SLEEP DIARY

User Guide

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CE

The PRO-Diary and PRO-Diary V are Class I Medical Devices (EU)

PRO-Diary and PRO-Diary V Regulatory Information

Medical Device Directive (European Union)

The PRO-Diary and PRO-Diary V are Class I Medical Devices 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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Australia.

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 10.1.

Safety Classification Information:

- PRO-Diary is **INTERNALLY POWERED EQUIPMENT**.
- PRO-Diary mode of operation is **CONTINUOUS OPERATION.**
- PRO-Diary 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 10

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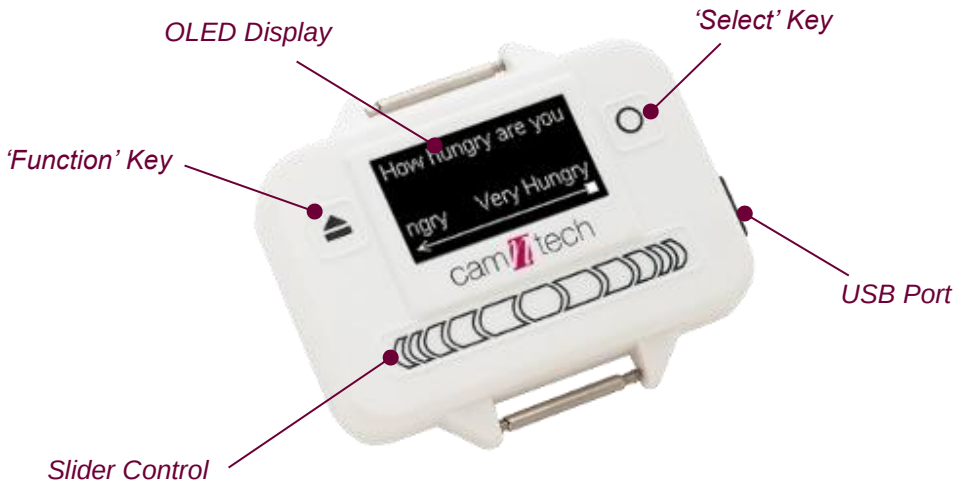
1 Introduction to the Sleep Diary System

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 0 for details of battery charging and expected life.

The PRO-Diary has a clear, high contrast OLED screen. 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 Intended Purpose

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.

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

1.3 Contraindications

The PRO-Diary 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 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 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.

1.6 Inspection Before Use

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

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

1.7 Service Life

The recommended service life of the PRO-Diary devices is **5 (five) years**.

1.8 Modifications

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

1.9 Adverse (Serious) Events

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

2 Installing the Sleep Diary Software

2.1 System Requirements

The Sleep Diary 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 Diary software:

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

In general, a faster processor will provide superior performance.
The software has NOT been tested with any variant of Apple MacOS and is not intended to be installed on devices running this operating system.

2.2 Software Registration

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

2.3 Software Installation Menu

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

2.4 Installing the USB Drivers

Upon connecting the PRO-Diary device to your computer for the first time, Windows® will automatically search on-line to locate and install the latest drivers. No user intervention is required and the PRO-Diary

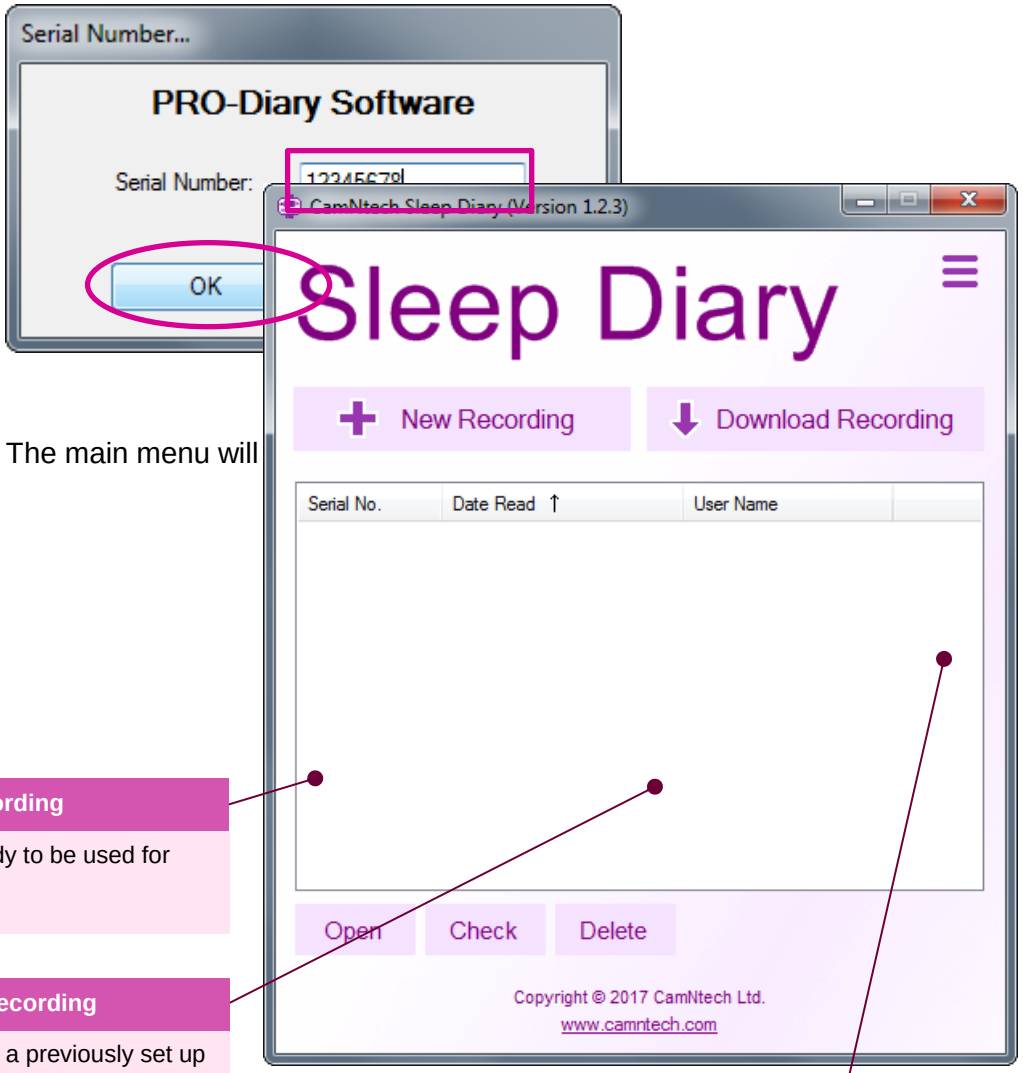
should remain connected until the process is complete. An internet connection is required to install the drivers automatically.

If the drivers cannot be loaded automatically, you should visit our web site drivers area: http://www.camntech.com/support/drivers.

