weisstechnik®
a schunk company

Stability Test Systems
PharmaEvent

weisstechnik vötschtechnik

www.weiss-technik.com

Our experience is your security.

Only tested pharmaceuticals get the required approval.

All drugs are subject to particularly strict guidelines. To determine the shelf life, the stability of chemical, microbiological and physical properties of pharmaceutical substances must be proven in long-term tests under strictly defined climatic conditions. Regulatory authorities and the pharmaceutical industry have jointly developed the ICH* Guidelines for the harmonisation of stability tests, which ensure uniform storage and define the assessment of the batches. Here is an overview:

Drugs in firm cases

Long-term testing	25 ±2 °C/60 ±5 % RH or 30 ±2 °C/65 ±5 % RH
Accelerated testing	40 ±2 °C/75 ±5 % RH
Intermediate testing	30 ±2 °C/65 ±5 % RH

Drugs in semi-permeable containers

Long-term testing	25 ±2 °C/40 ±5 % RH or 30 ±2 °C/35 ±5 % RH
Accelerated testing	40 ±2 °C/not more than 25 % RH
Intermediate testing	30 ±2 °C/65 ±5 % RH

Drug substances intended for storage in a refrigerator

Long-term testing	5 ±3 °C
Accelerated testing	25 ±2 °C/60 ±5 % RH

Drug substances intended for storage in a freezer

Long-term testing	-20 ±5 °C

During the entire test the deviation in temperature is stipulated at ±2 °C and the deviation in relative humidity is stipulated at ±5 % RH.

In the ICH Guideline Q1B the methods for performing photostability tests are established with an irradiation dose of 1.2 million lxh and an integrated UV part of 200 Wh/m².

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Test technology you can rely on.

Together with the pharmaceutical industry, we have developed climate simulation systems with which the stability testing of pharmaceutical products can be carried out safely and in accordance with legal requirements. The spectrum ranges from laboratory-scale systems to walk-in climate chambers for optimum long-term testing. All systems have the necessary documentation options according to FDA 21 CFR Part 11 as well as EU GMP Annex 11 and meet the ICH Guidelines Q1A and Q1B as well as national and international requirements. These include WHO, FDA and CPMP.

*International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

Safer and easier stability testing.

weisstechnik offers a complete package of state-of-the-art testing equipment, documentation, qualification, calibration, training and service.

Uni-Flow
Airflow design for best homogeneity even in loaded units.

Sterile Steam System (SSS)
The demineralised water is evaporated at +140 °C to kill eventually existing microorganisms.

Integrated Monitoring Centre (IMC)
To record all measurement data of control sensors or from the control loop independent sensors and alarms if an optionally integrated memory is available. The download and reporting of these data are possible with the optional Software **S!M**PAT!® **pharma.**

Pharma Light
For photostability testing cold white fluorescent tubes according to ISO 10977:1993 as well as UV fluorescent tubes from 320 to 400 nm with a maximum power between 350 and 370 nm according to ICH Guideline Q1B are integrated.

Exposure Equalisation Filters (EEF)
Due to the fact that fluorescent tubes have the highest intensity of radiation in the middle of the tube and lower intensities on the sides, equalisation filters have been developed to cut the maximum intensity in the middle and therefore get a homogenous illumination of the entire storage surface.

Qualification Documents
weisstechnik qualification documents for chambers and rooms and validation documents for software validations are prepared according to the risk-based approach of GAMP.

EU GMP Annex 11 Compliance
The computerised system, combined of the Controller **S!M**PAC® and the Monitoring Software **S!M**PAT!® **pharma**, are fully compliant to the requirements of EU GMP Annex 11 for computerised systems. This can be proven via the software validation.

FDA 21 CFR Part 11 Compliance
The Monitoring Software **S!M**PAT!® **pharma** is fully compliant to the requirements of FDA 21 CFR Part 11 of the American law for electronic documentation in the pharmaceutical and food industry according to manufacturer's declaration. This can be proven via the software validation.

DAkkS Calibrations
All measurement systems for temperature and humidity used within **weiss**technik for final testing, calibration and qualification on customer side are traceable to an ISO 17025 accredited calibration laboratory by our subsidiary Vötsch Industrietechnik GmbH.

The highest possible reliability.

Product diversity

For stability tests we offer a comprehensive range of basic climate chambers from 34 to 2,000 l as well as walk-in chambers from 10 to 300 m^3. In specific cases the stability test chambers can be adjusted to your premises and almost any design. Special sizes, e.g. 400 or 800 m^3, are also possible.

For photostability testing we have developed a special system. Furthermore there are solutions for continuous operation at 5 and –20 °C.

Moreover, climate chambers in a version executed as per ATEX are available for tests with substances containing alcohol. For all these demanding applications we offer you individual solutions with regard to volume, safety and design.

Documentation

For recording of measurement values regarding temperature, humidity or light numerous documentation options are available in accordance with the respective requirements, in this context each of these options is available with independent sensors and, upon request, also with control loop sensors.

In detail these are:

- Integrated datalogger for control and/or independent sensors; for viewing the Software **S!M**PATI® **pharma** is necessary.
- Software Package **S!M**PATI® **pharma** complying with FDA 21 CFR Part 11 and EU GMP Annex 11 for connection of test chambers to a PC or server according to manufacturer's declaration. Moreover, any existing temperature or climate devices can be connected to **S!M**PATI® **pharma** using additional sensors and interfaces.[1]
- Digital line recorders complying to FDA 21 CFR Part 11 (line recorder with memory and display).
- To connect the chambers to other monitoring systems, analogue signals 0 to 10 V or 4 to 20 mA from the control loops or additional sensors are possible as option.
- An integration into a LIMS is also possible.

