Coolvacuum
a Dara Pharma company

LYOMICRON

USER MANUAL

DOMINIQUE DUTSCHER SAS

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1. Prologue

Thank you for your reliance in COOLVACUUM for the purchase of your new freeze dryer. COOLVACUUM applies the most advanced technology for the design and manufacture of its equipment, using the best quality materials. Likewise, our machinery incorporates the best finished materials to comply with the demanding requirements of the industry.

The documentation provided with the freeze dryer includes the description, installation, operation and other technical instructions necessary for a good knowledge of the equipment, for a correct operation and to achieve the best performance of the equipment, always taking into account the user's safety.

It is therefore mandatory to read carefully and understand the instructions before installing, starting up or using this machine. Once you have finished reading, keep the manual in a safe place.

The COOLVACUUM Quality Department is at your disposal to clarify any doubts that may arise from reading the manual, thanking you in advance for any suggestions to improve it.

COOLVACUUM reserves the right to modify the characteristics of its machines without prior notice, provided that this is done to improve their performance, reliability or operation.

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COOLVACUUM TECHNOLOGIES, S.L.
Pol. Ind. Coll de la Manya – Galileo Galilei 13
08403 – GRANOLLERS (Barcelona) – SPAIN
coolvacuum@coolvacuum.com
Tel.: + 34 938 718 784

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2. Safety

The **COOLVACUUM** freeze dryers of the **LYOMICRON** series have been designed and built in accordance with European laws, complying with all required safety standards and including the following safety devices, among others.

- **Safe start and stop devices,** which allow any service during the automatic cycle, when performed after a cycle stop during a recognised steady-state stop.

- **Power disconnection devices,** which allow cleaning, maintenance and repair work to be carried out safely.

All these safety devices are integrated in the machine, forming part of it. Modification, annulment or lack of maintenance of any of these devices increases the risk of accidents and is a violation of Directive 2009/104/EC.

The manufacturer assumes no liability for damage resulting from modifications to the machine, removal or non-maintenance of machine components that have been carried out without the prior approval of the manufacturer.

Any repairs must be carried out by specialized technicians. Otherwise, repairs may involve dangerous risks for the user.

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3. General description

The Lyomicron freeze-dryer is designed to provide a complete freeze-drying service of the highest quality in the safest and most reliable way.

A series of protections and automatisms guarantee the total reliability and reproducibility of the process.

The equipment consists of a compact unit housing the system components and motors, including the condenser, refrigeration components, and other control elements. The vacuum pump is located outside this compact unit and must be located nearby and connected by means of a vacuum hose. In the upper part of the bench is where the chamber is located, where the product to be lyophilized must be introduced.

This manual contains useful information for the operation of the Lyomicron -55, with condenser temperature down to -55°C and Lyomicron -85 with condenser temperature down to -85°C plus 2 compressors in cascade.



Figure 1. General description - Models.

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Depending on the characteristics and format of the product to be freeze-dried, the freeze-dryer chamber could be different. In the following figure, as an example, the freeze dryer is equipped with a cubic chamber, but it could be circular, with manifolds...

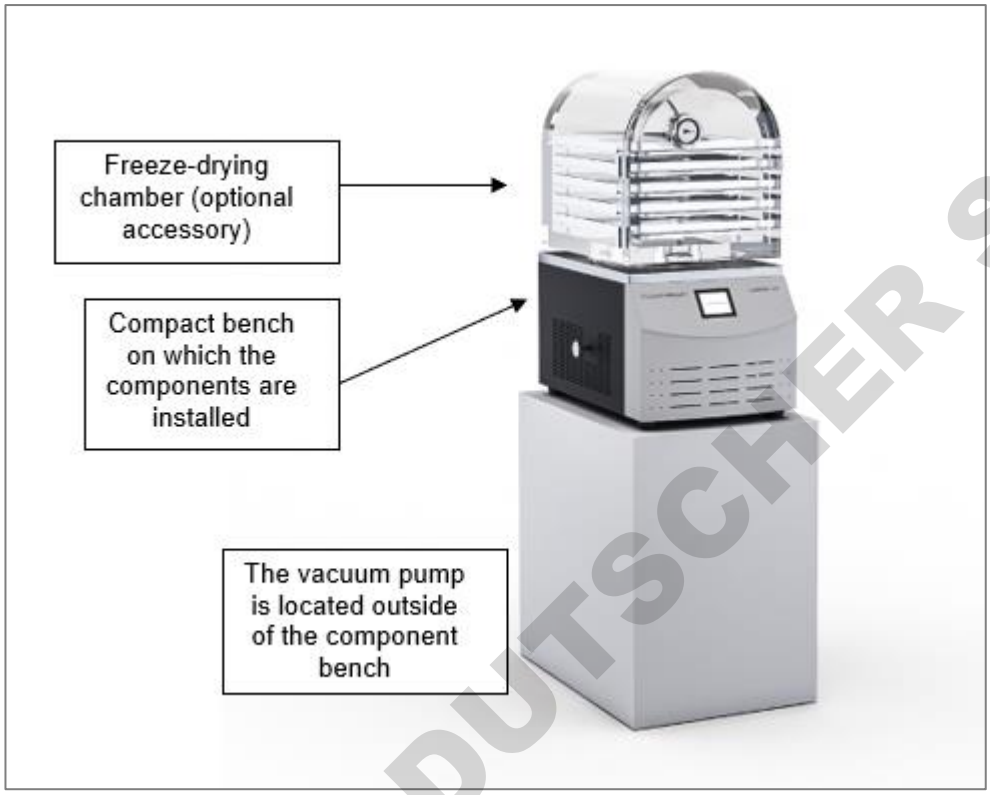


Figure 2. General description.

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The condenser of the freeze dryer has an internal coil through which refrigerant gas circulates. During the freeze-drying cycle, the moisture captured from the product is trapped around this coil in form of ice.

To melt the ice after each cycle, the Lyomicron has an automatic defrost cycle that works with hot gas. The hot gas is generated by the discharge of the compressors in the refrigeration circuit.

Before starting a new freeze-dryer cycle, the user must ensure that the condenser is free of ice and water, in other words, clean and dry.

The freeze dryer chamber (which is an optional accessory) is fitted to the freeze dryer frame or bench with a silicone gasket to ensure a watertight seal for proper vacuum operation.
The seal must be kept clean throughout the life of the freeze dryer. In case of damage, it must be replaced.



Figure 3. General description - Condenser.

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The choice of freeze dryer chamber depends on the product to be freeze dried and its format. The different lyophilisation chambers available for Lyomicron are described below:

Table 1. Optional chambers

Specifications	Chamber
Methacrylate circular chamber with 6 / 8 plates Number of plates: 6 / 8 Inter distance between plates (mm): 40 Size (mm): ø 200 Plate area (m^2): 0,18 / 0,24 Optional with resistances Optional with 6 valves with CN 29/32 connection for flasks	
Methacrylate cubic chamber with 5 rectangular plates Number of plates: 5 Inter distance between plates (mm): 40 Size (mm): 390 x 320 Plate surface (m2): 0,65 Optional with resistances	
Circular methacrylate chamber with manual vial closing system Number of plates: 3 useful + 1 for closure Inter distance between plates (mm): 70 Size (mm): ø 200 Plate surface (m2): 0,09 Optional with resistances	
Stainless steel manifold for 12 valves for flasks Valves: 12 Valve connection: CN 29/32 Height increase (mm): 570	

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4. Installation and start-up

The equipment must be located in a room with controlled temperature and humidity, not exceeding 25ºC for proper performance.

4.1. Connections

You can use one of Coolvacuum's video tutorials as a guide:

Search on YouTube:
Installation of laboratory freeze dryer– COOLVACUUM

https://www.youtube.com/watch?v=83urxdjlcVE

On the CE plate of the freeze dryer, it specifies the services required for its connection:

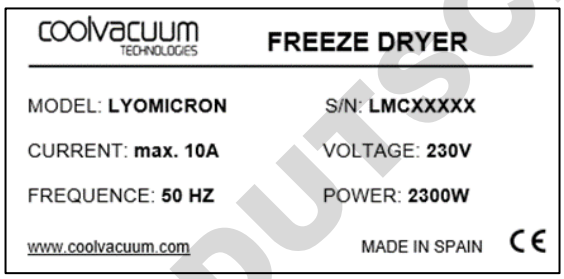


Figure 4. CE Plate.

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Power

The equipment must be connected to the power supply in accordance with the specifications:

Table 2. Electrical power specifications.

Specifications	
Maximum power	10A
Voltage and Frequency	230V; 50 Hz
Power	2300W

The freeze dryer is equipped with a cable to connect it to the power supply, the cable must be connected to the rear part of the freeze dryer.



Figure 5. Electric connection.

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Drainage

Water will drain out of this pipe after the defrosting cycle, therefore a container should be placed during defrosting to collect the water.

This pipe is the same one through which the air enters to break the vacuum in the chamber and the condenser after the freeze-drying cycle.

