New EV Software

Operator Manual

Document Reference EVSWOPMAN 8.docx
Issue 15 June 7th 2016
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Introduction

EVSW Update Summer 2016

This guide has been written alongside a new version of the EVSW Software with crucial behind the scenes updates for Windows 10.

In addition to these changes Comark has undertaken to re-write the Software Interface to give it a more modern look and feel.

The software is fully compatible with original versions of EVSW and EVSW PRO and therefore you can upgrade from earlier versions to this new version.

Validation Note

Please note that if you are running the EVSW PRO version and you have Validated the Software then this version will require re-validation to ensure that it is compatible with your processes. If unsure please contact Comark for assistance.

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.

Diligence EV Range Introduction

There are 6 EV models available:

EVt2 Single internal temperature data logger with display

N2011 Single internal temperature data logger with display

N2012 Internal and 4 external temperature data logger with display

N2013 Humidity and temperature data logger with display

N2014 3 Channel thermocouple + Ambient data logger with display

N2015 Single Channel 4-20mA Current Loop Logger with display

Overview of Evolution Functions

The range of Diligence EV instruments has a built in memory for storage of up to 16000 readings. These readings are sent directly to a PC via the USB interface. Logger operation is via the navigation button on the front of the logger. This controls all the logging functions and acts as alarm acknowledge.

External sensor connection to the N2000 loggers is via the proven Lumberg connector, which allows standard Comark probes to be used where applicable. All loggers feature alarm time delay and Password protection.

All Diligence EV data loggers have a green LED indicator to show that the data logger is active and a red LED indicator to alert the operator when an alarm condition is detected.

Programming and data retrieval using Comark Evolution software is performed by infrared communications (via the USB Interface, part number EVTCRU or N2000CRU) for convenience and reliability.

The Ev software has been specifically developed for use with all Diligence EV Loggers.

Installation and Running the software

EV Software comes in two different versions

- EVSW – Standard Version of the Software
- EVSWPRO – Professional Version of the Software for applications requiring 21 CFR Part 11

If you are running EVSW Standard Software please jump to Section…. See Getting Started - Using the EV software

If you are running EVSWPRO Professional Software please jump to Section…. See EVSW PRO First Use

EVSW PRO First Use

Click on the Desktop Icon to run the software.

Language Selection

Please select from one of the available languages….

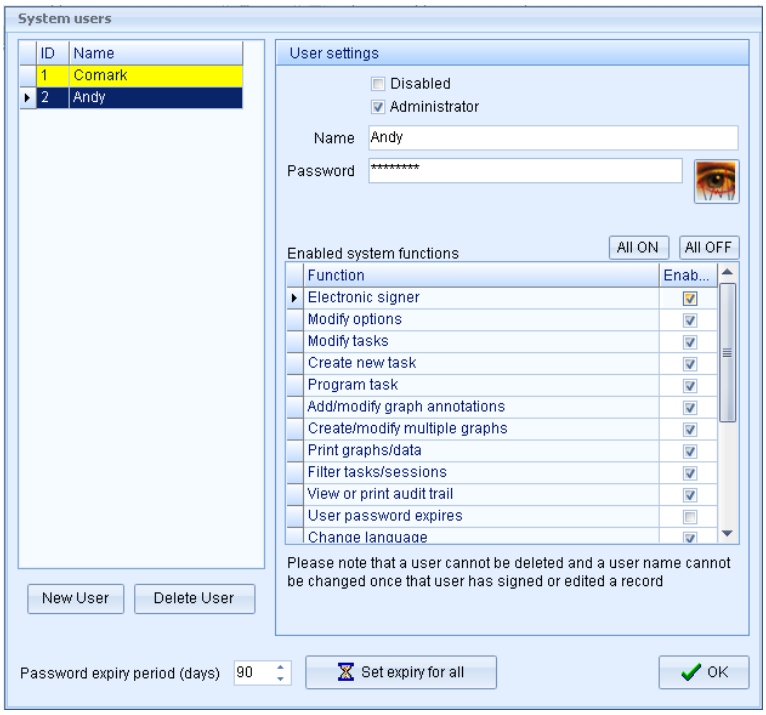
(At time of writing this includes, English, English United States, Spanish, Finnish, French, Italian, Norwegian, Swedish)

Click OK to confirm.

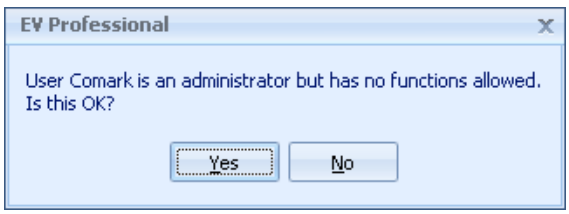
First Administrator

In order to use the software, Administrators and Users must be added. The software will automatically request that a First Administrator be setup on the software.

Simply enter a Username, Password and tick the box for Administrator, see below…



Then Click on OK and subsequently click OK to confirm this message…

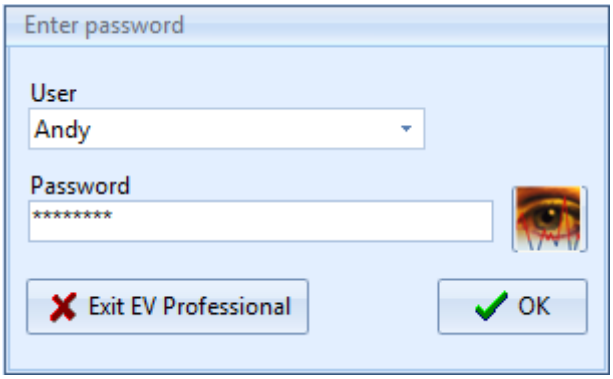


The First Administrator setup is now complete.

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:

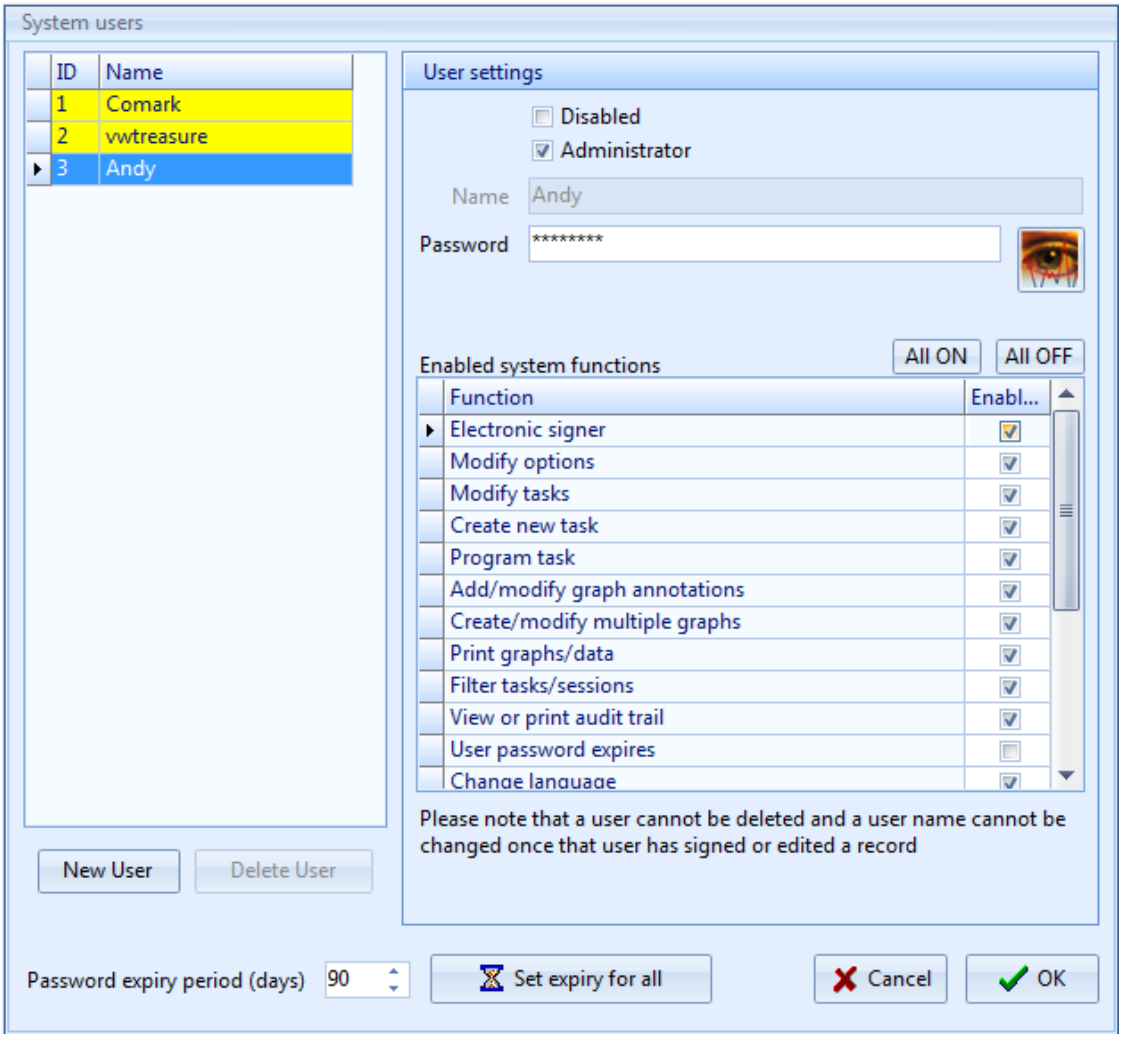
Re-enter your password and click on OK.



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.

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 pre-set 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.

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 button to check that the password you have entered is correct.

Passwords are not case sensitive.

