



FDM Environment Makers Products

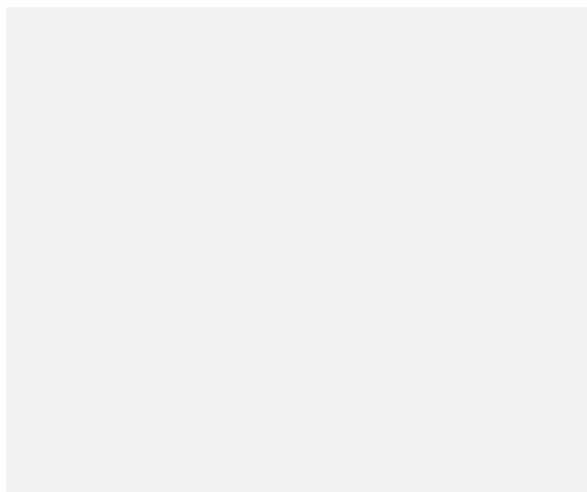
Climatic & Thermostatic Chambers

Growth Chambers

Environmental Chambers

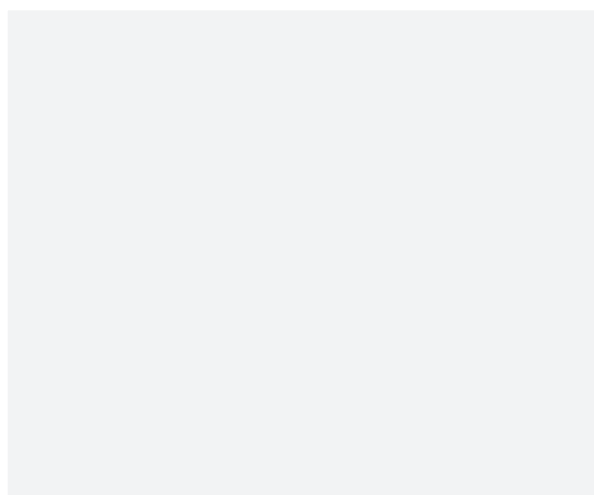
Ultrafreezers

Customised Solution



ICH Q1A/Q1B Test Chambers

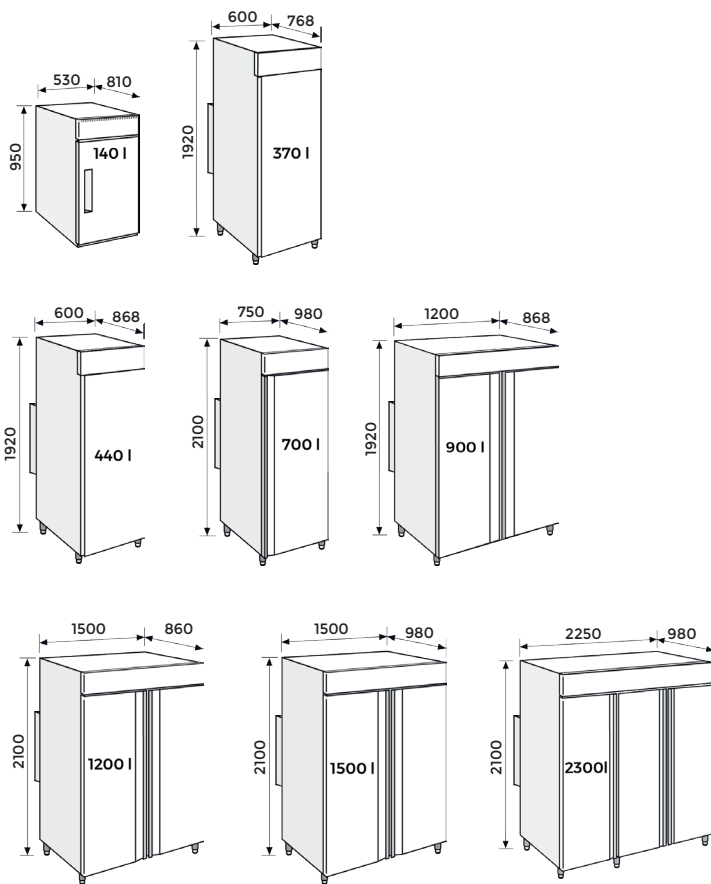
C/T SB - LHC/T SB Series



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Technical specifications are subject to change

Sizes



FDM chambers according to ICH Q1A test describes the stress tests to be carried out on drugs (Control parameters: temperature, humidity&duration). It determines the shelf life of a given product. Shelf life (also referred to as expiration dating period). The time period during which a drug product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label.

