Operation Manual English
Basic

1. Contents

In the interest of our customers we reserve the right to make any changes resulting from technical advances. Therefore, schemes, descriptions and extent of delivery are subject to change without notice!
This manual is valid as from software release 3.3x

The following pages have intentionally been left blank:

5.3 Menu Overview

5.3.1 „File" Menu

• **Readout Datalogger**
The datalogger data will be read. You may enter a file description, but you don't have to.

• **Read Status**
Reads the datalogger status. It will be directly displayed on screen.

• **Data read with auto-save mode**
The datalogger data will be read and automatically stored in the predefined target directory.

• **Open**
Opens an MDF file. It does not matter whether that file has been created by "elproLOG" under DOS or under Windows.

• **Save**
The current graph is saved under the file name displayed. If the graph has not yet been assigned a name, "Save As" is called automatically.
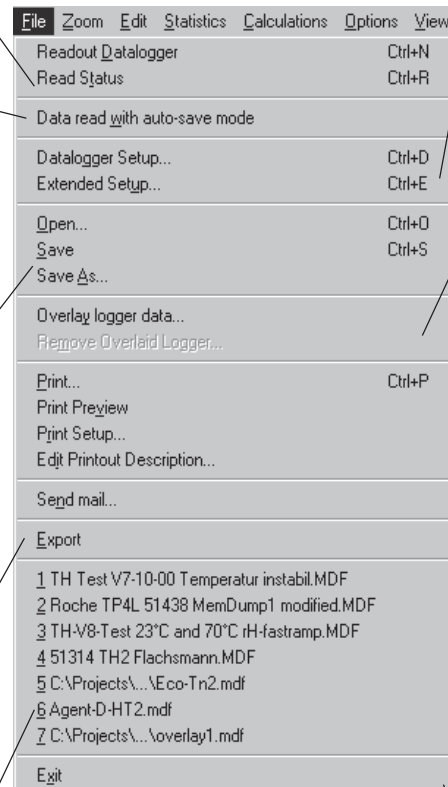
• **Save As**
You have to give the current graph a file name. For a better overview of saved data it is also possible to set individual paths. The default setting is defined under the properties of the start icon.

• **Export**
The data can be exported with a different format. Warning! It may be that not all data will be exported. (See "Options", "Format for Data Export..." or chapter 5.7.3).

• **1 TH Test V7-10-00....**
The files last called are listed here. They are quicker to load this way.

File | Zoom | Edit | Statistics | Calculations | Options | View

Readout Datalogger   Ctrl+N
Read Status   Ctrl+R

Data read with auto-save mode

Datalogger Setup...   Ctrl+D
Extended Setup...   Ctrl+E

Open...   Ctrl+O
Save   Ctrl+S
Save As...

Overlay logger data...
Remove Overlaid Logger...

Print...   Ctrl+P
Print Preview
Print Setup...
Edit Printout Description...

Send mail...

Export

1 TH Test V7-10-00 Temperatur instabil.MDF
2 Roche TP4L 51438 MemDump1 modified.MDF
3 TH-V8-Test 23°C and 70°C rH-fastramp.MDF
4 51314 TH2 Flachsmann.MDF
5 C:\Projects\...\Eco-Tn2.mdf
6 Agent-D-HT2.mdf
7 C:\Projects\...\overlay1.mdf

Exit

• **Datalogger Setup**
Measuring range, logging period, logging mode etc. can be set. (Chapter 5.8.1)

• **Extended Setup**
With some modules, this menu can be used to re-calibrate the sensor or carry out other module-specific adjustments. (Chapter 5.8.2)

• **Overlay logger data**
A master can be superimposed with up to 6 loggers. A maximum of 16 sensors can be displayed. (Chapter 5.5.10)

• **Remove Overlaid Logger**
Data already superimposed can be removed selectively. (Chapter 5.5.10)

• **Print**
The current screen display is printed. See chapter 5.6 for information on formatting the hardcopy.

• **Print Preview**
You get a preview of the page to be printed.

• **Printer Setup**
Depending on your printer, you may set the print mode (fast, normal, best quality), paper format, etc.

• **Edit Printout Description**
Use this menu item to edit the information printed on your hardcopy.

• **Send mail**
This function allows to send measurement data as emails.

• **Exit**
Correct termination of the program.

5.3.2 „Zoom" Menu

• Window
The mouse pointer changes to a red crosshair which you can use to select the start of the desired zoom area with a click. Then you drag the red rectangle until you have marked the desired section. The lower right corner is set with another click (left mouse button).The selected rectangle is now enlarged to screen size. For zooming at the page border it is advisable to start outside the data area and then select the desired window size.

• Skip forward
Shows next time period to the right.

• Skip backward
Show next time period to the left.

• Previous zoom
The window is displayed as it wasbefore the last zoom instructio

• Full range
The axes are set to the pre-set range (see "File", "Set Datalogger").

• Extended range
The axes are adjusted to the whole measuring range of the sensors.
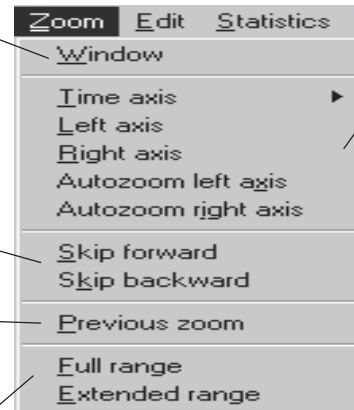
• Time Axis
If you click on this menu, you get the following selection:
  Hour
  Day
  Week
  Month
You can select the desired setting for the time axis (horizontal axis) with a mouse-click. To do this, select the desired range, e.g. 1 or 2 or 3 hours by dragging the borders. Then double-click with the magnifying glass into the area to be zoomed, and it is extended.

• Left Axis
The left axis can be extended manually independently of the time axis.

• Right Axis
As above, for the right axis.

• Autozoom left axis
The left axis is automatically set so that the readings of the left axis fill the displayed range optimally.

• Autozoom right axis
As above, for the right axis.

5.3.3 „Edit" Menu

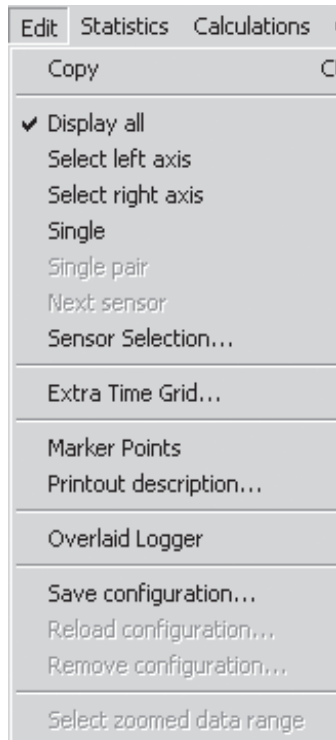| Edit	Statistics	Calculations
Copy		C
✔ Display all		
Select left axis		
Select right axis		
Single		
Single pair		
Next sensor		
Sensor Selection…		
Extra Time Grid…		
Marker Points		
Printout description…		
Overlaid Logger		
Save configuration…		
Reload configuration…		
Remove configuration…		
Select zoomed data range		

- **Copy:** a) Graph: an optimized copy of the screen graph is copied to the clipboard.
  b) Table: the marked table contents are copied to the clipboard.
- **Display all:** With this instruction, all graphs of the different sensors are visible again (standard).
- **Select left axis:** Only the graphs assigned to the left axis are displayed.
- **Select right axis:** Only the graphs assigned to the right axis are displayed.
- **Single:** Only the currently selected graph is displayed.
- **Single pair:** The graphs of one sensor pair are displayed (e.g. temperature and humidity).
- **Next sensor:** In single graph mode, the next graph is displayed on screen.
- **Sensor Selection:** In this window you may mark the sensors which should be drawn in the line chart.
- **Extra Time Grid:** A menu for the selection of the interval for additional time grid lines (X-axis) shows up.
- **Marker Points:** If you select this item, you get the following sub-menu:
  Set Marker Point
  Set Marker Point by Date / Time
  Delete Marker Point
  Delete All Marker Points

"Set Marker Point" changes the mouse pointer to a crosshair you use to click on the point to be marked. Then you get a circle containing the label. Place it at the desired position with a mouse-click. A message in the cursor display shows if you have "hit" a line.

"Delete Marker Point" lets you select individual points. With "OK", these points are deleted.

"Delete All Marker Points" deletes all set marker points.

- **Printout description:** A description is added to each document printed out. (see also chapter 5.6.3)
- **Overlaid Logger:** You can find a detailed description of this function in chapter 5.5.9.
- **Save configuration:** Saves the current graph settings (zoom, marker points,...).
- **Reload configuration:** Restores a saved configuration.
- **Remove configuration:** Deletes a selected configuration.
- **Select zoomed data range:** The marked data block corresponds to the current line chart.
  This function is only in the "View table" mode active.

5.3.4 „Statistics" Menu

Statistics
Histogram
Statistical data

- **Histogram**
The histogram is calculated and displayed from the reading currently displayed in the diagram. The number of readings contained in the classes are written on the bars.
- **Statistical data**
The following values are calculated from the readings currently displayed in the diagram:
> Mean value
> Variance
> Standard deviation
> Lowest/highest value
> Time: value > Max
> Time: value < Min
> Time: outside Min/Max
> Time: within Min/Max
> Range

These values are separately calculated and displayed for each sensor.

5.3.5 „Calculations" Menu

Calculations Options
F-Value
Dew Point

Calculate MKT...
Calculate ageing...
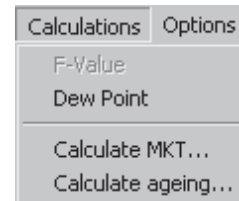
- **F-Value**
This value is used in cooking, pasteurizing and sterilizing procedures in connection with food. It is used to optimize cooking damage and the termination of bacteria in these processes.
F-value: heating effect
Further information can be found in specific technical literature.
- **Dew Point**
A new temperature curve is generated. This curve can be used to find the temperature at which precipitation takes place. Calculation is based on relative humidity and the corresponding temperature.
- **Calculate MKT**
Stability calculation for temperature sensitive products. The required parameters are defined in the „Define MKT" window (see also chapter 5.5.8).
- **Calculate Ageing**
Stability calculation for temperature sensitive products. The required parameters are defined in the „Define Ageing" window (see also chapter 5.5.9).
See also: http//www.pharmj.com/pdf/articles/pj_20010728_mca.pdf

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5.3.6 „Options" Menu

• **Define Min/Max**
It is possible to define minima and maxima for each Y axis. The set values can be made visible in the diagram with "On", line or hatching display being available. You can choose whether the Min/Max limits shall always be used for calculation or only when they are displayed on screen.

• **Define F-Values**
More detailed information can be found in chapter 5.5.8.

• **Humidity**
- Dew Point: You can assign dew point temperatures to a separate axis.
- Temperature compensations: Setting for the temperature compensation of the rH measurement.

• **Histogram**
Here you can set the parameters, i.e. delta and fixed point or automatic class formation for class size in the histogram. You can choose whether the Min/Max limits shall be used for calculating the histogram.
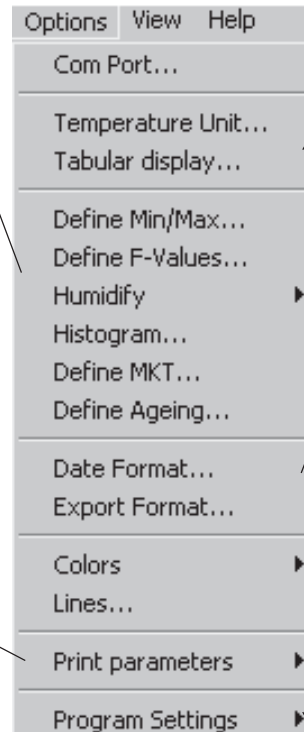
• **Define MKT; Define Ageing**
See chapter 5.3.5

• **Print Parameters**
You get a dialogue window in which you can make the following adjustments:
- Page Mode: You select between "Use whole page" and "Use half page". The half page will be printed much faster!
- Color Mode: "Convert to B/W" converts the colors to black-and-white. "Normal" prints colors if you have a color printer, and gray scales if you do not have a color printer.
- Orientation: You select between "Portrait" and "Landscape".
- Logo File: Use this command to select the logo file that shall be printed on all print outs. For more information see chapter 5.6.5 please.

Options   View   Help

Com Port…

Temperature Unit…
Tabular display…

Define Min/Max…
Define F-Values…
Humidify   ▶
Histogram…
Define MKT…
Define Ageing…

Date Format…
Export Format…

Colors   ▶
Lines…

Print parameters   ▶

Program Settings   ▶

• **Com Port**
You get a sub-menu in which you can set the parameters for data transfer from the interface or logger to your PC. For more detailed information see chapter 5.2.2 and 5.9.

• **Temperature Unit**
You can choose between °C or °F.

• **Tabular display**
normal: Normal scrollbar function
special: Allows besides the normal scrollbar function, to scroll page by page or to jump to the start or the end of the table

• **Date Format**
The date format can be selected, too. The default setting is DD.MM.YYYY.5.3.7 „View" Menu

• **Export Format**
More detailed information can be found in chapter 5.7.3.

• **Colors**
You get the following sub-menu:
- Line Colors: You can select the colors for the first 5 lines. "Default" sets the default colors. However, by clicking of the corresponding curve number, you can define the color yourself.
- Min/Max Colors: As under Line Colors, you can set the colors for the hatching of areas outside the Min/Max limits. Select your colors for the left and right y-axis.
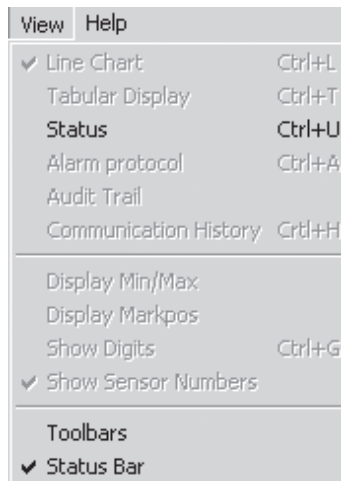- Color assignment: You can choose between if the color assignment should depend on the overlaid logger or not.

