Frozen in Time Ltd

Manufacturers of Freeze Drying Machines and Vacuum Cold traps

Operating Manual

Lablyo Extra

Main associated accessories:

Vacuum pump for Lablyo Extra
FIT/LYO/59/0

Includes IQ/OQ Qualification

Operating Manual

Lablyo Extra

Order Number:

Serial Number:

In case of enquiries please state the above

For service please contact:

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Contents

1. General Information

1.1. Introduction

What is freeze drying (lyophilisation)?

Freeze drying means: Removal of water from frozen material. The drying process takes place by direct conversion from ice to vapour. This process is called sublimation. Sublimation happens under vacuum when the temperature in the product is less than -10°C.
The aim of freeze drying is to obtain a readily water-soluble product which has the same characteristics as the original product after the addition of water. As the drying process takes place in the frozen state at low temperatures it is possible to dry proteins which will not denature. Most of the other chemical compounds will also remain unchanged.
Freeze drying products, of biological origin such as tissues, tissue extracts, bacteria, vaccines and sera transforms them into a dry product. During this process enzymatic, bacterial and chemical changes are largely avoided. Freeze drying is the gentlest process for preserving the biological properties of sensitive tissue and tissue components. Freeze drying can also be used for dry some inorganic products.

1.2. Applications

The **Lablyo Extra** is a laboratory and pre-production machine for the freeze drying of products in glass flasks, bottles, vials or dishes. The initial freezing of the products will require a flask freezing bath, laboratory freezer or in the pre-freezing of the products can be done in the **Lablyo Extra** chamber.

1.3. Technical data of freeze dryer

Lablyo Extra

Performance data	**-80ºC**
Ice condenser capacity	3 kg max.
Ice condenser performance(1):	2 kg per 24 hour maximum
Physical data	
Dimensions of the unit:	width: 700 mm height: 550 mm depth: 850 mm
Weight:	approx. 92 kg
Noise emissions according to DIN 45635:	54 dB(A)
Total Shelf Area	~0.27 m^2
Electromagnetic compatibility according to EN 55011:	class B
Refrigerant:	R507 - 0.65KG
Voltage	240V 50Hz (220V 60Hz special order)
Main fuse rating:	13 Amp
Ambient temperature	5°C to 30°C
Equipment connections:	
Vacuum connection:	19mm nozzle
Drain valve	1/4 BSP ball valve
Electrical connection	IEC connection

1.4. Safety instructions

1.4.1. Disconnect the mains plug before removing panels

The mains plug must be disconnected before the panels are removed or any maintenance work is undertaken.

1.4.2. Solvents

Acidic or high solvent concentration products should not be dried because of corrosion risk and damage to the vacuum pump.

1.4.3. Cleaning and Maintenance of the Unit

For infectious, toxic, pathogenic and radioactive substances, the danger information of the associated safety regulations must be observed.

1.4.4. Freezing of skin to surfaces

Make sure skin does not come into contact with freezing surfaces. Skin can only be detached from the surface by applying heat. Do not use liquid.

1.4.5. Transporting

The **Lablyo Extra** should be carried by two people and care must be taken when placing the unit down on a surface not to trap fingers. .

1.5. The Lablyo Extra should not be used when:

1. It is not properly installed.
2. The door is not closed properly.
3. Panels are missing.
4. The operator is not authorized or trained
5. Highly corrosive or solvent substances are present.
6. The accessories are not designed to be used with the unit or show signs of damage. Glassware can be susceptible to implosion causing potential risk during freeze drying.
7. In hazardous or dangerous locations.
8. The products are explosive or highly flammable.
9. The products are Infectious, toxic, pathogenic or radioactive unless in suitable vessels and in accordance with the relevant safety data.

2. Information on Freeze Drying

2.1. General Information on Freeze Drying

Freeze drying is the gentlest process for drying products. It uses the process of sublimation, the direct conversion from solid to gaseous state. The frozen product is dried under vacuum without thawing. The condenser chamber works as a cryogenic pump as it takes large quantities of vapour and condenses it to ice. The vacuum pump is only intended to remove the air from the drying chamber but not the vapor. In order to start the sublimation process, energy must be supplied to the product.
When drying takes place in glass flasks on a manifold, the heat energy is taken from the warmer surrounding air.
When drying takes place on shelves in an acrylic chamber, the heat energy source is radiation from the environment and directly by from the shelves if they are heated.
Primary drying removes the most of the water from the product. Secondary drying removes the last traces of water means of deep vacuum.

The main components of a freeze dryer are:

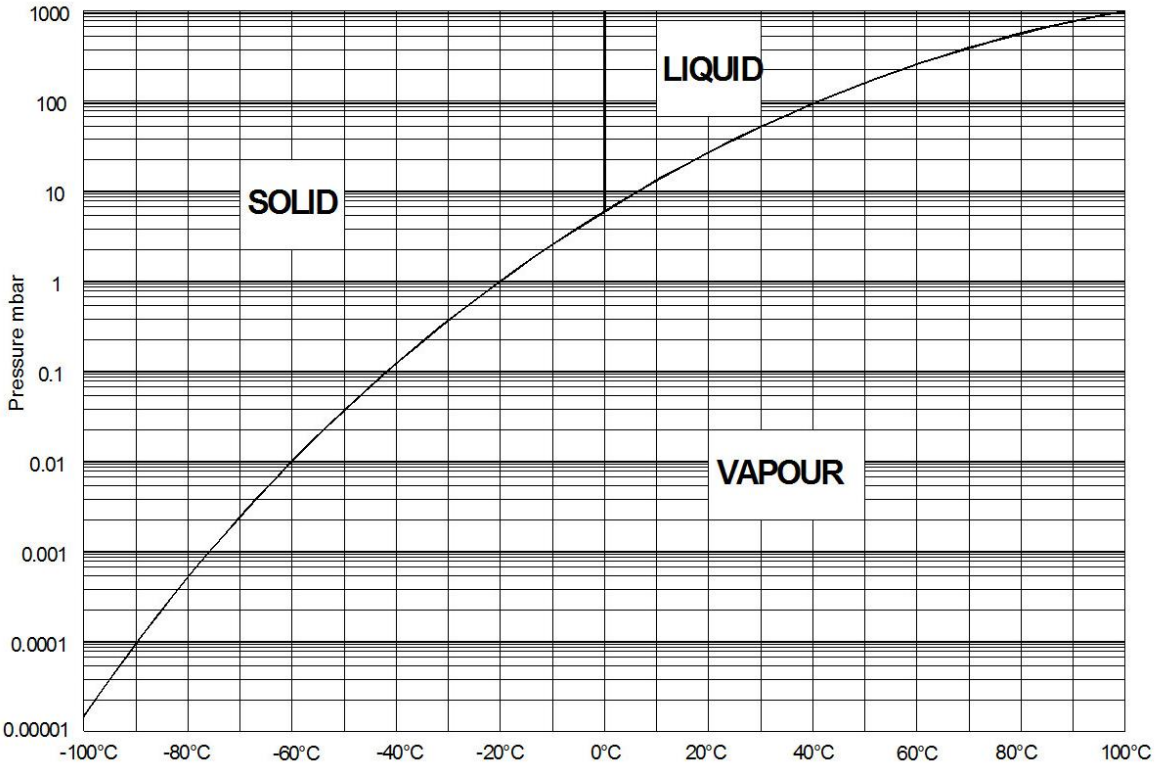
- Vacuum drying chamber or manifold
  a) plain or heated shelves for drying in dishes
  b) shelves with sealing device for drying in vials or small bottles
  c) rubber valves for connecting round-bottom flasks, bottles, etc.
  d) rubber nipples for connecting ampoules
- Vacuum pump to evacuate air.
- Ice condenser with a temperature of -55°C or -85°C to condense vapour.

