



## **The PRO-Diary Guide to Getting Started**

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## **PRO-Diary – Medical device information:**

The PRO-Diary is **not** classified as a medical device according to the following rationale from the UK MHRA:

*“A ‘medical device’ means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:*

- *Diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *Investigation, replacement, or modification of the anatomy or of a physiological process,*
- *Control of conception,*

*And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”.*

The PRO-Diary is an electronic patient diary; hence no medical claims are being made according to the above rationale.

## **Applicable Standards:**

Standard	Description
EN60601-1-2:2002	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.  Group 1 equipment / Class B – (emissions only)
EN60601-1-2:2002	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.  Non life supporting equipment (immunity section only)

## **Safety Classification Information:**



The PRO-Diary is INTERNALLY POWERED EQUIPMENT.

The PRO-Diary is a TYPE B APPLIED PART.

**For further safety and handling advice please refer to section 11**

## Contents

<b>1. Introduction to the PRO-Diary System</b>	<b>4</b>
1.1 An Overview of the PRO-Diary System	4
<b>2.0 Installing the PRO-Diary Software</b>	<b>5</b>
2.1 System Requirements	5
2.2 Software Installation Menu	5
2.3 Users upgrading from an earlier version of the Software	6
2.4 Installing the USB Drivers	6
2.5 Using the software for the first time	7
<b>3.0 Charging the PRO-Diary</b>	<b>8</b>
3.1 Charging the Diary from the PC	8
3.2 Charging Several Diaries from a USB Hub	8
3.3 Charging the Diary using the Mains Power Supply	8
<b>4.0 Editing Questionnaires</b>	<b>9</b>
4.1 Basic Concepts	9
4.2 Locked and Unlocked Items	10
4.3 Creating a New Question Database	10
4.4 Diary Menu Customisation	10
<b>5.0 Setting up a Diary</b>	<b>11</b>
5.1 User Name	11
5.2 Schedule	11
5.3 Question Size	11
5.4 Menu Customisation	11
5.5 Enable Keylock	12
5.6 Enable Reaction Test Game	12
5.7 Enable Demo Beeps	12
<b>6.0 Using the Diary</b>	<b>13</b>
6.1 Waking it up	13
6.2 Using Menus and Answering Questions	13
6.3 Answering a Scheduled Questionnaire	13
6.4 Requesting a Questionnaire	13
6.5 Silent Mode	14
6.6 Not Waterproof	14
<b>7.0 Downloading Results</b>	<b>15</b>
<b>8.0 Viewing Results</b>	<b>16</b>
8.1 Filtering by Questionnaire	16
8.2 Transposing the Results Table	17
8.3 Filtering by Scheduled/Requested	17
8.4 Other Exports/Data Analysis	17
<b>9.0 Frequently Asked Questions</b>	<b>18</b>
<b>10.0 Additional Documents</b>	<b>18</b>
<b>11.0 Safety and Handling Information</b>	<b>19</b>
11.1 Decontamination	19
11.2 Battery	19
11.3 Water Ingress	19
11.4 Disposal	19
<b>Appendix A – Installing USB Drivers Manually</b>	<b>20</b>
To begin installing drivers:	20

# 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 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. It can be used to monitor a wearer's condition and symptoms before treatment, or detect a change in the wearer's symptoms during or after intervention. It can also be used to remind the wearer to take treatment at regular or irregular intervals or to record events when marked by the wearer. The system is very flexible to different recording requirements for various areas of research.

The PRO-Diary system includes:

- PC software for designing questionnaires
- USB connection for setting up, downloading and charging the Diary
- The PRO-Diary itself, for wearing on the wrist or in the pocket
- PC software for viewing and exporting recorded answers

For up to date pricing and availability of these components, please contact CamNtech.

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 us or your watch supplier will also be able to assist if you are not confident inserting the spring loaded pins yourself.