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

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

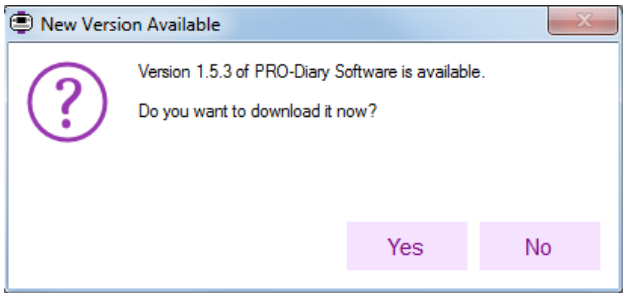
View and analyse downloaded recordings

Options Menu

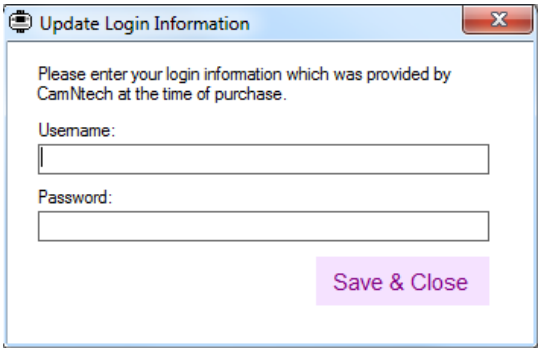
Access the application settings

2.6 Check for Software Updates

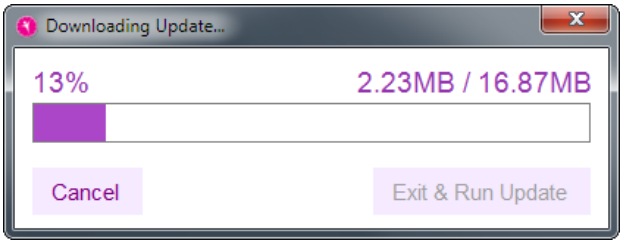
The Sleep Diary software will check for software updates once per day when it is run. It is also possible to manually check for software updates then automatically download and install them.
To manually check for updates, click the 'Help' menu and then select 'Check for updates'.
If a newer version is available, a prompt similar to the following will be shown:



Click 'Yes' to download the new version or click 'No' to ignore the update message.
Your CamNtech login details will be required to allow the software to connect and download the update. If these have not been previously entered, the following prompt will be shown:



Enter your Username and Password obtained from CamNtech when the software was registered (see Section 2.2 above). Click 'Save & Close' and your details will now be stored in the software. The download will begin:



When the download has completed, click the **Exit & Run Update** button to close the application and initiate the installer. The software update will then be installed.

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 questionnaires will be more demanding. However it should be at least 30 days in commonly expected uses.

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.

Charging indicator: The PRO-Diary display will show a charging indicator for 10 seconds when first connected to a charging source.

NOTE: if the Diary is shut down (as supplied), the charge indicator will not be shown however the Diary will still be charging.

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 PCs 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 experience any issues related to charging or battery life, we recommend using a mains power supply for charging to avoid this issue. Contact CamNtech technical support if you suspect the battery life has deteriorated.

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 Multiple Diaries using 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.
CamNtech can supply a suitable powered 7-port USB Hub if required – please contact your local distributor.

7-Port USB hub for charging. Order code 05-312

4 PRO-Diary Setup/Download

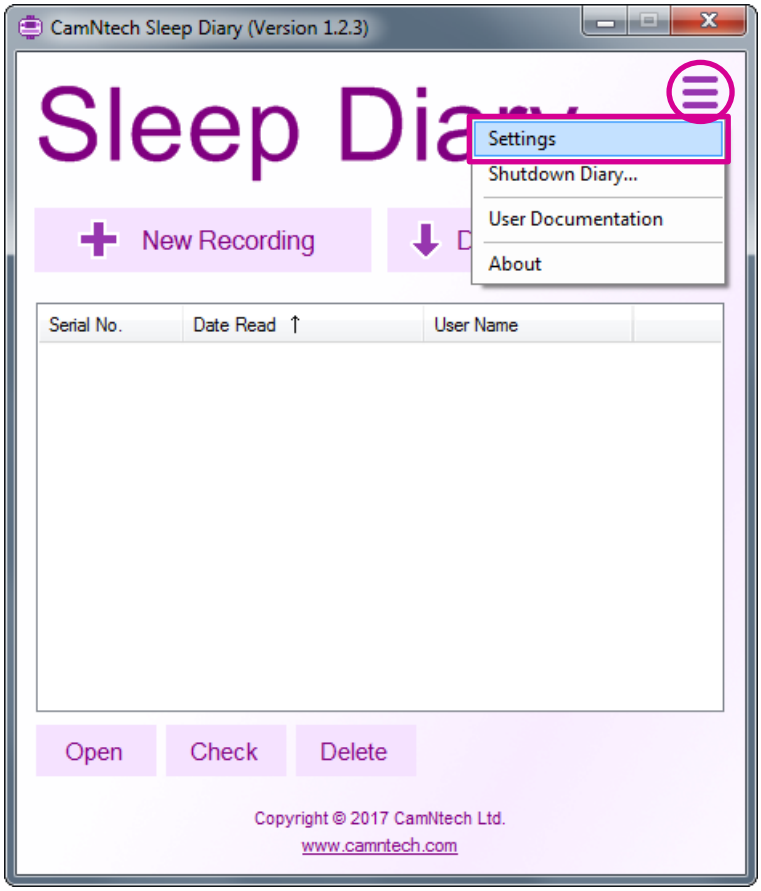
4.1 Introduction

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:

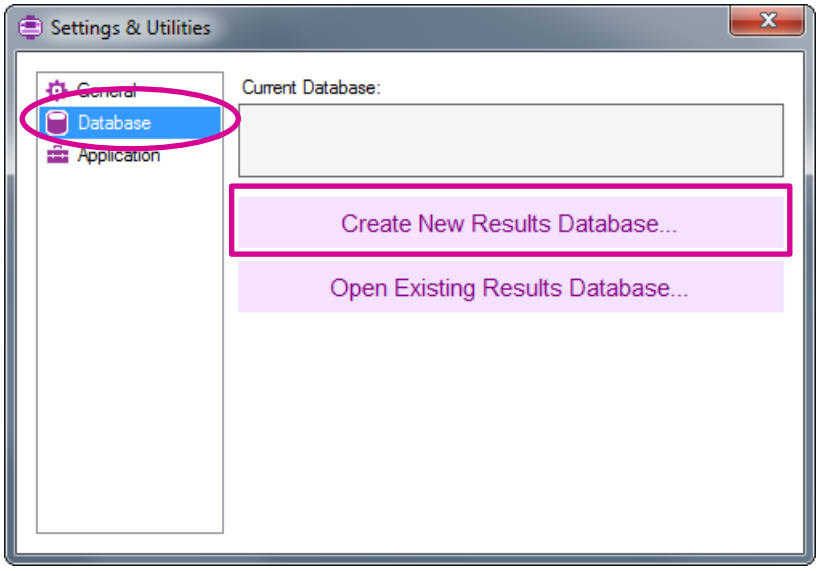
Questionnaire	Type	Time
Bed Time	On user request	Every evening (18:00-04:00)
Woke Up	On user request	Every morning (04:30-15:00)
Mood, Alertness & Sleepiness	Automatic	All Day

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.



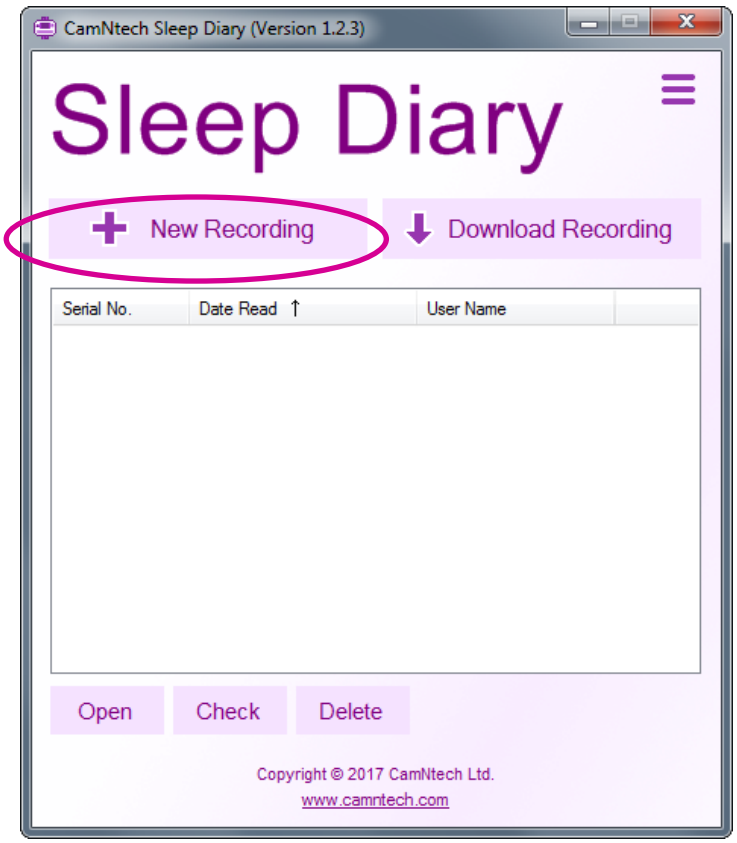
Click the **Create New Results Database…** button to open the file save dialog box. Select a save folder, enter a filename and save to create the database.

