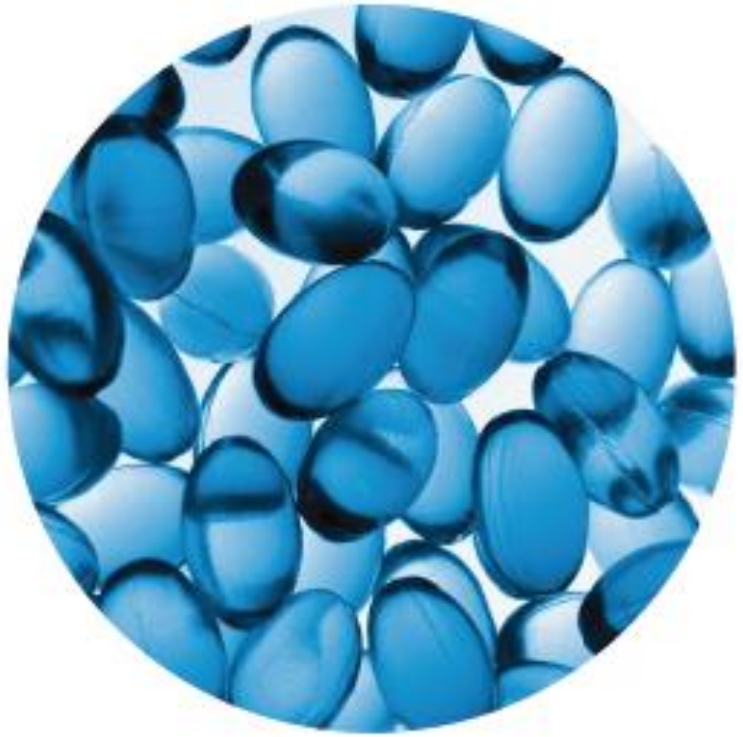
YOUR OWN CLIMATE



STABILITY

Stability Storage Chambers & Environmental Stability Rooms

ARALAB

ARALAB is a company specialized in designing, developing, manufacturing and servicing of **environmental chambers** and **controlled environment rooms**.

Since 1985 we have been perfecting ways to create and control **temperature, humidity, light, air flow** and many other environmental conditions.

What drives us is simple: to develop solutions that go beyond the expectations of users so customers can enjoy the **best equipment for their research and testing applications.**

aralab

YOUR OWN CLIMATE

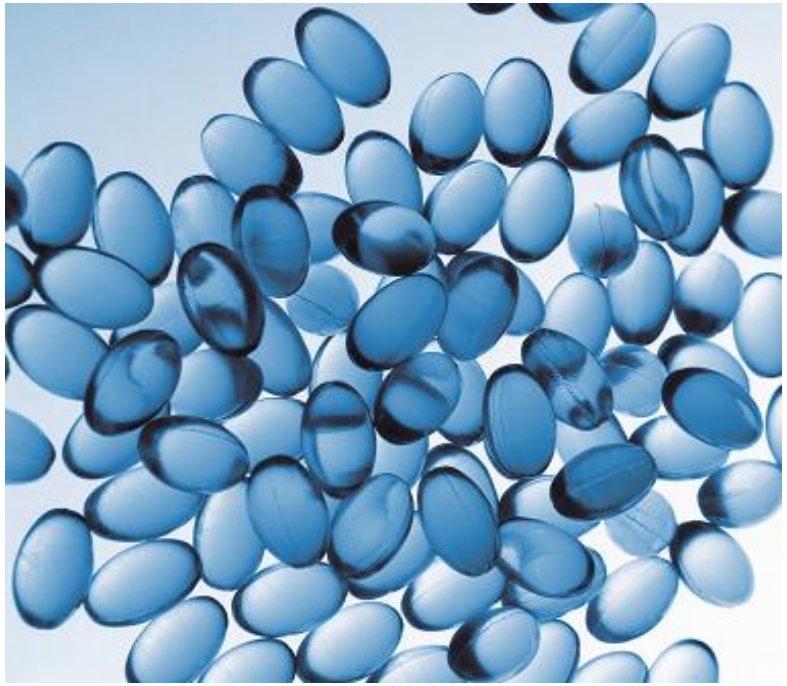
ISO 9001 BUREAU VERITAS Certification

Aralab is ISO:9001 certified for it's Quality Management System

ARALAB STABILITY

Pharmaceutical Stability Studies
Food and Beverages
Cosmetics
Veterinary
Storage and Conservation
Quality control and Research

FitoClima Stability chambers provide the environmental control and storage flexibility to meet the evolving needs of customers throughout the years.