FDM chambers according to ICH-Q1B, on the other hand, introduces the photostability test, i.e. the resistance of the products to prolonged exposure to sunlight. For this reason, in addition to the temperature, humidity and duration parameters already mentioned, the climate chamber must be equipped with specific lamps, that we call ICH-lamps.

FDM manufacturers climate/temperature chambers for photostability testing of all types, both standard and customized, for private research laboratories (Pharma/ Cosmetics companies) and for public research lab (Universities/Institutes).

Advantages

| |
|--|
| Capacity from 140 to 2300 liters |
| Adjustable temperature range -25°C...+70°C |
| Humidity range 10...80%. |
| LED and Neon lighting, vertical or horizontal disposition |
| Programmable controller revoFACE or for stillFACE stable tests |
| Internal forced and homogeneous ventilation |
| High and low temperature and humidity alarms |
| Electrical power 220-240V /50Hz or 110V |



Led lamps placed on the walls and homogeneity of light throughout the climatic environment.

Configuration examples



LHC700BXP/PRO
ICH-ILD200LED



LHC700BXP/PRO
ICH-IRD200LED

| Positive Range (S) | C/T140S | C/T370S | C/T440S | C/T700S | C/T900S | C/T1200S | C/T1500S | C/T2300S |
|---|--|---------|---------|---------|---------|----------|----------|----------|
| Negative Range (B) | C/T140B | C/T370B | C/T440B | C/T700B | C/T900B | C/T1200B | C/T1500B | C/T2300B |
| Temperature performance | | | | | | | | |
| Temperature range without humidity [°C] | 0...+70 (S) -25...+70 (B) | | | | | | | |
| Temperature uniformity depending on setpoint [± K] | 0.5..2.5 | | | | | | | |
| Temperature fluctuation depending on setpoint [± K] | 0.1..0.5 | | | | | | | |
| Average heating-up rate according to EN 60068-3-5 [K/min] | +2 | | | | | | | |
| Average cooling down rate according to EN 60068-3-5 [K/min] | -1 | -0.6 | -1 | -0.6 | -1 | -0.6 | -1 | -1 |
| Performance Data Climate | | | | | | | | |
| Temperature range [°C] with humidity on | 10/60 | | | | | | | |
| Humidity range in according to Chart*1 [% r.h.] | Light off | 10/90 | | | | | | |
| Humidity fluctuation depending on setpoint [± %] | ≤ 3 | | | | | | | |
| Humidification system | Ultrasonic humidification system | | | | | | | |
| Water filter | Water softening filter and replaceable cartridge equipped*2 | | | | | | | |
| Max Water hardness permitted | 600 ppm CaCO ₃ | | | | | | | |
| Water inlet | Pressure 0.2÷5 BAR - Temperature 10÷40°C - Pipe connection 3/4" | | | | | | | |
| Outer dimensions | | | | | | | | |
| Width net [mm] | 830 | 600 | 600 | 750 | 1200 | 1500 | 1500 | 2250 |
| Depth net [mm] | 810 | 768 | 868 | 980 | 868 | 860 | 980 | 980 |
| Height net [mm] | 950 | 1920 | 1920 | 2100 | 1920 | 2100 | 2100 | 2100 |
| Doors | | | | | | | | |
| Unit doors | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 3 |
| Internal Dimensions | | | | | | | | |
| Width [mm] | 450 | 500 | 500 | 600 | 1090 | 1340 | 1300 | 2090 |
| Depth [mm] | 540 | 480 | 580 | 670 | 580 | 570 | 670 | 670 |
| Height [mm] | 520.5 | 1257 | 1257 | 1340 | 1257 | 1350 | 1340 | 1340 |
| Measures | | | | | | | | |
| Interior net volume [L] | 130 | 310 | 370 | 530 | 810 | 1020 | 1180 | 1830 |
| Net weight of the unit (empty) [kg] | 78 | 100 | 110 | 167 | 197 | 212 | 215 | 367 |
| Permitted load per rack [kg] | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| *3 Fixtures | | | | | | | | |
| Number of shelves (std./max.) | 2/3 | 3/5 | 3/5 | 3/6 | 6/10 | 6/12 | 6/12 | 9/14 |
| Shelf Width [mm] | 400 | 460 | 460 | 530 | 460 | 530 | 530 | 530 |
| Shelf Depth [mm] | 500 | 470 | 570 | 650 | 570 | 550 | 650 | 650 |
| stillFACE Controller | | | | | | | | |
| Controller | Constant monitoring temperature and humidity controllers | | | | | | | |
| Interface port | Optional: RS485 | | | | | | | |
| revoFACE Programmer | | | | | | | | |
| Set-up Display | Programme status, set up temperature and humidity, date, time and language | | | | | | | |
| Programmer | 10 programs and 50 segments each, adjustable from 1 min. to 999 hrs. | | | | | | | |
| Calibration | Possibility to calibrate all parameters | | | | | | | |
| Interface port | Optional: RS485 - Ethernet - Wifi - Dedicated mobile app | | | | | | | |

