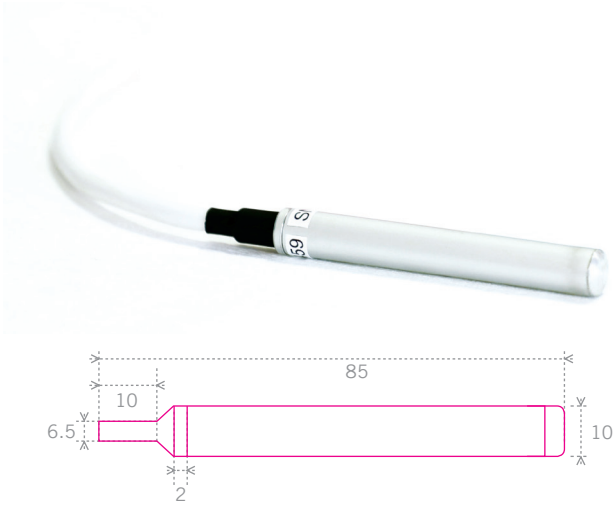
pharmalogger

COOL CHAIN
CHAIN OF CONFIDENCE



DATASHEET: PHARMALOGG PROBE TRH-40125
HUMIDITY AND TEMPERATURE PROBE

- Temperature range from -40 °C to +125 °C
- Relative humidity range from 0% to 100%
- Fully calibrated with 1.8%RH accuracy
- Fully calibrated with 0.2 °C accuracy
- Digital output, I2C interface
- Low power consumption
- Excellent long term stability

PHARMALOGG PROBE THR-40125 is humidity and temperature sensor of AliusGrupa d.o.o. is about to set new standards in terms of size and intelligence.
With a completely new designed CMOSens® chip, a reworked capacitive type humidity sensor and an improved band gap temperature sensor the performance has been lifted even beyond the outstanding level of the previous sensor generation. Every sensor is individually calibrated and tested. Lot identification is printed on the sensor and an electronic identification code is stored on the chip - which can be read out by command. Furthermore, the resolution of PHARMALOGG PROBE THR-40125 can be changed by command (8/12bit up to 12/14bit for RH/T), low battery can be detected and a checksum helps to improve communication reliability.

SENSOR CHIP
PHARMALOGG PROBE THR-40125 features a generation Sensirion 4C CMOSens® chip. Besides the capacitive relative humidity sensor and the band gap temperature sensor, the chip contains an amplifier, A/D converter, OTP memory and a digital processing unit.

MATERIAL CONTENTS
While the sensor itself is made of Silicon the sensors housing consists of a plated Cu lead-frame and green epoxy-based mold compound. The device is fully RoHS and WEEE compliant, e.g. free of Pb, Cd and Hg.

SENSOR PERFORMANCE:

Relative Humidity:

Parameter	Condition	min	typ	max	Units
Resolution [1]	12 bit		0.04		%RH
	8 bit		0.7		%RH
Accuracy tolerance [2]	typ		±1.8		%RH
	max	see Figure 1			%RH
Repeatability			±0.1		%RH
Hysteresis			±1		%RH
Nonlinearity			<0.1		%RH
Response time [3]	τ63%		8		s
Operating Range	extended [4]	0		100	%RH
Long Term Drift [5]	normal		< 0.5		%RH/yr

Temperature:

Parameter	Condition	min	typ	max	Units
Resolution [1]	14 bit		0.01		°C
	12 bit		0.04		°C
Accuracy tolerance [2]	typ		±0.2		°C
	max		see Figure 2		°C
Repeatability			±0.1		°C
Operating Range	extended [4]	-40		125	°C
Response time [6]	τ63%	5		30	%RH
Long Term Drift			<0.04		°C/yr

