STABILITY

STABILCLIMA
600 & 1200 STABILITY

TEMPERATURE AND HUMIDITY CHAMBERS
FOR CONTROLLED ENVIRONMENT STORAGE,
ICH STABILITY, AND PHOTOSTABILITY TESTING.

aralab

ICH, GMP, WHO, FDA COMPLIANT

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.

Control the Environment. Your Own Climate.

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

COMMON APPLICATIONS INCLUDE:

- PHARMACEUTICALS
- COSMETICS
- FOOD AND BEVERAGES
- VETERINARY
- STORAGE AND CONSERVATION
- QUALITY CONTROL AND RESEARCH

CERTIFIED
ISO 9001
ISO 14001

KEY FEATURES

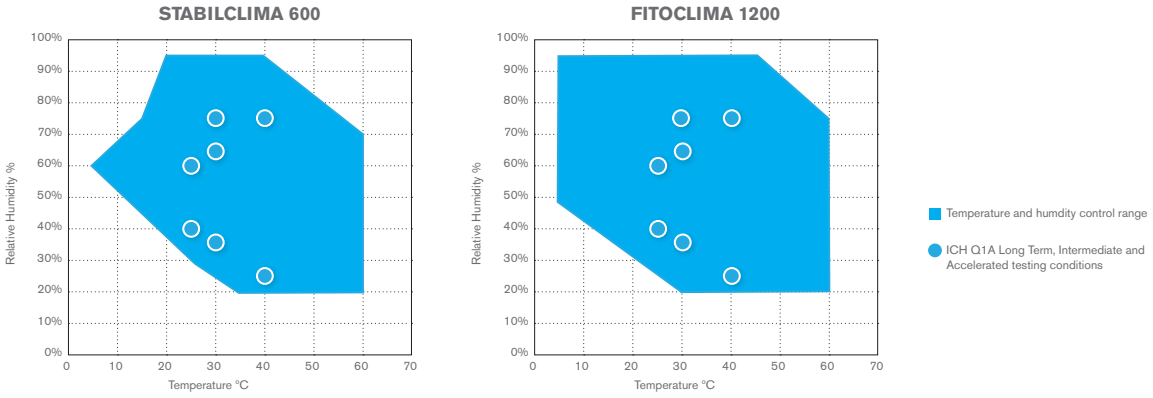
- Ready to use. No assembly needed.
- Minimal footprint, for efficient use of laboratory space.
- Future proof design. The interior can be reconfigured at any time for the most efficient use of the available storage space and content dimensions.
- Content protection, with configurable high / low temperature and humidity alarms and automatic email notifications.
- Remote diagnostics, allowing a fast and accurate technical support.
- FDA 21 CFR part 11 compliant software GAMP5.
- ECO mode energy saving function.
- Compliant and recognized by ICH, FDA, GMP and other leading industry standards.

TECHNICAL SPECIFICATIONS

TECHNICAL DATA FOR STABILCLIMA 600 & 1200 STABILITY CHAMBERS

TEMPERATURE RANGE [1]	-5°C to 60°C
EXTENDEND TEMPERATURE RANGE (OPTIONAL)	-20°C to 60°C (only for StabilClima 1.200 model)
TEMPERATURE FLUCTUATION IN TIME	±0.1°C to ±0.2°C
TEMPERATURE UNIFORMITY IN SPACE	± 0,15°C to ± 1,0°C
At 25°C / 60%rH	± 0,24°C
At 30°C / 65%rH	± 0,24°C
At 40°C / 75%rH	± 0,35°C
HUMIDITY RANGE	20% to 95% rH
HUMIDITY FLUCTUATION IN TIME	± 1%rH
HUMIDITY UNIFORMITY IN SPACE	± 2%rH
At 25°C / 60%rH	± 0,83%rH
At 30°C / 65%rH	± 0,69%rH
At 40°C / 75%rH	± 1,20%rH
SHELVES (STANDARD CONFIGURATION) [2]	StabilClima 600: 4 stainless steel wire shelves StabilClima 1 200: 8 stainless steel wire shelves
STANDARD WIRE SHELF SIZE	645mm x 515mm
STORAGE [2]	0.33 m² and 18 Kg weight load (per shelf)
STORAGE (STANDARD CONFIGURATION) [2]	StabilClima 600: 1,33 m² StabilClima 1 200: 2,67 m²
AIRFLOW	0.2 m/s uniform across the shelves
INTERNAL VOLUMES	StabilClima 600: 543 liters StabilClima 1 200: 1.194 liters

