

Software Overview

Most instruments produced by ROTRONIC feature a practical bi-directional interface for instrument configuration, the display of measured data and the download of recorded measurements from data loggers. Software is developed and maintained in-house at ROTRONIC by a skilled team of software developers, which ensures optimum performance with fast and competent support.

Since Rotronic first supplied PC compatible instrumentation, we have received many customer requests for new features and enhancements. The feedback we receive is always considered when we are developing our software. Together with the new HygroLog NT, HW4 software is a new development, with most features suggested by our customers. HW4 is probably the most comprehensively featured and user friendly package on the market today.

It is impossible to detail the functionality of HW4 here. We have prepared a free trial version for your convenience. Visit <http://www.rotrotron.ch/link/hw4>

HW4 Software overview

| Software type | Application | Functionality |
|---------------------------------|---|--|
| HW4 Trial Product key 05 xxx | Trial version | Full functionality of the Professional Edition, including OPC functions. Limited trial period of maximum 30 days. |
| HW4 -E Product key 24 xxx | Single instrument applications | For users with single instrument applications. Display of an unlimited number of loggers and their respective measurement values, one at a time. Monitoring, data logger programming, data retrieval, scaling, device settings, alarming, service and configuration tool for ROTRONIC devices, date/time synchronisation, adjustment and calibration of ROTRONIC probes. No password protection. |
| HW4 -P Product key 64 xxx | Networked applications in the pharmaceutical and food industry | All functions of the Standard Edition. Compliant with the requirements regarding electronic records and signatures (21CFR Part 11, EC appendix 11). Networking, grouping of devices, graph overlays, printing of protocols. |
| HW4-OPC Product key 88 xxx | Networked applications with integration in customer's software programs | All functions of the Professional Edition. Contains an OPC server by which data can be integrated in customer's own software such as SCADA, LIMS and BMS software. |
| HW4-VAL Product key 12 xxx | For users who are subject to regulatory requirements. (GxP) | Same as HW4 OPC. In addition, the "HW4 e-compliance package" is delivered. This substantial documentation supports the regulated user in qualification / validation of HW4-based solutions. |
| HW3 Product key 24 xxx | Software for the older devices such as HygroLog and HygroLog D | Programming of the older generation of data loggers, water activity instruments etc. Aw Quick function, display of measurement values and monitoring of max. 32 devices. Programming of HygroClip Alarm. |

Qualification / Computerized System Validation

Many ROTRONIC customers have come to depend on the accuracy and reliability of our humidity and temperature measurement systems. The advent of PC compatible products for measurement display and display archiving, as well as instrument configuration and maintenance, has opened many new application possibilities. In many high value and critical applications, accurate measurement is only part of the story. Data integrity and security is today an essential requirement, and many customers in the pharmaceutical and food industries must prove that their data is reliable and accurate. For this purpose software must be validated. ROTRONIC understands these requirements and provides solutions to our customers. The validation and compliance declaration, ERES white paper regarding electronic records and signatures as well as document templates for the system validation are available. Of particular importance is the fulfilment of the requirements of GxP and "E-compliance".

21 CFR Part 11:
Guideline of the American Food and Drug Administration (FDA). Specifies the requirements regarding the handling of electronic records and signatures.

EU-Annex 11:
Annex 11 regarding computerized systems to the "EU-Guidelines of Good Manufacturing Practice for Medicinal Products" Specifies the requirements regarding the use of computerized systems in GxP processes.

GxP:
Good "x" practice, where "x" means: Clinical (C), Distribution (D), Laboratory (L), Manufacturing (M).

PIC/S:
Guidance PI-011-2 "Good Practices for Computerized Systems in regulated GxP environments". Gives the "regulated user" instructions regarding the basic requirements for the use of computerized systems in GxP processes.

Electronic Records:
Electronic recording of measurement data, events and configuration parameters.

Electronic Signature:
Electronic signatures are signatures in digital form that allow the identification of users and devices when used with HW4 software.

Audit Trail:
System control routine which allows the tracking of data entry or processing of files to their origins. (APV).

Feature Overview



Connect handheld instruments for configuration, calibration, display and to record measured values.



Connect transmitters for configuration, calibration, measurement display and data acquisition.

