aralab

STABILITY AND PHOTOSTABILITY TESTING



FITOCLIMA
600 & 1200 STABILITY

STABILITY STORAGE AND PHOTOSTABILITY TESTING CHAMBERS

ICH, GMP, WHO, FDA COMPLIANT





Common applications include:

Pharmaceuticals
Cosmetics
Food and Beverages
Veterinary
Storage and Conservation
Quality control and Research

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





ARALAB

ARALAB is a company specialized in designing, developing, manufacturing and servicing of high quality climatic 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.

Only the highest quality components are used to manufacture our chambers so customers can have the best equipment for their research and testing purposes.

Aralab. Your own climate.

Certified ISO:9001 for its Quality Management System

KEY FEATURES

- Ready to use. No assembly needed
- Minimal footprint, for efficient use of laboratory space
- Future proof design. The interior can be reconfigured at any time for the most efficient use of the available storage space and content dimensions
- Content protection, with configurable high / low temperature and humidity alarms and automatic email notifications
- Remote diagnostics, allowing a fast and accurate technical support
- FDA 21 CFR part 11 compliant software
- Compliant and recognized by ICH, FDA, GMP and other leading industry standards

TECHNICAL SPECIFICATIONS

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 95% 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



INSTALLATION REQUIREMENTS

WATER (FOR MODELS WITH HUMIDITY CONTROL)	Distilled or demineralized water. 1 to 5 bar and ≤ 10µ siemens conductivity.
WATER DRAIN	Advisable: located at floor level and near the equipment, with a minimum inclination of 10° from chamber to drain
WEIGHT	FitoClima 600: 175 Kg FitoClima 1.200: 250 Kg
ELECTRICAL CONNECTION	1PH AC 230V ±10% 50Hz 4 to5A (depending on model)

FITOCLIMA MODELS REFERENCE – STANDARD CONTROLLED ENVIRONMENT VARIABLES

FITOCLIMA 600/1200 P	Temperature only
FITOCLIMA 600/1200 PH	Temperature and Humidity
FITOCLIMA 600 PLH	Temperature, Humidity, UV and Visible lights
FITOCLIMA 600 PLH-R	Temperature, Humidity, UV and Visible lights. Radiometer and light sensors are integrated with the chamber for an automatic control of the irradiation exposure of test specimens

[1] Temperature and Humidity uniformity performances in Stability Testing chambers. The Photostability testing model temperature range with lights on is 5ºC to 45ºC and will present greater variations 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

Performances measured in factory with room temperature between 20ºC and 25ºC.

TECHNICAL SPECIFICATIONS FOR PHOTOSTABILITY CHAMBER

FITOCLIMA 600 PLH / PLH-R

Developed to simulate and automatically reproduce the conditions required by the ICH Q1B Option 2 guideline for Photostability Testing

Programming Photostability tests to run and end automatically is easy with the new color touch-screen ClimaPlus®. Visible and UV Lights are independently controlled and can be programmed by % or intensity. Both UV and Visible light trays have integrated light sensors allowing a correct measurement of instantaneous and accumulated light intensity with the chamber controller (PLH-R model) and according to traceability standards.

FDA 21 CFR part 11 compliant, the FitoLog® software enables complete data logging of VIS and UV radiation, temperature and humidity information.

The equipment can also be used as a Stability chamber by simply removing the Photostability special shelves and light banks and replacing them with stainless steel wire shelves.