HUMIDITY WORKING RANGE



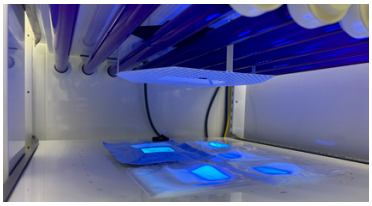
STABILITY MODELS REFERENCE – STANDARD CONTROLLED ENVIRONMENT VARIABLES

STABILCLIMA 600/1200 P	Temperature only
STABILCLIMA 600/1200 PH	Temperature and Humidity
STABILCLIMA 600 PLH	Temperature, Humidity, UV and Visible lights. Does not include light sensors for measuring accumulated light exposure.
STABILCLIMA 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
STABILCLIMA 1.200 PN/PHN	Negative temperatures (-20°C) with or without humidity control

[1] Temperature and Humidity uniformity performances in Stability Testing chambers according to IEC60068-3-5/6. The Photostability testing model temperature range with lights on is 5°C to 45°C 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 20°C and 25°C.

TECHNICAL SPECIFICATIONS FOR PHOTOSTABILITY CHAMBER

STABILCLIMA 600 PLH / PLH-R



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

Visible and UV light banks are independently controlled. On PLH model intensity is controlled by % and does not include sensors to measure accumulated light exposure. On the PLH-R model, both UV and Visible light trays have integrated light sensors allowing a correct measurement of instantaneous and accumulated light exposure according to traceability standards.

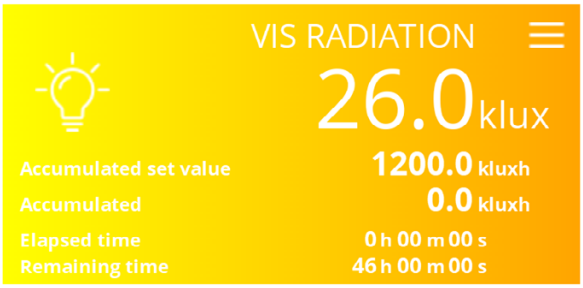
In the PLH-R version (with UV and Visible radiometers integrated with the controller), only fixed temperature and humidity setpoints can be programmed. Dynamic ramps or climate cycles are not available in this version.

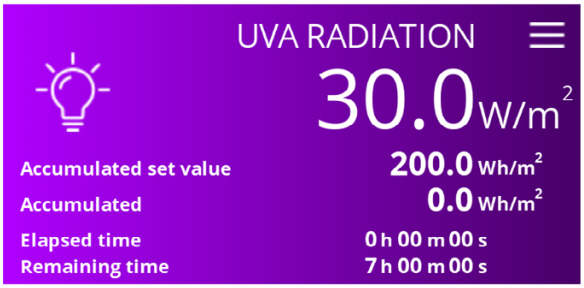
FDA 21 CFR part 11 compliant, the FitoLog® software enables complete data logging of Visible and UV radiation, temperature and humidity information.

