



CLIMACELL ECO & EVO - TEMPERATURE, HUMIDITY & OPTIONAL ICH Q1B LIGHTING

ICH STABILITY & PHOTOSTABILITY

FRIOCELL ECO & EVO - TEMPERATURE & OPTIONAL ICH Q1B LIGHTING



FDA CFR 21 PART 11 COMPLIANT



Your Partner for cGMP Process & Laboratory Equipment

BMT USA is a member of the MMM Group, a global supplier of sterilization and life science solutions with 70 years of designing and building cGMP pharmaceutical process and laboratory equipment. This depth of experience provides BMT USA a wide perspective when addressing a client's needs, ensuring the optimal solution is delivered for any given application.

ICH Q1A Stability & Q1B Photostability

CLIMACELL® and FRIOCELL® devices precisely control temperature, humidity (*CLIMACELL only*), and optional lighting to create exact, reproducible conditions for ICH Q1A stability testing of pharmaceutical, cosmetic and nutraceutical products. The devices also meet the requirements for ICH Q1B photostability studies when equipped with the EVO digital controller and programmable UV/VIS shelf lighting.



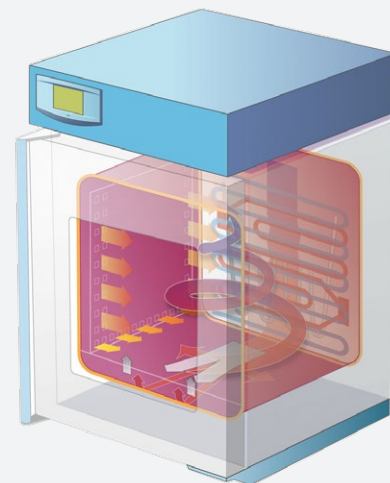
Pharmaceutical-Grade Chamber Design & Construction

BMT devices feature unmatched design and construction quality. The chamber of the CLIMACELL® and FRIOCELL® demonstrate this quality with a pharmaceutical-grade AISI 304 stainless steel chamber with a double wall construction to prolong life expectancy and 5 layers of insulation for precise internal conditions. The chamber also features a seamless, rounded corner design with fully removable inner walls for easier cleaning and sterilization. The door of the chamber employs a patented 4-point closing system that seals the door to the chamber gasket.

- AISI 304 stainless steel chamber (optional 316L stainless steel).
- Removable inner chamber with seamless, rounded corner design.
- 4-point closing system seals the door to the chamber gasket.
- Double wall chamber construction.

Patented Forced Air Heating & Cooling Technology

BMT's patented forced air convection system moves air vertically and horizontally inside the chamber for precise temperature uniformity and fast heating and cooling times. The process of heating from the bottom of the chamber to the top mimics natural airflow and allows for more precise simulation of climate conditions.



Digital LCD Controllers

The ECO digital controller and advanced EVO digital controller utilize fuzzy logic algorithm to automatically assess process data, including operation temperature, chamber size and other controlled elements. Based on the assessed data, the controller can make continuous adjustments to input values, such as heating intensity or cooling, to optimally regulate internal chamber conditions. To minimize the time required to meet set process parameters, the ECO and EVO controllers can quickly ramp up to the temperature setpoint without overshooting, resulting in reduced overall cycle time, power consumption, and recovery times.



3" ECO DIGITAL CONTROLLER

Audible & visual alarms -
temperature, time & humidity

9 programs each with up to 2 segments for varying loads and parameters, up to 99 cycles

USB flash & device, RS232 & optional Ethernet port

Integrated USB 30-day data logger for temperature measurement and recording

Optional **FDA CFR 21 Part 11** compliance with addition of Warmcomm 4.0F software



5.7" EVO DIGITAL CONTROLLER

Audible & visual alarms -
temperature, time & humidity

100 programs each with up to 100 segments for varying loads and parameters

USB device, RS232 & optional Ethernet port

Integrated SD card 30-day data logger & multi-level secure user authentication compliant

Optional **FDA CFR 21 Part 11** compliance with addition of Warmcomm 4.0F software

Optional Allen-Bradley or Siemens PLC control system with HMI available (*Replaces ECO/EVO controller*)

Programmable ICH Q1B Lighting

Lighting options including lighting placement, VIS & UV light sources, and light intensity controlled in 1% increments, allow CLIMACELL® and FRIOCELL® devices to meet ICH Q1B Photostability study requirements.

