User's Manual

Millrock REVO™ Series Freeze-Dryer

Opti-Dry/Opti-Dry Pro
21CFR Part11

CE

R2010.3

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Copyright Information

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Warranty

Millrock provides a warranty on all parts and factory workmanship. The warranty includes areas of defective material and workmanship, provided such defects result from normal and proper use of the equipment.

The warranty for all Millrock products will expire one year from date of installation, except when otherwise stated.

This limited warranty covers parts and manufacturer's factory labor, but not transportation, travel expenses and insurance charges. Under no circumstances shall seller, any subsidiary or any division thereof, have any liability whatsoever for loss of use or for any indirect or consequential damages. The warranty shall be void should the purchaser fail to adhere to maintenance programs prescribed by the seller, if replacement or spare parts not compatible with the machine are installed or if any alterations or repairs detrimental to the machine are performed. The warranty is limited to the first purchaser and is not transferable. No warranty shall apply in the event purchaser makes any change or modification to any part of the items ordered without the express written consent of seller.

Lamps and filters are not covered by this warranty.

Limitation of Liability

The disposal and/or emission of substances used in connection with this equipment may be governed by various federal, state, or local regulations. Millrock Technology is held harmless with respect to user's compliance with such regulations.

It is the responsibility of the customer to determine if the equipment is compatible with their application needs. At the users request, Millrock will provide MSDS sheets on materials that are exposed to the product being processed. The customer must determine the compatibility of the construction materials of the equipment on their application.

IP Rating
This equipment is rated IP20 when assessed to EN 60529.

Section 1: Introduction

Congratulations on your purchase of a Millrock Technology product. Freeze drying systems contain several key components which need to be understood to produce the best end product.

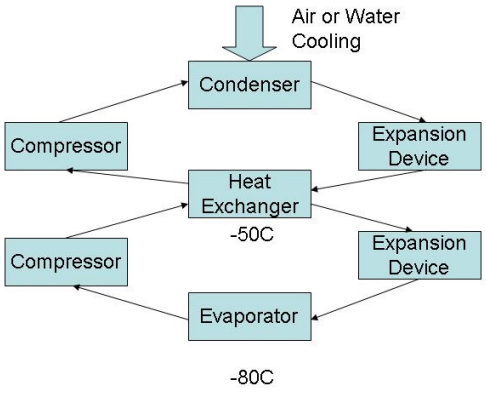
Freeze Drying

The process by which, water is removed from frozen materials by converting the frozen water directly from its vapor state without the formation of liquid. The basis for sublimation involves the absorption of heat by the frozen sample in order to vaporize the ice. To aid the process, a vacuum keeps the water below its triple point. The water vapor leaves the surface of the material and is collected on a cold surface called the condenser. The condenser should be 15°C below the eutectic point (melting temperature) of the product. When all the available water is removed from the product it is then considered freeze-dried.

Refrigeration System

A refrigeration system has 4 basic components: a compressor, a condenser, an expansion device, and an evaporator. The compressor takes a cold gas at a low pressure and squeezes it into a high pressure/high temperature state. Even though the pressure is high, the temperature prevents the gas from becoming liquid. The excess heat is removed using a condenser, which may be either air or water cooled. This process turns the gas into a liquid. The high pressure liquid is then expanded through an expansion device into an evaporator. The process of expansion absorbs heat, creating a cooling affect. Depending on the gases used, temperatures to -53°C can be achieved using a single compressor.

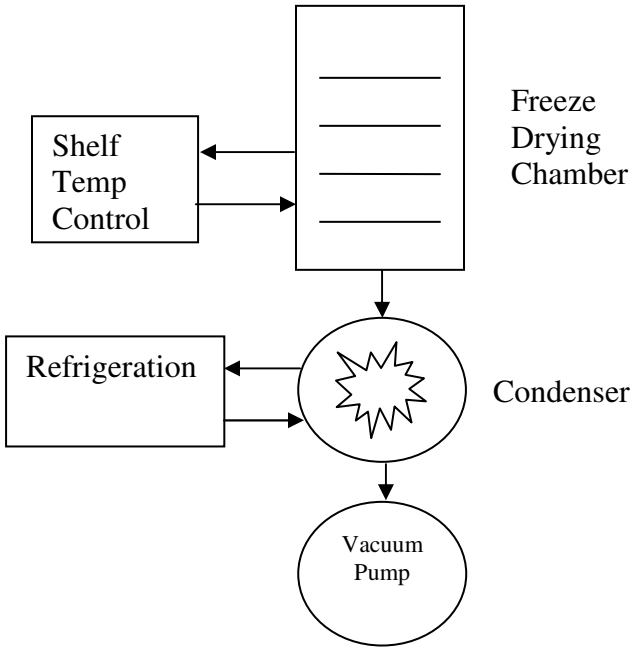
To achieve lower temperatures, a second refrigeration loop can be put into series with the first loop. The -53°C evaporator of the first stage acts as the condenser on the second stage. Therefore a lower boiling point fluid can be used in the second stage. The result is temperatures to as low as -100°C.



Cascade Refrigeration System Diagram

Vacuum System

For the freeze drying process to work, a vacuum must be created to provide the conditions where water can only exist as a solid or gas. A vacuum pump is critical to the operation of the freeze dryer. To get to the required vacuum levels a two-stage vacuum pump is used. These require oil for operation. Proper maintenance of the oil is required to protect the pump and for freeze drying to be successful.



Freeze Drying System

Section 2: Setup Requirements

General Operating Conditions

Operating Temperature

-This equipment will operate correctly in its intended ambient, at a minimum between +15°C and +22°C.

Relative Humidity

-The equipment will operate correctly within an environment at 50% RH, +40°C. Higher RH may be allowed at lower temperatures.
-Measures shall be taken by the Purchaser to avoid the harmful effects of occasional condensation.

Altitude

-This equipment will operate correctly up to 1000m above mean sea level.

Transportation and Storage

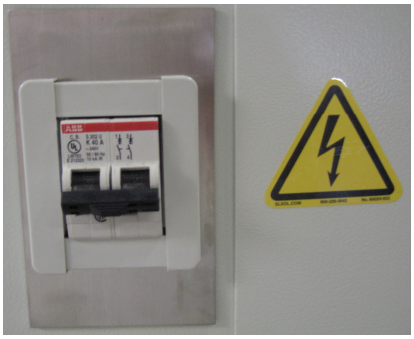
-This equipment will withstand, or has been protected against, transportation and storage temperatures of -25°C to +55°C and for short periods up to +70°C.

-It has been packaged to prevent damage from the effects of normal humidity, vibration and shock.

Electrical
Refrigeration systems are generally intolerant of low voltage conditions. Make sure that the voltage supply and wiring is designed to carry the required current at the required voltage. Compressors have a high starting current draw, which if the wiring is not proper, can result in a voltage drop that will prevent the compressor from starting.

- Voltage must operate between +/- 10% of nominal rating.
- A circuit breaker should be provided with a rating of 20% above the running amps of the system.
- Verify voltage at the source.
- Verify wiring size is sufficient to carry the in-rush current at compressor start-up.
- 208V/230V units are not supplied with a plug. A plug must be installed as per the local electrical code.

The main breaker/Disconnect acts as a Category 0 Stop for the equipment and the equipment must be installed in a manner that allows unfettered access to the D/C.



The primary service entrance ground bears the marking "PE". (Protective Earthing)

Ambient Air/Water

Air cooled condensers require both sufficient air flow and low ambient air temperatures to function properly. Ambient temperatures above 72°F (25°C) begin to reduce the performance of refrigeration systems. This is especially true in cascade refrigeration systems.

- Operating temperature range: 45°F to 90°F
- Relative humidity: <80%
- Provide at least 20" of air flow space on all sides of the equipment.
- Do not install the system in an enclosed room or closet.
- Provide sufficient cooling in the room to provide air below 80°F.

Air is drawn in through the condenser and blows over the compressors to provide cooling on the compressor shell.

Water cooled systems require sufficient water flow at 20°C. Flow rates will be supplied with the equipment.

Forseeable Misuse

Misuse of Equipment	
	Do not use this Equipment for any purpose not described in this Manual.
	Do not operate this equipment without all guards and covers in place.
	This is the electrical hazard symbol. It indicates that there are DANGEROUS HIGH VOLTAGES PRESENT inside the enclosure of this product. TO REDUCE THE RISK OF FIRE OR ELECTRIC SHOCK, do not attempt to open the enclosure or gain access to areas where you are not instructed to do so. REFER SERVICING TO QUALIFIED SERVICE PERSONEL ONLY. Do not operate this equipment from any power source that does not match the voltage rating stamped on the equipment. Refer to the Manufacturer's Identification Label for operational requirements.
	Do not use lubricants in this equipment that are not specified in the Maintenance Manual.
	VENTILATION – slots and openings in the cabinet are provided for ventilation and to ensure reliable operation of the product. To protect the unit from overheating, those openings must not be blocked or covered. This product should not placed in a built-in installation, such as a wall cutout unless proper ventilation is provided. hot temperatures will result
	WARNING! extreme cold! surface temperature of this equipment operates below 0°C (32°F). Use appropriate Personal Protective Equipment (PPE) when performing maintenance operations.
	CRUSH HAZARD! Keep hands away from moving parts.

