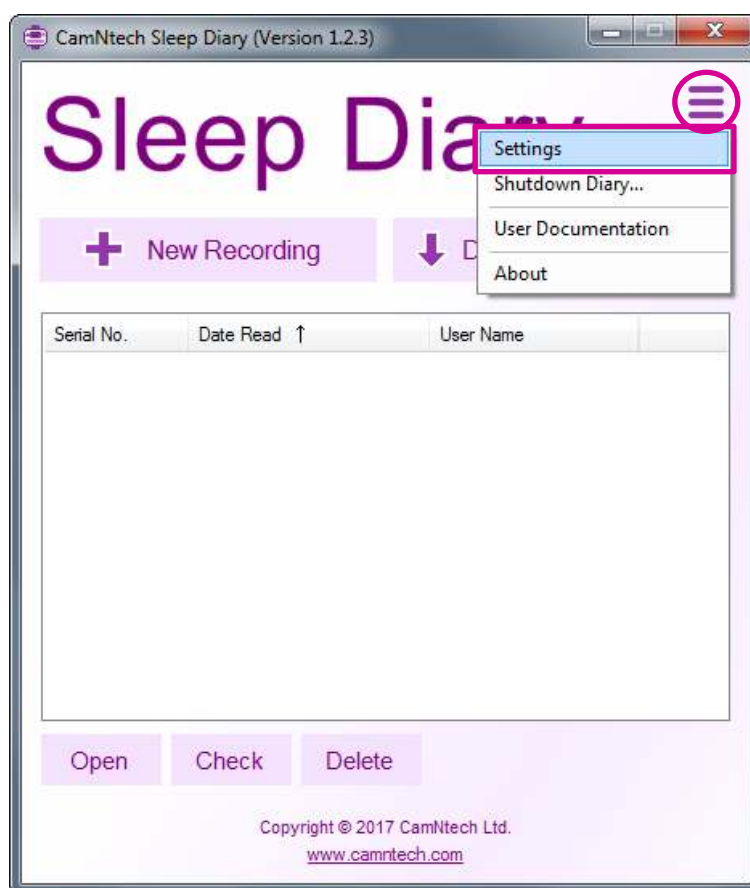
Click on the **Database** option to show the database settings.
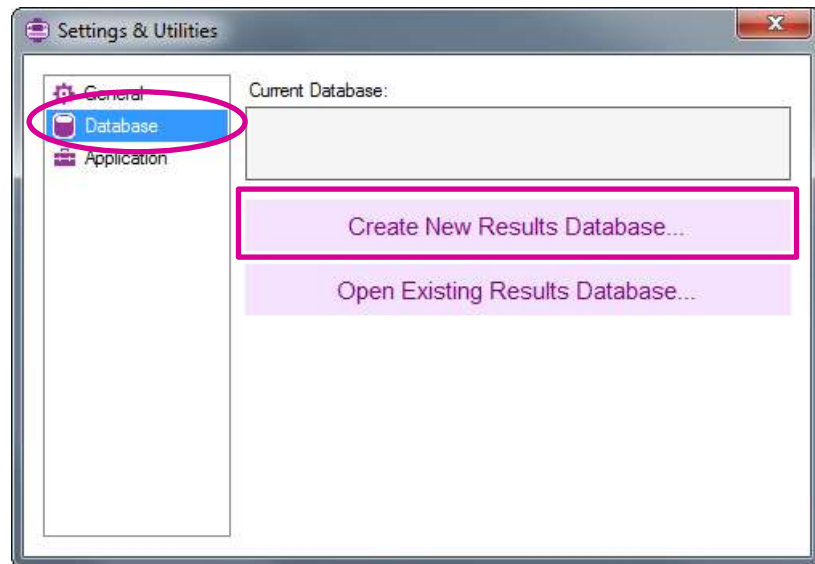
Click the **Create New Results Database…** button to open the file save dialog box. Select a save folder, enter a filename and save to create the database.

You can now close the settings window.

4.3   Running the Setup

Connect a PRO-Diary to the computer using the USB cable provided by CamNtech. **Please note: using your own USB cable may cause connectivity issues due to the type/size of the connector.**

Click on the **New Recording** option on the main menu to show the Recording Setup window.

Enter a User ID in the **User ID** box – this will be used to identify the recording when it has been downloaded.

The Diary can either be set up for **Sleep Only** (Bed Time + Woke Up questionnaires) or for **Sleep & Alertness** (Bed Time, Woke Up and Mood, Alertness & Sleepiness questionnaires). Select your desired setup type by clicking the corresponding option box.

The Diary can be configured with a screen lock to prevent unintentional inputs. To enable this on the Diary, ensure the **Enable Key Lock** option is checked.
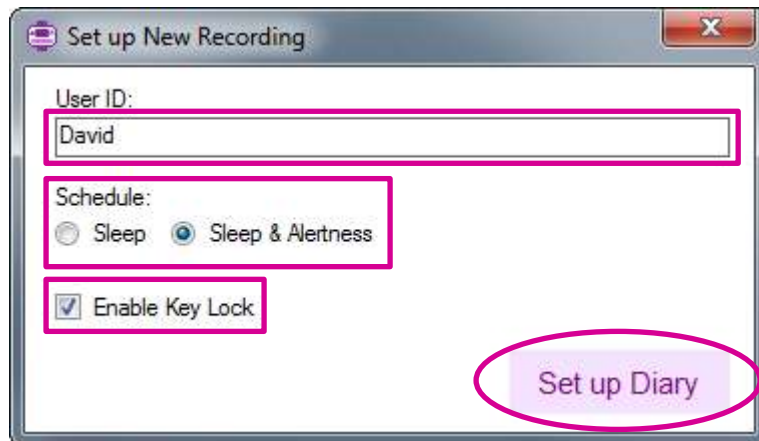
Click the **Set up Diary** button to send the setup to the Diary.
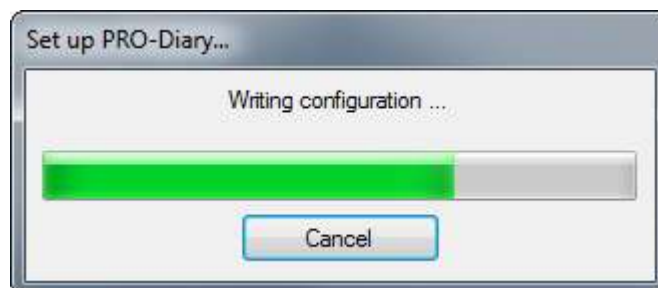
Once complete, remove the Diary from the computer.
It is now ready to be used.