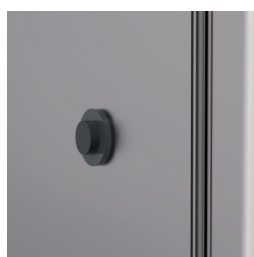
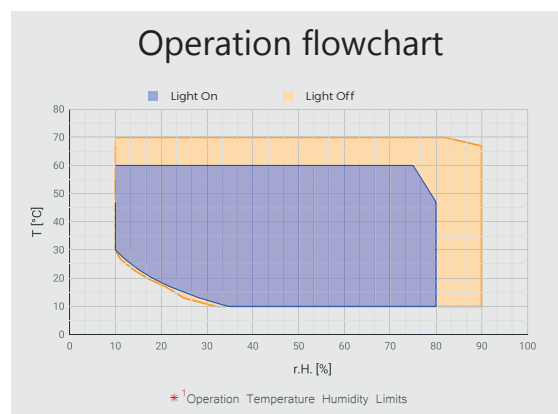
Product Code Generator

| LH | T/C | 140 | S/B |
|--|--|--|---|
| The LH portion of the code at the beginning denotes the presence of ICH equipped lamps | Temperature (T) or Climate (C) Control | Internal volume from 140 up to 2300 liters | S- T.range 0°/70°C B- T.range -25°/+70°C |

| Positive Range (S) | | C/T140S | C/T370S | C/T440S | C/T700S | C/T900S | C/T1200S | C/T1500S | C/T2300S |
|------------------------------|---------------|---|---------|---------|---------|---------|----------|----------|----------|
| Negative Range (B) | | C/T140B | C/T370B | C/T440B | C/T700B | C/T900B | C/T1200B | C/T1500B | C/T2300B |
| Environment-specific data | | | | | | | | | |
| Sound-pressure level [dB(A)] | | 60 | | | | | | | |
| Structure and insulation | | | | | | | | | |
| Exterior material | | White coated galvanized steel or full Stainless steel AISI 304 | | | | | | | |
| Internal material | | AISI 304 Stainless Steel | | | | | | | |
| Insulation | | CFC and HCFC free | | | | | | | |
| Shelf grill | | Removable and height adjustable steel grid | | | | | | | |
| Ventilation | | | | | | | | | |
| Fan | | forced ventilation | | | | | | | |
| Safety | | | | | | | | | |
| Temperature | | Class 2 independent adjustable temperature safety devices (DIN 12880) | | | | | | | |
| Alarm | | Audio-Visual | | | | | | | |
| Electrical data | | | | | | | | | |
| Rated Voltage [V] | | 220/240 | | | | | | | |
| Power frequency [Hz] | | 50 | | | | | | | |
| *Nominal power [kW] | Light off (S) | 1.4 | 1.5 | 1.4 | 1.8 | 2.2 | 2.4 | 2.6 | 2.7 |
| | Light off (B) | 1.6 | 1.7 | 1.7 | 2.3 | 2.6 | 2.7 | 2.9 | 3.1 |
| Unit fuse [A] | | 16 | | | | | | | |
| Phase (nominal voltage) | | 1 ~ | | | | | | | |