KEY FEATURES

- Climatic conditions controlled with consistent precision through the years
- Adaptive future proof design, with height adjustable trays and shelves that are easy to insert or remove depending on storage needs
- Pre-configured with shelves designed to provide the most efficient use of the available internal volume
- Content protection features, with configurable high / low temperature and humidity alarms and automatic remote notifications
- FDA 21 CFR part 11 compliant software
- Compliant and recognized by ICH, FDA, GMP and other leading industry standards
- IQ, OQ, PQ and ISO calibration procedures and documentation

SOME STABILITY CUSTOMERS

HIKMA QUALITY
BIOGÉNESIS-BAGÓ
AstraZeneca
sanofi aventis
Because health matters
Bial
NOVARTIS
infarmed
Instituto Nacional da Farmácia e do Medicamento
Vifor Pharma
HOVIONE
NORMON
NORMON
BAYER
ESTEVE
AGUETTANT
ESSENTIAL MEDICINES
SGS
TECNIMEDE GROUP
ATLAS
farmacêutica

FITOCLIMA PHARMA STABILITY

REACH-IN CHAMBERS FOR TEMPERATURE AND HUMIDITY STABILITY TESTING

REACH-IN CHAMBERS FOR TEMPERATURE, HUMIDITY AND LIGHT EXPOSURE TESTING

COMPLIANT WITH ICH Q1A + Q1B, FDA, GMP AND OTHER INTERNATIONAL QUALITY STANDARDS

FitoClima 600 & 1200 Stability & Photostability product range

FITOCLIMA 600 & 1200 PH

STABILITY REACH-IN CHAMBERS WITH TEMPERATURE AND HUMIDITY CONTROL – ICH Q1A

FitoClima 600 and 1200 PH (with optional double glazed door)