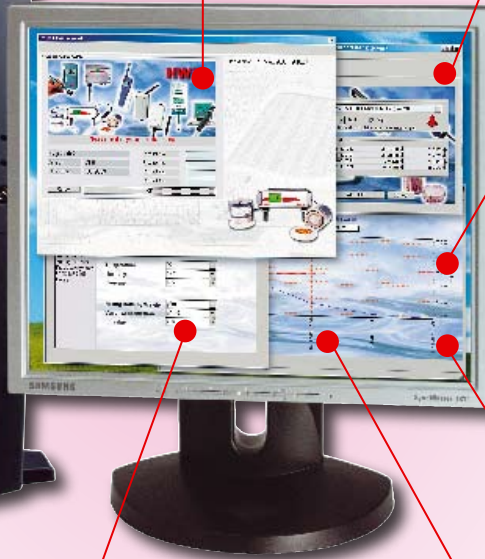
Validated software
FDA 21 CFR Part 11
compliant.



Program data loggers
and download data.



Monitoring and display of water activity measurements including accelerated analysis and automatic data capture.



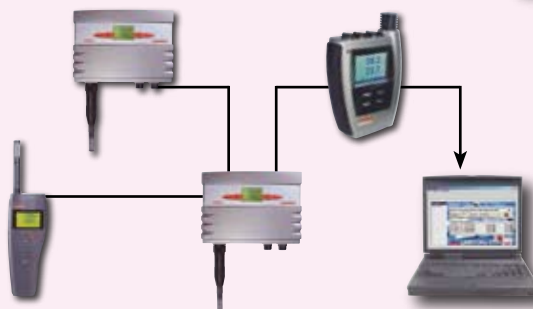
Display measured values from a network of HygroFlex or HygroLab instruments.



Setting and notification of alarms, audible, visual, SMS or e-mail.



Control the calibration and adjustment of digital probes, including production of calibration certificates.



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Software Overview

Functions overview

| All versions of HW4 support HygroLogNT, HygroFlex, HygroLab, HygroPalm, M33, IOEM and future devices. HW3 supports HygroLab Aw-Quick, HygroLog D, HygroWin, MOK-WIN, M1, HygroClip Alarm. All software versions are multilingual. | HW4-E | HW4-P | HW4-OPC | HW4-VAL | HW3 |
|---|-------|-------|---------|---------|--------|
| Measurement data / monitoring | | | | | |
| Scope presentation of measurement values for single and multiple devices | X | X | X | X | X |
| Scope presentation of an unlimited number of measurement values | X | X | X | X | Max.32 |
| Scope presentation of measurement values in groups | | X | X | X | |
| Comparison and overlay of measurement values of different groups | | X | X | X | |
| ROTRONIC networkable (unlimited number of devices) | | X | X | X | |
| Data storage | | | | | |
| Automatic storage of measurement data (monitoring) | X | X | X | X | X |
| New file creation period freely selectable | X | X | X | X | X |
| Presentation of measurement data | | | | | |
| Numerical and graphical presentation | X | X | X | X | X |
| Graphical comparison and overlay function | | X | X | X | |
| Graphic tools and alarm display | X | X | X | X | |
| Process display (01/2007) | | X | X | | |
| File format / data handling / Export functions | | | | | |
| Protected file format (Binary) and export to text format | X | X | X | X | |
| Text format | X | X | X | X | X |
| Analyse and calculations tool | | | | | |
| Psychrometric calculations X | X | X | X | X | |
| Statistics | X | X | X | X | |
| Printing / protocols | | | | | |
| Automatic creation of adjustment, calibration and configuration protocols | | X | X | X | |
| Numerical and graphical print out of measurement data | X | X | X | X | X |
| Users and passwords | | | | | |
| Password protection | | X | X | X | X |
| User and user rights freely selectable | | X | X | X | |
| Alarms | | | | | |
| Visual presentation of active alarms | X | X | X | X | X |
| Alarming via e-mail, SMS | | X | X | X | X |
| Alarm thresholds and alarm events freely definable | | X | X | X | |
| Alarm acknowledgment | | X | X | X | |
| Alarming: visual, by relays, printing of alarm report | | X | X | X | |
| OPC Server (OLE for process control) | | | | | |
| Server client functionality | | | X | X | |
| Electronic records, electronic signatures, audit trail (ERES) | | | | | |
| Registration of all HW4 user events and automatic creation of protocols | | X | X | X | |
| Detection and tracking of manipulations granted at any time | | X | X | X | |
| Tracking by protocols of all alarms and manipulations | | X | X | X | |
| Self event logging | | X | X | X | |
| Automatic electronic signature on all text files (protocols etc.) | | X | X | X | |
| Standards, Laws, Guidelines, Directives | | | | | |
| US FDA: 21 CFR 11 | | X | X | X | X |
| US FDA: 21 CFR 210-211, Drugs and 21 CFR 110, Human Food | | X | X | X | |
| EU Guidelines of Good Manufacturing Practice of Medicinal Products | | X | X | X | |
| EU Annex 11 to the EU Guidelines of Good Manufacturing Practice of Medicinal Products | | X | X | X | |
| Pic/s Guidance PI-011-2 "Good Practices for Computerized system in Regulated GxP" environments | | X | X | X | |
| GAMP 4 guide Validation of Automated Systems | | X | X | X | |
| GAMP Good Practices Guide "A Risk - Based Approach to Complainant Electronic Records and Signatures" | | X | X | X | |
| Validation | X | X | X | X | X |
| System Qualification Guide CD (English) | | | | X | |
| White Paper conformity | | | | X | |
| Qualification report | | | | X | |
| ERES assessment | | | | X | |
| System validation guide | | | | X | |
| System validation test report | | | X | | |
| Instruction manual: Software and all associated devices | | | | X | |
| Inspected by external supervisor | | | | X | |


