

SOFTWARE



SOFTWARE OVERVIEW

The new ROTRONIC devices are equipped with a practical interface for configuration of the devices and for the display and recording of data. The ROTRONIC HW4 software is one of the most comprehensive and user-friendly validated software packages available on the market today. It is not possible to describe the functionality of the software in full detail here.

A free trial version can be downloaded on the Internet from: www.rotronic-humidity.com

HW4 TRIAL Trial version

- Product key: 05 xxx
- Full functionality of the Professional Edition, including OPC functions
- Limited trial period of max. 30 days

HW4-E Single-user applications

- Product key: 24 xxx Standard Edition
- Display of an unlimited number of loggers and measured values
- Monitoring (one device at a time), data logger programming, data retrieval, scaling, device settings, alarm function, service and configuration tool for ROTRONIC devices, date/time synchronisation, adjustment and calibration of ROTRONIC probes
- No password protection

HW4-P Networked applications in the pharmaceutical and food industries

- Product key: 64 xxx Professional Edition
- All functions of the Standard Edition
- Fulfills the requirements for electronic data records and signatures (FDA 21 CFR Part 11, Annex 11)
- Grouping of devices, graph overlays, printing of reports

HW4-OPC Networked applications with integration in customer's software programs

- Product key: 88 xxx
- All functions of the Professional Edition
- Contains an OPC server with which the data can be integrated into the customer's own software

HW4-VAL For users subject to regulatory requirements (GxP)

- Product key: 12 xxx
- As HW4 OPC
- Includes «HW4 e-compliance package». This comprehensive documentation tool supports the user in the qualification/validation of HW4-based solutions

QUALIFICATION / COMPUTERISED SYSTEM VALIDATION

Data integrity and security are of essential importance today. Companies in the food, pharmaceutical and medical technology industries must prove that their data are measured and managed reliably. For this they need software and devices that can be validated. Combining ROTRONIC's HW4-compatible devices and HW4 software, ROTRONIC supplies a solution in which validation plays a central role. The devices and software are validated and compatible with FDA 21 CFR Part 11 (directive of the US Food and Drug Administration, FDA) and GxP.

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COMPLIANCE DECLARATION

DV04-30.787.03-1_11

for

Software

HW4 VERSION 2.0.1.15990

Physical devices

HYGROLOGNT: FIRMWARE RELEASE 1.2

DOCKING STATIONS FOR THE HYGROLOG NT:

DS-NT4, DS-NT4-WL, DS-U1; DS-U2, DS-U4, DS-U4-4-4-20, DS-U4-WL: v 1.4

DS-PT2, DS-PT4, DS-PT4-WL: v1.1

DS-R1 : v1.0

DS-U4WEB : v1.0

HYGROFLEX, HYGROFLEX M, HYGROLAB, HYGROPALM, M23, M33: FIRMWARE RELEASE 4.0

HYGROCLIP DI FIRMWARE VERSION 1

HYGROCLIP ALARM FIRMWARE VERSION 2

HYGROSTAT MB FIRMWARE VERSION 1

We attest that the validated version of the Rotronic HW4 software and associated devices fulfil the requirements defined in the Rotronic ERES White Paper, version 2.0, based on the following paragraphs:

21 CFR PART 11

21 CFR 110

21 CFR 210, 21 CFR 211

EU ANNEX 11 TO THE

EU GUIDELINES OF GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS

validated by ROTRONIC Instrument Corp.

Inspected by Kereon AG,

August 2007

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 MEASURED VALUES/MONITORING

Viewing of measured values is very easy and user-friendly. Files of any device shown in the device tree can be copied and opened directly with the HW4 explorer. The data is presented as required in either table or graph form. Both the table and the graph are shown for online monitoring.

The graph module can be configured by the user.

FILE FORMATS/HANDLING OF DATA/EXPORT FUNCTIONS

The file formats can be defined by the user. The formats .xls and .log are available for log files. The .log format saves the data in a binary format that can only be read by HW4, while the .xls format can be opened with an editor or Excel. The data can also be exported in other formats.



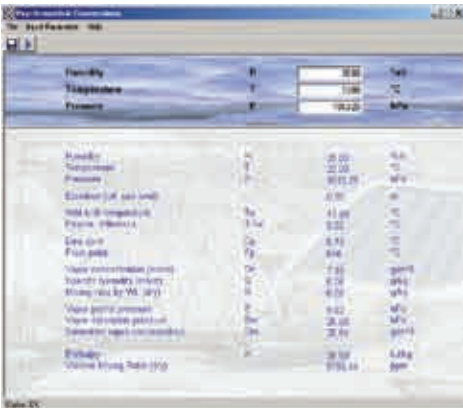
ARCHIVING OF DATA

The data can be written automatically into different files. For example, the user can configure the system to create a new file every hour, day, week, month or after 200,000 measurements.

ANALYSIS AND CALCULATION TOOL/PSYCHROMETRIC CALCULATIONS

All ROTRONIC devices measure relative humidity in %rh and temperature in °C/°F. These two values can be used to calculate other psychrometric values such as dew point, mixing ratio, enthalpy and wet-bulb temperature. The calculation module of the HW4 software uses WMO* verified formulas for these calculations and allows the user to define their own parameters (e.g. mixing ratio ratio & temperature) as input values in order to calculate the relative humidity from them. Other advanced options such as dew/frost point differentiation are also included.

* WMO = World Meteorological Organisation



STATISTICAL FUNCTIONS

For many users detailed data, which can be very extensive, is not necessarily of much interest. For them it is merely important that the measured values lie within a certain range. This is the role of the statistical function. It shows the following values:

- Minimum
- Maximum
- Mean
- Standard deviation
- Number of measured values
- Mean kinetic temperature

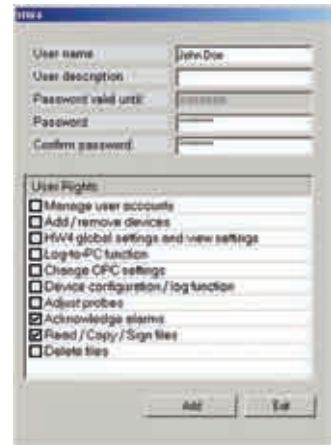


PRINTING OF REPORTS

If required, reports can be printed as desired or copied into other software for reporting, emailing etc.

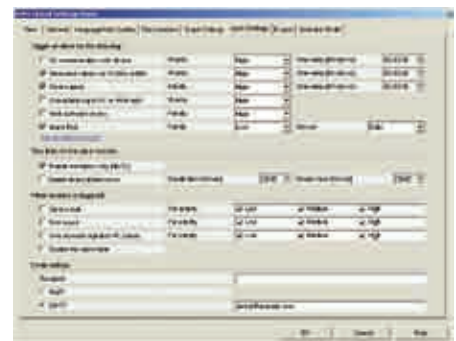
USERS AND PASSWORDS

User names and passwords may be assigned freely (HW4-P). Every user can be granted different rights. Users that have been deleted cannot be recreated under the same name.



ALARMS

In monitoring mode HW4 can trigger an alarm when certain events occur. Such an event can be when a device or a file storage path is not available, when a software error occurs, when measured values lie outside defined limits or when a data logger sends an error message. The alarms can be shown on the screen and/or printed out. Audible alarms are also possible. HW4 is even able to send an e-mail to one or more recipients (HW4-P).



OPC*SERVER

HW4-OPC contains an OPC server with which the measured values can be integrated into the customer's own software.



* Object Linking and Embedding for Process Control