Advanced Test Equipment Corp.

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Helping Make Safe & Reliable Products

Because people count on your products everyday




Cincinnati Sub-Zero

STABILITY CHAMBERS

www.cszproducts.com

PharmaEvent Stability Chambers

Keeping your products on schedule allows you to deliver life-saving products to patients sooner.

We understand the importance of having reliable and stable chambers to ensure tests are completed in a timely manner while complying with regulatory standards.

Whether your testing is for R&D, clinical trials or ongoing stability, our chambers provide uniform temperature/ humidity conditioned environments for worry-free operations with a control system that is easy to use and saves time.

Stability chambers are used for testing by a variety of industries, including:

- Pharmaceutical products / packaging
- Medical products / packaging
- Personal care products
- Consumer products
- Research

Stability Testing Applications

All stability chambers meet the requirements of ICH Q1A, USP, ISO, IEC, ISTA, ASTM and other test specifications within the performance range of the chambers.

Our reach-in stability chambers specifically meet the stability testing ICH Q1A guidelines for drug substances and products. These chambers adhere to the sections of the test standard overview listed below.

Section	Description	Condition		Duration
2.1.7.1 & 2.2.7.1	Storage Conditions for Drug Substances or Products	General Case Long Term	25°C, ±2°C/60% RH ±5% RH or 30°C, ±2°C/65% RH ±5% RH	12 months
		Intermediate	30°C, ±2°C/65% RH ±5% RH	6 months
		Accelerated	40°C, ±2°C/75% RH ±5% RH	6 months
2.1.7.2 & 2.2.7.4	Drug Substances or Products for Storage in a Refrigerator	Long Term	5°C, ±3°C	12 months
		Accelerated	25°C, ±2°C/60% RH ±5% RH	6 months
2.2.7.3	Drug products packaged in Semi-Permeable Containers	Long Term	25°C, ±2°C/40% RH ±5% RH or 30°C, ±2°C/35% RH ±5% RH	12 months
		Intermediate	30°C, ±2°C/65% RH ±5% RH	6 months
		Accelerated Not More than	40°C, ±2°C/75% RH ±25% RH	6 months

PharmaEvent Stability Chambers

Stability Testing According to ICH Guideline Q1A

Our PharmaEvent stability chambers have been specially developed to meet the requirements of test laboratories in the pharmaceutical industry. Temperature and humidity models are available in sizes ranging from the compact benchtop to the largest 3-door model (models C/280, C/600, C/1300 and C/2000). The exceptional quality construction, innovative product features, accuracy and smart touchscreen control allows for the safest, easiest, and most reliable stability testing.

The performance range of the chambers easily meet the requirements of the ICH Guideline Q1A. Furthermore, the systems are designed to work at 5 °C continuously without defrosting. 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 chamber'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).

PharmaEvent Specifications

	C/280	C/600	C/1300	C/2000
Workspace Volume cu. ft. (liters)	10 (280 l)	21 (600 l)	46 (1300 l)	71 (2000 l)
Internal Dimensions In (mm)	25.4"W x 26.5"D x 25.2"H (645 x 673 x 641)	24.4"W x 27"D x 50.4"H (621 x 687 x 1280)	52.8"W x 27"D x 50.4"H (1341 x 687 x 1280)	80.1"W x 27.3"D x 50.4"H (2035 x 695 x 1280)
External Dimensions In (mm)	45.6"W x 34.3"D x 40"H (1159 x 872 x 1017)	31.6"W x 41.7"D x 78.5"H (803 x 1060 x 1995)	60"W x 41"D x 78.5"H (1523 x 1043 x 1995)	85.8"W x 40.9"D x 78.7"H (2180 x 1040 cm x 2000 cm)
Temperature Range	+2°C to +70°C			
Temperature Control (in time)	±0.1°C to ±0.2°C			
Temperature Uniformity (in space)	±0.3°C to ±1°C			
Humidity Range	20% to 90% RH			
Humidity Control (in time)	±0.2 to ±1% RH			
Humidity Uniformity (in space) [1]	±0.5 to ±2% RH			
Dewpoint Temp Range	+5°C to +45°C			
Water Supply Built-in water tank and/or external supply	3.4 gal (13 l)	4.9 gal (19 l)		
Shelves (max)	2 (17)	6 (36)	12 (77)	18 (108)
Shelf Load	88 lbs. (40 kg) ea. distributed load			
Chamber Weight (kg)	330 lbs. total (135 kg)	420 lbs. total (191 kg)	610 lbs. total (275 kg)	805 lbs. total (365 kg)
Electrical	220/230 VAC ±10 %, 1 ph, 50/60 Hz, 15A, NEMA 6-15P plug included			
Power Consumption (kW)	1.1	1.2	1.4	2.0
Noise Level dB(A) [2]	52			
Heat Rejection BTU (kW)	1900 (0.5)	2000 (0.6)	2400 (0.7)	3400 (1.0)

This data is based on an ambient temperature of +25°C (77°F), 230V nominal voltage, without specimen, without additional equipment and heat compensation.
[1] Based on ICH Q1A conditions.
[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.

