

Vötsch

a schunk company

Stability Testing -
GMP- and FDA Compliant

Reliable Solutions for the
Pharmaceutical Industry

Stability Testing



Containment Systems



GMP Clean Rooms



Sterilization and Drying



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. 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.



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 deviation in temperature is stipulated at ±2 °C 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 of Pharmaceuticals for Human Use.

Safer and Easier Stability Testing

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



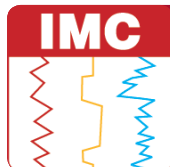
Uniflow

Airflow design for best homogeneity even in loaded units.



Sterile Steam System

The demineralised water is evaporated at 140 °C to kill eventually available 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 is possible with the optional software SIMPATI* Pharma.



Pharma Light

For photostability testing a cold white illumination according to ISO 10977:1993 as well as a UV-source from 320 to 400 nm with a maximum between 350 and 370 nm according to ICH guideline Q1B are integrated.



Exposure Equalisation Filters (EEF)

Due to the fact that fluorescence tubes have the highest intensity in the middle of the tube and lower intensities on the sides the exposure equalisation filters have been developed to cut the maximum in the middle and therefore get a homogenous illumination of the storage surface.



Qualification Documents

Vötsch 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 SIMPAC* and the monitoring software SIMPATI* Pharma are fully compliant to the requirements of EU GMP Annex 11 for computerised systems. This can be proven in the software validation.



FDA 21 CFR Part 11 Compliance

The monitoring software SIMPATI* Pharma is fully compliant to the requirements of FDA 21 CFR Part 11 the American law for electronic documentation in the pharmaceutical and food industry. This can be proven in the software validation.



DAkks Calibrations

All used measurement systems for temperature and humidity used within Vötsch Industrietechnik for final testing, calibration and qualification on customer side are traceable to a ISO 17025 accredited calibration laboratory of Vötsch Industrietechnik.

The Highest Possible Reliability ...

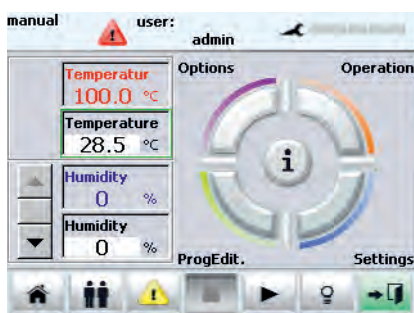
Product diversity

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 10 to 300 m³ 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. 400 m³ or 800 m³, 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. Furthermore solutions for continuous operation at 5 °C and -20 °C are available.

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

- Integrated Datalogger for control and/or independent sensors, for downloads the software SIMPATI* Pharma is necessary.
- SIMPATI* Pharma software package complying with FDA 21 CFR Part 11 and EU GMP Annex 11 for connection of test chambers to a PC or server.
- Moreover, any existing temperature or climate devices can be connected to SIMPATI* Pharma using additional sensors and interfaces.
- Analogue paper recorders.
- 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 0-10 V or 4-20 mA from the control loop or additional sensors are possible as option.
- An integration into a LIMS is also possible.

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
- DAkKS** ISO 17025 accredited calibrations with certificate
- DQ** Design-Qualification
- IQ** Installation-Qualification
- OQ** Operation-Qualification
- PQ** Performance-Qualification

Alternatively we offer also qualifications acc. 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 (also DAkKS calibration).

... 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, Vötsch Industrietechnik offers calibrations with its own laboratory accredited according to ISO 17025 and provides DAkkS calibration certificates for the measurable variables of air temperature, dew point 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 recognize DAkkS 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 inhouse 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