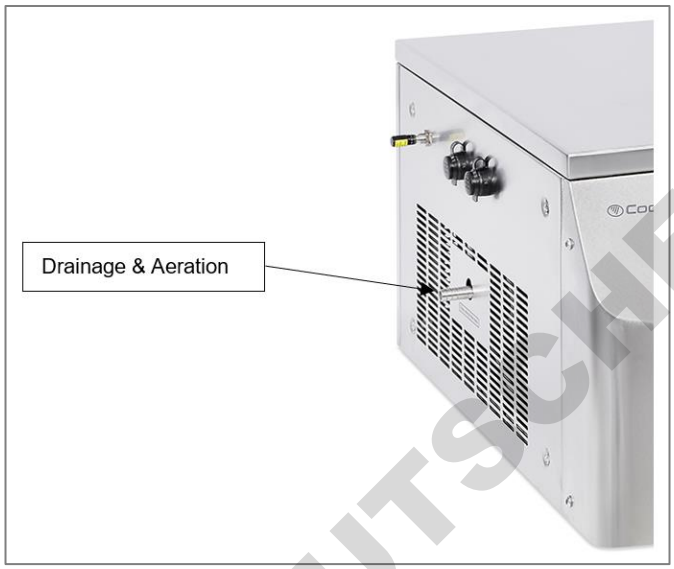


Figure 6. Connection - Drainage.

Ethernet

It is also possible to connect the freeze dryer to ethernet, an input on the back of the unit. In this way, it is possible to control the freeze dryer remotely via tablet or smartphone.
For remote control it is necessary to assign the freeze dryer a local IP and download the App Vijeo Design.

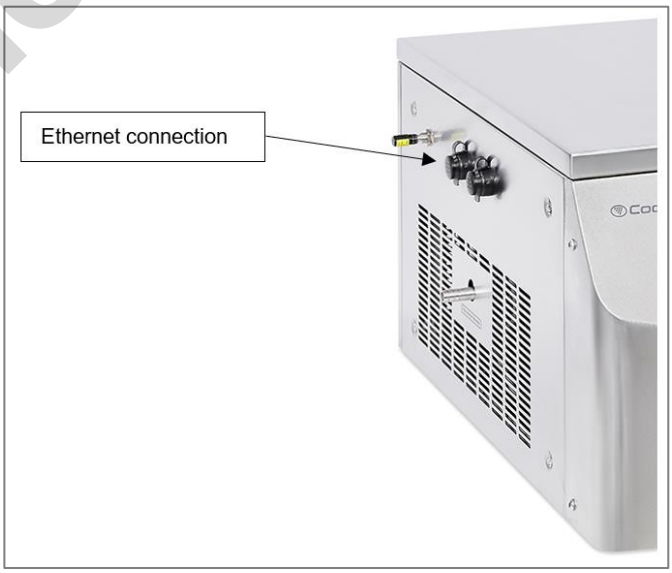


Figure 7. Ethernet - Connection.

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USB connection

On the side panel, next to the Ethernet port, there is a USB 2.0 connection that will allow the user to import and export cycle and recipe data.



Figure 8. USB - Connection.

Vacuum pump connection

The vacuum pump is an external device that is connected to the base of the device via the vacuum connection port, located on the rear of the device.

The components included to connect the equipment are: vacuum hose, stainless steel elbow, gaskets and clamps for all connection points as well as a non-return valve, which is connected to the inlet port of the pump.

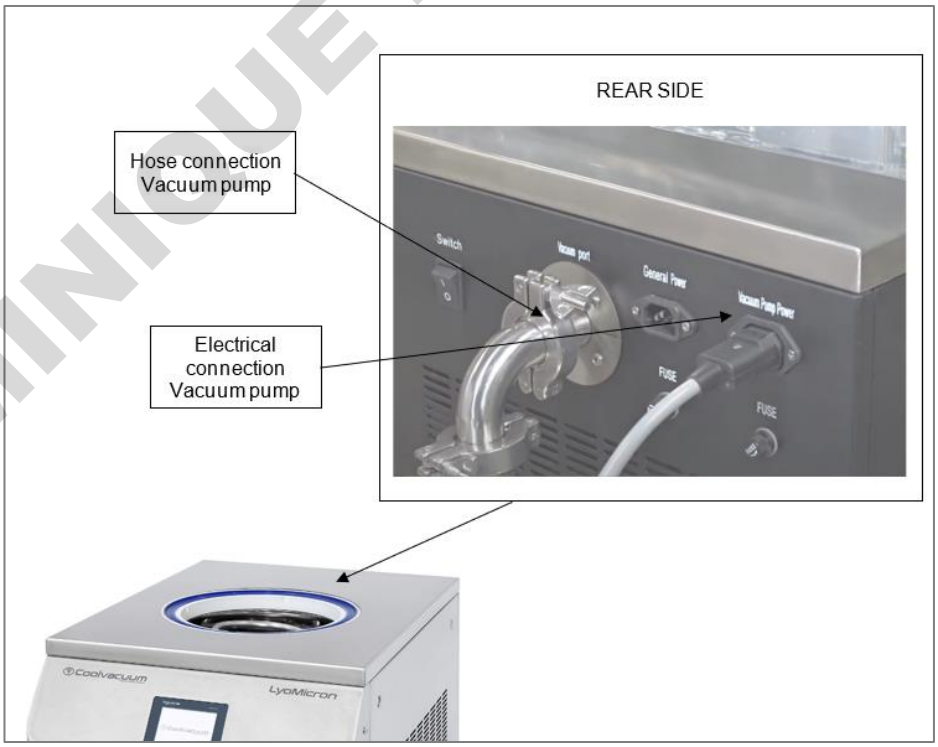


Figure 9. Connection - Vacuum pump.

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4.2. Vacuum pump

4.2.1. Oil filling

Before starting up the equipment, check whether the vacuum pump is filled with oil.

1. If you have received the freeze dryer together with the corresponding vacuum pump and it already contains oil inside, you can skip this step. This oil is clean and is valid for the operation of the equipment.

2. If your pump does not contain oil, you must fill it.

   You can use one of Coolvacuum's video tutorials as a guide:

   Search on YouTube:
   Changing the oil in a vacuum pump - COOLVACUUM

   https://www.youtube.com/watch?v=pUULHPrBRNo

4.2.2. Connections

Non-return valve

The vacuum pump is located outside the freeze dryer and must be connected to the main unit with a vacuum hose. At the connection between the pump and the hose, the non-return valve must be placed in the position shown in the figure.



Figure 10. Connection - Non-return valve.

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Filter at the smoke outlet

To prevent smoke from being expelled from the vacuum pump during the first few minutes of operation, a filter must be installed as shown in the photograph.

NOTE: The filter shown in the figure is an example, it may be another model, depending on the type of vacuum pump selected.



Figure 11. Connection - Non-return valve.

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4.3. Switch-on

Once the freeze dryer has been connected to all required services, switch it on.
The on/off switch is located on the right side of the unit.



Figure 12. Switch.

Once the freeze dryer has been switched on, the equipment is controlled by means of the touch screen on the front of the unit.

4.4. USB data collection

For the data to be stored, a USB stick must be connected at all times.

During freeze-drying and/or defrosting cycles, the freeze-dryer monitors the data from the vacuum and temperature probes and stores them on the USB stick located on the side of the freeze-dryer.

A .csv document is obtained, to be able to interpret the data correctly it is recommended to convert to an .xlsx document.

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On the USB Management screen, press the Download Data button.

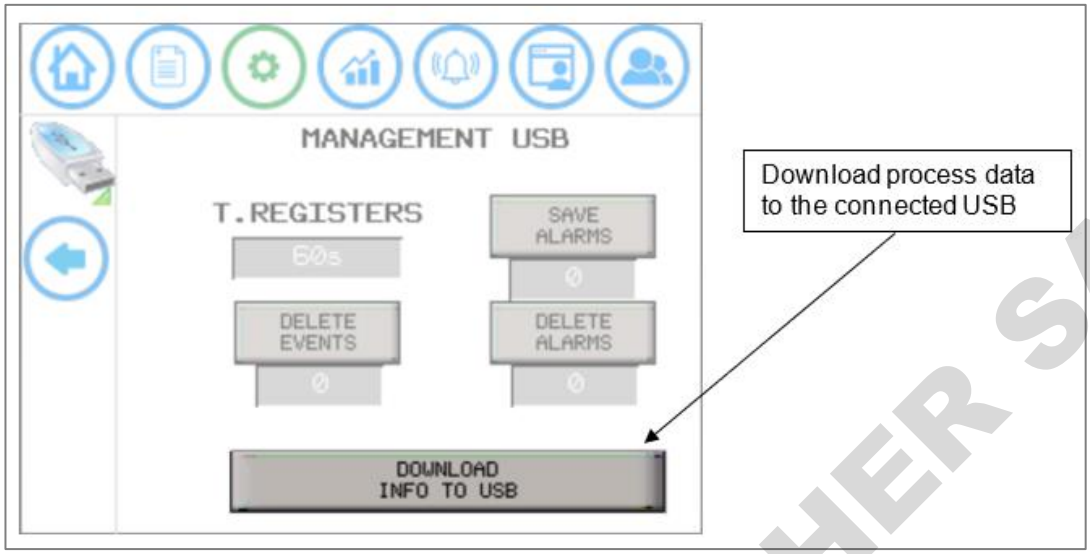


Figure 13. USB - Data collection.