DETAILS FOR STABILCLIMA 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 (approx. 345nm - 410nm)
UV LIGHT INTENSITY [1]	30 W/m² (approximately, ±12% uniformity)
NUMBER OF TEST SHELVES	One (1) for UV and one (1) for Visible light
OPTIMAL PHOTOSTABILITY TEST AREA	0,14m² per shelf
TEMPERATURE RANGE	5°C to 45°C (Lights On)
TEMPERATURE UNIFORMITY	± 2°C (Lights On)
HUMIDITY RANGE	40% to 80% (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 Q1B UV LIGHT TEST [2]	7 hours (200 W/m² accumulated)

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



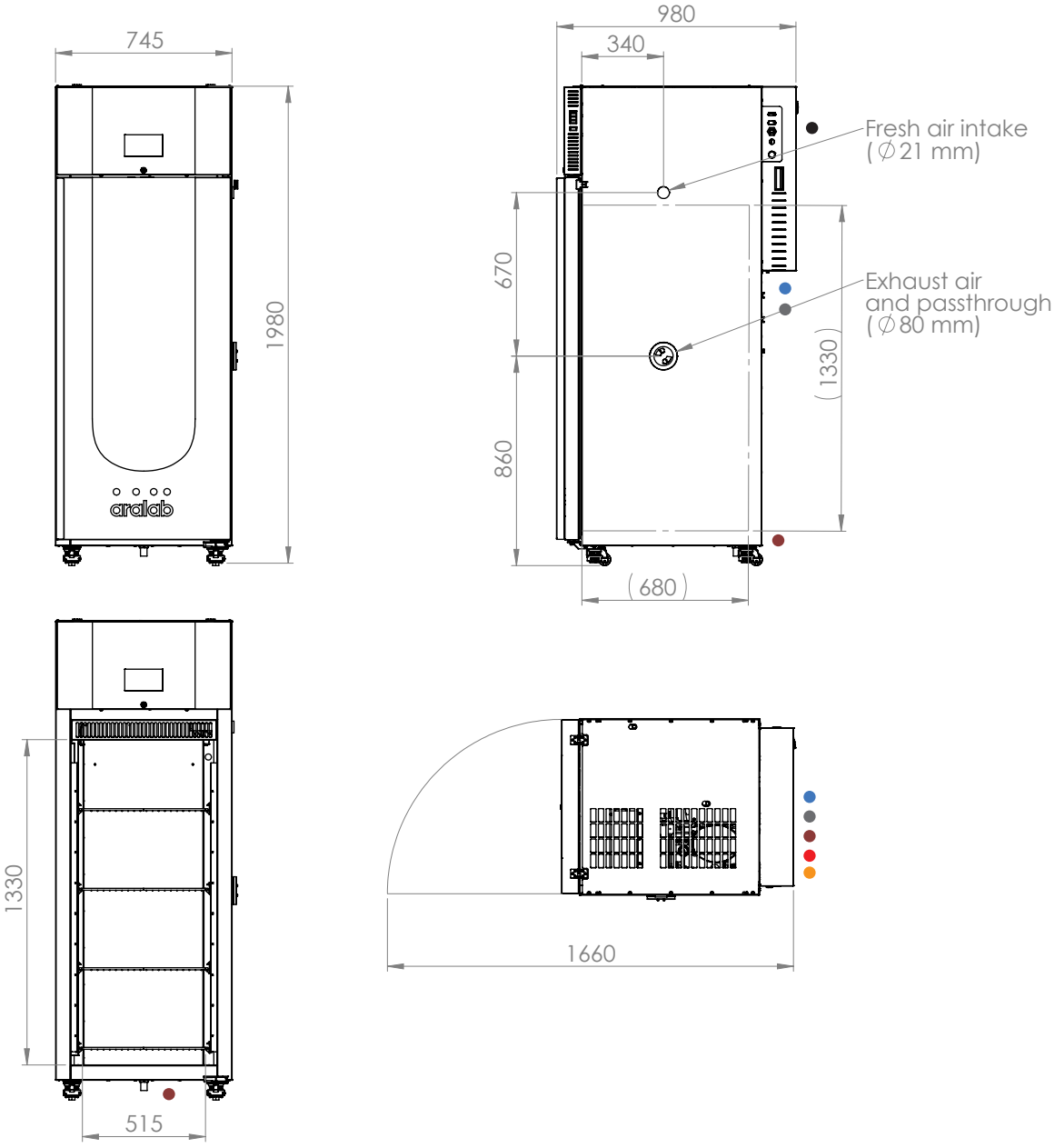


ClimaPlus controller specific for Photostability chambers with automatic integration of Visible and UV sensors and light meters according to traceability standards (PLH-R model. The PLH model does not include light sensors). Enables automatic running (with auto-stop) of test programs and FDA 21 CFR compliant data logging.