4.4   Using the Diary

The Diary should now be worn by the subject to collect movement and question data over a number of days. Brief instructions for this are provided in the **Sleep Diary Quick Guide** which should be handed to the subject along with the Diary. **Please note: the PRO-Diary is NOT waterproof.**

4.5   Downloading a Recording

Connect a previously set-up Diary to the computer using a USB cable.

Click on the **Download Recording** option on the main menu.

The application will immediately begin downloading the recording from the
Diary.
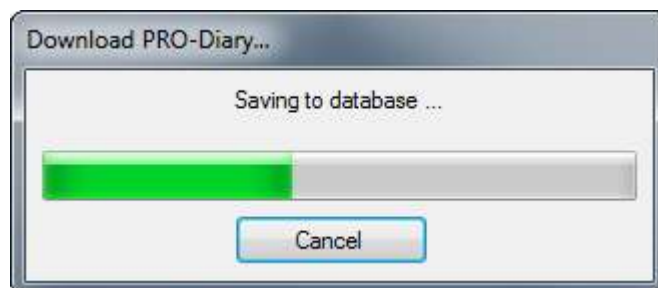
Once complete, a completion dialog box will be shown which contains options
to shut down the Diary, or leave it running to continue to capture data. Select
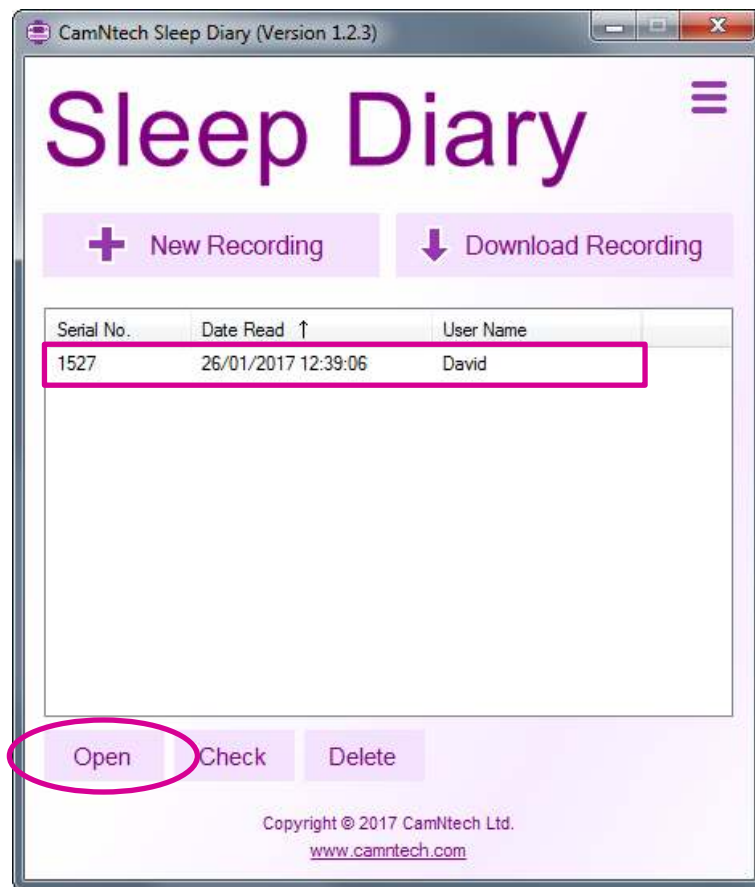the **Shutdown** option in this case.
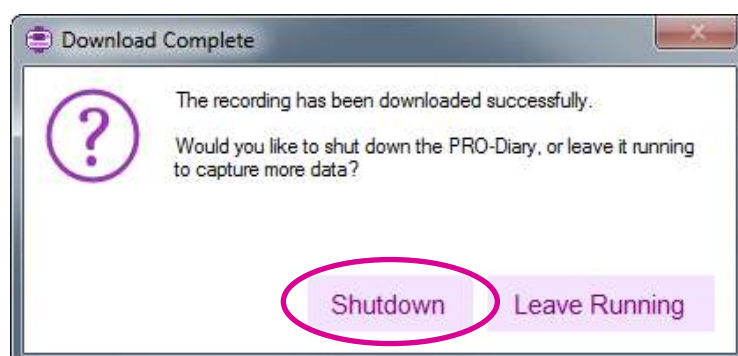
The Diary can be disconnected from the computer.

The newly downloaded recording will be automatically saved to your chosen Results database and the recordings list will show the new recording.
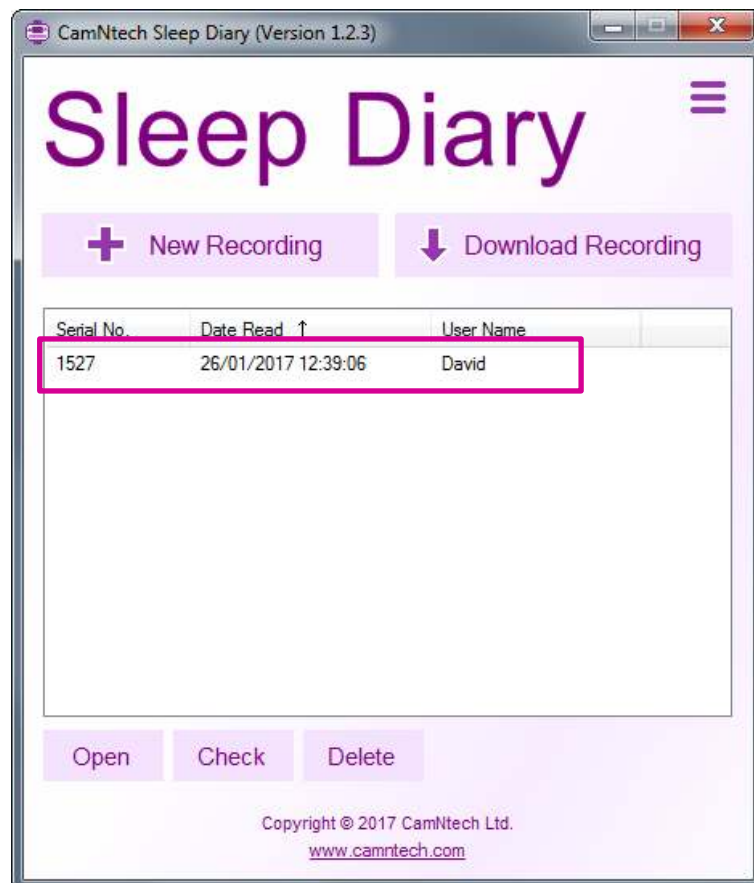
5 Opening Recordings for Analysis

5.1 Open Recordings

To open a recording, click on its entry in the recordings list and the click the **Open** button. You can also double-click on the entry itself.