Section 3: Getting Started

Unpacking

Carefully unpack your system and inspect it for damage.

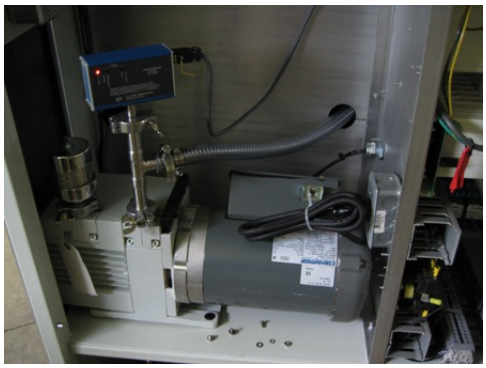
If your equipment is damaged you should immediately:

- Notify the carrier and retain the entire shipment intact for inspection by the carrier.
- Contact the factory for assistance.
- Obtain a Return Authorization Number should the equipment need to be returned.
- Do not discard the shipping material until the entire system has been operated and been deemed satisfactory.

Putting it all together

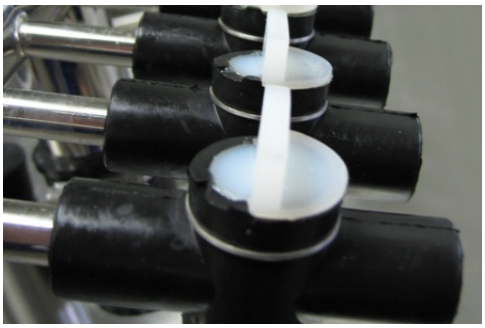
Setting up the equipment is simple. After unpacking, perform the following:

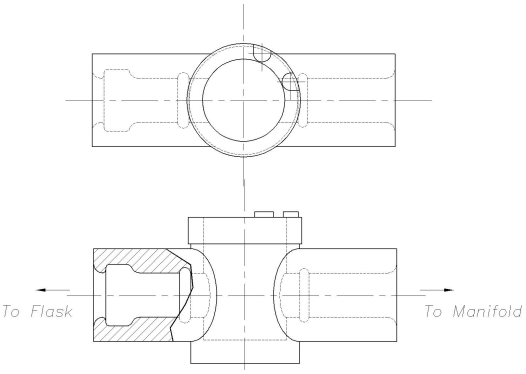
1) Place the equipment in a location with proper ventilation.
    a. Make sure there is at least 20" on each side of the equipment for proper air flow.
    b. Do not place the system in an enclosed room.
    c. Place the drip pan (provided) under the rear section of the machine to collect condensation from the compressors.
2) Install the vacuum pump in the space provided behind the front door panel.
    a. Check the oil level. Make sure it is between Min and Max.
    b. If the vacuum pump is not already mounted inside the system:
        i. Connect the vacuum hose.
            1. Make sure to tighten all the fittings.
            2. Check the hose for tightness.
            3. Attach the Oil Mist Eliminator to the output.
        ii. Plug the vacuum pump into the outlet provided in the system.
            1. This is important since the controller turns the pump on/off.



3) Connect the PC
    a. The PC connects to the RJ45 connector on the system via the cable supplied.
4) Check the shelves
    a. The shelves and condenser are held in place using tie wraps. Remove the tie wraps and shipping material.
    b. Inspect the shelves to make sure that they are free and clear of all objects.
    c. On stoppering systems, lift each shelf to make sure it moves freely.
    d. Verify that all liquid hoses are connected.

5) Optional Manifold Installation
    a. Mount the manifold to the port on the top of the machine.
    b. Connect the manifold using the rubber sleeve and clamps provided.
        i. Make sure to use vacuum grease inside the rubber sleeve.
    c. When placing the vacuum valves on to the manifold, make sure to have the "nubs" on the valve toward the manifold. The valve is designed with a recess inside one end for accepting vial tops. The other end is smooth and intended for use on the manifold.
6) Electrical
    a. A plug is not supplied with the system. A plug must be installed as per the local electrical code.
    b. After power is connected, turn the breaker ON.
7) Turn the PC ON.
8) Turn the Main Power Breaker ON(on the rear of the system).





IMPORTANT:
An important point to ensure before operation:

1- If using the gas backfill, make sure that the gas source is connected and is turned ON. If the source is connected, but not turned on the system will not release the vacuum.

Equipment Options:

LN2 Trap:

CAUTION: Oxygen Depletion when using Liquid Nitrogen

H2O2 sterilization:

WARNING: <u>DO NOT</u> open any Chamber Doors while unit is in process of H2O2 sterilization!

Stoppering Option:

Stoppering
For systems with stoppering capability a hydraulic cylinder is provided to lift and lower the shelf stack. By lifting the shelf, vials can be stoppered in place at the end of a run.
-Hydraulic Stoppering Pressure 10 PSI

Important: The hydraulic cylinder can not fully lift all the shelves to close without vials installed.

CAUTION:
Make sure individual shelves are fully loaded before stoppering. **DO NOT** stopper a partially loaded shelf. Partially loaded shelves may become damaged during stoppering. Use trays to fill empty shelves.

Photos of shelves in the down and up positions:

The shelves are raised and lowered via a manual switch on the front panel.

Toggle Switch

IMPORTANT:
During the freeze-dry run, the user should refrain from moving the shelves with the stoppering option because of the possibility of hoses cracking when low temperatures are achieved.

Section 4: OPTI-DRY Software

Menus are located on the right hand side of the screen. The three sections are Cycles, Data/Graphing, and Maintenance

Cycles allow the user to control the system and its functions.
Data/Graph provides the logging and display of data.
Maintenance allows the user to calibrate and tune the equipment.

Cycles
- **Freeze Drying (automatic)**
  - **Pressure Rise Test (Pro only)**
  - **Product Average Trigger (Pro only)**
  - **Pressure difference Trigger (Pro only)**
- **Defrost**
- **System Test**
- **Leak Rate**
- **Manual**
- **Maintenance**

Data/Graph
- **Data Logging By Run**
- **Data Logging By Day**
- **4 Hour FD**
- **24 Hour FD**
- **24 Hour Product**
- **Lyobrary**

Maintenance
- **Calibration**
- **Tune**
- **Instructions**

Millrock freeze dryers offer a full PC/PLC control system for operation. The software steps the user through the freeze-drying process.

Help Screens

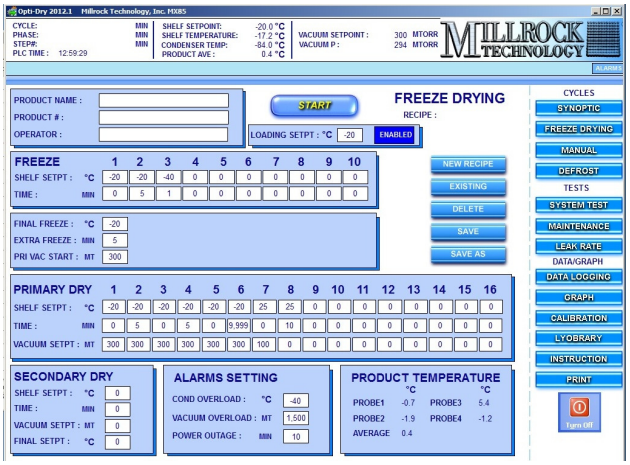
Each menu has help screens to define parameters and to help step the user through the operating process.

Main Menu/Synoptic

The main control panel provides the user selection of the major control areas.

Selecting a control button activates the screen for each of the selections. Active processes and screens are recognized by their green color (vs. red).

Section 4a: CYCLES



<u>FREEZE DRYING (Automatic)</u>

There are 10 phases to the freeze drying cycle. They are:

LOADING: The loading set point allows the user to pre-freeze the shelves to aid in the loading of the machine.

FREEZE CONTROL: This is an optional (does not have to be used) multi-step freezing routine where the product can be frozen at a controlled rate. 8 to 10 steps provided to provide a series of ramp and holds.

FINAL FREEZE: The final shelf set-point. The temperature used for the Extra Freeze Time to ensure product is frozen.

EXTRA FREEZE TIME: Additional freezing time after the shelves reach the final freeze set-point.

PRIMARY VACUUM START: The vacuum set-point. When achieved, the system will continue to primary drying.

PRIMARY DRYING: This is a multi-step shelf temperature and pressure control program.

SECONDARY DRYING: After primary drying, this is the last phase for controlled shelf temperature and vacuum.

FINAL SETPOINT: The temperature the machine will maintain after Secondary Drying.

FINISHED: After the secondary time expires and the shelf temperature has reached the final shelf set-point, a FINISHED message appears. At this time, back-filling and stoppering (if required) can be done before releasing vacuum.

RELEASE: This turns everything off except the vacuum release valve, which remains on for 5 minutes.
The following menus are actual help menus available in the software which describe each action.

The Automatic Run will energize the vacuum and check to see if a slight vacuum is pulled on the condenser, thus verifying the door, drain, and other valves are shut. When a slight vacuum is achieved the system will begin the automatic run.

