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A large version of the Holland Green Science logo, consisting of the text 'Holland Green Science' in blue and a stylized orange leaf to the right.

10407001

Xiros 2 Lyophilizer

# User Manual

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## II. Safety



### **IMPORTANT Safety Items to be Observed.**

#### **Safety Warnings**

The lyophilizer is designed in accordance with industry safety standards. Incorrect operation may result in safety hazards for personnel and/or the equipment.



#### **! DANGER (May cause serious damage to property and or casualties)**

1. Verify that all discharging ports are properly connected.
2. Utility requirements: ensure that the electrical meets the local standard and that the power supply is compatible to the Instrument nameplate. The power source must be properly grounded.
3. Avoid touching the pipelines (e.g. compressor exhaust pipes) to prevent scalding from high temperatures.
4. Avoid touching the chamber's inside and external surfaces due to high or low temperatures and to prevent scalding or frostbite.
5. Only trained refrigeration engineers may service the refrigeration system.
6. When conducting maintenance and or operations inside the chamber, ensure the door is securely held open.
7. Ensure appropriate PPE is worn at all times! Unprotected hands are not to open or close the door.
8. **Note:** Persons are not to enter the chamber.
9. It is prohibited to use flammable liquids or gas inside or around the instrument. The lyophilizer is not designed with explosion prevention.



#### **! WARNING (May cause property damage or personal injury)**

1. Do not stand on any instrument piping
2. Prior to operating this instrument, all operators are required to fully read this manual. Only trained and qualified operators should use the instrument.
3. It is prohibited to install any non-manufacturer authorised software onto this instrument
4. Nitrogen gas is recommended to detect any system leakage and avoid danger.
5. Power 'OFF' the power supply for PLC and all electrical equipment before working on the instrument.
6. Confirm the main power is 'OFF' prior to opening the cabinet door.

#### **IMPORTANT:**

7. Periodic checks of the heater junction box are required to ensure the terminal screws do not become loose or the wiring ages.



8. It is recommended that every five (5) years the electric heater be replaced.
9. It is recommended that once a month a qualified person checks the solid-state relay to confirm the solid-state relay is running correctly to avoid breakdowns.  
**Note:** The electrical heater will continuously heat in the event the solid-state relay breaks down, leading to the potential of a serious hazard.
10. Immediately power 'OFF' the electrical heater if the electrical heater over temperature alarm alerts / sounds. If the above is not resolved fully power 'OFF' and unplug from the main power supply and arrange a service technician to investigate and repair.



**! ATTENTION (May affect operational performance or service life)**

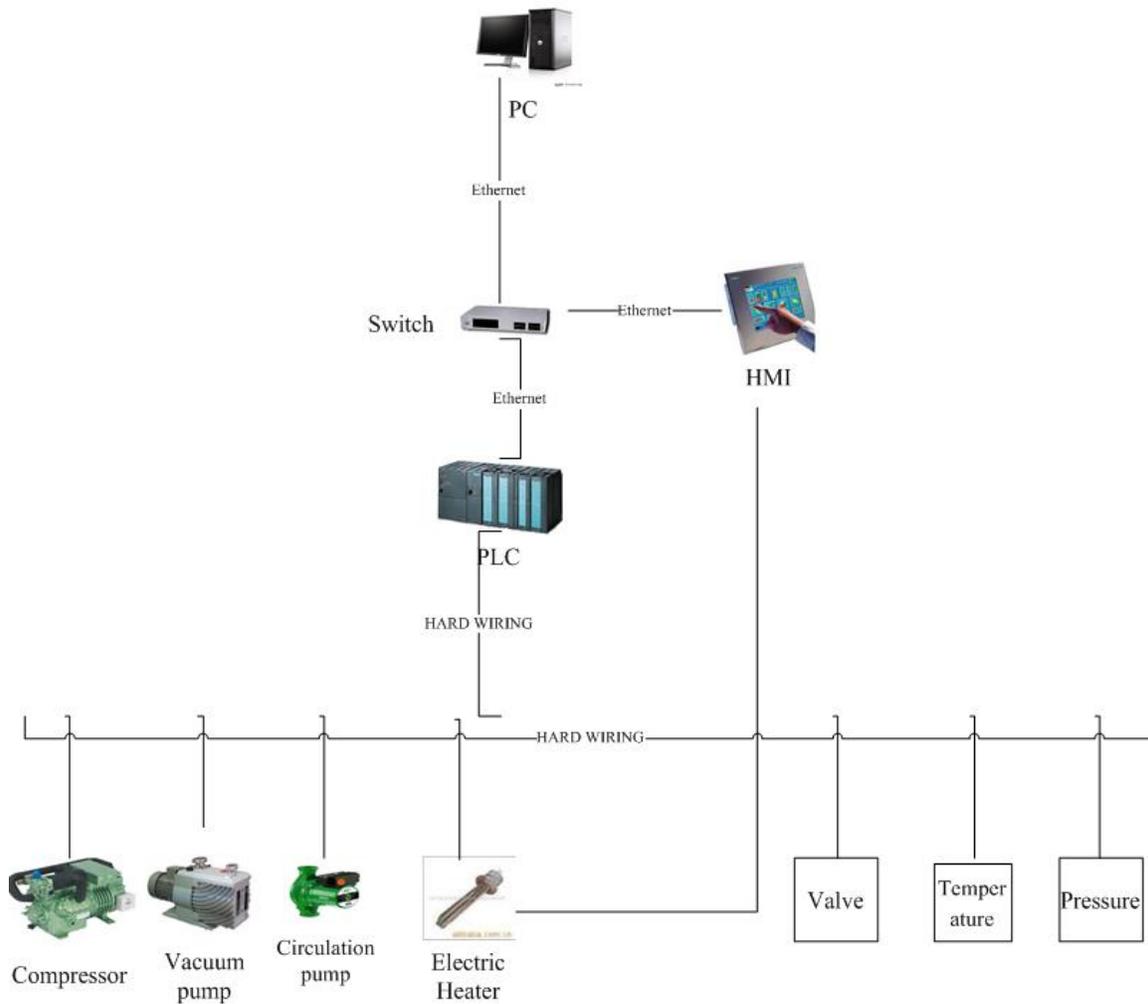
11. The overall safe operation of the instrument is the responsibility of the owner of the instrument and their assigned operator(s), who in turn are responsible for ensuring the user manual guidance is applied to, optimise the safety and protection of personnel and the Instrument before, during and after lyophilizer operation.
12. Timely maintenance of the instrument **MUST** be maintained to ensure continued safe operation, good instrument condition thus optimising the instruments service life.
13. Only accredited and qualified professional repair technicians can open the instrument or conduct required repairs. Persons performing repairs on the instrument other than those selected or approved by the Company shall operate to void any warranty contained hereinabove for the product.

## III. Xiros 2 lyophilizer Introduction

### 3.1 Purpose

This manual provides a basic overview of the Xiros 2 lyophilizer and guide to its operation. Please read the user manual carefully before using the freeze dryer.

### 3.2 Hardware Diagram



## 3.3 Hardware

All processing automation is controlled by SIEMENS HMI (Human Machine Interface) 6AV2124-0GC01-0AX0 using an 8GB memory card. A screen is used for process monitoring and control.

## 3.4 Software

The control and supervision of the lyophilizer is carried out by Portal V15 and the program monitors.

## 3.5 Abbreviations

<b>Unit</b>	<b>Meaning</b>
<b>s/sec</b>	second
<b>min</b>	minute
<b>P</b>	pressure
<b>T/h</b>	ton/hour
<b>h</b>	hour
<b>L</b>	litre

## 3.6 After Sales Support

If you have questions related to the product installation or need technical assistance, please contact the after-sales service department. The company may provide technical assistance and information regarding the instrument or equipment or service without charge at its sole discretion. Buyer assumes sole responsibility for any reliance on or use of such assistance and information, and the Company makes no warranty thereon.

Upon contact the following information is required to be provided

Product Serial Number (located on rear panel instrument nameplate)

- Warranty card
- Description of issue or problem (i.e., software or hardware)
- Method and or operating steps you have undertaken towards resolution.
- Your contact details inclusive of telephone number and email address.

For claims under the warranty please contact your local supplier. You may also send the instrument directly to manufacturer, enclosing the invoice copy and by giving reasons for the claim.

## 3.7 Proper Use

The lyophilizer is designed for use in large scale manufacturing and mining operations. It is ideal for academic and cooperate research laboratories. To prevent damage to the lyophilizer it should only be used in clean and safe environments free of corrosive gases and intense magnetic fields.

## IV. Technical Specifications

<b>Model</b>		10407001	
<b>Product Name</b>		Xiros 2 lyophilizer	
<b>External Dimensions (mm)</b>		2000 (D) x 1400 (W) x 2640 (H)	
<b>Chamber</b>			
<b>A. Design Specifications</b>			
<b>SN</b>	<b>Description</b>	<b>Specifications</b>	
1	Chamber type	Cylindrical	
2	Internal finish	Ra≤0.8μm	
<b>B. Technical Configuration</b>			
<b>SN</b>	<b>Name</b>	<b>MSM</b>	<b>QTY</b>
1	Chamber internal material	SS 304	N/A
2	External plate	SS 304, thickness 1.5mm	N/A
3	Insulation	Polyethylene material	N/A
4	Temp. sensors of thermal fluid	JUMO, A level Pt-100 hot resistance	2
<b>Shelf</b>			
<b>A. Design Specifications</b>			
<b>SN</b>	<b>Description</b>	<b>Specifications</b>	
1	Production methods	Plug welding	
2	Design pressure	3barg	
3	Temperature Range	-35~+25°C	
4	Finish	Ra≤0.8μm	
5	Level	≤±1mm/m	
<b>B. Technical Configuration</b>			
<b>SN</b>	<b>Name</b>	<b>MSM</b>	<b>QTY</b>
1	Shelf material	SS 304	N/A
2	Shelf gross dimensions	650x600x12mm	N/A
3	Shelves spacing	51mm	N/A
4	Total net shelf area	2.73m <sup>2</sup>	N/A
5	Quantity	7+1 (upper radiant shelf)	N/A
6	Trays	Size:295*650*40mm Material: 304 SS	14
<b>Door</b>			

<b>A. Design Specifications</b>			
<b>SN</b>	<b>Description</b>	<b>Specifications</b>	
1	Main door open direction	According to user's requirements	
2	Main door open angle	110°	
3	Internal finish	Ra≤0.8μm	
<b>B. Technical Configuration</b>			
<b>SN</b>	<b>Name</b>	<b>MSM</b>	<b>QTY</b>
1	Material of main door	SS 304	N/A
2	External cover of door	SS 304	N/A
3	Sight glass without illuminated	DN150	1
<b>Coils</b>			
<b>A. Design Specifications</b>			
<b>SN</b>	<b>Description</b>	<b>Specifications</b>	
1	Maximum ice capacity	10Kg/batch	
2	Minimum coiled temp.	-45°C	
<b>B. Technical Configuration</b>			
<b>SN</b>	<b>Name</b>	<b>MSM</b>	<b>QTY</b>
1	Coils pipe material	SS 304	N/A
2	Temp. sensors of coils	Jumo, A level Pt-100 Hot resistance	1
<b>Refrigeration System</b>			
<b>A. Design Specifications</b>			
<b>SN</b>	<b>Description</b>	<b>Specifications</b>	
1	Shelf cooling speed on empty load (Silicone oil inlet)	+25~-35°C≤60min.	
2	Coils cooling speed on empty load	+20~-40°C≤30min.	
<b>B. Technical Configuration</b>			
<b>SN</b>	<b>Name</b>	<b>MSM</b>	<b>QTY</b>
1	Compressor	Copeland	1
2	Refrigerant	CFC-free R448A	TBD
3	Solenoid valve	Danfoss	TBD
4	Expansion valve	Danfoss	TBD
5	Pressure meter	Refco	1