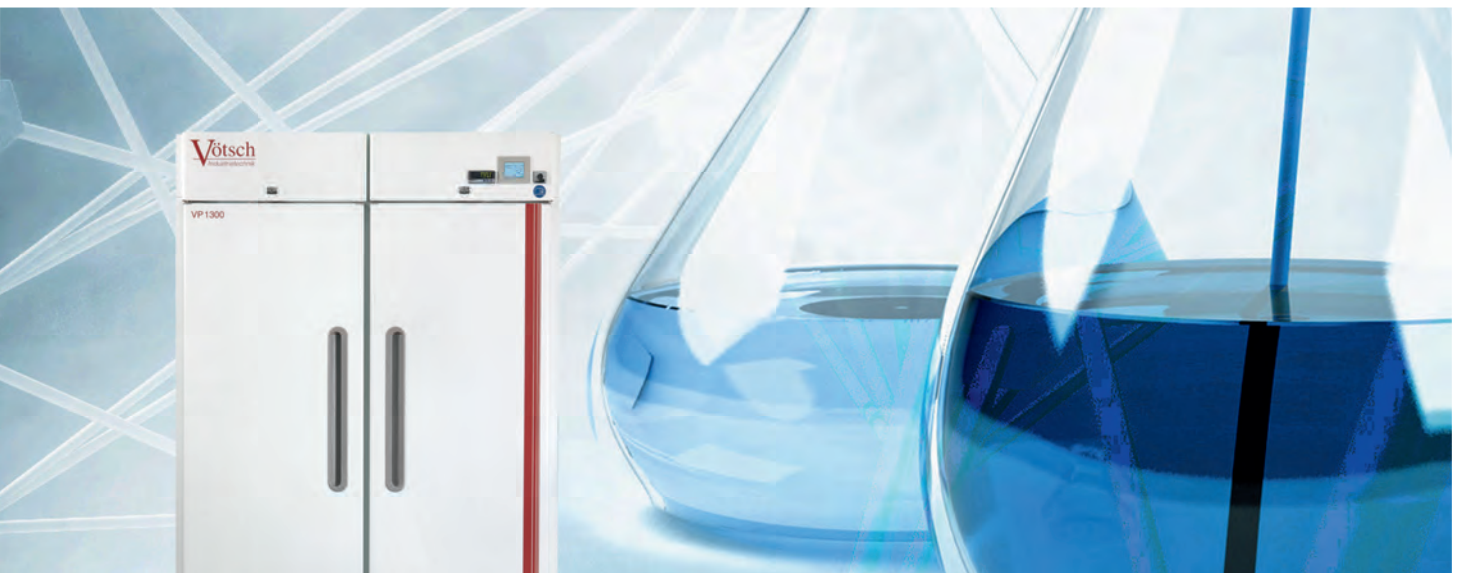
Whether it is maintenance, calibration or repair, we are available round the clock through our service centre. In Germany, we guarantee that a service technician will be on site within 24 hours after we have received a failure notification on weekdays.

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 with more than 300 technicians world wide 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.



Stability Testing according to ICH Guideline Q1A

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



Vötsch pharmaceutical cabinets have been specially developed to meet the requirements of test laboratories in the pharmaceutical industry. VP Series cabinets come in four sizes and can provide a constant climate (Types 280, 600, 1300 and 2000) or just a constant temperature (Types 280-T, 600-T, 1300-T and 2000-T). The exceptional build quality, innovative product features, accuracy and smart controls allow for the safest and easiest 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 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

- Microprocessor monitoring and control SIMPAC* with 3.5" colour touch panel for entering of set-point values
- Ethernet interface
- Fully integrated user management in the control panel³
- Calibration of 2 temperature and 2 humidity¹ values
- Software temperature limiter for min. and max. test space temperatures
- 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 demineralized humidification water¹
- Lockable doors
- 4 castors, of which 2 have brakes²
- Air-cooled refrigeration unit with low noise emission
- Patented vapour humidification system (Sterile Steam System)¹
- Capacitive humidity sensor¹
- Entry port, Ø 50 mm, in the right side panel
- Operating manual
- Multi language touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)
- 280 l units on 6 feet
- 280 l units are stackable

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 To program the user management the Software SIMPATI* Pharma is necessary



Technical data

| VP Series Cabinet Type | | | 280 | 600 | 1300 | 2000 |
|--------------------------|--|--|-----------------------|-------------|-------------|-------------|
| SHELVES | Number (Max) | - | 2 (16) | 6 (36) | 12 (72) | 18 (108) |
| | Width (Net) | mm | 530 | 530 | 530 | 530 |
| | Depth | mm | 650 | 650 | 650 | 650 |
| | Storage area (Max) | m ² | 0.69 (5.52) | 2.07 (12.4) | 4.14 (24.8) | 6.21 (37.2) |
| | Load per shelf | kg | 40 (distributed load) | | | |
| | Max load total | kg | 160 | 250 | 400 | 600 |
| EXTERNAL DIMENSIONS | Width | mm | 1159 | 782 | 1440 | 2156 |
| | Depth | mm | 872 | 1060 | 1040 | 1040 |
| | Height (with castors) | mm | - | 1995 | 1995 | 2001 |
| | Height (with feet) | mm | 1017 | 2050 | 2050 | 2050 |
| WEIGHT | kg | 135 | 150 | 250 | 350 | |
| TEST SPACE DIMENSIONS | Width | mm | 620 | 620 | 1340 | 2034 |
| | Depth | mm | 673 | 685 | 685 | 685 |
| | Height | mm | 641 | 1300 | 1300 | 1300 |
| ENTRY PORT | Entry port, ø 50 mm, in the right side panel | | | | | |
| TEMPERATURE | Working range | °C | +5 ... +60 | | | |
| | Fluctuation (in time) | K | ±0.1 ... ±0.2 | | | |
| | Homogeneity (in space) | K | ±0.3 ... ±1.0 | | | |
| | Gradient (Acc IEC 60068-3-5) | K | 1 ... 2 | | | |
| HUMIDITY ² | Humidity range | % r.h. | 20 ... 90 | | | |
| | RH Fluctuation (in time) | % r.h. | ±0.5 ... ±1.0 | | | |
| | Dew point temp. range | °C | +5 ... +40 | | | |
| | Water supply | Automatically via built-in water tank and/or external supply | | | | |
| | Water Specification | Demineralised water pH-value 6-7 Conductivity 5 to 20 Microsiemens/cm | | | | |
| CALIBRATION VALUES | +25 °C / 60 % r.h. and +40 °C / 75 % r.h. | | | | | |
| POWER | Mains | 1/N/PE, AC 220/230V ±10 %, 50 / 60 Hz | | | | |
| | Nominal | kW | 1.1 | 1.2 | 1.4 | 2.0 |
| NOISE LEVEL ¹ | dB(A) | 52 | | | | |

