EV Software

Operator Manual

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1.0 Introduction

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 whoever else in the organisation can be 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 dock is the term used in the software which refers to the interface or cradle for the logger.

Session = A period of data downloaded from a logger.

1.2 EV Software

The EV software is a newly developed software package to further enhance the EV range of data loggers.

The EV software now comes in two versions:

- EV
- EV Pro

The EV software is the standard version which replaces the current version of Evolution.

The EV Pro version is a further enhancement of the EV software but with the additions of a number of extra features and benefits as well as the new features designed to meet the requirements of 21 CFR (Code of Federal Regulations) Part 11.

2.0 Installing the Software

If you have EV Pro then continue to section 2.1

For EV Standard software then follow these instructions:

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

Once installed Select Start-Programs – EV Professional – EV Pro to run the software.

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

2.1 Daily Password

The EV PRO software is password protected. In order to install the software for the 1st time the user must obtain a daily password for the Comark Services website. You will need the following information:

Your name and company details including your e-mail address and a password of your choice.
The serial number from the CD itself. This is a 5 digit number with a slash then another number 1 or 2 digits, e.g. 12345/67. **Note : Please ensure that you add 'WO' in front of the password if not shown on the CD.**

Visit the following website www.comarksupport.com

The following image will appear;

Select Register and type your information into the following screen;
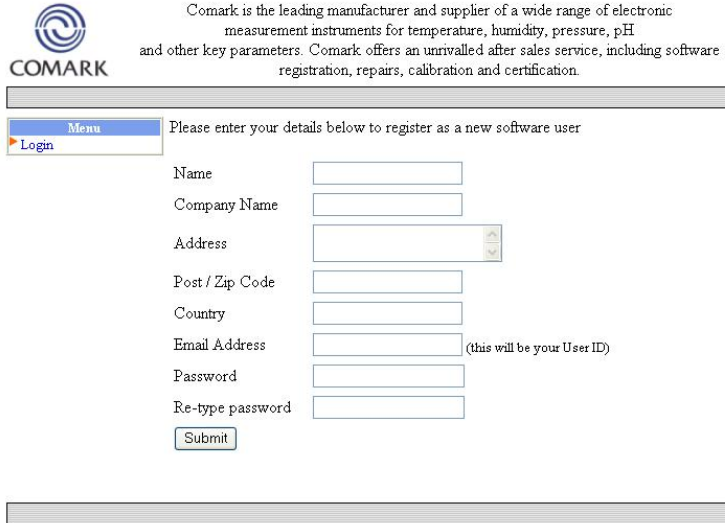
When you are happy with the information typed select 'Submit' to confirm registration.

Note:- Please be careful entering your e-mail address as this will become your user ID.

When you have registered you will then need to login.

Select login from the menu and enter your username and password into the boxes provided.

Once you have entered your user ID and password you can now register your software and receive the daily password.
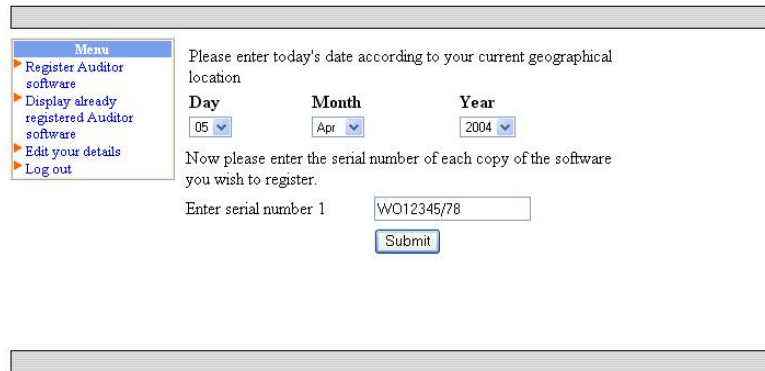
Select Register EV PRO software from the menu options.

Enter the number of copies of software that you wish to register then select GO.

Now enter the date for which you want the password to apply, i.e. to-day's date. Then enter the full serial number e.g. WO12345/67. Select Submit when you are happy with the information entered.

Note : Please ensure that you add 'WO' in front of the password if not shown on the CD.

The website will return with the password for the day you have selected, e.g. EV12345.

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

2.2 Installing EV PRO software

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

When the software has installed select Start-Programs – EV Professional – EV Pro to run the software.

You will be asked to enter a password:

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

2.3 Adding 1st Administrator (Super User)

At this stage of software installation it is necessary to add an Administrator or Super User to the system. This designated person or persons can then add additional users to the system including other administrators and will control the access that these Users have to the features of the software. A maximum of 3 administrators can be added/active at any one time.

In order to add the 1st Administrator click on the 'New User' Icon, see below.
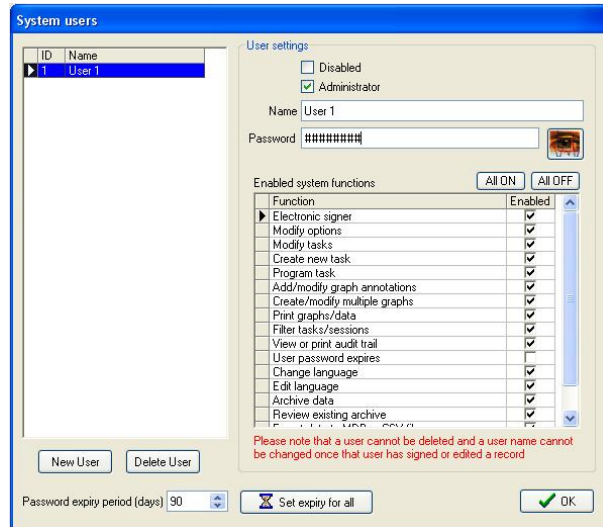
The user name can be changed to any other name, however the system will not allow two users with the same name. Note: The Username must be selected now, as it is not possible to change it later.

The 1st User must be an Administrator. Administrators are simple to set up simply click the box for administrator at the top of the screen. All the boxes in the list will be ticked apart from the one setting the User Password Expiry date. At least one of the Administrators must have a password that does not expire so that access to the software can be maintained in the future, this administrator is referred to as the Super User. At this point you will be asked to enter a password.

It is recommended that when entering passwords, for all users, that they are at least 8 characters long and contain alphanumeric characters. An expiry for the password can be set. All passwords should however be changed regularly or at least at the time of expiry. If a password is allowed to expire then only an administrator has the authority to re-enable to user. If all passwords are allowed to expire then only the Super User has access to the system to re-enable other administrators and Users.

Press OK to finish.

The new administrator will be required to log on to the software. Please enter your new password in the box shown below:
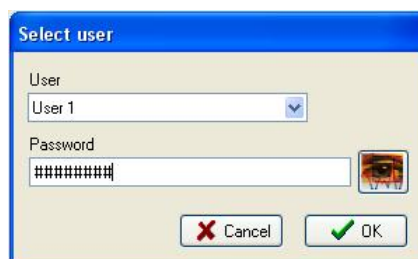
You will now be logged on to the software as a new user/administrator (Super User).

Note: If the Super user whose password does not expire no longer needs access to the software then he/she should be removed from the system by disabling the account. It is not possible to completely remove users from the system. At this time either a new super user must be created with a password that will not expire or an existing administrator profile should be updated.

2.4 Creating/Editing/Changing Users/New Users/Administrators

Adding new Users or Administrators is very simple. Select Edit-Edit Systems Users and the following dialog box will be displayed:

Re-enter your password and click on OK.