Software Overview

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| | HW4-E | HW4-P | HW4-OPC | HW4-VAL | HW3 |
|---|-------|-------|---------|---------|-----|
| Help | | | | | |
| Documentation, guidance | X | X | X | X | X |
| Online help, remote maintenance, Internet download and update information | X | X | X | X | |
| Supported interfaces | | | | | |
| USB, Ethernet, WLAN, Bluetooth, modem connection | X | X | X | X | |
| RS232 | X | X | X | X | X |
| RS485 | | X | X | X | X |
| OPC | | | X | X | |
| Diverse auto functions | | | | | |
| Autostart | X | X | X | X | X |
| Automatic file retrieval and archiving of logged data (04/2006) | | X | X | X | |
| Device specific functions | | | | | |
| Device settings, scaling, programming, data retrieval, monitoring, data logger function | X | X | X | X | X |
| Monitoring, alarming, servicing and configuration of ROTRONIC devices | X | X | X | X | X |
| Adjustment and calibration of ROTRONIC probes | X | X | X | X | X |
| Date / Time synchronisation X | X | X | X | | |
| Supported operating systems | | | | | |
| Microsoft Windows 95, 98, ME, NT, 2000 | | | | | X |
| Microsoft Windows NT4 (SP6a), 2000, XP, Server 2003, or better | X | X | X | X | |
| Central software management, multi-user compatible | X | X | X | X | |

Validation

All versions of HW4 are validated and controlled by an external body.



COMPLIANCE DECLARATION
DV04-30.787.01-1

for
 Software
 HW4 version 1.2.1.14714
 physical devices
 HygroLogNT: firmware release 1.2
 HygroFlex, HygroLab, HygroPlam, HygroMid: firmware release 4.0

We attest that the validated version of the rotronic HW4 software and associated devices fulfill the requirements defined in the rotronic ERES White Paper, version 1.0, based on the following paragraphs:
 21 CFR Part 11
 21 CFR 110
 21 CFR 210-211
 EU Annex 11

validated by ROTRONIC Instrument Corp.
 Inspected by Kereon AG,
 December 2005

The HW4 software and devices have been reviewed against the specifications and the ERES White Paper, version 1.0, in order to provide evidence that the above mentioned regulations are fulfilled accordingly. The measuring devices and the software have been validated and verified against the specifications provided by the manufacturer.

