

Title LSM60/40 Freeze Dryer

INSTALLATION AND OPERATION MANUAL



Issue 4

Date 07/07/23

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Please Read This Document before Operating the Machinery

INSTALLATION AND OPERATION MANUAL
LSM60/40 – Freeze Dryers

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1. INTRODUCTION

1.1 Purpose

This manual provides installation and operation instructions for the LSM60/40 Freeze Dryer.

This manual and all accompanying documentation must be read before operating the vacuum system.

Important safety information is highlighted as **WARNING** and **CAUTION** instructions; you must obey these instructions. The use of **WARNINGS** and **CAUTIONS** are defined below.

1.2 General safety



WARNING: Warnings are given where failure to observe the instruction could result in injury or death to persons.



CAUTION: Cautions are given where failure to observe the instruction could damage to the equipment, associated equipment or process. Refer to the accompanying manufacturers' instruction manuals for the technical data on individual components.



WARNING: Sodium Azide Explosion Hazard
Sodium Azide, which is sometimes used in the freeze-drying process, is a toxic and highly explosive material. In the process of pumping product containing this chemical, a reaction can occur in the presence of heavy metals (copper, lead, zinc and cadmium). The resulting reaction forms a highly unstable and very explosive

1.3 Unpack and inspect

Remove all packing material.



CAUTION: Remove all packing material before operating system. If the equipment is damaged notify your supplier and the carrier in writing within three days.

1.4 Installation and Commission

1.4.1 Initial setup

- I. Locate the freeze dryer in the required position, ensuring that the floor is adequate to support the equipment and that due consideration is given to:
 - a) Air flow for ventilation (1metre min)
 - b) Access to framework panels. (1metre min)
 - c) Adequate space for maintenance. (1metre min)

Note: we strongly recommend that the Freeze Dryer is installed in an air conditioned room
- II. After placement, remove all panels to carry out initial inspection. The panels are fitted with lockable latches. To remove panels, unlock the latch using the key provided, press the top end of the latch lever closest to key hole and lift bottom end of lever away from panel.
- III. The vacuum pump exhaust is internally ducted to a stub pipe located on the rear panel of the condenser unit. Exhaust gases must be ducted away for suitable disposal.



CAUTION: Exhaust gases must be ducted away from the surrounding atmosphere and suitably disposed.



CAUTION: Do not obstruct any vacuum pump exhaust port (refer to manufacturer's manual before operation).

- IV. The cooling circuit in the drying unit uses a heat transfer fluid (silicone oil). Check the chamber insulation for signs of oil leaks and confirm that the oil reservoir is (viewed from the left hand top side) is showing a level of 10mm below the top of the sight glass with the chamber vented and +20°C fluid temperature.

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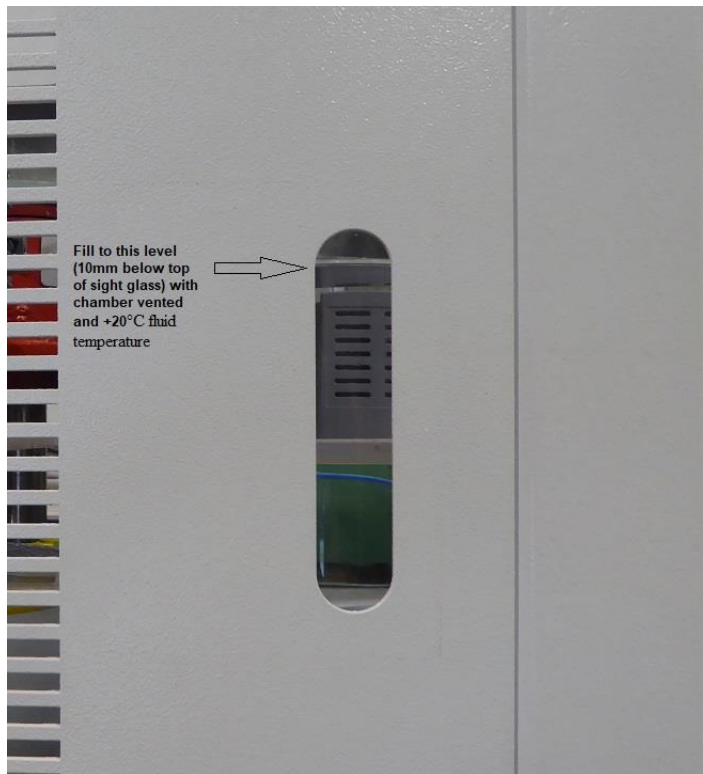


Figure 9

1.4.2 Electrical requirements



CAUTION: The unit is factory configured a 230volts (16 amps), single phase supply. Check that your voltage supply is compatible. If you operate the unit on the wrong voltage, you will damage it.

Voltage 230Vac
Frequency 50Hz
Loading/power consumption 3.2 KW
Earthing Class 1 (supply earth required)
Fusing 16A

The freeze dryer comes fitted with an IEC-EN60309 blue plug:
2P + Earth
IP44
16A
250V

Ensure that all framework panels are refitted before connecting to any services.

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WARNING: Failure to refit all panels prior to connecting to mains power may result in injury or death to the operator.