Each 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. It is easily recharged via the USB port or using a standard mains adaptor with a USB output. The USB interface is also used for setting up and downloading data to/from a PC.

## 2.0 Installing the PRO-Diary Software

### 2.1 System Requirements

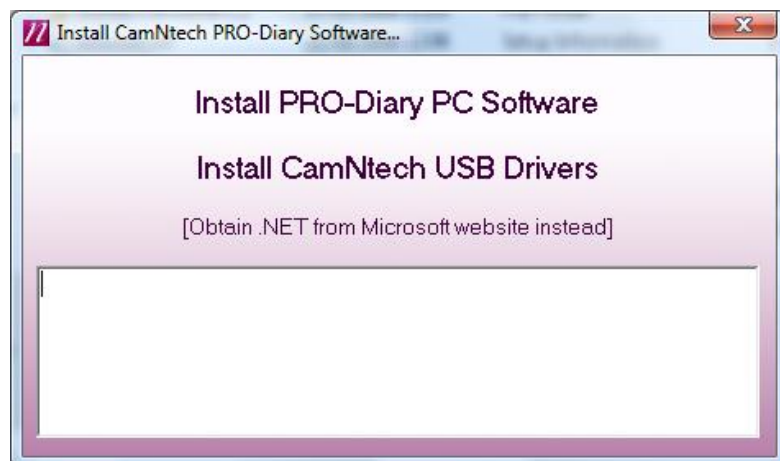
The PRO-Diary system is supplied with a CD containing all of the components of the software package, and the drivers to support the hardware required by the system. The following are the minimum requirements of a host PC for installing the software:

- Windows XP, Vista or Windows 7 operating system
- 500 MHz processor
- 512 MB RAM
- 500 MB hard disk space
- USB port
- A CD-ROM drive or equivalent
- 1024 x 768 pixel display

In general, a faster processor and increased RAM 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.

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 plug the PRO-Diary USB cable into a free USB Port. 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 still experience problems with the USB drivers, follow the procedure 'Installing USB Drivers Manually', which is included in Appendix A of this manual.

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.

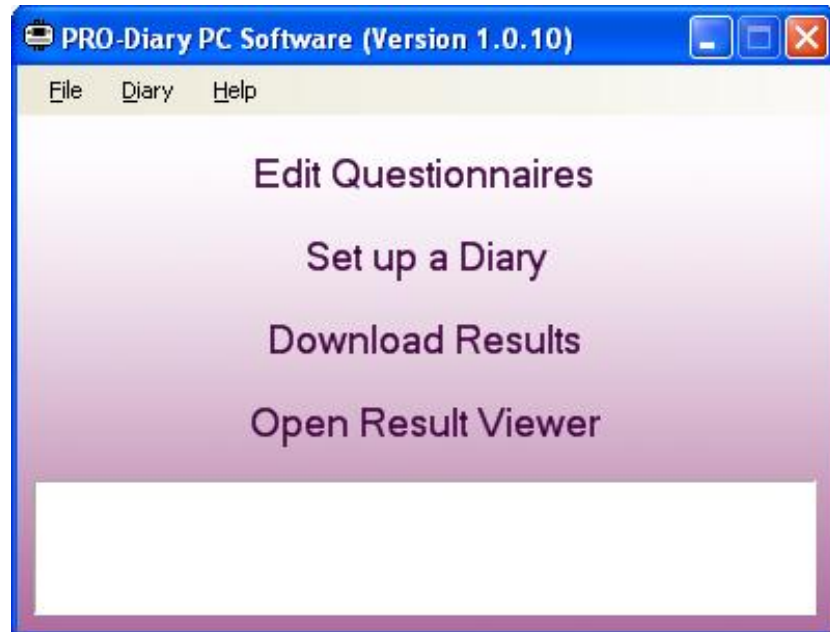
A screen may appear that tells the user that the driver is not digitally signed by Microsoft.

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.

