SuperModulyo 3-Shelf Freeze Dryer
INSTALLATION AND OPERATION MANUAL

Freeze Dryers &
High Vacuum Systems

MechaTech Systems Ltd
Thornbury UK

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Supermodulyo 3-Shelf Freeze Dryer Installation and Operation Manual

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For information about our products, please visit our website.

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1. Introduction

1.1 Who should use this manual?

This Operator's Manual is intended for anyone trained and authorised to operate the MechaTech Supermodulyo 3-Shelf Freeze Dryer.

1.2 Scope of this Manual

This manual attempts to cover all the issues that an operator is likely to encounter in normal, daily operation of the system.

1.3 Disclaimer

The purpose of this manual is to provide instructions and guidance for using the Supermodulyo 3-Shelf Freeze Dryer. Nothing contained in this manual constitutes a warranty of any kind in respect of the machine or of the results to be achieved by its use. The only warranties given by MechaTech Systems Ltd in respect of any machine are those expressly given by MechaTech Systems Ltd in the contract under which it sells the machine to its buyer.

The information contained in this manual is believed to be accurate as at the date of publication, but MechaTech Systems Ltd gives no guarantees in this respect. Note that it is the operating company's responsibility to ensure that it complies with such regulatory and other legal requirements as may be from time to time apply to operation of the machine.

1.4 Service and Sales Contact

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2. Safety Precautions

Instructions in this manual may require special precautions to ensure the safety of the personnel performing the operations on both the Freeze Dryer.

Potential safety issues are indicated by this symbol: 

Please read the safety information before performing any operation preceded by this symbol.

There are two levels of safety message: **WARNINGS** and **CAUTIONS**. The distinction between the two is as follows:

WARNING

Failure to observe this warning could result in death or serious injury.

CAUTION

Failure to observe this caution may cause minor injury, or damage to equipment.

Do not operate the machine until you have read the list of warnings and cautions below.

2.1 List of Warnings

WARNINGS

- Failure to follow safe installation and servicing procedures could result in death or serious injury.
- Only authorised personnel trained by MechaTech Systems Ltd and qualified by experience may perform maintenance on the Supermodulyo 3-Shelf Freeze Dryer.
- Do not make changes to this equipment of any kind without prior consultation with MechaTech Systems Ltd.
- Please note that international regulations and various safety requirements strictly prohibit the modification of this equipment in any way without first being approved by a competent specialist.
- Some protective covers may not be interlocked, as it is not intended for them to be removed during normal use of the machine.
- Do not attempt to override the safety circuit of the machine in any way. The safety circuit exists to ensure that a hazardous situation cannot arise during the operation of the machine.
- The customer is responsible for fitting and using machine safeguards to protect personnel from becoming trapped or crushed by moving parts of the machine. Failure to do so may cause death or serious injury.

WARNINGS

- The 3-shelf unit weighs approximately 180 kg. It is therefore important that the correct siting and lifting procedures are observed. Under no circumstances should the unit be lifted manually or without the aid of either a hydraulic lift, when packed, or a crane during the assembly procedure. When assembled on top of the supermodulyo the combined weight is approximately 360 kg. Movement on the castors should therefore be kept to a minimum, and then only over clean, even floor surfaces, to prevent the unit from toppling. This unit will topple if inclined at angles greater than 10°. Lifting the 3-shelf unit and the supermodulyo unit together must never be attempted.
- It is essential that the 3-shelf unit is earthed. The earthing provided by the supermodulyo is not sufficient to earth both units.

WARNINGS - SODIUM AZIDE EXPLOSION HAZARD

- Sodium azide, which is sometimes used as a stabilising agent in freeze drying processes, is a toxic and (when dry) highly explosive material. In the process of pumping product containing this chemical, a poorly understood reaction can occur in the presence of heavy metals such as copper, lead, zinc and cadmium. The result of this reaction is the formation of heavy metal azides which are highly unstable and present a very severe explosion hazard.
- If sodium azide is to be processed in this equipment, then the product probes and vacuum leadthrough (both of which contain copper) must be removed from inside the chamber. Refer to section 5 of this manual for modification procedure and for further details of sodium azide hazards
- If it is suspected that azide precipitation or formation has occurred, the user should not attempt to decontaminate or clean the suspected area; instead, the user should isolate the equipment and seek expert advice and assistance.

WARNING

Depending upon previous uses, the shelves inside the chamber may be either hot or very cold. In order to prevent possible injury care should be taken not to touch any hot or cold surfaces.

WARNING

Disconnect the electrical supply before carrying out any repair work. There are no user serviceable parts inside the electrical box.

WARNING

Before attempting to replace either the heater or the thermostat, make sure that the unit is not hot from previous usage and that it has been disconnected from the electrical supply.

2.2 List of Cautions

CAUTION

A shelf temperature that is too high may overload the supermodulyo, and this may result in melting the product. During the drying process, the indicated condenser temperature on the supermodulyo should not rise above-35°C.

CAUTION

- If vials fall off the shelves and break take care when cleaning that broken glass does not accumulate at the bottom of the chamber.
- Do not apply a force greater than 14 kgf (30 lbf) as this may cause the vials to shatter or the chamber to deform.

CAUTION

It is recommended that any faults inside the control box are repaired by MechaTech systems.

CAUTION

Do not overfill the oil tank as the oil can expand by up to 2 litres at high temperatures.

CAUTION

If the stoppering action becomes stiff, do not wrench the handle as this may permanently deform the chamber of framework.

CAUTION

Poor oil quality will give poor vacuum performance and will damage the vacuum pump.

3. Introduction to the Supermodulyo 3-Shelf Freeze Dryer

The Freeze Dryer is for the purpose of drying a wide range of aqueous products in a variety of different sizes of vials. Freeze drying is a method used to dehydrate materials via a process involving the sublimation of any water content (in the form of ice) under vacuum conditions. The process can be subdivided into three (3) stages; freezing, primary drying, where the bulk of the water content is removed by sublimation, and secondary drying where residual bound water is removed at higher temperatures.

LYOSCIENCE freeze dryers are capable of automatically performing all these functions in a controlled and reproducible manner. The equipment consists of a vacuum drying chamber mounted on top of a refrigerated condenser with integral vacuum pump. The drying chamber contains up to three (3) refrigerated shelves that can be moved up and down via a manually operated ram for stoppering processes. Both condenser and drying chambers are fitted with their own refrigeration systems. The temperature of the product shelves can be controlled between +60°C and –40°C. Both systems have a compact footprint allowing the equipment to be moved through standard sized doorways. Commissioning is simple and straightforward, requiring no external services other than mains power. All components are housed inside a free-standing cabinet with detachable inspection panels at the front, rear and sides for easy maintenance.