1.4.3 Mechanical requirements

Nitrogen backfill – 1Bar, 6mm push-in fitting
Pump exhaust – 25mm plain stub pipe

1.4.4 Additional Documents to be supplied.

Declaration of Conformity
Manufacturer's Manuals – non specific

Read these manuals before putting the unit into operation.

2. GENERAL DESCRIPTION

2.1 Freeze Drying – Basic Principles

The LSM60/40 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 six (6) refrigerated shelves that can be moved up and down via an electrically operated ram for stoppering processes. Both condenser and drying chambers are fitted with their own refrigeration systems, with the capability of switching the condenser refrigeration duty to the drying chamber. The temperature of the product shelves can be controlled between +60°C and –60°C (LSM60) or –40°C (LSM40). 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.

2.2 The Condenser 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 ~18Kg between defrost cycles. The minimum temperature of the chamber wall under vacuum conditions with no load applied is –80°C (LSM60) or –45°C (LSM40).

The condenser inlet is connected to the drying chamber via an electrically actuated high vacuum butterfly valve. The chamber outlet is connected to the inlet of a 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

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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 dry scroll pump vacuum pump is used to evacuate both condenser and drying chambers. 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 is monitored with a pirani gauge and a PT100 respectively; data can be continuously displayed on the touch screen if required.

2.3 The Drying Chamber

The drying chamber is situated on top of the condenser unit (refer to figure 1). The chamber is fitted with up to six temperature-controlled 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 electrically actuated ram with variable torque settings. The ram moves the shelves up and down allowing automatic stoppering of vials under vacuum and other controlled atmospheres. Operation of the ram is interlocked with a safety switch on the front door ensuring that the actuating mechanism is disabled when the door is opened.

Note: the switch should never be removed or tampered with.

Up to six (6) 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 T2550 modular process controller (PAC).

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 panels and function keys. User screen descriptions can be found later in this document.

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The PAC provides the Input/output interface for the control system, signal conditioning and PID control for the temperature.

These two instruments talk to each other via an Ethernet communication link.

The above setup provides a standard control solution for systems such as Freeze dryers.

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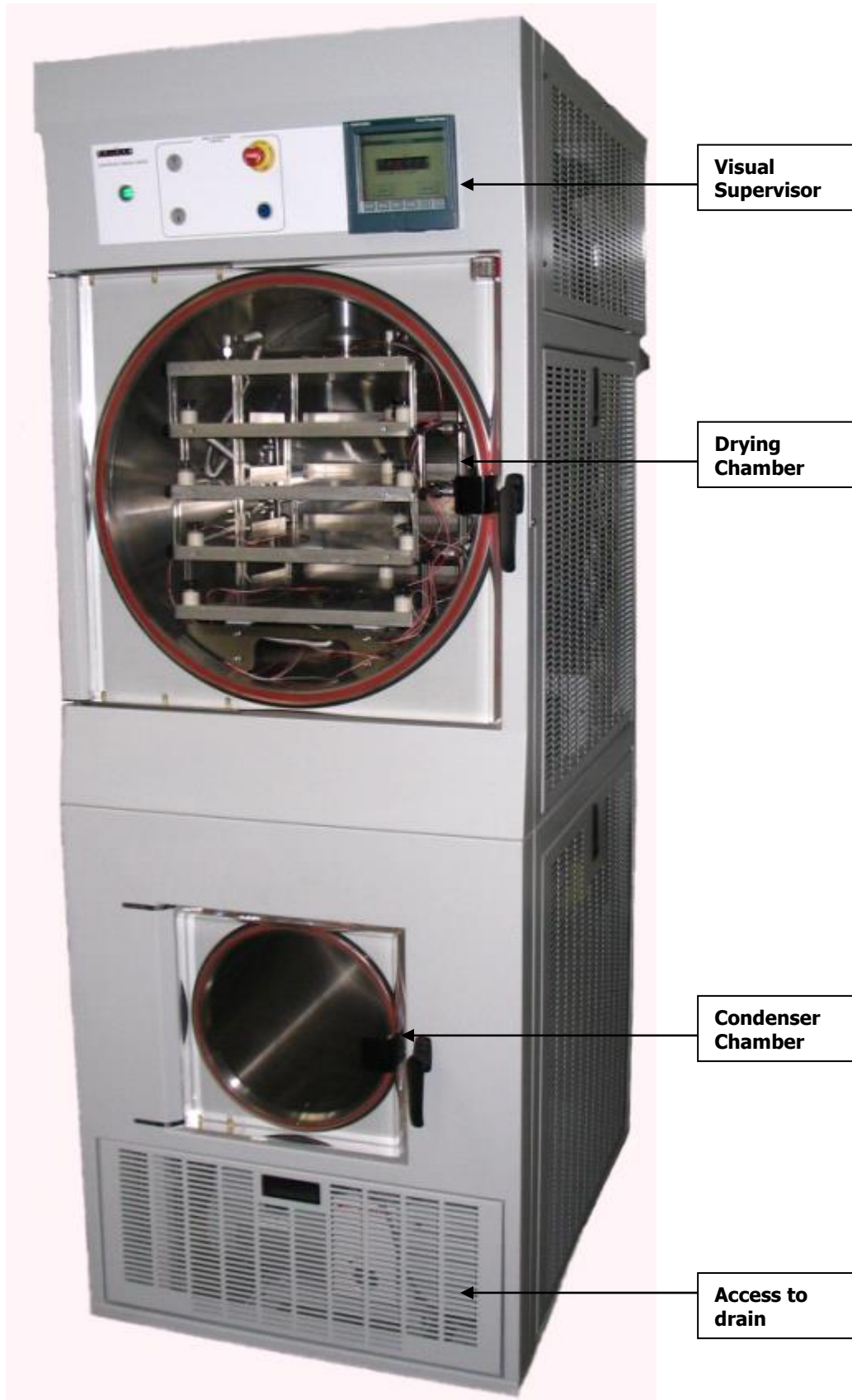