<b>Circulation System</b>			
<b>A. Design Specifications</b>			
<b>SN</b>	<b>Description</b>	<b>Specifications</b>	
1	Heating rate	Approx 1°C/min (unloaded, from -35°C to +25°C)	
2	Silicon oil viscosity	5cSt@25°C	
<b>B. Technical Configuration</b>			
<b>SN</b>	<b>Name</b>	<b>MSM</b>	<b>QTY</b>
1	Circulation pump	WILO, Top-SD40/10	1
2	Thermal fluid	Low viscosity silicone oil	TBD
3	Heater	4Kw	1
4	Plate heat exchanger	Alfalaval	1
5	Temp. sensors of thermal fluid	Jumo, A level Pt-100 Hot resistance	2
<b>Vacuum System</b>			
<b>A. Design Specifications</b>			
<b>SN</b>	<b>Description</b>	<b>Specifications</b>	
1	Final vacuum	2.6Pa	
2	Evacuation speed	From 1 atm. to 10pa≤30min	
3	Leakage rate	5×10 <sup>-3</sup> pa.m <sup>3</sup> /sec.	
<b>B. Technical Configuration</b>			
<b>SN</b>	<b>Name</b>	<b>MSM</b>	<b>QTY</b>
1	Vacuum pump	Youcheng, TRP-36	1
2	Valve for condenser isolation	DN50	1
3	Vacuum gauge	Edwards	1
<b>Aeration System</b>			
<b>A. Technical Configuration</b>			
<b>SN</b>	<b>Name</b>	<b>MSM</b>	<b>QTY</b>
1	Aeration valve	Edwards	1
2	Pipeline	SS304	TBD
<b>Control System</b>			
<b>A. Design Specifications</b>			
<b>SN</b>	<b>Description</b>	<b>Specifications</b>	

1	Electric standard	UL	
2	Protection class	IP22	
3	Software function	Freeze drying (manual and automatic). De-icing (manual)	
4	Max recipe number	Six(6)	
5	Date	History date, history audit, history alarm can be stored for a maximum of one month	
6	Permissions	3 Level permissions. (administrator, operator, parameter)	
7	User management		
<b>B. Technical Configuration</b>			
<b>SN</b>	<b>Name</b>	<b>MSM</b>	<b>QTY</b>
1	PLC	Siemens CPU-1200	1
2	Touch screen	Siemens TP700 smart Comfort	1
<b>Utility Requirements (Approx.)</b>			
<b>SN</b>	<b>Description</b>	<b>Requirements</b>	
1	Total power	19Kw @ 480V, 60Hz, 3P, 5W	
2	Clean air for aeration system	40L/min @ 0.5~1bar	
3	Room environment temperature	≤25°C	
<b>Standard Documentation</b>			
<b>SN</b>	<b>Name</b>	<b>QTY</b>	
1	Operation Manual (OM)	1	
2	Installation Manual (IM)	1	
3	Pipes & Instruments Drawing (P&ID)	1	
4	Layout Drawing	1	
5	Electric Drawing	1	

## V Inspection

### 5.1 Packing List

Unpack the equipment carefully and check for any damage which may have arisen during transport. In the event of identified damage, please contact [serviceusa@hollandgreenscience.com](mailto:serviceusa@hollandgreenscience.com) for technical support.

- Carefully unpack the shipping container.
- Remove the Instrument and place it onto a clean, level surface.
- Check the instrument and accessories against the below 'Packing List'.

If the instrument or accessories are found to be incorrect, or the accessories are incomplete or abnormal, please contact the supplier/ manufacturer.

No.	Type	Name	Unit	Qty.	Remark
1	Main Unit	Lyophilizer	pcs	1	
2		Quick Setup Card		1	
3	Spare part	Tray	pcs	14	
4	Spare part	Alarm light	pcs	1	
5	Spare part	Bellows of vacuum pump inlet	pcs	1	
6	Spare part	Vacuum gauge (EDWARDS)	pcs	1	
7	Spare part	Moisture filter DAB-90-90	pcs	1	
8	Spare part	Electric ball valve	pcs	1	
9	Spare part	Connection	pcs	1	
10	Spare part	Move the wheel	pcs	4	
11	Spare part	screws	pcs	16	
12	Spare part	Elbow	pcs	1	
13	Spare part	Sight glass	pcs	1	
14	Spare part	Clamp ISO50	pcs	3	
15	Spare part	Gasket ISO50	pcs	3	

No.	Type	Name	Unit	Qty.	Remark
16	Spare part	Clamp ISO38	pcs	5	
17	Spare part	Gasket ISO38	pcs	5	
18	Spare part	Clamp KF40	pcs	2	
19	Spare part	Gasket KF40	pcs	2	
20	Spare part	Older KF40	pcs	2	
21	Spare part	Vacuum pipe	pcs	1	
22	Spare part	After pressure pipe	pcs	1	
23	Spare part	Uninterruptible power supply (UPS)	pcs	1	
24	Spare part	Silicon oil	L	20	
25	Document	File package	box	1	



**Note:**

If you find any visible damage, please do not connect the instrument to a Power supply.

## VI. Installation

### 6.1 Safety Rule

Please read the user manual carefully before operating the lyophilizer. Only properly trained and qualified personnel should operate the lyophilizer.

### 6.2 Transportation

Before transporting the lyophilizer, drain the silicon oil and refrigerant into separate containers to avoid leakage during transportation.

### 6.3 On-Site Assembly

Before assembling the lyophilizer, make sure the area of use meets the following conditions:

- Remove any caustic, flammable and explosive materials from the workshop area. The lyophilizer should be located on a level flat surface.
- The lyophilizer should be operated in a temperature controlled environment between 5°C to 30°C.
- The workshop area must be free of excessive vibration for proper operation of the lyophilizer.
- The lyophilizer should not be directly exposed to sunlight.

### 6.4 Tools needed

- meter ruler, laser leveler



Fig 1: Meter Ruler.



Fig 2: Laser Leveller

## 6.5 Chamber set up

Benchmark choice of the general chamber

**The vertical surface of the box frame is the vertical reference.**

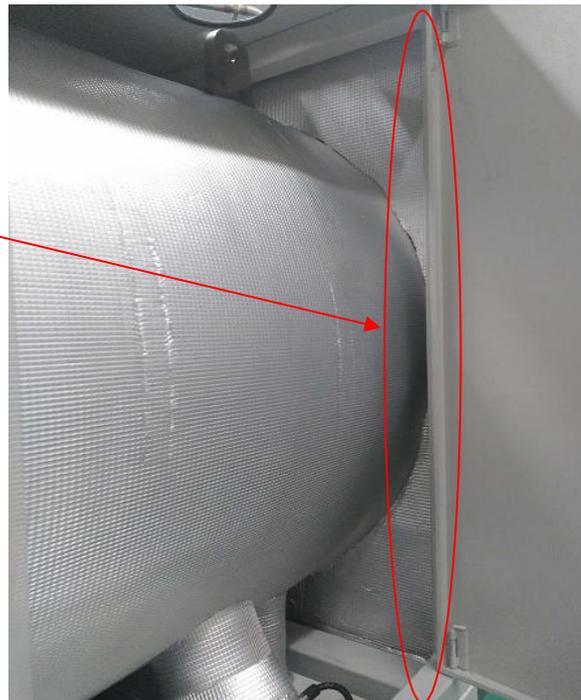


Fig 3

**Adjust the standard of the left and right sides of the box to the upper surface of the box door frame.**

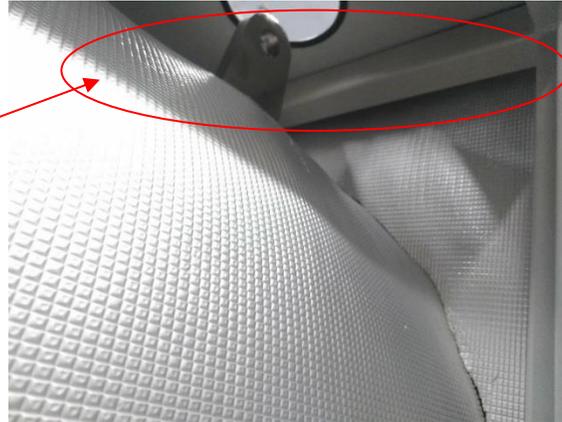


Fig 4

### 6.5.1 Chamber location (consider the chamber and the frame as a whole)

- When the lyophilizer arrives, move it to the location it will be used before removing the skids. Then secure and lock the pulleys to finish the chamber setup.
- Install the cable and bracket of the electric tank.

## VII. Components Assembly

### 7.1 Vacuum System Assembly

After securing the vacuum pumps as shown in Fig 6, connect the vacuum pipeline to the pump and chamber and clamp and secure the fixtures as shown in Fig 5.



Fig 5

**Vacuum Pipeline**



Fig 6

**Prior to Installation**

Install the pump isolation valve.



Fig 7

**Pump Isolation Valve**

**Lock Nut and Bolts**

## 7.2 Instrumentation Installation

The vacuum gauge measures the chamber and the pump vacuum pressure. The vacuum gauge is connected to the chamber with a quick union. See Fig 8 below.

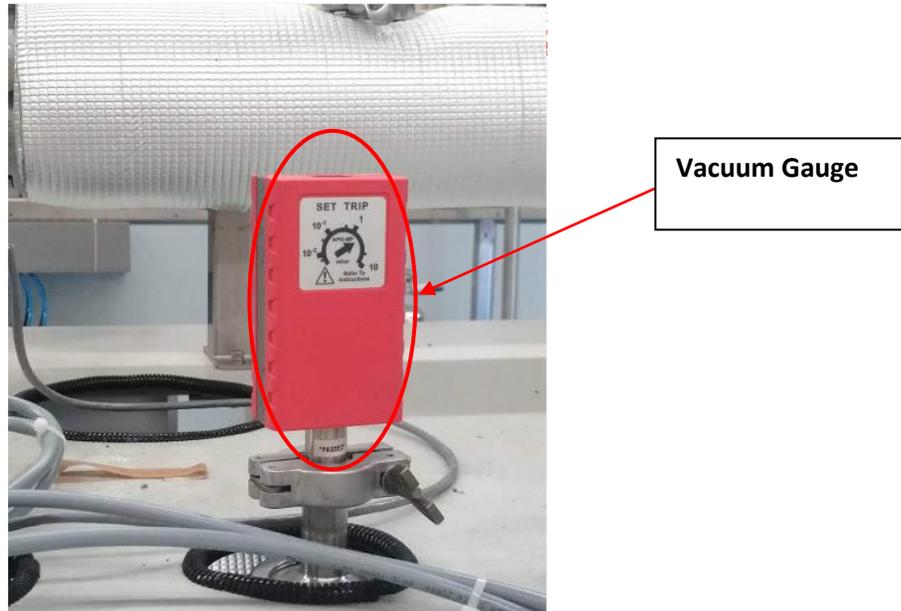


Fig 8

## 7.3 Electric Cabinet Installation

The UPS (Uninterrupted Power Supply) electrical connections are disconnected during shipping for packing convenience and must be assembled on site as follows:

- Connect the power line to the lyophilizer as shown in Fig 9 below.

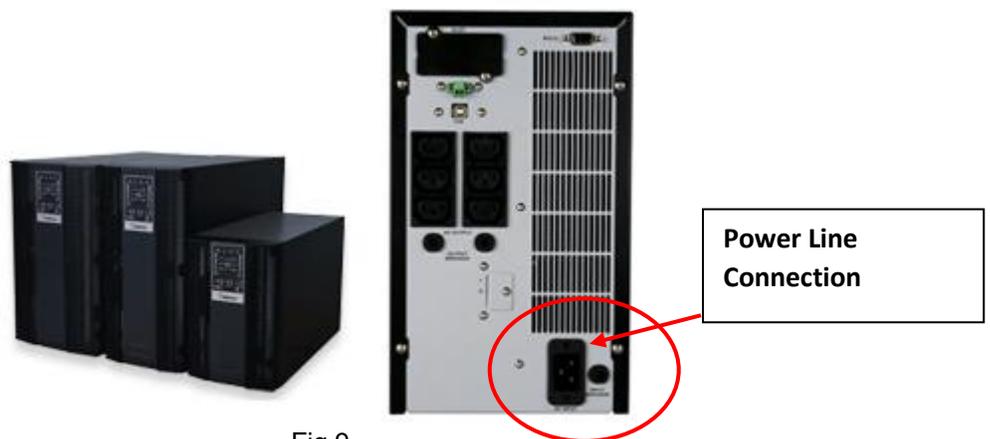


Fig 9

- The alarm indicator is to be installed on the top of the electrical cabinet as shown in Fig 10.