3.1 The Drying Chamber

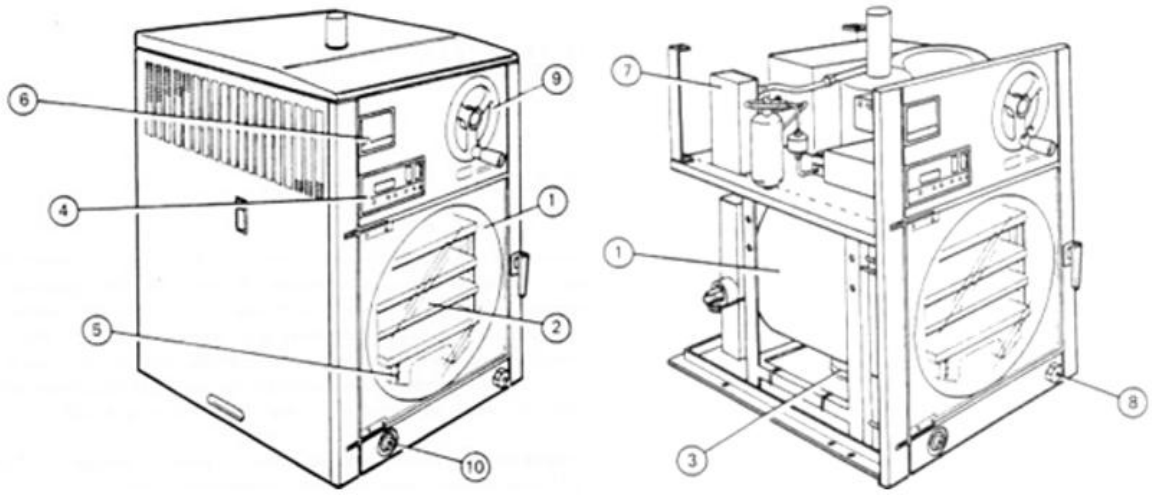


Figure 1 - Drying Chamber

The Drying Chamber comprises the following main components, identified on Figure 1:

1. Vacuum Chamber
2. Shelf Assembly
3. Isolation Valve (optional)
4. Instrument and Control Panel
5. Temperature Probes
6. Pirani Pressure Gauge
7. Refrigeration System
8. Air Admittance Valve
9. Stoppering Jack
10. Pressure Control Valve

The drying chamber is situated on top of the condensing unit. The chamber is fitted with three temperature controlled stainless steel product shelves, a refrigeration / heater plant with heat

transfer fluid circuit and a shelf stoppering mechanism. A transparent Perspex door at the front of the chamber provides access for loading and unloading and allows the operator to inspect the product during the freeze drying process.

Each shelf contains an internal network of channels through which the heat transfer fluid can flow freely and continuously. Heat is extracted or introduced into the fluid via the refrigeration / heater plant and is then distributed to each shelf in parallel through a common manifold and liquid re circulating pump. Sensors in the fluid circuit provide feedback for closed loop temperature control. Temperature control is achieved by modulating the open/closed state of a valve within the refrigeration system between 100% and 0%. Where –100% is always open, 0% is always closed. A PT100 sensor mounted in the fluid circuit provides temperature feedback for the loop.

The shelves are mechanically linked to a manually actuated ram. The ram moves the shelves up and down allowing stoppering of vials under vacuum and other controlled atmospheres. Operation of the ram is via a wheel situated on the front of the freeze dryer.

Up to three (3) product probe sensors (PT100's) can be connected and attached to the shelves or the product to enable continuous monitoring of the process.

The operation of the freeze dryer is controlled from the Eurotherm Visual Supervisor (Eycon10) and the Eurotherm 2550 modular process controller.

The Visual Supervisor combines process control, data acquisition, data logging, and setpoint programming and operator functionality. Features include comprehensive event and alarm management and local data logging facilities. The front-end colour touch screen provides the user interface. Navigation between the User screens is achieved using standard display panes and function keys. User screen descriptions can be found later in this document.

The T2550 modular process controller provides the Input/output interface for the control system, signal conditioning and PID control for the temperature and pressure. These two instruments talk to each other via ELIN (10/100Mbps Ethernet) communication using RJ45 type connector.

Each shelf contains an internal network of channels through which the heat transfer fluid can flow freely and continuously. Heat is extracted or introduced into the fluid via the refrigeration / heater plant and is then distributed to each shelf in parallel through a common manifold and liquid recirculation pump. Sensors in the fluid circuit provide feedback for closed loop temperature control. Temperature control is achieved by modulating the open/closed state of a valve within the refrigeration system between –100% and 0%. Where –100% is always open, 0% is always closed.

A RTD sensor mounted in the fluid circuit provides temperature feedback for the loop.

3.2 The Condensing Unit

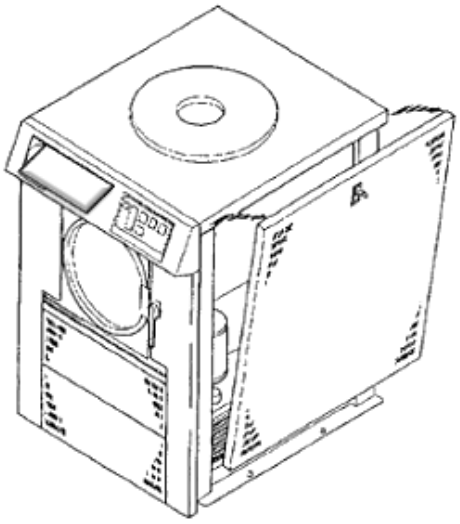


Figure 2 - Condensing Unit

The condenser unit consist of a cylindrical chamber with a 75 mm inlet port situated near the front of the chamber and a 40 mm (NW40) outlet port positioned at the rear of the chamber. The chamber condensing coil is cooled directly by an integral CFC free refrigeration system mounted in the base of the unit. During freeze drying, water vapour that is extracted from the product, is condensed onto the coil, resulting in the formation ice. The chamber has a total ice capacity of ~18 kg between defrost cycles. The minimum temperature of the chamber wall under vacuum conditions with no load applied is –50°C.

The condenser inlet is connected to the drying chamber via a pneumatically actuated high vacuum butterfly valve. The chamber outlet is connected to the inlet of an RV12 vacuum pump. A transparent Perspex door at the front of the condenser allows the operator to inspect the ice build-up and provides convenient access for cleaning purposes.

The condenser chamber has a hot water gas utility. The chamber is automatically defrosted when the condenser refrigeration system is turned off. The ice can be removed as a solid plug after defrosting the chamber for ~ 1 hr. Any ice that has melted can is removed via a manually operated drain port in the bottom of the chamber or removed by the operator during general maintenance.

An Edwards two stage oil-sealed rotary RV12 vacuum pump is used to evacuate both condenser and drying chambers. The pump outlet is fitted with a mist filter to prevent oil mist escaping to the atmosphere. The exhaust of the filter is piped to a stub connection at the rear of the freeze dryer, which in turn should be connected to the end user's exhaust extraction system. The condenser temperature and pressure are monitored with a pirani gauge and a PT100 respectively; data can be continuously displayed on the touch screen if required.

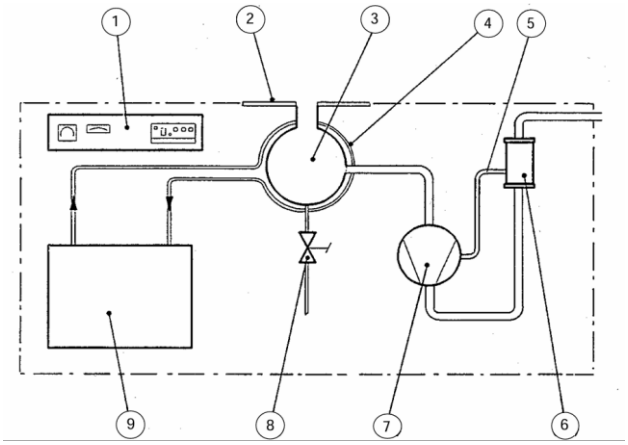


Figure 3 - Schematic illustration of the condenser chamber components

1. Control panel
2. Accessory flange
3. Condenser chamber
4. Cooling coil
5. Oil return tube
6. Oil mist filter
7. Vacuum pump
8. Drain valve
9. Refrigeration system

Refer to *Figure 4* for the location of items in the following description below of the refrigeration system in the condensing unit.