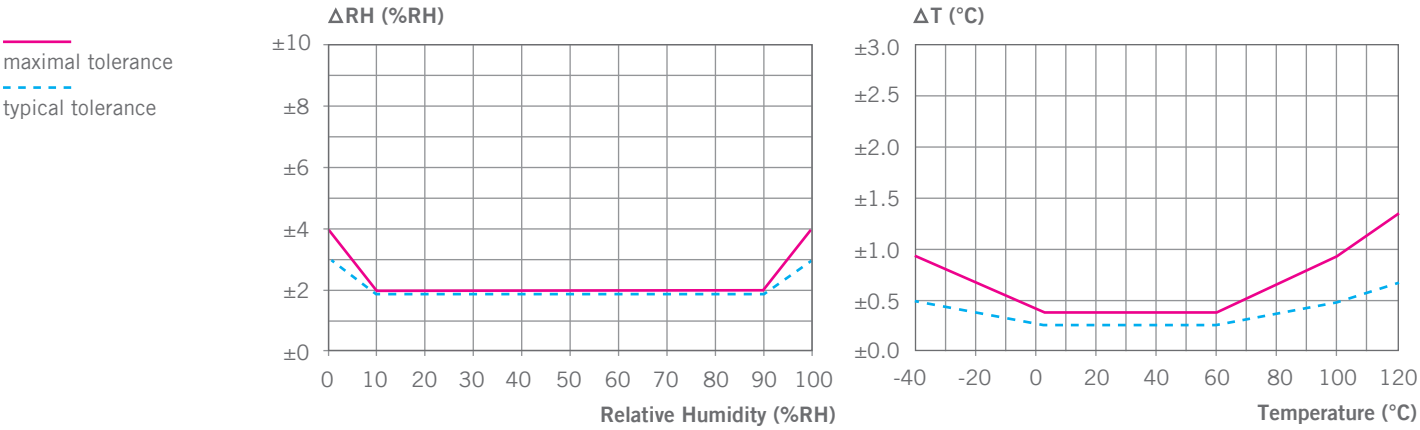


Figure 1: Typical and maximal tolerance at 25°C for relative humidity.

Figure 2: Maximal tolerance for temperature sensor in °C

1 Default measurement resolution is 14bit (temperature) / 12bit (humidity). It can be reduced to 12/8bit, 11/11bit or 13/10bit by command to user register.
2 Accuracies are tested at Outgoing Quality Control at 25°C and 3.0V. Values exclude hysteresis and long term drift and are applicable to non-condensing environments only.
3 Time for achieving 63% of a step function, valid at 25°C and 1m/s airflow.
4 Normal operating range: 0-80%RH, beyond this limit sensor may read a reversible offset with slow kinetics (+3%RH after 60h at humidity >80%RH).
5 Value may be higher in environments with vaporized solvents, out-gassing tapes, adhesives, packaging materials
6 Response time depends on heat conductivity of sensor substrate.

RH ACCURACY AT VARIOUS TEMPERATURES

Maximal tolerance for RH accuracy at 25°C is defined in Figure 1. For other temperatures maximal tolerance has been evaluated to be within limits displayed in Figure 3.