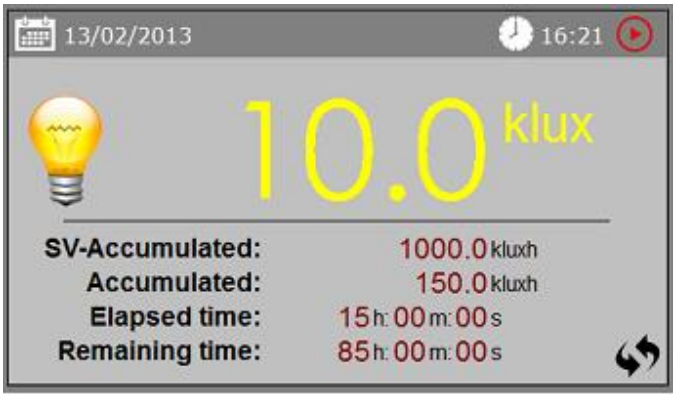
DETAILS FOR FITOCLIMA 600 PLH / PLH-R	
VISIBLE LIGHT TYPE	8 fluorescent HF “cool white” lamps
VISIBLE LIGHT INTENSITY [1]	26.000 Lux (approximately, ±6% uniformity)
UV LIGHT TYPE	8 fluorescent HF “UV-A” lamps
UV LIGHT INTENSITY [1]	30 W/m² (approximately, ±10% uniformity)
NUMBER OF TEST SHELVES	One (1) for UV and one (1) for Visible light
OPTIMAL PHOTOSTABILITY TEST AREA	0,14m² per shelf
TEMPERATURE UNIFORMITY	± 2°C (Lights On)
HUMIDITY UNIFORMITY	± 5%rh (Lights On)
APPROXIMATE TIME REQUIRED FOR ICH Q1B VISIBLE LIGHT TEST [2]	48 hours (1.2M Lux accumulated)
APPROXIMATE TIME REQUIRED FOR ICH O1B UV LIGHT TEST [2]	7 hours (200 W/m² accumulated)

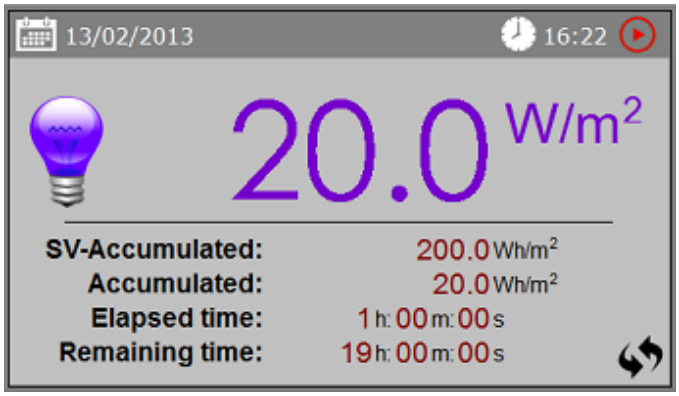




[1] Light intensities and light uniformity will vary with distance between lights and sensors (shelf test area) and with Temperature and Humidity set values
[2] Test time with light intensities mentioned in [1]. With lower light intensities test times will increase

Performances measurements with chamber stabilized at 25°C and 60%rH with sensors positioned inside designated ‘optimal test area’

