



Modular chambers for stability tests

ICH and FDA



The innovation as an attitude

The company

Ineltec is a company with more than 30 years of experience in the sector and 10.000 equipment installed all around the world. Our achievements are due to the ability of offering tailored solutions to perform any kind of test.

“Technology, research and innovation are the basis for creating equipment of high reliability.”



Model

ICH and FDA
Modular chambers



Our range of modular chamber for ICH and FDA stability tests are customized studying each case.

Model

Description of the equipment

ICH and FDA modular chamber are used to store products in stability conditions.

The temperature maximum ranges are from 0° being able to reach +60°C

ICH and FDA are used basically in sectors related on pharmaceuticals, cosmetics, veterinary, etc. products; because they fulfill ICH and FDA stability standards.

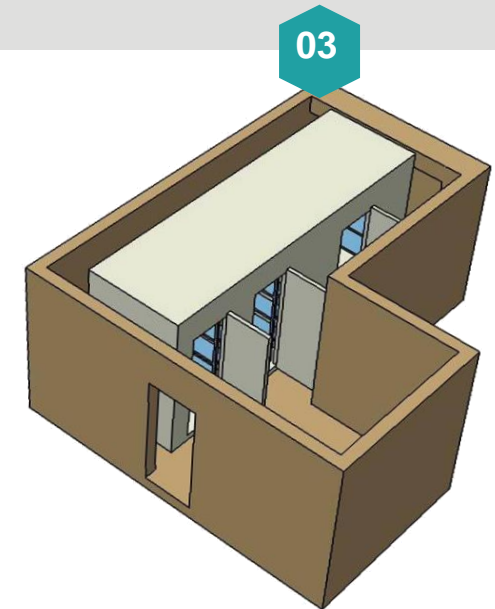
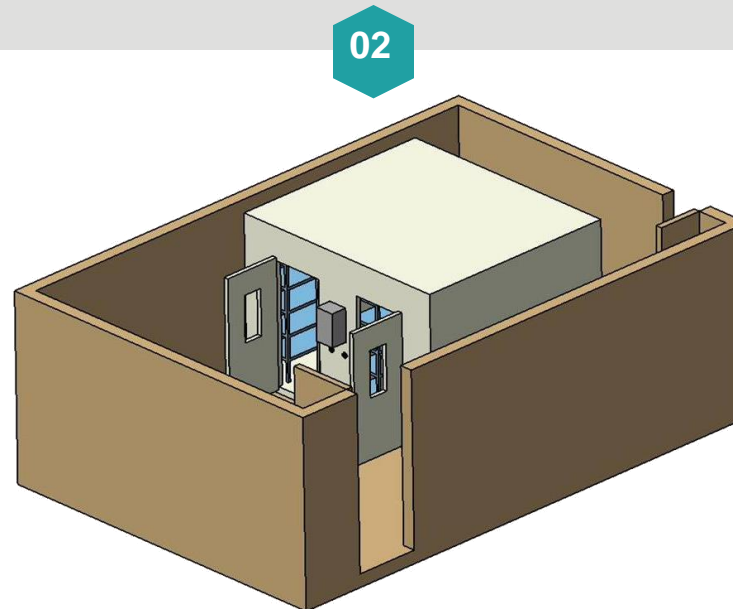
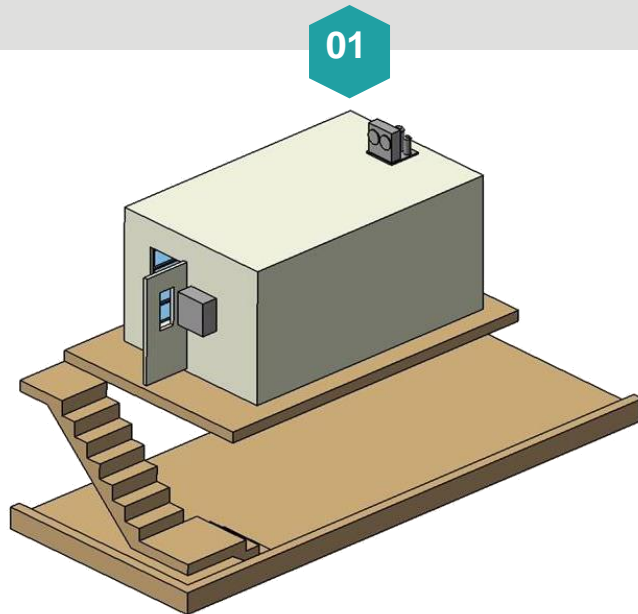
Constructions

01 1 compartment

02 2 compartment

03 3 compartment

*Etc.