FITOCLIMA 600 & 1200 PH

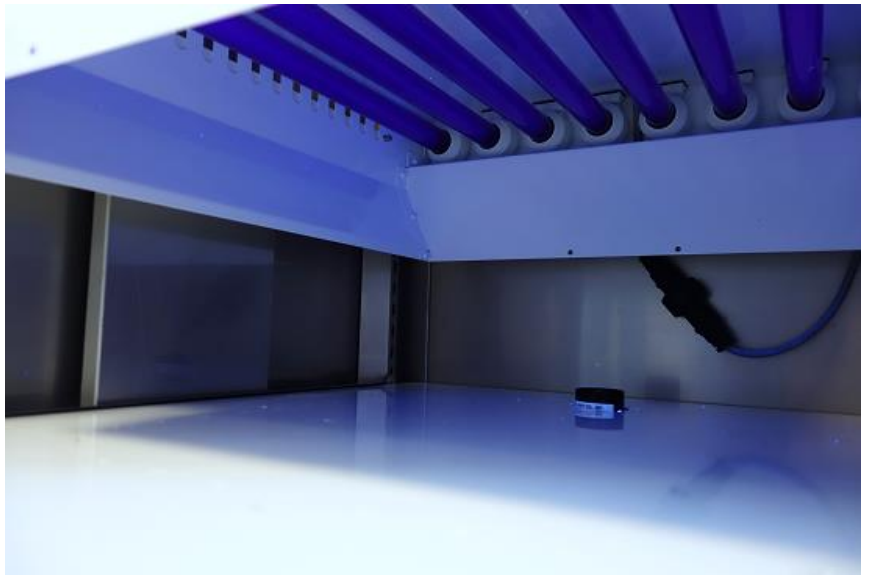
STABILITY REACH-IN CHAMBERS WITH TEMPERATURE AND HUMIDITY CONTROL – ICH Q1A

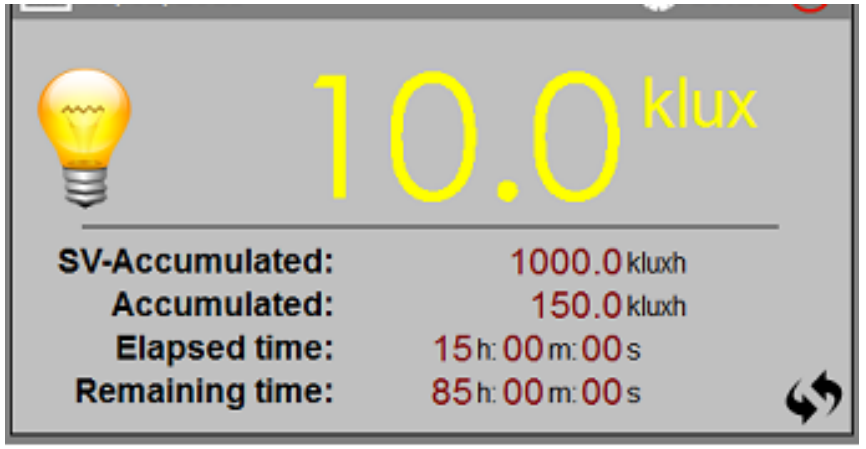
TECHNICAL DATA FOR FITOCLIMA 600 & 1200 STABILITY CHAMBERS	
TEMPERATURE RANGE [1]	-5ºC to 45ºC
TEMPERATURE PRECISION	± 0,5ºC
TEMPERATURE UNIFORMITY	± 1,0ºC
HUMIDITY RANGE [1]	35 to 90% rH
HUMIDITY PRECISION	± 1% rH
HUMIDITY UNIFORMITY	± 2% rH
SHELVES (STANDARD CONFIGURATION) [2]	FitoClima 600: 4 stainless steel wire shelves FitoClima 1.200: 8 stainless steel wire shelves
STANDARD WIRE SHELF SIZE	630mm x 520mm
STORAGE [2]	0.33m^2 and 18 Kg weight load (per shelf)
STORAGE (STANDARD CONFIGURATION) [2]	FitoClima 600: 1,33 m^2 FitoClima 1.200: 2,67 m^2
AIRFLOW	0.2 m/s uniform across the shelves
INTERNAL VOLUMES	600 and 1.200 liters

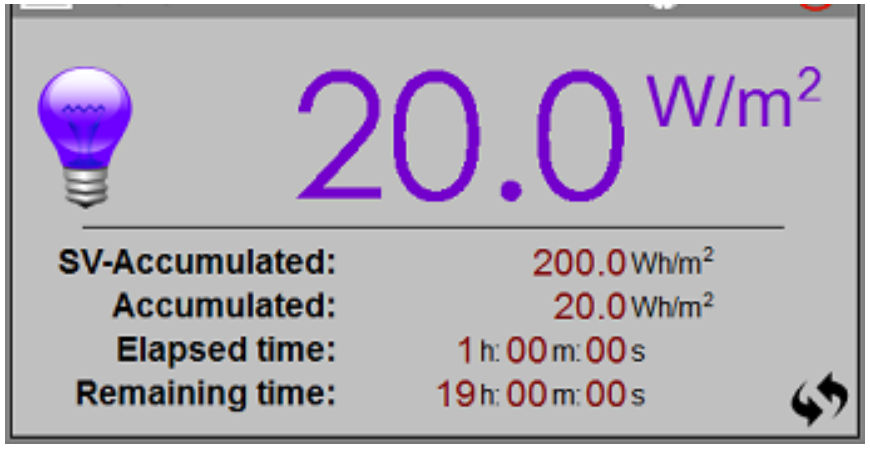
[1] Temperature and Humidity uniformity performances in Stability Testing. Photostability testing model will present greater differences in temperature and humidity uniformity due to heat dissipation from lamps
[2] Additional shelves can be fitted (600 model - up to 10 shelves; 1200 model - up to 20 shelves). Reinforced perforated shelves with 40Kg weight load also available