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.**

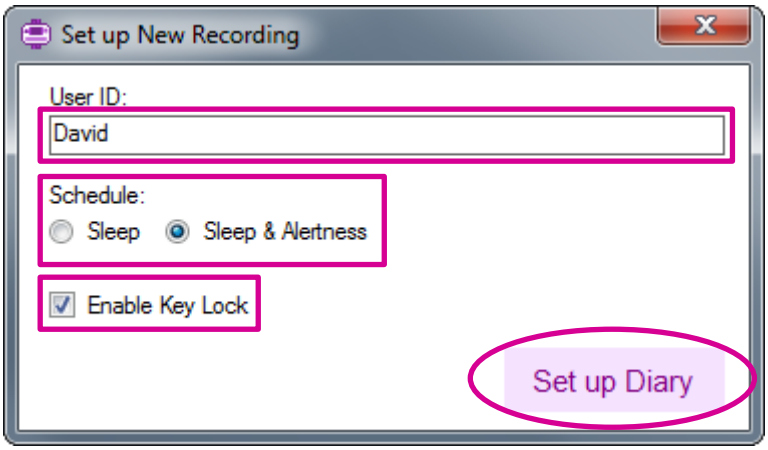
Click on the **New Recording** option on the main menu to show the Recording Setup window:



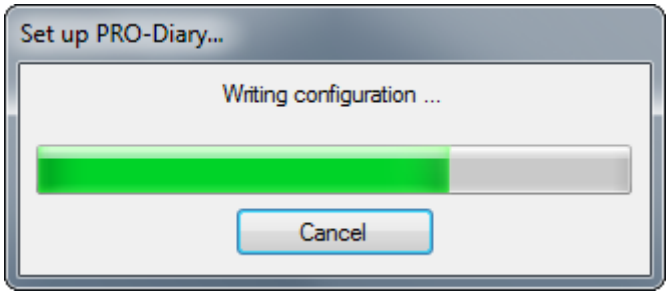
Enter a User ID in the **User ID** box – this will be used to identify the recording when it has been downloaded.

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.

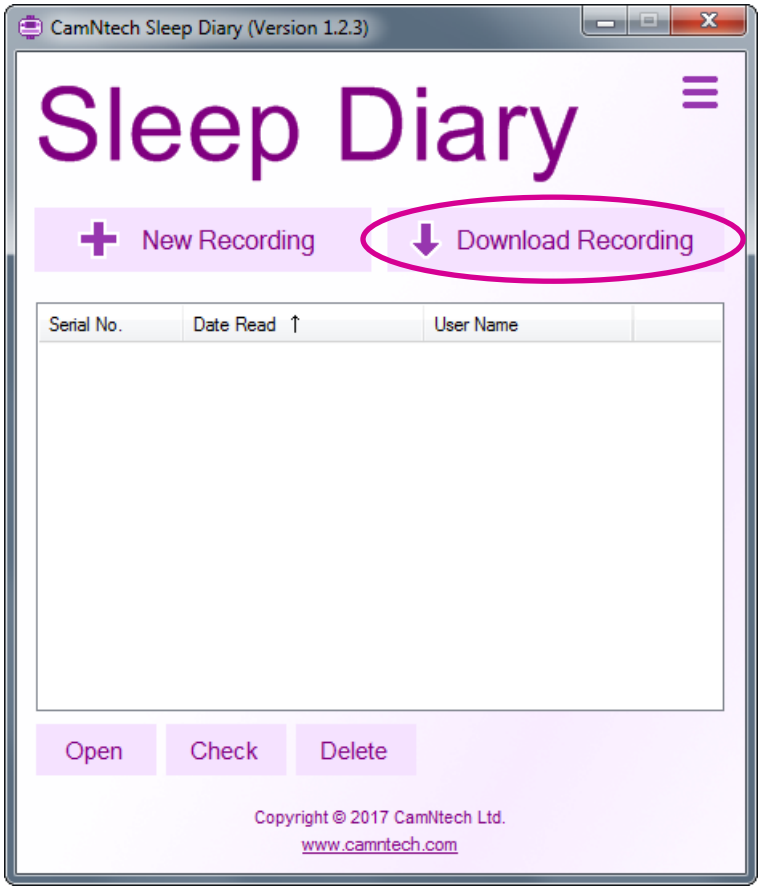
4.4 Using the Diary

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.**

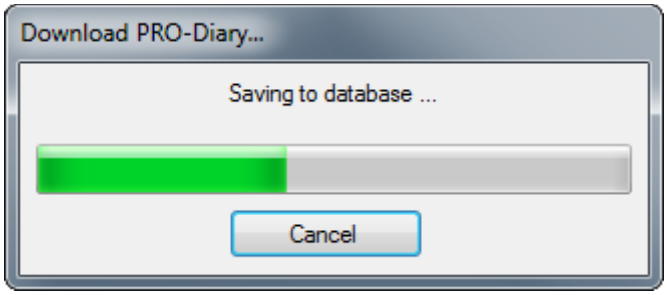
4.5 Downloading a Recording

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

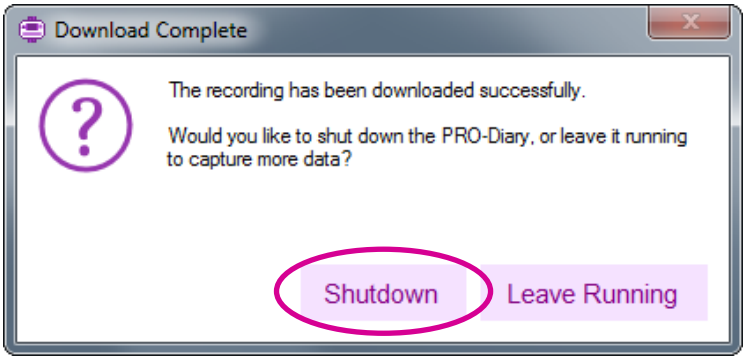
Click on the **Download Recording** option on the main menu.



The application will immediately begin downloading the recording from the Diary:

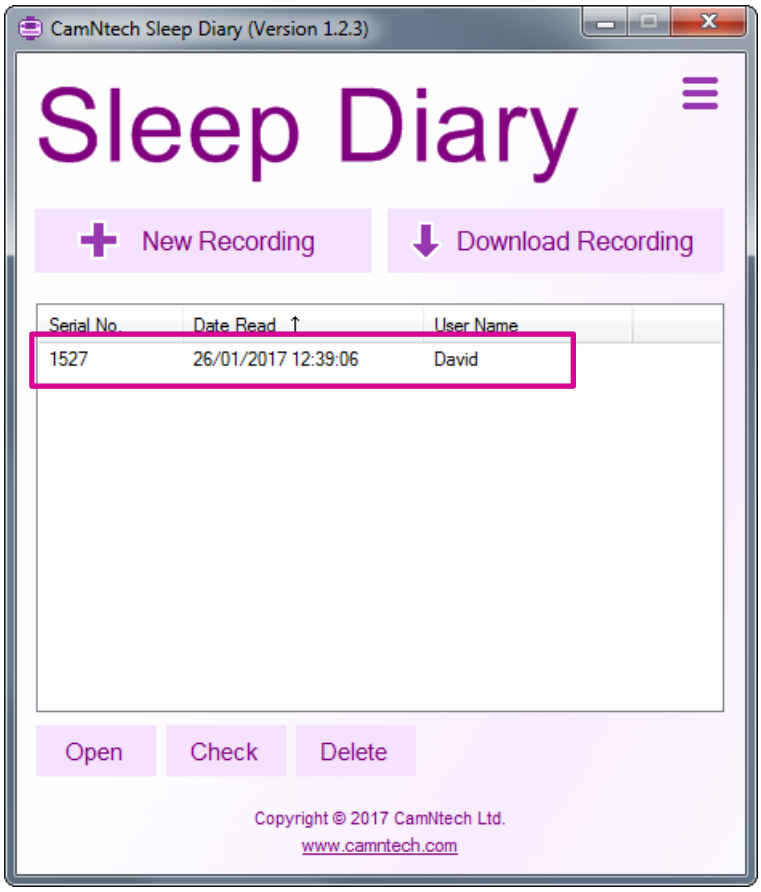


Once complete, a completion dialog box will be shown which contains options to shut down the Diary, or leave it running to continue to capture data. Select the **Shutdown** option in this case:



The Diary can be disconnected from the computer.