The following pop-up will then appear:

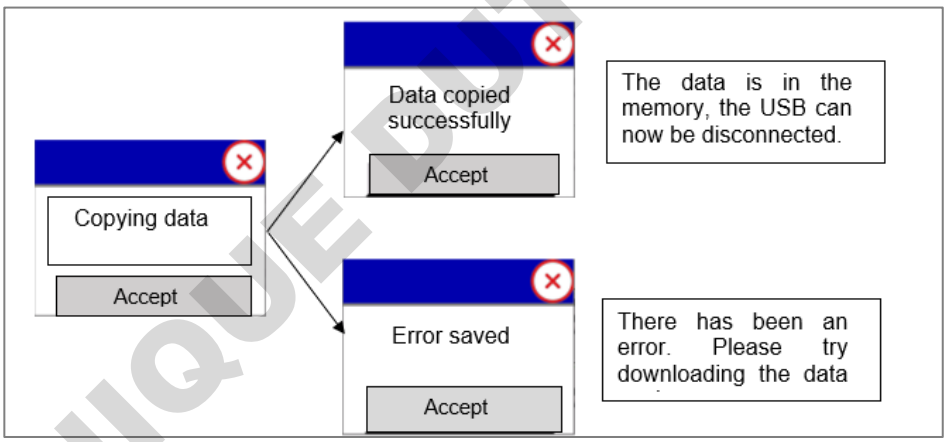


Figure 14. Pop-up - Data collection.

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4.5. Aeration of flasks individually (optional)

Once the freeze-drying cycle is completed, the freeze-dryer can be completely aerated by opening the aeration valve from the touch screen.
It is also possible to aerate one of the flasks individually (optional accessories).

During the freeze-drying cycle, the valves remain open, in the "open" position in the following picture.
To aerate 1 of the flasks individually, close the valve in the vertical "closed" position and carefully pull the flask downwards.



Figure 15. Aeration - Manifold adapter.

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5. Freeze-drying: steps to follow

1. Preparation: Before starting a freeze-drying cycle, check that the freeze-dryer is ready and in optimal conditions.
    - Check that the condenser must be clean and dry, with no traces of water from the last freeze-drying cycle.
    - Make sure that there is no water left inside by opening the drain from the control screen and verifying that no water comes out of the drain pipe.
    - Check the correct state of the oil in the vacuum pump.

2. Freezing of the product. The freezing of the product must be done in a separate freezer and preferably in the same trays/containers that will be introduced into the freeze dryer. The product introduced into the freeze dryer must always be previously frozen.

3. Drying: Start the freeze-dryer.

4. Aeration: Once the freeze-drying cycle is finished, the chamber must be aerated in order to unload the product.

5. Defrosting: Once the freeze-dried product has been removed, the ice accumulated in the condenser must be melted by applying a defrosting cycle.

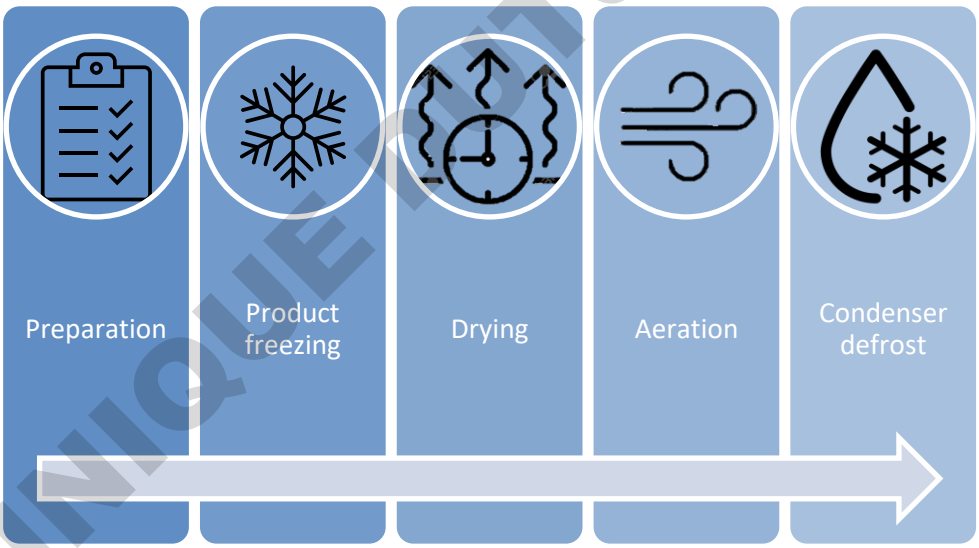


Figure 16. Freeze-drying: steps to follow.

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6. Screens navigation

This manual contains the most relevant information about the control system that monitors the freeze dryer. This application works from a touch screen located on the front of the unit.

On the upper part of the touch screen there is a navigation panel that indicates which screen we are on, at all times.

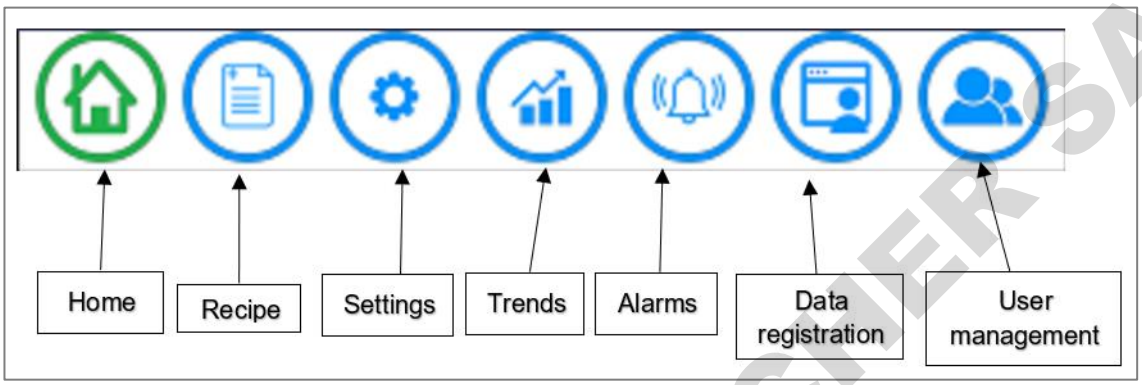


Figure 17. Navigation panel.

The functionality of all the screens is detailed below in the following order:

1. LogIn & User management
2. Home
3. Recipes
4. Settings
5. Trends
6. Alarms
7. Data registration

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When the main switch is activated, the system starts with the initial screen.

On this main screen, the contact details of the manufacturing company are displayed.

Optionally, batch and/or reference can be indicated in each freeze-drying cycle so that it appears referenced in this way in the cycle data Excel.

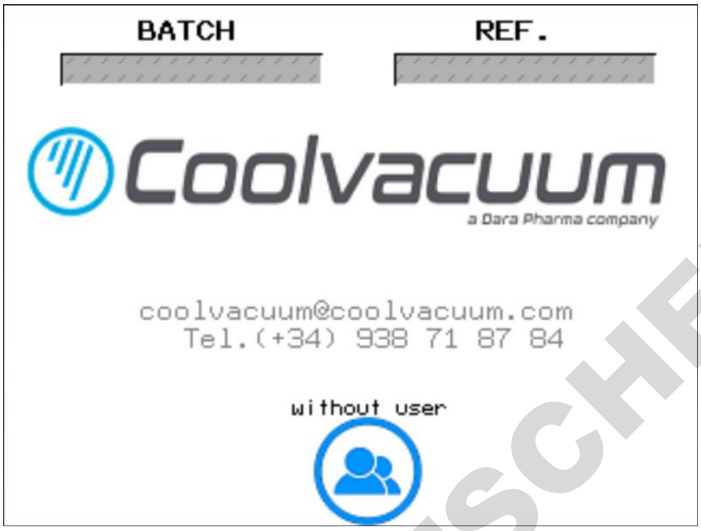


Figure 18. Initial screen.

To start the system, it is necessary to click in the middle of the screen to go to the Log-In screen.

6.1. Log In & User management

The system is user and password protected to restrict user access. To log in, enter your credentials and then click on the "Confirm user" button.

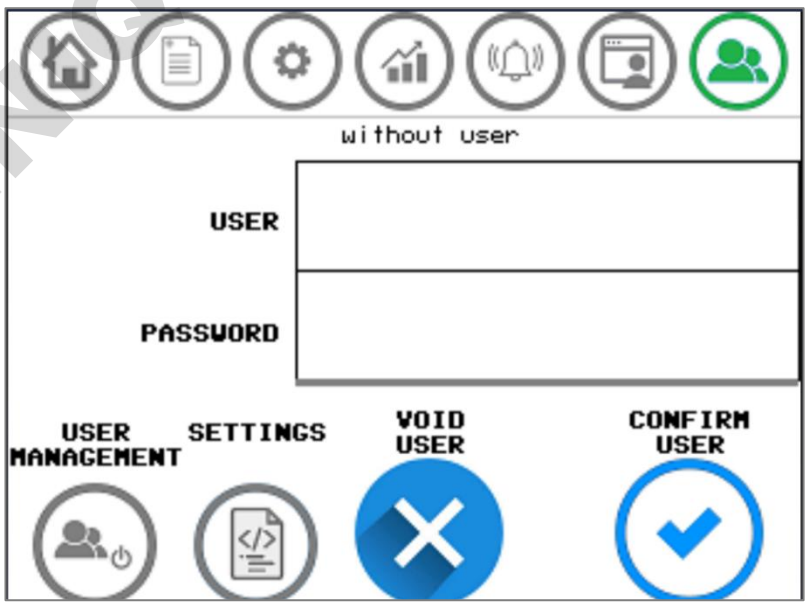


Figure 19. Log In - No registered user.