Standard Features

- S!MPAC® monitoring and control with 7" WEBSeason® multi-user interface and audit trail
- Ethernet interface
- Fully integrated user management of controls [1]
- Factory calibration of 2 temperature & 2 humidity values
- Software and independent temperature limiters for minimum and maximum protection.
- Alarm system according to GAMP
- Type 304 stainless steel interior
- Door ajar alarm
- Water storage reservoir for automatic and manual water supply of demineralized humidification water
- Alarm output (potential free contact) for monitoring of temperature and/or humidity
- Lockable door
- Analog output for temperature/humidity (0-10 VDC) to connect to other monitoring systems
- Rollable casters, with brakes for C/600/1300/2000
- Adjustable leveling feet for C/280
- Stacking capability for C/280
- Air-cooled refrigeration unit with low noise emission
- Patented vapor humidification system (SSS)
- Capacitive humidity sensor
- Entry port, 2 in (50 mm) in the right side panel
- Multi-language interface (English, German, French, Spanish, Polish, Czech, Russian, Chinese, Korean, Italian and Portuguese)

[1] User management performed remotely with S!MPATI® pharma software package

PharmaEvent Stability Chambers

Safe and Easier Stability Testing

- **Uni-Flow:** Airflow design for best uniformity even in loaded units.
- **Patented Sterile Steam System (SSS):** The demineralized water is evaporated at +140°C to eliminate any microorganisms.
- **Integrated Monitoring Center (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 data are possible with the optional Software S!MPATI® pharma.
- **WebSeason® Controller Interface - Program, Control and Monitor your testing** Up to six users can simultaneously use any web-based device (such as smart phones, tablets, or laptops) to connect to the controller remotely, in their own language. In addition, any user has remote access to view information, such as remaining test time, number of cycles, current steps and actual values, as well as warning and alarm notices.

- 7" Multi-user touch screen display
- Connect from any web-based device
- Manual and profile operation
- User management with 3 levels and password protection
- Software temperature limiter for minimum and maximum protection
- Audit trail
- Real time trend graph
- Available in 10 selectable languages
- Alarm system according to GAMP
- TCP/IP Ethernet interface

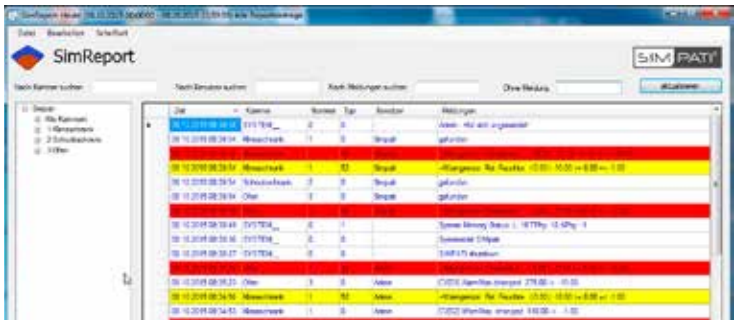
Popular Options

- S!MPATI® pharma software package
- Additional stainless steel shelves
- Demineralization unit for connection to local water supply
- Special voltages (115V/60 for C/280 and C/600)
- Qualification documentation and onsite execution for equipment and/or S!MPATI® pharma software

S!MPATI® pharma Software

Our control and documentation S!MPATI® pharma software enables you an even better use of your devices and systems with simple and secure data recording and archiving. All warning and alarm messages are recorded and, if necessary, transmit an alarm signal to the person in charge of the system. Access rights can be specifically defined for every user; the recording and storage of data are manipulation-safe but can still be used for further processing, e.g. in Excel. It goes without saying that the S!MPATI® pharma software complies with FDA 21 CFR Part 11 according to manufacturer's declaration.

Important Functions and Possibilities



- Manipulation-safe data registration
- Administration of multi-level access rights
- Audit trail
- Up to 99 units can be linked via the serial interface or Ethernet interface (TCP/IP)
- Alarm output via e-mail
- Recording/documentation of door openings and times
- Recording of alarms
- Recording of temperature and humidity curves
- Mobile solutions for site-independent monitoring of devices, e.g. by means of a tablet within the range of the installed WLAN
- Data recording via a special system network as well as via a TCP/IP network is possible
- Documentation of climate chambers and rooms irrespective of manufacturer
- Considering the alarm system of the connected devices S!MPATI® pharma fulfils the complete 5 steps risk-based approach according to GAMP 5. Category 3 software according to GAMP

Cincinnati Sub-Zero is a product brand of Weiss Technik North America, Inc. Weiss Technik North America is a member of the Weiss Technik group of companies, a division of the Schunk Group with its headquarters in Heuchelheim, Germany. Weiss Technik is the world's largest manufacturer of environmental simulation systems and employs more than 2,400 people in 22 group companies in 15 countries.

Testing Services

Our A2LA Accredited Test Laboratory provides environmental simulation testing utilizing the latest test technology to meet your testing needs from product qualification testing, overflow testing and /or third party product validation. Capabilities include Temperature, Humidity, and/or Vibration, Thermal Shock, Burn-in, Radiator Testing, Altitude, Vibration, HALT/HASS, Shock, Salt Spray, Cyclic Corrosion test and Drop Testing. Serving you from two locations in **Cincinnati, OH** and **Sterling Heights, MI**.

FOR MORE INFORMATION please call our Testing headquarters at **513-793-7774** or visit **www.wnatesting.com.**

A2LA ACCREDITED
503.1 & 503.2

Cincinnati Sub-Zero
The Testing Standard.

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