The System Users setup screen will be displayed:

To set up a new User/Administrator click on the 'New User' Icon. Change the name as required.

To set up a User then simply select the individual features from the list that the new user is to have access to.
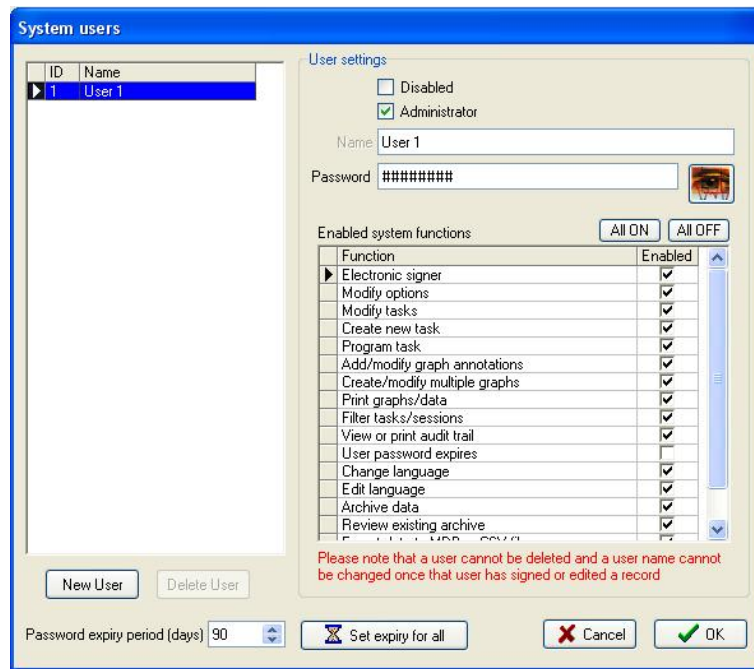
Here it is possible to amend any user profile as an administrator or to add another user/administrator profile to the software.

It is recommended that all users of the software for programming and data retrieval are set up as Users and that all administrators are purely for admin access only. All users can be given rights as though they are in fact administrators for the purposes of using the software, except for the ability to create new users and administrate existing ones.

To set up a new User/Administrator click on the 'New User' Icon. Change the name as required.

If the user is to be an Administrator then click on the administrator button as above to select all the items. In this case as the second or third administrator it is possible to select 'User password expires' so that the password will expire after the preset time. Expiry dates are set in days.

To set up a User then simply select the individual features from the list that the new user is to have access to.

Select any or all of the items from the list. This gives ultimate flexibility and control over who has access to what, and provides the best protection against unauthorised use of the software.

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It is recommended that all passwords are at least 8 characters long and include a mixture of letters and numbers. However they can be as short as required. Use the EYE button to check that the password you have entered is correct. Passwords are not case sensitive.

If a user logs on incorrectly three times in a row then he/she will not be allowed to log on to the system until he/she has been re-instated by an Administrator. To re-enable a user use the same process as above but this time un-tick the box marked disabled to re-instate the user. If necessary at this time the password can be changed.

If there is any suspicion that a password has been lost or that another user has been given another users password then change it immediately.

Once that the Users and Administrators have all been set up it is possible to use the software with your data loggers. Further users/administrators (up to 3) can be added at any time. However there is no practical limit to the number of ordinary users.

2.4.1 Switching Between Users

Whilst logged in it is possible to switch between users. Simply select Edit-Change User. Select the new user from the drop down menu and enter the new password.

Press OK to finish.

2.4.2 Changing Your Password

To change a password at User level first log on to the software.

The select 'Edit-Change Password'. The following screen will be displayed:

Simply enter the existing User password followed by the new password then a repeat of the new password. Click on the EYE icon at anytime to view the password.

2.4.3 Logging Off

It is not possible to log-off the software whilst leaving the software open. When you are finished close the software down. All the data you have generated will be saved. The next User/Administrator will simply open the software and login as normal.

3.0 Getting Started/Using the EV software

Once logged in, in the case of the Pro version or simply opened, EV basic, then the software will look like this:
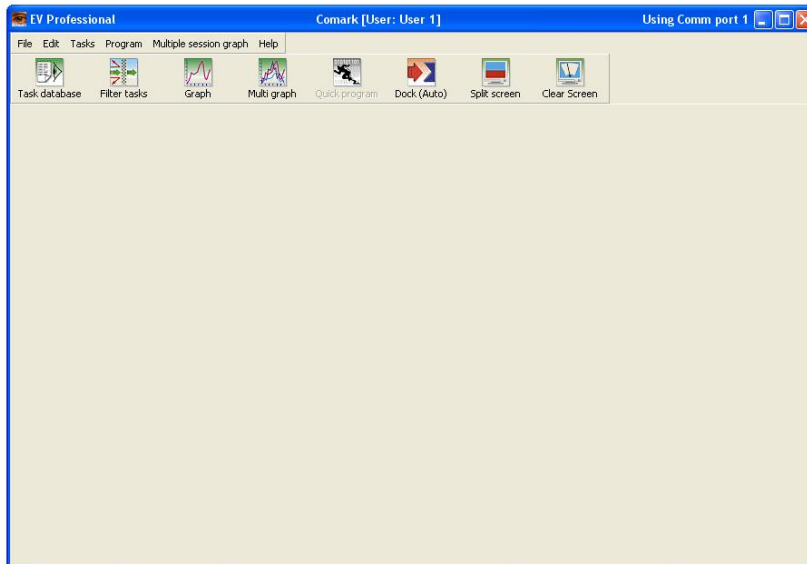
Along the top of the screen will be the version of software in use followed by the logged on user, if applicable, and then the communications port in use.

3.1 EV ICONS

Along the top of the screen are a number of ICONS which are used to navigate through the software.
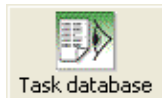
The Task database Icon will take the user to the task database view. This is a listing of all programs that have been written for EV loggers.
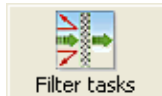
The Filter task Icon will take the user to the filter options menu for task and session data.
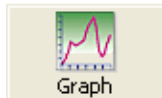
The Graph Icon will take the user to the graph and data listing view.
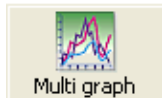
The Multi-Graph Icon will take the user to the multi-graph selection screen.

This is the Quick Program Icon. It has two modes one to show active (full colour) and one to show inactive (black and white). If Quick Program is active then the dock will have an active logger fitted. For more information on Quick program refer to section 4.0 Writing Tasks.

This is Quick Program (inactive). In this case the dock is most likely empty or the logger in the dock is inactive.

This is the Automatic 'Dock' Icon. This Icon has four modes. This one shows 'Dock' to indicate that nothing is in the dock or the logger in the dock is not active.

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This is the Automatic 'Docked' Icon. This indicates that there is an active logger in the dock.

This is the Manual 'Dock' Icon. In this case indicating that the dock is empty. In this mode the Icon must be selected to check the status of the Dock.

This is the Manual 'Docked' Icon. In this case indicating that a logger is in the dock.
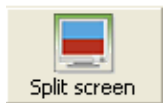
This is the Split Screen Icon. Selecting this will change the screen view to split screen to show the task database, graph and list data where applicable.

This is the clear screen Icon. Selecting this will clear the screen of all task and data.

3.2 Software Setup Options

The EV software has some set up features that need to be explained before the software is used for the first time.