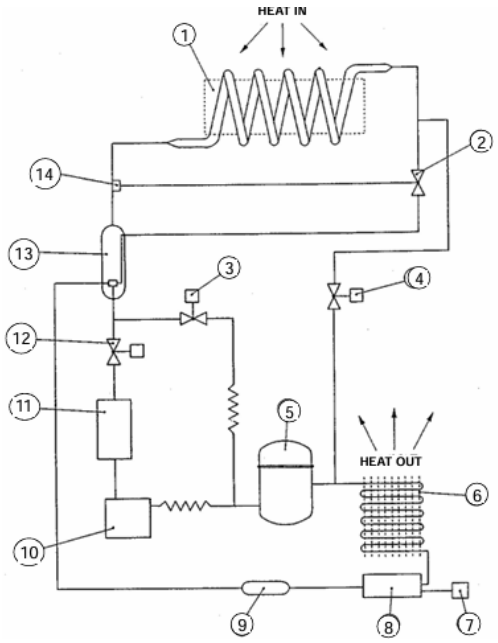


Figure 4 - Refrigeration system

The condenser chamber (1) is cooled by refrigerant, which evaporates in the cooling coil. The compressor (5) is a high capacity, air-cooled, hermetically sealed unit. A heat exchanger (13) sub-cools the liquid refrigerant to the evaporating temperature before expansion. This increases the efficiency of the system.

A suction-line accumulator (10) in the return line from the cooling coil to the compressor (5) prevents slugs of liquid refrigerant, which might cause damage, from reaching the compressor. A filter-dryer (9) in the line between the heat exchanger (13) and the liquid receiver (8) absorbs any residual particulate and water contamination in the system. The filter-dryer does not need to be serviced or replaced.

3.3 Flow chart of the Supermodulyo 3 - Shelf Unit

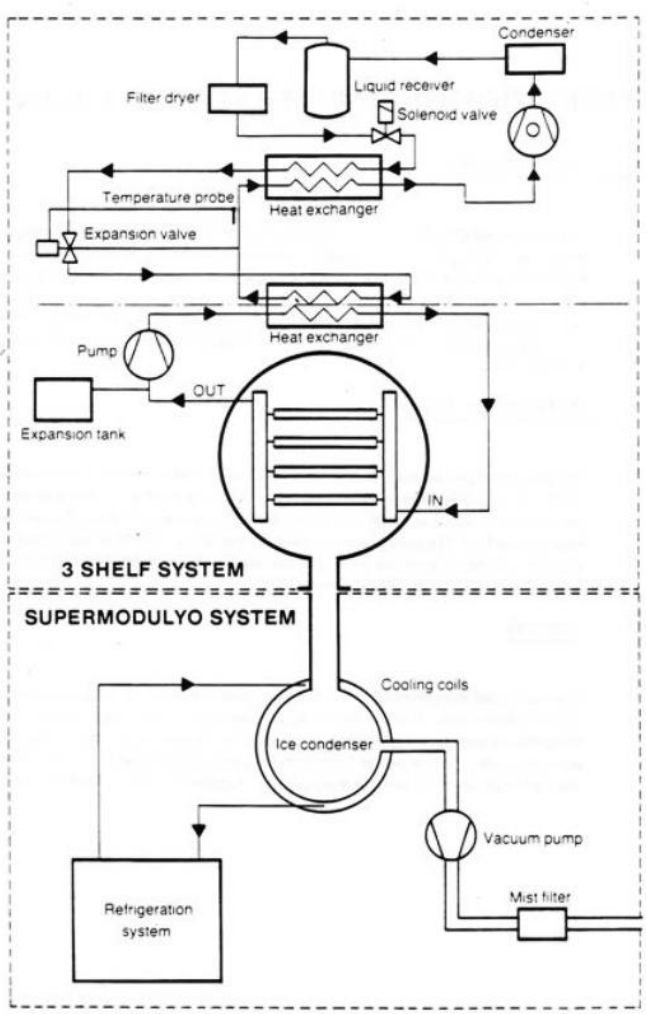


Figure 5 - Flow chart of the Supermodulyo 3 - Shelf Unit

3.4 The Freeze Drying Process

3.4.1 Freezing Process

The time taken to carry out the freezing process, although dependent upon the nature of the product, can be speeded up in some instances by first pre-cooling the shelves prior to loading. Care should be taken if using this method because some products suffer from thermal shock and in these instances a more gradual freezing is recommended.

3.4.2 Drying Process

Drying will commence as soon as the product is under vacuum, but once the vacuum falls to less than 0.1 - 0.5 mbar, the drying process becomes very slow. The process can be expedited by applying heat to the product; this is achieved by heating the fluid that circulates around the shelves. Shelf heating not only depends on the product, but also on the load conditions and plant capacity. The shelf temperature, therefore, should be chosen to suit both the product and the plant.

CAUTION

A shelf temperature that is too high may overload the supermodulyo and this may result in melting the product. During the drying process, the indicated condenser temperature on the supermodulyo should not rise above -35°C.

Shelf heating is usually initiated when the chamber pressure has reached 0.1 - 0.5 mbar (this pressure is typically reached within 30 minutes of starting pump-down). However, before deciding on shelf heating, observe the product. If the product has been correctly frozen then its cake (mass) is usually homogeneous in colour and compact. If the cake is uneven in colour or signs of boiling are visible, then the product has been incorrectly frozen or has undergone some change.

3.4.3 Secondary Drying

In some cases, it may be necessary to go through a secondary drying process in order to drive off the residual water content after going through the ordinary drying cycle. To facilitate secondary drying, the shelves can be heated to +60°C. Where there is no danger of melting the product and temperature control is not critical, the refrigeration compressor may be switched off at the front panel to save electricity. This may also be possible during the ordinary drying cycle, but this has to be individually assessed according to the nature of the product and determined by experiment.

3.4.4 Stoppering

The mechanical stoppering of vials within the chamber can be carried out under vacuum, or at atmospheric pressure. When stoppering at atmospheric pressure the chamber may be back filled with an inert gas by using the leak valve option. The shelves are moved by a low-geared screw mechanism which moves 1 mm with each revolution of the hand wheel. This enables the very large forces required for stoppering to be applied by most personnel.

4. Installation and Commission

MechaTech Systems Ltd engineers are commissioned to install and setup the system

4.1 Unpack and Installation

Remove all packing materials and inspect the Supermodulyo 3- Shelf freeze dryer. If the freeze dryer is damaged, notify MechaTech Systems and the carrier in writing within three days; state the Item Number and Serial Number of the Supermodulyo 3- Shelf freeze dryer together with your order number and your supplier's invoice number. Retain all packing materials for inspection. Do not use the Supermodulyo 3- Shelf freeze dryer if it is damaged.

4.2 Locate the Supermodulyo 3- Shelf freeze dryer

The Supermodulyo 3- Shelf freeze dryer is designed for use on a level floor. Locate the Supermodulyo 3- Shelf freeze dryer in its required operating position, ensuring that the floor is adequate to support the equipment, within convenient access to a suitable electrical supply. We recommend that you leave an air gap of at least 500mm between all four sides of Supermodulyo 3- Shelf freeze dryer and any wall or obstruction. If you do not leave a sufficient air gap, poor cooling of the Supermodulyo 3- Shelf freeze dryer may result in poor performance. When you locate the Supermodulyo 3- Shelf freeze dryer, you should also consider ease of access for maintenance and repair work, when you will need to remove the cover of the freeze dryer.

4.3 Electrical Connections

WARNING

The unit is factory configured for two separate 240volts (13 amps), single phase supplies. Check that your voltage supply is compatible. If you operate the machine on the wrong voltage, you will damage it.

