



# **The PRO-Diary Motion**

## ***User Guide***

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<b>Author:</b>	Tom Evans



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

## PRO-Diary Motion Regulatory Information

### Medical Device Directive (European Union)

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

### US FDA status

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

### Manufacturer:

CamNtech Ltd  
Upper Pendrill Court  
Papworth Everard  
Cambridgeshire  
CB23 3UY, UK

Tel: 01480 831223  
Fax: 01480 831733  
Email: [technical@camntech.co.uk](mailto:technical@camntech.co.uk)  
Web: [www.camntech.co.uk](http://www.camntech.co.uk)

### Australian Sponsor:

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

Emergo Australia  
Level 20  
Tower II, Darling Park  
201 Sussex Street  
Sydney, NSW 2000  
Australia

### Applicable Standards:

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

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

# IMPORTANT SAFETY INFORMATION

## WARNINGS



- Not Defibrillation proof.
- Not indicated for use on areas of broken, damaged or irritated skin.
- Devices removed from subjects must be considered to be contaminated – see SECTION12.

## Safety Classification Information:

- PRO-Diary Motion is **INTERNALLY POWERED EQUIPMENT**.
- PRO-Diary Motion mode of operation is **CONTINUOUS OPERATION**.
- PRO-Diary Motion is for **PRESCRIPTION USE ONLY (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 <b>yyyy-mm</b> 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 <b>TYPE B APPLIED PART</b> . (Internally Powered – no mains connection)

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 **CamNtech MotionWare Software** for off line analysis.

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.

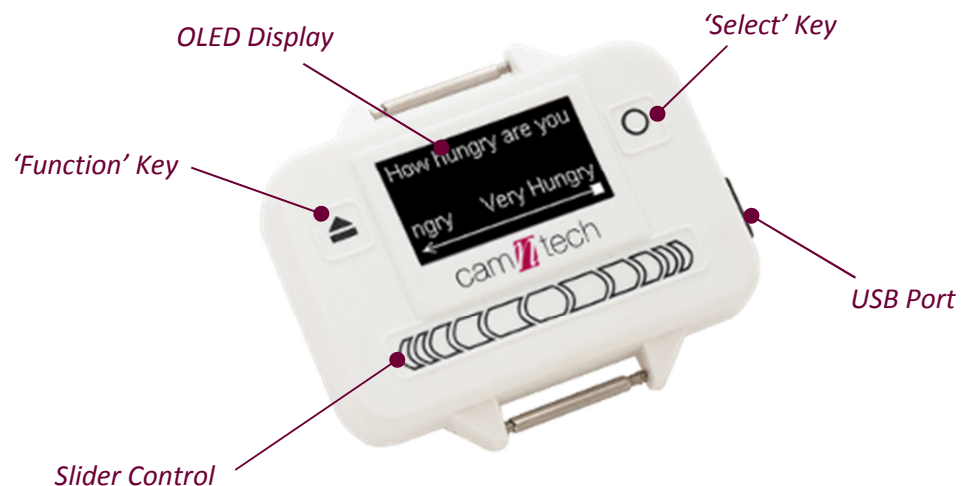
The PRO-Diary has a built-in score pad that allows the wearer to subjectively assign and enter responses to pre-programmed questions. The score pad can be used as a substitute or in addition to the traditional written patient diary in conjunction with activity monitoring.

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 Indications For Use**

The PRO-Diary is a compact, lightweight, body-worn activity monitoring device that may be used to document physical movement associated with applications in physiological monitoring. The device is intended to monitor limb or body movements during daily living and sleep. The PRO-Diary can be used to assess activity in any instance where quantifiable analysis of physical motion is desired. The PRO-Diary has a built-in score pad that allows the wearer to subjectively assign and enter responses to pre-programmed questions. The score pad can be used as a substitute or in addition to the traditional written patient diary in conjunction with activity monitoring.

## **1.3 Contraindications**

The PRO-Diary Motion is indicated for use on healthy, undamaged areas of skin. Where the patient has a history of skin irritation, a device should be worn for a brief period to test for skin irritation prior to commencing any recording.

## **1.4 Required Skills, Training & Knowledge of Intended Users.**

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

## **1.5 General Description of Use**

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

The PRO-Diary Motion contains a miniature accelerometer to allow measurement and recording of physical movement of the wrist which provides a close correlation to whole body movement. The data are sampled at 50Hz and processed into 'epochs' of user selectable length. These data are stored into an internal non-volatile memory and then downloaded for analysis at the end of the study period.

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

## 2 Installing the PRO-Diary Software

### 2.1 System Requirements

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

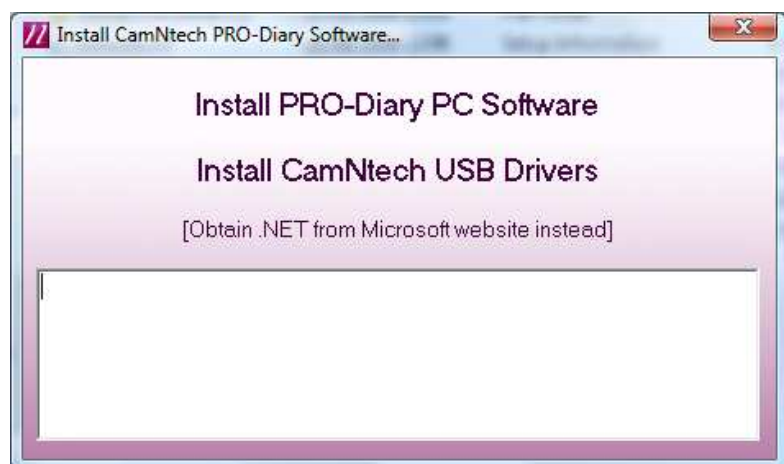
- Windows XP, Vista, Windows 7 or 8, 32 or 64bit operating systems.
- IBM compatible 2GHz + processor speed recommended
- 500 MB hard disk space
- One free USB port
- A CD-ROM or DVD drive for software installation
- Graphics SVGA(1280 x 1024) recommended

In general, a faster processor will provide superior performance.

### 2.2 Software Installation Menu

Do **not** connect a PRO-Diary at this stage.

Place the CD-ROM into the drive; the software should start automatically and display the following installation menu:



To install the software, click on 'Install PRO-Diary PC Software' and follow the installation process. Note that the installation will differ for new users and existing users as described in **Section 2.3** below.

