Tested and Approved . . .

Climate Test Chambers for Stability Tests on Pharmaceutical Products according to the ICH Guideline Q1A
Photostability Test Chamber according to the ICH Guideline Q1B

schunk Group

Weiss Umwelttechnik GmbH
Simulationsanlagen • Messtechnik

WEISS TECHNIK

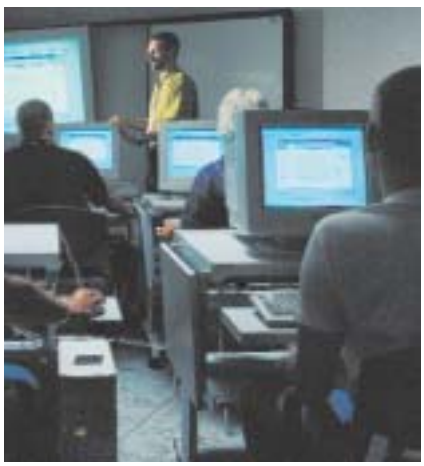
Our Experience . . .

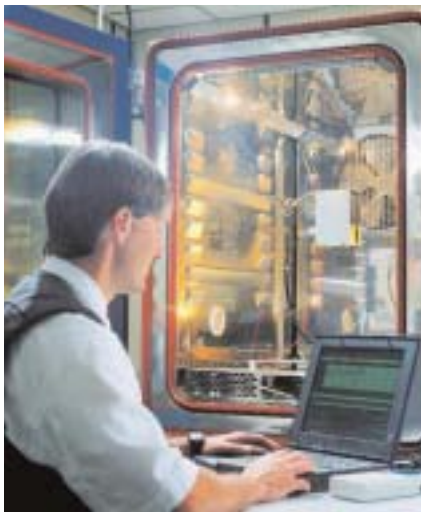
Weiss Umwelttechnik GmbH is one of the most important producers of standard test devices and special test systems for environmental simulation technology worldwide.
The range of products comprises systems for simulating exposure to weather as well as systems for temperature, temperature shock and corrosion tests in all test chamber volumes for applications in research, development, quality assurance and production.

In order to safeguard a constantly high quality and stability of medical and pharmaceutical products we offer you a comprehensive standard range of stability test chambers extending to walk-in test chambers and special systems of any size depending on your requirements. Our product range is based on the GMP, FDA and ICH guidelines.

Our efficient after-sales service ensures optimum support for our customers as well as a high degree of reliability of operation of the systems.

Decades of experience in the various fields of application as well as the intensive exchange of views with our customers from all over the world ensure a good co-operation.





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 is tested after exposure to the influence of temperature and humidity over a defined period.
To that end, the following climate conditions were established for long-term testing, accelerated testing and testing at intermediate conditions according to the ICH* Guideline Q1A.
Testing at intermediate conditions is carried out in case there are deviations between the first two forms of testing.

- **Long-term testing**
  at +25 °C / 60 % r.h. or
  30 °C / 65 % r.h.
- **Accelerated testing**
  at +40 °C / 75 % r.h.
- **Intermediate testing**
  Temperature +30 °C / 65 % r.h.

The following test conditions were stipulated for substances or pharmaceuticals in semi-permeable packaging:

- **Long-term testing**
  Temperature +25 °C / 40 % r.h.
- **Accelerated testing**
  Temperature +40 °C / < 25 % r.h.

During the entire test the deviation in temperature is stipulated at ± 2 K and the deviation in relative humidity is stipulated at ± 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 part of 200 Wh/m².

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.
To that end, 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 the authorities, but they are just as important for safeguarding the quality of the product in the framework of quality assurance.

Together with committees from the pharmaceutical industry experts from the authorities granting the required licenses, such as e.g. the FDA, have developed the ICH* Guidelines for the harmonisation 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 Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use*

The Highest Possible Reliability...

Product Diversity

Our comprehensive standard range of climate chambers from 34 l to 2000 l as well as the walk-in test chambers as standard solutions from 4 m^3 to 41 m^3 are available for the execution of stability tests. In specific cases the stability test chambers can be adjusted to your premises and almost any design. Special sizes, e. g. 200 m^3, are also possible.