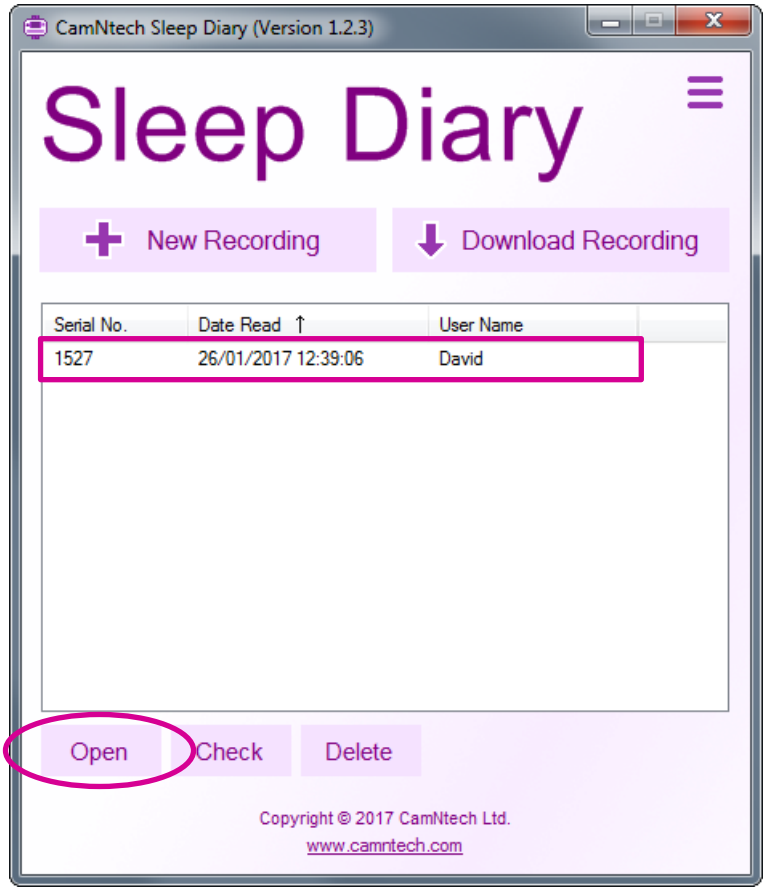
The newly downloaded recording will be automatically saved to your chosen Results database and the recordings list will show the new recording:



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:

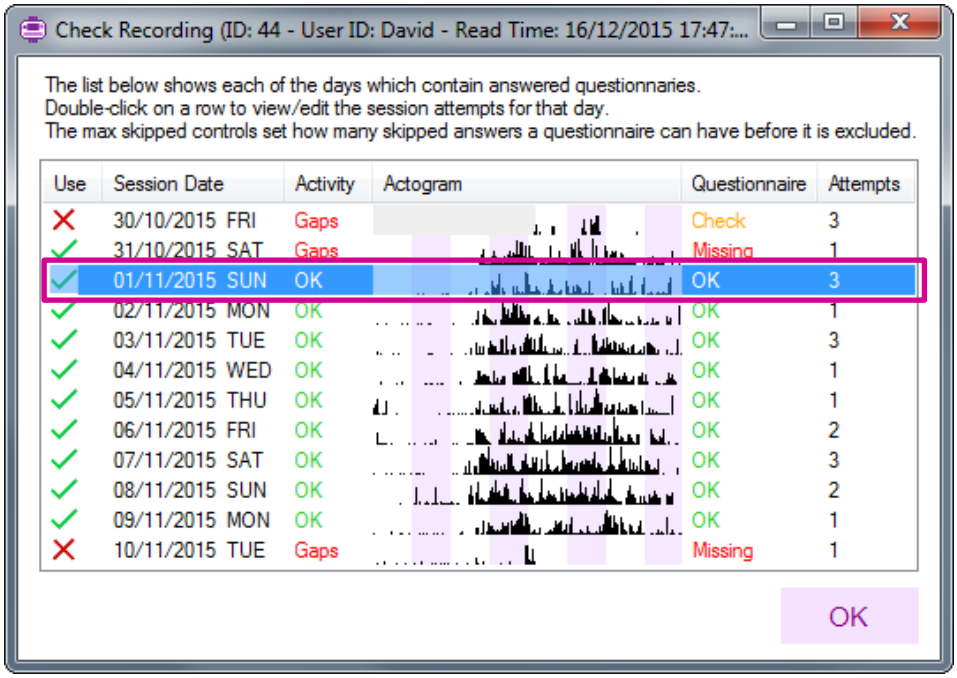


5.2 Checking Recordings

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.

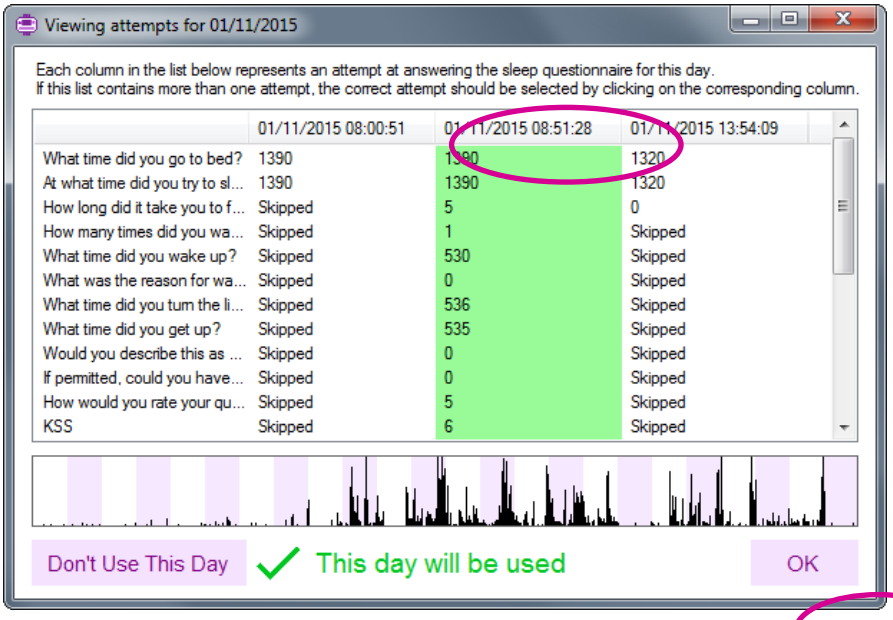


The software automatically analyses each attempt and picks the best attempt for days where there is more than one attempt.

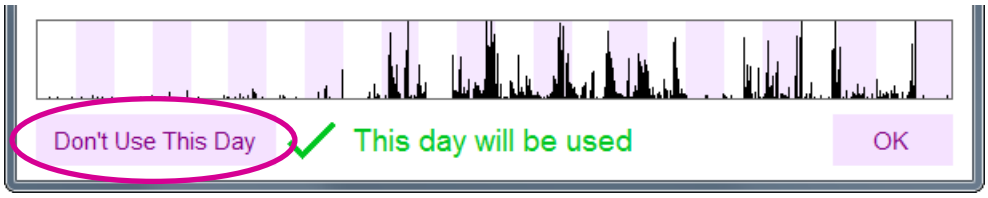
The software flags any days where the best questionnaire attempt for that day looks to be incomplete. This is shown in the **Questionnaire Status** column.