Note: For EV PRO users access must have been given to Modify Options to make any changes to this section.

Select Edit-Options to bring up the Preferences screen, see below.
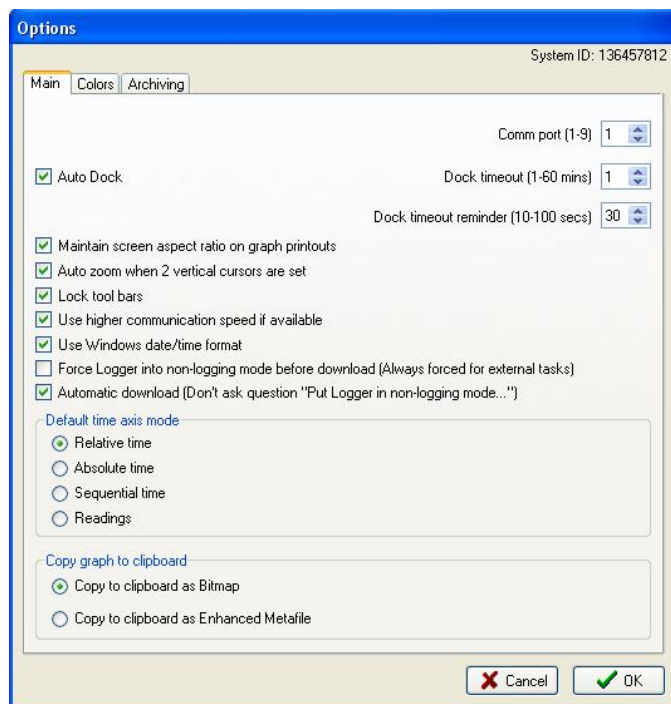
Note: The default for tick boxes is all ticked.

3.2.1 Comm Port

Use this setting to select the Comm port for the PC. The software is compatible with virtual comm ports for USB-Serial adaptors.

If you do not have a comm port available on the PC you will need a USB serial port adaptor which can be obtained locally or direct from Comark, quote part number ADP55.

3.2.2 Auto Dock/Timeout/Timeout Reminder

Auto dock is set as standard. In this mode the EV software will operate automatically to download loggers. However while a logger is in the dock it will be using battery power at a higher than normal rate. Therefore it is recommended that the Dock Timeout and Dock reminder settings are set as short as possible.

3.2.3 Maintain screen aspect ratio on graph printouts

If this box is ticked then graph printouts from the EV software will maintain the same aspect ratio as they have on screen. In this case the printout will be exactly as per the image on the screen.

If this box is not ticked then the printout will be stretched to fit the page. See section 9.0 Printing.

3.2.4 Lock Toolbars

This option is included to prevent accidental moving of the toolbars around the screen. To move the toolbars simply un-tick this box move the toolbar then lock it again afterwards. There are three toolbars on the EV software. The top toolbar 'File, Edit, Tasks, Program etc', the EV Icons, and another toolbar associated with the graph when visible. The position of the toolbars will be saved when the User/Administrator exits the software. The position of the toolbars is not user specific.

3.2.5 Auto Zoom

Using the Vertical Line function on the graph can enable automatic zooming to those settings when the mouse is released. This can be found in section 8.0 Graphing data.

3.2.6 Use higher comms speed if available

Future enhancements for the loggers include the addition of USB communications between the logger and the PC. Keeping this box ticked means that you will be ready to use this additional feature when it becomes available.

3.2.7 Use Windows Time/Date format

Date and time information for logged data will be shown in the database in the same format as the Windows date and time if this box is ticked.

3.2.8 Force logger into non-logging mode (Super User Only) (EV Pro Only)

In certain circumstances loggers that are left on the cradle or introduced to the cradle may still be logging when downloaded. In these circumstances if the logger is not stopped and returned to non-logging mode then there is a possibility that data may be lost. With this box ticked then no data is lost, as the logger will be taken out of logging mode before it is downloaded. If the box is not ticked but the logger is first stopped before downloading is activated then again no data will be lost. Un tick this box only when a logger is required to be re-used with the same task but you want to be able to download data during a logging session. Each time the logger is downloaded will create a new session of data.

If the logger was programmed on another PC or the task has been signed then the logger will always be downloaded and placed in non-logging mode.

This option should never be un-ticked in a 21 CFR Part 11 environment, and as such can only be disabled by the Super User.

3.2.9 Automatic download (EV Pro Only)

This option is used in conjunction with 3.2.8 above. If the box above is not ticked then the software will place the logger into non-logging mode if appropriate automatically should it be required before the data is downloaded. If this box is left un-ticked then the user will be warned that the logger needs to be placed in non logging mode before download can take place. Thus giving the option not to download at that time. Leave this box ticked for automatic download of data with no need for user intervention.

3.2.10 Default Time Axis Mode

It is possible to set the automatic default for the scale settings on multiple graphs.

Relative Time   –   All time bases will be referenced to 00:00:00

Absolute Time   –   All the time bases will be drawn on a real time scale.

Sequential Time   –   All the time bases will be drawn one after the other.

Readings   –   All graphs will be drawn referenced to the number of readings starting from zero each time.

3.2.11 Copy Graph to Clipboard

It is possible to copy the graph to the clipboard for export to another package such as Word or for copying to a presentation or other report. There are two options for the export of the graph, either Bitmap (drawing) or enhanced metafile (scalable drawing).

3.2.12 Colours

Select Colours from the tab at the top of the screen to reveal the selection of colours available, see below.
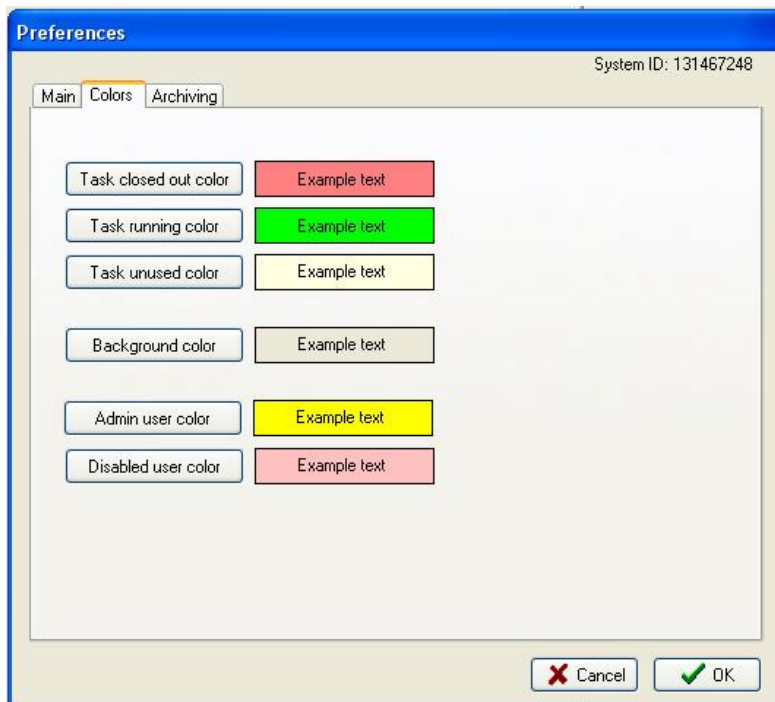
Here it is possible to set the colours for the features as described above. These colours are freely selectable. Simply select one of the tabs in the left column and choose another colour. The selection will be saved on exit from the program.