1. Voltage 240Vac
2. Frequency 50 Hz
3. Loading 8 amps / Supply
4. Fusing 13A / supply

WARNING

Failure to close all panels prior to connecting to mains power may result in injury to the operator.

4.4 Mechanical requirements

Compressed air – 6 Bar, ¼" BSPP Female

5. Operation

5.1 Power up

Power up and **Power down** is achieved via the two control power switches located on right hand side of the operator interface for the shelf unit and the right hand side of the condenser unit control panel.

A power indicator illuminates to confirm that control system is on.

The Visual Supervisor, after a short self-diagnostic routine, starts up automatically in one of two different ways:

Hot start, when control power is returned within 30 minutes, the system uses data about the current program that the Visual Supervisor automatically saves in case of power failure. Using this information, which is preserved through any power loss, the Visual Supervisor is able to automatically restart the program from the point it was.

Cold start, the freeze dryer reverts to its default 'Closed Down' status as follows:

- Compressors off
- Circulation pump off
- Vacuum pumps off
- Valves closed
- Freeze-drying cycle not running
- Shelf temperature set point set to "Setup" screen value

System status display reads 'Closed Down'

The power indicator extinguishes to confirm that control system is off.

System status: Visual supervisor, cooling compressors, fluid pump and vacuum pumps off, valves closed. Alarm contacts open.

5.2 System Access Control

The Visual Supervisor is set to use individual user accounts. Accounts are configured by the user and allocated to one of the standard access levels as follows:

1. Locked- Default level on power up. Read only with limited navigational ability.
2. Operator- User is able to set up batch identification, download programs run cycles, view alarm history, historical program trending, acknowledge alarms
3. Engineer- as Operator but in addition can and edit programs and user adjustable parameters and customise the data logging facility.

4. Administrator- allows individual security accounts to be set up with access rights appropriate to each level of user.

Access- the user is able to log on by the following operation.

1. Access to Access screen = “MENU” key / “ACCESS” button or “ACCESS” pane.
2. Enter Identity.
3. Enter Password.

When user is logged on it is possible to then change their specific password by the following operation.

1. Access to Access screen = “MENU” key / “ACCESS” button / “PASSWDS” button or “ACCESS” pane/ “PASSWDS” button.
2. Enter and confirm new password.
3. Press Change button.

5.3 Initial start up

Initial startup- before freeze-drying cycles can be run the user first has to switch on the Cooling compressors and Vacuum pump.

1. From the Overview page, press the Drying Chamber ‘REFRIGERATION’ field and select ON
2. From the Overview page, press the Condenser Chamber ‘REFRIGERATION’ field and select ON.
3. Wait until the temperature on the condenser is less than -20°C
4. From the Overview page, press the ‘Rotary Pump’ field and select ON.
5. The freeze dryer is now ready for running freeze drying programs.

5.4 Loading product

WARNING

The chamber should not be loaded / unloaded when the shelf temperature is less than 10oC. If it is essential to access the chamber under these conditions, then protective gloves or suitable PPE should be worn.

CAUTION

Do not use excessive force to open the chamber door. If the drying chamber is under vacuum (for instance when the vacuum dryer is first delivered) it will not be possible to open the chamber door.

NOTE: To open the chamber doors if the chamber is under vacuum, first vent the chamber to atmosphere.

5.5 Running automatic files

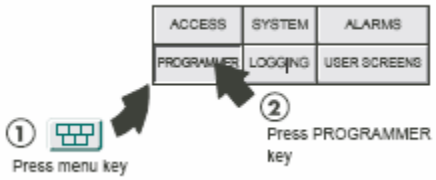
Run automatic cycles – user is able to load programmes and run/abort vacuum drying cycles. Programmes are started independently of the Batch engine. A program is initiated directly from the Program menu.

There are three ways to run a program.

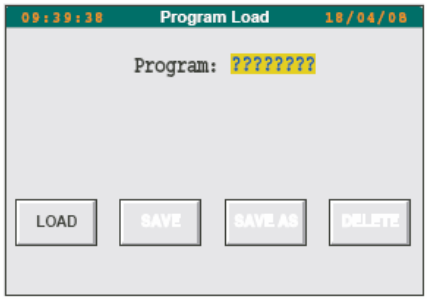
1. Run a program now
2. Run a program from a point
3. Schedule a program to run from a time

5.5.1 Run a program now

To run a program, first load the required program from the list of stored profiles.

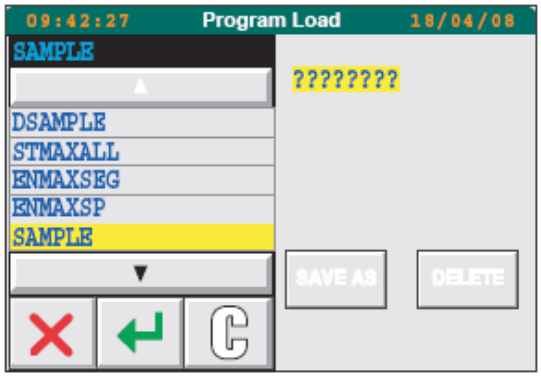


1. Press the MENU printed key
2. Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.



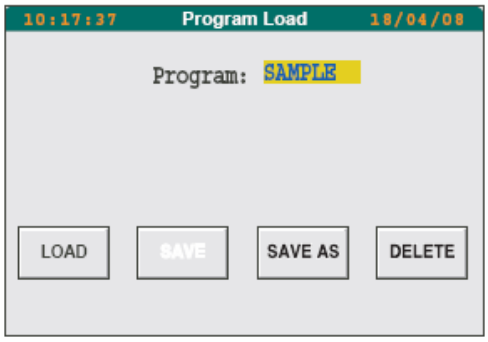
Note: this is example figure

3. Press the PROGRAM button. The *Load/Save Program* screen will be displayed.
4. Press the file name field. A list of program names will appear in the left half of the screen. From the list, press the name of the program to be loaded.



Note: this is example figure

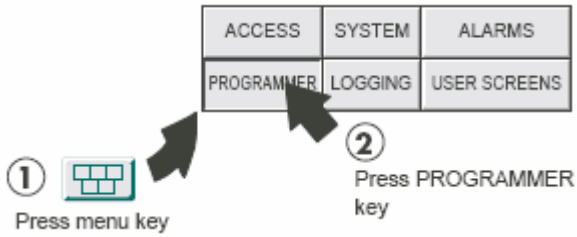
5. Press the green RETURN key. The display returns to the Load/Save screen and the file name field now displays the name of the program that has been selected.



Note: this is example figure

6. Press the LOAD button. At this stage, the selected program can either be run or modified from the Programmer screen. The program name and the program status will also be displayed in the program panel in the top left hand corner of the screen. At this stage, the program status is 'idle'.

7. Press the START button. The program panel changes to green indicting that the program is now running. The time when the program is due for completion is also displayed together with a number that indicates the number of segments that have been completed.