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

## **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.



## 3.0 Charging the PRO-Diary

Before the Diary can be used, the user must ensure that it is fully charged. You may charge it either from the PC or a separate USB hub. In either case it will take around **3-4 hours** to be fully charged.

### 3.1 Charging the Diary from the PC

Connect the Diary to a free USB port 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.

### 3.2 Charging Several Diaries from a USB Hub

A USB extension hub may be more convenient to charge several 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 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.

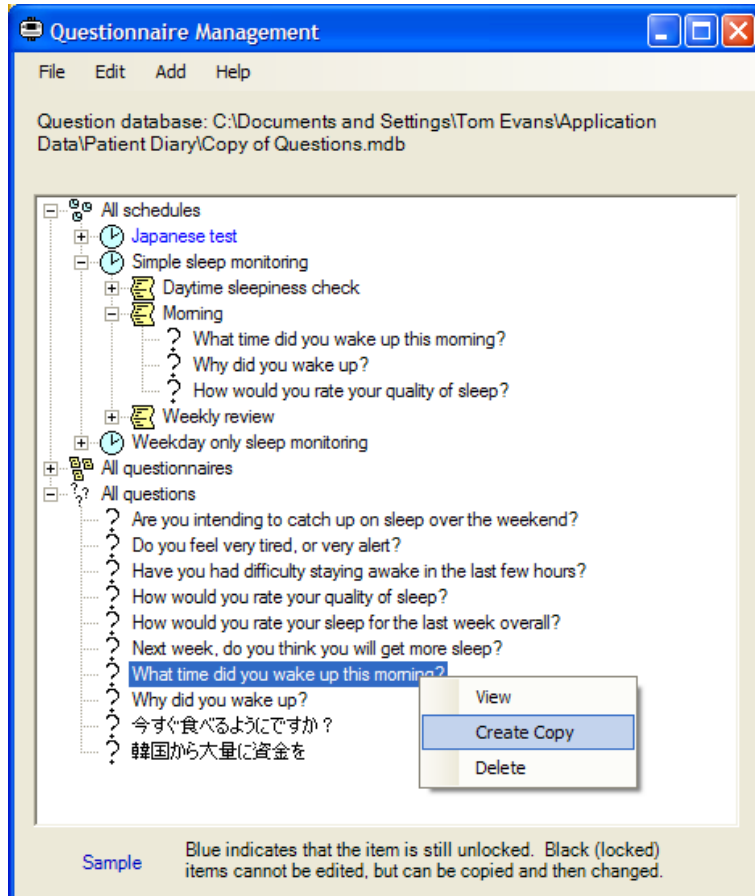
### 3.3 Charging the Diary using the Mains Power Supply

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).

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

## 4.0 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. It may also include a single audio prompt to be played as the question is asked.

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.

A more detailed introduction to questionnaires, including much more detail about the different types of question and scheduling options, is available through the help menu of this window. It is recommended that you read this before creating any important questionnaires, to familiarise yourself with the options available.

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 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.

## **4.3 Creating a New Question Database**

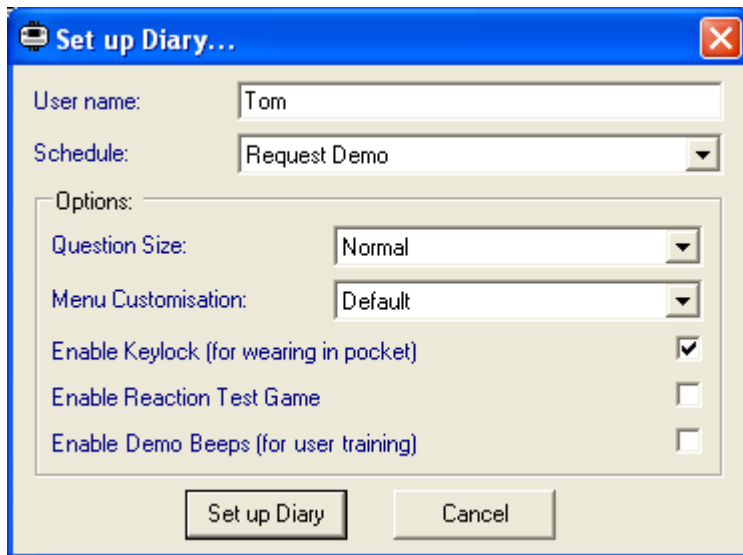
When you want to begin work on your own set of questions and schedules, you can create a new database file to contain these. This way it will not be cluttered up by the examples or any questions you have previously created for a different purpose. To do this, use the 'File -> New Question Database...' 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.