5.2 Checking Recordings

The first time a recording is opened a recording check window will be shown.

The Sessions Check window allows you verify each of the questionnaire answer sessions which have taken place throughout the recording.

The list of items contains each day in which at least one attempt at answering a **Woke Up** questionnaire was performed. This is to account for instances where the user may have chosen to answer multiple times, for example if the user was interrupted during one attempt and decided to attempt the questionnaire again at a later time during that day.
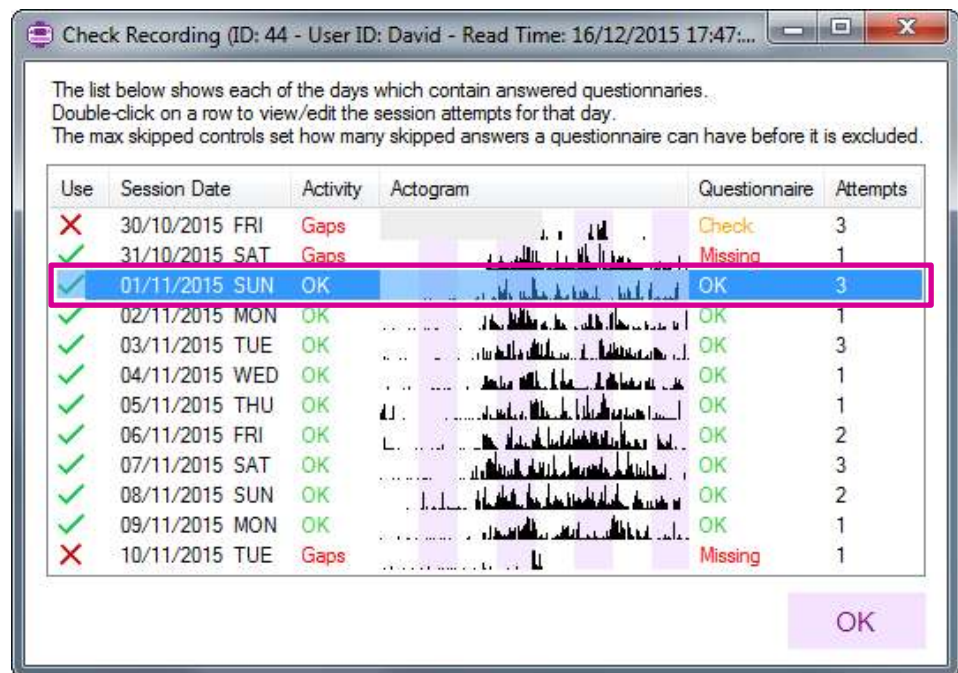
The software automatically analyses each attempt and picks the best attempt for days where there is more than one attempt.

The software flags any days where the best questionnaire attempt for that day looks to be incomplete. This is shown in the **Questionnaire Status** column.

The software also flags any days where there appears to be a large amount of empty motion data. This is shown in the **Activity Status** column.

To choose a different questionnaire attempt for a day, double-click on the **day entry in the list**. Then in the window which is shown, click on the column heading for the day you would like to use. The attempt which will be used will have its entire column highlighted in green. Click the **OK** button to confirm the selection.
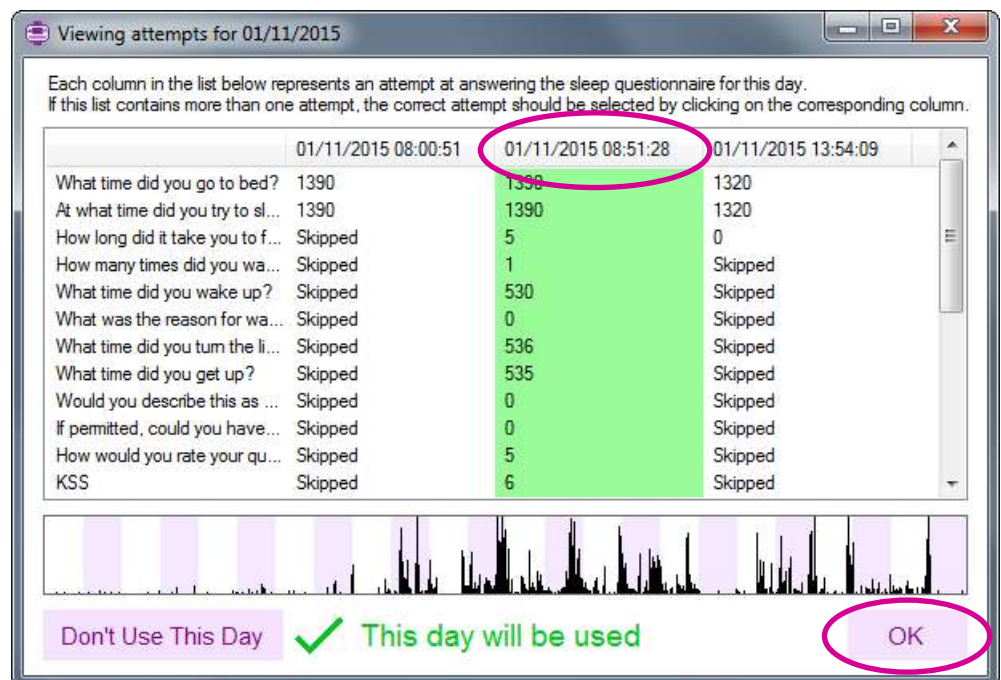
You can also exclude the entire days' worth of questionnaire attempts by clicking on the **Don't Use This Day** button. None of the selected day's questionnaire data will be used in the subsequent analysis.
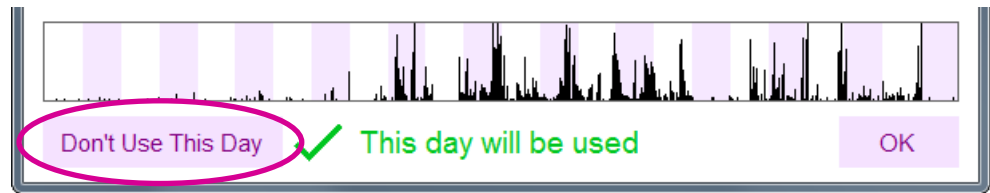

