Weiss Technik
Test it. Heat it. Cool it.

Weiss Technik North America, Inc. is the american subsidiary of Weiss Umwelttechnik GmbH, the world's largest manufacturer of environmental simulation systems.

The product range includes systems for climatic and temperature tests, weathering, thermal shock, corrosion and long-term tests of economy series-produced instruments to customized process-integrated systems.

The planning, manufacture and installation of all test chambers for research, development, quality assurance and production is our strength.

An expansive after-sales service network offers the best possible support and a high level of reliability of service for your systems. Our decades of experience, intensive exchange with developers, customers and committees, and our quality-oriented innovation management are the basis for the continual development of our products.

Weiss Technik - Always your best solution.

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Global Partner for Environmental Test Chambers

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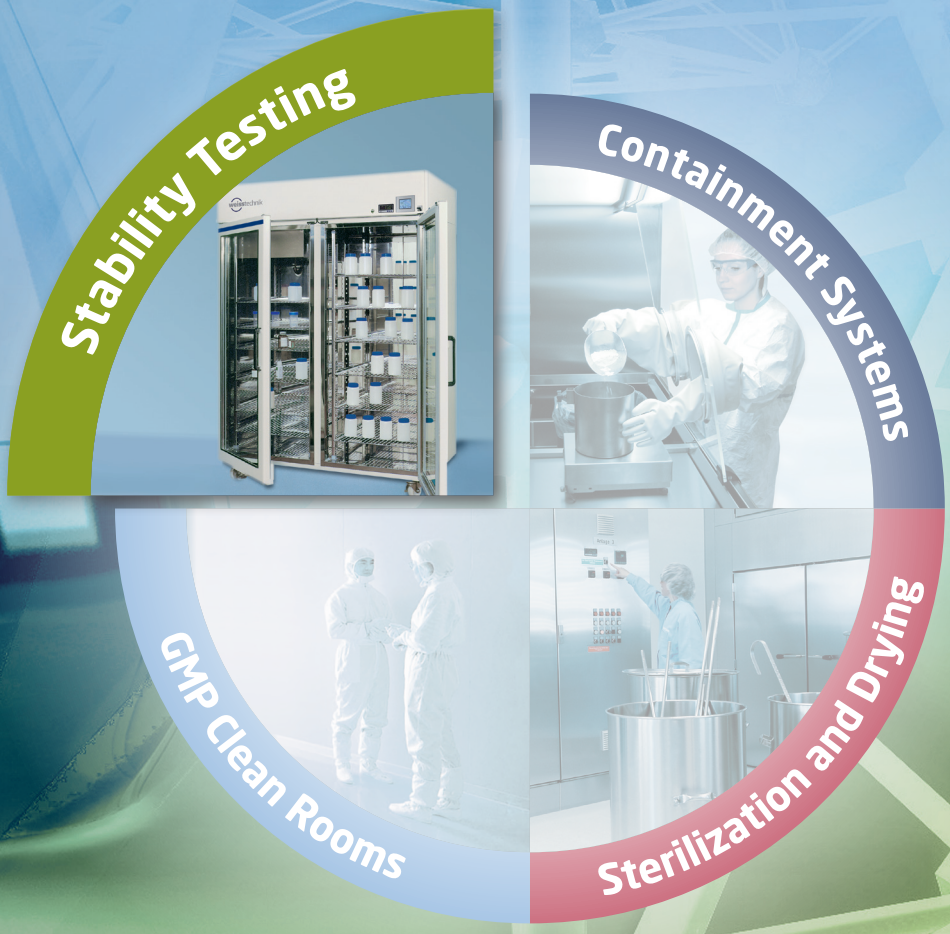
Stability Testing – GMP and FDA Compliant
Reliable Solutions for the Life Science Industry



Our Experience is Your Security

Only tested pharmaceuticals get the required approval

As quality criteria of the stability tests, the stability of chemical, microbiological and physical characteristics of pharmaceutical substances are tested after exposure to the influence of temperature and humidity over a defined period to determine the shelf-life time. For that, the following climate conditions were established for long-term testing, accelerated testing and testing at intermediate conditions according to the ICH* Guideline Q1A.

General case

Long Term	25 °C ±2 °C/60 % r.H. ±5 % r.H. or 30 °C ±2 °C/65 % r.H. ±5 % r.H.
Accelerated	40 °C ±2 °C/75 % r.H. ±5 % r.H.
Intermediate	30 °C ±2 °C/65 % r.H. ±5 % r.H.

Semi-permeable containers

Long Term	25 °C ±2 °C/40 % r.H. ±5 % r.H. or 30 °C ±2 °C/35 % r.H. ±5 % r.H.
Accelerated	40 °C ±2 °C/not more than 25 % r.H.
Intermediate	30 °C ±2 °C/65 % r.H. ±5 % r.H.

Drug substances intended for storage in a refrigerator

Long Term	5 °C ±3 °C
Accelerated	25 °C ±2 °C/60 % r.H. ±5 % r.H.

Drug substances intended for storage in a freezer

Long term -20 °C ±5 °C

During the entire test the uniformity in spatial temperature is required within ±2 °C, and the uniformity in spatial relative humidity is required within ±5 % r.H.

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 dose of 200 Wh/m^2.

Climate Test Chambers with optimized storage areas for reliable stability testing of pharmaceuticals

According to the ICH* Guideline Q1A, stability tests have to be performed under defined climatic conditions in order to furnish evidence of the stability of active substances and pharmaceuticals. For that, we have developed a specific range of test cabinets and test chambers together with the pharmaceutical industry. Stability tests are an important step in the course of the development of new drugs and pharmaceutical substances. They are an indispensable element of the process for granting of licenses for the product by governing agencies, and they are equally important for safeguarding the quality of the product in the framework of quality assurance. Together with committees from the pharmaceutical industry and experts from the governing agencies granting the required licenses, such as the FDA, the ICH* Guidelines were developed for the harmonization of stability tests which define standardized storage, the evaluation of the batches, as well as the time sequence of the required analytic tests. The guidelines are valid in the EU, Japan, and the USA. For other regions, climate zones have also been established; however, depending on the respective country, the execution of such tests may not be mandatory.

*International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use.

Safer and Easier Stability Testing

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

Uni-Flow
Airflow design for best homogeneity throughout the workspace, in loaded and unloaded conditions.

Sterile Steam System (SSS)
The demineralized water is evaporated at 140 °C to kill potential microorganisms.

Integrated Monitoring Center (IMC)
Integrated memory (optional) is available to record all measurement data of control sensors, or data from the independent sensors and alarms. The download and reporting of this data is possible with the optional software SIMPATI® Pharma software.