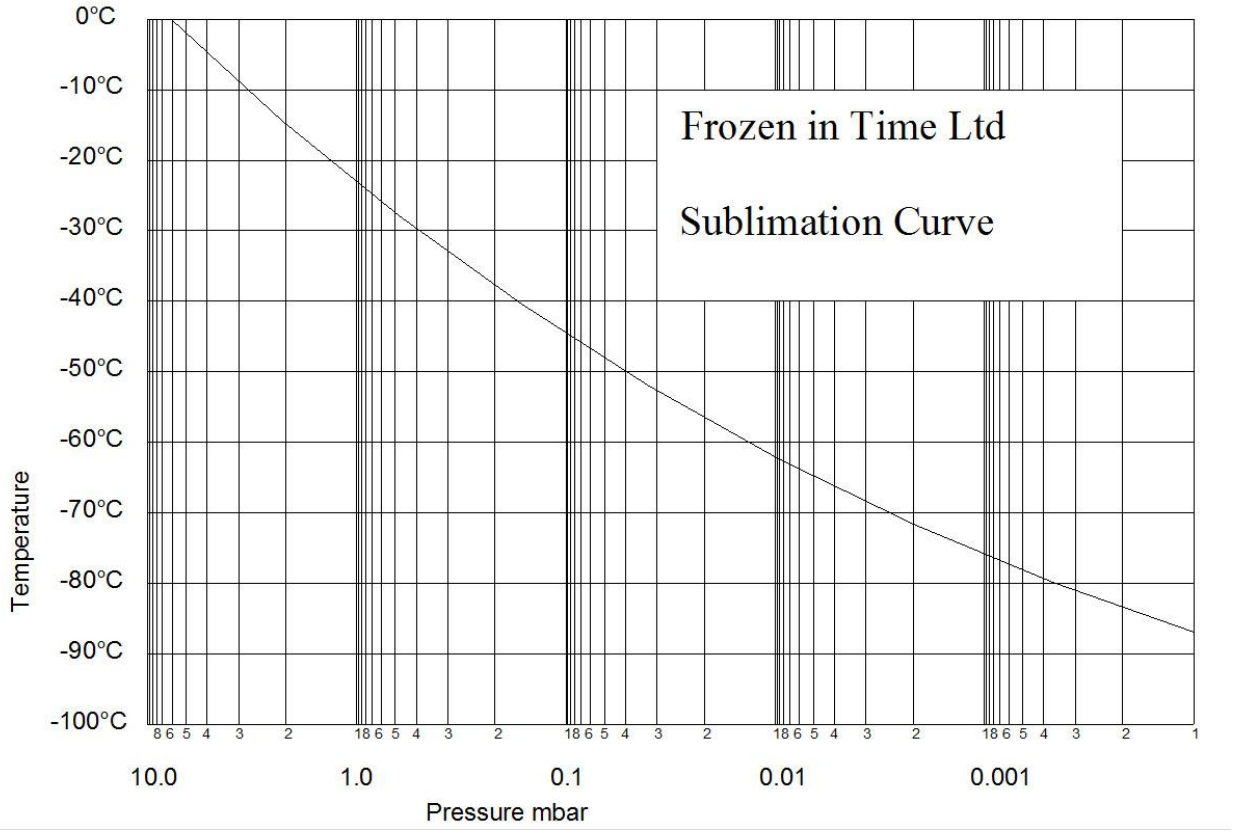
Sublimation

The principle of sublimation is briefly explained using the phase diagram of solid liquid and vapour. If the pressure is higher than 6.1 mbar, water passes through all three phases (solid, liquid, vapour) when the temperature is lowered or raised. At 6.1 mbar and 0ºC all three lines meet, this is called the triple point where all three phase can occur simultaneously. Below this point when the pressure is lower than 6.1 mbar, the ice is converted directly from a solid to a vapour on reaching the sublimation pressure curve.

The sublimation curve shows the vapour pressure of water as affected by temperature and pressure.

Phase diagram for solid, liquid and vapour





2.2. Freezing

Small product quantities can be frozen directly inside the ice condenser chamber of the **Lablyo Extra**. Larger quantities are pre-frozen in a deepfreeze. This the usual option for product to be freeze dried in trays or vials. Deep fill depths should be avoided by using wider containers filled to a shallower depth in order to maximize surface area. Liquids to be dried in narrow ampoules should be frozen in a spin freezer this causes the product to freeze in a thin section up the wall of the tube. Liquid to be dried in flasks should be rotated in a freezer bath. This causes the frozen material to form a thin layer, lining the flask. These procedures will help minimize the drying time.
It is advisable to pre-cool the shelves in order to avoid partial thawing during the evacuation.
Products containing solvent, high salt or sugar concentrations require freezing to lower temperatures.

2.3. Primary drying

The **Lablyo Extra** is taken to its operating temperature.
The vacuum pump is switched on.