DIMENSIONS AND DRAWINGS

STABILCLIMA 600

EXTERNAL DIMENSIONS (HxWxD) (mm)		1 980 x 745 x 980
INTERNAL DIMENSIONS (HxWxD) (mm)		1 330 x 600 x 680

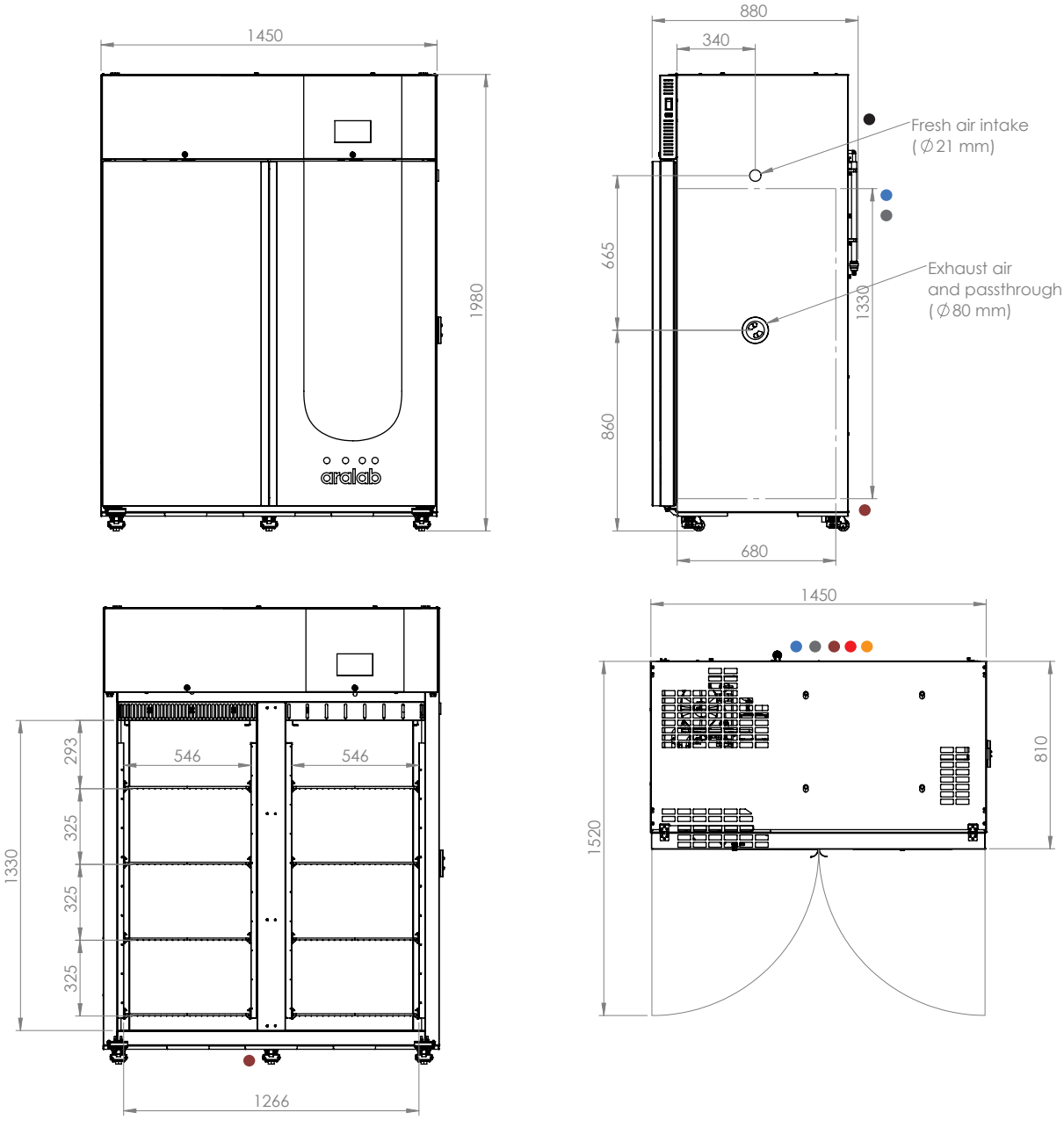


1. Standard refrigeration system is air cooled.
2. Services hub installation needs:
   - ¾" male demineralized water supply valve.
     Condutivity: <50µS/cm , TDS <35PPM.
     Pressure: 1-5 Bar.
     In case of reverse osmosis/cylinder (optional):
     ¾" male tap water valve connection.
     Pressure: 1-5 Bar.
   - 20mm water drain at floor level, female connection.
3. Electrical cabinet installation needs:
   Supply power: 230VAC, 50Hz (60Hz upon request), 12A / Single Phase + Neutral + Ground.
   Electrical protection: Circuit breaker 16A + N with 30mA differential.
   - RJ45 communication port.
4. Equipment weight: 170Kg (approx.).
5. Average heat dissipation: 0,3 kW.
6. Power Supply for Reverse Osmosis - 230VAC, 50Hz, 4A.

DIMENSIONS AND DRAWINGS

STABILCLIMA 1.200

EXTERNAL DIMENSIONS (HxWxD) (mm)		1 980 x 1 450 x 810
INTERNAL DIMENSIONS (HxWxD) (mm)		1 330 x 1 266 x 680



1. Standard refrigeration system is air cooled. (-20°C model is water cooled. See point 5.)
2. Services hub installation needs:
   - ¾" male demineralized water supply valve.