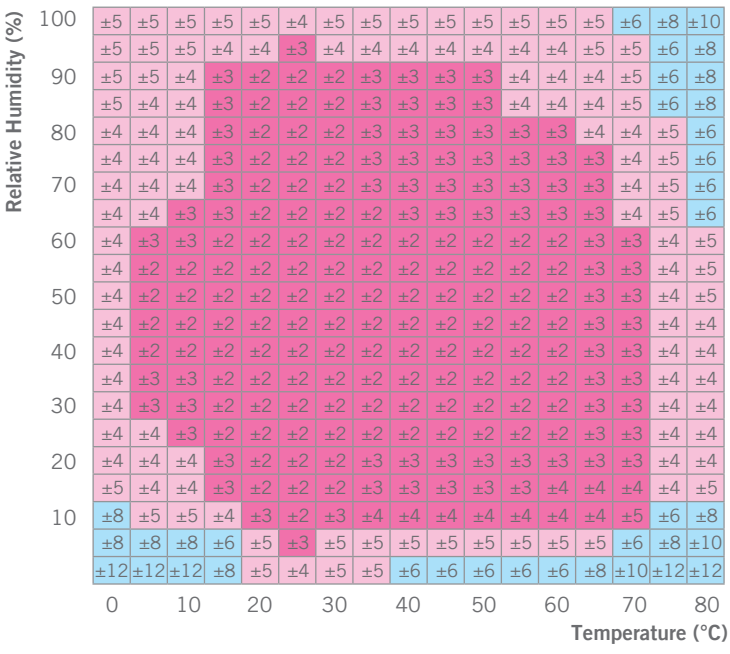


Figure 3: Maximal tolerance of relative humidity measurements given in %RH for temperatures 0-80°C

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DATASHEET: PHARMALOGGER CONTROLER
HUMIDITY AND TEMPERATURE DATA LOGGER

- Temperature range from -200 °C to +600 °C
- Relative humidity range from 0% to 100%
- Fully calibrated with 1.8%RH accuracy
- Fully calibrated with 0.2 °C accuracy
- GAMP compliance
- LAN interface (100Mbps Server communication)
- 4 Digital input, (4Xtemp-hum probe)
- 4 Analog input (door open switch,fault...)
- 1 RS485 input (RFID Reader...)
- 1 RS232 input (PLC, industrial...)
- 3 LED indicator (power, read data, error)
- Internal memory 100000 records
- Low power consumption
- Excellent long term stability
- 4Ah 12V Battery

PHARMALOGGER CONTROLER is a self-contained,precision data logger for recording and control environmental conditions in whole process of manufacturing,storage and distribution of temperature and humidity sensitive products. High performance advantage over competitive products by delivering higher accuracy, larger easurement capacity, and more features to make environmental data collection faster and easier than ever. The loggers provide a variety of features to reduce deployment time, and offer new logging modes for recording and displaying more detailed data without extensive post-processing or memory use.

The network connected Pharmalogger Controler Is a new type of temperature and humidity data logger equipped with a built-in function that enables connection to and use over the Internet or other network such as a LAN network.
The downloading of recorded data, the monitoring of current readings and the sending of warning e-mails and SMS can all be done easily over the Internet or LAN network. The use of an Internet connection provides to manage temperature and humidity data from long distances.

Versatile with many applications
Refrigerators, freezers, cold/hot chambers, incubators, laboratories, cold rooms, warehouses, manufacture in pharmaceutical industry; manufacture and storage all temperature and humidity products.

Built-in real time clock
All acquired data is time and date stamped.

Battery operation
Low-power operation runs on loose main power, and switch to 4Ah battery that provide up to 72h full functionality.

Programable alarm tresholds
Over/under alarms may be enabled for both temperature and RH to flag out-of-range-conditions.

NIST tracable option
The PharmaloggerControler can be provided with an NIST tracable certificate to satisfy contractual or regulatory requirements.

Memory	100000 data record (example 30min sampling 4 temp/hum probe = 520days)
Sampling Rate	1 minute to 24 hours, user-selectable
Battery Life	Min 72h
Dimensions	90X55X60mm
Temperature Range	-200°C - 600°C (depend on used probe)
Accuracy	Standard ± 0.2 °C ±0.1 °C with calibrated points acording to ISO 17025
Resolution	0.01°C
Response Time (airflow of 1 m/s)	3 minutes to 90%
Humidity Range	0-100%
Accuracy	Standard ±1.8% 1% with calibrated points acording to ISO 17025
Resolution	0.1%
Response Time (airflow of 1 m/s (2.2mph))	20 seconds to 90%

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DATASHEET: PHARMASOFTWARE

- **Characteristic & Benefits**
- aids in compliance with **FDA 21 CFR Part 11** and **GxP guidelines**
- sophisticated user friendly web interface
- Time and cost saving validated system, stands up to interrogation from auditors
- audit trail and automatic data security