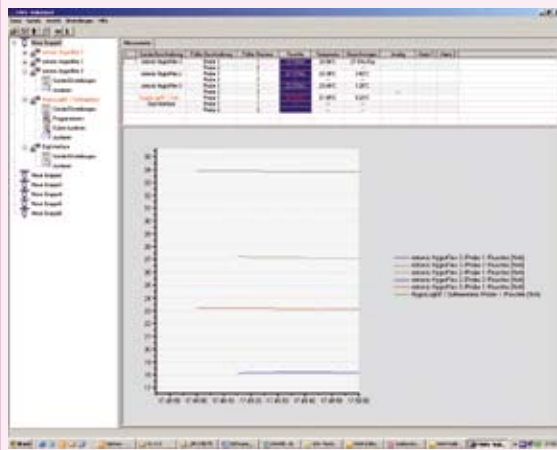
Inspected by Yves Samson
 Kereon AG

Accepted by the manufacturer
 ROTRONIC AG

HW4 Functions

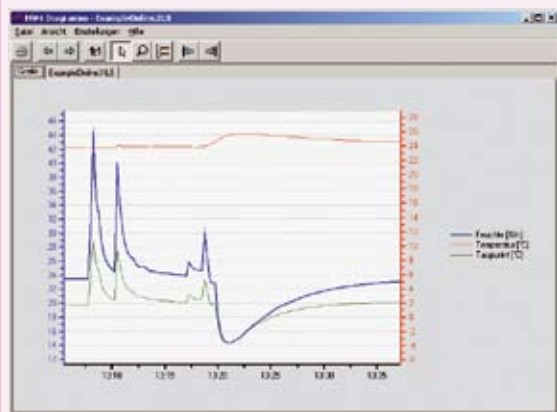
Viewing of measurement values / monitoring

Viewing of measurement values is very easy and user-friendly. Files of any device present in the device tree may be directly copied to a PC and opened by the HW4 explorer. Data is presented either in graphical mode or as a table. In the online monitoring mode, both a table and graph are displayed.



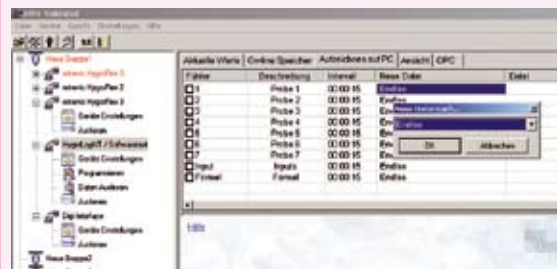
Presentation of measurement values

The measurement values may be displayed as a graph or in table form. The graph module may be configured by the user.



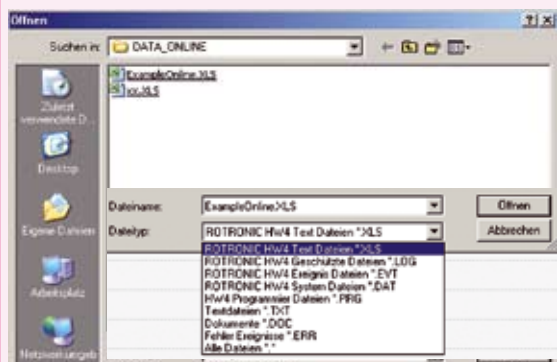
Archiving measurement data

Measurement data can be automatically written into different files. The user may configure the system to create a new file e.g. every month or after 200,000 measurements.



File formats / handling data / export functions

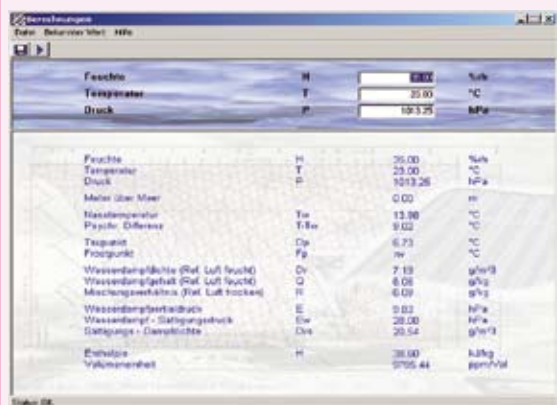
The file format may be determined by the user. For log files, the formats .xls and .log are available. The .LOG format saves the data in a binary format, which can be read by HW4 only, while the .XLS formatted files can be opened by a standard editor or MS Excel. Data may be exported.