- VIS & UV fluorescent combination light shelves for exposure studies up to 13 lux & 1.8 W/m² (measured 12 cm below lights).
- VIS LED & UV fluorescent light shelves for accelerated exposure studies.
- UV up to 2.99 W/m² & VIS up to 20,000 Klux (measured 12 cm below source).



Device Technical Data

CLIMACELL ECO & EVO - Temperature, Humidity & Optional ICH Q1B Lighting

FRIOCELL ECO & EVO - Temperature & Optional ICH Q1B Lighting

Chamber Volumes

55 (2 ft³) - *FRIOCELL only* • **111** (4 ft³) • **222** (8 ft³) • **404** (14.3 ft³) • **707** (25 ft³) • **1212** (43 ft³)

Device Internal Dimensions

55 - 16" w x 14" h x 15"D • **111** - 21.3" w x 21" h x 15"D • **222** - 21.3" w x 30" h x 21"D

404 - 21.3" w x 56" h x 21"D • **707** - 37" w x 56" h x 21"D • **1212** - 21.3" w x 56" h x 21"D

Device External Dimensions

55 - 25" w x 37" h x 29.7"D • **111** - 31" w x 47.8" h x 29.7"D • **222** - 31" w x 57" h x 36"D

404 - 43" w x 74" h x 35"D • **707** - 59" w x 74" h x 35"D • **1212** - 99.6" w x 75.4" h x 35"D

Shelf Capacity - (2.8" Min. Distance Between)

55 - (5) shelves • **111** - (7) shelves • **222** - (10) shelves • **404** - (19) shelves

707 - (19) shelves • **1212** - 3 x 19 shelves

Temperature Range

ECO: 0°C up to 100°C (10°C up to 95°C with humidity - *CLIMACELL only*)

(optional -10°C minimum temp with automatic defrost)

EVO: 0°C up to 100°C (10°C up to 95°C with humidity - *CLIMACELL only*)

(optional -20°C minimum temp with automatic defrost)

Temperature Sensor

PT100 RTD

Refrigerant

R 134a

Sterilization Cycle

160°C dry heat sterilization (*EVO devices only*)

Controlled Humidity - *CLIMACELL Only*

ECO 10% up to 95% – controlled in 1% increments

EVO 10% up to 98% – controlled in 1% increments

- Active dehumidification for humidity control as uniform as 2.5%
- Water tank with automatic pump for water supply included
- Wastewater vessel water pump to remove condensate

Humidity Sensor - *CLIMACELL Only*

Rotronic humidity sensor

Electrical Data

All CLIMACELL devices & FRIOCELL 1212 - 230V 50/60Hz

FRIOCELL 55, 111, 222, 404, 707 - 115V 50/60Hz

Certifications

CE, UL, CSA listed

Please visit www.bmtusa.com for more detailed CLIMACELL & FRIOCELL specifications.

Optional Equipment

- 160°C dry heat sterilization cycle
- GMP compliance
- 4-20mA contacts
- AISI 304 stainless steel exterior
- BMS remote monitoring system contacts
- VIS range door lighting
- waterproof 115V or 230V electrical outlet inside the chamber
- IQ/OQ protocols with (9) or 27-point temperature mapping
- Onsite execution of IQ/OQ protocols
- Heavy load chambers
- RO water supply systems
- (1), (9), or (3) humidity measurements
- Rolling carts for 55, 111 & 222 models
- Flexible sensors
- **Warmcomm 4.0 software - 21 CFR 21 Part 11 compliance**



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STERILIZATION & LIFE SCIENCE SOLUTIONS