The duration of the main drying phase depends mainly on:

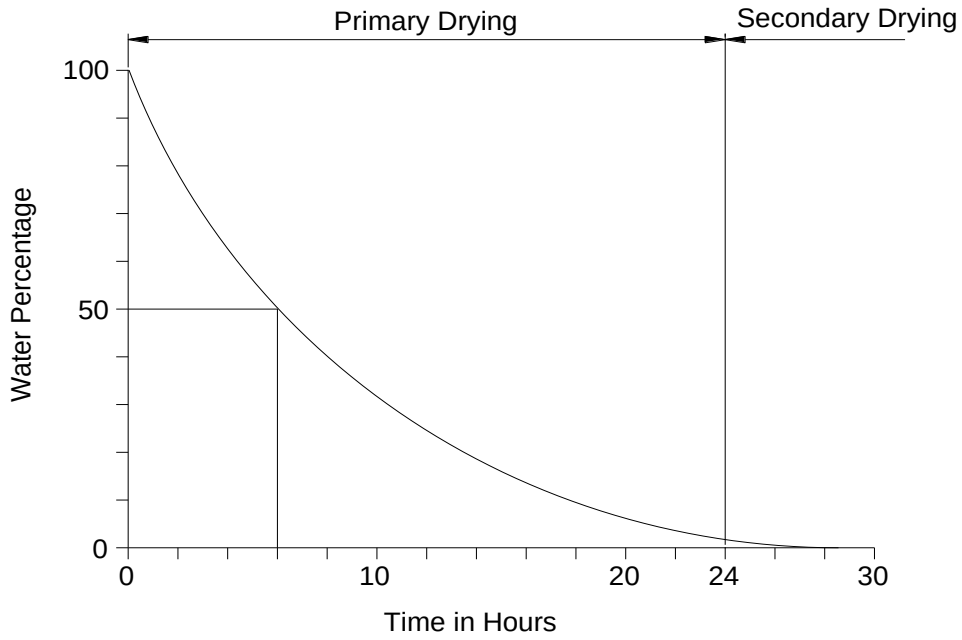
- The layer thickness of the product,
- The solid content of the product,
- The heat supplied to the product during the drying process,
- The vacuum pressure inside the drying chamber during the drying process.

With increasing pressure the rate of sublimation rises as long as it stays below the vapour pressure of the product. This is because at higher pressures the heat energy reaches the sublimation front of the ice core sooner. Therefore the drying period is shortened. The water vapor generated during the main drying phase is not intended to be removed by the vacuum pump. It is to be collected by the ice condenser. The purpose of the vacuum pump is to lower the partial pressure of the non-condensable gases so that the water vapor can be transported from the product to the ice condenser. However, small quantities of water vapor will be removed by the vacuum pump. The vacuum pump is equipped with a gas ballast valve that when open, removes traces of condensable vapors from the pump. For this reason the gas ballast valve can be open during the main primary phase. The gas ballast valve is not required for secondary drying and closing it will help achieve a lower level of vacuum.
During primary drying the moisture is removed by sublimation and during final drying the bound moisture is removed by desorption. The recommended vacuum pump should reach with open gas ballast valve, a vacuum level lower than the relevant water vapour pressure.

The residual moisture of the dried product depends mainly on:

- The temperature of the dried product during the final drying process,
- The final vacuum reached during the final drying process.

The end of the primary drying phase is reached, when the product temperature is nearly the same as the shelf temperature (temperature difference between shelf and product approximately 3 to 5ºC). Once the primary drying is completed the secondary drying will remove the bound water from the product. The following diagram shows the drying process for a product containing approximately 10 % solid matter. During the first quarter of the primary drying phase 50% of the water content is condensed. During the next quarter of the primary drying phase 50% of the remaining water content is condensed. This continues until the drying curve approaches the time axis asymptotically. This typical drying curve is due to the fact that the area of sublimation recedes into the product and the remaining water vapour must pass through the already dried layers. During the drying process the resistance increases. The drying curve is determined by the latent heat of sublimation and the amount of vapour transported. In order to increase the specific heat conduction properties of the product and to keep the water vapour volume as low as possible it is necessary that drying takes place as close as possible to the solidification point or eutectic point.



The drying time depends heavily on the vacuum level. The nearer the vacuum to the solidification point in accordance with the vapor pressure curve the shorter the drying time.

Facts regarding ice in a vacuum:

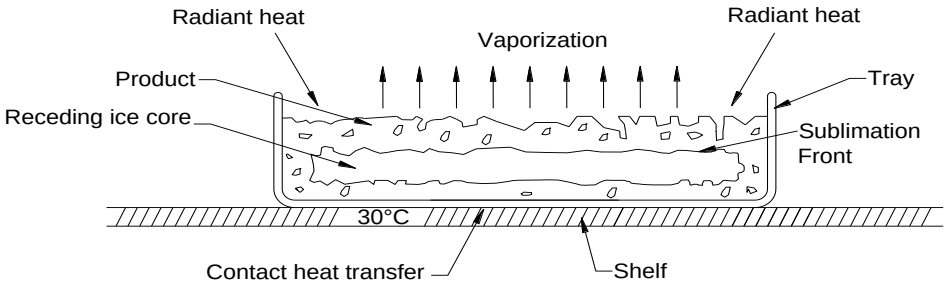
1.0 gram of ice at;
1.0 mbar assumes a volume of 1 m^3 vapor
0.1 mbar assumes a volume of 10 m^3 vapor
0.01 mbar assumes a volume of 100 m^3 vapor

Heat supply during drying

The required heat supply to the product to be dried takes place by;

- Conduction through contact in the drying chamber
- Mild conduction through low pressure vapour
- Radiant heat energy.

Effects of freeze drying of a product in a dish



Heat transfer takes place via the heated shelves by direct contact with the bottom of the tray. At the beginning of sublimation the transfer of heat is very effective from the wall of the tray to the frozen product. However, soon an area develops which is ice-free, porous, dried and has an insulating effect between the wall of the tray and the product. This slows down the heat energy transfer available to the ice core. The porous dried layer enables the passage of vapour from the ice core. If it is restricted the temperature will increase and ice core will thaw rather than sublimate. This applies especially to inhomogeneous products and to great layer thicknesses. During this drying phase it is important to regulate the heat supply and control temperature and pressure precisely.

2.4. Secondary drying

The final pressure in the drying chamber depends on the ice condenser temperature according to the vapor pressure curve above ice :

e. g. 1.030 mbar correspond to -20°C
0.370 mbar correspond to -30°C
0.120 mbar correspond to -40°C
0.040 mbar correspond to -50°C
0.01 mbar correspond to -60°C

The unit is in operating condition if the temperature of the ice condenser is lower than -50°C and the pressure is lower than 0.12 mbar. The final pressure measured when there is no product in the unit and its corresponding ice temperature is determined by the warmest ice surface in the condenser chamber.

2.5. End of drying and air admittance

The product is dry when it at or above ambient temperature while under the secondary drying vacuum level. The condenser temperature will also be lower than when under load.

The vacuum pump can be switched off and the condenser chamber drain valve can be opened as an air admittance valve. This valve can be used to purge the unit with nitrogen or another inert gas instead of using air. Then the unit is switched off and the product is removed.

2.6. Defrosting

Defrosting of the ice condenser is carried out by switching off the refrigeration and switching on the red defrost button. To let the water out the open the drain valve and allow to drain into an appropriate container. The defrost is self-regulating and will not overheat.