Figure 1

3. OPERATION

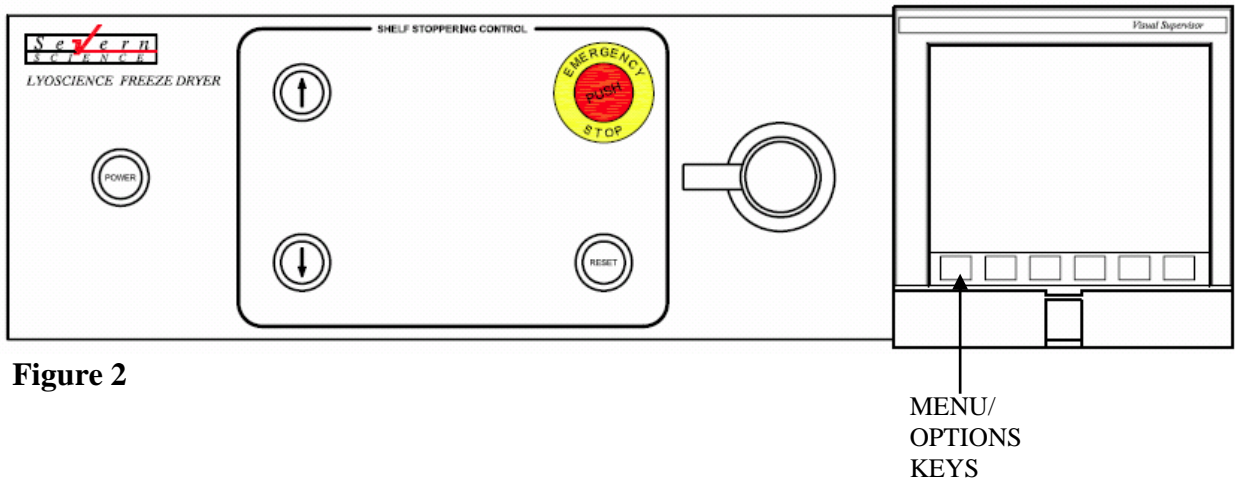


Figure 2

3.1 Power Up

Press the illuminated green “power” button located at the top left-hand side of the front panel of the drying unit.

The green indicator illuminates to confirm that control system is on. (See Figure 2)

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 1 hour (factory default) 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 status as follows:

- Condenser off (defrost)
- Refrigeration as per power down state
- Vacuum pump off
- Valves closed
- Freeze-drying cycle not running
- Shelf temperature as per power down set point

Note: The stoppering facility cannot be operated however until the ‘**RESET**’ button is pressed. (See figure 2)

System status display reads ‘FINISHED’

Power down is achieved via the illuminated green “power” button located at the top left-hand side of the front panel of the drying unit.

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

3.2 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 download recipes run cycles, view alarm history, historical program trending, acknowledge alarms and edit user adjustable parameters.
3. Supervisor- As Operator but in addition can and edit recipes 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.
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.
2. Enter and confirm new password.
3. Press Change button.

3.3 Start Up

3.3.1 Initial start up

Before freeze-drying cycles can be run the user first has to switch on the Cooling compressors, Circulation pump, and Vacuum pump.

1. From the Home page, press the field showing ‘**CONDENSER DEFROST**’. From the options press **CONDENSER RUNNING**.
2. Press the green RETURN key.

The Condenser unit will begin its cool down cycle. When a temperature of -40°C is reached, the vacuum pump will automatically switch on and both the refrigeration and vacuum pump will run continuously. The freeze dryer is then ready to use.



WARNING: The internal service of the condenser should not be touched when the temperature is less than 0°C. The cold surfaces will cause tissue damage. If it is essential to access the chamber under these conditions, then protective gloves or suitable PPE should be worn.

3. From the Home page, press the field showing '**REFRIGERATION OFF**'. From the options press REFRIGERATION ON.
4. Press the green RETURN key.

The Shelves will begin to control to the temperature set point value displayed on the home page.

3.3.2 Running automatic cycles

The user is able to load recipes and run/abort freeze-drying cycles. The *LYOSCIENCE* freeze dryer divides the freeze-drying cycle into two separate sequences, the drying profile (program) and the End of Program Sequence (EPS)
Cycle = Program + EPS

1. Loading product



WARNING: The chamber should not be loaded / unloaded when the shelf temperature is less than 0°C. If it is essential to access the chamber under these conditions, then protective gloves or suitable PPE should be worn.



CAUTION: The provided 'stoppering jacks' must be placed on all shelves prior to stoppering or damage to the shelves will result

The freeze dryer can be used for both vial and bulk drying. The door to the drying chamber can be opened using the handle as long as the chamber has been fully vented to atmospheric pressure.