     Condutivity: <50µS/cm , TDS <35PPM.
     Pressure: 1-5 Bar.
     In case of reverse osmosis/cylinder (optional):
     ¾" male tap water valve connection.
     Pressure: 1-5 Bar.
   - 20mm water drain at floor level, female connection.
3. Electrical cabinet installation needs:
   Supply power: 230VAC, 50Hz (60Hz upon request), 13A / Single Phase + Neutral + Ground.
   Electrical protection: Circuit breaker 16A + N with 30mA differential.
   - RJ45 communication port.
     Average Heat dissipation: 0,5 kW.
4. Equipment weight: 240Kg (approx.).
5. Requirements for water cooled condenser for -20C model: Inlet: 15°C to 25°C and 3 to 5 Bar; Hardness < 8 °dH (200 mgCaCO3/l); Free Chlorine < 1.0 ppm; PH between 7.5 and 9.
6. Power Supply for Reverse Osmosis - 230VAC, 50Hz, 4A.

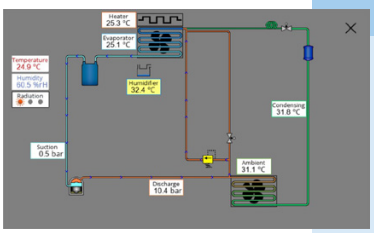
EQUIPMENT DESCRIPTION

CONSTRUCTION & CONTROL

- Multi-color 7-inch touch-screen ClimaPlus© controller.
- Open door alarm with configurable time-out function.
- Highly resistant stainless-steel.
- Polyurethane insulation.
- Exterior zinc plated steel and gray epoxy paint.
- Pivoting door(s) with spring lock, magnetic gasket and safety lock(s).
- 4 and 5 built-in casters brakes.
- Entry port Ø80mm.