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The following table describes the users and passwords that are defined as standard:

Table 3. Predefined login data.

Access details	Username	Password
Security group 04 ADMIN	admin	5555
Security group 02 MAN	man	4321
Security group 03 USER	user	1234

Once you have confirmed your username and logged in, the username with which you have registered will be displayed at the top of the screen. The freeze dryer functions can now be used.

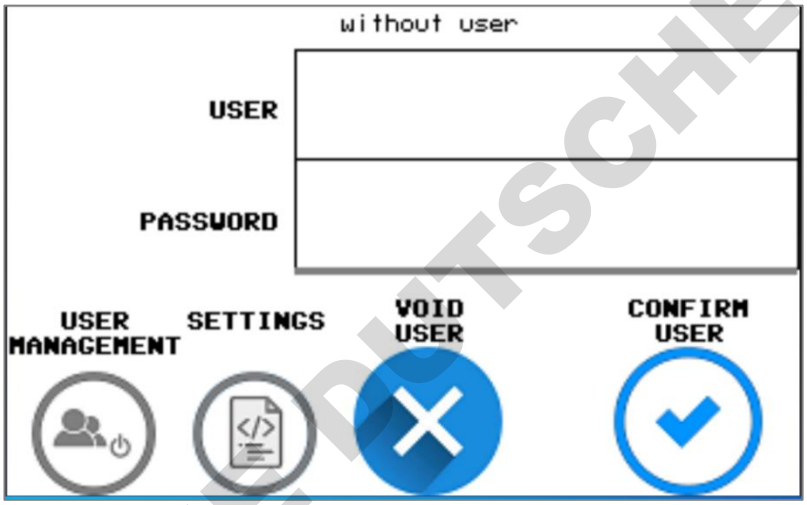


Figure 20. User registration - Log In.

On the LogIn screen you will find the User Management button.

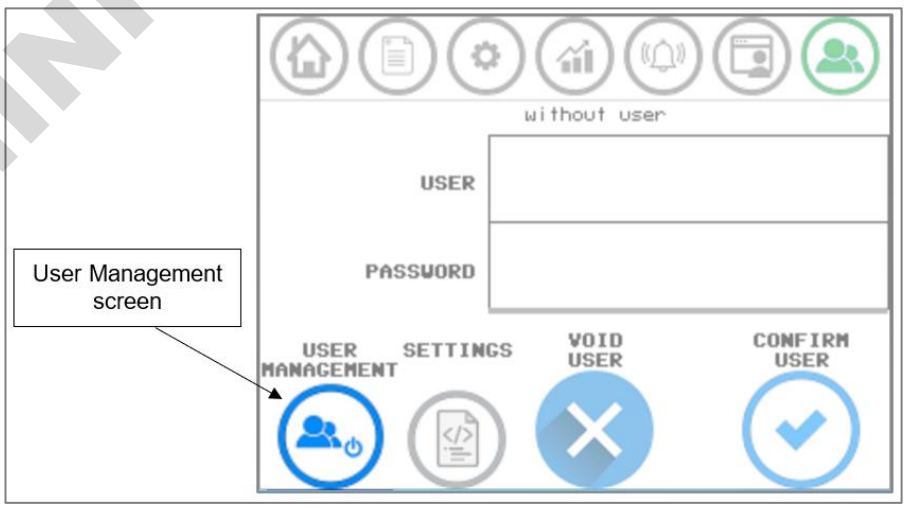


Figure 21. "User management" button.

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By clicking on the user management button, the following screen appears from where you can create / edit / or delete users, as long as you are registered with the appropriate level.

To create a new user:

1. Choose the group you belong to
2. Type a new user
3. Type a new password
4. Press **+**

To delete a user:

1. Select user
2. Press **-**

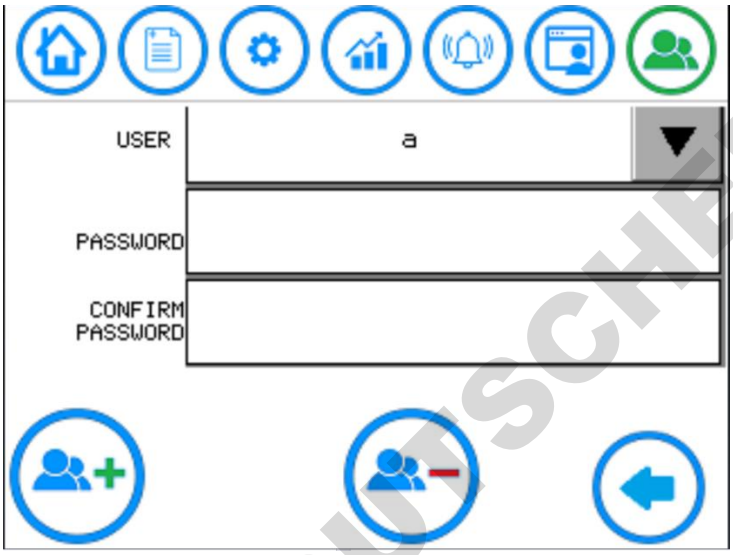


Figure 22. User management.

In this drop-down menu you can see the different groups that may be available.

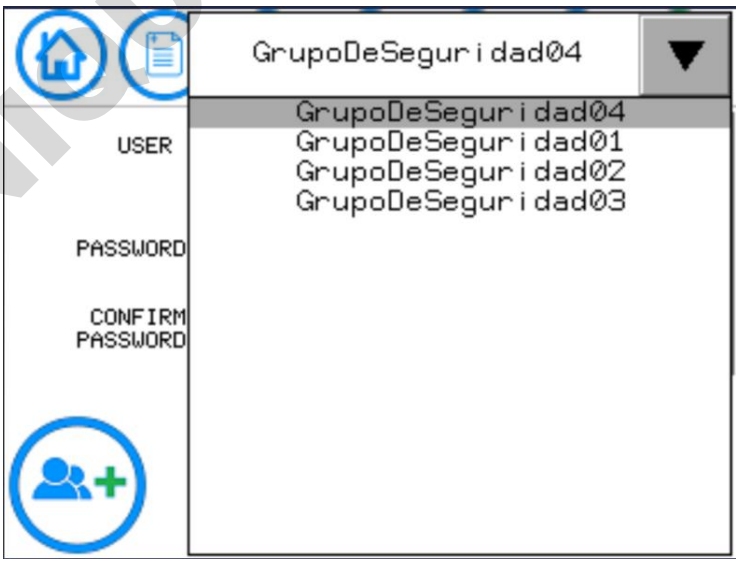


Figure 23. Security groups - User management.

The following table describes the access differences for each User Group:

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Table 4. User groups.

Description of the action	Grup 04 (ADMIN)	Grup 02 (MAN)	Grup 03 (USER)
User management	x		
Edit Set-Points parameters and settings	x	x	
Start of defrost	x	x	x
Edit Defrost parameters	x	x	
Manual mode	x	x	x

6.2. Home (-85)

Home is the main monitoring screen of the freeze dryer. From this screen you can see immediately the operation of the cycle.

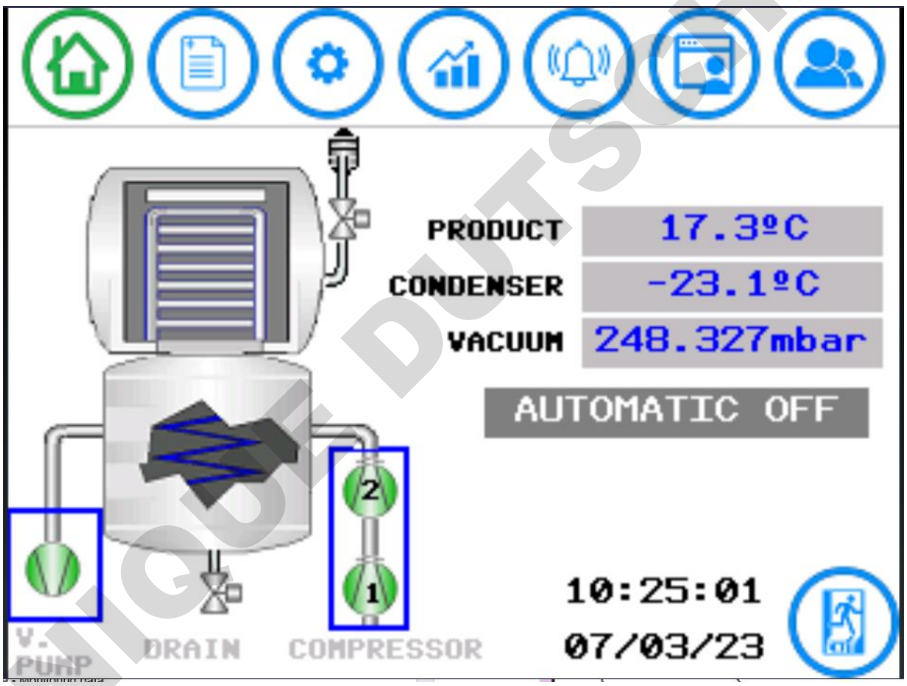


Figure 24. Home -85.