• **Lines**
More detailed information can be found in chapter 5.7.3.

• **Program Settings**
Opens a window to select a new work directory.

5.3.7 „View" Menu

View Help
✓ Line Chart   Ctrl+L
Tabular Display   Ctrl+T
Status   Ctrl+U
Alarm protocol   Ctrl+A
Audit Trail
Communication History Crtl+H
Display Min/Max
Display Markpos
Show Digits   Ctrl+G
✓ Show Sensor Numbers
Toolbars
✓ Status Bar

• **Line Chart**
The curves are displayed on screen.
• **Tabular Display**
The readings are displayed on screen
as a table.
• **Status**
The datalogger's status is displayed.
• **Alarm protocol**
The ECOLOG or HOTBOX SE alarm
protocl is displayed.
• **Audit Trail**
Not active in the standard version of
elproLOG.
• **Communication History**
The status of the last data transfer is
displayed.
• **Display Min/Max**
The Min/Max ranges are displayed as
lines or hatched, depending on what has
been selected.
• **Display Markpos**
Magnetic markings with HOTBOX Bx
dataloggers are displayed.
• **Show Digits**
Shows digits instead of real values at
cursor position.
• **Show Sensor Numbers**
Show or hide the sensor number within
the line chart.
• **Toolbars**
The symbol bars with the buttons are
displayed or not displayed.
• **Status Bar**
The status strip with the information
whether "Num Lock", Caps Lock" or
"Scroll Lock" are activated is displayed
or not displayed.

5.3.8 „Help" Menu

| Help |
| --- |
| Help Topics |
| Using Help |
| |
| About... |
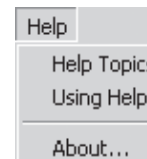
• **Help Topics**
Calls "elproLOG" Help. This online help is a valuable
supplement to this manual.
• **Using Help**
Calls Windows Help on the operation of HELP functions.
• **About**
Displays information on the "elproLOG" program used.
Here you can check which version of the program you
are using.
**The address of your ELPRO representative is also
displayed.**

5.4 Reading Module Data

• In the "File" menu you can find the instruction "**Readout Datalogger**". The program now reads the saved information from your datalogger (readings and status). You get the following window:
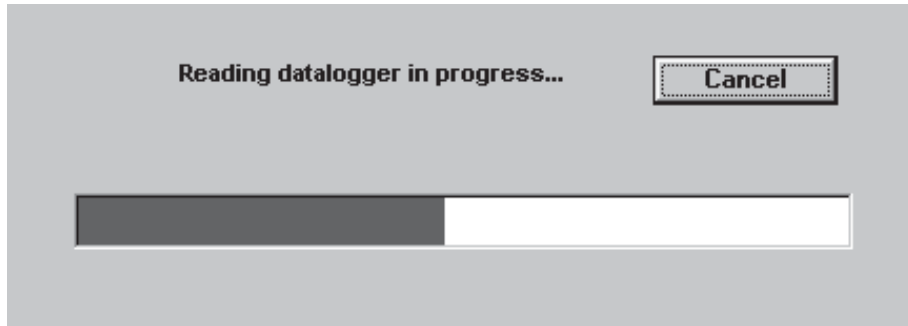
Should you have selected the reduced display, a static display is shown instead of the progress bar. After the data have been read, you may enter a description for the data. Note that this is not the file name. This information line is saved as evaluation info when the file is saved.
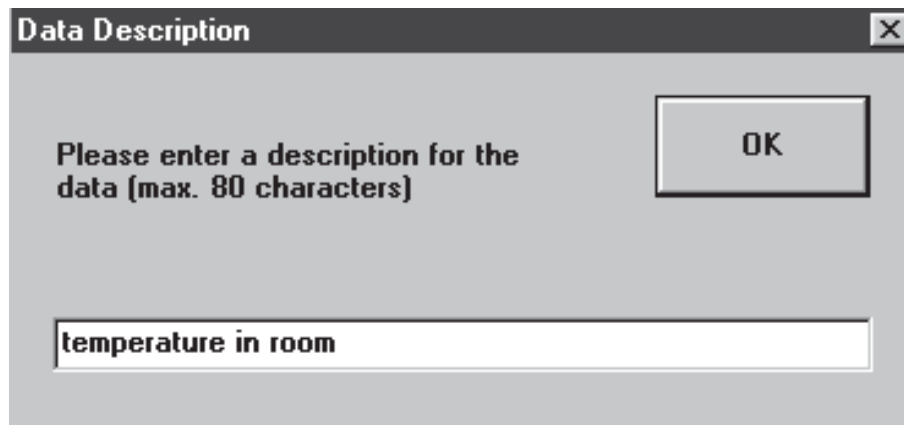
• In the „File" menu you can find the instruction „**Read Status**". Only the datalogger status is read and displayed. The readings are not read and are not available.

• You can also **load an existing graph.** To do this, select the item "Open" in the "File" menu. You get a window with all files that exist in the displayed directory. The drive and directory can be changed. The selected file is read to memory and displayed on screen.

• When reading a HOTBOX EURO with extended memory, another window appears during reading that asks you to select the **desired data block**. Mark the desired data block and click on OK to have it read.

• The read data are displayed as readings in accordance with axis scaling. The following data field codes are possible:

• UNDEF   The value has not yet been written after the adjustment of settings

• N.C.   "Not connected"; no (working) sensor is connected.

• S.C.   "Short-cut"; a short-cut has been recorded.

• <MIN   The measured values are not in accordance with possible
• >MAX   scaling (sensors effective or incorrect).

• #+1234 "Digits" display has been selected under "View"

5.5 Evaluation of Data

5.5.1 Different Displays (Overview)

The way data are displayed can be selected in the "View" menu. You may also use the buttons of the symbol bar for selecting graph, table or status display.

• **Graph**

The Min/Max values can be displayed and the functions available in the "Edit" menu can be selected.

Furthermore, individual readings can be directly selected with the freely movable cursor. To do this, "hold" the red cursor line with the mouse (holding down the left mouse button) and move the line by moving the mouse. You can also touch the point to be investigated with the arrow point and press the left mouse button. The cursor line will jump to your arrow point.

Although working with the mouse is quicker, precise targeting is better done with the keyboard. The cursor line can be moved by pressing the cursor keys "[‹-]" and "[-›]". The keys "[PgUp]" and [PgDn]" can be used to set the step size when jumping between readings (when moving the cursor line). With the keys „[Home]" and „[End]" it is possible to move the cursor line to the left or right hand side of the line chart. With the key „[Delete]" you may hide the cursor line and its numerical display. The left mouse button may be used to show the cursor line.

Individually marked points are shown this way.

Current value display of freely movable cursor.
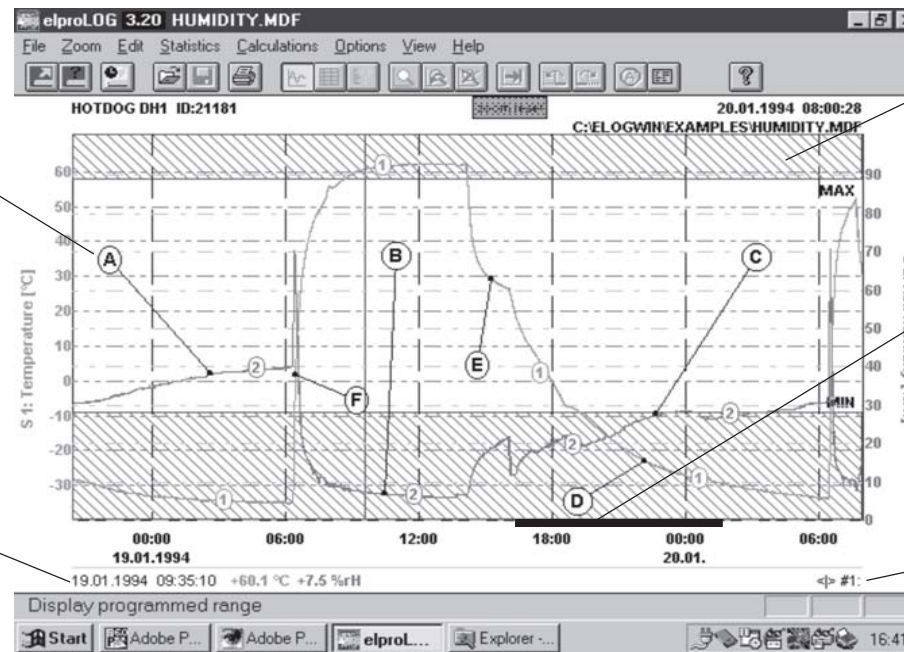
Min/Max hatching with labelling

The baseline contains the InPos markings of HOTDOG and HAMSTER and the D1/D2 markings of the HOTBOX EURO and ECOLOG.

The MarkPos of HOTBOX Bx modules generates a vertical red line in the curve.

Step size of jumps between values when moving the cursor (can be set with PgUp and PgDn keys).

• Table

The readings are displayed as a table. The table may be exported and copied, the format can be defined. (For details see chapter 5.7.3)

Click on the right-hand buttons to scroll.

• To the first reading	• Jump by one reading towards last reading
• Page-wise jump towards beginning of measurement	• Page-wise jump towards end of measurement
• Jump by reading towards first reading	• To the last reading

The readings are highlighted by clicking on the first index of the value to be highlighted and dragging the mouse downwards on the indices until the last value to be highlighted. The whole table can be highlighted by clicking on the left upper button on the table.

Or you may automatically take over the graphically displayed area as highlighted. The color of the readings indicates exceeding of the Min/Max limits. The info line displays the status of the digital inputs.

• Status

The current settings of the logger are displayed. The include:
- Master data (serial number, module type and first start-up)
- Programmed settings: measuring mode etc.
- Programming information
- Current status:
  - waiting for metering start (only START-STOP Mode)
  - logging in progress
  - metering terminated
  - calibration status etc.
  - battery status (ECOLOG and HOTBOX SE)
  - Event protocol (ECOLOG and HOTBOX SE)

• Alarm Protocol (ECOLOG and HOTBOX SE)

The last couple of measurement values and the duration of limit value violations are displayed.

• Communication History
The current status of the last connection with the logger is displayed. It contains the following items:
- Type of protocol
- Transmission settings (wake-up try, wake-up status, base type received etc.)
- Module-specific settings
- Interface settings
- Error messages

The illustration below shows an example.
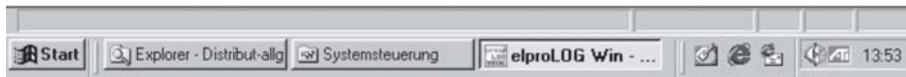
• Full Page View
With the exception of the table, all selected screen displays can be viewed as they would be printed. The print format view can be viewed in the "File" menu by selecting "Full Page View".
For the graph, you get the following picture:

You may insert your own logo (see chapter. 5.6.5)
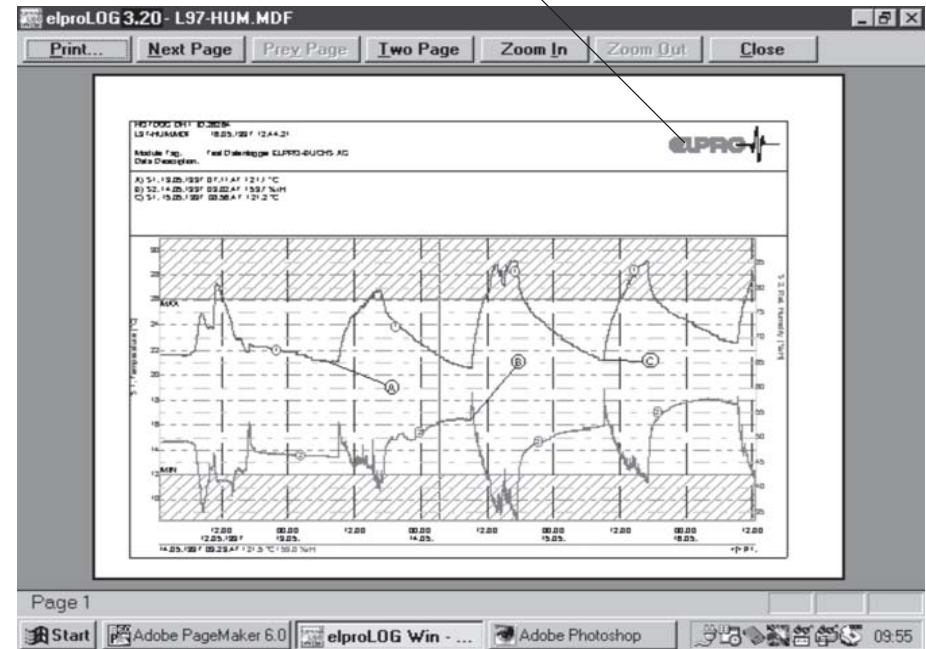
Using the magnifying glass or the menu item "Enlarge", you can enlarge the selected picture position step by step and reverse the process by using "Reduce".
"Close" takes you back to the normal screen view - or you "Print" that page.
More information on full page view is given in chapter 5.6 Printing.

5.5.2 Setting Marker Points

Particularly characteristic or meaningful values from your curve can be highlighted to be mark points.

Change to "Graph" view. In the "Edit" menu, you will find the item "Mark Points". Move the mouse pointer to this point an you will get the following sub-menu:
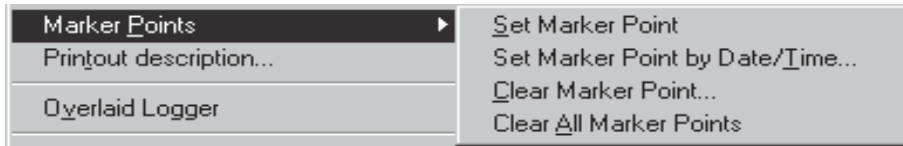
• Set Mark Point or Ⓐ

The mouse pointer changes into a crosshair. Click on the point of the curve to be marked. The cursor display will show whether you have hit a line. Place the labeling of the marked point on the graph. Mark points are automatically labeled with capital letters.