If operating in manual mode:

i. Turn the vacuum pump on
ii. Press the chamber door until it seals
iii. Turn off the vacuum pump
iv. Caution: Only initialize the vacuum seal, do not pull a low vacuum

Important notes on Automatic (Freeze Drying) runs:

General

- The time field is used to determine the ramp rate from the previous step to the current step. IE: If the last step ended at 10°C and this step ends at 20°C and the time is 20 minutes, then the ramp rate is 10°C/20 minutes = 0.5°C/min.
- A 0 (zero) in a time field will provide a ramp rate "as fast as possible".
- It is not necessary to put values in every step. If a step has all (0)'s, then it is skipped.

Loading

- Enter a set point and press the ENABLED/DISABLED button to enable or disable the pre-freeze step.
- Press the FINISHED LOADING button to continue after the machine is loaded.

Freeze

- The program assumes that you are starting at 20°C
    - For a controlled ramp - the first step should have the first freeze point and the time it should take from 20°C to that point. The set-point will start at 20°C and step down according to the time entered. IE: 20° to -40°C in 60 minutes will result in 1°C/min shelf temperature change.
    - If a "ballistic" ramp is required, place a (0) in the time field. The system will immediately change the setpoint to the end point and cool as fast as possible. Important: The next step must have a time in it.
- The time is used to determine the ramp rate from the previous step to the current step. IE: If the last step ended at 10°C and this step ends at 20°C and the time is 20 minutes, then the ramp rate is 10°C/20 minutes = 0.5°C/min.
- The final freeze temperature is a setpoint that must be reached before the "extra freeze" time starts counting. Important: The shelf temperature will NOT hold at this temperature, the shelves will continue to cool for the time period entered in FINAL FREEZE TIME.
- Assuming all of the steps have (0) time it will bypass this and go to the final freeze
- setpoint. If there are values, other than (0), in some time fields, the system will go to the shelf setpoint, as fast as possible, in the step that has the (0) time.

- Final freeze – A (0) in the time field will skip this phase and turn on the condenser. Actually, with (0) time in this field, there is about a 1 minute delay before turning on the condenser.
- IMPORTANT: Never put a (0) in the PRI VAC SETPOINT. The system will not reach a (0) vacuum and Primary drying will never start.

Primary

- The time is used to determine the ramp rate from the previous step to the current step. IE: If the last step ended at 10°C and this step ends at 20°C and the time is 20 minutes, then the ramp rate is 10°C/20 minutes = 0.5°C/min.
- A (0) in the time field will go to setpoint as fast as possible. It will skip all the remaining steps if they all have (0) in the time fields.
- After reaching condenser setpoint (Phase 4), the system turns on the vacuum pump, Phase 5. It will wait until it reaches this setpoint and then go to Primary Drying (Phase 6). With (0) in the field, the vacuum will never get there and it will not advance to Phase 6. After one hour, it will go back to Phase 3, Final Freeze, and start from there.
- In any step with (0), the system will go to the ultimate vacuum possible

Secondary

- A (0) entered will go to the ultimate vacuum possible.

Alarms

- Condenser Overload – the temperature at which you consider the system to be having a problem. If this temperature is reached, the system will
    - Turn off control to the shelves and vacuum
    - Provide maximum cooling to the condenser
    - Will attempt to recover
    - If in Primary Drying, if the situation does not recover in 30 minutes the system will return to the final freeze step.
- Vacuum Overload – the vacuum level at which you consider the system to be having a problem. If this level is reached, the system will go back to the final freeze step.
    - Turn off control to the shelves and vacuum
    - Provide maximum cooling to the condenser
    - Will attempt to recover
    - If in Primary Drying, if the situation does not recover in 30 minutes the system will return to the final freeze step.
- Power Outage – the time that power can be off before the system must return to either the final freeze step
    - If in Primary Drying, the system will return to the final freeze step and resume
    - If in Secondary Drying the system will resume

Please review the on-line HELP screens for more information.

Examples

Freeze – Example 1 – Ramp down to -40°C

1	2	3	4	5	6	7	8	9	10
-40°	-40°	0	0	0	0	0	0	0	0
120	240	0	0	0	0	0	0	0	0
Go from 20°C to -40°C in 120 min (0.5°C/min)	Hold at -40°C for 240 min	Skip	Skip	Skip	Skip	Skip	Skip	Skip	Skip

Freeze – Example 2 – Ballistic cool to -40°C

1	2	3	4	5	6	7	8	9	10
-40°	-40°	0	0	0	0	0	0	0	0
0	240	0	0	0	0	0	0	0	0
Set shelf to -40°C immediately and wait until the shelf reaches -40°C	Hold at -40°C for 240 min	Skip	Skip	Skip	Skip	Skip	Skip	Skip	Skip

Final Freeze – Example 1 – Wait to hit temp and start timer.

Final Freeze (°C)	-45°
Extra Time	120
Prim Vac	200

Allow the shelf to cool to -45°C; then Start the Extra Time timer. The shelves will continue to cool below -45°C for the next 120 minutes. Then pull vacuum to 200 mT.

Final Freeze – Example 2 - Skip step

Final Freeze (°C)	-45°
Extra Time	0
Prim Vac	200

Allow the shelf to cool to -45°C; do not hold, then pull vacuum to 200 mT. Note: Use this method if want to skip the final hold and do not want to cool the product below the setpoint.

Primary – Example 1 – Simple run

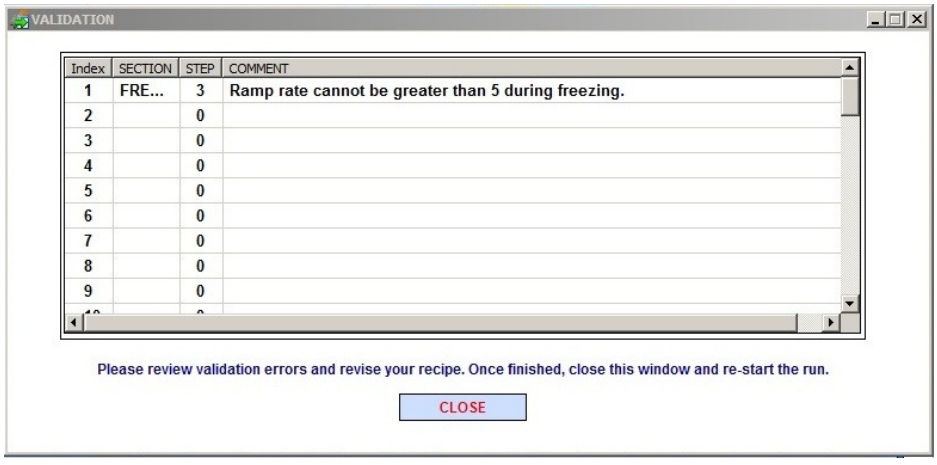
1	2	3	4	5	6	7	8	15	16
20°	20°	0	0	0	0	0	0	0	0
0	240	0	0	0	0	0	0	0	0
100	100	0	0	0	0	0	0	0	0
Ballistic ramp to 20°C vac at 100 mT	Hold at 20°C for 240 min, Vac at 100 mT	Skip	Skip	Skip	Skip	Skip	Skip	Skip	Skip

Primary – Example 2 – Ramps

1	2	3	4	5	6	7	8	15	16
-20°	-20°	0°	0°	20°	20°	0	0	0	0
25	240	0	240	0	480	0	0	0	0
100	100	100	100	100	100	0	0	0	0
Go from the Final Freeze setpoint to -20°C in 25 min, Vac at 100 mT	Hold at 20°C for 240 min, Vac at 100 mT	Go from -20°C to 0°C in as fast as possible, Vac at 100 mT	Hold at 0°C for 240 min, Vac at 100 mT	Go from 0°C to 20°C as fast as possible, Vac at 100 mT	Hold at 20°C for 480 min, Vac at 100 mT	Skip	Skip	Skip	Skip

Validation

OptiDry has a built in recipe validation function. This will check your entered recipe and point out any errors. The use must correct the errors prior to re-starting the freeze drying run. The Validation window contains a list of errors:



Opti-Dry Pro Features (OPTIONAL):

Opti-Dry Pro adds additional features to the standard Opti-Dry software including:

End of Freezing
By measuring several product probes during the freezing process the system can determine if the vials are frozen. The freezing routine is automatically advanced to a final freeze step to ensure that all product is frozen, thus optimizing the freezing cycle.

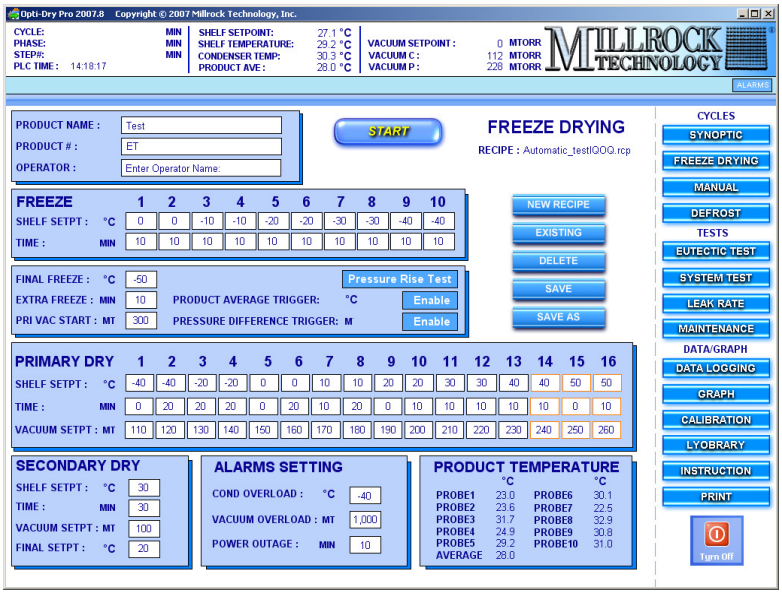
End of Primary Drying
Primary drying is typically the longest part of a freeze drying cycle and must continue until all the unbound water is removed. To optimize the primary drying phase of freeze drying one of several techniques can be used.