Most important Options

- Software package **SIMPATI*** Pharma for recording and processing of measurement values
- Integrated Datalogger
- Networking of several systems
- Serial interface RS 232 C
- Registration of temperature and /or humidity¹
- Integrated UPS to keep the recording alive during a power-failure
- Additional temperature and / or humidity¹ sensor
- Acoustic and optical warning signal
- Refrigeration unit, water-cooled
- Glass door, heated²
- Height adjustable feet³
- Additional shelves
- Additional entry ports
- Demineralisation unit with exchangeable cartridges for connection to local water supply¹
- Qualification documentation for equipment and **SIMPATI*** software
- Special voltages
- Analog outputs
- Maintenance contracts with defined response time

This data is 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.

² Not applicable for Pharma Series 280-T, 600-T, 1300-T and 2000-T.

¹ for types 280-T, 600-T, 1300-T and 2000-T only temperature.

² not for 280 I models

³ standard in 280 I models

Photostability Testing according to ICH Guideline Q1B

VP Series 250-L | 250-LT | 500-L | 500-LT



Vötsch VP Series photostability cabinets come in two sizes and can provide a constant climate (types 250-L and 500-L) or just a constant temperature (Types 250-LT and 500-LT). The photostability testing cabinets are characterized by an ideal light, UV, temperature and humidity (types 250-L and 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 set-point values in lxh and Wh/m² e.g. 1.2 Mio lxh and 200 Wh/m² is made possible to have a fully automated and with SIMPATI* Pharma also fully documented process. Vötsch photostability testing cabinets offer innovative product features, high accuracy, intelligent controls and an exceptional build quality.

Standard scope of delivery

- Microprocessor monitoring and control SIMPAC* with 3.5" colour touch panel for entering of set-point values
- Fully integrated user management in the control panel³
- 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
- Calibration of 2 temperature and 2 humidity values¹
- Alarm output (potential-free contact) for monitoring of tolerance band $\pm 2\text{ }^{\circ}\text{C} \pm 5\text{ \% r.h.}$ ¹
- Water storage reservoir with automatic and manual supply of demineralised humidification water¹
- Door contact switch
- Lockable doors
- Counter for total operating hours
- 4 castors, of which 2 have brakes²
- Air-cooled refrigeration unit with low noise emission
- Patented vapour humidification system (SSS Sterile Steam System)¹
- Capacitive humidity sensor¹
- Entry port, $\varnothing 50\text{ mm}$, in the right side panel
- Operating manual
- Multi-language touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

