



Technical Description

**Climate Chamber for Stability Tests
Type PharmaEvent C/600**

Mat. No.: 67566056 Weiss

Mat. No.: 67567016 Vötsch

FACTS

- All climate test cabinets series Pharma are designed for **stability tests according to ICH guidelines**
- Operating and monitoring is effected with the digital **measuring and control system Simpac**
- **7" Multiuser colour touch panel** arranged above the door, with simple menu guided operation (two-level password protection) is integrated
- **Integrated program editor and program storage** for 100 programs with 1000 segments in total, 250 loops and 9999 program cycles. Program input possible via software package Simpati (optional)
- **Lockable display** with diverse user levels
- **Alarm system according to GAMP**
- Internal test space provides a **large storage capacity**



- An optimum air flow ensures an **excellent air and temperature distribution in space**
- **Capacitive humidity sensors** as well as a **patented steam humidifier** (sterile steam system) are standard



- **Lockable doors**
- Heated glass doors are optionally available
- **System is delivered with a hermetic refrigeration unit (CFC-free refrigeration system)**
- Extremely **low sound pressure level**
- Maintenance-friendly design
- Energy consumption up to 50 % lower

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1 Technical Data

1.1 Technical Data PharmaEvent C/600

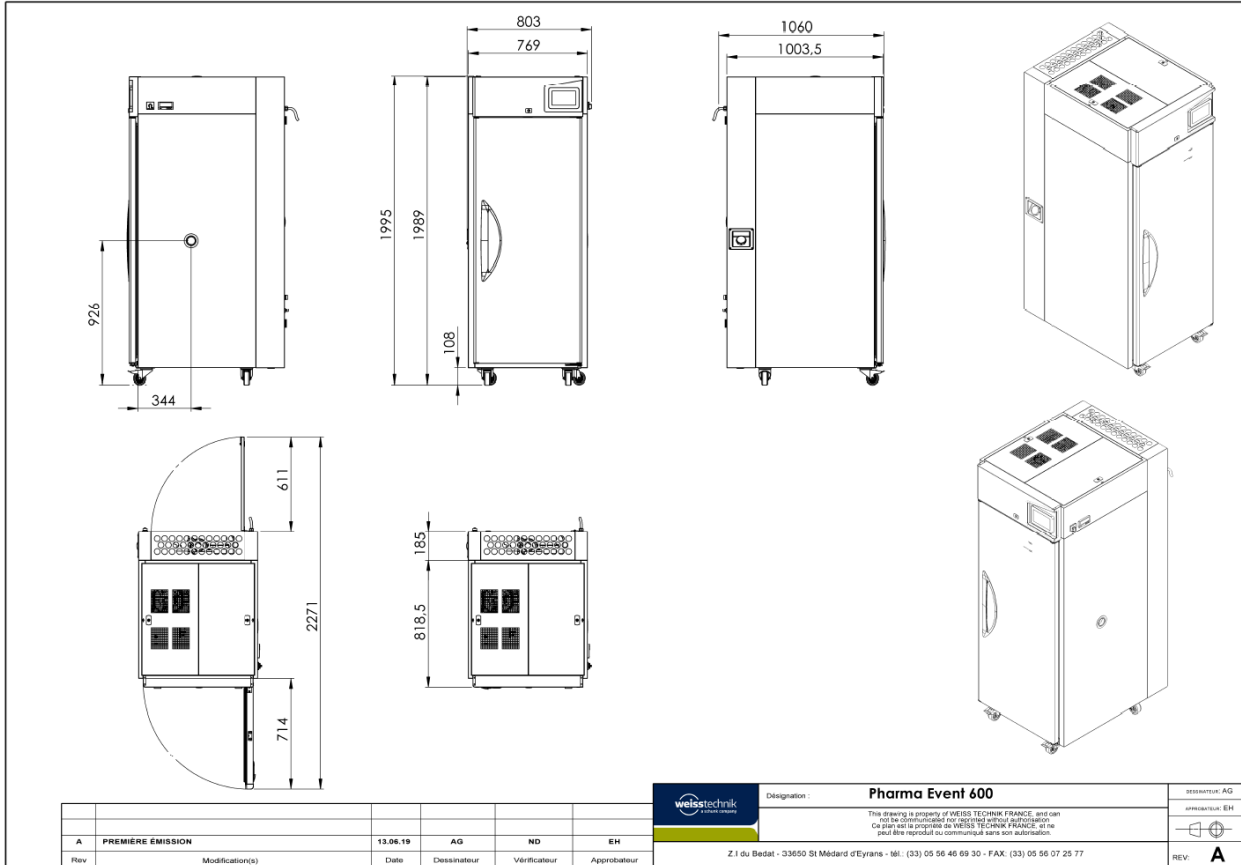
1.1.1 Test Space

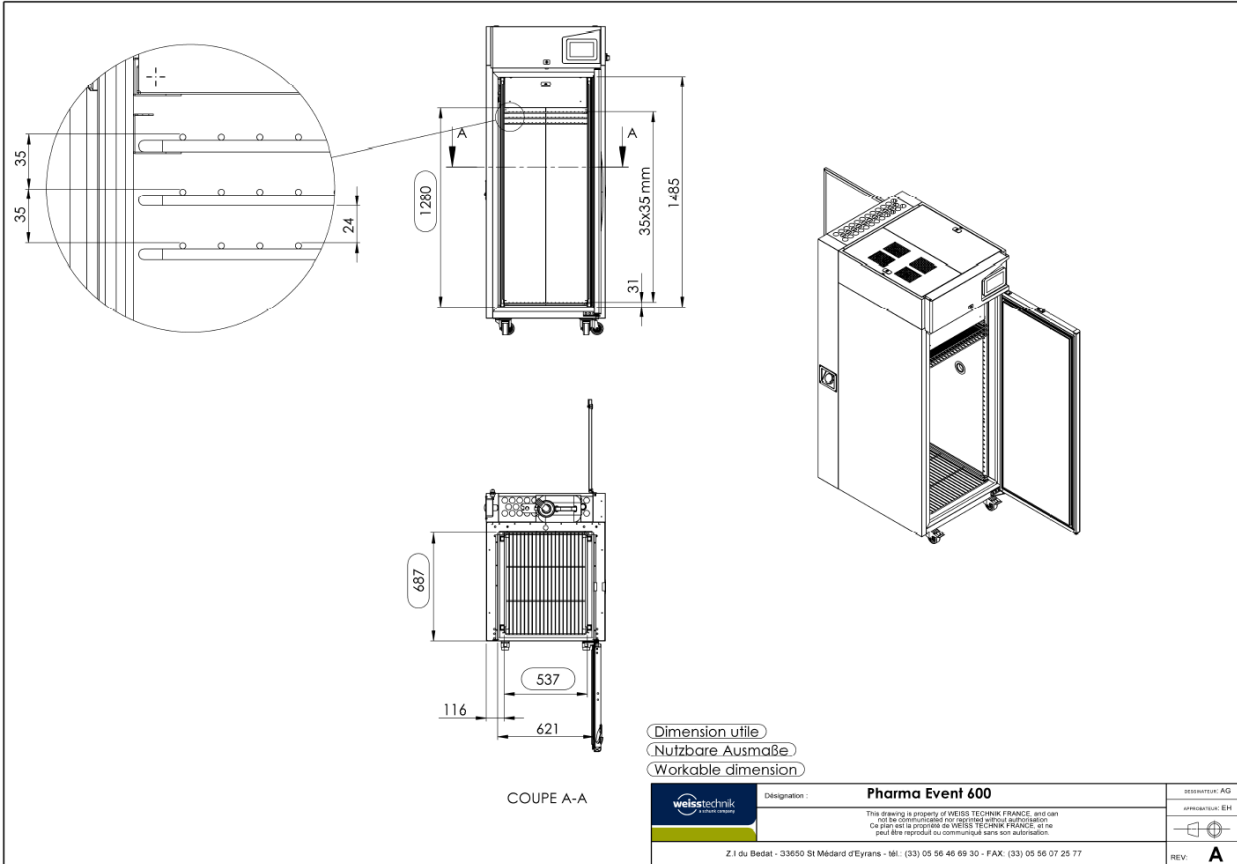
| | | | | | | | | | | |
|------------------------|---|---------|---------|---------|-------|---------|--------|-------|---------|--------|
| Interior test space | stainless steel | | | | | | | | | |
| Interior dimensions | <table> <tr> <td>height</td> <td>approx.</td> <td>1280 mm</td> </tr> <tr> <td>width</td> <td>approx.</td> <td>621 mm</td> </tr> <tr> <td>depth</td> <td>approx.</td> <td>687 mm</td> </tr> </table> | height | approx. | 1280 mm | width | approx. | 621 mm | depth | approx. | 687 mm |
| height | approx. | 1280 mm | | | | | | | | |
| width | approx. | 621 mm | | | | | | | | |
| depth | approx. | 687 mm | | | | | | | | |
| Volume of test chamber | approx. 600 l | | | | | | | | | |
| Max. loading | 250 kg | | | | | | | | | |
| Max. load per shelf | 40 kg distributed load | | | | | | | | | |