Pharma Light
For photostability testing per ICH Guideline Q1B, Option 2, dual lamp sources are provided; cool white lamps, for illumination according to standard ISO 10977:1993, as well as UV lamps, for specific energy from 320 to 400 nm with a maximum between 350 and 370 nm.

Exposure Equalization Filters (EEF)
Due to the fact that the fluorescent tubes have the highest intensity in the center of the light bank, and lower intensity on the sides, the filters have been developed to lower the center intensity, providing a more uniform illumination across the product shelf.

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

FDA 21 CFR Part 11 Compliance
The SIMPATI® Pharma software package (optional) is fully compliant to the requirements of FDA 21 CFR Part 11 (the governing document for the pharmaceutical and food industries). Software validation is available.

A2LA Calibrations
All temperature and humidity calibrations are performed through the ISO 17025:2005 accredited labs of Weiss Technik.

The Highest Possible Reliability

Product diversity

Our comprehensive range of constant climate cabinets from 1.2 ft³/34 l to 71 ft³/2000 l, as well as the walk-in test chambers with standard and custom designed solutions from 353 ft³/10 m³ to 10590 ft³/300 m³, are available for stability testing. The custom designed stability test chambers can be adjusted to your site requirements. Sizes over 10590 ft³/300 m³ are also available.

For testing of photostability, we offer you a solution tailored specifically to pharmaceutical guidelines. Additionally, stability solutions for continuous operation at 5 °C and -20 °C are also available.

Moreover, certain climate chambers are available in a special ATEX version for tests with preparations containing alcohol or other hazardous vapors. For all these demanding applications, we offer individual solutions with regard to volume, safety, and design.

Documentation

For recording of the measurement values of temperature, humidity and/or light, numerous documentation possibilities are available in accordance with the respective requirements. Each of these possibilities is available with independent sensors and, upon request, with the control loop sensors.

Documentation possibilities:

- Integrated datalogger for control and/or independent sensors are available; for viewing, the S!MPATI® Pharma software package is necessary.
- **S!MPATI® Pharma** software package complying with FDA 21 CFR Part 11 for connection of test chambers to a PC or server according to the manufacturer's declaration. Additionally, any existing temperature or climate device can be connected to S!MPATI® Pharma using additional sensors and interfaces (options required).
- Analog paper chart recorders are available.
- Digital paperless recorders complying to FDA 21 CFR Part 11 are available (recorder with memory and display).
- To connect the chambers to other monitoring systems, analog signals 0 to 10 V or 4 to 20 mA from the control sensor, or from additional monitoring sensors, are available.

Qualification

For the approval of active substances and/or providing evidence of proper stability testing, numerous measurements have to be carried out and confirmed over long periods of time. The purpose is ensuring flawless functioning of stability test chambers, such as compliance with allowable fluctuations in temperature and humidity.

These requirements are documented in the proper manner by means of our extensive qualification documentation.

The qualification system features:

A2LA	ISO 17025-accredited calibrations by Weiss Technik
DQ	Design Qualification
FAT	Factory Acceptance Test
IQ	Installation Qualification
OQ	Operation Qualification
PQ	Performance Qualification

Alternatively, we offer qualifications according to GAMP 5.

In addition to this, we provide all the required manual documentation such as electrical diagrams, component lists, calibration certificates, conformity and accreditation certificates (eg: ISO, CE), and maintenance recommendations.

Qualification documentation is provided for self-execution, or as a service typically provided by Weiss Technik, our trained technicians perform the entire qualification at your site.

Our Contribution to Medicinal Safety

Calibration

Various quality management systems require calibration and monitoring of test equipment that can be traced back to standards which are approved both nationally and internationally.

For this reason, we offer calibrations traceable to NIST standards, and A2LA accredited to ISO 17025: 2005. We provide certificates of calibration for each instrument upon completion, and copies are kept on file for future reference.

International acceptance of the A2LA calibration certificates is underlined by the membership of A2LA in ILAC (International Laboratory Accreditation Cooperation), all member countries of which must recognize A2LA 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 knowledgable team of instructors and engineers can advise you on all questions relating to stability testing, qualification, documentation, and other topics relating to environmental simulation and heat technology.

We offer periodic seminars and workshops on all current topics relating to our product range and its applications. This is offered at multiple locations both nationally and internationally, or at customer sites upon request.

Additionally, the Weiss Technik team 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, our extensive service network is available around the clock. In addition to this, we offer maintenance contracts specifically regarding expedited response time.

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 hand or at local service centers, we can promptly ship spare parts to our technicians and customers in order to ensure the best possible emergency part supply.

Our extensive service network ensures that we are always there when you need us. Whether we assist you from a local service center, or directly on site, our customers are always given top priority!

Stability Testing According to ICH Guideline Q1A

Pharma Series 280 | 280-T | 600 | 600-T | 1300 | 1300-T | 2000 | 2000-T

Weiss Technik Pharma Series pharmaceutical cabinets have been specially developed to meet the requirements of test laboratories in the pharmaceutical industry. The Pharma Series cabinets come in four sizes, providing either a constant temperature and humidity climate (models 280, 600, 1300 and 2000), or constant temperature only (models 280-T, 600-T, 1300-T and 2000-T). The exceptional build quality, innovative product features, accuracy, and smart controls allow for the safest, easiest, and most reliable stability testing.

The working range of the cabinets easily meets the requirements of the ICH Guideline Q1A. Furthermore, the systems are designed to work at 5 °C continuously without defrosting. The cabinets 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 either the influence of the cabinet's contents (absorption or emission of water vapor by the test specimens or their packaging, introduction of heat or cooling load by pre-conditioned product, etc), or by external influences (laboratory temperature, openings of door, etc)

Standard features

- S!MPAC® microprocessor monitoring and control; 3.5" color touch panel for entry of operating values, alarm management, trend screen viewing
- Ethernet interface
- Fully integrated user management of controls[3]
- Factory calibration of 2 temperature and 2 humidity[1] values
- Software and independent temperature limiter for min. and max. test space temperatures
- Alarm system according to GAMP
- Interior fittings made of stainless steel
- Door contact switch
- Water storage reservoir for automatic and manual water supply of demineralized humidification water[1]
- Alarm output (potential free contact) for monitoring of temperature and/or humidity[1]
- Lockable doors
- Rollable castors, with brakes[2]
- Adjustable leveling feet for 280, 280-T
- Stacking capability for 280, 280-T
- Air-cooled refrigeration unit with low noise emission
- Patented vapor humidification system (SSS)[1]
- Capacitive humidity sensor[1]
- Entry port, Ø 2 in/50 mm, in the right side panel
- Digital counter for total operating hours
- Operating manual with schematics, parts list, certificates, user instructions
- Multi-language interface (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

[1] Not applicable for Pharma Series 280-T, 600-T, 1300-T and 2000-T.
[2] Not applicable for Pharma Series 280 and 280-T.
[3] User management performed remotely with S!MPATI® Pharma software package.

