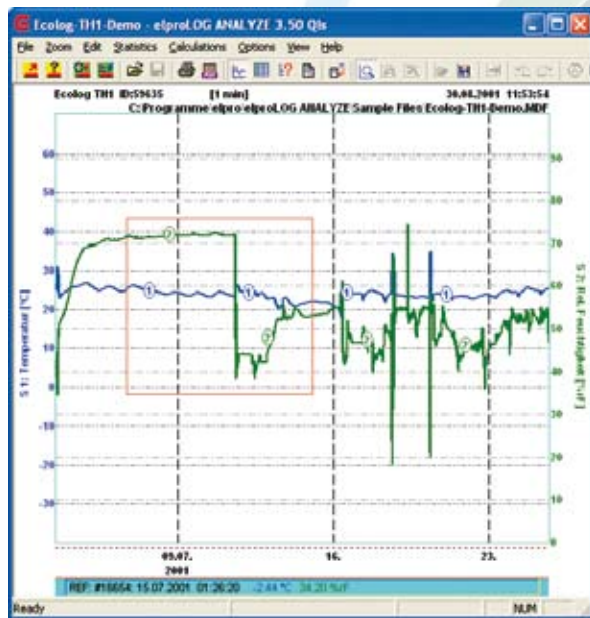**elproLOG ANALYZE**

Software package
for evaluation of data
measured by ELPRO dataloggers

elproLOG ANALYZE QLS

Software package
for qualified systems in
compliance with GMP/GLP/FDA
21 CFR Part 11

ELPRO™ **Datalogging**Company

elproLOG ANALYZE –
FOR EVALUATION OF YOUR MEASURED DATA

Software package elproLOG ANALYZE provides all the functions you require for simple and efficient work with dataloggers and measured data.
elproLOG ANALYZE is the result of many years of practice-oriented and GMP-conforming software development. Making your work with our dataloggers as easy and efficient as possible is always at the center of our development focus.

One software for all ELPRO dataloggers
In addition to the data analysis and report functions, elproLOG ANALYZE is the only tool you need to configure your ELPRO datalogger; the software recognizes all generations of instruments automatically.

Documentation accomplished in three steps
Use elproLOG ANALYZE and experience how you can use your measured data to create complete and clearly formatted reports in three easy steps:

1. Readout:
Easy instrument configuring and fast, problem-free readout of recorded data.

2. Analyze:
Broad choice of view formats and statistic functions to support analysis of measured data.
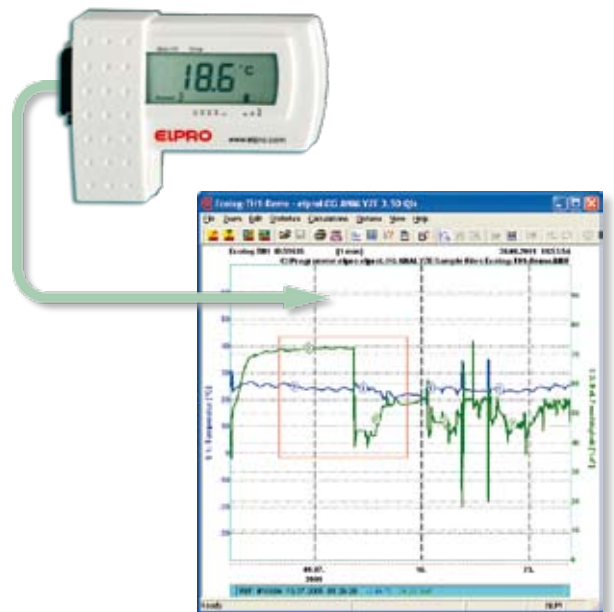
3. Report:
Creation of informative clearly laid-out documentation. The installed PDF function generates complete reports from the measured data in the universal Adobe® PDF format.

1 READOUT

elproLOG ANALYZE is the ELPRO software for simple and user-friendly communication with dataloggers. Irrespective of which ELPRO dataloggers you use, elproLOG ANALYZE recognizes the particular measuring instrument automatically. The software is also capable of opening and displaying PDF files generated with the Libero PDF datalogger and the contained raw data. These features make instrument configuration and data readout.

- Configuration of ELPRO dataloggers
- Saving of measured data
- Analysis of Libero PDF files

广州虹科电子科技有限公司 广州市五山华南理工大学国家科技园 2 号楼 504-505 室（510640）

电话： 020-3874 3030; 3874 3032   e-mail: sales@hkaco.com   网站：www.hkaco.com

2 ANALYZE

elproLOG ANALYZE offers a multitude of functions for analyzing recorded data. Choose between table and graphics displays for your data and use the zoom and marking functions for easy navigation through the logged data points.

In a matter of seconds, elproLOG ANALYZE can analyze complex graphs to provide the exact information which is important to you.