Main Options

- ETH100 - Ethernet interface for remote connection (included)
- UDB100 - USB Port (included)
- PE100 - Interior socket coverable universal 220-230 V
- CFR21 - Controller according to CFR21 Part 11 regulation
- TE110 - Power supply 110 V 50-60 Hz



• FD100

Cable hole installed on the side of the chamber that allows the passage of cables inside without loss of performance.



• UDB100

USB port for downloading test data with the possibility of viewing them on a PC in Excel format.



• GP100R

The reinforced stainless steel shelf differs from the standard one (pictured above) in that it has a higher supported load capacity.



• RT100

Swivel castors with chamber lock for easy movement.



• revoFACE

The touch-screen interface allows you to program segments autonomously and view the test progress in real time.



• WTO16

System of supply demineralized water tank 16 liters.

Click and go to Online Configurator

www.dellamarca.it



| Positive Range (S) | LHC/T140S | LHC/T370S | LHC/T440S | LHC/T700S | LHC/T900S | LHC/T1200S | LHC/T1500S | LHC/T2300S |
|---|-----------|-----------|-----------|---------------------------|-----------|------------|------------|------------|
| Negative Range (B) | LHC/T140B | LHC/T370B | LHC/T440B | LHC/T700B | LHC/T900B | LHC/T1200B | LHC/T1500B | LHC/T2300B |
| *5 Temperature performance | | | | | | | | |
| At 0% light [°C] | | | | 0...+70 (S) -25...+70 (B) | | | | |
| At 100% light [°C] | | | | 0...+60 (S) -10...+60 (B) | | | | |
| *6 Horizontal Shelf Illumination | | | | | | | | |
| Illumination on Shelf for UV-A lamps [W/m²] | 8 | 140 | 110 | 100 | 110 | 100 | 100 | 100 |
| Illumination on Shelf for White lamps [LUX] | 4.500 | 8.000 | 10.000 | 13.000 | 10.000 | 13.000 | 13.000 | 13.000 |
| Exposition time to reach 1,2 million of lux-h [Hours] | 267 | 157 | 118 | 92 | 118 | 92 | 92 | 92 |
| Exposition time to reach 200 W-h/m² of UV-A [Hours] | 25 | 1,4 | 1,7 | 1,9 | 1,7 | 1,9 | 1,9 | 1,9 |

All technical data are specified for units with standard equipment at an ambient temperature of +24 °C and a voltage fluctuation of ±10 %.

For all type of lamp the humidity data is: Humidity range [% RH] 10 to 80, Humidity fluctuation ≤ 3 ± % RH

*The cartridge should be change every 4+6 months at most.

*The installation of fluorescent walls illumination reduces the useful width of the shelves: for 140,370,440,900 liters size is reduced of 160 mm for 600, 700, 1200, 1500 liters volume size is reduced of 100 mm. The led walls illumination reduces the useful width of the shelves: for 370, 440, 900 liters is reduced of 40 mm.

*The nominal power with light ON varies, depending on the number and types of lamps installed.

*This data are specified with Fluorescent Lamps. With LED lamps installed the lux and PPFD values could vary by ± 10%. The W/m² decrease around 20%.

*This data are for shelf illumination at a distance of 15 cm from the lamps. Data are valid for new lamps at a temperature of 20°C. Please consider that illuminance power of lamps will decrease over time.

Layout and dimensions with lamps Neon or Led

| | Horizontal Shelf Lamps | Vertical Wall Lights |
|---|------------------------|----------------------|
| 700 liters chamber with LED lamps | | |
| 700 liters chamber with FLUORESCENT lamps | | |