• Set Marker Point by Date/Time command

By using this command you may set up to marker points by typing in date and time (see C, D, E, F).

• Clear Mark Point

You get a window with all set mark points. Designate the mark points to be deleted by clicking on them and confirm with OK. Please note that you can delete and overwrite the data of mark points in the print info using the backspace key.

• Clear All Mark Points

All mark points are deleted.

• Graph with Mark Points
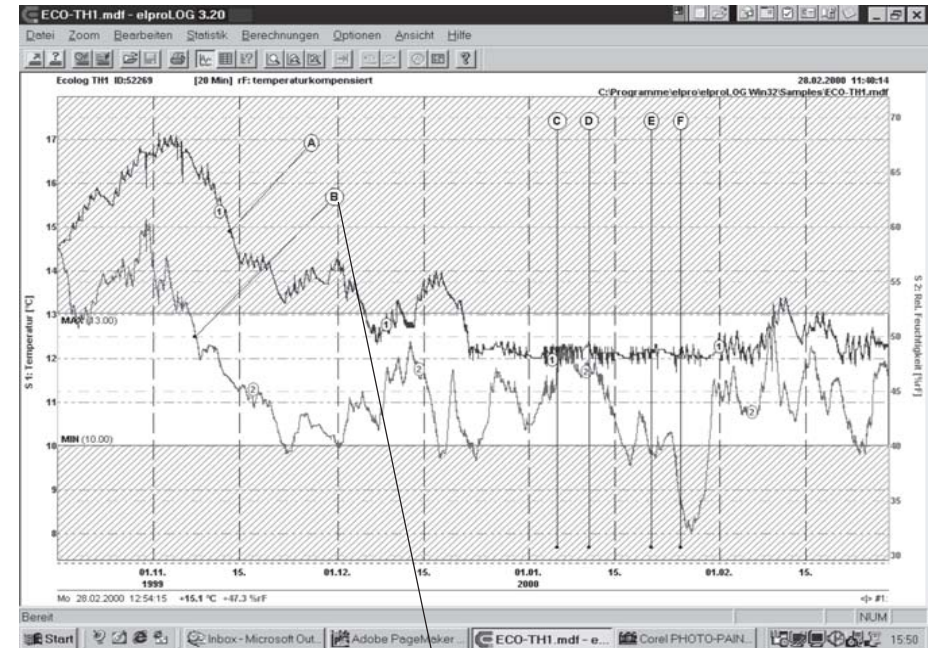
The legend to the mark points is automatically written into the print info, readings are only displayed if a line has been hit (see also 5.6.3).
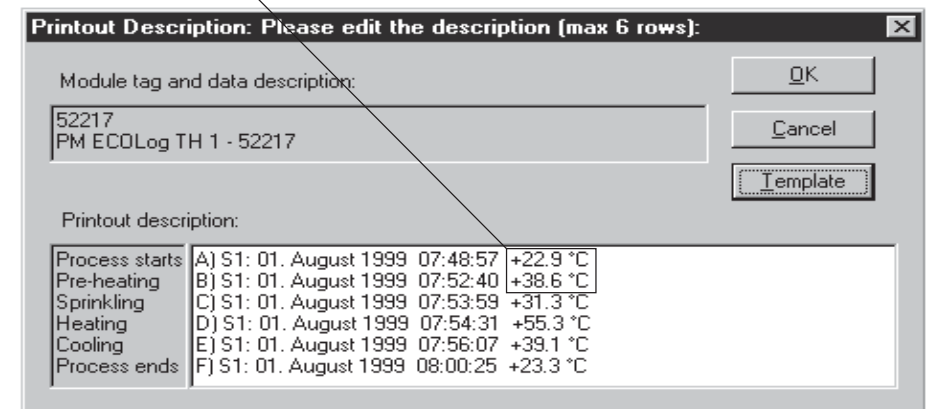
5.5.3 Minima and Maxima

It is possible to define and display upper and lower limits to your readings. You can see at a glance whether or not the readings exceed the range defined by you. The same limits apply to class formation in the histogram. Maxima and minima are used in the graph, in the histogram and in the statistics.

• Defining Min/Max
Select "Define Min/Max" from the "Options" menu. You get the following window:

"Left" and "right" refer to the axes in your graph.

Confirm with OK

Min/Max Settings

Global axis enable
☑ left   ☑ right

OK

Cancel

Limit settings
Logger alarm limits can be used as min/max limits if the logger has an alarm function. Limits can be loaded depending on the alarm function enable setting.

If a logger doesn't have an alarm function standard limits are always used.

☑ Use logger alarm limits as min/max limits

Alarm limit usage
◉ Use if logger alarm is selected
○ Use always

Standard Limits
	left	right
Max:	25	70
Min:	-2	12

Values for the Min/Max limits can be entered freely for each axis.

If this box is ticked (☑), the values are always taken into account in calculations. If not (☐), the limits are only calculated if the Min/Max lines are activated.

Calculation mode
☐ use always min/max limits

Draw mode
◉ Hatch
○ Line

Select display mode, either hatched area or just limit lines.

For more information about this particular window open the "Help-File - Option menu- Define Min/Max" or press key "F1". If you have already opened this window, just point with your mouse onto an interesting section of it and click the left mouse button to get more details.

• Display Min/Max Values
Select here whether only the Min/Max lines shall be shown, or whether the whole area outside the Min/Max limits shall be hatched.

• **Colors for Displaying the Min/Max Values in Diagrams**
The colors for the display can be set in the "Options" menu in item "Colors", "Min/Max Colors". You get the following window:

Min/Max Colors

Define the color for the min/max hatching for the left and the right axis.

left   OK

right   Cancel

set to default
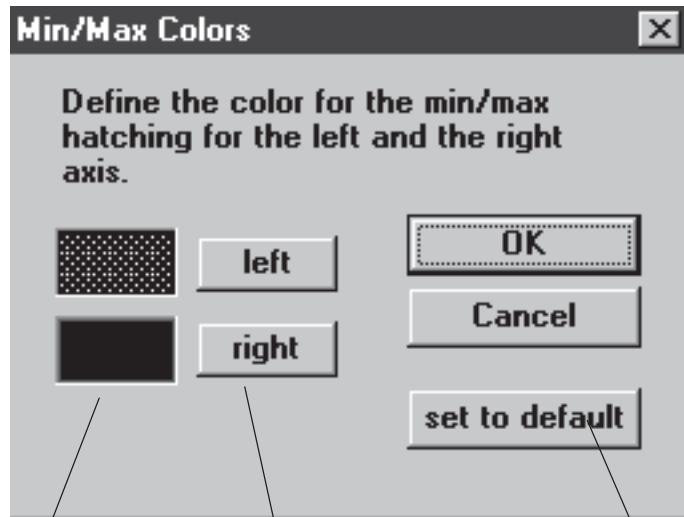
Current color setting

With a mouse-click you get the window shown to the right

The default colors are restored.

You can select the color for each axis individually. Click on either „left" or „right". You will get the „Color" window displayed to the right. Select your desired color by following the instructions below.
The "Default" button restores the default colors.

The colors in the "Basic Colors" area are standard. You can select any by clicking on it. You may also create your own colors. Click on "Define Colors". You get another window, in which you can mix your personal shades. This color appears in the area called "User-defined Colors". These, too, are selected with a mouse-click.

Color

Basic colors:
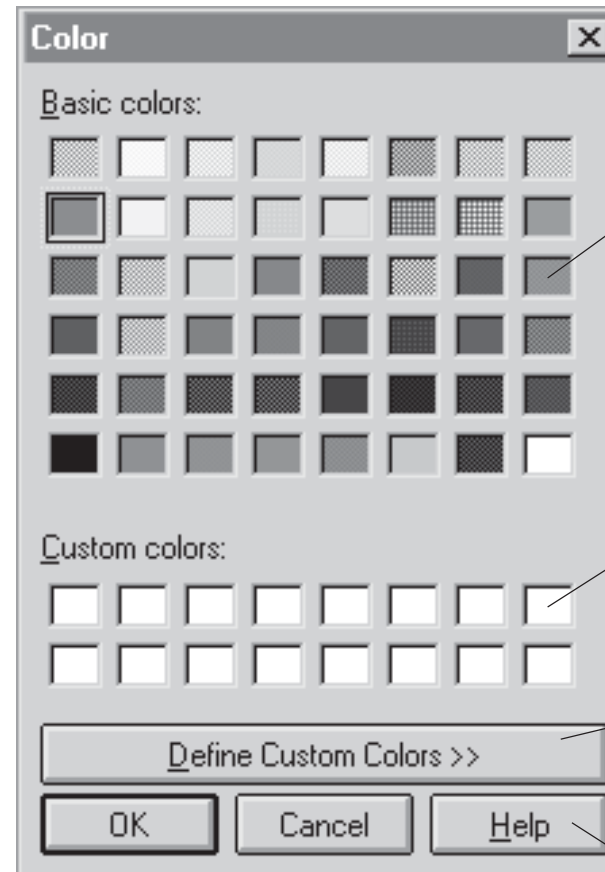
Mouse-click on the color to be selected

Custom colors:

Fields for user-defined colors

Define Custom Colors >>

Define your own colors

OK   Cancel   Help

Help for defining and selecting colors

5.5.4 Define Lines

• Line Colors
You can define the colors of the curves in the graphs yourself. Select "Colors" from the "Options" Menu, and then select "Curve Colors". You get the following window:
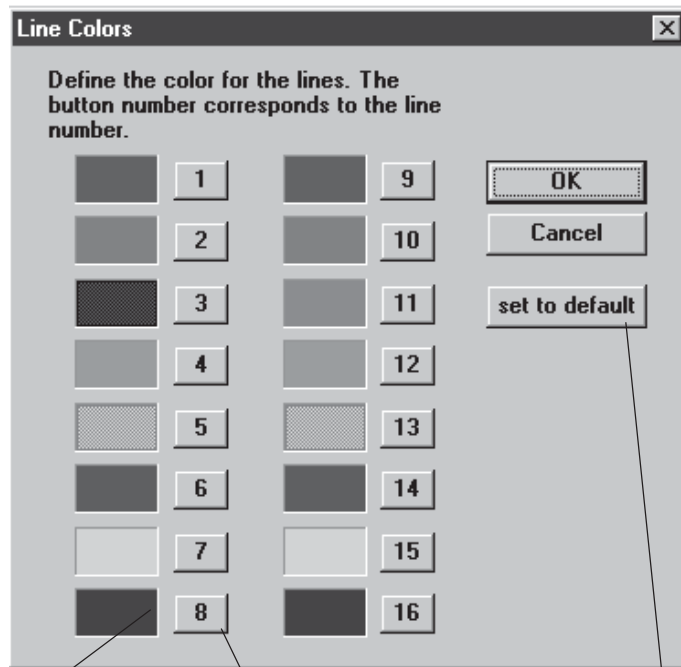
Current color settings

Curve number
You can select the color yourself with a mouse-click

Restores the default colors

For a more detailed description of the "Colors" window, see chapter 5.5.3 Minima and Maxima. You will get further information under the item • Colors for Displaying the Min/Max Values in Diagrams.

• Sensor Curves, Extra Time Grid, Grid Lines
With those 4 windows several settings with respect to the representation of axes, sensor- and grid lines are possible. For more information see the help-file please.
You will find these windows in menu point: „Option - Lines"
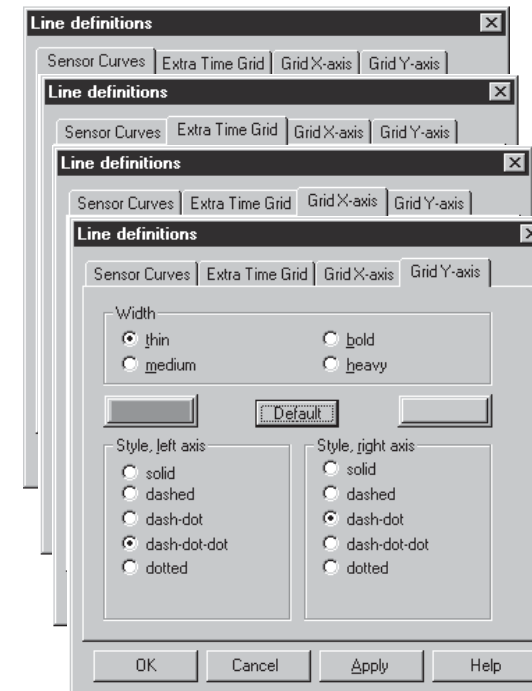
To open the help file click here

⚠ The time grid may be shown or not by clicking the right mouse button in the graphic window.

• Color assignement
You may find more information about this point in chapter 5.3.6.

5.5.5 Histogram

• **Histogram - Display**

Measured values can be displayed in a histogram by selecting "Statistics" from the "Histogram" menu.

The histogram is calculated from the readings currently displayed in the diagram. The individual classes to which the values are assigned are automatically generated by the program. This will be described later in this chapter.