- Clearly laid-out graphs and tables
- Multiple zooming functions
- Statistical data: min/max, mean value, standard deviation, variance
- Dew point calculation
- Histogram representation
- Superimposing
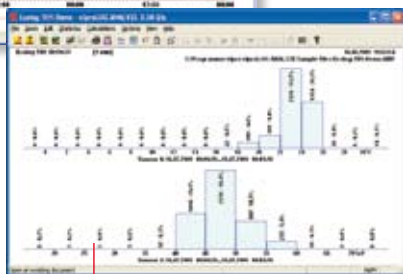- MKT (Mean Kinetic Temperature), Arrhenius calculation

3 REPORT

Create comprehensive reports directly from elproLOG ANALYZE. The software allows you to append comments and notes and it is possible to mark the most important occurrences in the data. Use the installed PDF printer and, at the press of a button, you can generate documentation printouts which contain all the relevant information.

- Tools for commenting and marking data
- Complete reports in PDF format directly from elproLOG ANALYZE
- Possibility of saving data extracts
- Data and graph export function (Excel format)
- E-mail: send data file via E-mail to receiver
- Hardcopy of all screens with print preview
- Status printout with infos about datalogger
- Own company logo on all documents

Tabular display with color-marking to highlight measured values outside alarm limits.

Reporting: Append reports and comments to measured data

Marking points for identification of important occurrences

Graphic display of logged data. The alarm limits configured in the datalogger are shaded red. Statistic functions such as min/max, standard deviation, etc. are available for analyzing measured data.
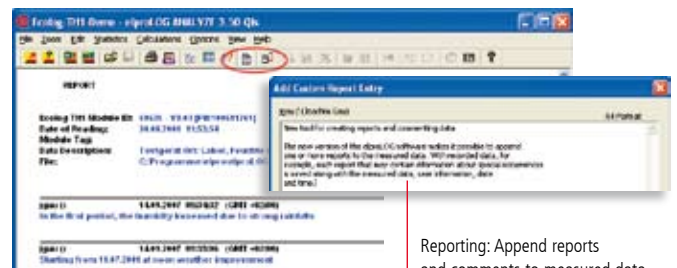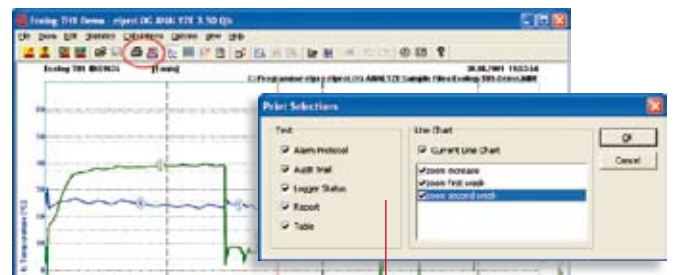
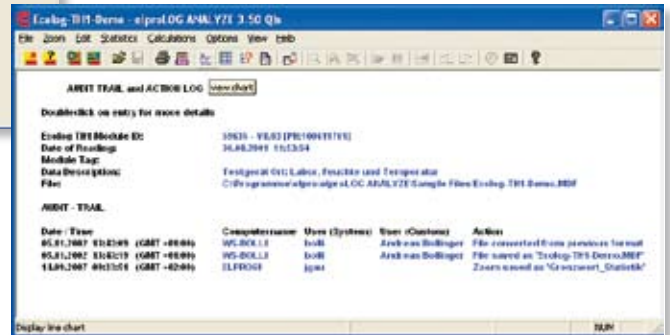Histogram representation of logged data

Reporting: Direct printout of complete, multi-page reports, either directly into a PDF file or to your printer

Report with logo, graphics, marking points and statistics

elproLOG ANALYZE QLS
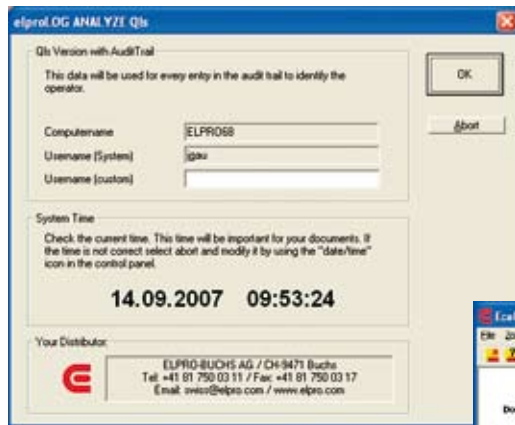
A personal logon is performed at software startup.

All activities related to measured data are recorded in an audit trail.

THE ELPRO QLS QUALIFIED LOGGER SYSTEM

elproLOG ANALYZE QLS is the software package for qualified systems. This software helps you comply with the provisions of FDA 21 CFR Part 11, GMP, GAMP4 and GLP. The detailed validation manual contains IQ/OQ templates for easy software qualification.

elproLOG ANALYZE QLS includes all ANALYZE software functions and implements numerous important tools to facilitate your work in qualified environments. For ELPRO, as for many of our customers, safety and traceability in processes are central issues. Consequently, all ELPRO development complies with GMP specifications. This guarantees the quality and security you expect.

