



The PRO-Diary User Guide

APPLICABLE TO PRO-DIARY AND PRO-DIARY V

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

Covering the following product variants:

Model	Cat Ref	Notes
PRO-Diary	05-111	Audible Alerts
PRO-Diary V	05-121	Vibratory Alerts

PRO-Diary and PRO-Diary V Regulatory Information

Medical Device Regulation (European Union)

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

Authorised Representative (European Union)



Authorised Representative (Switzerland)



US FDA status

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

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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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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 0.

Safety Classification Information:

- PRO-Diary is **INTERNALLY POWERED EQUIPMENT**.
- PRO-Diary mode of operation is **CONTINUOUS OPERATION**.
- PRO-Diary is for **PRESCRIPTION USE ONLY (Rx 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)
Medical Device		The PRO-Diary is a Medical Device. Medical Device Regulation 2017/745.

FOR FURTHER HANDLING & ENVIRONMENTAL INFORMATION PLEASE REFER TO SECTION 12

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1 Introduction to the PRO-Diary System

1.1 An Overview of the PRO-Diary System

The PRO-Diary system consists of a wrist-worn electronic patient diary and associated PC software which can record the user's answers to questions during daily living in a very flexible and easy to use way. The PRO-Diary incorporates a tri-axial accelerometer to allow objective actigraphy data to be collected while the device is worn. Actigraphy data may be saved and loaded into the optional **CamNtech MotionWare Software** (part number 04-112) for off line analysis.

PRO-Diary 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.

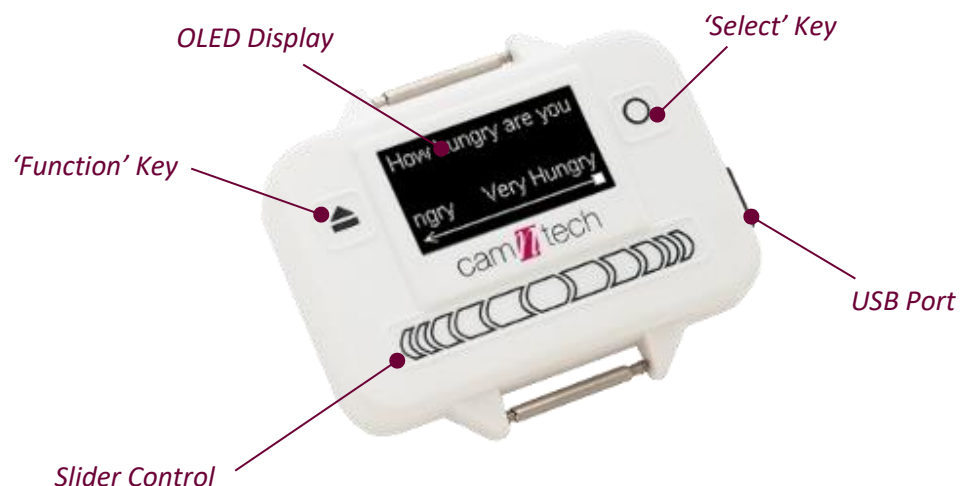
The PRO-Diary has a built-in score pad that allows the wearer to subjectively assign and enter responses to pre-programmed questions. The score pad can be used as a substitute or in addition to the traditional written patient diary in conjunction with activity monitoring. The PRO-Diary can be programmed to prompt the user with audible alerts (or haptic vibration alerts – 'V' model).

The PRO-Diary system comprises of:

- One or more PRO-Diary devices – to be worn or carried by the subject
- PC software for designing questionnaires, setting-up, downloading, viewing and exporting recorded answers.

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 display and the character size may be changed during configuration. 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 Operation

The PRO-Diary and PRO-Diary V provide 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 data may then be downloaded using the PC software. The resulting data may also be exported for further analysis in third party software packages.

The PRO-Diary and PRO-Diary V incorporate 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. Recorded activity data may be analysed off-line using the CamNtech 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 PRO-Diary Software

2.1 System Requirements

The PRO-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 PRO-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.

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

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

CamNtech recommends that the PRO-Diary is not connected to any PC other than a dedicated host PC which meets the above requirements and is running the PRO-Diary and (optionally) MotionWare software.

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 PRO-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.

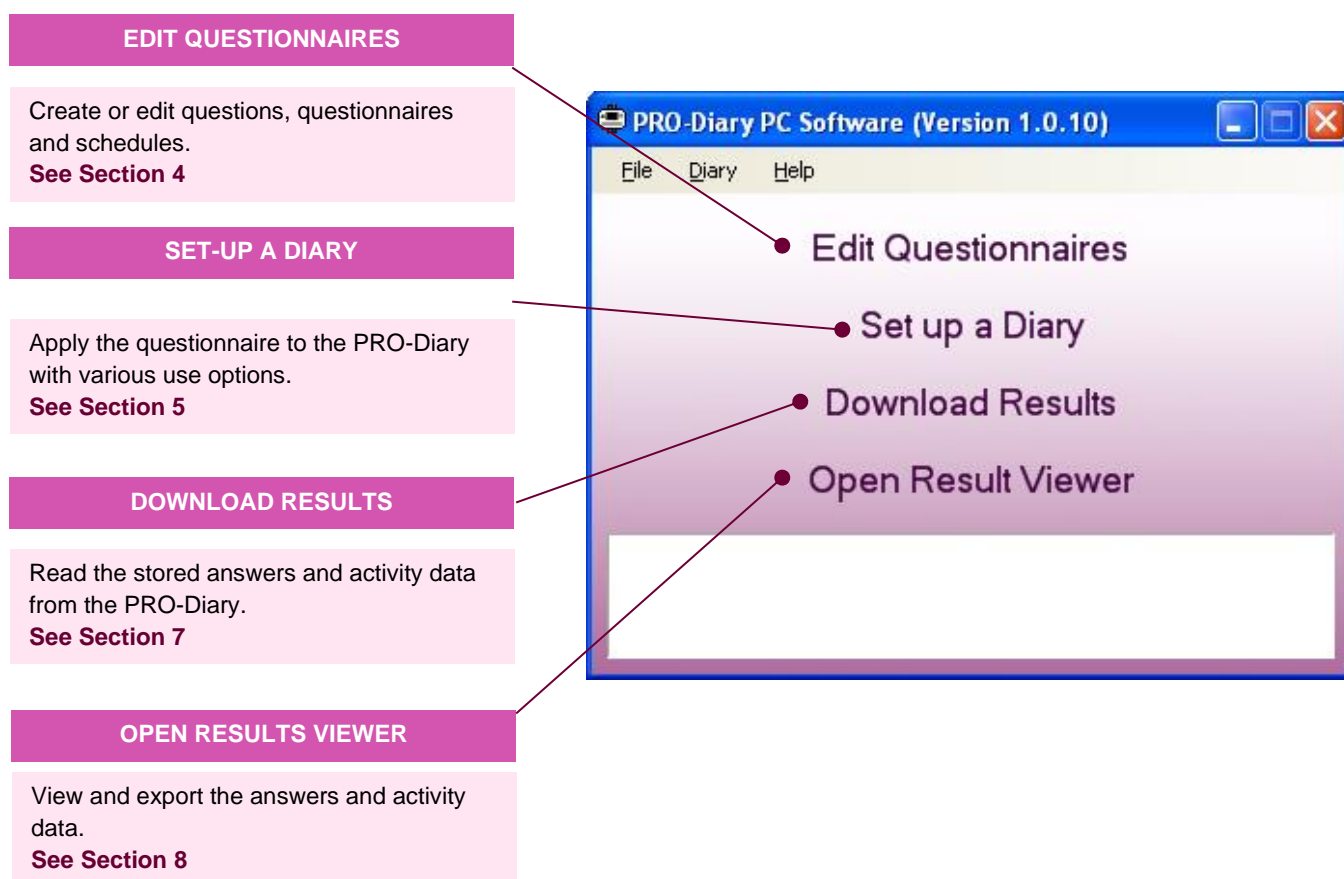
If the drivers cannot be loaded automatically, you should visit our web site drivers area: <http://www.camntech.com/support/drivers>.

Here you will find driver advice and be able to download the latest drivers for manual installation.

In cases where the target PC has no internet connection, use a different PC to download the drivers as described above then transfer the drivers to the target PC using a memory stick or other means.

2.5 Running the software for the first time

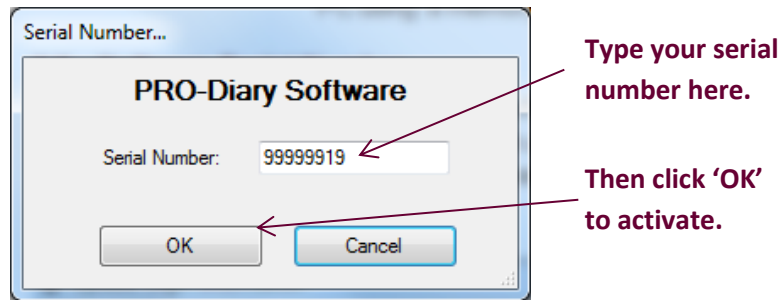
Double clicking on the PRO-Diary icon on the desktop will start the software. This will display the main menu as shown below. Each option is introduced in a section of this guide.



2.6 Software Serial Number

The PRO-Diary software requires a serial number (obtained at time of registration) which unlocks the software from 'Demo Mode'.

To enter the software serial number, click on the 'File' menu and select 'Serial Number...'; the following window will be shown:

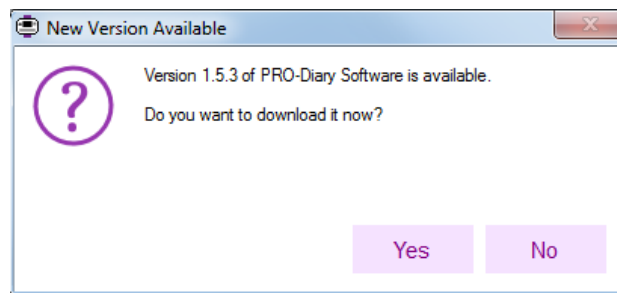


2.7 Check for Software Updates

The PRO-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.

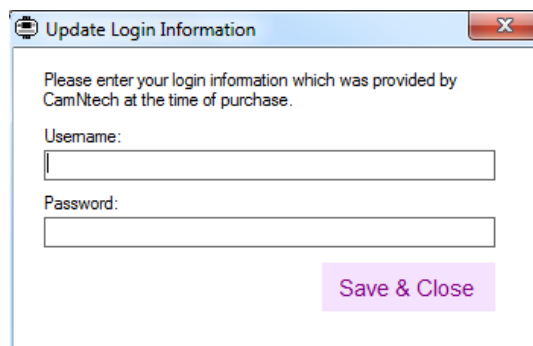
To manually check for updates, click the 'Help' menu and then select 'Check for updates'.

If a newer version is available, a prompt similar to the following will be shown:

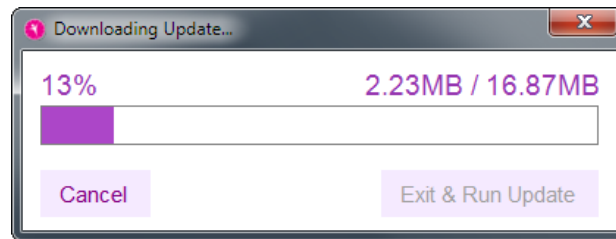


Click 'Yes' to download the new version or click 'No' to ignore the update message.