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

If the above menu is not automatically displayed, browse the CD and run the file 'SplashMenu.exe'.

Note that the software requires the Microsoft .NET framework to operate – this will be automatically installed if not present.



## **2.3 Users upgrading from an earlier version of the Software**

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

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

## **2.4 Installing the USB Drivers**

If the Installation menu is not already displayed, insert the supplied CD ROM into the CD/DVD drive on the host PC then connect the PRO-Diary to a free USB Port using the cable provided. The Installation menu should be automatically displayed (as shown in Section 2.2).

Depending upon the operating system in use and the current driver status, the computer may display a message saying 'Found New Hardware' and will then load the drivers with no user intervention. If the drivers loaded automatically, simply close the installation menu and the drivers should be ready to use.

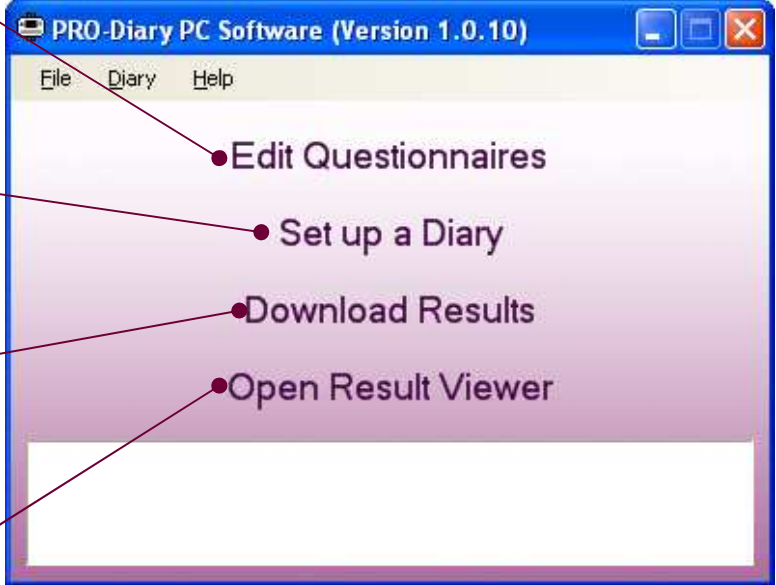
If the drivers do not load automatically, or if you wish to make sure they install correctly, you should select 'Install CamNtech USB Drivers' and carefully follow the on-screen instructions. If you have any problems installing the drivers, please read the help document and download the latest drivers from <http://www.camntech.com/drivers>.

Windows should automatically search the CD drive for the driver, but if it does not do so you will be required to 'Search manually' and then 'Browse' to point to the CD drive.

A screen may appear that tells the user that the driver is not digitally signed by Microsoft. Select 'Continue Anyway' (Please note that this is NOT a problem and just means that the CamNtech version of the driver software has not been assessed by Microsoft. In fact the actual drivers are Microsoft approved). The drivers will be installed and the computer will then tell the user that the new hardware is ready to use. If you change the USB port that the reader is plugged into then the driver may be automatically re-installed by Windows. This is an automatic process and the user need take no action.

## 2.5 Using 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.

<b>EDIT QUESTIONNAIRES</b>	
Create or edit questions, questionnaires and schedules. <b>See Section 4</b>	
<b>SET-UP A DIARY</b>	
Apply the questionnaire to the PRO-Diary with various use options. <b>See Section 5</b>	
<b>DOWNLOAD RESULTS</b>	
Read the stored answers and activity data from the PRO-Diary. <b>See Section 7</b>	
<b>OPEN RESULTS VIEWER</b>	
View and export the answers and activity data. <b>See Section 8</b>	

## 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.

### 3.1 Charging the Diary from the PC

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

Note that many PC's have power saving functions which may shut down the USB ports after a period of time; this will stop the diary charging until normal operation is resumed.

### 3.2 Charging the Diary using the Mains Power Supply

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

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

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

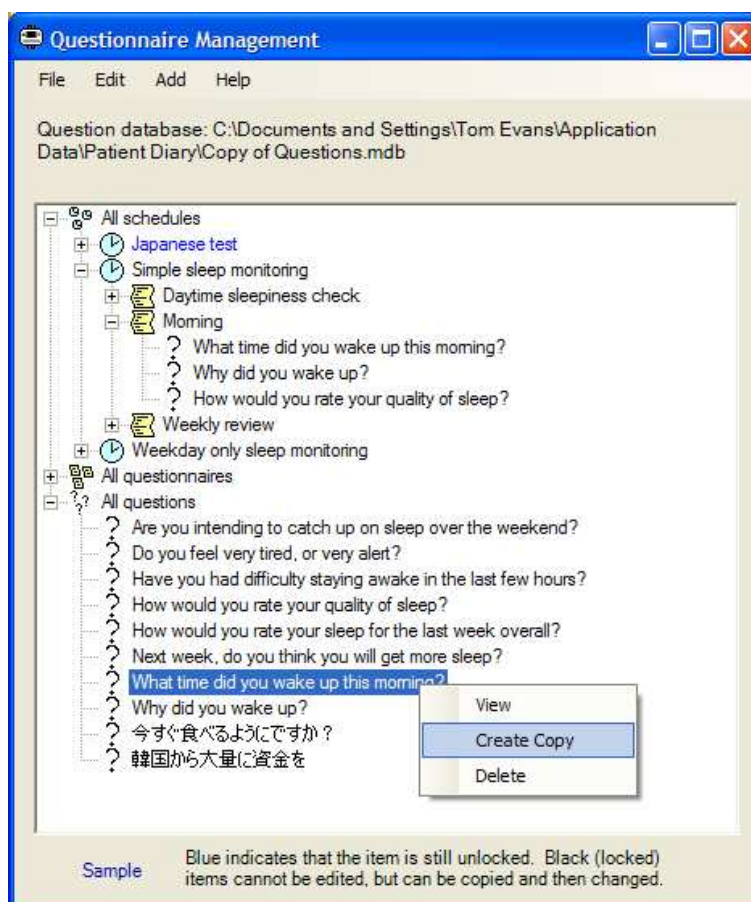
### 3.3 Charging Several Diaries from a USB Hub

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

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

## 4 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, that 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

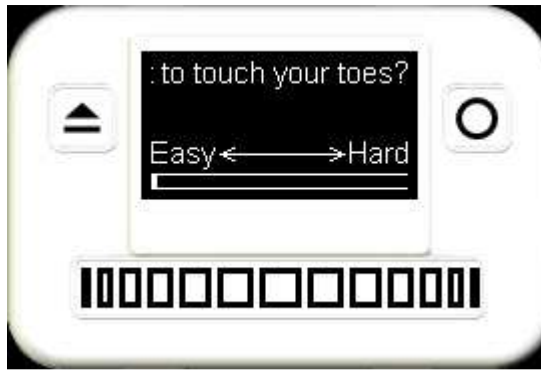
For example: "Which fruit do you prefer?", with possible answers of "Apples", "Oranges", or "Other".