3. Description of the Freeze Drying Processes

3.1. Freezing the product.

There are 3 ways to freeze the product when using the **Lablyo Extra**

1. Directly inside the Product Chamber
2. A laboratory freezer preferably -40ºC
3. Flask freezing in a glycol bath

3.1.1. Freezing inside the product chamber.

Product can be loaded into the freeze drier in an unfrozen state and then set the Lablyo Extra to freeze the product in-situ.

3.1.2. Freezing in an external freezer.

The product is prepared in vials or trays and then placed in a -40 ºC freezer until it is completely frozen.

3.1.3. Freezing in a glycol bath

Flasks containing product should only be partly filled then rotated/carefully dipped in the freezing glycol so a thin layer freezes evenly around the inside of the flask to maximize the surface area. These can then be attached to the four flask fittings on the left side of the unit.

3.2.1. Drying on heated shelves

Vials, bottles, trays or dishes containing frozen product are arranged on the shelves.
These shelves are ideal for product that requires faster drying or higher temperatures. Each shelf is has equal heat input and there is a temperature sensor sampling one shelf only. Product should be loaded equally over all the shelves to allow for even drying rates. The **Lablyo Extra** has an integrated temperature controller.

4. Installation and Commissioning of the Unit

4.1. Site of installation

In order to ensure the air circulation of the heat exchanger, do not place any paper, cloths or similar items behind the unit. The freeze dryer should be positioned horizontally. The ambient temperature should be between approx. +5°C and +30°C. The refrigeration compressor of the freeze dryer is air-cooled. Sufficient air circulation must be ensured. A distance of at least 30cm to the wall should be kept. The unit should not be positioned near radiators or heat sources. In the case of insufficient air circulation or too high ambient temperatures, the temperature and the pressure in the refrigerating system will increase. If the maximum permissible operating pressure is exceeded, this may cause the refrigeration unit to switch off. The following connections are required at the site:

4.2. Mains power

The operating voltage on the name plate must correspond to the local supply voltage. Frozen in Time freeze dryers are units of safety class I. The **Lablyo Extra** has a three-wire connection cable with a 230VAC 13 amp fused plug earth contact. The freeze dryer must be on a circuit protected with a 16 Amp fuse or circuit breaker.

4.3. Air admittance / Drain valve

The drain valve is also used for air admittance. If bottles have to be sealed in nitrogen the ice condenser chamber can be purged through the drain valve.
Take care not to over pressure the system.

4.4. Condensate and defrosting water

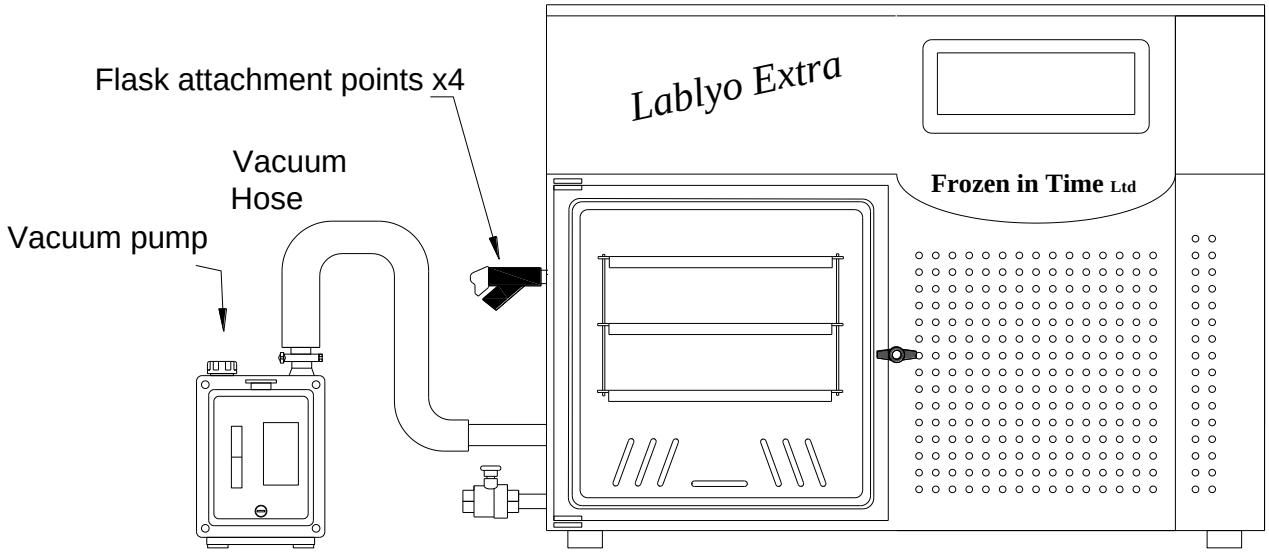
The condensate and the defrosting water are discharged through the drain valve.

4.5. Vacuum pump exhaust gases

The oil mist from the vacuum pump is normally trapped in an exhaust filter.
If this is not the case, the oil mist has to be discharged. A hose can be connected to the exhaust flange of the vacuum that leads into the open air or a vent. During installation of the pipe special care must be taken that condensate cannot flow back into the pump.

4.6. Initial start-up

Prior to start-up, make sure that the freeze dryer has been properly set up and installed



Installation of the vacuum pump
The vacuum pump can be powered through the Lablyo Extra via the IEC socket on the left hand side. Make sure that the vacuum exhaust gases are filtered or carried off.