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6.2.1. Monitoring data

- The first one indicates in (ºC) the temperature of the product probe.
- The second temperature indicates the temperature in (ºC) of the condenser.
- The third data indicates the vacuum level (mbar).

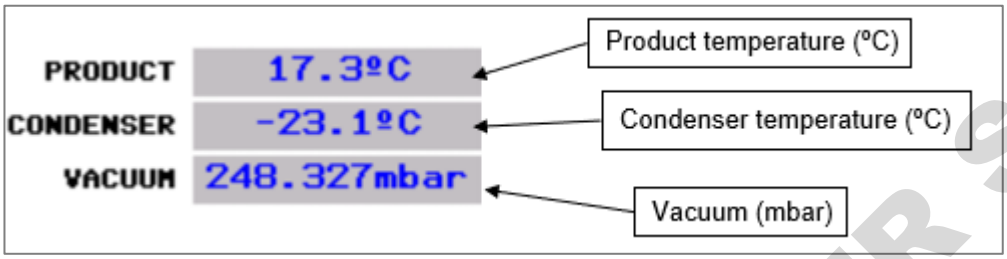


Figure 25. Home - Monitoring data.

6.2.2. Monitoring data (with resistances)

- The first one indicates in (ºC) the temperature of the product probe.
- The second one indicates the temperature in (ºC) of the condenser.
- The third data indicates the vacuum level (mbar).

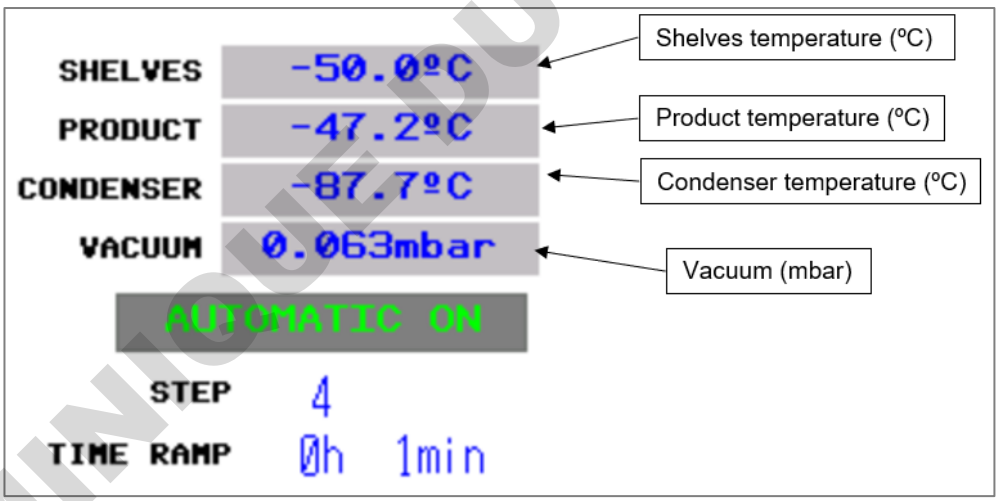


Figure 26. Home - Monitoring data with resistances (1/2).

Freeze dryers with the optional heating element have the option of programming freeze-drying recipes and therefore work in automatic mode.
To start the automatic mode, the "Automatic" button on the main screen must be pressed.

Below the "Automatic" button there is an overview of the recipe information.

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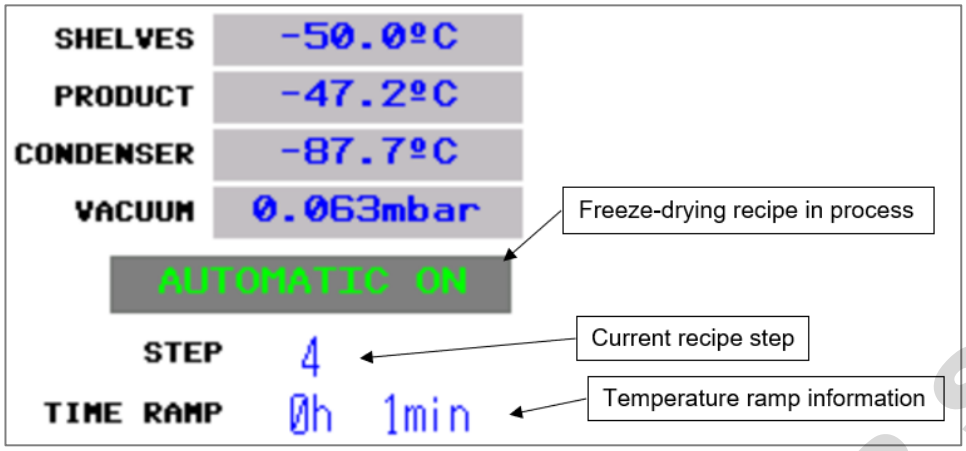


Figure 27. Monitoring data with resistances (2/2).

6.2.3. Manual mode

To start the freeze dryer in manual mode, simply press the components or valves you want to activate on the touch screen.
To start a freeze-drying cycle, we would activate the vacuum pump and the compressor(s).

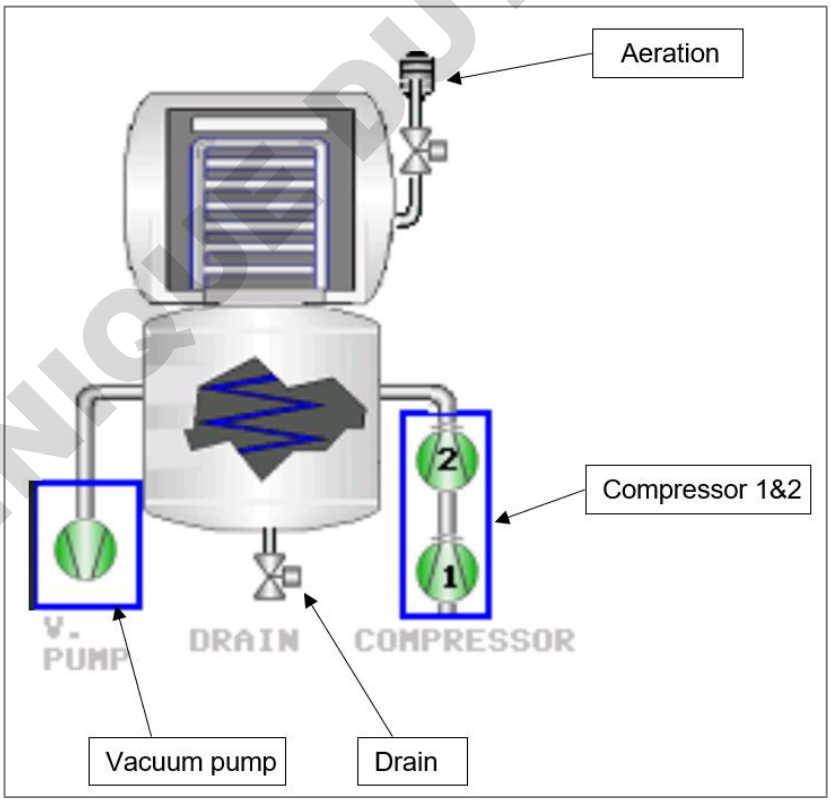


Figure 28. Home - "View more" button.

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On this same screen we can also observe the change of color of the condenser; blue while it is cooling and red if it is defrosting.

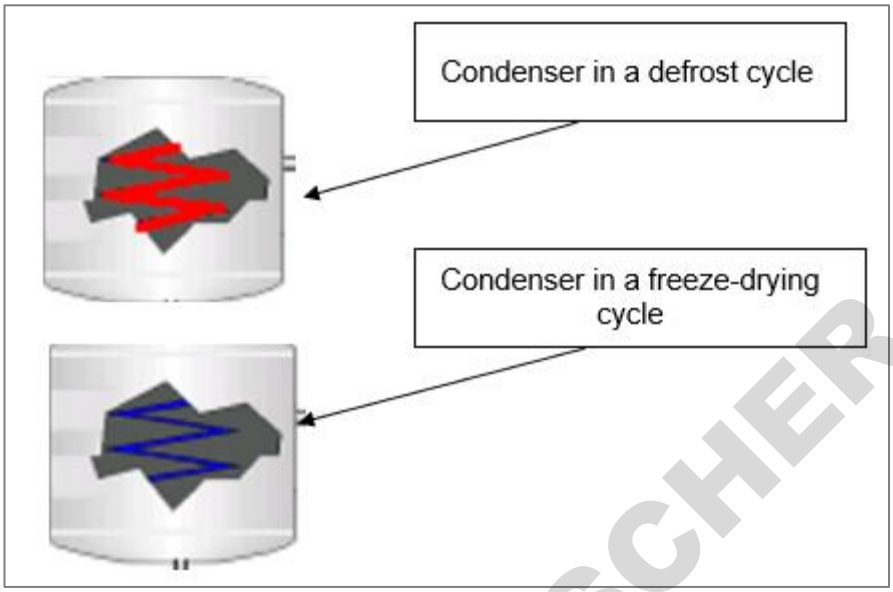


Figure 29. Home - Manual mode.