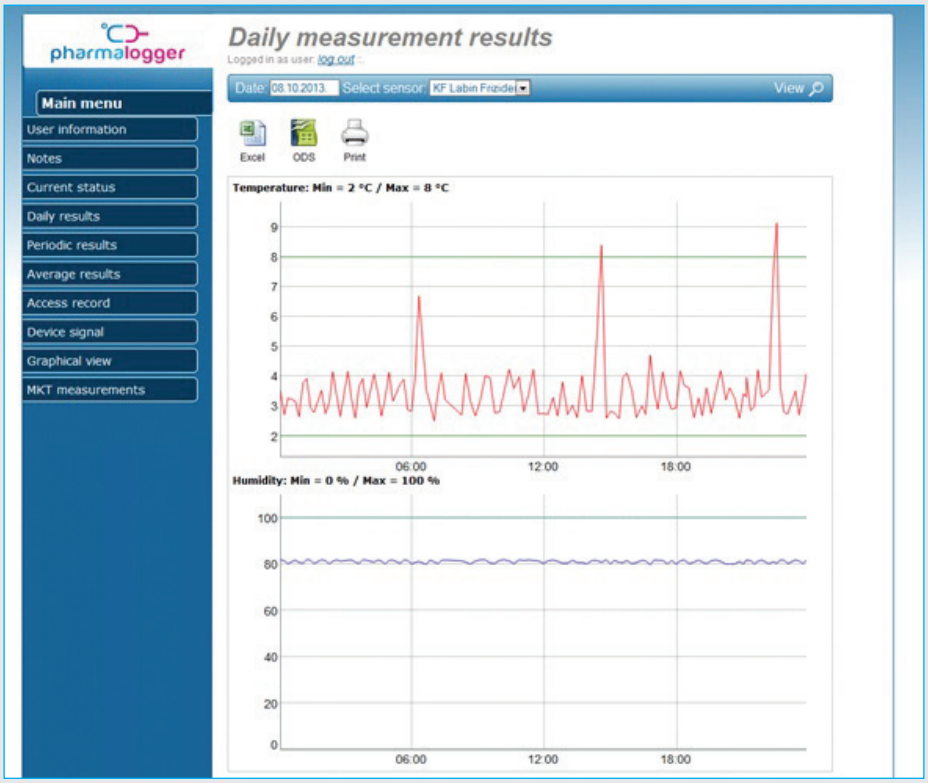
- **Applications**
- Pharmaceutical
- Laboratory
- Hospitals
- Transport vehicles
- Warehouses
- FDA regulated organisations
- Temperature Mapping

Pharmalogger software allows the user to effortlessly collect, display and analyze data. A variety of powerfull tools provide the ability to calculate, report and print simple proffessional report.

User management	Audit trail	Web based application	IQ/OQ/PQ protocols
Two levels of accesss - administrator and user. Administrator has access to all security settings, while users only have access to real time monitoring and analyzing data.	Administrator has insight into all updates created by users, changes made in settings, sent and confirmed alarm messages.	Application can be accessed from any computer and smartphone running any operating system with any web browser	Provided independent testing of the hardware and software components, as well as integrated testing of the complete Pharmalogger system.

