

LSG60/LSG40 Freeze Dryer Installation, Operator and Maintenance Manual

Freeze Dryers

And

Custom-Built High Vacuum Systems

MechaTech Systems Ltd Thornbury UK Revised 2022 Manual Issue no. 5

MechaTech Part No. LSG60/LSG40 Operator Manual

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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 LyoDry Grande (LSG).

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 System Maintenance

This manual does not cover maintenance issues other than basic cleaning and checking for warning signs of a problem. For detailed maintenance please refer to the OEM manufacturer's manuals provided.

For Planned Maintenance requirements, please refer to the Maintenance section.

For safety reasons, do not interfere with, modify, or attempt maintenance procedures on the LSG equipment unless you are qualified and authorised to do so.

1.4 Disclaimer

The purpose of this manual is to provide instructions and guidance for using the LSG 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.

Some of the pictures may differ slightly from the actual machine depending on model, version and options.

1.5 Service and Sales Contact

General Sales and Service Contact Information:

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2 Health and Safety

2.1 Safety Warnings in this Manual

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

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.



2.2 General Safety Precautions

Do not operate the machine until you have read the safety precautions below.

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 LSG system.
- 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.

2.3 LSG Safety Features

2.3.1 Emergency Stop (E-Stop)

There is an Emergency Stop button located on the front panel. Pressing this will stop the shelf stoppering ram from moving.

Two over temperature thermostats are fitted to the heat transfer circuit. If activated the heaters will turn off

Other equipment is continuously monitored for fault conditions.

If anything untoward is detected, then the system takes action automatically. Warnings will appear in red on the Operator Interface screen.



2.3.2 Interlocks

The LSG safety interlocks include:

- E-Stop controls: blue reset button and red e-stop button.
- Stoppering interlock: the drying chamber door must be closed before you can operate the stoppering mechanism.
- Nitrogen-pressure interlock: the drying process cannot begin without sufficient nitrogen pressure, which is used to backfill the drying chamber.

2.4 Health and Safety when using this equipment



WARNING

- This equipment is very heavy.
- Observe your Health and Safety at Work information, and wear suitable Personal Protective Equipment where appropriate.



WARNING

Do not interfere with system safeguards, and make sure that you read, understand and comply with the safety instructions in this manual.



3 Installation

3.1.1 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)



CAUTION

The ventilation holes in the framework panels must not be blocked or impeded in any way. If they are, overheating and damage may result.

- 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 keyhole and lift bottom end of lever away from panel.
- III. Check the sight glass located on the vacuum pump body (refer to <u>figure 4</u> and to the manufacturer's literature). The oil level must be between the MAX and MIN level indicators.
- IV. 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 manua before operation).





CAUTION

Check that the Gas Ballast control has not been left in the fully closed position (refer to manufacturer's manual before operation).

V. 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 approximately half full (see <u>figure 4</u>).

Mechatech Systems Limited engineers to install and commission

3.1.2 Electrical requirements



CAUTION

The unit is factory configured for 415volts (32 amps per phase), three phase supply. Check that your voltage supply is compatible. If you operate the unit of the wrong voltage, you will damage it.

Voltage 415Vac Frequency 50 Hz Loading/power consumption 15 KW Earthing Class 1 (supply earth required) Fusing 32A

The freeze dryer is supplied with a 32A socket (3p+N+E). Connect this to a suitable socket.

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



WARNING

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

3.1.3 Mechanical requirements

Compressed air – 6 Bar min, ½ BSP female. Cooling water - 10°C max, ½ BSP female. Flow and Return 1.2 m3/h flow rate Hot water defrost (optional) - 40°C min. 1/2 BSP female. Flow and Return Nitrogen backfill – 1Bar supply, ½ BSP female (Regulated to 3 psi) Pump exhaust – 25mm plain stub pipe



3.1.4 Lifting and Handling Instructions

General

The freeze dryer is designed to be moved as two separate units. The drying chamber assembly (left hand unit) and condenser assembly (right hand unit).

The freeze dryer assembly should therefore be split into these 2 component parts prior to moving. The silicon oil reservoir fitted at the top and left-hand side of the drying chamber assembly, must be removed if moving this unit through areas with a height restriction of less than 2110mm.

Separation of the LSG

The freeze dryer should be at ambient temperature with the condenser chamber fully drained. The vacuum valve must be fully closed and the shelves in the fully lowered position before commencing separation of the two units.

Ensure that power and all other services are safely and <u>fully</u> disconnected from the LSG assembly.

The four jacking feet on each unit should all be in full contact with the ground.

Draining the Silicon oil fluid circuit

The most efficient means of draining the Silicon oil fluid circuit is by the use of a vacuum pump and catchpot assembly.

The Silicon oil drain value is located at the rear and bottom of the drying chamber unit. The value can be identified by its yellow handle.

Connect the vacuum pump and catchpot assembly at this point. By opening the valve, the Silicon oil can now be evacuated from the system.

Remove aluminium covers from top of each unit. If required, the Silicon oil reservoir may now be carefully disconnected and removed.

All services that are connected between the condenser unit and the drying chamber unit can now be disconnected:

1. Unplug all of the (brown) Thermocouple cables from the top rear of the drying chamber unit (<u>see figure 1)</u>.

2. Disconnect the three pneumatic lines form the pneumatic control valves. And disconnect / unplug the control valve electrical leads.

- 3. Disconnect the Nitrogen supplies to the control valves.
- 4. Unplug the two electrical connections to the Unic 10 valve actuator.

5. Immediately beneath the Unic 10 actuator head is an insulated Ø22mm copper pipe. Remove the short piece of large diameter insulation and disconnect the Straight union found beneath. A second Ø22mm copper pipe under the above item should also be disconnected.

6. Remove the four clamps securing the ISO160 flexible metal pipeline to the Unic 10 valve body.

7. Disconnect the two Harting plugs. One to the side of the drying chamber and a larger one to the rear.

8. Disconnect the Earth link.



9. Disconnect the four grey flexible braided water-cooling hoses.

10. Now remove the six 8.0 x 100 socket head cap screws securing the two units together. Two are located in the top horizontal frame member. A further two in the middle horizontal frame member. The remaining pair is in the front and rear verticals, towards the base of the framework.

11. Un bolt Drying chamber door interlock switch

12. Remove silicon fluid PT100 sensor from rear of chamber (located in pipe junction) and thread back under pipe work.

13. Disconnect nitrogen inlet valve (V13) on chamber side and unplug Drying chamber vacuum sensor.

The two units can now be moved apart.

