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
- Fulfils 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.

rotronic

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   Accepted by the manufacturer
Kereon AG   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.
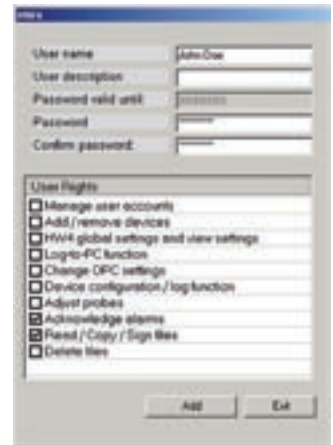
ALARMS

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.
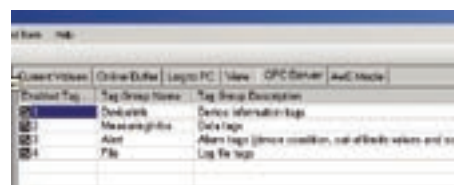
* Object Linking and Embedding for Process Control

CALIBRATION

Even though ROTRONIC probes have excellent long term stability , we recommend that they have their calibration checked regularly. One calibration per year normally suffices. Some of our customers calibrate their probes more often; the range of calibration intervals extends from once a year to calibration before every measurement – depending on internal quality assurance rules.

The long term stability of ROTRONIC probes is better than 1%rh per year under normal conditions. Normal conditions exist when the concentration of contaminants/pollutants in the air does not exceed maximum allowable concentration (MAC) levels.

Why is calibration essential?

Many companies today work to ISO 9000 standards and are therefore obligated to calibrate their measuring equipment on a regular basis. Regulatory authorities such as the US FDA, EMA, Swissmedic, etc. also demand that devices be calibrated with traceability to national standards. In some situations, internal company quality standards may also specify that a specific measurement uncertainty must be demonstrated and that this must be verifiable at all times. It is therefore in the interest of every user to have equipment calibrated and adjusted regularly in order to obtain the best-possible quality. We offer calibration devices for all our probes. We can even supply you with suitable devices for calibration of probes from other manufacturers. Our competitors trust our humidity standards. Please contact us regarding custom-made products.

Accredited calibration laboratory for humidity and temperature SCS 065

As a calibration laboratory accredited by METAS (Metrology and Accreditation Switzerland) for the parameters of relative humidity and temperature, we can offer you calibration services and Swiss Calibration Service (SCS) certificates in conformity with the national standard. Accreditations and certificates are acknowledged reciprocally by most national organisations (ILAC – MRA).

SCS* HUMIDITY STANDARDS

ROTRONIC humidity standards are delivered in packs of five ampoules of the same humidity value. Every ampoule is marked with its humidity value and a serial number. The most frequently used values are 35 and 80 %rh, which are used for two-point calibrations. All ampoules except for the 0 %rh standard contain an unsaturated salt solution; the 0 %rh standard consists of a highly porous molecular sieve. An SCS certificate documenting traceability to national standard and specifying the uncertainty of the humidity standard is enclosed with every pack. The different national agencies for metrology recognise each others' certificates reciprocally through the ILAC Mutual Recognition Agreement. As a result, an instrument calibration certificate from Switzerland (SCS) is accepted worldwide by local certification bodies.

Order information		
Order code	Humidity value	Uncertainty at 23 ± 2°C
EA00-SCS	0.5 %rh	± 0.1 %rh
EA05-SCS	5.0 %rh	± 0.1 %rh
EA10-SCS	10.0 %rh	± 0.3 %rh
EA11-SCS	11.3 %rh	± 0.3 %rh
EA20 SCS	20.0 %rh	± 0.3 %rh
EA35-SCS	35.0 %rh	± 0.5 %rh
EA50-SCS	50.0 %rh	± 0.9 %rh
EA65-SCS	65.0 %rh	± 0.9 %rh
EA75-SCS	75.3 %rh	± 0.9 %rh
EA80-SCS	80.0 %rh	± 1.2 %rh
EA95-SCS	95.0 %rh	± 1.2 %rh

Other values on request

DPH 911
Reference dew point mirror for certification of SCS* humidity standards

PROBE CALIBRATION BY SOFTWARE AND CALIBRATION INTERFACE

ROTRONIC probes can be calibrated and adjusted via the connected instrument with either an integrated keypad or a calibration interface to a PC running HW4 software.

* SCS: Swiss Calibration Service

CALIBRATION DEVICES

ROTRONIC calibration devices are small, airtight chambers that precisely fit ROTRONIC probes. The lower part of the device consists of a screw-on lid into which the humidity standard is poured onto an absorbent textile pad. The specified humidity is generated in the calibration device after a stabilisation period of 30...180 minutes. The probe can then be calibrated or adjusted in comparison with the reference value of the humidity standard.

We can also supply calibration devices suitable for other manufacturers probes, provided they are cylindrical, and have a leak proof construction. Ask us for a recommendation!

Calibration devices perform at their best only if they are properly maintained. Wash the calibration devices carefully after use, and let them dry. Make sure that no salt deposits form inside the device or threads, as this may cause errors. Worn O-rings should be replaced.