¹ Except for types 250-LT and 500-LT; ² Except for types 250-L and 250-LT

³ To program the user management the Software SIMPATI* Pharma is necessary

Technical data

| VP Series Cabinet Type | | | 250-L | 500-L | 250-LT | 500-LT |
|--------------------------|------------------------------|--|---|--------------------------------------|--------------------------------------|--------------------------------------|
| SHELVES | Number | - | 2 shelves: 1 UV, 1 White light | 4 shelves: 2 UV, 2 White light | 2 shelves: 1 UV, 1 White light | 4 shelves: 2 UV, 2 White light |
| | Storage area | m ² | 0.71 | 1.45 | 0.71 | 1.45 |
| | Load per shelf | kg | 25 (distributed load) | | | |
| | Max. total load | kg | 50 | 100 | 50 | 100 |
| EXTERNAL DIMENSIONS | Width | mm | 1159 | 740 | 1159 | 740 |
| | Depth | mm | 872 | 1050 | 872 | 1050 |
| | Height (with castors) | mm | - | 2070 | - | 2070 |
| | Height (with feet) | mm | 1017 | 2070 | 1017 | 2070 |
| WEIGHT APPROX. | | kg | 160 | 250 | 160 | 250 |
| TEST SPACE DIMENSIONS | Width | mm | 530 | 530 | 530 | 530 |
| | Depth | mm | 673 | 685 | 673 | 685 |
| | Height | mm | 641 | 1305 | 641 | 1305 |
| | Useful storage space | L | Approx. 235 | Approx. 460 | Approx. 235 | Approx. 460 |
| ENTRY PORT | | Entry port, ø 50 mm, in the right side panel | | | | |
| TEMPERATURE | Working range | °C | Without radiation: +10 ... +50 With radiation: +15 ... +50 | | | |
| | Fluctuation (in time) | K | ±0.1 ... ±0.5 | | | |
| | Homogeneity (in space) | K | ±0.5 ... ±1.0 (1.5 with radiation) | | | |
| | Gradient (Acc IEC 60068-3-5) | K | 1 ... 2 | | | |
| HUMIDITY | Humidity range | % r.h. | 20 ... 90 | | | |
| | RH Fluctuation (in time) | % r.h. | ±1 ... ±2 | | | |
| | Dew point temp. range | °C | +5 ... +40 | | | |
| | Water supply | | Automatically via built-in water tank and / or external supply | | | |
| | | | Water tank, 13 l | Water tank, 19 l | | |
| | Water specification | | Deminerilised water pH-value 6-7 Conductivity 5 to 20 Microsiemens / cm | | | |
| LIGHT | Intensity of light | lx | Approx. 15000 at +15 °C Approx. 18000 at +25 °C Approx. 25000 at +45 °C | | | |
| | Intensity of UV | W/m ² | 1.75 at +15 °C 3.0 at +25 °C 3.7 at +45 °C | | | |
| | Homogeneity (in space) | K | ±0.5 ... ±1.0 (1.5 with radiation) | | | |
| | Light distribution | % | Approx. ±8 | Approx. ±8 | Approx. ±8 | Approx. ±8 |
| | UV distribution | % | Approx. ±12 | Approx. ±12 | Approx. ±12 | Approx. ±12 |
| CALIBRATION VALUES | | +25 °C / 60 % r.h. and +40 °C / 75 % r.h. | | | | |
| POWER | Mains | 1/N/PE, AC 220 / 230 V ±10 %, 50 / 60 Hz | | | | |
| | Nominal | kW | 1.4 | 2.6 | 1.4 | 2.6 |
| NOISE LEVEL ¹ | | dB(A) | 52 | | | |



Shelf with UV-lights



Shelf with white lights

Most important options

- Software package SIMPATI* 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 humidity¹
- UV and Lux sensors with automatic measurement value integration
- Mapping of light distribution
- Additional temperature and / or humidity¹ sensor
- Acoustic and optical warning signal
- Refrigeration unit, water-cooled
- Glass door, heated
- Additional entry ports
- Demineralisation unit with exchangeable cartridges for Shelf with white Lights
- Connection to local water supply¹
- Qualification documentation for equipment and SIMPATI* software
- Special voltages
- Analogue outputs
- Maintenance contracts with defined response time
- Operation at 5 °C with full illumination

This data is 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.

¹ Except for types 250-LT and 500-LT

Walk-in Test Chambers

For stability testing according to ICH Guideline Q1A



...Walk-in test chambers for stability tests

The extremely accurate and reliable stability test chambers of Vötsch Industrietechnik 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 2700 mm; other dimensions are possible. Chamber volumes from 10 up to 300 m² can be supplied by Vötsch Industrietechnik.

Standard scope of delivery

- An excellent mechanical rigidity and optimum thermal insulation are ensured thanks to PU insulation chamber elements (CFC-free) with easy-to-clean, corrosion resistant double sided metal plate coating. Panels on the inside and outside are painted RAL9010.
- 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.
- Micro-processor controlled control system corresponding to GAMP-GUIDE and FDA 21 CFR Part 11 and EU GMP Annex 11, with maintenance-free electronic temperature/humidity sensor.
- Fully integrated user management in the control panel.*
- 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 acc. to the European Machinery Directive.
- Safety temperature limiter for electrical heater and test chamber.
- Specimen protection thermostat tmin/tmax and over humidity protection.
- Multi language touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean).

* To program the user management the Software SIMPATI® Pharma is necessary



Technical data

| | | |
|-----------------------------------|--------|--------------------------------------|
| Temperature working range | °C | +20 ... +45 |
| Temperature fluctuation (in time) | K | ±0.1 ... ±0.5 |
| Temp. homogeneity (in space) | K | ±0.5 ... ±1 accord. to IEC 60068-3-5 |
| Temperature gradient | K | 1 ... 2 accord. to IEC 60068-3-5 |
| Humidity range | % r.h. | 20 ... 80 |
| RH fluctuation (in time) | % r.h. | ±1 ... ±3 |
| Dew point temp. range | °C | +9 ... +41 |

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



Most important options

- Software package SIMPATI* 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)
- Shelf systems
- One-point calibration
- Spatial calibration
- Qualification documentation for equipment and SIMPATI* software
- Special voltages
- Analog outputs
- Maintenance contracts with defined response time
- Further options available on request

Special Solutions for your Special Applications

Vötsch VC³/0 Series | Vötsch VTL and VCL Series



If safety matters: Climate test chambers of the VC³/0 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 VC³/0 Vötsch Industrietechnik has developed a series of climate test chambers for real-time tests or tests under different climate conditions. The VC³/0 Series 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. The VC³ series is also available with temperature ranges from -40 °C to 180 °C and -70 °C to 180 °C and can be used for stress test or Freeze Thaw Cycles without explosion protection.