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:



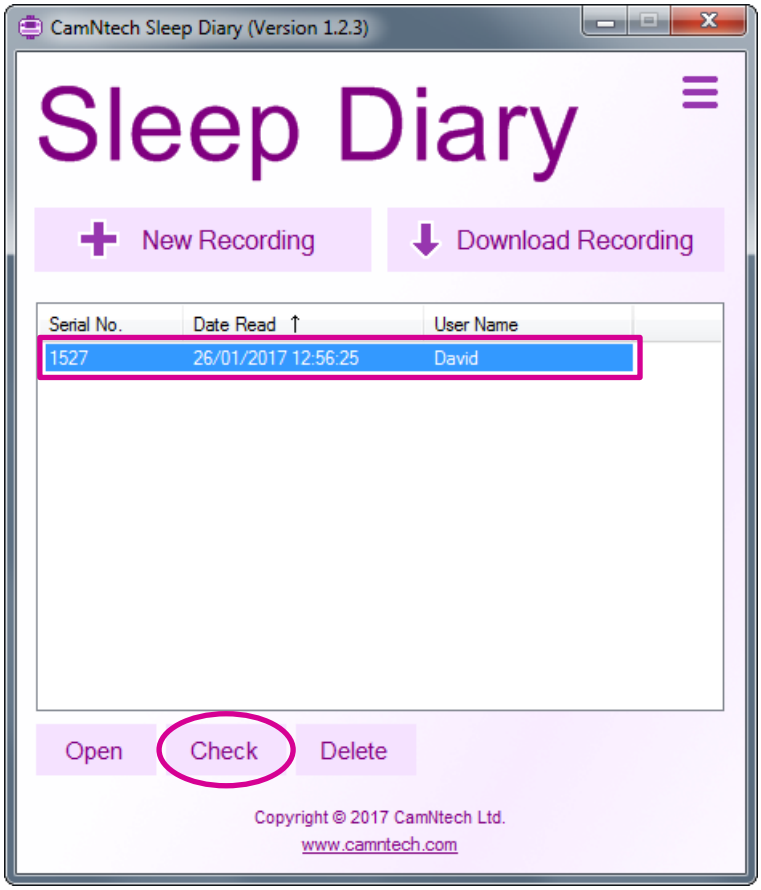
You can also exclude the entire days' worth of questionnaire attempts by clicking on the **Don't Use This Day** button. None of the selected day's questionnaire data will be used in the subsequent analysis:



The form will switch to the following:

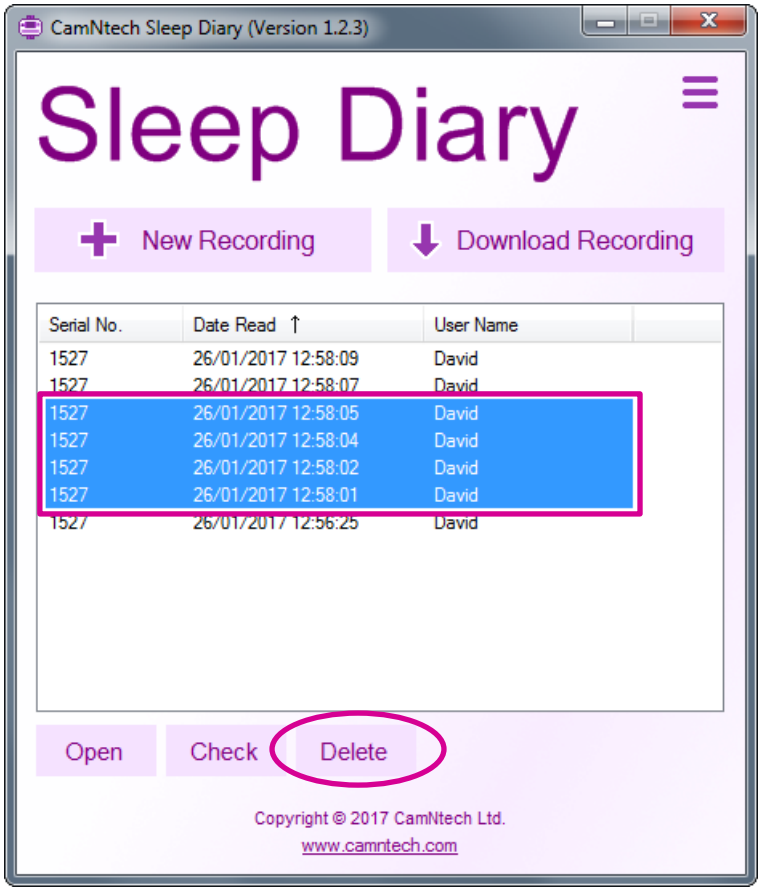
Click the **OK** button to confirm the options and continue loading the recording for analysis.

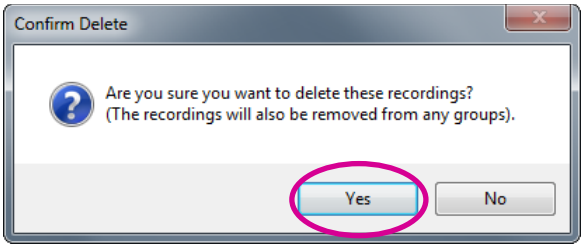
The Sessions Check window will not show again automatically. To check a recording again, select the recording in the recordings list and click the **Check** button. The Sessions Check window can also be run from within an analysis window, by clicking the **Check** menu item:



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:





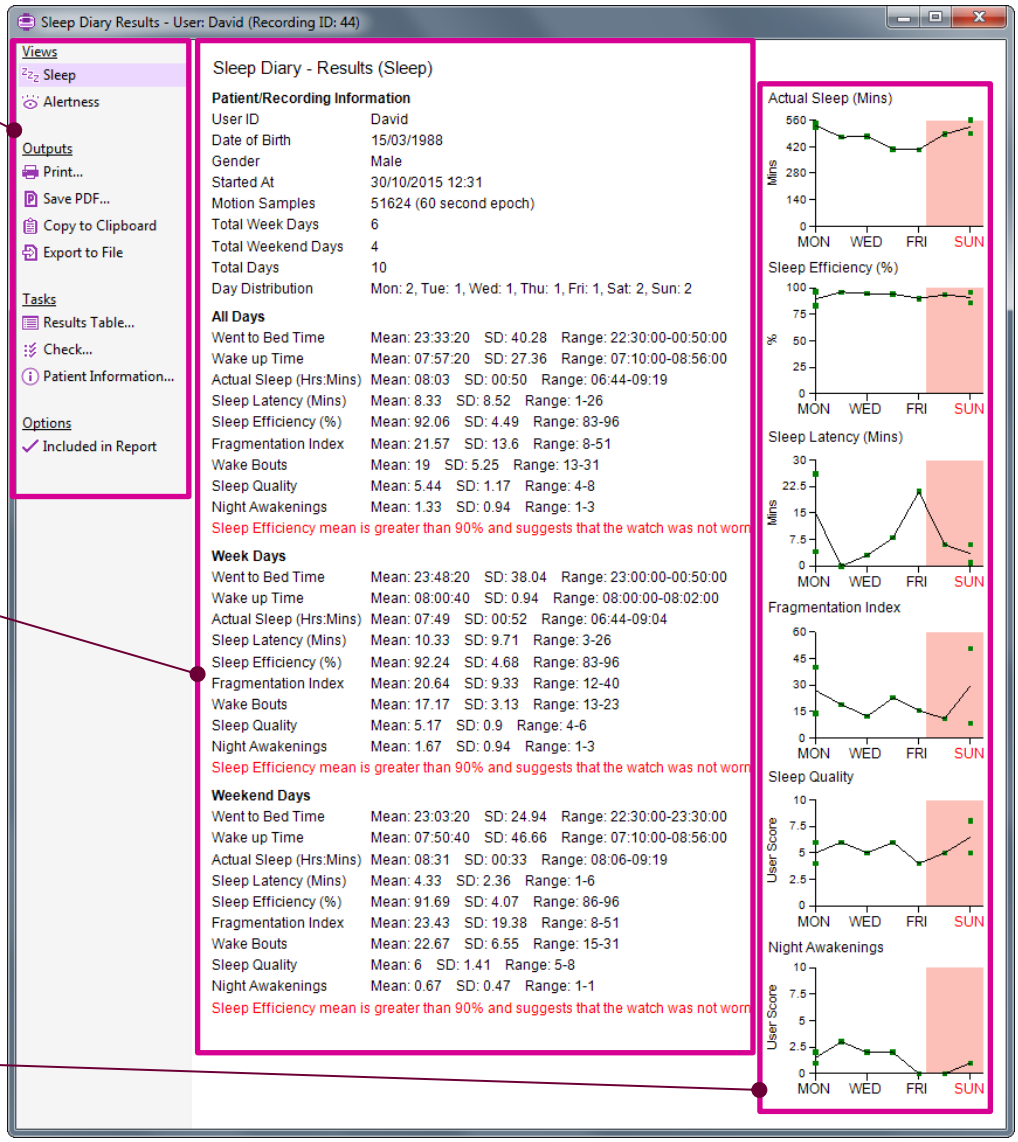
6 Analysis Window

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.*

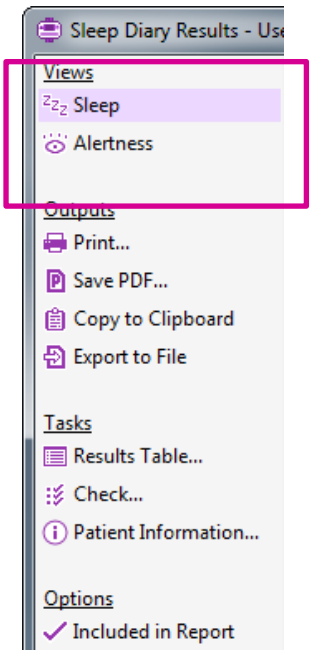
Results for each element are provided as a **Mean**, **Standard Deviation** and **Range** (lowest-highest).

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.

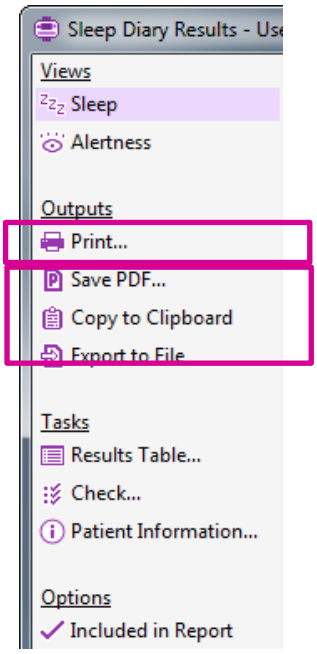
6.1 Changing Views

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.

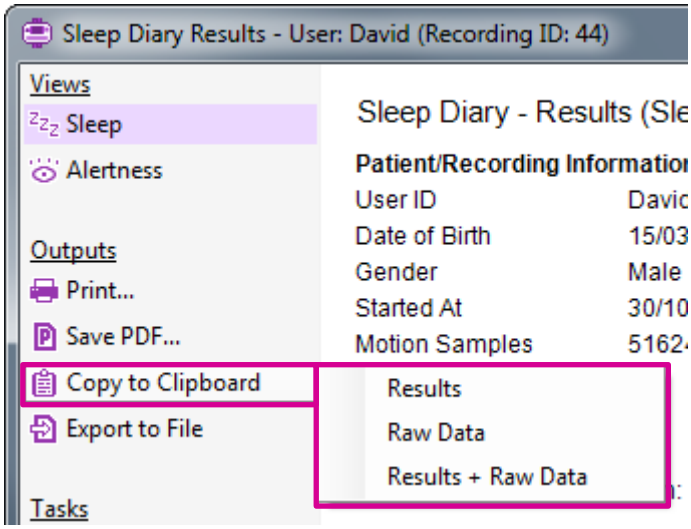
To save the report as a PDF, click the **Save PDF…** menu item – this will show the PDF save dialogue window.

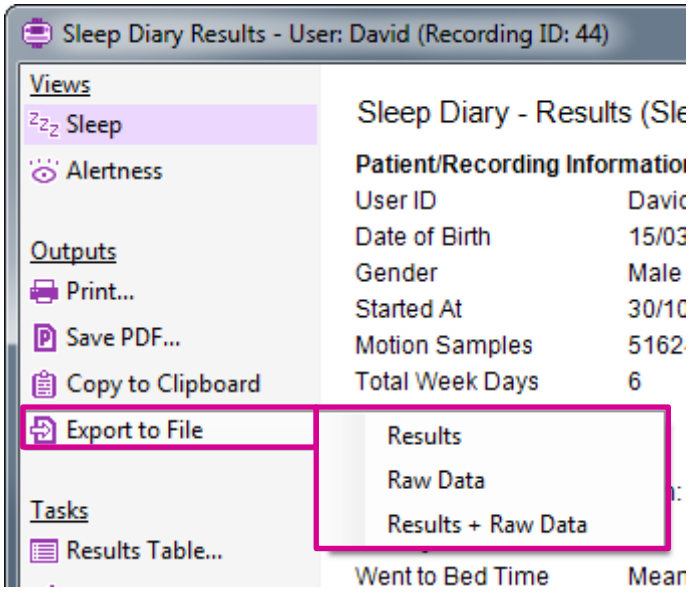
You can exclude either the **Sleep** or **Alertness** results from the printout/PDF by clicking the **Included in Report** menu item in either analysis view.

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:



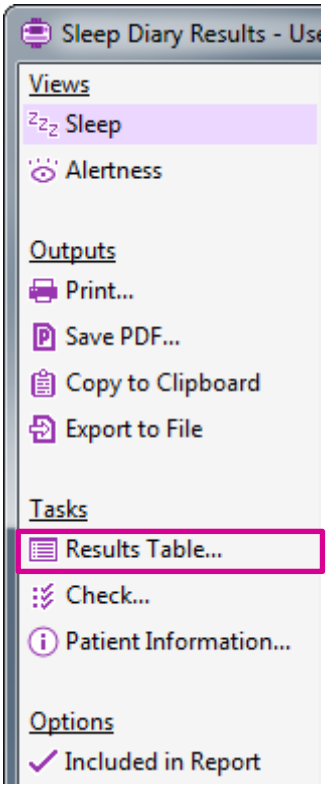


The **Copy to Clipboard** contents can be pasted directly into an external text editor or spreadsheet application.

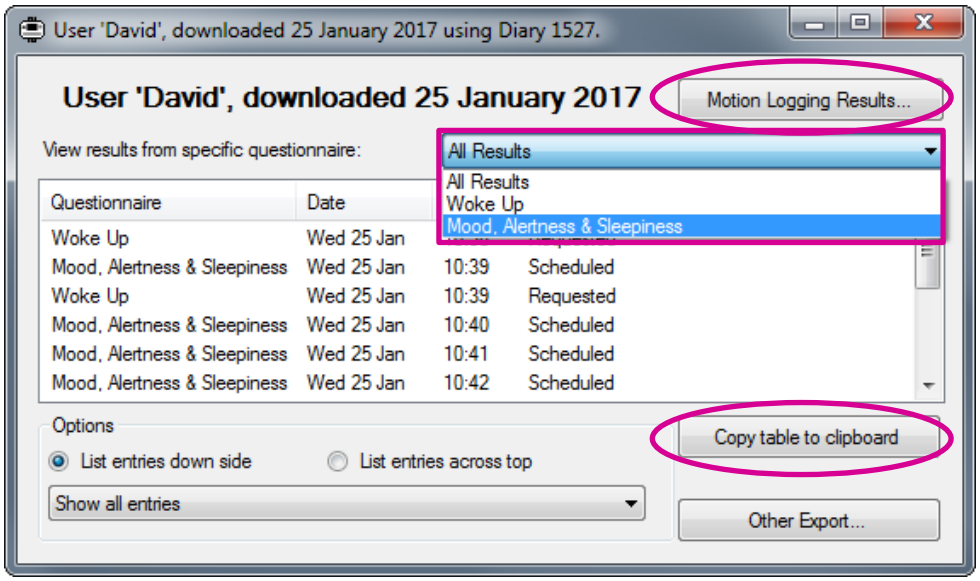
6.4 Viewing Raw Diary Data

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.