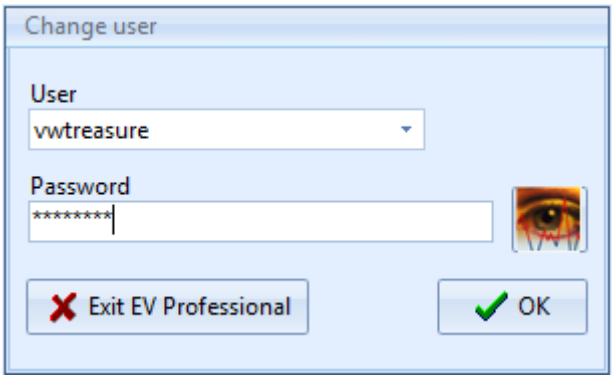
If a user logs on incorrectly three times in a row then he/she will not be allowed to log on to the system until he/she has been re-instated by an Administrator. To re-enable a user use the same process as above but this time un-tick the box marked disabled to re-instate the user. If necessary at this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

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.

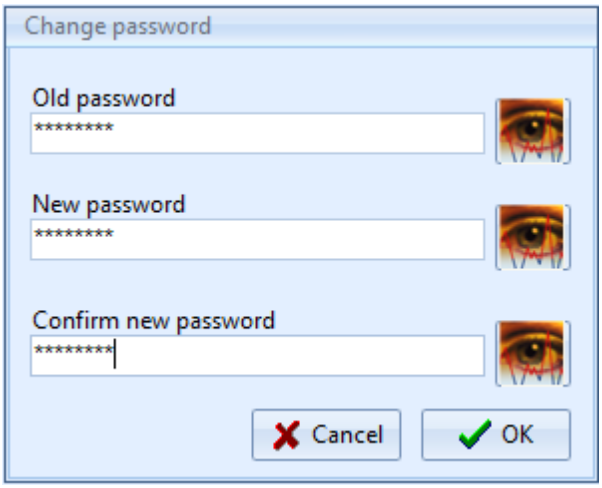


Press OK to finish.

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:



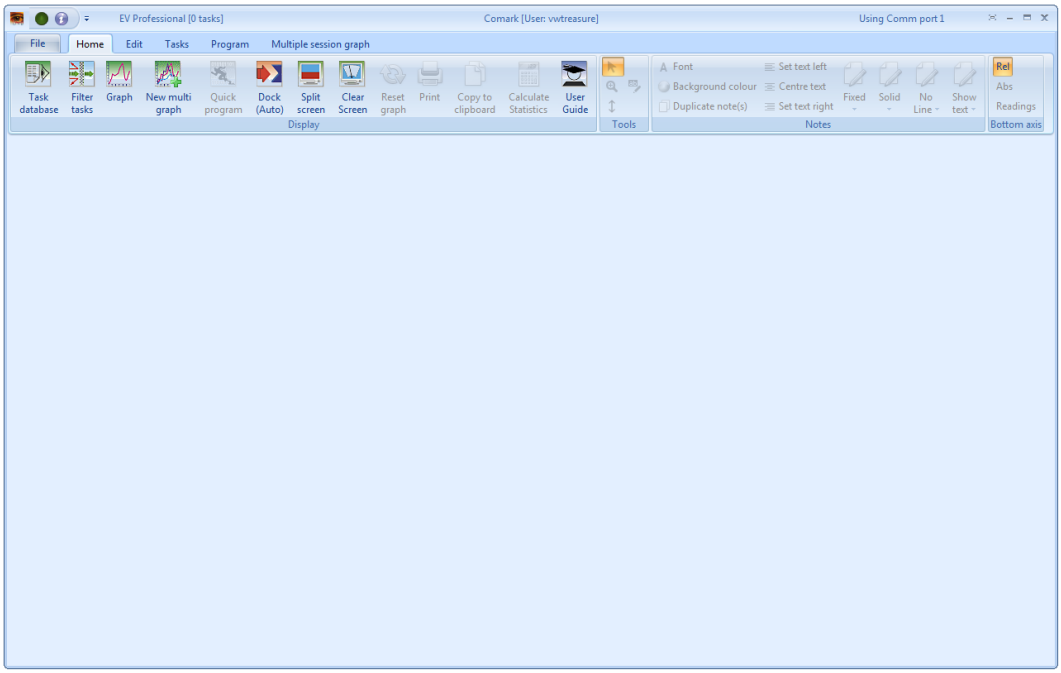
Simply enter the existing User password followed by the new password then a repeat of the new password. Click on the icon at any time to view the password.

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.

Getting Started - Using the EV software

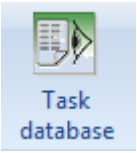
Once logged in, in the case of the Pro version or simply opened, EV Standard, then the software will look like this:



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.

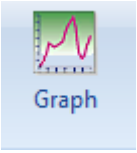
EV ICONS

Along the top of the screen are a number of ICONS which are used to navigate through the software.



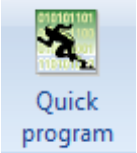
The Task database Icon will take the user to the task database view. This is a listing of all programs that have been written for EV loggers.

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

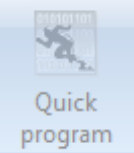


The Graph Icon will take the user to the graph and data listing view.

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 Quick program, click here.



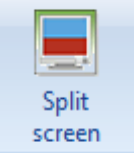
This is Quick Program (inactive). In this case the dock is most likely empty or the logger in the dock is inactive.

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.

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

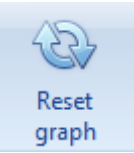
This is the Manual ‘Dock’ Icon. In this case indicating that the dock is empty. In this mode the Icon must be selected to check the status of the Dock.

This is the Manual ‘Docked’ Icon. In this case indicating that a logger is in the dock.

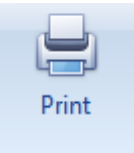


This is the Split Screen Icon. Selecting this will change the screen view to split screen to show the task database, graph and list data where applicable.

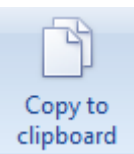
This is the clear screen Icon. Selecting this will clear the screen of all task and data.



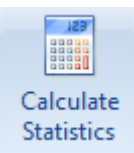
This is the Reset Graph Icon. Selecting this will reset the graph back to the original.



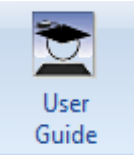
This is the Print Icon. Selecting this will initiate the Print Options.



This is the Copy to Clipboard Icon. Selecting this will copy the current Graph view to the Clipboard.



This is the Calculate Statistics Icon. Selecting this will calculate the statistics for the currently selected Logger Data Set.



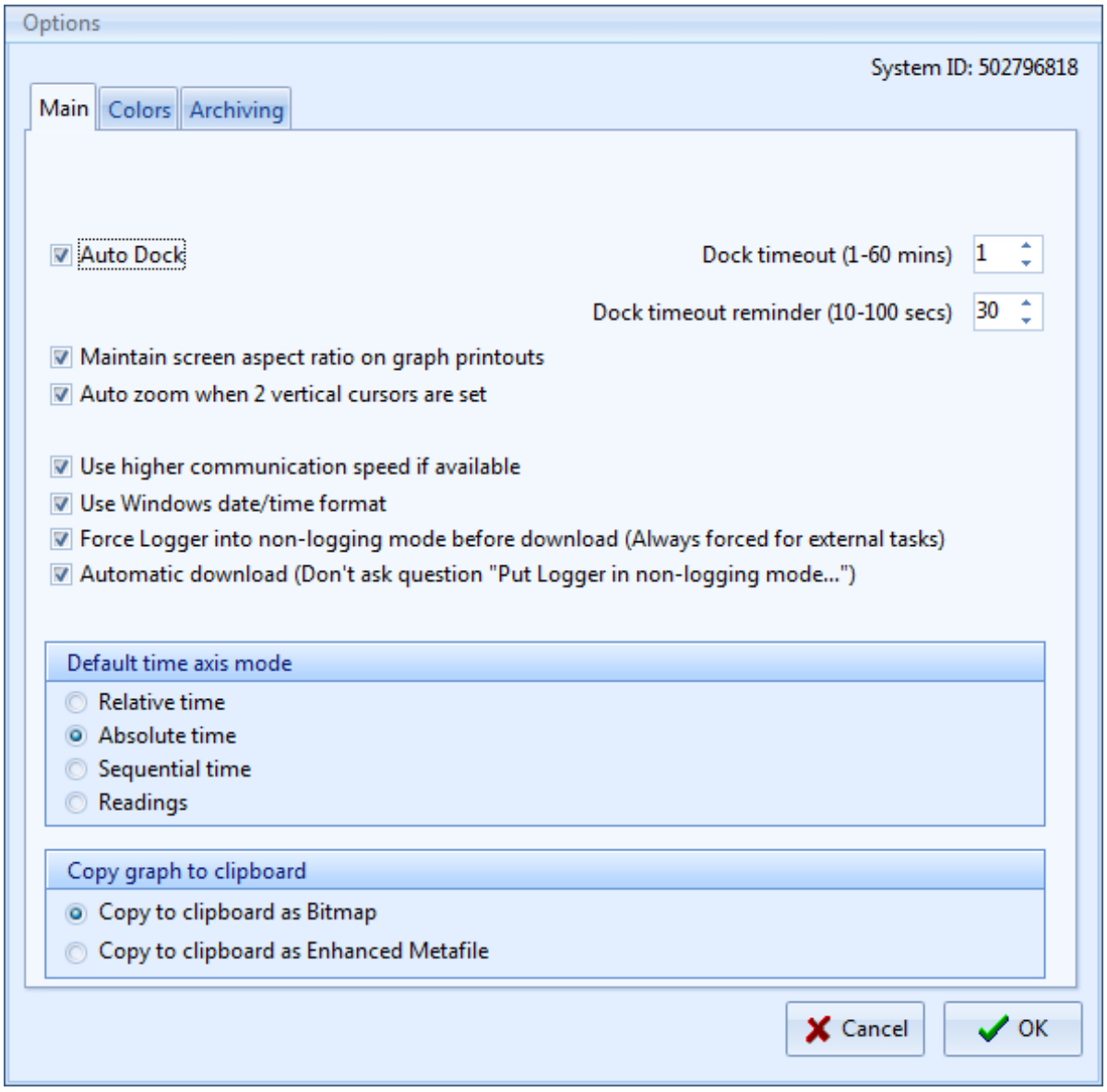
This is the User Guide Icon. Selecting this Icon will open this guide as a PDF.

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.

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.

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 Printing.

Auto Zoom

Using the Vertical Line function on the graph can enable automatic zooming to those settings when the mouse is released. See Graphing data.