1. Product Temperature End of Primary Drying Setpoint
The user enters an 'end of primary drying' product temperature (Tpe). When the product temperature average reaches (Tpe) the defined setpoint in the primary drying recipe, the program will automatically advance from the recipe to a predefined (3 step) finishing routine and then secondary drying. The finishing routine can be used to ensure that all vials have completed primary drying before entering secondary drying. If the finishing routine is not programmed, then the recipe jumps automatically to secondary drying. This feature is particularly useful for use with small lots of product.

2. Capacitance Manometer Differential Test (Capacitance manometer is required)
The Pirani vacuum gauge measures relative vacuum and responds to the vapor present in the freeze dryer. The capacitance manometer indicates the absolute vacuum and is not affected by vapor pressure. When the two gauges reach within a predetermined level the primary drying process can be considered complete. The user enters a differential (mT). During the primary drying process, when the differential is met, the program jumps to a finishing sequence and then secondary drying.

3. Pressure Rise (Isolation valve is required)
When the freeze drying chamber is isolated from the condenser and vacuum pump, the vapor pressure will force the vacuum to rise. With ice in the chamber the pressure will rise faster than without ice present, thus indicating that the product has not reached the end of drying. The user enters the test time, the acceptable pressure rise and how often to repeat the test during the primary drying recipe. The program will advance to a finishing sequence and then secondary drying when the pre-set pressure rise rate is reached.

End of Primary Drying Product Temperature = Shelf Temperature



Using 30 to 36 gauge thermocouples placed in the product, the presence of ice can be determined. This method assumes that if the ice is sublimated, then the product will approach the shelf temperature.

Setup

A. Place the product thermocouples in the center of the vial, touching the bottom of the vial.
    a. If using bulk material, tape the thermocouple to the bottom of the tray with the tip of the sensor exposed to the product.
B. Enable the product thermocouples on the SYNOPTIC screen that are being used and disable the thermocouples that are not being used.
C. On the FREEZE DRYING screen ENABLE ‘PRODUCT AVERAGE TRIGGER’.
D. In the space provided, enter the desired temperature (IE: 15C if the shelf is set at 20C at the end of primary drying).
E. When the PRODUCT AVERAGE TRIGGER temperature is met, the program will automatically jump to STEP 14 and will execute steps 14 thru 16 as a finishing sequence before secondary drying is activated.

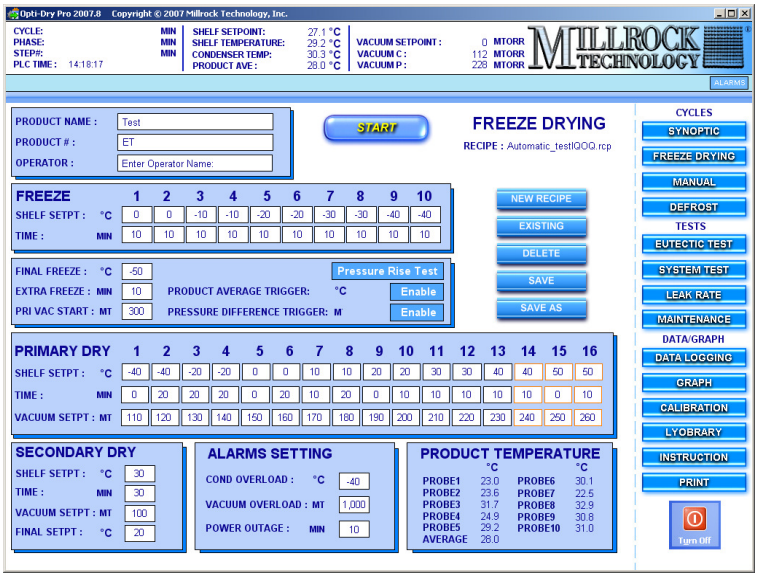
Operation

A. Make sure that PRODUCT AVERAGE TRIGGER is enabled. (There is a temperature indicated)
B. Start the FREEZE DRYING run as usual
C. During primary drying the average product temperature is calculated and compared to the ‘PRODUCT AVERAGE TRIGGER’. When the temperature is reached the program automatically jumps to STEP 14.

Comments:

A. ‘out of range’ or ‘open’ thermocouples are ignored
B. The placement of thermocouples is critical to proper operation.
C. Since the product temperature readings cannot measure all points and therefore can’t guarantee that all the ice has been sublimated, STEPS 14-16 are used as a ’finishing sequence’ to ensure all the unbound ice has been removed.

Capacitance Manometer Differential



When the freeze dryer is supplied with both a Pirani vacuum sensor and a Capacitance Manometer, a differential measurement can be used to determine 'end of primary drying'.

A Pirani vacuum sensor is affected by water vapor and therefore will read the relative vacuum, not the absolute vacuum.

A Capacitance Manometer is NOT affected by water vapor and will read the absolute vacuum.

It can be assumed that when the Pirani and Capacitance Manometer read the same that there is no longer water vapor present and the product has reached end of primary drying.

Setup

A. Enable PRESSURE DIFFERENCE TRIGGER
B. Enter a value for the pressure difference between the Pirani and Capacitance Manometer.
    a. Note: Due to linearity and accuracy of the two sensors, it is best to perform a dry run down to the desired vacuum level to determine the 'offset' between the Pirani and Capacitance Manometer. (IE: 100mT)
        i. Ex: If the CM=100mT and the Pirani reads 105mT, then you have a 5mT offset in a dry system.

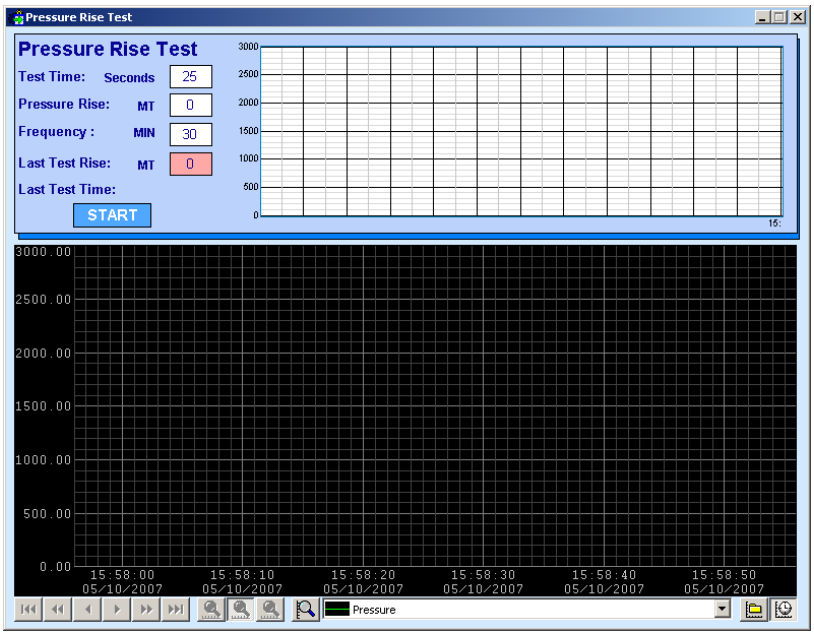
Operation

A. Make sure that PRESSURE DIFFERENCE TRIGGER is enabled. (There is a mT value indicated)
B. Start the FREEZE DRYING run as usual
C. During primary drying the two vacuum sensors are compared to the 'PRODUCT DIFFERENCE TRIGGER'. When the vacuum level is reached the program automatically jumps to STEP 14 for the finishing sequence before secondary drying.

Comments:

A. You may want to set the TRIGGER to slightly more than the 'offset' value and then use the 'finishing sequence in STEPS 14-16 to ensure that all the product is dry.

Pressure Rise Testing



Pressure rise testing is a more advanced technique to test for the presence of water vapor. When the product chamber is isolated from the condenser and vacuum pump any ice/water vapor will cause a rise in the chamber pressure. The rate of rise can be used to determine the end of primary drying.

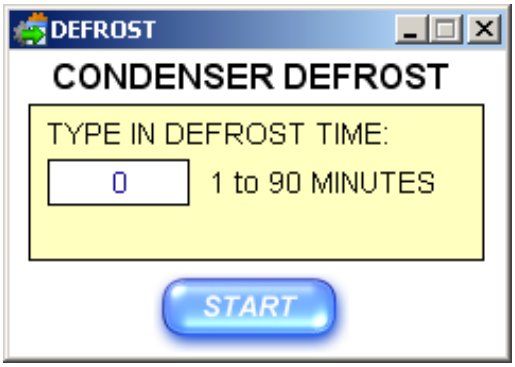
Pressure Rise Testing can be done in either MANUAL mode or FREEZE DRYING mode. In MANUAL mode, the operator can have the Pressure Rise Test performed periodically to help in developing protocols. In FREEZE DRYING mode, the results of the Pressure Rise Test are used to advance the recipe.