The vertical bars are labelled with the number of readings in their class and the corresponding percentage.
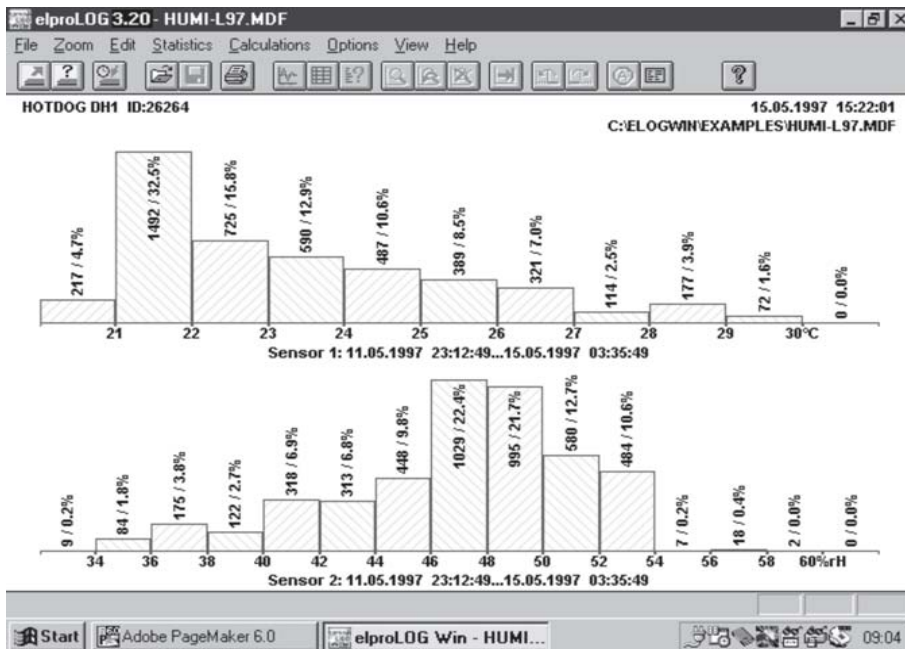
• **Setting the Parameters for Class Formation**

When you select "Histogram" from the "Options" Menu, you get the following window:
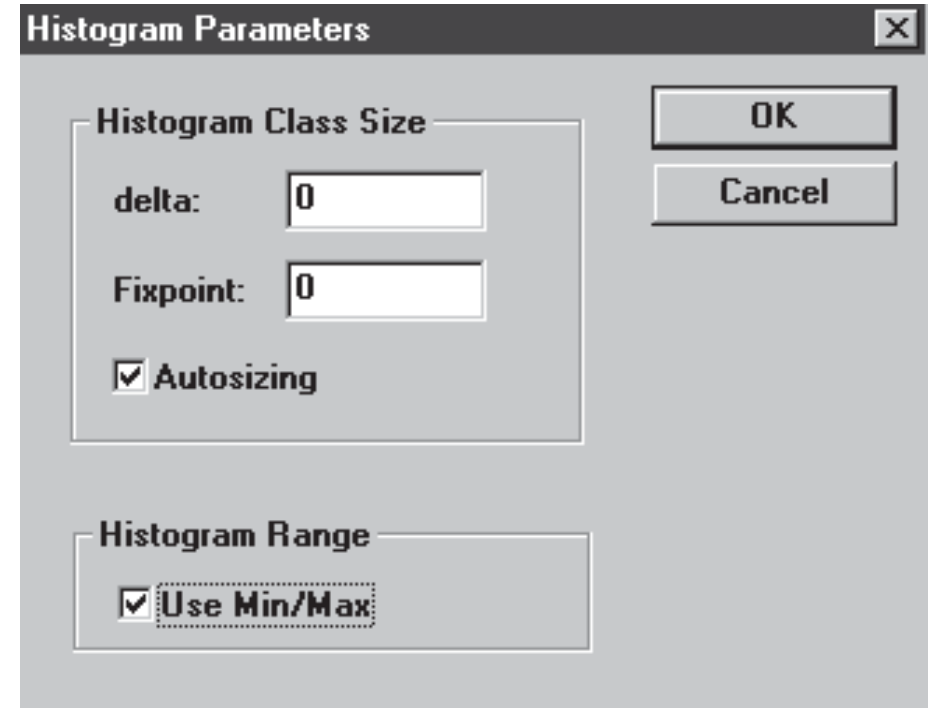
• **delta:**

The delta value describes class width.

• **Fixpoint:**

The fixed point defines the value from which the classes are calculated with the class width selected.

• **Autosizing:**

If this box is ticked, the program generates class size automatically.

• **Use Min/Max**

The class limits are set in accordance with the predefined Min/Max values (see chapter 5.5.3).

5.5.6 Statistical Data

Evaluation of the measured values under statistical aspects can be obtained by selecting "Statistical Data" from the "Statistics" menu. The values calculated are those shown on the illustration. You can find the mathematical formulae and descriptions on the next page.
You get the following screen:
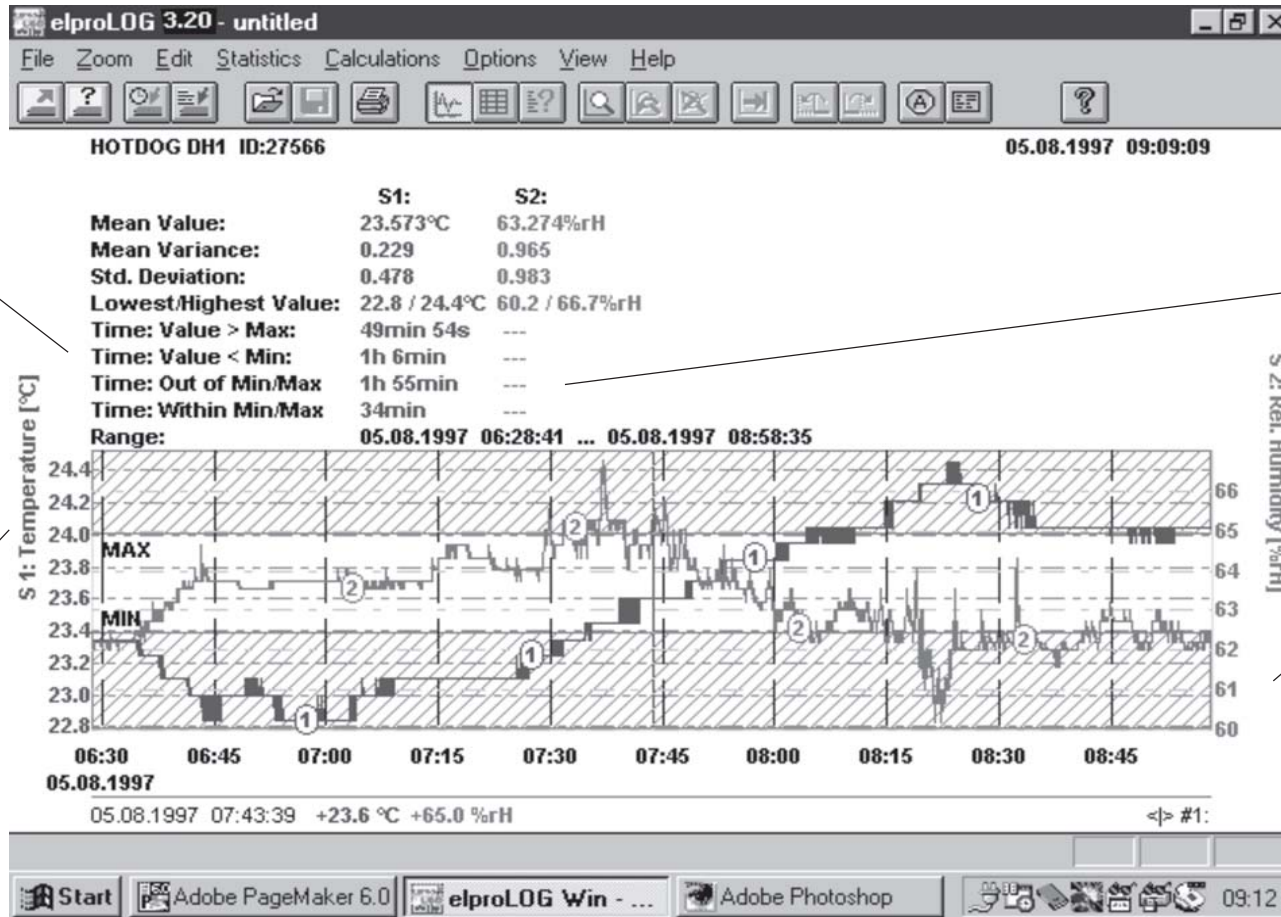
Statistical data, detailed description on next page

The axis descriptions only refer to the graph.

Display of the Min/Max values must be activated for calculation ("on"), otherwise they will not be taken into account.

Graph display. All operations, such as the freely movable cursor, are still available.

You can leave this type of display and return to the normal graph display by clicking on "Statistical Values" in the Statistics" Menu.

• Mean value

The mean value (empirical mean value, "average") is calculated by the sum of all measured values divided by their number.

Empirical mean value: $\bar{x} = \dfrac{1}{n} \bullet \sum\limits_{i=1}^{n} x_i$

• Variance:

Variance is calculated using the following formula:

Variance: $s^2 = \dfrac{1}{n-1} \bullet \sum\limits_{i=1}^{n} (x_i - \bar{x})^2$

• Std. deviation

The standard deviation (empirical straggling) is a measure for determining how much the measured values vary around the mean value. The lower straggling is, the more constant is the measured quantity. The calculation "Mean value ± Std. deviation" creates an area which contains (per definition) 68 % of all measured values.

Empirical straggling: $s = \sqrt{s^2}$

• Lowest/highest value

The highest and lowest values measured in the corresponding area are determined

• Times depending on Minimum / Maximum

The time period in which the defined condition applies is calculated as the sum of the individual time periods. Only the total time is calculated. This need not be a continuous stretch of time.

• Time period:

In an area "from...to", it is shown which measured values have been taken into account for the above calculations

5.5.7 F-Value

Here ("Options" menu, "Define F-Values") you can adjust the settings for the calculation of the F-value. (Take over the user defined values).
Set the name of the method (e.g. F-value, PE-value, C-value).
Enter the base temperature (e.g. 121°C, 80°C).
Define the Z-value.
The threshold is defined by elproLOG, modify it if necessary.
Activate the conditions for calculation.
This calculation is only with single graph representation possible (see also chapter 5.3.3).

5.5.8 Mean Kinetic Temperature (MKT)

• Introduction

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 the calculation of the mean kinetic temperature as a verification of exceeded storage conditions and if conditions are exceeded a second calculation to determine the reduction of shelf life with the help of the Arrhenius equation.

• Mean Kinetic Temperature (MKT)

The ICH stability testing guidelines[1] defines 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.

• Calculation

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 recognizes 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:

$$TK\,[K] = \frac{-\Delta H\,/R}{\ln\left(\dfrac{\sum\limits_{1}^{n}\exp\left(\dfrac{-\Delta H}{R \cdot T_n}\right)}{n}\right)}$$

where ΔH 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 and exp is the natural log base.

The practical application of this equation is less complex than it first appears. For a huge range of pharmaceutics ΔH 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. T_1 is the average temperature recorded over the first time period and T_n is the average temperature recorded over the nth time period.

References

1. Note for guidance on stability testing: stability testing of new drug substances and products (ICH):
   CPMP/ICH2736/99 (revision of ICH/380/95)

• MKT Definition in elproLOG

The definition of the MKT parameters are done in the following screen of the elproLOG data logger evaluation software:

• Effect and Calculation Example from elproLOG for Kinetic and Arithmetic Mean Temperatures

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. The following 2 screen shots show the different calculations for the MKT and the arithmetic mean temperature as it is done in the elproLOG evaluation software:

Activation energy:

As long as any detailed information about a proper activation energy is missing, the average value of 83 kJ/mol for pharmaceutics is a good choice. This value is set by default.

Limit temperature:

Comment

Mean Kinetic Temperature:
Value = 9.4°C
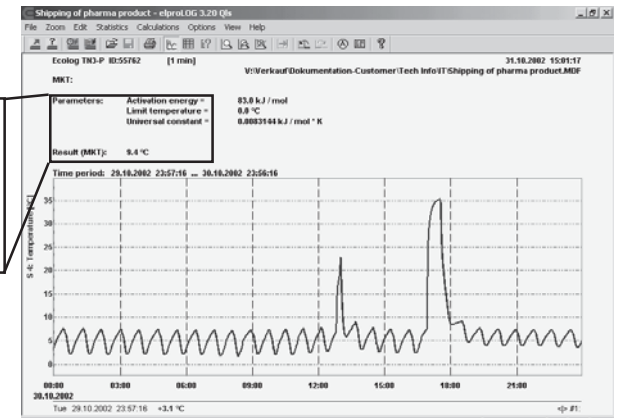
Arithmetic Mean Temperature:
Value = 6.3°C

• 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.
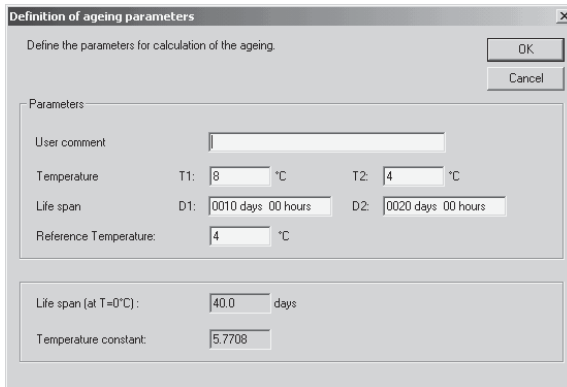
5.5.9 Ageing

This 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 Arrhenius[1] life-stress model.
To do this calculation the software elproLOG uses the following definition screen:

• Ageing Definition in elproLOG
The definition of the Ageing parameters are done in the following screen of the elproLOG data logger evaluation software:

T1, D1 and T2, D2:
Storage conditions 1 and 2 for the monitored product

Reference Temperature:
Minimal recommended storage temperature

Life span [at T=0°C]:
Calculated storage time at 0°C This value is used as a comprehension value for different products and their shelf life

• Effect and Calculation Example from elproLOG for Ageing
As an example of how the Ageing calculation is going to reduce the shelf life time of a pharmaceutical product, here is an illustration.

