

**EV SOFTWARE  
INSTALLATION AND TRAINING  
QUICK REFERENCE GUIDE**



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## 1.0 Introduction

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This guide is intended as a quick start guide for the EV software. It covers the basics of programming and data retrieval. Please refer to the main manual, which is included electronically with the software as a PDF file in "Help-User Guide", for more comprehensive instructions.

### 1.1 Explanation of Terms

Throughout this manual the following terms are used for clarity:

**User** = anyone who uses the software for programming and retrieving data from the EV range of loggers

**Administrator** = the user who has been designated to authorise other users or administrators.

**Super User** = An administrator whose password does not expire.

**ICONS** = Primary EV software functions.

**Tasks** = A series of instructions for a logger in order for that logger to perform a logging duty.

**Dock** = The term used in the software to refer to the interface or cradle for the logger.

**Session** = A time period of data downloaded from a logger.

## 2.0 Installing the Software

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### 2.1 For EV Standard software, follow these instructions:

Place the CD into the CD Drive on the PC and allow the software to install automatically.

Once installed Select: Start > Programs > EV Standard > EV to run the software.

Refer to section 3.0 of this guide 'Getting Started/Using the EV software'.

### 2.2 For EV Pro Software, follow these instructions:

#### 2.2.1 Daily Password

The EV Pro version of the software is password protected. In order to install the software for the first time the user must obtain a daily password from the Comark Support website. The following information will be needed:

- User name and company details including user's e-mail address and a password chosen by the user.
- The serial number from the CD itself. This is a 5 digit number prefixed with the letters WO with a forward slash followed by another number of 1 or 2 digits, e.g. WO12345/67.

**Note : Please ensure when entering the serial number that the letters 'WO' are added in front of the serial number if these are not shown on the CD.**

Now visit the Comark website: [www.comarksupport.com](http://www.comarksupport.com)

The following image will appear:



Select Register and type the required information into the following screen:

The screenshot shows the Comark logo and the same introductory paragraph as the previous image. Below the paragraph is a horizontal bar. Underneath the bar is a menu box with "Menu" selected and "Login" as an option. To the right of the menu is the text "Please enter your details below to register as a new software user". Below this text are several input fields: "Name", "Company Name", "Address" (with a dropdown arrow), "Post / Zip Code", "Country", "Email Address" (with a note "(this will be your User ID)"), "Password", and "Re-type password". A "Submit" button is located below the "Re-type password" field. Below the form is a horizontal bar.

Check the information entered and then select 'Submit' to confirm registration.

**Note: Please be careful when entering the user's e-mail address as this will become the user ID.**

After registration, the user will need to login. To do so:

Select login from the menu and enter the user name and password into the boxes provided.

**Please enter your login details below**

The screenshot shows a blue login form with two input fields: "User ID" and "Password". A "Submit" button is located at the bottom right of the form.

After entering the user ID and password the software can be registered and the daily password will be supplied.

Select Register EV Pro software from the menu options.

<b>Welcome registered software user, John Smith. Please select from the adjacent menu.</b>						
<table border="1"><tr><td style="text-align: center;">Menu</td></tr><tr><td>▶ Register Auditor software</td></tr><tr><td>▶ Display already registered Auditor software</td></tr><tr><td>▶ Edit your details</td></tr><tr><td>▶ Log out</td></tr></table>	Menu	▶ Register Auditor software	▶ Display already registered Auditor software	▶ Edit your details	▶ Log out	
Menu						
▶ Register Auditor software						
▶ Display already registered Auditor software						
▶ Edit your details						
▶ Log out						

Enter the number of copies of the software to be registered and select GO.