For testing of photostability we offer you a solution tailor-made specifically for this purpose in the form of a photostability test chamber.

Moreover, climate chambers in a version executed as per ATEX are available for tests with preparations containing alcohol.

For all of these demanding applications we offer individual solutions with regard to volume, safety and design for every customer.

Documentation

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

In detail these are:

- Analog line recorder (paper line recorder)
- Digital line recorder (line recorder with memory and display)
- Digital line recorder, complying with FDA 21 CFR Part 11 (line recorder with memory, display and possibility of an electronic signature)
- SIMPATI® **Pharma** software package complying with FDA 21 CFR Part 11 for connecting devices and test chambers to a PC.

Moreover, any existing temperature or climate devices can be connected to independent recorders or computers using our SIMPATI® **Pharma** software which complies with FDA 21 CFR Part 11.

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 e. g. 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:

FAT	Factory Acceptance Test
DKD	(German calibration service) Calibration Certificates
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operation Qualification
PQ	Performance Qualification

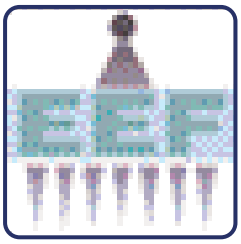
In addition to this we provide all the required documents such as circuit diagrams, component lists and certificates, e. g. ISO accreditation, EC conformity declarations or also maintenance recommendations.

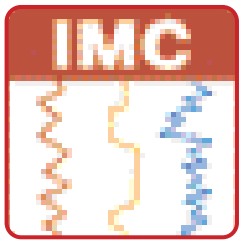
On request, our trained technicians carry out the qualification on site and can complement this with our comprehensive measurement and calibration facilities (also DKD calibrations).

Exposure Equalisation Filter

Homogeneous Airflow

Independent Monitoring Centre





. . . our Contribution to Medicinal Safety

Calibration

Various QM 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, Weiss Umwelttechnik GmbH offers calibrations at a laboratory accredited according to ISO 17025 and provides DKD calibration certificates for the measurable variables of air temperature, dew point temperature and relative humidity.

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

Our 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 relating to environmental simulation and heat technology at any time.

We offer **seminars and workshops** on all current topics relating to our product range and its application **regularly** 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 Maintainance

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

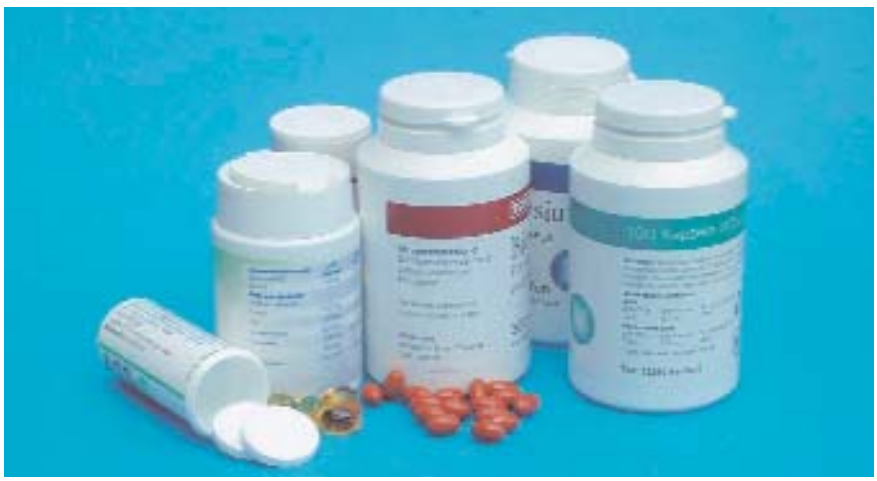
In addition to this, we offer maintenance contracts with a provision regarding a response time of 24 hours also on weekends.

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 with spare parts.

Our extensive service network 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.



Weiss Pharma Cabinets . . .