Note: Do not use excessive force to open the chamber door. 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 door.

Note: To open the chamber door if the chamber is under vacuum, first vent the chamber, as follows:

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- a) From the *Home* screen, press the field showing ‘**VENT CLOSED**’
- b) From the options press VENT OPEN.
- c) Press the green RETURN key.
- d) When the chamber reaches atmosphere, press the field showing ‘**VENT OPEN**’ again to close.

2. *Loading/Running a program*

The program variable parameters are as follows:

Table 1: Recipe variables

| Variable | Description | Limits |
|-----------|---------------------------------------------------|-----------------------|
| TEMP | Temperature set point | Max 60°C Min -60°C |
| VAC VALVE | Vacuum valve between Condenser and Drying chamber | OPEN or CLOSED |

Security level: Operator or supervisor

Note: Before a program will run the following conditions must be true:

Table 2: Program Interlocks

| | Status |
|---------------|---------|
| Condenser | On |
| Vacuum Pump | On |
| Refrigeration | On |
| Stoppering | Home |
| Alarms | Cleared |

These conditions can be viewed from the STATUS page accessed by pressing the ‘**STATUS**’ button from the Home page.

Any status preventing a program from running will be displayed in red text.

The user is able to load/run a program by the following operation:

- i. Access to the Load/Save Program page = ‘**MENU**’ key / ‘**PROGRAMMER**’ button / ‘**PROGRAM**’ button
 - ii. Touch ‘**File name**’
 - iii. Select required file from the pick list
 - iv. Press enter
 - v. To access the Programmer menu, press the ‘**LOAD**’ button
- Press the ‘**RUN**’ button

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The freeze-drying cycle will start automatically. The program panel changes to green-to-green indicating 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.

System status display reads 'Program'.

The freeze dryer will automatically run each segment of the selected program from the End Of Program Sequence page.

Select the required sequences by pressing the **YES / NO** field to display YES. On completion of the program, the cycle will automatically run any End of Program Sequences selected.

During End Point Determination (EPD) the program panel will change to blue. Program state 'Complete'.

During any of the subsequent sequences the program panel will change to grey. Program state 'Idle'.

3. *Running a cycle independently*- a program can be initiated directly from the Program menu.

There are three ways to run a program:

- a) Run a program now
- b) Run a program from a point
- c) Schedule a program to run from a time

- a) Run a program now

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

- Press the MENU printed key (see figure 3)
- Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
- Press the PROGRAM button. The *Load/Save Program* screen will be displayed.
- 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.
- 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.
- 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'.

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- Press the RUN button. The program panel changes to green indicating 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 (see figure 1).

b) 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.

- Press the MENU printed key (see figure 3)
- Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
- Press the PROGRAM button. The *Load/Save Program* screen will be displayed.
- 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.
- 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.
- 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'.
- Press the RUN FROM button. 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.
- To run the program, press the RUN key. The *Programmer* screen will appear. The program panel changes to green indicating 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.

c) 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.

- Press the MENU printed key (see figure 2)

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- Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
- Press the SCHEDULE button. The *Schedule Program* screen will be displayed.
- 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.
- 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.
- Press the **Start Date** field. Input the required start date on the numeric key pad (day:month:year). Press the green RETURN button.
- Press the **Start Time** field. Input the required start time on the numeric key pad (hours:minutes:seconds). Press the green RETURN button.
- To change the number of iterations (number of complete cycles 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.

4. *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 door. 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 door.

Note: To open the chamber door if the chamber is under vacuum, first vent the chamber, as follows:

- e) From the *Home* screen, press the field showing ‘**VENT CLOSED**’
- f) From the options press VENT OPEN.
- g) Press the green RETURN key.
- h) When the chamber reaches atmosphere, press the field showing ‘**VENT OPEN**’ again to close.

If the chamber is automatically vented to atmospheric pressure at the end of the process (as per the program), no further action is required before removing the product.



WARNING: The chamber should not be loaded/unloaded when the shelf temperature is less than 0°C. If it is essential to access the chamber under these conditions, then protective gloves or suitable PPE should be worn.

Aborting a cycle- the user is able to abort a running cycle at any stage by the following operation.

- i. Access to the Programmer menu = ‘**MENU**’ key / ‘**PROGRAMMER**’ button
- ii. Press the ‘**ABORT**’ button.

Note: If a program is aborted, any selected End Of Program sequences selected will not run.

6. *Close down-*the user is able to switch off the compressors and fluid pump by the following operation:

1. From the Home page, press the field showing ‘**REFRIGERATION ON**’. From the options press REFRIGERATION OFF.
2. Press the green RETURN key
3. From the Home page, press the field showing ‘**CONDENSER RUNNING**’. From the options press CONDENSER DEFROST.
4. Press the green RETURN key

The Condenser unit will begin its defrost cycle. The vacuum pump will turn off. When a temperature of >30°C is reached, the refrigeration will turn off. The condenser can be switched back on at any stage during the defrost cycle.

7. *Emergency Stop-* the user is able to isolate power to the Stoppering ram, by activating the E-stop located on the front panel. After an emergency stop condition has occurred, the pressed E-stop button must be released and the ‘**RESET**’ button pressed.