<table border="1"><tr><td style="text-align: center;">Menu</td></tr><tr><td>▶ Register Auditor software</td></tr><tr><td>▶ Display already registered Auditor software</td></tr><tr><td>▶ Edit your details</td></tr><tr><td>▶ Log out</td></tr></table>	Menu	▶ Register Auditor software	▶ Display already registered Auditor software	▶ Edit your details	▶ Log out	<p>Please enter today's date according to your current geographical location</p> <table><tr><td><b>Day</b></td><td><b>Month</b></td><td><b>Year</b></td></tr><tr><td><input type="text" value="05"/></td><td><input type="text" value="Apr"/></td><td><input type="text" value="2004"/></td></tr></table> <p>Now please enter the serial number of each copy of the software you wish to register.</p> <p>Enter serial number 1 <input type="text" value="WO12345/78"/></p> <p style="text-align: center;"><input type="button" value="Submit"/></p>	<b>Day</b>	<b>Month</b>	<b>Year</b>	<input type="text" value="05"/>	<input type="text" value="Apr"/>	<input type="text" value="2004"/>
Menu												
▶ Register Auditor software												
▶ Display already registered Auditor software												
▶ Edit your details												
▶ Log out												
<b>Day</b>	<b>Month</b>	<b>Year</b>										
<input type="text" value="05"/>	<input type="text" value="Apr"/>	<input type="text" value="2004"/>										

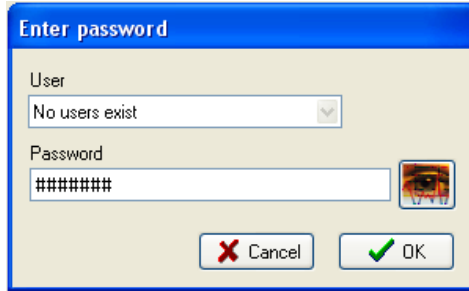
Enter today's date to obtain the daily password. The full serial number e.g. WO12345/67 must be entered. Check the information entered and then select submit.

**Note : Please ensure that you add 'WO' in front of the serial number if these are not shown on the CD.**

The website will then supply the password for the current day, e.g. EV12345.

**Important : Write this password down and then log out of the website.**

## 2.2.2 Installing EV PRO software



Insert the CDROM into the PC disc drive and let the software self-install.

When the software has installed select:

Start > Programs > EV Professional > EV Pro

to run the software.

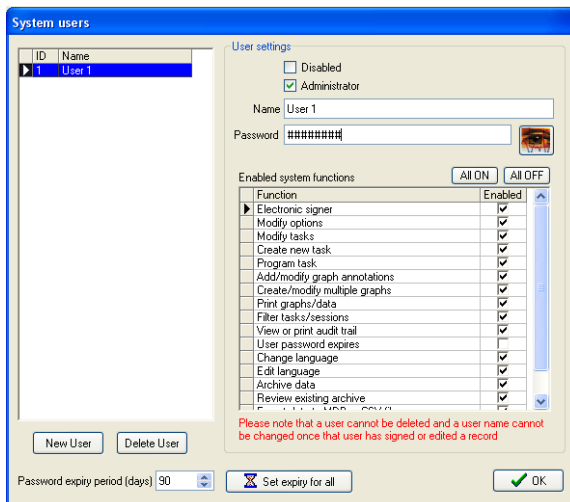
At this point a password must be entered.

Enter the EV daily password obtained from the Internet and select OK.

## 2.2.3 Adding First Administrator (Super User)

At this stage of EV Pro software installation it is necessary to add the First Administrator, who must be a "Super User", to the system

In order to add the First Administrator click on the 'New User' icon - see below.



The user name must be entered into the name box. Note: The system will not allow two users with the same name. Also, the user name cannot be changed after it has been used to create a task.

The First Administrator must be a Super User. It is recommended that when entering passwords for all users they are at least 8 characters long and contain alphanumeric characters.