## **4.4 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.

## 5.0 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 Reaction Test Game**

You should leave this option disabled in normal use.

CamNtech can create reaction time, memory, or other tests to be administered by the Diary if they may be appropriate for your application. This option enables a demonstration of the sort of test which could be created for you. Once enabled, it can be accessed through the right hand end of the system information menu. Please contact CamNtech if you have any queries about what can be done in this area.

## **5.7 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.

## 6.0 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.

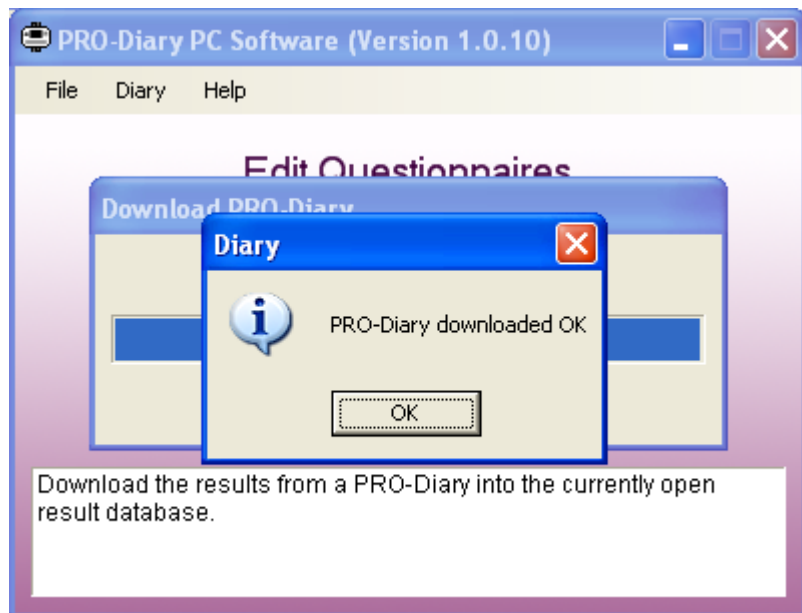
### ***6.6 Not Waterproof***

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.