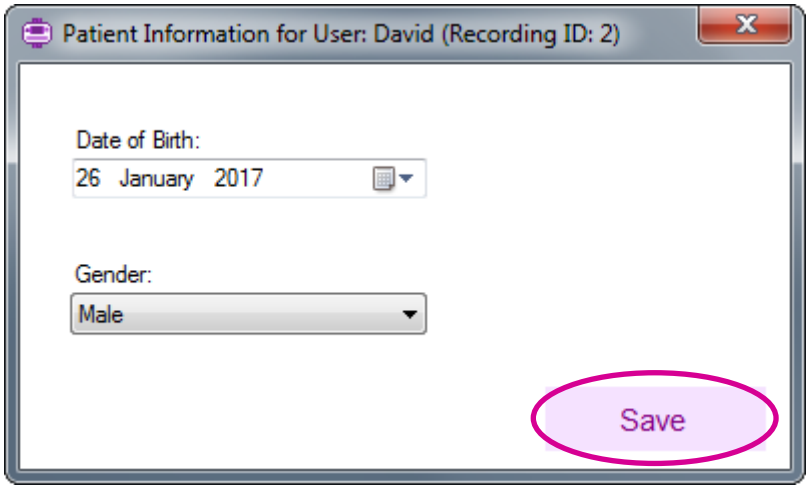


You can export the raw data by clicking the **Copy table to clipboard** button. The data will be copied to the system clipboard which will allow you paste the data into an external application such as a spreadsheet application.

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:



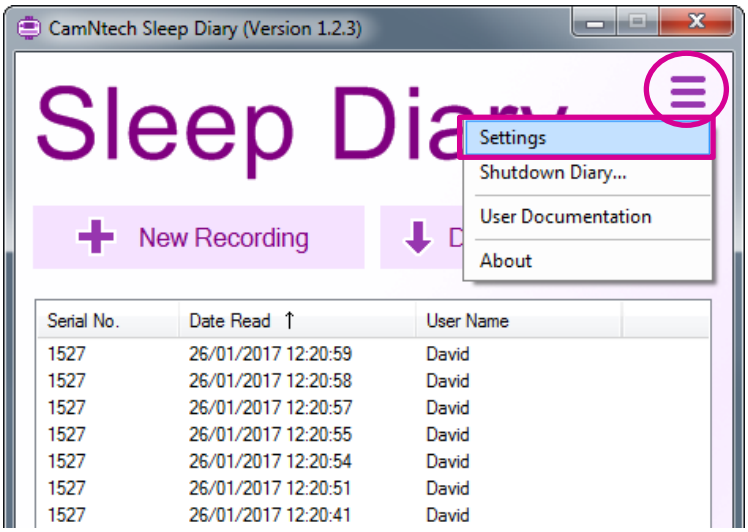
Click the **Save** button to save the changes. Any changes will be updated on the analysis view.

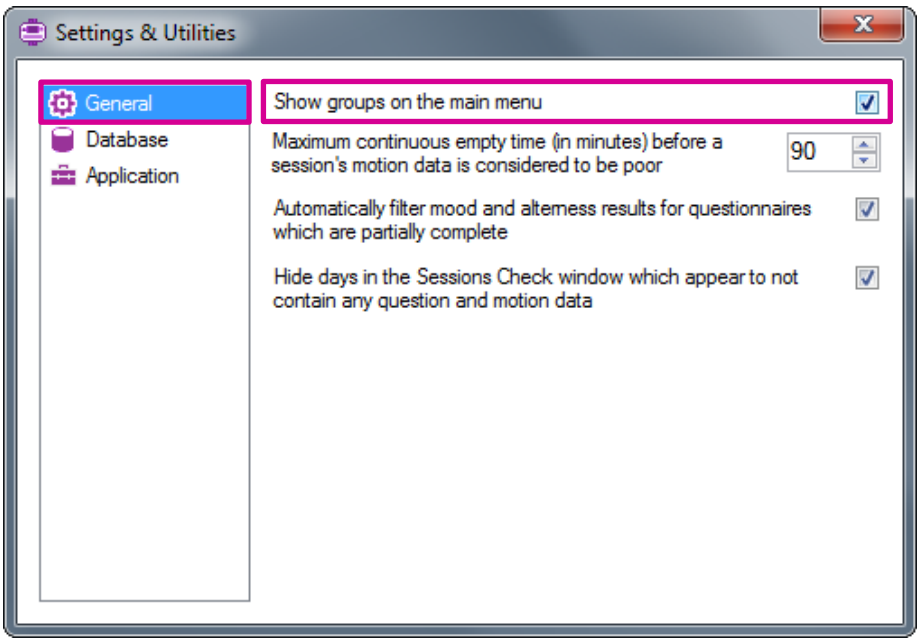
7 Miscellaneous

7.1 Groups

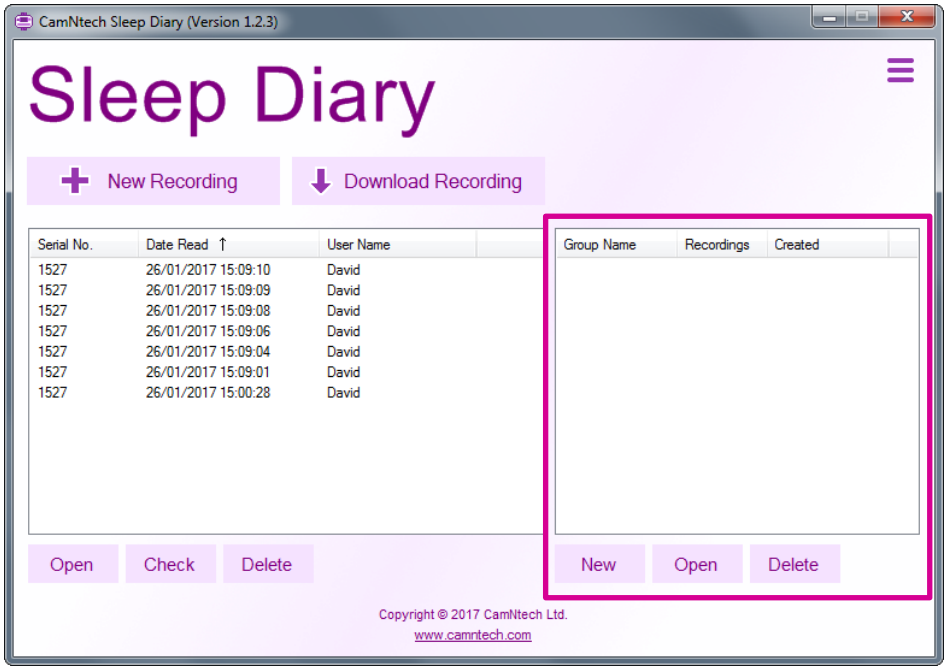
The software includes the functionality to assign recordings to groups. This is to provide easier management of recordings in a single results database. An example of this is when managing several users, each of who have several recordings. A group can be created for each user and their corresponding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