Fig 10

## 7.4 Expansion Tank Installation

- The expansion tank is to be positioned on the chamber or frame using bolts to compensate for silicone oil expansion.

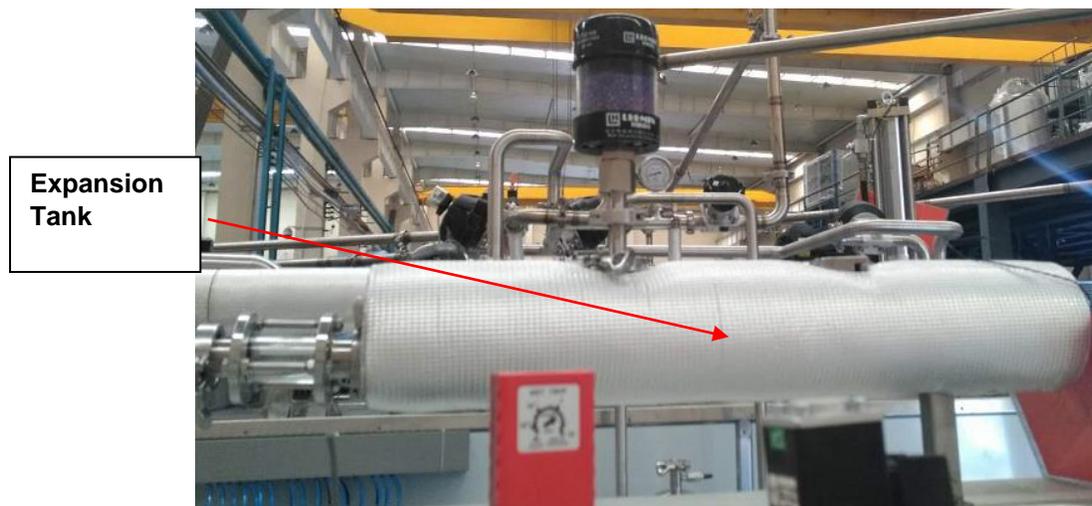


Fig 11

- Secure the bottom bracket bolt of the expansion tank.



Fig 12

- Position the expansion tank on the bracket, connect the bottom of the expansion tank and oil pipe with a clamp as shown in Fig 13 below.



Fig 13

**Note:** Above-mentioned components are optional and may not be included.

## VIII. Oil Refilling

The lyophilizer is shipped unassembled without silicon or hydraulic oil. Once the lyophilizer is properly installed the silicon and hydraulic oil tanks should be filled with the oils. Make sure to check the compressor and vacuum pumps oil level and add additional oil as needed.

### 8.1 Vacuum Pump Oil Level

The vacuum pumps oil level should be between the 'MAX' line and the 'MIN' markers as shown in Fig 14 below.

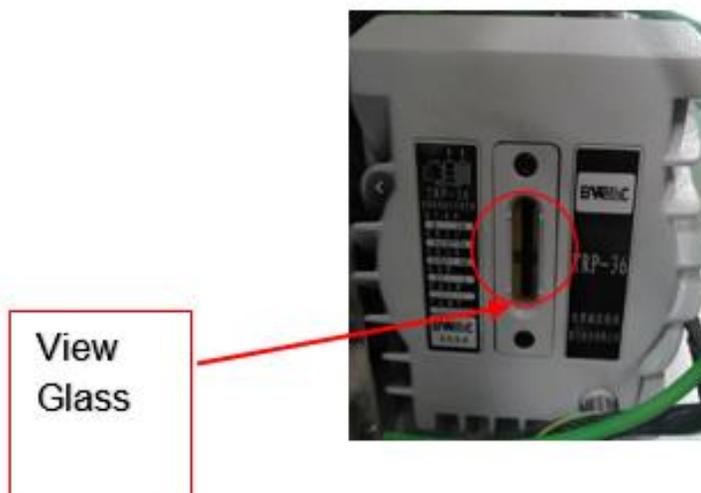


Fig 14

If the level is below the 'MIN' line marker add vacuum pump oil at the injection port shown in Fig 15 below.

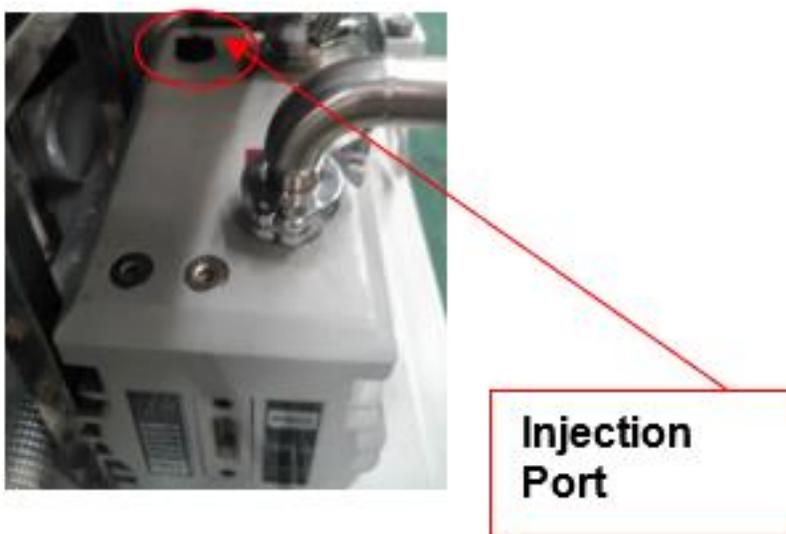


Fig 15

## 8.2 Refilling the Silicon Oil

The silicon oil contains air when filling which needs to be removed before operation according to the following steps:

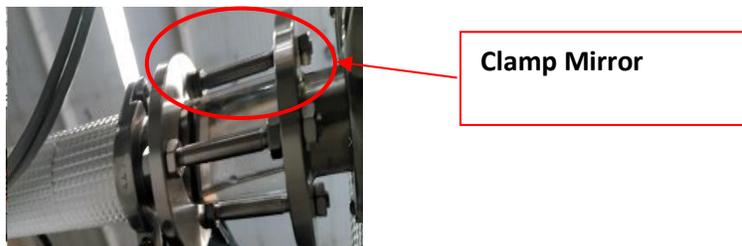


Fig 16

- Fill the silicon oil in the expansion tank until full as shown in Fig 16.
- Connect the circulation pipeline discharging valve and expansion tank with the flexible hose and then press 'START' to start the circulation pump. Open the discharge valve to vent any air inside the pipeline.
- Add silicon oil into the balance barrel until the silicon oil level indicated on the clip-on sight glass shows it is full.

## IX. Software Operation

### 9.1 User Permission Management

Start at the 'Main' page and click the 'UserManage' tab as shown in Fig 17 below.

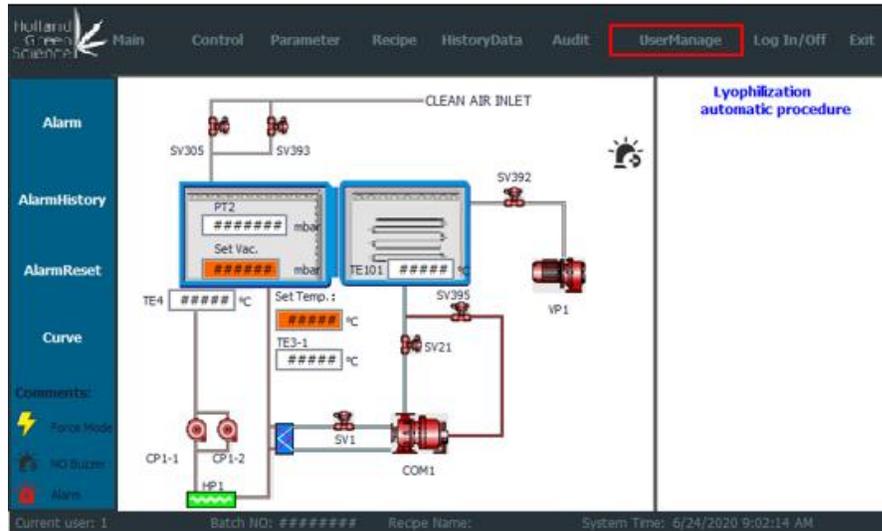


Fig 17

Once the page is shown as in Fig 18, select which password to modify under the "Password" column and click to modify.

User	Password	Group	Logoff time
1	*****	Administr...	30
Administrator	*****	Administr...	30
Operator	*****	Operator...	30
Parameter	*****	Paramet...	30
PLC User	*****	Unauthor...	5

Fig 18

A dialog box (shown below in Fig 19) will pop up prior to modifying the password. Type in the new password then retype the new password under “Confirmation”. Then click “OK”.

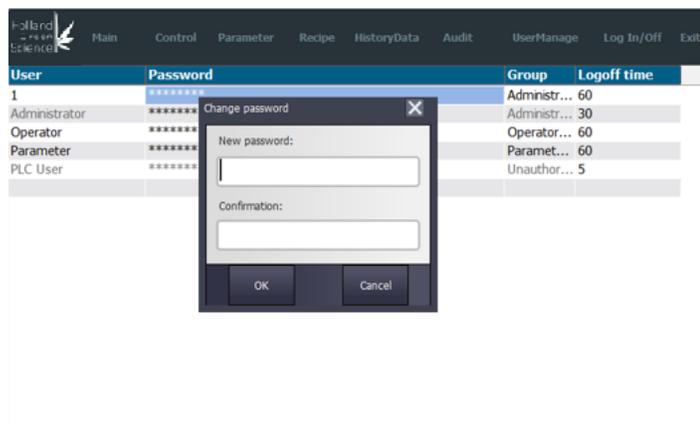


Fig 19

Once the above steps are completed the password is modified.

NOTE: Initial ID and password of the system

Description	(Level 1) Administrator	(Level 2) Parameters	(Level 3) Operator
User ID	1	2	3
Password	111	222	333

### Group Member Permissions

Description	(Level 3) Operator	(Level 2) Parameters	(Level 1) Administrator
Ability to Access Level Modify	No	No	Yes
Ability to Start & Stop AUTO/ Manual Lyophilisation Operation	Yes	No	Yes
Ability to Setup Parameter Changes for Each Phase	No	Yes	Yes
Ability to Create Recipe	No	Yes	Yes
Ability to Delete Recipe	No	No	Yes
Ability to Save Recipe	No	Yes	Yes

Description	(Level 3) Operator	(Level 2) Parameters	(Level 1) Administrator
Ability to Download Recipe	Yes	Yes	Yes
Ability to View Audit	Yes	Yes	Yes
Ability to View History Data	Yes	Yes	Yes

## 9.2 Software Operating Instructions

**Main:** Return to main interface.

**Control:** Enter control interface.

**Parameter:** Set up parameters.

**Recipe:** 'Recipe' permits the following operations:

View/NewRecipe/Save/Delete/Modify/Download.

**Current recipe:** View a current recipe.

**History Data:** View history data.

**Audit:** View logged data.

**User Manage:** Manage user accounts.

**Log in/Off:** Log in or out the system.

**Alarm:** View current alarm items.

**Alarm History:** View alarm historical data.

**Alarm Reset:** Reset the alarm.

**Curve:** View the curve.

**Force Mode:** Manually open or close motors or valves in this mode.

**No Buzzer:** Eliminate the buzzer.

**Alarm:** When there is an alarm the icon will turn red.

**Exit:** Exit the system.

## 9.3 Recipe

Once the following recipe setting page is shown(Fig 20), locate and click on the “Recipe” tab.