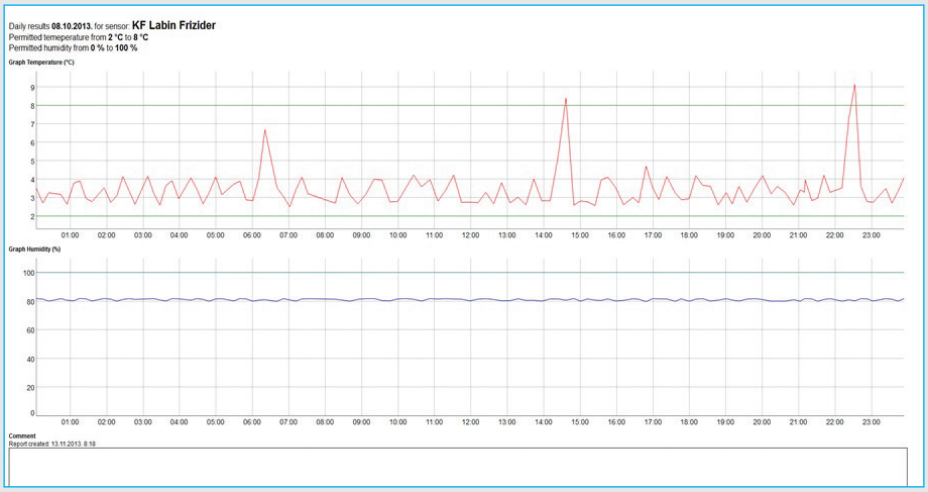
Real time monitoring and data view

Graphs and data grids are allowing the user to quickly and easily get information about temperature and relative humidity result.



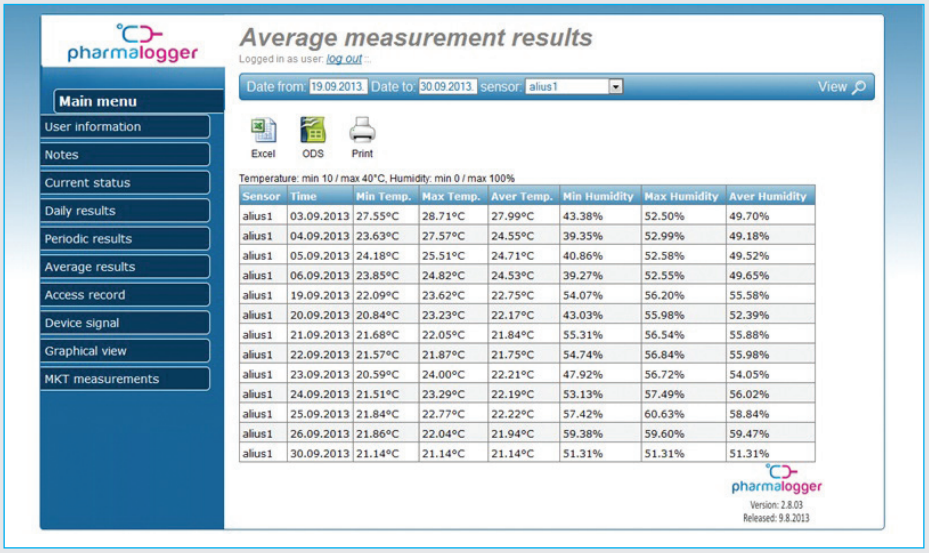
Data export and automatic reports

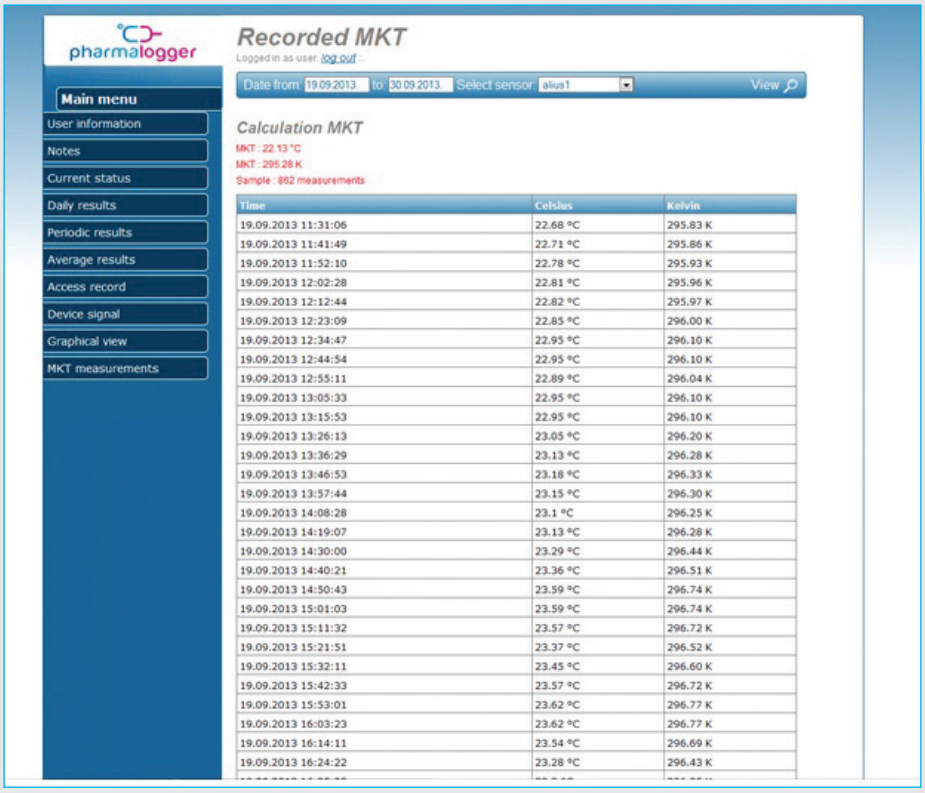
Export function enables easy data analyses and generating automated 21 CFR Part 11 Regulatory compliance reporting.