## 7.0 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.



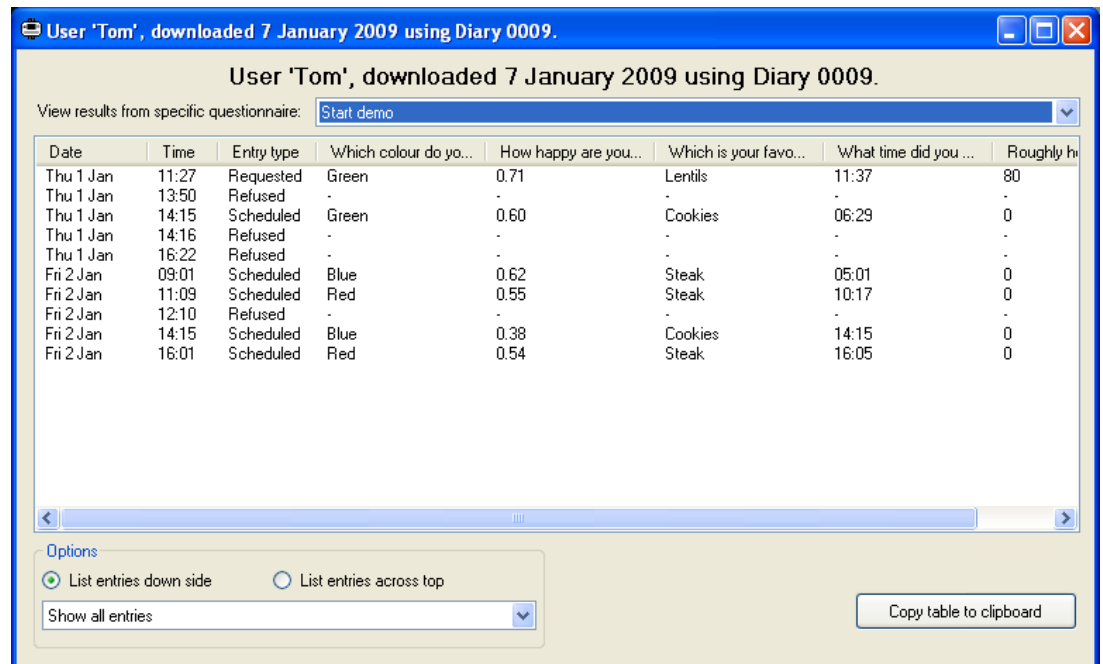
If you wish to create a new results database you should use 'File -> New Results Database...', after which the new database will be selected. You can then change your currently selected database as you wish using 'File -> Open Results Database'. This setting will affect both where your data is downloaded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

## 8.0 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.



The screenshot shows a software window titled "User 'Tom', downloaded 7 January 2009 using Diary 0009." The window contains a table of diary entries. The table has the following columns: Date, Time, Entry type, Which colour do yo..., How happy are you..., Which is your favo..., What time did you ..., and Roughly h. The data rows are as follows:

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

Below the table, there are options to "List entries down side" (selected) or "List entries across top", a "Show all entries" dropdown menu, and a "Copy table to clipboard" button.

### 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 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.

## 9.0 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. The use of audio recordings will reduce battery life, and the battery life will also decline with age.

### Will too many answers fill up the memory?

No, the answers do not take up a significant part of the memory. The memory is sufficient to allow up to around 6 minutes of total question recordings, along with question data and answers.

### 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.

## 10.0 Additional Documents

A number of extra guides and documents are included with the Diary software. These are listed below, and can be found from the windows Start Menu.

### Introduction to Questionnaires

This should be read to give some idea of how questions, questionnaires and schedules are constructed. We recommend you read this before creating any important questionnaires, to make yourself aware of the functions available.

### Questionnaire Sequencing

Ordinary questionnaires begin with the first question and proceed one by one to the last question. This document explains how to create more complex options than this, to skip items, reorder, or randomize as required.

### 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.

# 11.0 Safety and Handling Information

## 11.1 Decontamination

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

## 11.2 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.

## 11.3 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.

## 11.4 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

## Appendix A – Installing USB Drivers Manually

Sometimes the automatic installation of drivers will not work, often because your computer has previously had similar, but different, drivers installed on it before and sometimes because of flaws in the Windows installation process. To install drivers manually, follow the procedure below.