The Basis

The Weiss pharmaceutical cabinet series has been specially developed to meet the requirements of test laboratories in the pharmaceutical industry. These systems are available in the three sizes of Pharma 600, Pharma 1300 and Pharma 2000 and are of a robust design.

The interior fittings are entirely made of stainless steel offering a storage area of 2.07 m^2 (Pharma 600), 4.14 m^2 (Pharma 1300) and 6.21 m^2 (Pharma 2000) on 6, 12 or 18 loose shelves which are supplied as a standard feature.

The working range of the cabinets easily meets the requirements of the ICH Guideline Q1A. 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 set-point variations caused by

– the influence of the cabinet's contents (absorption or emission of water vapour by the test specimens or their packaging)

– external influences (e. g. laboratory temperature, opening of door).

Standard Scope of Delivery

- Micro-processor monitoring and control MINCON/32*
- Serial interface RS 232 C
- Lockable doors
- Door contact switch
- 4 castors, 2 of which with brakes
- Water tank, 19 l with automatic and manual water supply of demineralized humidification water
- Air-cooled refrigeration unit with low noise emission
- Patented vapour humidification system (Sterile Steam System)
- Capacitive humidity sensor
- Entry port, Ø 50 mm, in the right side panel

- Control panel with LCD display and key pad for entering of set-point values
- Adjustable specimen protection t_{min}/t_{max} as independent temperature limiter
- Calibration of 2 temperature and 2 humidity values

Options

- Colour touchpanel
- Software package SIMPATI* Pharma for recording and processing of measurement values
- Networking of several systems
- Centronics printer interface
- Registration of temperature and humidity
- Additional temperature and humidity sensor
- Acoustic and optical warning signal
- Refrigeration unit, water-cooled
- Glass door, heated
- Demineralisation unit with exchangeable cartridges for connection to domestic water supply
- Additional shelves
- Additional entry ports
- Height-adjustable feet
- Qualification documentation for Pharma test chamber and SIMPATI* Pharma software
- Special voltages

Technical Data

Type	PHARMA 600	PHARMA 1300	PHARMA 2000
External dimensions (mm)			
Height	1975[1]/2030[2]	1975[1]/2030[2]	2067[1]/2112[2]
Width	740	1460	2155
Depth	1050	1050	1050
Interior dimensions (mm)			
Height	1300	1300	1300
Width	620	1340	2034
Depth	685	685	685
Shelves (pieces) standard (650 x 530 mm)	6[3]	12[3]	18[3]
Storage area (m^2) standard	2.07[3]	4.14[3]	6.21[3]
Climate working range			
Temperature working range	°C	+10 … +50	
Humidity range	% r.h.	20 … 90	
Humidity fluctuation, in time	% r.h.	±1 … ±2	
Dew point temperature range	°C	+5 … +40	
Temperature fluctuation, in time	K	±0.1 … ±0.5	
Temperature fluctuation, spatial	K	±0.5 … ±1.0	
Temperature gradient[4]	K	1 … 2	
Electrical supply	1/N/PE AC 230 V ±10%/50 Hz		
	Safety plug		
Max. installed load (kW)	2.5	3	3.5
Noise level[5]	dB(A) 52	52	52
Humidity water	demineralised water pH-value 6-7 conductivity 5 to 20 Microsiemens/cm		
Weight (kg)	150	250	350

[1] *with castors* [2] *with height-adjustable feet* [3] *possible additions* [4] *according to IEC 60068-3-5*
[5] *free field, 1 m distance from the front, as per DIN 45635, part 1, accuracy class 2*
The performance values refer to an ambient temperature of +25 °C.
We reserve the right to make technical alterations.

Photostability Test Chambers Pharma 500-L...

Photostability Test Chamber According to ICH Guideline Q1B

The photostability test chamber Pharma 500-L is characterized by an ideal light, UV, temperature and humidity 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 energy this system can be equipped with corresponding light and UV sensors. With this option entering of the set-point values in lxh and Wh/m² is made possible and the remaining time until the pre-defined set-point values are reached is displayed.