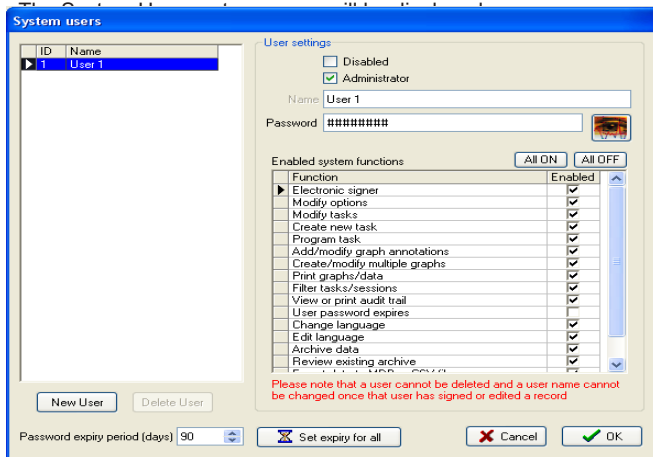
Press OK to finish.

The new First Administrator will be required to log on to the software by entering his/her new password in the box shown.

The user will now be logged on to the software as a new administrator.

## 2.2.4 Creating/Editing/Changing Users/New Users/Administrators

Adding more new Users or Administrators is very simple. The First Administrator must select Edit > Edit Systems > Users and re-enter his/her password and click on OK.



To set up a new user/administrator click on the 'New User' icon.

Enter the name required and select the individual features from the list that the new user will be allowed to access.

The new user can now use the software.

Please refer to the Quick Reference Guide section 3.0 Getting Started/Using the EV software.

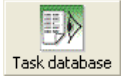
## 3.0 Getting Started/Using the EV software

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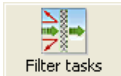
Basic system information is displayed at the top of the screen after the software is opened (EV Pro users need to login first).

### 3.1 EV Icons

A number of Icons are displayed across the top of the screen and these are used to navigate through the software.



The Task database Icon will take the user to the task database view. This is a listing of all programs that have been written for EV loggers.



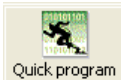
The Filter task Icon takes the user to the filter options menu for task and session data.



The Graph Icon takes the user to the graph and data listing view.



The Multi-Graph Icon takes the user to the multi-graph selection screen.



Quick Program Icon. For more information on Quick program refer to section 4.0 Writing Tasks.



Automatic 'Dock' Icon.



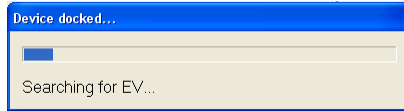
Split Screen Icon. Selecting this will change the screen view to split screen to show the task database, graph and list data where applicable.



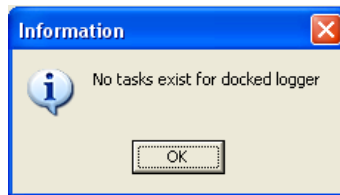
Clear Screen Icon. Selecting this will clear the screen of all task and data.

## 3.2 Introducing a logger for the first time

Select a logger and press the navigation button on the front. Diligence EV loggers must be placed face down in the interface. EVt loggers should be placed face up. For N3000 Graphic Display Monitors, simply connect the comms lead to the connector on the side of the instrument. The EV software will now interrogate the logger or monitor automatically.



The EV software will display an information message as follows:

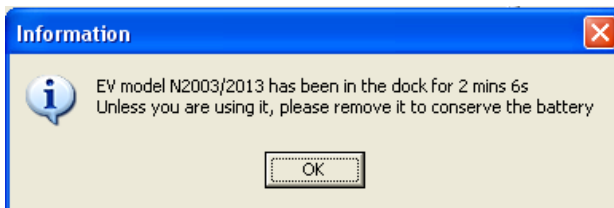


This is normal because the logger is not known to the software. Select OK to continue. This message will be repeated whenever a new logger is introduced to the software. This applies to new loggers not known to the software and to loggers known to the system but with no active tasks.

Note the change in state of the Quick Program Icon and the Docked Icon. Both will now be active.

If no further action is taken then the following information message will be displayed after a 1 minute:\*

\*Note: This message will be displayed repeatedly if the logger is left on the interface. In these circumstances the time shown will be updated.



To prevent the battery from being drained, click OK and remove the logger from the interface. The Quick program and Dock Icons will return to their inactive states.

Note: Clicking OK and leaving the logger on the interface will resume battery consumption.

For more information on this please refer to the user guide within the software section 3.2 Software Setup Options.