Ageing:
Loss of shelf life = 5.7days
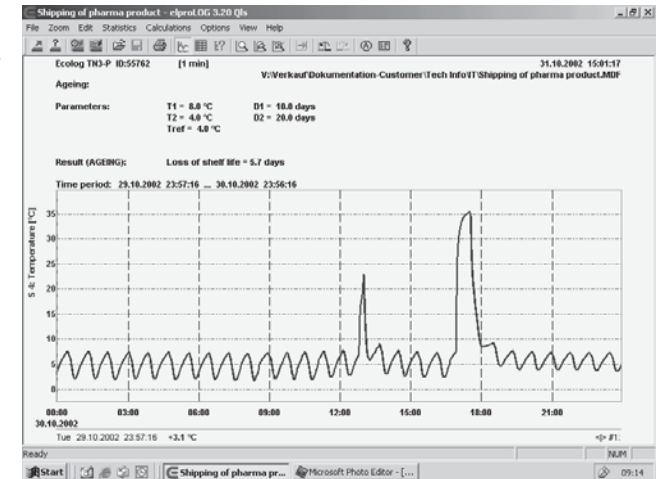
• Conclusion
Due to the incorrect treatment during the unloading of this pharmaceutical product, its shelf life has been dramatically reduced from 10 days down to 4.3 days!

References
1. Work of Svandte Arrhenius, Swedish physical chemist, 1887

5.5.10 Overlay Data

Due to the possibility of superimposing graphs, individual graphs from different dataloggers can be excellently compared with each other. Select "Overlaid Data" from the "Edit" menu. You get the window shown below:

Overlays

#1: S3+4:   DH1 ID:21181
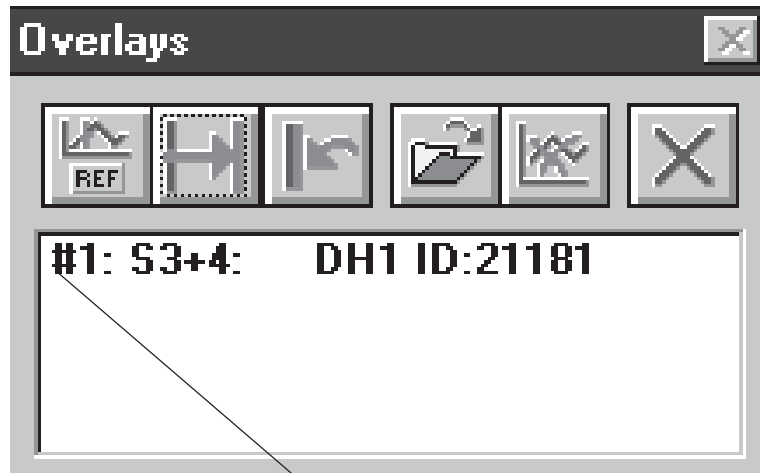
List of superimposed curves. The master graph does not appear on this list. This way, you are always in control which dataloggers have been superimposed. Furthermore, the list also shows the legend for graph numbering. The following operations can only be carried out with marked logger data:

• Set a Reference Point
Use the freely movable cursor to select a characteristic point on the master graph. It should be possible to set the point again in a recognizable way in the superimposed data.

• Move a Curve to the Reference Point
Before activating this button, move the freely movable cursor to the characteristic point in the superimposed graph. When clicking on this button, you get a window that shows the horizontal shift in time. After clicking on OK, the superimposed graph is shifted to the reference point. This is a very practical function for comparing graphs; you can see all deviations on a glance.

• Set Status as before Shifting
The graph is displayed as before shifting for the selected, superimposed logger. Any shifting is reversed.

• Add a Datalogger
You get the window "Open Superposition File". Select the datalogger to be added (max. 7 dataloggers or 16 plots, you can change drive and directories) and click on OK.

⚠️ Only comparable datalogger with identical measuring intervals can be superimposed. Watch out for this when setting the module parameters

• Remove a Datalogger
The window "Remove Datalogger" is opened. You get a list with all superimposed dataloggers. Click on the datalogger to be deleted and click on OK.

• Close Application
The "Superposition" window is closed. The graph, however, remains as before it was closed.

5.6 Printing

5.6.1 Print Setup

Here, you select printing quality, paper format, etc. In the "File" menu you can find the item "Print Setup
Refer to your Windows manual for further information. You get the following window:
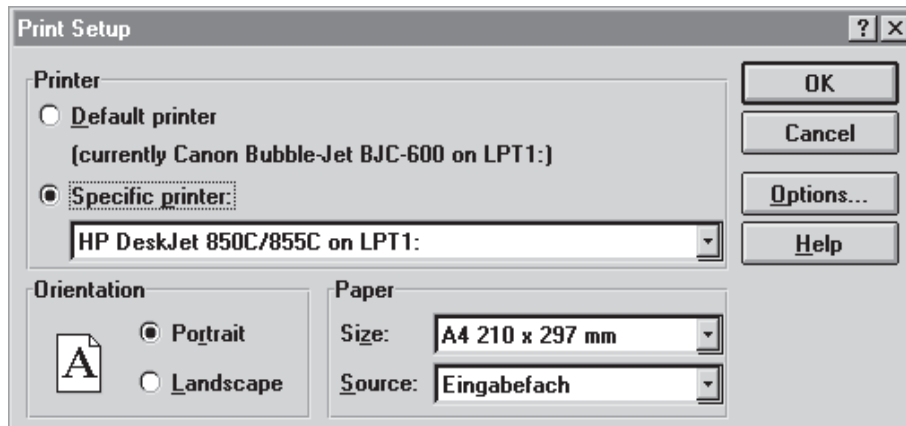
• **Printer**
- Default Printer: The printer used by Windows as the default printer is used.
- Special Printer: You get a list of all installed printers and can select the one you what to use.
- You will find information on the installation of new printers in your Windows manual.

• **Orientation**
- Portrait: The graph, table etc. will be printed in vertical format.
- Landscape: The graph, table etc. will be printed in landscape format.

• **Paper**
- Size: Select the paper format (A4$, US Letter, etc.) from a selection.
- Source: Depending on your printer, paper feed can be selected from a number of options such as certain feeder, individual sheets, continuous.

• **Options**
You get a printer-specific window. Here you can select printing quality, color or gray scale printing, medium (paper, foil etc.). (Black-and-white printing and page mode are set as described in chapter 5.6.2.) For a HP Deskjet, that window looks like this:

Select desired option by clicking on it.
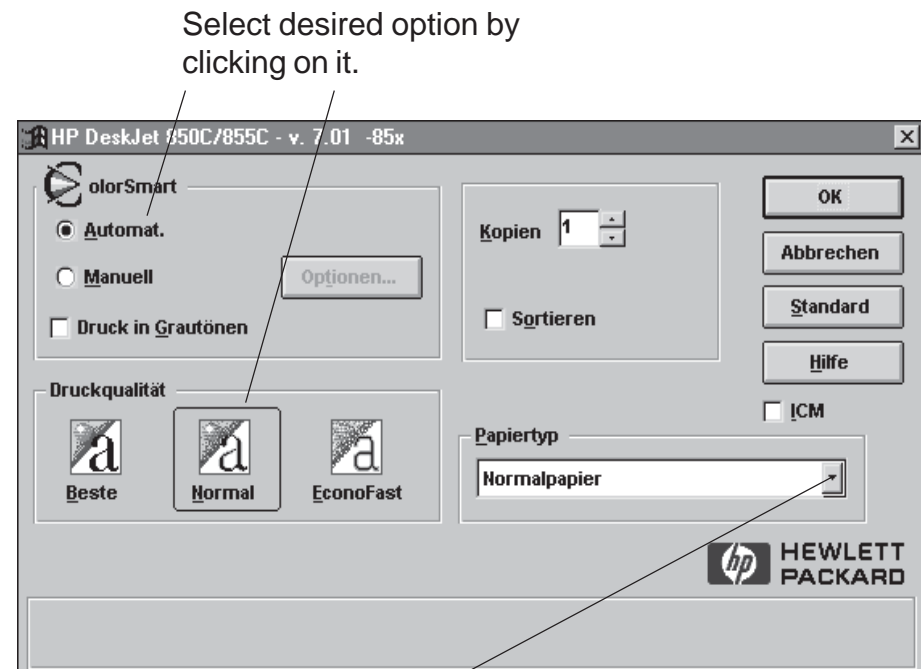
Click here to display available options.

5.6.2 Black-and-White Printing

You have the option of printing only in black and white. Select "Print Modes" in the "Options" menu. You get the following window:
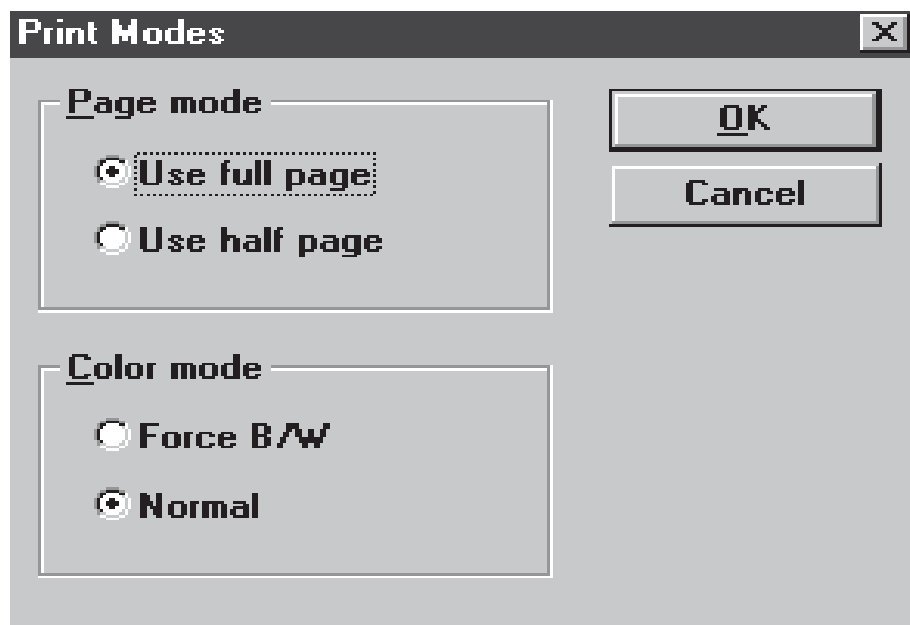
• **Page Mode**
- Use Whole Page: The page is filled completely when printing.
- Use Half Page: Only half of the page is used for printing. The advantages are higher printing speed and more space for your additional information.

• **Color Mode**
- Convert to B/W: Your graph is printed in black-and-white.

⚠ No gray levels will be printed.
In tabular printouts, measurement data outside limit values will be market with an asterisk in B/W-mode.

- Normal: Depending on your printer type, printing is in color or gray.

5.6.3 Printout Description

You have the option of printing an additional text of up to six lines. To do this, select "Edit Printout Description " from the "File" menu. You get the following window, in which you may enter your text.
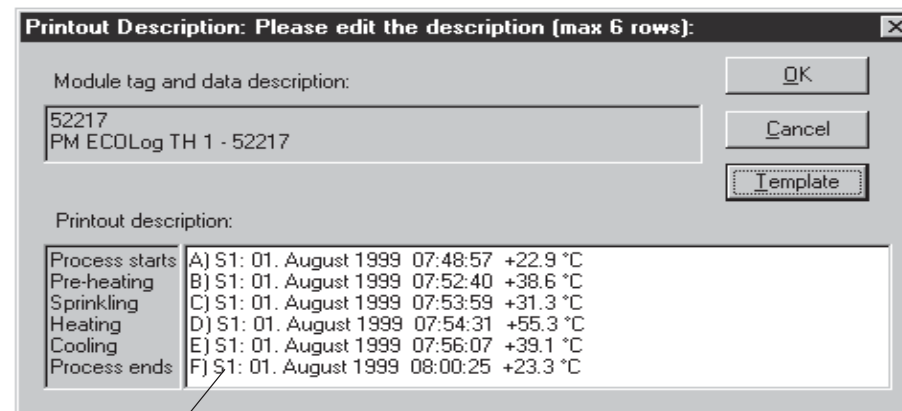
The text is intended for describing the graph and for the legend of any marked points. The legend of the marked points is created and inserted automatically, but can be deleted or edited. The text can be edited just like in a text editor. If you don not want any accompanying text, press "OK" while the editing window is empty.

• **Template**
Opens a window with the following functions:
- New template: Defines a new template
- Load template: Adds a template to a printout description
- Edit template: Allows to edit a selected template
- Remove template: Removes a template from a printout description
- Delete template: Deletes a selected template from template list
- Rename template: Allows to change the name of a template
- Standard template: Defines a standard template

5.6.4 Print Preview

Due to the print preview, it is no longer necessary to make trial prints. You will see the page exactly as it will be printed. Select "Print Preview" from the "File" menu. Depending on the selected settings, your window may look somewhat different. However, the menu bar stays the same for all settings. You can see an example for such a window below:

With several pages, this button shows the next page.

With several pages, this button shows the previous page.

Two pages are shown on the screen.

You can enlarge the upper right area two times.

Enlargement is reversed.

