

**Two 80m³ pharmaceutical
climatic chambers
→ 516 boxes per room**





Our pharmaceutical cells

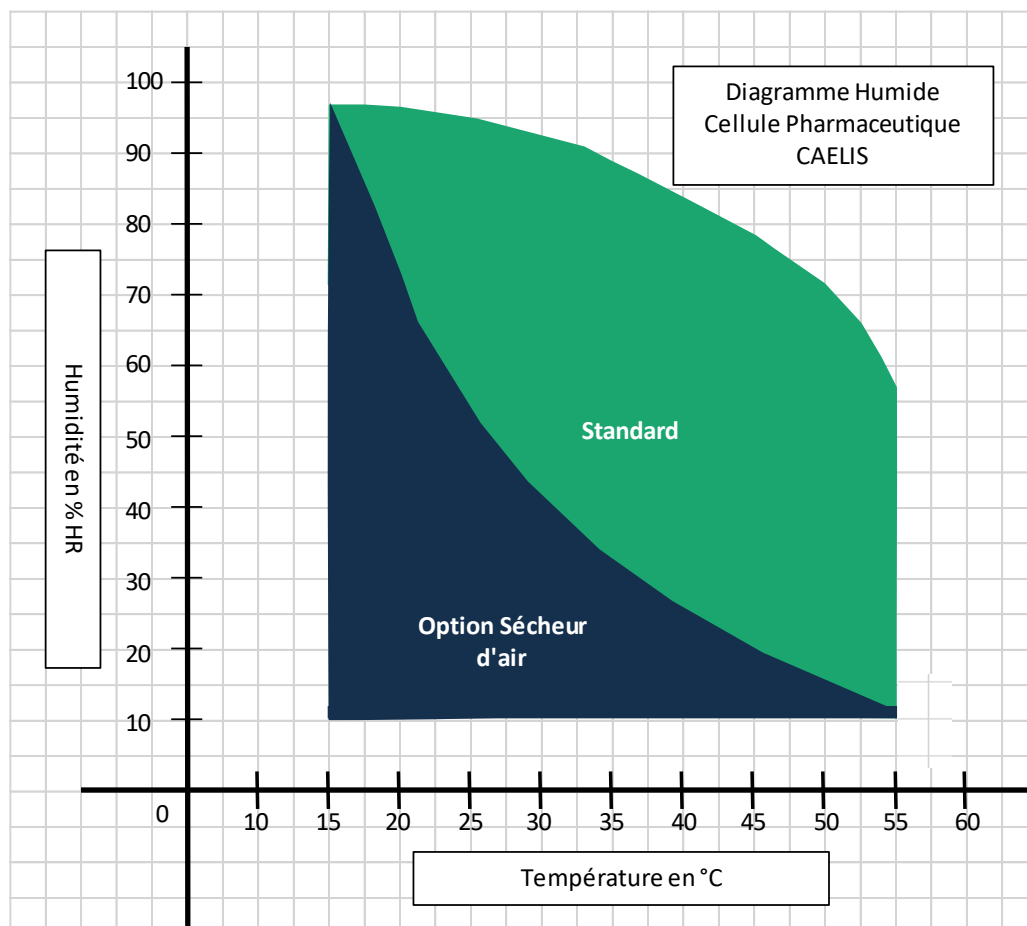
CAELIS climatic and thermal equipment is designed in accordance with the national and international recommendations of the pharmaceutical industry.

They comply with ICH, ICH GUIDELINES Q1Ar and Q1B, option 2 regulations, FDA, GLP, GMP, and 21CFR Part 210 and 211 guidelines.

Our equipment is designed for continuous operation 24 hours a day, 7 days a week

Conditions of use for an ambient temperature of between 15°C and 25°C

INSTRUCTIONS FOR USE



ICH Example:

- + 25°C / 60 % RH
- + 30°C / 65 % RH
- + 30°C / 75 % RH
- + 40°C / 75 % RH

Other instructions on request, to be specified when ordering

(e.g: + 25°C/40% RH, + 40°C/RH < 25% and 30°C/35% RH)





Similar project already completed

FRONT PHOTO



REAR PHOTO



PHOTO OF SCREENS



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Similar project already completed