The operator enters the length of time that the isolation valve is closed, the 'trigger' pressure rise, and the frequency of the test.

The results are displayed in graphic form on the Pressure Rise Test screen.

DEFROST

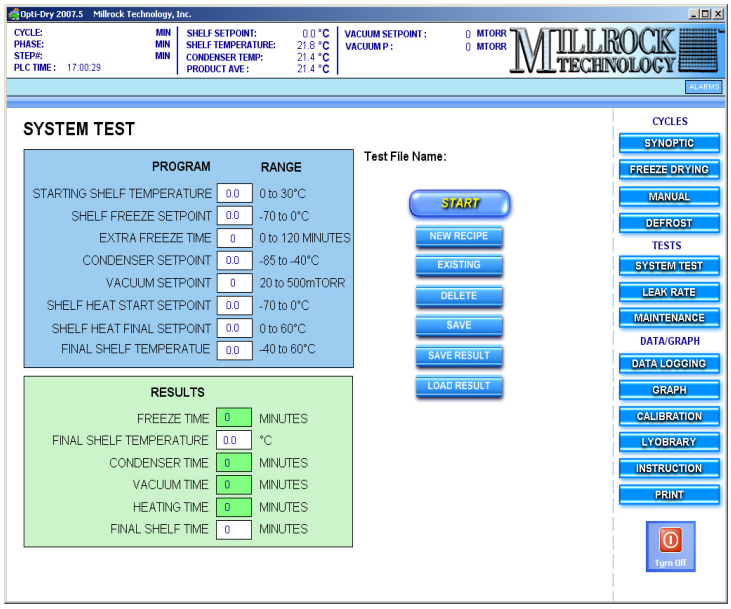
The defrost process is simple. By entering the time the defrost run is started. Hot gas from the refrigeration system is circulated in the condenser melting the ice collected.



SYSTEM TEST

The purpose of the System Test is to periodically examine the performance of the entire freeze dryer. Any developing problems with the unit can be detected by comparing the results of the test with that of the previous one as long as the programs are similar.

The test consists of simulating the main steps in freeze drying and recording the time it takes to reach the various set-points.



Step 1) Enter a Starting Set-point in the box. When the shelf temperature reaches this set-point the timer will start.

Step 2) Next, enter a Shelf Freezing Set-point. The refrigeration system will cool the shelves to this set-point and the time will be displayed in the first field under "RESULTS" – FREEZE TIME.

Step 3) After the freezing set-point has been satisfied, the shelves will continue to cool for the Additional Freezing Time entered in this box. The results are recorded as a Final Shelf Temperature.

Step 4) Enter a Condenser Set-point in the appropriate box. The time it takes to reach this set-point will be recorded.

Step 5) Next is the evacuation step. Enter a pressure set-point between 20 and 500 mT. The Condenser refrigeration will remain on during the pump-down. The time to reach this set-point is displayed as Vacuum Time.

Step 6) This is the shelf heating test. First, enter a Starting Shelf Set-point in the box. It should be a temperature that is 10° to 20°C warmer than the Shelf Freeing Set-point so the shelves do not have to cool again prior to starting. Then, enter a Finish Set-point. This should be at least 20°C warmer than the Starting Set-point. The timer will begin when the Starting Set-point is reached and stop when the Finish Set-point is satisfied. The results are shown as Heating Time.

Step 7) The last step is the control cooling. This is a test for the cooling for the shelves while the condenser is cold. Enter a Final Set-point that is at least 20°C colder than the Finish Set-point of the previous step. The shelves will slowly cool to the set-point and the results are displayed as Final Shelf Time.

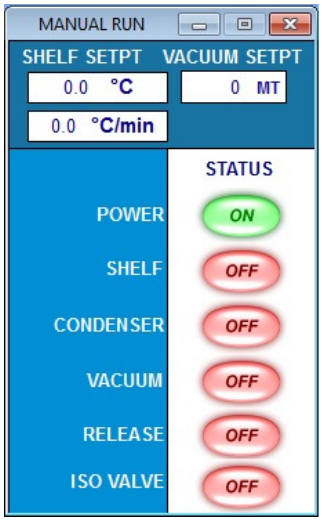
Suggested System Test Parameters

	-53°C Unit	-85°C Unit
Starting Shelf Temp	20°C	20°C
Shelf Freeze Setpoint	-30°	-40°
Extra Freeze Time	15	15
Condenser Setpoint	-40°	-70°
Vacuum Setpoint	200	100
Shelf Start Setpoint	-30°	-40°
Shelf Heat Final Setpoint	50°	50°
Final Shelf Temperature	20°	20°

The user has the option of loading old test data for reference use and the option of saving data for later reference in the menu.

MANUAL Operation

Manual operation simulates a manual operating panel, allowing the user or operator to test individual functions of the system for validation and troubleshooting.



On the master screen select the MANUAL icon. The manual screen will appear.

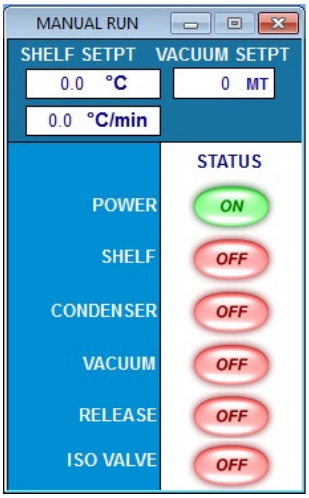
The manual operating screen allows the user to modify/set individual control points including:

- System Power On/Off
- Shelf On/Off – cools/heats and controls the shelves
- Condenser/Refrigeration On/Off
- Vacuum Control On/Off
- Vacuum Release On/Off
- Shelf Temperature Set-Point
- Vacuum Set-point

1) Make sure the front door is closed and that there is nothing in the chamber.
2) System Power ON
3) Make sure the front door is closed, the seal is complete and that there is nothing in the chamber.
    a. The vacuum pump can be activated on the Maintenance Screen.
        i. Turn the vacuum pump on
        ii. Press the chamber door until it seals
        iii. Turn off the vacuum pump
        iv. Caution: Only initialize the vacuum seal, do not pull a low vacuum
4) Shelf Freeze Setting
    a. Set the shelf temperature to -40°C
5) Shelf ON
    a. The shelf temperature will go to the Shelf Control Setting
6) Vacuum Setpoint
    a. Set the vacuum setpoint to 100mT
7) Vacuum ON
8) Condenser ON
    a. The condenser will go to its maximum low temperature
9) Start Data Logging
    a. The data logging process will start.
    b. The data will be displayed on the screen
    c. When moving from screen to screen, the Run Data screen will disappear. To recall it, press the Windows button on the keyboard and select Run Data on the menu bar.

The system will now run to the control points set in. It will take 30-45 minutes to attain the maximum low temperatures and vacuum levels.

Methods to PreFreeze Shelves

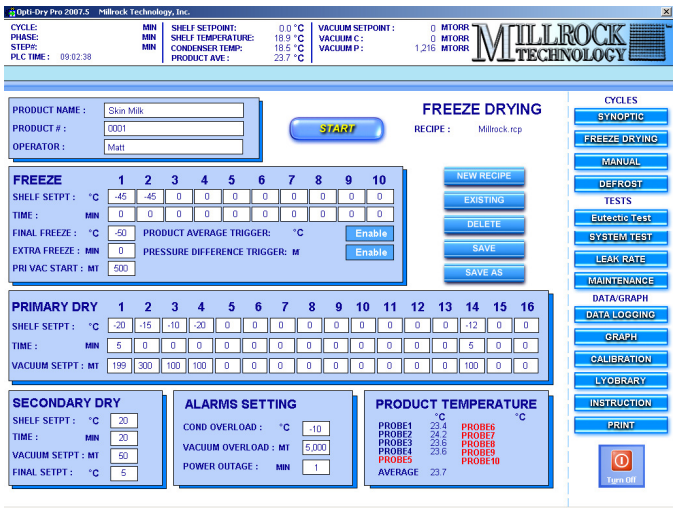


2 methods are described for precooling shelves for prefrozen product.