1.1.2 External Housing

| | | | | | | | |
|------------------|--|----------------|------------------------|---------------|--------|---------------|---------|
| Dimensions | <table> <tr> <td>Height approx.</td> <td>1995 mm (with castors)</td> </tr> <tr> <td>width approx.</td> <td>803 mm</td> </tr> <tr> <td>depth approx.</td> <td>1060 mm</td> </tr> </table> | Height approx. | 1995 mm (with castors) | width approx. | 803 mm | depth approx. | 1060 mm |
| Height approx. | 1995 mm (with castors) | | | | | | |
| width approx. | 803 mm | | | | | | |
| depth approx. | 1060 mm | | | | | | |
| Exterior housing | white coated (similar to RAL 9016) | | | | | | |
| Door | single-wing, lockable | | | | | | |

1.2 Installation Drawing





1.3 Equipment

| | |
|---|--|
| Shelf | 6 off, stainless steel (optionally extendable) |
| Minimum space between two shelves | 35mm |
| Loading area | 6 shelves (650 x 530 mm) give a useful area of 2.07 m ² (standard) |
| Port right side wall | 1 off, Ø approx. 50 mm |
| Refrigeration unit | compressor with air-cooled condenser |
| Refrigerant | R 134 A (free from chlorine, no ODP) |
| Heater | electrical heating element |
| Overheating thermostat (safety temperature limiter STB) | set to +80 °C |
| Humidity generation | steam humidifier (sterile steam system) |
| Temperature and humidity sensor | double sensor with temperature and capacitive humidity sensor (analogue signals) |
| Door contact switch | for monitoring and recording of door opening with software Simpati (optional) |
| Installation | 4 castors, 2 with brakes |
| Alarm system | based on a risk analysis according to GAMP |
| 7" Multiuser colour touch screen | arranged above the door, with simple menu guided operation panel with integrated storage |
| Control and programming | digital measuring and control system Simpac |
| Interface | 1 Ethernet interface (100/10 megabit) for connection to a network |
| Specimen protection | independently adjustable temperature limiter (min./max.) |



1.4 Performance Data

1.4.1 Temperature Test

| | |
|---|---------------------------|
| Temperature range | +2 °C ... +70 °C |
| Temperature deviation, in time (fluctuation), in steady state, depending on temperature | ±0.1...±0.2 K |
| Temperature homogeneity, in space (variation), in steady state, depending on temperature ³ | ±0.3...±1.0 K |
| Factory calibration (WKD) * | Values: +25 °C and +40 °C |

1.4.2 Climate Test

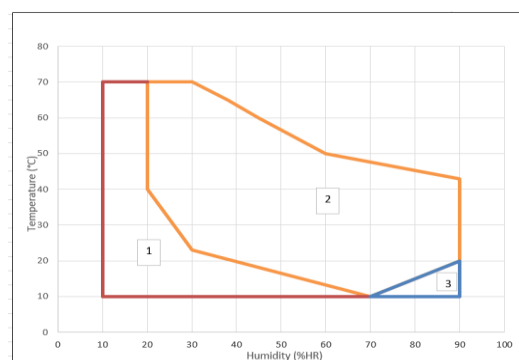
| | |
|---|---|
| Temperature range | +10 °C ... +70 °C |
| Temperature deviation, in time (fluctuation), in steady state, depending on temperature | ±0.1...±0.2 K |
| Temperature homogeneity, in space (variation), in steady state, depending on temperature ³ | ±0.2...±0.7 K |
| Humidity range (see humidity diagram) | 20 ... 90 % r.h. |
| Humidity deviation/fluctuation, in time | ±0.2 ... ±1.0 % r. h. |
| Dew point temperature range | +5 °C ... +45 °C |
| Factory calibration (WKD) * | Values: +25 °C / 60 % r.h. / +40 °C / 75 % r.h. |

Humidity diagram

Area 1 - defines the working area of the chamber with air dryer

Area 2 - defines the normal working area of the unit

Area 3 - defines the area with intermittent operation or discontinuous operation (defrosting becomes necessary after 8 hours at the latest)



³) In temperature range of min. temperature to +150°C.