5. Using the Lablyo Extra

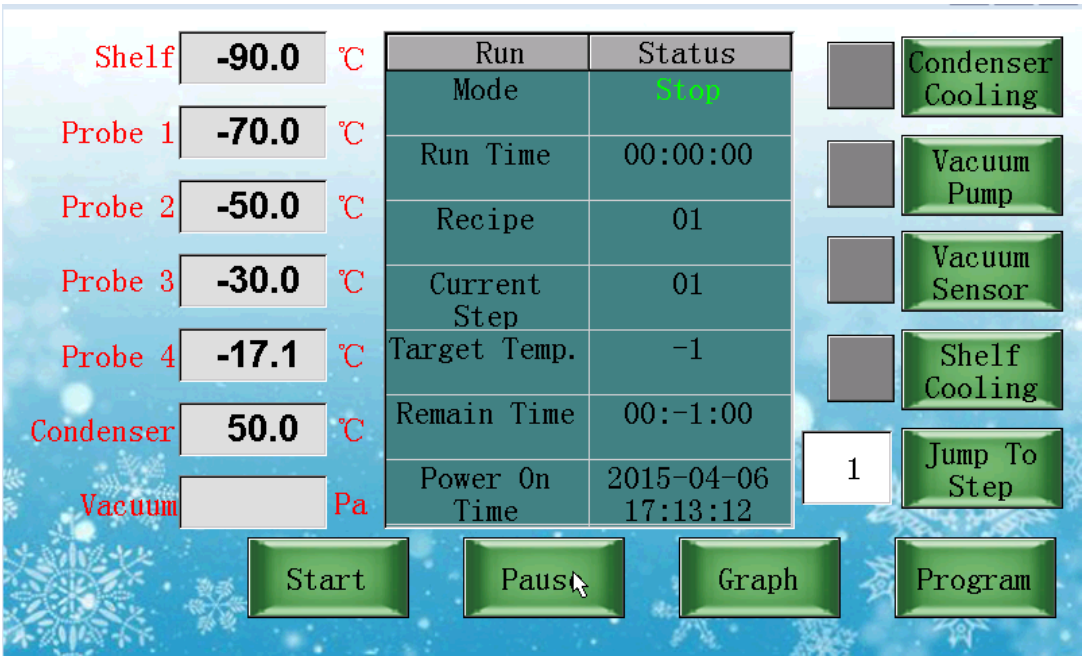
5.1. Switching on the unit

Switch the **Lablyo Extra** on at the power switch on the rear of the unit. The indicator light should now be on. The control panel should also now be active.

The screen on start up shows the Main Menu.

On the right there is:

- Shelf/chamber temperature
- Mobile probes 1 to 4 temperatures
- Condenser temperature.
- Vacuum level in Pascals



On the left top 5 there are buttons to control:

- Condenser Cooling
- Vacuum Pump
- Vacuum Sensor
- Shelf Cooling
- Jump to step # to be used to advance steps during an automated program.

In the centre we have the Run Status table:

- Work Mode - Stop when off and Run when the program is running
- Run time -
- Recipe number
- Current step that is running
- Target Temp.- for the current step
- Remaining Time - for the whole program
- Power on time - since last time the unit was switched on.

Along the bottom row we have the following buttons:

- Start - to start up the program in the above table.
- Pause – to temporarily stop the running of the current program
- Graph – will show the graph with the current data
- Program – this enables the operator to program a recipe for an automated cycle.

The refrigeration compressor will not start straight away if it has been just switched off. There is a delay and countdown timer shown in the red indicator.

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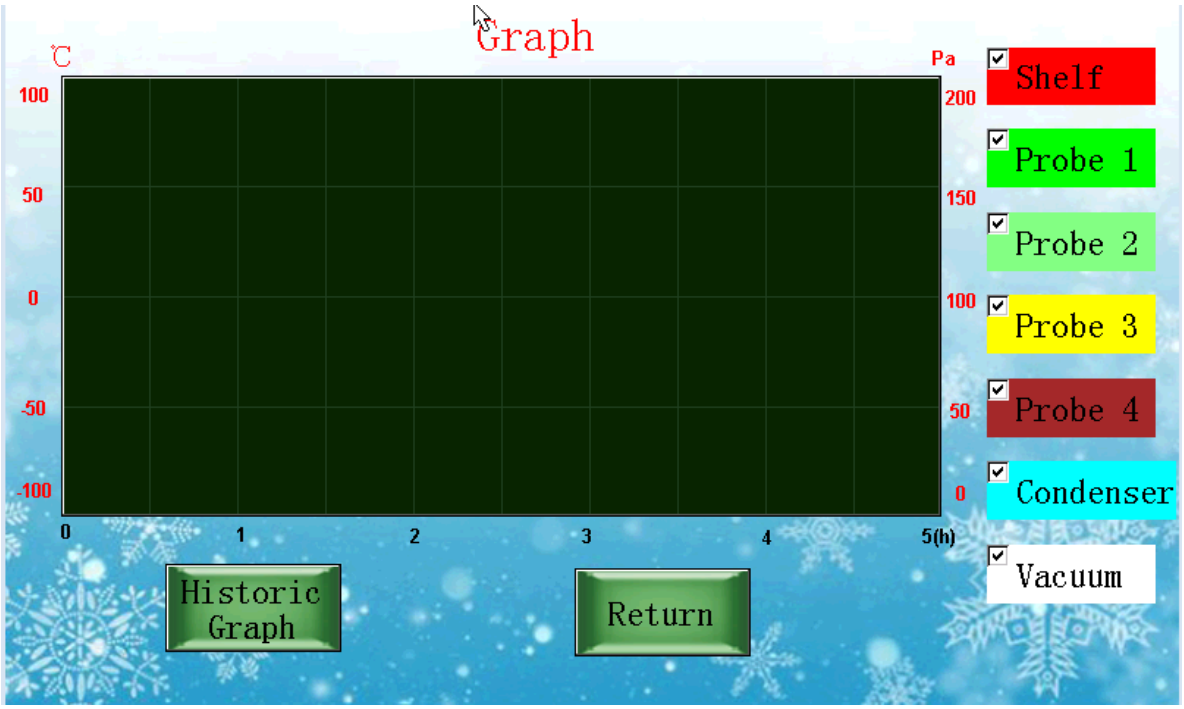
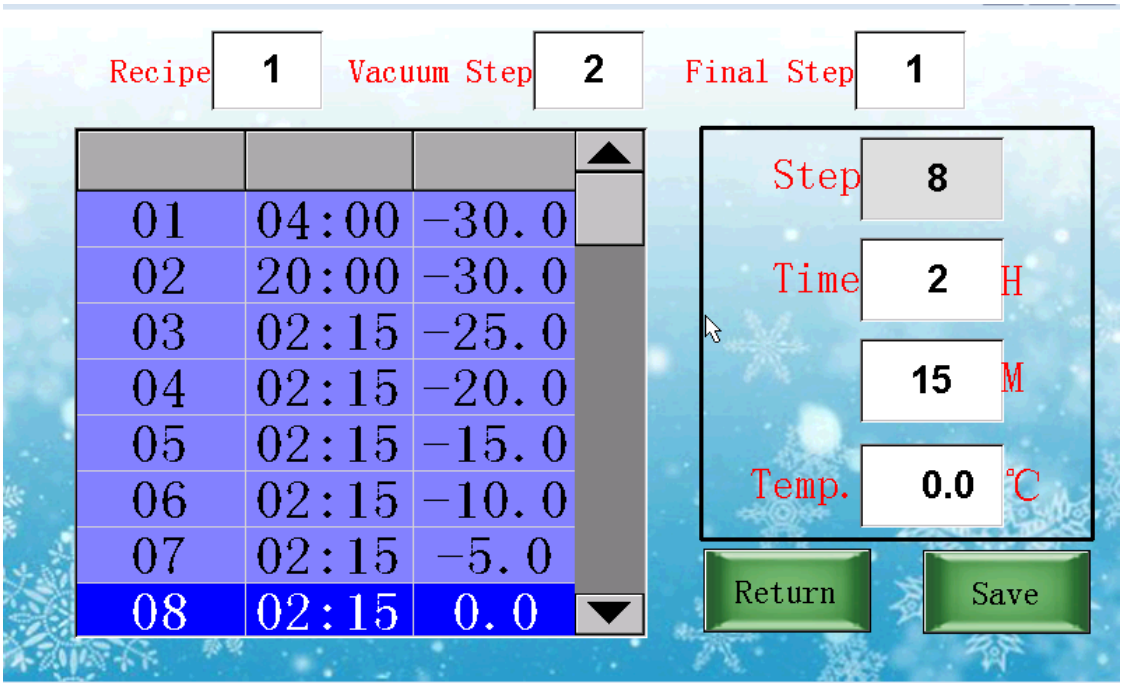
5.2. Graph