Take great care when moving these units to avoid damage.

Cap and protect all open pipe work and connections.

Protect the ISO 160 valve from ingress of dirt and foreign bodies.



WARNING

Please note that the drying chamber unit is top heavy. Exercise extreme caution when moving.

Moving of the separate LSG units

The primary means of moving should be by the use of a suitably rated forklift truck. For moving through doorways with restricted height and width (1945mm x 810mm minimum) the use of specially designed transport castors are available from Mechatech Systems Ltd. When using these castors, they must be restrained in the framework by use of the 'quick release pins' supplied. These castors are designed for use on level floors and at a <u>maximum</u> raised height of 8.0 - 10.0mm

(Floor to underside of frame base).

There are 4 Jacking feet positioned towards the corners of each unit. These can be used (if required) for levelling of the units when finally positioned and re-assembled.

Re assembling the units

Reassembly of the two units is a reversal of the disconnect procedure. If used, remove all transport castors.

Ensure that the two units are in their final position and that they are at the same height.

<u>All</u> fittings must be clean dry and degreased prior to re-assembly. Application of a smear of suitable pipe sealant (Loctite 577) should be applied to all compression fitting olives before reconnection. Do not over tighten.

The Silicon oil fluid circuit <u>must</u> be vacuum filled to avoid any possibility of trapped air in the system.





Figure 1



Figure 2

Silicon oil drain valve



3.1.5 Additional Documents to be supplied

Electrical circuit diagrams Publication ref 8408 P&ID publication ref 8484 P&ID Key publication ref 1HY085 Alarm schedule Publication ref 1HY086. Interlock schedule Publication ref 1HY087. Declaration of Conformity publication Manufacturer's Manuals – nonspecific

Important: Only authorised personnel trained by MechaTech Systems Ltd and qualified by experience may perform installation, setup, servicing and maintenance on the LSG system.



4 Introduction to the LSG

4.1 What is the LSG Freeze Dryer?

The LSG 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 large vacuum drying chamber mounted alongside a refrigerated condenser with integral vacuum pump. The drying chamber contains nine (9) refrigerated shelves that can be moved up and down via a hydraulically 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 $+60^{\circ}$ C and -60° C for the LSG60 and between $+60^{\circ}$ C and -40° C for the LSG40.

The condenser unit consist of a cylindrical chamber (290 X 860 mm) with a 160 mm (ISO160) 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 ~30Kg between defrost cycles. The minimum temperature of the chamber wall under vacuum conditions with no load applied is -85° C for the LSG60 and -55 °C for the LSG40.

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 an E2M28 vacuum pump. A transparent Perspex cover 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 defrost utility. An automatic defrost can be incorporated into the Freeze-Drying cycle.

An Edwards two stage oil sealed rotary E2M28 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.

Oil collected in the mist filter is continuously returned into the gas ballast port of the pump. The pump is operated on gas ballast to reduce the risk of water condensation in the pump oil (refer also to manufacturer's instructions).

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.



The drying chamber is situated alongside the condenser unit (refer to <u>figure 4</u>). The chamber is fitted with nine temperature-controlled product shelves, a refrigeration / heater plant with heat transfer fluid circuit and a shelf stoppering mechanism. An aluminium door at the front of the chamber provides access for loading and unloading and is fitted with a toughened glass viewing window which 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.

In order to prevent the cooling compressor from free running, when there is no cooling demand for sustained periods of time (cooling valve closed), which could result in oil starvation, a timer control is used. When the Cooling valve has not been called to open by the PID control for 2 minutes, the Auxiliary compressor is turned off. When the Cooling valve is next called to open the compressor restarts.

A PT100 sensor mounted in the fluid circuit provides temperature feedback for the loop.

The shelves are mechanically linked to a hydraulically actuated ram with variable pressure 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 nine (9) product probe sensors (Type T) 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 (Eycon20) and the Eurotherm T2550 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.

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.



5 Auxiliary Equipment and Interfaces

These are the main components of the LSG system.

5.1 Auxiliary Equipment

5.1.1 Chiller (not supplied as part of the LSG)



The chiller provides chilled water for the refrigeration compressors.

5.1.2 Air Compressor (not supplied as part of the LSG)



The air compressor operates control valves located inside the freeze dryer cabinet.



5.2 System Interconnections in the LSG

This is the general arrangement and interconnections of the main components of the LSG and the Vacuum Condensing Unit.

5.2.1 Vacuum Pump Exhaust Interface

This is a mechanical interface to a factory extraction system.

5.2.2 Condensate Drain Interface

This is a mechanical interface to the factory waste water drain.



6 How the LSG is Controlled

6.1 Operator Interface: touch screen device

6.1.1 I/O Interface

The Eurotherm T2550 Process Controller provides the interface for all sensors and plant actuators.

A relay output is provided responding to any alarm activation and is intended for connection to a Building Management System (BMS).

The connection socket for the alarm relay is located on the service panel on the rear of the freeze dryer.

Refer to page 3 of the Electrical circuit diagrams, Publication ref 8408, for connection details

6.1.2 Operator Interface

The Operator Interface (Visual Supervisor) provides a number of standard (Eurotherm configured) screens and a number of User (Mechatech Systems configured) screens. The user uses a combination of these screens to control and monitor the Freeze-Drying Process. This also includes editing and loading Freeze Drying Recipes, monitoring/acknowledging Alarms and security access.



Figure 3







The whole LSG system is driven via the Operator Interface, which is an industrial touchscreen device.

Just press firmly with your finger to operate the various function buttons.

Although the screen is fairly robust, DO NOT use sharp or metallic objects to operate the touch screen, because this may damage the surface. This is not covered by warranty

Note: Keep the touch screen clean. See "Cleaning the Touch screen" on screen 36.



6.1.3 What do you see on the screen?

Top menu

All screens have a menu bar across the top, like this example below:



These buttons may change colour to indicate status, namely:

- Green is Active
- Red means Alarm condition(s).
- Flashing Red means Unacknowledged Alarm(s).

Bottom menu

At the bottom of the screen is another menu. To operate the functions, press firmly on a button.