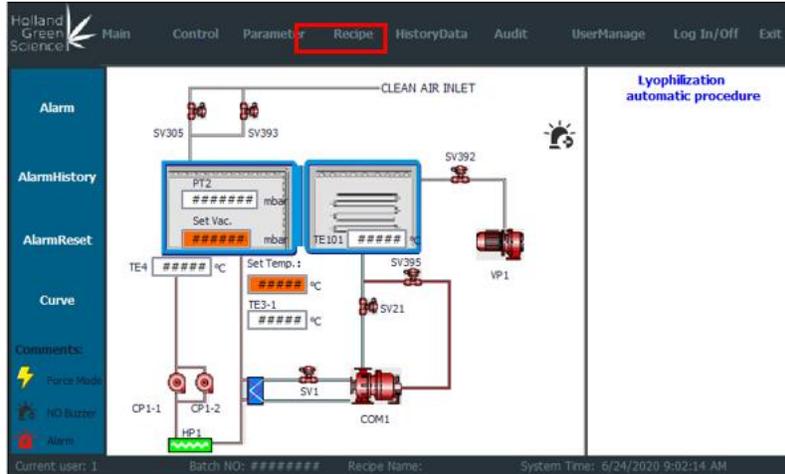


Fig 20

The next page will be displayed as shown in Fig 21. Click on “Recipe Setting” tab boxed in red.

Recipe Management		General Parameters	
Set Temp H(°C):	0.0	Set Temp L(°C):	0.0
Vacuum Alarm (mbar)	0.0000	Alarm Keep Time(s)	0
<input type="checkbox"/> Shelf precooling:			
Set Temp.:		+0.0	
<b>Shelf Freezing:</b>			
	Set Temp.°C	Ramp Time(min)	Soak Time(min)
Step1:	+0.0	0	0
Step2:	+0.0	0	0
Step3:	+0.0	0	0
Step4:	+0.0	0	0
Step5:	+0.0	0	0
<b>Coils Freezing:</b>			
Set Temp.(°C):		+0.0	
Soak Time(min):		0	
<b>System evacuation:</b>			
Set Vacuum (mbar)		0.0000	
<input type="checkbox"/> Unloading cooling			
Set Temp.(°C):		+0.0	

Primary Drying:			
	Set Temp.°C	Ramp Time(min)	Soak Time(min)
Step1:	+0.0	0	0
Step2:	+0.0	0	0
Step3:	+0.0	0	0
Step4:	+0.0	0	0
Step5:	+0.0	0	0
<input type="checkbox"/> Pressure rise test 1:			
Set Pressure(mbar)		0.000	
Test Time(min)		0	
Test Times		0	
Interval Time(min)		0	
<b>Secondary Drying:</b>			
	Set Temp.°C	Ramp Time(min)	Soak Time(min)
Step1:	+0.0	0	0
Step2:	+0.0	0	0
Step3:	+0.0	0	0
Step4:	+0.0	0	0
Step5:	+0.0	0	0
<input type="checkbox"/> Pressure rise test 2:			
Set Pressure(mbar)		+0.000	
Test Time(min)		0	
Test Times		+0.000	
Interval Time(min)		0	

Fig 21

The Recipe Management page will then be shown and a recipe can be created, saved, deleted, modified or downloaded. Refer to section 11.5 for detailed recipe management.

The screenshot displays the 'Recipe Management' interface with several sections:

- General Parameters:**
  - Set Temp H(°C): 0.0
  - Set Temp L(°C): 0.0
  - Vacuum Alarm (mbar): 0.0000
  - Alarm Keep Time(s): 0
- Shelf precooling:**
  - Set Temp.: +0.0
- Shelf Freezing:**

	Set Temp.°C	Ramp
Step1:	+0.0	0
Step2:	+0.0	0
Step3:	+0.0	0
Step4:	+0.0	0
Step5:	+0.0	0
- Coils Freezing:**
  - Set Temp.(°C): +0.0
  - Soak Time(min): 0
- System evacuation:**
  - Set Vacuum (mbar): 0.0000
- Unloading cooling:**
  - Set Temp.(°C): +0.0
- Primary Drying:**

	Set Temp.°C	Ramp Time(min)	Soak Time(min)
Step1:	+0.0	0	0
Step2:	+0.0	0	0
Step3:	+0.0	0	0
Step4:	+0.0	0	0
Step5:	+0.0	0	0
- Pressure rise test 2:**
  - Set Pressure(mbar): +0.000
  - Test Time(min):
  - Test Times: +0.000
  - Interval Time(min):

A central 'Recipe Management' dialog box is open, featuring a 'Recipe Name' dropdown menu and icons for adding, saving, deleting, and downloading recipes. A sidebar on the right contains navigation buttons: 'Current Recipe', 'Recipe Setting', and a home icon.

Fig 22

## 9.4 Recipe Setting Parameters

- Set Temp H (°C): Sets the upper limit of the process temperature.
- Set Temp L (°C): Sets the lower limit of the process temperature.
- Vacuum Alarm (mbar): Sets the maximum pressure value above which the vacuum alarm will trigger during the heating (drying) process. When the vacuum value exceeds the P2 pressure setting, the alarm is triggered. Once the P2 set time duration is over, air flow will be stopped and the shelf freeze initiated. The alarm is stopped when the vacuum pressure value is lower than P1.
- Alarm Keep Time (S): After alarm is triggered for the set time, air intake stops and the system begins cooling of the shelves.
- Shelf Precooling: An option for constant temperature regulation.
- Shelf Freezing: Shelves cooling.
- Set Temp (°C), Ramp Time (min) and Soak Time (min): The process is setup as required. There are 12 phases in the process that are controlled by Set Temp (°C), Ramp Time (min) and Soak Time (min) for every Step phase. The process may be considered complete using either the Set Temp (°C), or Ramp Time (min), or Soak Time (min).
- Coils Freezing: Cool coils to Set Temp (°C) and the time duration is Ramp Time (min).

- System Evacuation: the Vacuum value
- Set Vacuum: Set the level of the vacuum pressure (P1) required to start of heating during drying. If current vacuum > alarm P1, stop the heater.
- Primary Drying: Set Temp (°C), Ramp Time(min) and Soak Time(min): Sets the process temperatures and time as required. There are 12 possible phases available for process control. The required time and temperature of each phase is controllable. The process may be considered finished based on Set Temp (°C), or Ramp Time (min), or Soak Time (min).
- Pressure Rise Test: This option is available to the end of primary drying.
- Set Pressure(mbar): Set up the maximum pressure rise P (mbar).
- Test Time(min): Duration (min) for maximum pressure rise.
- Test Times: Repeat set test times if the pressure rise test has failed.
- Interval Time(min): The interval time between each test if the previous pressure rise test has failed.

**Note:**

The process proceeds to the next process phase automatically if the first pressure test is successful. If the first pressure test fails, the test should be repeated after drying is completed for a predefined time. If several tests fail, the operator needs to manually select continue run or abort the process.

- Secondary Drying: Set Temp (°C), Ramp Time(min) and Soak Time(min): Sets the process temperatures and time as required. There are 12 possible phases available for process control. The required time and temperature of each phase is controllable. The process may be considered finished based on Set Temp (°C), or Ramp Time (min), or Soak Time (min).
- Pressure Rise Test2: This option is available to the end of secondary drying.
- Set Pressure(mbar): Set up the maximum pressure rise P (mbar).
- Test Time(min): Duration (min) for maximum pressure rise.
- Test Times: Repeat set test times if the pressure rise test has failed.
- Interval Time(min): The interval time between each test if the previous pressure rise test has failed.

**Note:**

The process proceeds to the next process phase automatically if the first pressure test is successful. If the first pressure test fails, the test should be repeated after drying is completed for a predefined time. If several tests fail, the operator needs to manually select continue run or abort the process.

- Stoppering: An option for stoppering in a certain vacuum, it will be performed if it is selected.

- Unloading Cooling: An option for unloading in a certain temperature, it will be performed if it is selected (This temperature is the set temperature, and the temperature range is -35.0~+25.0°C).
- Set Temp: The set temperature for the shelf.

**Note:**

During the cycle of the recipe interface, you cannot load a recipe or make a new recipe etc.

## 9.5 Recipe Management

Select one recipe from the drop-down menu (See Fig 23 below).

The screenshot displays the 'Recipe Management' interface. It is divided into several sections:

- General Parameters:** Includes 'Set Temp H(°C): 0.0', 'Set Temp L(°C): 0.0', 'Vacuum Alarm (mbar) 0.0000', and 'Alarm Keep Time(s) 0'.
- Shelf precooling:** A checkbox is present, with 'Set Temp.: +0.0' below it.
- Shelf Freezing:** A table with columns 'Set Temp.°C' and 'Ramp'. It lists Step1 through Step5, all with '+0.0' and '0'.
- Coils Freezing:** Includes 'Set Temp.(°C): +0.0' and 'Soak Time(min): 0'.
- System evacuation:** Includes 'Set Vacuum (mbar) 0.0000'.
- Unloading cooling:** A checkbox is present, with 'Set Temp.(°C): +0.0' below it.
- Primary Drying:** A table with columns 'Set Temp.°C', 'Ramp Time(min)', and 'Soak Time(min)'. It lists Step1 through Step5, all with '+0.0', '0', and '0'.
- Pressure rise test 2:** Includes 'Set Pressure(mbar) +0.000', 'Test Time(min)', 'Test Times +0.000', and 'Interval Time(min)'.

In the center, a 'Recipe Management' pop-up window is open, featuring a 'Recipe Name' dropdown menu highlighted with a red box. Below the menu are icons for adding, saving, deleting, and switching between recipes (A/B), along with a download icon. On the right side of the interface, there are navigation buttons: a back arrow, 'Current Recipe', 'Recipe Setting', and a home icon.

Fig 23

Click 'Save Recipe' from the menu to save the recipe (See Fig 24).

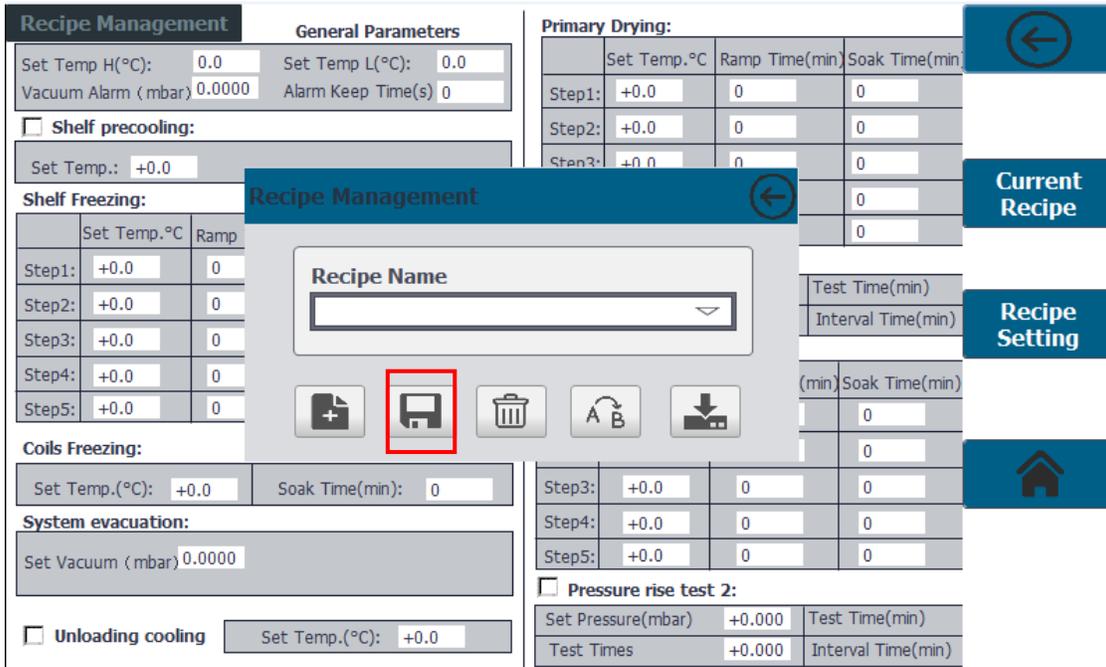


Fig 24

Click 'Modify' icon (see Fig 25 below, icon is circled in red) and modify the recipe.