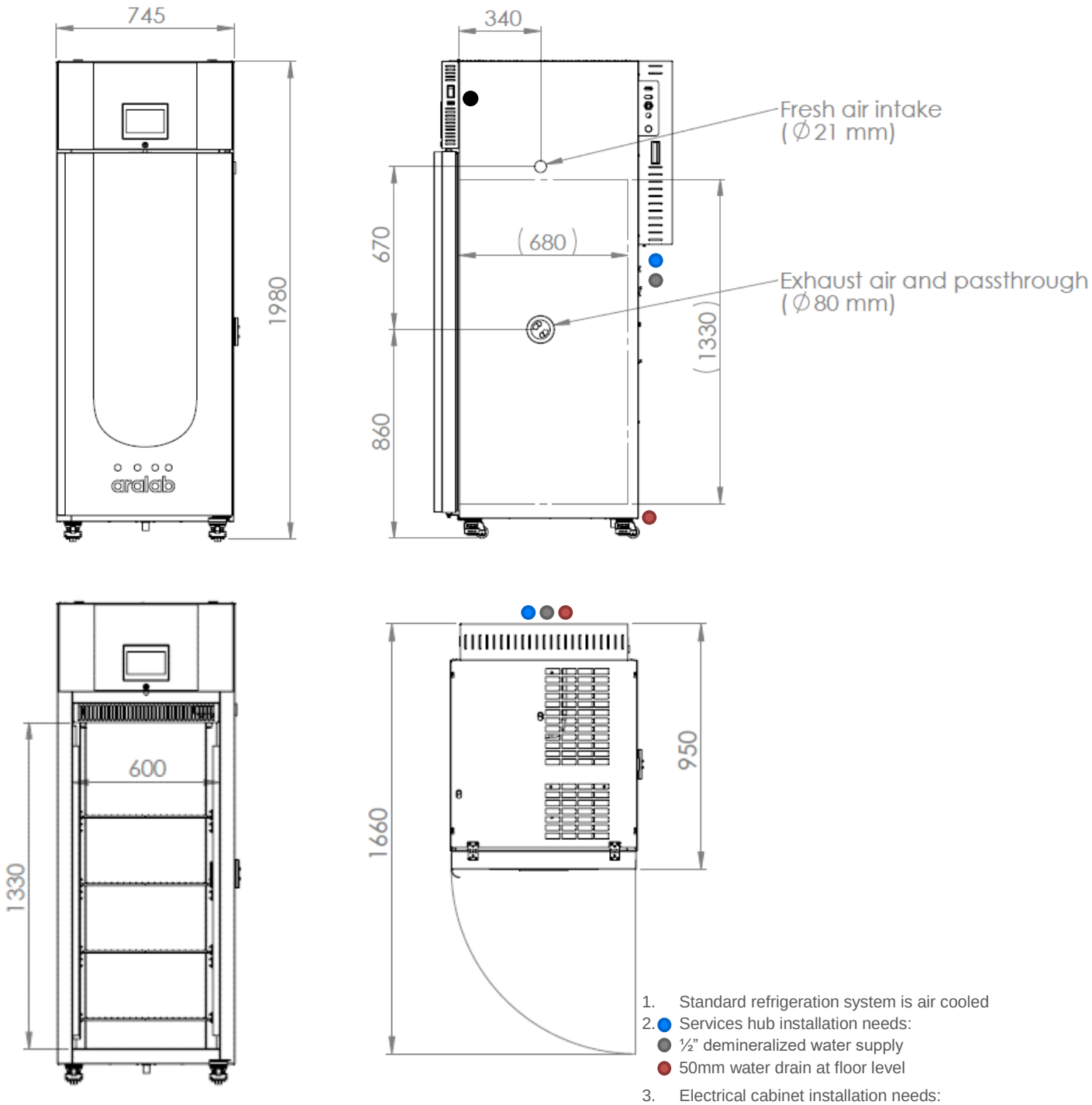




ClimaPlus controller specific for Photostability chambers with automatic integration of VIS and UV sensors and light meters according to traceability standards. Enables automatic running (with auto-stop) of test programs and FDA 21 CFR compliant data logging

DIMENSIONS AND DRAWINGS

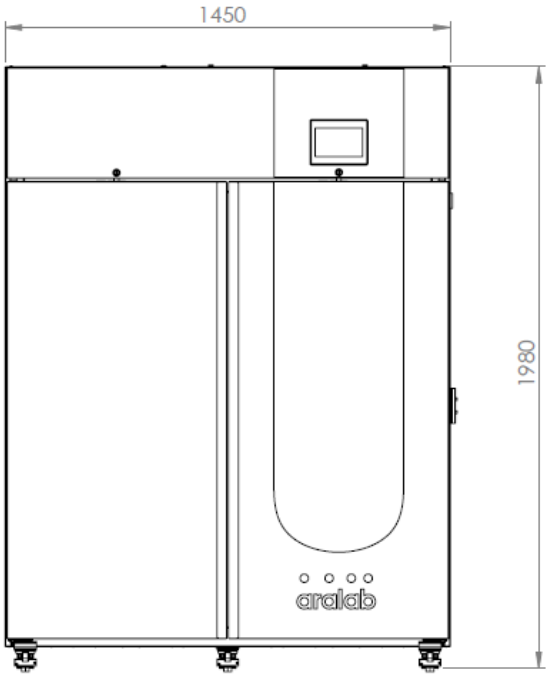
FITOCLIMA 600	
EXTERNAL DIMENSIONS (HxWxD) (mm)	1.980 x 745 x 945
INTERNAL DIMENSIONS (HxWxD) (mm)	1.330 x 600 x 650