3.2.13 Archiving

Database tasks cannot be deleted from the system unless there are unused, i.e. they have not been programmed into a logger. However as the software is used, more and more tasks will build up. Occasionally it is suggested that the database is archived. This database can be opened again at any time thereafter to review the data.

Note: If using EV PRO then the requirements of 21 CFR Part 11 will require the User to Electronically Sign any unsigned data in the database before it can be archived.

The archive options are listed below:
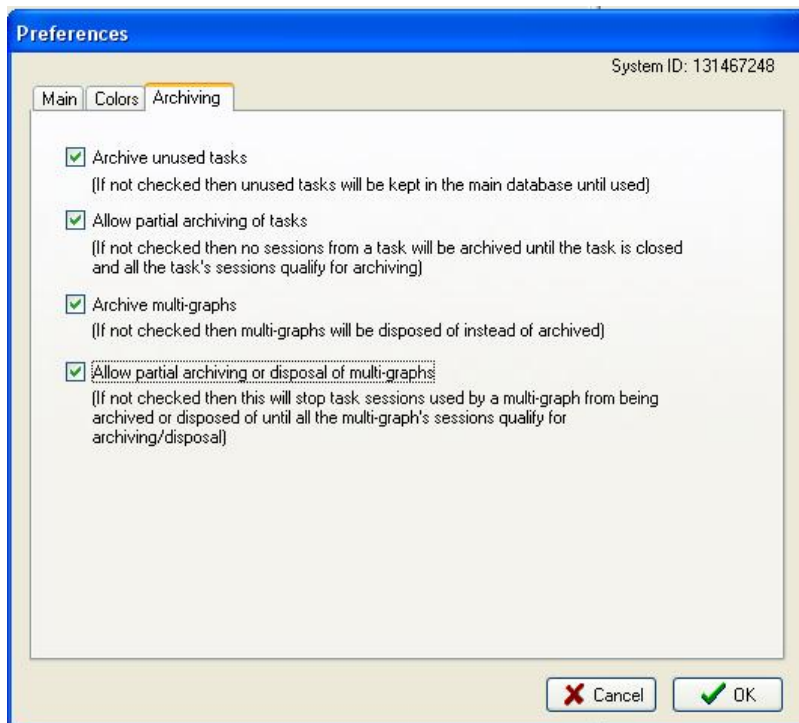
Select OK to complete set up. All changes will be saved when you exit from the software.

To archive the database select File-Archive Database. The following image will appear:

To change the date select the 'Date' Icon and choose another date. When the date has been selected click on OK to complete the archive process. Note: This process may take a few minutes depending on the size of the archive file.

3.3 Introducing a logger for the 1st time

At this stage it is possible to place a logger in the interface and begin using it with the EV software.

Take a logger and press the navigation button on the front. For Diligence EV loggers place face down in the interface. EVt loggers should be placed face up. N3000 EVg loggers, simply connect the comms lead to the connector on the side of the logger. The EV software will now interrogate the logger.
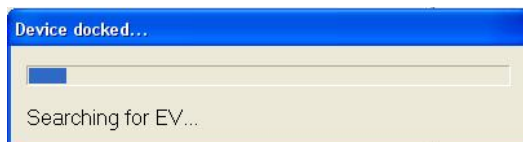
The EV software will then return an information message as follows:

Information

No tasks exist for docked logger

OK
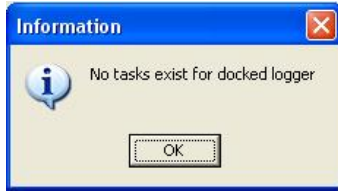
This perfectly normal as the logger is not known to the software. Press OK to continue. This message will be repeated whenever a new logger is introduced to the software or one that does not have any tasks written for it at that time.

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

If no further action is taken then the following information message will eventually be displayed:

Information

EV model N2003/2013 has been in the dock for 2 mins 6s
Unless you are using it, please remove it to conserve the battery

OK

While this message is visible then the logger will not be using excessive current. Therefore if you are called away from the PC you will not be draining the logger battery.

To continue click on OK and remove the logger from the interface.

The Quick program and Dock Icons will return to their respective inactive states.

In this example N2003/N2013 logger is now known to the software and tasks for it can be generated.

However the quickest way to program a logger is to use Quick Program. But quick program is only available when a logger is in the dock and active. Please see section 4.0 Writing Tasks for EV loggers.

4.0 Writing tasks for EV loggers

4.1 Creating Tasks

A task can be generated in a number of different ways.

Quick Program   – used when a logger is in the dock and active.
Create a Task from a Task   – used to repeat an existing task with only minor modification.
Create a New Task for selected model – create a new task with no logger present.

4.1.1 Quick Program

Quick program is used when a logger is in the interface and is active and a task is required quickly.

In Auto Dock mode take a logger and press the navigation button on the front. Place the EV logger face down (EVt face up) in the dock. The software will recognise the logger automatically and the Quick Program Icon will become activated. Note: If a logger contains un-retrieved data then this will be downloaded first.

Quick program will work in two different ways depending on the tasks available in the database. If no tasks exist for a logger, i.e. a new install of the software or simply a new logger type that has not been introduced, then the software will generate a blank task for that logger type.

However if tasks exist for the logger when an active logger is placed in the dock then the task database will automatically filter to list only the tasks for that model and the current task will be highlighted in the list. In this case it is possible to select one of these tasks for quick program. Quick program will copy the information in the existing task to make the new one. Useful for wanting to copy tasks with only small changes. Quick Program is the easiest way to create tasks for EV logger.

Press the quick program Icon and the software will display a new task applicable to the logger in the dock. See below:
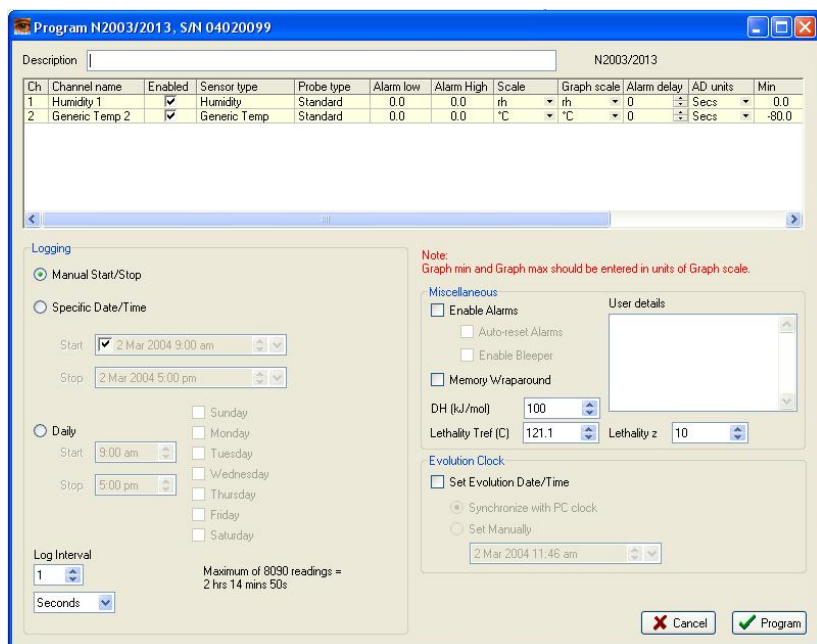
The task can be programmed to the Logger using the 'Program' button. It will also be automatically saved to the task database. If the logger has timed out and is no longer active then the task will be simply saved to the database.