FRONT PHOTO



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PHOTO OF THE SCREEN INTEGRATED INTO THE AHU





Similar project already completed

PHOTO OF THE INTERIOR

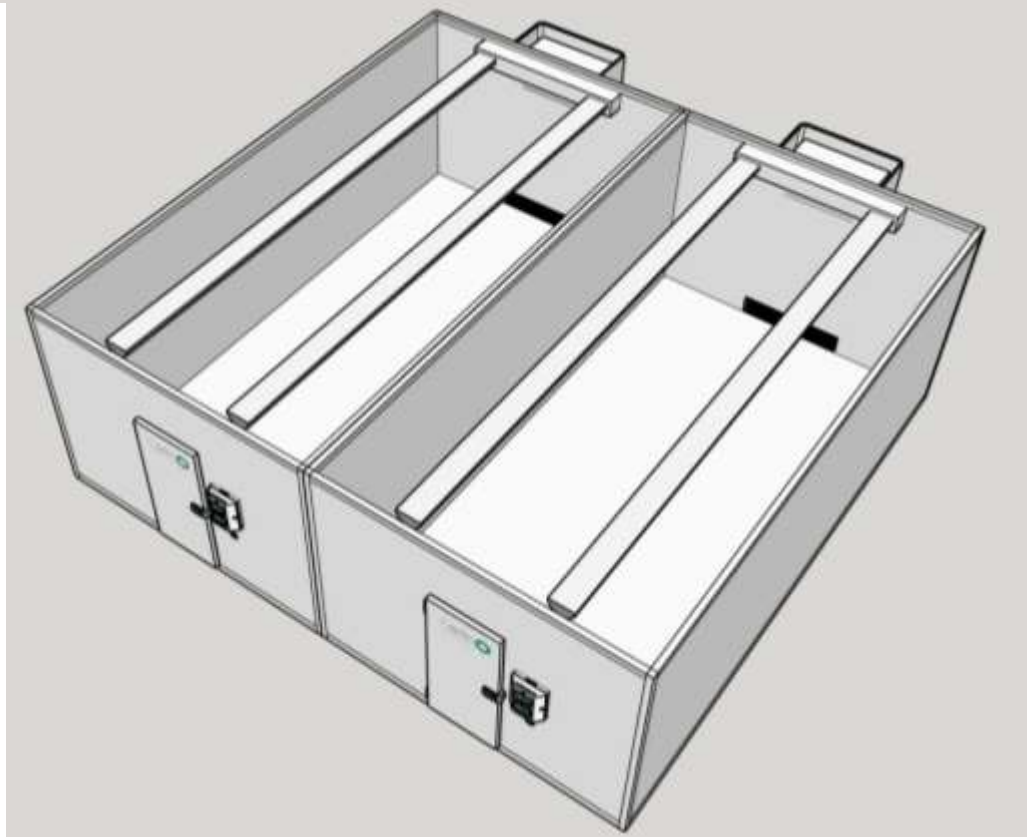
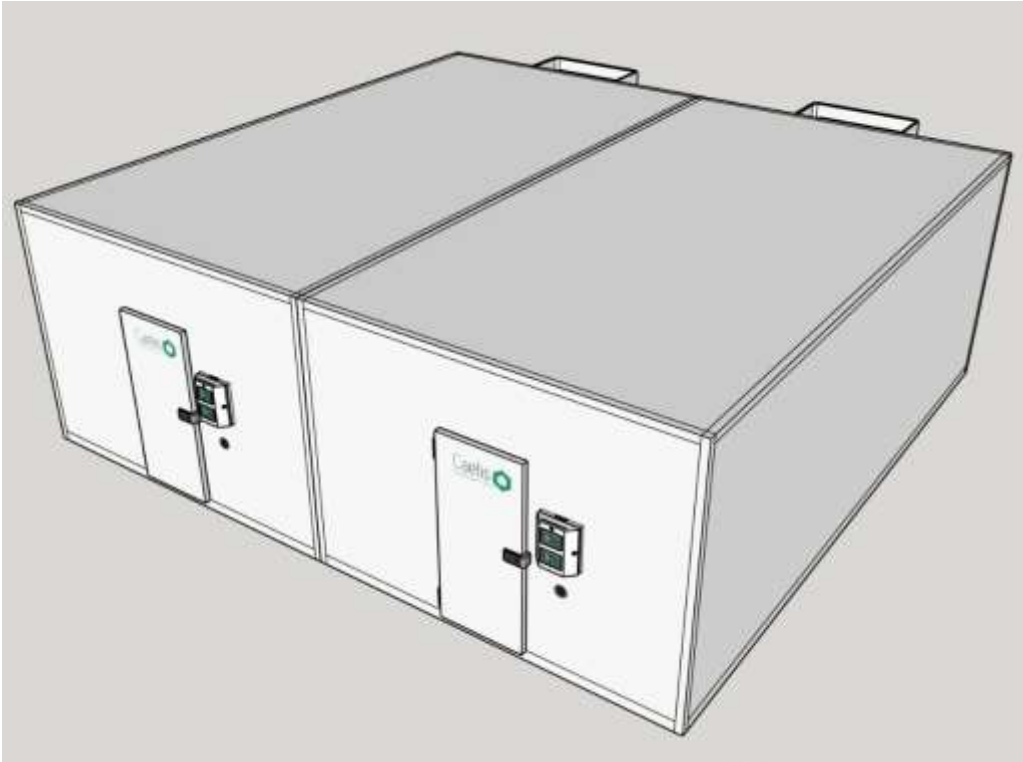


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Presentation of your project