7 Power Up and Shutdown Procedures

7.1 Plant Power Up: switching the overall system ON

Power up is achieved via the control power switch located below the operator interface (see Figure 3)

A power indicator illuminates to confirm that control system is on. (see Figure 3)

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 'Closed Down' status as follows:

- Compressors off
- Circulation pump off
- Vacuum pump off
- Valves closed
- Freeze-drying cycle not running
- Shelf temperature setpoint set to -20 °C

Note: The stoppering facility cannot be operated however until the **'RESET'** button is pressed. (See figure 3)

System status display reads 'Closed Down'

Power down is achieved via the control power switch located below the operator interface (see Figure 3)

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

System status: Visual supervisor, cooling compressors, fluid pump and vacuum pump off, valves closed, alarm contact open.





This is the HOME mimic screen for the LSG (actual screen layout may differ)

Some of the mimic parts are colour-coded grey if an item is OFF or CLOSED or green if the item is ON or OPEN.

If there are any alarms on the whole system, the small ALARM tab at the top right shows red or flashes red:

7.2 To View and Acknowledge the Alarms

The top right tab is the Alarm tab. It shows you how many alarms there are on the whole system, e.g. 3 in the following image. Only the most recent alarm tag is displayed, on the Alarm pane, if multiple active alarms exist.

Press on the red ALARM tab, and the Alarm Summary screen appears.

Unacknowledged alarms will cause the red box to flash. In order to acknowledge alarms, press **Acknowledge** or **Acknowledge all.** To display all the current alarms, press the **SUMMARY** button. The **Alarm Summary** appears:

| IDLE | BATCH2 | 95% 460-13:0 | me | 3/0 | (ireil) |
|-------------------------------|-----------------------------|--|-------------------|-----|----------|
| 44:44:69 | | Alarm : | Sunnary | | 23/18/14 |
| | TYPE | ACTIVE | CLEAR | ACK | |
| NI032CM1 DPT131 B1ALM_1 | Input OutRange CC DEV | 23/10/14 06*35 23/10/14 06*35 23/10/14 14:43 | *55 *56 :05 | | |

Example Alarm Summary screen

Power Up and Shutdown Procedures



7.2.1 Alarm Types

Alarm severities are listed in "Alarm schedule" Publication ref 1HY086.

All active alarms are displayed locally and the Alarm relay is de-energised.

7.2.2 Alarm Interfacing

Any active unacknowledged alarm de-energises the Alarm relay output.

A relay output is provided responding to any alarm activation and is intended for connection to a Building Management System (BMS).

The connection socket for the alarm relay is located on the service panel on the rear of the freeze dryer.

Refer to screen 3 of the Electrical circuit diagrams, Publication ref 8408, for connection details

7.3 Logging In

At the top is the Log in / User ID button, showing a person's name, job role, or "LOCKED":

| IDLE BATCH2 | 95% 2081-12: | ENGINEER | 322/11 D2HYDPID HiHi | [0] |
|-------------|--------------|----------|----------------------------|-----|

• If you are not already logged in, press this button. The **Security Access** screen appears:

| BATCH2 | 95% 751-04:1 | LOCKED | | | |
|-----------------------------------|------------------|--------|--|--|--|
| | Security | Access | | | |
| User ID and password, then LOG ON | | | | | |
| | Access: LOCKED | • | | | |
| | Identity: | | | | |
| | Password: ****** | * | | | |

• Tap in the yellow **Identity** box, and a keyboard appears:

| J | 10:59: DHN | 58 S_ | | | | | | Sec | curity | Access |
|--------|---------------|----------|-------------|-----|------------|---|---|-----|--------|--------|
| | Q | ¥ | E | R | T | Y | U | I | O | Р |
| Carsh. | A | s | ; D | F.F | G | н | J | к | L | |
| | t | z | x | с | v | В | N | м | | |
| | 1 | | (11 | | III | | × | + | 1 | C |

- Type your Name or User ID (8 characters maximum), which appears above the keys.
 - For CAPS press the Shift key
 The Shift indicator turns yellow

 Press again to release it.



- To edit / change a character, move the cursor left or right using the using the keys, then re-type that character.
- To Cancel and exit, press the red cross key X
- To Accept the entry press the green arrow key
- Now press on the yellow **Password** box enter your password as above.

Key functions:



Press once for Letters, press again for Numbers, punctuation, etc.



Move the cursor left one character.



Move the cursor right one character.



Cancel: closes the keypad without saving the entry.



OK / closes the keypad and saves the entry.

7.4 Modes of Operation

There are two modes of operation:

1. **Operator mode:** once the system is running, you can only start or stop the pre-set sequences that control the plant. This is the normal day-to-day operating mode.

2. Service mode: only someone with Engineer login access can enter Service mode, which allows the control of individual items of equipment from the mimic screen. The Service screen is accessed from the Home mimic by pressing the SERVICE button and then OK.

- Note that you cannot override Hardwire interlocks in manual mode.
- Operation of the individual plant item is carried out by pressing the relevant icon on the Service mode mimic screen.

Controllable parameters from the Service mimic are as follows:

- Condenser compressors
- Cool Cond valve
- Cool Liq valve



- Vacuum pump
- Diathermic pump
- Vacuum valve
- Vapour valve
- Condenser chamber air inlet valve
- Condenser chamber defrost valve
- Condenser chamber drain valve
- Product chamber air inlet valve
- Product chamber N2 backfill valve
- Product chamber N2 isolation valve
- Shelf temperature Auto/Man control
- Shelf temperature control output
- Drying Chamber Door Interlock override

7.5 Startup

7.5.1 Initial start up

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.

From the Mimic screen, press the 'START UP' button.

The freeze dryer controls to the default parameters.

System status display reads 'Ready'

There are various system checks along the way.

Data logging takes place continually within the system, and log files are transferred manually to the separate customer's PC. (See <u>Data Logging and External Reporting</u> on Screen 26).

The various red alarm conditions on the screen will gradually clear. In this condition, the plant is operational. The system is now ready for a drying process.



7.6 Shutdown Procedures for the whole system

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

1. From the Mimic screen, press the 'CLOSE DOWN' button.

System status display reads 'Closed Down'

Emergency Stop- the user is able to isolate power to the Stoppering ram, by activating the Estop 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.



8 **Running a Drying Process**

The user is able to load recipes and run/abort freeze-drying cycles. The 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

8.1 Initial Checks

To run a drying process, the freeze dryer needs to be powered ON and the System status display reads 'Ready'. Also:

- Check you have sufficient dry nitrogen available.
- Check on the Operator Interface panel that no alarm conditions are showing in red.
- Check the E-stop button is released and the reset button indicator is extinguished.