* Calibrations other than factory calibrations (WKD) are carried out by our subsidiary Vötsch Industrietechnik GmbH

1.5 Control and Programming Simpact

| | |
|---------------------|--|
| Operation unit | 7" Multiuser Colour touch panel with <ul style="list-style-type: none"> • Clear text display • User Management with password protection • Manual operation; program mode • Software temperature limiter for min. and max. test space temperatures • Error clear message • Program Editor • Audit Trail • Multiple languages • Alarm System according to GAMP, Risk analysis |
| Program memory | 100 programs |
| Segments | max. 1000 |
| Loops | 250 (nested) |
| Program cycles | max. 9999 |
| Password protection | User Management |

1.6 Connection / Others

| | |
|---|---|
| Power supply | 1/N/PE AC 220/230 V ±10 % 50/60 Hz |
| Socket | shock-proof, 16 A, connection cable ca. 3.5 m |
| Protection type | Test chamber and electrical panel IP 22, operating panel IP 54 |
| Noise emission | as per EN 61000-6-3 |
| Noise immunity | as per EN 61000-6-2 |
| max. connected load | approx. 1.2 kW |
| Sound-pressure level, measured at 1 m distance from front in 1.6 m height in free field measurement | approx. 52 dB(A) |
| Ambient conditions | +10 ... +35 °C, relative air humidity non condensing |
| Supply of demineralised water | water reservoir, 19 l, demineralised, to be connected to customer-provided water supply (ph 6/7, conductivity max. 20 µs/cm), hose connection external thread R ¾ “ manual filling possible |
| Condensation drain | hose connection |
| Weight | approx. 191 kg |

The above output data is based on an ambient temperature of +25 °C, 230 V, 50 Hz nominal voltage, without specimen, without additional equipment and heat compensation.

Subject to technical modifications.

2 Design and Functional Description

2.1 Construction

Our stability test chambers are supplied ready for connection. Thanks to their optimum insulation only a minimum of space is required.

These systems are available in four sizes, i.e. 280, 600, 1300 and 2000 litre test space capacity. Size 280 l is supplied with adjustable, vibration absorbing feet. The chamber sizes 600 to 2000 l are supplied on castors.



2.2 Exterior Housing

The self-supporting exterior housing of the unit is made from sheet-steel and coated (similar to RAL 9016).

The environment-friendly insulation between test chamber and exterior housing guarantees best insulation values and thus lowest possible operating costs.

2.3 Test chamber

The test chamber consists of a stainless-steel container, which is easy to clean. The test chamber ceiling incorporates a recirculated-air duct with built-in humidification/ dehumidification system, built-in heat exchanger, electric heaters and a recirculated air fan. The special air flow produces optimum ambient air and temperature distribution.



2.4 Test Chamber Door

The test chamber is provided with high-quality insulation. The door is sealed by a circumferential, special profile sealing. Thanks to the strong magnetic force an optimum contact pressure is guaranteed.



2.5 Access Port

All chambers have one access port (approx. 50 mm Ø). The port is installed in the right side wall and can be used for measuring and control wires, other supply connections or accessories.

If not required, the port is closed with the rubber plug supplied as standard.



2.6 Temperature and Humidity Conditioning

The large fan draws the air out of the space.

This recirculating air passes a fin-type heat exchanger, which cools the air, if necessary. The special design of the refrigerating system avoids unintended condensation precipitation on the heat exchanger during climatic operation and guarantees highest temperature and humidity constancies in time. An electrical heater, installed in front of the heat exchanger in air direction, is heating-up the recirculating air. Humidification is realised by a patented steam humidifier allowing an aerosol-free and sterile humidification. Steam is added to the air stream to ensure an optimum homogenisation.



2.7 Capacitive Humidity Measuring

The system is equipped with a capacitive humidity sensor to ensure continuation of long-term tests.