3D GENERAL VIEWS



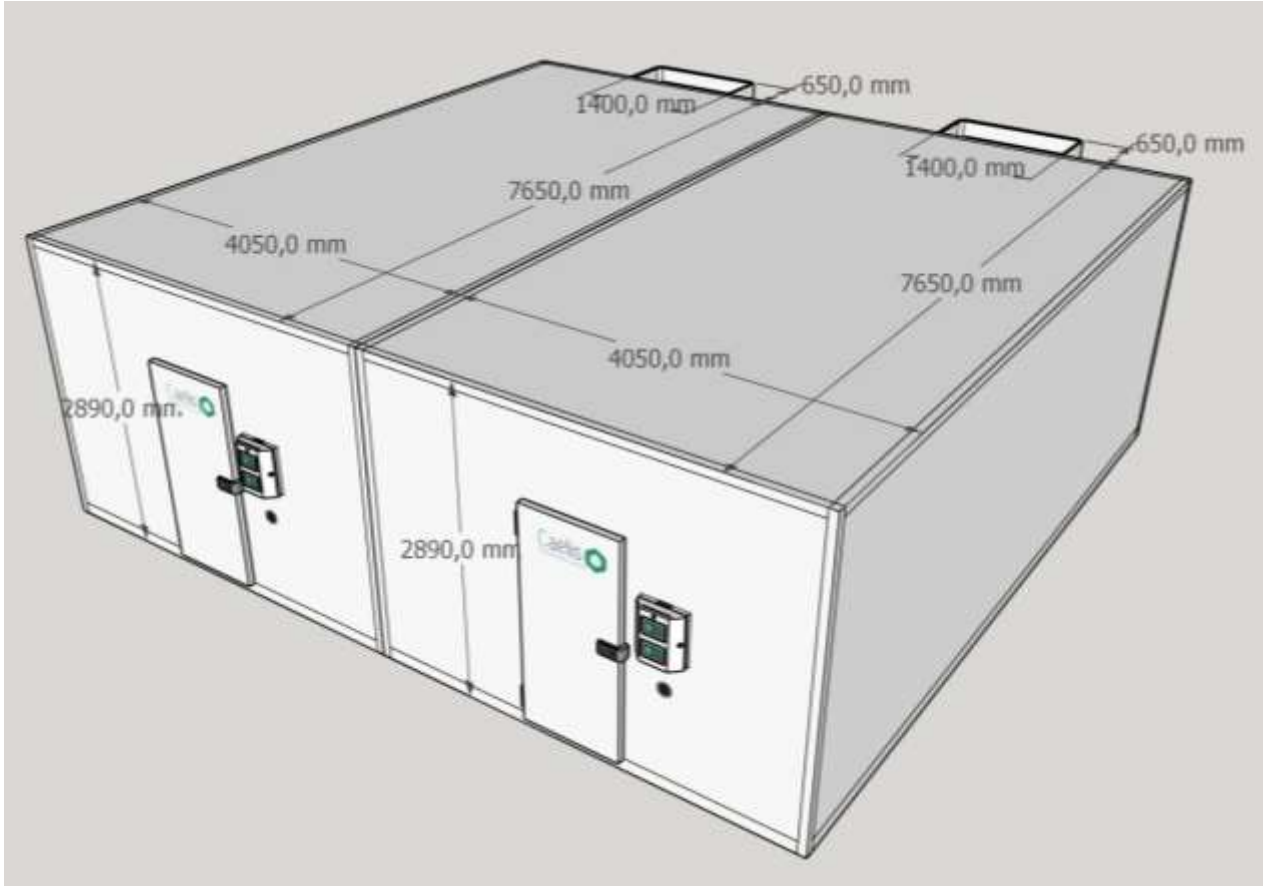
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Presentation of your project

3D VIEW OF THE EXTERIOR INCLUDING DIMENSIONS



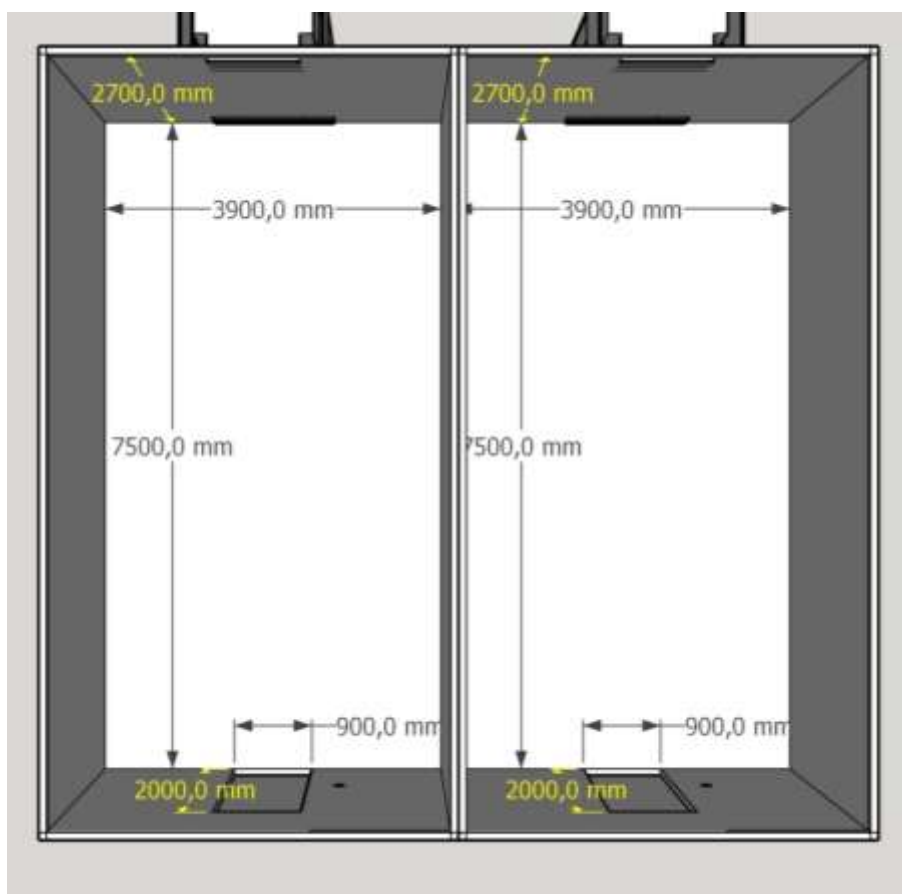
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Cell characteristics