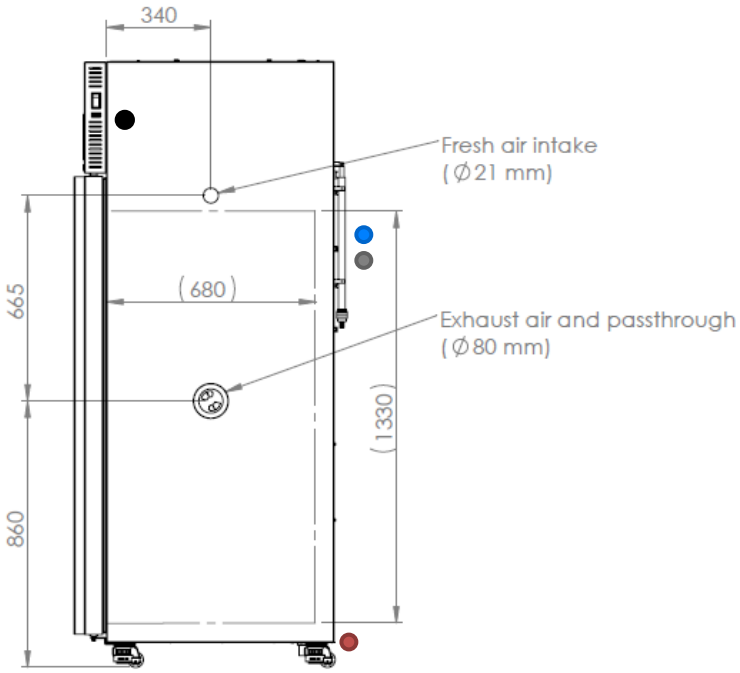


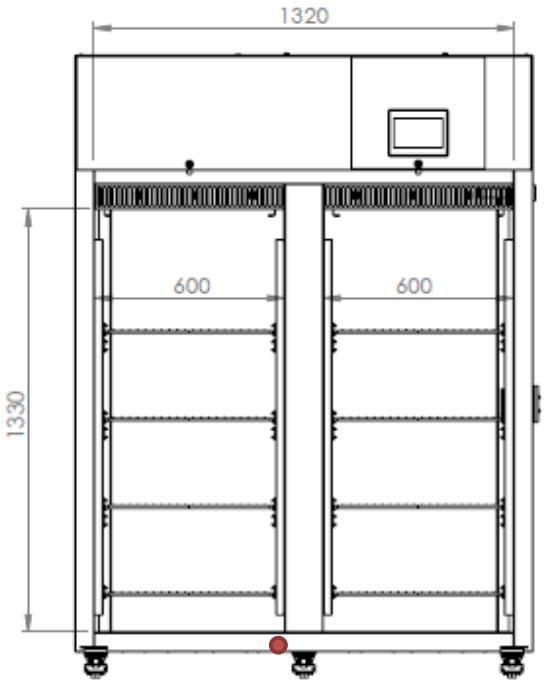
1. Standard refrigeration system is air cooled
2. Services hub installation needs:
   - ½" demineralized water supply
   - 50mm water drain at floor level
3. Electrical cabinet installation needs:
   Supply power:
   230VAC, 50Hz, 16A / Single Phase + Neutral + Ground
   Electrical protection: Circuit breaker 16A + N with 300mA differential
   - RJ45 communication port

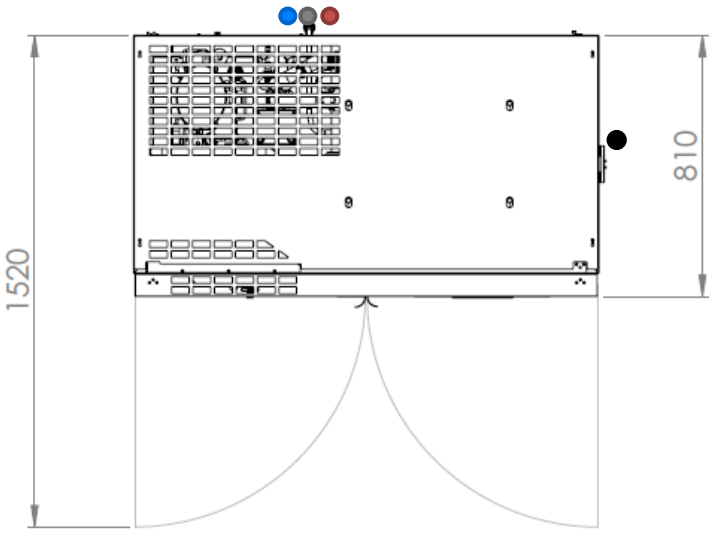
FITOCLIMA 1.200

EXTERNAL DIMENSIONS (HxWxD) (mm)	1.980 x 1.450 x 810
INTERNAL DIMENSIONS (HxWxD) (mm)	1.330 x 1.320 x 680