Psychrometric calculations tool

All ROTRONIC instruments measure percentage relative humidity (%rh) and temperature (°C/F). From the two values it is possible to calculate other psychrometric values such as dew point, frost point, wet bulb temperature, mixing ratio, absolute humidity, enthalpy, partial water vapour pressure, saturation vapour pressure and more. The calculation software in HW4 uses WMO* verified formulae to make these calculations, and also provides the user with the option to input their own parameters (e.g. input mixing ratio and temperature to calculate %rh). Other advanced options such as dew/frost differentiation, and pressure or altitude compensation are included.

* World Meteorological Organisation



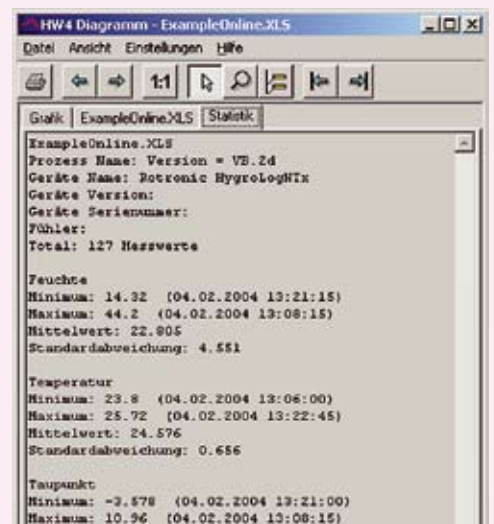
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Statistical functions

The detailed log data, which may be considerable, is of little interest for many users. For them, it is only important whether or not the values were within certain ranges during the period of interest. The statistical functions allow a fast overview.

The statistics will show the following values:

- Minimum
- Maximum
- Average
- Standard deviation
- Number of measurements



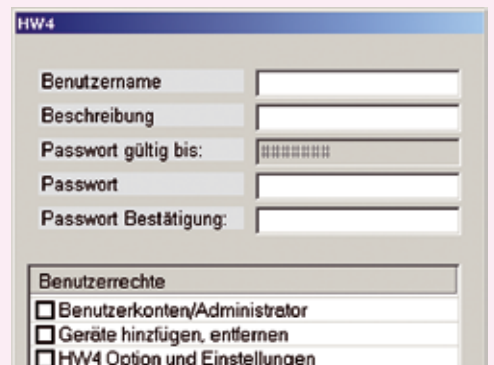
Printing /protocols

If so desired, protocols may be printed. The user may determine whether the standard editor or MS Word should be used for that purpose.



Users and passwords

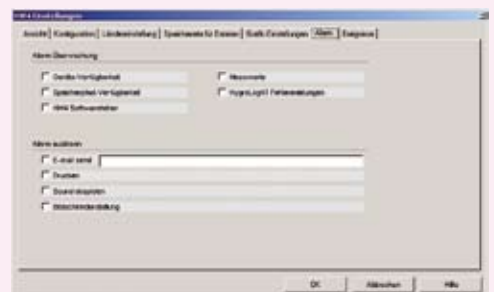
User name and passwords may be assigned freely. Each user may be assigned different rights. Users that have been deleted cannot be created under the same name.



Alarms

When in monitoring mode, HW4 can trigger an alarm when predefined conditions prevail. An alarm condition may be present when a device or file storage path is not available, a software error happens, measurement values exceed defined ranges or a logger sends an error message.

Alarms can be displayed on the screen, printed out or forwarded by e-mail. Mails can be sent to single or multiple recipients.



OPC Sever (Object Linking and Embedding for Process Control)

HW4-OPC features an OPC Server which enables the data integration into superior software.

| aktuelle Werte | On-line Speicher | Aufzeichnen auf PC | Ansicht | OPC |
|----------------------------|------------------|---|---------|-----|
| <input type="checkbox"/> 1 | DeviceInfo | Tags mit Geräteinformationen | | |
| <input type="checkbox"/> 2 | MeasuringInfos | Tags mit allen Messwerten | | |
| <input type="checkbox"/> 3 | Alert | Tags mit Geräte-, Software- und Fühleralarmen | | |
| <input type="checkbox"/> 4 | File | Tags für Dateidownload | | |