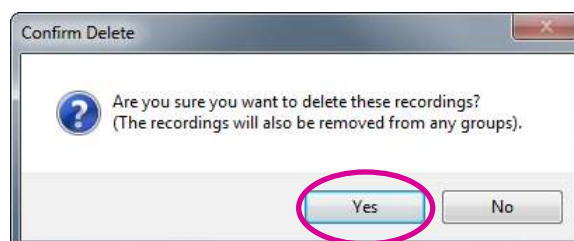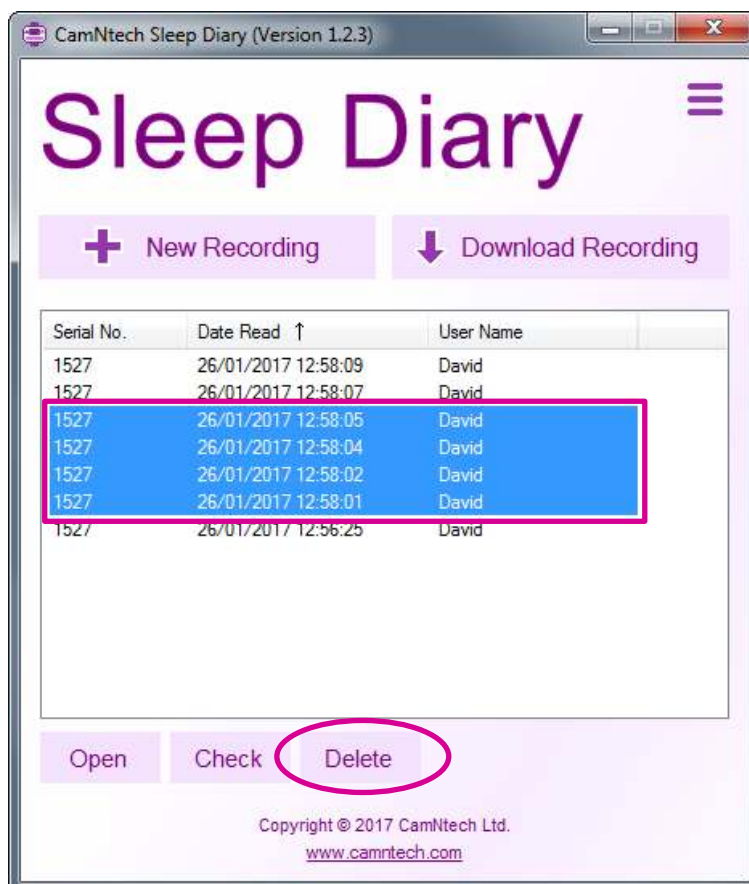The form will switch to the following:

Click the **OK** button to confirm the options and continue loading the recording for analysis.

The Sessions Check window will not show again automatically. To check a recording again, select the recording in the recordings list and click the **Check** button. The Sessions Check window can also be run from within an analysis window, by clicking the **Check** menu item.
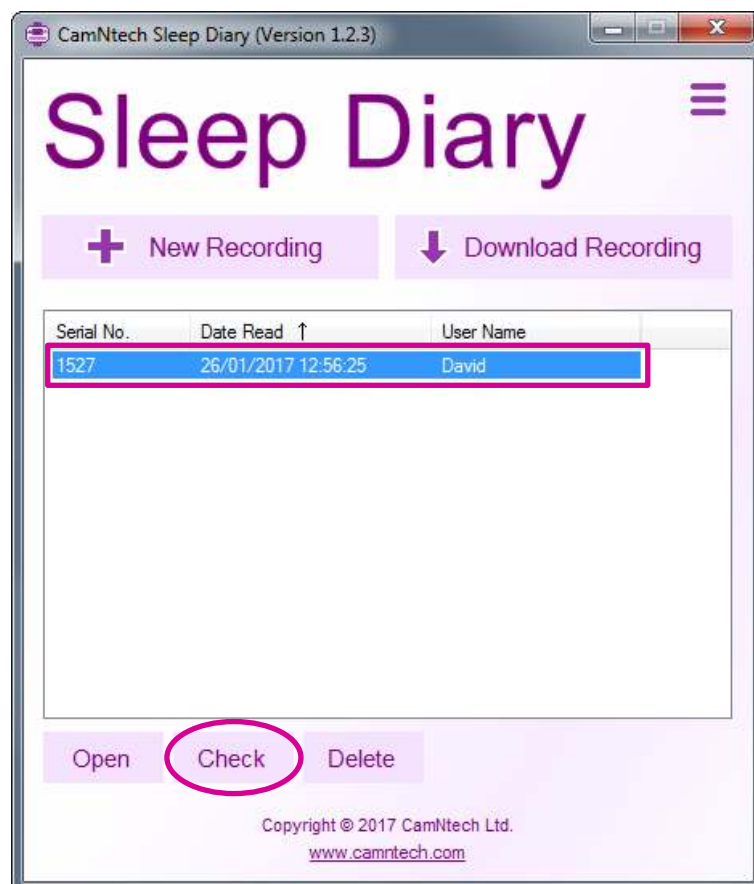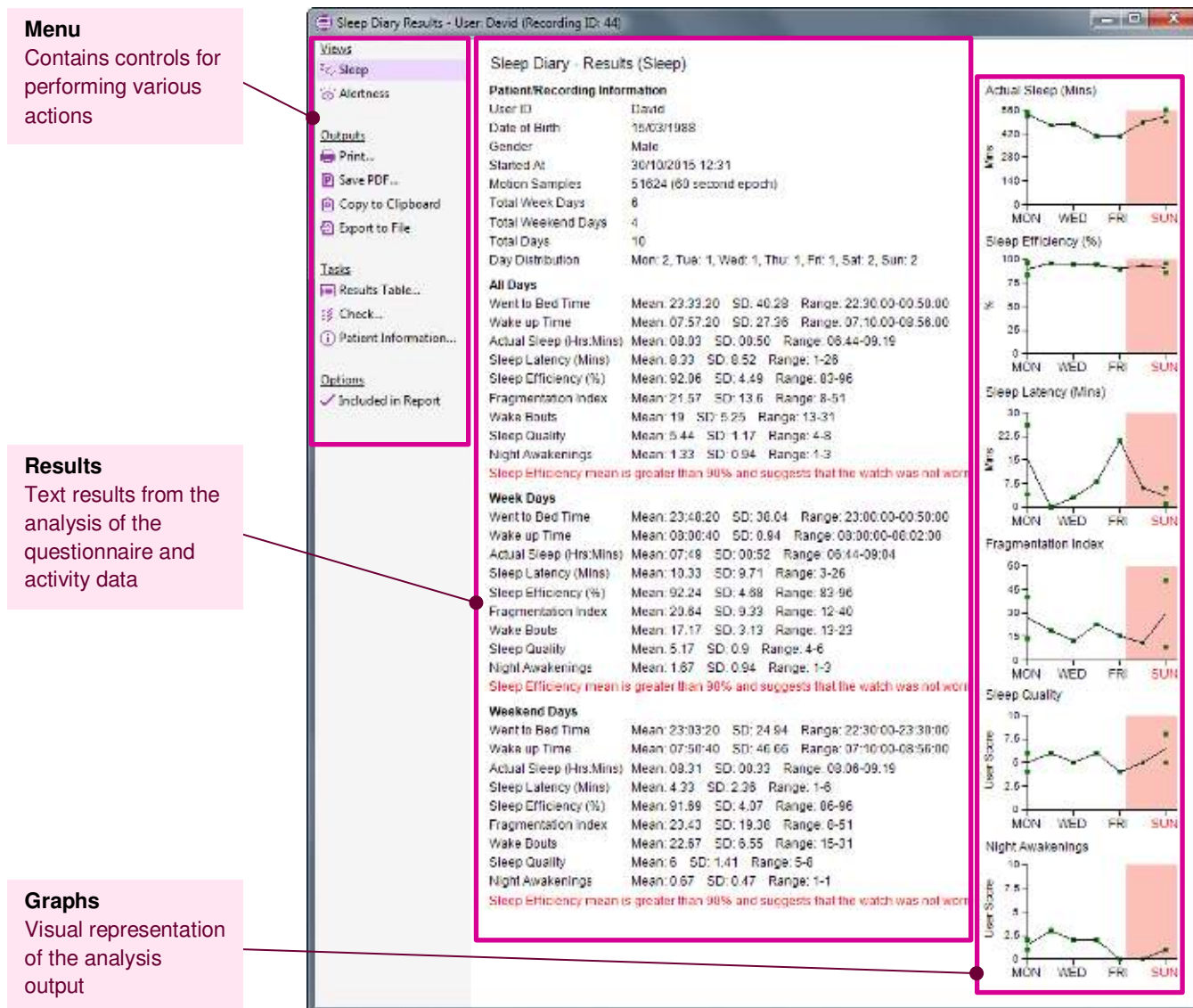
5.3   Deleting Recordings