[1]Perhaps options required.

Qualification

For the approval of active substances and/or providing evidence of stability tests numerous measures have to be carried out and confirmed over extremely long periods of time for the purpose of ensuring flawless functioning of stability test chambers, such as compliance with fluctuations in temperature and humidity.

These requirements are documented in a sustainable manner by means of our extensive qualification documentation.

The entire system qualification comprises:

DAkkS ISO 17025-accredited calibrations with certificate by Vötsch Industrietechnik GmbH
DQ Design Qualification
FAT Factory Acceptance Test
IQ Installation Qualification
OQ Operation Qualification
PQ Performance Qualification

Alternatively we offer also qualifications according to GAMP 5.

In addition to this we provide all the required documents such as circuit diagrams, component lists and certificates, e.g. ISO accreditation, EC conformity declarations or also maintenance recommendations.

On request, our trained technicians carry out the qualification on site and can complement this with our comprehensive measurement and calibration facilities (DAkkS calibration by Vötsch Industrietechnik GmbH).

Our contribution to medicinal safety.

Calibration

Various QM systems require calibration and monitoring of test equipment that can be traced back to national or international standards.

For this reason, we offer calibrations by the Vötsch Industrietechnik GmbH laboratory accredited according to ISO 17025 and provide DAkkS calibration certificates for the measurable variables of air temperature, dewpoint temperature and relative humidity.

International acceptance of the DAkkS calibration certificates is underlined by the membership of DAkkS in ILAC (International Laboratory Accreditation Cooperation), all member countries of which must recognise DAkkS calibration certificates.

Trained calibration technicians perform calibrations and spatial measurements of temperature and humidity both in our factory as well as on site.

Training

Our competent team of instructors would be pleased to advise you on all questions relating to stability testing, qualification, documentation as well as environmental simulation and heat technology at any time.

We regularly offer seminars and workshops on all current topics relating to our product range and its application both in our in-house training centre and on site (e.g. device qualification in actual practice).

Moreover, this team also ensures regular on-the-job training for our service technicians through workshops regarding service, maintenance, calibration and qualification.

Service and maintenance

Whether it is maintenance, calibration or repair, we are available round the clock through our service centre. On demand, we guarantee that a service technician will be on site within 24 hours after we have received a failure notification on weekdays in Germany.

In addition to this, we offer maintenance contracts with a provision regarding a response time of 24 hours also on weekends.

As specialists in the fields of refrigeration, climate and control technology our technicians are familiar with all the functions and components of such systems.

In addition to the range of spare parts which our technicians have on site, we forward spare parts to our technicians as well as customers every day in order to ensure the best possible supply.

Our extensive service network with more than 300 technicians worldwide ensures that we are always there when you need us. Whether we assist you from the service centre or directly on site – our customers are always given top priority.

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Our innovative Test Chambers are available as **weiss**technik or **vötsch**technik.

Stability testing according to ICH Guideline Q1A.

Stability Test Chambers PharmaEvent.

PharmaEvent has been specially developed to meet the requirements of test laboratories in the pharmaceutical industry. The series comes in four sizes and can provide a constant climate (types C/280, C/600, C1300 and C/2000) or just a constant temperature (types T/280, T/600, T/1300 and T/2000). The exceptional build quality, innovative product features, accuracy and smart controls allow for the safest and easiest stability testing.

The working range easily meets the requirements of the ICH Guideline Q1A. Furthermore the systems are designed to work at 5 °C continuously without defrosting. They also permit the implementation of tests with other specifications in the performance range of the respective system.
Controlling of temperature and humidity is performed with highly precise sensors in combination with a specially designed control unit. The control system responds quickly in order to correct setpoint variations caused by:

- Influence of the cabinet's contents (absorption or emission of water vapour by the test specimen or its packaging)
- External influences (e.g. laboratory temperature, opening of door)

Basic equipment

- Monitoring and Control **S!M**PAC® with 7" Multi-User Interface **WEB**Season® and audit trail
- Ethernet and USB interface
- Fully integrated user management in the control panel[1]
- Factory calibration of 2 temperature and 2 humidity values[1]
- Software temperature limiter, min./max.
- Alarm system according to GAMP
- Interior fittings are entirely made of stainless steel
- Door contact switch
- Water tank with automatic and manual water supply of demineralised humidification water[2]
- Lockable doors
- 4 castors of which 2 have brakes[3]
- Air-cooled refrigeration unit with low noise emission
- Patented vapour humidification system SSS[2]
- Capacitive humidity sensor[2]
- Entry port, Ø 50 mm, in the right side panel
- Operating manual
- Multi-language touch panel (German, English, French, Spanish, Czech, Russian, Chinese, Korean, Italian, Portuguese)
- 280-l units on 6 feet and stackable

[1]User management is possible in conjunction with **S!M**PAT!®.
[2]Not applicable for PharmaEvent T/280, T/600, T/1300 and T/2000.
[3]Not applicable for PharmaEvent C/280 and T/280.

Our innovative Test Chambers are available as **weiss**technik or **vötsch**technik.