6.3. Recipes

With a basic freeze dryer, it is not possible to program automatic freeze drying recipes. It is possible to freeze-dry in manual mode.

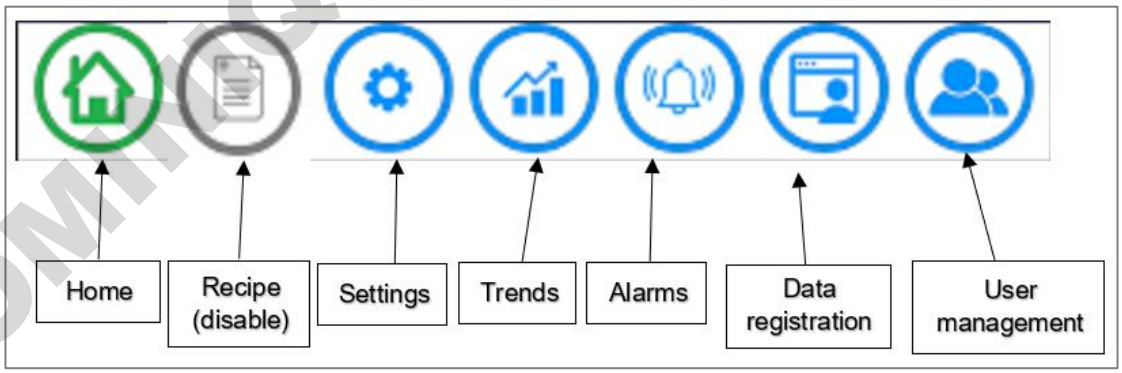


Figure 30. Recipes.

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6.4. Recipes (optional vacuum control)

With the optional vacuum control, it is possible to program freeze-drying recipes by setting time and vacuum level.

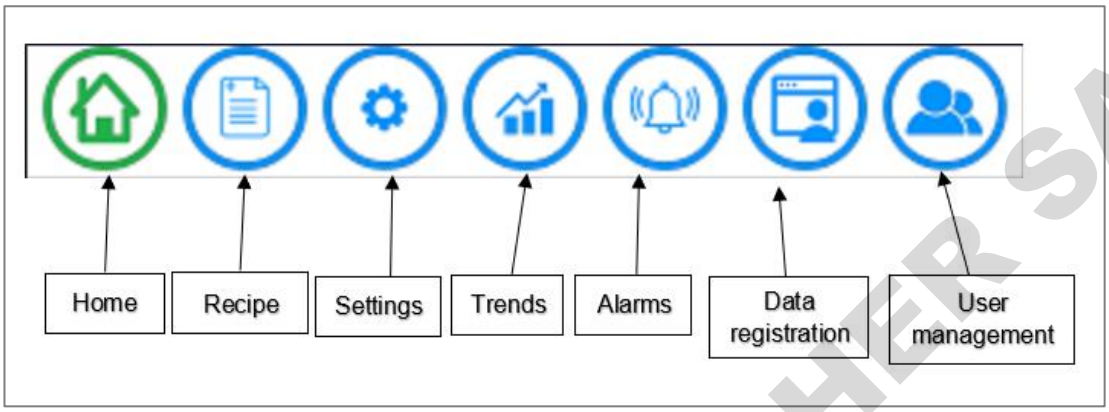


Figure 31. Vacuum control recipes (1/2).

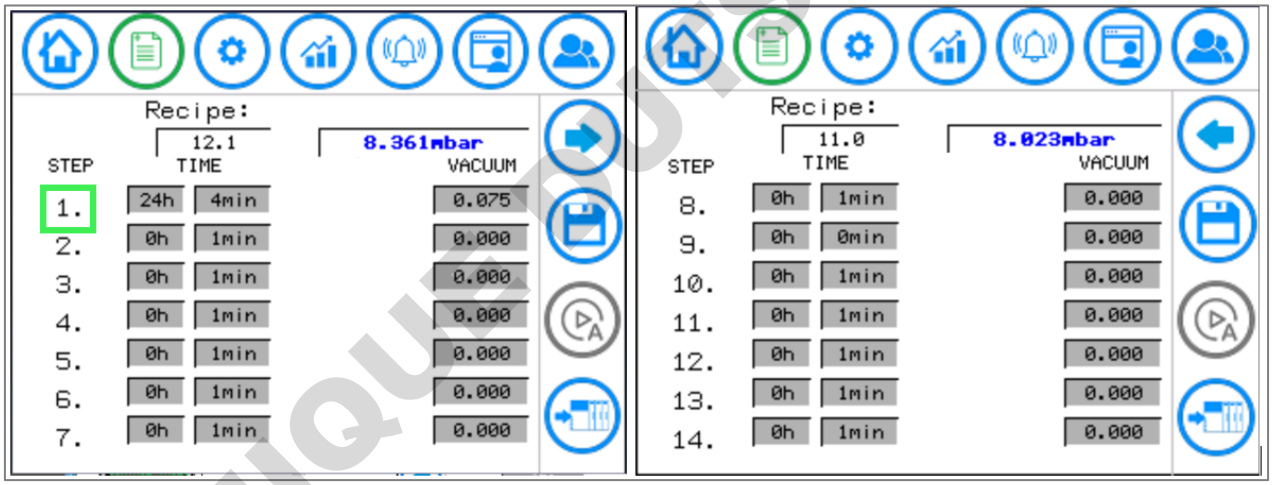


Figure 32. Vacuum control recipes (2/2).

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6.5. Recipes (optional vacuum and resistance control)

With the optional vacuum control and shelf heaters it is possible to program freeze-drying recipes by setting time, vacuum level and plate temperature.

The shelves only heat, so the temperature will always be positive.

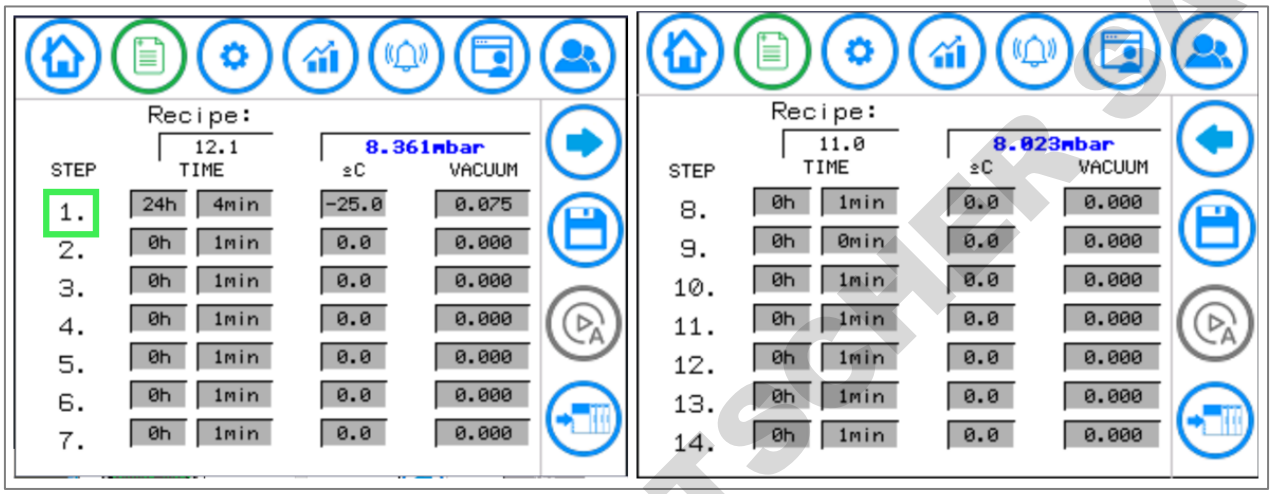


Figure 33. Vacuum control recipes and resistors.

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6.6. Settings

The settings screen contains all the programmed parameters relating to: defrost, set points, probe calibrations, motor counters, compressors and programmer settings.

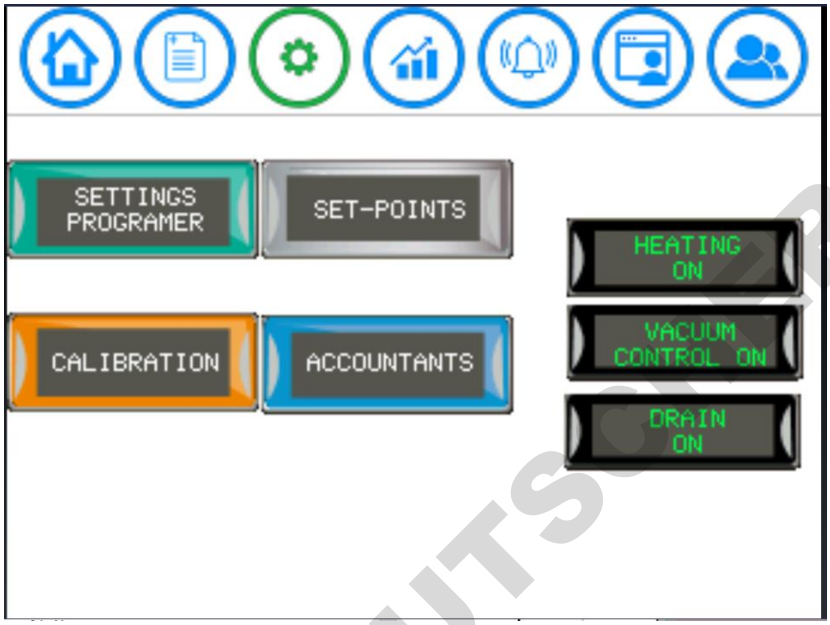


Figure 34. Settings.