Use higher Comms speed if available

This box should remain ticked for use with USB Dataloggers.

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.

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.

Automatic download (EV Pro Only)

This option is used in conjunction with 'Force logger into non-logging mode' see 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.

Default Time Axis Mode

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

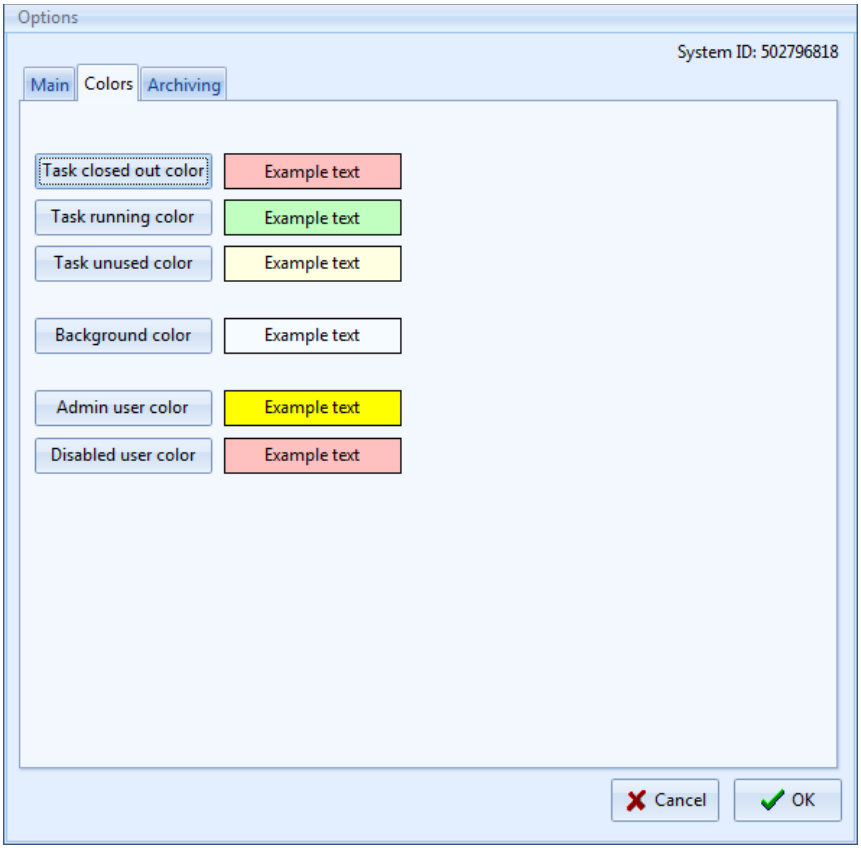
- Relative Time – All time bases will be referenced to 00:00:00
- Absolute Time – All the time bases will be drawn on a real time scale.
- Sequential Time – All the time bases will be drawn one after the other.
- Readings – All graphs will be drawn referenced to the number of readings starting from zero each time.

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).

Colours

Select Colours from the tab at the top of the screen to reveal the selection of colours available, see below.



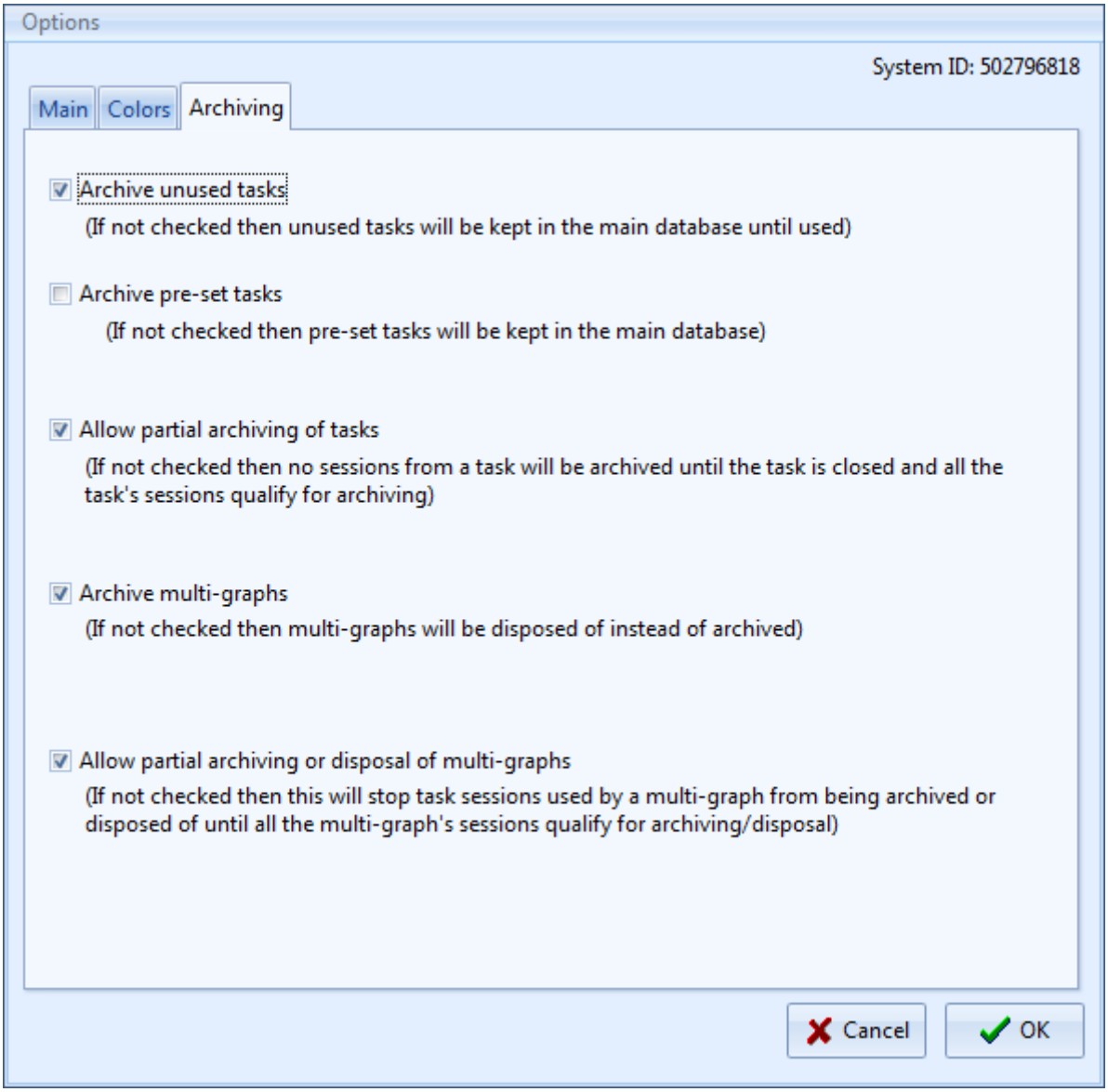
Here it is possible to set the colours for the features as described above. These colours are freely selectable. Simply select one of the tabs in the left column and choose another colour. The selection will be saved on exit from the program.

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.

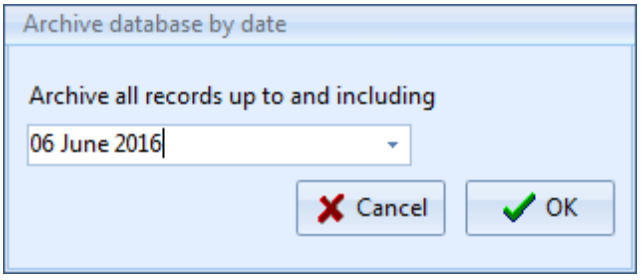
Note: If using EV PRO then the requirements of 21 CFR Part 11 will require the User to Electronically Sign any unsigned data in the database before it can be archived. Refer to Signing Tasks for more details.

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:

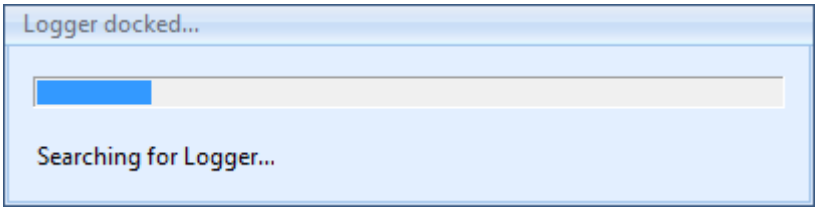


To change the date select the 'Date' Icon and choose another date. When the date has been selected click on OK to complete the archive process. Note: This process may take a few minutes depending on the size of the archive file.

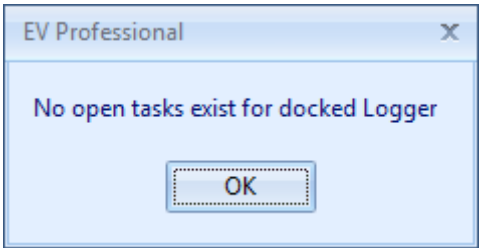
Introducing a logger for the 1st time

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. The EV software will now interrogate the logger.



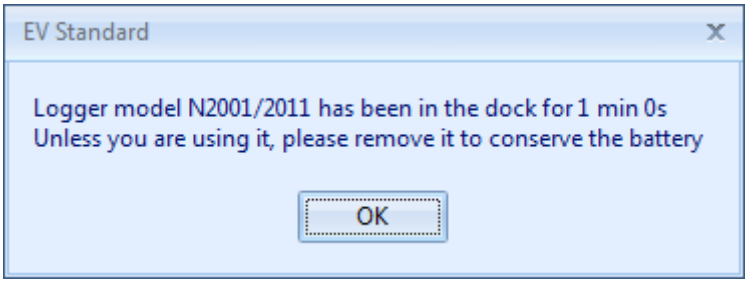
The EV software will then return an information message as follows:



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:



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 N2011 logger is now known to the software and tasks for it can be generated.

Note – A logger must be introduced to the software before a Task can be written.

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 below.

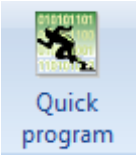
Writing tasks for EV loggers

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.