Dimensional properties

Cell	1 and 2
Internal cell volume (m ³)	78.98 m ³
Dim. Inside Cell (h x w x d) mm	2700 x 3900 x 7500 mm
Dim. Cell Exterior (h x w x d) mm	2890 x 4050 x 7650 mm
Dim. AHU (h x w x d) mm	2890 x 1400 x 650 mm
Cell conditions	+25°C / 60%RH or +30°C / 65%RH +30°C / 75%RH or +40°C / 75%RH



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Technical specifications

- Both cells have been designed with the same technical characteristics, as shown below

Structural characteristics

Partitions and ceilings	<ul style="list-style-type: none">Standard panel class B s2 d0 (M1)Panel thickness 60 mm.Panel surface: Smooth sheet metal white pack ice similar to RAL 9010 inside and out
Floor	<ul style="list-style-type: none">60 mm thick PU panels protected by a 9 mm thick CTBX counter panel, coated with phenolic resinInsulated floor allowing a static load of 3000kg/m² distributed<ul style="list-style-type: none">Height of the step to enter the room: 115 mm
Door(s)	<ul style="list-style-type: none">Hinged right - 60 mm thickDoor with 4 covering sealsClear opening dimensions 2,000 x 900 mm<ul style="list-style-type: none">Key lock and inside release handleIntegrated heating cordPanic bar included
Partition passages	Diameter 75 mm for qualifications
Air circulation	Diffusion via a made-to-measure textile duct, installed in the ceiling of the climatic chamber to ensure perfectly uniform temperature and hygrometry conditions inside the useful volume.
Air handling unit: AHU	It includes the heating and drying systems, the ventilation turbine, the humidifier and the electrical cabinet. The units will be moved outside just behind the wall in front of the chambers

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Cell performance

- The two cells have the same performance, as shown below

Temperature performance

T°C range

+15°C ... +55°C

T°C accuracy (\pm °C Max)

0.1

T°C stability (°C/Max)

< 0.5

T°C Homogeneity

+/- 1°C

Heating system

Shielded stainless steel electrical resistance controlled by a solid state relay

Cooling system

Hermetic compressor with ventilated fin condenser located just behind the wall in front of the chambers

Gas: 513a - GWP: 631

Humidity Performance

Range of humidity operation

20 to 98%RH according to the moist air diagram on page 2

Regulation accuracy Humidity

\pm 0.5 %RH/Max

Humidity Stability

< 1% RH/Max

Homogeneity in %RH

+/- 3% RH

Humidity Generator

By Ultrasound

Drying

Refrigeration Circuit

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Cell control

Our control system is a 7" touch interface that lets you navigate with ease in a reliable, accessible and high-performance environment.

Specially developed to control climatic cells using ICH stabilities, our system is intuitive to use and offers excellent settings

- Temperature and hygrometry setpoint adjustment via digital keyboard
- Display of read values and permanent setpoints
- Measurement and setpoint to the 10th of a degree
- Minimum and maximum temperature setting to setpoint value (monitoring band)
- Minimum and maximum hygrometry setpoint adjustment (monitoring band)
- Machine running indicator
- Machine stoppage indicator
- Machine events history
- Customised default messages (cause and solution)
- User account password
- Different user access levels can be configured (2 levels)
 - o Technician
 - o Administrator
 - o System capacity:
 - o 100 possible users
 - o Timed access management
 - o Permanent display of authorised access level
- Time delay management on door opening
- Data export via USB port (event log)
- System information page
- Permanent display of date and time
- Access to temperature and humidity offset settings
- Alarm report self-test (dry contact)



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Technical details

REGULATION AND AUTOMATION

- The two cells have the same type of regulation and automation, as shown below

Regulation and automation

HMI interface

The enclosure is equipped with a 7" touch screen HMI located near the door in the AHU
The screen is used to control and operate the equipment.
This interface is equipped with a USB port.

Regulation

Regulation is provided by a digital PID controller

Regulation Sensor

Capacitive type - 4-20mA or 0-10V transmitter

Safety Sensor

Type PT100 Class A independent of regulation

Temperature Safety

Thermostatic for machine safety.
Digital for sample protection.

Enclosed person safety

A push button is located inside the chamber at a maximum height of 80 cm from the floor.
This button stops the chamber and activates a visual and audible alarm as well as an up dry contact for GTC surveillance.

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Technical details

- The technical details below are identical for both cells

Equipment	
Order and display	7" touch screen
Interior lighting	Sealed LED tubes or plates
Dry contact fault report	1
Door opening report Dry contact	1
Export USB defects	1
Door opening management	Adjustable alarm delay. Once the programmed time has elapsed, the sensor goes into a non-blocking visual and audible fault, which is automatically cleared when the door is closed
Heating cord	All around the integrated anti-condensation door frame

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OPTIONAL 100% BACK-UP SYSTEM

- A permanent back-up system is built into the climatic chamber: all the regulation and safety elements (sensors, regulators, displays, circuit breakers, PLCs), hygrometry production, electrical resistance, refrigeration unit and ventilation are duplicated and operate independently. Switching between the two systems is automatic. It is also possible to switch from one to the other manually (for maintenance or testing operations, for example). Optional for customers: Secured power line.