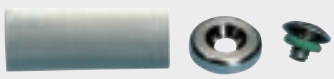| Order code	Use		Order code	Use	
Push-on calibration devices. Gasket with O-ring and thumb screw					
ER-15	For 1 probe Ø 14...15 mm Brass, nickel-plated		ERV-15	For 1 probe Ø 14...15 mm Vertical calibration position Brass, nickel-plated	
EDM 15/15	For 2 probes Ø 14...15 mm Brass, nickel-plated		EGL	For 1 probe Ø 10 mm Brass, nickel-plated	
ER-05	For 1 probe Ø 4...5 mm Brass, nickel-plated		ER-18K	For 1 probe Ø 18 mm Brass, nickel-plated	
ER-20K	For 1 probe Ø 20 mm Brass, nickel-plated		ER-10-MS	For 1 probe HF3x, L1x-S, M1x-S series Vertical calibration position Aluminium, anodised	
Screw-on calibration devices. Gasket with seal face on probe. Cannot be used for HC2-S probes					
EDM 15/25	For 2 probes 1 x Ø 15 mm (M12 x 1.5) 1 x Ø 25 mm (PG11) Brass, nickel-plated		EM-15	For 1 probe Ø 15 mm (M12 x 1.5) Brass, nickel-plated	
EM-25	For 1 probe Ø 25 mm (PG11) Brass, nickel-plated		EMV-15	For 1 probe Ø 15 mm (M12 x 1.5) Vertical calibration position Aluminium, anodised	
EMV-25	For 1 probe Ø 25 mm (PG11) Vertical calibration pos. Aluminium, anodised		EM-G	For probe types E, HP...IE... Screw-on probes (½"G)	
Calibration devices for special probes					
EBFC	For plate probes Types BFC & BFC-DIO Aluminium, anodised		WP14-S	For bell probes: AWD, AWVC, AW-DIO Stainless steel, DIN 1.4401/POM	
EGS	For all sword probes Aluminium, anodised				

ACCESSORIES

FILTERS

We have a range of filters available for optimum protection of the sensors. By choosing the right filter, you will obtain optimum performance regarding sensor protection and probe response times.

Technical data and order information for filters			
Order code	Probe	Material / Filter carrier	Filter element
NSP-PCB-PE **NSP-PCB-PE40** **NSP-PCB-WM** **NSP-PCB-TF**	HC2-S	Polycarbonate, black	Polyethylene, grey Polyethylene, white Wire mesh Teflon
NSP-PCW-PE **NSP-PCW-PE40** **NSP-PCW-WM** **NSP-PCW-TF**	HC2-S3	Polycarbonate, white	Polyethylene Polyethylene, white Wire mesh Teflon
NSP-PCG-PE **NSP-PCG-WM**	HF3x	Polycarbonate, grey	Polyethylene, grey Wire mesh
NSP-ME-WM	HC2-IC probes	Filter carrier, nickel-plated brass, HC2 thread	Wire mesh DIN 1.4401
NSP-ME-SS	HC2-IC probes	Filter carrier, nickel-plated brass, HC2 thread	Sintered steel DIN 1.4401
NSP-ME-TF	HC2-IC probes	Filter carrier, nickel-plated brass, HC2 thread	Teflon
SP-MC15	HC2-IM and HC2-IE probes	Filter carrier, nickel-plated brass, HC1 thread	Wire mesh DIN 1.4401
SP-SC15	HC2-IM and HC2-IE probes	Filter carrier, nickel-plated brass, HC1 thread	Sintered steel DIN 1.4401
SP-TC15	HC2-IM and HC2-IE probes	Filter carrier, nickel-plated brass, HC1 thread	Teflon
SP-T05	H2C-C05	Filter	Teflon
ET-Z10	HC2-HP28/50	Steel sinter filter, DIN 1.4401	

Technical data and order information for filter spare parts

Order code	Probe	Material / Filter carrier	
NSP-ME	HC2-IC probes	Filter carrier, nickel-plated brass, for HC2-IC probes Order filter element separately	
SP-MSB15	HC2-IM and HC2-IE probes	Filter carrier, nickel-plated brass, for HC2-IM/IE probes Order filter element separately	
SP-M15	All industrial probes	Wire mesh filter For use with NSP-ME or SP-MSB15	
SP-S15	All industrial probes	Steel sinter filter For use with NSP-ME or SP-MSB15	
SP-T15	All industrial probes	Teflon filter For use with NSP-ME or SP-MSB15	