Pharma Series Cabinet			280(-T)	600(-T)	1300(-T)	2000(-T)
INTERNAL TEST SPACE DIMENSIONS	Volume	cuft / l	10/280	21/600	46/1300	71/2000
	Width	inch/mm	24.4/620	24.4/620	52.8/1340	80.1/2034
	Depth	inch/mm	26.5/673	27/685	27/685	27/685
	Height	inch/mm	25.2/641	51.2/1300	51.2/1300	51.2/1300
EXTERNAL DIMENSIONS	Width	inch/mm	45.6/1159	30.8/782	56.7/1440	84.9/2156
	Depth	inch/mm	34.3/872	41.7/1060	40.9/1040	40.9/1040
	Height (with castors)	inch/mm	-	78.5/1995	78.5/1995	78.8/2001
	Height (with feet)	inch/mm	40/1017	78.9/2050	78.9/2050	78.9/2050
INTERNAL SHELVING CAPACITY	Shelves (max.)	-	2 (16)	6 (36)	12 (72)	18 (108)
	Shelf Width	inch/mm	20.9/530	20.9/530	20.9/530	20.9/530
	Shelf Depth	inch/mm	25.6/650	25.6/650	25.6/650	25.6/650
	Shelving Storage area (max.)	sqft / m^2	7.4/0.69 (59.4/5.52)	22.3/2.07 (133.5/12.4)	44.6/4.14 (267/24.8)	66.9/6.21 (400.4/37.2)
	Load per shelf	lb/kg	88.2/40 (distributed load)			
	Max load total	lb/kg	353/160	551/250	882/400	1323/600
TEMPERATURE	Working range	°C	+2 to +70			
	Control (in time)	°C	±0.1 to ±0.2			
	Uniformity (in space)	°C	±0.3 to ±1.0			
	Gradient (acc. to IEC 60068-3-5)	°C	±1 to ±2			
RELATIVE HUMIDITY[1]	Humidity range	% r.H.	20 to 90			
	Control (in time)	% r.H.	±0.5 to ±1.0			
	Uniformity (in space)	% r.H.	±2 to ±3			
	Dew point temp. range	°C	+5 to +40			
	Water supply	Automatic, via built-in water tank and/or external supply				
		gallon/l	Water tank, 3.4/13	Water tank, 4.9/19		
	Water specification	Demineralized water pH value range = 6 to 7 Conductivity range = 5 - 20 microsiemens/cm				
FACTORY CALIBRATIONS		+25 °C/60 % r.H. and +40 °C/75 % r.H.				
POWER	Mains	220/230 VAC ±10 %, 1 ph, 50/60 Hz				
	Nominal	kW	1.1	1.2	1.4	2.0
HEAT OF REJECTION		BTUH/kW	1900/0.5	2000/0.6	2400/0.7	3400/1.0
NOISE LEVEL[2]		dB(A)	52			

This data is based on an ambient temperature of +25 °C/77 °F, 230 V nominal voltage, without specimen, without additional equipment and heat compensation. This standard product contains fluorinated greenhouse gases with a global warming potential of 150 or more. Propane-based solutions are available.

[1] Not applicable for Pharma Series 280-T, 600-T, 1300-T and 2000-T (temperature only).
[2] Measured at 5 ft / 1.6 m height under free field conditions at 3 ft / 1 m distance from the front of the system.
[3] Not applicable for Pharma Series 280, 280-T.
[4] Standard for Pharma Series 280, 280-T.

Popular options

- 8" color touch panel
- S!MPATI® Pharma software package
- Integrated datalogger/recorder
- Chart recorder for temperature and/or humidity[1]
- Integrated UPS to maintain recording during power failure
- Additional temperature and/or humidity[1] sensor
- High prominence visual and audible alarm
- Water-cooled refrigeration system
- Chilled water-cooling system
- Propane-based cooling system
- Glass door(s), heated[3]
- Height-adjustable feet[4]
- Additional stainless shelves
- Additional entry ports and variable sizes
- Demineralization unit for purified water[1]
- Compressed air drier for low dewpoint operation
- Special supply voltages
- Analog outputs (0-10VDC, 0-20 mA)
- RS-232 serial interface
- RS-422/485 serial interface
- Ethernet interface cables (interface port is standard)
- Single or multi-point factory calibrations
- Preventatative maintenance, calibration, service contracts
- Spare parts package
- Qualification documentation and site execution for cabinet(s) and/or S!MPATI® Pharma software

Photostability Testing According to ICH Guideline Q1B

Pharma Series 250-L | 250-LT | 500-L | 500-LT

Weiss Technik Pharma Series photostability cabinets come in two sizes and can provide a constant temperature and humidity climate (models 250-L and 500-L) or just a constant temperature (models 250-LT and 500-LT). The photostability testing cabinets are characterized by an ideal white light, UV-A, temperature and humidity (models 250-L and 500-L) distribution, and provide the ultimate consistency of such conditions. The lighting system lamps comply with the ICH Guideline Q1B Option 2, and the power levels allow photostability tests to be carried out in less than 100 hours.

One of the most important requirements in photostability testing is the uniform irradiation of the specimens. For this reason, all the specimens should be positioned at the same distance from the light source, which is properly fixed within the Weiss Technik cabinet. The naturally non-uniform emission of lamps at close distance is rebalanced by special visible light and UV filter systems, for uniform irradiation of the shelving area. For recording of the cool white light illumination and UV-A irradiance, this system can be equipped with corresponding sensors. This option allows the entering of setpoint values in lxh and Wh/m^2 (e.g. 1.2 million lxh and 200 Wh/m^2) for a fully automated and user friendly process. The additional option of S!MPAT!® Pharma software provides for a fully documented process. Weiss Technik photostability testing cabinets offer innovative product features, high accuracy, intelligent controls, and exceptional build quality.