3.4 Creating/Editing the Program

Security level: Supervisor

3.4.1 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. When creating a new program for the first time, use the program called ‘PROG1’ which has been installed into the Controller memory prior to shipping. To load the ‘PROG1’ program, follow the instructions below:

- a) Press the MENU printed key (see figure 2)
- b) Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.

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- c) Press the PROGRAMS button. The *Load/Save Program* screen will be displayed.
- d) 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.
- e) 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.
- f) 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 row of cells (referred as ‘segment headings’) define the duration and the function name (e.g., freezing, primary drying etc) of each segment.

To configure the segment headings, follow the instructions below:

- a) 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).
- b) 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:

- a) 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@. These functions are described in more detail in Table 3).
- b) Select the function that is required and press the green RETURN key.
- c) 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 (refer to Table 3). Press the DONE button to update the program table (the set point data and code is displayed in each cell).

Table 3: Function Descriptions and Coding

| 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 | Temperature |
| Ramp | Temperature ramps to temperature set point at a constant rate over the duration of the segment | R | Temperature |
| Ramp@ | Temperature ramps to temperature set point at specified ramp rate | R@ | Rate (/hr) Temperature |

3.4.2 Inserting a segment

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

- a) 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.
- b) Press the INS SEG key. The *New Segment* screen will appear.
- c) Press the **Segment** field and use the keyboard to type in the segment name.
- d) 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.
- e) Configure the new segment as per section 3.4.1.

To save the updated program under the same file name after inserting a segment, or to save the program as a new file name, refer to section 3.4.4.

3.4.3 Deleting a segment

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

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

To save the updated program under the same file name after deleting a segment, or to save the program as a new file name, refer to section 3.4.4.

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

3.4.4 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. To insert or delete segments prior to saving, see sections 3.4.2 and 3.4.3.

- a) 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.
- b) Press the PROGRAMS button. The *load /Save Program* screen will appear.
- c) Press the OPTIONS printed key.
- d) To save the edited program under the same file name (shown in the **File Name** field), press the SAVE button.
- e) To save the edited program under a new file name, press the SAVE AS button. The *Save As* screen will appear.
- f) Press the **File Name** field and enter the new file on the keypad.
- g) Press the green RETURN key and the OK buttons to confirm.

3.5 Monitoring the Program

3.6 Trends

Security level: Operator or Supervisor

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

- a) Press the program panel in the top left-hand corner of the screen. The *programmer* screen will appear.
- b) Press the PRE-PLOT button. A graph will appear on the screen, headed with the title of the program in use. Process parameters are logged on the 'Y' axis as a function of time ('X' axis) with the direction of time, past to future, moving from left to right. A curve showing the pre - programmed target values, spanning 4 minutes before and after real time, is plotted in pink. A separate curve, plotted in red, gives the actual recorded value for the 4 minutes leading up to the current time. Current time is represented by a vertical line in the middle of the graph.

3.7 Setup

Security level: Supervisor

The Setup page can be accessed by touching the SETUP key from the Home page.

The following sub sequences can be setup:

3.7.1 End Point Determination

End Point Determination (EPD) is an automatic pressure rise test that can be run directly after the main drying phase, used to determine if the product has reached the required level of dryness. If this level (determined by the rate of pressure rise in the chamber with the vapour

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valve closed) has not been reached, then drying continues with temperature and pressure settings as per the last segment of the program.

Select/unselect the automatic backfill option by pressing the appropriate field which will toggle between YES and NO.

Note: this can also be used to abort this sequence at any stage.

The rate and repeat test time set point values can be modified by pressing the appropriate field and entering the value on the numeric keypad.

Note: these changes will be effective immediately, overwriting any previously downloaded values.

3.7.2 Secondary Drying

Secondary Drying is used to continue drying for a period (user adjustable) at a set temperature (user adjustable) after the main program and End Point Determination (if used) have finished.

Select/unselect the automatic backfill option by pressing the appropriate field which will toggle between YES and NO.

Note: this can also be used to abort this sequence at any stage.

The time and temperature set point values can be modified by pressing the appropriate field and entering the value on the numeric keypad.

Note: these changes will be effective immediately, overwriting any previously downloaded recipe values.

3.7.3 Automatic Backfill

Automatic Backfill is used to bring the Product chamber up to a desired level of pressure (user adjustable), by introducing nitrogen, prior to stoppering. Alternatively, the pressure setpoint can be set to atmosphere to fully vent the chamber with nitrogen.

Select/unselect the automatic backfill option by pressing the appropriate field which will toggle between YES and NO.

Note: this can also be used to abort this sequence at any stage.

The pressure set point value can be modified by pressing the appropriate field and entering the value on the numeric keypad.

Note: these changes will be effective immediately, overwriting any previously downloaded values.

3.7.4 Automatic Stoppering



CAUTION: The provided ‘stopping jacks’ must be placed on all shelves prior to stoppering or damage to the shelves will result

Note: The stoppering facility cannot be operated however until the ‘**RESET**’ button is pressed. (See figure 2)

Automatic stoppering, when used with stoppering jacks (see figure 3), is used to fully stopper semi stoppered vials by electrically closing the product shelves. Torque level monitoring is used for feedback to the control system to indicate the fully stoppered and limit switches are used to monitor the fully home position.

Select/unselect the automatic backfill option by pressing the appropriate field which will toggle between YES and NO.