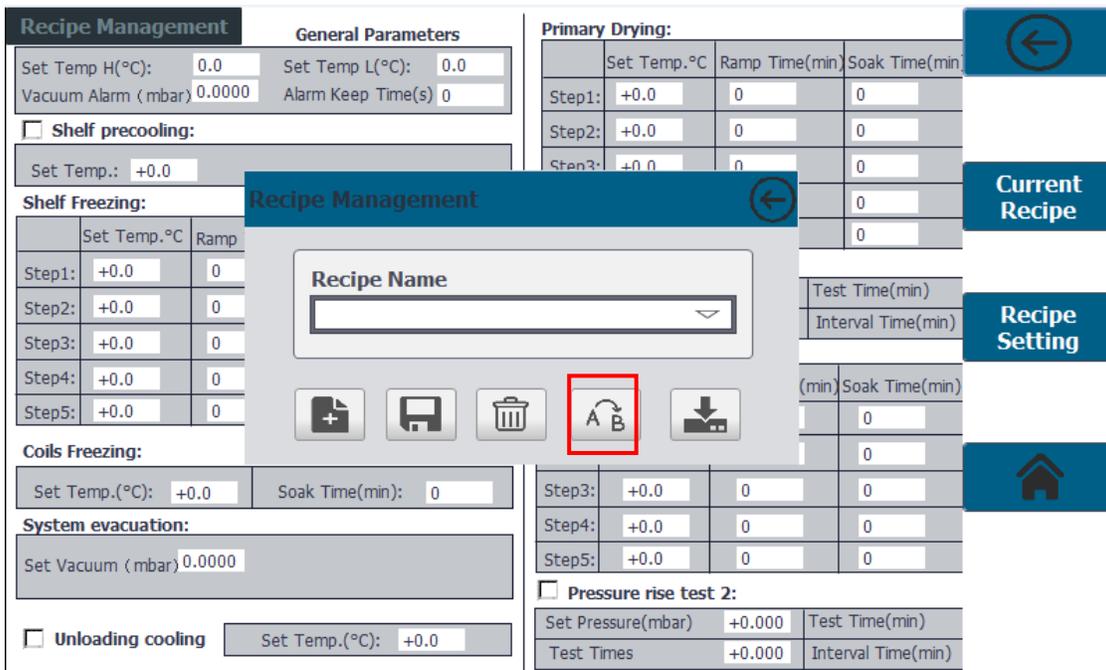


Fig 25

Click the 'Download' icon (see Fig 26 below, icon is circled in red) to download the selected recipe.

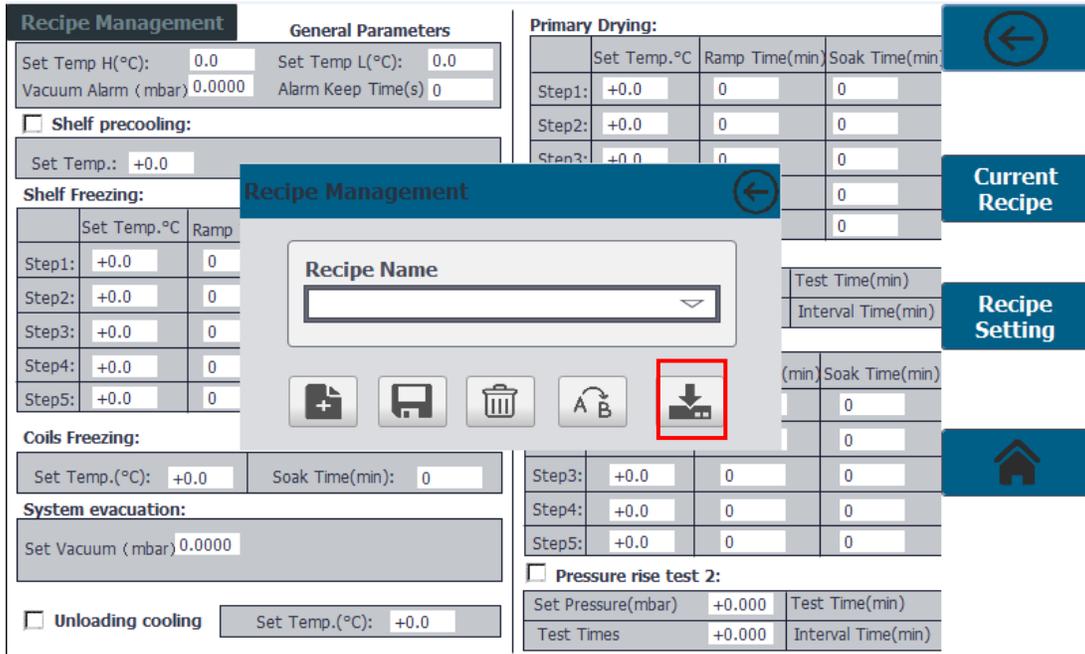


Fig 26

Click the 'Delete' icon (see Fig 27 below, icon is circled in red) to delete the selected recipe.

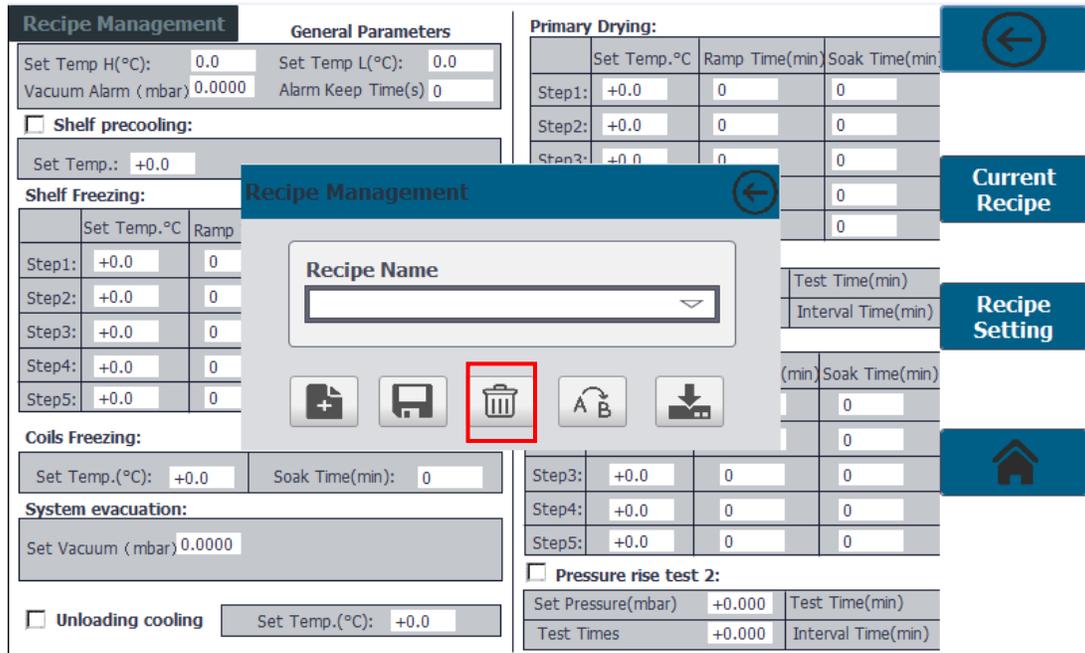


Fig 27

Click the 'New Recipe' icon (see Fig 28 below, icon is circled in red).

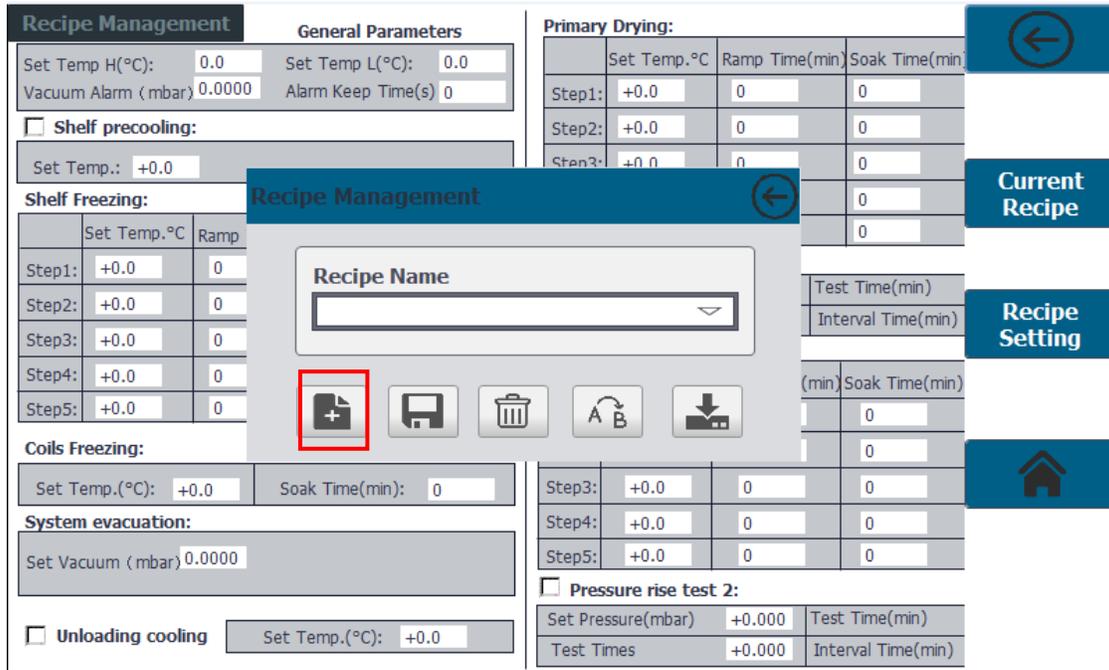


Fig 28

## 9.6 Parameter Manager

Return to the main page and click the 'Parameter' tab.