## 4.0 Writing tasks for EV loggers

Tasks must first be written and then programmed into the logger before it can be used. The Task will define the instructions for the logger to perform, i.e. to log data.

Program N2003/2013, SN 040Z0099

Description: N2003/2013

Ch	Channel name	Enabled	Sensor type	Probe type	Alarm low	Alarm High	Scale	Graph scale	Alarm delay	AD units	Min
1	Humidity 1	<input checked="" type="checkbox"/>	Humidity	Standard	0.0	0.0	rh	rh	0	Secs	0.0
2	Generic Temp 2	<input checked="" type="checkbox"/>	Generic Temp	Standard	0.0	0.0	°C	°C	0	Secs	-80.0

Logging

Manual Start/Stop

Specific Date/Time

Start:  2 Mar 2004 9:00 am

Stop: 2 Mar 2004 5:00 pm

Daily

Start: 9:00 am

Stop: 5:00 pm

Sunday

Monday

Tuesday

Wednesday

Thursday

Friday

Saturday

Log Interval

1

Seconds

Maximum of 8090 readings = 2 hrs 14 mins 50s

Note: Graph min and Graph max should be entered in units of Graph scale.

Miscellaneous:

Enable Alarms

Auto-reset Alarms

Enable Bleeper

Memory Wraparound

DH (kJ/mol): 100

Lethality Tref (C): 121.1

Lethality z: 10

Evolution Clock

Set Evolution Date/Time

Synchronize with PC clock

Set Manually

2 Mar 2004 11:46 am

Cancel Program

### 4.1 Quick Program

First make sure that you have an active logger in the dock/cradle. Press the quick program icon and the software will display a new task applicable to the logger in the dock. See above.

The task can be programmed into the Logger using the 'Program' button. It will also be automatically saved to the task database.

If the logger has timed out and is no longer active then the task will be simply saved to the database.

### 4.2 Completing the task form

The task form has four areas, General Setup, Logging Mode, Log Interval and Miscellaneous. At the top of the screen is the area for a task description plus the settings for the channels on the logger. In the example above, an N2003/N2013 is in the dock.

#### 4.2.1 General Setup

In General Setup, denoted by the display box with scroll bar at the top of the screen (see Section 4.0), there are several options to modify:

- Turn channels ON/OFF
- Set Low Alarm
- Set High Alarm
- Set scales for each channel
- Set scales for graph display (This setting can be changed even after data has been downloaded)
- Set Alarm Delay
- Set Units for Alarm Delay

Scrolling to the right will reveal that it is also possible to set the Graph Max and Min settings for the Y-Axis of Temperature and RH. (These can be changed after download) The Colours used for the lines on the graph can also be set at this time. (These can be changed after download). The line width for the graph can also be changed. (These can be adjusted after download)

For more detailed information on other sections of the task please refer to the main user guide within the software section 4.0 Writing Tasks for EV Loggers.

## **5.0 Programming tasks to Loggers**

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When the task is finished, select 'Program' to send the task to the logger and to save it to the task database. The logger is now ready for use.

### **5.1 After a task has been programmed**

After a task has been programmed to a logger there are two possible outcomes.

1. The logger is set for manual start
2. The logger is set for an automatic start, with delay (EVt only if programmed) or without delay (EV and EVG).

## 6.0 Logging Modes

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### 6.1 Manual Start/Stop Modes EV and EVt

When a logger has been set for manual start then the logger display (if fitted) will show the word MAN in the lower portion of the LCD. In this case the user must press and hold the navigation button on the front of the logger for 6 seconds to start logging. If manual stop is also selected then the logger will require the same key operation in order to stop logging.

#### 6.1.1 Delayed Start (EVt Only)

If a delayed start has been programmed then the logger will display 'dLAY' to indicate that it is counting down to the start time once the navigation button has been pressed to initiate the programmed task.