The required relative humidity is generated with the help of a patented vapour humidification system (Sterile Steam System). A capacitive humidity sensor is available for humidity measurement.

Technical Data Pharma 500-L

Volume	litres	gross approx. 700 net approx. 460
External dimensions Test space dimensions	W x H x D mm W x H x D mm	815 x 935 x 2070 595 x 600 x 1305
Temperature range Humidity range	°C % r.h.	+10 … +50 20 … 90
Temperature fluctuation, in time Temperature fluctuation, spatial Temperature gradient[1)] Humidity fluctuation, in time	K K K % r.h.	±0.1 … ±0.5 ±0.5 … ±1.0 1 … 2 ±1 … ±2
Illumination UV energy Light distribution UV distribution	lx W/m² % r.h. % r.h.	max. 25000 max. 3.7 approx. ±6 approx. ±10
Noise level[2)] Electrical connection	dB (A)	52 1N/PE AC 230 V ±10 %, 50 Hz

The performance values refer to an ambient temperature of +25 °C, [1)] according to IEC 60068-3-5, [2)] free field, 1m distance from the front, as per DIN 45635, part 1, accuracy class 2

Compact Dimensions . . .

Standard Equipment Pharma 500-L

- 32-bit control system SIMCON/32*-NET with MINCONTROL* control panel
- 2 shelves illuminated with UV light
- 2 shelves illuminated with white light
- Timers for light and UV light
- Counter for total operating hours
- Light and UV filters for optimum distribution
- Lockable door
- Water tank 19 l, with possibility of manual and automatic water supply
- Patented vapour humidification system (Sterile Steam System)
- Serial interface RS 232 C
- Calibration certificate

Options for Pharma 500-L

- Colour touchpanel
- UV and Lux sensors with automatic measurement value integration
- Analog line recorder
- Digital line recorder
- Ethernet/LAN interface (10/100 MBit) in connection with SIMPATI* for integration into a network
- SIMPATI* **Pharma** software package complying with FDA 21 CFR Part 11
- Qualification documentation
- DKD calibration certificate
- Mapping of light distribution
- Spatial measurements for temperature and humidity
- Maintenance contracts with response time

Temperature Test Chambers WTL and Climate Test Chambers WKL

Compact dimensions combined with outstanding performance form a prominent feature of the laboratory test chambers for temperature and climate by Weiss Umwelttechnik.

This means these test chambers fulfil the requirement of the performance of reproducible tests on a laboratory scale or stability tests according to ICH Guideline Q1A directly at the work station.

A range of 2 test space sizes with a test space volume of 34 l and 100 l and three temperature ranges +10 °C to +150 °C, –40 °C to +150 °C and –60 °C to +150 °C are available to that end.

The climate range is between 10 and 98 % rel. humidity at temperatures between +10 °C and +95 °C. Humidity is generated by a patented steam generator in a manner free of aerosols as well as sterile.

The devices of the WTL and WKL series are suitable for program and setpoint value operation and are equipped with a state-of-the-art efficient 32-bit MINCON/32* control and communications system. Up to 100 test programs can be stored and retrieved.

With regard to the technical data the temperature and climate devices fulfil test standards, such as e.g. DIN, ISO, MIL, IEC, DEF or ASTM.

The Comprehensive Standard Version

- 32 bit MINCON control system with MINCONTROL* control terminal
- Observation window
- Test space lighting
- Independent adjustable temperature limiter t_{min}/t_{max}
- Potential-free contact for test specimen switch-off
- Serial interface RS 232 C
- Air-cooled refrigeration circuit
- Psychrometric humidity measurement system
- 1 loose shelf

- 1 entry port 50 mm
- Calibration of 2 temperature values for WTL and 2 climatic values for WKL

Options

- Colour touchpanel
- Ethernet/LAN interface (10/100 MBit) in combination with SIMPATI* for integration into a network
- SIMPATI* software package
- Temperature measurement on test specimen
- Capacitive humidity measurement
- Interface IEEE 488
- Networking (RS 485 Interface)
- Centronics printer interface
- Compressed air dryer
- Additional entry ports
- Additional shelves
- Frame with castors (except for WTL/WKL 34/60)
- Autom. water supply (WKL)
- Demineralisation unit (WKL)
- Special voltages

For further information see brochure **Compact Dimensions – Outstanding Performance WTL/WKL.**

Walk-in Test Chambers . . .