FITOCLIMA 600 PLH-R

REACH-IN CHAMBER FOR STABILITY AND PHOTOSTABILITY TESTS – ICH Q1B







FITOCLIMA 600 PLH

REACH-IN CHAMBER FOR STABILITY AND PHOTOSTABILITY TESTS – ICH Q1B

DETAILS FOR FITOCLIMA 600 PLH / PLH-R	
VISIBLE LIGHT TYPE	8 fluorescent HF “cool white” lamps
VISIBLE LIGHT INTENSITY	26.000 Lux (approximately, ±6% uniformity)
UV LIGHT TYPE	8 fluorescent HF “UV-A” lamps
UV LIGHT INTENSITY	30 W/m^2 (approximately, ±10% uniformity)
NUMBER OF TEST SHELVES *	One (1) for UV and one (1) for Visible light
OPTIMAL PHOTOSTABILITY TEST AREA	0,14m^2 per shelf
TEMPERATURE UNIFORMITY	± 2°C (Lights On)
HUMIDITY UNIFORMITY	± 5%rh (Lights On)
APPROXIMATE TIME REQUIRED FOR ICH Q1B VISIBLE LIGHT TEST	48 hours (1.2M Lux accumulated)
APPROXIMATE TIME REQUIRED FOR ICH Q1B UV LIGHT TEST	7 hours (200 W/m^2 accumulated)

ARALAB STABILITY CHAMBERS

REACH-IN CHAMBERS EQUIPMENT DESCRIPTION

CONSTRUCTION

- 600 and 1.200 liters volumes
- Multiple adjustable shelving system
- Highly resistant stainless steel in the interior and exterior
- Polyurethane insulation
- Front panel with zincor steel and gray epoxy paint
- Pivoting door(s) with spring lock, magnetic gasket and safety lock(s)
- Casters with built in brakes for effortless mobility and control
- 35mm diameter entry-port
- New generation multi-color touch-screen ClimaPlus© controller
- Open door alarm with configurable time-out function
- Free slots for connecting and integrating external devices (Alarms, sensors, etc) Radiometers/Light sensors and many other) on the ClimaPlus controller
- Accessible technical compartment for faster maintenance procedures

ARALAB STABILITY CHAMBERS

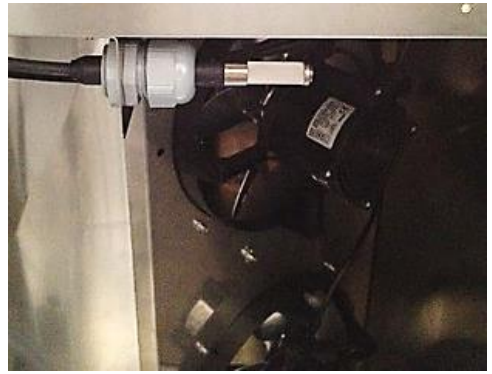
REACH-IN CHAMBERS EQUIPMENT DESCRIPTION

CLIMATIC CONTROL

- Air based, CFC free, mechanical refrigeration by hermetic condenser group
- Dual heating technology with hot gas by-pass and stainless steel electric heaters
- Humidification by ultrasonic generator with automatic water level control and self-cleaning function
- Dehumidification by condensation on the cooling system evaporator
- PT100 Class A temperature sensor and capacitive humidity sensor

PROTECTION FEATURES

- Independent thermostats for maximum and minimum temperature limits
- Automatic cut-off function, in case of excessive heating or cooling
- Configurable maximum and minimum temperature and humidity limits
- Visual and audible alarms for temperature and humidity band limits