8.2 Running automatic cycles

8.2.1 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 dying.

First ensure that the door is unlocked on the Home mimic. If it shows **CLOSED** initially.

- Press on the yellow Door Lock area the Door Lock control popup appears
- Press to select the 'OPEN'; then press the green arrow _____ button. The popup disappears and OPEN name appears in the yellow box.



The door to the dying chamber can be opened by first unscrewing the two swing clamps (see <u>figure 4</u>). With the swing clamps rotated clear the door can then be opened using the handle.

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

If the shelf temperature is below 0°C or if the E-Stop is activated it will not be possible to open the chamber door. An engineer can override this interlock in Service mode.

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

- a) From the *Home* screen, press the '**Vent Valve**' icon. The icon changes from Grey to Green.
- b) When the chamber reaches atmosphere, press the '**Vent Valve'** icon again to close. The icon changes from Green to Grey.

8.2.2 Load/Save Recipe



The system now needs to know which recipe you want to use.

• Press the Recipe status button from the Top Menu bar



• Press on the yellow File Name area – it may show ???????? initially. The RECIPE popup menu appears:





| 14:24:20 | Load/Save Recipe |
|------------------------------------|------------------|
| FED RESIN SLUDGE TEMPLATE | File Name: FED |
| Xee | |

• Press to select the required Recipe; then press the green arrow button. The popup menu disappears and the selected file name appears in the yellow box.

• Next, press the **LOAD** button. A popup menu appears:

| | Recipe | |
|---------|----------|---------|
| RECIPES | STATUS | MONITOR |
| EDIT | DOWNLOAD | ABORT |

- Press the **DOWNLOAD** button in order to download the recipe.
- If no recipe is chosen within 20 seconds, the popup disappears. In this case you will have to go back to the beginning.

The freeze-drying cycle will start automatically. The recipe panel changes to blue. 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.

System status display reads 'Program'

The freeze dryer will automatically run each segment of the selected program until it is complete. On completion, the cycle will automatically run any End of Program Sequences (EPS) selected.

During End Point Determination (EPD) the program panel will change to blue and the shelf temperature setpoint will remain unchanged. Program state 'Complete'.

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

The following EPS sequences can be aborted at any stage by selecting 'NO' for the particular sequence from the Setup screen.



The Setup screen is accessed from the Home mimic by pressing the **SETUP** button.

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

During End Point Determination the System status display reads 'EPD'

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.

During Secondary Drying the System status display reads 'Secondary Dry'

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.

During Automatic Backfill the System status display reads 'Auto Backfill'

Automatic Stoppering

Automatic stoppering, when used with stoppering jacks and stoppering frame (see figure 5), is used to fully stopper semi stoppered vials by hydraulically closing the product shelves. Pressure switches are used for feedback to the control system to indicate the fully stoppered and fully home positions (see figure 6). These switches can be adjusted to increase/reduce stoppering pressure. This activity should only be undertaken with Mechatech Systems assistance.

During Automatic Stoppering the System status display reads 'Auto Stoppering'



8.3 Monitoring the Recipe

The Recipe Monitor screen can be accessed by touching the MONITOR key from the recipe menu.

The following columns are displayed:

- RCP The recipe variable
- SP The value held in the recipe for each variable

SP (live) The current live value for each variable. Where the SP and SP (live) values differ, the value is highlighted in red, providing a useful diagnostic should a recipe download fail.

8.4 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.

8.5 Data Logging and External Reporting

The LSG system itself does not provide reports. Data is stored continually in the system's internal memory, and this is transferred to the separate Customer's PC as a continuous data log file via the USB connection.

This data can be interrogated later using the third party "Data Reviewer" software from Eurotherm. Use of this software is outside the scope of this manual.

You can retrieve data log files to a memory stick from the PC's USB port; copy files in the usual way using Windows Explorer.

You can also transfer log files to a memory stick from the Operator Interface USB port. For details, please refer to the **Eurotherm Eycon-10/20 Visual Supervisor Handbook**, section 3.4.3 "Archive Export", screen 3-13.

You are responsible for providing your own data log backup procedures.



8.6 End Cycle

8.6.1 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:

- c) From the *Home* screen, press the '**Vent Valve**' icon. The icon changes from Grey to Green.
- d) When the chamber reaches atmosphere, press the '**Vent Valve'** icon again to close. The icon changes from Green to Grey.

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



- Press the Program status button from the Top Menu bar
- Press the Abort button from the pop-up menus

System status display reads 'Ready'

Note: Once a program has been aborted the EPS will not run

Emergency Stop- the user is able to isolate power to the Stoppering ram, by activating the Estop 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



8.7 Creating/Editing the Recipe

If logged in with engineer level access, you can create new recipes and edit existing recipes.

- 1. Access to the Recipe Editor screen = 'MENU' key / 'RECIPE' button / 'EDIT' button
- 2. Touching a value in a recipe column, allows a new value to be entered
- 3. Press the 'SAVE' button to save any changes or press the 'SAVE AS' to make a copy of the file

Control variables as follows:

| Variable | Description | Limits |
|--------------------|--------------------------------------|-----------------|
| PROG NAME | program to run | N/A |
| NEXT READY | start program automatically | N/A |
| EPD select | End Point Determination selected | YES or NO |
| EPD rate mbar/s | End Point Determination fail rate | Max 10 mbar/s |
| | | Min 0.01 mbar/s |
| EPD retest [hrs] | End Point Determination duration | Max 60 hrs |
| | between tests | Min 0.1 hrs |
| SEC DRY select | Secondary Drying selected | YES or NO |
| SEC DRY temp [°C] | Secondary Drying temperature | Max 60 °C |
| | | Min -40 °C |
| SEC DRY time [hrs] | Secondary Drying duration | Max 60 hrs |
| | | Min 0.1 hrs |
| BACKFILL select | Automatic Backfill selected | YES or NO |
| BACKFILL press | Automatic Backfill pressure setpoint | Max 10 mbar |
| | | Min 0.01 mbar |
| STOPPER select | Automatic Stoppering selected | YES or NO |
| FINISH temp [°C] | Cycle completion temperature | Max 60 °C |
| | | Min -40 °C |

Table 1: Recipe Parameters

Access level of supervisor or greater is required to make recipe edits.



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

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.

8.7.2 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.

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

8.7.3 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.

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

8.7.4 Automatic Stoppering



CAUTION

The provided 'stoppering 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 <u>figure 3</u>).