Standard features

- S!MPAC® microprocessor monitoring and control; 3.5" color touch panel for entry of operating values, alarm management, trend screen viewing
- Ethernet interface
- Fully integrated user management of controls[3]
- Shelves illuminated with white light lamps and UV-A lamps
- Cool white light and UV-A exposure timers
- Cool white light and UV-A filters for even distribution (EEF)
- Factory calibration of 2 temperature and 2 humidity[1] values
- Software and independent temperature limiter for min. and max. test space temperatures
- Alarm system according to GAMP
- Interior fittings made of stainless steel
- Door contact switch
- Lockable doors
- Water storage reservoir for automatic and manual water supply of demineralized humidification water[1]
- Alarm output (potential free contact) for monitoring of temperature and/or humidity[1]
- Rollable castors, with brakes[2]
- Adjustable leveling feet for 250-L, 250-LT
- Stacking capability for 250-L, 250-LT
- Air-cooled refrigeration unit with low noise emission
- Patented vapor humidification system (SSS)[1]
- Capacitive humidity sensor[1]
- Entry port, Ø 2 in/50 mm, in the right side panel
- Digital counter for total operating hours
- Operating manual with schematics, parts list, certificates, user instructions
- Multi-language interface (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

[1] Not applicable for Pharma Series 250-LT and 500-LT.
[2] Not applicable for Pharma Series 250-L and 250-LT.
[3] User management performed remotely with S!MPAT!® Pharma software package.

Pharma Series Cabinet			250-L	500-L	250-LT	500-LT
INTERNAL TEST SPACE DIMENSIONS	Useful Volume	cuft / l	8/235	16/460	8/235	16/460
	Width	inch/mm	20.9/530	20.9/530	20.9/530	20.9/530
	Depth	inch/mm	26.5/673	27/685	26.5/673	27/685
	Height	inch/mm	25.2/641	51.4/1305	25.2/641	51.4/1305
EXTERNAL DIMENSIONS	Width	inch/mm	45.6/1159	29.1/740	45.6/1159	29.1/740
	Depth	inch/mm	34.3/872	41.3/1050	34.3/872	41.3/1050
	Height (with castors)	inch/mm	-	81.5/2070	-	81.5/2070
	Height (with feet)	inch/mm	40/1017	81.5/2070	40/1017	81.5/2070
INTERNAL SHELVING CAPACITY	Shelves	-	2 shelves: 1 UV, 1 CW light	4 shelves: 2 UV, 2 CW light	2 shelves: 1 UV, 1 CW light	4 shelves: 2 UV, 2 CW light
	Shelving Storage area	sqft/m²	7.7/0.71	15.6/1.45	7.7/0.71	15.6/1.45
	Load per shelf	lb/kg	55/25 (distributed load)			
	Max load total	lb/kg	110/50	220/100	110/50	220/100
TEMPERATURE	Working range	˚C	Lighting OFF: +10 to +50 Lighting ON: +15 to +50			
	Control (in time)	˚C	±0.1 to ±0.5			
	Uniformity (in space)	˚C	±0.5 to ±1.0 (1.5 with lighting)			
	Gradient (acc. to IEC 60068-3-5)	˚C	±1 to ±2			
HUMIDITY	Humidity range	% r. H.	20 to 90			
	Control (in time)	% r. H.	±1 to ±2			
	Uniformity (in space)	% r. H.	±3 to ±5			
	Dew point temp. range	˚C	+5 to +40			
	Water supply		Automatic, via built-in water tank and/or external supply			
		l/gallon	Water tank, 3.4/13	Water tank, 4.9/19		
	Water specification		Demineralized water pH value range = 6 to 7, Conductivity range = 5 to 20 microsiemens/cm			
LIGHT	Cool white light illumination	lux	~ 15,000 at +15 ˚C ~ 18,000 at +25 ˚C ~ 25,000 at +45 ˚C			
	UV-A irradiation	W/m²	~ 1.75 at +15 ˚C ~ 3.0 at +25 ˚C ~ 3.7 at +45 ˚C			
	Cool white uniformity	%	~ ±8 from median reading			
	UV-A uniformity	%	~ ±12 from median reading			
FACTORY CALIBRATIONS			+25 ˚C/60 % r. H. and +40 ˚C/75 % r. H.			
POWER	Mains		220/230 VAC ±10 %, 1 ph, 50/60 Hz			
	Nominal	kW	1.4	2.6	1.4	2.6
HEAT OF REJECTION		BTUH/kW	2400/0.7	4400/1.3	2400/0.7	4400/1.3
NOISE LEVEL[2]		dB(A)	52			

This data is based on an ambient temperature of +25 °C/77 °F, 230 V nominal voltage, without specimen, without additional equipment and heat compensation. This standarcd product contains fluorinated greenhouse gases with a global warming potential of 150 or more. Propane-based solutions are available.

[1] Not applicable for Pharma Series 250-LT and 500-LT (temperature only).
[2] Measured at 5 ft / 1.6 m height under free field conditions at 3 ft / 1 m distance from the front of the system.
[3] Standard for Pharma Series 250-L, 250-LT.

Shelf with UV-A lamps

Shelf with cool white lamps

Popular options

- 8" color touch panel
- S!MPATI® Pharma software package
- Integrated datalogger/recorder
- Chart recorder for temperature and/or humidity[1]
- Integrated UPS to maintain recording during power failure
- Cool white and UV-A sensors for light level display and automatic integration of exposure
- Factory and/or on-site mapping of cool white and UV-A light distribution
- Additional temperature and/or humidity[1] sensor
- High prominence visual and audible alarm
- Water-cooled refrigeration system
- Chilled water-cooling system
- Propane-based cooling system
- Operation at 5˚C (lighting ON) with chilled water-cooling system
- Height-adjustable feet[3]
- Additional entry ports and variable sizes
- Demineralization unit for purified water[1]
- Compressed air drier for low dew-point operation
- Special supply voltages
- Analog outputs (0-10VDC, 0-20 mA)
- RS-232 serial interface
- RS-422/485 serial interface
- Ethernet interface cables (interface port is standard)
- Single or multi-point factory calibrations
- Preventatative maintenance, calibration, service contracts
- Spare parts package
- Qualification documentation and site execution for cabinet(s) and/or S!MPATI® Pharma software

Pharma Series Walk-in Test Chambers According to ICH Guideline Q1A

Walk-in test chambers for stability testing

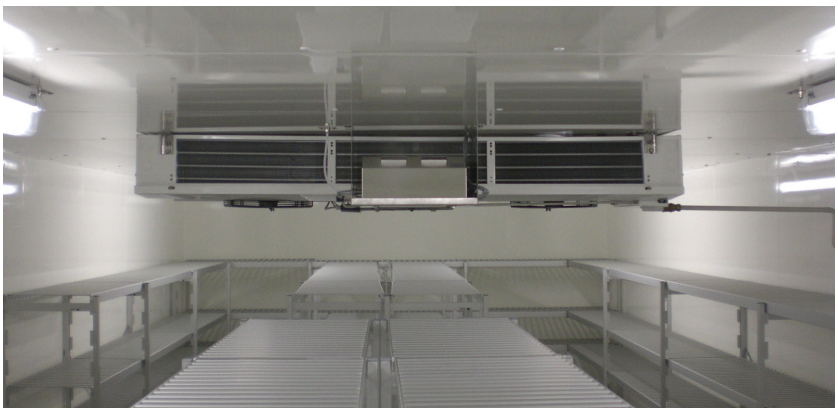
The extremely accurate and reliable stability test chambers of Weiss Technik are specifically designed to meet, and validate to, the requirements of the ICH Guideline Q1A. Flexible chamber sizes allow easy adaption to an existing building structure since standard dimensions are not required. Standard and custom designed chamber volumes range from 353 ft^3/10 m^3 to 10594 ft^3/300 m^3.