Pharmaceutical calculations & statistics

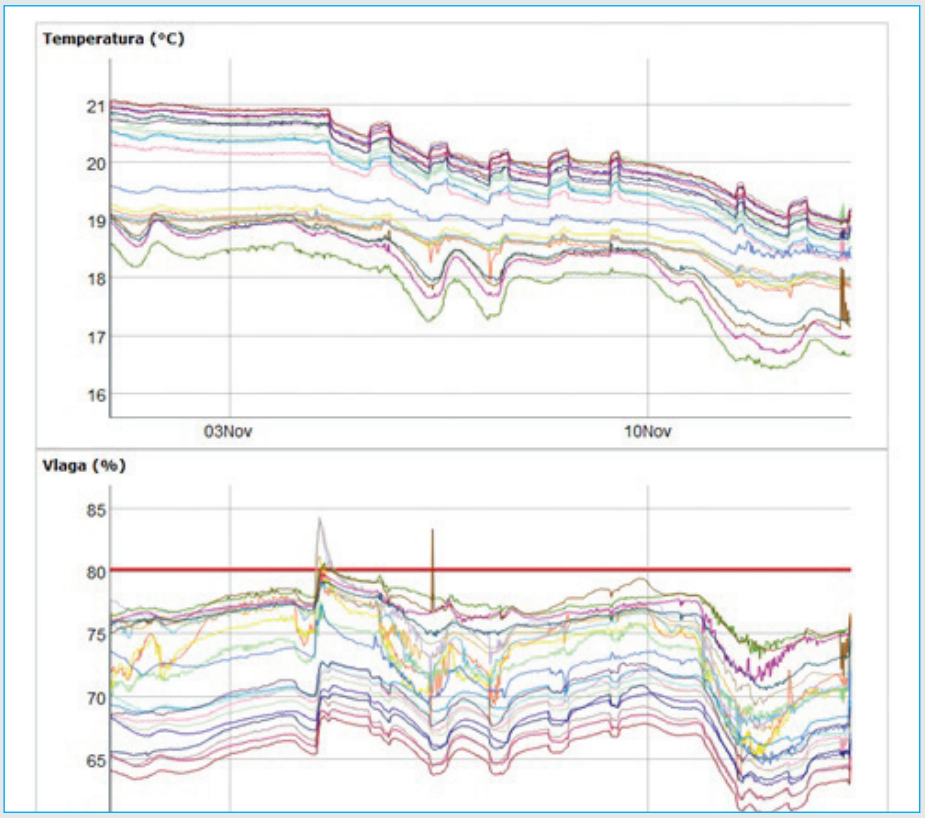
Software provides calculation as minimum, maximum and average measurement result on daily base, and MKT (Mean Kinetic Temperature) for the chosen time period.





Multiple graph data

Recorded data from multiple sensors can be easily combined in a single graph by simply selecting monitored area or specific sensors.



Real Time Alarm

Provides alarm notifications to cell phone, e-mail, or PC when temperature and/or humidity conditions exceed set thresholds.