Technical data

PharmaEvent			C/280	C/600	C/1300	C/2000
SHELVES	Number (max.)	pc.	2 (17)	6 (36)	12 (77)	18 (108)
	Width, net	mm	530	530	530	530
	Depth	mm	650	650	650	650
	Storage area (max.)	m²	0.69 (5.86)	2.07 (12.4)	4.14 (26.5)	6.21 (37.2)
	Load per shelf	kg	40 (distributed load)			
	Load total, max.	kg	150	250	500	750
EXTERNAL DIMENSIONS	Width	mm	1159	803	1523	2180
	Depth	mm	872	1060	1043	1040
	Height, with castors	mm	-	1995	1995	2000
	Height, with feet	mm	1017	2052	2052	2072
WEIGHT		kg	135	191	275	365
TEST SPACE DIMENSIONS	Width	mm	645	621	1341	2035
	Depth	mm	673	687	687	695
	Height	mm	641	1280	1280	1280
ENTRY PORT			Ø 50 mm, in the right side panel			
TEMPERATURE	Working range	°C	+2 to +70			
	Fluctuation, in time	K	+0.1 to ±0.2			
	Homogeneity, in space	K	±0.3 to ±1.0			
	Gradient, acc. to IEC 60068-3-5	K	0.5 to 2			
HUMIDITY[1]	Humidity range	% RH	20 to 90			
	Humidity deviation in time	% RH	±0.2 to ±1.0			
	Dewpoint temp. range	°C	+5 to +45			
	Water supply via water tank		Automatically via built-in water tank and/or external supply			
		l	13	19		
	Water specification		Demineralised water, pH value 6 to 7, conductivity 5 to 20 µS/cm			
CALIBRATION VALUES (WKD)			+25 °C/60 % r. F. und +40 °C/75 % r. F.			
POWER	Mains		1/N/PE, AC 220/230 V ±10 %, 50/60 Hz			
	Nominal	kW	1.1	1.2	1.2	1.2
NOISE LEVEL[2]		dB(A)	52			

These data are based on an ambient temperature of +25 °C, 230 V, 50 Hz nominal voltage, without specimen, without additional equipment and heat compensation. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more.
[1]Not applicable for PharmaEvent in temperature version (T/280, T/600, T/1300 and T/2000).
[2]Measured in 1.6 m height under free field conditions at 1 m distance from the front of the system.

Most important options

- Software Package **S!M**PAT!® **pharma** for recording and processing of measurement values
- Integrated datalogger
- Networking of several systems
- Serial interface RS 232 C
- Registration of temperature and/or humidity[3]
- Integrated UPS to keep the recording alive during a power failure
- Additional temperature and/or humidity sensor[3]
- Acoustic and optical warning signal
- Refrigeration unit, water-cooled
- Glass door, heated[4]
- Height-adjustable feet[5]
- Additional shelves
- Additional entry ports
- Demineralisation unit with exchangeable cartridges for connection to local water supply[3]
- Qualification documentation for equipment and Software **S!M**PAT!®
- Special voltages
- Analogue outputs
- Maintenance contracts with defined response time

[3]For PharmaEvent in temperature version (T/280, T/600, T/1300 and T/2000).
[4]Not for 280-l models.
[5]Standard in 280-l models.

Photostability testing according to ICH Guideline Q1B.

Photostability Test Chambers PharmaEvent.

PharmaEvent comes in two sizes and can provide a constant climate (types C/250/L and C/500/L) or just a constant temperature (types T/250/L and T/500/L). The photostability testing cabinets are characterised by an ideal light, UV, temperature and humidity (types C/250/L and C/500/L) distribution and can thus guarantee absolutely reproducible light, UV and climatic conditions. The lighting equipment used complies with the ICH Guideline Q1B Option 2 and enables photostability tests to be carried out in less than 100 hours.

One of the most important requirements in photostability tests is the homogeneous irradiation of the specimens. For this reason, all the specimens have to be positioned at the same distance from the light source. The inhomogeneous emission of light by fluorescent lamps is compensated with the help of special light and UV filter systems, thus a homogeneous irradiation of the entire storage area is achieved. For recording of the illumination and UV irradiance this system can be equipped with corresponding light and UV sensors. With this option, entering of setpoint values in lxh and Wh/m², e.g. 1.2 million lxh and 200 Wh/m², is made possible to have a fully automated and with **S!M**PATI® **pharma** also fully documented process. Photostability Testing Cabinets PharmaEvent offer innovative product features, high accuracy, intelligent controls and an exceptional build quality.

Basic equipment

- Monitoring and Control **S!M**PAC® with 7" Multi-User Interface **WEB**Season® and audit trail
- Fully integrated user management in the control panel[1]
- Shelves illuminated with UV light
- Shelves illuminated with white light
- Light and UV timer
- Light and UV filter for optimum distribution (EEF)
- Software temperature limiter for min. and max. test space temperatures
- Alarm system according to GAMP
- Interior fittings are entirely made of stainless steel
- Factory calibration of 2 temperature and 2 humidity values[1]
- Alarm output (potential-free contact) for monitoring of tolerance band ±2 °C ±5 % RH[2]
- Water storage reservoir with automatic and manual supply of demineralised humidification water[1]
- Door contact switch
- Lockable doors
- Counter for total operating hours
- 4 castors of which 2 have brakes[3]
- Air-cooled refrigeration unit with low noise emission
- Patented vapour humidification system SSS[2]
- Capacitive humidity sensor[2]
- Entry port, Ø 50 mm, in the right side panel
- Operating manual
- Multi-language touch panel (German, English, French, Spanish, Czech, Russian, Chinese, Korean, Italian, Portuguese)

[1]User management is possible in conjunction with **S!M**PATI®. [2]Except for PharmaEvent T/250/L and T/500/L. [3]Except for PharmaEvent C250/L and T/250/L.