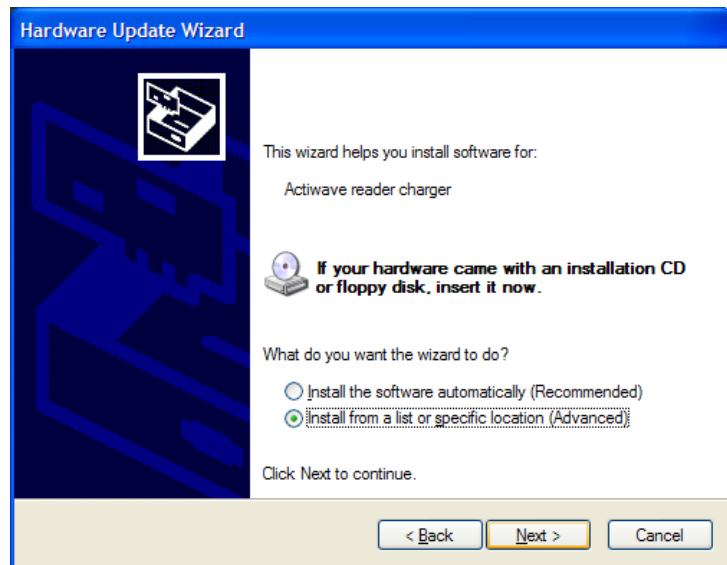
### *To begin installing drivers:*

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

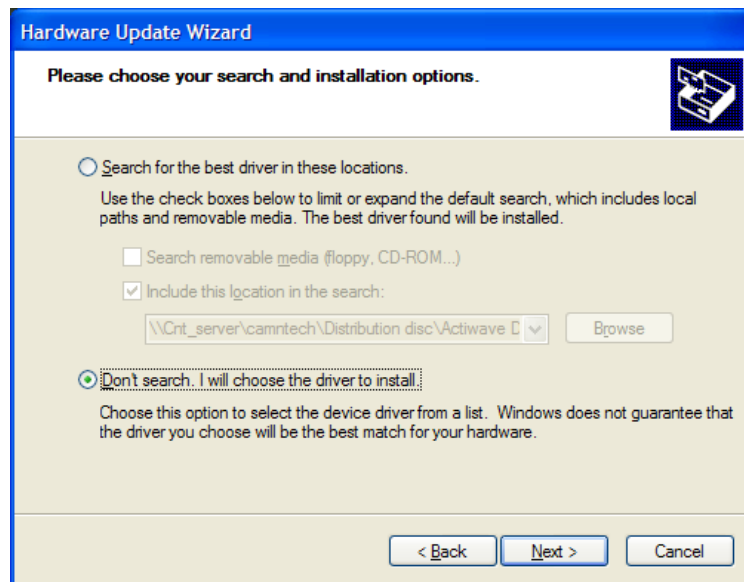
- Click on the Start menu, and open the Control Panel.
- Open 'System'. If you can't see this, choose 'Performance and Maintenance', then 'System'.
- Select the 'Hardware' tab, and click the 'Device Manager' button.
- Scroll down and open up the section called 'Universal Serial Bus controllers'. The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



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

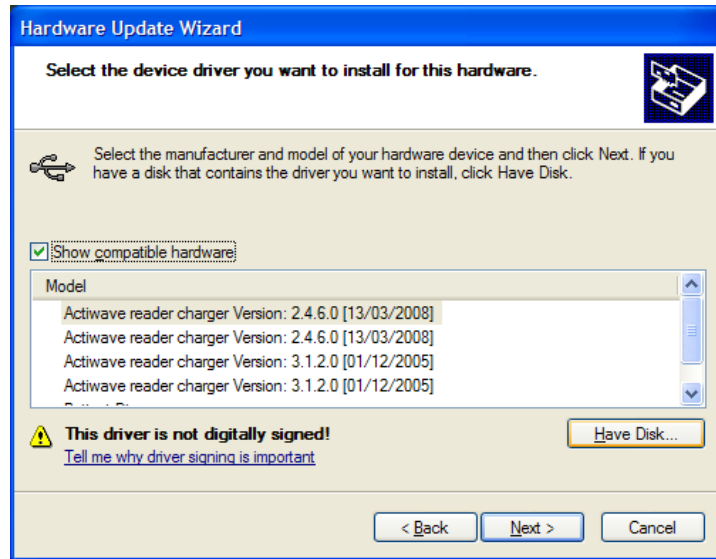


Select 'Install from a list or specific location (Advanced)' and click 'Next'.