Click on a recording to select it, or drag the mouse cursor to select multiple recordings in the recordings list, and then click the **Delete** button. The selected recordings will be permanently removed from the Sleep Diary database.

6 Analysis Window

Once the recording has loaded, the main analysis window will be shown.

Menu
Contains controls for performing various actions

Results
Text results from the analysis of the questionnaire and activity data

Graphs
Visual representation of the analysis output

The text results are presented in groups based on the day that the data was captured. These are **All Days (Mon-Sun)***, **Week Days (Mon-Fri)**, and **Weekend Days (Sat-Sun)**.

* By default the application uses Monday as the start of the week.

Results for each element are provided as a **Mean**, **Standard Deviation** and **Range** (lowest-highest).

The application also highlights discrepancies between the subjective data from the questionnaires and the objective data of the activity data. These are highlighted in red after each group of results (if applicable to those results).

The graph data is compounded into days of the week for sleep results and hours of the day for alertness results. This is to allow easier comparison of results between days of the week for sleep, or hours of the day for alertness.

6.1 Changing Views

There are two views in the analysis window: Sleep and Alertness. You can switch between the two by clicking on the corresponding menu item in the **Views** section of the main menu.
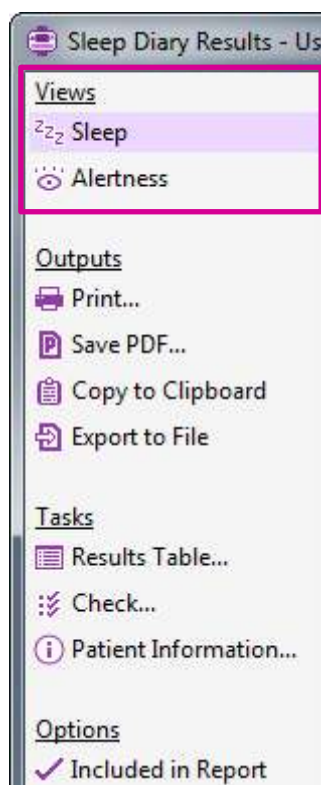
6.2 Printing & PDF creation

The printed report and PDF report are both based on the on-screen report for consistency. Print and PDF reports consist of both the sleep results and the alertness results in one document where both are available.
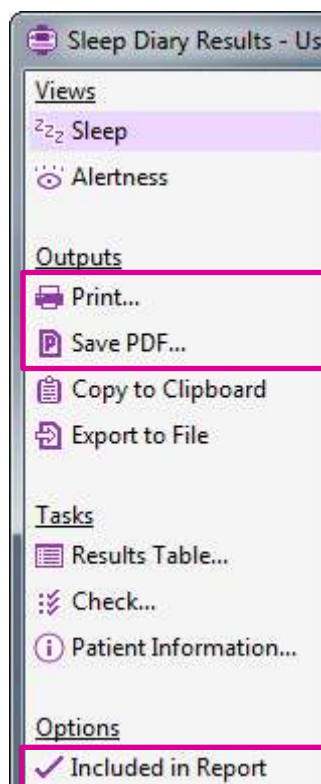
To print the report, click the **Print…** menu item – this will show the printer dialogue window.

To save the report as a PDF, click the **Save PDF…** menu item – this will show the PDF save dialogue window.

You can exclude either the **Sleep** or **Alertness** results from the printout/PDF by clicking the **Included in Report** menu item in either analysis view.

6.3   Exporting Results/Data

Exports are provided for the sleep analysis results and for the internal data used to produce the results. The **Copy to Clipboard** function and **Export to File** function both produce the same outputs. The export function can export results only, raw data only or both.