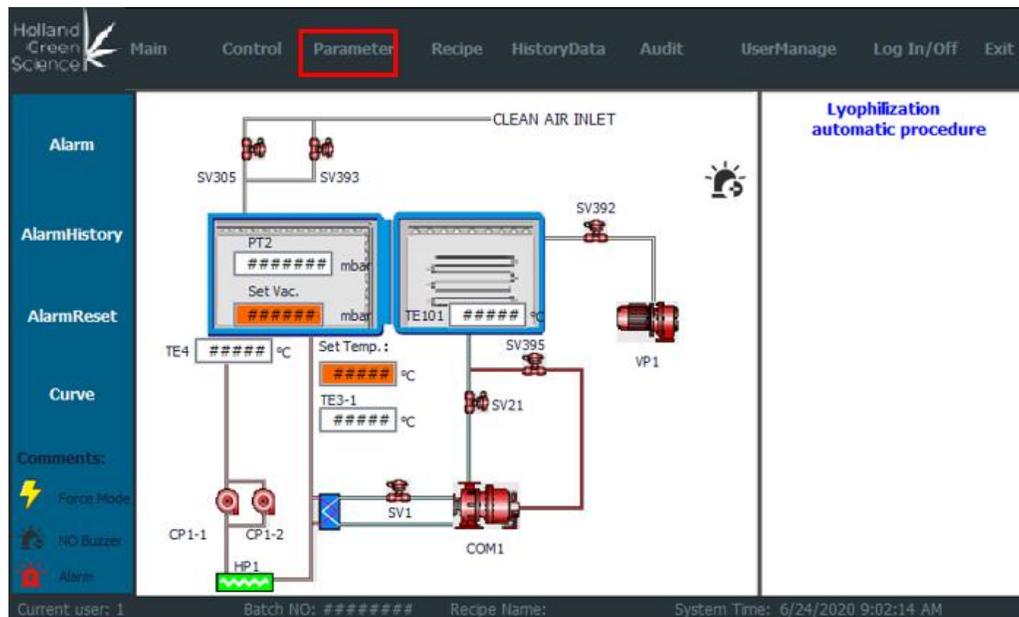


Fig 29

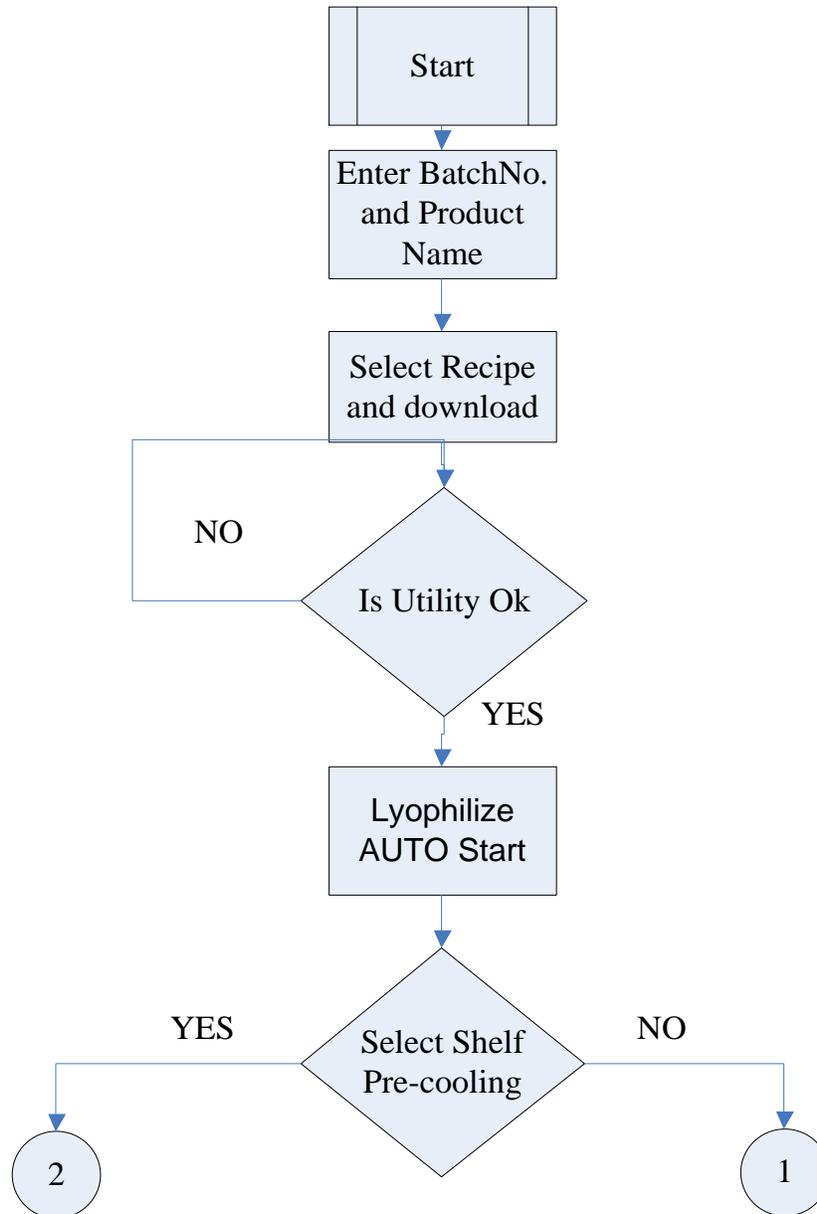
You should now be in the 'LYO Parameters' page (see Fig 30 below).

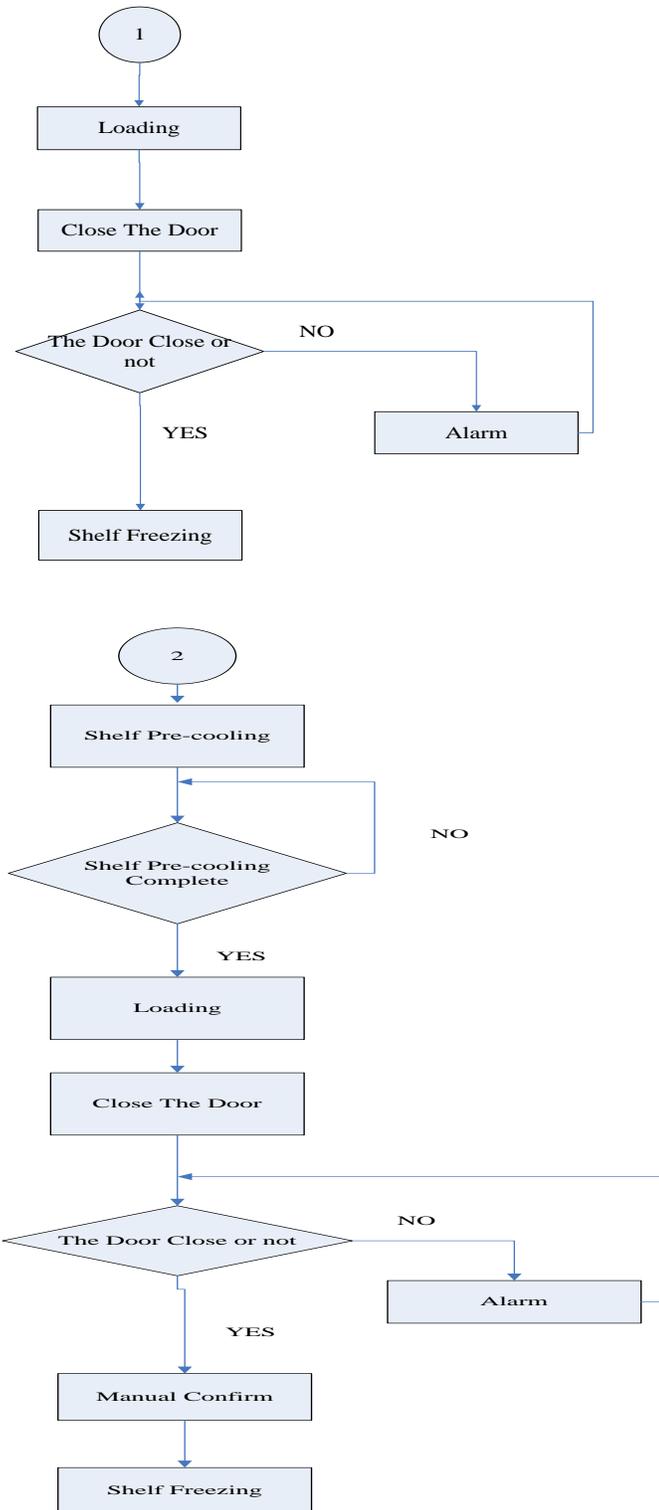
Fig 30

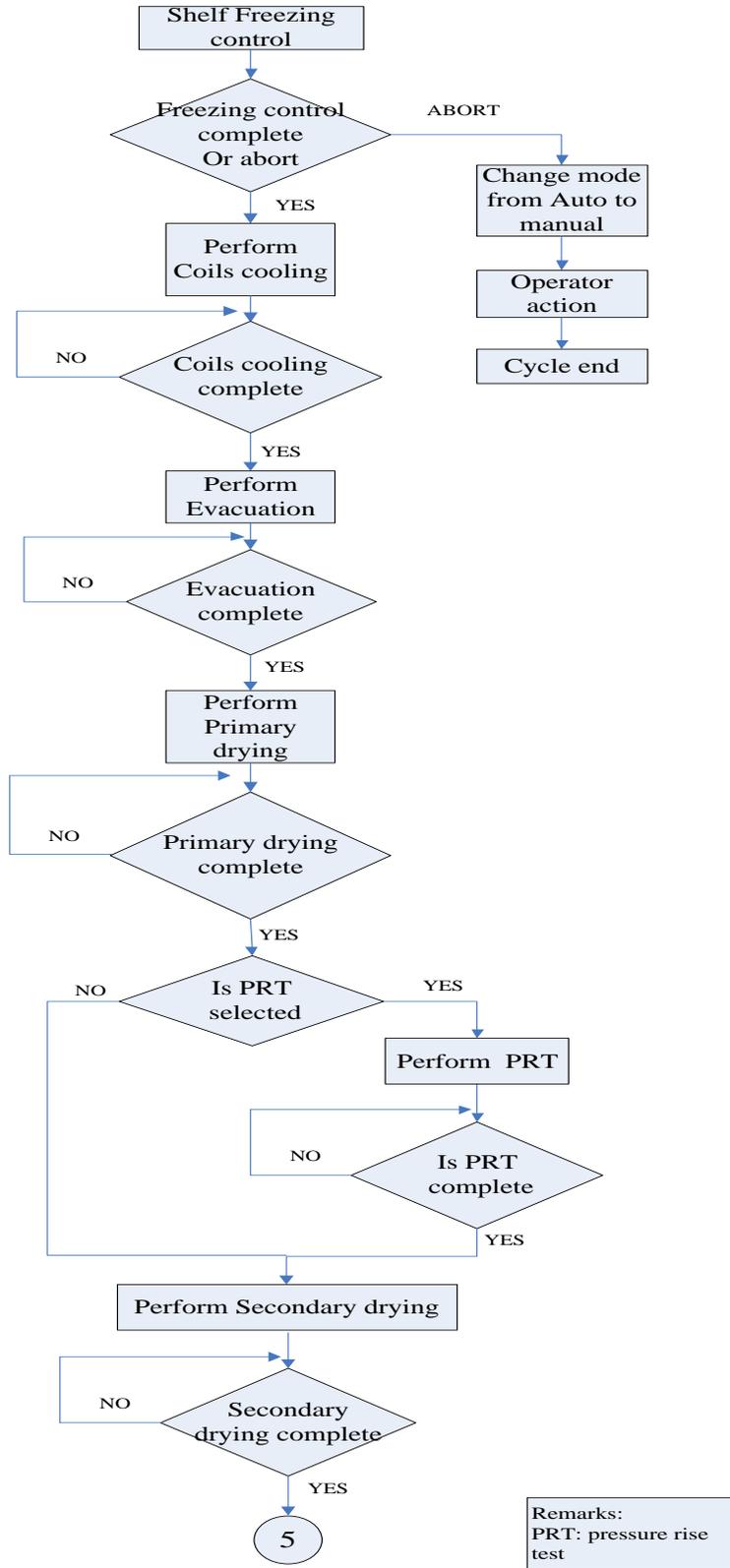
Additional parameters may be set when freeze drying and are listed below.

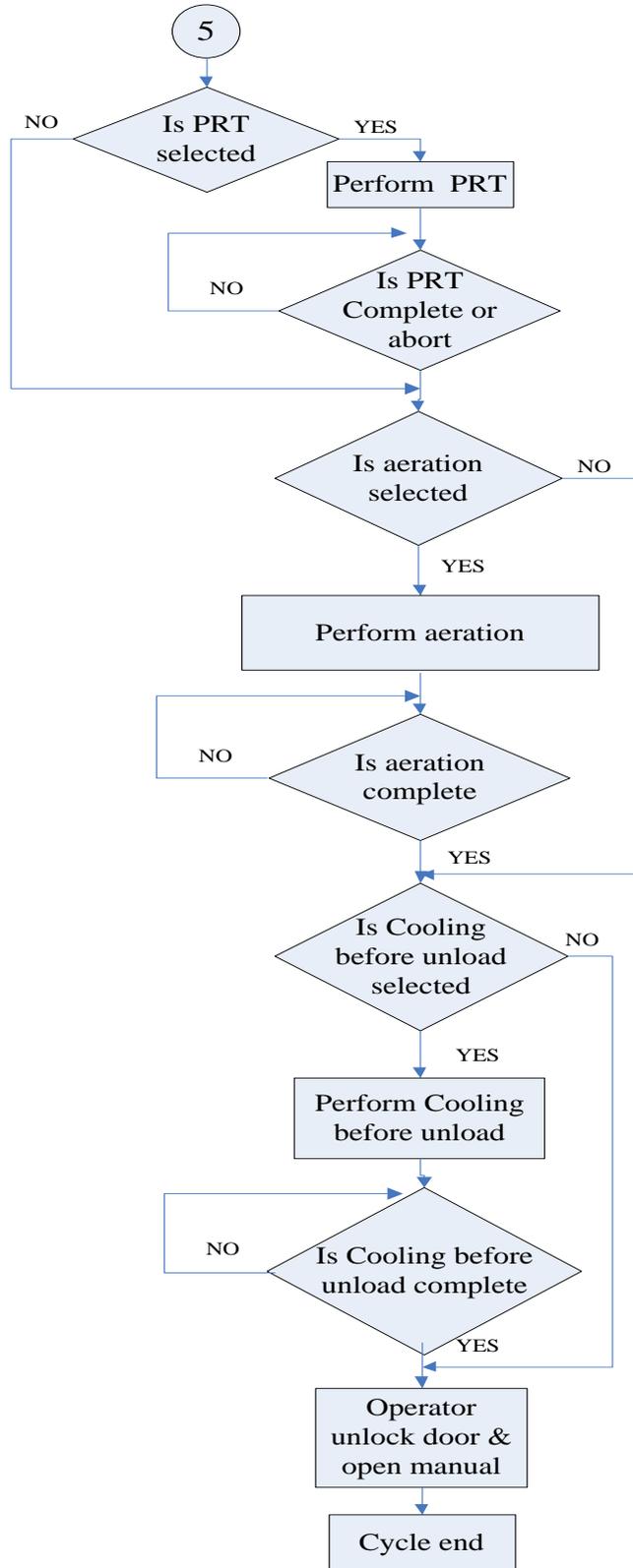
Items	Range
Heating PID_ P	0.000~9999.000
Heating PID_ I	0.000~99999.000
Heating PID_ D	0.000~99999.000
Cooling PID_ P	0.000~99999.000
Cooling PID_ I	0.000~99999.000
Cooling PID PID_ D	0.000~99999.000
Heating PID out	0~100
Cooling PID out	0~100
CP1 is on duty	/
CP2 is on duty	/