Note: this can also be used to abort this sequence at any stage prior to it starting.

Note: these changes will be effective immediately, overwriting any previously downloaded recipe values.

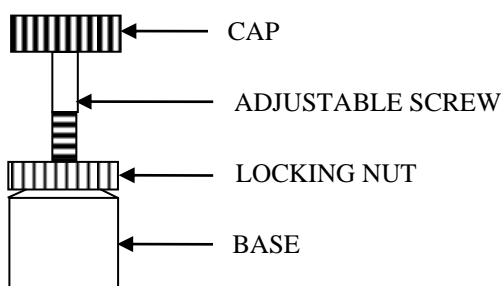


Figure 3

3.8 Manual Operation

Security level: Supervisor

Manual mode- user is able to control the system, by individually operating components from the mimic screen. Manual mode is accessible by pressing the Menu button on the printed keypad. Press the ‘**USER SCREENS**’ button. Press the ‘**MANUAL**’ button. Controllable parameters are as follows:

1. Condenser refrigeration
2. Shelf refrigeration
3. Vacuum pump
4. Diathermic pump
5. Vacuum valve

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6. Condenser chamber air inlet valve
7. Condenser chamber drain valve
8. Product chamber air inlet valve

3.9 Alarms

3.9.1 Alarm Types

All active alarms are displayed locally.

3.9.2 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.

3.9.3 Alarm Schedule for LSM40

| ALARM TAG | EQUIPMENT | TYPE | CAUSE |
|-----------|-------------------------|--------|----------------------------------------------------------------------------------|
| FLUID | Fluid Pump | TRIP | Circuit breaker trip |
| FRIDGE | Refrigeration | TRIP | Circuit breaker trip |
| VAC PUMP | Vacuum Pump | TRIP | Circuit breaker trip |
| HI PRESS | Vacuum System | SYSTEM | Chamber pressure greater than 10 mbar after 10 minutes from vacuum valve opening |
| CONDTEMP | Condenser Refrigeration | SYSTEM | Condenser temperature rises above -40° C after reaching -40° C for 10 minutes |
| DRYTEMP | Shelf Fluid System | SYSTEM | Fluid temp deviation Hi alarm 2° C from setpoint for 60 mins |

3.10 Historical Logging

Data can be logged to the 16MB internal memory during the freeze-drying cycle. Data is recorded as a text file (.ASC) and can be later imported into most spreadsheet applications.

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The Archive interval is user adjustable (max rate 5secs). Log files can be given an 8-character file name (using MS-DOS constraints).

The data logged to disk is:

1. Shelf Temp PV
2. Shelf Temp SP
3. Shelf Press PV
4. Shelf Press SP
5. Condenser Temp PV
6. Condenser Press PV
7. Product Probe PVs
8. Time/Date

Naming a Log file- the user is able to name a Log file using the following operation.

1. Access to Logging Groups screen = “MENU” key / “LOGGING” button / “GROUPS” button or “LOGGING” pane / ”GROUPS” button.
2. Enter File Name.

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 / “LOGGING” button / “GROUPS” button or “LOGGING” pane / ”GROUPS” button.
2. Enter Archive Interval (hh.mm.ss)

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 text editor 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 the floppy disk or USB device, as selected.

‘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.