Automatic stoppering, when used with stoppering jacks and stoppering frame (see <u>figure</u> <u>5</u>), is used to fully stopper semi stoppered vials by hydraulically closing the product shelves. Pressure switches are used for feedback to the control system to indicate the fully stoppered and fully home positions (<u>see figure 6</u>). These switches can be adjusted to increase/reduce stoppering pressure. This activity should only be undertaken with Mechatech Systems assistance.



Select/unselect the automatic stoppering 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 5

8.8 Creating/Editing the Program

8.8.1 Creating a new program

The program variable parameters are as follows:

| Variable | Description | Limits |
|----------|---|----------------|
| ТЕМР | Drying Chamber shelf fluid temperature setpoint | Max 60 oC |
| | | Win -60 oc |
| PRESSURE | Drying Chamber pressure setpoint | Max 10 mbar/s |
| | | Min 0.001 mbar |
| VAPOUR | Drying Chamber evacuation valve open | YES or NO |
| VACUUM | Condenser Chamber evacuation valve open | YES or NO |
| LIQ COOL | Shelf fluid boost cooling valve open | YES or NO |
| DEFROST | Condenser Chamber defrost valve open | YES or NO |
| DRAIN | Condenser Chamber drain valve open | YES or NO |

Table 2: Program Variables



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 "F004" which has been installed into the Controller memory prior to shipping. To load the 'F004' program, follow the instructions below:

- a) Press the MENU printed key (see figure 3)
- b) Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
- c) Press the PROGRAM 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* screen 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 choice of functions available include Dwell, Step, Ramp and Ramp@. These functions are described in more detail in <u>Table 3</u>).
- 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).

| 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 |

Table 3: Function Descriptions and Coding

8.8.2 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 <u>section 8.8.1.</u>

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 <u>section 8.8.4</u>.

8.8.3 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 <u>section 8.8.4</u>.

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

8.8.4 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 <u>section 8.8.2</u> and <u>section 8.8.3</u> respectively.

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

8.9 Setup

Security level: Supervisor

The EPS parameters used in the recipe can be manually overridden.

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

The following sub sequences can be setup:

8.9.1 End Point Determination

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 recipe values.



8.9.2 Secondary Drying

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.

8.9.3 Automatic Backfill

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 recipe values.

8.9.4 Automatic Stoppering



CAUTION

The provided 'stoppering 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 <u>figure 3</u>).

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 6



9 Basic Operator Checks

9.1 Cleaning

9.1.1 Cleaning the Touch screen

Clean the Operator Interface screen as and when required.

CAUTION

- To prevent possible damage to the Touch screen, make sure you use a lint-free cloth, moistened if necessary with a weak detergent solution. Do NOT use aggressive cleaning materials such as isopropyl alcohol because they damage the touch screen.
- DO NOT USE ABRASIVE CLEANERS OR INDUSTRIAL SOLVENTS. These may damage the unit beyond repair. This is NOT covered by warranty or hardware maintenance contracts. Touch screens are expensive to replace.
- 1. Have all your cleaning materials ready a clean, soft, lint-free cloth and weak detergent solution.
- 2. You can clean the screen when the system is powered OFF, but if you want to clean

the screen while it is powered ON, first press the **bottom menu** > button. This displays the **Trend** screen, which has no active areas that can cause a function or state change in the LSG. Even if you activate one of the other menu buttons, these only bring up different screens; if this happens during cleaning, select the **Trend** button again.

3. Gently clean the screen. We recommend that you allow it to dry before resuming use, to avoid leaving marks on the surface.

TREND



10 FAQs and Troubleshooting

10.1 What happens if there is a Power Cut?

If there is a mains power failure, the Operator Interface saves information on which program it is running. All electrical power to the LSG is cut off. The entire system stops where it is, except that the vacuum circuit will automatically flush through with nitrogen.

When power is restored, the Operator Interface system runs some diagnostics and then restarts in automatic mode, with the programmer reset (i.e. no program loaded), and all equipment off.

The system is ready for the operator to press **STARTUP**, at which the Startup procedure will be performed.

10.2 Troubleshooting

Refer to our web site <u>www.mechatechsystems.co.uk</u> for occasional updates about the system.

10.3 System does not power up

If you switch ON and nothing seems to happen, please contact your maintenance personnel or MechaTech Systems.



11 Appendix: Administrative Functions

Notes:

- 1. Access to all functions described in his chapter require ADMIN privileges.
- 2. The functions described in this chapter apply only to instruments fitted with the 'Auditor' option.
- 3. Figure numbers are taken from Eurotherm Eurotherm Eycon-10/20 Visual Supervisor Handbook and have separate sequencing to the other sections in this manual.

The Administration menu is accessed by operating the menu key at the bottom right of the screen, followed by operations of SYSTEM and ADMIN keys

Administration

11.1 User ID control

The use of passwords and user IDs is more strictly controlled in an instrument fitted with the Auditor option, than in instrument not so fitted. Access to User IDs and passwords etc. requires ADMIN permissions.

The major points to note are as follows:

- 1. It is not possible to edit a user's Identity, Name, Access Level or 'Attributes' once the SAVE key has been pressed.
- 2. Once a password has been allocated, it can not be used again either by the original user or by a new user.
- 3. A Password expiry period, amongst other things, can be set in the 'Properties' menu. Once this period has expired, the relevant passwords will no longer be usable.
- 4. A new user's initial password has a 24 hour expiry period. Within this time the user must log in and enter a new password. Once this is done, the new password will be allocated the expiry period set up in the Properties menu (default 90 days).
- 5. A Password must include one non-alpha character (i.e. it must have at least one character which is not one of A to Z or a to z.)
- 6. The password may not be the same as the User identity.
- 7. The 'Delete' key in the non audit-pack instrument is replaced by a 'Retire' key. When the Retire key is operated, with a user selected, that user's name is removed (after confirmation) from the security access screen. The details are, however, stored within the instrument to ensure that the same ID/password etc. cannot be used more than once.