ENVIRONMENTAL CONTROL

- Air-cooled mechanical refrigeration by hermetic compressor.
- StabilClima 1200 with -20°C upgrade is water cooled.
- Dual heating technology with hot gas by-pass and stainless steel electric heaters.
- Humidification in Stability chambers with clean steam generator.
- Humidification in Photostability chamber with ultrasonic generator.
- Dehumidification by condensation on the cooling system evaporator.
- Models with 'Temperature and Humidity control' are equipped with capacitive sensors
- Models with 'Temperature control only' are equipped with Resistive NTC sensor.
- Air renovation through adjustable lateral port-holes.
- Uniform air flow of approximately 0.2m/s across all shelves.
- Airflow speed adjustable on the ClimaPlus© controller.

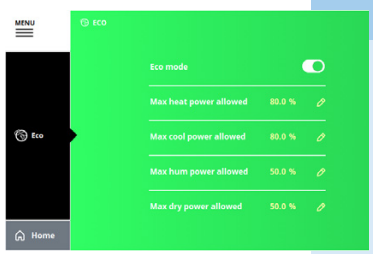


RESEARCH PROTECTION AND AUTOMATIC DIAGNOSTICS

- 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 limits.
- Synoptic: a self-diagnostics tool that checks all active components of the system allowing for faster procedures and minimizing any possible downtimes.

BUILT-IN DECONTAMINATION

- Heat Decontamination sets temperature to 60°C and other functions are disabled. Duration can be set manually as different contaminations can require custom durations.
- Hydrogen Peroxide bio-decontamination capable: StabilClima 600 / 1200 are resistant to H_2O_2 and now have a bio-decontamination function allowing the connection of a H_2O_2 atomizer system.

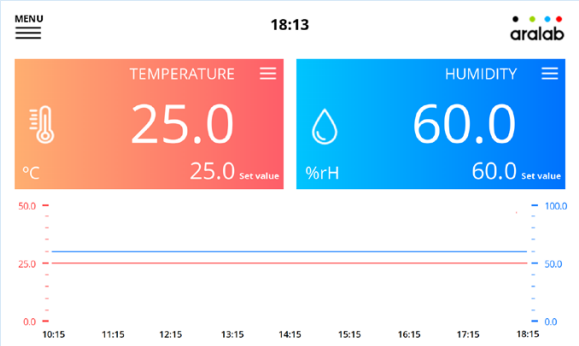


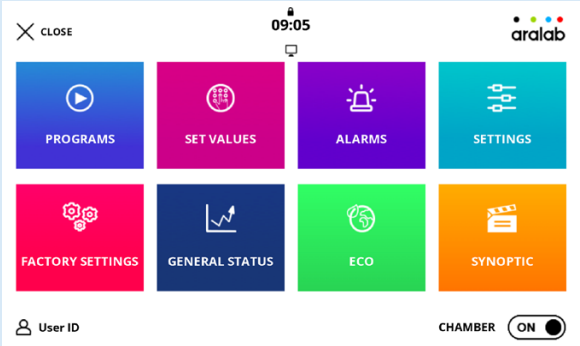
ECO MODE

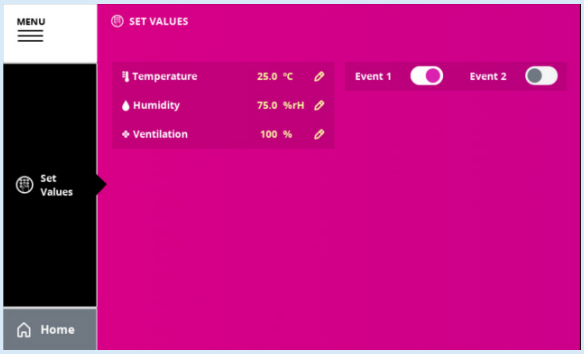
- The ECO Mode button turns on new power saving features.
- By decreasing some power related activities (depending on set-point conditions), the energy consumption can decrease, translating in cost savings.