Quick Program



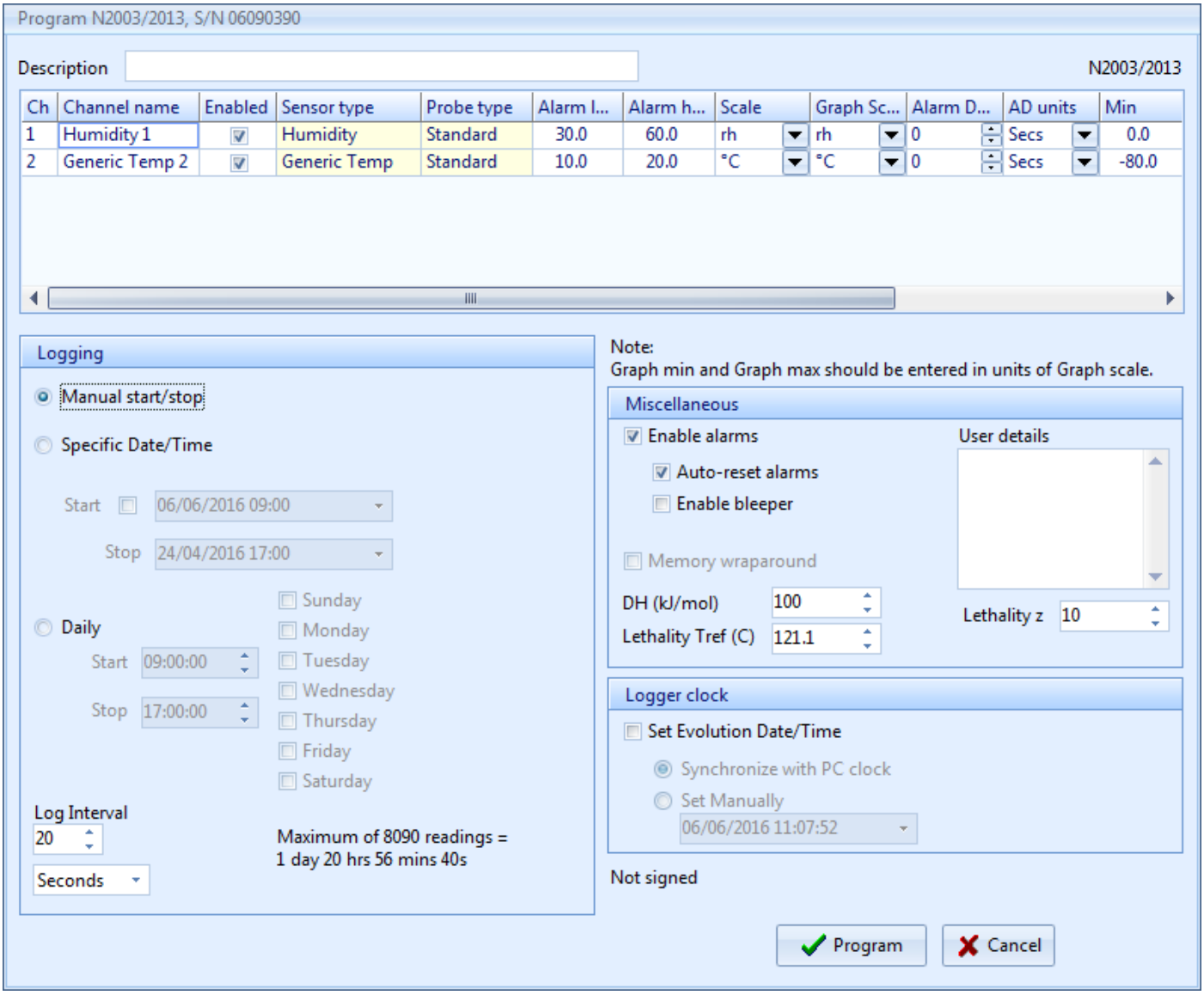
Quick program is used when a logger is in the interface and is active and a task is required quickly.

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.

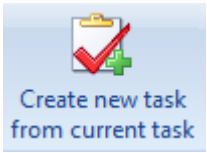
Press the quick program Icon and the software will display a new task applicable to the logger in the dock. See below:



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.

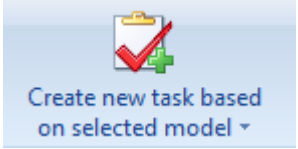
Refer to Completing the task form, see below, for more details on completing the task.

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.

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.

Completing the task form

The task form has four areas, Description and General Setup, Logging Setup, miscellaneous and Logging Clock. 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.

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.

Logging Setup

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

Manual Start/Stop

In this mode all EV loggers (except Evt 2) can be started and stopped any number of times whilst. 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.

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!

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.

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.

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 seconds, minutes, or hours.

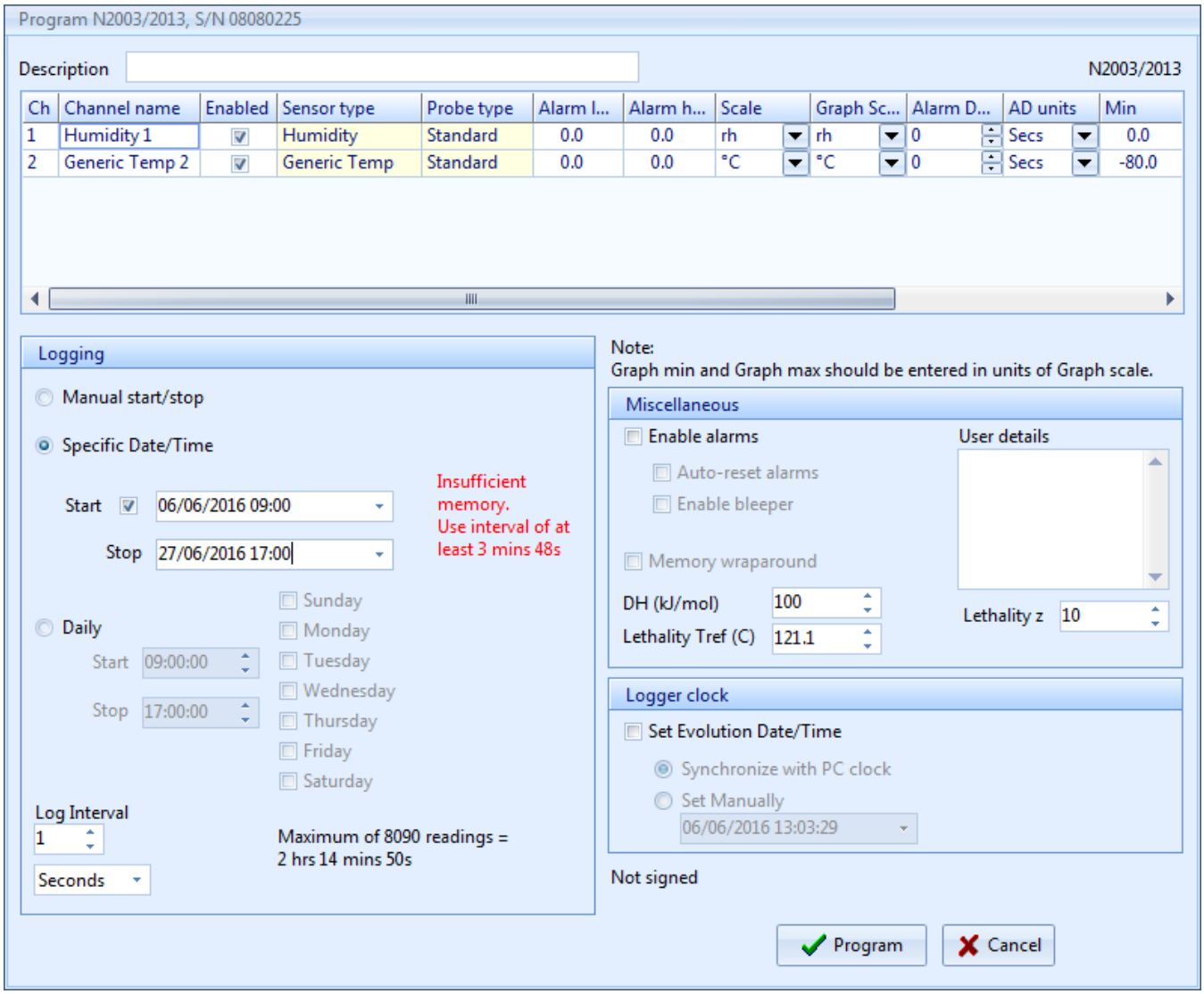
Log Interval

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

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 21 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 21 days we must set an interval to the nearest minute, in this case 4 minutes would suffice.



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.

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.

Memory Wraparound (Not EVt or EV Pro)

In this mode the logger will log indefinitely until the logger runs flat or is downloaded.

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.

Mean Kinetic Temperature and Pasteurisation (EV Pro Only)

Please refer to Mean Kinetic Temperature for more information.

Logging Clock

The Logging Clock section simply allows for the Clock to be set synchronized to the PC Clock or manually set.

Programming tasks to Loggers

Once a task is written and 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.

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.

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 (All other models)

Logging Modes

Manual Start/Stop Modes EV and EVt

When a logger has been set for manual start then the logger display 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.

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.

Automatic Start/Stop Modes EV and EVt

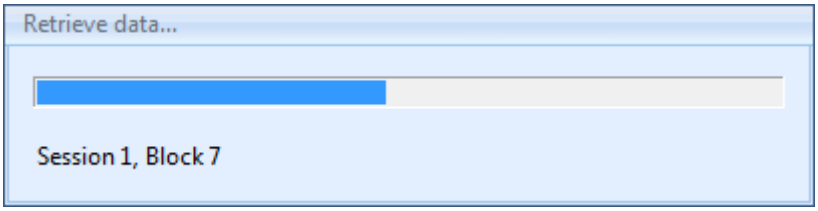
In the event that either the start and stop are pre-programmed or that automatic end is programmed then no further input from the user is required. Simply place the logger where it is to finally log temperature and leave it.

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.

Note: If the Data Logger is not recognised by the software then try pressing the button again to re-activate the logger. If that does not work then click on Auto-Dock to force communications to start.