Refer to section 4.2 Completing the task form, see below, for more details on completing the task.

4.1.2 Create Task from a Task

Select 'Tasks-Create task from a task' to generate a new task based on an existing task. Use this instead of Quick program when a logger is not present. When written the task can be saved to the database using the Save button for use later.

4.1.3 Create new task for selected model

Select 'Tasks-Create task for selected model' to generate a new task for a selected model of logger. Use this instead of Quick program when a logger is not present. When written the task can be saved to the database using the Save button for use later.

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 this case an N2003/N2013 is in the dock.

4.2.1 General Setup

In this area, denoted by the display box at the top with scroll bar we 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. (Can be changed after download)
    The Colours used for the lines on the graph can also be set at this time. (Can be changed after download)
    The line width for the graph can also be changed. (Can be adjusted after download)

In the lower half of the display we have three more sections making up the complete task. These are dealt with below.

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4.2.2 Task Logging

On the left hand side of the screen we have the 'Logging' setup. It is here that we set the logger for:

Manual Start/Stop
Manual Start/Timed Stop
Timed Start/Stop
Daily Logging (not EVt)
Start Delay (EVt only)
Log Interval

4.2.2.1 Manual Start/Stop

In this mode all EV loggers (except Evt 1) can be started and stopped any number of times whilst logging (CHECK FOR EVT2). Each logging period will create a new session in the database. If wraparound is set (not EV Pro) then the earliest data will be over written.

4.2.2.2 Manual Start/Timed Stop

In this mode the EV logger will create one session only. The logger requires a manual start and will stop logging when the time is reached or the memory fills up, whichever occurs 1st. If Wraparound is set (not EV Pro) it is possible to set a stop time whereby the logger will only record the last X readings, where X is the memory capacity of the logger. In this case the 1st readings may be lost!

4.2.2.3 Timed Start/Stop

I this mode, the logger requires no manual intervention and will start and stop automatically on the due times. The logger cannot be manually stopped. If Wraparound is set (not EV Pro) then the stop time could be set into the future beyond the capacity of the logger. When the due date occurs and the logger finally stops recording only the last X readings will be stored, where X is the capacity of the logger.

4.2.2.4 Daily Logging

In this mode it is possible to select the day or days of the week where logging is to take place. It is also possible to set the start and stop times during which the logger will log data. It is possible also to set logging to take place over midnight. If wraparound is NOT set the logger will continue to log until full. If wraparound is set (not EV Pro) then the logger will continue to log indefinitely until downloaded. At this time the logger will contain only the last X readings where X refers to the memory capacity of the logger itself.

4.2.2.5 Start Delay (EVt Only)

For EVt logging it is possible to set a start delay for manual start logging. This is in the range 1 – 99 sceonds, minutes, or hours.

4.2.2.6 Log Interval

A log interval for all modes can be programmed as either 1 – 99 seconds, minutes, or hours.

4.2.3 Logging Period

At every stage of logging set up the EV software will indicate the logging period that can be achieved with the current settings.

In this next example a timed start/stop has been set for a total of 21 Days. It can be seen that the chosen interval is not quite enough to cover all 23 days. We are warned to use a minimum log interval of 3 minutes and 48 seconds to ensure that we have enough memory to cope. In order to cover all 23 days we must set an interval to the nearest minute, in this case 4 minutes would suffice.
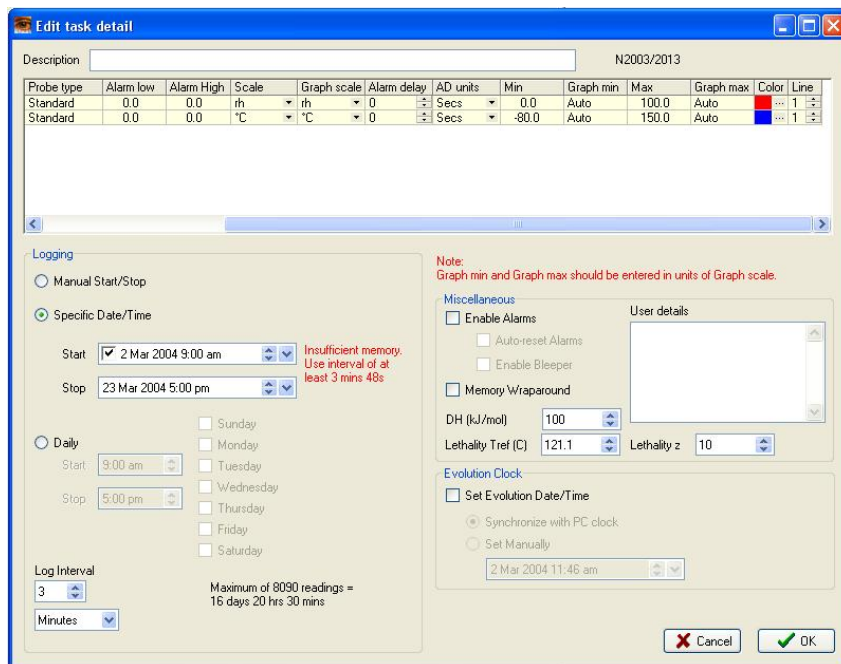
4.2.4 Miscellaneous Logging Setup

This section is perhaps one of the most important as there are a number of setting here to be dealt with.
Enable Alarms

If alarms have been entered into General setup then in order to make use of these then alarms need to be enabled. (Not applicable to EVt as alarms are activated automatically).

Auto Reset alarms can be set. In this mode the alarms will reset when the value drops inside the alarm limits. If this is not set then alarms are deemed to be latched and will stay activated until acknowledged, even if the current reading is not in alarm.

Enable bleeper will enable the bleeper where fitted.

4.2.4.1 Memory Wraparound (Not EVt or EV Pro)
In this mode the logger will log indefinitely until the logger runs flat or is downloaded.

4.2.4.2 User Details
This is a free form box for the addition of any other applicable notes for the task. These will be stored with the task but will be printed if required with the data.

4.2.4.3 Mean Kinetic Temperature and Pasteurisation (EV Pro Only)
Please refer to section 11.0

5.0 Programming tasks to Loggers

Once a task is written unless cancelled clicking on OK will save it to the database for use later.

If quick program was used for generating the task then it is possible to program the logger directly from the task itself.

When a task is programmed to a logger it will automatically be saved if it does not appear in the database already, i.e. it was not an unused task that was finally being used.

5.1 Selecting a Task to be programmed to a logger

Using Auto Docking place a logger in the Interface. The software will automatically recognise it and filter the task database accordingly.

It is now possible to select anyone of the existing tasks for the particular model type in question. Once selected if the task has been used then it cannot be re-used. However selecting Quick Program will create a new task based on the existing one, so it can be easily copied.

Any unused task for the logger type can be opened and then programmed to the awaiting logger in the dock.

5.2 Once a task has been programmed

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

1. The logger is set for manual start
2. The logger is set for an automatic start, with (EVt Only) or without delay.

6.0 Logging Modes

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 to finally log temperature and leave it.

6.3 Logging Modes for EVg (N3000) Series

For the logging modes available on the N3000 series EVg loggers please refer to additional range manual.

7.0 Retrieving Data from EV loggers

When the logger is ready to be downloaded then it must again be activated using the navigation button on the front of the logger and placed face down in the interface (face up for EVt).

If Auto docking is not active then press the dock Icon in the software to check dock and download the data.