## X. Flow Charts of Operations









## 10.1 Operation Sequence

1. Sequence 1: Enter main page (See Fig 17).
2. Sequence 2: Manage parameters (see 11.6).
  - Click each parameter to set proper value.
3. Sequence 3: Lyophilization
  - Lyophilizer automatically runs the process according to the parameters that have been set in sequence 2.
4. Sequence 4: Shelf pre-cooling is an option for constant temperature regulation.
5. Sequence 5: Pre-cooling
  - Step 5.1: Start circulation pump.
  - Step 5.2: Start compressor.
  - Step 5.3: Open shelves cooling valve until the temperature of the silicon oil inlet (already set-in parameter manage) is lower than or equal to set value.
  - Step 5.4: To ensure the product is completely frozen, make sure that the time condition at the specified temperature is met.
6. Sequence 6: Coils Cooling
  - Open the coils cooling valve, close the shelves cooling valve to cool the condenser until the temperature of condenser (already set in Parameter manage) is lower than or equal to the set value. The value is usually set around  $-40^{\circ}\text{C}$ .
7. Sequence 7: Establish Chamber Vacuum
  - Start the vacuum pump and then open the pump isolation valve to achieve the chamber vacuum required (the value is already set). The temperature of condenser should be approximately  $-40^{\circ}\text{C}$ .
8. Sequence 8: Primary drying
  - Step 8.1: When the pressure of chamber is lower than the value (as set in Recipe), start the electric heater to begin primary drying.
  - Step 8.2: The rate of heating of the product should be in accordance to the process recommendations. It is important to ensure the product is not allowed to thaw during the process (the temperature is less than the product's eutectic temperature).

**Note:** The temperature is controllable using the dialogue window. Additionally, the silicon oil inlet may be adjusted to control the temperature value.

9. Sequence 9: Pressure rise test as an option
  - If the pressure rise is distinctly slower than required for the primary drying process (based on set value), go to the next test. If this test fails, restart the last stage of primary drying again or else forcibly go to the next step.
10. Sequence 10: Secondary drying
  - It is identical to primary drying only at a higher temperature.

**Note:**

During the process, the rate of heat transfer will become very slow due to the reduction of the water content in the product. Additionally, the low-pressure vacuum environment of the

chamber also limits heat transfer. Therefore, it is necessary to decrease the pressure inside the chamber in order to speed up the rate of evaporation and enhance drying.

11. Sequence 11: The rate of chamber pressure increases may be used as an indication the process is complete and the cycle may be ended.

- If the required pressure change occurs over the allotted time, the cycle is over.  
If the test fails, rerun the last stage of secondary drying.  
If test fails again, rerun the test until it succeeds.

12. Sequence 12: The secondary drying is over if sequence 11 already occurred.

13. Sequence 13: Vacuum break and aeration

- When chamber is still under vacuum, open the chamber air inlet valve sv393 and begin sequence 14 when the pressure valve reaches the set point.

14. Sequence 14: Shelf cooling is optional and will regulate temperature when unloading.

15. Sequence 15: Cycle ends.

## **Warning**

Caution should be used when using nitrogen. The operator should make sure the chamber has no pressure when breaking the vacuum after the lyophilization process is finished. Do not stand near the door of the lyophilizer unless the door is locked securely.

## 10.2 Manual De-icing Operation

Click 'Entering Control System' tab (See Fig 31).  
Type Username and Password and enter into the Control page (See Fig 32).



Fig 31

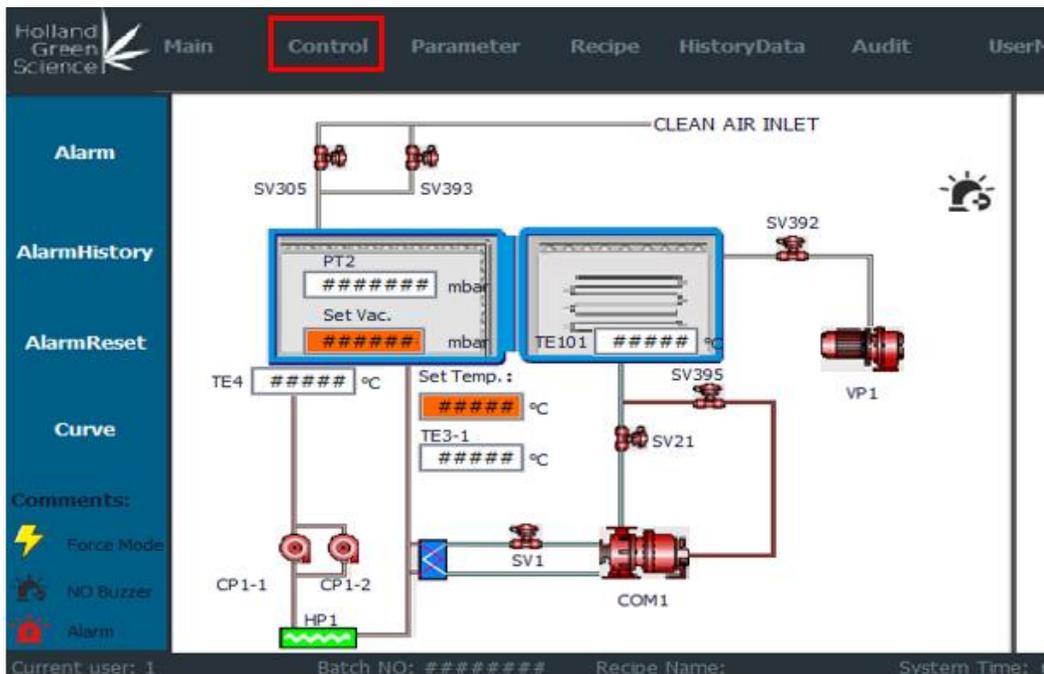


Fig 32

Click 'Control' to go to the next page (Fig 33).

Click 'Manual' and then Select 'Manual Start' as shown in Fig 33.

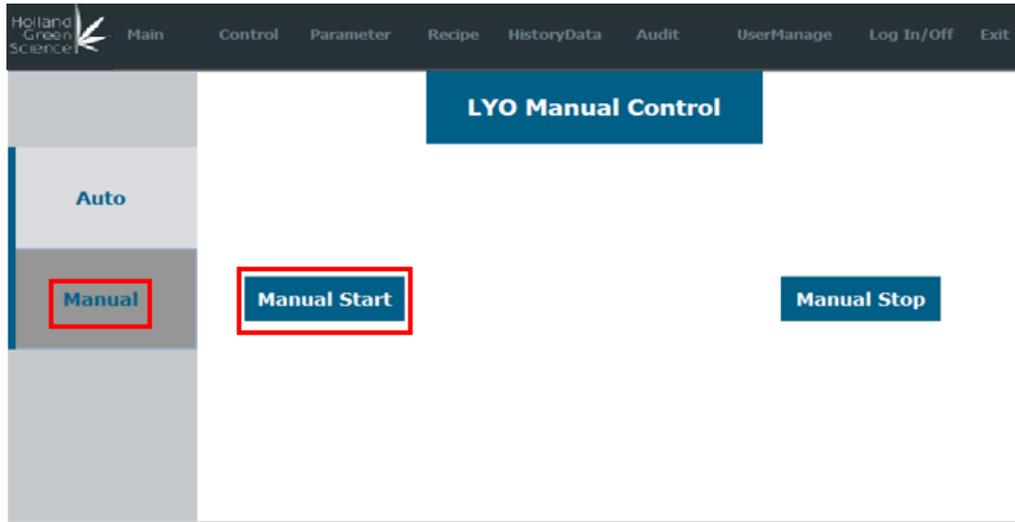


Fig 33

Start the compressor (COM1) and the de-icing valve (SV395).  
When the coil temperature rises to 20°C, close the de-icing valve (SV395) and stop the compressor (COM1). Please see Fig 34 for reference.

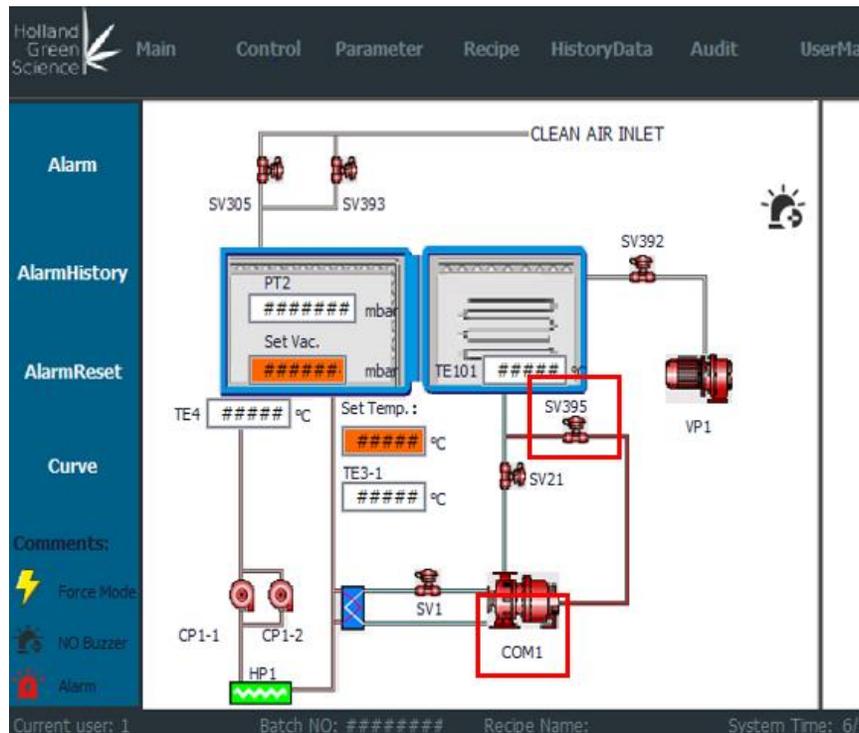


Fig 34

**Note:** Should Ice be on the coil or Ice has fallen under the box, it is necessary to run the de-icing program several times to clear.

## 10.3 Alarm/Safety Message

### 10.3.1 Check Alarm Messages

Click 'Alarm' icon as shown in Fig 35.

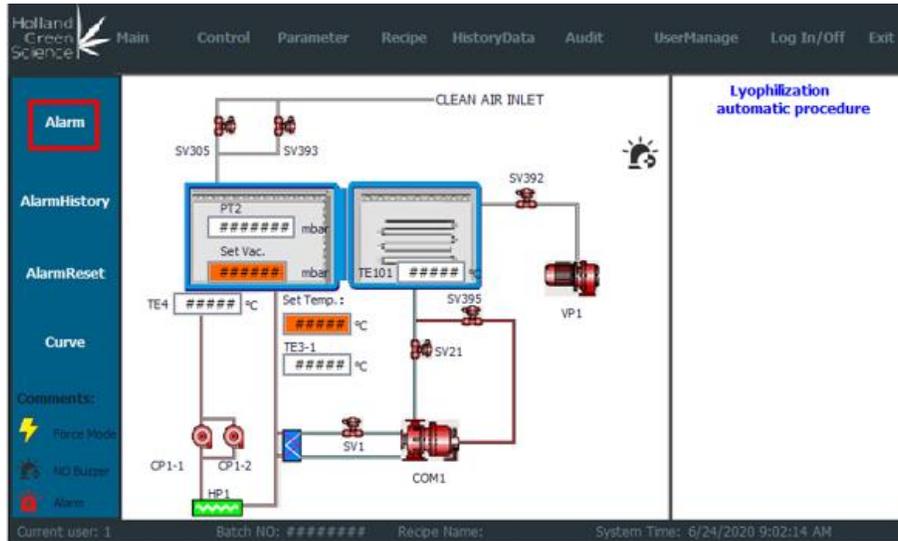


Fig 35

You should now be in the page as shown by Fig 36.