Our innovative Test Chambers are available as **weiss**technik or **vötsch**technik.

Technical data

PharmaEvent			C/250/L	C/500/L	T/250/L	T/500/L
SHELVES	Number	pc.	2 shelves: 1 UV, 1 white light	4 shelves: 2 UV, 2 white lights	2 shelves: 1 UV, 1 white light	4 shelves: 2 UV 2 white lights
	Storage area	m²	0.71	1.45	0.71	1.45
	Load per shelf	kg	25 (distributed load)			
	Total load, max.	kg	50	100	50	100
EXTERNAL DIMENSIONS	Width	mm	1159	803	1159	803
	Depth	mm	872	1060	872	1060
	Height, with castors	mm	-	2055	-	2055
	Height, with feet	mm	1017	2055	1017	2055
WEIGHT CA.		kg	161	250	161	250
TEST SPACE DIMENSIONS	Width	mm	530	530	530	530
	Depth	mm	673	687	673	687
	Height	mm	641	1305	641	1305
	Utilisable test space	l	ca. 235	ca. 460	ca. 235	ca. 460
ENTRY PORT			ø 50 mm, in the right side panel			
TEMPERATURE	Working range	°C	Without radiation: +5 to +50, With radiation: +5 to +50 (250 l) +10 to +50 (500 l)			
	Fluctuation, in time	K	±0.1 to ±0.5			
	Homogeneity, in space	K	±0.5 bis ±1.0 (1.5 with radiation)			
	Gradient acc. to IEC 60068-3-5	K	1 to 2			
HUMIDITY	Humidity range	% RH	20 to 90		-	
	Humidity deviation in time	% RH	±1 to ±2		-	
	Dewpoint temp. range	°C	+5 to +40		-	
	Water supply via water tank		Automatically via built-in water tank and/or external supply		-	
		l	13	19	-	
	Water specification		Demineralised water, pH value 6 to 7, conductivity 5 to 20 µS/cm		-	
LIGHT	Intensity of light	lx	ca. 5500 at +5 °C (only 250 l) ca. 12000 at +15 °C ca. 18000 at +25 °C ca. 25000 at +45 °C			
	Intensity of UV	W/m²	0.65 at +5 °C (only 250 l) 1.5 at +15 °C 3.0 at +25 °C 3.7 at +45 °C			
	Homogeneity, in space	K	±0.5 to ±1.0 (1.5 with radiation)			
	Light distribution	%	ca. ±8			
	UV distribution	%	ca. ±12			
CALIBRATION VALUES (WKD)			+25 °C/60 % RH and +40 °C/75 % RH			
POWER	Mains 250 l		1/N/PE, AC 220/230 V ±10 %, 50/60 Hz			
	Mains 500 l		1/N/PE, AC 230 V ±10 %, 50 Hz			
	Nominal	kW	1.4	2.6	1.4	2.6
NOISE LEVEL[1]		dB(A)	52			

These data are based on an ambient temperature of +25 °C, 230 V, 50 Hz nominal voltage, without specimen, without additional equipment and heat compensation. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more.
[1]Measured in 1.6 m height under free field conditions at 1 m distance from the front of the system.

Shelf with UV light

Shelf with cold white light

Most important options

- Software Package **S!M**PATI® **pharma**
- Integrated datalogger for recording and processing of measurement values
- Networking of several systems
- Serial interface RS 232 C
- Integrated UPS to keep the recording alive during a power failure
- Registration of temperature and/or humidity[2]
- UV and lux sensors with automatic measurement value integration
- Mapping of light distribution
- Additional temperature and/or humidity sensor[2]
- Acoustic and optical warning signal
- Refrigeration unit, water-cooled
- Glass door, heated
- Additional entry ports
- Demineralisation unit with exchangeable cartridges for shelf with white light
- Connection to local water supply[2]
- Qualification documentation for equipment and Software **S!M**PATI®
- Special voltages
- Analogue outputs
- Maintenance contracts with defined response time
- Operation at 5 °C with full illumination

[2]Except for PharmaEvent T/250/L and T/500/L.

Stability testing according to ICH Guideline Q1A.

Walk-In Stability Test Chambers PharmaEvent.

The extremely accurate and reliable Stability Test Chambers PharmaEvent can be validated and are designed specifically to help you meet the requirements of the ICH Guideline Q1A. The insulation elements of the chambers can be optimally adapted to an existing building structure since adherence to standard dimensions is not necessary. The standard height is 2,700 mm; other dimensions are possible. Chamber volumes come from 10 up to 300 m^3.