Printing is started. You get the "Printout Description" window, in which you can edit the text one more time. Click on "OK" to print the graph.
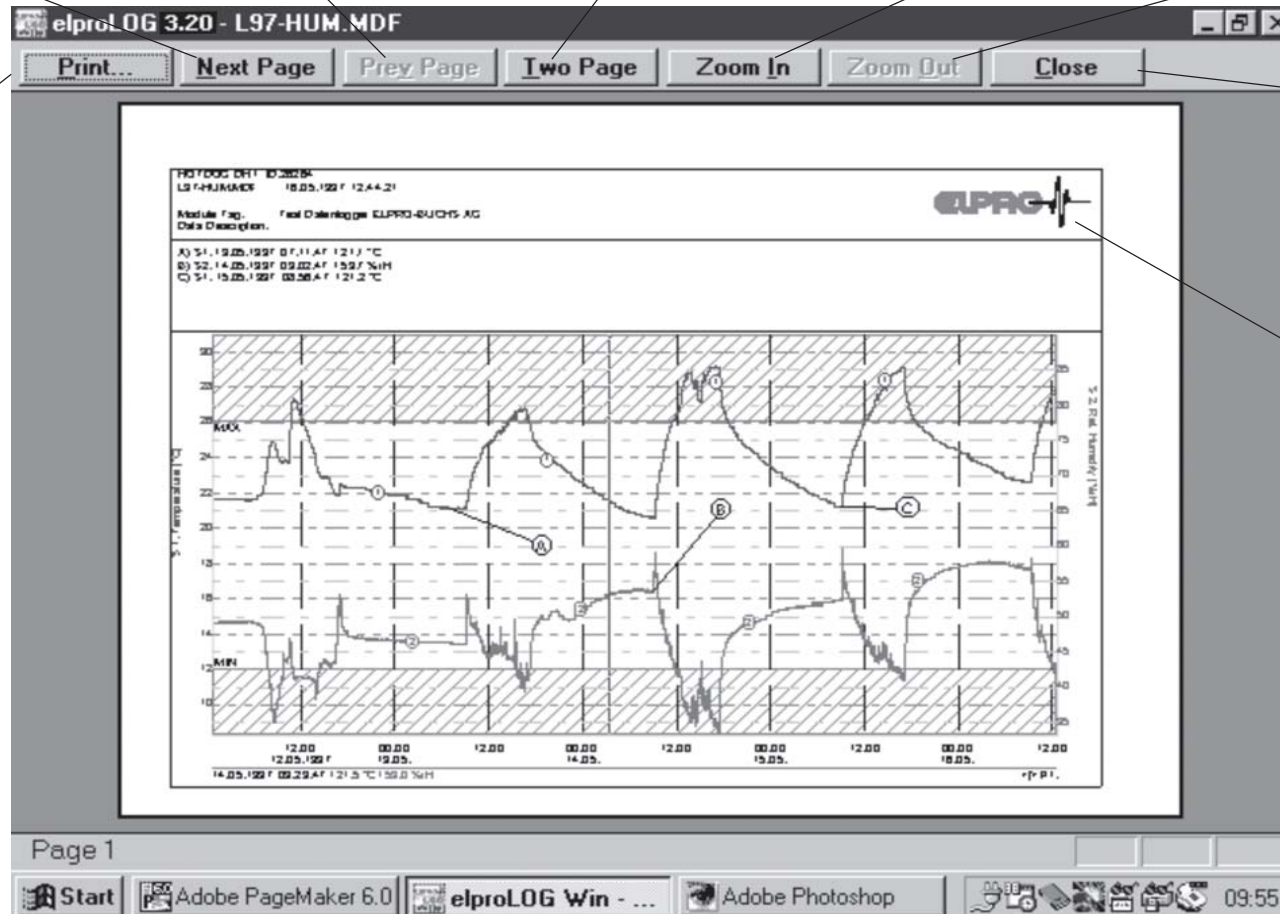
You quit page preview and return to your normal screen.

You may also include your own company logo on the print. More detailed information can be found in chapter 5.6.5 Company Logo.

5.6.5 Company Logo

You may attach you own company logo to the print. You should observe a few guidelines in creating the logo to prevent errors. You are going to select the desired logo in the following window: „Option - Print Parameters - Logo File"

• Guidelines: The logo file must be a Windows Bitmap (*.BMP)

• Recommendation: Use a height of 100 to 200 pixels and 16 colors (4 bits per pixel) for the bitmap. The logo's height will be adjusted to the amount available, and width will be adjusted in accordance with the scaling factor used. You should therefore be careful when creating very wide logos. Use the following rule: a height of 100 pixels should be accompanied by a width of about 250 to 400 pixels.

It is possible to define colors of 1, 4, 8 or 24 bits per pixel. The more bits per pixel, the more colors can be displayed at the same time. If the number of usable colors is high, colors may change when printing. At the same time, the amount of memory used and file size increase. Test several versions.

The illustration below shows one example of a company logo. Logos can be saved in color or black-and-white *.BMP files.

5.6.6 Print

In the "File" menu you will find the item "Print". The first window you get is "Print Description". You can find detailed information on this in chapter 5.6.3 Print Description. If select press "OK", you get the following window:
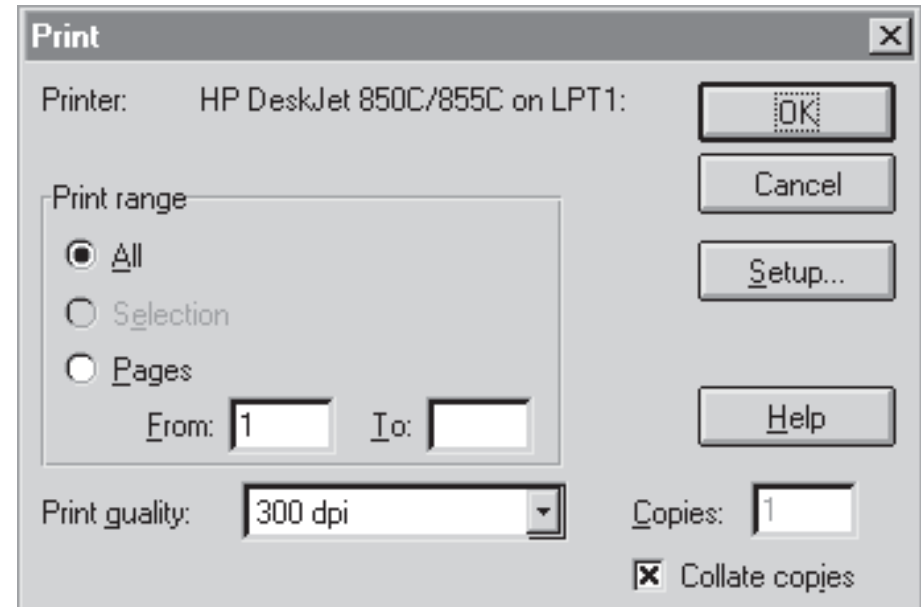
• **Printer**: The printer currently selected is displayed for your information. Change the printer if necessary as described in chapter 5.6.1 "Printer Setup".
• **Print range**
- Everything: All pages are printed
- Page: You may select the pages to be printed.
• **Printing quality**
You get a selection of printer-specific options.
• **Setup:**
You get a window as in chapter 5.6.1 "Printer Setup".
• **Copies:**
Select the number of copies to be printed.

5.7 Disk Operations

This chapter describes the saving, loading and exporting of measured values and graphs.

5.7.1 Saving Readings and Configuration

• Saving Readings

The readings can be saved using the item "Save" from the "File" menu. However, this requires that the curve has already been saved before. If this is not the case, you get the same window as if you had selected "Save As". This window looks as follows:

You may save the data to any directory you want.
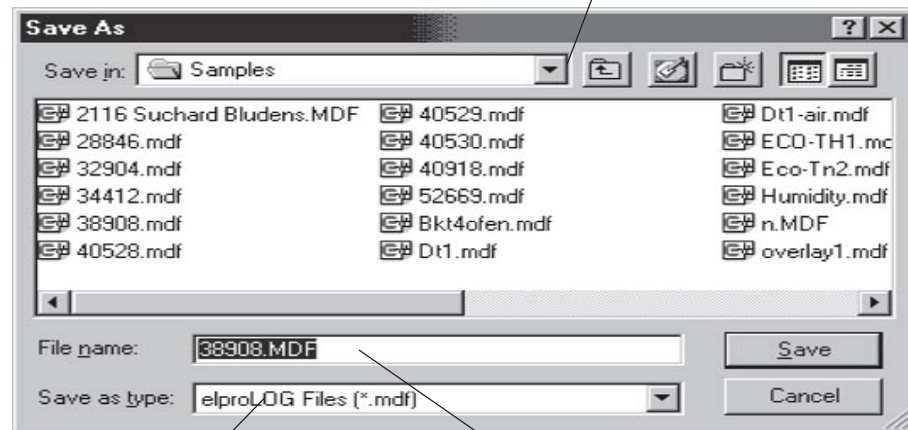
Extension that will be added.

Enter the file name. The extension is added automatically.

⚠ Change the settings and data before leaving the program.

• Saving Configurations

The settings selected by you, such as zoom, axes, mark points and many others, are saved. Select "Save Configuration" from the "Edit" menu. Give your configuration a name in the following window. It is also possible to save several configurations. The dialogue window looks as follows:
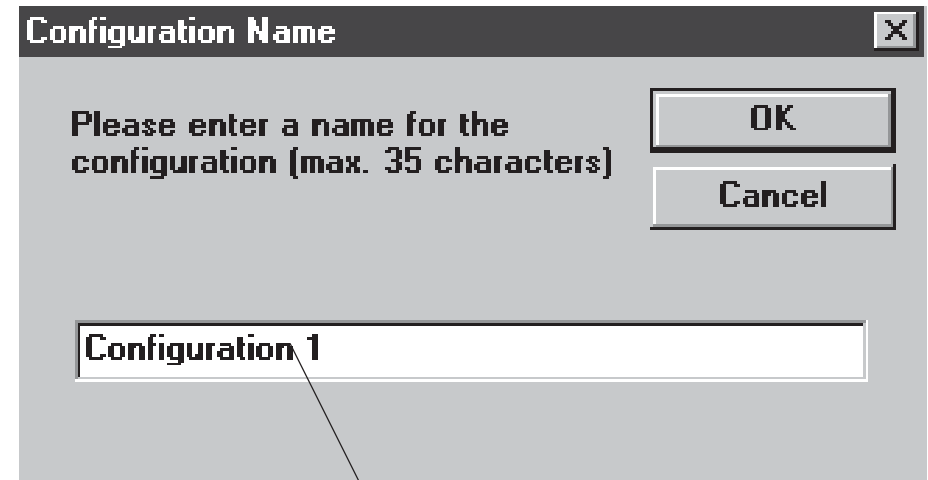
The configuration name may consist of up to 35 characters. Do not confuse it with the file name.

⚠ The configuration will be saved in the same file as the readings. If you have not yet saved the readings in a file, you should do this immediately.

5.7.2 Loading Readings and Configuration

As with the saving of a graph, reading a graph is divided into two sub-chapters.

• Loading Readings
With this instruction, saved data are again loaded to memory. Please note that you have to load any saved configurations separately. In the "File" menu you will find the item "Open". If you click on it, you get the following window:

With a mouse-click, the file name will appear in the File Name field. This file will be loaded when clicking on "OK".

Change to the directory to which your data files have been saved.
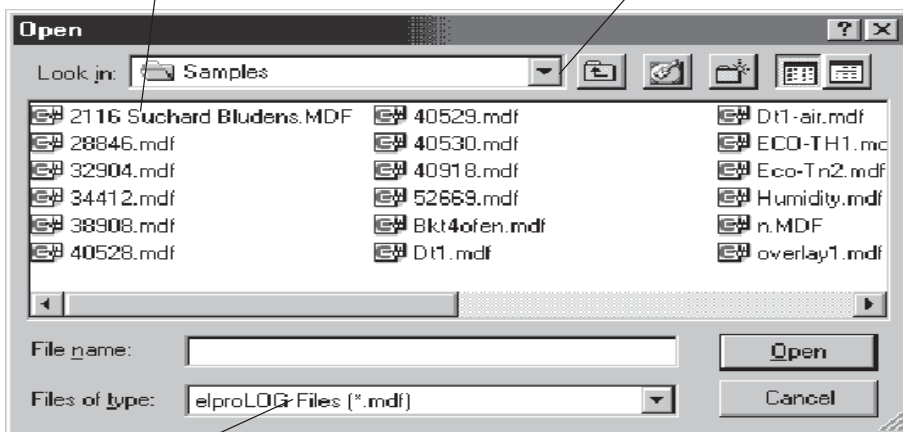
The extension must be *.MDF. Only files with that extension will be listed above.

⚠ The configuration is not loaded together with the data file. This should be loaded individually.

• Load Configurations
If configurations (screen settings) have already been saved, they can be loaded with this menu item.
To do this, select "Load Configuration" from the "Edit" menu. You get the following window:
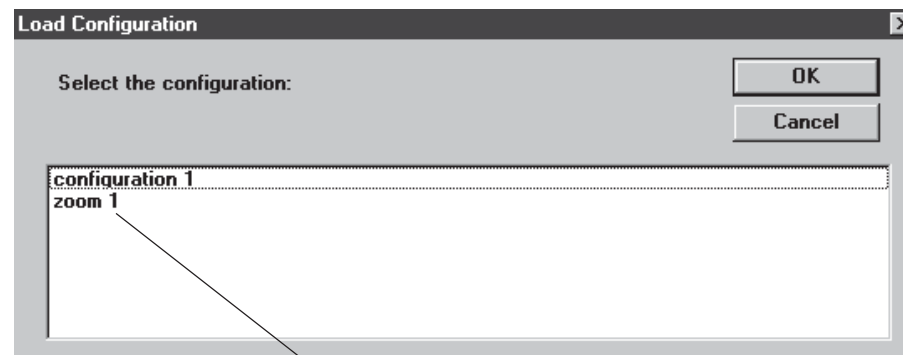
List of available configurations
You select the desired configuration by clicking on it. Then click on OK to load and implement the saved settings.

Configurations that are not used any more may be deleted from the list with the function „Remove Configuration".

5.7.3 Exporting Data

You can save (export) the readings in a special format and make it available to other programs.

• Export Format
You may decide yourself which format to use for data export. Select the format so that it corresponds to the program used for further editing (e.g. EXCEL, Lotus 1-2-3 etc.). You can save yourself a lot of work that way.
The format is selected under "Export Format" from the "Options" menu. You get the following menu:

A number of options is available for each point.
The displayed setting is usual for EXCEL.

With these options, certain information components can be suppressed when exporting.

Export only genuine readings. Suppress information such as NODATA; >MAX; NC; etc. This makes calculations with the data easier.

The selected configuration is displayed as a sample.

Export Settings

Format

Delimiter: Tabulator

Date Format: DD.MM.YYYY

Text Symbol: Double Quotation Mar

Decimal Point: Point

OK

Cancel

Exclusions
- ☐ Excl. File Header
- ☑ Excl. text symbols for indices
- ☑ Excl. text symbols for values
- ☑ Excl. indices
- ☐ Excl. Date and Time
- ☑ Export Err-Codes as Blank Fields
- ☐ Suppress hidden lines

Extended Settings
- ☐ Enable data reduction

Add on
- ☐ Add info column

Example
''30.11.1996''[TAB]'15:33:59''[TAB]-22.7[TAB][CR/LF]

By activating this option, the exported date are reduced according to the possibilities of the window: Export Data Reduction Settings.