The different setting screens are shown below for information purposes, but these parameters are already programmed in the factory, and it is not recommended to change them.

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6.6.1. Programming settings

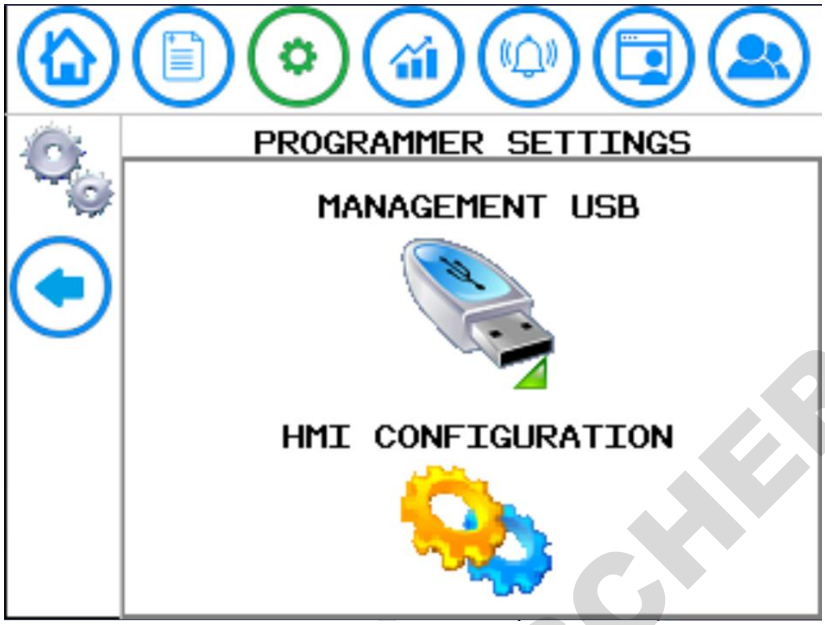


Figure 35. Settings - Programming settings.

6.6.1.1. USB MANAGEMENT

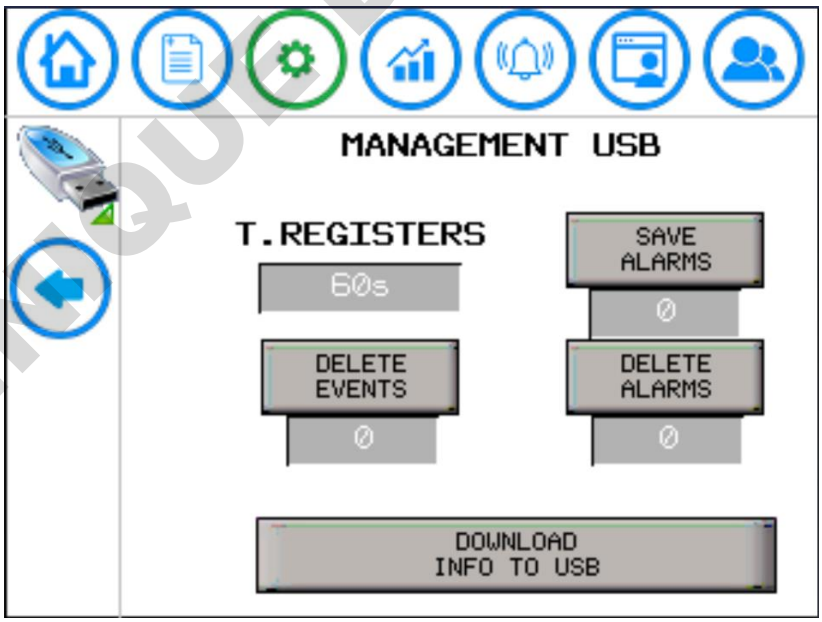


Figure 36. Settings - Programming settings - USB management.

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6.6.1.2. HMI Configuration

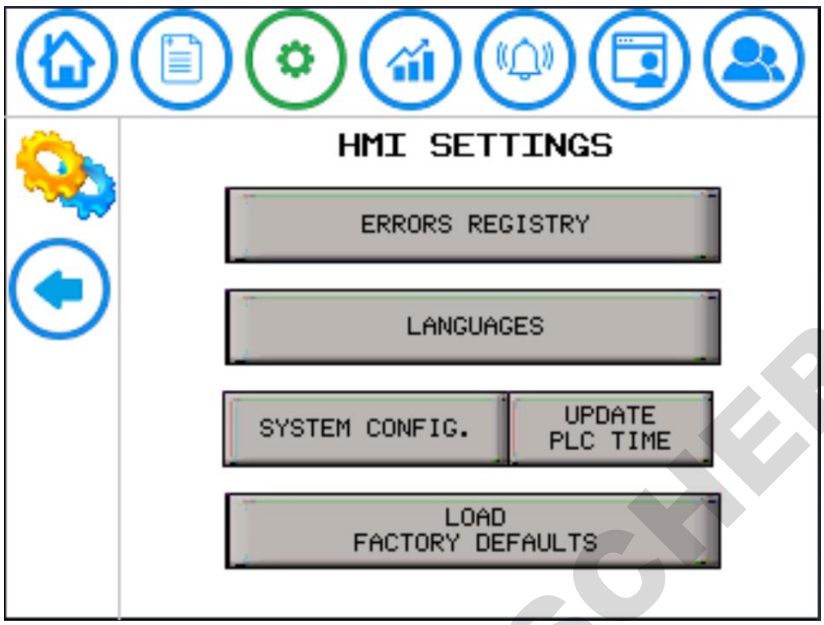


Figure 37. Settings - Programming settings - HMI configuration.

6.6.2. Set-points

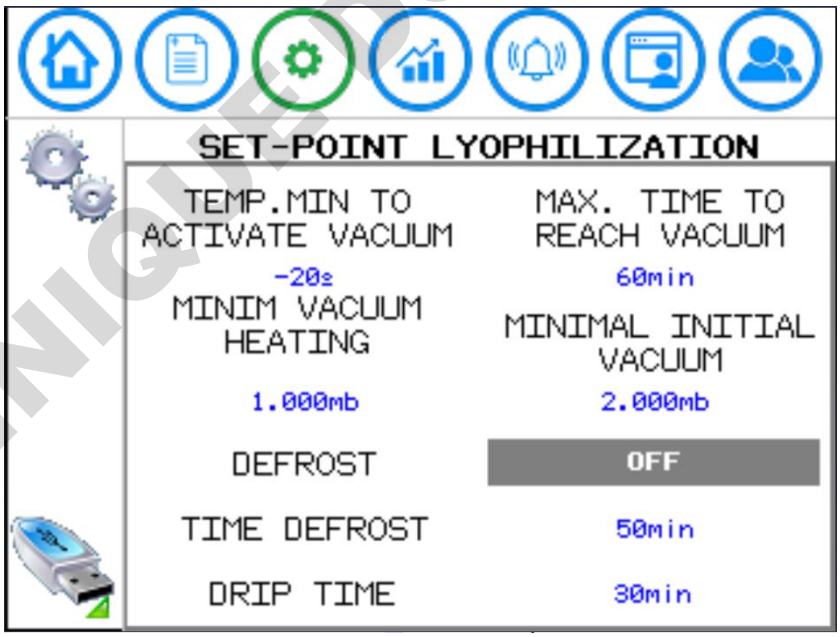


Figure 38. Settings - Set-points.

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6.6.2.1. Defrost

The cycle sequence is as follows:

1. Aeration: if there is a vacuum in the condenser, atmospheric pressure is reached first.
2. Defrost: By means of the refrigeration system connected in reverse, hot steam is injected into the condenser to melt the accumulated ice.
3. Condenser drain: Once the ice has melted, the water is drained.
4. End of cycle.



Figure 39. Defrost cycle.