4. OPERATOR DISPLAYS

4.1 User Screens

4.1.1 HOME

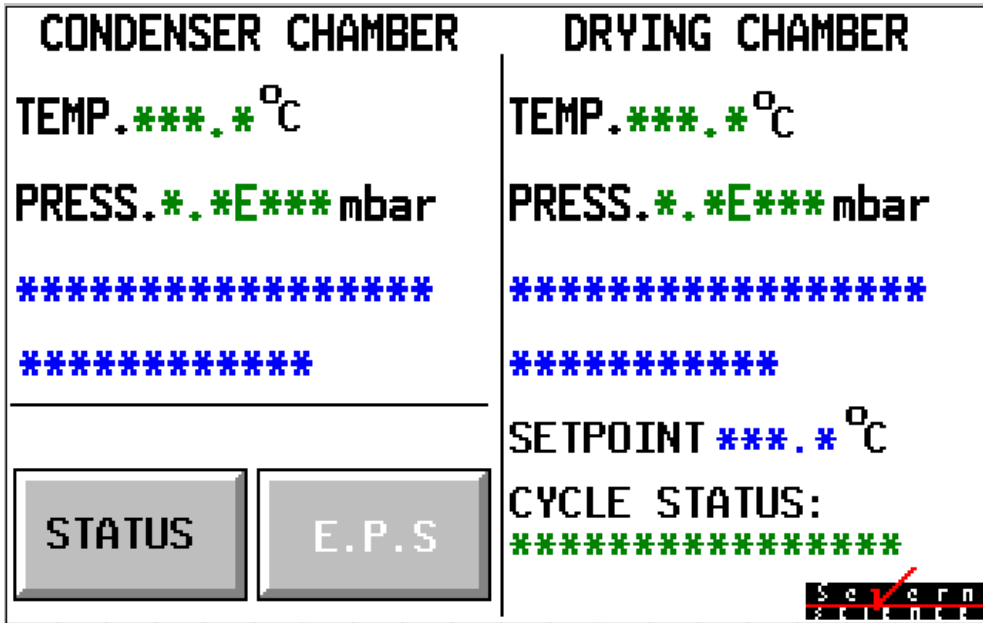


Figure 4

4.1.2 EPS



Figure 5

4.1.3 STATUS

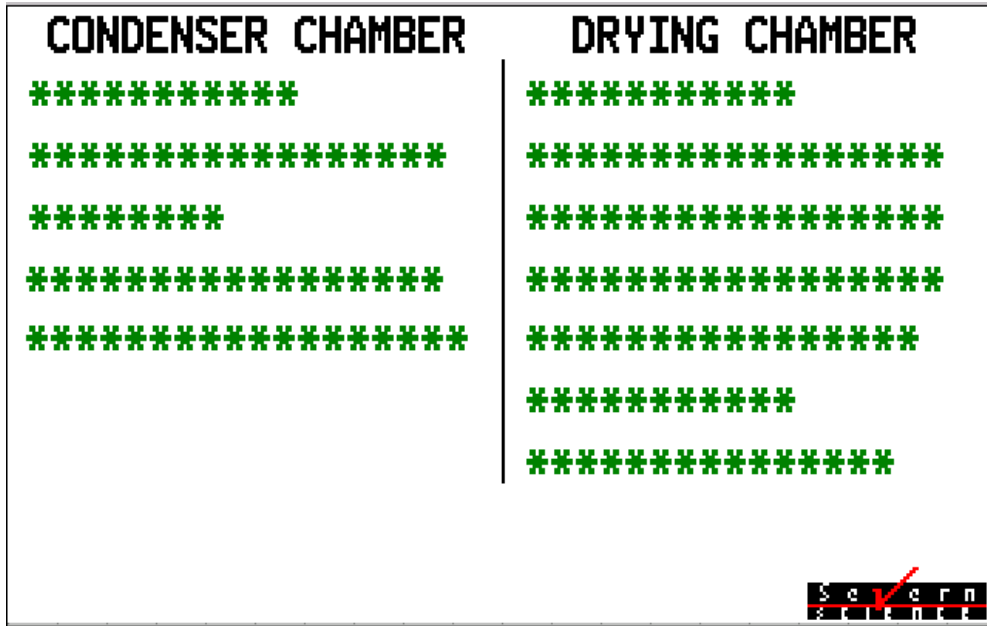


Figure 6

4.1.4 TREND

Example of a single trend page

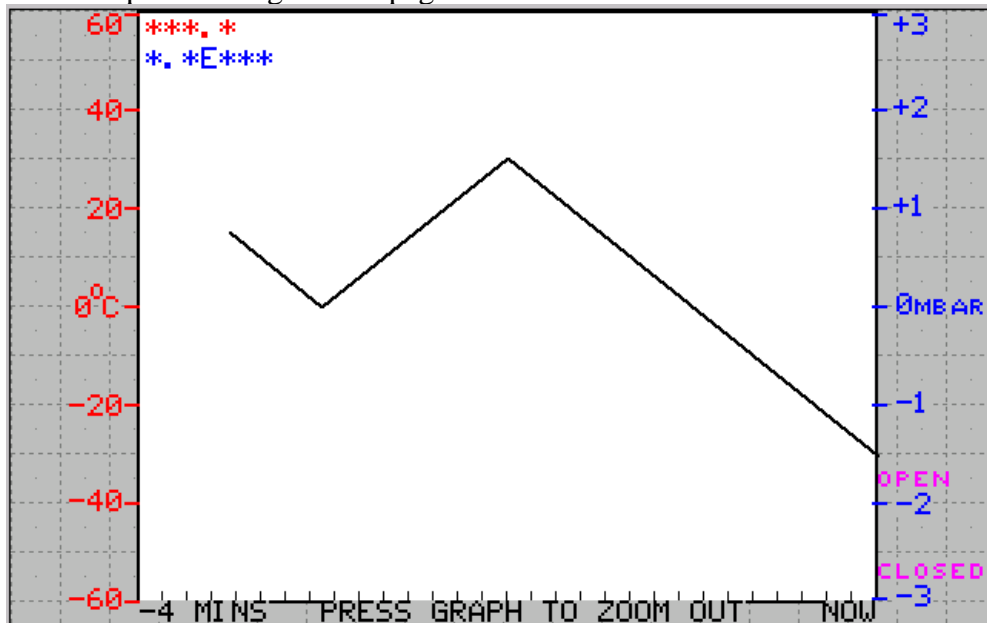


Figure 7

4.1.5 MANUAL

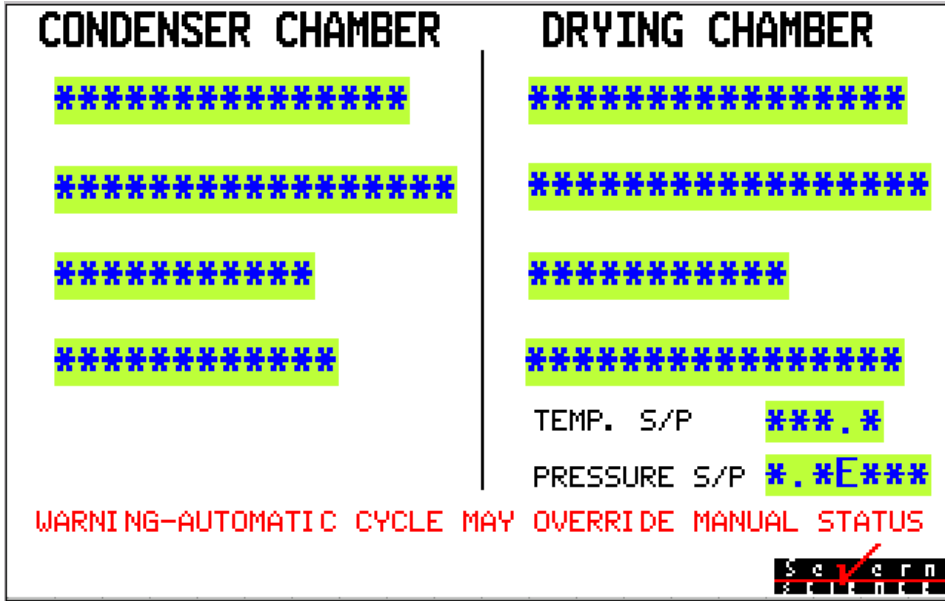


Figure 8

5. MAINTENANCE



WARNING: There is no safety interlock fitted to the electrical cabinet door. Ensure that the electrical supply is isolated before starting any maintenance work.

5.1 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.

5.1.1 Daily Maintenance

- Check chamber door o-ring

5.1.2 Weekly Maintenance

- Check silicon oil level

5.1.3 Six monthly

- Check operation of refrigeration cooling fans
- Check silicon fluid circuit for leaks
- Calibrate gauges

5.1.4 Calibration

It is recommended that all gauging and sensors fitted to this unit be returned to MTS (or a relevant competent body) for service and calibration at least every 12 months. The time interval between services must be reviewed by the customer during the units operating life.

5.2 Recommended Spares

5.2.1 General

Table 1: Recommended Spare Parts List

| Description | Part No | Supplier |
|---------------------|-----------|-------------------|
| Chamber Door Seal | LS-1-009 | MechaTech Systems |
| Condenser Door Seal | LS-1-010 | MechaTech Systems |
| Circulation Pump | UPS 15-15 | MechaTech |

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| | | |
|--------------------------------------------------------|------------------|-------------------|
| | | Systems |
| Silicon Oil | LS-1-013 (10ltr) | MechaTech Systems |
| 2 ch. Isolated universal analog IP for PT100 and volts | AI2-DC | MechaTech Systems |
| 2 ch. Isolated analogue output mA, volts | AO2 | MechaTech Systems |
| 8 ch. Non isolated digital IP (contacts only) | DI8C | MechaTech Systems |
| 8 ch. Digital output logic output 10mA max | DO8 | MechaTech Systems |