SECURITY ACCESS SCREEN

This screen is called by touching the ACCESS key from the root menu, and entering the ADMIN Identity and Password (both 'ADMIN' when despatched from the manufacturer). Once logged in as ADMIN, operation of the USERS key calls the Security Access Display screen, shown in figure 5.3.1.3a, below.

| TREND RUNNING 13:07 | :45 2 TREND | prog | 2.0 | 4-10:0 | 3 | ADM | IIN | 3/5 Eyco | N-20 BA | DBAT | • |
|------------------------|-------------|---------|----------|--------|----------|-------|------|-------------|---------|-----------|--------------|
| 10:17:20 | | | S | Secur | ity ac | cese | 3 | | | 10 | /04/06 |
| Identity | Name | | Access | | Attri | butes | 5 | Expires | 3 | . Referen | ce |
| ADMIN | ADMIN | I | ADMIN | | 000 | 0000 | 3 | 27/11/0 | 4 | 0 | |
| ADMIN2 | ADMIN2 | I | ADMIN | | 000 | 0000 | 3 | 27/11/0 | 4 | 0 | |
| COMMISSI | COMISSION | 0 | COMMISSI | ON | 000 | 0000 | 0 | 27/11/0 | 4 | 0 | |
| ENGINEER | ENGINEER | E | NGINEE | R | 000 | 0000 | 3 | 27/11/0 | 4 | 0 | |
| OPERATOR | OPERATOR | 0 | OPERATO | R | 000 | 0000 | 0 | 27/11/0 | 4 | 0 | |
| richard | LinMan1 | F | NGINEE | R | 000 | 0000 | 3 | 27/11/0 | 4 | 0 | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| SAVE CANCEL | NEW PROPE | RTIES M | | ATSF | REVISION | DEF | PLOY | | | | |
| | | | | | | | | | | | |
| | | F1 | F2 | F3 | 1 F | 4 | F5 | F6 | F7 | F8 | F9 |
| | | F10 | F11 | F17 | | 3 | F14 | F15 | E16 | F17 | F18 |
| | 드니는 | 110 | | | | - | 114 | | -110 | | 110 |
| | | F19 | F20 | F21 | I F2 | 2 | F23 | F24 | F25 | F26 | F27 |

Figure 5.3.1.3a Security Access Screen

As can be seen from the figure, the screen is divided into a number of columns. Other columns are used as follows:

IDENTITY

Touching a users Identity 'cell' calls the 'Identity' pop-up to appear (figure 5.3.1.3b). This allows a new password to be entered for the ID in the normal way. The new password has a 24 hour expiry, so the user has to login and provide a further new password within this time period. The pop-up also allows IDs to be 'Retired' or 'Disabled'.

| richard:Identity | | | | | | |
|-------------------|--------|--------|---------|--|--|--|
| Password: ******* | | | | | | |
| | onlin: | | | | | |
| oK | CanCEL | REtiRE | DiSaBLE | | | |

Figure 5.3.1.3b Identity pop-up



RETIRE

A 'retired' user is permanently removed from the Security Access screen, and all access privileges are terminated. Retired users' Identities, Names and passwords may not be reused. It is therefore recommended that a note is kept of all Retired users' details.

DISABLE

Users who are disabled (Identity and Name in Red) lose their access privileges in a nonpermanent way. To reinstate a Disabled user, the Identity cell is touched, the User's password entered and confirmed, and 'OK' touched. If the password is correct, the User is 're-enabled', and is shown in the normal blue colour on the screen. The expiry date remains as first set up for the user.

Notes:

- If a user fails to log in within the number of times specified (see Max login attempts in 'PROPERTIES' below), then the user is 'disqualified'. The effects are similar to being 'Disabled', but the 'DISABLE' key in the pop-up is replaced by a 'REINSTATE' key allowing the user's login to be re-enabled.
- 2. In the situation where there is a Visual Supervisor security master and one or more associated Visual Supervisor security slaves:
 - a. the identity pop-up (figure 5.3.1.3b, above) appears only at the master so it is not possible to reinstate a user from a slave.
 - b. If a user is disabled on a slave unit, then this user can be reinstated only using Security Manager software reinstatement cannot be achieved just by redeploying the master unit security.
 - c. If a user is disabled on a particular slave unit, deploying the master unit security does not disqualify the user at the master or at any other slave. In order to disqualify a user at the master, the login should be attempted using an incorrect password more times than the 'Max login attempts' setting for that login (see 'PROPERTIES' below). Once disqualified at the master, the user cannot log in at the master or at any of the slaves.

NAME

Operating this button calls the Name pop-up to the screen. For new users whose details have not yet been Saved, the name can be edited. Otherwise, as shown in figure 5.3.1.3c, this is a View only function.

| name:LinMan1 | | | | |
|--------------|-------|--|--|--|
| ok. | CanCE | | | |

Figure 5.3.1.3c Name pop-up



ATTRIBUTES

Touching a particular user's Attributes 'cell', calls the Attributes screen. This is used to define the users ability to 'sign' and 'authorise' changes, and to define whether the user can modify the instruments operation.

| Identity:Sign: richardYES Authorise: YES View Only: NO Admin Only: NO Remote:FTP: NONO |
|--|
| ok. CanCEL |

The numbers which appear in the attributes column can be decoded as shown in table 5.3.1.3. The values are additive, so if, for example, 'Sign' and 'Authorise' are both selected 'Yes', and all other fields are selected 'No', then the attributes value would be 00000003.

| • Sign | authorise | • View | • admin | • FtP | Remote | Display |
|--------|-----------|--------|---------|-------|--------|------------|
| | | only | only | | | |
| • no | • no | • no | • no | • no | • no | • 00000000 |
| • Yes | • no | • no | • no | • no | • no | • 00000001 |
| • no | • Yes | • no | • no | • no | • no | • 0000002 |
| • no | • no | • Yes | • no | • no | • no | • 00000004 |
| • no | • no | • no | • Yes | • no | • no | • 00000010 |
| • no | • no | • no | • no | • Yes | • no | • 00001000 |
| • no | • no | • no | • no | • no | • Yes | • 00002000 |

Table 5.3.1.3 Attribute Coding

EXPIRES

This column shows the expiry date for each Password, For each new user, the expiry date is 24 hours after the new user details are Saved. The user must log on and change the password within 24 hours, or the Password will lapse. The new password will have the Expiry period set in the Properties menu (described below) of the Security Access Screen.

SCREEN KEYS



These keys are located near the bottom of the screen. The SAVE and CANCEL keys operate in the same way as previously mentioned.



NEW

Operating the NEW key calls the New User pop-up menu to the display. Once the details have been entered, and 'OK' pressed, the new user appears in Green, on the screen.

| Identity: | |
|----------------|---------|
| Name: | |
| Access: OPERAT | OR |
| Password: **** | * * * * |
| Confirm: ***** | ** |
| oK | CanCEL |
| | |

Figure 5.3.1.3d

Note: Do not press SAVE until all other parameters (e.g. attributes) have been configured for this user,. Once SAVED, only the password can be changed.