Sectors



Pharmaceutical,
Cosmetic,
Veterinarian,
Food industry



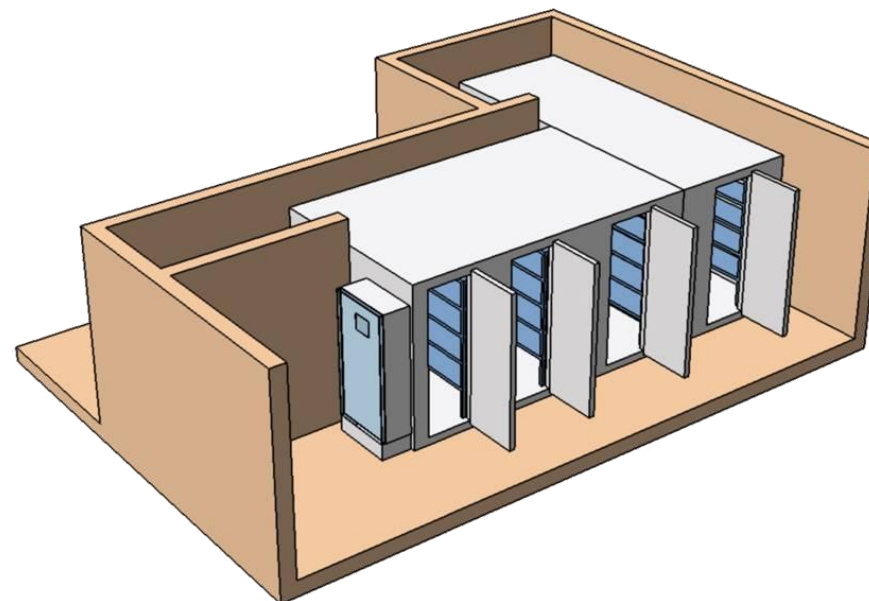
Plastic,
Chemical,
Petroleum,
Carton,
Paper,
Rubber



Biologic,
Biotechnologies,
Agrobiologic,
Insects



R+D,
Technological
centers,
Universities,
Laboratories



Standards

ICH

FDA

Features of the equipment

construction



01

01/ interior/exterior

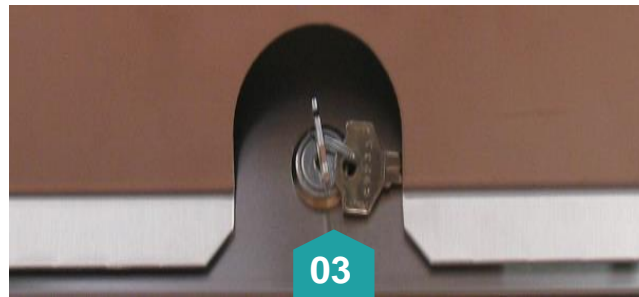
Both interior and exterior are made of polyurethane sandwich panels.



02

02/ Electrical cabinet

The electrical cabinet is located outside of the chamber.



03

03/ locking and security

A security keys locking is located on the door.



04

04/ Access Holes

Modular chambers have access ports to introduce the electrical wiring and the calibration sensors.



05

05/ shelves

It can be included shelves, adjustable in height to facilitate the air flow among samples.



06

06/ Control system

Touch screen: simple and intuitive, it allows programming the chamber



Features of the equipment

Functional properties

ICH and FDA Modular Model	Temperature Maximum range	R.H. Range (Optional)
Vol. Liters	0°C	10%
	+60°C	98%
from 2.000	*	*

Stability

Temp. $\pm 0,3^{\circ}\text{C}$ max.
 R.H. $\pm 2\%$ max.

Resolution

Temp. $0,1^{\circ}\text{C}$
 R. H. $0,1\%$

Accuracy

Temp. $\pm 0,5^{\circ}\text{C}$ max.
 R. H. $\pm 2\%$ max.

Homogeneity

Temp. $\pm 2^{\circ}\text{C}$ max.
 R. H. $\pm 2\%$ max.



Control System

Touch screen



Features

- | | |
|--|-----------------------------|
| 01 Alarm level of the water | 06 RS-232 Connection |
| 02 Alarm of the cooling unit | 07 RS-485 Connection |
| 03 Temperature alarm | |
| 04 Humidity / Drying Adjustment | |
| 05 Heat / cold Adjustment | |

software/ use

*It is delivered a software for programming the chamber, according to the **FDA CFR21, part 11**, standard. With this software, it is made the recording, control and analysis of the data.*

software/ features

- 1/ Parameterization of the data to be recorded
- 2/ Visualization and research of the results that were obtained in the records
- 3/ Visualization of the data that is being recorded
- 4/ Different access levels, controlled through keys and priorities
- 5/ Possibility of including notes on the recording.
- 6/ Automatic recording (access to the system, setting modifications, etc. Through Audit Train)
- 7/ Maintenance of passwords and automatic access
- 8/ Data encryption
- 9/ Protection on the data separation, concerning the Audit Trail, including on paper
- 10/ Electronic signatures and its validity date
- 11/ Alarm setting of temperature and humidity (minimum and maximum)
- 12/ Presentation of historical and events