### 6.2 Automatic Start/Stop Modes EV and EVt

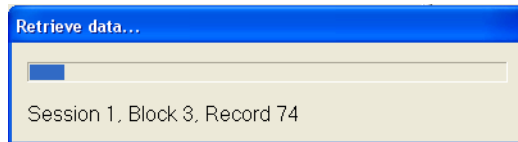
In the event that either the start and stop are pre-programmed or that automatic end is programmed then no further input from the user is required. Simply place the logger where it is required to log temperature and leave it.

## 7.0 Retrieving Data from EV loggers

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When downloading is required the logger must be activated, using the navigation button on the front of the logger, and placed in the interface (face down for EV loggers and face up for EVt loggers). To stop a logger in manual mode press and hold the navigation button for six seconds. The word LOG will disappear from the LCD (where fitted on the logger) and the logger will play a series of beeps. In automatic mode the logger will stop automatically at the programmed time.

If Auto docking is active the software will automatically detect the logger and begin the download process, see below:



When the data has been downloaded the software will automatically filter the task database, if displayed, for the current logger type, its serial number and the current task programmed to it, and it will automatically draw the graph with the settings as in the current task.

## 7.1 Important Note regards EV Pro and 21 CFR Part 11

If a logger has been programmed on a PC running EV Pro software, it will only be possible to use that logger on the same PC or another PC which is also running EV Pro software. This is to protect the data in accordance with 21 CFR Part 11.

## 8.0 Graphing Data/Calculations

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After the data has been downloaded the software will automatically graph the data for the session just downloaded. Please refer to the main user guide, which can be found in Help-User Guide in the software.

## 9.0 Printing

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Data from the graph can be printed in a number of ways. Please refer to the main user guide, which can be found in Help-User Guide in the software.

## 10.0 Exploring the Database

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### 10.1 Database Description

All the tasks for all the loggers known to the software and all the session information is stored in the database.

Select Task Database or Split Screen Icon to view the database.

The database is split into two sections. On the left is a list of all the tasks and on the right is the session information. When a logger is downloaded and information stored, a new session is created. The number of sessions created or possible per task is determined by how the logger was used.

If a logger in manual start stop mode is started and stopped many times, but not downloaded, then each block of data will create a new session of data.

If a logger logs continuously until its memory is full, and wraparound is off, the task will be completed when the data is downloaded. The data will be either a single block, and therefore a single session, or if it has been stopped and started again then multiple sessions are possible. To use the logger again will require the creation of a new task.

If a logger logs automatically from time X to time Y then the task will be closed when the logger is downloaded and a single session will be created.

If a logger is logging in daily logging mode until its memory is full then the task will be closed. If the logger has logged for more than one day then each day will become a session of data.

## 10.2 Editing Tasks/Sessions

After a task has been created it can only be deleted if it has not been programmed into a logger. Once it has been programmed to a logger it can not be deleted, but only archived.

Certain elements of the task can be edited after the task has been written, whether or not the data has been downloaded.

These include:

- Description
- Graph Scale
- Graph Max and Min
- Graph Line Colour and Line Width
- MKT/Lethality and Pasteurisation Values (EV Pro Only)

These will not affect the downloaded data except in the way they are presented and how some of the calculations are performed on the data.

Editing sessions includes only adding/changing the session description.

## 10.3 Task Useful Information

The tasks include useful summary information about the data after it has been downloaded.

This information includes:

- Description
- Model
- Serial Number
- Created Date/Time
- Data Start Date/Time
- Date End Date/Time
- Channel Summary
- Daily Days Summary
- Alarm Summary
- Created By (EV Pro Only)
- Modified Date/Time (EV Pro Only)
- Modified By (EV Pro Only)
- \*External Task Yes/No (EV Pro Only)

\*If a data logger that has been programmed with a task by another PC is introduced to the current PC data in the logger will still be downloaded, but a task will be created by the software from the data in the logger. This task will be marked 'External' to identify that it was created on another PC.

Tasks can be viewed/reviewed from the database by double clicking on them individually.