To export, click on the **Copy to Clipboard** menu item or the **Export to File** menu item, followed by the **Results** option, **Raw Data** option, or **Results + Raw Data** option.
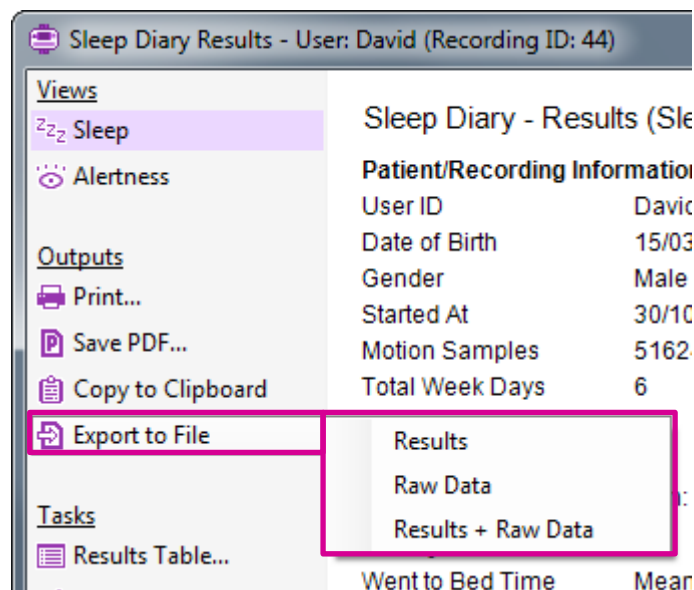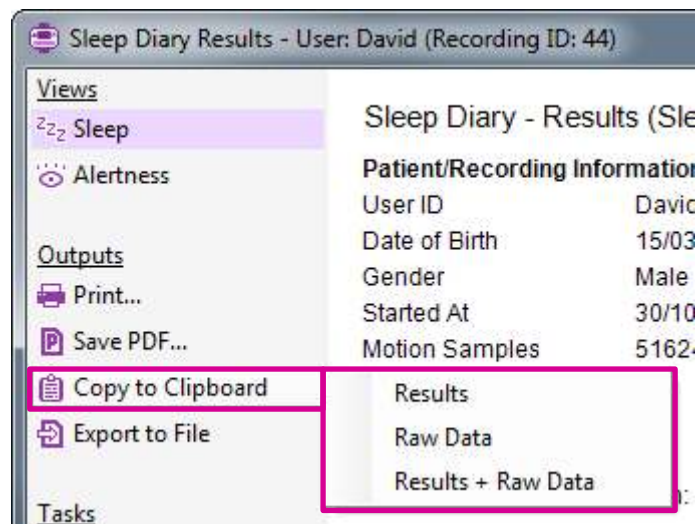
The **Copy to Clipboard** contents can be pasted directly into an external text editor or spreadsheet application.

6.4 Viewing Raw Diary Data

The **Results Table** lets you to view the raw/unanalysed questionnaire and question/answer data, and also provides functions for exporting raw the Diary data and Motion/activity data.

To open the **Results Table**, click the **Results Table…** menu item.
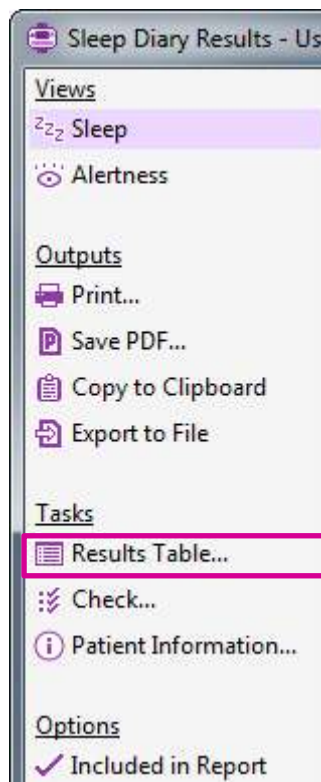
You can switch between the **Bed Time**, **Woke Up** and **Alertness (if applicable)** questionnaires by selecting the corresponding option in the **Questionnaire Dropdown** box.
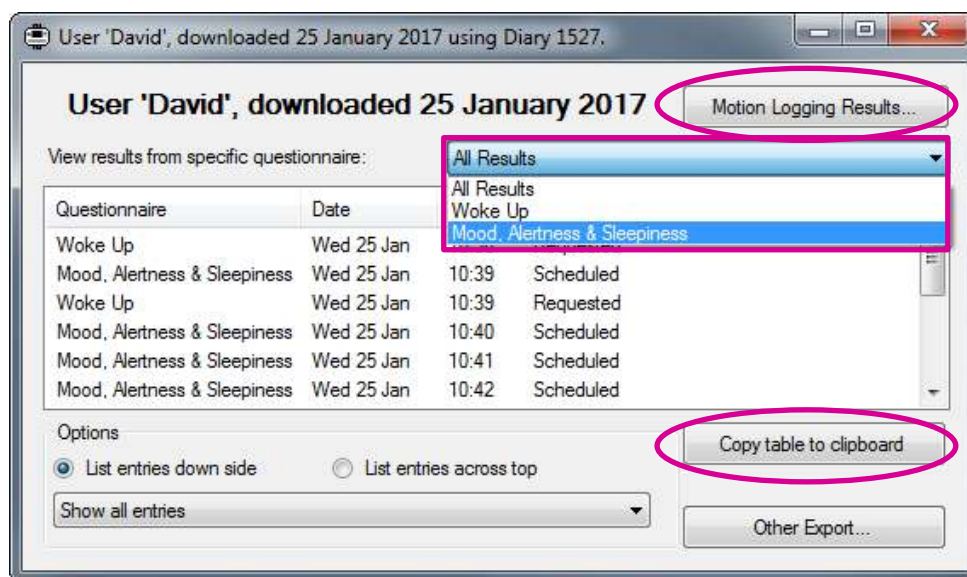
You can export the raw data by clicking the **Copy table to clipboard** button. The data will be copied to the system clipboard which will allow you paste the data into an external application such as a spreadsheet application.

You can export the raw Motion/activity data by clicking the **Motion Logging Results…** button. You can open the exported **.Mtn** file in an external application such as **CamNtech MotionWare** or a text editor.

6.5   Editing Patient Information

You can edit patient information by clicking the **Patient Information…** menu item.

Click the **Save** button to save the changes. Any changes will be updated on the analysis view.

7 Miscellaneous

7.1 Groups

The software includes the functionality to assign recordings to groups. This is to provide easier management of recordings in a single results database. An example of this is when managing several users, each of who have several recordings. A group can be created for each user and their corresponding recordings can be assigned to their group.