Technical Data

| Vötsch VC ³ /0 Series | | Vötsch VTL/VCL Series |
|--|--|---|
| Approx. 190 ... 1540 | Test space volume (litres) | Approx. 34, 64 and 100 |
| Performance for temperature tests | | |
| - 10 ... +90 / - 5 ... +90 / 0 ... +90 | Temperature working range (°C) | - 70 ... +180 / - 40 ... +180 / +10 ... +180 |
| ±0.1 ... ±0.5 | Temperature fluctuation (in time) (K) | VTL: ±0.3 ... ±1.0 VCL: ±0.3 ... ±0.5 |
| ±0.5 ... ±1.0 | Temp. homogeneity (in space) ² (K) | VTL: ±0.5 ... ±2.0 VCL: ±0.5 ... ±1.5 |
| 1 ... 2 accord. to IEC 60068-3-5 | Temperature gradient (K) | 1 ... 2 accord. to IEC 60068-3-5 |
| +4 and +90 | Calibration values (°C) | +23 and +80 |
| Performance for climatic tests³ | | |
| +10 ... +90 | Temperature working range ³ (°C) | +10 ... +95 |
| ±0.1 ... ±0.3 | Temperature fluctuation ³ (in time) (K) | ±0.3 ... ±0.5 |
| ±0.5 ... ±1.0 | Temp. homogeneity ^{2,3} (in space) (K) | ±0.5 ... ±1.5 |
| 10 ... 98 | Humidity working range ³ (% r.h.) | 10 ... 98 |
| ±1 ... ±3 | RH fluctuation (in time) ^{3,4} (% r.h.) | ±1 ... ±3 |
| +4 ... +89.5 | Dew point temp. range ³ (°C) | +5.5 ... +94 |
| +25 °C / 60 % r.h. and +40 °C / 75 % r.h. | Calibration values acc. ICH-Guidelines | +23 °C / 50 % r.h. and +95 °C / 50 % r.h. |
| 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 |
| 2.3 | Max. installed load (kW) | 1.8 ... 3.5 |
| Height: 1805 - 2005, Width: 875 - 1395, Depth: 1545 - 2610 | Overall dimensions (mm) | Height: 980 - 1880, Width: 640 - 780, Depth: 750 - 1105 |
| 420 - 920 | Weight (kg) | 110 - 210 |
| <46 | Noise level ¹ (dB(A)) | <59 |

This data is 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. ² Relative to the set value in temperature range from minimal temperature to +150 °C, Measured. ³ Not applicable for VTL. ⁴ For VC³/0... measured in the middle of the test space.

If available Space is limited

Temperature Test Chambers VTL
Climate Test Chambers VCL



Compact, quiet, yet powerful units are required to tackle special laboratory conditions that include limited space, even smaller specimens and the need to conduct re-producible tests on a laboratory scale or stability tests according to ICH Guide line Q1A tests directly at the workplace. The VTL and VCL series of temperature and climatic test chambers are ideally suited to such applications. These systems have a volume of 34 l, 64 l and 100 l respectively and provide an optimum solution where space is limited.

Humidity is generated by a tempered waterbath in a manner free of aerosols. The devices of the VTL and VCL series are suitable for program and constant set point operation e.g. for stress tests and Freeze Thaw cycles and are equipped with a state-of-the-art efficient 32-bit SIMPAC* 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.

Standard scope of delivery

- 32-bit control system SIMPAC* with 3.5" colour touch panel
- Fully integrated user management in the control panel*
- Observation window
- Test space lighting
- Independent adjustable temperature limiter tmin/tmax
- Potential-free contact for test specimen switch-off
- Ethernet interface
- USB interface for documentation of measuring data via USB-stick
- Air-cooled refrigeration circuit
- 1 shelf
- 1 entry port Ø 50 mm
- Calibration of 2 temperature values for VTL and 2 climatic values for VCL / VC³/0
- Automatic water supply (VCL and VC³/0 only)
- Multi-language touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

Most important options

- SIMPATI* software package
- 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 for VCL/VTL -70 °C / 34 l)
- Demineralisation unit (VCL and VC³/0)
- Special voltages

* To program the user management the Software SIMPATI* Pharma is necessary

VT 3050 Pharma

The VT 3050 Pharma is the alternative to a -20 °C freezer as well as usable for freeze thaw cycles and temperature stress test