Safety and service access

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SAFETY FEATURES

- Thermostatic for machine safety.
- Digital for sample protection.
- A display and an audible signal indicating equipment faults.
- Potential-free contacts for alarm reports on existing monitoring system or CTM (General fault - Door opening - Equipment on/off - Other information on request)
- Emergency stop on each cell to cut off the electrical and power supply in the event of imminent danger. A manual reset in the electrical cabinet will be necessary to restart the oven.
- Autonomous safety unit installed above each door, it provides an emergency light source inside the chamber and signals the way out in the event of a power cut. (1h Battery life)
- Noise level: 71dbA (+/- 3 dbA) at 1 metre from AHUs and in rooms
- A push button is located inside the chamber at a maximum height of 80 cm from the floor. This button stops the speaker and activates a visual and audible alarm.
- Timed Door Opening Management on non-blocking alarm.





Service access

Every service access must be brought to the technical room by the customer if we are responsible for the service access distribution network

The service access will be confirmed by the studies and may vary

- Power supply:
 - Voltage: 400V (3Ph+N+PE) - 50Hz.
 - Installed power:

	Cell 1	Cell 2	Cell 3	Total
Single AHU	5 kW	5 kW	5 kW	15 kW
AHU Back Up	10 kW	10 kW	10 kW	30 kW



- Demineralised water supply:
 - Required water quality: Demineralised water < 5 μ S/cm
 - Water temperature between +5°C and +40°C,
 - Pressure between 0.5 and 5 bar
 - No specific recommendations for PH.



- Compressed air network for the two climatic chambers
 - Clean, de-oiled air
 - Operating pressure: 7 Bars
 - Output flow rate from 60 to 120 m³/hour
 - Dew point of -20°C



- Condensate drainage
 - By gravity.



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Documentation and training

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DOCUMENTATION

Supplied in French and in duplicate, it includes:

- Drawings and operating principle diagram of the air handling unit,
- The nomenclature and specifications of all the parts in the schematic diagram,
- The electrical diagram,
- The electrical diagram nomenclature,
- The cell's maintenance file, together with a list of replacement parts,
- User manual for the cell and software
- EC certificate
- Leak test certificate in accordance with decree 737-2007

TRAINING

During commissioning, a training programme is provided for users of the air handling unit.

It includes:

- Presentation of the equipment
- Explanation of how the equipment works,
- Settings of the regulators, indicators and displays,
- Alarm settings,
- Precautions for using the equipment,

RESERVE

Any verbal agreement on technical specifications other than those mentioned above must be confirmed in writing, either in the commercial offer or in the technical offer

CAELIS reserves the right to modify or change the intrinsic characteristics of the equipment in line with developments in the techniques used and technological progress

Technical information is available on request - Non-contractual photos





Shelving Description

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GENERAL DESCRIPTION OF FERMOD SHELVING



- High rigidity thanks to its assembly design (longitudinal beam/pole) with (patented) tapered fitting and Duralinox assembly flange.
- Full depth corner return, without pole.
- Each level can be adjusted to the required height in 150 mm increments without the use of tools.
- Easy cleaning with removable racks (machine washable -30°C/+90°C).
- Neutral ladders supplied without flanges, which are supplied with the levels.
- The trays are made of polymer.
- Maximum load per level: 175 Kg evenly distributed.
- Maximum load 900 kg for a shelf between two ladders and 600 kg for each shelf in a configuration including one or more corner returns.

DESCRIPTION SPECIFIC TO YOUR PROJECT AS STANDARD

- Hygiene-compliant polymer shelving.
- Approved "Hygiène Alimentaire" French Standard by AFNOR.
- Height of ladders: 2160 mm.
- Shelving depth 460 mm.
- 6 levels of shelves.
- Level spacing: 250 mm
- The first level is 260mm from the floor, for hygiene reasons (need to be able to clean under the shelving).