Basic equipment

- An excellent mechanical rigidity and optimum thermal insulation are ensured thanks to PU insulation chamber elements (CFC-free) with easy-to-clean double-sided metal plate coating. Panels on the inside and outside are painted RAL 9010.
- Insulated heavy-duty floor construction covered with slip-resistant, chequered plate stainless steel.
- Lockable test chamber door with insulated observation window and emergency opening facility. The door frame heater prevents the forming of condensate during high humidity operation.
- A pressure relief valve is fitted to the chamber wall.
- Heating and cooling system consisting of ceiling evaporator with integrated electrical heater and air-cooled refrigeration unit.
- Powerful axial fans ensure continuous intensive air circulation as well as uniform air distribution and temperature conditioning.
- Climate conditioning system with energy saving ultrasonic humidifier and separate dehumidifier.
- Microprocessor-controlled system corresponding to GAMP Guide and FDA 21 CFR Part 11 and EU GMP Annex 11, with maintenance-free electronic temperature/humidity sensor.
- Monitoring and Control **S!M**PAC® with 7" Multi-User Interface **WEB**Season® and audit trail.
- The switch cabinet incorporates the complete electrical section with fuses, protection, switch, control and regulation appliances. Wiring and electrics are strictly conform to safety regulations for electrical installation and materials according to the European Machinery Directive.
- Safety temperature limiter for electrical heater and test chamber.
- Specimen protection thermostat, tmin./tmax., and high humidity protection.
- Multi-language touch panel (German, English, French, Spanish, Czech, Russian, Chinese, Korean, Italian, Portuguese).

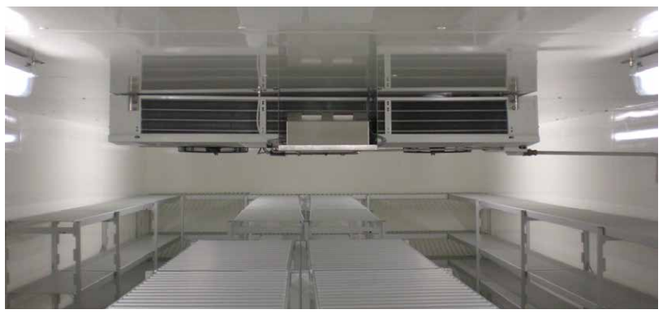
Our innovative Test Chambers are available as **weiss**technik or **vötsch**technik.

weisstechnik vötschtechnik

Technical data

PharmaEvent		
Temperature working range	°C	+20 to +45
Temperature deviation, in time	K	±0.1 to ±0.5
Temp. homogeneity, in space	K	±0.5 to ±1 acc. to IEC 60068-3-5
Temperature gradient	K	1 to 2 acc. to IEC 60068-3-5
Humidity range	% RH	20 to 80
Humidity deviation, in time	% RH	±1 to ±3
Dewpoint temp. range	°C	+9 to +41

The performance values refer to an ambient temperature of +10 to +32 °C. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more.



Most important options

- Software Package **S!M**PATI® **pharma** for recording and processing of measurement values
- Integrated datalogger
- Networking of several systems
- Serial interface RS 232 C
- Additional temperature and/or humidity sensor
- Acoustic and optical warning signals
- Refrigeration unit, water-cooled
- Connection to customer-provided chilled water circuit (e.g. +6 °C)
- Additional entry ports
- Demineralisation unit with exchangeable cartridges for connection to local water supply
- Constant temperature chamber (without controlled humidity)
- Versions +5 and -20 °C
- Shelf systems
- One-point calibration (factory calibration)
- Spatial calibration (factory calibration)
- Qualification documentation for equipment and Software **S!M**PATI®
- Special voltages
- Analogue outputs
- Maintenance contracts with defined response time
- Further options available on request

When safety counts.

Climate Test Chambers ClimeEvent.

In case you test samples containing alcohol and cannot exclude the possibility of leakage of vapours with certainty, you have to carry out a risk analysis and take corresponding safety precautions according to the classification as per ATEX.
Climate Test Chambers ClimeEvent were developed for real-time tests or tests under various climate conditions, which are characterised by very low energy consumption and whisper-quiet operation and can also include safety measures in accordance with ATEX on request. ClimeEvent is also available with temperature ranges from -40 to 180 °C and -70 to 180 °C and can be used for stress tests or freeze thaw cycles without explosion protection.

Technical data

ClimeEvent		LabEvent L
ca. 190 to 1540	Test space volume (l)	ca. 34, 64, 100 and 150
Performance for temperature tests		
-10 to +90/-5 to +90/0 to +90	Temperature working range (°C)	-70 to +180/-40 to +180/+10 to +180
±0.1 to ±0.5	Temperature fluctuation, in time (K)	T: ±0.3 to ±1.0 and C: ±0.3 to ±0.5
±0.5 to ±1.0	Temp. homogeneity, in space[1] (K)	T: ±0.5 to ±2.0 and C: ±0.5 to ±1.5
1 to 2 (acc. to IEC 60068-3-5)	Temperature gradient (K)	1 to 2 (acc. to IEC 60068-3-5)
+4 and +90	Calibration values (°C)	+23 and +80
Performance for climatic tests[3]		
+10 to +90	Temperature working range[2] (°C)	+10 to +95
±0.1 to ±0.3	Temperature fluctuation, in time[2] (K)	±0.3 to ±0.5
±0.5 to ±1.0	Temp. homogeneity, in space[1, 2] (K)	±0.5 to ±1.5
10 to 98	Humidity working range[2] (% RH)	10 to 95
±1 to ±3	RH fluctuation, in time[3, 4] (% RH)	±1 to ±3
+4 to +89.5	Dewpoint temp. range[3] (°C)	+5.5 to +94
+25 °C/60 % RH and +40 °C/75 % RH	Calibration values (acc. to ICH Guidelines)	+23 °C/50 % RH and +80 °C/50 % RH
General Data		
1/N/PE, AC 220/230 V ±10%, 50/60 Hz, safety plug	Electrical connection	1/N/PE, AC 220/230 V ±10 %, 50 Hz
2.6	Installed load, max. (kW)	1.8 to 3.5
895 to 1415 x 1442 to 2501 x 1805 to 2005	Overall dimensions, W x D x H (mm)	661 to 801 x 751 to 1335 x 1000 to 1872
420 to 920	Weight (kg)	154 to 370
<53	Noise level[4] (dB[A])	<59