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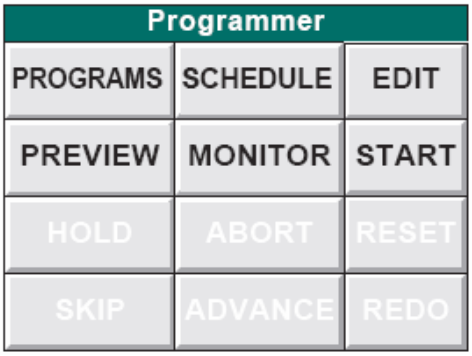

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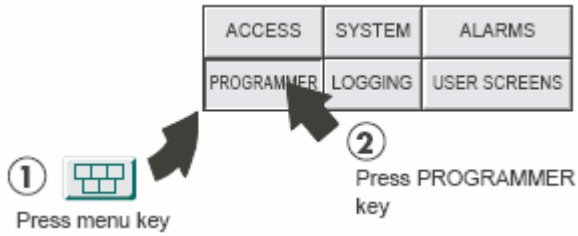
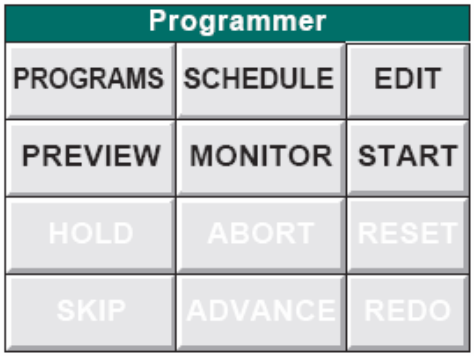
5.5.2 Run a program from a point

Select this function if you wish to run a program from a segment other than the start point of the selected program.



Note: this is example figure

1. Press the MENU printed key
2. Press the PROGRAMMER button. The Programmer Menu screen will be displayed.
3. Press the PROGRAM button. The Load/Save Program screen will be displayed.
4. Press the file name field. A list of program names will appear in the left half of the screen. From the list, press the name of the program to be loaded.
5. Press the green RETURN key. The display returns to the Load/Save screen and the file name field now displays the name of the program that has been selected.
6. Press the LOAD button. At this stage, the selected program can either be run or modified from the Programmer screen. The program name and the program status will also be displayed in the program panel in the top left hand corner of the screen. At this stage, the program status is 'idle'.
7. Press the RUN FROM button.



Note: this is example figure

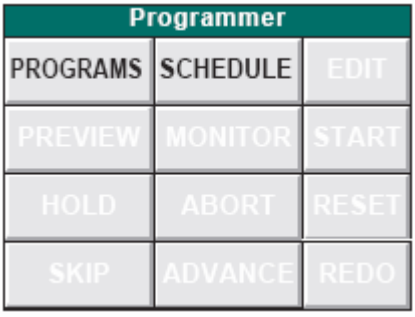
8. A screen headed with the name of the program is loaded. The total running time for the program selected is displayed. Press the Run From field (default setting is 00:00:00) and input the time on the numeric keypad (in hours: minutes: seconds) after the start of the program when the program should run from. Press the green RETURN key when inputting is complete. Details of the segment which will be running when the program starts will then be shown in the lower half of the display.
9. To run the program, press the RUN key. The Programmer screen will appear. The program panel changes to green indicting that the program is now running. The time when the program is due for completion is also displayed together with a number that indicates the number of segments that have been completed.

5.5.3 Schedule a program to run from a time

Security level: Operator or supervisor

Scheduling a program allows the operator to set a time at which a program will start and run automatically.

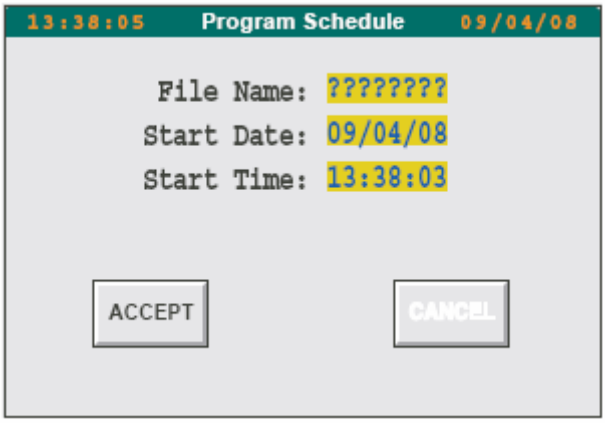
1. Press the MENU printed key
2. Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
3. Press the SCHEDULE button. The *Schedule Program* screen will be displayed.



Note: this is example figure

4. Press the **File Name** field. A list of program names will appear in the left half of the screen. From the List, press the name of the program to be loaded.
5. Press the green RETURN key. The display returns to the *Schedule Program* screen and the **file name** field now displays the name of the program that has been selected.

6. Press the **Start Date** field. Input the required start date on the numeric key pad (day:month:year). Press the green RETURN button.
7. Press the **Start Time** field. Input the required start time on the numeric key pad (hours:minutes:seconds). Press the green RETURN button.



Note: this is example figure

8. To change the number of iterations (number of complete cycle to be performed sequentially), press the **Iterations** field. Input the required number and press the green RETURN button.

NOTE: The default number of iterations is 1. Entering a value "0" will run the program continuously.

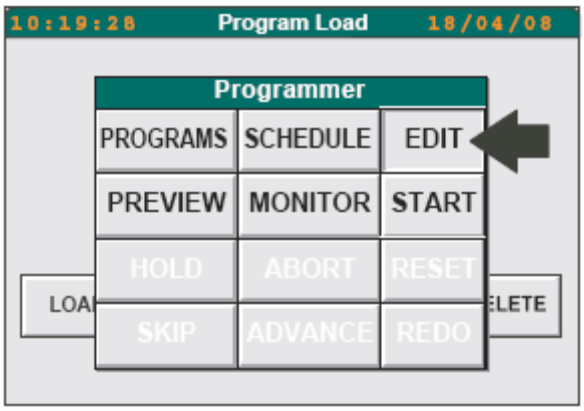
5.6 Creating/Editing the Program

5.6.1 Creating a new program

The method used to create new programs is based on editing an existing program and saving the modified program under a new name. To load any program, follow the instructions below:

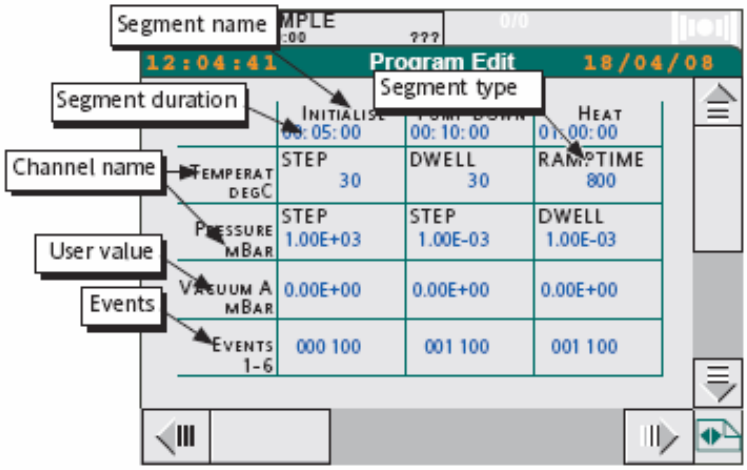
1. Press the MENU printed key
2. Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
3. Press the PROGRAM button. The *Load/Save Program* screen will be displayed.
4. Press the **file name** field. A list of program names will appear in the left half of the screen. From the List, press the name of the program to be edited.
5. Press the green RETURN key. The display returns to the *Load/Save* screen and the **file name** field now displays the name of the program that has been selected.
6. Press the LOAD button. At this stage, the selected program can either be run or modified. To edit the program, press the EDIT button. Details of the program will appear in the form of a table (referred to as the Editor Screen). Each column of the table represents a segment of the freeze drying process and each row describes the freeze drying conditions of either temperature or pressure (pressure is controlled by the high vacuum valve which is either open or closed). Individual cells (denoted SP cells) define the temperature or pressure set points for any particular segment. The top rows of cells (referred as 'segment headings') define the duration and the function name of each segment.
    a. If the program has components (parameters) which are not in the LIN database then an error message will appear and the program will not load.

After a successful load, the Programmer menu reappears.



Note: this is example figure

b. Press EDIT, the Program Editor Page appears showing various values in tabular form, starting with channels, followed by any user values and finally events.