The right hand side Y axis of the graph shows the temperature. Across the X axis it shows the time in hours. The left hand side of the Y axis shows the vacuum level in Pascals
The right hand side of the screen is where you can select which information you would like to appear on the graph, the button colour indicates the trace on the graph.



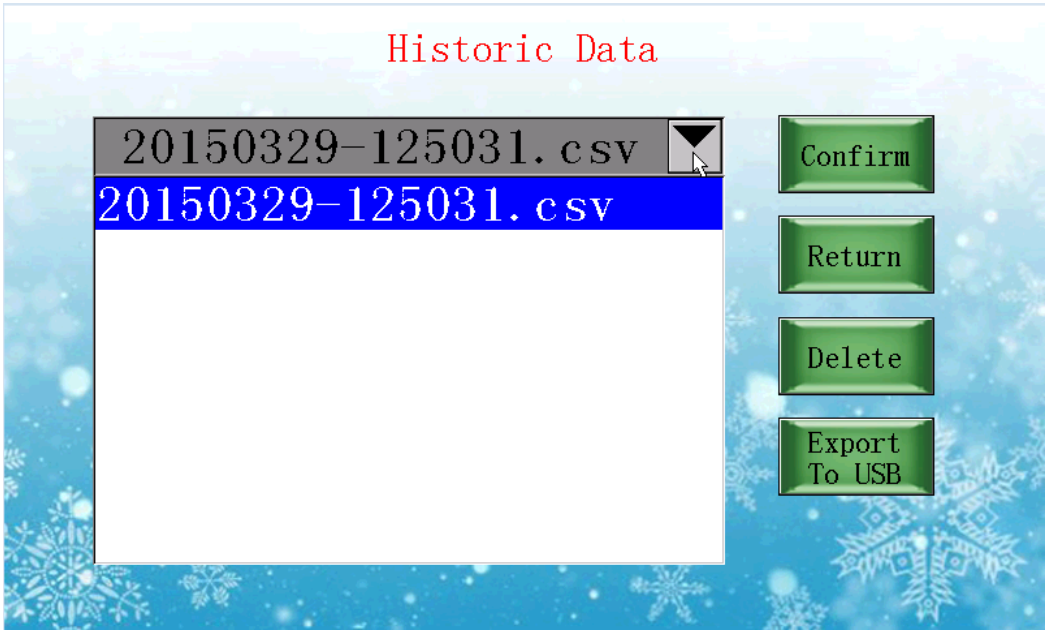
5.3. Program Steps



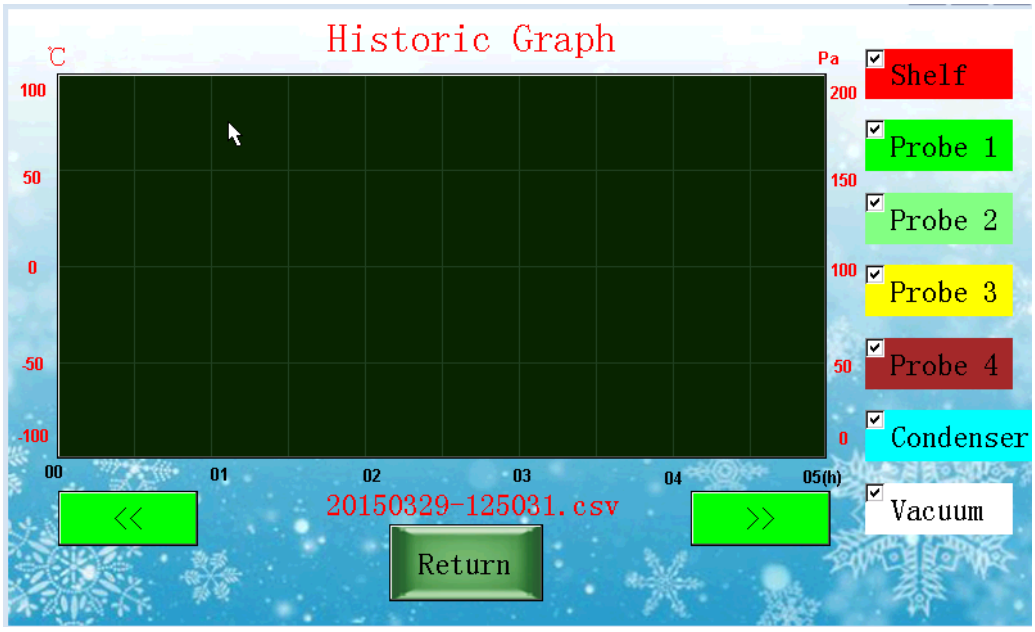
The program steps create a recipe to allow simple automation of the product chamber temperature using time to initiate the change in temperature.

- Several Recipes can be saved and entered in the top left box.
- The operator can choose within which step the vacuum will be applied in the centre top middle box.
- There are 40 available recipe steps, but it unlikely that all of them will be required. Use as many steps as is needed and indicate the last one in the box “Final step”
- By selecting one of the steps numbered 01 to 40 in the blue table it will become highlighted.
- Give the highlighted step its time frame and temperature level in the larger box on the right.
- When all steps have been programmed as planned press “Save”
- To return to the main screen press “Return”

5.4. Historic Data



- Data files get created for up to every 24 hours of run time.
- These files can be saved onto a USB stick or can be used within the control system to create a graph
- Select a file and press “Confirm”



Scroll back and forth to see the full time frame.
Select or deselect to show the traces that are most important.

5.5. Defrost

Defrost is not part of the control panel. The red illuminated switch on the side activates the defrost. Defrost will always be overridden by the refrigeration. Defrost should only be switched on to defrost ice and it must then be switched off. However the defrost heater is self-regulating and will not over heat.

5.6. Drain valve

The drain valve should be closed whenever the vacuum pump is activated. It should not be opened while the vacuum pump is still switch on.
The drain valve is used to drain defrosted condensate from the condenser chamber. It is also used to admit air or inert gases into the condenser chamber to break the vacuum.