These data are based on an ambient temperature of +25 °C, 230 V, 50 Hz nominal voltage, without specimen, without additional equipment and heat compensation. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more. [1]Relative to the setvalue in temperature range from minimal temperature to +150 °C measured. [2]Not applicable for LabEvent L. [3]For ClimeEvent measured in the middle of the test space. [4]Measured in 1.6 m height under free field conditions at 1 m distance from the front of the system.

Our innovative Test Chambers are available as **weiss**technik or **vötsch**technik.

Small can be this big.

Laboratory Test Chambers LabEvent.

Compact, quiet, yet powerful units are required to tackle special laboratory conditions that include limited space, even smaller specimens and the need to conduct reproducible tests on a laboratory scale or stability tests according to ICH Guideline Q1A tests directly at the workplace. The Temperature and Climate Test Chambers LabEvent are ideally suited to such applications. These systems have a volume of 34, 64, 100 and 150 l respectively and provide an optimum solution where space is limited.

Humidity is generated by a temperated water bath in a manner free of aerosols. LabEvent LT and LabEvent LC are suitable for program and constant setpoint operation, e.g. for stress tests and freeze thaw cycles, and are equipped with a state-of-the-art efficient 32-bit Control and Communications System **S!M**PAC®. Up to 100 test programes can be stored and retrieved.

With regard to the technical data LabEvent fulfils test standards, such as DIN, ISO, MIL, IEC, DEF or ASTM.

Basic equipment

- Monitoring and Control **S!M**PAC® with 7" Multi-User Interface **WEB**Season®
- Ethernet and USB interface
- Fully integrated user management in the control panel[1]
- Observation window
- Test space lighting
- Independent adjustable temperature limiter, tmin./tmax.
- Potential-free contact for test specimen switch-off
- Refrigeration circuit, air-cooled
- 1 shelf
- 1 entry port, Ø 50 mm
- Factory calibration of 2 temperature values for LabEvent LT and 2 climatic values for LabEvent LC respect. ClimeEvent
- Automatic water supply (LabEvent LC and ClimeEvent)
- Multi-language touch panel (German, English, French, Spanish, Czech, Russian, Chinese, Korean, Italian, Portuguese)

Most important options

- Software Package **S!M**PATI®
- Integrated datalogger
- Temperature measurement on test specimen
- Capacitive humidity measurement
- Interface RS 485/RS232C
- Compressed air dryer
- Additional entry ports
- Additional shelves
- Frame with castors (except LabEvent L -70 °C/34 l)
- Demineralisation unit (LabEvent LC and ClimeEvent)
- Special voltages

[1]In connection with **S!M**PATI® a user management is possible.

For special requirements on less than 1 m³.

Laboratory Test Chambers LabEvent T 500.

Technical data

LabEvent T 500		
Test space volume	l	500
Temperature range	°C	-30 to +100/-60 to +130
Temperature fluctuation[1]	K	±0,5
Deviation, in space	K	±1,5
Temperature gradient[1]	K	3
Temperature rate of change[1]		
Heating	K/min	2,0/4,5
Cooling	K/min	3,0/3,3[3]
Heat compensation, max.	W	1000/1250
Calibrated values	°C	-25 to +80/-4 to +80
Test space dimensions, W x D x H	mm	710 x 590 x 1250
External dimensions, W x D x H	mm	965 x 1051 x 1958 1025 x 1407 x 2130
Noise level[2]	dB(A)	< 60
Rated power	kW	2,4/6,7
Electrical connection		1/N/PE, AC 230 V ±10 %, 50 Hz 3/N/PE, AC 400 V ±10 %, 50 Hz

The performance values refer to +25 °C ambient temperature. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more.
[1]According to IEC 60068-3-5.
[2]Free field, 1 m distance from the front, as per DIN 45635, part 1, accuracy class 2.
[3]With option 3 K/min.

Basic equipment

- Monitoring and Control **S!M**PAC® with 7" Multi-User Interface **WEB**Season® and audit trail
- Ethernet and USB interface
- Software temperature limiter, min./max.
- Independent, adjustable temperature limiter, tmin./tmax.
- Potential-free contact
- Test space illumination
- Mobile design
- 1 entry port, Ø 80 mm
- 1 stainless steel shelf
- Refrigeration unit, air-cooled
- Factory calibration of 2 temperature values
- Multi-language touch panel (German, English, French, Spanish, Czech, Russian, Chinese, Korean, Italian, Portuguese)

Application

LabEvent T 500 is a good alternative to cabinets with deep-freeze function, outside it can be used for freeze-thaw cycles and temperature stress tests. Reliable temperature tests ranging from -30 to +100 °C for a large variety of applications are possible.