Note: this is example figure

To configure the segment headings follow the instructions below:

c. Press the segment heading that must be modified. A box displaying data about the segment will appear. To change the segment name press the segment field. Use the keyboard to input the required name. To change the segment duration press the Duration field and use the keyboard to input the required time (hours: minutes: seconds).
d. Press the green Return key. The Program Editor page reappears, showing the new segment name and duration.

Repeat for any segment heading as necessary.

NOTE: Changing the duration will not be permitted if the “Ramp @” function has been selected previously anywhere in that segment.

To configure the segment SP cells, follow the instructions below:

1. Press the SP cell that must be modified. A box displaying data about the cell will appear. Press the Type field. A list of optional functions will be displayed. The choices of functions available include Dwell, Step, Ramp and Ramp@.
2. Select the function that is required and press the green Return key.
3. Depending on the function selected, time and temperature set point values can then be modified by pressing the appropriate field and entering the value on the numeric keypad. Press the DONE button to update the program table (the set point data and code is displayed in each cell).

Function Name	Function Description	SP code	Set point fields
Dwell	Temperature set point is held for duration of segment	D	None
Step	Temperature ramps to temperature set point as fast as possible	S	Temperatu re
Ramp	Temperature ramps to temperature set point at a constant rate over the duration of the segment	R	Temperatu re
Ramp@	Temperature ramps to temperature set point at specified ramp rate	R@	Rate (/hr) Temperatu re

Table 2 - Functions Descriptions and Coding

5.6.2 Inserting a segment

To add a new segment to the freeze drying program, follow the procedure below:

1. From the program editor screen, press the heading that will proceed the new segment you wish to insert. A box displaying data about the segment will appear.
2. Press the INS SEG key. The *New Segment* screen will appear.
3. Press the **Segment** field and use the keyboard to type in the segment name.
4. Press the green RETURN button. Press the OK button on the *New Segment* screen. A column will then appear in the program table, representing the new segment.

5.6.3 Deleting a segment

To remove a segment from the freeze drying program, following the procedure below:

1. From the program editor screen, press the segment header to be deleted. Details of the segment will appear.
2. Press the DEL SEG button. The *Confirm Delete* screen will appear. Press OK, to confirm delete command.

NOTE: The first segment of a program cannot be deleted.

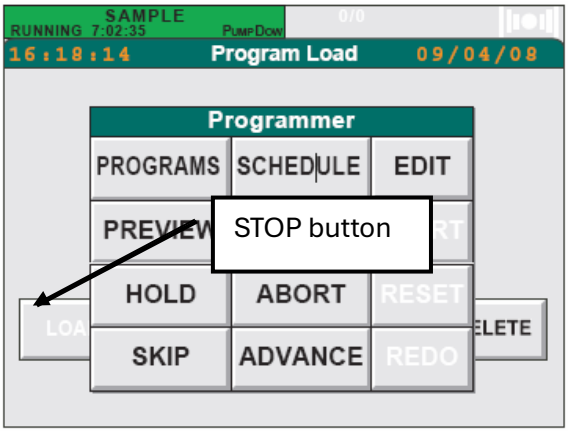
5.6.4 Save/Save as

To save the updated program under the same file name after editing is complete, or to save the program as a new file name, follow the procedure below.

1. From the program editor screen, press the MENU button on the printed keypad. From the menu options press the PROGRAMMER button. The *Programmer* screen will appear.
2. Press the PROGRAMS button. The *load /Save Program* screen will appear.
3. To save the edited program under the same file name (shown in the **File Name** field), press the SAVE button.
4. To save the edited program under a new file name, press the SAVE AS button. The *Save As* screen will appear.
5. Press the **File Name** field and enter the new file on the keypad.
6. Press the green RETURN key and the OK buttons to confirm.

5.7 Complete a program

The program panel changes to blue indicting that the program is now completed and the dryer will state resting on “complete” mode holding the pressure and the temperature inside the chamber. The operator will finish the program pressing the “STOP” button. At this state the inter-chamber valve will close and the chamber remain in vacuum until the operator manually vented by pressing the vent valve from the Overview screen.



Note: this is example figure

5.8 Monitoring the Program

There are two ways of monitoring a program as its running:

- *Viewing a textual/numeric display, generated by the Monitor facility*
- Viewing a graphical display, generated by the Pre-plot facility.

MONITOR displays text and numeric information about the program, as a list.

PREPLOT displays a graphic profile of the target and actual process variables (PVs).

Generally, MONITOR is used when precise values are needed; PREPLOT is used to provide an overview.

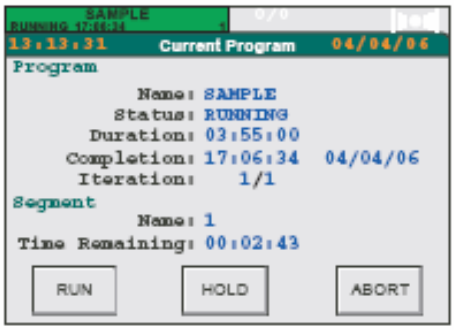
5.9 The monitor facility

With a program running and the Programmer menu displayed (step 8 in section 3.1.1 running a program now), press MONITOR.

The Current Program page appears, displaying the following information about the program as it is running (most of the fields are self-explanatory):

PROGRAM

Name:	Program name
Status:	Run, Hold, Held Back, Idle, Error, Complete.
Duration:	Running time, start to finish
Completion:	Time of completion of current run (assuming no interruptions)
Iteration:	Number of current run / number of runs requested.
Segment Name:	Segment name (usually a number)
Time Remaining:	Time remaining to completion of the current segment (decrementing second by second).



Note: this is example figure

5.10 Service Mode

User will be able to manipulate individually controlling system equipment from Service screen. Service mode is accessible by pressing the Service button on the overview screen (Security level: Operator or Supervisor). Service screen allows the operation of:

1. Diathermic pump
2. Rotary pump
3. Booster pump
4. Refrigeration compressor
5. Condenser defrost inlet valve

6. Condenser defrost drain valve
7. Vacuum valve
8. Inter chamber valve
9. Isolation valve
10. Bypass valve
11. Drying chamber vent valve
12. Condenser vent valve
13. Auto/man mode button (output status)
14. Shelf temperature set point
15. Pressure set point
16. Defrost/cooling valve
17. 17. Shelf cooling valve

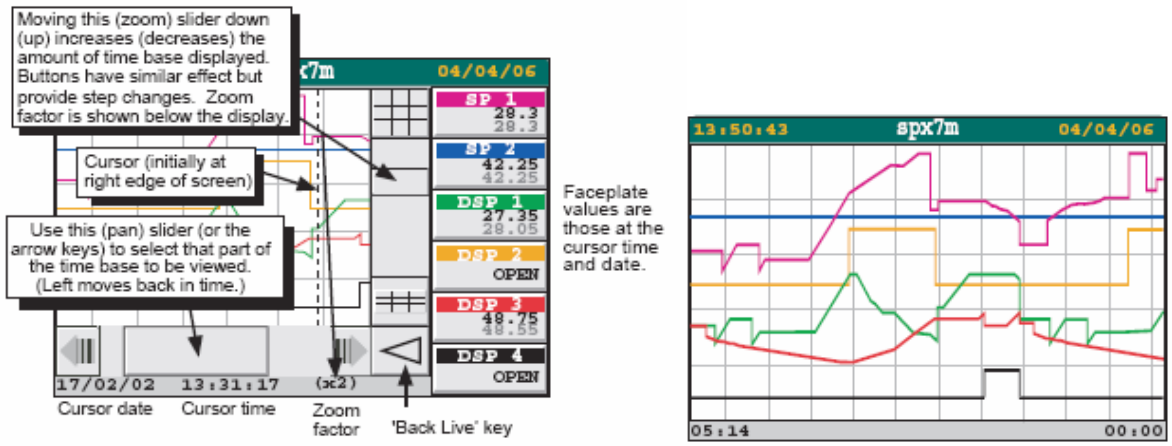
5.11 Trends

To view a summary of the program status in graphical form, follow the procedure below:

1. Press the program panel in the top left hand corner of the screen. The *programmer* screen will appear.
2. Press the PRE-PLOT button. A display appears, showing a profile of the target and the actual PV`s moving slowly (perhaps imperceptively) from right to left past a vertical cursor at the centre of the screen.