Passive connection cables

Order code	Use / Info	Description	Range of application
E2-XX	For OEM applications, panel connection	Connector plug for HygroClip2 probes, 30 cm connection wires, open ends	Max. 100 °C
E2-F3A	To separate probes from devices with self-heating	0.3 m extension cable for HygroClip2 probes, plug/socket. Colour: anthracite	Max. 100 °C
E2-nnA	For nn = 01, 02, 05	Extension cable for HygroClip2 probes, plug/socket. Colour: anthracite, nn = length in m	Max. 100 °C
E3-F3A	To separate probes from devices with self-heating	0.3 m extension cable for HygroClip2 probes, plug/socket. Colour: white	Max. 100 °C
E3-nnA	For nn = 01, 02, 05	Extension cable for HygroClip2 probes, plug/socket. Colour: white, nn = length in m	Max. 100 °C
E2-nnXX	For OEM applications Max. supply voltage: 5.2 VDC For nn = 01, 02, 05	Connection cable for HygroClip2 probes, open ends, tin-plated. Colour: anthracite nn = length in m	Max. 100 °C
E3-nnXX	For OEM applications Max. supply voltage: 5.2 VDC For nn = 01, 02, 05	Connection cable for HygroClip2 probes, open ends, tin-plated. Colour: white nn = length in m	Max. 100 °C
Connection cables with voltage regulator			
E2-nnXX-ACT	Supply voltage 5...24 VDC / 5...16 VAC For nn = 01, 02, 05	Adapter cable for HygroClip2 probes, open ends, tin-plated. Colour: anthracite nn = length in m	Max. 70 °C
E3-nnXX-ACT	Supply voltage 5...24 VDC / 5...16 VAC For nn = 01, 02, 05	Adapter cable for HygroClip2 probes, open ends, tin-plated. Colour: white nn = length in m	Max. 70 °C

Technical data and order information			
Extension cable for Pt100 probes			Range of application
AC1607/nn	nn = length in m For nn = 01, 02, 03,05, 10, 15, 20	Extension cable for Pt100 probes	Max. -40...90 °C
Active connection and converter cables			
AC3001	Replaces MOK-xx-WIN Requires AC adaptor AC1207	Active converter cable for HygroClip2 probes for direct USB connection to a PC	Max. 70 °C
AC3002	Replaces MOK-xx-WIN	Active converter cable for HygroClip2 probes for direct RS232 connection to a PC	Max. 70 °C
AC3003	Signal amplifier set for HygroClip2 probes	Enables cable lengths between probe and transmitter of up to 100 m	Max. 70 °C
AC3005	Connects HygroClip2 probes to an Ethernet network. Requires AC adaptor AC1211	For direct connection of a HygroClip2 probe to a TCP/IP network (Ethernet)	Max. 70 °C
AC3006	Connects AirChip3000 devices to a PC / HW4	Service cable, converts the UART signalto USB	Max. 70 °C
AC3007	For direct RS232 connection Requires mains adapter AC1207 (9 VDC)	Active converter cable for AC3000 devices Mini USB service interface to RS232	Max. 70 °C
AC3009	Active converter cable for AC3000 devices	Mini USB service interface to USB	Max. 70 °C
AC3010	For direct connection of networkable AirChip3000 devices in operation without master	USB to RS485 converter Cable with open ends	Max. 70 °C

Standard cables		
AC0001	Standard Ethernet patch cable, 3 m, RJ45	
AC0002	Standard USB A/B cable, 1.8 m	
AC0003	Standard USB A to Mini USB cable, 1.8 m	
AC0004	Standard RS232 cable, 1.8 m, 9-pin, male/female	
AC0005	Crossover Ethernet patch cable, 3 m RJ45	

Mains adapters and card readers		
AC0100	For HygroLog NT flash cards	Universal card reader	
AC1207	For active adapter and converter cables	Mains adapter RNG 11, 9 V / 200 mA, 3.5 mm stereo jack, tip +	
AC1211	For HygroLog NT / docking stations	Mains adapter 240 VAC ◊ 12 VDC	
AC1212	For HP2x series	Mains adapter 240 VAC ◊ Mini USB	
AC1213	For power supply via RS485	Power supply unit 85-264 VAC / 15 VDC, 100 W, DIN rail mounting	

Technical data and order information			
Mounting hardware			
AC5001	Adapter for 15 mm probes to 25 mm holes	25/15 mm probe adapter to HF4X and HF5X	
AC5002	For mounting of HF4x, HF5X, HF6X, transmitters on top hat rail	Mounting kit for DIN top hat rail (2 pc.)	
AC5003		Gasket for internal Ethernet interface	
AC5004	HF4, HF5, HF6, HP2X	Cover for service interface	
AC5005	For temperatures ‹100 °C	Mounting flange for 15 mm probes	
AC1301-M	For temperatures to 100 °C Perbunan gasket, M20 x 1.5 Brass, nickel-plated	Mounting gland for 15 mm probes	
AC1301-MEX	Ditto, for HygroClip EX probes	Mounting gland for 15 mm probes	
AC1302-M	For temperatures to 100 °C Perbunan gasket, M32 x 1.5 Brass, nickel-plated	Mounting gland for 25 mm probes	
AC1303-M	For temperatures to 200 °C Perbunan gasket, M20 x 1.5 Brass, nickel-plated	Mounting gland for 15 mm probes	
AC1304-M	For temperatures to 200 °C Perbunan gasket, M32 x 1.5 Brass, nickel-plated	Mounting gland for 25 mm probes	
AC1305	Ø 80 mm, steel, nickel-plated	Mounting flange for AC1301-M and AC1303-M	
AC1306	Ø 80 mm, steel, nickel-plated	Mounting flange for AC1302-M and AC1304-M	