500 litre temperature test space that takes up less than 1 m² floor space

Technical data

| | | |
|--|-------|----------------------------------|
| Test space volume | Litre | 500 |
| Temperature range | °C | -30/+100 |
| Temperature fluctuation ¹ | K | ±0.5 |
| Deviation in space | K | ±1.5 |
| Temperature gradient ¹ | K | 3 |
| Temparture rate of change ¹ | | |
| Heating | K/min | 2.0 |
| Cooling | K/min | 1.4 ² |
| Heat compensation max. | W | 650 |
| Calibrated values | °C | +23/+80 |
| Test space dimensions | mm | width 710/depth 590/height 1250 |
| External dimensions | mm | width 940/depth 1030/height 1955 |
| Noise level ³ | dB(A) | <60 |
| Rated power | kW | 1.9 |
| Electrical connection | | 1/N/PE AC 230 V ±10 %, 50 Hz |



Application

Reliable temperature tests ranging from -30 °C to +100 °C for a large variety of applications are possible with the VT 3050:

- Constant temperature tests
- Changing temperature tests
- Freeze thaw cycles
- -20 °C Freezer*

The performance values refer to +25 °C ambient temperature. This product contains fluorinated greenhouse gases with a global warming potential of 150 or more.

¹in accordance with IEC 60068-3-5

²with option 3 K/min

³free field, 1 m distance from the front, as per DIN 45635, part 1, accuracy class 2

Features

- Adjustable software temperature limiter min./max.
- Independent, adjustable temperature limiter tmin/tmax
- Potential-free contact
- Test space illumination
- Mobile design
- 1 Entry port 80 mm
- 1 Stainless steel shelf
- Air-cooled refrigeration unit
- WKD-calibration of 2 temperature values
- Ethernet interface
- Multilanguage 3.5" touch panel (German, English, French, Spanish, Polish, Czech, Russian, Chinese, Korean)

Options

- Software SIMPATI* Pharma
- Integrated datalogger
- Qualification documents
- Temperature measuring on test specimen
- Other entry ports and shelves
- Glazed door
- Special voltage
- Reinforced cooling unit
- Water-cooled design
- Compressed air dryer*

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

Simple and Secure

SIMPATI* Pharma software

Our control and documentation software SIMPATI* Pharma enables you to make even better use of your devices and systems. SIMPATI* Pharma allows for simple and secure recording and archiving of data.

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 is manipulation-safe but can still be used for further processing, e. g. in Excel.

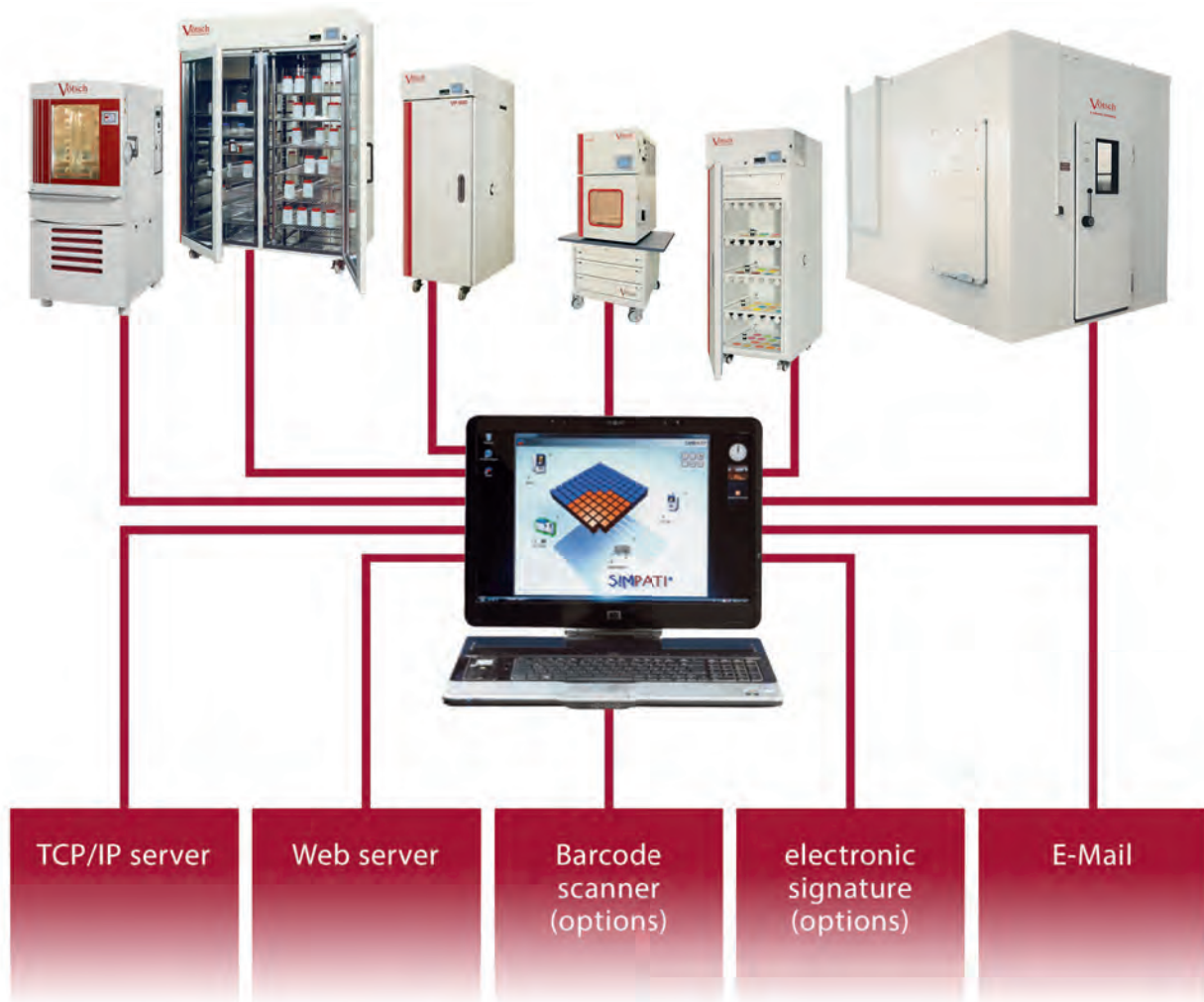
It goes without saying that the SIMPATI* Pharma software complies with FDA 21 CFR Part 11 and EU GMP Annex 11. Validation documents are also provided for the SIMPATI* Pharma monitoring system.