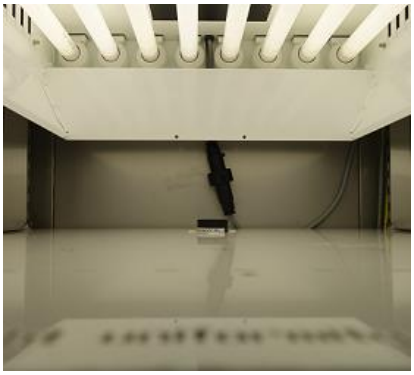
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   - RJ45 communication port

EQUIPMENT DESCRIPTION



CONSTRUCTION

- New generation multi-color 7 inch touch-screen ClimaPlus© controller
- Open door alarm with configurable time-out function
- Free slots for connecting and integrating external devices with the ClimaPlus controller
- Highly resistant stainless-steel interior
- Photostability chamber with shelves in reflective white coating for better light uniformity and distribution
- Polyurethane insulation
- Exterior zinc plated steel and gray epoxy paint
- Pivoting door(s) with spring lock, magnetic gasket and safety lock(s)
- 4 or 5 casters with built in brakes for effortless mobility and control
- 80mm diameter side port
- Accessible technical compartment for faster maintenance procedures



CLIMATIC CONTROL

- Air-cooled, CFC free, mechanical refrigeration by hermetic compressor
- 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 RTD temperature sensor and capacitive humidity sensor



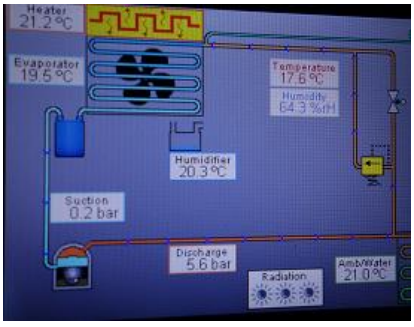
AIR FLOW

- Dynamic airflow with EC (variable) blower
- Air renovation through adjustable lateral port-holes
- Uniform air velocity of 0.2 meters per second across shelves
- Optional Airflow velocity adjustable at the ClimaPlus© controller



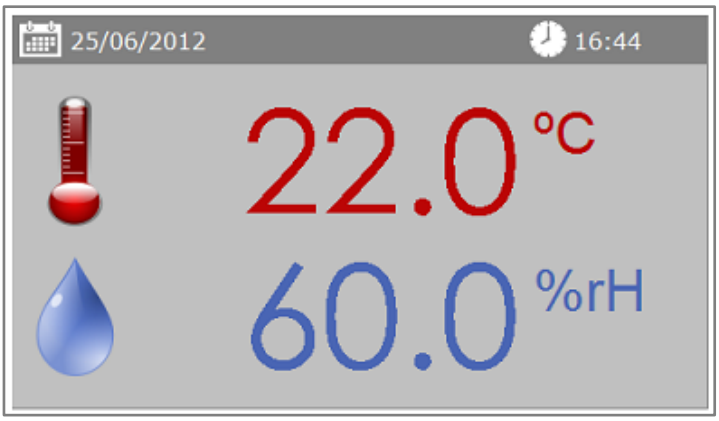
CONTENT PROTECTION AND AUTOMATIC DIAGNOSTICS

- 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
- New synoptic diagram function: a self-diagnostics tool that checks all active components of the system allowing for faster procedures and minimizing any possible downtimes