Standard features

- Excellent mechanical rigidity and optimum thermal insulation are provided by urethane core chamber panels (CFC-free), with easy-to-clean, corrosion-resistant double-sided steel skins, with standard RAL 9010 white finish. Various other interior and exterior skin materials and skin finishes are available on request.
- Insulated, heavy duty floor construction covered with slip-resistant, chequered plate stainless steel, as standard. Various other floor materials and floor coverings are available on request, and floor-less designs are also available.
- Lockable test chamber door with insulated observation window and emergency opening capability. Door ajar alarm is provided standard. Door frame and threshold heat prevents the formation of condensation during high humidity operation or cold temperature operation. For pressure equalization after door openings, a pressure relief port is provided on the chamber wall.
- Heating and cooling system consisting of ceiling evaporator with integrated electrical heater and standard air-cooled refrigeration unit, optional water-cooled and/or redundancy. Hot gas bypass and/or direct injection is provided for capacity control, and for defrost assistance below 5 C.
- Powerful, energy-saving axial fans ensure high air exchange for uniform air and temperature distribution.
- Climate conditioning system with energy-saving ultrasonic humidifier and separate desiccant or latent dehumidifier.
- Climate control system including maintenance-free stainless steel platinum element RTDs, and high accuracy capacitance-based humidity sensor.
- Energy-saving LED lights, with optional motion sensing or digital timer light switches.
- Microprocessor-based color touchscreen control system cormpliant to GAMP Guide and FDA 21 CFR Part 11. Fully integrated user management of controls may be performed remotely through the S!MPATI® Pharma software package (provided as standard).
- The control/switch cabinet contains all control components, fuses, circuit breakers, switches/relays, and other regulation devices. A separate OIT option provides a compact user interface panel by the chamber door. Components and wiring strictly conform to the safety regulations of NEC and UL.
- Safety devices ensure product protection. Two-stage alarms provide warning indication and then initiate shutdown actions. Compressor failure alarms provide immediate alarm action. Safety temperature limits are provided for the electrical heater and chamber space. Additionally, a specimen protection thermostat and humidity protection device is also provided.
- Multi-language touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean).

Temperature working range	°C	+20 to +45
Temperature control (in time)	°C	±0.1 to ±0.5
Temp. uniformity (in space)	°C	±0.5 to ±1
Temp. gradient (acc. to IEC 60068-3-5)	°C	1 to 2
Humidity range	% r.H.	20 to 80
Humidity control (in time)	% r.H.	±1 to ±3
Humidity uniformity (in space)	% r.H.	±3 to ±5
Dew point temp. range	°C	+9 to +41

This data is based on an ambient temperature of +10 °C/50 °F to +32 °C/90 °F. This standard product contains fluorinated greenhouse gases with a global warming potential of 150 or more. Propane-based solutions are available.



Popular options

- Extended temperature range to cold and freezing conditions (ex: 4 °C, -20 °C)
- Clean room design to ISO 6-8 classifications
- S!MPATI® Pharma software additional licences
- Integrated datalogger/recorder
- Chart recorder for temperature and/or humidity
- Integrated UPS to maintain recording during power failure
- Additional temperature and/or humidity sensors
- High prominence visual and audible alarm
- Water-cooled refrigeration system
- Chilled water-cooling system
- Propne-based cooling system
- Additional access ports and variable sizes
- Demineralization unit for purified water
- Desiccant wheel drier for low dewpoint operation
- Compressed air drier for ultra-low dewpoint operation
- Temperature-only operation (without humidity control)
- Touchscreen OIT panel by door, with control cabinet remotely located
- Motion sensing or digital timer light switch(es)
- Insulated wall panels rated to FM-4880
- Fully proportioning hot gas bypass valve
- Interior drop ceilings wth aluminum eggcrate, perforated clear, or acoustical tiles
- Mechanical redundancy (dual system: A & B)
- Architectural options of kickplates, ramps, corner guards, bumper rails, panel windows, vinyl floor matting
- Fixed or rollable shelving systems
- Casework with sink, water, and/or gas taps
- Flush or surface mount receptacles and/or data outlets
- Special supply voltages
- Analog outputs (0-10VDC, 0-20 mA)
- RS-232, 422, or 485 serial interface
- Ethernet interface cables (interface port is standard)
- Single or multi-point factory calibrations
- Preventatative maintenance, calibration, service contracts
- Spare parts package
- Qualification documentation and site execution for cabinet(s) and/or S!MPATI® Pharma software

Solutions for Your Special Applications

Endurance Series | WTL and WKL Series

Climate Test Chambers for Stress Testing and Freeze-Thaw Cycling

Weiss has developed a series of test chambers for simulation of extreme climates: the Endurance and WTL/WKL Series. Various industry guidelines for testing of life science products, medical components, and associated product packaging require exposure to extreme climatic conditions, and the Endurance and WTL/WKL Series meet those needs. Additionally, both series meet the requirements for rapid, low temperature freezing of bulk pharmaceutical product. For samples that contain alcohol and/or other explosive vaporous components, ATEX classification is available[5]. Temperature-only models are also available, in additional volume and temperature range offerings.