1- MANUAL mode
2- MANUAL/AUTOMATIC mode

1- MANUAL mode
   a. If the system will be operated in manual mode, then the shelves can be precooled to -40 by:
      i. Turn Power ON
      ii. Turn SHELF ON
      iii. Set SHELF SETPT to -40C
      iv. Load shelves
      v. Turn CONDENSER ON
      vi. When the condenser reaches -40C, turn VACUUM ON
      vii. Set the VACUUM SETPT to 200mT (or whatever vacuum level desired)
      viii. Adjust SHELF SETPT to freeze dry

2- MANUAL/FREEZE DRYING
   a. Turn machine on.
   b. Enter MANUAL Mode
   c. Cool shelves to some value to be set (-40 deg C).
      i. See MANUAL mode above
   d. Open door and load product on shelves.
   e. Exit MANUAL Mode by POWER OFF
   f. Enter FREEZE DRYING mode and START predefined run (first step at -40C)
      i. See FREEZE DRYING above
   g. Shelves will control and hold, when stable and the time is satisfied the program will move to FINAL FREEZE, when satisfied
   h. Condenser will cool to -40C
   i. Vacuum Pump will start



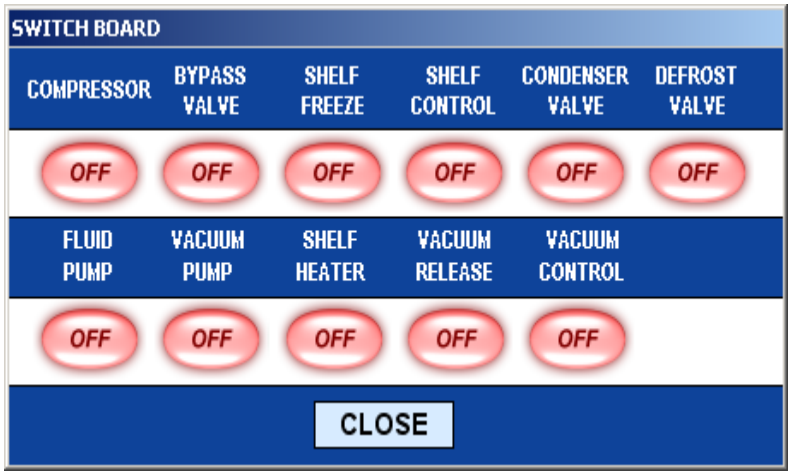
j. The Primary Drying preprogrammed steps (which can be modified on the fly) will activate. During the cycle the operator can change shelf temp and partial vacuum as needed to optimize processing of product.

k. When primary and secondary drying are complete....

i. The operator will be prompted that the cycle has ended and asked how to proceed. IE: Vacuum pump will stop, System will Vent

MAINTENANCE

The Maintenance Switchboard is designed to be fully interactive with the freeze dryer. To activate Maintenance the system must not be operating in Manual or Freeze Drying mode. Click the left mouse button on the MAINTENANCE button and a window will activate (turning the button Green). Each item on the screen can be activated and deactivated independently.



Make sure that all items are turned off prior to leaving the maintenance screen. Failure to do so will prevent the manual and the automatic routines from activating. The refrigeration, electrical, and heat transfer diagrams for the freeze dryer are accessed by clicking the appropriate button. The refrigeration diagram is interactive as well, giving part numbers and a function explanation.

Note: To Reset the vacuum pump timer, click on the pump and select the Reset Vacuum Pump Timer button. The time will be resent to (0). This should be done each time the oil in the vacuum pump is changed.

Section 4b: DATA/GRAPHING

The Opti-Dry software has two methods of storing and retrieving data. The first method is Historical Data/Graphing. The second method is Data Logging or Run Data.

Historical Graphing continuously saves data when the freeze dryer is in the Automatic Run mode. This data is collected on 5 second intervals and can be viewed in graphic mode on the Historical Screen.

DATA LOGGING

On several screens there is a button to START DATA LOGGING. This is a supplemental program that can be started and stopped at anytime, whether or not the system is performing a freeze drying run. This is a useful tool when the actual data needs to be displayed on the screen. The data is easily imported into Excel.

Run Data is stored in the c:\data\numeric folder.

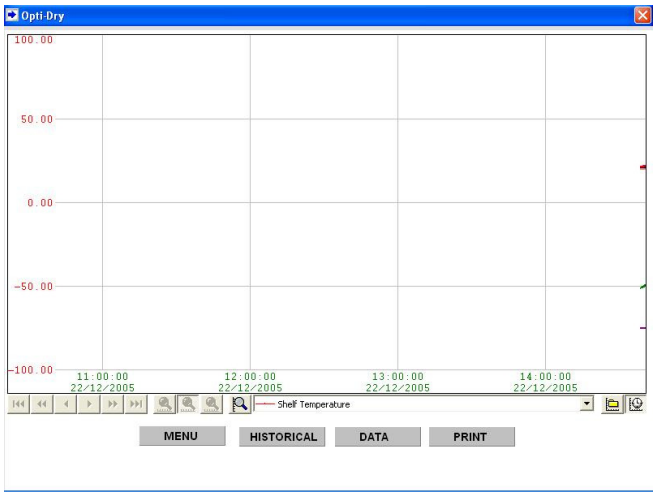
Nomenclature for the CYCLE and PHASE data columns:

Cycle		Phase	
0	Off	1	Controlled freeze a. Steps 1-10
1	Freeze drying	2	Final freeze temp a. Note that this is a trigger temperature, and a timer starts . Shelves continue to cool.
2	Defrost		
3	Manual		
4	Leak rate		
5	System test	3	Extra Freeze time
6	Sterilization	4	Condenser
7	-	5	Vacuum
8	Maintenance	6	Primary a. Steps 1-16
		7	Secondary
		8	Final
		9	Release

Historical/Graphs – 4 and 24 Hour FD and Product

Under the DATA/GRAPH menu section there is are selections for Historical information. The software has built-in function to graph critical data in multiple hour increments.

A sample format for a 4 hour graph.



When first viewing a graph, the data displayed is “live” data and is continuously updated.

Note: the graph/clock at the bottom right of the graph is selected.

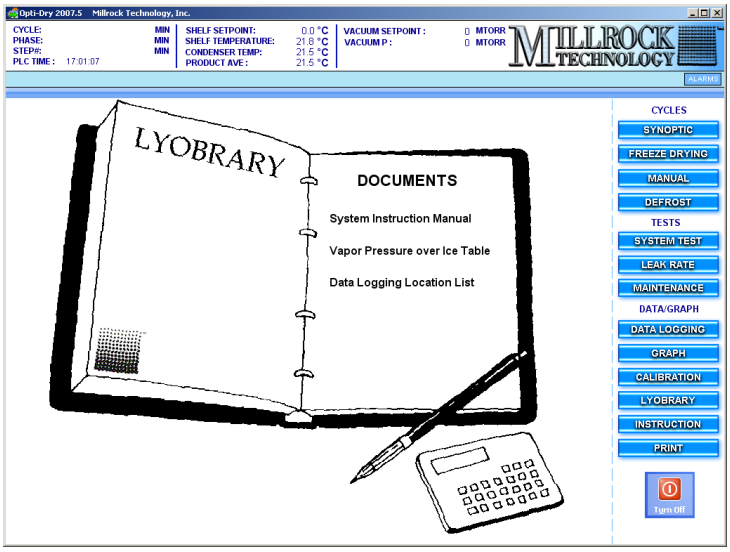
Note: the navigation buttons are disabled when viewing “live” data.

To view historic data, the graph/folder icon is selected. A menu will appear with file names that can be selected. When viewing historical data the navigation buttons are enabled. In addition, it is possible to select data points and view their individual values. The value selected will correspond with the line type selected (IE: Shelf Temperature or Condenser Temperature).

Historical data is stored in the c:\data\graph folder and can be imported into an Excel file.

LYOBRARY

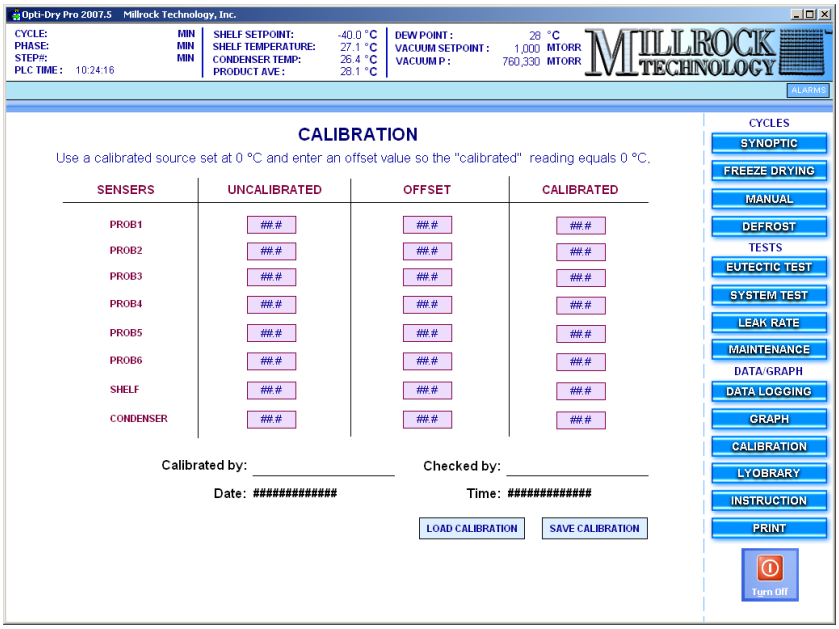
System instructions, a vapor pressure chart and a copy of the warranty are available on the Lyobrary screen.



Section 4c: Maintenance and Troubleshooting

CALIBRATION

The calibration for all the temperature probes is done on the CALIBRATION screen.



Caution: Only experienced operators should access this screen.

<u>Calibration</u>

The thermocouple sensors are calibrated using a known value source and adjusting the temperature offset for each probe.

A written record of the date and operator are kept by printing the page and completing the blank fields.

Old calibration data can be loaded for easy reference. Once the calibration data is set the operator has the option of saving that data for later comparison.