Automatic Time-Zone Correction

The Data Loggers employ Time-Zone Correction when they are downloaded. This means that the date and time of all data records are adjusted to the Local Time at the point the data is retrieved from the Data Logger to the PC. Therefore if you send loggers across several time-zones, for example transport, then the data will be time and date corrected for the receiver of the Data Logger. It is important however, that a PC used to download the data is programmed with the correct date and time and of course the correct Time-Zone.

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 refer to section Appendix 2 - Title 21 CFR Part 11 for more information.

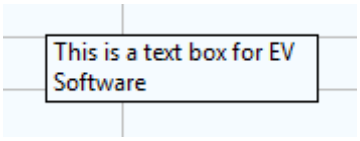
Graphing Data

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

Adding Annotations

From the toolbar for graphing select 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.



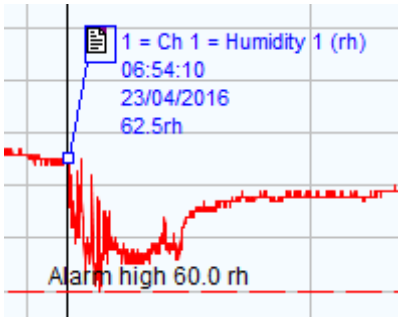
By double clicking on the text box it will become active for editing again. Select all the text then 'A' in the toolbar to change the font type, size and colour, select the colour box below 'A' to select the background colour for the text box. Use the justification icons to align the text to the left, 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.

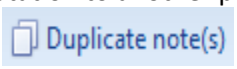
In the example below the text box above has been fixed to channel 2, a line has been drawn to a point on channel 2 and the text box has been converted to an Icon.



In the above example this ICON style can be achieved by the following method:

- Select the text box.
- Select Fixed to Channel 1.
- 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.

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.

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

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.

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 Software Setup Options, then the graph will automatically re-draw to the new values.

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.

Un-zoom

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

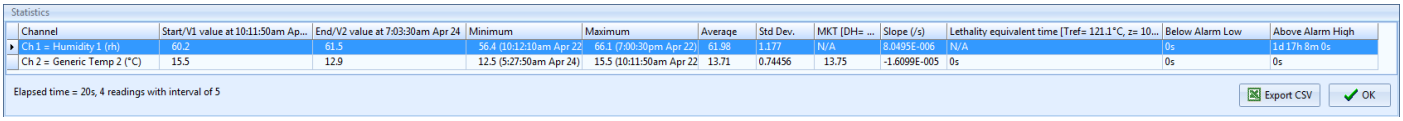
Zoom and Calculations

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

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:



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.

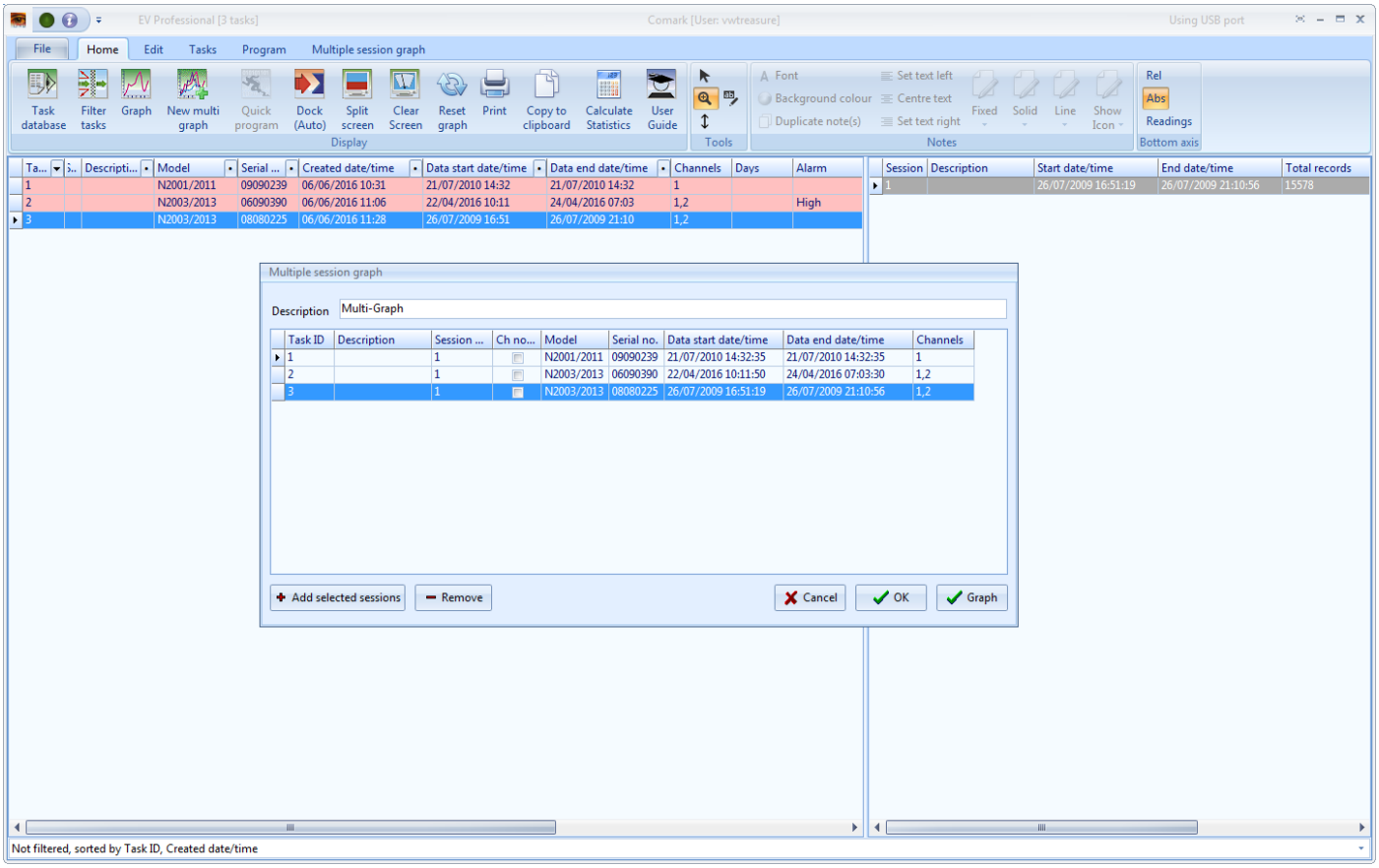
These readings can now be exported to a CSV file for report generation or printing.

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.

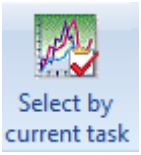
Select the Multi-graph Icon and the following screen will be displayed:



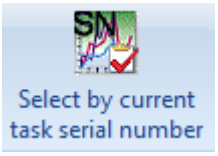
See EVSW Database for an explanation of the task database view.

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.

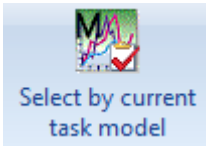
To view old multi-graphs select ‘Multiple session graph’ then either;



Select multi graph by Task… and the software will display a list of Multi-Graphs containing this Task



Select multi graph by serial number…and the software will display a list of Multi-Graphs containing the logger with the current serial number.

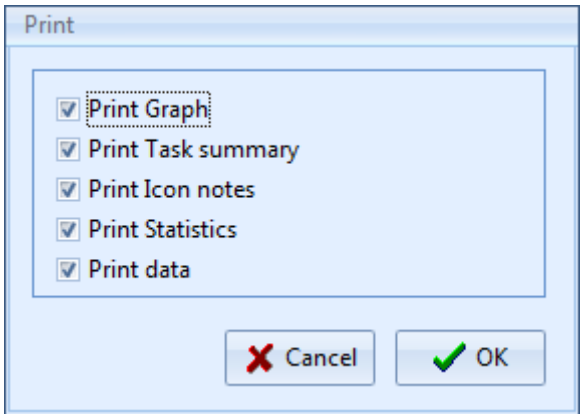


Select multi graph by model…and the software will display a list of Multi-Graphs containing this logger type.

Show last multi graph to display the last Multi-Graph.

Printing

Data from the graph can be printed in a number of ways. From the graph select the print 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, see section Software Setup Options.

EVSW Database

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 a single 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.

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 cannot 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 affect 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.

Task Useful Information

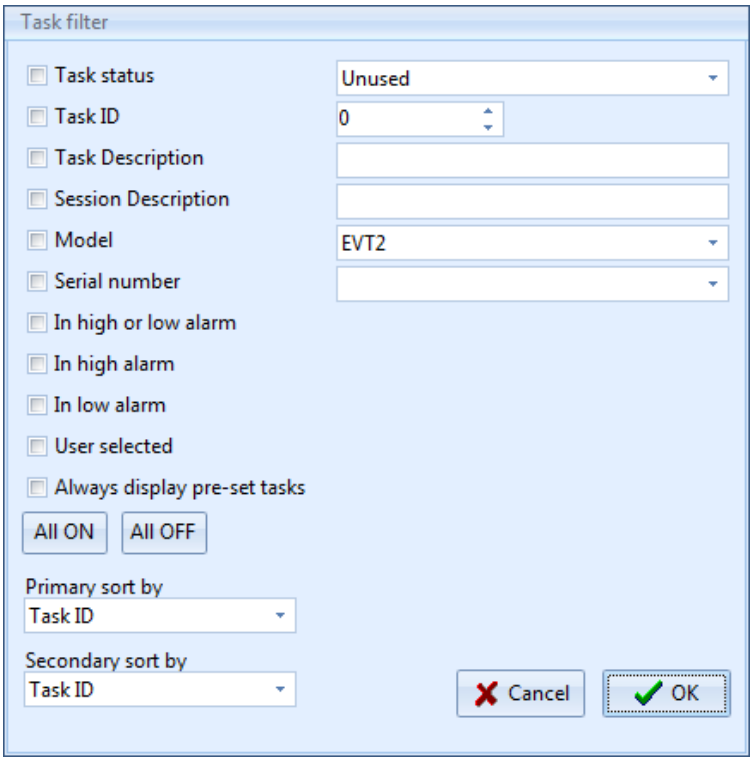
The tasks include useful summary information about the data after it has been downloaded. This information includes:

- 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.

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.