NOTE: The trend resolution is such, that short duration events (in particular zero duration spikes), will not be visible.

The cursor marks the current time. The actual PVs, SPs and digital outputs are to the left of the cursor and the target SPs are to the right. With the same program loaded but not running (idle), the display shown opposite appears, showing the profiles programmed for the four variables.



Note: this is example figure

5.12 Stoppering

CAUTION

If the stoppering action becomes stiff, do not wrench the handle as this may permanently deform the chamber or framework.

CAUTION

There is no automatic shut-off system on the shelf mechanism, so to prevent damage to the vials and chamber by excess pressure. A visual check is required to confirm that the stoppers are fully home. If vials do not stopper correctly, do not use excessive force (greater than 14 kgf) as this may damage the vials and chamber

The mechanical stoppering of all vials held inside the drying chamber of the 3-Shelf unit is achieved by a hand turned screw jack, the procedure for which is detailed in the paragraphs below. If problems are encountered during stoppering it is most likely due to the incorrect size of stopper being used, or the stoppers themselves have become hard or dry and are no longer a good fit in the vials. In these instances, do not wrench the stoppering handle. Sometimes the stoppering action may become stiff due to lack of lubrication of the screw jack. If this happens, apply some light grease to the grease nipple on the screw jack body.

If the vials within the chamber are to be stoppered, (See Figure. 6) using the mechanical stoppering device, the following procedure should be observed:

1. Ensure that the vials are evenly loaded on all three shelves and that the stoppers are aligned correctly.
2. Bring the shelves into contact with the vials by rotating the hand-wheel in an anti-clockwise direction.
3. Continue rotating the hand-wheel anti-clockwise with slightly more force until all stoppers are fully in place on each of the shelves.
4. Open the shelf stack by rotating the hand-wheel in a clockwise direction until the shelves are fully open.

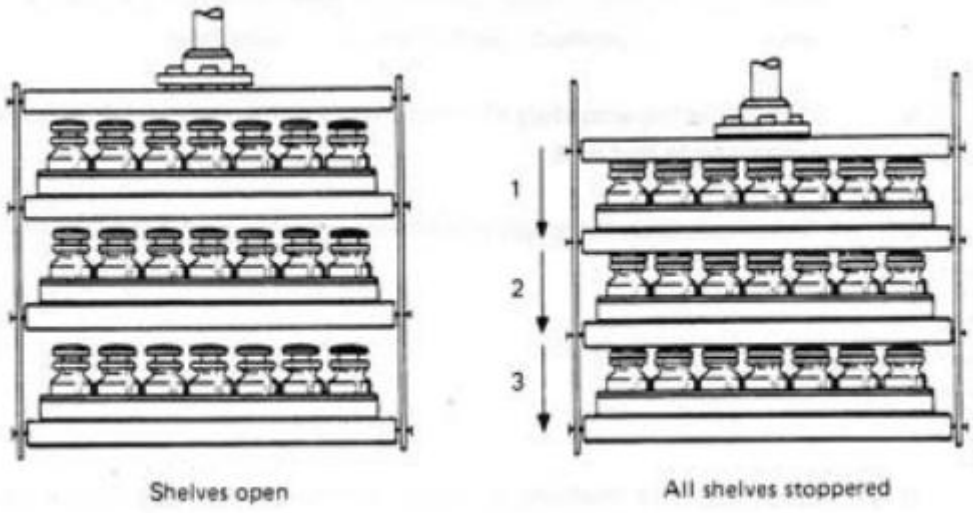


Figure 6 - Stoppering

5.12 Alarm Display and Acknowledgement

The Alarm pane displays information relating to current alarms.

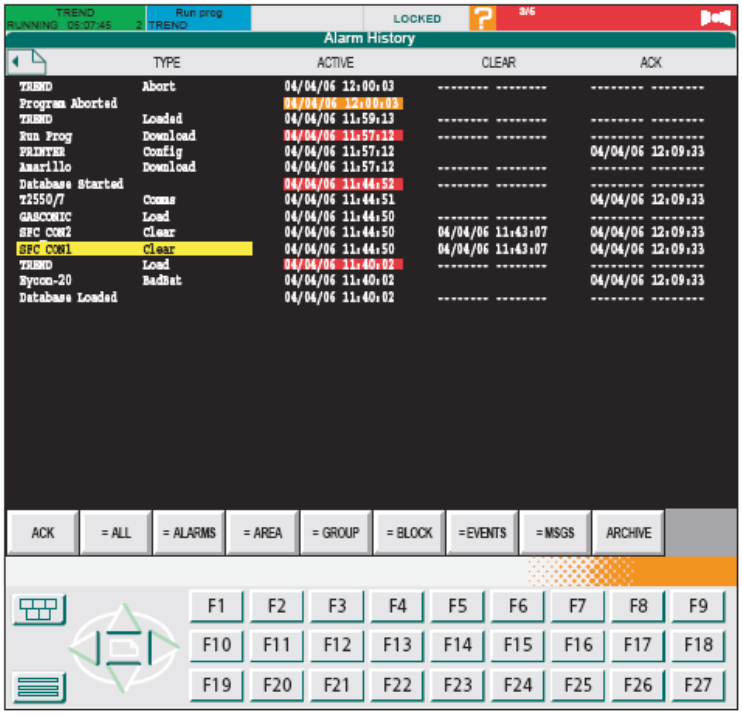
When at least one Alarm is active but unacknowledged the Alarm pane flashes red, when the alarm is active but acknowledged the Alarm pane is steady red and if alarm has cleared but is unacknowledged the Alarm pane flashes black.

Only the most recent alarm tag is displayed, on the Alarm pane, if multiple active alarms exist.

Acknowledgement- user is able to acknowledge alarms individually or all together using the following operation:

1. Access to Alarm pane = “MENU” key / “PROGRAMMER” button / “ALARM” button or “PROGRAMMER” pane /”ALARM” pane.
2. Press Acknowledge or Acknowledge all button.

History- an alarm history screen displays a list of current and previously active alarms indicating when they occurred and if appropriate when they were cleared or acknowledged. A total of 250 alarms can be displayed and when this is exceeded the oldest alarm is deleted when a new alarm occurs.



Note: this is example figure

5.13 Historical Logging

Program data is automatically recorded as a text file (.txt) and can be easily imported into Excel.

The archive interval is user adjustable.

The data logged to disk is:

1. Time/Date Active alarms
2. User name
3. Condenser temp (CON_TEMP)
4. Condenser pressure (CON_TEMP)
5. Shelf temp SP (TEMP_SP)
6. Shelf temp PV (TEMP PV)
7. Drying Chamber Vacuum SP (PRESS SP)
8. Drying Chamber Vacuum PV (PRESS PV)
9. Product temp sensor 1 PV (PT1-DRec)
10. Product temp sensor 2PV (PT2-DRec)
11. Product temp sensor 3PV (PT3-DRec)
12. Event history (included run initiated, Run ended, User log on/off)
13. Time/Date

Setting the Archive interval- the user is able to set the Archive interval using the following operation.