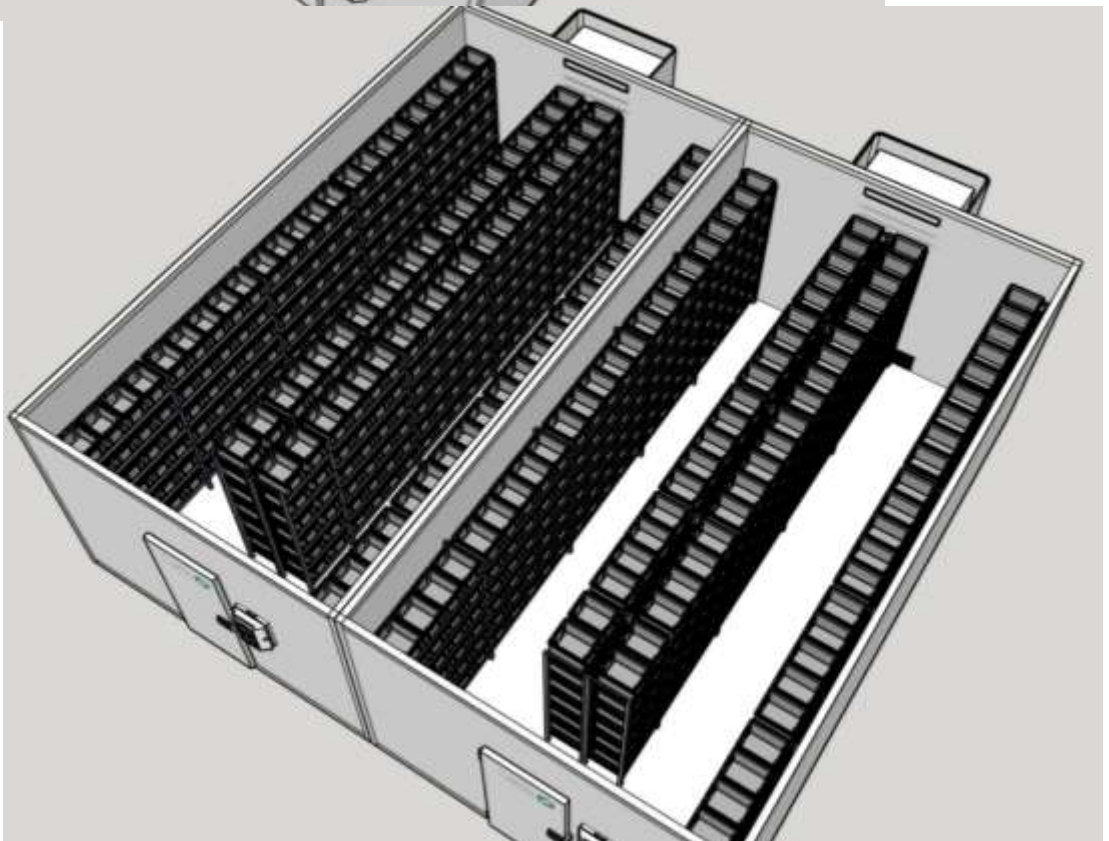
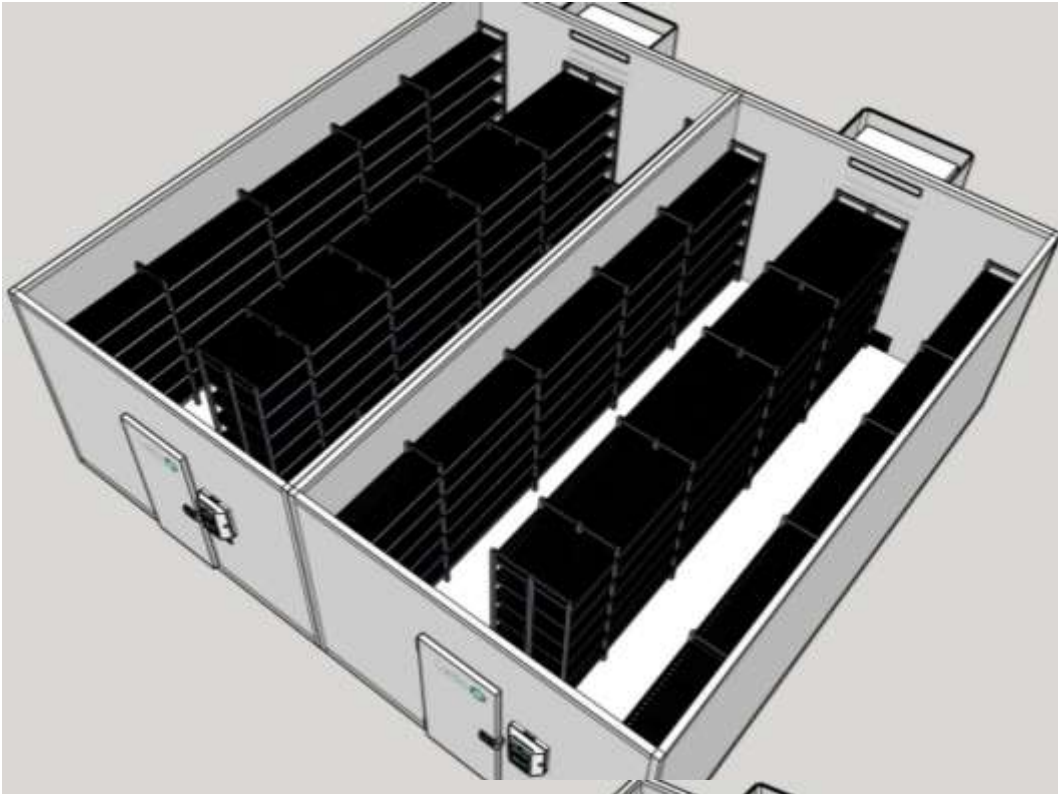
Description by number of levels	Number of levels	Height of highest level in mm	Space between shelves in mm	Total linear length in metres	Shelf area in m ²	Useful volume on shelf in m ³
Cell (79 m ³)	6	2010	300	166.68	76.67	23.00





Shelving Description

3D PICTORIAL VIEWS (WITH AND WITHOUT BOXES)