If Auto docking is active then the software will automatically detect the logger and begin the download process, see below:
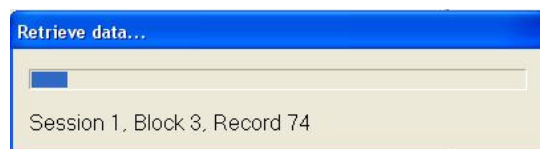
When the data has been downloaded the software will automatically filter the task database, if displayed, for the current logger type and serial number and it will automatically draw the graph with the settings as in the task.

7.1 Important Note regards EV Pro and 21 CFR Part 11

If a logger is taken and programmed and subsequently downloaded on a PC running the EV Pro software then it will not then be possible to download the data onto any other PC not running the EV Pro version. Therefore if the logger is to be programmed and sent to another PC for downloading then this PC must also be running the EV Pro version and therefore be running in accordance with the requirements of 21 CFR Part 11.

Please see section 12.0 for more information regards 21 CFR Part 11.

8.0 Graphing Data

Once the data has been downloaded then the software will automatically graph the data for the session just downloaded. There are a number of features within the graphing package that can be explored at this time. These include:

Adding annotations
Graph Title
Zoom Function
Editing Task Information
Changing x-axis readings
Printing
Calculations of Max, Min, Ave, MKT, Lethality and Pasteurisation
Copying graph to clipboard

8.1 Adding Annotations

From the toolbar for graphing select 'ab' to add a new note. Move the cursor over the graph and drag it to create a text box. Write your text in the box. Click anywhere else on the graph to complete the process and the box will re-size to the amount of text in your box. See example below.
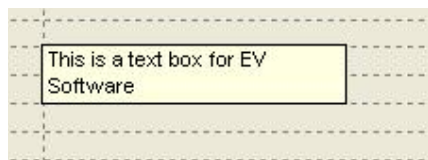
By double clicking on the text box it will become active for editing again. Select all the text then 'A' in the toolbar to change the font type, size and colour, select the colour box below 'A' to select the background colour for the text box. Use the justification icons to align the text to the left, centre, or right hand side of the box.

Click outside the box anywhere on the graph to finish.

Click on the select icon ' ' then once on the box to select the text box and more options become available.

Fixed	–	The box can be tied to a position in space on the graph, to a line or point on the graph and fixed either to the X or Y axis.
Solid/Transparent	–	The box can be either solid or transparent with regards to the background.
No Line/Line	–	The box can be shown as being tied to a line on the graph by the addition of a visible line.
Show Text/Show Icon	–	The text in the box can be shown in full or as an Icon only.

In the example below the text box above has been fixed to channel 2, a line has been drawn to a point on channel 2 and the text box has been converted to an Icon.
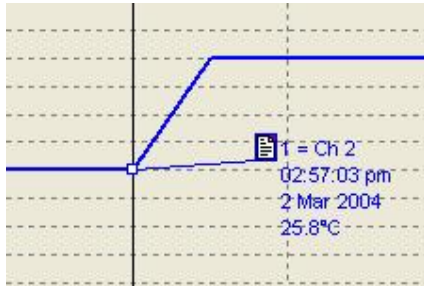
In the above example this ICON style can be achieved by the following method:

Select the text box.
Select Fixed to Channel 2.
Select Line.
Drag the line to a position on the graph.
Select Show Icon.

When printing the graph it is possible to select to print the details of the text boxes.

Duplicate notes are also possible where you want to add a quick annotation to another point on the graph. Select the note that you wish to copy then select the duplicate note (s) icon ' ', and the note will be copied. If the note is in icon format then they will be numbered sequentially from 1-n. These will be automatically numbered in sequence.

8.2 Graph Title

The graph description is in the 1st instance generated by the software itself in the case that there is neither a task description or a session description, see example below:

If a description is entered into the 'description' field of the task itself then this will default to the graph title. If however a description has been added to the session information then this will default to the graph title. See Matrix below for simple explanation:

Graph Description	Automatic	Task Description	Session Description
Task Description	None	Yes	Don't Care
Session Description	None	None	Yes

When creating multi-graphs then a title can be written independently of the individual task and session descriptions.

8.3 Zoom Function

A powerful zoom function has been included in the software, see options below:

Zoom Function
Vertical Cursors Graph
Vertical Cursors Listed Data
Un-zoom
Zoom and Calculations

8.3.1 Zoom Function

Click on the magnifying glass icon to activate zoom. Select a point in space on the graph then drag the magnifying glass across the graph to zoom in. Zooming will be automatic when you let go of the mouse.

8.3.2 Vertical Cursors Graph

Select the vertical cursor icon ' ↕ '. Use the mouse to position the 1st vertical cursor then drag the line across the graph to the next point. When you release the mouse the second vertical cursor will be drawn. If Auto Zoom has been ticked, see section 3.2, then the graph will automatically re-draw to the new values.

8.3.3 Vertical Cursors Listed Data

Select the vertical cursor icon ' ↕ '. Now select a position in the listed data to become the 1st line, you can release the mouse at this point. Now scroll down the data to the next point required. Press the CTRL key then select the point in the list. The graph will automatically zoom between the two chosen points.

8.3.4 Un-zoom

Select the un-zoom or graph reset icon 📊 to re-draw the graph.

8.3.5 Zoom and Calculations

If zoom is active then the calculations function will work on the selected data only.

8.4 Calculations

There are powerful calculation functions within the EV package.

Select the portion of data that you wish to perform the calculations on using zoom above or un-zoom to perform the calculations on the whole file. Select the calculations Icon 🖩 to perform the calculations. The software will display the results as follows:

Channel	1:17:59 pm 2 Mar	2:25:24 pm 2 Mar	Minimum	Maximum	Mean	Std Dev.	MKT [DH=100.0 kJ/mol]	Slope (/s)	Lethality equivalent time
1 = Thermocouple 1 (°C)	8.6	18.6	8.6	19.6	10.38	1.1904	10.49	0.0024722	0s
2 = Thermocouple 2 (°C)	7.8	18.2	7.8	19.2	9.75	1.1913	9.86	0.0025711	0s
3 = Thermocouple 3 (°C)	7.8	18.0	7.8	19.4	9.70	1.2222	9.83	0.0025216	0s
4 = Generic Temp 4 (°C)	8.6	11.3	8.6	11.3	9.83	0.86661	9.88	0.00066749	0s

Elapsed time = 1 hr 7 mins 25s, 4046 readings with interval of 1s   [Export CSV]   [✔ OK]

The statistics include the following information:

Date Time of 1st reading used including its value (typically the 1st reading in the session)
Date Time of the last reading used including its value (typically last reading in the session)
Minimum recorded reading between the two times above
Maximum recorded reading between the two times above
Standard deviation of the readings between the two times above
Mean Kinetic temperature between the two times above and using the values entered in the Task
Slope reading
Lethality equivalent time based on the values entered in the Task

Elapsed time is also included so that it can be clear for how long the readings apply, including the number of logged readings and the logging interval.

These readings can now be exported to a CSV file for report generation or printing.

8.5 Creating Multi-Graphs

It is possible with the EV software to create a Multi-Graph. This consists of a number of graphs overlaid on top of each other to form another graph. There is no limit to the number of graphs that can be overlaid on each other. Graphs can also be overlaid for different logger types.