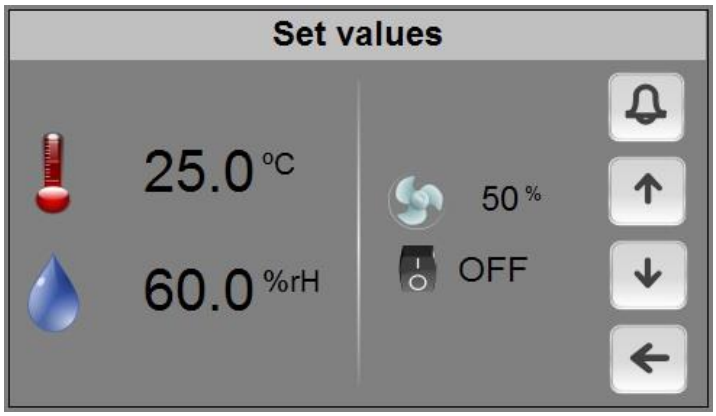


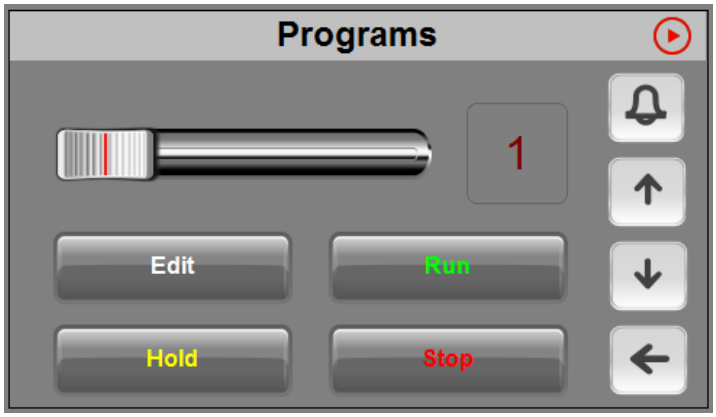
CLIMAPLUS CONTROLLER

- Programmable Logic Controller exclusively developed by Aralab for FitoClima chambers
- Easy to use touch-screen interface
- 190mm x 150mm multicolor display
- Controls every environmental variable available for any specific FitoClima model (Temperature, Humidity, Lights, Airflow, CO2, 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
- Ethernet and Wi-Fi for connecting computers to the controller
- ClimaPlus controller functions also available at the PC/Laptop with the FitoLog software pack