- Constant temperature tests
- Changing temperature tests
- Freeze thaw cycles
- -20 °C freezer[4]

Options

- Software Package **S!M**PATI®
- Integrated datalogger
- Qualification documents
- Temperature measuring on test specimen
- Other entry ports and shelves
- Glass door
- Special voltage
- Reinforced cooling unit
- Water-cooled design
- Compressed air dryer[4]

[4]For continuous operation with negative temperatures the option compressed air dryer as well as compressed air are necessary to avoid icing.

Our innovative Test Chambers are available as **weiss**technik or **vötsch**technik.

weisstechnik vötschtechnik

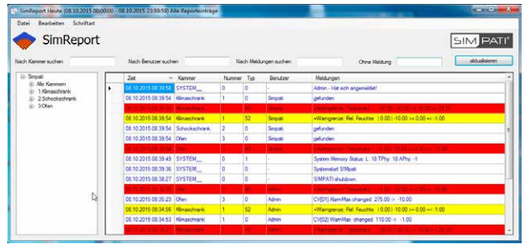
Pretty smart.

Software Package S!MPATI® pharma.

Our Control and Documentation Software **S!M**PATI® **pharma** enables you an even better use of your devices and systems with simple and secure data recording and archiving – guaranteed.

All warning and alarm messages are recorded and, if necessary, transmit an alarm signal to the person in charge of the system. Access rights can be specifically defined for every user; the recording and storage of data are manipulation-safe but can still be used for further processing, e.g. in Excel.

It goes without saying that the Software **S!M**PATI® **pharma** complies with FDA 21 CFR Part 11 and EU GMP Annex 11 according to manufacturer's declaration. Validation documents are also provided.



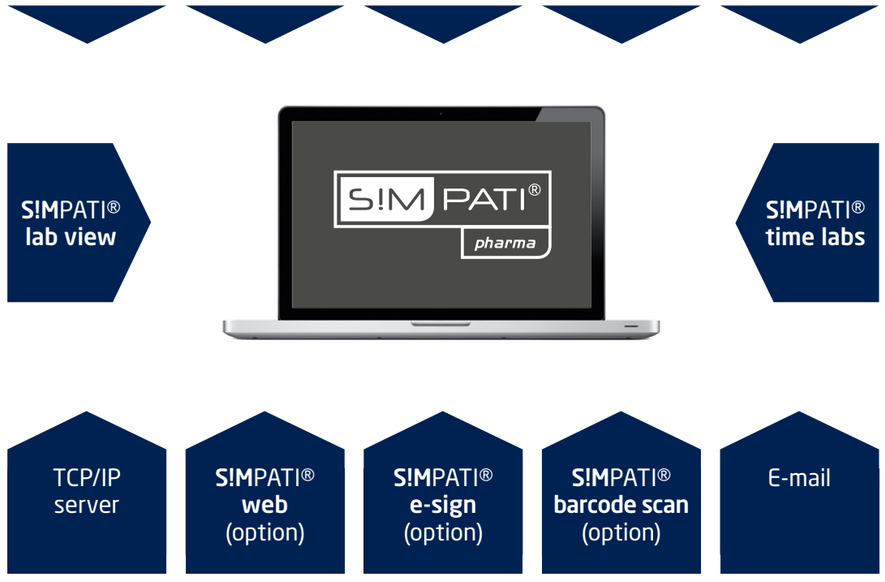
Audit trail

S!MPATI® web.

Operation of our systems is simple and time-saving. **S!M**PATI® can be integrated into your PC network and operated at individual stations without requiring special software – simply by using your Internet browser[1]. Furthermore, it can be installed on virtual servers.

[1]Perhaps options required.

Connections



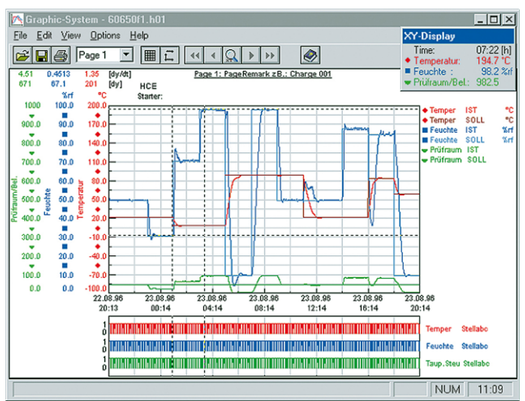
Important functions and possibilities.

- Recording and archiving of all test data
- Manipulation-safe data registration
- Administration of multi-level access rights (user management)
- Password alteration
- Compliance with FDA 21 CFR Part 11 according to manufacturer's declaration
- Compliance with EU GMP Annex 11 according to manufacturer's declaration
- Audit trail
- Up to 99 units can be linked via the serial interface or Ethernet interface (TCP/IP)
- Alarm output via e-mail
- Recording of door openings and documentation of opening times
- Recording of alarms
- Recording of temperature and humidity curves
- Recording of light and UV intensity during photostability tests
- Mobile solutions for site-independent monitoring of devices, e.g. by means of a tablet within the range of the installed WLAN
- Data recording via a special system network as well as via a TCP/IP network is possible
- Documentation of climate chambers and rooms irrespective of manufacturer
- Considering the alarm system of the connected devices **S!M**PATI® **pharma** fulfils the complete 5 steps risk-based approach according to GAMP 5
- Category 3 software according to GAMP
- Available in German, English, French, Czech, Russian, Spanish, Chinese, Korean, Italian, Portuguese