ARALAB STABILITY ROOMS

WALK-IN CHAMBERS FOR TEMPERATURE AND HUMIDITY STABILITY TESTING

COMPLIANT WITH ICH, FDA, GMP AND OTHER INTERNATIONAL QUALITY STANDARDS

ARALAB STABILITY ROOMS

WALK-IN CHAMBERS FOR TEMPERATURE AND HUMIDITY STABILITY TESTING

TEMPERATURE RANGE [1]	15ºC to 45ºC
TEMPERATURE PRECISION	± 0,5ºC
TEMPERATURE UNIFORMITY	± 1,0ºC
HUMIDITY RANGE	35 to 90% RH
HUMIDITY PRECISION	± 1% RH
HUMIDITY UNIFORMITY	± 2% RH
SHELVES [2]	Shelves with 5 levels each. Anodized aluminium structures with polyethylene trays. Storage capacity will vary with final implementation layout and number of levels on each rack
APPROXIMATE STORAGE CAPACITY [3] FitoClima 5.000 PH FitoClima 12.000 PH FitoClima 25.000 PH	 10 m² 19,5 m² 32 m²
LIGHT	Interior is illuminated by fluorescent lights located at the ceiling in a protected cover. Lights can be operated by manual switch, triggered by door opening or controller integrated (programmable)
AIRFLOW VELOCITY	Can be adjusted by set-point % on the controller
INTERNAL VOLUMES [4]	Ranging from 5.000 to 25.000 liters

[1] Temperature range extension available from 5ºC to 45ºC. Please contact Aralab for other technical requirements
[2] Aralab Stability rooms are pre-configured with shelves (5 levels with approximate 500mm of depth each) to provide the most efficient use of the available space. Also available stainless steel AISI 304 shelves as option.
[3] Additional trays/levels can be added to shelving configuration.

ARALAB STABILITY ROOMS

WALK-IN CHAMBERS EQUIPMENT DESCRIPTION

CONSTRUCTION

- Panels: 80 mm thick, EN 14509 sandwich type high density injected polyurethane foam modular panels
- Floor: slip resistant stainless steel floor
- Columns, corners and beams in high quality solid PVC
- Shelving and trays: 5 levels, all around the chamber with adjustable positioning
- Ø 80mm entry port
- New generation multi-color touch-screen ClimaPlus© controller
- Door with double gasket, observation window with key and safety opening mechanism from the inside
- Open door alarm with configurable time-out function
- Free slots for connecting and integrating external devices with the ClimaPlus controller

ARALAB STABILITY ROOMS

WALK-IN CHAMBERS EQUIPMENT DESCRIPTION

CLIMATIC CONTROL

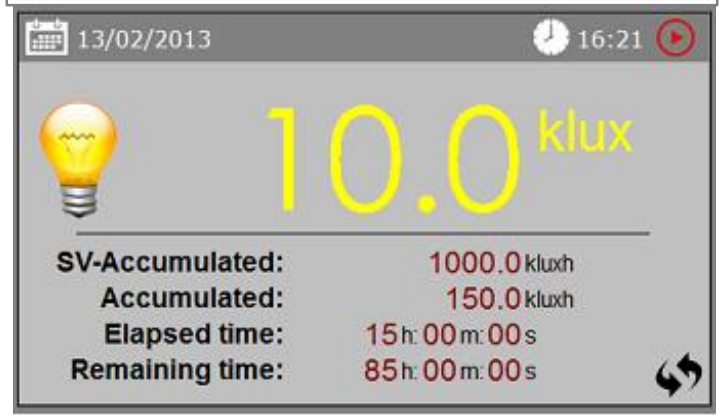
- Air based, CFC free, mechanical refrigeration by sealed condenser group
- Dual heating technology with hot gas by-pass and stainless steel electric heaters
- Humidification by ultrasonic generator with automatic water level control and self-cleaning function
- Dehumidification by condensation on the cooling system evaporator
- PT100 Class A temperature sensor and capacitive humidity sensor