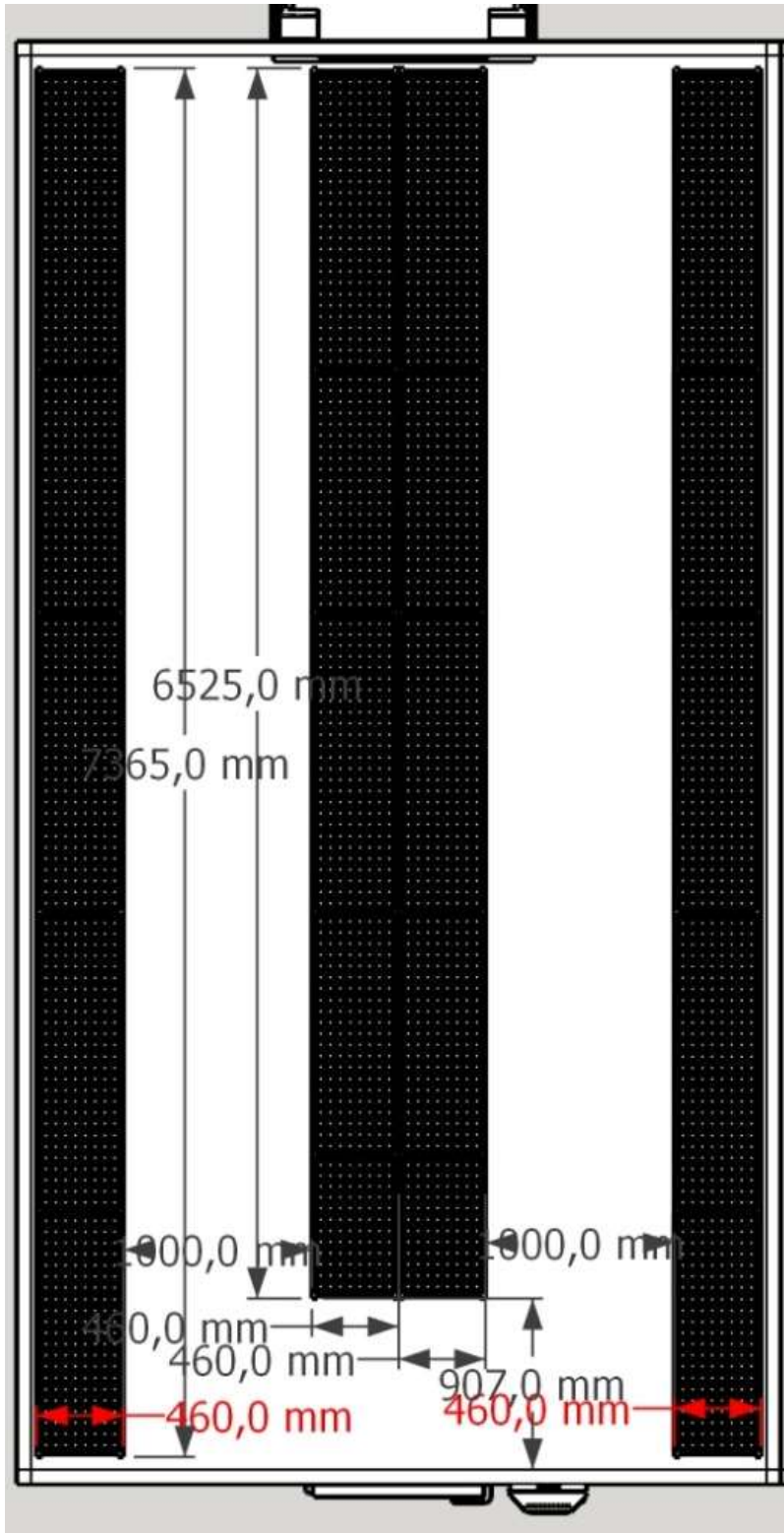


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Shelving Description

TOP VIEW OF A ROOM WITH 2D DIMENSIONS

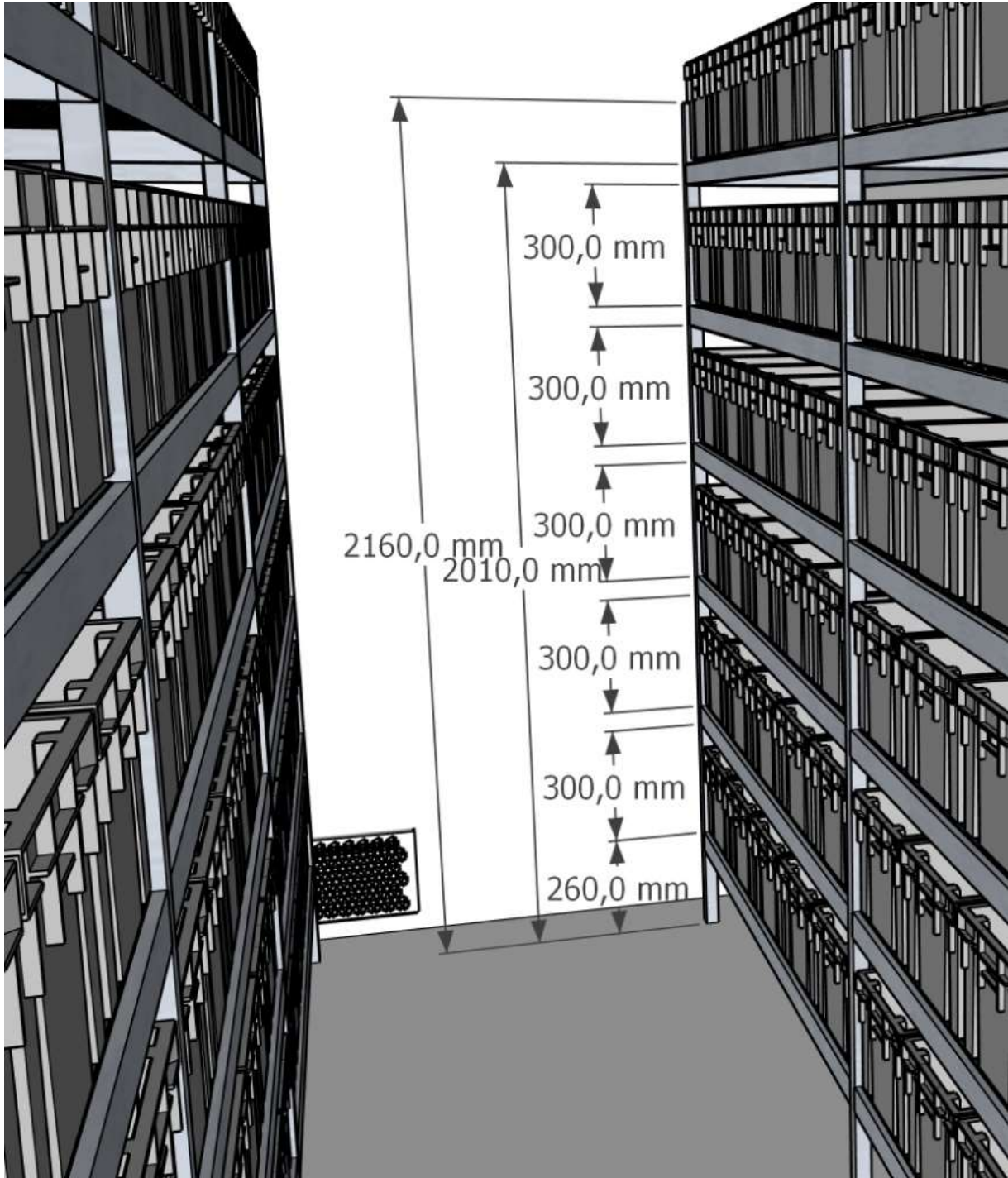


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Shelving Description

3D PICTORIAL VIEW



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IQ/OQ/PQ qualification

IQ: Installation Qualification

- The purpose of this qualification is to provide documented proof that the equipment meets the customer's requirements

OQ: Operational Qualification

- The purpose of this qualification is to check the regulation parameters, sample safety and protection, and the accuracy of temperature and humidity measurements in accordance with standard FDX 15-140.

This OQ includes:

- Function tests
- Alarm tests
- No-load mapping in accordance with FDX 15-140 for one condition per chamber:
 - 12 hours for one condition on crate 1
 - 12 hours for one condition on crate 2
 - with the switch from crate 1 to crate 2
 - with the switch from crate 2 to crate 1
 - Door opening under load for one minute for one condition on crate 1
 - Door opening under load for one minute for one condition on crate 2
 - 30-minute power failure test on chamber and recovery time on crate 1
 - 30-minute power failure test on chamber and recovery time on crate 2

PQ: Performance Qualification

- Performance qualification is carried out under load, using COFRAC-connected measuring equipment, when the climatic chambers are commissioned at their place of use, in accordance with standard FDX 15-140

This PQ includes:

- Load mapping in accordance with FDX 15-140 for one condition per chamber:
 - 12 hours for one condition on crate 1
 - 12 hours for one condition on crate 2