## 10.4 Filtering/Sorting Tasks/Sessions

**Task filter**

**Status** Unused

**Task ID** 6

**Task Description** Steve

**Session Description**

**Model** N2003/2013

**Serial number** 08010015

**Data date range** 15 Jan 2004 to 15 Jan 2004

**Data last n days** 30

**Creation date range** 5 Nov 2003 to 5 Dec 2003

**Creation last n days** 30

**Created by**

**Modified date range** 5 Nov 2003 to 5 Dec 2003

**Modified last n days** 30

**Modified by**

**Channel** 2

**Above value** Temperature 0 °C

**Below value** Temperature 0 °C

**Daily logging days >>>>**

**In high alarm or low alarm**

**In high alarm**

**In low alarm**

**Externally created**

**Daily logging days**

Sunday

Monday

Tuesday

Wednesday

Thursday

Friday

Saturday

**Primary sort by** Task ID

**Secondary sort by** Task ID

For EV Standard users there is a reduced filtering set. Please refer to section 10.4 of the user guide within the software.

At this point it is possible to filter and sort the task database. To select a filter option tick the appropriate box then select/enter the filter criteria. **Note: Items below marked # relate to EV Pro only.**

**Status Filter** - The tasks will be filtered by one of three options; Unused, Active and Closed.

**Task ID** - Everything except a specific task in the database can be filtered out.

**Task Description** - Use this filter to filter out tasks with a specific description or one that contains a word or phrase.

**Session Description** - Use this filter to filter out tasks with a specific session description or one that contains a word or phrase.

**Model** - Use this filter to show only those tasks that apply to a particular model type.

**Serial Number** - Show all the tasks for a particular logger serial number, i.e. a specific individual logger.

**#Data Date Range** - It is possible to filter the tasks by data date range by entering two dates - "from" and "to".

**#Data last n Days** - Filter by the most recently downloaded data.

**#Creation Date Range** - Filter tasks by created date range by entering two dates - "from" and "to".

**#Creation Last n days** - Filter tasks by the most recently created task.

**#Created By** - Filter tasks by Users/Administrators who have created them.

**#Modified Date Range** - Filter tasks by when they were modified by selecting two dates - "from" and "to".

**#Modified last n days** - Filter tasks by those modified most recently.

**#Modified By** - Filter tasks by User/Administrator who modified them.

**#Channel** - Filter tasks by those with a certain active channel.

**#Above Value** - Filter Tasks/Sessions by parameter and scale above a certain value.

**#Below Value** - Filter Tasks/Sessions by parameter and scale below a certain value.

**#Daily Logging Days** - Filter tasks by those with daily logging days. Any combination of days may be selected.

**In High or Low alarm** - Filter the tasks to show only those with readings in either high or low alarms.

**In High Alarm** - Filter the tasks to show those with readings in high alarm.

**In Low Alarm** - Filter the tasks to show those with readings in Low Alarm.

**#Externally Created** - Filter tasks that were originally not generated on the current PC.

**Primary Sort/Secondary Sort** - The results can be sorted by:

- Task ID
- Task Description
- Generic Model
- Serial No
- Date start date/time
- Date end date/time

## 10.5 Filter Recall

It is possible to recall a previously used Filter without the need to set up the filter again.

Using the Task Database view or the split screen view click on the drop down menu at the bottom of the task database list to reveal the last used Filters. See example below:

The screenshot shows the EV Professional software interface. The title bar indicates the user is 'Comark [User: Andy]' and is using 'Comm port 1'. The menu bar includes File, Edit, Tasks, Program, Multiple session graph, and Help. The toolbar contains icons for Task database, Filter tasks, Graph, Multi graph, Quick program, Dock (Auto), Split screen, and Clear Screen.