1. Access to Logging Groups screen = “MENU” key / “SYSTEM” button / “APPLN” button or “FB MGR” button / select “D-Trend” block.
2. Enter Archive Interval (sec)

The user is able to start logging manually using the following operation:

1. Access to Logging screen = “MENU” key / “LOGGING” button / “MONITOR” button or “LOGGING” pane / ”MONITOR” pane.
2. Select logging ON.
3. To stop logging select OFF.

The logged data from the internal memory storage can be archived by the user to a removable device such as a floppy disk or memory stick. The data can be restored for viewing in either a chart or a spreadsheet.

The user is able to archive log files using the following operation:

1. Access to Archive Manage page = “MENU” key / “LOGGING” button / “MANAGE” button or “LOGGING” pane / ”MANAGE” pane.
2. Press ‘**EXPORT’** or ‘**EXPORT ALL’** button

‘Export’ causes the currently displayed file to be copied to a USB device.

‘Export All’ causes all files in the internal archive to be copied to the floppy disk or USB device. If the device becomes full during archive a message appears asking the user to fit a new disk.

5.14 Removing product

If the chamber is left under vacuum, at the end of the process (as per the program) product can be removed by first ensuring that the isolation valve is closed and then manually venting the chamber.

NOTE: Do not use excessive force to open the chamber doors. If the drying chamber is under vacuum (for instance when the freeze dryer is first delivered) it will not be possible to open the chamber doors.

NOTE: To open the chamber doors if the chamber is under vacuum, first vent the chamber, to atmosphere.

WARNING

The chamber should not be loaded/unloaded when the shelf temperature is less than 10°C. If it is essential to access the chamber under these conditions then protective gloves or suitable PPE should be worn.

5.15 Defrost/Drain

The user is able to carry out the defrost function by the following operations:

1. Slowly open the drain valve to admit air to the chamber
2. From the Overview page, press the Condenser Chamber 'ROTARY PUMP' field and select OFF.
3. From the Overview page, press the Condenser Chamber 'DEFROST VALVE' field and select ON.
4. Open the condenser chamber front door
5. When the plug of ice in the condenser is free to move, carefully remove it use an ice handle or wear protective gloves. Place the ice in a suitable container and allow it to melt fully before disposing of it.
6. Close the drain valve.
7. Close the condenser chamber door.
8. From the Overview page, press the Condenser Chamber 'DEFROST VALVE' field and select OFF.
9. Wait until the temperature on the condenser is less than -20°C
10. From the Overview page, press the Condenser Chamber 'ROTARY PUMP' field and select ON.

5.16 Close down

Close down - the user is able to switch off the compressors and vacuum pump by the following operation.

1. From the Overview page, press the Drying Chamber 'REFRIGERATION' field and select OFF
2. From the Overview page, press the Condenser Chamber 'REFRIGERATION' field and select OFF.
3. From the Overview page, press the 'Rotary Pump' field and select OFF.

6. Sodium Azide

6.1 Explosion Hazard of Sodium Azide

Sodium Azide, which is sometimes used as a stabilising agent in freeze drying processes, is a toxic and (when dry) highly explosive material. In the process of pumping product containing this chemical, a poorly understood reaction can occur in the presence of heavy metals such as copper, lead, zinc and cadmium. The result of this reaction is the formation of heavy metal azides which are highly unstable and present a very severe explosion hazard.

For this reason, all components in the chamber, vacuum pipework and pumps should be free of copper, lead, zinc and cadmium. Stainless steel, aluminium, cast iron and most elastomers/polymers are suitable materials of construction to prevent heavy metal azide formation. Cadmium and zinc plating must be avoided; the situation regarding alloys is not entirely clear and they should also be avoided.

The areas where problems have most often been identified are as follows:

1. The exhaust system
2. The gas ballast piping where copper tubing has been fitted
3. Inappropriate vacuum pumps (i.e. other than those specifically recommended by MechaTech Systems.

If Sodium Azide is to be processed in this equipment, then the product probes and vacuum leadthrough (both of which contain copper) must be removed from inside the chamber-refer Section 6.2 for recommended procedure. The remainder of the 3-Shelf unit has been constructed using safe materials.

WARNING

If it is suspected that azide precipitation or formation has occurred, the user should not attempt to decontaminate or clean the suspected area; instead, the user should isolate the equipment and seek expert advice and assistance.

6.2 Procedure for Removing Product Probes and Vacuum Leadthrough

Before processing Sodium Azide, the product probes and vacuum leadthrough must be removed because they contain copper.

1. To remove the probes and leadthrough proceed as follows:
2. Ensure that the RC3S unit is switched off and is isolated from the electrical supply.
3. Disconnect the probes from below the bottom shelf.
4. Remove the plastic sockets from the fascia below the bottom shelf. The sockets clip into place from the rear of the fascia.
5. Using a small screwdriver, push the pins out of the plastic sockets.
6. When the pins have been removed from all three sockets unscrew the nut holding the vacuum leadthrough in place. This is located on the inside rear of the chamber.
7. Carefully pull the vacuum leadthrough and attached wires from the rear of the chamber.
8. Plug the hole at the rear of the chamber with a suitable size rubber bung (plug).

NOTE: The removal of the product probes will leave the RC3S unit without temperature indication for the inside of the chamber.

7. Maintenance

WARNING

There is a safety interlock fitted to the electrical cabinet door. Ensure that the electrical supply is isolated before starting any maintenance work.

7.1 Planned Maintenance

When performing the following operations, refer to the components own working instructions for details on how to carry out the specified items; all of the necessary working instructions are supplied with this manual.

7.1.1 Daily Maintenance

- Check oil level in vacuum pump
- Check self-chamber door O-ring
- Check condenser chamber door O-ring

7.1.2 Weekly Maintenance

- Check oil level in vacuum pump
- Check silicon oil level level.

7.1.3 Six monthly

- Check operation of refrigeration cooling fans
- Check silicon fluid circuit for leaks
- Change the vacuum pump oil

7.2 Calibration

It is recommended that all gauging and sensors fitted to this unit be serviced and calibrated at least every 12 months. The time interval between services must be reviewed by the customer during the unit's operating life.

8. Technical Specifications

FUNCTION	MODEL / PERFORMANCE
Minimum condenser temperature (@ 25ºC ambient)	-50ºC
Minimum shelf temperature (@ 25ºC ambient)	-40ºC
Heater	250 watts
Maximum shelf temperature	60ºC
Temperature uniformity	± 0.5ºC
Temperature control	± 1ºC
Temperature Operation System	Centrifugal Pump using Indirect Heat Transfer Fluid
Fluid	Baysilone M5 silicon oil
Refrigerant	R408A
Compressors	0.75 hp
Condenser capacity	18 kg
Defrost time (for ice plug removal)	Approx 60 minutes
Stoppering	Mechanical screw jack rated at 2.5 tonnes
Vacuum Pump 1. Type 2. Nominal Pumping speed 3. Pump down time (to 0.5 mbar)	 Edwards RV12 12 m3/hr Approx 10 minutes
Electrical a) Supply b) Power rating	 230V, 50Hz, 1 ph, 6 KW
Dimensions (w x h x d) (including turret)	1970 x 655 x 795 mm
Weight	360 Kg
Number of Shelves	3 active plus 1 compensating
Shelf dimensions (w x d)	300 mm x 450 mm
Total Shelf area	0.405 m^2
Drying Chamber Diameter	500 mm
Noise	<50 dB