| Date | Time | Chamber | No. | Type | Message |
|------------|----------|---------|-----|------|--------------------------|
| 26.10.2001 | 08:58:20 | System | 00 | 00 | Systemstart SIMPATI |
| 26.10.2001 | 08:59:22 | WK1 | 01 | 00 | deleted |
| 26.10.2001 | 08:59:26 | System | 00 | 00 | login user: superuser |
| 26.10.2001 | 08:58:53 | WK1 | 01 | 01 | Alarm Range: temperature |
| 26.10.2001 | 09:00:22 | WK1 | 01 | 01 | Alarm Range: humidity |
| 26.10.2001 | 09:00:22 | WK1 | 01 | 01 | Warn Range: humidity |
| 26.10.2001 | 09:00:34 | WK1 | 01 | 01 | Warn Range: humidity |

Audit trail

Operation of our systems is simple and time-saving. SIMPATI* can be integrated into your PC network and enables operation at individual stations without requiring special software – simply by using your internet browser. Furthermore SIMPATI* can be installed on virtual machines e.g. Windows 2008 server.

Connections



The most important Functions and Possibilities

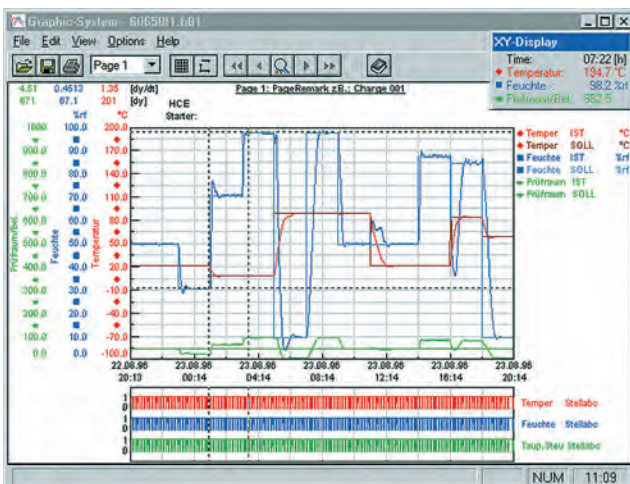


- Recording and archiving of all test data
- Manipulation-safe data registration
- Administration of multi-level access rights (user management)
- Password alteration
- Compliance with FDA 21 CFR Part 11
- Compliance with EU GMP Annex 11
- Audit trail
- Up to 99 units can be linked via the serial interface or Ethernet interface (TCP/IP)
- Alarm output via E-Mail, SMS, phone
- 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
- Documentation of climate chambers and rooms irrespective of manufacturer
- Available in German, English, French, Czech, Russian, Spanish, Chinese, Korean
- Considering the alarmsystem of the connected devices SIMPATI* Pharma fulfills the complete 5 steps risk based approach acc. to GAMP 5
- Category 3 software according to GAMP

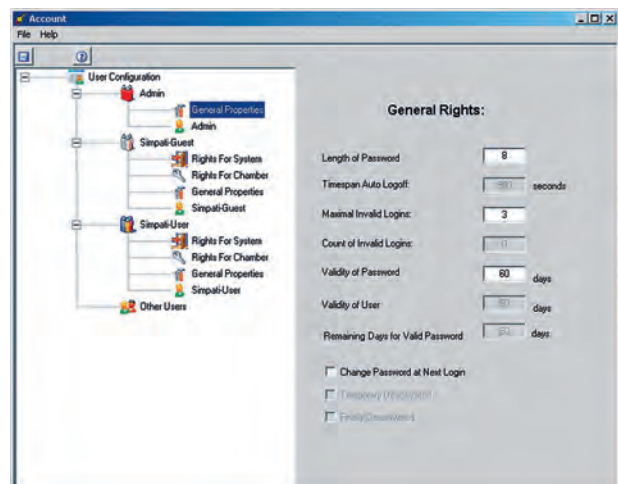
In some cases further options or special infrastructure at the customer's facilities are required for the functions described.