Cleaning

If it should become necessary to clean this equipment, disconnect the unit from its power source first. Do not use, aerosols, abrasive pads, scouring powders or corrosives. Use a soft cloth lightly moistened with a mild detergent solution or rubbing alcohol. Ensure the surface cleaned is fully dry before reconnecting power.

Cleaning Gaskets

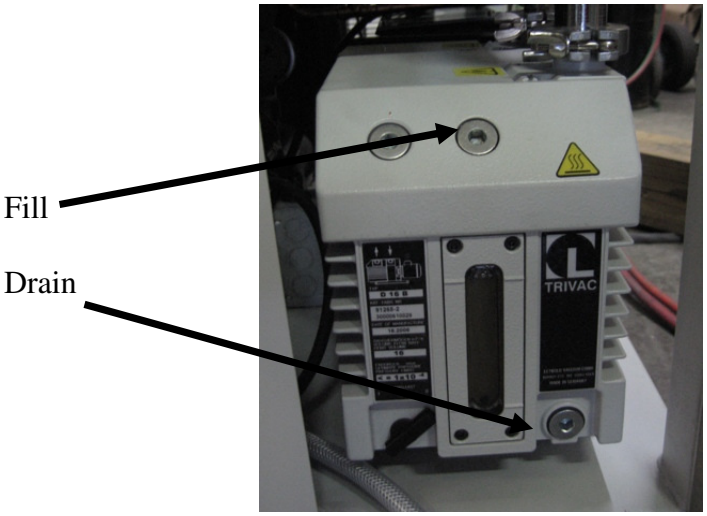
Remove the gasket(s) from the chamber(s). Rinse the gasket(s) with warm water. Use dish detergent to remove residue/dirt. Rinse the gasket(s) with warm water to remove any residual detergent. Make sure to dry the gasket completely with a dry, lint free towel. Re-Install gasket(s) on the freeze dryer.

Note Gasket must be completely dry before starting a run.

Changing Vacuum pump oil
(Oil Type – Double Distilled VPO, contact Millrock Technology)

The oil in the vacuum pump should be changed between 500 and 1000 hours of operation, or sooner if the oil in the pump is milky or dark in color.

Drain - Move the pump so it sticks over the edge. Place a drain pan beneath the pump drain. Drain the oil by removing the bottom plug. Replace the plug.



Add oil by removing the top plug. Add to the fill line toward the top of the sight glass. Replace the plug.

When the pump is first started the oil level will drop slightly. This is normal and not a concern.

Reset the counter in the software on the machine. On the main screen click on the vacuum pump icon. Press "resent vacuum pump timer". The time will reset to (0) hours.

Line Cord Replacement

"If the cordage for this equipment is damaged and requires replacement, it is the responsibility of the Installer to supply a suitable length of medium heavy duty flexible supply cordage.

It should meet the following requirements:

- It must be approved for use in the country in which this equipment is installed or bear the <HAR> Mark.
- The maximum length of the cordage should not exceed the values established by the National Code of the country in which it is installed.
- The outer jacketing of the cordage should be rated for exposure to water, oil and other similar substances.
- The Voltage and Ampere rating of this equipment, as noted on the Manufacturer's Identification Label, should be consulted when selecting the proper size (mm^2) of the cordage
- A suitable industrial style attachment plug should be selected for connecting to the branch circuit. As an alternative, the end that terminates at the building supply source may be permanently connected in accordance with local wiring rules.
- The supply cordage should be routed to the Lyophilizer in a manner that does not allow it to be stepped on, pinched, subject to abrasion, excessive bending, or other physical abuse."

Software File Structure

All programs and data are stored on the C: drive.

Data Storage:

Graphic data	C:\data\graphic	file names yr/month/day .T0A
Numeric data	C:\data\numeric	file names month/day/yr .RUN and .LOG
Recipes	C:\opto22\utilitiesst\recipe	
Display program	C:\opto22\optodisp\xxx Company Name DISP	
Control strategy	C:\opto22\optoctrl\xxx Company Name CTRL	

Section 5: Periodic Maintenance

Operation	Frequency	Comment
Gaskets and O-rings	As needed	Wipe clean and grease where required with vacuum grease
Check/Change Vacuum Pump Oil	Weekly Change the oil every 500 to 1000 hours.	Verify that the oil has not turned hazy or milky in color. Verify that the level of oil is sufficient. If the vacuum pump oil is changed, reset the timer. On the maintenance screen click on the vacuum pump and select Reset Timer.
Check Rubber Components for wear	Monthly	Visually inspect and run fingers over the parts feeling for cracks
Vacuum the Condenser Fins to remove dust.	Every 6 months	Dust will build up and reduce the performance of the system
Dust off Internal Components	Every 6 months	
Verify the Fan Motor is operating (air cooled units only)	Every month	Visually inspect rotation during operation

Troubleshooting

Symptom	Problem	Solution
System will not start	Low voltage Contactor or fuse open	Verify voltage and correct if necessary Check relays and contactors for proper operation
System will not get to maximum low temperature	Ambient temperature too high (air cooled systems) Water flow insufficient (water cooled systems) Source voltage is too low causing the second stage compressor to cycle on/off Condenser is blocked Outlets of cabinet are blocked Loss of refrigerant	Make sure room temperature is below 80°F Verify proper water flow. Check hoses for kinks and valves for proper orientation. Verify voltage during operation and correct Check for dust or that the system is too close to the wall Check for dust or that the system is too close to other objects If the first stage loses refrigerant the second stage will not start If the second stage loses refrigerant, the first stage will operate properly, but the second stage will turn on/off
System will not cool	The cool solenoid is not working	Check voltage Check the coil
System will not pull vacuum	Verify vacuum pump connect	Check all hoses and fittings
(Start at the vacuum pump and work your way out)	Verify pump has proper oil fill Verify proper condition of oil Check vacuum sensors Check vacuum sensor wiring Verify that all doors are closed Verify all fittings are tight Check tubing for cracks Check that vacuum valves are not open (if included with system)	Oil should be between Min and Max lines Make sure the oil is not cloudy or milky, indicating water or corrosive contamination. If necessary flush pump and add new oil. Change the sensor to eliminate the sensor as an issue

For Service, please contact:

Millrock Technology
Service/Tech Support
39Kieffer Ln
Kingston, NY 12401
845-339-5700
845-339-7557 Fax
service@millrocktech.com

Spare Parts – REVO Series

Part#	Description
5300010	Oil Mist Eliminator for 400lpm vacuum pump (D16B)
8010019	Vacuum Pump Oil for use in Leybold vacuum pumps
7030017	Chamber Gasket RD
5240002	Vacuum Grease
7030016	Condenser Gasket RD
3160003	Product probes, 72”
6110006	Refrigeration Solenoid Valve Coil
3040002	Vacuum Release Solenoid Coil
3040001	Vacuum Control Solenoid Coil
3070016	PLC Digital Output module
3070018	PLC Thermocouple Input module
3140002	Fan Motor 16W 220v (Optional, Air Cooled Units ONLY)

Acrylic Door Compatibility Chart

Material Compatibility R=Resistant LR=Limited Resistance N=Non Resistant:

Chemical	Code	Chemical	Code
Acetic Acid (5%)	LR	Hydrogen Peroxide (3%)	R
Acetic Acid (Glacial)	N	Hydrogen Peroxide (28%)	LR
Acetone	N	Isopropyl Alcohol (30%)	LR
Ammonium Chloride	R	Kerosene	R
Ammonium Hydroxide (10%)	R	Lacquer Thinner	N
Ammonium Hydroxide (Conc.)	R	Methyl Alcohol (30%)	LR
Aniline	N	Methyl Alcohol (100%)	N
Battery Acid	R	Methyl Ethyl Ketone (MEK)	N
Benzene	N	Methylene Chloride	N
Butyl Acetate	N	Mineral Oil	R
Calcium Chloride (Sat.)	R	Nitric Acid (10%)	R
Calcium Hypochlorite	R	Nitric Acid (40%)	LR
Carbon Tetrachloride	LR	Nitric Acid (Conc.)	N
Chloroform	N	Oleic Acid	R
Chromic Acid	LR	Olive Oil	R
Citric Acid (10%)	R	Phenol Solution (5%)	N
Cottonseed Oil (Edible)	R	Soap Solution (Mild dish soap)	R
Detergent Solution (Heavy Duty)	R	Sodium Carbonate (2%)	R
Diesel Oil	R	Sodium Carbonate (20%)	R
Diethyl Ether	N	Sodium Chloride (10%)	R
Dimethyl Formamide	N	Sodium Hydroxide (1%)	R
Dioctyl Phthalate	N	Sodium Hydroxide (10%)	R
Ethyl Acetate	N	Sodium Hydroxide (60%)	R
Ethyl Alcohol (30%)	LR	Sodium Hypochlorite (5%)	R
Ethyl Alcohol (95%)	N	Sulfuric Acid (3%)	R
Ethylene Dichloride	N	Sulfuric Acid (30%)	R
Ethylene Glycol	R	Sulfuric Acid (Conc.)	N
Gasoline	LR	Toluene	N
Glycerine	R	Transformer Oil	R
Heptane	R	Trichloroethylene	N
Hexane	R	Turpentine	R
Hydrochloric Acid	R	Water	R
Hydrofluoric Acid (25%)	N	Xylene	N

Millrock Technology, Inc.