To create a multi-graph switch to Task Database view or Split Screen. Select the Multi-graph Icon and the following screen will be displayed:
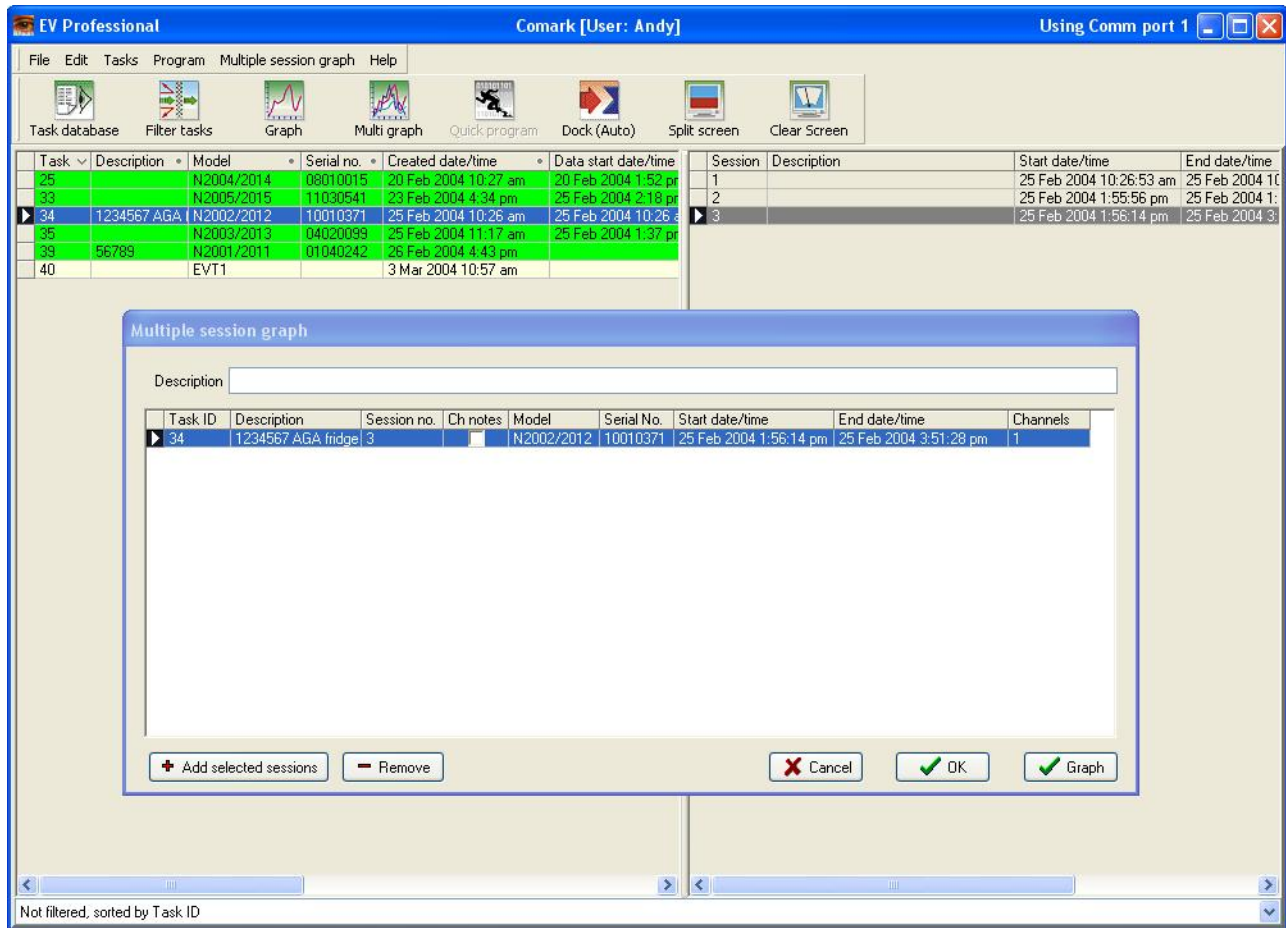
See Section 10.0 for an explanation of the task database view.

At this point it is possible to select tasks and therefore sessions to be added to the multi-graph. Simply select the sessions that you want to add the click 'Add selected sessions'. If the sessions have graphs associated with them that include channel notes then tick 'Ch notes' and these notes will be copied to the multi-graph. When all the sessions have been selected click on 'Graph' to save and graph the new multi-graph or simply 'OK' to save for later.

To view old multi-graphs select 'Multiple session graph' then either;

    Select multi graph by Task…
    Select multi graph by serial number…
    Select multi graph by model…
    Show last multi graph

Select from the list provided.

9.0 Printing

Data from the graph can be printed in a number of ways. From the graph select the print Icon [printer icon] and the following selection will be offered:

Here there are options for Printing the graph, task summary, Icon notes, or the data, in any combination.
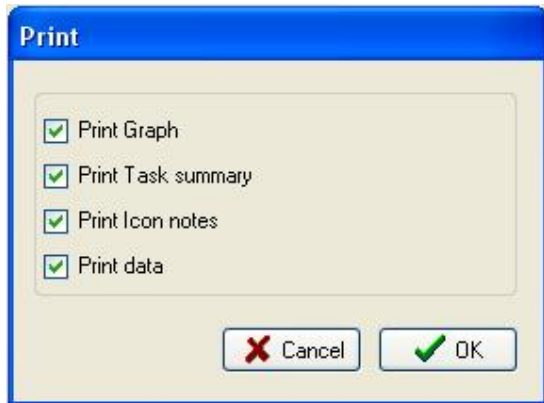
The graph will be printed as per the selection made in options, section 3.2 Software Setup Options

10.0 Exploring the Database

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 are all the tasks and on the right is the session information. When a logger is downloaded and information stored this creates a new session. Depending on how the logger was used will determine the number of sessions created or indeed possible per task.

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 the logger has not logged to full then the task will not be closed and the logger can be started again.

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

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 on daily logging mode and has logged to 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 deleted if it has not been programmed into a logger. Once it has been used it can not be deleted only archived.

However certain elements of the task can be edited after the task has been written and data has or has not been downloaded.

These include:

Description
Graph Scale
Graph Max and Min
Graph Line Colour and Line Width
MKT/Lethality and Pasteurisation Values

None of these will effect the downloaded data simply the way that it is 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 is introduced to the system that has not been programmed with the same PC and therefore does not have a task associated with it then the data will be downloaded in any case but the task will be re-created by the software from data in the logger. This task will be marked as being 'External' so as to identify that it was not created on this PC.

10.4 Filtering/Sorting Tasks/Sessions EV Standard version

Select 'Task Filter' Icon to enter the task filter options. The following dialog box will be displayed;

At this point it is possible to filter and sort the task database view using a number of different filters.

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

Task ID
You can filter out all but a specific task in the database.

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 of 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.

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.

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 Filtering/Sorting Tasks/Sessions EV Pro version

At this point it is possible to filter and sort the task database view using an expanded number of filters over the standard version:

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

Task ID
You can filter out all but a specific task in the database.

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 of 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 too and from by entering two dates.

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

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

Creation Last n days
Filter tasks by the most recently created.

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

Modified Date Range
Filter tasks by when they were modified by selecting too and from date range.

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 those with a value above a certain value, freely selectable type, value and scale.

Below Value
Filter Tasks/Sessions by those with a value below a certain value, freely selectable type, value and scale.

Daily Logging Days
Filter tasks by those with daily logging days, freely selectable days.

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.