Options:

- SIMPATI* e-Sign: Electronic signature with recording of biometric data
- Barcode reader for batch management



Graphical recording



User management

SIMPATI* barcode reader

Batch registration using barcode scanners

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

Advantages

- Simple to use - even in cleanroom conditions
- "Fault-free" input of lot numbers and product ID's
- Scanning of process data
- Automatic assignment of process cycles to existing products
- Wireless scanner technology scans and transfers the information, e.g. during the loading of test chambers



Always in control ...

wherever you are!

SIMPATI* provides a comfortable means of operating and monitoring from your desktop PC. SIMPATI* also supports the modern possibilities of internet communication for monitoring via internet browser and information via e-mail. SIMPATI* 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 cellular phone network (option).



SIMPATI* e-Sign

Biometric data based on your handwriting



The consistent solution from an 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 people. 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.

SIMPATI* e-Sign as a supplement to the software package compliant with FDA 21 CFR Part 11 and EU GMP Annex 11. SIMPATI*-Pharma enables signing all measurement data whilst capturing biometric data based on your handwriting.

SIMPATI* e-Sign offers legal security, whereby the undersigned 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. An expert report stated that the judicial value as evidence is provided by a signature given using this technology.

It is confirmed by an independent handwriting expert, allowed to appear in court, that the same conclusions can be reached from these components as from a handwritten signature on paper. Functional security was verified based on more than 200,000 signatures.

All aspects from FDA 21 CFR Part 11 are complied with. 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 (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.

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 longterm storage.

The following Companies and Business Partners already benefit from the Solutions offered by Vötsch Industrie-technik Subsidiaries worldwide:

- Abbott Laboratories, Abbvie
- Actelion
- AKZO Diosynth
- Allergan
- Aspen Pharmacare
- Astellas
- AstraZeneca
- BASF
- Baxter International
- Bayer
- Beiersdorf
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Celanese Chemicals
- Clariant
- Covidien
- CSL Behring
- Daiichi Sankyo
- Dong-A
- Dr. Reddy's
- Eli Lilly
- Ferring Arzneimittel
- Gedeon Richter
- GlaxoSmithKline
- Hanmi Pharmaceuticals
- Ipsen
- Janssen-Cilag
- Johnson & Johnson
- Krka
- Lupin
- Meda Pharma
- Medimmune
- Merck & Co (MSD)
- Merck KGaA Darmstadt
- Merck Millipore
- Merz
- Novartis
- Novo Nordisk
- Pfizer
- Procter & Gamble
- Qilu Pharmaceutical
- Roche
- Sandoz
- Sanofi
- Santen
- Solvay
- Stada
- Takeda
- Torrent Pharmaceutical
- UCB
- Vetter Pharma
- Wockhardt
- Teva
- and many more



Vötsch Industrietechnik ...

Vötsch Industrietechnik is a subsidiary of Weiss Technik and one of the pre-eminent manufacturers of environmental simulation systems. With these test systems, all climatic conditions around the globe can be simulated in time-lapsed motion. Vötsch Industrietechnik supplies systems for climate and temperature tests, environmental stress screening, corrosion, emissions and stability tests in all sizes ranging from standard models to customised, process-integrated systems. The high-precision test systems guarantee extremely high reproducibility of the test results.

Vötsch Wärmetechnik is a division of Vötsch Industrietechnik. With an experienced team of engineers and designers, we develop, plan and produce high-quality and reliable heat technology systems for virtually every field of application. These include heating and drying cabinets, clean room dryers, hot air sterilisers, microwave systems, infrared ovens and through-flow ovens. Here, too, we provide a sophisticated standard range, as well as customised solutions for individual production processes.

Weiss Technik, the parent company of Vötsch Industrietechnik, also offers reliable air conditioning solutions for optimum climatic conditions in industrial production processes, hospitals, mobile operation tents or in the field of IT and telecommunications centres.

Vötsch Industrietechnik GmbH

Beethovenstrasse 34
72336 Balingen-Frommern
Germany
Tel +49 7433 303-0
Fax +49 7433 303-4112
info@v-it.com
www.voetsch.de



D-Nr. VIT 0.18E/Aw3 1 06 2015