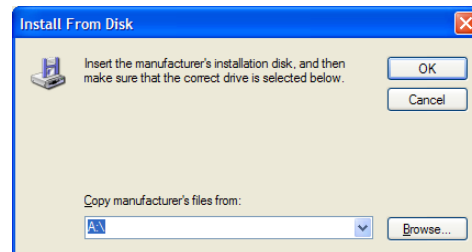


Select 'Don't search. I will choose the driver to install.' and click 'Next'.

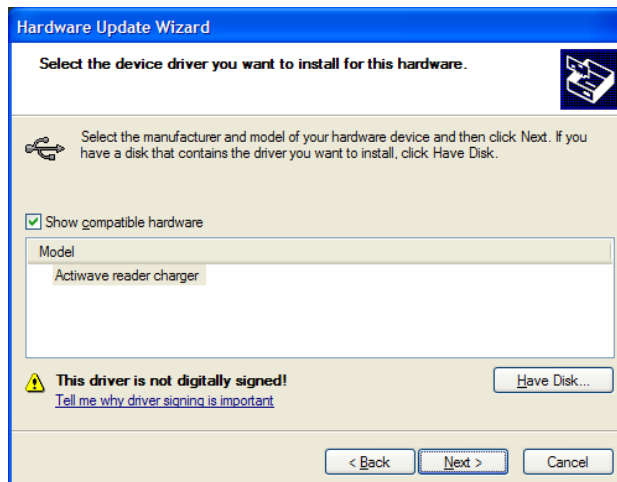
The window on the next page should appear. Sometimes, windows will decide to display some other windows first, possibly appearing to lock up for a minute or two at one point. If it does this, you may be forced to choose a device category. Choose any, and look out for the 'Have Disk..' button next, which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



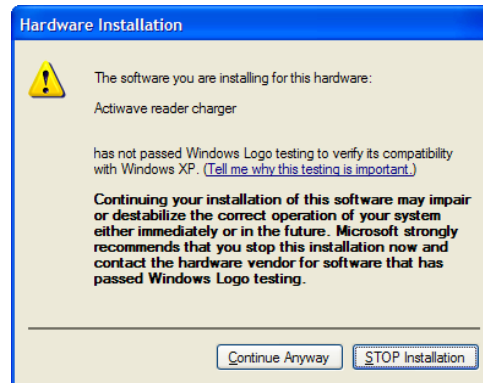
Ignore the items in the list, and click 'Have Disk...' instead.



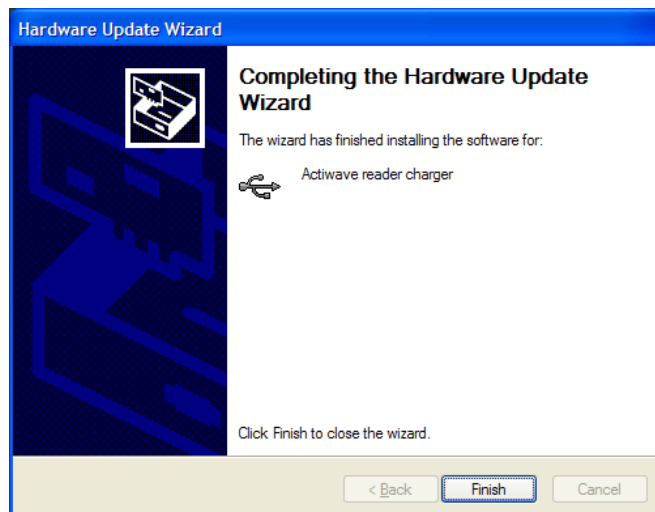
Click on 'Browse...' and then use the standard file window to find the 'USB drivers' folder on the CD. Select 'ftdibus.inf' from this folder and click on 'Open'. The window above will re-appear with a filename at the bottom. Then click 'OK'.



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



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



When this window appears your drivers are installed.

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

<http://www.camntech.com/drivers.htm>