. . . Walk-in Test Chambers for Stability Tests

Stability test chambers by Weiss Umwelttechnik can be validated and are designed specifically to meet your requirements.
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 2700 mm; other dimensions are possible.

Quality Features

- PU insulation chamber elements (CFC free) with easy-to-clean, double sided metal plate coating.
- Lockable test chamber door with emergency opening facility.
- Heating and cooling system consisting of ceiling vapouriser with integrated electrical heater and air-cooled refrigeration unit.
- Climate conditioning system with energy saving ultrasonic humidifier and separate dehumidifier.
- Micro-processor controlled control system corresponding to GAMPGUIDE and FDA 21 CFR Part 11, with maintenance-free electronic temperature/humidity sensor.
- Safety temperature limiter for electrical heater and test chamber.
- Specimen protection t_{min}/t_{max}

Options

- Temperature and humidity range extensions
- Unit as a temperature chamber (without controlled humidity)
- Entry ports
- Observation window
- Shelf system
- Explosion-proof components
- SIMPATI® **Pharma** software package for recording and processing of measurement values
- One-point calibration
- Spatial calibration

. . . further options available on request.

Climate Range

Standard volumes	m^3	4, 10, 15, 25, 32, 41
Temperature range	°C	+20 … +45
Temperature fluctuation, in time	K	±0.1 … ±0.5
Temperature fluctuation, spatial	K	±0.5 … ±1 according to IEC 60068-3-5
Temperature gradient[1)]	K	1 to 2
Humidity range	% r.h.	20…80
Humidity fluctuation, in time	% r.h.	±1 … ±3
Dew point temperature range	°C	+9 … +41

The performance values refer to an ambient temperature of +25 °C, [1)] In accordance with IEC 60068-3-5

...S!MPATI* the Pharma Software

Our control and documentation software S!MPATI* **Pharma** enables you to make even better use of your devices and systems and simplifies data recording as well as archiving of data.
All warning and alarm messages are recorded and, if necessary, an alarm signal can be transmitted to the person in charge of the system.