Task Status
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.

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.

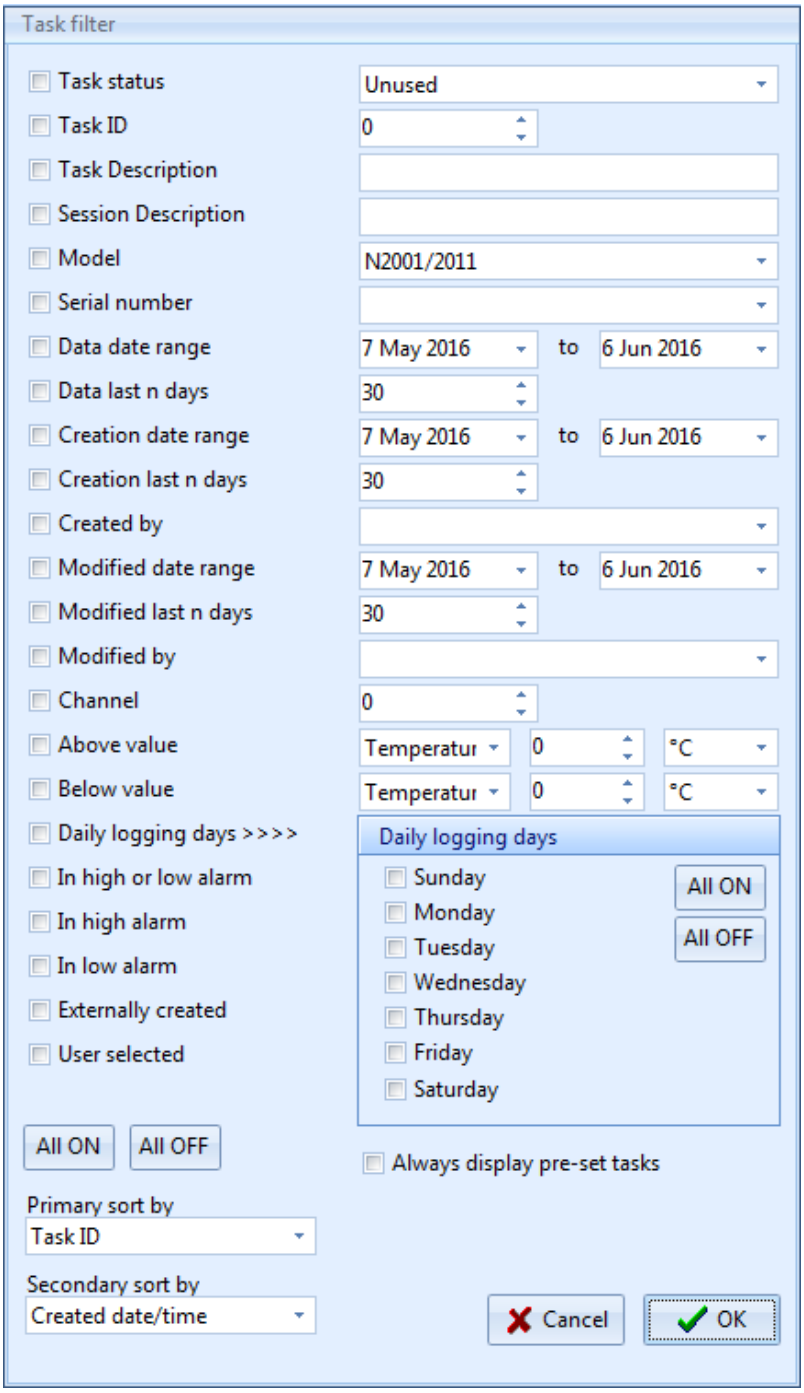
Always Display pre-set Tasks
If Ticked then the Database view will be filtered to the Tasks Manually Ticked as ‘pre-set’.

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

Filtering Tasks EVSW PRO



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 to 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;

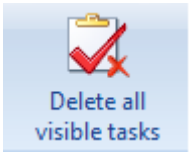
- Task ID
- Task Description
- Generic Model
- Serial No
- Date start date/time
- Date end date/time

General Task Management

There are a number of Task functions available to the user as part of the management of the database.

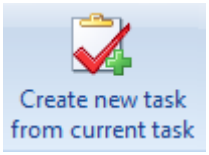
Delete Tasks

Delete All Visible Unused Tasks – Any visible task, after task filtering, that has not been used to collect any data can be deleted.

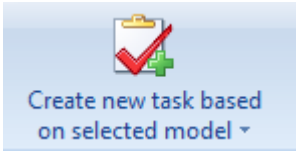


Delete All Visible Tasks – Standard Software Only – Any visible task, after task filtering can be deleted.

Create New Tasks

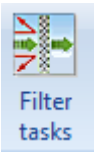


Create New Task from Current Task – Create a new task from the current selected task, the current settings will be duplicated.

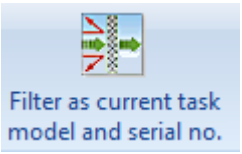


Create New Task based on selected model – Create a new blank task for a specific Logger Model, select from list.

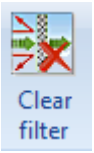
Filter Tasks



Filter Task – Brings up the current Task Filter, see Filtering Tasks EVSW or Filtering Tasks EVSWPRO



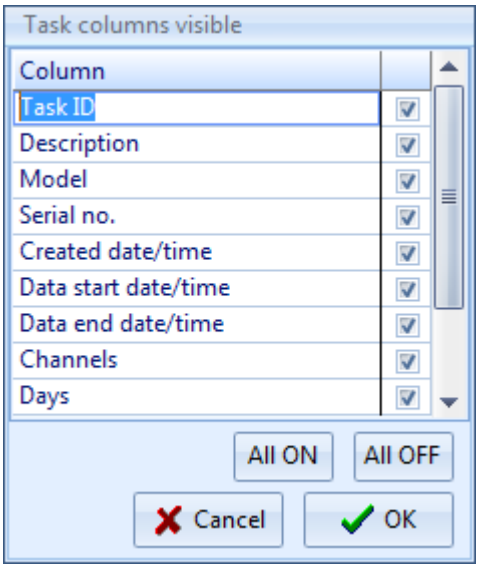
Filter as current task model and serial no – Filter by current selected model and serial number to see all tasks for this specific logger



Clear Filter – Clear filter to return to un-filtered database

Editing Visible Task Columns

Selecting Editing Visible Task Columns brings up this Window…

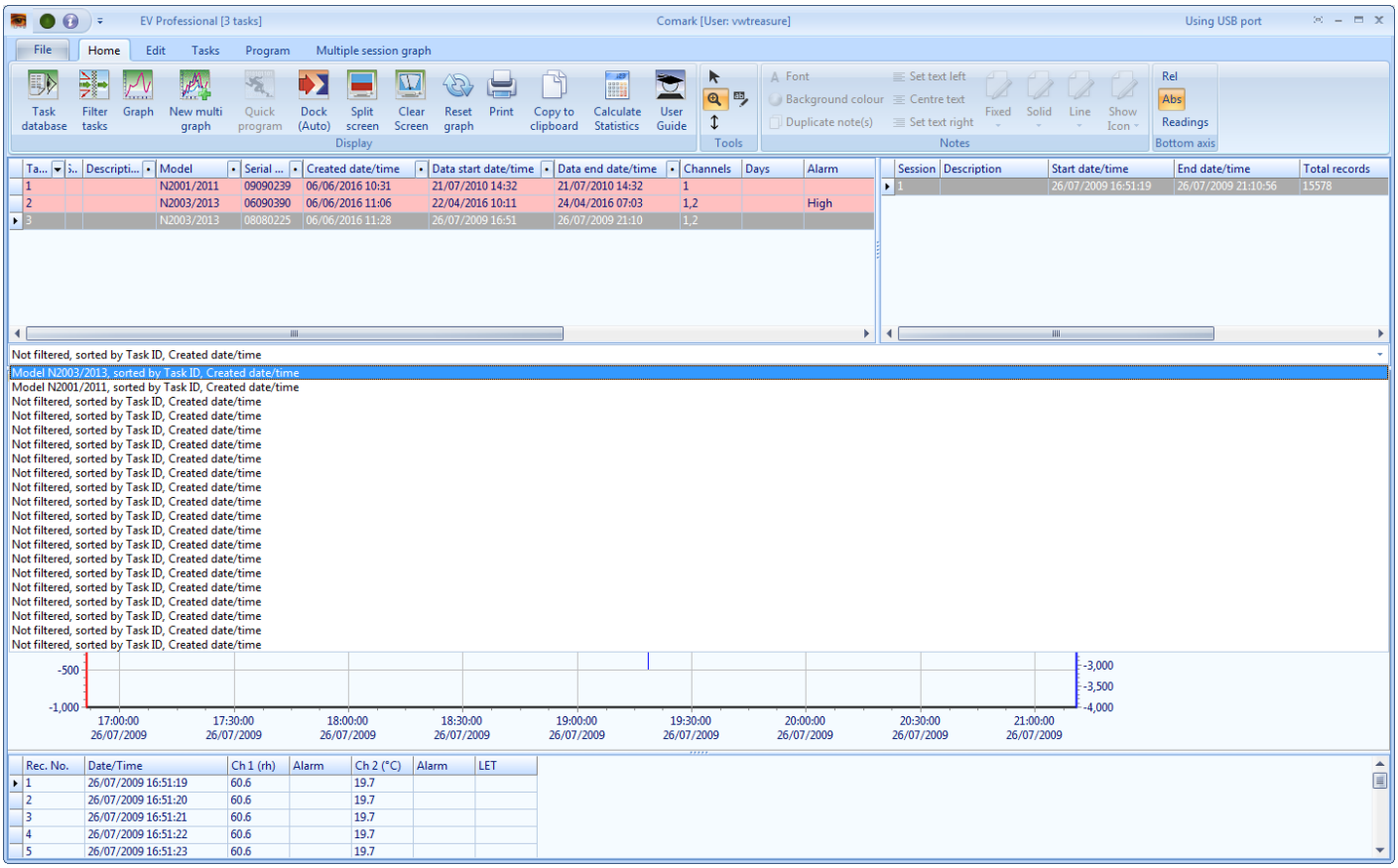


Here you can remove columns that you do not use. Make your selection and then click OK to confirm.