 - with the switch from crate 1 to crate 2
 - with the switch from crate 2 to crate 1
 - Door opening under load for one minute for one condition on crate 1
 - Door opening under load for one minute for one condition on crate 2
 - 30-minute power failure test on chamber and recovery time on crate 1
 - 30-minute power failure test on chamber and recovery time on crate 2



Financial conditions

Designation	Qty	Total amount excl. VAT
79m3 climatic chamber without Back-Up Type: CMI-60-C		
VAT rate		0%
Special features and options		Amount excl. VAT

- 100% Back-Up (See Page 11)
- Air dryer option with supply of two air dryers (one per chamber) for dry conditions (See Page 2)
- IQ/OQ/PQ qualification (see page 24)
- Shelves (including supply and installation)
- 2400 mm ladders instead of 2130 mm for shelves
- Delivery
- Installation, Commissioning and User Training
- Option to replace R513a gas with R1234YF gas (GWP of 4) in compliance with standard NF EN 378 on the 4 circuits
- Flash beacon in each room
- 1-metre remote sound alarm (60dB) in each room
- Supply and installation of a monitoring probe. Connection of the monitoring probe to your monitoring system is not included in the service

TOTAL with options

Total with options and discounts

Total with options, discounts and warranties

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Financial conditions

Designation	Total amount excl. VAT
Total with options, discounts and warranties	

VAT rate

0%

Validity of the offer

Deadline

Between 20 and 24 weeks

Terms of payment

Warranty

2 years (Parts, Labour and Travel) date of delivery
Requires preventive maintenance on the 1st anniversary
at the customer's expense

Your Contact

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