AIR FLOW

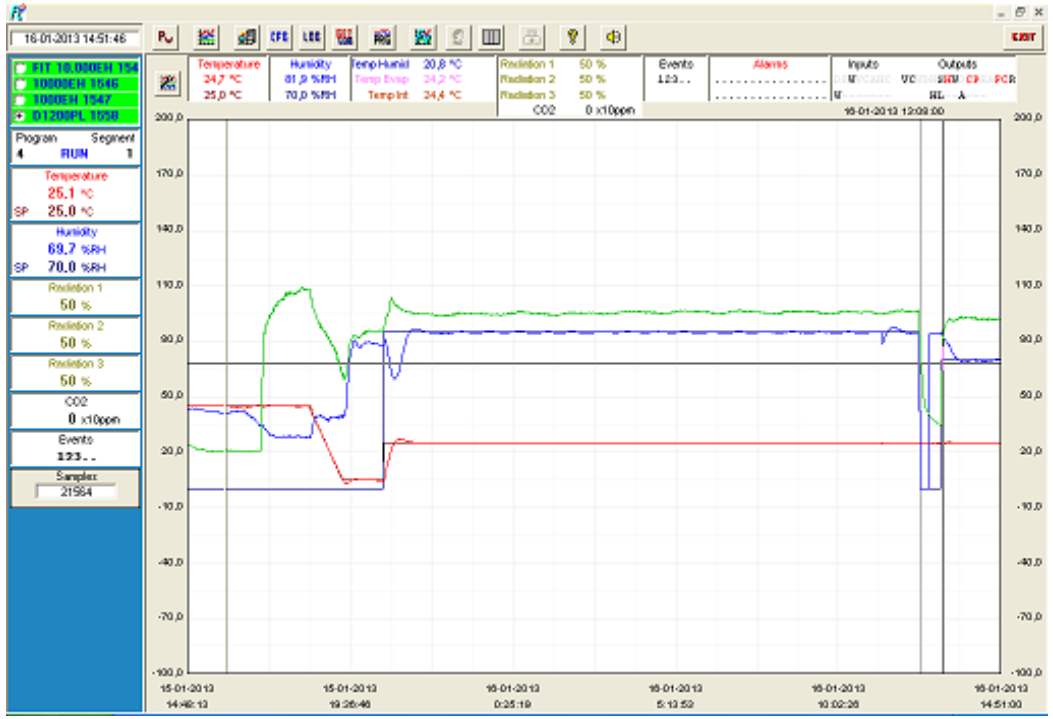
- Dynamic airflow with EC (variable) blower
- Forced in horizontal and downward direction
- Horizontal laminar airflow across the shelves to assure uniformity to all storage area
- Air renovation through adjustable lateral port-holes

CLIMAPLUS CONTROLLER

- Programmable Logic Controller exclusively developed by Aralab for FitoClima chambers
- Easy to use touch-screen interface with 168mm x 112mm multicolor display
- Controls every environmental variable available for any specific FitoClima model (Temperature, Humidity, Lights, Airflow, CO2, O2 and connected external devices)
- Friendly program editor for creating 32 programs of 24 segments each, allowing the design of complex and comprehensive climatic simulation programs
- Password protection of the controller functions
- Content and research protection feature, with configurable High and Low Temperature and Humidity alarms and automatic notifications
- Managing, monitoring and recording of all alarms
- Non-volatile memory, allowing the automatic restart of previously defined set-points or on-going programs due to power failure, without losing data
- Real-time monitoring of all the functions and active components of the equipment, allowing for a fast and accurate diagnostic in case of malfunction
- Possibility to control and program events by external commands and with external devices
- Graphical view of programs and climatic variables
- ClimaPlus controller functions also available at the PC/Laptop with the FitoLog software pack