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:



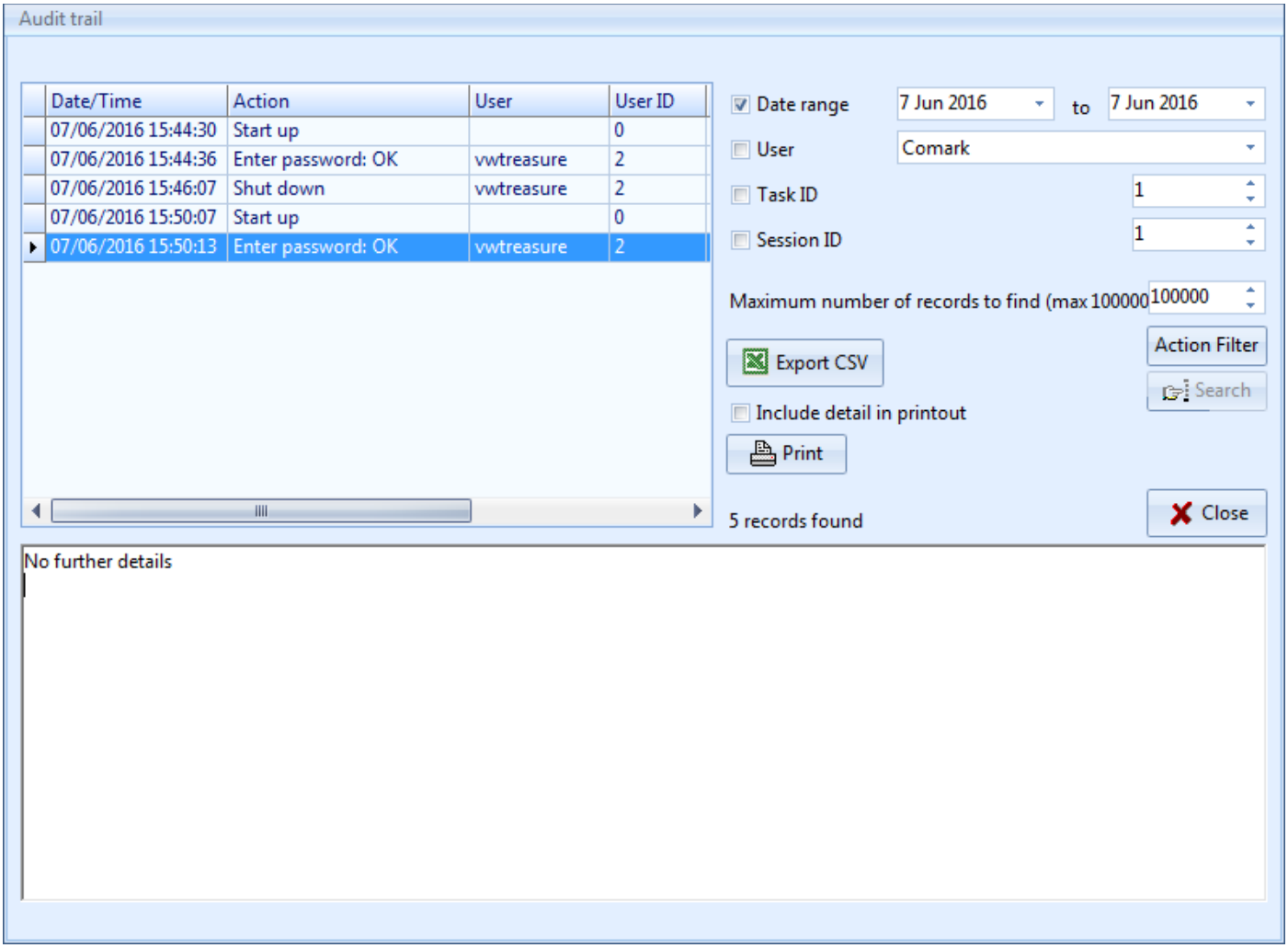
It is possible therefore to set up a number of favourite filters which can then be re-called at any time without the need to set them up again.

Audit Trail EVSW PRO Only

The EVSW PRO software has an Audit Trail in order to be compliant with 21 CFR part 11. This section explains how to access and use the Audit Trail.

Open Audit Trail

Select File-View-Print Audit Trail and the Audit Trail Window will open.



There are a number of useful tools here:

Top left of the Window will be the Audit Trail for today, showing all Software activity for today.

If there are any additional details pertaining to the action recorded these will appear in the Window below.

Across to the right hand side of the Window there are other Filter Options…

- Date Range – Select to and from Dates to display
- User – Tick the Box and then select the User results you want to view
- Task ID – Tick the box and then select the Task ID that you are interested in
- Session ID – Tick the box and then select the Session ID that you are interested in

If you wish to restrict the maximum number of records to be displayed, please use the drop down.

Select the Action Filter to filter the results by Action

When ready Click on Search to filter the Audit Trail as per your settings.

It is possible at this point to export the Audit Trail to a CSV file for reporting and it is possible also to Print the Audit Trail if necessary, with or without the details.

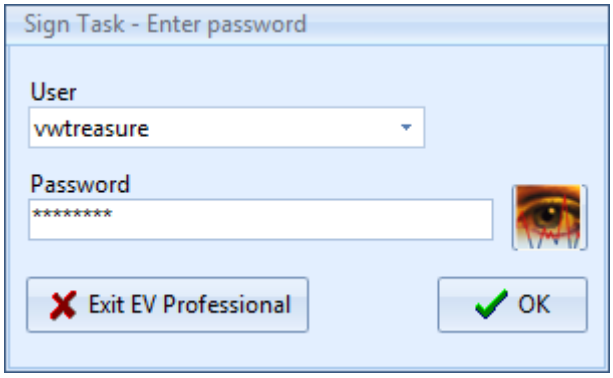
When you are finished simple press Close to exit.

The Audit Trail is updated whenever you complete actions in the software, such as programming Data Loggers. It is not possible to edit or alter the records in the Audit Trail.

Signing Tasks – EVSW PRO Only

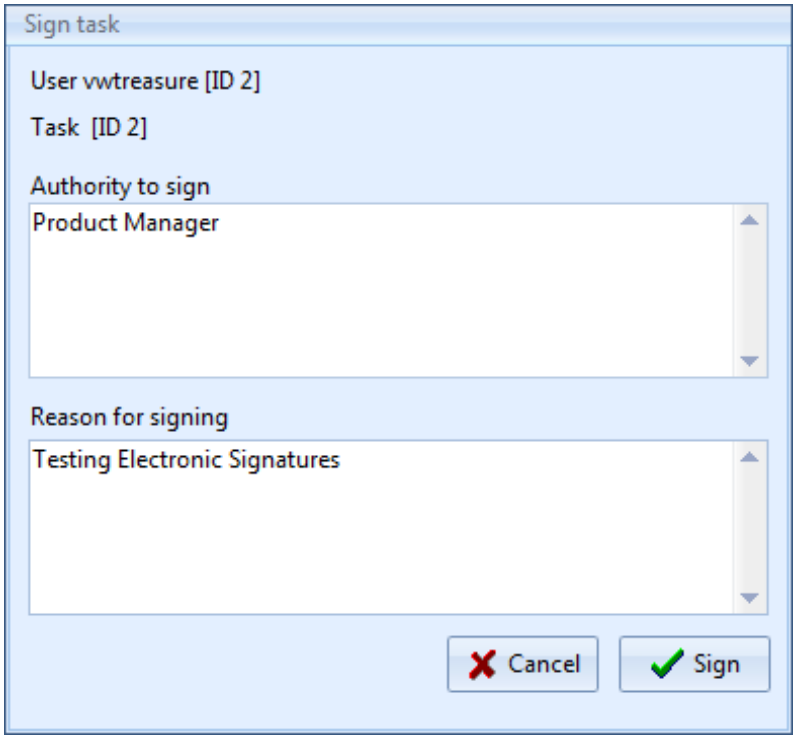
When a Task is complete and data recorded, it is possible to Sign that Data for record purposes and to confirm that the data is true.

Signing Data is a straightforward process. Simply select the Task you wish to Sign (Tasks along with all Session Data will be signed together. It is not possible to sign off one single session), then select Tasks-Sign Task to bring up this screen….



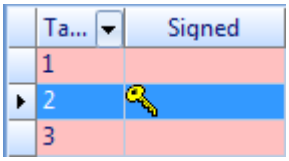
Enter your password and Click OK to continue.

You must now provide your Authority for Signing Data and the reason for signing the data….



Click Sign to complete the process.

Once signed the Task will have a Key Symbol in the Signed Column of the Database.



Appendix 1 - 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 Graphing Data.

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 sub-stance 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'.

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.

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.

Appendix 2 - Title 21 CFR Part 11

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.

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 is 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 is on the system.

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.

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.

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.

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.

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.

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 lose their compatibility with the Standard version and older versions of Evolution software where applicable.

Appendix 3 - EV and EV Pro Differences

The EV and EV Pro software have been developed in conjunction with several leading pharmaceutical companies to reflect their needs with the 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.

Appendix 4 – 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)

Appendix 5 IP67 and EN 12830

IP67

IP67 means that the instrument after submersion in water at a depth of 1m at a temperature within 5°C of that of the instrument for a duration of 30 minutes, shall suffer only limited ingress. If any ingress occurs it shall not cause the instrument to operate incorrectly or to become unsafe.

Comark tests all products rated to IP67 for no ingress.

BS EN12830

The EVt2 and N2011 Data Loggers have been improved in response to European Standard EN12830:2002. The standard dictates that all temperature monitoring instruments used in the transport, warehousing and storage of Quick Frozen Foodstuffs comply and furthermore, documents must be kept to prove that the instruments comply.

If you work in this industry and have to comply with this standard than EVt2 and N2011 can form part of your daily management procedures.

Appendix 6 – Evt2 Data Logger LCD Enunciators

The LCD on the EVt2 Data logger includes the following Enunciators.