Task	Description	Model	Serial no.	Created date/time	Data start date/time	Session	Description	Start date/time
25		N2004/2014	08010015	20 Feb 2004 10:27 am	20 Feb 2004 1:52 pm			
33		N2005/2015	11030541	23 Feb 2004 4:34 pm	25 Feb 2004 2:18 pm			
34	1234567 AGA	N2002/2012	10010371	25 Feb 2004 10:28 am	25 Feb 2004 10:28 am			
35		N2003/2013	04020099	25 Feb 2004 11:17 am	25 Feb 2004 1:37 pm			
39	56789	N2001/2011	01040242	25 Feb 2004 4:43 pm				
40		EVT1		3 Mar 2004 10:57 am				

Task Desc. "Williams", sorted by Task ID  
 Not filtered, sorted by Created date/time, Task ID  
 Not filtered, sorted by Data start date/time, Task ID  
 Model N2005/2015, sorted by Task ID  
 Not filtered, sorted by Task ID  
 Not filtered, sorted by Task ID  
 Not filtered, sorted by Task ID  
 Model EVT1, sorted by Task ID  
 Model N2003/2013, sorted by Task ID  
 Model N2001/2011, sorted by Task ID  
 Model N2004/2014, sorted by Task ID  
 Model N2002/2012, sorted by Task ID  
 Session Desc. "", sorted by Task ID  
 Session Desc. "", sorted by Task ID  
 Session Desc. "", sorted by Task ID  
 Session Desc. "", sorted by Task ID  
 Not filtered, sorted by Task ID  
 Not filtered, sorted by Task ID  
 Not filtered, sorted by Task ID  
 Not filtered, sorted by Task ID

It is possible to set up a number of favourite filters which can then be recalled at anytime without the need to set them up again.

## 11.0 Mean Kinetic Temperature/Lethality/Pasteurisation (EV Pro Only)

---

It is possible via the task set up to enter values for:

Mean Kinetic Temperature  
Lethality  
Pasteurisation

Please refer to the user guide within the software for more information on the calculations for MKT/Lethality and Pasteurisation.

## 12.0 21 Title CFR Part 11

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### 12.1 What is 21 CFR Part 11?

The FDA (Food and Drug Administration) in the USA, issued regulations Title 21 CFR (Code of Federal Regulations) Part 11 that provide criteria for acceptance by FDA or an approved regulatory body, for the acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. These regulations, which apply to all FDA program areas, are intended to permit the widest possible use of electronic technology, compatible with the FDA's responsibility to promote and protect public health. Part 11 applies to any record governed by an existing FDA predicate rule that is created, modified, maintained, archived, retrieved, or transmitted using computers and/or saved on durable storage media. In other words any record from a data logger, for instance that is at some stage stored on a PC or where a PC is used to retrieve the data, 21 CFR Part 11 can be applied.

### 12.2 Title 21 CFR Definitions

**Electronic Record** - Any combination of text, graphics, data, audio, pictorial or other information representation in digital form, that is created, modified, maintained, archived, retrieved or distributed by a computer system.

**Electronic Signature** - A computer data compilation of any symbol or series of symbols, executed, adopted or authorised by an individual to be legally binding equivalent of the individual's handwritten signature.

**Digital Signature** - An electronic signature based upon cryptographic methods or originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

**Closed System** - An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

**Open System** – An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

Standard Operating Procedures (SOPs) - Guidelines and rules defined by the organisation implementing Title 21 CFR Part11 compliance to instruct users what they are and are not permitted to do and how they are to perform the relevant tasks.

EV Professional Software - The EV Professional Software includes a number of settings and data protection devices that, when used with with the EV, EVG and EVt series of data loggers, will give the user a compliant system if adopted into their SOPs. The software can control the access to areas of the software by individual user by means of Administrators who can set up and allocate individual users with their own unique access levels to the software. However it is always the responsibility of the organisation to make sure that any particular user is responsible and understands that any document he/she signs using this software under a 21 CFR environment is the equivalent of a handwritten signature. It is important that you enter the information into these two boxes that will provide the correct amount of information for future viewers of the task.

### 12.3 Electronic Signatures (EV Pro Only)

To be compliant with the requirements of 21 CFR Part 11 Electronic Signatures have been added to the EV Pro software.