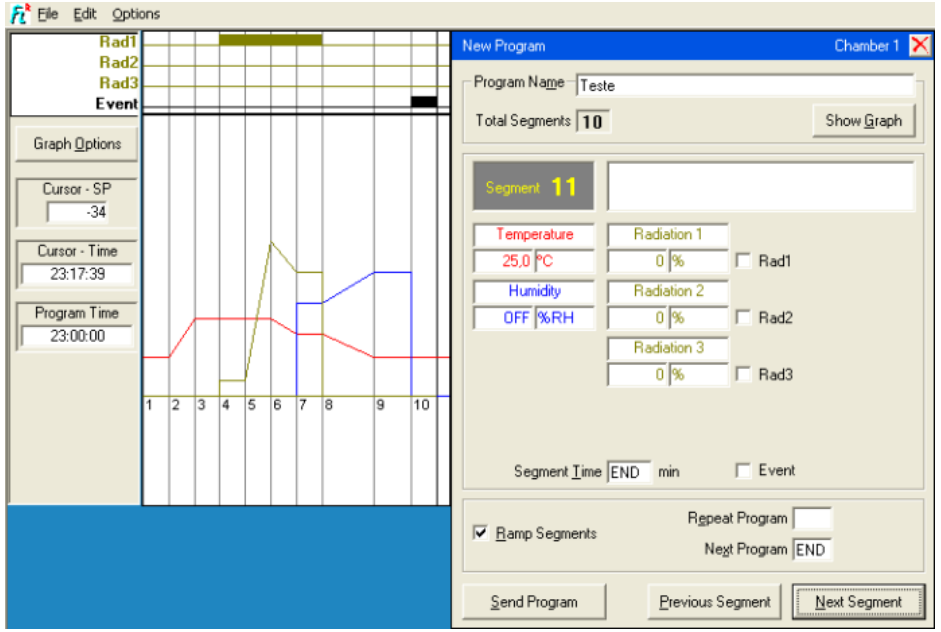


FITOLOG SOFTWARE (FDA 21 CFR PART 11 COMPLIANT)



FitoProgram: This application simplifies the creation of programs and its integration on the chamber ClimaPlus controller.

FitoLogView: One can view, print and export the log contents to other file types, and analyse the data in other data management software



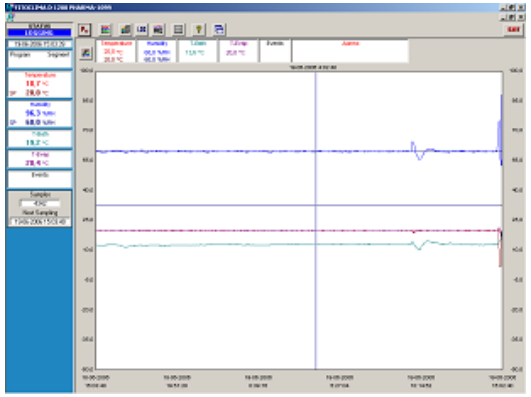
FitoLog: Records and displays in real time all data and details related to the set-points, running variables and equipment behaviour. It also retrieves information about the active components of the chamber, running processes, errors, alarms and allows the configuration of periodic or alarm triggered remote notifications (by email or SMS, depending on existing connections and accessories).

CONTENT SECURED WITH ALARMS, NOTIFICATIONS, FAST DIAGNOSTICS AND PROMPT TROUBLESHOOTING: With **FitoLog** it is possible to gather data from each of the chambers systems, which makes it a very useful tool to diagnose any necessary maintenance. This tool works as the “black box” of the equipment, giving Aralab technicians the necessary data to remotely carry out a fast and efficient diagnostic. All that is needed is a FitoLog file.

ARALAB FITOCLIMA STABILITY

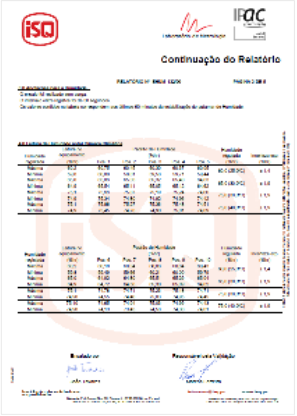
FREQUENT ACCESSORIES

- FitoLog® software pack for PC/Laptops, enabling data monitoring, logging (FDA 21 CFR part 11 compliant) and managing operations directly on a computer
- IQ, OQ, PQ procedures and documentation
- ISO 17025 calibration
- Wireless / portable data loggers for temperature and humidity control of external areas
- Additional shelves and racks
- Shelves and interior in AISI 304 stainless steel
- Ethernet / Wi-Fi / Other connections for computer connection
- Additional entry ports
- Extended temperature ranges
- Integrated water tank
- Wall mounting conductivity meter, for water quality control, with assembling accessories