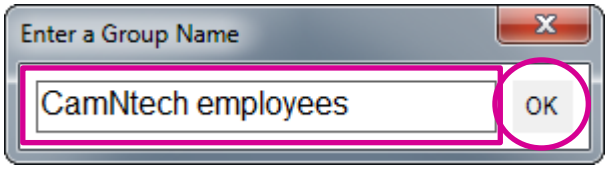


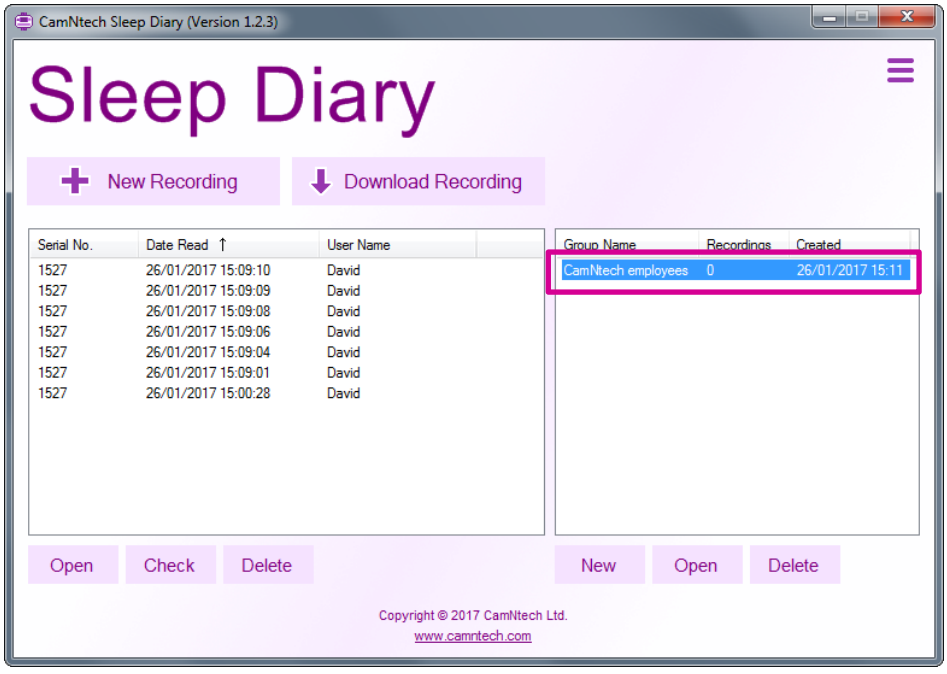


The **Group** controls will now be shown on the Main Menu.

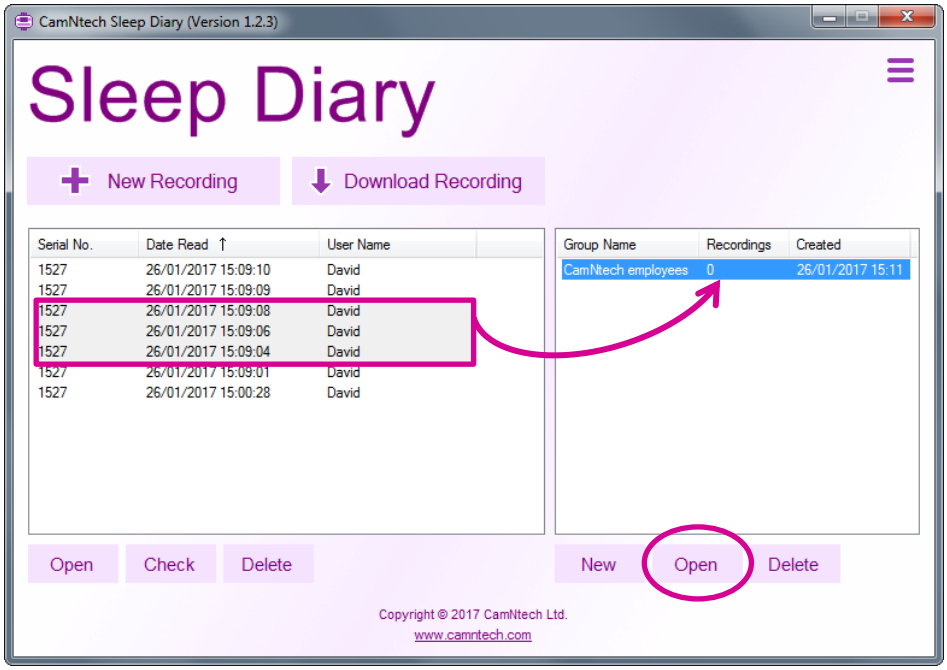


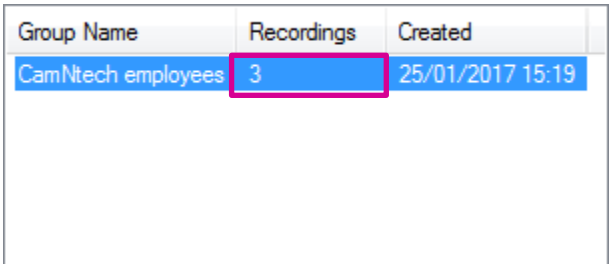
To create a group, click the **New** button, enter a group name in the textbox and click the **OK** button. The new group will be added the groups list:



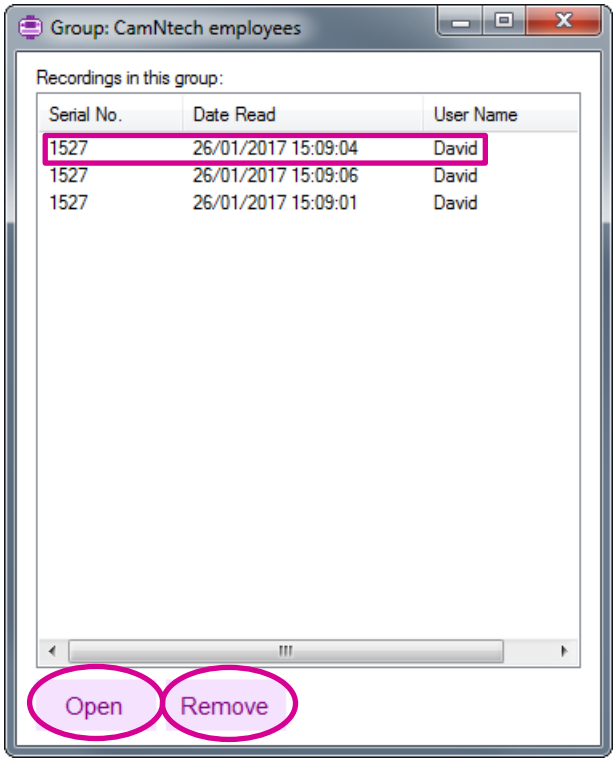


Recordings can now be assigned to the group by dragging a single recording, or selecting and dragging multiple recordings from the recordings list onto the group in the groups list.





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 Decontamination

- All used devices must be considered to be contaminated with surface borne bacteria and must hence be de-contaminated using a suitable disinfection and cleaning procedure.
- Care must be taken to use the correct de-contamination procedure and cleaning materials because long term exposure to certain cleaning materials is known to attack plastics which can lead to premature failure of the mechanical integrity of the medical device casing.
- CamNtech recommend the use of aqua based disinfection products and our recommended products are Clinell® Universal Wipes or Spray. These products do not contain chemicals known to cause deterioration of plastics. The PRO-Diary is **not waterproof** hence care should be taken during cleaning.
- Do not use products containing Glutaraldehyde, Glucoprotamin, Isopropyl, ethyl, or methyl alcohols, hydrogen peroxide, or bleach products. Do not use plasma sterilization or ethylene oxide sterilization procedures, Do not autoclave.
- Do not apply self-adhesive labels or tapes to the casing.

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 at End of Life

Waste Electrical & Electronic Equipment (WEEE) The EU requires, under the Waste Electrical and Electronic Equipment Directive 2012/19/EU that manufacturers and/or distributors of Electronic and/or Electrical Equipment manage and pay for the collection and further handling of WEEE products, as well as provide WEEE-related information to their customers.

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

- CamNtech has registered with an approved producer compliance scheme (PCS) in accordance with the requirements of the WEEE Directive.

- CamNtech will provide free recycling for all of its WEEE products when returned to CamNtech.
- CamNtech WEEE products will be designed with recycling, reuse and waste management as a consideration.
- CamNtech WEEE products will be labelled or stamped with the WEEE marking in accordance with European Standard EN 50419.

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
1.2.3	1.5.7	07/02/19	Updates to regulatory information (C0462), re-write of software installation section, updated cleaning advice, added reference to vibrating alert 'V' model, Updated decontamination section. Added note re charge indicator	H Smith
1.5.7	1.5.7a	31/12/19	Updates to include information updated in PRO-Diary User Guide. Format updates. CamNtech address updated, removed Win 7	M Dewey