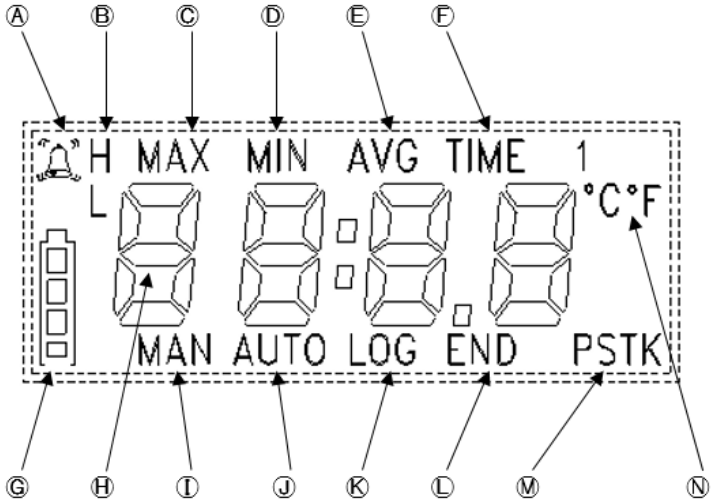


Fig 1 Datalogger LCD

Ⓐ Alarm Indication.
Ⓑ H for High Alarm. L for Low Alarm
Ⓒ Indicates MAXimum recorded temperature
Ⓓ Indicates MINimum recorded temperature
Ⓔ Indicates AVErage recorded temperature
Ⓕ Indicates current TIME
Ⓖ Indicates battery status
Ⓗ 4-Digit display for Temperature/Time
Ⓘ Indicates ready for MANual start
Ⓙ Indicates ready for AUTO Start
Ⓚ Indicates LOGging in progress
Ⓛ Indicates LOGging finished
Ⓜ Indicates the Sensor Type in use
Ⓝ Indicates current scale

Appendix 7 – N2000 Data Logger LCD Enunciators

The LCD on the N2000 Data loggers includes the following Enunciators.

Note: Note all enunciators will be available on all versions of the Loggers.

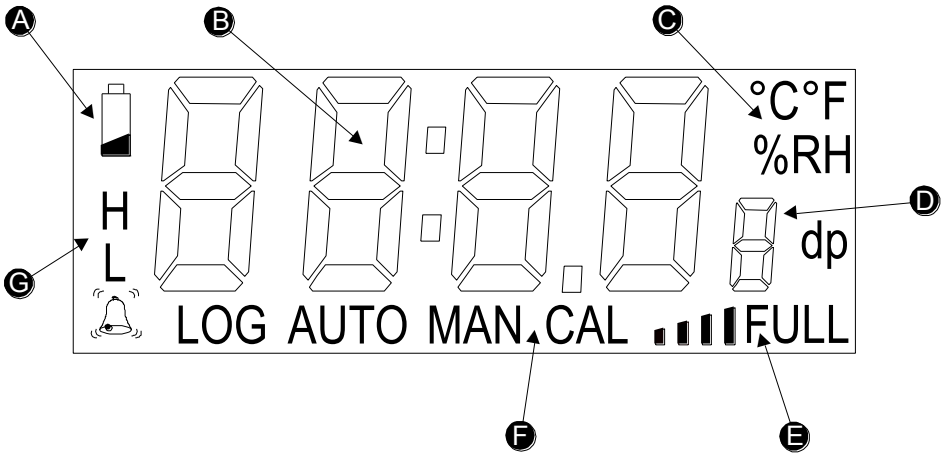


Fig 1. N2000 Data Logger LCD

The following items appear on the display:

Ⓐ Low Battery Symbol
Ⓑ 4 Digit readings area/Time display
Ⓒ Scales °C/°F/%RH/dp
Ⓓ Channel number display
Ⓔ Indicates AVErage recorded temperature
Ⓕ LOG Indicates logging active
AUTO Indicates dated logging start
MAN Indicates manual logging start
CAL Indicates calibration due
Ⓖ Alarm Status display

Appendix 8 – Specifications

Sensor Type

Temperature

EVt2/N2011/N2012/N2013	Thermistor
N2014	Thermocouple

Humidity

N2013	Capacitive Polymer

Other parameters

N2015	4-20mA Current

Measurement Range

EVt2		-30°C to 70°C (-22°F to 158°F)
N2011		-40°C/-40°F to +70°C/+158°F
N2012	Internal sensor	-40°C/-40°F to +70°C/+158°F
	External Sensor	-40°C/-40°F to +150°C/+302°F
N2013	Temperature	-20°C/-4°F to +60°C/+140°F
	Humidity	0 to 97% RH non condensing
N2014	External T Sensor	-200°C/-328°F to +400°C/+752°F
	External K Sensor	-200°C/-328°F to +1372°C/+2500°F
	Ambient Sensor	-40°C/-40°F to +70°C/+158°F
N2015		3.9mA to 20.1mA

Displayable Scales

Temperature	°C or °F
Humidity	%rh or dew point

Display Resolution

(EVt2, N2011, N2012, N2013)	
Temperature	0.1°
Humidity	0.1% rh

System Accuracy (N2011, N2012, N2013)

Temperature	-25°C/-13°F to +50°C/+122°F±0.5°C/1°F
	-40°C/-40°F to +80°C/+176°F±1°C/2°F
	-40°C/-40°F to +150°C/+302°F ±2°C/4°F (typical)
Humidity	-20°C/-4°F to +60°C/+140°F ±3% RH

Resolution (N2014)

Ambient Sensor	0.1°
Thermocouple	0.2°C/0.5°F (-200°C/-328°F to +300°C/+572°F)
	0.5°C/1°F (Above 300°C/572°F)

Accuracy (N2014)

Ambient +20°C/68°F	± (0.5°C/0.9°F + 0.3% Reading)
Ambient –20°C/-4°F to 40°C/104°F	± (0.5°C/0.9°F + 0.5% Reading)
Ambient –40°C/°F to 70°C/158°F	± (1°C/1.8°F + 1% Reading)

Ambient (CJC)

–20°C/-4°F to 40°C/104°F	± 0.3°C/0.6°F
–40°C/-40°F to 70°C/158°F	± 0.5°C/0.9°F

Accuracy (N2015)

Ambient 20°C/68°F	+/-0.3% of Full Scale
Ambient -40°C/°F to 70°C/158°F	+/-0.5% of Full Scale

Display Resolution (N2015) 0 or 1dp

Logging Memory Capacity

1 channel	3000 Samples (Evt2)
	16,181 samples (N2011)
2 channels	8,090 samples
3 channels	5,393 samples
4 channels	4,045 samples
5 channels	3,236 samples

Communications via infra-red interface

Logging Frequency Programmable between 1 second and 99 hours

Internal Sensor Response Time T_{90} =15 to 30 minutes in ambient air

Ambient Storage -40°C/-40°F to +70°C/+158°F

Battery	1 x AA size 3.6V replaceable lithium battery (Customer replaceable) ½ x AA size 3.6V replaceable lithium battery (non-replaceable)
Battery Life	Up to 2 years (EVt2) and up to 5 Years (N2000) (1 reading every 15 minutes at 20°C ambient with alarms off)
Case Material	N2000 – ABS EVt2 – Over-moulded Polycarbonate
Environmental Protection	IP67, EN60529, IEC529
Other Certifications	
EVt2 and N2011	Certified to meet Transport Standard EN 12830:1999
LED Indication	Red = alarm, green = logger active
Dimensions	L 88mm (including fixing lug) W 80mm D 35mm
Weights	
EVt2	77g/2.73 oz
N2011	103gms/ 3.6oz
N2012	119gms/ 4.2oz
N2013	117gms/ 4.1oz
N2014	119gms/ 4.2oz
N2015	119gms/ 4.2oz

Appendix 8 –Wiring N2015

The Diligence EV N2015 allows monitoring and logging of the loop current in a 4-20mA system. The unit does not provide loop power and is intended for wiring into an existing transmitter circuit. The N2015 socket accepts a Lumberg SV60 locking plug. A pre-wired plug with wire tails is supplied to facilitate wiring into the current loop. The red wire is positive, white is negative.

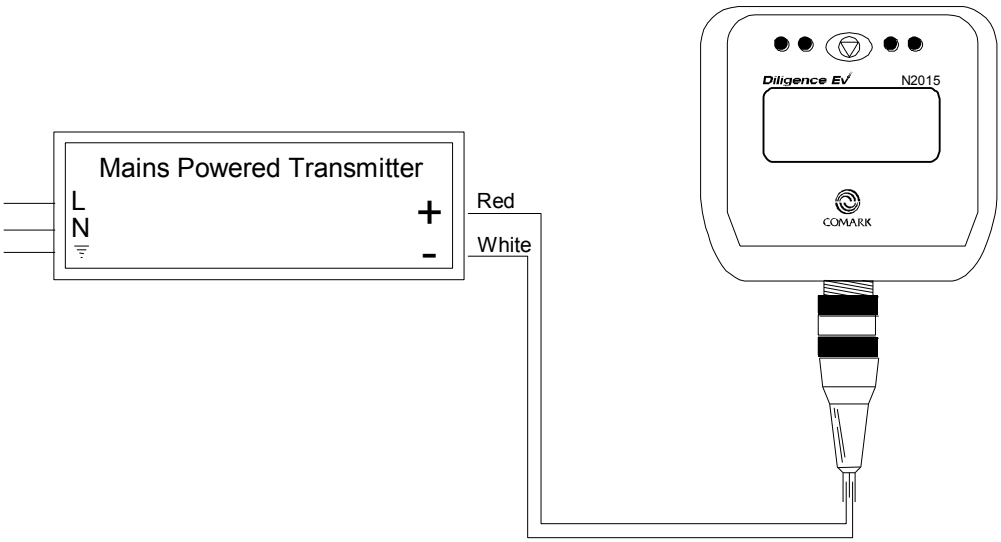


Fig 1. Example Wiring

The pin-out is given below if the user wishes to make his own connector arrangement.

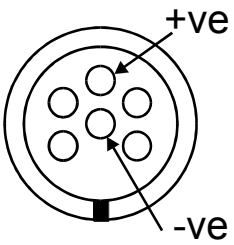


Fig 2. Connector Pin-out

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