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 fiddly to operate.

### Visual Analogue

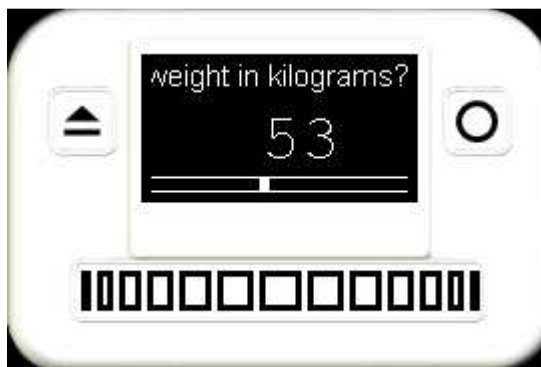
For example: "How difficult is it to touch your toes?", with the text "Easy" at the left hand end of the slider bar and "Hard" at the right hand end.



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

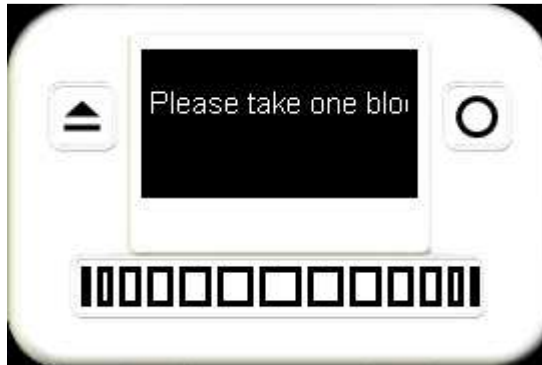
For example: "What time did you wake up this morning?", with a time of "07:07" displayed.



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 off 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

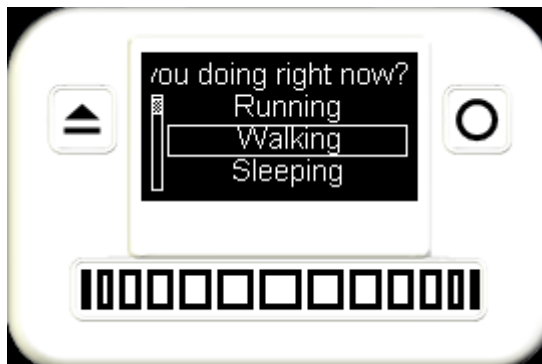
For example: "Please take one blood pressure pill now" with no additional information or prompt.



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

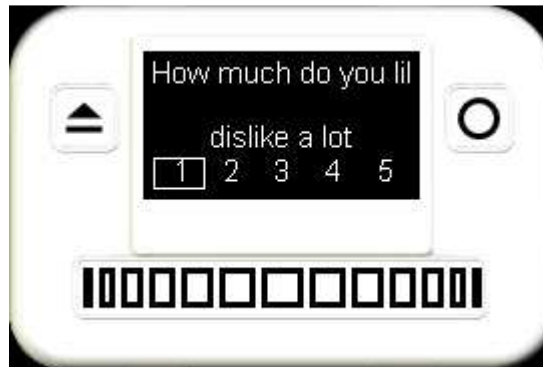


your finger early to cancel. If you do enter an incorrect letter then simply select the symbol to the left of the main alphabet, 'DEL', to delete the previous letter.

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, 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 the 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 "Actiwatch-compatible counts" mode records movement in a measure compatible with previously-existing "Actiwatch" products. This measure is well validated for sleep monitoring, and has been used for daytime activity monitoring also. In future updates an additional mode refined for activity intensity monitoring may be introduced.

## 4.5 Locked and Unlocked Items

When an item has just been created (either 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 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:

Editing new Questionnaire

Questionnaire Name:

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

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 below.

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 appear 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:

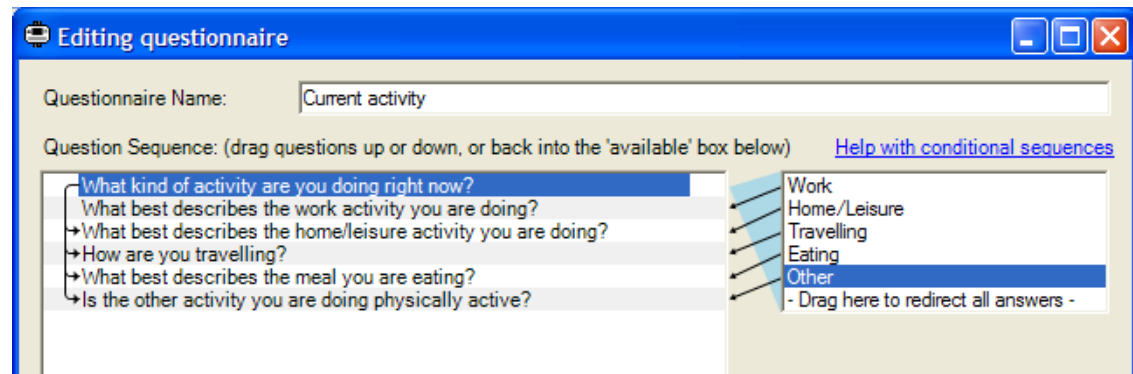
As can be seen, there are no arrows within the list because it is currently still a straightforward sequence from top to bottom. The top question is selected, but every answer from it is pointing at the question just below.