The group functionality is disabled by default, but it can be enabled by opening the settings, selecting the **General** option and enabling the **Show Groups on the Main Menu** checkbox.
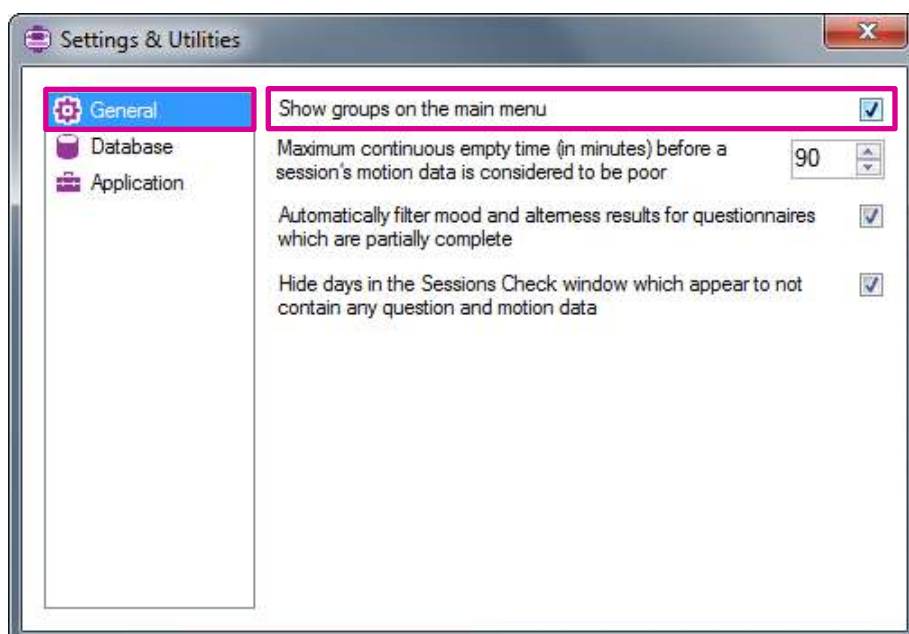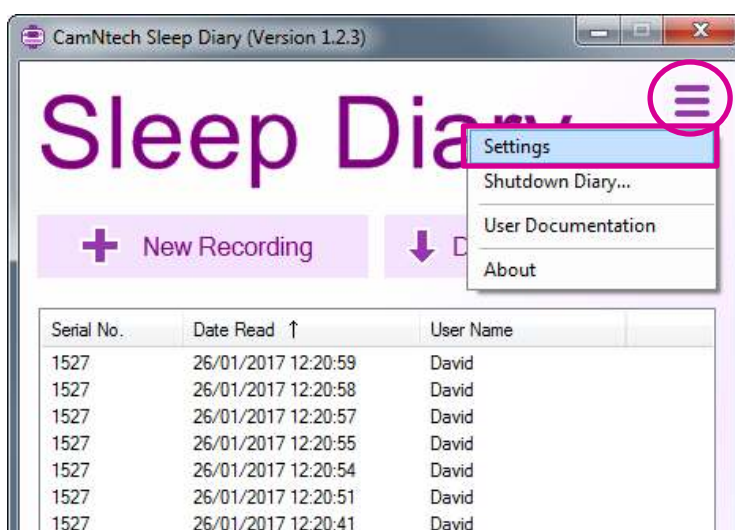
The **Group** controls will now be shown on the Main Menu.
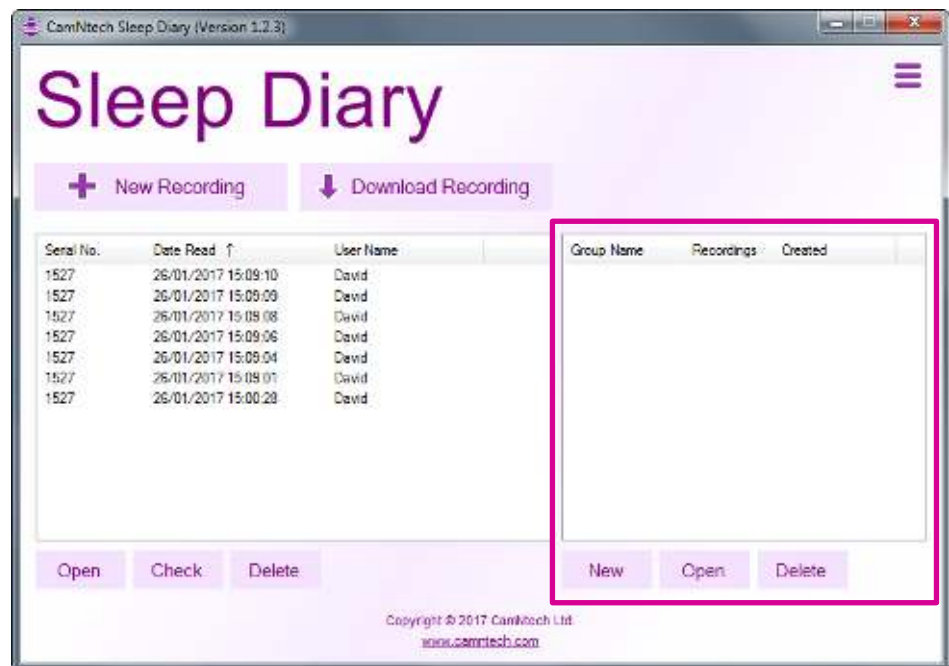
To create a group, click the **New** button, enter a group name in the textbox and click the **OK** button. The new group will be added the groups list.
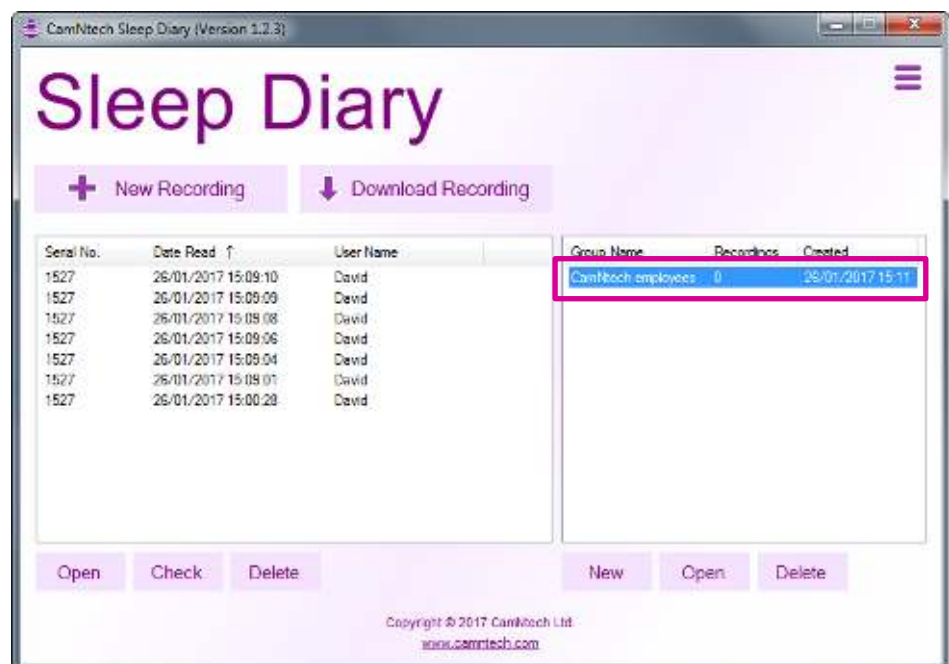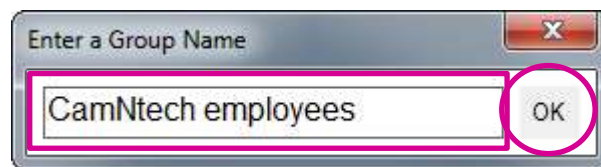
Recordings can now be assigned to the group by dragging a single recording, or selecting and dragging multiple recordings from the recordings list onto the group in the groups list.
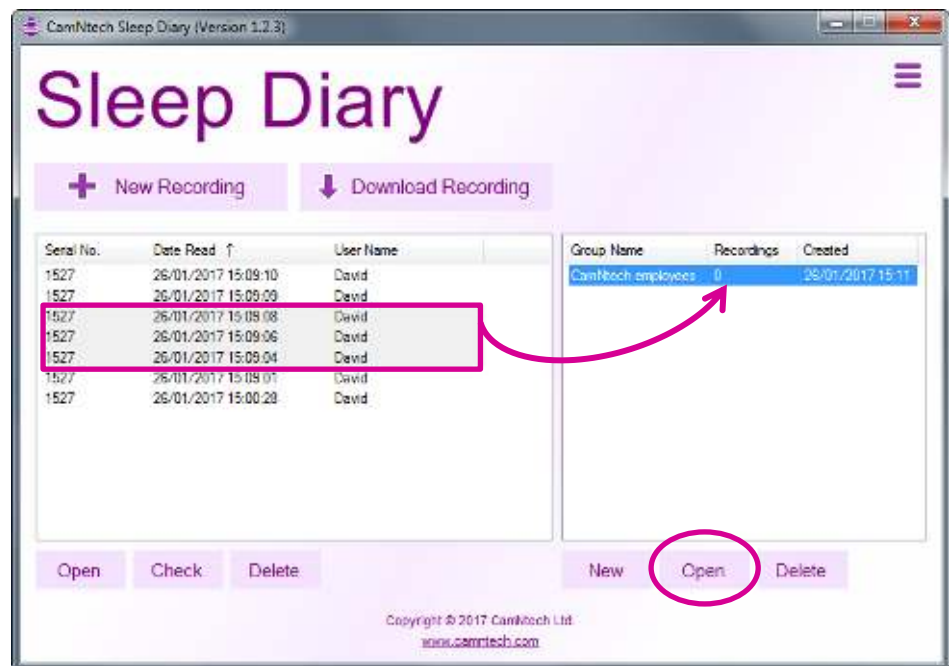
The contents of a group can be viewed by clicking on a group in the groups list to select it, and then clicking the **Open** button.
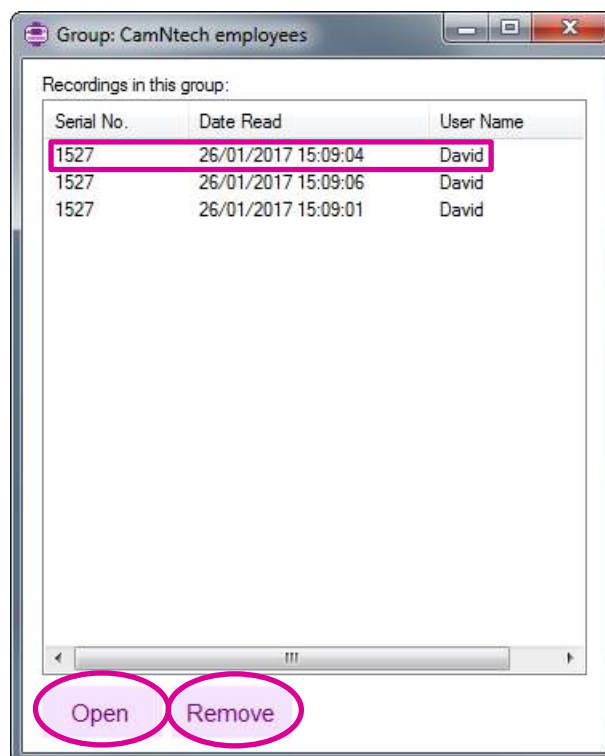
The recordings in a group can be opened as usual by clicking on a recording to select it and then clicking the **Open** button.