5.7. Vacuum connection

The IEC socket connection at the back of the unit is used to power a vacuum pump through the Lablyo Extra making use of the control panel functions.

6. Accessories and part numbers

FIT/LYO/37/0 **Vacuum hose 1m for vacuum pump**

Additional option for the:

Vacuum Pump FIT/LYO/59/0

7. Troubleshooting

7.1. Power failure

The refrigeration and vacuum pump will restart after a power failure. In the event of a power failure in the drying phase, the batch may become unusable. Whether the batch can be saved or not depends on the drying phase the product was in when the power failure occurred. If power returns within a few minutes then it is unlikely that any damage will have occurred. It is important to distinguish between the primary drying phase and the secondary drying phase. The product is in the secondary drying phase if the residual moisture has reached approximately 5 %. Below this value, the product is generally not damaged by a power failure.
If the product is in the primary drying phase, we recommend removing it for refreezing.
It is advisable to defrost the condenser chamber at this point.
If the product is considered to be still usable then it can be placed back in the freeze drier and the process can be started again.

7.2. Insufficient vacuum

7.1.1. Easy initial checks

Check that the drain valve is closed. Open the door and check there is no damage to the door seal. Ensure the door is in contact with the seal in all places. Align or replace the seal if necessary.
If the door now seals then the seal was at fault.
If the door does not seal then the drain valve, vacuum hose or vacuum pump is at fault.
Check that the vacuum pump is running and that there is suction. If there is, check that the hose push on connections between Lablyo Extra and vacuum pump are tight. Make sure that the drain valve is not leaking by checking for suction when it is closed.

7.1.2. Checks to make using the vacuum readout

The following steps require that the there is no ice or water inside the chamber. Dry the chamber with a cloth. To test the Lablyo Extra, connect to the vacuum pump and close door of the chamber. It will not achieve the same level of vacuum as a direct reading off the pump but it should probably be lower than 0.1 mbar.
To check the vacuum pump directly it is necessary to use a separate vacuum sensor. Make sure that the vacuum pump is warm and there should be a vacuum reading of 0.04 mbar or less.

7.3. Unit does not work

If the indicator light does not work and the refrigeration system is not running after the mains switch has been activated, the following tests must be performed:

- Check that the Lablyo Extra is plugged in.
- Check the breakers or fuses for the circuit.
- Check the plug fuse.

7.4. Insufficient ice condenser temperature

The refrigeration will stop if the ambient temperature is too high or the airflow is restricted to the heat exchanger. Once the permissible operating conditions are reached again the refrigeration unit is switched on automatically via the motor protection switch or via the pressure switch.
The minimum ice condenser temperature of approximately -80°C is reached when the ice condenser is not under load. Sufficient air circulation is very important. Do not place any objects behind the unit!

8. Maintenance

8.1. Ice condenser coils

Before each start-up, ensure that all water residues have been removed from the chamber and condensing coils and that the vessel is dry. Before every drying process it is recommended to open and close the drain valve.

8.2. Heat exchanger

The refrigeration heat exchanger is used to cool the refrigerant compressed by the refrigeration unit. The heat exchanger is located at the back of the unit and should be checked for dust or dirt residues every few months. It must be cleaned whenever necessary. The heat exchanger can be cleaned best by brushing, by using a vacuum cleaner from the outside or by using compressed air from inside of the unit. Excessive build up on the heat exchanger leads to a decrease in performance and may cause a failure of the unit!

8.3. Rubber valves and seals

Special attention must be paid to the rubber valves. If the valves are stiff, they must be dismantled, cleaned, slightly greased with vacuum grease and reassembled.

8.4. Vacuum pump

For the maintenance of the vacuum pump, please refer to the separate operating manual. Additionally, we would like to emphasize the following points: The oil level of the vacuum pump must be regularly checked at the sight glass (in case of continuous operation at least once a day). Top up oil to the required level via the oil inlet. Due to possible operation with gas ballast, oil consumption cannot be avoided. For topping-up see the operating manual of the pump. The oil change should always be carried out with warm pump.

8.5. Exhaust filter

If the unit is equipped with an exhaust filter (necessary if the exhaust gases cannot be extracted into the open air or into a vent), take care that the condensate in the filter does not rise too high.

8.6. Cleaning

8.6.1. Cleaning the freeze dryer and shelves

Use soapy water or other water-soluble, mild cleaning agents to clean the freeze dryer and shelves. Avoid corrosive and aggressive substances. Do not use alkaline solutions or solvents or agents with abrasive particles. Remove product residues from the ice condenser coils using a long handled brush (ex, kitchen tumbler brush) and a cloth. It is recommended to leave the door open when the freeze dryer is not in use so that moisture can evaporate.
If there is the risk of toxic, radioactive or pathogenic contamination, special safety measures must be considered and adhered to.

8.6.2. Maintenance of the air admittance/drain valve

Special attention must be paid to the air admittance/drain valve. If residues from previous drying processes deposit on it, the freeze dryer may not achieve correct vacuum levels. Therefore, take care that no product or other residues will get into the valve.

8.7. Checks by the operator

The operator has to ensure that the important parts of the freeze dryer that are necessary for safety are not damaged. This especially refers to:

- Lid or drying chamber
- Seals
- Oil level of vacuum pump
- Accessories, especially changes like corrosion, wear and abrasion of material etc.
- PAT test must be carried out annually.

9. IQ/OQ Qualification

This Qualification Protocol is solely intended to be used with Lablyo Extra freeze driers which are new or relocated.

It is written to assist the end-user in validation of predetermined specifications. The protocol begins with planning the site for the piece of equipment and therefore is of value prior to receipt of delivery.

The use of this document does not replace the need for the Lablyo Extra User's Manual and is in this case attached. Information within the User's Manual is required to complete this IQ/OQ Protocol. If the manual has been misplaced, copies can be obtained from the manufacturer or down-loaded from their website, www.freezedriers.com

9.1. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
1	**Site Planning**			
1a	Space Requirements	Refer to **1.3 Technical data of freeze dryer** Check in the User's Manual for dimensions of the model you have chosen. Has adequate floor or counter space been provided for placement of the equipment? (A minimum of 100mm is required between the back of a freeze dryer and the wall and between the sides and the walls for proper airflow through the refrigeration system.)	Y	N
1b	Electrical Service	Refer to the User's Manual for electrical requirements. Are services available for the equipment to be connected to an electrical circuit of adequate size and the proper voltage?	Y	N
1c	Vacuum Pump	Refer to the User's Manual. Have accommodations been made to provide a suitable vacuum pump? It must be capable of: at least 100 Liters/min With an inlet fitting suitable for a ¾-inch ID vacuum hose on one end and a KF25 on the other. It must have the same voltage rating as the freeze dryer? And have the means to be powered by an IEC connection. (An oil mist eliminator exhaust filter is recommended.)	Y	N