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

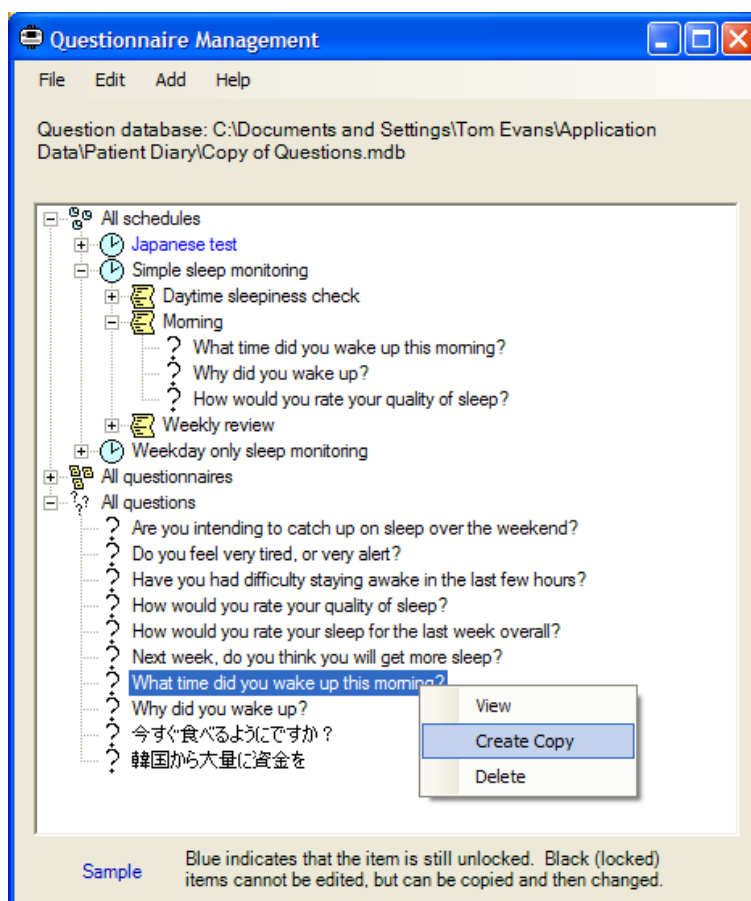
A USB extension hub may be more convenient to charge several PRO-Diary devices at once without requiring a PC to be connected. This hub must be powered by a separate mains adapter. CamNtech can supply a suitable powered 7-port USB Hub if required – please contact your local distributor.



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

4 Creating and Editing Questionnaires

The Diary is set up using a combination of questions, questionnaires, and schedules. It is easiest to familiarise yourself with these by exploring the examples included with the PC software. After clicking on 'Edit Questionnaires' in the main menu, you will be presented with the quick view window, as shown in the example below. You can explore this tree by right-clicking or double clicking on various items to get an idea of how the system operates.



4.1 Basic Concepts

It may be useful to clarify the terminology used in programming the Diary:

The Diary presents the user with questions, either at specific times or when the wearer requests it, and logs their answers. '**Questions**' are grouped together into '**questionnaires**', and a '**schedule**' instructs the diary when to offer each questionnaire to the wearer.

A '**question**' is the basic question presented to the wearer. It may be one of half a dozen basic types, and includes the question itself and various optional answers, or default settings for entering numbers, times, etc.

A '**questionnaire**' is a sequence of questions. It may, optionally, include more complicated instructions for skipping or jumping around in the sequence depending on the answers to some questions.

A '**schedule**' is a list of schedule entries, each with a time and day which tell the Diary to do something at that time. These may prompt the user, or simply make available a user-requested questionnaire during a given period. They may also apply to 'every Tuesday' or 'every weekday' rather than a specific day.

It will be easiest to set up your first test recording using one of the example schedules provided, rather than having to create your own first.

4.2 Questions

There are eight types of questions:

- Multiple choice
- Visual analogue
- Enter a number
- Enter a time
- Just a message
- List
- Free Text
- Likert Scale.

All types include a main 'question' message, but a selection of different answer mechanisms.

Multiple Choice

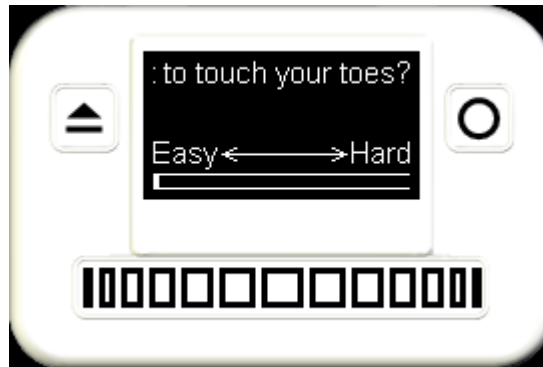
For example: "Which fruit do you prefer?", with possible answers of "Apples", "Oranges", or "Other".



Each question has 1-8 answers. The user positions the slider directly by tapping or dragging, and the chosen answer is taken from this. The currently selected answer is displayed at the bottom of the screen just above the slider bar. This is the easiest way to question the user for up to around 5-6 answers, but above that the list may be less cumbersome to operate.

Visual Analogue

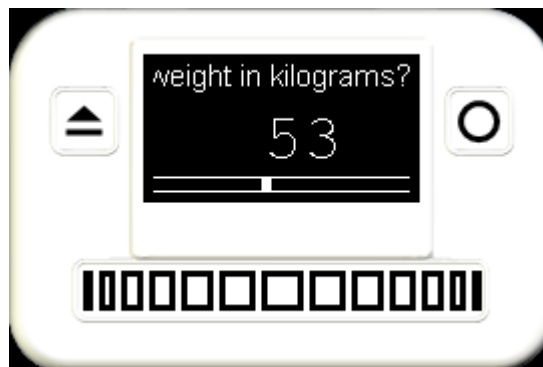
For example: “How difficult is it to touch your toes?” with the text “Easy” at the left hand end of the slider bar and “Hard” at the right hand end.



The user positions the slider directly wherever they feel is appropriate between the two ends. These ends are described by extra prompts, displayed just above the slider bar. Ideally these should be short enough to fit at each end of the bar with a gap in the middle. If it is longer than that it will be repeatedly scrolled through, but this is not ideal.

Enter a Number

For example: “What is your weight in kilograms?” with the answer 53 displayed below and a range up to 120.

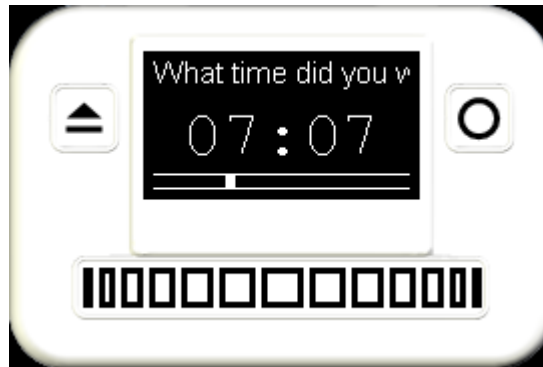


The user drags the slider left or right to change the displayed number until they are happy with the answer. They may also hold it at either end to scroll up or down continuously.

Questions include a default value, decimal point position, and minimum and maximum values. The decimal position specifies how many digits to include after the decimal point. When you are editing an 'Enter a number' question, a message will be displayed explaining the current meaning of your settings.

Enter a Time

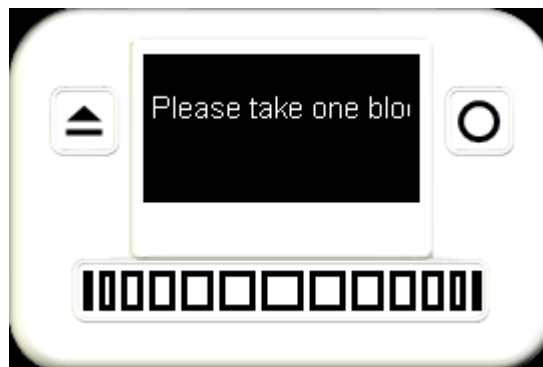
For example: “What time did you wake up this morning?” with a time of “07:07” displayed.



This functions similarly to ‘Enter a number’, except as the user drags the slider the displayed time changes. They can move it until they are happy with the displayed time, to an accuracy of 1 minute in 24 hours. Dragging beyond the beginning or the end of the 24 hours results in the time wrapping round. The Diary automatically starts with the current time when the question is asked.

Just a Message

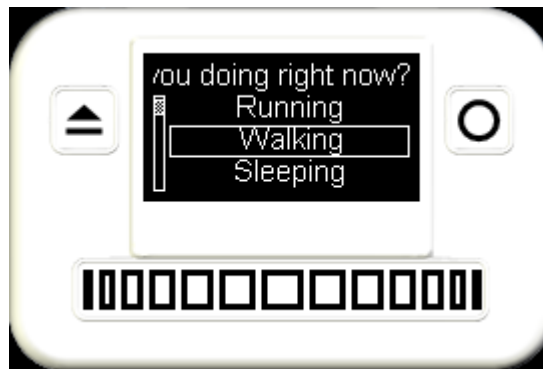
For example: “Please take one blood pressure pill now” with no additional information or prompt.



No extra parameters are needed, and no answer may be selected. The main question is simply displayed in the middle of the screen until OK is pressed.

List

For example: “What activity are you doing right now?” with a list of 20-30 activity types to select from.



The Diary will display the question along with part of the list and a scrollbar to indicate the user can scroll up or down the list by dragging their finger on the slider. They may also hold their finger at either end for a period to scroll continuously. This interface makes it much easier to present a larger number of options, but is a little more complex for simple questions. It cannot be combined with the large text setup option, as the screen of the Diary is not large enough.

Free Text

For example: “What did you just eat?” with the ability to type in any text as an answer.

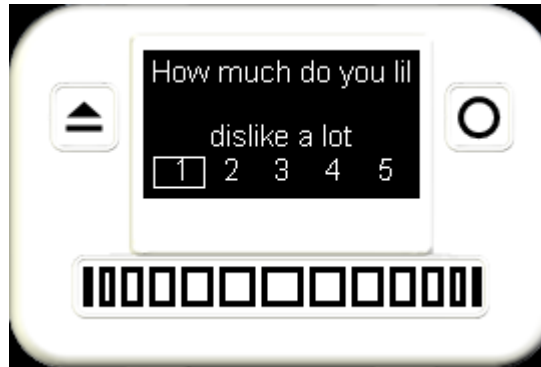
This is much slower to input than any other question type, but may be invaluable if you really need to capture any possible answer to a single question.

The Diary will present the question along with a compressed alphabet. To select a letter, place your finger approximately under that letter. The alphabet will begin zooming in. Keep ‘steering’ your finger onto the correct letter as it zooms. Once a box appears around the letter, you can release your finger and the letter will be added to your answer. If you become confused when zooming in, simply release your finger early to cancel. If you do enter an incorrect letter then simply select the symbol to the left of the main alphabet, ‘DEL’, to delete the previous letter.

Because the free text entry is considerably slower and more difficult to operate than other question types, you should only use it if necessary and if you believe your target population will be comfortable with it. You will need to demonstrate the free text entry to users before they can operate it.

Likert Scale

For example: “How much do you like fruit?” with a scale of five answers.



This allows the user to select from a numerical scale, whilst also attaching a small text description to each level. The text is displayed above the selected number scale similarly to a multiple choice question, but with the addition of the highlighted number display below.

4.3 Questionnaires

A questionnaire can simply be a list of questions presented in the order they should be asked. The user will be asked the question at the top of the list first, and proceed down the list one by one. This is all that is required if the user should be asked all of the questions every time.

Simple questionnaires can be designed for the PRO-Diary by dragging questions from the available list at the bottom of the window into the main list. The questions can be placed directly where they are wanted in the sequence, or re-ordered later by dragging them up or down the list. To remove a question, simply drag it back onto the available list below.