| 8 ch. Relay output module with disconnects | RLY8 | MechaTech Systems |
| Solid State relay 10A | AB700-SH10GZ25 | MechaTech Systems |

5.3 Edwards vacuum pump

For the Edwards Vacuum pump refer to the individual manufacturer's literature for spares.

5.4 Manufacturers literature

Manufacturers literature for all major components have been included.

6. TECHNICAL SPECIFICATIONS

Table 5: Technical Specifications

| FUNCTION | MODEL | PERFORMANCE |
|----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-------------------------------------------------------------|
| Minimum condenser temperature (@ 25°C ambient) | LSM60 LSM40 | -80°C -45°C |
| Minimum shelf temperature (@ 25°C ambient) | LSM60 LSM40 | -60°C -40°C |
| Shelf cool down times (with no load, from 23°C) | LSM40 (to -35°C) (to -40°C) LSM60 (to -55°C) (to -60°C) | 90 minutes 180 minutes 130 minutes 160 minutes |
| Maximum shelf temperature | LSM60/40 | 60°C |
| Temperature uniformity (between shelves measured at the inlet) | LSM60/40 (to 0°C) (to -20°C) (to -40°C) (to -60°C) | ± 0.6°C ± 0.8°C ± 1.5°C ± 2.0°C |
| Temperature uniformity (across each shelf measured along the front) | LSM60/40 (to 0°C) (to -20°C) (to -40°C) (to -60°C) | ± 0.3°C ± 0.8°C ± 1.1°C ± 1.9°C |
| Temperature control | LSM60/40 | ± 1.0°C |
| Condenser capacity | LSM60/40 | 18 kg |
| Defrost time (for ice plug removal) | LSM60/40 | Approx 60 minutes |
| Vacuum Pump 1. Type 2. Nominal Pumping speed 3. Pump down time (to 0.5 mbar) | LSM60/40 | RV12 vacuum Pump Approx 10 minutes |
| Electrical a) Supply b) Power rating | LSM60/40 | 230V, 50Hz, 1 ph, 3.2 KW |
| Dimensions (w x h x d) (including turret) | LSM60/40 | 700 x 2120 x 1050 mm |
| Weight | LSM60/40 | 525 Kg |
| Shelf area (per shelf) | LSM60/40 | 0.172 m ² |
| Noise | LSM60 LSM40 | 80 dB |

7. ENVIRONMENT SPECIFICATIONS

- Temperature Operation 0 to + 30°C
- Temperature Storage -10 to +70°C
- Humidity Operation 50 to 85% RH (non condensing)
- Humidity Storage 5 to 95% RH (non-condensing)
- Protection IP22