2.8 Control and Programming

Simpac is a self-monitoring, digital 32 bit measuring and control system and has been designed especially for the use in test systems. Thanks to its computing efficiency Simpac meets the requirements of process technology; the input is facilitated by the control panel.

- **Control panel**

- * 7" Multiuser colour touch screen
- * clear text display
- * User Management with password protection
- * manual operation; calls saved test programs
- * software temperature limiter for min. and max. test space temperatures
- * error clear text message
- * program editor
- * Alarm system according to GAMP

- **System**

Simpac handles all the functions necessary for control and programming. In addition to temperature and humidity control it also contains an efficient logic, which coordinates, monitors all functions and provides information on operating failures.



2.9 Additional Safety Devices

2.9.1 Specimen Protection

The climate test chamber is equipped with an upper and lower temperature protection (specimen protection with separate sensor) according to EN 60519-2 (1993). The signal is indicated visually **and** acoustically. A potential-free contact to switch off power supplies is available to the customer.

2.9.2 Permanently Memorised Overheating Safety Thermostat

A **steady** state overheating safety thermostat is installed that automatically switches off the heater if the test chamber's maximum temperature range is exceeded.

3 Power Supply

Each functional circuit is equipped with its own safety device, which, in the event of trouble, turns off the affected circuit or the entire chamber. The nature of the trouble is visually displayed.

Wiring and electrics are governed by the latest technology and comply with the regulations for the prevention of industrial accidents.

The climate test chambers, SYSTEM WEISS, are standardly equipped with a lockable main switch according to VDE.



4 General

The temperature accuracy mentioned is measured temporal in the centre of the test space. This is with stabilized conditions, without test specimens, without heat load and without optional accessories in the test space.

The factory calibration of the temperature values will be made by using DAkkS-DKD calibrated measuring equipment in the centre of the test space. The calibration is documented with a calibration sheet. Optionally we can offer a DAkkS-calibration as well as a spatial calibration according to factory(WKD)- or DAkkS-DKD-calibration. The DAkkS is member of EA (European co-operation for Accreditation) as well as ILAC (International Laboratory Accreditation Cooperation).

All figures are average values of the basic equipment and are valid at +25 °C ambient temperature, and a nominal voltage of 230 V/50 Hz, without test specimens, without heat load and without optional accessories.

The equipment can also be connected to a 1/N/PE AC 220 V +/- 10 % 50 Hz power supply. The main difference at nominal voltage 220 V is then an approx. 10 % reduction in the heating temperature change rate.

The equipment is designed for installation in dry and aerated rooms with max. permissible air contamination according to EN 50178 class 2: 1997.

The EMC test (electromagnetic compatibility) and the statements regarding interference are according to EN 61000-6-3: 2007 / EN 61000-6-4: 2007. The interference immunity is according to EN 61000-6-2: 2005.

Test space with low emission due to application of tempered silicone components. If the test space has to be emission-free, this has to be clarified technically and can be offered on request.

The illustrations are examples of designs. Deviations resulting from technical progress are possible.

5 Scope of Delivery

| Mat.-No. | Description |
|----------|--|
| 67566056 | Climate Test Chamber for stability tests, System Weiss, Type PharmaEvent C/600 |
| 67567016 | Climate Test Chamber for stability tests, System Vötsch, Type PharmaEvent C/600 |

complete and ready for connection, including:

- Program control with 7" Multiuser colour touch panel
 - * program storage with 100 programs incl. 1000 segments in total
 - * clear text display
 - * program editor
 - * User Management with password protection
 - * Audit Trail
 - * manual and automatic operation
 - * software temperature limiter for min. and max. test space temperatures
 - * error clear text report
 - * integrated inspection system
 - * guaranteed dwell time function
 - * battery-buffered real-time clock
- Ethernet Interface
- Alarm system according to GAMP
- 1 port, approx. 50 mm Ø, incl. plugs, right side wall
- Shelves, 6 off
- Lockable single-wing door
- Door contact switch for door monitoring
- 4 castors, 2 lockable
- Capacitive humidity sensor
- Water storage reservoir 19l with automatic and manual supply of demineralised humidification water
- Steam humidifier (sterile steam system)
- Alarm output (potential-free contact) for monitoring of tolerance band $\pm 2K \pm 5\%$ RH
Door alarm, water alarm, collective fault
- Air cooled refrigeration unit
- Factory calibration (WKD) of 2 temperature and 2 climate values
- Operating manual