It is also possible to design questionnaires with more complex sequencing once the ‘advanced mode’ of the questionnaire editor is enabled. The question sequence may then be modified by the user’s answers to a multiple choice question. In this case, each alternative answer to that question may have a different following question number attached to it. This allows a ‘detail’ section to be skipped if it is not relevant. This is described in more detail in Section 4.8.

4.4 Schedules

A schedule consists of a list of schedule entries, and an optional motion logging configuration. Each schedule entry makes a questionnaire available at a certain time or times, either prompting the user or simply being available on the menu when the unit is woken. Every entry consists of a questionnaire, a day designation, and time/type of entry.

Day Designation

Each entry is applied on certain days, chosen from the options below. Thus, any single schedule entry may cause the Diary to act on many days throughout a month's recording rather than just one.

- Every day
- Every weekday
- Every weekend day
- Every Monday, Tuesday, ... or Sunday
- Day n of the recording (n from 1 to 30).

Time/Type of Entry

Entries may be marked to prompt the user either at a fixed time, or at a randomly allocated time within a certain period. This can be used to avoid consistently prompting at exactly the same time every day, when the user might normally be busy or begin to expect the prompt.

Entries may also be marked as 'On request' during a period of time. This means that if the user wakes up the Diary at any time during that period then they can choose to answer the questionnaire at that time, rather than waiting for an alarm. They can then for example tell the Diary that they have woken up, eaten, or intend to go to bed now.

Motion Logging

Motion logging may be enabled as part of the schedule. This will cause the Diary to record how much it is moved throughout the day, logging at a chosen "epoch" interval of between 1 and 60 seconds. The resulting data can be used to monitor sleep or daytime activity profiles, and analysed using the CamNtech MotionWare software package.

The "MotionWatch-compatible counts" mode records movement in a measure compatible with CamNtech MotionWatch products in Mode 1. This measure is well validated for sleep monitoring, and has been used for daytime activity monitoring also.

The "MotionWatch Triaxial counts" mode records movement using all three movement axes in exactly the same way as CamNtech MotionWatch products in triaxial mode. This produces more reproducible results for physical activity across a range of intensities and mountings. It is not directly validated for sleep monitoring, though the analysis options remain available and results are similar.

4.5 Locked and Unlocked Items

When an item has just been created (a question, questionnaire or schedule), it is considered to be 'unlocked'. It will remain unlocked as you edit it and combine it with other items. When you first use an item when setting up a Diary, all the used items will be locked. This is necessary so that you have an accurate record of exactly what went into setting up each Diary, in order to interpret the data downloaded from it. If you subsequently decide you did not want exactly the same setup, but rather a slight variant on it, you must right click and 'Create Copy' to create a new unlocked copy with a slightly different name. This copy can then be modified. This allows you to keep track of your progress with

modified options, as each one is stored separately with a version number tagged on the end of the item name.

4.6 Creating a New Question Database

When you want to begin work on your own set of questions and schedules, you can create a new database file to contain these. This way it will not be cluttered up by the examples or any questions you have previously created for a different purpose. To do this, use the 'File -> New Question Database...' option in the quick view window. You can later switch between question databases using 'File -> Open Question Database...'. Your current database file is also shown in the quick view window.

4.7 Diary Menu Customisation

There is an option in the File menu of the quick view window for menu customisation. This allows you to change the text shown by the Diary during common actions. You can use this to translate the menu text of the Diary to a different language. You can also use it simply to clarify or slightly change the English messages if you wish. Once you have created a set of menu customisations using this option, you must select one from the drop down list when setting up a Diary in order to make use of it.

4.8 Conditional Questionnaire Sequences

Simple questionnaires can be designed for the PRO-Diary by dragging questions to and from the available list. The questions will always be asked one after the other from the top to the bottom. They can be re-ordered by dragging them up or down the list. However, it is also possible to design questionnaires with more complex sequencing once the 'advanced mode' is enabled. This section describes how to create and modify questionnaires with different sequencing.

Quick Summary

- Select a question to see its answers
- Each answer has an arrow showing which question will then follow if that answer is chosen
- Drag an answer to a different place in the questionnaire to create a link for that answer
- Do this for as many answers as you want to
- If you want all answers to lead to the same place, drag the '- Drag here to redirect all answers -' item
- If you want to remove your links, so all answers just lead to the question below, press the button for 'Clear links from this question'
- A sequence of questions can be marked for random ordering, but only if there are no conditional links within them.

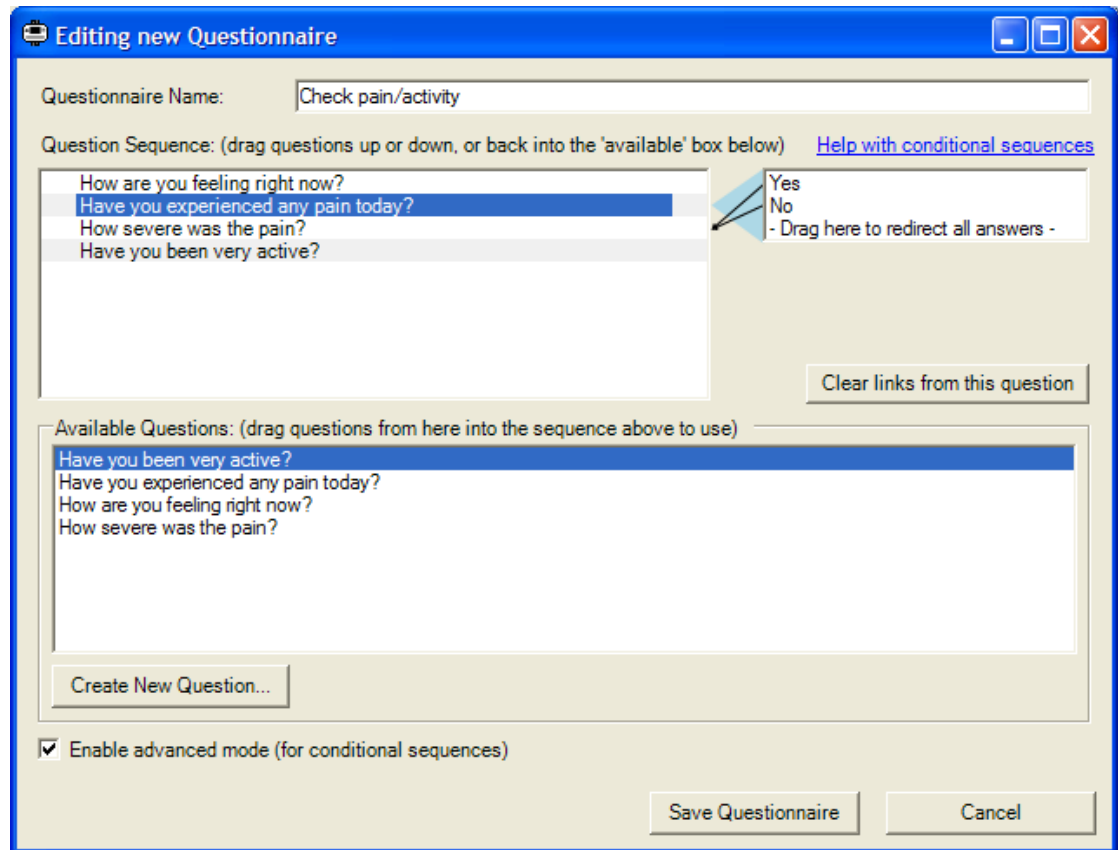
Note that:

- You can only create a split in the sequence using a multiple choice question, because only these have several different answers
- Small arrows will be added to the side of the question list whenever an answer leads anywhere except the question below

- You can drag answers to just below the bottom of the list to direct straight to the end of the questionnaire.

Simple example (to omit some questions depending on a previous answer)

In the first example, we show how to make a part of the questionnaire optional, depending on the answer to a question. First, drag all the questions you want into the questionnaire. An example with four questions is shown below, with the second question selected:



You can see the question 'Have you experienced any pain today?' is highlighted, and a box is displayed to its right including the answers 'Yes' and 'No' from that question. Both of these answers have arrows leading from them to the next question in the main list. This means that giving either answer will lead to the same following question, which is always the default. However, we would like to omit the next question if the answer is 'No'.

Move the mouse cursor over the 'No' answer, and press and hold the left mouse button to drag it from here over the question list to the left. As you do this you will see the mouse pointer change, and the target question is highlighted. Release the mouse to 'drop' the answer on the question 'Have you been very active?'. The window will now look as follows:

Editing new Questionnaire

Questionnaire Name: Check pain/activity

Question Sequence: (drag questions up or down, or back into the 'available' box below) [Help with conditional sequences](#)

How are you feeling right now?
 Have you experienced any pain today?
 How severe was the pain?
 Have you been very active?

Yes
 No
 - Drag here to redirect all answers -

Clear links from this question

Available Questions: (drag questions from here into the sequence above to use)

Have you been very active?
 Have you experienced any pain today?
 How are you feeling right now?
 How severe was the pain?

Create New Question...

☒ Enable advanced mode (for conditional sequences)

Save Questionnaire Cancel

As you can see, there are now changes in the arrows to show the new question sequence. The arrow from the 'Yes' answer still leads to the immediately following question, but the arrow from 'No' now leads to the new target question. So the user will move to a different next question depending on their answer at this point. In addition, a small arrow has appeared to the left of the main question list to show an alternative sequence is present here. You can always see the exact sequence by selecting a question to reveal the answers.

Bigger example (to present a nested set of options)

You may wish to allow the user to select from a larger number of options, but have them organised in a logical structure rather than a longer list. One way to present, for example, ~20 answers would be as a nested set of questions. To ask what the user is doing right now, the answers could be divided into a number of categories, with options within them:

Work

- Sitting at a desk
- In a meeting
- Manual work
- Other
- Home/Leisure

Housework/DIY

- Talking to friends/family
- Watching TV
- Outdoor activity
- Indoor exercise
- Other

Travelling

- Driving
- Public transport
- Walking
- Cycling
- Other

Eating

- Breakfast
- Lunch
- Dinner
- Other (small meal)
- Other (large meal)

Other

- Physically active
- Inactive.

The category can then be chosen with a single 'top-level' question. The answer to this then determines which category question will be shown. With questions entered for the top-level, and each of the categories above, the questionnaire design window looks like this:

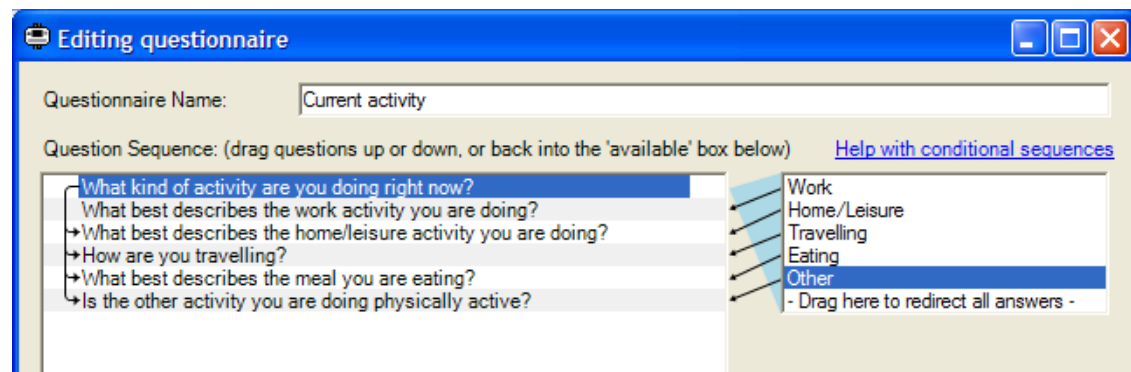
The screenshot shows a window titled "Editing questionnaire". At the top, there is a text field for "Questionnaire Name:" containing "Current activity". Below this is a section for "Question Sequence:" with instructions to drag questions up or down. A list of questions is shown, with the first one, "What kind of activity are you doing right now?", selected. To the right of this list is a tree view showing a hierarchy: "Work", "Home/Leisure", "Travelling", "Eating", and "Other". Arrows point from each of these categories to the selected top-level question. Below the tree view is a button labeled "Clear links from this question". At the bottom of the window is a section for "Available Questions:" with a list of questions that can be dragged into the sequence. A checkbox labeled "Enable advanced mode (for conditional sequences)" is checked. At the very bottom are "Save" and "Cancel" buttons.