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

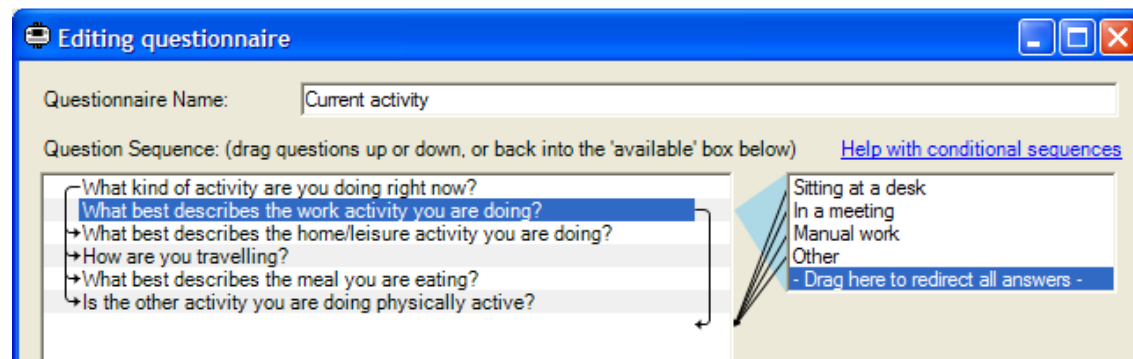
- Drag the 'Work' answer onto the work activity question
- Drag the 'Home/Leisure' answer onto the home/leisure question
- Drag the 'Travelling' answer onto the travelling question
- Drag the 'Eating' answer onto the eating question
- Drag the 'Other' answer onto the 'other activity' question



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. (The link between the 1st and 2nd question is not shown, as the list would be very cluttered if these were always shown)

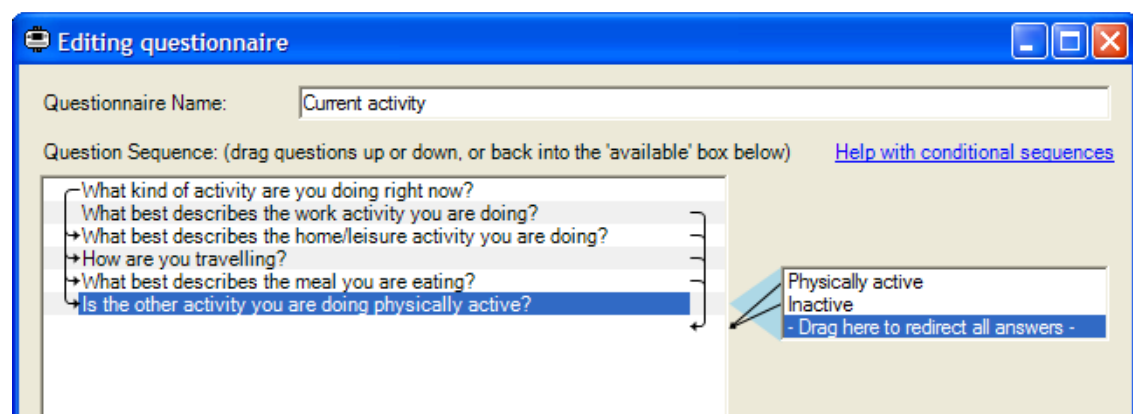


We now need to ensure that the user will jump to the correct following question after their 'category question'. Otherwise they will simply step down the list and be asked all of the questions below it. To start this, first select the 'What best describes the work activity you are doing?' question. Now 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:

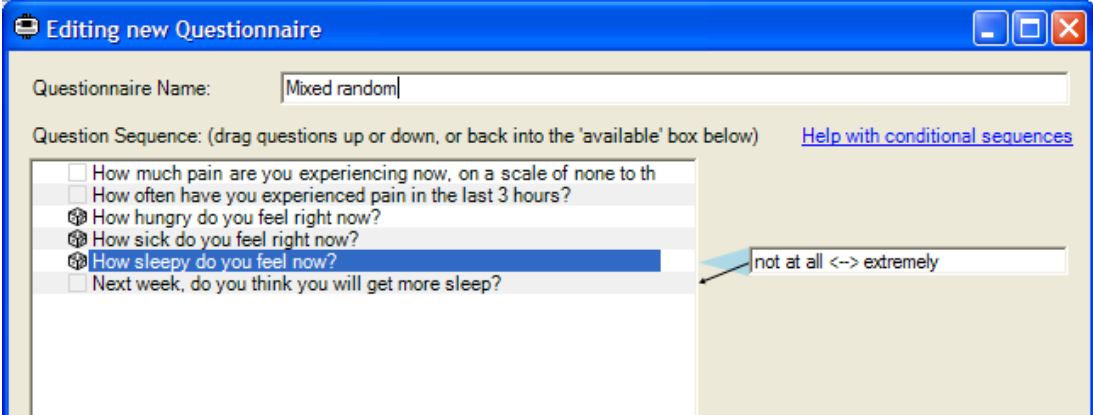


Note that this completed set shows both a set of arrows down the left from the first question, and a set down the right leading from each of the category questions to the common following point below (which happens to be the end of this questionnaire).

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.



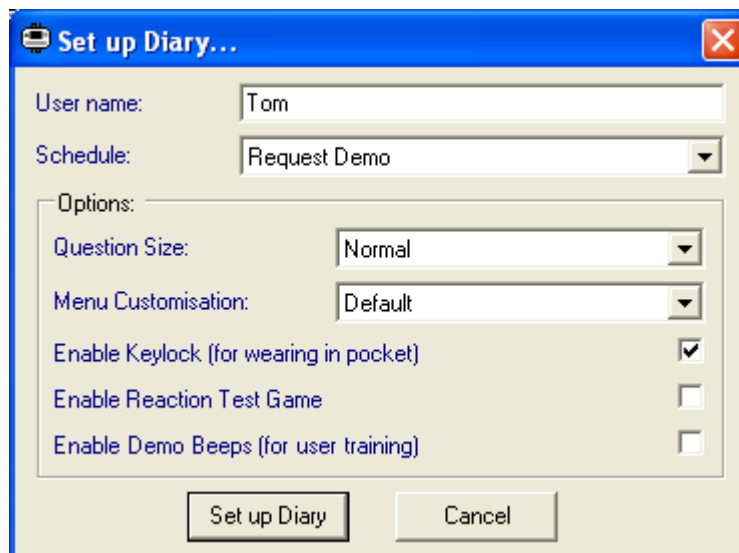
The screenshot shows a window titled "Editing new Questionnaire". At the top, there is a text field for "Questionnaire Name:" containing the text "Mixed random". Below this, a label reads "Question Sequence: (drag questions up or down, or back into the 'available' box below)" followed by a link "Help with conditional sequences". A list of questions is displayed in a box on the left. Each question has a small icon to its left. The first two questions have empty checkboxes, while the next three have dice icons. The last question has an empty checkbox. The questions are:

- ☐ How much pain are you experiencing now, on a scale of none to th
- ☐ How often have you experienced pain in the last 3 hours?
- ☒ How hungry do you feel right now?
- ☒ How sick do you feel right now?
- ☒ How sleepy do you feel now?
- ☐ Next week, do you think you will get more sleep?

