

ICH Q1A/Q1B Test Chambers.

C/T SB - LHC/T SB Series

FDM Environment Makers Products

Climatic & Termostatic Chambers

Growth Chambers

Environmental Chambers

Ultrafreezers

Customised Solution

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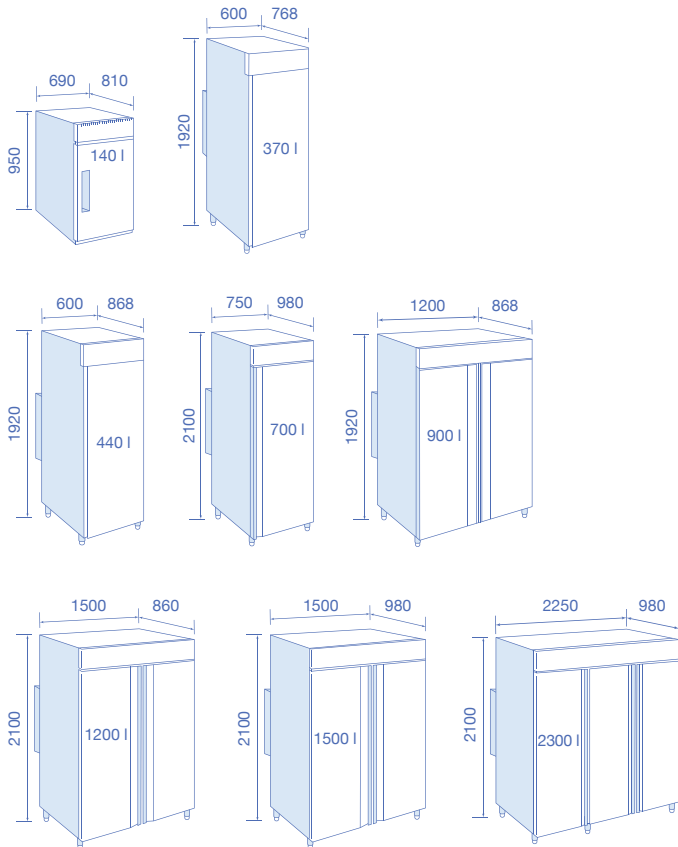
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Volumi



Description

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



LHC700BXPRO
ICH-ILD200LED



LHC700BXPRO
ICH-IRD200LED

ICH Q1A	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	-0.6	-1
	Performance Data Climate									
	Temperature range [°C] with humidity on	10/60								
	Humidity range in according to Chart*1[% r.h.]	10/90								
	Humidity fluctuation depending on setpoint [± %]	Light off	≤ 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]	690	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	
	*3Fixtures									
	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									

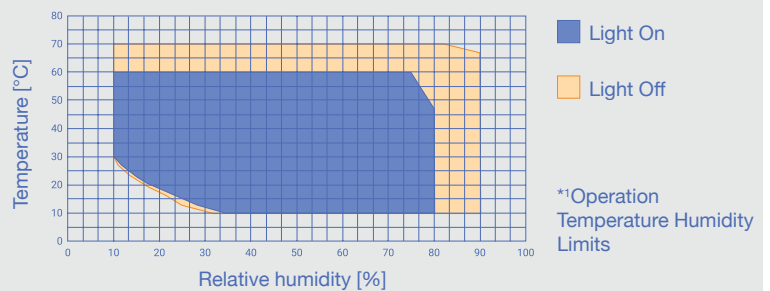
Product Code Generator			
LH	T/C	140	S/B
The LH portion of the code at the beginning denotes the presence of ICH equipped lamps	Controllo Temperatura (T) o anche Climatico (C)	Internal volume from 140 up to 2300 liters	S- T.range 0°/70°C B- T.range -25°/+70°C

ICH Q1A	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								
	*4Nominal 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

Operation flowchart



- **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.



- **WT016**
System of supply demineralized water tank 16 liters.

Click and go to Online Configurator
www.dellamarca.it

ICH Q1B	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...+55 (S) -10...+55 (B)								
	At 100% light [°C]	+5...+50 (S) -5...+50 (B)								
	^{*6} Horizontal Shelf Illumination									
	Illumination on Shelf for UV-A lamps [W/m ²]	8	140	110	100	110	100	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	13.000
	Exposition time to reach 1,2 million of lux-h [Hours]	267	157	118	92	118	92	92	92	92
	Exposition time to reach 200 W-h/m ² of UV-A [Hours]	25	1,4	1,7	1,9	1,7	1,9	1,9	1,9	1,9

For all type of lamp the humidity data is: Humidity range [% RH] 10 to 80, Humidity fluctuation $\leq 3 \pm \% RH$

^{*2}The cartridge should be change every 4÷6 months at most.

^{*3}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.

^{*4}The nominal power with light ON varies, depending on the number and types of lamps installed.

^{*5}This data are specified with Fluorescent Lamps. With LED lamps installed the lux and PPFD values could vary by $\pm 10\%$. The W/m² decrease around 20%.

^{*6}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.

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

Layout and dimensions with lamps Neon or Led

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