As can be seen, there are no arrows within the list because it is currently still a straightforward sequence from top to bottom. The top question is selected, but every answer from it is pointing at the question just below.

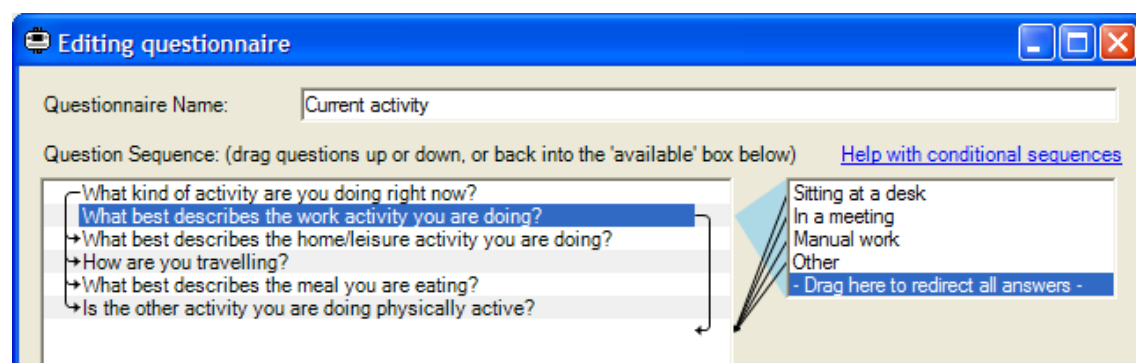
Next, we wish to create links so that the correct question will be jumped in sequence, depending on the answer to the first question. So, using the mouse:

- Drag the 'Work' answer onto the work activity question
- Drag the 'Home/Leisure' answer onto the home/leisure question
- Drag the 'Travelling' answer onto the travelling question
- Drag the 'Eating' answer onto the eating question
- Drag the 'Other' answer onto the 'other activity' question.

The window should now look as below, showing each answer leading to a different one of the questions below. There is also a set of arrows down the left of the question list summarising the same thing (NB the link between the 1st and 2nd question is not shown, as the list would be very cluttered if these were always shown).

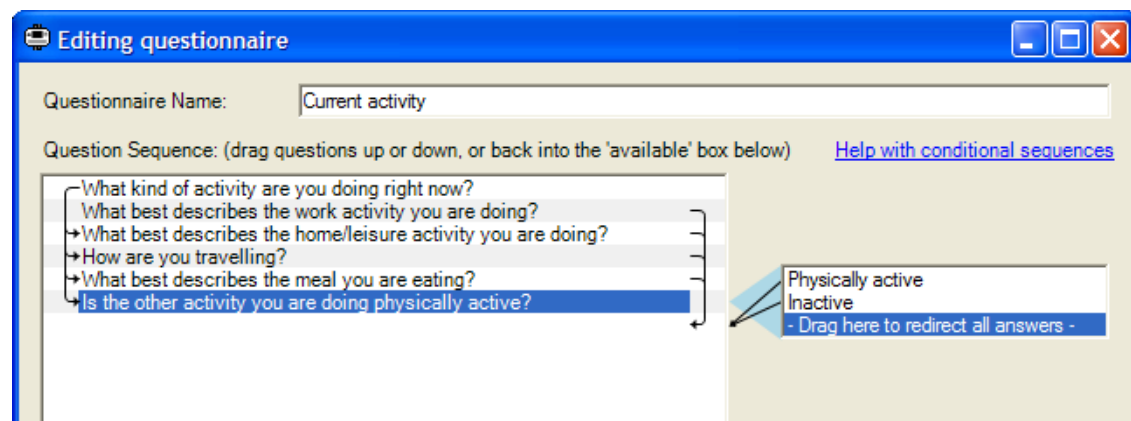


We now need to ensure that the user will jump to the correct following question after their 'category question'. Otherwise they will simply step down the list and be asked all of the questions below it. To start this, first select the 'What best describes the work activity you are doing?' question. Now use the mouse to drag the special entry at the bottom of the answers list onto the very bottom of the questionnaire (below the last question). You should then see this:



Here, you can see that every answer to the 'work activity' question now points to the line just below the bottom of the question list. This means that they will go to the end of questionnaire straight away, with no further questions. Obviously there could be a sequence of other questions here below the categories instead.

Select each of the category questions in turn, and drag each of their ‘ - Drag here to redirect all answers – ’ to below the bottom of the questionnaire. You should now see:

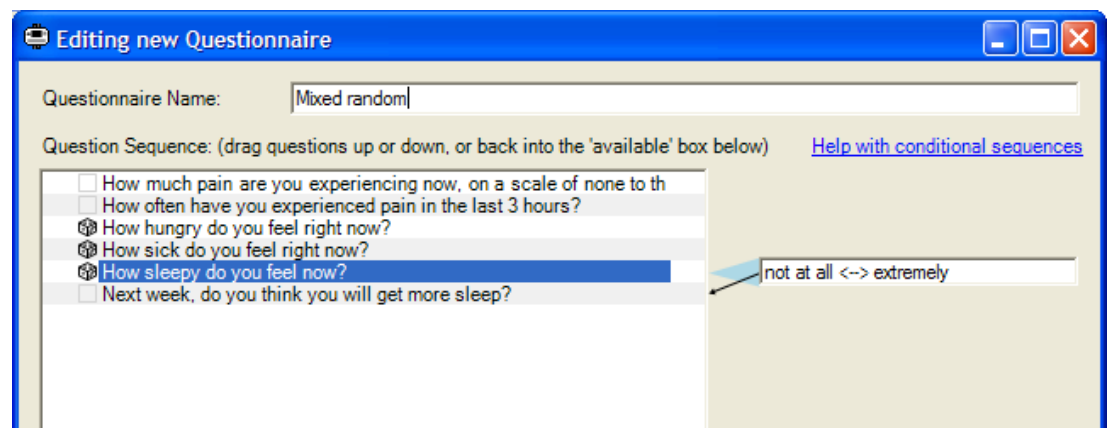


Note that this completed set shows both a set of arrows down the left from the first question, and a set down the right leading from each of the category questions to the common following point below (which happens to be the end of this questionnaire).

Using conditional/linked questions, we now have a questionnaire where the user can choose between 22 different options based on a logical set of categories, rather than having to scroll through a long single list. Obviously the better choice will depend on your application, but the Diary can support either method.

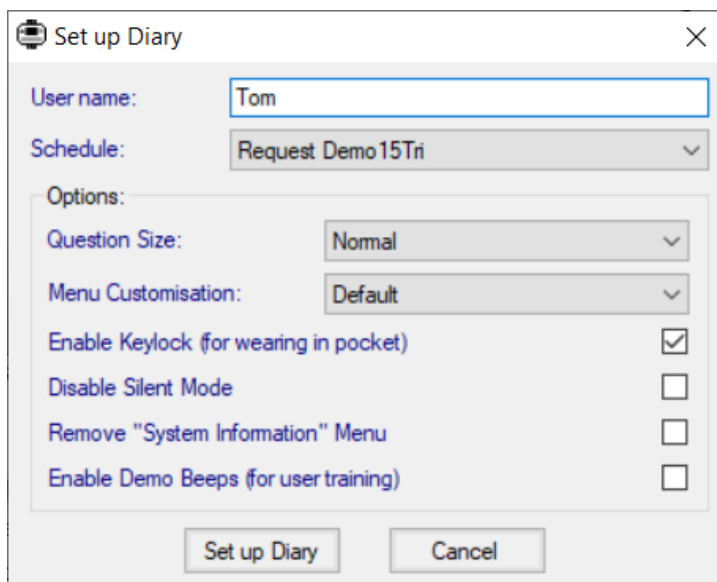
Random Ordering Example

To avoid the wearer becoming fatigued with a certain set of questions, it is possible to randomize all or part of a questionnaire. To do so, first enable the advanced mode, then click just to the left of each question to display a dice symbol next to it. Any contiguous block of questions labelled with the dice will then be placed in random order each time they are scheduled. In the example shown below, the three central questions will be randomized, but the other questions will not.



5 Setting up a Diary

Selecting the option to 'Set up a Diary' from the main menu will result in a window similar to that shown below. This shows the various setup options available. These options will be affected by the currently opened question database – i.e. only schedules and customisations from the current question database will be available.



There are a number of options:

5.1 User Name

This field can be used to enter the wearer's name or any patient/volunteer ID number you wish to be stored in the Diary to identify the wearer. It will not affect the setup, but will be stored along with the data when the Diary is downloaded after use.

5.2 Schedule

This determines which questionnaires will be available or prompted for at what times, once the Diary is set up. All the available schedules in the current question database are listed. Additional schedules can be created or edited using the 'Edit Questionnaires' option. The 'Request Demo' schedule in the example database will make a demo questionnaire available on request as soon as the Diary is set up.

5.3 Question Size

Text can be displayed on the Diary in the standard size, or a large version. The large option may be useful if you are working with a group of wearers who have difficulty with the standard text size. However, it is a compromise as text will take longer to read as it scrolls across the display.

5.4 Menu Customisation

As introduced previously, this allows translation or modifications of the standard pieces of text in the Diary if you wish. If you have created a new customisation, it will be available in this list. Otherwise you should select 'Default'.

5.5 Enable Keylock

The Diary may be carried in the pocket as an alternative to being wrist worn. In this case you must enable the keylock to prevent accidental data entry. This will require the wearer to smoothly run their finger across the slider before accessing the Diary (they may move their finger relatively quickly or slowly for this, it is only important that they move it across the slider at a steady rate).

5.6 Disable Silent Mode

Normally the Diary allows a “Silent Mode”, whereby the user can choose to silence the device temporarily. This allows them to continue to wear it during an occasion when they do not want any noise to be produced, rather than removing the device. You may select this option if you particularly wish to prevent the user from making their Diary silent. Beware the user may then choose to remove the device on occasion instead.

5.7 Remove “System Information” Menu

At the right-hand end of the normal device wakeup menu there is the System Information item. This allows the user to see current schedule name, battery status and firmware version. If you particularly wish to simplify operation of the device for your users then you may choose to remove this option, but it will remove the ability to quickly check the configuration of the Diary.

5.8 Enable Demo Beeps

You will normally leave this option disabled. When training your users, it may be useful to have a ‘training’ Diary set up to demonstrate to them what will happen when they are wearing it. If this option is enabled, then a function is created at the right hand end of the system information menu to artificially begin a beeping questionnaire. When you activate this, the Diary will begin beeping (or vibrating) just as if a timed questionnaire had been scheduled for exactly that moment. You then hand the Diary to the new user and talk them through responding to the questionnaire. The questionnaire shown will be the first one available on request at that point in time. If there are no questionnaires available on request, this function will do nothing. You will probably want to combine this option with a schedule designed just for training/demonstration.