Endurance Series		WTL/WKL Series
7/190 to 54/1540	Volume (cuft/Liters)	1.2/34, 2.2/64, 3.5/100
Performance for temperature tests		
-70 to +180 / -40 to +180	Temperature working range (°C)	-70 to +180 / -40 to +180 / +10 to +180
±0.1 to ±0.3	Temperature control (in time) (°C)	WTL: ±0.3 to ±1.0, WKL: ±0.3 to ±0.5
±0.5 to ±1.0	Temp. uniformity[1] (°C)	WTL: ±0.5 to ±2.0, WKL: ±0.5 to ±1.5
1 to 2 (acc. to IEC 60068-3-5)	Temperature gradient (°C)	1 to 2 (acc. to IEC 60068-3-5)
+23 and +80	Calibration values (°C)	+23 and +80
Performance for climatic tests		
+10 to +95	Temperature working range[2] (°C)	+10 to +95
±0.1 to ±0.3	Temperature control[2] (in time) (°C)	±0.3 to ±0.5
±0.5 to ±1.0	Temp. uniformity[1, 2] (in space) (°C)	±0.5 to ±1.5
10 to 98	Humidity working range[2] (% r. H.)	10 to 98
±1 to ±3	Humidity control (in time)[2, 3] (% r. H.)	±1 to ±3
±3 to ±5	Humidity uniformity (in space)[2, 3] (% r. H.)	±3 to ±5
-3 to +94	Dew point temp. range[2] (°C)	+5.5 to +94
+23 °C/50 % r. H. and +95 °C/50 % r. H.	Calibration values (°C / % r.H.)	+23 °C/50 % r. H. and +95 °C/50 % r. H.
General data		
220/230 VAC ±10 %, 1 ph, 50/60 Hz	Electrical connection	220/230 VAC ±10 %, 1 ph, 50/60 Hz
2.3	Max. nominal power (kW)	1.8 to 3.5
Height: 70/1780 to 80.6/2047, Width: 34.2/870 to 54.7/1390, Depth: 58/1475 to 99.2/2520	Overall dimensions (inch/mm)	Height: 38.6/980 to 74.0/1880, Width: 25.2/640 to 30.7/780, Depth: 29.5/750 to 43.5/1105
950/431 to 2050/930 (-70: 2450/1111)	Weight (lb/kg)	243/110 to 463/210
<70	Noise level[4] (dB[A])	<59

This data is based on an ambient temperature of +25 °C/77 °F, 230 V 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 set-point value in temperature range from minimal temperature to +150 °C measured.

[2] Not applicable for WTL.

[3] For Endurance, measured in the middle of the test space.

[4] Measured in 5 ft / 1.6 m height under free field conditions at 3 ft / 1 m distance from the front of the system.

[5] ATEX option available through the Weiss WK3/0 Series and special WTL/WKL Series.

If Available Space is Limited

WTL - Temperature Test Chambers
WKL - Climate Test Chambers

Compact, quiet, yet powerful units are required to tackle special laboratory conditions that include limited space, even smaller specimens, and the need to conduct stress testing, freeze-thaw cycling, or stability testing according to ICH Guideline Q1A. The WTL and WKL series of temperature and climatic test chambers are ideally suited to such applications. These systems have a volume as compact as 1.2 cuft / 34 l, providing an optimum solution where space is limited.

The devices of the WTL and WKL series are suitable for typical setpoint programming of stress testing and freeze-thaw cycling, and are equipped with a state-of-the-art, 32-bit S!MPAC® control and communications system. Up to 100 test programs can be stored and retrieved.

Standard features

- S!MPAC® microprocessor monitoring and control; 3.5" color touch panel for entry of operating values, alarm management, trend screen viewing
- Fully integrated user management of controls[2]
- Lockable door with observation window
- Interior lighting
- Software and independent temperature limiters for min. and max. test space temperatures
- Alarm output (potential free contact) for monitoring of temperature and/or humidity[1]
- Ethernet interface
- Digital counter for total operating hours
- USB interface for transfer of measuring data via USB stick
- Air-cooled refrigeration unit with low noise emission
- Interior fittings made of stainless steel
- Stainless steel product shelf
- Entry port, Ø 2 in/50 mm, in the right side panel
- Adjustable leveling feet
- Factory calibration of 2 temperature values and 2 humidity values[1]
- Water storage reservoir for automatic and manual water supply of demineralized humidification water[1]
- Operating manual with schematics, parts list, certificates, user instructions
- Multi-language interface (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

Popular options

- S!MPATI® software package
- 8" color touch panel
- Integrated datalogger/recorder
- Additional temperature and/or humidity sensors
- Capacitive humidity sensor
- Analog outputs (0-10VDC, 0-20 mA)
- RS-232, 422, or 485 serial interface
- Ethernet interface cables (interface port is standard)
- Water-cooled refrigeration system
- Compressed air drier
- Additional entry ports
- Additional shelves
- Frame with rollable castors, with brakes (except for WKL/WTL -70 °C, 1.2cf/34L and 2.2cf/64L)
- Demineralization unit for purified water[1]
- Special supply voltages
- ATEX explosion safe classification
- Single or multi-point factory calibrations
- Preventatative maintenance, calibration, service contracts
- Spare parts package
- Qualification documentation and site execution for cabinet(s) and/or S!MPATI® software

[1] Not applicable for WTL Series.
[2] User management performed remotely with S!MPATI® software package.

WT 500/30 Pharma

Laboratory Chambers for Stress Testing, Freeze-Thaw Cycling, and Stability

Chamber footprint of only 10.8 ft² / 1 m²!

Volume	cuft/Liters	18 / 500
Temperature range	°C	-30²/+100
Temp. control (in time)	°C	±0.2 to ±0.5
Temp. uniformity (in space)	°C	±0.5 to ±1.0
Product heat load max.	W @ °C	1000W @ +20, 680W @ 0
Calibrated values	°C	+23 and +80
Internal test space dimensions	inch/mm	Height: 49.2/1250 Width: 26.8/680 Depth: 23.2/590
External dimensions	inch/mm	Height: 77.8/1975 Width: 37.2/945 Depth: 42.1/1070
Weight	lb/kg	661/300
Noise level[1]	dB(A)	56
Max. nominal power	kW	2.4
Electrical connection		220/230 VAC ±10 %, 1 ph, 50/60 Hz

This data is based on an ambient temperature of +25 °C, 230 V 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 at 5 ft / 1.6 m height under free field conditions at 3 ft / 1 m distance from the front.

[2] For continuous operation below freezing, the optional compressed air drier is required.

[3] User management performed remotely with S!MPATI® software package.

Applications

- Stress temperature testing
- Stability temperature testing
- Freeze-thaw cycling
- -20°C ICH stability freezer²
- Areas with limited space!