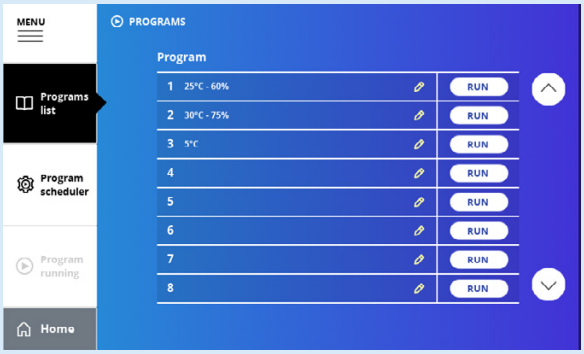
CLIMAPLUS HMI CONTROLLER

- Programmable Logic Controller exclusively developed by Aralab for StabilClima chamber.
- Multi-language, easy-to-use touch-screen interface (EN, FR, DE, IT, PT, ES and other languages on request).
- 90mm x 155mm (7 inch) multicolor display.
- Controls every environmental variable available for any specific StabilClima 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.
- In the PLH-R version (with UV and Visible radiometers integrated with the controller), only fixed temperature and humidity setpoints can be programmed. Dynamic ramps or climate cycles are not available in this version.
- Password protection of the controller functions.
- Content and research protection feature, with configurable High, Low and Band 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.
- ECO mode energy saving function.









FITOLOG SOFTWARE GAMP 5

The FitoLog software pack - FDA 21 CFR part 11 and Eudralex compliant according to GAMP5 risk based approach - is a set of applications designed to facilitate the programing, monitoring, managing and recording of programs and data from the StabilClima chambers. It consists of 3 applications: **FitoLog**, **FitoLogView** and **FitoProgram**.

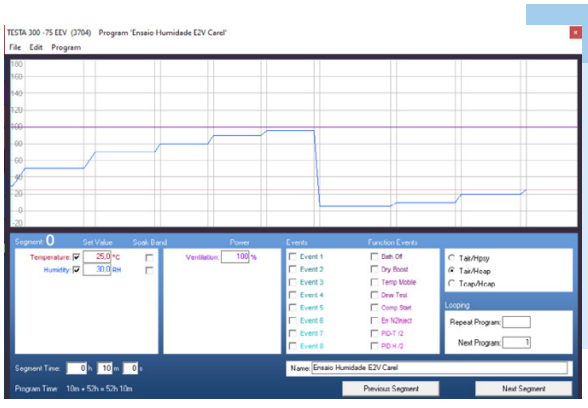
FITOLOG

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).

User Access Levels can be managed and configured (exclusive for FitoLog FDA 21CFR part11 compliant version)

FITOLOGVIEW

It is a working tool to process 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.



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.

In the FitoLog FDA 21CFR part11 compliant version, Fitoprogram functionality is not available.

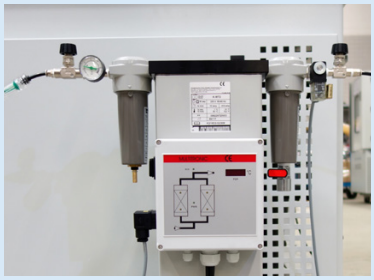
CONTENT SECURED WITH ALARMS, NOTIFICATIONS, FAST DIAGNOSTICS AND PROMPT TROUBLESHOOTING

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

PLEASE CONSULT ARALAB FOR OTHER ITEMS

FitoLog® software pack for PC/Laptops, enabling data monitoring, logging and managing operations directly on a computer – FDA 21 CFR part 11 and Eudralex compliant according to GAMP5.
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.
Additional Drying Capacity.



Additional Drying Capacity

Water treatment solutions

Reinforced SS shelves (40Kg load).

External Water tank

FitoLog FDA 21 CFR part 11 compliant

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.

Let's meet!
aralab@aralab.pt
www.aralab.pt
T: +351 219 154 960

Configure your chamber

See it on the Showroom

/AralabChambers
/company/aralab
/user/AralabChambers
/Aralab_
/aralabchambers

aralab

Control the environment

Your own climate