Once you are happy with the options selected, click on ‘Set up Diary’ to set up the Diary currently connected to the PC. Only one Diary must be connected at this point.

6 Using the Diary

The Diary is designed to be as simple and intuitive to use as possible. This section guides you through basic use in case of any difficulty. We recommend that you demonstrate the use of the Diary in front of each volunteer before a trial, and then ask them to work through your questionnaire on it whilst you are available to answer any questions. This may be easiest to arrange with a spare 'teaching diary' which is already set up to have a relevant questionnaire available on request.

6.1 Waking up the Diary

Once it is set up, the Diary can be woken by placing your finger across the left hand button with the triangular icon, and leaving it there for 1-2 seconds. You should not use any force, simply place your finger over the button for the time required.

If the 'keylock' function has been enabled, you will then be prompted to swipe your finger smoothly across the slider below the screen. You may do this quickly or slowly and in either direction, but your finger must move at a steady speed.

6.2 Using Menus and Answering Questions

Once you have woken the Diary you can choose between options in a menu by putting your finger on the slider and moving it around to the left or right. The slider is always used to explore or change options, and will never actually activate anything, so you can operate it freely without fear of changing anything. Once you are happy with the option or answer displayed, select it by putting your finger on the round button to the right of the screen.

6.3 Answering a Scheduled Questionnaire

When scheduled, the Diary will beep repeatedly to alert the wearer that there are some questions to answer. They may then choose (by moving their finger across the slider) to either answer the questions immediately, wait a few minutes, or cancel the session entirely. As above, once they have chosen their favoured option they simply put their finger on the right hand button to activate it.

If the wearer chooses to delay the question session for a few minutes, they can manually re-wake the Diary at any point during that period to begin answering the questions.

6.4 Requesting a Questionnaire

If a questionnaire has been made available on request, the user may open it whenever they choose. It will be available in the main menu when the Diary has been woken normally, as one of the first items in the menu (before the silent mode and system information options). If they select it, they will begin answering that questionnaire.

This can be used for reporting a painful incident, or exercise taken, or food eaten, etc. Because of the nature of these events, the user can choose to enter as many such events as they like whilst the questionnaire is available on request.

All will be recorded. This may be valuable or even essential to capture important data.

However, be aware that it may make it more difficult to process the final results data in a regular manner.

6.5 Silent Mode

The Diary may be set to silent mode from the main menu after waking it; this will stop the audible sounder or vibration. To do this, move your finger until the 'Enter silent mode' option is displayed, and activate it with the right hand button. The option will then be renamed to 'Quit silent mode'. This confirms that you are now in silent mode. The Diary will remain in silent mode until the wearer activates the option again to change it back. Obviously, you would encourage your volunteers to use this mode sparingly, but it is a better alternative to leaving the Diary behind somewhere (where it may be forgotten) when going to a meeting or similar.

6.6 Not Waterproof

Anybody wearing or carrying the Diary must be warned that it is not fully waterproof, mainly due to the presence of the USB socket. With the USB bung fitted, it will withstand accidental splashes in daily use, but it must be protected from any greater exposure to water.

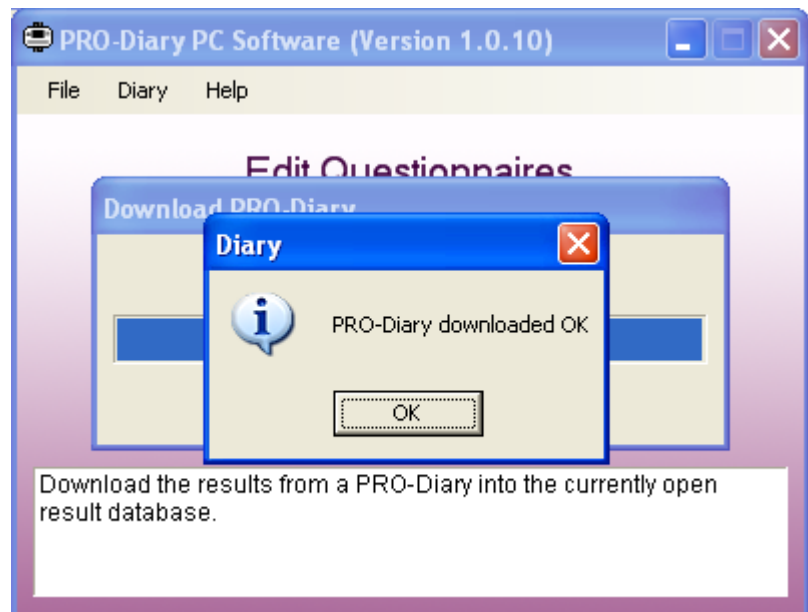
6.7 Wearing & Strap options

The PRO-Diary is designed to be worn on the wrist with replaceable fabric straps or washable plastic straps available from CamNtech. It uses standard sprung watch pins for the attachment so you can obtain alternative straps from any watch supplier. Either CamNtech or your watch supplier will also be able to assist if you are not confident inserting the spring loaded pins yourself.

7 Downloading Results

After the end of a trial with the Diary, the results can be downloaded to your PC for analysis. For convenience, results are stored in a database file, so that you can keep many downloads together in one file. You can then also create a new file when you want to group together another series of downloads. A default results database file is created when you first use the software.

To download data, connect the Diary to the PC and click on 'Download Results'. The data will be downloaded to the current results database, and a popup window will confirm when the download is finished. This is normally very quick, and will look as shown below when successful:



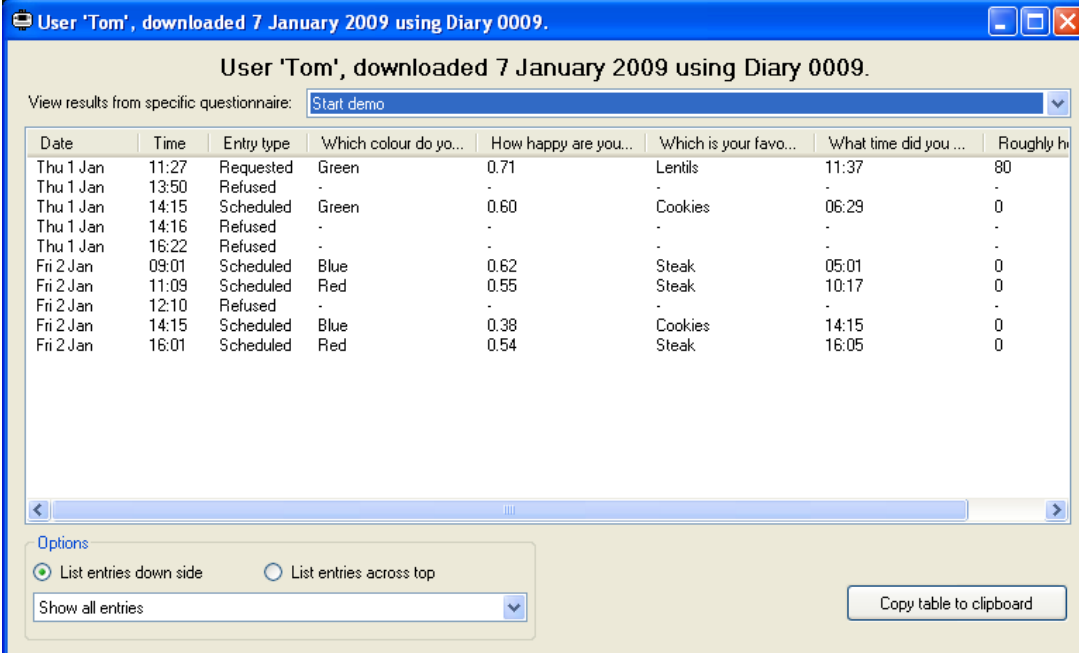
If you wish to create a new results database you should use 'File -> New Results Database...' after which the new database will be selected. You can then change your currently selected database as you wish using 'File -> Open Results Database'. This setting will affect both where your data is downloaded to, and the database which will be opened when you click on 'Open Result Viewer'.

8 Viewing Results

When the 'Open Result View' option on the main menu is clicked, the software will display a list of all the downloaded data in the currently selected result database. If you want to look in a different result database, use 'File -> Open Result Database...' before selecting the viewer option.

You can open any entry in the results list by double-clicking on it, or selecting it then clicking 'Open'. However, you must have a copy of the question database which was used to set up the Diary for each entry. The software will attempt to find this automatically when you try to open an entry; if it cannot do so then it will ask you which question database it should look in to find the Diary setup.

Once you have opened a download, you will see results similar to the image below. This is a table of all the answers the Diary recorded. The contents of the table can be changed using the filtering functions described below, and the data can then be exported using the button in the bottom right of the window. This will create a plain text table which can be pasted directly into Excel to create a spreadsheet of results, or used for your own analysis.



Date	Time	Entry type	Which colour do yo...	How happy are you...	Which is your favo...	What time did you ...	Roughly h
Thu 1 Jan	11:27	Requested	Green	0.71	Lentils	11:37	80
Thu 1 Jan	13:50	Refused	-	-	-	-	-
Thu 1 Jan	14:15	Scheduled	Green	0.60	Cookies	06:29	0
Thu 1 Jan	14:16	Refused	-	-	-	-	-
Thu 1 Jan	16:22	Refused	-	-	-	-	-
Fri 2 Jan	09:01	Scheduled	Blue	0.62	Steak	05:01	0
Fri 2 Jan	11:09	Scheduled	Red	0.55	Steak	10:17	0
Fri 2 Jan	12:10	Refused	-	-	-	-	-
Fri 2 Jan	14:15	Scheduled	Blue	0.38	Cookies	14:15	0
Fri 2 Jan	16:01	Scheduled	Red	0.54	Steak	16:05	0

8.1 Filtering by Questionnaire

The table can either be used to display a row for every set of answers, or only those from a specific questionnaire. Showing every set is comprehensive, but does not allow the answers to be shown, as these would require different sets of column headers. Choosing a specific questionnaire will show all the answers given to that questionnaire. Most of the individual answers are self-explanatory, but the visual analogue value is given as a decimal value between 0.00 and 1.00, with the former corresponding to the left hand end of the scale and the latter to the right hand end.

8.2 Transposing the Results Table

Depending on the aspect of data you are looking at, it may be more convenient to have the table arranged with a swap of columns and rows. You can choose between these slightly different tables using the 'List entries down side' and 'List entries across top' options.

8.3 Filtering by Scheduled/Requested

You can use the drop down list in the options area to filter just those entries which relate to scheduled entries (even if they are refused), or only those which the user had requested. By default, all entries are shown.

8.4 Exporting Motion Logging Data

If the Diary recording contains motion logging data in addition to the questionnaire results, the results window will contain a button for accessing that additional data. This can be used to save the data for the MotionWare analysis software (as a Motion format file), or optionally in an Actiwatch-compatible format for analysis with your existing sleep software. The latter format will not save some details of the file data, particularly only marking questionnaire times to a per-epoch resolution, and having no method of marking data periods "missing" rather than simply zero, but is adequate for most analysis. Note that you can save in several formats simultaneously by leaving them selected. The raw recording is also kept in the Diary software, so can be re-exported using this method at any point.

8.5 Other Exports/Data Analysis

The data viewing and export interface is designed to be functional for those who wish to analyse their own data. However, there are many different methods to proceed with that analysis. If you need more assistance with your data analysis, please contact CamNtech to discuss this; we may be able to make some arrangement to assist you.

If you are performing your own data analysis, but require clarification of the data export or want some raw information which appears to be missing from the export interface, please contact us.