To the right of the list, there is a text field containing "not at all <--> extremely". An arrow points from the dice icon of the "How sleepy do you feel now?" question to this text field.

## 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 this 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 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 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 it up

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. 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.



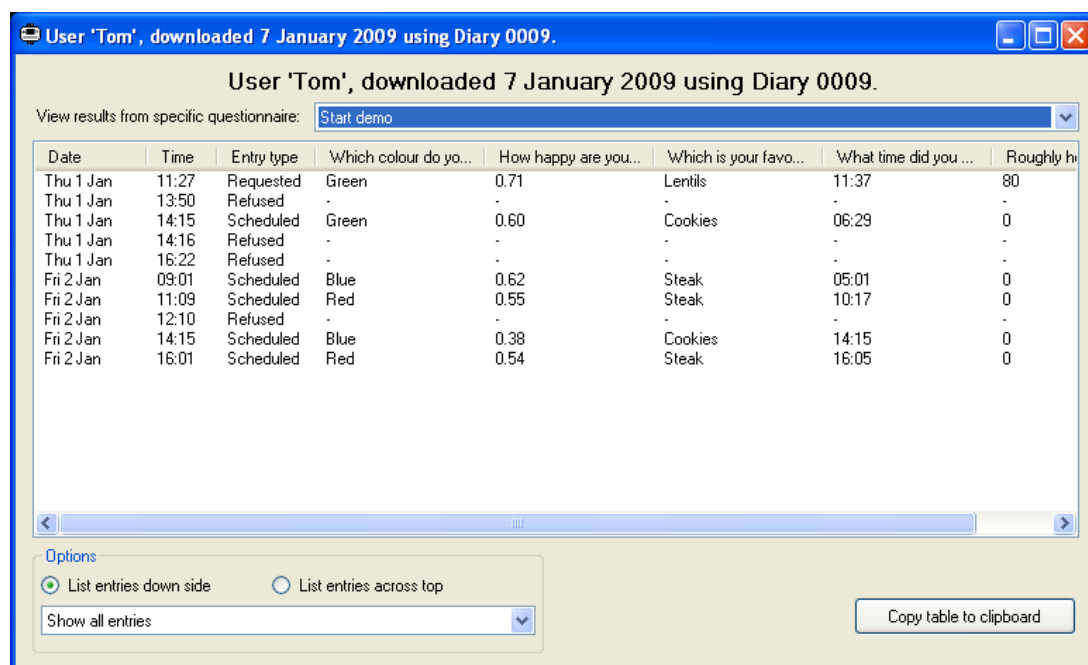
If you wish to create a new results database you should use 'File -> New Results Database...', after which the new database will be selected. You can then change your currently selected database as you wish using 'File -> Open Results Database'. This setting will affect both where your data is downloaded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



### 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 motion 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.**

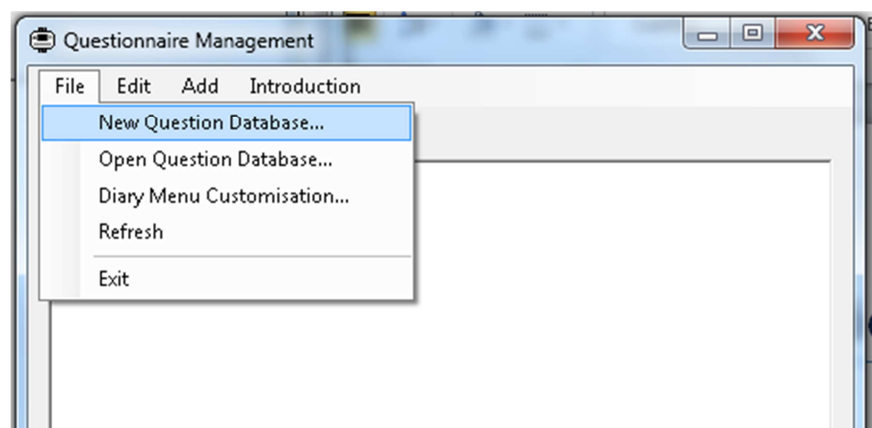
The system will be set up to monitor sleep using a few features, introduced here step by step:

- 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.