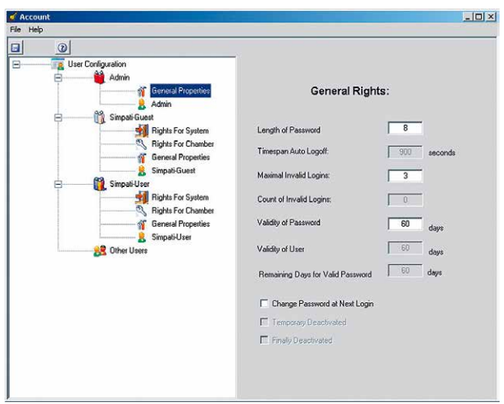
In some cases further options or special infrastructure at the customer's facilities are required for the functions described.

Options

- **S!M**PATI® **e-sign**: electronic signature with recording of biometric data
- Barcode reader for batch management
- Datalogger



Graphical recording



User management

Our innovative Test Chambers are available as **weiss**technik or **vötsch**technik.

Batch registration using barcode scanners.

S!MPATI® barcode scan.

Optional barcode scanning technology can also be used for batch registration and storage management in the system. This optional module must always be adapted to the individual data structures of the user. An automatic report can be created.

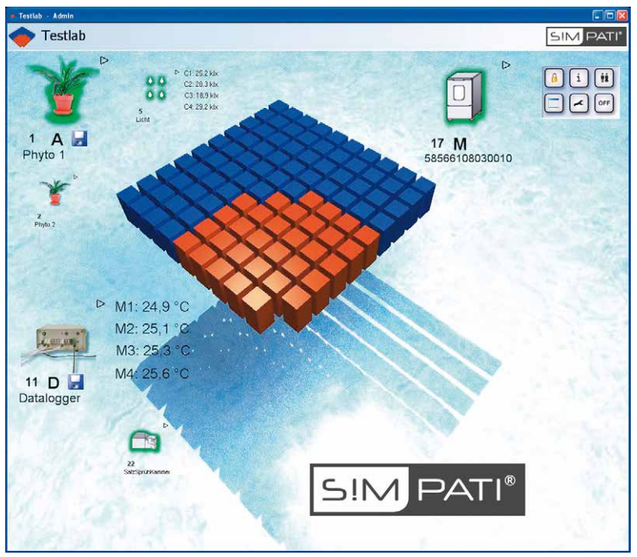
Advantages

- Simple to use – even in clean room conditions
- "Fault-free" input of lot numbers and product IDs
- Scanning of process data
- Automatic assignment of process cycles to existing products
- Wireless scanning technology scans and transfers the information, e.g. during the loading of test chambers

Everything under control.

Wherever you are!

S!MPATI® provides a comfortable means of operating and monitoring from your desktop PC. **S!M**PATI® **web** also supports the modern possibilities of Internet communication for monitoring via Internet browser[1] and information via e-mail. This option not only provides process information at your desktop PC but also virtually anywhere in the Internet. It is ensured that you can permanently recall actual data via the mobile phone network.



[1]Perhaps options required.

Biometric data based on your handwriting.

S!MPATI® **e-sign.**

The consistent solution from electronic documentation of measurement values through to the delivery of electronic documents to the authorities.

Many lawyers would like to see the introduction of a truly **active biometric component** to identify persons. In their opinion, a hand-written electronic signature is the only real active declaration of intent that could never be given unwillingly or by force. **S!M**PATI® **e-sign**, as a supplement to the Software Package **S!M**PATI® **pharma** (compliant with FDA 21 CFR Part 11 and EU GMP Annex 11, according to manufacturer's declaration), enables signing all measurement data whilst capturing biometric data based on your handwriting.

S!MPATI® **e-sign** offers legal security, clearly identifying the signer!

To enable also a subsequent identification of the signer, there are special software graphic components which, in case of dispute, could be used by handwriting experts. Because comparable conclusions can be reached from these components as from a hand-written signature on paper. Functional security was verified, based on more than 200,000 signatures.

All aspects from FDA 21 CFR Part 11 and EU GMP Annex 11 are complied with according to manufacturer's declaration. The system can be easily qualified.

Qualification weisstechnik Documentation

EU GMP Annex 11 weisstechnik Compliance

21 CFR Part 11 weisstechnik Compliance

This system is based on a state-of-the-art electronic signature which is accepted for all documents which do not explicitly require the written form by law (such as the German Civil Code), directives or standards. For all legally valid internal company signatures, i.e. including those in the laboratory, this way of signing is sufficient and also compliant with FDA 21 CFR Part 11 and EU GMP Annex 11, according to manufacturer's declaration. The data are encoded using a multi-stage asymmetrical encoding process. This code is filed in the document. A hash value (checksum) is formed over the signed document and stored. Even the transmission from the high-resolution graphic tablet to the PC is encoded. A so-called public key/ private key infrastructure (PKI) is used when sealing the document. These codes, however, must be generated from an independent office and, for legal security purposes, the private key must be stored in the same place. The storage of the data is carried out in accordance with ISO 19005 in a generally readable data format, with no possibility of changes being made to it, suitable for long-term storage.

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