2	**Prior to operation**			
2a	Damage Claims	Have the delivered products been inspected fo any signs of damage that may have occurred while in transit? Keep packaging materials until inspection is complete. WARNING: Do not attempt to pull a vacuum on a freeze dryer with any damage to any of the accessories manifolds/chambers etc. Implosion and potential for injury can occur. If damaged contact Frozen in Time 01347 878158 or the distributer from whom it was purchased	Y	N
2b	Handling Solvents	Has the Safety Officer or equivalent reviewed the safe handling and disposal of solvents trapped as well as used vacuum pump oil?	Y N/A	N
2c	Vacuum Pump Installation	Install the vacuum pump per the User's Manual. Is the pump attached to the vacuum port at the top of the chamber with the correct rubber hose and clamps provided?	Y	N
2d	Vacuum Pump Electrical	Is the vacuum pump plugged into the rear of the freeze dryer and the pump's power switch turned to the ON position?	Y	N
	Vacuum Ballast	The vacuum pump's ballast should remain closed. Is the pump's ballast closed?	Y	N
	Electrical Connection	Plug the freeze dryer into a dedicated electrical outlet. Has the electrical service been verified to be adequate in size and voltage? (The ID plate on the rear of the freeze dryer has the electrical requirements.)	Y	N
2e	Electrical Grounding	Has the ground on the electrical service been verified?	Y	N

9.2. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
1	**Freeze Drier**			
1a	Condenser Chamber Refrigeration	With the freeze dryer system at ambient temperature, turn the Main Power Switch Switch on Condenser Chamber Cooling Does the refrigeration system start? Record the time it started. _____	Y	N
1b	Power to Vacuum Pump	Press the button labeled “Vacuum Pump.” Does the vacuum pump start? Record the time it started. _____	Y	N
1c	Refrigeration Effectiveness	Does the condenser chamber temperature reach -40°C in less than 40 minutes? (With the system under vacuum and 21°C ambient temperature.) NOTE: Freeze Dryers are tested to -80°C in the factory. Conditions may vary in the field resulting in warmer acceptance temperatures.	Y	N
	Product /Shelf Chamber Refrigeration	Set the Product Chamber Cooling to Does the refrigeration system start? Record the time it started. _____		
1d	Verify Displayed Temperature	The temperature indicated on the display is measured on the collector coil. There is a mobile probe that hangs free inside as well. The values were calibrated at the factory by correlating its reading with that of a reference gauge attached to a sensors. Does the display correlate to the reference Gauge +/- 2$_o$C? Ref. Instrument? _____ If the temperature does not correlate, contact Frozen in Time 01347 878158	Y N/A	N
1e	Vacuum Leaks	Verify that the system is leak-free by continuously running the vacuum pump with the refrigeration system ON. The rate the freeze dryer without samples achieves a low level of vacuum, (less than 13 Pa), it is dependent upon many factors: Inside volume & surface area of the system. Cleanliness or cleaners used on interior. Condition & size of the vacuum pump. Period of time the parts have been exposed to environmental conditions. Based on the freeze dryer’s displayed vacuum level, the freeze dryer	Y	N

		should reach its lowest level in less than 18 hours. If not, refer to Vacuum Troubleshooting Guide in the User's Manual. Does the system reach a displayed vacuum level of less than 6Pa in 18 hours?		
1f	Temperature Graph Display	The temperature graph traces on the control panel is a quick reference of the temperatures. Verify these graphs are operating properly. Compared to the readouts.	Y	N
1g	Vacuum Wave Display	The control panel's vacuum trace is a quick reference of vacuum level. Verify this is operating properly. Compared to the readouts.	Y N/A	N
1h	Verify Displayed Vacuum	The vacuum level indicated on the LCD display is measured between on the condenser chamber. The value was calibrated at the factory by correlating its reading with that of a reference gauge. The calibration was performed at a very low level, approximately 10Pa. NOTICE: Factory calibration was performed using a precision Active Piranni Gauge calibrated to a Capacitance Manometer standard. Despite the system's calibration and repeatability, the readings taken at such a low level of vacuum should only be considered as a verification of a leak-free system. Vacuum swings can be attributed to contamination of surfaces, which could take days to outgas. Adjustments are discouraged. Before any adjustments are made to the factory calibration of the vacuum measurement, answer positively to these questions: 1) Is the vacuum standard being used to verify the freeze dryer accepted by the organization to be precise and has it organization to be precise and has it been calibrated recently? 2) Is the level of accuracy we are attempting to reach pertinent to the freeze drying applications? Does the vacuum display correlate to the reference gauge? Ref. Instrument? _____	Y N/A	N

		If vacuum is to be calibrated, contact Labconco Product Service for calibration procedure.		
1i	Defrost	With the refrigeration switched OFF, press the “defrost” button ON. Does the condenser chamber become warm to the touch?	Y N/A	N

2	**Routine Maintainance**	Below are helpful hints to be included in the organization's preventive maintenance plan.		
2a	Vacuum Grease	Vacuum grease should be applied to rubber components as required. In general, vacuum grease should be the first step in trouble shooting vacuum leaks. Thin layers of grease are adequate for all seals. Only use grease specially formulated for low vacuum service. Is vacuum grease readily available and documented? Type of grease used? _____	Y	N
2b	Vacuum Pump Oil	The vacuum pump oil should be changed as needed. Change oil that appears cloudy or discolored. At a minimum, oil should be changed every 1000 hours of service. Has there been a preventive maintenance plan established for the vacuum pump? Type of oil to be used? _____	Y	N

3	**Personnel Training**			
3a	User Training Related to Equipment	Have personnel that will use the Lablyo Extra freeze drier been adequately trained? Are personnel familiar with: All the buttons and displays on the front; Collector capacity limits before defrosting; Defrosting and draining methods; Safe handling of solvents drained; The use of vacuum grease; Opening, closing and venting sample valves; Cleaning of the freeze dryer and neutralization of acids?	Y	N
3b	User's Manual	Are the personnel who are to use or maintain the Lablyo Extra able to locate the User's Manual for the machine?	Y	N

9.3. Summary

Lablyo Extra freezedrier IQ/OQ Document
Equipment Location _____
FreeZone Ser. No. _____ Model No._____
User Protocol _____ Revision (or Date published) _____
Contact (print name):_____
Title: _____
Review the "Response" columns for answers of "NO." Use the area below to describe the deficiency or unacceptable results. Those deficiencies are to be followed with an instruction for "Corrective Actions." Once acceptable results are obtained, the deficiency is "accepted" by signing the Corrective Action.

Step	Deficiency followed by Corrective Action	Signature