Control system

software/
screens

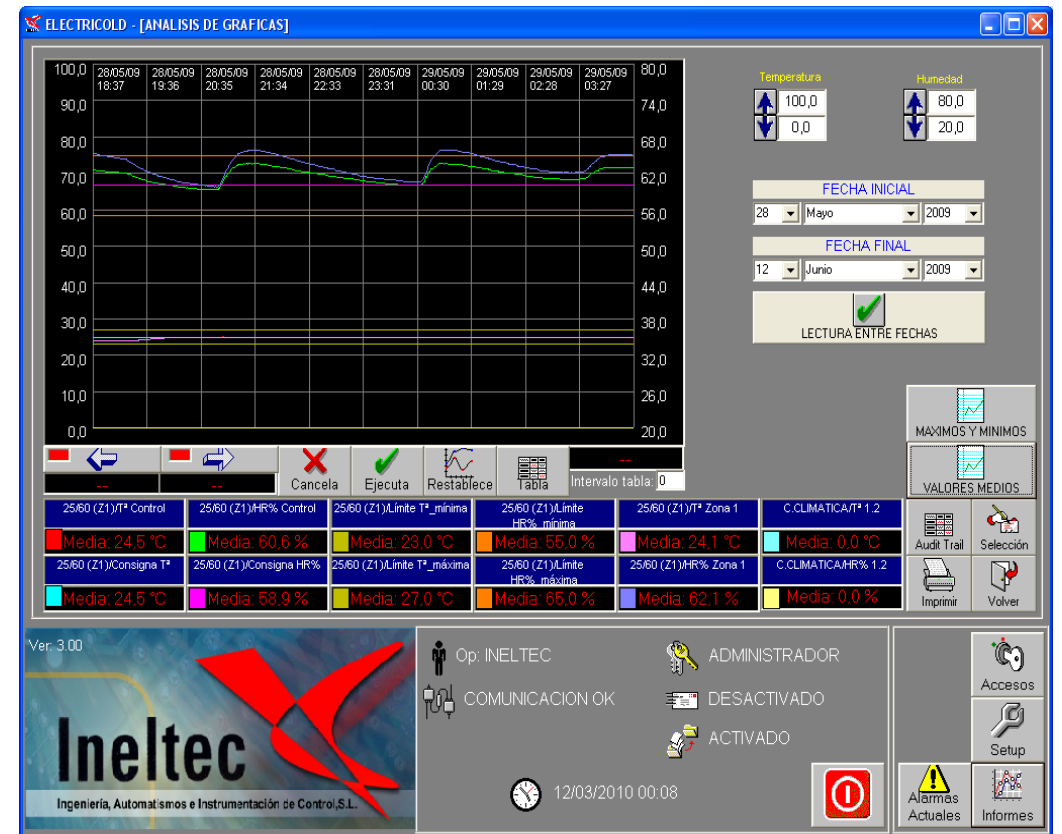
Main menu



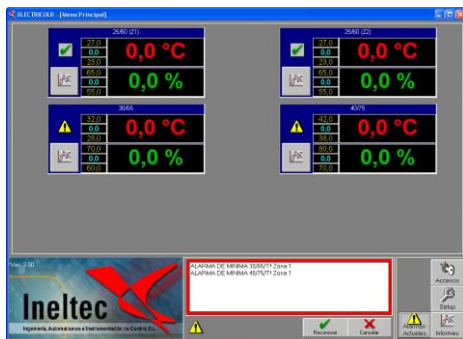
Settings



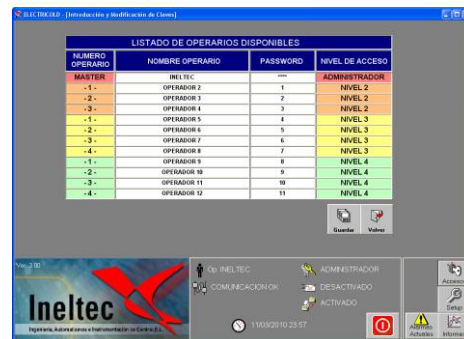
Software 21CFRV3 / historical



Alarms



Access



International presence



Range of products

Climatic Modular Chamber
ICH and FDA / INELTEC

ES Simulation equipment



Climatic chambers



Modular chambers



Thermal shock



Combined tests



Specials



Stability



Generator groups



Calorimetric



Corrosion - combined



Corrosion



Frost / Defrost



Tightness – rain



Tightness – air/wind



Freezer cabinet



Thermostatic bath



Furnace



Heating

Range of products

BE Testing bench



Fatigue endurance



Characterization



Pulsating pressure



Rupture



Bursting



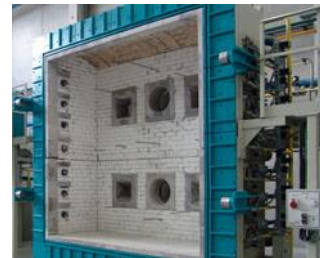
Liquid Thermal Shock



Standardization



Resistance to the fire - I



Resistance to the fire - II



Reaction to the fire - I



Reaction to the fire - II

MC Measurement and control



Artificial vision - I



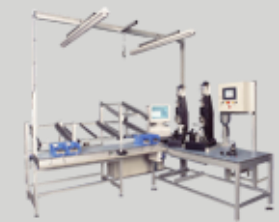
Artificial vision - II



Artificial vision - III



End of line control - I



End of line control - II



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