By activating the "Add info column", status information like InPos, Alarm, Digital inputs are exported as well.

• Exclusions

All description apply to the activated state (box ticked) and refer to the window "Export Format".

- *Excl. File Head*: The file head is not exported.

- *Excl. Text Symbol for INDEX*: All readings are given continuous numbers. This makes the index. In this case, the index is exported as a plain figure.

- *Excl. Text Symbol for Values*: The readings are exported as plain figures. This is very practical for calculations.

- *Excl. INDEX*: The numbering of readings is not exported.

- *Excl. Date and Time*: In addition to its index, each reading is provided with date and time. This information can be suppressed using this box.

- *Excl. Export of Error Codes as Blanks*: Error codes are e.g. the following information: NODATA, >MAX, NC, etc. They are exported as tabulators without text content. In EXCEL this results in an empty column.

- *Suppress Graphs not Displayed*: Only the curves shown on screen in the graph window are exported. This option only takes effect with modules with several sensors in single graph mode.

• Export Data

Exporting of data is selected in the "Export" item from the "File" menu. You get the window "Save As". Enter the file name. The data are now saved in the selected format as ASCII text file (*.TXT). You can easily work on this file with a spreadsheet program such as Excel, Lotus 1-2-3, Dbase or similar.

• Procedure for Data Export

• Select the format for the data to be exported.

• Select the area to be exported. This can be done by zooming in the graph window or by highlighting the corresponding readings in a table. Further information can be found in the corresponding chapters.

• Save the data using the menu item "Export".

⚠ Depending of the format and selected area, very large files may be created!

5.8 Programming the Datalogger

This chapter explains how to reprogram a logger. It is assumed that the interface is connected to the PC and that a datalogger is connected to the interface. If the connection with the interface does not work, a corresponding error message is displayed. Refer to chapter 6 Error Messages for possible causes and their correction.

5.8.1 Datalogger Setup

You may program measuring mode, start of logging, logging interval, etc. Select "Datalogger Setup" from the "File" menu. You get the following window: (the individual points are described in detail on the following pages.)

⚠ **Print the logger status as a precaution. The old configuration will no longer be available after reprogramming.**
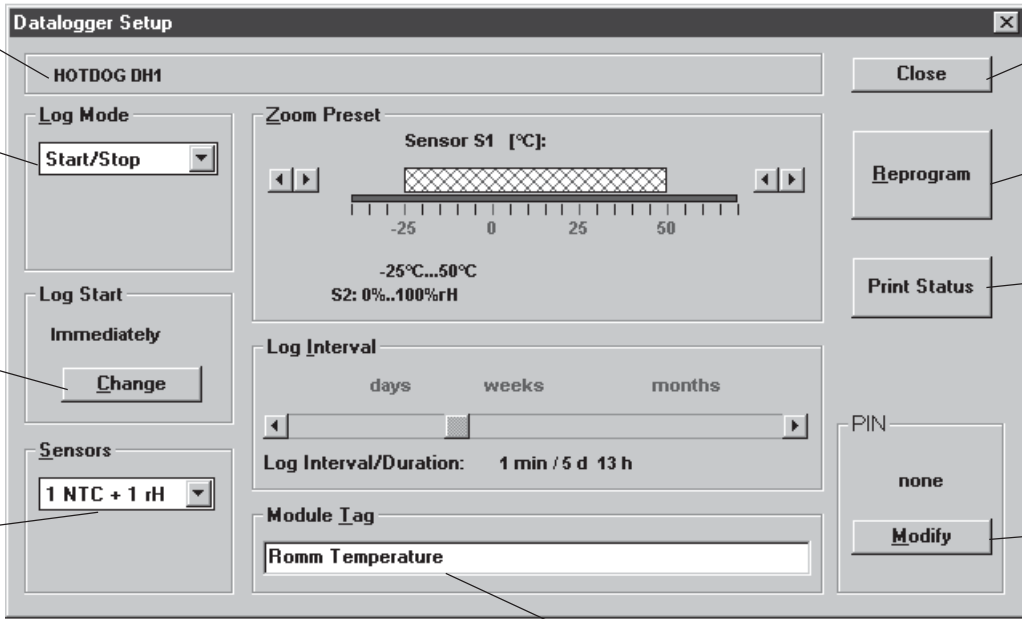
Logger type is detected automatically.

The measuring mode can be set to Start/ Stop or Endless.

Logging can start immediately or at a later time.

Here you can see which sensors are connected to your logger. You can choose which of these you want to configure.

This menu is cancelled. No changes will be made to the old settings.

"Reprogram" writes your settings to the module.

Let's you print out the current status of the logger.

You can add a password to your settings. In this case, the data can be read and evaluated without a password, but the module can only be reprogrammed or a configuration safed with the password.

Datalogger Setup

HOTDOG DH1   Close

Log Mode
Start/Stop ▼

Zoom Preset
Sensor S1 [°C]:
◄ ► [▨▨▨▨] ◄ ►
-25   0   25   50
-25°C...50°C
S2: 0%..100%rH

Reprogram

Print Status

Log Start
Immediately
Change

Log Interval
days   weeks   months
◄ [▯   ] ►
Log Interval/Duration: 1 min / 5 d 13 h

Sensors
1 NTC + 1 rH ▼

Module Tag
Romm Temperature

PIN
none
Modify

You can select your own module description. When you click into this field, a cursor will show up. You can now delete the old text and enter a new one.

• Mode

- START/STOP: In this mode, you determine the time logging starts. The end of logging is automatically determined by the start of logging and the selected metering interval. The starting time can only be entered after a metering interval has been set. However, it is still possible to change the interval (and thus, the duration of metering) after the starting time has been set. Please refer to the point "Start of Logging" for entering the starting time.

⚠ Only when the module status or the readings are read is it possible to determine whether the module is logging or inactive.

- ENDLESS: Logging is done continuously. First the data memory of the module is filled. If the memory is full, each further metering overwrites the oldest data with the latest. The oldest value is irretrievably lost. The set metering interval determines the period in which no values will be overwritten.

⚠ There is no warning when readings are about to be overwritten!

• Start of Logging

The starting time is displayed. You can determine it yourself by clicking on "Change". You get the following window:
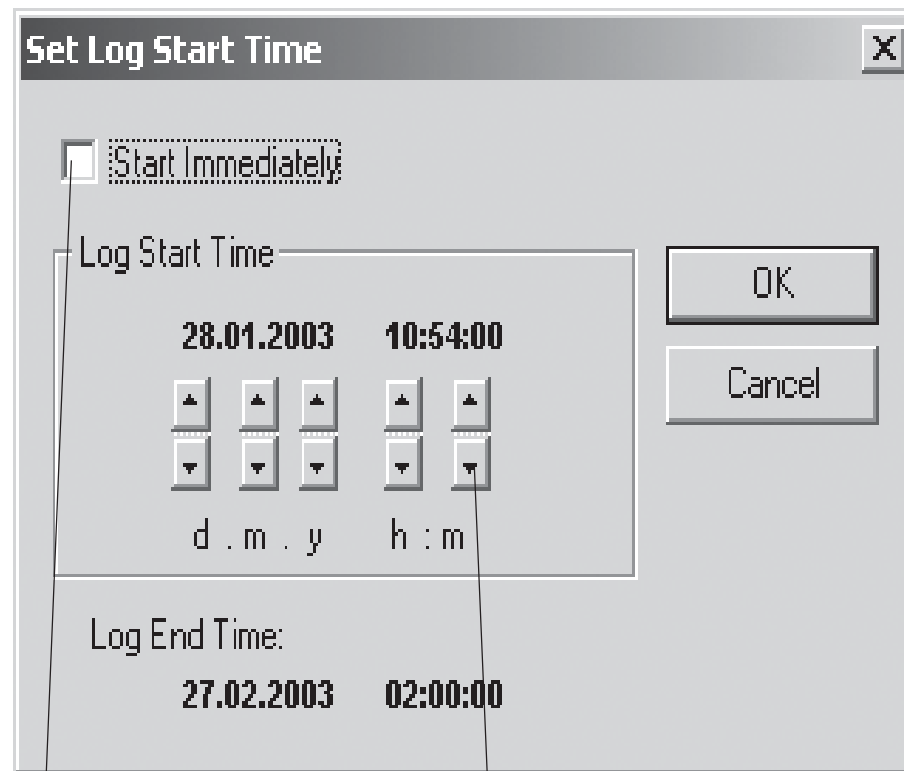
If this box is ticked(☑), the starting time and the starting date are set by the PC. The settings above are disregarded. If you want to determine starting time and starting date yourself, deactivate this box by clicking on it (☐).

Clicking on the arrows changes the displayed values by one step each.

• **Zoom Preset** (there may be device-specific differences)
Here you enter the range within which metering takes place. This preset range should not be confused with the whole measuring range of the module. For example, if you want to measure a temperature between 0°C and 30°C (room temperature), it is sensible to limit the measuring range. During evaluation, the temperature axis is extended over the programmed measuring range. It is, however, still possible to have the whole measuring range displayed ("Zoom" menu, "Extended Range"). No readings are lost by range preset (except old HAMSTERs). The upper and lower range limits are set by clicking on the corresponding arrow buttons at the display rims.

• **Logging Interval** (there may be device-specific differences)
Under this item, you can set the time period over which data shall be collected. The measuring interval (Interval) and the total duration of metering (Duration) are displayed. You can select a measuring interval from 2 seconds up to 3 hours. This means that the total duration of metering can be between 4h 26 min and 1000 days. You can adjust settings by clicking on the arrow buttons at the interval display rim or by dragging the rectangular button in the Interval field. (Set mouse pointer to button, press and hold down left mouse button while moving the button by moving the mouse.)

• **Module Description**
You may enter information into the module. that information is stored in the logger and is available until the next reprogramming. Usually, the information entered is about the company or department using the module or about the way it is used. Details on measurements can be added later to the evaluation information during evaluation. It is not necessary to enter the date and time of measurements, as they are recorded and saved automatically.

• **Password (PIN)**
As with time, the current status is displayed. The password protects the device against unauthorized reprogramming. However, reading and evaluating data is still possible.

-No protection wanted: - no code   (display: none)
                                        - code "0"   (no password)
- Protection wanted: - code   1 to 9,999,999
                                        - Hamster code 1 to 65,000 only

If you want to use a password, click on "Modify".
You get the following window:
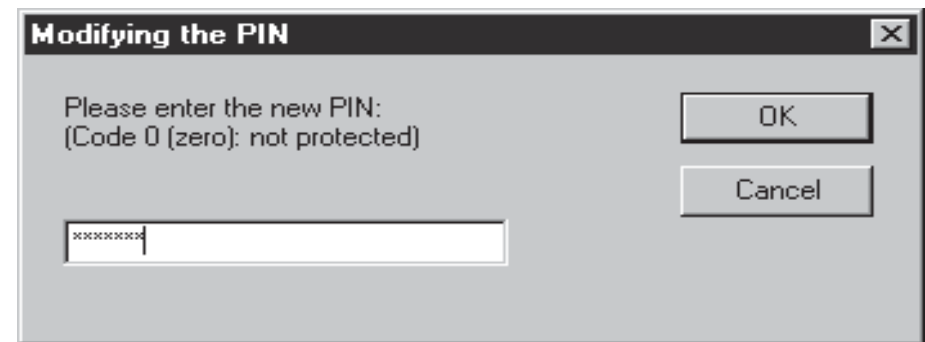
Enter your password. Only figures are permitted. Please make sure that you have typed in what you wanted to. After pressing "OK", you are asked as a precaution to repeat the password. If the two are the same, the password is set.
If you have forgotten your password, you have to send the logger back to your dealer or to the manufacturer, who is able to reset the password.

• **Programming**
The new settings are saved in the logger.

⚠ The old settings are irretrievably lost.

5.8.2 Extended Setup

Further information can be found in the data sheets of each datalogger.
Examples for advanced setup are:
- Humidity calibration of rH devices
- Assignment of axis parameters with mA and Volt devices
- Cable compensation with PT100 devices
- Programming the alarm limits with HOTBOXeuro and ECOLOG
- Setting of date and time of the logger internal watch
- Define of printerlanguage and selecting of printer type
- Programming of battery change time.
  Important for HOTBOX and ECOLOG

5.8.3 Definition of Alarm Parameters

The dataloggers HOTBOX euro, SE and ECOLOG have an alarm indication feature and all models except the TN2 are also equipped with an alarm contact. The alarm parameters are defined in the following window.

• Hysteresis
The switching hysteresis is used to avoid uncontrolled on/off switching off the alarm contact. To move the alarm contact, the measurement value has to differ from the limit value by the value defined in this field.

• Alarm Delay Time
normal: To close the alarm contact, the duration of a measurement value, outside the limit values, has to be longer than the delay time defined in the "normal" data entry field.

defrost on: If the "check defrost" function is selected and the defrost contact D1 is closed, then the duration of a measurement value, outside the limit values, has to be longer than the delay time defined in the "defrost on" data entry field

• Alarm indication
The alarm indication is independent of the sensor number, but all sensors that may cause an alarm have to be selected in the measurement function. The alarm indication has to be reset manually. It is possible to reset the alarm indication by the PC software, the keyboard or the alarm reset connector.

• Alarm contact
In case off an alarm indication, the alarm contact is closed (except for a TN2). The alarm contact is independent of the sensor number, but all sensors that may cause an alarm have to be selected in the measurement function. The alarm contact is reset automatically as soon as the alarm condition is cleared.

By activating this check box, the alarm function is active
(ECOLOG and HOTBOX SE only)

Data entry field for switching hysteresis

Data entry field for delay time

Data entry field for delay time under "defrost on" condition

By activating this check box, the de-frost contact is controlling the delay time

Selection feeld for the Alarm output (ECOLOG only) e.g. CRA bracket: power on time for a piezo beeper or a flash light is extended

Data entry field for lower limit value

Data entry field for upper limit value

5.10 Shortcut Keys

Shortcut keys are available in *elproLOG Win* for important instructions.
Each shortcut consists of a letter and is pressed together with the Ctrl key.