Configure the users Attributes, as described above, then press SAVE.

The user Identity and Name change to Blue, and the Password expiry date appears as next day. If the user Password is to expire at any period other than that set in the PROPERTIES menu (described in Figure 5.3.1.3d New User screen), this should now be set.

ADMIN should now be logged out of, and the new user logged in and a new password entered.

PROPERTIES

The properties screen depicted with default values in figure 5.3.1.3e, allows the login parameters be set, as described below.



Figure 5.3.1.3e Properties default values



| in User ID Length | 3 to 8 | |
|---------------------|----------|--|
| Min Password Length | 3 to 8 | Passwords must have at least one non-alpha character. |
| Max Login attempts | 1 to 99 | The number of attempts at logging-in that may be made before the account is disabled. |
| Password Expiry | 1 to 180 | The password expires after the specified number of days have elapsed since the last time the value was edited. |
| User Timeout | 1 to 720 | The user is logged out after the specified number of minutes has elapsed since previous screen activity. |

MAINTENANCE

| Account Maintenance | | | | | | |
|----------------------|---------------------------------|----------------------------------|--|--|--|--|
| Recovery Account:YES | | | | | | |
| Mast | Master Access: <mark>YES</mark> | | | | | |
| Edit | Own Ex | pired Password: <mark>YES</mark> | | | | |
| | oK | CanCEL | | | | |

Figure 5.3.1.3f Maintenance screen

Operating the 'MAINT' key at the bottom of the Security Access screen calls the 'Account Maintenance' screen to the display, as depicted in figure 5.3.1.3f.

- **Recovery Account** If recovery account is set to YES, this enables a recovery in the event of all ADMIN accounts becoming unusable. This requires a maintenance contract with the manufacturer.
- **Master Access** Setting Master Access to 'NO', means that the editing of Account systems is not possible.
- Edit Own Expired Password If set to Yes, the user will be forced to change password when attempting to log in. If set to 'No', only a user with ADMIN permissions may enable a new pasword for a user whose password has expired.



STATISTICS

Operating the STATS key at the bottom of the Security Access screen calls the 'Statistics' screen, as depicted in figure 5.3.1.3g, below.





This window shows:

How many users have been configured out of the total available. For example, Users: 6/100 means that six of the 100 possible users have been configured. How many users have been retired. For example, 1/200 means that 1 user window has been retired, and that 199 further users may be retired.

Note: Retiring the 201st user causes the 1st Retired user (by time/date) to be removed from the list.

This results in Event 20 (Purged user) being set. This user's data can now be re-used.

REVISION

Touching this key, calls the configuration revision screen, as depicted in figure 5.3.1.3h, below.

| Revision Information | | | | | |
|-------------------------------|--|--|--|--|--|
| Revision: 0 | | | | | |
| Operational Changes: 0 | | | | | |
| Revised On: 10/04/06 10:23:25 | | | | | |
| Revised By: (Fred) | | | | | |
| Reason:FACTORY | | | | | |
| ОК | | | | | |

Figure 5.3.1.3h Revision page



DEPLOY

A master access system can 'deploy' its own access system to other Visual Supervisors across its ELIN network. This 'Deployment' is in three stages:

- 1. Select the number of nodes nitially 0)
- 2. Enter the node numbers to be deployed to.
- 3. Initiate the deployment.

The initial display screen appears when the 'DEPLOY' key is first pressed (Figure 5.3.1.3i), and shows that the number of nodes is zero.

| Deploy Acc | ess | 10/04/ 06 |
|---------------|-----------------------------|--|
| Number of sla | IVE 0 | |
| | | |
| | | |
| | | |
| | | |
| NFIG | USER | |
| | | |
| | Deploy Acc Number of sla | Deploy Access Number of slave 0 NFIG |

Figure 5.3.1.3i Initial Deploy configuration screen

Touching the CONFIG key, allows the number of nodes to be deployed-to, to be entered. The display shows one configuration box each, for the number of nodes selected, to allow the required node numbers to be entered. Initially, all these contain '0', although this value cannot be used. (Figure 5.3.1.3 k.)

| 10:26:06 | Deploy A | ccess - Config | 10 /04/ 06 |
|----------|-------------|---------------------|------------|
| | Number of a | lave <mark>5</mark> | |
| | Slave | | |
| | 0 0 | 0 0 | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| 0 | CLEA | FIL | SOR |
| | | | |
| | | | |

Figure 5.3.1.3j Node number configuration.

Operation of the FILL key at this point will fill the node number configuration boxes with nodes 1 to n, where n is the number of nodes selected.

If, instead, the first node is entered by the user (say node 10), the FILL operation will automatically fill in the remaining node numbers, (starting at 11 in this example).



If non-consecutive node numbers are entered, say nodes 17, 3, 9, 103 and 14, then the SORT button can be used to reorder the nodes in ascending order (3, 9, 14, 17, 103).

The CLEAR key is used to reset all the mode numbers to '0'.

Operation of the OK key, returns to the previous screen, only this time, the newly configured items appear.

| 10:27:48 | Deploy Access | 10 /04/ 06 |
|----------|------------------------|------------|
| | Number of slave nödes: | |
| | Slave | |
| | 3 9 1 1 10 | |
| | | |
| | | |
| | | |
| DEPLOY | CONFIG | USER |
| | | |
| | | |

Figure 5.3.1.3k Completed configuration

Operation of the DEPLOY key causes the deploy to be initiated, once signed and authorized if necessary. Figure 5.3.1.31 shows the confirmation screen.

| Doploy Access | |
|---------------------------|----|
| Deploy Access | |
| number of slave nodes: 5 | |
| Slave nodes: 3 9 14 17 10 |)3 |
| Confirm Action: DEPLOY | |
| | |
| Reason: | |
| Signed by Ident: | |
| | |
| Password Politic ******** | |
| Authorised by Ident: | |
| Password: ******* | |
| OK CANCE | EL |
| | |
| | |
| | |
| | |
| | |



11.1.1 ELECTRONIC SIGNATURES

Enabling electronic signatures

Note: Once Electronic signatures have been enabled, they can not subsequently be disabled.