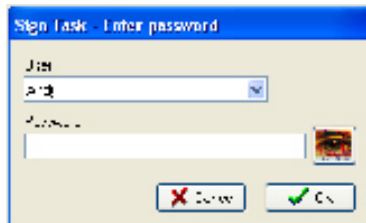
When deciding when to sign a task it is important to remember what state the task is in before signing and there are a number of rules that need to be recognised before signing should take place:

Any task that is signed will be closed.

When a task is closed there may still be a logger that has yet to be docked and have data downloaded. The consequence of this is that the data from that logger will no longer be associated with this task, but will have a new task assigned that is deemed to be externally created.

Once a task has been signed it cannot be modified in any way. Users must accept the current graph settings for this task as they cannot be changed once the task is signed. This includes the task description.

A signed task will include both the name of the signer and an encryption code which will be stored with the task. This allows anyone to know that the task has been signed correctly. This is particularly important when emailing archive databases to another user. The code can only be recognised by other users with the Pro version of the software. It allows another user to be sure that the task was properly signed.



Users must ensure that the task they select to sign is the correct one, because once a task has been signed it is saved as a unique record and cannot be changed.

Use the mouse to left click the required task in the list of tasks. The selected task will be highlighted in blue.

Select Tasks > Sign Task to bring up the dialog box above.

If the current user's name is not shown as the current user, select the required user name from the dropdown list. Enter the password for the current user. The task is not signed at this time.

Press OK to continue.



There are two text boxes to be completed, Authority to Sign and Reason for Signing

**Authority to Sign** is for the user to note his/her authority to sign.

**Reason for signing** is for the user to note his/her reason for signing.

It is possible to sign a task that has no data associated with it.

When both boxes have some text then the 'sign' option will become active. Only when this option is clicked on will the task be signed and closed.

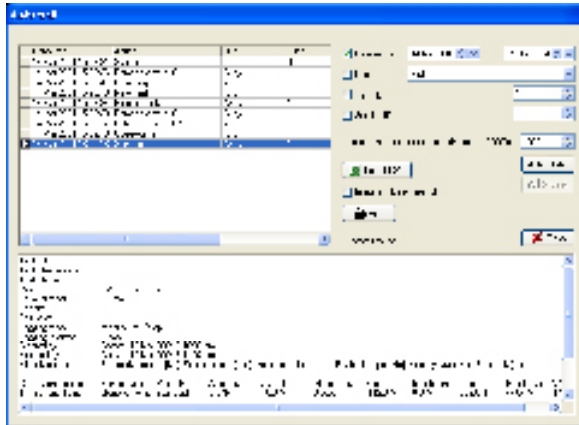
Once signed the task will appear in the task database with a Key symbol in the 'S' column for signatures.

## 12.4 Audit Trails (EV Pro Only)

As part of the changes to bring the software into line with the requirements of 21 CFR Part 11 there is an extensive Audit trail within the software.

This shows full and partial history of what took place with the software. Only users with specific access to the Audit trail can view it or indeed access the filtering and reporting functions included.

Select View/print Audit trail:



It is now possible to view the current Audit trail for the software.

The Audit trail shows by date/time the action completed, the user, user ID, Task ID and Session ID.

There are a number of filters for the Audit Trail:

- Date Range
- User
- Task ID
- Session ID
- Maximum number of readings to display.

The filtered results are then exportable to Excel.

The results can be printed in either detailed form or as just the summary information.

The audit trail for any given database will be saved when archived so that it can be reviewed when the archive database is reviewed.

## 12.5 21 CFR Part 11 Policy Statement

Comark does not at any time imply that the use of this software package and Comark EV loggers will automatically give the customer protection and compliance with 21 CFR Part 11. The EV Pro software from Comark is designed to be integrated into the SOPs as part of a 21 CFR Part 11 system. A number of tools have been put into place in order to provide an excellent basis for complying with the requirements of 21 CFR Part 11. If the SOPs are updated to include the use of EV Pro and loggers then compliance is not guaranteed but it will be more likely. In any case the system in place will need to be discussed with an FDA Auditor. EV Pro and EV data loggers are a vital link in the path to compliance.







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