6.6.3. Calibrations

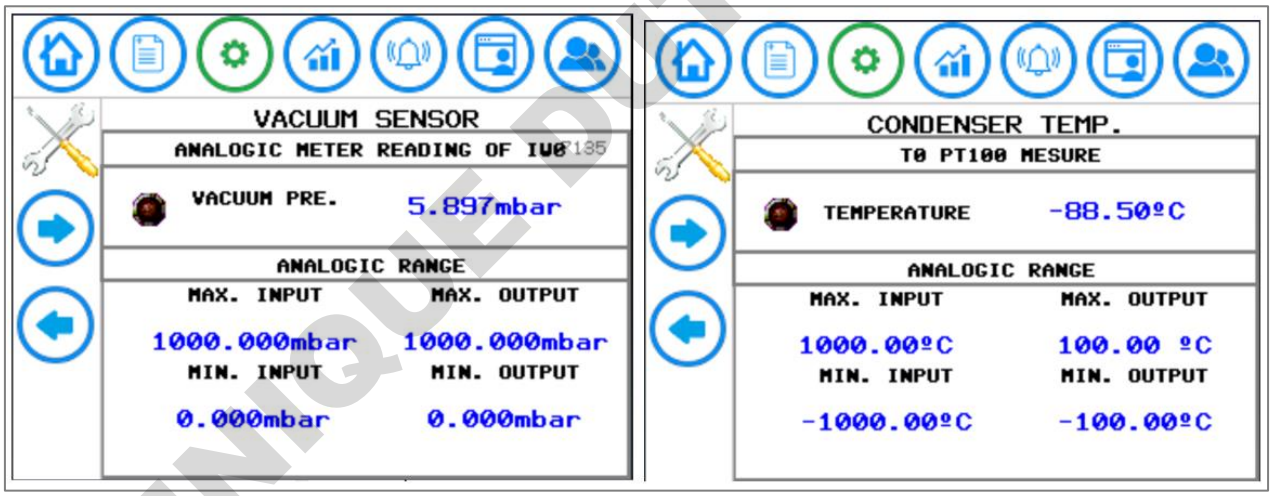


Figure 40. Settings - Calibrations.

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6.6.4. Counters

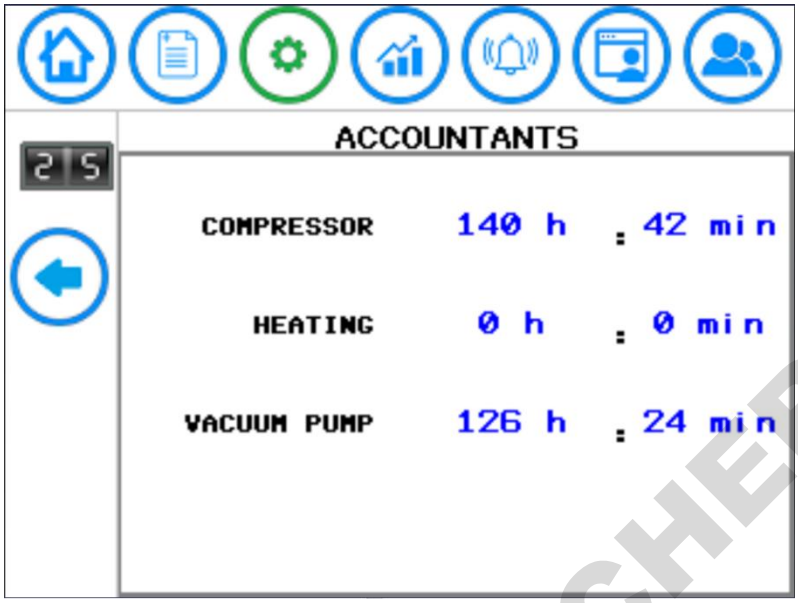


Figure 41. Settings - Counters

6.7. Trends

The graphical display shows the evolution of the cycles.

IMPORTANT: In order for this screen to work, it is necessary to connect an external USB memory stick to the USB input on the front of the freeze dryer.

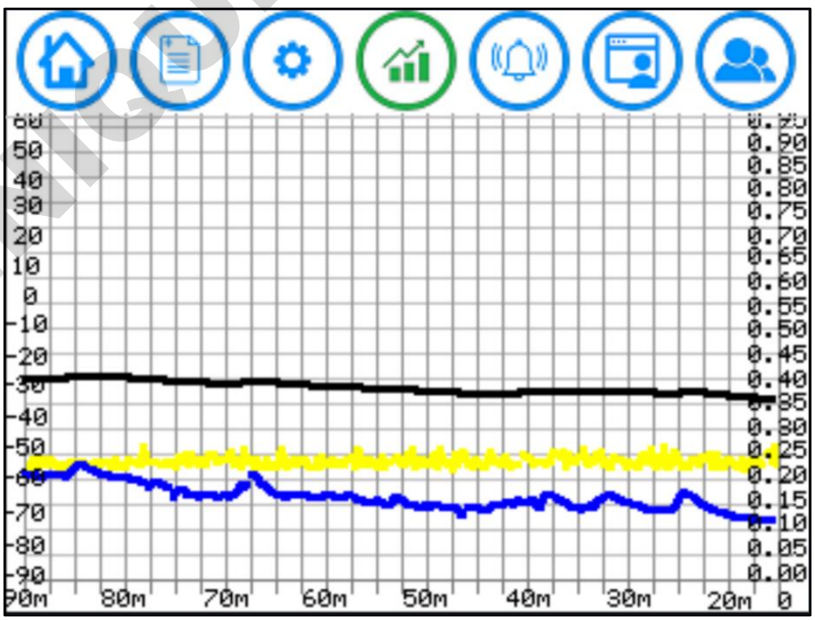


Figure 42. Trends.

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6.8. Alarms

On the alarm screen you can view the Alarm records and user logs.

In in addition to an alarm showing up on the system, a red line flashes on the display, until it is restarted.
To reset the alarms, the problem must be solved first and then press the "Reset" button.

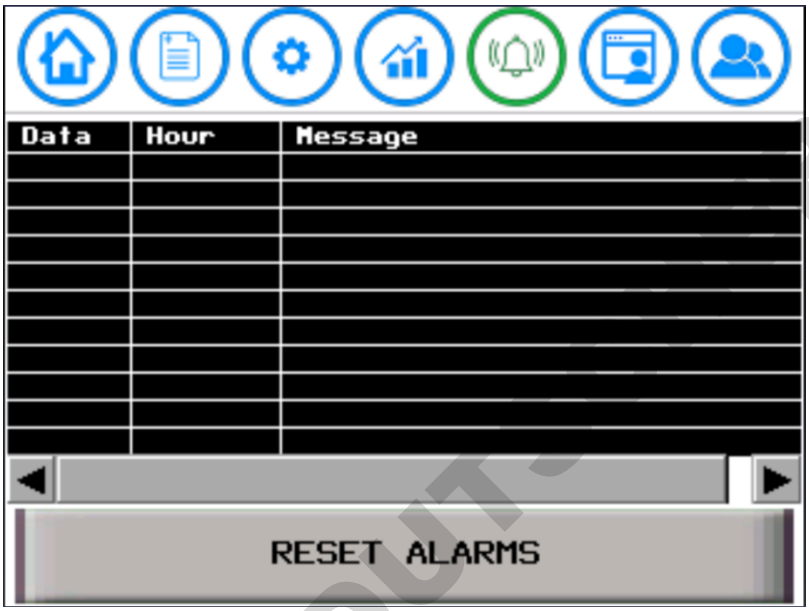


Figure 43. Alarms.

6.9. Data registration

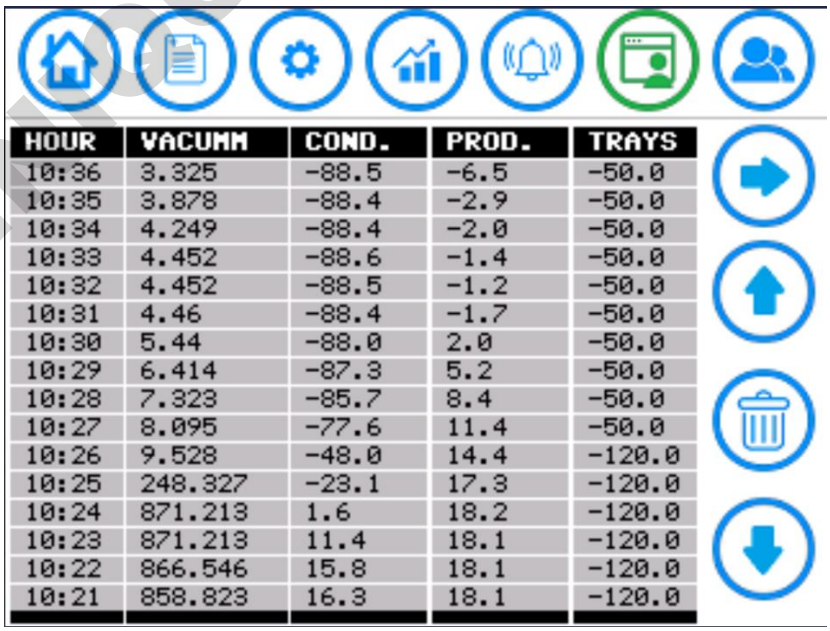


Figure 44. Data registration.

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7. Maintenance

Lyomicron freeze dryers are very robust that require very minimal maintenance. The following is a list of maintenance actions that can be carried out during the lifetime of the equipment:

- Change the vacuum pump oil.
- Keep the refrigeration system evaporators clean.
- Keep the condenser clean and dry.
- Keep the seals clean and dry.

7.1. Recommended spare parts

Description	Brand	Model
Temperature sensor condenser	Wika	TR40 PT100
Vacuum probe	Leybold	TTR91RN - 16KF
Product temperature sensor	TC	1-T-B20-2 MTRS-CL1
Oil filter (from refrigeration system)	DANFOSS	DCL 053S
Gasket	COOLVACUUM	-
Vacuum pump oil	Cogelsa	CP 100
Compressor oil	Fuchs	Triton - SEZ32

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