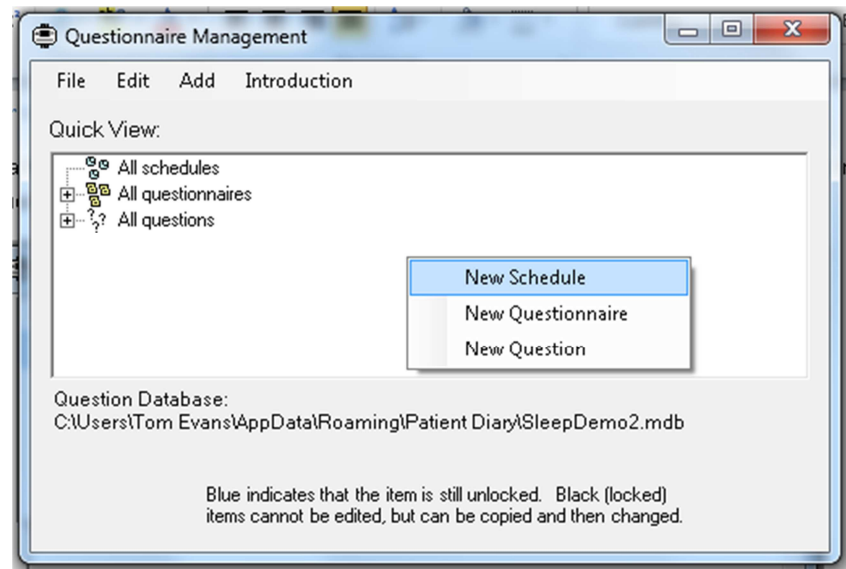
### 9.1 Create a Schedule

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

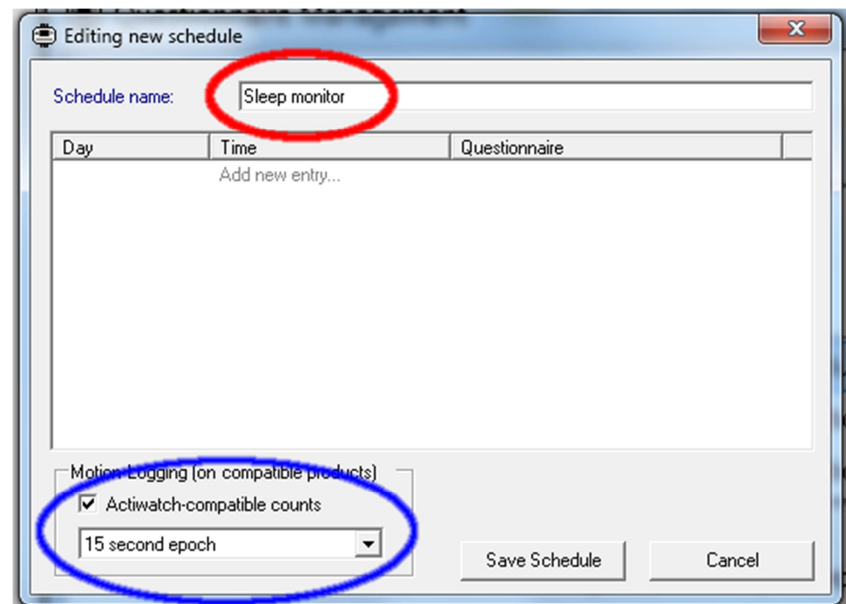


You can create the database in the default folder, or in whatever location you choose on your computer. Putting your new work into a new database like this simply avoids confusion with any existing questions.

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 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.

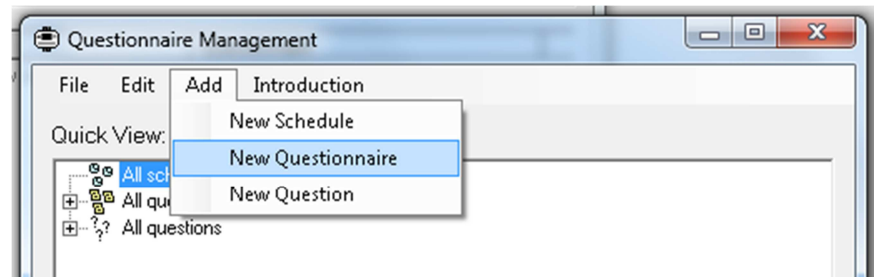
## 9.2 Waking Up

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

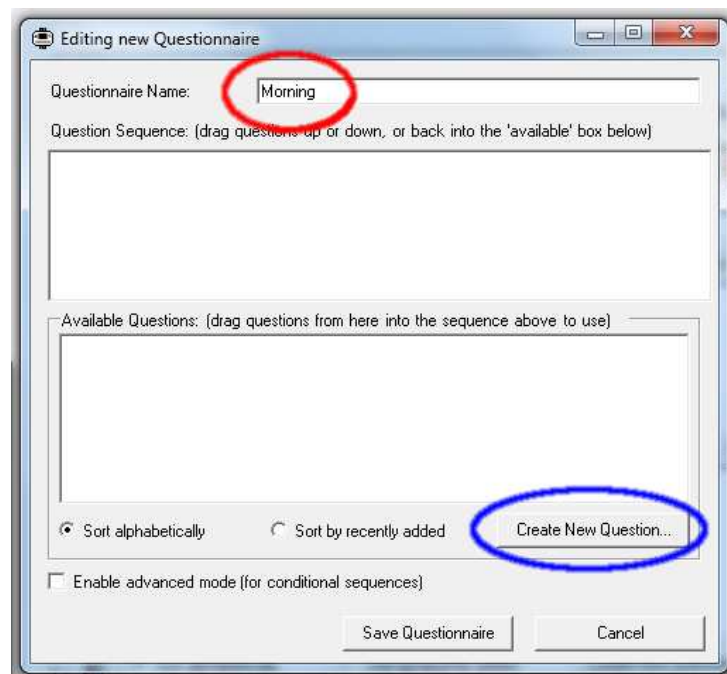


mark in the resulting actigraphy data which makes analysis easier (in exactly the same way as the marker button on simpler actigraphy devices).

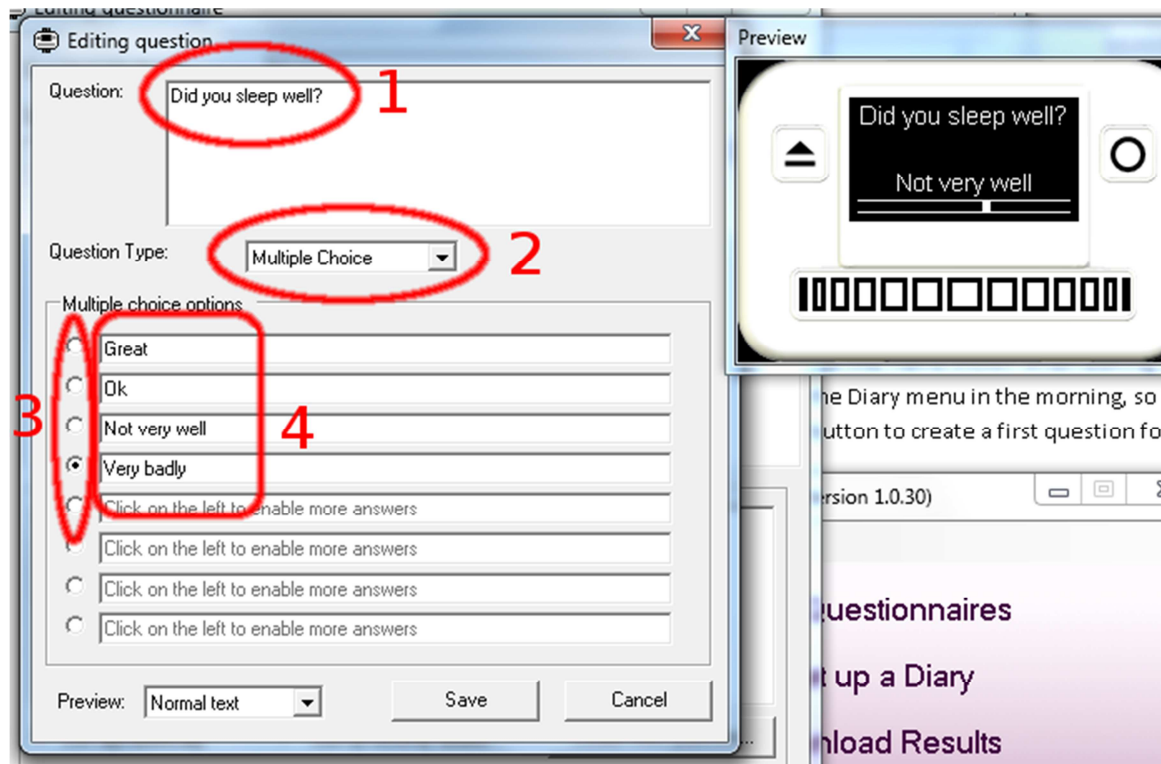
First, return to the Questionnaire Management window and use the Add menu (or right click in the main window) to create a new Questionnaire:



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:

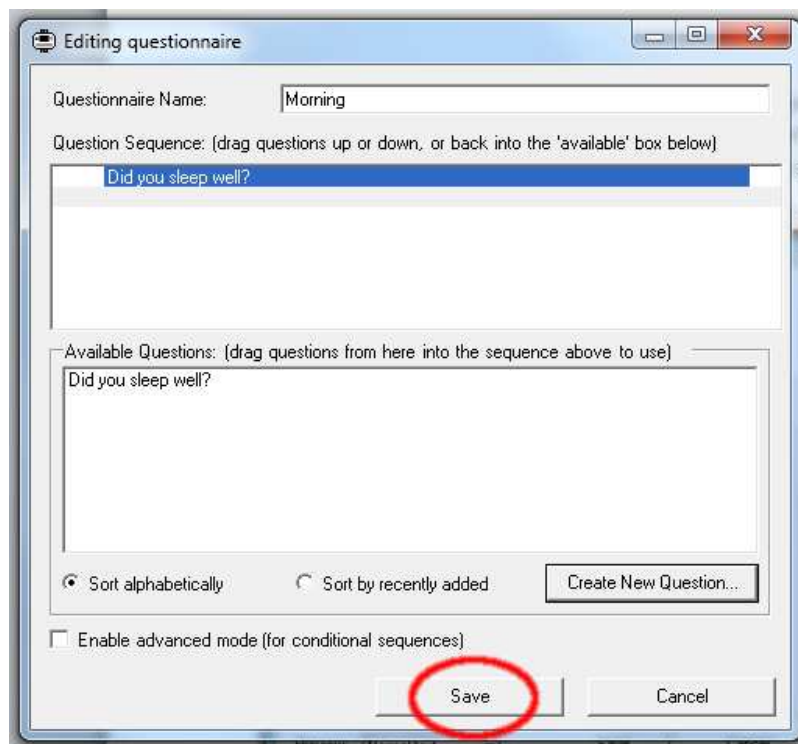


Configure the parts circled in red above:

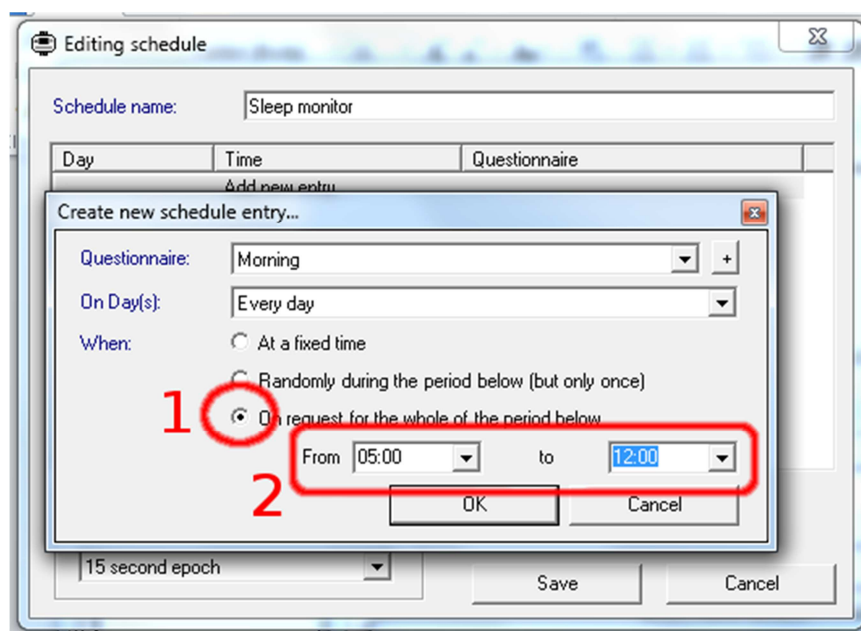
1. Type in the question "Did you sleep well?"
2. Ensure the "Multiple Choice" question type is selected
3. Select the fourth mark down on the left to enable four answer boxes to the right
4. Fill in the answers as suggested

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 to 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...”:



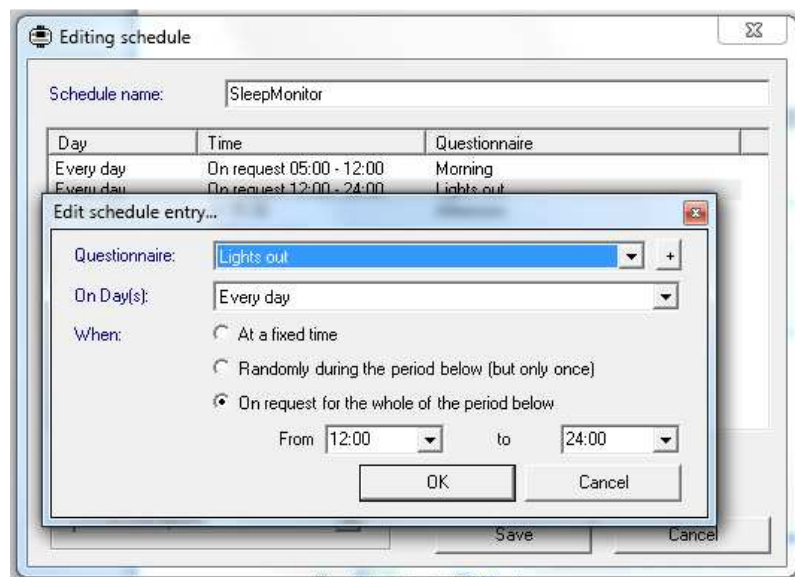
The questionnaire and “Every day” options should already be set by default, and you should set the other options. Firstly choose “On request...” which will not set an alarm for the user but instead simply make the questionnaire available to the user when they wake the Diary. Then set the start and finish 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.