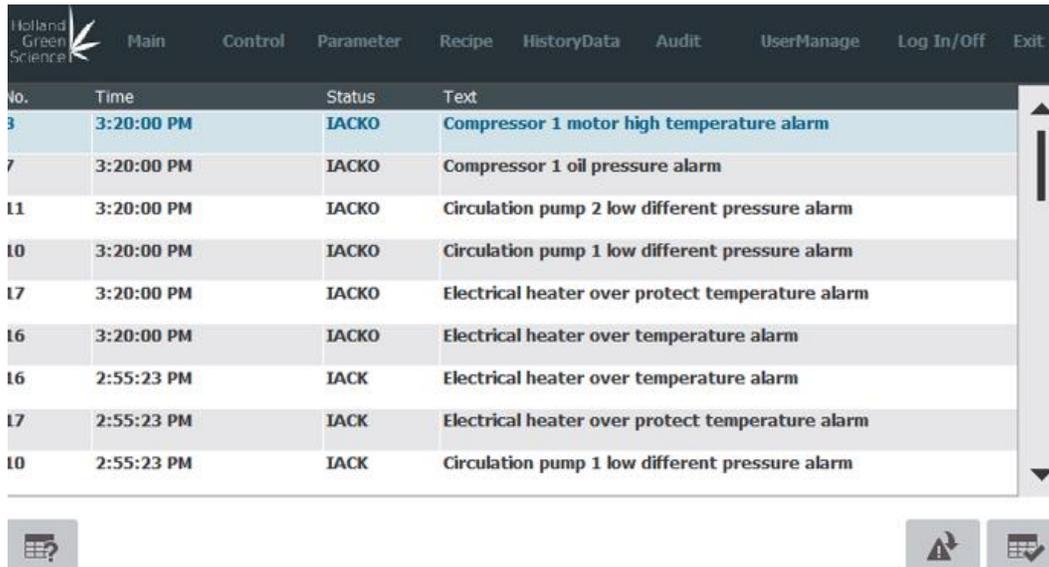


Fig 36

1. No.: 1
2. Time
3. Status:
4. Text (displays the alarm information)
5. Icon  (Click to check the information)
6. Icon  (Click to check the the selected alarm message information and confirm the alarm)
7. Icon  (Click to confirm the alarm)

## 10.3.2 Alarm Records

Click the 'AlarmHistory' icon as shown in Fig 37.

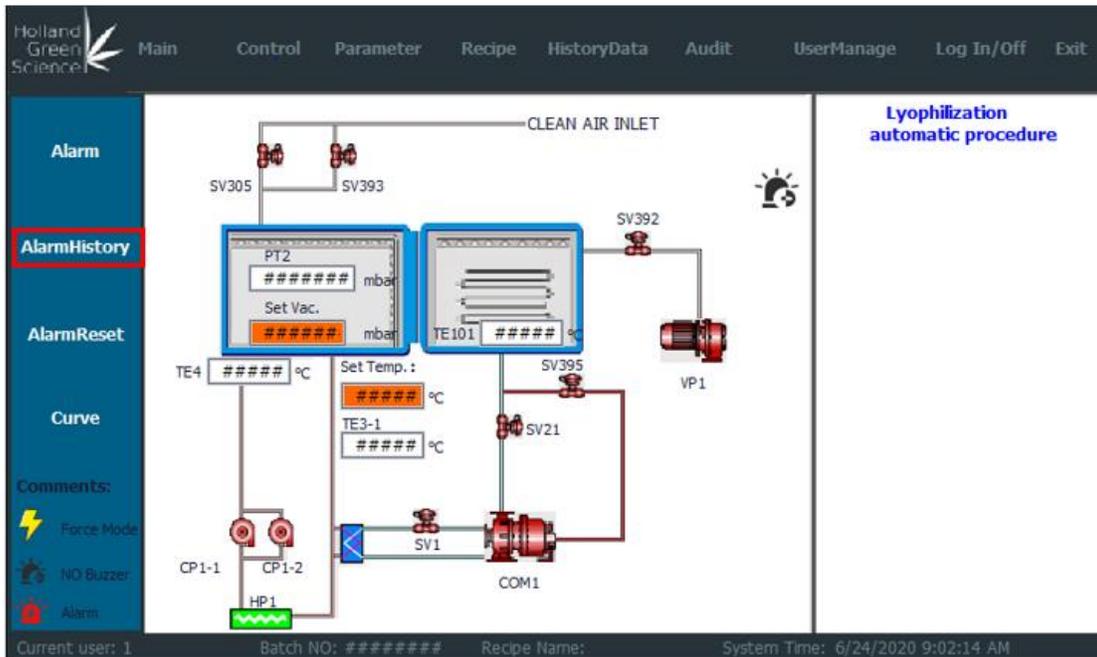


Fig 37

You should now be in the page as shown by Fig 38 below.

No.	Time	Status	Text
3	3:20:00 PM	IACKO	Compressor 1 motor high temperature alarm
7	3:20:00 PM	IACKO	Compressor 1 oil pressure alarm
11	3:20:00 PM	IACKO	Circulation pump 2 low different pressure alarm
10	3:20:00 PM	IACKO	Circulation pump 1 low different pressure alarm
17	3:20:00 PM	IACKO	Electrical heater over protect temperature alarm
16	3:20:00 PM	IACKO	Electrical heater over temperature alarm
16	2:55:23 PM	IACK	Electrical heater over temperature alarm
17	2:55:23 PM	IACK	Electrical heater over protect temperature alarm
10	2:55:23 PM	IACK	Circulation pump 1 low different pressure alarm

Time: 5/13/2020 3:33:09 PM

Fig 38

**Note:** Operation steps to apply are the same as Section 12.3.1 Check Alarm Messages.

## 10.3.3 Alarm List

No.	Alarm Message	Possible Cause
1.	Power phase abnormal	<ol style="list-style-type: none"> <li>1. No power.</li> <li>2. Component failure.</li> <li>3. Line fault.</li> </ol>
2.	Chamber recirculation pressure 1 signal abnormal alarm	<ol style="list-style-type: none"> <li>1. Circulating pressure is low.</li> <li>2. Circulating pump 1 fault.</li> <li>3. Component failure.</li> <li>4. Line fault.</li> </ol>
3.	Chamber recirculation pressure 2 signal abnormal alarm	<ol style="list-style-type: none"> <li>1. Circulating pressure is low.</li> <li>2. Circulating pump 1 fault.</li> <li>3. Component failure &amp; set error.</li> <li>4. Line fault.</li> </ol>
4.	Control system emergency stop alarm	Control system emergency disconnect & electrical fault
5.	Chamber vacuum alarm	<ol style="list-style-type: none"> <li>1. Check vacuum setting during drying.</li> <li>2. High rate of temperature increase</li> <li>3. Component failure.</li> <li>4. Vacuum system failure or pipeline leak.</li> <li>5. Improper parameter setting.</li> </ol>
6.	Compressor 1 high pressure alarm	<ol style="list-style-type: none"> <li>1. Insufficient condenser cooling.</li> <li>2. Low pressure leak.</li> <li>3. Component failure &amp; set error.</li> <li>4. Line Fault.</li> </ol>
7.	Compressor 1 oil pressure alarm	<ol style="list-style-type: none"> <li>1. Oil pipes are blocked &amp; oil level is low.</li> <li>2. Component failure &amp; line fault.</li> </ol>
8.	Circulation pump 1 overload alarm	<ol style="list-style-type: none"> <li>1. Motor overload.</li> <li>2. High or excessive current surge.</li> <li>3. Component failure &amp; line fault.</li> <li>4. Current setting value is incorrect.</li> </ol>
9.	Circulation pump 2 overload alarm	<ol style="list-style-type: none"> <li>1. Motor overload.</li> <li>2. High or excessive current surge.</li> <li>3. Component failure &amp; line fault.</li> <li>4. Current setting value is incorrect.</li> </ol>

No.	Alarm Message	Possible Cause
10.	Compressor 1 overload alarm	<ol style="list-style-type: none"> <li>1. Motor overload.</li> <li>2. High or excessive current surge.</li> <li>3. Component failure &amp; line fault.</li> <li>4. Current setting value is incorrect</li> </ol>
11.	Vacuum pump 1 overload alarm	<ol style="list-style-type: none"> <li>1. Motor overload.</li> <li>2. High or excessive current surge.</li> <li>3. Component failure &amp; line fault.</li> <li>4. Current setting value is incorrect</li> </ol>
12.	Electrical heater overload alarm	<ol style="list-style-type: none"> <li>1. Motor overload.</li> <li>2. High or excessive current surge .</li> <li>3. Component failure &amp; line fault.</li> <li>4. Current setting value is incorrect</li> </ol>
13.	Compressor1 electronic thermal protect signal abnormal alarm	<ol style="list-style-type: none"> <li>1. Motor overload.</li> <li>2. High or excessive current surge.</li> <li>3. Component failure &amp; line fault.</li> <li>4. Current setting value is incorrect</li> </ol>
14.	Shelf inlet temperature higher alarm	<ol style="list-style-type: none"> <li>1. Check the high temperature during drying.</li> <li>2. Too high a rate of temperature increase.</li> <li>3. Component failure.</li> <li>4. Vacuum system failure or pipeline leak.</li> <li>5. Improper parameter setting.</li> </ol>
15.	Shelf inlet temperature lower alarm	<ol style="list-style-type: none"> <li>1. Check the high temperature during drying.</li> <li>2. Too high a rate of temperature increase.</li> <li>3. Component failure.</li> <li>4. Vacuum system failure or pipeline leak.</li> <li>5. Improper parameter setting.</li> </ol>
16.	Electrical heater 1 overheats abnormal alarm	Electrical heater temperature too high
17.	Electrical heater over temperature safety signal abnormal alarm	Electrical heater temperature > protection temperature

## 10.3.4 Events List

No.	Description
1	Login and logout system
2	User login and logout
3	Start and stop automatic mode
4	Start and stop manual mode
5	Open and close each valve or pump
6	Change parameters
7	New recipe
8	Download recipe
9	Delete recipe
10	Modify recipe

## XI. Final Commissioning Checks

### 11.1 Preparation

- Clean the chamber thoroughly and remove all grease, dirt etc.
- Ensure that the chamber is dry and place the product evenly on the shelves.
- Confirm the chamber door and seal are free of contaminants.

### 11.2 Inspection Prior to Operation

- Test the electric motor in the forward and reverse directions.
- Confirm the product temperature probe is in the correct position and secured.
- Confirm all switches on the control system are reset.
- Confirm all alarms are off.
- Confirm the key in the electrical cabinet is turned to 'ON'.

### 11.3 Utility Data and Parameters

Utility Parameters

No.	Specification Category	Specification
1	Electricity Total Electrical Load	19KW 380V, 60HZ, 3 Phase, 5 Wire
2	Ambient Temperature	T≤25°C

## XII. Maintenance and Cleaning

Proper maintenance and operation of the lyophilizer as stated below will ensure the equipment stays in good working condition during its service life.

The lyophilizer should be kept dry and cleaned after routine operations.

Take care to clean the outer surface with a non-abrasive cleanser and only connect the power supply when the entire instrument surface is dry.

If liquid or moist solids are spilled on or near the lyophilizer, please immediately disconnect the power supply and contact the service department.

- Power must be disconnected before any maintenance or cleaning.
- Surface stains on the lyophilizer should be cleaned only by a clean, soft rag and detergent.
- Keep the product clean and ensure no cleaning solution is spilled inside the lyophilizer.
- Avoid cleaning the lyophilizer with any corrosive cleaning solutions.
- If the lyophilizer is left unused for a long period, switch 'OFF' the power and store it in a clean and dry area on a level surface at room temperature.



### **Caution!**

Before any Maintenance or Inspection, the Power Cable **MUST** be removed from the power socket.