As shipped, electronic signatures are disabled. The 'Enable signatures' Signature Configuration screen (figure 5.3.2.1) appears on the first operation of the SIGN CONFIG key in the Administration menu.

The only choices are to quit the screen (by selecting another screen using the menu key) or Enable electronic signatures.

| | Administration | |
|--|---|------------|
| | NET AUDIT SIGN CONFIG | |
| | | |
| 10:29:28 | Signatur Configuration | 10 /04/ 06 |
| The "ENABLE' signatures. turned on and | button may be used to turn on el Once signatures have been saved, they cannot be turned | ectronic |
| | ENABLE | |

Figure 5.3.2.1 Enable Signatures page

When 'Enable' is operated, a dialogue box appears requiring two separate ADMIN passwords before the Signature Configuration screen (figure 5.3.2.2a) appears.



Signature Configuration

Figure 5.3.2.2a shows the Signature Configuration screen. The administrator IDs in 'Revision Level' are, initially the IDs of the administrators who enabled the Electronic Signature feature. Subsequently the IDs are those of the administrators who signed/authorized the previous Configuration Save.

| Revision: | 1 10/04/06 10:31:25 2ADMIN ADMIN |
|---------------|----------------------------------|
| Function: | Security Access |
| SAVE : | No |
| Account | Confirm only |
| Account | Signature |
| User Password | Sign & Authorise |
| RETIRE : | Action disabled |
| DISABLE: | Sign & Authorise |
| ENABLE : | Sign & Authorise |
| REINSTATE | Action |
| DEPLOY : | Signature |
| SAVE | |
| | DEFACE |
| | |

Figure 5.3.2.2a Signature Configuration page

Access Levels

As can be seen from figure 5.3.2.2a, above, a number of instrument features can have an access level assigned to them. The possible access level definitions are as follows:

As can be seen from figure 5.3.2.2a, above, a number of instrument features can have an access level assigned to them. The possible access level definitions are as follows:

| No Confirmation | The instrument behaves as if electronic signatures are turned off. |
|------------------|---|
| Confirm only | A dialogue box with OK and CANCEL buttons appears, before the action is undertaken. |
| Signature | A password entry by a user with Signature Permissions is required before the action is performed. |
| Sign & Authorise | A password entry by a user with Signature Permission and a further entry by a user with authorization permission are required before the instrument will respond to the requested action. |
| Action Disabled | This causes the relevant button caption to be 'greyed out' thus becoming inaccessible to the user. Thus the action may not be undertaken at all. |

Note: Some functions cannot be allocated some access levels. Administrative functions, for example, always require a minimum level of 'Signature', and some functions cannot be assigned 'Action Disabled'.



The available functions are in a number of categories, a picklist of categories being displayed when the 'Function' field is touched. Figure 5.3.2.2b, below shows this picklist.

The button functions at the bottom of the screen are as follows:

| Securit | V |
|-------------|------|
| A | |
| Security Ac | cess |
| Application | n |
| Setup | |
| Cloning | |
| File Manage | er |
| Administra | tion |
| Alarms | |
| Overview | |
| Programmer | |
| Recipe | |
| Batch | |
| Logging | |
| V | |
| → X | G |

Figure 5.3.2.2b Function



12 Maintenance

12.1 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.

12.1.1 Daily Maintenance

- Check oil level in vacuum pump
- Check chamber door o-ring

12.1.2 Weekly Maintenance

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

12.1.3 Six Monthly

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

12.1.4 Yearly

- Clean & Overhaul vacuum pump
- Clean the oil-sight glass
- Clean the E2M28 motor fan cover
- Check silicon fluid circuit for leaks
- Inspect vacuum 'O' ring seals, change if necessary
- Calibrate gauges

12.1.5 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 to be reviewed by the customer during the unit's operating life.



12.2 Recommended Spares

12.2.1 General

Table 4: Recommended Spare Parts List

| ITEM # | DESCRIPTION | QTY |
|--------|---|-----|
| 1.00 | HOCKEY PUCK RELAY | 1 |
| 2.00 | ONE POLE DETECTOR | 1 |
| 3.00 | PSV PROPORTIONING ELECTROMAGNETIC VALVE | 1 |
| 4.00 | CONDENSER THERMOCOUPLE | 1 |
| 5.00 | FLUID THERMOCOUPLE | 1 |
| 6.00 | FIREROD CARTRIDGE HEATER | 1 |
| 7.00 | CUSTOM LEVEL SWITCH | 1 |
| 8.00 | APG100-XM LINEAR PIRANI GAUGE NW16 | 1 |
| 9.00 | 3/8" AXIAL VALVE. D/ACTING | 1 |
| 10.00 | 1/2" AXIAL VALVE. D/ACTING | 1 |
| 11.00 | 5/2 SINGLE SOL VALVE 24VDC | 1 |
| 12.00 | 3/2 SINGLE SOL VALVE 24VDC | 1 |
| 13.00 | PRESSURE SWITCH | 1 |
| 14.00 | 12MM NUPRO VALVE N/C | 1 |
| 15.00 | 8MM NUPRO VALVE N/C | 1 |
| 16.00 | UNIPUMPII 2 STAGE service kit | 1 |
| 17.00 | HUBER SILICON OIL. 5 LTRS. | 1 |
| 18.00 | 10" REPLACEMENT SEAL | 1 |
| 19.00 | KF40 ANGLE VALVE | 1 |
| 20.00 | ALUMINIUM METAL SEAL | 2 |
| 21.00 | SILICON & VITON O RING & CORD SET (16 pieces) | 1 |
| 22.00 | HYDRAULIC POWER PACK SERVICE KIT | 1 |
| 23.00 | DC ANALOGUE I/P MODULE | 1 |
| 24.00 | TC ANALOGUE I/P MODULE | 1 |
| 25.00 | ANALOGUE O/P MODULE | 1 |
| 26.00 | DIGITAL O/P | 1 |
| 27.00 | RELAY O/P | 1 |
| 28.00 | RELAY O/P | 1 |
| 29.00 | E2M28 CLEAN & OVERHAUL KIT | 1 |

12.3 Edwards vacuum pump

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

12.4 Manufacturers literature

Manufacturer's literature for all major components have been included.



12.5 Self-Diagnostic Facilities

Both Eycon20 and T2550 perform their own self check routines on start-up. T2550 I/O module or hardware errors and Ethernet communication failures are checked for within the configurations and raise alarms if a fault is detected.

12.6 Technical Specifications

General Sales and Service Contact Information:

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