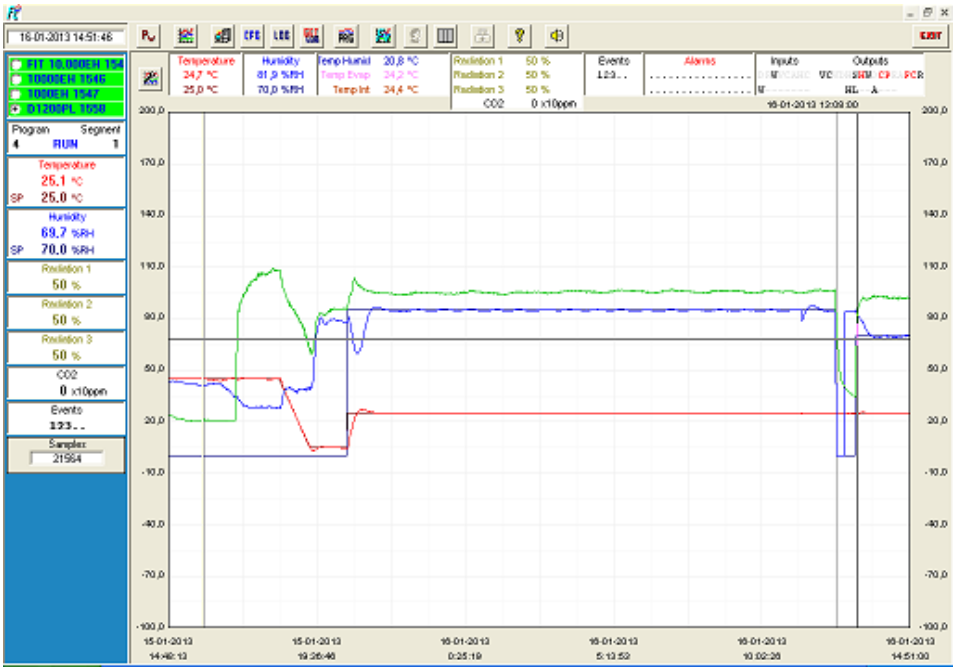


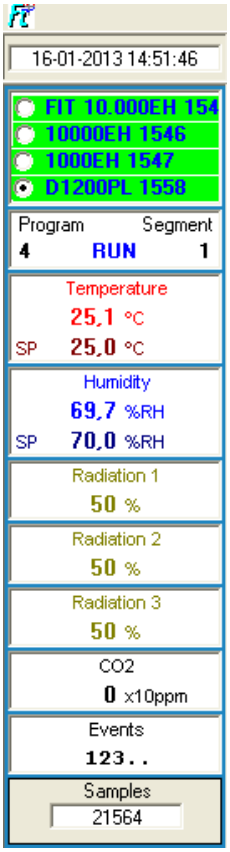




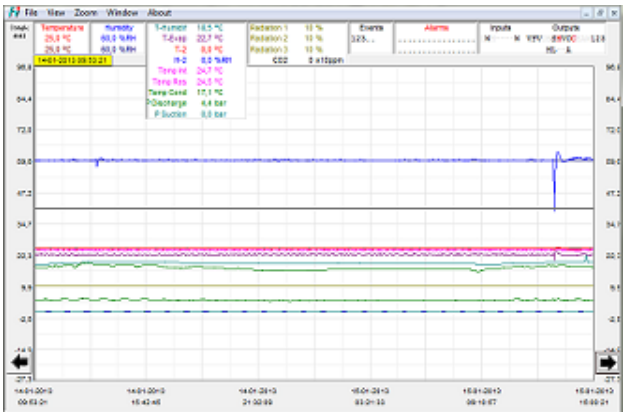
FITOLOG SOFTWARE

The FitoLog software pack (**FDA 21 CFR part 11 compliant**) is a set of applications designed to facilitate the programing, monitoring, managing and recording of programs and data from the FitoClima chambers. It consists of 3 applications: **FitoLog**, **FitoLogView** and **FitoProgram**.

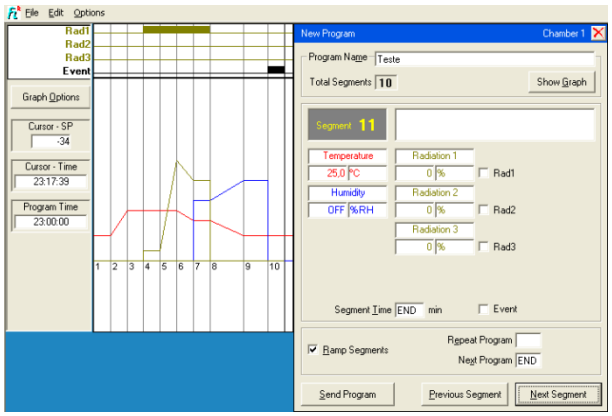




FitoLog: Displays and records in real time all data and details related to the set-points, running variables and equipment behaviour. It also retrieves information about the active components of the chamber, running processes, errors, alarms and allows the configuration of periodic or alarm triggered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



FitoLogView: It is a working tool to process the data recorded by the FitoLog program. One can view, print and export the log contents to other file types, and analyse the data in other data management software (Excel, Star Office, Access or others).



FitoProgram: This application simplifies the creation of programs and its integration on the chamber ClimaPlus controller. Up to 32 programs, each with 24 segments, can be designed and linked to create detailed environmental profiles and simulations.

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.

COMMON ACCESSORIES

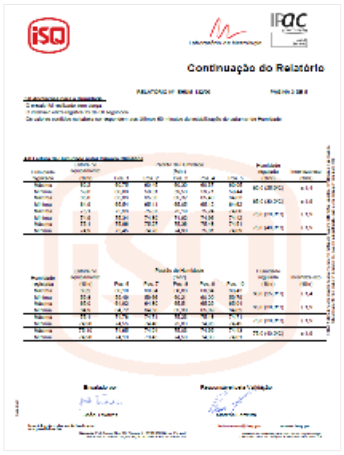
- FitoLog® software pack for PC/Laptops, enabling data monitoring, logging and managing operations directly on a computer – FDA 21 CFR part 11 compliant
- IQ, OQ, PQ procedures and documentation
- ISO 17025 Temperature and Humidity calibrations
- Additional stainless steel wire shelves
- Additional lateral entry port
- Reinforced stainless steel shelves for heavier test specimens
- 20 liter water tank with electric pump and security valve
- Conductivity meter, for water quality control
- 5 stage Reverse Osmosis with pre-decalcification system
- Wireless connections
- Double glazed glass doors



Reinforced stainless steel shelving



FDA 21 CFR part 11 compliant software



Qualification and Calibration documents



Integrated water treatment systems

CONSULT ARALAB FOR OTHER ACCESSORIES

Features and specifications are subject to change. Aralab continuously studies ways to further develop its products to achieve better performances and overall product quality. As a result, characteristics and specifications provided in this document may be subject to changes.

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