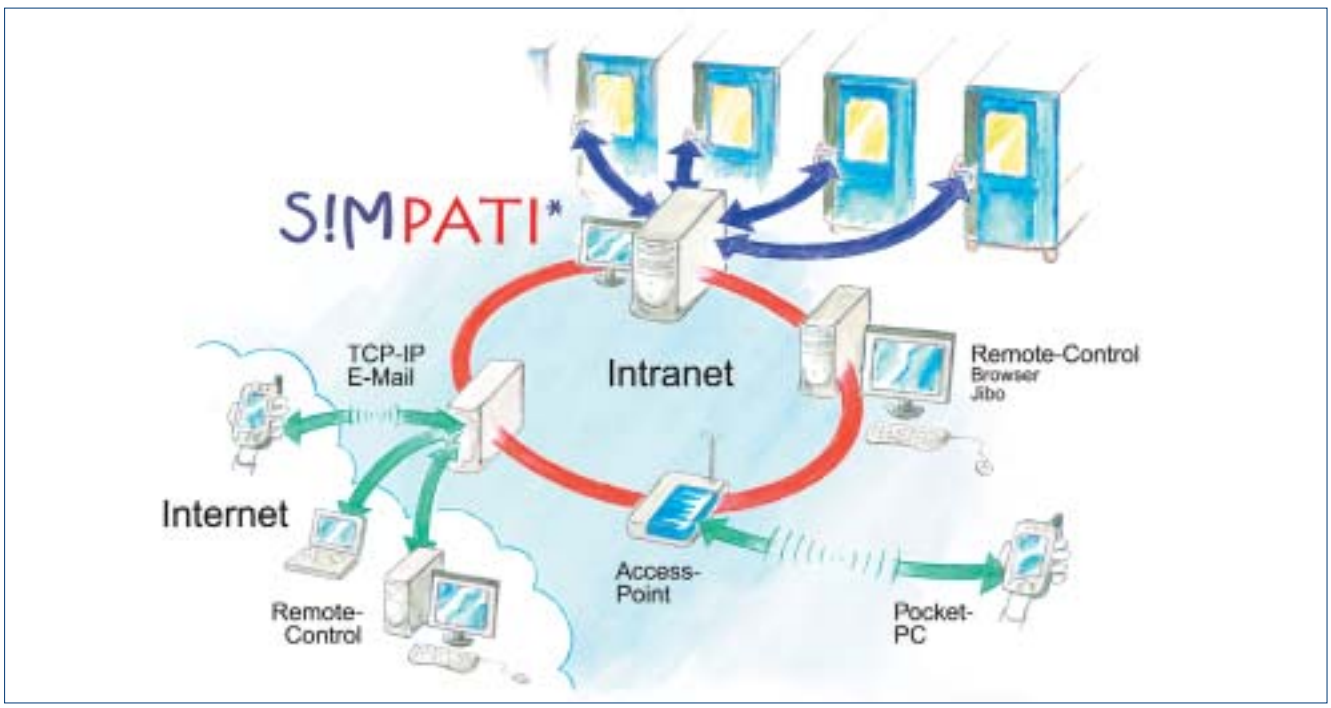
Access rights can be defined individually for every user; the recording and storage of data is manipulation-safe but can still be used for further processing, e. g. in Excel.
The S!MPATI* **Pharma** software complies with FDA 21 CFR Part 11 and is subject to category 3 as per GAMP 4.
We also provide a qualification documentation with Audit Trail for our control and test management software S!MPATI* **Pharma** for the documentation requirement as per GAMP 4.

Operation of our systems is simple and time-saving. S!MPATI* can be integrated into your PC network and enables operation at individual stations without requiring special software – simply by using your internet browser.

The Most Important Functions and Possibilities

- Barcode reader for batch management
- Remote alarming
- Alarm output via e-mail, SMS, telephone or alarm contact
- 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 PDA within the range of the installed WLAN
- Data recording via a special system network as well as via a TCP/IP network is possible
- Manipulation-safe data
- Administration of access rights
- Conformity with FDA 21 CFR Part 11
- Documentation of climate chambers and rooms irrespective of manufacturer

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



Test Systems for Professionals. Test the Best . . .

If Safety Matters: Climate Test Chambers of the WK 111 Series

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.**

With the WK 111 Weiss Umwelttechnik has developed a series of climate test chambers for **real-time tests** or **tests under different climate conditions,** which is characterised by very low energy requirements and operation at low noise levels and which can also comprise safety precautions as per ATEX upon a request to that end.

Technical Data

Series		**WK 111**
Test space volume	approx. litres	190 … 1540
Temperature tests		
Temperature range	°C	–10 / –5 / 0 …+90
Temperature fluctuation, in time	K	±0.1 … ±0.5
Temperature fluctuation, spatial	K	±0.5 … ±1.0
Temperature gradient[1)]	K	1 … 2
Calibration values	°C	+4 and +90
Calibration tests		
Temperature range	°C	+10 … +90
Temperature fluctuation, in time	K	±0.1 … ±0.3
Temperature fluctuation, spatial	K	±0.5 … ±1.0
Temperature gradient[1)]	K	1 … 2
Humidity range	% r.h.	10 … 98
Humidity fluctuation, in time	% r.h.	±1 … ±3
Calibration values as per ICH Guideline		+25 °C / 60 % r.h. and +40 °C / 75 % r.h.
Noise level[2)]	dB (A)	47
Electrical connection		1/N/PE AC 230 V ±10 %, 50 Hz

The performance values refer to an ambient temperature of +25 °C [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

For further information see brochure **Constant Climates WK 111.**

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