Recordings can be removed from a group by clicking on a recording to select it and then clicking the **Delete** button. **Note: the recording will only be removed from the group and will NOT be deleted from the database.**

8 Frequently Asked Questions

What limits the recording life?

The battery is used mainly whilst the display is on and the user is actually answering questions. When the battery is brand new and fully charged, it will run for around 5 hours of continuous questioning, equivalent to about 20 minutes per day for two weeks with motion data recording in the background. However it is possible to design a questionnaire which will take more or less of the wearer's time than this.

Will too many answers fill up the memory?

No, the answers to questions do not take up a significant part of the memory. Short epoch motion data will take much more memory, but in most cases the recording time will be limited by battery life rather than memory.

Will the data be lost if the battery runs flat?

No. Plug the device into a USB port to recharge for an hour or so, and try to download again. If you still have difficulty recovering data, contact CamNtech before doing anything else with the Diary. We will do our best to recover data even from badly damaged devices.

9 Additional Documents

In addition to this manual, the document below is provided and can be found from the windows Start Menu once the Diary software is installed.

Sleep Diary Quick Guide

This provides a single-page guide for using the Sleep Diary. You may wish to print this out for your users or simply work through it with them before departure.

10 Safety and Handling Information

10.1 De-contamination

- 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 must use gloves to handle such devices before and during de-contamination.

10.2 Battery

- The device is battery operated and operates at voltages below 5VDC; there is hence no risk from electric shock (equipment Type B).
- The battery is **NOT** user replaceable.

10.3 Water Ingress

- The PRO-Diary is **not waterproof**. When the USB bung is fitted, it should withstand accidental splashes in daily use, but the Diary must be removed before any greater exposure to water.

10.4 Disposal

Waste Electrical & Electronic Equipment (WEEE) The EU requires, under the Waste Electrical and Electronic Equipment Directive 2002/96/EC, that manufacturers and/or distributors of Electronic and/or Electrical Equipment manage and pay for the collection and further handling of WEEE products, as well as provide WEEE-related information to their customers.

CamNtech has taken the following approach to complying with this Directive:

- CamNtech has registered with an approved producer compliance scheme (PCS) in accordance with the requirements of the WEEE Directive.
- CamNtech will provide free recycling for all of its WEEE products when returned to CNT.
- CamNtech WEEE products will be designed with recycling, reuse and waste management as a consideration.
- CamNtech WEEE products will be labelled or stamped with the WEEE marking in accordance with European Standard EN 50419.

Document Revision History

Issue From	Issue To	Date	Description	Initiator
1.2.1	1.2.2	18/11/16	Created first issue of document	DW
1.2.2	1.2.3	25/01/2017	Updates to screenshots and functions to match latest version of software	DW