Standard features

- S!MPAC® microprocessor monitoring and control; 3.5" color touch panel for entry of operating values, alarm management, trend screen viewing
- Fully integrated user management of controls[3]
- Lockable door
- Interior lighting
- Software and independent temp. limiters for min./max. test space values
- Alarm output (potential free contact) for monitoring of temperature
- Ethernet interface
- Digital counter for total operating hours
- USB interface for transfer of measuring data via USB stick
- Air-cooled refrigeration unit with low noise emission
- Stainless steel product shelf
- Entry port, Ø 3 in/80 mm, in the right side panel
- Rollable castors
- Factory calibration of 2 temperature values
- Operating manual with schematics, parts list, certificates, user instr.
- Multi-language interface (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

Popular options

- S!MPATI® software package
- Extended temperature range to -40°C
- Integrated datalogger/recorder
- Additional temperature sensors
- Analog outputs (0-10VDC, 0-20 mA)
- RS-232, 422, or 485 serial interface
- Water-cooled refrigeration system
- Observation window
- Compressed air drier
- Additional entry ports
- Additional shelves
- Special supply voltages
- Single or multi-point factory calibrations
- Preventatative maintenance, calibration, service contracts
- Spare parts package
- Qualification documentation and site execution for cabinet(s) and/or S!MPATI® software

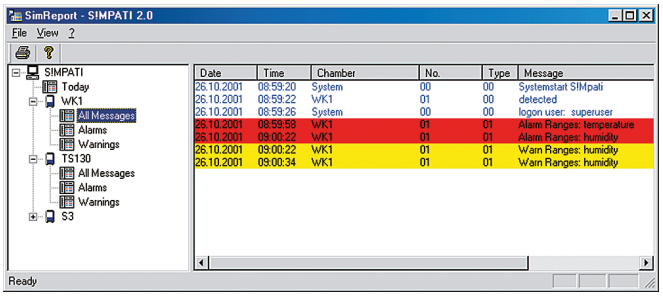
Simple and Secure

S!MPATI® Pharma software

The S!MPATI® Pharma control and documentation software enables you to make even better use of your devices and systems. S!MPATI® Pharma allows for simple and secure recording and archiving of data, and fully complies with FDA 21 CFR Part 11.

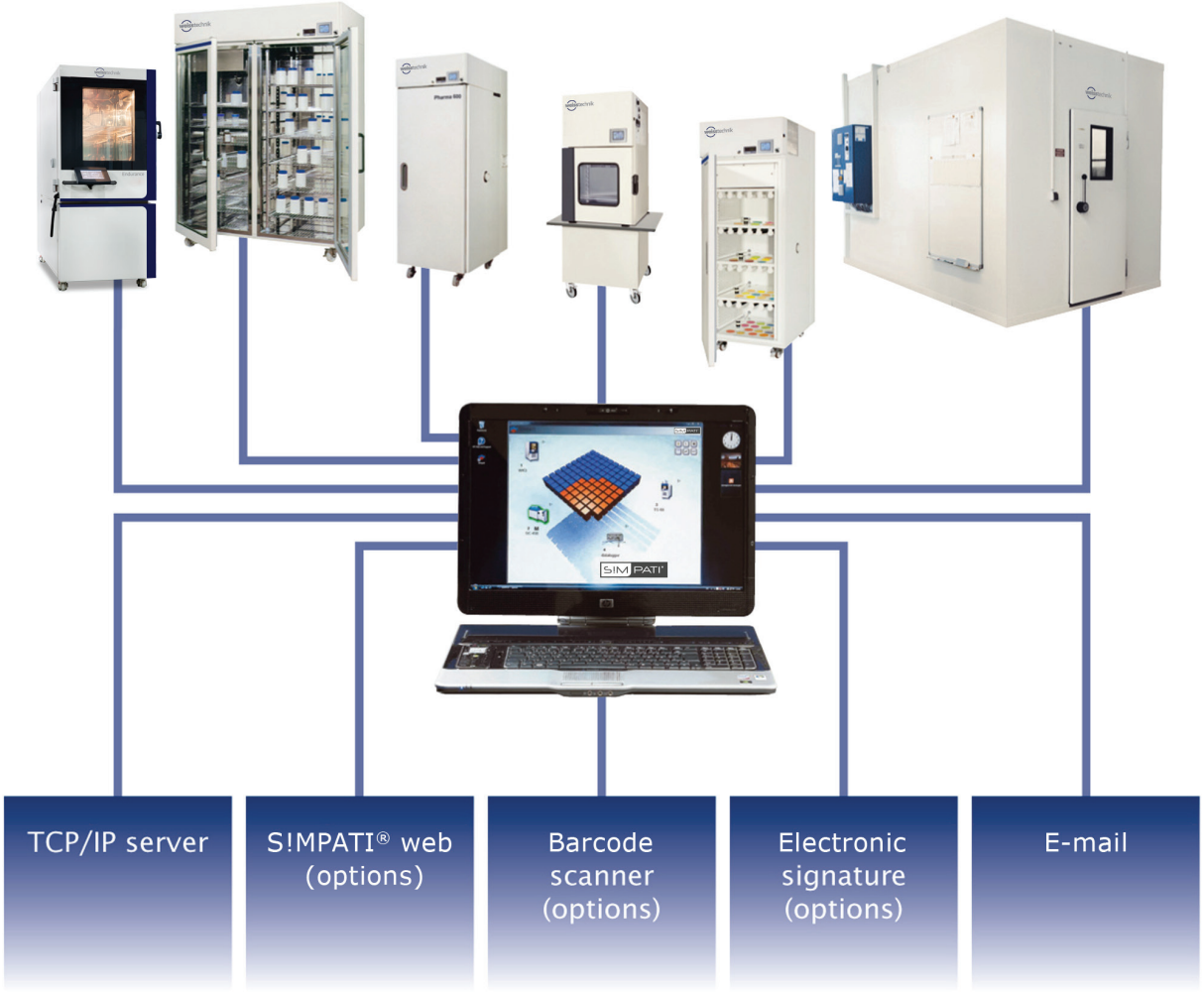
All warning and alarm messages are recorded and, if necessary, transmit an alarm signal to the person in charge of the system. Access rights can be specifically defined for every user; the recording and storage of data are manipulation-safe but can still be used for further processing, e.g. in Excel.

Operation of our systems is simple and time-saving. S!MPATI® Pharma can be integrated into your PC network (with options) and enables operation at individual stations without requiring special software - simply use your Internet browser. Additionally, S!MPATI® Pharma can be installed on virtual servers.