FitoLog (FDA 21 CFR part 11) software pack

Integrated water supply tank



Qualification and Calibration documents

ARALAB TURNKEY STABILITY PROJECTS

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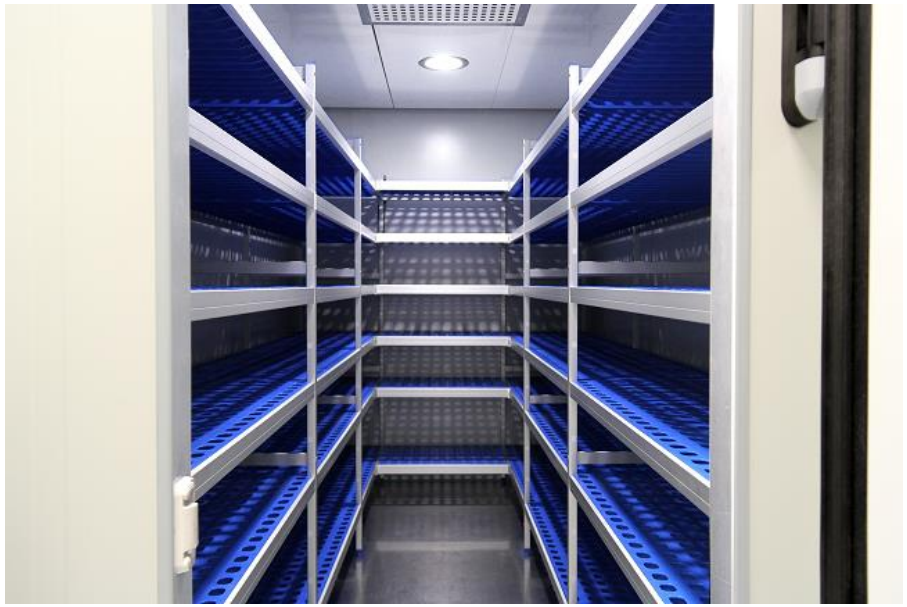
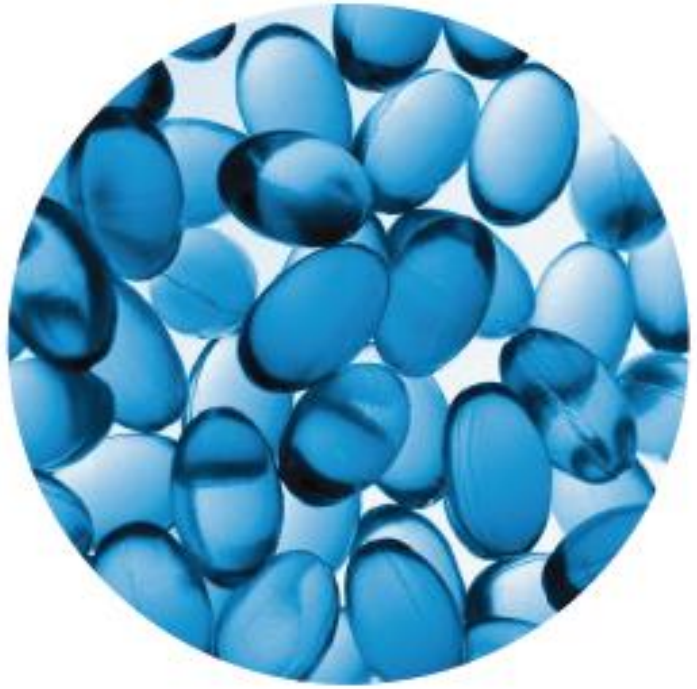


ARALAB TURNKEY STABILITY PROJECTS

ARALAB TURNKEY STABILITY PROJECTS

ARALAB TURNKEY STABILITY PROJECTS

THANK YOU



YOUR OWN CLIMATE

Our main goal

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