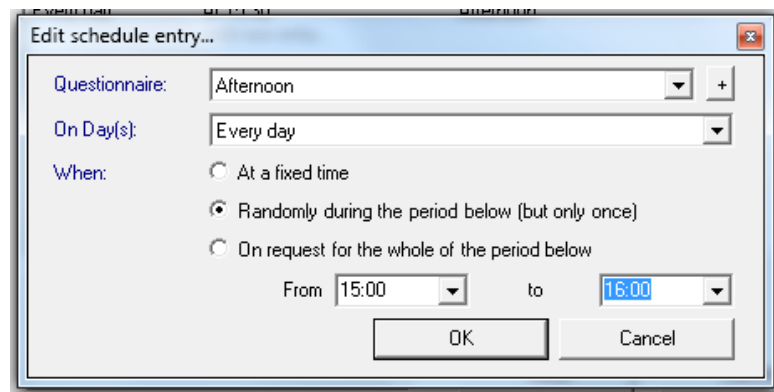
- Return to the Questionnaire Management window
- Use Add -> New Questionnaire to create a new questionnaire
- Fill in the questionnaire name “Lights Out”
- Click on “Create New Question...” in the questionnaire window
- Type “Did you feel like falling asleep at any point today?” in the question textbox 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 timewindow
- Click “OK” to create the new schedule entry

## 9.4 Afternoon Tiredness

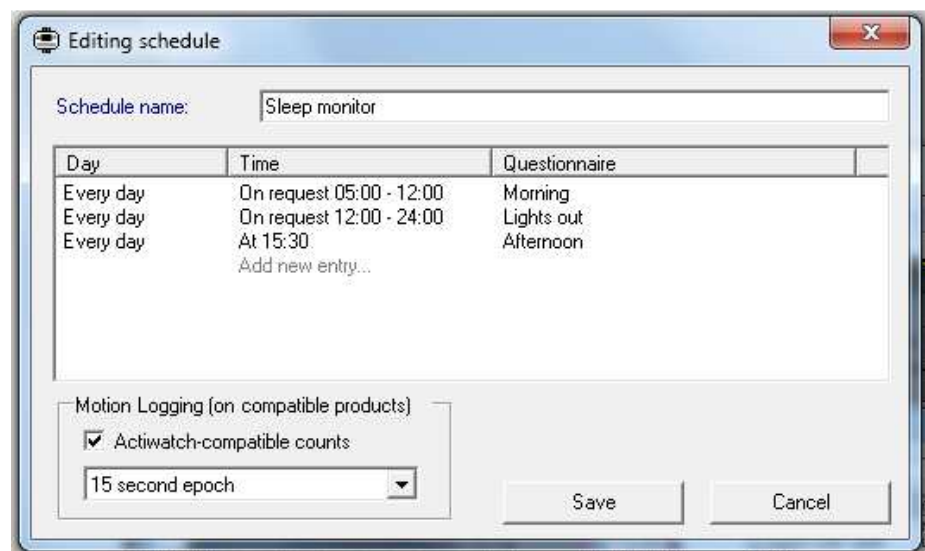
If you wish, you may now also create a questionnaire to monitor sleepiness in the afternoon. The questionnaire may be created following a similar procedure to the above. The schedule entry would be different, such as this:



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.

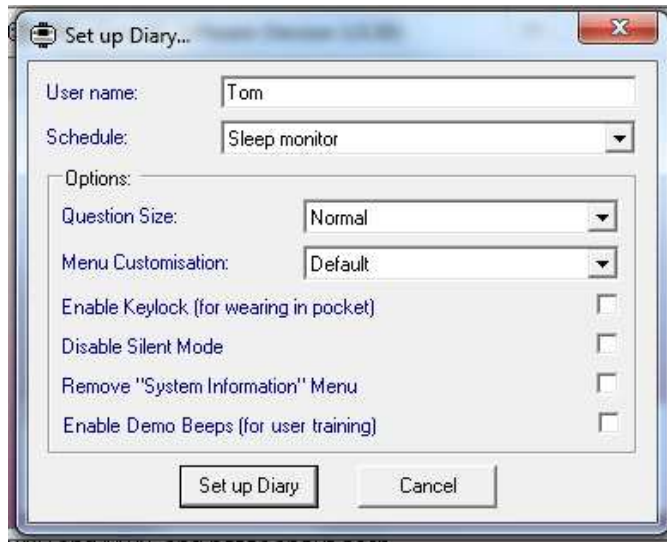
## 9.5 Using the Schedule

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



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

Connect a PRO-Diary Motion 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)

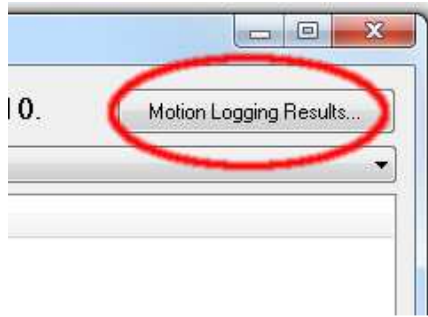
You can then continue to wear the Diary throughout the day, and follow similar instructions to select the “Lights out” questionnaire before going to sleep in the evening. If you have also added the afternoon entry as suggested, then the Diary will beep at you to begin that questionnaire.

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 Manual 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 manual 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 these credit-card sized guides 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.

## 12 Safety and Handling Information

### 12.1 De-contamination

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

### 12.2 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.

### 12.3 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.

### 12.4 Disposal



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

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

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

## Document Revision History

Issue From	Issue To	Date	Description	Initiator
1.1.14	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