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5. INDEMNITY

5.1 Millrock Technology warrants that the Application Software shall be delivered free of any rightful claim for infringement of any United States patent or copyright. If notified promptly in writing and given authority, information and assistance, Millrock Technology shall defend, or may settle, at its expense, any suit or proceeding against Customer so far as based on a claimed infringement which would result in a breach of this warranty and Millrock Technology shall pay all damages and costs awarded therein against Customer due to such breach. In case the Application Software is in such

suit held to constitute such an infringement and its use is enjoined, Millrock Technology shall, at its expense and option, either procure for Customer the right to continued use, or replace same with a non-infringing product or part, or modify the Application Software so that it becomes non-infringing, or remove the software and refund the license charge pertaining thereto (less reasonable depreciation for any period of use) and any transportation costs separately paid by Customer. The foregoing states the entire liability of Millrock Technology for patent and copyright infringement by the Licensed Software or any part thereof.

5.2 The indemnity under the preceding paragraph shall not apply to any use of Application Software in conjunction with any other product in a combination not furnished by Millrock Technology as a part of this transaction. As to any such use in such combination, Millrock Technology assumes no liability whatsoever for patent and copyright infringement and Customer will hold Millrock Technology harmless against any infringement claims arising there from.

6. TERM AND TERMINATION

6.1 You may terminate the license granted hereunder at any time by destroying the Licensed Software together with all copies thereof and notifying Millrock Technology in writing that all use of the Licensed Software has ceased and that same has been destroyed.

6.2 Millrock Technology, upon thirty (30) days notice, may terminate this Agreement or any license hereunder if Customer fails to perform any obligation or undertaking to be performed by it under this Agreement or if Customer attempts to assign this Agreement without the prior written consent of Millrock Technology. Within twenty (20) days after any such termination of this Agreement, Customer shall certify in writing to Millrock Technology that all use of the Licensed Software has ceased, and that same has been returned or destroyed, in accordance with Millrock Technology's instructions.

6.3 Sections 4, 6 and 7 of this Agreement shall survive any expiration or termination and remain in effect. Termination of this Agreement or any license hereunder shall not relieve Customer of its obligation to pay any and all outstanding charges hereunder nor entitle Customer to any refund of such charges previously paid.

7. EXPORT

7.1 If you intend to export (or re-export), directly or indirectly, the software products or technical information relating thereto supplied hereunder or any portion thereof, it is your responsibility to assure compliance with U.S. export control regulations and, if appropriate, to secure any required export licenses in your own name.

8. GENERAL

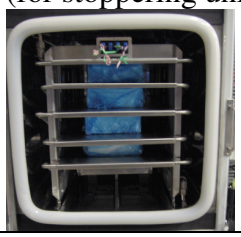
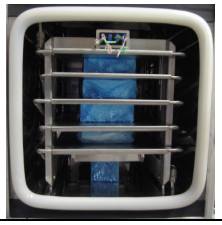
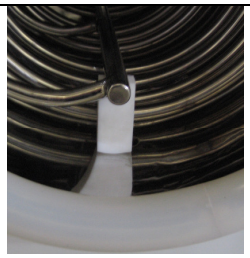
8.1 This Agreement shall be governed by the laws of the State of New York, without regard to its conflict of law provisions. The provisions of the United Nations Convention on the International Sale of Goods shall not apply to this Agreement.

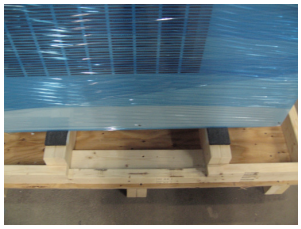
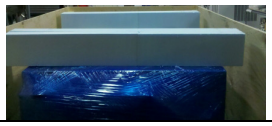
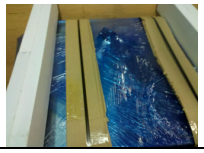
Should you have any questions concerning this Agreement, you may contact Millrock Technology by contacting: 1-845-339-5700 in Kingston, New York**.**

YOU ACKNOWLEDGE THAT YOU HAVE READ THIS AGREEMENT, UNDERSTAND IT AND AGREE TO BE BOUND BY ITS TERMS AND CONDITIONS. YOU FURTHER AGREE THAT IT IS THE COMPLETE AND EXCLUSIVE STATEMENT OF THE AGREEMENT BETWEEN US AND SUPERSEDES ANY PROPOSAL OR PRIOR AGREEMENT, ORAL OR WRITTEN, AND ANY OTHER COMMUNICATIONS BETWEEN US RELATING TO THE SUBJECT MATTER OF THIS AGREEMENT. FURTHER, NO CHANGE OR AMENDMENT TO THIS AGREEMENT SHALL BE EFFECTIVE UNLESS AGREED TO BY WRITTEN INSTRUMENT SIGNED BY A DULY AUTHORIZED REPRESENTATIVE OF MILLROCK TECHNOLOGY.

Re-Packaging of Equipment

This equipment will withstand, or has been protected against, transportation and storage temperatures of -25°C to +55°C and for short periods up to +70°C.
-It has been packaged to prevent damage from the effects of normal humidity, vibration and shock.

1	Disconnect the freeze dryer from the power source.
2	Wrap line cord together and secure with zip ties.
3	(for stoppering units) Cut/Place 1" foam piping around shelf hoses. 
4	(for stoppering units) Cut/Place 8"x12"x1" pieces of foam board in between the shelves. 
5	(for stoppering units) Raise the shelves using the stoppering switch until shelves stop moving.
6	(for stoppering units) Place a properly sized piece of wood (2"x4"), centered under the bottom shelf to secure the shelves from moving. 
7	Place a foam bag/board behind the wrapped line cord on the back of the unit. 
8	Make sure block is secure under condenser coil. 

9	Wrap the entire machine with plastic wrap to secure all of the outer foam supports and to protect the exterior of the machine. 
10	Place wrapped machine on crate base (Forklift req'd), making sure unit base is centered on foam pads.  
11	Using banding(metal) to secure the machine to the base. 
12	Using banding(metal) to secure the additional pieces to the base. 
13	Install our walls of crate. Make sure to secure with nails/screws every 8-12".
14	Before installing top, place large foam pieces on top of the unit to protect against damage from the top.  

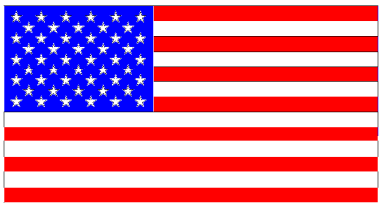
15	Install top making sure to secure with nails/screws every 8-12”. 
16	Use banding (metal) to wrap the outside of the crate to secure for shipment. 
17	Properly mark the crate for proper lifting. 
18	Apply the proper packing list to the side of the unit.

Declaration of Noise Emission

The Millrock Technology, Incorporated Model REVO Sound Pressure Level per EN ISO 11202 is as follows:

Model No:		
	Operating	Idle
L_{pAm} (Operator Position)	64.0 dB (A)	40.0 dB (A)
L_{pAm} (Bystander Position)	70.0 dB (A)	39.0 dB (A)
Peak C-weighted instantaneous SPL in the Operator's position	68.0 dB (c)	---
Sound power emitted where the equivalent continuous A-weighted SPL exceeds 80 dB (A).	0.0 Bel	---
The average difference between the extraneous noise level and the sound intensity level at each measuring point is:	L_{pAm} Δ = 30.0 dB (A)	
Ambient Correction Factor K3A calculated according to EN ISO 11204 Appendix A.	4 dB(A)	
Measurements were made at a height of 1.5 m and 1 m from the Operator Position and all four sides of the equipment.		

The figures quoted are emission levels and are not necessarily safe working levels. While there is a correlation between the emission and exposure levels this cannot be used reliably to determine whether or not further precautions are required.
Factors that influence the actual level of exposure of the workforce include characteristics of the work room, the other sources of noise, etc. such as the number of machines and other adjacent processes. Also, the permissible level of exposure can vary from country to country.
This information, however, will enable the user of the machine to make a better evaluation of the hazard and risk.



Millrock Technology, Inc
39 Kieffer Ln
Kingston, NY 12401
845-339-5700

CE

EC DECLARATION OF CONFORMITY WITH COUNCIL DIRECTIVE 2006/95/EC CE	
Date of Issue:	
Directive:	Low Voltage Directive 2006/95/EC
Conforming Equipment:	Lyophilizer Model: Serial No:
Manufacturer:	Millrock Technology Inc. 39 Kieffer Lane Kingston, NY 12401 USA
Harmonised Standards Referenced or Applied:	BS EN 61010-1:2001 – Safety requirements for electrical equipment for measurement, control and laboratory use.
Specifications with which Conformity is Declared:	Principal elements of the safety objectives for electrical equipment designed for use within certain voltage limits of Annex I of the Low Voltage Directive.
We hereby certify that the electrical equipment described above conforms with the essential health and safety requirements of Council Directive 2006/95/EC on the approximation of the laws of the Member States relating to the safety of electrical equipment designed for use within certain voltage limits.	
Signed:	
Signatory:	

Technical File Reference Number	STR11186A1.MTI