• Instructions from the "File " Menu

Readout Datalogger	Ctrl +	N
Read Status	Ctrl +	R
Datalogger Setup	Ctrl +	D
Extended Setup	Ctrl +	E
Open File	Ctrl +	O
Save File	Ctrl +	S
Print File	Ctrl +	P

• Instructions from the "Edit" Menu

Copy File to Clipboard	Ctrl +	C

• Instructions from the "View" Menu

Show Line chart	Ctrl +	L
Show Tabular Display	Ctrl +	T
Show Status	Ctrl +	U
Show Communication History	Ctrl +	H
Show Digits	Ctrl +	G

• Common Purpose Instructions

Language switching for (Win 2000 or NT4.0 only)	F3	
Marking of multiple blocks in tabular display	Ctrl +	left mouse button

elproLOG 3.20 Qls - Ecolog-TN3P-QLS

File   Zoom   Edit   Statistics   Calculations   Options   View   Help

AUDIT TRAIL and ACTION LOG

Doubleclick on entry for more details

Ecolog TN3-P Module ID: 55757 - V5.01 [PN:100510842]
Initialized on: 11.01.2001 08:48:38
Last reprogrammed: 27.06.2001 10:47:01
Module Tag: ELPRO-Buchs AG

AUDIT - TRAIL

Date / Time		Computername	User (System)	User (Custom)	Action
03.12.2002 14:51:39	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	File converted from previous format
03.12.2002 14:52:03	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	File saved as 'Ecolog-TN3P-QLS.MDF'
03.12.2002 14:55:07	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Configuration saved as 'Sample'

ACTION - LOG

Date / Time		Computername	User (System)	User (Custom)	Action
03.12.2002 14:53:23	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Data exported to Ecolog-TN3P-QLS.txt.
03.12.2002 14:53:46	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Mail-Message with file attachment created.
03.12.2002 14:59:41	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Printed out Graph to 'HP LaserJet 6L'
03.12.2002 15:02:23	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Printed out Graph to 'HP LaserJet 6L'
03.12.2002 15:07:18	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Printed out Graph to 'HP LaserJet 6L'
03.12.2002 15:08:56	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Printed out Histogramm to 'HP LaserJet 6L'
03.12.2002 15:19:19	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Printed out Table to 'HP LaserJet 6L'
03.12.2002 15:25:43	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Printed out Status to 'HP LaserJet 6L'
03.12.2002 15:27:35	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Printed out Alarmhistory to 'HP LaserJet 6L'
03.12.2002 15:30:27	(GMT +01:00)	ELPRO52	agubler	Andreas Gubler	Printed out Audittrail to 'HP LaserJet 6L'

Ready   NUM

QLS Supplement

QLS Supplement

⚠ Safety of stored configuration against manipulation according to guideline 21CFR11 is granted with this release (3.3x).
To fulfil this guideline all older releases have to be updated with this one.

1. Introduction

1.1 Operating System Information

The software elproLOG 3.3x QLS uses the security functions of the Windows operating system. Therefore this software version works as QLS version under Windows NT4, 2000 or XP only. Older Windows versions do not support the QLS functions and the software will run in the base mode. In the base mode no audit trail function is available!

1.2 File Conversion

Logger data that have been recorded with previous releases may be converted by the version 3.3x QLS to a new file with audit trail. Files that have been converted to the QLS format are not readable by any other elproLOG versions anymore.

1.3 Serial Number and Installation

QLS versions are registered software versions. Your installation will be succesful only, by using the registered QLS serial number. Any other serial number will lead to an installation running in base mode.

1.4   elproLOG Language Support

All documents need for software validation are available in English only.

Remarks
Language used for Help-Files depends on your regional setting in the control panel of your PC.
If you select typical the installation mode, the language of the help files installed will depend on the regional settings. If you select all languages for the help files in the user defined installation mode, the language that matches your regional setting will be used.
Windows NT4 / 2000 / XP allows toggling of the used language during run time. To enable, use function key F3. The used language of the help files will match the selected language, if applicable.

1.5   Responsibility for 21 CFR 11 Requirements

The elproLOG system is regarded as a closed system according to the definition of the 21 CFR 11. Persons who get access to the system are responsible for the content of the electronic records.

- Electronic signature are not applicable for the elproLOG data files.
- The user administration of the operating system must be installed correctly.
- Each user of the system must be documented in a user administration form, defining user name, user password and access rights to the system.
- To get access to the system, each user must be logged in at the operating system. The user name and the correct password must be used.
- At the end of each session the user must log-out or use a secure system to prevent un-authorized access to the system

ELPRO dataloggers are often sent to worldwide destinations. Therefore the datafiles .MDF have to be mobile too.Due to this the Audit Trail is a added part of each datafile, starting from the very beginning when a datalogger is read. The data generated by the elproLOG software system are of non database type. Each file is an individual complete secure record where the raw data can not be manipulated or changed in any form. The complete MDF file is protected with a check sum

The advantage of this type of audit trail is:
- Full compliance to electronic records requirement
- The user can send files from one destination to another
- Security: as the .MDF files can only be operated, modified and used by any other person using the QLS evaluation software elproLOG
- Clear audit trail for the documentation of any previous modification
- Audit trail can not be removed from the .MDF file

The audit trail consists of a time-stamp to record all entries and actions: create, convert, save as, save configuration, modify or delete information in the MDF record. It can be displayed and an overview can be printed in a paper form.

The additional action log is monitoring user activities as all printing, send mail and export datas which are not directly requested by the 21CFR11 as they do not alter the data.

2.   Start-Up Window
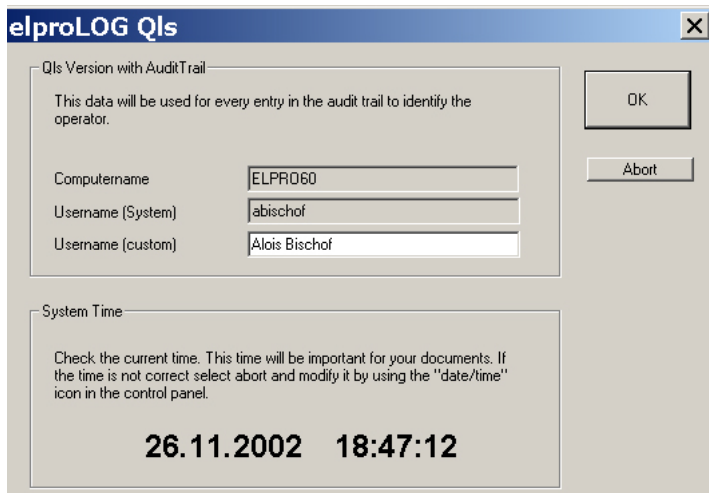
• Computer name
- From operating system generated system name
- Can not by altered when starting elproLOG

• Username (system)
- From operating system generated by user log-in (access rights by user name and user password)
- Can not by altered when starting elproLOG

• Username (custom)
- Optional clear-text username for easier identification of the user, as the system user names often uses unclear short forms or even numbers
- This option is not a CFR requirement, as the secure user access and verification is done by the operation system
- It is recommended to use the full name of the user as a confirmation

3.   Menu Changes

3.1   „Edit" Menu
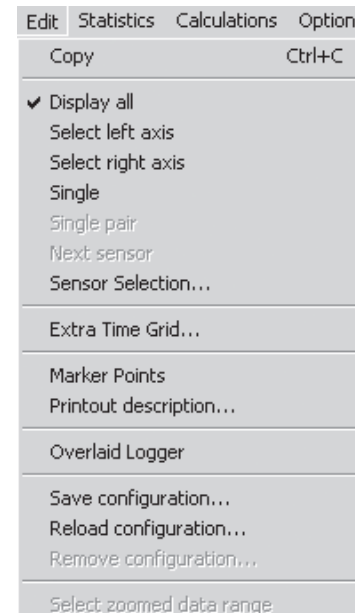
3.2   „View" Menu

• Save configuration
Saves the current graph settings (zoom, marker points,...).

• Reload configuration
Restores a saved configuration.

• Remove configuration
Not possible in the elproLOG QLS version. Therefore saved configuration are protected against changes and deleting.

• Audit Trail
The audit trail information is displayed.

4. Audit Trail and Action Log

```
elproLOG 3.20 Qls - Ecolog-TN3P-QLS                                    _ □ ×
File  Zoom  Edit  Statistics  Calculations  Options  View  Help

    AUDIT TRAIL and ACTION LOG

    Doubleclick on entry for more details

    Ecolog TN3-P Module ID:        55757 - V5.01 [PN:100510842]
    Initialized on:                11.01.2001  08:48:38
    Last reprogramed:              27.06.2001  10:47:01
    Module Tag:                    ELPRO-Buchs AG

    AUDIT - TRAIL

    Date / Time                    Computername  User (System)  User (Custom)  Action
    03.12.2002 14:51:39 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  File converted from previous format
    03.12.2002 14:52:03 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  File saved as 'Ecolog-TN3P-QLS.MDF'
    03.12.2002 14:55:07 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Configuration saved as 'Sample'

    ACTION - LOG

    Date / Time                    Computername  User (System)  User (Custom)  Action
    03.12.2002 14:53:23 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Data exported to Ecolog-TN3P-QLS.txt.
    03.12.2002 14:53:46 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Mail-Message with file attachment created.
    03.12.2002 14:59:41 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Printed out Graph to 'HP LaserJet 6L'
    03.12.2002 15:02:23 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Printed out Graph to 'HP LaserJet 6L'
    03.12.2002 15:07:18 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Printed out Graph to 'HP LaserJet 6L'
    03.12.2002 15:08:56 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Printed out Histogramm to 'HP LaserJet 6L'
    03.12.2002 15:19:19 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Printed out Table to 'HP LaserJet 6L'
    03.12.2002 15:25:43 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Printed out Status to 'HP LaserJet 6L'
    03.12.2002 15:27:35 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Printed out Alarmhistory to 'HP LaserJet 6L'
    03.12.2002 15:30:27 (GMT +01:00) ELPRO52     agubler        Andreas Gubler  Printed out Audittrail to 'HP LaserJet 6L'

Ready                                                                    NUM
```
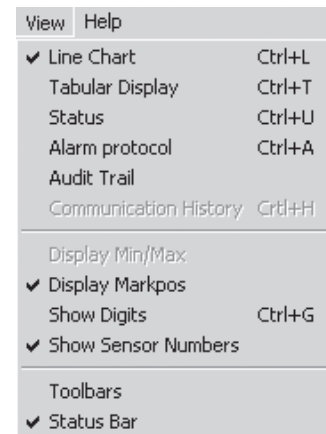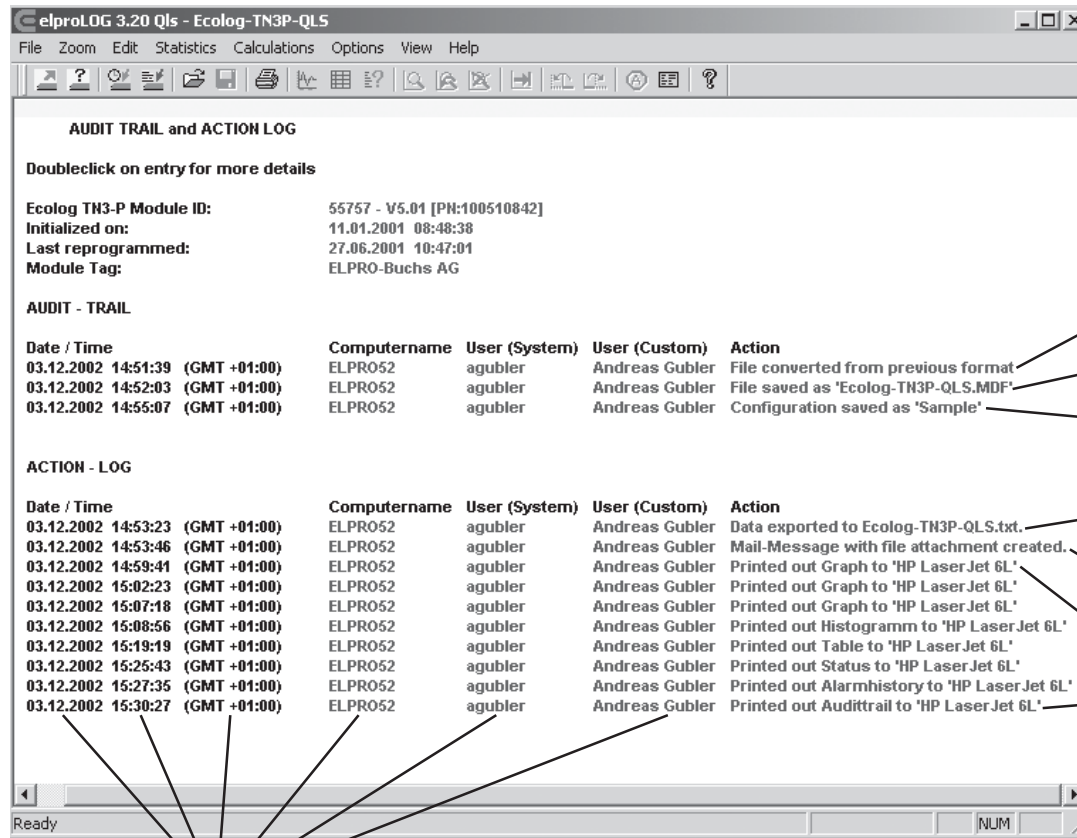
File from an an older release has been converted to the QLS file format.

File has been saved

A configuration with name: Sample has been saved

This file has been exported into a txt-file. Any further actions on the exported file are not traceable anymore.

File has been sent by mail.

Several print actions
(Graph, Histogramm, Table, Status, Alarmhistory, Audittrail)

Thos entries depend on date, time, location, PC and user

(GMT +01:00)
This indication of time gives any user the possibility to recalculate the time axis for any place the logger has been previously

Operation Manual English 3.3x
QLS Supplement **D-SE-3002Bd**