SECURITY FOR VALIDATED ENVIRONMENTS

- **Software validation with ELPRO validation manual for 21 CFR Part 820**
- **Forgery and manipulation protection – coded data transfer from logger to PC**
- **Multipath transmission with check sums**
- **Compact coded data file**

- **Compliance with FDA 21 CFR Part 11**
- **Automatic audit trail creation at data readout**

AUDIT TRAIL

An audit trail is created automatically during data readout from the datalogger. All data-relevant transactions are recorded. Each file generated in this manner is an individual and completely safe document. The raw data (source file) cannot be manipulated. The audit trail is attached to the file which contains the measured values. The resulting electronic document has the advantage of being a completely independent record which can easily be e-mailed or printed at any time.

The advantages of an audit trail solution

- All requirements for electronic documents are in compliance with FDA 21 CFR Part 11.
- You can send the files from any PC.
- Security: The elproLOG ANALYZE QLS software is required to open the generated data files. For this reason, the audit trail function guarantees a complete data security solution.
- Clear, understandable audit trail documents all previous modifications.
- The audit trail cannot be removed from the source file (*.mdf).

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PRACTICE-ORIENTED QUALIFICATION DOCUMENTATION

elproLOG ANALYZE QLS is not just the result of many years of branch-specific software development; it's a complete qualification solution. In combination with the software package, you receive a complete set of qualification documentation which passes on our know-how in the form of guidelines and templates for your qualification process. We take you step by step through the individual stages of the qualification process, saving you time and money.

Qualification Documentation
for elproLOG ANALYZE QLS

QUALIFICATION DOCUMENTS – SUMMARY

With elproLOG ANALYZE QLS you get two binders of valuable qualification documents for your ELPRO datalogging system.

How to use

Our goal is to make the qualification work as easy and smooth as possible for you. Therefore, we included detailed checklists which guide you step by step through the qualification procedure.

Vendor Software Quality

The ELPRO QLS Workbook includes many important information about the GMP compliant product development process at ELPRO. In addition to this, you will find a declaration of compliance to FDA 21 CFR Part 11 and a copy of the ISO 9001 certificate of our company.

Installation Qualification

The installation qualification (IQ) templates contained in the workbook allow an easy qualification, step-by-step. To give you further assistance, you will find a complete IQ, the so-called vendor qualification, enclosed on yellow pages in the workbook.

Operation Qualification

During the operation qualification (OQ) all relevant functions of the elproLOG ANALYZE QLS software are being tested, from the read-out of the data to the report generation. All the qualification steps are listed in clearly laid-out forms to assist you in performing the qualification. And to simplify your work, we have included also here a complete ELPRO vendor qualification.

Software installation

Software installation elproLOG ANALYZE and ANALYZE QLS can be implemented as a stand-alone application or as a network-based solution. It is installed locally on each computer, either from a CD or via the network. Run the software directly from the CD or network drive without performing installation.
An additional license is required for each QLS version installation. It is possible to define a working directory for access to shared data.

Made in Switzerland – for 20 years 🇨🇭

SYSTEM REQUIREMENTS

Operating system: **Win2000, XP, Vista**
PC requirements: **Pentium 1.5GHz**
Memory: **512 MB RAM**

Free memory on HD: **50MB**
Screen resolution: **min. 800x600 pixels**
Interface: **RS232, USB or LAN**

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CH - 9470 Buchs SG
Switzerland
web   www.elpro.com

AVAILABLE PARTS

Part No. 2338-CDV
elproLOG ANALYZE

Part No. 2338-CDU
elproLOG ANALYZE
Update version

Part No. 2335-BL
elproLOG ANALYZE QLS
Base license

Part No. 2335-FL
elproLOG ANALYZE QLS
Additional license

Part No. 2335-BLU
elproLOG ANALYZE QLS
Base license, update version

Part No. 2335-FLU
elproLOG ANALYZE QLS
Additional license, update version

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DIRECTIVES & STANDARDS

ISO 9001: 2000
SGS certificate no. CH98/0013
ATEX
SNCH 01 ATEX 3280/Directive 94/9/EC
EX1, CE 0499
Approval for EX protection zone 1
(EN 50014 and EN 50020)
CE
EN 50081-2 and EN 50082-2
EN12830/EN13485/EN13486
Temperature recorder for transport,
storage and distribution of foodstuffs

GZ1480
Exceptional approval for calibration
GZ1480/2000 from 10.4.2000, BEV,
Austria

INTEGRATED REGULATIONS & RECOMMENDATIONS

GMP/GLP/GAMP 4
Software validation in accordance with
21 CFR Part 820, Electronic Records
21 CFR Part 11, 21 CFR Part 210/211,
21 CFR Part 110, 21 CFR Part 58
EG/EU
Regulation (EC) 37/2005
Directive 2002/95/EC (RoHS)
HACCP
Hazard Analysis Critical Control Points

SERVICE & QUALITY

- ISO 9001 quality system
- Vendor and internal audits
- Expert systems
- Own production and development
- Own calibration laboratory
- Calibration according to all standards
- Customer calibration service
- Modern facilities
- Datalogger service since 1989
- Repair service
- IQ/OQ qualifications
- Temperature mapping service
- Worldwide distributors
- Return of ELPRO instruments and batteries
  for eco-friendly disposal

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