9 Tutorial

The PRO-Diary is designed to provide a flexible package combining accurately logged subjective results with epoch-by-epoch actigraphy data. This allows a uniquely integrated approach to data collection for sleep and lifestyle monitoring, but inevitably makes the system slightly more complex to configure. **This tutorial leads the researcher step-by-step through a simple sleep monitoring configuration; it is recommended that you work through it as an introduction to the system.**

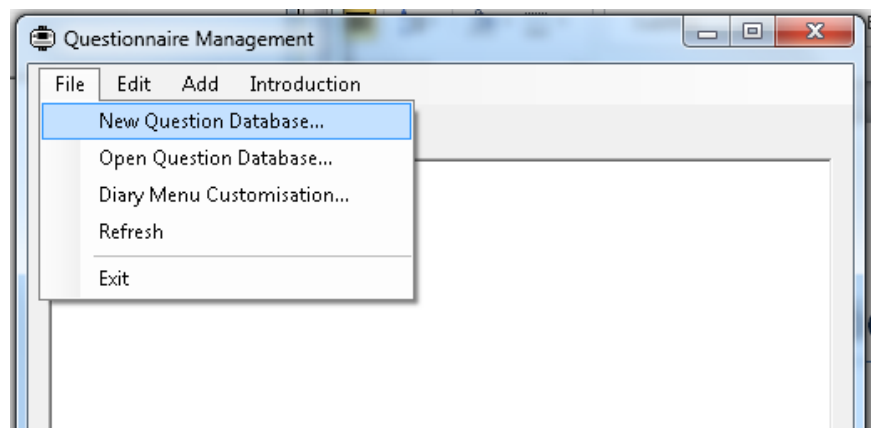
The system will be set up to monitor sleep using a few features, introduced here step by step:

- Epoch-by-epoch motion logging
- Subjective sleep information collected at lights out and getting up times
- An extra mid-afternoon questionnaire to assess sleepiness.

You can omit the motion logging if you do not need it for your application or are using a PRO-Diary without the feature.

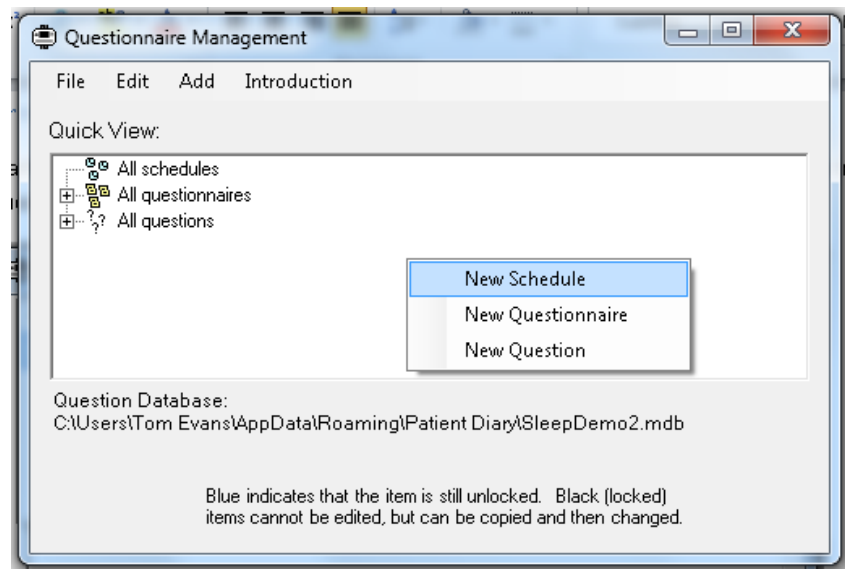
9.1 Create a Schedule

Start the PRO-Diary software, and click on the “Edit Questionnaires” option. Then create a new question database using the File menu:

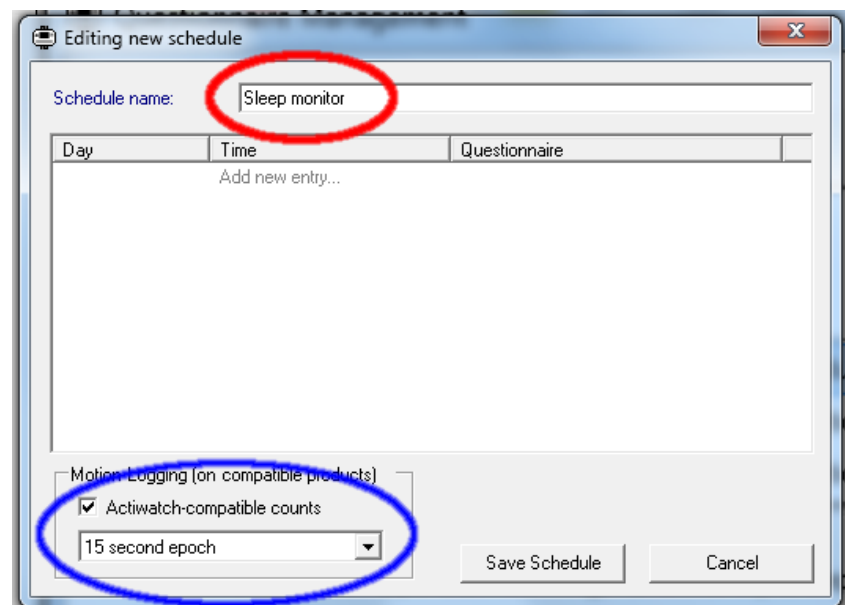


You can create the database in the default folder, or in whatever location you choose on your computer. Putting your new work into a new database like this simply avoids confusion with any existing questions.

Next, we will create a new “Schedule”. This is a set of instructions saying when and how the Diary should collect data. Use the “Add” menu or right click on the main window area to find the New Schedule function:



The software will display a blank new schedule. You should then edit the schedule as shown below:



The red circle highlights the schedule name – this is fairly self-explanatory and allows you to refer to several schedules within the question database. It must be set to something meaningful before saving the schedule, but is not otherwise important.

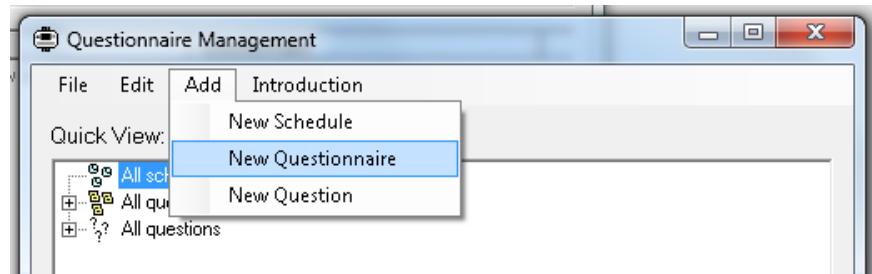
The blue circle shows settings controlling the motion logging of the PRO-Diary device, and in this example the software is set to record Actiwatch-compatible counts on a 15 second epoch. This means that a single number will be recorded every 15 seconds summarising how much movement there was within that period. The Actiwatch compatible mode is designed to recreate a compatible measure which is already well validated for sleep use. In future software there may be additional measures targeted more for the intensity of daytime activity.

You can now save the schedule if you wish (with no entries listed in the central part of the window), or leave it open for now.

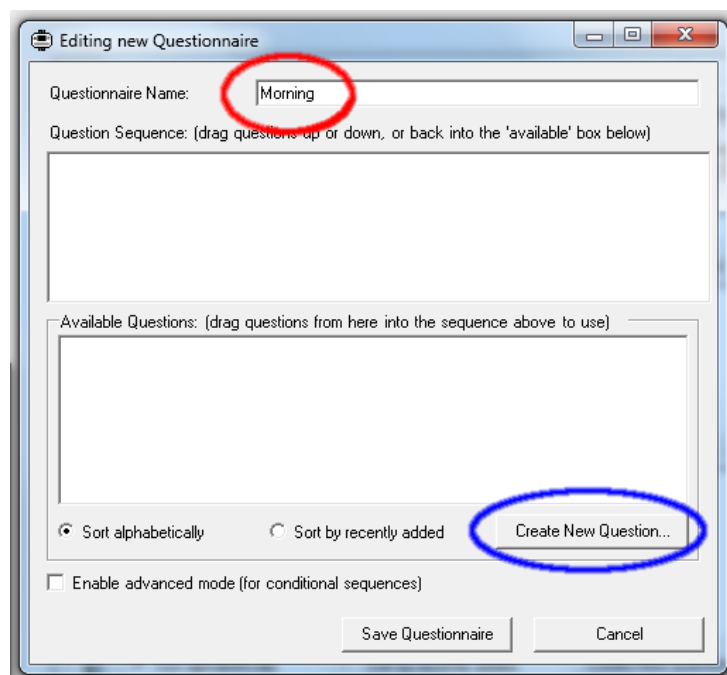
9.2 Waking Up

Next, we will create a questionnaire for the user to complete after they wake up. This both collects subjective data at the start of the day, and additionally places a mark in the resulting actigraphy data which makes analysis easier (in exactly the same way as the marker button on simpler actigraphy devices).

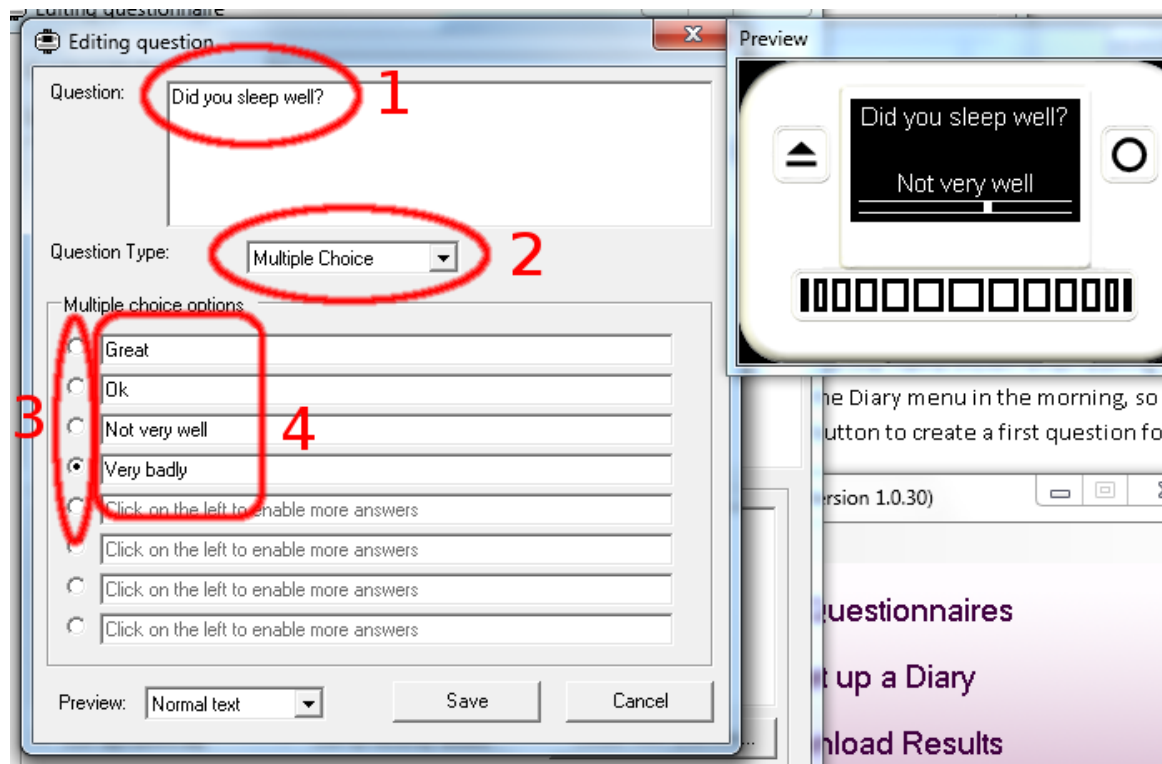
First, return to the Questionnaire Management window and use the Add menu (or right click in the main window) to create a new Questionnaire:



This will create an empty new questionnaire, as shown below. First change the questionnaire name to “Morning” as in the red circle. This is not just the name shown when editing, but also the name of the item which the user must choose from the Diary menu in the morning, so it must be short and appropriate. Next use the blue highlighted button to create a first question for the questionnaire:



We will simply create an example question which could be asked of a user at the start of each day. It is best to become familiar with this interface by experimenting with the different question types available, but for now follow step-by-step instructions to create the question below:

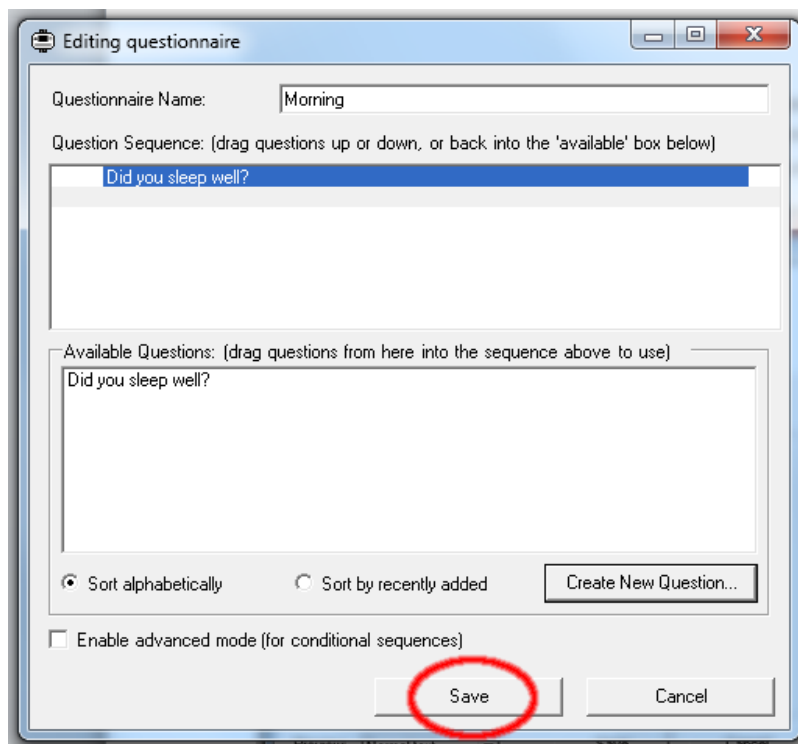


Configure the parts circled in red above:

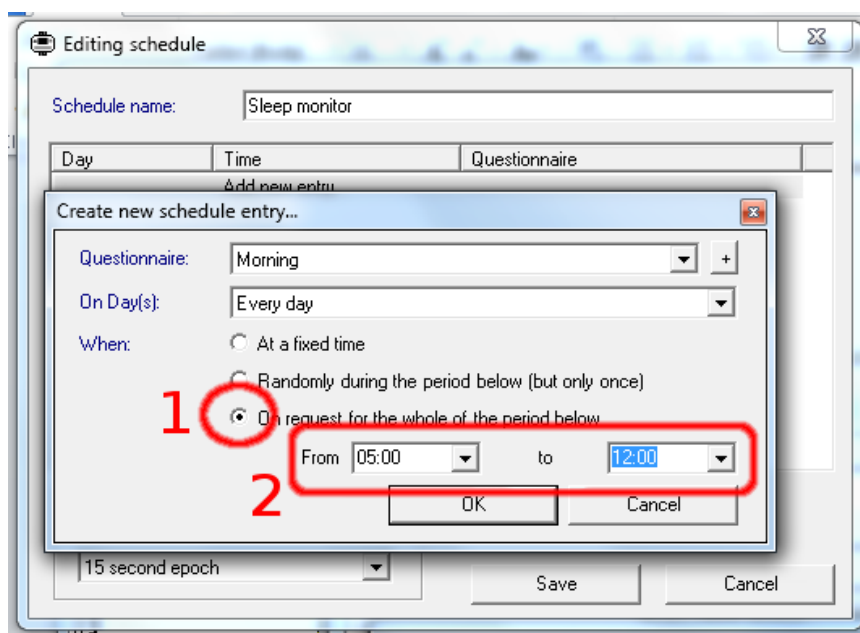
1. Type in the question “Did you sleep well?”
2. Ensure the “Multiple Choice” question type is selected
3. Select the fourth mark down on the left to enable four answer boxes to the right
4. Fill in the answers as suggested.

Note the preview window on the right. This allows you to see how well the question and answers fit on the screen of the PRO-Diary. You can move your mouse across the selection bar below the display of the Diary to show different answers. If the preview window is not visible you can create it using the drop-down in the bottom left of the question window.

Click “Save” in the question window to add the question to the Morning questionnaire. You can then continue do add more questions if you wish, experimenting with other question types. Then save the questionnaire using the “Save” button circled in red:



Next, we will add the “Morning” questionnaire to the schedule, so that it will be available for the user to select in the morning. Return to the schedule window, or double-click the schedule in the Questionnaire Management window if you had already saved it. Then click on “Add new entry...”:

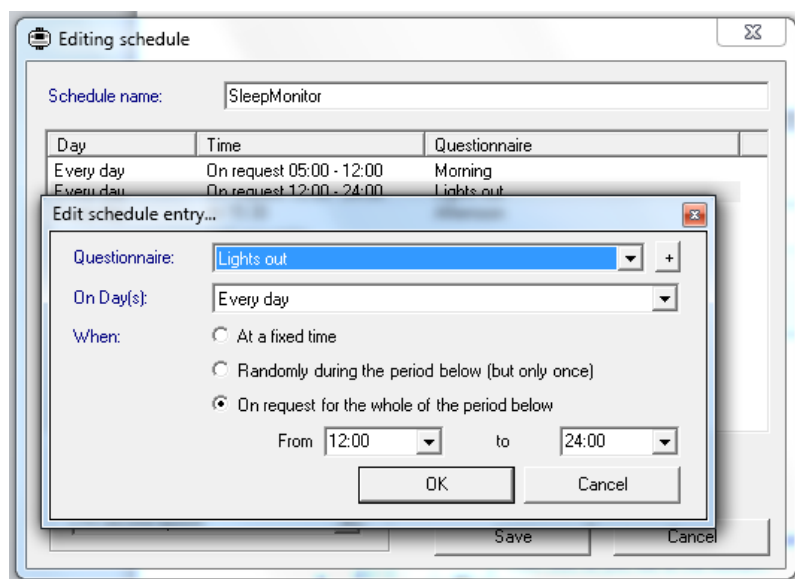


The questionnaire and “Every day” options should already be set by default, and you should set the other options. Firstly choose “On request...” which will not set an alarm for the user but instead simply make the questionnaire available to the user when they wake the Diary. Then set the start and finish times of the time window it will be available for. The suggestion shown is from 5am until midday, which may cover typical use. Then click the “OK” button to create the schedule entry.

9.3 Going to Bed

Next, we need another questionnaire for the user to complete just before they go to sleep. Again, this both collects subjective data, and additionally places a mark in the resulting actigraphy data. The steps required are as follows. Screenshots will be similar to the “Waking Up” section above, and are omitted for brevity.

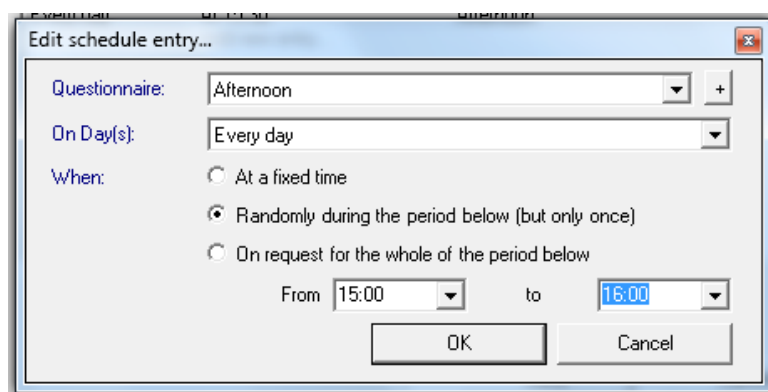
- Return to the Questionnaire Management window
- Use Add -> New Questionnaire to create a new questionnaire
- Fill in the questionnaire name “Lights Out”
- Click on “Create New Question...” in the questionnaire window
- Type “Did you feel like falling asleep at any point today?” in the question textbox near the top of the window
- Make sure “Multiple Choice” is selected
- Click the third mark down to the left of the list of answers to open three boxes for answers
- Type in the answers in the three boxes:
 - Yes, lots
 - Once or twice
 - Not at all
- Click “Save” to save the question
- Add more questions if you wish using the “Create New Question...” button.
- Click on “Save” to save the questionnaire
- Return to the schedule window (if necessary re-open it by double-clicking on the schedule in the Questionnaire Management window)
- Create a new entry in the schedule as below:



- Note that the new schedule entry must select the “Lights out” questionnaire, not the “Morning” one
- The new schedule entry should be “on request” for an appropriate evening time window
- Click “OK” to create the new schedule entry.

9.4 Afternoon Tiredness

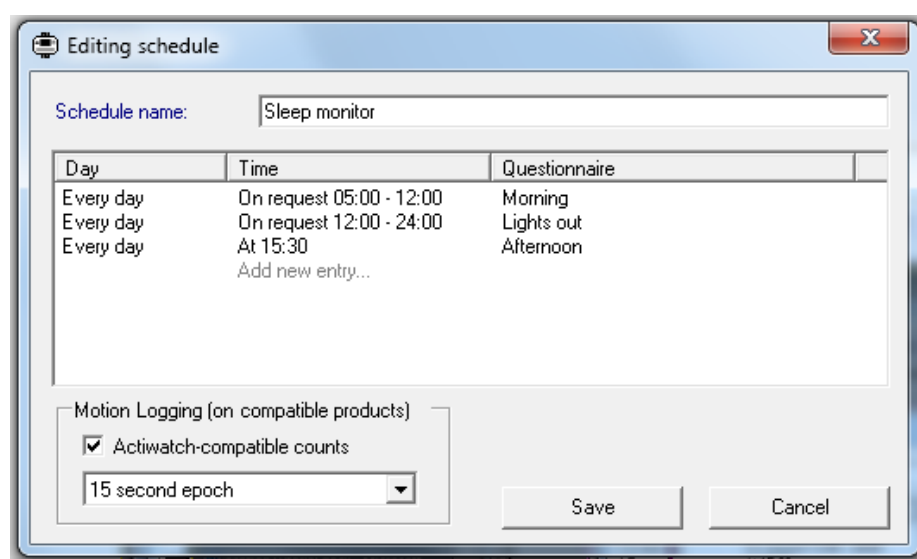
If you wish, you may now also create a questionnaire to monitor sleepiness in the afternoon. The questionnaire may be created following a similar procedure to the above. The schedule entry would be different, such as this:



The “Randomly during the period below” function allows you to avoid consistently clashing with the user doing a particular activity at a precise time. Alternatively you can schedule it for a fixed time using the option above. The user can in either case choose to delay the prompt by a few minutes before they answer it.