User Selected
Use the tick boxes on the tasks to select individual tasks or groups of tasks. When you have subsequently filtered by these tasks it is then possible to archive these individual tasks by selecting 'File - Archive Visible Tasks'. In this way individual tasks no longer required can be removed from the database.

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

10.6 Filter Re-call

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

From 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:

It is possible therefore to set up a number of favourite filters which can then be re-called 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

In the EVPro version of EV software only.

The values entered are used to create the values for Mean Kinetic Temperature/Lethality and Pasteurisation as shown in the Calculations feature of graphing. See section 8.4

11.1 Mean Kinetic Temperature (MKT)

Good warehousing and distribution practice requires that warehouse temperatures are monitored and controlled and that appropriate actions are taken if temperatures exceed the specified storage conditions.

Those actions are based on the calculation of the mean kinetic temperature as a verification of exceeded storage conditions.

With the EV Pro software from Comark it is now possible to calculate the mean kinetic temperature (MKT).

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) stability testing guidelines define mean kinetic temperature (MKT) as 'a single derived temperature which, if maintained over a defined period, would afford the same thermal challenge to a pharmaceutical product as would have been experienced over a range of both higher and lower temperatures for an equivalent defined period'.
In other words, MKT is a calculated, fixed temperature that simulates the effects of temperature variations over a period of time. It expresses the cumulative thermal stress experienced by a product at varying temperatures during storage and distribution. Mean kinetic temperature refers to a datum, which can be calculated from a series of temperatures. It differs from other means (such as a simple numerical average or arithmetic mean) in that higher temperatures are given greater weight in computing the average. This weighting is determined by a geometric transformation, the natural logarithm of the temperature number. Disproportionate weighting of higher temperature in a temperature series according to the MKT recognises the accelerated rate of thermal degradation of materials at these higher temperatures.
MKT accommodates this non-linear effect of temperature.

The formula for MKT is: $TK[K] = (-DH / R) / \ln \{(SUM (\exp (-DH / (R * Tn)))) / n\}$ where DH is the activation energy, R is the universal gas constant (0.0083144 kJ/molK), T is the temperature in degrees K, n is the total number of (equal) time periods over which data are collected, ln is the natural log and exp is the natural log base. SUM is the mathematical function of building up a total over n periods, starting with period 1.

The practical application of the equation is less complex than it first appears. For a huge range of pharmaceutics DH is within the range of 42 - 125 kJ/mol. In cases where an exact knowledge of the activation energy is important, it is possible to determine this factor with the help of a differential scanning calorimetry (DSC) analysis. T1 is the average temperature recorded over the first time period and Tn is the average temperature recorded over the nth time period.

As an example of how the MKT calculation will affect an expressed mean for a calculation (important for the long term storage of critical drugs and chemicals), here is an illustration. If the temperature is constant for a period of time, but is 'out of specs' for some moments of time, there will be a difference in the calculated arithmetic mean (the sum of all of the measurements divided by the number of measurements - a simple mean) and the kinetic mean. Mean kinetic temperature: value = 9.4C Arithmetic mean temperature: value = 6.3C Conclusion : Depending on temperature conditions the effect may be dramatic, it is clear that the MKT method weights the higher temperatures in a series more than the lower temperatures. This is a more appropriate way of calculating an overall thermal effect because of the acceleration of thermally driven processes of degradation at higher temperatures.
Ageing a secondary calculation is used to determine the shelf life reduction due to incorrect storage conditions of a drug substance or drug product. The formula for this calculation is based on the Arrhenius2 life-stress model. Not included with EV Pro.

Example: Due to the incorrect treatment during the unloading of a pharmaceutical product, its shelf life has been dramatically reduced from ten days down to 4.3 days.

If the channel does not read in temperature then the result will be shown as 'N/A'.

11.2 Lethality

Lethality equivalent time is calculated using the formula:

$$LET = (SUM(10^{((Tn-Tref)/Z)}))*Tinc$$

Tn is a reading in temperature in Celcius
Tref is the reference temperature in Celcius
Z is a constant just known as the 'Z value'
Tinc is the reading time increment in seconds
Tref and Z are entered on task setup form.

Standard lethality (Fo) uses Tref = 121.1°C and Z = 10

These are the default values in the setup used by EV, but can be changed at any time.

11.3 Pasteurisation

The above lethality formula is well known in the food industry, however specific values of Tref and Z must be set up. Z varies according to the organism that you are trying to kill, see Appendix 1 for a list of some of the more common ones.

12.0 Title 21 CFR Part 11

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

12.2.1 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.

12.2.2 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.

12.2.3 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.

12.2.4 Closed System

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

12.2.5 Open System

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

12.2.6 Standard Operating Procedures (SOP's)

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.

12.2.7 Diligence EV Professional Software

The Diligence EV Professional Software includes a number of settings and data protection devices that along with the EV and EVt series of data loggers will give the user a compliant system if adopted into their SOP's. 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 organisation's responsibility 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.

12.3 Electronic Signatures

Electronic Signatures can now be added to tasks in the database. The electronic signature can only be added by users with the specific function allowed in their profile and contains all the required elements, name, date, time, reason for signing and authority to sign.

12.4 Audit Trails

Along with Electronic Signatures a full audit trail has been included with the software that gives a record of all the activities on the workstation by those users who have logged into the EV PRO software. Vital for record keeping in a 21 CFR Part 11 environments.

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 that this will automatically give the customer protection and compliance with 21 CFR Part 11. The FDA is very strict on this. 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 software 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.

12.5 21 CFR Part 11 restrictions

In order for the EV Pro software to be used in a 21 CFR Compliant system there are a couple of restrictions over the EV standard version.

The Wraparound function within the task has been removed. In that way it is not possible to allow the logger to continue logging and over write existing data. If the memory capacity of an individual logger is not acceptable then the log interval should be increased to cover the full period.

Loggers that are used with the EV Pro version will loose their compatibility with the Standard version and older versions of Evolution software where applicable.

13.0 EV and EV Pro – What's New!

This new EV and EV Pro software has been developed in conjunction with several leading pharmaceutical companies to reflect their needs with the new demands of 21 CFR Part 11 in particular.

Both versions of the software include the same new user interface to make programming and downloading of EV loggers even easier. Extensive reporting and filtering functions have made it easier for the user to see what's happening with his/her data and the additional of the Audit Trail, required for 21 CFR Part 11, EV Pro Only, enables full and partial history of who did what when and where.

The format of the software has removed the need for file open, and file save as all data is stored in one secure database. The screen layouts have been improved to include the task, graph, session data and listed data all in the one place for easy identification.

Possibly the most noticeable feature of the new software is the automatic download, simply activate the logger and place it on the cradle and let the software do the rest. Hidden in the background are improvements to both the download speed of the logger and safeguards to protect the logger from tampering. Hidden from view but nonetheless important additions.

Each task can now be signed electronically again to meet the requirements of 21 CFR Part 11 but will also find many uses in other logging environments, EV Pro Only.

14.0 Appendix 1 – Pasteurisation Values

The following list is a non-exclusive list Z values for some of the more common organisms used in the calculation of Pasteurisation:

Enterococus Faecalis (6.7)
Staphylococus aureus (4.6)
Salmonella seftenberg (5.7)
Lactobacillus plantarum (12.5)
Listeria monocytogenes (6.7)
Clostridium boulinum non-proteolytic B (9.7)
Clostridium boulinum non-proteolytic E (9.4)
Clostridium butyricum (8.3)
Byssochlamys fulva (7.8)
Zygosaccharomyces bailii (5.0)