Audit trail

Connections



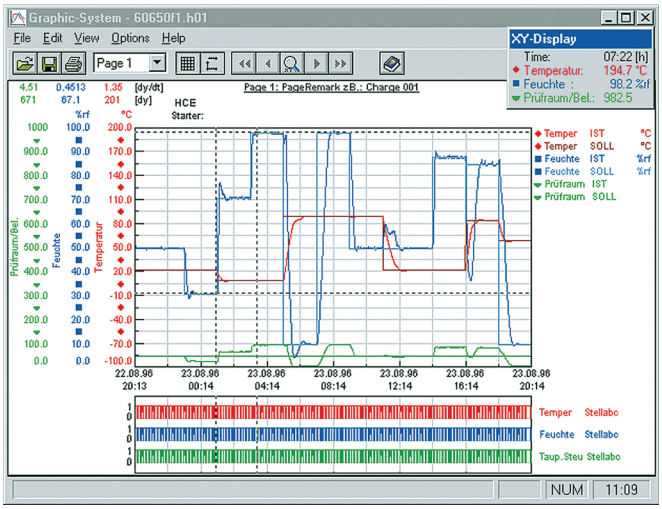
The Most Important Functions and Possibilities

- Recording and archiving of all test data
- Manipulation-safe data registration
- Administration of multi-level access rights
- Password alteration
- Compliance with FDA 21 CFR Part 11
- Audit trails
- 99 unit capacity via the serial interface or Ethernet interface (TCP/IP)
- Alarm messaging via e-mail, SMS, phone, tablets
- Recording of all general alarms, door openings, and documentation of opening times
- Recording of temperature and humidity values
- Recording of visible light and UV intensity during photostability tests
- Mobile solutions for site-independent monitoring of devices (ex: by means of a PDA within the range of the installed WLAN)
- Data recording via special system network, as well as via a TCP/IP network
- Documentation of climate chambers and rooms from other suppliers (requires options)
- Category 3 software according to GAMP
- Fulfillment of the complete 5 step risk based approach according to GAMP 5 (considers alarm system of the connected devices)
- Available in German, English, French, Czech, Russian, Spanish, Chinese, Korean

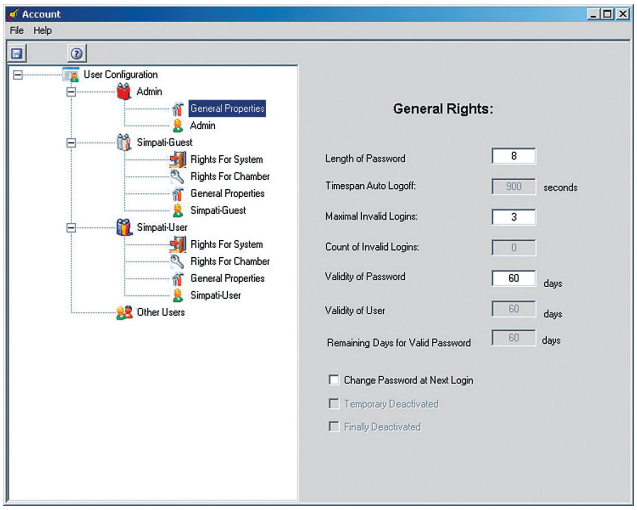
Note: For some of the functions described above, further options or special infrastucture at the customer's facility may be required.

Options:

- Validation documentation package (includes DQ, IQ, OQ)
- S!MPATI® e-Sign: Electronic signature with recording of biometric data
- S!MPATI® Barcode Scan: Barcode reader for batch management
- Datalogger / recorder



Graphical recording



User management

S!MPATI® Barcode Scan

Batch registration using barcode scanners

Optional barcode scanning technology can also be used for batch registration and storage management. This optional module is customized and adapted to the specific requirements of the user.

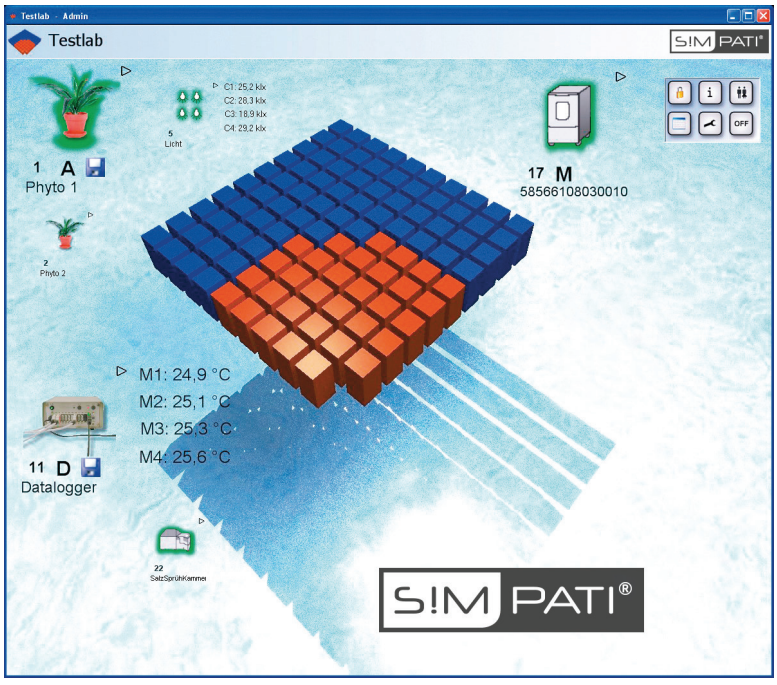
Advantages

- 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
- Creation of automatic reports
- Wireless scanner technology scans and transfers the information (ex: during the loading of test chambers)

Always in Control ...

Wherever you are!

S!MPATI® Pharma provides a comfortable means of operating and monitoring from your PC. S!MPATI® Pharma also supports the modern possibilities of Internet communication for monitoring via Internet browser and via e-mail. S!MPATI® Pharma not only provides process information at your Desktop PC, but also virtually anywhere on the Internet. Additionally, you can access data via the cellular phone network (option).



S!MPATI® e-Sign.

Biometric data based on your handwriting.

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

Legal professionals 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!MPATI® e-Sign is a supplement to the software package, and compliant with FDA 21 CFR Part 11. S!MPATI® Pharma enables signing all measurement data while capturing biometric data based on your handwriting.

S!MPATI® e-Sign offers legal security, where the signature is clearly identifiable!

In order to also be able to identify the undersigned at a later date, there are special software graphic components which, in case of dispute, could be used by handwriting experts. Comparable conclusions can be reached from these components, compared to a hand-written signature on paper. Functional security was verified, based on more than 200,000 signatures.

Full compliance to FDA 21 CFR Part 11. The system can be easily qualified.

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, or other 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.

The data is 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. The transmission from the high-resolution graphic tablet to the PC is also encoded. A 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.

Our Customers and Partners Include the “Who’s Who” of the Life Science Industry

Around the world, companies benefit from solutions provided by Weiss Technik; solutions tailored to the specific product and process requirements of each valued customer. Our extensive customer reference list is available upon request.