9.5 Using the Schedule

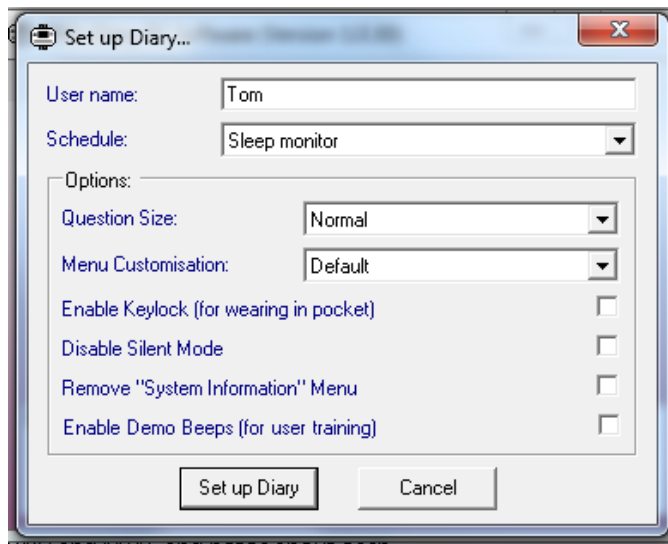
After following the instructions so far, you should have a finished schedule which looks similar to this:



Day	Time	Questionnaire
Every day	On request 05:00 - 12:00	Morning
Every day	On request 12:00 - 24:00	Lights out
Every day	At 15:30	Afternoon

You should use the “Save” button to save this schedule, and can now close the Questionnaire Management window entirely.

Connect a PRO-Diary to the PC, and click on the “Set up a Diary” button to configure it:



Enter the User name as you wish, and ensure the Sleep monitor schedule you have created is selected. You need not select any of the other options – consult the normal PRO-Diary Guide to Getting Started for more information. Then click on “Set up Diary”; the software will confirm when it is set up after a minute or two.

Now wear the Diary on the wrist for a few days. After waking up in the morning:

- Hold your finger over the button to the left of the display for a few seconds
- Move your finger on the to select “Morning” in the display
- Select using the button to the right of the display
- Answer the morning question(s)

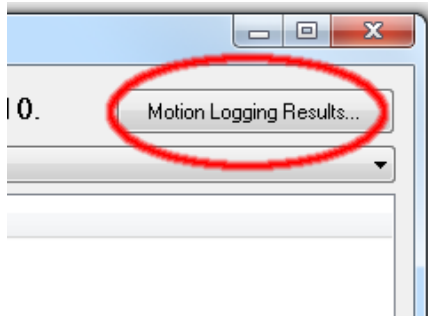
You can then continue to wear the Diary throughout the day, and follow similar instructions to select the “Lights out” questionnaire before going to sleep in the evening. If you have also added the afternoon entry as suggested, then the Diary will beep at you to begin that questionnaire.

When wearing the Diary, you can check the time at any point simply by holding your finger over the button to the left of the display for a few seconds. Place your finger there again to turn the display off again. In this way the Diary can be worn in place of a user’s normal watch if they wish.

9.6 Downloading Results

To download the results from the Diary, first plug it into the PC and start the PRO-Diary software. Click on the “Download Results” option from the main menu. Confirm if you wish to save to the current results database (doesn’t matter for testing, but create a new results database for a genuine study).

Next click “Open Result Viewer” and then double-click on the relevant recording which should be at the top of the list of results. This will allow you to see the normal Diary results table (see elsewhere in the User Guide for more details), but also contains a button in the top right to export the motion logging results:



From this window, you can choose to save the motion data for use in the MotionWare analysis software (as a Motion format file), or optionally in an Actiwatch-compatible format for analysis with your existing sleep software. The latter format will not save some details of the file data, particularly only marking questionnaire times to a per-epoch resolution, and having no method of marking data periods “missing” rather than simply zero, but is adequate for most analysis. Note that you can save in several formats simultaneously by leaving them selected. The raw recording is also kept in the Diary software, so can be re-exported using this method at any point.

9.7 Demonstrating a Timed Questionnaire

We would recommend that before giving any new wearer the PRO-Diary, you first demonstrate to them how to operate the device. This is easiest using a spare device already set up with a single questionnaire on request, and selecting the “Enable Demo Beeps” option during setup. You can then show them:

- How to turn on the device by holding their finger over the left button.
- That this allows them to read the time.
- How to select one of the currently available questionnaires, such as Morning.
- Lead them through answering all the questions in that questionnaire.
- How the Diary will appear when it is beeping for a timed questionnaire.

This can be demonstrated by:

- Take the Diary from the wearer
- Wake it using the left button
- Select the right-most option “System Information” and select it
- Select the right-most option “Timed demo” and select it
- Hand the Diary back to the wearer as it beeps
- Explain how they can then choose either the OK, In a few minutes, or Cancel option

It is usually preferable to perform this demonstration using a version of one of the questionnaires they will later receive so that they can see both the operation of the Diary and the nature of the questions they will be asked at the same time.

10 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 10 hours of continuous questioning, equivalent to about 20 minutes per day for one month. 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.

11 Additional Documents

Subsections of this user guide are provided for quick reference from the PRO-Diary software. In addition, the document below is provided and can be found from the windows Start Menu once the Diary software is installed.

Templates for Cue Cards

Depending on your users, you may consider printing out and laminating the credit-card sized guides provided with the device software to give out with the Diary. These include a few hints to operate the Diary. You might wish to modify them as desired for your application.

Appendix A Safety and Environmental Information

A1 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.

A2 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.

A3 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.

A4 Disposal at End of Life



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

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

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

A5 EMC Declaration and Guidance

The following table provides a declaration of compliance and user guidance regarding Electromagnetic Compatibility (EMC) of the PRO-Diary devices.

Electromagnetic Emissions

Guidance and Manufacturers Declaration – Electromagnetic emissions		
The PRO-Diary is intended for use in the electromagnetic environment specified below. The customer or the user of the PRO-Diary should assure that it is used in such an environment.		
Emissions Tests	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The PRO-Diary uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The PRO-Diary is suitable for use in professional healthcare and home healthcare environments. The PRO-Diary has not been tested for use in the following special environments: Military areas. Heavy Industrial Areas. Medical treatment areas with high powered ME equipment. Inside the shielded room of an MRI system.
Harmonic Emissions EN61000-3-2	Not Applicable	
Voltage Fluctuations / flicker emissions EN61000-3-3	Not Applicable	

Essential Performance

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

Adjacent Equipment

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

Connecting Cables

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

Use adjacent to Portable RF Communications equipment

WARNING: Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations and walkie-talkies should be used no closer than 30 cm (12 inches) to any part of the PRO-

Diary, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Immunity

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
The PRO-Diary is intended for use in the electromagnetic environment specified below. The customer or the user of the PRO-Diary should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Radiated Field Immunity	IEC61000-4-3 IEC61000-4-3	10 V/m 80-2700 MHz 1 kHz 80% am 9-28 V/m 385-6000 MH pulse mode	The PRO-Diary is suitable for use in professional healthcare and home healthcare environments.
Electrostatic Discharge (ESD) IEC 61000-4-2	IEC 61000-4-2 IEC 61000-4-2	+/-8kV Contact +/-15kV Air	

Appendix B Technical Specifications

B1 Functional Specifications

Size mm:	34(l) x 51(w) x 8(d excluding strap)
Mass:	9.1 grams (including battery, excluding strap)
Accelerometer:	Tri-axial, MEMs technology. 0.01g to 8g range, 3 – 11Hz
Battery:	Rechargeable Li-ion polymer, nominal 3.7V DC
Battery Life:	At least 30 days common usage following full charge cycle
Memory:	4Mbytes non-volatile RAM (NVRAM)
Waterproof:	IP42: protected against splash water from any direction
Epoch:	1, 2, 5, 10, 15, 30, 60 seconds
Comms:	Direct USB, Plug & Play drivers, Micro USB cable.

B2 Operating & Storage Conditions

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

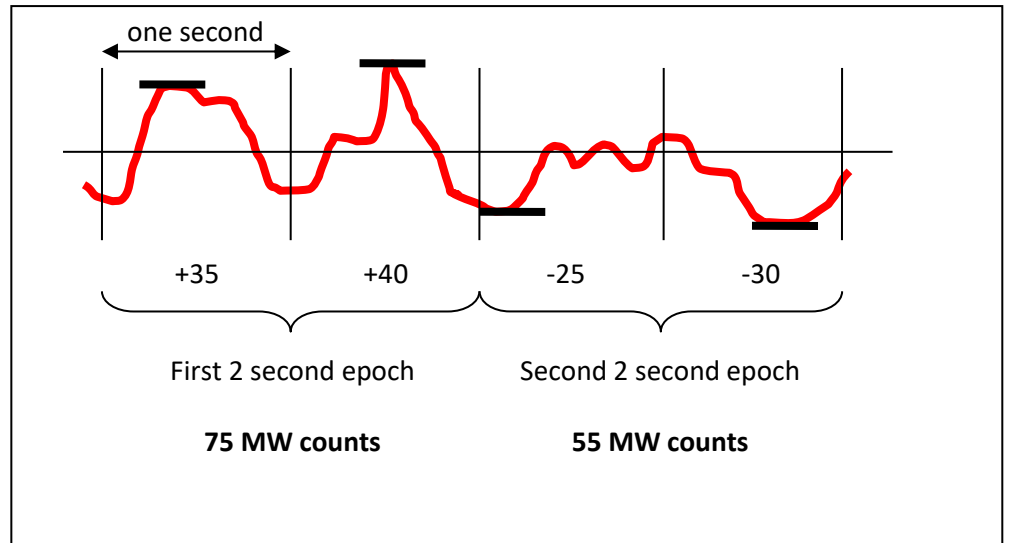
	Operating	Storage
Temperature	+5°C to + 40°C	-25°C to +70°C
Relative Humidity	0 to 93%	0 to 93%
Atmospheric Pressure	70kPa to 106kPa	70kPa to 106kPa

B3 Accelerometer Processing

Raw acceleration measurements are processed by the on-board software of the PRO-Diary to produce a quantitative measure of the activity during each epoch. This is a four stage process which is applied to the accelerometer data:

1. The channel perpendicular to the Diary is separated and subjected bandwidth filtering (3-11Hz).
2. The peak acceleration (either positive or negative) during each second is recorded.
3. This is compared to a minimum “not moving” threshold of approximately 0.1g. Values below this threshold are ignored to simplify the final activity graph.
4. The result from each second is summed over the epoch and scaled to produce a standard result in controlled jig testing. This value is then recorded as the count for the epoch.

This process is illustrated in the diagram below, showing the acceleration waveform over two epochs, each containing two seconds of data:



Document Revision History

Issue From	Issue To	Date	Description	Initiator
1.1.14	1.1.15	04/12/13	Added Australian Sponsor Details	HS
1.1.15	1.1.15a	10/12/13	Updated indications for use to align with FDA submission	HS
1.1.15a	1.1.15b	03/03/14	Updated FDA clearance status	HS
1.1.15b	1.2.1	10/02/15	Minor updates to match software changes	TE
1.2.1	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	HS
1.5.7	1.5.7a	31/12/19	Updates to include requirements of the Medical Device Regulation 2017/745. Technical specs and EMC information added. CamNtech address updated, removed Win 7.	M Dewey
1.5.7a	1.5.7b	24/11/20	Added EC Authorised Representative details	HS
1.5.7b	1.5.7c	06/01/21	Minor revisions following EC Rep high level review	HS
1.5.11	1.5.11a	30/06/22	Added CH-REP details	HS
1.5.11a	1.5.14	23/5/23	Triaxial accelerometer mode	TE